The Australian Orthopaedic Association National Joint Replacement Registry

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ABSTRACT

- In the financial year ending June 2002, 26 689 hip replacements and 26 089 knee replacements (total, 52 778) were performed in Australia.
- Hip and knee replacement procedures have increased between 5%–10% each year for the past 10 years, with a combined increase in hip and knee replacement of 13.4% in the past year.
- The revision rate for hip replacement surgery in Australia is unknown but is estimated to be 20%–24%; the revision rate for hip replacement surgery in Sweden is 7%.
- Although data collection for the Registry is voluntary, it has 100% compliance from hospitals undertaking joint-replacement surgery

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The Australian Orthopaedic Association (AOA) has recently completed implementation of a National Joint Replacement Registry (AOA NJRR). The purpose of the Registry is to provide quality demographic information on the practice of joint-replacement surgery, improve outcomes, and establish a mechanism of audit for hospitals and individual surgeons. It is an initiative of the AOA and is funded by the Federal Government. The Registry is voluntary, yet receives cooperation from all hospitals undertaking joint-replacement surgery. Here, we outline the reasons for establishing the Registry, some issues related to its implementation, and examples of early outcomes.

Reasons for establishing the Registry

Changing incidence of joint replacement surgery

Joint replacement surgery is a major area of health expenditure. In 2002, over 50 000 hip and knee replacement procedures were performed in Australia, at an estimated cost of well over $500 million. Until recently, the rate of joint replacement surgery has increased by 5%–10% a year; the past 2 years have seen increases of more than 10%. The ageing population and increasing use of joint replacement in younger people will ensure that this rate of increase will continue. The number of revision procedures will also increase as more patients survive longer than the life expectancy of the replacement joint.

Revision surgery

The outcomes of joint replacement surgery in Australia are unknown. The requirement for revision surgery is a clear endpoint which indicates failure, and is therefore a critical outcome measure.

Currently, in Australia, the percentage of hip replacements that are revision procedures is just over 14%.[1] This probably equates to a revision rate of 20%–24%. Sweden has had both hip and knee replacement registries for over 20 years; as a consequence the revision rates there are well defined. The rate for hip replacement surgery in Sweden is 7%.[2] Why this difference exists remains to be established, but it highlights the need to collect information and undertake appropriate analysis to determine Australia-specific outcomes.

Reducing the revision rate is a principal focus of the AOA NJRR. This has been a well established effect of the Swedish registries.[3,4] Revision operations are associated with less satisfactory outcomes and considerable morbidity and mortality when compared with primary procedures.[5-7] Reducing reoperation is also associated with significant cost savings. A conservative estimate of savings accompanying a 1% reduction in the percentage of revision operations is $10 million. Identifying and publishing outcomes specific to prostheses, surgical techniques and particular clinical situations is a critical step to achieving this reduction.

Reasons for revision

The most common reason for revision surgery is aseptic loosening. This occurs as a result of a localised inflammatory reaction induced by the production of wear particles. The inflammation results in periprosthetic bone loss, with consequent component loosening and pain. The extent of

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inflammation depends on the number and nature of the particles produced, which is related to the type of prosthesis and its positioning, as well as extent of use and time since implantation. The occurrence of other reasons for revision, including recurrent dislocation, fracture, infection, ongoing pain of uncertain aetiology and component breakage, are also known to vary with the type of prosthesis

Need for postmarketing surveillance

As early as 1993, the AOA identified the need to introduce a comprehensive postmarketing surveillance program for joint-replacement prostheses. Currently, in Australia, there are over 100 different prostheses used for hip replacement and more than 50 different knee-replacement prostheses. Because of the rapid introduction of new technologies, the mid-term and long-term survival rates for the vast majority of prostheses remain unknown. Inadequate outcome data, as well as variability of surgical techniques, methods of bone fixation and clinical situations, make it difficult to determine the relative effectiveness of different prostheses. These difficulties are further compounded by changes in the performance of established prostheses resulting from minor design alterations or changes in the manufacturing process.

Prosthesis recalls

Two recent company-initiated recalls clearly highlighted the need for the Australian Joint Replacement Registry. Both of these recalls have been discussed in recent annual reports of the Registry. The first was the zirconia femoral head recall.[1] A problem became evident when a small number of fractures of this ceramic prosthesis were identified in other countries. A change in the manufacturing process had altered the ceramic, making it vulnerable to sudden disintegration. This affected several batches of the material. At the time, it was estimated that almost 9000 patients in Australia had received the prosthesis.

In the absence of an Australian registry, a number of difficulties soon became evident. These include:

- It was not easy to identify patients who had received the prosthesis. It involved companies going through incomplete records and individual hospitals examining case notes of patients who had undergone total hip replacement for the period that the prosthesis was used. This process was time-consuming and did not identify all patients.
- It was not possible to provide ongoing monitoring of patients who have had a recalled device implanted. It was known that the number of failures was small, but it was not known how much the failure rate might increase, or if different modes of failure might become evident.

The second recall related to a number of prostheses manufactured by Sulzer Orthopaedics.[1] Changes in the manufacturing process left residual bone-toxic oil-based lubricant on the prosthesis surface. This was associated with failure of bone ingrowth and rapid loosening of the prosthesis. Almost 17 000 prostheses were implanted in the United States before the problem was recognised. Adequate postmarketing surveillance would have identified the problem much earlier.

Registry overview

The specific aims of the Registry are to:

- record demographic and diagnostic information about patients undergoing joint replacement surgery;
- provide accurate information on the types of prostheses used in both primary and revision joint replacements;
- evaluate the effectiveness of different types of joint replacement prostheses and surgical techniques;
- compare the Australian joint replacement data to those of other countries;
- provide confidential data to individual surgeons and hospitals in auditing their joint replacement surgery;
- educate Australian orthopaedic surgeons in the most effective prostheses and surgical techniques; and
- provide a mechanism to enable device tracking of implanted joint replacement prostheses — in particular, to rapidly identify patients with an implanted device that has been subject to recall.

Implementation of the Registry commenced in 1999. This was undertaken in a staged manner, beginning in South Australia and then progressing through each state until national completion in 2002. All 294 hospitals (both public and private) that undertake hip and knee joint replacement surgery supply information to the Registry, which is currently receiving notification of more than 5000 procedures a month.

The management of the Registry is the responsibility of the federal board of the AOA through its Registry Management Committee. This Committee is responsible for advising on policy and management decisions, and reports directly to the board of the AOA. The day-to-day management of the Registry is the responsibility of the Director, who works in close association with the Chairman of the Registry Committee and the Registry Coordinator. These AOA appointees meet weekly with personnel from the Data Management and Analysis Centre at the University of Adelaide, which manages and analyses the Registry data.

Data, consent and confidentiality

The essential purpose of the Registry dataset is to identify, by catalogue and lot number, all prosthetic components that have been implanted into a patient. The dataset is simple, and includes patient details (name, date of birth, sex, and address including postcode), hospital, type of procedure (hip replacement [partial, primary total or revision], knee replacement [patellofemoral, unicompartmental, primary total or revision]), side (left or right), diagnosis, and details (make, catalogue and lot number) of all components used. Surgeon code can also be used, but this is not compulsory.

Patient consent is obtained using the "opt off" approach. This requires that patients are provided with information on the purpose of the Registry, how the information is collected and an explanation of the simple, cost-free avenues to take

should patients wish to have their information excluded. To date, only 5 patients out of 140 000 have elected not to have their details recorded by the Registry.

No patient, surgeon or hospital is identified in the reports and publications produced by the Registry. Surgical and prosthesis data are managed in accordance with the Guidelines for the Protection of Privacy in the Conduct of Medical Research. Personal data collected are for use by the AOA National Joint Replacement Registry only, and are protected by the Registry's listing as a Federal Quality Assurance Activity.

Data collection and entry

The Registry currently collects information by means of a paper-based system, with data entered by skilled data entry personnel. This method was implemented because of its simplicity and ability to rapidly identify and correct errors in information provided.

Initial discussions with hospitals indicated that most would prefer to send the information to the Registry electronically. However, no hospitals currently collect all the information required by the Registry on either theatre or hospital information systems. The Registry has worked closely with a number of hospitals to develop appropriate systems for secure electronic data transfer, but the hospital currently trialling direct electronic entry has raised concerns about the expense, increased time and reduced accuracy when compared with the paper-based system.

Data validation

Critical to the success of any registry is the quality control of the collected information. The AOA NJRR validates its data by using both internal systems and external data sources. This process has required continued development and refinement. The most important external data source is state health department data. This involves a sequential multilevel matching process. Registry and state health department data are initially matched using hospital and hospital identity number. Subsequent matching is undertaken on relevant procedure codes and admission period. This individual patient and procedure validation has been undertaken for South Australian, Western Australian and Victorian data used. This process has confirmed that the initial notification rate to the Registry varies between 95% and 97% for these three states. The process also identifies procedures that have not been notified. Direct contact with the hospitals concerned provides a mechanism for obtaining missing data, thereby ensuring that data collection approaches 100% of all procedures.

The Registry is still developing validation procedures for the individual components used. This will be achieved by obtaining data from all orthopaedic manufacturing and distributing companies supplying prostheses in Australia. Cooperation from companies has been good, and it is anticipated that the implementation of this additional verification mechanism will begin in 2004. Once established, almost all of the minimum dataset collected by the Registry will be able to be validated from external data sources.

Early outcomes

Despite the Registry's short period of existence, it has already achieved some very important outcomes. It has shown that it is possible to develop voluntary national registries within Australia. This has been achieved by obtaining effective cooperation of federal and state governments, hospitals, clinicians, nursing and administrative staff and, most importantly, patients. This, in turn, has been facilitated by the involvement of the professional body and providing a clear explanation of the purpose and benefits of the Registry.

The Registry has quickly established itself as the authoritative organisation for information on joint-replacement surgery. Quality current demographic information is now freely available to organisations and individuals. Almost 85% of all operations are recorded within 6 weeks, and 95% within 3 months. Important collaborations involving data analysis to examine regional differences in availability, effectiveness and true costs of service delivery are being undertaken.

For the first time, information on the method of fixation and the types of prostheses used is now available. The Registry has identified not only major differences in the practice of joint-replacement surgery between Australia and other countries, but also significant variation between states within Australia. An excellent example of this is the use of cement fixation for both acetabular and femoral components in primary total hip replacement. Sweden has an incidence of cement fixation for both components exceeding 90%, while, in Australia, the incidence is 18.2%, with variation between 4.5% (New South Wales) and 40.5% (Queensland).

There are also considerable differences in the use of prosthetic types. Over 75% of hip replacements undertaken in Sweden involve the use of five different prostheses. In Australia, it has become evident that surgeons are mixing and matching femoral and acetabular components from different designs and different companies. This is occurring to such an extent that just under 600 different combinations of femoral and acetabular components have been recorded by the Registry.

The critical outcome measure determined by the Registry is the revision rate. The ability to determine this will be enhanced with time, as increasing numbers of primary procedures recorded by the Registry are revised. Despite the Registry's short existence, it has already identified specific prostheses or prosthetic combinations with high early failure rates. The Allegretto knee, one of the most common unicompartmental knee-replacement prostheses used in this country, has a 10% revision rate at 2.5 years, which is considerably greater than other unicompartmental knee-replacement prostheses.

The Registry has also identified different outcomes based on generic features common to a variety of prostheses. An example of this is the direct relationship between decreasing

risk of early hip replacement revision with increasing diameter of the head of the femoral component.[1]

Conclusion

The Registry has already proven to be an important healthcare initiative. It has been able to provide quality demographic information, determine outcomes, identify both prostheses that perform well and poorly, as well as establish a national system for device-tracking of joint-replacement prostheses. There is no doubt that the Registry's work will result in significantly improved outcomes, as well as major cost savings, in joint-replacement surgery in Australia.

Competing interests

None identified.

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