

Research Article

Cemented versus uncemented hemiarthroplasty for displaced femoral neck fractures: A randomized controlled trial with two years follow-up

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ABSTRACT

Objective: The aim of this prospective randomized trial was to compare cemented (CHA) and uncemented bipolar hemiarthroplasty (UCH) in patients with femoral neck fractures (FNF).

Methods: The study included 158 patients aged ≥ 76 years who underwent bipolar HA for displaced FNF. Patients were randomized in two groups: the cemented group (CHA, $n=79$) was treated with cement and the uncemented group (UCH, $n=79$) without cement. The groups were compared for operating time, blood loss and peroperative morbidity and mortality rates.

Results: Both the CHA and the UCH group did not differ significantly in terms of age (86 ± 5 vs. 84 ± 4 years), sex (58.3% male vs. 60.7% female), and comorbidities ($p=0.49$). The CHA group had a significantly longer operating time ($p=0.038$) and a greater intraoperative blood loss ($p=0.024$). In the CHA group there were 8 (10.1%) events of intraoperative drop in the oxygen saturation (SaO₂), whereas no such events were noted in the UCH group ($p=0.009$). Despite no significant difference between these two groups, we found that the CHA group was associated with a higher early postoperative mortality (8.8% in the CHA group versus 3.8% in the UCH group, $p=0.009$). Intraoperative fracture occurred in two patients (2.5%) of the UCH group. Over a 2-year follow-up period there were no significant differences between the groups regarding the rate of dislocation ($p=0.56$) or rate of postoperative periprosthetic fracture ($p=0.56$). There was a trend towards a better postoperative functional recovery at 6 week for the CHA group (77.1 ± 13.1 versus 71.3 ± 16.3), although the mean Harris Hip Score (HHS) at the end of 2 years was comparable ($p=0.55$).

Conclusion: Both CHA and UCH are acceptable methods for treating displaced femoral neck fractures. However, based on our results perioperative cardiovascular disturbances are less frequent and resulting in a potential lower early mortality with UCH. Therefore, UCH is particularly appropriate for elderly patients with pre-existing cardiovascular comorbidities.

Level of Evidence: Level II, Randomized Controlled Trial

Femoral neck fractures (FNF) are a growing problem in our aging society and have been associated with high morbidity and mortality. In European series, hip-fracture patients have a 30-day mortality of more than 10% and a 1-year mortality of 25–30% (1). Hemiarthroplasty (HA) using modular-head partial prostheses has become a common surgical procedure used to treat elderly patients who have suffered FNFs. However, controversy persists as to whether cemented or uncemented HAs are preferable. With cemented hemiarthroplasty (CHA), polymethylmethacrylate bone cement is used during surgery to create a solid bone-implant interference medium. A potential advantage of cement is less postoperative mid-thigh pain, because the femoral stem is more firmly fixed within the femur (2). CHAs, on the other hand, are associated with a higher risk of cardiac and respira-

tory complications secondary to the toxic effects of cement or pulmonary embolization of bone-marrow contents and polymethylmethacrylate particles (3). Uncemented hemiarthroplasty (UCHA) relies on the primary press-fit stability in the femur with long-term stability occurring secondary to endosteal microfractures at the time of preparation and subsequent bone ingrowth. UCHAs are suspected to be associated with a higher risk of periprosthetic fractures. The purpose of our study is to compare the results of HA using a cemented vs. press-fit uncemented femoral stem while focusing on any differences in intraoperative events, functional outcomes, and rates of postoperative complications between groups. We hypothesize that uncemented femoral stems used in UCHA for displaced FNFs in the elderly are associated with less perioperative adverse events compared to

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Table 1. Inclusion and exclusion criteria for participants in the study**Inclusion criteria**

- Displaced intracapsular hip fracture (Garden III–IV) in the patients aged over 76 years
- No concurrent joint disease
- Intact cognitive function
- Ability to ambulate independently with or without walking aids

Exclusion criteria

- Undisplaced or minimally displaced intracapsular hip fracture (Garden I–II)
- Patients with a pathological fracture secondary to malignant disease
- Patients with rheumatoid arthritis or symptomatic osteoarthritis
- Previous treatment to the same hip for a fracture
- Patients with a pre-existing hip abnormality requiring total hip replacement
- Patients who were deemed unsuitable for the surgical procedures by the anesthesiologist

a CHA using a cemented stem, and that the uncemented stem could be a reason for higher levels of residual pain, resulting in worse functional outcomes and a higher risk of periprosthetic fractures.

Materials and Methods

This prospective randomized study compares data of 158 patients aged ≥ 76 years who underwent bipolar HAs for displaced FNFs using an uncemented (CHA, $n=79$) or cemented (UCHA, $n=79$) bipolar HA with a 2-year follow up. All patients presenting to our institution between January 2013 and December 2015 having displaced FNFs were considered for inclusion in this study. The inclusion criteria were as follows: displaced FNF (Garden III–IV), patients' aged ≥ 76 years having no concurrent joint disease or previous hip fractures, those having intact cognitive functions (i.e., no diagnosis of dementia and at least seven correct answers on a 10-item Short Portable Mental Status questionnaire), and those having the ability to ambulate independently with or without walking aids. We excluded patients having nondisplaced or minimally displaced intracapsular hip fractures (Garden I–II), patients having pathological fractures, and those having rheumatoid arthritis or symptomatic osteoarthritis. We also excluded patients who were

deemed unsuitable for surgical procedures by the anesthesiologist. The inclusion and exclusion criteria are listed in Table 1. Informed consent was obtained from all individual participants included in the study. This research was approved by the Scientific Ethics Committee review board of the University Medical Centre Maribor.

In our study, patients were randomized into one of two groups. The CHA group was treated with the cement, and the UCHA group was treated without cement. After anesthetic assessment, patients were randomized using sealed, numbered, and opaque envelopes for treatment either with a cemented or an uncemented stem. Although the patients were blinded for the type of HA they received, we acknowledge the possibility that they may have been able to view their radiographs during their outpatient clinical visits. Surgeons and outcome assessors were aware of the allocated arms. Both groups were compared in terms of preoperative features (e.g., age, sex, associated comorbidities, and pre-fracture ambulatory status), intraoperative and postoperative complications, mortality rates, pain thresholds, and activity levels. Outcomes measured during operation included operating times (defined as skin-to-skin surgical time, measured in minutes), blood loss (in milliliters), and intraoperative blood-pressure changes.

Nine consultant or specialist orthopedic-trauma surgeons performed all operations. All were experienced in the use of cemented and uncemented stems, and they had performed a median of 14 operations each (range 7–23). All procedures were performed using a standard anterolateral approach. After removing the femoral head, the femoral canal was prepared by sequential reaming using reamers of increasing diameter. After cortical reaming was attained, the trial femoral head was inserted, the hip was reduced, and the stability of the hip joint was tested. Eventually, cementing was performed and a modular bipolar prosthesis was inserted as per stem and cup size. Cementing was done with 80-mg Palacos cement (Heraeus, Wehrheim,

MAIN POINTS

The objective of this prospective randomized trial was to compare cemented hemiarthroplasty (CHA) and uncemented bipolar hemiarthroplasty (UCHA) in patients who have suffered femoral neck fractures (FNF). Both CHA and UCHA are acceptable methods for treating displaced FNFs. However, based on our results, perioperative cardiovascular disturbances are less frequent and result in potentially lower early mortality with UCHA. Therefore, UCHA is more appropriate for elderly patients with pre-existing cardiovascular comorbidities.

Table 2. Baseline characteristics

	CHA group (n=79)	UCH group (n=79)	p
Sex, n			0.86
Female (%)	46 (58.3)	48 (60.7)	
Male (%)	33 (41.7)	31 (39.3)	
Age at fractures (years), mean (SD)	86 (5)	84 (4)	0.38
ASA score, n (%)			0.49
1-2	40 (50.6)	46 (58)	
3-4	39 (49.4)	33 (42)	
Preoperative Harris hip score, mean SD	76.3 (17.3)	79.8 (19.4)	0.29

*Values are expressed as mean, with standard deviation in parentheses, or as number of hips, with percentage in parentheses

CHA: compare cemented hemiarthroplasty; ASA: American Society of Anesthesiologists; SD: standard deviation; n: sample number

Germany). The cementing technique involved vacuum mixing, cement plugging, saline pulsed lavage, and retrograde introduction of cement with a cement gun. All implanted endoprostheses were produced by Ecofit™ (Implantcast). Closed-suction drains were placed in all patients. Similarly, uncemented modular bipolar HA was performed using the above-mentioned technique.

All patients lacking contraindications (e.g., allergy/hypersensitivity, risk or history of thrombosis or thromboembolism) received 2-g tranexamic acid (TXA) administered intravenously in two doses. The first dose was given preoperatively, and the second was given immediately postoperatively in the recovery room. All patients received perioperative antibiotic prophylaxis and 6-weeks' low molecular-weight heparin as a thromboembolic prophylaxis. After surgery, all patients were mobilized immediately with no restriction on hip movements or weight-bearing. Analgesia was standardized in both groups, and patients were discharged to their homes as soon as their conditions allowed.

Patients were initially reviewed after discharge at 6 weeks. Subsequent assessments were made at 3, 6, and 12 months. The final assessment was completed 2 years after the HA procedure.

Table 3. Comparison of cemented vs. uncemented bipolar HA

Parameter	CHA group (n=79)	UCH (n=79)	p
Operating time, mean±SD	67±18 min	51±16 min	0.038
Intraoperative bleeding	378±154 mL	296±131 mL	0.024
Intraoperative SaO2 drop	8 (10.1%)	0	0.009
Drop (≥30 mmHg) in systolic BP during stem insertion	15 (18.9%)	4 (5.1%)	0.007
Intraoperative femoral fracture	0	2 (2.5%)	0.31
VAS score			
6 week after surgery	4.7±2.1	5.4±2.5	0.25
6 month after surgery	3.4±1.6	3.3±1.4	0.78
Late periprosthetic fracture	1	2 (1.3%)	0.56
Dislocation	2 (2.5%)	1 (1.3%)	0.56
Deep infection	3 (3.7%)	0	0.31
Intraoperative death	0	0	1.00
Mortality			
Within 7 days	7 (8.8%)	3 (3.8%)	0.19
Within 24 month	24 (30.4%)	27 (34.2%)	0.61
Harris hip score			
6 week after surgery	77.1±13.1 (n=72)	71.3±16.3 (n=76)	0.09
24 month after surgery	81.2±9.5 (n=45)	79.6±8.4 (n=49)	0.55

n: sample number; SD: standard deviation; VAS: visual analog scale; SaO2: oxygen saturation of arterial blood; BP: blood pressure, mmHg: millimeters of mercury; CHA: compare cemented hemiarthroplasty

The main outcome measures of this study include complication rate and functional results between CHA and UCHA groups. Both groups were compared in terms of perioperative features (e.g., demographics and associated comorbidities per their American Society of Anesthesiologists (ASA) scores), intraoperative and postoperative complications, mortality rates, and hip function. Surgical methods were evaluated while accounting for the following aspects: operating time, intraoperative blood losses, suspected fat-embolic events (i.e., any intraoperative drop in blood pressure of more than 30-mm Hg or any unexplained drop in oxygen saturation (SaO₂) of more than 5%), or any unexplained cardiovascular disturbance during or immediately after stem implantation. Postoperative pain was assessed 6 weeks and 6 months after surgery using the visual analog scale (VAS) with responses ranging from 0 to 10. During the postoperative follow-up period, periprosthetic fractures, dislocations, and infections were recorded. Hip function was rated using the Harris Hip Score (HHS) (4), ranging from 0 to 100 points and covering a maximum of 44 points for absence of pain, 47 points for function, and 9 points for range of motion and absence deformity.

The two groups were compared using the 2-tailed Fischer's exact test for dichotomous variables and a Student's t-test was used for HHS, VAS scoring, and continuous variables (e.g., surgery time, blood loss, VAS, and HHS). A p value of <0.05 was considered statistically significant.

Results

The CHA and UCHA groups did not differ significantly in terms of gender (58.3% vs. 60.7% female), age (86±5 vs. 84±4 years), preoperative HHS (76.3±17.3 vs. 79.8±19.4), or comorbidities reflected by ASA classification. Table 2 summarizes the demographic and baseline characteristics of treated patients.

The clinical characteristics of patients during and after the HA procedure are presented in Table 3.

The CHA group had significantly longer operating times and greater intraoperative blood losses. The mean intraoperative blood loss was 378 mL (standard deviation (SD) 154 mL) in the CHA group and 296 mL (SD 131 mL) in the UCHA group, $p=0.024$). The mean operating time was 67 min (SD 18 min) for the CHA group and 51 min (SD 16 min) for the UCHA group. In the CHA group, there were eight (10.1%) events of intraoperative drops in SaO₂. No such suspected fat-embolic events were noted in the UCHA group. The difference was statistically significant ($p=0.009$). A hypotensive circulatory disorder, defined as a drop of systolic blood pressure of more than 30 mm after prior exclusion of other causal factors (i.e., volume deficit, bleeding), was also more pronounced in the group receiving a cemented stem (15 patients in the CHA group vs. 4 patients in the UCH group, $p=0.007$), suggesting cardiorespiratory disturbances may have been more common when using a cemented stem.

A total of seven patients died within 7 days postoperatively (8.8% in the CHA group and 3.8% in the UCHA group.) There were no major differences in the rate of mortality at 24 months between these groups (24 patients in the CHA group vs. 27 patients in the UCH group, $p=0.61$). In the UCHA group, two intraoperative periprosthetic fractures occurred. Both were treated with cerclage wires. One additional late periprosthetic fracture (13 months postoperatively) was fixed using a plate and screws. One dislocation in the UCHA group was caused by an undersized stem, which subsided and dislocated. This stem was revised to a cemented stem. The only two mechanical complications that occurred in the CHA group were two prosthesis dislocations after a fall. Both were treated with closed reduction.

There were no intraoperative deaths. However, there were seven (8.9%) postoperative deaths within 7 days in the CHA group compared to three (3.8%) deaths in the UCHA group. The 2-year mortality rate was similar between the two groups, with 30.3% in the CHA group and 34.2% in the UCHA group. At 3 months, the mean HHS was better in the CHA group compared with the UCH group ($p=0.09$). At the 24-month follow-up the mean HHS did not differ significantly ($p=0.55$). The mean HHS of the CHA group at this time was 81.2±9.5, and that of UCHA was 79.6±8.4 points. In summary, patients in both groups achieved similarly good functional results at 2 years. Of all patients, three (3.7%) in the CHA group developed deep postoperative infections. Reoperations with a two-stage strategy were required for all three patients. One of those patients died at 1 year postoperatively. The reported incidence of early deep infections following HA in literature varies specifically from 1.6% (5) to 4.9 (6).

Discussion

With the trends of global aging, FNFs have become an increasingly serious problem for elderly patients. Comparisons between CHA and UCHA mostly favored cemented fixation because of its superior pain relief, better postoperative hip functionality, and fewer loosening prostheses and periprosthetic fractures (2). However, many hip-fracture patients endured significant cardiovascular and cerebral comorbidities with little functional reserve. In these frail patients, operative time and blood loss greatly influence outcomes. Therefore, some surgeons prefer to apply the UCHA technique, because they believe it can reduce operation times and intraoperative blood losses. However, considerable evidence suggests that cementing has potential adverse physiological side effects. For example, cardiac arrhythmias and cardiorespiratory collapse, which occasionally occur upon cement application, are caused by the embolism of marrow contents forced into circulation or by the direct toxic effects of the cement. Pitto et al. showed severe embolic events and intraoperative pulmonary impairments during fixation of the cemented femoral component in total hip arthroplasty, whereas fixation without cement clearly demonstrated lower risks of embolism (7). Two large studies of over 20,000 patients each showed that perioperative death was significantly increased when cement was used (8, 9). Therefore, guidelines minimizing the risk

for bone-cement implantation syndrome both by surgeons and anesthesiologists have been published (10).

Despite no significant difference between the two groups we studied, we found that CHA was associated with higher early postoperative mortalities (8.8% in the CHA group vs. 3.8% in the UCHA group), and there were similar rates of mortality between the CHA (30.4%) and the UCHA groups (34.2%, $p=0.61$) at 2 years. Registered studies have shown higher mortalities during the first operative days of CHA (11-13). Based on these results and our analysis, we concur with the Scottish Intercollegiate Guideline Network that the use of UCHA in elderly patients having significant co-morbid disease is appropriate.

In our study we noted statistically significant less blood loss in the UCHA group ($p=0.024$), which is probably caused by significantly shorter operation times. All patients in both groups without contraindications received 2 g of TXA. Although the use of TXA increases the risk of thromboembolic events (i.e., deep-vein thrombosis), such increases were not observed in our study, which is consistent with other findings reported in randomized trials (14, 15). This indicates that, in our case, the use of TXA was not associated with increased thromboembolic events, because TXA acted as a clot stabilizer and not as a clot promoter (16).

Our results demonstrate that CHA was associated with significantly prolonged operation times, which is consistent with other studies (17, 18). These findings probably result from cement insertion and the waiting period for cement solidification. In addition to the operating time, there was a tendency toward higher infection rates in the CHA group, although no significant difference was found between the two groups. The most probable explanation could be that the shorter operation time lowered the risk of infection owing to less exposure to perioperative contamination. Prolonged operating times are not the only explanation for the higher infection risks for cemented HAs. An additional explanation could be that the cementation in some way created conditions that were conducive to the growth of bacteria. Necrotic bone tissue around the cement caused by cement toxicity or heat generation during curing could also foster growth media. The insertion of uncemented stems with less tissue necrosis and less exposition to perioperative contamination caused by shorter procedures may, therefore, lower the risk of infection.

In contrast to our hypothesis that the degree of residual pain was lower in patients treated with a cemented prosthesis, we did not find a significant difference in mid-thigh pain between the two groups. Although not significant, the VAS score was slightly higher 6 weeks after surgery in the UCHA group ($p=0.25$), whereas this difference was negligible at 6 months after surgery (3.4 in the CHA group vs. 3.3 in the UCH group, $p=0.78$). From the literature, mid-thigh pain is known to be more prevalent in uncemented prostheses. However, the reported incidence differs tremendously (2, 19, 20). Several factors can influence postoperative mid-thigh pain, including sizing, design, and prosthetic stiffness (21).

Major doubts regarding uncemented HA in the literature have been generated by the propensity for intraoperative and postoperative periprosthetic fractures. Late postoperative periprosthetic fractures and revisions caused by failure of osteointegration are known risks when using uncemented stems in elderly patients (22). In our study, intraoperative fractures occurred in two patients (2.5%) in the UCHA group. This higher risk, which was not statistically significant, was probably caused by the more technically difficult procedure that aims to achieve tight contact between the prosthesis and the endosteal bone surface. Furthermore, during the follow-up periods, there were no significant differences between groups regarding rates of dislocation (i.e., two dislocations (2.5%) in the CHA group vs. one dislocation (1.3%) in the UCHA group) or postoperative periprosthetic fractures (one (1.3%) in the UCHA group). Then again, 2-year follow-ups may not be sufficient to reach conclusions about implant loosening. Nonetheless, our results and findings were similar to those of DeAngelis regarding intraoperative periprosthetic fractures in randomized controlled trials of 130 patients with 1-year follow-ups, which indicated that uncemented stems could be used for elderly patients with osteoporotic FNFs without a high risk of periprosthetic fractures (23). Furthermore, prior studies showed that the CHA technique led to improved joint-function recovery (24). Although we did not demonstrate a statistically significant difference between the two groups, our study revealed a trend toward better postoperative functional recovery for CHA at 6 weeks. The postoperative hip function at 2 years was nearly the same, indicating that cemented prostheses delivered better functional results during the early stages ($p=0.09$) and over time. Following the operation, the differences of functional recovery became smaller.

Elderly patients having displaced FNFs and existing comorbidity suffer the highest risks of mortality. Our results add credence to the suggestion that uncemented femoral stems lower the risk of early perioperative death with similar outcomes as its cemented counterpart. Based on our results, there are more advantages of using an uncemented HA: less intraoperative bleeding, shorter durations of surgery, and lower risks of infection. Complications were distributed in both CHA and UCHA groups and were statistically insignificant. Functional outcomes at 1- and 2-year mortality rates were comparable between groups. Based on the results of this prospective randomized study, UCHA represents a good method for the surgical treatment of displaced FNFs and is particularly appropriate for elderly patients having pre-existing cardiovascular comorbidities.

Ethics Committee Approval: Ethics committee approval was received for this study from the Ethics Committee of University Medical Centre Maribor (146/02/12).

Informed Consent: Written informed consent was obtained from all individual participants included in the study.

Conflict of Interest: The author has no conflicts of interest to declare.

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