The Swedish Elbow Arthroplasty Register and The Swedish Shoulder Arthroplasty Register

Two new Swedish arthroplasty registers

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ABSTRACT – Two new national orthopedic quality registers were started in Sweden in 1999, the Swedish Shoulder Arthroplasty Register and the Swedish Elbow Arthroplasty Register. Both are owned by the Swedish Shoulder and Elbow Section of the Swedish Orthopedic Association. The purpose of the registers is to improve surgical techniques and selection of implants and identify individual risk factors. Two of the main problems in starting a new national quality register involve inducing all centers in the country to participate and deciding on the data to register.

The Swedish Shoulder and Elbow Arthroplasty Registers were introduced on January 1, 1999. Both are owned by the Swedish Shoulder and Elbow Section (SSES) of the Swedish Orthopedic Association. The shoulder register is administered by the Orthopedic Department at Danderyd Hospital in Stockholm, and the elbow register by the Orthopedic Department at Västerås Hospital.

Both registers are modeled on the Swedish Hip and Swedish Knee Arthroplasty Registers. These registers have reduced the revision rate due to the selection of well-documented implants and better surgical techniques (Herberts and Malchau 2000, Robertsson et al. 2000).

General considerations

The principal problems when starting a new national register are getting all centers to agree on what to register and then to participate. During the last 2 years, several meetings took place in the SSES before agreement could be reached about a form acceptable to nearly all clinicians involved. We discussed the inclusion of a preoperative classification of radiographs, choice of prophylactic antibiotics, postoperative radiographs, functional scores, etc, but doubted that a complicated form would be filled in. Such forms are sometimes used in Sweden. For instance, in the south-east of Sweden, a shoulder register has been in use since 1996. 6 orthopedic clinics send their reports to this register, which today includes 220 patients (personal communication with Dr. R Ihrman). This regional register collects data and sends it to the national register so that the surgeon only has to fill in one form for every shoulder joint replacement performed.

It was our goal to make a form that could be filled in by the surgeon before leaving the operating room and immediately sent to the national register to prevent delay and missing reports. This must be the responsibility of the surgeon and no one else. The reason is that shoulder and elbow arthroplasties are performed infrequently and it seems unrealistic to have an organization, as in the hip or knee registers, where the reports are routinely handled by secretaries.

It is hard to devise a form that will satisfy every surgeon, but eventually a decision has to be made about when to start register.

We used a paper form because we expected very few operations in each center. This form can be completed immediately after surgery and this should take the surgeon no more than 2 minutes.

We register 1) identifying data (hospital, date, patient data, operated side), 2) diagnosis (primary

and reason for revision), 3) previous surgery on the joint, 4) type of operation (primary/revision/ reoperations other than prosthetic revision), 5) surgical data (type of prosthesis, fixation, additional surgery, etc), 6) batch and article number (implant tags are pasted to the form). Instructions are printed on the back of it. Since both registers are new, we expect minor changes during the first few years as regards the manner of registration.

Our goal is to register not only primary replacements and revisions, but also other reoperations on replaced joints. For instance, a hemiarthroplasty may be converted to a total shoulder replacement, or a patient with an elbow prosthesis may undergo surgery for a postoperative nervus ulnaris entrapment.

An important issue when deciding what to register is to decide about the endpoints. We plan to use revision or extraction of the implant as the endpoint, as in the other arthroplasty registers. It may be argued that other situations also constitute failure. Malfunction and/or persistent pain must also be regarded as failures. However, a much more elaborate form would be needed to record such parameters and compliance would probably be poor. On the other hand, one could argue that revision due to loosening, after 10 years, of a previously well-functioning elbow arthroplasty in a rheumatoid patient is not a failure.

To determine whether all arthroplasties are reported, the registers are cooperating with manufacturers of all implants sold in Sweden. Thus one can compare the number of implants sold with the number reported as implanted. The number of arthroplasties recorded is also compared to the number reported to the National Board of Health and Welfare.

Swedish Elbow Arthroplasty Register

On the basis of the number of arthroplasties reported to the National Board of Health and Welfare until 1998 and on our own experience, we have estimated the annual incidence of elbow arthroplasties to be nearly 1/100,000, which means about 80 arthroplasties/year in Sweden. We found only 4 studies (Ewald et al. 1993, Kraay et al. 1994, Risung 1997, Trail et al. 1999) published since 1990 including more than 80 arthroplasties, but none compared different designs and techniques.

Table 1. Diagnoses preceding elbow arthroplasty and secondary surgery

Diagnosis	Number
Rheumatoid arthritis	49
Juvenile rheumatoid arthritis	8
Fracture distal humerus	7
Pseudoarthrosis	4
Malunion	1
Secondary arthrosis	1
Malpositioning of implant	1
Wound healing problem	1
Infected arthroplasty	1
Total	73

During the first year after starting the register, 73 operations were reported by 14 centers. This was slightly fewer than expected and there are two main explanations for this: it takes some time to induce all surgeons to take part and there seems to have been a general decline in planned surgery in Sweden during 1999. Most surgeons who perform elbow replacements have now contributed, and participation continues to increase, so we believe the register will become representative of Swedish elbow arthroplasty surgery. The commonest diagnosis preceding surgery was rheumatoid arthritis (Table 1). 67 primary arthroplasties and 3 revision arthroplasties with primary operation in 1988, 1997 and 1998 have been reported. The remaining 3 operations were one extraction of an implant due to recurrent dislocation and loosening of the humeral component, one synovectomy in an infected arthroplasty, both of which were operated on with arthroplasty before the register started, and one was a local cutaneous flap coverage. The commonest implant was the Kudo prosthesis (Table 2).

We plan to summarize the results at least once annually and in future, it is hoped that this will be done continuously on a website, where the sur-

Table 2. Implants used for elbow arthroplasty

Implant type	Number
Kudo	35
Capitello condylar	13
Coonrad-Morrey	9
Souter	6
GSB	4
Pritchard Monte II	2
Linked resection prosthesis Souter	1
Total	70

geons will be able to see their own figures in relation to national figures and the public can see the national figures.

Svenska Axel
Atroplastik
Registret

Swedish Shoulder Arthroplasty Register

During the first year after starting the register, 363 surgical procedures performed at 31 hospitals were reported. Most of the Swedish orthopedic surgeons who perform shoulder replacement have taken part. Only two major hospitals are missing and, after the first year, we estimate the number of procedures missing to be less than 15%. We believe that the register will become representative of Swedish shoulder arthroplasty surgery.

336 (94%) procedures were primary replacements and 23 (6%) were revision procedures. All but 2 of these revisions have an index procedure before this register started. 4 shoulders had reoperations other than a prosthetic revision, 2 had an arthroscopy performed and 2 lavage due to infection.

Rheumatoid arthritis, primary fracture and arthrosis (primary arthrosis and cuff tear arthropathy) were almost equally common diagnoses whereas malunion, nonunion and osteonecrosis were less common (Table 3). The incidence of fracture (35% including nonunion, mal-union and osteonecrosis) as the reason for replacement is higher than for other joints. The distribution is about the same as that reported in the Norwegian Arthroplasty Register in 113 shoulders (Furnes et al. 1996), and that reported in Aarhus in 500 shoulder arthroplasties (Søjbjerg et al. 1999).

Table 3. Indications for primary shoulder arthroplasty and secondary surgery

Diagnosis	Number
Arthritis	106
Primary osteoarthritis	75
Cuff arthropathy	15
Fracture	100
Malunion	15
Nonunion	14
Caput necrosis	8
Other diagnosis	3
Revision	23
Reoperation (arthroscopy/lavage)	4
Total	363

Table 4. Implants used for shoulder arthroplasty

Implants	Number
3M modular	158
Global	49
Neer 2	46
Nottingham	35
Biomodular	25
Delta 3	17
Bipolar	12
Other types	17
Total	359

Hemiarthroplasties (humeral head replacements) were performed in 312 (87%) of the shoulders, including 21 bipolar replacements and 3 articular resurface procedures without a stem. The remaining 47 (13%) procedures were total replacements. 24 shoulders required additional surgery (rotator cuff reconstruction, subacromial decompression and lateral clavicular resection) at the same time as the shoulder replacement. The 3M-modular was the commonest implant (Table 4).

The reports on revision surgery are not always detailed enough to permit a clear understanding of the reason for the operation and the procedure. This matter will be discussed in the Swedish Shoulder and Elbow Section, and the solution in these cases may be to ask for the patient records, as is done by the other national arthroplasty registers (hip and knee) in Sweden.

By collecting data regarding all secondary procedures, not only revision arthroplasty, we can distinguish between secondary problems, such as AC-joint pain or impingement and implant failure. This should help us to know what to expect in the total population, in terms of survival rate of the implants, and the forth-coming incidence of some conditions needing subsequent surgery.

In the long run it may be possible to make recommendations on the basis of the data in the register. We may be able to detect whether the incidence of reoperation due to loosening of the glenoid implant in a total shoulder is higher or lower than the incidence of reoperation due to attrition of the glenoid in a hemishoulder, and whether there is a difference in time after the first procedure. On the other hand, we will not yet be able to study any subjective or observer-dependent variables such as the functional outcome. Variables of pain, range of motion, daily function and strength (as well as patient satisfaction) would be better analyzed in randomized studies with confirmed follow-ups and standardized measurements, which cannot be done in a nationwide register.

Discussion

The number of shoulder or elbow arthroplasties performed by each surgeon is much lower than those of hip and knee arthroplasties. Consequently it is much more difficult for the surgeon to evaluate the various prosthetic designs and surgical techniques. This is one main reason why a national register is needed to increase the knowledge about such designs and techniques and to analyze risk factors.

Despite the fact that our forms are short and easy to fill in, many of them are not properly filled in and have to be returned. This has convinced us that a more elaborate form would be impossible to use.

Most shoulder arthroplasties done in Sweden are humeral head replacements (hemiarthroplasties). The reasons for this are the high incidence of radiolucencies around the glenoid component (Brems 1993, Stewart and Kelly 1997) and the difficulties of inserting a glenoid component. However, total shoulder replacement gives better pain relief and motion (Rodosky and Bigliani 1996, Gartsman et al. 2000). In a national register, it should be possible to establish whether hemiarthroplasties have to be converted to total shoulder replacements. Another question to be answered is whether the humeral component should be cemented. In rheumatoid patients, cement fixation is recommended (Sneppen et al. 1996, Stewart and Kelly 1997), but in these series, the Neer II implant, which does not have enough stem sizes to fill the medullary canal, was used.

Today, the third generation of shoulder prostheses has come on the market. They permit a more anatomically suitable placement of the humeral component with variable head offset and thus the rotator cuff is not compromised. The bipolar (Arredondo and Worland 1999) and delta prostheses (Grammont and Baulot 1993) are new concepts. In Sweden, they are used for revision surgery and in patients with severe damage to the rotator cuff. When new concepts become available on the market, it is important to have a national register, so that unsafe implants and other complications, like instability, can be quickly detected.

Fewer than 100 elbow replacements are performed annually in Sweden, but at least 5 types of elbow implants are used. The commonest are the non-constrained implants (Kudo, Capitellocondylar), but semiconstrained implants (GSBIII, Conrad-Morrey) are used for revision and in patients with instability. Of all total joint replacements, the elbow has the highest complication rate (Ferlic 1999). A questionnaire will soon be sent to all patients in the elbow register asking them about the functional outcome and their opinion of the procedure.

The annual feedback to participating departments about their own and national results should improve the outcome. In future, we hope to give each participating hospital the option of accessing the central register and submitting reports directly to a website on the Internet.

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Appendix

Data entered in The Swedish Elbow Arthroplasty form

Hospital:
Date of surgery:
Social security number:
Side: right / left
Diagnosis
- Arthritis: RA; juvenile RA; psoriatic arthritis; other
- Osteoarthritis: primary; secondary
- Fracture: fresh; malunion; pseudarthrosis
- Loose prosthesis: humeral component; ulnar comp.
- Infected arthroplasty
- Dislocation of prosthesis
- Fracture close to prosthesis
- Other diagnosis

Prior surgery: None; synovectomy; nervus ulnaris neurolysis; interposition arthroplasty; arthroplasty with prosthesis; fracture surgery; surgery due to infection; extraction of prosthesis; other
Primary arthroplasty
Secondary procedure: primary prosthesis; primary year of implantation
- Type: new humeral component; new ulna component; extraction of prosthesis; reconstruction of extensor mechanism; surgery due to infection; surgery due to fracture; nervus ulnaris neurolysis; nervus ulnaris transposition; other

Ulnaris symptoms prior to surgery: yes / no
Exposure: posterior; lateral; medial; other
Nervus ulnaris during surgery: not exposed; neurolysis; transposition
Implant type: Kudo; Capitello condylar; Souter; GSB; Coonrad–Morrey; other
Fixation:
- Humerus: no cement; partially cemented; cemented
- Ulna: no cement; partially cemented; cemented

Bone transplant:
- Humerus: yes / no
- Ulna: yes / no

Implant ID-tags:
Comments:

Data entered in The Swedish Shoulder Arthroplasty form

Hospital:
Date of surgery:
Social security number:
Side: right / left
Diagnosis
- Arthritis: RA; juvenile; psoriatic; other
- Arthrosis: primary; secondary; other
- Fracture: < 2 weeks; >2 weeks; malunion; nonunion; healed
- Cuff arthropathy
- Caput necrosis
- Other

Previous surgery: None; synovectomy; osteosynthesis; arthroplasty (implant); extraction of implant; surgery due to infection; surgery performed but unknown procedure; stabilising procedure; interposition arthroplasty, cuff reconstruction; subacromial decompression; A-C joint resection; arthroscopic procedure; other
Primary arthroplasty or
Revision and new procedure: primary implant; primary surgery year
- Cause:
  - Dislocation: superior; inferior; anterior; posterior
  - Loosening: humeral implant; glenoid implant
  - Glenoid attrition
  - Infection
  - Periprosthetic fracture
  - Other
- Type of surgery: extraction of stem; adding a new stem; change of modular head; extraction of glenoid component; adding glenoid component; reposition of dislocation; arthroscopy; subacromial decompression; A-C joint resection; refixation of tubercles; excision of bone fragment; surgery due to infection; osteosynthesis; other

Surgical data:
- Implant: Neer 2; 3M-modular; Bi-polar; Bio-modular; Delta-3; Global; Scan shoulder; Sulzer-Anatomical; HAS; Aequalis-Tornier; Nottingham; Bigliani-Flatow; other
- Type: hemi; total; bipolar; other
- Stem: modular; monoblock; other
  cemented / uncemented
- Caput: conventional; variable offset, asymmetrical; other
- Glenoid: all plastic; metal backed; other
  - Fixation: keel; pegs; screws; other
    cemented / uncemented
- Cuff reconstruction: yes / no
- A-C joint resection: yes / no
- Subacromial decompression: yes / no

Implant ID-tags: