Efficacy and Safety of the Ultrasound Bone Scalpel in Lumbar Laminectomies

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INTRODUCTION:

Lumbar laminectomy is commonly performed to address complaints of neurogenic claudication or radicular leg pain and has been shown to have durable improvement in patient reported quality of life and physical function. Despite recent advances in applied instruments and surgical techniques, the incidence of iatrogenic dural injuries caused by traditional laminectomy techniques is still considerable and has been reported in as many as 16% of lumbar surgeries.

The ultrasonic bone scalpel (UBS) is a tool that uses high-frequency oscillation to create localized tissue disruption and preferentially cut through hard surfaces such as bone. This technology has been shown to improve speed and reduce iatrogenic complications in laminectomies when compared to traditional methods utilizing high-speed burr, punch forceps, rongeurs or osteotomes. Both operative and postoperative complications can significantly impact patient recovery and patient reported outcomes (PROs). Currently, there is a paucity of evidence describing how surgical instrumentation choice (UBS vs traditional instruments) affects PROs and complication rates following lumbar laminectomy.

The present study sought to evaluate whether the use of an ultrasonic bone scalpel would result in equivalent safety, efficacy and PRO improvement when compared to traditional methods of laminectomy. We hypothesize that lumbar laminectomies performed using the UBS will demonstrate equivalent safety, efficacy and PROs while decreasing rates of durotomies when compared to traditional methods of laminectomy.

METHODS:

Data from a prospectively collected, single-institution registry was queried between 01/01/2019-09/01/2021 for patients with a primary diagnosis of lumbar stenosis who underwent an isolated laminectomy, laminectomy and fusion, or laminectomy and fusion with an interbody. Our two patient groups included those undergoing laminectomies using traditional methods vs UBS method. Outcomes included 3-month and 12-month values for all PROMIS subdomains, NRS pain scores, ODI percentage, and PHQ-9 scores. Also included were post operative complications, reoperations, or readmissions within 3 months. Patients who received a lumbar laminectomy by traditional methods were propensity matched against patients who received a lumbar laminectomy by the UBS in a 2:1 fashion. Covariates selected for matching included age, operation type, and number of levels. A variety of statistical tests were used to compare the traditional vs UBS groups.

RESULTS:

231 patients who received a laminectomy with traditional methods were propensity matched against 32 patients treated with the ultrasound bone scalpel, resulting in 64 “traditional” patients and 32 “UBS” patients. Post-match analysis found no differences between the traditional and UBS groups for demographic and baseline measures with the exception of race and ethnicity (Table 1). For the matched sample, there were no differences in all PROMIS subdomain scores, NRS back/leg pain scores, %ODI or PHQ-9 at 3 or 12 months (Table 2). In addition, no significant differences existed between the two groups for overall complications, reoperation rates, or readmission rates. There was a significant difference in the rate of iatrogenic durotomies between the traditional and UBS groups (12.5% vs 0.0%, p=0.049) (Table 3). Among those patients experiencing iatrogenic durotomy, 12.5% required re-operation.

DISCUSSION AND CONCLUSION:

Laminectomies are commonly performed on the lumbar spine to remedy a variety of spine pathologies; however, the procedure is not without risk. Notably, the most common complication resulting from a lumbar laminectomy procedure is an iatrogenic durotomy. While previous studies have reported improved operative speed and decreased complications for laminectomies performed by the UBS in the cervical and thoracic regions, the efficacy of the UBS for lumbar laminectomies has remained understudied. Our study sought to compare outcomes between patients who received a lumbar laminectomy via traditional methods vs UBS method. Although PROs remained unchanged, results showed the high-frequency oscillation technology implemented by the UBS helps to decrease the rate of injury to the dura, thus reducing the overall incidence of iatrogenic durotomies.

This study should be interpreted in light of its inherent limitations. First, the study contained data from a single institution. Patient selection and laminectomy method were at the discretion of the surgeon with potential for bias. Even though propensity matching was performed, our study had a smaller number of UBS patients and could be underpowered to detect differences in multiple outcomes. The heterogeneity of lumbar surgical cases is another limitation. Future studies analyzing these methods separately would be recommended.

We believe these data provide valuable information to surgeons and patients about the safety and efficacy of the UBS in performing lumbar laminectomies. Further studies may investigate if the UBS decreases operative time for lumbar laminectomies compared to traditional laminectomy methods.

Table 1: Baseline Characteristics			
	Traditional N = 64	UBS N = 32	p-value
Age	63.2 ± 11.98	62.5 ± 13.3	0.873
Gender			0.248
Female	34.0 (53.1%)	13.0 (40.6%)	
Male	30.0 (46.9%)	19.0 (59.4%)	
BMI	30.1 ± 5.8	30.8 ± 4.8	0.563
Ethnicity			0.041
Hispanic	1.0 (1.6%)	1.0 (3.1%)	
Not Hispanic	61.0 (95.3%)	26.0 (81.2%)	
Prefer not to answer	2.0 (3.1%)	5.0 (15.6%)	
Race			0.026
Black	3.0 (4.7%)	1.0 (3.1%)	
Mixed	1.0 (1.6%)	0.0 (0.0%)	
Native	1.0 (1.6%)	0.0 (0.0%)	
No Response	1.0 (1.6%)	5.0 (15.6%)	
Other	0.0 (0.0%)	1.0 (3.1%)	
White	58.0 (90.6%)	25.0 (78.1%)	
Smoking Status			0.797
None	60.0 (93.8%)	31.0 (96.9%)	
Daily	2.0 (3.1%)	1.0 (3.1%)	
Occasional	2.0 (3.1%)	0.0 (0.0%)	
Lami Levels			0.475
1	38.0 (59.4%)	16.0 (50.0%)	
2	16.0 (25.0%)	13.0 (40.6%)	
3	6.0 (9.4%)	2.0 (6.2%)	
4	4.0 (6.2%)	1.0 (3.1%)	
Total Levels			0.981
1	34.0 (53.1%)	17.0 (53.1%)	
2	20.0 (31.2%)	11.0 (34.4%)	
3	6.0 (9.4%)	3.0 (9.4%)	
4	4.0 (6.2%)	1.0 (3.1%)	
Surgery Type			0.819
Laminectomy	14.0 (21.9%)	7.0 (21.9%)	
Laminectomy + fusion (instrumented)	4.0 (6.2%)	3.0 (9.4%)	
Laminectomy + instrumented fusion with interbody graft (also TLIF)	46.0 (71.9%)	22.0 (68.8%)	

Table 2: Outcomes			
	Traditional, N = 64	UBS, N = 32	p-value
Preoperative			
PROMIS			
Physical function t-score	35.2 ± 5.6	34.5 ± 4.0	0.705
Anxiety t-score	52.0 ± 9.1	53.2 ± 9.3	0.553
Depression t-score	49.6 ± 8.6	50.4 ± 9.0	0.668
Fatigue t-score	53.4 ± 8.7	55.6 ± 9.1	0.182
Sleep disturbance t-score	52.5 ± 8.1	53.2 ± 7.8	0.839
Ability to participate in social roles t-score	41.9 ± 8.0	40.2 ± 7.1	0.342
Pain interference t-score	65.6 ± 6.4	66.7 ± 5.0	0.418
NIH			
NRS Back pain in past 7 days	6.3 ± 2.3	6.5 ± 1.8	0.651
NRS Leg pain in the past 7 days	6.4 ± 2.4	6.8 ± 1.9	0.537
Total ODI sum score	20.6 ± 8.3	20.2 ± 7.0	0.763
ODI percentage	41.2 ± 16.6	40.5 ± 13.9	0.763
PHQ-9 score	6.3 ± 6.1	5.8 ± 5.1	0.861
3 months Post Op			
PROMIS			
Physical function t-score	44.0 ± 6.9	45.8 ± 8.4	0.558
Anxiety t-score	47.5 ± 7.8	45.2 ± 7.8	0.185
Depression t-score	47.7 ± 9.2	46.3 ± 7.1	0.632
Fatigue t-score	48.5 ± 8.7	47.0 ± 9.3	0.562
Sleep disturbance t-score	49.6 ± 7.3	46.6 ± 8.5	0.145
Ability to participate in social roles t-score	51.2 ± 8.3	51.0 ± 9.6	0.759
Pain interference t-score	54.8 ± 8.1	53.8 ± 8.7	0.584
NIH			
NRS Back pain in the past 7 days	2.9 ± 2.6	2.2 ± 2.3	0.332
NRS Leg pain in the past 7 days	2.4 ± 2.9	1.7 ± 2.5	0.294
Total ODI sum score	11.1 ± 7.7	9.3 ± 8.3	0.259
ODI percentage	22.2 ± 15.4	18.6 ± 16.6	0.259
PHQ-9 score	3.1 ± 3.7	2.4 ± 3.0	0.472
12 months Post Op			
PROMIS			
Physical function t-score	45.3 ± 6.7	43.1 ± 7.9	0.237
Anxiety t-score	48.4 ± 9.4	49.2 ± 10.9	0.916
Depression t-score	48.4 ± 8.9	49.5 ± 8.7	0.419
Fatigue t-score	49.0 ± 9.1	51.2 ± 12.5	0.493
Sleep disturbance t-score	49.2 ± 8.7	51.1 ± 10.9	0.431
Ability to participate in social roles t-score	51.4 ± 8.9	49.6 ± 11.1	0.705
Pain interference t-score	53.7 ± 8.8	56.2 ± 10.2	0.497
NIH			
NRS Back pain in the past 7 days	2.7 ± 2.6	3.2 ± 2.7	0.465
NRS Leg pain in the past 7 days	2.5 ± 2.5	3.8 ± 3.2	0.179
Total ODI sum score	9.4 ± 6.8	10.5 ± 10.7	0.843
ODI percentage	18.8 ± 13.7	21.0 ± 21.3	0.843
PHQ-9 score	3.6 ± 5.2	5.5 ± 6.9	0.204

Table 3: Complications			
	Traditional, N = 64	UBS, N = 32	p-value
Pneumonia	0.0 (0.0%)	0.0 (0.0%)	
DVT	0.0 (0.0%)	0.0 (0.0%)	
UTI	0.0 (0.0%)	0.0 (0.0%)	
SSI	1.0 (1.6%)	1.0 (3.1%)	>0.999
Neuro Deficit	0.0 (0.0%)	0.0 (0.0%)	
Durotomy	8.0 (12.5%)	0.0 (0.0%)	0.049
Root Injury	0.0 (0.0%)	0.0 (0.0%)	
Neurological Complication	0.0 (0.0%)	1.0 (3.1%)	0.333
No Complication	56.0 (87.5%)	31.0 (96.9%)	0.264
Return to OR	5.0 (7.8%)	1.0 (3.1%)	0.660
Readmission	10.0 (15.6%)	2.0 (6.2%)	0.326