

Reorientation program on research methodology for Ayurveda academicians: A clinical pharmacologist's perspective

Sir,

We at the Department of Clinical Pharmacology, TNMC and BYL Nair Ch. Hospital have recently conducted a Continued Medical Education programme in “Research Methodology for Ayurvedic faculty members” (supported by Rashtriya Ayurved Vidyapeeth [RAV], Department of AYUSH). This programme was attended by 30 participants from different states of the country. As a faculty member of the department organising the programme, I had an opportunity to participate in the programme as an observer and to closely interact with the participants. They were interactive, and have shown active involvement throughout the programme. This communication is based on my observations about attitude and practices of the Ayurvedic faculty toward research methodology,^[1] which are summarized below.

The most appreciated lectures in the whole programme were related to experimental pharmacology. However, a majority of the participants failed to apprehend the procedural details, possibly due to limited exposure to this kind of work. Further, they were not interested in taking up such studies at their institution in view of the scarcity of resources and infrastructure available at the Ayurvedic Institutions. To overcome this, the concept of “collaborative research” with aid of modern technology was put forth which however did not appear to be very appealing to them for reasons that were not clear to us.

All the participants had basic knowledge regarding research methodology. However, very few participants had an in-depth understanding of the subject for example, the difference between “exploratory” and “efficacy” study was not clear to many participants. This may be because most of the studies conducted in Ayurvedic Institutions as a part of MD/PhD thesis are generally efficacy oriented. The exploratory clinical studies usually involve limited

human exposure to assess safety and activity and have no therapeutic or diagnostic intent.^[2,3] In Ayurvedic context, exploratory studies do not mean First-in-Human (as is the case with conventional medicine) studies since Ayurvedic medicines are already in use since ages together, but these studies are carried out with a structured protocol for documenting the first time evidence.

Another important aspect of research methodology is “ethics.” It was observed that although the participants were aware of the ethics principles like justice, respect, and beneficence, a majority of them had not received any formal training in ethics and good clinical practice (GCP). In a role played by the participants on “Informed consent,” many participants could not appreciate the difference between medical ethics and research ethics. It is well known that a role of physician differs from an investigator in evaluating a therapy with limited knowledge about safety and efficacy. This might result in “therapeutic misconception” by potential participants interested to take part in the study for cure of the disease.

The participants were more comfortable in expressing their data in terms of frequencies and numbers. They feel that the “tests of significance” are not essential for MD/PhD thesis and are required mainly when the research project is being done at National/International level.

Although many of the speakers recommended the need for adverse drug reaction monitoring for ASU drugs, the participants were not very enthusiastic about this concept and the NPC-ASU (National Pharmacovigilance Centre -Ayurveda, Siddha and Unani) programme.^[4] It is disappointing to know that 3 years after the launch of the NPC-ASU programme and many orientation/awareness programmes, the Ayurvedic fraternity is still finding it difficult to accept the flip side of Ayurveda.

Almost all participants were willing to conduct research studies; however, availability of funds was a major issue with them. Although there are various funding schemes made available by different government agencies like AYUSH, Council of Scientific and Industrial Research (CSIR), Indian Council of Medical Research (ICMR), Department of Science and technology (DST), Department

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of Biotechnology (DBT), the ayurvedic physicians were either unaware of the same or reluctant to approach these agencies and procure funds, as their opinion was that their chances of getting adequate funds was low.^[5] As a result, apart from student dissertations, other research activities are NOT taken up by a majority of the Ayurvedic Institutions.

Most importantly, there was a dilemma in the minds of participant about how to conduct clinical evaluation of traditional medicines within the specific framework of rigorous clinical pharmacological principles without ignoring the Ayurvedic concepts like *dosha*, *prakriti*, etc. This emphasizes need for suitable research methodology in Ayurveda based on its principles.

These observations are based on my personal interpretation and have not been captured through any structured questionnaire or participants' feedback forms, as they were sent to RAV in a sealed envelope. However, they sufficiently highlight the need of robust and frequent training programmes in research methodology for Ayurvedic researchers to improve the quality and conduct of evidence based research, being carried out at Ayurvedic Institutions and also to increase their active participation in major research programmes. The sound knowledge of conventional research methodology can also help to evolve Ayurvedic research methodology.

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