Best practices in Homoeopathic research

Homoeopathy is practiced in about 80 countries either as an independent or as complementary/integrated to Modern system. The clinical practice is primarily based on traditional wisdom available in the form of Materia Medica, drug proving's and experiences recorded many decades ago. These are available in the form of text books and various softwares. Majority of researches are focused on interpretation of this wisdom that often lacks scientific planning and statistical rigor. India has admirable environment conducive for the growth of Homoeopathy in the form of Government recognition; around 300 thousand registered practitioners, about 190 university-affiliated colleges imparting undergraduate and postgraduate qualifications, more than 13,000 students qualifying annually, and millions of patients are prescribed homoeopathic drugs every day with variable success. However, the research output is very limited as clinician seldom report their success and more than 70% of articles uploaded for publications in our journal are rejected. This may be due to number of factors, one of which could be lack of formal knowledge in conducting and reporting research along with inadequate exposure of quality research environment in medical schools/colleges. Considering spreading skepticism and fast-changing health scenario, traditional wisdom in Homoeopathy is required to be further validated using evidence and science-based tools. Everyone can contribute in research for growth and improvement of Homoeopathy. Previously, we have discussed research strategies to evaluate and assess different aspects of Homoeopathy;[1] now, we will be briefly discussing three important facets of best practice in research (Research design, its conduct and reporting) and how these are relevant to Homoeopathy.

Design

The approach and methods of research have evolved over the years to become more efficient and precise. With technology advancements and well-defined guidelines, conducting research has become simpler provided we know them. The first important decision a researcher needs to take after deciding the research question and objectives is selection of research design which should be such that inferences derived are generalizable to other potential recipients (high external validity) and they must also estimate outcome effects that can be reliably attributed to the intervention (high internal validity).[2] Design could be experimental or exploratory study covering hypothesis testing through intervention and descriptive study with no intervention and no prior hypothesis. Studies further can be randomized and nonrandomized.[3] The random allocation of treatment avoids selection bias or confounding by indication and is meant to create treatment groups that have comparable prognosis with respect to the outcome under study.[4]

A large inclusive, multicenter, fully blinded, randomized control trial (RCT) incorporating subgroup analysis is likely to provide the best possible evidence of effectiveness, but there will always be circumstances in which randomization is unnecessary, inappropriate, misleading, or impossible.[5] In these special situations, well-designed observational studies, including cohort and case–control studies, may provide an alternative. There has been constant debate over superiority of randomized or nonrandomized trials. RCTs are being criticized for excluding many of those to whom the results will subsequently be applied.[6] The nonrandomized studies are considered more inclusive in contrast; however, there are many criticisms of it like selection bias. In observational studies, one can choose to investigate superiority or equivalence of treatment using the same assumptions and methodology as in clinical trials.[7] The false conflict between those who advocate randomized trials in all situations and those who believe that observational data provide sufficient evidence needs to be replaced with mutual recognition of the complementary roles of the two approaches.[5] Every research study should have a protocol, the detailed plan, and it should be written and approved by the authorities. Further, the trials must be registered with Clinical Trials of India.[8] Then, comes implementing the research proposal and conducting the trial with full scientific rigor.

Conduct

RCTs form the foundation for "evidence-based medicine," but such research can be relied upon only if it is conducted according to principles and standards collectively referred to as "Good Clinical Research Practice" (GCP).[9] Compliance with GCP provides public assurance that the rights, safety, and well-being of research subjects are protected and respected.[10] Use of quality-driven approach in conducting research studies must be promoted. Methodological quality defined as the confidence that the trial design, conduct, and analysis have minimized or avoided biases in its treatment comparisons must be kept under consideration and any methodological flaw must be avoided. Further, areas where methodological development is required should be highlighted and worked upon. The fact is that higher quality studies are more likely to produce results that are closer to the true result as they are less prone to bias or distortions from the true value. The scientific rigor by means of adherence to protocol, maintenance of records of observations/data with high-quality standards, proper use of statistical tools, detailed literature review must be followed.

The evaluation of the validity of the studies is an essential component of any systematic review (that provides high level of evidence on the effectiveness of healthcare interventions).

The extent to which a systematic review can draw conclusions about the effects of an intervention depends on whether the data and results from the included studies are valid. In particular, a meta-analysis of invalid studies may produce a misleading result, yielding a narrow confidence interval around the wrong intervention effect estimate. Variations in study quality can explain differences in the findings of studies that are included in a systematic review.[11] The assessment of the quality of controlled trials is essential because variations in the quality of trials can affect the conclusions about the existing evidence.[12] In a review of trials evaluating primarily medical treatments, Moher *et al*. demonstrated that trials that did not include features such as blinding and allocation concealment tended to report an exaggerated treatment effect compared with trials that did include these features. These facts emphasize the importance of methodological quality assessment to provide accurate information on therapeutic effects. Many scales are being used to evaluate the methodological quality of RCTs in health care research, many of which need to be tested for validity and reliability.[13] Future researches in Homoeopathy can be based on prognostic factors,[14] and it could become one of the main pillars of Homoeopathy's scientific identity. The basic aim of prognosis research is to improve reliability of Materia Medica and Repertory. It compares the prevalence of homoeopathic symptoms/characteristics in populations responding well to specific homoeopathic medicines with the prevalence of these symptoms in the remainder of the population. Using various statistical techniques, these results can be translated into prognostic models in homoeopathy.[15]

Reporting

Research is not complete until it is written up and its results shared, not only with other scientists who may build upon it to further advance the science, but also with those who may benefit from it, who may use it, and who have a stake in it. Well-designed studies are, however, not sufficient to ensure transparency in medical research. It is the presentation of evidence that is of great importance in the published scientific article. To ensure this transparency and accuracy of reporting medical research, several guidelines have been gradually introduced.[16] The purpose of reporting guidelines in medical research is to create a manual for the authors to follow, which should lead to total transparency, accurate reporting, and easier assessment of the validity of reported research findings.[17] A study examined the relationship between reporting quality and methodological quality of published RCTs. Assessments of methodological quality depend on the quality of reporting, and incomplete reporting is often interpreted as of low quality.[18] It concluded that reporting quality is associated with methodological quality, but similar quality of reporting may hide important differences in methodological quality and well-conducted trials may be reported badly. Studies that show a significant effect of treatment are more likely to be published and such studies are therefore also more likely to be identified and included in systematic reviews, which may introduce bias. A known threat to the validity of meta-analysis is publication bias, which occurs when studies with statistically significant or clinically favorable results are more likely to be published than studies with nonsignificant or unfavorable results.[19]

New and future researchers may refer specific reporting guidelines for presenting their research studies and outcomes [Table 1].

Modern system has, over the period, developed several guidelines which they are trying to adhere while doing/reporting any research. Additionally Homoeopaths have developed guidelines as supplement to these standard reporting tools, their knowledge can enhance the quality of research and will promote best practices.

Reporting Experiments in Homoeopathic Basic Research

Reporting experiments in basic research in homoeopathy is an important issue as comprehensive description of what exactly was done is required. So far, there is no guideline for authors available unlike criteria catalogs common in clinical research. A guideline for Reporting Experiments in Homoeopathic Basic Research (REHBaR)[20] was compiled to be applied by authors when preparing their manuscripts and to be used by scientific journals in the reviewing process. Furthermore, the guideline is a commitment to a certain minimum quality level needed in basic research, for example, blinding and randomization.

Model Validity of Randomized Controlled Trials of Homoeopathic Treatment

A method for assessing the model validity of RCTs of Homoeopathy is needed. To date, only conventional standards for assessing intrinsic bias (internal validity) of trials have been invoked, with little recognition of the special characteristics of Homoeopathy. The six judgmental domains enabled model validity of RCTs of homoeopathic treatment (MVHT)[21] to be

Table 1: Reporting guidelines for specific study designs

Guideline	Study type	Website
PRISMA	Systematic reviews and meta-analyses	http://www.prisma-statement.org/
CONSORT	Parallel-group randomized controlled trials	http://www.consort-statement.org
STROBE	Observational studies in epidemiology	http://www.strobe-statement.org
CARE	Case reports	http://www.care-statement.org/
SPIRIT	Standard protocol items for clinical trials	http://www.spirit-statement.org/
MOOSE	Meta-analyses of observation studies in epidemiology	http://www.equator-network.org/reporting-guidelines/
ARRIVE	Animal Research: Reporting of In Vivo Experiments	https://www.nc3rs.org.uk/arrive-guidelines

assessed with "fair" to "almost perfect" concordance in each case. It recommends that future systematic reviews of RCTs in Homoeopathy should adopt the MVHT method as part of a complete appraisal of trial validity.

Reporting Data on Homoeopathic Treatments (RedHot)

An international Delphi panel was convened to develop consensus guidelines for reporting homoeopathic methods and treatments. The panel agreed 28 treatment and provider-specific items that supplement the consolidated standards of reporting trials statement. The authors recommend these for adoption by authors and journals when reporting trials of Homoeopathy.[22]

Hom-Case

A criteria catalog serves as a guideline for authors to improve the quality of reporting clinical case reports in Homoeopathy. An online Delphi process was initiated with a panel of 19 homoeopathic experts from Europe, the USA, and India. Homoeopathy-specific item selection took place in three rounds of adjusting. The selected items can be used as an extension of the CARE clinical case reporting guideline. Use of the HOM-CASE[23] guideline extension will contribute to transparent and accurate reporting and can significantly improve the quality and reliability of clinical case reports in Homoeopathy.

Recently, the WHO has recommended the Guidelines for Accurate and Transparent Health Estimates Reporting (GATHER). GATHER define best reporting practices for studies that calculate health estimates for multiple populations (in time or space) using multiple information sources. Dr. Christopher Murray, Director of Institute for Health Metrics and Evaluation, has opined, "If researchers are not willing to be completely open about their sources of information and methods used for analysis, the credibility of their findings may be questioned. Those who adhere to the guidelines will raise the bar in terms of research excellence".[24]

A number of colleges are taking interest in Homoeopathy research and approaching the Council for directions in this regard. Research initiative in colleges must be encouraged with all possible help in providing guidance for building research aptitude in students. This journal tries to publish article based on the recommended reporting guidelines of studies conducted within the Council and at various educational institutes/hospitals. In the current issue, we are publishing papers of three different designs, one randomized comparative trial on the Management of Alcohol Dependence,[25] an exploratory study for usefulness of homoeopathic treatment in nonerosive gastroesophageal reflux disease,[26] and an observational study on improvement in activities of daily living of knee osteoarthritis patients with homoeopathic medicines.[27] A case report of corneal abscess[28] treated with homoeopathic medicine shall generate considerable interest and many colleagues may feel motivated to report the outcome of some of the difficult, rare, and chronic incurable cases. The readers will appreciate the changes made in the journal format which we have done keeping in view its global outreach.

We are also bringing in this issue the conference report[29] of the International Convention on the World Homoeopathy Day held to commemorate the 261st birth anniversary of Dr. Samuel Hahnemann on 9th–10th April 2016 at Vigyan Bhawan, New Delhi, India. This report comprises in brief the recommendations of the convention. Further, we plan to formally publish the proceedings of the convention in due time, about which the journal will keep its readers informed.

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