

Efficacy and safety of minimal pedicle screw fixation for thoracolumbar fractures: a meta-analysis

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Abstract. – **OBJECTIVE:** Minimal and open pedicle screw fixation procedures have been widely used in the treatment of thoracolumbar fractures. However, the efficacy and safety of these approaches remain unclear. This meta-analysis was conducted to evaluate perioperative, functional and radiological outcomes of percutaneous versus open pedicle screw fixation for thoracolumbar fractures.

MATERIALS AND METHODS: To obtain relevant literature, a systematic search was performed using the MEDLINE, EMBASE, and Cochrane databases. The Cowley criteria were used to evaluate the risk of bias for the included studies. A database that included patient demographic information and perioperative outcomes was established. Summary odds ratios (ORs) and weighted mean differences (WMDs) with 95% confidence intervals (CIs) were estimated. Analyses were performed for the two subgroups of Chinese studies and studies from other nations. Publication bias was assessed using the funnel plot method.

RESULTS: Eleven comparative observational studies that satisfied our inclusion criteria were identified via a literature search in the MEDLINE, EMBASE, and Cochrane databases. Relative to the open approach, the minimal approach was associated with less blood loss (WMD=-218.10, 95% CI: -266.31 to -169.88, $p<0.00001$) and shorter operative time (WMD=-15.31, 95% CI: -24.73 to -5.88, $p=0.001$). Evidence indicated that a significant difference was observed between Chinese studies and other studies with respect to blood loss ($p=0.02$). We also found that the minimal approach was associated with a lower postoperative visual analog scale (VAS) score (WMD = -1.06, 95% CI: -1.32 to -0.8, $p<0.00001$) and less correction loss (WMD=-0.59, 95% CI: -1.16 to 0.02,

$p=0.04$) than the traditional open approach. No significant difference between these approaches was found with respect to complication rate (OR 0.78, 95% CI: 0.39 to 1.55, $p=0.48$).

CONCLUSIONS: The evidence indicated that the minimal approach had better functional and radiological outcomes than the open approach. Neither approach was superior with respect to complication rate. Relative to the open approach, the minimal approach might be associated with decreased operative time, less blood loss and a shorter hospital stay.

Key Words

Percutaneous, Minimal, Open, Thoracolumbar Fractures, Meta-Analysis.

Introduction

Thoracolumbar fractures constitute the majority of spine fractures caused by the failure of both the anterior and middle columns of the vertebral body, with or without flexion force¹. Surgical fixation of thoracolumbar fractures can effectively decrease complications associated with prolonged recumbence². The goals of surgical fixation include stabilization of the spine, fracture reduction, and, as appropriate, decompression of neurological structures³. Pedicle screw systems, which were first introduced by Boucher, have been widely used in the instrumentation of the lumbar spine⁴. Open operations, such as operations using the traditional midline approach or

a paraspinous approach, have proven to be safe and have become standard methods for lumbar fusion surgery. Magerl⁵ reported the first use of percutaneous pedicle screw instrumentation in 1977. However, open procedures are associated with significant perioperative morbidities, such as blood loss or complications. Therefore, minimally invasive techniques for spinal surgery have increased in popularity^{6,7}. Compared to the open approach, the minimal approach has many advantages for the treatment of thoracolumbar fractures, such as a small incision, no paraspinous muscle dissection and less blood loss⁸. Decreased control of the reduction, the maintenance of lordosis and longer fluoroscopy time are limitations of the percutaneous approach⁹.

Long-term outcomes of percutaneous pedicle screw fixation for thoracolumbar fractures have been reported¹⁰⁻¹³. This meta-analysis was conducted to evaluate perioperative, functional and radiological outcomes of percutaneous versus open pedicle screw fixation for thoracolumbar fractures. Chinese studies and other studies were the subgroups evaluated in this study.

Materials And Methods

Search Strategy and Inclusion Criteria

To obtain relevant literature, a survey of articles published by May 2017 in the MEDLINE, EMBASE and Cochrane databases was conducted. All fields were screened using the key terms “Minimally invasive”, “Percutaneous pedicle screw” or “Open pedicle screw” and “thoracolumbar fracture” or “lumbar fracture”. Pertinent articles in reference lists were also examined. All eligible publications written in English or Chinese that addressed the association between percutaneous and open pedicle screw fixation were searched.

Studies were included in this meta-analysis if they satisfied the following criteria: 1) the study design was a comparative cohort study (i.e., minimal compared to open pedicle screw fixation); 2) the study population consisted of adult patients suffering from thoracolumbar fractures without neurological deficits; 3) the study reported at least one desirable outcome with respect to perioperative results (e.g., operative time or blood loss), complications, visual analog scale (VAS) score, or correction loss; 4) patients were followed up for at least 6 months after surgery; and 5) each

group included at least 10 patients. Case reports, reviews, biomechanical studies, cadaveric studies, and duplicate studies were excluded from this meta-analysis.

Data Extraction and Quality Assessment

The following information was extracted from each publication: 1) the first author’s last name, study year, country and study design; 2) basic study characteristics, including the number and ages of enrolled patients and the gender ratio for these patients; 3) perioperative results, such as operative duration, blood loss, and hospitalization; 4) rates of complications (e.g., infection or screw misplacement); and 5) correction loss. Data regarding both intraoperative and postoperative complications were extracted.

The quality of the included studies was evaluated using the Cowley criteria. A Cowley score of at least 9 out of a possible 17 was regarded as indicative of high methodological quality^{14,15}.

Statistical Analysis

This analysis was conducted using the statistical software Review Manager, version 5.3 (Cochrane Collaboration). As the included studies reported similar findings, only results produced by a random effects model were presented. Continuous outcomes were assessed by calculating weighted mean differences (WMDs) and 95% confidence intervals (CIs). Dichotomous variables were summarized using odds ratios (ORs) and 95% CIs. Heterogeneity was evaluated using the I^2 statistic. I^2 values of <25%, 25-50%, 50-75%, and >75% were regarded as indicative of no, low, moderate, and high heterogeneity, respectively. Funnel plots were utilized to assess the possibility of publication bias.

Results

Literature Survey and Study Characteristics

Eleven comparative studies were identified (Figure 1). The basic search strategy yielded 144 records. Eighty-two articles were screened by title and abstract. Thirty-one case reports, reviews, biomechanical studies, and cadaveric studies were excluded. One duplicate study was found¹⁶. Finally, studies that reported outcomes for a total of 575 patients were included in the meta-analysis.

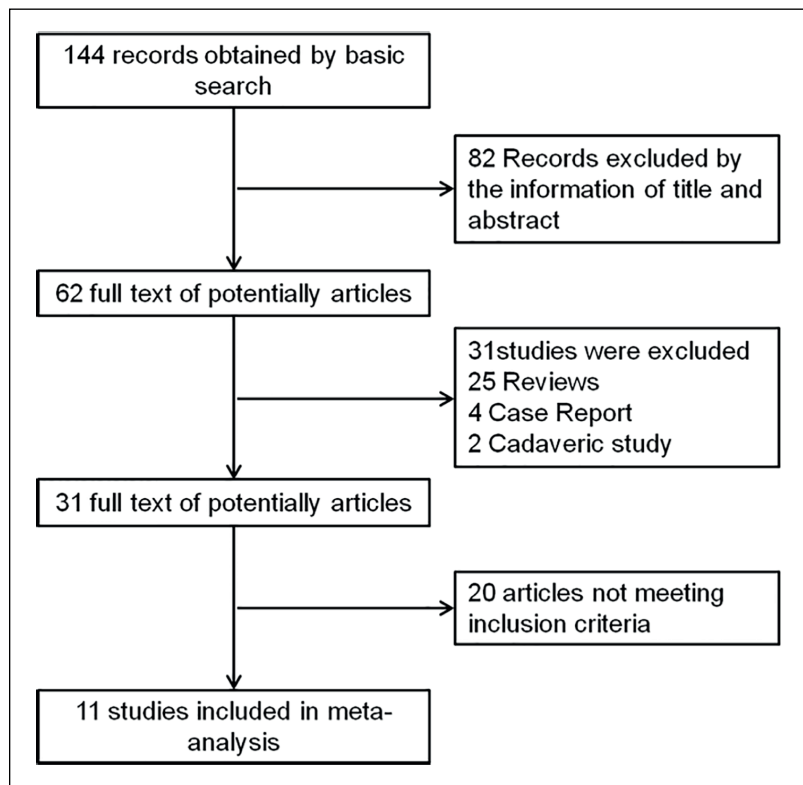


Figure 1. Flow diagram of the selection process.

All of these patients had been diagnosed with thoracolumbar fracture without neurological compromise via X-rays, computed tomography (CT) scans and magnetic resonance imaging (MRI)^{10-13,17-23}. The overall baseline characteristics of the included studies are shown in Table I.

The included articles were scored using the Cowley criteria (Table I). The Cowley scores of these 11 comparative studies ranged from 11 to 13 out of a possible 17. Therefore, the included studies were considered to be of high methodological quality.

Table I. Main characteristics of these studies included in this meta-analysis.

	Year	Country of origin	Minimally/Open				Quality assessment
			Case number	Mean age (years)	Male (%)	Mean follow-up (month)	
Wild et al ¹⁰	2007	Germany	10/11	49.1/33.5	90.00/63.64	67.9/67.9	13
Huang et al ¹⁷	2008	China	30/30	37.6/35.2	56.67/60.00	24/24	12
Tian et al ¹¹	2011	China	47/50	46/42	65.96/66.00	12/12	13
Ma et al ¹⁸	2012	China	24/20	39.8/37.8	62.50/70.00	16.4/13.6	13
Jiang et al ¹⁹	2012	China	31/30	44.4/41.3	67.74/66.67	58.3/59.0	13
Dong et al ¹²	2013	China	18/21	37.6/35.1	72.22/57.14	15.2/19.0	12
Lee et al ²¹	2013	Korea	32/27	45.6/48.2	62.50/70.37	30.2/39.7	12
Grossbach et al ²⁰	2013	USA	11/27	40.1/27.4	100.00/66.67	9/18.5	12
Vanek et al ²²	2014	UK	18/17	39.4/45.6	77.78/82.35	16/16	11
Wang et al ²³	2016	China	22/39	46/41.3	77.27/64.10	22.6/21.1	13
Lyu et al ¹³	2016	China	30/30	45.8/43.7	50.00/40.00	17.7/17.7	11

Note: OS: optimum placed pedicle screw, RS: re-directionally correctly placed pedicle screw.

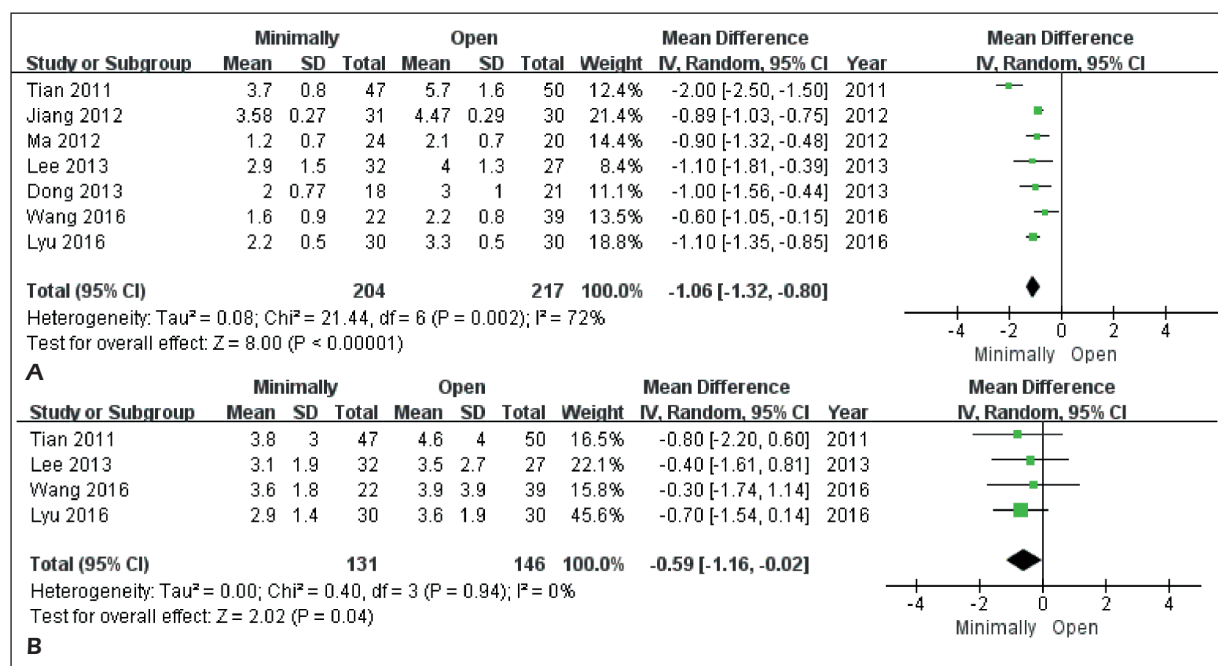


Figure 2. Schematic diagram of screw channels and image of placed pedicle screws. **A**, RS channel (the solid arrow in the left) and the OS channel (the dotted arrow in the right). **B**, RS was placed in the left pedicle, while OS was placed in the right pedicle.

Meta-Analysis Results

Clinical Outcomes

Postoperative VAS outcomes for back pain were reported in eight studies^{11-13,18,19,21-23}. One study provided means and *p*-values²², whereas the other seven studies reported adequate mean and standard deviation data^{11-13,18,19,21,23}. The WMD for VAS score was 1.06 lower for the minimal group than the open group (95% CI: -1.32 to -0.8, *p*<0.00001). Moderate heterogeneity existed among studies (*I*²=72%, *p*=0.002; Figure 2).

Radiological Outcomes

Data regarding correction loss were available for four studies, none of which reported significant differences between the minimal and open approaches^{11,13,21,23}. Overall, there was a significant difference in correction loss between these approaches (WMD = -0.59, 95% CI: -1.16 to 0.02, *p*=0.04). There was no evidence of significant heterogeneity among studies (*I*²=0%, *p*=0.94; Figure 2).

Blood Loss

Details regarding intraoperative blood loss were available for all included studies^{10-13,17-23}. A significant difference was found between the two groups (WMD = -218.10, 95% CI: -266.31 to -169.88, *p*<0.00001), with less blood loss associat-

ed with the minimal approach than the open approach. However, significant heterogeneity among studies was detected (*I*²=96%, *p*<0.00001; Figure 3). Chinese studies and other studies significantly differed with respect to blood loss data (*p*=0.02, *I*²=81.7%; Figure 3). However, both Chinese studies^{11-13,17-19,23} (WMD=-177.50, 95% CI: -229.75 to -125.25, *p*<0.00001) and other studies^{10,20-22} (WMD=-317.85, 95% CI: -423.17 to -212.42, *p*<0.00001) showed a statistically significant difference in blood loss between the two procedures.

Operative Time

Operative time was recorded in the 11 included studies^{10-13,17-23}, three of which reported that operative time was significantly lower for the minimal approach than the open approach^{19,21-22}. The WMD for operative time was 15.31 min shorter for the minimal group than the open group (95% CI: -24.73 to -5.88, *p*=0.001). There was high heterogeneity among studies (*I*²=90%, *p*<0.00001; Figure 3). However, evidence from Chinese studies^{11-13,17-19,23} showed no significant difference in operative time between the two types of procedures (WMD=-7.27, 95% CI: -15.22 to 0.68, *p*=0.07). Similar results were reported in studies performed outside China (WMD=-30.83, 95% CI: -65.11 to 3.45, *p*=0.08)^{10,20-22}. Subgroup analysis showed similar trends in Chinese studies and other studies (*p*=0.19; Figure 3).

Complications

Eight studies reported complications associated with surgery^{11,13,18-23}. Infection, thrombus, screw misplacement and breakage of the pedicle screw were observed. The overall complication rates in the minimal and open groups did not significantly differ (OR 0.78, 95% CI: 0.39 to 1.55, $p=0.48$). There was no evidence of significant

heterogeneity among studies ($I^2 = 0\%$, $p=0.54$; Figure 4). No significant difference in complication rates between the two types of procedures was found either in studies originating in China (OR 1.12, 95% CI: 0.47 to 2.66, $p=0.8$)^{11,13,18-19,23} or in other included studies (OR 0.4, 95% CI: 0.12 to 1.36, $p=0.14$)²⁰⁻²². Similar trends were observed in the two subgroups ($p=0.18$; Figure 4).

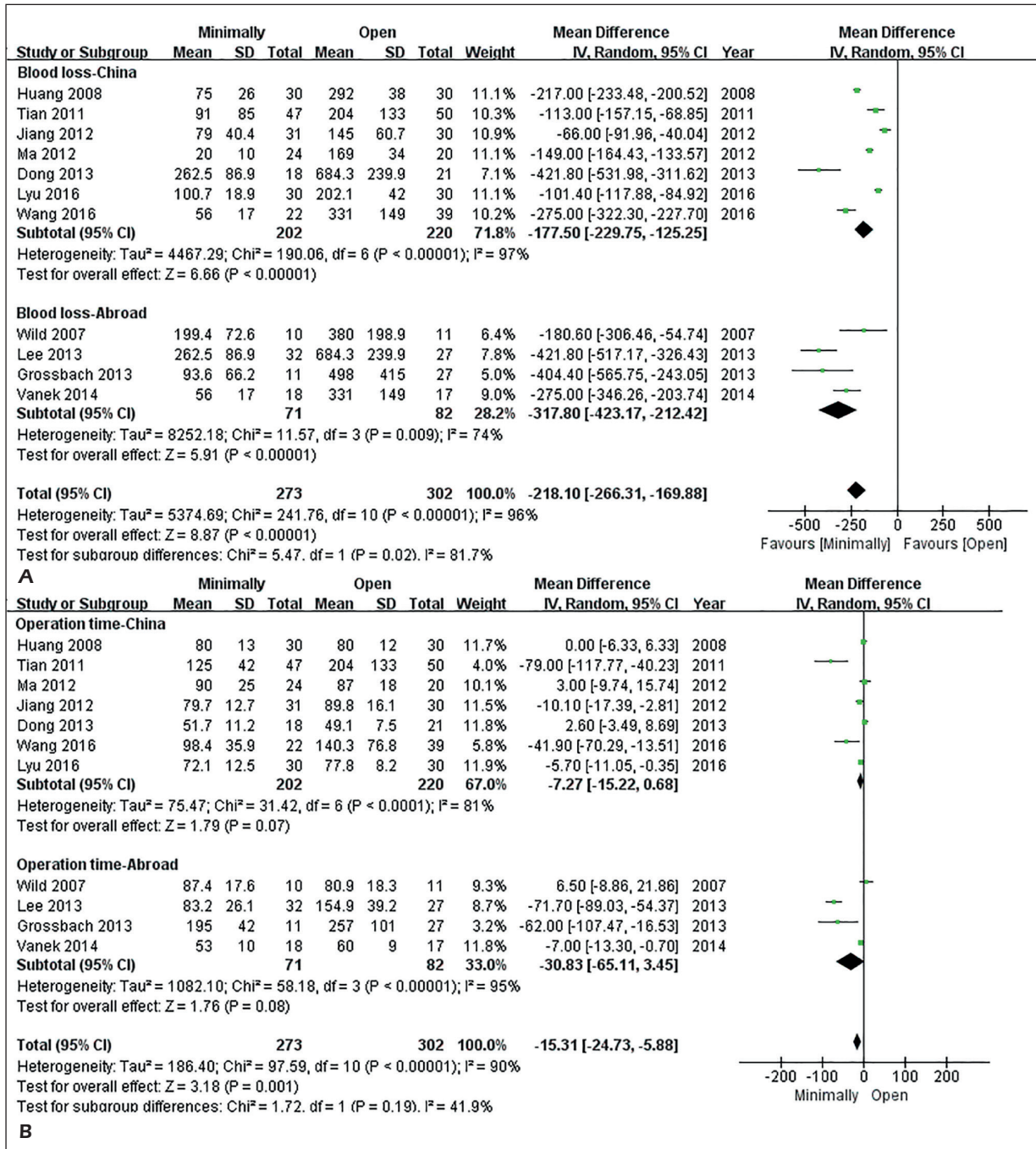


Figure 3. Forest plot illustrating postoperative blood loss (A) and operative time (B) of minimally and open approach.

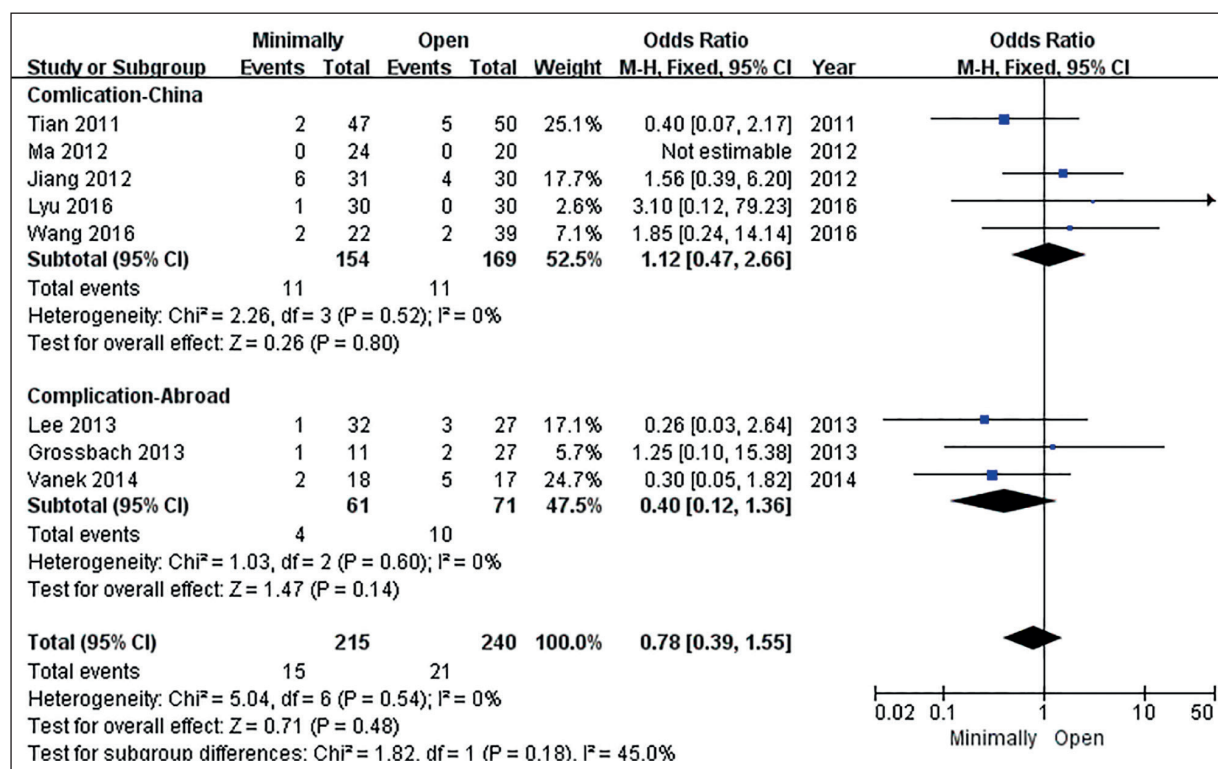


Figure 4. Forest plot illustrating complication rate of minimally and open approach.

Publication Bias and Sensitivity Analysis

Sensitivity analysis was conducted by reanalyzing the data after the sequential omission of individual studies. Significant funnel plot asymmetry was observed for blood loss, operative time, and postoperative VAS outcomes (Figures 2 and 3). This finding indicated that there was significant publication bias among the studies included in this meta-analysis.

Discussion

The question of whether percutaneous screw fixation or open screw fixation is a better treatment for thoracolumbar fracture without neurological deficits remains controversial. Evidence from this updated meta-analysis, which was based on 11 epidemiological studies of high methodological quality, indicated that relative to the open approach, the minimal approach resulted in a lower VAS score, less correction loss, shorter operative time and less blood loss. However, high heterogeneity existed among the included studies. A significant difference was observed between Chinese studies and other studies with respect to blood loss. Complication rates for

the two types of procedures did not significantly differ. Because of its particular anatomical features, the thoracolumbar region has the highest incidence of spinal fractures²⁴. Although open posterior instrumented spinal procedures cause extensive damage to soft tissue that inevitably results in a high incidence of syndromes associated with failed back surgery, such procedures have been widely accepted approaches for managing various types of thoracolumbar fractures²⁵. In recent decades, there has been a clear trend toward minimizing soft tissue injury during spinal surgery. Percutaneous screw fixation has been used to treat thoracolumbar fractures²⁶. However, percutaneous screw fixation and open screw fixation treatments for thoracolumbar fractures, particularly those without neurologic deficits, remain controversial. The results of our research address previously reported advantages of percutaneous pedicle fixation compared to the open approach. Reductions in blood loss due to the use of a minimal approach have been demonstrated in many domains of surgery^{27,28}. Although high heterogeneity among studies was detected, our findings are consistent with these observations. This phenomenon may be associated with damage to paraspinal muscles in the open approach²⁹. Publication bias is a possible

reason for the statistically significant difference that we observed between Chinese studies and other studies with respect to blood loss. Percutaneous screw insertion is sometimes regarded as a more technically demanding and time-consuming technique than the standard open technique³⁰. Based on our analysis of the 11 included studies, we observed that shorter operative time was required in the minimal group than in the open group. Thus, we do not agree with the perception that percutaneous screw insertion is more time-consuming than open screw insertion. However, there was no significant difference between the minimal and open approaches in either subgroup (Chinese studies and other studies). The minimal technique requires a certain level of experience. Unnecessary damage to the paraspinal muscles and direct access to the screw entry points may lead to shorter surgical durations¹². However, we require additional clinical data to support this conclusion. Low complication rates were observed in both groups, and complications were mostly limited to screw misplacement and infection.

Our study found lower postoperative VAS scores in the minimal group than in the open group. The extent of paraspinal muscle dissection might play a prominent role in early clinical outcomes. A significant difference in correction loss between the two approaches was shown in our study. A possible reason for this result is that the minimal approach avoided damaging soft tissue and thereby preserved the integrity of ligament structures and reduced correction loss. Additionally, in our study, the two tested approaches did not significantly differ with respect to complication rate. This result suggested that although the minimal technique has a long learning curve and is associated with a higher rate of complications during early application, this approach could reach a similar accuracy of screw placement as the open approach with the assistance of radiography equipment^{31,32}.

For spinal surgeries, safety and efficacy should be paramount goals in developing better techniques. A percutaneous approach might be a satisfactory choice. However, more randomized controlled studies are needed to support this conclusion.

Similar to other analyses, our study had certain limitations. First, relatively few high-quality randomized controlled trials were included, and such trials are increasingly important in the evaluation of surgical treatments. Furthermore, certain subgroup analyses involved relatively small samples. When continuous outcomes were pooled,

statistical heterogeneity was evident; this finding might be explained by differences in study design and quality and diverse technical specifications. A further limitation is that clinical outcome data were sometimes incomplete. Finally, a meta-analysis is inherently simply a statistical test that is subject to many methodological restrictions and does not allow for the control of all relevant factors. Despite the aforementioned weaknesses, our meta-analysis still has academic value.

Conclusions

The evidence showed that relative to open pedicle screw fixation, the minimal approach resulted in less blood loss, shorter operative times and lower postoperative VAS scores. With respect to complication rate, the two types of fixation procedures did not significantly differ. In addition, minimal pedicle screw fixation was associated with less correction loss than the open approach.

Conflict of Interests:

The authors declare that they have no competing interests.

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