

The Foundation of NCVD PCI Registry: The Malaysia's First Multi-Centre Interventional Cardiology Project

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SUMMARY

The National Cardiovascular Database for Percutaneous Coronary Intervention (NCVD PCI) Registry is the first multi-centre interventional cardiology project, involving the main cardiac centres in the country. The ultimate goal of NCVD PCI is to provide a contemporary appraisal of PCI in Malaysia. This article introduces the foundation, the aims, methodology, database collection and preliminary results of the first six-month database.

KEY WORDS:

Cardiovascular, Percutaneous coronary intervention, Registry

INTRODUCTION

Cardiovascular disease is the leading cause of death in Malaysia and accounts for 15-16% of all Ministry of Health (MOH) Hospitals' deaths annually for the 1995 – 2003 period. Ischemic heart disease (IHD) was the commonest cause of cardiovascular mortality; accounting for 2556 deaths in 2002 and a further 896 deaths due to heart failure of ischemic origin. Despite improvement in health services, mortality has been rising steadily since 1990. Nationally, IHD probably account for 20-30% of all-cause mortality annually.

Multi-centre registries play an important role in the era of evidence-based medical practice by addressing the gap between clinical trials' findings and 'real-life' practice. Large databases have been used to develop risk-adjusted multivariate predictive models; and these "practice-based evidence" also provide new insights to future directions in research and development. Registries are also a form of post-marketing surveillance for PCI devices, and form the foundation for evaluation of patient outcomes, effectiveness and satisfaction.

In Malaysia, percutaneous coronary intervention (PCI) was introduced in the year 1983, and has grown over the last two decades. Today, at least 35 public, private and teaching institutions performed approximately 9000 PCI procedures annually. However, there is no national registry to record clinical data. Minority of hospitals collect information for local use only, with variable data elements.

It is against this background, the PCI registry is established to fulfil the need, for a large scale national level, multi-centre, collaborative group; to ensure uniform data collection and clinical follow-up. The PCI registry was the second registry

established under the National Cardiovascular Disease Database (NCVD). Henceforth, the registry was named NCVD PCI Registry. (See Table I as a milestone of development)

The National Cardiovascular Disease database (NCVD)

The NCVD is an initiative under the Malaysian Ministry of Health (MOH) that collects information about cardiovascular disease. The information can be used to estimate the incidence of cardiovascular disease according to type, and evaluate risk factors and treatments in the country. Such information is useful in assisting the MOH, non-governmental organizations, private providers and industry in planning and evaluation strategies for cardiovascular disease prevention and control.

Malaysia already had several cardiovascular disease databases in public and private healthcare providers located in Kuala Lumpur, Sarawak, Penang, Johore and at the National Heart Institute (Institut Jantung Negara, IJN). The NCVD Database was established to integrate these various databases and other data sources to achieve a nation-wide database. The NCVD is sponsored and coordinated, by the Clinical Research Centre (CRC), a research body within the MOH, and the National Heart Association of Malaysia (NHAM), the main professional body representing cardiologists and allied professionals in the field of cardiovascular medicine.

The Governance Board was established in year 2006 to oversee operations of the NCVD. The MOH, universities, professional bodies, NGOs and private healthcare providers are represented in this committee to ensure that the NCVD stays focused on its objectives, its continuing relevance and justification.

Aims of NCVD PCI Registry

The eventual goal of NCVD PCI is to provide a contemporary appraisal of Malaysian interventional cardiology practice, and to improve short-term and long-term outcomes of coronary artery disease. Ultimately, we hope the registry will engage all interventionalists to commit to this nationwide effort towards continuous quality improvement, and facilitate the introduction of international, multi-centre, randomized clinical trials in interventional cardiology.

The objectives of NCVD PCI are:

- To determine the number, and evaluate and monitor the outcomes of PCI based on selected performance indicators.

- To determine the cost of cardiovascular disease to the nation, and evaluate the cost-effectiveness of treatment and prevention programs.
- To determine the level of adherence to current practice guidelines.
- To stimulate and facilitate research.
- To facilitate quality improvement activities of participants (e.g. door-balloon-time in primary infarct PCI).
- To act as a reference for future studies (e.g. volume, pattern of practice, temporal trend, etc.)
- To facilitate future research and development.
- To benchmark with other national PCI registries.

It is hoped that this voluntary collaborative group will act as a catalyst for individual research ideas and projects. All participants share 'ownership' with access and utilization of the NCVD PCI database. This provides the platform to facilitate local audits and other quality-assurance activities at participating sites. It is also expected that this registry shall inculcate a culture of quality assurance, amongst interventional cardiology trainees; with plans for regular presentations at annual scientific meetings of the NHAM, and other national, regional, and international meetings. Interaction and collaboration with other collaborative groups and professional bodies, is anticipated in the near future.

MATERIALS AND METHODS

Design

The NCVD PCI registry is a voluntary, multi-centre collaboration amongst the main PCI centres in Malaysia. Consecutive patients undergoing PCI are included in the database.

Establishment of dataset

The standardized data abstraction form and dataset definitions were adopted from those of the Melbourne Interventional Group (MIG) PCI Registry. The MIG collaborative group has consented to the adoption as a

goodwill gesture and in anticipation of future collaboration. The MIG abstraction form was developed with reference to current international databases including the American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR), and interventional databases at Cleveland Clinic and Washington Hospital Centre, USA. The case report forms (CRF) were designed to collect detail demographic, past medical history, clinical and procedural information and pharmacotherapy. The PCI registry shares the same demographic component of the NCVD ACS registry.

There are three notifications: Initial notification form for the PCI procedure, patient follow-up at 30-day, six-month and 12-month. We recognized from the out-set; the importance of comprehensive data fields that are sufficient to address the important clinical questions in PCI, and yet ensure that it is not too large and cumbersome to manage. After several meetings and much deliberation, consensus was made on a dataset to reflect the contemporary PCI practice in Malaysia.

With the introduction of electronic web-based CRF (eCRF), certain data fields were deemed compulsory so as not to compromise the objectives of the registry. It was felt that these compulsory data fields were important to record, in particular lesion characteristic, procedural details, in-hospital outcomes and 30-day outcomes. The initial notification is in four-page format comprising nine sections that include: demographics, clinical status, clinical examination and baseline investigations, previous revascularization, cardiac status at time of PCI, cathlab visit (including adjunctive pharmacotherapy), PCI procedural details, procedural outcome, clinical status at discharge. (See <http://www.macr.org.my/encrd/zAu-data-standard.jsp> for the case report form)

Data collection

Consecutive patients undergoing PCI, both elective and urgent cases, were enrolled by participating sites. Commencement of data recordings started from 1st January

Table I : Milestones of the Registry

Chronicles: Milestones of the Registry	
♥	9th August 2006 ♥ Exploratory Meeting of PCI registry, by <i>pro tem</i> committee; initiated by IJN, MOH-CRC
♥	7th December 2007 ♥ 1st Working Committee meeting ♥ Worked on foundation of the registry ♥ Commitment of sponsorship MOH-CRC & NHAM
♥	13th January 2007 ♥ Registry initiation meeting ♥ Pilot Sites initiation ♥ Backdated data collection from 1st January 2007
♥	6th February 2007 ♥ e-PCI, web application uploaded online ♥ 12 participating sites, involves IJN, MOH heart centres, universities centres and private sectors
♥	14th April 2007 ♥ First presentation of the NCVD PCI database; during NHAM Annual Scientific Meeting ♥ First meeting for all "ground-staff" (interventionalists, trainees, cathlab nurses, research nurses) ♥ "Brainstorming": feedback on the challenges faced in initiation and operation of the database; ♥ Proposal for future

2007, and were initiated in 12 centres. The cases were initially notified using data abstraction form, completed at each site by interventional cardiologist, fellows, or nurses. The CRF were compiled and maintained at each site. Subsequently, with the launch of the web-based registry, the data were transcribed to the electronic CRF (eCRF).

All participating sites also submit a monthly notification, enlisting the PCI cases by the seventh of each month. Patients' contact telephone number were recorded to facilitate phone call follow-ups at 30 days and then six months, after the index procedure; and at 12 months preferably by clinic visit. Longer term follow-ups shall be considered depending on future funding status.

The registry is coordinated by a data manager at the Clinical Research Centre (CRC). Monthly census of each participating centre will be collected at the coordinating centre to keep track on the number of PCI performed. Data queries are referred to the participating sites, for clarification of possible errors and omissions. At present, individual sites may generate simple reports of their own centre to facilitate local audit activities. In future, regular audit program will be considered to ensure data quality.

Thirty-day, six-month, 12-month follow-up was performed by cathlab nurses, or dedicated research coordinators by respective centres. The follow-up data was then centralised at CRC. Since January 2007, approximately 2500 PCI patients have been enrolled in the registry, and 30-day follow-up completed for 90% of these cases.

Web Application

The data will be entered online. Individual sites submit names of interventionalists and coordinating nurses to the Registry data manager, to apply for individual username and password. The website address is at www.acrm.org.my/ncvd. The electronic CRF is launched online on 6th February 2007. The application applies a 2-tier security system where users will access the web application by using their username and password assigned by the registry manager. Once details are submitted, an authentication code will be sent to the particular user via short-messaging-system (sms), allowing access into the system. The participating centre has access to their own database but they are not given access to view the database of other centres.

Participating centre

PCI registry involves cardiac centres of the Ministry of Health Malaysia, National Heart Institute, universities and private centres that provide the majority of PCI service in the country. PCI registry has completed one year of data collection by 1st January 2008. Eight centres out of 12 contributed data in the first year.

Participation of individual centres is voluntary, and spearheaded by heads of respective centres. This collaborative venture has been successfully implemented into the workflow of the participating centres. By targeting institutions rather than individual cardiologists, the group felt this will ensure continuity and sustainability of the registry. Collaborators from participating centres together form the Working Committee, which has a democratic management structure

to facilitate harmonious working of the group. The following centres are actively contributing to the Registry: National Heart Institute (IJN); Penang Hospital; Sultanah Aminah Hospital, Johore; Sarawak General Hospital; Serdang Hospital; University Malaya Medical Centre (UMMC); Hospital Universiti Kebangsaan Malaysia (HUKM); Selangor Medical Centre.

Ethics approval

All centres practice the standard institutional procedure for obtaining informed consent from patients preceding their PCI procedure. Separate informed consent for participation of the NCVI PCI Registry was waived. The collection of patient data and follow-up was considered "observational" and non-interference to the patient care process. Confidentiality is secured via restricted access to the database as already described earlier.

RESULTS

Presentation of first six-months database

An introductory presentation of the Registry was made during the Annual Scientific Meeting of the National Heart Association of Malaysia (NHAM) in April 2007. Six months after the launch, an interim analysis of the registry was presented during the annual meeting (My LIVE) of the Malaysian Society of Interventional Cardiology (MSIC) in July 2007.

A total of 2349 PCI cases was enrolled in the first six month of 2007. Amongst the 1249 patients that have been reported and analyzed, the mean age was 56 years (min of 23, max of 86). Eighty two percent were males. Hypertension and dyslipidaemia are the most prevalent risk factors at 70.5% and 70.3% respectively. Diabetes affected 42.8%, of the cohort, and 6.7% has chronic renal failure.

Twenty four percent of these cases presented as acute coronary syndrome, of which 48% was STEMI, 22.7% NSTEMI, and unstable angina 26.3%.

Majority of PCI was on elective basis (87.4%). Transfemoral approach comprised 59% of cases, with 34% transradial. Fifty percent of cases involved multi-vessel disease. Drug eluting stents were used in 46.5% of PCI, with mean stent length of 22.4mm, and diameter of 3.0mm.

Procedural complications include peri-procedural myocardial infarction 0.8%, emergency reintervention 0.88% (11 cases of stent thrombosis). There was no bailout CABG. Overall, bleeding complications occurred in 1.5% of procedures. For 544 patients in the first six months, the 30-day mortality was 0.37%.

DISCUSSION

Future direction

There is ongoing effort to encourage the participation from other hospitals. The need for data quality is recognized by the Working Committee and in future, audit shall be carried out. At present, the responsibility for accurate data rests with the respective centres having to perform data verification,

and local audit. It is anticipated that with the growth of the database volume, subgroup analysis will be performed. It is hoped the analysis of the database shall provide the contemporary pattern of practices in Malaysia, as well as provide a platform for local research in health economics that will contribute useful information for public health policy, and assist in formulation of clinical practice guidelines.

CONCLUSION

The NCVD PCI Registry is the first Registry comprising the main hospitals and centres that provide PCI services in Malaysia. This Registry represents the voluntary collaboration of interventional cardiologists to provide a contemporary appraisal of Malaysian interventional cardiology practices. The Registry documents demographic, clinical and procedural details of consecutive patients undergoing PCI. Follow-up is planned up to 12 months. This venture shall facilitate continuous quality improvement in PCI, and facilitate the introduction of international clinical trials in interventional cardiology.

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