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Outcomes of the Fluoroscopically-Guided vs. Computed-Tomography-Guided Transforaminal Epidural Steroid Injection in Low Back Pain: A Propensity-matched Prospective Cohort

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Abstract

Background: Low back pain (LBP), the most common musculoskeletal condition, imposes a significant burden on healthcare and triggers mental and physical disorders. Before surgery, patients are eligible for minimally-invasive treatments, including transforaminal epidural steroid injection (TFESI). We aimed to compare fluoroscopically- and CT-guided TFESI in patients with subacute (4-12 weeks) and chronic (≥12 weeks) LBP.

Methods: In this prospective cohort study, 121 adults with subacute or chronic LBP were recruited. Using propensity score matching (PSM), we created two age, sex, and body mass index (BMI) matched groups of fluoroscopically- and CT-guided TFESI, each including 38 patients. The outcomes of interest were the Oswestry disability index (ODI) and numerical rating scale (NRS), which were measured in all patients before the procedure and at the three-month follow-up. Then, the ODI and NRS mean changes were compared between Fluoroscopy and CT groups using repeated measures ANOVA. All analyses were performed with IBM SPSS Statistics for Windows, version 26 (IBM Corp., Armonk, NY, USA).

Results: Of the total 76 matched patients with a mean (SD) age of 66.22 (13.49), 81 (66.9%) were female. ODI and NRS scores significantly decreased from baseline to the three-month follow-up in both treatment groups. The ODI score mean change from baseline to follow-up compared between the two groups was insignificant (fluoroscopy vs. CT mean difference (95% CI): 1.092 (-0.333-2.518), $P = 0.131$). Similarly, the NRS score mean change from baseline to follow-up compared between the two groups was insignificant (fluoroscopy vs. CT mean difference (95% CI): -0.132 (-0.529-0.265), $P = 0.511$).

Conclusion: Fluoroscopically- and CT-guided TFESI show similar therapeutic effectiveness in patients with subacute and chronic LBP.

Keywords: Low Back Pain, Nerve Block, Epidural Injection, X-Ray CT scan, Fluoroscopy, Steroid

Conflicts of Interest: *None declared*
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Introduction

As the most common musculoskeletal condition, low back pain (LBP) accounts for a lifelong prevalence of 60-

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↑What is "already known" in this topic:
Transforaminal epidural steroid injection (TFSEI) is a minimally invasive technique for subacute and chronic Low Back Pain (LBP) performed under fluoroscopy or computed tomography (CT). Certain studies investigated fluoroscopically- and CT-guided nerve block treatments for LBP. However, most of the literature does not compare CT scan and fluoroscopy.

→What this article adds:
We compared fluoroscopically- and CT-guided TFESI. Both methods significantly reduced LBP symptoms three months after the procedure, and there was no difference between the two methods in terms of symptom relief outcomes was not significant. We concluded that fluoroscopically- and CT-guided TFESI have similar outcomes in LBP patients.

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90% worldwide (1). LBP burdens healthcare tremendously and costs billions of dollars (2). Also, LBP enormously impacts patients' lives in terms of mental and physical health (3). Acute LBP lasts less than four weeks and is typically self-limiting. Subacute pain lasts more than four weeks but less than 12 weeks, and chronic pain lasts more than 12 weeks (4). Subacute and chronic LBP treatment differs depending on the underlying cause, symptoms, and severity. These methods are classified into four types: non-pharmacological, pharmacological, invasive non-surgical, and surgical. Exercise, superficial heat, massage, and acupuncture are all recommended non-pharmacological treatments for acute LBP. If no improvement is seen, pharmacological treatment with NSAIDs and muscle relaxants is the next step (5).

In the subacute phase, treatment aims to alleviate symptoms and identify risk factors that may lead to chronic pain. The treatment objective shifts to symptom management and disability prevention if the pain becomes chronic. As in the acute phase, the treatment of choice for these two stages is a conservative treatment that includes non-pharmacological symptom relief, exercise, and pharmacological treatment. If non-pharmacological and pharmacological conservative treatments fail, invasive treatments are the next line. The two categories of invasive methods are minimally invasive non-surgical and invasive surgery. In subacute and chronic LBP patients with symptoms such as radiculopathy and severe debilitating chronic back pain, it is extremely challenging to choose between non-surgical and surgical treatments (6, 7).

Although we are aware that the surgical procedure has specific indications in a small number of patients, including progressive and severe motor weakness and cauda equina syndrome (8, 9), in the absence of these severe symptoms, surgery should not be considered before minimally-invasive treatments. For instance, in the cases of radiculopathy caused by disc herniation, mild leg drop, and slight movement defects, surgery is not a definite indication, and minimally invasive non-surgical treatment is preferred. Elective surgery is performed only if the patient's quality of life is significantly diminished and does not respond to frequent non-surgical minimally invasive treatment courses (10, 11). However, unfortunately, the use of surgical options before minimally invasive treatments is increasing worldwide (12), a trend that needs to be reversed in the future.

According to the studies, nerve root compression due to disc herniation, canal stenosis, and unsuccessful spine surgery are some indications for a minimally invasive non-surgical treatment known as nerve root injection or lumbar transforaminal epidural injection. In this transforaminal technique, local anesthetic and/or corticosteroids are injected at the nerve root site that is the source of the pain (13). Transforaminal epidural steroid injection (TFSEI) is a minimally invasive technique performed under fluoroscopy, computed tomography (CT) scan, or ultrasound guidance, and the evidence supports its accuracy, efficiency, and limited complications (14, 15).

In this study, we compared the therapeutic outcomes of the fluoroscopically- and CT-guided TFESI in patients with subacute and chronic LBP.

Methods

Patient population and study design

In this prospective cohort study, all patients with LBP undergoing TFESI at Golestan hospital, Tehran, Iran, between October 2021 and September 2022 were recruited. All patients were interviewed before the TFESI procedure and followed up three months after. This study was designed and written according to the STROBE guideline (16).

Eligibility

The eligibility criteria were as follows: 1. Adult patients (≥18 years old); 2. Diagnosed with subacute or chronic LBP not responding to at least six months of conservative treatments; 3. Patients with chronic LBP in whom TFESI was indicated at a neurologist's request and consented to undergo the procedure; 4. Patients in whom the TFESI was performed by injecting triamcinolone acetate (80-120 mg) using a puncture 22-gauge needle; 5. Patients in whom the procedure was carried out under either fluoroscopy or CT scan guides; 6. Without any history of established allergy to triamcinolone; 7. Without a history of LBP surgery in the recent three months; 8. Without any history of opium addiction and untreated mental diseases.

Instruments and outcome variables

All participants were interviewed right before the procedure and three months post-procedure. Baseline characteristics recorded at the first interview, including age, sex, and body mass index (BMI), were considered as the confounding variables. Participants were exposed to two methods of treatment, TFESI under fluoroscopy guide or CT scan guide.

The main outcomes of interest were Oswestry Disability Index (ODI) score and the numerical rating scale (NRS). In both interviews, participants were asked to fill out NRS, which shows pain intensity on a scale of zero to ten, with zero demonstrating "no pain" and ten demonstrating "worst pain imaginable," and ODI, a well-renowned questionnaire evaluating lumbar pain, designed and formulated by Fairbank et al. in 1980 (17), with certain modifications further implemented in the following decades (18, 19). The questionnaire consists of 10 sections scored from 0 to 5, assessing the patient's pain in 10 different daily life situations that include pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, traveling, and employment/homemaking. The ten sections' scores sum up, and an overall score from 0 to 50 is attributed to each patient. Eventually, for each patient, ODI and NRS were calculated. In the present study, we used the Persian version of the modified ODI validated and tested for reliability by Baradaran et al. (20). The Persian version of the modified ODI was deemed reliable in terms of test-retest reliability (mean intraclass correlation coefficient= 0.676) and internal consistency (Cronbach's α coefficient= 0.69). Furthermore, convergent validity was carried out, and the Persian version of the modified ODI showed a strong correlation with a previously-validated Persian questionnaire

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(20).

Propensity score matching

Using propensity score matching (PSM), we minimized the selection bias resulting from heterogeneous nonrandomized cohorts. To calculate the propensity scores, we used a logistic regression model. The treatment group was measured as a dependent variable, and possible confounding variables included age, sex, and BMI. A 1:1 nearest neighbor method without replacement with a caliper width of 0.1 was implemented (21).

Ultimately, we formed two propensity score-matched groups (fluoroscopy and CT scan) with strictly matched patients' baseline characteristics. The PSM was performed using the FUZZY extension for SPSS (22).

Statistical analysis

The normality of the data was assessed with the Shapiro-Wilk test. Categorical variables were shown as frequency (%) and were analyzed using the Chi-squared test. Continuous variables were demonstrated as mean (standard deviation (SD)), mean difference (95% confidence interval (CI)) or median (interquartile range (IQR)). The baseline characteristics were compared between treatment groups using an independent t-test. ODI or NRS scores between baseline and three-month follow-up were compared using paired t-test separately for each treatment group. Similarly, the comparison of ODI or NRS scores between treatment groups was performed using independent t-test separately at baseline and three-month follow-up. The homogeneity of variances was checked using Levene's test before conducting t-tests.

The difference in ODI or NRS scores between baseline and three-month follow-up were compared between treatment groups using repeated measures ANOVA (RM-ANOVA). Certain assumptions of RM-ANOVA were checked beforehand, including normality, homogeneity of variances using Levene's test, equality of covariances using Box's test, and compound symmetry using Mauchly's test of sphericity. The significance level was set at a two-sided $P < 0.05$. Analyses were performed using IBM SPSS Statistics for Windows, version 26 (IBM Corp., Armonk, NY, USA).

Results

Demographics

A total of 121 patients with a mean (SD) age of 66.22 (13.49) and a mean (SD) BMI of 27.68 (3.42) participated in the study, of whom 81 (66.9%) were female. Of these, 38 (31.4%) underwent TFESI under the fluoroscopy guide and 83 (68.6%) under the CT scan guide (Table 1). Furthermore, we carried out a PSM, and two age-, sex-, and BMI-matched groups of fluoroscopy and CT scan were formed, and each included 38 patients (Table 1). Of a total of 76 matched patients with a mean (SD) age of 66.16 (12.71) and a mean (SD) BMI of 27.12 (2.80), 52 (68.4%) were female.

Outcomes of each treatment group through time

In the fluoroscopy treatment group, the mean (SD) ODI score significantly decreased in the three-month follow-up compared to the baseline (13.89 (2.62) vs. 27.55 (5.08), $P < 0.001$). In accordance, the mean (SD) NRS score was significantly reduced after three months compared to the baseline (2.97 (0.82) vs. 8.10 (0.79), $P < 0.001$) (Table 2).

Likewise, in the CT scan treatment group, the mean (SD) ODI score was significantly diminished in the three-month follow-up compared to the baseline (13.23 (2.88)

vs. 26.02 (5.60), $P < 0.001$). Also, the mean (SD) NRS score significantly declined after three months compared to the baseline (3.10 (0.92) vs. 8.23 (1.07), $P < 0.001$) (Table 2).

Outcome difference between treatment groups at baseline and at follow-up

At baseline, the ODI score did not significantly differ between the treatment groups (fluoroscopy vs. CT mean difference (95% CI): 1.526 (-0.918-3.970), $P = 0.217$). Similarly, the NRS score was not significantly different between the groups (fluoroscopy vs. CT mean difference (95% CI): -0.131 (-0.565-0.302), $P = 0.547$) (Table 3).

Table 1. Baseline demographic characteristics

Variable	Unmatched population (n=121)			PSM population (n=76)		
	Fluoroscopy (n=38)	CT scan (n=83)	*P* value	Fluoroscopy (n=38)	CT scan (n=38)	*P* value
Age (years), mean (SD)	66.32 (11.32)	60.35 (14.05)	0.023*	66.32 (11.31)	66.00 (14.12)	0.915
Sex (female), n (%)	27 (71.1%)	54 (66.7%)	0.515	27 (71.1%)	25 (65.8%)	0.622
BMI (kg/m^2), mean (SD)	27.03 (2.59)	27.97 (3.71)	0.159	27.03 (2.59)	27.21 (3.02)	0.776

BMI, body mass index; CT, computed tomography; PSM, propensity-score-matched; SD, standard deviation.
**P*-value<0.05
***P*-value<0.001

Table 2. Comparison of ODI and NRS within each treatment group

Treatment group	ODI †, 0	ODI, 3 months	Mean difference (95% CI)	*P* value	NRS, 0	NRS, 3 months	Mean difference (95% CI)	*P* value
Fluoroscopy	27.55 (5.08)	13.89 (2.62)	13.65 (11.84-15.47)	<0.001**	8.10 (0.79)	2.97 (0.82)	5.13 (4.95-5.30)	<0.001**
CT scan	26.02 (5.60)	13.23 (2.88)	12.78 (10.80-14.77)	<0.001**	8.23 (1.07)	3.10 (0.92)	5.13 (4.94-5.32)	<0.001**

CI, confidence interval; CT, computed tomography; NRS, Numerical Rating Scale; ODI, Oswestry Disability Index, SD, standard deviation.
**P*-value<0.05
***P*-value<0.001
†ODI and NRS amounts are reported as mean (SD).

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Table 3. Comparison of mean ODI and NRS between two treatment groups through time

Time	Comparison	ODI		NRS	
		Mean difference (95% CI)	P value	Mean difference (95% CI)	*P* value
0	Fluoroscopy-CT scan	1.526 (-0.918-3.970)	0.217	-0.131 (-0.565-0.302)	0.547
3 months	Fluoroscopy-CT scan	0.657 (-0.604-1.920)	0.302	-0.131 (-0.531-0.268)	0.514

CI, confidence interval; CT, computed tomography; NRS, Numerical Rating Scale; ODI, Oswestry Disability Index.
**P*-value<0.05
***P*-value<0.001

Table 4. Total mean difference of ODI and NRS from 0 to 3 months, between treatment groups

Scale	Comparison	Mean difference (95% CI)	*P* value
ODI	Fluoroscopy-CT scan	1.092 (-0.333-2.518)	0.131
NRS	Fluoroscopy-CT scan	-0.132 (-0.529-0.265)	0.511

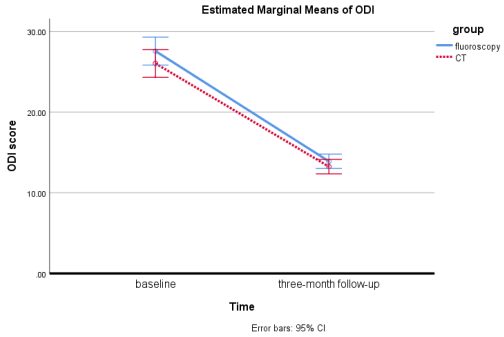
CI, confidence interval; CT, computed tomography; NRS, Numerical Rating Scale; ODI, Oswestry Disability Index.
**P*-value<0.05
***P*-value<0.001

At the three-month follow-up, the difference between ODI scores between treatment groups (fluoroscopy vs. CT mean difference (95% CI): 0.657 (-0.604-1.920), P = 0.302), as well as NRS score between the groups (fluoroscopy vs. CT mean difference (95% CI): -0.131 (-0.531-0.268), P = 0.514) were both insignificant (Table 3).

Between-group comparison of outcomes mean difference

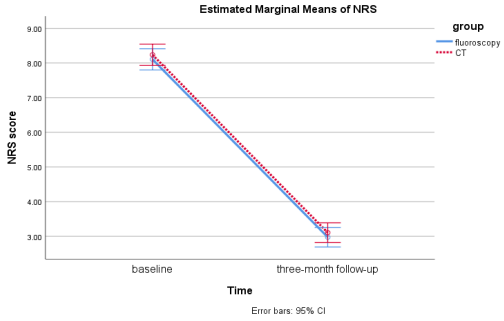
The ODI score mean change from baseline to three-month compared between the two groups yielded insignificant results (fluoroscopy vs. CT mean difference (95% CI): 1.092 (-0.333-2.518), P = 0.131) (Table 4). Figure 1 shows the ODI change through time compared between the two groups.

Likewise, the NRS score mean change from baseline to three-month follow-up yielded as well, insignificant results (fluoroscopy vs. CT mean difference (95% CI): -0.132 (-0.529-0.265), P = 0.511) (Table 4). Figure 2 indicates the NRS change through time compared between the two groups.



ODI, Oswestry Disability Index

Figure 1. ODI reduction from baseline to follow-up



NRS, Numerical Rating Scale

Figure 2. NRS reduction from baseline to follow-up

Discussion

This study indicated that fluoroscopically-guided and CT-guided TFESI for LBP both significantly improved patients' symptoms. Also, the difference between these two methods in alleviating pain was insignificant. Thus, these two methods were shown to have the same effectiveness in the LBP treatment, as measured by ODI and NRS scales at baseline and three-month follow-up.

There are several studies comparing epidural injection under ultrasonography and fluoroscopy. In 2021, Senkal et al. compared the treatment effectiveness of ultrasonography- and fluoroscopy-guided epidural steroid injections (ESI) in chronic LBP. By measuring ODI and NRS, they observed significant improvement in the score in each group, although there was no significant difference between the groups. However, ultrasonography, relative to fluoroscopy, yielded a significantly shorter procedure duration and higher successful procedure rate on the first attempt. Given the lower radiation exposure, they suggested the superiority of ultrasonography (1). This result is in line with the study by Yoon et al., which showed that ESI outcomes under ultrasonography were not significantly different from fluoroscopy. In addition, ultrasonography does not expose the person to radiation and is more convenient to conduct (23). Accordingly, in a recent randomized controlled trial (RCT) by Poutoglidou et al. in 2021, the efficacy of the outcomes of ESI assessed using ODI, and the Visual Analogue Scale (VAS) did not significantly differ between ultrasonography and fluoroscopy guidance (24). Even though ultrasonography is proposed as effective and less hazardous than fluoroscopy, there exist certain drawbacks in these studies. For instance, in obese patients, the accuracy of ultrasonography in needle placement in the epidural space is drastically diminished, leading to treatment failure (25). As supporting evidence, Rauch et al. conducted ultrasonography-guided nerve block for LBP with fluoroscopy as the control in obese patients (BMI>30). They observed a procedure success rate of 62%, thus disqualifying ultrasonography in obese patients (26). Moreover, the success rate of ultrasonogra-

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phy guidance is remarkably reduced in LBP patients with failed back surgery, leading to epidural space deformity. Hence, in these cases, fluoroscopy is favored (25).

Several studies evaluated fluoroscopically- or CT-guided nerve block treatments for LBP. However, the majority of the literature does not investigate the comparison between CT scan and fluoroscopy. In a prospective study, Fotiadou et al. investigated CT-guided nerve root block in 86 patients with LBP. Before and three months after the treatment, they used ODI to evaluate the pain. According to the study's results, 85% of patients reported significant pain reduction. This study showed that the CT scan is a very accurate and safe method to guide nerve block treatments (27). Similarly, Germann et al., in 2021, performed CT-guided TFESI in 204 patients. They reported a significant pain reduction in 46.6% of patients (28). These results are in line with our study.

Lee et al., in 2019, evaluated fluoroscopically-guided ESI in 68 disc-herniated- chronic LBP patients. They observed significant one-year pain improvement measured by NRS and function enhancement (29). Likewise, Chang et al. in 2018 compared pre- and post-procedure NRS scores in chronic LBP patients undergoing fluoroscopically-guided TFESI. They documented a significant pain intensity improvement in the three-month post-procedural period (30). Our study as well demonstrated similar results.

Dietrich et al., in 2019, designed a prospective cohort study to compare fluoroscopically- and CT-guided TFESI in terms of radiation exposure and outcome. They assessed pain intensity reduction using the Patient Global Impression of Change (PGIC) scale in one-day, one-week, and one-month intervals and demonstrated no significant difference between fluoroscopy and CT scan guidance (31), which supports the results of our study, although they have not implemented well-established multifactorial questionnaires like ODI which we used. However, the main focus of the study revolved around comparing radiation exposure between the two groups. Besides similar treatment effectiveness, regarding safety, they concluded that patients under fluoroscopy guidance receive significantly lower radiation relative to CT scan, whereas physicians, in contrast, are exposed to significantly higher radiation in fluoroscopy compared to CT scan (31).

Limitations and Strengths

As an observational study with limited sample size, the study's results cannot be generalized to the general population. Moreover, the TFESI procedures were performed by at least two different physicians, which might be a source of variability and interoperator bias. However, as a strength point of the research, we did propensity score matching, adjusting for age, sex, and BMI, with a match tolerance of 0.1 caliper width (half the commonly-used caliper, i.e., 0.2) to ensure that matched groups were as closely matched as feasible. This is the first study to compare the two common methods of CT scan and fluoroscopy in minimally-invasive treatment for LBP patients, as the majority of previous studies did not compare the two methods and only mentioned one. Moreover, some studies compared less precise methods like ultrasonography. In contrast, no studies have compared these two methods using precise, reliable, and valid questionnaires.

Further studies, particularly RCTs, are required to ensure the results of this study.

Conclusion

This study demonstrated that in both treatment groups of fluoroscopically- and CT- guided TFESI for LBP, ODI and NRS scores significantly decreased three months after the procedure. Furthermore, there was no significant difference between the treatment groups either at baseline or the three-month follow-up in terms of ODI and NRS scores. Most importantly, the mean ODI and NRS changes between baseline and follow-up did not significantly differ between the two treatment groups. Overall, we provide evidence that fluoroscopically- and CT-guided TFESI both yield similar results in patients with LBP.

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We hereby thank all the participants of the study.

Authors contributions

AR (Ali Rafati): idea, editing, statistical analysis, final draft writing, final editing, and submission; HG: final draft writing and editing, supervision; BA: primary and final draft writing, editing, and correspondence; AR (Aryoobarzan Rahmatian) and SH: data gathering, data interpretation, and editing; All authors read and approved the final manuscript.

Ethical Consideration

The research ethics committee of AJA university of medical sciences approved the study (code IR.AJAUMS.REC.1400.293). Written informed consent was obtained from all the patients. In all stages of the research, we adhered to the statement of Helsinki (32). Patients' data were kept confidential.

Conflict of Interests

The authors declare that they have no competing interests.

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