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Risk Factors Associated with Fixation Failure in Intertrochanteric Fracture Treated with Cephalomedullary Nail

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Purpose: Cephalomedullary (CM) nailing is widely performed in treatment of elderly patients with femoral intertrochanteric fractures. However, in cases of fixation failure, re-operation is usually necessary, thus determining factors that may contribute to fixation failure is important. In this study, we examined factors affecting the occurrence of fixation failure, such as age or fracture stability, after CM nailing in elderly patients.

Materials and Methods: This study was conducted retrospectively using registered data. From April 2011 to December 2018, CM nailing was performed in 378 cases diagnosed with femoral intertrochanteric fractures, and 201 cases were finally registered. Cases involving patients who were bed-ridden before injury, who died from causes unrelated to surgery, and those with a follow-up period less than six months were excluded.

Results: Fixation failure occurred in eight cases. Comparison of the surgical success and fixation failure group showed that the mean age was significantly higher in the fixation failure group compared with the control group (81.3±6.4 vs. 86.4±6.8; P=0.034). A significantly high proportion of unstable fractures was also observed (139/54 vs. 3/5; P=0.040), with a significantly high ratio of intramedullary reduction (176/17 vs. 5/3; P=0.034). A significantly higher ratio of unstable fractures compared with that of stable fractures was observed in the intramedullary reduction group (132/49 vs. 10/10; P=0.033).

Conclusion: Fixation failure of CM nailing is likely to occur in patients who are elderly or have unstable fracture patterns. Thus, care should be taken in order to avoid intramedullary reduction.

Key Words: Femur, Intertrochanteric fractures, Intramedullary nailing

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INTRODUCTION

With the progression of aging globally, the prevalence of diseases that can adversely affect bone metabolism, such as osteoporosis, is increasing[1]. As a result, the prevalence of femoral fractures is also increasing worldwide[2]. Intertrochanteric fracture (ITF) may occur as a result of low-energy trauma in elderly patients with low bone density and low muscle mass, resulting in unstable fractures and a higher rate of severe complications that can be difficult to manage[3,4]. In addition, an association of its morbidity with a high rate of mortality has been reported[5].

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The purpose of surgical treatment for ITF is to reduce the potential for complications by obtaining anatomical reduction with firm fixation to enable a pre-fracture level of function. Wide use of dynamic hip screws, cephalomedullary nail (CM nail), bipolar hip arthroplasty, and CM nail, which are less invasive and offer biomechanical advantages, for treatment of ITF has recently been reported[6-8]. In general, in postoperative radiographic examination, the tip-apex distance (TAD) must be within 25 mm to be considered stable[9-13]. In particular, performance of an extra-medullary reduction in cases of unstable ITF is important[14,15].

Fixation failure, which is cut out or cut through of the nail, regardless of patient bone quality or error during surgery, is a serious complication that can occur after surgery for treatment of an ITF. Re-operation or conversion surgery to hip arthroplasty is usually required in cases of fixation failure[16,17]. However, for elderly patients, additional surgery itself can place a burden on their condition, and damage to soft tissue and bone, leg length discrepancy, and muscle atrophy as a complication resulting from previous surgery can lead to a poor prognosis[18].

In research on the causes of fixation failure, relatively few studies have compared the CM nail to dynamic hip screws. In this study, we examined the factors affecting the occurrence of fixation failure after CM nailing in patients with ITF. TAD and reduction status are regarded as factors that are determined by the individual competency of the operator. In this study, we attempted to identify other factors that can affect the determination of TAD and reduction status.

MATERIALS AND METHODS

This study was conducted retrospectively using registered data at Seoul Medical Center. From April 2011 to December 2018, proximal femoral bone fixation was performed in 378 cases with a diagnosis of ITF. Of 378 cases, 26 patients who were in bed-ridden state before the fracture, 53 patients who died regardless of surgery, and 98 patients with a follow-up period of less than six months were excluded, so that 201 cases were finally registered (Fig. 1). This study was approved by the Institutional Review Board (IRB) of Seoul Medical Center (IRB No. 2019-08-005) and the written informed consent was waived by the IRB due to the retrospective nature of the study.

In this study all operations were performed by three hip specialists in a single institution. Surgery was performed under general anesthesia or spinal anesthesia; following positioning of the patient on the fracture table in a supine position, on fluoroscopy traction, adduction and internal rotation was performed in order to obtain closed reduction, and surgery was then performed according to the standard procedure. Three implants were used for treatment of ITFs: Trochanteric Gamma Locking Nail, Gamma U-Blade Lag Screw (Stryker), and Zimmer Natural Nail (Zimmer). None of the patients underwent open reduction. All patients were able to sit 2 or 3 days after surgery. Considering the potential effect on patient prognosis, in cases where the patient's condition was tolerable, rehabilitation training such as tilted-table standing or walking with an orthosis for partial weight bearing was started under consultation with the rehabilitation center (Fig. 2).

Radiological evaluation was performed using anteropos-

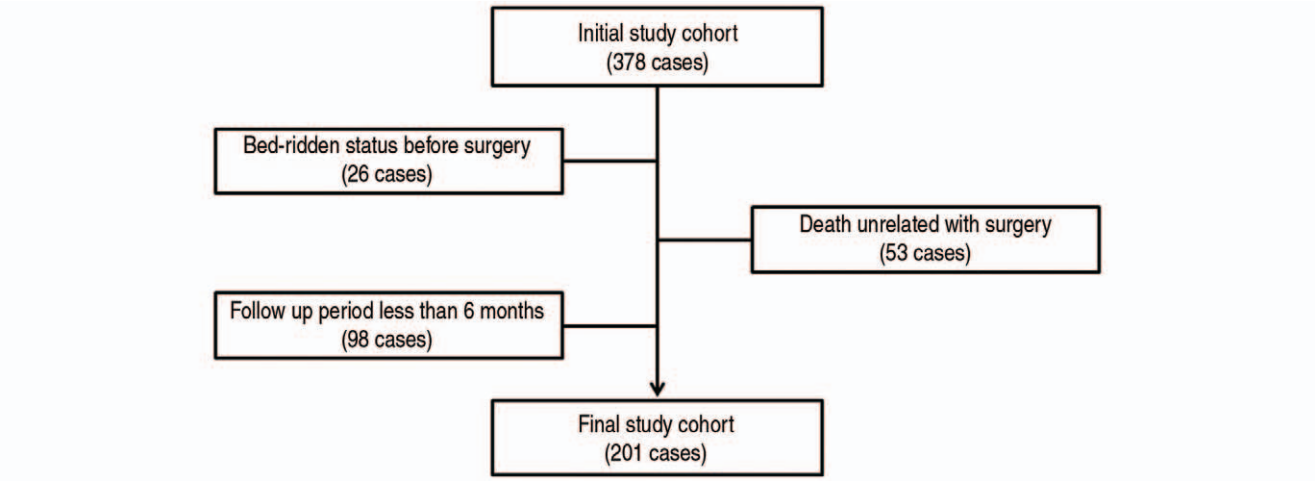

Fig. 1. The flow-chart of final study cohort in this study.

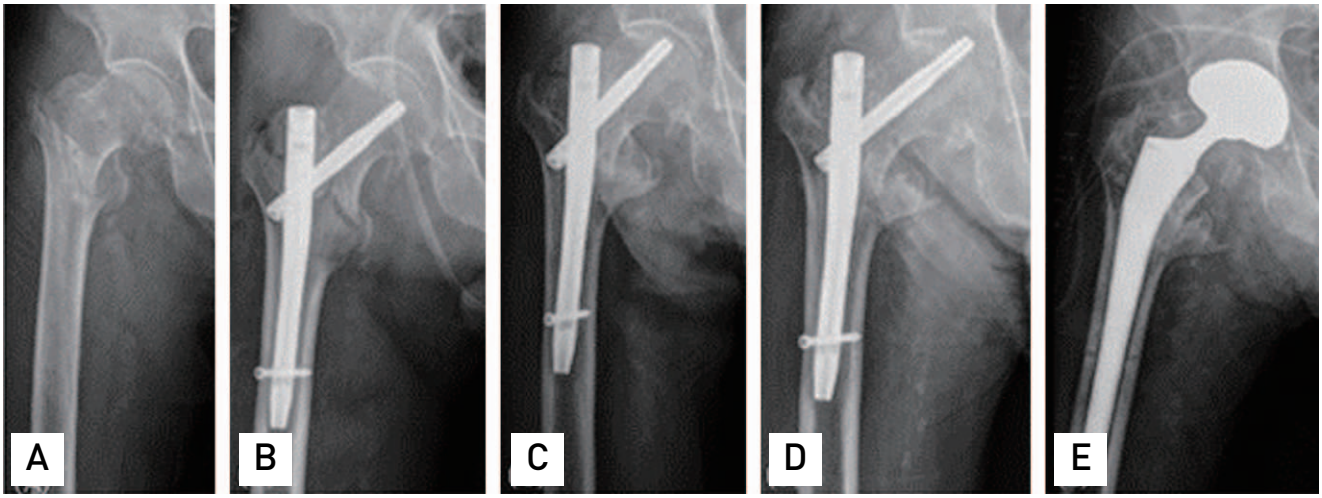

Fig. 2. (**A**) A 96-year-old male patient visited our emergency room due to right sided hip pain after slip down. (**B**) We conducted cephalomedullary nailing, and the patient discharged without complication. (**C**) After 6 months, we could find varus alignment of bone fragment, but there was no cut through or cut out of implant. (**D**) After 10 months, we could find cut through of lag screw. (**E**) Conversional operation to total hip arthroplasty was done.

Table 1. Statistical Comparison of Nonfailure and Failure Groups

Variable	Normal (n=193)	Failure (n=8)	*P*-value
Age (yr)	81.3±6.4	86.4±6.8	0.034
Sex			0.440
Male	63 (32.6)	1 (12.5)	
Female	130 (67.4)	7 (87.5)	
BMD (g/cm^2)	3.3±1.0	3.8±1.0	0.187
BMD			0.999
T score >−2.5	42 (21.8)	1 (12.5)	
T score ≤−2.5	151 (78.2)	7 (87.5)	
BMI (kg/m^2)	22.1±3.7	22.5±3.4	0.513
BMI*			0.902
Underweight	32 (16.6)	1 (12.5)	
Normal	124 (64.2)	5 (62.5)	
Overweight	37 (19.2)	2 (25.0)	
ASA class			0.713
1, 2	118 (61.1)	6 (75.0)	
3, 4	75 (38.9)	2 (25.0)	
Koval grade			0.311
1	68 (35.2)	3 (37.5)	
2, 3	84 (43.5)	5 (62.5)	
4, 5, 6	41 (21.2)	0 (0)	
Type of fracture			0.040
Stable	139 (72.0)	3 (37.5)	
Unstable	54 (28.0)	5 (62.5)	
Reduction status			0.034
Stable reduction	176	5	
Unstable reduction	17	3	
TAD			0.711
≤25 mm	176	5	
>25 mm	17	3	

Values are presented as mean±standard deviation, number (%), or number only.
BMD: bone mineral density, BMI: body mass index, ASA: American Society of Anesthesiologists, TAD: tip-apex distance.
* Underweight: <18.5 kg/m^2, Normal: 18.5-25 kg/m^2, Overweight: >25 kg/m^2.

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Table 2. Statistical Comparison of Good and Poor Reduction Groups

Variable	Anatomical or extra (n=181)	Intramedullary (n=20)	*P*-value
Age (yr)	81.2±6.4	84.1±7.1	0.073
Sex			0.088
Male	61 (33.7)	3 (15.0)	
Female	120 (66.3)	17 (85.0)	
BMD (g/cm^2)	3.2±1.0	3.6±0.9	0.109
BMD			0.257
T score >−2.5	41 (22.7)	2 (10.0)	
T score ≤−2.5	140 (77.3)	18 (90.0)	
BMI (kg/m^2)	22.0±3.6	22.7±4.6	0.481
BMI*			0.398
Underweight	28 (15.5)	5 (25.0)	
Normal	119 (65.7)	10 (50.0)	
Overweight	34 (18.8)	5 (25.0)	
ASA class			0.748
1, 2	111 (61.3)	13 (65.0)	
3, 4	70 (38.7)	7 (35.0)	
Koval grade			0.851
1	64 (35.4)	7 (35.0)	
2, 3	81 (44.8)	8 (40.0)	
4, 5, 6	36 (19.9)	5 (25.0)	
Type of fracture			0.033
Stable	132 (72.9)	10 (50.0)	
Unstable	49 (27.1)	10 (50.0)	

Values are presented as mean±standard deviation or number (%).
BMD: bone mineral density, BMI: body mass index, ASA: American Society of Anesthesiologists.
* Underweight: <18.5 kg/m^2, Normal: 18.5-25 kg/m^2, Overweight: >25 kg/m^2.

terior and translateral X-ray images of the hip, which were assessed during the follow-up period, monthly after the operation for three months, and six months after that. X-rays that showed cut-out or cut-through of an instrument, destroyed alignment of fracture fragments, or nonunion were regarded as fixation failure of CM nailing, and in cases of implant failure, reoperation was planned if the pain was severe or walking was not possible. Radiological evaluation was performed by two independent orthopedic surgeons who did not participate in the surgery. Assessment of the stability of the fracture, the state of reduction in the postoperative image, and the distance between tip-apex was performed. Regarding fracture stability, cases involving a fracture line that extended to the posteromedial and lateral aspect of the greater trochanter or to the subtrochanteric region (reverse oblique pattern) were defined as an unstable fracture. Other fractures were classified as stable fractures. The reduction state of the fracture was confirmed by determining whether the reduction state was outside the bone marrow cavity, anatomical reduction, or in the bone marrow cavity. It was assumed that reduction outside the bone marrow cavity and anatomical reduction was desirable.

For statistical analysis, Student's *t*-test and Mann–Whitney test were used to examine the association between categorical data. The significance level was set to a *P*-value of 0.05. The statistics program used IBM SPSS Statistics (ver. 28; IBM).

RESULTS

Of 201 cases, there were 193 cases of successful fixation, eight cases of failure, 181 cases of anatomical reduction or extramedullary reduction, 20 cases of reduction in intramedullary reduction, 137 cases of TAD less than 25 mm, and 64 cases of excess. The following implants were used for fixation: Trochanteric Gamma Locking Nail 72 cases, Gamma U-Blade Lag Screw 90 cases, and Zimmer Natural Nail 39 cases. Comparison of the entire patient group was based on three paradigms (i.e., normal group vs. surgical failure group, anatomical or extramedullary reduction group vs. intramedullary reduction group, TAD ≤25 mm group vs. TAD >25 mm group).

Table 3. Statistical Comparison of Good and Poor TAD Groups

Variable	TAD 25 mm or less (n=137)	Above TAD 25 mm (n=64)	*P*-value
Age (yr)	81.5±6.5	81.5±6.7	0.978
Sex			0.068
Male	38 (27.7)	26 (40.6)	
Female	99 (72.3)	38 (59.4)	
BMD (g/cm^2)	3.3±1.0	3.2±0.9	0.394
BMD			0.394
T score >−2.5	27 (19.7)	16 (25.0)	
T score ≤−2.5	110 (80.3)	48 (75.0)	
BMI (kg/m^2)	22.2±3.9	21.7±3.2	0.332
BMI*			0.367
Underweight	22 (16.1)	11 (17.2)	
Normal	85 (62.0)	44 (68.8)	
Overweight	30 (21.9)	9 (14.1)	
ASA class			0.163
1, 2	89 (65.0)	35 (54.7)	
3, 4	48 (35.0)	29 (45.3)	
Koval grade			0.412
1	46 (33.6)	25 (39.1)	
2, 3	65 (47.4)	24 (37.5)	
4, 5, 6	26 (19.0)	15 (23.4)	
Type of fracture			0.553
Stable	95 (69.3)	47 (73.4)	
Unstable	42 (30.7)	17 (26.6)	

Values are presented as mean±standard deviation or number (%).
TAD: tip-apex distance, BMD: bone mineral density, BMI: body mass index, ASA: American Society of Anesthesiologists.
* Underweight: <18.5 kg/m^2, Normal: 18.5-25 kg/m^2, Overweight: >25 kg/m^2.

Comparison of the normal group and the surgical failure group showed that the mean age (81.3±6.4 vs. 86.4±6.8; *P*=0.034) and the ratio of unstable fractures were significantly higher in the surgical failure group (139/54 vs. 3/5; *P*=0.040). A significantly higher proportion of intramedullary reduction was also observed in the surgical failure group compared with that of the normal group (176/17 vs. 5/3; *P*=0.034); however, the results of comparison showed no statistical difference between the TAD groups (Table 1).

Comparison of the factors influencing the intramedullary reduction group with those of the anatomical or extramedullary reduction group showed a significantly higher ratio of unstable fractures (132/49 vs. 10/10; *P*=0.033) (Table 2). However, regarding factors that can cause excessive TAD (over 25 mm), comparison between groups showed that there were no statistically significant factors (Table 3).

DISCUSSION

In this study, we attempted to determine the factors affecting the occurrence of CM nail fixation failure, as well as those that cause excessive TAD, which are known factors of fixation failure, intra-medullary reduction. According to Ciufo et al.[19], fixation failure of proximal femur nail was caused by following factors; lateral wall fractire or posteromedial fracture of intertrochanteric area, basicervical fracture pattern with more than 3 mm step-off, malreduction of femur neck shaft angle 5 or more degree varus or more than 15˚ valgus alignment, and a lag screw located in superior portion of femoral head. Despite the weak statistical basis, the findings of this study demonstrated that the older the patient and the more unstable the fracture, the greater the chance of fixation failure, and intra-medullary reduction was more likely in unstable fractures.

The TAD value is calculated by summing the distance from the end of the lag screw to the apex of the femur head in the anteroposterior, trans-lateral view. According to general knowledge, the probability of fixation failure increases when the TAD value exceeds 25 mm[11-15]. According to Müller et al.[20], the closer the position of the lag screw to the middle part of the femur head while showing a better TAD value, the lower the occurrence of complications caused by

CM nailing. In addition, according to Caruso et al.[21], TAD remains the most accurate factor for predicting cut-out when it exceeds 30.7 mm. However, according to Shon et al.[22], TAD showed no statistical significance between the fixation failure group and the fixation success group. In our study, a comparison of patient factors causing TAD to exceed 25 mm was performed with 137 cases in the TAD 25 mm group and 64 cases in the TAD 25 mm group; measurements were based on radiographic images taken at the last outpatient follow-up, and no statistically significant factors were identified. In this regard, TAD as a factor affecting fixation failure is difficult to repudiate; however, conduct of additional research will be required in order to determine the precise cut-off value.

Various factors, including screw position within the head, as well as location of reduction, can also be regarded as risk factors for fixation failure. According to Shao et al.[23], compared with extramedullary reduction, an intramedullary fracture reduction pattern places a substantial burden on the implant. In accordance with our previous study, the potential association between cut-out and baseline characteristics (e.g., age, sex, bone mineral density, fracture type, implant type, screw position within the head, location of reduction, TAD) was examined; however, no significant associations were observed[24].

This study has the following limitations. First, the size of the group in which postoperative fixation failure occurred is small, thus the statistical power is small. This should be reflected in future studies through collection of more cases of CM nail fixation as well as cases of fixation failure. Second, a large number of patients were excluded because their collection period was less than six months based on the time the paper was written. Of 378 cases where surgery was performed, 98 cases did not meet the requirement for the collection period, and most ITFs occurred in elderly patients, who often died during the collection period and failed to meet the requirement for a collection period of six months or longer.

CONCLUSION

In treatment of ITF with CM nailing, fixation failures are likely to occur in elderly or unstable patients. Therefore, avoidance of intramedullary reductions during CM nail fixation is imperative.

FUNDING

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CONFLICT OF INTEREST

Sang-Min Kim has been an editorial board member since January 2022, but had no role in the decision to publish this article. No other potential conflict of interest relevant to this article was reported.

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