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Fluoroscopic C-Arm Guided versus Ultrasound Guided Therapeutic Injection of Lower Cervical Radiculopathies

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Abstract

Background

Chronic pain imposes significant impact on individuals and the health system as it is often accompanied by significant physical, emotional and social burden. It is frequently associated with anxiety disorders, depression, substance abuse disorders and post-traumatic stress disorder. Severe chronic pain is also associated with increased risk of morbidity and mortality.

Objective

To compare the therapeutic efficacy and safety of ultrasound-guided selective cervical intra-tubercular nerve root block versus fluoroscopic guided cervical interlaminar epidural block on cervical nerve roots in lower cervical radiculopathies through assessment of pain relief and functional improvement.

Patients and Methods:

This study was conducted on 60 patients with lower cervical radiculopathies confirmed by cervical MRI, not responding to conventional medical treatment. These patients were randomly allocated to receive cervical injection guided by either ultrasonography or C-arm Fluoroscopy. Patients were initially assessed and followed up at 1 week, 2 weeks, 3 months, 6 months, and 12 months by Visual Analog Scale, Mankoski Pain Scale and Brief Pain Inventory Scale.

Results

In the present study both groups showed significant improvement from baseline till 3 months post injection regarding pain and functional scales. However, in fluoroscopic group the improvement continued till 6 months and 12 months versus patients in ultrasound group.

Conclusion

Ultrasound-guided selective cervical intra-tubercular nerve root block and fluoroscopic-guided cervical intra-laminal epidural injection showed the same response in lower cervical radicular pain at 3 months with better outcome in fluoroscopic group at 6 months and 12 months.

INTRODUCTION

Cervical radicular pain is an impediment that interferes with the patient's daily activities. The process of cervical radiculopathy is mostly associated with a compressed and inflamed cervical nerve root which

usually leads to neck pain and radicular pain in the upper limbs [1, 2]. Cervical spondylosis and cervical disc herniation are the most leading causes of cervical radicular pain [1]. Cervical radiculopathy is an important medical aspect that needs more scientific and medical research to improve the patient's quality of life. Few previous studies disscused cervical radiculopathy and tried to find other interventional medical solutions instead of conservative and surgical treatment to decrease patient's pain leading to an unclear rate of incidence and prevalance with a limitation of epidemiological data. The rate of 83.2 per 100,000 people was the incidence rate of cervical radiculopathy in a previous large retrospective study [3]. So, the aim of the current study is to compare the therapeutic efficacy and safety of Ultrasound-guided selective cervical intra-tubercular nerve root block versus Fluoroscopic guided cervical interlaminar epidural block on cervical nerve roots in lower cervical radiculopathies through assessment of pain relief and functional improvement.

METHODS

This is a randomized controlled study that was conducted on 60 patients with lower cervical radiculopathies confirmed by cervical MRI, not responding to conventional medical treatment, patients were recruited from Ain Shams University hospital from August 2020 to August 2022. A written informed consent was obtained from all participants and the study was approved by local research ethics committee of the Faculty of Medicine, Ain Shams University (FMASU MD 172/2020) and registeried by Pan African Clinical Trial Registry (PACTR) and study's unique identification number for the registry is PACTR202205801336085. Patients were randomly allocated to receive cervical injection guided by either ultrasonography (Group A included 30 patients) or C-arm Fluoroscopy (Group B included 30 patients) by simple randomization. Patients were included if they were above 18 years old, suffered from lower cervical radiculopathy (sensory and/or motor symptoms of C5,6,7 nerve roots distribution) confirmed by clinical assessment and cervical MRI, showed no response to conventional medical treatment and refused surgical treatment. Patients were excluded if they were pregnant, suffered from tumor or metastasis in the involved area of the spine, had active coagulopathy, severe systemic, or metabolic conditions, known allergies to contrast, dye or local anesthetics. All patients were subjected to complete history taking including personal data, past history, risk factors, detailed history of current illness, and drug history. The nature of cervical radicular pain was confirmed by general and neurological examination. Cervical MRI to confirm cervical radiculopaty due to cervical disk protrusion or cervical canal stenosis was done for all patients. Laboratory investigations as Prothrombin Time and International Normalized Ratio were checked for all patients. Patients with cervical radiculopathy were initially assessed and followed up at 1 week, 2 weeks, 3 months, 6 months, and 12 months by clinical evaluation of symptoms. Signs, degree of improvement and complications were investigated to compare safety of each technique by the following scales **(Visual Analog Scale** (VAS)[4], **Mankoski Pain Scale** (MPS)[5], and **Brief Pain Inventory Scale**[6]). During injection session in both groups, strict sterile percautions were done with good skin sterilization by Povidone-iodine. Patients in group **A**, lay on the lateral decubitus position, a standard device (Esaote, mylife lab5) with a high-frequency linear array transducer (LA523,12MHz) was used to perform ultrasound examination. Initially, in a transverse

position, the transducer was put in the lateral aspect of the neck to show a transverse axial view for determination of the cervical level, the transverse process of seventh cervical vertebra has a rudimentary anterior tubercle and a prominent posterior tubercle that distinguish it from the above vertebral levels. by moving the transducer upward, the sixth cervical transverse process could be identified by its characteristic sharp anterior tubercle, by this technique, the above cervical transverse processes levels could be visualized. Once the the transverse processes of C5, and C6 were visualized, a 22-gauge, blunt-tip spinal needle was used in plane view with the ultrasound transducer's beam. During real time ultrasound guidance, the needle was pushed posteriorly to reach the target cervical nerve root (C5 and C6) inbetween the posterior and anterior tubercles of the transverse process. Finally, a 2ml mixture of betamethasone with bupivacaine for the therapeutic block was injected[(7)]. Procedure, in group **B**, was done with patients in a prone position with flexed neck on a pillow for ideal visualization of interlaminar space and monitoring of patient's vital data during the whole procedure. Initially, the target vertebral levels were identified by fluoroscopic C-arm (SIEMENS, Model No: 10893686), directed in anterior-posterior view. Tilting of C-arm tube in cephalic or caudal directions was done for increasing the interlaminar space. Under guidance of fluoroscopic image and after injection of local anathesia in surrounding skin, a needle (18 gauge Touhy epidural needle) was inserted in the same direction of the C-arm tube and pushed deeply with an intermittant imaging from skin to deep structure (subcutanous and paraspinal muscles). At ligamentium flavium, the examiner felt a resistance to confirm the depth and the site of needle, the lateral view of C-arm was obtained. The needle's stylet was replaced by a plastic loss of resistance syringe filled with normal saline (2ml) and advanced slowly with a continuous gentle pressure on the LOR syringe's plunger. Once felt a loss of resistance by penetration of ligamentium flavium into epidural space. At this level, the LOR syringe was exchanged by a needle containing non-iodinated contrast, carefully to avoid furthuer pushing of the needle. Next, the examiner injected a small amount of contrast to confirm the site of needle in the epidural space and avoid arterial injection by observing the view of asymmetrical vacuolated contrast in the epidural space. Once the ideal spread of contrast in epidural space was seen, finally, the therapeutic block was done by injection of a 2ml mixture of betamethasone with bupivacaine[(8)]in the epidural space. Neurological examination was performed 30 minutes after the injection approach in both groups.

Statistical Method

The data was analyzed by SPSS (statistical package for social science) version 26.0 on IBM compatible computer (SPSS Inc., Chicago, IL, USA). The qualitative data was described as number and percentage “n (%) ” and analyzed using Chi square test and Fisher’s exact test. Quantitative data were tested for normality using Shapiro-Wilks test, assuming normality at $P > 0.05$. Quantitative data was described as mean, standard deviation and range, using Student's "t" test, if normally distributed, and Kruskal-Wallis test, if not normally distributed. The accepted level of significance in this work was started at 0.05 ($P < 0.05$ was considered significant).

RESULTS

There was no significant statistical difference between both groups regarding socio-demographic data, our findings showed that, in group A and B, the mean age was 44.33 ± 12.13 and 44.87 ± 11.59 respectively (P = 0.862), as regard to gender, our study revealed that the percentage of male and female was 36.7% (11), and 63.3% (19) in group A and 43.3% (13), and 56.7% (17) in group B respectively with female predominance (60%)(P = 0.598), and the main risk factors among participants were diabetes mellitus, hypertension and ischemic heart disease in group A (8 (26.7%), 9 (30%), and 3 (10%) respectively) and in group B (6 (20%),7 (23.3%), and 2 (6.7%) respectively) (P = 0.990).In the present study, both groups showed significant improvement from baseline till 3 months post injection regarding pain and functional scales [by VAS, and MPS with P < 0.0001]. It is worth mentioning the main items of Brief Pain Inventory scale in details as the following:- 1- Pain interference with general activity score was 7.23 ± 0.85 at baseline to 1.77 ± 1.04 at 3 months in US group and 7.77 ± 0.77 at baseline to 1.67 ± 0.76 at 3 months in FL group (P < 0.0001) -2- Pain interference with mood scale was 6.97 ± 1.03 at baseline to 1.87 ± 0.82 at 3 months in US group and 7.87 ± 0.73 at baseline to 1.77 ± 0.82 at 3 months in FL group (P < 0.0001) -3- Pain interference with sleep score was 7.3 ± 1.06 at baseline to 1.83 ± 1.05 at 3 months in US group and 7.8 ± 0.61 at baseline to 1.67 ± 0.71 at 3 months in FL group (P < 0.0001). However, in FL group the improvement continued till 6 months and after that they show slight decline in response till 12 months which was higher in US group (7.3 ± 1.24) in compare to FL (2.97 ± 1.27) with P < 0.0001 in VAS, and MPS. In the Brief Pain Inventory scale – 1-Pain interference with general activity score was 3.5 ± 1.22 at 6 months to 6.4 ± 1.22 at 12 months in US group and 1.73 ± 0.83 at 6 months to 2.3 ± 1.12 at 12 months in FL group (P < 0.0001) -2-Pain interference with mood scale was 3.53 ± 1.36 at 6 months to 6.47 ± 1.14 at 12 months in US group and 1.77 ± 0.77 at 6 months to 2.27 ± 1.05 at 12 months in FL group (P < 0.0001, and P < 0.009 respectively) -3-Pain interference with sleep score was 3.27 ± 1.33 at 6 months to 6.53 ± 1.36 at 12 months in US group and 1.7 ± 0.88 at 6 months to 2.3 ± 1.15 at 12 months in FL group (P < 0.0001) .In addition by comparing both groups, we found statistically significant improvement regarding pain and functional assessment in US group in first week mainly and no significant statistical differance inbetween groups at 2 weeks with P < 0.0001 and = 0.002 respectively in VAS and P < 0.0001 and = 0.003 respectively in MPS. Brief Pain Inventory scale revealed that pain interference with general activity score was 3.3 ± 2.07 at 1 week to 2 ± 1.1 at 2 weeks in US group and 6.9 ± 0.87 at 1 week to 2.27 ± 1.05 at 2 weeks in FL group (P < 0.0001 and = 0.221 respectively), Pain interference with mood scale was 3.17 ± 1.82 at 1 week to 1.87 ± 1.07 at 2 weeks in US group and 7.13 ± 0.78 at 1 week to 2.27 ± 1.11 at 2 weeks in FL group (P < 0.0001 and = 0.125 respectively), and Pain interference with sleep score was 3.2 ± 1.83 at 1 week to 1.83 ± 1.05 at 2 weeks in US group and 3.2 ± 1.83 at 1 week to 2.3 ± 1.12 at 2 weeks in FL group (P < 0.0001 and = 0.081 respectively) with taking into our consideration that the other items of Brief Pain Inventory scale obtained similar results to a large extent to the main scale's items that explained before. Moreover, no statistical difference inbetween groups was reported at 3 months by functional scales (VAS, MPS, and Brief Pain Inventory scale)(P = 0.382, 0.382, and > 0.05 respectively), but after that the US group show significant decline in response than FL group from 6 months to 12 months follow up according to functional scales (P < 0.0001 at 6 months and 12 months in all scales) as seen in Table 1, and 2. In view of the above, our study was revealed early onset of action in US group and long acting time in FL group (P < 0.0001).

As regard to complications in our study, we did not find significant difference between US and FL group (P > 0.05), except for mild inflammation at site of injection more in FL group (6 (20%)) than in group A (2 (6.7%)).

DISCUSSION

In the present randomized controlled study we aimed to compare the therapeutic efficacy and safety of ultrasound-guided SNRB versus fluoroscopy-guided CIEI with radiofrequency in lower cervical radiculopathies through assessment of pain relief and functional improvement. To our knowledge, this was the first study that compares the effect of FL guided injection versus US guided injection with early follow up at 1 week then continuous follow up at 2 weeks, 3 months, and 6 months with late follow up at 12 months.

Recently, different studies have shown the reliability of US guided cervical SNRB[9]. The primary benefit of US is direct real-time visualization of soft tissue structures, bony surfaces, and needle manipulation, it is especially useful for cervical spine injections, where a lot of vital soft tissue structures and vessels are condensed in a small area and frequently in the path of the projected needle trajectory. This means that US can identify vulnerable vessels before its puncture while fluroscopy can only detect vulnerable vessels after injection inside a punctured vessel[10]. Moreover, intravascular injection can be avoided in US guided procedures with shorter time of the procedure in comparison to FL-guided procedure[11]. US guidance also avoid exposure of both patient and doctor to ionizing radiation. The use US-Guided selective cervical root injection was first reported by Galiano et al. in 2005. This was followed by several studies that reported the effectiveness and safety of this procedure[9, 12, 13]. However, few studies compared the US-guided technique to other standard methods such as fluoroscopy-guided TFESI or IL-ESI.

Our study showed significant improvement in both groups from baseline till 3 months post injection regarding pain and functional scales (VAS, MPS and Brief Pain Inventory). These findings are in agree with a recent retrospective study[11]that found significant improvement at 1, 3, and 6 months after the last injection in both groups, with no significant differences by comparing both groups at baseline and at 1, 3, and 6 months after the last injection. In other retrospective study that compared US-guided SNRB, FL-guided IL-CESI, and TF-CESI; They found improvement at 1, 3, and 6 months after the last injection in all groups, with no significant differences between groups by using neck disability index and verbal numeric scale scores[14]. On another study, there was improvement in US-guided SNRB and FL-guided TFCESI groups through 12 weeks regarding NDI improvement at 12 weeks and VNS improvement at 12 weeks, however, no significant difference was reported between both groups[15]. Regardless differences in the injection target and the spread pattern of the injectants, studies comparing the treatment efficacy between FL-guided and US-guided injections found no significant differences[11, 15, 16]. One of the hypotheses tried to explain these results by the effect of hydrostatic pressure and osmotic effects, which lead to further absorption of the treatment solution into the nerve fibers[9]. Regarding drug delivery, some

studies reported that only approximately 30% of injections resulted in the typical epidural spread that can be achieved under FL guidance[15]. In another study[16], 1 ml of contrast agent was observed in the proximal spinal canal and the intraspinal epidural space in 29.7% patients who received US-guided SNRB. Although Both techniques are effective in treatment of resistant cervical radiculopathies yet they are highly dependent on the operator, and to obtain a good image and safely direct the needle to the target structure, the practitioner must have prior experience[17].

Our results show early improvement of symptoms in US group in comparison to fluoroscopy group starting the first week. This finding may be contributed to the direct selective injection of C 5 and C 6 roots done in the UL versus FL group that depend mainly on diffusion of injection that takes longer time for the medication to affect the roots. We also found longer duration of response in FL group till 6 months and 12 months which may be due to direct injection of steroids in epidural space which insures a better spread of injectables in epidural space and a large volume and distrubation of the injectable materials could help in a hydroneuroplasty around cervical roots.

In our study, we did not find significant difference regarding complications between US and FL group, except for mild inflammation at site of injection more in FL group. These results are different from previous reports that show a variety of complications of FL-guided CIESI; These include inadvertent dural puncture, subdural or epidural hematoma, epidural abscess, paralysis, permanent spinal cord injury and death[18]. Other previous studies using US-guided SNRB reported only temporary minor complications with absence of major complications as spinal cord or brain infarction, paralysis, infection, and death with absence of any intravascular injections[15, 16]. In another previous study, symptoms of intravascular injection were not identified during US-guided SNRB in any case, whereas five and six patients in the FL-guided groups exhibited such symptoms[14].

This study had some limitations, that we could not entirely prevent the use of other treatments such as medications and physical therapy during the follow-up period, also we did not use FL to confirm appropriate injection of the drug into the targeted area during US-guided SNRB. So we recommend having further randomized control trails to study the effect of combining both techniques to gain the advantage of the rapid improvement of US-guided SNRB and longer duration of FL-ILESI.

CONCLUSION

US-guided SNRB has more rapid onset of action with significant improvement in lower cervical radicular pain in first 3 months than FL-ILESI and significant improvement in functional parameters during the first week. However, FL-ILESI had long duration of action as it had sustained effect at 6 months and 12 months than reported by US-guided SNRB.

Clinical Trials

This study was registeried by Pan African Clinical Trial Registry **(PACTR)** and study's unique identification number for the registry is **PACTR202205801336085**.

Abbreviations

SNRB
selective cervical intra-tubercular nerve root block
CIEI
cervical interlaminar epidural block
C
Cervical
VAS Scale
Visual Analog Scale
BP
Back pain
MPS
Mankoski Pain Scale
DALY
Disability Adjusted Life Years
US
Ultrasound
FL
Flurosocpy
LOR
loss of resistance
SPSS
statistical package for social science
SD
Standard deviation
CESI
Cervical Epidural Steroids Injection
IL
Intra-laminal
TF
Trans-foraminal
CT
computed tomography
VNS
verbal numeric scale
NDI

neck disability index.

Declarations

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Author contributions

AE: data collection, research project execution and analysis of data. HS: contribution to the concept and design and drafting the manuscript. AA: conception of the work, manuscript revision and acquisition of data. MF: analysis and interpretation of data. NF: conception of the work and Approved the version to be published. AE: Conception and design and revised the manuscript critically for important intellectual content. All authors have agreed to conditions noted on the Authorship Agreement Form and have read and approved the final version submitted. The content of the manuscript has not been published, or submitted for publication elsewhere. All authors read and approved the final manuscript.

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Availability of data and materials

All raw data will be available on the editor request through communication with the corresponding author.

Ethics approval and consent to participate The authors obtained permission to conduct this study that was approved by the Research Ethics Committee at the Faculty of Medicine, Ain Shams University (FMASU MD 172/2020). All participants signed an informed consent. The procedures followed were in accordance with our protocol.

Consent for publication

Not applicable.

Disclosure of Conflicts of Interests

None of the authors has any conflicts of interest to disclose.

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Tables

Tables are available in the Supplementary Files section.

Supplementary Files

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