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Combination of Epidural Pulsed Radiofrequency with Neuro-Stimulation and Epidural Steroid in Treatment of Pain and Neurological Deficit in Failed Back Surgery Syndrome

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Original Article

ABSTRACT

***Background**: Patients with neuropathic pain secondary to failed back surgery syndrome (FBSS) typically experience persistent pain, disability, and reduced quality of life. We hypothesized that spinal cord stimulation (SCS) and epidural pulse radiofrequency is an effective therapy in addition to conventional medical management (CMM) in this patient population. **Objective**: To assess the value of combination of epidural pulsed radiofrequency with neuro-stimulation and epidural steroid in treatment of pain and neurological deficit in failed back surgery syndrome. **Patients and Methods**: We randomized a clinical trial study of 60 FBSS patients with predominant leg pain of neuropathic radicular origin and neurological deficit to receive epidural pulsed radiofrequency and spinal cord stimulation plus conventional medical management. The primary outcome was the proportion of patients achieving >70% or more pain relief in the legs by assessment of SLRT ,VAS immediately, 2 months and 6 months follow up. **Results**: Secondary outcomes were improvement of neurological deficit, health-related quality of life, functional limitation, use of pain medication and non-drug pain treatment, and incidence of complications and adverse effects. Crossover after 2 and 6-months visit was permitted and all patients were followed up to 6 months. **Conclusion**: epidural pulsed radiofrequency and stimulation of the lumbosacral DRG combined with epidural steroid injection showed a modest advantage in reducing pain intensity*

Keywords: *Pain, Neurological Deficit, management, Epidural Pulsed Radiofrequency, Epidural Steroid*

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1. INTRODUCTION

Low back pain (LBP) has been estimated to have a lifetime prevalence of 60%–80% among the global population, making it one of the most common health complaints (1). Approximately 10% of individuals suffering from LBP have symptoms that persist for longer than 3 months (2). As a consequence of the large number of patients with LBP who have sought treatment, a substantial increase in those undergoing surgery has been observed over the past two decades.

Failed back surgery syndrome (FBSS) is a term used to describe a clinical entity that has been acknowledged since the advent of spinal surgery. It was perhaps best described by Follett and Dirks (3) as the "surgical end stage after one or several interventions on the lumbar neuro axis indicated to relieve lower back pain, radicular pain or the combination of both, without effect". A more functional definition is "when the outcome of lumbar spinal surgery does not meet the pre-surgical expectations of the patient and surgeon" (4).

The term FBSS has been criticized for being a clinical misnomer for both patients and surgeons alike (5). The qualifier "failed" does little to elucidate the entity, and it is perhaps most appropriate to abandon this term entirely. The diagnostic term "postsurgical spine syndrome" perhaps more accurately describes the aforementioned clinical entity (6).

Between 1998 and 2008, the yearly number of lumbar fusion surgeries performed in the United States increased from 77,682 to 210,407, with the total number of spinal operations exceeding one million in 2002 (7,8). The direct yearly cost of spinal fusion surgery in the United States was over 16 billion US$ in 2004 (9), whereas the overall failure rate of lumbar spine surgery was estimated to be 10%–46% (10). Given that these rates have not changed substantially over the years despite advances in technology and surgical technique, the number of patients developing FBSS can be expected to continually increase (11).

The potential widespread occurrence of this condition necessitates accurate assessment of this challenging patient population to best address their symptoms and deliver the most effective treatment. Repeat spinal surgery is a treatment option with diminishing returns. Although more than 50% of primary spinal surgeries are successful, no more than 30%, 15%, and 5% of the patients experience a successful outcome after the second, third, and fourth surgeries, respectively (12). The prevalence and incidence of patients with FBSS are comparable with those of patients with rheumatoid arthritis. However, patients with FBSS

and neuropathic pain experience higher levels of pain and a poorer quality of life and physical function compared with those with osteoarthritis, rheumatoid arthritis, complex regional pain syndrome, and fibromyalgia (13).

There are different factors lead to failed back surgery syndrome including patient's factors such as poor psychosocial wellbeing, smoking, obesity and others. Operative and post operative factors are also associated with FBSS.

Management modalities of FBSS including assessment of patients, Conservative treatment, repeated surgery and Neuromodulation.

Pulsed Radiofrequency (RF)

Pulsed radiofrequency (RF) is a wellestablished treatment for joint and nerve pain. The procedure differs from radiofrequency neurotomy (RFN) treatment where the probe is heated. Pulsed RF treatment applies an intermittent electrical pulse to the probe, thereby avoiding heating the nerve. This in turn, minimizes further nerve damage.

RF treatment doesn't cause weakness or loss of normal sensations, and has been shown to reduce pain.

Pulsed RF can be used to treat:

- Radicular pain (neuropathic pain from the spine)
- Occipital neuralgia (pain in the back of the head or base of the skull)
- Post-surgical neuropathic pain
- Suprascapular nerve for shoulder pain
- Medial branch nerves for facet joint spinal pain.

Epidural Pulsed RF

(EPRF) at the dorsal nerve roots and dorsal root ganglia (DRG) can be used to treat radicular neuropathy. Epidural placement enables treatment of multiple spinal levels via a single needle, and targetry of nerves inaccessible due to normal anatomy, foraminal stenosis, or hardware. Temperature control at 42°C limits thermal effects and ensures safety (14-17)

The average duration of pain relief is between four and 26 months, depending upon which nerve is being treated. However, pain relief may range from anywhere between four weeks to 18 months. In some cases, there is no benefit.

Like all procedures, RF treatment carries some risks, including:

Allergic reaction to the medications used in the procedure or sedation is possible but can be

treated on the day: nausea is not uncommon following sedation. Infection is extremely unlikely with the possibility minimized by the use of sterile techniques in an operating theatre. The needles are all disposable.

It is uncommon for even a day of work to be lost; however, if there was an infection or excessive pain, there is a possibility of some time off work.

Generally, you will be discharged from the hospital within two hours and may resume normal activities on the following day. Simple analgesics are often required for a few days. If you've been using stronger analgesics, you may require stronger analgesia for a few days.

2. PATIENTS and METHODS

This was a randomized clinical trial included sixty patients ., which was conducted at specialized nursing house Hospital and Al-Arabi private hospital from July 2018 to March 2020. All participants provided written and informed consent. Eligible patients were adults aged 18–80 years, with CLRP of at least 6-month duration which was unresponsive to pharmacotherapy or physical therapy, and who had magnetic resonance imaging evidence of nerve root involvement at the targeted levels.

Exclusion criteria:

1. patients who were surgical candidates
2. coagulopathy
3. allergy to any of the study medications
4. psychiatric problems
5. language barriers
6. Pregnant

Procedures:

In operation theater ,under full monitoring (pulse rate,SPO2,blood pressure), aseptic condition, prone position ,fluoroscopic and ultrasound guidance , through sacral hiatus identification by linear probe ultrasound under local anesthesia infiltration by 3 ml-5 ml 2% lidocaine cosman introducer needle 18 gauge passed through it ,cosman catheter 40 cm length blunt end 2mm diameter passed epidurally in the spinal canal and reached the target level guided by fluoroscope , hydro dissection and adhesolysis of fibrosis by normal saline maximum of 30 ml, steering of the catheter according to the targeted root ,steroid injection

,with contrast confirmation ,then pulsed radiofrequency to 40 centigrte 4 min for each targeted level and target root, motor maximum of 3 volts, in 5 HZ frequency and sensory bursts stimulation from 5 to 20 burst in maximum of 3 volts and 200 HZ done at the damaged roots in case of neurological deficit and timing depend on the severity of neurological deficit, steroid was methylprednisolone (depomedrol)80 mg, triamcinolone(kenacort) 40 mg diluted with 6-8 ml saline. The procedure time range from 30-45 minutes

Statistical analysis

Data of the 60 cases were transferred into computerized database with statistical analysis utility. SPSS version 26 used in all statistical analysis and procedures. Appropriate statistical tests and procedures were applied accordingly at a level of significance ≤ 0.05 .

3. RESULTS

There were 60 patients enrolled in this study with a mean age of 53.9 ± 10.2 (Range: 32 – 75) years. Moreover, majority of the patients aged more than 40 years. Males were relatively dominant with a male to female ratio of 1.22 to one. Pain duration ranged 1 – 14 with a mean of 6.5 ± 2.8, (**Tables 1)**, Regarding presentation and complaints, all patients presented with low back pain, furthermore, on clinical assessment, foot drop reported in 23 (38.3%) patients, minimal foot drop reported in 7 (11.7%) while the remaining patients had no foot drop. Other finding was multiple disc prolapses, spinal canal stenosis and cauda equina syndrome (CES) which are reported in 68.3%, 25% and 15%, respectively, (**Table 2**)

Comparison of straight leg raising test (SLRT) before and at each follow up period revealed a significant reduction in the frequency of positive test after treatment, where before treatment the number of patients with positive SLRT was 55 (91.7%), immediately after treatment the number was 18 (30%), at two months after treatment only 10 (16.7%) patients with positive SLRT then at 6 months the number of cases with positive SLRT increased to 31 (51.7%), however, it still lower than that before treatment, (P. value < 0.001), (**Table 3**). From other point of view, the mean SLRT degree showed significant increase at each follow up period than its baseline level before treatment, (P. value < 0.001), (**Table 4**).

A significant reduction was reported in VAS scoring at each follow up period than its baseline level before treatment; the mean VAS was 8.1 before treatment reduced to 2.9 at immediate assessment after treatment , reach 0.8 at 2 months after treatment and then re increased to 2.7 after 6 months , but still much lower than its level before treatment, (P. value < 0.001), (**Table 5**).

Changes in frequency and grading of Motor deficit before and after treatment are shown in (**Table 6**), where a significant improvement in grading was reported at each follow up period, (P. value = 0.003). From other point of view, cases who did not have motor deficit after treatment increased from 33 before treatment to 44 immediately after treatment, 42 at 2 months and 42 at 6 months after treatment, (P. value < 0.001), (**Table 7**).

A significant improvement in the functional activity of the patients, where patients with Functional Limitation were 52 before treatment while only one at 2 months and 14 at 6 months after treatment, (P. value < 0.001), (**Table 8**)

Table 1. Baseline characteristics of the patients

Variable		No.	%
Age (year)	≤ 40	8	13.3
	41 – 50	22	36.7
	51 – 60	14	23.3
	> 60	16	26.7
	Mean (SD)	53.9 (10.2)	-
	Range	32 - 75	-
Gender	Male	33	55.0
	Female	27	45.0
	M:F Ratio	1.22	-
Pain duration	*Mean (SD)*	6.5 (2.8)	
	Range	1 - 14	-

SD: Standard deviation of mean

Table 2. Presentations and complains of the patients

Presentations / complain	No.	%
Low back pain	60	100.0
Foot drop*	30	50.0
Multiple disc prolapses	41	68.3
Spinal canal stenosis	15	25.0
Cauda equina syndrome (CES) * Foot drop in 7 of 30 cases was minimal	9	15.0

Table 3. Changes in SLRT before and after treatment at each follow up period

Follow-up	SLRT			
	Positive		Negative	
	No.	%	No.	%
Before	55	91.7	5	8.3
Immediate	18	30.0	42	70.0
2 months	10	16.7	50	83.3
6 months	31	51.7	29	48.3

Table 4. Changes in SLRT before and after treatment at each follow up period

SLRT (degree)	Mean	SD
Before	48	10.3
Immediate	69	1.6
2 months	70	0.0
6 months	69	2.1
Overall P .value* < 0.001 significant		
P. value before vs. immediate < 0.001 significant		
P. value before vs. 2 months < 0.001 significant		
P. value before vs. 6 months = 0.113 not significant		

*Repeated measure ANOVA test used in comparison

Table 5. Changes in Visual analogue scale (VAS) before and after treatment at each follow up period

VAS	Mean	SD
Before	8.1	1.5
Immediate	2.9	1.4
2 months	0.8	1.4
6 months	2.7	2.0
Overall P .value* < 0.001 significant		
P. value before vs. immediate < 0.001 significant		
P. value before vs. 2 months < 0.001 significant		
P. value before vs. 6 months < 0.001 significant		

*Repeated measure ANOVA test used in comparison

Table 6. Changes in frequency and grading of Motor deficit before and after treatment at each follow up period

Motor deficit	Before treatment	After treatment		
		Immediate	2 months	6 months
Grade 0	3	0	0	0
Grade 1	2	1	0	0
Grade 2	10	1	1	1
Grade 3	1	9	6	6
Grade 4	7	5	9	9
Minimal	4	0	2	2
None	33	44	42	42
P. value = 0.003 significant				

Table 7. Overall frequency of Motor deficit before and after treatment at each follow up period

Motor deficit	Before	After treatment		
		Immediate	2 months	6 months
Present	27	16	18	18
None	33	44	42	42
Total	60	60	60	60
P. value < 0.001 significant				

Table 8. Frequency distribution of Functional Limitation before and after treatment at each follow up period

Functional Limitation	Before	After treatment	
		2 months	6 months
Yes	52	1	14
No	8	59	46
Total	60	60	60
P. value < 0.001 significant			

4. DISCUSSION

Post spinal surgery neuropathic pain is a common health problem , unfortunately, many patients still having pain and dysfunction affecting their quality of life and their daily activities (18). Traditional treatment shows some effective management in management of these patients, but only few medication used effectively like gabapentin (19–21), however, management of pain remains one of the challenges in clinical practice , particularly in chronic cases, that facing clinicians on their daily practice. Hence, a large efforts paid and many trials performed to obtain an optimal treatment modality to help these patients given a large concern about the safety , effectiveness and cost of treatment method that will adopted (20,22). Spinal Cord stimulation (SCS) showed to be one of the promising modalities that are currently widely used to improve back and leg pain, physical function and quality of life. Nonetheless, despite SCS has been documented to be economically accepted in most studies (23–25), there still a debate about its aggressiveness, epidural pulsed radiofrequency with neuro-stimulation proved to have good outcome in clinical practice, however, the long effect and absolute advantage of this method still an issue among researchers and need further evaluation(26,27), hence , the present study aimed to assess the value of combination of epidural pulsed radiofrequency with neuro-stimulation and epidural steroid in treatment of pain and neurological deficit in failed back surgery syndrome among group of Iraqi patients, therefore, this study included 60 FBSS patients with predominant leg pain of neuropathic radicular origin and neurological deficit managed and followed up to assess their response based on achieving 50% or more of pain relief in

the legs and improvement of back and leg pain and the improvement in the neurological deficit , functional capacity and other parameters.

In the current study, majority of the patients were older than 40 years, and more than half of them were males, which agreed the epidemiological picture of LBP and FBSS (28–30). On the other hand, all patients in our study presented with low back pain for different duration ranged 1 – 14 months, Multiple disc prolapses and foot drop were the next more frequent presenting feature , while other features like Spinal canal stenosis and Cauda equina syndrome reported in 25% and 15%, respectively, these findings were not unexpected due to the nature of the study population , these findings also reported in previous studies (29,31–33).

The current study found good immediate improvement and significant reduction in the frequency of positive SLRT immediately after procedure and after 2 months, however, the frequency of positive SLRT re increased but still lower than the baseline rate, this reflect the effectiveness of management modality in our study in short term response and also after 6 months, this is better than the use of traditional management alone which based on chronic use of medications or even surgery .

Furthermore, in the current study , good reduction reported in VAS score immediately , at two months and at 6 months after procedure . On the other hand , a significant improvement in motor deficit grading was reported at each follow up period, additionally, at the end point , the total number of patients with motor deficit reduced significantly by almost one-third, from 27 before procedure to only 18 after 6 months.

Functioning was significantly improved where only one patient still have functional limitation after 2 months while 14 only after 6 months, compared to 52 patients before treatment.

Different recent and earlier studies assessed the effectiveness of epidural pulsed radiofrequency with neuro-stimulation on pain, motor deficit and functionality, however, studies that investigate the effect of combined epidural pulsed radiofrequency with neuro-stimulation and epidural steroid, are very scattered or unavailable, particularly in our country. In previous reviewed literatures and published paper, authors, assess the effect of epidural pulsed radiofrequency with neuro-stimulation or epidural steroid separately or compared them. For instance, Munjupong et al. (34) in their randomized clinical trial

reported that assess the effectiveness of pulsed radiofrequency combined with transforaminal epideural steroid injection, on chronic lumbar radicular pain and found that VAS was significantly lowered in treatment group at 2, 3 and 4 months follow up, but the quality of life was not significantly improved , nonetheless, authors concluded that combined therapy had modest effect compared to transforaminal epidural steroid injection alone, with no effect on the quality of life.

An earlier study conducted by Simopoulos et al. concluded almost similar results regarding the effect of pulsed radiofrequency (35). There are different theories and mechanisms that explain the effect of pulsed radiofrequency ; change in transmission of pain signals in the dorsal horn, and decrease glial cell activation

Other mechanism, is induction of endogenous opioid release and the third mechanism is facilitating the descending inhibitory pain pathway (35).

Another clinical trial conducted by Lee et al. in 2016 compare the effect of pulsed radiofrequency and transforaminal steroid injection for radicular pain in patients with disc herniation and found that both pulsed radiofrequency and transforaminal steroid injection had the same effect (36).

Fortunately, no serious adverse effect reported in our studied group after treatment, which agreed that reported in previous studies where several studies, reported pulse radiofrequency technique did not cause any damage to the tissues and it is effective and safe (34,37). However, longer duration of follow up still needed for assessment of long term effect of this technique.

5. CONCLUSIONS

Combination of epidural pulsed radiofrequency with neuro-stimulation and epidural steroid was effective and safe in treatment of pain and neurological deficit in failed back surgery syndrome through its effect in reduction of frequency of SLRT positivity, reduce VAS score, improve motor deficit and functionality, at immediate, 2 and 6 months of follow up. Therefore, implementation of combination of epidural pulsed radiofrequency with neuro-stimulation and epidural steroid in treatment of pain and neurological deficit in failed back surgery syndrome. We suggest to conduct further studies with large sample size and longer

duration for further evaluation

Ethical Clearance: Ethical clearance and approval of the study are ascertained by the authors. The Institutional Review of Arabic board Committee approved this study. All ethical issues and data collection were in accordance with the World Medical Association Declaration of Helsinki 2013 for ethical issues of researches involving humans, informed consent obtained from all patients. Data and privacy of patients were kept confidentially.

Conflict of interest: Authors declared none

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