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Discussion Kernel

Ayurveda research-are we on the right track?

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Among the various things that we as Indians can be proud of, is our ancient culture. When clans were progressing into societies in western countries, the Vedas were written in India. Greek mathematicians were trying to calculate the length of the hypotenuse when Indians had determined the distance between the earth and the sun. While elsewhere, medicine was practiced by shamans and magicians, plastic surgery was practiced and taught in India. Students from all over the world came to Taxila and Nalanda, the earliest universities in the world. If all these advances have come to a naught, we need to revisit history, to find out where and how our science and culture lost out.

Science in India is so old that it predates written history. The origins of Ayurveda too are lost in the mists of history; there is no record when this system developed, but it was in use as early as 5000 years ago. Originally shared as oral tradition, Ayurvedic concepts find mention in the Vedas, that are dated variously between 3000 and 500 BC [1,2]. Teaching and practice of Ayurveda flourished in the sub-continent till the beginning of Sultanate period in 13th century [3]. Thereafter Ayurveda shared the place of eminence with Unani, which had the patronage of Sultans of Delhi [4,5].

Both these traditional systems lost out to a different system of medicine that the British brought to India [6]. In 1600, the East India Company brought a surgeon, John Woodall (of St. Bartholomew's Hospital) to cater to the needs of company's settlements and

factories, introducing western medicine to India [7]. This medicine, was solely for the elite, the white colonialists and their native supporters, but Ayurveda was officially discouraged. Formal teaching of Ayurveda resumed in 1889 [8], while the first medical college was established in 1822 [9], the colonial government dismantled the existing system of traditional medicine, making people dependent on western medicine.

It is over seventy years now, that the colonial rule has made way for self-rule. Resurgence of Indian systems has however, been slow and it was only in 1995 that the government of India established a separate department now known as AYUSH (Ayurveda, Yoga, Unani, Siddha and Homoeopathy [10]. Currently there are 301 Ayurvedic Colleges against 542 colleges teaching western medicine. Facilities for education and research in Ayurveda are so poor that it is not the first career choice of youngsters. The stunted growth of research in Ayurveda can be attributed to budgetary constraints [11,12], but equally important is the fact that western principles are imposed on it.

It is acknowledged that Ayurveda does not believe in "one shoe fits all", in fact it celebrates individuality of patients. It may be noted that western medicine too has realized that no two individuals are equal and for best results, treatment needs to be customized [13]. Patient stratification and carefully choosing drugs is the main strategy for balancing efficacy and toxicity of anti-cancer drugs [14]. This has been happening in the treatment of other diseases too, but customisation of therapy is essential in cancer [15].

Concepts of physiology or pathology in Ayurveda differ from those of western medicine. However, just because western medicine has recent origin that does not mean that its concepts have greater validity. For hundreds of years, ulcers were believed to be caused by *hurry*, *worry* and *curry*, but in 1983 Barry Marshall showed that they were caused by an infection [16]. Similarly the aetiology of many diseases has changed over the last century, thus all other existing theories need not be accepted as the gospel truth.

Western medicine has always been obsessed with trying to prove that the newer drug is better than older ones, mainly because the drug is patented, and evidence of superiority meant profits for the innovator. To compare between two drugs for a given disease or condition, there is no better trial design than a randomized, controlled, trial (RCT). The RCT is therefore the gold standard for western medicine (though it has been pointed out that the trusted parachute has never been tested by this method) [17]. In Ayurveda,

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there is no fight for patents, and the goal of medicine is health of the patient and not of the industry. For this reason alone, RCT may not be the best design to study Ayurvedic medicines.

One of the main drawbacks of RCTs is that though they may be good to compare two drugs, they are not suitable for comparing multi modal therapies for a condition. RCTs also compare the efficacy and safety of drugs under strict experimental conditions. In fact the inclusion and exclusion criteria of trials are so tough that hardly 10% of patients seen clinically, fit in the criteria and can be recruited in a trial. Trials are thus done on carefully selected 10% of patients and the results obtained are used to treat the balance (90%) patients. No surprise that results in the clinic after marketing the drug, rarely match the results obtained in trials.

We need to look at Ayurveda from a different angle; here where the objective is not to prove one drug to be better than others, but to identify the best therapy for the patient. There is, thus a subtle difference in the objectives in western versus Ayurvedic research. We therefore have to design trials differently if we want to evaluate Ayurvedic therapies vis a vis western medicines [18]. Using one test procedure for two different therapies with different objectives can hardly be called scientific. It is here that all must come together to suggest different trial designs, no doubt a challenging task.

Once we agree that "one shoe does not fit all" there is no reason that the treatment group in trials be treated with single drug (or dose) only. In fact participants in the treatment group may receive different drugs and dosages, judged to be most suitable by the physicians. This choice could be based on participants' gender, age, co-morbidities, prakriti, or anything else that the physician thinks is relevant. Such a treatment group be compared with a control group, the participants of which may receive standardized dose of an Ayurvedic medicine. I believe, such a study will test whether "one shoe fits all" or does it not. After this is done for a variety of diseases, one could compare an Ayurvedic regime with that from the western medicine. Essentially the trial will not be between drugs, but treatments.

At the risk of being repetitive, I would affirm that the trial should test which treatment will best treat the patient, and not which drug will be better for the patient. The focus shifts from the superiority of the drug to the superiority of treatment for the patient. It would be rather difficult, but not impossible to blind such a study, and this design could be used retrospectively or prospectively. I admit that the above design is merely a postulate, untested loud thinking, but if one's thought is allowed to run freely, many more such designs could emerge from our peers and students. However, new designs alone cannot end all problems faced by Ayurveda today.

Currently, there is a problem in publication and the plight of Ayurveda journals has been eloquently described by Rastogi [19]. There are just a handful of journals devoted to Ayurveda [20], as against the thousands for western medicine. Though Ayurvedic research is not so widely done as western medicine research, the small number of journals do not allow the publication for but a select number of papers. The Declaration of Helsinki requires the publication of both positive and negative results as do many of our scientists [21], but is this feasible? Do we have an adequate number of journals to accommodate the knowledge that is being generated? Do we also have the required number of reviewers, who understand both Ayurveda and research methodology? Lastly, if reviewers approve only papers that fit in the western research method mould, would Ayurveda ever grow? These questions beg answers now.

The experience with COVID 19 infection has taught us a number of things. First and foremost, it showed us that newer and costlier drugs are not the answer [22]. India with its vast population, and relatively poor healthcare system has had a much lower infection and case fatality rate; something that no one has been able to explain. Is this an indicator of failure of the western medicine or a failure of our trial methodology? Could it be that our largely

vegetarian diet, including herbal products have boosted our immunity? Frankly there are no answers, but it is time to think deeply on this question, and ask ourselves, should we change the direction of research and methodology of trials? Ayurveda has ensured survival of our people for thousands of years, we need to have a broader vision while studying it.

I had the privilege of discussing a study conducted at a reputed Ayurvedic centre. The scientists designed a good trial to study the protective effect of Ayurvedic medicine against COVID 19 infection in a high risk group. The control group received only standard care, but the standard care used by this particular centre was so good that none from the control or treatment groups developed infection. Had the standard care been slightly less vigorous, there would have been infection in the control group but not in the treated group. The work is important and the data obtained is very useful, but which journal would be ready to publish it? Negative results must be put in the public domain, but journals are not keen to do it, how do we overcome this hurdle? I agree that I have raised more questions, but I believe a beginning would have been made.

Declaration of competing interest

None.

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