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Evaluating the effectiveness of interlaminar epidural steroid injections for cervical radiculopathy using PROMIS as an outcome measure

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ABSTRACT

Background: Cervical interlaminar epidural steroid injections (CIESI) are frequently used to treat cervical radiculopathy due to cervical nerve root impingement.
Objective: The purpose of this study was to evaluate the therapeutic effect of CIESI for patients with cervical radiculopathy.
Methods: We conducted a retrospective review of consecutive adult patients with cervical radicular pain and corroborative cervical spondylotic foraminal stenosis on MRI that failed at least 6 weeks of conservative management consisting of medication and physical rehabilitation seen at a multidisciplinary, tertiary academic spine center. Patient Reported Outcome Measurement Information System (PROMIS) domains of Physical Function (PF) v1.2/v2.0 and Pain Interference (PI) v1.1 were collected at all patient visits. Scores were recorded at baseline, 3-months, 6-months and 12-months post-procedure. Statistical analysis comparing baseline scores with follow-up postprocedural PROMIS scores was performed. The percentage of patients reporting improvement greater than the minimal clinically important difference (MCID) was calculated for responders and for the worst case scenario.
Results: 179 patients met inclusion criteria. PROMIS PI at 3-, 6-, and 12-month follow-up statistically improved by 1.5 (95 % confidence interval [CI] 1.4–1.6; $p = 0.02$), 1.5 (95 % CI 1.4–1.6; $p = 0.03$) and 1.7 (95 % CI 1.6–1.8; $p = 0.4$), respectively. Follow-up PROMIS PF at 3-month follow-up improved by 1.6 (95 % CI 1.5–1.7; $p = 0.04$) but did not significantly differ at 6- or 12-month follow-up. The percentage of patients that exceeded MCID thresholds of clinical significance was 44 % (95 % CI 36%–53 %) at 3-months, 49 % (95 % CI 39%–59 %) at 6-months, and 54 % (95 % CI 41%–66 %) at 12-months. Worst case scenario analysis demonstrated that 32 % (95 % CI 36%–53 %) of patients exceeded the MCID thresholds at 3-months, 31 % (95 % CI 24%–37 %) at 6-months, and 21 % (95 % CI 15%–27 %) at 12-months.
Discussion/conclusions: Our study demonstrated that CIESI leads to an improvement in function and pain for patients with cervical radiculopathy. This study was limited by retrospective design, loss to follow-up, and variation in steroids used.

1. Introduction

Cervical nerve root impingement is a common cause of neck and upper extremity radicular pain that can lead to disability and a significant financial burden for patients [1]. Conservative management consists of prescription medications and physical rehabilitation. Patients with persistent debilitating pain and loss of function despite conservative treatment may be offered surgery. For patients whose symptoms fail to improve with physical therapy, cervical interlaminar epidural steroid injections (CIESI) are an accepted treatment option and may delay or prevent surgical need [2].

Previous work has demonstrated that CIESI are effective in treating cervical radiculopathy [3–5]. The effectiveness of interventional spine procedures has often been determined using legacy surveys such as the neck disability index (NDI), numeric pain rating scales, and the visual analog scale [6]. Patient Reported Outcomes Measurement Information System (PROMIS) was developed by the NIH with response theory and computer adaptive testing functionality to provide a standardized and efficient means for collecting patient reported outcomes to aid in research [7]. PROMIS has been utilized extensively in the spine surgery

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patient population [8–12]. A recent study demonstrated a strong correlation between PROMIS survey results with legacy surveys [13]. To a lesser degree, PROMIS has been utilized to assess the effectiveness of interventional spine procedures [14–17]. To our knowledge, no prior literature has been conducted to assess the effectiveness of CIESI for cervical radiculopathy using PROMIS as an outcome measure.

The purpose of our study was to assess the effectiveness of CIESI in treating patients with cervical radiculopathy. Our hypothesis is that CIESI would improve function and pain as measured by PROMIS scores for patients with cervical radiculopathy.

2. Material and methods

2.1. Patient selection

Our institutional review board approved our retrospective review (RSRB #00008561). We included consecutive adult patients seen at a single multidisciplinary, tertiary academic center between January 01, 2015 and January 31, 2024 by one of sixteen fellowship trained interventional spine and pain physicians for patients who had failed greater than 6 weeks of conservative treatment including physical therapy and/or a home exercise program. Patients were included if they had radicular pain radiating to the upper extremity with corroborating MRI findings of cervical nerve impingement. The presence of trigger points and the prior use of trigger point injections did not preclude patients from inclusion as long as there were radicular symptoms into the upper extremity. Patients were excluded for predominance of axial neck pain, prior spine surgery or lack of pre-procedure and/or any follow-up survey data.

2.2. Procedure Description

Cervical interlaminar epidural steroid injections were performed via paramedian approach as described in *Atlas of Image-Guided Spinal Procedures, 2nd Edition* by Dr. Michael Furman. After anesthetizing soft tissues with 1 % lidocaine, an 18-gauge Tuohy needle was used to access the epidural space at the C7-T1 level in most cases, with the C6-C7 level used only if the treating provider deemed there to be sufficient space to have no impact on procedure safety. Initial approach was performed slightly oblique ipsilateral to symptoms ('off AP' view). Ventral depth was monitored in a contralateral oblique view, with a loss-of-resistance technique performed to confirm clearance of ligamentum flavum at the ventral interlaminar line. Contrast dye was injected under live fluoroscopic imaging to confirm epidural flow in the contralateral oblique and AP views, ensuring dye flow covered symptomatic laterality. Injectate was injected slowly into the epidural space with additional monitoring of the patient with verbal communication.

2.3. Outcome measures

At our institution, PROMIS Physical Function v1.2/v2.0 (PF) and Pain Interference (PI) v1.1 scores are collected at each spine and pain clinic visits via iPad during check-in. Pre-procedure baseline scores were defined as scores within 1 year prior to CIESI. We included PROMIS scores at 3-, 6- and 12-month follow-up visits. PROMIS PI scores were distinguished by the T-score cutoff values (normal <55, 55–60 = mild, 60–70 = moderate, and >70 = severe). This study was retrospective in nature, therefore follow up visits varied based on a shared decision between the physician and patients. In our study, 130 patients were seen at 3-month follow-up, 112 had 6-months post-procedure (34 of whom were not initially seen at 3-months), and 69 had 12-months post-procedure scores.

Patient data was collected from electronic medical records of included patients by the first author (A.S). This data included patient age, race, gender, and BMI, prior surgery, presence of radicular symptoms, cervical level injected, performing physician, steroid and dose used, adjuvant mixed with steroids, MRI pathology and pain numeric rating scale (NRS) at pre-procedure visits and follow-up visits.

We hypothesized that fluoroscopically guided CIESI would lead to a significant improvement in pain as measured by PROMIS PI.

2.4. Statistics

Number and percent were calculated for demographic categorical variables. Mean and standard deviation (SD) were calculated for quantitative variables. Effect size was calculated using Cohen's d test and t tests were calculated between mean pre- and follow-up PROMIS PF and PROMIS PI scores and NRS pain scores. The change in PROMIS PI scores from follow-up to baseline were compared to previously published minimal clinically important differences (MCID) value of 1 by Hung et al. [18]. Due to significant missing data at follow-up time periods, a worst-case scenario analysis was performed assessing the number of patients with clinically significant improvement. The percent of patients who had clinically significant improvement in PROMIS PI scores at 3-month post-procedure for each pre-procedure PROMIS PI division was calculated and a chi-square test was performed with the mild division as reference. Chi-square analysis was also conducted to assess the association of pre-procedure opioid use with having a clinically significant change in 3-month post-procedure improvement of PROMIS PI. Chi-square analyses were also conducted to assess the association of lidocaine use within injectate and different steroid combinations with having a clinically significant change in 3-month post-procedure improvement of PROMIS PI.

3. Results

A total of 179 patients met inclusion criteria. The average age was 54.7 (±12.8) and was 60.9 % female. Demographic data is reported in Table 1.

At 3-month follow-up, PROMIS PI and PF scores improved by 1.5 points ($p = 0.02$) and 1.6 points ($p = 0.04$) respectively. At 6-month and 12-month follow-up, PI scores improved by 1.5 points ($p = 0.03$) and 1.7 points ($p = 0.03$; Table 2), respectively. There was no significant difference between post-procedure long-term scores with baseline PROMIS PF scores (Table 2). Patient reported NRS was significantly better at an average of 4.7 months follow-up (4.3 ± 3.1) compared to baseline (7.0 ± 2.2, $p < 0.001$).

The percentage of patients that exceeded MCID thresholds of clinical significance was 44 % (95 % CI 36%–53 %) at 3-months, 49 % (95 % CI 39%–59 %) at 6-months, and 54 % (95 % CI 41%–66 %) at 12-months. Worst case scenario analysis demonstrated that 32 % (95 % CI 36%–53 %) of patients exceeded the MCID thresholds at 3-months, 31 % (95 % CI 24%–37 %) at 6-months, and 21 % (95 % CI 15%–27 %) at 12-months. Patients with a pre-procedure PI score within the normal range did not have any clinically significant difference in PROMIS PI scores at 3-month follow up. The percentage of patients who had a clinically significant improvement in PROMIS PI scores at 3-month was 28 % for patients with Mild PROMIS PI pre-procedure scores, 45 % for patients with moderate PROMIS PI pre-procedure scores, and 74 % for patients with severe PROMIS PI pre-procedure scores (Table 3).

Pre-procedure opioid use (Table 4) and use of lidocaine (Table 5) within injectate adjuvant was not associated with a clinically significant improvement of PROMIS PI at 3-months post-procedure. There was no difference significant difference between the use of betamethasone, methylprednisolone or dexamethasone (Table 6).

4. Discussion

This work demonstrated that CIESI improves pain for patients in the short- and long-term who have failed conservative management. Our findings are consistent with prior literature. Previous work has demonstrated that CIESI were successful in improving pain by >50 % in approximately 60 %–70 % of patients [5,19–26]. To our knowledge, this

Table 1
Patient and procedure demographics.

Variable	Mean/N	Standard Deviation/%
Age	54.7	12.8
Female	109	60.9 %
Race		
White	138	77 %
Black	23	13 %
Hispanic	11	6 %
Asian	3	2 %
Other	4	2 %
BMI	30.4	6.4
Level of Pathology of Imaging		
C3-4	3	1.7 %
C4-5	23	12.9 %
C5-6	73	41 %
C6-7	64	36 %
C7-T1	5	2.8 %
Imaging Unavailable	10	5.6 %
Level Injected		
C5-6	2	1 %
C6-7	17	9 %
C7-T1	146	82 %
T1-2	14	8 %
Steroid Used		
Betamethasone	34	19 %
8 mg	3	
9 mg	4	
10 mg	1	
12 mg	26	
Dexamethasone	77	43 %
8 mg	43	
10 mg	2	
15 mg	32	
Methylprednisolone	67	37 %
40 mg	4	
60 mg	17	
80 mg	46	
Injectate Adjuvants		
Lidocaine 1 %	11	6.2 %
NaCl 0.9 %	66	37.7 %
Lidocaine/NaCl	72	41.1 %
None (steroid alone)	26	14.9 %
Number of Injections	1.5	1.2
Pain Interference Pre-op Category		
Normal	14	8 %
Mild	23	13 %
Moderate	100	56 %
Severe	42	23 %
Pre-Procedure Medications		
Opioids	60	34.3 %
NSAIDs	118	67.4 %
Tylenol	38	21.7 %
Duloxetine	34	19.4 %
Neuroleptics	104	59.4 %
Tricyclic Antidepressants	11	6.3 %
Anti-spasmatic	71	40.6 %

is the first study to assess pain relief after CIESI utilizing PROMIS PI. When compared to previously reported MCID values [27], our findings demonstrated a clinically significant improvement in pain between baseline and follow-up PROMIS PI scores.

Our study also demonstrated that patients with greater pre-procedural pain as measured on PROMIS PI had a greater likelihood of achieving a clinically significant improvement. No patients with normal PI scores had any improvement that exceeded the MCID whereas about 3/4 of patients with severe PI pre-procedure scores had a clinically significant improvement. Physicians can utilize pre-procedural PROMIS PI when counseling patients regarding the likelihood of noting a significant improvement after CIESI. Specifically, physicians may want to consider not offering an injection for patients who's PROMIS PI scores are within the normal range.

Our study demonstrated that patients experienced a functional improvement in PROMIS PF scores at short-term follow-up. This is

Table 2
Comparison of baseline and follow-up patient reported outcomes measurement information system scores after cervical interlaminar epidural steroid injections.

Variable	Baseline		3 month-Follow-up				6-month Follow-up				12- month Follow-up			
	Mean (SD)	95 % Confidence Intervals	Mean (SD)	p value	Cohen's d		Mean (SD)	95 % Confidence Intervals	p value	Cohen's d	Mean (SD)	95 % Confidence Intervals	P value	Cohen's d
Physical Function	36.8 (6.9)	35.8–37.8	38.3 (8.3)	0.04	0.2		37.5 (7.6)	36.1–38.9	0.21	0.16	38.0 (8.2)	36.1–39.9	0.14	0.16
Pain Interference	65.0 (6.4)	64.1–66.0	63.5 (6.7)	0.02	0.23		63.0 (6.0)	62.2–64.8	0.03	0.22	63.3 (6.7)	61.8–64.9	0.04	0.26

Table 3
Percentage of patients with a clinically significant improvement in pain interference scores at 3-month follow-up per pre-procedure pain interference severity classification.

Pre-procedure Pain Inference Severity	N	Improvement N (%)	P value[a]
All	130	58 (44 %)	–
Normal	12	0 (0 %)	0.045
Mild	18	5 (28 %)	Reference
Moderate	73	33 (45 %)	0.18
Severe	27	20 (74 %)	0.002

[a] Chi Square Analysis.

Table 4
Correlation of opioid use with the likelihood of having a clinically significant improvement in pain interference scores at 3-month follow-up.

Opioid Use	N	Improvement N (%)	P value[a]
Yes	39	19 (48.7 %)	–
No	90	38 (42.2 %)	0.50

[a] Chi Square Analysis.

Table 5
Correlation of lidocaine use in injectate with the likelihood of having a clinically significant improvement in pain interference scores at 3-month follow-up.

Lidocaine Use	N	Improvement N (%)	P value[a]
Yes	71	33 (46.5 %)	–
No	58	24 (41.4 %)	0.56

[a] Chi Square Analysis.

Table 6
Correlation of steroid type with the likelihood of having a clinically significant improvement in pain interference scores at 3-month follow-up.

Steroid Type	N	Improvement N (%)	P value[a]
Dexamethasone	57	24 (42.1 %)	–
Betamethasone	21	9 (42.9 %)	0.95
Methylprednisolone	51	24 (47.1 %)	0.61

[a] Chi Square Analysis.

consistent with prior work that has demonstrated improvement in NDI scores after CIESI at 2–3 months post-injection [3,4]. This difference in our study was not maintained in the long-term which differs from work that has demonstrated improvement in NDI scores to last upwards of 24 months [3]. The NDI was developed to assess disability directly caused by neck pathology [28]. PROMIS PF questions relate to overall functional abilities. Although we failed to demonstrate sustained functional improvement on the PROMIS PF, it is possible that this survey is not specific enough to the neck/upper limb to note lasting improvement.

Our study also demonstrated that there was an improvement in NRS at follow-up of about 2.7 compared to pre-procedure scores. This is similar with Levin et al. study that found about a 3-point improvement in median pre- and post-procedure NRS scores [29].

4.1. Limitations

Several limitations are worth mentioning. Our study was limited by factors inherent with a retrospective design. Specifically, patient reported outcomes were only collected if patients felt the need to be seen at their follow-up visit or were seen in another musculoskeletal clinic where PROMIS scores were collected. Given this, it is possible that patients with resolution of their symptoms were unlikely to schedule follow-up visits. Conversely, patients may have pursued care elsewhere. Given the retrospective design, opioid use was recorded based on active prescription at time of procedure in the electronic medical record and may not reflect the degree of active use in all patients. Our study was limited by a loss to follow-up. We did not compare our results to placebo, nor did we compare them to patients who received transforaminal injections. Given that multiple physicians were included in this study, we were not able to account for minor differences in training or technique. Additionally, some of the physicians at our institution perform both interlaminar and transforaminal cervical injections. Although determining which procedure to perform was not a controlled variable, the decision is often based on pathology seen on MRI. Likewise, some physicians only exclusively perform interlaminar injections and referral patterns may be based on if the referring provider feels a IESI vs a transforaminal is warranted. Given this, our study is likely limited by selection bias. Our study was limited by a low non-response bias which is a real-world limitation of patient reported outcomes. Additionally, this study was not designed to evaluate variations in cervical level of injection, volume of injectate, or type of steroid used. The procedure performed in this study adheres to typical guidelines and safety standards of proceeding at C6-7 or below [30,31]. However, there is debate as to the basis of this standard practice and whether the level of injection should be selected based on the level of pathology and the expected spread of the injectate [32].

5. Conclusion

Though limited by a significant loss to follow-up, our study found that CIESI was effective in providing a statistically and clinically significant short- and long-term improvement in pain for patients with cervical radiculopathy who presented at follow-up visits. A prospective study is needed to adequately evaluate PROMIS outcomes after CIESI.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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