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ORTHOPAEDIC SURGERY

Hemiarthroplasty versus internal fixation in super-aged patients with undisplaced femoral neck fractures: a 5-year follow-up of randomized controlled trial

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Abstract
Introduction There were higher rates of revision, complication, non-union, delayed union, and poorer functional outcomes reported in super-aged patients of undisplaced femoral neck fractures treated with internal fixation. Therefore, we designed this randomized comparative study aiming to compare the effectiveness and long-term follow-up results of hemiarthroplasty (HA) with that of multiple cannulated screws (MCS).
Materials and methods Eligible participants were randomly assigned into two groups for different methods of operation (hemiarthroplasty group and internal fixation group). The related indexes and data of two groups were collected for comparative analysis during the average follow-up period of 38.68 ± 28.24 months.
Results There were only two patients performed reoperation in HA group, and the reoperation rate of HA group (5.41%, 2/37) was significantly lower than that of IF group (21.4%, 9/41) (P value = 0.000). The comparison of survival curves for reoperation showed significant differences between two groups (P value = 0.031).The results of Cox proportional hazards model suggested that only operation method significantly affected the occurrence of reoperation (P value = 0.049). The results of survival analysis showed that there was no significant difference in survival time between two groups (P value = 0.682). And in the Cox proportional hazards model, only age significantly affected the occurrence of death (P value = 0.000). The average Harris scores of two groups were all above 75 points, and there was no significant difference in Harris scores between the two groups (P value greater than 0.05). But in the early term follow-up, the excellent and good rate of hip joint function in HA group was significantly higher than that in IF group (P value less than 0.05).
Conclusions Hemiarthroplasty with less postoperative complications, low reoperation rate and better function recovery in early stage provide a good choice for the treatment of super-aged patients with nondisplaced femoral neck fracture.

Keywords Hemiarthroplasty · Undisplaced · Super-aged · Femoral neck fractures · Internal fixation

Introduction

Femoral neck fracture was a common trauma in clinic. The number of patients was estimated to reach 63 million all over the world in 2050 [1]. It was reported that the elderly patients made up an overall majority, especially patients over 80 years old, accounting for 62% of the total [2].

For these super-aged patients with femoral neck fractures, scholars generally recommend the use of artificial hip arthroplasty for the treatment of displaced femoral neck fractures, but there still were disputes for the treatment of non-displaced femoral neck fractures.

In the beginning, all patients with non-displaced femoral neck fractures, whether the young or elderly even the super-aged, were indiscriminately treated with internal fixation. The internal fixation methods included multiple

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cannulated screws (MCS), dynamic hip screw (DHS), locking plate and others [3–10]. Among these methods, MCS was the most common one [3, 5, 7, 9].

But the results of internal fixation treatment were rather unsatisfactory, as opposed to what we had expected. There were higher rates of revision, complication, non-union, delayed union, and poorer functional outcomes reported in elderly patients [11–13]. And these poor results were particularly prominent in super-aged [5, 13–15]. These super-aged patients had been reported to have more than 16% failure rate of internal fixation and over 30% reoperation rate [5, 13, 15]. Compared with younger patients, their length of hospital stay was significantly prolonged and the mortality was increased obviously [3].

Faced with poor performance of internal fixation, the scholars explored the way to solve the problem. Since internal fixation was directly or indirectly associated with troubles, some scholars put forward another alternative surgical treatment to the internal fixation—hemiarthroplasty (HA) [13, 15–18], and good clinical results had been obtained [13, 17, 18].

At present, different scholars hold different views on these two methods of surgical treatment for super-aged patients with undisplaced femoral neck fractures [13, 17, 19], thus there existed great disputes on the advantages and disadvantages of them. And for these previous clinical studies were all retrospective researches, the accuracy and credibility were low.

Therefore, we designed this randomized comparative study aiming to compare the effectiveness and long-term follow-up results of hemiarthroplasty (HA) with that of multiple cannulated screws (MCS) in treating super-aged patients with undisplaced femoral neck fractures.

As far as we know, there have been no other reports published on this prospective randomized comparative research on the two treatments of internal fixation and hemiarthroplasty for super-elderly patients with non-displaced femoral neck fracture.

Patients and methods

There were two participating regional medical centers: Affiliated Taizhou People's Hospital of Nantong University and Affiliated Hospital of Jiangnan University.

From January 2008 to December 2010,participants were enrolled consecutively from super-aged patients with undisplaced femoral neck fracture treated in the two medical centers. Inclusion criteria were: Over 80 years of age, fresh, capable of walking independently or with aids before injury, clear consciousness and no serious cognitive impairment: score of three or more in short portable mental status questionnaire (SPMSQ) [20], ASA classification between level 1 and 3, and time of injury to surgery was not more than 72 h. Exclusion criteria were: pathological fracture, pain in the hip before injure, refused to join this study.

A total of 78 patients were admitted into this study (45 patients in Affiliated Taizhou People's Hospital of Nantong University and 33 patients in Affiliated Hospital of Jiangnan University) (Fig. 1).

There were male 20 cases, female 58 cases, age 80 ~ 100 years, mean 86.04 ± 4.30 years old in 78 patients. According to Garden classification [21], there were 38 cases of type I fracture and 40 cases of type II fracture. The follow-up time ranged from 1 to 92 months, averaged (38.68 ± 28.24) months. According to computer-generated random numbers, 78 participants were randomly assigned to two groups of different operation methods: internal fixation (IF) group (41 patients) and hemiarthroplasty (HA) group (37 patients). This study was approved by the human research ethics committee of two participating medical centers, complying with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Surgical procedures

All operations were completed by two groups of well experienced expert surgeons with the standard operation procedure under general anaesthetia.

Multiple cannulated screws (MCS)

Patients underwent internal fixation surgery on orthopedic table. Then three 6.5 mm cannulated screws (AO) were inserted into the femoral necks, and the implant placement was the same as described by Probe and Ward [22].

Hemiarthroplasty (HA)

All hemiarthroplasties were performed using a modified hardinge approach [23] in the lateral decubitus position. Artificial Joint Prosthesis used was a cemented exeter stem (Smith & Nephew Medical Lid, UK) and a bipolar head (Smith & Nephew Medical Lid, UK) with 28 mm diameter inner head in all cases. Above processes used same cement (Tecres S.P.A., Italy) using third-generation cementing techniques.

All patients were given intravenous infusion of cefazolin 2 g as antibiotic prophylactics for 3 days after surgery, and subcutaneous injection of low molecular weight heparin as thromboembolic prophylactics for 10 days after the operation.

Measurement and assessment

The relevant data of operation were recorded by an independent full-time nurse each group. The complications related to operation such as nonunion, osteonecrosis, loosening and migration of implant were confirmed by

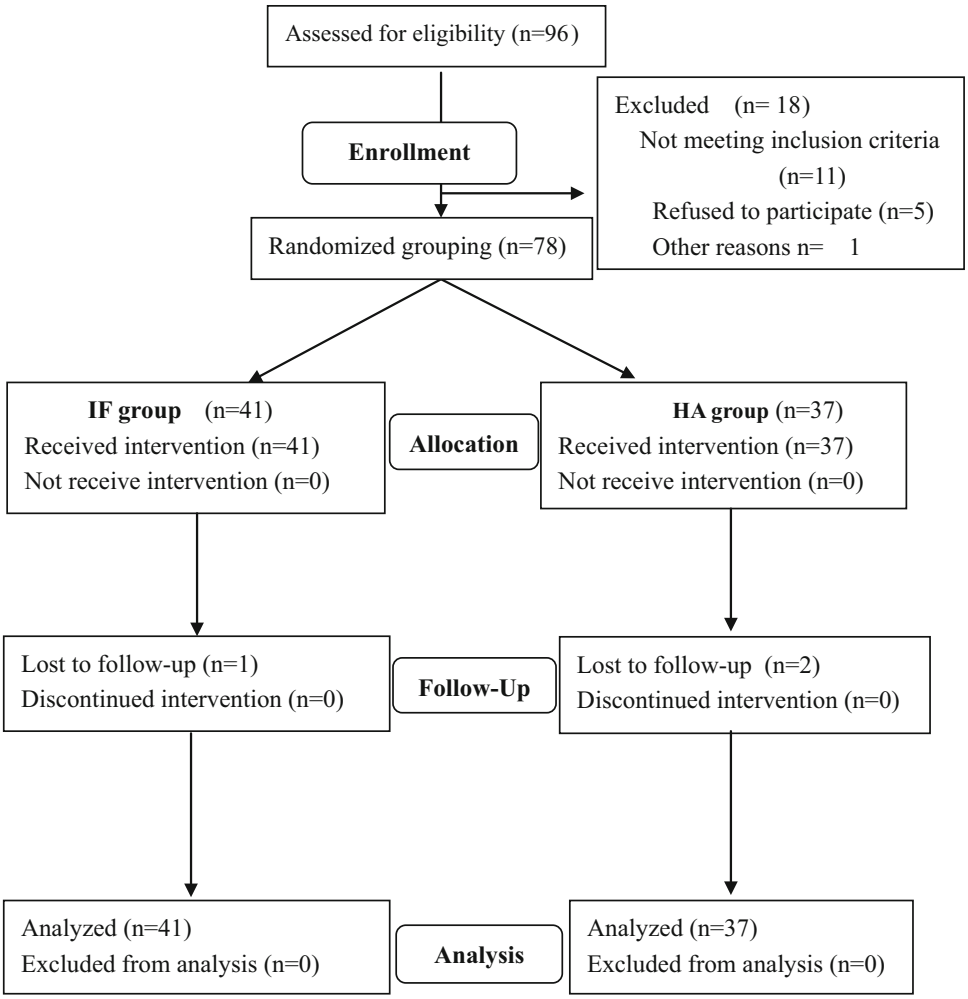

Fig. 1 The consort flow diagram

digital radiographs and CT of hip joint. All digital radiographs and CT were assessed by an independent senior radiologist who played no other roles in this study. This evaluation of postoperative hip function were accomplished by Harris hip score (HHS) [24].

Statistical analysis

The group size of this study was estimated using the power analysis through statistical analysis system (SAS) 9.0 software. With $\alpha = 0.05$, $\beta = 0.2$ and a power of 80%, the power analysis showed that the required sample size was 70.8 cases. According to the results of calculation, we enrolled 78 patients in this study.

Ten variables were chosen for survival analysis in this study. The Kaplan–Meier method was used to depict the survival curves, and differences between two groups were analyzed for significance by the log-rank test. Multivariate analysis was performed using the Cox proportional regression model to assess the relationship of selected factors with reoperation and survival time.

This study used IBM SPSS Statistics 19 to make survival analyses. The *P* value of less than 0.05 was considered to be statistically significant difference.

Results

As shown in Table 1, the demographic data and preoperative related indicators had no differences between two groups ($P > 0.05$). But in comparison of the two groups of surgery related indicators, IF group showed overwhelming advantage (*P* value was 0.000) (Table 2).

The results of this study showed that the incidence of perioperative complications was basically equivalent in two groups (8/41 VS 8/37, *P* value was 0.818), while the incidence of complications directly related to surgery in HA group was significantly less than that in IF group. No artificial joint dislocation occurred in HA group during follow-up, and prosthesis loosening occurred in only one patient in postoperative 48 months. But in IF group, internal fixation related complications included early

Table 1 Baseline data of general characteristics for all patients included in the study

	MCS ($n = 41$)	HA ($n = 37$)	P value
Gender (n, %)			
Males	12 (29.3%)	8 (21.6%)	0.604[a]
Females	29 (70.7%)	29 (78.4%)	
Age (years) ($M \pm$ SD)	85.85 ± 3.93 (80 ~ 95)	86.24 ± 4.72 (81 ~ 100)	0.692[b]
Garden (n, %) classification			
Type I	20 (48.8%)	18 (52.4%)	0.991[a]
Type II	21 (51.2%)	19 (51.4%)	
Cause of injury (n, %)			0.666[a]
Simple fall	32 (78.0%)	27 (72.9%)	
Fall from a height	6 (14.6%)	5 (13.5%)	
Vehicular trauma	3 (7.3%)	5 (13.5%)	
Injury-surgery interval (h) (n, %)			0.907[a]
<6	5 (12.2%)	5 (13.5%)	
6 ~ 12	12 (29.3%)	8 (21.6%)	
12 ~ 24	11 (26.8%)	9 (24.3%)	
24 ~ 48	8 (19.5%)	10 (27.0%)	
48 ~ 72	5 (12.2%)	5 (13.5%)	
Mean preoperative Hb (g/L) ($M \pm$ SD)	106.4 ± 13.8	106.76 ± 16.3	0.926[b]
BMI (body mass index) (kg/m^2) (n, %)	26.58 ± 6.10 (17 ~ 39)	26.62 ± 5.70 (18 ~ 39)	0.979[b]
Up to 25 (normal weight)	17 (41.5%)	13 (35.1%)	0.880[a]
25 ~ 30 (overweight)	14 (34.1%)	14 (37.8%)	
More than 30 (obese)	10 (24.4%)	10 (27.0%)	
Osteoporosis (N) (n, %)			0.856[a]
Osteoporosis	18 (43.9%)	17 (45.9%)	
No	23 (56.1%)	20 (54.1%)	
Walking aids (n, %)			0.766[a]
None	19 (46.3%)	20 (54.1%)	
Stick or crutches	16 (39.0%)	13 (35.1%)	
Walking frame	6 (14.6%)	4 (10.8%)	
Comorbidities (n, %)			
Hypertension	6 (14.6%)	9 (24.3%)	
Diabetes	4 (9.8%)	3 (8.1%)	
IHD	3 (7.3%)	2 (5.4%)	
COAD	2 (4.9%)	4 (10.8%)	
Cerbral infarction	1 (2.4%)	0 (0)	
Renal inadequacy	0 (0)	1 (2.7%)	
Hypertension and diabetes	5 (12.2%)	4 (10.8%)	
Hypertension and IHD	3 (7.3%)	2 (5.4%)	
IHD and COAD	2 (4.9%)	1 (2.7%)	
Hypertension and COAD	2 (4.9%)	2 (5.4%)	
Hypertension and CI	2 (4.9%)	0 (0)	
Hypertension and diabetes and IHD	1 (2.4%)	1 (2.7%)	
ASA classification (n, %)			0.669[a]
1	11 (26.2%)	8 (21.6%)	
2	18 (42.9%)	14 (37.8%)	
3	13 (31.0%)	15 (40.5%)	

MCS multiple cannulated screws, *HA* hemiarthroplasty, *M* mean, *SD* standard deviation, *N* number of patients, *Hb* haemoglobin, *N/A* not applicable, *ASA* American Society of Anaesthesiologists, *CCF* congestive cardiac failure, *COAD* chronic obstructive airways disease, *IHD* ischaemic heart disease, *DHS* dynamic hip screw, *CI* cerebral infarction

[a] χ^2-test

[b] Independent-sample t test

Table 2 Comparison of operative outcomes in two group for treatment of undisplaced femoral neck fractures in super-aged patients

	MCS ($n = 41$) ($M \pm SD$)	HA ($n = 37$) ($M \pm SD$)	P value
Length of incision (cm)	3.8 ± 0.53	12.3 ± 2.57	0.000[a]
Operation time (min)	43.80 ± 6.47	64.03 ± 8.76	0.000[a]
Blood loss (mL)	28.66 ± 6.41	175.08 ± 25.69	0.000[a]
Haemoglobin drop (g/L)	17.73 ± 4.19	32.16 ± 6.14	0.000[a]
Blood transfusion	2/41	18/37	0.000[b]
Hospital stay (days)	10.44. ± 1.83	14.16 ± 1.32	0.000[a]

M mean, *SD* standard deviation, *MCS* multiple cannulated screws, *HA* hemiarthroplasty

[a] Independent-sample *t* test

[b] χ^2-test

displacement failure of internal fixation in two cases, nonunion in three cases, avascular necrosis of femoral head in four cases, and symptomatic prominence of the screws in one case. Therefore, so many internal fixation related complications increased the total incidence of complications of IF group (43.90%, 18/41) which was significantly higher than that of HA group (24.32%, 9/37) (*P* value was 0.000).

This study showed that the vast majority of the reoperations in IF group were performed for the treatment of internal fixation related complications. Two cases of internal fixation failure, early displacement and three cases of nonunion patients of IF group underwent hemiarthroplasty for reoperation. In four patients with femoral head necrosis, two patients were operated on by means of artificial hip arthroplasty surgery for progressing to stage IV in follow-up. Hardware removal was performed in 22 months after operation for symptomatic prominence of the screws in one case. The final reoperation in IF group occurred in 34 months after surgery. This patient received the operation of proximal femoral nail antirotation (PFNA) for intertrochanteric fractures caused by falls (Table 3). But in HA group, there were only two patients underwent reoperation, thus the reoperation rate of HA group (5.41%, 2/37) was significantly lower than that of IF group (21.4%, 9/41) (*P* value was 0.000) (Table 3).

The Fig. 2 showed the survival curves of reoperation in two groups. The comparison of survival curves showed significant differences between two groups (*P* value = 0.031), and the reoperation of IF group was significantly more than that of HA group. The results of Cox proportional hazards model suggested that only operation method significantly affected the occurrence of reoperation (*P* value = 0.049), (HR 4.656; 95% CI 1.048–21.594).

The survival curves of cumulative survival (Fig. 3) showed that the HA group's survival curve was above the IF group's. But there was no significant difference between two groups (*P* value = 0.682). In the Cox proportional hazards model, only age significantly affected the occurrence of death (*P* value was 0.000) (HR 1.197; 95% CI 1.132 ~ 1.266).

The results of postoperative hip joint function showed that the average Harris scores of two groups were all above 75 points. But there was no significant difference in Harris scores between the two groups (*P* value greater than 0.05) (Table 4). The excellent and good rate of hip joint function in HA group was over 50% during the follow-up. Especially in the early term follow-up (6 ~ 12 months), the excellent and good rate of hip joint function in HA group was significantly higher than that in IF group (*P* value less than 0.05) (Table 4).

Discussion

Internal fixation was a common surgical operation method for the treatment of undisplaced femoral neck fractures in elderly. But a high proportion of internal fixation related complications occurred after surgery. On the one hand, due to the blood supply of femoral neck and head had been damaged at the moment of injury [25], there would still be a part of patients who developed nonunion (3.1–15.38%) [3, 5, 9, 15] and femoral head necrosis (3.5–11.53%) [3, 8, 9, 15]. In this research, the nonunion rate was 7.32% (3/41) and the rate of femoral head necrosis was 9.76% (4/41), which was essentially equivalent to the previous reports. On the other hand, the osteoporotic bone of elderly patients could also have an impact on the treatment of internal fixation. The holding force of the screws on fracture broken end might decrease for osteoporotic bone, while the relative extension of fracture healing time caused by destruction of femoral neck blood supply required internal fixation more firmly. The contradiction between the two could result in internal fixation loosening, displacement or even failure. In this study, two patients had the loosening and displacement of internal fixation, which accounted for 4.88% (2/41) of all patients of IF group. All the above complications were directly related to internal fixation.

Table 3 Data on the 11 patients undergoing reoperations

Patient number	Gender	Age (years)	Group	Reason for reoperation	Time	Reoperation
42	Female	82	IF group	Nonunion	10 months	HA
10	Female	84	IF group	Nonunion	8 months	HA
34	Male	85	IF group	Nonunion	9 months	HA
16	Female	84	IF group	Avascular necrosis	16 months	HA
40	Female	82	IF group	Avascular necrosis	32 months	HA
14	Male	80	IF group	Early loss of reduction	2 months	HA
25	Male	86	IF group	Early loss of reduction	3 month	HA
36	Female	83	IF group	Prominent screwheads	22 months	Remove screws
2	Male	85	IF group	Re-fracture for fall	34 months	PFNA
49	Female	82	HA group	Prosthesis loosening	46 months	Revision surgery
44	Female	84	HA group	Deep infection	5 weeks	Epluchage and Drainage

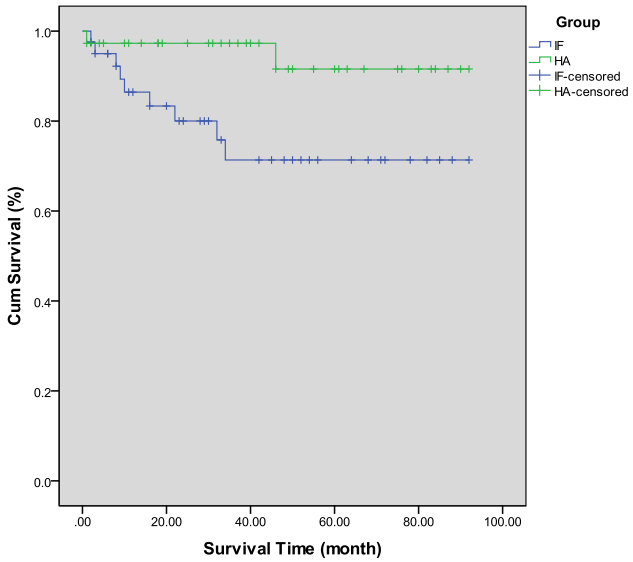

Fig. 2 Survival curves for re-operation after hemiarthroplasty and internal fixation. *Cum* cumulative

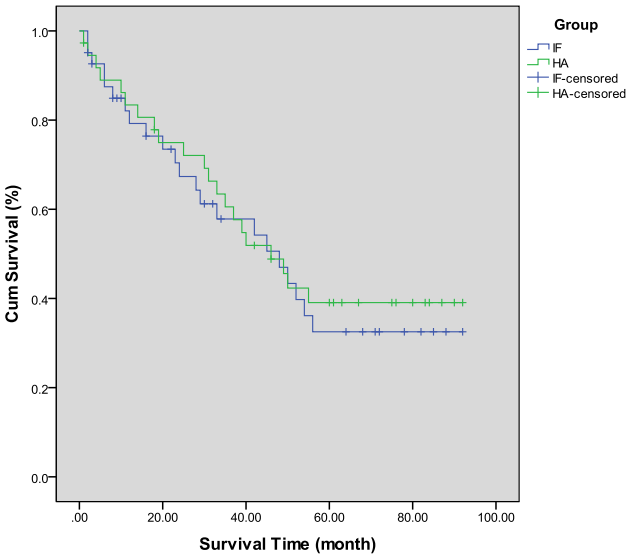

Fig. 3 Cumulative survival after hemiarthroplasty and internal fixation. *Cum* cumulative

Unlike IF group, HA group had very few complications related to operation. However, the related complications might occur after artificial joint replacement operation, including joint dislocation and prosthesis loosening, etc. But the artificial joint was more stable for using bipolar hemiarthroplasty, and no joint dislocation occurred in HA group. Meanwhile, the amount of daily activity of overaged was little, so the wear of the prosthesis was relatively small, and thus the loosening rate was low. There was only one case of femoral prosthesis loosening.

After complications occurred after surgery, the subsequent question was how to deal with these complications, which was bound to involve reoperation. Therefore, the high incidence of internal fixation related complications would lead to a high rate of reoperation. Han et al. [15] reported the reoperation rate of non-displaced femoral neck fractures in patients over 70 years of age was, as high as 30.1% after internal fixation operation. For patients over 80 years, the reoperation rate of internal fixation was reportedly 16.22–31% [5, 13], which was significantly higher than that of hemiarthroplasty [13, 17]. Also in this study the reoperation rate of IF group was 21.95% (9/41). With the exception of one case caused by fall, the remaining eight cases of reoperation were all related to internal fixation (Table 3).

Both survival curves and Cox proportional hazards regression analysis showed that internal fixation surgery would significantly increase the risk of reoperation, while hemiarthroplasty was the opposite (*P* value less than 0.05).

In this study, the results of mortality and survival time analysis were not significantly different between the two

Table 4 Comparison of hip function in two group postoperative for treatment of undisplaced femoral neck fractures in super elderly

Harris score	IF group ($n = 41$)	HA group ($n = 37$)	The value of P
6 months score ($n = 66$)[a]	76.18 ± 12.5 (46 ~ 98)	81.53 ± 11.6 (55 ~ 95)	0.076[c]
Hip function[b]	$n = 34$	$n = 32$	0.042[d]
Excellent	7	12	
Good	6	11	
Fair	13	4	
Poor	8	5	
Excellent and good rate	38.23% (13/34)	71.88% (23/32)	
12 months score ($n = 58$)[a]	77.25 ± 9.4 (62 ~ 95)	81.07 ± 12.3 (45 ~ 95)	0.191[c]
Hip function	$n = 28$	$n = 30$	0.034[d]
Excellent	3	11	
Good	8	9	
Fair	12	4	
Poor	5	6	
Excellent and good rate	39.29% (11/28)	66.67% (20/30)	
24 months score ($n = 48$)[a]	79.00 ± 14.3 (45 ~ 95)	79.73 ± 11.8 (55 ~ 95)	0.847[c]
Hip function	$n = 22$	$n = 26$	0.881[d]
Excellent	6	5	
Good	7	10	
Fair	4	6	
Poor	6	5	
Excellent and good rate	59.09% (13/22)	57.79% (15/26)	
36 months score ($n = 37$)[a]	80.88 ± 11.9 (65 ~ 93)	79.62 ± 10.8 (65 ~ 95)	0.767[c]
Hip function	$n = 16$	$n = 21$	0.168[e]
Excellent	7	5	
Good	2	8	
Fair	3	1	
Poor	4	7	
Excellent and good rate	56.25% (9/16)	61.90% (13/21)	
48 months score ($n = 28$)[a]	80.00 ± 15.4 (55 ~ 93)	80.20 ± 11.8 (55 ~ 94)	0.969[c]
Hip function	$n = 13$	$n = 15$	0.095[e]
Excellent	6	2	
Good	3	9	
Fair	0	1	
Poor	4	3	
Excellent and good rate	69.23% (9/13)	73.33% (11/15)	
60 months score ($n = 21$)[a]	81.89 ± 6.4 (71 ~ 91)	80.75 ± 5.4 (73 ~ 88)	0.664[c]
Hip function	$n = 9$	$n = 12$	0.796[e]
Excellent	1	0	
Good	5	8	
Fair	3	4	
Poor	0	0	
Excellent and good rate	66.67% (6/9)	66.67% (8/12)	

[a] Missing values due to patients dead and lost; 6 months, $n = 12$;12 months, $n = 8$; 24 months, = 10; 36 months, $n = 11$; 48 months, = 9; 60 months, $n = 7$

[b] Hip function: excellent, ≥90 points; good, 80 ~ 89 points; fair, 70 ~ 79 points; poor, <70 points

[c] Independent-sample t test

[d] χ^2-test

[e] Fisher's exact test

groups, which were different in some previous clinical reports [17, 19]. The reason for the opposite of the two outcomes was that some patients with relatively poor physical condition might be underwent hemiarthroplasty in previous studies, which would have contributed to an increase in mortality. But in this study, we set criteria for the physical status of the patients who enrolled. In this way, all patients with poor surgical tolerance were removed. Thus, there was no significant difference in mortality between the two groups. However, only age significantly affected the death of super-aged patients in Cox regression multivariate analysis (P value $= 0.000$). This result might be related to the life expectancy of patients. After 5 years of follow-up, most patients over 80 years old were close to the end of life, so age become unique factor of mortality.

The results of this study showed the advantage of hemiarthroplasty in the recovery of hip function early. In 1 year after surgery, the Harris score of HA group was higher than that of IF group, and the excellent and good rate in HA group was also significantly higher than that in IF group (P value less than 0.05). The reason was probably that hemiarthroplasty could not only allow early ambulation but also avoid internal fixation related complications, both of which were beneficial to the recovery of hip joint function. But in the middle and late stage of postoperative follow-up, patients with "problems" in IF group were excluded for reoperations or even death. Accordingly, the Harris score and good rate of IF group were essentially flat with HA group (Table 4).

However, it should be pointed out that hemiarthroplasty also had significant deficiency in all surgery related indicators: length of incision, operation time, blood loss, etc. The reasons might be related to the relatively complex equipment and operation process of artificial joint replacement surgery.

Some limitations of our study were only two central hospitals participation, unable to study in wider area with more eligible participants, and collection and measurement of parameters were performed separately by two hospitals, rather than at one place, which increased the error probably.

Conclusion

Hemiarthroplasty with less postoperative complications, low reoperation rate and better function recovery in early stage provide a good choice for the treatment of super aged patients with nondisplaced femoral neck fracture.

Compliance with ethical standards

Conflict of interest The authors declare that we have no conflict of interest related directly or indirectly to this article.

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