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Research article

The comparison study of laminectomy with unilateral and bilateral pedicle screws fixation and laminectomy alone without fusion interbody in young patients with lumbar spinal stenosis: A randomized clinical trial

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ABSTRACT

Background: There are many reports about the risk factors for recurrence after laminectomy surgery. Some surgeons use unilateral and bilateral fusion to provide sufficient stability to the lumbar spine. However, its strength, safety, and effectiveness in young patients are not widely known. Therefore, this study was conducted to compare surgical methods of laminectomy with unilateral and bilateral fixation and laminectomy alone without interbody fusion in young patients with lumbar spinal stenosis.
Methods: 90 patients eligible for lumbar spinal stenosis surgery were selected through convenience sampling and randomly divided into three groups: laminectomy without fixation (A), laminectomy with unilateral fixation (B), and bilateral fixation (C). Pain, functional disability, quality of life, recurrent disc, adjacent segment disease (ASD), and fusion rate were evaluated and compared among the three groups six months post-surgery. The data were analyzed using SPSS version 16.
Results: Six months after surgery, the mean score of functional disability in the bilateral group was significantly higher than the other groups (12.92 (3.30) vs 5.52 (1.91) and 4.30 (1.84), $P < 0.05$). Also, the highest mean score of pain after surgery was observed in the bilateral group (4.33 (0.70) vs 1.81(0.68) and 1.63(0.56), $P < 0.05$). The mean score of quality of life in the unilateral group was significantly higher than the other groups (87.81 (5.67) vs 68.58 (3.08) and 56.07 (4.04), $P < 0.05$). No significant difference was observed between the groups ($P > 0.05$) regarding fusion, recurrent disc herniation, and adjacent segment disease.
Conclusions: Unilateral fixation provides the same benefits as bilateral fixation but has the additional benefits of being less invasive and minimizing the disadvantages of other investigated techniques during and after surgery.

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1. Introduction

Previously, lumbar spinal stenosis (LSS) was a common occurrence in older individuals, often associated with degenerative spine changes. However, it is now more prevalent in younger people [1]. The spinal injuries that young individuals suffer are the result of an active lifestyle and intensive sports. Initially, surgeons implement conservative remedies. However, surgical intervention is required if symptoms persist [2]. The most common surgical technique in young patients is decompression [3]. Decompression alone can significantly improve the physical performance of patients. However, the majority of patients require additional surgery as a result of spinal instability and disc recurrence. Several studies have suggested decompression with unilateral and bilateral fixation surgical to minimize disc recurrence with successful fusion [4,5].

Bilateral pedicle screw fixation (BPSF) is a traditional method that corrects many abnormalities in various levels of the spine [6]. However, the fused motion segments' increased stiffness reduces the bone mineral content in the adjacent vertebrae cent to the fusion. It has a positive effect on the degeneration of the adjacent segments [7]. Consequently, the implant's reduced stiffness has resulted in the utilization of unilateral pedicle screw fixation (UPSF). Biomechanical studies have shown that clinical results with UPSF variable screw placement instrumentation were almost identical to those of BPSF instrumentation [8,9]. UPSF can also save operation time and avoid contralateral soft tissue damage, which may reduce the risk of dural rupture and complications that could aggravate radiculopathy [10]. In contrast to other studies, the UPSF cohort has demonstrated increased hardware failure, postoperative back discomfort, cage displacement, and poorer clinical outcomes [11]. Consequently, the appropriateness of unilateral fixation remains uncertain. To our knowledge, scientific research on the clinical efficacy of UPSF versus BPSF without intervertebral fusion in young patients is unavailable. The contradictory findings have resulted in uncertainty regarding selecting an effective method for young patients who require high levels of activity to acquire new skills and earn money. Future research is necessary to address treatment modifications on this subject, considering the most recent evidence and identifying potential limitations in the existing literature. Therefore, the present study was conducted to compare the surgical methods of laminectomy with unilateral and bilateral pedicle screw fixation and laminectomy alone without interbody fusion in young patients with LSS.

2. Materials and methods

2.1. Study design and setting

This prospective randomized clinical trial was conducted in Iran's Qom province without blinding (IRCT20230222057496N2 on 2023-12-6). The study enrolled patients from April to July 2022 through the convenience sampling procedure. The researcher recruited the participants and established the allocation sequence. Subsequently, they were allocated to three intervention groups, A, B, and C, according to a randomized block design that contained six patient blocks.

Group A: Laminectomy without fixation.

Group B: Laminectomy with UPSF (Unilateral Pedicle Screw Fixation).

Group C: Laminectomy with BPSF (Bilateral Pedicle Screw Fixation).

Patients participating in this study had severe lumbar spinal stenosis caused by bilateral or unilateral disc herniation. Surgery was performed under general anesthesia, and all patients were operated by the same surgeon in a center. The electrocautery voltage was set the same for all patients to assess the bleeding quantity accurately. All patients were matched from the beginning of anesthesia to the administration of analgesics in the recovery department to determine the effects of anesthetic drugs on the risk of infection or postoperative pain in patients. All patients were followed up for six months. The manuscript was prepared following the integrated standards outlined in the CONSORT (Consolidated Standards of Reporting Trials) guidelines [12].

2.2. Sample size calculation

According to Sánchez et al. (2017), the mean Oswestry Disability Index (ODI) scores in the UPSF and BPSF groups were 35.67 ± 15.67 and 39.92 ± 9.92, respectively, at six months post-intervention [13]. Consequently, we calculated the sample size for each group. The sample size was 24 participants per group using a Type I error level of 0.05 and an 80 % power for the study. To account for a 25 % dropout rate, each group comprised 30 participants.

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}}+Z_{1-\beta}\right)^{2}(\delta_1^2+\delta_2^2)}{(\mu_1-\mu_2)^2}$$

2.3. Inclusion and exclusion criteria

2.3.1. Inclusion criteria

- Age ≤ 40 years

- Radiological evidence of LSS at the L3-L5 level on magnetic resonance imaging (MRI) (with discopathy at either the L3-L4 or L4-L5 vertebral levels).
- Minimum six weeks of conservative treatment.
- Body Mass Index (BMI) between 20 and 30.
- Visual analog scale (VAS) score before surgery ≥ 7

2.3.2. Exclusion criteria

- Previous surgery in the lumbar
- Associated diseases (rheumatoid arthritis, osteoporosis, hypertension, diabetes)
- Long-term use of opioid
- The presence of any pathological or discopathy in other vertebrae

2.4. Surgical technique

2.4.1. Intervention A: laminectomy without fixation

A midline incision of 4 cm was made. The paravertebral muscles of one side were dissected, and decompression was performed (laminectomy, facetectomy, flavectomy, and discectomy). The decompressed disc and freed roots were then closed layer by layer [14].

2.4.2. Intervention B: laminectomy with unilateral pedicle screw fixation (UPSF)

A midline incision of 6–7 cm was made. The paravertebral muscles of one side were dissected, and decompression was performed similarly to the previous technique. Following disc evacuation, a pilot hole was made with a Lenke-type probe (diameter 3 mm). The selected screw geometry was a solid core with titanium alloys (length ranging from 40 to 50 mm and outer diameter 6–6.5 mm). Two screws were embedded in the pedicles of one side. Subsequently, a pedicle screw anchoring procedure was performed, and the incision site was closed layer by layer [15].

2.4.3. Intervention C: laminectomy with bilateral pedicle screw fixation (BPSF)

A midline incision of 8–9 cm was made. Paravertebral muscles were dissected on both sides, and bilateral decompression was performed. Following the previous surgical procedure, a pilot hole was created bilaterally. Two screws were implanted in the pedicles on each side, and then the pedicle screw anchoring process was performed [5].

2.5. Clinical assessment

The accumulated blood in the bottle suction was measured, and the bleeding rate was recorded using blood gases 10×10 (1 gram equals one cc). The surgical time from the skin incision to the last suture was recorded by a stopwatch [16].

Patients' pain level was evaluated using a visual analog scale (VAS) before surgery and in the first and sixth months after surgery. This scale is graded from 0 to 10. Zero indicates absolute painlessness, and 10 indicates unbearable pain. The patient puts a mark on the continuum according to the intensity of his pain in the last 48 h [17].

Patients' functional disability was assessed using the Oswestry Disability Index (ODI). The self-completed questionnaire contains ten topics concerning intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel. This questionnaire consists of ten parts. Each part contains six questions. Each question is scored on a scale of 0–5, with the first statement being zero and indicating the least amount of disability. The last statement is scored 5, indicating the most severe disability. We calculated the score by summing the points, dividing the sum by 50, and multiplying the result by 100. (range of 0–100). Zero was equated with no disability, and 100 was the maximum disability possible. The final analysis yielded five groups: 0–20 % (patients with mild disability), 21–40 % (moderate disability), 41–60 % (severe disability), 61–80 % (incapacitated), 81–100 % (bedridden) [18].

The Short Form Health Survey (SF-36) evaluated patients' quality of life and has 36 questions. It consists of 8 subscales: physical function (10 questions), role function-physical (4 questions), bodily pain (2 questions), general health (5 questions), vitality (4 questions), social function (2 questions), role function-emotional (3 questions), and mental health (5 questions). Question 2 is not used in any subscale (this question individually examines the change in the individual's health status over one year). Each subscale consists of 2–10 items. Scores can range from 0 to 100, representing the lowest and highest quality of life. This questionnaire was completed before and in the first and sixth months after surgery. This questionnaire was completed before surgery and in the first and sixth months after surgery [19].

2.6. Radiographic assessment

The loosening of screws, interbody fusion, disc recurrence, and adjacent segment disease (ASD) were independently evaluated by an experienced neuroradiologist and radiologist based on dynamic radiography and computed tomography (CT scan) in the latest follow-up (6 months post-surgery).

Interbody fusion was assessed using the modifie Brantigan Steffee–Fraser (mBSF). This scale categorizes interbody fusion into three grades: Grade 1 indicates false arthrosis on radiographs (radiographic pseudoarthrosis). Grade 2 represents indeterminate fusion (indeterminate fusion). Grade 3 indicates complete fusion on radiographs (solid radiographic fusion). Screw pull-out, implant breakage, radiolucency (>1 mm) around the screws, segmental movement on dynamic x-ray greater than 2°, or evident absence of bridging bone on CT was categorized as grade I (pseudarthrosis). A transverse radiolucent line with segmental movement <2° without implant failure and uncertain bridging bone was classified as grade II (indeterminate fusion). The presence of trabecular bridging bone at more than half the fusion area on sagittal or coronal CT scanning without movement was categorized as grade III (solid radiological fusion) [20].

Disc recurrent and ASD were evaluated by the Combined Task Forces (CTF) classification system. This system classifies lumbar disc herniation into a normal disc (a disc with no displacement is located within the disc space boundaries) and a bulging disc (there is a defuse displacement of the disc material more than 50 % beyond the disc space boundaries it is further classified into asymmetric and symmetric). In central stenosis, the spinal canal is divided into four grades: grade 1, in which there is a normal spinal canal. Grade 2 (mild stenosis) is mild obliteration of cerebrospinal fluid (CSF) space with clear separation of the nerve roots and cauda equina. Grade 3 (moderate stenosis), in which there is moderate spinal stenosis with aggregation of cauda equina nerve roots, and grade 4 (severe stenosis), in which there is severe spinal stenosis with the whole cauda equina nerve roots becoming a bundle [21].

The criterion for pedicle screw loosening (PSL) on a CT scan was a signal-free area that encompassed the entire screw body in the image. A signal area was not visible at the screw head due to metal artifacts, and we did not regard it as screw loosening. The criteria for screw loosening on X-ray imaging included a radiolucent area with a thickness of 1 mm or the presence of a "double halo" around the screw [22].

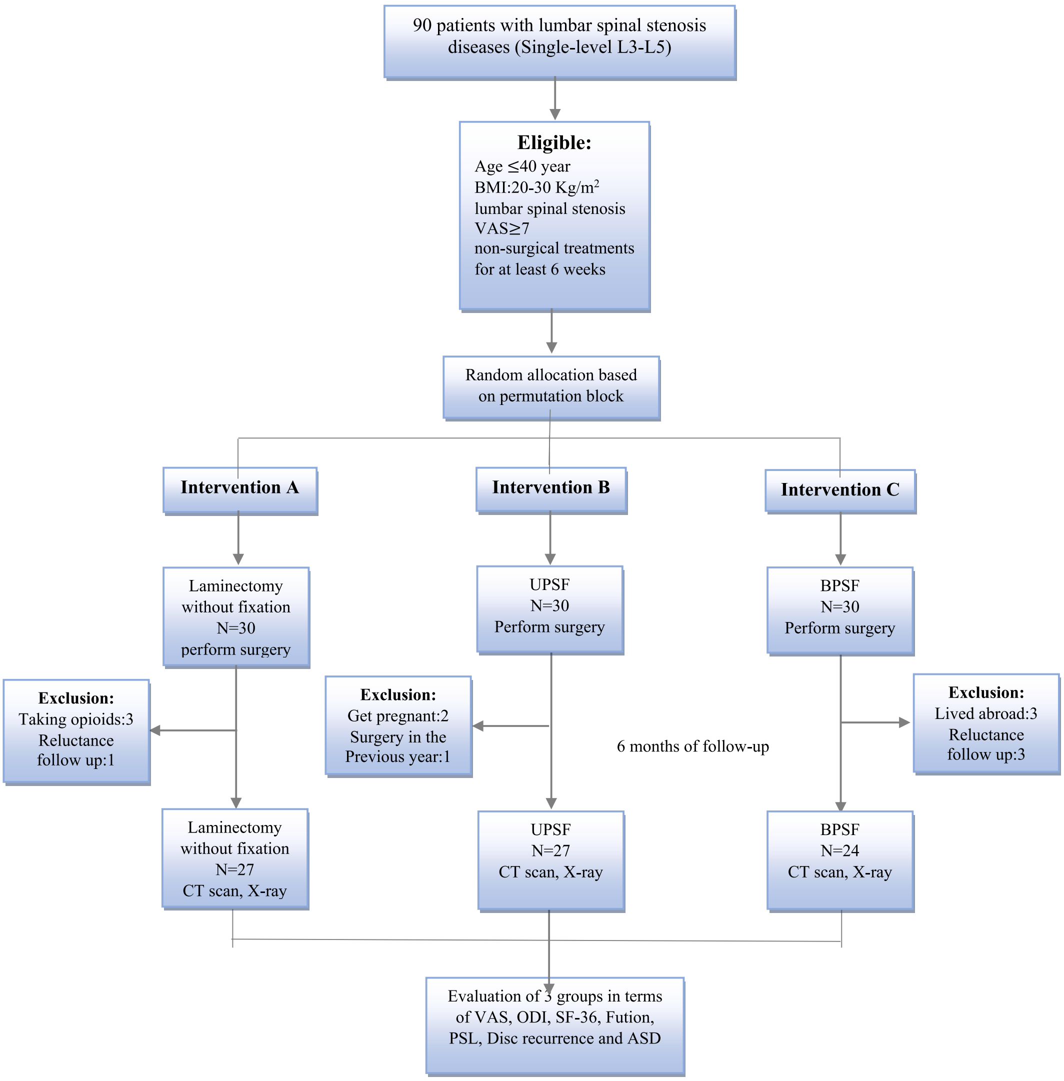


Fig. 1. Consort.

2.7. Statistical analysis

Data analysis was performed using SPSS version 16 software. First, the data (Demographic and clinical characteristics) were analyzed using Levene's test and the Shapiro-Wilk test for equality of variance and normality assumption, both at $p > 0.05$. Continuous data are expressed as mean (SD). The significance level of reporting for the Continuous data of demographic and clinical characteristics of patients before surgery was greater than the error level of 0.05. Therefore, One-way ANOVA test was used. Categorical variables were presented as number (%) and tested using the chi-square test. The results of the Kolmogorov Smirnov test for the normality of the VAS, ODI and SF-36 of the patients showed that the significance is smaller than the error level of 0.05. Therefore, Preoperative to postoperative ODI, VAS and SF-36 changes within each group were analyzed with Kruskal-Wallis non-parametric test. The results of show a significant significant difference was detected between the groups then a post hoc test for the individual comparisons was performed for the 3 comparisons (laminectomy vs UPSF, laminectomy vs BPSF, UPSF vs BPSF). The classified radiological results were evaluated using the chi-square goodness-of-fit test.

3. Results

3.1. Baseline characteristics

Ninety patients were included in the study according to the criteria (30 patients in each group). Six months following the surgery, 12 patients were excluded from the study due to migration, unwillingness to follow up, absence of access to patients, and other factors (Fig. 1). These patients were categorized as follows: six in the BPSF group three in the UPSF group, and three in the laminectomy without fixation group. Table 1 demonstrates the characteristics of the patient groups in the study. There was no difference between the groups regarding age, gender, employment status, marital status, level of education, or risk factors for fusion (e.g., body mass index, bone mineral density, and smoking). Regarding operational level, there was no significant difference between the two groups. L3/4 was the most common operating level, followed by L4/5 in both groups. Both groups demonstrated similar preoperative pain, disability index scores, and quality of life ($P > 0.05$) (Table 1).

3.2. Clinical outcomes

The results of the study showed that the mean of bleeding in the BPSF group is significantly higher compared to other groups (228.9

Table 1
Demographic and clinical characteristics of the 3 groups.

Characteristics	Laminectomy N = 27	UPSF N = 27	BPSF N = 24	*p*-value[a]
Age(yr),[†] mean(SD)	30.63 (5.91)	31.37 (6.44)	31.21 (6.30)	0.900
Sex,[a]No(%)				0.982
Male	13 (48.1 %)	13 (48.1 %)	11 (47.4 %)	
Female	14 (51.8 %)	14 (51.8 %)	13 (54.1 %)	
Height (cm),[†] mean(SD)	172.07 (7.35)	170.96 (9.23)	171.33 (6.42)	0.869
Weight (kg),[†] mean(SD)	83.9 (8.31)	83.5 (10.1)	85.2 (10.4)	0.687
BMI(Kg/m^2),[†] mean(SD)	28.1 (3.31)	28.8 (4.76)	29.1 (4.03)	0.650
Employment status,[a] N. (%)				0.683
Unemployed	10 (37.04 %)	11 (40.74 %)	7 (29.17 %)	
Employed	17 (62.9 %)	16 (59.2 %)	17 (70.8 %)	
Smoking status,[a] No. (%)	–	–	–	
Yes	21 (77.7 %)	20 (74.07 %)	19 (79.1 %)	0.904
No	6 (22.2 %)	7 (25.9 %)	5 (20.8 %)	
Marital status,[a] No. (%)				0.838
Single	17 (62.9 %)	18 (66.6 %)	17 (70.8 %)	
Married	10 (37.04 %)	9 (33.3 %)	7 (29.1 %)	
Level of education,[a] No. (%)				0.910
≤ Diploma	14 (51.8 %)	13 (48.1 %)	(45.8 %) 11	
Callegiate	13 (48.1 %)	14 (51.8 %)	(54.1 %) 13	
BMD (T-score),[†] mean(SD)	−1.03 (0.12)	−1.18 (0.46)	(0.4) 1.33-	0.016
Fusion level,[a] No. (%)				0.842
L3-L4	NA	15 (55.5 %)	%)58.3 (14	
L4-L5	NA	12 (44.5 %)	10 (41.7 %)	
Pre-VAS[†], mean(SD)	8.51 (0.80)	8.59 (0.93)	8.37 (0.82)	0.741
Pre-ODI,[†] mean(SD)	69.2 (3.24)	70 (3.35)	69.6 (3.23)	0.977
Pre-SF-36[†], mean(SD)	18.1 (5.20)	18.5 (4.02)	19.5 (4.07)	0.580

[†]one-way ANOVA, [†]Kruskal wallis.
Abbreviation: BMI: Body mass index, BMD: Bone minimal density, UPSF: unilateral pedicle screw fixation, BPSF: bilateral pedicle screw fixation, VAS: visual analogue scale, ODI: Oswestry disability index, SF-36: short form health survey, NA: not applicable.
Chi-Square.
Statistical significant as $p < 0.05$.

(20.5) vs 141.1 (16.1) and 80.9 (13.01), $P < 0.05$). Also, the three groups found Significant differences in mean operating time. The longest surgery time belongs to the BPSF group, and this difference is statistically significant (102.7 (10.4) vs 70.7 (4.45) and 46.8 (5.15), $P < 0.05$). No significant difference was observed between all three groups in terms of other factors (hospital stay and follow-up time after surgery) ($P > 0.05$) (Table 2).

The average pain score in all three groups showed a decreasing trend one month after surgery compared to before surgery. The BPSF group experienced the most pain, with a statistically significant difference (5.13 (0.85) vs 2.26 (0.81) and 2.19 (0.79), $P < 0.05$). Additionally, the pain level in all three groups decreased six months after surgery compared to one month after. The mean of pain in the BPSF group compared to other groups was significantly higher (4.33 (0.70) vs 1.81 (0.68) and 1.63 (0.56), $P < 0.05$) (Table 3).

The average functional disability score of the patients decreased one month after surgery compared to before surgery in all three groups. The highest level of functional disability was observed in the BPSF group, and this difference was statistically significant (28.58 (1.41) vs 21.52 (2.69) and 20.22 (2.31), $P < 0.05$). Similar results were reported in the final follow-up (6 months after the operation). The average score of functional disability in all three groups was decreasing, and again, the highest level of functional disability was observed in the BPSF group (12.92 (3.30) vs. 5.52 (1.91) and 4.30 (1.84), $P < 0.05$) (Table 3).

The average quality of life score of patients increased significantly one month after surgery compared to before surgery in all three groups, and the highest quality of life was observed in the UPSF group (71.15 (3.54) vs 58.29 (4.81) and 49.44 (3.24), $P < 0.05$). Also, the average quality of life score six months after surgery compared to one month after surgery was higher in all three. The highest level of quality of life was observed in the UPSF group, and this difference was statistically significant (87.81 (5.67) vs 68.58 (3.08) and 56.07 (4.04), $P < 0.05$) (Table 3).

The results indicate significant differences between the groups in terms of clinical results. Subsequently, a post hoc test was implemented to evaluate individual comparisons across three comparisons (laminectomy-UPSF, laminectomy-BPSF, UPSF-BPSF). According to Table 4, the BPSF group experienced the most pain during the first and sixth months following surgery, and this difference between the two groups was statistically significant (laminectomy-BPSF and BPSF-UPSF). There was no statistically significant difference between the other groups (laminectomy-UPSF) ($P > 0.05$). Also, similar results were reported in the field of patients' functional disability. In other words, the highest level of functional disability was observed in the BPSF group in the first and sixth months after surgery, and this difference with both groups was statistically significant (laminectomy-BPSF and BPSF-UPSF). No significant difference was observed between the other groups (laminectomy-UPSF) ($P > 0.05$) (Table 4).

As can be seen in Table 4, the level of quality of life in the first and sixth months after surgery in the UPSF surgical method is significantly higher than in other groups (laminectomy-UPSF, UPSF-BPSF) ($P < 0.05$). Additionally, the analysis that compares two groups of laminectomy without fixation and BPSF reveals that the average quality of life score in the BPSF group is substantially higher than that of the laminectomy without fixation group in the first and sixth months following the surgery ($P < 0.05$) (Table 4).

3.3. Radiographic outcomes

According to Table 5, the significance level of the chi-square goodness-of-fit test is greater than 0.05. Therefore, there was no significant difference between the UPSF and BPSF groups regarding interbody fusion (Solid fusion, Indeterminate fusion, pseudoarthrosis). There was no significant difference in pedicle screw loosening (PSL) in UPSF and BPSF groups, and only one patient had PSL in the BPSF group. The significance level of the chi-square goodness-of-fit test for disc recurrence was more significant than 0.05 for all three groups. In other words, there was no significant difference between the three surgical groups regarding disc recurrence, but several patients in the laminectomy group had disc recurrence (Table 5). In Fig. 2, the images of a patient who underwent surgery with the BPSF technique can be seen. Image A is during surgery and Image B is 6 months after surgery (Fig. 2). In Fig. 3, the images of a patient who underwent surgery with the UPSF technique can be seen. Image A is during surgery and Image B is 6 months after surgery (Fig. 3).

3.4. Complications

None of the patients had a dural tear during surgery or infection after surgery. One of the patients had a screw fracture, which was operated by BPSF method (Table 5). Improper placement of screws, displacement of screws and neurological complications after surgery (foot drop), and adjacent damage complications were not observed in any of the patients.

Table 2
Comparison of perioperative parameters between groups.

Variable	Laminectomy N = 27	UPSF N = 27	BPSF N = 24	*p*-value[a]
Operation time (min)[a],mean (SD)	46.8 (5.15)	70.7 (4.45)	102.7 (10.4)	0.000
Bleeding (cc),[a] mean (SD)	80.9 (13.01)	141.1 (16.1)	228.9 (20.5)	0.000
Hospital stay (day),[a]mean (SD)	2.67 (0.73)	2.85 (0.60)	2.83 (0.76)	0.570
Folow up (months)[a],mean (SD)	6.33 (0.55)	6.22 (0.57)	6.25 (0.60)	0.766

Abbreviation: UPSF: unilateral pedicle screw fixation, BPSF: bilateral pedicle screw fixation.
one-way ANOVA.
Statistical significant as $p < 0.05$.

Table 3
Comparison of postoperative outcomes between groups.

	Variable	Laminectomy N = 27	UPSF N = 27	BPSF N = 24	*p*-value[a]
VAS	**Post early VAS[a],**mean (SD)	2.19 (0.79)	2.26 (0.81)	5.13 (0.85)	0.000
	Post VAS[a],mean (SD)	1.63 (0.56)	1.81 (0.68)	4.33 (0.70)	0.000
ODI	**Post early ODI[a],**mean (SD)	20.22 (2.31)	21.52 (2.69)	28.58 (1.41)	0.000
	PostODI[a],mean (SD)	4.30 (1.84)	5.52 (1.91)	12.92 (3.30)	0.000
SF-36	**Post early SF-36[a],**mean (SD)	49.44 (3.24)	71.15 (3.54)	58.29 (4.81)	0.000
	PostSF-36[a],mean (SD)	56.07 (4.04)	87.81 (5.67)	68.58 (3.08)	0.000

Abbreviation: UPSF: unilateral pedicle screw fixation, BPSF: bilateral pedicle screw fixation, VAS: visual analogue scale, ODI: Oswestry disability index, SF-36: short form health survey.
one-way ANOVA.
Statistical significant as $p < 0.05$.

Table 4
Comparison of postoperative outcomes pairwise.

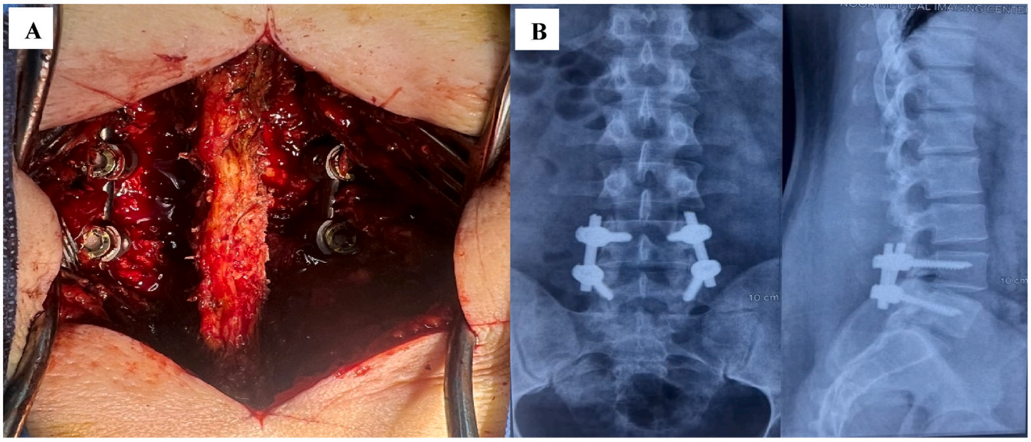
Pairwise Comparisons of Group					
	Sample1-Sample2	Test Statistic	Std. Error	Std. Test Statistic	Sig[a]
Post early VAS[a]	Laminectomy-UPSF	−1.09	6.021	0.181-	.8560
	Laminectomy-BPSF	−39.40	6.206	−6.348	.0000
	UPSF-BPSF	−38.30	6.206	−6.172	.0000
PostVAS[a]	Laminectomy-UPSF	−3.815	5.886	0.648-	.5170
	Laminectomy-BPSF	−40.245	6.067	−6.634	.0000
	UPSF-BPSF	−36.431	6.067	−6.005	.0000
Post early ODI[a]	Laminectomy-UPSF	−8.537	6.141	−1.390	.1650
	Laminectomy-BPSF	−43.238	6.330	−6.830	.0000
	UPSF-BPSF	−34.701	6.330	−5.482	.0000
PostODI[a]	Laminectomy-UPSF	−9.222	6.132	−1.504	.1330
	Laminectomy-BPSF	−43.431	6.321	−6.871	.0000
	UPSF-BPSF	−34.208	6.321	−5.412	0.000
Post early SF-36[a]	Laminectomy-UPSF	−21.808	6.349	−3.435	0.001
	Laminectomy-BPSF	−49.093	6.159	−7.971	0.000
	UPSF-BPSF	27.285	6.349	4.298	0.000
PostSF-36[a]	Laminectomy-UPSF	−25.299	6.350	−3.984	0.000
	Laminectomy-BPSF	−50.537	6.160	−8.204	0.000
	UPSF-BPSF	25.238	6.350	3.975	0.000

Abbreviation: VAS: visual analogue scale, ODI: Oswestry disability index, SF-36: short form health survey, UPSF: unilateral pedicle screw fixation, BPSF: bilateral pedicle screw fixation.
Post Hoc.
Statistical significant as $p < 0.05$.

Table 5
Comparison of radiological outcomes between groups.

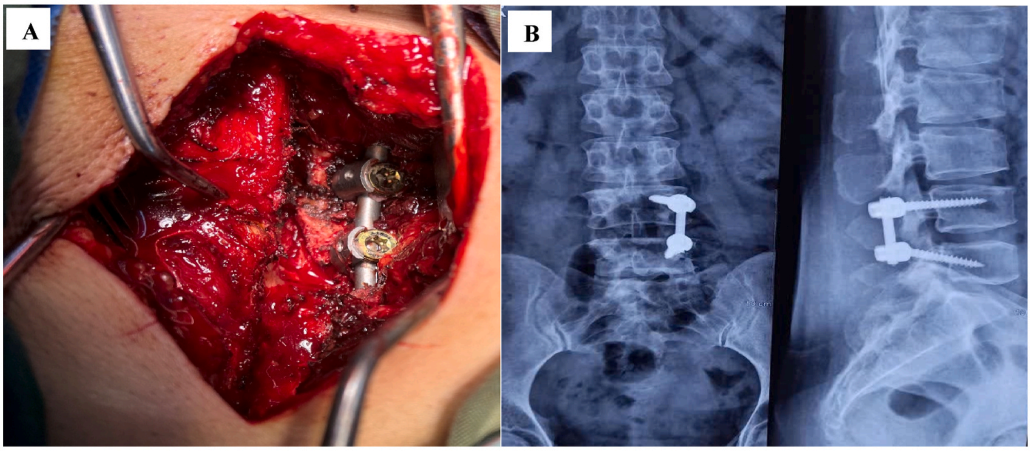
Variable	Laminectomy N = 27	UPSF N = 27	BPSF N = 24	Sig[a]
Fution,[a] N.(%)				
Solid	NA	20 (74.0 %)	21 (87.5 %)	0.876
Indeterminate	NA	3 (11.2 %)	2 (8.3 %)	0.655
Pseudarthrosis	NA	4 (14.8 %)	1(4.2 %)	0.180
Screw loosing,[a] N.(%)				
Yes	NA	0 (0.0 %)	1 (4.2 %)	–
No	NA	27 (100.0 %)	23 (95.8 %)	0.572
Ricurrent disc herniation,[a] N.(%)				
Yes	8 (29.6 %)	0 (0.0 %)	0 (0.0 %)	–
No	19 (70.4 %)	27 (100.0 %)	24 (100.0 %)	0.497
Fracture Screw,[a] N.(%)				
Yes	NA	0 (0.0 %)	1 (4.2 %)	–
NO	NA	27 (100.0 %)	23 (95.8 %)	0.572

Abbreviation: UPSF: unilateral pedicle screw fixation, BPSF: bilateral pedicle screw fixation, NA: not applicable.
Goodness of fit Test.
Statistical significant as $p < 0.05$.



Case 1: A adult patient with Lumbar spinal stenosis at the level of L4-L5 vertebrae. First, a discectomy was performed for the patient and the patient underwent lumbar spine fixation by bilateral method at the level of L4-L5 vertebrae. Figure **A** is during surgery and Figure **B** is 6 months after surgery.

Fig. 2. Surgical technique BPSF during (A) and 6 months after surgery (B).



Case 2: A adult patient with Lumbar spinal stenosis at the level of L4-L5 vertebrae. First, a discectomy unilateral was performed for the patient and the patient underwent lumbar spine fixation by unilateral method at the level of L4-L5 vertebrae. Figure **A** is during surgery and Figure **B** is 6 months after surgery.

Fig. 3. Surgical technique UPSF during (A) and 6 months after surgery (B).

4. Discussion

Data regarding pedicle screw fixation of the lumbar spine without the utilization of interbody cages in young patients with high physical activity, exposure to work-related injuries, sports, and improper posture in industrial societies are scarce and controversial, despite the existence of numerous studies that assess the outcomes of UPSF and BPSF in lumbar fusion. Therefore, the present study was conducted to compare surgical methods of laminectomy with UPSF and BPSF and laminectomy alone without fusion interbody in young patients with LSS. Data analysis showed that the highest bleeding and surgery time was observed in the BPSF group, followed by the UPSF group. There were no statistically significant differences regarding the fusion rate between the UPSF and BPSF methods. In this regard, Badikillaya et al. (2021) believed there was no significant difference in the interbody fusion rate between the two groups, and they were similar regarding postoperative complications [5]. According to a recent prospective, randomized study, two-level UPSF is a safe and effective treatment for lumbar spinal stenosis diseases, resulting in reduced blood loss and operative times [23]. In contrast to the findings above, a report indicated that UPSF is insufficient for the stabilization of a multilevel UPSF vertebral disease. In this injury, BPSF is effective for stabilization, regardless of whether it is symmetrical or asymmetrical [24]. The difference in the findings of numerous studies is attributable to the patients' levels of spinal stabilization. Consequently, the UPSF stabilization may not be effective due to its inherent asymmetry as the number of static vertebral surfaces increases. Peng et al. (2022) confirmed the findings by demonstrating that the BPSF method was more effective than UPSF in multi-level biomechanical fixation and achieved a more successful fusion [6]. Also, different studies use different criteria to evaluate fusion) CTF, Lenke, Bridwell, and CT-HU(, which sometimes may even consider pseudarthrosis as a successful fusion. The type of complication before surgery appears to be a significant factor in selecting a surgical technique. Patients with single-level spinal stenosis who participated in the current study underwent successful fusion. However, UPSF may not be effective in patients with severe spinal disorders. In this regard, Luo et al. (2014) demonstrated that patients with spondylolisthesis associated with arcus vertebrae spondylolysis had a higher rate of fixation failure in unilateral pedicle fixation than in bilateral pedicle fixation [25].

The data analysis showed that the average VAS and ODI scores in the two groups of laminectomy without fixation and UPSF did not differ significantly in the final follow-up. However, the VAS and ODI levels in the UPSF group were significantly lower compared to the BPSF group. Škoro et al. (2016) showed that the rehabilitation and functional recovery rate in the laminectomy group with fixation was 90 %, and in the laminectomy group without fixation was 58 % [26]. Rasras et al. (2018) also reported similar results [27]. In line with the present results, Aoki et al. (2012) study showed that patients in the UPSF group had a more significant improvement in terms of VAS score for low back pain, lower limb, and limb numbness compared to the BPSF group [28]. However, the results of some studies have shown that there is no statistically significant difference between the two groups, UPSF and BPSF, in terms of pain and functional disability two years after surgery [5,16]. Sánchez et al. (2017) also reported similar results [13]. A prosthesis in the lumbar region increases the stiffness of the instrumented segment, causing patients to complain of prosthesis pain after surgery. Therefore, unilateral prosthesis use increases flexibility in the lumbar region, making patients feel more comfortable [29]. Additionally, UPSF exclusively employs unilateral laminectomy for decompression, which minimizes the damage to fascia and paravertebral muscles. The preservation of anatomical structure and unilateral dissection of muscles result in early recovery and increased functional rehabilitation following the surgery. Another reason is the short stretching time of the paraspinal muscles during surgery in the UPSF and Laminectomy groups. According to Nam et al. (2014), the paraspinal muscles' traction for more than 80 min accounts for only approximately 50 % of the total muscle strength at six months postoperatively. The authors also reported that the insufficiency of these muscles could result in low back pain (LBP) and increased functional disability [30].

In the final follow-up, the average quality of life score in the UPSF group was significantly higher than that of the other groups, and the lowest average quality of life score was observed in the laminectomy without fixation group. In this regard, Huarong et al. (2017) examined two groups of laminectomy surgery without fixation and laminectomy with UPSF. They believed that patients in the UPSF group had more improvement and enjoyed a high quality of life [31]. Contrary to the above results, most studies showed that the highest average quality of life score belonged to the laminectomy group without fixation [32]. Pei Lu et al. (2018) demonstrated no significant difference in quality of life one year after surgery between the UPSF and BPSF groups [33]. The age group of patients may be the reason for the discrepancy in results between the present study and other studies. Young patients have an active lifestyle and must perform high physical activities, carry heavy objects, perform sudden and fast movements, and work in specific jobs. Nevertheless, patients who undergo laminectomy without fixation are restricted to performing daily activities due to their concern of recurrent disc and reoperation, which hurts their quality of life and individual performance. Remes et al. (2006) conducted a study on young people. They found that, following laminectomy, the patients experienced a diminished quality of life, and a few of them experienced disc recurrence one year later [34].

The study showed that the disc did not recur in either UPSF or BPSF groups. However, some patients had a recurrent disc in the laminectomy group without fixation. In line with the results of the present study, Zecheng et al. (2020) also showed that 24 months after surgery, no recurrent disc was observed in any of the UPSF and BPSF fixation groups [29]. Huarong et al. (2017) state that in the laminectomy group without fixation, they witnessed a decrease in vertebral height and recurrent discs in some patients 24 months after surgery [31]. Shin et al. (2019) reported a similar finding [3]. One advantage of laminectomy is that it provides sufficient working space and outstanding discernibility by removing posterior elements, including the spinous process, the supraspinous ligament, and the interspinous ligament. The laminectomy removes the bony structure that causes secondary instability of the spine and trunk extensor weakness. The instability of the spine leads to a decrease in the height of the evacuated disc space after surgery, and the possibility of disc recurrence is common in most cases. Reoperation is necessary for disc recurrence. Reoperations are associated with a risk of surgical failure and dura mater injury as a result of the adhesion resulting from the previous surgery and the alteration in the anatomical structure. Therefore, the restriction of the spine minimizes this complication.

In the present study, no cases of adjacent segment disease (ASD) were observed in either the UPSF or BPSF groups. However, contrary to these findings, it is reported that extreme rigidity caused by bilateral screw fixation leads to the development of adjacent segment disease (ASD). Fukushima et al. (2020) reported that some patients in the BPSF group developed ASD 24 months after surgery [4]. Similar results were reported by Serdar et al. (2017) [8]. Aoki et al. (2012) noted that ASD was observed six months after surgery in the BPSF group and 12 months after surgery in the UPSF group [28]. The absence of interbody cage use in the present study is the reason for the difference in our results compared to other studies. During the discectomy procedure, interbody cage placement with PSF leads to loss of motion function during the arthrodesis period and accelerates adjacent segment degeneration. PSF without an interbody cage can limit the inactive range of motion and disc loads between adjacent vertebrae while maintaining control over the functional range within natural limits [35]. Some studies have shown that cageless UPSF can delay the disc degeneration rate between vertebral levels following surgery [31]. According to some researchers, the BPSF Method is more stable than UPSF regarding lateral flexion and axial rotation. At the same time, the latter is less secure in terms of preventing the fusion cage from withdrawing [36]. The results of Kim et al. (2014) showed that the stability of unilateral fixation was related to the way of decompression. Unilateral decompression could reduce the stress concentration of the adjacent segment and provide high mechanical stability for the fusion segment. Conversely, bilateral decompression could not provide adequate mechanical stability for the fusion segment [37]. Overall, unilateral spinal column fixation prevents posterior element degeneration, preserves the anatomical structure, enhances patient recovery, and improves quality of life by preventing height reduction and disc recurrence. In other words, unilateral spinal fixation, while preserving paravertebral muscles, facet joints, lamina, and contralateral ligamentum flavum, minimizes the risks during and after surgery compared to other investigated methods.

5. Limitations

One of the limitations of the study is its focused nature. In other words, the type of surgery, the speed of the surgeon's operation, and the facilities of the treatment centers are among the factors affecting the treatment results. Therefore, there is a need to conduct more extensive studies in multiple treatment centers. Furthermore, the current study's sample size may not be sufficient to demonstrate significant differences between groups. By increasing the sample size, the statistical results become more accurate. It is reported that significant differences may be observed in certain data. Therefore, more studies with a larger sample size are needed. Furthermore, the duration of follow-up may differ among studies, which may result in differences in results when compared to other studies. In other words, patients' radiological results and disc recurrence may exhibit different results as the follow-up time increases.

6. Conclusion

The laminectomy without fixation surgical method has a shortened operating time and less bleeding; however, disc recurrence, the need for reoperation, and reduced quality of life in young patients are significant adverse outcomes. The fusion rate was reported to be the same in BPSF and UPSF groups. However, the bleeding and operation time of the BPSF procedure are greater than those of other methods. In addition, the BPSF method reported a higher level of pain and functional disability than the other groups as a result of the installation of bilateral screws. Therefore, the surgical method of unilateral fixation without a cage, while preserving the anatomical structure, provides favorable intraoperative outcomes and clinical and radiological results after surgery in two-level disorders of young patients.

Ethics approval

This study was reviewed and approved by Ethics Committee of Hamedan University of Medical Sciences with the approval number: IR.UMSHA.REC.1402.553, dated 1-8-2023.

Consent to participate

All patients provided written informed consent to participate in the study, publication of radiological images and for their data to be published. The principles of the Helsinki Declaration were adhered to in this study.

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Availability of data and materials

Data associated with the study has not been deposited into a publicly available repository. Data are available from the corresponding author on reasonable request.

CRediT authorship contribution statement

Parisa Hajilo: Visualization, Project administration, Formal analysis. **Behzad Imani:** Writing – review & editing, Supervision, Investigation. **Shirdel Zandi:** Writing – original draft, Investigation, Data curation. **Ali Mehrafshan:** Validation, Methodology, Funding acquisition. **Salman Khazaei:** Validation, Software, Formal analysis.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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