

Safety and efficacy issues in Ayurveda: Exploring opportunities through criticism

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How to cite the article

Rastogi S, Singh RH, Safety and efficacy issues in Ayurveda: Exploring the opportunities through criticism, Ann Ayurvedic Med. 2021; 10(3) 198-200 DOI:10.5455/AAM.107599

Since its recent reuptake by the global community, Ayurveda is repeatedly confronting an uncomfortable tug of war between its practitioners / researchers and those from biological health care science. The tussle is primarily about its safety or adversity pushed tirelessly and respectively by the former and the latter (1, 2, 3). Unfortunately for an onlooker, the push from both sides is desperately disproportionate and unrealistic in either conditions.

Ayurveda generally enjoys the trust of the people on two largely intangible grounds. One is its safety having a notion that being natural in origin, Ayurveda interventions are safe. The other is the disease eradicating potential of Ayurveda equated with uprooting a pathology (4). Although believed by the masses, both of these beliefs are yet to be tested through parameters of science for their approval. We see that the stakeholders from Ayurveda have actually never shown any interest to put these beliefs under scanner.

Notwithstanding the fact that such beliefs play a big role in sustaining Ayurveda in India, a large benefit of which is actually reaped by the pharmaceutical companies working in the sector, one cannot deny the factual observations related to commercial malpractices prevailing in the name of herbal products (5, 6). It is this consumer's perception of safety, which actually upholds the outstanding performance of such products in the market. Not buying into this belief by those holding the responsibility of carrying

Ayurveda forward, makes us suspect that they do not wish to address these issues for obvious conflicts of interests shared by the beneficiaries.

Similarly, for those who find pointing at the limitations of the others highly interesting, need to be encouraged to do so, albeit in the interest of science, and absolutely not for any other reason. Obviously, such criticism should always be merit based and constructive by all means, and should focus upon the limitations of the materials and methods referring to the particular publication rather than extrapolating it to whole systems or its followers (7, 8, 9). A golden rule in this regard is to keep a clear distinction between the lay media and evidence based scientific publications. A true scientist should only be a scientist adhering to the principles of science, and should make inferences in light of his ignorance of many other knowledge domains, which may not directly be connected to his field of expertise.

If we try to look through the published literature on adversities caused by various systems of medicine in the past few decades, we will certainly find bigger numbers associated with modern medicine compared to fewer cases reported in Complementary and Alternative health care. Although such observations never endorse that adversity does not occur in Ayurveda, but certainly demonstrate lower incidence by comparison with more advanced health care systems.

Ayurveda may immediately learn some quick lessons from

any such criticism focusing upon its supposed limitations in validity, safety, responsiveness and efficacy. If taken diligently and responsibly, any such criticism, may eventually give Ayurveda the opportunity to step one place higher than where it is now. First lesson: it is not important to merely note an adversity related to the use of a drug; more important is to establish a cause and effect relationship between the intervention and the effect. There are established scales to measure such a relationship. The WHO-UMC causality scale, the Naranjo scale and the RUCAM (Roussel Uclaf Causality Assessment Method) scale are good, reliable examples (10, 11). These scales can distinguish the ADRs as certain, probable/ likely, possible, unlikely, conditional and un-assessable on the basis of available data to ascertain the reliability of the relationship between event and the drug in question. This is obvious to understand that mere observation of an adversity in the context of a drug consumption cannot victimize a drug unless it fulfills all the set criteria to prove it as the sole cause of the event.

When adversities are present, it is more important to see their incidence in proportion to the people consuming it. Drug related adversities are realities in health care practices irrespective of class of drug or the people consuming it. Knowing more about its mechanism, identifying the people more vulnerable to it, dosing and co-consumptions of other medications, and the possibility of any herb-drug, herb-herb interaction leading to adversity is crucial to minimize such eventualities.

What makes more sense in clinical practice is to look at the earliest signs of impending adversity and to identify the most practical ways to minimize its impact.

Ayurvedic single drugs and formulations are often been criticized for not having any data related to their safety derived through phase 1 clinical trials. This is countered by pointing out that Ayurvedic formulations have been in human use for centuries, and there had not been such cautions related to their adversity in published literature so far. Keeping in place, the conceptual, literary and experience-based evidence is crucial in this regard.

Without giving enough space for others to grow in their own manner, a simple insistence on use of modern medical methods in testing Ayurveda on all matters related to safety and efficacy seems to be unhealthy and hindering for Ayurveda.

Rather than reinventing the wheel and insisting for phase 1 trials for ayurvedic herbs, what seems to be more feasible is a simple exercise of accumulating and analyzing the data from previously conducted clinical trials referring to particular drugs and formulations irrespective of clinical conditions where they are used. This may easily generate real and trustworthy data about drug safety in Ayurveda without going into exploring the safety data from pre-clinical and phase 1 clinical studies. A mechanism to study safety of Ayurveda interventions through previously conducted study, somewhat on the lines of systematic review or meta-analysis may actually make the claims of safety in Ayurveda more acceptable globally. It is not out of place to state here that, contrary to 'evidence-based practice' approach of modern medicine where evidence is produced prior to practice, traditional health care systems follow a 'practice-based evidence' approach, where evidence is generated on the basis of practice already in vogue.

If consciously attempted, each criticism may give Ayurveda an opportunity to clear the mist and become more acceptable globally. Adopting the tools of information technology to carefully synthesize safety related data from clinical studies may come as an immediate answer to ever mongering issue of safety pertaining to Ayurveda interventions.

Conflict of Interest

Dr Sanjeev Rastogi is senior editor and Prof Ram Harsh Singh is founder Chief Editor of Annals of Ayurvedic Medicine.

Acknowledgement

Authors express their sincere gratitude to Prof Alex Hankey in refining the draft of the article.

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Source of Support : Nil
Conflict of Interest : None