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Risk factors for fixation failure in intertrochanteric fractures treated with cephalomedullary nailing: a retrospective study of 251 patients

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This study aimed to identify the variables associated with fixation failure in intertrochanteric fractures treated with cephalomedullary nailing (CMN). We retrospectively analyzed 251 consecutive patients who underwent surgery between January 2016 and July 2019. In order to identify predictors of failure (cut-out, cut-through, and/or nonunion), we analyzed: gender, age, fracture stability (according to the AO/OTA Classification), femoral neck angle (FNA), FNA as compared to the contralateral hip, lag screw position, and tip-apex distance (TAD). The failure rate was 9.6%: there were 10 cut-outs (4%), 7 non-unions (2.8%), and 7 cut-throughs (2.8%). Univariate logistic regression analysis showed that the risk factors for fixation failure were: female sex (p= 0.018), FNA <125° (p= 0.003), a difference in FNA of 7.5° as compared to the contralateral hip on the lateral radiograph (p= <0.0001), superior (p= 0.0141) and anterior position (p= <0.0001) of the lag screw, and TAD >25mm (p= 0.016). According to the multivariate analysis, female gender (OR 12.92 ; p 0.0019), the difference in FNA on the lateral view (OR 1.36; p < 0.001), and the anterior position of the screw in the femoral head (OR14.01;p <0.001) were confirmed as independent predictors of failure. In order to avoid failures in intertrochanteric hip fractures treated with CMN, this study confirmed the importance of achieving an accurate reduction on the lateral plane and avoiding the anterior position of the screw on the femoral head.

Keywords: intertrochanteric fracture; cephalomedullary nailing (CMN); femoral neck angle (FNA); lag screw position; tip-apex distance (TAD).

INTRODUCTION

Though much progress has been made in implant design and surgical techniques, there is still a high failure risk of proximal femur fracture fixations in elderly patients. In this population, failed osteosynthesis of the proximal femur has been reported to have a considerable impact (11%-24%) on morbimortality in the first year after surgery[1,2]. Therefore, identifying predictors of fixation failure is particularly relevant.

Cephalomedullary nailing (CMN) is increasingly becoming the treatment of choice for intertrochanteric fractures[2,3]. Predictors of failure of extramedullary implants are extensively found in the literature[4-7], however nail failure has not been much studied[8-11]. Considering that the biomechanical behavior of extramedullary and intramedullary implants is different, implant-failure predictors may also be different.

The objective of this study was to analyze whether demographic variables, fracture stability, femoral-neck angle (FNA), quality of reduction, screw position, and tip-apex distance (TAD), either alone or combined, are predictors of failure in intertrochanteric fractures treated with CMN.

MATERIALS AND METHODS

We retrospectively reviewed the medical records of patients with intertrochanteric hip fractures who underwent surgery in 2 centers between January 2016 and June 2019. This study was conducted with the approval of the Institutional Ethics Committee.

Patients aged > 65 years treated with short CMN were included in the study. Our exclusion criteria were: pathologic fractures, history of previous surgery on the contralateral hip, and lack of clinical/radiological follow-up data to assess fracture healing, either due to patients' death or loss to follow-up.

All patients underwent minimally invasive surgery with intraoperative radioscopy on a traction table in supine position. Closed reduction was attempted in all cases. CMNs used were made of steel, had an angle of 130°, a single cephalic lag screw into the head (no blade), and allowed single dynamic distal locking.

From the first postoperative day, all patients were allowed full weight-bearing with aids as tolerated, except for patients who could not walk before the surgery.

Radiological images were obtained before and at six weeks and 3, 6, 9 and 12 months after surgery. The radiological evaluation was based on anteroposterior (AP) and lateral (L) views of the hips.

We recorded age, gender, and side of fracture. Preoperative radiographs on AP and L views were evaluated to determine fracture type and stability according to the AO/OTA classification (A2.1 stable; A2.2 unstable)[12]. Immediate postoperative radiographs were analyzed for FNA, quality of reduction, lag screw position, and tip-apex distance (TAD).

The FNA was measured in the fixed and the contralateral hip on AP and L radiographs to calculate the difference between them. Reduction quality (modified Baumgartner's method) was based on two criteria and assessed on AP and L radiographs[5]. The first criterion was a FNA of 125-130º on the AP view and <20º on the L view. The second criterion was <4mm displacement of any fragment in both views. Reduction quality was classified as good (if both criteria were met), acceptable (if only one criterion was met), or poor (if no criteria were met).

To determine the position of the screw, the femoral head was divided into three regions on the AP (superior, central, inferior) and L (anterior, central, posterior) views using the Cleveland method[13]. TAD was measured using the Baumgartner`s method[5], according to which a distance of £25mm is considered adequate. These measurements were obtained by two independent authors and discrepancies were resolved by a senior reviewer.

Non-union was defined as the absence of bone callus nine months after surgery and no signs of radiographic healing for the last 3 months. Complications related to loss of fixation of cephalic screws in the femoral head (i.e. cut-out and cut-through) were also registered. Cut-out was defined as the extrusion of the screw from the superior cortex of the femoral head or neck, and cut-through as the axial migration of the screw with joint penetration. The study population was divided into two groups (failure and non-failure) based on the presence of non-unions, cut-outs, and cut-throughs.

Continuous variables were expressed as mean and standard deviation (SD), or mean and interquartile range (IQ R), while categorical variables were expressed as frequencies and percentages. Continuous variables between the failure and the non-failure groups were compared with the Student's t-test or Wilcoxon´s test, and a Chi-square test was used to analyze the relationship between categorical variables. When test assumptions were not met, Fischer's exact test was used.

In order to analyze whether a variable exerted any influence on the incidence of complications, researchers applied logistic regression analysis and selected variables using a step-by-step method. When assessed separately, Firth's logistic regression was used due to the low frequency of each individual complication. The results of uni- and multivariate logistic regression analyses were presented as odds ratios (OR) for statistically significant variables. A $p<0.05$ value was considered statistically significant. The statistical analysis was conducted using R Software (Language and Environment for Statical Computing, R Foundation for Statical Computing, Vienna, Austria)

RESULTS

Out of the 287 patients initially examined, 251 patients with 251 fractures met the inclusion criteria. Thirty-six patients were excluded: 15 were lost to follow up, 5 died before fracture healing, 3 presented pathological fractures, and 13 had previously received surgery on the contralateral hip.

Two hundred and nine (83.26%) patients were women and 42 (16.73%) were men. The mean age was 81.5 ± 10.3 years (range 66-99). The right hip was affected in 117 (46.61%) cases and the left in 134 (53.38%). The median follow-up was 19.5 months (range 8-39).

The union rate was 90.43% (227 hips) for an average period of 11 weeks (range 9-16). Twenty-four remaining fractures (9.56%) were classified as failures: ten cut-outs (3.98%), seven cut-throughs (2.78%), and seven non-unions (2.78%).

The comparative analysis between the failure (n24) and the non-failure (n227) groups showed no differences (p=0.822) regarding age. (Table I)

Regarding gender, all the patients who presented complications were women (p=0.0181).

The distribution of fracture type (A2.1-A2.2) was similar between groups. Approximately 60% of fractures were classified as unstable in each group (p = 0.9999).

The failure rate increased significantly as the reduction quality decreased (p = 0.0478).

The mean overall FNA was 128.9°± 6.1 (range: 112°-152°). The mean FNA was lower in the failure group (126.4°± 6.6) than in the non-failure group

Table I. — Descriptive comparison: patients with failures versus patients without failures

	Total n=251	Non - Failure (n=227, 90.4%)	Failure (n=24, 9.6%)	*p* value
Age Mean (SD)	81.5 ± 10.3	81.5 ± 10.6	81.4 ± 6.71	0.822
Gender n (%),				
Female	209 (83.3)	185 (81.5)	24 (100.0)	0.018
Male	42 (16.3)	42 (18.5)	0 (0.0)	
Fracture type n (%)				
A2.1	102 (40.6)	92 (40.5)	10 (41.7)	0.999
A2.2	149 (59.4)	135 (59.5)	14 (58.3)	
Reduction quality n (%)				
Good	120 (100)	114 (95)	6 (5)	
Acceptable	97 (100)	84 (86.6)	13 (13.4)	0.047
Poor	34 (100)	29 (85.3)	5 (14.7)	
FNA difference Mean (IQ R)				
AP	3 (3)	3 (3)	4.5 (5.25)	0.075
L	0 (5)	0 (5)	7.5 (10)	<0.0001
FNA Mean (SD)	128.9 ± 6.1°	129.1 ± 6.0°	126.4 ± 6.6°	0.063
FNA ³125° n (%)	206 (82.1)	192 (84.6)	14 (58.3)	0.003
Lag Screw placement (AP view) n (%)				
Inferior	51 (20.3)	45 (19.8)	6 (25)	
Central	183 (72.9)	170 (74.9)	13 (54.2)	0.014
Superior	17 (6.8)	12 (5.3)	5 (20.8)	
Lag Screw Placement (L view) n (%)				
Posterior	46 (18.3)	44 (19.4)	2 (8.3)	
Central	173 (68.9)	164 (72.2)	19 (37.5)	<0.0001
Anterior	32 (12.7)	19 (8.4)	13 (54.2)	
TAD Mean (SD)	22.7 (5.6)	22.5 (5.4)	24.9 (7.2)	0.125
TAD > 25mm n (%)	77 (30.7)	64 (28.2)	13 (54.2)	0.016

(129.1 ± 6.0°), but this difference was not statistically significant (p = 0.0631). When classifying patients by FNA, the percentage of patients with FNA³125° was higher (84.6%; 192 patients) in the non-failure groups than in the failure group (58.3%; 14 patients) (p = 0.0036).

The difference in FNA was larger on the AP radiographs of the failure group (4.5º vs 3.0º ; p = 0.075). On the L view, the mean difference was 7.5º for the failure and 0º for the non-failure group respectively. This difference was statistically significant (p = <0.0001).

According to Cleveland zones, the most frequent position of the lag screw was center-center (51.5%) in non-failure groups and superior-center (33.3%) in the failure group. Figure 1 shows the zone distribution and failure rates of each zone. In the AP view, the superior zone (p = <0.0001) and in the L view, the anterior zone (p = 0.01413), were related to the failure.

The overall mean TAD was 22.7 ± 5.6mm (range 7-45). The mean TAD was larger in patients with failure, though differences were not significant (p = 0.1258). When classified by TAD, 64 (28.2%) patients in the non-failure groups and 13 (54.2%) had TAD >25mm. Such a difference was statistically significant (p = 0.0167).

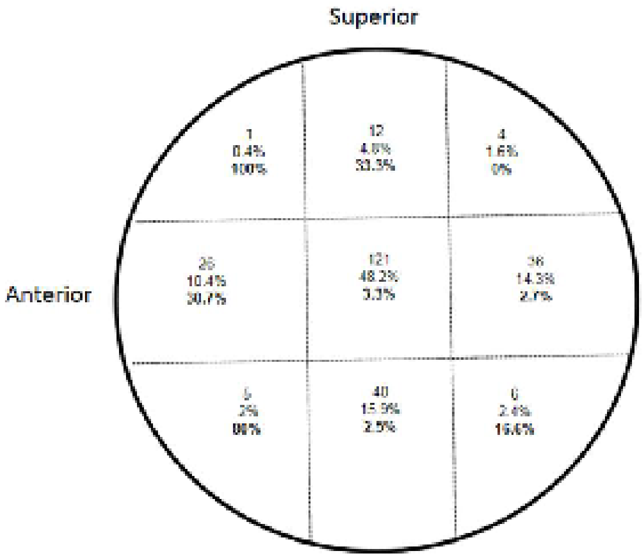

Figure 1. — Lag screw position on the femoral head. Frequency, percentage, and failure rates of each zone.

Table II. — Univariate logistic regression analysis.

	Odds Ratio	(95% Confidence Interval for OR)	*p value*
Female gender	11.22	1.51 - 1435.07	0.011
FNA (<125° vs ³125°)	3.93	1.61 - 9.35	0.003
Reduction quality			
Good vs Acceptable	2.81	1.09 - 7.97	0.052
Poor vs good	3.28	0.94 - 11.08	
FNA difference $_{Lat}$	1.28	1.16 - 1.43	<0.001
TAD (>25mm vs ≤25 mm)	2.94	1.29 - 7.14	0.011
Lag Screw Position (AP)			
Superior vs Central	5.56	1.76 - 17.08	0.015
Superior vs Inferior	3.13	0.82 - 11.11	
Lag Screw Position (L)			
Central vs Posterior	1.03	0.28 - 5.52	<0.001
Anterior vs Central	12.32	3.32 - 67.38	

Table III. — Multivariate logistic regression analysis

	OR	(95% CI for OR)	p value
Female Gender	12.92	1.39 - 1736.99	0.019
FNA difference $_{Lat}$	1.36	1.21 - 1.55	<0.001
Lag Screw Position			<0.001
Central vs Posterior	0.63	0.14 - 3.79	
Anterior vs Central	14.01	3.15 - 90.99	

All variables with $p < 0.05$ were included in the univariate analysis. According to the logistic regression model, the variables that were related to an increased failure risk were: female gender, FNA <125°, the difference in FNA on L radiograph, TAD >25mm, and superior placement of lag screw on the AP radiological view, and anterior placement on L view. (Table II)

After adjusting the multivariate logistic regression model, the following variables had a significant influence on the probability of failure: female gender, the difference in FNA on the lateral radiological view (**Figure** 2), and the anterior position of the screw. (**Table** III).

DISCUSSION

Failed osteosynthesis of the proximal femur after hip fracture may occur due to patient-dependent or patient-independent factors. Many authors have attempted to address the risk factors for mechanical fixation failure of proximal femur implants[5-7,9,14,15].

Reduction quality has been pointed out as a predictor of failure after proximal femur fixation with CMN[14,15]. In the present study, we observed that the failure rate increased significantly as the reduction quality decreased. Our findings are consistent with Kashigar et al.[16], who also used Baumgartner's classification. As

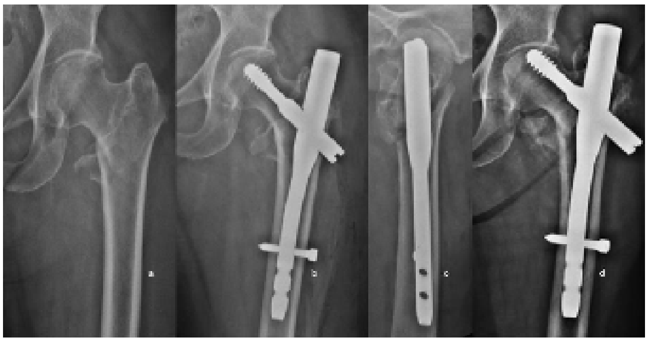

Figure 2. — A-B. Unstable trochanteric hip fracture (AO 31A2) in 82 years old female patient, fixed with short CMN. C. Note the poor reduction in L view. D. Three-month postoperative X-ray shows cephalic screw cut-out.

in our series, their logistic regression did not show a significant association between reduction quality and increased failure risk[16]. In a subjective interpretation, the wide range encompassed by Baumgartner's criteria (<20° difference in L radiological view) may account for these results. In contrast, a multivariate analysis conducted by Murena et al.[14] demonstrated that poor reduction quality is significantly correlated with fixation failure (cut-out).

Varus malreduction has been reported as a risk factor for failure as it exerts a greater force on the interface between the screw and the femoral head and restricts screw placement to a position above the femoral head[16-18]. Ciuffo et al.[18] reported a significant > 5° difference in varus reduction as compared to the contralateral hip. The univariate regression analysis of our data shows that FNA<125° was a risk factor for fixation failure.

The difference in FNA measured on the lateral radiological view showed a mean difference of 7.5° between the failure and non-failure groups. Univariate analysis showed such difference was associated with an increased risk of failure — a conclusion that was confirmed through multivariate regression. These results could be useful to design a new method to achieve proper reduction quality and may account for the fact that, in our series, Baumgartner's method failed to demonstrate that poor reduction quality leads to an increased failure risk.

Baumgartner et al.[5] defined TAD and recommended values lower than 25mm to prevent dynamic hip screw cut-outs after the fixation of trochanteric fractures. Even though some authors validate the use of TAD in intramedullary implants[4-6], others have pointed out the need to redefine this distance due to the biomechanical differences between intramedullary and extramedullary implants[16]. Although there is some consensus on the predictive value of TAD, no agreement has yet been reached on the ideal cut-off value. Nikoloski et al.[19] state that TAD should be between 20mm and 30 mm, while Kraus et al.[20] claim is should be < 30 mm. Geller et al.[8], like us, recommend a TAD < 25 mm to reduce cut-out risk. Our data analysis does not show TAD >25mm as an independent variable related to the failure.

Seven (2.8%) patients in our series presented cut-through. This suggests that this type of failure is not exclusive to helical blade fixation as initially stated by some authors[11,15,16]. Weil et al.[21] in a biomechanical study, reported that this type of failure could occur with helical blades and screws. It may be due to osteoporosis, TAD <20 mm, and failure of the blade/screw sliding mechanism[18].

There is no agreement regarding the ideal placement of the screw in the femoral head. While a central placement is accepted on the L view is accepted, some authors consider that a central position[5] and an inferior position[16] on the A-P view are also acceptable. Baumgartner et al.[5] reported greater cut-out with the anterior placement of the screw, while Yoo et al.[15] reported posterior placement as the position leading to greater cut-out[5]. In our analysis, we found that both an anterior and a superior screw position are associated with a significantly increased risk of failure. However, only the first one was identified as an independent variable.

In this study, age, side of the fracture, and AO fracture classification were not found to be related to fixation failure. Unlike many authors[16,22], we were not able to prove the existence of a direct relationship between fracture pattern (AO/OTA classification) and failed osteosynthesis. Finally, we found a statistically significant association between female gender and potential failure. (p=0.0181). In line with Caruso et al.[22], the higher index of osteoporosis in female patients combined with age (mean age of 81.5 years) may explain these results. However, the large confidence interval obtained calls for a cautious interpretation.

Study limitations include those inherent to retrospective studies, the low number of failures and the fact that this study has not analyzed other variables suggested as predictors of failure in the treatment of intertrochanteric fractures with CMN. The strengths of this study include the number of patients enrolled and a thorough statistical analysis.

CONCLUSION

Based on the results of this study, surgeons should strive to achieve a good reduction on the AP and L planes, and secure proper implant placement. We identified 3 predictors of failure in our multivariate logistic analysis: female gender, malreduction (7.5°) on the lateral plane, and anterior placement of the screw on the femoral head. The univariate analysis identified varus reduction <125°, TAD >25 mm, and superior placement of the screw as predictors of fixation failure.

Ethics approval: All procedures followed were in accordance with the ethical standards of the British Hospital of Buenos Aire's committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. (Project number 2257) Informed consent was obtained from all patients for being included in the study.

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