Drug consumption copmparison after transforaminal epidural steroid injection versus radiofrequency application in patients with lumbosacral radicular pain

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ABSTRACT

Objectives: This study aims to investigate the efficacy of transforaminal epidural steroid injection (TFESI) versus radiofrequency application on drug consumption for lumbosacral radicular pain relief .

Patients and methods: The study, which was conducted between September 2012 and September 2014, included 40 patients with lumbosacral radicular pain. All injections were applied under C-arm fluoroscopy guidance, using a mix of bucaine and lidocaine. patient's intake of analgesic medication was measured at the baseline before the intervention, and again after the intervention by one week ,after 1 month and after three months , to determine the effect of intervention on analgesic drug consumption , amount of drug consumption measured in mgs per day.

Results: There was statistically significant difference in the NSAIDs consumption post procedure between the two groups, steroid group had a decrease in NSAIDs (Ibuprofen) consumption more then the PRF group (P-value<0.05), There was statistically significant difference in the tramadol consumption post procedure between the two groups specially after one week and one month, steroid group had a decrease in tramadol consumption more then the PRF group (P-value<0.05) , There was no statistically significant difference in the pregabaline consumption post procedure between the two groups, but steroid group had a decrease in pregabaline consumption more then the PRF group (P-value < 0.05).

Conclusion: In this follow-up study, transforaminal epidural steroid injection was found to be effective in both the early period and in the mid-term, And improve the drug consumption more than the radiofrequency application .

Keywords: Pulsed Radiofrequency Treatment; Transforaminal Epidural Steroid Injection; Radicular Pain

INTRODUCTION

Chronic Lumbo-Sacral radicular pain is the most common neuropathic pain; its annual prevalence among general populations is about 10 to 25%. LSR pain commonly affects sciat-ic nerve and lower lumber nerve roots and is mainly caused by herniation of one or more of lumbar or sacral intervertebral discs, hypertrophied bulging ligments, epidural adhesion after spine surgeries. The lifetime incidence of this condition is estimated to be between 13% and 40%. The condition has the potential to become chronic and intractable, with major socio-economic implications **(Merskey and Bokdu, 1994).**It could be proposed that radicular pain in sciatic nerve roots arises from a complex interaction of inflammatory, immune, and pres-sure-related elements***(Brisby et al., 2002b).***

Farrar et al reported that Intervertebral disc herniation is the most common cause of LBP followed by failed back surgery syndrome (FBSS) that affects 20% to 40% of the patients who underwent lumbar surgery each year, ***(Farrar et al., 2001)*** and spinal stenosis (SS) a common cause of pain and functional limitations in the elderly ***(Van Zundert et al., 2005).*** In our study, there are many

patients who were suffering from chronic back pain for various rea-sons. Herniated disc and FBSS were the commonest cases, about 85% of them. Most of them were on medical treatment for long period such as pregabalin, gabapentin, tricyclic antide-pressant, opioids and NSAIDs. These medications failed to relieve their pain completely.

Transforaminal approach is typically performed for the treatment of back pain with radiculopathy conforming to a known nerve root distribution. A selective transforaminal ap-proach allows for better delivery of a concentrated dose of medication directly to the affected nerve root, and allows for more direct access of medication to the ventral epidural space***(Staal et al., 2009).***

The idea of Pulsed Radiofrequency (PRF) was spawned after a chance meeting in 1993, and the first PRF procedure—on a lumbar dorsal root ganglion, took place on February 1, 1996 ***(Cosman, 2005, Sluijter, 2005, Sluijter and van Kleef, 2007).*** Since then, there had been reports that it has been successfully used for the treatment of myriad pain conditions.

Patients and Methods:

our prospective randomized controlled single blind study was conducted at National Cancer Institute (NCI), Cairo University after obtaining approval from the local Ethics Committee and informed consent was taken. The study was conducted from the period march 2014 to December 2016 on Forty adult patients divided randomly in to two equal groups, each group 20 patient :

- The 1st group receiveded steroid injection at the affected lumbosacral nerve roots
- The 2nd group received pulsed radiofrequency for the affected lumbosacral nerve roots.

Inclusion criteria

- Presence of chronic low back pain more than 6 months with dermatomal distribution.
- In patients aged over 18years old.
- Pain score equal or more than 5 on visual analogue scale .
- Pain due to :
  - Disc prolapse with nerve root compression
  - Failed back syndrome
  - Lumber canal stenosis

Exclusion criteria

- Coagulation defects
- Presence of neurological defects
- Epidural metastases
- Vertebral collapse
- osteolytic lesions
- Local infections
- Psychiatric illness

Assessment before intervention

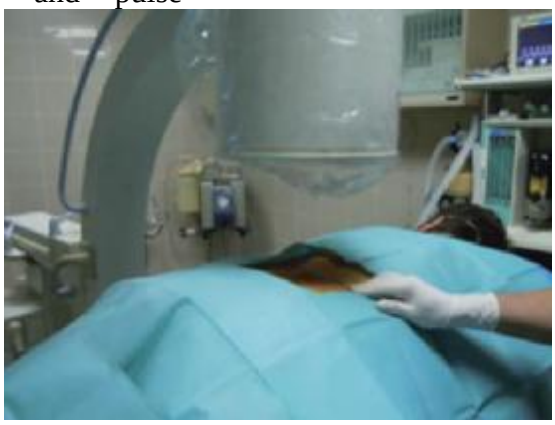
- Patient history should be taken
- Investigations
- CBC
- PT , prothrombine concentration and INR
- Bleeding time
- Lumbosacral MRI
- Visual analoge scale (VAS)

Pre Technique preparation :

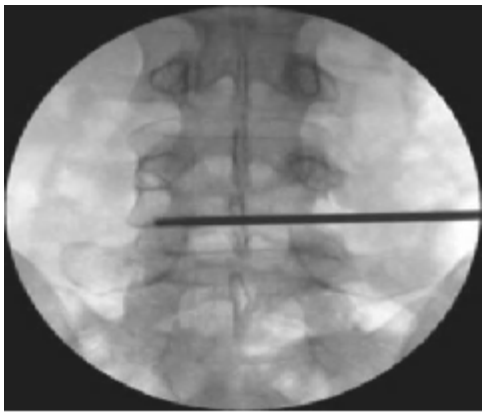
Patients would be screened at national cancer institute pain clinic . Based on the history and clinical examination, a diagnosis of chronic low back pain involving one or more spinal segments is made and noted. The patient is considered eligible for the study if a CT or MRI of lumbar spine done within the last 6 months demonstrates pathology that is concordant with the patient's clinical symptoms. Patients fulfilling the inclusion criteria were informed about the procedure. interventions involved and the possible complications after which an informed consent will be taken.. All interventions will be done as day-care procedures in the OR.

The patient will have an established IV access, putted in prone position,

involved area of back is sterilized using chlorohexidine 2%. The patient connected to continuous monitoring of 3 lead ECG, NIBP, and pulse oximetry. Sedation if used will be minimal to obtain the necessary response of the patient.



(a)



(b)

Figure (1): (a,b) Mark the level of entry for lumbar transforaminal block.

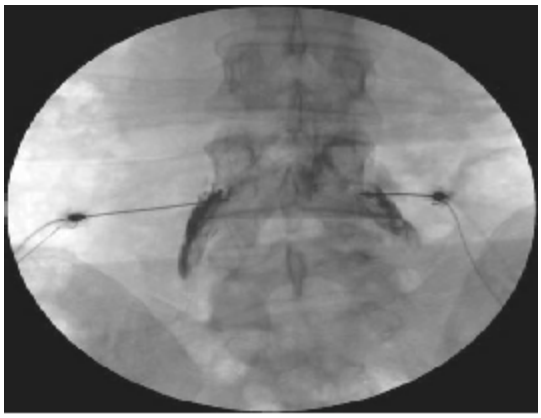


Figure (9): Bilateral transforaminal injection due to bilateral inflammation.

The procedures were performed according the subpedicular transforaminal technique. The patient was positioned prone with a pillow under the upper abdomen in order to decrease the physiologic lumbar lordotic curve and allow for optimum visualization , then the skin was prepped with sterile technique. We identifiey the target levels and the targeted vertebrae, then The fluoroscope was positioned to provide an oblique view to identify the subpedicular space. 1% lidocaine (preservative-free) was used for skin and soft tissue analgesia. A sterile 22 gauge 3.5, 5, or 7 inch spinal needle was then positioned at the superior aspect of the foramen above the exiting spinal nerve. Precise needle placement was confirmed by AP, oblique, and lateral fluoroscopy.

With the patient in prone position, a true AP fluoroscopic view of the lumbar spine is obtained. 1st of all we align the targeted vertebrae then The fluoroscopy beam is rotated 15- 30 degrees in the oblique view in the same affected side until scotty dog appearance appeared, the entrance point is subpedicular at about 6 clock subpedicular , when fluoroscopy beam is parallel to the needle this makes tunnel vision view . the curved spinal needle is advanced enface, parallel to the fluoroscopy beam to within 1 to 2 cm of the foramen.

Needle insertion continues until we note either resistance to further advancement or the patient experiences a dysethetic radicular-type pain. If resistance is met during needle insertion, a lateral fluoroscopic view should be obtained. If a posterior element of the spine, transverse process, lamina, or SAP is preventing passage, we bend the needle tip to pass around the structure. Occasionally, withdrawal of the needle up to 5 mm may be required to bypass the impeding structure. If on lateral view the needle is noted to have contacted the dorsal-lateral aspect of the vertebral body, withdrawal 2–3 mm is advised. This lessens the chance of the radicular artery having been “trapped” between bone and needle and accidentally cannulated.

We must be sure that The final needle-tip is within the foramen, subpedicular, approximately halfway between the ventral and dorsal extent of the pedicle when imaged in a true lateral view. This location will place the needle tip rostral and lateral to the DRG and segmental nerve, and dorsal to the anterior radicular artery .

If radicular pain is noted by the patient at any point during needle insertion, the spinal nerve or DRG may have been touched, and the needle should be immediately withdrawn a few millimeter . If marked pain continues after withdrawal of the needle, we should terminate the procedure . If the pain is noted to decreased , a lateral view should be obtained. If the needle tip is noted to lie within the foramen, and on AP view the tip is seen to be within the “safe triangle” , we continued the procedure without further needle advancement.

1–2mLof omnipaque 300 contrast dye was injected through the needle under live fluoroscopy. If there was intravascular uptake, the needle was repositioned until no intravascular uptake was evident and until an epidural flow pattern was observed. 2 ml was injected for each nerve root , the injectate solution formed of 40mg of depomedrol mixed with 4ml of marcaine of 0.125% concentration completed to 10 ml saline .

Pulsed radiofrequency

For radiofrequency group a RF needle (Bayliss: 22-G needle, 5-mm curved active tip and 10 cm) is used. With an appropriate fluoroscopy view the needle is inserted to the target location

as the same technique of the 1st group , after we reach the target site we start to do sensory and motor stimulation to be in the ideal position. Ideal sensory stimulation should be felt between 0.4 and 0.6 V. If stimulation is felt at less than 0.4 V, the tip of the needle is too close to the DRG; and if stimulation is felt at greater than 0.6 V, the tip is too far away from the DRG. Motor stimulation is then performed at 2 Hz. There should be a clear dissociation between motor and sensory stimulation; that is, the voltage required to see motor fasciculations at 2 Hz should be at least two times the voltage that produces sensory stimulation at 50 Hz. Thus, if good sensory stimulation at 50 Hz is noted at 0.5 V, the motor fasciculations at 2 Hz should not be seen at voltages less than 1.0 V. The point of dissociation defines the position of the DRG. If dissociation between sensory and motor stimulation cannot be obtained, the tip of the needle is not in alignment with the DRG, and lesioning at this point is not recommended. Once satisfactory placement is obtained, pulsed radiofrequency for 120 seconds at maximally 42°C is performed for 2 cycles . A local anesthetic does not need to be injected prior to removal of the needle. **(kline M et al., 1996).**

Post procedure instructions

All patients were admitted after the procedure into a ward for at least 4 hours with, recording of any adverse effects or complications. Blood pressure and pulse oximetry continuously monitored. Any complains such as pain, vomiting, or leg weakness or numbness were reported. Patients, who suffered from lower limbs weakness, were reassured and waited for one hour. Vomiting was treated by antiemetic drugs and intravenous fluid, whereas pain in the back or leg was managed by reassurance and analgesic drugs after excluding serious events. Before discharge, each patient received the necessary instructions and contact numbers.

Evaluation parameter post technique

patient's intake of analgesic medication was measured at the baseline before the intervention, and again after the intervention by one and three months to determine the effect of intervention on analgesic drug consumption , amount in mgs per day which is measured.

Results

1- NSAIDs (Ibuprofen) Drug consumption

There was statistically significant difference in the NSAIDs consumption post procedure between the two groups, steroid group had a decrease in NSAIDs (Ibuprofen) consumption more then the PRF group (P-value<0.05)

Table(1): NSAIDs (Ibuprofen) Drug consumption in study groups.

	Group 1 (steroid group)	Group 2(PRF group)	P-value
Basal	**600 (200)**	**600 (200)**	
1week	**550 (200)**	**400 (150)**	**0.01***
1month	**550 (200)**	**400 (200)**	**0.01***
3month	**600 (200)**	**400 (200)**	**0.003***

Data presented as mean(SD). * P-value < 0.05

Drug consumption dose expressed in mg per day.

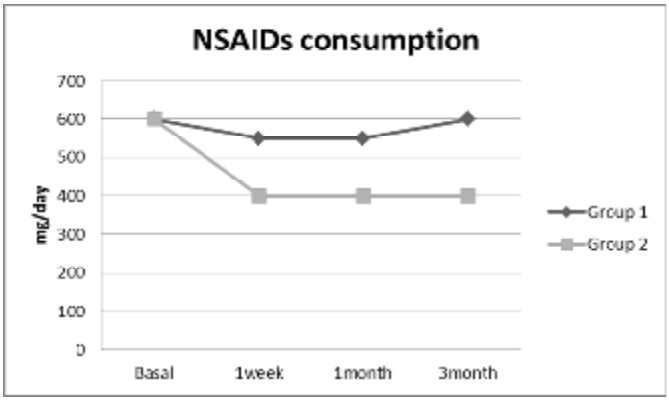


Figure (2): NSAIDs (Ibuprofen) consumption in study groups.

2- Tramadol Drug consumption

There was statistically significant difference in the tramadol consumption post procedure between the two groups specially after one week and one month, steroid group had a decrease in tramadol consumption more then the PRF group (P-value<0.05)

Table(2): Tramadol Drug consumption in study groups.

	Group 1	Group 2	P-value
Basal	**250 (100)**	**250 (100)**	
1week	**175 (50)**	**225 (100)**	**0.005***
1month	**175 (50)**	**225 (100)**	**0.005***
3month	**200 (50)**	**225 (100)**	**0.04***

Data presented as mean(SD). * P-value < 0.05

Drug consumption dose expressed in mg per day.

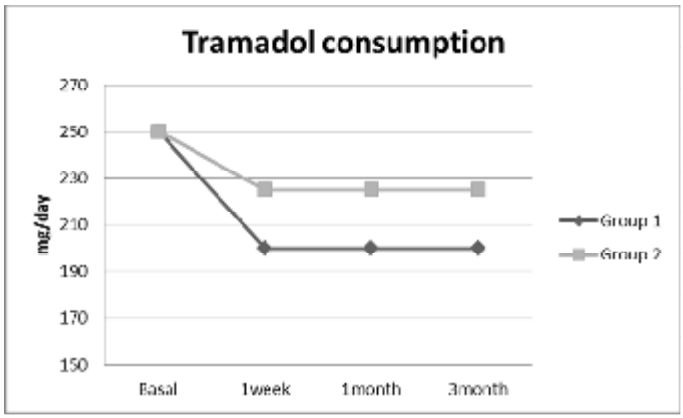


Figure (3): Tramadol consumption in study groups.

Pregabline Drug consumption

There was no statistically significant difference in the pregabaline consumption post procedure between the two groups, but steroid group had a decrease in pregabaline consumption more then the PRF group (P-value < 0.05)

Table(3): Pregabline Drug consumption in study groups.

	Group 1	Group 2	P-value
Basal	**250 (125)**	**250 (125)**	
1week	**175 (75)**	**225 (100)**	**0.08**
1month	**175 (75)**	**225 (100)**	**0.08**
3month	**200 (75)**	**250 (100)**	**0.38**

Data presented as mean(SD). * P-value < 0.05

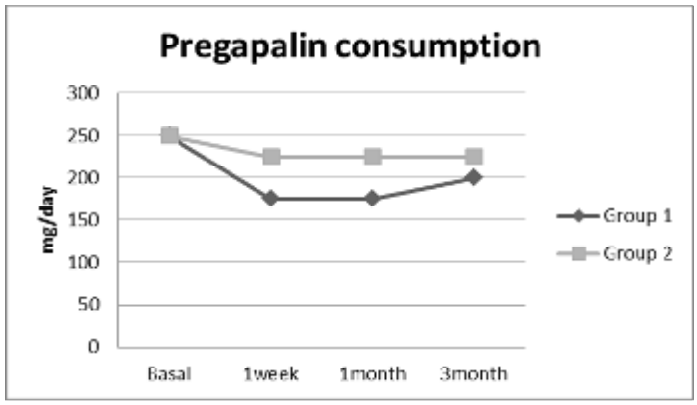


Figure (4): pregabaline consumption in study groups.

Discussion

our prospective randomized controlled single blind study was conducted at National Cancer Institute (NCI), Cairo University after obtaining approval from the local Ethics Committee and informed consent was taken. The study was conducted from the period march 2014 to December 2016 on Forty adult patients divided randomly in to two equal groups, each group 20 patient :

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in our study There was statistically significant difference in the NSAIDs consumption post procedure between the two groups, steroid group had a decrease in NSAIDs (Ibuprofen) consumption more then the PRF group (P-value<0.05), There was statistically significant difference in the tramadol consumption post procedure between the two groups specially after one week and one month, steroid group had a decrease in tramadol consumption more then the PRF group (P-value<0.05) , There was no statistically significant difference in the pregabaline consumption post procedure between the two groups, but steroid group had a decrease in pregabaline consumption more then the PRF group (P-value < 0.05).

Cooper et al.,when conservative therapies prove inadequate, invasive therapies may be tried including the epidural administration of corticosteroids. The level of evidence in managing LBP with epidural steroids is strong for short-term relief but limited for long-term relief ***(Cooper et al., 2004).*****Geurts et al.,** there were no significant differences between 2 methods of treatment regarding to adverse events and complications, and no serious complications or side effects arose in either selective epidural or PRF patients ***(Geurts et al., 2003).*****Geurts et al.,** the trial did not show a significant

difference in treatment effect between lumbosacral radiofrequency treatment of dorsal root ganglia and control treatment. Consequently, the use of this type of radiofrequency lesioning as routine treatment in lumbosacral radicular pain should not be advocated***. (Geurts et al., 2003).***

In accordance with our study, Lutz and others studied and investigated the outcome of patients with lumbar herniated nucleus pulposus and radiculopathy using administration of fluoroscopic transforaminal epidural steroid injections. Patients were evaluated by an independent observer and were followed for an average period of 80 weeks, they concluded that fluoroscopic transforaminal epidural steroids are an effective and had less drug consumption as nonsurgical treatment option for patients with lumbar herniated nucleus pulpous and radiculopathy in whom more conservative treatments are not effective, and that they should be considered before surgical intervention **(Lutz et al., 1998).**

Kikuchi et al. studied the therapeutic effect of transforaminal nerve root injections. They reported that this procedure not only had therapeutic effect but also had great diagnostic value in functional as well as morphological aspects. They reported that all patients experienced more than 6 months of pain relief and thus were able to avoid surgical intervention. Furthermore, they reported that over the long term, relief was seen in 64% of these patients **(Kikuchi S,et al. 1984) .**

Simopoulous and others concluded that patients with lumbosacral radicular pain showed significant reduction of drug consumption than the PRF-DRG group **(Simopoulos T. T. et al., 2008).**

Abejon et al said that PRF have A significant reduction in pain and in analgesic consumption in the patients with a disc herniation **(Abejon D et al., 2007).**

On the other hand Shanthanna et al said that The effectiveness of PRF treatment for chronic lumbar radicular Pain resulted in a small effect of the treatment at 4 weeks and at 3 months, with no difference in drug consumption from the patients in the placebo group **(Shanthanna Het al. 2014).**

Conclusion: transforaminal epidural steroid injection was found to be effective in both the early period and in the mid-term, And improve the drug consumption more than the radiofrequency application .

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