The Swedish Knee Arthroplasty Register: a review.

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INSTRUCTIONAL REVIEW - KNEE

The Swedish Knee Arthroplasty Register

A REVIEW

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We are entering a new era with governmental bodies taking an increasingly guiding role, gaining control of registries, demanding direct access with release of open public information for quality comparisons between hospitals. This review is written by physicians and scientists who have worked with the Swedish Knee Arthroplasty Register (SKAR) periodically since it began. It reviews the history of the register and describes the methods used and lessons learned.

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Introduction

The Swedish Knee Arthroplasty Register (SKAR) was established in 1975 and was the first national register of this type. Every Swedish inhabitant has a social security number which allowed easy tracking, as well as a healthcare system providing free care for arthroplasty surgery mainly in publicly funded hospitals, and made the start relatively easy compared with many other countries. At the time, knee arthroplasty was not commonly performed and was limited to relatively few hospitals and surgeons. The profession had realised that it would be difficult for an individual surgeon to base his choice of optimal implants and operative techniques on his own experience, which triggered a nationwide study.

The first registered patient was a 54-year-old female with a Geomedic prosthesis implanted one year after a fracture of the tibial condyle. Despite the performance of surgery with bone transplantation and screw fixation, she had severe valgus deformity and pain. The prosthesis worked for almost 14 years when she suffered increasing pain on weight-bearing and radiographs showed a fractured and loose tibial component. She was revised with an early Porous Coated Anatomic (PCA) prosthesis (Howmedica Inc, Rutherford, New Jersey) (with pegs). After the revision, she lived for a further 11 years without any known complications.

Of the first 100 patients in the register, 54% had rheumatoid arthritis (RA). Around 20% of the implants were hinges (mostly Guepar) while unicompartmental knee replacement (UKR) was used in 68% (mostly Marmor (Richards Manufacturing Company, Memphis, Tennessee) and Schlitten (Waldemar LINK GmbH and Co, Hamburg, Germany)), of which more than a third was bicompartmental (a UKR in both the medial and lateral compartment). This, of course, is in sharp contrast to the situation today, with 96.5% of the patients receiving surgery for osteoarthritis (OA) and less than 2% for RA. Total knee replacement (TKR) is performed in 95% of patients, and bicompartmental UKR is no longer used.[1]

Only those with severe disability were offered surgery in the early days of the register. With few alternative treatment options, even a short-term improvement was considered a success as long as it did not pose harm to the patient. Thus, the initial focus of the register was on early failures and complications, and the surgeons were requested to report complications that arose within the hospital as well as the health status at regular intervals (one, three, six and ten years). However, as arthroplasty soon proved to be a procedure with low mortality,[2] and as relatively few early severe complications except for infection were reported, the focus of the register soon moved on to the long-term outcome.

By the increasing popularity of knee replacement and the accompanying workload of registration, surgeons became less interested in reporting what they considered

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to be minor complications. This left the register with a large number of incompletely registered variables that were difficult to interpret. Furthermore, the number of hospitals offering surgery increased, of which many were not interested in participating in the project due to the imposed workload. Therefore, the register completely abandoned extensive registration in 1989, and focused on acquiring a minimal dataset with as complete a registration as possible from all units in order to provide valid and reliable information.

Survivorship analyses for evaluating outcome started in the early 1980s[3,4] and the SKAR was prompt in adapting this method[5,6] as it was fortunate to be located near to the Lund University Hospital Tumor Registry that used the census technique with mortality as an outcome measure. Survivorship calculations use the time passed between a treatment and a defined end-point. Thus, revision became the preferred end-point in the case of arthroplasty because, unlike other measures such as loosening, pain or radiological findings, it is a definite event, its occurrence cannot be questioned nor the time at which it occurred. However, we were, from the start, aware of the relative indication for revision that to some extent may be related to the surgeon and ease of revision.

At the same time as the minimal data collection started in 1989, a special computer programme was developed so that the surgeons themselves could enter data for their own use, as well as for reporting to the register, which at the time was a groundbreaking methodology. For the sake of simplicity, special contact physicians and secretaries were appointed that could be reached in case further information was needed. In order to identify new implants that often were introduced without informing the register, the computer programme allowed the surgeons themselves to fill in information on the implant they were using. With respect to revisions, the secretaries sent complete copies of the operating reports and discharge letters, so that the responsible register physician could classify the reasons for, as well as the type, of revision.

The new method of minimal data collection immediately improved the completeness of data and increased participation of hospitals so that the register covered all hospitals in Sweden in the beginning of the 1990s. In order to compensate for the lack of information that regular follow-ups might have provided, the register started sending out mail to patients inquiring about their satisfaction with the surgery as well as asking them to fill in validated generic and disease-specific health questionnaires.

A validation of the registry was performed in 1997 by a postal survey to all living registered patients in order to find out if they had been revised without this having been reported to the register, and if the official patient administrative systems could be helpful in detecting such unreported revisions.[7] Of the patients, 99% could be located and 93% answered. The result was that one fifth of the revisions was missing but by using the official databases 85% of missing revisions could be captured. The register was updated accordingly, after which 94% of the revisions were estimated to be accounted for. The main reasons for the missing operations were that minor revisions (e.g. patellar additions) were sometimes forgotten and that operations for infection, when the patients had stayed in infection wards but not in orthopaedic wards, had often not been reported because the secretaries were not familiar with the reporting procedures.

However, decentralised reporting by computer also had drawbacks which concerned branding of implants by the surgeons and the source of information. As different versions of a specific implant brand were introduced over time (e.g. mark I, mark II), this resulted in different versions of the same brand being available concurrently and without surgeons always being aware of it, which in turn could make it very difficult for the register to know exactly what implant had been used. Furthermore, the source of information was unclear (e.g. the surgeon himself, a discharge letter, or an operation report).

For these reasons, the register decided to move the registration process into the operating theatre. The personal computer (PC) registration was therefore discontinued in 1999, after which SKAR again reverted to paper forms that were to be completed in the operating theatre, and to which the implant and cement stickers were to be attached. The registrations became independent of the ward the patient stayed in after operation, and exact information on implant parts could be gained by registration of their part, as well as lot, numbers.

This improved the completeness, of the reporting and instead of being stuck with a predefined branding of implants, the information on part numbers made additional retrospective classification of implant brands possible. Comparison of register data with official inpatient registers for the year 2007 indicated that the SKAR was capturing at least 96% of the surgeries. With good completeness and well established procedures and after gathering only a minimal dataset for 20 years, in 2009 the register felt confident that it could ask for limited additional data without hampering compliance and participation. Thus, in 2009 a new one-page form was introduced that included questions about previous surgery on the affected knee, methods used (tourniquet, drainage, computer-assisted surgery, minimally invasive surgery) and prophylaxis (infection, thrombosis).

Validation of completeness, as well as accuracy of data has been performed during the last two years and has shown high quality in the registration.[1]

As mentioned above, in the 1990s the register started evaluating patient-reported outcome measures (PROMS) by mailing patients questionnaires which included both generic (Nottingham Health Profile (NHP),[8] the Short Form-12 (SF-12)[9] and the Short Form-36 (SF-36)[10]) and disease-specific (Oxford-12 Knee Score[11] and the Western

Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[12]) instruments, as well as inquiries about patient satisfaction. From this work,[13] it proved to be difficult to use such scores as a single proxy of outcome because the results of disease-specific scores were affected by the general health of patients as well as their satisfaction with the surgery, which again is related to pre-operative expectations.[14]

In recent years, there has been renewed interest in PROMS mainly by authorities who want to use them as a quality indicator of the care provided. The EQ-5D questionnaire has been of specific interest as it had been used extensively in health economic calculations. After evaluating this instrument, we came to the conclusion that the weighted EQ-5D index was problematic because of bimodal distribution[15] although individual domains could be evaluated separately. Thus, we are doubtful if aggregated instruments can be used for comparison of joint prostheses on the quality of health care on a national level. However, the use of the instrument has been pushed by the authorities and we have started gathering data from those hospitals that want to participate. Time will tell how successful the registration will be and if it will be of any value in comparing units.

Lessons learned

As we have shown, the development from a research project undertaken by relatively few interested surgeons, using a new technique on selected patients at relatively few hospitals and to a national registration capturing more than 97% of surgeries performed by general orthopaedic surgeons at most orthopaedic departments, has not been without difficulties.

The first lesson learned by the register was that, at least in a voluntary registration, it is important to start by not asking for too much data. Until a project has proved itself viable and valuable it is difficult to motivate others to invest their time.

We learned that it is important to evaluate carefully all requested information with respect to what information is needed. Consideration of how questions should be posed, classified and entered into a database in order to allow easy processing is also important. Just asking for information that might be nice to have and later figure out how to use, is not a good idea.

It is important to realise that quantity of data or a large number of variables cannot compensate for bad quality. If register information is to be used for changing treatment and improving quality of care, the evaluation of data has to be based on sound scientific practices if the likelihood of improvement is to be better than that achieved by pure chance.

Data should be entered (on a form or a computer) during or immediately after the event at which answers to the questions were generated (e.g. at the pre-operative patient visit, during surgery or at discharge). At this time, information is readily available and it may prove difficult or impossible to answer questions or recapture them at a later time from hospital data. During our validation of SKAR by hospital visits, it was not unusual that data which had been reported to the register could not be verified in hospital records as they had been lost or not recorded.

Rapid scrutinising of incoming data quickly helps detect problems with ambiguous or misunderstood questions and answers. Gathering data for a year just to find out that it was of little value is not a good use of the participant surgeon's efforts.

It is important to provide feedback to participants as soon as possible. Even simple reports with summary data show that the register is alive and that the information is examined. There is nothing worse than for those reporting units to think that nobody will notice what or if they report.

Participants (hospitals/surgeons) should be provided with their own data, preferably classified in a useful and understandable way. This allows them to examine their own production and results and make them more willing to provide complete and correct data.

By keeping contact with the participants, promptly answering their questions, arranging regular meetings and sending them or informing them of data presented in peer-reviewed publications, it is demonstrable that their work is appreciated, which again will improve the surgeon's willingness to co-operate.

As the oldest register of this type, the SKAR learned most lessons by trial and error. This list is, of course, not exhaustive but is an extract of what we consider important lessons learned during the early years that might be of interest to those struggling with starting up a register.

The importance of SKAR

The difference between outcomes published by national registers compared with scientific studies is that the former show what was achieved for the average patient by the average surgeon at the average hospital, while the latter are typically performed at high-volume centres by interested surgeons on a select group of patients. It is uncertain and even unlikely that the results shown for a complicated implant in the hands of a high-volume surgeon, when operating on otherwise healthy patients with osteoarthritis, between 55 and 75 years of age, will be the same as for the average surgeon when operating on older or younger patients with diseases such as osteoporosis or previous fractures. Therefore, it is not surprising that scientific studies have been shown to indicate better results than those observed by registries.[16]

A major benefit of national arthroplasty registers is that they can provide early warnings regarding major problems with implants and methods. Historically, we have observed that when problems arise, blame is often put on surgical errors or inferior units. By revealing that a problem is not localised, but general, there is an increased likelihood that it will be promptly addressed. This was the

case with the PCA and Oxford unicompartmental implants.[17,18] The former was withdrawn from the market while the producing company improved the education of surgeons for the latter.

However, as registries rely on a relatively minimal dataset and most often use crude outcome such as revision as a measure of failure, they are better at detecting problems than explaining them, for which focused studies are superior. Thus, a register is often a 'generator' of hypotheses, providing information about areas that need to be looked into further, and is an important source of information for spin-off projects. Such projects that the SKAR has been associated with have included studies of reasons for infections,[19] preventive measures,[20] their different treatment modalities [21-23] and change in bacteriology and resistance over time.[24,25] In 1981, studies of retrievals showed higher risk of deformation and loosening when the polyethylene was too thin (< = 6 mm)[26] and in an early era, when UKR was widely used (often bilaterally), the register quickly demonstrated that the method was particularly unsuitable for patients with rheumatoid arthritis, after which its usage for this disease halted. Mortality and malignancy after knee arthroplasty have also been studied[27,28] showing, among other things, a higher mortality after simultaneous bilateral arthroplasty and an elevated long-term risk of myelodysplastic syndromes, and possibly melanoma.[29]

While such spin-off projects have proved valuable for the development of knee arthroplasty surgery, the national registration itself has a positive effect beyond an early warning system. A mere summary of results will improve performance as surgeons and institutions will attempt to do their best. Providing them with information on implants, methods and patient selections that have solid outcomes will help them in making decisions. We believe that such information provided by the SKAR over time partly explains why the long-term average revision rate after TKR in Sweden (4%) is very low when compared internationally.[30]

Future research perspectives

Considering that new or changed implants are constantly introduced, we believe that there is still a need for monitoring overall revision rate. Furthermore, the present registration of part and lot numbers is practically the only way for rapid identification of individual patients should it become necessary to call them for a check or revision. Although the hospitals are obliged to keep track of what has been inserted, we have repeatedly observed during hospital visits when validating the content of the SKAR that they would have had difficulties doing that in a timely fashion, if at all.

A drawback with national register studies has been that, as they cannot control for selection bias, it is possible that some selected groups of patients are given a specific treatment more often than others; for example, patients who are older or more unwell could be given a different type of implant, antithrombotic or antibiotic prophylaxis. Randomised controlled studies would be needed to solve such issues, but at present the enormous cost to start such trials is hampering clinical progress. However, for some relevant questions of interest to the profession as a whole, a way to solve this would be to perform a nationwide randomisation with respect to a specific treatment and to follow the outcome in the register. Furthermore, randomisation might even be performed on a unit level.[31]

The register could be used in combination with retrieval analyses. By systematically collecting all explanted, newly introduced implants for retrieval analysis, information from the register could be used for detailed analyses based on cumulative revision rate, patient data and specific modes of failure derived from the filed revision report.

There is also a possibility of cross-running the SKAR against the national prescription registry in order to investigate whether certain types of medication may have an effect on outcome. New treatment for osteoporosis and sarcopenia may well have an impact.

With arthroplasty surgery increasingly performed in younger age groups with a longer life expectancy, the register will have to focus not only on the outcome of the primary procedure but also on revisions, in an attempt to find the most successful types of secondary procedures, for example the effect of allo *versus* synthetic bone grafting.

The mechanisms for approval of implants are changing as the predicative route for approval of similar devices will change both in Europe and the USA in 2014. It will no longer be possible to get approval for a new device just by referring to prior approvals.[32,33] This will result in the need for a post-market surveillance of new bio-similars on an individual level, and the national arthroplasty registries could serve as an excellent tool for handling legal issues in co-operation with the industry.

Where are we heading?

After the millennium, the Swedish government rediscovered the importance of registers and their use in the maintenance of quality control. Consequently, they began to support the start of new registries and produced structured mechanisms for applying for financing as well as for register certification. This has resulted in more than 100 healthcare registries at different stages of establishment in Sweden.

The authorities want registration of variables that can be quickly evaluated and publicly presented. The aim is that those hospitals with poorer results will use the information for quality improvement, or the patients will seek medical help elsewhere. Register data are also to be used when purchasing healthcare instruments and implants. Furthermore, register staff are to be actively involved in local 'quality improvement' at hospitals. To increase research, the registers are to open up their databases so that interested researchers, after approval themselves, can have access for analysis.

However, for a joint implant register such as SKAR, the outcome has to be viewed in the long term. There is no guarantee that a good two-year result will be a long-term one. On the contrary, problems because of wear generally do not show up during the first years and in spite of our analyses spanning ten years, the failures are relatively few. Therefore, the register has in fact stated that ranking hospitals by such figures is unreliable and not of practical use for patients seeking health care.[34]

The only way to give rapid feedback, with the exception of infections, is by using surrogate measures, i.e. process indicators, which are known to correlate with outcome. The SKAR registers the time and dosage of antibiotic and antithrombotic drugs and is therefore able to give quick feedback to units with respect to how these drugs are administrated and thus if official recommendations are being adhered to. At present, this is the only type of variable reported by the register that hospitals might be able to use for quality improvement in the short term.

Examples of variables that could be evaluated in national arthroplasty registries include the adherence to evidence-based guidelines for screening and correcting overt diabetes, and whether advice was given to stop smoking before having surgery.[35] However, as we use the operating theatre as the point of care for filing the primary report, this is not the best place for gathering such information. The SKAR would have to initiate new reporting routines with the registration being performed at admission or discharge of patients.

When register data are used in the purchase of implants as well as for the ranking of hospitals and surgeons, the incentive for accurate reporting may change. Similarly, the accuracy of information provided by the patient might detoriate if the patients know that their data are to be used to decide their place on waiting lists.

We think that there is an urgent need for an open discussion regarding the mission and tasks national implant registries should have, preferably under the auspices of the now established International Society of Arthroplasty Registers (ISAR).[36]

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- O. Robertsson: Initial concept, Initial draft
- J. Ranstam: Reviewed and edited the paper
- M. Sundberg: Reviewed and edited the paper
- A. W-Dahl: Reviewed and edited the paper
- L. Lidgren: Reviewed and edited the paper

ICMJE Conflict of Interest:

- O. Robertsson is the manager of the Swedish Knee Arthroplasty Register which is being described in the paper, and thus is not an unbiased author.