

Original Article

The Foundation and Launch of the Melbourne Interventional Group: A Collaborative Interventional Cardiology Project

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Available online 27 October 2005

The Melbourne Interventional Group (MIG) is a voluntary collaborative venture of interventional cardiologists practicing at 12 major public and private hospitals in Victoria, designed to record data pertaining to percutaneous coronary interventions (PCI) and perform long-term follow-up. The potential advantages of collaboration involve large-scale analysis of current interventional strategies (e.g. drug-eluting stents, evaluation of new technologies and cost-effective analysis), provide a basis for multi-centred clinical trials and allow comparison of clinical outcomes with cardiac surgery. The established registry documents demographic, clinical and procedural characteristics of consecutive patients undergoing PCI and permits analysis of those characteristics at 30 days and 12 months. The registry is co-ordinated by the Centre of Clinical Research Excellence (CCRE), a research body within the Department of Epidemiology and Preventive Medicine (Monash University, Melbourne). The eventual goal of MIG is to provide a contemporary appraisal of Australian interventional cardiology practice, with opportunities to improve in-hospital and long-term outcomes of patients with coronary artery disease.

(Heart Lung and Circulation 2006;15:44–47)

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Keywords. Percutaneous coronary intervention; Coronary stents

Introduction

The ability to record clinical data pertaining to interventional coronary angioplasty procedures is the founda-

tion for evaluating future outcomes. In Australia, the majority of institutions collect information for local use only, with varied data elements collected and variable definitions used. At present, no uniform data collection or clinical follow-up exists, indicating a need for a large-scale collaborative group. Multicentre data collection has proven to be a useful tool in examining short and long-term success, with an ability to identify variables associated with higher

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risks. These variables can ultimately be used to develop predictive risk-adjusted multivariate models.^{1–4} Cardiology registries also address the gap between the highly selected type of patient enrolled in randomised clinical trials and real-world practice.⁵ Retrospective analyses also bring in to play problems of missed data and recall bias; hence, prospective data collection via a central standardised registry is essential.

The Melbourne Interventional Group is a collaborative venture to record current interventional coronary procedures and perform longer term follow-up. This model is similar to the established Cardiac Surgical database (Australasian Society of Cardiac and Thoracic Surgeons).^{6,7} The potential advantages of collaboration involve large-scale analysis of current interventional strategies (e.g. drug-eluting stents, evaluation of new technologies and cost-effective analysis), provide a basis for multi-centred clinical trials and allow comparison of clinical outcomes with our surgical colleagues.

Aims of Melbourne Interventional Group

The goals of MIG are twofold: (1) To establish a collaborative coronary angioplasty registry with 30-day and 12-month clinical follow-up and (2) facilitation of multi-centred randomised clinical trials targeted at interventional cardiology. The development and implementation of the registry appears critical as it provides a basis for performing clinical trials. The eventual goal of MIG is to provide a contemporary appraisal of Australian interventional cardiology practice, with opportunities to improve in-hospital and long-term outcomes of patients with coronary artery disease. Ultimately, it is hoped that if this model is successful, it may become the platform to launch a national interventional cardiovascular registry.

The collaborative group of interventionists is envisaged to act as a 'sounding board' for individual research ideas and projects. All participants have access to and utilisation of the MIG database. It is anticipated that opportunities will arise for education and training (e.g. by attracting interventional cardiology trainees) with plans for a regular annual meeting around the Cardiac Society of Australia and New Zealand annual meeting, or ultimately stand-alone meetings. Interaction with other collaborative groups and educational bodies, e.g. the Cardiac Society of Australia and New Zealand appears paramount. Future involvement in internationally based clinical trials will be a central goal of MIG.

Methodologic Approaches

Establishing a Dataset

MIG case report forms are designed to document detailed demographic, clinical and procedural characteristics and current interventional practice patterns for patients undergoing PCI in Victoria (Supplementary data, Appendix B). Additionally, we aim to document medical therapy in the peri-procedural period. These factors are analysed with reference to in-hospital and 12-month clinical outcomes.

The four-page standardised data abstraction form was developed by a database working group within MIG. The members of this group have had considerable experience in the implementation and analysis of cardiology databases. Consensus was achieved for the final fields for the MIG registry after a number of interventional workshops.

Reference was made to a number of current interventional databases including the American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR), and established interventional databases at Cleveland Clinic and Washington Hospital Centre (USA).¹ A spreadsheet of the potential data fields from all referenced databases was developed and these were then compared and refined. We anticipated somewhere between 100 and 120 data fields would be sufficient to provide a comprehensive yet manageable dataset. It was important to ensure this dataset was not too large, yet detailed enough to address important clinical questions. It was not designed to cover all research needs as this would potentially lead to a cumbersome dataset that would likely remain incomplete. Each patient-related variable and clinical diagnosis required a standardised definition for uniform application across different hospitals. The dataset (current MIG database) was finalised for field use after field testing at two interventional centres (Royal Melbourne and Austin Hospitals).

The specific data, which we felt were important to record, included indication for the interventional procedure, peri-procedural anticoagulation strategies and planned duration of clopidogrel use post-procedure (Supplementary data, Appendix B). Lesion characteristics are captured in significant detail, as is the interventional treatment including stent type, size and length. At 30-day and 12-month follow-up, standard events are documented (e.g. death, myocardial infarction, target lesion and vessel revascularisation). Additionally, we targeted medication therapy and the development of heart failure.

Data Collection

Consecutive patients undergoing PCI by participating interventionalists are enrolled in the registry. The data abstraction form is completed at each site by interventional cardiology fellows or research nurses. Case-report forms are then transmitted via fax to the central registry for entry of de-identified data into a computerised database (Department of Epidemiology and Preventive Medicine, Monash University) where they are checked for possible errors or omissions. The registry is co-ordinated by the Centre of Clinical Research Excellence (CCRE), a research body within the Department of Epidemiology and Preventive Medicine (Monash University, Commercial Road, Melbourne). Data queries are referred to the originating centre before being processed into the databank. A contact phone number is provided for the central site to optimise communication with participating centres, and allows data queries to be addressed. Individual hospital or composite MIG updates can be readily obtained. The data are queried and a regular audit program is planned to ensure data are of high quality.

Thirty-day and 12-month follow-up is performed by a research co-ordinator at the respective hospital. Follow-up annually to 5 years has been targeted, and this goal depends on future resource allocation. This duration of follow-up would allow comparison with the National Cardiac Surgery Database, providing critical appraisal of coronary revascularisation strategies within Australia.⁶

It is anticipated that a centralised follow-up system will ensue (from the Department of Epidemiology and Preventive Medicine, Monash University); however, steps towards this transition are in their infancy. Since June 2004, 1100 PCI patients have been enrolled in the registry and 30-day follow-up has been completed in 800 PCI patients. Analyses are prospectively planned by a central publication committee to ensure data quality, the absence of publication bias and feedback to and acknowledgement of all investigators. The initial patient registry will provide data for analysis of clinical efficacy and cost effectiveness of drug-eluting stents.

Informed Consent

Collection of patient data and follow-up for the MIG database was approved by the ethics committee of each participating institution. A written 'plain-language' statement is provided to patients preceding their interventional procedure, which explains the purpose of obtaining patient and procedural information (Appendix A). We employed an 'opt-off consent' which requires the patient to sign a declaration only if they refuse to contribute their relevant information, or do not want to be followed up beyond the coronary intervention. This model has been used for the National Cardiac Surgery Database, and has been a highly effective consent tool with high rates of participation.⁶ This method also assists in minimising the "Hawthorne effect" (i.e. a phenomenon in observational research where outcome variables are effected by the fact that the participants of the study know they are participating in the study).

Participating Centres

The Melbourne Interventional Group (MIG) is a collaborative venture of interventional cardiologists practicing at 12 major public and private hospitals in Victoria. The participation of individual interventional cardiologists is purely voluntary. The MIG collaboration felt that targeting individual cardiologists rather than institutions, and having a democratic management structure would be more beneficial for harmonious working of the group.

The following hospitals have selected interventional cardiologists contributing to this venture: Royal Melbourne and Melbourne Private Hospitals; Austin and Warrigal Hospitals; Alfred Hospital; Western Hospital Footscray; Geelong and Geelong Private Hospitals; Box Hill Hospital; Frankston and Peninsula Hospitals; Knox Private Hospital.

Conclusions

The MIG collaborative group comprising a broad range of Victorian hospitals will provide an insight into contemporary Australian interventional Cardiology practice. The

established registry documents demographic, clinical and procedural characteristics of consecutive patients undergoing PCI and permits analysis of those characteristics at 30 days and 12 months. The collaborative venture will facilitate multi-centred randomised clinical trials targeted at interventional cardiology. Ultimately, it is anticipated that this will facilitate improvements in short and long-term outcomes for patients with coronary artery disease.

Acknowledgements

We wish to thank Prof. Andrew Tonkin for his support and guidance. We wish to also thank Mr. Gil Shardey and Mr. Peter Skillington, representing the Cardiac Surgical Database (Australasian Society of Cardiac and Thoracic Surgeons), for allowing concepts used within their Ethics Committee application to facilitate our applications. Dr. Duffy is supported by a Career Development Award (No. 182830) from the National Health and Medical Research Council of Australia.

Appendix A. Patient Information Sheet

Melbourne Interventional Group Database

ROYAL MELBOURNE HOSPITAL. Background

You are about to have (or have recently had) a coronary artery procedure ("intervention") that aims to improve the blood supply to your heart and improve your symptoms. Most procedures involve the use of a balloon ("angioplasty") and a metal scaffold ("stent") to open up any blockages in your coronary arteries. Generally, these procedures are successful and improve the quality of the patient's life, with a small risk of death or major complications. Your doctor will have explained these risks to you. Some people, however, can have a recurrence of their original symptoms, usually due to re-narrowing of the vessel ("restenosis"). There are continuous improvements in techniques and equipment that reduce the risk of complications and restenosis in clinical trials, but whether these improve outcomes in "real life" is often unknown.

In order to improve the immediate success and long-term outcomes of these coronary procedures, we need to know what factors increase a patient's risk of complications and restenosis. By knowing this we hope to improve procedural success and long-term outcomes of patients undergoing these procedures. As you would reasonably expect, many hospitals already have databases on the in-hospital outcome of coronary interventions, but there is no statewide or national data available about long-term outcomes in Australia. To obtain this important information a group of cardiologists (heart specialists) have formed a group called the Melbourne Interventional Group. There are representatives from most Melbourne hospitals in this group. **Our aim is to set up a statewide database that will record information on every adult coronary artery interventional procedure.** The success of the database depends on the amount of information we get, and to be truly representative we want to include all patients.

We are asking you to participate in the Melbourne Interventional Group Database by allowing us to document information about your cardiac condition and procedure. Importantly, we also want to see how you progress over time by collecting follow-up information about your cardiac health.

What Information Do We Need?

The information we require includes your name, date of birth, Medicare number, hospital identification number, the name of your hospital, the reason you are having a coronary intervention, technical details of the procedure, any complications that you have in hospital, and your follow-up cardiac health information. All of your information will be freely available to you from your treating hospital.

We Will Keep Your Information Confidential

Your personal information is confidential and cannot be used outside the database. Procedures are in place to protect your information and keep it confidential. You will be assigned a unique number which will be used to identify you. The data is accessible by authorised staff of the Melbourne Interventional Group Database project. Only group data will be made available publicly to groups such as participating hospitals, the Department of Health and the National Heart Foundation. You cannot be identified in any reports produced by the database project.

How Will We Collect the Information?

The hospital staff will complete the forms that contain the relevant details during your hospital stay. You will be called 30 days, 1 and 2 years after your procedure to briefly obtain information about your cardiac health. We will ask you about any new heart symptoms, any further procedures that you have had, and what medications you are taking. The information will be entered into a secure database computer.

Risks and Benefits to You

Your information is protected and we are not allowed to identify you by law. The database will produce general reports on the short- and long-term success of coronary procedures, which we anticipate will improve the quality of procedures in the future.

You Can Choose Not to be in the Database

We understand that not everyone is comfortable about having details related to their heart procedures entered into a database. If you feel this way, and do not want your information added to the database or to be contacted for follow-up, please contact the Project Coordinator (Angela Brennan) on 1800 285 382 at any time.

A decision on whether or not you wish to be involved in the database does not affect your treatment in any way.

Appendix B. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.hlc.2005.08.001.

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