**Clinical Research** 

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# Cemented or Uncemented Hemiarthroplasty for Femoral Neck Fracture? Data from the Norwegian Hip Fracture Register

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Received: 30 January 2019 / Accepted: 2 May 2019 / Published online: 6 June 2019 Copyright © 2019 The Author(s). Published by Wolters Kluwer Health, Inc. on behalf of the Association of Bone and Joint Surgeons

### Abstract

*Background* A displaced femoral neck fracture in patients older than 70 years is a serious injury that influences the patient's quality of life and can cause serious complications or death. Previous national guidelines and a Cochrane review have recommended cemented fixation for arthroplasty to treat hip fractures in older patients, but data suggest that these guidelines are inconsistently followed in many parts of the world; the effects of that must be better characterized.

Each author certifies that he or she has no commercial associations (consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article. The Norwegian Hip Fracture Register is financed by the Western Norway Regional Health Authority (Helse-Vest) (GSD).

Each author certifies that his or her institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research. This work was performed at the Norwegian Hip Fracture Register, Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen, Norway.

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All ICMJE Conflict of Interest Forms for authors and *Clinical Orthopaedics and Related Research*<sup>®</sup> editors and board members are on file with the publication and can be viewed on request. *Questions/purposes* The purpose of this study was to evaluate a large group of patients in the Norwegian Hip Fracture Register to investigate whether the fixation method in hemiarthroplasty is associated with (1) the risk of reoperation; (2) the mortality rate; and (3) patient-reported outcome measures (PROMs).

Methods Longitudinally maintained registry data from the Norwegian Hip Fracture Register with high completeness (93%) and near 100% followup of deaths were used for this report. From 2005 to 2017, 104,993 hip fractures were registered in the Norwegian Hip Fracture Register. Fractures other than intracapsular femoral neck fractures and operative methods other than bipolar hemiarthroplasty, such as osteosynthesis or THA, were excluded. The selection bias risk on using cemented or uncemented hemiarthroplasty is small in Norway because the decision is usually regulated by tender processes at each hospital and not by surgeon. A total of 7539 uncemented hemiarthroplasties (70% women, mean age, 84 years [SD 6] years) and 22,639 cemented hemiarthroplasties (72% women, mean age, 84 years [SD 6] years) were eligible for analysis. Hazard risk ratio (HRR) on reoperation and mortality was calculated in a Cox regression model adjusted for age, sex, comorbidities (according to the American Society of Anesthesiologists classification), cognitive function, surgical approach, and duration of surgery. At 12 months postoperatively, 65% of patients answered questionnaires regarding pain and quality of life, the results of which were compared between the fixation groups.

*Results* A higher overall risk of reoperation for any reason was found after uncemented hemiarthroplasty (HRR, 1.5; 95% CI, 1.4–1.7; p < 0.001) than after cemented hemiarthroplasty. When assessing reoperations for specific

causes, higher risks of reoperation because of periprosthetic fracture (HRR, 5.1; 95% CI, 3.5-7.5; p < 0.001) and infection (HRR, 1.2; 95% CI, 1.0–1.5; p = 0.037) were found for uncemented hemiarthroplasty than for cemented procedures. No differences were found in the overall mortality rate after 1 year (HRR, 1.0; 95% CI, 0.9-1.0; p = 0.12). Hemiarthroplasty fixation type was not associated with differences in patients' pain (19 versus 20 for uncemented and cemented hemiarthroplasties respectively, p = 0.052) or quality of life (EuroQol [EQ]-VAS score 64 versus 64, p = 0.43, EQ5D index score 0.64 versus 0.63, p = 0.061) 1 year after surgery. Conclusions Our study found that the fixation method was not associated with differences in pain, quality of life, or the 1-year mortality rate after hemiarthroplasty. Uncemented hemiarthroplasties should not be used when treating elderly patients with hip fractures because there is an increased reoperation risk.

Level of Evidence Level III, therapeutic study.

#### Introduction

Displaced femoral neck fractures in elderly patients are serious injuries that influence quality of life [14] and are associated with morbidity and an increased risk of death [38]. In Western countries, hemiarthroplasty is now the most common treatment for displaced femoral neck fractures [5]. Several recently published studies have shown that stem fixation with cement is associated with a lower reoperation risk than fixation with uncemented stems [16, 28, 39]. In addition, a review study and a Cochrane review have described less pain and better function after cemented hemiarthroplasty than after uncemented hemiarthroplasty [21, 34]. An earlier randomized controlled trial with 5 years of followup indicated better long-term Harris Hip scores in patients with uncemented hemiarthroplasty than in those with cemented hemiarthroplasty [23]. However, bonecement implantation syndrome has been described previously [9, 33], and the risk of serious harm associated with cementing in older patients who may have cardiovascular comorbidities remains a concern.

The National Institute for Health and Care Excellence guidelines in the UK [29] and the American Academy of Orthopaedic Surgeons recommendations [6], as well as a Cochrane review [34], support the use of cemented fixation when performing arthroplasties for hip fractures in elderly patients. But data suggest that these guidelines are inconsistently followed in many parts of the world [1, 3, 30], and the effects of that need to be better characterized. Minimizing the risk of reoperation and death and determining which approach is most likely to provide the patient with pain relief and a good quality of life are important goals when choosing the hemiarthroplasty fixation method for femoral neck fractures. Investigating uncommon endpoints (in particular fracture and death) in a randomized study is difficult, and to our knowledge, no large register study has been done that evaluated those endpoints. Our national (Norway) register has the benefit of providing all these endpoints in the same population with more than 12 years of followup.

Therefore, we thought to use the Norwegian Hip Fracture Register to determine whether the hemiarthroplasty fixation method is associated with (1) the risk of reoperation; (2) the mortality rate; and (3) PROMs.

# **Patients and Methods**

This nationwide (Norway) observational study was based on longitudinally maintained data in the Norwegian Hip Fracture Register from 2005 to 2017 [15]. The Norwegian Hip Fracture Register has high registration completeness (93%), and 100% of hospitals are covered by it [2]. Data on death and emigration were provided by the National Registry in Norway [42]. The Norwegian Hip Fracture Register has approval from the Norwegian Data Inspectorate to process health data. The followup rate of deaths is nearly 100% [36]. After each primary operation and reoperation for femoral neck fracture, surgeons complete a paper form that is sent to the register. This form includes detailed patient information such as the unique 11-digit Norwegian personal identification number, age, sex, comorbidities (according to the American Society of Anesthesiologists [ASA] classification), time of fracture, time of the start of surgery, type of fracture, type of surgery, fixation of hemiarthroplasty, duration of surgery, surgical approach, and type of implant (identified by catalog numbers). In Norway, the choice of implant and fixation is mainly regulated by a tender process that occurs every fourth year in the hospital or health region. Factors influencing this decision are clinical documentation, implant costs, and service from manufacturer. Based on our annual hospital reports, most hospitals have used either an uncemented or a cemented stem for all patients in a given time period. The fact that a hospital has used only one fixation technique for a time period mitigates this selection bias. Therefore, we performed a subanalysis on these patients including only these hospitals to compare with our main findings. From the register's inception in January 2005 to the end of 2017, 104,993 primary operations for hip fractures were reported to the Norwegian Hip Fracture Register. We excluded patients with pathologic fractures (n = 1356), fractures other than intracapsular femoral neck fractures (n = 46,764), operation methods other than bipolar hemiarthroplasty such as THAs and osteosyntheses (n = 22,948(unipolar hemiarthroplasties are used in fewer than 1% [n =

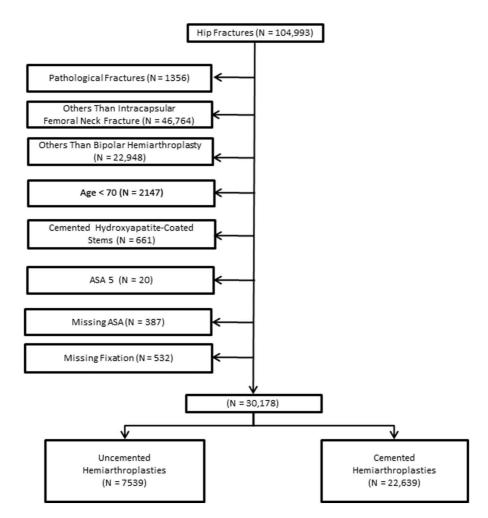


Fig. 1 A flowchart of the inclusion and exclusion process is shown.

317] of patients with hip fractures in Norway), patients younger than 70 years (n = 2147), patients with uncemented stems that had been fixed with cement (n = 661), patients with ASA Grade 5 physical status (n = 20), and patients with incomplete information in the Norwegian Hip Fracture Register dataset regarding the ASA grade or fixation method (n = 919) (Fig. 1). A total of 30,178 bipolar hemiarthroplasties (7539 uncemented and 22,639 cemented) were eligible for the final analyses regarding reoperations and mortality. All patients were observed for reoperation for any reason until death, emigration, or until December 31, 2017.

The mean age was 84 years (range, 70-104 years), and 71% of the patients were women. The median followup duration was 2 years (interquartile range, 0.5–4.2 years). The duration of surgery was shorter for uncemented fixation than for cemented fixation (61 versus 80 minutes). There were more women in the uncemented group than in the cemented group (72% versus 70%). The posterior approach was used more frequently in uncemented hemiarthroplasties (17%)

than in cemented hemiarthroplasties (8%) (Table 1). Other than the differences identified above, the groups were not different in terms of any parameters apart from the intervention in question.

PROM questionnaires were distributed to patients from 2005 to 2016. Patients receiving questionnaires in 2017 (n =2366) were excluded because their 1-year results were not ready for analysis at the time we prepared this manuscript. Because of a lack of resources from 2007 to 2009, only a randomly selected group of patients were asked to answer the questionnaires, and most patients (n = 4520) did not receive questionnaires in this period. We excluded patients with cognitive impairment (mainly dementia; n = 3147) to improve the quality of information; we believe this did not likely have a differential between-group effect. In addition, we excluded those who died within the first year postoperatively (n =7459). There were no differences between the uncemented and cemented groups in terms of the proportion of patients who returned PROMs questionnaires (66% (n = 2299 of 3499) versus 65% (n = 5930 of 9087); p = 0.64) (Fig. 2).

| Patient-related<br>factors                 | Baseline reoperations and mortality |                             |                      | Baseline PROMs                |                             |                      |  |
|--|-------------------------------------|-----------------------------|----------------------|-------------------------------|-----------------------------|----------------------|--|
|  | Uncemented hemiarthroplasties       | Cemented hemiarthroplasties | p value              | Uncemented hemiarthroplasties | Cemented hemiarthroplasties | p value              |  |
| Total number, n                            | 7539                                | 22,639                      |                      | 3499                          | 9087                        |                      |  |
| Age (years, SD)                            | 84 (6)                              | 84 (6)                      | $0.55^{\dagger}$     | 83 (6)                        | 83 (6)                      | 0.77 <sup>+</sup>    |  |
| Women                                      | 70%                                 | 72%                         | 0.007*               | 73%                           | 75%                         | 0.005*               |  |
| Duration of<br>surgery (min)               | 61                                  | 80                          | < 0.001 <sup>+</sup> | 61                            | 81                          | < 0.001 <sup>+</sup> |  |
| ASA class                                  |                                     |                             | < 0.001*             |                               |                             | < 0.001*             |  |
| ASA 1, n (%)                               | 150 (2)                             | 517 (2)                     |                      | 97 (3)                        | 269 (3)                     |                      |  |
| ASA 2, n (%)                               | 2581 (34)                           | 7237 (32)                   |                      | 1542 (44)                     | 3670 (40)                   |                      |  |
| ASA 3, n (%)                               | 4236 (56)                           | 13,358 (59)                 |                      | 1707 (49)                     | 4819 (53)                   |                      |  |
| ASA 4, n (%)                               | 572 (8)                             | 1527 (7)                    |                      | 153 (4)                       | 329 (4)                     |                      |  |
| Cognitive impairment,<br>n (%)             | 2123 (28)                           | 6001 (27)                   | < 0.001*             |                               |                             |                      |  |
| Approach                                   |                                     |                             | < 0.001*             |                               |                             | < 0.001*             |  |
| Anterior, n (%)                            | 516 (7)                             | 1748 (8)                    |                      | 291 (8)                       | 707 (8)                     |                      |  |
| Lateral, n (%)                             | 5663 (75)                           | 18,741 (83)                 |                      | 2642 (76)                     | 7485 (82)                   |                      |  |
| Posterior, n (%)                           | 1280 (17)                           | 1805 (8)                    |                      | 525 (15)                      | 720 (8)                     |                      |  |
| Missing approach, n<br>(%)                 | 80 (1)                              | 345 (2)                     |                      | 41 (1)                        | 175 (2)                     |                      |  |
| Frequency of<br>response (PROMs), n<br>(%) |                                     |                             |                      | 2299 (66)                     | 5930 (65)                   | 0.64*                |  |

#### Table 1. Baseline

\*Chi-square.

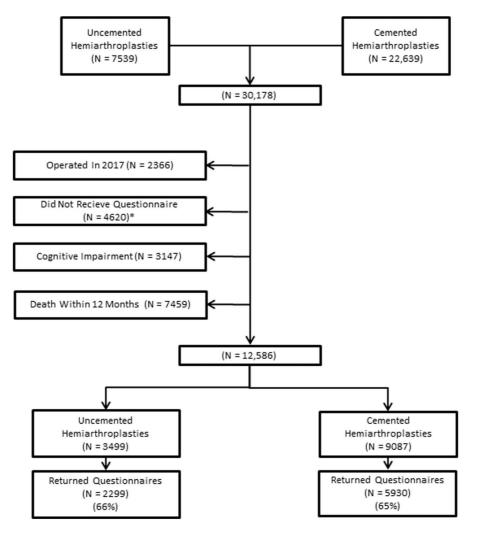
+Student's t-test.

PROMs = patient-reported outcome measures; ASA = American Society of Anesthesiologists.

PROM paper questionnaires were sent to patients at 4, 12, and 36 months after primary surgery to collect VAS scores for pain in the operated hip (range, 0-100; 0 means no pain, 100 means unbearable pain), EuroQol (EQ)-VAS scores, and EQ-5D-3L scores. The EQ-5D-3L questionnaire comprises five dimensions (walking ability, ability for self-care, ability to perform usual activities, pain or discomfort, and anxiety or depression) [12]. Preoperative EQ-5D-3L questionnaire swere collected retrospectively along with the questionnaire sent to the patients 4 months postoperatively, and these questionnaires were sent to patients who underwent reoperation, as well. In this report, we chose to present the PROM data 12 months after surgery, in line with published recommendations for PROM data in registries [40].

Patients who returned the PROMs questionnaires were younger than the overall group of patients at baseline (median age, 83 versus 84 years) and healthier (according to ASA classification) (Table 1). Among the PROM questionnaire responders, the cemented hemiarthroplasty group had more women, longer surgical times, and the posterior approach was used less often compared with the uncemented group. The surgical approach, stem fixation, and other details when performing hemiarthroplasty were selected according to each hospital's routine protocol; more than 99% of cemented hemiarthroplasties in Norway are implanted with antibiotic-loaded cement [32]. In Norway, the decision about which implant type should be used in hospitals is driven by a tender process at the regional level. The hemiarthroplasties included in the analyses were performed at 54 hospitals, of which one only used uncemented hemiarthroplasties, 14 only used cemented hemiarthroplasties, and 39 used both types of hemiarthroplasties. Mainly contemporary implants were used (Table 2). Bipolar heads were usually (about 85% of the time) from the same manufacturer as the stem. Accordingly, we did not consider the brand of the bipolar head when analyzing the results.

A reoperation was defined as any secondary procedure performed after primary hemiarthroplasty. The surgeons report reoperations, including closed reduction for dislocation, osteosynthesis for periprosthetic fracture, or softtissue débridement for infection. Reoperations were linked to the primary operation using the unique 11-digit Norwegian personal identification number and side that was



**Fig. 2** This figure shows a flowchart of patients with patient-reported outcome measures 1 year after surgery. \*From 2007 to 2009, because of a lack of resources, only a randomly selected group of patients were asked to answer the questionnaires

operated on, regardless of the hospital at which the primary operation was performed.

### **Statistical Analysis**

We used the Pearson chi-square test to compare categorical variables, and we used an independent t-test for continuous variables in independent groups. Data is presented in a Cox model in line with a recent published recommendation when estimating relative revision risk from arthroplasty register data [37]. The Cox regression model was used to calculate hazard rate ratios (HRRs) for any reoperation, reoperations for specific causes and mortality, with adjustments for age, sex, comorbidities (ASA class), cognitive function, surgical approach, and duration of surgery.

Patients without reoperations were censored at the time of death or emigration, or on December 31, 2017. Because death is a potential competing risk that may influence the accumulated probability of reoperation, regression analyses for competing risk were performed. We applied the Fine and Gray regression model for subhazards [13]. These results were compared with the results of the Cox proportional hazards regression model, and no important differences between the analyses were identified, so we present herein results from our Cox model. Additional analyses of patients who underwent bilateral operations were not performed; a previous study showed that adjusting for bilateralism would have a negligible influence on the results [25]. The significance level was set at 0.05. The statistical analyses were performed using the statistical package IBM SPSS Statistics, version 24 (IBM

| Table | 2. | Type ( | of | imp | lants |
|-------|----|--------|----|-----|-------|
|-------|----|--------|----|-----|-------|

| Uncemented hemiarthroplasty                 |            |       | Cemented hemiarthroplasty                     |            |       |  |  |  |
|---|------------|-------|---|------------|-------|--|--|--|
| Name  | Number (%) |       | Name  | Number (%) |       |  |  |  |
| Total number                                | 7539 (100) |       | Total number                                  | 22,639     | (100) |  |  |  |
| Corail <sup>®</sup> (DePuy Synthes)         | 5979       | (79)  | Exeter <sup>™</sup> (Stryker)                 | 11,604     | (51)  |  |  |  |
| Filler® (Biotechni)                         | 854        | (11)  | Lubinus® SP II® (Link)                        | 3003       | (13)  |  |  |  |
| Polarstem <sup>™</sup> (Smith and Nephew)   | 252        | (3)   | Charnley <sup>®</sup> (DePuy Synthes)         | 2445       | (11)  |  |  |  |
| SL-PLUS <sup>™</sup> (Smith and Nephew) 164 |            | (2)   | Charnley Modular <sup>®</sup> (DePuy Synthes) | 1896       | (8)   |  |  |  |
| HACTIV <sup>®</sup> (Evolutis) 111          |            | (2)   | Spectron <sup>™</sup> (Smith and Nephew)      | 1385       | (6)   |  |  |  |
| Furlong <sup>®</sup> (JRI Orthopaedics) 109 |            | (1)   | CPT <sup>®</sup> (Zimmer Biomet) 8            |            | (4)   |  |  |  |
| Other                                       | 70         | (0.9) | Titan <sup>™</sup> (DePuy Synthes)            | 817        | (4)   |  |  |  |
|   |            |       | C-Stem <sup>®</sup> (DePuy Synthes)           | 356        | (2)   |  |  |  |
|   |            |       | MS-30 <sup>®</sup> (Zimmer Biomet)            | 223        | (1)   |  |  |  |
|   |            |       | Other   | 69         | (0.3) |  |  |  |

DePuy Synthes is located in Leeds, UK; Stryker is located in Kalamazoo, MI, USA; Biotechni is located in La Ciotat, France; Smith & Nephew is located in Memphis, TN, USA; LINK is located in Hamburg, Germany; JRI Orthopaedics is located in Sheffield, UK; Evolutis, in Briennon, France; Zimmer Biomet is located in Warsaw, IN, USA.

Corp, Armonk, NY, USA) and the statistical package R (http://CRAN.R-project.org). This study was performed in accordance with the Reporting of Studies Conducted using Observational Routinely-collected Data (RECORD) statement and Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [4].

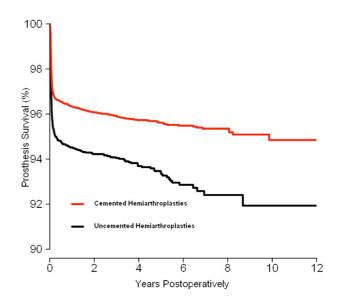
## Results

After controlling for relevant confounding variables like age, sex, comorbidities, cognitive function, surgical approach, and duration of surgery, there was a higher overall risk of reoperation for any reoperation in patients with uncemented hemiarthroplasties (HRR, 1.5; 95% CI, 1.4–1.7; p < 0.001) than for those with cemented hemiarthroplasties (Fig. 3). When assessing reoperations for specific causes, we found there were higher risks of reoperation because of periprosthetic fracture (HRR, 5.1; 95% CI, 3.5–7.5; p < 0.001), infection (HRR, 1.2; CI, 1.0–1.5; p = 0.037), aseptic loosening (HRR, 3.9; 95% CI, 1.4–10.9; p = 0.008), and reoperation for other reasons (HRR, 1.9; 95% CI, 1.3–2.6; p < 0.001) for uncemented hemiarthroplasties than for cemented hemiarthroplasties (Table 3).

After controlling for relevant confounding variables like age, sex, comorbidities, cognitive function, surgical approach, and duration of surgery, there was no difference in the 1-year mortality rate between the fixation groups (HRR, 1.0; 95% CI, 0.9–1.0; p = 0.12). Patients with uncemented hemiarthroplasty, however, had lower mortality at days 0 and 1 than patients with cemented hemiarthroplasty (HRR, 0.4; CI, 0.3–0.5; p < 0.001) (Table 4). For the

remainder of the patients' lifetimes, as well as in aggregate, there were no differences in mortality (Fig 4).

No differences between uncemented and cemented hemiarthroplasties were found regarding pain (19 versus 20, p = 0.052) in the operated hip, and quality of life (EQ-VAS score 64 versus 64, p = 0.43, EQ5D index score 0.64 versus 0.63, p = 0.061) 1 year after surgery (Table 5). Additionally, no differences were found between the groups when measuring the



**Fig. 3** In this figure, a Cox regression curve for reoperations after uncemented and cemented Hemiarthroplasties is shown, with adjustments for age, sex, comorbidities (American Society of Anesthesiologists [ASA] class), cognitive function, surgical approach, and duration of surgery.

| Reasons for<br>reoperations | Uncemented hemiarthroplasty |         | Cemented her | HRR*    | 95% CI |          |         |
|-----------------------------|-----------------------------|---------|--------------|---------|--------|----------|---------|
|                             | Number                      | Percent | Number       | Percent |        | 95% CI   | p value |
| Total                       | 433                         | 6       | 834          | 4       | 1.5    | 1.4-1.7  | < 0.001 |
| Infection                   | 179                         | 2       | 425          | 2       | 1.2    | 1.0-1.5  | 0.037   |
| Fracture                    | 88                          | 1       | 53           | 0.2     | 5.1    | 3.5-7.5  | < 0.001 |
| Dislocation                 | 95                          | 1       | 237          | 1       | 1.1    | 0.8-1.4  | 0.55    |
| Aseptic loosening           | 9                           | 0.1     | 8            | 0.04    | 3.9    | 1.4-10.9 | 0.008   |
| Other                       | 62                          | 0.8     | 111          | 0.5     | 1.9    | 1.3-2.6  | < 0.001 |

#### Table 3. Reoperations

\*Cox regression analysis adjustments for age, gender, comorbidity (ASA class), cognitive function, surgical approach, and duration of surgery; ASA = American Society of Anesthesiologists.

change in the index EQ-5D-3L score from preoperatively to 1 year postoperatively (-12.9 versus -12.7 ; p = 0.75), or when comparing the proportion of patients in each group whose EQ-5D-3L score at 1 year postoperatively reached the preoperative EQ-5D-3L score (37% versus 36%; p = 0.81).

Subanalyses on reoperations and mortality, adjusted for same variables as the main results, were performed on patients from hospitals that used either an uncemented (n = 3286 of 7539) or a cemented stem (n = 12,644 of 22,639) for all patients in a given time period. A higher overall risk of reoperation for any reoperation was found with uncemented hemiarthroplasties (HRR, 1.7; 95% CI, 1.4–2.1; p < 0.001) than for those with cemented hemiarthroplasties. Patients with uncemented hemiarthroplasties, however, had lower mortality at days 0 and 1 (HRR, 0.4; CI, 0.2–0.7; p = 0.001) and from day 2 to 7 (HRR, 0.7; CI, 0.5–0.9; p = 0.003) than patients with cemented hemiarthroplasty. For the remainder of the patients' lifetimes there were no differences in mortality.

#### Discussion

Reoperation is a devastating complication for an elderly and frail patient with a hip fracture. Therefore, efforts

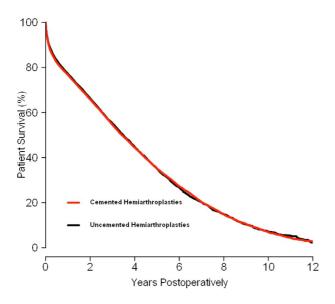
| Table 4. | Morta | lity |
|----------|-------|------|
|----------|-------|------|

should be made to improve treatment to minimize the likelihood of this event. Many recommendations suggest cement, though these suggestions are inconsistently followed. Based on data reported in the Norwegian Hip Fracture Register, with its high completeness and generalizability, we have studied the rate of reoperations, mortality, and PROMs. We found a lower risk of reoperation after cemented hemiarthroplasty than after uncemented hemiarthroplasty, mainly because of fewer periprosthetic fractures and infections. One year postoperatively, the type of hemiarthroplasty fixation was not associated with differences in mortality, pain scores, or quality of life.

This study had some limitations. First, in a register study, the patients, methods, and surgeons are not randomized, leading to a risk of confounding factors and possible selection bias. From our annual hospital reports, we have seen that most hospitals have used either an uncemented or a cemented stem for all patients in a given time period. Therefore, we performed subanalyses that we compared with our main findings to mitigate selection bias. We adjusted for possible registered confounders such as age, sex, comorbidities (ASA class), cognitive function, surgical approach, and duration of surgery. Because this study reflects a broad sample of practice across an entire

| Time from surgery<br>to death | Uncemented hemiarthroplasty |     | Cemented hemiarthroplasty |    | HRR* | 95% Cl          | p value |
|-------------------------------|-----------------------------|-----|---------------------------|----|------|-----------------|---------|
|                               | Nunber of deaths            | %   | Number of deaths %        |    |      | <i>33</i> /0 Ci | pruide  |
| Total                         | 4830                        | 64  | 13,903                    | 61 | 1.0  | 1.0-1.0         | 0.64    |
| 0-1 days                      | 38                          | 0.5 | 272                       | 1  | 0.4  | 0.3-0.5         | < 0.001 |
| 2-7 days                      | 195                         | 3   | 571                       | 3  | 0.9  | 0.8-1.1         | 0.21    |
| 8-30 days                     | 384                         | 5   | 1142                      | 5  | 1.0  | 0.9-1.1         | 0.51    |
| 31-365 days                   | 1281                        | 19  | 3587                      | 17 | 1.0  | 0.9-1.1         | 0.75    |
| > 1 year                      | 2932                        | 55  | 8331                      | 56 | 1.0  | 1.0-1.1         | 0.61    |

\*Cox regression analysis adjustments for age, gender, comorbidity (ASA class), cognitive function, surgical approach, and duration of surgery; ASA = American Society of Anesthesiologists.



**Fig. 4** A Cox regression curve for mortality after uncemented and cemented Hemiarthroplasties is shown, with adjustments for age, sex, comorbidities (American Society of Anesthesiologists [ASA] class), cognitive function, surgical approach, and duration of surgery.

country, we believe that the study has high generalizability (external validity), and that the results also likely would generalize well to practice in other countries. Second, a large study like this may identify statistical differences that are not necessarily clinically important (such as the small difference in the risk of death identified in the first few days after surgery, which was not observed at subsequent time points when we observed no between-group differences). Readers must use good judgment when interpreting findings with very small effect sizes in large, observational trials; we believe this is a shortcoming worth tolerating, since randomized studies-which almost inevitably are much smaller-may fail to detect even larger (and clinically important) between-group differences owing to limited power, especially those pertaining to less common but still important complications. Additionally, since patients who undergo hemiarthroplasty sometimes are frailer, there would be a risk that only the healthiest patients would volunteer for a randomized study, and they would not be generalizable to the typical population.

Third, the difference in volume between the cemented hemiarthroplasty and uncemented might represent a confounding variable; Norwegian surgeons may have greater expertise with the cemented stem. We do not believe this affected results to any great degree because hospitals using uncemented hemiarthroplasties also use uncemented stems for planned THAs and have done this for many years, and thus have more-than-sufficient experience with this procedure.

There were additional limitations, as well. For example, low-grade infection is often difficult to diagnose and may present only as prolonged wound drainage or later aseptic loosening, and may, therefore, have been misreported in the register on the day of reoperation. In addition, such lowgrade infections in elderly and frail patients may be treated only with antibiotic suppression without reoperation. Hence, the infection burden may be even higher than reported. There is, however, no reason why the treatment strategy was different for cemented and uncemented hemiarthroplasties. Moreover, different bipolar heads used in combination with different stems might affect the rate of reoperation, especially in procedures performed for dislocation. The different stems were usually used with a bipolar head from the same manufacturer, and we could not adjust for bipolar heads in the Cox regression analyses. The stem and bipolar head must be seen as one unit. In addition, comparisons of many brands of cemented and uncemented hemiarthroplasties should be interpreted with caution. Differences in reoperations after cemented hemiarthroplasties with an increased risk of periprosthetic fracture for polished taper-slip stems have been reported [22]. One study [18] found inferior survivorship with the Titan<sup>™</sup> (DePuy Synthes, Leeds, UK) stem. When survivorship is lower with one particular device, it reduces the aggregate survivorship for the group in which it is reported. Still, most of the stems in our study had well-

 Table 5. Comparison of patient-reported outcome 1 year after surgery

| Patient-reported outcome measures | Uncemented<br>Mean | Cemented<br>Mean | Mean difference (95% CI) | p value*          |  |
|-----------------------------------|--------------------|------------------|--------------------------|-------------------|--|
| Pain                              | 19                 | 20               | -0.9 (-1.9-0.01)         | 0.052             |  |
| EQ-VAS                            | 64                 | 64               | 0.5 (-0.7-1.6)           | 0.43              |  |
| EQ-5D index                       | 0.64               | 0.63             | 0.01 (-0.005-0.03)       | 0.061             |  |
| ΔEQ-5D                            | -12.9              | -12.7            | -0.2 (-1.6-1.1)          | 0.75              |  |
| Percent reached preop EQ-5D       | 37%                | 36%              |                          | 0.81 <sup>+</sup> |  |

\*Students t-test.

†Chi-square test.

EQ = EuroQol.

documented excellent long-term results in register studies on THAs [11, 19]. The way the data were collected may have influenced results; for example, the preoperative EQ-5D-3L data were retrospectively collected 4 months after surgery, but there is no reason to believe that recall bias would be different between the two groups. One study comparing recalled data and prospective data found only moderate agreement concerning the patients' preoperative status [26]. In contrast, Howell et al. [20] found that the correlation between recalled data and prospective data was good. Finally, the patient response rate to the questionnaires was rather low (64%), probably because of old age and its associated comorbidities. Still, a response rate higher than 60% was considered acceptable by recent published recommendations for PROM data in registries [40].

After controlling for relevant confounding variables like age, sex, comorbidities, cognitive function, surgical approach and duration of surgery, our large registerbased study showed that the risk of reoperation was much higher for the uncemented hemiarthroplasties. These findings were strengthened by our subanalyses on patients from hospitals that only operated uncemented or cemented hemiarthroplasties for a time period, which mitigated selection bias. Our study with large numbers, strong methods, and high generalizability adds important information to existing evidence [8, 16, 27, 28, 43, 44] and national guidelines [6, 29-31] in the decisionmaking process. Our results are similar to previous studies and support those findings. Still, in our study, we found a total HRR of 1.5 for reoperations with uncemented hemiarthroplasties, which is lower than the HRR reported in an earlier study using data from the Norwegian Hip Fracture Register (2.1) [16]. One study [22] compared different stem designs and found more reoperations after hemiarthroplasties with polished taper-slip stems than with matte straight and anatomic composite beam stems. The increased proportion of taper-slip stems, used in the later years in our study, could explain why the HRR was lower in the present study than that in previous research. We also found a higher infection risk after uncemented hemiarthroplasty than after cemented hemiarthroplasty. Yli-Kyyny et al. [44] found a nonimportant tendency towards more infection after uncemented hemiarthroplasty than after cemented hemiarthroplasty in their large observational study in Finland. An earlier study, based on patients with data in the Norwegian Hip Fracture Register [16], found more reoperations for superficial infections after uncemented hemiarthroplasty than after cemented hemiarthroplasty. One possible explanation for more infections in uncemented hemiarthroplasty could be that antibioticloaded bone cement, which protects against postoperative infection, is used in nearly all cemented hemiarthroplasties in Norway [32].

After controlling for relevant confounding variables like age, sex, comorbidities, cognitive function, surgical approach and duration of surgery our large register study found no differences in overall mortality after 1 year. This is in line with a recent review [43] and earlier observational studies [8, 16]. This is, however, in contrast to a study from the National Hip Fracture Database in the UK, which reported a lower mortality rate for cemented hemiarthroplasty than for uncemented hemiarthroplasty [7]. Even if the overall mortality after 1 year is no different, our results are in concordance with other studies suggesting increased peri- and early postoperative mortality after cemented fixation [8, 16, 35, 41]. Bone-cement implantation syndrome could be an explanation for this [9, 33]. We recommend following the recently published safety guidelines from the Association of Anaesthetists of Great Britain and Ireland [17] to reduce the mortality risk when using cemented hemiarthroplasty for hip fracture. Engesæter et al. [10] found reduced intramedullary pressure when drilling a distal venting hole in the femur before cementation; this study, to our knowledge, has not been reproduced and could stimulate further investigations in this area.

In our large group of patients, we found similar PROMs between patients undergoing uncemented hemiarthroplasty and those undergoing cemented hemiarthroplasty, suggesting that fixation type does not affect the patients' quality of life when contemporary hemiarthroplasties are used. The mean values for EQ-5D-3L and pain scores in our study were comparable with those in a Swedish register-based study [24]. A systematic review and a Cochrane review have reported less pain and better function after cemented hemiarthroplasty than after uncemented hemiarthroplasty [21, 34]. However, most uncemented implants in these reviews are no longer in use. A randomized controlled trial comparing cemented and uncemented hemiarthroplasties with 5 years of followup found better Harris hip scores after uncemented hemiarthroplasty than after cemented hemiarthroplasty [23], but there was no difference in the index EQ-5D-3L score.

In summary, our study supports the use of cemented hemiarthroplasty to decrease the risk of reoperation, a potentially devastating complication for elderly and frail patients. The fixation method was not associated with differences in pain, quality of life, or the overall mortality rate 1 year after surgery. Uncemented hemiarthroplasty should not be used when treating elderly patients with hip fractures.

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**Acknowledgments** We thank Norwegian orthopaedic surgeons who have faithfully completed the paper forms for the Norwegian Hip Fracture Register that have made this study possible.

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