Key Words: indirect decompression, leg pain, clinical outcomes, stenosis
Running Title: Indirect Decompression for Leg Pain

Study Design: Retrospective review of a single institution.

Objective: To determine if resting leg pain level is a predictor of success for indirect decompression in the setting of lumbar spinal stenosis, with lower levels of rest pain correlating with greater likelihood of successful indirect decompression.

Methods:
Reviewed patients anterior or lateral lumbar interbody fusions from T12 to L5-S1 patients with a posterior-based pedicle screw-rod construct. Patients were separated into two groups based on a pre-operative response to Oswestry Disabilty Index Question 7 regarding level of pain at rest in the supine position. Responses of 0-2 (minimal rest pain) were Group 1 (N=54) and responses 3-5 (significant rest pain) were Group 2 (N=16).

Results:
Pre-operative difference detected between Groups 1 and 2, in ODI (38 vs 63, $p<0.001$) and NRS Back (6.8 vs 7.9, $p=0.023$). 3 month NRS Leg and Back scores were significantly lower in Group 1 (Leg: 1.9 vs 4.8, $p<0.001$; Back: 3.5 vs 6.4, $p=0.001$). A significant difference was further noted in the percentage decrease in NRS Leg and Back scores from pre- to 3 months post-operatively between Groups 1 and 2 (Leg: 68.4% vs 22.7%, $p<0.001$; Back: 40.0% vs 7.4%, $p=0.012$). Group 1 reached MCID for leg pain more often than Group 2 (83.3% vs 43.8%, $p=0.001$).

Conclusion:
Pre-operative assessment of rest pain level in the supine position has a significant association with reduction in NRS Leg and Back scores in patients undergoing indirect decompression for lumbar spinal stenosis. This tool may successfully indicate which patients will be candidates for indirect decompression with interbody fusion from an anterior or lateral approach.

Introduction:

The use of indirect decompression for spinal stenosis is becoming increasingly common despite nebulous indications for when the addition of an open decompression is warranted[15]. Irrespective of surgical approach, the addition of an interbody fusion can restore disc height and relieve symptoms of nerve compression[3,4,6]. Indirect decompression is achieved through restoration of tension on the annular fibers with subsequent unbuckling of the ligamentum flavum[12].

The prospect of forgoing an open decompression in the setting of interbody fusion while still achieving an excellent outcome is appealing to avoid potentially unnecessary decompression surgery. Previous success has been described with the ability of anterior lumbar interbody fusion (ALIF) to restore disc height and provide indirect decompression with good functional outcome scores[7,9,14].

The purpose of this study was to elucidate the use of preoperative rest pain as an indicator of success for isolated indirect decompression. The authors believe that lower levels of rest pain are correlated with greater likelihood of successful indirect decompression surgery.

Methods:

The study performed was a retrospective chart review. The authors identified all patients that underwent either a primary ALIF or lateral lumbar interbody fusions (LLIF) from T12 to L5-S1 with a posterior-based pedicle screw-rod construct between January 2015 and December 2016 for radiculopathy dominant, surgically-indicated degenerative and deformity pathologies of the lumbar spine. Surgical procedures were performed by two experienced spine surgeons at a single institution through a standard mini-open anterior approach performed with a vascular approach

surgeon for ALIF, or a minimally invasive lateral retroperitoneal approach for LLIF. Exclusion criteria included patients that underwent direct neurologic decompression at the time of the index procedure, revision surgeries, and patients that reported no preoperative leg pain as indicated by Numeric Rating Scale (NRS) leg scores.

Patients were separated into two groups based on a preoperative response to Oswestry Disabilty Index Question 7, how back and leg pain affects sleeping habits: 0) my sleep is never disturbed by pain; 1) my sleep is occasionally disturbed by pain; 2) because of pain I have less than 6 hours sleep; 3) because of pain I have less than 4 hours sleep; 4) because of pain I have less than 2 hours sleep; 5) pain prevents me from sleeping at all. This response was used as an indicator of rest pain level. Responses of 0 through 2 were categorized into Group 1, or minimal rest pain (54 patients) and responses 3 through 5 were categorized into Group 2, or significant rest pain (16 patients). We compared 3 month NRS Leg and Back scores in each group. Three month follow-up was chosen for this pilot study to avoid confounding variables and directly evaluate response to the index procedure. Minimal Clinically Important Difference (MCID) of back and leg pain were compared and the thresholds were set at 1.2 and 1.6, respectively[2]. Three month follow-up was specifically chosen to isolate the effect of the index procedure.

All statistical analyses were performed using Statistical Package for the Social Science (SPSS) v. 24 (Armonk, NY: IBM Corp). Wilcoxon Signed-Rank test was used to assess significant differences between the two groups. Chi-square was used to test for differences amongst categorical variables. Statistical significance was set at alpha of 0.05.

Results:

Two hundred and ninety-five patients were initially identified and 70 patients met inclusion criteria. No significant difference between Groups 1 and 2 were noted with age, BMI, levels treated, and presence of preoperative neurogenic claudication (Table 1). Preoperative NRS Leg scores were similar between groups ($p = 0.585$). Preoperative difference was noted between Groups 1 and 2, with regard to ODI ($p < 0.001$) and NRS Back ($p = 0.023$). Three month NRS Leg and Back scores were significantly lower in Group 1. A significant difference was further noted in the percentage decrease in NRS Leg and Back scores from pre- to 3 months postoperatively between Groups 1 and 2. Group 1 reached MCID for leg pain more often than Group 2, but no difference was seen for MCID NRS back.

When analyzing only those with less than 3 levels treated and an upper instrumented vertebrae (UIV) at L3 or below (Group 1, 38 patients; Group 2, 10 patients) the change in 3 month NRS Leg and Back scores remained significant (Leg: $p = 0.012$; Back: $p=0.037$) as did the percentage decrease in NRS Leg score at 3 months ($p = 0.012$) (Table 2). No longer significant in this sub analysis were the percentage change in 3 month NRS Back score or the MCID for both Leg and Back.

Discussion:

This pilot study is the first to identify an easily accessible preoperative screening tool for guidance in identifying patients that may be amenable to indirect decompression in a relatively large cohort. In the setting of an interbody fusion, an open laminectomy or laminoforaminotomy may not be needed in the absence of leg pain at rest based on the results of this study.

An attempt was made through this study to isolate patients with neurogenic leg pain to best identify the effect of indirect decompression. This was achieved by creating as homogenous a

population as possible based on preoperative symptomatology. Though ODI Question 7 takes into consideration both back and leg pain, isolated back pain may be considered less likely to be pure neurogenic in origin. Therefore, utilizing NRS scores, patients reporting negligible leg pain were excluded. Furthermore, all revision procedures at the index level as well as any patients undergoing concomitant posterior decompressions were excluded to better elucidate the effect of indirect decompression.

Several prior studies have attempted to define various radiographic measurements associated with restoration of interbody height and indirect decompression. Kepler et al[8] showed an average foraminal area increase by 35% on x-ray after LLIF with associated average increase in anterior and posterior disc height of 3.6 mm and 2.6 mm, respectively. Marulanda et al[13] performed a cadaveric study examining the difference between LLIF with lateral plating and pedicle screw fixation measured on CT scan. In the lateral plate and pedicle screw groups, respectively, foraminal area increased by 25.3% and 61.5% on the right and 48.3% and 57.8% on the left. Canal area was increased by 32.3% and 33.3%, respectively. Castellvi et al[1] evaluated 158 patients who underwent LLIF with CT scans and found that foraminal area, 24%-31%, and canal area, 7%, were maintained at 1 year postoperatively. Fujibayashi[4] examined the effect of LLIF in 28 patients at 48 levels on cross-sectional area of the thecal sac evaluated by MRI. The mean cross-sectional area increased 30.2%. Rao et al[16] studied 140 patients with 184 operatively treated levels with anterior lumbar interbody fusion assessed with postoperative CT scan. Significant improvement in foraminal dimensions (area: 67%, height: 21%, and width: 38%) was noted. Sato et al[17] evaluated 20 patients that underwent an oblique lumbar interbody fusion and utilized MRI to assess indirect decompression. MRI at 6 months postoperatively revealed axial and sagittal canal diameter increases of 12% and 32%, respectively. Spinal canal area was

increased by 19% and foraminal area by 21% on the right and 39% on the left. Gates et al[6] developed a computer algorithm to aid in assessment of volumetric and cross-sectional area of indirect decompression via MRI following LLIF. Using their algorithm, they examined 5 levels centrally and 16 foramina and found percentage increase of area by 32.8% and 67.6%, respectively.

Prior attempts at identifying pathology that is not amenable to indirect decompression have shown varying results. Malham et al[11] undertook a prospective examination of 122 patients undergoing LLIF. Eleven patients underwent unplanned second stage decompression. Seven patients had underappreciated spondylolisthesis from high grade arthropathy with instability and bony lateral recess stenosis, three had iatrogenic leg pain through cage misplacement, and one had failure of indirect decompression that could not be explained. Gabel et al[5] attempted to define an algorithm to predict successful indirect decompression in a prospective series of 28 patients undergoing LLIF. They examined several criteria in their algorithm including lack of facet fusion on CT, absence of free disc fragment or compressive facet joint cyst on MRI, absence of frank osteoporosis, lack of congenital and/or severe spinal stenosis (defined as a complete loss of cerebrospinal fluid signal on preoperative MRI), and significant reduction (greater than 50%) in leg and back pain at rest. One patient required a delayed secondary decompression at 1.3 years postoperatively.

Lang et al[10] performed a systematic review of 20 studies (1080 patients) analyzing indirect decompression after LLIF. Lang found postoperative mean foraminal area, central canal area, and subarticular diameter increased by 31.6 mm^2, 28.5 mm^2, and 0.85 mm, respectively. The authors concluded that cage width is the most important surgical factor determining successful indirect decompression.

In this pilot study 3 month follow-up was chosen particularly in an attempt to isolate the effectiveness of indirect decompression as a surgical technique. Our concern with follow-up beyond this time period is the occurrence of new leg pain or other confounders that may not be directly related to the procedure in question. Further prospective studies are underway to evaluate the longevity of indirect decompression.

Preoperative differences regarding ODI and NRS may be viewed as a potential study bias. The preoperative difference found in ODI is inherent to the study design, since groups were defined entirely based on question 7 and this represents one-tenth of the total ODI score. Preoperative differences in the NRS back pain score was found between groups. However, the effect of indirect decompression on back pain was not a focus of the study despite showing significant percentage decrease in scores at 3 months. Lack of significant preoperative difference in NRS leg pain score is an important control between the two groups studied and further isolates rest pain level as the study variable.

Further limitations of this pilot study include the retrospective nature of the data collection. Another is the small sample size included. Additionally, this current study lacked radiographic correlation. Though, the intent of the study is to identify a key exam question irrespective of radiographic findings to aid in identifying candidacy for isolated indirect decompression. That being said, the degree of disc height loss and central stenosis may provide an interesting additional factor to consider as a correlate, along with the quantitative radiographic change occurring operatively via interbody cage height and degree of correction. The authors plan to include radiographic analysis in future studies.

Conclusion:

Preoperative assessment of resting pain level in the supine position has a significant association with reduction in NRS Leg and Back scores in patients undergoing indirect decompression for lumbar spinal stenosis. This tool can be utilized to screen for patients that may be candidates for indirect decompression with interbody fusion from the anterior or lateral approach.

Informed consent: Informed consent was not required as this is a retrospective observational study. This study did receive IRB approval (IRB-13-6297)

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