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Correspondence

Ayurveda formulations: A roadmap to address the safety concerns

Sir,

I read with great interest the article by Patwardhan K et al. on 'Ayurveda formulations: A roadmap to address the safety concerns' [1]. The article genuinely tried to revive an old unsettled issue pertaining to the safety of Ayurvedic formulations, although such attempts are always found short lived surfacing only as a startled response reacting to a finger pointing out something fishy in the system.

Safety in Ayurveda has always been a matter of concern not only today but it is also discussed in the history. Ancient Ayurvedic literature has many guidelines about drug quality, procurement, storage and processing. There are further references about judicious use of drugs by meticulously judging the disease and personalized therapeutic. We see that where the former part of safety has much to do with Good Manufacturing Practices (GMP), the later is concerned with Good Clinical Practices (GCP). This is pertinent here to point a few common observations seen regularly in current Ayurvedic clinical practice. Regarding the quality standards of Ayurvedic formulations, a common observation in the clinic is that the same Ayurvedic formulation manufactured at different pharmacies has difference in colour, taste and effects. For few medicines prescribed for a longer period of time, the consumers notice that the medicine procured each time from the market, despite their similar name, they look and taste differently and eventually have a different effect. A practitioner, when questioned about genuineness of the variants available in the market, has no clear replies. Sometimes, this variation leads to adverse events as well. There are clinically noticeable adversities related to many common drugs like *Shadabindu taila* which is highly irritating sometimes when used in *nasya*, *Brahmi vati* being a highly gastric irritant, *guggulu* causing urticarial reactions [2] and *bhallataka* causing burning sensation at the glans penis. What should be done to ensure the uniformity of classical formulations of Ayurveda available in the market is a question requiring serious thought. If this can be assured, adversities due to manufacturing lapses of the formulations can eventually be minimized to a substantial number. The best way to ensure the finished product quality is to develop a thorough organoleptic, physical, and chemical characterization of all such formulations and to ensure that all the products available in the market essentially meet such standards and the guidelines.

Besides quality standards of formulations, contemporary Ayurvedic clinical practice is another area requiring urgent attention. Even a drug of optimal quality cannot assure safety if it is not used judiciously. Obviously, here the onus lies upon the physician for being the in-charge of the health care delivery team. There are multiple practice-based reasons of drug adversity in Ayurveda. The first, which requires due attention is the possibility of cumulative toxicity (CT). CT is a phenomenon where a prescription contains formulations having common ingredients with the potential of causing an adversity. Formulations containing *vatsanabha, kupilu, bhallataka* and metals are recommended to be used cautiously in terms of their dose. The doses of such formulations are determined on the basis of their independent and solitary use. If more than one formulation containing such components is prescribed, their net dose should remain within the normal limit. However, the fact remains largely neglected and the ignorance makes an easy slip for adversity to creep in due to inadvertent over-dosing. The commonest example of such adversity is the concomitant use of *Sanjeevani vati* and *Tribhuvan kitri rasa* both containing *vatsanabha* and hence having a possibility of aconite toxicity if their net dosage is not adjusted cautiously [3,4].

The other area of concern is idiosyncratic reactions related to the individual drug usage. Ayurveda emphasizes that the drugs should be selected on the basis of individual variations [5]. We are aware that *bhallataka* and *guggulu* have a possibility of causing adversity in *pitta* dominant people. Such pharmacogenomic approach however, so far could not find a place in Ayurvedic practice where the medicines are needed to be genuinely prescribed on the basis of drugs and their suitability in the individual.

Irrational prescribing is one more area of concern in Ayurvedic practice. It has been observed that herbo-metallic (*rasa*) preparations and proprietary drugs often outnumber the herbal and classical Ayurvedic formulations in practice without a rational for the same [6]. Prescription errors (errors in the form of omission or commission of information in the prescription) and prescribing errors (errors in choosing the right drug as per the *roga* and *rogi bala*) are commonly observed errors in Ayurvedic clinical practice and have been recently brought into the notice [7].

Another very important aspect of potential adversity is the practice of integrative medicine. A large section of patients of chronic illness like hypertension, diabetes, arthritis, thyroid disorders etc. on modern medicine seek Ayurvedic treatment. There is no clear protocol for patients of chronic illness, currently on modern medication and seeking Ayurveda should be helped. Due to lack of understanding about the potential interaction between modern and Ayurvedic drugs both are used concomitantly with observance of an empirical caution of consuming both with some time lag. We know that for drugs having a delayed clearance, the chances of interaction remain high despite observing such a time lag. This was indicated by demonstrating possibility of interaction between *Shankapushpi* and phenytoin sodium in patients of epilepsy [8]. The interaction revealed that *Shankpushpi* reduced the bioavailability of

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phenytoin by acting through the same pathway as was used by the phenytoin. Unfortunately such studies are largely missing from the core research focus of Ayurveda. The patients are exposed to unforeseen threat of herb-drug interaction in such conditions where modern medicine can't be abruptly discontinued and where Ayurvedic medicine can't be completely relied for having an effective control of the condition.

While talking about all sorts of possible adversities related to Ayurvedic drugs, in particular, to that of heavy metal use, a case report on Ayurvedic preparations in intensive care units also requires attention. This report describes the use of some Ayurvedic herbo-metallic preparation in a comatose patient of hepatic encephalopathy. Despite the drugs containing heavy metals, the drug use resulted in substantial improvement in the hepatorenal profile of the patient and was backed by the corresponding clinical improvements. This report argued that rendering the whole class of herbo-metallic Ayurvedic drugs as potentially toxic may be unjust and exaggerated and hence the judgment should be made on case to case basis and considering conditions where they have been used [9]. There is evidence suggesting that current methods of measurement of the heavy metal contents in Ayurvedic formulations are not adequate and sufficient to test the claims of safety of classical Ayurvedic formulations. A continued use of such formulations by the Indian population and diaspora further supports the view that such toxicity claims should be properly weighed in terms of quality and their methods of use and not merely on the basis of only heavy metal contents.

Ayurveda still needs a long way to go to bring clarity and standardization in its practice in order to ensure a safe and dependable health care delivery. This is obvious to note that a continuous vigilance and an ongoing research touching various areas of concern, although important but not yet explored, is the only way to progress. Let's keep moving.

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None.

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