Outcome following unilateral versus bilateral instrumentation in patients undergoing minimally invasive transforaminal lumbar interbody fusion: a single-center randomized prospective study

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Object. Minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) is used to treat a wide variety of lumbar degenerative disorders. Although there are some reports showing efficacy of unilateral instrumentation during MIS-TLIF, a controlled randomized prospective study has not been done.

Methods. Forty-one patients were randomly assigned to receive either bilateral or unilateral instrumentation following 1-level unilateral MIS-TLIF. Four patients were lost to follow-up in the unilateral group and 1 patient was lost to follow-up in the bilateral group. Preoperative and postoperative scores on a visual analog scale (VAS) for back pain and leg pain (VAS-BP and VAS-LP, respectively), Oswestry Disability Index (ODI), and 36-Item Short Form Healthy Survey version 2 (SF-36v2) were collected. Additionally, preoperative and postoperative segmental Cobb angles and radiographic evidence of fusion were analyzed.

Results. There was no statistically significant difference in baseline demographic characteristics between the 2 groups. The VAS-BP, VAS-LP, ODI, and SF-36v2 physical component scores improved significantly after surgery in both groups (p < 0.05); there was no statistically significant between-groups difference in the degree of improvement. Blood loss was significantly higher in the bilateral instrumentation group and hospital stay was longer in the unilateral instrumentation group. There was no statistically significant between-groups difference with respect to change in segmental lordosis or fusion rate. The average duration of follow-up was 12.4 months for the bilateral instrumentation group and 11.4 months for the unilateral instrumentation group.

Conclusions. Clinical and radiographic outcomes of unilateral and bilateral instrumentation for unilateral MIS-TLIF are similar 1 year after surgery. (http://thejns.org/doi/abs/10.3171/2013.5.FOCUS13171)

Key Words • bilateral • instrumentation • minimally invasive • spine • transforaminal lumbar interbody fusion • unilateral

MINIMALLY invasive transforaminal lumbar interbody fusion is a popular technique used to treat a variety of lumbar degenerative disorders. There has been tremendous evidence supporting tubular surgery as offering multiple advantages over traditional open surgery including decreased wound infections, CSF leaks, pain, and length of hospitalization; tubular surgery is associated with faster recovery, and many surgeons consider it as the standard of care when indicated.1,8–11

During the MIS-TLIF procedure, a unilateral facetectomy and discectomy is accomplished through a working channel, following which an interbody spacer is introduced with minimal or no retraction on the thecal sac. Most surgeons use bilateral pedicle screw supplementation to accomplish the circumferential segmental fusion. The use of unilateral fixation during open, mini-open, and MIS-TLIF has been shown to be sufficient, with good outcome, in a few studies.3,4,16 Most of these studies, however, are either retrospective in nature or lack a comparison group. Hence, we conducted a prospective randomized study comparing clinical and radiographic outcomes following unilateral and bilateral instrumentation during single-level MIS-TLIF.

Methods

After institutional review board approval was obtained from both the University of Chicago and Northwestern University, 41 patients were randomized into 2
groups receiving either bilateral or unilateral instrumentation following single-level unilateral MIS-TLIF. Enrollment started in March 2005 and ended in January 2008. The inclusion criteria included age between 25 and 85, symptomatic back and/or leg pain for over 4 months' duration, and single-level degenerative spondylosis or spondylolisthesis, Grade 1 or 2. Patients with multilevel pathology, trauma, or tumor were excluded. The minimum duration of follow-up required was 6 months. Preoperative and postoperative clinical outcome measures included VAS-BP, VAS-LP, ODI, and SF-36v2 scores. Radiographic outcome measures included preoperative and postoperative focal Cobb angle. The Cobb angle measured was between the rostral endplate of the rostral vertebral body fused and the caudal endplate of the caudal vertebral body fused.

Fusion was assessed with the use of dynamic flexion-extension radiographs during the patients' 6-week, 3-month, 6-month, and last follow-up, which averaged 1 year after surgery. Fusion was defined as absence of angulation on dynamic flexion-extension radiographs, evidence of bridging bone, and absence of hardware lucency or migration. When the occurrence of fusion was in question, a CT scan was obtained.21

Following randomization, 21 patients were enrolled in the bilateral instrumentation group and 20 in the unilateral instrumentation group. One patient was lost to follow-up in the bilateral group and 4 patients were lost to follow-up in the unilateral group; hence, clinical and radiographic outcomes were analyzed for 20 patients in the bilateral group and 16 patients in the unilateral group.

Statistical Analysis

Variables were expressed as means ± SDs. We used the unpaired Student t-test for continuous variables, such as estimated blood loss, hospital stay, VAS scores, ODI, SF-36, and Cobb angle. The chi-square test was used for categorical variables, including age, sex, and fusion status. Probability values < 0.05 were considered statistically significant.

Surgical Technique

The unilateral MIS-TLIF technique is described in detail elsewhere. Patients who were randomized to receive unilateral instrumentation underwent pedicle screw placement ipsilateral to the side of the facetectomy and interbody cage placement. All patients were positioned on a Wilson frame during the procedure. All patients received similar instrumentation with Sextant system (Medtronic). All cages were supplemented with rhBMP.

Results

Baseline characteristics for patients in both groups are summarized in Table 1. The average age, sex distribution, average BMI, and distribution of spinal levels treated were similar in both groups.

The average estimated blood loss was significantly lower in the unilateral instrumentation group than in the bilateral instrumentation group (95 ml vs 156 ml, respectively; p = 0.03). The average duration of hospitalization was less in the bilateral group than in the unilateral group (2.8 days vs 4.1 days, respectively; p = 0.02).

The average follow-up duration was 11.4 months for the unilateral instrumentation group and 12.4 months for the bilateral instrumentation group; there was no statistically significant difference between the groups with respect to length of follow-up.

Clinical Outcomes

Preoperative scores on the VAS-BP, VAS-LP, ODI, and SF-36 physical component were similar in the 2 groups (Fig. 1). The average preoperative SF-36 mental component score was significantly higher in the unilateral instrumentation group (p = 0.04) (Fig. 1, Table 1). Following surgery, postoperative scores on the VAS-BP, VAS-LP, ODI, and SF-36 physical component improved significantly in both groups, while the SF-36 mental component score did not significantly improve in either group (Fig. 1, Table 2). When comparing the groups, the degree of improvement was not significantly different (p > 0.05).

Radiographic Outcomes

The preoperative segmental lordosis was −13.7º in the bilateral instrumentation group and −9.3º in the unilateral instrumentation group. Following surgery the segmental lordosis did not change significantly in either group (with postoperative values of −14.1º in the bilateral group and −11.4º in the unilateral group; Table 3). Furthermore, there was no statistically significant difference in change in lordosis between the groups. All but one of the patients in each group had radiographic evidence of fusion, and none demonstrated radiographic evidence of adjacent-segment degeneration during the follow-up period.

Complications

One patient in the bilateral instrumentation group suffered a superficial wound infection that was successfully treated with oral antibiotic therapy. One patient in the unilateral instrumentation group suffered from postoperative pulmonary edema and was hospitalized for 8 days. There were no hardware complications or CSF leaks in the cohort studied.

Discussion

Multiple biomechanical studies have demonstrated superiority of bilateral pedicle screws, compared with unilateral pedicle screw placement during open and MIS-TLIF constructs.6,13,14,18 While biomechanically offering less rigid constructs, unilateral fixation may be sufficient for radiographic fusion and attainment of good clinical outcomes. In the minimally invasive spine surgery literature, a few reports and studies demonstrated good outcomes and fusion rates following unilateral pedicle screw fixation during minimally invasive, or mini-open, TLIF. These studies were limited by their retrospective nature, lack of a comparison group, or inadequate follow-up.

To date, only 4 randomized prospective studies com-
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pare unilateral and bilateral instrumentation—2 studies during TLIF and 2 during posterolateral fusion. All of these studies were done through conventional open surgical techniques.

Fernández-Fairen et al. randomly assigned 82 patients with degenerative spondylolisthesis to receiving unilateral or bilateral instrumentation for 1- or 2-level pathology. Outcome was measured with the SF-36v2. All fusions were posterolateral and no interbody cages were placed. The study showed no between-groups difference

TABLE 1: Characteristics of patients undergoing unilateral or bilateral instrumentation for unilateral MIS-TLIF*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Bilateral Instrumentation (20 pts)</th>
<th>Unilateral Instrumentation (16 pts)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>age in yrs (mean)</td>
<td>57.3 ± 11.2</td>
<td>62.2 ± 13.1</td>
<td>NS</td>
</tr>
<tr>
<td>BMI (mean)</td>
<td>27.0 ± 4.4</td>
<td>29.0 ± 6.1</td>
<td>NS</td>
</tr>
<tr>
<td>male sex</td>
<td>30%</td>
<td>25%</td>
<td>NS</td>
</tr>
<tr>
<td>vertebral level treated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>L3–4</td>
<td>5%</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td>L4–5</td>
<td>60%</td>
<td>75%</td>
<td></td>
</tr>
<tr>
<td>L5–S1</td>
<td>35%</td>
<td>19%</td>
<td></td>
</tr>
<tr>
<td>preop VAS-BP (mean)</td>
<td>5.7 ± 2.5</td>
<td>5.7 ± 2.6</td>
<td>NS</td>
</tr>
<tr>
<td>preop VAS-LP (mean)</td>
<td>5.8 ± 2.9</td>
<td>5.7 ± 3.1</td>
<td>NS</td>
</tr>
<tr>
<td>preop ODI (mean)</td>
<td>39.2 ± 12</td>
<td>37.4 ± 9.2</td>
<td>NS</td>
</tr>
<tr>
<td>preop SF36-P (mean)</td>
<td>31.5 ± 7.3</td>
<td>26.8 ± 6.3</td>
<td>NS</td>
</tr>
<tr>
<td>preop SF36-M (mean)</td>
<td>43.8 ± 14.6</td>
<td>53.4 ± 10.9</td>
<td>0.04</td>
</tr>
<tr>
<td>EBL in ml (mean)</td>
<td>156 ± 68</td>
<td>95 ± 42</td>
<td>0.03</td>
</tr>
<tr>
<td>LOS in days (mean)</td>
<td>2.6 ± 0.8</td>
<td>4.1 ± 1.5</td>
<td>0.02</td>
</tr>
<tr>
<td>follow-up mos (mean)</td>
<td>12.4 ± 7.2</td>
<td>11.4 ± 6.1</td>
<td>NS</td>
</tr>
</tbody>
</table>

* Mean values are given ± SDs. EBL = estimated blood loss; LOS = length of hospital stay; NS = not significant; pts = patients; SF36-P = SF-36 physical component; SF36-M = SF-36 mental component.
in outcomes. The demographic characteristics, blood loss, need for transfusion, hospital stay, complications, rate of fusion, and effect on the adjacent segment were similar in the 2 groups. The length of the operation was significantly lower in the unilateral instrumentation group. In the bilateral instrumentation group, 3 pedicle screws were misplaced, causing symptomatic radiculopathy and requiring reoperation, compared to no screw misplacement in the unilateral instrumentation group. The pseudarthrosis rate was 7.3% in the bilateral instrumentation group and 10% in the unilateral instrumentation group, but the difference was not statistically significant. The average follow-up was 55.6 months for the bilateral group and 60.8 months for the unilateral group. These results are similar to our study, which demonstrated no differences in clinical or radiographic outcomes.

Suk et al. assigned 87 patients to receive unilateral or bilateral instrumentation during posterolateral lumbar fusion: 47 patients were treated with unilateral instrumentation and 40 with bilateral instrumentation. Clinical outcome was assessed as excellent, good, fair, or poor. There was no significant difference between the groups in terms of clinical outcome, blood loss, fusion rate, or complication rate. The cost, length of hospital stay, and operative time were significantly less in the unilateral instrumentation group.

Aoki et al. randomly assigned 50 patients to receive unilateral TLIF with unilateral pedicle screws or bilateral TLIF with bilateral pedicle screws. The patients were followed up for a minimum of 2 years. Baseline demographic characteristics were similar in both groups, as was preoperative and postoperative segmental lordosis. Operative time and estimated blood loss were significantly less in the unilateral group. With respect to VAS-BP and VAS-LP, as well as VAS leg numbness, both groups improved postoperatively; however, the degree of improvement was significantly better in the bilateral cage and bilateral instrumentation group. There were 2 cases of cage migration in the unilateral cage and instrumentation group, compared with 1 cage migration in the bilateral cage and instrumentation group. The results are at variance with our study, possibly due to the fact that Aoki et al. compared patients with bilateral cage placement and unilateral cage placement.

Xue et al. randomly assigned 37 patients to unilateral instrumentation and 43 patients to bilateral instrumentation during open TLIF. The outcome measures used were modified Prolo, VAS, and ODI scores. At a mean follow-up of 25.3 months, there was significant improvement in both groups, but there were significant between-groups differences. The unilateral instrumentation group had significantly shorter operative time, less blood loss, and reduced implant cost. The total fusion rate, screw failure, and complications were similar in both groups. These findings are consistent with our study.

Our study is the first prospective randomized study in the minimally invasive spine surgery literature that compares unilateral and bilateral instrumentation during MIS-TLIF. Utilizing 3 different measures, we demonstrated similar outcomes in our 2 groups. Moreover, the groups demonstrated similar radiographic outcomes, including segmental lordosis and fusion rates. The longer hospital stay in the unilateral instrumentation group can be ascribed to the fact that 1 patient suffered pulmonary edema and was hospitalized for a long period of time.

Our study is limited by its short follow-up, averaging about a year in both groups, and small sample size. Moreover, the use of rhBMP might have also accounted for similar high fusion rates in both groups.

### Conclusions

For single-level pathology, outcomes of unilateral and bilateral instrumentation for unilateral MIS-TLIF are similar at 1 year after surgery, and hence unilateral instrumentation for MIS-TLIF may be a more cost-effective procedure.
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Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author contributions to the study and manuscript preparation include the following. Conception and design: Fessler. Acquisition of data: all authors. Analysis and interpretation of data: Fessler, Dahdaleh, Lawton, Wong, Smith. Drafting the article: all authors. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Fessler. Statistical analysis: Dahdaleh. Study supervision: Fessler.

References


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