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Research Article

Cervical Epidural Steroid Injections Improves Cervicalgia Greater than Radiculopathy: Efficacy and Safety of Epidural Steroids in a Single-Center Retrospective Study

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Abstract

Background: Epidural steroid injections are widely used in the lumbar and to a lesser extent in the cervical region despite concerns about their efficacy and safety.

Objectives: Safety and Efficacy of cervical epidural steroid injections (CESI) were evaluated.

Study Design: A single-centre retrospective study was designed to evaluate CESI safety and efficacy. Patients suffering from chronic, resistant cervical radiculopathy and treated with interlaminar (IL) CESI were included. Results were compared to published data.

Setting: Patients were treated at the pain centre of the Hôtel-Dieu de France hospital in Beirut-Lebanon between 2005 and 2022. These patients received one or more CESI using the IL approach.

Methods: The medical records of included patients were reviewed. Patients were contacted by phone between May and June 2023 to evaluate improvements in their symptoms after CESI. Data on pain numeric rating scale (NRS) before and after the injections and Odom's criteria defined as patient satisfaction were collected. A multivariate analysis of covariance (MANCOVA) was used to compare the mean pain numeric rating scale value before and after the procedure, for cervicalgia and cervical radiculopathy respectively. Complications and the need for referral to surgical management were noted.

Results: A total of 60 CESI using the IL approach were performed for the 45 included patients, the majority of whom (84.4%) were suffering from chronic resistant cervicalgia and cervical radiculopathy. Minor complications (n=6, 10%) were noted during and after the injections, including vasovagal episodes (6.67%), a dural puncture (1.67%) and a halt of the procedure following a bloody tap (1.67%). Complications rate was similar to that found in the literature. A significant statistical reduction in pain scores was found when comparing pain numeric ratings for cervicalgia (p=0.030), but not for cervical radiculopathy (p=0.115) despite a clinically significant improvement in pain scores from 8/10 to 4/10. The Odom's criteria classified patients between « completely satisfied » (31%), « partially satisfied » (56%) and « dissatisfied » (13%), all the latter were offered surgical management.

Limitations: The retrospective aspect, the lack of comparison with the transforaminal approach and the limited number of patients are limitations of this study.

Conclusion: CESI is a safe and efficient technique for the treatment of cervical radiculopathy secondary to cervical disc herniation. Around 9 patients out of 10 are satisfied, with a lasting improvement in symptoms after undergoing the procedure. Minor complications could be seen, but clinically significant ones are very rare, involving mostly the transforaminal (TF) approach. Following IL CESI, cervicalgia was found to be significantly improved compared to cervical radiculopathy. However, prospective randomized studies comparing both symptoms are needed.

Keywords: Cervical; epidural injections; interlaminar; particulate corticosteroids; complications; intervertebral disc herniation.

Introduction

Epidural steroid injections have been used as a mean of treatment for chronic resistant radiculopathies since the early 1950s, with Robecchi and Capra reporting the first periradicular infiltration with hydrocortisone of the first sacral nerve in 1952 [1]. The first studies on the cervical region started emerging in the 1980s [2], claiming that epidural steroid injections are effective for relieving pain of cervical spine origin. Ever since, many articles supported the theory, and the technique quickly became widespread, leading to the progressive emergence of complications. In April 2014, the FDA issued a notice warning of the rare but serious adverse events that may be encountered with the cervical epidural steroid injections citing loss of vision, stroke, paralysis and death [3]. It required drug labels of injectable corticosteroids to be modified, with an added section describing these risks. This came as a result of a literature review done in 2009, after a total of 90 serious and sometimes fatal neurologic events were reported to the FDA Adverse Event Reporting System (FAERS) between 1997 and 2004 [3]. It concluded that the effectiveness and safety of these drugs for this practice have not yet been established and did not approve injectable corticosteroids for such use. The list included methylprednisolone, hydrocortisone, triamcinolone, betamethasone, and dexamethasone. The American Society of Interventional Pain Physicians, American Society of Regional Anesthesia and Spinal Injection Society were among many to counter this warning [4,5], claiming further clarification and evidence were needed. It asked the FDA to modify its statement replacing it with an evidence-based warning emphasizing the risk of an off-label use of epidural steroids when performed without appropriate precautions [4]. In this context, it seems interesting to evaluate the efficacy and safety of cervical epidural steroid injections. A single-Center retrospective study including patients with chronic resistant cervicalgia and cervical radiculopathy, treated with IL CESI at the pain Center of the Hôtel-Dieu de France hospital in Beirut-Lebanon was conducted. Results were compared to published data.

Methods

Patients: The medical records of the patients treated at our pain Center between 2005 and 2022 and suffering from cervical radiculopathy secondary to cervical disc herniation were reviewed. These patients received one or more cervical epidural steroid injections using the interlaminar approach (ICESI).

Methods: One anaesthesiologist, pain specialist performed the cervical epidural steroid injections using the interlaminar central approach and "hanging drop" technique (HD). The procedure was done under local anaesthesia and in sterile conditions. Patients were placed in the sitting position with their neck flexed. Since fluoroscopy usage needed patients to be placed in prone position, ultrasound guidance (US) was used to locate the interlaminar space and evaluate the skin to dura matter distance. 80 mg of methylprednisolone were administered at the C6-C7 level close monitoring of the vital signs before, during and after the procedure. All the patients were evaluated for bleeding disorders prior to IL CESI using a detailed clinical history and blood tests. In the presence of bleeding disorders, IL CESI was contraindicated. Injections could be repeated at ten days interval up to three

injections every six months depending on symptoms improvement.

Data Collection: The collected data included: cardiovascular risk factors (hypertension, diabetes, dyslipidemia, and smoking), history of previous cervical spine surgery, number of cervical infiltrations required, interval between 2 consecutive infiltrations, duration of symptoms (cervicalgia and radiculalgia), affected side and the symptomatic dermatome, the level and type of disc herniation on imaging as well as Estimated Epidural space Depth on US and Measured Epidural space Depth on HD in cm. Complications encountered in our study population were recorded: the safety of the technique was evaluated by comparing their incidence to that found in previous published data. Patients were interviewed by phone between May and June 2023 to evaluate their symptoms after epidural steroid injections. Improvement in pain numeric rating scale (NRS), the Odom's criteria defined as patient satisfaction and the need for further referral to surgical management was noted during this interview. A physician affiliated with the neurosurgery department and not involved in the therapeutic management of the included patients conducted the phone interview. Mean pain numeric rating scale values for cervicalgia and cervical radiculopathy were simultaneously compared before and after the procedure (IL CESI) using a multivariate analysis of covariance (MANCOVA). The number of infiltrations and the duration of symptoms were included in the model as quantitative covariates, and time and the presence of osteophytes as grouping variables. Two-way interaction terms for time with the other covariates were included in the model. Effect size and the statistical power of the study were derived "post hoc". The categorical values were expressed in percentages, while the continuous and ordinal ones were expressed as mean ± standard deviation, or as median and its interquartile range, according to the sampling distribution evaluated by the Kolmogorov–Smirnov test. The statistical analysis was done using the SPSS v22 software (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.).

Results

During the study period, 45 patients were included and a total of 60 CESI using the IL approach were recorded. The patients were mainly suffering from chronic resistant cervicalgia and cervical radiculopathy (84.4%). The remaining 15.6% showed symptoms of isolated cervical radiculopathy without cervical pain.

Demographic data are shown in Table 1.

Only 1 patient (2.2%) had undergone a previous cervical spine surgery. Most patients needed 1 injection (75.5%), while the remaining needed 2 (15.5%) or 3 (8.89%) injections to alleviate their pain. The median time between the first and second injection was 6 [4 -8] weeks, and 12 [4 – 77] weeks between the second and the third one.The symptoms more frequently affected the right side (56.8%) and the C6 or C7 dermatomes (62.2% and 35.6% respectively). Intervertebral disc anomalies were noted on MRI of the cervical spine in 95.6% of the cases, with osteophytes contributing to the cervicalgic and radicular symptoms in 48.9% of cases (sometimes combined with disc anomalies). There were 6 minor complications (10%) noted during the procedure including: vasovagal episodes (6.67%), one Dural puncture (1.67%) and a halt of the procedure following a bloody tap (1.67%) (Figure 1). The only significant statistical difference was found when comparing the pain numeric ratings for cervicalgia (p=0.030), which went down from 8/10 before the injections to an average of 3/10 afterwards, but not for cervical radiculopathy (p=0.115) despite a clinically significant pain scores reduction from 8/10 to 4/10 (Figure 2, Table 2). The Odom's criteria classified patients between « completely satisfied » (31%), « partially satisfied » (56%) and « dissatisfied » (13%). Patients classified as "Dissatisfied" represented all the patients that needed referral to surgical management (Figure 3).

Age (y) – mean ± SD	47.18 ± 10.58
Gender – n (%)	
Male	21 (46.6%)
Female	29 (64.4%)
Smoking – n (%)	16 (35.6%)
Hypertension – n (%)	7 (15.6%)
Diabetes – n (%)	5 (11.1%)
History of cervical surgery – n (%)	1 (2.2%)
Cervicobrachialgia – n (%)	38 (84.4%)
Isolated cervical radiculopathy	7 (15.6%)
Duration of cervicobrachialgia before CESI (weeks) – mean ± range	127.2 ± 194.2
Duration of cervical radiculopathy before CESI (weeks) – mean ± range	53.9 ± 102.2
Imaging findings – n (%)	
Cervical disc herniation	21 (46.7%)
Osteophytes	1 (2.2%)
Both	23 9 (51.1%)
Estimated Epidural space Depth in cm (US) - mean ± SD	4.94±0.8
Measured Epidural space Depth in cm (HD) - mean ± SD	4.96±0.9

Table 1: Demographic data.

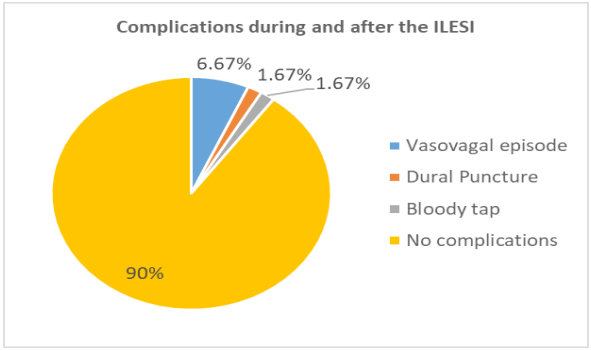

Figure 1: Encountered complications during and after the interlaminar epidural steroid injection (IL CESI).

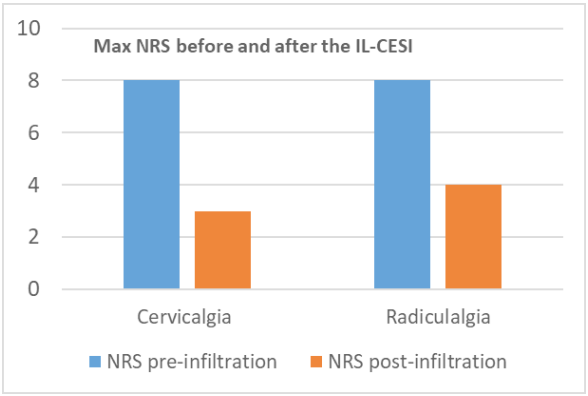

Figure 2: Comparison of the max NRS before and after the interlaminar epidural steroid injection (IL CESI) for cervicalgia and radiculalgia.

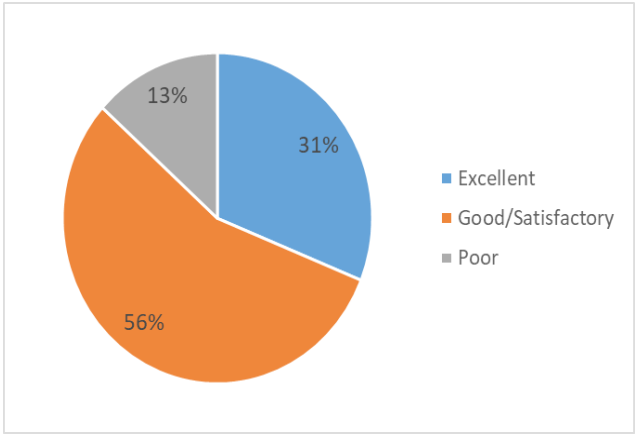

Figure 3: The Odom's criteria evaluated after the IL CESI.

(a): computed at alpha 5%				
MANCOVA Model :				
Multivariate Tests	Wilks' Lambda	p-value	Partial Eta²	Observed Power[a]
Between Subjects				
Intercept	.295	.000	.705	1.000
Number of infiltrations	.924	.390	.076	.200
Duration of symptoms	.989	.880	.011	.068
Présence of ostéophytes	.953	.560	.047	.137
Within Subjects				
Time	.824	.098	.176	.461
Time * Number of infiltrations	.975	.741	.025	.093
Time* Duration of symptoms	.996	.950	.004	.057
Time * Presence of osteophytes	.920	.370	.080	.210
Univariate Tests: Source: Time				
Number of infiltrations	C	.115	.096	.348
	R	.030	.176	.602
Duration of symptoms	C	.451	.023	.114
	R	.489	.019	.104
Présence of ostéophytes	C	.869	.001	.053
	R	.755	.004	.061

Table 2: MANCOVA The MANCOVA model used to assess: Max NRS before and after the IL CESI for cervicalgia (C) and radiculalgia (R).

Discussion

Despite contradictory findings regarding their effectiveness, epidural steroid injections are widely being used as a mean of treatment for spinal and radicular pain. A retrospective cohort study of usage patterns highlighted a 99% increase per 100 000 Medicare beneficiaries in the US from 2000 to 2014 [6]. Cervical and thoracic injections in particular account for nearly 12% of procedures with more than 210,000 injections being performed in the US Medicare populations in 2014 alone [6]. This notable growth in numbers has been accompanied by an increasing rate of reported complications. The type, incidence and potential etiology of such complications are unique to each route of administration. In 2007, a review of the literature on complications of IL CESI included studies published between 1996 and 2005 [7]. The reposted rate of complications varied between 0 and 16.8%. Most complications were minor and transitory in nature such as procedure-related pain, vasovagal reactions, and steroid side effects. Major complications included epidural hematoma, dural puncture, subdural blocks and permanent spinal cord injury [7]. Most articles reviewed were however limited to retrospective studies, case reports, and some of the data extrapolated from lumbar and thoracic procedures. In a review of malpractice claims collected from the American Society of Anaesthesiologists' closed claims database between 2005 and 2008, a total of 20 incidents of direct spinal cord injury after IL CESI were reported [8]. It must be noted that more than 600,000 interlaminar cervical/thoracic epidural steroid injections were performed on Medicare beneficiaries alone during the same period from 2005 to 2008 [6]. A multi-institutional cohort that evaluated complications associated with epidural steroid injection (ESI) was published by El-Yahchouchi et al. in 2015 [9]. It featured over 16,000 injections, 10% of which were performed in the cervicothoracic level (around 1,408 IL CESI). Identified adverse events were divided between immediate and more delayed ones with respective rates of 2.4% and 4.9% of ESIs. The most common immediate adverse event was vaso-vagal reactions with an incidence of 1.2%. Other immediate adverse events included dural puncture (0.1%) and aborted procedure due to bloody tap (0.8%). Delayed adverse events were also minor and similar in nature, the two most common being central steroid effect (sleeplessness,

flushing, non-positional headache) (2.6%) and increased pain (2.1%). The authors concluded that ESIs are safely performed by either the transforaminal (TF) or interlaminar (IL) approach when evidence-based practice guidelines are followed [9].

Our study reported similar rates of minor complications to that found in published data. There were no recorded major complications, ischemic in particular, which had motivated the warning emitted by the FDA in 2004 regarding the use of particulate steroids [3]. Our results join those found by El-Yahchouchi et al, certifying the safety of the IL CESI when appropriately performed [9]. A strong knowledge of the cervical spine anatomy is crucial for understanding the etiology of potential major complications and performing safe IL CESI. The posterior cervical epidural space contains a rich venous plexus rather than an arterial vasculature. The risk of ischemic neurological events is therefore minimal, unlike the risk of spinal cord compression due to epidural hematoma formation. In addition, the distance to the dura is 2 to 3 mm less compared to the lumbar space, and has been found to rapidly diminish above the C7-T1 level [10]. Thus, major neurologic complications following the IL approach are mostly related to aberrant needle placement. The multidisciplinary pain workgroup recommended that all IL CESI be performed using image-guidance at C7-T1 and preferably not higher than the C6-C7 level [11] but ultimately left up to the clinical judgment of the physician. Accordingly, only one anaesthesiologist-pain specialist experienced in the technique performed the IL CESI technique at our centre. Ultrasound imaging was used to facilitate the procedure performed at C6-C7 level. For the TF CESI, minor adverse events incidence is similar to the IL route [9]. Nevertheless, major complications associated with TF CESI are more frequent, and encompass a variety of neurologic events attributable to infarction of central nervous system [11]. In 2007, Scanlon et al. identified in an anonymous survey of the American Pain Society a total of 78 major complications following TF CESI. Of these complications, 30 were spinal cord and brain infarcts, and, overall, 13 cases had a fatal outcome [12].In 2010, Benny et al. reported in their review of the literature 105 complications including brain infarction, brain edema, spinal cord infarction and blindness [13]. Several mechanisms of injury have been proposed, such as arterial dissection, transection, vasospasm or thrombosis related to needle misplacement. Since the FDA Safe Use Initiative, there have also been reported cases of dexamethasone related conus infarction, dispelling the theory that this is a particulate steroid related matter. [14-17]. Deleterious effects of intra-arterial particulate corticosteroid have been demonstrated in animal models [18]. One hypothesis is the formation of macro-aggregates larger than red blood cells, leading to emboli and arteriole occlusion (19). On the other side, the size and aggregates of non-particulate corticosteroids are much smaller, which explains in theory why dexamethasone lacks the embolic risk of other steroids (20). Moreover, to our knowledge, there are no published reports to date on cases of infarction following TF CESI with dexamethasone. Gharibo et al. reported a single case of a conus medullar is infarction following a lumbar TF epidural steroid injection with dexamethasone. The authors however theorized that this catastrophic complication was probably secondary to a vasospasm or thrombosis of the anterior spinal artery due to the needle-tip and inject ate, rather than an intravascular injection of dexamethasone [17]. In terms of effectiveness, several studies have compared clinical outcomes between particulate and non-particulate corticosteroids, with regard to pain relief and functional outcomes. Makkar et al. in their 2016 meta-analysis that included 7 studies and more than 4000 patients concluded that particulate steroids seems to be associated with slightly better VAS scores [21]. In two recent studies, Bensler et al. reported more pain reduction in patients receiving lumbar particulate steroids using the TF [22] and the IL approaches [23]. Other studies [24-28] and one meta-analysis [29] found no advantage for particulate over non-particulate corticosteroids injections in lumbar and cervical regions of the spine while coming under criticism for their conclusion. For example, the Kennedy article [28] compared an extremely high and non-equivalent dosage of dexamethasone 15 mg to triamcinolone 60 mg. In the dexamethasone arm six times as many patients required three injections to reach the desired effect. 33.5% of patients in the Kennedy study proceeded to spine surgery. In terms of current clinical practice, a survey performed by Doan et al. showed that 75% of surveyed clinicians use particulate steroids for cervical interlaminar epidural injections while 25% use dexamethasone. 89.5% of clinicians surveyed use particulate steroids for lumbar interlaminar epidural injections while 10.5% use dexamethasone [30]. In another survey performed by Gharibo et al. 72% of clinicians surveyed use particulate steroids for cervical transforaminal injections while 28% use dexamethasone. 64% of clinicians surveyed use particulate steroids for lumbar transforaminal injections while 36% use dexamethasone (31). Thus, considering the controversial efficacy of both steroid types on one hand, and the serious side effects encountered with TF CESI using particular corticosteroids on the other hand, non-particulate corticosteroids are recommended when performing TF CESI [11,32]. As for therapeutic cervical IL injections, the literature is sparse, and no specific type of corticosteroid can be advocated at the moment [11]. All this being said and keeping in mind that all cases of ischemic complications with particulate steroids reported in the literature were associated with TF CESI only [14-16], particulate steroids administered by the IL approach were used in this study without any recorded major complication. These findings add to the controversy regarding the use of particulate steroids in epidural infiltrations, motivating the need

for further large, randomized trials to better compare interlaminar and transforaminal approaches, in terms of safety and efficacy linked to the type of the steroid used.

Finally, each injection approach presents with different neurological and vascular mechanical risk and has its unique advantages and disadvantages. Majority of the literature that shows benefit of the TF over the IL approach are based on particulate steroids [33]. The IL approach is beneficial when facing multilevel sources of pain because it ensures a cranio-caudal spread of injected corticosteroids [34]. Several studies have highlighted the efficacy of IL [35-42] and TF CESI [43-48]. However, the methodological heterogeneity of available studies and the lack of placebo control treatment groups limit their interpretation in terms of the clinical superiority of each approach. It seems that a clinically applicable comparison is no particulate TF ESI to particulate IL ESI. Patients enrolled in this study reported a high level of satisfaction: 87% of them were satisfied and skipped surgery. Pain scores were also significantly improved for cervicalgia ($p=0.030$), but the statistical significance was not achieved for radiculopathy although pain scores were reduced from 8/10 to 4/10 ($p=0.115$). This reduction in pain intensity is of great clinical significance even if not proven statistically. These results add to the data that supports the efficacy of the interlaminar approach [35-42] but the retrospective aspect, the lack of comparison with the transforaminal approach and the limited number of patients included should be mentioned as limitations of this study. ASIPP, MPW and many experts advocate that the ultimate choice of what approach and agents to use (IL vs. TF; particulate vs. non particulate) should be made by the treating physician by balancing potential risks vs. benefits of the decision made for each given patient [11]. In this perspective, the authors would like to emphasize on the reasons that motivated the choice of the interlaminar approach under ultrasound guidance: Presence of an anaesthesiologist-pain specialist with good experience in Ultrasonography and IL CESI using the hanging drop technique: Different techniques are available for identifying epidural space. The hanging drop (HD) technique used in this study relies on the aspiration of a small volume of fluid from the hub of the needle as the pressure at the tip decreases below atmospheric level upon entering the epidural space. The loss of resistance (LOR) is another technique for identification of epidural space. Both air and fluid can be used as a medium. Air, on one hand, allows avoiding the technical difficulties associated with increased friction between the plunger and barrel of the LOR syringe, but is more linked with air embolism and incomplete analgesia as air particles surrounding nerve routs can cause patchy blocks [49]. On the other hand, disadvantages with saline include dilution of local anesthetic agent affecting sensory blockade, and confusion with cerebrospinal fluid. There is still an ongoing debate to which medium is superior for the LOR technique. Many studies have compared air and saline in terms of the LOR technique for identification of the epidural space and reduction of complications, with no significant difference in results [50,51]. Epidural pressure depends on the patient's position (lateral, prone or sitting) as well as the site of injection (cervical, thoracic or lumbar), with negative sub atmospheric pressure being consistently encountered at the cervical level when a sitting position is used [52]: patients in this study were placed in sitting position making the HD well adapted for identifying the epidural space for CESI, especially when combined to US. When using the HD, the epidural needle is held between the thumb and index of both hands, with the ulnar border of the hands positioned on the patient's back, granting more control and stability while advancing the needle when compared to LOR. Another advantage is that only a drop of saline is used and therefore reduces confusion with cerebrospinal fluid [53]. Preference of ultrasound guidance over fluoroscopy (economic impact): Ultrasound machine represents a standard equipment of the authors' pain Center. Therefore, patients' accessibility to this kind of resource is easier at no supplemental cost. In contrast, fluoroscopy access requires further bookings to be made and generates an extra cost.

Traditionally, CESI procedures have been performed with imaging guidance (computed tomography (CT) scan and mostly fluoroscopy) to improve the accuracy of needle placement, medication delivery, and reduce procedure-related complications. In this study, ultrasound guidance was used instead. Using a 6~12 MHz linear probe, a pre-procedural scanning allowed identifying the midline and the appropriate intervertebral C6-C7 level. Compared to using surface landmarks or palpation, identification of a specific intervertebral level is more accurate with US, especially in obese patients or patients with variability in vertebral anatomy [54]. US also provided information on the depth of the epidural space and the angle of needle insertion: epidural space was found using HD technique at a depth of (4.96cm±0.9) which was in complete concordance with the estimation provided by the pre-procedural US scanning (m± SD) (Table 1). On the other hand, at a mean depth of 4.96cm, it seems unlikely that the injection could be equivalent to a trigger point injection especially with the significant clinical improvement achieved on cervicalgia and radiculopathy. In contrast to fluoroscopy, US provides excellent imaging of soft tissues. Moreover, unlike fluoroscopy and CT scan, US does not expose the patient and physician to the risks of radiation, nor require a specific infrastructure for installation. Ultrasound, with its advantages in visualization of vessel and the spread of injectant, may potentially decrease the complication rate of intravascular injection. It is also the most affordable technique. Many studies have compared the therapeutic efficacy and safety of CESI with US to fluoroscopic guidance, with promising results [55-57]. Less discomfort for patients in terms of minor complications rate [9]. Major complications involving ischemic events were

reported when particulate steroids were associated with the transforaminal approach (TF CESI) [14-16]. This might explain the noted increase in the frequency of usage of the transforaminal approach for ESI's in the lumbar region, whereas in the cervical region most physicians still prefer the interlaminar approach [6].

Conclusion

Cervical epidural particulate steroid injections' using the interlaminar approach under ultrasound guidance seems to be safe and efficient therapeutic option for cervicobrachial neuralgia secondary to cervical disc herniation. Around 9 patients out of 10 are satisfied with a lasting improvement in symptoms long after the procedure. Although published data reported severe and fatal complications with the transforaminal approach (TF-CESI), only minor complications were reported in this study combining particulate steroids to the interlaminar approach (IL-CESI). This study also showed better improvement in cervicalgia when compared to cervical radiculopathy. Further randomized controlled trials involving larger numbers of patients are needed to compare interlaminar and transforaminal approaches and their effects on both symptoms. Finally, it is important to consider the easiness, safety, accessibility of resources and clinical situation before adopting any technique. In this perspective, US guidance seems promising to facilitate epidural steroids injections and future studies comparing it to fluoroscopy are needed.

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