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Predictors of the Pedicle Screw Misplacement in Patients with Thoracolumbar Fracture

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Objectives: To investigate the prevalence and risk factors of the misplacement of the pedicle screw in patients with thoracolumbar spine fracture. **Methods:** Patients who underwent posterior stabilization procedure due to thoracolumbar spine fracture were included. Association between potential risk factors and the misplacement of the pedicle screw were evaluated by logistic regression analysis. **Results:** A total of 88 consecutive patients with thoracolumbar spine fracture who underwent posterior stabilization surgery using pedicle screws and rods (mean age 43 ± 14, male 52.3 %). On post-operation CT evaluation, 98 (14.8 %) pedicle screws were misplaced (34 thoracic screws and 64 lumbar screws) and the prevalence of the misplaced pedicle screw was not significantly different between thoracic and lumbar screws (13.2 % vs. 15.8 %, p = 0.347). Among risk factors including location of spine fracture, multiple spine fracture and location of screws, the AO classification of spine fracture was significantly associated with the misplacement of the pedicle screw (OR = 1.27, 95 % CI 1.06 - 1.53, p = 0.011). **Conclusion:** High grade spine fracture, as assessed by the AO classification, was significantly associated with pedicle screw misplacement in patients with thoracolumbar spine fracture.

Keywords: Spine, Fracture Fixation, Pedicle Screws, Prevalence, Risk Factor.

Introduction

A spine fracture is the fracture of the vertebrae which is caused by various types of high velocity injuries such as car accidents, high falls and sports activities, and often requires surgical stabilization of the injured spine [1]. Posterior stabilization is a gold standard procedure which uses pedicle screws and rods to restore spine stability [2 - 6], and the positioning of the pedicle screw is a crucial part of the procedure [7]. There are several techniques to place the pedicle screws including free-hand (FH), fluoroscopy-assisted, computed tomography (CT) navigation guided and robot-assisted techniques [8], however, the FH technique is the most commonly used technique because of the technical simplicity and low cost [4]. In the FH technique, surgeons use anatomic landmarks of the vertebrae to guide the insertion of the screws through the pedicle of the vertebrae

[7]. Therefore, surgical success of the FH technique depends on the presence of anatomical references and the experience of the surgeons. Despite massive improvements in FH technique over the last decades, misplacement of the pedicle screw is still a most common complication in the posterior stabilization procedure [9], and it can induce neurological, visceral and vascular injuries and compromise stability of the spine instrumentation [10]. In recent years, secondary wound infection related to the loosening of the spine instrumentation caused by misplaced pedicle screw after posterior stabilization procedure is also considered as a procedure related complication [11]. The Arbeitsgemeinschaft für Osteosynthesefragen (AO) classification of the thoracolumbar fracture is a systematic approach to classify any fractures including adjacent tissue injuries [12]. Therefore, it not only provides valuable information about the fracture but also it can guide treatment approaches for individual patients. Recent studies have shown that the AO classification has some incremental value for decision making in treatment of traumatic thoracolumbar fracture [13]. However, relationships between AO classification and the misplacement of pedicle screws were not investigated thoroughly. In the present study, we investigated the association between fracture related risk factors including AO classification and the misplacement of the pedicle screw in patients with thoracolumbar spine fracture who underwent posterior stabilization procedure using the FH technique.

Materials and Methods

Study protocol

In the current study, investigators selected patients with traumatic thoracolumbar fracture who underwent posterior stabilization surgery at the National Orthopaedic and Trauma Research Center from January 2021 to December 2021. All patients had CT scan to assess fracture related risk factors including location of the fracture and AO classification of the fracture before the surgery. Based on location of the fracture, patients were classified into two subgroups, thoracic fracture and lumbar fracture groups. After that, all patients underwent posterior stabilization surgery using the pedicle screws. The misplacements of the pedicle screw, outcome variable (study endpoint), was evaluated within 7 days from the surgery on second CT scan. Study flow chart has illustrated in Figure 1. Demographic and clinical variables including age, gender, body mass index (BMI), hospital admission days and pain scale were collected from the patient's medical record during the hospitalization.

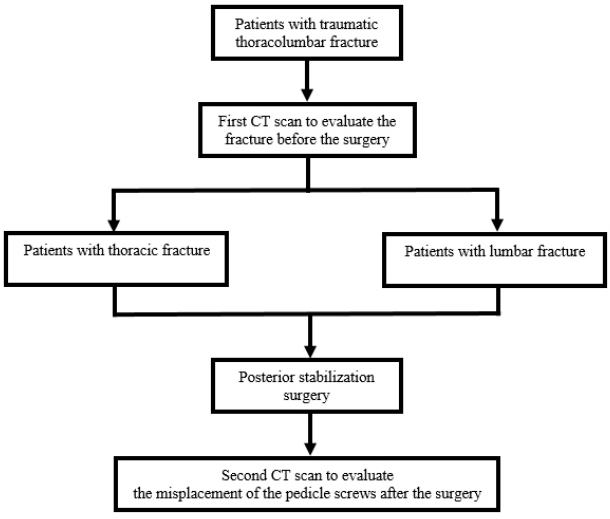

Figure 1. Study flow chart.

Sample size calculation

In the present study, we used sample size calculation formula which was suggested by Kelsey et al. [14] to calculate the sample size. The proportion of unexposed with outcome (incidence of the pedicle screw misplacement in patients with stable lumbar fractures) was 6.2 % as reported by Smith et al. [15], the proportion of unexposed with outcome (incidence of the pedicle screw misplacement in patients with unstable thoracic fractures) was 33.8 % as reported by Fisher et al. [16] and the ratio of unexposed to exposed (incidence of spine fracture in lumbar vertebrae compared to thoracic vertebrae) was 3 fold higher as reported by Reinhold et al. [17]. According to the above-mentioned sample size formula and proportions in previous studies, the patient number needed for the present study was 63 patients or more.

Assessment of the spine fracture

Spine fractures were evaluated by standard AO classification for each patient on pre-operative CT scan and graded as A3 (incomplete burst), A4 (complete burst), B1 (transosseous tension band disruption), B2 (posterior tension band disruption) and C (displacement) [18]. Additionally, spine fractures were classified as single or multiple fractures depending on the number of spines involved.

Surgical procedure

According to the institutional protocol, posterior stabilization surgery was performed by experienced orthopaedic surgeon using the FH technique. Surgical procedure was previously established [7]. Briefly, the pedicle screw entry points were chosen by surgeon based on the anatomical landmarks (Figure 2A), pedicle screws were inserted using the pre-defined entry points (Figure 2B) and the position of the pedicle screws were verified using fluoroscopy (Figure 2C). All surgical procedures were performed by same surgical team using the same technique.

Evaluation of the pedicle screw misplacement

After the surgery, all patients underwent post-operative computed tomography (CT) to assess position of the pedicle screw. Post-operative CT was done within 1 week after the surgery. Misplacement of the pedicle screw was evaluated for each screw from the axial plane of the post-operative CT images which were archived in the hospital picture archiving and communication system (Figure 4). All post-operative CT images were evaluated by independent evaluator who is unaware about the surgical outcome. Additionally, pedicle screw misplacement was classified into 3 categories: no misplacement, minor misplacement (< 3 mm) and major misplacement (≥ 3 mm) [15].

$$n_1 = \frac{(Z_{\alpha/2} + Z_{\beta})^2 p(1-p)(r+1)}{r((p_0 - p_1)^2}$$

$$p = \frac{(p_0 - r p_1)}{r+1}$$

– standard normal deviate (1.96) for two-tailed test based on alpha level; - standard normal deviate (0.80) for one-tailed test based on beta level; - proportion of unexposed with outcome (misplacement of the pedicle screw); - proportion of exposed with outcome (misplacement of the pedicle screw); - The ratio of unexposed to exposed.

Statistical analysis

Continuous variables are presented as mean ± standard deviation when normally distributed (assessed by the Shapiro–Wilk test and distribution histograms) and as median [and interquartile range (IQR)] when not normally distributed. Categorical variables are presented as frequencies and percentages. Differences in continuous variables between study groups (patients with thoracic fracture vs. patients with lumbar fracture in Table 1 and thoracic screw vs. lumbar screw in Table 2) were evaluated using independent samples t-tests (and Mann-Whitney U tests when indicated), whereas differences in categorical variables were compared using chi-square tests (Fisher's exact tests was used when cell frequency was less than 5). Changes in pain scale before and after the surgery was evaluated using paired samples t-tests. Univariable logistic regression analysis was used to determine association between potential risk factors and misplacements of the pedicle screws. All statistical tests were two-sided, and a p-value of < 0.05 was considered to be statistically significant. Statistical analysis was performed using SPSS for Windows version 25.0 (IBM Corporation, Armonk, New York, USA).

Ethical statement

Study protocol was approved by the Ethical Committee of the Mongolian National University of Medical Sciences (Approval No. 2021/3-13) and an informed consent form was taken from all patients. The investigation conforms with the principles outlined in the "Declaration of Helsinki" [19].

Results

Baseline characteristics

A total of 88 consecutive patients with thoracolumbar injury who underwent posterior stabilization procedure using pedicle screws and rods (mean age 43 ± 14, male 52.3 %). Age (44 ± 13 vs. 43 ± 14, p = 0.659), BMI (25.2 ± 3.7 vs. 25.7 ± 4.8, p = 0.699), hospital admission days (12 days IQR [10; 14] vs. 12 days IQR [11; 14]) were comparable between study groups. The frequency of male and female patients (46 % vs. 54 % for male and 54 % vs. 46 % for female patients) was similar between thoracic and lumbar fracture groups. The pain scale has significantly reduced 7 days after posterior stabilization procedure (8.7 ± 1.1 vs. 4.3 ± 1.1, p < 0.001) (Figure 4).

Prevalence of spine fracture

Lumbar fractures occurred for 66 patients (75 %) and 22 patients had thoracic fractures (25 %). Multiple spine fractures (≥ 2) occurred for 7 patients (8 %) and there was no significant difference in prevalence of multiple spine fractures between

Table 1. Demographic data and prevalence of spine fracture.

Variables	All patients (n = 88)	Patients with thoracic fracture (n = 22)	Patients with lumbar fracture (n = 66)	p-value
	Mean ± SD	Mean ± SD	Mean ± SD	
Age, (years)	43 ± 14	44 ± 13	43 ± 14	0.659
BMI, (kg/m^2)	25.6 ± 4.5	25.2 ± 3.7	25.7 ± 4.8	0.669
Hospital admission, (days)	12 ± 10	12 ± 14	12 ± 11	0.562
Gender	N (%)	N (%)	N (%)	
Male	46 (52)	10 (46)	36 (54)	0.460
Female	42 (48)	12 (54)	30 (46)	
Fracture type				
Single fracture	81 (92)	21 (95.5)	60 (90.9)	0.675
Multiple fracture	7 (8)	1 (4.5)	6 (9.1)	
AO classification				
A3 type fracture	39 (44.3)	10 (45.5)	29 (43.9)	
A4 type fracture	27 (30.7)	6 (27.3)	21 (31.8)	
B1 type fracture	1 (1.1)	-	1 (1.5)	
B2 type fracture	17 (19.3)	4 (18.2)	13 (19.7)	
C type fracture	4 (4.5)	2 (9.1)	2 (3)	

AO, Arbeitsgemeinschaft für Osteosynthesefragen; BMI, body mass index.

Table 2. Prevalence of pedicle screw misplacement.

Variables	All screws (n = 662)	Thoracic screw (n = 258)	Lumbar screw (n = 404)	p-value
	N (%)	N (%)	N (%)	
Screw position				
Correct position	564 (85.2)	224 (86.8)	340 (84.2)	0.347
Misplaced	98 (14.8)	34 (13.2)	64 (15.8)	
Direction of screw misplacement				
Medial misplacement	77 (11.6)	20 (12.5)	57 (11.4)	0.547
Lateral misplacement	21 (3.2)	7 (4.4)	14 (2.8)	
Extent of screw misplacement				
None	564 (85.2)	133 (83.1)	431 (85.9)	0.697
Minor	73 (11)	20 (12.5)	53 (10.6)	
Major	25 (3.8)	7 (4.4)	18 (3.6)	

thoracic and lumbar region (4.5 % vs. 9.1 %, p = 0.495). According to the AO classification of spine injury, 39 patients (44.3 %) had A3 type fracture, 27 patients (30.7 %) had A4 type fracture, 1 patient had (1.1 %) had B1 type fracture, 17 patients (19.3 %) had B2 type fracture and 4 patients (4.5 %) had C type fracture. The frequency of fracture types according to the AO classification was similar between thoracic and lumbar fractures (45.5 % vs. 43.9 % for A3 type fracture, 27.3 % vs. 31.8 % for A4 type fracture, 0 % vs. 1.5 % for B1 type fracture, 18.2 % vs. 19.7 % for B2 type fracture and 9.1 % vs. 3 % for C type fracture) (Table 1).

Prevalence of the pedicle screw misplacements

A total of 662 thoracolumbar pedicle screws from 88 patients (258 thoracic screws and 404 lumbar screws) were evaluated (Table 2). On post-operation CT evaluation, 98 (14.8 %) pedicle screws were misplaced (34 thoracic screws and 64 lumbar screws) and the prevalence of misplaced screw was did not

Table 3. Univariable logistic regression analysis for the misplacement of the pedicle screw.

Variables	OR	95% CI	p-value
Age	1.03	1.01 - 1.04	0.003
Gender	1.65	1.07 - 2.55	0.023
BMI	0.97	0.92 - 1.01	0.122
Number of fractured spine	1.15	0.66 - 2.00	0.634
Thoracic fracture	1.23	0.76 - 2.00	0.397
Thoracic screw	0.81	0.52 - 1.26	0.347
AO classification			
A3 type fracture /reference value/	1.0	-	-
A4 type fracture	0.88	0.55 - 1.42	0.603
B1 type fracture	0.58	0.11 - 2.96	0.513
B2 type fracture	1.81	0.92 - 3.54	0.085
C type fracture	7.54	1.04 - 56.3	0.049

AO, Arbeitsgemeinschaft für Osteosynthesefragen; BMI, body mass index.

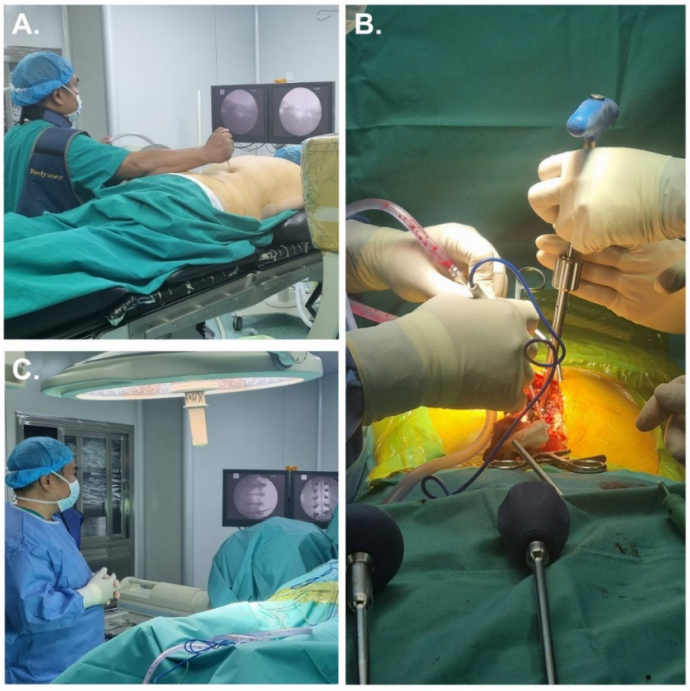

Figure 2. Surgical steps of the posterior stabilization procedure in patients with spine fracture. Choosing the entry points of the pedicle screw according to the anatomical landmarks (A), insertion of the pedicle screws (B) and verification the position of the pedicle screws (C).

significantly different between thoracic and lumbar screws (13.2 % vs. 15.8 %, p = 0.347). The prevalence of medial and lateral misplacement of screws were 78.6 % and 21.4 %, respectively. There was no significant difference in medial and lateral misplacement of screws for thoracic and lumbar screws (12.5 % vs. 11.4 % and 4.4 % vs. 2.8 %) (p = 0.547). There were 73 minor misplacement (74.5 %) and 25 major misplacement (25.5 %) and extent of screw misplacement was not significantly different between thoracic and lumbar screws for minor misplacement (12.5 % vs. 10.6 %) and major misplacement (4.4 % vs. 3.6 %) (p = 0.697), respectively.

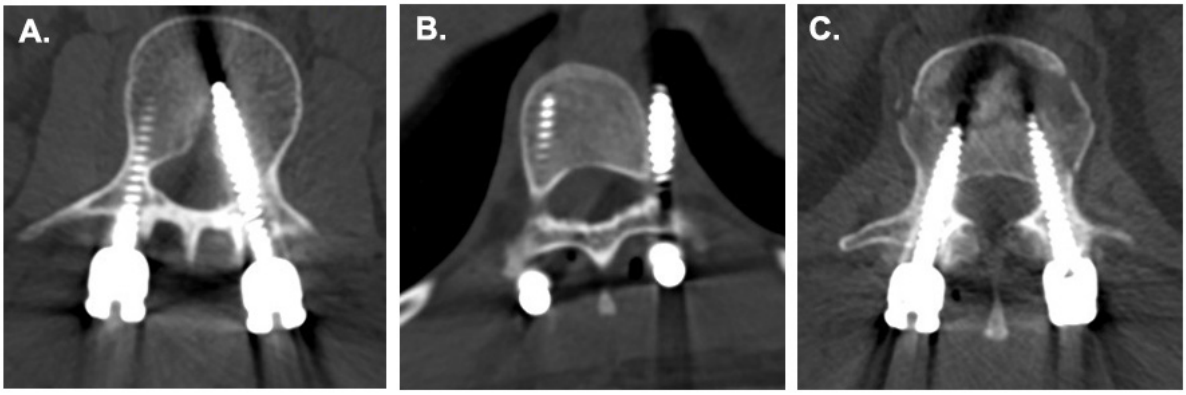

Figure 3. Post-operative CT image from the axial view of the case with medially (A) and laterally (B) misplaced of pedicle screw, and the case without (C) misplacement of pedicle screw.

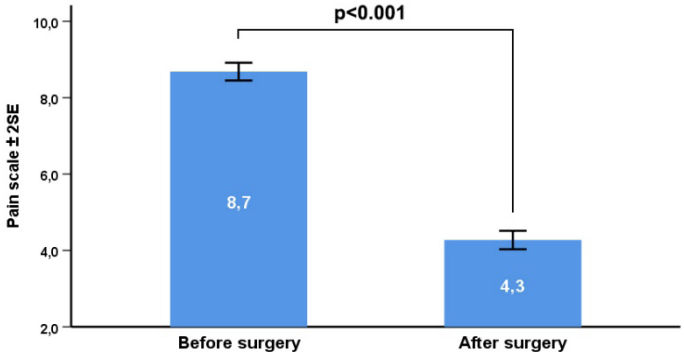

Figure 4. Pain scale before and after surgery.

Predictors of the pedicle screw misplacement

To investigate the association between fracture related predictors and the misplacement of the pedicle screw, univariable logistic regression analysis was performed (Table 3). In univariable analysis, age (OR = 1.03, 95 % CI 1.01 - 1.04, p = 0.003), gender (OR = 1.65, 95 % CI 1.07 - 2.55, p = 0.023) and C type fracture (OR = 7.54, 95 % CI 1.01 - 56.3, p = 0.049) compared to other subtypes when A3 type fracture, assessed by AO classification, were significantly associated with the increased risk of pedicle screw misplacement. Despite the occurrence of pedicle screw misplacement, there was no neurological complications related to the misplaced pedicle screws.

Discussion

The posterior stabilization procedure using the pedicle screws and rods is a gold-standard of spine stabilization in patients with traumatic thoracolumbar fractures [2, 3, 6]. It is not only preventing major neurological and functional deficits but also restores structural stability of the spine in patients with traumatic spine fractures [3]. Despite the technological advances in recent decades, the FH technique is still a most frequently used technique to place the pedicle screws during the posterior stabilization procedure due to technological simplicity and cost effectiveness [4].

During the FH technique, surgeons use specific anatomic landmarks to choose the entry points of the screw and to guide the direction of the screw. The prevalence of the pedicle screw misplacement is higher in the FH technique compared to other techniques such as CT navigated technique [20]. As reported by previous studies, the prevalence of the pedicle screw misplacement was 12 % in the FH technique [10]. In the present study, prevalence of the pedicle screw misplacement was 14.5 % which was comparable to previous studies. Kreinest et al. [21] reported higher rate of pedicle screw misplacement in the lateral

direction compared to medial direction (11.5 % vs. 6.4 %). Interestingly, the rate of pedicle screw misplacement was higher in medial direction compared to lateral direction (12.5 % vs. 4.4 % for thoracic screws and 11.4 % vs. 2.8 % for lumbar screws) in the present study. We suggest that the difference between two studies could be caused by operator's technique.

Rate of the misplacement of the pedicle screw is more common in patients with unrecognizable anatomical landmarks due to complex spine deformity. Gruenberg et al. demonstrated that the severe spinal deformity is the risk factor of the pedicle screw misplacement. The influence of anatomy (normal versus scoliosis. In high grade spine fractures, as assessed by AO classification, adjacent supporting structures of the spine, such as the posterior tension band, could be affected by the fracture or fractured vertebrae can dislocate into various directions in severe cases [18]. Therefore, high grade complex spine fractures can induce severe vertebral deformity which could lead to the pedicle screw misplacement. As reported by Fisher et al. [16], the prevalence of pedicle screw misplacement was 33.8% when screws were inserted using anatomic landmarks in patients with unstable thoracic fractures. Beck et al. [23] demonstrated that the pedicle screw misplacement occurred for 91 screws (22 %) of 414 screws which were inserted based on anatomical references in patients with unstable thoracolumbar fractures.

Furthermore, osteoporotic vertebrae is one of the most common causes of the spine fracture in elderly population [24] and it is not only induce more complex spine fracture but also cause insufficient stability of the pedicle screw in patients with traumatic thoracolumbar injury [25]. In Mongolia, the prevalence of osteoporosis is significantly higher in both sex compared to neighboring and developed countries [26] and therefore, elderly patients who experienced thoracolumbar spine fracture are high risk patients.

In the present study, we demonstrated significant association between the spine fracture grade, as assessed by AO classification, and the pedicle screw misplacement. Moreover, there was a trend toward significant association between the fracture with posterior tension band disruption (B2 type fracture) and the pedicle screw misplacement, while the fracture with dislocation (C type fracture) was significantly associated with pedicle screw misplacement.

Future studies should be addressed to comparing the different screw insertion techniques including advanced navigation systems such as CT navigation guided and robot-assisted techniques in patients with complex thoracolumbar fractures. Also, post-operational spine stability is the most important factor related to long-term clinical outcomes. Therefore, restoration of the spine stability after the surgery should be investigated using follow-up CT scans in the future studies.

The present study has several limitations. The sample size in the current study is relatively small, therefore, analysis of the current study should be validated by future studies with large sample size. The data used in current study originate from a single center, therefore, results of the present study should be confirmed by future studies from other centers. All the surgeries were performed by same surgical team; therefore, selection bias could be introduced.

In conclusion, the prevalence of thoracolumbar pedicle screw misplacement in FH technique was 14.8 %, however, rate of major pedicle screw misplacement was low (3.8 %). The C type spine fracture was significantly associated with increased probability of the pedicle screw misplacements in the FH technique. Therefore, a more advanced pedicle screw guiding system should be considered in those high-risk patients with complex spine fractures.

Conflict of interest

The authors state no conflict of interest.

Acknowledgements

All individuals who contributed to this publication have been included as authors.

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