

Patient-related risk factors leading to aseptic stem loosening in total hip arthroplasty

A case-control study of 5,035 patients

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Background We hypothesized that certain patient characteristics have different effects on the risk of early stem loosening in total hip arthroplasty (THA). We therefore conducted a case-control study using register-database records with the aim of identifying patient-specific risk factors associated with radiographic signs of aseptic loosening of the femoral component in THA.

Method Data were derived from a multinational European registry and were collected over a period of 25 years. 725 cases with radiographic signs of stem loosening were identified and matched to 4,310 controls without any signs of loosening. Matching criteria were type of implant, size of head, date of operation, center of primary intervention, and follow-up time. The risk factors analyzed were age at operation, sex, diagnosis and previous ipsilateral operations, height, weight, body mass index and mobility based on the Charnley classification.

Results Women showed significantly lower risk of radiographic loosening than men (odds ratio (OR) 0.64). Age was also a strong factor: risk decreased by 1.8% for each additional year of age at the time of surgery. Height and weight were not associated with risk of loosening. A higher body mass index, however, increased the risk of stem loosening to a significant extent (OR 1.03) per additional unit of BMI. Charnley Class B, indicating restricted mobility, was associated with lower risk of loosening (OR 0.78).

Interpretation An increased activity level, as seen in younger patients and those with unrestricted mobility, is an important factor in the etiology of stem loosening. If combined with high BMI, the risk of stem loosening

within 10 years is even higher. A younger person should not be denied the benefits of a total hip arthroplasty but must accept that the risk of future failure is increased. ■

Aseptic loosening is the most frequent cause of early component failure in total hip arthroplasty (Ahnfelt et al. 1990, Herberts and Malchau 1997, 2000, Havelin 1999, Puolakka et al. 2001). Aseptic loosening is multifactorial; in addition to immunological mechanisms and/or implant design and surgeon skills, patient-specific characteristics appear to be the most prominent factors leading to prosthetic failure. On balance, however, the findings to date have been inconclusive due to the fact that most previous studies have been based on small patient series and/or have described risk factors for one specific implant only (Lühmann et al. 2000). There has been a lack of prospective randomized studies.

We assessed stem loosening diagnosed by radiographic imaging. Although the intra- and interobserver variabilities are a possible source of error in these assessments (Kramhoft et al. 1996), survival calculations based on revision rates may overestimate prosthetic lifetimes. Elderly patients living alone or in care settings can spend years with an asymptomatic but loose component, or may deny a revision intervention for other health reasons. In addition, patients in need of a revision may have long waiting times, especially in state-adminis-

tered health care systems such as Canada (Saleh et al. 1997), England (Chakravarty et al. 2005), or Scandinavia (Lofvendahl et al. 2005).

The aim of our study was to identify patient characteristics that may increase the risk of early stem failure, i.e. failure within 10 years of the primary intervention. The investigation was designed as a case-control study based on prospectively collected multicenter-based register data.

Patients and methods

We used the total hip arthroplasty database managed by the Institute for Evaluative Research in Orthopaedic Surgery of the University of Berne, Switzerland. Data collection was initiated in 1967 and is still in progress. All data were recorded by orthopedic surgeons on a routine yet voluntary basis, and represent information from 45 hospitals in 8 European countries. Once a hospital had accepted to take part in the data collection, all THR surgeries performed were reported, including hemiarthroplasties and revision interventions. Currently, the database holds records of about 48,000 primary surgeries and over 77,000 follow-up examinations. All preoperative, intraoperative and postoperative information is collected on machine-readable code sheets according to the standards of IDES (International Documentation and Evaluation System) (Paterson 1993 a, b, Röder 2003a). The IDES A form covers the preoperative assessment and technical aspects of the primary intervention, whereas the IDES C form is used to gather follow-up information from clinical and radiographic examinations. These case report forms meet the requirements of AAOS, SICOT and the American Hip Society regarding a standardized terminology for collecting data on total hip replacement (Johnston et al. 1990). We chose the case-control methodology in order to neutralize influential factors related to surgeon- and hospital-specific treatment methods, surgical techniques and technological improvements over time. Moreover, different component designs, follow-up strategies and observer variability in radiographic assessment can be incorporated and neutralized in such a study. Inclusion criteria were age older than 20 years at the time of surgery and osteoarthritis,

rheumatoid arthritis, fracture, osteonecrosis or hip dysplasia as indication for surgery. In addition, at least one follow-up sheet with all the information necessary for matching and a radiographic evaluation of the mechanical component status had to be available.

Definition of cases

Radiographic loosening of the stem was defined as: 1) signs of subsidence of more than 3 mm (Brand et al. 1986), 2) continuous radiolucencies at the shaft-bone or bone-cement interface or progressive radiolucencies > 2 mm in the same region (Gruen et al. 1979, Greiner et al. 1997, Carlsson and Gentz 1980), 3) formation of multiple small cavitations or large defects around the stem (Dihlmann et al. 1991), and 4) possible fractures of the shaft or the cement mantle (Dihlmann et al. 1991).

Regarding progression of radiolucencies, follow-up radiographs were compared with those taken immediately after surgery to account for primarily existing radiolucent lines due to poor cementing technique. We found 725 cases that met one or several of these criteria.

Definition of controls

Controls were defined as patients with a primary implant and at least 1 valid follow-up examination without any of the above-mentioned signs of loosening. The controls were matched to cases according to the following criteria: 1) duration of follow-up: the period between the intervention date and the follow-up date had to be within ± 0.5 years, 2) calendar period: the time of the primary surgery of cases and controls had to be within ± 2.5 years to account for technical improvements (e.g. cementing technique) over time, 3) identical stem type (product), including fixation technique (cemented or uncemented) and surface-specific coating in order to exclude implant-specific influences, 4) head size, and 5) the center at which the intervention was performed, to account for any factors related to surgical techniques and aspects of patient recruitment (e.g. urban vs. country regions).

Using these criteria, a control group of 4,310 patients could be identified. 466 patients had undergone bilateral surgery. All cases were matched to one or more controls and on average 5.9 controls were matched to each case, ranging from 1 to 99

controls per case. The average difference in follow-up time between cases and controls was 1.04 days. 50% of all case-control pairs differed by less than 46 (SD 61) days. The entire study population covered 60 different prosthesis types/designs, both cemented and uncemented. The cases and controls came from 30 of the 45 participating hospitals in 8 European countries (Switzerland, France, Germany, Belgium, the Netherlands, Spain, Austria, and Italy). From 15 hospitals, no cases and/or controls fulfilling the matching criteria were found. For 3 implant types, more than 50 cases were included. For 13 types, the case numbers ranged between 10 and 38, and for 44 designs, 1 to 9 cases were included.

51% of patients were women and 92% of all patients had undergone surgery after 1980.

Data analysis

We used multivariate conditional logistic regression models to examine the following factors regarding the risk of stem loosening: (1) age at operation categorized into groups < 60, 60–70, 71–80, and > 80 years, (2) sex, (3) indication for surgery, (4) height and weight, (5) BMI, (6) body mass index – weight (kg)/(height in m)² categorized into the following groups: < 25 (normal), 25–30 (overweight), > 30 (obese) (National Heart, Lung and Blood Institute), and (7) mobility level according to Charnley (1972) using classes A, B and C. Class A describes a patient with one hip affected, but otherwise unrestricted mobility. Class B represents patients with both hips affected, but otherwise unrestricted mobility. Finally, class C includes patients whose normal mobility is restricted by multiple joint lesions or systemic illnesses.

We performed the data analysis in multiple steps. Initial models were used to analyze overall effects of age and BMI as continuous explanatory variables, and adjustments were made for sex, diagnosis, Charnley class and history of previous surgery by including corresponding co-variables. Similar models in which weight and body height replaced BMI were used to estimate the respective risks. A final model was used to assess the consistency of risks of continuous variables across the range of observed data, and to estimate effects of categorical or continuous variables classified into groups as described above.

The results of continuous variables were interpreted as an estimate of the change in risk per unit increase of each variable, and categorized or grouped variables were interpreted as difference in risk to a reference level (Tables 2–4). Additional models with the same structure were used to assess those cases and controls with osteoarthritis alone as diagnosis (Table 4) and for unilateral THA (598 cases, 3,583 controls).

Power calculations for a 1:5 case-control ratio were performed for all exposure levels of age, sex, Charnley class and BMI (Dupont 1988). All computations were carried out using PROC PHREG for conditional logistic regression (SAS version 8.2; SAS Institute, Cary, NC). The significance level was set at $p < 0.05$.

Results

The demographic traits of the population and the distribution of the primary indications are given in Table 1.

Age at operation

The mean age at operation was 65 years (female patients 66 and male patients 64). Analysis of age as continuous variable yielded a significant loosening risk reduction of 1.8% for each additional year of age at the time of surgery. The age-dependent risk reduction was linear through all age groups (< 60, 60–70, 71–80, and > 80 years); see Tables 2–4.

Sex

Sex was significantly associated with the risk of loosening. Women showed lower risk than men (OR = 0.64, 95% CI: 0.52–0.78; $p < 0.001$).

Weight, height and BMI

Neither weight nor height were significant predictors of early loosening. BMI, however, was significant: the risk of loosening increased by 2.6% per additional BMI unit ($p < 0.02$) (Tables 3 and 4).

Diagnosis and previous operations

No statistically significant associations were found regarding the type of diagnosis or history of previous ipsilateral operations. Osteonecrosis, however,

Table 1. Basic demographic and diagnostic data of the study population

	Cases (%)	Matched controls (%)
Sex		
Female	322 (6.4%)	2,266 (45%)
Male	403 (8.0%)	2,044 (40%)
Mean age at operation	63 (SD 9.5)	65 (SD 9.9)
Female	64 (SD 10)	66.19 (SD 10)
Male	62 (SD 8.8)	65 (SD 9.7)
Age group		
< 60	254 (5.0%)	1,175 (23%)
60–70	302 (6.0%)	1,617 (32%)
71–80	155 (3.1%)	1,305 (26%)
> 80	14 (0.3%)	213 (4.2%)
Mean weight (kg)	74.6 (SD 14)	73.4 (SD 13)
Mean height (cm)	165 (SD 8.8)	165 (SD 8.6)
Mean BMI	27 (SD 4.3)	27 (SD 4.0)
< 25 kg/m ²	255 (5.1%)	1,601 (32%)
25–30 kg/m ²	322 (6.4%)	1,940 (39%)
> 30 kg/m ²	148 (2.9%)	769 (15%)
Main diagnosis		
Osteoarthritis	574 (11%)	3,491 (69%)
Developmental dysplasia	55 (1.1%)	291 (5.8%)
Inflammatory arthritis	23 (0.5%)	163 (3.2%)
Fracture	21 (0.4%)	145 (2.9%)
Osteonecrosis	52 (1.0%)	220 (4.4%)
Mobility		
Charnley Class A	480 (9.5%)	2,869 (57%)
Charnley Class B	227 (4.5%)	1,349 (27%)
Charnley Class C	18 (0.4%)	92 (1.8%)
Previous surgery		
Not present	668 (13%)	4,046 (80%)
Present	57 (1.1%)	264 (5.2%)
Calendar period at surgery		
1967–1979	55 (1.1%)	146 (2.9%)
1980–1989	391 (7.8%)	2,491 (50%)
After 1989	279 (5.5%)	1,673 (33%)
Fixation		
Cemented	616 (12%)	3,590 (71%)
Uncemented	109 (2.2%)	719 (14%)
General		
Unilateral hip arthroplasty	598 (13%)	3504 (77%)
Bilateral hip arthroplasty	20 (0.4%)	447 (9.8%)
Mean years of follow-up ^a	5.3 (SD 3.1)	3.8 (SD 2.7)

^a Differences in average follow-up time are related to the case-control ratio of 5.9. The difference in follow-up time between matched cases and controls was less than 0.001 years.

showed a tendency of being a risk factor for loosening ($p = 0.08$).

Classification of mobility according to Charnley

Charnley class A was defined as the reference level (67% of all patients). Class B (31% of the population) showed a substantial reduction in risk of loosening by a factor of 0.78 (95% CI: 0.63–0.96;

$p = 0.02$). Class C (2% of the patients) showed insignificantly reduced risk ratios (OR = 0.97, 95% CI: 0.54–1.74; $p = 0.9$).

Additional models for patients with osteoarthritis

Patients with osteoarthritis represent the patient group with probably the greatest choice regarding the time of operation during the course of the disease. Restriction of the model to these patients reduced the risk of early loosening from 1.8% to 2.3% for each additional year of age at the time of surgery, and increased the risk of failure from 2.6% to 3% per additional BMI unit (Tables 3 and 4).

A further model fitted to a restricted data set including cases with unilateral THA merely indicated subtle changes for most risk estimates. However, risk of loosening in obese patients (BMI > 30) was significant in this population, with about 40% increased risk (OR 1.38, 95% CI: 1.04–1.83).

Power analysis

Power levels of most outcome variables with significant influence were above 0.8. An exception was Charnley class B vs. A (power 0.43). In the case of non-significant results, the sample sizes of the studies would allow the detection of odds ratios of less than 2 at a power of 0.8.

Discussion

Risk factors

We found male sex, younger age and high BMI to be risk factors with respect to stem loosening within 10 years. Weight alone was not a risk factor, however. The risk of stem loosening increased linearly with decreasing age. For osteoarthritis, the risk increased by almost 50% if the patients were operated at the age of 50 years compared to when operated at the age of 70 years (Table 4).

Various studies have provided evidence that in general women are operated at a rather later stage

Table 2. Effects of sex, age, body weight, height and BMI on stem loosening in a model with categorized explanatory variables

Variable	Odds ratio	95% confidence interval	P-value
Sex:	Male ^a	1.00	
	Female	0.64	0.52–0.78
Age groups: ^c	< 60 years ^a	1.00	
	60–70 years	0.83	0.67–1.04
	71–80 years	0.61	0.47–0.79
	> 80 years	0.39	0.21–0.71
Body weight: ^c	< 64 kg ^a	1.00	
	64–73 kg	1.05	0.80–1.38
	73–82 kg	1.06	0.80–1.40
	> 82 kg	1.14	0.86–1.51
Height: ^c	< 160 cm ^a	1.00	
	160–165 cm	0.95	0.71–1.26
	165–170 cm	1.09	0.82–1.46
	> 170 cm	0.84	0.62–1.13
BMI: ^c	< 25 ^a	1.00	
	25–30	1.10	0.90–1.35
	> 30	1.26	0.98–1.63
Main diagnosis			
	Osteoarthritis ^a	1.00	
	Developmental dysplasia	0.75	0.52–1.10
	Inflammatory arthritis	0.96	0.58–1.61
	Fracture	0.83	0.48–1.43
	Osteonecrosis	1.38	0.96–1.98
Charnley class ^c			
	Charnley A ^a	1.00	
	Charnley B	0.78	0.63–0.96
	Charnley C	0.97	0.54–1.74
Previous surgery			
	Not present ^a	1.00	
	Present	1.04	0.72–1.49

^a Reference level.
^b Significant odds ratio, $p \leq 0.05$.
^c Categorized data.

than men (Katz et al. 1994, Hawker et al. 2000). Moreover, women tend to accept the operation at a later time than men (Karlson et al. 1997). Also, women are more prone to take physiotherapy prior to surgery (Geissberger et al. 2001). Likewise, the cost of preoperative medication is higher in women. Geissberger et al. (2001) showed that 38% of men underwent physiotherapy in the year before the operation, whereas the percentage of women was 57%. The Swedish Hip Registry has shown that during the past 10 years, the age at operation has been relatively constant but increasing slightly for women, whereas in male patients there has been a strong tendency towards earlier interventions (Annual report 2002). Our data indicate a difference in age of 1.8 years at the time of surgery between male and female patients, and are therefore consistent with the findings above.

Our findings concerning weight and BMI support the hypothesis that increasing relative body weight only has a detrimental effect on the stability of the implant.

Hozack et al. (1990) showed that the life expectancy of cemented implants was lower in Charnley class A patients than in class B patients. However, it is

Table 3. Effects of demographic factors and diagnosis on stem loosening analyzed in a model with continuous explanatory variables for all diagnoses: Model 1: all diagnoses, 725 cases and 3,230 controls adjusted for sex, diagnosis, Charnley class, previous surgery and flexion

Variable	Odds ratio	95% confidence interval	P-value
Body weight	1.00	1.00–1.01	0.6
Height	0.99	0.98–1.00	0.08
BMI ^a	1.03	1.00–1.05	0.02 ^c
Age ^b	0.98	0.97–0.99	< 0.001 ^c

^a Risks increased per additional unit of BMI.
^b Risks decreased per additional year of intervention postponement.
^c Significant odds ratio, $p \leq 0.05$.

Table 4. Effects of demographic factors and diagnosis on stem loosening analyzed in a model with continuous explanatory variables for osteoarthritis. Model 2: Osteoarthritis only, 545 cases and 3,141 controls adjusted for: sex, diagnosis, Charnley class, previous surgery and flexion

Variable	Odds ratio	95% confidence interval	P-value
Body weight	1.01	1.00–1.02	0.08
Height	0.99	0.98–1.01	0.4
BMI ^a	1.03	1.00–1.06	0.02 ^c
Age ^b	0.98	0.96–0.99	< 0.001 ^c

^a Risks increased per additional unit of BMI.
^b Risks decreased per additional year of intervention postponement.
^c Significant odds ratio, $p \leq 0.05$.

questionable whether the Charnley classification combined with age and sex is a valid indicator of activity. Nevertheless, we assume that the reduced risk of component loosening in women is related to a lower postoperative level of physical activity, a fact that was recently confirmed (Röder et al. 2003b). Although well-trained and functioning muscles optimize force transmission as well as coordination, and favor the stability of the hip joint (Lu et al. 1997, Gotze et al. 2003), activity is not a neglectable factor in the etiology of implant wear and consequent aseptic loosening (Iannotti et al. 1986, Soyer et al. 1997, Prakash et al. 1999).

Method

It can be argued that cases and controls need to represent the entire population of patients with or without component loosening. Patient selection within hospitals may therefore be a critical issue with respect to bias. Our case definition, however, implicitly defines a source population for cases—and controls should consequently be drawn from this same population. Bias is therefore mainly related to factors concerning how cases and controls are ascertained and included in the study, i.e. controls should be representative of this distinct base population (Rothman 1998).

Because cases and controls were matched within the same hospital and within the same time frame, we consider these types of bias as not being relevant to our study. Measurement errors of exposure factors may be another possible source of bias. Exposure factors were, however, either given by patient demography (such as age and sex) or were determined at the time of the primary intervention (BMI, diagnosis, range of motion, etc.) long before loosening was diagnosed. It is therefore unlikely that bias occurred in this context.

The reliability of the data collected was ascertained by a preselection of hospitals whose data is used for scientific evaluations. These make up about two-thirds of all participating hospitals and distinguish themselves with a long-term commitment and a certain required number of documented cases. Moreover, the IDES system itself (as a tool) makes documentation of total and partial hip arthroplasties possible so that all hip replacement interventions are recorded. Also, as a result of the broad spectrum of participating academic and

non-academic centers and the multitude of prostheses included, generalization from our findings becomes possible.

Clinical relevance

As shown by Woolf et al. (1994), a successful hip surgery does not necessarily lead to weight reduction from increased activity as a consequence of less pain. Thus, patients with a BMI of over 25 should be told about the increased risk and—more importantly—obese patients should be encouraged to reduce their weight prior to surgery.

The question of the optimal time for surgery deserves special mention. It has been shown that patients starting with a poor overall status regarding pain, function and activities of daily living can be expected to have a poor outcome, resulting in reduced quality of life (MacWilliam et al. 1996, Fortin et al. 2002, Hajat et al. 2002, Holtzman et al. 2002). On the other hand, to concentrate solely on life quality and mobility is somewhat questionable since the obvious early benefits may be outweighed by a higher likelihood of revision. The additional costs of a revision are obvious, and the risk of general complications up to a lethal incident is higher for patients undergoing revision (de Thomasson et al. 2001).

If it is considered wise to postpone the time of surgery, special attention should be given to preserving the patient's functional status and pain level. To delay the time of operation, reducing the risk of revision, pain reducing medication and non-operative therapies may be used. Long-term medication, however, may have deleterious effects on various organ systems and must therefore be used selectively. The goal of future studies should be the assessment of the trade-off between an early intervention to preserve good function and cardiopulmonary status, and a late intervention to minimize the risks of revision surgery and perioperative complications. The optimum intervention time is a compromise—representing a balance between these two factors based on patient needs and preferences.

Contributions of authors

PM wrote the paper as part of his Master of Public Health (MPH) thesis and had the idea of conducting the analysis with a case-control design. The topic is based on previous, yet unpublished research of CR and AB. CR supported the

first author in writing the manuscript and on all questions related to orthopedics. AB was responsible for all methodological, i.e. statistical and epidemiological aspects of the study. UA-L was the thesis supervisor of PM in the MPH program and contributed with her public health knowledge.

This study was feasible because of the existence of a voluntary patient register that has been in use since 1967. We are indebted to all hospitals and physicians who provided data for this project.

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