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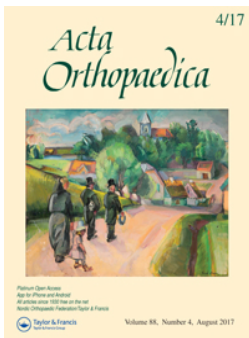
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Revision after shoulder replacement for acute fracture of the proximal humerus

A Nordic registry-based study of 6,756 cases

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Background and purpose — For more than half a century, stemmed hemiarthroplasty (SHA) has been used in the treatment of comminuted and displaced fractures of the proximal humerus. Reverse shoulder arthroplasty (RSA) has been increasingly popular in cases where it is difficult to obtain satisfactory fixation of the tuberosities. We report revision rates and reasons for revision after shoulder arthroplasty for acute fractures of the proximal humerus.

Patients and methods — This study was based on a common dataset from the Nordic Arthroplasty Register Association (NARA), which includes data reported to the national shoulder arthroplasty registries in Denmark, Sweden, and Norway. We included 6,756 shoulder arthroplasties performed for acute fractures between 2004 and 2013.

Results — There were 6,112 SHAs (90%) and 565 RSAs (8.4%). The cumulative arthroplasty survival rate after 5 years was 0.96 for both SHA and RSA. The relative risk of revision of RSA was 1.4 (95% CI: 0.9–2.2) with SHA as reference. For both types of arthroplasty, the most common reason for revision was infection (SHA 0.8%, RSA 2.1%). The relative risk of revision due to infection was 3.1 (95% CI: 1.6–5.9) for RSA with SHA as reference. The relative risk of revision for patients who were less than 75 years of age was 2.8 (95% CI: 2.0–3.8) compared to older patients.

Interpretation — Revision after shoulder arthroplasty for acute fractures was rare. Survival rates were similar between SHA and RSA, but RSA had a statistically significant and clinically relevant higher risk of revision because of infection.

For more than half a century, stemmed hemiarthroplasty (SHA) has been a treatment option for severely comminuted and displaced fractures of the proximal humerus. The functional outcome has been regarded as superior to that of non-surgical treatment, but recently, randomized trials have reported comparable outcomes (Olerud et al. 2011, Boons et al. 2012). One of the main reasons for a poor result is non-union of the tuberosities with subsequent rotator cuff insufficiency and joint instability (Hasan et al. 2002).

Reverse shoulder arthroplasty (RSA) has been increasingly popular in cases where it is difficult to obtain satisfactory fixation of the tuberosities (Brorson et al. 2013, Mata-Fink et al. 2013, Anakwenze et al. 2014). Only 1 small randomized controlled trial reported that the outcome of RSA used for acute fractures of the proximal humerus was superior to that of SHA (Sebastian-Forcada et al. 2014). There have been few reports of arthroplasty survival rates and reasons for revision for SHA—and particularly for RSA.

National shoulder arthroplasty registries have been established to monitor outcome after shoulder arthroplasty and for early detection of inferior arthroplasties (Rasmussen et al. 2012). The high number of arthroplasties makes the national registries suitable for reporting of revision rates and reasons for revision. Here we report revision rates and reasons for revision of shoulder arthroplasty types used for acute fractures of the proximal humerus.

Patients and methods

This study was based on a common dataset from the Nordic Arthroplasty Register Association (NARA), which is a collab-

Table 1. Hierarchy of reasons for revision

Hierarchy	Comments
Infection	An infection that requires revision of the arthroplasty.
Periprosthetic fracture	A fracture that requires revision of the arthroplasty.
Luxation and instability	Instability is only reported as “others” in the Danish and the Swedish registries.
Loosening	Loosening of any arthroplasty component.
Rotator cuff problem	Rotator cuff problem is only reported as “others” in the Norwegian registry.
Others	Glenoid wear; biomechanical problems including dislocation or overstuffing; and pain with no other reason reported.

oration between the national shoulder arthroplasty registries in Denmark, Sweden, and Norway (Rasmussen et al. 2016). The dataset contains 19,857 shoulder arthroplasties and covers the period 2004–2013. The degree of completeness of reporting during the entire study period was 92% in Denmark, 80% in Sweden, and 95% in Norway. The dataset includes variables on demography (sex, age, and nationality), primary procedure (primary diagnosis, date of surgery, arthroplasty type, and brand), and revision procedure (date of revision, reason for revision, number of revisions, and new arthroplasty type).

Definitions were established through consensus in the group of authors (Rasmussen et al. 2016). An acute fracture was defined as a proximal humeral fracture that was not categorized as fracture sequelae, regardless of time from injury to operation. Fracture sequelae included fractures reported as non-union, malunion, previous osteosynthesis, osteoarthritis, and humeral head necrosis if reported together with fracture.

A revision was defined as removal or exchange of any component or the addition of a glenoid component. We used a hierarchy of reasons for revision in cases where more than 1 reason was reported. Thus, only 1 reason for revision was registered (Table 1). Survival rates were calculated using revisions reported to the national registries until December 2013, and by checking for deaths in the national population registry of each country.

Statistics

Student's t-test (for continuous variables) and chi-square test (for categorical variables) were used to compare differences in demography between SHA and RSA. The Kaplan-Meier method including 95% confidence intervals (CIs) were used to analyze the cumulative survival rate, and the log-rank test was used for comparison. A Cox regression model was used to analyze the relative risk of revision of RSA, with SHA as reference. Age, gender, and year of surgery were included in the model.

Although it violated the assumption of independence, patients with bilateral replacements were included in the sur-

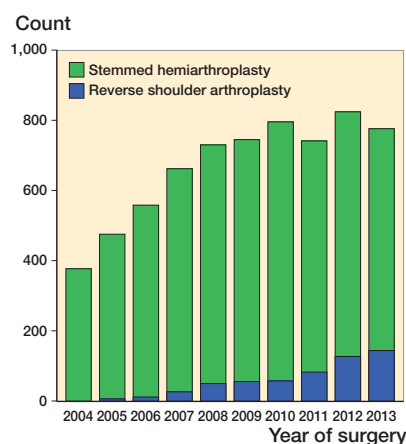


Figure 1. Distribution of SHA and RSA during the study period.

vival analyses as if they were independent. The level of statistical significance was set at $p < 0.05$, and all p-values were 2-tailed.

Ethics

Ethics committee approval was not required. No competing interests declared.

Results

6,756 prostheses were used for acute fractures of the proximal humerus between 2004 and 2013. The incidence increased at the beginning of the period, but stabilized within the last 5 years (Figure 1). The number and proportion of RSAs steadily increased in the study period. For the group of patients treated with an RSA, the proportion of patients who were less than 75 years old (38%) was similar over the entire study period. Mean age was 72 (SD 11) years overall: 72 (SD 11) years in the SHA group and 77 (SD 9.0) years in the RSA group ($p < 0.001$). Females accounted for 80% of the patients in each group.

There were 6,112 SHAs (90%) and 565 RSAs (8.4%). The most commonly used SHA brands were Bigliani-Flatow (Zimmer, Warsaw, IN) (29%), Global Fx (DePuy, Raynham, MA) (24%), and Aequalis Fracture (Tornier, Saint-Ismier, France) (9%). The most commonly used RSA was Delta Xtend (DePuy) (82%).

222 arthroplasties (3.3%) were revised within the period (SHA 3.3%, RSA 3.5%). The cumulative survival rates after 1 year, 5 years, and 10 years were 0.99 (CI: 0.98–0.99), 0.96 (CI: 0.95–0.96), and 0.95 (CI: 0.94–0.96) for SHA, and 0.96 (CI: 0.94–0.98) and 0.96 (CI: 0.94–0.98) for RSA, but data on 10-year survival rates were not yet available for RSA (Figure 2). The differences were not statistically significant ($p = 0.2$). The relative risk of revision of RSA compared to SHA was 1.4 (CI: 0.9–2.2). The most common reason for revision of both arthroplasty types was infection (Table 2).

Table 2. Reasons for revision after SHA and RSA. "Others" include glenoid wear, malpositioning of the arthroplasty, and pain with no other reasons reported

	SHA		RSA	
	n	%	n	%
Infection	51	0.8	12	2.1
Periprosthetic fracture	8	0.1	1	0.2
Luxation and instability	26	0.4	2	0.4
Loosening	5	0.1	1	0.2
Rotator cuff problem	47	0.8	0	0
Others	50	1.8	3	0.5
Missing	15	0.2	1	0.2
Total	202	3.3	20	3.5

51 SHAs (0.8%) and 12 RSAs (2.1%) were revised because of infection. All revisions of RSA were performed within the first postoperative year, while revision of SHAs due to infection was done within a period of more than 5 years (Figure 3). The relative risk of revision due to infection was 3.1 (CI: 1.6–5.9) for RSA with SHA as reference.

There were 3,758 patients (56%) who were less than 75 years old at the time of surgery. The relative risk of revision was 2.8 (CI: 2.0–3.8) compared to older patients. The 10-year survival rate was 0.93, which was statistically significantly different from that in older patients ($p < 0.001$) (Figure 4). In the sub-population of younger patients, there were 3,489 SHAs (93%) and 215 RSAs (5.7%), of which 159 (4.6%) and 13 (6.0%), respectively, were revised. The survival rates of patients with SHA who were less than 75 years old were worse than those for older patients ($p < 0.001$) (Figure 5). The number of RSAs was too small for comparison of patients according to age.

Discussion

We found similar high arthroplasty survival rates for both SHA and RSA. The factors that lead to the decision to revise are not fully understood, and reported survival rates do not necessarily reflect the functional outcome of the patients. Some failures are never revised, and some revisions lead to good functional outcome and cannot be considered to be failures. Acute fracture patients more often have comorbidities than elective patients, and are less amenable to revision surgery. Inclusion of a patient-reported outcome in the dataset would have added important information to our study. This was not possible, however. The Danish and the Swedish regis-

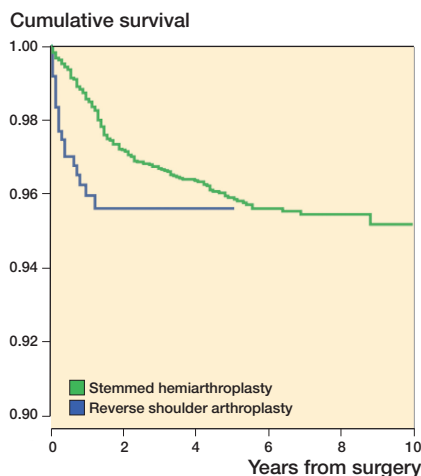


Figure 2. Cumulative survival over the years.

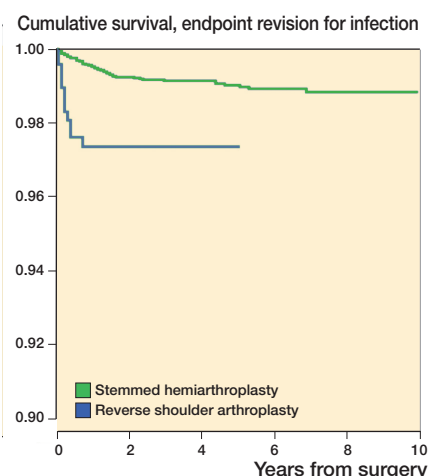


Figure 3. Cumulative survival over the years, with endpoint revision for infection.

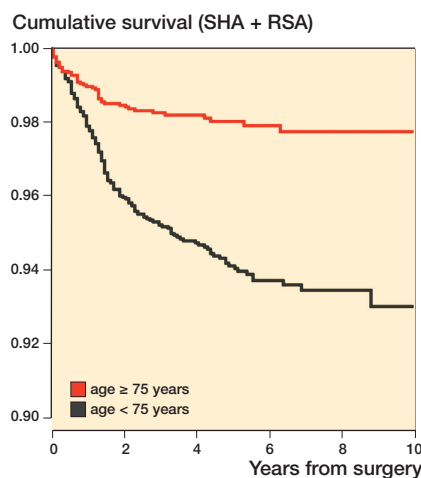


Figure 4. Cumulative survival of both SHA and RSA over the years in 2 age groups.

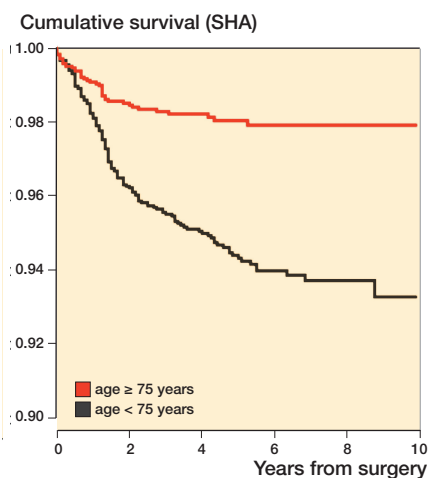


Figure 5. Cumulative survival of SHA alone over the years in 2 age groups.

tries use the same patient-reported outcome criteria, but with different follow-up times, and the Norwegian registry does not systematically register patient-reported outcome (Rasmussen et al. 2016).

A low revision rate after fracture hemiarthroplasty, compared to other indications, has been reported. Fevang et al. (2009) reported revision rates of 1% and 3% after 5 and 10 years for SHA for acute fractures. The National Joint Replacement Registry in Australia (Australian Orthopaedic Association 2015) reported revision rates of 2.6% for SHA and 2.9% for RSA after 1 year, and 7.5% and 4.6% after 5 years. The total proportion of revisions covering the period from 2008 to 2013 was 5.6% for SHA and 3.3% for RSA.

Several systematic reviews have reported postoperative complications and revision rates after SHA for acute fractures. Kontakis et al. (2008) systematically reviewed 16 studies including 810 SHAs for acute fractures. Complication rates

were provided in 15 studies. They reported complication rates of 11% related to tuberosity fixation, 9% related to heterotopic ossification, and 7% related to proximal migration of the humeral head. Superficial infection was reported in 1.6% and deep infection in 0.6%. Revision rate was not clearly reported. In a systematic review, Mata-Fink et al. (2013) reported functional outcome in 377 RSAs for acute fractures. They did not find more complications than after SHA. Anakwenze et al. (2014) systematically reviewed 9 studies covering 247 fractures treated with RSA. Complication data were available for 172 patients. Scapular notching was reported in 32%, ectopic ossification in 9%, dislocations in 4%, and infection in 3%. Only 1.2% of the arthroplasties were reoperated. Brorson et al. (2013) included 18 studies covering 430 RSAs for acute fractures. They reported 1.6% dislocations, 2.1% neurological complications, and 1.2% infections. Scapular notching was reported in 11 studies (0–94%, median 25%). Reoperation rates were not reported. Namdari et al. (2013) systematically reviewed 14 studies with 495 patients treated with SHA or RSA for acute fractures. They found that RSA was associated with a 4.0 times greater risk of a postoperative complication compared to SHA. The overall reoperation rate was 6% after RSA and 9% after SHA.

Discrepancies in revision rates between systematic reviews and data from national registries may be related to inclusion criteria. The systematic reviews are based on clinical studies that often use inclusion and exclusion criteria in order to make the population as homogenous as possible, whereas the national registries often include all patients irrespective of age and comorbidity. Data from clinical studies may be less useful for generalization of revision rates and reasons for revision, as the number of patients may be low. On the other hand, without 100% completeness, registry data may hide some systematic differences between the reported arthroplasties and those that are missing. We do not know the consequences of the lower completeness in the Swedish registry, but if relatively higher numbers of revision arthroplasties than of primary arthroplasties are missing, the survival rates will be overestimated.

Any comparison of SHA and RSA should be interpreted with caution. The RSA is a new design, and it can be hypothesized that it may have been introduced first in the most experienced centers and used in selected patients only. The revision procedure for an RSA may be more challenging than revision of an SHA, and some surgeons may hesitate to revise an RSA, thus leading to an underestimation of the real number of failures. The patients treated with an RSA were generally older than patients treated with SHA, and they may have been in a worse medical condition. Moreover, fracture arthroplasties are inserted in most centers whereas revision is done only in large centers. Surgeons who have performed a primary operation may hesitate to refer their patients for revision. RSA was more often used at the end of the study period, suggesting that the indication for RSA in the treatment of acute fractures has changed during the study period. The reason for this is

unclear, but is worth considering. Thus, learning curves may have influenced the revision rate for RSA, and as there is no control over the indication for the type of arthroplasty, selection bias may have influenced the comparison.

The risk of infection was higher after RSA than after SHA. All revisions of RSA due to infection were performed within the first postoperative year, while revision of SHA was found throughout the study period. The reason for this is not clear, but a likely reason is a greater dead space after RSA—which could lead to hematoma and infection. Other reasons for a higher infection rate after RSA might be the possibly longer operation time and an older group in worse medical condition.

The inclusion of bilateral procedures in the survival analyses violates the assumption of independence. However, previous studies of hip and knee arthroplasties have reported that this has few practical consequences. Furthermore, the Kaplan-Meier method and the Cox regression model are based on the underlying assumption that there is no competing risk which is, of course, violated in arthroplasty survival analysis. Patients are censored when they die and will therefore no longer be at risk of revision. Thus, the arthroplasty survival will be underestimated. Finally, in the Cox regression model the assumption of proportional hazards was violated, and the hazard ratios may have been overestimated (Ranstam et al. 2011). The statistical limitations are worth considering when our results are being interpreted.

The present study had some limitations. It had the inherent limitation of observational studies in general and registry studies in particular. This includes selection bias, especially in terms of choice of arthroplasty type. Furthermore, there is a relatively low degree of completeness in the Swedish registry. Without 100% completeness, the survival rates are overestimated if the proportion of missing revisions is higher than the proportion of missing primary arthroplasties. There were also limitations related to the minimal dataset, which only included basic variables. Thus, there was no information about comorbidity and no patient-reported outcome.

In summary, revisions after shoulder arthroplasty in acute fractures were rare. Arthroplasty survival was similar between SHA and RSA, but RSA had a statistically significant and clinically relevant higher risk of revision due to infection than SHA. Independently of arthroplasty type, young patients had a statistically significant and clinically relevant higher risk of revision than older patients.

This paper is the result of collaboration between representatives of the Nordic national registries. All authors participated in the conception and design of the study, and in interpretation of the results. AMF, BS, and JVR prepared data from the national registries. JVR performed the statistical analysis. SB, YD, AMF, and BS participated in preparation of the manuscript. JVR incorporated input from all the other authors and was responsible for writing the manuscript.

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