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REVIEW ARTICLE





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KEYWORDS

Lumbar vertebrae; Meta-analysis; Screw fixation; Spinal fusion; Unilateral pedicle Summary A series of studies have been conducted to evaluate the effectiveness of unilateral versus bilateral pedicle screw fixation in lumbar spinal fusion, but there is still controversy about which one is more superior. We performed a meta-analysis to more accurately estimate the effectiveness of unilateral versus bilateral pedicle screw fixation in lumbar spinal fusion. Studies on the comparison between unilateral and bilateral pedicle screw fixation in lumbar spinal fusion were identified from PubMed, SpringerLink, China National Knowledge Infrastructure (CNKI), the Wanfang database and the China Biology Medical literature database (CBM) and related references were searched. The included trials were screened according to the criteria of inclusion and exclusion. The quality of included trials was evaluated. Data were extracted by two reviewers independently. RevMan 5.1.1 was used for data analysis. The fixed or random effect model was selected based on the heterogeneity test among studies evaluated using the I^2 statistic. A total of nine studies involving 567 patients were included in the analyses for the effectiveness of unilateral versus bilateral pedicle screw fixation in lumbar spinal fusion. Unilateral pedicle screw fixation was performed in 287 patients and bilateral pedicle screw fixation in 280 patients. The results of the meta-analysis indicated that statistically significant differences were observed between the two fixation procedures with regard to mean operation time and amount of bleeding. There were no differences in hospitalisation days, fusion rate, complication rate, and excellent and good rates. This meta-analysis suggested that both unilateral and bilateral pedicle screw fixation are effective in one or two segmental lumbar spinal fusion. In comparison with bilateral fixation, unilateral fixation can shorten the

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operation time, reduce the amount of bleeding, and reduce medical expenses. There were similar effects with regard to hospitalisation days, fusion rate, complication rate, and excellent and good rates.

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Introduction

Lumbar spinal fusion surgery for the treatment of instability and deformity is considered to be effective for some degenerative spine disorders, such as spondylolisthesis, spinal stenosis associated with deformities, or discogenic pain [1]. Posterior lumbar interbody fusion has the advantages of no external immobilisation, early ambulation, restoration of sagittal alignment and segment height, and improved fusion rate [2-5]. However, segmental rigidity increases and mobility decreases after fusion [6]. The increased stiffness of the fused motion segments not only reduces the bone mineral content in the vertebrae adjacent to the fusion [7,8], but also has a positive effect on the degeneration of the adjacent segments [8–10]. Therefore, this has led to the use of unilateral pedicle screw fixation, because of decreased stiffness of the implant. In 1992, Kabins et al. [11] reported that clinical results with unilateral variable screw placement instrumentation were nearly identical with those of bilateral instrumentation. A recent prospective, randomised study also reported that unilateral instrumentation for the treatment of degenerative lumbar spondylolisthesis was as effective as bilateral instrumentation, when performed in addition to one- or two-level posterolateral fusion [12]. To our knowledge, few data are available on the clinical efficacy of unilateral versus bilateral pedicle fixation in lumbar degenerative diseases. We performed this meta-analysis to evaluate the curative effect of unilateral and bilateral pedicle screw fixation in lumbar fusion surgery and to provide clinical evidence.

Materials and methods

Literature and search strategy

A computerised literature search was conducted for the relevant available studies published from seven databases including PubMed, Web of Science, ScienceDirect, SpringerLink, Cochrane Library, China National Knowledge Infrastructure (CNKI), the Wanfang database and the China Biology Medical literature database (CBM). The search strategy to identify all possible studies involved the use of combinations of the following keywords: "lumbar spinal fusion", "pedicle screw fixation", "unilateral", and "bilateral". The reference lists of review articles, clinical trials, and meta-analyses were also hand-searched for the collection of other relevant studies. If more than one article was published using the same case series, only the study with the largest sample size was selected. The literature search was updated on October 1, 2013.

Inclusion criteria

(1) Study type: a prospective or retrospective study of unilateral and bilateral pedicle screw fixation used in lumbar fusion operations (either domestic or international) which took place between January 1991 and October 2013; randomised controlled trials (RCTs) of more than two patients at baseline (RCT agreement), without language restrictions. (2) The object of study: sex (male or female) is not restricted and by physical examination and imaging (computed tomography or magnetic resonance imaging) for the diagnosis of lumbar degenerative disease with or without spondylolisthesis (first degree or second degree), regular conservative treatment is invalid. (3) Intervention: posterior lumbar decompression and interbody fusion and unilateral pedicle screw fixation as the experimental group; bilateral pedicle fixation as the control group. (4) The ending index: index including preoperative and postoperative visual analogue scale (VAS) score, function improvement, average operation time, the amount of bleeding, hospitalisation days, complications, excellent and good rates, and fusion rate.

Exclusion criteria

(1) Nondegenerative lumbar degenerative disease, infection, fracture, spinal tumour, bone tumour, osteoporosis, and other diseases; (2) patients with lumbar operation history; and (3) other interventions, such as the anterior posterior lumbar decompression operation, simple, and minimally invasive operation treatment methods.

Data extraction

Data were carefully extracted by two authors independently from each study based on the inclusion criteria mentioned above. If conflicting evaluations were encountered, an agreement was reached following a discussion; if agreement could not be reached, then a third author was consulted to resolve the debate. The following information was extracted from each study: (1) name of the first author; (2) year of publication; (3) numbers of cases; (4) sex and age of enrolled participants; and (5) the ending index.

Quality assessment of clinical trial reports

The three-item Jadad scale (Table 1) was used to assess the quality of clinical trial reports. Scale scores can range from zero to five points, with higher scores indicating better quality.

Table 1The three-item Jadad scale.								
Question	Response option							
(1) Was the study described as randomised?	'Yes or no'							
(2) Was the study described as double-blind?	'Yes or no'							
(3) Was there a description of withdrawals and dropouts? 'Yes or no'								
Scoring								
For each question, award one point for an affirmative response or zero p	oints for a negative response.							
Question 1								
Award a bonus point if the method of randomisation is appropriate (e.g.,	computer generated)							
Deduct one point if the method of randomisation is inappropriate								
Question 2								
Award a bonus point if the method of double-blinding is appropriate (e.g.	., identical placebo)							
Deduct one point if the method of double-blinding is inappropriate								

Statistical analysis

Data analysis was performed using RevMan version 5.1 (Cochrane, USA). Heterogeneity among studies was assessed using the I2 statistic. The combined estimate of measurement data and numeration data were estimated by

calculating pooled odds ratios (ORs) and confidence interval (CI), mean difference (MD) and 95% CI, respectively. The DerSimonian and Laird random effect model (REM) was used as the pooling method when I2 > 50%, otherwise, the Mantel-Haenszel fixed effect model (FEM) was considered to be the appropriate choice. Influential analysis was undertaken

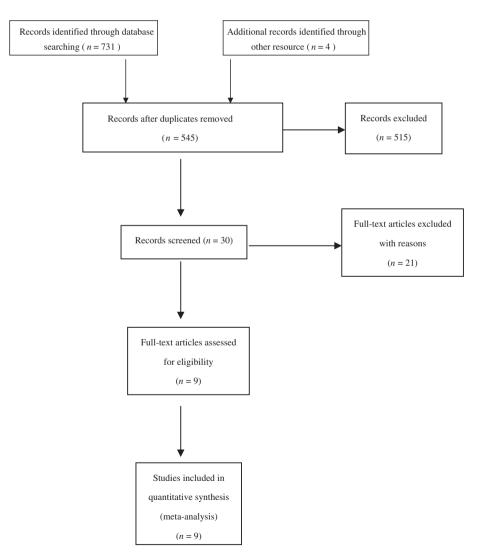


Figure 1 Flow chart of study selection based on the inclusion and exclusion criteria.

	Table 2	General	characteristics	of included	individual	studies.
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First author	Year	Cases [total (Uni/Bi)]		Sex (M/F)		age (y)	Main index
			Uni	Bi	Uni	Bi	
Kabins [11]	1992	36 (16/20)	8/8	9/11	52	48	AOT, AAB, FR
Suk [13]	2000	87 (47/40)	13/34	9/31	53	54.7	AOT, AAB, FR, HD,
							COM, SF-36, COS, EGR
Fernández-Fairen [12]	2007	82 (40/42)	16/24	15/27	60.8	61.4	AOT, AAB, FR, HD,
							COM, EGR, SF-36
Feng [14]	2011	40 (20/20)	12/8	10/10	53.75	53.2	AOT, AAB, HD,
							COM, COS, ODI, JOA, VAS
Aoki [15]	2012	50 (25/25)	8/17	12/13	66.2	65.6	AOT, AAB, FR, JOABPEQ, VAS
Xie [16]	2012	108 (56/52)	24/32	24/28	56.2	55	AOT, AAB, FR, HD,
							COM, VAS, ODI
Kai [17]	2013	68 (33/35)	14/19	10/25	59.4	55.7	AOT, AAB, FR, HD,
							COM, VAS, ODI, SF-36, COS
Zhao [18]	2010	53 (32/21)	20/12	13/8	52	50.5	AOT, AAB, HD
Wang [19]	2012	61 (28/33)	16/12	18/15	54.3	56.1	AOT, AAB, COS, FR,
							EGR, VAS, ODI

AAB = average amount of bleeding; AOT = average operation time; Bi = bilateral; COM = complications; COS = cost; EGR = excellent and good rate; F = female; FI = function improvement; FR = fusion rate; HD = hospitalisation days; JOA = Japanese Orthopedic Association scores; JOABPEQ = Japanese Orthopaedic Association Back Pain Evaluation Questionnaire; M = male; ODI = Oswestry Disability Index; SF = social function; Uni = unilateral; VAS = visual analogue scale score.

by removing an individual study each time to check whether any single study could bias the overall estimate. Probability <0.05 was judged to be significant, except for the I2 statistic.

quality assessment scale, nine studies were regarded as high quality literature (Table 3) and six studies as low quality literature. Thus, a total of nine studies were finally included in the meta-analysis (Table 2).

Results

Table 3

Characteristics of studies

Our systematic search identified 735 relevant publications. After removal of duplicate studies (n = 190) and screening of titles and abstracts, we retrieved 30 publications (Fig. 1). Of these, eight studies were excluded by reading the full-text. One study investigated if instrumentation (unilateral vs. bilateral fixation) has an effect on the rate of fusion cage migration, one study used a minimally invasive method, two studies were duplicates, one study was a meta-analyses, and another five studies were excluded for patients with previous lumbar operation history. Six studies lacked enough data for pooling. According to the Jadad

Quantitative data synthesis

Average operation time

Nine research studies reported the average operation time (Fig. 2). The research had statistically significant heterogeneity (p < 0.00001, $I^2 = 92\%$). REM was used as the pooling method. There was a significant difference between the unilateral and bilateral fixation methods in onelevel fusion (MD = -40.04, 95% CI = $-60.49 \sim -19.59$, p = 0.0001) and two-level fusion (MD = -34.62, 95%) $CI = -62.14 \sim -7.09, p = 0.01$).

Average amount of bleeding

Nine researches reported the average amount of bleeding (Fig. 3). The research had statistically significant

Jadad scores

Individual study	Randomised	Double-blind	Follow-up
Kabins [11]	Not clear	Not clear	Described
Suk [13]	Not clear	Not clear	Described

Quality assessment of included individual studies.

Kabins [11]	Not clear	Not clear	Described	3
Suk [13]	Not clear	Not clear	Described	3
Fernández-Fairen [12]	Appropriate	Appropriate	Described	5
Feng [14]	Appropriate	Appropriate	Described	5
Aoki [15]	Appropriate	Not clear	Described	4
Xie [16]	Appropriate	Not clear	Described	4
Kai Z [17]	Appropriate	Appropriate	Described	5
Zhao [18]	Not clear	Not clear	Described	3
Wang [19]	Not clear	Not clear	Described	3

	un	ilatera	I	bi	ateral			Mean Difference	Mean Diffe	erence
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% C	I IV, Random	n, 95% Cl
2.1.1 one level										
Ferndndez 2007	168	37	40	203	35	42	14.5%	-35.00 [-50.61, -19.39]	-	
Kabins MB 1992	291	40	16	275	35	20	12.8%	16.00 [-8.89, 40.89]		
Wang Bin 2012	141	31.2	28	223	24.8	33	14.7%	-82.00 [-96.32, -67.68]	•	
Xie Y 2012	129	30	56	168	29	52	15.1%	-39.00 [-50.13, -27.87]	•	
Yasuchika Aoki 2012	161	21	15	221	35	17	13.8%	-60.00 [-79.74, -40.26]	*	
ZhaoXD 2010	60	20	32	90	25	21	14.9%	-30.00 [-42.74, -17.26]	•	
Zhou-Feng 2011	106.8	23	20	113.2	29	20	14.4%	-6.40 [-22.62, 9.82]	. +.	
Subtotal (95% CI)			207			205	100.0%	-34.55 [-55.12, -13.97]	♦	
Heterogeneity: Tau ² = Fest for overall effect:				df = 6 (F	P < 0.0	0001);	l² = 92%			
2.1.2 two level										
	208	26	33	257	37	35	48.8%	-49.00 [-64.13, -33.87]	-	
Kai Z 2013	208 208.5		33 47			35 40	48.8% 51.2%	. , ,		
Kai Z 2013 Suk 2000								-20.90 [-33.42, -8.38]	•	
Kai Z 2013 Suk 2000 Subtotal (95% CI)	208.5	27.8	47 80	229.4	31.2	40 75	51.2% 100.0%	-20.90 [-33.42, -8.38]	•	
2.1.2 two level Kai Z 2013 Suk 2000 Subtotal (95% CI) Heterogeneity: Tau ² = Test for overall effect:	208.5 344.62; (27.8 Chi² =	47 80 7.87, d	229.4	31.2	40 75	51.2% 100.0%	-20.90 [-33.42, -8.38]	•	
Kai Z 2013 Suk 2000 Subtotal (95% CI) Heterogeneity: Tau ² =	208.5 344.62; (27.8 Chi² =	47 80 7.87, d	229.4	31.2	40 75	51.2% 100.0%	-20.90 [-33.42, -8.38]	•	
Kai Z 2013 Suk 2000 Subtotal (95% CI) Heterogeneity: Tau ² =	208.5 344.62; (27.8 Chi² =	47 80 7.87, d	229.4	31.2	40 75	51.2% 100.0%	-20.90 [-33.42, -8.38]	-500 -250 0	250

Test for subgroup differences: $Chi^2 = 0.00$, df = 1 (P = 1.00), $I^2 = 0\%$

Figure 2 Forest plot for meta-analysis of average operation time between unilateral and bilateral fixation methods.

heterogeneity (p < 0.00001, I2 = 98%). REM was used as the pooling method. There was a statistically significant difference between the unilateral and bilateral fixation methods (MD = -106.47, 95% CI = $-173.88 \sim -39.82$, p = 0.002).

Hospitalisation days

Five studies reported the number of hospitalisation days (Fig. 4). The research had significant statistically heterogeneity (p < 0.1, I2 = 97%); we found that sources of heterogeneity may have been derived from Fernández-Fairen [12]. Heterogeneity decreased significantly after excluding Fernández-Fairen [12] (p < 0.1, I2 = 85%). REM was used as the pooling method. MD was applied to analysis of the overall effect. There was a statistically significant difference between the unilateral and bilateral fixation methods (MD = -1.65, 95% CI = $-3.03 \sim -0.24$, p = 0.02).

Excellent and good rates

Three studies reported excellent and good rates (Fig. 5). The research had no significant statistically heterogeneity (p > 0.1, 12 = 0%). FEM was used as the pooling method. OR was applied to analysis of the overall effect. There was no statistically significant difference between the unilateral and bilateral fixation methods (OR = 1.18, 95% CI = 0.58 - 2.43, p = 0.65).

Fusion rate

Seven studies reported the fusion rate (Fig. 6). The research had no significant statistically heterogeneity (p > 0. 1, 12 = 0%). FEM was used as the pooling method. OR was applied to analysis of the overall effect. There was no statistically significant difference between the unilateral and bilateral fixation methods (OR = 0.55, 95% CI = 0.25 - 1.22, p = 0.14).

Complications

Five studies reported complications (Fig. 7). The research had no significant statistically heterogeneity (p > 0.1, I2 = 0%). FEM was used as the pooling method. OR was applied to analysis of the overall effect. There was no statistically significant difference between the unilateral and bilateral fixation methods (OR = 0.76, 95%) CI = 0.38 - 1.52, p = 0.44).

Publication bias

The possibility of publishing bias was not assessed by the funnel plot analysis because too few studies (<10) were included in our meta-analysis.

Discussion

In this study, we found that there were no statistically significant differences between the unilateral and bilateral pedicle screw fixation methods with regards to clinical outcome, fusion rate, and complication rate. The duration of operating time and the average amount of bleeding in the unilateral fixation group were significantly shorter than those in the bilateral fixation group. Clinical outcomes in unilateral pedicle screw fixation were nearly identical to those in bilateral pedicle screw fixation. Therefore, we concluded that unilateral pedicle screw fixation was as effective as bilateral pedicle screw fixation in lumbar spinal fusion. We did not conduct a meta-analysis in terms of Japanese Orthopedic Association scores (JOA), Oswestry Disability Index (ODI), social function (SF) etc., because not enough data were available in those studies.

Lumbar spinal surgery includes such procedures as decompression, correction of deformities, and fusion. After decompression or correction of deformities, spinal fusion

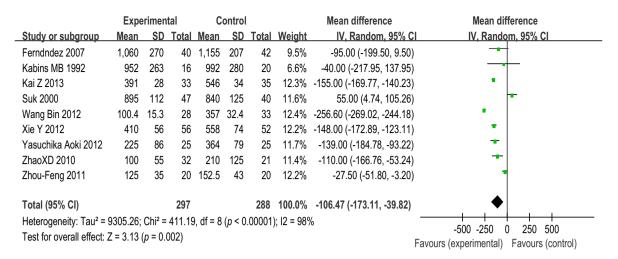


Figure 3 Comparison of average amount of bleeding between unilateral and bilateral fixation methods.

	Un	ilatera		Bi	lateral			Mean difference		Меа	n differer	nce	
Study or subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl		IV, R	andom, 9	5% CI	
Ferndndez 2007	3.97	1.01	40	3.85	0.54	42	20.7%	0.12 (-0.23, 0.47)			•		
Kai Z 2013	12.5	1.2	33	13.7	0.86	35	20.4%	-1.20 (-1.70, -0.70)			•		
Suk 2000	12.3	2.1	47	15.7	3.3	40	18.2%	-3.40 (-4.59, -2.21)			•		
Xie Y 2012	9	1	56	12	0.98	52	20.6%	-3.00 (-3.37, -2.63)			•		
Zhou-Feng 2011	10.65	1.1	20	11.55	0.9	20	20.1%	-0.90 (-1.52, -0.28)			1		
Total (95% CI)			196			189	100.0%	-1.64 (-3.03, -0.24)					
Heterogeneity: Tau ² = 2.41; Chi ² = 155.37, df = 4 (p < 0.00001); l2 = 97% Test for overall effect: Z = 2.30 (p = 0.02)										-50	0	50	100
		ŭ	,					F	avours	(experimer	ital) Favo	ours (cont	rol)

Figure 4 Forest plot for meta-analysis of hospitalisation days between unilateral and bilateral fixation methods.

with bone graft is performed in most cases. Internal fixators, including pedicle screws, have been developed rapidly during the past years, and now spinal fusion with pedicle screws is widely used [20,21]. The addition of pedicle screw instrumentation to the fusion procedure increases the initial stability and the probability of achieving a successful spinal fusion in the fusion segment [2,24]. However, there are some drawbacks, such as a larger surgical exposure, greater blood loss, a higher likelihood of reoperation, nerve injury, etc. [20–22]. The increased stiffness of the fused segments will reduce the bone mineral content in adjacent vertebrae, and biomechanical studies have indicated that increased stress at the levels adjacent to the fusion may increase adjacent segment pathology [8,23–25]. To achieve optimal biomechanical conditions in the fused segment and fewer adverse effects in the adjacent levels caused by instrumentation, the use of less rigid systems of fixation is advocated [26,27]. Therefore, unilateral pedicle screw fixation had been considered as a means to decrease the stiffness of the instrumented

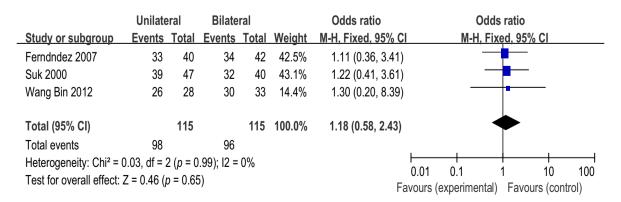


Figure 5 Forest plot for meta-analysis of the excellent and good rate between unilateral and bilateral fixation methods.

	Unilate	eral	Bilate	ral		Odds ratio	Odds ratio
Study or subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% C	M-H, Fixed, 95% Cl
Ferndndez 2007	36	40	39	42	22.3%	0.69 (0.14, 3.31)	
Kabins MB 1992	14	16	17	20	11.0%	1.24 (0.18, 8.46)	
Kai Z 2013	30	33	33	35	17.0%	0.61 (0.09, 3.88)	
Suk 2000	43	47	39	40	21.0%	0.28 (0.03, 2.57)	
Wang Bin 2012	26	28	32	33	12.3%	0.41 (0.03, 4.73)	
Xie Y 2012	56	56	52	52		Not estimable	
Yasuchika Aoki 2012	21	24	22	23	16.4%	0.32 (0.03, 3.31)	
Total (95% CI)		244		245	100.0%	0.55 (0.25, 1.22)	•
Total events	226		234				
Heterogeneity: Chi ² = 1	.41, df = 5	(p = 0.	92); I2 =	0%			
Test for overall effect: 2	z = 1.47 (p	= 0.14)			F	0.01 0.1 1 10 100 avours (experimental) Favours (control)

Figure 6 Forest plot for meta-analysis of the fusion rate between unilateral and bilateral fixation methods.

	Unilate	eral	Bilate	ral		Odds ratio	Odds ratio
Study or subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% C	I M-H, Fixed, 95% Cl
Ferndndez 2007	0	40	3	42	18.2%	0.14 (0.01, 2.79)	
Kai Z 2013	3	33	4	35	19.0%	0.78 (0.16, 3.76)	
Suk 2000	7	47	3	40	14.9%	2.16 (0.52, 8.97)	-+ -
Xie Y 2012	4	56	5	52	26.0%	0.72 (0.18, 2.85)	
Yasuchika Aoki 2012	2	15	5	17	21.9%	0.37 (0.06, 2.27)	
Total (95% CI)		191		186	100.0%	0.76 (0.38, 1.52)	•
Total events	16		20				
Heterogeneity: Chi ² = 3	.90, df = 4	(p = 0.4	42); I2 = 0)%			
Test for overall effect: Z	с = 0.77 (р	= 0.44)	-			F	0.001 0.1 1 10 1000 avours (experimental) Favours (control)

Figure 7 Forest plot for meta-analysis of the complications rate between unilateral and bilateral fixation methods.

segment. Chen et al. [28] demonstrated that unilateral fixation was good enough to maintain the stability of the spine in a biomechanics study [28]. A recent prospective, randomised study suggested that two-level unilateral instrumented transforaminal lumbar interbody fusion (TLIF) is an effective and safe method with reduced operative times and blood loss for multiple-level lumbar diseases [17].

This meta-analysis shows that there was a statistically significant difference in terms of the average operation time and blood loss between unilateral and bilateral pedicle fixation. Unilateral fixation only involves unilateral laminectomy for decompression, leads to less injury to the surrounding muscles and fascia, and two or more pedicle screw placements are not required. Compared to bilateral fixation, therefore, the operation time and intraoperative blood loss was significantly less. These meta-analysis results are consistent with the actual theory. This is also demonstrated by many previous studies [11–20]. As surgeons become familiar with this technique, we believe blood loss and operation time can be lower.

No significant differences were seen in terms of hospitalisation days, fusion rate, excellent and good rate, or complication rate between unilateral and bilateral pedicle fixation, indicating that the surgical procedure is feasible and safe. There was a report, however, that unilateral fixation is inadequate for stabilising a two-level unilateral vertebral disease. Bilateral fixation, whether symmetrical or asymmetrical, provides good stabilisation for this injury [29]. We found that there were no statistically significant differences between the unilateral and bilateral pedicle screw fixation methods in fusion rate; it was high in both fixation methods. Therefore, we conclude that unilateral pedicle screw fixation can provide excellent biomechanical stability and maintain the position of an interbody fusion cage and meet the conditions of achieving fusion.

The complication rates of unilateral and bilateral pedicle fixation were 8.37% (16/191) and 10.75% (20/186), respectively, and were not statistically significantly different. Theoretically, unilateral pedicle screw fixing reduces the number of pedicle screws and decreases the possibility of nerve root injury. As the rigid stability decreases in unilateral pedicle fixation, so the fixation failure rate becomes the focus in clinical practice. Suk et al. [13] reported that there were six metal failures in the

unilateral group and two metal failures in the bilateral group, but this was not statistically significant. Further analysis showed that patients suffering from spondylolisthesis associated with arcus vertebrae spondylolysis had higher fixation failure rates in unilateral pedicle fixation than that in bilateral pedicle fixation; the difference was statistically significant. Therefore, when patients suffer from spondylolisthesis associated with vertebral arch isthmus spondylolysis, bilateral pedicle fixation is advised.

The excellent and good rates of unilateral and bilateral pedicle fixation were 85.2% (98/115) and 83.47% (96/115), respectively; there was no statistically significant difference. There were studies which reported that the excellent and good rates of unilateral and bilateral pedicle fixation were >80% suggesting that both unilateral and bilateral pedicle fixations.

In summary, unilateral fixation can shorten the operation time, reduce the amount of bleeding, and reduce medical expenses. There are no significant differences in terms of inpatient stay, fusion rate, complication rate and excellent and good rates.

Conflicts of interest

All authors declare no conflicts of interest.

Acknowledgements

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