

Ghada Mosaad Abdel-Razik Attia¹, Soad Sayed Abdel-All Elgaby², Al Shaimaa Ahmed Ezzat Mohammed³, Suzan Mohamed Abdelkareem Mohamed^{4*}

¹Resedent of Anaesthesia, Intensive Care & Pain Management, Faculty of Medicine for Girls, Cairo, Al Azhar University

²Professor of Anaesthesia, Intensive Care & Pain Management, Faculty of Medicine for Girls, Cairo, Al Azhar University

³Lecturer of Radiology, Faculty of Medicine for Girls, Cairo, Al Azhar University ⁴Lecturer of Anaesthesia, Intensive Care & Pain Management, Faculty of Medicine for Girls, Cairo, Al Azhar University

*Corresponding author: Suzan Mohamed abdelkareem Mohamed Mobile: 01009925814

E-mail: mailto:Szn8001@yahoo.com

ABSTRACT

Background: Small doses of medication injected into the ventral epidural space using transforaminal epidural steroid injections (TF-ESIs) are highly effective. However, the needle comes dangerously close to the spinal nerve, increasing the risk of nerve injury. Therefore, a different technique known as the oblique interlaminar epidural (OIL) approach is adopted, Aim and objectives: The aim of the research was to compare lumbosacral pain and unilateral radiculopathy treatment outcomes after CTguided transforaminal versus oblique interlaminar epidural steroid injection, Subjects and Methods: This prospective, randomized, controlled investigation involved 40 cases of both sexes, ages 30 to 60, with lower back and unilateral lumbosacral radicular pain at the L3 / L4 to L5 / S5 lower levels. They did not respond to a fourweek course of analgesics and physical therapy. Individuals were assigned to one of two categories at random. 20 individuals received a transforaminal lumbar epidural (TF) and 20 individuals received OIL, Results: In terms of age, gender, height, weight, procedure level, patient satisfaction, and side effects, there was not a significant distinction among the groups. There was no significant variation among the pre-operation pain score and the pain scores after 2 hours, 2 weeks, and 6 weeks after the surgery, **Conclusion:** In the treatment of low back and unilateral lumbosacral radicular pain, ESIs administered using the OIL technique are as successful as TFadministered ESIs regarding pain reduction and functional improvement.

Keywords: Transforaminal epidural steroid injections; Oblique interlaminar (OIL); low back pain; Radicular Lumbosacral pain

INTRODUCTION

The administration of corticosteroids epidurally is merely one of numerous treatment options for chronic low back pain. This condition affects between 15% and 39% of the population and has significant medical, social, and economic consequences. The

caudal, interlaminar, and transforaminal routes, together referred to as selective nerve root epidural injection, are three of the several ways to reach the epidural space in the lumber region.^{1,2}

Since its first in 1952, epidural steroid injections (ESIs) have been used to alleviate pain caused by several disorders. Low back pain that travels to the legs, and less frequently neck discomfort that travels to the arms, can be effectively treated without surgery thanks to ESIs.³

Steroids are injected into the epidural space to alleviate pain that has a discogenic source. If the epidural steroid injection is effective, the patient will feel less discomfort and be able to resume their normal activities or physical therapy program.

Since steroid injections can block pro-inflammatory molecules, they might considerably lessen pain in affected areas. The molecular foundation of neurological signaling is altered and proper neuronal membrane development is encouraged by these medications. By increasing blood flow in the epidural space's vessels, the injection of fluidy substance may also impact pain. The transmission of pain signals may be reduced to some extent as a result of this. In addition to reducing pain, the injected substance may repair injured nerve cells and remove inflammatory molecules from the epidural area.^{6,7}

In the TF technique, a needle is inserted into the epidural space just above the affected nerve root. When compared to the oblique inter-laminar technique, this one has a number of benefits, such as a lower risk of dural puncture, drug injection closer to the ventral nerve root where the lesion is located, drug distribution to the ventral epidural area, and a less amount of medications needed. Thus, a method is required that provides efficient medication administration to the ventral epidural area. ⁸

A needle is inserted between two vertebrae using a parasagittal (oblique) inter-laminar technique. Several studies have demonstrated that ESIs administered via the ventral epidural distribution of contrast with minimum nerve damage effectively relieves pain and improves functional status in the treatment of low back and lumbosacral radicular pain.⁹

Interventional radiologists are increasingly making use of CT. However, both the medical establishment and the general public are growing increasingly worried about the risks of radiation exposure from medical procedures.¹⁰

The research aimed to assess the effectiveness of Transforaminal versus Oblique Interlaminar ESIs for the treatment of lumbosacral pain and unilateral radiculopathy using computed tomography (CT).

PATIENTS AND METHODS

With permission from Al-Azhar University's Department of Anesthesia's Ethics Committee, this randomized controlled trial was conducted & obtaining an informed written consent from the patients from (october2021 to october2022) population at Nasr city Health Insurance hospital. This study included 40 patients of both sexes, aged 30 to 60 years. Suffering from L3–L4 and L5–S1 lumbosacral radicular discomfort in the lower back and one side of the body. Analgesics and physical therapy for four weeks failed to alleviate their pain.

Sample size calculation: Calculating a suitable sample size depends on mean reduction in VAS score between 2 groups post procedure in group with OIL retrieved from previous research. ¹¹ after utilizing G*power version 3.0.10 to calculate sample size based on a two-tailed test, α error =0.05 and power = 90.0%, effect size 0.823, the total calculated sample size was 18 in each group. However, after adding 20% to

compensate for probable drop out, the total sample size was increased to 20 in each group.

Exclusion criteria: discomfort in the low back without any spreading discomfort, Previous struggles with substance misuse, A history of adverse consequences caused by the usage of steroids, deficiencies in the neurological system, Coagulation disorders, Diabetic patients and Hypertensive patients.

Equipment and material used: Computed Tomography (CT) unit (Toshiba Aquilion-Prime-160 slice-Japan). Anesthetic machine (Drager, primus GS Germany) was prepared, Monitor screen for Electrocadiography (ECG), non-invasive blood pressure, oxygen saturation (Spo2), Endotracheal tube, Laryngeoscope & Ambu bag, Cannula (22or24 gauge), Intravenous (IV) line and Nasal cannula, Drugs that used when any expected adverse effect occurs such as: (Ephedrine (vasopressor) for hypotension, Hydrocortisone for hyper sensitivity reactions and Atropine for bradycardia), Drugs used for injection at the study: (Local anesthetic (lidocaine HCL 1 %) and Steroids (betamethasone ,Betafos 14 mg) Water soluble contrast solution (Ultravist), Spinal needles (22 – gauge Tuohy needle), Syringe for the measurement of loss of resistance, sterile gloves and drapes, and betadine 10%.

Group allocation: Subjects were randomly divided into two groups: TF (n: 20) and OIL (n: 20).

Oblique Interlaminar Epidural Steroid Injection (medial approach): To keep the patient as comfortable as possible, it's best to pick a route that stays away from the periosteum and uses as little of the back muscles as possible. Using a CT scan image, we located the interlaminar gap between two adjacent vertebrae and injected local anesthetic (lidocaine1%) into the skin and underlying tissue after marking the skin at an acceptable point near the midline. An epidural spinal needle was introduced into the desired injection location through a midline or paramedian route between the spinous processes. The needle enters the epidermis, then the subcutaneous tissue, the supraspinous ligament, the paraspinal muscles, and finally the ligamentum flavum, working its way from the surface to the depths. Injecting only 2 ml of air or normal saline into the epidural space required a fast drop in pressure, which allowed the syringe to push the needle through. To verify that the needle was successfully inserted into the epidural space, 1 ml of water-soluble contrast solution (Ultravist) was administered into a new syringe that had replaced the loss of resistance syringe. After visual confirmation of contrast distribution, the epidural space was injected with 14 mg (2 mL) of steroid (Betafos) and 20 mg (2 mL) of local anesthetic (lidocaine 1%). After that, pressure was kept on the injection site to stop the bleeding while the needle was removed

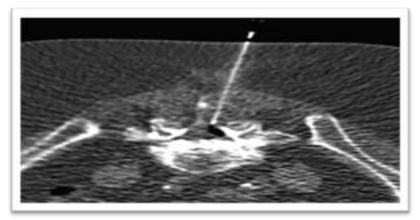


Figure (1): selected axial CT image demonstrate the introduction of needle in interlaminar technique

Transforaminal Epidural Steroid Injection (lateral approach): Local anesthetic (lidocaine 1% was administered under the patient's skin and into the surrounding tissue at the site indicated on the CT image as the lateral foraminal gap between two adjacent vertebrae. A 22-gauge Tuohy needle was placed at the site of disc pathology following local infiltration with 1% lidocaine. The epidural space was accessed by a decrease of resistance to fluid, and a needle was inserted. After confirming that no CSF or blood was aspirated during insertion of the needle, the procedure can proceed. One milliliter of water-soluble contrast media and 14 milligram of dexamethasone (Betafos) were injected into the epidural space along with 20 milligrams of lidocaine, 1%.



Fig 2 selected axial CT image demonstrate the introduction of needle in transforminal technique

The primary outcome of the research was to reduce the pain after the procedure. The assessment of the back and leg pain using visual analogue scale (VAS), Time of assessment at the pre-procedure, 2- hours post procedure, 2-week and 6-week visits: **(VAS)** is a score for assessment of back and leg pain from (0 to 10) scoring as: 0 - No pain, 5 - Distressing pain and 10- Unbearable pain.

Depend on intensity, location, onset, duration and quality in addition to; "Facies" pain rating scale & **the secondary outcome** was to recorded the changes as regard disability; between first visit and 6-week visit using: Oswestry Disability Questionnaire (ODQ) & Roland-Morris disability questionnaire (RMDQ)

Ventral & contralateral spread of contrast medium were recorded & compared in both groups at time of injection.

Patient satisfaction was assessed using a four-point scale over the course of six weeks, with the following categories: (extremely unhappy), (somewhat dissatisfied), (somewhat satisfied), and (very satisfied).

Complications: Although rare, were also evaluated and recorded; possible complications include: Allergic reaction, Dural puncture causing positional headache, Transient back or lower extremity pain, Paralysis (very rare), Nausea, Vomiting, Dizziness, Hypotension and Local anesthetic toxicities

Statistical analysis: SPSS (statistical program for the social sciences) version 22 was used to examine the data. Quantitative data was checked for normality utilizing the Shapiro-Wilk test and then reported using the mean, standard deviation, median, and range. Qualitative data was provided as raw numbers and percentages. Based on the characteristics of the data, the following statistical analyses were performed: For categorical data, we utilized Chi-Square, and for continuous data, we used either Spearman or Pearson correlation.

Demographic data	Group A(TF) n=20	Group B (OIL) N=20	P-value
Sex			0.240
Male	11	8	
Female	9	12	
Age(years)			
Mean ± SD.	52 ± 5.7	51 ± 9.4	
Range (Min-Max)	(44-60)	(30-68)	
Weight(kg)			0.263
Mean ± SD.	66.4 ± 10.2	63.6 ± 9.1	
Range (Min-Max)	39(40-79)	24(56-80)	
Height(cm)			0.443
Mean ± SD.	161.3 ± 8.0	163.0 ± 8.9	
Range (Min-Max)	25(148-173)	33(150-183)	
Procedure level			
L3-L4	1(6.9%)	2(10)	0.669
L4-L5	17(86.2%)	17(86.2)	1
L5-S1	2(10%)	1(6.9)	0.972

RESULTS

P-value>0.05 is considered insignificant, $p \le 0.05$ is statistically significant, $p \ge 0.01$ is highly statistically significant,

Table (1): Demographic Data among two studied groups and procedure level. There was no statistically significant variance (P-value >0.05) among 2 groups regarding age, gender, height, weight and procedure level **table (1)**.

Time	Pain score	Group A(TF) n=20	Group B (OIL) N=20	P- value between 2 groups
Pre-procedure	Mean ± SD.	6.0 ± 0.98	6.4 ± 0.49	0.111
	Median (Min-Max)	6 (4-6)	6 (6-7)	0.111
2hrs. post-procedure	Mean ± SD.	3.3 ± 0.47	5.3 ± 0.57	.0.001**
	Median (Min-Max)	3 (3-4)	5 (4-6)	<0.001**

2 weeks post-	Mean ± SD.	0.65 ± 0.49	3.5 ± 0.76	<0.001**
procedure	Median (Min-Max)	1 (0-1)	4 (1-4)	<0.001
6 weeks post-	Mean ± SD.	0.65 ± 0.49	1.3 ± 0.57	<0.001**
procedure	Median (Min-Max)	1 (0-1)	2 (1-3)	<0.001***
P-value inter same group		<0.001**	<0.001**	

Table (2): Pain score (VAS) difference between two study groups at different time.

Pain score in pre-procedure was insignificant, (P-value >0.05) while pain score 2hrs. post-procedure, two weeks post-procedure, 6 weeks post-procedure pain score was statically highly significant ($p \le 0.01$) table (2)

Ventral epidural contrast spread	Group A(TF) n=20	Group B (OIL) N=20	P-value
At injection			0.013*
Yes, n (%)	19(96.6)	15(73.3)	
No, n (%)	1(3.4)	5(26.7)	

Table (3): Ventral epidural contrast spread Consistent with the Approaches in 2 study groups; at injection.

As regard contrast spread, the contrast medium spread to the ventral epidural space at an injection rate of 96.6% in group TF and only 73.3% in group OIL. When contrasted with group TF epidural steroid injection, the ventral epidural distribution of contrast medium upon injection was significantly smaller in the group OIL (P = 0.013). table (3).

Contralateral epidural contrast spread	Group A(TF) n=20	Group B (OIL) N=20	P-value
W0-ESI			<0.001**
Yes, n (%)	0(0)	9(46.7)	
No, n (%)	20(100)	11(53.3)	

Table (4): Contralateral epidural contrast spread According to the Approaches intwo study groups.

In the group OIL, the contralateral epidural spread of the contrast medium was 46.7%, whereas in the group TF, there was no evidence of a contralateral epidural spread of the contrast medium. **table (4)**.

Patients' Satisfaction	Group A(TF) n=20	Group B (OIL) N=20	P-value
Very satisfied	14(70)	13(65)	1.000
Somewhat satisfied	5(25)	4(20)	1.000

Somewhat dissatisfied	1(5)	2(10)	1.000
Very dissatisfied	0(0)	1(5)	1.000
Total	20(100)	20(100)	

Table (5): Patients' satisfaction between two study groups after the Procedure.

There were no significant variances in cases' satisfaction among the groups table (5).

Side effects	Group A(TF)	Group B (OIL)	P-value
	n=20	N=20	
toxicity from LA	0(0)	0(0)	-
Hematoma	0(0)	0(0)	-
Paraplegia	0(0)	0(0)	1.000
Nausea	2 (10)	3 (15)	1.000
Vomiting	0(0)	0(0)	1.000
Headache	3 (15)	2 (10)	1.000
Hypotension	2 (10)	3 (15)	1.000
Dizziness	5 (25)	6 (30)	0.749

Table (6): Side effects recorded in both groups.

There is no significant variance among group OIL & group TF as regards side effects as toxicity from LA, hematoma, paraplegia, nausea, vomiting, headache, hypotension and dizziness (p>0.05) **table (6)**.

DISCUSSION

Analysis of study recently found that demographic data there is no statistically significant variance among 2 groups.

This results in agreement with many studies that done by Choi et al. ¹¹ Ghai et al. ¹² & Makkar et al.¹³

Participants' levels of pain were measured at 2-, 4-, and 6-weeks post-intervention utelizing a VAS ranging from 0 (no pain) to 10 (the worst agony imaginable). When there was a significant reduction in pain from baseline as measured by VAS in both .groups, we considered the method to have been successful

When administered locally, ESIs can decrease inflammation by blocking the production or secretion of inflammatory mediators.¹⁴⁻¹⁶

In accordance with the outcomes of **Choi et al**., we discovered that in the treatment of low back and unilateral lumbosacral radiating pain, the OIL-ESI was just as effective as the TF-ESI.^{11,17}

The present research found that the OIL group had a less diffusion of contrast medium into the ventral epidural space contrasted with the TF epidural steroid injection group. Compared to group TF, group OIL had more contralateral epidural distribution of the contrast medium.

It is evidence of ESI's success that the medicine has reached the ventral epidural region. Our research, along with that of **John et al. & Choi et al.**, verified this finding. ^{18,11} However, the most recent investigation by Candido et al. focused on analyzing the differences between the interlaminar and TF methods to parasagittal flow, and they found that the epidural spread was either 100% or 75% in the ventral region. ¹⁹

Injectable IL and TF were shown to be equivalent in recent trials and meta-analyses. **Rados et al.** found that both TF and IL therapies for patients with chronic unilateral radiculopathy significantly reduced symptoms of disability & discomfort.^{20, 21-24}

According to clinical outcome following OIL-ESI in comparison to that following TF-ESI, we recorded patients' satisfaction at the 6-week visit following the intervention, & There was no significant distinction among the 2 groups, as measured by the proportion of patients reporting themselves to be "very satisfied" (60%) between the OIL and TF groups.

The level of patient satisfaction following surgery was also evaluated at the 12-week follow-up, as reported by **Choi et al**. Patients in group OIL were more likely to report being "somewhat dissatisfied" with treatment than those in group TF. ¹¹

Adverse responses from systemic absorption of local anesthetics are possible, although usually brief and mild. Minor symptoms include disorientation and muscular twitching, whereas significant symptoms include seizures and unconsciousness. The amount of local anesthetic administered determines the degree of pain.²⁵

Goodman et al. evaluated the risks & benefits of lumbar ESIs, finding that problems are exceedingly rare and that most may be prevented with proper needle insertion, clean methods, and guided injections.²⁶

CONCLUSION

To alleviate pain and restore function after lumbosacral radicular discomfort or low back injury, ESIs provided using the OIL technique are equally effective as those administered using the TF approach. For individuals with low back pain who are apprehensive about significant adverse effects or for whom transforaminal ESI is difficult to conduct owing to anatomical abnormalities, OIL-ESI can be a useful alternative to transforaminal ESI for delivering drugs to the ventral epidural region. **REFERENCES**

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