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Design and methodology of heart failure registry: Results of the Persian registry of cardiovascular disease

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Original Article

Abstract

BACKGROUND: Heart failure (HF) resulted from ultimate pathway of many cardiovascular diseases (CVDs) or as a separate entity poses a considerable increasing prevalence and economic burden, but its registry for better management is less frequently done. In this study, we aimed to design and implement HF registry.

METHODS: Persian Registry Of cardioVascular diseasE (PROVE) was initiated from March 2015 and continuously collected information of patients suffering from HF, ST-elevation myocardial infarction (STEMI), atrial fibrillation (AF), percutaneous coronary intervention (PCI), stroke, familial hypercholesterolemia (FH), congenital heart disease (CHD), chronic ischemic cardiovascular disease (CICD), and acute coronary syndrome (ACS) from 18 different cardiac centers. Data of patients with HF were collected from their medical forms and recorded in a registry system of PROVE/HF plus telephone follow-up survey of 1, 6, and 12 months after the date of HF attack.

RESULTS: Assessment of all related questions led to definition of a final questionnaire including 27 items regarding demographic information, underlying disorders and their complications, patients' symptoms and signs, and laboratory and relevant para-clinic data at admission time, during hospitalization, and post discharge. Follow-up information was mostly based on patients' general status and medication usage.

CONCLUSION: PROVE execution was a successful and hopeful project providing data of major CVDs in order to design appropriate preventive actions and better management and treatment strategies plus a valuable data center being utilized in multiple future comprehensive projects.

Keywords: Heart Failure, Methodology, Registries, Iran

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Introduction

Heart failure (HF) syndrome is the ultimate pathway of many cardiovascular diseases (CVDs)[1] and is considered as one of the major public health problem.[2] HF prevalence has increased in recent decades because of population aging as well as therapeutic advances in the management of patients in the earlier stages of heart disease allowing them to survive until they finally develop HF.[3]

Although about 80% of CVDs occur in low-income as well as developing countries,[4-7] most studies done in developed and European nations and few published articles reported high prevalence of these disorders among Asian countries.[8]

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While most HF survival rates data all over the world are based on their national registry systems, there are few available reliable epidemiologic statistical information in order to estimate the incidence or prevalence of CVDs or even long-term survival rates in Iran.[9,10] Moreover, these Iranian studies have mostly evaluated short-term results or were performed with small study population. The first registry program of CVDs in Iran was launched in Isfahan City (as a pilot study) in 2015, named the Persian Registry Of cardioVascular diseasE (PROVE) because of necessity for implementing a national data registry of individuals suffering from CVDs and further data analysis and follow-up assessments. This ongoing project registers information of patients with HF, ST-elevation myocardial infarction (STEMI), atrial fibrillation (AF), percutaneous coronary intervention (PCI), stroke, familial hypercholesterolemia (FH), congenital heart disease (CHD), chronic ischemic cardiovascular disease (CICD), and acute coronary syndrome (ACS).[11] To the best of our knowledge, PROVE is the first national comprehensive CVDs database registry done in Iran with the least similarity in the Eastern Mediterranean region.

The purpose of this registry is to improve and develop the care of patients with diagnosis of HF by providing continuous information about care and therapy. Moreover, establishing this national HF registry enables an assessment of how thoroughly participating units are following recommended guidelines on diagnosis and treatment of patients with HF in addition to the creation of a platform for an open discussion of these important issues. Current study describes the design and implementation of PROVE/HF registry methodology in Isfahan.

Materials and Methods

PROVE/HF is a registry of HF patients' data from certain hospitals in Isfahan. This city is the capital of the third widest province located in central part of Iran. This registry project was started in late 2014 and launched in March 2015. Ethics Committee affiliated to Isfahan University of Medical Sciences approved this study. A checklist was designed according to the outcomes of the Swedish Heart Failure Registry (SHFR)[12] and Thai Acute Decompensated Heart Failure Registry (Thai ADHERE)[13] for data registration of individuals with HF. After completion of the first draft of the checklist, 10 faculty members including cardiologists and other experts unaware of the project were invited to evaluate the content of the checklist in a way that they were asked to determine whether the questions would appropriately measure the desired outcome and contain the entire content of what was needed, and after that all relevant questions were considered in the checklist, the protocol and the related dictionary were written in addition to full description of the procedure plus explanation of all pre-defined questions, options, and codes.[14] Finally, questionnaire, protocol, and dictionary were approved by Quality Control (QC) of PROVE Committee.

Afterwards, based on the prepared checklist and protocol as well as dictionary, data entry method was taught to the personnel. The training began with three two-hour sessions on how to extract data from medical records, complete data sheets, and read diagnostic tests as needed as well as explanation of the objectives and the protocol. Moreover, managers and principal investigators who were allowed to visit the archives of the hospital and correct probable mistakes had monthly sessions. The registry information was gathered from 18 distinct cardiac centers with appropriate equipment and trained personnel in terms of both diagnosing and management of HF including ten, five, and three teaching, private, and governmental hospitals, respectively. List of patients diagnosed with HF by International Classification of Diseases, 10th Revision (ICD-10) such as those with preserved and low ejection fraction (EF) or with acute or exacerbated and decompensated status hospitalized in all cardiac hospitals having medical history in that health care center were given to data collectors.

Diagnosis of HF had been confirmed by cardiologists' opinion written in patients' medical records. Consent form was signed by each participant before admission to the hospital. For data confidentiality and not disclosing patient personal information, a unique code with Huffman phonetic codes using combination of last name, first name, and date of birth was utilized for each participant.[15,16] At the initiation of the study, it was defined to obtain data with two distinct methods of prospective and retrospective manner simultaneously. However, due to occurrence of some problems and probable biases in terms of data gathering in retrospective method, we decided to continue the project with only prospective way. Furthermore, we just collected data with hospital-based method in a way that eligible patients admitted with diagnosis of HF could be enrolled in our registry. Data collectors recorded data in

questionnaires using the data in the medical records of hospitals' archives. Then, they delivered the completed questionnaire to the Registry Unit at the Isfahan Institute of Cardiology on a weekly basis. The questionnaires were reviewed by the data management team and any observed missed or mistaken cases was returned back. Data were entered into the relevant software after being approved by the data management team.

Patients were followed 1, 6, and 12 months after the date of HF occurrence by telephone. In absence of answer for three times within a period of 24 hours, the subject follow-up data would be discarded form the project. In cases of doubting about HF diagnosis or unavailability of basic information in their records, they were invited to a face to face meeting provided by a specialist. If death occurred, the date and etiology (cardiac or non-cardiac) as well as decease place (home or hospital) data would be assessed from the relatives.

In addition to internal QC of PROVE/HF, this project was controlled by the team's supervisor and externally evaluated by the committee which consisted of experienced and trained members who were not one of the PROVE executive members and were unaware of it and performed an external and continuous control over the entire registry components from the beginning to the end.

Results

After confirmation of the QC committee, a questionnaire consisting of 27 items was finally designed. The questionnaire included data on demographic variables, underlying diseases and comorbidities leading to HF plus past medical history, pre-admission medications usage and treatments, implementation of any procedures during admission, diagnostic and laboratory test results, patients' symptoms and signs, and results of para-clinic examinations including electrocardiography (ECG), echocardiography, and chest X-ray. We collected data both at admission time and during hospitalization as well as discharge date. During follow-up periods after 1, 6, and 12 months, information on current patients' status and medications usage was collected and in cases of death, the cause and place were also recorded.

Discussion

Questionnaires of HF registries in the world often contain comprehensive information and items including demographic factors, underlying diseases and complications, drug usage and treatment methods, diagnostic and laboratory test results, symptoms and signs, and results of relevant examinations.[12,17-22] The important difference in PROVE/HF questionnaire was that most of the questions were filled in three periods including at admission and discharge time plus during hospitalization period. This manner enabled us to monitor the patient status in the treatment process from admission to discharge. As mentioned above, some of the disease registrations were performed through prospective and some through retrospective method with their own advantages and disadvantages. For example, prospective way needs more personnel and would be consequently more costly, also it is highly associated with data missing especially during holidays or the time personnel would not be at work. However, since information could be registered simultaneously with the incidence of the cardiovascular events, it leads to a more complete access to relevant information and more accurate registration outcome. On the other hand, retrospective registration can be performed months or years after the CVDs incidence and needs fewer personnel, but could be associated with incompleteness or inaccuracy of data due to usage of past records.[23]

Because of extensive PROVE/HF questions and limited personnel for data gathering, registration began retrospectively; however, due to tendency for joining EURObservational Research Programme (EORP)[22] and collaboration with them and considering this point that most HF registry data are gathered prospectively and through web-based method and also due to high prevalence of data incompleteness via retrospective model, hospitals affiliated to Isfahan University of Medical Sciences have switched to prospective registration way.[12,17,18]

In literature, data registry of patients with HF is divided to two distinct methods including outpatient or hospital-based ones.[17,19,22] Due to limited staff, numerous number of patients, and lack of specialized clinics, PROVE/HF was performed through hospital-based method. It should be considered that in some registers, the follow-up questionnaires may have more information about the patient's condition, medications, and treatments.[22] The collection of long-term follow-up data is often the pivotal step in the registry's objectives[24] and is an important component of the disease registries usually performed for one year,[19,22] providing mortality during the desired follow-up.[24] Participants in PROVE/HF study were followed for longer duration after hospital discharge

with multiple intervals. Because of prospective method of data collection and periodical follow-up assessment in a short interval period to minimize patients' loss, information and data on current patients' status and medication usage were available with acceptable accurateness.

We presented the way of development and implementation of our feasibility study of the national comprehensive CVDs registry. Also, we discussed the patients' recruitment methods, follow-up duration, data collection, and QC measurements. Disease registry databases are used for evaluating that whether a therapeutic option is done appropriately for the disease or not. Moreover, these critical databases would help understand how to improve care quality and consider probable outcomes that might be achieved using these databases. Also, these registries could be useful in terms of health-related issues for policy makers for implementing proper strategies for disease control and even prevention.

CVDs are the leading cause of mortality worldwide, specifically in Iran. A registration system for patients with CVDs, especially HF, stroke, AF, and ACS could be useful for better assessment of diseases courses, proper diagnosis and treatment, acute phases and chronic conditions, medications, in and out-of-hospital complications plus clinical outcomes. Coronary angiography and intervention made improvements in the field of cardiology and the safety and efficacy of these treatment methods were challenged through these database registries based on the patients' information.[11]

Although PROVE/HF was the first registration for patients with HF in Iran and provided information on appropriate admission to collect data from patients, it was not free from limitations that identification of them might help for better generalization of the results.

Due to retrospective design of data gathering in PROVE/HF registry at first which might be associated with missing data and confounding variables, generalization of our findings related to the medical documents and patients' records must be done cautiously; however, we tried to complete the missing information and questionnaires as much as possible in follow-up sessions from patients and their families. Moreover, one year after initiation, registration of this disease changed to EORP/HF based on related protocol as prospective method.

Less accurate data gathering method on follow-ups by telephone on drug usage and awareness of participants about follow-up checklists might affect our outcomes. Another limit would be hospital-based design of data collection which provided less comprehensive information compared to population-based method.

Conclusion

PROVE development and implementation as a feasibility study seemed to be a successful project. Although this project was initiated in Isfahan, scale-up pilot study in other parts of the country has been started. This registry can be used in several sections including improving the current CVDs management in participating centers and at a national level, filling the gaps in preventative care, establishing effective treatment and disease control guidelines, and as a useful source for local and international studies.

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Conflict of Interests

Authors have no conflict of interests.

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