e-ISSN 1643-3750 © Med Sci Monit, 2016; 22: 890-897 DOI: 10.12659/MSM.897639

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MO	NITOR				e-ISSN 1643-37 © Med Sci Monit, 2016; 22: 890-8 DOI: 10.12659/MSM.8976		
Received Accepted Published	l: 2016.01.18 l: 2016.02.11 l: 2016.03.18	-	Unilateral Pedicle Screw Graft <i>vs</i> . Bilateral Pedic Bone Graft or Cage: A C	Fixation w Screw Fix Omparative	ith Bone ation with Study		
Authors S Da Statist Data In Manuscript Liter Func	s' Contribution: Study Design A ta Collection B tical Analysis C terpretation D t Preparation E ature Search F ds Collection G	ACDE 1 ABDE 2 AE 1,3 BC 4 DF 3 D 1 ACE 1,3	Si-Dong Yang* Qian Chen* Wen-Yuan Ding Jian-Qiang Zhao Ying-Ze Zhang Yong Shen Da-Long Yang	 Department of Spinal Surgery, Shijiazhuang, Hebei, P.R. China Department of Orthopaedic Su Shanghai, P.R. China Hebei Provincial Key Laborator Hebei, P.R. China Department of Orthopaedic Su P.R. China 	The Third Hospital of Hebei Medical University, Irgery, Zhongshan Hospital, Fudan University, y of Orthopaedic Biomechanics, Shijiazhuang, Irgery, Longyao County Hospital, Longyao, Hebei,		
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Background: Material/Methods: Results:		ground: lethods: Results: lusions:	The aim of this study was to explore the clinical effer (UPSFB) in treating single-segment lumbar degenerati fixation with bone graft (BPSFB) or with cage (BPSFC) Medical records were retrospectively collected betwo According to surgical methods used, all patients were BPSFC group. Clinical outcomes were evaluated by blo tal stay, postoperative complications, interbody fusion faction survey, and JOA score. Ninety-five patients were included and underwent 2.5 As compared to the BPSFB group and BPSFC group, the fusion, as well as shorter hospital stay (p <0.05). Medic There were no significant differences among the 3 gro reoperation rate, JOA score, and patient satisfaction (As compared to BPSFB and BPSFC, UPSFB has the sam	cacy of unilateral pedicle ve diseases (LDD), as com een 01/2010 and 02/201 e divided into 3 groups: U bod loss, blood transfusion n rate, reoperation rate, m -year follow-up, with 7 pa e UPSFB group had less b al expenses were far lowe ups in postoperative comp all p>0.05). ne reliability and effective	screw fixation with bone graft pared to bilateral pedicle screw 5 in Longyao County Hospital. PSFB group, BPSFB group, and n, duration of operation, hospi- nedical expenses, patient satis- tients lost to regular follow-up. plood loss and less blood trans- r in the UPSFB group (p <0.001). plications, interbody fusion rate,		
MeSH Keywords:		ywords:	LDD with unilateral radicular symptoms in a single lower extremity, with the additional advantage being less expensive. Bone Transplantation • Orthopedic Fixation Devices • Spine				
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Background

Lumbar pedicle screw fixation and interbody fusion is a commonly used and effective surgical method to treat single-level lumbar degenerative diseases (LDD), such as spondylolisthesis, discogenic pain, and lumbar spinal canal stenosis associated with deformities [1,2]. Bilateral pedicle screw fixation and interbody fusion with cage (BPSFC) is widely used for managing lumbar spinal fusion [3-6]. It can provide initial stability, correct deformities, maintain the height of the intervertebral disc, improve interbody fusion, and accelerate the recovery process from spine surgery. However, a patient with more implants experiences more extensive dissection, more blood loss, longer duration of operation, and higher risk of implant-related complications. Also, it may mean greater medical costs, thus increasing economic burden to patients living in poor areas. To reduce these problems some researchers have performed unilateral pedicle screw fixation and interbody fusion surgery, which has obtained satisfactory clinical outcomes [1,7–10].

To the best of our knowledge, interbody fusion surgery has never been performed with local bone graft; most surgeons use a cage instead. However, in some poor areas, fusion with local bone graft is still used because it is less expensive and has a satisfactory effect. Located in a poor area, Longyao County Hospital has performed many interbody fusion operations with local bone graft, including unilateral pedicle screw fixation and interbody fusion with bone graft (UPSFB) and bilateral pedicle screw fixation and interbody fusion with bone graft (BPSFB). Previous studies have all focused on comparing the effectiveness of unilateral pedicle screw fixation and bilateral pedicle screw fixation. However, there is little reported data on whether UPSFB and BPSFB has the same effect on patients. Therefore, in the present study we systematically compared the effectiveness and safety of UPSFB and BPSFB for single-segment LDD with unilateral radicular symptoms in a single lower limb. In addition, BPSFC was included to compare it with the 2 surgical procedures above, in an effort to better understand these 3 different surgical methods.

Thus, the aim of this study was to explore the effect of UPSFB on patients diagnosed as having LDD with unilateral radicular symptoms in a single lower limb, as compared with BPSFB and BPSFC.

Material and Methods

Ethics statement

Informed consent was obtained from all subjects and the study was approved by the Ethics Committee of our hospital (No.

1008213926). All procedures were carried out in accordance with the approved guidelines (ISO14155).

Patients and inclusion criteria

We retrospectively collected medical records of patients who were diagnosed as having LDD and who underwent pedicle screw fixation and interbody fusion between 01/2010 and 02/2015 in our hospital. Inclusion criteria of the present study were as follows. 1) No history of previous spinal surgery existed. 2) No history of other operations on the same lower limb with radicular symptoms. 3) No other peripheral nerve diseases on the same lower limb with radicular symptoms. 4) No other concurrent trauma and pathologic diseases existed in spine or in lower limb. 5) All patients had undergone lumbar pedicle screw fixation and interbody fusion surgery for LDD. 6) All patients had been diagnosed as having LDD with radicular symptoms in a single lower limb. Patients who did not undergo regular follow-up visits or who had systemic disorders were excluded.

Methods

In total, 102 patients were identified. Of them, 7 patients were lost to regular follow-ups. Thus, 95 patients were admitted into this study. All 95 patients included were divided into 3 groups according to surgical methods performed by the same surgeon: the UPSFB group (n=30), the BPSFB group (n=31), and the BPSFC group (n=34). All patients after surgery were routinely asked to return to the same hospital for a check-up at 6 months. In the present study, clinical outcomes were evaluated by comparing blood loss, blood transfusion, duration of operation, length of hospital stay, postoperative complications, interbody fusion rate, reoperation rate, medical expenses, patient satisfaction, and lumbar JOA score at the last follow-up.

Statistical analysis

Statistical analysis was performed using SPSS for Windows, version 18.0 (SPSS Inc., USA). All measurement data are presented as the mean \pm SD (standard deviation) when data satisfied criteria for normality with p>0.10. Otherwise, it data are presented as the median (interquartile range, IQR). When data satisfied criteria for normality and homogeneity of variance, statistical analyses among multiple groups were performed using one-way analysis of variance (ANOVA), followed by the *t* test for pairwise comparison. Otherwise, statistical analysis was performed using the Mann-Whitney U test. For count data, the chi-square test or Fisher exact test was used for data analysis. Values for p<0.05 were regarded as significant.



Figure 1. The postoperative X-ray images of UPSFB, BPSFB, and BPSFC. (A, B) Are representative of UPSFB. (C, D) Are representative of BPSFB. (E, F) Are representative of BPSFC. UPSFB – unilateral pedicle screw fixation with autologous bone graft; BPSFB – bilateral pedicle screw fixation with autologous bone graft; BPSFB – bilateral pedicle screw fixation with cage.

Results

As shown in Figure 1, the postoperative X-ray images are representative of UPSFB, BPSFB, and BPSFC, respectively. There were a total of 95 cases incorporated into this study, including 42 males and 53 females. The median age was 45 (IQR 16) years, ranged from 28 years to 65 years. All included patients were followed up for at least 6 months; the longest follow-up period was 5 years, with an average of 2.5 years. Among them, 70 cases had LDD at the L4-5 level, and 25 cases had LDD at the L5-S1 level. The age and sex distribution were both well matched among the 3 groups.

Blood loss and blood transfusion

As shown in Tables 1 and 2, the UPSFB group had less blood loss (t test, both p<0.001) and had less need for blood transfusion

(Mann-Whitney U test, p=0.002 and p=0.005, respectively), as compared to the BPSFB group and BPSFC group. However, there was no significant difference between the BPSFB group and BPSFC group regarding blood loss and blood transfusion (p=0.607 and p=0.646, respectively).

Operation duration and hospital stay

As shown in Table 3, the UPSFB group and BPSFB group had shorter operation duration (*t* test, p=0.013, p=0.0009, respectively) as compared to the BPSFC group. As shown in Table 4, hospital stay both in BPSFB group and BPSFC group was longer than in the UPSFB group (Mann-Whitney U test, p=0.012 and p=0.002, respectively). However, there was no significant difference between the BPSFB group and BPSFC group regarding hospital stay (Mann-Whitney U test, p=0.535).

Table 1. Comparisons among UPSFB group, BPSFB group and BPSFC group regarding blood loss.

Croups	Blood loss (ml)	Voreus	Student's t-test	
Groups	Mean ±SD	versus	t-value	<i>p</i> -value
UPSFB group	340±85	BPSFB group	7.00	<0.001
BPSFB group	490±84	BPSFC group	0.52	0.607
BPSFC group	505±95	UPSFB group	7.28	<0.001

UPSFB – unilateral pedicle screw fixation with autologous bone graft; BPSFB – bilateral pedicle screw fixation with autologous bone graft; BPSFC – bilateral pedicle screw fixation with cage.

Table 2. Comparisons among UPSFB group, BPSFB group and BPSFC group regarding blood transfusion.

Cround	Blood transfusion (ml)	Mann-Wh		ey U test
Groups	Median (IQR)	versus	Z-value	<i>p</i> -value
UPSFB group	0 (400)	BPSFB group	3.11	0.002
BPSFB group	400 (200)	BPSFC group	0.46	0.646
BPSFC group	400 (200)	UPSFB group	2.84	0.005

UPSFB – unilateral pedicle screw fixation with autologous bone graft; BPSFB – bilateral pedicle screw fixation with autologous bone graft; BPSFC – bilateral pedicle screw fixation with cage; IQR – interquartile range.

Table 3. Comparisons among UPSFB group, BPSFB group and BPSFC group regarding duration of operation.

Crowns	Operation duration (mins)	Marque	Student's	Student's t-test	
Groups	Mean ±SD	versus	t-value	<i>p</i> -value	
UPSFB group	129±30	BPSFB group	1.01	0.318	
BPSFB group	137±32	BPSFC group	3.48	0.0009	
BPSFC group	158±35	UPSFB group	2.56	0.013	

UPSFB – unilateral pedicle screw fixation with autologous bone graft; BPSFB – bilateral pedicle screw fixation with autologous bone graft; BPSFC – bilateral pedicle screw fixation with cage.

Table 4. Comparisons among UPSFB group, BPSFB group and BPSFC group regarding hospital stay.

Crowne	Hospital stay (days)	Maraua	Mann-White	Mann-Whitney U test	
Groups	Median (IQR)	versus	Z-value	<i>p</i> -value	
UPSFB group	12 (3)	BPSFB group	2.50	0.012	
BPSFB group	14 (5)	BPSFC group	0.62	0.535	
BPSFC group	15 (5)	UPSFB group	3.15	0.002	

UPSFB – unilateral pedicle screw fixation with autologous bone graft; BPSFB – bilateral pedicle screw fixation with autologous bone graft; BPSFC – bilateral pedicle screw fixation with cage; IQR – interquartile range.

Postoperative complications

In this study, postoperative complications were analyzed, including nausea and vomiting, deep vein thrombosis, infection, stroke, myocardial infarction, pulmonary embolism, bedsore, cerebrospinal leak, and subdural hematoma. As shown in Table 5, the UPSFB group had the lowest incidence of postoperative complications (23.3%) and the BPSFC group had the highest incidence (41.2%). However, there was no significant

Table 5. Comparisons among UPSFB group, BPSFB group and BPSFC group regarding postoperative complications.

Crowne	Complications?	Incidence		<i>p</i> -value
Groups	Yes/No		Chi-Square	
UPSFB group	7 cases/23 cases	23.3%		
BPSFB group	12 cases/19 cases	38.7%	2.559	0.278
BPSFC group	14 cases/20 cases	41.2%		

UPSFB - unilateral pedicle screw fixation with autologous bone graft; BPSFB - bilateral pedicle screw fixation with autologous bone graft; BPSFC - bilateral pedicle screw fixation with cage.

Table 6. Comparisons among UPSFB group, BPSFB group and BPSFC group regarding medical expenses.

Cround	Expenses (USD)	Voreus	Student	Student's t-test	
Groups	Mean ±SD	Versus	t-value	<i>p</i> -value	
UPSFB group	3,500±500	BPSFB group	10.15	<0.001	
BPSFB group	4,800±500	BPSFC group	12.34	<0.001	
BPSFC group	6,500±600	UPSFB group	21.56	<0.001	

UPSFB – unilateral pedicle screw fixation with autologous bone graft; BPSFB – bilateral pedicle screw fixation with autologous bone graft; BPSFC - bilateral pedicle screw fixation with cage.

Table 7. Comparisons among UPSFB group, BPSFB group and BPSFC group regarding interbody fusion rate.

Crowne	Fusioned?	Fusion voto	Varaus	Fisher exact test
Groups	Yes/No	rusion rate	versus	<i>p</i> -value
UPSFB group	29 cases/1 cases	96.7%	BPSFB group	0.98
BPSFB group	30 cases/1 cases	96.8%	BPSFC group	0.60
BPSFC group	32 cases/2 cases	94.1%	UPSFB group	0.62

UPSFB – unilateral pedicle screw fixation with autologous bone graft; BPSFB – bilateral pedicle screw fixation with autologous bone graft; BPSFC - bilateral pedicle screw fixation with cage.

difference among the 3 groups when compared with each other (chi-square test, χ^2 =2.559, p=0.278).

Medical expenses

As shown in Table 6, medical expenses were far lower in the UPSFB group (\$3500±500 USD, as compared to the other 2 groups (t test, both p<0.001) and medical expenses in the BPSFC group were the highest (\$6500±600 USD).

Interbody fusion, reoperation, patient satisfaction and JOA score

As shown in Table 7, based on an average of 2.5 years followup, the interbody fusion rate was 96.7% in the UPSFB group, 96.8% in the BPSFB group, and 94.1% in the BPSFC group. There was no significant difference among the 3 groups in interbody fusion rate (Fisher's exact test, p>0.05). As shown in Tables 8–10, there was no significant difference among the 3 groups regarding reoperation rate, patient satisfaction, and lumbar JOA score, respectively (Fisher's exact tests, all p>0.05).

Discussion

Bilateral pedicle screw fixations have been regarded as the standard surgical procedure to provide rigid lumbar spinal fixation [8,11,12], but this construct is suspected to result in adjacent segment degeneration, probably due to the excessive rigidity of the system. Moreover, it may increase new morbidity, implant-related complications, and recurrence rate, all of which should be carefully considered. In addition, concerns about large medical expenses have arisen from implant use, especially in low-income areas. These shortcomings clearly need to

able 8. Comparisons amon	g UPSFB group, BPSFE	group and BPSFC group	regarding reoperation rate.

Crowne	Reoperation?	Reoperation rate	Versus	Fisher exact test
Groups	Yes/No			<i>p</i> -value
UPSFB group	1 cases/29 cases	3.33%	BPSFB group	0.57
BPSFB group	2 cases/29 cases	6.45%	BPSFC group	0.50
BPSFC group	1 cases/33 cases	2.94%	UPSFB group	0.93

UPSFB – unilateral pedicle screw fixation with autologous bone graft; BPSFB – bilateral pedicle screw fixation with autologous bone graft; BPSFC – bilateral pedicle screw fixation with cage.

Table 9. Comparisons among UPSFB group, BPSFB group and BPSFC group regarding patient satisfaction.

Crowne	Patients	Satisfaction rate Versus	Maraua	Fisher exact test	
Groups	Satisfied/dissatisfied		versus	<i>p</i> -value	
UPSFB group	28 cases/2 cases	93.3%	BPSFB group	0.975	
BPSFB group	29 cases/2 cases	93.5%	BPSFC group	0.462	
BPSFC group	30 cases/4 cases	88.2%	UPSFB group	0.481	

UPSFB – unilateral pedicle screw fixation with autologous bone graft; BPSFB – bilateral pedicle screw fixation with autologous bone graft; BPSFC – bilateral pedicle screw fixation with cage.

Table 10. Comparisons among UPSFB group, BPSFB group and BPSFC group regarding lumbar JOA score.

Cround	JOA score		Mann-Whitney U test	
Groups	Median (IQR)	versus	Z-value	<i>p</i> -value
UPSFB group	19 (6.0)	BPSFB group	0.38	0.704
BPSFB group	21 (5.0)	BPSFC group	0.16	0.873
BPSFC group	20 (5.0)	UPSFB group	0.45	0.653

UPSFB – unilateral pedicle screw fixation with autologous bone graft; BPSFB – bilateral pedicle screw fixation with autologous bone graft; BPSFC – bilateral pedicle screw fixation with cage; IQR – interquartile range.

be overcome. Thus, some authors have reported that unilateral pedicle screw fixation may be as effective as bilateral fixation. It was reported that clinical outcomes of unilateral pedicle screw fixation were nearly the same as those of bilateral fixation [9,13]. Recently, some surgeons [7,14,15] have reported that transforaminal lumbar interbody fusion (TLIF) with unilateral pedicle screw fixation is an effective and convenient procedure of treating single-segment lumbar degenerative disease.

However, it is not just limited to single-level research. Zhang et al. [16] suggested that unilateral pedicle screw fixations with reliable anterior support can be used in 2-level lumbar diseases. Mao et al. [12] reported that bilateral decompression via a unilateral approach using unilateral pedicle screw fixation for 2-level lumbar stenosis with instability, which can maintain the lumbar lordosis and the disc space height, is an effective and less invasive method than using bilateral constructs. In the field of spine surgery, it is still controversial whether a patient is suitable for unilateral fixation or bilateral fixation. Previously, it has been found that unilateral pedicle screw fixation was as effective as bilateral pedicle screw fixation in lumbar interbody fusion surgery, which was independent of the number of fusion levels (1 level or 2 levels), and independent of pedicle screw systems [9]. However, some biomechanical studies have revealed that unilateral fixation after TLIF decreased the rotational stability and stiffness when compared to bilateral pedicle screw fixation, but such studies have inherent limitations [17,18]. In addition, the maintenance of lumbar stability simply relied on unilateral pedicle screw fixation without any support device. The current general consensus is that unilateral fixation should be confined to a single-level fusion and should not be extended to multi-level fusion due to its inadequate fixation strength [19].

It has been previously reported that unilateral instrumentation has advantages over bilateral fixation in terms of reduced operation time, medical expenses, blood loss, and hospital stay duration [20,21], which is consistent with the results of the present study. In fact, pedicle screw fixation and interbody fusion with bone graft includes 2 subtypes of surgical procedures. As mentioned early, one is UPSFB and the other is BPSFB. It appears that many clinical results are similar when comparing UPSFB with BPSFB, which is reasonable given their similarity. However, there are important differences between these 2 procedures and BPSFC. Firstly, because of the different number of pedicle screws and cages used, the medical expenses in the UPSFB group and BPSFB group are lower than in the BPSFC group, which reduces the economic burden for low-income patients. Secondly, bone autograft for interbody fusion is safer than cage use, giving that implant-related complications may be somewhat reduced. Therefore, the surgical procedure of fusion with local bone graft may have these 2 advantages over methods using cages.

In the present study, all patients in the UPSFB group underwent single-level TLIF, while the patients in the BPSFB group and BPSFC group underwent single-level posterior lumbar interbody fusion (PLIF). This differs from previous studies mentioned above in that our study focused on comparing the UPSFB method and BPSFB method. It is well-known that most researchers in the field of spine surgery agree that unilateral pedicle screw fixation is as safe and effective as bilateral pedicle screw fixation. Thus, the focus of this study was to compare the merits and shortcomings of efficacy between the UPSFB method and BPSFB method, while including the BPSFC method as a parallel control.

It is true that elderly patients with lumbar degenerative diseases are very different from younger patients with the same disease. Elderly patients have longer hospital stay after undergoing a lumbar fusion operation compared to younger patients. In addition, it takes a long time for elderly patients to recover from operation trauma, due to the aged body and their weak physical functioning. Therefore, during that period, postoperative complications such as lower-limb deep vein thrombosis (DVT) and lower-limb muscle atrophy are more likely to occur and increase. Because our previous study has already discussed

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the prophylaxis of postoperative complications, especially DVT, in the process of recovery from spinal surgery [22], we did not address this issue in the present study.

In the present study we found that the lumbar JOA score was not significantly different among the 3 surgical procedures. Some studies used ODI and VAS scores to assess the postoperative effect, but these were not used in the present study because the lumbar JOA score includes an evaluation of pain sensation and neural function. Hence, lumbar JOA score can properly determine the evaluation. Generally, fusion is most important factor to consider in deciding whether the operation is successful. In our study, based on an average of 2.5 years follow-up, interbody fusion rates were 96.7%, 96.8%, and 94.1% in the UPSFB group, BPSFB group, and BPSFC group, respectively, and there was no significant difference among the 3 groups regarding interbody fusion rate. Similarly, a recent meta-analysis of RCTs reported fusion rates of 90.6% (230/254) and 94.0% (251/267) in unilateral and bilateral pedicle screw fixation groups, respectively, which were not significantly different [1]. In another study, fusion rates were 92.2% (249/270) in the unilateral group and 96.0% (264/275) in the bilateral group, without significant difference [10], and there was no significant difference among the 3 surgical procedures in reoperation rate and patient satisfaction.

Although the results of the present study have great clinical significance, it also has some limitations. Firstly, as a retro-spective single-center study, it lacks extensive representative-ness. Secondly, we did not use blind methods throughout the study. Thirdly, the sample size of patients included in the study is not large. Future research on this topic should have a larger sample size and use prospective, multicenter, randomized, blind methods to provide more reliable clinical research data.

Conclusions

We found that UPSFB is as reliable and effective as BPSFB and BPSFC as a surgical procedure in treating single-segment LDD with unilateral radicular symptoms in a single lower extremity, and that UPSFB has the advantage of lower medical cost.

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