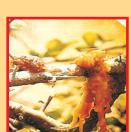
# EVIDENCE BASE **AYURVEDA**



Tinospora cordifolia



Commiphora wightii



Centella asiatica



Withania somnifera



Alst onia scholaris

Euphorbia nerifolia





Glycyrrhiza glabra



CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES **Ministry of AYUSH** (Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy) **Government of India** 

# **SAFETY AND EFFICACY**

The health care services of Ayurveda are being successfully catered to the masses in India through a huge network of 443634 registered practitioners, 13887 government dispensaries, 2394 hospitals with 42087 beds, 225 colleges conduction degree course, 61 post graduate centres, 7786 manufacturing units and 39 research centres functioning under the Central Council for Research in Ayurveda and Siddha (CCRAS). Manufacturing of medicines is regulated under Drugs & Cosmetics Act and licensing of manufacturing premises and products within GMP requirements is mandatory legally. About 65% of population in India is reported to use Ayurveda and medicinal plants to help meet their primary health care needs' and the safety of this vibrant tradition is attributed to time-tested use and textual reference. Besides, synergy of ingredient in conjunction with individualized Prakriti-based treatment plan forms the basis of efficacy and safety Ayurvedic formulations. Specific guidelines are prescribed for the use of apparently toxic medicinal plants with certain detoxification processing that also enhance the bioavailability and efficacy of the final product.

# **CURRENT SCENARIO**

In the current scenario use of Ayurveda has expanded globally and is continued to be used for primary health care of the poor in India and in certain other developing countries where conventional medicine is predominant in the national health care system. With the growing use of Ayurveda and its pharmaceutical sector, the safety and efficacy as well as quality control concerns of both regulatory authorities and the public are being addressed

Standard operating procedures (SOPs) and Pharmacopoeal standards have been evolved for Ayurvedic drugs to prevent batch to watch quality variation. Apart form GMP requirements necessary regulations are in place to ensure the quality of products. The products should pass the physico-chemical quality control parameters and also limits for microbial load, heavy metal content, pesticide residue and aflatoxins.

# **EVIDENCE BASED RESEARCH**

In Ayurdeda the process of learning, research and clinical practice are scientific and evidence based. The knowledge is scientifically validated through Pramanas, the most evidence based approaches viz. Pratyaksa (Direct perception), Anumana (Logical inference), Aptopadesa (Authentic documentary testimony), and Yukti (Experimental evidence).

The Government of India has set up the Central Council for Research in Ayurveda and Siddha (CCRAS) as an opex body in the country for formulation, Co-ordination and promotion of research in Ayurveda and Siddha on scientific lines. The Fllds areas comprise AYUSH Literature Research, Drug Research and Clinical Research including Bio-medical instrumentation and child Health Care Research.

#### SOME OF THE EVIDENCES EMERGED FROM DOUBLE BLIND RANDOMIZED CONTROLLED **CLINICAL TRIALS AND OTHER EFFICACY TRIALS ARE:**

# Ashwagandha (Withania somnifera) on the process of ageing

Ashwagandha Vs Placebo: 3 gm. of root powder of Ashwagandha (withania somnifera) administered in dosage of two tablets three times daily with milk for one year showed statistically significant increase in Hemoglobin, RBC count, Hair melanin & Seated stature and decrease in serum cholesterol and ESR<sup>2</sup>.

# Ayush-64 an Ayurvedic drug in P. vivax malaria

Ayush-64 Vs Control Chloroquine: 3 gm. of Ayush-64 was given per day in divided doses for 4 days. Significant decrease in lymphocytes, total disappearance of parasites with clinical improvement was seen in 72.4-95.4% case<sup>3</sup>s

# Vacha (Acorus calamus) in Ischemic Heart Disease (IHD)

Vacha (1.5gm. three times a day) Vs Guggulu (4gm. Three times a day) and Placebo: Significant improvement in symptoms like chest pain and respiratory distress was observed in treated group⁴.

#### THE SCIENCE OF LIFE

Ayurveda-literally meaning the science of life is a comprehensive system of health care great antiquity, based on experiential knowledge and down with compendia of Indian wisdom called Vedas, which are believed to be documented around 6000 years back. Rigveda and Atharvaveda are replete with information on health and maladies and their management with natural modes and codalities. the knowledge expanded further with laying down of fundamentals and concepts of Ayurveda and systematization in classical texts like Charak Samhita, Sushruta Samhita and Astang Sangrah. Present form of Ayurveda is the outcome of continued scientific inputs that has gone in to the evolution of its principles, theories and guidelines of heathy living and disease management. Considering health of an individual as dynamic integration of environment, body, mind and spirit, Ayurveda lays great emphasis on preservation and promotion of health and preventing the occurrence of disease. Besides, it advocates employing holistic approach to understand all aspects of human life including diagnosis and management of disease.

#### **REVERENCE AND STRENGTH**

Ayureda attributes primary importance to preventive medicine and the maintenance of positive health. The major preventive approaches for maintaining and improving the quality of life include individualized specific daily regimen (Dinacharya), seasonal regimen (Ritucharya), behavioral and ethical considerations (Sadvritta). Healthy lifestyle is semphasized as the determinant of longevity of life, which by and large depends on the Prakriti (bio-identity i.e. body-mind constitution) of an induvidual, proper understanding of Prakriti leads the physician in making right diagnosis, prognosis and treatment plan and in guiding patients as well as disease-free individuals what dos and don'ts need to follow for resoration and maintenance of

The therapeutic streams advocated in Ayurveda Comprise Daivavyapasraya chikitsa (Spiritual measures), Yuktivyapasraya chikitsa (Pharmacological therapies) and Satvavajaya (Non-pharmacological Psychotherapies). The treatment plan is worked out on the basis of underlying morbidity keeping in mint the strength of the disease and the tolerability of the patient. Four-pronged treatment plan consisting of avoidance of causative and precipitating factors of disease (Nidan Parivajan), bio-purification (Samshodhan), use of palliative remedies (Samshamana) and health-promoting regimen (Pathya Vyavastha) is the hall mark of Ayurvedic therapeutics recommended for physicians to prescribe, Specific diet and lifestyle guidelines are always prescribed along with the drugs and therapies so as to facilitate restoration of bio-humoral balance and health status.

Credible therapeutic modalities of Ayurveda include bio-purification therapy called Panchakarma, minimal invasive para surgical measure for management of fistula-in ano and piles called Ksharsutra and specialized health care called Rasayana. These modalities are proven to have an edge over conventional medical approach in dealing with chronic and refractory disease conditions.

Panchakarma is a bio-cleansing regimen comprising of five procedures that facilitates better bioavailability of the pharmacological therapies, helps to bring about homeostasis of bodyhumors, eliminates disease-causing complexes from the body and checks the recurrence and progression of disease. The five fold measures comprehended in this therapy are-Vamana (Therapeutic Emesis), Virechana (Therapeutic Purgation), Asthapana Vasti (Therapeutic Decoction Enema), Anuvasana Vasti (Therapeutic Oil Enema), Nasya Karma (Nasal administration of medicaments). Panchakarma procedures are preceded by Snehana (therapeutic Oleation) and Swedana (Sudation) applications to make the body system conducive for elimination of bio-taxins and cleansing of channels. This is effective in managing autoimmune, neurological, psychiatric and musculoskeletal diseases of chronic and metabolic origin.

Ksharsutra is a unique minimal invasive para-surgical measure successfully practice as promising therapy for the management of no-rectal disorders especially in fistula-in-ano, piles and anal fissure, with low recurrence rate in comparison to the undesirable outcome of surgical interventions. Another plus point of this measure is that the patients need not be hospitalized and they can attend to their routine as usual without much discomfort. Scientific studies have validated the efficacy, acceptability and usefulness of Ksharsutra technique.

Rasayana therapy is a specialized branch of clinical medicine in Ayurveda meant for preventing the effects of complexion and sensory and motor functions. Numerous single and compound Rasauama drugs possessing diversified actions like immuno-enhancerment, freeradical scavenging, adaptogenic or anti-stress and nutritive effects are described in Ayurveda literature for their use in health promotion and management of diseases with improvement in the quality of life.

# Guggulu (Commiphora wightii) in Hyperlipidaemia

Guggulu 8 gm. per day (Commiphora wightii) Vs Placebo: Cardinal clinical manifestations of disease like precordial pain and dyspnoea were relieved in most of the cases. Substantial fall in lipid fractions like cholesterol 27% triglycerides 36% phospholipids 20% and free fatty acids 37% indicated the possibility of regression of atherosclerosis. The reversal of ECG changes substantiated the antiischemic effect of the drug in treatment of ischemic heart diseases<sup>5</sup>.

# Brahmi (Bacopa monnieri) in the management of Senile Dementia.

Brahmi Vs Placedbo: Administration of 1gm. of powered extract of Brahmi Twice a day for 5 years has shown significant reduction in the progression of memory loss in persons suffering from senile dementia<sup>6</sup>.

# Sallaki (Boswelia serrata) in Rheumatoid arthritis. (RA).

Sallaki Diclofenac sodium: 600 mg. of Sallaki 3 times in a day and 50 mg. of Diclofenac Sodium. 3 times in a day was given in treated and control groups respectively for 4 weeks. Efficavcy of Sallaki was found to be comparable to that of Diclofenac in relieving the symptoms of Rheumatoid arthritis. Sallaki was even better tolerated than Diclofenac sodium by patients of RA, who demonstrated predisposition for gastric intolerance with anti-inflammatory medication<sup>7</sup>.

# Ayush-82-An Ayurvedic hypoglycemic formulation

Ayush 82 consisting of Amra Bija (Seed of Magnifera indica), Karvellaka Bija (seed of Momordica charantia), Jambu beeja (Seed of Syzygium cumini), Gudmara (leaves of Gymnema sylvestre) was tried on a fairly large sample size (350 patients) in as controlled clinical study revealed statistically significant reduction in fasting and post prandial blood sugar in Non Insulin Dependent Diabetes Mellitus<sup>8</sup>.

# Ksharsutra (Ayurvedic medicated thread ) in the management of fistula in ano

Ksharsutra Vs Surgery: Multicentric randomized controlled clinical trials reveled the Ksharasutra offers effective ambulatory and safe alterative to surgery in fistula in ano with a low recurrence rate of 4% when compared with 11% with replication?.

#### Bhumyamalaki (Phyllanthus amarus)-a promising Hepato-protective agent A clinical trial of Bhumyamalaki (Phyllanthus amarus) in chronic viral hepatitis for a period of

three months revealed remarkable recovery of liver function and inhibition of HBV replication<sup>1</sup>.

# Ayushman-8 Vs Placebo in mental Retardation

Ayushman-8 consisting of Brahmi (Centella asiatica), Shankhapushpi (Convolvulus pluricaulis) and Vacha (Acorus calamus) given in the dose of 700 mg. twice a day with honey showed significant numerical increase in the mental age in the trial drug group<sup>11</sup>.

# Yastimadhu (Glycyrrhiza glabra for Post menopausal women)

Yasstimadhu (Glycyrrhiza glabra) Vs Soy extract were studies for anti-oxidant and lipid modulation effects in pre and post menopausal women. Yashtimadhu root powder at the dose of 2.5 g with 3.5% gylcerrhizic acid content (n=19) and Soy extract at the dose of 9 (n=20) were given for a period of 12 weeks. The study revealed decline in the lipid peroxides without significant change in serum lipid levels which were statistically significant (p<0.05)<sup>12</sup>.

# Management of Hemiplegia by Panchakarma therapy

Panchakarma Vs Palliative: In a comparative study on 744 hemiplegics revealed at that 552 subject who received Panchakarma therapy showed significant recovery from illness, besides improvement in motor function and quality of life in comparison to subjects who received shamana therapy (Palliative therapy) alone.15

# Further information can be obtained from:

# **Director General**

**Central Council for Research in Ayurvedic Sciences** No. 61-65, Institutional Area, Opp. 'D'-Block, Janakpuri, New Delhi-110058 Telephone: +91-11-28525520/28524457, Fax: +91-11-28520748

E-mail: dg-ccras@nic.in Website: www.ccras.nic.in www.indianmedicine.nic.in

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