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No increased risk of early revision during the implementation phase of new cup designs

Analysis of 52,903 hip arthroplasties reported to the Swedish Hip Arthroplasty Register

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Background and purpose — In Sweden, less than 5% of patients who undergo total hip arthroplasty (THA) have revision. Younger patients have an increased risk of revision. New prosthetic designs are being introduced in order to improve outcomes further. We investigated whether the introductory phase of new cup designs would increase the revision rate.

Patients and methods — All THAs and first-time cup revisions performed from 1993 through 2011 were identified in the Swedish Hip Arthroplasty Register. The 15 types of cups used in more than 500 operations and inserted in more than 50 cases in each hospital (n = 52,903) were selected. All cups were given an order number, based on the order in which the cup had been inserted at each hospital. The influence of order number on the risk of revision was analyzed in a regression model, which was adjusted for potentially confounding demographic and surgical data. Revision within 2 years for all reasons (n = 940) was used as primary endpoint. Changes in the risk of revision based on the order number were analyzed using a spline.

Results — The order number of the cup had no influence on the risk of early revision ($p \geq 0.7$). Categorizing the order number using cutoff values obtained from the splines did not result in any statistically significant changes in risk of revision ($p \geq 0.2$).

Interpretation — We did not find any increased risk of early revision during the implementation phase of new cup designs. This finding is unexpected, and partly conflicts with data from other registries. The structured and stepwise introduction of new prosthesis designs, facilitated by the annual feedback from the Swedish Hip Arthroplasty Register, may partly explain this discrepancy.

The average survival of the hip implants used in Sweden is about 94% at 10 years (Garellick et al. 2014). Younger patients, however, being more active and having a longer life expectancy, certainly have a higher risk of late revision, which has stimulated the introduction of new designs that supposedly have longer durability. Recently, there have been reports of increased risk of early failure when new implants are being introduced (Anand et al. 2011). Peltola et al. (2013) analyzed 39,125 THAs from the Finnish Arthroplasty Register and found an increased risk of early revision surgery during the introductory phase of new implants in Finnish Hospitals.

In Sweden, the Nordic country with the highest proportion of cemented fixation (Havelin et al. 2009), about half of all THAs inserted are still all-cemented (Garellick et al. 2014) and the choice of implant design is comparatively homogenous. 4 different cemented cups cover 90% of the market, but some of these have been introduced rather recently or have been subject to minor or more pronounced change in design during the last decade. There is, however, more heterogeneity in uncemented cups, where 5 cups have a market share of less than 70% and the ranking between them in terms of usage changes from year to year (Garellick et al. 2013, 2014). According to data from the Swedish Hip Arthroplasty Register (SHAR), the risk of revision due to dislocation is higher when uncemented acetabular designs are used, both in primary THA (Garellick et al. 2014) and in revision THA (Mohaddes et al. 2013). It could be argued that Swedish surgeons are more familiar with cemented fixation and would therefore experience difficulties when new uncemented cup designs are introduced. During the last 5 years, uncemented cups have been used in Sweden in about 20% of all THAs (Garellick et al.

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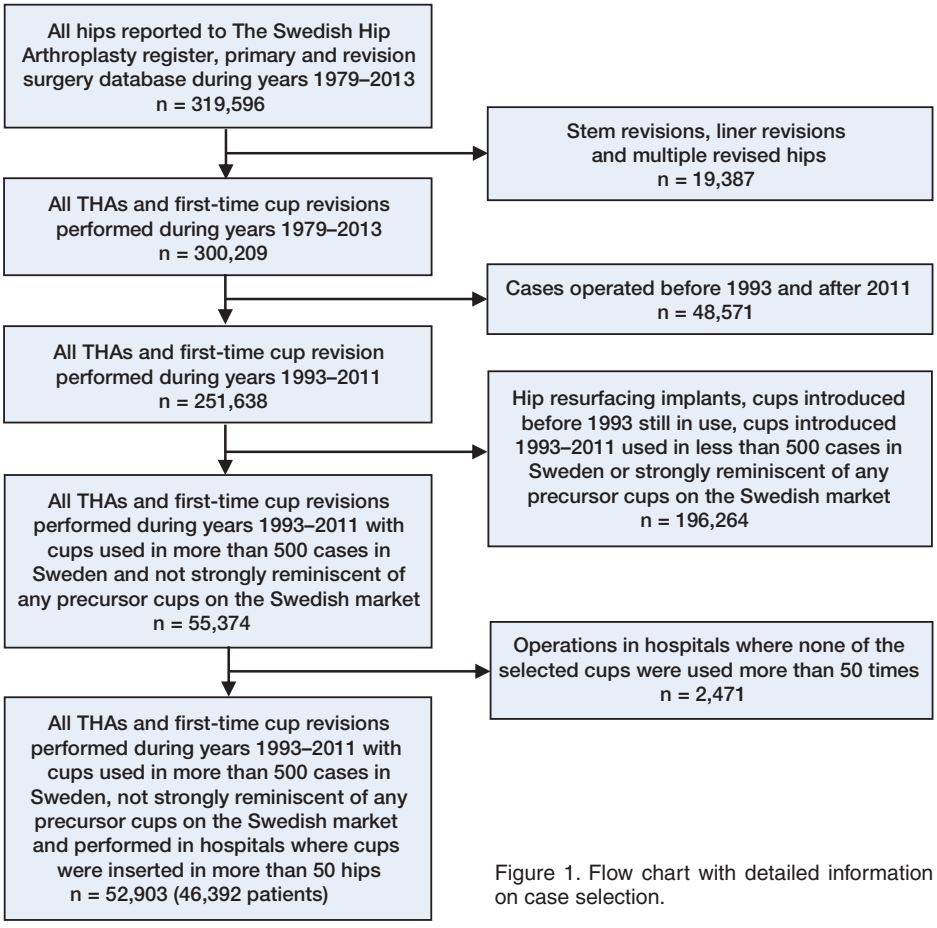

Figure 1. Flow chart with detailed information on case selection.

Date of operation	10/Nov./2009	11/Nov./2009	12/Nov./2009	13/Nov./2009
Hospital A	Cup design X order number = 1	Cup design Y order number = 1	Cup design X order number = 2	Cup design Z order number = 1
Hospital B	Cup design Y order number = 1	Cup design X order number = 1	Cup design Y order number = 2	Cup design Y order number = 3

Figure 2. Explanation of how the cup order number was ascertained.

2014) and in about 50% of all first-time acetabular revisions (Mohaddes et al. 2014). In the USA, where a higher proportion of uncemented designs are used, the most frequent cause of revision is dislocation (Bozic et al. 2009). Based on the aforementioned studies and observations from the SHAR, we hypothesized that introduction of new acetabular designs in Swedish hospitals would be associated with a higher risk of early revision.

Patients and methods

All hospitals performing primary and revision THA in Sweden report to the SHAR. Data completeness in the SHAR is 98% for primary THA (Garellick et al. 2014) and 90% for revision THA (Soderman et al. 2001). Revision in the SHAR is defined as exchange, removal, or addition of any implant components in an existing prosthesis. Revision cases have been reported in detail since the foundation of the SHAR in 1979. In 1992, the data reported to the SHAR were extended by including detailed information on all primary THAs (e.g. implant information on individual THAs). The date of death can be retrieved because the SHAR is linked to the population register.

We extracted data on all THAs and first-time cup revisions during the period 1993 through 2011 that were reported to SHAR (n = 251,638). We excluded operations in which data on cup fixation or cup design were not reported (n = 655). Acetabular designs used in more than 500 cases during the period 1993–2011 were identified. We only included designs implanted in more than 50 operations in each hospital (Figure 1). This selection was made to prevent potential bias from unconventional acetabular designs being inserted by single surgeons in particular hospitals. Designs reminiscent of any precursor cup were excluded. The last step of the selection was carried out by JK, and the manufacturer was consulted if there was still uncertainty. A cup order number variable was created (Figure 2). This corresponded to the order in which the cup had been inserted in each hospital, and it was used as a surrogate variable to monitor the introduction of new cup designs.

Study population

The mean age of the study population (n= 52,903) was 67 (SD 12), which was slightly younger than for all THAs reported to the SHAR during years 1993-2011 (n = 251, 638). There was a slightly larger proportion of men in the study group, and proportionately more patients were operated due to primary osteoarthritis. Uncemented fixation was more common, and a proportionately more patients were operated in university and private hospitals (Table 1).

Table 1. Baseline demographic and surgical data. Age is presented as mean (SD). All other numbers are given as n (%)

Data	Newly introduced designs n = 52,903	All hips n = 251,638	p-value [a]
Age, mean (SD)	67 (12)	70 (11)	< 0.001
Sex			< 0.001
Female	30,505 (58)	149,662 (59)	
Male	22,398 (42)	101,976 (41)	
Diagnosis			< 0.001
Primary osteoarthritis	43,373 (82)	199,708 (79)	
Femoral neck fracture	3,770 (7)	26,312 (10)	
Others	5,760 (11)	25,618 (10)	
Surgery			< 0.001
Primary	48,331 (91)	236,053 (94)	
Revision	4,572 (9)	15,585 (6)	
Hospital type [b]			< 0.001
University	11,280 (21)	39,285 (16)	
County	19,200 (36)	95,638 (38)	
Rural	13,798 (26)	90,401 (36)	
Private	8,625 (16)	26,306 (10)	
Abroad	- -	4 (0)	
Cup fixation [c]			< 0.001
Cemented	34,968 (66)	218,846 (87)	
Uncemented	17,935 (34)	29,455 (12)	
Resurfacing	- -	2,678 (1)	
Others	- -	4 (0)	

[a] The p-values are for nonparametric tests comparing the novel design group with all other designs used in THA and first-time revisions reported to the SHAR during the years 1993–2011.
[b] 4 hips with missing information on hospital type.
[c] 655 hips with missing information on cup fixation method.

Table 2. Novel cup designs introduced onto the Swedish market during years 1993–2011 and inserted in more than 500 THAs or first-time cup revisions

Cup design	Manufacturer	n	%
Cemented cups		34,968	66
Contemporary Hooded Duration	Stryker, Newbury, UK	10,686	20
ZCA	Zimmer, Warsaw, IN	10,264	19
FAL	Link, W. Link, Germany	6,397	12
OPTICUP	Biomet, Brigend, UK	4,182	8
Weber all-poly cup	Zimmer, Warsaw, IN	1,665	3
Exeter X3 RimFit	Stryker, Newbury, UK	1,400	3
Avantage Cemented	Biomet, Brigend, UK	374	1
Uncemented cups		17,935	34
Trilogy	Zimmer, Warsaw, IN	10,661	20
Trident HA	Stryker, Newbury, UK	2,551	5
Allofit	Zimmer, Warsaw, IN	1,523	3
TMT	Zimmer, Warsaw, IN	879	2
Ranawat/Burstein	Biomet, Brigend, UK	652	1
Reflection	Smith & Nephew, USA	625	1
ABG II	Stryker, Newbury, UK	616	1
TOP Press fit HA	Link, W. Link, Germany	428	1
Total		52,903	100

Statistics

All patients were followed until revision (exchange or removal of the cup) or death. Since the main purpose of the study was to examine early failures, the follow-up was limited to 2 years after the operation. Any kind of revision, for any reason, was used as primary endpoint. Isolated acetabular revision, excluding cases performed due to infection, was used as secondary endpoint. Revisions due to infections were excluded, since there was an increased risk of revision due to infection after primary THA during the period 1995–2009 (Dale et al. 2012) and there is controversy regarding the best practice for treatment of the early postoperative infection (Parvizi et al. 2012). Nonparametric testing using Mann-Whitney U-test was applied for comparison of demographic and surgical data. Kaplan-Meier survival analysis was used to determine the survival at 2 years for the study group and other hips operated during years 1993–2011. The results from the survival analysis are presented as percentages with 95% confidence intervals (CIs).

A binary logistic regression analysis was used. The cup order number representing the order in which individual designs had been introduced in each hospital was entered as a continuous variable into an unadjusted regression model.

The cutoff values for cup order number were identified using cubic residuals from the regression model and Akaike information criteria (Akaike 1987). The order numbers of cups were categorized into 4 groups (0–120, 121–280, 281–600, and > 600). The data were then adjusted for age, sex, primary diagnosis (3 categories: primary osteoarthritis, femoral neck fractures, or other diagnosis), type of surgery (primary/revision), hospital type (4 categories: university hospital, county hospital, rural hospital, or private hospital), and method of cup fixation (cemented/uncemented). The results from the adjusted regression models are presented as odds ratios (ORs) with 95% CIs and p-values.

Ethics

The study was approved by the regional ethics review board in Gothenburg (reference number 720-14).

Results

In the study group, 7 cemented cup designs and 8 uncemented cup designs had been used (Table 2). The Contemporary Hooded Duration (Stryker, Newbury, UK) was the most frequently used cemented design and the Trilogy cup (Zimmer, Warsaw, IN) was the most commonly used uncemented design. There were 940 revisions during the first 2 years. The most common reason for revision was dislocation (n = 326), followed by infection (n = 279) (Table 3). The most common reasons for isolated acetabular revision (n = 358) were dislocation (n = 199), infection (n = 55), and aseptic loosening (n = 48) (Table 4).

Table 3. Reasons for all revisions performed during the first 2 years

Reason for revision	n	%
Dislocation	326	35
Deep infection	279	30
Periprosthetic fracture	118	13
Aseptic loosening	99	11
Technical reasons	95	10
Other reason	23	2
Total	940	100

Table 4. Reasons for isolated cup revisions performed during the first 2 years

Reason for revision	n	%
Dislocation	199	56
Deep infection	55	15
Aseptic loosening	48	13
Technical reasons	38	11
Periprosthetic fracture	6	2
Other reason	12	3
Total	358	100

Using revision for any reason as endpoint, the unadjusted 2-year survival for the study population was 98.2% (CI: 98.1–98.3), and for all other hips it was 98.6% (CI: 98.5–98.6). Corresponding figures using isolated acetabular revision (excluding infections (n = 303)) were 99.4% (CI: 99.3–99.5) and 99.6% (CI: 99.6–99.6), respectively.

The overall risk of revision, adjusted for differences in baseline demographics was not influenced by the order number of the cup (OR = 1.0; p = 1.0) (Table 5). The overall risk of revision within 2 years was lower in females (OR = 0.7; p < 0.001). Patients with femoral neck fracture had a higher risk of revision (OR = 2.5; p < 0.001). The overall risk of revision was higher in patients who were operated with an uncemented design (OR = 1.4; p < 0.001) and in patients with first-time cup revisions (OR = 1.8; p < 0.001). In isolated acetabular revisions, the order number of the cup had no influence on the outcome (OR = 1.0; p = 0.68) (Table 5).

The splines suggested an increased risk for the first 120 cups and in cups implanted with order numbers 280–600. In the regression analyses, use of these limits as cutoff values did not result in any statistically significant changes in the risk of revision within 2 years (p ≥ 0.2) (Table 6).

Discussion

We studied 15 newly introduced cup designs used in 52,903 primary THAs and first-time cup revisions, which were

Table 5. Adjusted binary logistic with revision within 2 years as endpoint. Cup order number has been entered as a numerical variable

	All revisions regardless of reason (n = 904)			Isolated cup revisions, excluding infections (n = 303)		
	OR	95% CI	p-value	OR	95% CI	p-value
Age	1.0	1.0–1.0	0.6	1.0	1.0–1.0	0.5
Sex						
Male	ref			ref		
Female	0.7	0.6–0.8	< 0.001	1.1	0.9–1.4	0.4
Diagnosis						
Primary osteoarthritis	ref			ref		
Femoral neck fracture	2.5	2.0–3.0	< 0.001	2.9	2.0–4.1	< 0.001
Others	1.6	1.3–1.9	< 0.001	2.1	1.5–2.8	< 0.001
Surgery						
Primary	ref			ref		
Revision	1.8	1.4–2.1	< 0.001	3.5	2.6–4.6	< 0.001
Type of hospital						
University	ref			ref		
County	1.0	0.9–1.2	0.6	0.7	0.6–1.0	0.03
Rural	0.9	0.7–1.1	0.2	0.7	0.5–1.0	0.05
Private	1.3	1.0–1.6	0.04	1.0	0.6–1.5	0.9
Cup fixation						
Cemented	ref			ref		
Uncemented	1.4	1.2–1.6	< 0.001	1.3	1.0–1.8	0.03
Cup order number	1.0	1.0–1.0	1.0	1.0	1.0–1.0	0.7

OR: odds ratio; CI: confidence interval.

Table 6. Adjusted binary logistic with revision within 2 years as endpoint. Cup order number has been categorized using cubic splines

	All revisions regardless of reason			Isolated cup revisions, excluding infections		
	OR	95% CI	p-value	OR	95% CI	p-value
Age	1.0	1.0–1.0	0.6	1.0	1.0–1.0	0.5
Sex						
Male	ref			ref		
Female	0.7	0.6–0.8	< 0.001	1.1	0.9–1.4	0.4
Diagnosis						
Primary osteoarthritis	ref			ref		
Femoral neck fracture	2.5	2.0–3.0	< 0.001	2.9	2.1–4.2	< 0.001
Others	1.6	1.3–1.9	< 0.001	2.1	1.5–2.8	< 0.001
Surgery						
Primary	ref			ref		
Revision	1.8	1.4–2.1	< 0.001	3.4	2.5–4.5	< 0.001
Type of hospital						
University	ref			ref		
County	1.0	0.9–1.2	0.6	0.7	0.6–1.0	0.03
Rural	0.9	0.7–1.1	0.2	0.7	0.5–1.0	0.05
Private	1.3	1.0–1.6	0.04	1.0	0.6–1.5	0.9
Cup fixation						
Cemented	ref			ref		
Uncemented	1.4	1.2–1.6	< 0.001	1.3	1.0–1.7	0.03
Cup order number						
0–120	1.1	0.9–1.3	0.4	1.2	0.9–1.6	0.2
121–280	0.9	0.7–1.1	0.2	0.8	0.5–1.1	0.2
281–600	1.1	0.9–1.4	0.2	0.9	0.7–1.3	0.8
> 600	ref			ref		

OR: odds ratio; CI: confidence interval.

reported to the SHAR during the period 1993–2011. Contrary to our hypothesis, the risk of revision within 2 years was not increased during the implementation of new cup designs.

Anand et al. (2011) analyzed data on all new hip and knee prostheses reported to the Australian Orthopaedic Association National Joint Replacement Registry (AOA NJRR). They identified 73 newly introduced cup designs during the years 2003–2007, with only 12 designs that were used in more than 100 cases. According to their findings, 3 of the 12 new cup designs had a higher revision rate than the 3 best-performing designs in the AOA NJJR. The authors did not report the time of follow-up of the newly introduced designs. If the follow-up was shorter in this group than for well-established cups, this difference might have had an influence on the outcomes. We hypothesized that new designs have an increased risk of revision in the short term because of the learning curve caused by unfamiliarity and because of the behavior of the implant itself during implantation.

We limited the follow-up to 2 years. Furthermore, we used the order number in which the cup was inserted rather than comparing the new designs with established acetabular components. One could argue that we should instead have used controls involving well-established and frequently used implants, but such a comparison would have included possible design-related differences and would therefore have been less appropriate. We think that our analysis evaluated early complications associated with new designs being introduced reasonably well, accounting for the learning curve on a hospital basis. Longer follow-up will be needed to determine whether there are any long-term benefits in using novel designs.

Peltola et al. (2013) analyzed data from the Finnish Arthroplasty Register on 39,125 THAs, and found an increased risk of early revision in the first 15 operations with a new model of stem or cup. They concluded that this increased risk should be considered when new implants are being introduced. The authors described difficulties in quantifying the true amount of technical change associated with the introduction of a specific implant. We excluded newly introduced implants that could be regarded as being essentially similar to their predecessor.

These designs were not believed to introduce any changes in surgical technique during their insertion and could be expected to have about the same handling characteristics as their predecessors. In the report from Peltola et al. (2013), there was a lack of reliable information on the reason for revision. There has been more detailed information on all revisions reported to the SHAR since 1979. In the current analysis, the risk of revision (regardless of reason) was not elevated during the introduction of new implants.

The present study had several limitations. Information on the surgeons who perform primary THAs and revisions is not available from the SHAR. It could be argued that individual surgeon volume may have an influence on the outcome in hip arthroplasty. This has been debated (Shervin et al. 2007). It would have therefore been of interest to determine the influence of individual surgeons, including their operative volume, and any effect of these factors on the risk of early revision. However, the main purpose of our study was not to analyze the learning curve of individual surgeons but rather—from a national healthcare standpoint—address any concerns associated with increased risk of revision when new acetabular designs are being introduced. A second limitation was that patient-reported outcome measures (PROMs) were not studied. With a survivorship of about 98% at 2 years for the contemporary prosthesis designs and with about 10% of patients not being fully satisfied 1 year after THA (Garellick et al. 2014), new implants being introduced should not only be measured according to their early risk of revision. Although the SHAR has been registering PROMs on THAs since 2002, the revision cases are not included in the PROMs program. Furthermore, in the cohort selected the number of cases with complete PROMs data in the SHAR was most probably too low for a meaningful analysis. In future studies, such an analysis might very well be worthwhile. Thirdly, it could be argued that comorbidity of patients might influence the surgeons' willingness to perform a second intervention, making patient-reported outcomes (PROs) a more valid outcome measure. However, according to a publication from the New Zealand Joint Registry (Rothwell et al. 2010), there is a correlation between PROs and the rate of revision.

In summary, by analyzing more than 50,000 primary THAs and first-time revisions reported to the SHAR during the years 1993–2011, we found that the risk of revision within 2 years is not increased during the introduction phase of a new cup design. Our findings may partly be explained by the structured and stepwise introduction of implants in Sweden, facilitated by the continuous feedback given from the SHAR.

MM had the original idea for the study, processed the data, performed the statistical analyses, and prepared the first version of the manuscript. All the authors took part in planning of the study, in analysis and interpretation of the data, and in writing of the manuscript.

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