

SAFETY AND EFFICACY- DILEMMA OF CURRENT DAY AYURVEDA

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ABSTRACT

Objective: To analyse the Safety and efficacy in *Ayurvedic* practice regarding all its Educational, Pharmaceutical, Clinical, Research etc. perspectives in current era. **Material:** This article has been studied under different aspects of *Ayurveda*, like Education, Diagnosis, Treatment, Drug manufacturing, Researches and Patenting in *Ayurveda*. **Discussion:** The efficacies of *Ayurvedic* principles are not questionable. Its efficacy is questioned when the followers of *Ayurveda* have misunderstood the principles of *Ayurveda*. Many government as well as private faculties are working hard to bring genuine *Ayurveda* in front; but their efforts are yet to get noticed by the people in our country and the world.^[1] **Conclusion:** Thus the dilemma in the safety and efficacy of current day *Ayurveda* will only be resolved if more manpower is projected towards the generosity work in *Ayurveda*.

Keywords: Safety, efficacy, current day *Ayurveda*, principles of *Ayurveda*, etc.

INTRODUCTION

Ayurveda forms an important component of health care in India. This is based upon centuries old observations, rich in traditional wisdom and with its own strong basic principles and philosophy as its skeleton and body. Many other countries are also day by day trying to understand and accept this medical science.^[2,3] Indian *Ayurvedic* practitioners, scientists and researchers are also trying to bring the essence of *Ayurveda* forward for the benefits of humanity. But modern medicine and modern technology have proven themselves and built strong roots in the universe with their improving knowledge due to multiple researches and latest technology. For nearly last two centuries modern medicine has been evolved due to repeated studies and researches for betterment of their science, to bring more precision in their diagnosis and better

results in treatment, which has created the utter faith in modern medical science by the whole world. But in all this journey of evolution of modern medicine; the advancement of our *Ayurvedic* medical science remained unnoticed or slightly untouched. Now a days *Ayurvedic* practitioners and researchers are really looking forward for the better recognition of our medical science in the whole world as well as the followers of *Ayurveda* know that *Ayurveda* doesn't just alleviate the diseases in patients but it also teaches us the real healthy way of life. As the aim of *Ayurveda* quoted in great *Sushrut Samhita* as, "*Vyadhyupasrushtanam vyadhi parimokshaha, Swasthasya rakshanam cha||*" meaning "to cure the disease if any and to prevent the human body from diseases by maintaining the healthy well-being".^[4] But when looking at the

current situation of *Ayurveda* in all its perspectives like academics, clinical practice, pharmaceuticals and researches being studied; one very terrifying yet most important question arises in any sensible *Ayurvedic* student's mind whether really the current day *Ayurveda* (*Ayurvedic* practice) is Safe and Effective or Not? So the fact that remains with us is that, though *Ayurveda* is great with its treasured principles; but the world today does not seem to have enough faith in *Ayurveda* and its practice. While saying so, one thing should be taken into consideration that over a long period of time some genuine, sincere and intelligent *Ayurvedacharyas* had been working on the same by deciphering the correct meaning out of the verses written in the ancient *Ayurvedic samhitas* (Classical textbook). But for any work to get noticed by the world there require a huge amount of research work by collecting more evident Data. Thus now this is a need of time that all the *Ayurvedic* students and professors, practitioners and researchers should now focus on the betterment of *Ayurveda* in the sense of its Safety and Efficacy.

Material:

The safety and efficacy of *Ayurveda* practice can be studied under numerous aspects of *Ayurvedic* literature, clinical practice, *Ayurvedic* pharmaceuticals, *Ash-tanga Ayurveda* (eight components of *Ayurveda*), Public health, research works and many more. But in order to limit the overt expansion of this highly flaming subject, this essay will focus on the following points: 1) Education 2) Diagnosis 3) Treatment 4) Drug manufacturing 5) Researches and 6) Patenting in *Ayurveda*.

Education:

The modern technology nowadays is so developed that it's even proved efficiency in the education system. It comes under information technology. The documentation of ancient texts as well as current going on researches has become easier with the help of computers and internet. Various websites, mobile applications, E-journals, E-books (*e-samhitas*), Teleconferencing, E-lecturing, TKDL etc are definitely helping in improvising the knowledge of *Ayurveda* in current generation. One of the recent projects that run

under AYUSH department is Manuscriptology, which means collecting, conserving, cataloguing, translating, editing and publishing the ancient manuscripts of our science, which is utterly beneficial for future of *Ayurveda*. These all infotechs are improving the Efficacy of current day *Ayurveda* undoubtedly. But the group of doctors and *Ayurvedic* researchers should be of that calibre to assimilate such great knowledge.

To get better results of any work the base should be fair and strong. The same is with the education system. If the education system is corrupt and has the loop holes within it then the next generation being developed in such universities may lack in talent. Or if the teacher is not thorough in his knowledge then students will definitely not develop to their maximum potentials.

Ayurveda in ancient days used to be learnt in 'Gurukul' System of education; where the student has to reside in his teacher's house until teacher qualifies the student as a doctor. For the field like this which deals with the healthcare of the people this system would ensure the excellence of the doctor getting through this qualification. Thus this would also validate the safety and efficacy in the treatment given by such experienced, talented and qualified doctor. This system was not bound to time in months or years but the only thing important in learning here was the complete, thorough knowledge of *Ayurveda* should be acquired by the student so that there won't be any malpractice. But in current day *Ayurvedic* institutes, it is a real doubt whether the students qualified from them are actually experienced and well learned or not. Even though there are certain examinations conducted to check the knowledge acquired by students but there is a big question over the nobility and honesty of the students appearing those exams. Also in this time bound education system it becomes very difficult for teacher to explain complex theories of *Ayurveda* to students in a short span of 4-5 years. It is even more difficult for a student who had no scent of *Ayurveda* in his earlier education and all of sudden is forced to learn an altogether different science explained in ancient language of India i.e. *Sanskrit*. Thus students find it sometimes difficult to grasp the principles of

Ayurveda in such a short span of academics. Thus there remains a doubt whether these passed out doctors really understand *Ayurveda* and its principles.

Diagnosis:

After getting qualified as a doctor when first patient comes to the clinic, the first important thing comes forward is that to diagnose the disease exactly. *Ayurvedic* diagnosis is done by *Nidanpanchak* (Five components of Diagnosis) i.e. *Nidan* (Cause), *Purvarupa* (Early Symptoms), *Rupa* (Signs & Symptoms), *Samprapti* (Etiology) and *Upashaya* (Relief) traditionally. Nowadays use of several tools for diagnosis like stethoscope, microscope, radiology, ultrasonography etc are advancing the efficacy of current day *Ayurveda*. The recent researchers and scientists are really working hard and inventing new gadgets to diagnose the patient accurately. One of such invention is *Naaditarangini Yantra*. This instrument calculates the *tridoshaj naadi* (Pulse having characteristics of three fundamental energies of body) of a patient and helps doctor to give perfect information about the *doshaj vikriti* (Vitiation of Fundamental energies) in patient; hence makes diagnosis easier.^[5]

There is one more invention of a new application for easy perception of *Ayurvedic* verses and for better diagnosis, the app named '*Triskandha Kosha*' invented by Dr Gadgil Sir. This is a unique project where information technology, *Ayurveda* and *Sanskrit* have come under the one roof to provide information from *Ayurvedic* texts in a classified manner. The main aim and objective of this project were to create an electronic database for fast retrieval of information in an easier and fast accessible format and develop diagnostic and treatment software^[6]

Thus the gadgets, otherwise used to use by modern medicine, are now also utilised by *Ayurvedic* practitioners for diagnostic purpose without violating the actual principles of *Ayurveda* and such remarkable inventions are surely making *Ayurvedic* practice more safe and efficacious. Though the technology is being a helping hand for the diagnostic purpose, the question remains behind whether the user of these technologies i.e. *Ayurvedic* doctor is learned enough to evaluate the clinical analysis from their results. Even there are

many quacks imposter themselves as *Ayurvedic* doctors may not diagnose the disease according to *Ayurvedic* theories of *Tridosha* (Three fundamental energies of body), *Saptadhatu* (Seven tissues), *Trimala* (Three waste products of body) and *Panchamahabhuta* (Five fundamental elements of universe). These become the reason for the disgrace of *Ayurveda*.

Treatment:

The *Ayurvedic* treatment is mainly divided into two: *Daivavyapashraya* and *Yuktivyapashraya*. *Daivavyapashraya chikitsa* literary means the divine therapy which includes chanting of *mantras* and performances of *homas* (Sacred bonfire). The real strength of this treatment style is not known to the recent world; but the other type of treatment is the clinical practice that is operative as the main *Ayurvedic* treatment for many years till date. *Yuktivyapashraya chikitsa* is further divided into *shamana* and *shodhana chikitsa*. Out of these the prior is the palliative form where disease is cured by pacifying the *vikrit doshas* inside the body itself, and the other is the form of treatment where the *vikrit doshas* are thrown out of the body.

When it comes to prescribing a treatment, there are no proper guidelines or protocol that a novice doctor would follow. Besides there are way too many medicines explained in various ancient as well as recent textbooks of *Ayurveda*, for just one symptom or disease. For instance, if we take *Jwara* (fever), first it is difficult to locate whether it has appeared as a disease or just a symptom of other diseases. Then when we decide to give treatment for it considering all the *dosha vikriti* in it; then there is a long list of medicines from *Samshamani vati* (single drug made of *Guduchi [Tinospora Cordifolia]*) to a complex herbomineral drugs like *Tribhuvankirti* or *Anandbhairav rasa*. While it is a good thing to have such a long range of medicines and some textbooks have mentioned the pharmacodynamics and pharmacokinetics of that drug but there is very less information about to use which drug in which condition. There are various researches going on. The comparative studies to show the efficacy of the particular group of medicines with similar or different ingredients in a particular disease but still there is a lot of scope to do research in this field.

In addition, the dosage explained in ancient texts might not be appropriate for the patients in current era, as there is a significant change in the *Rugna bala* (Patient strength) and *Aushadhi dravya bala* (Medicinal strength). So researches are needed to reprove the dosage for the patients nowadays. Besides there is a need of time to invent the newer dosage forms for the easy acceptance by the patients. The researchers are working on all these points but looking at the huge task in front of the current day *Ayurveda*, there is lacking a good, skilled manpower in research.

Drug manufacturing:

Drug manufacturing plays an important role in Safety and Efficacy of *Ayurvedic* treatment. A potent drug is very essential for effective treatment. Also the drug should be cost effective. All the ancient acharyas have mentioned about the *Chikitsa chatushpaada* (Four pillars of treatment) in which, *Oushadhi dravya* (Drug) is one of the important pillar. *Acharya Charaka* has also explained the 4 properties of potent drug like *bahu gunam, bahu kalpam, sampanam, yogyam*^[7]. While discussing about drugs' safety and efficacy, it should be considered in fields like Drug authentication and potency and GMP regulation, etc.

Drug authentication and potency:

In any drug preparation, first comes the procurement of potent raw material and its authentication. As *acharyas* have already mentioned that the raw drug should be *sampanam* i.e. it should possess all its natural characteristics and properties (*rasa-virya-vipaka-prabhava-guna*). Thus it becomes of primary importance to collect potent drug to produce effective medicines. And to cultivate potent, effective herbal medicinal plants, one should start with the abundant source of fruitful fertile land whose pH is checked regularly. Then next important thing is rich source of potable water. It also requires organic manures. Then the rest of the factors contributing in the plentiful cultivation of rich potent plants are air, atmosphere and season. The department of AYUSH is running the National Medicinal Plant Board (NMPB) which is working for the conservation and cultivation of medicinal plants. Till the date NMPB has achieved in in-situ

conservation on more than eighty thousand hectares of area. It has also worked in ex-situ conservation and cultivation of medicinal plants supported in more than two lac hectares of area.^[8]

Where India's arable land area of more than 150 million hectares is the second largest in the world; this arable land per capita is decreasing due to many reasons. One of the important reasons is abundant use of heavy chemical fertilisers, pesticides and herbicides which mostly contain high amounts of heavy, toxic elements like lead, arsenic, cadmium, nickel, mercury; even some of the fertilisers contain some radioactive elements. All these deteriorate the quality of the soil. As well as farmlands in the periphery of industrial area emitting out toxic substances into the soil, air and potable water of surrounding area, resulting into the soil pollution. The studies conducted to analyse this fact then it was observed that the plants growing on such fields are absorbing these toxic substances. When such medicinal plants are used as raw materials in the drug manufacturing, then the final product will also contain traces of these heavy toxic metals. The manufacturer unaware of this fact also sales such contaminated *Ayurvedic* drugs in the market, resulting into the health hazards in the patients consuming them. Then the *Ayurvedic* drugs are blamed in the world for having ill effects. But the fact is that even if the manufacturer underwent all the traditional cleansing procedures of the minerals, metals as well as herbal drugs, due to these contaminated raw materials the final products are not safe for consumers.

The next thing important about raw materials is their identification and authentication. The pharmacies procure the raw materials in bulk quantities. But nowadays the sources of medicinal plants are getting diminished due to the increased number of *Ayurvedic* pharmacies using and wasting the precious *Ayurvedic* raw materials in haphazard manners. Even the important drugs like *triphala* and *dashamoola* are difficult to obtain. So it is quite possible that there might be an adulteration of the raw materials. The drugs like *van-shalochana* are scarcely available in the market, so it is very difficult to attain their authenticity. Certain herbal as well as mineral drugs are banned for the use

or sale by the government of India like *Pushkarmoolam*, *Raktachandanam*, *Pravalam*, *Manahshila*, etc. Yet these drugs or the adulterants under the name of these drugs are sold in the large quantities in the market. Thus when the product is prepared with such adulterated raw materials, then there arise a question of the safety and efficacy of the *Ayurvedic* product.

The last important thing, which all the *Ayurveda-charyas* should keep in mind is that the *Ayurvedic* pharmaceuticals is mainly based on the herbal raw materials. As mentioned in the above paragraph, it becomes the important fact that even if the department of AYUSH is conducting projects on the conservation and cultivation of the medicinal plants; yet the hundreds of the medicinal plant species present all over the world are at the risk of extinction. And if the main backbone of the *Ayurvedic* pharmaceuticals gets extinct up to the remarkable quantities then it won't be any exaggeration that the future of *Ayurveda* is not that bright. Thus it is our prime duty to personally look into this problematic situation *Ayurveda* may face in near future.

GMP regulation:

The Good Manufacturing Practices for ASU Drugs as described in Rule 157 of Drugs & Cosmetics Rules 1945 with conditions as specified in Schedule T / GMP are to ensure that: (I) Raw materials used in the manufacture of drugs are authentic, of prescribed quality and are free from contamination (II) The manufacturing process is as has been prescribed to maintain the standards (III) Adequate quality control measures are adopted (IV) The manufactured drug which is released for sale is of acceptable quality (V) To achieve the objectives listed above, each licensee shall evolve methodology and procedures for following the prescribed process of manufacture of drugs which should be documented as a manual and kept for reference and inspection. However, under IMCC Act, 1970 registered *Vaidyas*, *Siddhas* and *Hakeems* who prepare medicines on their own to dispense to their patients and not selling such drugs in the market are exempted from the purview of Good manufacturing Practice (GMP). The legal provisions related to GMP

are described under Drugs and Cosmetics Rules 1945, particularly Rule 151 to 160 and Schedule T.^[9] GMP if followed religiously then there will be a total assurance about the safety and efficacy of the *Ayurvedic* products; but as revealed earlier that there are many industries who may not be GMP certified. They do not possess any license from Government to manufacture *Ayurvedic* drugs. One of the news report confirms that there are nearly 75% of the *Ayurvedic* pharmacy who are not certified under GMP guidelines or do not possess any practicing license. If we are unable to control this then there is no doubt that all the *Ayurvedic* products available in market nowadays are genuine.

Researches in Ayurveda:

Research in *Ayurveda* is still in its primitive stage and has to upgrade and update to the current trends. In the current era while various observational, clinical, literary researches are being carried out in the field of *Ayurveda*; yet there is a large scope for *Ayurvedic* researchers to explore many more things about *Ayurveda* for better authenticity, safety and efficacy as well as for global recognition of *Ayurveda*.

The literary research involves-the revival and publication of ancient classical literature; collection, compilation and documentation of Subject-wise references related to drugs and diseases from ancient classical literature, lexicographic works, contemporary literature and allied modern sciences. These are a few aspects of literary research work in *Ayurveda* which will certainly enrich *Ayurveda*, bringing out the latent potentialities that are lying dormant and unexplored in its vast literature. Unfortunately it is quite possible that there would be forged or repeated literary works published in the journals or publication magazines. So it becomes essential for the newcomer of *Ayurveda* that the previous research he is searching is published in a reputed international or national peer reviewed journal for the safety and efficacy of the current day *Ayurvedic* literature work.^[10]

Clinical trials form the main source of evidence-based medicine (EBM) and thereby forming the backbone of clinical practice. Evidence-Based Practice (EBP) has

become the treatment of choice and is a combination of research, clinical experience and patient preferences. Dept. of AYUSH, Ministry of Health & Family Welfare, Govt. of India has drafted guidelines on Good Clinical Practices (GCPs) for Clinical trials on *Ayurveda, Siddha, Unani* (ASU) Medicines, which have been circulated very recently in November 2011. Good Clinical Practice (GCP) is a set of guidelines which encompasses the design, conduct, termination, audit, analysis, reporting and documentation of the studies involving human subjects. The guidelines seek to establish two cardinal principles: protection of the rights of human subjects and authenticity of *Ayurvedic* medicine clinical trial data generated. More than 400,000 registered *Ayurvedic* physicians at more than 250 government- accredited universities or colleges form a major resource for carrying out clinical trials related to the field. However, a recent review of 225 original studies published in Indian *Ayurveda* journals concluded a non-satisfactory diagnoses and inconclusive outcomes being used in nearly 90% of the published studies. The fact is that *Ayurvedic* medicine needs more rigorous scientific research for evaluating safety, quality and efficacy to be acceptable to the scientific communities^[11]. Hence, for novice researchers, an update on the various aspects of *Ayurvedic* clinical studies such as study design, nature of intervention, details of funding and the institutions/investigators carrying out research is necessary to fill their knowledge gap, avoid duplication of research that is being carried out in other centres and improving the research transparency.

Patenting in *Ayurveda*:

Perceiving need of digitalisation of traditional knowledge of India to protect it from patent bio-piracy especially in field of medicine a multiparty as well as multi-centric project was launched in the form of the 'Traditional Knowledge Digital Library (TKDL)'. Humble purpose of establishing TKDL is to assimilate the scattered and non-documented literature on traditional knowledge and bring it into a format which can be easily accessed, understood and retrieved by International Patent Examiners. This will have significant impact on the system of search and examination while

granting patents in the area of traditional knowledge whereby the possibilities of granting of wrong traditional knowledge patents will be significantly reduced. Hence, it is resulted into the safety of the *Ayurvedic* traditional knowledge^[12]

DISCUSSION

Ayurveda is an age old and traditional medical system of India. But *Ayurveda* is not just about the treatment. It is the way of life. It is the thought which inspires oneself towards health and healthy lifestyle. From daily morning chores of brushing, bathing, etc. to the good night's sleep; from the first christening ceremony to the last righteous rituals; from *baala samskara* (Rituals for new borns) to the *vivaha samskara* (Wedding ceremony) and celibacy; from student seeking education to the teacher providing it; from health to the disease; from *dravya* to treatment; and from *purush* (A person) to *paramatma* (An Ultimate Almighty), everywhere, every aspect of life is a lesson of *Ayurveda*. *Ayurveda* is not just what is written on the great *Ayurvedic samhitas*; but it is far beyond that. It is the holy science and every word in it is '*Apta*' (The excellent, unbiased and intelligent teacher/ mentor); hence truthful. Thus the efficacy of *Ayurveda* is not questionable. Its efficacy is questioned when the followers of *Ayurveda* have misunderstood the principles of *Ayurveda*.

Nowadays every step of drug manufacturing, from raw materials to the GMP regulations and pharmacy and pharmacovigilance, there lacks the standard procedures and there by authenticity of the product prepared.

Though many institutes are encouraging new generation researchers for the research studies; there are very few genuine researches going on in the present day. Thus the values obtained from such fake research works for the prevalence studies in public health or for deciding protocols for the basic treatment for the common diseases are committing nothing but the descent of the original traditional medicine. Many government faculties as well as private sectors or institutes are definitely working harder to bring the genuine *Ayurveda* in front of the whole world; but their

efforts are yet to get noticed by the people in our country and world. Therefore, the safety and efficacy of current day *Ayurveda* is a sure dreadful question in front of us.

CONCLUSION

Thus the dilemma in the safety and efficacy of current day *Ayurveda* will only be resolved if more manpower is projected towards the generosity work in *Ayurveda*. At the end of the day-month or universe, the fact is that the *Ayurveda* is immortal and perpetual without any flaw. Thus the bifurcations from main stream *Ayurveda* should be checked often for the safety and efficacy purpose of *Ayurveda*.

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