

Global Challenges and Limitations in Standardizing AYUSH Products

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ABSTRACT

The present study deals with the obvious limitations and challenges in standardization of AYUSH drugs both with reference to quality and efficacy. Herbal drugs are very difficult to standardize because the diversity and quantity of secondary metabolites within the same species of plant harvested from different geographic areas show great difference. Instead of working on mitigating the global challenge in herbal drugs, the metal based and mineral based drugs of AYUSH drugs can be perfectly standardized and therefore this group of drugs, AYUSH must focus and rest of the herbal preparations must be promoted more for nutraceutical benefits, complimentary and paramedical uses. Details of the analysis is included in the article.

Key words – AYUSH, Metal based drugs, Faith based healing system, Siddha

INTRODUCTION

The acronym- AYUSH is greatly comprised of Siddha system of healing practice that got evolved in southern part of India, that is Tamil Nadu and Ayurveda that prevails rest of India. Yoga, Unani and Homeopathy also form part of the above basket (1).

If we track the history of Siddha and Ayurveda healing practices, we can clearly understand the fact that both the healing practices are not man made, but are indeed God made wonder and that is why the system not only can help people to remain healthy and cure all diseases on earth but also help people to live without death for thousands of years if they follow all aspects of AYUSH in letter and spirit and verbatim and literatim (2). Not even an iota of deviation should be allowed or accepted and only then the above

goal can be achieved. Tirumoolar, Theraiyar and many other Siddhars are reported to have lived for several thousands of years and they only invited their death and otherwise we would be able to see them even today (3).

The Siddha system was a great gift of "Lord Siva" to his dear wife "Lord Parvathi". "Lord Parvathi", due to her extravagant kindness of humanity, gifted the blessings to the first Siddhar – Lord Agasthyar and the first Siddhar was the one who transferred the sacred wisdom to the rest. On the contrary, Lord Dhanvanthri incarnation of Vishnu spread Ayurveda.

Since the wisdom about Siddha and Ayurveda directly came from Lord himself, we, the mortal being have not right to question, validate or doubt the sacred science and instead must believe, trust, follow and spread the system selflessly, which many institutionally qualified siddha graduates in private practice are not doing and instead they are engaged in cross pathy and projecting self as allopathic practitioner. According to law and honorable Supreme Court of India, such an act is nothing but quackery and those who engage in quackery are quacks (4,5).

Since the authors are experts in Siddha system and also practitioner/follower of the same, the article is devoted much to Siddha system than Ayurveda.

General concept and composition of Siddha system of medicine

Siddha system in general is laid on the principle of Tridosha, pancha booth and taste and smell (nava-rasa) (6). The vata, pitta and kapha are the three humer that control the whole body and mind to be in harmony and any slight imbalance occur to the above three humer, the result would be

disease. Just by correcting the imbalance, health can be achieved is the cardinal principle of Siddha system. The cause for such imbalance is life style change, change in food habits, thinking process, lack of belief in God, not doing spiritual practices, chanting hymns, not following amulets, not having any faith in Talisman, fear in ghost or evil force etc.

Dinacharya, ritucharya, what to eat during the day, night, during different seasons, how to dress, how to respect the elders etc., are well presented in Siddha and Ayurveda systems.

As far as the composition of the Siddha system is concerned, Siddha system uses all most all aspects of nature, be it animate or inanimate aspects as drug, either directly or after processing the same. The waste materials of several animals and birds, feather, hair, tooth, horn, turtle shell, deadly toxic materials such as Arsenic, Lead, Mercury, several poisonous plants and plant materials etc., are vastly used in Siddha system (7).

The divine wisdom and divine power of great Siddhars transformed all toxic materials into wonder drugs and thereby they achieved curative power from such drugs for all most all diseases on earth. No disease on earth, we can say we cannot heal and cure through Siddha system, best example is Rasagandhimezhugu (8).

To mitigate the global challenges of Siddha system (its drugs), we need to divide the composition of the Siddha system (drugs) into two which is made more for better understanding and communication and otherwise such nomenclature does not exist in reality.

Herb based medicaments/recipes of Siddha system of medicine and mineral/metal based medicaments/recipes of Siddha system.

Constraints and challenges in herb based Siddha drug standardization

The wisdom of Siddhars in thrusting the healing potential of herbs is certainly linked with evolutionary concepts/postulates of Charles Darwin.

Herbs/autotrophs/photosynthetic organisms evolved much before man and we can confidently conclude that man is the last product of evolution and beyond man, more powerful and wiser than man, the evolution cannot offer or produce.

Therefore, the possible cause of all the subsequently evolved species of life have to be assumed as the consequent product of the pre-existing one. Due to the above possibility, the later evolved species has to depend on the pre-existing

one directly or indirectly and the pre-existing species must carry or store several necessary pre-requisites for the later evolved species. From the pedestal of such definition, the plants must have several beneficial aspects for total goodness of humanity which our ancient Siddhars have understood several thousands of years ago.

In the ancient days, most of the Siddha recipes were prepared afresh, customized and so was the therapy. The herbal resources were available in plenty, the population was low and the Vaidya would collect the herbal drug largely from the same geographic locality where he alone has the knowledge of the plant. Therefore, the drug thus made with such herbs may not show any deviation between batches. This would partially explain why the ancient Siddhars would not have faced any quality issues. Further, the customization of Siddha drugs and treatment methodology to each patient followed then may be due to quality issues of the recipe than diagnosis of the disease. Thus, the situation would have warranted such customization of the treatment and recipe according to each patient.

But today the scenario has changed totally. Population has grown in industrial scale and so are the disease burden. This has necessitated increased urbanization, increased cultivation and land utilization. Necessarily such change has to come at the expense of clearing the forest and immaculate landmass where the medicinal plants were growing naturally without any hindrance and pollution. The need for all such medicinal herbs also increased due to the increased disease burden and people's liking for siddha therapy. Which further triggered the cultivation of all such herbs artificially, barring geography, agro-climatic factors, cultivation practice and finally harvest specific instructions mandated by Siddha system. With the arrival of such bouquet of approach in making siddha drugs, quality issue, inferior therapeutic value and delayed treatment success etc., have also grown alongside of commercially growing Siddha system. Commercial benefits and considerations alone prevailed and purity, quality and therapeutic effect took the importance of how the 'extras' in the movies.

The best example is the illegal trade mark registration of 777 oil. A private Siddha drug manufacturing company in Chennai, without taking prior permission or even intimation to CCRAS (Central Council for Research in Ayurveda and Siddha, Govt. of India,) or NRDC (National Research Development Corporation, Govt. of India,

New Delhi), secretly took the trademark registration of 777 oil, the exclusive invention of CCRAS (Central Council for Research in Ayurveda and Siddha, Govt. of India,) where, Dr. Velluchamy, then head of CCRAS was the principal inventor. The said company filed cases against all those who use 777 oil name with the prefix or suffix of their company. Sanjeevi Pharma along with the first author fought the case and made sure the Chennai based Siddha drug manufacturing company write an apology letter to Director General of CCRAS (Central Council for Research in Ayurveda and Siddha, Govt. of India,) for the illegal act and finally the Sanjeevi Pharma won the case for everyone***. The above example is given only to show how commercial benefits and not truth, integrity and honesty perpetuated by Siddha system is ever followed or cared by some Siddha drug manufacturers.

How and what in herb form drug

Plants in general produce and accumulate several chemical constituents which are broadly classified as 'primary' and 'secondary' metabolites (9). Primary metabolite is nothing but the essential constituent of the plant and that is starch and sugars. Whereas the secondary metabolites, on the other hand are non-essential constituents for the plant with reference to direct survival value of the plant. It means, the role of secondary metabolites is attributed to have some role in defense, identity and phenotype uniqueness and finally for pollination/seed dispersal (plant reproduction).

The secondary metabolites are therefore produced in the plant case to case basis, meaning, when a need is there, they will be produced and otherwise may not be produced or produced in lesser or greater quantity.

Multitude and problem of plenty

Besides the above reasons, the list of secondary metabolites present in each plant is huge both in quantity and diversity. Same species of plant living adjacent to each other or are from two distinct regions can also show such variability in quantity difference and diversity of secondary metabolites (10). This unknown and unexplainable reason makes the standardization of Siddha drugs, almost impossible.

Standardization based on a few metabolites may be possible to achieve but that would only speak a little about the authenticity of the species of plant and not about the therapeutic or pharmacological benefit.

Curcumin, capsaicin, andrographaloid etc., are some of the secondary metabolites proved to have a vague therapeutic value. If we use any of them as fingerprints for standardization, then we only have to isolate the same from the plant and use, as these compounds are present in the plant at very low level. Isolation of these compounds will come with huge cost and the end result when turns weak, naturally the means does not justify the ends and therefore such an option is not viable. The above scenario is true with all most all herbs and therefore standardization of herbal drugs is possible only partially, half-baked and with enough and more 'ifs and buts'. Such preparations can only carry great legacy, a lot to speak but not the therapeutic merit that is expected from a drug which would give the desired relief and benefit to the end user.

What is the way forward for total herbal preparations?

The bold, brave, courageous and scientific approach would be to accept the reality, limitations and the necessary omniscience of such limitations in AYUSH drugs and re-define the role of AYUSH drugs for supplementary benefits. Paramedical value of the Siddha recipes is if promoted, the system would gain greater recognition and acceptance. None of the herbal preparations of Siddha and AYUSH can be standardized like allopathic drug, even if we attempt to achieve the above, 5-10% standardization also not possible to achieve because, quantity of each metabolite, diversity and synergy, all the three factors play a role which cannot be identified, illustrated or established. This is why we made the caveat in the beginning itself, the wisdom must be believed, trusted and followed should not be questioned or debated or attempt to prove.

200% standardization is possible with metal and mineral based Siddha drugs

Metal and mineral based Siddha drugs can be standardized perfectly and can be promoted globally. Standardization is possible with the above group of drugs but the onus of proving safety, efficacy and pharmacokinetic details also is with the system. It is easy to establish and once it is established, the world would prostrate and kneel before Siddha system for its wonderful metal and mineral based drugs and how the system has converted toxic arsenic, mercury, lead etc., into wonder drugs.

The missing links – Government support, public reception and cross pathy

Government is supporting AYUSH and Siddha system humongous-ly and extravagantly and all most all Siddha graduates in government sector are doing their best to develop the system. General Public is also overwhelmingly supportive to siddha system. The only black-hole in the system is some siddha graduates in private practice who are engaged in cross pathy proving siddha system is ineffective and only piggybacking on allopathic system, siddha system can survive. However small this group may be but the damage they cause to the system is quite huge. Government of Tamil Nadu must take strict action against quackery and quacks as defined by Honorable Supreme Court of India and cross pathy must be stopped and only then the glory and greatness of siddha system can be restored.

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