Lumbar Lateral Interbody Fusion (LLIF): Comparative Effectiveness and Safety versus PLIF/TLIF and Predictive Factors Affecting LLIF Outcome

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Abstract

Study Design Systematic review.

Study Rationale The surgical treatment of adult degenerative lumbar conditions remains controversial. Conventional techniques include posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF). A new direct approach known as lumbar lateral interbody fusion (LLIF), or extreme lateral interbody fusion (XLIF®) or direct lateral interbody fusion (DLIF), has been introduced.

Objectives The objective of this article is to determine the comparative effectiveness and safety of LLIF, at one or more levels with or without instrumentation, versus PLIF or TLIF surgery in adults with lumbar degenerative conditions, and to determine which preoperative factors affect patient outcomes following LLIF surgery.

Materials and Methods A systematic review of the literature was performed using PubMed and bibliographies of key articles. Articles were reviewed by two independent reviewers based on predetermined inclusion and exclusion criteria. Each article was evaluated using a predefined quality rating scheme.

Results The search yielded 258 citations and the following met our inclusion criteria: three retrospective cohort studies (all using historical cohorts) (class of evidence [CoE] III) examining the comparative effectiveness and safety of LLIF/XLIF®/DLIF versus PLIF or TLIF surgery, and one prospective cohort study (CoE II) and two retrospective cohort studies (CoE III) assessing factors affecting patient outcome following LLIF. Patients in the LLIF group experienced less estimated blood loss and a lower mortality risk compared with the PLIF group. The number of levels treated and the preoperative diagnosis were significant predictors of perioperative or early complications in two studies.

Conclusion There is insufficient evidence of the comparative effectiveness of LLIF versus PLIF/TLIF surgery. There is low-quality evidence suggesting that LLIF surgery results in fewer complications or reoperations than PLIF/TLIF surgery. And there is insufficient evidence that any preoperative factors exist that predict patient outcome after LLIF surgery.
Study Rationale and Context

The surgical treatment of adults degenerative lumbar conditions remains very controversial. Lumbar interbody arthrodesis, with or without instrumentation, provides better fusion rate but not better clinical results.

To reduce surgical morbidity and achieve satisfactory, long-standing results, a new direct approach to the lumbar spine, known as lumbar lateral interbody fusion (LLIF), direct lateral interbody fusion (DLIF), or extreme lateral interbody fusion (XLIF®; Nuvasive, San Diego, CA, United States), has been introduced.

A comparative analysis of this new approach versus conventional posterior lateral interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF) techniques is the aim of this study.

Objectives

The objective of this article is to determine the following:

- The comparative effectiveness and safety of LLIF, XLIF, or DLIF surgery at one or more levels with or without instrumentation versus PLIF or TLIF surgery, in adults with lumbar degenerative conditions including degenerative scoliosis
- What preoperative factors, if any, affect patient outcomes following LLIF, XLIF, or DLIF surgery.

Materials and Methods

Study design: This study is a systematic review.

Search: The databases included PubMed, Cochrane, and National Guideline Clearinghouse Databases, as well as bibliographies of key articles.

Dates searched: The dates were searched till November 2013.

Inclusion criteria: The inclusion criteria of the study were as follows: (1) patients 18 years or older, (2) lumbar degenerative disc disease (DDD) (with or without canal stenosis and with or without degenerative spondylolisthesis) or lumbar degenerative scoliosis, (3) studies with at least 10 patients per treatment group (comparative effectiveness) or studies with at least 20 patients total (predictive factors), and (4) comparison of LLIF/XLIF/DLIF with PLIF/TLIF surgery (comparative effectiveness).

Exclusion criteria: The exclusion criteria of the study were as follows: (1) patients younger than 18 years, (2) those involving traumatic onset, fracture, thoracic disc disease, infection, or neoplasms; (3) case reports, comparative studies with fewer than 10 patients per treatment group; and (4) cadaveric studies, nonhuman in vivo, in vitro, and biomechanical studies.

Outcomes: The outcomes of the study include the following: (1) perioperative complications, (2) reoperation risk, (3) complications or adverse events, (4) postoperative pain, (5) neurological improvement, and (6) sagittal and coronal balance.

Analysis: Descriptive statistics. Pooling of data was not done due to concerns regarding heterogeneity of treatments and populations as well as study quality.

Overall strength of evidence: Risk of bias for individual studies was based on using criteria set by The Journal of Bone and Joint Surgery1 modified to delineate criteria associated with methodological quality and risk of bias based on recommendation from the Agency for Healthcare Research and Quality.2,3 The overall strength evidence across studies was based on precepts outlined by the Grades of Recommendation Assessment, Development and Evaluation Working Group4 and recommendations made by the Agency for Healthcare Research and Quality.2,3

Details about methods can be found in the online supplementary material.

Results

From 258 citations, 11 citations were evaluated for full-text review. Three retrospective cohort studies (all using historical cohorts) (class of evidence [CoE] III) examining the comparative effectiveness and safety of LLIF/XLIF/DLIF versus PLIF/TLIF surgery and one prospective cohort study (CoE II) and two retrospective cohort studies (CoE III) reporting predictive factors following XLIF surgery met the inclusion criteria and form the basis for this report (►Fig. 1). Characteristics of studies investigating the comparative effectiveness of the surgical techniques are outlined in ►Table 1 and those examining predictive factors following LLIF/XLIF/DLIF are outlined in ►Table 2. Refer to the online supplementary material for critical appraisal, a list of excluded articles, and detailed outcome tables.

Comparative Effectiveness of LLIF/XLIF/DLIF versus PLIF/TLIF

None of the included studies reported radiographic or patient-reported outcomes for both treatment groups.
<table>
<thead>
<tr>
<th>Investigator (y) Study design CoE</th>
<th>Population</th>
<th>Condition</th>
<th>LLIF/XLIF/DLIF</th>
<th>PLIF/TLIF</th>
<th>Follow-up (% followed)</th>
</tr>
</thead>
</table>
• Age (mean): 55.5 y  
• Male: 65% | • Degenerative spine conditions (details NR)  
• Symptom duration: NR | • XLIF from L1–L2 to L4–L5 and MIS TLIF/transacral fusion at L5-S1  
• Type of graft: NR  
• n = 109  
• Number of levels: 2  
• 2006–2009 | • Open PLIF (historical cohort)  
• Type of graft: NR  
• n = 102  
• Number of levels: 2  
• Prior to 2006 | Follow-up period NR (% NR) |
| Rodgers et al (2010) Retrospective cohort (using historical cohort from same institution) CoE: III | • N = 60  
• Age (mean): 83.4 y  
• Male: 42% | • Degenerative spine conditions (stenosis, spondylolisthesis, scoliosis, postlaminectomy)  
• Symptom duration: NR | • XLIF with unilateral or bilateral pedicle screws, percutaneous (n = 39)  
• Type of graft: composite of demineralized bone matrix, cancellous allograft, local bone source, and bone marrow aspirate  
• n = 40  
• 1-level (n = 25), 2-level (n = 7), 3-level (n = 8); mean 1.6 levels from L1-L5 (62.5% including L4-L5) | • Open PLIF (historical cohort) with unilateral or bilateral pedicle screws, open exposure  
• Type of graft: composite of demineralized bone matrix, cancellous allograft, local bone source, and bone marrow aspirate  
• n = 20  
• 1-level (n = 4), 2-level (n = 7), 3-level (n = 7), 5-level (n = 1), 7-level (n = 1); mean 2.6 levels from T10-S1 (80.0% including L4-L5) | ≥ 3 mo (% NR) |
• Age (mean): 61 y  
• Male: % NR | • Degenerative spine conditions (details NR)  
• Symptom duration: NR | • XLIF or DLIF  
• Type of graft: NR  
• n = 58  
• 1-level (n = 38), 2-level (n = 19), 3-level (n = 1); from T12-L5  
• 2004–2006 | • Open PLIF (historical cohort)  
• Type of graft: NR  
• N = 40  
• Number of levels: NR, excluded L5-S1  
• 1992–1998 | XLIF or DLIF: 15 mo (3–34 mo) (% NR) PLIF: follow-up period NR (% NR) |

Abbreviations: CoE, class of evidence; DLIF, direct lateral interbody fusion; f/u, follow-up; LLIF, lumbar lateral interbody fusion; MIS, minimally invasive surgical techniques; NR, not reported; PLIF, posterior lateral interbody fusion; TLIF, transforaminal lumbar interbody fusion; XLIF, extreme lateral interbody fusion.
Table 2  Characteristics of studies evaluating predictive factors affecting outcomes following LLIF/XLIF/DLIF for lumbar degenerative disease

<table>
<thead>
<tr>
<th>Investigator (y) Study design CoE</th>
<th>Population</th>
<th>Condition</th>
<th>Surgical procedure</th>
<th>Follow-up (% followed)</th>
<th>Predictive factors evaluated</th>
<th>Outcomes evaluated</th>
</tr>
</thead>
</table>
Age (mean): 69 y (45–87)  
Male: 41% | DDD, spondylolisthesis, or degenerative scoliosis | LTIF from L1–L5, with posterior instrumentation or standalone  
Number of levels: mean 2.3 levels/patient | ≥ 6 mo (% NR) | Demographic factors: age, sex, BMI  
Surgical factors: none  
Other factors: preoperative sagittal alignment at instrumented levels (degrees) | Postoperative lumbar lordosis |
Age (mean): 68.4 y (45–87)  
Male: 27% | Adult thoracolumbar scoliosis, with back pain, radicular pain, combined back/leg pain, or neurologic deficits  
Symptom duration: > 2 y (78% of patients) | XLIF from T11-L5 or direct anterior/ AxiLIF/ posterior interbody approach at L5-S1 either standalone or with instrumentation (percutaneous posterior pedicle screws or lateral fixation)  
Number of levels involved: mean 4.4 levels/patient | 6 wks (% NR) | Demographic factors: age, sex, BMI, comorbidities, severity of deformity  
Surgical factors: inclusion of specific levels, number of levels treated, additional posterior decompression, type of fixation  
Other factors: none | Perioperative complications |
Obese group  
N = 156  
Age (mean): 58.9 y (30–87)  
Male: 41%  
BMI (mean): 36.0 kg/m²  
Nonobese group  
N = 157  
Age (mean): 62.9 y (24–88)  
Male: 45%  
BMI (mean): 25.7 kg/m² | Degenerative spine disease in lumbar and thoracic spine, including stenosis, spondylolisthesis, DDD, scoliosis, HNP, or postlaminectomy instability | XLIF, range of levels NR  
Number of levels involved: NR | 3 mo (% NR) | Demographic factors: BMI, age, sex, height and weight, smoking, comorbidities (including diabetes mellitus, coronary artery disease, chronic obstructive pulmonary disease, chronic steroid use)  
Surgical factors: number of levels treated  
Other factors: preoperative diagnosis | Early complications (within first 3 mo), including wound, nerve, cardiac, renal, GI, respiratory, vertebral body-related, and hardware-related |

Abbreviations: AxiLIF, axial lumbar interbody fusion; BMI, body mass index; CoE, class of evidence; DDD, degenerative disc disease; GI, gastrointestinal; HNP, herniated nucleus pulposus; NR, not reported; LTIF, lateral transpsoas interbody fusion; XLIF, extreme lateral interbody fusion.

aObese group included patients who were obese (BMI ≥ 30 kg/m² and ≤ 40 kg/m²) or morbidly obese (BMI > 40 kg/m²) (Rodgers et al, 2010).
Comparative Safety of LLIF/XLIF/DLIF versus PLIF/TLIF

Perioperative Outcomes

- Length of hospital stay was reported by all three studies and found to be shorter in the LLIF group compared with the PLIF group in two studies (Table 1, Table 3, Table 2).
- Estimated blood loss measured by two different methods was reported by two studies and found to be significantly less in the LLIF group compared with the PLIF group in both studies.

Reoperation Risks

- Only one study reported reoperation risks for both treatment groups, with the LLIF group experiencing a lower reoperation risk compared with the PLIF group (Table 4).

Complications

- Overall, complication risks ranged from 7.5 to 22.4% in the LLIF group and from 22.5 to 60.0% in the PLIF group in two studies (Table 4, Figs. 1 and 2).
- Neurological complications following LLIF were reported in three studies, ranging from 0.9% of treated cases in one study to 13.8% in another study.
- Mortality was higher in those with open PLIF (mean age, 84.2 years) compared with XLIF (mean age, 82.6 years) in one study (30 vs. 2.5%) but not different in another.

Factors Affecting Patient Outcome after LLIF/XLIF/DLIF Surgery

Three factors were found to be associated with various poor outcomes following surgery (Table 2, Table 5).

- Only one study reported early reoperation for complications after XLIF; however, no specific reoperation timeframe is reported in the available studies.
- Five studies reported data on reoperations either following posterior open procedures or lumbar lateral interbody fusion.

Abbreviations: DLIF, direct lateral interbody fusion; LLIF, lumbar lateral interbody fusion; NR, not reported; NS, not significant; PLIF, posterior lateral interbody fusion; TLIF, transforaminal lumbar interbody fusion; XLIF, extreme lateral interbody fusion.

**Table 3** Studies comparing LLIF/XLIF/DLIF with PLIF/TLIF: perioperative outcomes

<table>
<thead>
<tr>
<th></th>
<th>LLIF/XLIF/DLIF</th>
<th>PLIF/TLIF</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of hospital stay</td>
<td>1.2 d</td>
<td>3.2 d</td>
<td>NR</td>
</tr>
<tr>
<td>Deluzio et al (2010)</td>
<td>1.3 d</td>
<td>5.3 d</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Knight et al (2009)</td>
<td>5 d (1–12)</td>
<td>5 d</td>
<td>NS</td>
</tr>
<tr>
<td>Estimated blood loss</td>
<td>1.4 g</td>
<td>2.7 g</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Rodgers et al (2010) a</td>
<td>136 mL</td>
<td>489 mL</td>
<td>0.0000</td>
</tr>
</tbody>
</table>

*Blood loss measured by average preoperative to postoperative hemoglobin change (Rodgers et al, 2010).
Clinical Guidelines
None found.

Evidence Summary
Overall, there is insufficient evidence of the comparative effectiveness of LLIF surgery versus PLIF surgery. There is low-quality evidence suggesting that LLIF surgery results in fewer complications or reoperations than PLIF surgery. And there is insufficient evidence that any factors exist that predict patient outcome after LLIF surgery (►Table 6).

Illustrative Case
A 65-year-old woman, with no significant medical history, presented with a long history of severe pain in the lumbar spine. No radicular pain was present. Symptoms made her ambulation difficult, as well as performing daily domestic activities.

Imaging revealed a degenerative thoracolumbar, left-sided convex scoliosis with apex at L2–L3 and L1–L2 (►Figs. 5 and 6).

She was initially treated with conservative care and medical drugs but without clinical benefit. Surgery was performed

Table 4  Studies comparing LLIF/XLIF/DLIF with PLIF/TLIF: reoperation risks and adverse events

<table>
<thead>
<tr>
<th>Reoperation risks and cause</th>
<th>LLIF/XLIF/DLIF, %</th>
<th>PLIF/TLIF, %</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rodgers et al (2010)</td>
<td>5.0 (2/40)</td>
<td>15.0 (3/20)</td>
<td>NS</td>
</tr>
<tr>
<td>Knight et al (2009)</td>
<td>1.7 (1/58)</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Overall complication risk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rodgers et al (2010)</td>
<td>7.5 (3/40)</td>
<td>60.0 (12/20)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Knight et al (2009)</td>
<td>22.4 (13/58)</td>
<td>22.5 (9/40)</td>
<td>NR</td>
</tr>
<tr>
<td>Mortality risk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rodgers et al (2010)</td>
<td>2.5 (1/40)</td>
<td>30 (6/20)</td>
<td>0.0018</td>
</tr>
<tr>
<td>Knight et al (2009)</td>
<td>0 (0/58)</td>
<td>2.5 (1/40)</td>
<td>NR</td>
</tr>
</tbody>
</table>

Abbreviations: DLIF, direct lateral interbody fusion; LLIF, lumbar lateral interbody fusion; NR, not reported; NS, not significant; PLIF, posterior lateral interbody fusion; TLIF, transforaminal lumbar interbody fusion; XLIF, extreme lateral interbody fusion.
Table 5  Summary of demographic, surgical, and other factors evaluated as predictive factors for outcome following LLIF/XLIF/DLIF surgery

<table>
<thead>
<tr>
<th>Outcome evaluated</th>
<th>Multivariate analysis to control for confounders</th>
<th>No multivariate analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic factors</td>
<td>Perioperative complications</td>
<td>Early complications</td>
</tr>
<tr>
<td>Age</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Sex</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>BMI</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Height/weight</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Comorbidities</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Severity of deformity</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Surgical factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of levels treated</td>
<td>↑</td>
<td>NS</td>
</tr>
<tr>
<td>Inclusion of specific levels</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Type of fixation</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Additional posterior decompression</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Other factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative diagnosis</td>
<td></td>
<td>↑</td>
</tr>
<tr>
<td>Preoperative sagittal alignment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index; DLIF, direct lateral interbody fusion; LLIF, lumbar lateral interbody fusion; NS, not significant; XLIF, extreme lateral interbody fusion; ↑, increased risk of outcome.

Note: Empty cell indicates that factor was not evaluated.

Table 6  Evidence summary

<table>
<thead>
<tr>
<th>In adult patients, what is the comparative effectiveness of LLIF/XLIF/DLIF surgery compared with PLIF or TLIF surgery?</th>
<th>Strength of evidence</th>
<th>Conclusions/comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>LLIF/XLIF/DLIF versus PLIF/TLIF</td>
<td>Insufficient Low Moderate High</td>
<td>None of the studies reported the comparative effectiveness of radiographic or patient-reported outcomes.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In adult patients, what is the comparative safety of LLIF/XLIF/DLIF surgery compared with PLIF or TLIF surgery?</th>
<th>Strength of evidence</th>
<th>Conclusions/comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>LLIF/XLIF/DLIF versus PLIF/TLIF</td>
<td>Insufficient Low Moderate High</td>
<td>Overall, the evidence on the comparative safety of LLIF compared with PLIF is low. The LLIF treatment group had less estimated blood loss and a lower mortality risk than the PLIF treatment group. However, results for other outcomes were inconsistent. Two studies reported a shorter length of hospital stay for the LLIF group, yet one study reported the same length of hospital stay for both treatment groups. One study reported a significantly lower complication risk for the LLIF group, but another study reported approximately the same risk for both treatment groups. And only one study reported the reoperation risk for both treatment groups.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In adult patients, are there any factors affecting patient outcome after LLIF/XLIF/DLIF surgery?</th>
<th>Strength of evidence</th>
<th>Conclusions/comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>LLIF/XLIF/DLIF</td>
<td>Insufficient Low Moderate High</td>
<td>Overall, the evidence that factors predict patient outcome after LLIF surgery is insufficient. The three studies examined predictive factors for different outcomes. Two studies performed a multivariate analysis to control for confounders: one study found that number of levels treated was a significant predictor of</td>
</tr>
</tbody>
</table>
with a two-level XLIF at the apex of the deformity (L2–L3, L1–L2), followed by a posterior open correction and fixation from Th11 down to L5 (►Figs. 7 and 8).

Following such procedure, a good balance and alignment of the spine were obtained as well as improvement of pain. Full recovery of her domestic activity as well of ambulatory ability was achieved.

Discussion

• This systematic review is limited by the following:
  ▪ The majority of included studies were CoE III.
  ▪ There was a paucity of studies comparing LLIF surgery with PLIF or TLIF surgery.
  ▪ All three studies investigating the effectiveness of LLIF used historical controls who received PLIF or TLIF: two studies used a comparison group from the same institution5,6 and one study used a comparison group from the senior author’s practice.7 Therefore, patients in the LLIF treatment group might have been subject to changes in policies or supportive care.
  ▪ The new direct lateral approach to the lumbar spine proves to be safe and effective, and at least comparable with the PLIF/TLIF techniques. This approach cannot be used for the L5/S1 level for anatomic limitations.
  ▪ The complications’ rate shows to be inferior in the XLIF/DLIF/LLIF compared with the PLIF/TLIF studies.6,7
  ▪ More studies with longer follow-up, including randomized trials, are necessary to evaluate the theoretical benefit of direct lumbar lateral approach and to assess whether the results of this strategy are superior and durable as the ones achieved by PLIF/TLIF technique performed in open or minimally invasive surgery.
  ▪ Potential limitations may also be related to some authors’ conflicts of interest.6,7,9,10

Disclosures

Analytic support for this work was provided by Spectrum Research, Inc. with funding from AOSpine.
Fig. 6  Preoperative lateral radiograph.

Fig. 7  Postoperative anterior posterior radiograph following two-level XLIF and posterior open correction and fixation.

Fig. 8  Postoperative lateral radiograph.
References
2 Methods Guide for Effectiveness and Comparative Effectiveness Reviews AHRQ Publication No. 10(12)-EHC063-EF.2012; Available at: www.effectivehealthcare.ahrq.gov

Editorial Perspective

The EBSJ reviewers felt that this topic was an excellent and timely choice made by the authors. There are many variants of the same idea being offered by industry, all of them based on the premise to avoid the extensor backside of patients while finding the magic interval between the lumbar plexus and the large vessels for the sake of decreased muscle dissection. Although the timing of this systematic review may appear premature to the point of offering the predictable “need more research” conclusion, this study does provide a valuable overview of the current state of research on this largely industry-driven technique-based procedure variant. That said, there is no doubt that the findings of this systematic review strongly support a comparative effectiveness-based project.

Criticisms of the reviewers revolved around the uncontrolled variables—curve deformity and subluxation, osteoporosis, previous surgery, and level of surgery. Access to the L4-5 level in particular can be difficult with lateral techniques due to the variable height of the pelvic crest and somewhat unpredictable bifurcation anatomy, leading to the question of how much “effectiveness” will mirror the rather positive “efficacy” results presented by experts in these early technique-based publications.

Finally, the reviewers raised the very critical point of potential for conflict of interest. As stated earlier, this technology is very clearly based on an industry “push.” The question of the relationship of the investigators and the implant manufacturers, who are commonly newer to the market and tend to be more aggressive than the more established manufacturers, certainly warrants careful review of the disclosures made.

Finally, this is a very helpful status check and hopefully will help the EBSJ community advance their insights into this emerging surgical technique.