

INTRODUCTION

Percutaneous Coronary Artery Interventions (PCI) represents one of the cornerstone management modalities for patients with coronary artery disease. This applies for a wide range of clinical presentations ranging from patients with stable angina up to patients presenting with acute infarction. Not only patients with single vessel disease but also the broader spectrum of patients with multi vessel disease⁽¹⁾.

In spite of the very high early success rates of PCI, the main concern nowadays lies on long term outcomes for these patients as compared with other treatment modalities such as CABG. There are several randomized trials that have evaluated the relative value of PCI and CABG in patients with coronary artery disease^(2,3,4).

Long term follow up series have been published over the past years from various world wide follow up registries^(5,6).

Results of international literature long term follow up has shown the equality of long term

outcomes of patients under going PCI with those receiving optimal medical treatment in the stable angina sub group⁽⁷⁾.

Yet, differences between practice guidelines have been noticed.

In Egypt, we are lacking such follow up registries with their precious feed back data. However, In Cardiology department, Ain Shams University hospital we started the registry in 2006 but with no long term follow up. In this study we start the follow up of patients who had or undergoing PCI and it will be a part of Euro- Heart Survey.

The need for such system is highly indicated to evaluate our performance and compare it with national and international standards. So, Egyptian follow up results will create a base for quality control to the participating centers. This itself will improve Egyptian standards.

There are many systems that present in different specialized centers all over the world. One of these systems is EURO-HEART SURVEY program.

EURO-HEART SURVEY program was launched in 1998 by ESC aiming to provide systematic information on the management of patients with suspected cardio-vascular disease⁽⁸⁾.

AIM OF THE WORK

An observational study of one year clinical follow up of patients under going PCI intervention in Ain Shams University Cath Labs.

DEFINITIONS OF REGISTRIES

Till now there is no definite definition of registry. In 1949 Bellows defined a registry as a system of recording, frequently used in the general field of public health. Decades after, Brooke stated that a registry is a file of documents containing a uniform information about individual persons, collected in a systematic and comprehensive way, in order to serve a predetermined purpose. In 1991 Solomon proposed a new definition for a medical registry being as a database of identifiable persons containing a clearly defined set of health and demographic data collected for a specific public health purpose⁽⁹⁾.

In 2002 the ARTS investigators defined the medical registry as a systematic collection of a clearly defined set of health and demographic data for patients with specific health characteristics, held in a central database for a predefined purpose⁽¹⁰⁾.

Accordingly, the term "registry" is usually used to describe health-oriented database. The difference between registries and other databases is that the

data collected in registries are related to specific, identifiable persons⁽⁹⁾. However, the term "observational databases" can be used to refer to medical registries⁽¹⁰⁾.

Some elaborate registries prespecified "to be matched control group", using identical inclusion/exclusion criteria and a sample size based on a power calculation, these "registry controlled trials" (ReCTs) with a power calculation and a primary endpoint have to be differentiated from the simple registries without a power calculation and therefore without a primary end point⁽¹¹⁾.

Development of Registries:

Over the years, several developments in health care such as progress in information technology and increasing demands for accountability have led to an increase in the number of medical registries⁽⁹⁾. Early registries were homegrown, today they are also available for purchase or free access (sometimes only to participants in a particular program)^(11,12).

In the field of interventional cardiology because of high utilization, cost, and complication rates, invasive cardiac procedures are closely monitored and

frequently measured using national benchmark databases and public reports⁽¹³⁾. Many registries have been conducted for this purpose. Of these, there were two old British examples: in 1969 Graham Miller at the Brompton Hospital in London established a computer based cardiac catheter laboratory reporting system that developed an extensive diagnostic library and was subsequently widely adopted internationally. In 1971 Rachael Balcon at the London chest Hospital established an institutional based registry for angiographically defined coronary artery disease severity; it is still being used to generate long term outcome information⁽⁹⁾.

Then, as the use of invasive techniques increased, several large registries were created to accumulate data on PCI and to lesser extent, cardiac catheterizations⁽¹³⁾. These registries had been used to study patient and procedural characteristics, post-procedure treatments, immediate in-hospital outcomes, and long-term outcomes. Many different analysis of these data had been performed in an effort to improve the quality of care that coronary patients received⁽¹⁴⁾.

Value of medical registries in any institute:

Registries are an integral part of the nation's public health system. Their importance for surveillance, research, health service delivery, and the documentation of events is firmly established⁽⁹⁾.

Ultimately, data repositories from disease registries shared by government agencies, health systems, and academic centers can serve as the substrate for continuing education of health professionals⁽¹⁵⁾.

Prospective registries performed in consecutive patients with frequent cardiac diseases and procedures are able to provide important information about therapies complications, clinical outcome, and temporal trends in cardiology⁽¹⁶⁾.

Wyse and Taylor⁽¹⁶⁾conducted that collecting and centralizing national and international data had several benefits. They included patient risk stratification and risk prediction at both a national and center-by-center level, unit benchmarking and development of effective nationally oriented and center-oriented quality improvement programs, understanding and rationalizing resource utilization,

and use of data to leverage governments and other healthcare providers to affect policy⁽¹⁶⁾.

Bestehorn⁽¹⁷⁾ emphasized on the role of registries in contributing substantially to healthcare research which provides knowledge about the benefit of established measure and healthcare situation, thus helps the target-oriented distribution of increasingly limited healthcare resources.

Traditionally, registries are understood as tools of epidemiological research. Nowadays, medical registries have encountered new tasks in quality management and research on medical care⁽¹⁸⁾.

Benchmarking:

The basic principle of benchmarking is that a point for comparison is identified, a benchmark, against which all can compare⁽¹⁹⁾. This identified benchmark reflects best practice, traditionally identified from leaders in the field, so that through comparison a benchmarking member can identify how their performance compares with others, and then collaboratively share the process that support attainment of best practice⁽¹⁹⁾.

It is a method that can be used to assess any function or process by identifying and comparing it to the "best in class"⁽²⁰⁾.

Table (1): Types of benchmarking activity used in health service⁽¹⁹⁾

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|---------------------------------------|--|
| Competitive benchmarking | Competitive benchmarking uses performance measures to inform how well or badly a person or company is performing against direct competitors. |
| Comparative benchmarking | Comparative benchmarking focuses upon how similar functional activities are handled by different organizations. This removes the competitive edge and therefore provides a greater potential for learning. |
| Collaborative benchmarking | Collaborative benchmarking involves the sharing of knowledge about a particular activity, with all hoping to improve based upon what they learn. |
| Clinical practice benchmarking | Clinical practice benchmarking involves the structured comparison and sharing of best practice in clinical aspects of care. |
| Essence of care benchmarking | Essence of care involves the structured comparison and sharing of qualitative good practices. |

Examples of medical registries:

The national heart, lung and blood institute percutaneous transluminal coronary angioplasty (PTCA) registries:

In 1979, the National heart, Lung and Blood Institute (NHLBI) established a voluntary registry to characterize coronary angioplasty. Patients were enrolled in two subsequent registries providing the first comprehensive description of technical and clinical results⁽²¹⁾.

From 1979 to 1982, 3248 patients were entered from 105 clinical sites and in 1982; the registry stopped entering new cases and shifted its effort to follow-up. Sixteen of the largest centers participated in the five year follow-up⁽²²⁾.

A number of official reports were published in 1983-1984 from this registry. These reports provided important information about this new procedure regarding its short-term complications, in-hospital mortality and others⁽²³⁻²⁵⁾.

In August 1985, the PTCA registry of NHLBI reopened at its previous sites to document changes in angioplasty strategy and outcome⁽²⁶⁾. In this registry

the investigators want to assess whether gender influenced the outcome of PTCA or not. They found that women were older and had more unstable angina (class 3 or 4). Men had more MVD and abnormal LV function. Also, this registry showed that women had a higher incidence of coronary dissection and high in hospital mortality⁽²⁷⁾.

In 1990, the NHLBI established a new registry to evaluate safety and efficacy of new coronary interventional devices for example (mechanical atherectomy catheter, expandable balloon stents and ablative lasers). This was the New Approaches to Coronary Intervention (NACI) registry⁽²⁸⁾. The primary purpose of this registry was not to compare these devices but to create a way to follow simultaneously the progress of multiple devices in a parallel fashion⁽²²⁾.

The registry was finished in March 1994 after recruitment of 4429 patients. It showed 75.5% of cases were heavily dependent on balloon angioplasty⁽²⁸⁾.

In July 1997, the NHLBI PTCA registry and NACI registry were renewed through June 2002⁽²²⁾. The purpose of what could be considered a fourth registry was to keep pace with and evaluate the evolving nature of interventional cardiology. To

achieve its goal, the Dynamic Registry was designed to ensure the recruitment of successive waves of approximately 2000 consecutive patients^(22,29).

The NHLBI "Dynamic Registry", which for years has provided objective, "real world" assessment of the changing practice of percutaneous coronary intervention (PCI) was extended through June 2007 in order to continue annual patient follow-up from 3 to 5 years. This dynamic registry was formed from 4 waves of distinct patients cohorts each wave comparing approximately 2000 patients who survived to hospital discharge after PCI⁽²²⁾.

The NHLBI "Dynamic Registry", has been the only formal registry of consecutive PCI-treated cases that captures both in-hospital and long-term outcomes, while characterizing initial procedural strategy and outcome in great detail on the patient and lesion level⁽²²⁾.

In 2009 this dynamic registry have concluded that inspite of high procedure success utilizing IVUS, one year follow-up showed no reduction in repeated PCI (in waves 1997-2006)⁽³⁰⁾.

The American College of Cardiology-National Cardiovascular Data registry (ACC-NCDR™):

The American college of Cardiology (ACC) set out in 1987 to create a database to standardize what and how information was collected for patients receiving cardiac catheterizations and PCIs. Its plan was to create national database for patients undergoing invasive cardiac procedure⁽¹³⁾.

From 1991 to 1996, approximately 300 hospitals enrolled in the original ACC data registry and contributed information on more than 300000 cardiac catheterizations and 166000 PCIs. The first report of aggregated data from 1991 through January 1996 was completed in late 1996⁽¹⁴⁾.

In 1998, the original data registry program was extensively modified and then launched as the American College of Cardiology-National Cardiovascular Data Registry™ (ACC-NCDR™). This national registry was designed to be the most comprehensive comparative database for both inpatient and outpatient cardiovascular care available in United States⁽¹³⁾. It aimed at standardizing reporting of catheterization laboratory outcomes so that the data could be used to feed local hospital continuous quality improvement initiatives⁽³¹⁾.

Standardizing data definitions and reporting provided an effective benchmark for comparison among facilities. Other goals of this registry were accurately reporting safety and effectiveness of cardiovascular care, also reducing the amount of redundant data healthcare providers must generate⁽¹³⁾.

In June 2004, the ACC-NCDR launched the 1st national on site program⁽¹³⁾.

In June 2005, the ACC-NCDR closely partnered with the Heart Rhythm society (HRS) to launch a new registry, ICD registry. This registry meets an April, 2006. Centers for Medicare and Medicaid Services (CMS) mandate to specifically track activity in 1,300 electrophysiology laboratories nationwide for implantable cardioverter-defibrillators for the primary prevention of sudden death⁽³¹⁾.

For example, in 2008 ICD registry showed that dual chamber ICD selection is associated with racial and socioeconomic disparities⁽³²⁾.

In 2007, cath PCI registry reported that the introduction of DES into clinical practice has coincided with a significant increase in the use of PCI even with patient having ACC class I indication for CABG⁽³³⁾.