

Research design in Homoeopathy: A perspective

As much we are talking about the evidence-based medicine and in the quest to answer the scientificity of Homoeopathy, much focus is being laid on conducting randomised controlled trials (RCTs) which are considered the gold standard of evidence. However, time and again, conclusion of these RCTs is compromised and debated.^[1] Further, a meta-analysis conducted using these RCTs is also criticised for ‘cherry-picking’ of studies, disputed selection criteria and purposeful exclusion of studies.^[2]

Another aspect of debate is the inherent issues of homoeopathic research methodology that may not be acceptable to critics challenging the results causing, and may continue to cause, confusing results. It has been seen in almost all the meta-analyses including trials that do not follow the principles of Homoeopathy and are not a true reflection of the problem of using a remedy for a specific pathology.^[3] Hence, the overall conclusions are compromised. It is reported that clinical trials in Homoeopathy face the conflict between fulfilling statistical demands and meeting the homoeopathic reality.

Further, the success of any clinical trial also depends on the prescriber, the skills to individualise and prescribe the *similimum* i.e., the individualised medicine in Homoeopathy. Prescriptions without justifications in clinical trials lead to questionable results. It has been observed that there is shortcoming in the teaching of Homoeopathic Materia Medica and Repertory as well. Homoeopathic polycrest remedies are mostly used by prescribers and clinicians as these drugs are taught well and in detail and are easier to select. The skill of making individual totality and selection of medicine based on signs and symptoms needs to be made more scientific and rational.^[4]

Trial designs are being revisited in both conventional and Homoeopathy. Focus is being laid on personalised medicine^[5] and scientific tools for assessing the reliability and validity of homoeopathic trials have also been developed.^[6] In this issue, we include a randomised, double-blind, placebo-controlled clinical study using a single drug *Sepia* to demonstrate its efficacy in the management of menopausal symptoms.^[7] This type of single-drug model of RCT in Homoeopathy is very unique and can support the efficacy of homoeopathic drug in particular type of illness. However, it is important that more such studies on different drugs are conducted at sites where the footfall of patients is sufficiently high for screening and enrolling as per the large sample size required for such kind of study.

Lot of evidence, on the other hand, is generated from the observational trials in Homoeopathy, especially when RCTs are not very feasible, there are methodological difficulties or when trials are done as a pilot study only. Such trials can also

be referred during clinical practice or while planning for larger controlled trials. The issue includes an open-label prospective observational trial that examines the effects of individualised homoeopathic medicines in serum uric acid level and quality of life in patients suffering from gout. The authors illustrated that limited research evidence is available for the usefulness of Homoeopathy in gout, thus further research on this disease is warranted. Comparing the serum uric acid level at baseline and after Homoeopathic treatment at 3 months, makes the trial results evidence based. The positive results from this observational study can be used as preliminary evidence and further utilised in planning rigorous and high-quality RCTs with larger sample size.

An article is included in this issue where a team of interdisciplinary researchers have undertaken experiment to assess the effect of medicine which is not prepared through the traditional potentiation methods. Their experiment is conducted to observe and compare the effect of serial dilution and succussion with the effect of succussion alone using homoeopathic medicine. The authors concluded that when there is no dilution, the amount of drug available is same for all potencies from 6C to 200C and a larger number of nanoparticles are produced by succussion and the antibacterial effect is more as compared with other set of medicine with increased dilution. Scientists have conducted experiments to show the existence of nanoparticles and nanoassociates in homoeopathic high dilutions as an attempt to validate the scientific foundation of homeopathy.^[8]

Homoeopathy includes nosodes prepared from biological sources prepared according to the standard methods of manufacturing for homoeopathic medicinal products laid in pharmacopoeias.^[9] Although these nosodes are often prescribed by homoeopathic doctors and practitioners, their benefits and safety concerns need to be researched and debated upon.^[10] A study to demonstrate the preparation and standardisation of Homoeopathic nosode prepared from *Plasmodium falciparum* parasites is included in this issue. The author has argued that using scientific techniques and *in-vitro* and *in-vivo* experimentation, the efficacy of nosodes from *P. falciparum* can be demonstrated and further researched.^[11]

The first case report in this issue is of a 35-year-old patient suffering from hepatic haemangioma with ovarian cyst. The authors shared their success in homoeopathic management of the patient with multimorbidity showing improvement of diagnostic parameters.^[12] Another case is an unusual presentation of alopecia areata in an 11-year-old boy managed with Homoeopathy. Alopecia areata is a common, chronic inflammatory disease with no specific treatment other than corticosteroids, immunotherapy and

light therapy.^[13] Homoeopathic literature also includes many indicated medicines for this, and the case in the issue showed improvement with complete disappearance of bald patches without any recurrence.^[14]

Case reports show the challenges and clinical implications in the management of unusual cases with multimorbidity, as these cases are mostly excluded from standard RCTs. Thus, more and more such success stories from the practitioners, researchers and clinicians are encouraged for publication. Such studies prove the holistic healing by the homoeopathic medicines.

Effective communication and exchange of knowledge among researchers must be facilitated within and between researchers, thereby enriching science and securing the position of Homoeopathy across the world. Thus, this issue includes a segment of 'Letter to Editor' as a scientific forum for discussion where communication received on one of the papers published previously on *Lycopodium clavatum* for the management of urolithiasis is published.^[15] The authors gladly replied and elaborated on their study.^[16]

Acknowledging the reviewers' contribution in reviewing and improving the quality of articles published this year completes this issue of the Journal.

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