VOLUME-I

Glimpses of CCRAS Contributions
(50 Glorious Years)

CLINICAL RESEARCH AND DRUG DEVELOPMENT

CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES
Ministry of AYUSH, Government of India
New Delhi

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PROLOGUE

The Central Council for Research in Ayurvedic Sciences was established in 1969, since then it has been engaged in clinical research for validation of classical Ayurveda drugs and drug development of new/coded formulations based on leads from classical texts, contemporary scientific, pharmacological leads and from the folklore collected from various parts of the country for important diseases of National importance based on strength of Ayurveda.

Council has generated scientific evidence on safety and efficacy of 82 classical Ayurvedic formulations on more than 30 diseases/conditions of national importance and validation of 35 classical Ayurvedic formulations is continuing for generation of scientific evidence on safety and efficacy. The finding of this research is being disseminated through research papers in various journals and also through books and monographs. This book also comprises brief information of various monographs and books published by the council since inception in clinical research.

The Council has been putting efforts to translate the research findings into practice and make available to the needful at large. In this direction, the technologies of new coded drugs and formulations developed by the Council such as Ayush-64 for Malaria, Ayush-56 for Epilepsy, and Ayush-82 for Diabetes mellitus etc have been transferred to the Industry through National Research Development Corporation, Department of Scientific and Industrial Research, Ministry of Science & Technology, Government of India.

This comprehensive document proving the glimpse of the work done by the council since inception in the field of clinical research of classical drugs and new drug development. It will help the readers to know about various strength areas of Ayurveda and will help as a ready document for further planning of research moreover this book will provide a quintessence of various research work done by the council for validation of classical drugs, new drug development and the books and monographs published on clinical research of various domains.

EXECUTIVE SUMMARY

Ayurveda, the science of life, evolved as a comprehensive system of healthcare systematically through scientific experimentations of high order backed by sound and reproducible evidence base and stood the test of the time. Several strategies and road maps are being drawn to carry forward merits of this science so as to meet the current day health needs and mainstream its core strengths alongside through research & development in this country and across the globe.

The core component of clinical research comprise of validation of the fundamental principles of Ayurveda; Validation and development of diagnostic/assessment tools ; standardization and validation of the therapeutic procedures and generation of scientific evidence of safety and efficacy of Ayurveda formulations and approaches and generation of new formulations taking leads from classical texts, contemporary scientific and pharmacological leads for important diseases of National importance based on strength of Ayurveda and from the folklore collected from various parts of India by the Council.

The Council undertakes validation of classical Ayurvedic formulations already in the healthcare system through clinical studies to generate evidence on clinical efficacy and safety and scientific validation of new combinations (coded drugs) collected through folklore claims from various parts of the country, under drug development. The classical Ayurvedic formulations are already in the healthcare system and coded Ayurvedic drugs are made available into the healthcare system through systematic process of drug development viz. drug standardization and quality control, preclinical safety/toxicity studies and biological activity studies (as appropriate) and clinical trials as per requirement.

The Council is working toward validation of these drugs in the diseases of National importance. So far more than 30 diseases of National importance have been studied upon with more than hundred classical drugs in different combinations. The council is also working hard to revive the traditional systems and knowledge prevailing among tribes and in villages through collection of their folklore claims for various ailments and is working towards validation of these claims so the knowledge can be used for masses.

The Council has identified classical Ayurveda formulations for identified disease conditions referring from Ayurvedic pharmacopeia /Ayurvedic Formulary of India, Essential Drug list of ASU medicines (2013), Ministry of AYUSH and other Ayurveda classical texts. These formulations are being validated through Council's institutes engaged in clinical research in

a phased manner. Some of the formulations are clinically validated for different disease conditions and some are used in different combinations for the same or different disease conditions.

In the recent past the Council has generated scientific evidence on safety and efficacy of approximately 82 classical Ayurvedic formulations on more than 32 diseases/conditions viz. Allergic Conjunctivitis, Bronchial Asthma, Chronic Bronchitis, Cognitive Deficit, Dry Eye Syndrome, Dyslipidemia, Type II Diabetes Mellitus, Essential Hypertension, Irritable Bowel Syndrome (IBS), Iron Deficiency Anemia, Menopausal Syndrome, Osteoarthritis, Obesity, Osteoporosis/Osteopenia, Rheumatoid Arthritis, Rasayana for healthy ageing, Dysmenorrhea, Psoriasis, Gout, Polycystic Ovary Syndrome, Hemorrhoids, Mental Retardation, Generalized Anxiety Disorder and Computer Vision Syndrome etc.

Further, validation of approximately 35 classical Ayurvedic formulations is continuing for generation of scientific evidence on safety and efficacy on 14 diseases/conditions viz. viz. Psoriasis, Urolithiasis, Uterine Fibroids, Rheumatoid Arthritis, Hemorrhoids, Osteoarthritis, Gout, Osteopenia/Osteoporosis, Obesity, Iron Deficiency Anemia, Menopausal Syndrome, Cervical Spondylosis, Cognitive Deficit and Chronic Allergic Conjunctivitis in various institutes of the Council engaged in clinical research.

The research outcomes of these studies are being published in journals especially in council's official publication JRAS (Journal of Research in Ayurvedic Sciences) and JDRAS (Journal of Drug Research in Ayurvedic Sciences) for wider dissemination. The evidence on clinical efficacy and safety of Ayurvedic formulations which are vogue and available in the market is highly useful to practitioners and consumers for their rational use. The evidence of their safety and rational use will also strengthen integration of Ayurveda with other systems of medicine and also help in convincing scientific community across the world which may also improve its market in the country and world at large.

New drug development

The Council is engaged in drug development of new/coded formulations. Till date, 12 technologies such as Ayush 64 for malaria, Ayush SG for Rheumatoid Arthritis, Ayush 82 for Diabetes mellitus have been developed and commercialized through National Research Development Corporation (NRDC) for wider public utility.

CCRAS has undertaken the development of the various coded formulations for different disease conditions viz. AYUSH Manas for Mental retardation/cognitive deficit, AYUSH

QOL 2C for improving Quality of Life of Cancer patients, AYUSH Rasayan A & B in geriatric health, AYUSH C1 Oil for wound healing, AYUSH PJ-7 for Dengue fever, AYUSH M-3 for Migraine, AYUSH SL for Filariasis, AYUSH A for Bronchial Asthma, AYUSH D for Type II Diabetes Mellitus, Carctol S for Cancer, AYUSH K1 for Chronic Kidney Diseases, Ayush coded drug for fatty liver degeneration and Ayush coded drug for hepato-protection as adjuvant to ATT which are at different phases of drug development. These studies are being conducted in collaboration with reputed institutes like AIIMS New Delhi, NIMHANS Bengaluru, BHU, ICMR and St. John's Medical College Bengaluru etc.

Council is also putting efforts in validation and standardization of various fundamental principles and diagnostic tools of Ayurveda to further strengthen the Ayurveda system of medicine. Presently validation work of *prakriti* assessment tool and Validation and reliability testing of Ayurveda Diagnostic Tools is going on.

The council has also laid its vision document 2030 with short term goal and long term goal in for achieving its objectives and further strengthening of scientifically validated Ayurveda for achieving the ultimate goal of '***Health for all***'

The council is dedicated dissemination of its research finding through monographs and book publications. Since inception the Council has published more than 266 books and monographs apart from 5089 research publications.

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CHAPTER 1

GENESIS AND OVERVIEW

BACKGROUND

The science of Ayurveda has been in vogue in this country from the earliest times and serving the medical needs of most of our people. These systems were developed by ancient scholars on the basis of their own philosophy, oriental methodologies and practices prevalent in that era and have popularised and almost completed it in all aspects as a system of medicine. The advent of foreign invasions and cross cultural interaction had definite impact on these systems. The beginning of twentieth century saw efforts to revive these systems. The members of the Imperial Legislative Council got the resolution of investigations and recognition of these systems was accepted in the year 1916. The Indian National Congress also passed similar resolution in 1920. This led to establishment to number of colleges of Ayurveda.

In the post independence era, the efforts to develop research gained momentum. As per recommendation of the various Committees, grant-in-aid projects were sanctioned to selected colleges. The Central Council for Ayurvedic Research as an Advisory body was established in 1962 and finally the Central Council for Research in Indian medicine & Homoeopathy (CCRIM&H) was established in 1969. This Council initiated research programmes in the Indian systems of Medicine & Homoeopathy in different parts of the country and started coordination at the National level for the first time.

The Central Council for Research in Ayurveda & Siddha (CCRAS), an apex body for the formulation, coordination and development of research in Ayurveda & Siddha on scientific lines was established in March 1978 after reorganization of CCRIM&H. The Minister of Health & Family Welfare is the President of the Governing Body of the Council while the Joint Secretary chairs the Standing Finance Committee. The Scientific /Research Programmes are supervised by the respective Scientific Advisory Committee chaired by eminent scholars of the system.

The Central Council for Research in Ayurvedic Sciences is a Registered Society under Societies Registration Act XXI of 1860 on 29.07.2011 (Formerly Registered as Central Council for Research in Ayurveda and Siddha on 30th March, 1978).

Research areas

The Central Council for Research in Ayurvedic sciences (CCRAS), an autonomous body under Ministry of AYUSH, Govt. of India is apex body in India for undertaking, coordinating, formulating, developing and promoting research on scientific lines in Ayurvedic sciences. The activities are carried out through its 30 Institutes/Centres/Units located all over India and also through collaborative studies with various Universities, Hospitals and Institutes. The research activities of the Council include Medicinal Plant Research (Medico-ethno Botanical Survey, Pharmacognosy and Tissue Culture), Drug Standardization, Pharmacological Research, Clinical Research, Literary Research & Documentation. Besides this, Council has conducting outreach activities viz. Tribal Health Care Research Programme, Ayurveda Mobile Health Care programme, Swasthya Rakshan Programme and National Programme for Prevention and control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS).

Objectives

1. The formulation of aims and patterns of research on scientific lines in Ayurvedic sciences.
2. To undertake any research or other programs in Ayurvedic sciences.
3. The prosecution of and assistance in research, the propagation of knowledge and experimental measures generally in connection with the causation, mode of spread and prevention of diseases.
4. To initiate, aid, develop and co-ordinate scientific research in different aspects, fundamental and applied of Ayurvedic sciences and to promote and assist institutions of research for the study of diseases, their prevention, causation and remedy.
5. To finance enquiries and researches for the furtherance of objects of the Central Council.
6. To exchange information with other institutions, associations and societies interested in the objects similar to those of the Central Council and especially in observation and study of diseases in East and in India in particular.
7. To prepare, print, publish and exhibit any papers, posters, pamphlets, periodicals and books for furtherance of the objects of the Central Council and contribute to such literature.

8. To issue appeals and make applications for money and funds in furtherance of the objects of the Central Council and to accept for the aforesaid purpose gifts, donations and subscriptions of cash and securities and of any property whether movable or immovable.
9. To borrow or raise monies with or without security or on security mortgage charge, hypothecation or pledge of all or any of the immovable or movable properties belonging to the Central Council or in any other manner whatsoever.
10. To invest and deal with the funds and monies of the Central Council or entrusted to the Central Council not immediately required in such manner as may from time to time be determined by the Governing Body of the Central Council.
11. To permit the funds of the Central Council to be held by the Government of India.
12. To acquire and hold, whether temporarily or permanently any movable or immovable property necessary or convenient for the furtherance of the objects of the Central Council.
13. To sell, lease, mortgage and exchange, and otherwise transfer any of the properties movable or immovable of the Central Council provided prior approval of the Central Government is obtained for the transfer of immovable property.
14. To purchase, construct, maintain and alter any buildings or works necessary or convenient for the purpose of the Central Council.
15. To undertake and accept the management of any endowment or trust fund for donation, the undertaking or acceptance whereof may seem desirable.
16. To offer prizes and grant of scholarships, including travelling scholarships in furtherance of the objects of the Central Council.
17. To create administrative, technical and ministerial and other posts under the Society and to make appointments thereto in accordance with the rules and regulations of the Society.
18. To establish a provident fund and/or pension fund for the benefit of the Central Council's employees and/or their family members.
19. To do all such other lawful things either alone or in conjunction with others as the Central Council may consider necessary or as being incidental or conducive to the attainment of the above objects.
20. To undertake R & D Consultancy projects and transfer of patents on drugs and process to industry.

21. To undertake R & D projects sponsored by industries in public/private sector.
22. To undertake international and interagency collaboration.
23. Utilization of results of research conducted and payment of share of royalties/consultancy fees to those who has contributed towards pursuit of such research.
24. To enter into arrangements with scientific agencies of other countries for exchange of scientists, study tours, training in specialized areas, conducting joint projects etc.
25. To provide technical assistance to Govt./Private agencies in matters consistent with the activities of the Council.
26. To assist Medicinal Plants Board, Government of India in achieving its objectives.
27. To constitute small Management Committees consisting of eminent Scientists/ Physicians of local areas to monitor the R & D activities and suggest remedial measures for the improvement of activities of all Central as well as Research Institutes of the Council.

CCRAS Network Map

LIST PARTICIPATING INSTITUTES/CENTRES/UNITS

S.No.	Name of peripheral institute
1.	Central Ayurveda Research Institute for Cardiovascular Diseases New Delhi
2.	National Ayurveda Research Institute for Panchakarma Cheruthuruthy
3.	Central Ayurveda Research Institute for Hepatobiliary Disorders Bhubaneswar
4.	Central Ayurveda Research Institute for Drug Development Kolkata
5.	Central Ayurveda Research Institute for Respiratory Disorders Patiala
6.	Raja Ramdeo Anandilal Podar (RRAP) Central Ayurveda Research Institute for Cancer Mumbai
7.	National Institute of Indian Medical Heritage Hyderabad
8.	Regional Ayurveda Research Institute for Eye Diseases Lucknow
9.	M.S. Regional Ayurveda Research Institute for Endocrine Disorders Jaipur
10.	Regional Ayurveda Research Institute for Drug Development Gwalior
11.	Regional Ayurveda Research Institute for Skin disorders Vijayawada
12.	Regional Ayurveda Research Institute for Mother and Child Health Nagpur
13.	Regional Ayurveda Research Institute for Metabolic Disorders Bangalore
14.	Regional Ayurveda Research Institute for Life style related Disorders Thiruvananthapuram
15.	Regional Ayurveda Research Institute for Infectious Diseases Patna
16.	Regional Ayurveda Research Institute for Gastro-Intestinal Disorders Guwahati
17.	Regional Ayurveda Research Institute Gangtok
18.	Regional Ayurveda Research Institute Itanagar
19.	Regional Ayurveda Research Institute for Urinary Disorders Jammu
20.	Regional Ayurveda Research Institute for Nutritional Disorders Mandi
21.	Regional Ayurveda Research Institute for Skin Disorders Ahmedabad
22.	Regional Ayurveda Research Institute Ranikhet
23.	Regional Ayurveda Research Institute Jhansi
24.	Regional Ayurveda Institute for Fundamental Research Pune
25.	Captain Srinivasa Murthy Regional Ayurveda Drug Development Institute Chennai
26.	Advanced Center for Ayurveda in Mental Health & Neurosciences Bangalore
27.	Dr. Achanta Lakshmipati Research Centre for Ayurveda Chennai
28.	Regional Research Center of Ayurveda Port Blair
29.	Herbal Ayurveda Research Centre (HARC) Nagaland University Lumami Nagaland

CHAPTER 2

VALIDATION OF CLASSICAL FORMULATIONS AND APPROACHES

The council since inception is dedicated in the validation of classical Ayurveda formulations through series of clinical studies. To consolidate the use of Ayurveda classical formulations, backed by proper scientific evidence.

The Central Council for Research in Ayurvedic Sciences has undertaken clinical validation of Ayurvedic formulations/therapies in certain identified diseases/conditions of National importance, the council has undertaken multicentre observational studies across its peripheral institutes that comprise musculo skeletal and neuromuscular disorders viz. *Amavata* (Rheumatoid Arthritis), *Gridhrasi* (Sciatica), *Pakshaghata* (Hemiplegia); metabolic disorder viz. *Madhumeha* (Diabetes Mellitus), *Medoroga* (Obesity & Lipid Disorder); neurological and psychiatric conditions viz. *Manodvega* (Anxiety Neurosis), *Apasamar* (Epilepsy); visual disorder viz. *Timira* (Myopia); respiratory disorders viz. *Tamak Shwasa* (Bronchial Asthma); diseases of GIT system viz. *Grahani* (Irritable Bowel Syndrome), *Kamala* (Jaundice), *Parinama Shula* (Duodenal Ulcer), *Atisar* (Diahorrea), *Arash* (Haemorrhoids), *Bhagandara* (Fistula-in-ano); refractory skin disease viz. *Kitibha* (Psoriasis) and infectious diseases viz. *Visam jwara* (Malaria) and *slipada* (Filariasis).

The principle objective of these multicentre observational studies was to ascertain the clinical efficacy and safety of classical Ayurvedic formulations and therapies, observing the protocols and parameters with modest clinical and laboratory facilities available at CCRAS peripheral institutes.

Further the Ministry of AYUSH (then Dept. of AYUSH, Ministry of Health and Family Welfare), has emphasized on generation of scientific evidence on safety and efficacy of classical Ayurveda formulations, formulations for which standards are available in API and medicines reflecting in Essential Drug List (EDL) of Ayurveda.

Further broadly, the assessment of response in certain studies has been categorized as Good response (75% and above relief in symptomatology and laboratory parameters tending towards normalcy), Fair response (50% and above relief in symptomatology and significant improvement in laboratory parameters), Poor response (25% and above relief in presenting symptomatology and insignificant improvement in laboratory parameters) and No response

(no relief in presenting symptomatology of the disease) as specified in protocols for periodical assessment.

The council has already validated 80 classical formulations for different diseases. At present validation process of 34 classical Ayurveda formulations are in progress and many more are under pipeline at various stages. Following are the diseases wise categorisation of various studies for safety and efficacy done by the council since inception for validation of classical drugs.

2.1.–AMAVATA (RHEUMATOID ARTHRITIS)

Background

Rheumatoid arthritis (*Amavata*) is an autoimmune inflammatory disease that causes pain, swelling, stiffness, joint destruction & its functional disability. It is defined as a chronic multisystem disease characterized by persistent inflammatory synovitis, usually involving peripheral joints in a symmetric distribution with a potential to cause cartilage destruction and bone erosions. As the etio-pathogenesis of Rheumatoid arthritis (*Amavata*) is unknown, there is no specific treatment. The Ayurvedic treatment of *Amavata* (Rheumatoid arthritis) is being increasingly recognized as an alternative approach to its treatment.

According to Ayurveda, *Amavata* (Rheumatoid arthritis) is caused due to malfunctioning of the gastro intestinal system. It is a very painful disease and causes great discomfort during its aggravation period. The main cause of this disease is formation of *Ama* (a toxic substance) due to *Agnimandya*. The etiological factors such as *viruddhahara* (improper and irregular dietary habits), *Viruddhachesta* (improper physical and psychological activities), *mandagni* (improper digestion and metabolism), sedentary habits and exercise immediately after food lead to the formation of *Ama* which gets circulated by *vyan vayu* to various *kapha sthana* especially joints and causes inflammation which leads to disease *Amavata* and it may be correlated with Rheumatoid arthritis due to its similar symptomatology. The cardinal features of *Amavata* are swelling and severe pain that seems to be of scorpion bite over the joints like hands and legs (especially knee, ankle wrist, metacarpals and metatarsals). The other symptoms are body pain, loss of appetite, excessive thirst, laziness, heaviness of the body and fever. Based on the cardinal feature and other associated features, many effective regimens are described in Ayurvedic classics.

Council has done following studies since inception for validation of classical drugs in the management of *Amavata*:

Study 1: *Shunthi Guggulu*- A combination of equal parts of powder of dry rhizomes *Shunthi* (*Zingiber officinale)* and gum resin of *Guggulu (Commiphora wightii),* has been given internally in the dose of 2 gm. three times a day. *Valuka Sveda* (dry fomentation) was applied on the affected parts. The observations made on 497 patients showed that about 2/3rd patients (67%) have very good effect under a course of 6-week treatment. General functional capability and improvement in general condition of the patients was noticed.

Study 2: A combination of 3 drugs *Mahayograja guggulu* 1 gm three times a day with warm water, *Vaishwanar churna* 3gm. twice daily after meal and *Simhanada guggulu 2* gm at bed time has been studied on 518 patients. Local fomentation was also given.The results indicate that about 60% of the patients have shown definite improvement in their clinical symptoms.

Study 3: *Aswagandha (Withania somifera* Dunal) *churna- A* combination of *Ashwagandha chuma* 3 gm thrice a day and *Eranda taila* 15 ml. at bed time, has been administered. The dry fomentation *(Valuka Sveda)* has also been given for the total duration of 6 weeks. 57% of the patients have shown improvement.

Study 4: *Vachadighana-Haridradighana* groups of medicines mentioned in *Sushruta Samhita* have been administered in the dose of 3 gm. three times a day with warm water in two separate groups of the patients. *Vettumaran Gutika* 1 tablet three times a day was given internally. The external application of the dry fomentation *(Valuka Sveda)* was given. The results indicate positive efficacy in about 80% of patients.

Study 5: Open label Interventional study was done with *Samira Pannagarasa* - 250 mg thrice a day with honey for six weeks *Pippali Vardhamana Ksheera Paka* – Day one starts with one pippali and add one every day upto 21 days thereafter reduce one pippali every day upto next 21 days. The study was conducted at 10 Centres viz.Regional Ayurveda Research Institute for Drug Development, Gwalior, Central Ayurveda Research Institute for Drug Development, Kolkata, Regional Ayurveda Research Institute for Eye Diseases, Lucknow, RRA Podar Central Ayurveda Research Institute for Cancer, Mumbai, Central Ayurveda Research Institute for Respiratory Disorders, Patiala, Regional Ayurveda Research Institute, Itanagar, Regional Ayurveda Research Institute for Nutritional Disorders, Mandi, Regional Ayurveda Research Institute for Infectious Diseases, Patna, Regional Ayurveda Research Institute for Life style related Disorders, Thiruvananthapuram and at Regional Ayurveda Research Institute for Skin disorders, Vijayawada.Total 959 cases were enrolled. Out of them, 141 patients got good response, 305 patients got fair response, 236 patients got poor responseand 46 patients got no response. 231 patients were dropped out.

Study 6: Open label Interventional study was done with combination of *Shunthi* (*Zingiber officinale*), *Guggulu (Commiphora mukul)* and *Godanti (Calcium sulphate)* in the ratio of 1:2:1-total 2gm thrice a day with honey for six weeks. The study was conducted at 15 Centres

viz. Regional Ayurveda Research Institute for Drug Development, Gwalior, Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar, Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi, M.S. Regional Ayurveda Research Institute for Endocrine Disorders, Jaipur, Central Ayurveda Research Institute for Drug Development, Kolkata, Regional Ayurveda Research Institute for Eye Diseases, Lucknow, RRA Podar Central Ayurveda Research Institute for Cancer, Mumbai, Central Ayurveda Research Institute for Respiratory Disorders, Patiala, Regional Ayurveda Research Institute, Itanagar,Regional Ayurveda Research Institute for Urinary Disorders, Jammu, Done at Regional Research Institute (Ay.), Junagarh (Later merged with Regional Ayurveda Research Institute for Skin Disorders, Ahmedabad), Regional Ayurveda Research Institute for Nutritional Disorders, Mandi, Regional Ayurveda Research Institute for Infectious Diseases, Patna, Regional Ayurveda Research Institute for Life style related Disorders, Thiruvananthapuram and at Regional Ayurveda Research Institute for Skin disorders, Vijayawada. In the study total (n=2047) cases were studied. Out of them, 335 patients, 620 patients, 422 patients, 243 patients got good response, fair response, poor response, no response respectively and 527 patients were dropped out.

Study 7: Open label Interventional study was done with 500mg of *Suranjana* (*Colchicum luteum*) and *Shallaki* (*Boswellia serrata*) thrice a day with water. The study was conducted at 3 Centres viz. M.S. Regional Ayurveda Research Institute for Endocrine Disorders, Jaipur, Central Ayurveda Research Institute for Respiratory Disorders, Patiala, Regional Ayurveda Research Institute for Nutritional Disorders, Mandi, and at Regional Ayurveda Research Institute for Mother and Child Health, Nagpur.In the study total (n=358) cases were studied. Out of them, 50 patients, 92 patients, 88 patients, 20 patients got good response, fair response, poor response, no response respectively and 108 patients were dropped out.

Study 8: Open label Interventional study was done with *Deepana pachana* with *Balaguduchyadi kwatha* , thrice a day for 14 days, *Snehapana* with *Indukanta Ghrita* for 3-7 days, *Swedana* (*Vashpasveda*) for one day, *Vamana* for one day followed by *Samsarjanakarma* for 7 days. The study was conducted at 5 Centres viz. Central Ayurveda Research Institute for Drug Development, Kolkata, National Ayurveda Research Institute for Panchakarma, Cheruthuruthy, Regional Ayurveda Research Institute for Urinary Disorders,

Jammu, Central Ayurveda Research Institute for Respiratory Disorders, Patiala and atCentral Ayurveda Research Institute for Cardiovascular Diseases, New Delhi. In the study total (n=313) cases were studied. Out of them, 72 patients, 130 patients, 53 patients, 22 patients got good response, fair response, poor response, no response respectively and 36 patients were dropped out.

Study 9: Open label Interventional study was done with *Snehapana* with *Indukanta Ghrita* for 3-7 days, *Swedana* (*Vashpasveda*) for one day, *Vamana* for one day followed by *Samsarjanakarma* for 7 days.The study was conducted at 5 Centres viz. National Ayurveda Research Institute for Panchakarma, Cheruthuruthy, Central Ayurveda Research Institute for Drug Development, Kolkata, Regional Ayurveda Research Institute for Urinary Disorders, Jammu, Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar and at Central Ayurveda Research Institute for Respiratory Disorders, Patiala. In the study total (n=313) cases were studied. Out of them, 72 patients, 130 patients, 53 patients, 22 patients got good response, fair response, poor response, no response respectively and 36 patients were dropped out.

Study 10: Open label Interventional study was done with *Samira Pannagarasa* - 250 mg thrice a day with honey for six week, *Pippali Vardhamana Ksheera Paka* – Day one starts with one *pippali* and add one every day upto 21 days thereafter reduce one *pippali* every day upto next 21 days along with *Panchakola Churna* as *Prakshepa dravya*, *Pinda sweda.* The study was conducted at 3 Centres viz. National Ayurveda Research Institute for Panchakarma, Cheruthuruthy, Regional Ayurveda Research Institute for Mother and Child Health, Nagpur and at Regional Ayurveda Research Institute for Urinary Disorders, Jammu. The study was conducted at 3 Centre and total (n=213) cases were studied. Out of them, 44 patients, 82 patients, 49 patients, 9 patients got good response, fair response, poor response, no response respectively and 29 patients were dropped out.

Study 11: A Multicentric open labeled, non-controlled prospective study executed at OPD level at 4 peripheral centres viz. Regional *Ayurveda* Research Institute for Skin Disorders (RARISD), Vijayawada, Central *Ayurveda* Research Institute for Cardiovascular Diseases (CARICD), New Delhi, Regional *Ayurveda* Research Institute for Endocrine Diseases (RARIED) Jaipur and at Achanta Lakshmipathi Research Centre for *Ayurveda* (ALRCA), Chennai. Total patients enrolled 225. In **Group I** cases were treated with *Vatari Guggulu* 1.5

gm (3 tablets of 500 mg each) twice daily after food with lukewarm water, and *Rasnasaptaka Kashaya* 15 ml with *prakshep* of 1 gm *Shunthi churna* twice daily before food was given internally and in **Group II** along with these two drugs *Brihat Saindhavadya taila* 20 ml was used twice daily for external application over affected joints. The duration of treatment was for 12 weeks. **In Group1** after 12 weeks of trial period the mean DAS-28 Score (**Primary outcome**) reduced from 6.68 at baseline to 4.98 on 84th day showing statistically significant improvement. In disability index (**Secondary outcome**) the mean score at baseline was 1.53 and was reduced to 0.89 on 84th day showing statistically significant improvement. The acute phase reactant ESR (**Secondary outcome**) was 42.17 at baseline reduced to 39.6 on 84th day but the change was statistically insignificant. In Health Survey Questionnaire SF-36 (**Secondary outcome**) Physical functioning domain the mean score at baseline was 26.95 which was increased to 52.26 on 84th day showing statistically significant improvement. **In Group** 2, after 12 weeks of trial period the mean DAS-28 Score (**Primary outcome**) reduced from 6.62 at baseline to 4.89 on 84th day showing statistically significant improvement. In disability index (**Secondary outcome**) the mean score at baseline was 1.59 and was reduced to 0.82 on 84th day showing statistically significant improvement. The acute phase reactant ESR (**Secondary outcome**) was 41.35 at baseline reduced to 40.15 on 84th day but the change was statistically insignificant. In Health Survey Questionnaire SF-36 (**Secondary outcome**) Physical functioning domain the mean score at baseline was 27.37 which was increased to 54.56 on 84th day showing statistically significant improvement. CTRI//2014/05/004629

Study 12: A prospective open label multicentre trial executed at three peripheral centres viz. Research Ayurveda Regional Institute for Gastro-Intestinal Disorders, Guwahati, Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar, Regional Ayurveda Research Institute for Infectious Diseases, Patna. Total of 180 participants were enrolled. The study medications included quality assured tab *Vatari Guggulu* 1 gm (2 tablets of 500mg each) thrice daily after food with Lukewarm Water for 12 weeks, *Hingvastaka Churna* Orally 3 gm twice daily along with first bolus of food mixed with ghee for 12 weeks and *Brihat Saindhavadya Taila* 20 ml local Application twice daily, for 12 weeks. The study shows significant improvement in DAS 28 Score of patients suffering from rheumatoid arthritis after 84 days of treatment. Significant improvement in Disability Index Score were also seen ($p<0.001$). Also there was significant improvement in ESR and CRP score.

Conclusion

The outcome of these studies indicates that the patients of rheumatoid arthritis could be managed successfully with Ayurvedic therapies. It is also noted that the effects on these patients are lasting and relapse is rarely observed. No adverse drug reactions / adverse events have been reported in any in any study. These drugs can be safely used for the management of Rheumatoid Arthritis.

Tab 2.1.1. Therapeutic Response at a glance

S.N.	Interventions	Good response	Fair response	Poor response	No response
1.	*Shunthi Guggulu* with *baluka sweda* (n = 497)	67% have shown good response			
2.	*Mahayograja guggulu, Simhanada guggulu* and *Vaishwanar churna* (n =518)	60% have shown good response			
3.	*Aswagandha, Eranda taila* with *baluka sweda*	57% have shown good response			
4.	*Pippali VardhamanaKsheera Paka* and *Samira Pannagarasa*(n=728)	19.37% (n=141)	41.90% (n=305)	32.42% (n=236)	6.32% (n=46)
	Combination of *Shunthi Guggulu* and *Godanti* (n=1520)	22.04% (n=335)	40.79% (n=620)	27.76% (n=422)	9.41% (n=143)
5.	*Suranjan* and *Shallaki* (n=250)	20% (n=50)	36.8% (n=92)	35.2% (n=88)	8% (n=20)
6.	**Panchakarma:** a) *Deepana Pachana* (*Balaguduchyadi kwatha), Snehapana* with *Indukanta Ghrit Svedana* and *Vamana* (n=277)	26% (n=72)	46.93% (n=130)	19.13% (n=53)	7.94% (n=22)
	b) *Snehapana* with *Indukantaghrita, Swedana, Vamana* and *Samsarjana*.(n=450)	31.33% (n=141)	47.11% (n=212)	16.22% (n=73)	5.33% (n=24)
7.	The above course Without *Panchakarma* using *PanchakolaChurna* (n=184)	23.91% (n=44)	44.57% (n=82)	26.63% (n=49)	4.89% (n=9)

Table 2.1.2: Showing the effect of treatment on RA Factor in study no. 11

RA Factor (Immune Turbidity test)	Group							
	I				II			
	Baseline		84th day		Baseline		84th day	
	No. of patients	%	No. of patients	%	No. of patients	%	No. of patients	%
Negative	41	36.3%	44	38.9%	43	38.4%	53	47.3%
Positive	72	63.7%	69	61.1%	69	61.6%	59	52.7%
Total	113	100.0%	113	100.0%	112	100.0%	112	100.0%

Fig. 2.1.1 Therapeutic Response in different interventional groups

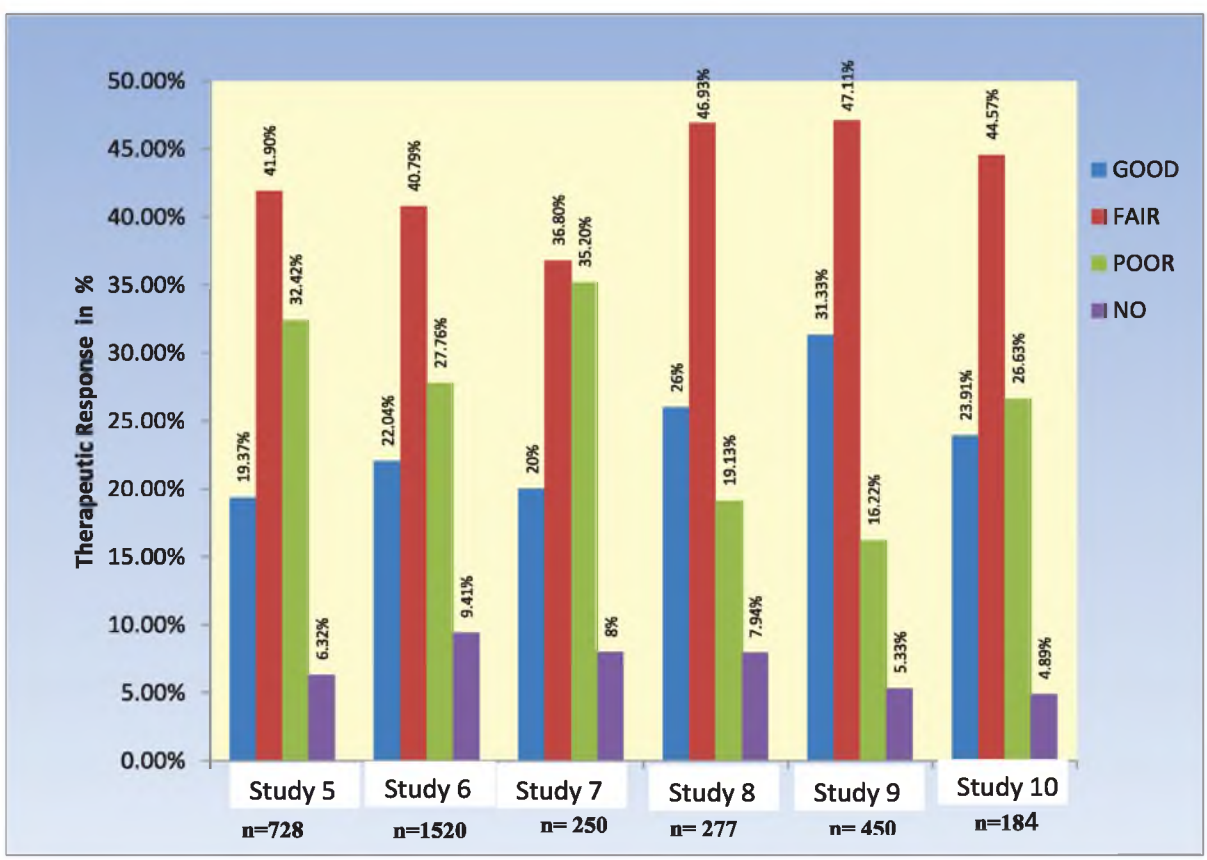


Fig. 2.1.2: Effect of the treatment on Outcome parameters in study 12

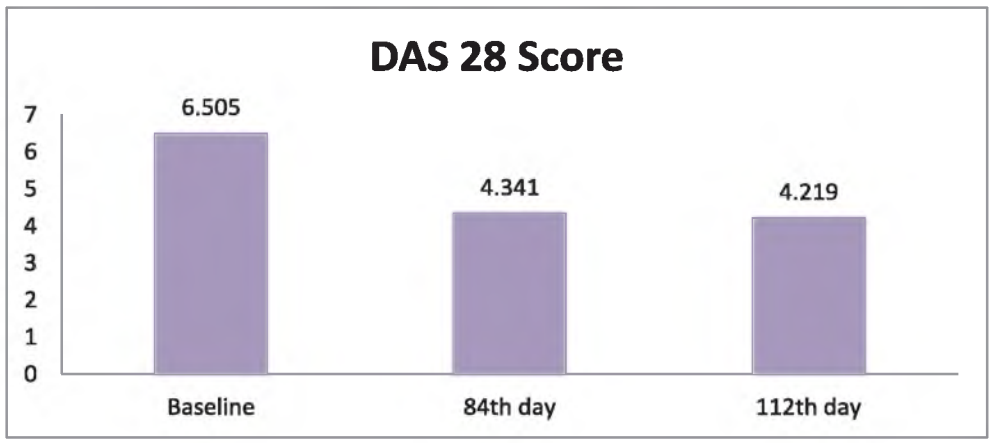
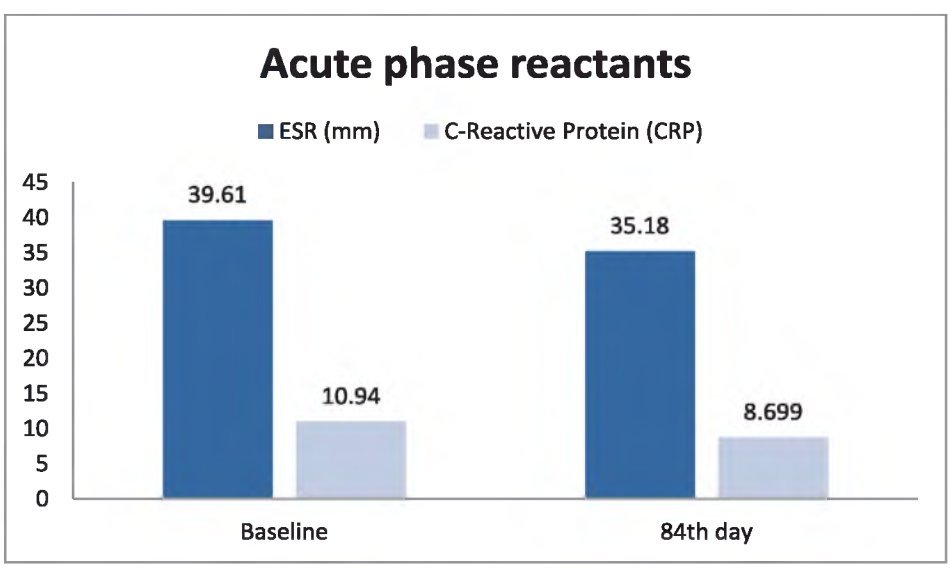


Fig. 2.1.3: Effect of the treatment of Acute phase Reactants, ESR & CRP in study 12



2.2. - GRIDHRASI (SCIATICA)

Background: Sciatica refers to pain, numbness, and tingling of lower limb resulting from injury or compression of sciatic nerve. The pain of sciatic nerve originates from lower back and radiates towards buttocks, back of thighs, below the knee up to the foot. The pain is usually get worse on prolonged sitting, standing and walking and relived by lying down.The sciatica mostly affects the early and middle aged peoples, heavy weight lifters and persons who are engaged in the occupations in which continuous pressure on back is used. The common causes of sciatica are herniated disc, spinal stenosis, spondylolisthesis, piriformis syndrome, osteoarthritis, osteoporosis and sometimes during pregnancy.

As the sciatica is considered as a manifestation of underlying diseases, the line of treatment is to treat underlying cause which irritate/ compress the sciatic nerve. Besides this, bed rest, physiotherapy, analgesics and muscle relaxants are being used. Sometimes surgical intervention may be required.

In Ayurveda, *Gridhrasi* (Sciatica) is considered as one of the important *Vata Vyadhi* (Neurological disorders). The disease is characterized by stiffness, pain and pricking sensation initially at the hip and gradually radiating towards waist, back, thigh, knee and calf region along with frequent pulsation at these sites. Two types of *Gridhrasi* have been described viz. *Vataja* and *Vatakaphaja.* In both the main vitiated *dosha* is *Vata*. Various approaches of the treatment including *Panchakarma* therapies have been recommended in Ayurvedic Classical texts. *Snehopachara* (internal and external oleation) *Swedana* (sudation) and mild *Samshodhana* (clensing) is considered as the foremost treatment for *Vata* diseases. Among *pachakarma, Vastikarma* (therapeutic enema) is best suited for *Vata* predominant diseases in particular. *Vastikarma* is a procedure in which a mixture of medicine in suspension is directly administered into the *Pakwashaya* (large Intestine) through anal route by using specialized instrument. In the present study different Ayurvedic procedures and medicines were used.

Council has done following studies since inception for validation of classical drugs in the management of *Gridhrasi*:

Study 1: The purified *Bhallataka (marking nut)* as per the procedure laid down in the Ayurveda has been given to the patients in gradually increasing doses and then gradually tapering the dose to the initial dose. Apart from such a course, the purified *Bhallataka* has

also been given in a uniform dose of 250 mg. to 500 mg. three times a day to 128 patients.The effect of the *Bhallataka* has been assessed on the basis of clinical improvement and functional tests. The observations indicate encouraging response and 52% of the patients have shown efficacy.

Study 2: The *Trayodasharga Guggulu* 1 gm. three times a day with warm water and *Visatinduka Vati* 250 mg. three to four times a day has been given internally along with external application of oil massage and fomentation. Thestudy was conducted on 128 patients. The results have been assessed on the basis of clinical features and functional capacity of the patients. 57% of the patients showed encouraging response.

Study 3: The *Panchakarma* regimen given consists of *Snehana* (Oleation), *Svedana* (Sudation) and *Vasti* (Medicated enema). Different drugs have been used for the preparation of massage oil and decoction for each study. A number of studieshave been conducted with different drugs on a large number of patients. The effect of the therapy was encouraging and 75-100% patients under different studied have shown improvement.

Study 4: Open label Interventional study was done with *Hingutriguna Taila* – 10 ml to 15 ml thrice a day for 21 days. The study was done at 6 centres, viz. Regional Ayurveda Research Institute for Eye Diseases, Lucknow, Regional Ayurveda Research Institute, Gangtok, Regional Ayurveda Research Institute, Itanagar, National Ayurveda Research Institute for Panchakarma, Cheruthuruthy, Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi and at Regional Ayurveda Research Institute for Infectious Diseases, Patna. In the study total 211 cases were studied. Out of them, 21 patients, 63 patients, 54 patients, 16 patients and got good response, fair response, poor response and no response respectively. 57 patients were dropped out from the trial.

Study 5: Open label Interventional study was done with *Hingutriguna Taila* – 10 ml. to 15 ml. thrice a day for 21 days, *Dasamoola Bala Kwatha* 20 ml. thrice a day for 21 days and *Nirgundi Patra pinda Sweda* twice a day for 21days. The study was done at two centres, viz. Regional Ayurveda Research Institute, Itanagar and at National Ayurveda Research Institute for Panchakarma, Cheruthuruthy. In the study total 229 cases were studied. Out of them, 54 patients, 91 patients, 39 patients and 17 patients and got good response, fair response, poor response, no response respectively. 28 patients were dropped out from the trial.

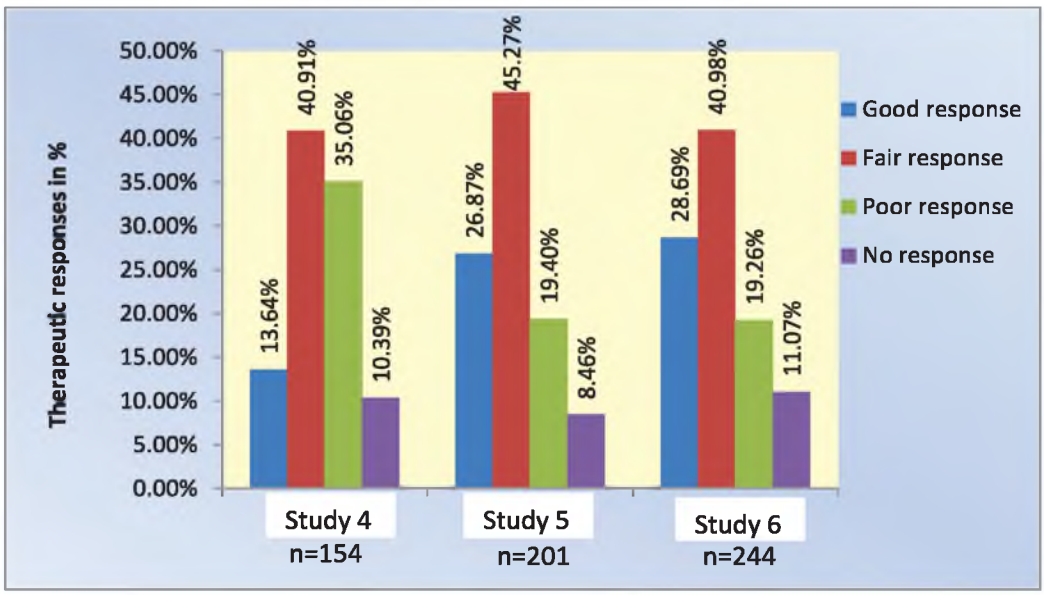
Study 6: Open label Interventional study was done with *Panchakarma chikitsa* including *Snehapana* with *Dasamoola Bala Taila* for 7 days, *Vashpa Sweda* for 3 days, *Virechana* with *Eranda Taila* for 1 day, *Samsarjana Karma* for 7 days and *Vaitarana Vasti* for 7 days. The study was done at two centres, viz. Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi and at National Ayurveda Research Institute for Panchakarma, Cheruthuruthy. In the study total 294 cases were studied. Out of them, 70 patients, 100 patients, 47 patients, and 27 patients got good response, fair response, poor response, no response respectively and 50 patients were dropped out.

Conclusion: The studies have shown promising results in alleviating the symptoms of Sciatica. The patient with *Gridhrasi* can be successfully managed with Ayurveda line of treatment.

Tab 2.2: Therapeutic Response at a glance in *Gridhrasi*

Sl.No.	Interventions	Good response	Fair response	Poor response	No response
1.	*Bhallataka (n=128)*	52% patients have shown good response			
2.	*Trayodasharga Guggulu* and *Visatinduka Vati* (n= 128)	57% patients have shown good response			
3.	Hingu Triguna Taila (n=154)	13.64% (n=21)	40.91% (n=63)	35.06% (n=54)	10.39% (n=16)
4.	Hingu Triguna Taila, Dashmoola Bala Kwath, Nirgundi Patra Pinda Sweda (n=201)	26.87% (n=54)	45.27% (n=91)	19.40% (n=39)	8.46% (n=17)
5.	Pancakarma Chikitsa: Snehapana Svedana, Virechana, Samsarjana Vasti(n=244)	28.69% (n=70)	40.98% (n=100)	19.26% (n=47)	11.07% (n=27)

Fig.2.2. Therapeutic Response in different interventional groups



2.3: PAKSHAGHATA (HEMIPLEGIA) & PANGU (PARAPLEGIA)

BACKGROUND

Pakshaghata (Hemiplegia) is one of the major neurological disorders manifested as inability to move the group of muscles of either in left or right side of the body. In classical books of Ayurveda the terms *Pakshaghata*, *Pakshavadha* and *Ekangaroga* are used to denote the clinical condition in various contexts. *Charaka* included *Pakshaghata* in the list of *nanatmajavyadhi* among the eighty types of *vata* disorders which are considered as *mahavyadhi*, which is (difficult to cure). *Pakshaghata* may vary in severity from a weakness in a limb with slight numbness to a profound loss of functions in half of the body. The mode of onset, organs involved, spread of impairment, functions impaired i.e., motor, sensory and mental function may vary considerably from case to case according to the underlying etiology.

According to modern terminology, hemiplegia is usually the sequel of cerebro-vascular disorders or stroke and most cerebrovascular diseases are manifested by the abrupt onset of a focal neurologic deficit. The clinical manifestations of stroke are highly variable because of the complex anatomy of the brain and its vasculature. Features other than the weakness decreased movement controlled, clonus, spasticity; exaggerated deep tender refers and decreased endurance. Hemiplegia is the leading cause of disability resulting into enormous socio economic implications.

The general pathology described for *Pakshaghata* is *dhatukshaya* (nutritional deficiency) and *margavarodha* (obstruction in the pathways). In *Pakshaghata* both the above factors have definite role in the pathogenesis. The circulatory disturbance affected due to these leads to the impairment in the supply of nutrition to the brain cells which is the vital part (*Marma*) and controlling Centre of motor and sensory functions. The clinical research conducted in hemiplegia with different treatment schedule in various study groups revealed that the complete recovery from the illness is very rare; however the therapy was useful to improve the functional ability and quality of life of the disabled patients.

Parpalegia indicates paralysis of both lower extremities. This mayoccur in diseases of spinal cord, spinal roots peripheral nerver or maybe hysterical. If the onset is acute, it may be difficult to distinguishspinal from neuropathic paralysis because the element of spinal shockmay result in abolition of reflexes and flacidity.

Walking disability due to the drawing up (contractions) of *Kandara* (muscle tendon) of one leg by deranged *Vayu* situated at *Kati* (lumbosacral) region is the main symptom of *Kharya* (monoplegia) andwhen both legs are similarly affected the disease is called *Pangu*(Paraplegia). It originates at *Kati* due to the vitiated*Vata,* (a humor)probably the *Katyasrita Vata* - that is *Apanavayu* is involved. The main complaints are disturbed visceral reflexes (micturition anddefection), loss of sensation, inability to walk due to *Apanavaigunya.*The definition of *Vata* itself explains that the normal function of *Vata* isthe regulation of motor and sensory functions. Therefore, vitiation of *Vata* leading to the onset of a disease usually manifests as an impairment of these functions.

Council has done following studies since inception for validation of classical drugs in the management of *pakshaghata*:

Study 1: Open label Interventional study was done with *Snehapana* by *Ksheerabala Tail* for up to 7 days, *Svedana* (*Vaspa sveda*) for 3 days, *Virechana* by *Eranda Taila* 30ml for 1 day, *Vastikarma* (*Yoga vasti*): *Dasamoola kwatha* (*Niruha*) for 3 days, *Ksheerabala taila* (*Anuvasana*) for 5 days and *Nasya* by *Ksheerabala taila* for 7 days. The study was done at 5 centres viz.National Ayurveda Research Institute for Panchakarma, Cheruthuruthy, Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi, Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar, Central Ayurveda Research Institute for Respiratory Disorders, Patiala and at Regional Ayurveda Research Institute for Mother and Child Health, Nagpur. In this study total 431 cases were studied. Out of them, 36 got good response, 142 got fair response, 115 got poor response, while 26 had no response and 112 were dropped out.

Study 2: Open label Interventional study was done with *Dhanadanyadi Kwatha* 60ml plus k*sheerabala taila* (7times) 10 to 20 drops for 30 days, *abhyanga* by *ksheerbala taila, Patra pinda Sveda* for 14 days and *Virechana* by *Eranda Taila* 30ml for 1 day. Study was done in five centres viz. National Ayurveda Research Institute for Panchakarma, Cheruthuruthy, Central Ayurveda Research Institute for Respiratory Disorders, Patiala, Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar, Regional Ayurveda Research Institute for Mother and Child Health, Nagpur and at Advanced Center for Ayurveda in Mental Health & Neurosciences, Bangalore. In this study total 475 cases were studied. Out of them 39 got good response, 172 got fair response, 146 got poor response, while 24 had no response and 94 were dropped out.

Study 3: Open label Interventional study was done with *Maha Vata vidhwansana* 250 mg TDS for 14 days, *Abhyanga* by *Ksheerbala Taila, Swedan* by *Dhanyamla* 3 litres for 14 days, *Virechana* by *Eranda Taila* 30ml for 1 day and *Sirovasti* by *Ksheerbala Taila* for 7 days. The study was done at three centres viz. Central Ayurveda Research Institute for Respiratory Disorders, Patiala, National Ayurveda Research Institute for Panchakarma, Cheruthuruthy and Regional Ayurveda Research Institute for Mother and Child Health, Nagpur. This study comprising of interventions like Maha VatavidhwansanaRasa, Dhanyamla Seka, Virechana and conducted at 3 centres. Total 204 cases were studied. Out of them, 14 got good response, 71 got fair response, 53 got poor response, while 8 had no response and 58 were dropped out.

Other studies: Apart from these six other clinical studies were also done by CCRAS. The effect of *snehapana, swedana, virechana, bastikarma, nasya and shirobasti* with different medicated oils was studied under *Sodhana.* The *Shamana* therapy with medicated oils and herbo mineralpreparations were also done. *Sastikasali pinda sweda* was given as *Swedana* therapy and its role in the management of *Paksaghata* wasstudied. The results obtained in 744 patients of *Paksaghata* treated inthe following six major studies have been reported:

1. Effect of *Panchakarma* treatment with *Masadiyoga* in 112 patients
2. Effect of *Bhadradarvadi kasaya, Danwantarma gutika* & medicated oils in 109 patients
3. Effect of *Nirgundi taila, Sahacara taila* & *Bhadradarvadi taila*-comparative study in 266 patients.
4. Effect of *J.J. taila* - internally and externally in 80 patients
5. Effect of *Panchakarma* therapy and *Sirobasti* with *Masa taila in 66* patients
6. The effect of herbo-mineral preparations *(internal) and application of Sastikasalipinda sveda with Brhatmasa taila (external) a*long with *Panchakarma* therapy in 111 patients.

Conclusion

The study comprised 744 patients of *Paksaghata* out of which 552 received *Panchakarma* therapy with various single and compound medicinal preparations. 192 patients were given *Samaria* therapy.The result of this treatment showed that *Panchakarma* therapy is useful to improve the functional ability of patients and improve the quality of life. It is the most effective method of treatment for *Paksaghata.*The complete recovery from the illness is very rare but the therapy is useful to improve the functional ability and the quality of living of disabled patients.

***Pangu* (Paraplegia)**

Drug/Regime	No. of patients
i. *Sahacharadi Yoga* and *Sodhana*	60
ii. Comparative study of the effects of *Sahacharadi Tailam, Nirgundi Tailam & Bhadradarvadi Tailam* in *Sodhana* and *Samana* therapies	20
iii. Effects of *Prabhajan Vimardanam Tailam* in Sodhana & Samana therapies	58
iv. The role of Ayurvedic drugs and physiotherapy in the management of *Pangu*	54
v. Action of *Asvagandha Chuma &Gorochanadi Vati* internal and *Balashvagandhalakshadi Tailam* external in *Kharya* and *Pangu*	32
vi. A comparative study of certain Ayurvedic formulations and *Panchakarma* therapy in the management of *Pangu*	20

Conclusion

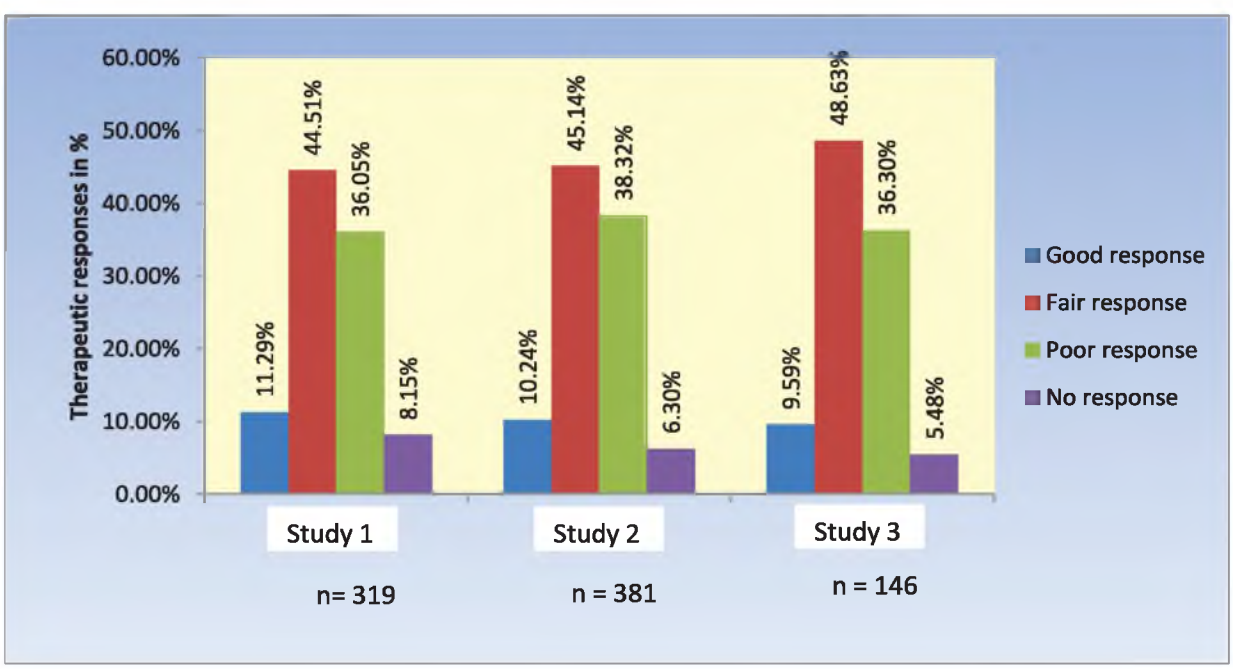
The clinical trials revealed that these regimens were found to beeffective in management of paraplegia. The results were encouraging and statistically significant. On comparison of result obtained with different studies. The Sahacharadi group was found to be the most effective and this encouraging result was also observed in the sahacharadi group (II group).

In order to confirm the therapeutic potentialities of *Sahachara* and to find out the mechanism of action of this drug detailed pharmacological studies were undertaken and the results obtained confirm its clinical claims in the management of paraplegia. The result obtained with *Nirgundi* group in the II study was also encouraging and hence this drug was also taken up for the pharmacological studies. The results obtained were found to be supporting the clinical findings.

Tab 2.3.Therapeutic Response at a glance in Hemiplegia

Sl.No.	Interventions	Good response	Fair response	Poor response	No response
1.	*Snehapana, Svedana, Virechana, Samsarjana, Vastikarma Yogavasti (Nirooha & Anuvasana), Nasya* (*n*=319)	11.29% (*n*=36)	44.51% (*n*=142)	36.05% (*n*=115)	8.15% (*n*=26)
2.	*Dhanadanyadi Kwatha with Ksheerbala Taila; Abhyanga, Patra Pinda Sveda,Virechana*(*n*=381)	10.24% (*n*=39)	45.14% (*n*=172)	38.32% (*n*=146)	6.30% (n=24)
3.	*Maha Vatavidhwansana Rasa Dhanyamla Seka, Virechana* (*n*=146)	9.59% (*n*=14)	48.63% (*n*=71)	36.30% (*n*=53)	5.48% (*n*=8)

Fig. 2.3. Therapeutic Response in different interventional groups



2.4: MADHUMEHA (DIABETES MELLITUS)

Background: Diabetes mellitus (*Madhumeha*) is a group of metabolic diseases characterized by hyperglycaemia which are caused due to reduced insulin secretion, decreased glucose utilization and increased glucose production. The secondary pathophysiologic changes occur in multiple organ systems due to metabolic dysregulation associated with Diabetes mellitus. The two categories of diabetes are type I or Insulin Dependent Diabetes Mellitus (IDDM) & type II or Non Insulin Dependent Diabetes Mellitus (NIDDM). Complete or near total insulin deficiency is found in type I. Type II diabetes mellitus is characterized by variable degree of insulin resistance, impaired insulin secretion and increased glucose production. The classical symptoms of diabetes mellitus are polyuria (frequent urination), polydipsia (increased thirst) and polyphagia (increased hunger).

Diabetes mellitus is one of the major global health problems with an increase in worldwide prevalence from about 30 million cases in 1985 to 177 million cases in 2000 and world wide estimates project that more than 360 million individuals will have diabetes by the year 2030. The prevalence of the disease increases with the age and affects men and women similarly but is slightly greater in men > 60 years. Types II diabetes mellitus is increasing more rapidly due to obesity caused by sedentary life habits and changed life style.

Insulin is the only treatment for type I diabetes and conventional modern medicine provides a number of drugs for controlling the blood sugar level in the patients of diabetes mellitus type II. However, with the prolonged treatment doses of the drugs often needs to be increased to control the blood sugar level and a time comes when patient has to be switched over to insulin. Such patients become cases of insulin dependent diabetes mellitus. With a view to help the suffering community there is a need to find a safer drug, which can be used to control the blood sugar level to use safely for longer periods.

Madhumeha has been vividly described in classical Ayurvedic Texts. A number of predisposing and etiological factors and complications of this disease are described in great detail. Acording to Ayurveda, *Madhumeha* is a type of *Prameha*. All types of *Prameha* ultimately lead to *Madhumeha*. The food items and life styles which vitiate *kapha* may predispose *Prameha*. Sedentary life style, excessive sleep and over consumption of curd, meat soups, fat rich food, milk, milk products, jaggery preparations etc. causes *Prameha*. Ayurveda emphasizes on the elimination of the etiological factors as the main principle of

treatment of the disease. Accordingly regulation of diet and exercise has been laid special emphasis. The use of herbal and herbo-mineral preparations for the treatment of the disease is also mentioned. Different Ayurvedic formulations were used in this study series for clinical evaluation.

Council has done following studies since inception for validation of classical drugs in the management of *Madhumeha*:

Study 1: An interventional open label study was done with *Karela* (*Momordica charantia Linn.*) along with *Jamun* seeds (*Syzyguim cumini L. skeals*) and *Ghana satva vati* – 1 gm. thrice a day with water. The study was done at three centres viz. Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar, Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi and at Regional Ayurveda Research Institute, Itanagar. In the study, total 464 cases were studied. Out of them, 82 patients, 85 patients, 58 patients, 22 patients got good response, fair response, poor response and no response respectively and 217 patients were dropped out.

Study 2: An interventional open label study was done with Combination of leaves of *Bilwa* (*Aegle marmelos Corr*), *Neem* (*Azadirachta indica A. Juss*), *Tulasi* (*Ocimum sanctum Linn.*) along with *maricha* (*Ghana vati*) - thrice a day with water. The study was done at two centres viz. Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi and at Regional Ayurveda Research Institute, Itanagar. In the study total 156 cases were studied. Out of them, 21 patients, 36 patients, 22 patients, 10 patients got good response, fair response, poor response and no response respectively and 67 patients were dropped out from the trial.

Study 3: An interventional open label study was done with *Nisha Amalaki* powder- 1grm, TDS with water along with Meditation & Yoga. The study was done at three centres viz. Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar, Regional Ayurveda Research Institute for Gastro-Intestinal Disorders, Guwahati and at Regional Ayurveda Research Institute, Itanagar. In the study total 128 cases were studied. Out of them, 35 patients, 23 patients, 30 patients, 21 patients got good response, fair response, poor response and no response respectively and 19 patients were dropped out.

Study 4: An interventional, open randomized multi-centre clinical study was done. The study was conducted in 04 centres i.e. Dr. Achanta Lakshmipathi Research Centre for Ayurveda (ALRCA), Chennai; Regional Ayurveda Research Institute for Skin Diseases (RARISD), Vijayawada; Ayurvedic Regional Ayurveda Research Institute for Nutritional Disorders (RARIND), National Ayurveda Research Institute for Panchakarma (NARIP), Cheruthuruthy. Subjects in were treated with *Nisha Katakadi Kashaya* in a dose of 15 ml (diluted with 45 ml water) twice daily before food with luke warm water. In Group-II, Cap. *Yashada Bhasma* 125 mg thrice in a day was administered with luke warm water before food and in Group-III, *Nisha Katakadi Kashaya*, 15 ml (to be diluted with 45 ml water) twice daily & Cap. *Yashada Bhasma,* 125 mg thrice in a day was administered. The duration of treatment was 12 weeks (84 days) in all the groups and the effect of the drug was assessed up to 14th week. Changes in Blood sugar Fasting (10-12 hrs after dinner) and change in Blood sugar Post - Prandial (100-120 minutes after breakfast), changes in Diabetes Symptoms Questionnaire (DSQ) score, Glycosylated haemoglobin (HbA_1c), and health related quality of life were assessed. Total 193 subjects who fulfil the inclusion and exclusion criteria were randomly selected (Computer generated randomization) into 3 groups on 1st come 1st basis (ALRCA -56, RARISD - 60, RARIND - 60 and NARIP-17) and enrolled for the study, out of which 178 cases were completed. These drugs shown statistically significant ($P<0.001$) effect in relieving subjective parameters like Diabetes Symptoms Questionnaire (DSQ) score & SF-36-Health Survey Score, without changes/altering objective parameters viz., HbA_1c% & Blood sugar levels, and also found significant improvement in clinical symptoms and patient's well-being in all the groups, while it comprises very good results in Group III when compared with other groups in improving clinical symptoms.CTRI/2014/05/004613

Study 5: It was an open label, non-comparative, prospective, pragmatic trial. The study was conducted in only one centres i.e. RARIDD, Gwalior. Therapeutic Combination of *Gokshuradiguggulu* (Ref. The Ayurvedic Pharmacopoeia of India. Part-II, Volume-II, 1sted, New Delhi, 2008. p. 112-114) 1 gm (two tablets of 500 mg) twice in a day along with *Guduchi churna* (The Ayurvedic Pharmacopoeia of India. Part-I, Volume-I, 1sted, 2008. p. 53-55) 3 gm twice daily with lukewarm water after food up to 12 weeks were used in this study.General and systemic examinations as well as bio-chemical investigation, clinical assessment as per Diabetes symptoms questionnaire, assessment of Ayurvedic parameters, RAND SF36 health survey score were assessed in the study. Total 50 subjects who fulfilled the inclusion and exclusion criteria had enrolled in the study.At baseline visit mean

glycosylated hemoglobin (HbA_{1C})was 8.27 ±0.23, which was significantly reduced 7.99±0.33after 84th day treatment with these medicines, mean blood sugar fasting (10-12 hrs after dinner) was 147.92 ± 2.05, which was significantly reduced to 139.14 ± 3.72, mean blood sugar post prandial (100-120 minutes after breakfast) was 241.34 ± 4.63, which was also significantly reduced 238.02 ± 7.35, the mean Diabetes symptoms questionnaire (DSQ)score was 23.18±2.133, which was significantly reduced to 12.18±1.20 and the mean SF-36 HSQ score was 472.47±1.22 which was significant to the 568.65±1.16. All safety lab parameters were found within normal limits. Overall conclusion of this study, the effect of this therapeutic combination is significant ($p<0.001$).CTRI/2014/09/005048

Conclusion: The studies have shown very promising results of Ayurveda intervention in the management of diabetes, though it cannot be completely cured but can be successfully managed with different modalities of Ayurveda. The Ayurvedic intervention is also free from any adverse events thus can provide a safe and effective option for the management of diabetes.

Tab 2.4.1. Therapeutic Response at a glance in the management of diabetes

Sl. No.	Interventions	Good response	Fair response	Poor response	No response
1.	Karela, Jamun seed Ghanasatva (n=247)	33.2% (n=82)	34.41% (n=85)	23.48% (n=58)	8.91% (n=22)
2.	Bilva, Neem, Tulsipatra, Kalimarich (n=89)	23.60% (n=21)	40.45% (n=36)	24.72% (n=22)	11.24% (n=10)
3.	Nisha Amalaki Churna Meditation & Yoga (n=109)	32.11% (n=35)	21.10% (n=23)	27.52% (n=30)	19.27% (n=21)

Fig.2.4. Therapeutic Response in different interventional studies

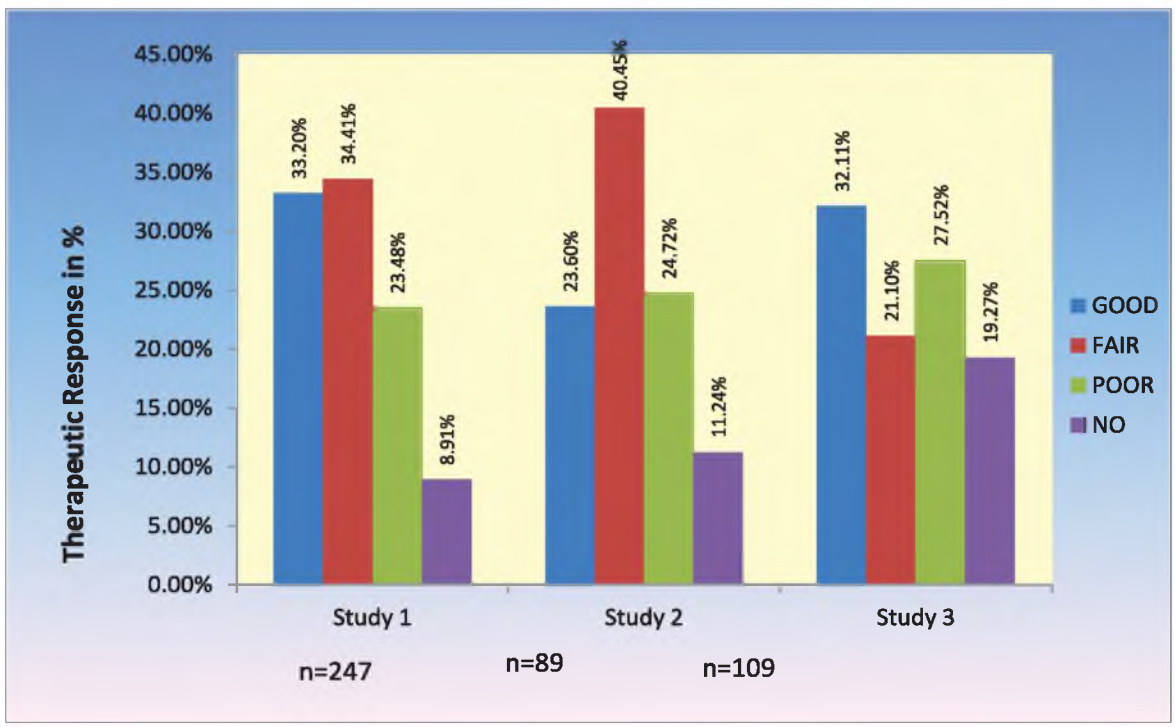


Table 2.4.2: Effect of treatment on chief complaints in the subjects of Type II DM (n=50) in Study 5

Clinical symptom	No. of patients		Percentage of relief	P value
	Start of the treatment	End of the treatment		
Polyuria (Excessive urine)	39	06	84.61	<0.001
Polyphagia (Excessive hunger)	36	14	61.11	<0.001
Polydipsia(Excessive thirst)	29	16	44.82	<0.004
Exhaustion/tiredness	39	24	38.46	<0.001
Bodyache	31	16	48.38	<0.001
Giddiness	11	05	54.54	<0.146
Polyneuritis(Numbness/tingling)	19	12	36.84	<0.118
Visual disturbance	00	00	00	0.000

Table-2.4.3: Assessment of pathological and bio-chemical investigation in Study 5

Laboratory Parameters	Start of the treatment (Mean ± SEM)	End of the treatment (Mean ± SEM)
FBS(Blood sugar fasting)mg/dl	147.92 ± 2.05	139.14 ± 3.72
PPBS(Post prandial blood sugar) mg/dl	241.34 ± 4.63	238.02 ± 7.35
HbA1c%	8.27±0.23	7.99±0.33

2.5: SHLEEPADA (FILARIASIS)

BACKGROUND

Filariasis is well known to ancient Indians by the name of *Shleepada*. It is described that the word *Shleepada*must be understood as an increase in the size of the foot. The word '*Shleepada'* is derived from *"Silavath padam Shleepadam",* where the limb/foot becomes hard like stone. *Charaka* and *Sushruta* have a similar view suggesting that the stony hard foot is the clear picture in manifested *Shleepada*. *Vagbhata* holds the similar opinion. The disease *Shleepada that* was described in classical Ayurvedic texts is now well recognized as Filariasis due to similarity in epidemiology and clinical features. Earliest reference of *Shleepada* (Filariasis) can be found in *Charaka Samhita*. In *Caraka Samhita* the symptoms and treatment were described in chapter *Shotha*. *Sushruta* has defined and classified the disease, vividly described the epidemiological aspects and prognosis also in the chapter *Vriddhi* and *Upadamsa. Vagbhata* holds the *Susruta's* view but, defined the disease elaborately and specified the various stages of manifestations in the chapter of *Granthi* and *Arbuda. Madhava* has given an independent disease entity to *Shleepada*, whereas his predecessor *Acharyas* included the *Shleepada* under the disease *Sotha*. He described detailed note on epidemology, aetiopathogeneses, classification and prognosis of this condition and specified it is a *kaphaja* predominant disease though it is a *Tridoshaja vyadhi.* Roughness, blackish discolouration of affected part, hardness and pain are the symptoms of *Vataja Shleepada*. In *Pittaja Shleepada* patient suffers from fever, Lymphangitis, Tenderness and incresed local temparature. *Kaphaja Shleepada* can be distinguished by oiliness', heaviness of affected part with knots and tumor like appearance.

India is the largest Filariasis endemic country in the world. Now India contributes about 40% of total global burden of Filariasis and accounts for about 50% of the people at risk of infection. According to modern view Filariasis (*Shleepada*) is a vector born parasitic disease caused by three lymphatic dwelling, nematode parasites viz, Wuchereria bancrofti, Burgia malayi and Burgia timori. Among them Wuchereria bancrofti is most common in India (98%). According to the estimates made in 1995 globally, there are nearly 1100 million people are at the risk of Filariasis and there are 120 million cases of Filariasis. According to another study in India the population exposed to of infection was 25 million in 1953 and 420 million in 1995.

Council has done following studies since inception for validation of classical drugs in the management of *Shleepada*:

Study-1: Three drugs Ayush-64, *Saptapama Ghanavati* and *Nityananda Rasa* have been evaluated on 93 patients of micro-filaria.Ayush-64 (*Saptapama, Kiratatikta, Katuki, Latakaranja),* 2 tablet (500 mg each) thrice daily with water for 2 weeks, *Saptapama Ghana Vati*, 2 tab. (500 mg. each) thrice daily with water for 2 weeks, *Nityananda Rasa*, 2 tab. (500 mg. each) thrice daily with water for 2 weeks. *Saptapama Ghanawati* was found most effective (91%) in elimination of the parasite while the *Nityananda Rasa* was least effective (26%).

Study-2: Various combinations of *Sudarsana Ghanavati* have been studied on more than 900 patients suffering from chronic swelling/deformities. The results were assessed on the basis of reduction in the size and Volume of the swelling, the feeling of general well being and functional Improvement. Various dose of medicine given was as follows,

i) *Sudarsana Chuma* was given 3 gm thrice daily with warm water, and *Punamavadyarista* 20 ml with water after meals twice daily.

ii) *Sudarsana Ghanavati* 700 mg thrice daily with water for 4 weeks.

iii) *Sudarsana Ghanavati* 500 mg. thrice daily with water after food, and *Punamavadyarista* - 20 ml. twice daily with water after food.

iv) *Sudarsana Ghanvati,* 500 mg. thrice daily with water.Ayush-55 (500 mg. each)- 2 tablets thrice dally with water.

v) *Punamavadyarista* - 25 ml. twice daily with water after food.

Out of 690 patients who completed the treatment about 65% showed positive response.

Study 3: An interventional open label study was done with *Kanchanara guggulu* 500mg with *Gokshuradi guggulu* 500mg thrice daily along with lukewarm water after food for 4 weeks. Study was done at three centres viz. Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar, Regional Ayurveda Research Institute for Infectious Diseases, Patna and at Regional Ayurveda Research Institute for Skin Disorders, Vijayawada. In this study total 620 cases were studied. Out of them, 95 got good response, 279 fair response, 99 poor response, 30 had no response and 117 were dropped out.

Study 4: An interventional open label study was done with *Shleepadari Rasa* 250 mg along with *Punarnava, Triphala* and *Pippali churna* 5 gm twice daily with water after food for 30

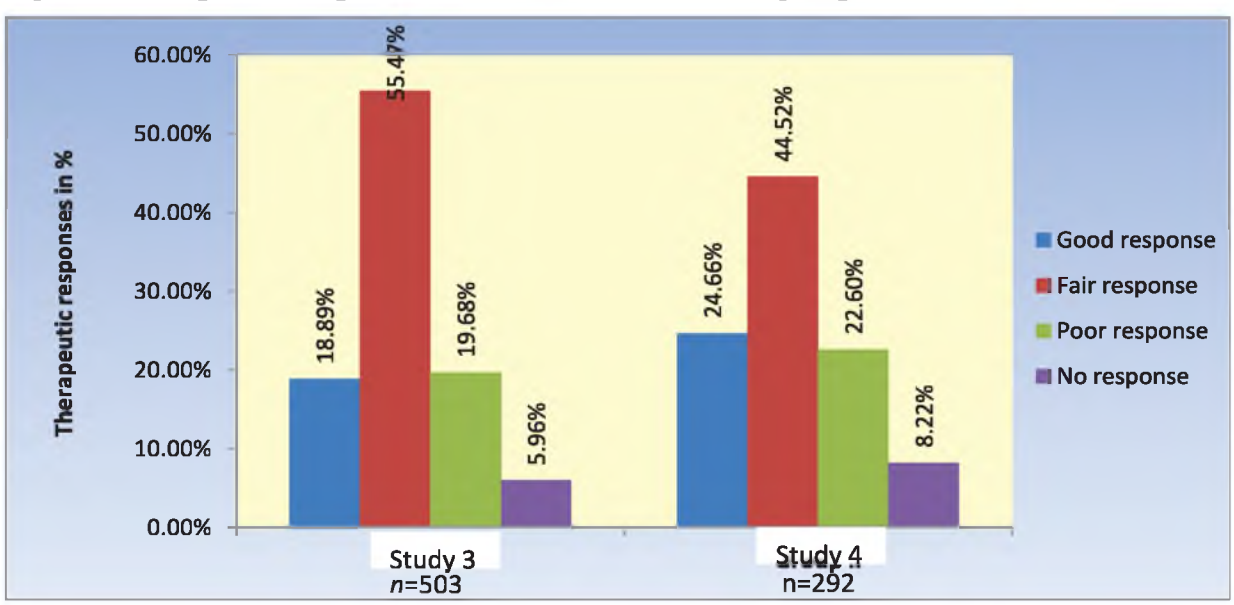
days. Study was done at three centres viz. Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar, Regional Ayurveda Research Institute for Infectious Diseases, Patna and at Regional Ayurveda Research Institute for Skin Disorders, Vijayawada. In this study total 328 cases were studied. Out of them 72 got good response, 130 got fair responses, 66 got poor responses, while 24 had no response and 36 were dropped out.

Conclusion: Ayurveda shown promising results in the management of Filariasis and can be used in the management of the disease effectively.

Tab 2.5.Therapeutic Response at a glance in filariasis

S.N.	Interventions	Good response	Fair response	Poor response	No response
1.	*Grp 1: Saptapama Ghanavati* and Grp 2: *Nityananda Rasa* Grp 3: Ayush-64 (n= 93)	Grp 1 was found most effective (91%) in elimination of parasites			
2.	Various combinations of *Sudarsana Ghanavati* (n= 690)	65% patients shows positive results			
3.	*Kanchanar guggulu* and *Gokshuradi guggulu* (*n*=503)	18.89% (n=95)	55.47% (n=279)	19.68% (n=99)	5.96% (n=30)
4.	*Shlipadari Rasa* and *Punarnava kwath* (n=292)	24.66% (n=72)	44.52% (n=130)	22.60% (n=66)	8.22% (n=24)

Fig. 2.5. Therapeutic Response in different interventional groups



2.6: ARSHA (HAEMORRHOIDS)

BACK GROUND

Haemorrohoids (*Arsha*) is a common anorectal disease which arises from the congestion of the internal and/or external venous plexuses around the anal canal. The disease is characterized by fleshy sprouts in anorectal region. Haemorrhoids are of two types, external and internal. The external haemorrhoids occurs outside the anal verge and are often painful when accompanied by swelling and irritation.The internal haemorrhoids occur inside the rectum and are usually not painful but may bleed when irritated. This condition is extremely common in adults and the incidence is same in both sexes. The aetiology of the disease is unknown but mostly they are associated with constipation, low fibre diet, increased intraabdominal pressure (prolonged straining), and sitting posture for long periods of time. The treatment is generally preventive, symptomatic and palliative in modern medicine. Surgery is the last resort.

According to Ayurveda, the disease which causes pain like enemy and great discomfort by producing obstruction in the anal passage is called *Arsha* (haemorrhoids). Managing constipation and promotion of *Agni*, avoiding very hot and irritant food are the main principles of conservative treatment. In addition to the medical and surgical management certain parasurgical procedures namely *Ksarakarma, Ksharasutra and Agnikarma* are recommended and practiced in Ayurveda. Sushruta has described four fold methods for the treatments of Arsha, which are *Bheshaja, Kshara, Agni* and *Shastra*. *Bheshaja* i.e. Medical/conservative treatment includes various Ayurvedic medicines which are mild laxative, styptic, anti-inflammatory and decrease intra-abdominal pressure. Some other oils/like *Kashishadi taila* when used locally (*lekhana*) imparts relief in *Arsha*. In certain other cases *Ksarakarma* and *Ksharasutra* are used effectively. Plain thread ligation of prolapsing internal hemorrhoids is also a popular method of treating the hemorrhoids on outpatient basis. *Raktavasecana, Agnikarma* and *Shastrakarma* are some other methods. *Bheshaja* (Medicine) treatment is the most suitable treatment in the small *Arsha* with history of mild/moderate bleeding. *Bheshaja chikitsa* can however be mixed with other techniques or therapeutic measures. It is safe and easily available method with good acceptability of patient.

Council has done following studies since inception for validation of classical drugs in the management of *Arsha*:

Study 1: The study to evaluate the six-fold approach of the treatment has been taken up in the Clinical Research Enquiry of the CCRAS at BHU, Varanasi to evaluate *Ksara sutra* in comparison to plain thread ligation. The outcome of the study conducted on 800 cases of haemorrhoids and 200 cases of centinal piles and anal warts recommended and practiced. The study gives very promising results and good response was found in maximum patients

Study 2*: Ksara sutra* application and internal medication with *Kankayan Vati* and *Triphala Churna* and local application of *Kashishadi Taila* on 774 patients. The observations indicate positive response to the treatment ranging from 85-95% with a less recurrence rate

Study 3: An Open label Interventional was done with *Kankayan Vati* 500 mg thrice a day, *Triphala Churna* 5 gm at bed time and *Kashishadi Taila* 2 ml before defecation (local application) for three month. The study was done at 10 centres viz. Regional Ayurveda Research Institute for Eye Diseases, Lucknow, Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi, Regional Ayurveda Research Institute for Drug Development, Gwalior, Central Ayurveda Research Institute for Drug Development, Kolkata, (RRAP) Central Ayurveda Research Institute for Cancer, Mumbai, Regional Ayurveda Research Institute for Metabolic Disorders, Bangalore, Regional Ayurveda Research Institute for Urinary Disorders, Jammu, Regional Ayurveda Research Institute for Nutritional Disorders, Mandi, Regional Ayurveda Research Institute for Infectious Diseases, Patna and at Regional Research Centre (Ay.), Hastinapur (Presently merged with CARICD, New Delhi). In this study total 2768 cases were studied. Out of them, 1081 patients, 669 patients, 414 patients, 128 patients got good response, fair response, poor response, no response respectively and 476 patients were dropped out.

Study 4: An Open label Interventional was done with *Kravyadi Rasa* 500 mg thrice a day, *Triphala Churna* 5 gm at bed time and *Kashishadi Taila* 2 ml before defecation (local application) for three month. The study was done at 10 centres viz. Central Ayurveda Research Institute for Drug Development, Kolkata, Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi, Regional Ayurveda Research Institute for Eye Diseases, Lucknow, Regional Ayurveda Research Institute for Metabolic Disorders, Bangalore, Regional Ayurveda Research Institute for Urinary Disorders, Jammu, Regional

Ayurveda Research Institute for Nutritional Disorders, Mandi, Regional Ayurveda Research Institute for Infectious Diseases, Patna, Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar, (RRAP) Central Ayurveda Research Institute for Cancer, Mumbai and at Regional Ayurveda Research Institute for Drug Development, Gwalior. In this study total 718 cases were studied. Out of them, 246 patients, 240 patients, 109 patients, 17 patients got good response, fair response, poor response, no response respectively and 106 patients were dropped out.

Study 5: An Open label Interventional study was done with *Kankayan Vati* 500 mg thrice a day, *Kravyadi Rasa* 500 mg thrice a day, *Abhayarishta* 15 ml thrice a day and *Kashishadi Taila* 2 ml before defecation (local application). The study was done at 6 centres viz. Regional Ayurveda Research Institute for Drug Development, Gwalior, Central Ayurveda Research Institute for Drug Development, Kolkata, Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi, (RRAP) Central Ayurveda Research Institute for Cancer, Mumbai, Regional Ayurveda Research Institute for Urinary Disorders, Jammu and at Regional Research Centre (Ay.), Hastinapur (Presently merged with CARICD, New Delhi). In this study total 691 cases were studied, out of them 243 patients, 178 patients, 118 patients, 21 patients got good response, fair response, poor response, no response respectively and 131 patients were dropped out.

Study 6: An Open label Interventional study was done with *Rasajan Sigru Ghan Vati.* The study was done at 3 centres viz. Regional Ayurveda Research Institute for Drug Development, Gwalior, Central Ayurveda Research Institute for Drug Development, Kolkata and at (RRAP) Central Ayurveda Research Institute for Cancer, Mumbai. In this study total 131 cases were studied. Out of them, 42 patients, 32 patients, 30 patients, 4 patients got good response, fair response, poor response, no response respectively and 23 patients were dropped out.

Study 7: A prospective open label multicentre trial executed at two peripheral centres viz. Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi and RRAP Central Ayurveda Research Institute for Cancer, Mumbai. Total of 124 participants were enrolled in the study. The study medications included quality assured *Pranada gutika* in the dose of 500 mg orally thrice daily after food with Lukewarm Water for 04 weeks and *Abhayarishta* in the dose of 20 ml orally twice daily after food with Lukewarm Water for 04 weeks. The study revealed significant improvement in the chief complaints of patients

suffering from Arsha (haemorrhoids). The complaint of Severity of bleeding P/R was observed in 28.05% patients at baseline which was reduced to 5.08% patients at the end of treatment (<0.001). Complaint of Pain in pile mass was observed in 45.73% patients at baseline which was reduced to 13.62% patients at the end of treatment (<0.001) and Itching ani was observed 28.86% patients at baseline which was reduced to 4.88% patients at the end of treatment (<0.001). Significant improvement was found in Health Survey Scores (<0.001). No any adverse effect was noted during the study.

Conclusion: Ayurveda treatment regimen and *Kshaar sutra* have shown very promising results and are very effective in the management of *Arsha*.

Tab 2.6.1: Therapeutic Response at a glance in *Arsha*

Sl.No.	Interventions	Good response	Fair response	Poor response	No response
1.	*Kankayan Vati*, *Triphala Churna* and *Kashishadi Taila* with *kshar sutra* (n= 744) **Study 2**	85% patients shows good response			
2.	*Kankayan Vati*, *Triphala Churna* and *Kashishadi Taila* locally. (n=2292) **Study 3**	47.16% (n=1081)	29.19% (n=669)	18.06% (n=414)	05.58% (n=128)
3.	*Kravyada Rasa*, *Kasishadi Taila, Triphala churna* (n=612) **Study 4**	40.20% (n=246)	39.22% (n=240)	17.81% (n=109)	02.78% (n=17)
4.	*Kankayan Vati, Kravyada Rasa Abhyarishta* and *Kashishadi Taila/Jatyadi Taila* (n=560) **Study 5**	43.39% (n=243)	31.79% (n=178)	21.07% (n=118)	03.75% (n=21)
	Rasanjan Sigru Ghan Vati (n=108) **Study 6**	38.89% (n=42)	29.63% (n=32)	27.78% (n=30)	3.70% (n=4)

Fig. 2.6.1. Therapeutic Response in different interventional groups

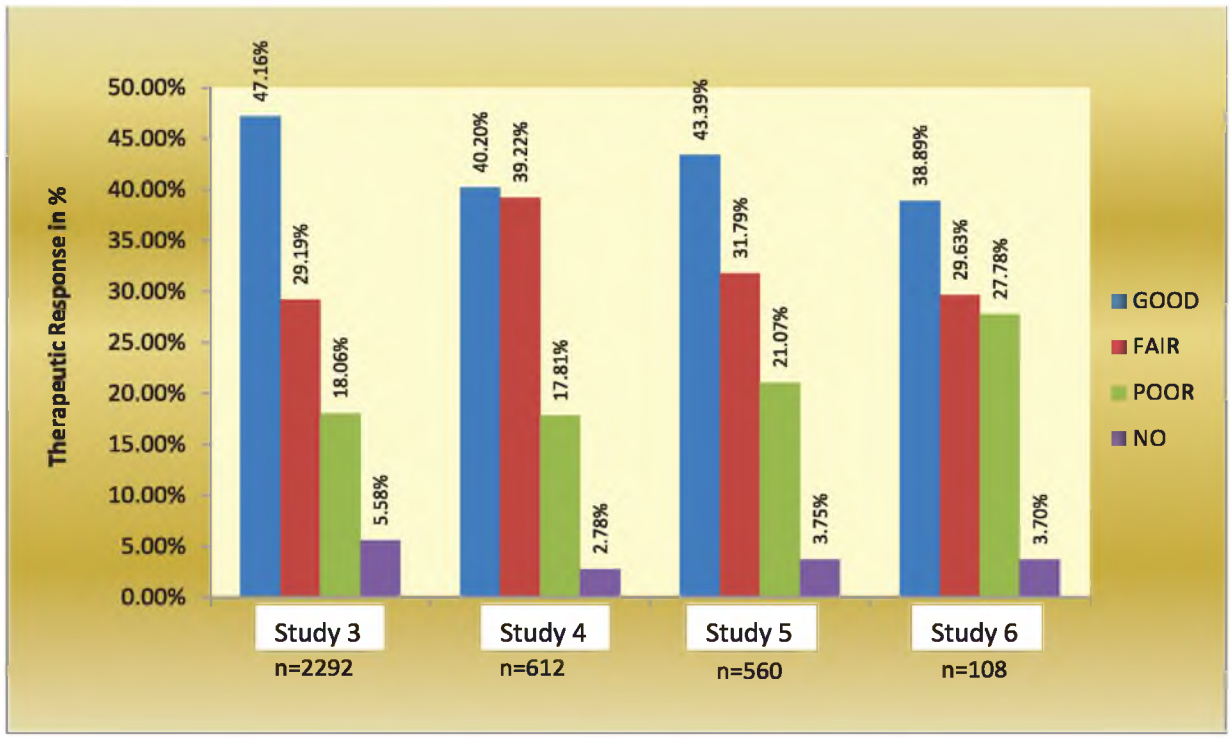
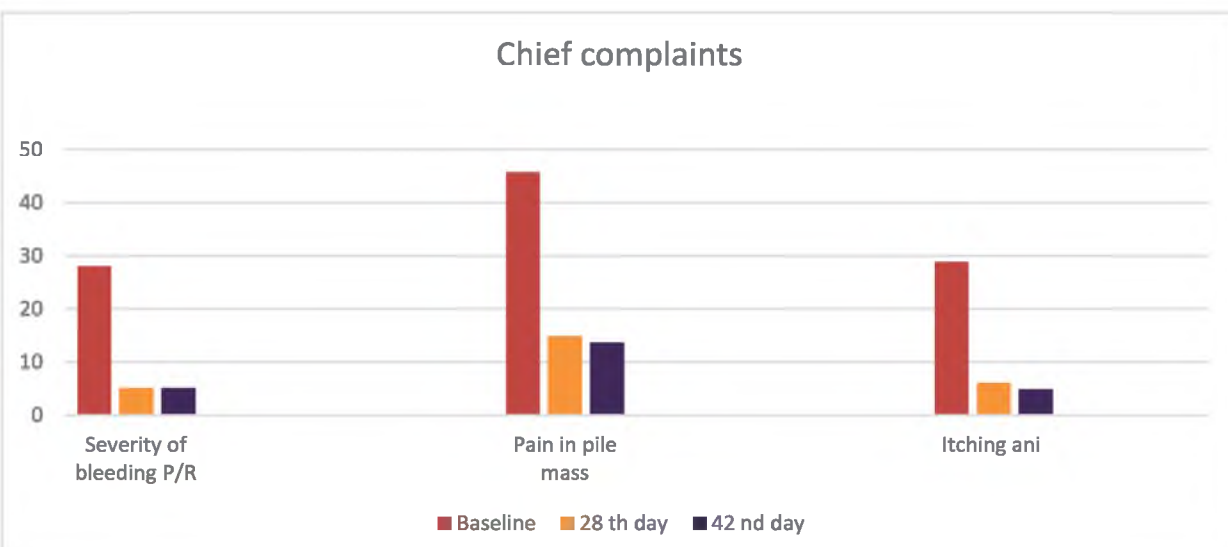


Fig. 2.6.2: Effect of the treatment on chief complaints/Outcome parameters in study 7



2.7 MEDOROGA (OBESITY & LIPID DISORDER)

BACK GROUND

Obesity (*Medoroga)* is a condition in which there is excessive accumulation of fat in the body. It is defined as a state of excess adipose tissue mass and is generally assessed on the basis of body mass index. Obesity is more common among women.Globally the disease is prevalent in about more than 300 million adults worldwide (WHO World Health Report, 2003). In India obesity is increasing at an alarming rate with morbid obesity affecting about 5% of the Indian population.People having 'android obesity' (abdominal fat distribution) are at increased risk from those having 'gynoid obesity' (peripheral fat distribution around the body).

Because of imbalance between energy intake and expenditure, the excess fat accumulates in the body. Although no satisfactory etiological classification of obesity is well defined but number of factors are known to be associated with its development. There are certain professions in which obesity is common. Familial tendency exists in many cases. Endocrine factors and energy imbalance are also responsible for the obesity. There are certain drugs which cause obesity like steroids, oral contraceptives, phenothiazine, insulin etc.

As per Ayurvedic concept, the excess of fat accumulation in *Medorogis* causes pendulous movement of buttocks, belly etc. The obese person willsuffer the shortening of life span, difficulty in physical activity, difficult copulation, general weakness, bad odour of the body, excess of sweating, excessive appetite and thirst. Acharya Sushruta has advocated that the excessive intake of *madhur dravya* (sugar and carbohydrate) gets converted into *sneha dravya s*(lipids) leading to *Medoroga*. *Apatarpana chikitsa* is beneficial in the management of this disease. The uses of herbal and herbo-mineral preparations for the treatment of the obesity are mentioned in Ayurvedic classics. Out of them some Ayurvedic formulations were used in the present study.

Council has done following studies since inception for validation of classical drugs in the management of *Medoroga*:

Study 1: The effect of *Commiphora wightii* on serum cholesterol and serum lipids, was studied on 75 patients; 25 were kept as the control group, 25 received crude drug and 25 petroleum ether (PE) extract of *Guggulu* for three months. Serum cholesterol was

significantly reduced in the treated group as compared to the control group. The reduction was 24.2% in crude drug and 30.0 % in P.E.extract treated group.

Study 2: In a series of 12 patients the total lipid was estimated in term of serum turbidity and coagulation time before and after one month of treatment with *Commiphora wightii*. The fall in total lipids was about 15.8% and rise in coagulation time was 63.8 per cent.

Study 3: Considering the role of triglyceride in atherogenesis, in another series of twelve cases, triglyceride was estimated before and after treatment with *Commiphora wightii*. The fall in serum triglyceride was about 24%.

Study 4:44 cases of hyperlipoproteinaemia were studied for a mean period of 12 weeks. 20 patients were treated with fraction 'A' of P.E. extract (*Guggulu*), 12 with Clofibrate and 12 with Su-13437-Ciba. Fraction 'A' (*Guggulu*) reduced the serum total lipids by 34%, serum total cholesterol by 27%, serum triglycerides by 29% and serum phospholipids by 18%, as compared to 24%, 24%, 4% and 14% fall respectively in the various fractions of lipids with Clofibrate, and 37%, 46, 21% and 30% fall in these fractions of lipids with Su-13437-Ciba. Thus, fraction A' had its effect on all lipid fractions which was found to be statistically significant ($p<0.001$). Further, no significant side effects with fractionA' (Guggulu) were observed during this study except mild diarrhoea (3 cases), hiccough (1 case) and restlessness (1 case).

Study 5: 51 cases of hyperlipoproteinaemia after initial work up were followed on therapy for a period of 75 weeks. 41 cases were treated with fraction 'A' and 10 cases with clofibrate in order to evaluate the long term clinical efficacy of fraction *'A'(Guggulu)* and for its comparison with clofibrate. The effect on serum lipid profile, i.e. total cholesterol and triglycerides was evaluated. Initially, the lipid profile was reviewed at intervals of 4-5 weeks. Subsequently, the serum lipid analysis was repeated every 8-10 weeks for the long term follow up analysis. With fraction 'A' *(Guggulu)* the reduction in serum cholesterol and triglycerides was found to be statistically significant ($p<0.001$) for the entire period of treatment, i.e. from 5th week onwards upto the conclusion of the study. Percentage fall in serum cholesterol ranged from 8.2%-36.8 % (mean 26.2%), in serum triglycerides, ranged from 8.4-50.2%(mean 36.5%). While during the course of treatment with clofibrate the reduction in serum cholesterol and triglycerides was also found to be statistically significant ($p<0.001$), i.e. the fall in serum cholesterol ranged from 8.9-43.5%, (mean

reduction 31.3%) and serum triglycerides it ranged from 8.0-50.8%(mean reduction 33.3%).

Study 6: An open interventional study was done with Combination of *Vacha* (Acorus Calamus) and *Kutaki* (Picrorhiza Kurro) in equal ratio in the dose of 1 gm TDS with Luke warm water. The study was done at eight centres viz. National Ayurveda Research Institute for Panchakarma, Cheruthuruthy, Regional Ayurveda Research Institute for Eye Diseases, Lucknow, (RRAP) Central Ayurveda Research Institute for Cancer, Mumbai, Central Ayurveda Research Institute for Drug Development, Kolkata, Central Ayurveda Research Institute for Respiratory Disorders, Patiala, Regional Ayurveda Research Institute for Gastro-Intestinal Disorders, Guwahati, Regional Ayurveda Research Institute for Urinary Disorders, Jammu and at Dr. Achanta Lakshmipati Research Centre for Ayurveda, Chennai. In the study total 912 subjects were studied. Out of them 350 patients were dropped out and remaining 166 patients, 216 patients, 147 patients, 33 patients and patients got good response, fair response, poor response, no response respectively.

Study 7: An open interventional study was done with *Triphala sodhita Guggulu*1 gm thrice a day. The study was done at three centres viz. (RRAP) Central Ayurveda Research Institute for Cancer, Mumbai, Central Ayurveda Research Institute for Respiratory Disorders, Patiala and at Regional Ayurveda Research Institute for Urinary Disorders, Jammu. In the study total 170 cases were registered and out of them 30 patients were dropped out and others like 29 patients, 53 patients, 45 patients, 13 patients and patients got good response, fair response, poor response, no response and respectively.

Study 8: An experimental study has been conducted on chicks. Prevention on cholesterol and fat induced hypercholesterolemia and hyperlilidemia was observed with the crude drugs as well as with the petroleum ether extract. In the subsequent experiment its effect on aortic atherosclerosis and coronary thrombosis was also extended and it was observed that *Guggulu* retarded the process of atherosclerosis to a great extent and prevented the process of thrombosis. Both the lesions were fully developed in the control group.

Study 9: In order to find out the effect of *Guggulu* on endogenous hyperlipimia, its effect on neomercazole and estrogen induced hypercholesterolemia and hyperlipidemia was also studied. This reveals an important fact that it successfully neuturalized the action of

neomercazole on thyroid. This gave a lead that hypocholesterolemic and hypolipidemic action of this drug is mediated through the thyroid gland.

Study 10: To evaluate *Guggulu* anti-obesity property, its effect on adipose tissue was studied. For this purpose C14 labelled triglyceride (radioactive) was administered to the control as well as to the treated group of rats receiving high fat diet. It was observed that the concentration of radio-active material in the adipose tissue of the treated group was much less than the control group. This showed that it prevented the deposition of fat in the adipose tissue, probably due to increasedlipolysis.

Study 11: Three crystalline substances of *Guggulu* were isolated by means of successive extraction and column chromatography with different melting points. All of these gave positive test for triterpenoid. Molecular formula of one of them was calculated to be C21 H30 03. Its yield is about one mg. per gram of the crude drug. The effect of this principle was also tested on the serum lipids and thyroids. The response was similar as in case of petroleum ether extract. Another pure compound Z guggulsterone also increased the thyroid activity as evidenced by increase in the thyroid activity by increased iodine uptake and increase in proteolytic and peroxidase activity.

Study 12: It was a prospective, multicentric, single arm study. The trial drugs were administered for 12 weeks with a follow up at the end of 14th week without any interventions. A total number of 146 individuals were enrolled in the study.The study was conducted at three peripheral institutes viz. Regional Ayurveda Research Institute for Skin Diseases (RARISD),Vijayawada; National Ayurveda Research Institute for Panchakarma (NARIP), Cheruthuruthy. Central Ayurveda Research Institute for Respiratory Disorders (CARIRD), Patiala *Vyoshadi guggulu* (VG) (Ayurvedic Pharmacopoeia of India, part-II, Volume-II) was administered orally in a dose of one gram (2 tablets of 500 mg each) thrice daily after food with lukewarm water and *Haritaki Churna* (HC) (Ayurvedic Pharmacopoeia of India, part-I, Volume-I) in a dose of 3 grams twice daily for twelve weeks. Vyoshadi *Guggulu* contains *Trikatu* (*Sunthi*, *Pippali*, &*Maricha*), *Triphala* (*Haritaki, Vibhitaka* & *Amalaki*), and *Trimada* (*Chitraka*, *Vidanga* & *Musta*) in one part each and *Guggulu* contain nine part in the formulation.The mean breathlessness score which was 38.7 ± 29.4 before the treatment reduced to 19.5 ±17.7and 17.8 ± 17.85 at the end of the treatment i.e.84th day and after follow up i.e. 98th day respectively. The mean score of Paraesthesia which was 26.2 ± 26.15 at baseline, reduced to 9.8 ± 15.9 and 9.25 ± 16.1 respectively at the end of the treatment and

after follow up without intervention. The mean score of confusion which was 21.9 ± 27.5 at baseline, reduced to 7.2 ± 14.96 at the end of the treatment period and 6.5 ± 14.1 at the end of follow up period; and the mean score of fatigue which was 42.1 ± 27.0 before the treatment, reduced to 16.6 ± 19.1 at the end of the treatment and 15.75 ± 18.8 at the end of 98th day. The result is statistically significant (P < 0.001).There was a significant reduction (p = 0.003) in the mean Serum cholesterol (mg/dl) levels which was 214.8 at the baseline and reduced to 208.3 at the end of treatment period. There was no significant difference in the parameters viz. Serum TG Serum LDL and Serum VLDL.The finding of the study shows that the scores received on eight domains of SF-36 health survey questionnaire all shown statistically significant (P<0.001) improvement. CTRI/2012/03/002527

Conclusion: Ayurveda drug have shown promising results in the management of Dyslipidemia and Obesity and can be used as primary line of treatment in the management of the disease.

Tab 2.7.1. Therapeutic Response at a glance in *medoroga*

Sl.No.	Interventions	Good response	Fair response	Poor response	No response
1.	*Commiphora wightii* in crude and PE form (n=75)	reduction in cholesterol was 24.2% in crude drug and 30.0 % in P.E.			
2.	*Commiphora wightii* (n=12)	avg. fall in total lipid 15.8% and rise in coagulation time 63.8%			
3.	*Commiphora wightii* (n=12)	avg. fall in serum triglyceride was about 24%			
4.	Grp 1: P.E. extract *Guggulu (n=20),* grp 2*:* Clofibrate (n=12) and grp 3: Su-13437-Ciba. Fraction 'A' *Guggulu* (n=12)	grp 3 was found most significant p < 0.001 with effect on all lipid fraction followed by grp 1 and grp 2			
5.	Long term clinical efficacy of fraction *'A' Guggulu* in comparison to clofibrate (n=51)	reduction in serum cholesterol and triglycerides was found statistically significant (p<0.001) with guggulu			
6.	*Vacha & Kutaki* equal parts (n=562)	29.54% (n=166)	38.43% (n=216)	26.16% (n=147)	5.87% (n=33)
7.	*Triphala SiddhaGuggulu* (n=140)	20.71% (n=29)	37.86% (n=53)	32.14% (n=45)	9.29% (n=13)

Fig. 2.7.1. Therapeutic Response in different interventional groups

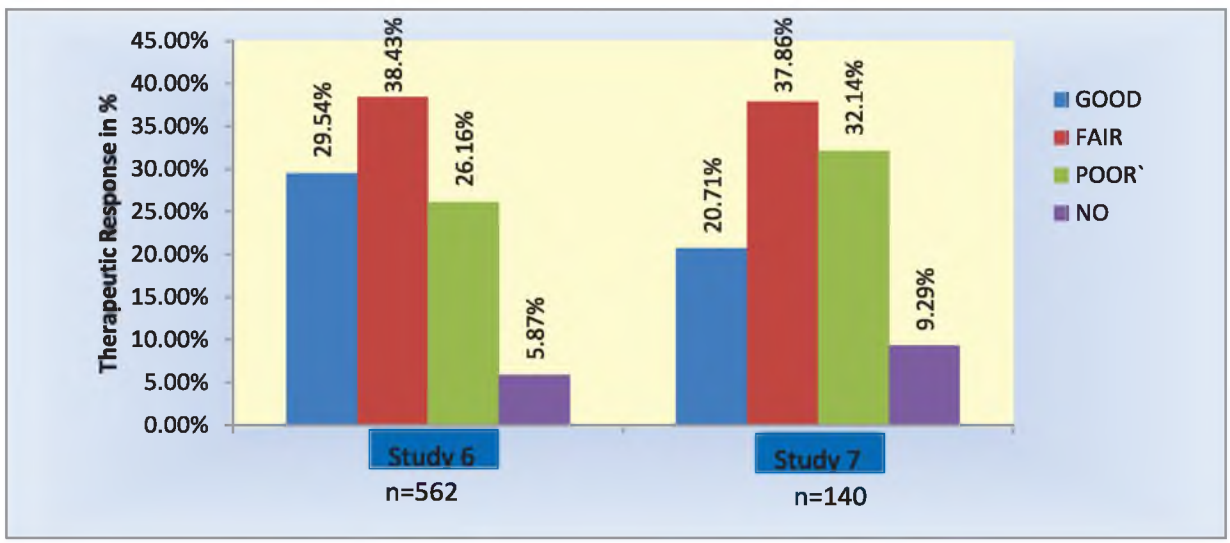
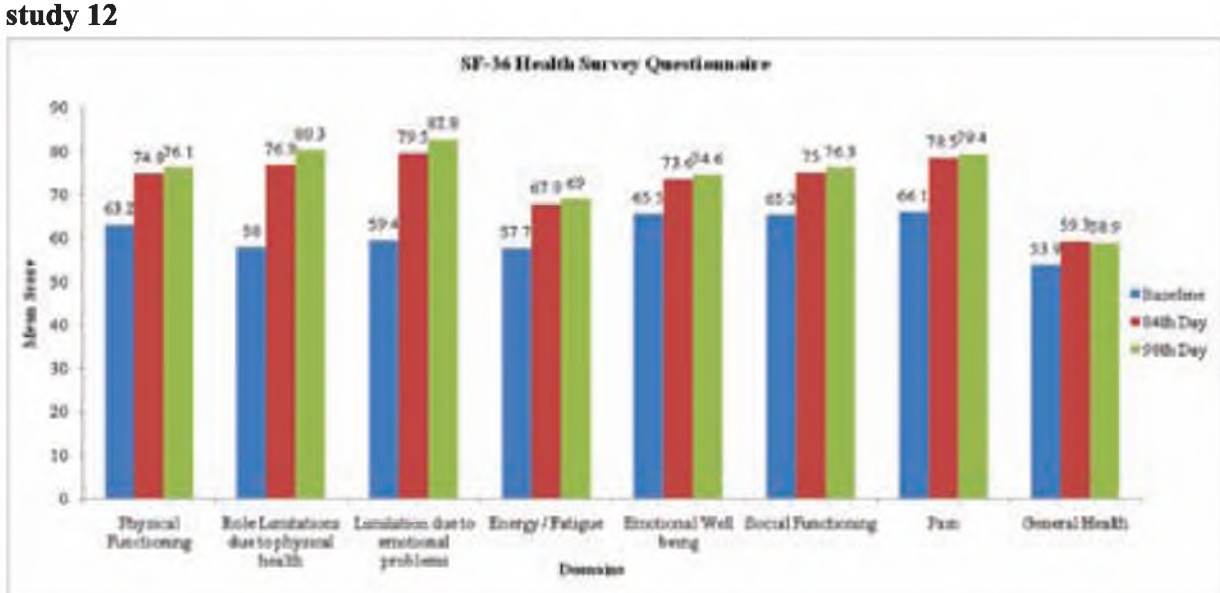


Table 2.7.2: Effect of trial drugs on lipid profile (n- 146) in Study 12

Variable	Baseline (Mean± SD)	84th day (Mean± SD)	't' value	'P' value
Serum cholesterol (mg/dl)	214.8 ± 33.5	208.3 ± 35.1	3.05	0.003*
Serum Triglyceride (mg/dl)	164.1 ± 67.75	158.3 ± 77.1	1.2	0.23
Low Density Lipoprotein (LDL) (mg/dl)	135.7 ± 32.8	132.85 ± 37.8	1.3	0.2
Very Low Density Lipoprotien (VLDL) (mg/dl)	32.8 ± 13.5	31.6 ± 15.4	1.2	0.23

Fig. 2.7.2: Effect of trial drugs on quality of life of the study participants (n -146) in study 12



2.8 GRAHANI ROGA (IRRITABLE BOWEL SYNDROME)

BACKGROUND

Irritable bowel syndrome (IBS) is a gastrointestinal (GI) disorder characterized by altered bowel habits in association with abdominal discomfort or pain in the absence of detectable structural and biochemical abnormalities. This all basically happens due to alteration in GI motility, secretion and sensation.The symptomatic analysis of IBS, points to *Grahani, Kaphaja Pravahika, Shokaja Atisara, Bhayaja Atisara* etc. mentioned in *Ayurveda* classics which are characterized by altered bowel habits and other gastrointestinal symptoms.

The pathogenesis of *Grahani* begins with the vitiation of *Agni* (digestive fire) in terms of its quality, quantity and function. All metabolic physiological transformations in the body are carried out under the influence of *Agni. Mandagni* (quantitative, qualitative and functional decrease of *Agni*) is the root cause of *Ama Dosha* and it is a crucial factor for manifestation of most of the diseases. *Ama Dosha*, resulting from *mandagni,* plays a pivotal role in the pathogenesis of gastro intestinal disorders such as *Grahani Roga. Bhayaj Atisara, Shokaj Atisara etc.* Vitiation of *Samana* and *Apana Vayu*, affects the enteric nervous system, alters the GI motility and hormone activity producing the symptoms of *Grahani.* All these diseases have psychological factors such as fear and anxiety as aetiology and IBS also has psychological factors responsible for its origin.

The modern IBS therapies include bulk forming agents, anti- diarrhoeal, anti-spasmodic and anti - depressants etc which lack demonstrable efficacy. While considering the cost and potential risks (severe constipation, severe diarrhoea, ischemic colitis) against potential benefits, potential risks outweigh the possible benefits. Therefore, exploring alternative medicines for therapeutic options, which are effective, economical and safe, are needed.

Council has done following studies since inception for validation of classical drugs in the management of *grahani roga*:

Study 1: An interventional open label study was done with *Panchamrita Parpati Kalpa* 500 mg thrice daily along with milk after food for 30 days. Study was done at Regional Ayurveda Research Institute for Drng Development, Gwalior. In this study total 86 cases were studied. Out of them, 10 got good response, 17 got fair response, 20 got poor response, while 7 had no response and 32 were dropped out.

Study 2: An interventional open label study was done with *Bilwa Majja churna* 3 gm along with *Takrarishta* 25 ml thrice daily after meal for 30 days.Study was done at two centres viz. Regional Ayurveda Research Institute for Drug Development, Gwalior and at Regional Ayurveda Research Institute, Gangtok. In this study total 220 cases were studied. Out of them 29 got good response, 77 got fair responses, 38 got poor response, while 8 had no response and 68 were dropped out.

Study 3: A total of 171 patients were enrolled in the study entitled- 'Clinical Evaluation of *Bilvadi Leha* in the Management of Irritable Bowel Syndrome (IBS)' in which 22 patients dropped out in the course of the study. Among the total dropouts, 8 were not included for analysis. LOCF (Last observation carried forward) was applied on 14 patients who had completed at least 2 visits. Thus a data of 163 (171-22+14) patients was used for analysis. Effect of *Bilvadi Leha* on, disease specific symptoms, IBS severity score and WHO QOL-BREF Score was statistically significant (p-value<0.001). Chronic or recurrent abdominal discomfort was present in 90.8% of cases at baseline and after completion of treatment remained only in 26.4%. Likewise abdominal bloating was present in 89.6% cases at the baseline which was reduced to 42.3% at the end of 84th day. No significant adverse events or adverse reactions were observed during the study. Both, the Liver Function Tests (LFT) & Kidney Function Tests (KFT) tests were found to be in normal limits before and after the trial. (CTRI no. CTRI/2012/04/002577)

Study 4: A total of 180 patients were enrolled in the study entitled 'Clinical Evaluation of *Kutajarishta* in the Management of Irritable Bowel Syndrome (IBS)' 10 patients had dropped out in the course of the study, LOCF (Last observation carried forward) was applied on 08 patients who had completed at least 2 visits. Thus a data of 178 (180-10+8) patients was used for analysis.The dropout patientswere not included in the study as they could not turn up for follow up in time due their prior engagement out of the city. One patient reported increased frequency of bowels and did not continue the study. Effect of *Kutajarishta* on chief complaints, disease specific symptoms, IBS severity Score and WHO QOL-BREF Score was highly significant (*P<.001*), for example chronic or recurrent abdominal discomfort or pain was present in 99.4% of cases at baseline and after completion of treatment it was present in 24.7% of cases. Likewise urgency of bowel movements was present in 86.5% cases at the baseline which was reduced to 16.3% at the end of 84th day. No significant adverse events or adverse reactions were observed during the study. Both, the Liver Function Tests (LFT) &

Kidney Function Tests (KFT) tests were found to be in normal limits before and after the trial. (CTRI/2014/09/005066)

Study 5: An interventional, open level, perspective, single arm study of 14 weeks was done at National Research Institute of Ayurvedic Drug Development, Kolkata. *Brihat Gangadhara Churna* in a dose of 3 gm twice a day orally after intake of food with honey for 12 weeks. Total 90 subjects were enrolled out of which 85 completed and 05 dropped out from the study due to miss the follow up. 90 (100%) patients at baseline were complaining chronic or recurrent abdominal discomfort or pain but after 84th day treatment 81 (90%) and 14 days follow up 80 (88.9%) patients having no pain. 81 (90%) patients complaining of abdominal bloating but after 84thday treatment 78 (86.7%) and follow up 76 (84.4%) patients having no such complains. 48 (53.3%) patients complaining of Constipation but after 84thday treatment and follow up both same i.e.87 (96.7%) patients having no such complains. 89 (98.9%) patients complaining of diarrhoea but after 84thday treatment 88 (97.8%) and follow up 89 (98.9%) patients having no such complains. At baseline 83 (92.2%) patients complaining of urgency of bowel movements but after 84th day treatment 79 (87.8%) patients and follow up 75(83.3%) patients having no such complains. 90 (100%) patients complaining feeling of incomplete evacuation but after 84th day treatment 41 (45.6%) patients and follow up 48 (53.3%) patients having no such complains and 90 (100%) patients complaining passage of mucus but after 84th day treatment 50 (55.6%) and follow up 49 (54.4%) patients having no such complains. The treatment has shown statistically significant effect on 84th day and follows up at the end of 14th week. IBS severity Score shows decrease trend of Mean and SD in all the 8 visits. Thus the "t" value always shows significant in compare to base line. Gradually that value increase to 24.113.The WHO QOL BREF also shows similar trend of highly significant result. No any adverse effect was noted during the study. CTRI/2016/01/006550

Conclusion: IBS is a condition that significantly affects the quality and productivity of life. *Nidana parivarjana* and synchronising the harmonious activity of *Agni* and *Vata* in the intestine are the key factors in managing IBS. From these studies it can be concluded that, in spite of the differences in gender, socioeconomic status, age group, *Prakrti* and geographic region; Ayurveda interventionproved to be very much safe, effective and tolerable in the management of IBS.

Tab 2.8.1 Therapeutic Response at a glance in IBS

Sl.No.	Interventions	Good response	Fair response	Poor response	No response
1.	*Panchamrita Parpati Kalpa* with milk(*n*=54)	18.52% (n=10)	31.48% (n=17)	37.04% (n=20)	12.96% (n=7)
2.	*Bilwa Majjachurna* and *Takrarishta*(n=152)	19.08% (n=29)	50.66% (n=77)	25.00% (n=38)	5.26% (n=8)

Table 2.8.2: Efficacy and safety profile of the patients in study 3 and 4

Parameters	*Bilvadi Leha*			*Kutajarishta*		
	Baseline	84th day	p-	Baseline	84th day	p-
LFT						
Conjugated bilirubin	0.18	0.16 (0.096)	0.047	0.14 (0.096)	0.14	0.966
Unconjugated bilirubin	0.49	0.49 (0.162)	0.910	0.55 (0.242)	0.55	0.860
SGPT (ALT) (IU/L)	26.39	23.78	<0.001	30.21(14.948)	30.10	0.916
SGOT (AST) (IU/L)	26.85	25.81(7.628)	0.093	25.85 (8.152)	25.06	0.242
Serum Alkaline	148.02	118.11	<0.001	127.20	124.73	0.291
Total Protein (gm/dl)	7.23	7.23 (0.570)	0.988	7.12 (0.551)	7.09	0.523
S.Albumin (gm/dl)	4.32	4.21 (0.488)	0.008	4.11 (0.386)	4.06	0.115
S.Globulin (gm/dl)	2.92	3.02 (0.475)	0.086	2.99 (0.525)	3.02	0.517
RFT						
Blood urea (mg/dl)	24.87	25.09	0.626	24.76 (6.594)	24.30	0.446
S.creatinine (mg/dl)	0.90	0.86 (0.158)	0.002	0.93 (0.512)	0.92	0.871
Serum Uric Acid in	5.18	5.22 (1.102)	0.593	5.41 (1.1258)	5.35	0.585

(A *p-value* of <0.05 is considered significant)

Table 2.8.3: IBS Severity Score in study 5

IBS Severity Score	Paired Differences					t-value	df	p-value
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Baseline – 14th day	108.444	62.650	6.604	95.323	121.566	16.421	89	<0.001
Baseline – 28th day	146.278	66.774	7.039	132.292	160.263	20.782	89	<0.001
Baseline – 42nd day	171.200	67.563	7.122	157.049	185.351	24.039	89	<0.001
Baseline – 56th day	177.489	76.962	8.112	161.370	193.608	21.878	89	<0.001
Baseline – 70th day	184.778	75.528	7.961	168.959	200.597	23.209	89	<0.001
Baseline – 84th day	204.889	77.071	8.124	188.747	221.031	25.220	89	<0.001
Baseline – Follow up at the end of 14th week	204.100	80.301	8.464	187.281	220.919	24.113	89	<0.001

Fig.2.8.1 Therapeutic Response in different interventional groups in the management of IBS (study 1 and 2)

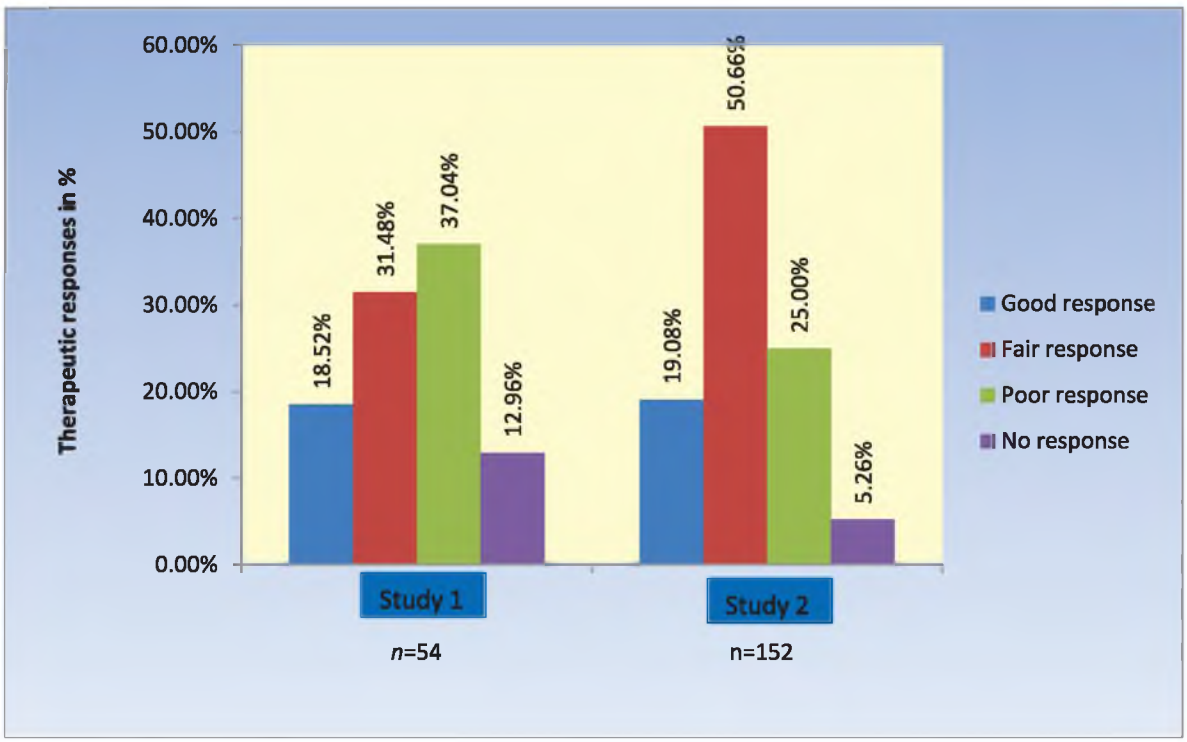
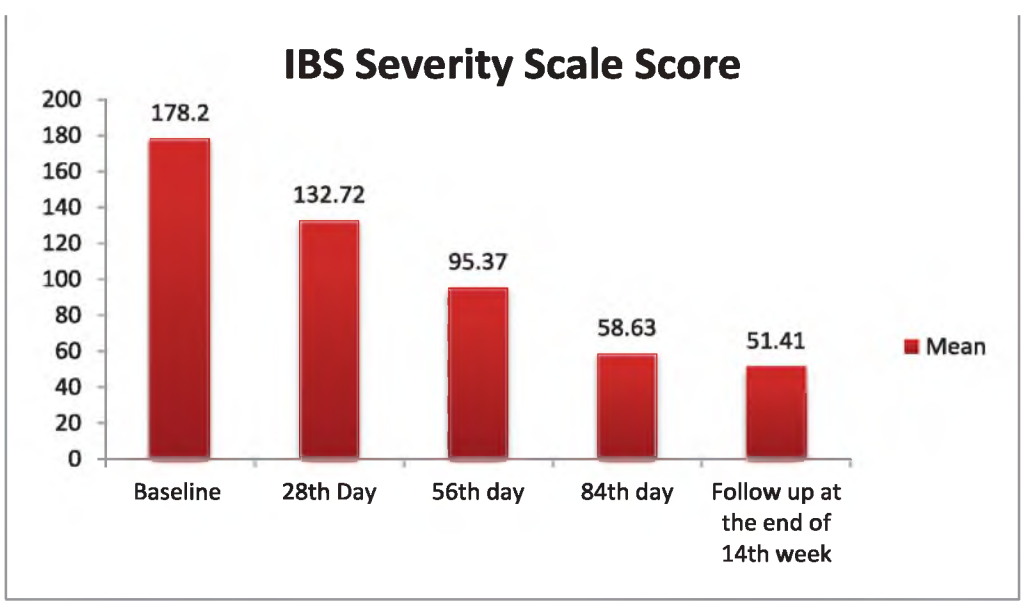


Fig. 2.8.2.IBS Severity Scale Score in study 3



2.9: PARINAMASHULA (DUODENAL ULCER)

BACKGROUND

The acid peptic diseases, non-ulcer dyspepsia, gastric ulcer andduodenal ulcers are identified as separate disease entities in Ayurveda. The disease *Parinamasula* mentioned in Ayurvedic literature can be taken as duodenal ulcer of contemporary science. The name *Parinamasula* indicates that the pain appears during the digestion of food. According to modern,peptic ulcers are open sores or erosions in the lining of either the duodenum (duodenal ulcers) or the stomach (gastric ulcers). Peptic ulcers are usually caused by either Helicobacter pylori (H pylori) bacteria or non-steroidal anti-inflammatory drugs (NSAIDs). H Pylori bacteria are responsible for about four-fifths of all gastric ulcers and 95% of duodenal ulcers, while NSAIDs are known to cause about 20% of gastric ulcers and 5% of duodenal ulcers. Patients typically present with epigastric pain (from food in stomach for gastric ulcers and from a lack of food in duodenum for duodenal ulcers) as well as satiety and possibly nausea. Ayurveda offers a wide range of drugs for this condition and some such combinations are taken up for clinical evaluation in the present study series.

The various aspects of the diseases etiopathogenesis, clinical featuresand management are discussed in details. Many drugs-herbal andherbomineral, and *Sodhana-panchakarma,* procedures have beenselected for investigations on more than 2000 patients in variousresearch institutes under Council. The effect of purificatory measures *Sodhana* has also been investigated by application of selected *Panchakarma* procedures.

Council has done following studies since inception for validation of classical drugs in the management of *Parinamasula*:

Study 1: *Indukanta Ghrita and Mahatiktaka Ghrita:* The *Ghrita* preparations are given before other purificatory measures are applied. They are also given as palliative (*Shamana*) therapy. The *Indukanta*and *Mahatiktaka Ghrita* are given in two separategroups of patients with another grouping as *Shamana* and a small courseof *Sodhana.* The studies in four groups of patients have been conducted onabout 1200 patient. The diagnosis and assessment of efficacy has beenmade on the basis of modem investigations including endoscopy. Itwas noted that both the *Ghrita* preparations are effective in 75 to 80%of patients. The efficacy is further enhanced if a course of *Sodhana* isgiven before administration of *Ghrita.* The effect of *Mahatiktaka Ghrita* was found relatively better.

Study 2: *Amashya sodhana:* Induced *Vamana* or emesis has been recommended as an approach to treatment for such diseases. However, to make it more acceptable the procedure has been modified and stomach wash with decoction of herbal drugs- *Varuna and Apamarga* has been taken up. The radiologically positive patients of duodenal ulcer have been included. The stomach wash *(Amasayasodhan)* was given twice a week for 6 weeks.The patients were advised to come with empty stomach and the contents of stomach are aspirated through Ryle's tube. The decoction of drugs are introduced into stomach and withdrawn through the tube.The trial of this procedure has been conducted on 265 patients. The response has been encouraging since about 80% of patients shown relief.

Study 3: The compound *Nimbidin* is isolated form *Neem* seed oil by process of extraction. The drug has been administered in endoscopically diagnosed patients of duodenal ulcer. The drug has been administered 1 in the form of 100 mg capsules thrice times a day.The overall effect of the drug has been good and 78.89% showedpositive response.

Study 4: The study on *Narikela lavan* (70%) *Yastimadhu* (68.81%) and *Suta Sekhara Rasa* combinations (74%) have also shown good response in the management of duodenal ulcers.

Study 5: An interventional open label study was done with *Indukanta Ghrita* 10 gms twice daily with milk for 60 days. Patients are advised to take warm water after the *Ghritapana* at every half an hour for 3 hours. The study was done at three centres viz. Regional Ayurveda Research Institute for Urinary Disorders, Jammu, Regional Ayurveda Research Institute for Skin disorders, Vijayawada and at Central ResearchUnit, Kottakal (presently merged with National Ayurveda Research Institute for Panchakarma, Cheruthuruthy). In this study total 97 cases were studied. Out of them, 42 got good response, 28 fair response, 7 poor response, while 1 had no response and 19 were dropped out.

Study 6: An interventional open label study was done with *Mahatikta Ghrita*10gms twice daily with milk for 60 days. Patients are advised to take warm water after the *Ghritapana* at every half an hour for 3 hours. The study was done at three centres viz. Regional Ayurveda Research Institute for Skin disorders, Vijayawada, Regional Ayurveda Research Institute for Urinary Disorders, Jammu and at Central ResearchUnit, Kottakal (presently merged with National Ayurveda Research Institute for Panchakarma, Cheruthuruthy). In this study total 113 cases were studied. Out of them 49 got good response, 38 got fair responses, 5 got poor responses, while none had no response and 21 were dropped out.

Study 7: An interventional open label study was done with *Satavari Madhuyashti Ghana Satva Vati* 1 gm thrice daily with water for 30 days. The study was done at two centres viz. Regional Ayurveda Research Institute for Skin disorders, Vijayawada and at Regional Ayurveda Research Institute for Urinary Disorders, Jammu. In this study total 43 cases were studied. Out of them, 11 got good response, 29 got fair responses, 2 got poor responses, while nonehad no response and 1was dropped out.

Study 8: An interventional open label study was done with *Amalaki Rasayana* 5 gm thrice daily with milk for 4 weeks. The study was done at three centres viz. Regional Ayurveda Research Institute for Skin disorders, Vijayawada, Regional Ayurveda Research Institute for Urinary Disorders, Jammu and at Central ResearchUnit, Kottakal (presently merged with National Ayurveda Research Institute for Panchakarma, Cheruthuruthy). In this study comprising total 77 cases were studied. Out of them, 13 got good response, 36 got fair response, 12 got poor response, while 3 had no response and 13 were dropped out.

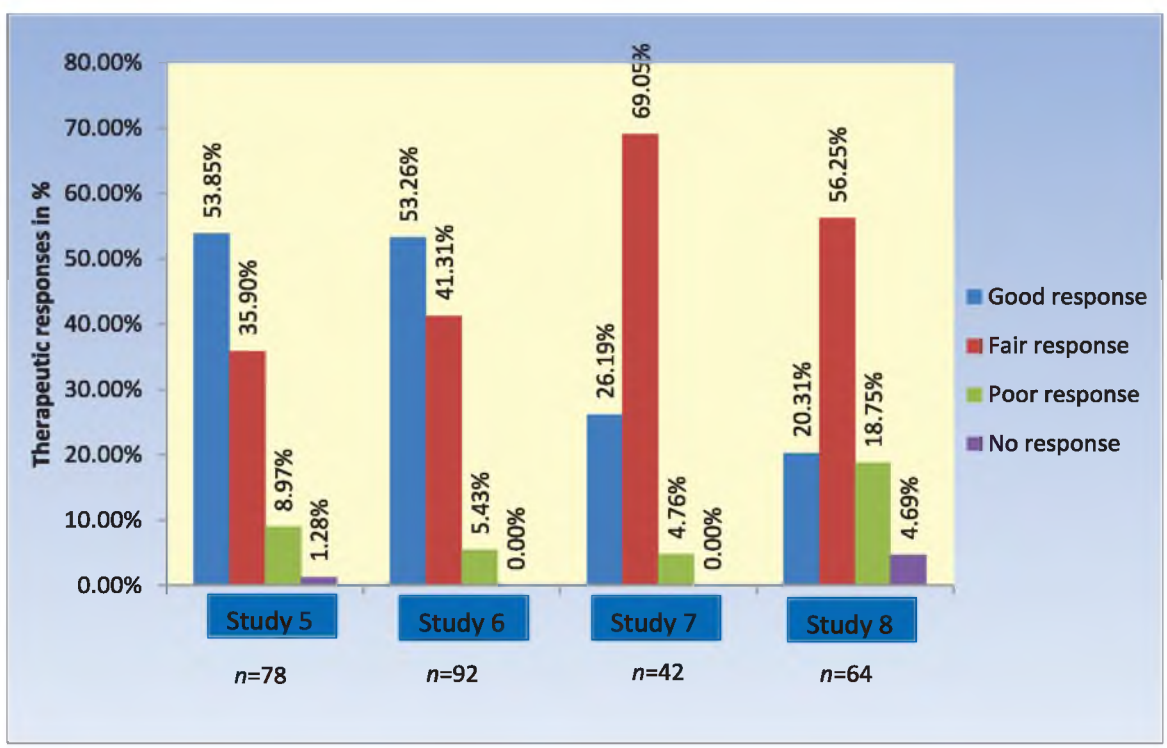
Conclusion: It may be seen that this condition could be successfully managed through Ayurvedic drugs and procedures.

Tab 2.9.Therapeutic Response at a glance in *parinam shula*

Sl.No.	Interventional Groups	Good response	Fair response	Poor response	No response
1.	*Indukanta Ghrita* and *Mahatiktaka Ghrita* with and without *shodhan* in 4 grps(n=1200)	All grps shows response from 75 to 80%, maximum respsonse was found in *Mahatiktaka Ghrita* with *shodhan grp.*			
2.	*Amashya sodhana* with *vamana* (n=265)	80% of patients showed good relief.			
3.	*Nimbidin* is isolated form *Neem* seed oil	78.89% showed positive response.			
4.	*Narikela lavan, Yastimadhu* and *Suta Sekhara Rasa*	70%, 68.81% and 74% good response respectively			

5.	*Indukanta Ghrita* (*n*=78)	53.85% (*n*=42)	35.90%(*n*=28)	8.97%(*n*=7)	1.28% (*n*=1)
6.	*Mahatikta Ghrita* (*n*=92)	53.26%(*n*=49)	41.31%(*n*=38)	5.43%(*n*=5)	0.00% (n=0)
7.	*Satavari Madhuyashti Ghana Satva Vati*(*n*=42)	26.19%(*n*=11)	69.05%(*n*=29)	4.76% (*n*=2)	0.00% (*n*=0)
8.	*Amalaki Rasayana* (*n*=64)	20.31%(*n*=13)	56.25%(*n*=36)	18.75% (*n*=12)	4.69% (*n*=3)

Fig.2.9. Therapeutic Response in different interventions in *parinam shula*



2.10: KAMALA (JAUNDICE)

BACKGROUND

Jaundice (*Kamala*) is a common liver disorder caused due to the dysfunction of the liver. It is characterized by the yellow appearance of the skin, sclera and mucous membranes resulting from an increased bilirubin concentration in the body fluids. It is clinically detectable when the plasma bilirubin exceeds 3 mg/dl. The disease has been categorized into hepatocellular (hepatic), haemolytic (prehepatic) and obstructive (posthepatic) types. Symptoms of Jaundice are extreme weakness, headache, fever, dull pain in the liver region, yellow discoloration of the eyes, tongue, skin and urine, loss of appetite, nausea, vomiting, diarrhea, itching all over the body.The infective hepatitis (viral) is one of the most common causes of jaundice. Viral hepatitis is the infection of the liver caused by hepatitis Jaundice viruses A, B, C, D, E, and G. Hepatitis A is highly infectious and is spread by the faecal-oral route. Hepatitis A is a less severe form of self limiting disease. According to WHO about 10-50 persons per 100,000 are affected annually by hepatitis A virus. Hepatitis B is usually transmitted by the parenteral route. Hepatitis B viral infection is a global problem; more than 2 billion people worldwide have evidence of past or current HBV infection and 350 million are chronic carriers of the virus. Although viruses are the main causes of liver diseases, the liver lesions arising from excessive drug therapy, environment pollution and alcoholic intoxication are not uncommon. Modern drugs have very little to offer for alleviation of hepatic ailments.

Kamala (Jaundice) is mentioned as clinical entity in Ayurveda. According to Ayurveda, it is a pitta dominant disease caused by vitiation of *pitta dosha* due to excessive intake of *pittavardhak* substances. The therapy of this disease is also related to general treatment of *Pandu* though certain specific therapies for this disease have also been recommended in texts. Many single and compound herbal and herbomineral preparations are mentioned in Ayurvedic classical text books.

Council has done following studies since inception for validation of classical drugs in the management of *Kamala*:

Study 1: An open label interventional study was done with *Punarnava Mandura* 500 mg thrice a day with honey, *Arogyavardhini* vati 1 gm thrice a day with water, *Phalatrikadi Kwatha* twice a day with water. Study was done at Regional Ayurveda Research Institute for Eye Diseases, Lucknow. In the study total 145 cases were registered. Out of them, 53

patients, 29 patients, 10 patients and 2 patients got good response, fair response, poor response, and no response respectively. 51patients were dropped out from the trial.

Study 2: An open label interventional study was done with *Punarnava Mandura* 500 mg thrice a day with honey, *Arogyavardhini* vati 1 gm thrice a day with water, *Sweta Parpati 250 mg* twice a day with honey Study was done at Regional Research Centre (Ay.), Hastinapur (presently merged with Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi). In the study total 47 cases were studied. Out of them, 13 patient, 4 patients, 29 patients, 0 patients got good response, fair response, poor response and no response respectively and 1 patient was dropped out.

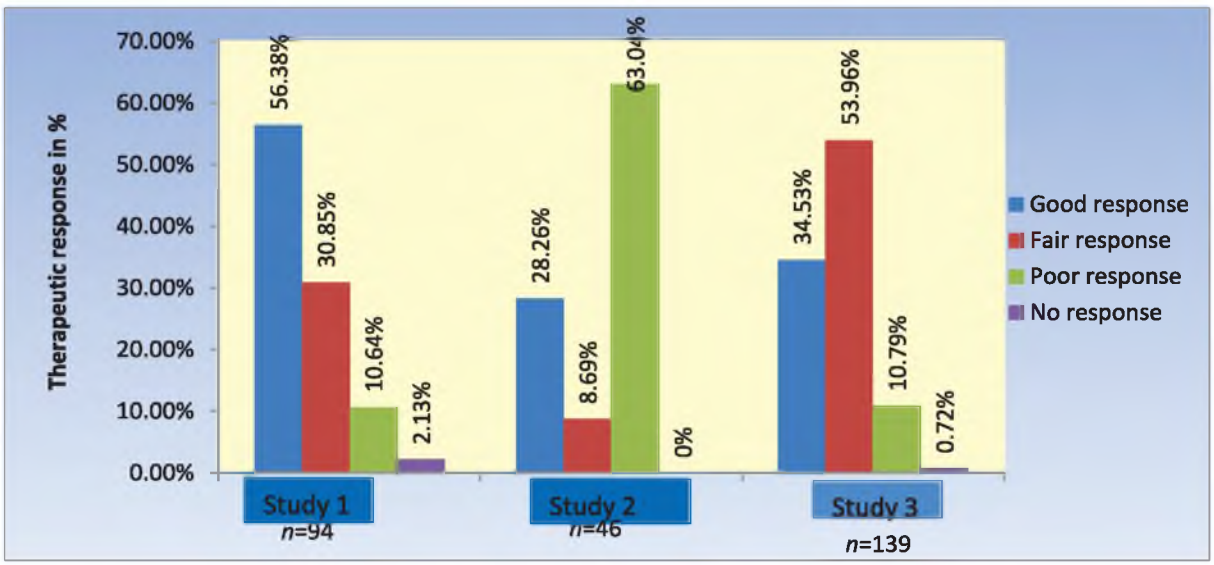
Study 3: An open label interventional study was done with *Punarnava Mandura* 500 mg thrice a day with honey, *Punarnavashtaka Kwatha* 10-20 ml twice a dayStudy was done at Regional Research Centre (Ay.), Hastinapur (presently merged with Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi). In the study total 140 cases were studied. Out of them, 48 patients, 75 patients, 15 patients, 1 patient got good response, fair response, poor response and no response respectively and 1 patient was dropped out.

Conclusion: Ayurveda has shown very promising results in the management of Jaundice. Though in the above studies Obstructive jaundice, Haemolytic Jaundice and Cirrhosis of Liver were in exclusion criteria, hence it does not comment on Jaundice caused by above conditions. Moreover Ayurveda herbs also have shown good hepato-protective effects and can be implemented in clinical practices for the management of jaundice.

Tab.2.10. Therapeutic Response at a glance in the management of *Kamala*

S. N.	Interventions	Good response	Fair response	Poor response	No response
1.	Punarnava Mandur, Arogyavardhani, Phaltrikadi Kwath (*n*=94)	56.38% (*n*=53)	30.85% (*n*=29)	10.64% (*n*=10)	2.13% (*n*=2)
2.	Punarnava Mandur, Arogyavardhani, Swetaparpati (*n*=46)	28.26% (*n*=13)	8.69% (*n*=4)	63.04% (*n*=29)	0% (*n*=0)
3.	Punarnava Mandur, Punarnavashta Kwath (*n*=139)	34.53% (*n*=48)	53.96% (*n*=75)	10.79% (*n*=15)	0.72% (*n*=1)

Fig. 2.10. Therapeutic Response in different interventional groups



2.11: ATISARA (DIARRHOEAL DISEASE)

BACKGROUND

Diarrhoea is defined as the passage of three or more loose or liquid stools per day (or more frequent passage than is normal for the individual). Frequent passing of formed stools is not diarrhoea. It is usually a symptom of an infection in the intestinal tract, which can be caused by a variety of bacterial, viral and parasitic organisms. Infection is spread through contaminated food or drinking-water, or from person-to-person as a result of poor hygiene. In 2004, diarrhoeal disease was the third leading cause of death in low-income countries, causing 6.9% of deaths overall. In children under five years old, diarrhoeal disease is the second leading cause of death. According to Ayurveda, this disease is named as *Atisara*. The excessive use of heavy (hard to digest), too much dry, spicy, cold, and incompatible articles, irregular eating habits, indigestion, poisoning, fright, grief, impure water & food, change of season or physical contrarieties are contributing factors for causation of *Atisara*. Ayurveda has recommended different medicines for the treatment of *Atisara* and a coded formulation GVK compound was used in the present trial.

Council has done following studies since inception for validation of classical drugs in the management of *Atisara*:

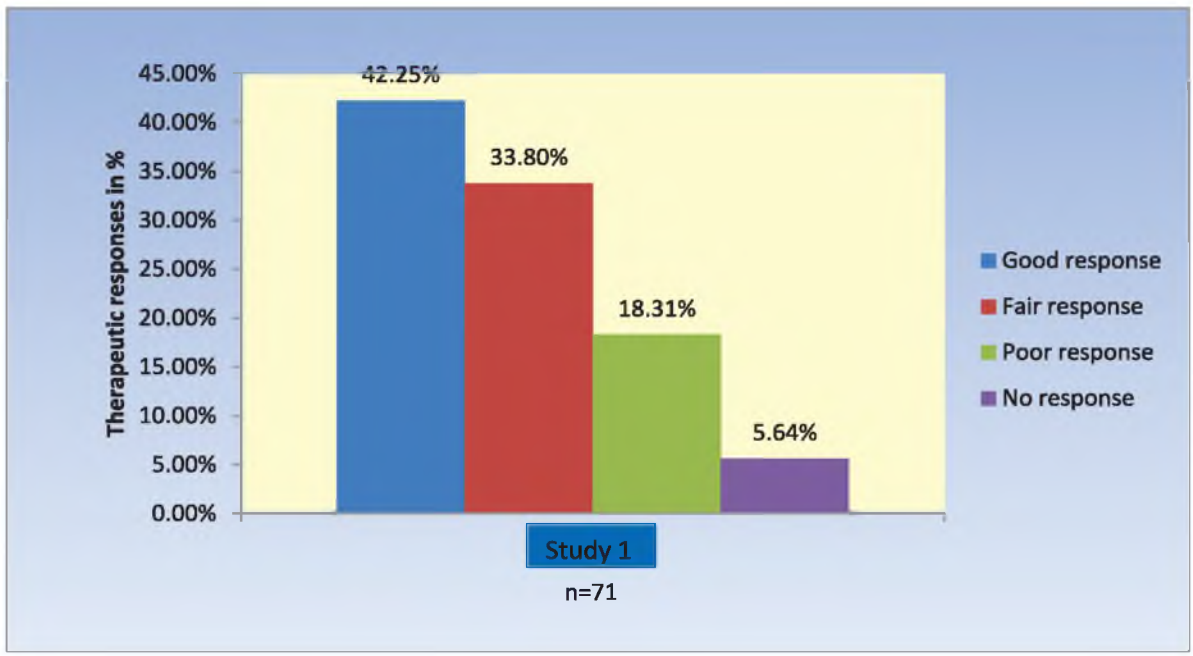
Study 1: An open label interventional study was done with Coded drug GVK compound 2 cap (250mg each) thrice daily after food with butter milk. The study was done at Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi. In the study total 73 cases were studied. Out of them, 30 got good response, 24got fair response, 13 got poor response, while 4 had no response and 2 were dropped out.

Conclusion: Ayurveda has shown promising results in the management of uncomplicated Diarrheoa and may be successfully used in its management.

Tab.2.11. Therapeutic Response at a glance

Sl.No.	Interventions	Good response	Fair response	Poor response	No response
1.	GVK compound (n=71)	42.25% (n=30)	33.80% (n=24)	18.31% (n=13)	5.64% (n=4)

Fig. 2.11. Therapeutic Response in different interventional groups: Graphical representation



2.12: BHAGANDARA (FISTULA-IN-ANO)

BACKGROUND

Bhagandara (Fistula-in-ano) is a track which opens deeply in the anal canal or rectum and superficially on the skin around the anus. Sometimes, the track may have may have a single opening which is called as sinus. Generally, this track develops from ano-rectal abscess (*Bhagandrapidika*) that burst spontaneously or is incised inadequately. An anal fistula may occur with or without symptoms. There may be intermittent swelling with pain, discomfort and discharge of pus in the perineal region. This track does not heal usually due to fecal contamination, presence of unhealthy granulation and lack or rest to the part. This is a purely surgical condition but surgery has lot of complications and recurrence rate is also quite high after surgery.

According to Ayurveda, the disease condition in which there is tearing (cutting) pain in the area of *bhaga, guda* and *basti* is named as *Bhagandara*. Detailed description regarding its etiology, types, signs and symptoms including its many fold treatment is available in Ayurvedic literature. *Ksharsutra* treatment has been emphasized by Acharya Sushruta, the father of Indian Surgery in difficult cases and debilitated persons who are unfit for surgical treatment. *Ksharsutra* (medicated thread is an minimum invasive surgical Ayurvedic technique which was revived, developed and standardized in early seventies in Banaras Hindu University, Varanasi by Late Prof. P.J. Deshpande. The *Ksharsutra* is prepared by smearing the cotton thread with several layer of fresh latex of plant Snuhi (*Euphorbia nerrifolia*), Kshar powder (ashes extract of the plant *Achyranthus aspera*) and Turmeric powder (*curcuma longa*).

The usage of *Ksharsutra* in the treatment of fistula has got advantage over the conventional surgery as it is an ambulatory procedure and no hospitalization is required. Patients can undergo treatment without paralyzing their routine work. Moreover, it can be used in patients who are otherwise not fit for surgery.

Kshar Varti is also found to help in such cases. The *Kshar varti* are prepared from a standard mixture of snuhi ksheera, haridra churna and Kshar powder. The dry *Kshar* powder and turmeric (*haridra*) powder are added to the *snuhi* latex and the mixture is allowed to harden into a paste. When sufficiently thickened, the paste is rolled into small sticks (*varti*) of various lengths measuring from one to three inches each. The *varti* thus prepared are further dried to make them adequately stiff. When dried, the sticks are exposed to ultra-violet rays

and sealed in the polyethylene pouches to be ready for clinical use. The present study was planned to evaluate the results of *Ksharsutra* and *Kshar varti* application.

Council has done following studies since inception for validation of classical drugs in the management of *Bhagandar*:

Study 1: About 700 patients, including 200 patients of recurrent fistulae after operation have been studied by Clinical Research Enquiry at IMS, BHU, and Varanasi with Ksara sutra therapy. Out of 700 patients691 (98.7%) have been completely cured.

Study 2: Kshar sutra study on 395 patients has been conducted in the Council's Research Institutes and the outcome has been very promising, 386 (97.72%) patients responded with good improvement.

Study 3: Open label interventional study with *Ksharsutra* applied depending upon the severity and depth of fistula. The study was done at three centres viz. Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi, Central Ayurveda Research Institute for Drug Development, Kolkata and at (RRAP) Central Ayurveda Research Institute for Cancer, Mumbai. In the study total 729 cases were studied. Out of them, 544 patients, 124 patients, 24 patients, 6 patients got good response, fair response, poor response, no response respectively and 31 patients were dropped out.

Study 4: Open label interventional study with *Kshar Varti,* applied for 7 times at the interval of every two days. The study was done in two centres viz. (RRAP) Central Ayurveda Research Institute for Cancer, Mumbai and at Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi. In the study total 69 cases were studied. Out of them, 18 patients, 22 patients, 16 patients, 9 patients got good response, fair response, poor response, no response and 4 patients were dropped out.

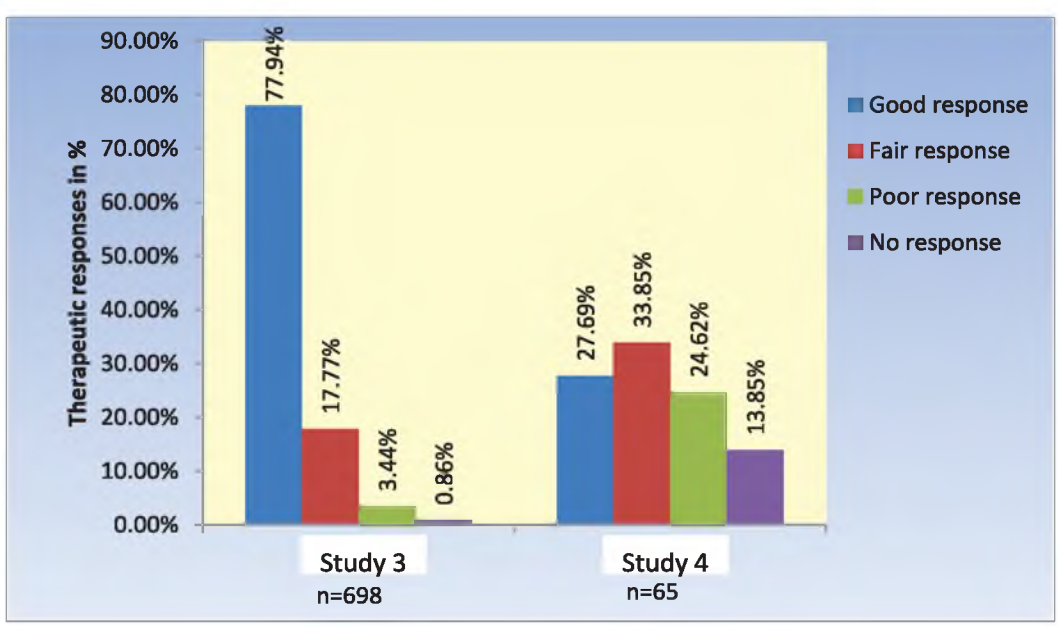
Conclusion: This technique has been very well accepted/adopted by the practitioners of Ayurveda. The efficacy of this approach has also been proved by studies conducted by Indian Council of Medical Research (ICMR). This therapy is very effective in the management of *Bhagandara.* The Ksara-Sutra being an OPD procedure does not requireanaesthesia, heavy medication and hospitalization. After application ofKshara-sutra, patients can perform their routine duties. There are noside effects/complications like incontinuance of stool, delayed

healing which may lead to infection. Besides being economical the tissue damage and pain is relatively lesser in this therapy.

Tab. 2.12. Therapeutic Response at a glance in the management of *bhagandara*

Sl.No.	Interventions	Good response	Fair response	Poor response	No response
1.	Ksara sutra therapy at BHU (n= 700)	98.7% have been completely cured			
2.	Kshar sutraStudy (n=395)	386 (97.72%) patients responded with good improvement			
3.	Kshar Sutra Karma (n=698)	77.94% (n=544)	17.77% (n=124)	3.44% (n=24)	0.86% (n=6)
4.	Kshar varti (n=65)	27.69% (n=18)	33.85% (n=22)	24.62% (n=16)	13.85% (n=9)

Fig.2.12. Therapeutic Response in different interventional groups



2.13: KITIBHA (PSORIASIS)

BACK GROUND

Psoriasis (*Kitibha*) is a common chronic non-infectious inflammatory skin disease. It is characterized by erythematous sharply demarcated papules and rounded plaques covered by silvery micaceous scale. In Psoriasis, main abnormality is of increased epidermal proliferation due to excessive multiplication of cells in the basal layers. There are five types of Psoriasis –Plaque, Guttate, Inverse, Pustular and Erythrodermic. The most common type is Plaque psoriasis in which red and white hues of scaly patches appears on the topmost layer of the epidermis which gives it a silvery white appearance. Psoriasis causes skin redness and irritation.

People of any age can be affected by psoriasis, but mostly the disease begins between 15 and 35 years of age. Globally about 1% of the world's population is affected by Psoriasis. The etiology of Psoriasis is unknown. The disease has genetic predisposition .The precipitating factors like trauma, infections, stress and medications (lithium, beta blockers & antimalarials) may cause flare of the disease. The current modern therapy includes topical use of agents such as coal tar, salicylic acid and anthralin which are now largely replaced by topical glucocorticoids, calcipotriene and a retinoid (tazrotene).Ultraviolet radiation is also used as local measure to manage psoriasis. These drugs give temporary symptomatic relief and often produce toxic side effect.

As per Ayurvedic concept, *Kitibha* is classified under *Kshudra Kushtha*. In Ayurveda the causative factors of skin disease are elaborately classified. Continued practice of *Apathya Ahara* and *vihara* vitiates the *dosha& dhatu* and causes *Kitibha*. Acharaya Sushruta has clearly indicated the genetic origin of the disease. In *Kitibha, vatakaphadosha* are predominantly involved. *Kitibha* may be co-related with Psoriasis of modern medical diagnosis. The line of treatment for *Kitibha* is advocated in accordance with the general treatment of *kushtharoga*. The main treatment is *Sodhana* followed by *Samana* and *Rasayana* therapy. Many single and compound herbal and herbomineral preparations are mentioned in Ayurvedic classical text books. In the present study different Ayurvedic procedures and medicines were used for clinical evaluation.

Council has done following studies since inception for validation of classical drugs in the management of *Kitibha*:

Study 1: Combination of internal administration of *Nimbidin* an isolatefrom Neem seed oil and *Lajjalukeram* as external applications have beentaken for trial.*Nimbidin* 200 mg twice daily and Lajjalukeram quantity sufficient for 60 days. Clinical trial has been conducted on 362 patients and about 60%of the patients have shown good control as evidenced by the relief ofthe signs and symptoms of the disease and no relapse was noticed.

Study 2: An interventional open label study with *Arogyavardhini* tablet 500 mg along with *Kaishore guggulu* tablet 1 gm. and *Chakramardataila* for local application thrice a day for 3 months. The study was done at seven centres viz. Central Ayurveda Research Institute for Respiratory Disorders, Patiala, Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar, National Ayurveda Research Institute for Panchakarma, Cheruthuruthy, Regional Research Centre (Ay.), Hastinapur (presently merged with CARICD, New Delhi), Regional Research Institute (Ay.), Junagarh (presently merged with RARISD, Ahmedabad), Regional Ayurveda Research Institute for Urinary Disorders, Jammu and at Regional Ayurveda Research Institute for Life style related Disorders, Thiruvananthapuram.In the study total 680 cases were studied. Out of them, 169 patients, 202 patients, 100 patients, 20 patients got good response, fair response, poor response, and no response respectively and 189 patients were dropped out from the trial.

Study 3: An interventional open label study with *Panchanimba lauha churna* 2 gms, *Kamadudha rasa* 250 mg and *Haridrakhanda* 3 gm (mixed together in a single dose) twice a day for 3 months. Study was done at 5 centres viz. Central Ayurveda Research Institute for Respiratory Disorders, Patiala, Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar, Regional Research Centre (Ay.), Hastinapur (presently merged with CARICD, New Delhi), Regional Ayurveda Research Institute for Urinary Disorders, Jammu and at Regional Ayurveda Research Institute for Life style related Disorders, Thiruvananthapuram.In the study total 372 cases were studied. Out of them, 65 patient, 126 patients, 66 patients, 14 patients got good response, fair response, poor response and no response respectively and 101 patients were dropped out.

Study 4: An interventional open label study with *Snehapana* for 7 days with *Mahatiktaka Ghrita*, *Mridu Swedana* for one day, *vamana* (mild) for a day and *Samsarjana-*

Rasayanaprayoga with *Bhallataka* for 3 months. Study was done at 2 centres viz. Central Ayurveda Research Institute for Respiratory Disorders, Patiala and at National Ayurveda Research Institute for Panchakarma, Cheruthuruthy.In the study total 245 cases were studied. Out of them, 41 patient, 86 patients, 48 patients, 1 patient got good response, fair response, poor response and no response respectively and 69 patients were dropped out.

Study 5: A Prospective, open label multicentre study was carried out at two peripheral centres. A total of 85 people (45 from NRIP, cheruthuruthy and 40 from CARIDD, Kolkata) were enrolled in the trial after obtaining the written informed consent and 70 patients completed the trial. Pre-*Panchakarma Snehana* was done with *Mahatiktaka Ghrita* with starting dose 30 ml in the first day and gradually increased taking into consideration the status of *Agni* in patients, till the 7^{th} day (stopped when symptoms of proper oleation was observed in the 7^{th} day). *Swedana* procedure was done by hot water bath for 15 minutes daily for 2 days. *Vamana Karma* was done on the 10^{th} day by administering Madanaphala, Yastimadhu, Saindhava Lavana, Madhu, Vacha and milk. This was followed by *Samsarjana Karma* for 7 day. *Takra dhara* was done from 18^{th} day to 24^{th} day with *Takra* prepared from using Amalaki, Mustha and milk. *Rasayana* therapy were administered for 49 days with 100 mg *Yasada Bhasma* twice daily and *Triphala Choorna* 3 gm twice daily starting from the 18 th day along with *Takra Dhara*, with water as *Anupana*. There was considerable change in all the symptoms of plaque psoriasis including exfoliation (percentage improvement =56.6%), circular erythema (35%), itching (49.4), dryness (39.8), roughness (43.4) and Auspitz's sign (84.4). Assessments on by PASI scale revealed that there was statistically significant improvement with *p–value* <0.001. Statistically significant improvement was observed in all the parameters of DLQI including symptoms and feelings, Daily activities, Leisure, Work & School, Personal Relationships, Treatment and total DLQI score with *p –value* <0.001 CTRI/06631.

Study 6: An interventional and open label multi centric study conducted at OPD level in 2 peripheral centers of CCRAS viz, NARIVBD, Vijayawada and ACRI, New Delhi. Total number of 112 (NARIVBD, Vijayawada- 60, ACRI, New Delhi 52) cases were enrolled for the study. Vajraka Ghritam 6 gm twice daily before food with luke warm water, and Arogyavardhini Vati 250 mg twice daily after food with luke warm water was given internally and Dineshavalyadi taila was used twice daily for external application over affected area of skin. Before the treatment itching was present in all the cases 111 (100%) and after

treatment ie 84th day it was observed in 95 (85.6%) cases. Likewise at baseline Dryness of the skin was in 111 (100%) cases and after treatment 62 (55.9%), Roughness 111(100%) at base line 70 (63.1%) after treatment, Circular erythema was found in 111 (100%) cases and in 102 (91.9%) cases after treatment Expoliation was in 111(100%) at base line and 79 (71.2%) cases after treatment. Hyper pigmentation was observed in 110 (99.1%) initially and it was reduced to 104 (93.7%) cases AT. Hypo pigmentation was found in 2 (1.8%) cases and reduced to 1 (0.9%) after the treatment. Pinpoint bleeding after removal of skin was observed in 110 (99.1%) cases before treatment and it was reduced to 65 (58.6%) cases after treatment. These drugs have shown significant improvement in all the clinical parameters, Psoriasis Area and Severity Index (PASI) score and Dermatological Life Quality Index (DLQI) score.

Conclusion: Ayurveda intervention in the management of Psoriasis (*Kitibha*) has shown very promising results and it can be successfully implemented in the management of Psoriasis for improving quality of life in the patient.

Tab. 2.13.1. Therapeutic Response at a glance in the management of *Kitibha*

S. N.	Interventions	Good response	Fair response	Poor response	No response
1.	*Nimbidin* and *Lajjalu keram* (n=362)	60% of the patients have shown good control			
2.	Arogyavardhani, Kaishore Guggulu & Chakramard Taila for external application (n=491)	34.42% (n=169)	41.14% (n=202)	20.37% (n=100)	4.07% (n=20)
3.	Panchanimba Lauha churna, Kamadudha Rasa & Haridra Khanda (n=271)	23.99% (n=65)	46.49% (n=126)	24.35% (n=66)	5.17% (n=14)
	Snehapana, Swedana, Vamana & Samsarjana (n=176)	23.30% (n=41)	48.86% (n=86)	27.27% (n=48)	0.57% (n=1)

Table 2.13.2. Effect of treatment in PASI and DLQI in study 5

Parameter	Baseline	66th day	$t-value	p- value
PASI score	23.59 (12.378)	5.19 (6.403)	13.518	<0.001
DLQI				
Symptoms & Feelings	4.25 (1.981)	1.20 (1.332)	13.484	<0.001
Daily Activities	3.82 (2.280)	0.87 (1.267)	11.612	<0.001
Leisure	3.61 (2.321)	0.94 (1.310)	10.446	<0.001
Work & School	0.96 (1.565)	0.42 (1.159)	3.855	<0.001
Personal Relationships	2.72 (2.711)	0.47 (0.874)	8.540	<0.001

Treatment	1.54 (1.382)	0.29 (0.595)	8.564	<0.001
Total DLQ1 Score	16.94 (9.822)	4.19 (5.171)	11.918	<0.001

Values are expressed as Mean (SD), $ Compared using paired t-test at baseline and 66th day

Table 2.13.2. Effect of treatment in DLQI in study 6

DLQI – Total Score	Paired Differences					t-value	df	p-value
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower Bound	Upper Bound			
Baseline – 14th day	.739	1.746	.166	.410	1.067	4.457	110	<0.001
Baseline – 28th day	1.703	2.291	.217	1.272	2.134	7.831	110	<0.001
Baseline – 42nd day	2.631	2.806	.266	2.103	3.158	9.879	110	<0.001
Baseline – 56th day	3.495	3.495	.332	2.838	4.153	10.537	110	<0.001
Baseline – 70th day	4.568	4.356	.413	3.748	5.387	11.047	110	<0.001
Baseline – 84th day	5.946	5.457	.518	4.919	6.972	11.480	110	<0.001
Baseline – Follow up at the end of 14th week	6.198	5.687	.540	5.128	7.268	11.483	110	<0.001

Fig. 2.13.1. Therapeutic Response in different interventional groups

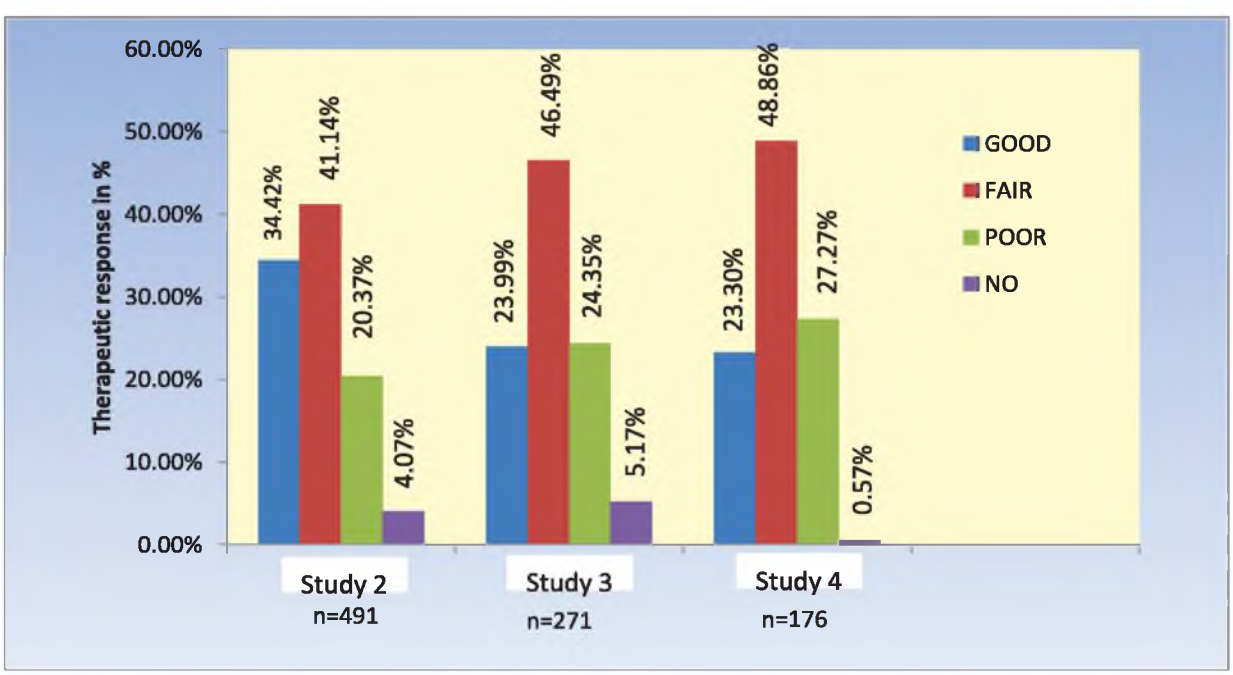
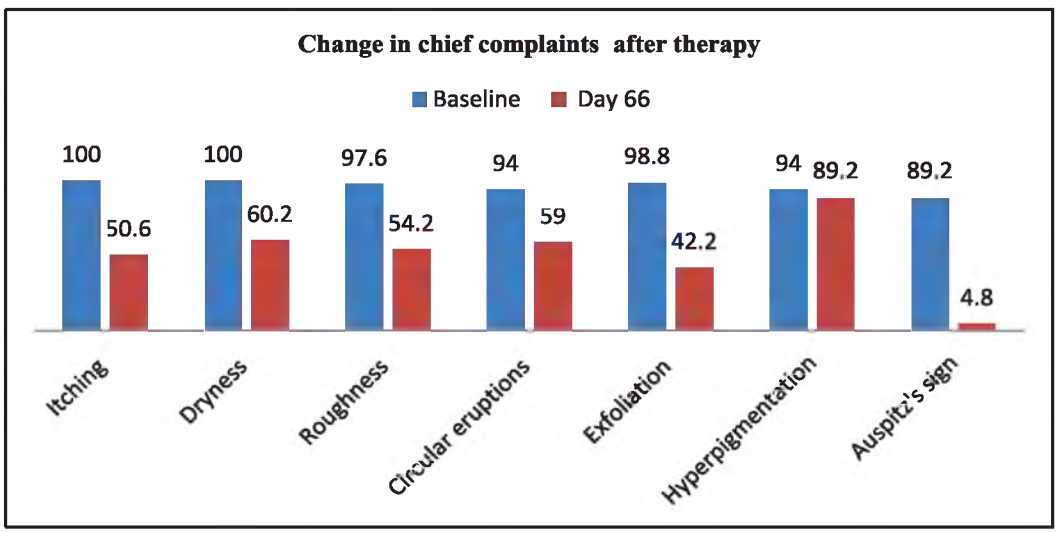


Fig. 2.13.2. Demonstrating change in symptoms from baseline to 66th day in study 5



2.14: VISHAMJWAR (MALARIA)

BACKGROUND

Malaria *(Vishama Jvara*) is one of the most prevalent diseases, which is difficult to control. Malaria is a protozoal disease caused by infection with parasites of the genus plasmodium and transmitted to man by certain species of infected female Anophelese mosquito.

The incidence of malaria worldwide is estimated to be 300-500 million clinical cases each year & Malaria is estimated to kill between 1.1 and 2.7 million people worldwide each year. It is mostly caused by Plasmodium falciparaum. In India, during 2003 about 1.65 million cases were reported with 943 deaths and there were 0.7 million cases of P. falciparum malaria.

In Ayurvedic literature Malaria fever is known as *Vishama jvara* (Intermittent fever). The disease was well known to Ayurvedic physicians as *Vishama jvara* from ancient times. Ayurvedic literature contains many drugs prescribed for the treatment of *Vishamajawara*. In the present study different combinations of Ayurvedic medicines were taken up for assessment of clinical efficacy.

Council has done following studies since inception for validation of classical drugs in the management of *Vishama Jvara*:

Study 1: An open label interventional study was done with *Sphatika Bhasma* 500 mg thrice a day, *Guduchi Satva* 500 mg thrice a day and Ayush-64 1gm thrice a day for seven days. Study was done at six centres viz. M.S. Regional Ayurveda Research Institute for Endocrine Disorders, Jaipur, Regional Ayurveda Research Institute for Infectious Diseases, Patna, Regional Ayurveda Research Institute, Itanagar, Regional Ayurveda Research Institute for Mother and Child Health, Nagpur, Regional Research Centre (Ay.),Hastinapur (presently merged with CARICD, New Delhi) and at Dr. Achanta Lakshmipati Research Centre for Ayurveda, Chennai. In the study total 1336 cases were studied. Out of them, 496 patients, 340 patients, 167 patients, 17 patients got good response, fair response, poor response, and no response respectively and 316 patients were dropped out from the trial.

Study 2: An open label interventional study was done with *Saptaparna Twaka Ghanavati* 500 mg thrice a day with water for seven days. Study was done at five centres viz.M.S. Regional Ayurveda Research Institute for Endocrine Disorders, Jaipur, Regional Ayurveda Research Institute for Infectious Diseases, Patna, Regional Ayurveda Research Institute for

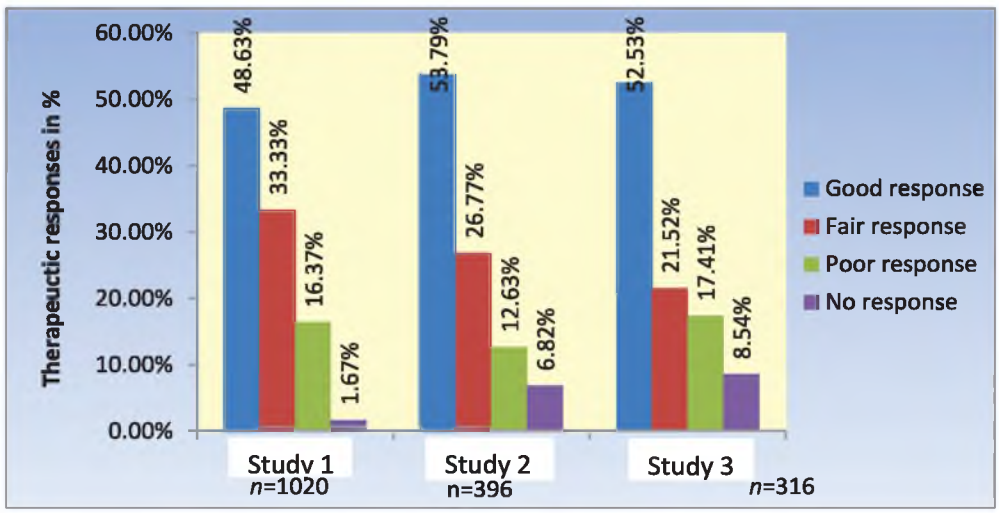
Mother and Child Health, Nagpur, Regional Ayurveda Research Institute, Itanagarand at Dr. Achanta Lakshmipati Research Centre for Ayurveda, Chennai. In the study total 564 cases were studied. Out of them, 213 patient, 106 patients, 50 patients, 27 patients got good response, fair response, poor response and no response respectively and 168 patient was dropped out.

Study 3: An open label interventional study was done with *Parijata Patra Ghanavati* 500 mg thrice a day with water for seven days. Study was done at five centres viz.Regional Ayurveda Research Institute for Mother and Child Health, Nagpur, Regional Ayurveda Research Institute for Infectious Diseases, Patna, Dr. Achanta Lakshmipati Research Centre for Ayurveda, Chennai, Regional Research Centre (Ay.), Hastinapur (presently merged with CARICD, New Delhi) and at Regional Ayurveda Research Institute for Gastro-Intestinal Disorders, Guwahati. In the study total 483cases were studied. Out of them, 166 patient, 68 patients, 55patients, 27 patients got good response, fair response, poor response and no response respectively and 167 patients was dropped out.

Tab.2.14. Therapeutic Response at a glance in the management of *vishama jwara*

Sl.No.	Interventions	Good response	Fair response	Poor response	No response
1.	Sphatika Bhasma, Guduchi Satva and Ayush 64 (*n*=1020)	48.63% (*n*=496)	33.33% (*n*=340)	16.37% (*n*=167)	1.67% (*n*=17)
2.	Saptaparna Ghanavati (n=396)	53.79% (*n*=213)	26.77% (*n*=106)	12.63% (*n*=50)	6.82% (*n*=27)
3.	Parijata Patra Ghanavati (*n*=316)	52.53% (*n*=166)	21.52% (*n*=68)	17.41% (*n*=55)	8.54% (*n*=27)

Fig. 2.14. Therapeutic Response in different interventional groups



2.15: MANODVEGA (ANXIETY NEUROSIS/ GENERALIZED ANXIETY DISORDER)

BACK GROUND

Generalized Anxiety Disorderis state of mental discomfort characterized by a series of symptoms due to faulty adaptation of stress. Anxiety disorders are among the most prevalent psychiatric conditions in the world. Generalized anxiety disorder is defined as excessive anxiety and worry about several events or activities for a majority of days during at least six month period. The worry is difficult to control and is associated with symptoms such as muscle tension, impaired concentration, autonomic arousal, restlessness and insomnia etc.The anxiety is subjectively distressing and produces impairment in important areas of a person's life. A person's genetics, biochemistry, environment and psychological profile may contribute to the development of anxiety disorders. The prevalence of generalized anxiety disorder is about 5-6%.

As per Ayurvedic concept *Manodvega* (Anxiety neurosis) is one of the Manasika Vikara. *Manodvega* may be defined as a *Manas* (mind) + *Udvega* (anxiety) = *Manoodvega* (Anxious status of mind). Mind is a dual faculty (*Ubhayendriya*) or sensory-motor faculty (*Jnana-Karmendriya*), it perceives and responds. The physical well being as well as illness is reflected in mind. The influence of mind cannot be ruled out in origin, existence or cure of any disease. When allowed to persist for long time the psychic and somatic disorders get combined with each other. In *Manodvega*, when the mind is afflicted with anxiety, fear, agitation etc. this leads to worry, apprehension, depression, psychological arousal as anger, irritability and ultimately lead to disturbance in personal, familial and social harmony. The Ayurvedic principle of synthesis of mind, body and soul to consider man as integrated entity, helps to treat mental disorders effectively. Medhya rasayanas and Satvavajaya chikitsa are such measures, which can be utilized for the treatment of *Manodvega*.

Council has done following studies since inception for validation of classical drugs in the management of *Manodvega*:

Study 1: An open label interventional study was done with *Vacha, Brahmi Ghana Satva* 500 mg thrice a day with water. Study was done at five centres viz. Central Ayurveda Research Institute for Respiratory Disorders, Patiala, (RRAP) Central Ayurveda Research Institute for Cancer, Mumbai, Regional Ayurveda Research Institute for Eye Diseases, Lucknow, Regional Ayurveda Research Institute for Metabolic Disorders, Bangalore and at Advanced Center for Ayurveda in Mental Health & Neurosciences, Bangalore. In the study total 435

cases were studied. Out of them, 103 patients, 200 patients, 54 patients, 4 patients and 74 patients got good response, fair response, poor response, no response and dropped out respectively.

Study 2: A prospective open label randomized clinical trial was conducted at, Advanced centre for Ayurveda, NIMHANS A unit of CCRAS at Bengaluru. 100 *Manodwega* (GAD) patients were randomised into two groups. Grp 1 receiving *Ashwagandha churna* (1.5 gms.) and *Mandookaparni churna*(1.5 gms.) twice daily for 12 weeks or Grp 2 receiving*Ashwagandha churna* (1.5 gms) and *Mandookaparni churna* (1.5 gms) twice daily for 12 weeks alongwith *Shirodhara* with *Ksheerabala Taila* for 30 minutes daily for the initial 7 days. Outcome measure was improvement in total and individual constituents of Hamilton anxiety Rating Scale which were assessed at baseline and on 28th day, 56th day and 84th day. At the end of 12 weeks compared with baseline statistically significant improvement was observed in Hamliton rating scale score (p-value < 0.001) in both the groups.The treatment was found to be safe and effective as all the safety parameters were in stipulated range. No adverse drug reaction or event was reported during the trial period. (CTRI /2017/07/009095)

Conclusion: Ayurveda management has shown very promising results in the management of Anxiety neurosis (Manodvega). The studied drugs are safe and effective and can be used successfully in its management.

Tab.2.15.1. Therapeutic Response at a glance in the management of *Manodvega*in study-1

Sl.No.	Interventions	Good response	Fair response	Poor response	No response
1.	Vaca, Brahmi Ghana Satwa (n=361)	28.53% (n=103)	55.40% (n=200)	14.96% (n=54)	1.11% (n=4)

Table 2.15.2: Effect of treatment on chief complaints assessed by Hamilton Anxiety Rating in study 2

Hamilton Anxiety Rating Scale Score	Group I (n = 50)			Group II (n = 50)		
	Mean (SD)	t-value	p-value	Mean (SD)	t-value	p-value
Baseline	19.38 (4.318)			18.62 (4.802)		
28th day	17.32 (4.483)	12.291	<0.001	16.26 (4.650)	12.938	<0.001
56th day	15.70 (4.550)	11.688	<0.001	14.76 (4.502)	12.940	<0.001
84th day	15.02 (4.520)	12.683	<0.001	14.38 (4.629)	13.139	<0.001

Fig.2.15.1. Therapeutic Response in study 1

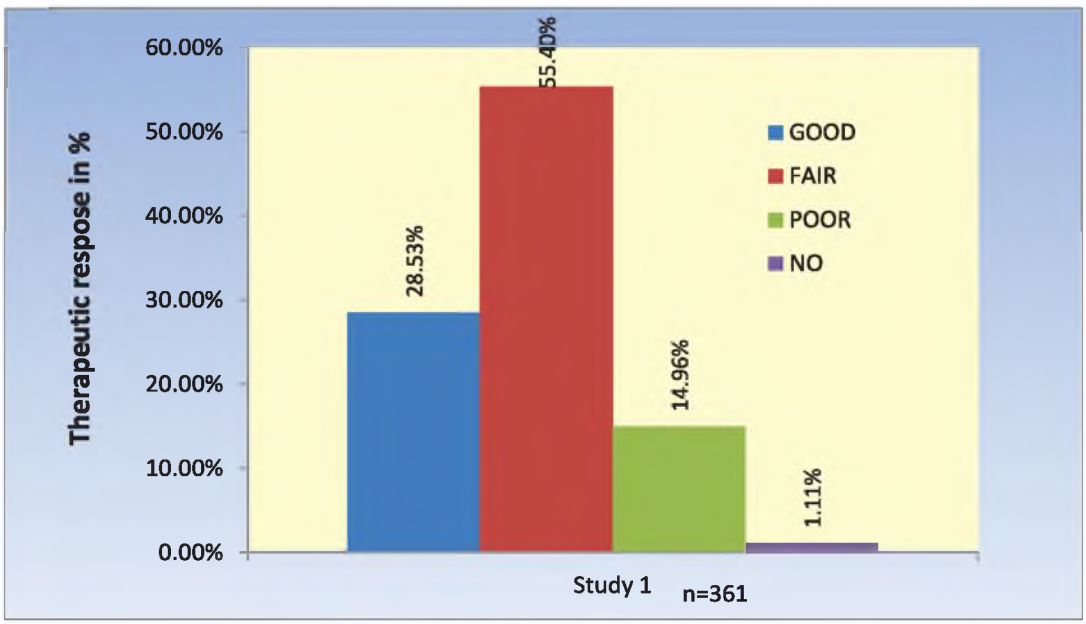
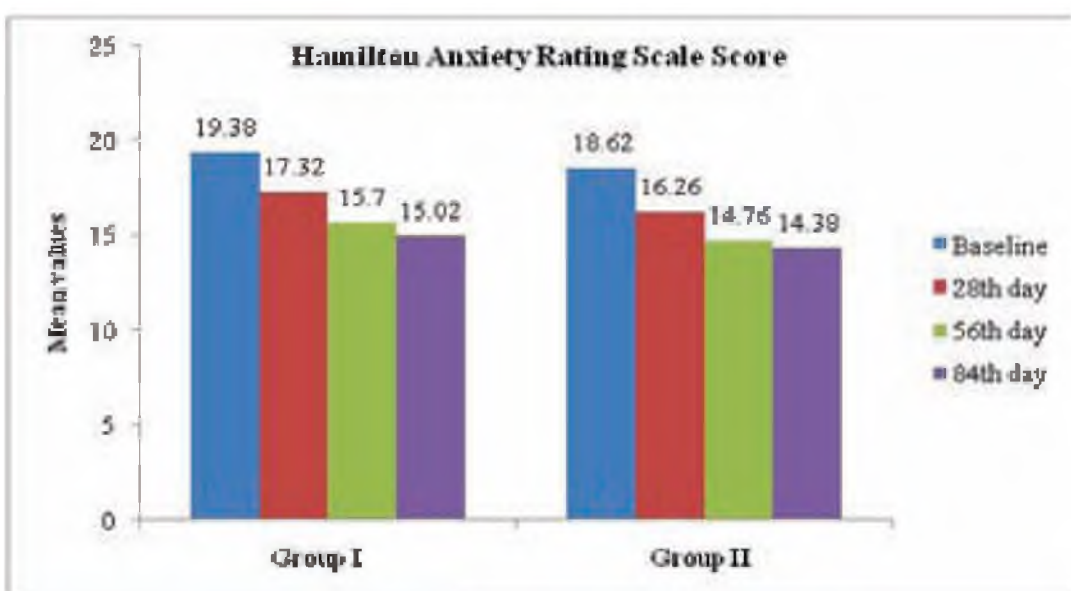


Fig.2.15.2. Effect of treatment assessed by Hamilton Anxiety Rating Scale of study 2



2.16: APASMAR (EPILEPSY)

BACK GROUND

Epilepsy (*Apasmara*) is defined as a condition in which a person has recurrent seizures due to chronic underlying process. Seizures are episodes of disturbed brain function that cause changes in attention or behavior. It is a chronic neurological condition caused by abnormal cerebral nerve cell activity. More than 2 million people in the United States and over 50 million people worldwide suffer from epilepsy. The incidence of epilepsy is between 0.3 – 0.5 percent in different population throughout the world and the prevalence of epilepsy is roughly in the range 5-10 persons per 1000.

On the basis of the etiology, epilepsy is divided into two categories idiopathic and acquired. In idiopathic epilepsy no specific cause is found but patients with idiopathic epilepsy sometimes have a genetic predisposition. Head injury, cerebral vascular disease, various allergic reactions cerebral degenerative and demyelinating diseases, toxic and metabolic disorders are important causes of seizures. There is a great variation in symptoms from brief lapses of awareness, simple localized focal jerks, turning of head and eyes, change in posture, vocalization, hallucinations to loss of consciousness and violent convulsions depending upon the specific type of seizure. The chief division of seizure types is between partial (focal) seizures in which paroxysm neuronal activity is limited to one part of the cerebrum and generalized seizures where the electrophysiological abnormality involves large areas of both hemispheres simultaneously and synchronously. It is manifested by a variety of clinical symptomatology.

The treatment of epilepsy is based on medical therapy (use of anti-epileptic drugs) and sociologic management. Surgical therapy in cases where the patients with potentially remediable lesions such as brain tumour or any space occupying lesions are resorted to if needed.

According to Ayurveda, loss of *smriti* (consciousness) has been ascribed to be the cardinal feature of the disease *Apasmara* S*mara*or *smriti* means memory, which indicate, intelligence and consciousness and *Ap* means loss. The *nidana* (causative factors) of *apasmara* are *sharirika* (physical) like *aharaja* and *viharaja* and *manasika* (psychological) like *kam, krodha* , *bhaya* etc. and *agantuka hetus* are like poison, injury etc. Signs and symptoms of *Apasmara* mentioned in Ayurveda are cardiac pain, visual hallucination, falling down, twitching of tongue and eyes, frothing salivation, tremors of hands and feet.

Council has done following studies since inception for validation of classical drugs in the management of *Apasmara*:

Study 1: An open label interventional study was done with *Vachadi yoga Ghana Satwa* tablet 500 mg. thrice a day for 6 months. The study was done at two centres viz. Advanced Center for Ayurveda in Mental Health & Neurosciences, Bangalore and at Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi. In the study total 48 cases were studied. Out of them, 4, 20, 4 and 5 patients got good response, fair response, poor response, no response respectively and 15 patients and were dropped out from the trial.

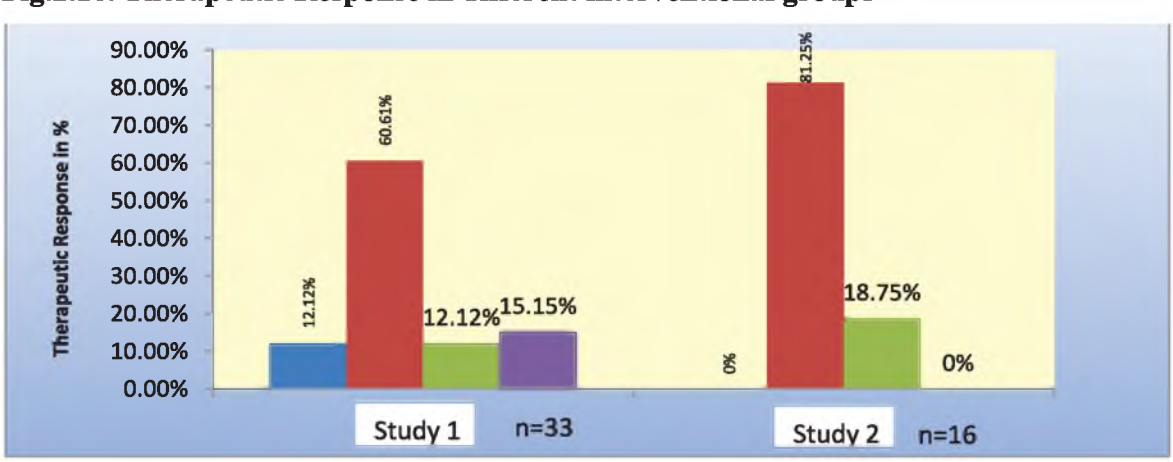
Study 2: An open label interventional study was done with *Brahmyadi yoga* powder 3 gm. thrice a day for 6 months. The study was done at Advanced Center for Ayurveda in Mental Health & Neurosciences, Bangalore. In the study total 22 cases were studied. Out of them, no patient, 13 patients and 3 patients, no patients got good response, fair response, poor response and no response respectively and 6 patients were dropped out from the trial.

Conclusion: Studies have shown promising results of Ayurveda management in epilepsy. The studied drugs may be successfully used in the management of uncomplicated epilepsy.

Tab.2.16. Therapeutic Response at a glance in the management of *Apasmara*

S.N.	Interventions	Good response	Fair response	Poor response	No response
1.	Vachadi Yoga (n=33)	12.12% (n=4)	60.61% (n=20)	12.12% (n=4)	15.15% (n=5)
2.	Brahmyadi Yoga (n=16)	00% (n=0)	81.25% (n=13)	18.75% (n=3)	00% (n=0)

Fig.2.16. Therapeutic Response in different interventional groups



2.17: UNMADA (SCHIZOPHRENIA)

Background

Schizophrenia is a severe mental disorder characterised by specific psychological symptoms and leading to disorganisation of the personalityof the patients, distortion of thinking and disturbed perception etc.The disease has been discussed in Ayurveda from the earliest timesand the practitioners of Ayurveda have been successfully treating suchpatients.

According to Ayurveda, schizophrenia is compared with *unmada*. Lack of mental discipline, indulgence in negative thoughts and activities, negative emotions like hatred, anger cause imbalance in *satva*, *raja* and *tama* which then leads to this condition. It is also believed that the vitiated *doshas* evade the brains of the persons with less *satva* or whose mind is under *rajsik* and *tamsik* influences. These *doshas* then block the channels of mind or *manovahisrotas* and nerve impulses. As a result, the functioning of mind and intelligence get affected. Due to this the patient fails to differentiate between real and virtual, correct and incorrect.

Council has done following studies since inception for validation of classical drugs in the management of *Unmada*:

Study 1: Double blind clinical trial was done with *Brahmyadiyoga* containing *Brahmi* (*Centella asiatica* (Linn.), *Vacha* (*Acorus calamus* Linn.), *Sarpagandha* (*Rauwolfia serpentina* Benth. ex Kurz.), *Kushta* (*Saussurea lappa* C.B. Clarke), *Tagara* (*Valeriana wallichi* DC.) and *Jatamansi* (*Nardostachys jatamansi* DC.). The study was done on 108 patients divided into 4 groups. The affect of trial drugs *Brahmyadi yoga* and *Tagara* were compared with the placebo and known anti-psychotic drug chlorpromazine. The results were evaluated on the basis of clinical symptoms, psychological assessment and multiphasic questionnaire. The data were statistically analyzed and it was concluded that the *Brahmyadi yoga* has statistically significant effect in comparison to placebo and *Tagara*. The effect was also comparable to chlorpromazine. The study shows *Brahmyadiyoga* was more effective than the placebo. Chlorpromazine was found significantly better than both *brahmyadi yoga* and placebo.

Study 2:A double blind controlled study was also carried out on 65 patients of chronic schizophrenia to study the efficacy of *Brahmyadiyoga*. In comparison to chlorpromazine and placebo in three groups. Psychiatric diagnosis was made on the basis of the WHO glossary of

mental disorder and guide to this classification. Assessment of therapeutic response was done by using psychiatric symptoms rating scale and by Testing Reaction Time, Critical Flicker Fusion Threshold, Vigilance test and Ferguse Falls Behavior Rating Scale. Ayurvedic assessment was done by examination of mental status and *laksana*. The total duration of treatment was 75 days. In this study also the study drug was found to be effective as compared to the placebo but chlorpromazine was more efficacious than both the groups.

Conclusion: *Brahmyadiyoga* is free from toxicity or side effects, however, on long term use blood pressure and liver function should be assessed. It can be used as an on treatment to modem anti-psychotic drugs.

Tab. 2.17. Therapeutic Response at a glance in the management of *Unmada*

S.N.	Interventions	Result
1.	*Brahmyadiyoga, Tagara, Placebo* and Chlorpromazine(n=108)	*Brahmyadiyoga* has statistically significant effect then placebo and *Tagara* but less then Chlorpromazine
2.	*Brahmyadiyoga, Placebo* and Chlorpromazine (n= 65)	*Brahmyadiyoga* has statistically significant effect then placebo but less then Chlorpromazine

2.18: RESPIRATORY DISORDERS: *SHWAS* (BRONCHITIS) AND *TAMAKA SHWAS* (BRONCHIALASTHMA)

BACKGROUND

Tamaka Shwasa (Bronchial asthma) is prevalent all over the world. It is characterized by chronic airway inflammation and increased airway responsiveness resulting in symptoms of wheeze, cough, chest tightness and dyspnoea. It is also functionally characterized by the airflow limitations usually reverses spontaneously or with treatment. The available treatment in modern medical science like bronchodilators, steroids even in the form of inhalers and leukotrienes modifiers have made tremendous success in providing instant or symptomatic relief in Bronchial asthma. But there is recurrent acute exacerbation and remissions and treatment has many side effects like nausea, vomiting, tremor, huskiness of voice, disturbance of hypothalamus – pituitary –adrenal axis.

Chronic bronchitis is a well-defined clinical condition in contemporary medical science classified under the broader heading of chronic obstructive pulmonary diseases (COPD) that is a progressive preventable condition, without cure. In modern medicine; antibiotics, anti-histaminic, bronchodilators, expectorants etc., are commonly used for the management of chronic bronchitis. Although, they are effective in reducing the severity of the disease and suppressing the symptoms; none of these modalities of treatment provide a permanent cure and have limitations owing to their unwanted effects.

In Ayurveda, the concept, etio-pathogenesis and treatment of *Shwas* and *Tamaka Shwasa* have been described in detail. The clinical manifestations of *Shwasa* described in Ayurveda classics have a striking similarity to the clinical manifestation of Bronchial asthma respectively. Many single and compound herbal and herbo-mineral preparations are mentioned in Ayurveda classical text books.

Council has done following studies since inception for validation of classical drugs in the management of *Shwas* and *Tamak Shwas*:

Study 1: The two combinations of *Naradiya Lakshmi Vilasa Rasa* with *Godanti Bhasma* and *Swasa Kesari* (*Kantakari* with *Godanti Bhasma*) have been evolved and put on trial in separate groups of patients.*Group A:* This group constituted *Naradiya Laksmi Vilasa Rasa* and *GodantiBhasma* in a dose of 500 mg. and 1 gm. respectively thrice a day.*Group B:*This

group constituted *Shwasa Kesari* tablets (500 mg. each) three tablets thrice a day.The efficacy of the treatment has been evaluated on the basis ofclinical improvement i.e. changes in signs and symptoms of the disease.In addition, a quantitative assessment of pulmonary functions testssuch as vital capacity, peak flow rate, breath holding time etc. have alsobeen undertaken. The data has been statistically analyzed.Out of 783 patients studied with Shwasa Kesari, most of the patients showed good response. Only less than 5% showed poor effect onthe disease. Laksmi *Vilasa Rasa, Godanti* combination was equally effective and about 8% did not show any effect of the therapy.

Study 2: *Kantakari*, whole plant was studied on 151 patients. The drugwas administered in the form of *Kwatha* (Decoction) in the dose of 30ml. three times a day. The effect of the drug was evident in most of thepatients (59.09%) who completed full course of 4 weeks.

Study 3: An open label interventional study was done with *Pippli Vardhamana Ksheera Paka* with *Samira Pannaga Rasa* 250mg. thrice daily for 6 weeks.Study was done at five centres viz. Central Ayurveda Research Institute for Respiratory Disorders, Patiala, Regional Ayurveda Research Institute for Metabolic Disorders, Bangalore, Regional Ayurveda Research Institute for Skin Disorders, Vijayawada, Regional Ayurveda Research Institute for Infectious Diseases, Patna and at Regional Research Institute (Ay.), Junagarh (presently merged with RARISD, Ahmedabad). In the study total 431 cases were studied. Out of them, 56 patients, 153patients, 37 patients, 39 patients and 146 patients got good response, fair response, poor response, no response and dropped out respectively.

Study 4: An open label interventional study was done with *Shirisa Twak Kwatha* 30 ml. thrice daily for 6 weeks. Study was done at six centres viz. Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar, M.S. Regional Ayurveda Research Institute for Endocrine Disorders, Jaipur, Central Ayurveda Research Institute for Respiratory Disorders, Patiala, Regional Ayurveda Research Institute for Metabolic Disorders, Bangalore, Regional Ayurveda Research Institute for Skin Disorders, Vijayawada and at Regional Research Institute (Ay.), Junagarh (presently merged with RARISD, Ahmedabad). In the study total 863cases were studied. Out of them, 165 patients, 243 patients, 152 patients, 29 patients and 274 patients got good response, fair response, poor response, no response and dropped out respectively.

Study 5: An open label interventional study was done with *Shodhan Chikitsa* (*Snehana, svedana, vamana, and virechana).*Study was done at two centres viz. Regional Ayurveda Research Institute for Skin Disorders, Vijayawada and at Regional Ayurveda Research Institute for Metabolic Disorders, Bangalore. In the study total 139 cases were studied. Out of them, 71 patients, 44 patients, 11 patients and 13 patients got good response, fair response, poor response and dropped out respectively.

Study 6: A Prospective, open-label multicenter study was carried out in three peripheral centers viz. Regional Ayurveda Research Institute for Metabolic Disorders, Bengaluru; Regional Ayurveda Research Institute for Skin disorders, Vijayawada; and M.S. Regional Ayurveda Research Institute for Endocrine Disorders, Jaipur. Total of 210 participants were enrolled in the trial. The patients were administered *Kanakasava* (API-Part-II; Vol.-II: Pg. 31) 20 ml twice daily with equal amount of water twice a day after meals and *Trivrit Churna*(API-Part-I; Vol.-III; Pg. 213) 3 gm once at bed time with luke warm water for 12 weeks and follow up was done after 2 weeks without medication.Breathlessness was the chief complaint in majority of the patients and the complaint got relieved in 52.1% (97.1% - 45.0%) and 56% (97.1% - 41.1%) of the patients by the end of 84^{th} day and at the follow-up at the end of 14^{th} week respectively. Wheezing was another major symptom which got relieved in 66.5% at the end of trial period with intervention. Cough (56%) and expectoration of sputum (40.6%) also improved considerably at the end of 84^{th} day. Tightness of chest (49.8%) and worsening of symptoms at night (45.0%) also got relieved at the end of the trial. There was considerable improvement (39.3%) in the habit of awakening at night due to exacerbation of symptoms.The combined therapy also produced statistically significant change, with p *–value*<0.001, in PEFR and FEV1 at the end of the trial and also at the end of the follow up. Statistically significant change was observed in all the four domains of St. George Respiratory Questionnaire with p *–value*<0.001.No change was observed in safety parameters during the study. CTRI/2016/04/006801

Study 7: An Open label multicentre study was done at three centres viz. RARISD, Vijaywada, RARIED, Jaipur and at RARIMCH, Nagpur. Total 147 patients were enrolled in the study. *Vyaghri Haritaki* was given in the dose of 10 gm., twice daily with Luke warm water for 84 days. Comparing the baseline and after the trial period, clinical improvement was significantly seen in 69.43% of cases. Significant improvement was observed in subjective parameters as well as objective parameters like PEFR (Ltr/min) (p-value < 0.001),

FEV_1% (p-value < 0.001), in the domains of St. George Respiratory Questionnaire domain-symptoms (p-value = 0.010), domain – activity (p-value < 0.001), domain – impact (p-value < 0.001) and total score (p-value < 0.001), Asthma Control Questionnaire Score (p-value < 0.001). No significant adverse events or adverse reactions were observed during the study. CTRI/2012/04/002584

Study 8: An Open label multicentre study was done at three centres viz. RARISD, Vijaywada, CARIDD, Kolkata and at RARIDD, Gwalior. Total 147 patients were enrolled in the study. *Vyaghri Haritaki* was given in the dose of 10 gm., twice daily with Luke warm water for 84 days. After the trial period, clinical improvement was significantly seen in dyspnoea, wheezing, chest pain, sore throat, nasal congestion. No significant adverse events or adverse reactions were observed during the study. After treatment relief in dyspnoea was obtained in 61.1% is reduced in 21.4%, Wheezing 22% reduced by 0.8% and Nasal congestion reduced by 10.3% during the baseline and there was significant improvement in all these qualitative parameters as PEFR, FEV1, and St. George Respiratory Questionnaires (SGRQ) score. After the trial period, clinical improvement was significantly seen in 93% of cases. After the trial period, significant changes were obtained in all these qualitative parameters as PEFR, FEV1, and St. George Respiratory Questionnaires (SGRQ) score. CTRI/2012/02/002427

Study 9: An Open label multicentre study was done at three centres viz. RARISD, Vijaywada, RARIED, Jaipur and at RARIMCH, Nagpur. Total 126 patients were enrolled in the study. *Vasavaleha* was given in the dose of 10 gm., twice daily with Luke warm water for 84 days. Significant effect of *vasavaleha* was also seen on the common complaints faced by patients suffering from Chronic Bronchitis. The complaint of productive cough was observed in 126 patients at baseline which reduced by 26.2% and was found only in 89 patients at the end of treatment. Complaint of dyspnoea reduced in 39.7% patients, wheezing was reduced in 21.4% patients. Likewise complaint of chest pain, sore throat and nasal congestion was reduced in 37.2% patients, 64.3% and 57.2% respectively. Effect of the study medications was also assessed by paired t-test on PEFR (litres/min), FEV_1 (litres/min) and St.George' Respiratory Questionnaire compared at baseline and at 84^{th} day al, parameters shown significant improvement. CTRI/2014/06/004704

Study 10: An Open label multicentre study was done at three centres viz. RARIMCH, Nagpur, RARIED, CARIDD, Kolkata and at RARIDD, Gwalior. Total 193 patients were enrolled in the study. *Kushmandak rasayan* was given in the dose of 10 gm., twice daily with Luke warm water for 84 days.

Conclusion: *Tamak Shwas* (Bronchial Asthama) is one of the major problem in present time, though it cannot be cured completely but Ayurveda management has shown very promising results and can be used as primary or adjuvant treatment in the management of Bronchial Asthma.

Tab.2.18.1. Therapeutic Response at a glance in the management of *Tamaka Shwas* (in study 1 to 5)

Sl.No.	Interventions	Good response	Fair response	Poor response	No response
1.	Grp 1: *Naradiya Lakshmi Vilasa Rasa* with *Godanti Bhasma* and Grp 2: *Swasa Kesari* (n= 783)	87% shows good response. Both grps were effective		5%	8%
2.	*Kantakari* (n=151)	59.09% patients shows good response			
3.	*Pippli Vardhamana Ksheera Paka, Samira Pannaga Rasa* (*n*= 285)	19.65% (*n*=56	53.68% (*n*=153)	12.98% (*n*=37)	13.68% (*n*=39)
4.	*Shirisa Twak Kwatha* (*n*=589)	28.01% (*n*=165)	41.26% (*n*=243)	25.81% (*n*=152)	4.92% (*n*=29)
5.	*Shodhan Chikitsa* (*n*=126)	56.35% (*n*=71)	34.92% (*n*=44)	8.73% (*n*=11)	0% (*n*=0)

Fig.2.18.1. Therapeutic Response in different interventional groups

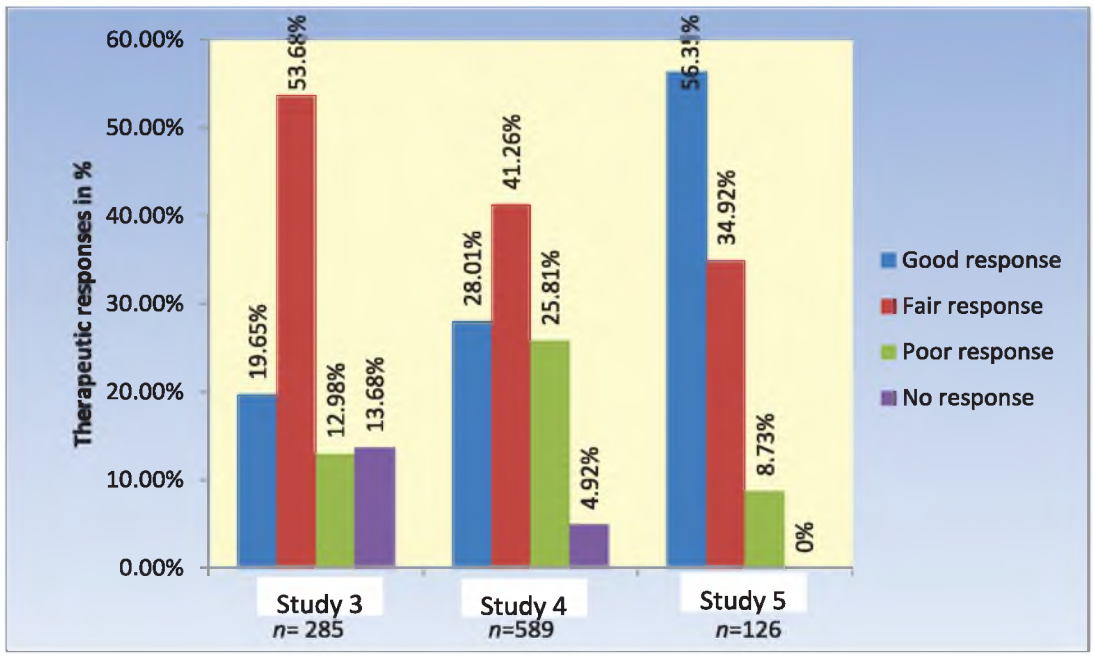


Table 2.18.2. Effect of treatment on Disease specific symptoms (Ayurveda) in before and after the treatment in Study 6

Chief complaints (n = 209)	**Baseline**	**84th day**
AseenoLabhateSaukhyam	185 (88.5%)	88 (42.1%)
Aruchi	104 (49.8%)	9 (4.3%)
Bhṛshma Artimana	73 (34.9%)	0 (0%)
Jwara	10 (4.8%)	0 (0%)
KantheGhurGhur Shabda	158 (75.6%)	24 (11.5%)
Kasa	155 (74.2%)	40(19.1%)
Kanthodhwaṃsa	103 (49.3%)	4 (1.9%)
KricchacchknotiBhaṣitum	104 (49.8%)	1 (.5%)
LalataSweda	75 (35.9%)	7(3.3%)
MuhushwasoMuhuschaivavdhamyate	190 (90.9%)	61 (29.2%)
MeghatVardhate	138 (66.0%)	110 (52.6%)
Na chapiLabhateNidra	86 (41.1%)	20 (9.6%)
Pinasa	101 (48.3%)	23 (11.0%)
PranaprapiḍakamTivrashwasa	79 (37.8%)	3 (1.4%)
Pramoha	14 (6.2%)	2(1.0%)
Parshvashula	65 (31.1%)	14(6.7%)
PragvatamVardhate	138 (66.0%)	90 (43.1%)

ShleṣmanyamUnmuchyamaneTu BhrishamBhavati Dukhitah	84 (40.2%)	45 (21.6%)
Shitodakavardhate	166 (79.4%)	148(70.8%)
Shitarituvardhate	191 (91.4%)	149 (71.3%)
ShleṣmalaAharavardhate	164 (78.5%)	148 (70.8%)
Shitopcarenaprashamana (Santamaka Shwasa)	77 (36.8%)	46 (22.0%)
Tamah Pravesha	12 (5.7%)	2 (1.0%)
Trṣna	29 (13.9%)	6(2.9%)
Tamasa Vardhate(Pratamaka Shwasa)	62 (32.1%)	3 (1.4%)
SaukhyamUṣnam	160 (76.6%)	87 (41.6%)
Ucchṛta-Netra	1 (.5%)	0 (0%)
Visuṣhkasyata	28 (13.4%)	4 (1.9%)
Vamathu	2 (1.0%)	0 (.0%)

Values are expressed as n (%)

Fig. 2.18.2: Effect of the treatment on PEFRand FEV1 in study 6

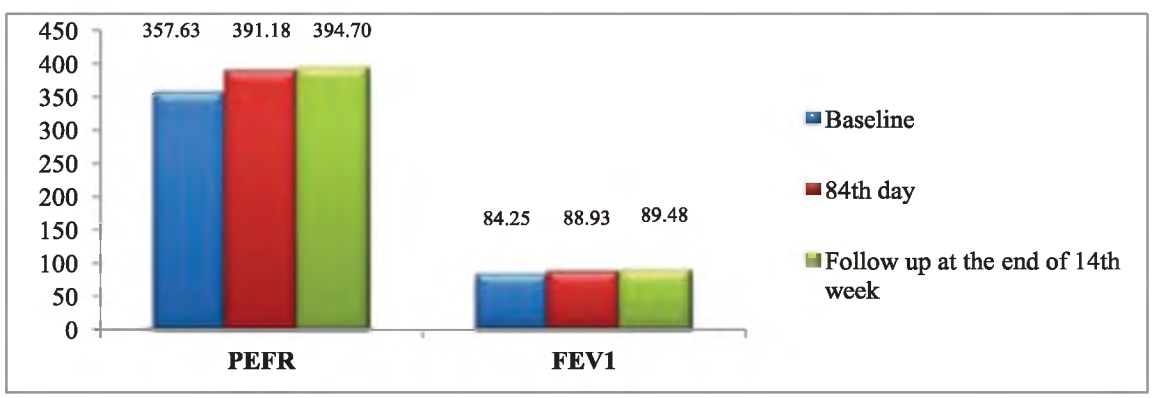


Table 2.18.3: Effect of the treatment on St. George Respiratory Questionnaire in study 6

St. George Respiratory Questionnaire							
Name of domain	Baseline	84 th day	Followup at 14thweek	*t-value	*p-value*	#t value	*p-value*
Symptoms	48.494 (23.14)	32.7116 (27.80)	32.271 (27.99)	16.595	<0.001	16.977	<0.001
Activity	22.0515 (14.56)	17.040 (8.53)	17.254 (8.81)	8.779	<0.001	9.028	<0.001
Impact	29.820 (13.42)	24.332	14.512 (8.94)	0.561	0.575	23.109	<0.001
Total Score	30.579 (14.58)	18.370 (11.21)	18.289 (11.20)	24.870	<0.001	25.924	<0.001

Values are expressed as Mean (SD), * Compared using paired t-test at baseline and 84th day,# Compared using paired t-test at baseline and follow up at the end of 14th week, *p-value* of *<0.05* has been considered as significant

Table 2.18.4: Effect of the treatment on outcome measures in study 7

Parameters (n=142)	Baseline	84th day	Follow up at the end of 14th week	$t-value	p-value
PEFR (Litres/min)	301.70 (65.23)	334.85 (85.64)	335.43 (84.90)	7.887	<0.001
FEV_1 (Litres/min)	1.83 (0.48)	2.12 (0.52)	2.14 (0.50)	9.379	<0.001
Asthma Control Questionnaire	2.95 (1.32)	1.43 (0.64)	1.35 (0.66)	10.871	<0.001
St.George's Respiratory Questionnaire					
Domain - Symptoms	70.86 (14.87)	69.43 (14.72)	68.44 (14.70)	2.607	0.010
Domain - Activity	47.15 (26.19)	26.78 (19.49)	24.91 (18.87)	13.944	<0.001
Domain – Impacts	45.59 (21.09)	20.76 (17.19)	18.81 (17.36)	15.360	<0.001
Total Score	50.46 (20.26)	30.74 (16.06)	28.97 (15.89)	16.370	<0.001

Values are expressed as Mean (SD), $ Compared using paired t-test at baseline and 84th day, p-value of <0.05 has been considered as significant

Table 2.18.5: Effect of the treatment on PEFR (litres/min), FEV_1 (litres/min) and St.George' Respiratory Questionnaire in study 9

Parameters (n=126)	Baseline	42nd day	84th day	Follow up at the end of 14th week	$t-value	*p-value
PEFR (litres/min)	351.69(89.04)	396.29(96.26)	419.25(100.109)	417.37(96.908)	14.930	<0.001
FEV_1 (litres/min)	1.845(.6345)	1.9686(.562)	2.001(.555)	2.051(.589)	4.106	<0.001
St.George's Respiratory Questionnaire	52.314(21.37)	45.56(24.78)	38.72(28.51)	38.15(28.32)	9.747	<0.001

Values are expressed as Mean (SD), $ Compared using paired t-test at baseline and 84th day, * p-value of <0.05 has been considered as significant

2.19: TIMIRA (MYOPIA)

BACKGROUND

Current management of myopia includes optical and surgical methods. Optical measures such as use of spectacles. Contact lens and low vision aids have a great role in improving the visual acuity of myopias to a great extent. But, myopias are more prone to injuries and occasionally eyeball may be injured due to shattering of glasses. In some cases use of contact lens causes corneal irritation leading to opacities of cornea. Surgical methods such as radial keratotomy, scleral resection, filtering operation, etc. have been found to be ineffective and none of these has been safe.

Owing to all the above adverse effects of different optical and surgical measures, it is at this juncture that the need for drugs/measures that could effectively tackle the myopia without any adverse effects.

Ayurveda has identified three important factors being responsible for the causation of all types of disease, which include ophthalmic problems too, viz. Incompatible contact of sense organs (eyes) with their respective sensation (*asatmye indriyartha samyoga*), Misuse of intellect *(Prajnaparadha)* and Abnormal cycles of sensons *(rituviparyaya)*.

To overcome these three factors ancient medical scholar prescribed specific diet (*ahara*), drugs (*ausadha*) and practices (*vihara*). Out of these three, *vihara* or practices play a central role in the prevention and cure of eye diseases. Practices advised for the protection of the eyes such as padabhyanga (massage of feet), *sitalodaka upacara* (cold water applications) are mentioned in various texts of Ayurveda. Solar therapy (*suryopasana*) is found in *Netropanisad* resembles therapeutic principles of yoga and naturopathy.

It is seen that the contemporary yoga movement supplanted its philosophical values and got shrouded with art of physical culture. This phase is characterized by rapid movement of *hathayoga*, which includes adaptation of *yogasanas* and *pranayama* procedures to protect the eyes from different affections.

In the present time's new eye diseases have become a major threat to the mankind and hence significance of multidisciplinary approach becomes mandatory. Integration of concepts of Ayurvedic Opthalmology, principles of yoga and naturopathy and practices of eye exercises may turn a new leaf in tackling eye problems.

Description concerning aetiopathogenesis, clinical features and the line of management of different ametropic conditions (refractive errors) including myopia is found in Ayurvedic

texts. Sushruta Samhita –the most authentic work on Ayurvedic ophthalmology describes different afflictions of tunics of the eye (*drishtigata patalas*), which are comparable to refractive media of the eye viz., cornea, uveatract, lens, vitreous and the photo sensitive layer, the retina. Clinical features of afflictions of the first three *patalas* broadly reflect the concept of refraction and errors of refraction. Identical comparable condition of myopia is found as one of the clinical feature of *timira* of third *patala* (*medo ashrita patala),* where reduced visual acuity for distance is the striking feature ascribed to the affection of *doshas* in the upper part of the tunic. By considering the above description it can be concluded that the afflictions of I, II, III *patalas* may be comparable to errors of refraction. In affections of III *patals,* when *doshas* invade the upper part of the tunic patient feels difficulty in observing distant objects. This particular stage may be considered as myopia.

Council has done following studies since inception for validation of classical drugs in the management of *Timira*:

Study 1: A comparative evaluations of the *Mahatriphla Ghrita* and *SaptamriLahua* has been conducted on patients of myopia. The effect of treatment was assessed on the basis of changes in the vision observed through Snellen's chart. It was observed that both the treatments have been reasonably well effective in the improvement of vision. However, the effect of *Mahatriphala Ghrita* was more pronounced.

Study 2: Clinical study was conducted on 264 patients of Myopia preferably children and young adults without suffering from anyother eye diseases. An Ayurvedic regimen consisting of internal and local treatment was given for 2 to 6 months to the patients. *Saptamrita lauha* 500 mg.thrice a day with milk was given orally. A regular eye wash once aday with *Triphala jala* was prescribed to the patients. The patients were also subjected to instillation of with juice mixed honey once aday and *Netra bindu* application twice a day.The patients with slight vision defects showed better response to treatment. Best results were obtained in the patients with 1.00 diapters deficiency of vision. A long term two months or 6 months duration of treatment showed better result. Out of 264 patients, 41 patients showed three line improvements, 50 patients showed two line improvement and 80 patients showed one line improvement. No response was observed in 93 patients.

Study 3: An open label interventional study was done with *Saptamrita Lauh* 500 mg twice daily along with honey/milk after food for 3 months. *Netra Bindu* (eye drops) instillation

twice a day for 3 months. Study was done at Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi. In this study total 402 cases were studied. Out of them, 53 got good response, 109 fair response, 132 poor response, while 72 had no response and 36 were dropped out.

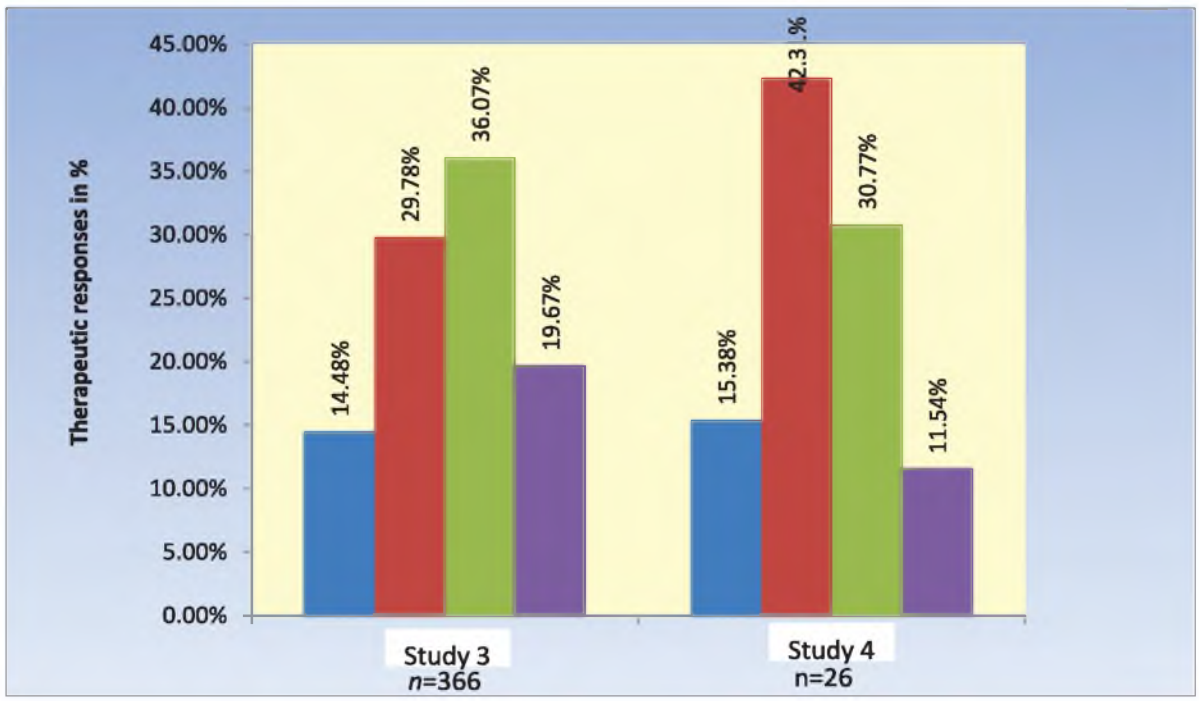
Study 4: An open label interventional study was done with *Saptamrita Lauh* 500 mg. twice daily along with honey/milk after food, *Netra Bindu* (eye drops) instillation twice a day and *Akshi Tarpana* with *Triphala kwath* for 3 months. Study was done at Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi. In this study comprising of interventions like *Netrabindu, Saptamrita Lauh* + *Akshi Tarpana* with *Triphala kwatha* and conducted at 1 center. Total 26 cases were studied. Out of them 4 got good response, 11got fair responses, 8 got poor response, while 3 had no response.

Conclusion: These regimens may be effective by increasing the nutritionof the lens, helping better accommodation and cleanse themicrochannels. Though there is no complete cure of the condition but Ayurveda has shown promising results in controlling the extent of Myopia and improvement was also found to a good extend. Myopia is a important condition with increasing prevalence and with this Ayurveda regimen we can certainly control this condition.

Tab 2.19. Therapeutic Response at a glance in the management of *Timira*

Sl.No.	Interventions	Good response	Fair response	Poor response	No response
1.	Grp 1: *Mahatriphla Ghrita* and Grp 2: *Saptamri Lauha*	Both groups have good response in improving vision			
2.	*Saptamrita lauha* and *Triphala jala* (n=264)	41 patients	50 patients	80 patients	93 patients
3.	*Netrabindu, Saptamrita Lauha*(*n*=366)	14.48% (n=53)	29.78% (n=109)	36.07% (n=132)	19.67% (n=72)
4.	*Netrabindu, Saptamrita Lauha +Akshi Tarpana* with *Triphala kwatha*(n=26)	15.38% (n=4)	42.31% (n=11)	30.77% (n=8)	11.54% (n=3)

Fig. 2.19. Therapeutic Response in different interventional groups



2.20: MUTRASMARI (UROLITHIASIS)

BACKGROUND

Urolithiasis is the presence of calculi in the renal or urinary tract is the world wide problem. It has been discussed elaborately in ancient Ayurvedic texts. Susruta, the father of surgery was of the view that the dietary factors are much more responsible for the calculus formation the urinary tract *(Mutrasmari)*. A drug which can correct crystalloid colloid imbalance and relieves the binding mucin of calculi, antiseptic, antispasmodic and diuretic, can relax the muscles of urinary bladder and prevent the supersaturation of crystalloids and possessing anti inflammatory properties on renal tissue may have a possible role in the management of urolithiasis. The Council, since its inception has been engaged in finding out effective, inexpensive, non invasive and safe treatment modalities.

Council has done following studies since inception for validation of classical drugs in the management of *Mutrasmari*:

Study 1: The effect of Ayruvedic drugs *Sveta Parpatti* with *Pasanabheda* and *Goksuru* in the management of *Mutrasmari* (Urolithiasis) was conducted. Under this study 30 radiologically established cases of renal and ureteric calculi were included. One gm of *Sveta parpati* with 50 ml of *Pasanabheda-goksuru kwatha* was given thrice daily. The assessment of the response of the therapy was made on the basis of relief in presenting symptoms and the radiological findings. The study shows complete cure in maximum patients. The radiological findingsalso support the elimination of stone/reduction of their size.

Study 2: The effect of *Palasa ksara* in the management of *Mutrasmari* (Urolithiasis) was studied on 50 radiologically established cases.Out of total 50 cases, 24 were having renal calculus *(Vrkkasmari*) and 26 were having ureteric calculus *(Gavini asmari). Palasa ksara*was given in the dose of 1 gm. thrice daily with water for 30 days.Observations of the results of the treatment were made on the basisof clinical improvement and radiological findings before and afterthe treatment. The study has shown that urolithiasis could be well managed with Ayurvedic therapies. The radiological findings also support the elimination of stone/reduction of their size.

Conclusion: The study shown that Ayurvedic line of treatment is very effective and safe in the management of Urolithiasis and can also be effectively used in ureteric calculus.

Tab. 2.20. Therapeutic Response at a glance in the management of *Mutrasmari*

S.N.	Interventions	Result
1.	*Sveta Parpatti* with *Pasanabheda* and *Goksuru* (n=30)	Complete cure was seen in maximum patients
2.	*Palasa ksara* in *vrikkashmari* (n=24) and *Gavini asmari* (n=26)	Maximum patients shows complete cure of the problem

2.21: HRIDROGA (HEART DISEASES)

Background

Heart diseases (*Hrid Roga*) have been elaborately discussed inAyurveda. The five types of heart disease have been classified on thebasis of *Dosa*. These descriptions and practices by physicians could be useful for management of present day challenges posed by the heartdiseases. Many studies have been conducted by premier Institutions of Ayurveda and Modem medicine and allied disciplines.

Council has done following studies since inception for validation of classical drugs in the management of *Hrid Roga*:

Study 1: A preliminary study was conducted on 40 patients for a period ofthree months to evaluate changes in all the fractions of lipid. Thecrude drug (*Guggulu)* was administered 12-16 gm. per day in divided dosesin the patients suffering from lipid disorders obesity, coronary heart disease, hemiplegia etc. A progressive fall was recorded in all thecomponents of lipids. At the end of three months, the percentageof average fall was serum cholesterol 25.4% triglyceride 30%, phospholipid 21.5% and serum free fatty acid 35.1%. In addition to this fall in the serum lipids, reduction in body weight was alsorecorded which was approximately 1 kg per patient per month. Simultaneously, the clinical relief in the symptoms of hemiplegia and coronary heart diseases was also observed. One of the significant findings has been that some of the cases in whom Twave was inverted or S-T segment was depressed got corrected after three months treatment.

Study 2: A further controlled clinical trial on 135 patients of Ischaemic Heart Disease. The trial of 3 months course of *Guggulu* in two groups ofpatients; 25 patients as the control group and 110 patients trial group, showed very good effect of drug in the patients of coronary insufficiency. The precordial pain and dyspnoea on effort, cardinal features of the disease were relieved completely in about 70% ofthe patients in the treated group and substantially reduced in the remaining patients. The control group of patients did not show any appreciable change in their clinical condition. Simultaneously, there was a significant fall in various fractions of serum lipids serum cholesterol (26.31%), phospholipids (26.84%), triglycerides (36.11%) and free fatty acids (37.94%). The electrocardiographic findings also showed improvement.

Study 3: Dried and powered roots of *Puskaramula* (*Inula racemosa* Hook F.)were mixed to coarse granules of oleroresin of *Commiphora wightii (Guggulu, Sodhita (*purified*)* in *triphala kasaya)* to formulate the drug *Puskara guggulu* which was administered in the divided doses of 8 to10 gm. per day for a period of three to six months.The presenting clinical symptomatology along with ECG findings and biochemical parameters were recorded initially and afterwards for the assessment of the response of the therapy. Response of the treatment was found to be very encouraging in patients who completed full course. The precordial pain, dysponoea and palpitation was completely absent after the treatment. Their ECG pattern returned to normal with considerable improvement observed through various biochemical parameters.

Study 4: In further studies, 355 patients of CHD, with evidence of Ischemia(in ECG) and exertional angina, when treated with *Puskaraguggulu* (1: lw/w) powder for a period of 6 months, 6-8 gms./day in divideddoses, showed significant fall in cholesterol, triglycerides and totallipids. Symptoms of CHD viz. pericordial pain, dyspnoea,palpitation, hypertension, diabetes mellitus, giddiness, cough, anorexia and flatulence were ameliorated and functional status ofthe patients was improved. The overall results showed positiveresponse in over 80 percent of patients.

Study 5: The drug has been administered in the form of tincture preparedfrom roots of *Nerium indicum* (*Karvira*). The observation on 99 patientsof Congestive Cardiac Failure due to Rheumatic Heart Disease, Hypertension, Mycardial infarction for 6 weeks. About 90% of patientsshowed relief and relapse could be noted in about 20% of these patients.

Conclusion: Studies have shown very promising results in various cardiac disorders and can be effectively used in their management.

Tab.2.21. Therapeutic Response at a glance in the management of *Hrid roga*

S.N.	Interventions	Result
1.	*Guggulu* in IHD (n=40)	average fall was serum cholesterol 25.4% triglyceride 30%, phospholipid 21.5% and serum free fatty acid 35.1% also correction in inverted T wave was noted in some cases
2.	*Guggulu* in IHD, controlled study	very good clinical improvement in 70% cases

	(n=135)	in trial group and significant fall in serum cholesterol (26.31%), phospholipids(26.84%), triglycerides (36.11%) and free fatty acids (37.94%) along with improvement in ECG
3.	*Puskara guggulu* in IHD	precordial pain, dysponoea and palpitation was completely cured ECG pattern returned to normal with considerable improvement in maximum patients
4.	*Puskara-guggulu* in CHD (n=355)	Overall results showed positive response in over 80 percent of patients.
5.	*Karvira* tincture (n=99)	About 90% of patients showed relief and relapse could be noted in about 20% of these patients only

2.22: VYANBALVAISHYMA (HYPERTENSION)

Essential Hypertension or Primary hypertension is defined as a chronic elevation in blood pressure [systolic BP 140-159 and diastolic 90-99 mmHg according to 7th report of the ***Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High blood pressure (JNC-VII report)***] with no defined cause. Essential hypertension usually remains silent and is diagnosed accidentally in a routine clinical examination or after the target organ involvement, and hence considered a major risk factor to human health. With every rise of 20 mmHg in Systolic BP and 10mmHg in Diastolic BP, there is an increased risk for the target organ injury and cardio-vascular damage. Elevated blood pressure is one of the major risks for micro and macro vascular injury which results in increased risks of heart attack, heart failure, stroke and kidney diseases.

The direct description of hypertension is not found anywhere in the available Ayurvedic classical texts, because its diagnosis is based on the measurement of blood pressure by sphygmomanometer. So in Ayurveda the disease hypertension can be understood on the basis of etiopathology, symptomatology and complications (about which plenty of literature is available). *Vyanabala Vaishmya* or Hypertension is not described as such in classical Ayurvedic literature. Some Ayurvedic scholars call it *Raktagata-Vata.* According to a WHO Expert Committee on Hypertension control met in Geneva (1994), it is the commonest cardiovascular disorders, posing major public health challenge to society.

Council has done following studies since inception for validation of classical drugs in the management of Hypertension:

Study 1: The Council has taken up clinical investigations on a large sample with following drug formulations viz. *Ushiradi churna* 3-6 gm twice daily for six weeks and *Tagaradi churna* 3-6 gm twice daily for six weeks. The study has been conducted on 964 patients in two groups. The observations indicate control in most of the patients (above 65-75%) in both groups.

Study 2: Clinical study was conducted to evaluate efficacy and safety of *Ashvagandhadyarishta*, *Jatamamsi Arka* and *Sarpagandha Vati* in the dose of 25ml BD, 10 ml BD and 1gm BD respectively for a period of 12 weeks at three peripheral institutes viz. Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi; Regional Ayurveda Research Institute for Infectious Diseases, Patna and at Regional Ayurveda Research Institute for Nutritional Disorders, Mandi. Total 164 patients were recruited for this

single arm open labeled interventional prospective study for 12 weeks of treatment with two weeks follow-up period during the Year 2011-12. The patients of essential hypertension with systolic Blood Pressure between 140-159 mm Hg. and Diastolic B.P. between 90 and 99 mm Hg. of either sex aged ≥18 years were selected for the study as per inclusion criteria. The patients were assessed on the basis of changes in systolic and diastolic BP, Hamilton Anxiety Rating Scale (HARS) and SF-36 Health Survey Score for quality of life (Q.O.L.) Mean systolic BP before treatment was 149.09± 5.28mm of Hg and after treatment it was 125.16 ± 10.04 mm of Hg. Mean diastolic BP before treatment was 94.16 mm of Hg and after treatment it was 80.46 mm of Hg. The initial mean of HARS was 13.54 and after treatment it was 7.26.The change was found to be statistically significant. The quality of life was assessed by SF-36 Health Survey Questionnaire which revealed statistically significant improvement ($p<0.001$) in Physical Functioning, Energy / Fatigue, Emotional well being, Social Functioning and General Health. During the study no adverse effect was noticed. (The study was registered under CTRI vide no. CTRI/2012/03/002525)

Study 3: An open label clinical study was done at two centres viz. Regional Ayurveda Research Institute, Itanagar and at M.S. Regional Ayurveda Research Institute for Endocrine Disorders, Jaipur. Total 99 patients were enrolled. *Rudraksha Churna* (API –Part 1 Vol. 4 Page 104-105) was given in a dose of 2 gm twice daily with water for 12 weeks. Significant improvement was seen in clinical symptoms of Hypertension of Headache, Anxiety, Dizziness, Tinnitus, Confusion, Fatigue, Shortness of Breath, Nausea, Increased Sweating, Abnormal Sleep and Palpitation. Hamilton Anxiety Rating Scale Score also showed significant improvement. Blood pressure showed mild improvement only. There was no adverse effect during the study.

Study 4: A multicentric open label study was done with *Vacha, Brahmi, Jatamanasi* and *Arjuna* in eual parts in a dose of 3 gm thrice a day for six weeks with water. Total 898 patients were enrolled. Study showed highly significant effect in all the symptoms with <0.001 at 78.66%, 67.44%, 68.21%, 70.21%, 74.22% and 56.31% of relief in *Sirashula, Shrama, Bhrama, Anidra, Kshubdhata* and *Daurbalya* respectively.

Study 5: A multicentric open label study was done with *Chandraprabha Vati, Shweta parpati* and *Punarnava Mandoora* (500 mg each) thrice daily for six week with water. Total 663 patients were enrolled. Study showed highly significant effect in all the symptoms with

<0.001 at 70.84%, 68.24%, 72.37%, 72.42%, 67.94% and 66.52% of relief in *Sirashula, Shrama, Bhrama, Anidra, Kshubdhata* and *Daurbalya* respectively.

Study 6: A multicentric open label study was done with *Vacha, Brahmi, Jatamanasi* and *Arjuna* in a dose of 3 gm thrice daily for six week with water along with meditation. Total 37 patients were enrolled. Study showed highly significant effect in symptoms with <0.001 at 90.03%, 74.31% and 72.44% relief in *Sirashula, Bhrama* and *Daurbalya* and significant effect in symptoms with <0.05 at 80.55%, 87.37% and 76% of relief in *Shrama, Anidra* and *Kshubdhata* respectively.

Conclusion: The study shows that Ayurveda intervention is very promising in the management of uncomplicated Hypertension and can be used effectively in its management.

Tab.2.22.1 Therapeutic Response at a glance in the management of *Hypertension*

S.N.	Interventions	Result
1.	*Ushiradi churna* and *Tagaradi churna* (n=964)	maximum patients in both grp both groups (above 65-75%) achieve control in Hypertension

Tab. 2.22.2: The Effectiveness of treatment in Reducing Systolic and Diastolic Blood Pressure after treatment in study 2

Outcome measure	Assessment stage	Paired Differences					t-value	df	p-value
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower Bound	Upper Bound			
Systolic in mm Hg	Baseline - 14th day	16.793	10.759	.840	15.134	18.452	19.988	163	<0.001
	Baseline - 84th day	23.933	11.672	.911	22.133	25.733	26.259	163	<0.001
	Baseline – Follow up at the end of 14th week	17.360	11.540	.901	15.580	19.139	19.264	163	<0.001
Diastolic in mmHg	Baseline - 14th day	9.707	5.717	.446	8.826	10.589	21.744	163	<0.001

	Baseline - 84th day	13.695	6.001	.469	12.770	14.620	29.224	163	<0.001
	Baseline – Follow up at the end of 14th week	10.488	7.265	.567	9.368	11.608	18.487	163	<0.001

Table 2.22.3: Change in blood pressure systolic in study 3

Blood Pressure – Systolic (mmHg)	Mean	N	Std. Deviation	Std. Error Mean
Baseline	148.10	100	7.227	.723
14th day	140.36	100	8.703	.870
28th day	138.64	100	8.654	.865
42nd day	133.85	100	10.074	1.007
56th day	133.28	100	9.545	.955
70th day	132.14	100	8.077	.808
84th day	130.00	100	8.234	.823
Follow up at the end of 14th week	129.63	100	8.204	.820

Table 2.22.4: Change in blood pressure diastolic in study 3

Blood Pressure – Diastolic (mmHg)	Mean	N	Std. Deviation	Std. Error Mean
Baseline	92.90	100	4.543	.454
14th day	89.70	100	5.863	.586
28th day	88.00	100	6.254	.625
42nd day	86.39	100	5.115	.511
56th day	85.42	100	6.352	.635
70th day	85.08	100	6.013	.601
84th day	84.16	100	5.083	.508
Follow up at the end of 14th week	84.64	100	5.036	.504

Table 2.22.5: Change in Hamilton Score in study 3

Hamilton Anxiety Rating Scale Score	Mean	N	Std. Deviation	Std. Error Mean
Baseline	7.01	99	3.986	.401
14th day	5.53	99	3.224	.324
28th day	5.26	97	2.891	.294

42nd day	4.74	99	2.590	.260
56th day	4.23	100	2.620	.262
70th day	3.85	100	2.337	.234
84th day	3.19	100	2.087	.209
Follow up at the end of 14th week	3.14	100	1.980	.198

Fig. 2.22.1: Blood pressure systolic in study 4,5 and 6

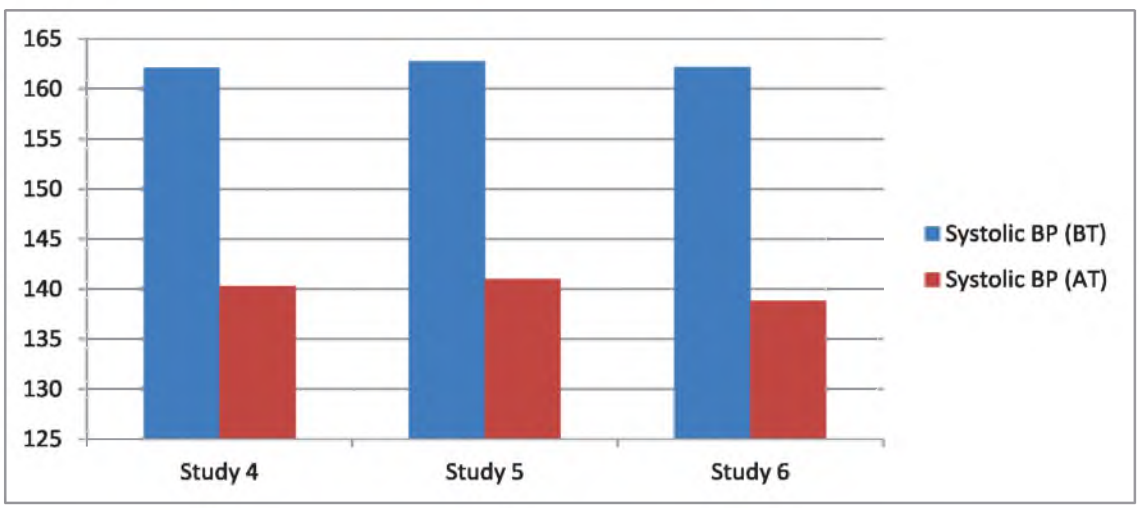
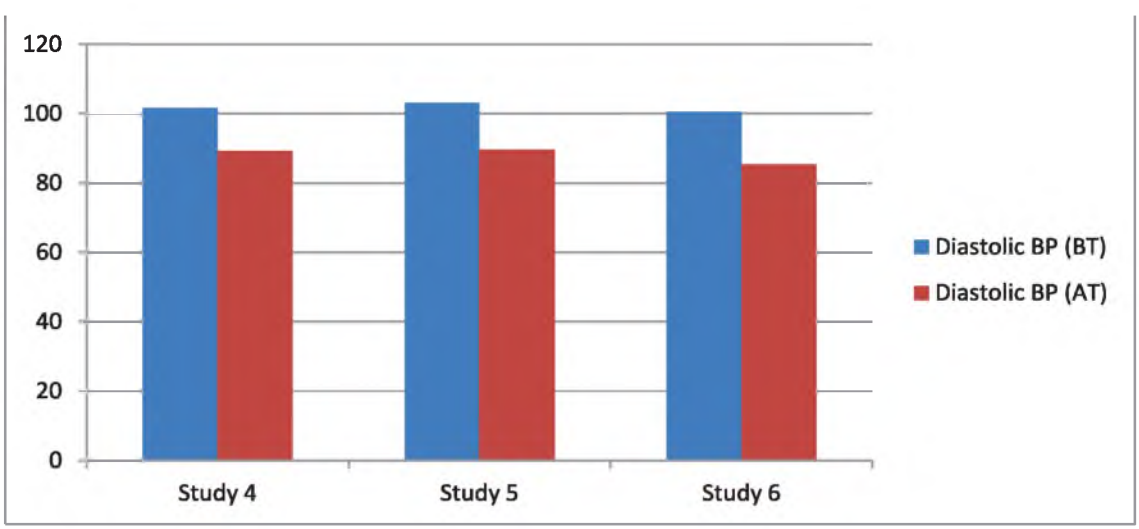


Fig. 2.22.2: Blood pressure diastolic in study 4,5 and 6



2.23: VATARAKTA (GOUT)

BACKGROUD

Joint diseases are becoming the main health problem in the present era as a result of changes in diet, lifestyle and environmental factors. *Vatarakta* viz-a-viz gout is a common condition in both primary care and specialist practice.Although not life-threatening, it has a significant impact on quality of life. *Vatarakta* viz-a-viz gout is a very painful condition and it curtails the output or day-to-day work of the patient. It is the commonest crystal arthropathy occurring in men over 40 years of age, presenting usually in the form of *"podagra"* (acute onset of pain, erythema and swelling of the first metatarsophalangeal joint). It has been called as *"the disease of kings"* due to its association with rich foods and alcohol consumption. Gout is a crystal-deposition disease that results from chronic elevation of uric acid levels above the saturation point for monosodium urate monohydrate (MSUM) crystal formationand it is associated with intense pain and enhanced vascular permeability evidenced by oedema and erythema that may extend beyond the joint margin.The fundamental bio-chemical hallmark of gout is hyperuricaemia and can result from increased production or decreased excretion of uric acid or from a combination of the two processes. Uric acid is the end product of metabolism of purines. Elaborate descriptions of *Vatarakta* (gout) in traditional Indian medicine show that it was one of the main articular diseases in the past itself. Descriptions of several disorders having symptom of pain, inflammation and burning sensation in the joints have been referred to in Vedic literature. Sedentary lifestyle is one of the main etiological factors of *Vatarakta*. Many people, due to their non-manual work practices, are having sedentary life style. When aggravated *Vata* is obstructed by aggravated *Rakta*, thus obstructed *Vata* again vitiates the *Rakta*. This pathological state is known as *Vatarakta* or *Vatasonitam*. The chief complaint of the patient is severe *Sandhi-shula* (joint pain) onset on *Hasta* (hand), P*ada mulagata sandhi* (MTP joints) and then migrates to other *Sandhi* (joint) in a way similar to *Ak-huvisa* (rat poison). It produces various signs and symptoms like *Ruka* (excruciating pain), *Swayathu* (swelling), *Daha* (burning sensation), *Stabdha* (stiffness of joint), *Shyaba-rakta Varna* (blackish red in colour), *Sparsha-ashatwa* (hyperesthesia) etc. Ayurvedic scholars have correlated *Vatrakta* with Gout on the basis of its various aetiological factors and clinical manifestations. The mainstay of treatment during the acute attack is the administration of anti inflammatory drugs such as colchicines; non steroidal anti inflammatory drugs (NSAIDs) or glucocorticoids depending on the age of the patient and co morbid conditions. The colchicines and NSAIDs may be quite toxic in the

elderly particularly in the presence of renal insufficiency and gastrointestinal disorders. Therefore, there is a definite need to explore more efficacious and radical cure to this illness. Ayurveda in its herbarium has lots of herbo-mineral compounds which can fill up this gap.

Council has done following studies since inception for validation of classical drugs in the management of *Vatarakta*:

Study 1: A total 100 subjects (25-65 years) of primary gouty arthritis fulfilling the diagnostic criteria as recommended by the American College of Rheumatology were selected for the present study from OPD of two peripheral centres ofCentral Council for Research in Ayurvedic Sciences irrespective of their sex, religion and socio-economic status. Only those subjects were selected for clinical trial, who presented themselves with at least 6 of 12 criteria's of American College of Rheumatology (1977). *Amrita Guggulu* was given 1000mg twice daily orally and Pinda Taila was applied locally 10 ml twice daily. The trial therapy was assessed on the basis of improvement in clinical features, VAS score, patient's global assessment scale score, physician's global assessment scale score, SF-36 Health Survey Score for quality of life (Q.O.L.) and biochemical parameters. Each patient was subjected for routine blood test, serum uric acid, liver function tests and renal function tests before treatment and after 84th day of treatment. The trial combination showed statistically significant improvement in the clinical manifestations, quality of life as well as reduction in marker of hyperuricemia i.e. serum uric acid; the mean serum uric acid at the baseline was 7.76 mg/dl which was reduced to 6.50 mg/dl after the trial period of 84 days. There was also decrease in the level of VAS score, patient's global assessment scale score and physician's global assessment scale score. There were no impairment in liver function test and renal function test, indicating the good safety profile of trial therapy.(CTRI/2014/08/004929).

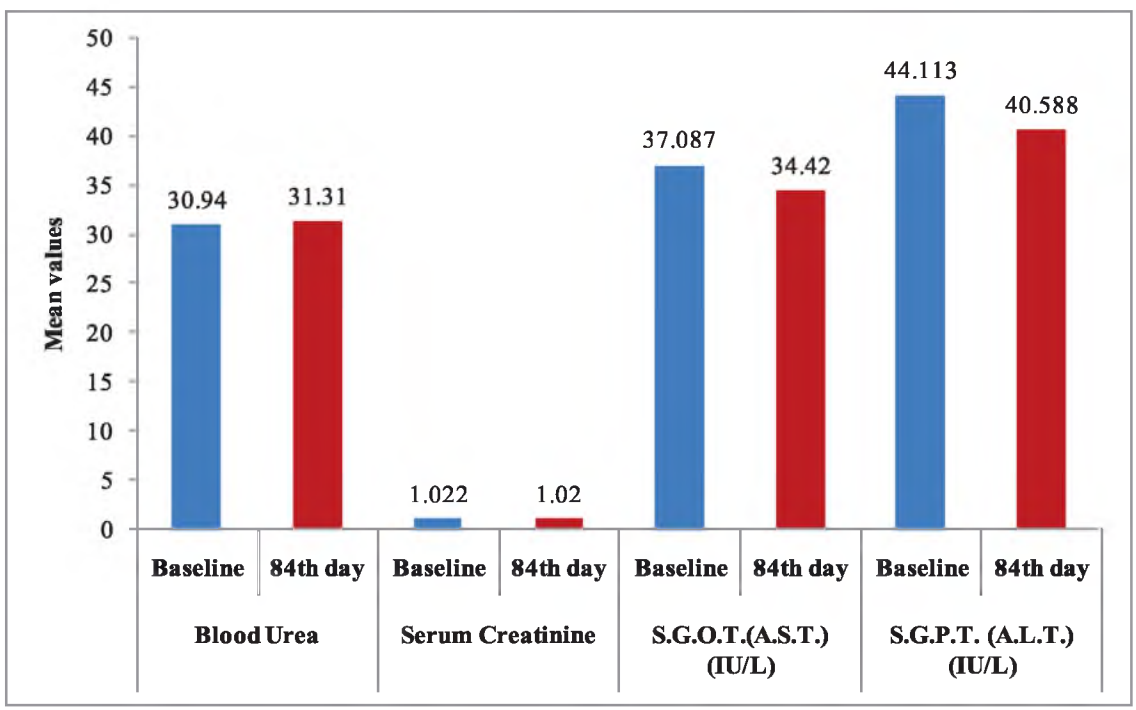
Conclusion: The study suggests very promising results of Ayurveda intervention in the management of *Vatarakta* (gout), and it can be successfully used in the management of Gouty arthritis.

Table 2.23: Effect of the trial drugs on Outcome measures of study 1

Parameters (n = 100)	**Baseline Mean (± SD)**	**84th day Mean (±SD)**	**t-value**	**p-value**
Serum Uric Acid (mg/dl)	7.76 (0.75)	6.50 (1.25)	11.02	<0.001
Pain (Assessed by VAS)	5.28 (1.78)	1.51 (1.78)	17.84	<0.001
Quality of Life (SF-36 health survey Score)				
Physical Functioning	54.35 (21.39)	84.15 (15.14)	12.27	<0.001

Role limitation due to physical	25.00 (41.44)	88.75 (31.46)	12.55	<0.001
Limitation due to emotional	27.66 (41.85)	88.67 (31.51)	11.75	<0.001
Energy/fatigue	51.05 (14.04)	66.55 (12.34)	8.8	<0.001
Emotional well being	62.40 (15.0)	71.24 (12.5)	5.21	<0.001
Social functioning	55.44 (22.55)	78.75 (17.81)	8.35	<0.001
Pain	53.15 (20.35)	79.65 (19.08)	10.3	<0.001
General health	45.60 (15.7)	67.90 (12.29)	11.81	<0.001

Figure 2.23: Effect of trial drug on safety parameters in study 1



2.24: KASTARTAVA (DYSMENORRHOEA)

BACKGROUND:

Dysmenorrhoea is a medical condition of pain during menstruation but more realistic definition includes cases of sufficient magnitude so as to incapitate daily activities. A pain which is of uterine origin and directly linked to menstruation but with no visible pelvic pathology is called Primary dysmenorrhoea. Pain reaches a maximum between ages of 18 and 24 years and thereafter diminishes. The pain is mainly felt in hypogastrium and is often referred to inner and front aspects of the thighs. During a severe attack the patient looks drawn and pale and may sweat; nausea and vomiting are common; there may be diarrhoea and rectal and bladder tenesmus. As per Ayurvedic classics, pain occurred in any part of the body due to aggravation of *Vata dosha* and the main two reasons for it are obstruction in the passage (*Margavarodha*) or loss of body tissues (*Dhatukshaya*). In certain conditions or gynecological disorders (*Yonivyapad)* like *Vataj Rajodushti, Udavarta* or *Udavartini, Antarmukhi* and *Suchirmukhi Yonivyapad* pain occurred during menstruation. According to *Maharshi Charaka*, in *Udavartini yonivyapad,* menstrual blood is pushed in upward direction by the aggravated *Apana vayu* (the governing force of menstrual force) due to obstruction in its normal flow in *Pakwashaya* (pericolon and pelvic region).

On the basis of the symptom 'immediate relief of pain following discharge of menstrual blood' mentioned by *Charaka,* it appears to be the nearer to primary or spasmodic dysmenorrhoea. Population surveys suggest a wide variation in prevalence rate of dysmenorrhoea from studies around the world including India reporting a range between 28% and 71.7%. It is reported in a study that Dysmenorrhoea is a common problem in India (79.67%) and most of them (37%) suffered regularly from dysmenorrhoea severity. In conventional system, drug therapy includes Prostaglandin Synthetase Inhibitors for pain management. However, their use is contraindicated in women with GI ulcers, bronchial asthma. Side effects include nausea, vomiting, diarrhoea, abdominal pain, constipation, heart burn and dizziness. Other drugs include hormone therapy and calcium channel blockers. To regulate uterine contractions and uterine tone, many effective Ayurvedic regimens are described in Ayurvedic classics and various studies have also been conducted; but a proper statistical analysis and interpretation are not available.

Council has done following studies since inception for validation of classical drugs in the management of *kastartava*:

Study 1: A multi-centric prospective observational study was done between March, 2011 and August, 2012 from 09 participating centres viz. Ayurvedic Central Research Institute, Delhi, Nagpur, Ayurvedic Contraceptive Drug Research Institute, Ahmedabad; National Ayurvedic Dietetics Research Institute, Bengaluru; Dr. Achanta Laxmipati Research Centre for Ayurveda, Chennai; National Research Institute for Panchakarma, Cheruthuruthy; Ayurveda Regional Research Institute, Jammu and Ayurvedic Research Institute for Mother & Child health Care, Thiruvanantapuram. Total of 368 patients were enrolled in the study.Changes in the intensity of menstrual pain assessed by Visual Analogue Score (VAS) and Quality of life assessed by SF-36 (RAND) Health survey questionnaire. The base line characteristics of demographic information: the average age of the subjects was 22.0 ± (5.40) years (range 21-25 years), majority of subjects (62.1%) were students, 82.7 % were having education up to 10th or above. The menstrual pattern (amount and duration of menstrual flow and interval of cycle) was normal in all the subjects. 54.3% (n=159) subjects were having the family history of dysmenorrhoea. Majority of subjects 56.3% (n=202) were having *Pittaj-kaphaja Prakriti*.The findings of this study shows that the score received on the various domains of SF-36 scales were improved at the end of 90th day and effect seen were also significant ($p<0.001$).The subjects also got relief on the associated symptoms like nausea, vomiting, constipation, giddiness, breast tenderness, diarrhea, headache and fainting. All subjects tolerated the treatment well. None of the subjects developed any adverse drug reaction. There was no remarkable change in any of the safety lab parameters.

CTRI No- CTRI/2015/01/005429

Table 2.24: Overall effect of the trial drug on primary outcome measures

Variables	**After intervention period (90th day) (n %)**			
Relieved	**Static**	**Worse**	**Chi square**	**P value**
Pain in abdomen	137 (38.16)	222 (61.83)	135.08	<0.01
Low Backache	185 (51.67)	167 (46.64)	165.88	<0.01
Pain in lower limbs	199 (55.43)	155 (43.17)	182.59	<0.01

Conclusion

Ayurveda intervention has shown very promising results in the management of primary dysmenorrhoea and clinically meaningful improvement of quality of life of the dysmenorrhoic women.

2.25: POLYCYSTIC OVARY SYNDROME (PCOS)

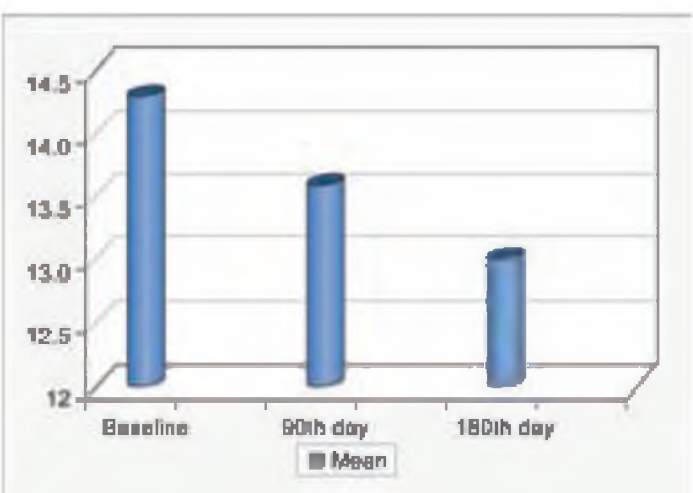
BACKGROUND

Polycystic ovary syndrome is characterized by any of oligo-anovulation, clinical or biochemical hyperandrogenism, and polycystic ovaries. The syndrome affects around 4 to 9% of women of reproductive age. Insulin resistance (IR) accompanied by compensatory hyperinsulinemia constitutes another major biochemical feature of PCOS, which leads to early luteinizing hormone (LH) sensitivity of the follicle and to stimulation of both ovarian and adrenal androgen production. Oligo-anovulation due to ovarian dysfunction continues to be the pivotal feature that makes this syndrome the major cause of anovulatory infertility in developed countries. The European Society for Human Reproduction and the American Society of Reproductive Medicine or Rotterdam criteria 2003 are the agreed international di agnostic criteria for PCOS. Hyperandrogenism clinically (hirsutism)/or biochemically (elevated serum testosterone concentrations), anovulation/or oligomenorrhea (cycles of 35 days or longer), or amenorrhea (no menses in the last 6 months) after negative screening pregnancy test and/or polycystic ovary are the three main diagnostic criteria, and two out of these three confirm the diagnosis, with exclusion of other androgen excess etiologies. Polycystic ovary syndrome is the most common cause of anovulatory infertility affecting 90 to 95% of women, attending infertility clinics. Hirsutism and hyperandrogenism in PCOS occur in 60% of women and result from increased synthesis and release of ovarian androgens. Due to the high prevalence of IR, PCOS shares components of metabolic syndrome: Abdominal obesity, impaired glucose tolerance, gestational and type II diabetes, abnormalities in lipid profile, hypertension, endothelial dysfunction, and probably cardiovascular disease. Women with PCOS also have an increased risk of endometrial carcinoma because of longstanding unopposed estrogen stimulation. The features of PCOS may be correlated with "*PuspaghneeJataharinee*" described in Ayurvedic classics (*Kashyap Samhita, Kalpasthana*) having the clinical features, viz. *Vrutha Pushpa* (may be correlated with amenorrhea/ anovulatory cycle), *Sthula lomasha Ganda,* i.e., obese cheeks with hairs (may be correlated with hirsutism/ hyperandrogenism).12 But there is no treatment principle/ treatment available in the said classic. But to regulate the menstruation and ovulation, weight reduction, and assisting fertility, many effective Ayurvedic regimens are described, namely *Rajahpravartini Vati, Dasamularista/Kwatha, Ashokarista, Kumaryasava, Phalaghrita, Rajadoshaharavati, Vyoshadi Guggulu, Kanchanar Guggulu*, etc.

Council has done following studies since inception for validation of classical drugs in the management of PCOS:

Study 1: A multicenter, prospective, single-arm studywas done with 60 women enrolled. The study was conducted in two institutes of Council for Research in Ayurvedic Sciences, viz., Regional Ayurveda Research Institute for Life Style Related Disorders, Poojapura, Thiruvananthapuram, Kerala, India and Central Ayurveda Research Institute for Respiratory Disorders, Moti Bagh Road, Patiala, Punjab, India. Three Ayurvedic classical formulations, viz., *Rajapravartini Vati* [Ayurvedic Formulary of India (AFI), Part-1 12:25], *Kanchanar Guggulu* (AFI, Part-1, 5:1), *Varunadi Kashaya (Sahasra Yoga, Prathama Prakarana, Kashaya Yoga/472)* werepreparedas per the standard procedures mentioned in Ayurvedic Pharmacopoeia of India and were tested forquality and safety parameters, viz., heavy metals, aflatoxin, microbial load, and pesticide residue, which were within the permissible limit. It was administered in a doseof 250 mg, 500 mg, and 20 mL with 40 mL lukewarm water respectively twice a day in the morning and evening afterfood for 180 days. Changes in menstrual cycle length, changes in the degree of hirsutism, acne score, improvement in QOL by using PCOS-QOL and changes in hormone level were assessed. From the result, it is concluded that the trial drugs have a significant effect on hirsutism, oligomenorrhea, and overall improvement in the QOL of women with PCOS. CTRI/2015/03/005649

Fig: 2.25: Effect of the drugs on hirsutism (Ferriman–Gallwey score) (Study 1)



Conclusion: Ayurvedic intervention has shown very promising results in improving quality of Life in patient with PCOD.

2.26: SANDHIVATA (OSTEOARTHRITIS)

BACKGROUND

Osteoarthritis (OA) is a chronic degenerative disorder of multifactorial etiology characterized by loss of articular cartilage, hypertrophy of bone at the margins, subchondral sclerosis and range of biochemical and morphological alterations of the synovial membrane and joint capsule. Pathological changes in the late stage of OA include softening, ulceration and focal disintegration of the articular cartilage; synovial inflammation also may occur. Typical clinical symptoms are pain, particularly after prolonged activity and weight bearing; whereas stiffness is experienced after inactivity. It is also known as degenerative arthritis, which commonly affects the hands, feet, spine, and large weight-bearing joints, such as the hips and knees. It can present as localized, generalized or as erosive osteoarthritis. Most cases of osteoarthritis have no known cause and are referred to as primary osteoarthritis. Primary osteoarthritis is mostly related to aging. Secondary osteoarthritis is caused by another disease or condition. Epidemiological profile of this disease in India is not clear but it is estimated that osteoarthritis (OA) is the second most common rheumatologically problem and is most frequent joint disease with prevalence of 22%–39% in India. Eleven COPCORD (Community Oriented Program for Control of Rheumatic Disorders) reports show knee OA data: there were 3328 knee OA patients out of a total surveyed pooled sample of 41,884. The pooled prevalence of knee OA thus becomes eight percentages. Knee Osteoarthritis prevalence increases with age, so that about 11% of all women over the age of 60 years have symptoms due to knee OA.

The guidelines for treatment of the OA of the knee from the National institute of health and clinical excellence (NICE), the American college of rheumatology and the European league against rheumatism recommend non-drug treatments including the education of the patients, social support, physical exercises and weight loss . Non-steroidal anti-inflammatory drugs (NSAIDs) are still used as the initial treatment in primary care as anti-inflammatory and analgesic agents by inhibiting the synthesis of prostaglandins. NSAIDs are associated with a number of side effects, most importantly the increased risk of gastrointestinal (GI) bleeding and renal failure as well as increasing risk of myocardial infarction and stroke especially in the COX-2 inhibitor category. The intra-articular injections of corticosteroid and sodium hyaluronate etc. are also in practice but have limited role. Finally end stage forms of OA are

treated with knee replacement therapy. This is frequently associated with pain relief but however hold a substantial post-operative risk and financial burden. On the basis of limitations, the use of alternative therapies, such as acupuncture, medicinal herbs is on the rise and according to reports; about 60–90% of dissatisfied arthritis patients are likely to use the complementary and alternative medicine (CAM) approach for overcoming pain and associated problems. An increasing number of people in the United States are adopting complementary or alternative medicine approaches to meet their personal health problems. Arthritis (both OA and RA) is one of the foremost diseases for which patient seeks option of complementary or alternative medicine. In treating osteoarthritis, glucosamine and chondroitin sulfate, two of the molecular building blocks found in articular cartilage, are the most commonly used alternative supplements.

Sandhivata nomenclature available in Ayurvedic literatures for this clinical entity, which is similar to Osteoarthritis. The cause of *sandhivata* in Ayurveda is attributed to improper diet, life style, and old age etc. leading to degeneration of body elements (*dhatu kshaya*), aggravation of *vata*; the humor responsible for all the movements and functions of the body and reduction in *shleshaka kapha;* a slimy substance present in the joints. The aggravated *vata* brings *laghutva* (lightness), *rukshyata* (dryness), *kharatva* (coarseness) in the joints causing degeneration. In *sandhivata, sandhi shula* (pain in affected joint) is the main feature. The other features are including *shotha* (swelling), *stabdata* (stiffness) and, *atopa* (crepitus) and difficulty in performing the functions of involved joint.

Council has done following studies since inception for validation of classical drugs in the management of Osteoarthritis:

Study 1: An open label, multicenter, non-comparative, prospective, pragmatic trial was done, in three centres of CCRAS viz. ALRCA Chennai, NRIASHRD Gwalior and NADRI, Bengaluru for one year. Therapeutic Combination of *Vatari guggulu* (Ayurvedic Formulary of India, Part I, P.37) 500 mg thrice in a day along with *Maharasnadi Kwatha* 20 ml twice daily with equal amount of lukewarm water and *Narayan taila* 20 ml twice in a day for external application with gentle massage for 15 min up to 12 weeks were used in this study.Changes in TotalWestern Ontario and McMaster Universities Osteoarthritis Index (WOMAC), changes in the intensity of pain assessed by Visual analogue scale (VAS) and changes in WOMAC subscale score were assessed. Total 142 subjects who fulfilled the inclusion and exclusion criteria were enrolled in the study.At baseline visit, the mean knee

joint pain score assessed on Visual Analogue Scale (VAS) was 41.48 ± 2.59. The mean knee joint pain score (VAS) reduced significantly from baseline to 29.77 ± 2.15 after 14th day treatment with this medicines. The mean pain score further reduced significantly from baseline to 23.11 ± 1.75; 19.87 ± 1.704; 17.88 ± 1.61; 14.76 ± 1.43 and 13.03 ± 1.50 on days 28th, 42nd, 56th, 70th and 84th respectively. The mean score of total Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was reduced significantly from 48.87 ± 0.99 to 19.43 ± 01.25 at the end of the study.Further, the mean of physician's global assessment of disease activity at the baseline was 30.35 ± 1.65 and 64.15 ± 1.63 was at end of the study.The mean of laboratory parameters i.e. CBC, Hb%, ESR, Renal Function Tests, Liver Function Tests were not significantly changed at baseline and at the end of the study.CTRI/2014/02/004388

Study 2: An open label, multicenter, non-comparative, prospective, pragmatic trialwas carried out at three (03) peripheral institutes of Central Council for Research in Ayurvedic Sciences.viz. 1. Central Ayurveda Research Institute for Cardiovascular Diseases, Road No.66, Punjabi Bagh (west), New Delhi 2.Central Ayurveda Research Institute for Neuromuscular and Musculoskeletal Disorders, Cheruthuruthy, P.O. Thrissur, Kerala. 3. Regional Ayurveda Research Institute for Gastro-intestinal disorders, Borsojai (Bhetapara), Beltola, Guwahati. In the study *Yogaraj Guggulu*500 mg (Thrice a day) orally (crushed into powder) with luke warm water after food for 12 weeks, *Gandharvahasta Taila* - 6 ml orally with luke warm water just before bed time and *Dhanwantara Taila* – 20 ml locally for 12 weeks (Twice a day) were given. Total WOMAC(Western Ontario and Mc Master Universities osteoarthritis Index) mean score found reduced subsequently from baseline to 28^{th}, 56^{th}, 84^{th} and 112^{th} day.This reduction in Total WOMAC mean score was statistically highly significant ($p<0.001$). At the end of treatment (84^{th} Day), reduction in the numbers of patient having presence of cardinal features of Osteoarthritis knee (Disease specific Ayurvedic parameters) was observed in the study. Numbers of patient with cardinal features reduced further at the end of follow up (112^{th} day) except in case of *Sandhishula* (Joint pain).Mean Quality-of-Life score assessed on World Health Organization Quality-of-Life Scale (WHOQOL-BREF) improved from baseline to end of the treatment (84^{th} day) & follow up (112th day). The improvement in QOL score was found on all the 4 Domains of QOL viz.: physical health, psychological health, social relationships & environment and was statistically highly significant ($p<0.001$). It is observed that, safety laboratory parameters such as Total

Leucocyte Count (TLC), Differential Leukocyte Count (DLC), ESR, liver & kidney function tests, were not changed significantly from baseline to the end of the treatment.

CTRI/2016/01/006552

Fig. 2.26.1: Shows the effect of therapy on pain in knee joint assessed by Visual Analogue Scale (study 1)

Fig. 2.26.2: Shows the effect of therapy on WOMAC parameters in study 1

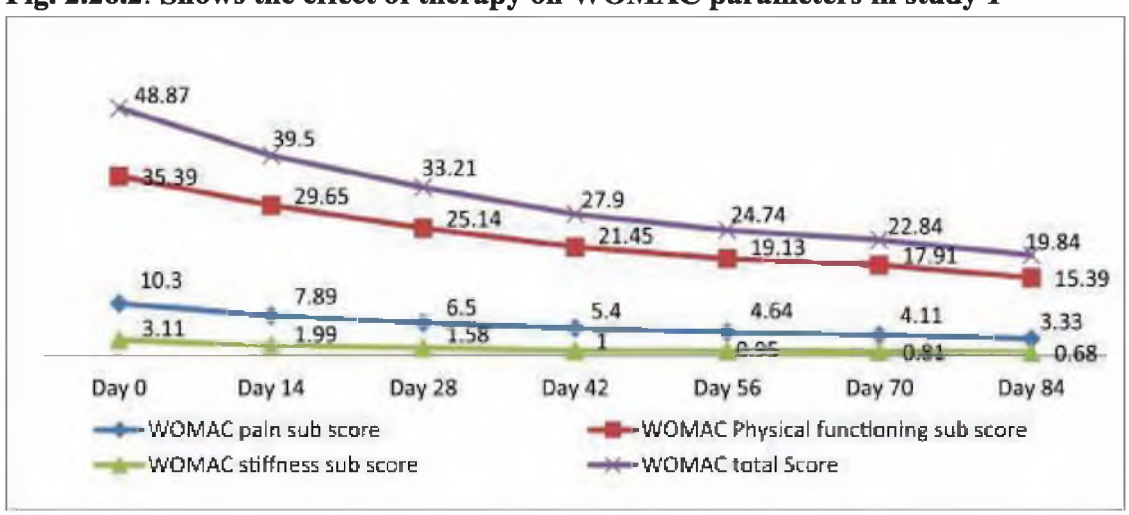


Table 2.26.2. Effect of treatment on chief complaints (Study 2)

Chief complaint	Base line (n)	84th day (n)	% of relief	112th day (n)	% of relief
Joint pain on movement	115	99	**13.9**	85	**26.1**
Joint pain at rest	87	10	**88.5**	14	**83.9**
Restricted movement of joint(s)	104	53	**49.03**	41	**60.6**
Joint stiffness	113	54	**52.2**	55	**51.33**
Crepitus/crunching in the joint(s)	115	107	**6.9**	104	**9.6**
Weakness of affected joint(s)	83	36	**56.6**	35	**57.8**
Swollen joint(s)	48	23	**52.1**	21	**56.2**
Bony enlargement of the joint	04	04	**00**	04	**00**
Bony tenderness	109	81	**25.7**	64	**41.3**
Palpable warmth of the affected knee joint	08	01	**87.5**	03	**62.5**

Figure 2.26.3: Shows the effect of therapy on WOMAC total score in study 2

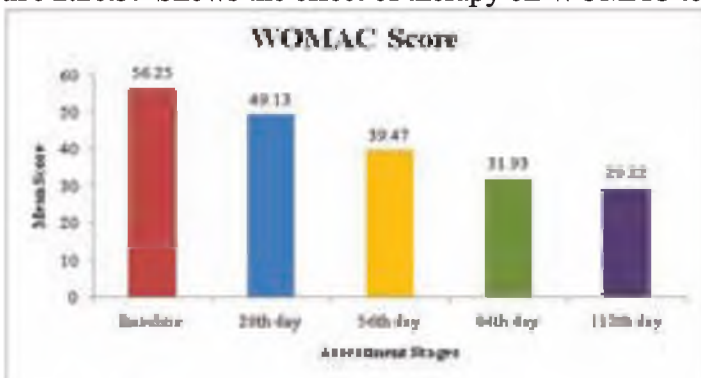


Figure 2.26.4: Shows the effect of therapy on WHOQOL BREF Score

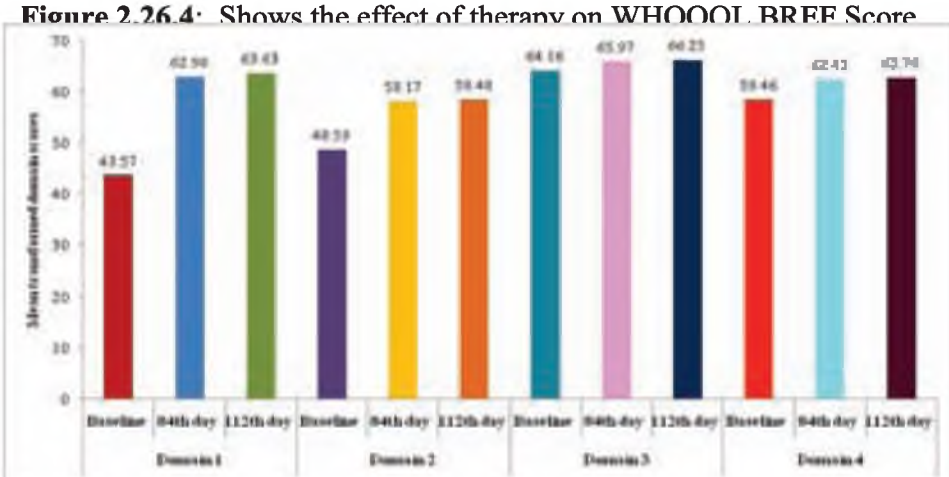


Table 2.26.3: Effect of trial drugs on outcome parameters in study 3

Outcome parameters (n=60)	Base line	84th day	Follow up at 112th day	t-value$	p-value
Total WOMAC Score	66.82 (10.651)	41.47 (12.357)	40.08 (12.431)	19.054	<0.001
Domain - Pain	13.53 (2.696)	8.12 (2.656)	7.90 (2.589)	14.888	<0.001
Domain – Stiffness	5.77 (1.345)	2.78 (1.316)	2.60 (1.304)	15.056	<0.001
Domain – Physical functioning	47.55 (7.599)	30.57 (8.990)	29.65 (9.089)	18.652	<0.001
Visual Analog Scale (VAS) Score	8.05 (1.199)	5.52 (1.742)	5.37 (1.895)	10.095	<0.001
Patient's global assessment of disease activity Score	80.17 (11.273)	51.17 (16.374)	49.00 (18.567)	12.672	<0.001
Physician's global assessment of disease activity Score	78.17 (10.969)	50.33 (15.510)	47.17 (17.281)	13.167	<0.001

Values are reported as mean (SD); $compared using paired t-test at baseline and 84th day; *p-value < 0.05 considered as significant

2.27: SHUSHKAKSHIPAKA (COMPUTER VISION SYNDROME & DRY EYE SYNDROME)

BACKGROUND

The computer has become a part of the everyday life at present. In the world it has been estimated that nearly 60 million people experience vision problems as a result of computer use. According to the US National Institute for Occupational Safety and Health, computer vision syndrome affects about 90% of the people who spend three hours or more a day at a computer. Computer vision syndrome (CVS) is a group of symptoms which crop up from the extended viewing of the Video display terminal (VDT), when the demands of the task exceed the abilities of the viewer. Symptoms comprising CVS are dry and irritated eyes, eye strain/fatigue, blurred vision, redness in eyes, burning sensation of in the eyes, excessive tear secretion, double vision, headache, light or glare sensitivity, contact lens discomfort, slowness in changing focus, changes in color perception and pain in neck, shoulder and back. These symptoms of CVS are due to ocular (ocular-surface abnormalities or accommodative spasms) and/or extra ocular (ergonomic) etiologies.

No remedial measures for the prevention or cure of this pathology prevail in the domain of modern medicine except using ocular surface lubricants, computer glasses, and counseling for judicious computer use.

Dry eye syndrome is characterized by instability of the tear film or poor quality of tear filmthat cause to insufficient amount of tear production which results in increased evaporation of the tears. Dry and gritty feeling in the eyes is the main symptom of dry eye syndrome and additional symptoms such as burning sensation, foreign body sensation (sandy/scratchy/itching), pricking pain, rough lids/mucoid discharge/mild blepharitis, stuck eye lids, blurred vision, inflammation/redness, narrowing of palpebral aperture. Dry eye disease can also be subdivided into pure aqueous deficiency dry eye and evaporative dry eye

On critical review of pathology of this disease it seems to be a *Vata–Pittaja* ocular cum systemic disease which needs systemic as well as topical treatment approach. Acharya Vagbatta has indicated cooling and rejuvenating therapies for eyes affected by bright light, high-voltage electric spark and heat exposure. This phenomenon is also close to the etiopathology of CVS.

Council has done following studies since inception for validation of classical drugs in the management of CVS:

Study 1: The study was a prospective, open label single centre trial.The trial was executed at CCRAS Institute i.e. Central Ayurveda Research Institute for Cardiovascular Diseases (CARICD), New Delhi. In Preparatory phase, *Hingwashtak churna* was given in a dose of 3-5gms before meals twice a day for 3 days followed by *Virechana* with *Avipattikar Churna* 5gms once at bed time with luke warm water. *Nasya* (nasal drops) with *Anu Taila* was given in a dose of 8-8 drops in the morning for 7 days (Day 1 to Day 7). *Akshi Tarpana* with *Mahatriphaladya ghrita* was done for 3 consecutive days in the morning and repeated at an interval of 15 days. (i.e. Day 8, Day 9, Day 10 and Day 26, Day 27 and Day 28) *Mahatriphaladya Ghrita* was also given orally in a dose of 5 ml twice a day on empty stomach in the morning and 3 hours before taking meals in the evening with luke warm water for total of 42 days starting from Day one. Reduction in signs and symptoms of CVS assessed by Visual Analogue scale. A significant ($p<0.001$) improvement in chief complaints was observed at all subsequent visits (8^{th}, 26^{th} and 42^{nd} Day) and follow up (56^{th} Day) compared to baseline. However effect of treatment on dry & irritated eyes and excessive tearing was statistically significant at 1% level on 8^{th} day. Improvement in redness of eyes was insignificant on 8^{th} day. No any change in safety parameters were noted thus the treatment was safe. The improvement remained steady even after two weeks of completion of treatment. This shows the efficacy and long-term benefits of the treatment.CTRI/2017/08/009518.

Study 2: An open label clinical trial was done at Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi and at Ayurveda Regional Research Institute, Patna. *Mahatriphaladya Ghrit* (15ml) orally (empty stomach in the morning and 3 hrs before taking meals in the evening) twice daily, with lukewarm water and *Mahatriphaladya Ghrit (20ml)* topically (once a day) in the morning for 12 weeks. Total 60 patients were enrolled in the study. The study revealed significant improvement in the common complaints of patients suffering from **dry eye syndrome**. The complaint of dryness was observed in 62.29 % patients at baseline which was reduced to 17.8 % patients at the end of treatment (<0.001). Complaint of Burning sensation was observed in 45.34% patients at baseline which was reduced to 8.9% patients at the end of treatment (<0.001).and Foreign body sensation was observed 54.66% patients at baseline which was reduced to 12.71 % patients at the end of

treatment (<0.001), Pricking pain was observed 33.9% patients at the baseline which was reduced to 4.24 % patients at the end of treatment (<0.001), Rough lids/mucoid discharge was observed 38.56% at the baseline which was reduced to 9.75 % at the end of treatment (<0.001), Stuck eyelids was observed 23.73% at baseline which was reduced to 1.69 % at the end of treatment (<0.001), Blurred vision was observed 34.75 % at the baseline which was reduced to 5.93 % at the end of treatment (<0.001), Inflammation/redness was observed 29.66 % at baseline which was reduced to 1.27 % at the end of treatment (<0.001) Narrowing of palpeberal aperture was observed 25.42% at baseline which was reduced to 5.08% at the end of treatment (<0.001) . No any adverse effect was noted in the study.

CTRI/2012/03/002532

Conclusion:

Ayurveda intervention was found safe and it significantly reduces chief complaints of Computer Vision Syndrome. It can be effectively used for long term benefit and management of CVS and in dry eye syndrome.

Fig. 2.27.1: Effect of the treatment on chief complaints assessed by VAS (Study 1)

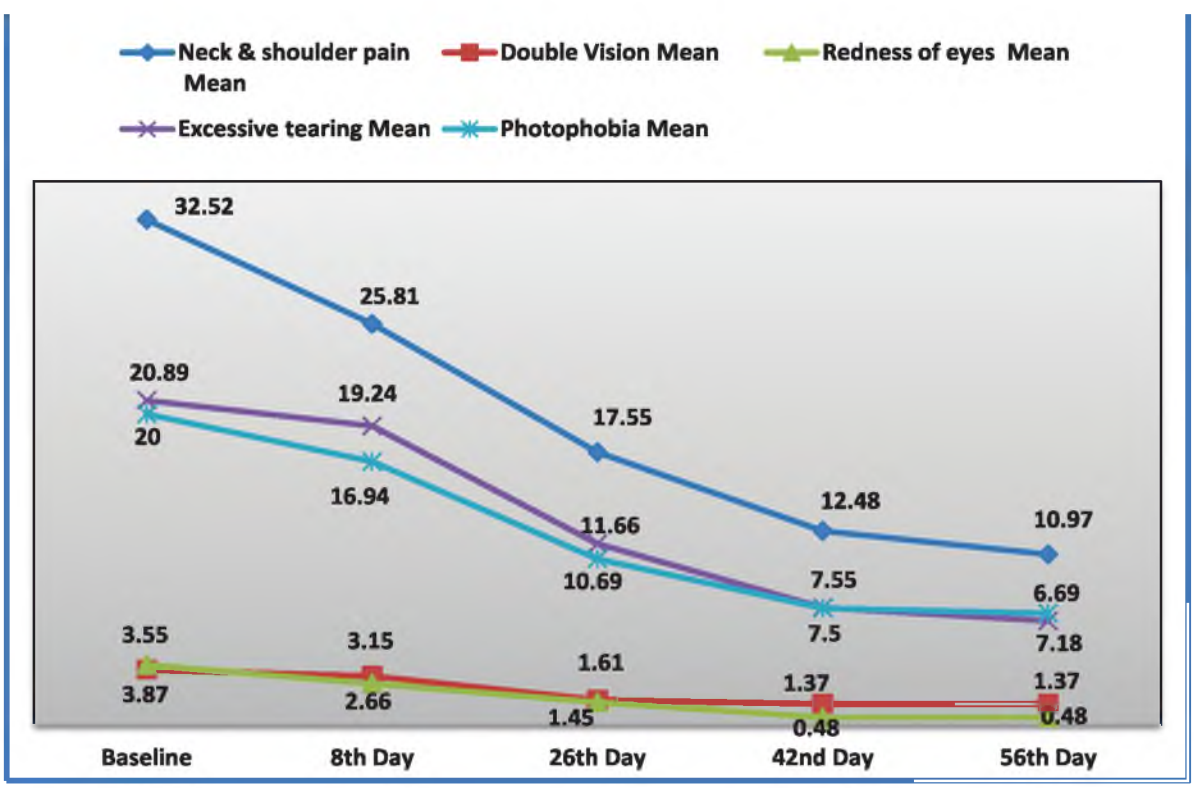
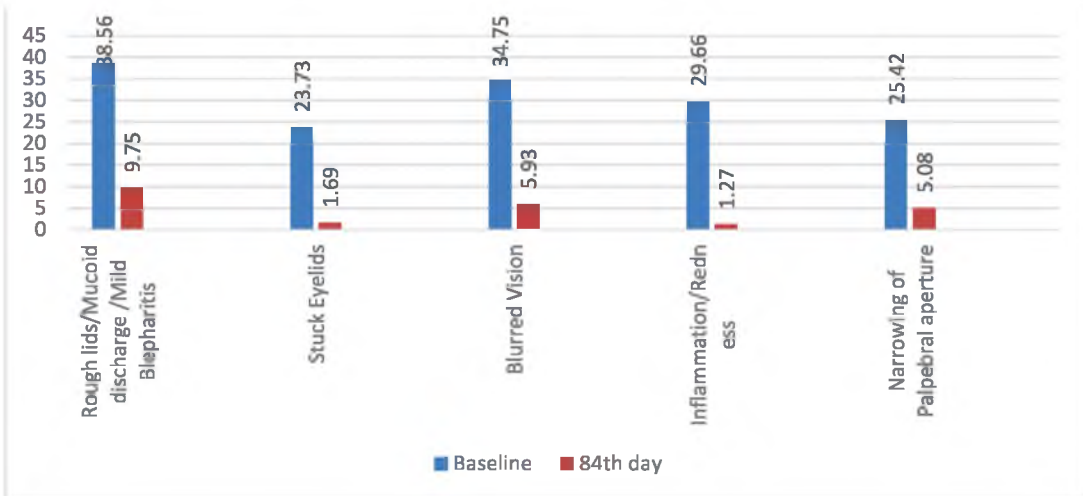


Table 2.27.1 Effect of the treatment on Schirmer's I test (Study 1)

Schirmer's I test (mm)	Baseline	42nd day	t-value	p-value
Baseline	10.69 (4.09)	12.89 (3.65)	8.750	<0.001

Values are expressed as Mean (SD), $ Compared using paired t-test at baseline and 42nd day

Fig. 2.27.2: Effect of the treatment on chief complaints/Outcome parameters in study 2



2.28: MENOPAUSAL SYNDROME

BACKGROUND

Women, who constitute half of the world's population, are currently enjoying a life expectancy of 84.3 years approximately in developed countries. Menopause is a natural phenomenon and mostly occurs at the age of 50 to 52 years in a woman. Different stages, i.e., perimeno-pause, menopause, and postmenopause, comprise a half or a third of a woman's life, particularly in developing countries. It is characterized by an altered hormonal status and a subsequent decrease in quality of life, affect-ing each woman differently. Specifically, the decline and eventual cessation of estrogen production are associated with the appearance of uncomfortable symptoms (hot flushes, night sweats, breast tenderness, vaginal dryness, irregular menses, mood changes, and vaginal atrophy) as well as pathologies, such as osteoporosis, heart disease, hypercholesterolemia, endothelial dysfunction, vascular inflammation, hyperglycemia, and depression.

Clinical studies indicate that the use of hormone replacement therapy (HRT) in menopause needs to be carefully assessed and risks and benefits of the therapy should be evaluated by the clinician for each individual woman. Herbal preparations, food supplements, healthy living, and healthy mental status were mentioned as pos-sible alternatives for managing menopausal symptoms. In Ayurveda, *Rajonivritti kala* (the period of permanent cessation of menstrual cycle) is considered as 50 years mentioned by all classical texts without any controversy. It is a consequence of *Jaraawastha* (senility), and *Vata* remains dominant during this period.

Council has done following studies since inception for validation of classical drugs in the management of menopausal syndrome:

Study 1: A multicenter single-arm studywas conducted at three peripheral Institutes of Central Council for Research in Ayurvedic Sciences, namely, Regional Ayurveda Research Institute for Mother and Child Health Care, Nagpur; Regional Ayurveda Research Institute for Skin Disorders, Ahmedabad; and Regional Ayurveda Research Institute for lifestyle related disorders, Thiru-vananthapuram.Total 116 menopausal women were recruited. *Ashokarishta* (Ayurvedic formulary of India. Part-I, 2nd ed. New Delhi: Department of AYUSH, Ministry of Health and family welfare, Government of India; 2003. p. 8.), *Ashvagandha churna* (Ayurvedic pharmacopeia of India. Part-I, Vol-I. 1st ed. New Delhi:

Department of AYUSH, Ministry of Health and family welfare, Government of India; 2001. p. 19-20) and *Pravala pishti* (Bhat A, A comparative pharmaceutico clinical study of Praval Pishti and Praval Bhasma in special reference of management of Hyperacidity, MD thesis, Jamnagar, Rasa Shastra and Bhaishajya Kalpna Department, IPGT and RA, 2003). *Ashokarishta* was administered orally in a dose of 25 mltwice a day with equal quantity of water after food. *Ash-vagandha churna* (3 gm) and *Pravala pishti* (one capsule of250 mg) were administered orally twice a day with milk just half an hour before food intake.At baseline, the MRS total score was 22.43 (8.24) and 36.82% reduction was seen 77.44% after 14 weeks. The effect of therapy has shown statistically significant (p-value <0.001) decrease in MRS total score. The test formulations also showed statistically significant ($p < 0.001$) improvement in all the three MRS subscale scores (somatic, psychological, and urogenital symptoms) at all time intervals when compared with their respective baseline score. In somatic subscale at the end of 14th week, the score was 2.23 (1.67) and 75.3% reduction was seen. Further, in psychological and urogenital subscales, the effect of the treatment was 74.17% (2.58 ± 2.01) and 85% (0.51 ± 1.13) respectively, at the end of 12 weeks and 75.87% (2.41 ± 2.09) and 87.35% (0.43 ± 0.98) at the end of 14 weeks respectively. A significant reduction in total MENQOL scores was observed after the treatment of 12 weeks and also at the end of 14 weeks (2-week follow-up period) in comparison to the baseline. Further, in vasomotor domain, the reduction in the symptoms at the end of 12 weeks was 2.3 (2.79), i.e., 77.84%, and 14 weeks 1.91 (2.5), i.e., 81.6% in comparison to baseline score, i.e., 10.38 (4.9); on psychosocial domain the reduction in the symptoms at the end of 12 weeks was 8.75 (6.54), i.e., 60.8% in com-parison with baseline score, i.e., 21.0 (7.54). Similarly, in physical domain, the reduction in the symptoms at the end of 12 weeks was 18.2 (11.8), i.e., 57.7%, and at the end of 14 weeks 16.9 (11.8), i.e., 60.8% in comparison with baseline, i.e., 42.98 (13.1). In sexual domain, the reduction of symptoms from baseline score was 3.6 (5.1) to 0.8 (2.33), i.e., 78.1% at the end of 12 weeks and 0.7 (2.2), i.e., 80.6% at the end of 14 weeks. CTRI/2012/03/002538

Conclusion: Ayurveda intervention are effective in thetreatment of menopause-associated symptoms and can promote the quality of life of menopausal woman. Hence, these Ayurvedic formulations can be used effectively for the management of menopausal symptoms in place of HRT and other therapies.

2.29: CONJUNCTIVITIS

Background

Allergic Conjunctivitis is a mild, nonspecific inflammation of the conjunctiva due to allergy with symptoms of redness (mainly due to vasodilatation of the peripheral small blood vessels), edema (swelling) of the conjunctiva, itching (most typical symptom of ocular allergy) and increased lacrimation (production of the tears) without any known specific condition for pathology to develop or with undermined etiology that is mostly and easily attributed to allergy. Symptoms are usually worse for patients when weather is warm and dry, whereas cooler temperatures and rain tend to minimize symptoms. It is a very common ocular problem in routine ophthalmic practice. Conjunctiva is very much sensitive about ten times to skin. It has been reported that allergic conjunctivitis alters patient's routine limiting certain activities such as going outdoors, reading, sleeping and driving in addition to the physical discomfort. The symptoms are due to release of histamine and other active substances by mast cells which in turn stimulate dilatation of blood vessels, irritate nerve endings and increase tear secretion. Therefore treating patients with allergic conjunctivitis may improve their everyday quality of life.

Modern trend of management to such conditions advocates avoidance of the allergen and treatment with either topical or systemic steroids/decongestant drops/mast cell stabilizers along with antihistamine and anti-inflammatory agents. This management is not much satisfactory and seems to be temporary, used only during exacerbations and also has their side/adverse effects. Considering this; it becomes very necessary to find out safe and effective drug which could effectively treat such conditions. There is vivid description of many Ayurvedic formulations and procedures in Ayurveda classics which are beneficial in the treatment of such conditions.

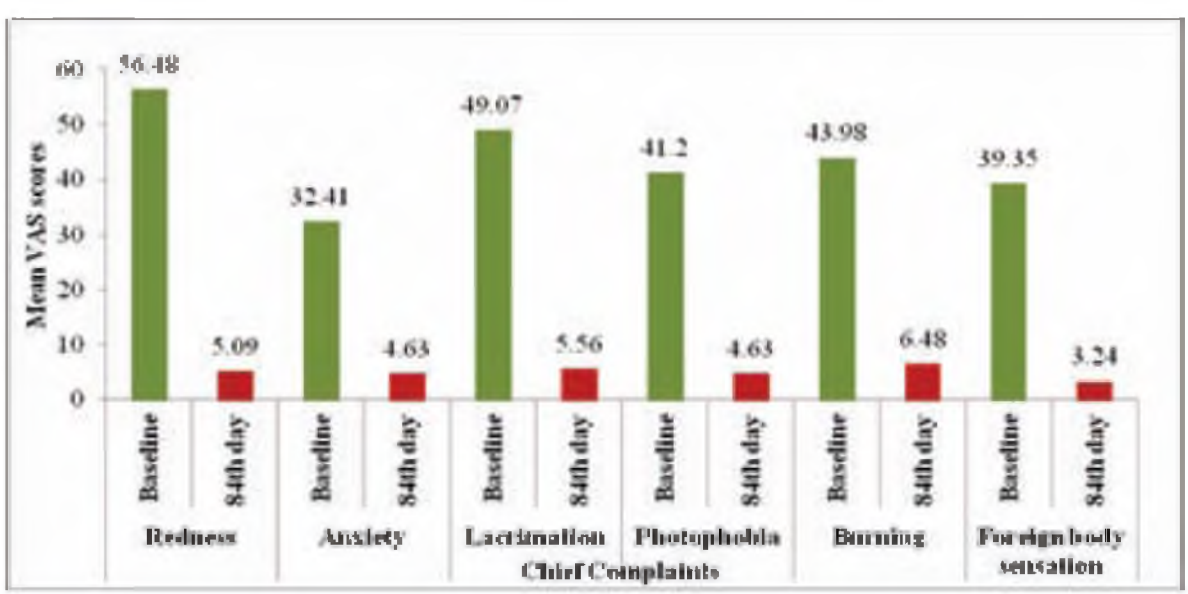
Council has done following studies since inception for validation of classical drugs in the management of conjunctivitis:

Study 1: A prospective open label multicentre trial was done. A total of 54 participants were enrolled at two centres viz; Regional Ayurveda Research Institute for Infectious Diseases, Patna and Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi. The study medications included quality assured *Mahatriphaladya Ghrita* in the dose of 15 ml twice daily was given with lukewarm water (empty stomach in the morning & 3 hours before meals in the evening) for a period of 12 weeks and topical instillation *(aschyotana)* of 10

drops of *Triphala kwath* in the conjuctival sac in supine position was done twice a day for 12 weeks. Before treatment all subjects were subjected to a preparatory phase comprising of *Dipana* for 3 days with *Hingvastaka Churna* 3-5 g (based on assessment of Agni) orally before meal twice a day with lukewarm water followed by *Virechana* with *Avipattikar Churna* 5 g once at bedtime with lukewarm water. The study revealed significant improvement in the common complaints of patients suffering from allergic conjunctivitis. The complaint of redness was observed in 56.48% patients at baseline which was reduced to 5.09% patients at the end of treatment (<0.001). Complaint of anxiety was observed in 32.41% patients at baseline which was reduced to 4.63% patients at the end of treatment (<0.001).and lacrimation was observed 49.07% patients at baseline which was reduced to 5.56% patients at the end of treatment (<0.001), photophobia was observed 41.2% patients at the baseline which was reduced to 4.63% patients at the end of treatment (<0.001), burning was observed 43.98% at the baseline which was reduced to 6.48% at the end of treatment (<0.001), foreign body sensation was observed 39.35% at baseline which was reduced to 3.24% at the end of treatment (<0.001). No any adverse effect was found in the study. CTRI/2012/07/002777

Conclusion: The study provides the evidence in support of the potential efficacy and safety of Ayurveda intervention in the management of allergic conjunctivitis. Ayurvedic intervention can be effectively used in the management of Conjunctivitis. CTRI/2012/07/002777

Fig. 2.29.1: Effect of the treatment on chief complaints/Outcome parameters in study 1



2.30: GERIATRIC CARE

Background

With the growing number of elderly individuals in today's society the health problems of old age are becoming more and more overt. Accordingly Geriatrics is emerging as a major medical specialty world over. In India too the last decade has projected significantly rising rate of population-aging and hence a great need is now felt to strengthen the geriatric care system in this fast developing most populous country. *Ayurveda* is essentially the science of life and longevity. It presents a sound concept of aging, its prevention and management. *Ayurveda* specially incorporates *Rasayana Tantra* as one of its *Astanga* specialties, which is exclusively devoted to nutrition, immunology and geriatrics. Aging is essentially a physiological phenomenon which results because of overwhelming of inherent evolutionary processes by the involutionary (involuntary) changes occurring in the mind-body system. The main issue in geriatric care is not merely the concern about the physiological phenomenon which is inevitable; rather it is more the medical health problems afflicting an individual in old age warranting medical management in order to sustain a comfortable and healthy aging. Thus geriatric care has to address to two-fold problems, firstly the basic anti-aging care to retard the rate of physiological aging and secondly the medical management of diseases and disorders. *Ayurveda* has addressed these issues in a unique holistic manner involving not merely the biological care, rather also encompassing the psychosocial and spiritual dimensions. There are strong possibilities to develop a safe and cost-effective package for geriatric care on the basis of *Ayurvedic* life-style management, *Rasayana therapy* and by practice of *Yoga*. Whatever is possible through the control of *mind* and *prana,* can be acquired through it.

Council has done following studies since inception for validation of classical drugs in the management of geriatric care:

Study 1: A study was done to evaluate the *Rasayana* effect and clinical safety of *Ashwagandhadi lehya* on apparently healthy elderly individuals at three peripheral institutes of CCRAS viz. Achanta Lakshmipathi Research Centre for Ayurveda, Chennai; Regional Ayurveda Research Institute for Metabolic Disorders, Bangalore; RRA Podar Central Ayurveda Research Institute for Cancer, Mumbai. *Ashwagandhadi Lehya* was given in the dose of 10 gm BD after meals with Luke warm milk for 12 wks (84 days). (*Kostha Shudhi*,

where required was done by administering 10-20ml of *Eranda tail* with Luke warm milk, two hours after food at bed time on Day '0'). Total 156 healthy elderly volunteers of 50-75 years were included in the study. The symptoms like Dizziness, Constipation, Urge incontinence, Aching muscles, Pain in joints, Stiffness in joints, Abnormal sleep, Loss of appetite, Fatigue, Generalized weakness and Sense of wellbeing is measured by using Visual analogue scale (VAS) at baseline were statistically highly significant (P <0.001) in every visit till the end of 84th day and sustained the result in the Follow up (FU) visit also. The *Rasayana* effect of *Ashwagandhadi lehya* in improving quality of life by using WHO-QOL BREF SCORE i.e. Physical health (Domain 1), Psychological (Domain 2), Environment (Domain 4) at Baseline with 84th day & FU were highly significant (P <0.001) and it is significant in case of Social relationship (Domain 3) (Table 1.30.1) at Baseline with 84th and FU consecutively (P = 0.002, 0.001). Hamilton Depression Rating Scale Score (HAM-D) also shows highly significant improvement. The statistical analysis of *Rasayana* effect of *Ashwagandhadi lehya* on PGI Memory Scale like Remote Memory, Recent Memory, Mental balance, Attention & Concentration, Delayed Recall, Immediate Recall, Verbal retention for Similar Pairs, Verbal Retention for Dissimilar Pairs, Visual Retention, Visual Recognition and PGI Memory Total Score at Baseline with 84th and FU were highly significant (P <0.001). No any adverse effect was noted.

Study 2: The clinical study was undertaken at three peripheral institutes viz. CARIHD, Bhubaneswar; CARIDD, Kolkata and RARIMD, Bengaluru. 180 participants were included in the study. *Brahma Rasayana* in the dose of 15 grams twice a day with luke warm milk was given orally for a period of 12 weeks. It was observed from the study that *Brahma Rasayana* has highly significant effect (p<0.0001) on Hamilton Depression Rating Scale after a period of 84 days. *Brahma Rasayana* provided highly significant effect *(p<0.0001)* on the individual domains of PGI Memory Scale, viz. recent memory, mental balance, attention & concentration, delayed recall, immediate recall, verbal retention for dissimilar pairs, visual retention, visual recognition and also in PGI Memory Total Score. In the domain; Verbal retention for similar pairs, it was highly significant in the level of p<0.001. Statistically significant effect (p<0.0001) was obtained at the end of 84th day on all the four domains of WHO QOL BREF Score after administration of *Brahma Rasayana*. CTRI/2015/03/005659

Study 3: An open labeled prospective multicentre clinical trial was conducted at three peripheral centers viz. Dr. Achanta Lakshmipathi Research Centre for Ayurveda (ALRCA),

Chennai; Central Ayurveda Research Institute for Cancer (RRAPCARIC), Mumbai; Regional Ayurveda Research Institute for Metabolic Disorders (RARIMD), Bengaluru. Total of 214 subjects were enrolled in the trial. *Chyavanaprasha* (API, Part-II, Page-13-16) in the form of *lehya* was administered in a dose of 12 gm twice daily on empty stomach along with milk in the morning and evening for a period of 12 weeks. In all the domains of WHO QOL BREF score; physical health, psychological health, social relationships and environmental aspects, statistically significant change (p<0.001) was observed at the end of the trial period. A significant increase (p<0.001) in 6 min. walk test and QOL was seen from baseline value and at the end of the treatment period, which implies that *Rasayana* is effective in enhancing the level of physical activity which is an indicator of improved status of body tissues, specifically blood, muscle and bone. There was significant improvement in *Aharashakti* of the individuals at the end of the trial period. The number of individuals with *Pravara Agni* increased from 16(7.5%) to 117(54.7%). *Vyayama Shakti* improved to Pravara in 145(67.8%) when compared with 94(43.9%) at baseline. No any adverse effect was noted during the study. CTRI/2016/03/006701.

Conclusion: The Ayurvedic intervention shows very promising results being used as palliative care for geriatric age group and it effectively help in improving quality of life.

Table 2.30.1 Quality of Life Index - WHO QOL BREF Score in study 1

WHO QOL BREF Score	Mean ± Std. Deviation					P-value	95% Confidence Interval for Difference(a)	
	Baseline	28th day	56th day	84th day	Follow up at the end of 14th week		Lower Bound	Upper Bound
Domain 1	22.86± 2.546	23.44± 2.151	23.56± 2.064	24.03± 1.782	23.81± 1.744	<0.001	-1.517	-0.379
Domain 2	21.50± 3.252	22.15± 3.080	22.79± 3.084	23.63± 2.881	23.90± 2.844	<0.001	-3.009	-1.796
Domain 3	9.82± 2.648	10.16± 2.583	10.12± 2.589	10.40± 2.532	10.48± 2.539	0.001	-1.145	-0.180
Domain 4	27.55± 4.884	28.24± 4.207	28.66± 4.151	29.23± 3.622	29.40± 3.491	<0.001	-2.623	-1.066

Table 2.30.2: PGI Memory Scale

PGI Memory Scale	Mean ± Std. Deviation					P-value	95% Confidence Interval for Difference(a)	
	Baseline	28th day	56th day	84th day	Follow up at the end of 14th week		Lower Bound	Upper Bound
Remote Memory	5.38± 0.759	5.49± 0.707	5.52± 0.607	5.65± 0.543	5.68± 0.522	<0.001	-0.454	-0.143
Recent Memory	4.67± 0.499	4.77± 0.425	4.84± 0.381	4.97± 0.211	4.95± 0.209	<0.001	-0.399	-0.172
Mental Balance	6.49± 1.914	6.75± 1.915	7.01± 1.873	7.26± 1.857	7.34± 1.848	<0.001	-1.143	-0.572
Attention & Concentration	10.88± 4.493	11.35± 4.133	11.43± 4.040	11.81± 3.786	11.97± 3.727	<0.001	-1.613	-0.568
Delayed Recall	7.55± 1.605	8.17± 1.494	8.25± 1.599	8.68± 1.445	8.75± 1.511	<0.001	-1.531	-.872
Immediate Recall	8.77± 2.159	8.97± 2.008	9.18± 2.053	9.44± 1.909	9.56± 1.950	<0.001	-1.177	-0.395
Verbal Retention for Similar Pairs	4.12± 1.012	4.58± 0.838	4.67± 0.848	4.71± 0.747	4.81± 0.664	<0.001	-0.887	-0.489
Verbal Retention for Dissimilar Pairs	5.86± 4.182	6.40± 3.878	7.00± 3.682	7.64± 3.743	7.85± 3.644	<0.001	-2.518	-1.456
Visual Retention	7.94± 3.873	8.84± 3.198	9.25± 3.043	9.77± 2.889	9.74± 2.928	<0.001	-2.423	-1.174
Visual Recognition	8.64± 1.370	8.99± 1.026	9.13± 1.230	9.44± 0.870	9.58± 0.823	<0.001	-1.220	-0.650
PGI Memory Total Score	70.30± 11.827	73.95± 11.080	76.30± 11.493	79.37± 11.163	80.23± 11.211	<0.001	-11.656	-8.214

Table 2.30.3: Effect of the therapy on outcome parameters in study 2

Outcome Parameters	Baseline	84th day	$t-value	p-value
Hamilton depression Rating Scale	15.71 (7.35)	6.22 (4.59)	18.906	<0.001
PGI Memory Scale				
Remote Memory	5.35 (.855)	5.86 (.474)	8.682	<0.001
Recent memory	4.61 (.655)	4.94 (.253)	7.250	<0.001
Mental balance	6.59 (1.687)	7.91 (1.443)	12.082	<0.001
Attention & Concentration	11.11 (3.88)	12.58 (3.608)	8.857	<0.001
Delayed Recall	7.96 (1.767)	9.05 (1.183)	9.632	<0.001
Immediate Recall	8.59 (2.62)	10.58 (1.87)	12.453	<0.001
Verbal retention for similar pairs	4.41 (.738)	4.82 (.398)	7.622	<0.001
Verbal retention for dissimilar pairs	9.71(3.14)	12.41(2.842)	11.935	<0.001
Visual retention	10.28 (8.69)	10.77 (2.315)	0.790	0.431
Visual recognition	8.39(1.669)	9.27 (.966)	9.964	<0.001
PGI Memory Total Score	76.04 (13.85)	88.16 (11.29)	15.883	<0.001
WHO QOL BREF SCORE				
Domain 1 (physical health)	21.89 (3.82)	26.45 (3.476)	16.390	<0.001
Domain 2 (psychological)	20.38(3.14)	23.54 (2.70)	15.948	<0.001
Domain 3 (social)	10.31 (1.701)	11.01(1.791)	8.464	<0.001
Domain 4 (environment)	26.33(3.956)	28.68(4.11)	9.991	<0.001

Values are expressed as Mean (SD), $ Compared using paired t-test at baseline and 84th day, * p-value of <0.05 has been considered as significant

Table 2.30.4: Effect of the treatment on Assessment Parameters in study 3

Parameters (n = 214)	Baseline	84th day	$t-value	p-value
WHO QOL BREF Score				
Domain 1 (Physical Health)	63.36 (11.869)	77.46 (11.409)	15.665	<0.001
Domain 2 (Psychological)	64.80 (11.838)	76.48 (13.067)	11.514	<0.001
Domain 3 (Social relationships)	68.61 (11.342)	73.74 (12.538)	7.284	<0.001
Domain 4 (Environment)	69.52 (11.422)	76.44 (12.200)	9.009	<0.001
6 minute walk test (m)	369.70 (82.824)	401.87 (85.911)	12.284	<0.001

Values are expressed as Mean (SD), $ Compared using paired t-test at baseline and 84th day, * p-value of <0.05 has been considered as significant

2.31. BUDHIMANDYATA (COGNITIVE DEFICIT)

Background

Cognitive deficit or cognitive impairment is an inclusive term to describe any characteristic that acts as a barrier to the cognition process. The term may describe deficits in global intellectual performance, such as mental retardation. Learning disorders, dyslexia are some specific types of the cognitive deficits, the other may be drug induced cognitive/memory impairment such as cognitive impairment caused by glucocorticoids, and benzodiazepines

It is an intellectual impairment which begins in childhood due to which child shows significant limitations in their ability to learn and function. It may range from vast intellectual impairment with minimal functioning to mild impairment in specific tasks. The areas which may get affected in cognitive deficit may be attention, decision making, perception, judgment, reasoning, memory, language, general knowledge and many more. In children, the impairment leads to poor orientation in academic tasks, school work will be disorganized, and frequently incomplete and are prone to behavioral disturbances. The cause of Cognitive deficits may be congenital or may caused by environmental factors such as brain injuries, neurological disorders or mental illness

Cognitive deficit can be correlated with *Budhimandyata* in *Ayurveda*. According to *Ayurveda Budhimandyata* occurs due to *Beeja Dosa* (genetic factor), *Ahitaahara & Vihara* (incompatible and improper diet, emotional and behavioral factors of the mother (*karma, asaya, kala, dosa, ahara, vihara*) disturbs the endocrinal system and digestive system which further leads to abnormalities in the shape , color and emotions of fetus (*samsthana*, *varna*, *indriya*).

Bhela has enumerated genetic factor (*beejadosa*) of parents along with improper diet (apathy), suppression of natural urges (*vegadharana*), and gynecological disorders (*yonidosa*) as the causative factors for fetal disorders (*garbhavikriti)* like cognitive deficit.

According to *Sushruta* non fulfillment of desires of pregnant women (*dauhridyaavamanana*) leads to vitiation of *vatadosa* in fetus and produces various diseases like cognitive deficit, mental retardation, other abnormalities and even death (*jada/mandabudhi* etc.). He also added that atheism of parents and their bad deeds in previous life are also causes various abnormalities like *Buddhi Mandyata* in fetus.

Council has done following studies since inception for validation of classical drugs in the management of Cognitive deficit:

Study 1: An interventional, open label executed at Advanced Center for Ayurveda in Mental Health & Neurosciences Bangalore. Total of 45 participants were enrolled in the trial. The study medications included *Sarasvata Ghrita* in the dose of 6 gms twice a day before food with warm water (ushnodaka) for a period of 3 months. Effect of the study medications was assessed by paired t-test on IQ (by BKT), MMMSE, abnormal behavioral test and parental perception evaluation compared at baseline and at 90th day, all parameters shown significant improvement in the management of Cognitive deficit. No any adverse effect was noted in the study. CTRI/2014/03/006656

Conclusion: The study shown that the Ayurvedic medication taken internally in cognitive deficit children is helpful in improving their IQ, MMSE and ABC scores. It is also safe as it does not produce any harmful effect.

Table 2.31.1: Effect of the treatment on IQ (by BKT), MMMSE and Abnormal Behavioral Test in study 1

Parameters (n=126)	Baseline	30th day	60th day	90th day	$t-value	p-value
IQ (by BKT)	72.89 (5.831)	-	-	78.37(7.385)	11.215	<0.001
MMMSE	34.20 (3.027)	35.38(2.674)	36.07(1.698))	36.29(1.471)	6.359	<0.001
Abnormal Behavioral Test	27 (22.91)	21.67(19.42)	17.13 (15.48)	11.22 (9.936)	7.157	<0.001

Values are expressed as Mean (SD), $ Compared using paired t-test at baseline and 90th day, * p-value of <0.05 has been considered as significant

2.32: PANDU (IRON IDEFICIENCY ANEMIA)

BACKGROUND

Anemia is the most common nutritional deficiency disorder in the world. Iron deficiency anemia is the most significant contributor of all types of anemia and around 30 to 52% of non-industrialised population has anemia in general and iron deficiency in particular. Iron deficiency anemia was considered as one among the top 10 risks globally and regionally. It causes 8.4 lakh deaths and 35 million cases of disability adjusted life years. Anemia is defined as qualitative and quantitative reduction of circulating RBC and/or the percentage of hemoglobin concentration in relation to standard age and sex. The prevalence of anemia in all the age groups is higher in India as compared with other developing countries. The main reasons for IDA have been determined to be inadequate intake of iron, low bioavailability of dietary iron from plant foods due to inhibitory factors, low levels of absorption enhancers in the diet, and increased needs during growth and development among children and adolescents. Anemia and iron deficiency are known to have several functional consequences. In children, IDA adversely affects cognitive performance, behavior, and physical growth. Preventive strategies are through food-based approaches that cause multi-nutritional benefit. Conventional approach for IDA is through iron supplements, such as ferrous sulfate. Adherence to this type of medication is difficult due to various side effects, such as epigastric discomfort, nausea, diarrhea, or constipation. Side effects can be minimized by drug intake along with food; however, doing this reduces the iron absorption by 40%. Iron preparations inhibit the absorption of other drugs, such as tetracyclines, sulfonamides, and trimethoprim. Hence, there is a need to look for newer agents that have better therapeutic utility and less adverse effects. Complementary and alternative medicine or traditional medicines, which are widely used by the ailing community, need to be explored.

Council has done following studies since inception for validation of classical drugs in the management of IDA:

Study 1: An open-labeled prospective multicenter clinical trial was conducted at three peripheral institutes, viz.; Regional Ayurveda Research Institute for Nutritional Disorders, Mandi; M.S. Regional Ayurveda Research Institute for Endocrine Disorders, Jaipur; and Central Ayurveda Research Institute for Respiratory Disorders Patiala. A total of 150 patients were enrolled in the study. Patients of either sex aged between 18 and 50 years, with

hemoglobin level ranging from 8 to 10 gm% and serum ferritin level. The trial drug (*Navayasa Churna*) in capsule form was administered to selected patients in the dose of 1 gm (2 capsules of 500 mg each) twice daily after food along with water as *anupana* for a period of 90 days. Weakness was observed in 97.3% patients initially and was completely absent in 46.7% of cases by the end of 120 days. Symptoms, such as fatigue, dizziness, headache, palpitation, shortness of breath got completely relieved in 66.0, 44.7, 44.7, 42.0, and 43.3% respectively. *Navayasa Churna* provided highly significant statistical results in hemoglobin level at every follow-up period (p-value). By the 90th day, 18% of patients achieved normocytic normochromic blood smear picture, while 24% of patients achieved it in 120 days. There is no any significant change in the total leukocyte count, differential leukocyte count, and erythrocyte sedimentation rate with baseline. No significant change in mean corpuscular hemoglobin concentration (MCHC), mean corpuscular volume (MCV), reticulocyte count, and serum iron levels were witnessed after the trial. Significant change was observed in packed cell volume (PCV) percentage and total iron binding capacity. No any adverse effect was noted in the study.

Study 2: A prospective open-label multicenter trial executed at three peripheral centers viz. Central Ayurveda Research Institute for Respiratory Disorders, Patiala, M.S. Regional Ayurveda Research Institute for Endocrine Disorders, Jaipur, and Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar. A total of 103 patients were recruited in the study. The study medications included *Punarnavadi Mandura* in the dose of 500 mg (two tablets of 250 mg) twice daily given with water for a period of 12 weeks and *Dadimadi Ghrita* in a dose of 10 gm twice daily given orally before food, with lukewarm water. The complaint of weakness was observed in 89 patients at baseline, which reduced by 25%, and was found only in 66 patients at the end of treatment. Complaint of fatigue reduced in 43.8% patients and dizziness reduced in 68.5% patients. A significant reduction was also seen in the complaint of headache, which reduced in 75.08% patients. Effect of the study medications was also assessed by paired t-test on hematological parameters compared at baseline and at 84th day. Table 4 shows the results of the analysis on hematological parameters. Mean hemoglobin (g/dL) level increased from baseline value of 9.29 to 9.40 at 84^{th} day, which was, however, not statistically significant. A significant increase in mean serum iron (µg/dL) level ($p = 0.005$) was also seen, which rose from baseline value of 41.13 to 50.02 at the end of the treatment.

Conclusion: The studies have shown very promising results in the management of Iron Deficiency Anemia or Nutritional Anemia with Ayurvedic intervention.

Table 2.32.1: Effect of the treatment on haematological parameters in study 1

Parameters (n=150)	Baseline	90 th day	$t- value	p-value
Hb (gm/dl)	9.07 (0.655)	9.68 (1.010)	9.366	<0.001
MCHC (g/dl)	29.35 (2.219)	29.30 (2.300)	.305	0.761
MCV (fl)	80.20 (11.119)	80.52 (11.668)	.407	0.685
PCV (%)	31.58 (3.936)	32.56 (4.854)	2.632	0.009
Serum Ferritin (ng/ml)	10.26 (7.530)	14.19 (12.102)	5.781	<0.001
Serum Iron (µg/dl)	39.52 (28.742)	42.78 (26.895)	1.604	0.111
TIBC	437.63 (68.882)	424.00 (73.804)	2.388	0.018

Values are expressed as Mean (SD), $ Compared using paired t-test at baseline and 84th day, * p-value of <0.05 has been considered as significant

Table 2.32.2: Effect of the treatment on chief complaints in study 1

Presence of Chief Complaints (n = 150)	Baseline	90th day	120th day
Weakness	146 (97.3)	90 (60.0)	80 (53.3)
Fatigue	144 (96.0)	57 (38.0)	45 (30.0)
Dizziness	96 (64.0)	26 (17.3)	29 (19.3)
Headache	111 (74.0)	32 (21.3)	44 (29.3)
Palpitation	98 (65.3)	32 (21.3)	35 (23.3)
Shortness of breath	117 (78.0)	55 (36.7)	52 (34.7)
Irritability	125 (83.3)	50 (33.3)	44 (29.3)
Pallor	111 (74.0)	82 (54.7)	67 (44.7)

Values are expressed as n (%)

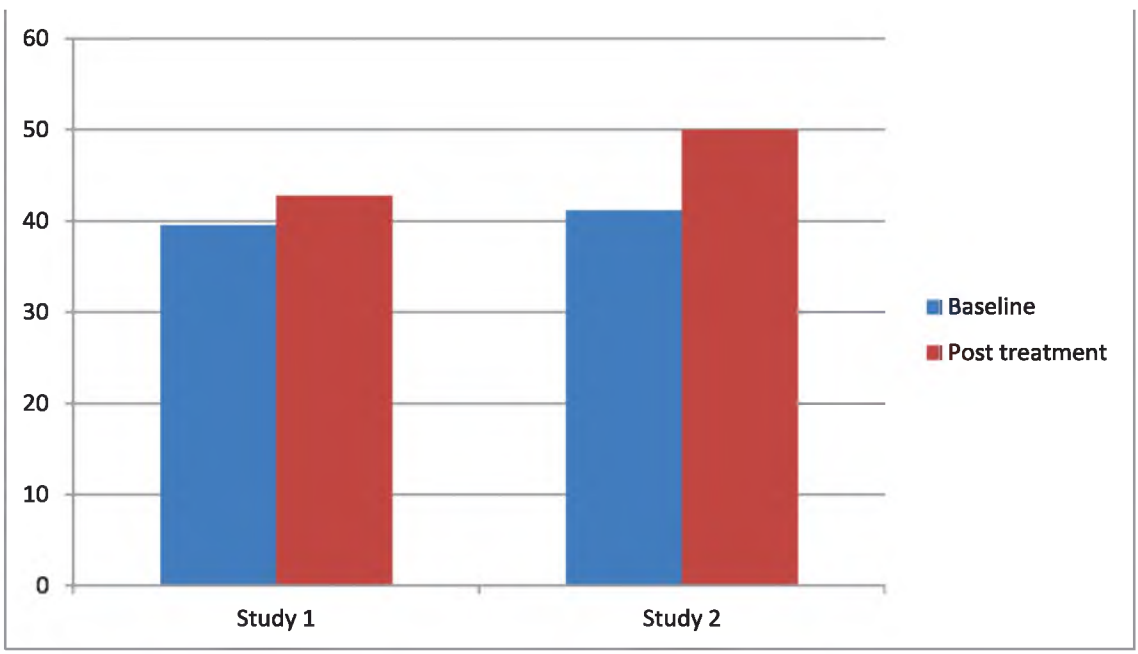
Table 2.32.3: Table 3: Effect of the treatment on chief complaints in study 2

Chief Complaints (n = 90)	Baseline	84th day	Follow up 14th week
Weakness	89 (98.9)	66 (73.3)	64 (71.1)
Fatigue	89 (98.9)	50 (55.6)	40 (44.4)
Dizziness	54 (60.0)	17 (18.9)	14 (15.6)
Headache	52 (57.8)	13 (14.4)	14 (15.6)
Palpitation	29 (32.2)	08 (8.9)	07 (7.8)
Shortness of breath	21 (23.3)	08 (8.9)	09 (10.0)

Irritability	47 (52.2)	12 (13.3)	09 (10.0)
Taste disturbances	18 (20.0)	06 (6.7)	06 (6.7)
Pallor	54 (60.0)	39 (43.3)	39 (43.3)
Brittle nails (Spoon shaped)	01 (1.1)	0 (0.0)	0 (0.0)
Pica	10 (11.1)	03 (3.3)	02 (2.2)
Glossitis	19 (21.1)	03 (3.3)	03 (3.3)
Angular stomatitis (Sores at corners of the mouth)	10 (11.1)	02 (2.2)	02 (2.2)
Ringing in the ears	14 (15.6)	01 (1.1)	0 (0.0)

Values are expressed as n (%)

Fig. 2.32.1: Effect of the treatment on Serum Iron levels in study 1 and study 2



2.33: OSTEOPENIA/OSTEOPOROSIS

BACKGROUND

Osteopenia/Osteoporosis is a condition characterised by decrease in Bone Mineral Density. According to estimates, out of the 230 million Indians expected to be over the age of 50 years in 2015,20%, i.e., almost 46 million, are women with osteoporosis. Thus, osteoporosis is a major public health problem especially for women, in India. It is also one of the major risk factor for fractures, especially among elderly women. Osteoporosis is a silent disease until it is complicated by fractures that occur following minimal trauma or, in some cases, with no trauma. Dietary changes, supplementation of Vitamin D and calcium supplementation, anti-resorptive agents and hormonal therapies along with exercise, regular monitoring of Bone Mineral Density and assessment of biomarkers related to bone tumour are advised in the management of this condition.

The clinical picture of Osteopenia/Osteoporsis is similar to the condition of *Asthidhatukshaya* described in Ayurveda which is characterized by the gradual loss of quality (*Saarata*) of *Asthidhatu* leading to increased predisposition to other bone related pathologies. It happens due to the *prakopa* of *Vata* that occurs in *Asthi*. *Prithvi*, *Ap* and *Vayumahabhutas* contribute to the formation and function of *asthidhatu*. When qualities of *asthidhatu* such as *guru*, *kathina*, *sthira*etc gets reduced due to vitiation of *Vata*, *asthisoushirya* occurs resulting in the inability of *asthidhatu* to perform its normal function of *dehadharana*. Complex treatment approaches including medication, purification techniques including *Panchakarma*, diet and lifestyle advices etc. are useful in the management of this condition.

Council has done following studies since inception for validation of classical drugs in the management of Osteopenia/Osteoporsis:

Study 1: A prospective open label multicenter trial was executed at two peripheral centers viz. Regional Ayurveda Research Institute for Drug Development, Gwalior and at Raja RamdeoAnandilalPoddar Ayurveda Cancer Research Institute, Mumbai.The patients were administered orally,*LakshaGuggulu,* 1gm twice daily (500mg tablet), twice a day after food with lukewarm Water and *Mukta-ShuktiPishti*, 250 mg twice daily (250 mg capsule),twice a day after food with lukewarm Water for 12 weeks. Total 88 patients were enrolled.

Assessment was done on Quality of life score QUALEFFO-41 scale and BMD T-score, significant improvement was seen in both parameters after treatment. Safety parameters were found to be within the normal range. No significant adverse events could be identified as due to drug, during the study. CTRI/2012/03/002533

Study 2:A prospective open label multicenter trial was executed at two peripheral centers viz. Regional Ayurveda Research Institute for Metabolic Disorders, Bengaluru and at Raja RamdeoAnandilalPoddar Ayurveda Cancer Research Institute, Mumbai.The patients were administered orally, fine whole root powder of the medicinal herb *Ashwagandha*[*withania somnifera* (L.) Dunal] (API Part-I; Vol.-I) in the dose of 6 grams (3 gms in divided doses) with lukewarm water for 12 weeks and medicinally prepared fine powder of *Pravalapishti* (coral) (AFI-Part-I) in the dose of 500 mg per day (250 mg capsules twice daily) with lukewarm water for 12 weeks. Total 90 patients were enrolled. The trial combination showed a decreasing trend in Serum Osteocalcin, reduction in Serum Bone specific Alkaline Phosphatase and significant decrease in mean domain score of all domains of QUALEFFO-41 scale parameters. No any adverse effect was noted in the study.CTRI/2015/01/005406.

Conclusion: Evaluation of safety and efficacy of *LakshaGuggulu, Mukta-ShuktiPishti, AshwagandhaChurna and PravalaPishti* were done through studies conducted at peripheral institutes of CCRAS spread throughout various bio-geographical areas of India. The analysis of outcome gives very promising results in the management of Osteopenia/Osteoporosis. No adverse reactions were noticed during the trial period. Hence Ayurveda intervention is safe and effective in the management of Osteopenia/Osteoporosis.

Table 2.33.1: Effect of trial drugs on Osteoporosis related imaging and blood biochemical parameters in study 2

Osteoporosis related blood biochemical parameters (n=90)	**Baseline**	**84th Day**	**t value**	**p value**
BMD T score	-1.978 ± 0.61	-1.952 ± 0.65	0.940	0.350
Bone Specific alkaline phosphatise (HI Derived)	25± 8.1	24.67± 7.6	0.397	0.693
Serum Osteocalcin (ng/ml)	21.22 ± 6.83	20.99 ± 7.99	0.325	0.746
Serum Calcium (in mg/dl)	9.067 ± 0.53	9.23 ± 0.51	2.59	0.011**
Vitamin D3 (LC- MS/MS) ng/ml	25.18 ± 14.59	21.15 ± 11.88	3.641	<0.001***

Table 2.33.2: Safety profile of the patients in two clinical trials

Parameters	*LakshaGugguluandMukta-ShuktiPishti*(n = 88)			*AshwagandhaChurnaandPravalaPishti* (n = 90)		
	BT	AT	p-value	BT	AT	p-value
Liver Function Test						
S. Bilirubin (Conjugated) (mg/dl)	0.29 (0.191)	0.26 (0.159)	**<0.05**	0.15 (0.065)	0.16 (0.090)	>0.05
S. Bilirubin (Unconjugated) (mg/dl)	0.48 (0.192)	0.45 (0.158)	**<0.05**	0.39 (0.207)	0.40 (0.252)	>0.05
SGPT (IU/L)	29.90 (15.546)	30.46 (19.555)	>0.05	18.41 (9.290)	16.73 (8.014)	**<0.05**
SGOT (IU/L)	28.15 (9.415)	29.13 (13.100)	>0.05	20.74 (7.054)	20.30 (6.612)	>0.05
S. Alkaline Phosphatase (IU/L)	80.59 (19.138)	81.17 (21.017)	>0.05	73.08 (20.464)	73.23 (19.483)	>0.05
Total Protein (gm/dl)	6.74 (0.537)	6.79 (0.541)	>0.05	7.00 (0.388)	6.96 (0.429)	>0.05
Albumin (gm/dl)	4.13 (0.264)	4.11 (0.329)	>0.05	4.28 (0.220)	4.24 (0.197)	>0.05
Globulin (gm/dl)	2.63 (0.375)	2.69 (0.406)	>0.05	2.72 (0.381)	2.71 (0.398)	>0.05
Kidney function test						
Blood urea (mg/dl)	22.02 (6.602)	22.02 (5.578)	>0.05	19.58 (5.144)	19.31 (4.924)	>0.05
S. Creatinine (mg/dl)	0.88 (0.167)	0.82 (0.116)	**<0.01**	0.79 (0.179)	0.78 (0.183)	>0.05
Uric Acid (mg/dl)	4.52 (1.092)	4.59 (1.135)	>0.05	4.73 (1.258)	4.74 (1.323)	>0.05

Values are reported as Mean(SD), compared using paired t-test, p-value of <0.05 has been considered as significant

Fig 2.3.1: Improvement in clinical symptoms in study 1

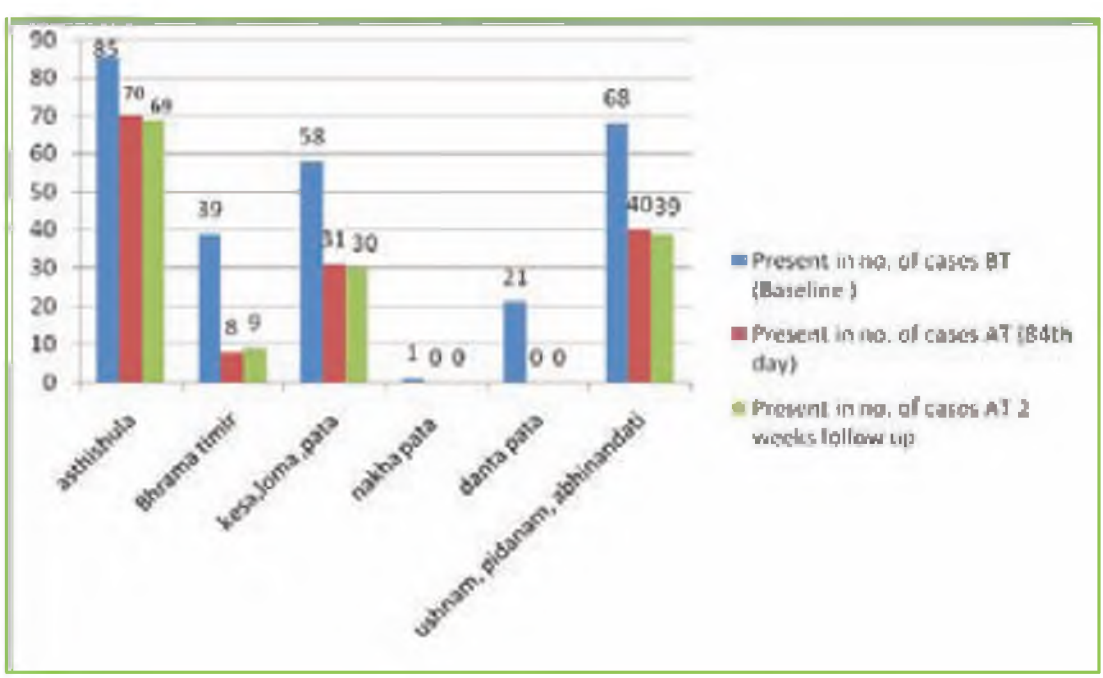
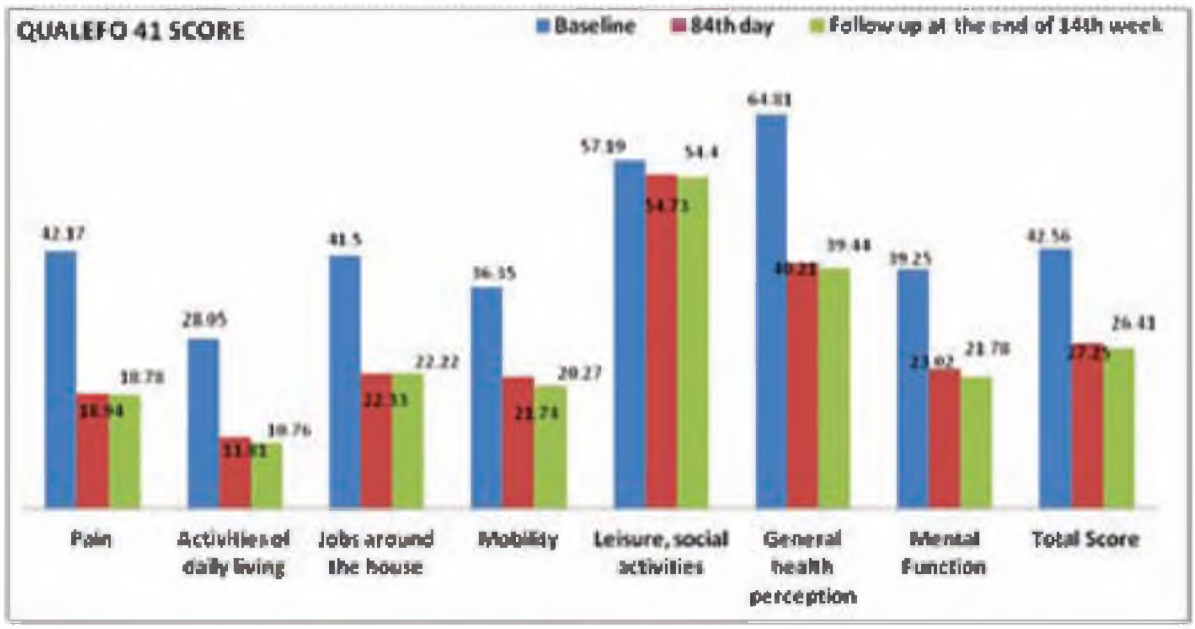


Fig 2.33.2: Effect of trial drugs on QUALEFFO-41 index in study 2



CHAPTER 3

DRUG DEVELOPMENT

The Central Council for Research in Ayurvedic Sciences has been engaged in clinical research and drug development of new/ coded formulations based on leads from classical texts, contemporary scientific and pharmacological leads for important diseases of National importance based on strength of Ayurveda and leads from folk lore claims collected by the council from various parts of India.

The Council has been putting efforts to translate the research findings into practice and make available to the needful at large. In this direction, the technologies of new coded drugs and formulations developed by the Council have been transferred to the Industry through National Research Development Corporation, Department of Scientific and Industrial Research, Ministry of Science & Technology, Government of India.

Till date, 12 technologies have been developed and commercialized through National Research Development Corporation (NRDC) for wider public utility.

Council has developed the following drugs since inception for various diseases of national importance, and has transferred the technology to the industry for mass usage of the knowledge.

3.1. AYUSH 64: ANTIMALARIAL DRUG

Background

Malaria, a tropical diseases is widely prevalent all over the world and has claimed millions of lives. However, by using modern anti-malarial drugs like quinine, chloroquine & also insecticides to kill mosquitoes the disease is temporarily controlled. Nevertheless, it has been found that mosquitoes have developed immunity to the insecticides and their breeding, continues unabated. It has also been realized that the modern allopathic anti-malarial drugs are highly toxic and their repeated use causes numerous side- effects resulting in ocular disturbances etc.

Descriptions concerning its aetiopathogenesis, clinical features and line of management are detailed under '*Vishamajwara*' in ancient classical literature of Ayurveda. Two types of *Mashak* (Mosquito's) bite features are encountered in Ayurvedic literature (*Charak Chikitsa* 23/157) where in one is curable (mild toxic) with complaints of itching, slight swelling and mild pain; the other is incurable (potent toxic/fatal) one wherein on biting, features of incurable insect bite like expansion of swelling, burning sensation & intense smell at biting spot, heaviness in the eyes,dyspnoea, fever, bodyache, vomiting, , diarrhoea, thirst, loss of consciousness etc. appears in patient (*Charak Chikitsa* 23/157, *Sushruta Kalpsthan* 8/36, *Astanga Sangrah Uttarsthan* 43/17, *Yoga Ratnakar Vishadhikar*).

In order to provide safe, inexpensive and effective remedy for malaria, CCRAS has developed a poly herbal safe, anti-malarial drug **'Ayush-64'** through extensive pharmacological, toxicological and clinical studies. This has been patented by the Council through National Research and Development Corporation, New Delhi.(Patent No:152863)

Drug Profile

S.No.	Ingredients	Botanical name	Part used
1.	Kiratatikta	*Swertia chirata* Buch-ham	Whole Plant
2.	Saptaparna	*Alstonia scholaris* R.Br	Stem Bark
3.	Katuki	*Picrorhiza kurroa* Roylux Benth	Root
4.	Kuberaksha	*Caesalpinia crista* Linn.	Seed

Pharmacological/Safety/Toxicity Studies

- In albino mice, oral administration of Ayush -64 at doses of 250-750mg/kg for five days exhibited significant anti-malarial property.
- Ayush-64 administered in dose of 500 mg/ kg body weight in rats for 12 weeks was considered safe and non-toxic.

Clinical efficacy

- Clinical trials of Ayush-64 were conducted on 1442 positive cases of malaria at various Research institutes and Centres of the Council located in different part of the country. The response of treatment was 89% and the findings were comparable with known Anti-malarial drugs-chloroquine and primaquine.
- OPD & IPD level double blind studies were conducted on 178 patients revealed that the formulation is effective in 95.4% of patients. Normal temperature besides clearance of malarial parasite was achieved within 5-7 days.
- **Collaborative studies with National Malaria Eradication programme (Govt. of Haryana & Tamil Nadu):** These studies conducted on 496 patients have shown clearance of parasites and clinical improvement in 72-90% in 5-7 days.
- **Epidemic Malaria control programme (Western Rajasthan 1984, Assam, 1995):** During epidemic Malarial control programmes at Rajasthan and Assam approximately 3,600 and 10,000 *P.vivax* cases were treated respectively. Clinical improvement was observed in almost all cases. Positive *P.falciparum* was observed in some cases and parasite clearance and clinical improvement was found in few numbers of cases.

  Side effects: No side/toxic effect in prescribed doses

  Recommended Dose: As mentioned below or as directed by the physician

Adult	:	4 tablets (500 mg per tab.) thrice daily for 5-7 days
Children (5-12 years)	:	2 tablets thrice daily for 5-7 days
Infants (below 5 years)	:	Powder of 1 tablet with honey, three times a day

Katuki (*Picrorhiza kurroa* Royale)

Kuberaksa (*Caesalpinia crista* Linn.)

Kiratatikta (*Swertia chirata* Buch-ham)

Saptaparna (*Alstonia scholaris* R.Br)

Besides anti-malarial activity the drug was also found to be effective in fevers of unknown etiology, filarial lymphlangitis and derangement of lever functions.

3.2 PIPPALYADI YOGA-AN ORAL CONTRACEPTIVE

The *PippaLyadi Yoga* a combination of *Pippali (Piper longum* Linn.) fruit, *Vidanga (Emblia ribes* Burm.f.) fruit and *Tankana* (Borax) has been extensively studied by the Council in fertile female volunteers through its centres at Central Research Institute for ayurveda, Kolkata and Research Scheme for Screening of Contraceptive agents, Ahmedabad.

Criteria for Selection

This trial was conducted on fertile female volunteers in age group Of 20-34 years having a menstrual cycle between 26-30 days (with 3-5 days menstruation period) and with inter-pregnancy period between 13-24 months.

Type of study: Open Trial

Results

Dose schedule was 500 mg. b.d. from 5th day to last day of the cycle consecutively for three cycles. Significant improvement in efficacy of the drug was observed with successive modifications. Further study (of this drug with a dose of 500 mg. b.d. from day one to last day of cycle consecutively for three cycles had shown 100% efficacy of the drug since no pregnancy was reported due to drug failure in this study.

Efficacy of this drug with different doses is shown in the table.

S.N.		Dose 1: 500 mg. O.D. D5 to full cycle	Dose 2(a) 500 mg. B.D. D5 to full cycle	Dose 2 (b) 500 mg. B.D. D1 to full cycle
1.	Women studied	162	540	722
2.	Cycles studied	850	4001	1117
3.	Maximum cycles followed	36	31	20
4.	No. of Pregnancies			
	Drug failure	**5**	**4**	**0**
	Drug Omission	**20**	**25**	**2**
	Combined	**25**	**26**	**5**

5.	Pearl index- per hundred women year (HWY)			
	Drug failure	7.06	1.20	0.00
	Drug Omission	28.24	6.60	5.37
	Combined	35.29	7.80	5.37

Side effects

The prolonged administration of this drug has not shown any significant side effect or adverse effects.

Conclusion

The study with the dose of 500 mg. b.d. from day one has established the efficacy of *Pippalyadi Yoga* in prevention of conception.

3.3. LOCAL CONTRACEPTIVE (SPERMICIDAL) EFFECT OF NEEM OIL

Nunba (Neem) *(Azadirachta indica* A Juss.) is an important medicinal plant used in various forms in Ayurveda. The Neem seed oil is used for application on infected wounds and is stated to have anti-microbial properties. The spermicidal effect of Neem oil has been studied in rhesus monkey, and water soluble fraction containing sodium nimbinidate is spermicidal in human sperms in-vitro. Accordingly, the contraceptive efficacy of Neem oil has been taken up in fertile female volunteers.

Method of administration

1 ml. of Neem oil locally introduced in vagina through a plastic applicator, five minutes prior to coitus.

Clinical studies

The study has been conducted on 225 fertile female volunteers In the age group of 18-35 years (mother of at least one child) in OPD of Central Research Institute (Ayurveda), Punjabi Bagh, New Delhi and selected population in community.

The drug has been found very effective since only three women conceived due to drug failure. 43 volunteers continued upto 36 cycles and more. (Table-I).

Efficacy on Neem Oil

Table 1.

No of women studied	No. of cycles studied	Max. No. of cycles followed
	1700	52

Table 2 (Pregnancy rate -as per Pearl Index-HWY)

Drug failure	Drug omission	Combined
	21.1	23.2

Conclusion

It is well tolerated and accepted except foul smell. Further efforts may be done to make the drug more acceptable by modifying dosage form.

3.4. AYUSH-56: An Ayurvedic Anti-Epileptic Drug

Background

Epilepsy (*Apasmara*) is a transient loss of consciousness with terrifying physical movements born of derangement of memory, intellect and mind. Epilepsy is a Greek word meaning "A condition of being overcome or seized or attached". The clinical picture of *Apasmara* presented in Ayurveda and that of epilepsy in modern medicine are almost identical. Ayurveda considered the involvement of both body and mind in the causation of the disease. About 30%of the patients of epilepsy do not respond to the current available modern drugs besides their adverse effects.

In view if this, the Central Council for Research in Ayurvedic Sciences, through extensive pharmacological/toxicological and clinical studies has evolved a new safe toxic coded drug Ayush-56 for the management of epilepsy. This has been patented by the Council through National Research and Development Corporation, New Delhi. (Patent No: 141170)

Drug Profile

	Ingredients	**Botanical name**	**Parts used**
1.	Sunisannaka	*Marsilea minuta* Linn	Whole Plant
2.	Jatamansi	*Nardostachys jatamansi* DC.	Root/Rhizome

Safety/Toxicity Profile: Acute and sub-acute toxicity studies revealed no toxic effects of the drug.

Clinical Efficacy:

Clinical studies on 423 subjects were carried out at three peripheral research Institutes/Units of the Council to ascertain the efficacy of **Ayush-56** in the treatment of Epilepsy (*Apasmara*). The study showed significant reduction (65%) in frequency and duration of epileptic fits. It is found useful as on add on to the modern anti-epileptic treatment. No adverse event in prescribed doses was reported. Further, no withdrawal effect was observed after slowly tapering the modern medicine with this drug. The overall effect of the drug Ayush-56 is given in the **Table-1.**

Table- 1: Showing the overall effect of the drug Ayush-56 (n=273)

Sl. No.	Result	No. of cases
1.	Complete control	87
2.	Marked control	48
3.	Moderate control	41
4.	No control	97

Recommended Dose

Adults: Two tablets (250 mg each), three times a day for six months or as directed by physician

Children: One tablet (250 mg each), three times a day for six months or as directed by physician

Ingredients

Jatamansi (*Nardostachys jatamansi* DC.)

Sunisannaka(*Marsilea minuta* Linn)

3.5. AYUSH-82: An Ayurvedic Drug for Diabetes Mellitus

Background

Diabetes mellitus (*Madhumeha*) is a group of metabolic diseases marked by high level of blood glucose resulting from defects in insulin production, insulin action or both. Diabetes may lead to serious complications involving multiple organs. Ayurvedic literatures vividly describe about the aetiology, pathogenesis, prognosis, complications, its management and scientifically attributed the causal relationship of dietary, lifestyle, environmental and genetic factors. CCRAS has developed a polyherbal formulation, **Ayush-82** for the management of Diabetes mellitus.

Drug Profile

S.N.	Drug name	Botanical/English name	Part used
1.	Jambu	*Syzygium cumini* (L.) Skeels	Seed
2.	Karvellaka	*Momordica charantia* Linn.	Seed
3.	Meshashringi	*Gymnema sylvestre* R.Br.	Leaf
4.	Amra	*Mangifera indica* Linn.	Seed

Safety/toxicity profile

Acute Toxicity Studies of **Ayush-82** administered orally in Swiss Albino (I.B) mice revealed no pre-terminal deaths, no toxic signs and abnormal behavior in the animals at 10 times of intended therapeutic dose.

Sub-Acute Toxicity Studies of **Ayush -82** in Wistar rats showed no significant effect in the blood biochemistry, haematology and weight of the vital organs in comparison to the control suggestive of its safety.

Clinical efficacy

The study has been carried out on 886 patients at Council's peripheral Central Research Institutes wherein **Ayush-82** was administered thrice daily. The results indicate statistically significant reduction in fasting and post prandial blood sugar level along with clinical improvement. No adverse events were reported during the treatment period.

Recommended Dose

15 g per day in 3 divided doses along with 500 mg Shuddha Shilajita twice daily.

Ingredients

Jambu (*Syzygium cumini* (L.) Skeels)

Meshashringi(*Gymnema sylvestre* R.Br)

Amra (*Mangifera indica* Linn.)

Karvellaka (*Momordica charantia* Linn.)

3.6 NIMBATIKTAM: An Ayurvedic Drug for Psoriasis and Duodenal ulcer

Background

Nimba is one of the most commonly used plant in AyurvedaAyurveda classics advocate the use of seed oil in various disease conditions like skin disease, ulcers, diabetes, fever etc. Owing to its therapeutic importance, Central Council for Research in Ayurvedic Sciences has developed **Nimbatiktam** , the major bitter component obtained from the seed oil of Nimba (A*zadirachta indica* A. Juss.) . The Council has conducted studies of Nimbatiktakam for its efficacy in Psoriasis and Duodenal Ulcer.

Drug Profile

Ingredients	**Botanical name**
Nimba	*Azadirachta indica* A.Juss.

INGREDIENT OF NIMBATIKTAM

Nimba (*Azadirachta indica* A.Juss.)

Safety/toxicity profile:

In albino rats and mice acute toxicity studies, *Nimbatiktam* showed no toxicity up to 2000 mg/kg orally and 1000mg/kg intra peritoneally. Sub acute toxicity studies in albino rats up to 100 mg/kg daily for 6 weeks and 10 and 20 mg/kg orally in dogs for 4 weeks did not reveal any systemic toxicity. Teratogenic studies in rats also did not reveal any toxic manifestations or foetal abnormalities.

I. NIMBATIKTAM FOR PSORIASIS

Clinical efficacy

- ***Nimbatiktam* with *Lajjalukeram***

A combination of internal administration of *Nimbatiktam* 200 mg twice daily and Lajjalukeram as external application were taken for trial at Councils peripheral institute.

The trial has been conducted on 386 patients and about 56% of the patients have shown good and fair response

- ***Nimbatiktam* with *Aragwadha kera***

A double blind clinical study was carried out on 40 patients randomly grouped into 2 groups (20 in each group with *Nimbatiktam* 200 mg capsule twice daily and the other group with Lactose (Placebo) 200 mg capsule orally for 60 days and *Aragwadha kera* 50 ml for external application daily in both the groups) to assess the therapeutic activity of *Nimbatiktam* in Psoriasis (Discoid Psoriasis) proved that the effect of *Nimbatiktam* in the treatment of psoriasis is statistically significant at 5% level. $P<0.05$ than the placebo.

Case Report: A 60 year old male patient with well-defined psoriatic lesions and no complication was administered *Nimbatiktam* 100mg (Capsule) thrice daily orally and 1g *Nimbatiktam* mixed in 100 g of Coconut oil externally for 72 days. The patient recovered from all the symptoms of Psoriasis.

II. NIMBATIKTAM FOR DUODENAL ULCER

Pharmacological Profile:

Antiulcer effects: The drug in 20 mg/kg dose level (P.O.) was found to have significant anti-ulcer activity in shay ulcers in rats and histamine ulcer in guinea pigs. The same dose had significant anti peptic activity in rats and guinea pigs. However, 40 mg/kg dose possessed anti-secretary effect in shay rats. The ulcer healing effect of *Nimbatiktam* could be attributed to its anti-secretary and anti-peptic activity associated with an enhancement of local healing process.

Clinical efficacy

- *Nimbidin* Extract 100 mg was administered twice daily in 13 cases of active duodenal ulcer for 60 days. Ulcer completely healed as observed in the review endoscopy in 3 patients, ulcer healing was in process in 5 patients, no healing effect was observed in 5 patients at the end of trial.
- *Nimbatiktam* 150 mg was administered thrice daily with water for 30 days at Council's peripheral institute. The results seem quite significant as 16 (40%) cases had relief of more than 75% and 4(10%) cases had moderate relief (51%-74%).

Recommended Dose

- For Psoriasis : Nimbatiktam 200mg twice daily orally for 60 days along with external application lajjalu kera or Aragwadha kera
- For Duodenal ulcer: Nimbatiktam 100mg-150 mg twice or thrice daily orally for 30-60 days

3.7. *AYUSH POSHAK YOGA* and *PEYA* for immuno-modulatory, anti-stress and general health promotion

Background

Ayurveda emphasizes on prevention of disease and improve the quality of health as well as life span. A number of medicinal plants have been recommended for this purpose. These plants provide specific resistance and make the body strong to counteract any adverse physical, chemical or biological stress. The people belonging to Antarctica region are exposed to environmental stress viz. cold, mental and nutritional stress including others factors like radiations, food preservatives etc. which generate free-radicals in the body thus suppressing the immune system and causing early ageing. To combat such adverse situations, Council developed *Ayush poshak yoga* and *peya* for improving general wellbeing.

Drug profile

Ayush Poshak Yoga

S.N.	Name	Botanical/English name
1.	*Badam*	*Prunus amygdalus* Stokes
2.	*Kaju*	*Anacardium occidentale* L.
3.	*Akhrot*	*Juglans regia* L.
4.	*Pista*	*Pistacia vera* L.
5.	*Saunf*	*Foeniculum vulgare* Mill.
6.	*Aswagandha*	*Withania somnifera* (L.) Dunal
7.	*Guduchi*	*Tinospora cordifolia* (Willd.) Miers
8.	*Trapush*	*Cucumis sativus* L.
9.	*Tarbooj*	*Citrullus vulgaris* Schrad.
10.	*Kharbooj*	*Cucumis melo* var.Utilissimus Dutt & Fueller
11.	*Shunthi*	*Zingiber officinale* Rosc.
12.	*Pippali*	*Piper longum* L.
13.	*Safed musli*	*Chlorophytum tuberosum* (Roxb.) Baker
14.	*Maricha*	*Piper nigrum* L.
15.	*Khas khas*	*Papaver somniferum* L.

16.	*Pumpkin*	*Cucurbita pepo* L.
17.	*Sita*	Sugar Candy

SOME IMPORTANT INGREDIENTS OF AYUSH POSHAK YOGA

Badam (*Prunus amygdalus* Stokes)

Kaju (*Anacardium occidentale* L.)

Akhrot (*Juglans regia* L.)

Pista (*Pistacia vera* L.)

Saunf (*Foeniculum vulgare* Mill.)

Ashwagandha(*Withania somnifera* (L.) Dunal)

Guduchi (*Tinospora cordifolia* (Willd.) Miers)

Ayush Poshak Peya

Sl. No.	Sanskrit / Local Name	Botanical name
1.	*Tea Leaf*	*Camellia sinensis* (L.) O.Kuntze
2.	*Sukshmaila*	*Elletaria cardamom* Maton
3.	*Dalchini*	*Cinnamomum verum* Breyn.
4.	*Kumkuma*	*Crocus sativus* L.
5.	*Arjuna*	*Terminalia arjuna* (Roxb.) Wight & Arn.

Ingredients of Ayush Poshak Peya:

Tea Leaf (*Camellia sinensis* (L.) O.Kuntze)

Elaichi (*Elletaria cardamom* Maton)

Dalchini (*Cinnamomum verum* Breyn.)

Kumkuma (*Crocus sativus* L.)

Arjun(*Terminalia arjuna* (Roxb.) Wight & Arn.)

Clinical efficacy

The combined intake of Ayush Poshak Yog and Peya helped in the management of stress related symptoms as evident by notable changes in immunoglobulin level and antioxidant enzymes. The formulations significantly improved quality of life of individuals.

Recommended Dose

- *Ayush Poshak Yoga* 45-50gm.
- *Ayush Poshak Peya* 125-150 ml.

3.8. SHUNTHI GUGGULU: Rheumatoid Arthritis (*Amavata*)

Background

Rheumatoid Arthritis (Amavata) is an autoimmune inflammatory disease that causes pain, swelling, stiffness, destruction, and functional disability in the affected joints. In chronic cases, the disease may cause deformity and total incapacitation. Descriptions concerning aetiopathogenesis, clinical features and line of management are detailed under Amavata in Ayurveda. According to Ayurveda, the main cause of the disease is formation of *Ama* due to *Agnimandya* i.e gastrointestinal dysfunction. The cardinal features of *Amavata* are swelling and severe pain that seems to be of scorpion bite over the joints and other symptoms include body pain, loss of appetite, excessive thirst, laziness, heaviness of the body and fever. The general principles of treatment of this disease in Ayurveda lay emphasis on stimulating and normalizing the impaired *Agni* for the correction of digestion and metabolism. Based on the cardinal features and other associated features, use of different herbal, herbo-mineral preparations & regimens are described in Ayurvedic classics. CCRAS has developed a herbal safe Ayurvedic Drug for Rheumatoid Arthritis (*Amavata*) through a series of clinical studies.

Drug Profile

S. N.	Ingredient	Botanical Name
1.	***Guggulu***	***Commiphora wightii*(Arn.)Bhandari**
2.	***Shunthi***	***Zingiber officinale* Rosc.**

Clinical efficacy

Multicentre observational study revealed satisfactory improvement of symptoms viz. reduction in pain, morning stiffness, swelling in joints besides reduction in ESR levels. The observations made on 497 patients showed that about 2/3rd patients (67%) have very good effect under a course of 6 weeks treatment. General functional capability and improvement in general condition of the patients was noticed. The observations in another clinical trial of *Sunthi-Guggulu* on 50 patients of Amavata-rheumatoid arthritis showed significant effect as about 80% of the patients who completed full course of treatment showed either marked or completely relief .

Ingredients of *Shunthi Guggulu*

Guggulu

(*Commiphora wightii* (Arn.)Bhandari)

***Shunthi* (*Zingiber officinale* Rosc.)**

Recommended Dose

2 gm- 4 g thrice a day for six weeks with warm water.

3.9. KSHARSUTRA IN ANO RECTAL DISORDERS

Background

Improper food habits and faulty life styles are the main causes of ill health. This may lead to abnormal bowel movement, which if persists, causes various ano-rectal diseases. Besides the above, heredity also has its contribution towards this disease. Commonly occurring ano-rectal diseases are fistula-in-ano, piles and fissure in-ano. The chronicity and recurrent nature of these diseases leaves physical and psychological agony to the sufferer. *Ksharasutra*, a unique para surgical measure is advocated in Ayurveda to treat these disorders. *Ksharasutra* involves insertion of a medicated thread into the fistulous tract. It has many advantages over the modern surgical measure. Application of *Ksharasutra* is an OPD measure; which does not require hospitalization, heavy medication and is completely safe with an advantage of simultaneous cutting and healing. Tissue damage is very less, hence chance of infection is very minimal and rate of recurrence is negligible .It is economic, minimal invasive and the patients can carry out their routine work during the treatment. This measure has been very well accepted/ adopted by the practitioners of Ayurveda and such services are being provided at various clinical facilities of CCRAS in the country.

Drug Profile

S.N.	Ingredients name	Botanical Name
1.	*Snuhi*	*Euphorbia neriifolia* L.
2.	*Haridra*	*Curcuma longa* L.
3.	*Apamarga*	*Achyranthus aspera* L.

Ingredients of Kshara Sutra

Snuhi (*Euphorbia neriifolia* L.)

Haridra (*Curcuma longa* L.)

Apamarg (*Achyranthus aspera* L.)

Clinical efficacy

A study was conducted at Clinical research enquiry on *Ksharasutra ttherapy* (unit of CCRAS) at Institute of Medical Science, Banaras Hindu University, Varanasi. In this study total 805 patients were registered and 700 patients (500 non-recurrent cases and 200 recurrent cases) completed the study. The *kshara* sutra result showed efficacy in almost all patients (98.77%). Out of 700 cases, 691 were completely cured. Further, out of 200 recurrent cases 197 (98.5%) patients were cured without much difficulty. The result also revealed that the average Unit Cutting Time (UCT) in the total (n=700) patients was 5.68 days/cm and the average UCT in recurrent (n=200) was 6.55 days/cm. Further studies on 395 patients have been conducted in the Council's peripheral Research Institutes and 386 (97.72%) patients responded to the procedure.

3.10. AYUSH BALARASAYANA for promotion of health in children

Background

Malnutrition is the underlying contributing factor in about 45% of all child deaths under the age of 5. It makes children more vulnerable to severe diseases. From the end of the neonatal period and through the first 5 years of life, the main causes of death are preterm birth complications, intrapartum-related complications, diarrhoea, pneumonia and malaria. According to WHO, the mortality rate of children under 5 years is very alarming. 5.9 million Children under age five died in 2015, at the approximate rate of 16 000 every day. Ayurveda, the ancient science of life provides utmost focus on promotion/maintenance of health. The susceptibility of young children towards various infections or diseases is mainly due to their poor immunity. The Rasayana drugs provide longevity optimum strength of physique, improves memory and intelligence. Considering the general ailments affecting the infants and children, the *Ayushbalarasayana* has been scientifically developed by the Central Council for Research in Ayurvedic Sciences for promotion of health in children and patented through National Research and Development Corporation, New Delhi.

Drug Profile

Table 3.10: Showing content of *Balarasayana*

Sl. No.	Ingredient	Botanical /English Name
1.	*Bala*	*Sida cordifolia* L.
2.	*Guduchi*	*Tinospora cordi*folia (Willd.) Miers
3.	*Amalaki*	*Emblica officinalis* Gaertn.
4.	*Shatavari*	*Asparagus racemosus* Willd.
5.	*Bhumyamalki*	*Phyllanthus fraternus* G.L.Webster
6.	*Mandukparni*	*Centella asiatica* (L.) Urb.
7.	*Mukta Shukti Bhasma*	*Calcined shell of pearl oyster(Ostrea edulis)*

Clinical efficacy

Clinical studies conducted by CCRAS, New Delhi at its various peripheral centres to establish the efficacy of *Balarasayana* showed significant improvement immunity. Significant improvement in duration and episodes of excess cry, diarrhea and vomiting was observed. Highly significant improvement in episodes of cough/cold and fevers was also observed when compared to placebo.

Recommended Dose

***Balarasayana*:** 1 tablet (250mg) twice a day up to 5 years of age

2 tablets (250mg) twice a day for more than 5 years of age

IPR Status: Patent No: 19691

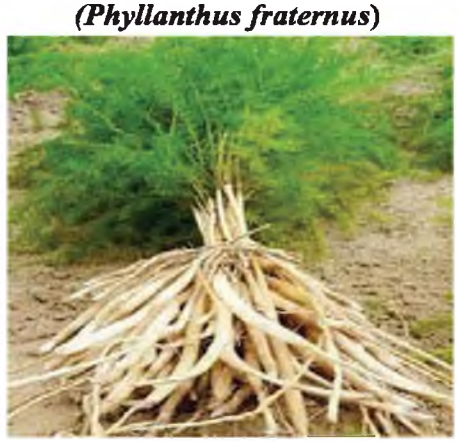
Fig. 3.10. Showing ingredients of *Balarasayana*

***Bala* (*Sida cordifolia* L.)**

***Guduchi* (*Tinospora cordifolia*)**

***Bhumyamalki* (*Phyllanthus fraternus*)**

***Amalaki* (*Emblica officinalis*)**



***Shatavari* (*Asparagus racemosus*)**

***Mandukparni* (*Centella asiatica*)**

***Mukta Shukti Bhasma* (*Calcined shell of pearl oyster*)**

3.11: AYUSH GHUTTI for prevention of diarrhoea and fever in children

Background

Infant mortality rate amounts very high in tropical countries like India due to infantile diarrhoea. In spite of enormous expenditure incurred to improve health standards of the masses, diarrhoea still poses the same threat especially in rural areas. Although it is not a deadly disease as such yet due to ignorance, lack of medical facilities and late treatment, children suffer heavily and by the time they reach some proper medical institution the cases turn complicated to the extent of irreversible state.[1] Considering the gravity of the disease, the ***Ayush Ghutti*** has been scientifically developed by the Central Council for Research in Ayurvedic Sciences (CCRAS) to prevent diarrhoea and fever in children. This is useful for development of proper digestion and assimilation as well as prevents the said disease conditions in childhood. The drug is patented through National Research and Development Corporation, New Delhi.

Drug Profile

AYUSH - Ghutti (Prevention of Diarrhoea and Fever)

S. N.	Ingredient	Botanical Name	Part used
1.	*Dadima*	*Punica granatum* L.	Fruit rind
2.	*Haritaki*	*Terminalia chebula* Retz.	Fruit
3.	*Amra*	*Mangifera indica* L.	Seed Kernel
4.	*Bilwa*	*Aegle marmelos* (L.) Corrêa	Fruit pulp
5.	*Kamala*	*Nelumbo nucifera* Gaertn.	Seed Kernel
6.	*Sunthi*	*Zingiber officinale* Roscoe	Rhizome
7.	*Jahar Mohara pisti* (Serpentine stone)		Calx

Some Important Ingredients

Dadima (*Punica granatum* L.)

Haritaki (*Terminalia chebula* Retz.)

Amra (*Mangifera indica* L.)

Bilwa (*Aegle marmelos* (L.) Corrêa)

Clinical Efficacy

Clinical studies to establish the efficacy of AYUSH Ghutti were carried out at RSSCA, Varanasi. AYUSH Ghutti was tried in 50 cases each in trial and control group. Significant improvement was noted in the episodes and duration of diarrhoea and excess cry. Significant improvement in C_3 and C_4 levels (enhancement of immunity) was also reported.

Dosage Schedule

Ayush – Ghutti: 1 – 3 ml twice a day

IPR Status: Patent No:193336

3.12. AYURVEDIC FORMULATIONS FOR ANTENATAL CARE

Background

Pregnancy and child birth is a joyful event in every woman's life. The growing foetus is totally dependent on its own mother in every aspect. Thus a proper antenatal care would result in a good maternal and foetal outcome. Any negligence towards her health may lead to untoward effects and thus cause maternal & foetal complications or even could be fatal. Ayurveda has described *"Garbhini Paricharya" i.e.* antenatal care right from conception up to the birth of the baby. In Ayurveda, antenatal care comprises of *Aahar* (dietary regimens), Vi*h*ara (life style) and *Aushadhi* (medicines). In view of the potential of Ayurveda in promoting the health of pregnant women and foetus, it is high time to mainstream Ayurvedic management. The Central Council for Research in Ayurvedic Sciences, New Delhi has developed certain formulations viz. AYUSH AG Tablet, AYUSH PG Tablet, AYUSH GG Tablet and AYUSH AD candy for antenatal care to promote the health of pregnant women and foetus and minimize the complications associated with pregnancy and mortality rate mother and foetus.

Drug Profile:

AYUSH AG Tablet for Promotion of general health of woman and fetal growth

Sl. No.	Ingredient	Botanical Name
1.	Amalaki	*Emblica officinalis* Gaertn.
2.	Ashwagandha	*Withania somnifera* (L.) Dunal
3.	Shatavari	*Asparagus racemosus* Willd.
4.	Mandur bhasma	*Calcined of iron rust*
5.	Mukta shukti Bhasma	*Calcined shell of oyster pearl*

AYUSH GG tablet for Edema during pregnancy

Sl. No.	Ingredient	Botanical Name
1.	Gokshura	*Tribulus terrestris* L.

AYUSH PG tablet for Pregnancy Induced Hypertension (PIH)

Sl. No.	Ingredient	Botanical Name
1.	Gokshura	*Tribulus terrestris* L.
2.	Punarnava	*Boerhavia diffusa* L.

AYUSH AD tablet for prevention of Nausea and Vomiting during pregnancy

Sl. No.	Ingredient	Botanical Name
1.	Amalaki	*Emblica officinalis* Gaertn.
2.	Draksha	*Vitis vinifera* L.
3.	Ela	*Elettaria cardamomum* Maton

Safety/Toxicity profile:

1. **AYUSH AG Tablet:** No mortality in mice was reported at graded doses of Ayush-AG (100, 200, 500, 1000 and 2000/Kg, P.O) in acute toxicity study. Sub-Acute studies in 40 albino rats revealed that no significant changes in the haematology, blood biochemistry and weight of the vital organs in comparison to the control at the graded dose level of 200, 800 and 1600 mg/Kg continuous up to 15 days were observed.

2. **AYUSH PG tablet:** No mortality in mice was reported at graded doses of Ayush-PG (100, 200, 500, 1000 and 2000/Kg, P.O) in acute toxicity study. Sub-Acute studies in 40 albino rats revealed that no significant changes in the haematology, blood biochemistry and weight of the vital organs in comparison to the control at the graded dose level of 100, 500 and 1000 mg/Kg continuous up to 15 days.

Some Important Ingredients

***Amalaki* (*Emblica officinalis* Gaertn.)**

***Askwagandha* (*Withania somnifera* (L.) Dunal)**

***Gokshuru* (*Tribulus terrestris* L.)**

***Punarnava* (*Boerhavia diffusa* L.)**

Ela (*Elettaria cardamomum* Maton)

Shatavari (*Asparagus racemosus* Willd.)

Clinical efficacy

Clinical studies to ascertain the efficacy of above four coded Ayurvedic formulations were carried out by Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of AYUSH, Govt. of India with technical support from Indian Council of Medical Research (ICMR), Government of India in selected areas of two districts *viz.* Mandi & Kangda at Himachal Pradesh. Total 2465 participants were enrolled in the study and data of 1746 participants was analyzed. It is observed that the mean of Hb% at baseline was (1st trimester) 9.78 ± 0.79 and 10.11± 0.77 at the end of treatment which is statistically significant ($p<0.001$). Further, significant improvement in various outcome indicators such as minimal complications during pregnancy, achievement of full term pregnancy and no still birth and neonatal death were observed in the study. It is interesting to note that birth weight of most of the baby was comparable to standard i.e. $\geq$ 2.5 kg, which indicated the effect of interventions on neonatal health.

Dosage Schedule:

A. **AYUSH PG (Pregnancy Induced Hypertension):** 1 tablet (500 mg) BD for 7 to 15 days with water

B. **AYUSH AD (Prevention of Nausea and Vomiting during pregnancy):** To be kept in mouth SOS but not more than 8 in a day.

C. **AYUSH AG Tablet (Promotion of general health of woman and fetal growth):** 1 tablet (500 mg) TDS, from 3rd month onwards of pregnancy up to post-delivery – 3 months with water.

D. **AYUSH GG tablet:** 1 tablet (500 mg) BD during 6th to 8th month of pregnancy.

CHAPTER 4

FUNDAMENTAL RESEARCH (DISEASES AND DIAGNOSTIC)

Fundamental research is the sole of any science. Council is dedicatedly working in validation and standardization of the fundamentals of Ayurveda in all aspects viz. Clinical methods, diagnostics, literary, pharmaco-therapeutics in order to generate tangible evidence for Ayurveda.

Following work has been done in the fundamentals of diagnostic methods of Ayurveda

4.1 DEVELOPMENT AND VALIDATION OF *PRAKRITI* ASSESSMENT QUESTIONNAIRE/SCALE

The individualized treatment of diseases is the unique approach of Ayurveda which recognizes every individual with a specific constitution vis-à-vis *Prakriti.* Ayurveda classifies all individuals into specific types of '*Prakriti*' based on the theory of *Tridosha* (Three humours as functional entities of the body) *i.e. Vata, Pitta & Kapha* and their relative ratios. *Prakriti* of an individual is decided during the intra-uterine life which may be broadly envisaged into seven types i.e. relative predominance of one *dosha (Eka doshaja Prakriti*), three due to relative predominance of two *doshas (dwi-doshaja)* and due to the equilibrium of all the three *doshas (Sama Prakriti)). Sama Prakriti* persons are less susceptible to any disease while the rest of them are always likely to suffer. *Vataja Prakriti* persons are more prone to get afflicted with *Vataja* diseases (e.g. bodyaches, Joint disorders & neuro-muscular problems etc.), similarly *Pittaja Prakriti* individuals are prone to get afflicted with *Paittika* diseases (e.g. Acid peptic disorders, skin diseases & inflammatory reactions etc.) and *Kaphaja Prakriti* individuals are susceptible to *Kaphaja* diseases (e.g. respiratory diseases, worm infestations & itching problems etc.) during their life span.

The determination of *Prakriti* has significant importance in healthy / unhealthy states of an individual. This information can be successfully applied clinically in diagnosis, treatment (for deciding appropriate drug, dose, duration, diet and life style) and prognosis of the disease. Even the daily and seasonal regimens adopted for promotion of health also vary according to *Prakriti.*

For the determination of Prakriti, the characteristic features mentioned in Ayurvedic texts are subjective in nature and the clinicians/Ayurvedic experts apply their own wisdom and experience to capture these features. There is a need to develop a uniform method for capturing these predictors for assessment and reliability of the data which is lacking in the public domain. Based on these observations it was strongly felt that a *Standardized Prakriti Assessment Tool* is the need of the hour.

Considering the above facts, Central Council for Research in Ayurvedic Sciences (CCRAS), being an apex organization under Ministry of AYUSH, Govt. of India, New Delhi has undertaken the initiative to develop the *'Prakriti Assessment Scale'* with rationality, reliability, validity and reproducibility.

The project comprises the following major tasks

1. Development of a comprehensive questionnaire/scale for assessment of *Prakriti*
2. Development of SoPs for the application of questionnaire/scale in the form of User Manual
3. Validation of the questionnaire/scale
4. Development of Software for the validated Prakriti assessment tool

1. Development of a comprehensive questionnaire/scale for assessment of *Prakriti*

Following steps have been under taken-

a) Preparation of an exhaustive list of characteristic features (Predictors) for assessment of *Prakriti* available in the classical texts of Ayurveda (Pooling up of items)

All predictors for determination of the *Prakriti* as mentioned in the Ayurvedic classics viz. *Charaka Samhita, Sushruta Samhita, Ashtanga Samgraha, Ashtanga Hridaya, Sharangdhara Samhita, Bhavaprakash, Harita Samhita, Bheal Samhita, Yogaratnakara* and *Vangasena* were compiled together. An exhaustive list of 583 predictors has been prepared. Utmost care has been taken to include each and every possible predictor described in the classics. As the terminology of the predictors is in Sanskrit language, the nearest translation of each predictor has been determined in English after detailed discussions with Ayurveda experts of Basic principles (*Maulik Siddhant*), Medicine (*Kayachikitsa*) and other disciplines so as to match the

exact meaning with applied (clinical) approach. Wherever the exact correlate was not available, definition of the Sanskrit terminology has been given.

b) Reduction of predictors

The list of the predictors was thoroughly analyzed and it has been found that-

- some predictors are repetitive
- some are having same meaning with different terminology
- some predictors are the outcome indicators of a particular *Prakriti*
- some predictors are difficult to assess due to ethical issues.

All the above points has been considered to reduce the predictors in the manner elaborated below:

Predictors recurring twice/ multiple times were removed to avoid repetition. e.g. *Bhurikrodha* (Short tempered) is mentioned both in *Ashtanga Samgraha* & *Ashtanga Hridaya*; *Dantakhadi* (Grinding of teeth during sleep) is mentioned in *Ashtanga Samgraha* & *Sushruta Samhita*; *Ashrita-vatsala (Affectionate to dependants) in Ashtanga Samgraha and Ashtanga Hridaya*; *Shighrakshobha* (Quickly gets agitated) in *Charaka Samhita* & *Ashtanga Samgraha*; *Alpakrodha* / *Shanta* (Calm & patient) in *Ashtanga Hridaya* & *Charaka Samhita*; *Kritaghna* (ungrateful) is mentioned both in *Ashtanga Hridaya* & *Sushruta Samhita.* The number of predictors after reduction is 471.

It has also been found that some predictors are nearly synonyms or equivalents as they are conveying the similar meaning clinically e.g. *Apachita* (*Charaka Samhita)/Krisha* (*Sushruta Samhita)/Krisha akriti (Ashtanga Hridaya*) were conveying the clinical sense as thin built only. As per linguistics these terms though are dissimilar, but are capturing similar features clinically. Thus such type of terms have been merged together, i.e. all such terms have been reduced into one predictor.

Further, some predictors are found as probable outcome indicators of a particular *Prakriti* and not directly helpful in assessing the *Prakriti* e.g. *Bahuapatya* in Kaphaj *Prakriti*; *Alpadhana* in Vataj *Prakriti*; Madhyabala in Pittaja *Prakriti*. Further, the predictors that are difficult to

assess on ethical ground like *Kalahapriya* (quarrelling in nature), etc. have also been removed from the list.

After reduction by following the above methods, the number of predictors has been reduced to 215 from 583.

c) The method developed for capturing of each predictor

The methods for capturing these predictors have been discussed in a series of consultative expert group meetings comprising of experts from both Ayurveda and modern fraternity (as required). After several discussions, the methodology to capture each and every predictor clinically has been taken into account. As the predictors are features related to physical, physiological, psychological and behavioural traits, they are broadly grouped into these four traits which are further sub-grouped into various domains e.g. built, appearance, skin texture etc.

It has been inferred that three methods can be applied for capturing the predictors i.e. (i) Anthropometric measurement, (ii) Observation and (iii) questionnaire

2. Development of SoPs for the application of questionnaire/scale in the form of User Manual

The Standard Operative Procedures (SOPs) for capturing each predictor have been developed by adopting above methodology. The same has been elaborately discussed in '***National Consultative Expert Group Meet***' comprising of learned experts from various fields of Ayurveda and other contemporary sciences for content validity.

3. Validation of the questionnaire through multi-centre studies for construct validity of developed *Prakriti* assessment Scale

For construct validity the developed scale has been given to 20 Ayurvedic physicians, already trained on User Manual, at 10 centers situated at different geographical regions of the country for a sample size of 500. Online Data capturing Form has also been developed for easy collection of the data and it's day to day monitoring. In this double blind validation process, two Ayurvedic physicians at each center have applied the scale on the same person at different times (minimum seven days interval) keeping their findings confidential so as to generate the data of 50 apparently healthy volunteers at each center. Data from 10 centers has been

analyzed and same has been discussed in a meeting comprising of all the Investigators and experts. Based on the inputs from the meeting the User Manuals and data capturing form have been again modified and sent to the participating centers for data collection. Analysis of the data will be carried out after completion of the target population at all participating centers.

Future Strategy

After data analysis and inputs from the investigators, necessary changes as required will be made in the *Prakriti* Assessment questionnaire to make it more comprehensive & user friendly making further reductions which will be subjected for final validation. After standardization of *Prakriti* Assessment Scale, the study on correlates of *Prakriti* with genomes and other relevant factors may be planned to establish the concept of *Prakriti* on scientific footings.

4.2. VALIDATION AND RELIABILITY TESTING OF AYURVEDA DIAGNOSTIC TOOLS

Diagnosis forms the most important part of any medicine as this directly influence the outcome of any treatment. Diagnosis in Ayurveda can be grouped into *Roga Pareeksha* and *Rogi Pareeksha*. The examination of disease is done through *nidana panchaka* (*Nidana, Purvarupa, Rupa, Upasaya- Anupasaya* and *Samprapthi*) and *Rogi Pareeksha* is done through *Astasthana* and *Dasavidha Pareeksha* commonly. Ayurveda has dealt with these examination methods in depth but attaining a uniform diagnosis encompassing all these factors after detailed examination still remains difficult. Bio-medicine has come up with excellent tools of case recording for the purpose of diagnosis. Current Ayurveda graduates are exposed to both systems and though there is an arbitrary system in place to achieve the objective of clinical case recording, the reproducibility in terms of measurable parameters is non-uniform and hence the diagnosis comes out vague. Keeping in view, it's the need of the hour to "prepare standardized diagnostic protocol(s)/tools" which are aptly integrated with latest Information Technology tools such as *Internet of things* (IoT) to aid Ayurvedic Physician in proper diagnosis and assessment of *roga, rogibala* and achieve the objective of "*Anapayi Chikitsa*".

Objective (s)

To develop Standardized Ayurvedic Case Taking Protocol(SACTP) in consideration with elements of diagnosis/Case recording from Ayurveda and current Standard health record format(s) is the primary objective and developing standard diagnostic protocols for selected diseases frequently managed is considered in conjunction for uniform diagnosis. Developing an interface for integration/ Customization and development of diagnostic gadgets which are integrated with latest information technology tools for accurate and easy diagnosis is the secondary objective.

Methodology

A Standardized Ayurvedic Case Taking Protocol incorporating comprehensive patient history, recording the disease in Subjective, Objective, Assessment and Plan (SOAP) format wherein subjective and objective parameters are recorded in problem oriented medical record format (POMR) examination of etiology, recording of parameters of *Dasavidha Pareeksha*, in-depth recording of *Samprapthi Ghataka* to assess pathogenesis of the disease is to be prepared and it includes the following steps:

1. Preparation of inventory of items(literary compilation)
2. Section wise preparation of items (questionnaires)
3. Item wise feasibility testing (field testing)
4. Integration of clinical case recording elements(SACTP)
5. Validation testing
6. Reliability Testing
7. Release of Standardized Ayurvedic Case Taking Protocol(SACTP)

CHAPTER 5

RESEARCH PROJECTS

Central Council for Research in Ayurvedic Sciences (CCRAS), an Autonomous body under Ministry of AYUSH, Govt. of India is an apex body in India for undertaking, coordinating, formulating, developing and promoting research on scientific lines in Ayurvedic Sciences. The Minister of AYUSH, Govt. of India is the President of the Governing Body of the Council, while the Joint Secretary chairs the Standing Finance Committee. The Scientific/Research Programs are supervised by the Scientific Advisory Board and Scientific Advisory Group.

The Council has been executing its research programs with a network of 30 peripheral Institutes/centres/units with the headquarters office responsible for control, monitoring and supervision. Research work of the Council is executed by 792 officers and staff, though the sanctioned strength of officers and staff is 1983 and also through collaborative studies with various Universities, Hospitals and Institutes.

5.1. AREAS OF RESEARCH

The broad areas of research comprises of:

- Clinical Research
- Fundamental Research
- Pharmacology Research (Preclinical Safety/Toxicity and Biological Activity Studies)
- Medicinal Plant Research (Medico-Ethno Botanical survey, Cultivation, Pharmacognosy) Drug standardization Research
- Literary Research & Documentation

The outreach activities include Tribal Health Care Research Program, *Swasthya Rakshan* Program, Ayurveda Mobile Health Care Program under Scheduled Castes Sub Plan (SCSP), Integration of AYUSH (Ayurveda) with National Program for Prevention and Control of Cancer, Diabetes, Cardio-vascular disease and Stroke (NPCDCS), Information, Education and Communication (IEC) etc.

Among these research areas the council is working in following aspects in clinical and fundamental research:

5.1.1. Clinical Research:

Validation and development of formulations for disease/clinical conditions viz. Fistula-in-Ano, Epilepsy, Filariasis, Cardiovascular disease, Hemiplegia, Malaria, Obesity & Lipid disorder, Paraplegia, Peptic Ulcer, Sciatica, Urolithiasis, Mental Retardation, Bronchial Asthma, Chronic Bronchitis, Cognitive Deficit, Dry Eye Syndrome, Allergic Conjunctivitis, Dyslipidemia, Essential Hypertension, Irritable Bowel Syndrome (IBS), Iron Deficiency Anaemia, Menopausal Syndrome, Osteoarthritis, Obesity, Osteopenia / Osteoporosis, Rheumatoid Arthritis, *Rasayana* (Geriatric Health), Dysmenorrhea, Type II Diabetes Mellitus, Psoriasis, Generalized Anxiety Disorder, Haemorrhoids, Polycystic Ovarian Syndrome, Uterine fibroids, Computer vision syndrome, Gout etc. 17 Ayurvedic formulations for Reproductive and Child Health Care (RCH) program have also been developed. Further, the Council has been conducting clinical research in collaboration with reputed institutes in certain disease conditions/areas viz. improving quality of life in cancer patients, Mental Retardation, geriatric health.

5.1.2. Fundamental Research:

Steps have been taken to develop a Standardized Questionnaire for Assessment of *Prakriti* and its relevance with the parameters of health and disease and also diagnostic tools are under study for validation and formation of a standard assessment tool.

5.2. ONGOING INTRA MURAL CLINICAL RESEARCH PROJECTS

Apart from various clinical research work done by council mentioned in preceding chapters following projects are going on at present in the council.

1. Clinical evaluation of efficacy of *Panchtiktaguggulu Ghrita* and *Brihanmarichadya Taila* in the management of Psoriasis w. s. r. to *Pathya-apathya*
2. Clinical evaluation of *Goksura churna* and *Sveta parpati* in the Management of *Mutrasmari* (Urolithiasis)
3. Clinical Evaluation of *Khadirarishta* and *Kanchanara guggulu* in the management of Uterine Fibroids- An exploratory study.
4. Clinical evaluation of *Punarnava Guggulu* and *Rasna Saptaka Kashaya* in the management of Rheumatoid Arthritis (*Amavata*)
5. A Clinical evaluation of *Triphala Guggulu* and *Kasisadi Taila* in the management of *Arsha* (Haemorrhoids)

6. Therapeutic evaluation of *Rasnadi Gutika* and *Chandrakala lepa* in *Janusandhigata vata* (Osteoarthritis)
7. Clinical evaluation of *Kaishore Guggulu* and *Madhusnuhi Rasayana* in the management of GOUT (*Vatarakta*)
8. Clinical evaluation of *Abhadya Churn*a and *Muktashukti Bhasma* in the management of Osteopenia / Osteoporosis (*Asthikshaya*)
9. Clinical evaluation of *Laksha Guggulu* and *Muktashukti Bhasma* in the management of Osteopenia/Osteoporosis
10. Clinical Evaluation of Certain Ayurvedic Formulations In The Management of *Sthoulya* (Obesity)
11. Clinical evaluation of *Panchamrit Lauha Guggulu* and *Panchgunataila* in the management of Cervical Spondylosis (*Greevagraha*)
12. Clinical evaluation of *Mandura vataka* in the management of Iron Deficiency Anaemia
13. Clinical evaluation of *Sukumara Ghritam* and *Brahmi Churnam* in the management of Menopausal Syndrome
14. Clinical evaluation of *Haridrakhand* and *Triphala Kwath* in the management of Chronic Allergic Conjunctivitis (*Kaphaja Abhishyanda*)
15. Clinical Evaluation of *Shwadanshtradi Kashaya & Hajarulayahuda Bhasma* in the management of *Mutrashmari* (Urolithiasis)
16. Clinical evaluation of *Maha Rasnadi Kvatha*, *Trayodashanga Guggul* and *Brihatsaindhavadya Taila* in the management of Knee (*Janugata Sandhivata*)
17. Clinical evaluation of *Kalyanak Ghrita* in the management of Cognitive Deficit (*Smriti Daurbalya*)
18. Clinical efficacy of *Sitopladi Churna* in the management of *Kasa* (Stable Chronic Bronchitis)

5.3. RESEARCH ACTIVITIES IN NEW DRUG DEVELOPMENT

In order to disseminate the knowledge of newly developed drugs the councils is working towards commercialization of these drugs.

Table 5.3.1. List of Technologies Transferred To Industry by CCRAS (10)

S. No	Product Name	Process
1.	AYUSH-64	A process for the preparation of a therapeutically active anti-malarial preparation.
2.	AYUSH Ghutti	A herbo-mineral formulation for cough and cold
3.	AYUSH –SS granules	A process for preparation of an Ayurvedic herbal compound preparation for post-natal care (to enhance the quality and quantity of breast milk in mother having deficient lactation)
4.	AYUSH AG Tablet	A process for preparation of an Ayurvedic herbal compound preparation of AYUSH AG Tablet (*Shatamuli Mandura*) for Ante natal care
5.	AYUSH PK Avleha	A process for preparation of an Ayurvedic herbal compound preparation of AYUSH *Panchkola Avleha* for post-natal care (to enhance the process of recovery after delivery and other complications of puerperal period)
6.	AYUSH PG Tablet	A process for preparation of an Ayurvedic herbal compound preparation of AYUSH PG Tablet for Ante natal care
7.	AYUSH B R Leham	A process for preparation of an Ayurvedic herbal compound preparation AYUSH *Bala Rakshak Leham* for pediatric care
8.	AYUSH KVM Syrup	A preparation for the treatment of running and stuffy nose, productive or non-productive cough with or without fever and to a process for the preparation thereof for Paediatric care
9.	AYUSH 82	An Anti-Diabetic Ayurvedic Formulation
10.	AYUSH SG	An Anti-Rheumatoid Arthritis preparation

5.4. DRUG DEVELOPMENT STUDIES IN PROGRESS

CCRAS has undertaken the development of the various coded formulations for different disease conditions

Mental retardation/cognitive deficit: CCRAS has completed a multi centric clinical study for validation of a coded drug named AYUSH Manas drug for Mental retardation/cognitive deficit.

Cancer: CCRAS has undertaken work for developing a coded drug named AYUSH QOL 2C for improving Quality of Life of Cancer patients in stage III & IV Non Small Cell Lung Cancer and patients of Local Non-Metastatic Breast Cancer to prevent side effects of Chemotherapy. Clinical study for this has been completed successfully.

Geriatric health: Collaborative Multi-centric Clinical trial to study the effect of Ayush Rasayana (A&B) on Ageing on apparently healthy elderly subjects is going on at AIIMS New Delhi, IMS BHU and CARIDD Kolkata.

Wound healing: Controlled clinical Trial to assess the effectiveness of topical application of C1 herbal oil on superficial external wound and split thickness skin graft donor's site for surgical wound healing at AIIMS New Delhi.

Dengue: CCRAS is working on a collaborative research work for the assessment of safety and efficacy of a coded drug AYUSH PJ-7 for the management of Dengue

Apart from these collaborative studies are going on for the development of coded drug for several disease of National importance including: AYUSH M-3 for Migraine, AYUSH SL for Filariasis, AYUSH A for Bronchial Asthma, AYUSH D for Type II Diabetes Mellitus, Carctol S for Cancer, AYUSH K1 for Chronic Kidney Diseases which are at different phases of drug development. These studies are being conducted in collaboration with reputed institutes like AIIMS New Delhi, NIMHANS Bengaluru, BHU, ICMR, St. John's Medical College Bengaluru etc.

5.5. CCRAS INITIATIVES IN RESEARCH TOWARD INTEGRATION OF AYUSH WITH MODERN SYSTEM OF MEDICINE

Integration of all system of medicine with true medical pluralism can be the way forward to achieve the ultimate goal of health for all in preventive and curative aspect without putting burden on national budget as mentioned in National Health Policy 2017. CCRAS has undertaken following work toward integration of AYUSH system of medicine:

Integration of Ayurveda in RCH program: CCRAS carried out the study in a pilot mode for introducing Ayurveda health care system in the conventional system for Antenatal, postnatal and neonatal care with technical support from Indian Council of Medical Research (ICMR), Government of India. It was implemented in some selected areas of Himachal Pradesh. Significant improvement in various outcome indicators such as improvement in

Hb%, minimal complications such as vomiting, oedema etc. during pregnancy, achievement of full term pregnancy and zero still birth and neonatal death were observed in the study. No adverse drug reaction (ADR) or adverse event (AE) was reported during the study period.

Osteoarthritis (Knee): The Council-WHO India country office conducted an operational study to explore the feasibility of integrating Ayurveda with modern system of medicine in a tertiary care hospital (Safdarjung Hospital New Delhi) for the management of Osteoarthritis (Knee) in 2007. The Ayurvedic treatment provided to 201 patients was found effective in the management of Osteoarthritis Knee with respect to reducing the symptoms, improving the quality of life and reducing the intake of rescue medication (analgesics). The project established a cross referral system and revealed a shift in service seeking behaviour of the patients.

Integration of AYUSH (Ayurveda) with National Program for prevention and control of Cancer, Diabetes, Cardio-vascular disease and Stroke (NPCDCS) Program: CCRAS, Ministry of AYUSH in collaboration with Directorate General of Health Services, Ministry of Health & Family Welfare has implemented and executed a program viz. Integration of AYUSH (Ayurveda) component with NPCDCS program in the identified districts of 3 states, **Bhilwara (Rajasthan), Surendranagar (Gujarat) and Gaya (Bihar)** to cater health care services and reduce the burden of NCDs by combining the strength of Ayurveda and Yoga.

The aforesaid program is now successfully functional in 52 centers (49 CHCs and 3 District Hospitals) of the all 3 identified districts, through AYUSH- NPCDCS Clinic/Lifestyle modification Clinics, established for prevention and management of selected NCDs by Ayurvedic intervention, Lifestyle modifications and Yoga Advice. An interim analysis has revealed that the dosage or components of conventional medicines/ prescription were either reduced or discontinued, in consultation and supervision of Modern doctors, after integrating the intervention of Ayurveda, lifestyle modification & Yoga in patients of Diabetes, Hypertension and Dyslipidemia. Till December 2017, **241886** patients have been screened and, out of which **54991** patients have been enrolled for selected NCDs under this program. Total beneficiaries of Yoga classes are **84,418**.

CHAPTER 6

Books and Monographs

Background: The council is dedicated in dissemination of its research finding through monographs and book publications. Since inception the council has published more than 266 books and monographs apart from 5089 research publications. Among them 29 research work are done in clinical research.

Following are some of the major publications done by the council.

6.1. Journal of Drug Research in Ayurvedic Sciences

Publication **Quarterly**

ISSN 2279-0357

Description Journal of Drug Research in Ayurvedic Sciences (JDRAS), is a peer-reviewed, open accessed journal of Central Council for Research in Ayurvedic Sciences (CCRAS). The journal is published quarterly and is available in both print and digital form. It is devoted to the Indian traditional knowledge especially in Ayurveda. The journal publishes editorials, original articles, case studies, review articles, research articles, correspondence, book reviews, etc. pertaining to Drug Research with special emphasis on Ayurveda in the following areas:

- Drug development and Pharmaceutical Research in Ayurveda (Dravyaguna, Rasa Shastra and Bhaishajya Kalpana etc.)
- Fundamental and Applied aspects of Drug Research in Ayurveda
- Phytochemistry, Quality Control and Drug Standardization including Pharmacognosy
- Pharmacology/Toxicology Research
- Biochemistry, Molecular Biology and Biotechnology
- Local Health Traditions (LHTs/ Folk Medicine/ Ethno-Medicine)
- Medicinal Plant Research (Medico-Ethno Botanical Survey and Cultivation of Medicinal Plants)
- Any other areas of related field etc.

6.2. Journal of Research in Ayurvedic Sciences

Publication Quarterly

ISSN 2456-5601

Description

Journal of Research in Ayurvedic Sciences (JRAS) is a peer-reviewed, open access journal of Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi. The Journal is published quarterly and is available in both print and online form. It is devoted to Research in Ayurveda, the Indian traditional health care system. The Journal publishes Editorials, Original Articles, Case Studies, Reviews, Technical reports of projects, Correspondence and Book Reviews, etc. pertaining to Ayurveda with special focus on Original and Review Articles on the following:

- Clinical Research focusing on Clinical safety and Efficacy.
- Fundamental Research on various aspects Viz. diagnosis and development of diagnostic tools, disease course and disease management based on Ayurvedic concepts.
- Health promotion and preventive medicine.
- Studies on Health Seeking Attitude and Medico-Social aspects including medical anthropology.
- Health Systems Research with focus on Ayurveda and Traditional medicine.
- Epidemiological studies and health related demography.
- Development of methodologies of Clinical Research Related to Ayurveda and Traditional Medicines.
- Pharmacovigilance and pharmaco-epidemiology.
- Integrative Medicine.
- Any other areas of related field etc.

6.3. Medicinal Plants in Geriatric Health Care: An Evidence Based Approach

Year of Publication: 2008

Description A vast number of indigenous plant drugs coupled with innumerable claims of their varied uses in alleviating wide range of Geriatric problems calls for scientific validation for their attributes and principles. The present compendium comprises of information on about 35 Ayurveda and Siddha medicinal plants used in Geriatric Care, common formulations and a profile of evidence based research on safety and clinical efficacy.

6.4. Brain Ageing Ayurveda

Year of Publication **2008**

Description

Ayurveda signifies science of longevity, having holistic approach to health. The Ayurveda stress on prevention rather than cure only. Utilizing this approach the authors have compiled their original work and experiences in the form of this book, which may be useful not only for the elderly but for the planners and the common public. Considering the complexities of neurodegenerative disorders that the etio-pathogenesis of diseases ranges from oxidative injury, autoimmune complexities, inflammatory markers to platelet aggregations, from synthesis and degradation of amyloid proteins to neurotransmitters, from cerebro-vascular pathology to neuronal degeneration, this book is an effort to document the potential role of single and polyherbal Ayurvedic formulations in the prevention and management of age related neuro-psycho physiological deterioration.

6.5. Tribal Health Care Research Programme (Assam) Guwahati

Year of Publication: 2002-2008

Description

The present monograph covers the information concerning the health statistics, collected during the survey conducted by Regional Research Institute (Ayurveda), Guwahati under THCRP (Tribal Health Care Research Programme) of the council. The study was carried out on individuals of randomly selected 22 villages for a period of six years in remote areas of Assam, during 2002-2008.During the survey it was noted that diseases like *Twakroga* (skin diseases) *Kasa* (bronchitis), *Amlapitta* (hyperacidity), *Jvara* (pyrexia) etc. Are prevalent in these areas. Besides this, the common and most prevalent health practices /claims in these communities have been recorded.

6.6. Ayurvedic Management of Common Disease Conditions

Year of Publication **2013 (Vol-1)**

ISBN 978-81-910195-9-9

Description

As per Ayurvedic principles, diseases are caused due to an imbalance in the tridosa due to various factors. In such cases several descriptions regarding medicines and various procedures along with lifestyle and diet modifications have been prescribed in Ayurvedic texts for restoration of health. This book is a compilation of such basic information about the management of some common diseases which can be managed by Ayurveda. It covers general information about the disease, preventive aspect, curative (medicines, therapies and yoga) and promotive aspects (lifestyle and dietary advises) with approximate cost of the selected treatment modalities.

6.7. Clinical Evaluation of certain Ayurvedic Formulations In the Management Of Mental Retardation

Year of Publication 2011

ISBN 978-81-910195-3-7

Description: This monograph is based on the date of clinical trial of selected Ayurvedic herbal preparations in mental retardation (manasa mandata) conducted at Dr. Achanta Lakshmipati Research Centre for Ayurveda (ALRCA) , Chennai of the council during 1973to 1975,1975to 1977and 1992to 1995.

6.8. Clinical Studies Of Certain Ayurvedic Formulations In the Management of Paraplegia (Pangu)

Year of Publication 2010

Description

The present work consisting of the date of clinical studies conducted on Pangu (paraplegia) with studies of different Ayurvedic formulations. Each study comprises of two groups. These studies were conducted at two peripheral research institutes of CCRAS. These studies were carried out with the objectives to find out more effective herbomineral formulations for the management of Pangu. A total number of 235cases of Pangu were diagnosed and recruited for clinical research as per the protocol specially prepared by the Council.

6.9: Clinical Safety And Efficacy of *Dhatri Lauha* (A Classical Ayurvedic Formulation In Iron deficiency Anaemia (*Pandu Roga*)

Year of Publication: 2010

ISBN 978-81-907420-2-3

Description

The present work consists of the data of multicentric clinical study conducted on Iron Deficiency Anaemia (*Pandu Roga*) with an Ayurvedic formulation, *Dhatri Lauha*. The objective of current study was to assess the clinical safety and efficacy of *Dhatri Lauha* in the patients of Iron Deficiency Anaemia through measurable objective parameters. This multicentric study was conducted in 12 peripheral research institutes of Central Council for Research in Ayurveda and Siddha to evaluate the safety and efficacy of *Dhatri Lauha* with 45days of treatment.

6.10 Ayurvedic Management Of Select Geriatric Disease Conditions

Year of Publication: 2010

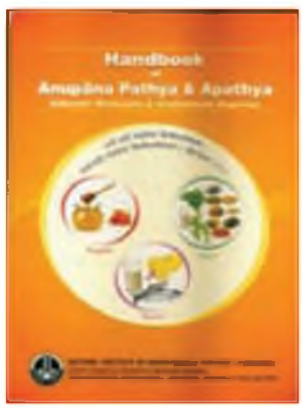
ISBN 978-81-907420-2-3

Description:

The CCRAS and WHO India country office have joined together for developing a concise and comprehensive document on Ayurvedic Management of Selected Geriatric Disease Conditions (Treatment Protocols for Geriatric Disorders) focusing on general information about the disease, diagnosis, preventive aspect, treatment (medicines, procedure based therapies and yoga), general and dietary advises and the approximate cost of the treatment modalities.

6.11 : Hand Book of Anupana Pathya Apathya

Year of Publication: 2012



Description: The knowledge of Anupana and dietary regimen is essential for an Ayuvedic physician who very judiciously plans and administers the treatment. A wise physician who has in depth understanding about these concepts succeeds in the management of patient care.

In order to create awareness and rationality regarding diet and dietetics, this handbook has been designed based on diseases from various classical texts of Ayurveda.

6.12: Reported Medical Practices on Prevention, Management of Vector Borne And Infectious Diseases through Ayurveda And Siddha

Year of Publication: 2010

ISBN 978-81-907420-3-0

Description

The council initiated a multicenter intramural project on **"Documentation of reported medical practices/claims on prevention and management of Vector borne/infectious diseases through Ayurveda and Siddha"** and executed through field institutes located in different states across the country. The information gathered from various sources viz. Ayurvedic colleges, physicians from Ayurveda, Siddha Hospitals, dispensaries, clinics, private physicians, local healers, NGOs etc. has been systematically recorded in a specially developed information generation tool format and documented.

6.13: Inventory of Animal Products Used In Ayurvrda Sidda And Unani

Year of Publication: 2008 (Part-I)

ISBN 978-81-907420-0-9

Description: This book on "Animal Inventory" is unique work of CCRAS, which describes General In- formation, Habitat and Morphology, Parts Used for Medicinal/ Cosmetic uses described in different Systems of Medicine and Classical Formulations. Considering the significance of Medicinal and cosmetic uses of animal products, this work is carried out with certain basic objectives and methodology: To identify Animal Bio-Resources used in

Ayurveda, Siddha, Unani and Homoeopathy Systems and for Cosmetic purpose. To identify parts used for Medicinal/ Cosmetic purpose, indications (General and Specific of these resources). To collect information about single drug/ compound drug formulations wherein, animal bio-resources are ingredients and to identify pharmacies manufacturing such drugs, from published data like research papers, authentic texts etc. To descried the method of preparation of these drugs. To design a format for uniformity in collection and presentation of data on animal resources.

6.14: Inventory of Animal Products Used In Ayurvrda Sidda And Unani

Year of Publication 2008, (Part-II)

ISBN 978-81-907420-1-6

6.15: Clinical Safety of Selected Ayurvedic Formulations and Panchakarma Procedures

Year of Publication: 2008

Description: Panchakarma is a unique bio-cleansing regimen of Ayurveda comprising of five procedures. The Council has conducted huge research on revalidation of the clinical safety, efficacy of Panchakarma therapy and generated scientific evidence base concerning its safety and efficacy as well, this book comprises of a comprehensive information on safety of certain Ayurveda formulations and Panchkarma procedure based on the research work done.

6.16: Clinical Studies of Certain Ayurvedic Formulations in the Management of *Vyanabala Vaisamya* (Essential hypertension)

Year of Publication: 2009

Description: The monograph is based on the data of clinical research studies conducted on 1598 subjects at 15 peripheral research institutes of the Council during 1983 to 2007. The scientific research studies were focussed on establishing the clinical safety and efficacy of certain Ayurvedic formulations viz. Combinations of *Vaca, Bramhi, Jatamansi* and *Arjuna* (Study -I); *Candraprabha Vati*, *Punarnava mandura* and *Sweta Parpati* (Study-II) and the drugs used in Study-I along with Yoga and Meditation (Study-III)

6.17: Report of Pharmacological Profile and Safety/ toxicity of Yogaraj Guggulu and Mahanarayana Taila (Classical Formulations)

Year of Publication: 2014

ISBN 978-93-83864-00-3

Description: The present volume contains standard manufacturing procedures including in process standardization, final product standardization with chromatography techniques and preclinical studies in laboratory animals which will prove useful not only for Ayurvedic doctors but also for scholars of other specialties. This monograph contains standard manufacturing procedure including standardization, biological activity and safety studies of *Yogaraj Guggulu* and *Mahanarayana taila* in lab animals. The results showed the anti-arthritic activity of both the dregs and also found to be safe at their therapeutic dose levels in animals. This will prove useful not only for Ayurvedic practitioners but also for scholars of other specialities.

6.18: Evidence Based Safety of Ayurvedic Herbo- Mineral Formulations

Year of Publication: 2015
ISBN 978-93-83864-10-2

Description: The information form published sources such as books, monographs, journals, and wed based search engines etc .has been compiled, systematically arranged and edited by experts in concerned fields to make the document as an authentic source of reference.

6.19: Healthcare Seeking Trends in Ayurveda – A CCRAS Perspective

Year of Publication: 2015
ISBN 978-93-83864-09-6

Description: This document is an attempt to present the data healthcare seeking behaviour of the patients attending CCRAS units for various illnesses. The data available in our annual reports of 24 Institutes from year 2009-10 to 2011-12 have been analysed by using appropriate scientific methods and presented in this document by a team of committed officers. The document demonstrates age wise, gender wise data of about 62 lakh patients distributed in six geographical zones of India. However, this sample size may not represent the entire population of India because CCRSA units attract patients on the basis of their specific research mandate. Moreover, majority of CCRSS clinical units are located in major cities only.

6.20: Validation Studies of Vamana Procedure

Year of Publication: 2015
ISBN 978-93-83864-13-3

Description: Validation studies of the *Vamana* have been planned to document physiological changes in the volunteer, the progress of the procedure and the safety of procedure. It also gives a clear idea about the acceptance and tolerance of the procedure by the volunteers in modern era. This monograph is an untiring effort made by the contributors to analyse and comprehend the *Vamana* procedure in light of science and bring it to all the academician, scientists, physicians and researchers.

6.21: Salakyatantra Ayurvediya Netraroga Vijnana

Year of Publication: 2016

Description:

The present work documents Ophthalmological information in Ayurvedic literature spanning form ancient to present era. This comprises an account on antiquity of Ayurvedic Ophthalmology; description of Eye diseases: management of Eye diseases by medical measures and enumerates single drugs of plant, mineral and animal origin; and compound Ayurvedic formulations along with their therapeutic use in different ophthalmic conditions. Further, the work also provides information on pharmacological and clinical studies carried out on Ayurvedic drugs and formulations in different ocular conditions. These findings evidence the safety and efficacy of Ayurvedic drugs and therapies in Eye diseases.

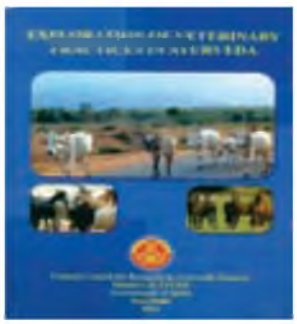
6.22: A Practical Handbook of Panchakarma Procedures

Year of Publication 2016

Description: This book deals with the commonly practiced, popular Panchakarma procedures in simplified form for the benefit of students and Ayurvedic practitioners. It has been tried to give the material requirements, name and doses of commonly used medicines with administration time, indications and contraindications with necessary photographs. The assessment of minimum required manpower in various procedures has also been done. This book also recommends space and staff requirements for a model Panchakarma unit. Textual references are also given wherever possible.

6.23: Exploration of Veterinary Practices in Ayurveda

Year of Publication: 2016



Description: Exploration of veterinary practices in Ayurveda is an intramural research project sanctioned by Central Council for Research in Ayurvedic Sciences. The main objective of the study is identifying, Compiling categorizing and finally exploring the Ayurvedic Veterinary manuscripts/ rare books for potential Veterinary practices.

List of monographs and books published by the council

Table 6.1. Publication on Clinical Research:

Sl. No.	Name of Book	Year of Publication
1.	Aetio-pathogenesis and Treatment of Timira with Saptamrta Lauha and Mahatriphala Ghrita (E)	1987
2.	Ayurvedic Drugs in the Management of Cancer (E)	1999
3.	Ayurvedic Management of Arsha (Haemorrhoids) - English	1999
4.	Ayurvedic Management of Unmada (Schizophrenia) - English	1999
5.	Ayush-56 An Ayurvedic Anti-Epileptic Drug	1987
6.	Ayush-64 A New Anti-Malarial Herbal Compound (English)	1987
7.	Clinical & Experimental Studies on Rasayana Drugs & Panchakarma Therapy (English)	1993
8.	Clinical and Experimental trial on Guggulu in Medoroga (Lipid disorders)	1989
9.	Clinical Studies of Certain Ayurvedic Formulations in the Management of Vyanabala Vaisamya (Essential Hypertension)	2009
10.	Clinical Studies of Certain Ayurvedic Formulations in the management of Paraplegia (Pangu)	2010
11.	Clinical Studies of Certain Ayurvedic Formulations in the Management of Mutrashmari (Urolithiasis)	2009
12.	Clinical Studies on Kamala (Jaundice) and yakrid Roga (Liver disorders) with Ayurvedic Drugs (English)	1988
13.	Effect of Varuna (Crataeva Nurvala) in Enlarged Prostate, associated urinary disorders (English)	1987
14.	Management of Bhagandara (Fistula-in-Ano) with Kshara-Sutra (English)	1989
15.	Management of Hemiplegia by Panchakarma & Shamana Therapy (English)	2000
16.	Management of Khanja and Pangu (English)	1999

17.	Management of Mutrasmari by Three Ayurvedic Drugs Varuna, Kulattha and Gokshuru (English)	1987
18.	Parinamashula - A Report of Assessment of Classical Therapy (English)	1979
19.	Study of Health Statistics under Mobile Clinical Research ProgrammeAyurveda (English)	1987
20.	Tamaka Shwasa (Bronchial Asthma)- A Clinical Study (English)	1997
21.	Clinical Evaluation of Certain Ayurvedic Formulations in the Management of Mental Retardation (Manasa Mandata)	2011
22.	Clinically Safety and Efficacy of Dhatri Lauha (A Classical Ayurvedic Formulation) in Iron Deficiency Anaemia (Pandu Roga)	2010
23.	Reported Medical Practices on Prevention, Management of Vector Borne And Infectious Diseases Through Ayurveda and Siddha- A Technical report	2010
24.	Management of Chikungunya Through Ayurveda and Siddha – A Technical Report	2009
25.	Good Clinical Practices- Guidelines for Clinical Trials in Ayurveda, Siddha and Unani Medicine	2013
26.	Evidence Based Ayurvedic Practices (E)	2014
27.	Evidence Based Ayurvedic Practices (H)	2014
28.	Evidence Based Safety of Ayurvedic Herbo-Mineral Formulations.	2015
29.	Validation studies of Vamana Procedure	2016

Apart from these some other publications done by the council related with clinical research

Table 6.2.Other Publication

Sl. No.	Name of Book	Year of Publication
1.	Woman and Child Health Care Through Ayurveda and Siddha	2009
2.	Workshop on Rasashastra – Souvenir	1992
3.	Seminar on Research in Ayurveda and Siddha March 20-22, 1995 – Abstract	1995
4.	Samanya Rogahar Vanaspatiyan (Hindi)	1987
5.	Rogotpatti Swarop Vimarsh	1992
6.	Manual on Geriatric Health Care Through Ayurveda	2009
7.	Museum Guide Part I	1970
8.	Museum Guide Part II	1971
9.	National Campaign on Ayurveda and Siddha for Geriatric Health Care 23rd – 24th Jan, 2008	2009
10.	National Campaign on Role of Ksharasutra (A minimal invasive Ayurvedic Para-Surgical Measure) in Ano-Rectal Disorders	2008
11.	National Workshop on Quality Control of ASU Drugs with Pharma Industry as a Partner 24th Jan.,2009, Patiala	2009

12.	Parameters for Quality Assessment of Ayurveda and Siddha Drugs Part-A	2005
13.	Peruvoside and other Cardiotonic Glycosides of Thevetia Neriifolia Juss. (E)	1972
14.	Souvenir – Silver Jubilee Celebration 1969-94	1994
15.	Standard Nomenclature of Ayurvedic Medicinal Plants (English)	1999
16.	Directory of CCRAS	2009
17.	Hand book of Domestic Medicine and Common Ayurvedic Remedies (E)	2005
18.	Essential Ayurvedic Drugs for Dispensaries & Hospitals	2001
19.	Feasibility of Integrating Ayurveda with Modern System of Medicine in a Tertiary Care Hospital for Management of Osteoarthritis (Knee)- A CCRAS-WHO India Country Office Collaborative Study	2007
20.	Hand Book of Domestic Medicine and Common Ayurvedic Remedies - Urdu	1999
21.	Himalayi Luptapraya Vanya Jantu Kasturi Mrig (Musk Deer) evam Mahaushdhi-Kasturi (Musk) (Hindi)	2000
22.	Interactive Meeting with International Delegates for Global Propagation of Ayurveda 16th – 17th March 2009	2009
23.	Janpadodhavansh (Mahamari) Niyantrana mein Ayurveda ka Yogadan (H)	1999
24.	Laboratory Guide for the Analysis of Ayurveda and Siddha Formulations	2010
25.	Common Healing Herbs – (Revised Edition)	1998
26.	Cumulative Index of Journal of Research in Ayurveda and Siddha (1980-99)	1999
27.	Clinical Research in Certain Chronic Diseases	2001
28.	Clinical Research Protocols for Traditional Health Sciences	2010
29.	Clinical Safety of Selected Ayurvedic Formulations and Panchakarma Procedures	2008
30.	Classical Ayurvedic Prescriptions for Common Diseases	2010
31.	Brain Ageing and Ayurveda	2008
32.	Bulletin of Indian Institute of History of Medicine (Special Volume)	2003
33.	An Insight on Strengths of Ayurveda & Siddha for Geriatric Care (Rasayana Therapies)	2008
34.	Ayurvedic Home Remedies	2010
35.	Ayurvedic Management of Select Geriatric Disease Conditions (Treatment Protocols – Guidelines and Costing of Select Geriatric Disorders)	2011
36.	Ayurvediya Ausadhiya Avam Samanya Gharelu Upchaar (English)	1998
37.	Ayurvediya Ausadhiya Avam Samanya Gharelu Upchaar(Hindi)	2003
38.	Ayurvediya Gharelu Upchar (Hindi)	2008
39.	A Practical Handbook of Panchakarma Procedure	2010
40.	Activities and Achievements of CCRAS (Hindi & English)	1986
41.	2nd Interactive Meeting with International Delegates for Global Propagation of Ayurveda	2010
42.	Guidelines on Basic Training and Safety in Panchakarma	2008
43.	Medicinal Plants in Geriatric Health Care: An evidence based approach	2008

44.	Teaching & Training Modules for Surgeon's Training Programme on Ksharsutra Therapy	2008
45.	Training Module for Geriatric Health Care	2008
46.	A Manual for Doctors on Mainstreaming of AYUSH under NRHM	2008
47.	Compendium of Drug Registration Formats of Selected Countries Vol.- I	2009
48.	ABC Pictorial Card of Medicinal Plants	2010
49.	ABC Pictorial Guide of Medicinal Plants	2010
50.	Ayurveda – The Science of life with CD	2012
51.	CCRAS Research an overview	2002
52.	Ayurvedic Management of Common Disease Conditions- Treatment Protocols-Guidelines and Costing of management	2013
53.	Healthcare Seeking Trends in Ayurveda - A CCRAS Perspective	2015
54.	Drug development for select disease conditions	2016

Also the council has published certain select research papers on important diseases of national priority

Table 6.3. Select Research Papers

Sl. No.	Name of Publication	Year
1.	Select Research Papers on Ayurveda and Siddha Geriatrics	2008
2.	Select Research Papers on Ayurvedic Ophthalmology	2008
3.	Select Research Papers on Evidence Based Drugs in Ayurveda	2001
4.	Select Research Papers on Ksharasutra (A minimal invasive Ayurvedic ParaSurgical Measure)	2009
5.	Select Research Papers on Reproductive and Child Health care in Ayurveda and Siddha	2010
6.	Select Research Papers on Rheumatoid Arthritis (Amavata)	2009
7.	Select Research Papers on Safety and Efficacy of Panchakarma	2008

Appendix

RESEARCH POLICY OF CCRAS FOR VARIOUS RESEARCH ACTIVITIES

To meet the objectives of quality research, CCRAS has adopted following schemes:

1. **Intra Mural Research Scheme**: The regular scientific staff of CCRAS are at liberty to develop the project keeping in view the following areas: National Priority Areas, Mandate of the Institute, Strength areas of Ayurveda

2. **Collaborative Research Scheme at National level**: There are certain areas in which infrastructure/facilities available at CCRAS peripheral institutes are not adequate. There is a need of support from other reputed institutes where such facilities along with expertise are available e.g. areas of cancer, HIV/AIDS, tuberculosis, malaria, leprosy etc. Further, there are some other areas like filariasis, bronchial asthma, metabolic syndrome, hypertension, diabetes mellitus including complication, rheumatoid arthritis etc. in which the association of other specialized institutes will boost the quality of research.

3. **Collaborative Research Scheme at International level**: Due to increasing global interest in Ayurveda, very often foreign countries have shown interest to collaborate in the field of research in Ayurveda and it has become imperative on the part of the Council to initiate/ execute/coordinate or monitor such activities. CCRAS has laid guidelines for such collaborations.

4. **Collaborative research in Ayurveda with industries**: Benchmarks have been laid for Undertaking Research / Research Consultation for already commercialized / marketed Ayurveda products.

CCRAS research policy is available online at http://www.ccras.nic.in/content/ccras-research-policy.

CCRAS VISION DOCUMENT 2030

Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of AYUSH, Government of India, has formulated and projected "CCRAS Vision Document 2030" with a strategy of research and development for research outcomes in next 15 years considering the strength of Ayurveda and current unmet medical needs. The core components of the document comprise sustainable development goals (SDGs) of CCRAS for vision 2030 for 15 years, 7 years strategy (long-term vision), and 3 years action document, fundamentally harmonized with the goals and recommendations of major national and international health policy documents.

CCRAS has laid its vision document 2030 To develop scientific evidence in Ayurvedic Principles, drug therapies by way of integrating ancient wisdom with modem technology and to bring Ayurveda to the people through innovations related diagnostics, preventive, promotive as well as treatment methods and also introduce scientific research for sustained availability of quality natural resources, to translate them into products and processes and in synergy with concerned organizations to introduce these innovations into public health systems.

The National Population Policy 2000, 6 National Health Policy 2002, and the National Commission on Macroeconomic and Health—2005 of the Ministry of Health and Family Welfare, Government of India, emphasized on reorientation and prioritization of research in Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) and to validate therapy and drugs in chronic and lifestyle-related diseases, mainstreaming from Indian systems of medicine and homoeopathy (ISM&H). Further, the recent three major documents related to health policy, viz., National Health Policy (NHP) 2017; Situation Analyses—Backdrop to NHP 2017, Ministry of Health and Family Welfare, Government of India; and Three-Year Action Agenda 2017–2020 (draft),10 NITI Aayog, Government of India, highlighted on prevention through lifestyle advocacy, health care delivery through integration, co-location, and medical pluralism.

In the same way, considering the strength of Ayurveda in current unmet medical needs, the council has proposed a strategy of research and development with focused research outcomes in next 15 years emphasizing on development of new drugs based on leads from classical Ayurveda texts for diseases of national importance and systematic validation of classical

formulations and therapies with a vision statement "To develop scientific evidence in Ayurvedic Principles, drugs, therapies by way of integrating ancient wisdom with modem technology and to bring Ayurveda to the people through innovations related to diagnostics, preventive, promotive as well as treatment methods and also introduce scientific research for sustained availability of quality natural resources, to translate them into products and processes and in synergy with concerned organizations to introduce these innovations into public health systems." Principally analogous with the larger goals and strategies of important health-related policies, core strength of Ayurveda, and current health needs, the document is framed with core components, viz., SDGs of CCRAS for vision 2030 (15 years), 7 years strategy (long-term vision), and 3 years action document.

15 years strategy: SDGs of CCRAS for vision 2030 (15 years) emphasizes on broader goals set for 15 years, such as translation of research outcomes into practice and making them accessible to health care providers and public, mainstreaming of Ayurveda therapies through integration, generation of evidence on safety and efficacy of classical Ayurveda approaches, dissemination of research outcomes, and infrastructure development for research and development.

7-years strategy: From 2017–2018 to 2023–2024 (long-term vision) to convert the long-term vision into implementable policy and action as a part of the National Development Agenda with a mid-term review after 3 years, i.e., the year ending March 2020, focuses on development and validation of Ayurvedic drugs and regimen for inclusion in the important national programs, such as add-on and adjunct therapies for multidrug-resistant tuberculosis; generation of evidence for prevention and management of disorders of vision, reproductive and child health, human immunodeficiency virus/acquired immunodeficiency syndrome, cancer; important communicable diseases, viz., malaria, dengue, filariasis, and non-communicable diseases like diabetes, osteoarthritis, anemia; improvement of memory and cognitive function other psychiatric diseases, such as anxiety neurosis, dementia, etc.; scientific evidence on safety of selected Ayurveda herbo-mineral drugs, etc.

3-years strategy: A 3-years action document from 2017–2018 to 2019–2020 aligned to the predictability of financial resources during the 14th Finance Commission Award period. This is also to help translate into action the goals of the government to be achieved by 2019 highlights upon development of the directives addressing different research needs; validation

of fundamental principles of Ayurveda including Ayurveda biology; development of standard Ayurvedic terminologies, modules on behavioral change communication focusing on Ayurveda-based lifestyle interventions for prevention, health promotion, formats for clinical diagnosis, and clinical examination based on Ayurveda principles: Clinical decision support systems and hospital information management system (HIMS); projects on occupational health; drug development and commercialization of research products for cancer, wound healing, dengue, diabetes; dosage forms of hepato-protective agents; validation of classical Ayurveda formulations or classical Ayurveda drugs for chronic and refractory diseases, rheumatoid arthritis, osteoarthritis, hypertension, gout, urolithiasis, polycystic ovary syndrome, bronchial asthma, and chronic bronchitis; and dissemination of research outcomes.

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Glimpses of CCRAS Contributions (50 Glorious Years)

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