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Displaced humeral head after intramedullary nailing for proximal humeral fracture is associated with worse short-term outcomes—a multicenter TRON study

Yutaka Hiramatsu, MD[a], Yasuhiko Takegami, MD, PhD[a,*], Tokutake Katsuhiro, MD, PhD[b], Yu Matsuura, MD[a], Koichiro Makihara, MD[a], Tokumi Kanemura, MD, PhD[c], Shiro Imagama, MD, PhD[a]

[a]Department of Orthopedic Surgery, Nagoya University Graduate School of Medicine, Nagoya, Japan
[b]Department of Hand Surgery, Nagoya University Graduate School of Medicine, Nagoya, Japan
[c]Department of Orthopedic Surgery, Konan Kosei Hospital, Konan, Japan

A R T I C L E I N F O

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Level of evidence: Level III; Retrospective Cohorts Comparison; Prognosis Study

Background: In recent years, complex and unstable proximal humeral fractures (PHFs) are treated with intramedullary nails (IMNs) in the elderly; however, the postoperative radiographic findings related to the clinical outcome are not clear. This study evaluated the association of clinical outcomes with the radiographic findings of PHFs treated with IMNs.
Methods: We collected data of patients aged >60 years with PHFs treated with IMNs from 2015 to 2019 in 13 associated centers' database (named TRON). We excluded patients lost to follow-up of <6 months postoperatively (PO6M). We evaluated clinical outcomes with the University of California at Los Angeles (UCLA) score at PO6M and defined a score of <27 as poor. We assessed the radiographic findings on the anteroposterior view of the humeral head postoperatively, and each radiographic finding such as humeral head height (HHH), head shaft angle, and cranialization of the greater tuberosity was divided into two groups: poor and good. Factors associated with poor UCLA at PO6M were extracted by logistic regression analysis, and the factors were divided into two groups (poor and good) and matched for age, sex, and fracture type. The UCLA score at PO6M between the groups was examined by the Mann-Whitney U test, and the significance level was set at 0.05. The minimal clinical important difference in the UCLA score was set 2 points.
Results: The study included 243 patients (mean age, 76 years; range, 60-95 years). The mean follow-up period was 12 months (range, 6-56 months). The correlation coefficients indicated that there was either no or only a weak correlation between HHH, head shaft angle, and cranialization of the greater tuberosity. A poor HHH (HHH <0 or >10 mm) was extracted as a factor associated with a poor UCLA score at PO6M by logistic regression analysis (odds ratio: 5.78, 95% confidence interval = 1.2-27.7, $P = .0287$). In matched pair analysis, the UCLA score at PO6M was significantly lower in the poor HHH group (26 [range: 9-33] vs. 24 [range: 10-35], $P = .0458$).
Conclusion: We revealed that the HHH was an independent risk factor for poor short-term outcomes. There was a significant difference in the UCLA score between groups divided by the HHH in cases treated with IMNs. The HHH can be used intraoperatively or postoperatively as a reliable parameter to predict clinical outcomes in PHFs treated with IMNs.

The incidence of complex and unstable proximal humeral fractures (PHFs) is increasing with aging of the population as a result of lower bone quality in the elderly.[3,4] The treatment of displaced or unstable PHFs in elderly patients is challenging, especially when multiple fracture fragments, comminuted fractures, and osteoporosis with bone loss are present.[7,12,22] Fixations with locking plates and intramedullary nails are the surgical treatments mainly used for PHFs. Previous reports described that intramedullary nails have

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*Corresponding author: Yasuhiko Takegami, MD, PhD, Department of Orthopaedic Surgery, Nagoya University Graduate School of Medicine, 65 Tsurumai-cho, Showa-ku, Nagoya 466-8550, Japan.
E-mail address: takegami@med.nagoya-u.ac.jp (Y. Takegami).

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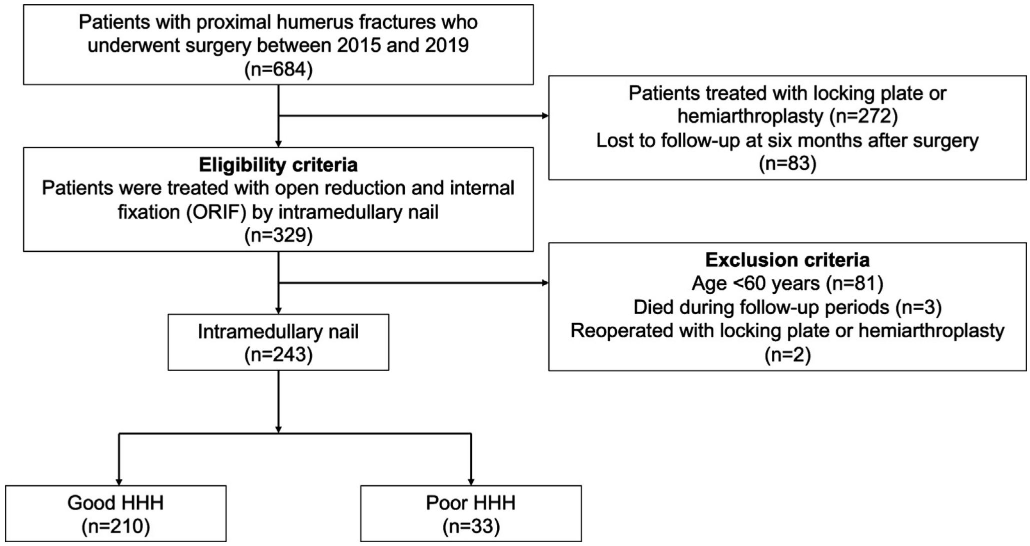

Figure 1 Inclusion criteria. We included 243 patients with proximal humeral fracture who were treated by intramedullary nailing and whose age was older than 60 years. We divided the patients into the good HHH group and the poor HHH group. *HHH*, humeral head height.

also been used to treat 3- and 4-part PHFs because of the rotational and vertical stability.[2,6,10,19]

In the patients with PHFs treated by locking plate fixation, previous reports revealed that several postoperative radiological findings such as humeral head height (HHH), head shaft angle (HSA), and cranialization of the greater tuberosity (CGT) are associated with poor clinical outcomes.[2,16,18,20] However, the postoperative radiographic findings related to the clinical outcome of PHFs treated with intramedullary nails are not fully understood. Thus, the aim of this study was to evaluate the association of clinical outcomes after PHF treated by intramedullary nailing with radiographic findings including HHH, HSA, and CGT.

Material and methods

This multicenter retrospective study used data obtained from the Trauma Research Group of Nagoya (TRON) database, in which member hospitals have registered orthopedic trauma surgery cases annually since 2014. The study was conducted in accordance with the ethical standards of the responsible committee and the ethical principles of the 1975 Declaration of Helsinki. The study was approved by the ethics committee of each participating hospital (reference number: 2020-0564), and informed consent was obtained from the patients for the publication of this study. The hospitals participating in the TRON database are all located in central Japan. We collected cases of PHFs from this database that were treated surgically. These surgeries were performed by about 80 orthopedic surgeons. Data collection was performed independently by 13 researchers who were not involved in patient care.

Subjects

We selected 684 patients diagnosed as having PHF and who underwent surgical treatment from 2015 to 2019 at 13 institutions and included 329 patients aged greater than 60 years who were treated with intramedullary nails. Excluded were 81 patients whose postoperative follow-up was less than 6 months, three patients who died during follow-up, and two patients who underwent reoperation with locking plates or hemiarthroplasty after internal fixation with intramedullary nails. Thus, 243 patients were included in this study (Fig. 1).

Data collection

The following demographic data were collected from each patient's medical records: age, sex, body mass index, smoking, diabetes mellitus, hypertension, dislocation, affected side, and other factors. The causes of injury included simple fall (204 cases), traffic accident (22 cases), and others (17 cases).[2] If the patients had an open fracture, we classified the severity as per the Gustilo classification.[11] Surgery time blood loss was recorded as surgery-related factors.

Clinical evaluation

We assessed the University of California at Los Angeles Shoulder Score (UCLA Shoulder Score). We obtained UCLA scores for each patient at 6 and 12 months postoperatively. The UCLA score consists of five components: pain, function, active forward flexion, strength of forward flexion, and satisfaction. The maximum score is 35 points, and we defined a UCLA score of less than 27 as a "poor UCLA" score based on a previous study.[15]

Complications included superficial or deep infection and nonunion. We defined nonunion as the existence of a fracture line on the radiographic image obtained at the last follow-up as described in a previous report.[8]

Radiographic evaluation

We assessed the postoperative anteroposterior (AP) view and oblique view of the humeral head. The AO/OTA classification was recorded for the fracture type. We divided the fractures into two types: AO/OTA-11A2 type was considered a simple fracture, and AO/OTA-11B and 11C types were considered a complex fracture. We defined the free fragment as a bone fragment of the greater tuberosity that is displacement by more than 5 mm on AP or oblique radiographs.

We measured the postoperative HHH, which was measured on the X-ray image by calculating the distance between the tangent of the apex of the humeral head and the most proximal point of the greater tuberosity in mm (Fig. 2*A*).[2] If the most proximal point of the greater tuberosity was proximal to the apex of the humeral head, it was measured as a negative value. A previous anatomical

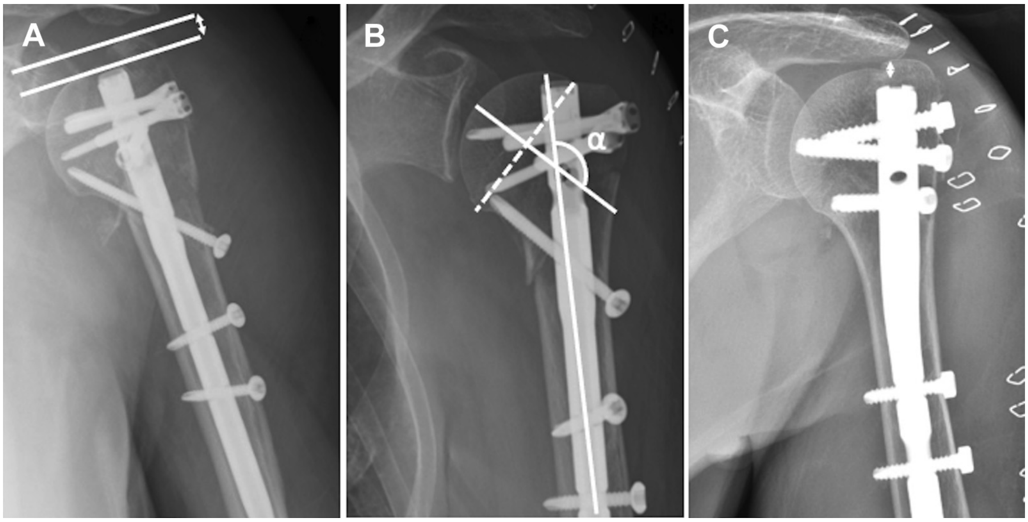

Figure 2 X-ray images of the humeral head. (**A**) The humeral head height was defined as the distance between the tangent of the apex of the humeral head and the most proximal point of the greater tuberosity (*double-headed arrow*). (**B**) The head shaft angle (angle α) was determined as follows: a first line (dashed line) was drawn from the superior border to the inferior border of the articular surface, and a second line was drawn perpendicular to the first line. A third line bisecting the humeral shaft and the angle between the second and third lines was defined as head shaft angle α. (**C**) Cranialization of the greater tuberosity was defined as the amount of dislocation of the greater tuberosity bone fragment in the humeral shaft direction (*double-headed arrow*).

analysis reported that the superior margin of the humeral head articular surface is normally superior to the top of the greater tuberosity by 5-10 mm.[17,21] As per these reports, we defined malalignment as HHH <0 mm or >10 mm (poor HHH) and the anatomical HHH as that between 0 mm and 10 mm (good HHH).

The HSA (angle α) was determined as follows: a line (dashed line) was first drawn from the superior border to the inferior border of the articular surface, and a second line was drawn perpendicular to the first line. A third line bisecting the humeral shaft and the angle between the second and third lines was defined as HSA α (Fig. 2*B*).[18] We defined malreduction of the HSA as <120 degrees or >150 degrees, as previously reported.[1,18]

CGT was defined as the amount of dislocation of the greater tuberosity bone fragment in the humeral shaft direction in mm (Fig. 2*C*). Malreduction of the CGT is defined as a dislocation of ≥5 mm, following the report by Schnetzke et al.[18] If patients did not have free fragments of the greater tuberosity, we defined the CGT of PHF as “NA” (not applicable).

Two observers evaluated the radiographs and assessed agreement of the diagnosis. The Kappa value was 0.86 (95% confidence interval: 0.80-0.94), and if the diagnoses differed, the determination of the first author was adopted.

Surgical technique

The deltoid split approach was used with the patient in the beach-chair position on a radiolucent table. A C-arm was set up on the contralateral side of the table, and true AP images were used to perform coronal alignment, determine entry point positioning, and check the reduction. After fracture reduction, a guide pin was inserted at the entry point, and the proximal cortex was breached using a reamer. The intramedullary nails were then manually inserted using a targeting device to confirm the reduction of the fracture, and an adequate number of locking screws were inserted proximally. Whether to perform suturing of the rotator cuff or bone fragments depended on the surgeon’s decision. We checked the reduction position under fluoroscopy.

We used six kinds of implants: MultiLoc (Synthes GmbH, Oberdorf, Switzerland), T2 nail (Stryker, Mahwah, NJ, USA), ARISTO Proximal humeral nail (MDM, Tokyo, Japan), POLARUS humeral nail, (Acumed LLC, Portland, OR, USA), TRIGEN humeral nail (Smith & Nephew, Memphis, TN, USA), and HAI humeral nail system (HOMS, Chino, Japan).

The surgeons allowed the patients' active range of motion with sling immobilization immediately after the operation. Passive range of motion rehabilitation was started after almost two weeks.

Statistical analysis

First, we examined the correlation between the three radiographic findings (HHH, HSA, and CGT). We then divided the patients into two groups as per a threshold UCLA score of 27 points at 6 months postoperatively. We performed a univariate analysis for HHH, HSA, and CGT between these two groups. Next, we performed logistic regression analysis to identify the risk factors associated with a poor UCLA score as the response variable and with all factors examined in this study as the explanatory variables. Finally, we compared the UCLA score at 6 months postoperatively and at the last follow-up for the factors predicting a poor UCLA score as indicated by logistic regression analysis after matching for age, sex, and fracture type. The mean UCLA score was analyzed with the Mann-Whitney U test, and all statistical analyses were performed using EZR (Jichi Medical School, Tochigi, Japan). The significance level was set at $P < .05$.

Results

Table I shows the background data of the patients. Their mean age (±standard deviation) was 76.0 ± 7.9 years, and 194 patients (79.8%) were female, and 49 patients (20.2%) were male. The mean follow-up time was 12.8 ± 7.5 months (range: 6-56 months).

Table II shows the correlation between HHH, HSA, and CGT. There was either no or only a weak correlation between any of these factors.

Univariate analysis showed that HHH, age, and nonunion were predictors of a poor UCLA score (P = .00154, P = .000839, and P = .0187, respectively), whereas HSA and CGT were not predictors (Table III). Multivariate logistic regression analysis identified the

Table I
Patient demographics.

Factor	Value
Number, n	243
Age, yr, mean ± SD	76.00 ± 7.91
Sex, M/F	49/194
BMI, kg/m^2, mean ± SD	22.87 ± 4.48
Follow-up period, mo, mean (range)	12.00 (6.0-56.0)
Fracture type, n (%)	
Simple fracture	147 (60.5)
Complex fracture	96 (39.5)
Smoking, n (%)	46 (18.9)
DM, n (%)	67 (27.6)
HT, n (%)	129 (53.1)
Dislocation, n (%)	4 (1.6)
Affected side, n (%)	
Right	125 (51.4)
Left	118 (48.6)
Gustilo classification (%)	
Type I	3 (1.2)
Type II	1 (0.4)
Mechanism, n (%)	
Fall	204 (84.0)
Traffic accident	22 (9.0)
Others	17 (7.0)
Other factors, n (%)	31 (12.8)
Blood loss, mL, mean (range)	44.00 (0.0-600.0)
Operation time, min, mean (range)	90.00 (34.0-368.0)
Post HHH, good/poor	210/33
Post HSA, good/poor	186/57
Post CGT, good/poor/NA	109/12/122

SD, standard deviation; *BMI*, body mass index; *DM*, diabetes mellitus; *HT*, hypertension; *HHH*, humeral head height; *HSA*, head shaft angle; *CGT*, cranialization of the greater tuberosity; *NA*, not applicable.

Table II
Spearman's rank correlation coefficient for radiographic findings.

	HHH		HSA		CGT	
	Coefficient	*P* value	Coefficient	*P* value	Coefficient	*P* value
HHH	—					
HSA	0.337	<.01	—			
CGT	−0.294	<.01	0.0289	.753	—	

HHH, humeral head height; *HSA*, head shaft angle; *CGT*, cranialization of the greater tuberosity.

HHH as the risk factor for a poor UCLA score at 6 months postoperatively (odds ratio: 5.78, 95% confidence interval = 1.20-27.8, $P = .0287$; Table IV). Therefore, we focused on the HHH for clinical evaluation. We divided the patients into the good HHH group and the poor HHH group (Fig. 1). Patient background data after matching for age, sex, and fracture type are shown in Table V. After matching, 33 patients were matched to both the good HHH and poor HHH groups. There were no significant differences in patient background data between the two groups after matching. There was a statistically significant difference in the UCLA score at 6 months postoperatively between the good HHH group and the poor HHH group (26 [range: 9-33] vs. 24 [range: 10-35], $P = .0458$). However, there was no statistically significant difference in the UCLA score at 12 months postoperatively (29 [range: 10-33] vs. 26 [range: 10-35], $P = .287$).

As for complications, 5 patients in the good HHH group developed postoperative infections, whereas no infections were seen in the poor HHH group. Nonunion was identified at the last follow-up in 14 patients (6.7%) in the good HHH group and 4 patients (12%) in the poor HHH group.

Table III
Risk factors for a poor UCLA score at 6 months postoperatively by univariate analysis.

Variable	Odds ratio	95% CI	*P* value
Age	1.059	1.02-1.10	**<.001**
Sex			
Male	1 (Ref)		
Female	1.47	0.781-2.75	.233
BMI	0.980	0.925-1.038	.0515
Fracture type			
Simple	1 (Ref)		
Complex	1.44	0.855-2.43	.171
Smoking			
No	1 (Ref)		
Yes	0.8	0.420-1.52	.492
Other factors			
No	1 (Ref)		
Yes	1.18	0.549-2.53	.674
Mechanism			
Fall	1 (Ref)		
Traffic accident	0.719	0.297-1.74	.464
Others	2.80	0.885-8.85	.0801
Nonunion			
No	1 (Ref)		
Yes	4.57	1.29-16.2	**.0187**
Infection			
No	1 (Ref)		
Yes	3.40	0.376-30.9	.276
Post HHH			
Good	1 (Ref)		
Poor	4.46	1.77-11.2	**<.01**
Post HSA			
Good	1 (Ref)		
Poor	1.44	0.787-2.65	.236
Post CGT			
Good	1 (Ref)		
Poor	4.65	0.971-22.2	.0544

BMI, body mass index; *CI*, confidence interval; *HHH*, humeral head height; *HSA*, head shaft angle; *CGT*, cranialization of the greater tuberosity.
Bold value indicates statistically significance.

Discussion

This study focused on the association of radiographic findings with the clinical outcomes of patients with PHF treated with intramedullary nailing. We revealed that (1) the HHH was an independent risk factor leading to a poor PHF outcome, (2) the clinical outcome of patients with a poor HHH, defined as <0 mm or >10 mm, was significantly inferior to that of the patients with a good HHH, and (3) the HHH had only weak correlation with CGT.

Several studies have reported the relationship between the HHH and clinical outcomes after surgery for PHF treated with locking plates or hemiarthroplasty. A previous study reported that a 10-mm displacement from the tangent of the head to the greater tuberosity is the factor causing poor clinical outcomes in patients who underwent hemiarthroplasty for 3- or 4-part PHF.[5] Another report also showed that a >5-mm decrease in the HHH during follow-up is related to the impairment of shoulder function.[2] The location of the humeral head and the greater tuberosity is strongly related to the function of the rotator cuff.[9] From the anatomical perspective, the nonanatomical prominence of the greater tuberosity can cause subacromial impingement and rotator cuff symptoms. Excessive increases in the HHH may anatomically increase rotator cuff tension, which may indicate decreased shoulder function and a decreased HHH.

Other previous reports found that posterior greater tuberosity displacement is known as a significant cause of functional impairment. Bono et al demonstrated that combined posterior and superior displacement led to a greater change in deltoid force required for abduction than did superior displacement alone.

Table IV
Risk factors for a poor UCLA score at 6 months postoperatively by multiple regression analysis.

Variable	Odds ratio	95% CI	*P* value
Age	1.056	1-1.12	.072
Sex			
Male	1 (Ref)		
Female	2.77	0.654-11.74	.167
BMI	0.893	0.794-1.01	.0737
Fracture type			
Simple	1 (Ref)		
Complex	1.079	0.379-3.07	.886
Smoking			
No	1 (Ref)		
Yes	2.778	0.549-14.05	.216
Other factors			
No	1 (Ref)		
Yes	1.727	0.469-6.37	.411
Mechanism			
Fall	1 (Ref)		
Traffic accident	0.333	0.066-1.68	.183
Others	2.227	0.459-10.82	.321
Nonunion			
No	1 (Ref)		
Yes	2.11	0.327-13.7	.432
Infection			
No	1 (Ref)		
Yes	2.088	0.071-61.4	.67
Post HHH			
Good	1 (Ref)		
Poor	5.78	1.2-27.7	**.0287**
Post HSA			
Good	1 (Ref)		
Poor	1.178	0.461-3.01	.733
Post CGT			
Good	1 (Ref)		
Poor	2.096	0.336-13.11	.428

BMI, body mass index; *CI*, confidence interval; *HHH*, humeral head height; *HSA*, head shaft angle; *CGT*, cranialization of the greater tuberosity.
Bold value indicates statistically significance.

Another study showed that patients with GT displacement in the posterior-superior direction had significantly worse outcomes than did patients with GT displacement in anterior-inferior or anterior-superior directions in isolated greater tuberosity fracture. However, the magnitude of “acceptable” posterior GT displacement remains unclear. These results suggested that CGT in the anterior-posterior view may be insufficient to demonstrate the degree of displacement because of the effect of the humeral head varus deformity and the posterior malposition.[14] On the other hand, the HHH is the distance between the upper edge of the humeral head and the upper edge of the greater tuberosity in the direction of the humeral axis. The HHH may encompass CGT. It might be possible that the HHH had a much impact on the clinical results and the reason which the HHH had only weak correlation with CGT.

Another previous report found that residual anatomical deformities such as a poor HSA and poor CGT in patients treated with intramedullary nails impaired shoulder motion but did not significantly affect their daily activities.[13] This result suggested that the patient has achieved bony fusion; the clinical results may be acceptable even with residual deformation in the elderly.

This study has some limitations. First, this is a retrospective study using a clinical database, and subjects were not randomly assigned, so the possibility of the selection bias exists. Second, dislocation progression of the reduction position was not assessed during each follow-up period. If the alignment worsens during follow-up, the clinical outcome may be poor, even if the postoperative reduction position was good. However, we suggest that we can improve malalignment intraoperatively or in the early postoperative period by evaluating the reduction position after internal fixation rather than by assessing changes over time. Third, we assessed the radiographic findings using only the AP view and oblique view of the humeral head. The displacement of greater tuberosity should be assessed by the scapula Y view. Three-dimensional radiographic

Table V
Patients' demographics after matching.

	Good HHH	Poor HHH	*P* value
Number, n	33	33	
Age, yr, mean ± SD	78.67 ± 7.94	78.55 ± 7.96	.951
Sex, M/F	6/27	6/27	1
BMI, kg/m^2, mean ± SD	23.38 ± 3.67	22.18 ± 4.29	.227
Follow-up period, mo, mean (range)	12.0 (6.0- 42.0)	12.0 (6.0-40.0)	.277
Fracture type, n (%)			1
Simple fracture	14 (42.4)	14 (42.4)	
Complex fracture	19 (57.6)	19 (57.6)	
Smoking, n (%)	9 (27.3)	5 (15.1)	.367
DM, n (%)	9 (27.3)	7 (21.2)	.775
HT, n (%)	21 (63.6)	16 (48.5)	.321
Dislocation, n (%)	0 (0.0)	1 (3.0)	1
Affected side, n (%)			.617
Right	18 (54.5)	21 (63.6)	
Left	15(45.5)	12 (36.4)	
Gustilo classification (%)			1
Type I	0 (0.0)	1 (3.0)	
Type II	1 (3.0)	0 (0.0)	
Mechanism, n (%)			1
Fall	26 (78.8)	27 (81.8)	
Traffic accident	4 (12.1)	3 (9.1)	
Others	3 (9.1)	3 (9.1)	
Other factors, n (%)	6 (18.2)	1 (3.0)	.105
Blood loss, mL, mean (range)	50.00 (0.0-200.0)	45.00 (0.0-600.0)	.891
Operation time, min, mean (range)	90.0 (41.0-218.0)	80.0 (40.0-249.0)	.434

SD, standard deviation; *BMI*, body mass index; *HHH*, humeral head height; *DM*, diabetes mellitus; *HT*, hypertension.

assessment is needed in the further study. Finally, we assessed clinical outcomes only with the UCLA score. Although the UCLA score consists of five components, we could have assessed clinical outcomes in more detail by using other scores.

Conclusion

The HHH was an independent radiographic risk factor for poor outcomes as indicated by the UCLA score, and there was a significant difference in UCLA scores between the group with a good and that with a poor HHH. We recommend defining the HHH intraoperatively or postoperatively as a reliable parameter to predict clinical outcomes at a short term in PHF treated with intramedullary nailing.

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