

A comparison of three different surgical procedures in the treatment of type A thoracolumbar fractures: a randomized controlled trial

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Abstract

Purpose The aim of the study was to evaluate the efficacy of three different surgical procedures in the treatment of type A thoracolumbar fractures.

Materials and methods Between September 2012 and January 2015, a total of 90 patients with type A thoracolumbar fractures were randomly assigned into three groups of 30 each. Patients in group A, B, and C were treated with three-level percutaneous fixation, two-level percutaneous fixation, and three-level open fixation, respectively. Blood loss, duration of surgery, VAS scores, Cobb angles, and anterior height ratios of fractured vertebrae were collected for statistical analysis.

Results The average follow-up was 17.7 months. Post-operative Cobb angles were significantly corrected and anterior height ratios of fractured vertebrae were well restored in all three groups ($p < 0.01$). Back pain was efficiently relieved according to VAS score change ($p < 0.01$). There were significant differences in values of blood loss and post-operative VAS scores (at three months) between group A and group C ($p < 0.01$). No significant difference concerning post-operative anterior height ratios of fractured vertebrae, Cobb angles and

correction losses was observed between group A and group B ($p = 0.580, 0.840, 0.215$, respectively).

Conclusion Percutaneous fixation not only provides the same reduction effect as open fixation, but also has an advantage of causing less operation related trauma which is beneficial to post-operative rehabilitation. The efficacy of three-level percutaneous fixation and two-level percutaneous fixation in the treatment of type A thoracolumbar fractures is not significantly different.

Keywords Thoracolumbar fracture · Percutaneous pedicle screw · Minimally invasive surgery (MIS) · Randomized controlled trial (RCT)

Introduction

Thoracolumbar fractures are the most common spinal injuries. It is controversial to treat those patients who are without neurological deficits with surgery. Nevertheless, researches have shown that clinical and radiological outcomes of patients who accepted operations were more favorable than those treated without surgical intervention [1]. The surgical treatment via posterior approaches, known as traditional open surgery, was popular for decades. In recent years, percutaneous pedicle screw fixation technique has been widely used [2, 3]. The use of additional screws in the intermediate pedicles is also disputable. In order to compare the efficacy of different surgical treatments, a randomized controlled trial was conducted between September 2012 and January 2015 in the department of Orthopaedics, Changhai Hospital, Second Military Medical University, Shanghai, China.

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Table 1 Baseline demographic characteristics of the three groups

Group	Age (years)	Gender		Fractured site				AO classification		
		Male	Female	T11	T12	L1	L2	A1	A2	A3
A	45.8±7.8	15	15	3	10	14	3	15	4	11
B	45.3±8.3	16	14	4	11	12	3	19	5	6
C	43.7±8.8	12	18	2	9	14	5	17	5	8
<i>p</i> -value	0.58	0.561		0.938				0.711		

Materials and methods

Between September 2012 and January 2015, a total of 104 consecutive patients were diagnosed as type A thoracolumbar fractures. Among them, 90 cases who had given informed consent were selected according to the following criteria. The inclusion criteria for this study were as follows: age 18–60 years, single-level fresh thoracolumbar fracture (within two weeks), no neurological deficit. Exclusion criteria were Type A1.1 fractures, pedicle fracture, osteoporotic or pathologic fracture, previous spinal trauma or disease, other major organ system or musculoskeletal injuries, pregnancy, and female patients who were in the menstrual period. According to AO classification, there were 51 A1 cases, 14 A2 cases and 25 A3 cases among them. Ninety patients were randomly assigned to three groups of 30 cases each. Patients in group A were treated with three-level percutaneous fixation. Patients in group B underwent two-level percutaneous fixation. And patients in group C accepted three-level open fixation via traditional posterior approaches. There was no statistically significant difference in age, gender, fractured site or types of AO classification among the three groups ($p > 0.05$) (Table 1).

Plain X-radiographs, computed tomography (CT) scans and magnetic resonance imaging (MRI) were obtained in order to determine the type of fracture, the compression ratio of spinal canal, whether there was an injury of posterior ligamentous complex (PLC), etc. [4]. Thoracolumbar injury classification and severity scores (TLICS) [5] of all cases were calculated. Each patient received plain X-radiographs two days after surgery. CT scans were also a necessity if there had been obvious compression of spinal canal before surgery.

The procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000.

Description of percutaneous fixation surgery

A single shot of antibiotics was administered pre-operatively. Under general anaesthesia with endotracheal intubation, each patient was positioned prone on a Jackson operating table. Chest and pelvis were supported by gel pads fixed on the table. Postural reduction was performed before surgery. Lateral fluoroscopy was taken with the purpose of determining the efficacy of postural reduction. Posteroanterior (PA) fluoroscopy was used for locating one level above and below the injured vertebra. The corresponding positions of pedicles were marked on the patient's back. After undergoing disinfection of the surgical area, skin incisions were made 1.5-cm lateral from the marks of those pedicles. Underlying fascia was cut by an electrosurgical knife and paraspinal muscles were split by a finger. Under PA fluoroscopy, each pedicle was cannulated by a Jamshidi needle at the lateral and medial margin. The insertion directions were adjusted according to lateral fluoroscopy. The needle was then slowly implanted through a pedicle. Via PA view it was made sure that each needle was not passed across the medial border of the corresponding pedicle, which suggested that there was no violation of spinal canal. A guidewire was placed into the vertebral body through the needle, followed by sequential dilators which could protect paraspinal muscles while creating a space for tapping. The dilators were then removed, allowing a percutaneous

Fig. 1 Images from a 35-year-old female in group A. **a, b** Preoperative radiographs indicating a fracture of T12. **c, d** Post-operative radiographs indicating favorable restoration of anterior height of T12 vertebra and correction of Cobb angle

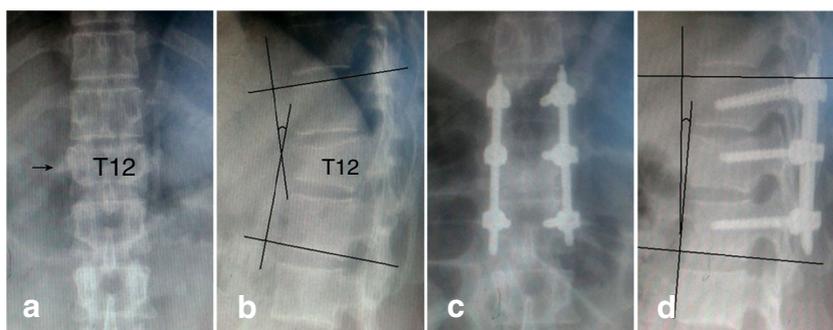
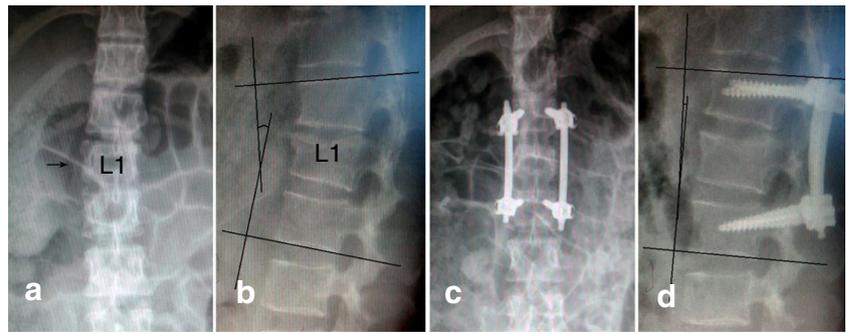


Fig. 2 Images from a 43-year-old male in group B. **a, b** Pre-operative radiographs indicated a fracture of L1. **c, d** Post-operative radiographs indicated favourable restoration of anterior height of L1 vertebra and correction of Cobb angle



pedicle screw to be inserted into the pedicle and vertebral body along the wire which was also pulled out soon after. Each percutaneous pedicle screw was inserted into a pedicle and a vertebral body in the same way. The adjacent levels of fractured vertebrae were implanted with bilateral pedicle screws in group B while an additional pair of screws were implanted into the fractured vertebra in group A. Therefore, there were six percutaneous pedicle screws implanted into each patient's thoracolumbar region in group A (Fig. 1d, e) and four screws in group B (Fig. 2d, e). The length of rods was assessed according to the distance between cranial and caudal screws. An appropriately bent rod was placed in the screws' heads of one side below the fascia. The height of fractured vertebra was further restored by applying a hyperlordosing force through the posterior elements just before the set of screws were tightened. The same procedure was followed on the other side. Good location of internal fixation and satisfactory correction of kyphosis were confirmed by PA and lateral fluoroscopy. Finally, incisions were irrigated and closed layer-by-layer without drainage.

Description of open fixation surgery

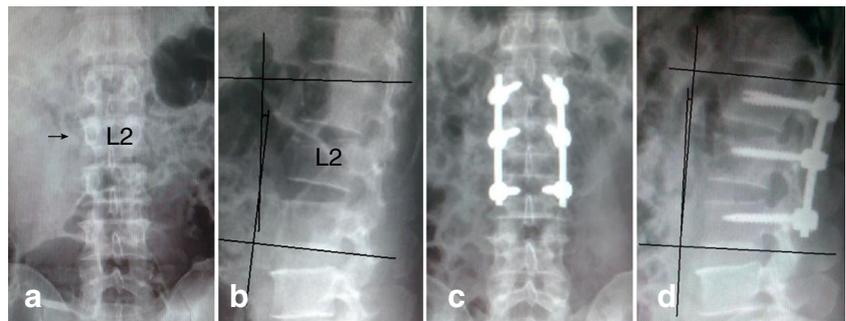
Dose-appropriate antibiotics were also administered at the induction. General anaesthesia and endotracheal intubation were conducted in the same way in group A and group B. Postural reduction and skin disinfection were also performed in a prone position for patients in group C on a Jackson operating table before the surgical procedure. After posterior

thoracolumbar elements were clearly exposed through the traditional posterior approaches, the fractured and adjacent vertebrae were implanted with a total of six pedicle screws by free hands. Appropriately sized rods were placed in screws' heads and kyphosis was corrected by a hyperlordosing force. Subsequently, locking screws were tightened (Fig. 3d, e). Irrigation of the incision was repeatedly executed and drainage was placed before those layers were strictly closed. Generally, drainage was removed within 48 hours after the surgical procedure.

In the pre- and post-operative period, all patients were encouraged to do muscle flexing of lower limbs with the purpose of avoiding muscle atrophy and reducing the risk of deep venous thrombosis. Each patient in group A and group B was encouraged to have ambulatory activities while wearing a thoraco-lumbar-sacral brace three days after surgery. The starting time of ambulatory activities for patients in group C was two weeks post-operatively. All patients commenced back muscle exercises a fortnight after surgery. The brace was kept until three-month follow-up. Neither sports nor strenuous labour was allowed within six months after surgery. Plain X-radiographs were obtained at one month, three months, six months, one year and two years post-operatively. All patients accepted surgery of instrumentation removal during the period of six months to one year when plain X-radiographs confirmed good healing of fractured vertebra.

The following radiological data were collected. Anterior height ratios (AHR) of fractured vertebrae and Cobb angles (CA) (Fig. 4) were measured in pre- and postoperative plain X-radiographs (Figs. 1, 2 and 3b, e). The anterior height ratio

Fig. 3 Image from a 38-year-old male in group C. **a, b** Pre-operative radiographs indicated a fracture of L2. **c, d** Post-operative radiographs indicated favourable restoration of anterior height of L2 vertebra and correction of Cobb angle



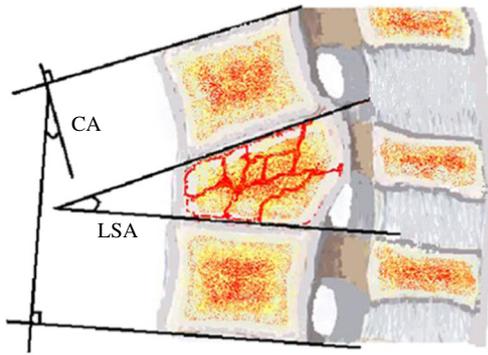


Fig. 4 Cobb angle (CA) and local sagittal angle (LSA)

of a fractured vertebra was calculated by dividing the anterior height of the fractured vertebra by its normal height. And the normal height of a fractured vertebra was estimated by taking the average between the anterior heights of upper and lower adjacent vertebrae. A Cobb angle was measured between the superior endplate of the upper vertebra and the inferior endplate of the lower vertebra. A correction loss was calculated by subtracting the Cobb angle of final follow-up from the first post-operative one.

Clinical parameters consisted of duration of surgery, intra-operative blood loss and visual analogue scale (VAS). VAS scores, assessing the magnitudes of patients' back pain, were measured at pre-operative time, three months follow-up and the final follow-up.

Statistical analysis methods

All radiological and clinical data were analyzed by using SPSS statistical package, version 16.0 (SPSS, Chicago, IL, USA). Chi-square test was used for analyzing categorical data among three different groups. Continuous variables were recorded as the mean \pm SD. Among-group comparisons were made using ANOVA. If there was statistical significance, between-group comparisons were made by performing Dunnett-*t* test. For each analysis, a *P* value of <0.05 was considered statistically significant.

Results

The average follow-up was 17.7 months (range 11–25 months). There was no significant difference in baseline demographic characteristics among three groups ($p > 0.05$) (Table 1). No significant among-group difference concerning pre-operative VAS score, Cobb angle or anterior height ratio of fractured vertebra was observed ($p > 0.05$). No neurological complication was noted. One case in group A who had been diagnosed as diabetes suffered from post-operative wound infection four days after surgery. The infection was soon controlled after treatments, including irrigation, debridement and

Table 2 Clinical parameters (group A vs group C)

Parameter	Group A	Group C	<i>p</i> -value
Duration of surgery	72.1 \pm 12.5	77.8 \pm 8.2	0.068
Blood loss	100.7 \pm 18.9	202.1 \pm 42.0	<0.001
VAS at three months	2.2 \pm 0.5	3.3 \pm 0.5	<0.001

rational use of antibiotics, without the removal of internal fixation. Screw loosening was observed in one case in group B at three months with no clinical symptom. The patient was suggested to reduce ambulatory activities, increase back muscle exercises and keep wearing a brace until the time when good healing of the fracture was confirmed. The instrumentation of the patient was removed six months after the first surgery, and the outcome was favourable at the final follow-up.

The average durations of surgery in group A, group B and group C were 72.1 \pm 12.5 min, 64.4 \pm 9.8 min and 77.8 \pm 8.2 min; and the values of intra-operative blood loss were 100.7 \pm 18.9 ml, 89.1 \pm 17.3 ml and 202.1 \pm 42.0 ml, respectively. Duration of surgery was significantly shorter in group B than group A ($p < 0.05$). There was no significant difference concerning duration of surgery between group A and group C ($p = 0.068$). The values of intra-operative blood loss in group A were significantly less than those in group C ($p < 0.05$). VAS scores for back pain at three months after surgery were 2.2 \pm 0.5, 2.4 \pm 0.5 and 3.3 \pm 0.5 points in group A, group B and group C. The scores in group A were significantly lower than those in group C ($p < 0.05$). The difference between group A and B was not statistically significant ($p = 0.612$) (Table 2).

Post-operative Cobb angles were significantly corrected and anterior height ratios of fractured vertebrae were well restored in all three groups ($p < 0.05$) (Figs. 1, 2 and 3). However, correction loss, which was reflected in significant increases of Cobb angles, was observed in all three groups at the last follow-up ($p < 0.05$). The increases of Cobb angles in group A, B and C were 2.9 \pm 1.4°, 3.7 \pm 2.2° and 3.6 \pm 1.9°. There were no significant among-group differences in post-operative Cobb angles, anterior height ratios of fractured vertebrae or correction loss ($p > 0.05$) (Table 3).

Table 3 Radiological parameters (group A vs group B)

Parameter	Group A	Group B	<i>p</i> -value
Pre-operative CA	16.7 \pm 5.5	17.3 \pm 3.6	0.717
Post-operative CA	5.6 \pm 2.5	5.9 \pm 1.4	0.840
CA at the final follow-up	8.6 \pm 2.1	9.6 \pm 2.2	0.162
Correction loss	2.9 \pm 1.4	3.7 \pm 2.2	0.215
Pre-operative AHR	65.1 \pm 9.3	66.0 \pm 7.6	0.381
Post-operative AHR	88.8 \pm 6.2	89.5 \pm 3.7	0.580

CA Cobb angle, AHR anterior height ratio

Discussion

The highest incidence of spinal fractures happened at the thoracolumbar region because of its special anatomical features [6]. It is considered that a vertebral height loss of more than 50 %, a local sagittal angle (LSA) (Fig. 4) of more than 20 degrees or posterior ligamentous complex (PLC) injury may be unstable findings for traumatic thoracolumbar fractures [7]. Type A thoracolumbar fractures are without PLC injury. Both conservative management and surgical intervention are advocated [8, 9]. Surgical fixation provides not only better fracture reduction, but also initial stability which enables early mobilization. Thus, it can effectively decrease complications associated with prolonged recumbence [1, 7]. Although the outcomes of traditional open surgery for patients who had indications are generally favourable, the extensive damage of soft tissue unavoidably results in a relatively high incidence of failed back surgery syndromes [10, 11]. With the rapid development of minimally invasive techniques for spine in recent years, percutaneous pedicle screw fixation has gained its popularity because the technique has an obvious advantage in protecting paraspinal muscles from iatrogenic denervation and atrophy. Lee et al. [12] pointed out that when compared with conventional posterior surgery, the current minimally invasive procedure had advantages of costing less surgical procedure-related trauma and ensuring earlier recovery. The results of this study also showed that the values of intra-operative blood loss in percutaneous fixation groups were significantly less than those in the open fixation group. Patients who underwent minimally invasive surgery had lower post-operative VAS scores at three-month follow-up, which indicates that back pain is properly associated with the damage of paraspinal muscles in the open surgical procedure. Besides, patients in the percutaneous fixation group are allowed to have ambulatory activities much earlier, and will be less exposed to complications of bed rest [13].

In the study, there was no significant difference concerning kyphosis correction between three-level percutaneous fixation and three-level open fixation. Although the current minimally invasive fixation technique has so many advantages, it is still at its early stage. Inevitably, disadvantages, including more exposure to radiation and higher degree of difficulty with fracture reduction cannot be ignored. However, such disadvantages are undoubtedly going to be reduced or even be avoided by the development of technology concerning spinal surgery navigation, robotic guidance and so on [14].

Even before the application of minimally percutaneous fixation procedure, the idea of placing pedicle screws at the level of the fractured vertebra, causing considerable controversy, was proposed by some authors. They considered the reduction procedure with short segment fixation across fractured vertebra, or named two-level fixation, to be indirect. Moreover, a higher proportion of instrumentation failure and a larger

degree of correction loss were observed in patients with two-level fixation. In 1994, Dick et al. [15] conducted a study which indicated that the use of additional screws in the intermediate pedicles increased axial, sagittal, and torsional stiffness by varying degrees. Therefore, the technique could probably decrease correction loss. Besides, the three-level fixation provides a better pull-out strength and thus theoretically reduces the rate of instrumentation failure. However, in this study, there was no significant difference in Cobb angle restoration and correction loss between two-level fixation and three-level fixation. The reasons may be as follows. Firstly, the sample size of the study was not big enough, which resulted in an error. Secondly, there had been no damage at posterior elements of thoracolumbar in all patients, so the two-level fixation might be adequate for fracture reduction and stability maintenance. Thirdly, assisted by a thoraco-lumbar-sacral brace after surgery, the two-level fixation could sufficiently maintain the stability of the injured segment. Thus, it is not necessary to treat every case of thoracolumbar fracture with intermediate screws. In spite of the result of this study, the conclusion that the three-level fixation increases the stiffness of the fractured segment cannot be refuted. The use of intermediate screws is recommended when a patient is with severe osteoporosis, obesity, obvious injury of posterior column, etc.

Furthermore, it is worth noting that no posterolateral bony fusion was performed either in percutaneous surgery or in the traditional open procedure in the study, as several researches proved that posterior pedicle instrumentation without fusion could get comparable results as fixation with fusion [16].

There are two main limitations in the study. First, the study failed to use sagittal index (SI) to describe sagittal deformity, which influenced the accuracy of the results to some extent. Second, a few cases were not followed up long enough. Thus, long-term clinical outcomes of these cases, for instance, correction loss after the removal of instrumentation, could not be observed.

Although there are some deficiencies in this study, the results still show that the outcomes of both percutaneous and open surgery are satisfactory. Compared with the open fixation surgery, the percutaneous fixation surgery has an advantage of causing less operation-related trauma which is beneficial to postoperative rehabilitation. The efficacy of three-level percutaneous fixation and two-level percutaneous fixation in the treatment of type A thoracolumbar fractures is not significantly different.

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Compliance with ethical standards

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Conflicts of interest The authors have no competing interests to declare.

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