Review Article

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A REVIEW ON THE NEED FOR REAL EVIDENCE-BASED PRIORITY SETTING

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Received on: 11/12/19 Accepted on: 17/01/20

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DOI: 10.7897/2277-4343.11012

ABSTRACT

As healthcare system becomes progressively more integrated and multi-sectored, effectively implementing evidence-based interventions and measuring their impact at real world environment becomes very needful. Given this density, a framework and analytical method linking multi-sectored planning, coordination and implementation processes at core program level with their ultimate health care factor impact is a significant tool for understanding what works and why under real world conditions more importantly for Ayurvedic clinical data. This piece of writing aims to suggest a need for adapting an implementation of real-world evidence in the field of traditional medicine especially Ayurveda, a life science which has its own unique fundamental approach to diseases through which it can assess effectiveness of interventions without any controlled setting.

Keywords: Real World Evidence, Ayurveda, Real World Data, Review study, Ayurvedic clinical data.

INTRODUCTION

Real-world evidence (RWE) is the clinical evidence that are generated, or which exists in the real world. It is regarding the usage and potential benefits or risks of a drug derived from analysis of Real-world data (RWD). RWD includes the data of patient's health status and/or the delivery of health care routinely collected from a variety of sources like, Electronic health records (EHRs), Claims and billing activities, patient registries, medical charts or medical claims data, with patient identity markers removed to maintain patient privacy. They are captured in a non-interventional, observational manner, in a natural, uncontrolled setting – outside of traditional clinical trials. Real-world data (RWD) and real-world evidence (RWE) are playing an increasing role in today's health care sectors.[1]

In contrast, Randomized Controlled Trial (RCT's) which is often considered as a gold standard for clinical trials, a cornerstone of clinical research on interventions, the hallmark of evidence-based medicine forms the basis for translating research data into clinical practice.[2] They are also the most reliable method available for testing new treatments as they do Good randomization which may "wash out" any population bias, easier to blind/mask than observational studies, results can be analyzed with well-known statistical tools, and populations of participating individuals are clearly identified. But not all RCTs are made of 24-carat gold as they are expensive in terms of time and money, volunteer biases are common as the population that participates may not be representative of the whole, and there may also be loss to follow-up which may be attributed to treatment.[3] In general clinical trials are based on the analysis of safety and efficacy of drugs and are administered in controlled environment whereas data from electronic records are used in RWE will provide a much greater look at the disease population in terms of demographic, socio-economic characteristics and other important co-morbid factors.[4] No matter what we may achieve in terms of characterizing the safety profile of a drug in up to Phase III trials, unless the drug is tested in the real world, where no patient can be excluded, where the drug is not given free of cost, where there is no monitoring for compliance, the full safety profile of the drug can never be fully characterized. This is why it is said in the Oxford Textbook of Clinical Pharmacology that, unless a drug is capable of doing some harm, it is unlikely that it will have much of an effect. Practice-based medicine is another term that is bandied about as bedside to bench is also an important way to advance science and not only bench to bedside. However, for this to happen, one should be clinician, researcher and investigator. Just as there is a time and place for everything and everything in its place, just as there is a place for both generics and patent-protected innovator drugs, so also there is a place for both RCT generated and real-world evidence. There are limitations with both RCTs and real-world analyses. Taken together, information from both RCTs and real-world analyses, it is important to confirm the validity of safety and efficacy data for new agents.

What makes real-world data robust? Preferably, a naïve patient population, adjustment for differences in baseline characteristics using a statistical tool called propensity score matching (to create comparable cohorts in the real world, after observing how a doctor decides which drug for which patient), large patient numbers, prospective evaluation and a long study period and extensive follow-up.[5] RWE increases efficiency in R and D and bridges the gap between the proof of adequacy required to pass regulatory scrutiny and the demonstration of likely effectiveness needed to satisfy health technology assessment bodies. It most importantly helps in understanding the effectiveness of interventions or practice including socioeconomic, geographic and demographic and groups differentiated by different diseases/health conditions. They provide epidemiologic information on prevalence/ incidence of diseases, natural history and co-morbidities. It also possess few limitations which need to be tackled to make this raw data very useful in this traditional medicine like Ayurveda, which can help in bringing about a great difference in terms of real world evidence based practice, and can also be the best tool in this era of research domain. A major issue is a lack of a clear policy framework that suggests when and where RWE is useful, it has unclear regulatory landscape which should be dealt with, bear concerns in terms of ethical considerations and investigator's lack of confidence, it also takes enormous time to analyze the huge raw data, costs of data, and

data quality may be high as there are large variety of data that needs to be collected and analyzed. The true challenge is analyzing unstructured and semi-structured data and doing it in a way that yields scientifically important bits of knowledge.[6]

Dr. Christian Kessler, Hanover Medical School, Germany writes in his paper "Criteria for the establishment of Ayurveda," that there are no electronic databases for Ayurvedic studies. Many publications are only retrievable via hand-search of references and interviews of experts. In common Western databases and complementary and alternative medicine databases, only a small number of Ayurvedic studies are listed. Various studies are published in regional languages, many of them only as abstracts. A large number are postgraduate dissertations and Ph.D. theses, and about 800 are documented every year. The majority of studies belong to Cochrane evidence-levels 2 to 4 with very few from levels 1a or 1b. Group sizes are small in these studies. This makes the studies vulnerable for methodological error. The rationale for selected study designs is not always properly described. Missing values compromise calculations of probability and power. There are no networks of competence or centers for excellence. Therefore, potential sources to get data are restricted to personal experience, colleagues or experts, classical textbooks and commentaries written on them. Before implementation of the clinical trial, approval of the study protocol by the institutional ethics committee is mandatory. Before the trial begins, it may be worthwhile for investigators to have a preliminary discussion with their statistician to discuss the study design and sample size. With these preparations, investigators can begin the actual clinical trial work in their hospital or outpatient department.[7]

DISCUSSION

The research protocols should be designed on the basic concepts of Ayurveda. RWE can work appropriately if done in a right way. Previously our clinical studies were using the "reverse pharmacology" or "bed to bench side" approach for validating the studies. There are many instances which suggest that Ayurvedic medicines work better than other complementary medicines but needs to be validated with evidence.

Ayurveda which is based more of empirical treatment finds difficult to fit to designs which are most acceptable to the modern world as it is traditional based rather than evidence based. While safety is another reason which we all are keen about, we should question ourselves saying, do we always use our clinical experience to improve our patient's lives? We should also understand that there is always a gap between Research, Evidence and Practice. This needs to be understood in depth for which real-world studies are conducted. The final outcome for all clinical trials or studies done is patient benefit with least or no risks involved rather than anything else. As the discussion about getting new formulations, treatment methods or advanced diagnostic tools to the external setting continues, procuring the right source and the evidence has become critical. If we can do this successfully, we might one day be able to increase access to the right Ayurvedic medications for the right patients at the right time.

In the meantime, rather than competing and veering towards the Western medicine, the Ayurvedic scientists should work to enhance the core competency of Ayurveda without compromising its fundamental principles. It could also let somebody know the concept of Ayurvedic clinical practice which aims differently for each patient in terms of rogi bala (personal characteristics) like Prakruti (Inherent characteristic/ Constitution of body), Vikruti (Pathological examination), Sara (Examination of elemental tissue and mind; the essence of the Dhatu), Samhana (Examination of compactness of body), Pramana (Measurement of height, weight etc. using anguli pramana), Satmya (suitability/ habitual characteristics), Satva (Examination of mental constitution), Aaharashakti (Examination of digestive power in terms of power of ingestion and digestion), Vyayamashakti (Examination of strength by exercise), Vaya (Examination of age).[8] For instance, the management of Bell's palsy which is commonly correlated with the disease Ardita in Ayurveda, is solely dependent on the involvement of vata dosha, whether alone (kevala vatajanya ardita) or associated with other doshas (margavarana janya ardita). The line of management in these both differs and is determined based on disease condition, dosha's involved and physician's yukti. If vata dosha is aggravated or vitiated, snehana should be given both internally (snehapana) and externally in the form of shiroabhyanga (oil massage of head), nasya (snuffing), tarpana (oleation of eyes through medicated ghee), snehana (oleation), swedana (fomentation) through medicated pastes along with sneha dravyas; if kapha dosha is vitiated, the disease is associated with swelling of the affected area and vamana (emesis) is indicated and if there is burning sensation and redness of affected side due to vitiated pitta dosha, siravyadha (venesection) is the line of management.[9]

Hence, it's now time to concentrate towards RWE which can simplify our age-old problem of getting right study designs. This lack of a well-designed scientific study needs to be addressed promptly making it a gold standard for traditional medicine. As practitioners nowadays who, even in their busy practice, are able to collect different patterns in their practice. Proceeding further they can be made responsible to contribute to the research field by formulating a research hypothesis and then proceed to assess it under real world situation with prior consent and following certain ethics. Thus, he can be as good at both good clinical practice (GCP) and good clinical research practice (GCRP). This will mutually contribute to the field, and this way science can advance.

CONCLUSION

Research creates new knowledge or advances existing one, focuses on different groups, has a long-term benefit, minimizes risk and enriches one's practice. It was long term considered that Randomized controlled trials are the cornerstone of clinical research on interventions. Now it's time to turn our focus towards real world evidence-based studies especially in the field of Ayurveda, as this may be considered as a new dimension which can be opted for the delivery of real-world data of Ayurvedic clinical practices to the external world.

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Cite this article as:

Bhavya B. M. and Shubhashree M. N. A Review on the need for real evidence-based priority setting. Int. J. Res. Ayurveda Pharm. 2020;11(1):10-12 http://dx.doi.org/10.7897/2277-4343.11012

Source of support: Nil, Conflict of interest: None Declared