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Evaluation of fluoroscopically guided transforaminal epidural steroid injections for cervical radiculopathy utilizing patient reported outcome measurement information system as an outcome measure

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ABSTRACT

Background: Cervical radiculopathy is a common cause of pain. For patients who fail conservative management, a transforaminal epidural steroid injection (TFESI) is an accepted intervention and alternative to decompression surgery.

Objective: The purpose of this study was to evaluate the therapeutic effect of TFESIs for patients with cervical radiculopathy.

Methods: Adult patients treated at a multidisciplinary, tertiary academic spine center with cervical radicular pain and MRI evidence of corroborative cervical spondylotic foraminal stenosis and who had failed at least 6 weeks of conservative management consisting of medication and physical rehabilitation were included in this study. 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 baseline and at 3-, 6-, and 12-month follow-up visits. Statistical analysis comparing baseline score with follow-up post-procedural PROMIS scores was performed. The percentage of patients who reported improvement exceeding the minimal clinically important difference was calculated for survey responders and for the worst case scenario.

Results: 87 patients met inclusion criteria. PROMIS PI at 3-, 6-, and 12-months follow-up statistically improved by 2.2 (95 % confidence interval [CI] 2.1–2.4, $p = 0.02$), 2.3 (95 % CI 2.1–2.5, $p = 0.03$), and 2.7 (95 % CI 2.5–3.0, $p = 0.03$) points, respectively. Follow-up PROMIS PF score did not significantly differ from baseline scores. The percentage of patients that exceeded MCID thresholds of clinical significance was 59 % (95 % CI 47%–70 %) at 3-months, 52 % (95 % CI 41%–63 %) at 6-months, and 60 % (95 % CI 50%–72 %) at 12-months. Worst case scenario analysis demonstrated that 51 % (95 % CI 39%–62 %) of patients exceeded the MCID thresholds at 3-months, 32 % (95 % CI 22%–43 %) at 6-months, and 23 % (95 % CI 13%–33 %) at 12-months.

Conclusions: Our study demonstrated that TFESI leads to a long-term improvement up to a year in pain for patients with cervical radiculopathy.

1. Introduction

Cervical nerve root impingement is a common cause of neck and upper extremity radicular pain causing functional limitations [1]. Conservative management consists of prescription medication and physical rehabilitation. Patients with persistent debilitating pain and loss of function despite conservative treatment may pursue cervical decompression surgery. In an effort to prevent or delay a surgical procedure, epidural corticosteroid injections are an accepted treatment option.

Relative to the lumbar spine, there is limited peer reviewed literature regarding the effectiveness of epidural corticosteroid injections for cervical radiculopathy. Traditionally, an interlaminar approach has been used [2]. More recently, some studies have postulated that a transforaminal epidural steroid injection (TFESI) can provide greater specificity to targeted pathology, and thus, theoretically, improved efficacy [2,3]. Literature directly comparing the effectiveness of these procedures is limited [4,5] and the International Pain and Spine Interventional Society guidelines leaves approach choice up to the provider [6]. Given the anatomical proximity of the TFESI approach to vascular structures and potential for catastrophic neurovascular complications, proper preparation and technique are required to safely perform this procedure. Complications after cervical TFESI are well documented [7]

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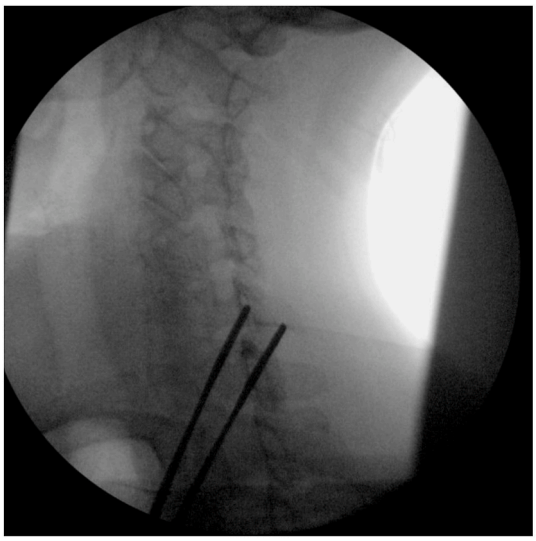


Fluoroscopic oblique view demonstrating left C7 transforaminal epidural steroid injection. Starting position with spinal needle held over the posterior inferior portion of the foramen using a clamp.

Fig. 1. Fluoroscopic oblique view demonstrating left C7 transforaminal epidural steroid injection. Starting position with spinal needle held over the posterior inferior portion of the foramen using a clamp.

though these are mostly limited to case studies with higher level evidence demonstrating limited severe complications [8]. Further work is needed to assess patient reported outcomes to understand the effectiveness of cervical TFESI.

The purpose of our study was to assess the effectiveness of TFESI in treating patients with cervical radiculopathy. Our hypothesis is that TFESI would significantly improve the function and pain of patients with cervical radiculopathy as measured by Patient Reported Outcomes Measurement Information System (PROMIS) scores.

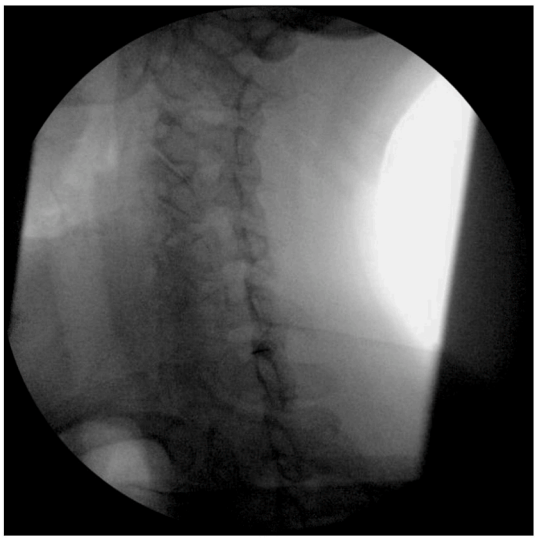
2. Material and methods

2.1. Patient selection

Our institutional review board approved our retrospective review. We included consecutive adult patients seen at a single multidisciplinary, tertiary academic spine center between January 2015 and January 2024 by fellowship trained interventional spine physicians. After electronic data base query, 659 patients underwent a CTFESI during this time period. 374 patients were excluded for insufficient PROMIS scores at either pre- or post-procedure time frames. 192 were excluded as they were performed by non-interventional spine trained providers. Six patients were excluded for non-cervical TFESI injections. Charts were screened to ensure that patients had radicular pain radiating to the upper extremity with corroborating MRI findings of cervical spondylotic foraminal stenosis and consequent cervical nerve impingement. Patients would have also been excluded for axial neck pain, worker's comp claims, presence of an infection, spinal mass or fracture. Of the 87 patients available for chart review, all met inclusion criteria. At the initial clinic visit, patients undergo a thorough physical exam to exclude obvious peripheral nerve etiologies [9].

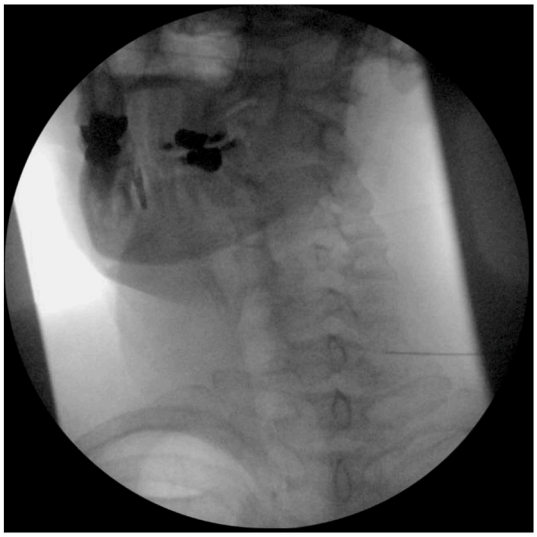
2.2. Procedure description

Cervical transforaminal epidural steroid injections (CTFESI) were performed with the patient lying in an oblique position supported with a foam wedge. Patients' shoulders are depressed, and the head rotated away from the side to be injected to provide easier access to the cervical



Fluoroscopic oblique view of a C7 transforaminal epidural steroid injection with the needle in the posterior inferior C7 foramen.

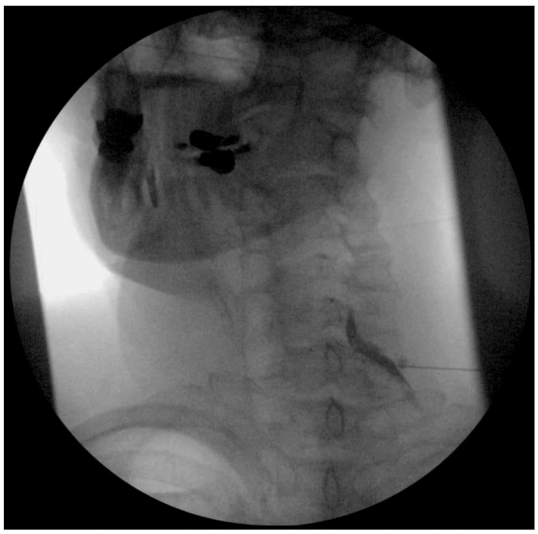
Fig. 2. Fluoroscopic oblique view of a C7 transforaminal epidural steroid injection with the needle in the posterior inferior C7 foramen.



Fluoroscopic AP view of a C7 transforaminal epidural steroid injection with the needle underneath the lateral boarder of the superior pedicle.

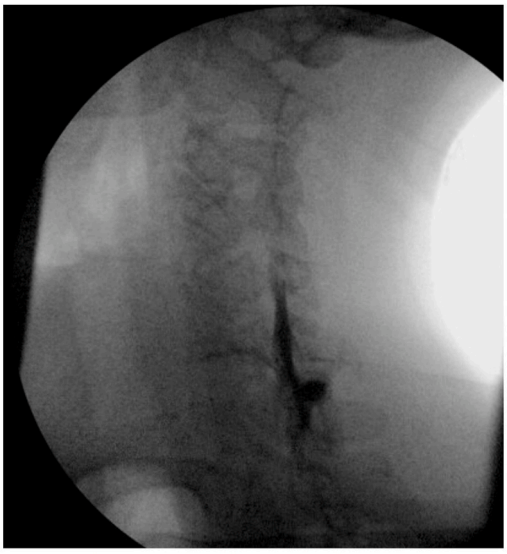
Fig. 3. Fluoroscopic AP view of a C7 transforaminal epidural steroid injection with the needle underneath the lateral boarder of the superior pedicle.

foramina. The skin is prepped in a sterile manner with isopropyl alcohol and chlorhexidine gluconate. A GE 9800 or 9900 OEC super C-arm was utilized to obtain all live and static fluoroscopy images. The C-arm is rotated into an optimal oblique position defined as the largest cross-sectional area of the foramen to be injected as seen on the fluoroscopic monitor. A long-handled sponge clamp is utilized to confirm the correct foramen is being targeted and to initiate accurate starting position over the posterior inferior portion of the foramen for needle puncture of the skin (Fig. 1). After confirming the correct and optimal oblique view of the target foramen, a 25 G 3½-inch spinal needle is passed through the neck soft tissues through the point overlying the posterior half of the target foramen and advanced down to the lateral mass of the posterior foramen under live fluoroscopic visualization. The



Fluoroscopic AP view of a C7 transforaminal epidural steroid injection. Contrast injection demonstrating correct placement.

Fig. 4. Fluoroscopic AP view of a C7 transforaminal epidural steroid injection. Contrast enhancement demonstrates transforaminal epidural flow.



Fluoroscopic oblique view of a C7 transforaminal epidural steroid injection. Contrast injection demonstrating correct placement.

Fig. 5. Fluoroscopic oblique view of a C7 transforaminal epidural steroid injection. Contrast enhancement demonstrates transforaminal epidural flow.

inferior articular process provides an excellent bony landmark for a stepwise entrance into the cervical foramen. The needle tip is guided to contact the lateral mass adjacent to the caudal half of the foramen. Once bony contact has been made, the needle is slightly withdrawn, rotated, and advanced under live fluoroscopic visualization so that the needle is directed and advanced slightly anteriorly so that the needle tip is adjacent to the posterior inferior foramen (Fig. 2). The needle placement is verified to be in the extreme posterior portion of the foramen. At this point, the C-arm is rotated into the sagittal (AP) plane. It is imperative to make certain that the spinous processes of the segment being injected are equidistant from the pedicles on either side. Then, under live fluoroscopic visualization the needle should be slowly advanced until the needle is under the lateral border of the pedicle immediately above the target foramen designating placement at the distal portion of the targeted foramen (Fig. 3). Once needle placement is verified, a lewer lock extension tubing is attached to the spinal needle for infusion to decrease the risk of inadvertent needle tip movement from multiple interfaces that are subsequently necessary. Infusions through the needle are always performed under live fluoroscopic visualization to confirm that the needle is not being inadvertently advanced medially into the spinal canal. A small amount of non-ionic contrast agent (0.5–1.0 mL) is then infused to determine needle placement. Ideally, contrast should be infused under live digital subtraction fluoroscopy to better identify subtle intra-arterial injections that may otherwise be missed on plain fluoroscopy (Fig. 4). Contrast enhancement should also be visualized on an oblique image demonstrating filling of the targeted foramina and epidural flow (Fig. 5). It should not be rapidly carried away in a cephalad direction as this suggests a vertebral or radicular artery injection or in a serpentine manner suggesting a Batson's plexus injection. The contrast agent should also not rapidly diffuse across the midline in a homogeneous manner suggesting a subarachnoid injection. Once contrast enhancement confirms transforaminal epidural flow, 2 cc of 2 % Lidocaine is infused to function as a physiologic challenge to further verify nonvascular uptake. If after 120 s the patient does not experience signs or symptoms of vascular update (e.g. paresthesia of the face, dizziness, lightheadedness, etc.), 15 mg of dexamethasone can be safely infused.

2.3. Outcome measures

PROMIS Physical Function version (v)1.2/v2.0 (PF) and Pain Interference (PI) v1.1 scores are collected at our institution as part of the standard of care prior to each clinic visit. PROMIS is a computer adaptive test that utilizes response theory that was created by US National Institutes of Health [10]. It has increased in popularity especially in orthopedics [11–26]. It has been used to measure functional improvements after common procedures and surgeries in the spine patient population [27–31]. Literature has demonstrated high compatibility with legacy patient reported outcome surveys in the spine population [26,32,33].

PROMIS Pre-procedure baseline scores were defined as scores within 1 year prior to TFESI. Scores obtained at 3-, 6-, and 12-month follow-up visits were pulled through our electronic database. Future surgical procedures were also obtained. Given the retrospective nature of this study, follow up visits varied based on a shared decision between the physician and patients. In our study, 68 patients (78 %) had 3-month score, 52 (60 %) had 6-months post-procedure scores (12 of whom were not initially seen at 3-months), and 31 (36 %) had 12-months post-procedure scores. Pre-procedure and post-procedure visual analog scores (VAS) were also obtained.

2.4. Statistical analysis

Number and percent were calculated for demographic, categorical variables; mean and standard deviation (SD) were calculated for quantitative variables. Two-sample student t tests were calculated between mean pre-procedure and follow-up PROMIS PF and PROMIS PI scores. Effect size was calculated using Cohen's d test. For interpreting Cohen's *d*, a small effect size approximately 0.20, medium ES is approximately 0.50, and a large ES is approximately 0.80. 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. [22]. Given extensive missing data at follow-up time frames, a worst-case scenario analysis was performed assessing the percentage of patients with clinically significant improvement.

3. Results

A total of 87 patients met inclusion criteria. Demographic values are

Table 1
Demographics.

Variable	Mean/N	Standard Deviation/%
Age	55.2	11.7
Female	45	56.20 %
Race		
White	78	90 %
Black	3	3 %
Hispanic	2	1 %
Asian	1	1 %
American Indian	1	1 %
Other	3	3 %
BMI	28.6	6.5
Level		
C4	3	3 %
C5	10	11 %
C6	43	49 %
C7	31	35 %
C8	2	3 %
Prior Surgery	12	15 %
Number of Injections	2.3	1.0

reported in Table 1.

PROMIS PI at 3-, 6-, and 12-months follow-up statistically improved by 2.2 ($p = 0.02$), 2.3 ($p = 0.03$), and 2.7 ($p = 0.03$) points, respectively. Follow-up PROMIS PF score did not significantly differ from baseline scores. (Table 2).

A total of 16 patients (18 %) went on to need surgery at an average of 304 days after initial cervical TFESI (range: 35–1089 days). Pre-procedure VAS were 7.18 (±2.3) and improved to 3.56 (±2.5) at an average follow-up of 81.1 days.

The percentage of patients that exceeded MCID thresholds of clinical significance was 59 % (95 % CI 47%–70 %) at 3-months, 52 % (95 % CI 41%–63 %) at 6-months, and 60 % (95 % CI 50%–72 %) at 12-months. Worst case scenario analysis demonstrated that 51 % (95 % CI 39%–62 %) of patients exceeded the MCID thresholds at 3-months, 32 % (95 % CI 22%–43 %) at 6-months, and 23 % (95 % CI 13%–33 %) at 12-months.

4. Discussion

This study demonstrated that cervical TFESI improves pain for patients in the short- and long-term for patients who have previously failed conservative management consisting of prescription medication and physical rehabilitation. The improvement in pain lasted up through a year.

This is consistent with prior literature which has shown that cervical TFESI were effective in improving pain by approximately 40–60 % of patients and in improving function [8,34,35]. Much of the current literature for TFESI is limited by short-term follow-up [7,36]. A randomized control trial by Andenberg et al. found no difference between steroid and placebo, but their study was limited by a short follow-up duration of only 3 weeks [37]. Consistent with our study, Lee et al. demonstrated that TFESI can decrease pain for up to an average of 9 months [34]. Their work, however, included patients who received repeat injections. In our study, none of the patients required a repeat injection. Goyal et al. has demonstrated that pain relief can be up to 1–2 years post-procedure [38]. Additionally, Goyal et al. showed that overall health and quality of life improved for patients after cervical TFESI as measured by PROMIS global health surveys [38]. To our knowledge, this is the first study to assess pain relief after cervical TFESI utilizing PROMIS PI. When compared to previously reported minimal clinically important differences (MCID) values [39], our findings demonstrate a clinically significant improvement in pain between follow-up and baseline scores. Specifically, 58 % and 56 % of patients had an improvement in PROMIS PI that exceeded MCID thresholds at short- and long-term follow-up, respectively. This study supports the growing body of literature that demonstrates cervical TFESI to be effective in improving pain for patients who have failed to respond to prolonged conservative care. Although there have been reports of severe complications in the literature [7], further work has demonstrated cervical TFESI to be safe and major complications to be quite rare. In Conger et al. systematic review of 17 articles, no major adverse events were reported [8]. In Bush et al. study evaluating 1047 cervical TFESI, they reported no major complications and only 6 minor complications [40]. Recently, Beckworth et al. evaluated 200 consecutive patients who underwent cervical TFESI and did not note any major complications. Their study also queried the providers who performed over 6200 cervical TFESI procedures. None of these providers recalled any major complications occurring within the 17 year study time frame [41]. Although future work will be beneficial in understanding the safety and efficacy of cervical TFESI, this work and the body of literature suggests cervical TFESI to be a safe and effective treatment for patients with cervical radiculopathy [42].

No functional improvement was demonstrated in our study as measures by PROMIS PF. This differs from prior work that has shown improvement of disability and function as measured by the neck disability index (NDI) survey [43,44]. The NDI was developed to assess disability related to conditions specific to the neck [45]. PROMIS PF questions relate to functional activities regarding the whole body. Although we failed to demonstrate functional improvement on the PROMIS PF, it is possible that this survey is not specific enough to the neck/upper limb to note functional improvement.

4.1. Limitations

Several limitations are worth noting. There was no control group. Though physicians at our institution perform interlaminar epidural steroid injections, the training of those providers may differ from that of the included providers performing TFESIs, thus indications may vary between the two procedures. Additionally, this was a retrospective review, so our results were not compared to a placebo. Our study was also limited by non-response bias which is a real-world limitation of patient reported outcomes. Our study demonstrated that 19 % went on to need surgery. This is lower than previously work that has shown future surgery need to be >30 % [46,47] but consistent with Conger et al. who demonstrated that 18 % of their population required surgery within one year [48]. Our results could be an underestimation given that patients may have pursued surgical care outside our health care system. Also, most of our patients were referred to one of two spine surgeons. Indications for surgery may vary between health care systems.

5. Conclusion

Our study found that cervical TFESI was effective in providing a statistically and clinically significant short- and long-term improvement in pain for patients with cervical radiculopathy.

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

Variable	Baseline	3-month-Follow-up			6-month Follow-up			12-month Follow-up		
	Mean (SD)	Mean (SD)	p value	Cohen's d	Mean (SD)	p value	Cohen's d	Mean (SD)	P value	Cohen's d
Physical Function	38.4 (8.0)	39.2 (6.9)	0.26	0.10	38.7 (7.2)	0.40	0.04	40.8 (8.0)	0.08	0.30
Pain Interference	64.2 (6.5)	61.9 (6.7)	0.02	0.33	61.8 (7.7)	0.03	0.33	61.4 (7.3)	0.03	0.39

Finding statement

This study did not receive any funding.

Declaration of interests

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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