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Comparison of pain score changes following CT- guided and fluoroscopy- guided epidural injection of methylprednisolone in patients with lumbar disc herniation

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ABSTRACT

Background: Imaging- guided ESI performed under the guide of fluoroscopy or CT- scan, is an effective non-surgical treatment for lumbar disk herniation. Theoretically, CT- scan is superior over fluoroscopy regarding its higher spatial resolution; however, it is not clear whether CT- guided ESIs yield better treatment outcomes. *Purpose:* We hypothesized that the choice of imaging guide impacts the treatment outcome after ESI. This study aimed to evaluate the influence of imaging guide on the treatment outcomes of ESI. *Materials and Methods*: This is a non-randomized interventional study involving 30 patients with clinical and MRI findings of lumbar disk herniation, half received CT- guided and the other half fluoroscopy-guided trans-foraminal epidural injections of methylprednisolone. Sampling method was convenient. Student t test and SPSS 10 statistical software were employed for statistical analysis. *Results:* The mean pain scores before and after ESI in CT- scan group were 7.06 ± 2.18 and 2.26 ± 1.79 compared to 7.06 ± 2.34 and 2.53 ± 2.03 in fluoroscopy group, respectively. The difference between mean pain scores in each group were statistically significant (P- value < 0.0001). The mean pain score differences between CT- scan group (4.80) and fluoroscopy group (4.53) were statistically non-significant (P- value = 0.643). *Conclusion*: Both CT- guided and fluoroscopy-guided ESIs significantly improved low back pain in patients with lumbar disk herniation; however, we observed no association between the treatment outcomes and the type of imaging modality at all evaluated time points of this study.

Keywords: Epidural steroid injection, Imaging- guided ESI, Lumbar disk herniation.

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1. INTRODUCTION

About 70% of people develop low back pain in their lifetime, so that back pain is now recognized as the most common and costly disease in middle age; 40% of low back pain is due to lumbar intervertebral disc herniation (van Tulder et al., 1995). Disc herniation is part of the degenerative process and is seen in all people over the age of 60 without exception (Sutton et al., 2003). Treatments are divided into surgical or non- surgical options (Johnson et al., 1999). Non-surgical methods include bed rest, oral or injectable administration of analgesics and steroids, and epidural steroid injections (Silbergleit et al., 2001). Epidural Steroid Injection (ESI) was first performed in the 1950s and gradually during the 1970s, it became a cornerstone in management of low Back Pain (LBP) mainly based on palpable landmarks for guiding the injection needle. Blind injection without the use of an imaging-guide carries a chance of needle misplacement of 25- 38% even in experienced hands (Palmer, 2016), and can lead to complications such as arachnoiditis and nerve root damage. In people with severe radicular pain who have not responded well to other non- surgical treatments or who have been banned from systemic corticosteroids due to an underlying disease (peptic ulcer, hypertension, diabetes mellitus) or drug interactions (especially digitalis) and, on the other hand, are not candidates for surgery, this type of treatment is an alternative and safe because localized injection of steroid in the area of pain prevents its systemic complications (Johnson et al., 1999; Silbergleit et al., 2001). Without the use of imaging-guide (including CT scan and fluoroscopy), there is a 30% chance that the needle will enter the intrathecal space incorrectly, which in addition to treatment ineffectiveness, can cause complications such as adhesive arachnoiditis and nerve root damage.

In terms of radiation dose in both Fluoroscopic and CT-guided steroid injections, a recent non-randomized observational study has revealed that the mean radiation dose in fluoroscopy group is higher for interventionalist and lower for the patients compared to the CTscan group (Dietrich et al., 2019). The risk of fluoroscopic injection complications using contrast media is 1% and mainly includes mild headache, nausea, transient dizziness and rarely, vasovagal or allergic shock. Various steroid drugs have been used by various researchers for periradicular and epidural injections, including dexamethasone, betamethasone, triamcinolone, and methylprednisolone (Silbergleit et al., 2001). There is no consensus among researches about the best steroid medication is used in ESIs as well as the number of injections; although a recent study (Tagowski et al., 2019) shows that particulate (triamcinolone) steroids are more efficient than non-particulate steroids (dexamethasone) for patients presented with higher numerical rating scales.

A recent study has showed similar efficacy in relieving pain and improving leg function after ESI of both methylprednisolone and dexamethasone (Kim & Brown, 2011). Some other studies (McCormick et al., 2015) reported statistically better results in terms of short-term pain relief for triamcinolone than betamethasone, while the injection safety of the former has recently been a matter of debate. Of all these drugs, methylprednisolone is widely used in musculoskeletal injections as an effective and long-lasting injectable medication. It is available in two types of methylprednisolone acetate under the brand name Depo-Medrol and methylprednisolone succinate under the brand name Solu-medrol in the Iranian pharmaceutical market. Methylprednisolone is a medium-acting glucocorticoid which is 5 times stronger than Hydrocortisone. The onset of its action is very slow, the peak effect is seven days and duration of action is 1-5 weeks. Its succinate type (Solu-medrol), unlike acetate, has good solubility.

Although various studies (van Tulder et al., 1995; Silbergleit et al., 2001) have presented CT scan superior to fluoroscopy due to more accurate representation of anatomy of the injection site, especially periradicular injection, all of these comparisons are based on studies which were completely different in terms of injection substance, injection volume, cause of low back pain and time of review of outcomes after injection. On the other hand, more accurate determination of the anatomy of the injection site means faster injection, the need for fewer sections, and thus reducing the dose received by the patient and staff. According to the above and availability of CT scans in most imaging centers, including Poursina, we decided to compare the outcomes of periradicular injection of methylprednisolone guided by CT scan and fluoroscopy in patients with lumbar disk hernia referring to this center.

2. MATERIALS AND METHODS

Procedure (with Statistical Analysis and Ethical Considerations)

The studied population included those patients with low back pain referred to the neurosurgery clinic of Poursina Hospital since July 2019 until January 2020, who underwent clinical examination and MRI and were diagnosed with radiculopathy due to lumbar disc herniation (Ethical Code: IR.GUMS.REC.1384.382). Age and gender do not limit the study. Patients should have no exclusion criteria and no symptoms of sensory or motor neurological impairment. Severity of pain is not a criterion; however, there are some factors (McCormick et al., 2014) that could impact the treatment outcome such as greater baseline pain, history of lack of worsening pain with walking and positive femoral stretch test. Thus, we decided to match the patients in both groups considering these factors as much as possible. Para-clinical diagnosis of disc herniation in all patients is based on MRI (table 1).

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The hypotheses examined in this study are:

H0: There is no difference in mean pain score changes after CT-guided and fluoroscopy- guided transforaminal injection of methylprednisolone.

H1: There is a difference in pain score changes after CT-guided and fluoroscopy- guided transforaminal injection of methylprednisolone.

Table 1 variables

Variable	Role	Scale	Practical Definition	Unit	State
pain score	dependent	ordinal	Determining the severity of radicular pain based on a score of zero to 10 of patients	individual	-
imaging guided type	independent	nominal	transforaminal injection can be guided by CT scan or fluoroscopy	individual	-

Exclusion Criteria

Presence of local infection at the injection site

Congenital anomaly at the injection site

Pregnancy

Bleeding disorders such as hemophilia or treatment with anticoagulants such aswarfarin

Previous lumbar disc surgery

A history of severe reaction to any previous injection that required hospitalization

After neurological examination, examining the injection site and taking a history to reject the above criteria, the obtained information is recorded and kept in the patient's file along with MRI. All patients are given the necessary information about benefits and possible side effects of this treatment. A written consent form is then provided to the patient to sign if agreed. Patients are reminded that they should provide the medicine, but they are not required to pay for the injections (neither CT scan nor fluoroscopy patients). Patients are also reassured that if they wish to leave the project at any stage, this will not affect their diagnosis and treatment. This project is a pre- and post-intervention project.

The number of patients is 30, which are divided into two groups. The two groups are matched in terms of weight and above-mentioned factors as much as possible. After the patient goes to the imaging center, a pre-injection pain score is firstly assigned to the patient, and to do this, patients are asked to rate their pain from zero (means no pain) to 10 (means the severest pain they have ever experienced). The accuracy of the scores again confirmed using clinical scale based on straight leg raising examination. Before the injection, blood pressure is monitored, the heart and lungs are auscultated, and the patient's file is re-checked. In the case of fluoroscopic guidance, the patient is placed on a fluoroscopy table in a prone position. The puncture site, which corresponds to the site of maximum pain and MRI findings, is marked with a radiopaque marker, and the c-arm is positioned. The skin at the injection site is then prepped with betadine. Local anesthetics are obtained by injecting 3 cc of 1% lidocaine subcutaneously. The position of the c-arm is oblique then posterior and lateral with a caudal angle of 30-45 degrees to determine the lower surface of the pedicle above the desired foramen (Figure1).

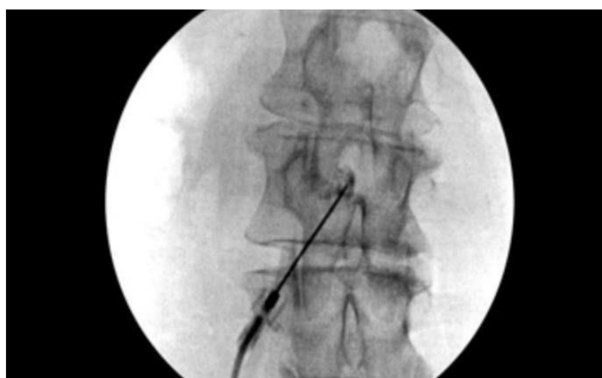

Figure 1 Fluoroscopy- guided injection

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Under continuous fluoroscopic control, a 22 G spinal needle is carefully inserted into the neuroforamina with a lateral or dorsal approach. Fluoroscopic control is intermittent and short (1- 2 seconds). After ensuring the correct position of the needle tip, the injection substance (40 mg methylprednisolone diluted with 5cc sterile water) is injected gradually into the foramen within 30 seconds. The injection substance is methylprednisolone under brand name power Solu-Medrol (Pharmacia & Upjohn N.V./S.A-puurs-Belgium). The medication is the same for all patients. In CT-guided injection, the patient is placed on a CT scan table in a prone position. The prep and anesthetics are similar to fluoroscopy. First, lateral topogram is taken from the patient, which is used to obtain 2mm thin sections from the desired segment. The most appropriate section is selected to display the neural foramen, based on which, with continuous CT-guidance, spinal needle 22 G is inserted into the neural foramen space. The dose and injection technique are the same as fluoroscopy (Figures 2 and 3).

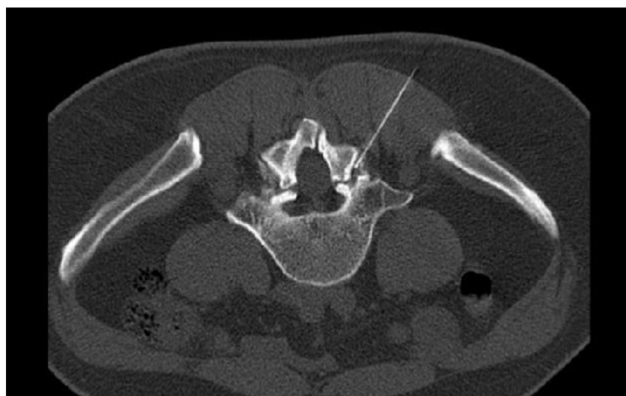

Figure 2 CT-guided injection

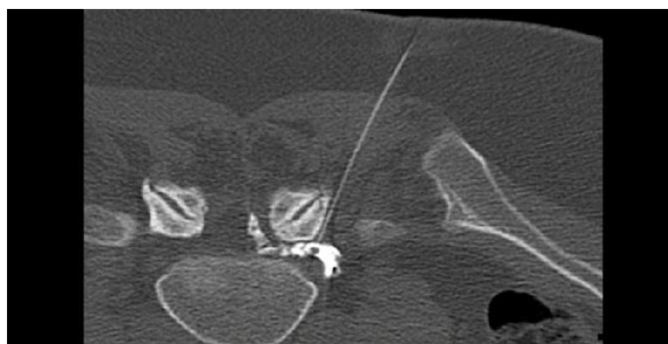

Figure 3 Transforaminal CT-guided injection

After completing the procedure, the patient is monitored for one hour in the recovery room for possible complications and then discharged by checking the vital signs. Patients are advised to return to this center a week later to estimate the pain score after the injection. Data collections backup, pain score tables before and after injection are adjusted separately in CT scan and fluoroscopy groups. The mean scores before and after injection in each group were compared separately by statistical analysis of paired T-test and the mean changes in pain scores of the two groups are compared by statistical analysis of student t-test with SPSS 10 statistical software.

Sampling and Sample Size

Sampling method is convenient (non-probability). The number of samples required for each group, considering $\mu 1 = 4.5$, $S1 =, 1.2$, $\mu 2 =, 2.8$, $S_2 = 1.4$ (Dietrich et al., 2019), is assigned 12 people for each group. Finally, considering disagreements or possible losses in similar studies, 15 people are included in each group.

$$n = \frac{(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 \times (s_1^2 + s_2^2)}{(\mu_1 - \mu_2)^2} = \frac{10 \times (1.44 + 1.96)}{(4.5 - 2.8)^2} = 11.76 \approx 12$$

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3. RESULTS

Patients presented with a mean pre injection pain score of 7.06± 2.18 and 7.06± 2.34 in CT –scan and fluoroscopy groups, respectively. Mean pain scores detected after a week of ESI appeared as 2.26±1.79 and 2.53± 2.03, respectively. The mean pre-post pain score changes after CT- scan ESI was measured as 4.80 compared to fluoroscopic ESI which deducted as 4.53. Table 2 presents distribution of numerical value of pain in patients before and after injection in two groups. After analyzing the data and using SPSS statistical software and paired t-test, it was found that there is a statistically significant difference (table 3) between mean scores of pain before and after injection in both CT scan and fluoroscopy groups (P <0.0001). After analyzing the data and using SPSS statistical software and paired t-test, it was found that there is no statistically significant difference (table 4, figure 4 & 5) between the two groups regarding mean before- after injection pain scores (P = 0.643).

Table 2 Distribution of numerical value of pain in patients before and after the injection in two groups

No.	group	before	after	difference
1	CT-Scan	5	1	4
2	CT-Scan	5	2	3
3	CT-Scan	6	1	5
4	CT-Scan	6	2	4
5	CT-Scan	7	2	5
6	CT-Scan	7	3	4
7	CT-Scan	8	4	4
8	CT-Scan	8	2	6
9	CT-Scan	3	0	3
10	CT-Scan	4	0	4
11	CT-Scan	9	1	8
12	CT-Scan	9	2	7
13	CT-Scan	9	4	5
14	CT-Scan	10	7	3
15	CT-Scan	10	3	7
16	Fluoroscopy	4	0	4
17	Fluoroscopy	3	0	3
18	Fluoroscopy	5	3	2
19	Fluoroscopy	6	2	5
20	Fluoroscopy	6	3	3
21	Fluoroscopy	7	2	5
22	Fluoroscopy	7	3	4
23	Fluoroscopy	8	0	6
24	Fluoroscopy	8	4	5
25	Fluoroscopy	9	8	7
26	Fluoroscopy	9	4	6
27	Fluoroscopy	4	0	4
28	Fluoroscopy	10	4	6
29	Fluoroscopy	10	8	2
30	Fluoroscopy	10	4	6

Table 3 Comparison of pain means in two groups before and after injection

group	before		after	
	mean	SD	mean	SD
CT-scan	7.06	2.18	2.26	1.79
Fluoroscopy	7.06	2.34	2.53	2.03

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Table 4 Comparison of mean pain score before and after injection in two groups

group	mean difference	standard deviation
CT-scan	4.80	1.56
Fluoroscopy	4.53	1.55
P=0.643		

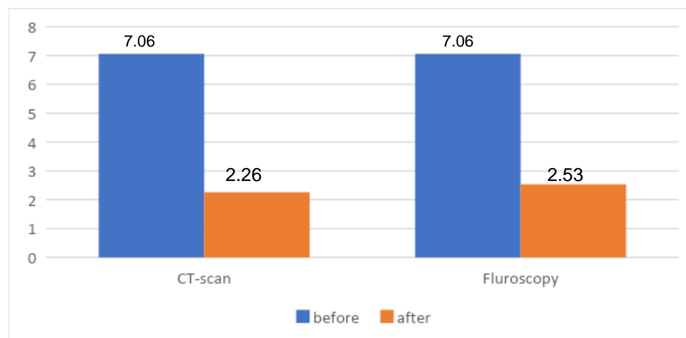

Figure 4 Comparison of mean pain scores before and after injections in each group

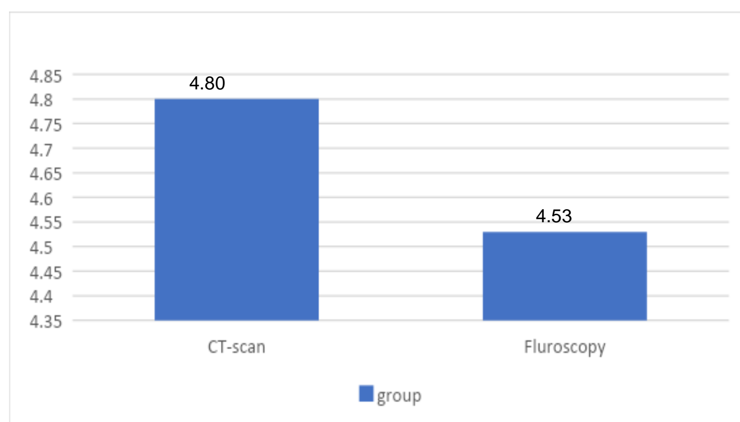

Figure 5 Comparison of mean pain score changes between the two groups

4. DISCUSSION

This study showed that imaging guided epidural injection of methylprednisolone significantly reduced pain intensity, both in the fluoroscopy and CT scan group, and this is something that previous studies have clearly addressed. It also challenges some recent studies' results that have shown similar pain relief and complication risk in both blind and image- guided injections (Yoon et al., 2019). This study also showed that although the mean reduction in pain score in the CT scan group is slightly higher than the fluoroscopy group, this difference is not statistically significant. That is, the type of imaging (CT scan or fluoroscopy) is not an effective factor in the outcome of epidural steroid injection. In other words, the criterion for selecting either of the two imaging modalitiesis its availability; however, CT scan has at least one advantage, and it is possible to use it in patients with a history of allergies to injections, without the need for a contrast agent. The second advantage is the possibility of preparing fine cross sections and even a reconstructed image of the desired location.

Another point to note is reduction in pain intensity in all patients, while in some older studies (Bowman et al., 1993) there have been cases of persistence or even an increase in pain score. It seems that the cause could be inaccurate diagnostic criteria used in older studies or not having access to MRI. As a result, patients with a wide range of low back pain causes problems such as canal stenosis or trauma are included in these studies that can justify different treatment responses (Green, 1975; Green et al., 1980). There are several methods for assessing and grading the severity of pain and how patients respond to treatment, including patient questionnaire, visual analog scale (including the famous Roland- Morris questionnaire) and clinical scale (based on Straight leg Raising). Obviously, the more of these methods are used in a study, the more accurate and better the evaluation of the patient's response to treatment and the ability to generalize the results. Of the previous studies, a few used all three of these grading types, and most of the studies usually used only one grading method.

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In our study, pain intensity assessment was based on questionnaires as well as clinical scales which are practical, simple and fast. Comparison of initial pain scores (pre injection) in previous studies and newer studies including our study also shows that the tendency of patients with severe LBP to try non-surgical methods such as epidural injections is gradually increasing; In fact, mean initial pain scores increased from 3.4 in Bowman et al., (1993) to 4.8-5.9 in recent ones and to 7.06 in our study, indicating that the threshold for surgery in cases of severe LBP is increasing. The rate of side effects in previous studies was about 1% and included mild pain in the injection site, mild headache and dizziness, nausea and vomiting as well as vasovagal shock. However, in our study, none of these side effects or other new adverse effects related to treatment was observed. Due to the relatively short follow-up period of patients (1 week), we did not miss any of our patients.

5. CONCLUSION

The data from this study clearly showed that both CT-guided and fluoroscopy- guided ESIs significantly improve symptoms in patients with lumbar disk herniation. More specifically, it revealed that despite the higher spatial resolution of CT- scan compared to fluoroscopy, CT- scan guided injections showed no significant superiority over fluoroscopy guided ones in terms of treatment outcomes one week after injections. As a result, this study will help interventional physicians to adapt between these two modalities based on their availability, radiation considerations and costs as well as the patients' preferences. The limitations of this project were firstly, a short follow up period and secondly, a relatively small sample size. We hope this study would encourage other researchers to conduct similar studies with larger sample sizes and longer observational periods (i.e. 2 weeks, 1month and 3 months). Moreover, we recommend comprehensive non- randomized studies be conducted focusing on comparison of CT-scan or fluoroscopy with non-ionizing radiation modalities such as ultrasound and MRI as the guiding modalities for ESI.

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This study has not received any external funding.

Conflict of Interest

The authors declare that there are no conflicts of interests.

Data and materials availability

All data associated with this study are presented in the paper.

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