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Letter to Editor

Registry Disease Studies in Cardiology in India: The Need of the Hour

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Sir,

Research is an important goal of every academician and clinician. Research can be carried out in several different ways, examples include 'clinical research' i.e. double blind randomised placebo controlled clinical trials, 'drug utilization studies' i.e. the study of the utilization of drugs for the treatment of various communicable and non-communicable diseases, 'qualitative studies' i.e. a study used to gain an understanding of underlying reasons, opinions, and motivations. Apart from all these there is another important and interesting study known as 'registry study'.

Registry studies are basically observational studies that characterize the natural history of a disease or intervention i.e. they document the routine patterns of diagnosis, medical care, treatment type, long-term disease related clinical events, health related quality of life and re-admission rates.[1] The combination of the extent of health resource use with the caregiver burden will enable a more comprehensive outline of the social burden of the disease beyond the clinical outcomes. Disease registries commonly have aims that are primarily descriptive, such as describing the typical clinical features of individuals with a disease, variations in phenotype, and the clinical progression of the disease over time (natural history).[2]

Global registry studies are usually designed as global, multinational, prospective, and non-interventional with longitudinal data collection. Such a robust design provides a comprehensive assessment of the therapy patterns and related outcomes as well as the use of healthcare resources, and the quality of life and burden of both the patients and the caregiver/family. Usually the Registry protocol will not interfere with the local standard of care of the patients.[3] The target population in a registry study will be all patients with a common disease. Inclusion and exclusion criteria will usually be limited and non-specific when compared to randomised clinical trials. They also do not need a comparison group. Creating a patient registry is one of the major activities. A patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purpose.[2] With respect to ethics, since these are pure observational/non-interventional studies the major and only ethical consideration is maintaining the confidentiality of the health information.

The potential impact of the registry studies are manifold, the predominant being, it gives a broad overview of the differences between the routine medical practices throughout different geographic locations.[3] Registry studies have an important role to play in cardiology as most of the cardiovascular diseases have a chronic pattern, examples include heart failure, hypertension, ischemic heart disease, cardiomyopathy etc.

Some of the popular international registry studies in cardiology that have made a major impact in cardiac care include the Euro Heart failure survey programme,[4] conducted to ascertain if appropriate tests were being performed with which to confirm or refute a diagnosis of heart failure and how this influenced subsequent management. This registry came to a major conclusion that considerable diagnostic uncertainty remains for many patients with suspected heart failure, even after echocardiography, which must be resolved in order to target existing and new therapies and services effectively. OPTIMIZE-HF[5] is another major registry study conducted to examine the relationship between the day of the week patients are hospitalized for HF and death rate, length of stay (LOS), and rehospitalisation rate. This study came to the conclusion that no differences in death rate by day of admission or discharge for HF hospitalizations and understanding the factors responsible for the increased LOS and potential adjustments in staffing to facilitate weekend discharges may improve the efficiency of HF hospital care. In fact there are a total of five OPTIMIZE studies that have been conducted and published till date.

Only a couple of Indian registry studies in cardiology have been published so far. These include the AFAR (Acute Heart Failure Registry)[6] study conducted in AIIMS which came to a conclusion that a higher in-hospital and follow-up mortality rates in acute decompensated heart failure patients who present at younger ages than reported in Western literature and the THFR study[7] (Trivandrum Heart Failure Registry) conducted to evaluate the presentation, management, and outcomes of patients hospitalized for heart failure (HF) in Trivandrum, India. THFR study concluded that Patients hospitalized with HF in the THFR were younger, more likely to be men, had a higher prevalence of IHD, reported longer length of hospital stay, and higher mortality compared with published data from other registries. Other registry studies in India in the pipeline are the REPORT-HF study by Novartis pharmaceuticals and the MHFR (Manipal Heart Failure) study. REPORT-HF is an International registry to assess medical practice with longitudinal observation for treatment of heart failure. Its primary goal is to characterize patients (newly diagnosed and CHF patients) at hospitalization and assess in-hospital and post discharge events' incidence i.e. cardiac and non-cardiac primary cause of re-hospitalization and mortality. MHFR is a similar study to identify and characterize the clinical profile of heart failure patients, healthcare resource utilization of patients, during hospitalization

and after discharge, drug utilization review, mortality and quality of life over a period of 2 years in the department of cardiology in Manipal.

Keeping in mind the high mortality rate of cardiovascular diseases, these small, single centre registry studies need attention from all the stakeholders. The global burden of disease study estimate of age standardized CVD death rate of 272 per 100 000 population in India is higher than the global average of 235 per 100 000 population.[8] Nevertheless, reliable data are lacking because of inadequate surveillance system. It is here that the registry studies have an important role to play. Some of the advantages include, ideal for description of local disease standards, generalizable cohorts, identification of rare events and economical when compared to randomized clinical trials. Registry studies in India do have some disadvantages like variable and questionable quality of data and data that cannot be used for comparative outcomes research. Above all the innumerable confounding factors (culture, diet and other life style differences) could be a major concern.[9] It is high time that the concerned stakeholders join hands and carry out large scale multicentric registry studies for diseases like DVT, MI, cardiomyopathy etc.

To conclude registry studies have the potential to produce databases that are an important source of information regarding health care patterns, decision making, and delivery, and their subsequent association with patient outcomes. The utility and applicability of registry data rely heavily on the quality of the data analysis plan and its users' ability to interpret the results.

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