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Original Article

Posterolateral instrumented fusion with and without transforaminal lumbar interbody fusion for the treatment of adult isthmic spondylolisthesis: A randomized clinical trial with 2-year follow-up

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Abstract

Background: Spondylolisthesis is a common cause of surgery in patients with lower back pain. Although posterolateral fusion and pedicle screw fixation are a relatively common treatment method for the treatment of spondylolisthesis, controversy exists about the necessity of adding interbody fusion to posterolateral fusion. The aim of our study was to assess the functional disability, pain, and complications in patients with spondylolisthesis treated by posterolateral instrumented fusion (PLF) with and without transforaminal lumbar interbody fusion (TLIF) in a randomized clinical trial. **Materials and Methods:** From February 2007 to February 2011, 50 adult patients with spondylolisthesis were randomly assigned to be treated with PLF or PLF+TLIF techniques (25 patients in each group) by a single surgeon. Back pain, leg pain, and disability were assessed before treatment and until 2 years after surgical treatment using visual analog scale (VAS) and oswestry disability index (ODI). Patients were also evaluated for postoperative complications such as infection, neurological complications, and instrument failure. **Results:** All patients completed the 24 months of follow-up. Twenty patients were females and 30 were males. Average age of the patients was 53 ± 11 years for the PLF group and 51 ± 13 for the PLF + TLIF group. Back pain, leg pain, and disability score were significantly improved postoperatively compared to preoperative scores ($P < 0.001$). At 3 months of follow-up, there was no statistically significant difference in VAS score for back pain and leg pain in both groups; however, after 6 months and 1 year and 2 years follow-up, the reported scores for back pain and leg pain were significantly lower in the PLF+TLIF group ($P < 0.05$). The ODI score was also significantly lower in the PLF+TLIF group at 1 year and 2 years of follow-up ($P < 0.05$). One screw breakage and one superficial infection occurred in the PLF+TLIF group, which had no statistical significance ($P = 0.373$). **Conclusion:** It seems that accompanying TLIF with PLF might lead to better functional improvement and pain reduction in patients with spondylolisthesis.

Key words: Posterolateral instrumented fusion (PLF), spine, spondylolisthesis, transforaminal lumbar interbody fusion (TLIF)

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INTRODUCTION

Adult Isthmic spondylolisthesis, which is associated with "spondylolysis," is defined as an osseous discontinuity of the vertebral arch at the isthmus (the *pars interarticularis*), which usually occurs in the fifth lumbar vertebra.[1,2] The prevalence of isthmic spondylosis is proposed to be about 6-8%[2,3] in different studies and the incidence varied 4-8%[1,4] but the incidence may even rise up to 26% among the Eskimo populations,[5] which is proposed to affect more men than women.[2,3]

Conservative treatments including braces, physical therapy, and medication are shown to be effective for some patients; however, surgical treatments are mainly the final effective treatment. There are several different options for surgery among which posterolateral fusion (PLF) is considered as the method of choice.[3] It is shown that PLF is more effective than conservative treatments such as exercise. The fusion helps to fix the motion of the affected segment and therefore, might lead to pain reduction.[6] Decompression (gill laminectomy), supplemental instrumentation, and supplemental anterior column support are also considered for treatment.[6] These treatment strategies can be used separately or in any combination; however, studies trying to compare separate treatments with a combination of them have led to inconsistent results.[7]

Supplementary pedicle screw might be added to fusion methods for fixation and it is proposed that they have the ability to correct the deformity, reduce the listhesis, and increase the fusion rates[8] although a majority of the studies comparing instrumented PLF and noninstrumented PLF could not show the superiority of instrumented approaches.[8-11]

Some modifications in PLF have also been studied for their effectiveness. For example, a clinical study did not show any better effect in addition to anterior lumbar interbody fusion (ALIF),[12] bone graft substitution,[13] and decompression.[14]

Blume also described a unilateral approach to posterior lumbar interbody fusion (PLIF) to address some of the potential complications of the standard PLIF. [15] The unilateral transforaminal lumbar interbody fusion (TLIF) is a surgical technique in which bilateral anterior column support can be achieved through a unilateral posterolateral approach. In this method, posterior as well as anterior column stability is achieved when pedicle screw fixation is added.[16] Spinal fusion procedures are indicated with severe disabling symptoms and radiographic evidence of increased segmental motion that fails to respond to adequate conservative trial.[17] Segmental fusion provides solid fixation, restores the spinal stability, and maintains loadbearing capacity of the spine.[18] Considering all these advantages, PLIF has long been the "gold standard" surgical technique for lumbar segmental instability (LSI)[19] but since TLIF (a modification of PLIF by Harms[20]) has been introduced, it has been found to be a better technique for different other spinal disorders.[21-23] An alternative method of reconstructing the anterior column is *via* posterior lumbar interbody fusion. The transforaminal posterior lumbar interbody fusion technique involves a transforaminal approach to the anterior interspace, and it was thought that the disadvantages associated with the TLIF, for example, the epidural scarring, can be potentially avoided.[20] The hypothesis of the present study was that PLF with TLIF technique had less neurological complications such as postoperative pain compared with PLF alone. To the best of our knowledge, the effect of accompanying TLIF with PLF in treating spondylolisthesis has not been examined yet. The purpose of our study was to compare the two surgical procedures and identify procedure-specific complications. In the present study, we tried to study and compare the functional disability, pain, and complications in adult patients with spondylolisthesis treated by PLF with or without the TLIF method.

MATERIALS AND METHODS

Study design and participants

Fifty adult patients diagnosed with isthmic spondylolisthesis who referred to Al Zahra Hospital were recruited from February 2007 to February 2011, and assigned to be treated with PLF or PLF + TLIF techniques (25 patients in each group) by a single surgeon. The treatment method was randomly selected for 50 subjects by a statistician who was not aware of the study objectives. Sampling of patients was sequential and the patients randomly divided into two groups of intervention (25 patients) and control (25 patients) and the surgeon did not know about the division patients. Therefore, the surgical strategy was not recognizable for the surgeon and our study method became double-blind randomized clinical trial. The important point of this study was to abide by the medical ethics; all patients (case and control) received classical treatment (PLF). Patients were not included in the present study if they were younger than 20 years of age and had previous surgery or trauma in their spine. Fusion was assessed at the final follow-up on plain anteroposterior and lateral radiographs using the criteria suggested by Christensen *et al.*[24]

Surgical procedure

The patient is placed in prone position on a radiolucent spine table. Manipulative reduction should be applied first if obvious kyphosis is detected. Fluoroscopy is used to locate the fractured vertebral body. A posterior midline straight incision centered on the affected level is made to expose the laminae level above and below the affected level. Subperiosteal dissection is performed with an electric cuter until the facet joints on both sides are visualized.

Pedicle screws are introduced at a level below and above the affected level and also the fractured vertebral body[25,26] if the pedicles are intact and not expected to be removed for the purpose of decompression.

Spinal process and both laminae of the affected level are removed by rongeurs to decompress the posterior aspect of the thecal sac. Once posterior decompression was completed, the screws of both sides are distracted axially with contoured longitudinal rods to restore the segmental height and realign

the spinal columns, which are verified by C-arm x-ray monitoring. Then the screws of the more severe damaged side are released, and the ipsilateral facet joints are resected to reveal nerve roots. Epidural veins and radicular veins are cauterized with bipolar forceps to avoid massive bleeding. Dura mater is repaired if it is lacerated. Any adhesion between the posterior longitudinal ligament and the anterior surface of the thecal sac is released and thus, the thecal sac can be easily retracted to provide better exposure of the posterior portion of the vertebral body and the intervertebral discs. Then, the thecal sac and nerve root are gently retracted and protected with a nerve retractor, and the adjacent intervertebral discs are completely removed.

The retropulsed fragment of the fractured vertebral body is hammered anteriorly back into the corpus using an "L" angle dissector to recontour the posterior wall of the fractured vertebral body, at the same time decompressing the anterior aspect of the thecal sac.

Then, granulated bone graft made from the removed bone tissue is packed into the intervertebral space and some of the bone graft is packed into the vertebral body through the fractured endplate. Usually, the autougenous bone is not enough and additional allograft bone is needed. The appropriate size of cage is confirmed by models and the cage is packed with granulated autougenous bone, and then the cage is put into the intervertebral space and is positioned exactly at the midline. The same decompression procedure is performed on the contralateral side if it is necessary, and before that the longitudinal rod is changed to the other side.

When the decompression procedure is finished by a recheck of all the neural elements involved, a second rod is placed and tightened. A final verification of the screws and cages' positioning, alignment of the spinal columns, and vertebral body height is done using posteroanterior and lateral fluoroscopies, and then a drain is placed and the muscle, fascia, and skin are closed in the standard fashion.

Outcome variables

Back pain and leg pain were assessed using a visual analog scale (VAS) asking for the magnitude of the worst pain the patient experienced in his/her back or leg. The VAS questionnaire consisted of a 10 mm line that ranged from 0 (no pain) to 10 (intolerable pain). Disability score was quantified using the oswestry disability index (ODI). ODI is a validated 10-item ordinal scale instrument for the evaluation of spinal disorders in which each item has six response choices.[27] The items ask about pain intensity, personal care, ability to lift, walk, sit, stand, sleep, sex life, social life, and travelling. Normal function in each item is 0 and 5 is assigned when the disability is worst. The sum of the 10 items multiplied by 2 constitutes the total ODI score, which ranges 0-10.

Patients were also evaluated for postoperative complications such as infection, neurological complications, and instrument failure.

Statistical analysis

The differences between pain index and ODI scores for the comparison of scores before and after surgery visits within each study group were tested using repeated measures analysis of variance (ANOVA). Comparisons between groups were done using Student's *t*-test. In addition, the means and their corresponding standard deviations (SDs) are presented in tables and figures. Categorical variables including infection rate, postoperative complications, neurological complications, and instrument failure were compared using chi-square or Fisher's exact test where needed. All statistical procedures were accomplished using the Statistical Package for Social Sciences (SPSS, version 20.0 for Windows, SPSS, Inc., Chicago, IL). *P* value less than 0.05 was considered as statistically significant.

RESULTS

All patients completed the 2-year follow-up period and were included in the analysis. Participants' baseline characteristics based on surgical procedure including age, gender, ODI score, back pain, and leg pain are presented in Table 1. There was no statistical difference among the intervention groups according to baseline characteristics ($P > 0.05$).

Also In this study among 50 patients there were 36 cases (19 cases of TLIF and 17 cases of PLF) with grade I Spondylolisthesis, 13 cases (5 TLIF and 8 PLF) with grade II and there was a case (of TLIF) with grade III. There was no case of grade IV (Table 2).

None of patients in the PLF group experienced infection; however, in the PLF+TLIF group there was a patient (4%) with infection after the surgery. The infection was not significantly different between the two surgical procedures ($P = 0.37$). Instrument breakage was not seen in either group.

Back pain and leg pain were decreased in both the intervention groups ($P < 0.05$). There was no difference in back pain and leg pain between the surgical procedures up to the 3 months after the surgery. However, patients undergoing the PLF+TLIF procedure experienced significantly lower pain in the 6th month and first year and second year after the surgery (*P* value <0.05). The mean ± standard error of the mean (SEM) for VAS pain score in the back and leg according to follow-up

Table 1: Baseline clinical and demographic data[1]

Characteristics	PLF[♣] (*n* = 25)	PLF+TLIF[§] (*n* = 25)	*P* value
Male (*n*)	11 (44%)	9 (36%)	0.71
Female (*n*)	14 (56%)	16 (64%)	
Age	53.4±11.5	51.7±13.2	0.53
VAS[†] back pain	9±1.3	8.7±2.9	0.37
VAS leg pain	8.1±1.6	7.8±2.3	0.41
ODI[‡]	68±12	65±13	0.53

[1]Data are mean ± standard deviation (SD) otherwise indicated; ♣PLF = Posterolateral instrumented fusion; [§]TLIF =Transforaminal lumbar interbody fusion; [†]VAS = Visual analog scale; [‡]ODI = Oswestry disability index

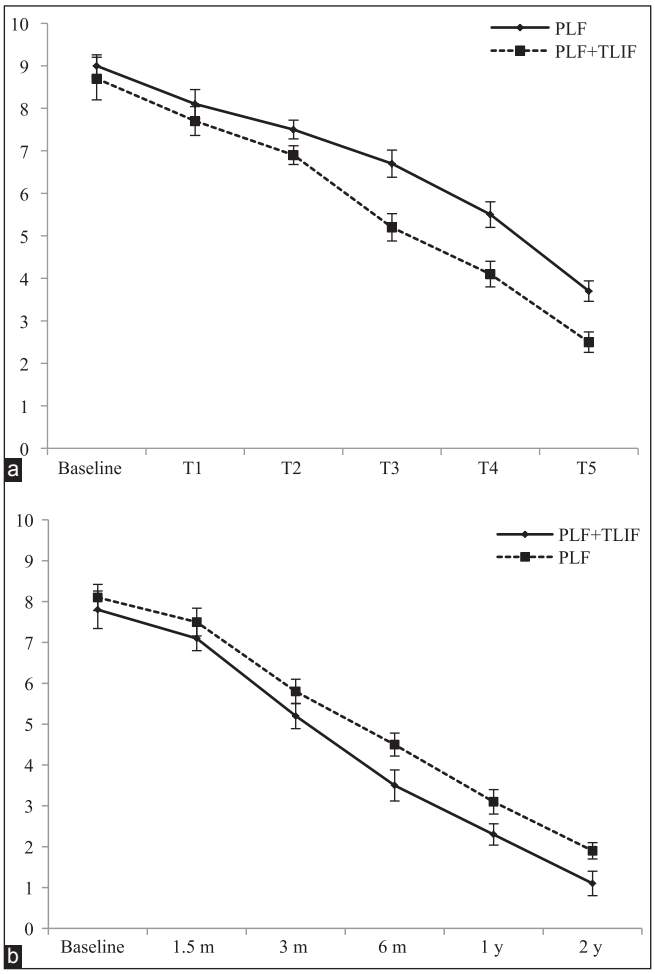

Figure 1: Mean Vas score for back (a) and leg (b) at the baseline and follow-up visits in patients treated with PLF and PLF + TLIF procedures

visits are presented in Figure 1. We drew the same results in ODI assessment. ODI significantly decreased within both the surgical methods ($P < 0.05$). There was no difference in ODI up to 1.5 months after the surgery. However, patients undergoing the PLF+TLIF procedure showed lower ODI measurements in the 3rd month and 6th month, first year, and second year after the surgery (P value <0.05). The mean ± SEM of ODI measurements according to follow-up visits are presented in Figure 2.

DISCUSSION

The current clinical trial with 2 years of follow-up revealed that the PLF+TLIF procedure might be more effective in treating the pain and disability in patients with isthmic spondylolisthesis compared to PLF alone.

The goal of the surgical treatment of spondylolisthesis includes: the stabilization of the motion segment, the decompression of neural elements, the reconstitution of disk space height, and the restoration of sagittal plane translational and rotational alignment. The goal of stabilizing the spondylolytic level is

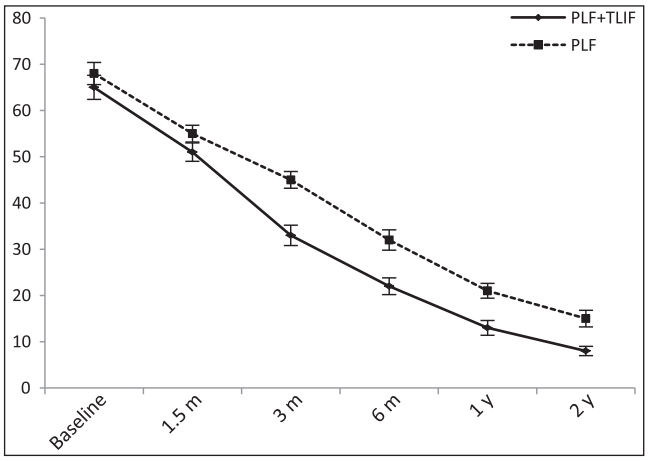

Figure 2: Mean ODI at the baseline and follow-up visits in patients treated with PLF and PLF + TLIF procedures

Table 2: Distribution frequency of grades in two groups

Grade	TLIF§ (%)	PLF⁂ (%)	*P* value
I	19 (76)	17 (68)	0.406
II	5 (20)	8 (33)	
III	1 (4)	0 (0)	
IV	0 (0)	0 (0)	

§TLIF = Transforaminal lumbar interbody fusion; ⁂PLF = Posterolateral instrumented fusion

accomplished by arthrodesis from a posterior, anterior, or combined approach. Depending on the severity and clinical features of the spondylolisthesis, it may also be desirable to reduce the forward translation, increase disk space height, decompress the neural elements, and increase or restore lumbar lordosis. Posterolateral instrumented or noninstrumented fusion (with or without decompression), anterior interbody fusion, and circumferential fusion have all been reported to provide acceptable fusion rates and clinical outcomes in adult patients with spondylolisthesis.[28,29]

PLF is a common and acceptable surgical approach to treat spondylolisthesis. There are few studies trying to examine the effect of PLF in comparison with PLF+TLIF.

Several studies have been accomplished trying to compare various surgical procedures to treat isthmic spondylolisthesis. For instance, a randomized control trial was performed to examine the effect of fusion instrumentation and could not provide an evidence for the beneficial effect of adding instrumentation to regular fusion methods and it concluded that an anterior-posterior fusion method might be more reliable for a successful clinical outcome.[30] In another study, Suk *et al.*[31] treated 56 participants with pedicle screw fixation and either posterior alone or anterior-posterior fusion. They showed that disc height and slip angle reduction appeared to be better maintained in the combined surgery group.

PLF was revised by Lin.[28] The chip PLF procedure entails less retraction of the spinal cord and increases the bone fusion surface area but it does not provide the additional mechanical support of an interbody cage. Interbody fusion techniques were developed in an attempt to preserve the load-bearing capacity of the spine, restore the sagittal plane alignment, and use the compressive loading on the bone to enhance the likelihood of fusion. The interbody fusion immediately produces a biomechanically stable postoperative spine, thus enhancing the opportunity for arthrodesis.[32-34] A posterolateral graft is easily added to this procedure, further enhancing the stability and likelihood of fusion. Additionally, the posterior approach avoids the morbidity factors associated with an anterior path to the spine. The PLF procedure has gained popularity, with indications including spinal stenosis, instability, degenerative disc disease, spondylolisthesis, spondylolysis, and bilateral disc herniation. Although the PLF procedure is useful in many cases, there are complications and contraindications. To obtain unobstructed access to the disc, the surgeon must retract the dural sheath out to the midline. This manipulation can lead to nerve damage or neurogenic pain.

Madan and Boeree[35] in their study compared the lateral instrumented fusion with or without posterior lumbar interbody fusion and represented better clinical outcomes in patients treated with posterolateral fusion alone although the fusion rate appeared higher in the posterior lumbar interbody fusion group. Swan *et al*., compared two common fusion techniques including the single level posterior-lateral instrumented fusion and combined anterior- and posterior-lateral instrumented fusion. They concluded that the combined method might lead to better clinical outcomes.[36] Although we could not find any study trying to compare PLF to PLF+TLIF, some studies have assessed PLF in comparison with the TLIF method in treating spondylolisthesis. In 2002, Madans and Boeree showed that although both PLF and TLIF led to pain reduction among patients, there was no difference between these two methods.[35] Audat *et al*. also examined the effect of three methods including PLF, PLF, and TLIF in patients with degenerative lumbar spine. They represented that these three methods were equal in intra- and postoperative complications. The ODI decreased over time, using all three methods but there was not a significant difference between the surgical approaches.[37] Humphreys *et al*.[22] found that patients undergoing the PLF procedure had a higher incidence of complications, including radiculitis, which they attributed to the need for greater medial retraction of the thecal sac with the PLF technique.

In the present trial, we tried to compare posterolateral instrumented fusion (PLF) with or without TLIF procedure. We are aware of no study with the same objectives. PLF is a common and accepted surgical approach to treat spondylolisthesis. It is proposed that the use of fixation instruments, particularly pedicle screw with PLF might have a great role in the success of the fusion. The TLIF technique was described by Harms and Jeszenszky[38] as a modification of the well-established PLF procedure. The TLIF uses a posterior approach to the spine that runs through the far lateral portion of the vertebral foramen accesses the disc space, which provides the surgeon with a fusion procedure that may reduce many of the risks and limitations associated with PLF and yet produces similar stability in the spine. This has been shown to reduce the incidence of postoperative radiculitis.[22] TLIF is usually a performed unilateral approach preserving the interlaminar surface on the contralateral side, which can be used as a site for additional fusion. The important advantage of TLIF in comparison with PLF is the existence of more trabecular bone to accomplish the fusion because in some patients the transverse process make it hard to gain access to the posterolateral fusion. As mentioned, in TLIF there is a decreased potential neurological injury and improvement in lordotic alignment, given graft placement within the anterior column, and minimizing lamina, facet, and pars dissection, which leads to protection of posterior column integrity compared to PLF.[39]

Similar to PLF, TLIF is easily enhanced when combined with posterolateral fusion and instrumentation. Both procedures can provide circumferential spinal stabilization through a single posterior approach but the more lateral access to the disk space in the TLIF technique requires less retraction of the thecal sac and neural elements than with the PLF technique.

Because the cauda equina obstructs the approach to the disc when PLF is performed, the spine surgeon must perform the discectomy and graft insertion in a bilateral fashion, increasing the operative time. In contrast, the angle of approach normally obtained during TLIF allows unilateral approach to the disc space, thus reducing operative time and blood loss.

Results of our study showed that back pain and leg pain were decreased in both the intervention groups ($P < 0.05$). There was no difference in back pain and leg pain between surgical procedures up to 1.5 months after the surgery (VAS back pain was 9 ± 1.3 *via* 8.7 ± 2.9 and VAS leg pain was 8.1 ± 1.6 and 7.8 ± 2.3 in PLF and PLF+TLIF, respectively). However, patients undergoing the PLF+TLIF procedure experienced significantly lower pain in the 3rd month and 6th month, first year and second year after the surgery (P value <0.05). Also, we arrived at the same results in ODI assessment. ODI significantly decreased within both the surgical methods (ODI was 68 ± 12 and 65 ± 13 in PLF and PLF+TLIF, respectively). There was no difference in ODI up to 1.5 months after the surgery ($P < 0.05$). However, patients undergoing the PLF+TLIF procedure showed lower ODI measurements in the 3rd month and 6th month, first year, and second year after the surgery (P value <0.05).

Our study had some limitations that must be considered while interpreting its results. Although we could find significant results in the clinical outcomes after the 3rd month, the study sample size was relatively low, and the generalization of these results to other populations might be hard. Therefore, the replication of our study in other populations is needed to confirm our results. Longitudinal intervention trial studies might produce outcome biases because of changes in clinical or social situations by time (for instance, improved surgeon

experience or technique, economic forces affecting work availability). Although there are limitations, the study has much strength, randomization of study participants between surgical procedures, use of validated outcome measures, participants who fully completed the study protocol and questionnaires, and long-term follow-up.

Increased surgery time and increases in some complications (although they might be neglect able) are against the early clinical benefits of the combined method used in the present study.

CONCLUSION

In conclusion, it seems that accompanying TLIF with PLF might lead to better functional improvement and pain reduction in patients with spondylolisthesis. Future studies including more patients are highly needed to confirm our results.

Results of our study showed that the TLIF procedure is simpler and is as safe and effective as the PLF technique.

Increased surgery time and increases in some complications (although they might be neglectable) are against the early clinical benefits of the combined method used in the present study.

In conclusion, it seems that accompanying TLIF with PLF might lead to better functional improvement and pain reduction in patients with spondylolisthesis. Future studies including more patients are highly needed to confirm our results.

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Conflicts of interest
There are no conflicts of interest.

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