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Safety and feasibility of mini-open Wiltse approach in posterolateral lumbar stabilization and fusion: intra- and post-operative evaluation

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Abstract

Background Expected operative challenges in minimally invasive spine surgeries as a result of restricted surgical field, unfamiliarity with surgical approaches and fear of complications are behind the preference of using traditional "open" spine surgery.

Objectives To evaluate the safety and feasibility of mini-open Wiltse approach in comparison with the conventional midline approach for posterolateral lumbar stabilization and fusion.

Patients and methods A retrospective comparative study conducted on 49 patients with low grade single level lumbar spondylolisthesis who were surgically treated in our Department between May 2020 and May 2022. Patients who were surgically treated with traditional midline approach were included in group (A) and patients in whom the mini-open Wiltse approach was used, were assigned to group (B). The two groups were compared regarding various intra and postoperative parameters.

Results Group (A) included 27 patients (55.1%) operated upon with the classic midline approach and 22 patients (44.9%) were surgically treated using the Wiltse approach (group B). The mean patients' age (50.43 ± 5.538) years and L4-5 was the most commonly affected level (71.4%). The intra-operative parameters (operation time, blood loss and fluoroscopy time) showed significant lower results ($P < 0.001$) among patients of group (B). No cases in the group (B) required blood transfusion versus 5 cases in group (A) ($P = 0.033$). Postoperatively, the Oswestry Disability Index (ODI) and Visual analogue scale (VAS) scores were significantly improved in each group in comparison to the preoperative scores ($P < 0.001$). However, after 3 months the ODI score in group (B) was superior to that in group (A) ($P = 0.045$) and postoperative VAS score in group (B) was significantly improved compared to that in group (A) at discharge ($P = 0.016$), and also after 1 and 3 months ($P < 0.001$). Patients operated with Wiltse approach had a shorter duration of hospital stay but the difference was not statistically significant ($P = 0.090$).

Conclusions Because of minimal trauma to the muscles and soft tissues, the mini-open Wiltse approach can be faster, safer and requires less recovery time as opposed to the classic midline approach.

Keywords Wiltse approach, Classic midline approach, Spondylolisthesis, Minimally invasive

Introduction

Lumbar spondylolisthesis, in which one vertebral body slips forward relative to the vertebral body below, commonly occurs at the L4-L5 level and is one of the most prevalent diseases requiring spine surgery [1]. Dynamic X-ray, Computerized Tomography (CT) and Magnetic

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Resonance Image (MRI) of the lumbosacral spine are essential for its diagnosis and management [2].

Successful surgical treatment necessitates adequate nerve roots decompression, stabilization, reduction or restoration of balance, and obtaining a good fusion [3, 4]. The classic posterior midline approach necessitates complete separation of the paraspinal muscles from their attachment points on spinous processes and lamina. This approach may be associated with ligament and muscle damage and frequent intraoperative hemorrhage. Postoperative back pain and long standing physical restrictions may be a drawback of the classic approach that increases the costs of care [5].

Minimally invasive approaches to the lumbar spine have revolutionized the way of management for different lumbar disorders. A controversial aspect regarding the minimally invasive techniques is the cost-effectiveness, on whether the reduction in blood loss and hospitalization times can compensate for the costlier materials needed to perform minimally invasive surgeries [6].

One of the minimally invasive techniques is the Wiltse paraspinal approach that has been identified by Wiltse in 1968 and originally used double-skin incision; that was improved to one-skin incision since 1988 [7, 8]. The mini-open Wiltse approach was described as an alternate direct approach to the facet joint and transverse process [9, 10]. Being a muscle-splitting approach through the sacrospinalis muscle and between the multifidus and longissimus muscles, the Wiltse approach theoretically can minimize the intraoperative tissue damage [11].

Expected operative challenges in minimally invasive spine surgeries as a result of restricted surgical field, unfamiliarity with the surgical approaches and fear of complications are behind the preference of using traditional "open" spine surgery. And so, our objective was to evaluate the safety and feasibility of the mini-open Wiltse approach in comparison with the conventional midline approach for posterolateral lumbar stabilization and fusion.

Patients and methods

Study design and patients population

After approval by the local ethical scientific committee of our institution (IRB approval number: 3–2023.NEUS.1–4), this retrospective comparative study was conducted on patients with a diagnosis of low grade single level lumbar spondylolithesis who were admitted and surgically treated in our Neurosurgery Department between May 2020 and May 2022.

We included patients with radiological diagnosis (through lumbosacral radiographs, CT scan and MRI) of one-segment lumbar spondylolithesis of grade 1 or 2 combined with a complaint of low back pain, radiating

pain in lower limbs or intermittent claudication; with no response to conservative treatment for a minimum of three months after diagnosis. We excluded patients with: (1) more than one lumbar segment lesion that needed surgery, (2) history of previous lumbar surgery, or (3) insufficient data.

Patients who met our inclusion criteria were divided into 2 groups according to the used surgical approach; group (A) included patients who were surgically treated with the traditional midline approach and group (B) included patients in whom the mini-open Wiltse approach was used. The two groups were compared regarding various intra and postoperative parameters and also regarding the short-term outcome results.

Sample size estimation

The sample size to study the results of the current study with a significant $P < 0.05$ and power of study of 80% was calculated by the academic research department in our institution and so, at least, 20 patients should be recruited in each of the 2 groups of the study with a minimal total sample size of 40 participants.

Data collection

The preoperative data, operative notes and postoperative results were collected from the patients' medical records of our department. Preoperative data included: age; sex; previous lumbar surgery; duration of symptoms; clinical presentations; radiological criteria including (level and degree of spondylolithesis, associated conditions such as intervertebral disc protrusion or degenerative lumbar stenosis). Operative notes included: operation time; intraoperative blood loss; the need for intraoperative blood transfusion; intraoperative fluoroscopic time. Postoperative data included: drainage volume, need for blood transfusion; pain improvement; length of postoperative hospital stay; the position of pedicle screws and interbody fusion cages in plain X-ray and/or CT scan of the lumbar spine.

Surgical techniques

For all cases, surgery was done under general anesthesia with the patient in prone position on a radiolucent operating table with two supports placed between the chest and the pelvis. Fluoroscopy was used for marking the desired level. Skin preparation with antiseptic solution followed by draping.

For classic midline approach

A midline skin incision was made then fascia was incised vertically. The paraspinal musculature was detached from the spinous process and laminae in a subperiosteal fashion and bilaterally retracted. The entry site for pedicle

screws in the lumbar region is at the junction of the lateral facet and transverse process. The area surrounding the entry point was first decorticated by using a high speed drill or rongeur. A medially curved pedicle probe was used to develop a path for the screw into the vertebral body. A ball-tipped pedicle-sounding probe was used to palpate for any breach of the four cortical surfaces and the depth.

Next, the path can be tapped with smaller diameter threads. Screws of adequate length and diameter were then inserted along the created path. Antero-posterior (AP) and lateral fluoroscopy may be used at any of the previously steps to confirm trajectory. The screws were later connected to a rod by using set screws that are tightened to the appropriate amount of torque; then bone graft was placed.

Decompression and interbody fusion was performed using standard techniques to remove the spinous process, lamina, and ligamentum flavum, along with facetectomy and decompression of exiting nerve root and finally insertion of the cage. Hemostasis was performed and copious antibiotic irrigation of the exposed tissues was performed at the completion of the procedure. Figure 1 illustrates the pre and postoperative radiological images for a patient with L4-5 grade 1 spondylolisthesis; the patient was operated through the classic midline approach.

For Wiltse approach

Either two paramedian skin incisions nearly 1.5–2 cm from midline followed by two longitudinal incisions in

the muscular aponeurosis or a single midline incision was performed followed by subcutaneous dissection. Superficial and deep fascia was opened longitudinally. There was no tissue damage due to blunt dissection by finger from the loose cleavage line between the pars lumborum section of the longissimus muscle and the multifidus muscle. Identifying the transverse process by palpation before deperiostization is important to avoid excessively deep approach. The lumbar transverse processes were denuded of soft tissue all the way up to their tips and well around their superior and inferior borders, for visualization of anatomical landmarks. Facet joints of the desired lumbar vertebrae were easily reached. The laminae of the vertebrae to be fused were exposed well up onto the sloping basis of the adjacent spinous process.

After dissection, facetectomy was done for decompression and interbody fusion. Laminectomy and removal of the hypertrophic ligamentum flavum was done. Discectomy was made (in Wiltse's approach there is easy access to extraforaminal and foraminal portions of the disc space). Transforaminal interbody fusion (TLIF) was done using a PEEK cage packed with autograft after decompression of the spinal canal. After the entry site was determined, the guide pin was inserted using guider according to the entry direction measured before operation then pedicle screws were inserted between the muscles (pedicle screws need more convergence and screw heads go deeper than in midline approach). The same intramuscular approach was used to place the pedicle screws on the opposite side. Fascia was closed with running stitches. It is important to close the superficial

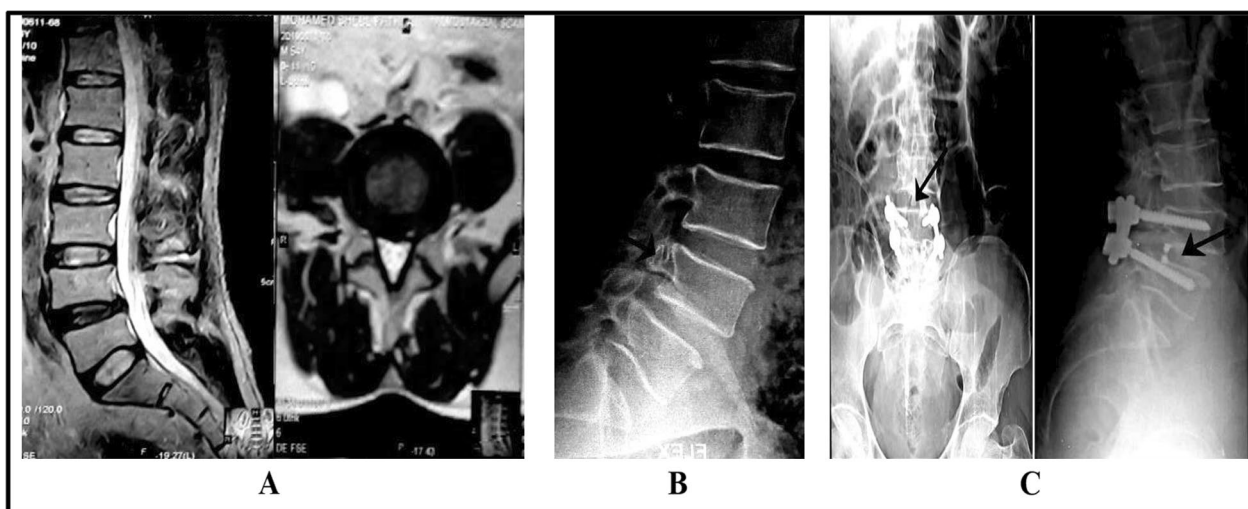


Fig. 1 Adult patient above 50 years, presented with low back pain and claudication pain with no neurological deficit. Patient underwent decompression, stabilization and fusion using the Conventional Midline Approach. **A** Preoperative MRI of lumbosacral spine showing slippage of L4 over L5 and L4-5 diffuse disc prolapse; **B** Preoperative X-ray showing fracture pars at level 4,5; **C** Postoperative X-ray showing pedicle screws in L4 and L5; the arrow points to the cage

fascia with the subcutaneous tissue to avoid seromas. Skin was then closed with an intradermic suture. Figure 2 illustrates the pre and postoperative radiological images for a patient with L4-5 grade 1 spondylolisthesis; the patient underwent posterolateral stabilization and fusion through the Wilts approach.

Postoperatively for all cases:

(1) Drain was removed at 24–72 h after operation according to drainage volume, followed by routine dressing, (2) antibiotics, analgesia and anti-inflammatory drugs were given, (3) patients were encouraged to exercise out of bed as early as possible, and (4) lumbar brace was advised.

Indicators for comparison

Intraoperative indicators: (1) operation time (the total time from skin incision to skin closure), (2) intraoperative blood loss (the total blood loss collected in the aspirator during operation plus blood loss in gauzes estimated by weighing), (3) the need for intraoperative blood transfusion, and (4) intraoperative fluoroscopic time (total number of radiation shots that reflects automatic accumulation of exposure time to C-arm X-ray machine during operation).

Postoperative indicators: (1) drainage volume (total drainage volume after operation), (2) blood transfusion

rate (the proportion of patients who needed postoperative blood transfusion), (3) length of hospital stay after surgery, (4) Oswestry Disability Index (ODI) demonstrated in Table 1 [12], and (5) Visual Analogue Scale (VAS) score for lower back pain, where 10 points reflects the worst imaginable pain while no pain takes 0 points. Both the ODI and VAS scores were assessed at discharge and at 1 and 3 months after operation then compared to the preoperative scores.

Statistical analysis

To tabulate and statistically analyze the results, SPSS V.22 (IBM Corporation, 1 Orchard Rd, Armonk, NY 10504, USA), and Microsoft Excel 2010 (Microsoft Corporation, One Microsoft Way Redmond, WA 98052–6399 USA) were used. The descriptive statistics included mean (\bar{x}), and standard deviation (SD). The count data were expressed as the rate and analyzed using the chi-square test (χ^2). Standard Student t-test (t) for paired samples was used for the comparison between different pre and postoperative means. Standard Student t-test (t), for independent samples was used for comparing the means between the 2 groups in various factors of the study. P value ≤ 0.05 was considered statistically significant.

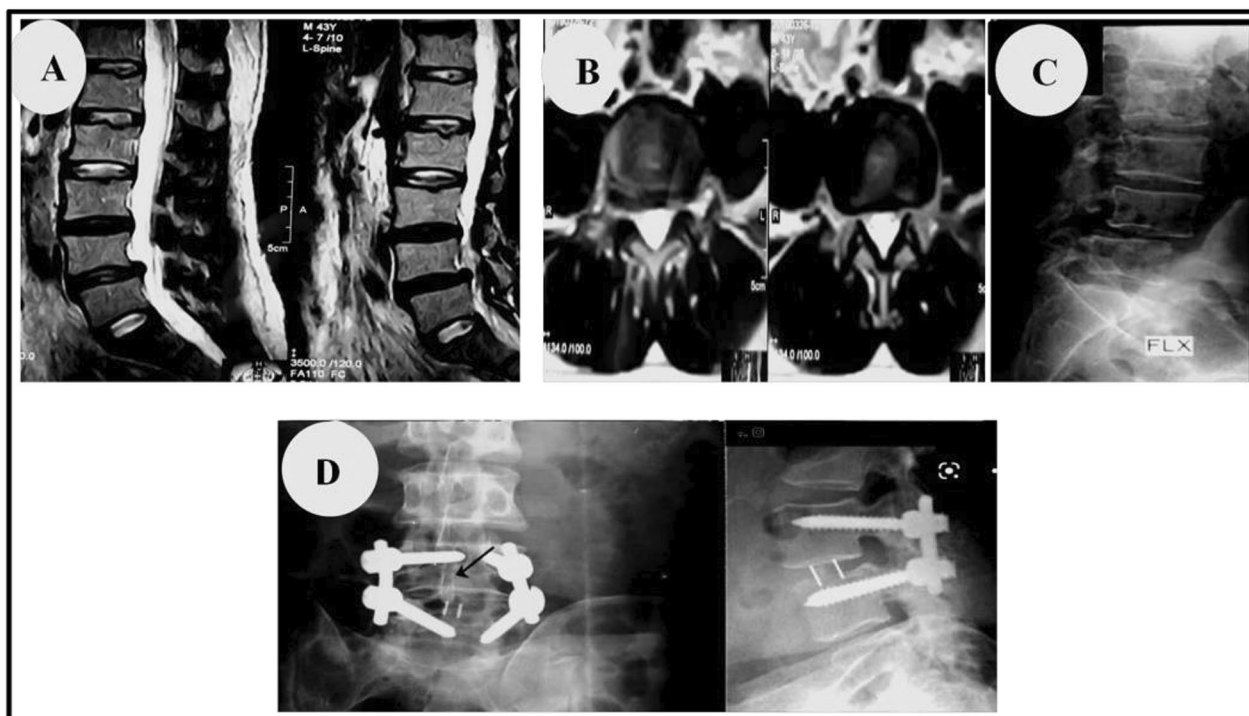


Fig. 2 Adult patient above 40 years, presented with low back pain and sciatic pain, was operated by Wiltse Approach. **A** MRI sagittal view showing slippage at L4-5; **B** MRI axial view showing pseudo-disc with no significant stenosis; **C** X-ray showing L4-5 grade 1 slippage with fracture bars interarticularis; **D** Follow up X-ray (A-P and lateral views) after 3 months with arrow pointing to the cage and the lamina was preserved

Table 1 The Oswestry disability index [12]

Score	Description
0–20% Minimal disability	The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting, sitting and exercise
21–40% Moderate disability	The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity and sleeping are not grossly affected and the patient can usually be managed by conservative means
41–60% Severe disability	Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation
61–80% Crippled	Back pain impinges on all aspects of the patient's life. Positive intervention is required
81–100%	These patients are either bed-bound or exaggerating their symptoms

Table 2 Preoperative data of patients in the two groups:

Parameters	Group A (n = 27)	Group B (n = 22)	P value
Age in years (mean ± SD)	51.56 ± 4.774	49.05 ± 61.84	0.115
Gender (Male/Female)	11/16	8/14	0.754
Clinical presentations			0.910
Back pain	27	22	
Unilateral radiculopathy	18	15	
Bilateral radiculopathy	7	6	
Weakness	3	2	
Symptoms duration (months)	9.96 ± 4.519	10.82 ± 2.684	0.438
Comorbidities	5	4	0.976
Level			0.971
L3-4	3	2	
L4-5	19	16	
L5-S1	5	4	
Degenerative conditions			0.696
LDH	3	2	
LCS	6	3	

Group A: patients operated with conventional approach; Group B: patients operated with Wilts approach; Comorbidities: including hypertension, Diabetes Mellitus or other chronic diseases; LDH: Lumbar disc herniation; LCS: Lumbar canal stenosis

Results

For the entire sample; the mean age of included patients was (50.43 ± 5.538) years, females constituted the majority of included cases (61.2%), and L4-5 was the most commonly involved lumbar level (71.4%). Group (A) included 27 cases (55.1%) that were treated using the conventional midline approach and group (B) included 22 cases (44.9%) in whom Wiltse approach was used.

Table 2 demonstrates the preoperative data of patients in the two groups. Noticeably, there were no statistically significant differences between the 2 groups in regards to age, gender, symptoms duration, clinical presentations, spondylolithesis level or concomitant degenerative conditions ($P > 0.05$).

Table 3 Intra and postoperative data of patients in the two groups:

Parameters	Group A (n = 27)	Group B (n = 22)	P value
<i>Intra-operative indicators</i>			
Operation Time (min)	126.85 ± 10.571	111.50 ± 10.441	< 0.001*
Intraoperative blood loss (ml)	381.33 ± 129.600	210.45 ± 65.780	< 0.001*
Fluoroscopy time (shots)	17.74 ± 1.953	13.36 ± 2.083	< 0.001*
<i>Postoperative indicators</i>			
Volume of Drain (ml)	149.41 ± 53.485	91.36 ± 17.195	< 0.001*
Blood transfusion rate	5	0	0.033*
Hospital stay (days)	2.74 ± 1.023	2.32 ± 0.568	0.090

Group A: patients operated with the conventional approach; Group B: patients operated with the Wilts approach; min: minutes; ml: milliliters; *statistically significant

Intra and postoperative data (Table 3)

The intra-operative parameters (operation time, intraoperative blood loss and fluoroscopy time) showed statistically significant lower results ($P < 0.001$) among patients of group (B). In the early postoperative period, the volume of blood collected in drains was significantly smaller ($P < 0.001$) in group (B) compared to that in group (A). No cases in group (B) required blood transfusion versus 5 cases in group (A) ($P = 0.033$). Patients operated with Wilts approach had a shorter duration of hospital stay but the difference was not statistically significant ($P = 0.090$). Postoperative complications are illustrated in Fig. 3; with no significant difference between the 2 groups ($P = 0.411$).

Clinical outcome (ODI and VAS scores)

As demonstrated in Table 4; there were no significant differences between the two groups in regards to ODI or VAS scores before operation ($P > 0.05$). Considerably, the postoperative ODI and VAS scores were significantly improved in both groups in comparison to the

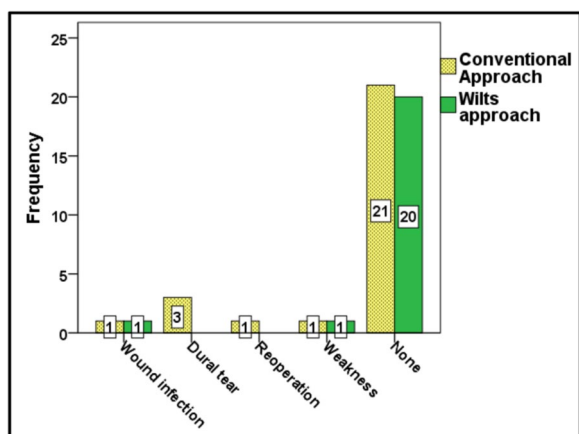


Fig. 3 Postoperative complications among patients of the 2 groups. The incidence of operative related complications was higher among patients operated with the conventional approach, however the difference was not statistically significant ($P=0.411$). Postoperative complications were encountered in 6 cases belonged to group (A) versus 2 cases in group (B). No cases in group (B) had intraoperative dural tear and also none of them required re-surgery

Table 4 Clinical outcome among patients in the two groups:

Parameters	Group A (n=27)	Group B (n=22)	P value
<i>VAS scoring</i>			
Preoperative	8.33 ± 0.734	8.14 ± 0.774	0.367
At discharge	3.85 ± 1.064	3.09 ± 1.065	0.016*
After 1 month	3.15 ± 0.718	1.32 ± 0.839	<0.001*
After 3 months	2.74 ± 0.813	1.27 ± 0.827	<0.001*
<i>ODI</i>			
Preoperative	67.56 ± 10.885	69.59 ± 8.081	0.457
After 3 months	29.56 ± 6.991	25.73 ± 5.775	0.045*

Group A: patients operated with conventional approach; Group B: patients operated with Wiltse approach; VAS score: Visual Analogue Scale score; ODI: Oswestry Disability Index; m: months; *statistically significant

preoperative scores ($P<0.001$). There was significant difference between the 2 groups regarding the postoperative ODI score at 3 months ($P=0.045$) where the ODI score in group (B) was superior to that in group (A). Also, VAS scores in group (B) were significantly improved in comparison to group (A) at discharge ($P=0.016$), then at 1 and 3 months after operation ($P<0.001$).

Discussion

Our study was conducted on 49 patients who underwent pedicle screws insertion plus interbody fusion for single level low grade lumbar spondylolithesis. A comparison of the intra and postoperative parameters was made between cases operated through the conventional mid-line approach (group A) versus those operated through

Wiltse approach (group B) in order to identify the points of safety and feasibility of using the Wiltse approach in lumbar spine stabilization and fusion.

In our study, there were no significant differences ($P>0.05$) between the 2 groups regarding all the preoperative data and this is consistent with most of previous studies that addressed a comparison between the 2 approaches for lumbar spine surgery [13–15].

Figure 4 illustrates the difference between the two approaches regarding the intraoperative parameters. In patients operated through Wiltse approach; the intraoperative blood loss and postoperative blood exudation caused by excessive intraoperative peeling of paraspinal muscles was avoided, where the mean intraoperative blood loss was (381.33 ± 129.600) ml in group (A) compared to (210.45 ± 65.780) ml in group (B) with a significantly decrease ($P<0.001$). The mean postoperative drainage volume in group (B) was (91.36 ± 17.195) ml, which was also significantly lower ($P<0.001$) compared with that in group (A) (149.41 ± 53.485) ml. In group (B), no patients required blood transfusion compared to 5 patients (18.5%) in group (A).

Our results are similar to that reported by Oliver et al. [8], Tsutsumimoto et al. [16] and Patel et al. [17] in terms of perioperative hemorrhage. Also, Ulutaş M and associates [18] reported that a significant difference was found between the classic approach and Wiltse approach regarding the perioperative hemorrhages ($P=0.001$). Li et al. [15] also reported significant decrease in the intraoperative bleeding and postoperative drain volumes in patients operated through Wiltse approach ($P=0.01$).

In lumbar spine fusion surgery, fluoroscopy is of great importance in verifying the accuracy of positions for pedicle screws and interbody fusion cages. In our study and although the local anatomical structures were used to guide the position of screws in both groups; the fluoroscopic time in group (A) was longer than in group (B) ($P<0.001$). The explanation why less radiation exposure was needed in cases operated through the Wiltse approach can be due to, in Wiltse approach, accurate head–tail tilt angles of pedicle screw could be obtained according to the positioning of supraspinous ligament. Our result is in agreement with Li et al. [15] study, they reported a shorter time of fluoroscopy use in mini-open TLIF via Wiltse approach in comparison to the conventional open TLIF for treating single-segment lumbar degenerative disease ($P<0.01$).

In our case series, the mean operative time was (126.85 ± 10.571) minutes in group (A) versus (111.50 ± 10.441) minutes in group (B) with statistically significant difference ($P<0.001$). This result comes in accordance with the results of previous studies. Li et al. [15] reported a significant difference in the operation

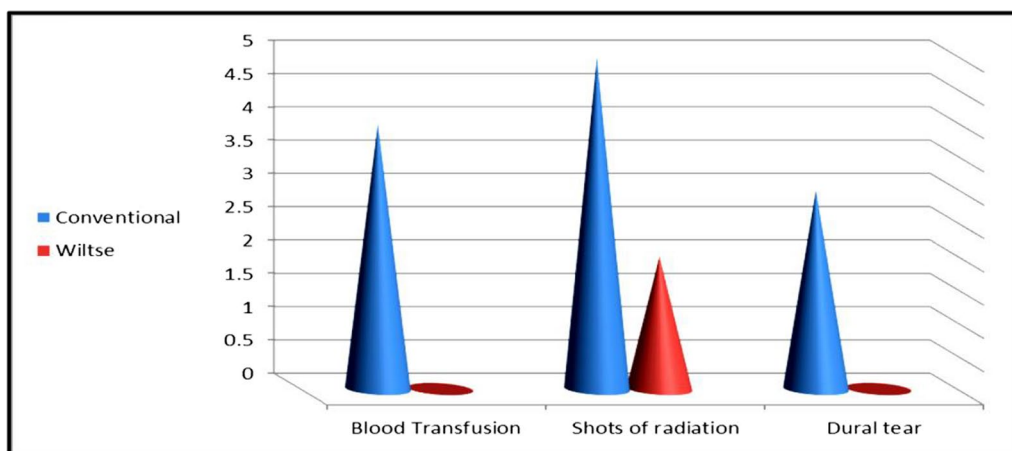


Fig. 4 Comparison of the intraoperative parameters (Dural tear, Shots of radiation, Blood transfusion) between the two groups. These parameters showed significant lower results ($P < 0.001$) among patients of group (B)

time ($P = 0.028$) where the time was (125.1 ± 20.0) minutes for classic approach and (115.2 ± 18.8) minutes for Wiltse approach. Also, in Jin et al. [19] study the operation time was (145.65 ± 16.98) minutes for classic approach and (119.20 ± 14.64) minutes for Wiltse approach ($P < 0.05$). On the other hand, some of previous studies did not find significant difference regarding the time of surgery between the conventional approach and Wiltse approach [13, 18].

In regards to the postoperative VAS score for low back pain; we found significant improvement in patients operated upon with the Wiltse approach compared to those operated through classic approach. The significant difference was observed at time of discharge ($P = 0.016$), and during follow up at 1 and 3 months postoperatively ($P < 0.001$). Our finding is similar to the result reported in Ulutaş et al. [18] study where significant lower values of VAS score were found in patients operated with Wiltse approach (0.023 and 0.039) at 1 and 6 months after surgery. Also, in Li et al. [15] study significant decrease in the VAS score was reported ($P < 0.01$) at 3 days, 1 week after surgery and the time of the last follow up. Jin et al. [19] reported postoperative improvement of the VAS scores in the Wiltse TLIF group than those in the conventional open group ($P < 0.05$). Furthermore, in Mohi Eldin et al. [14] study where mini-open TLIF combined with transpedicular screw fixation was used for spondylolisthesis and degenerative disc disease, the mean VAS was 7.5 preoperatively, 1.86 at discharge, 1.68 after 3 months, and 1.38 after 6 months with significant difference ($P < 0.05$).

In our case series, although the duration of hospital stay was shorter in patients operated with Wiltse approach, the difference was not statistically significant

($P = 0.090$). Our result is similar to that reported by Street JT and associates [13] in their study where there was no significant difference regards the duration of hospital stay where the mean duration was 7.5 days in conventional approach versus 6 days in Wiltse approach ($P = 0.069$). In contrary to our result, Li et al. [15] reported a significant difference regarding the hospital stay ($P = 0.009$). Also Ulutaş et al. [18] found that the mean duration of stay was (3.42 ± 1.27) days in conventional approach versus (2.26 ± 0.96) days in Wiltse approach ($P = 0.001$). Jin et al. [19] also reported significant decrease in duration of hospitalization among patients operated through Wiltse approach ($P < 0.05$).

We found that, although the postoperative ODI score (3 months after surgery) was improved in each group in comparison to the preoperative score, a significant difference was statistically found between the two groups ($P = 0.045$) where the ODI score in group (B) was superior to that in group (A). Li et al. [15] study also reported a significant difference between the groups in ODI at the last follow up ($P = 0.01$). Jin et al. [19] reported that preoperative ODI score was improved in each group ($P < 0.05$) however, no significant difference was found between the 2 groups where ODI was (14.39 ± 7.45) in classic approach and was (15.38 ± 6.12) in Wiltse approach.

With regards to the operative related complications in our series, there was no significant difference between the 2 groups. Wound infection was encountered in 2 cases; one in each group; the two cases improved with antibiotics plus repeated dressings. Three cases in group (A) had dural tear but this was recognized intraoperative and dura was sutured. Two patients had postoperative weakness; one in each group and this was improved

with medication and physiotherapy. One patient belongs to group (A) required repeated surgery for realignment of screws. Nearly all previous studies didn't report significant difference in postoperative complications between the conventional or the wiltse approaches [13, 15, 18–20].

Study limitations

Limitations of our study come from its retrospective nature. Operations were done by different surgeons. Also, this study was a single center experience and to a lesser extent of a small sample size. However, we believe that this baseline information can encourage the wide use of Wiltse approach in our region.

Conclusions

Because of minimal trauma to the muscles and soft tissues, the mini-open Wiltse approach can be faster, safer and requires less recovery time as opposed to the classic midline approach. So, when feasible, the Wiltse approach might have the preference for patients undergoing posterolateral stabilization and fusion for lumbar low degree instability.

Abbreviations

AP	Antero-posterior
CT	Computerized topography
cm	Centimeter
ml	Milliliter
MRI	Magnetic resonance imaging
ODI	Oswestry disability index
TLIF	Transforaminal interbody fusion
VAS	Visual analogue scale

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Author contributions

All authors made a significant contribution to the work reported, whether that was in the conception; study design; execution; and acquisition, analysis and interpretation of data. All authors took part in drafting, revising and final approval of the article. All agreed to be accountable for all aspects of the work.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by the clinical research committee of the Menoufia University Hospital and it followed the tenets of the Declaration of Helsinki. (IRB approval number: 3-2023.NEUS. 1-4). Being a retrospective study, patients' consents for participation in the study were not applicable.

Consent for publication

Not applicable because of the retrospective nature of our study.

Competing interests

The authors declare that they have no competing interests.

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