



## Comparison of the Posterior and Paraspinal Approaches for the Treatment of Thoracolumbar Burst Fractures: A Randomized Controlled Trial

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**Purpose:** Burst fractures cause over half of all thoracolumbar fractures, for which the posterior approach has been considered the standard approach. The paraspinal approach has proven safe and effective for thoracolumbar injury. This study aimed to compare the clinical and radiographic outcomes between the two approaches.

**Methods:** This randomized controlled trial included 24 patients with isolated thoracolumbar burst fractures between July 2016 and August 2018. Patients were categorized into two groups: paraspinal and posterior approaches. The primary outcome was postoperative pain on days 1, 2, 3, and 14. The corrected Cobb's angle; operation time; intraoperative blood loss; opioid usage on days 1, 2, and 3; Oswestry Disability Index (ODI, Thai version); and percentage reduction loss at 3 months were secondary outcomes. Participants were assessed on post-intervention days 1, 2, 3, 14, and 90.

**Results:** The mean visual-analog-scale (VAS) scores on postoperative days 1, 2, 3, and 14 ( $8.6 \pm 0.8$ ,  $7.1 \pm 0.6$ ,  $5.5 \pm 1.3$ ,  $5.5 \pm 0.8$ ); intraoperative blood loss ( $395.8 \pm 113.7$  mL); opioid usage on days 2 and 3 ( $13 \pm 1.5$  mg,  $8.3 \pm 1.9$  mg); and postoperative ODI ( $23.5 \pm 3.5$ ) were significantly lower ( $P < 0.05$ ) in the paraspinal-approach group than in the posterior-approach group (mean VAS on postoperative days 1, 2, 3, and 14 [ $9.2 \pm 0.5$ ,  $8.3 \pm 0.3$ ,  $7.5 \pm 0.8$ ,  $6.7 \pm 0.5$ ]; intraoperative blood loss [ $590 \pm 70.1$  mL]; opioid usage on days 2 and 3 [ $15.8 \pm 1.9$  mg,  $11.7 \pm 1.6$  mg]; and postoperative ODI [ $40 \pm 4.2$ ]). There was no statistical differences in operative time, corrected Cobb's angle, and percentage reduction loss.

**Conclusions:** The paraspinal approach is significantly advantageous over the conventional posterior approach regarding postoperative pain, intraoperative blood loss, opioid usage, and ODI at 3 months, thus corroborating the minimally invasive concept.

**Keywords:** Thoracolumbar fracture, Posterior approach, Paraspinal approach, Minimal invasive concept

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Traumatic spinal fractures potentially cause spinal instability and neurological deficits. The majority of such fractures occur at the thoracolumbar junction (T11–L2), predominantly due to regional biomechanics in which the rigid, kyphotic thoracic spine is juxtaposed with the more mobile, lordotic lumbar spine. Burst fractures account for 30–64% of thoracolumbar spinal fractures<sup>(1)</sup>. Posterior thoracolumbar surgery is one

of the most common surgical approaches for the treatment of thoracolumbar fractures. The wide range of paravertebral muscle splitting and pulling in the conventional posterior approach causes ischemic necrosis and muscle denervation, leading to flatback deformity and intractable back pain<sup>(2)</sup>. In 1968, Wiltse first described the paraspinal sacrospinalis-splitting approach between the multifidus and longissimus. This approach results in less bleeding and less soft tissue injury than the single midline incision approach<sup>(3,4)</sup>. Also, it showed better kyphosis correction and restoration of vertebral height<sup>(5)</sup>. Regarding the management of traumatic thoracolumbar burst fractures, the highest degree of controversy involves deciding whether to operate on neurologically intact patients. If a patient is determined to require surgery, no consensus exists regarding the appropriate technique to be used.

This study randomized 24 patients with thoracolumbar burst fractures who required surgical treatment. The surgeon used either the posterior approach or paraspinal approach (Wiltse's approach) to compare treatment outcomes. Herein, we report the outcomes between the conventional posterior approach and Wiltse's paraspinal approach in patients with non-neurological deficit thoracolumbar fracture who are candidates for surgical treatment. The primary outcome was the visual analog scale (VAS) score. The secondary outcomes were operative time, intraoperative blood loss, opioid usage, Oswestry disability index (ODI) (Thai version)<sup>(6)</sup> at 90 days, corrected Cobb's angle, and percentage reduction loss.

## METHODS

The present study was approved by the Research Ethics Committee of Hatyai Hospital (protocol number: 69/2559). Between July 2016 and August 2018, we recruited patients with thoracolumbar burst fractures in a southern regional hospital. All subjects were recruited, treated, and assessed in the Department of Orthopedic Spinal Team, Southern Regional Hospital, Thailand.

## Inclusion criteria

The inclusion criteria were as follows: 1) an isolated burst fracture within the thoracolumbar region (T10 to L2) as observed on anteroposterior and lateral radiographs, 2) age of 18–60 years, and 3) thoracolumbar injury classification and severity (TLIC) score > 3.

## Exclusion criteria

The exclusion criteria were as follows: (1) burst fracture types D and E from the Denis classification, (2) neurological deficit, (3) medical illnesses that potentially preclude operative intervention, (4) ongoing cancer, (5) infection, (6) bleeding disorder, (7) skin disease, (8) declined surgery, and (9) declined treatment.

## Sample size

The calculated sample size for continuous data in a randomized controlled trial using the N4 Studies application required 11 patients in each group. The study referenced a pilot study's first-day postoperative VAS 8.35 (SD 0.75) and 9.22 (SD 0.70) in paraspinal and posterior approach, respectively. Considering a significance level at 0.05, power 80% with anticipation of a 10% loss to follow-up; ratio 1:1, we planned to recruit 24 patients. The formula:

$$k = \frac{n_2}{n_1} = 1$$

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2 / K)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

$$n_1 = \frac{(0.75^2 + 0.70^2 / 1)(1.96 + 0.84)^2}{0.8700000000000001^2}$$

$$n_1 = 11$$

$$n_2 = K * n_1 = 11$$

$\Delta = |\mu_2 - \mu_1|$  = absolute difference between two means

$\sigma_1, \sigma_2$  = variance of mean # 1 and # 2

$n_1$  = sample size for group # 1

$n_2$  = sample size for group # 2

$\alpha$  = probability of type I error (usually 0.05)

$\beta$  = probability of type II error (usually 0.2)

$z$  = critical Z value for a given  $\alpha$  or  $\beta$

$k$  = ratio of sample size for group # 2 to group # 1

### Surgical approach

Surgery was performed under general anesthesia, and the fracture site was determined with a locator using fluoroscopic equipment. Patients were placed in the prone position with a vacated abdomen. After standard surgical site preparation and draping, in the paraspinous approach (group A), the surgeons made a posterior midline incision at the target segment. Thereafter, the second dissection was performed up to the outer edge of the facet joints and proceeded through the intermuscular plane between the multifidus and longissimus muscles. The pedicle entry point was clearly exposed using a miniretractor.

In the conventional posterior approach (group B), the surgeons made a posterior midline incision at the target segment and striped the paraspinous muscle along the spinous process through the vertebral lamina. Subsequently, the facet joints and roots of the transverse process were exposed using an automatic retractor.

In both groups, guide wires were inserted, and fluoroscopic equipment was used to check whether the guide wires were in the pedicle of the vertebrae before pedicle screws were placed. If the guide wires were in a favorable position, the surgeon inserted eight pedicle screws (long segment fixation); otherwise, they adjusted the guidewire position. After rod installation and distraction for restoration, the positions of the fractured vertebrae, pedicle screws, and height were confirmed using fluoroscopic equipment. A Radivac drain was applied, and fascia, subcutaneous tissue, and skin were sutured in both groups. Postoperative care was applied using the same postoperative protocol (the pain control regimen on the first day included intravenous (IV) morphine dripped at a rate of 0.5–1 mg/h and 1 mg for breakthrough pain every 2 h; on the second and third postoperative days, a 5-cm<sup>3</sup> dose diluted with 3 mg morphine IV was administered pro re nata every 4 h), and data were collected on postoperative days 1, 2, 3, and 14. The patients were followed up after discharge at 14 days, 1 month, and 3 months.

### Study outcomes

Intraoperative and postoperative observations were prospectively recorded to compare intraoperative blood loss; postoperative corrected Cobb's angle; VAS scores at postoperative days 1, 2, 3, and 14; analgesic therapy (morphine) at postoperative days 1, 2, and 3; percentage reduction loss; and ODI (Thai version) three months after the operation. Cobb's angle was measured at the following three time points: 1) at the time of initial injury, 2) at postoperative day 1, and 3) at 3 months' follow-up. Cobb's angle was measured by another orthopedic staff member using a picture archiving and communication system (PACS) (Fig. 1). Furthermore, the staff member was blinded to both surgical groups at the time of measurement using PACS. The kyphotic angle was not used for analysis because irregular end plate fractures were less effective than smooth end plates of Cobb's angle. All radiographic studies and measurements were performed in the supine position.

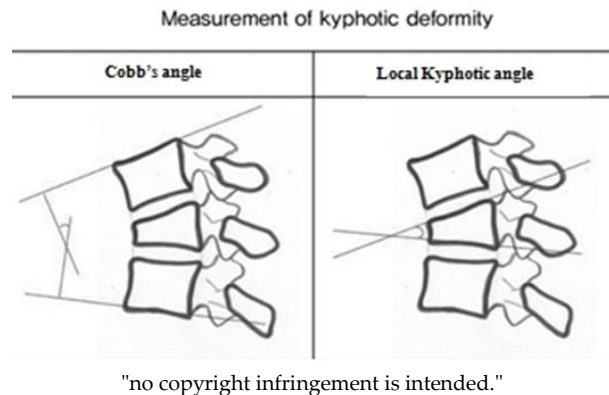


Fig. 1. Measurement of kyphotic deformity<sup>(7)</sup>.

### Statistical methodology

Data were compared between groups using Student's t-test. The t-test and one-way analysis of variance (ANOVA) were used to compare means between the groups, and repeated measures ANOVA was performed using STATA (version 13.0; Stata Corp, College Station, TX, USA) to analyze VAS data collected at four time points (day 1, day 2, day 3, and day 14) and data on analgesic morphine therapy at three time points (day 1, day 2, and day 3).

## RESULTS

Initially, 37 patients were enrolled; however, 13 were excluded from the randomization. Three patients declined treatment, four declined surgery, and six had significant neurological deficit. The remaining 24 patients were equally assigned to the paraspinal and posterior-approach groups. Baseline characteristics, including sex, age, smoking, diabetes status, level of fracture, cause of accident, and severity of fracture, were collected for both groups (Table 1). The posterior-approach group had one patient lost to follow-up. (Fig. 2)

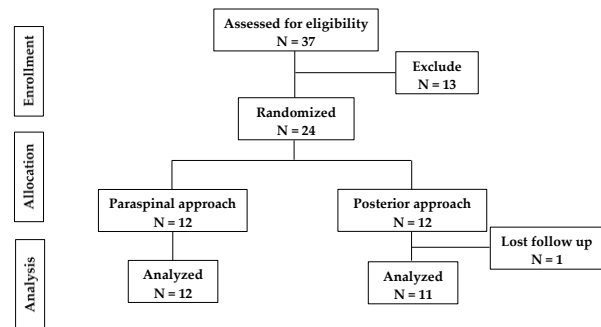
**Table 1** Baseline characteristics of the paraspinal-approach and posterior-approach groups.

	Paraspinal approach (Group A)	Posterior approach (Group B)	p-value
<b>Patient (N)</b>	12	11	-
- Male	6	7	-
- Female	6	4	-
<b>Age (years)</b>	37.8 ± 9.8	44.5 ± 9.2	0.11
<b>Smoking</b>			
- Yes	3	6	
- No	9	5	
<b>Diabetes</b>			
- Yes	0	2	
- No	7	3	
- *N/A	5	6	
<b>Level of fracture</b>			
- T12	1	6	
- L1	6	3	
- L2	5	2	
<b>Cause of accident</b>			
- Fall from height	6	6	
- Traffic accident	5	5	
- Hit by objects	1	0	
<b>Severity of fracture</b>			
- Mean Cobb's angle (°)	12.5 ± 4.8	14.6 ± 3.4	0.25
- Kyphotic angle (°)	11.2 ± 6.5	14.9 ± 5.4	0.16
- % of height loss	41.8 ± 13.4	40.8 ± 14.0	0.86

\*N/A = Not applicable

The mean VAS scores on postoperative days 1, 2, 3, and 14 ( $8.6 \pm 0.8$ ,  $7.1 \pm 0.6$ ,  $5.5 \pm 1.3$ , and  $5.5 \pm 0.7$ , respectively); intraoperative blood loss ( $395.8 \text{ mL} \pm 113.7 \text{ mL}$ ); opioid usage on days 2 and 3 ( $13 \pm 1.5 \text{ mg}$  and  $8.3 \pm 1.9 \text{ mg}$ , respectively); and postoperative ODI (Thai version) ( $23.5 \pm 3.5$ ) were significantly lower ( $P < 0.05$ ) in the paraspinal-

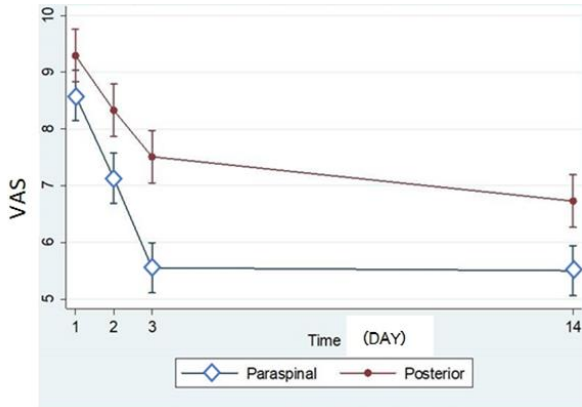
approach group than in the posterior-approach group (mean VAS on postoperative days 1, 2, 3, and 14 [ $9.2 \pm 0.5$ ,  $8.3 \pm 0.3$ ,  $7.5 \pm 0.8$ , and  $6.7 \pm 0.4$ , respectively]; intraoperative blood loss [ $590 \text{ mL} \pm 70.1 \text{ mL}$ ]; opioid usage on days 2 and 3 ( $15.8 \pm 1.9 \text{ mg}$  and  $11.7 \pm 1.6 \text{ mg}$ , respectively) (Fig. 3,4); and postoperative ODI [Thai version;  $40 \pm 4.2$ ]). There were no statistical differences in operative time, corrected Cobb's angle, and percentage reduction loss (Table 2).



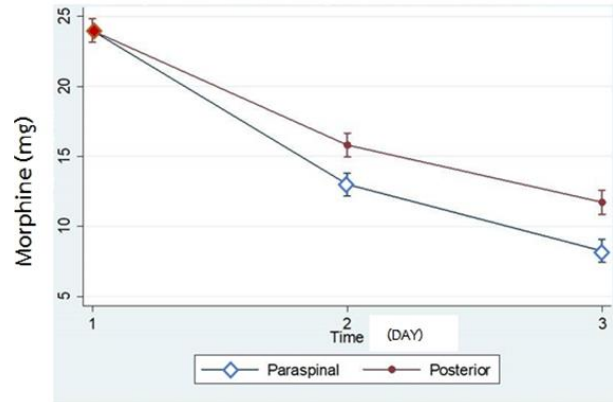
**Fig. 2.** Flow diagram of patients included in the trial.

**Table 2** Comparison of data between the paraspinal-approach and posterior-approach groups.

	Paraspinal approach (N=12)	Posterior approach (N=11)	p-value
<b>VAS scores</b>			
- Postoperative day 1	8.6 ± 0.8	9.2 ± 0.5	0.028
- Postoperative day 2	7.1 ± 0.6	8.3 ± 0.3	0.0001
- Postoperative day 3	5.5 ± 1.3	7.5 ± 0.8	0.0001
- Postoperative day 14	5.5 ± 0.8	6.7 ± 0.5	0.0001
<b>Analgesic therapy</b>			
<b>Morphine (mg)</b>			
- Postoperative day 1	24.0	24.0	-
- Postoperative day 2	13 ± 1.5	15.8 ± 1.9	0.001
- Postoperative day 3	8.3 ± 1.9	11.7 ± 1.6	0.0001
<b>Operation time (min)</b>	112.5 ± 12.0	112.3 ± 9.8	0.96
<b>Intraoperative blood loss (mL)</b>	395.8 ± 113.7	590 ± 70.1	0.0001
<b>Corrected Cobb's angle (°)</b>	8.6 ± 4.0	9.9 ± 3.1	0.38
<b>Postoperative day 90</b>			
- The Oswestry Disability Index (Thai version)	23.5 ± 3.5	40 ± 4.2	0.0001
- % of Reduction loss (°)	0	0	-



**Fig. 3.** Comparison of VAS scores at days 1, 2, 3, and 14.



**Fig. 4.** Comparison of analgesic therapy (morphine) at days 1, 2, and 3.

## DISCUSSION

In this study, we conducted a trial comparing the classic posterior approach with Wistle's paraspinal approach in treating thoracolumbar fractures without neurological deficit (TLIC score > 3). The surgeon discussed the advantages and disadvantages of surgery with each patient; nonetheless, decision making depended on the patient. The primary outcome was the postoperative VAS score, which was significantly lower in the paraspinal-approach group than in the posterior-approach group. However, the VAS score on day 1 was high (8.6–9.2/10) because it was measured immediately after the patient was transferred from the operating room to the patient's ward. The VAS score was only significant statistically and not clinically. The initial VAS score was < 3.4, and a 1.3-score change represents a clinically significant change in pain; however, among patients with initial VAS scores  $\geq 6.7$ , a 2.8-score change was required to represent a clinically significant change in pain<sup>(6)</sup>. Consistent with the beneficially lower muscle injury associated with the paraspinal approach, significantly lower intraoperative blood loss was observed in the paraspinal-approach group (395.8 $\pm$ 113.7 mL) than in the posterior-approach group (590 $\pm$ 70.1 mL). The results demonstrated that the paraspinal approach potentially decreases intraoperative blood loss, thus implying that patients can be saved from blood transfusion challenges. Intraoperative blood

loss was determined using the volume of shed blood in the suction bottle and surgical sponges and subsequently estimated by an anesthesiologist. In this study, we analyzed intraoperative blood loss by determining which procedure represented less soft tissue trauma during the operative procedure.

Opioid usage on the first day of surgery was not different between the two groups due to the similar pain-management regimen, that is, morphine IV drip at 0.5–1 mg/h together with 2 mg pro re nata every 2 h, unless morphine injection was requested by patients due to pain. The paraspinal-approach group exhibited significantly different opioid usage from that in the posterior-approach group on day 2 (13 $\pm$ 1.5 vs 15.8 $\pm$ 1.9 mg) and day 3 (8.3 $\pm$ 1.9 vs 11.7 $\pm$ 1.6 mg). Less morphine usage is advantageous for recovery and early rehabilitation.

Wu et al.<sup>(9,10)</sup> found that operative time was significantly different between the two groups. However, the present study found no difference in operative time between the two groups. The paraspinal approach was not widely used for traumatic spine injury because the surgeon had less experience with the paraspinal technique than with the conventional technique. Nevertheless, the corrected rate of Cobb's angle and rate of loss reduction were similar between the two groups, suggesting that the mini-open approach was similar to the conventional method in terms of clinical outcomes. The paraspinal approach has

advantages over the conventional approach in these aspects. These results are consistent with those of a previous study<sup>(11,12)</sup>. The previous study presented less intraoperative bleeding, postoperative pain relief, and functional improvement in the posterior paraspinal muscle than the post-middle approach<sup>(13)</sup> and the results were similar to this present study. Moreover, this study added analgesic therapy (morphine) to evaluate and confirm pain reduction so as to mitigate bias from exclusively subjective data (VAS). The two groups were treated with long-segment instrumentation without fusion as the result of radiological and clinical parameters, demonstrating that spinal fusion is not necessary in long-segment posterior instrumentation for the management of thoracolumbar fractures<sup>(14)</sup>.

This study has certain limitations. First, the sample size was relatively small; however, the data generated are substantially different from those reported in other studies involving larger numbers of patients. Second, this study was characterized by lower external validity, as it was conducted in a single center. Third, this study involved a short-term follow-up of approximately 3 months. Certain outcomes, such as percentage reduction loss and ODI score (Thai version), may change during long-term follow-up.

## CONCLUSION

The paraspinal approach has a statistically significant advantage over the conventional posterior approach in terms of postoperative pain on days 1, 2, 3, and 14; intraoperative blood loss; opioid usage on days 2 and 3; and ODI score (Thai version) at 3 months. This approach is in concordance with the minimally invasive approach.

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## POTENTIAL CONFLICTS OF INTEREST

None.

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