EVIDENCE-BASED USE OF AYURVEDA IN GLOBAL HEALTH PROBLEMS

Dr. M.M. Padhi
Deputy Director (Technical)
Central Council for Research in Ayurvedic Sciences
(Department of AYUSH, Ministry of Health and Family Welfare, Government of India)
New Delhi
INDIA
www.ccras.nic.in
Email: padhimm@yahoo.co.in, ccras_tec@nic.in
Evidence base of Ayurveda

- **Codified** - Original dimensions of Ayurveda are inbuilt in the ancient compendia of Indian wisdom called Veda, documented around 6000 years back.

- **Updation and addition** - The knowledge expanded from time to time with systematization of classical texts like Charaka Samhita, Sushruta Samhita and Astanga Sangraha.

- **Present form of Ayurveda** - Several research studies have established the efficacy in indicated diseases as described in the text of Ayurveda.
Strength of Ayurveda

Chronic and life style disorders
- Rheumatoid Arthritis
- Complications of Diabetes
- Quality of life in Cancer patients
- Cardiovascular disorders/Hypertension
- Bronchial Asthma
- Obesity
- Other Non communicable diseases
Ayurveda in India

- Registered Practitioners: 3,87,976
- UG colleges: 261
- PG colleges: 76
- Universities: 2
- Annual admission capacity, UG: 10,472
- Annual admission capacity PG: 1709
- Hospitals: 2408
- Hospital bed capacity: 42,830
- Dispensaries: 15,927
- Drug manufacturing units: 7744

Source: AYUSH IN INDIA 2013
Organizational Setup

Central Level

- Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) under Ministry of Health & Family Welfare, Govt. of India
- Central Council of Indian Medicine
- Central Research Councils
- Universities/National Institutes/Colleges
- National Medicinal Plant Board
- Pharmacopoeial Commission of Indian Medicine
- Central Pharmacopoeia Laboratories
- Manufacturing Units
- Hospitals & dispensaries

AYUSH Research Councils
Organizational Setup

State level

- AYUSH Department or Ministry
- State Directorates
- State Boards/Councils for Registration of Practitioners
- State Licensing/Drug Control Authorities
- State Colleges/Institutions
- State Pharmacies
- State Drug Testing Laboratories
- State Medicinal Plant Boards
- Hospitals & Dispensaries
Important Policies/Guidelines

National
- Udupa Committee Report -1958
- The National Health Policy of 1983
- The National Population Policy 2000
- The National Policy on ISM&H 2002
- National Rural Health Mission- 2005
- Guidelines for GAP, GMP, GLP, GCP etc.

Global
- WHO Alma Ata 1978
- WHO documents and guidelines
- Commonwealth Health Ministers Conference 1998 and so on....
Regulatory Structure

**Major Acts -**

- Drugs & Cosmetics Act, 1940 and Rules 1945 with a dedicated chapter for regulation of Ayurveda, Siddha and Unani drugs.
- Drugs & Magic Remedies (Objectionable Advertisements) Act 1954.
Regulatory Structure

Other Relevant Acts

- Indian Forests Act 1927 to conserve the medicinal plants species used in medicines.
- The Narcotic Drugs and Psychotropic Substances Act 1985.
- Bio-diversity Act 2002 to regulate the exploitation of certain plants and animal species used in medicines etc.
- Food Standard & Safety Act 2006 to regulate the safety and standards of food items etc.
Traditional Knowledge Digital Library

- Collaborative project between Council of Scientific and Industrial Research and Department of AYUSH.
- Created to prevent the misappropriation of Traditional Knowledge at International Patent Offices so that the cases on bio piracy such as Turmeric and Neem could be prevented.
Traditional Knowledge Digital Library

- Traditional knowledge existing in local languages is converted into English, French, German, Spanish and Japanese in International Patent Classification format for the convenience of its use by international patent examiners.

- European Patent Office (EPO), one of the International Search Authorities has signed the TKDL Access Agreement. EPO is a regional office with 34 member states such as UK, France, Germany, Italy, Poland, Norway, etc.

- Negotiations with USPTO for providing access to the TKDL database are continuing.
Global Scenario of Ayurveda

- Ayurveda can offer management of chronic and degenerative diseases. There is a resurgence of interest in Ayurveda among the consumers over the World.
- At policy level in countries like Myanmar, South Africa, Malaysia, Hungary, Sri Lanka Ayurveda is officially recognized. In many countries, there is no restriction to practice Ayurveda, though it is not officially recognized.
- However, this Indian system is also popular in many foreign countries including USA and Europe. People use Ayurvedic medicines, which are marketed as dietary/nutritional/herbal supplements.
- There are several educational institutions imparting Ayurveda courses/training
Central Council for Research in Ayurvedic Sciences (CCRAS)

- Apex body for research and development in the field of Ayurveda and Sowa-Rigpa under Dept. of AYUSH, Ministry of Health and Family Welfare, Government of India
- Nationwide network of 30 Institutes with varied focus areas namely:
  - Literature and Basic concepts
  - Survey & Cultivation of Medicinal plants
  - Drug research
  - Clinical Research
  - Tribal Health Care Research
  - Reproductive and Child Health Research
Phases of Drug Development

Identification of raw drugs

Standardization of Raw Drugs (with chemical profile)

SOP for the preparation of formulation

Standardization of Formulation

Preservation, Packing and Storage

Safety and Toxicity Studies on animals

clinical protocol, IEC clearance

Clinical Trial
STANDARDIZATION OF AYURVEDIC DRUGS

- Ash values
- Extractive Value
- Chromatographic Profile
- Marker Component
- Pesticide Residue
- Microbial Count
- Heavy Metal Contaminants
- Foreign Matter
- Organoleptic Evaluation
- Macroscopy & Microscopy
- Volatile Matter
- Extractive Value
- Chromatographic Profile
Other important issues in drug development

- Good Cultivation Practices - stress on organic farming
- Good Collection Practices - parts of the plants to be used, the time, place and season of collection, conservation, sustainable use
- Good Manufacturing Practices - mandatory to all manufacturing units
- Animal experimentation as per Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) and other guidelines.
- All clinical trials should comply with Good Clinical Practices Guidelines
Country Profile of Diseases/Death Germany

Proportional mortality (% of total deaths, all ages)

- CVD: 45%
- Cancers: 26%
- Respiratory diseases: 4%
- Diabetes: 3%
- Other NCDs: 13%
- Communicable, maternal, perinatal and nutritional conditions: 5%
- Injuries: 4%

NCDs are estimated to account for 92% of all deaths.

Source: WHO, 2011
Country Profile of Diseases/Death India

Proportional mortality (% of total deaths, all ages)

- Communicable, maternal, perinatal and nutritional conditions: 37%
- CVD: 24%
- Other NCDs: 10%
- Diabetics: 2%
- Respiratory diseases: 11%
- Cancers: 6%
- Injuries: 10%

NCDs are estimated to account for 53% of all deaths.

Source: WHO, 2011
## Comparison of Mortality Rate

<table>
<thead>
<tr>
<th>Disease</th>
<th>Germany</th>
<th>India</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardio Vascular Diseases</td>
<td>45%</td>
<td>24%</td>
</tr>
<tr>
<td>Cancer</td>
<td>26%</td>
<td>06%</td>
</tr>
<tr>
<td>Respiratory Diseases</td>
<td>04%</td>
<td>11%</td>
</tr>
<tr>
<td>Other Non-Communicable Diseases</td>
<td>13%</td>
<td>10%</td>
</tr>
<tr>
<td>Communicable Diseases</td>
<td>05%</td>
<td>37%</td>
</tr>
<tr>
<td>Injury</td>
<td>04%</td>
<td>10%</td>
</tr>
</tbody>
</table>
Status of TM/CAM in Germany

- National policy was formed on TM/CAM in 1976.
- Herbal medicines are regulated as prescription medicine, OTC medicines and self-care purposes.
- Approximately 7700 traditional/herbal/homoeopathy medicines are registered in Germany.
- The Herbal Medicinal Products Directive (THMPD) was established to provide a regulatory approval process for herbal medicines in the European Union (EU).
- Since 30 October 2005, herbal medicines in the EU are controlled under the EU regulation, 2004/24/EC (THMPD).

Main Source: National Policy on Traditional Medicine and Regulation of Herbal Medicines - Report of a WHO Global Survey, 2005
• The company needs to demonstrate the safety and efficacy of the herbal medicine through traditional use for at least 30 years out of which 15 years should be within the EU.
• From 1st May 2011 all unlicensed herbal products marketed in the EU now have to be either registered as traditional herbal medicinal product or get marketing authorization as regular medicinal product, or carry on as dietary supplements.
Steps taken by the Department of AYUSH

- India exports various herbal ingredients to European Union.
- In the past Department of AYUSH has been persistently voicing its concerns on the THMPD against requirement of 15 years of documented usage in a European country and suggested to replace with 30 years safe usage criteria anywhere in the world with supportive bibliographic evidence.
- The 5th India-EU Summit held at The Hague on 8th November, 2004 resulted in Draft Joint Action Plan which included initiation of discussion on harmonization of registration procedures for Indian Pharmaceutical products in the EU.
Steps taken by the Department of AYUSH

- As a result of India’s efforts market authorization of Ayurveda products was included as an Agenda Item in the India – EU Joint Working Group on Pharma & Biotechnology set up in 2006 under the aegis of India EU Strategic Partnership.

- An Indian team of officials and experts made a presentation on Ayurveda to the European Medicine Evaluation Agency (EMEA) in London in May, 2006 on the Evidence Base of Ayurveda and quality control of Ayurveda medicines.
Steps taken by the Department of AYUSH

- A three member EU Commission team visited India in January, 2007 and had discussions with experts from Deptt. of AYUSH, CSIR, ICMR and AYUSH drug industry and also visited R&D, health care and manufacturing facilities.
- EC officials explained their stand on the Directive and agreed for further negotiations and inputs from India on Committee on Herbal Medicinal Products (HMPC) monographs.
- Relevant information for HMPC monographs are being uploaded on HMPC Secretariat website (http://www.ema.europa.eu) by CCRAS from time to time.
Evidence Based Research Profile

- Standard process is followed by in accordance with the guidelines for Ayurvedic drug development in India.
- Revalidation of classical medicines/procedures are the subject of research.
- Development of new combinations are also undertaken.
- Majority of clinical studies are conducted mostly on formulations and not on single plants.
- Some examples are.........
Amalaki (Emblica officinalis)

**Classical Reference:** Charaka Samhita and others

**Standards:** Ayurvedic Pharmacopoea of India (API)

**Pharmacology:** Antioxidant activity

**References:**


**Clinical:** Rasayana and antidiabetic activity

**References:**


**Evidence Based Research Profile**

**Aswagandha (Withania sominifera)**

**Classical Reference:** Charaka Samhita and others

**Standards:** Ayurvedic Pharmacopoea of India

**Chemical Constituents:** Withaferin A, Withanolides, Withaferins, Sitoinsides

**Pharmacology:** Immunomodulatory, Adaptogenic

**Reference:**

**Clinical:** Anxiolytic action

**Reference:**
Tulasi (Ocimum Sanctum)

**Classical Reference:** Veda/Ayurveda

**Standards:** Ayurvedic Pharmacopoea of India

**Chemical Constituents:** Eugenol, B-caryophyllene, Bornyl-acetate etc.

**Pharmacology:** Found to protect guinea pigs against histamine and *Acacia arabica* induced asthma. Reported to be safe.


**Clinical:** Anti-stress effect

Guggulu (Commiphora mukul)

Classical Reference: Charaka Samhita, Sushruta Samhita
Standards: Ayurvedic Pharmacopoea of India
Chemical Constituents: Guggulusterone-E, Guggulusterone-Z, Guggulusterone-I-VI, Cholesterol, Sesamin, Camphorene, Cambrane A etc.

Pharmacology: Significant anti-inflammatory, anti-stress, safe in prescribed dose

Clinical: Anti-obesity, hypocholesterol effect
Evidence Based Research Profile

Eranda (*Ricinus communis*)

**Classical Reference:** Charaka Samhita  
**Standards:** Ayurvedic Pharmacopoeia of India  
**Chemical Constituents:** Ricinine, albumin, ricin, 1-methyl-3 cyano-4-methoxy-2-pyridine, β sitosterol, octacosanol, ricinine, gallic acid  

**Pharmacology:** Anti-inflammatory property,  
**Reference:** Annual Report, P.R.U., Calcutta.  

**Clinical:** Rheumatoid Arthritis  

Cont...
Guduchi (*Tinospora cordifolia*)

**Classical Reference:** Charaka Samhita

**Standards:** Ayurvedic Pharmacopoeia of India

**Chemical Constituents:** Tinosporine, Tinosporon, Tinosporic acid, Tinosporide

**Pharmacology:** Inhibit lipid peroxidation. Free radical scavenging and metal chelation capabilities must be acting in a competitive and comprehensive mode to ameliorate the radiation induced oxidative stress.


**Clinical:** Antidiabetic activity

Haridra (Curcuma longa)

**Classical Reference:** Charaka Samhita

**Standards:** Ayurvedic Pharmacopoeia of India

**Chemical Constituents:** Curcumin, ar-tumerone, methyle curcumin etc.

**Pharmacology:** Significant anti-inflammatory activity in comparison with hydrocortisone acetate and phenylbutazone.


**Clinical:** Nishamalaki is antidiabetic

**Reference:** Database on medicinal plants used in Ayurveda, CCRAS, Vol. 1, 154, 2000
Evidence Based Research Profile

Pippali (*Piper longum*)

**Classical Reference:** Charaka Samhita

**Standards:** Ayurvedic Pharmacopoeia of India

**Pharmacology:** Hepato-protective, gastric ulcer healing activity, bioavailability enhancer. Reported safe.

**Reference:**
Evidence Based Research Profile

**Arjuna (**Terminalia arjuna)**

**Classical Reference:** Charaka Samhita

**Standards:** Ayurvedic Pharmacopoeia of India

**Chemical Constituents:** Arjunolic acid, masilinic acid, arjunic acid, arjuetic acid, arjuolitin, arjuolone, tomentosic acid, maslinic acid.

**Pharmacology:** Dose-dependent decrease in blood pressure and heart rate and inhibits carotid occlusion response without affecting the pressure responses. It has also been demonstrated that the hypotensive and bradycardic effects are mainly of central origin.

**Reference:** Indian Drugs 1992; 29: 144.


**Clinical:** Useful in Chronic Stable Angina

Anti anxiety effect of an Ayurvedic compound drug – A cross over trial

Double blind study with a sequential crossover design comparing the efficacy of Ayurvedic preparation with modern control.
Ayurvedic preparation Vs. Diazapam and Placebo
Ayurvedic formulation of Mandukaparni (Centela asiatica), Yasti (Glycyrrhiza glabra), Jatamansi (Nardostachys Jatamansi) in the ration of 1:1:2 suspended in Ksirabala taila.

Results: Psychological parameters show that Ayurvedic drug is more effective in enhancing the perceptual discrimination and Psychomotor performance than the other two control drugs.

Source: Select research papers on evidence based drugs in Ayurveda, CCRAS, New Delhi
Evidence Based Research Profile

Effects of a Composite Indian Herbal Preparation (CIHP) on combat effectiveness in low-intensity conflict operations.

Drug & Dosage: CIHP Vs Placebo

CIHP is a combination of following extracts
1. Asparagus racemosus: Root
2. Withania somnifera: Root
3. Pueraria tuberosa: Tubers
4. Mucuna pruriens: Seeds
5. Dioscorea bulbifera: Rhizomes
6. Argyria speciosa: Whole plant
7. Piper longum: Fruit
8. Sphatik

Results: Assessment through various tests indicated that CIHP helps to cope with combat stress and sustain mental performance in adverse environment.

Role of the Ayurvedic Drug Brahmi (Bacopa monnieri) in the management of Senile Dementia

Brahmi Vs Placebo Brahmi in the form of powdered organic extract in doses of 1 gm. twice a day.
Duration: 5 years

Results: The drug not only arrests further memory loss but slows the process of subsequent acetylcholine reduction in person suffering from senile dementia.
Reference: Pharmacopsycocology (1990), 3, 47-52.
Double blind Randomized controlled trial of Sallaki Vs Diclofenac in treatment of Rheumatoid arthritis.

Sallaki (Boswellia serratta) Vs Diclofenac sodium

Sallaki, 600 mg 3 times in a day.

Diclofenac sodium, 50 mg 3 times in a day.

**Duration:** 4 weeks

**Results:** Efficacy of Sallaki was comparable to that of Diclofenac in relieving the symptoms of RA. Sallaki is even better tolerated than Diclofenac sodium who have demonstrable predisposition for gastric intolerance with anti-inflammatory medication.

Source: Select Research Papers on Evidence based drugs in Ayurveda, CCRAS, New Delhi
Comparative clinical study on Musta, Aswagandha and Pancha karma therapy in Amavata- Rheumatoid Arthritis

Study was conducted on 120 patients in 3 groups
Gr.1-Musta churna 3 gm with Valuka sweda, 90 days
Gr.2-Aswagandha churna 3 gm TID with Valuka sweda, 90 days
Gr.3-Pancha karma therapy with murchita taila Shaddharana churna (7 days) along with Valuka sweda

Results: Though significant result was obtained in all the 3 groups, Panchakarma group was better in comparison with other 2 groups.

Reference: Select research papers on Rheumatoid Arthritis, 2009, CCRAS Publication, Page-166-173
Evidence Based Research Profile

Shirodhara - For Neurological and Psychological problems

Department of AYUSH/CCRAS have maintained an open access web portal (www.ayushportal.ap.nic.in) containing around 17,790 abstract/full research papers of AYUSH Systems of medicine till now.

In this portal, information on researches related to Ayurveda, Unani, Siddha, Homoeopathy, Yoga & Naturopathy, conducted in India and other countries are being updated from time to time.
Future of Ayurveda in Europe

- Ayurveda is an ancient Indian codified holistic system of medicine.
- It is evidence based and being further validated by using modern scientific parameters from time to time.
- Ayurveda can play an important role in improving healthcare scenario globally.
- There is consumer awareness and demand but some regulations are very stringent.
- To bridge the gap between the consumers and the Government, feasible and realistic policy interventions are essential keeping in view the benefit of the consumer.
- The provisions for relaxation of norms may be considered for already validated and proven products.
Thanks!