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Research Article

Comparison of Ultrasound and fluoroscopy guidance in selective lumbar nerve root injection for treatment of radicular pain

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Abstract

Background: Ultrasound can provide imaging with good visualization of the nerve roots, which aids greatly in interventions such as selective nerve root injection (SNRI). **Objectives:** To evaluate the efficacy and safety of ultrasound in selective lumbar nerve root injection compared with fluoroscopy-guided injections for the treatment of lumbar radicular pain. **Methods:** 74 patients who received an SNRI for unilateral lumbar radicular pain were split into two equal group: The ultrasound group (US) or the fluoroscopy group (FL). A mixture of 5 ml of injectate consisting of 3 ml of 1% lidocaine and 2 ml (8 mg) of dexamethasone was used. The efficacy of ultrasound was detected by the assessment of the Visual Analogue Scale (VAS), the patient's Oswestry disability index (ODI), and analgesic needs. The time of procedure, complications, and the accuracy of the needle tip in the US group detected by fluoroscopy were recorded. The data was collected before the injection, one, two weeks, one, two, and three months after the injection. **Results:** VAS scores, ODI, and analgesic requirements were significantly lowered in both groups compared to baseline, and there was no significant difference between the two groups. The time procedure in the US group was lower in comparison to the FL group (P value <0.001), with no significant complication in both groups. Also, the accuracy of ultrasound-guided needle positioning was 91.9%.
Conclusions: The ultrasound-guided SNRI via fluoroscopic evaluation is as efficient and safe as a fluoroscopy-guided injection in treating lumbar radicular pain.

Keywords: Selective nerve root injection; ultrasound-guided; lumbar radicular pain.

Introduction

Chronic radicular and low back pain (LBP) is described as persistent pain for over three months; globally, about 11.9% of the population complains of LBP[(1)]. It leads to disability and deterioration of the patient's way of life as emotional stability, and productivity, also, pain can rising healthcare costs[(2, 3)]. Radicular pain usually develops from compression or inflammation of the nerve root, which creates neurological manifestations radiating down through the back to the dermatome supplied by this root[(4)].
Nerve root blocking intends to administer corticosteroids and local anesthetic therapy around the affected roots, and a selective nerve root injection (SNRI) is the term used to describe this method. Steroids relieve central sensitization by inhibiting ectopic discharge from unmyelinated C fibers. Also, they inhibit the production of inflammatory markers such as phospholipase A2 at the epidural space [(5, 6)], lowering the need for analgesics and postponing surgery [(7)].

The SNRI usually needs some tools to confirm the injection site and visualize the needle tip. Traditionally, computed tomography (CT) and fluoroscopy with dye were used to verify the insertion site [(8, 9)]. Nevertheless, the risks of

radiation exposure to patients and operating room staff are among its main drawbacks. Also, this technique needs a well-equipped theater with expensive equipment and will train personnel such as radiologists or technicians to operate this equipment at a high cost [10].

In recent years, ultrasound (US) has gained so many advantages such as, avoiding radiation exposure, reliable, effective, real-time injection guidance, and well-accepted by patients and doctors [11, 12]. Ultrasound was used several years ago for epidural injections, block of the median branch, and facet joint injections. They proved its accuracy and reliability [13,14]. However, there are still limited studies about its accuracy in pain management in patients who underwent spine injection therapy as SNRI, the time consumed for this injection, and its benefits as pain relief and disability [15]. These limited studies are mostly due to the shadow produced by the bony structures in the foraminal area, which prevented visualization of the accurate site of the needle tip at the targeted site. However, some studies have tried to illustrate periradicular injections due to the benefits of US-guided blocks [16-19]. In addition, technological advancements in ultrasound have led to improved visualization and image quality.

The main objective of our research is to evaluate the effectiveness of selective lumbar nerve root steroid injection guided by ultrasound by the assessment of the Visual Analogue Scale (VAS) and the patient's Oswestry Disability Index (ODI). Additionally, the safety of ultrasound by assessing the operative time with exposure to X-ray during procedure and detect the rate of complication by comparing it with fluoroscopy-guided injections to treat chronic lumbar radicular pain.

Methods

Study Design: The current study was a prospective, controlled, randomized study. The study carried out this trial with the assistance of the pain unit at Minia University Hospital between April 6, 2021, to May 16, 2022. The protocol of this study was approved by the Institutional Ethics Committee of Minia University Hospital, 18th, January 2021. **Approval IRB number: 10-2021** and registered in the ClinicalTrials.gov **ID: NCT05290779**. Each patient enrolled in the trial provided their written, informed consent.

Participant

Seventy-four participants of both sexes, 18-60 years old, visited our pain clinic with unilateral chronic lumbar radicular pain persisting longer than three months and failed to respond to medical treatment with VAS >4. A neurologist identified the patients as having single-level lumbar disc prolapse causing lumbar radicular pain through clinical presentation, examination, computed tomography (CT), or magnetic resonance imaging (MRI).

Exclusion criteria: the patients with uncontrolled diabetes, infection at the site of injection, spine fractures or deformity, peripheral neuropathy, motor or sphincteric disturbance, and previous lumbar operation with rods and screws. Also, the patients with bilateral radicular pain or who had an allergy to any substance that was injected.

Randomization

The patients were randomly assigned according to the computer-generated random numbers with closed-sealed envelopes into two parallel groups (37 patients in each group) according to sample size. Group S: Patients received lumber SNRI guided by ultrasound and accuracy of its site assessed by fluoroscopy and Group F: Patients received lumber SNRI guided by fluoroscopy.

Procedure Steps

All patients were admitted to an operating room to receive the injections. Intravenous access was inserted after local anesthetic skin infiltration, and standard monitoring of pulse oximetry, 5-lead electrocardiography, and noninvasive blood pressure was applied. Patients were positioned prone and elevated the abdomen with a pillow. Disinfected the back of the patient by Povidone-iodine and draped with sterile drapes, and the skin entry point was disinfected and anesthetized with 2ml of 1% lidocaine subcutaneously. All patients received injections from the same experienced pain specialist with more than ten years of experience in ultrasound and fluoroscopy techniques.

- **Ultrasound (US) guided technique:**

The ultrasound device used was (Sonosite, M-Turbo) with a curved array (MHz C60xi/5-2 MHZ Transducer). The ultrasound probe was covered with a sterile sheath and sterile gel. The specialist started to produce a posterior

paravertebral parasagittal longitudinal scan of the lumbar paravertebral region to localize the different spinal levels. The transducer was then moved up to the landmark structure as the sacrum to find the spinous process with its inter-spinous process line and then count the spinous processes from below upwards to reach the target level. Then, the probe was rotated 90 degrees clockwise in the transverse axial plane in a paramedian position so the structure as spinous process, lamina, facet joint, and the transverse process can be identified. The nerve root emerging can be detected below the transverse processes in the foramen between the vertebral body anteriorly and the facet joint posteriorly. The 22-gauge spinal needle was advanced with the in-plane technique under ultrasound scanning. Then, subsequent fluoroscopy was checked to confirm its position in AP and lateral view. If the needle tip was not in the right site, it was redirected and guided with fluoroscopy until it was in the correct site; once the needle was in place, the contrast was injected to show the nerve root. Then, the test for any unintendedly intravascular puncture by aspiration was done, and a mixture of 5 ml injectate consisting of 3ml of 1% lidocaine and 2ml (8 mg) dexamethasone (dexamethasone, Amriya Pharmaceutical Industries)

- **Fluoroscopy (FS) guided technique:**

In the FS group, Under the guidance of C-arm, the image intensifier is positioned around the patient in an anteroposterior view, which makes the X-ray project at an angle of about 45° to see the classic view called “Scotty dog”. Cephalo-caudal tilting of the C-arm until the front of the upper articular process of the same vertebra at the midpoint of the posterior edge of the upper endplate of the vertebra where the injected nerve root was located. The nerve root normally exists from the foramen a few millimeters below the Scottie dog's eye. A 22-gauge spinal needle was carefully inserted until the tip was positioned at the exiting root in the “Kambin triangle”. The needle position is confirmed in the lateral view, and then 0.5 to 1 ml of a radio-opaque dye (Omnipaque, GE healthcare) is injected; the dye will track the nerve root if the needle positioning is correct. Then a drug mixture was injected, as in the US group.

All patients of both groups are monitored for 6 hours and then discharged to be examined after one week.

Outcome Measures

The efficacy of injection on pain relief and clinical improvement was assessed by using the VAS (0, no pain to 10, worst pain) [(20)], the patients recorded the pain level by making a handwritten mark on a 10-cm straight line and Oswestry disability index (ODI) which is a ten-item questionnaire used to assess the quality of health status and each item have a point that describes the patient's problem was assessed and recorded. Each item is rated from 0 to 5 on a six-point scale. We collected the total points, which were divided by ‘50’ and multiplied by ‘100’ = percent disability which is called the ODI score [(21)]. The VAS and ODI are assessed before the procedure as a baseline, then at the end of the first and second weeks, and then at the end of the 1st, second, and third months. Analgesic daily dose requirement was recorded before the injection for each patient as the baseline. Then, the average dose during the past period is recorded during follow-up visits.

The usual analgesic drug daily dose before the injection for each patient was recorded as the baseline for this individual patient. Then during follow up visits the average dose during the past period is recorded and compared to the baseline as a percentage.

The operative time (in seconds) (the time from the point at which the patient's back was draped until the end of injection of medication) was recorded and compared between the two groups.

The accuracy of needle insertion in group US was confirmed using fluoroscopy with the injection of radio-opaque dye. If the pattern of the dye shows peri-neural, the injection of medication was done. The position was considered "optimal position", but if the needle position or the dye pattern were not in the right position, readjustment of needle position was corrected using ultrasound guidance and followed by confirmation using fluoroscopy and the dye again. The initial positioning of the needle was considered as "needing repositioning".

Complications such as vasovagal reaction, accidental intravascular injections, hematomas, dural punctures, nerve damage, or severe back pain during or after the injection were recorded.

Statistical Analysis

Sample Size Calculation before the study, the number of patients required in each group was determined after a power calculation according to data obtained from pilot study. In that study, the mean VAS at 3 months in group A was 3±0.95 and in group B was 2.4±0.85. A sample size of 37 patients in each group was determined to provide 80% power for Independent Samples T test at the level of 0.05 significance using G Power 3.1 9.2 software.

Data were checked, entered, and analyzed using IBM SPSS software, version 26 Chicago, IL, USA, for data processing. For categorical variables, we used frequencies and percentages. Chi-square test and Fisher's exact test were used to compare categorical variables. Results were presented as mean ± SD for normally distributed data and compared using a two-sample Student's t-test. The non-parametric data presented as median and IQR and Mann-Whitney U-tests were calculated to compare medians of two independent groups. The paired t-test was used for parametric data, and Wilcoxon signed-rank test was used for nonparametric data to perform pairwise comparisons. A P-value less than 0.05 was considered statistically significant.

Results

A total of 74 patients were qualified and evaluated; they were randomized and allocated into two equal groups, one of them receiving ultrasound-guided lumber SNRI (Group US, n=37) and the other group receiving fluoroscopy-guided lumber SNRI (group FL, n=37). The study flowchart is presented in (Figure 1).

The two groups were comparable in age, sex, height, weight, and body mass index (BMI). The target roots involved in the injection showed no statistical difference between the two groups (Table 1).

The VAS scores and the ODI scores of the two groups showed a significant reduction compared to the baseline value *(P values <0.05)*, which indicated a significant clinical improvement in pain control and improving disability in patients of the two groups after the injection without a significant difference between the two groups *(P values >0.05)* (Figures 2, 3).

The analgesic requirement showing that the need for analgesics was reduced in both groups after the injection. But group to group comparison shows no significant difference in the analgesic requirement as shown in (Table 2)

The operative time in the ultrasound group showed a significant reduction compared to the fluoroscopy group *(P value < 0.001)*, as shown in (Table 3).

The accuracy of needle position in the ultrasound group was accurate in 34 out of 37 patients, which was 91.9% of all the patients in this group, as shown in (Figure 4).

We did not encounter complications in the form of vasovagal reaction, accidental intravascular injections, hematomas, dural punctures, or nerve damage during our study, except for one patient in the ultrasound group who had severe pain at the start of the injection, but the needle was withdrawn a few millimeters then the injection was done without pain and this patient showed no further complication after the injection and during follow-up period. So, there was no significant difference between the two groups regarding complications.

Table 1: Patient characteristics

Variables		US N=37	FL N=37	P value
Age[C] **(**years)		43.7±8.8	46.9±8.7	*0.119*
Sex [F]. No (%)	*Male* *Female*	20(54.1%) 17(45.9%)	17(45.9%) 20(54.1%)	*0.485*
Height[C] **(**cm)		168±6.9	169.3±7.1	*0.428*
Weight [C] (Kg)		69.7±9.1	70.8±10.1	*0.621*
BMI [C] (Kg/m^2)		24.7±2.5	24.7±2.8	*0.993*
Target root[F] No (%)	*L2* *L3* *L4* *L5* *S1*	2(5.4%) 4(10.8%) 11(29.7%) 15(40.5%) 5(13.5%)	1(2.7%) 4(10.8%) 13(35.1%) 15(40.5%) 4(10.8%)	*0.975*

Values are presented as Mean ± SD or number (%). Data were analyzed using Independent Samples T-test[C] *and chi square test and Fisher's Exact T*est[F]. *Significant Level at P value < 0.05. US = ultrasound group -FL= fluoroscopy group

Table 2: Analgesic requirement between the two groups

average daily analgesic dose compared to baseline	US N=37	FL N=37	P value
At 1 week	50(0-100)[#]	50(25-75)[#]	*0.156*
At 2 weeks	50(0-75)[#]	50(0-75)[#]	*0.322*
At 1 month	33(0-66)[#]	25(0-75)[#]	*0.065*
At 2 months	25(0-75)[#]	25(0-50)[#]	*0.733*
At 3m months	25(0-66)[#]	25(0-50)[#]	*0.728*

*Values are presented as median and interquartile range (IQR). *: Significant Level between the two groups at P value < 0.05 by Mann Whitney test, #: Significant Level at P value < 0.05 (Within each group vs baseline by Wilcoxon Signed Rank test. US = ultrasound group -FL= fluoroscopy group.*

Table 3: Operative time between the two groups

Variable	US N=37	FL N=37	P value
Operative time (in seconds) *Mean ± SD* [C]. *Median (Range)*	414.8± 49.1 409 (346-536)	552.2±44.5 565 (450-642)	<0.001*

*Values are presented as Mean ± SD and median and interquartile range. *Significant Level at P value < 0.05. by Independent Samples T-test*[C]. *US = ultrasound group -FL= fluoroscopy group*

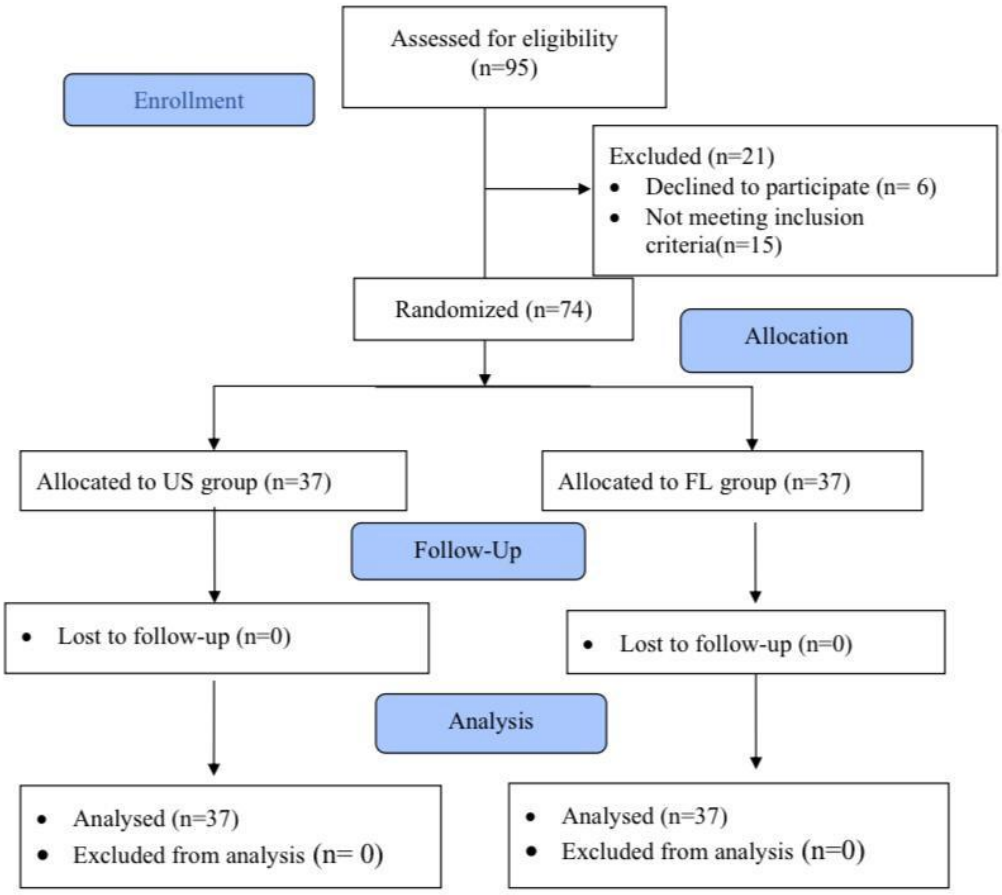

Figure 1: Flowchart for patient requirement

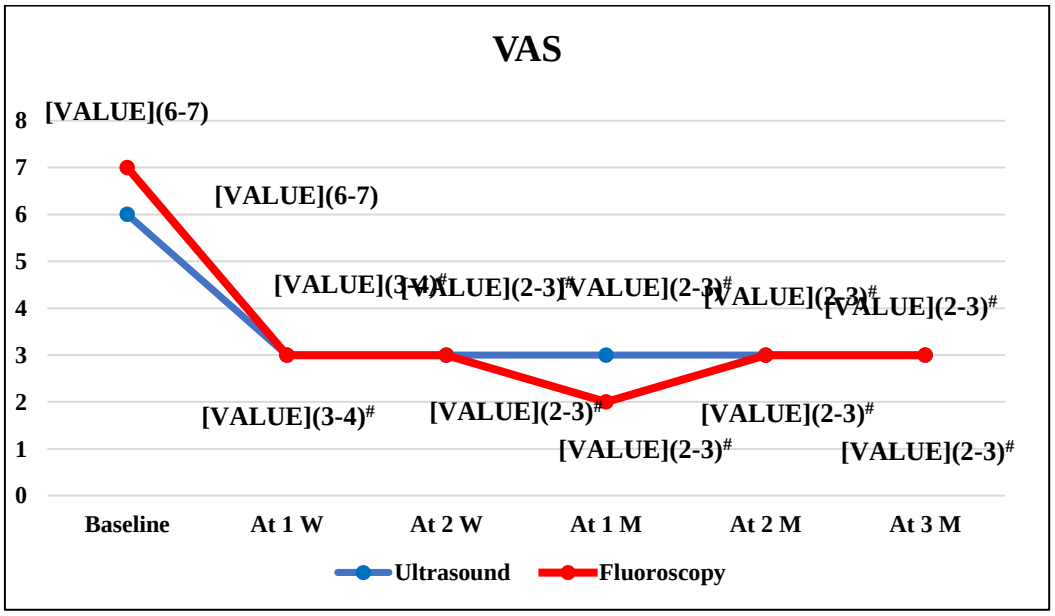

Figure (2): Comparison of VAS between the two groups. *Values are presented as median and interquartile range (IQR). *: Significant Level between the two groups at P value < 0.05 by Mann Whitney test, #: Significant Level at P value < 0.05 (Within each group vs baseline by Wilcoxon Signed Rank test. US = ultrasound group -FL= fluoroscopy group.*

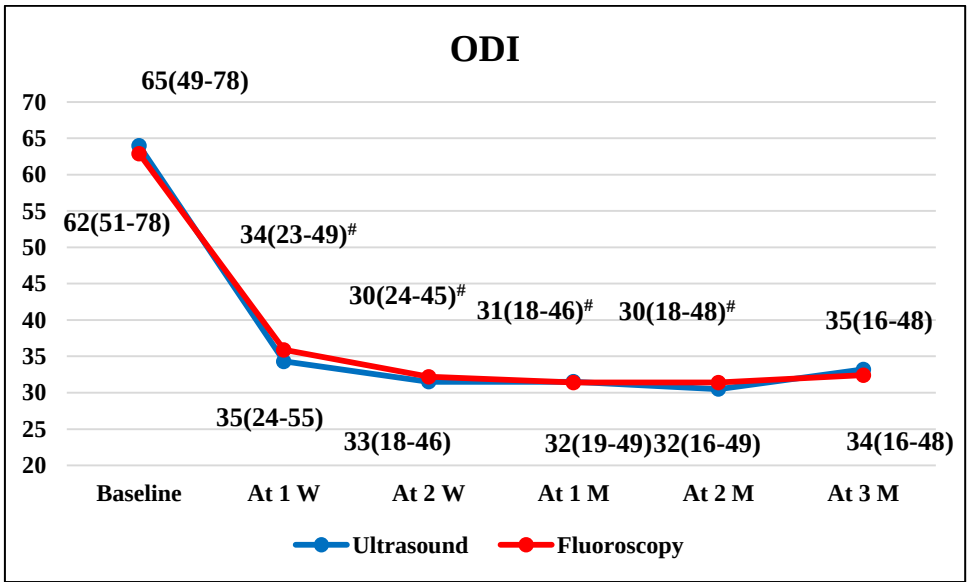

Figure (3): Comparison of ODI score between the two groups. *Values are presented as median and interquartile range (IQR). *: Significant Level between the two groups at P value < 0.05 by Mann Whitney test, #: Significant Level at P value < 0.05 (Within each group vs baseline by Wilcoxon Signed Rank test. US = ultrasound group -FL= fluoroscopy group.*

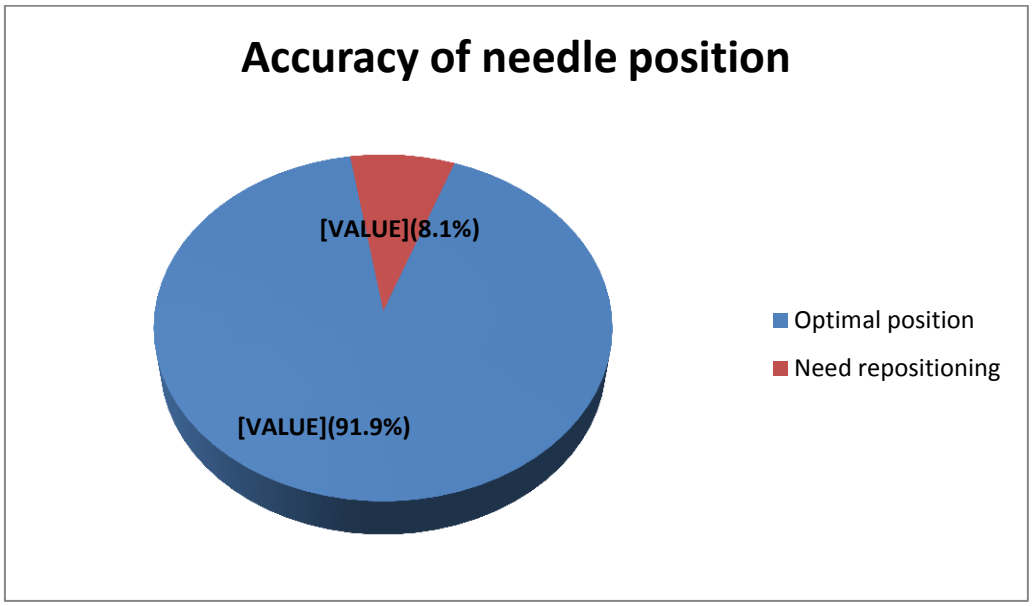

Figure (4): Accuracy of needle position in ultrasound group using fluoroscopy confirmation. *Values are presented as number (%).*

Discussion

The use of fluoroscopy to perform SNRI as a method of guidance has some disadvantages, including the dangers of radiation exposure to the patients and the personnel in the operating room, the high cost of fluoroscopy equipment that are only available in specific operating rooms, and the need for a radiologist or a technician that can operate these equipment [(22)]. So, with the growing interest in ultrasound-

guided nerve blocks and injections, especially in the lumbar spine region, which has shown great reliability and accuracy in reducing greatly the hazards of radiation, it has been suggested that ultrasound can be an effective tool for guidance in this type of injection [23].

In our study, regarding the efficacy of pain relief and analgesic requirement, both groups showed significant VAS and ODI scores decline and a decrease in analgesic requirement compared to baseline, which shows that both techniques were effective in pain management, implying that the US group is comparable to FL group in pain control. Regarding to the operative time in the US group was significantly shorter than that of the FL group, and the accuracy of needle position in the ultrasound group was accurate in 91.9% of all the patients with no significant difference as regards complications between the two groups.
A case reported by Ahn et al., [24] of a female patient pregnant for 18 weeks who complained of low back pain radiating to the right leg with a pain scale (NRS) was 5–6 out of 10. After diagnosis with MRI, it showed a diffuse bulging disc at L4–5 with an annular tear. Pararadicular blocking was guided with ultrasound, and 5 ml of 0.2% lidocaine injection using a paramedian sagittal oblique approach was performed. After the block, the pain score became 0/10. Follow-up was done at two months, and her NRS was still at 0/10. Her pregnancy and childbirth had no complications. This case report signifies the importance of this technique when we must avoid radiation at all in pregnant women.

Our results is in agree with Sato et al., [25] who used ultrasound with nerve stimulation to do a nerve root block of lumber five on seventy-eight patients with radicular pain. They also confirmed with an X-rays and contrast agents to evaluate its distribution. The pain was resolved after the injection in all patients except for only three. Shows that ultrasound-guided nerve root block is an effective method with comparable safety, as no major complications were observed during the interventions.

In accordance with our study, the Cui et al., [17] trial involved 156 patients diagnosed with cervical spine radiculopathy (CSR) who were randomized to receive either FL-guided TFESI or US-guided SNRB, which was confirmed by FL. Before therapy, at 1, 3, and 6 months following the intervention, the neck disability index (NDI) was used to quantify functional disability and the Numeric Rating Scales (NRS) were used to assess pain intensity. Furthermore, provided were the puncture time and frequency of complications. They found that the US method required less time and no radiation exposure, offered comparable pain relief, and improved function while making it easier to identify important vessels next to the foramen. As such, it was a compelling substitute for the traditional FL technique.

Additionally, according to the Jang et al., [26] study, there is a lower risk of major problems with US-guided SNRB injection compared to FL-guided interlaminar and transforaminal cervical epidural steroid injection because of its low intravascular injection rate. furthermore, US-guided SNRB offers comparable pain reduction and functional gains in a shorter amount of time after injection.

The operation time in the US group in Yang et al.,[27] and Zhang et al.,[28] studies were significantly shorter than the FL group ($P<0.05$), which was near to our results as the operation time in the US group in our results was significantly shorter than the FL group ($P<0.001$). Also, there was no difference between the two groups in pain alleviation, and no complications were noticed in either of the studies.

The accuracy of needle insertion in lumbar peri-radicular injections using ultrasound was the aim of a study done by Galiano et al.,[29] performed 50 ultrasound-guided needle insertions at various levels between L1 and S1 vertebrae in human cadavers and compared the needle positioning with CT guided needle insertions. Their results were near to ours as they showed that the ultrasound-guided technique is feasible and accurate compared to the CT-guided technique, as they both had the same mean measurements.

Another study by Gofeld and his colleagues [23] that supports our study was conducted to assess the accuracy and viability of using ultrasound guidance in lumbar transforaminal epidural injections, which was confirmed using fluoroscopy. Out of 50 planned injections, they

successfully inserted the needle in a correct foraminal position after 46 attempts. Their study emphasized how ultrasound can be useful for replacing fluoroscopy in outpatient and bedside settings with no radiation exposure.
In line with our findings, Loizides et al., [16], as they did peri-radicular injections in the lumbar spine, confirmed the needle tip position by CT and compared it with another group that used CT-guided injections. The ultrasound accuracy was 90%, and the mean time to final needle placement was significantly shorter than the CT group, which had a significantly higher radiation exposure dose.

In contrast, Chumnanvej et al., [30], in research they performed 78 SNRI under ultrasound guidance to assess the accuracy of needle placement. The accuracy of needle position was checked using fluoroscopy and contrast material injection. Ultrasound guidance gave good results, with 62.82% of attempts on optimal position. This difference from our study, where the accuracy was (91.9%); in their study, there were (7.5%) with scoliotic lumbar spine and (12.5%) with previous lumbar operation with rods and screws, which were excluded from our study. Also, our study was done with the same experienced pain specialist who had an experience of more than ten years of ultrasound nerve block maneuvering with a more advanced device.

Additionally, Hashemi et al., [11] evaluated the accuracy of needle placement during lumbar transforaminal epidural steroid injection using the ultrasound by a confirmation image using fluoroscopy. Their results revealed that ultrasound is a viable option with a 100% and 80% success rate at levels L3-4 and L4-5, respectively. Considering that selective nerve root injection and transforaminal epidural injection are comparable, this study can also support the feasibility of ultrasound in the latter approach.

Limitations of the study:
However, our study has numerous limitations, including a small sample size, necessitating additional research with a bigger sample size may be needed to confirm our results. Our patients had relatively low body mass index, without any previous spine operation, as such patients may be a challenge to the ultrasound guidance.

Conclusion
We conclude that the ultrasound-guided SNRI can be a viable alternative to FL-guided SNRI in terms of precisely targeting the affected region to achieve similar levels of pain relief and functional advantages. In addition, it reduces the operative time, which can be more comfortable for patients and help speed up the turnover of patients while being safe for patients, less exposure to X-rays, and not increasing the very low rate of complications of this procedure.

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