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Posterior paraspinal muscle versus post-middle approach for the treatment of thoracolumbar burst fractures

A randomized controlled trial

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Abstract

Background: This randomized controlled trial (RCT) aimed to compare the clinical outcomes of thoracolumbar burst fractures (TLBFs) treated with open reduction and internal fixation via the posterior paraspinal muscle approach (PPMA) and the post-middle approach (PA).

Methods: Patients with a traumatic single-level TLBFs (T_{10}-L_2), treated at our hospital between December 2009 and December 2014, were randomly allocated to Group A (PPMA) and Group B (PA). Sex, age, time from injury to surgery, the American Spinal Injury Association Impairment Scale score (ASIAIS), comorbidities, vertebral level, pre- and postoperative kyphotic angle (KA), visual analog scale (VAS) pain score, and the Oswestry Disability Index (ODI) scores were included in the analysis. Operative time, intraoperative blood loss, x-ray exposure time, postoperative drainage volume, superficial infection, and occurrence of deep infection were documented. The patients were followed up at 2 weeks; 1, 3, and 6 months; 1 and 2 years; and every 6 months thereafter. Radiological assessments were performed to assess fracture union and detect potential loosening and breakage of the pedicle screws and rods at each follow-up. Postoperative VAS and ODI scores were used to evaluate the clinical outcomes.

Results: A total of 62 patients were enrolled (30 in Group A and 32 in Group B, respectively). The operative time ($P<.001$) and x-ray exposure time ($P<.001$) in Group A were significantly longer than those in Group B. However, compared to Group B, there were less intraoperative blood loss ($P<.001$), lower postoperative drainage volume ($P<.001$), lower VAS scores (2-week ($P=.029$), 1-month ($P=.023$), 3-month ($P=.047$), and 6-month follow-up ($P=.010$)), and lower ODI scores (2-week, $P=.010$; 1-month, $P<.001$; 3-month, $P=.028$; and 6-month follow-up, $P=.033$) in Group A.

Conclusions: Although PPMA required a longer operative time and x-ray exposure time, PPMA provided several advantages over PA, including less intra-operative blood loss and lower postoperative drainage volume, and greater satisfaction with postoperative pain relief and functional improvement, than PA, especially at the 6-month follow-up after surgery. Further high-quality multicenter studies are warranted to validate our findings.

Abbreviations: ASIAIS = American Spinal Injury Association Impairment Scale, KA = kyphotic angle, MRI = magnetic resonance imaging, ODI = Oswestry Disability Index, PPMA = posterior paraspinal muscle approach, RCT = randomized controlled trial, TLBFs = thoracolumbar burst fractures, VAS = visual analog scale.

Keywords: kyphotic angle, Oswestry Disability Index, posterior paraspinal muscle approach, post-middle approach, randomized controlled trial, thoracolumbar burst fractures, visual analog scale

1. Introduction

Thoracolumbar burst fractures (TLBFs) comprise an estimated 64% of thoracolumbar spine fractures in adults.[1] TLBFs result from high-energy axial loading, such as occurs in automobile accidents, vertical falls and sporting injuries.[2] These fractures can lead to severe pain, loss of vertebral height, and possible

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neurological deficits.[3,4] Such patients, especially those with neurological deficits, are generally good candidates for surgical intervention.[5] Surgery can provide immediate stability and deformity correction, as well as allow for early mobilization.[6] The pedicle screw–rod system is a commonly used surgical method.[7,8] However, the mean spine pedicle width in the Asian population is only approximately 8 mm,[9] increasing the risk pedicle screw placement failure, which can lead to serious surgical complications, such as neurovascular injury, visceral injury and decreased vertebral stability.[10] To reduce the potential risk for failure, most clinicians tend to choose a large-incision post-middle approach (PA) for implantation. However, the PA approach results in extensive soft-tissue damage, secondary to stripping of the posterior paraspinal muscles away from the spine. In 1959, Watkins[11] first proposed use of a posterior paraspinal muscle approach (PPMA) to the lumbar spine. Subsequently, Wiltse et al[12,13] adapted the PPMA to approach the thoracic spine between the lateral border of the multifidus and the longissimus, demonstrating that a PPMA might provide easy access to the facet and transverse process and, therefore, be useful as a surgical approach for pedicle screw placement and posterolateral fusion, without creating vertebral canal decompression.

Whether a PPMA can provide an alternative method of approach for the treatment of TLBFs has been not confirmed. Our review of studies on this topic[14–17] did not identify any randomized controlled trials comparing the short- and long-term outcomes for the PA and PPMA approaches. Thus, the aim of our randomized controlled single blind study was to determine if PPMA provides superior clinical and surgical outcomes to PA for the treatment of TLBFs using pedicle screws and rods.

2. Patients and methods

2.1. Patients

Patients with a traumatic single-level TLBF (T_{10}-L_2), treated in our hospital between December 2009 and December 2014, were eligible for enrollment in our study. The inclusion criteria were as follows: age, 20 to 55 years; with Grade D or E spinal cord injury, according to American Spinal Injury Association Impairment Scale (ASIAIS);[18] intact posterior longitudinal ligament, confirmed by magnetic resonance imaging (MRI); no displacement of bone fragments into the spinal canal; the absence of concomitant fractures at other body sites; time from initial injury to surgery $\leq$2 weeks; and patient's consent to the surgical treatment. Patients having sustained a pathological fracture, as well as those with a previous fracture of the spine or lower extremities, cognitive impairment, cerebral hemorrhage or infarction, or injury to the organs of the thoracic and abdominal cavities, were excluded.

Patients who met the inclusion criteria were numbered by computer-generated numbers, which were calculated via "=INT (100*RAND())" in Microsoft Office Excel. Patients with an even number were allocated to Group A (PPMA), with those with an odd number being allocated to Group B (PA). The surgeons were not blinded to group allocation, but the patients were. The follow-up time in the 2 groups was ≥24 months. All procedures were performed by a senior surgeon.

2.2. Surgical technique

2.2.1. Posterior paraspinal muscle approach.

The fracture site was determined using a locator and C-arm fluroscopy. After general endotracheal anesthesia, patients were placed in the prone position and a midline incision was performed through the skin, subcutaneous tissue and lumbodorsal fascia. The subcutaneous tissue was separated through a 2.0 to 3.0-cm incision, extending from midline to one of the 2 sides. Approximately 1 cm lateral to the spinous process, a longitudinal incision was made into the lumbodorsal fascia, until a finger could access the facet joint. Then, between the first and second tendon in the most medial erector spinae muscle, a longitudinal blunt separation of the muscle gap was performed, down to the facet joint and transverse process. The lateral facet joint was dissected by electrocoagulation. The position in the lumbar spine was determined from the ridge or transverse process, while the position of the thoracic vertebra was determined using the root of the transverse process and vertebral lamina junction. Bone fragments unsuitable for reconstruction were removed. All patients underwent posterior pedicle instrumentation and connecting rod attachment to achieve vertebral reduction and spinal canal decompression. Four pedicle screws were inserted one level above and one level below the burst fracture segment. Next, 2 ipsilateral pedicle screws were longitudinally attached to each other by a connecting rod, which was also secured by 2 contralateral pedicle screws. The 2 longitudinal connecting rods were connected by another transverse connecting rod. After hemostasis, 2 drainage tubes were placed and the incisions in the lumbodorsal fascia, subcutaneous tissue, and skin were sutured.

2.2.2. Post-middle approach.

After induction of general endotracheal anesthesia, patients were placed in a prone position. A midline incision was performed by subperiosteal dissection of the paraspinal muscles, using an electrosurgical unit at the level of the transverse and articular processes, and the muscles were retracted to expose the operative field. Bone fragments unsuitable for reconstruction were removed. The fracture was then reduced and fixed using posterior pedicle instrumentation and connecting rod attachment, as per the PPMA procedure previously described. After hemostasis, 2 drainage tubes were placed, and the incisions in the lumbodorsal fascia, subcutaneous tissue and skin were sutured in order.

According to Denis' three-column theory,[19] the posterior column bears 20% of the weight of the spine. If the posterior column is damaged, the weight of the spine will be added to the internal fixation device, resulting in fatigue fracture over time.[20] Therefore, it is important to reiterate that all patients in our trial had an intact posterior longitudinal ligament. Moreover, no patients with bone fragments displacement into the spinal canal were included in our study group and, therefore, no decompression surgery was required in either approach.

2.3. Clinical and radiological assessment

The following clinical outcomes were measured to evaluate between-group differences in efficacy: operative time, intraoperative blood loss, x-ray exposure time, postoperative drainage volume, postoperative kyphotic angle (KA), postoperative visual analog scale (VAS) score, Oswestry Disability Index (ODI) score, superficial infection, deep infection, and loosening and breakage of the pedicle screws and rods. Measurement of the KA was performed in accordance with the description by Song et al.[21] Clinical outcomes were determined by comparison of the data obtained at short-term (2 weeks and 1, 3, and 6 months) and mid-term (1and 2 years and each 6 months thereafter) follow-up in the 2 groups as follows: VAS to evaluate low back pain (on a scale of 0–10),[22] while ODI was used for the functional assessment (on a scale of 0%–100%).[23] A radiological assessment was performed to assess fracture union and detect potential loosening and breakage of the pedicle screws and rods at each follow-up.

2.4. Statistical analysis

All statistical analyses were performed using SPSS 21.0 software (SPSS Inc., Chicago, IL). Continuous variables are expressed as mean ± SD based on the normal data or median (quartile range) for the non-normally distributed data, while categorical variables are expressed as frequency (percentage). As for continuous variables, the independent 2-sample *t* test (or Mann–Whitney U (2 sample) test) was used to compare data between the 2 groups, while the categorical variables were compared with Pearson chi-square test (or Fisher's exact test). *P* values < .05 were considered statistically significant.

2.5. Ethical considerations

This study was approved by the Institutional Ethical Board of the 3rd Hospital of Hebei Medical University, and all patients signed informed consent. The study approval number was KE-2009-002-19.

3. Results

3.1. Patient characteristics

A total of 70 patients were enrolled (35 in Group A and 35 in Group B). Five patients in Group A and 3 in Group B were lost during follow-up, and the data of 62 patients were included in our final analysis. Group A included 19 men and 11 women, with a mean age of 46.2 ± 5.4 years (range, 35–55 years), with the following distribution of levels affected: T_{10} (3 cases), T_{11} (6 cases), L_{12} (7 cases), L_1 (12 cases), and L_2 (2 cases). Group B included 21 men and 11 women, with a mean age of 44.7 ± 6.6 years (range, 29–55 years), with the following distribution of levels affected: T_{10} (4 cases), T_{11} (5 cases), L_{12} (5 cases), L_1 (15 cases), and L_2 (3 cases). The mean follow-up period was 28.3 ± 3.0 months for Group A and 29.0 ± 2.6 months for Group B. There were no significant between-group differences regarding sex, age, time from injury to surgery, ASIAIS grade (all grade E fractures), comorbidities, vertebral level, preoperative KA, preoperative VAS score, preoperative ODI score, or follow-up period (Table 1).

Table 1

Baseline patient characteristics.

	PPMA (Group A)	PA (Group B)	$t/\chi^2/Z$	Significance (*P* value)
Patients (n)	30	32	–	–
Sex (male: female)	19:11	21:11	–	–
Mean age, years	46.2 ± 5.4	44.7 ± 6.6	1.009	.317
Time from injury to surgery, days	2.0 (2.0)	3.0 (1.0)	−0.640	.522
ASIAIS grade (n)				
D	6.0 (20.0%)	10.0 (31.3%)	1.024	.312
E	24.0 (80.0%)	22.0 (68.8%)	1.024	.312
Comorbidities				
CHD	2.0 (6.7%)	1.0 (3.1%)	0.003	.954
DM	1.0 (3.3%)	2.0 (6.3%)	0.000[a]	1.000
HT	2.0 (6.7%)	2.0 (6.3%)	0.000[a]	1.000
CBD	0.0 (0.0%)	1.0 (3.1%)	0.000[a]	1.000
Vertebral level (n)				
T_{10}	3.0 (10.0%)	4.0 (12.5%)	0.000[a]	1.000
T_{11}	6.0 (20.0%)	5.0 (15.6%)	0.203	.652
L_{12}	7.0 (23.3%)	5.0 (15.6%)	0.589	.443
L_1	12.0 (40.0%)	15.0 (46.9%)	0.298	.585
L_2	2.0 (6.7%)	3.0 (8.8%)	0.000[a]	1.000
Preoperative KA (°)	11.5 ± 3.5	11.3 ± 3.3	−0.215	.831
Preoperative VAS score	7.5 (2.0)	7.0 (2.0)	−0.858	.391
Preoperative ODI score (%)	50.0 (8.0)	53.0 (7.0)	−1.955	.051
Follow-up period, months	28.3 ± 3.0	29.0 ± 2.6	−0.988	.327

a = $t/\ \chi^2/\ Z < 0.001$, ASIAS = American Spinal Injury Association Impairment Scale, CBD = cerebrovascular disease, CHD = coronary heart disease, DM = diabetes mellitus, HT = hypertension, KA = kyphotic angle, L = lumbar vertebral fracture, NA = not applicable, ODI = Oswestry Disability Index, PA = post-middle approach, PPMA = posterior paraspinal muscle approach, T = thoracic vertebral fracture, VAS = visual analog scale.

3.2. Outcomes assessed

The operative time was 98.5 (14.3) minutes in Group A and 82.5 (6.8) minutes in Group B, which indicated that PPMA required a longer operative time (*P* < .001) than PA. Similarly, PPMA resulted in less mean blood loss (*P* < .001) when compared to PA (194.0 (7.5) mL versus 256.0 (14.5) mL, respectively). Additionally, longer x-ray exposure time was seen in Group A (14.0 (2.3)) when compared to Group B (10.0 (2.8)) (*P* < .001). The postoperative drainage volume was 94.0 (22.0) mL in Group A and 160.0 (19.0) mL in Group B (*P* < .001) (Table 2).

The respective VAS scores at 2-week follow-up were 6.0 (1.0) in Group A and 6.0 (2.0) in Group B (*P* = .029). At 1-month follow-up, the VAS scores were 2.0 (1.0) in Group A and 3.0 (2.0) in Group B (*P* = .023). The 3-month follow-up VAS scores were 1.0 (1.0) in Group A and 2.0 (0.8) in Group B (*P* = .047). The 6-month follow-up VAS scores were 1.0 (1.0) in Group A and 1.0 (1.0) in Group B (*P* = .010). The 2-week follow-up ODI scores were 42.5 (5.0) % in Group A and 45.0 (2.5) % in Group B (*P* = .010). The 1-month follow-up ODI scores were 32.5 (5.0) % in Group A and 37.5 (5.0) % in Group B (*P* < .001). The 3-month ODI scores were 30.0 (5.0) % in Group A and 32.5 (7.5) % in Group B (*P* = .028), while the 6-month ODI scores were 22.5 (0.6) % in Group A and 22.5 (2.5) % in Group B (*P* = .033). No significant intergroup difference in VAS or ODI scores were observed at 1-year or 2-year follow-up in VAS scores (*P* = .514 and *P* = .536) or ODI scores, respectively (*P* = .867 and *P* = .924) (Table 2).

There were no intergroup differences in KA (2-week (*P* = .375), 1-month (*P* = .364), 3-month (*P* = .459), 6-month follow-up (*P* = .434), 1-year (*P* = .362) and 2-year (*P* = .485)) (Table 2). We observed grade E in all patients.

Superficial infection developed in 2 of 30 patients in Group A and 5 of 32 patients in Group B (*P* = .476). A deep infection developed in 1 of 30 patients in Group A and 3 of 32 patients in Group B (*P* = .652). Pedicle screw and rod loosening occurred in 2 of 30 patients in Group A and 4 of 32 patients in Group B (*P* = .729), with breakage occurring in 1 patient in Group A and 2 patients in Group B (*P* = 1.000) (Table 2).

4. Discussion

In this study, we compared the clinical outcomes of TLBFs treated with open reduction and internal fixation using either a PPMA or PA. The multifidus, longissimus, and iliocostalis are the principal muscles affected by surgical treatment of TLBFs. The multifidus is a major posterior stabilizing muscle of the spine,[24] with several

Table 2

Outcomes of patients undergoing either PPMA or PA.

	PPMA (Group A)	PA (Group B)	$t/\ \chi^2/\ Z$	Significance (*P* value)
Operative time, minutes	98.5 (14.3)	82.5 (6.8)	−6.043	.000*
Blood loss, mL	194.0 (7.5)	256.0 (14.5)	−5.631	.000*
x-ray exposure time, seconds	14.0 (2.3)	10.0 (2.8)	−6.147	.000*
Postoperative drainage volume, mL	94.0 (22.0)	160.0 (19.0)	−6.768	.000*
ASIAIS grade (n)				
D	0	0	–	–
E	30	32	–	–
Postoperative KA (°)				
2-week follow-up	4.3 (5.6)	4.8 (5.1)	−0.888	.375
1-month follow-up	4.9±3.1	5.7±3.1	−0.915	.364
3-month follow-up	4.4 (5.4)	4.7 (5.2)	−0.740	.459
6-month follow-up	4.3 (5.5)	4.7 (5.1)	−0.782	.434
1-year follow-up	4.9±3.1	5.6±3.1	−0.919	.362
2-year follow-up	4.2 (5.1)	4.7 (4.8)	−0.698	.485
Postoperative VAS score				
2-week follow-up	6.0 (1.0)	6.0 (2.0)	−2.182	.029
1-month follow-up	2.0 (1.0)	3.0 (2.0)	−2.281	.023
3-month follow-up	1.0 (1.0)	2.0 (0.8)	−1.990	.047
6-month follow-up	1.0 (1.0)	1.0 (1.0)	−2.578	.010
1-year follow-up	0.0 (1.0)	0.0 (1.0)	−0.653	.514
2-year follow-up	0.0 (1.0)	0.0 (1.0)	−0.6196	.536
Postoperative ODI score (%)				
2-week follow-up	42.5 (5.0)	45.0 (2.5)	−2.578	.010
1-month follow-up	32.5 (5.0)	37.5 (5.0)	−5.911	.000*
3-month follow-up	30.0 (5.0)	32.5 (7.5)	−2.203	.028
6-month follow-up	22.5 (0.6)	22.5 (2.5)	−2.127	.033
1-year follow-up	17.5 (5.0)	20.0 (5.0)	−1.168	.867
2-year follow-up	17.5 (2.5)	18.8 (6.9)	−0.095	.924
Superficial infection (n)	2.0 (6.7%)	5.0 (15.6%)	0.507	.476
Deep infection (n)	1.0 (3.3%)	3.0 (9.4%)	0.203	.652
Loosening of pedicle screws and rods (n)	2.0 (6.7%)	4.0 (12.5%)	0.120	.729
Breakage of pedicle screws and rods (n)	1.0 (3.3%)	2.0 (6.3%)	0.000[a]	1.000

a = $t/\ \chi^2/\ Z < 0.001$, KA = kyphotic angle, ODI = Oswestry Disability Index, PA = post-middle approach, PPMA = posterior paraspinal muscle approach, VAS = visual analog scale.
* $P < .001$.

vertebral attachments, including to the spinous processes medially, the lamina ventrally and the superior articular processes laterally.[25] Due to its midline location, the multifidus muscle is the most likely to be injured when using a PA.[26] Exposure of the facet joint and transverse process unavoidably disrupts the insertion of the multifidus on the superior articular process, and may even place the neurovascular bundle at risk of injury.[25] Moreover, no intersegmental nerve but the medial branch of the dorsal ramus supplies the multifidus.[27] As such, once the nerve has been damaged during posterior spinal surgery, postoperative muscle atrophy is likely to develop, leading to pain and impaired function.[28,29] These limitations prevent the wider application of the PA approach.[30]

Conversely, PPMA is a relatively minimally invasive approach, utilizing blunt separation of the multifidus and longissimus muscles only. As extensive dissection of the paraspinal muscles is not required, postoperative stability is facilitated, with a lower risk of neurovascular injury. Given these factors, PPMA is associated with less intra-operative blood loss, blood transfusion volume and postoperative drainage volume. These findings in our study are comparable to those of previous studies.[14–17] However, these previous studies did not report on the infection rate for the different surgical approaches. Surgical site infection following spinal surgery is a frequent complication that reportedly occurs in 0.7% to 12.0% of patients and results in higher postoperative morbidity, mortality, and health care costs.[31] Increased estimated blood loss and prolonged surgical time were risk factors for surgical site infection, especially in posterior instrumentation.[32,33] In this study, we failed to deduce that PA has a higher postoperative infection rate. However, in PA, the extensive electric burn and coagulation necrosis of tissue secondary to electrosurgical treatment increased the risk of postoperative infection.[34] Therefore, we hypothesize that PA will result in a higher postoperative infection rate when compared to PPMA. In addition, pedicle screw and rod loosening and breakage were possible complications associated with the internal spinal fixation device. Although our results did not demonstrate a significant difference between the 2 approaches, we speculated that PA might have a higher pedicle screw and rod loosening and breakage rate due to the related extensive destruction of the paraspinal muscles and subsequent reduction of stability.

VAS score was used to evaluate low back pain. Our results indicated that PPMA had a lower mean postoperative short-term VAS score. Although Cai et al[14] and Dai et al[16] both reported VAS scores, they did not perform long-term follow-up. Furthermore, the respective sample sizes included in their 2 studies were only 53 and 45, which might be insufficient to draw a credible conclusion. Our study ultimately included 62 patients, compared long-term VAS scores, and found no statistically significant difference between the 2 approaches. Despite the negative results, this observation further enriched our understanding of this approach. Specifically, it is insufficient to assess PPMA using VAS score only.[14,16] To comprehensively evaluate the clinical efficacy of this approach, ODI score was used to assess functional assessment. We found that PA yielded a poorer result with a higher ODI score. In contrast to PPMA, conventional PA requires extensive dissection and prolonged intraoperative traction of the paraspinal muscles, which is closely associated with muscle atrophy.[35] Muscle atrophy and relevant pain largely limit patients' postoperative activities. Therefore, PA had a higher mean ODI score. Nonetheless, these advantages of PPMA over PA will become less obvious with rehabilitation. Furthermore, it is acknowledged that PPMA had longer operative time and x-ray exposure time than PA. Several potential reasons for this were assumed, including abundant lumbodorsal muscles and soft tissue along with the relatively deep small joints limiting the surgical field of vision. This greatly increases the technical difficulty, particularly since the surgery is performed endoscopically.

PPMA has obvious advantages over PA. Thus, PPMA is a more reliable surgical approach for treating TLBFs. There is one physiological gap between the multifidus and the longissimus muscles at the thoracolumbar vertebral segment, the transverse and articular processes can be approached while retaining the integrity of the posterior ligament complex and without damaging the paraspinal muscles. In addition, the strong internal fixation obtained using the pedicle screw–rod system can restore vertebral height, which allows early mobilization and a faster functional recovery. Therefore, our findings indicate that PPMA can avoid some of the drawbacks associated with the traditional wide-open PA, making it a potential alternative to this traditional procedure.

Our study had four limitations which should be acknowledged. First, as this is a single-site study, selection bias is unavoidable, despite the controlled experimental design. Second, although our study group included 62 patients, the study remained underpowered. Third, we did not compare the PPMA to a percutaneous approach, a comparison which should be undertaken in future studies. Fourth, PPMA was only applied to those patients with slight neurological symptoms.

5. Conclusions

Although PPMA required a longer operative time and x-ray exposure time, PPMA provided several advantages over PA, including less intra-operative blood loss and lower postoperative drainage volume, and greater satisfaction with postoperative pain relief and functional improvement, than PA, especially at the 6-month follow-up after surgery. Further high-quality multicenter studies are warranted to validate our findings.

Author contributions

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