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Efficacy of Lumbar Transforaminal Epidural Steroid Injections for Lumbosacral Radiculopathy in Individuals with Spine Surgery: A Retrospective Comparative Study

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Abstract

Introduction: Transforaminal epidural steroid injections (TFESI) have demonstrated their efficacy in both short-term and long-term treatment of radicular pain with their targets being the anterolateral epidural space and dorsal root ganglion. Although the evidence for transforaminal injections in treating radiculitis secondary to discherniation and lumbar stenosis is strong, evidence is limited regarding its effect on axial pain and in patients with failed back surgery syndrome (FBSS).

Methodology: 61 patients were registered in this retrospective comparative study who underwent lumbar TFESI for lumbosacral radiculopathy from March 2021 to March 2022. All patients were assessed for difference in pain relief, disability and functional outcome at baseline and at the time of follow up using NRS, ODI & PROMIS. As a secondary objective the patients were divided into two groups those with previous history of spine surgery (Group A) and non-operated patients (Group B) to Compare the mean levels of pain relief, functional outcome and disability in spine surgery patients compared to non-operated patients. After Ethical committee approval and informed consent from patient baseline scores (NRS, ODI & PROMIS) were accessed from the MRD and follow up scores were obtained by sending a questionnaire across to the patient by email. The average follow up time was 1 year and 4 months (Mean).

Results and Observations: A minimum clinically important difference (MCID) of >2.0 was selected for the change in NRS to further determine the proportion of responders who experienced a clinically significant reduction of pain. Success in achieving MCID is defined by ≥3 t score change for all PROMIS instruments. Success in achieving MCID for ODI is defined as at least 30% score change at follow up from baseline score.

There is no significant difference in pain relief, disability improvement, functional outcome as assessed by NRS, ODI & PROMIS between the two groups. In this study the success in achieving MCID for

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NRS was 70% in Group A and 63% in group B and overall 67% indicating that total 41 patients (67%) had significant reduction in NRS after TFESI. In this study success of achieving MCID for ODI was 38.7% among Group A which was comparable to 23.3% among Group B and the difference was not statistically significant. The overall success of achieving MCID for ODI was total 19 patients (31.1%) indicating only 31% patients had significant improvement in disability post TFESI. There is no significant difference in functional outcome as assessed by PROMIS instruments between the two groups. For PROMIS PF, PI, SD the success of achieving MCID was greater than 70% overall and for both the groups.

Conclusion: There is no doubt regarding the efficacy and therapeutic effect of TFESI in axial lumbosacral pain/radicular pain in non-operated patients. This study demonstrates the success rate of TFESI in spine surgery patients (FBSS) as well by utilizing PROMIS as an outcome measure and by use of a control group demonstrating improved Physical Function, less pain interference & improved sleep.

Keywords: TFESI; PROMIS; Epidural; Transforaminal.

INTRODUCTION

Epidural steroid injections have been utilized to treat lower back and radicular pain symptoms since the 1950s.[1,2] Over the years, epidural injections have demonstrated efficacy in managing radicular back pain providing pain relief and improving function, decreasing opioid dependence, and reducing the need for surgical intervention.[2] Transforaminal epidural steroid injections (TFE9SI) represent a relatively new approach for radicular pain symptoms secondary to disc herniation or stenosis.[2] There have been several studies demonstrating their efficacy in both short-term and long-term treatment of radicular pain,[2,3] with their targets being the anterolateral epidural space and dorsal root gang lion.[3,4] Examples of advantages of the transforaminal approach are its specificity with respect to specific nerve root symptoms, as well as requiring a smaller injectate volume in order to provide symptom relief. Although the evidence for transforaminal injections in treating radiculitis secondary to discherniation and lumbar stenosis is strong,[5,6] evidence is limited regarding its effect on axial pain and in patients with failed back surgery syndrome (FBSS).[5,6] This is an important area of consideration as we anticipate a growing sub set of patients with FBSS as the number of spine surgeries continues to increase.

Performing epidural steroid injections can be difficult in post-surgical patients secondary to post-operative fibrosis in the epidural space. There has been heavy reliance on caudal epidural injections for post-surgical patients due to their relative ease.[4–7] However, this approach is not free from limitations, such as the in ability to spread the injected medication to lumbar levels above L3,[8] lack of specificity for individual spinal levels, and the requirement of large injectate volumes.[4] As a result of this lack of specificity, caudal epidural injections do not provide any prognostic in put when determining the contribution of a specific spinal level to a patient's symptoms, and thus have a limited role in aiding decisions regarding future surgical interventions.[7,8] In comparison, the transforaminal epidural approach efficiently in stills the injectate into the epidural space and may offer prognostic input for future surgery due to its increased specificity.[9,10] One study has also demonstrated superiority of the unilateral transforaminal over the caudal injection approaching patients with FBSS.[11]

Simultaneous bilateral transforaminal epidural steroid injections have emerged as viable treatment options for patients with bilateral radicular back pain supported by three studies in the literature to date.[10,12,13] The aim of our study is to assess the therapeutic and prognostic potential of lumbar transforaminal epidural steroid injections in patients with prior lumbar laminectomy and/or fusion compared to non-operative patients. The primary objective is to assess the efficacy of TFESI in patients with lumbosacral radiculopathy using NRS, ODI and PROMIS scores. The secondary objective is to compare mean levels of pain relief, disability and functional outcome in patients with lumbar fusion or laminectomies who underwent lumbar transforaminal epidural steroid injections compared to non-operated patients using Numeric rating Scale (NRS), the Oswestry Disability Index (ODI) and Patient Reported Outcome Measurement Information System (PROMIS). We hypothesize that there is no significant difference in pain relief, disability, and function in spine surgery patients compared to non-operated patients.

Justification/Lacuna in knowledge: TFESI for Spinal Stenosis- Two outcome studies respectively reported 26 of 48 patients.[14] and 6 of 10 patients[15] having 50% relief of pain at 6 months.

TFESI For disk herniation, the review[16] found that the literature is sufficiently abundant to show that lumbar TF injection of steroids is not universally

effective but, nevertheless, benefits a substantial proportion of patients and is not a placebo. A retrospective case series[17] found that simultaneous bilateral TFESIs have a therapeutic and prognostic role in managing patients with bilateral radicular back pain after previous lumbar spine surgery.

However these studies have various short comings short and inconsistent follow up period~2-12 weeks, no inclusion of functional measures such as the Oswestry Disability Index and PROMIS in assessing response to injections, which would have been beneficial in understanding baseline limitations and the effects of TSEF Is on function. Therefore in our study we plan to evaluate the difference in pain relief, disability, and function outcome in patients with lumbar fusion or laminectomies who underwent lumbar transforaminal epidural steroid injections compared to nonoperated patients using NRS, ODI & PROMIS at baseline and at the time of follow up.

MATERIALS AND METHODS

Study Area: Department of Chronic Pain Medicine, Lilavati Hospital & Research Centre, Mumbai.

a) Study Population: 61 patients (aged 18 - 65 years old) were registered in this retrospective comparative study who underwent lumbar TFESI for lumbosacral radiculopathy from March 2021 to March 2022. All patients were assessed for difference in pain relief, disability and functional outcome at baseline and at the time of follow up using NRS, ODI & PROMIS. As a secondary objective the patients were divided into two groups those with previous history of spine surgery (Group A) and non-operated patients (Group B) to Compare the mean levels of pain relief, functional outcome and disability in spine surgery patients compared to nonoperated patients. After Ethical committee approval and informed consent from patient baseline scores (NRS, ODI & PROMIS) were accessed from the MRD and follow up scores were obtained by sending a questionnaire across to the patient by email. The average follow up time was 1 year and 4 months (Mean).

b) Inclusion Criteria:

1. All patients who underwent lumbar TFESI for lumbosacral radiculopathy during the study period aged 18-65 years old.
2. All Patients with previous laminectomy and/ or fusion surgery who underwent lumbar TFESI for lumbosacral radiculopathy.
3. Male and female patients.
4. All patients willing to participate in the study design.

c) Exclusion criteria:

1. Patients lost in follow up.
2. Facet joint intra articular injection.
3. Median branch block.
4. Sacro-iliac joint injection.
5. Greater than 4 level TFESI.
6. Incomplete survey information/incompletely filled forms.

Assessment Tools

Numeric Rating Scale (NRS): Each patient was asked to describe their cumulative pain, including axial and bilateral radicular symptoms, using a numerical rating score (NRS) from 0 to 10 prior to the procedure (baseline), specifying that a score of 0 correlated with no pain and 10 correlated with excruciating pain. Responders were defined as patients who experienced an NRS pain reduction of any degree post-injection, and non-responders as patients who experienced no change (NRS Δ ¼ 0). A minimum clinically important difference (MCID) of >2.0 was selected for the change in NRS to further determine the proportion of responders who experienced a clinically significant reduction of pain. Suzuki *et al.* (2020) previously defined the value of MCID_2.0 as a definitive indicator of the rapeutic outcome for the change in NRS in treating patients with lumbar back pain.[18]

Oswestry Disability Index (ODI): The Oswestry Disability Index (ODI) is one of the most commonly used outcome measures for low back pain. It is a self-administered questionnaire divided into ten sections designed to assess limitations of various activities of daily living.

Each section is scored on a 0–5 scale, 5 representing the greatest disability. Success in achieving MCID for ODI is defined as at least 30% score change at follow up from baseline score.

Promis 29: The US National Institutes of Health, using item response theory and computer adaptive testing, developed Patient Reported Outcome Measurement Information System (PROMIS). PROMIS is reliable, accurate, correlates with legacy PROs, and possesses improved psychometric properties. The PROMIS-29 profile is a self-administered questionnaire which assesses pain intensity using a single 0–10 numeric rating item and seven health domains (physical function,

fatigue, pain interference, depressive symptoms, anxiety, ability to participate in social roles and activities, and sleep disturbance) using four items per domain. It is a validated health related quality of life instrument for various chronic conditions including back pain. Higher scores on PROMIS PI and PROMIS D represent increased morbidity. Higher scores on PROMIS PF represent increased PF. Success in achieving MCID is defined by ≥ 3 t score change for all PROMIS instruments.

Procedure

A single fellowship trained interventional spine physician with greater than 20 years experience performed all fluoroscopically guided TFESI(s). The level of injection was determined based on the dermatomal pattern of radicular pain and imaging findings corresponding to the symptoms. The fluoroscopically-guided transforaminal injections were then performed following the technique outlined by Derby, Bogduk, and Kine (1993).[19] Injections performed at a maximum of upto 4 levels.

Each of the injections were reviewed for appropriate contrast spread prior to steroid injection while under fluoroscopy. TFESIs were performed at the level below the targeted disc level utilizing medial, cephalad and ventral flow of injectate in order to adequately deliver steroid to the ventral epidural space along the posterior aspect of the targeted intervertebral disc and site of any potential inflammatory process. For example, if targeting the L5−S1 disc level, the TFESI was performed through the S1 foramina. All paPents were positioned prone on a standard fluoroscopy table and the lumbosacral spine was exposed, prepped and draped in sterile fashion. Fluoroscopy was utilized to identify the correct level for the procedure taking into account lumbosacral transitional vertebrae when present. A skin wheal was raised with 1% lidocaine in the paraspinal region over the inferior aspect of the pedicle of the vertebral body directly inferior and adjacent to the targeted disc level. Utilizing an oblique trajectory view, a 23 or 22 gauge 3-1/2" spinal needle was advanced to the 6 o'clock position of the targeted pedicle. Depth and proper needle placement was confirmed utilizing an anteroposterior view. After confirming appropriate needle location and nonvascular uptake with contrast, 1 mL of Triamcinolone (20 mg/mL) combined with 1 mL of Lidocaine 1% administered at each level. It should be noted that only 22 and 23 gauge needles were used to directly access the epidural space and no major/clinically significant hemorrhagic complications, including epidural and/or soft-tissue hematomas, were reported.

Statistical Analysis

Data analysis was performed utilizing STATA software. Statistical analysis for change in NRS will be performed using a paired t-test with a p value of <0.05 considered significant.

Descriptive statistics will be used for patient demographics. Age, gender, pain location, level and laterality of TFESI, physical therapy enrollment, and MRI findings would be characterized. Two tailed, paired sample t tests will be used to test the hypothesis that there would be no changes in PROMIS scores between pre and post injection time points.

The significance level will be set at 0.05. Person correlation would be performed to investigate the relationship between PROMIS instruments. An exploratory analysis investigating success in achieving MCID is defined by ≥ 3 t score change for all PROMIS instruments. The predetermined, threshold value for MCID achievement is determined from prior studies.[20,21] PROMIS variables were evaluated at the end of treatment within group by using Wilcoxon sign rank test and changes between groups by Mann Whitney U test. The success rate (MCID) for ODI is defined as at least 30% improvement at follow up from previous studies.[22] A minimum clinically important difference (MCID) of >2.0 was selected for the change in NRS to further determine the proportion of responders who experienced a clinically significant reduction of pain.

RESULTS AND OBSERVATIONS

A total of 61 patients (31 in Group A, 30 in Group B) were included in the final analysis. Mean no of TFESI administered per patient equalled 3.1 for group A and 2.0 for Group B. Average follow up time was 1 year 4 months post TFESI. Patient demographics are presented in Table 1.

Table 3 shows that follow up combined mean NRS score showed a significant fall of 50.7% from baseline NRS score which was comparable to 47.8% for group A and 53% for group B however the difference was not statistically significant.

Table 4 shows that at baseline, the mean score of ODI among Group A was 30.19 was comparable to 30.87 among Group B, and the difference was not statistically significant. At Follow up mean ODI score showed a significant fall of 21.5% which was comparable to 19.8% among Group B and the

Table 1: Demographics

Demographic	Demographic data	Group A	Group B
	No. of patients	31	30
	Mean Age (Range)	59.7 (Range 32-65 years)	58.7 (Range 32-65 years)
Gender	Male	18 (58.1%)	17 (56.7%)
	female	13 (41.9%)	13 (43.3%)
Prior back surgery	Laminectomy	17 (54.8%)	No history of surgery
	Laminectomy + Fusion	14 (45.2%)	
Laterality of TFESI	Bilateral	13 (41.9%)	08 (26.7%)
	Left	08 (25.8%)	11 (36.7%)
	Right	10 (32.5%)	11 (36.7%)
Level of TFESI	L2	08 (8.2%)	03 (5.0%)
	L3	16 (16.5%)	05 (8.3%)
	L4	26 (26.8%)	17 (28.3%)
	L5	36 (37.1%)	28 (46.7%)
	S1	11 (11.3%)	7 (11.7%)
	Total	97	60
No of TFESI per patient	1	01 (3.2%)	11 (36.7%)
	2	5 (16.1%)	11 (36.7%)
	3	14 (45.2%)	05 (16.7%)
	4	11 (35.5%)	3 (10.0%)
Mean no of TFESI per patient	X	3.1	2
Physical therapy enrollment	Yes	12 (38.7%)	10 (33.3%)
	No	19 (61.3%)	20 (66.7%)
Outcome	Repeat TEFSI	4 (12.9%)	1 (3.3%)
	Spine Sx after TFESI	2 (6.4%)	5 (16.7%)

Table 2: Temporal relation of PROMIS score collection to TFESI

PROMIS Score Collection	Mean	Min	Max
Time Duration prior to TFESI	1 day 14 hours	1 day	4 days
Time Duration after TFESI	1 year 4 months	1 year 1 month	1 year 10 months

Table 3: Comparison of changes in mean score of NRS between the groups

Period	Combined Mean NRS Score ($\overline{X}$ ± SD)	Mean NRS Score ($\overline{X}$ ± SD)		P value
		Group-A (N = 31)	Group-B (N = 30)	
Baseline	06.71 ± 1.08	06.81 ± 0.95	06.60 ± 1.19	0.332(NS)
Follow up	03.29 ± 2.21	03.48 ± 2.36	03.10 ± 2.02	
Mean diff (Baseline-Follow up) (p value)	*-3.41 ± 02.39 (0.001)	*-3.32 ± 02.48 (0.001)	*-3.50 ± 02.30 (0.001)	0.960(NS)

Table 4: Comparison of changes in mean score of ODI between the groups

Period	Combined Mean ODI Score ($\overline{X}$ ± SD)	Mean ODI Score ($\overline{X}$ ± SD)		P value
		Group-A (N = 31)	Group-B (N = 30)	
Baseline	30.52 ± 6.15	30.19 ± 6.02	30.87 ± 6.26	0.810(NS)
Follow up	24.23 ± 7.10	23.71 ± 8.29	24.77 ± 6.99	
Mean diff (Baseline-Follow up) (p value)	*-6.29 ± 5.88 (0.001)	*-6.48 ± 06.14 (0.001)	*-6.10 ± 05.59 (0.001)	0.841(NS)

difference was not statistically significant. Follow up combined mean ODI score showed a significant fall of 20.6% from baseline ODI score which was comparable to 21.5% for group A and 19.8% for group B however the difference was not statistically significant among the groups. Table 5 reveals that, at baseline, mean score of Physical function among the Group A was 10.26 which was comparable to 09.60 in Group B, and the difference was not statistically significant. At Follow up mean Physical function score showed a significant rise of 35.6% which was comparable to 39.3% among Group B and the difference was not statistically significant. Table 6 states that at baseline, the mean score of Depression among Group A was 7.35 which was comparable to 6.73 in Group B, and the difference was not statistically significant. At Follow up mean depression score showed a significant fall of 19.3% which was comparable to 18.3% among Group B and the difference was not statistically significant.

According to the data in Table 7 at Baseline the mean Score of Pain Interference among Group A was 12.97 which was comparable to 13.97 in Group B, and the difference was not statistically significant. At Follow up, the mean pain interference score showed

Table 5: Comparison of changes in mean score of physical function between the groups

Period	Combined Mean Physical Function Score ($\overline{X}$ ± SD)	Mean Physical Function Score ($\overline{X}$ ± SD)		P value
		Group-A (N = 31)	Group-B (N = 30)	
Baseline	9.94 ± 3.30	10.26 ± 3.39	09.60 ± 3.16	0.528 (NS)
Follow up	13.64 ± 4.02	13.90 ± 3.86	13.37 ± 4.17	
Mean diff (Baseline-Follow up) (p value)	*3.71 ± 3.20 (0.001)	*3.65 ± 3.18 (0.001)	*3.77 ± 3.52 (0.001)	0.944 (NS)

*Significant NS = Not Significant

Table 6: Comparison of changes in mean score of Depression between the groups

Period	Combined Mean Depression Score ($\overline{X}$ ± SD)	Mean Depression Score ($\overline{X}$ ± SD)		P value
		Group-A (N = 31)	Group-B (N = 30)	
Baseline	7.05 ± 2.72	07.35 ± 2.43	06.73 ± 2.96	0.170(NS)
Follow up	5.72 ± 2.65	05.94 ± 2.56	05.50 ± 2.73	
Mean diff (Baseline-Follow up) (p value)	*-1.33 ± 2.30 (0.001)	*-1.42 ± 02.16 (0.001)	*-1.23 ± 02.43 (0.015)	0.561(NS)

*Significant NS = Not Significant

Table 7: Comparison of changes in mean score of pain interference between the groups

Period	Combined Mean Pain Interference Score ($\overline{X}$ ± SD)	Mean Pain Interference Score ($\overline{X}$ ± SD)		P value
		Group-A (N = 31)	Group-B (N = 30)	
Baseline	13.46 ± 2.89	12.97 ± 2.26	13.97 ± 3.35	0.183(NS)
Follow up	9.08 ± 3.77	09.13 ± 3.90	09.03 ± 3.62	
Mean diff (Baseline-Follow up) (p value)	*-4.38 ± 4.05 (0.001)	*-3.84 ± 04.12 (0.001)	*-4.93 ± 03.89 (0.015)	0.293(NS)

*Significant NS = Not Significant

a significant fall of 29.6% which was comparable to 35.3% among Group B and the difference was not statistically significant. Table 8 states that there was a significant correlation between Promis Physical Function and Pain Interference, Promis Physical Function and ODI among both the groups. Table 11 shows that success of achieving MCID for ODI was 38.7% among Group A which was comparable to 23.3% among Group B and the difference was not statistically significant Table 11. The overall success of achieving MCID for ODI was total 19 patients (31.1%) indicating only 31% patients had significant improvement in disability post TFESI.

Table 8: Pearson correlation of PROMIS instruments

Categorical Variables	Pearson Correlation of PROMIS Instruments			
	Group-A (N = 31)		Group-B (N = 30)	
	R (95% CI)	P value	R (95% CI)	P value
PROMIS PF/PI	-0.495 (-0.7226, -0.1706)	*0.004	-0.555 (-0.7599, -0.2498)	*0.001
PROMIS PF/D	-0.201 (-0.5184, 0.1651)	0.278 (NS)	-0.384 (-0.6499, -0.0343)	0.066 (NS)
PROMIS PI/D	0.117 (-0.2476, 0.4526)	0.530 (NS)	0.496 (0.1719, 0.7232)	*0.005
PROMIS PF/ODI	-0.823 (-0.9115, -0.6616)	*0.001	-0.759 (-0.8774, -0.5535)	*0.001
PROMIS SD/F	0.167 (-0.1991, 0.4922)	0.369 (NS)	0.556 (0.2511, 0.7605)	0.071 (NS)

Table 9: Comparison of success of achieving MCID for NRS score between groups

Categorical Variable	Success rate of MCID for NRS			P value
	Total No (%)	Group A (N=31) No (%)	Group B (N=30) No (%)	
NRS	41 (67.2%)	22 (70.9%)	19 (63.3%)	0.194 (NS)

Table 10:. Success of achieving MCID for PROMIS instruments between the groups

Categorical variable	Success rate of achieving MCID for PROMIS Instruments			P value
	Total No (%)	Group A (N = 30) No (%)	Group B (N = 31) No (%)	
PROMIS PF	46 (75.4)	22 (71.0)	24 (80.0)	0.412 (NS)
PROMIS PI	44 (72.1)	22 (71.0)	22 (73.3)	0.836 (NS)
PROMIS D	30 (49.2)	16 (51.6)	14 (46.7)	0.699 (NS)
PROMIS F	39 (63.9)	18 (58.1)	21 (70.0)	0.331 (NS)
PROMIS A	36 (59.0)	17 (54.8)	19 (63.3)	0.500 (NS)
PROMIS SD	48 (78.7)	25 (80.6)	23 (76.7)	0.704 (NS)
PROMIS SR	42 (68.9)	26 (83.9)	16 (53.3)	*0.010

Table 11:. Success of achieving MCID for ODI between the groups

Categorical variable	Success rate of achieving MCID for ODI			P value
	Total No (%)	Group A (N = 31) No (%)	Group B (N = 30) No (%)	
ODI	19 (31.1)	12 (38.7)	07 (23.3)	0.194 (NS)

By Chi Square Test NS=Not Significant

DISCUSSION

Prior studies have reported mixed results regarding the benefit for epidural steroid injections for chronic low back pain. This study has utilised PROMIS as an outcome measure with improved psychometric properties and a long average follow up period of 1 year and 4 months.

This study utilises strict, explicitly defined indications, clinical and radiographic criteria and delivery of injectate to inflammatory pathophysiologic process via-Fluoroscopic guided TFESI.

Laterality, level and number of TFESI was decided after thorough history, clinical examination and corroborative pathologic findings on lumbar spine MRI.

Failed back surgery syndrome (FBSS) describes post surgical population with suboptimal outcomes, persistant pain & impaired function. The incidence of FBSS is reported to be as high as 80,000 cases/year.[23] Options for procedural

management of chronic pain associated with FBSS include caudal epidural steroid injections, TFESI, Epidural adhesiolysis & spinal cord stimulation.[23] A retrospective case series by Francine Zeng *et al.*[17] Affirms that simultaneous bilateral TFESIs can provide therapeutic pain relief in postsurgical patients. Suzuki *et al.* (2020) most recently published a study defining MCID for NRS as a mean reduction of 2.0 postintervention in lower back pain.[24] We selected an MCID >2.0 as clinically significant and the average NRS pain reduction in our study was 3.41. In our study the success rate of achieving significant pain relief that is MCID>2 was 70% in Group A and 63% in group B and overall 67% (see table 9) indicating that total 41 patients (67%) had significant reduction in NRS after TFESI here by affirming that TFESI are equally effective in FBSS for a long follow up time. The follow up mean time in this study is 1 year and four 4 months providing a reasonable alternative to patients who wish to avoid surgery or have already undergone surgery.

Benchmark studies have demonstrated PROMIS instruments correlate to legacy outcome measures and possess improved psychometric properties. Tishelman *et al.* demonstrated a strong correlation between Oswestry Disability Index (ODI) and PROMIS instruments (PI and PF) in back pain patients.[25] Shahgholi *et al.* demonstrated the PROMIS PI, PF and pain behavior (PB) instruments were responsive in detecting change and correlated to Numeric Rating Scale (NRS) and Roland Morris Disability Index (RMDI) in patients undergoing spinal augmentation procedures.[26] In this study, for Promis PF, the success rate of achieving MCID for PROMIS Instruments was 71.0% among Group A which was comparable to 80% among Group B and the difference was not statistically significant and an overall success rate of 75.4 % Table 10 indicating that a total 46 patients (75.4%) had significant improvement in physical function post TFESI in FBSS as well for a long follow up time. For Promis PI, the success rate of achieving MCID for PROMIS Instruments was 71.0% among Group A which was comparable to 73.3% among Group B and the difference was not statistically significant. The overall success rate was 72.1 % indicating that total 44 (72.1%) patients had a significant reduction in pain interference post TFESI. For Promis SD success rate of achieving MCID for PROMIS Instruments was 80.6% among Group A which was comparable to 76.7% among Group B and the difference was not statistically significant. The overall success rate was 78.7% indicating that total 48 patients (78.7%) had significant improvement in sleep post TFESI for a long follow up time. PROMIS instruments correlate to legacy outcome measures and possess improved psychometric properties helping to analyze physical function, pain interference, sleep disturbance, anxiety, depression, fatigue & social roles The success rate (MCID) for ODI is defined as at least 30% improvement at follow up from previous studies.[22] In this study success of achieving MCID for ODI was 38.7% among Group A which was comparable to 23.3% among Group B and the difference was not statistically significant Table 11. The overall success of achieving MCID for ODI was total 19 patients (31.1%) indicating only 31% patients had significant improvement in disability post TFESI.

There is no doubt regarding the efficacy and therapeutic effect of TFESI in axial lumbosacral pain/ radicular pain in non operated patients.[27] This study demonstrates the success rate of TFESI in spine surgery patients (FBSS) as well by utilizing PROMIS as an outcome measure and by use of a control group demonstrating improved Physical Function, less pain interference & improved sleep.

This study has certain limitations. This being a retrospective study we could not control patient demographics and concomitant comorbidities. The sample size was small and future research is needed to establish the MCID values.

CONCLUSION

TFESI are equally efficacious in spine surgery patients (FBSS) as well as non operated patients for management of lumbar radiculopathy with regards to pain relief and improvement of functional outcome.

Ethics Committee Approval

Ethics committee approval was received for this study from the Ethics Committee for Biomedical and Health research, Lilavati hospital & Research centre, Mumbai (Date: 22.02.2023).

Informed Consent

Written informed consent was obtained from patients who participated in this study.

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