Comparison of the performance of hip implants with data from different arthroplasty registers

This study evaluated the feasibility of using published data from more than one register to define the performance of different hip implants. In order to obtain estimates of performance for specific types of hip system from different register, we analysed data from the annual reports of five national and one Italian regional register. We extracted the number of implants and rates of implant survival at different periods of follow-up. Our aim was to assess whether estimates of cumulative survival rate were comparable with data from registers from different countries, and our conclusion was that such a comparison could only be performed incompletely.

Registers are important tools in evidence-based clinical practice. Arthroplasty registers collect data on primary and revision procedures performed in a defined geographical area. They usually operate on a national basis, but some regional registers also exist.

In the Scandinavian countries arthroplasty registers have been functioning for some decades and have recently come together into the Nordic Arthroplasty Register Association (NARA). Finland established its national arthroplasty register in 1980, whereas in other countries, such as Australia, England and Wales, and New Zealand, the national arthroplasty register has been established in the last ten years. A national joint registry was recently started in Malawi and a hip registry is being formed in Italy and will start to operate in 2010.

In the field of hip arthroplasty, data from registers are used to produce reliable estimates of the performance of implant systems in terms of effectiveness and safety. However, because each national register is integrated into a particular health system, its data are context specific and reflect the standards of practice in that nation. Differences between countries, such as experience in cementing techniques, various implant designs, surgical approaches, regimens of rehabilitation or the general organisational and cultural features of the health system, may affect the outcome of the operation.

Some of the problems of interpretation of information in registers from different countries have recently been highlighted by Labek et al., who concluded that to make data from different registers available and useful for surgeons, healthcare providers and patients, more international co-operation is required.

The aim of this study was to evaluate the feasibility of using published data from more than one register to define the performance of different hip implants. In order to obtain estimates of performance for specific types of systems from different registers, we analysed data from the annual reports of five national and one Italian regional register. We extracted the number of implants and the survival rate at different periods of follow-up, and assessed whether estimates of the cumulative survival rate were calculable using the data of registers from different countries.

Materials and Methods

The basis for our analysis was a report produced for the first Italian Health Technology Assessment Programme. The Ministry of Health commissioned the National Agency for Regional Healthcare (AGE.NA.S.) to assess whether the prostheses for total hip replacement which were available and used in Italy were employed on the basis of documented evidence of good performance. We used some of the findings of this report to conduct a further analysis on the comparison of performance of hip implants from data from different orthopastry registers.

We carried out a PubMed search using the terms ‘arthroplasty’ and ‘register’ to identify any paper using or discussing data from arthroplasty registers. We intentionally used a
wide research strategy to collect all available evidence on the subject. Two of the authors (AM, ER) screened the citations by title and abstract. Those considered potentially relevant were obtained in full text and analysed in detail.

We also searched the internet using the same strategy on Google for references to national arthroplasty registers and accessed the EFORT portal. We identified 14 arthroplasty registers. Of these, 13 presented periodic reports which could be downloaded from the website. We excluded those that were not in English. This left 12 for detailed analysis. Nine reports from national and three from Italian regional registers were analysed in detail. They were from Australia, Canada, Denmark, England and Wales, Finland, New Zealand, Norway, Scotland, Sweden, and Emilia-Romagna.

We extracted data from those reporting the performance of a specific type of hip system, identified by the name of the acetabular and femoral components, and expressed as the revision rate the percentage of implants revised at a given time, or as the survival rate the percentage of implants in place at a given time. In arthroplasty registers, revision is defined as the replacement or removal of one or more of the components. The revision rate, expressed as a percentage, is the survival rate subtracted from 100.

Because our aim was to assess whether estimates of the cumulative survival rate were calculable using data from different registers, we analysed data related to hip systems collected in at least two registers. We then extracted the number of procedures performed and the survival rate, expressed as a percentage, at three, five and ten years. When revision rates were reported instead of survival rates, we converted the values. In order to obtain estimates of the cumulative survival rate using data from different registers, we calculated a weighted mean from the number of procedures performed using the same specific hip system.

Results

Our PubMed search on 30 November 2008 identified 209 items. After a first screening of citations by title, 69 were considered potentially relevant and were obtained in full text. None of these studies reported a direct comparison between implant survival data from different registers. Of the 69 studies, 67 extracted data from one arthroplasty register alone. Only two studies discussed the issue of comparison between registers: Labek et al and Kolling et al. We have briefly described the former in the introduction of this paper. Kolling et al carried out an exhaustive international survey to assess the differences between 15 arthroplasty registers worldwide. They gave detailed information about the funding and maintenance of the registers, data handling, and feedback to the hospitals or to the public. From their analysis, the authors concluded that the methods of collection and handling of the data differ widely, as well as the legal conditions under which the registers work. The number of single-register studies indicates that they are used by the organisers of the register for the diffusion of their scientific findings.

There were 32 studies from the Norwegian register, ten from the Swedish register, nine from British regional registers, eight from the Finnish register, four from regional Italian registers, and two from the German register. The remaining two studies reported data from the registers of Denmark and New Zealand, respectively.

Other authors who have compared the information in registers from different countries noted some important differences. We focused on data presented in the last available periodic report.

Our analysis showed that, at present, comparison between registers can be only performed incompletely. Not all the registers reported the survival or revision rates, and when described, some were not systematically referred to specific hip systems. Moreover, stratification was rarely performed (Table I).

Only six of 12 periodic reports presented the variables of interest for our study, namely, the number of implants undertaken and the relative survival or revision rates per specific hip system. These were the Australian, Danish, England and Wales, Finnish and Swedish registers, and that of Emilia-Romagna in Italy.

The periods of follow-up were three, five and ten years. The year of inception of the register was important. Those of recent introduction, such as Australia, England and Wales and Emilia-Romagna, cannot show data with a long follow-up. However, they have based their organisation, data collection and analysis on the long experience of the Scandinavian countries. Well-established registers, such as the Swedish, report data for five and ten years of follow-up only, so comparison of results with the more recent registers is not possible. The Danish register is the only one reporting data on specific hip systems with follow-up at three, five and ten years.

The Finnish periodic report gives the survival analysis of specific hip systems in the form of Kaplan-Meier curves. Although these are very useful to observe the trend of performance for each system, they are not comparable with the reporting format of the other registers, which give a percentage value reported in tabular form. As our aim was not to focus on information referred to specific hip systems but to assess the comparability of data in registers from different countries, we identified the systems appearing in two or more registers. Using this ‘two-registers rule’, we constructed Tables II and III. A total of 11 hip systems were identified: four were cemented (Charnley acetabular and femoral component; Charnley-Ogee acetabular component with Elite Plus femoral component; Contemporary acetabular component with Exeter femoral component; ZCA acetabular component with CPT femoral component), four were uncemented (ABG II acetabular and femoral components; CLS acetabular and femoral components; Fitmor acetabular and CLS femoral component; Trident acetabular and ABG II femoral component), and three were hybrid (Mallory-head acetabular and Exeter femoral component; Reflection acetabular and
Spectron EF femoral component; and Secur-Fit acetabular and Omnifit femoral component).

Tables II and III do not show data at ten years of follow-up. Although such information is available for seven of the 11 hip systems identified, they were reported in only one of four registers considered, and hence fell outside our ‘two-registers’ rule and were excluded from our analysis.

### Discussion

Randomised controlled trials (RCTs) are universally regarded as the best method to provide robust estimates of treatment or causal effects. In some cases, however, observational studies, such as registry-based assessments, may present clear advantages over RCTs, as the design of the latter may be affected by ethical and/or feasibility concerns, such as the length of follow-up required to define the long-term performance of a hip system.

However, national registers are integrated into a particular health system, and their data may be affected by context-specific factors. In order to extend the value of the information in registers outside national boundaries, a degree of standardisation in reporting is needed.

We assessed whether estimates of cumulative survival rate were calculable using data from registers of different countries. Ideally, these estimates may provide a general indication of how the specific hip systems perform...
internationally, and may generalise the context-specific data reported in national registers. We are conscious that survival and revision rates represent a crude measure of implant failure but, as noted by others, the need for a revision operation is probably the only quantifiable event which forces the patient to return to hospital. If a national arthroplasty register allows estimates of performance that can be generalised on a national basis and if data are extracted from registers of different nations, estimates of performance can be generalised internationally. In order to do this, it is crucial for the different registers to collect and report the same variables. This is especially the case for those such as the indications for intervention, the type of hip system, the body mass index, age and gender. Furthermore, to perform comparative analysis between registers, the data should be reported in the same format and the same language.

A number of variables are related to the performance of a specific implant, some to the design and material of the implant and others to the age and gender of the patient and the indications for operation. Periodic reports of registers should present a stratification by variables that have been demonstrated to play a role in the survival of the implant. Only the Finnish, Swedish and Emilia-Romagna registers give stratification by age, indications and gender.

We agree with those who call for more co-operation between countries that have established a national arthroplasty register. Lack of comparability is greatly affected by lack of data and/or heterogeneous reporting. Loss of data implies the thinning of our knowledge base and heightens the risk related to the use of devices about which there is insufficient move.

A tentative move towards a federation of registers from different countries is the aim of the EAR (European Arthroplasty Register), in co-operation with EFORT (European Federation of National Associations of Orthopaedics and Traumatology) and the established European registers. It has defined three basic characteristics for an arthroplasty register: registration in central database of all primary and revision operations performed in a defined geographical area; follow-up of the implant until it has to be revised or the patient dies or emigrates; and a definition of failure as revision of at least one component.

A safer use of hip implants may be possible in the future owing to standardisation of reporting and collection of data. Other important measures in this field will come after the recent reclassification by the European Commission of joint implants from risk class IIb into risk class III.

The authors thank F. Bernardini from AGE.NA.S. who carried out the bibliographic searches.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References