Does Level of Baseline Leg Pain Influence Outcomes Among Patients with Severe Back Pain undergoing Minimally Invasive Transforaminal Lumbar Interbody Fusion?

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INTRODUCTION: Limited literature has evaluated the influence of varying severity of concomitant leg pain on outcomes of minimally invasive transforaminal interbody fusion (MIS TLIF) among patients presenting with severe back pain. We aim to evaluate the impact of coexisting leg pain on patient-reported outcome measures (PROMs) and minimal clinically important difference (MCID) achievement amongst patients with severe back pain receiving MIS TLIF.

METHODS: A retrospective dataset of a singular spine surgeon was reviewed to identify patients receiving primary, single-level MIS TLIF with preoperative Visual Analog Scale (VAS) back ≥7. Patients missing preoperative VAS back or VAS leg score and those receiving MIS TLIF for infection, trauma, or cancer, were excluded. Patients were grouped by preoperative VAS leg into VAS leg <7 and VAS leg ≥7. Demographic information and perioperative characteristics were collected and compared between groups. PROMs were collected in the preoperative period and at 6-weeks, 12-weeks, 6-months, 1-year, and 2-years following the MIS TLIF and included VAS back/leg, Oswestry Disability Index (ODI), 12-Item Short Form (SF-12) Physical Composite Score (PCS), and Patient Reported Outcome Measurement Information System physical function (PROMIS-PF) which were compared within and between groups. MCID achievement was assessed by comparing PROM change scores to established thresholds in literature, and differences in achievement rates were compared between cohorts.

RESULTS: 131 patients were included in the final cohort. 63 patients were in the VAS leg <7 group and 68 patients were in the VAS leg ≥7 group. Majority of patients presented with degenerative spondylolisthesis (51.9%), followed by isthmic spondylolisthesis (33.6%). Most patients also presented with central stenosis (91.6%). 1-year arthrodesis rates were 95.7% and 94.6% in the VAS leg <7 and VAS leg ≥7 cohorts, respectively. No significant intergroup differences were observed in demographic or perioperative characteristics. VAS leg <7 patients significantly improved from preoperative to postoperative PROM score for all surveys at all time points, with the exception of PROMIS-PF at 6-weeks ($p \leq 0.041$, all). VAS leg ≥7 patients improved significantly throughout the entire postoperative period for all PROM surveys ($p \leq 0.033$, all). VAS leg <7 patients had lower VAS leg, VAS back, and ODI preoperatively ($p \leq 0.011$, all); however, no significant differences were observed for postoperative scores for any PROM. Nonetheless, VAS back/leg and ODI postoperative scores trended to be greater throughout the postoperative period. MCID achievement rate was significantly higher among patients with VAS leg <7 for SF-12 PCS at 2-years ($p = 0.030$), while achievement rates for overall VAS leg and at 6-weeks, 12-weeks, 6-months, and 2-years for VAS leg were significantly higher among VAS leg ≥7 patients ($p \leq 0.003$, all).

DISCUSSION AND CONCLUSION: Patients with severe back pain and relatively greater coexisting leg pain generally suffered from higher pain scores and disability preoperatively and postoperatively, albeit post-surgical differences in PROMs did not reach statistical significance. Meanwhile, patients with less concomitant leg pain experienced higher rates of MCID achievement for SF-12 PCS, while those with a higher degree of concomitant leg pain largely demonstrated higher rates of achievement for VAS leg throughout most of the postoperative period.

Table 1. Patient Demographics

Characteristic	Total (n=131)	VAS leg <7 (n=63)	VAS leg ≥7 (n=68)	*p-value
Age (mean ± SD, years)	50.7±11.0	50.6±11.4	50.9±10.7	0.891
BMI (mean ± SD, kg/m²)	30.7±6.6	31.0±6.3	30.4±6.9	0.641
Gender				0.607
Female	42.0% (55)	39.7% (25)	44.1% (30)	
Male	58.0% (76)	60.3% (38)	55.9% (38)	
Ethnicity				0.125
Caucasian	71.5% (93)	81.0% (51)	62.7% (42)	
African-American	13.9% (18)	9.5% (6)	17.9% (12)	
Hispanic	8.5% (11)	3.2% (2)	13.4% (9)	
Asian	3.1% (4)	3.2% (2)	3.0% (2)	
Other	3.1% (4)	3.2% (2)	3.0% (2)	
Diabetic Status				0.883
Non-Diabetic	90.1% (118)	90.5% (57)	89.7% (61)	
Diabetic	9.9% (13)	9.5% (6)	10.3% (7)	
Smoking Status				0.473
Non-Smoker	89.3% (117)	87.3% (55)	91.2% (62)	
Smoker	10.7% (14)	12.7% (8)	8.8% (6)	
Hypertension Status				0.902
Non-hypertensive	72.5% (95)	73.0% (46)	72.1% (49)	
Hypertensive	27.5% (36)	27.0% (17)	27.9% (19)	
ASA Classification				0.316
<2	78.1% (100)	82.0% (50)	74.6% (50)	
≥2	21.9% (28)	18.0% (11)	25.4% (17)	
CCI Score (mean ± SD)	1.8±1.7	1.7±1.8	1.8±1.6	0.615
Insurance				0.838
Medicare/Medicaid	3.8% (5)	4.8% (3)	2.9% (2)	
Workers' Compensation	28.2% (37)	27.0% (17)	29.4% (20)	
Private	67.9% (89)	68.3% (43)	67.7% (46)	

ASA = American Society of Anesthesiologists; CCI = Charlson Comorbidity Index; SD= standard deviation

Boldface indicates significance

Table 2. Perioperative Characteristics

Characteristic	Total (n=131)	VAS leg <7 (n=63)	VAS leg ≥7 (n=68)	*p-value
Spinal Pathology				
Degenerative Spondylolisthesis	51.9% (68)	50.8% (32)	52.9% (36)	0.806
Isthmic Spondylolisthesis	33.6% (44)	34.9% (22)	32.4% (22)	0.756
Recurrent HNP	9.9% (13)	6.4% (4)	13.2% (9)	0.188
Degenerative Scoliosis	3.8% (5)	3.2% (2)	4.4% (3)	0.712
Central Stenosis	91.6% (120)	93.7% (59)	89.7% (61)	0.416
Foraminal Stenosis	43.5% (57)	47.6% (30)	39.7% (27)	0.361
Operative Time (Mean ± SD; min)	129.1±28.9	130.5±34.6	127.9±22.5	0.602
Estimated Blood Loss (Mean ± SD; mL)	51.9±29.6	55.2±32.8	48.9±26.1	0.226
Length of Stay (Mean ± SD; hours)	36.3±20.2	32.4±19.6	40.0±20.2	0.034
Postoperative Vas pain				
POD 0	5.5±1.8	5.3±2.0	5.7±1.7	0.240
POD 1	5.1±1.7	5.2±1.6	5.1±1.7	0.845
Postoperative Narcotic Consumption (OME)				
POD 0	65.1±31.0	63.4±32.2	66.7±29.9	0.537
POD 1	51.8±34.7	48.4±32.6	54.9±36.6	0.292
1-year Arthrodesis	95.1% (97)	95.7% (44)	94.6% (53)	0.814

rHNP = recurrent herniated nucleus pulposus; POD = postoperative day; mL = milliliters; OME = oral morphine equivalents; SD= standard deviation

*p-values calculated using Student's t-test for continuous variables and chi-square analysis for categorical variables

Boldface indicates significance

Table 3. Mean Patient Reported Outcomes

PROM	VAS leg <7 Mean ± SD	*p-value	VAS leg ≥7 Mean ± SD	†p-value	*†p-value
PROMIS PF					
Preoperative	36.7±7.5	-	33.5±7.6	-	0.121
6-weeks	39.0±7.9	0.075	36.1±6.9	**0.005**	0.138
12-weeks	40.7±8.6	**0.007**	40.5±6.6	**0.001**	0.900
6-months	43.6±7.6	**0.001**	42.4±7.2	**0.001**	0.584
1-year	45.2±9.7	**<0.001**	43.2±9.5	**<0.001**	0.486
2-year	44.0±8.5	**<0.001**	41.5±9.3	**0.033**	0.406
SF-12 PCS					
Preoperative	28.9±8.2	-	31.7±12.5	-	0.235
6-weeks	32.5±10.2	**0.041**	30.7±8.5	**0.040**	0.371
12-weeks	34.7±11.1	**<0.001**	35.4±10.0	**0.005**	0.770
6-months	37.9±11.5	**<0.001**	39.4±11.7	**<0.001**	0.606
1-year	41.0±11.2	**<0.001**	37.0±10.0	**<0.001**	0.156
2-year	39.4±10.7	**<0.001**	38.1±11.4	**0.008**	0.681
VAS back					
Preoperative	7.9±0.8	-	8.6±1.0	-	**0.001**
6-weeks	4.4±2.3	**<0.001**	4.3±2.6	**<0.001**	0.902
12-weeks	4.1±2.7	**<0.001**	4.6±2.6	**<0.001**	0.361
6-months	3.7±2.7	**<0.001**	4.0±2.7	**<0.001**	0.584
1-year	3.0±2.6	**<0.001**	3.8±2.7	**<0.001**	0.255
2-year	3.7±2.7	**<0.001**	3.8±3.2	**<0.001**	0.929
VAS leg					
Preoperative	3.9±2.7	-	8.3±0.9	-	**<0.001**
6-weeks	2.9±2.7	**0.023**	3.7±3.0	**<0.001**	0.161
12-weeks	3.0±3.0	**0.007**	3.4±2.6	**<0.001**	0.478
6-months	2.8±2.8	**0.007**	3.4±3.0	**<0.001**	0.268
1-year	1.8±2.4	**<0.001**	3.4±2.8	**<0.001**	0.028
2-year	2.6±2.6	**0.001**	3.6±3.1	**<0.001**	0.307
ODI					
Preoperative	42.4±12.3	-	50.3±17.4	-	**0.011**
6-weeks	35.1±18.7	**0.003**	39.7±20.3	**<0.001**	0.214
12-weeks	28.7±18.8	**<0.001**	34.1±17.5	**<0.001**	0.144
6-months	25.5±19.7	**<0.001**	30.6±19.7	**<0.001**	0.191
1-year	18.8±18.6	**<0.001**	26.7±18.1	**<0.001**	0.095
2-year	24.0±20.0	**<0.001**	28.1±25.5	**0.009**	0.577

*p-values calculated using paired sample t-test to determine preoperative to postoperative improvement in VAS leg <7 cohort

†p-values calculated using Student's t-test to determine preoperative to postoperative improvement in VAS leg ≥7 cohort

*†p-values calculated using Student's t-test to compare mean PROMs between both cohorts

Boldface indicates significance

Table 4. Minimum Clinically Important Difference

PROM	VAS leg <7 %, (n)	VAS leg ≥7 %, (n)	*p-value
ODI			
6-weeks	36.4% (20)	45.0% (27)	0.347
12-weeks	53.1% (26)	58.5% (31)	0.581
6-months	60.7% (34)	61.7% (29)	0.918
1-year	68.8% (22)	73.3% (22)	0.691
2-year	52.4% (11)	65.0% (13)	0.412
Overall	67.2% (41)	75.8% (50)	0.286
PROMIS-PF			
6-weeks	44.8% (13)	38.5% (10)	0.633
12-weeks	42.3% (11)	57.9% (11)	0.302
6-months	54.2% (13)	70.0% (14)	0.283
1-year	75.0% (15)	82.4% (14)	0.588
2-year	58.8% (10)	66.7% (10)	0.647
Overall	69.4% (25)	75.8% (25)	0.558
SF-12 PCS			
6-weeks	54.8% (23)	47.5% (19)	0.511
12-weeks	64.1% (25)	70.0% (21)	0.606
6-months	65.6% (21)	71.4% (20)	0.630
1-year	81.5% (22)	66.7% (18)	0.214
2-year	88.0% (22)	60.0% (12)	**0.030**
Overall	86.3% (44)	76.0% (38)	0.186
VAS back			
6-weeks	68.5% (37)	75.4% (46)	0.411
12-weeks	68.0% (34)	75.0% (39)	0.433
6-months	65.5% (36)	73.3% (33)	0.397
1-year	77.4% (24)	80.7% (25)	0.755
2-year	70.0% (14)	75.0% (15)	0.723
Overall	83.3% (50)	93.8% (60)	0.067
VAS leg			
6-weeks	37.0% (20)	71.7% (43)	**<0.001**
12-weeks	32.0% (16)	75.0% (39)	**<0.001**
6-months	32.7% (18)	75.6% (34)	**<0.001**
1-year	48.4% (15)	67.7% (21)	0.123
2-year	33.3% (7)	80.0% (16)	**0.003**
Overall	51.7% (31)	90.6% (58)	**<0.001**

*p-values calculated using chi-square analysis

Boldface indicates significance