Dual Mobility Acetabular Cup Versus Hemiarthroplasty in Treatment of Displaced Femoral Neck Fractures in Elderly Patients: Comparative Study and Results at Minimum 3-Year Follow-up

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Abstract

Background: Hip fractures are serious injuries associated with relatively high mortality rates and disabilities, commonly seen in elderly persons. There is an ongoing debate regarding the advantages of various hip arthroplasty devices. This study aimed to analyze the long-term advantages of 2 different surgical procedures and assess if the dislocation rate, Harris Hip Score (HHS), and functional independence measure (FIM) are more favorable in dual mobility (DM) than those in hemiarthroplasty (HA). Hypothesis: Dual mobility procedures provide better postoperative outcomes than HA in terms of HHS, FIM, and dislocation rate. Materials and Methods: The survey was a prospective, comparative interventional single-blinded study performed at the University Clinical Center of Kosovo, a tertiary health-care institution. A total of 94 patients underwent DM or conventional bipolar HA for repair of displaced femoral neck fractures within 2 weeks of injury. Primary outcomes were postoperative dislocation rate, FIM, and HHS. Secondary outcomes included duration of surgery, estimated intraoperative blood loss, time to first postoperative full weightbearing, time to walking ability with and without crutches, mortality rate, and postoperative infection rate. Results: There were no significant differences for most parameters between the groups. We found a significant difference in the dislocation rate between the 2 groups, wherein there were no dislocations in the DM group and 3 dislocations in the HHS group (0% vs 6.4%). In terms of postoperative HHS at 12 months and 3 years, DM provided better outcomes (<0.034 and <0.014, respectively). Discussion: Dual mobility compares favorably to HA in terms of dislocation rate and HHS, while no difference was found for FIM. In order to have a more complete overview, we recommend more intense long-term studies including several heterogeneous parameters to compare the clinical outcomes between DM and HA. Level of evidence (with study design): Level II.

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Introduction

Based on their location, femoral neck fractures account for 45% to 53% of hip fractures. The simplified Garden classification groups femoral neck fractures as displaced and nondisplaced. The 3 major treatments for femoral neck fractures in clinical practice are internal fixation, hemiarthroplasty (HA), and total hip arthroplasty (THA).¹ An international survey concluded that surgeons prefer internal fixation for younger patients and arthroplasty for older patients; however, they disagree on the optimal implants for internal fixation or arthroplasty.² In displaced femoral neck fractures in elderly patients, there is an ongoing clinical and scientific discourse among orthopedists regarding the most satisfactory arthroplasty device. The optimal surgical approach is focused on acquiring better function with lower risks of complications in patients with displaced femoral neck fractures.^{3,4}

The incidence of dislocation is significantly lower with the dual-mobility (DM) cup than with the unipolar cup.⁵ Nevertheless, higher physical demands, even in older adults, occasionally necessitate conversion surgery to THA; these processes are likely to increase both the possible risks and the associated costs.^{6,7} A recent study suggested that medium-term outcomes for THA after hip fracture in fit older patients are excellent.⁸

The aim of our study was to address the following questions:

- 1. Does DM as surgical procedure have lower postoperative dislocations in comparison to HA?
- 2. Does DM show better outcome as measured by the Harris Hip Score (HHS) and Functional Independent Measure (FIM) in comparison to HA?
- 3. Does the length of operation (time) and blood loss in DM impact the infection and mortality rate in comparison to HA?

Patients and Methods

Patients

The participants of this study were the patients registered in the multicenter trauma unit at the Orthopaedic Clinic of University Clinical Center of Kosovo (UCCK) who underwent DM or HA for repair of displaced femoral neck fractures within 2 weeks of injury. The patients were informed of the study, and after written informed consent was obtained, we initiated the procedures. Inclusion criteria were as follows: (1) displaced femoral neck fractures; (2) patient aged 70 years or older; (3) informed consent obtained, (4) treated with HA or DM, and (5) followed-up for minimum 3 years. Exclusion criteria included the following: (1) patients with pathological fractures; (2) patients with

any type of neurological disorder that could affect (directly or indirectly) bone density or future recuperation (including paresis or hemiparesis, multiple sclerosis, Parkinson's disease, and other chronic neurodegenerative diseases); and (3) patients with preexisting coxarthrosis in the same hip.

In order to eliminate bias in patient selection for surgical procedures, treatment decisions were made in a random manner where even-numbered patients underwent DM and odd-numbered patients underwent HA. Patients were divided into 2 equal groups based on the procedure: group HA and group DM. The patients were blinded to the modality of the surgical procedures in order to obtain the single-blinded status (Figure 1).

All together 293 patients with displaced femoral neck fracture registered in UCCK Orthopedic Clinic from January 2008 till January 2014. In the study were included only patients who were admitted on the shift of the appointed study senior surgeon giving 114 eligible patients. Each of these patients before surgery underwent an examination from anesthesiologist, neurologist, and data-collecting junior orthopedic surgeon. A total of 18 patients were excluded: 4 of them did not give consent to be part of the study, 3 had dysplastic coxarthrosis on the injury side, 7 had neurological disorder (hemiparesis, Parkinson, and dementia), and 4 with American Society of Anesthesiologists (ASA) 4 who refused surgery due to possible complications.

We have conducted sample size analysis using G*Power software by comparing the mean values of HHS of each group. The power of 0.80 and a significance level of 0.05 showed that there is a minimum of 35 patients at follow-up in each group to detect a clinically significant difference.

The study protocol was approved by institutional review board's approval at the UCCK. All data obtained during study were managed anonymously using the codes and no names of patients. This study was performed according to the ethical standards of Declaration of Helsinki for clinical trials subject.

Methods

This was a prospective, comparative interventional study, single-blinded, performed in the University Clinical Center of Kosovo, a tertiary health-care institution. The period of enrollment was 6 years: January 2008 to January 2014.

All surgeries were performed by a single senior surgeon specialized in HA and THA. Only spinal anesthesia was performed. Preoperative intravenous cefazolin was administered, and deep vein thrombosis prophylaxis was applied. Mobilization at day-1 postoperatively was encouraged.

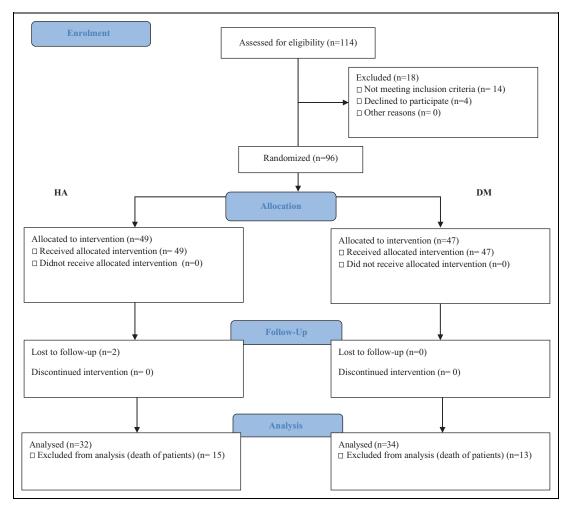


Figure 1. CONSORT trial flow diagram.

Patients were positioned laterally, and a posterior approach was used to expose the proximal femur, the capsule, and the acetabulum. The joint capsule was opened using a T-shaped capsulotomy, and the femoral head was extracted. The acetabulum was prepared by eroding with acetabular reamers for the DM. The femoral neck was cut following measurement for the femoral stem. The femoral canal was prepared using progressive rasps to achieve a good fit of the trial implant into the shaft. The range of motion and joint stability were checked with the trial implants in place. The implant was placed, and the posterior capsule was sutured.

Patients with DM received cementless acetabular components: Dual Mobility Cup (HAP Quattro VPS cup; GroupeLépine, Genay, France), material CoCr, Anatomic and Cylindro spherical design, 6 equatorial fins, and 4 tropical spikes for primary stability. Dual mobility liner: UHMWPE material, adapted for 22.2- or 28-mm heads. Patients with HA received the Bipolar cementless acetabular prosthesis UHL (GROUPE LÉPINE). In both groups, cemented and cementless PAVI femoral stem (GroupeLépine) with neck shaft angle 135°, option versus 130°, was used (cementless 34.4% and cement 65.6%). Orthopedic surgery bone cement (AMINOFIX 3; GroupeLépine) was used.

Methods of Assessment

Patient demographic and analyzing factors were as follows: gender, age, body mass index, ASA level, fracture type, mechanism of injury, FIM, HHS, intraoperative blood loss (the blood loss measured in the suction bottles minus lavage fluid and total blood loss (in litres) =PBV \times (Hctpre – Hctpost) \times Hctave), length of operation, postoperative full weight-bearing, walking ability timing with/out crutches, mortality rate, and postoperative complication rate (dislocation, infection, and periprosthetic fracture).

The major outcomes were evaluated at 3, 6, 12, and 36 months, by examinations mentioned above, together with anterior–posterior (AP) and axial plain radiographs.

Statistical Analysis

All variables were summarized using appropriate descriptive statistics and graphics. The normality of the data was checked using the Shapiro-Wilk test. The differences between both groups with respect to the clinical results were assessed using independent t tests or nonparametrical Mann-Whitney U tests.

 Table 1. Patient Demographics.

	HA (n = 47)	DM (n = 47)	P Value
Age, years	77.64 <u>+</u> 4.7	78.11 ± 5.4	40.670
BMI, kg/m ²	26.66 ± 3.36	26.96 ± 3.3	20.667
Gender, male/female (%)	68/32	49/51	.019
ASA level, n (%)			1.000
I	14 (29.8)	13 (27.6)	
II	25 (53.2)	24 (51.I)	
III	8 (17.0)	10 (21.3)	

Abbreviations: BMI, body mass index; ASA, American Society of Anesthesiologists; DM, dual mobility; HA, hemiarthroplasty.

Table 2. Analysis of HHS.^a

	HA	DM	U Value	P Value
HHS 3 months post-op	(n = 43)	(n = 43)	826.000	.376
	86.81 mean	87.95 mean		
	6.464 SD	5.682 SD		
HHS 6 months post-op	(n = 39)	(n = 42)		
	87.33 mean	90.93 mean	633.000	.077
	8.679 SD	6.979 SD		
HHS I-year post-op	(n = 33)	(n = 39)		
	88.45 mean	92.28 mean	457.000	.034
	8.273 SD	7.163 SD		
HHS 3 years post-op	(n = 29)	(n = 34)		
	88.31 mean	92.47 mean	315.500	.014
	7.691 SD	5.986 SD		

Abbreviations: HHS, Harris Hip Score; SD, standard deviation; DM, dual mobility; HA, hemiarthroplasty.

^aAll participants, *P* values statistically significant (*P* < .05, Mann-Whitney *U* test).

Mortality was compared between groups using Pearson chisquare tests and chi-square test for 2×2 contingency tables as well as using Fisher exact test. A *P* value of <.05 was considered statistically significant. The IBM SPSS Statistics 20 program was used for all statistical analyses.

Results

In the patient cohort (n = 94), the mean age of patients undergoing HA and DM was 77.64 and 78.11 years, respectively. No significant differences in baseline demographic characteristics were found, except in gender (Table 1).

The rate of postoperative complications within 90 days was 8.5% (6.5% dislocations and 2.0% infection) in the HA group and 6.3% (4.2% superficial infection, 2.1% periprosthetic fracture, and no dislocation) in the DM group. There were no dislocations in the DM patients, while in the HA group there were 3 (0% vs 6.4%). Two dislocations occurred due to hip hyperflexion: one during rapid sitting (in the bathroom) on day 21 and the other during transfer from bed to chair on day 16. Another dislocation occurred while getting up from the bed on day 30. Dislocation cases in the HA group were managed by open reduction. One patient developed deep tissue infection

Table 3. Analysis of Secondary End Points of Patients (HA vs DM).^a

	HA	DM		Р
	(n = 47)	(n = 47)	U/t Value	Value
Blood loss intra-op/ ml	159.26 mean 25.216 SD	178.19 mean 20.600 SD	3.987 ^b	<.000
Duration of surgery/ min	57.77 mean 4.979 SD	63.72 mean 5.261 SD	473.500 ^c	<.000
Time to first postoperative full weight-bearing	2.40 mean .681 SD	2.47 mean .584 SD	999.500°	.348
Time to walking ability with 2 crutches, weeks	2.36 mean .640 SD	2.23 mean .428 SD	1035.500 ^c	.492
Time to walking ability with I crutch, weeks	4.00 mean .676 SD	3.92 mean .587 SD	653.000 ^c	.692
FIM	83.19 mean 6.103 SD	84.94 mean 4.870 SD	933.500 ^c	.193

Abbreviations: FIM, functional independence measure; SD, standard deviation; DM, dual mobility; HA, hemiarthroplasty.

^aAll participants, *P* values statistically significant (P < .05, ^bIndependent *t* test, ^cMann-Whitney *U* test,).

(*Staphylococcus aureus* identified) in the HA group, which was managed by wound incision, open lavage, perfusion drainage, and antibiotics; however, no implant removal was required. In the DM group, 2 superficial wound infections were managed with antibiotics, and 1 fracture of the greater trochanter was managed conservatively. In all cases of infections, a 5-course sample culture was obtained until the culture became sterile.

In terms of HHS, the differences between the DM and the HA groups increased over time in favor of the DM group. There were no significant differences between the groups at the third (P=.376) or sixth month (P = .077). However, the HHS at first and third year postoperatively showed significantly better results (P < .05 for both) in the DM group (Table 2). Postoperative FIM showed no significant differences between the groups.

The mean length of surgical procedure was significantly longer (P = .001) in the DM group (63.33 \pm 5.036) than that in the HA group (57.00 \pm 4.551). Mean blood loss was greater in the DM group (173.13 ± 2 0.526) than that in the HA group (152.67 \pm 31.275, P < .05). Mean walking ability time with 2 crutches and 1 crutch for both groups showed no significant differences (Table 3).

There was no difference in the mortality rate between the groups: at 30 days (P = 1.000), 60 days (P = .536), 1 year (P = .199), and 3 years (P = .652). There were no significant associations between the types of surgery and the mortality rates on the basis of gender at each measured time point: female, after 30 days (P = 1.000), after 90 days (P = .142), at 1 year (P = .085), or after 3 years(P = .141) and male, after 30 days(P = .707), after 90 days (P = .726) after 1 year (P = 1.000), or after 3 years (P = .561; Table 4).

		30 days	90 days	l year	3 years
HA	n (%)	4 (8.5%)	7 (14.9%)	12 (25.5%)	15 (31.9%)
THA P-value	n (%)	4 (8.5%) I.000 ^b	5 (10.6%) .536°	7 (14.9%) .199°	13 (27.7%) .652 ^c

Table 4. Mortality Rate of Patients (HA vs DM).^a

Abbreviations: THA, total hip arthroplasty; DM, dual mobility; HA, hemiarthroplasty.

^aAll participants, P values statistically significant (P < .05, ^bPearson Chi-square, ^cFisher Exact Test).

Discussion

There is still an ongoing debate whether DM or HA has better advantages for displaced femoral neck fractures in older population.^{7,9} To our knowledge, this is the first study to evaluate the HHS for a period of 3 years tending to prove this parameter in long-term approach compared to other studies. The results of this study show that DM has better primary outcome compared to HA.

In structured analyses of the parameters, we found that DM had significantly lower postoperative dislocations than did HA. This result matches with 2 previously performed studies.^{4,10} In our series, there were 3 (6.4%) dislocations in the HA group, all within the first 90 days; they were managed by open reduction.

Literature reports HA dislocation incidence of 1% to 15%,¹¹⁻¹³ with influencing factors divided into 3 categories: patient, surgeon, and surgical factor. Manipulation of some of these factors has the potential to reduce the incidence of dislocations and improve patients' overall outcomes.¹⁴ Patient factors have been excluded in our study; however, we have surgeon and surgical factor. Many studies favored the anterolateral approach over the posterior approach basing their recommendations primarily on the lower dislocation rate. These studies include that of Unwin and Thomas who analyzed 3118 consecutive HAs and noted a 3.3% versus 9% dislocation rate for anterolateral versus posterior approach, respectively.¹⁵ Varley and Parker reviewed 81 papers and pooled data relating to HA dislocation following the use of cemented and uncemented stems.¹⁶ They reported dislocations in 144 of the 6863 uncemented cases in comparison to 157 dislocations of the 4322 cemented cases. This difference was not statistically significant when adjusted for surgical approach.²⁶

There were no dislocations in the DM group. The DM group showed excellent results at more than 10 years of follow-up with less than 1% to 2% dislocation rates in primary, revision, recurrent THA dislocation, and THA after femoral neck fractures.¹⁷ Furthermore, THA with DM for young patients was demonstrated to be a relevant surgical option with no dislocations and excellent clinical results and survival rates at more than 10 years of follow-up.^{18,19}

Furthermore, we analyzed some secondary parameters and observed that operation length of time and blood loss during DM had no impact on infection and mortality rate at 1 year compared to that in HA, and we concluded that these treatment outcomes are highly dependent on other conditions. The differences in intraoperative blood loss, operation length of time, and outcomes scores favoring the DM group are statistically significant, but the clinical significance is questionable, as the true differences are small hence limiting studying conclusions.

The Kosovar population is considered relatively young; nevertheless, recently the birth rate has begun to decrease. The proportion of people at aged 65 years and older was only 8% of nearly 2 million inhabitants.²⁰ Therefore, the number of hip fractures will continue to increase as the population ages, and the optimal selection of method for THA will remain a priority. Altogether, the demographic data of patients enrolled in the study did not show significant differences between the groups (DM vs HA), particularly in terms of age (P < .327). In both study groups, the number of male patients was higher, more so in the DM group than in the HA group (68.1% vs 31.9% and48.9% vs 51.1%). Our results confirm some findings of previous studies, while in terms of other indicators, we found differences. The comparison of surgical technique (THA vs HA) did not show significant differences in terms of several indicators. The comprehensive analysis of primary outcomes of the study also revealed no significant differences in most of the parameters.

However, there was 1 deep tissue infection in the HA group that was managed by wound incision, perfusion drainage, and antibiotics; however, no implant removal was required. This increased the reoperation rate to 8.5% in the HA group. In the DM group, there were 2 superficial wound infections that were managed by antibiotics, and there was one fracture of the greater trochanter that was managed conservatively. The results of this study demonstrate similar short-term complication and mid-term revision rates following HA and THA with DM for intracapsular hip fracture. The data suggest that both procedures are safe alternatives; however, further study is needed to clarify the differences in functional outcomes and long-term revisions for patients undergoing these procedures following hip fracture.

We found a significant difference between the groups in terms of HHS postoperatively at 1 and 3 years (<.034 and <.014, respectively). The HHS increased progressively over time and was more significant in the third year of follow-up, suggesting that DM was a more reliable surgical technique. Previous orthopedic trials have addressed the effect of DM versus HA on patient outcomes; however, the trials conducted to date were limited by small sample sizes, lack of concealed randomization, and differential expertise biases²¹ that lacked sufficient power to provide conclusive information. Orthopedic surgeons appear to currently favor HA, although current evidence suggests more optimal patient outcomes with THA.^{22,23}

A later study suggested that total hip replacement has longterm advantages over bipolar HA; however, these findings were less definite.²⁴ Another study reported that THA was associated with better functional outcomes and lower reoperation rates than HA for the treatment of displaced femoral neck fractures in the elderly individuals, similar to findings by Liao et al.²¹ However, more current data showed no significant differences in the complication rates between HA and THA.^{10,21,25,26} Moreover, the literature shows lower risk of reoperation after THA compared to HA and better functional outcomes for patients following THA than that with $HA^{6,10,22,26}$ as observed in this study.

The National Institute for Health and Care Excellence clinical guidelines¹⁹ recommend that patients should be offered THA for displaced intracapsular hip fractures if they are able to walk independently outside with only 1 cane, are not cognitively impaired, and are medically fit for anesthesia and the procedure. Recognizing the ambiguity of the evidence, this guidance clearly allows for a significant amount of clinical judgment to be made by the orthopedic surgeon as to how suitable they believe the patient is for THA.

Several retrospective studies^{23,27} and review articles²² have reported that patients who undergo THA for displaced femoral neck fractures experience less pain, have better hip function, and are less likely to undergo revision surgeries than those undergoing HA, primarily if they underwent THA with DM to avoid dislocations. Therefore, THA with DM provides both efficacy and stability with good functional results, especially for high-risk patients.^{19,28}

We have considered several study limitations. Simple randomization was used, and due to complex procedures of registration and waiting list of patients for surgical intervention, we could not apply other modalities of randomization. The inability to follow-up the FIM in the 3-year period of the study. We have followed the FIM only up to the first year of the study. No patient-recorded outcome was used, and due to official protocol procedure in our home institution, no ASA 4 patients were included in the study.

Conclusions

Dual mobility has advantages over HA for the treatment of displaced femoral neck fractures in elderly patients, related to the safety indicators, postoperative complications, and functional performance. Although we did not find difference in FIM indicator and to obtain more comprehensive conclusion, we generally recommend that more inclusive target studies need to be performed in order to demonstrate other advantages of DM to HA.

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Contribution of author

Skender Ukaj contributed to study conception and design, data acquisition, manuscript drafting, and critical revision. Osman Zhuri contributed to study conception and design and data acquisition. Fatime Ukaj contributed to data analyses and interpretation. Vlora Podvorica and Kushtrim Grezda contributed to data acquisition, manuscript drafting, and critical revision Jacques Caton and Jean Louis Prudhon contributed to Study conception and design. Shaip Krasniqi contributed to Manuscript drafting and critical revision

Declaration of Conflicting Interests

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