

## Improving Validity and Reliability of Homoeopathy

Homoeopathy is based on patient-driven data in the form of symptoms, signs and experiences, which dates back to 1830 when the first volume of *Materia Medica Pura*<sup>[1]</sup> was published. This and many other such publications after that are still considered as source books and referred for decision-making. These books are still main source of knowledge and are seldom updated in spite of available data from proving, clinical experiences and other experiments. These vast data generated over the decades have not been captured properly. The data in these books have been mixed up and one cannot easily differentiate proving; patient experiences and toxicological, pharmacological and intuitive data from the drug pictures given in the *Materia Medica*'s; hence, the question of reliability always haunts homoeopaths while making prescribing decisions for an individual patient. As world is progressing towards innovations in data science and new statistical tools are being developed including usage of artificial intelligence in improving the decisions, we need to gain skills like a data scientist, as these big data in Homoeopathy need to be constantly captured, improved, processed and analysed scientifically for efficient usage, so that our future generation may not face the same dilemma. The success rate of Homoeopathy depends upon high quality and reliable data.

### IMPROVING DATA VALIDATION

The process of selecting a remedy after a detailed case taking, coming to a similitum, is a comprehensive procedure. However, this practice makes a prescriber gain immense experience of the subject, and this experience in turn can be utilised in validating the big data in Homoeopathy. Further, there are many schools of thoughts that are based on different methods of approaching a case that is propagated and described by respective experts. It is stated that this is based on heuristics and will inevitably have bias associated with them. This judgement can be based on predefined sequence of steps i.e., algorithmic approach or on empirical rules or heuristics.<sup>[2]</sup> However, for improvement of science, we must try to be free from any such biases.

We must try to validate the traditional knowledge and improve<sup>[3]</sup> Homoeopathy by unbiased recording of symptoms. The drug proving (human pathogenetic trials) and clinical verification studies<sup>[4]</sup> undertaken by Council are considered as scientific methods for data validation. Repeating of existing drugs can be beneficial to improve the *Materia Medica*, this also gives an opportunity to students to learn from these trials. It is important that drug proving is conducted on standard protocols and predefined objectives.<sup>[4]</sup> A study was conducted to observe the validity and reliability of homoeopathic provings as a drug discovery tool found that provings of *Arsenicum album*

contain useful clinical predictors for the successful therapeutic use of medicine using fairly strict outcome criteria.<sup>[5]</sup> Further, clinical verification of proving symptoms was advocated by Dr. Samuel Hahnemann, as mandatory for a pure *Materia Medica* and repertory.<sup>[6]</sup>

### Improving Validity of Clinical Trials

Most of the clinical trials conducted in Homoeopathy suffer from low methodological quality and, thus, are excluded from the systematic reviews.<sup>[7]</sup> The quality of controlled trials is of obvious relevance to systematic reviews, as clinical trials are the raw material for them. If any systematic review is conducted with clinical trials of low quality, the results cannot be relied. It is important that clinical trials are based on robust protocols and conducted rigorously. In a review of homoeopathic trials, validity problem was found in most of the trials with poor sampling, inadequate measurement and reporting.<sup>[7]</sup> The Cochrane risk-of-bias tool for randomised trials is the recommended tool to assess the risk of bias in randomised trials included in Cochrane Reviews.<sup>[8]</sup> The parameter given in the tool can be referred while designing a study protocol along with the standard reporting guidelines in order to make the trial robust.

### BIASES IN CLINICAL TRIALS

The internal validity of any clinical trial (i.e. how well a clinical trial provides evidence to support the claim) is threatened by biases such as selection bias, performance bias, detection bias and attrition bias.<sup>[9]</sup>

Selection bias occurs in studies with comparative groups with biased allocation of patients to the groups. Many systematic reviews suggest the possibility of selection bias in favour of Homoeopathy for many studies reported.<sup>[7]</sup> Performance bias occurs if additional treatment interventions are provided preferentially to one group. Detection bias arises if the knowledge of patient assignment influences the assessment of outcome. These biases can be safeguarded by adequate blinding of study investigators. Finally, the attrition bias is biased occurrence and handling of deviations from protocol and loss to follow-up.

### Other Biases in Homoeopathy

Being aware of statistics and prejudice is helpful for practitioners, as it leads to unbiased decisions and results. We must first try to improve Homoeopathy by doing more systematic and scientific research. Preventing any of the bias to influence our results is a challenge which can be addressed if we have proper knowledge and adequate training of the subject.

A confirmation bias is a type of cognitive bias that involves favouring information that confirms your previously existing

beliefs or biases. In Homoeopathy, chance of this type of bias is more, as once we think about a probable or suitable medicine for a patient, we tend to inquire further to confirm the same medicine. It happens often in our clinical practice. Further, even while assessing the results, in follow-up, the same bias is possible. This can lead to biased and skewed results in research. Further, during drug validation and Likelihood Ratio (LR) assessment, it has been found that confirmation bias could also influence expert opinion and the prescription of medicines. Thus, it is important that it is prevented by having rigorous protocols in clinical trials, prospective investigation of symptoms and prior guidelines to include all relevant information in validation studies, so that any significant information is not missed.<sup>[10]</sup>

The recall bias happens when participants do not remember previous events or experiences accurately or omit details. If a patient does not recall to his or her symptoms adequately and responds to particular questions, there are chances that a characteristic symptom is missed. Here, to reduce this, we must carefully interview patients so that any important symptom is not missed or carefully select the research question. Sometimes, any of family members can also be asked for confirmation. In research, use of appropriate data collection tool or study design can address this problem.<sup>[11]</sup>

The concept of Bayes' theorem in homoeopathic prescribing can be simply defined as using experience in predicting future. Like when a homoeopath make selection of indicated medicine based on symptoms, which they have observed earlier in their practice and based upon that experience he selects the medicine. Mostly considered intuitive, the homoeopathic prescribing involves scientific aspects as well, which can be described using statistical or mathematical concepts like Bayes' theorem, prognostic factor research. These are very well elaborated in a recently published book 'Prognostic Factor Research in Homoeopathy' written by Dr. Lex Rutten and published by Central Council for Research in Homoeopathy for students and researchers. A review of this book has been included in this issue; the readers may get familiar with the layout and its content book which is highly recommended for all homoeopathic practitioners, researchers and students.<sup>[12]</sup>

In this issue, we are also publishing clinical verification study where for first time prevalence and likelihood ratio of general symptoms of 29 less frequently prescribed homoeopathic medicines has been evaluated retrospectively. This is a multicentric study where total 166 general symptoms of 29 medicines have been evaluated using PFR, Likelihood ratio and confined Likelihood ratio >1.5 for 6 and 49 symptoms respectively.<sup>[13]</sup>

An observational study included in this issue assesses the role of homoeopathic treatment in post-caesarean backache wherein the individualised homoeopathic medicine was found useful. The study outcomes were measured using a validated, Bengali-translated version of the Short-form McGill Pain Questionnaire and Oswestry Low Back Pain Disability

Questionnaire. The paper also elaborates the strengths and weakness of the study along with future research strategy on the subject.<sup>[14]</sup> Further, research protocol of the study to evaluate individualised homoeopathic medicine in cases of wrist ganglion is also being published.<sup>[15]</sup>

### Experimental Advancements to Improve Reliability

*Urtica urens*, a widely used homoeopathic medicine, is studied for its pharmacognostic and physicochemical properties.<sup>[16]</sup> Another paper in this issue evaluates the antibacterial and antioxidant potential of some homoeopathic mother tinctures. The authors prepared ten mother tinctures and tested them against five clinically important human pathogenic bacteria (*Salmonella typhi*, *Escherichia coli*, *Bacillus subtilis*, *Staphylococcus aureus* and *Pseudomonas aeruginosa*) by both microdilution methods with ciprofloxacin as a positive control. They reported that the tested mother tinctures have antibacterial and antioxidant potential.<sup>[17]</sup>

This issue also includes a study which investigates, for the first time, the inhibitory effect of two most commonly used drugs for prevention and treatment of Dengue and Chikungunya i.e. – *Eupatorium perfoliatum* and *Crotalus horridus* in different dilutions (6CH, 12CH, 30CH and 200CH). This study in experimental models of inflammation and Complete Freund's adjuvant (CFA)-induced arthritis inferred that these medicines are effective in minimizing inflammation and arthritis in CFA-induced model.<sup>[18]</sup> Finally, case report in this issue on lumbar spondylosis is shared with the readers along with research highlights of this quarter.

**Raj Kumar Manchanda**

Editor-in-Chief,

E-mail: [rkmanchanda@gmail.com](mailto:rkmanchanda@gmail.com)

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