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Review article

Registries in orthopaedics

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ABSTRACT

The first nationwide orthopaedic registry was created in Sweden in 1975 to collect data on total knee arthroplasty (TKA). Since then, several countries have established registries, with varying degrees of success. Managing a registry requires time and money. Factors that contribute to successful registry management include the use of a single identifier for each patient to ensure full traceability of all procedures related to a given implant; a long-term funding source; a contemporary, rapid, Internet-based data collection method; and the collection of exhaustive data, at least for innovative implants. The effects of registries on practice patterns should be evaluated. The high cost of registries raises issues of independence and content ownership. Scandinavian countries have been maintaining orthopaedic registries for nearly four decades (since 1975). The first English-language orthopaedic registry was not created until 1998 (in New Zealand), and both the US and many European countries are still struggling to establish orthopaedic registries. To date, there are 11 registered nationwide registries on total knee and total hip replacement. The data they contain are often consistent, although contradictions occur in some cases due to major variations in cultural and market factors. The future of registries will depend on the willingness of health authorities and healthcare professionals to support the creation and maintenance of these tools. Surgeons feel that registries should serve merely to compare implants. Health authorities, in contrast, have a strong interest in practice patterns and healthcare institution performances. Striking a balance between these objectives should allow advances in registry development in the near future.

1. Introduction

The first registry on joint prostheses was created 45 years ago (in 1969) at the Mayo Clinic in Rochester, MN, USA. In 1975, efforts led by Professor Bauer led to the establishment in Sweden of the first nationwide registry, which collected data on total knee arthroplasty (TKA) [1].

The objective of this work is to review the current status of orthopaedics and traumatology registries, to discuss their impact, and to highlight their limitations. Traumatology registries are few in number, largely confined to Scandinavian countries, and designed only for epidemiological purposes. This paper is therefore confined to nationwide registries of TKA and total hip arthroplasty (THA), which are the oldest and most informative.

2. What is a registry?

In France, a decree issued on 6 November 1995 by the National Registry Committee (Comité national des registres, CNR) defines a "qualified registry" as "a continuous and exhaustive collection of nominative data about one or more health-related events in a geographically defined population, by a team having specific expertise, to be used for research and public health studies". Unfortunately, article 2 of this decree proscribes the creation of registries for implantable medical devices and the collection of outcome data on implant recipients [2]. This legislative barrier is among the main reasons France is far behind other countries in the area of orthopaedic implant registries.

3. How is a registry created?

Orthopaedic and traumatology registries collect data from a single or multiple sites, within a specific geographic region or nationwide. Only a limited amount of information is collected, to reflect the limited purpose of the registry. Thus, the minimum dataset established by the International Society of Arthroplasty Registries (ISAR) contains only 14 items [3].

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Longitudinal data are collected to assess the outcome of the implant(s) in each patient. In contrast to disease-based registries, which collect the vital status of the patients, implant registries assess the survival of the implants. Thus, the death of a patient whose implant is still in place is classified as a probable or relative success of the implant procedure. Implant revision is the only indisputable endpoint, although it is affected by a number of factors (e.g., patient health status, inadequate implant monitoring, or missed diagnosis of implant failure). The term "revision" must, however, be clearly defined. The Swedish registry uses the following stringent definition: any new surgical procedure during which one or more prosthesis components are replaced, removed, or added. The Norwegian registry, in contrast, defines revision as the removal of all the implant components and therefore classifies patellar resurfacing, for instance, as a simple re-operation.

The key to ensuring the efficacy of an implantable medical device registry is the use for each patient of a single identifier, preferably the statutory health insurance number or national identity number. This identifier ensures that a primary prosthesis implanted at a given institution at a given date can be connected to subsequent revision of the implant at a different institution. Recording the side is informative in patients with bilateral arthroplasty. This automatic cross-referencing function is effective only if data collection is exhaustive.

When comparing implant performance for benchmarking purposes, survival curves are the best tool. To plot survival curves, information must be available on the vital status and, therefore, the identity of the patients. Many countries have laws forbidding the collection of data on patient identity. The Australian registry circumvents this problem by using the revision rate per 100 observed component years, which allows comparative analyses without knowledge of patient death dates. The same method is used in the British registry (patient time incidence rate), European Arthroplasty Register (EAR), and French SoFCOT THA registry (https://sofcot.memdoc.org/) [4,5].

Despite these limitations, registries allow epidemiological and demographic studies, as well as comparisons of outcomes across implants and institutions within a country. Registries are designed to collect information from all surgeons, instead of only from the highly specialized groups that contribute most of the studies published in the international medical literature. Thus, registries provide a more accurate view of the real-life healthcare provided to the population.

Management of a registry requires large amounts of time and other resources, most notably when exhaustive data are collected. For many registries (e.g., in Sweden and Finland), the registries were created under the impetus of professional societies. Elsewhere (e.g., in Canada and the UK), the health authorities required that healthcare institutions establish registries and, therefore, contributed to the data recording effort. In many cases, these two situations followed one upon the other.

4. Historical overview

Whereas Scandinavian countries have been maintaining orthopaedic registries since 1975, the first English-language orthopaedic registry was not created until 1998 (in New Zealand) and both the US and many European countries are still struggling to establish similar tools. To date, there are 11 registered nationwide registries of TKA and THA (Table 1).

4.1. The Swedish Knee Arthroplasty Register and the Swedish Hip Arthroplasty Register

The Swedish Knee Arthroplasty Register created in 1975 (http://www.knee.se) and the Swedish Hip Arthroplasty Register created in 1979 (http://www.shpr.se/en/) remained confidential until 1989, when their results were first reported in an international journal [6]. Since then, they have gained increasing international prominence, as their contents are described in an English-language report every 2 years [7]. Sweden now has 73 nationwide registries, whose total cost of 35.6 million € per year is entirely covered by non-industrial sources [2].

4.2. The Finnish National Arthroplasty Register

The Finnish National Arthroplasty Register (http://www.fimea.fi/frontpage) was started in 1980 to collect data on both THA and TKA. Data reporting to the register was initially on a voluntary basis but has been mandatory since 1997. The THA revision rate was 19.6% in 1999 when the population of Finland was 5.1 million [8] and remained as high as 15.2% in 2001–2010.

4.3. The Norwegian Arthroplasty Register of THA

The Norwegian Arthroplasty Register of THA (http://wwwnrlweb.ihelse.net/eng/) was created in 1987. It is ill suited to comparisons of implants and collects outcomes of the few thousand THA procedures performed annually in this small country with a population of 4.5 million. In 2003, the 10-year probability of non-revision for 78,534 primary THA procedures was 88.6% and the revision rate was 14.5% [9].

4.4. The Danish Hip Arthroplasty register

The Danish Hip Arthroplasty register (http://www.dhr.dk/ENGLISH.htm) was first envisioned in 1989 but was not initiated until 1995. The first report was for the 1995–1999 period and showed a 15.5% revision rate [10]. This registry now has nearly 100 000 patients and the number of new entries is 9000 per year in this country with a population of 5.3 million. Denmark has 60 to 70 accredited clinical registries, which are entirely funded by regional taxes, their total cost being 6.5 million € [2].

4.5. The New Zealand Joint Registry for THA and TKA

The New Zealand Joint Registry for THA and TKA (http://www.nzoa.org.nz/nz-joint-registry) started in 1998 was the first English-language arthroplasty registry. It contains only limited data on arthroplasty outcomes. For the 5579 THA procedures done in 2003, the revision rate was 13.3%, and the revision rate in the latest report was 11.5%.

4.6. The Australian Orthopaedic Association (AOA) National Joint Replacement Registry

The Australian Orthopaedic Association (AOA) National Joint Replacement Registry (https://aoanjrr.dmac.adelaide.edu.au/) initiated in 1999 is funded by the Ministry of Health. Data collection was extended to the entire country in 2007 with funding via a fee included in the price of each implant. With over 266 000 primary THA procedures, this registry complements the Swedish registry, as only 18% of all implants are cemented and some implant models are unavailable on the Swedish market.

4.7. The nationwide Canadian Joint Replacement Registry (CJRR)

The nationwide Canadian Joint Replacement Registry (CJRR) established by the Canadian Institute for Health Information (CIHI) (http://www.cihi.ca/cjrr) was started in 2001 as an extension of