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Cemented Versus Uncemented Hemiarthroplasty for Displaced Femoral Neck Fractures: A Prospective Trial with Two Years Follow-Up

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Abstract

Introduction: The optimal treatment for elderly patients remains controversial regarding the use of cement when treating displaced femoral neck fractures with hemiarthroplasty. Previous randomized trials comparing cemented (CHA) and Uncemented Hemiarthroplasty (UCH) have conflicting results. We conducted a prospective trial to compare cemented versus uncemented bipolar hemiarthroplasty in any differences in intraoperative events, differences in functional outcomes and the rates of postoperative complications between these two groups.

Material and Methods: This prospective study compares data of 135 patients aged ≥ 76 years who underwent bipolar hemiarthroplasty for displaced femoral neck fracture using a cemented (n=56) or uncemented (n=79) bipolar hemiarthroplasty with a 2 year follow up.

Results: The cemented and uncemented group did not differ significantly in terms of age, sex, and comorbidities. The cemented group had significantly longer operating time (p=0.038) and greater intraoperative blood lose (p=0.024). There were 6 (10.7%) events of intraoperative drop of the SaO2 in the cemented group and no such events in the UCH group. Despite no significant differences between the 2 groups, we found that the CHA group was associated with higher early postoperative mortality (8.9% versus 3.8% in the UCH group). Intraoperative fracture occurred in 2 patients (2.5%) in the UCH group. During the 2-year follow-up period there were no significant differences between the groups regarding the rate of dislocation or rate of postoperative periprosthetic fracture. There was a trend towards better postoperative functional recovery at 6 weeks for CHA group, although the mean Harris hip score at the end of 2 years was almost the same.

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

Keywords: Femoral neck fracture; Hemiarthroplasty; Cemented hemiarthroplasty; Uncemented hemiarthroplasty

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Introduction

Femoral neck fractures are a rising problem in our aging society, frequently troubled with multiple and severe co-morbidities, and are 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% to 30% [1]. Hemiarthroplasty (HA) using modular head partial prostheses is a common surgical procedure used to treat elderly patients with femoral neck fractures. Hip HA is superior to internal fixation for displaced femoral neck fractures, enabling earlier mobility, less reoperations, and better functional outcome at one year. However, controversy persists as to whether cemented or uncemented HA is preferable for elderly patients. The discussion about cemented or uncemented HA is similar to the discussion about cemented or uncemented prostheses in primary total hip arthroplasty. In HA for hip fracture surgery there is insufficient data from randomized trials to conclude on the superiority of either type of arthroplasty.

In cemented hemiarthroplasty (CHA), polymethylmethacrylate bone cement is used during surgery to create solid bone-implant interference. A potential advantage of cement is less post-operative mid-thigh pain, as the femoral stem is more firmly fixed within the femur [2] whereas

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

Inclusion criteria	Displaced intracapsular hip fracture in the patients aged over 76
Exclusion criteria	Undisplaced or minimally displaced intracapsular hip fracture
	Patients with a pathological fracture secondary to malignant disease
	Previous treatment to the same hip for a fracture
	Patients who were not considered to be fit of either of the surgical procedures
	Patients with a pre-existing hip abnormality requiring total hip replacement

CHA are associated with a higher risk of cardiac and respiratory complications secondary to the toxic effect of cement or pulmonary embolization of bone marrow contents and polymethylmethacrylate particles [3]. Uncemented Hemiarthroplasty (UCHA) relies on primary press-fit stability in the femur with long-term stability occurring secondary to endosteal micro fractures at the time of preparation and subsequent bone in growth. UCHA have been thought to be associated with a higher risk of periprosthetic fractures. In HA for hip fracture surgery there is insufficient data from randomized trials to conclude on the superiority of either type of HA. The purpose of our study was therefore to compare the results of HA using a cemented versus press-fit uncemented femoral stem focusing on any differences in intraoperative events, differences in functional outcomes and the rates of postoperative complications between these two groups.

Material and Methods

This prospective study compares data of 135 patients aged ≥ 76 years who underwent bipolar HA for displaced femoral neck fracture using an uncemented (n=79) or cemented (n=56) bipolar HA with a 2 year follow up. All patients presenting to our institution between January 2013 and December 2015 with a displaced intracapsular fracture of the proximal femur were considered for inclusion in the study. The inclusion and exclusion criteria are listed in (Table 1). Informed consent was obtained from all individual participants included in the study. During the study period, there were no institutional guidelines regarding the choice between cemented or uncemented stems. Some patients were therefore operated by surgeons that prefer to apply the UCHA technique, because they believed that this procedure can reduce operation time, intraoperative blood loss and the risk of Bone Cement Implantation Syndrome (BCIS). The second group of patients was operated by surgeons that favoured cemented fixation because of their belief in superior outcome in pain relief, better postoperative hip function recovery, less prosthesis loosening and lower incidence of complication such as periprosthetic fracture. In our study patients were divided into one of two groups: CHA group was treated with the cement and UCHA group without cement. Both groups were compared in terms of preoperative features (age, sex, associated comorbidities and pre-fracture ambulatory status), pre- and postoperative complications, mortality rates, and pain and activity levels. Postoperative pain was assessed using the visual analog scale with responses ranging from 0 to 10. Outcomes measured during operation were operating time (defined as skin-to-skin surgical time, measured in minutes), blood loss (in millilitres) and intraoperative blood pressure changes. All operations were performed or supervised by one of the orthopaedic-trauma surgeons and all through a standard anterolateral approach. After removing the femoral head, the femoral canal was prepared by sequential reaming with 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. Finally cementing was performed and modular bipolar prosthesis was inserted as per stem and cup size. Closed suction drains were placed in all patients. Similarly, uncemented modular bipolar HA was done using the above-mentioned technique. All patients without contraindications (allergy/hypersensitivity, risk or history of thrombosis or thromboembolism) received 2 g of TXA administered intravenously in 2 doses: the first dose was given preoperatively, and the second dose was given immediately postoperatively in the recovery room. All patients received peri-operative antibiotic prophylaxis and 6 weeks of low molecular weight heparin as thrombo-embolic prophylaxis. After surgery all patients were mobilized as soon as they were able, with no restriction on hip movements or weight bearing. Analgesia was standardized in both groups and patients were discharged home as soon as their general condition allowed. Patients were initially reviewed six weeks after discharge. Subsequent assessments were at 3, 6 and 12 month and finally two years after the HA procedure. The main outcome measures of this study were complication rate and functional results between CHA and UCHA group. Both groups were compared in terms of perioperative features (demographics and associated comorbidities – ASA score), intra and postoperative complications, mortality rates and hip function. The surgical methods were evaluated taking the following aspects into account: operating time, perioperative blood loses, suspected fat-embolic events, which were defined as any intraoperative drop in blood pressure of more than 30 mm Hg or any unexplained drop in SpO2 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. In postoperative follow-up periprosthetic fractures, dislocations and infections were also recorded. Hip function was rated with Harris Hip Score (HHS) [4], which ranges from 0 to 100 points 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 primary outcome was the HHS after 24 months. For the statistical analysis the 2 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 score and continuous variables (such as surgery time, blood loss, VAS and HHS). A p value of <0.05 was considered statistically significant.

Results

In total 135 patients were analysed. 56 patients were treated with CHA and 79 were treated with UCHA. (Table 2) summarizes the demographic and baseline characteristics of treated patients. No statistically significant difference between CHA and UCH group were observed comparing the gender (62.5% *vs.* 60.7% female), patient's age (86 ± 5 *vs.* 84 ± 4 years), preoperative Harris hip score (76.3 ± 17.3 *vs.* 79.8 ± 19.4) and comorbidities reflected by American Society of Anesthesiologists (ASA) classification. The CHA group

Table 2: Baseline characteristics.

	CHA group (n=56)	UCH group (n=79)	p value
Sex, n			0.86
Female (%)	35(62.5%)	48(60.7%)	
Male (%)	21(37.5%)	31(39.3%)	
Age at fractures (years), mean (SD)	86(5)	84(4)	0.38
ASA score n (%)			0.49
1-2	29(51)	46(58)	
3-4	27(49)	33(42)	
Preoperative Harris hip score, mean SD	76.3(17.3)	79.8(19.4)	0.29

Table 3: Comparison of cemented versus uncemented bipolar hemiarthroplasty.

Parameter	CHA group (n=56)	UCH (n=79)	P value
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	6(10.7%)	0	0.004
Drop (≥ 30 mmHg) in systolic BP during stem insertion	11(19.6%)	4(5.1%)	0.01
Intra-operative femoral fracture	0	2(2.5%)	0.51
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	0	1(1.3%)	1
Dislocation	1(1.8 %)	1(1.3%)	1
Deep infection	2(3.6 %)	0	0.17
Intraoperative death	0	0	1
Mortality			
Within 7 days	5(8.9%)	3(3.8%)	0.27
Within 24 month	17(30.3%)	27(34.2%)	0.71
Harris hip score			
6 week after surgery	77.1 ± 13.1 (n= 47)	71.3 ± 16.3 (n= 73)	0.09
24 month after surgery	81.2 ± 9.5 (n= 34)	79.6 ± 8.4 (n=49)	0.55

had significantly longer operating time and greater intra-operative blood loss. The mean intra-operative blood loss was 378 ml (standard deviation (SD) 154 ml) in the CHA group and 296 ml (SD 131 ml) in the UCH 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 UCH group. There were 6(10,7%) events of intraoperative drop of the SaO2 in the CHA group. There were no such suspected fat-embolic events in the UCH group. The difference was statistically significant (p<0.01). A hypotensive circulatory disorder, which was defined as a drop of systolic blood pressure of more than 30 mm under prior exclusion of other causal factors (volume deficit, bleeding), was also more pronounced (11 patients) in the group receiving a cemented stem, suggesting cardio respiratory disturbances may be more common when using a cemented stem. A total of 8 patients died within 7 days postoperatively (8,9% in CHA group and 3.8% in UCHA group). There was no big difference in the rate of mortality at 24 months between the CHA (17 of 56, 30.3%) and UCH group (27 of 79, 34.2%, p=0.55). In the UCHA group, 2 intraoperative periprosthetic fractures occurred. Both were treated with cerclage wires. 1 additional late periprosthetic fracture (13 month postoperatively) was fixed with a plate and screws. 1 dislocation in the UCHA group was due to an undersized stem, which subsided and dislocated. This stem was revised to a cemented stem. The only mechanical complication that occurred in the CHA group was the dislocation of prosthesis after a fall, which was treated with closed reduction. There were no intraoperative deaths, but there were 8.9% postoperative deaths within 7 days in the group receiving a cemented stem, compared with 3.8% of in the uncemented group. The 2-year mortality rate was similar between groups, with 30.3% in the cemented group and 34.2% in the uncemented group. At 3 month, the mean HHS was better in the CHA group than in the UCH group (p=0.09). At the follow-up 24 month after surgery the mean HHS did not differ significantly. The mean HHS of the CHA group at this time of period was 81.2 ± 9.5, and that of UCHA was 79.6 ± 8.4 points (no significant difference; p=0.55). Thus, patients in both groups at 2 years attained similarly good functional results. Of all patients, 2 patients in CHA group developed deep postoperative infection. In both reoperations were needed with a 2 stage strategy, where removal of prosthesis, debridement of soft tissue and bone was performed, and a joint spacer was inserted. Following removal of the infected prosthesis, antimicrobials with activity against the infecting organisms were administered for 6 weeks. Reimplantation of a new prosthesis was undertaken following completion of antibiotic therapy. One of those patients died at 1 year postoperatively. In the literature the reported incidence of early deep infection following HA

specifically varies from 1.6% [5] to 4.9 [6].

Discussion

With the trend of global aging, femoral neck fractures have become an increasingly serious problem for elderly patients. HA, as an effective treatment, can help resume the walking ability as soon as possible, thereby reducing the risk of respiratory infection and urinary tract infection. In elderly patients with a displaced femoral neck fracture HA is therefore the widely accepted treatment of choice. Comparisons between CHA and UCHA have mostly favoured cemented fixation because of superior outcome in pain relief, better postoperative hip function recovery, less prosthesis loosening and periprosthetic fractures [2]. On the other hand, many hip fracture patients have significant cardiovascular and cerebral co-morbidities with little functional reserve. In these frail patients, operative time and blood loss can influence outcome. Therefore, some surgeons prefer to apply the UCH technique because they believe it can reduce operation time, and intraoperative blood loss. In addition, there is considerable evidence that cementing has potential physiologically adverse side effects. The major side effects, cardiac arrhythmias and cardio-respiratory collapse, which occasionally occur upon cement application, are caused by embolism from marrow contents forced into the circulation or by a direct toxic effect of the cement. Pitto et al. [7] have already shown severe embolic events and intraoperative pulmonary impairment during fixation of the cemented femoral component in total hip arthroplasty, while fixation without cement clearly demonstrated a low risk of embolism. In addition, 2 large studies of over 20.000 patients each have shown that perioperative death is significantly increased when cement is used [8,9]. Therefore guidelines to minimize the risk for BCIS by both surgeons and anesthesiologists are published [10]. Despite no significant difference between the 2 groups, we found that CHA was associated with higher early postoperative mortality (8.9% in the CHA group versus 3.8% in the UCH group) and there were similar rates of mortality between the CHA (17 of 56, 30.3%) and UCH group (27 of 79, 34.2%, p=0.55) at 2 year. Also the register studies show higher mortality in the first operative days in 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 with significant co-morbid disease is appropriate. In our study we found statistically significant less blood loss in UCH group (p=0.024) which is probably due to significantly shortened operation time in this group. All patients in both groups without any contraindications received 2 g of TXA administered intravenously in 2 doses: the first dose was given preoperatively, and the second dose was given immediately postoperatively in the recovery room. Although the use of TXA increase the risk of thromboembolic events (especially deep vein thrombosis), in our study such increases were not observed, which is consistent with other findings reported in randomized trials [14,15]. The use of TXA is not associated with increased thromboembolic events, because effects of TXA are more pronounced in operative wounds than in peripheral venous blood. This is because generation of tissue plasminogen activator ensues in wounds. Thus, TXA acts as a clot stabilizer and not a clot promoter [16]. Our results demonstrated that CHA was related with significantly prolonged operation time, which was consistent with other studies [17,18]. These results probably result from the process of cement insertion and the waiting time for solidification of cement. In addition to the operating time, there was a tendency of higher infection rate in the CHA group although no significant difference was found between two groups. Probable explanation could be that the shorter operation time lowers risk of the infection due to less exposition to perioperative contamination. The prolonged operating time is probably not the only explanation for the higher infection risk for cemented HAs. Additional possible explanation could also be that the cementation per se in some way creates conditions that are conductive to the growth of bacteria following the apparently unavoidable contamination perioperatively. Necrotic bone tissue around the cement, caused by cement toxicity or heat generation during curing of the cement, could be the potential growth medium. The insertion of uncemented stems with less tissue necrosis and less exposition to perioperative contamination due to shorter procedure may therefore lower the risk of infection. In contrast to our hypothesis that the degree of residual pain is lower in those treated with a cemented prosthesis, we did not find a significant difference in mid-thigh pain between two groups. Although not significant, the VAS score was just slightly higher 6 weeks after surgery in UCH group (p=0.25), whereas this difference 6 month after surgery was negligible (3.4 in CHA group versus 3.3 in UCH group, p=0.78) In the literature mid-thigh pain is known to be more prevalent in uncemented prostheses, however the report incidence differs tremendously [2,19,20]. Several factors can influence post-operative mid-thigh pain such as sizing, design and stiffness of prosthesis [21]. The major doubt with uncemented hemiarthroplasty stems in the recent literature is the propensity for intraoperative and also late post-operative peri prosthetic fracture. Late post-operative periprosthetic fracture and revision due to failure of osteointegration are known risk factors when using uncemented stems in elderly [22]. In our study intraoperative fracture occurred in 2 patients (2.5 %) in the UCH group. This higher risk of intraoperative femoral shaft fracture in the UCH group, which was not statistically significant, is probably due to the technically more difficult procedure of trying to achieve a tight contact between the prosthesis and the endosteal surface of bone. Also, during a follow-up period there was no significant difference between the groups regarding the rate of dislocation (1 (1.8%) in CHA group and 1 (1.3%) in UCH group) or postoperative periprosthetic fracture (1 (1.3% in UCH group), but two-year follow up may not be sufficient to make conclusions about implant loosening. However, our results and also similar to results of De Angelis [23] regarding intraoperative periprosthetic fractures in an RCT of 130 patients with a 1-year follow up indicated that the uncemented stem could be used for elderly patients with osteoporotic fractures of the femoral neck without high risk of periprosthetic fractures. In addition, previous studies [24] showed that CHA technique could bring better joint functional recovery. In our study, although we could not demonstrate a statistically significant difference between the 2 groups, there was a trend towards better postoperative functional recovery for CHA at 6 weeks. The postoperative hip function at 2 years was almost the same, indicating that cemented prostheses brought better functional result in the early stage (p=0.09), and then with the time passing after the operation the difference in functional recovery is getting smaller.

Limitations

This study suffers from three main limitations: having a nonrandomized design, an unequal number of subjects in the two groups and a relatively short follow-up period. A larger group of patients would have improved its statistical power.

Conclusion

Elderly patients with displaced femoral neck fracture and existing comorbidity are at highest risk of mortality. Our results

add credence to the suggestion that on one hand an uncemented femoral stem lowers the risk of early peri-operative death and on the other hand in experienced hands offers similar outcomes to its cemented counterpart. Based on our results the advantages of using an uncemented HA are also less intraoperative bleeding, shorter duration of surgery and thereby lower risk of implant infection. Complications were distributed in both cemented and uncemented hemiarthroplasty groups and were statistically insignificant. Functional outcomes at 1-year and 2-year mortality were comparable between groups. Based on results of this prospective study it could be concluded, that uncemented hemiarthroplasty represents a good method for the surgical treatment of proximal femoral fractures, particularly appropriate for elderly patients with pre-existing cardiovascular comorbidities.

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