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Can tip-apex distance and calcar reference tip-apex distance predict lag screw cut-out in elderly patients with trochanteric femoral fractures treated with gamma3 nails

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ABSTRACT

Background: The most common complication of cephalomedullary nail fixation for femoral fractures is lag screw cut-out. The significance of the tip-apex distance (TAD) in predicting lag screw cut-out is still debated. There has been no study conducted on the calcar reference tip-apex distance (CalTAD) regarding its impact on lag screw cut-out. To compare the average TAD and CalTAD between groups with and without lag screw cut-out and to determine the TAD and CalTAD values associated with the highest risk of lag screw cut-out.
Methods: This was a prognostic prediction study utilizing a retrospective cohort of 756 patients with trochanteric femoral fractures treated with Gamma3 nails. This study compared the differences in TAD and CalTAD values between the two groups.
Results: The group without lag screw cut-out had lower TAD and CalTAD values compared to the group with lag screw cut-out (TAD; 20.3±5.3 mm vs. 22.1±5.7 mm; p=0.044); (CalTAD 22.3±4.4 mm vs. 25.2±5.3 mm; p<0.001). The cutoff points of TAD >23 mm and CalTAD >25 mm were associated with the highest risk of lag screw cut-out (TAD: OR, 2.91; 95% CI, 1.47-5.77; p=0.002); (CalTAD: OR, 3.43; 95% CI, 1.73-6.80; p<0.001).
Conclusions: The lag screw cut-out group had higher TAD and CalTAD values. TAD values greater than 23 mm and CalTAD values greater than 25 mm were associated with the highest risk of lag screw cut-out.

Keywords: CalTAD, Gamma3 nail, Lag screw cut-out, TAD, Trochanteric femoral fractures

INTRODUCTION

The incidence of hip fractures in elderly Thai individuals is high, ranging from 151 182 cases per 100,000 individuals.[1] Approximately two-thirds of these fractures occur at the trochanter, resulting in significant healthcare costs of approximately 110,415 baht per case.[1,2] Falls are the primary cause of falls, and they frequently lead to various complications. In addition, there is an increased risk of disability or mortality associated with age.[3] The standard treatment for hip fractures involves surgical fixation with bone implants. In cases of unstable fractures, the preferred method is to use a cephalomedullary nail, which provides stability and allows faster postoperative mobility.[4] The most common complication encountered when using cephalomedullary nails is lag screw cut-out, where the screw head penetrates outside the femoral head.[5,6] This complication occurs in approximately 1.9-13.0% of patients.[5-15] Patients experiencing this complication often require additional surgical interventions, such as implant removal, revision of internal fixation, or hip arthroplasty, leading to an increased risk of

further complications.[16] Among cephalomedullary nails, the Gamma3 nail is one of the most widely used, especially in Thailand, as it is designed to suit the Asian femoral anatomy.[20] The Lampang Hospital has been using the Gamma3 nail since 2007 and has become the most commonly used cephalomedullary nail, with approximately 1,005 cases performed between 2012 and 2019.

Lag screw cut-out has been observed in approximately five cases per year. One factor that may contribute to this issue is the tip-apex distance (TAD) (the distance from the tip of the screw to the apex of the femoral head), as shown in figure 1).

There is debate regarding whether TAD is an accurate predictor of lag screw cut-out and the optimal cutoff for TAD. Furthermore, there have been no studies on calcar reference tip-apex distance (CalTAD) (the distance from the screw tip to the point where it closely contacts the femoral calcar and the medial border of the femoral head, as shown in figure 2) and whether it affects lag screw cut-out."[7-9,15]

To study TAD and CalTAD as predictors of lag screw cut-out in elderly patients with trochanteric hip fractures treated with Gamma3 nails, and to determine the TAD and CalTAD values associated with the highest risk of lag screw cut-out.

METHODS

Study design

A retrospective cohort study design was used for patients with trochanteric hip fractures treated with Gamma3 nails.

Study place

The study was conducted in Lampang Hospital in Thailand.

Study duration

The study period was between January 2012 and December 2019.

Inclusion criteria

The inclusion criteria were patients aged≥60 years who received treatment with Gamma3 nails.

Exclusion criteria

Exclusion criteria included patients with less than one year of follow-up, incomplete or non-standard radiographic images in true AP and true lateral views, fractures caused by tumors or infections, surgical site infections, prior hip fractures on the same side and fractures more than 10 days of age.

Data collection

Data were collected using electronic health records, including general information and clinical data such as age, sex, surgical side, comorbidities, ASA of Anesthesiologists classification, tip-apex distance and calcar reference tip-apex distance. The primary outcome was the mean TAD and CalTAD (in millimeters) in the groups with and without lag screw cut-out following fixation with Gamma3 nails. The secondary outcomes were the cutoff values and ranges of TAD and CalTAD associated with the highest risk of lag-screw cut-out. STATA 16 was used to analyze the data.

Demographic data

The demographic data comparison between the lag screw cut-out and non-lag screw cut-out groups was performed using the exact probability test for categorical variables and Student's t-test for continuous variables. TAD and CalTAD comparisons between the groups are presented using box-plot graphs. Intra-observer and inter-observer correlations for measuring the TAD and CalTAD were assessed using Pearson's correlation coefficient. Logistic regression analysis with odds ratios and 95% confidence intervals was performed to determine the TAD and CalTAD values associated with the highest risk of lag screw cut-out. The predictive abilities of the TAD and CalTAD for lag screw cut-out were compared using a receiver operating characteristic (ROC) curve.

Sample size

The sample size calculation used the formula 'Sample size for comparing the accuracy of two diagnostic tests'.[21]"

$$n = \frac{\left[Z_{\frac{\alpha}{2}}\sqrt{V_{H0}(\widehat{AUC}_1 - \widehat{AUC}_2)} + Z_{\beta}\sqrt{V_{H1}(\widehat{AUC}_1 - \widehat{AUC}_2)}\right]^2}{[AUC_1 - AUC_2]^2}$$

Based on the reference to the study by Caruso and colleagues, it was found that the area under the ROC curve for TAD is 0.72 and the area under the ROC curve for CalTAD is 0.67 (designated as AUC1=0.72 and AUC2=0.67). With a 95% confidence level (alpha (a)=0.05, Z (0.975) =1.59964) and study power of 80% (beta (β)=0.20, Z (0.80) =0.842), the sample size calculation yielded 709 cases.[8]

This research project was approved by the Hospital Ethics Committee for Human Research (EC code: NO. 35/64) and funded by the Hospital Research Promotion Committee.

RESULTS

Between January 2012 and December 2019, 873 patients with trochanteric hip fractures were treated with Gamma3 nails. After exclusion, 117 patients were excluded,

including those aged less than 60 years (67 patients), pathologic hip fractures (2 patients), fractures on the same side (1 patient) and those with a follow-up period of<1 year (47 patients). This resulted in remaining 756 patients in the study (figure 1). 75% of the patients were female, with an average age of 78 years. Among these patients, 35 (4.6%) underwent lag screw cutouts. In the group with lag screw cut-out, postoperative radiographs showed a significantly greater TAD (22.1±5.7 mm vs. 20.3±5.3 mm, p=0.004) and a significantly greater CalTAD (25.2±5.3 mm vs. 22.3±4.4 mm; p<0.001) (table 1) (figure 2).

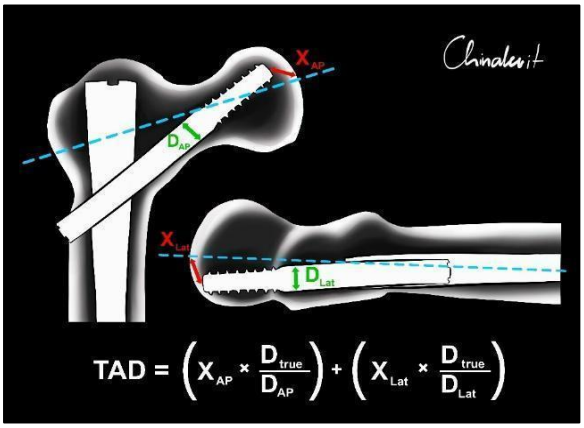

Figure 1: Tip-apex distance (TAD).

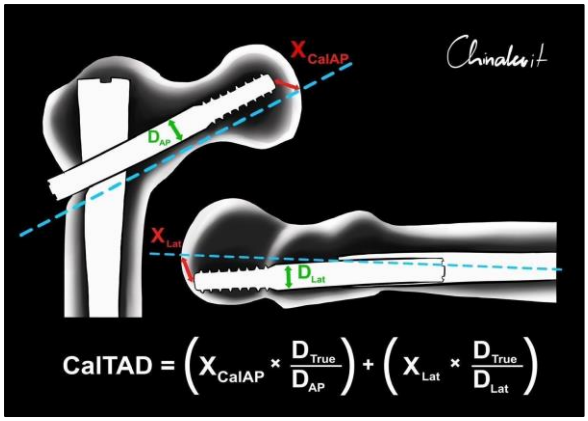

Figure 2: Calcar reference tip-apex distance (CalTAD).

Both TAD and CalTAD demonstrated excellent concordance at a very high level of intra-observer and inter-observer correlation coefficient (>0.975). However, when comparing intra-observer and inter-observer, CalTAD had closer agreement than TAD (p=0.393 vs. 0.073) (table 2). CalTAD had a slightly better predictive ability for lag screw cut-out than TAD (AUROC, 66.74% vs. 60.94%, p=0.228) (figure 3). When analyzing the cutoff points for TAD in a previous study that used TAD >25 mm as a threshold, the risk of lag screw cut-out 2.16 times (95% CI: 1.03, 4.53; p=0.041). However, using a TAD >23 mm further increased the risk by 2.91 times (95% CI, 1.47, 5.77, p=0.002).[21] In contrast, there was no previous study on CalTAD; however, using CalTAD>25 mm increased the risk of lag screw cut-out 3.43 times (95% CI, 1.73, 6.81, p<0.001) (table 3).

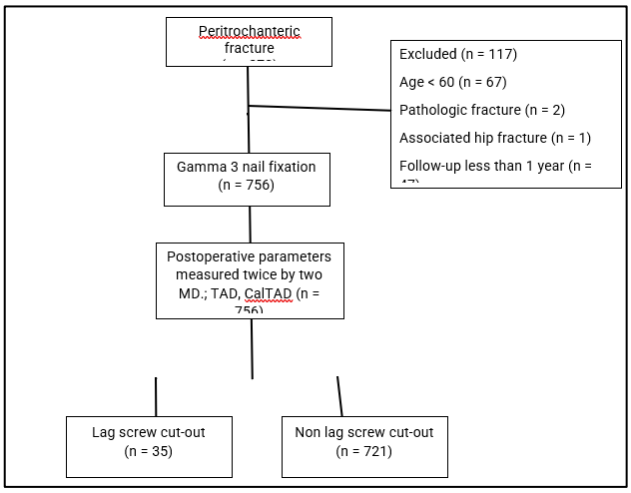

Figure 3: Study flow.

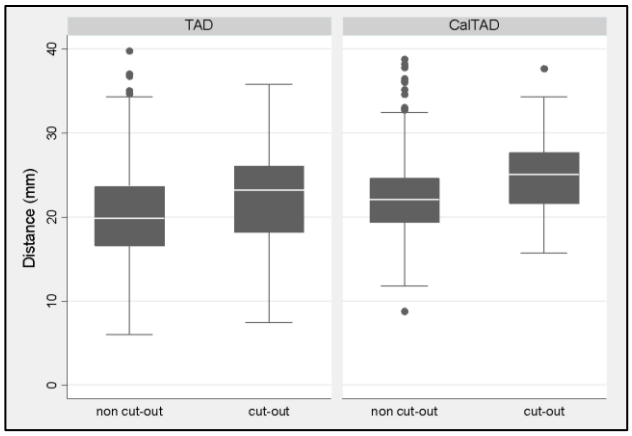

Figure 4: Box plots showing tip-apex distance (TAD) and Calcar reference tip-apex distance (CalTAD) values between groups with and without lag screw cut-out.).

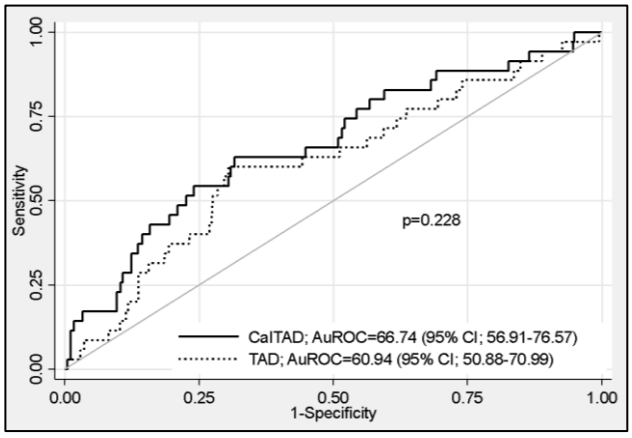

Figure 5: Prediction ability of lag screw cut-out risk between tip-apex distance (TAD) compared to Calcar reference tip-apex distance (CalTAD).

Intra-class correlation coefficients within observers showed excellent agreement for both TAD (intra-observer) 0.987 (95% CI 0.985–0.989) and CalTAD (intra-observer) 0.982 (95% CI 0.979–0.984). The agreement between observers was excellent for both TAD (inter-observer) 0.978 (95% CI 0.974–0.981) and CalTAD (inter-observer) 0.986 (95% CI 0.983–0.988). When analyzing the relationship between specificity and 1-sensitivity by varying cutoff values (Receiver Operating Characteristic curve) for TAD and CalTAD, it was found that TAD and CalTAD accuracies were not significantly different, with areas under the curve of 0.61 (95% CI 1.002-1.134) and 0.67 (95% CI 1.063-1.220), respectively (p=0.228) (figure 2). The analysis found the most suitable cutoff points with the highest odds ratios, which were 23 mm for TAD (OR, 2.89; 95% CI, 1.46, 5.73; p=0.002) and 25 mm for CalTAD (OR, 3.43; 95% CI, 1.73, 6.80; p<0.001).

Table 1: Demographic data and population characteristics comparison between groups.

Data	Cut-out, case percentage, (n=35)	Non-cut-out, case percentage (n=721)	P value
Gender			
Male	10 (28.6)	186 (25.8)	0.696
Female	25 (71.4)	535 (74.2)	
Age (years), mean±SD	78.3±6.4	78.6±7.6	0.833
Fracture side			
Left	19 (54.3)	385 (53.4)	1.000
Right	16 (45.7)	336 (46.6)	
ASA classification			
I	0 (0)	7 (1.0)	0.583
II	4 (11.4)	113 (15.7)	
III	31 (88.6)	566 (78.5)	
IV	0 (0)	35 (4.8)	
Comorbidity			
Diabetes	6 (17.1)	131 (18.2)	1.000
Cerebrovascular disease	1 (2.9)	38 (5.3)	1.000
Chronic obstructive pulmonary disease	1 (2.9)	35 (4.9)	1.000
Coronary artery disease	2 (5.7)	19 (2.6)	0.253
Other diseases	27 (77.1)	434 (60.2)	0.051
TAD mean±SD **min, max**	22.1±5.7 7.4, 35.8	20.3±5.3 6.0, 39.7	0.044
CalTAD mean±SD **min, max**	25.2±5.3 15.7, 37.6	22.3±4.4 8.8, 38.8	<0.001

Table 2: Concordance of TAD and CalTAD measurements when evaluated using Pearson correlation coefficient.

Variable	Intra-observer coefficient, (95% CI)	Inter-observer coefficient, (95%CI)	P value 2	P value 1
TAD	0.987 (0.985, 0.989)	0.978 (0.974, 0.981)	0.154	0.073
CalTAD	0.982 (0.979, 0.984)	0.986 (0.983, 0.988)	0.569	0.393

Table 3: Comparison of TAD and CalTAD cut-off points with the highest lag screw cut-out risk.

Variable	OR	95%CI	P value
TAD>25 mm	2.16	1.03-4.53	0.041
TAD>23 mm	2.91	1.47-5.77	0.002
CalTAD >25 mm	3.43	1.73-6.81	<0.001

DISCUSSION

In this study, the occurrence of lag screw cut-out was found to be 4.6%, which is similar to previous studies with comparable domains (ranging from 2.85% to 6%).[8,11,12,14,15] Previous studies have debated the relationship between TAD and CalTAD with lag-screw cut-out.[7-15] Average TAD values vary among population groups.[7-8,10-15] In most cases, the average values were higher than those reported in this study. One similar result was from a study carried out in Germany, where the group with and without lag screw cut-out had average TAD values of 29.0±5.1 mm vs. 20.1±5.2 mm, p=0.002.[9] This

difference in average TAD values between studies could be attributed to variations in measurement methods, which were not specified in the current study or additional predictive factors, such as reduction quality and improper entry points.[10] In contrast, CalTAD had a better discriminatory ability (AuROC=66.74%), which was similar to a previous study (AuROC=67.0%).[8]

Baumgaertner and colleagues found that patients with TAD≤25 mm did not experience lag screw cut-out in trochanteric hip fractures treated with Dynamic Hip Screw.[24] A cut-off point of TAD>25 mm was subsequently used as a reference point. However, this value serves as a proportion reference. This study found that the risk of lag screw cut-out increased by 2.16 times with TAD>25 mm (OR, 2.16; 95% CI, 1.03-4.53; p=0.041), which is similar to a previous study (OR, 2.10; 95% CI, 0.60-7.10; p=0.240).[11] In Western orthopedic practice, maintaining a TAD less than 25 mm is recommended to reduce the risk of complications.[10] In this study, it was found that TAD>23 mm had the highest increased risk (OR, 2.91; 95% CI, 1.47-5.77; p=0.002) in the Western population. They suggested a cutoff point of TAD>30.7 mm (OR, 3.10; 95% CI 1.34-7.20; p=0.008) and TAD>34.8 mm (OR, 4.40; 95% CI, 1.13-17.03; p=0.032), which may not be practical for assessment and could lead to overestimation in the Asian population.[8]

CalTAD has recently been discussed in studies conducted approximately 20 years after its introduction. Kuzyk et al. found that screws placed near the calcar had the highest axial and torsional stiffnesses in Sawbone models, which contributed to the study of the relationship between CalTAD and lag screw cut-out.[7-9,15,25] However, a clear practical cutoff point for CalTAD has not yet been established. In this study, a CalTAD cut-off point of >25 mm provided the highest odds ratio (OR, 3.43; 95% CI, 1.73-6.81; p<0.001).

This study has limitations, as it was a retrospective study and did not collect data on body mass index, bone density, patient mobility and postoperative rehabilitation. It also did not consider surgical factors, such as the entry point and distal locking techniques, which could be confounding variables. However, the strengths of this study include the large sample size, high-quality radiographs assessed for true anteroposterior (AP) and true lateral views according to the selection criteria, and the measurement of TAD and CalTAD for both intra-observer and inter-observer assessment. This study was one of the first in Asia to introduce TAD and CalTAD cutoff points that could be applied in clinical practice.

CONCLUSION

The lag screw cut-out group had higher TAD and calTAD values. The cutoff points of TAD>23 mm and CalTAD>25 mm was associated with the highest risk, and the ability to discriminate lag screw cut-out between CalTAD and TAD did not differ significantly.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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