ORIGINAL ARTICLE

Comparison of cutout risk factors between single- and double-screw proximal nails in intertrochanteric femur fractures - a multicentric study

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ABSTRACT

Aim Significant risk factors for femoral nail cutout are well-documented, primarily in the context of single-screw proximal nails. However, it remains uncertain whether those same risk factors are applicable when considering different implant devices. The aim of this retrospective cohort study was to compare cutout risk factors between single- versus double-screw proximal femoral nails.

Methods Patients over the age of 75 with intertrochanteric femur fractures (AO Classification 31-A1 or 31-A2) were included in the multicentre study. A study group was treated with a double-screw nail, while a control group received single-screw device. Demographic data, surgical time (min), fracture pattern, distal locking, reduction quality, comorbidities, tip-apex distance (TAD) and 12-month functional scores was collected.

Results Two hundred patients were enrolled, 100 for each group. Nine patients experienced a cutout complication, five in the study and four in the control group. The main differences were in distal locking configurations ($p<0.05$) and in TAD values ($p<0.05$). The TAD value was higher in the study than in the control group (30.40±0.89 versus 26.79±1.79). No differences at 12-month follow up were reported according to functional scores.

Conclusion This study provides insights into the choice of nail systems for intertrochanteric femur fractures, highlighting the importance of distal locking configurations and TAD values. The double screw nail exhibits quite a tolerance by having a higher average TAD value. These findings may guide clinical decision-making in the treatment of this challenging fracture type.

Key words: internal fixation, nailing, postoperative complication, proximal femoral fractures

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INTRODUCTION

Intertrochanteric femur fractures are extracapsular fractures of the proximal femur that occur usually in osteoporotic patients from a low-energy trauma (i.e. falls). Elderly people over 65 years of age are the most affected, especially when associated with osteoporosis and other comorbidities such as obesity (1,2). The management of these fractures is usually surgical and is considered urgent, not emergent. This allows many comorbidities to be optimized before surgery to reduce the risk of morbidity and mortality (2). Non-operative treatment is rarely indicated (3).

Intramedullary nailing is the most widely used device to treat intertrochanteric fractures, including more unstable patterns such as reverse obliquity pattern, thanks to biomechanical advantages and soft tissue respect of this surgical technique (4).

Among the most common implant-related complications there is screw cutout. This phenomenon recognizes several risk factors including the tip apex distance (TAD); a TAD greater than 25 millimetres of cephalomedullary screw is related to more implant failures (5).

Cutout is the migration of the proximal screws and the TAD represents a determining parameter (6).

Previous studies on single-lag screw nails or dynamic hip screws explored mechanical and clinical factors for cutout (5). Furthermore, there are some studies that show how the smaller diameter screws in dual-lag designs would be more prone to migration through the femoral head, increasing the risk of cutout (6). On the other hand, recent studies have shown that double-screw designs provide greater or equivalent resistance against neck rotation and varus collapse compared with a single-lag screw implant (6,7).

Although previous studies have stated the increased risk of implant failure for TAD values greater than 25 mm, development of device design and materials in the last 30 years has significatively contributed to reduce prevalence of cutout and other complications (8).

The aim of this study was to compare cutout risk factors between single- versus double-screw proximal femoral nails.

PATIENT AND METHODS

Patients and study design

A retrospective cohort study between January 2019 and September 2021 was conducted. Patients with intertrochanteric femur fractures recruited from Bari at Policlinico and Di Venere Hospital were treated with the Endovis BA2 (EBA2) (Citieffe, Calderara di Reno, Bologna, Italy) as a study group and Trochanter Fixation Nail Advanced (TFNA) (DePuy Synthes, West Chester, PA, USA) nail systems as control.

Inclusion criteria were age >75 years, and trochanteric femur fractures (AO Classification 31-A1 or 31-A2) surgically treated (9). Patients with fractures categorized as type 31A3 and those with poor reduction were excluded. A total of 200 patients were included in the study, meeting the inclusion criteria.

Pathological fracture, open fracture, requirement for open reduction, and absence of imaging follow-up for at least 3 months following surgery were all exclusion criteria.

Senior trauma surgeons carried out all of the surgeries in accordance with the manufacturer's operational technique (10, 11). A multidisciplinary team handled the patients in accordance with our hospital's defined peri-operative procedure. The patients were checked in two, four, and twelve weeks. At twelve months, a phone call was made to assess for any late adverse outcomes.

The age, gender and body mass index (BMI), side of fracture were recorded for each patient. Comorbidities were classified using the American Society of Anesthesiologists (ASA) classification (12). Fracture types on the AO/OTA classification (9). Surgical variables, such as the duration of surgery (express in minutes) and quality of reduction were imported.

Ethical review and approval were waived for this study. All individuals provided a written consent before being included in the research.

The paper followed the STROBE rules (13).

Methods

Baumgartner et al. criteria were applied to assess the fracture reduction quality after intramedullary nailing (14,15). The tip-apex distance (TAD) was measured for each patient.

The TAD is the sum of the distances recorded in millimetres from the tip of the screw to the apex of the femoral head on anteroposterior and lateral radiographs for single screw nail as stated by Baumgartner et al. (14). Conversely, in the double screw nail, the distance to the apex of the femoral head with the middle between the tips of the two screws in the AP view was calculated (Figure 1) (16). TAD is calculated as the length from the apex of the femoral head and the tip of the proximal lag screw in lateral view (Figure 1). The point of junction between the subchondral bone and a line running through the centre of the femoral neck is designated as the apex of the femoral head. The Picture Archiving and Communication System (PACS) (Centricity; General Electric Health Systems, Waukesha, WI, USA) radiographs were utilized to assess the quality of the reduction and TAD and obtained after surgery by two authors (AA and EC) blinded to each other's measurements.

After 12 months, a functional evaluation was performed using the modified Harris Hip Score and a timed up and go test (17). The first assessment evaluates hip function including pain, gate, functional activities, hip motion and absence of deformity. It yields a total score, ranging from 0 (severe disability) to 100 (minimal disability) (18). The Timed Up and Go Test (TUG) assesses mobility and fall risk: individuals rise from a chair, walk three meters, turn, and return to sit, with the time recorded. It is a quick, widely used measure to evaluate functional mobility, particularly in older adults and those with mobility impairments (19).

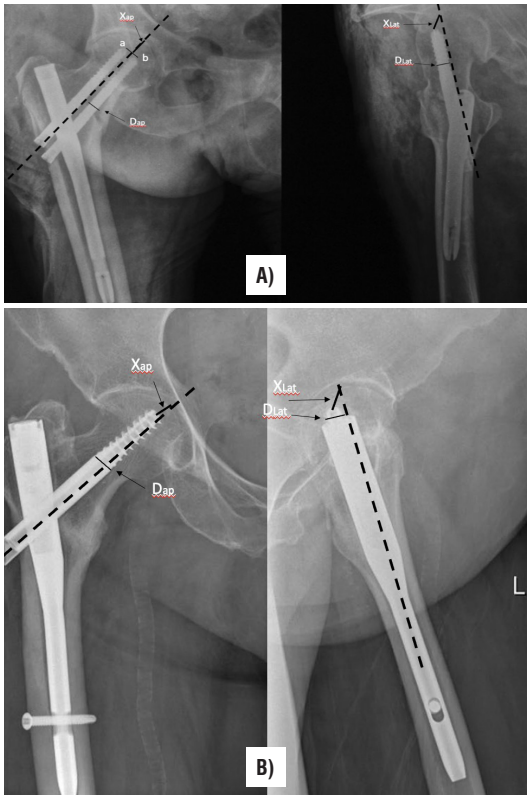

Figure 1. Tip-apex distance in anterior ad lateral views of intertrochanteric femur nailing A) for study and B) for control group: Xap was measured as the distance from the apex of the femoral head to a midpoint between the tips of the two screws, Xlat was the distance between the tips in lateral view and the femoral head, Dap and Dlat were the diameter of the screws respectively in the two views (Di Venere Hospital, 2019)

As the primary endpoint, the assessment of cutout risk factors in groups was analysed. The TAD threshold predictive of cutout and 12 months functional outcomes were set as the secondary endpoint.

Statistical analysis

For the entire sample descriptive statistics were computed. Categorical variables were presented as percentages and numbers. Mean and standard deviation (SD) were used to express continuous variables. Non-parametric tests were calculated due to the non-homogeneous distribution of the values using the Kolmogorov-Smirnov test ($p>0.05$). The categorical and continuous parameters were analysed using the Mann-Whitney and Fischer's test. The cutoff value of TAD for the cutout diagnosis were established using the ROC analysis. The TAD thresholds were set using Youden's J statistic as a suitable cutoff that maximized the distance to the identity (diagonal) line on the ROC curve.

RESULTS

Two hundred consecutive patients who underwent intertrochanteric femur fractures were enrolled in this study and allocated into two groups, 100 in each group (Table 1). The study group mean age was 83.40±7.19 years with 77 (77%) females, and BMI was 26.30±5.01. The control group was made up of 100 patients, mean age 26.52±4.83, 62 (62%) females, and BMI was 26.52±4.83. No statistical differences emerged between the groups according to preoperative features except for affected side.

The study compared only cutout patients in both groups (Table 2): five (5%) patients in the study and four (4%) in the control group. Differences in distal locking configurations and TAD values were demonstrated: a failure only in no distal locked TFNA nail was registered in comparison

Table 1. Characteristics of the study population

Variable	Study (EBA2) group (n=100)	Control (TFNA) group (n=100)	Total (n=200)	p
		Mean±SD		
Age (years)	83.40±7.19	82.45±5.93	82.93±6.59	0.21
BMI (Kg/m²)	26.30±5.01	26.52±4.83	26.42±4.91	0.74
Surgical time (minutes)	29.05±9.80	28.13±8.59	28.59±9.21	0.79
		No (%) patients		
Gender				0.09
Male	23 (23)	13 (13)	36 (18)	
Female	77 (77)	87 (87)	164 (82)	
Side				0.01
Left	29 (29)	62 (62)	91 (45.5)	
Right	71 (71)	38 (38)	109 (54.5)	
Fracture classification				0.09
31-A1	62 (62)	49 (49)	111 (55.5)	
31-A2	38 (38)	51 (51)	89 (44.5)	
Distal locking				0.79
No	52 (52)	48 (48)	100 (50)	
Dynamic	35 (35)	16 (16)	71 (35.5)	
Static	13 (13)	36 (36)	29 (14.5)	
ASA Classification				0.89
> 2	46 (46)	52 (52)	106 (53)	
≤ 2	54 (54)	48 (48)	94 (47)	
Reduction				0.32
Good	60 (60)	52 (52)	115 (57.7)	
Acceptable	40 (40)	48 (48)	85 (42.5)	

EBA2, Endovis BA2; TFNA, Trochanter Fixation Nail Advanced; BMI, body mass index; ASA, American Society of Anesthesiologists

Table 2. Comparison within the cutout groups

Variables	Study (EBA2) group (n=5)	Control (TFNA) group (n=4)	p
	Mean±SD		
BMI (Kg/m²)	27.00±6.96	26.75±5.38	1.00
Surgical time (minutes)	26.20±6.05	25.75±1.50	1.00
Tip apex distance (mm)	30.40±0.89	26.79±1.79	0.03
	No (%) patients		
Fracture classification			0.52
31-A1	1 (20)	2 (50)	
31-A2	4 (80)	2 (50)	
Distal locking			0.05
No	1 (20)	4 (100)	
Dynamic	2 (40)	0	
Static	2 (40)	0	
ASA Classification			0.78
> 2	2 (40)	2 (50)	
≤ 2	3 (60)	2 (50)	
Reduction			1.00
Good	1 (20)	1 (25)	
Acceptable	4 (80)	3 (75)	

EBA2, Endovis BA2; TFNA, Trochanter Fixation Nail Advanced; BMI, body mass index; ASA, American Society of Anesthesiologists

with different locking configurations EBA2 y nails. The mean TAD value in the study group was higher than the control (30.40±0.89 versus 26.79±1.79) (Figure 2).

For TFNA group, a cutoff value of 25.39 mm was determined in the Receiver Operating Characteristic (ROC) analysis with sensitivity of 0.750, 1-specificity of 0.350 ($p<0.05$), and an area under the curve (AUC) of 0.810. A cutoff value of

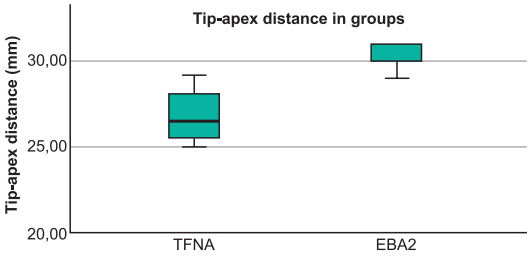

Figure 2. Comparison of Tip-apex distance (TAD) in Endovis BA2 (EBA2) and Trochanter Fixation Nail Advanced (TFNA) groups

29.50 mm was calculated for double screw nail with sensitivity of 0.800, 1-specificity of 0.108 ($p<0.01$) and an area under the curve of 0.940.

No intraoperative complication was recorded.

After 12 months, 18 (18%) patients in the study group and 12 (12%) in the control were lost at follow-up. Fifteen out of 18 died, three did not respond to control. Two control patients refused to come to follow-ups, eight died, and two did not respond. Functional scores at 12 months showed no differences between the two groups (Table 3).

DISCUSSION

Table 3. Functional outcome at 12 months

Variable	Mean±SD		
	EBA2(n=82)	TFNA (n=78)	p
Modified Harris hip scores	70.68±11.29	69.98±15.18	0.61
Timed up and go test (seconds)	20.67±9.59	21.48±13.53	0.91

EBA2, Endovis BA2; TFNA, Trochanter Fixation Nail Advanced;

Our study focused on surgically treated proximal femur fracture. The ingrowing aging in the population (20) and their fragility, as well as the limited amount of healthcare resources require to find different ways to reduce the incidence of complications when treating intertrochanteric femoral fractures (3). The optimal treatment using endomedullary nails with one or two lag screws for proximal femur fractures including subtrochanteric remains a matter of debate (21).

The importance of the position of the lag screw within the femoral head has been recognized since early reports of clinical results associated with the use of sliding hip screw (22). However, Baumgaertner et al. definitively developed a simple technique to describe the placement of the lag screw within the femoral head and introduced the concept of tip apex distance to demonstrate its clinical usefulness as a strong predictor of cutout of the screw used for proximal fixation of intertrochanteric fractures of the hip (14). The TAD

is defined as a sum of the distance from the tip of the cephalic screw to the apical portion of the femoral head, measured on X-rays in AP and LL views (23). Subsequent literature showing TAD greater than 25 mm is a strong predictive factor for single screw nails cutoff (24-26). Our study agrees with this hypothesis.

Different authors have highlighted that Baumgaertner's TAD cutoff of 25 mm is not supported by clinical evidence: Yam et al. raised the traditional TAD cutoff from 25 to 27 mm (27), Caruso et al. raised the TAD cutoff from 25 to 34.8 mm in their retrospective cross-sectional study on 604 patients (28). It is interesting how factors such as a type of distal locking (dynamic vs static) and the use of double vs single-screw cephalic nail were able to increase the risk of cutout, although if associated with stronger predictive factors (29-31). A research gap recognized from the literature urges the need to be explored further.

There are few studies that analysed risk factors in two lag screws nail. Sisman et al. demonstrated that in double screw nail cutout risk depends on quality reduction, TAD, proximal screw placement and osteoporosis suggesting as in single-screw implant, in double screw implants there is a higher risk of cutout when TAD is more than 25mm (32).

Buyukdogan et al. found a TAD value <25mm is a risk factor for cutout even in double-screw nails (30). The population group recruited in our study was homogeneous in terms of age, risk factors, and comorbidities. Our research demonstrated TAD and distal locking were different risk factors in two groups. Indeed, TAD is statistically higher in study than in control group.

Furthermore, from a functional recovery perspective, no significant differences were observed in the 12-month outcome of patients with proximal femur fractures treated with TFNA and EBA2 in our data. In fact, at the last follow-up after surgery, assessment scales and tests such as the Harris Hip Score and Timed up and go test showed overlapping values between patients treated with TFNA and those treated with EBA2 as emphasized in similar studies (30).

Our study has some limitations. This is a retrospective study, with a relatively small number of involved patients, with a follow-up limited at 12 months. Additionally, our study directly compares two specific nails, albeit certain parameters, such as the presence of osteoporosis in the medical history of selected patients or other comorbidities that could influence the short- and long-term surgical outcomes, were not included.

On the other hand, our study also has some fundamental advantages. Firstly, it is one of the first to directly compare TAD values in a specific single-screw nail like TFNA and a double-screw nail like EBA2 in relation to the risk of cutout. Moreover, our study also shows that the 12-month outcome in patients treated with TFNA is comparable to those treated with EBA2, despite patients treated with EBA2 highlighted a higher mean TAD value compared to those treated with TFNA.

In conclusion, the double cephalic screw nail has proven equally valuable for the treatment of intertrochanteric fractures with a higher value of Tip-apex distance regardless of the distal locking screw configuration. In the future, further studies are necessary to delve deeper into the relationship between TAD and the risk of cutout in double screw nails compared to single screw nails, and studies that compare different double screw nails and various single screw nails. It will be crucial to involve a larger number of patients and have a longer follow-up period beyond 12 months.

Further studies will be needed to evaluate the accuracy of the surgical procedure by considering a larger number of patients and different types of intramedullary nail.

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TRANSPARENCY DECLARATION

Competing interests: None to declare.

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