**Minimally Invasive Lateral Lumbar Interbody Fusion for Adult Spinal Deformity**

**: Clinical and Radiological Efficacy with Minimum Two Years Follow-up**

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Running head : Efficacy of LLIF in ASD

**Abstract**

**Study design.** A retrospective cohort study

**Objective.** To evaluate the clinical and radiological efficacies of supplementing minimally invasive lateral lumbar interbody fusion (LLIF) with open posterior spinal fusion (PSF) in adult spinal deformity (ASD).

**Summary of Background Data.** Minimally invasive techniques have been increasingly applied for surgery of ASD. There are few reports on direct comparison of LLIF combined to PSF to conventional PSF for ASD.

**Methods.** To evaluate advantages of minimally invasive LLIF for ASD, patients that underwent minimally invasive LLIF followed by open PSF (combined group) were compared with patients that underwent only posterior spinal fusion (only PSF group). Clinical outcome and radiological outcome for deformity correction and indirect decompression were assessed. In addition, occurrence of PJK and PJF were also evaluated.

**Results.** There were no significant differences in clinical outcomes of Oswestry Disability Index (ODI), visual analog scale (VAS), and major complications including reoperations between the groups. There was no additional advantage for coronal deformity correction, restoration of lumbar lordosis in the combined group was significantly higher at postoperative (15.3° vs 8.87°, p=0.003) and last follow-up (6.69° vs 1.02°, p=0.029) compared to that of the only PSF group. In subgroup analysis for indirect decompression for the combined group, significant increase of canal area (104 mm2 vs 122mm2) and foraminal height (16.2mm vs 18.5mm) were noted. The occurrence of PJK or PJF was significantly higher in the combined group than in only PSF group (p<0.039).

**Conclusion.** LLIF has advantages of indirect decompression and greater improvements of sagittal correction compared to only posterior surgery. LLIF should be conducted considering such benefits and complications including PJK or PJF in ASD.

**Keywords**: Adult spinal deformity, open posterior spinal fusion, minimal invasive, lateral lumbar interbody fusion, complication.

**Level of Evidence:** 4

**Key points**

There is no additional advantage for clinical outcomes by supplementary minimally invasive lateral lumbar interbody fusion (LLIF) for adult spinal deformity.

Approach related complications such as lower extremity weakness, even transient, occurred in 39.6% (18/48).

LLIF has advantages of indirect decompression and greater improvement of sagittal correction compared to only posterior surgery.

Occurrence of PJK or PJF was significantly greater in LLIF and posterior spinal fusion group than in only the posterior group.

**Mini-abstract**

Supplementary lumbar interbody fusion (LLIF) in adult spinal deformity (ASD) doesn’t provide better clinical outcomes, but has advantages of indirect decompression and greater improvement of sagittal correction compared to only posterior surgery. The LLIF should be conducted considering such benefits and complications in ASD.**Minimally Invasive Lateral Lumbar Interbody Fusion for Adult Spinal Deformity**

**: Clinical and** **Radiological Efficacy with Minimum Two Years Follow-up**

**Introduction**

Adult spinal deformities (ASD) are three-dimensional rotational deformities presented with chronic back pain and neurogenic symptoms leading to decreased quality of life.1,2 In patients with pain refractory to conservative treatment, operative interventions are recommended and cost-effective as well.3,4 Neural decompression and deformity correction should be considered for surgical intervention for ASD. Traditional anterior and/or posterior surgical techniques have been applied for these purposes even if associated with high morbidity and risk of complications.5-7 Minimally invasive techniques have been increasingly popular to reduce perioperative complications for treatment of ASD in morbid elderly patients.8,9 Since minimally invasive lateral lumbar interbody fusion (LLIF) first described by Ozgur, et al.10 in 2006, this trans-psoas approach has been applied for various degenerative spine disease including ASD. Promising clinical results have been reported with effectiveness of indirect decompression, better fusion rates and deformity correction in addition to a minimally surgical approach for degenerative spinal deformities.11-16

However, there are few reports on direct comparison of the LLIF combined to posterior spinal fusion (PSF) to the conventional PSF for the ASD.17-19 Therefore, the purpose of this study was to evaluate the clinical and radiological efficacies of supplementing minimally invasive LLIF with open PSF in ASD by comparing results of conventional surgery. In addition, the effect on proximal junctional kyphosis (PJK) and proximal junctional failure (PJF) was also investigated.

**Methods**

*Patient population*

A clinical and radiological database from 2012-2015 was retrospectively reviewed in an institution. We included ASD patients that underwent deformity surgery with the following criteria: scoliosis>10°, sagittal vertical axis (SVA)≥5cm, more than 4 levels fusion, and minimal 24 months of follow-ups. Patients with 3-column osteotomy, anterior column release (ACR), percutaneous PSF were excluded. One-hundred thirty-six patients that underwent reconstructive surgery for ASD were screened and a total of 91 patients were enrolled in this study. Forty-eight patients with minimally invasive LLIF combined open posterior spine fusion (PSF) were included for Group I (Figure 1). Surgical procedures of LLIF were conducted as previously described under EMG monitoring to prevent injury of the lumbar plexus. 10 Forty-three patients that underwent conventional PSF were included for Group II (Figure 2).

*Outcome parameters*

Patient demographics including age, sex, BMI (body mass index), BMD (bone mineral density), the number of fusion levels, and follow-up periods was assessed. Clinical outcomes included the Oswestry Disability Index (ODI) and 10-point visual analog scale (VAS) of back and leg pain at pre- and post-operative three months, post-operative two years and last follow-up. Surgical outcomes such as operation time, estimated blood loss (EBL) and amount of transfusion, post-operative major complications and re-operations were compared between the two groups. LLIF related complications including lower leg symptoms were also evaluated. Post-operative lower extremity symptoms included anterior thigh pain, hip flexion weakness, sensory changes and neurological deficits.

Radiological parameters including coronal Cobb’s angle (CA), coronal imbalance (CI), pelvic incidence (PI), pelvic tilt (PT), sacral slope (SS), sagittal imbalance (SI), thoracic kyphosis (TK), T1-pelvic angle (TPA) at pre-operative and post-operative and last follow-up were measured by two independent orthopedic surgeons. Regarding indirect decompression effects of LLIF, post-operative MRI was conducted after LLIF in the combined group. Changes of canal area and foraminal height on MRI were also evaluated. Proximal junctional angle (PJA) was measured at post-operative, post-operative two-years and the last follow-up. Incidence of PJK and PJF was assessed with minimum two-year follow-up that was not significantly different between two groups. PJK is defined as a proximal junctional sagittal Cobb angle≥10° and at least 10° greater than the pre-operative measurement.20,21 PJF is defined as the presence of the PJK combined with structural failure.21-23

*Statistical analysis*

Perioperative continuous variables presented with mean values with standard deviation were compared using unpaired student t-test between each group and paired t-test within each group. Categorical variables were compared using Fisher’s exact test or Pearson’s chi-square test depending on distribution and size of the sample. Statistical analysis was conducted using the SPSS software (IBM, 24.0version) with a level of significance of 0.05.

**Results**

Patient demographic and surgical outcomes between two groups are presented in Table 1. Demographic data such as age, sex, BMI, BMD, total fusion were not significantly different. Operation times in the combined group were significantly lengthier than in the only PSF group (438 minutes vs. 305 minutes, p<0.0001). Significant difference of estimated blood loss was observed between the two groups (1966 mL vs. 2930 mL, p=0.042) and amount of transfusion was lower in the combined group (1350 mL vs. 1752 mL, p>0.203).

*Clinical outcomes*

Clinical outcomes including pre-operative and post-operative three-month, post-operative two-years, last follow-up ODI and VAS are reported in Table 2. Pre-operative VAS of back and leg pain, and ODI were not significantly different. VAS of back pain was similar in both groups during the follow-up period (Figure 3A). However, improvement of VAS of leg pain was significantly different between the two groups at post-operative three-months (2.32 point vs. 4.26 point, p<0.038). Subsequent post-operative two-years and last follow-up VAS were similar (Figure 3B). ODI scores were also not significantly different each time (Figure 3C).

Post-operative major complications and re-operations are presented in Table 3. Three patients (6.3%) in the combined group and five patients (11.6%) had major complications in only the PSF group. All patients (6.3%) with complications in the combined group and one patient (2.3%) in only the PSF group underwent re-operations. There were no significant differences of major complications and re-operations between the two groups. Major complications were treated without any sequelae with re-operations and conservative treatment.

Approach related complications by LLIF procedures are recorded in Table 4 (19 of 48 patients, 39.6%). Eight patients (16.7%) complained of anterior thigh pain followed by thigh numbness (12.5%), hip flexion weakness (8.3%) but all lower leg symptoms were resolved spontaneously within six months. One patient with incisional hernia was treated with laparoscopic herniorrhaphy.

*Radiological outcomes*

Radiological outcomes including coronal and sagittal parameters are presented in Table 5. Although post-operative Cobb angles were significantly improved compared with pre-operative values in both groups, there was no significant difference between the two groups. Improvement of lumbar lordosis in the combined group was better than in only the PSF group at postoperative and last follow-up (post-operative; 15.3° vs. 8.87°, p=0.003, last follow-up; 6.69° vs. 1.02°, p=0.029). At the last follow-up, patients in the combined group had significant improvement of sacral slope (3.97° vs 0.79°, p=0.041), sagittal imbalance (-11.6mm vs 15.3mm, p=0.019) and TPA (-0.87° vs 1.90°, p=0.019). Changes of all other radiographic parameters were similar without significance.

Regarding indirect decompression effects of LLIF, significant increase of cross-sectional area of spinal canal (104 mm2 vs 122mm2, p < 0.0001) and foraminal height (16.2mm vs 18.5mm, p<0.0001) at the index level was noted. LLIF contributed 56.2% in coronal correction and 71.9% in sagittal correction when the degree of correction after 1st LLIF procedure and 2nd PSF operation was compared.

Post-operative proximal junctional angle (PJA) was similar in both groups. There was a trend that PJA in the combined group was greater than in only the PSF group at post-operative two-years and last follow-up (Figure 4A). Of 48 patients treated with LLIF procedure, PJK developed in nine patients (18.8%) and PJF developed in eight patients (16.7%). However, PJK developed in four patients (9.3%) and PJF developed in three patients (7.0%) of 43 patients in only the PSF group. Occurrence of PJK or PJF was significantly greater in the combined group than in only the PSF group (p<0.039). The PJK or PJF free survival time was significantly different from the combined group and only the PSF group (Figure 4B) (p=0.035 on log rank test).

**Discussion**

The purpose of this study was to evaluate the efficacy of supplementary LLIF combined with PSF compared to only the PSF operation in ASD over two-year follow-up. Although previous studies of LLIF in the ASD have been in case series, there were two studies to assess the use of combination LLIF and open PSF in ASD.17,18 Strom, et al. reported a study of six months follow-up including 3-column osteotomy and Theologis, et al. demonstrated investigation of case-matched 32 patients with two-year follow-up.17,18

In our study, patients treated with LLIF and PSF had significantly lengthier operation time (133 minutes) and less EBL (964mL) than patients treated with only posterior surgery. Strom, et al. also reported significantly lengthier operation time (100 minutes) and less blood loss (704mL) in the combined group.17 The lengthier operation time was associated with staged procedures and positional change during surgery. There was a certain advantage of reducing bleeding and intraoperative transfusion because of minimal invasive approach.

ODI and VAS for back and leg pain were significantly improved in each group compared to pre-operative values at every follow-up. It was consistent with previous studies on ASD patients treated with LLIF that reported improvement in VAS pain and ODI after surgery. 11-16 However, there were no significant differences between the two groups. Theologis, et al. also demonstrated similar post-operative improvement in ODI and VAS for back and leg pain in both groups.18 It is noteworthy that improvement of VAS leg pain in the combined group was significantly lower than in only the PSF group at post-operative three-months. It may be associated with lower leg symptoms that eight patients had in LLIF group reported worse VAS of leg pain at post-operative three-months than at pre-operative while two patients in only the PSF group complained of worse leg pain.

Post-operative major complications including neurological deficit, implant failure and PTE occurred in eight patients (8.8%) in all patients. All patients (6.3%) with complications in the combined group and one patient (2.3%) in only the PSF group underwent re-operations. The rate of major complications and re-operations (8.8% and 4.3%) in this study compares favorably to the previous study concerning supplementing LLIF in ASD (34.4% and 15.6%).18 Interestingly, major complications and re-operations in each group were associated with open PSF that was consistent with the study of Issac, et al.14

Eighteen patients (37.5%) that underwent LLIF procedures complained of lower leg symptoms including anterior thigh pain, thigh numbness and hip flexion weakness that resolved spontaneously within six months. Other studies reported incidence of any post-operative lower extremity symptoms related with LLIF procedure ranged from 0%-60.7% and symptoms persisted ranging from 1.7%- 56.8% of patients at six months follow-up.24-26 Many authors demonstrated that these were not actual complications, but side effects of psoas manipulation during operations.27-29

Radiological outcomes in patients treated with LLIF and PSF were interesting in our study. Previous studies reported that LLIF was effective for coronal correction, but results of sagittal correction were inconsistent.15,30-32 Acosta, et al. demonstrated that correction of the coronal Cobb angle and restoration of LL were respectively 11.7° and 4.1° in patients with degenerative scoliosis.15 In contrast, Caputo, et al. reported that multilevel LLIF and posterior fusion decreased LL from 10.1°-9.2°.16 In this study, although there were improvements of coronal correction in the combined group, it was not significantly different compared with those in only the PSF group (13.3° vs 12.2°). However, restoration of lumbar lordosis in the combined group was significantly greater than without LLIF procedure (15.3° vs 8.87°) that was remained at last follow-up (6.69° vs 1.02°, p=0.029). Strom, et al. also reported that LLIF and PSF operations provided more LL restoration (22° ± 13°) than only posterior operations without 3-column osteotomy (11° ± 7°).17 In addition, this marked improvement of regional lordosis may have an effect on global sagittal alignment. At last follow-up, patients in the combined group had significant improvements of sacral slope, sagittal imbalance, and TPA.

Significant increase of canal area (104 mm2 vs 122mm2) and foraminal height (16.2mm vs 18.5mm) at the index level validated the effect of indirect decompression of LLIF. Tessitore, et al. also demonstrated the indirect decompression of LLIF that increased canal area (115.7mm2 vs 136.5mm2) and disc height (7.0mm vs 10.9mm) leading to improvement of clinical outcomes including ODI and EQ-5D.33 Despite radiological effect of indirect decompression by LLIF, there were no significant differences of clinical outcomes of ODI and VAS after open PSF between the groups. It is possible that posterior neural decompression conducted in both groups was sufficient to resolve the neurological symptom originating from the lower lumbar spine.

The effect of LLIF on the occurrence of PJK and PJF was rarely reported in previous studies. Post-operative PJA was similar in both groups, but PJA at post-operative two-year and last follow-up was greater in the combined group. Incidence of PJK and PJF was 35.4% in the combined group in contrast to 16.2% in only the PSF group. The PJK or PJF free survival time was significantly different from the combined group and only the PSF group. Some studies have found that combined anterior-posterior approach increased the risk of PJK.21,34-36 Especially, Kim, et al. demonstrated that PJK is three times more likely to develop in patients with combined anterior-posterior approach compared to only posterior surgery.36 In addition, Hart, et al. noted that anterior approaches were an independent risk factor for PJF.21,22 LLIF combined to posterior operation also increased risk of PJK and PJF like other anterior surgery. However, pathomechanism and how anterior approaches increase risk of PJK and PJF has not been validated. Further trials are needed to evaluate the risk factor of PJK or PJK in LLIF operations.

This study has limitations. First, this study was a retrospective review that should be carefully assessed. There may have been a selection bias that influenced results. In our study, some pre-operative outcomes including SS and LL were significantly different between the two groups. Therefore, significant differences of pre- and post-operative outcomes between groups were significant.

Second, outcome measures such as occurrence of PJK or PJF, and clinical improvements may have been influenced by other factors that were not included in this study. Further prospective studies are needed to validate our results.

In conclusion, there was no difference of clinical outcomes including ODI and VAS for back and leg pain between the combined group and only the PSF group. LLIF related lower leg symptoms occurred in 37.5% in this study and may be associated with lesser improvement of post-operative VAS leg pain in the combined group. However, LLIF has advantages of indirect decompression and greater improvements of sagittal correction compared to only posterior surgery. LLIF should be conducted considering such benefits and complications including PJK or PJF in ASD.

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**Figure legend**

**Figure 1. (A)** Pre-operative whole spine radiograph revealing degenerative scoliosis and sagittal imbalance. **(B)** Whole spine radiograph revealing coronal and sagittal correction after lateral lumbar interbody fusion (LLIF). **(C)** Post-operative whole spine radiograph revealing coronal and sagittal correction after open posterior spinal fusion (PSF) in staged operation.

**Figure 2. (A)** Pre-operative whole spine radiograph revealing degenerative scoliosis and sagittal imbalance. **(B)** Post-operative whole spine radiograph revealing coronal and sagittal correction after open PSF in a stage without LLIF.

**Figure 3. (A)** Visual analog scale (VAS) of back pain at pre- and post-operative three months, post-operative two years and last follow-up. **(B)** VAS for leg pain each time. **(C)** Oswestry Disability Index (ODI) each time.

**Figure 4. (A)** Proximal junctional angle (PJA) at post-operative, post-operative two years and last follow-up. **(B)** Kaplan-Meier survivorship curve revealing the cumulative proximal junctional kyphosis (PJK) or proximal junctional failure (PJF) free survival rate.