

Malaysian Cardiothoracic Surgery Registry - A Patient Registry to Evaluate the Health Outcomes of Patients Undergoing Surgery for Cardiothoracic Diseases in Malaysia

R Anas*, **I Rahman****, **H Jahizah*****, **A Hassan******, **T Ezani*******, **Y H Jong*******, **E Norzalina*******, **G Ziyadi*******, **S Balan*******, **J Ramadan*******, **T O Lim*******, **H Jamaiah*******, **H Hidayah*******

Department of Cardiothoracic Surgery, *Penang Hospital, Jalan Residensi, 10990 Penang, **Hospital Sultanah Aminah, 80100 Johor Bahru, Johor, ****Institut Jantung Negara, 145 Jalan Tun Razak, 50400 Kuala Lumpur, *****Sarawak General Hospital, Jalan Tun Ahmad Zaidi Adruce, 93586 Kuching, Sarawak, *****Hospital Universiti Sains Malaysia, 16150 Kubang Kerian, Kelantan, Department of Cardiac Anaesthesia, ***Penang Hospital, Jalan Residensi, 10990 Penang, ****Institut Jantung Negara, 145 Jalan Tun Razak, 50400 Kuala Lumpur, *****Sarawak General Hospital, Jalan Tun Ahmad Zaidi Adruce, 93586 Kuching, Sarawak, *****Hospital Sultanah Aminah, 80100 Johor Bahru, Johor, *****Hospital Serdang, Jalan Puchong, 43000 Kajang, *****Clinical Research Centre, Level 3, Dermatology Block, Hospital Kuala Lumpur, 50586 Jalan Pahang, Kuala Lumpur, Malaysia

SUMMARY

The formulation of the Cardiothoracic Registry. Cardiothoracic surgery is the field of medicine involved in surgical treatment of diseases affecting organs inside the thorax (the chest). It is a general treatment of conditions of the heart (heart disease) and lungs (lung disease). In Malaysia, due to lack of data collection we do not have estimates of number and outcome of such procedure in the country. Western figures are often used as our reference values and this may not accurately reflect our Malaysian population. The Malaysian Cardiothoracic Surgery Registry (MyCARE) by the Ministry of Health will be a valuable tool to provide timely and robust data of cardiology practice, its safety and cost effectiveness and most importantly the outcome of these patients in the Malaysian setting.

KEY WORDS:

Patient registry, Cardiothoracic surgery

INTRODUCTION

Cardiovascular disease (CVD) is a modern global disease which, despite recent advances in therapeutics, continues to rise in incidence. CVD accounts for 25% of all deaths in Malaysia in 1998¹. Acute coronary syndrome (ACS) accounted for nearly 35,000 acute admissions into Government hospitals in Malaysia within year of 2001². Treatment and prevention of CVD include 1) the identification of persons at risk of developing CVD and predisposing factors, 2) the development and clinical evidence of drugs and other interventional procedures that halt or modulate atherosclerosis, and 3) the implementation of clear strategies based on sound clinical evidence at all stages of the disease and clinical manifestation.

In addition, it is also known that death from aneurysmal rupture is one of the 15 leading causes of death in most series.

The estimated incidence of thoracic aortic aneurysms is 6-10 cases per 100,000 person-years³. In addition, the overall prevalence of aortic aneurysms has increased significantly in the last 30 years. This is partly due to an increase in diagnosis based on the widespread use of imaging techniques. However, the prevalence of fatal and nonfatal rupture has also increased, suggesting a true increase in prevalence. Population-based studies suggest an incidence of acute aortic dissection of 3.5 per 100,000 persons; an incidence of thoracic aortic rupture of 3.5 per 100,000 persons; and an incidence of abdominal aortic rupture of 9 per 100,000 persons. An aging population probably plays a significant role. Untreated, 75% to 80% of thoracic aortic aneurysms will eventually rupture. Five-year untreated survival ranges between 10% and 20%. Rupture risk increases with age and female gender⁴. The critical ascending aortic aneurysm diameter is 6cm (31% rupture risk) meanwhile the critical descending aortic aneurysm diameter is 7cm (43% rupture risk). Unfortunately all these data are "Western Data" does not reflect the local disease pattern. The wealth of clinical and epidemiological evidence has allowed for clear practice guidelines to be formulated both internationally and locally³⁻⁵. These issues have been rightfully addressed by the cardiology group and the surgical group intends to complete the picture by providing the results through the registry.

The Malaysian Cardiothoracic Surgery Registry (MyCARE) will seek to address the issues related to the specifically identified diseases namely coronary artery disease, aortic aneurysmal diseases and valvular heart diseases that were subjected to surgical referral and subsequently various surgical treatment modalities. The committee realized the lack of accurate and up-to-date data in Malaysia, which addressed the issues of prevalence, surgical treatments and the outcomes of these diseases following surgery and this registry is established to overcome these issues. The registry itself will be a useful tool to provide a timely, accurate and

robust data that reflects the Malaysian population and it can be mined for other research as well. It is hoped that this database will gradually streamline on all data pertaining to these issues.

As a kick-start, MyCARE will cover the adult cardiac surgery procedure as the primary scope which involves any cardiac surgery that is done for patient with age 12 years and above. In future, the committee is planning to include other additional 2 scopes which are paediatric cardiac surgery procedure and other thoracic surgery procedure. Thus, it is crucial for MyCARE to run the primary scope toward the expectation in order to make sure that the objectives are fulfilled and the establishment of other scopes will become reality.

OBJECTIVE

1. Determine the number of referrals, the time trend of waiting for surgery and the risk as well as surgical outcomes in Malaysia for coronary heart disease, valvular heart disease and aortic aneurysm.
2. Determine the socio demographic profiles of these patients to better identify the high-risk group in our Malaysian population.
3. Determine the number, evaluate and monitor the outcomes of each disease and surgical intervention based on selected performance indicators.
4. Determine the efficiency of, and adherence to current guidelines treatment guidelines.
5. Determine the cost to the nation by cardiothoracic disease and the cost-effectiveness of treatment and prevention programs.
6. Stimulate and facilitate research cardiothoracic disease research using this database.

MATERIALS AND METHODS

Design

MyCARE is a voluntary, MOH sponsored and multicentre hospital based cohort study.

Patient Selection

All patients age 12 years and above who are diagnosed with Coronary, Valvular and Aortic Aneurysm Diseases where surgical management is an option are eligible to be recorded. The patients must be referred to and seen at any of the participating centres.

Duration of Study

Currently, this study is in piloting phase which started on July of 2008 and it is expected to be launched on September 2008. The patient records are collected during the attendance, ward admission, surgery and he/she will be followed up till 30 days after surgery.

Source Data Provider

Participating sites include centres in government hospitals, universities and private centres. Currently, the government centres are Hospital Pulau Pinang, Hospital Umum Sarawak, Hospital Serdang dan Hospital Sultanah Aminah Johor Bahru. The participating universities centres are Hospital Universiti

Kebangsaan Malaysia (HUKM) and Hospital Universiti Sains Malaysia (HUSM). The only private centre that is currently involved in this registry is National Heart Institute or IJN. We are expecting and welcoming other cardiothoracic surgery centre to voluntarily participate in the registry in the future. However, under piloting period, only MOH hospitals will be collecting the data and after the registry is officially launched, the other SDPs (HUKM, HUSM and IJN) will follow the procedure.

Data Collection

All patients who underwent surgery will be registered on attendance at participating sites. The case report form will be filled up with the details of the patient by surgeon and anaesthetist that are involved in the surgery. The surgery procedure details are also filled up in the same case report form (CRF) as per Appendix 1. The CRF is designed using datasets from other similar registries from our countries as our references. The datasets are taken from the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database 2.61 24 August 2007; the Australasian Society of Cardiac and Thoracic Surgeons (ASCTS) – The National Cardiac Surgery Database Version 1, 30/04/01; and SCTS The Society of Cardiothoracic Surgeons of Great Britain and Ireland - National Adult Cardiac Surgical Database dataset version 3.8.

The CRF design is matched to Malaysian surgery procedures and during piloting period, hardcopy CRF is used to record the patients' details. The registry is coordinated by a registry 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 surgery performed.

Upon the completion of the pilot study, the data collection will be done electronically using eCRF through web application. Stringent information security policies will be implemented to maintain confidentiality. The participating centres have access to their own database but they do not granted access to database of other centres.

CONCLUSION

The Malaysian Cardiothoracic Surgery Registry is the first database to record detailed information of patients who undergo cardiothoracic surgery in Malaysia. Currently, it is in the piloting stage and it is expected to be launched soon. Its' first report is anticipated a year after data collection has started.

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