ACCURACY AND POSTOPERATIVE ASSESSMENT OF PEDICLE SCREW PLACEMENT IN SCOLIOSIS SURGERY WITH COMPUTER-ASSISTED NAVIGATION: A META-ANALYSIS

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INTRODUCTION

The use of pedicle screw in scoliosis has been more and more common in decades, and has proven to be reliable and effective. Many studies reported that pedicle screw instrumentation could offer a greater curve correction than hook instrumentation [1,2]. Meanwhile, accurate placement of pedicle screws in scoliosis patients also offers a greater challenge for spine surgeon than normal thoracic and lumbar surgery, due to the severe deformity of scoliosis patients. According to former studies, malposition of thoracic pedicle screws is the most commonly reported complication of scoliosis surgery [3]. And even minor cortex or pedicle violation could lead to severe complication such as neurologic or vascular injury [4].

With the advantages of obtaining intraoperative real-time images, computer-assisted navigation technique has been thought to be promising and mature in spine surgery currently, especially in high-risk area like cervical spine or for patients with spine deformity [5]. Thus, computer-assisted navigation technique may help improving the accuracy reducing complication rate of pedicle screw placement for scoliosis patients. However, there are still many controversies about the indications of this technology. Previous studies had different ideas about whether navigation technique could improve the accuracy of thoracic pedicle screw placement. Kosmopoulos and colleagues concluded that no advantage in the use of navigation was found in thoracic levels for both the in vivo and cadaveric populations [6]. While Tang and colleagues concluded that accuracy of pedicle screw placement were significantly increased when navigation techniques were used in comparison to conventional techniques [7]. Thus, this meta-analysis of the published researches was conducted concentrating on accuracy of pedicle screw placement and postoperative assessment in scoliosis patients using computer-assisted navigation technique.

MATERIALS AND METHODS

Inclusion criteria Studies fulfilling the following criteria were included for meta-analysis: (1) the patients in the studies needed to be idiopathic or congenital scoliosis or scoliokyphosis. (2) The report needed to be a comparative clinical study including randomized controlled trials (RCTs) or retrospective studies. Case reports, reviews and conference reports were excluded. (3) The methods used to insert pedicle screws needed to be navigation technique compared to conventional technique. (4)

The studies needed to be in vivo. Cadaveric, model and animal studies were excluded. (5) The postoperative screw evaluation in the study needed to be performed using CT scan.

Search strategy The online databases of PubMed, Cochrane, Web of Science (1995 to September, 2014) were searched with the following search terms: (“scoliosis”) and ((“navigation”) or (“Stereotaxic Techniques”) or (“Stereotactic”) or (“Surgery, Computer-Assisted”) or (“computer assisted”) or (“assistance”) or (“aided”)) and ((“Bone Screw”) or (“screw”) or (“Pedicle”) or (“Placement”) or (“Perforation”) or (“Fusion”) or (“Insertion”) or (“Accuracy”)).

Screening and data extraction Two of the authors (CZ and YA) screened the titles and abstracts from search result independently to identify all potential citations. Disagreements were discussed until a consensus was reached.

We extracted relevant data on study design, patient characteristics, pedicle screw placement assessment and other information about surgeries (surgery time, Cobb’s angle correction rate, navigation methods) from the original papers.

Pedicle perforation and malposition rate was summarized using odds risk (OR) and 95% confidence intervals (CIs). The level of significance was set at $P<0.05$. Heterogeneity was evaluated by using the χ^2 test. A value of $P<0.1$ and $I^2>50\%$ was considered to be significant for heterogeneity. Fixed-effect models were used unless statistical heterogeneity was significant, in which case a random-effects model or sub-group analysis was used. Publication bias was assessed using examining funnel plots, Begg's test and Egger's test based on perforation rate and malposition rate. Analysis was performed using the statistical software Stata Version 12.0 (StataCorp, USA).

RESULTS

359 potentially papers were obtained after screening. And 8 papers [8-15] met all of the inclusion criteria of study design. One of them was RCT [11], and others are retrospective comparative studies [8-10,12-15]. 321 patients and 3821 screws were included in the 8 studies. 1920 screws were inserted using navigation techniques, and 1901 screws were inserted in conventional methods. The summary of these studies was shown in Table 1. The quality of reports were assessed using the Newcastle-Ottawa Scale (NOS) if the study was nonrandomized retrospective [16], and using Jadad Score if was RCT [17].

Author and year	Type of study and class of evidence	Patients
Abe/2011	Retrospective comparative study (III)	N=30 Nav n=15/Con n=15

Cui/2012	Retrospective comparative study (III)	N=59 Nav n=28/Con n=31
Kotani/2007	Retrospective comparative study (III)	N=45 Nav n=20/Con n=25
Rajasekaran/2007	Randomized controlled trial (I)	N=33 Nav n=17/Con n=16
Sakai/2008	Retrospective comparative study (III)	N=40 Nav n=20/Con n=20
Shi/2012	Retrospective comparative study (III)	N=46 Nav n=21/Con n=25
Sun/2013	Retrospective comparative study (III)	N=26 Nav n=13/Con n=13
Ughwanogho/2012	Retrospective comparative study (III)	N=42 Nav n=29/Con n=13

Table 1. Characteristics of included studies
* The Newcastle-Ottawa Scale (NOS); ** Jadad Score for RCTs.

Five papers [8,9,11-13] defined the accuracy of screw placement in grade 0 (no perforation), I (pedicle breach <2 mm), II (pedicle breach 2-4 mm), III (pedicle breach>4 mm). One paper [10] only published number of screws penetrated. And two papers [14,15] defined the accuracy of screw placement using 1/4 diameter of the screw as the criteria. A screw with more than 2 mm of pedicle breach (grade 2&3) was considered malpositioned, according to the description by Modi [18]. Thus, in this study, the perforation rate was defined as the number of pedicle breach>0 mm/total number of screws, and the malposition rate was defined as the number of pedicle breach> 2mm/total number of screws. The summary of screw number and criteria was shown in Table 2.

Author and year		Number of screws and creteria			
Abe/2011	N=503	≤0 mm	<2 mm	2-4 mm	>4 mm
	Nav:243	142	92	8	1
	Con:260	131	104	22	3
Cui/2012	N=1040	≤0 mm	<2 mm	2-4 mm	>4 mm
	Nav:483	458	16	9	0
	Con:557	498	30	29	0
Kotani/2007	N=138	≤0 mm	>0 mm		
	Nav:57	56	1		
	Con:81	72	9		
Rajasekaran/2007	N=478	≤0 mm	<2 mm	2-4 mm	>4 mm
	Nav:242	228	3	4	7
	Con:236	144	23	32	37
Sakai/2008	N=478	≤0 mm	<2 mm	2-4 mm	>4 mm

	Nav:264	205	29	27	3
	Con:214	115	39	17	43
Shi/2012	N=581	≤0 mm	<2 mm	2-4 mm	>4 mm
	Nav:273	255	15	3	0
	Con:25	258	27	20	3
Sun/2013	N=118	≤0 mm	≤1/4 D	>1/4 D	
	Nav:58	52	6	0	
	Con:60	51	5	4	
Ughwanogho/2012	N=485	≤0 mm	≤1/4 D	>1/4 D	
	Nav:300	222	69	9	
	Con:185	77	91	17	

Table 2. Grade of screws of included studies

ANALYSIS

Meta-analysis for accuracy of pedicle screw placement

Eight papers [8-15] reported the perforation rate of pedicle screw placement (Figure 1). Meta-analysis revealed a significant difference between two groups (OR: 0.33, 95%CI: 0.21, 0.53, I^2=82.5%, *p*<0.001).

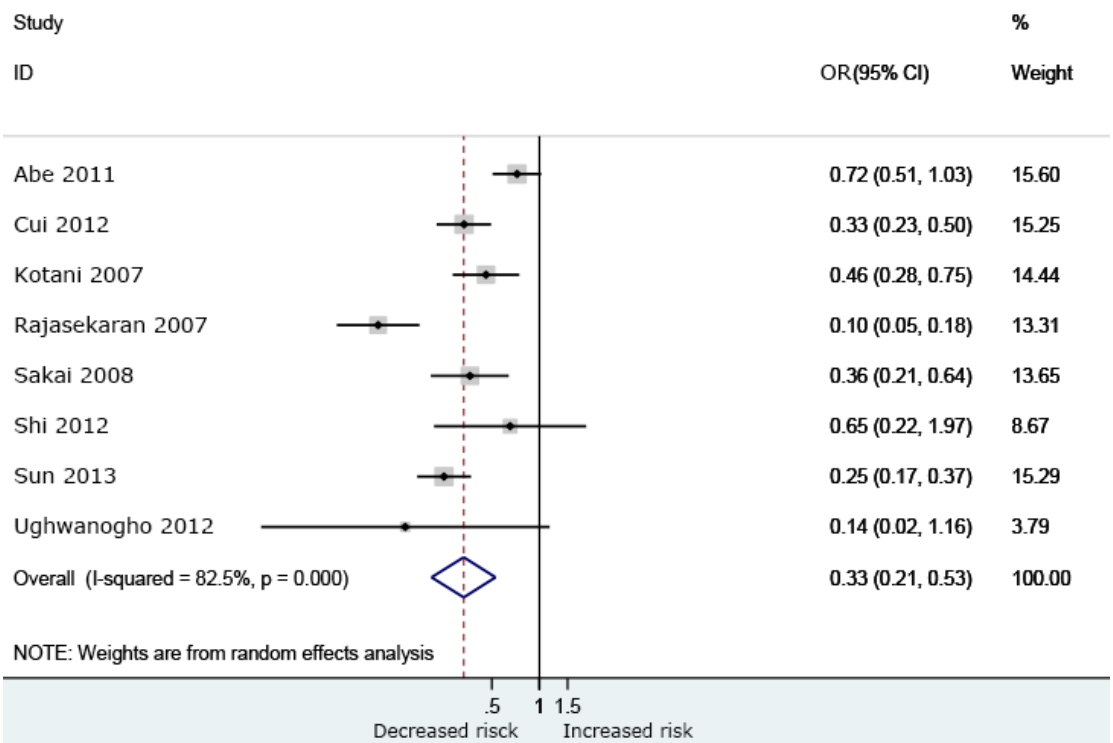

Figure 1. Forest plot comparing perforation rate with and without navigation

Five papers [8,9,11-13] reported the malposition rate of pedicle screw placement (Figure 2). Meta-analysis revealed a significant difference between two groups (OR: 0.24, 95%CI: 0.15, 0.40, I^2=55.0%, *p*=0.064).

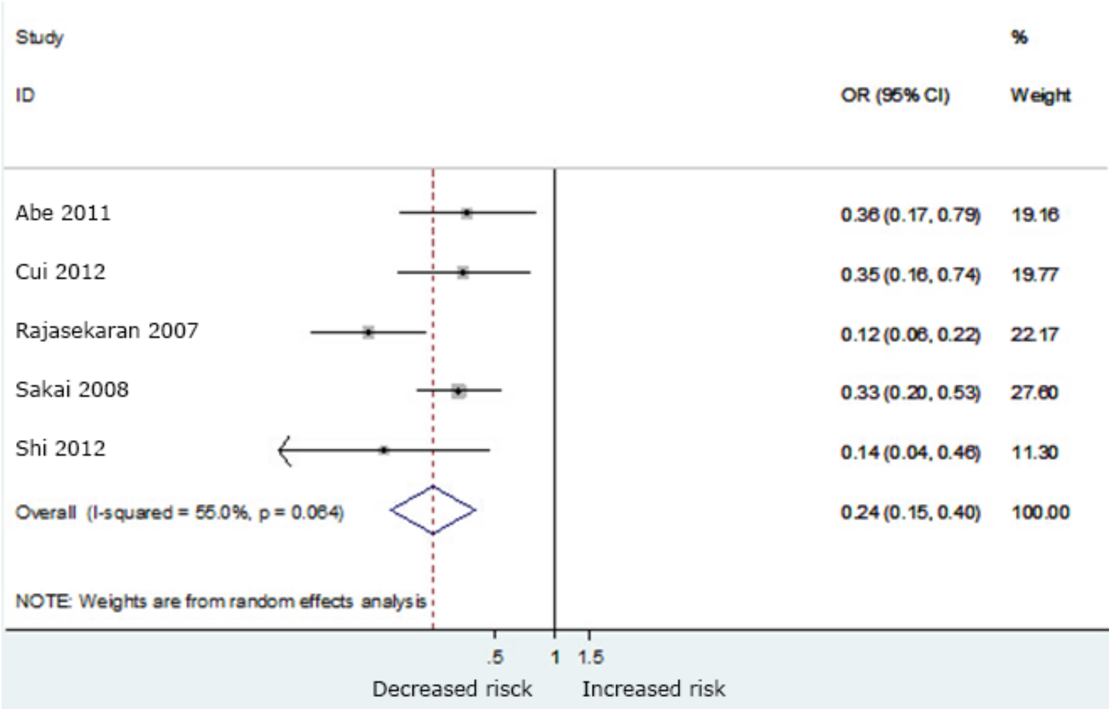

Figure 2. Forest plot comparing malposition rate with and without navigation

Meta-analysis for operation time

Three papers [8,12,14] reported the average operation time in both groups (Figure 3). Meta-analysis revealed no significant difference between two groups (WMD: 2.26, 95%CI: -23.20, 27.72, z=0.17, P=0.862, I^2=0.0%, *p*=0.759).

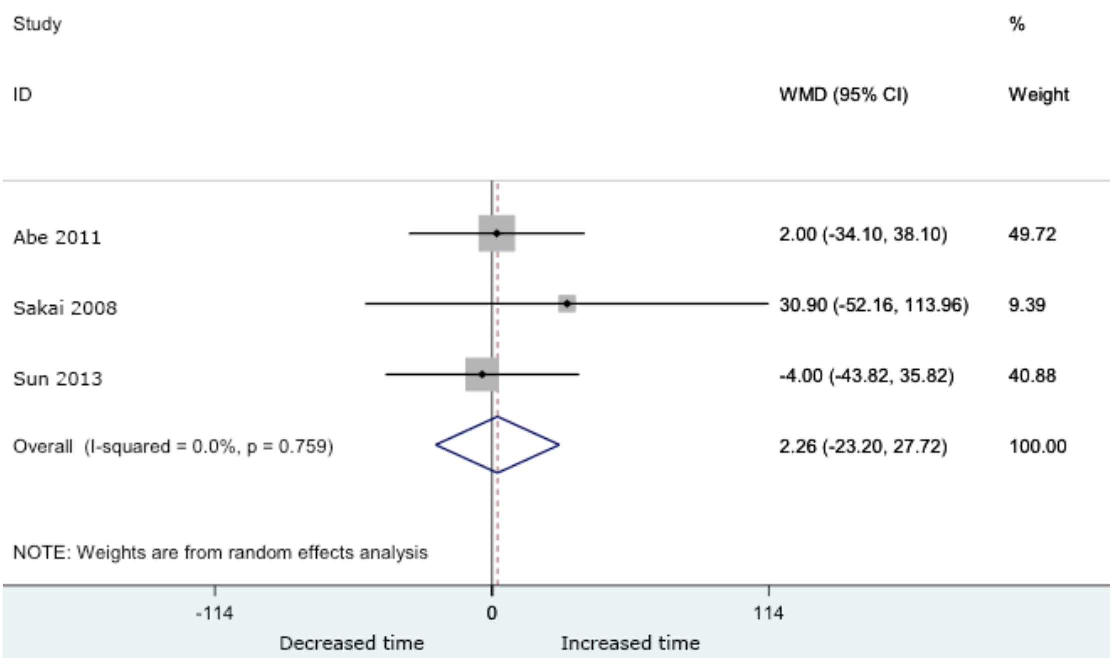

Figure 3. Forest plot comparing operation time with and without navigation

Two papers [9,11] reported the average screw insertion time in both groups (Figure 4). Meta-analysis revealed a significant difference between two groups (WMD: -1.86, 95%CI: -2.60, -1.11, z=4.89, P<0.001, I^2=98.3%, p<0.001).

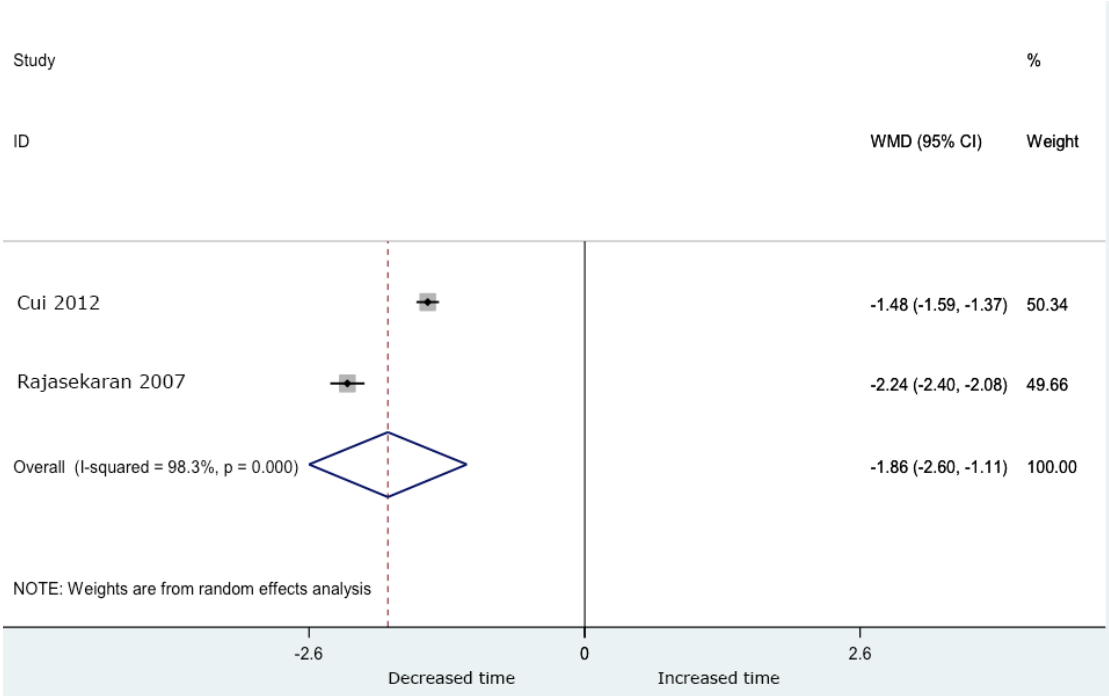

Figure 4. Forest plot comparing screw insertion time with and without navigation

Meta-analysis for correction rate

Three papers [9,12,14] reported the average scoliosis correction rate in both groups (Figure 5). Meta-analysis revealed no significant difference between two groups (WMD: -1.56, 95%CI: -6.68, 3.55, z=0.60, P=0.549, I^2=0.0%, p=0.747).

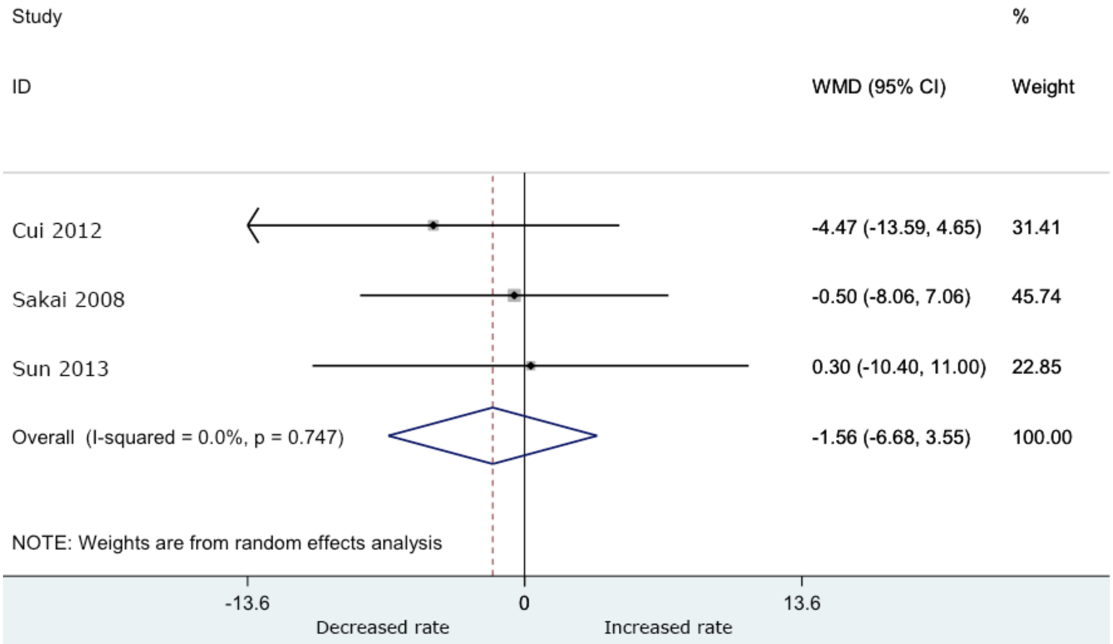

Figure 5. Forest plot comparing correction rate with and without navigation

Publication bias

The graphical funnel plot based on pedicle screw perforation rate suggested no publication bias. Begg's test based on perforation rate suggested no publication bias (z=0.37, Pr=0.711). And Egger's test based on perforation rate suggested no publication bias (t=-0.66, p=0.533).

Sensitivity analysis and subgroup analysis

Subgroups were defined by different navigation techniques, area of patients, year of publication of studies, and average ages of patients. Heterogeneity test and meta-regression were performed among subgroups. Six studies [8-10,12-14] had patients from South-east Asia (China and Japan), and two studies [11,15] were performed on patients from other countries (U.S.A. and India). OR of perforation rate in South-east Asia subgroup (OR: 0.46, 95%CI: 0.32, 0.65) was significantly higher than another subgroup (OR: 0.16, 95%CI: 0.06, 0.41) (p=0.006). Three papers [10-12] were reported before 2010, and five papers [8,9,13-15] were reported from 2010 to 2014. OR of perforation rate in earlier published subgroup (OR: 0.18, 95%CI: 0.06, 0.50) was significantly lower than current published subgroup (OR: 0.44, 95%CI: 0.28, 0.70) (p=0.049). No significant difference was found between subgroups using different navigation techniques (p=0.283). And no significant difference was found between subgroups with different average ages of patients (p=0.262). The results were shown in Table 3.

One study [14] reported congenital scoliosis patients only, while other studies reported idiopathic scoliosis patients or patients with either of idiopathic or congenital scoliosis.

A sensitivity analysis was performed removing the paper with only congenital scoliosis patients, and result was identical with main result (OR: 0.31, 95CI%: 0.19, 0.51).

Subgroup analyses	No. of studies	OR (95% CI)	Heterogeneity test		Meta-regression
			p value	I^2 (%)‡	(p value)
Navigation techniques					
ISO-C or Intraop CT	6	0.30(0.19-0.46)	0.001	75.3	0.283
Preop CT	2	0.45(0.11-1.91)	0.135	55.3	
Area					
South East Asia	6	0.46 (0.32-0.65)	0.053	54.2	0.006
Not South East Asia	2	0.16 (0.06-0.41)	0.009	85.5	
Year of publication					
Before 2010	3	0.18(0.06-0.50)	0.003	83.0	0.049
2010-2014	5	0.44(0.28-0.70)	0.002	75.9	
Age					
≤17 yr	6	0.39(0.25-0.61)	0.002	73.5	0.262
>17 yr	2	0.21(0.05-0.99)	<0.001	93.7	

Table 3. Subgroup analyses of OR for patients from navigation group compared with non-navigation

5. Discussion

The surgical instrumentation for scoliosis has been changing during few decades. The use of pedicle screw in scoliosis has been more and more common, and has been proven to be more reliable and effective than hook [1,2]. However, the popularity of using pedicle screw also brings more challenge to spine surgeons, since the malposition of screw could cause disastrous complications. Even minor cortex or pedicle violation in scoliosis patients could lead to severe complication such as neurologic or vascular injury [4]. Since Amiot and colleagues [19] first reported pedicle screw fixation using a computer-assisted navigation system in 1995, navigation technique has been applied in various kind of spine surgery worldwide. Because computer-assisted navigation system could help surgeons obtaining intraoperative real-time images and showing three-dimensional anatomic construction, it takes a great advantage in complicated spine surgery, especially in patients with severe deformity such as scoliosis. However, there was not enough high quality studies concentrating on screw insertion accuracy in scoliosis patients aided with navigation techniques. Only one RCT paper [11] was found discussed the use of navigation compared with conventional ways. And deficiencies still remain in the study, such as no discussion about correction rate was mentioned in the paper, and number of patients was still limited (17 in navigation group, 16 in control group).

This study indicates that computer-assisted navigation techniques could increase the accuracy of pedicle screw placement significantly compared to conventional method, while the correction effect of the operation between two methods had no difference. And it seems to have no difference in accuracy among different navigation systems (such as preoperative CT, intraoperative CT and ISO-C navigation) according to the result. It is different with result of former studies, which reported intraoperative CT as the highest accuracy [9]. But the limited number (only 4 studies using intraoperative CT navigation) of studies included in this meta-analysis could be the reason of this diversity.

Heterogeneity was identified among the reported perforation rate in different studies. This heterogeneity could be resulting from different patient demographic characteristics, diversity of surgeons' skills, dimensions of screw and pedicle. By subgroup analysis, it was found that patients' country and publish year of studies affected the result, but it could be caused by composite factors of technical issues and racial factors.

The term of "safe zone" has been mentioned a lot in former studies, but there is no specific proof that any extent of screw perforation is acceptable. Some studies reported that a perforation less than 2 mm is relatively acceptable [18]. This study showed that reduced severe perforation (>2 mm) rate by using navigation technique (OR=0.24) was higher than perforation more than 0 mm (OR=0.33).

Another important finding of this review was that the average operation time between navigation and conventional surgery showed no difference, but the average screw insertion time using navigation technique was significantly shorter than using conventional method. It indicated that navigation technique could actually improve the speed of operation if the procedure preparation and registration could be more fluently and simplified in the future.

The selection of inclusion criteria in this study was organized cautiously. All of studies were prospective or retrospective in vivo studies. Because according to former analysis of screw placement accuracy, the results of cadaveric and in vitro studies were significantly different to those of clinical trials [20,21]. And only studies using postoperative CT to evaluate screw insertion accuracy were accepted, because CT could provide the most exact position of screws compared to X-ray.

Some limitations still remain in this analysis. First, the number of studies included in this analysis was limited, especially only one prospective study in this area was published. Second, we didn't discuss the direction of screw violation. Although the postoperative symptom could be significantly different between medially and laterally perforated screws, the quantity of published studies discussed specific direction of perforated screws were too limited to perform meta-analysis. Third, the heterogeneity was remarkable among studies even we excluded in vitro studies, and heterogeneity was still great in subgroups. It brought some limits to the analysis.

In conclusion, this meta-analysis confirmed that navigation system does indeed improve the accuracy of pedicle screw placement in scoliosis surgery, without prolong the surgery time or decrease the deformity correction effect. And the increased safety by using navigation techniques may not only be attribute to a greater accuracy, but also less neurovascular complications.

CONFLICT OF INTEREST

The authors have no conflict of interest to declare.

REFERENCES

1. Liljenqvist U R, Halm H F, Link T M. Pedicle Screw Instrumentation of the Thoracic Spine in Idiopathic Scoliosis[J]. Spine, 1997, 22(19).
2. Kim Y J, Lenke L G, Cho S K, et al. Comparative Analysis of Pedicle Screw Versus Hook Instrumentation in Posterior Spinal Fusion of Adolescent Idiopathic Scoliosis[J]. Spine, 2004, 29(18):2040-2048.
3. Hicks J M, Singla A M, Shen F H, et al. Complications of Pedicle Screw Fixation in Scoliosis Surgery: A Systematic Review[J]. Spine, 2010, 35(11).
4. Rajasekaran, S., et al. (2007). "Randomized clinical study to compare the accuracy of navigated and non-navigated thoracic pedicle screws in deformity correction surgeries." Spine (Phila Pa 1976) 32(2): E56-64.
5. Tian W, Lang Z. Placement of pedicle screws using three-dimensional fluoroscopy-based navigation in lumbar vertebrae with axial rotation[J]. European Spine Journal, 2010, 19(11):1928-1935.
6. Kosmopoulos V P, Schizas C M P F. Pedicle Screw Placement Accuracy: A Meta-analysis[J]. Spine, 2007, 32(3).
7. Tang J, Zhu Z, Sui T. Position and complications of pedicle screw insertion with or without image-navigation techniques in the thoracolumbar spine:a meta-analysis of comparative studies[J]. The Journal of Biomedical Research, 2014, (3).
8. Abe Y, Ito M, Abumi K, et al. A novel cost-effective computer-assisted imaging technology for accurate placement of thoracic pedicle screws: Technical note[J]. Journal of Neurosurgery: Spine, 2011, 15(5): 479-485.
9. Cui G, Wang Y, Kao T H, et al. Application of intraoperative computed tomography with or without navigation system in surgical correction of spinal deformity: a preliminary result of 59 consecutive human cases[J]. Spine, 2012, 37(10): 891-900.
10. Kotani Y, Abumi K, Ito M, et al. Accuracy analysis of pedicle screw placement in posterior scoliosis surgery: comparison between conventional fluoroscopic and

computer-assisted technique[J]. Spine, 2007, 32(14): 1543-1550.

11. Rajasekaran S, Vidyadhara S, Ramesh P, et al. Randomized clinical study to compare the accuracy of navigated and non-navigated thoracic pedicle screws in deformity correction surgeries[J]. Spine, 2007, 32(2): E56-E64.
12. Sakai Y, Matsuyama Y, Nakamura H, et al. Segmental pedicle screwing for idiopathic scoliosis using computer-assisted surgery[J]. Journal of spinal disorders & techniques, 2008, 21(3): 181-186.
13. Shi X, Zhang Y, Zhang X, et al. Application of intraoperative CT navigation in posterior thoracic pedicle screw placement for scoliosis patients[J]. Chinese journal of reparative and reconstructive surgery, 2012, 26(12): 1415-1419.
14. Sun L, Song Y, Gong Q, et al. Short-term effectiveness of spinal navigation with intra-operative three-dimensional-imaging modality in pedicle screw fixation for congenital scoliosis[J]. Chinese journal of reparative and reconstructive surgery, 2013, 27(2): 129-134.
15. Ughwanogho E, Patel N M, Baldwin K D, et al. Computed Tomography–Guided Navigation of Thoracic Pedicle Screws for Adolescent Idiopathic Scoliosis Results in More Accurate Placement and Less Screw Removal[J]. Spine, 2012, 37(8): E473-E478.
16. Wells G, Shea B, O'Connell D, Peterson J, Welch V, Losos M, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. Available from: URL: http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp [cited 2011 Oct 6].
17. Jadad AR, Moore RA, Carroll D, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary? Control Clin Trials 1996; 17:1–12
18. Modi H, Suh SW, Song HR, Yang JH: Accuracy of thoracic pedicle screw placement in scoliosis using the ideal pedicle entry point during the freehand technique. Int Orthop 33: 469–475, 2009
19. Amiot LP, Labelle H, DeGuise JA et al (1995) Computer-assisted pedicle screw fixation. A feasibility study. Spine 20(10):1208–1212
20. Verma R, Krishan S, Haendlmayer K, Mohsen A (2010) Functional outcome of computer-assisted spinal pedicle screw placement: a systematic review and meta-analysis of 23 studies including 5, 992 pedicle screws. Eur Spine J 19:370–375
21. Tian NF, Xu HZ (2009) Image-guided pedicle screw insertion accuracy: a meta-analysis. Int Orthop 33:895–903