



SAFETY AND EFFICACY DILEMMA OF CURRENT DAY AYURVEDA

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ABSTRACT :

Safety and efficacy has been much discussed in Ayurveda. In spite of Ayurveda being the oldest medicinal science having survived 5000 years of history ridden with both Mughal and British invasions and efforts to neutralize and discourage this age old tried and tested medicinal branch.

It is the need of the times that every aspect of medicinal science needs to be presented in scientific manner with clinical trails to prove its efficacy and safety. In today's day and age aapta vakya still demands proof and providing this proof will help us to bring this indigenous science back to its glory days which is the duty of every practitioner and believer of Ayurveda.

We can very well use this opportunity to present before the world the safety and efficacy of ayurveda and its medicines and ones and for all remove this dilemma regarding these aspects.

Public interest for the treatment with traditional system of medicine is mainly due to increased side effects in synthetic drugs, lack of curative treatment for several chronic diseases, high cost of new drugs, microbial resistance, and emerging diseases, etc.

Furthermore, there have been controversies due to a few biased and flawed studies that claim the use of toxic materials in ayurvedic preparations. The lack of randomized, controlled trials has only increased the public's distrust.

Keywords : Ayurveda, Safety & Efficacy, Medicinal Plants, Herbs, Mental.

Discussion

Dilemma regarding the active principles of the drug. There has been much research to understand the mode of action of herbs but unfortunately many of these research works are concentrated on the basis of the active principles of the herb which many times fail to give the same effect as the drug on its whole thus raising questions on its efficacy

Due to the use of the whole herb or combination of herbs in Ayurvedic formulation, there is the possibility of interactions between the potential bioactive ingredients of the herbs, leading to the development of a distinct component between herbs in Ayurvedic medicines, which helps to fight the disease

In Ayurveda, this statement has been true for thousands of years, where the combined effect of various herbs or the whole herb is responsible for the therapeutic efficacy rather than action of a single active ingredient. Our classical texts of charaka, sushruta, vaghabhata too have mentioned combinations of drugs for treatment of various diseases. These combinations have proven useful in patients when used with proper understanding of the dosh, desh, bala, kaal of the patients. Ayurveda practitioners have used these combinations and have seen their clinical results.

But this dilemma regarding their efficacy can only be removed if proper documented evidence regarding the prognosis and the stages of improvement of the patients health record is maintained and published. This shall help to show

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the medical fraternity the affectivity of these age old herbal formulations and prove to the world the safety along with the efficacy of these drugs.

The use of metals in ayurveda

Ayurveda has two types of medicines. Firstly the shodhana therapies and then the shamana therapies. Rasashastra medicines play a very important role in shamana. These can only be used under the strict supervision of an Ayurvedic physician. These being very potent and fast acting, they can have severe side effects if taken without the guidance of an Ayurvedic doctor.

Herbo-metallic formulations have been drawn attention of the world both for good as well as bad reasons. These formulations are more popular in therapeutics because of its smaller dose, palatability, shelf life, and efficacy. Herbo-metallic formulations are prepared from processed metals (mercury, gold, iron, arsenic, etc.) minerals, alloys, or their compounds. By various pharmaceutical processes, these metals are converted into nontoxic forms suitable for the treatment of various diseases. Herbal drugs are also used in pharmaceutical process which act as a chelating agent and provide large number of trace elements. Ayurvedic classics have described some basic rules for all formulations (herbal or herbo-metallic/mineral) regarding their preparation and prescription such as dose, duration, adjuvant, and diet restriction. In short, safety and efficacy of herbal and herbo-metallic formulations depend on proper pharmaceutical procedures and judicious prescription.

Due to their ability to act as a catalyst, increasing metabolism at cellular level (agnideepana), capacity for targeted and controlled drug delivery and immunomodulatory qualities, they are very useful in treating autoimmune disorders.²

The bhasmas are produced by shodhana which is a rigorous process by which the toxicity of the metals is removed by processes like multiple trituration, and heating of the raw metals to high temperatures, which removes unwanted parts from the raw material and separates the impurities.³

These processes are repeated anywhere from seven times to as many as 100 times to make sure the heaviness or toxic effect of the metal is nullified. The reason for nontoxic nature of metals (bhasma) is because the metals in Ayurvedic formulation are not present in elemental form but in inorganic form.

Bhasmas can be correlated to nanomedicines as the particle size ranges from 2µm for gold (swarna bhasma) to 5- 50nm for the other bhasmas⁴ which gives them the qualities of quick action and being very potent.

To check the non-toxicity of these formulations, it was shown in a prospective study of 86 patients with rheumatoid arthritis who were given Makardhwaja, which has mercury, sulfur and gold, for three weeks. Besides significant reduction in symptoms and RA factor, there was an increase in urinary mercury suggesting elimination of mercury from the system. There was no change in liver and kidney function in all the cases.⁵

To evaluate safety of mercury based Ayurvedic formulations, a study was done on rats where it was found that the mercuric chloride group showed necrosis of neurons in cerebrum, inflamed portal zone in liver and disruption of epithelium in proximal convoluted tubules in kidney. In comparison there was no abnormal histopathological change in the group given required dose of Makardhwaja, which is herbometal containing mercury.⁶



No increase in hepatic or renal damage or any other toxicity was found in the usage of mahayograj guggul, which is a herbometal ayurvedic formulation, in an observational study of 163 subjects for a maximum of 4 months.⁷

Gold containing drugs comprise a class of distinctive anti-arthritic agents (DMARDs) used when NSAIDs are insufficient to treat severe cases of rheumatoid or psoriatic arthritis. The reported remissions of rheumatoid arthritis was of the order of 30 per cent with gold therapy⁸

These studies show the non-toxicity of metals in Ayurvedic medicines as well as their efficacy in treating chronic diseases.

These clinical studies have succeeded in presenting before the world the efficacy of ayurvedic herbo-mineral and mineral based medicines but much work is still needed.

The dilemma surrounding rasa shastra medicines can only be reduced with such evidence based medicines.

Lack of pharmacovigilance

Some not all but few pharma companies in order to gain some profit differ from original procedures of drug manufacture to increase their productivity. It is necessary to keep a check on such companies as they further contribute to the dilemma regarding the safety of ayurveda medicines. The department of AYUSH has now taken steps towards pharmacovigilance to monitor such companies and to bring them under government regulations and norms with strict quality control to ensure the safety and quality of drugs manufactured.

Ayurveda , Panchakarma and its safety

Panchakarma is often called a five-fold therapy. It is customized to suit every individual, based on the needs of the person. It varies a lot

and depends on the Ayurvedic constitutional type, the individual's doshic imbalances, age, digestive strength and immune strength. Depending on the needs, all or only parts of the five therapies are utilized. Sometimes two or three of the therapies are linked together to form the basis of the treatment.

Ayurvedic texts have given a wide range of do's and don'ts regarding these therapies even mentioning and clearly stating individuals who are eligible to these treatments

But indiscriminate use of these therapies without minding the specificities has been on the rise due to the spa culture, subjecting every individual approaching towards ayurveda treatment to panchkarma has further raised questions on the safety and efficacy of these treatment therapies thus creating a dilemma of this otherwise safe and highly effective mode of treatment given in ayurveda.

As with every science panchkarma too has its side effects described as vyapada in our texts if used indiscriminately or without proper knowledge of the individuals health. It is necessary to maintain and follow a strict protocol regarding these therapeutic procedures in order to safeguard the health of individuals and to maintain the efficacy of these procedures.

Need for integration with modern times

Ayurveda introduces itself as a 5000-year-old science. Many Ayurveda practitioners are proud to be a part of this age-old science. Tradition and culture also change according to the current trends. There is no or little change in the form of Ayurveda as it is being practiced since all these years. Although the principles of Ayurveda are called immortal (that never die and are always applicable), it is a need to be contemporary with the current scientific trends for the benefit of the society and for nurturing Ayurveda.



Improvement in quality of herbal drugs

Most of the Ayurvedic Rasayanas (Medhya, Jeevaniya, and Lekhaniaya, etc.) are based on the herbal products. Many herbs such as Ashwagandha (*Withania somnifera* Dunal.), Shatavari (*Asparagus racemosus* Willd.), Guduchi (*Tinospora cordifolia* (Thunb.) Miers), Amalaki (*Embellica officinalis* Gaertn.), and Bhallataka (*Semecarpus anacardium* Linn.) are well-known Ayurvedic Rasayanas, which are proven immunomodulators. Adjutants are required for many of weak immunogenic vaccines, and Ayurvedic rasayanas may offer better and safer immune drugs that can be used as adjuvant in such vaccines and also in cancer treatment.⁹

Herbal extracts of therapeutic relevance are of great importance as reservoirs of structural and chemical diversity. Research in his field have proven more than 120 distinct phytochemicals from different plants have capability as lifesaving medicines. These compounds have been achieved through chemical and pharmacological screening of only 6% of the total plant species.¹⁰

The National Institute of Health has started extensive research for anti-inflammatory compounds from turmeric, ginger, and Boswellia with the aid of Ayurvedic knowledge. The screening of numerous herbs for treating cancer has been done using traditional knowledge on such herbs.¹¹

In case of herbal drugs, consistency in the chemical composition and bioactivity are essential requirements for their safe and effective use because the quality is the primary need for safety and efficacy of plant-derived medicines.

Drug Abuse by over the counter medications and non qualified practitioners

Another major concern regarding the safety of ayurveda drugs is the availability of over the counter prescription medicines.

Ayurvedic medicines since being natural and herbal based are widely taken over the counter from persons other than qualified doctors. Many of these medicines may contain several active ingredients intended to treat multiple symptoms. You may take such medications even though you have only one of the symptoms listed and over medicate yourself unknowingly.

The most commonly used over the counter medicines are laxative without knowing the harmful effects of overusing these laxative medicines because many a times the body becomes dependant on them.

This risk also applies to senna or cassia laxatives, which are frequently marketed as natural. These laxatives may decrease your colon's ability to contract, and over time may damage your large intestine's nerves, muscles, and other tissues. The cumulative lifetime use of commercial laxatives has even been associated with increased risk of colon cancer.¹²

Many of these medications are often not prescribed but just here say or the result of some half baked knowledge of individuals.

Dilemma regarding folk lore medicines

Many of the folk lore medicines have their roots in ayurveda classical texts. It is the need of the times to document these folklore medicines and subject them to tests and trails to prove their efficacy and present it to the world their vast implications in health management at primary health care. As demonstrated in many instances of jaundice and hepatitis cases. This will further



help to prove their efficacy and diminish the dilemma with

Conclusion

The dilemma regarding the use of herbal extracts and active principles as opposed to combined formulations given in classical texts can be cleared with more studies and clinical trails with regards to these formulations and presenting to the people the scientific basis with regards to the working of these formulations

The use of and preparation of metals for medicinal properties is an advanced and precise science. Failure to adhere with the proper steps in these medicinal preparations can then lead to presence of impurities and harmful substances .A strict regulatory body to preside over the medicinal preparation process and a strong governments norms to regulate and standardize these process can go a long way in maintaining and abolishing the dilemma surrounding the safety and efficacy of these drugs.

Improving the quality of drugs available in the market and standardising them too can go a long way in proving the efficacy of ayurvedic formulations.

Proper and judicious use of ayurvedic panchkarma therapies keeping in mind the dosha, desha bal and kaala of the patients for the benefit of the patient and not just for its monetary benefits can go a long way in securing the safety and security of these panchkarma therapies.

There is a need for integration with modern diagnostic tools in order to prove the efficacy of ayurveda drugs as such documented evidence can bring about a change in which the world looks as ayurveda as not just as an traditional system of treatment but as a medical science.

It is the need of the hour to set up a regulatory body to ensure quality control of medicines and systems for pharmacovigilance need to be set up to safeguard the quality of medicines produced by ayurvedic pharmaceutical companies.

Over the counter medications prescribed by persons other than ayurveda practitioners have greatly contributed to the dilemma surrounding the efficacy of ayurveda medications and strict laws need to be implemented to curb these practices in order to safeguard the efficacy and authenticity of ayurveda medicines

Folk lore medicines have played a major role in keeping the knowledge of ayurveda alive among the masses these folk lore medicines need to be documented and subjected to clinical trials to abolish the dilemma surrounding the efficacy and safety of these medicines

Safeguarding , documenting and standardising folk lore medicines will help to prove the safety of these traditional medicines and also prove the efficacy of these traditional and distinct formulations which are many times indigenous to the specific areas and help to control and prevent the most common diseases of the area.

The need for study of safety and efficacy in Ayurveda.

In order for ayurveda to regain the recognition it deserves to first ensure the safety of ayurvedic drugs and have documented evidences based on clinical trails to prove to the medical world the efficacy of ayurvedic medicines in treating chronic as well as acute diseases. There are many areas where the dilemma regarding the safety and efficacy of ayurveda arises, as a practitioners and believers of ayurveda need to work on those areas to



prove to the medical world that ayurveda is not just a traditional system of medicine but also an age old and highly advanced science dealing with healing of human mind and body.

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