Intertrochanteric Fractures in Elderly Adults: Analysis of Risk Factors Associated With Failure in Osteosynthesis With a Cephalomedullary Nail

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ABSTRACT

Objectives: Intertrochanteric fractures are increasingly frequent due to population aging. Osteosynthesis with cephalomedullary nail is widely used for the treatment of these fractures. The objective of this study is to analyze the rate of failure in osteosynthesis associated with cephalomedullary nail and the risk factors for this event. **Materials and Methods:** All cases of patients older than 75 years with intertrochanteric fractures treated in our center with cephalomedullary nails between January 2016 and December 2019 were retrospectively analyzed. The cervico-diaphyseal angle of the operated hip was determined in the immediate postoperative period. We also analyzed the tip-apex distance (TAD) and the position of the lag screw in the femoral head. **Results:** 66 patients were included in the study. There were 8 cases of failure in osteosynthesis (12.12%). It was found that previously recognized factors in the literature (TAD>25 mm and reduction in varus) were also significant risk factors for failure in osteosynthesis in our cohort. The inadequate position of the lag screw was a risk factor that showed statistical significance in the univariate analysis, but not in the multivariate one in this study. **Conclusions:** When treating intertrochanteric fractures with cephalomedullary nail, a neutral or slightly valgus reduction aiming for a TAD ≤25 mm significantly reduced the risk of failure in osteosynthesis. We found evidence that a superior or posterior location of the lag screw increases the risk of fixation failure, although the location of the screw was not a significant risk factor in the multivariate analysis.

Key words: Intertrochanteric fractures; cephalomedullary nail; risk factors; cut-out; pull-out.
Level of Evidence: II

Fracturas intertrocantéricas en adultos mayores: análisis de los factores de riesgo asociados con falla en la osteosíntesis con clavo cefalomedular

RESUMEN

Objetivos: Las fracturas intertrocantéricas son cada vez más frecuentes debido al envejecimiento de la población. La osteosíntesis con clavo cefalomedular se utiliza ampliamente para tratar estas fracturas. El objetivo de este estudio fue analizar la tasa de fallas en la osteosíntesis con clavo cefalomedular y sus factores de riesgo. **Materiales y Métodos:** Se evaluó retrospectivamente a pacientes >75 años con fracturas intertrocantéricas tratados con clavo cefalomedular, en nuestro Centro, entre enero de 2016 y diciembre de 2019. Se analizó el ángulo cervicodiafisario de la cadera operada en el posoperatorio inmediato, la distancia punta-ápice y la posición del tornillo deslizante en la cabeza femoral. **Resultados:** Se incluyó a 66 pacientes. Hubo 8 casos de fallas en la osteosíntesis (12,12%). Se comprobó que ciertos factores ya establecidos (distancia punta-ápice >25 mm y reducción en varo) también fueron factores de riesgo significativos para falla en la osteosíntesis, en nuestra cohorte. La posición inadecuada del tornillo deslizante fue un factor de riesgo con significación estadística en el análisis univariado, pero no en el multivariado. **Conclusiones:** Al tratar las fracturas intertrocantéricas con un clavo cefalomedular, la reducción en neutro o ligero valgo, apuntando a una distancia punta-ápice ≤25 mm redujo significativamente el riesgo de falla en la osteosíntesis. Hallamos que una localización superior o posterior del tornillo deslizante aumenta el riesgo de falla en la fijación, si bien la localización del tornillo no fue un factor de riesgo significativo en el análisis multivariado.

Palabras clave: Fracturas intertrocantéricas; clavo cefalomedular; factores de riesgo; *cut-out*; *pull-out*.
Nivel de Evidencia: II

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INTRODUCTION

The incidence of intertrochanteric femur fractures is increasing due to demographic factors, such as an aging population[1] and increased life expectancy. Most of these fractures require surgical resolution for the patient to regain the ability to walk early on and thus reduce the risk of complications of prolonged immobilization, such as thromboembolic disease, pneumopathy, and bedsores. Depending on the type of fracture, the surgical treatment options that are most commonly used are the cephalomedullary nail, the dynamic hip nail-plate. or arthroplasty. The cephalomedullary nail is considered the reference standard for unstable intertrochanteric fractures.[2] Rates of complications related to this implant vary between 6.5% and 21.2% in the literature.[3,4] Several authors have evaluated the risk factors for failures in cephalomedullary nail fixation and these include, among others, a tip-apex distance (TAD) >25 mm,[5] the inadequate location of the sliding screw in the femoral head,[6] varus reduction, or a very lateral entry point in the greater trochanter.[7-9] Understanding the causes of failure to use this implant when treating intertrochanteric fractures in older adults is a fundamental requirement for optimizing post-surgical outcomes in a population that leaves no room for errors due to age and comorbidities.

The main objective of this study was to analyze the rate of osteosynthesis failures resulting from cephalomedullary nail fixation of intertrochanteric fractures in patients >75 years of age. The secondary objective was to identify risk factors for these implant-related complications.

MATERIALS AND METHODS

Patients

We conducted a retrospective study that included patients >75 years of age with a diagnosis of intertrochanteric fracture treated with cephalomedullary nail in our Center, between January 2016 and December 2019. All imaging studies and medical records were extracted from the electronic health records of the patients, who had simple preoperative radiographs (anteroposterior pelvis radiograph and surgical profile radiograph of the affected hip). The exclusion criteria were age <75 years, subtrochanteric fracture or pathological fracture, inadequate postoperative radiographs that prevented accurate measurements, a contralateral hip disease that prevented an adequate comparison of the affected hip with the unaffected hip, follow-up <3 months.

Surgical technique, rehabilitation, and follow-up

The surgeries were performed by two different surgeons, both specialists in orthopedic trauma. A closed reduction was performed using a traction table and closed manipulation techniques under radioscopic control with an image intensifier. When the reduction was unacceptable, open reduction techniques were also used to improve the quality of the alignment obtained. The guide pin was inserted at the tip of the greater trochanter, then the proximal fragment was reamed and the cephalomedullary nail was inserted. The central positioning of the sliding screw in the femoral head was sought, both in the anteroposterior and lateral views. The implant used was a titanium cephalomedullary nail with a cervico-diaphyseal angle of 130° or 135° (depending on the estimated angulation of the unaffected hip). All implants were of the same brand.

Simple radiographs were obtained in anteroposterior (in the supine position on the chassis and with the hips in 20° of internal rotation) and surgical profile projections (in the supine position, hip and knee on the opposite side in 90° of flexion and with the chassis placed proximal to the hip evaluated, forming an angle of 45° with the midline of the body and perpendicular to the table) on the first postoperative day, when rehabilitation was also initiated. Partial weight-bearing on the operated lower limb was authorized two weeks after surgery. Clinical and radiographic follow-up was performed at months 1, 2, 6, 12, and 24 after hospital discharge.

Data analysis

Demographic data

Demographic data, such as gender and age, were collected. In addition, data on comorbidities, such as high blood pressure, diabetes, and cognitive impairment, were analyzed. Preoperative radiographs were evaluated to determine the type of fracture according to the AO/OTA classification.[10] Fractures types 31A1 and A2.1 were considered stable, while patterns A2.2, A2.3, and A3 were considered unstable.[11]

Trauma intensity was classified as low- or high-energy according to ATLS *(Advanced Trauma Life Support)* guidelines.[12]

Radiographic parameters

The cervico-diaphyseal angle was measured on the first postoperative radiograph and on the last available follow-up radiograph. The cervico-diaphyseal angle is defined as the angle formed between the axis of the femoral neck and the axis of the femoral diaphysis on anteroposterior radiographs (Figure 1). This angle was also measured in the unaffected femur.

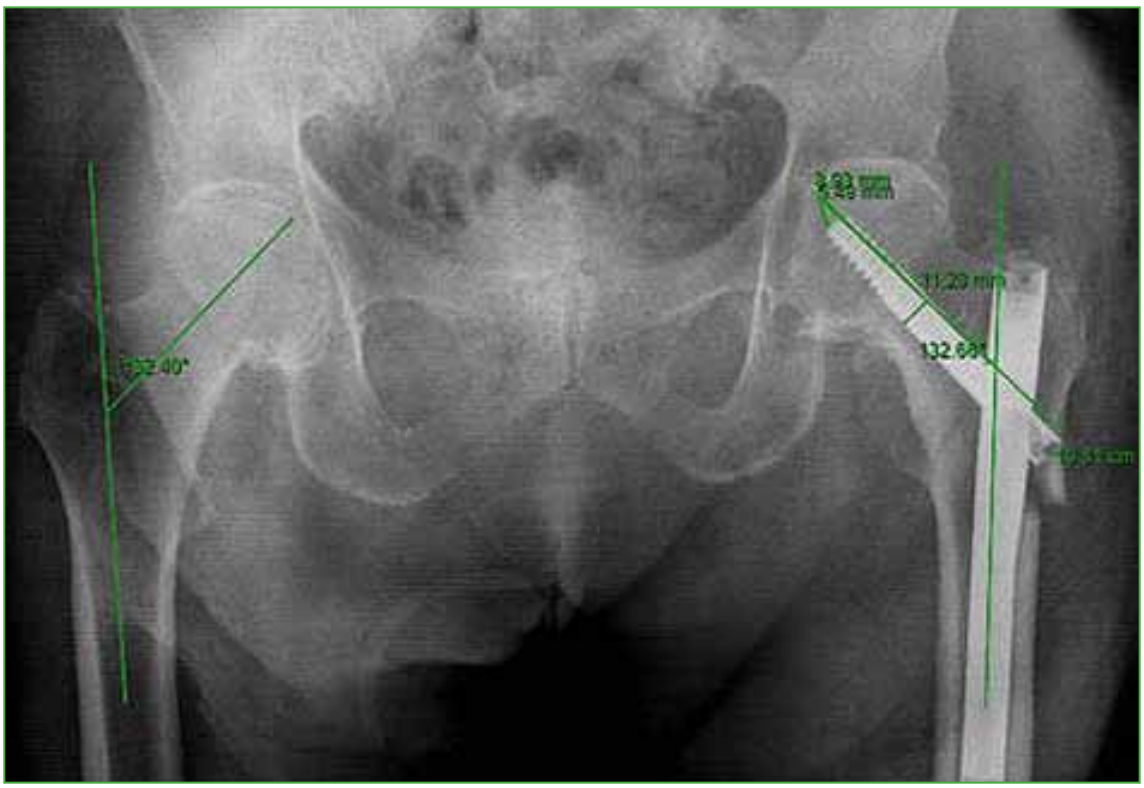

Figure 1. Measurement of the cervico-diaphyseal angle.

The postoperative alignment was divided into three groups: varus (<125°), neutral (125-135°), and valgus (>135°). We consider postoperative varus alignment as inadequate and postoperative valgus or neutral alignments as adequate.[13]

The position of the sliding screw on the femoral head was evaluated as described by Cleveland et al.[14] According to this method, the femoral head is divided into upper, central, and lower thirds in the anteroposterior radiograph and anterior, central, and posterior thirds in the lateral radiograph, thus delimiting a total of nine zones where the sliding screw can be located. The center-center or lower-center locations were considered adequate and all other positions were considered inadequate.[15]

TAD[5] was analyzed and categorized at 25 mm and >25 mm. TAD consists of the "sum of the distances (in millimeters) from the tip of the sliding screw to the apex of the femoral head, measured in the anteroposterior and lateral radiographs after the correction of the magnification".

Analysis of risk factors

To assess risk factors for fixation failure, patients were divided into two groups. In group A, no osteosynthesis failures were evidenced during follow-up. Group B included patients with osteosynthesis failures, defined as: 1) "cut-out" (perforation of the femoral head by the sliding screw of more than 1 mm in any view),[13] 2) "pull-out" (migration and lateral exit of the sliding screw in an uncontrolled way due to failure of the cephalic anchorage).[16]

Statistical analysis

The STATA 13.0 program was used. Differences between groups were assessed with Fisher's exact probability test for categorical data and with the Mann-Whitney U test for continuous variables. A p-value <0.05 was considered statistically significant. All variables with statistical significance in the univariate analysis were included in the multivariate analysis, which was performed using logistic regression.

RESULTS

At our Center, 82 fractures were treated with cephalomedullary nails between January 2016 and December 2019. 16 patients were excluded; therefore, the series included 66 patients. Figure 2 summarizes the number of patients at each stage of the study. The mean follow-up time was 9.72 months (range 3-36).

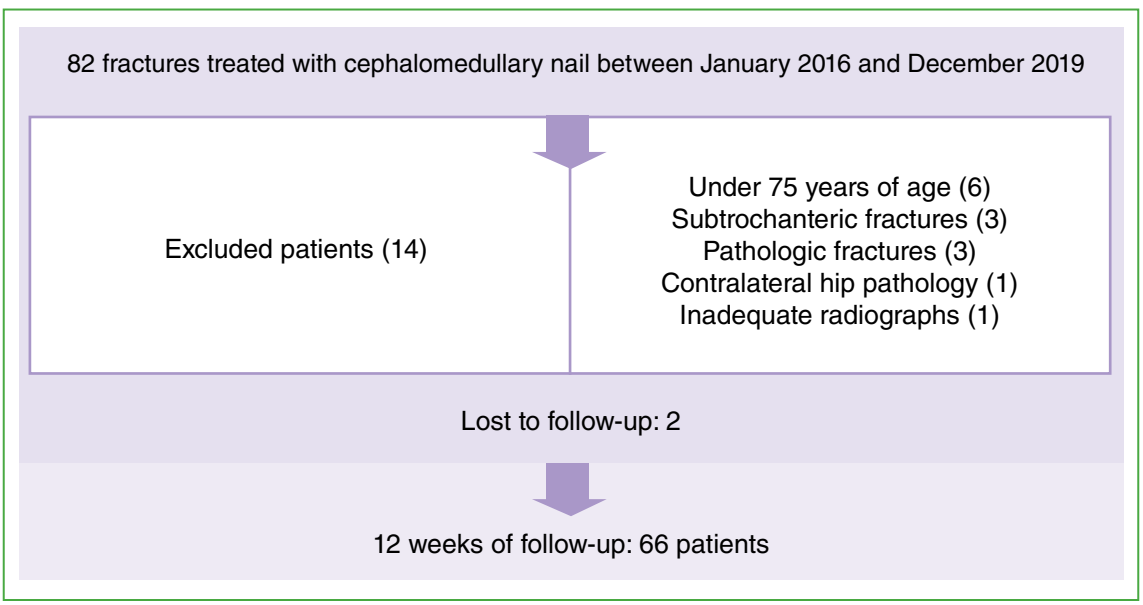

Figure 2. Summary of the number of patients at each stage of follow-up.

Demographic data

The demographic information of the patients is detailed in Table 1. Forty-seven were women (71.21%) and 19 (28.79%) were men. Mean age was 84.5 years (standard deviation 4.71). 51.51% (34 patients) had high blood pressure; 10.61% (7 cases), diabetes; and 6.06% (4 cases), cognitive impairment.

Most of the fractures were 31A1 of the AO/OTA classification (32 fractures; 48.48%). Twenty-six (39.39%) were 31A2 and eight (12.13%), 31A3. 74.24% (49 patients) had a stable fracture and 25.76% (17 patients) had unstable patterns.

98.48% (65 fractures) had been caused by low-energy trauma, most of them by falling from their own height. In three patients (4.55%), open reduction techniques were used to improve the quality obtained. None of them presented failure in osteosynthesis.

Table 1. Patient demographics and univariate analysis

Factor	All	Group A [n = 58 (%)]	Group B [n = 8 (%)]	p[a]	OR[b]	95% CI for OR
Age	84.5	84.276	86.125	0.278	1.095	0.922-1.300
Sex				0.213	2.867	0.636-12.17
Male	19 (28.79)	15 (25.86)	4 (50)			
Female	47 (71.21)	43 (74.14)	4 (50)			
Laterality				0.708	0.56	0.122-2.563
Right	33 (50)	28 (48.28)	5 (62.5)			
Left	33 (50)	30 (51.72)	3 (37.5)			
High blood pressure				0.71	1.667	0.364-7.629
No	32 (48.49)	29 (50)	3 (37.5)			
Yes	34 (51.51)	29 (50)	5 (62.5)			
Diabetes				1.00	1.238	0.129-11.856
No	59 (89.39)	52 (89.66)	7 (87.5)			
Yes	7 (10.61)	6 (10.34)	1 (12.5)			
Cognitive impairment				1.00		
No	62 (93.94)	54 (93.1)	8 (100)			
Yes	4 (6.06)	4 (6.9)	0 (0)			
Injury mechanism				1.00		
Low-energy	65 (98.48)	57 (98.28)	8 (100)			
High-energy	1 (1.52)	1 (1.72)	0 (0)			
AO/OTA Classification				0.87		
31A1	32 (48.48)	29 (50)	3 (37.5)			
31A2	26 (39.39)	22 (37.93)	4 (50)			
31A3	8 (12.13)	7 (12.07)	1 (12.5)			
Fracture stability				0.669	2.667	0.304-23.425
Stable	49 (74.24)	42 (72.41)	7 (87.5)			
Unstable	17 (25.76)	16 (27.59)	1 (12.5)			
Cervico-diaphyseal angle (°)						
Healthy hip	132.18	132.24	131.79	0.051	0.989	0.878-1.114
Operated hip	131.1	131.66	126.99	0.853	0.884	0.778-1.005
Difference	-1.08	-0.58	-4.8	0.105	1.095	0.980-1.224
Postoperative alignment				**<0.0001**		
Varus (<125°)	11 (16.67)	6 (10.35)	5 (62.5)			
Neutral (125-135°)	34 (51.52)	34 (58.62)	0 (0)			
Valgus (>135°)	21 (31.82)	18 (31.03)	3 (37.5)			
Postoperative alignment				**0.0002**	14.444	2.740-76.135
Varus	11 (16.67)	6 (10.35)	5 (62.5)			
Neutral/Valgus	55 (83.33)	52 (89.65)	3 (37.5)			
Screw Location (AP)				0.311		
Superior	8 (12.12)	6 (10.35)	2 (25)			
Center	43 (65.15)	39 (67.24)	4 (50)			
Inferior	15 (22.73)	13 (22.41)	2 (25)			
Screw location (profile)				0.166		
Anterior	16 (24.24)	15 (25.86)	1 (12.5)			
Center	29 (43.94)	27 (46.55)	2 (25)			
Posterior	21 (31.82)	16 (27.59)	5 (62.5)			
Screw location				**0.043**		
Adequate	24 (36.36)	24 (41.38)	0 (0)			
Inadequate	42 (63.64)	34 (58.62)	8 (100)			
TAD				**0.004**	11.5	2.056-64.338
≤25 mm	48 (72.73)	46 (79.31)	2 (25)			
>25 mm	18 (27.27)	12 (20.69)	6 (75)			

Significant p-values are shown in bold (<0.05). CI95% = 95% confidence interval.
[a]p = Fisher's test of exact probability for categorical data and Mann-Whitney U test for continuous data.
[b]Odds ratio: logistic regression analysis.

Primary outcomes: Complications and reoperations

Fifty-eight patients (87.88%) recovered without complications (group A). The remaining eight (12.12%) had failure in fixation (group B): six 6 "cut-out" (9.09%) and two (3.03%) "pull-out". There was no pseudarthrosis or implant ruptures.

Six patients in group B were operated on again, three with revision to arthroplasty (1 hemiarthroplasty and 2 total hip arthroplasties). One implant was revised (with placement of a shorter sliding screw) and, in one patient, the sliding screw was removed. In one patient, "pull-out" was observed with osteomyelitis of the femoral head, so a resection arthroplasty (Girdlestone surgery) was performed.

Details of complications and reoperations are described in Tables 2 and 3.

Table 2. Complications

Complications (n = 8)	n
"Cut-out" (penetration of the screw into the hip joint)	6
"Pull-out" (migration and lateral exit of the sliding screw in an uncontrolled way)	2

Table 3. Reoperations

Procedure (n = 6)	n
Total hip arthroplasty	2
Hemiarthroplasty	1
Resection arthroplasty (Girdlestone surgery)	1
Implant revision with shorter sliding screw	1
Removal of the sliding screw	1

Secondary outcomes: analysis of risk factors

As shown in Table 1, the univariate analysis revealed that a TAD >25 mm, improper location of the sliding screw, and postoperative varus alignment were significantly associated with failure in osteosynthesis ($p < 0.05$). In the multivariate analysis, only postoperative varus alignment and TAD >25 mm were statistically significant risk factors for fixation failure (Table 4).

Table 4. Multivariate analysis of risk factors

Factor	p	OR	95%CI for OR
Postoperative alignment in varus	**0.006**	14.390	2.116-97.847
TAD >25 mm	**0.014**	11.458	1.629-80.592

Significant p-values are shown in bold (<0.05). Odds ratio, 95%CI = 95% confidence interval, TAD = tip-apex distance.

Cervico-diaphyseal angle

The mean cervico-diaphyseal angle of the unaffected hip was similar in group A and group B (132.24° and 131.79°, respectively; p = 0.051). The mean cervico-diaphyseal angle of the hip operated on in the immediate postoperative period was 131.66° in group A and 126.99° in group B. There was no statistically significant difference between the two groups (p = 0.853).

In group A, the mean cervico-diaphyseal angle of the operated side differed by -0.58° compared to the unaffected side on immediate postoperative radiographs. In group B, after surgery, the operated side had 4.8° more varus alignment than the contralateral hip. Although the immediate postoperative cervico-diaphyseal angle was more varus in group B, this was not statistically significant (p = 0.105).

Postoperative alignment

In group A, 34 patients (58.62%) had neutral alignment; 18 (31.03%), valgus alignment; and six (10.35%), varus alignment.

Seven patients (10.61%) suffered a secondary varus displacement during follow-up (decrease of more than 10° in the cervico-diaphyseal angle compared to the radiograph of the immediate postoperative period);[13] all had a neutral or valgus alignment in the immediate postoperative period.

There were 52 patients (89.65%) with adequate alignment (neutral or valgus) in group A and three (37.5%) with adequate alignment in group B (p = 0.0002). Postoperative varus alignment led to fixation failure in 45.45% of cases, while postoperative valgus alignment reduced the risk of osteosynthesis failure to 14.29%. No patients with postoperative neutral alignment with subsequent failure in fixation were detected.

Sliding screw position

The distribution of the position of the sliding screw on the femoral head is illustrated in Figure 3. An adequate position of the sliding screw (center-center or lower-center) was achieved in 24 patients (36.36%). No patients with a screw in the proper position had a fixation failure (p = 0.043).

In 58.62% of group A, the position of the sliding screw was inadequate. All patients who suffered a failure in osteosynthesis had a cephalic screw in an improper position.

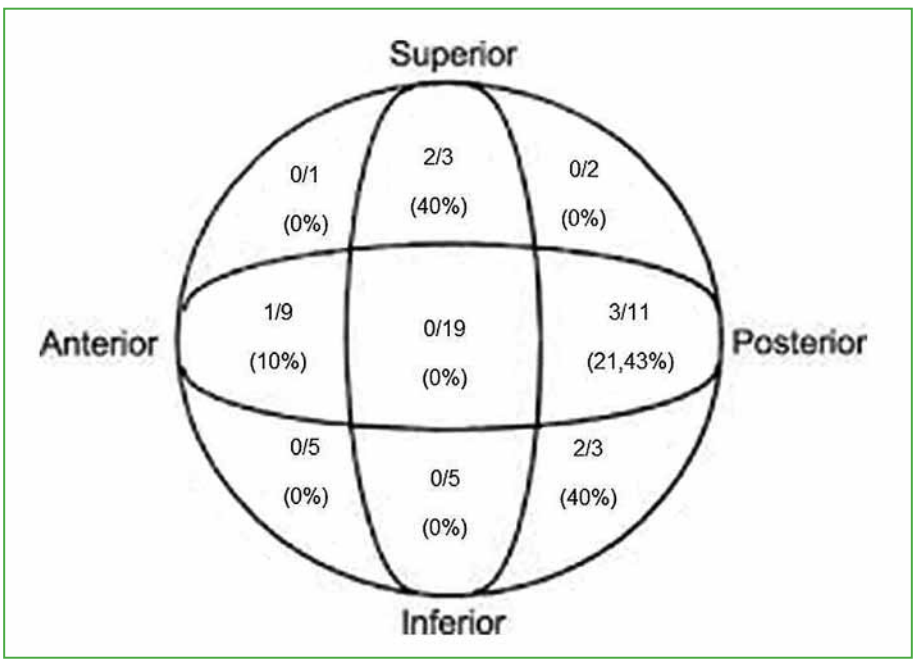

Figure 3. Position of the sliding screw on the femoral head. The first number represents the number of patients in group B, while the second number represents patients in group A (the percentage indicates the rate of failure in fixation in each quadrant).

Tip-apex distance

In group A, 46 patients (79.31%) had a 25 mm TAD and 12 (20.69%) had a TAD >25 mm. In contrast, in group B, two (25%) had a 25 mm TAD (p = 0.004). Thus, a TAD >25 mm was associated with a risk of failure in the fixation of 33.33%, while a TAD ≤25 mm reduced the risk to 4.17%.

DISCUSSION

The main objective of this study was to analyze the rate of failure in osteosynthesis resulting from cephalomedullary nail fixation of intertrochanteric fractures in patients >75 years. The rate of implant-related complications (cut-out and pull-out) was 12.12%. This value is comparable with the data obtained by Jiamton et al.,[13] who reported 15.84% of implant-related complications in their series of 101 intertrochanteric fractures. They analyzed parameters such as TAD >25 mm, varus reduction, and inadequate position of the sliding screw, among others, as risk factors for failure in osteosynthesis.

The secondary objective of this study was to define the risk factors for the fixation failure of intertrochanteric fractures treated with cephalomedullary nail in patients >75 years. We found that a TAD >25 mm and a varus postoperative cervico-diaphyseal angle are determinants of greater risk of failure in osteosynthesis. We found evidence that an upper or posterior location of the sliding screw in the femoral head increases the risk of fixation failure, although the location of the screw was not a statistically significant risk factor in the multivariate analysis.

The standard of a TAD ≤25 mm to reduce the risk of "cut-out" was described by Baumgaertner et al.,[5] and confirmed by several authors.[17,18] Our data also confirm the importance of TAD ≤25 mm in reducing the incidence of implant-related complications.

An initial postoperative varus-aligned cervico-diaphyseal angle increases the risk of greater secondary varus displacement and "cut-out". Some studies even recommend a slight valgus reduction with a 5-10° greater cervico-diaphyseal angle compared to the contralateral hip.[19] Our study was able to corroborate that postoperative varus alignment correlates significantly with failure in osteosynthesis.

Several authors demonstrated that the proper position of the sliding screw on the femoral head is one of the most important factors in preventing mechanical failure of osteosynthesis. The center-center or lower-center locations of the sliding screw are those that are usually recommended.[4,15,20,22] Although the importance of proper screw location was demonstrated in the univariate analysis of our study, this parameter was not statistically significant in the multivariate analysis.

This study has limitations. First, this is a retrospective study; therefore, information that was not initially collected in the patients' health records could not be evaluated. Risk factors, such as osteoporosis, were not analyzed because bone mineral density was not documented in all cases.

A minimum, relatively short, follow-up period of three months was established because Baumgaertner et al.[5] determined that "cut-out" episodes occurred in this time span. However, some complications may have occurred after this period and were not considered in this study.

CONCLUSIONS

The failure rate of osteosynthesis resulting from cephalomedullary nail fixation of intertrochanteric fractures in patients >75 years was 12.12% in our cohort. Several already studied risk factors for osteosynthesis failure have been established when treating intertrochanteric fractures with cephalomedullary nail in older adults. It was found that a TAD ≤25 mm and an initial reduction with a neutral or slightly valgus cervico-diaphyseal angle significantly reduce the risk of implant-related complications. We found evidence that a high or posterior location of the sliding screw increases the risk of fixation failure.

In future research, the objective will be to include a greater number of patients to expand the sample and also optimize the validity of the study and determine bone mineral density to establish its importance as a determining risk factor for failure in osteosynthesis with cephalomedullary nail.

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Conflict of interests: The authors declare they do not have any conflict of interests.

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