PRESENTATION AND MANAGEMENT OF FAILED BACK SURGERY SYNDROME BY STEERABLE EPIDURAL CATHETER

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Submitted: 12/10/2020; Accepted: 22/4/2021; Published: 21/9/2021

ABSTRACT

Background

Failed back surgery syndrome (FBSS) is a frequently occurring disease following lumbar spinal surgery. It has also been named "post lumbar surgery syndrome," and much research has been done. The patients share continued back and extremity pain following one or more spinal operations. It may be due to inadequate operations, operative complications, progression of degenerative processes, or a new pathology.

Objectives

To successfully use a steerable epidural catheter to treat 'Failed Back Surgery Syndrome' patients. Study Design a case series was carried out on 50 patients with FBSS.

Methods

Clinical data were collected from patients with FBSS, pain symptoms, MRI findings. (VAS) the visual analog scale has been used for pain degree evaluation, (ODI) Oswestry disability index was used for functional improvement evaluation. Percutaneous adhesiolysis under fluoroscopy guide has been performed, and the patients were assessed at one month and three months intervals from the day of the procedure.

Results

In comparing to baseline values, there was a significant decrease of the mean and median VAS after one month and three months of the intervention ($p < 0.001$). The same is for the ODI%, where it is clear that its median decreased from 48% to 22% after one month ($p < 0.001$) and to 8% after three months ($p < 0.001$).

Conclusion

Steerable epidural catheter was effective in FBSS treatment with improvement in pain and function.

Keywords: *FBSS, Epidural adhesiolysis, Oswestry Disability Index, steerable epidural catheter, chronic low back pain.*

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https://doi.org/10.17656/jsmc.10313

INTRODUCTION

Failed Back Surgery Syndrome (FBSS) is a term applied to a heterogeneous group of individuals who share continued back and extremity pain following one or more spinal operations [1]; approximately 15-20% of patients will experience persistent or recurrent symptoms [2].

The etiology of FBSS is multi-factorial; it happens mainly due to improper patient selection, like failure to recognize psychological abnormalities that adversely affect outcomes [3], It may be due to inadequate operations, operative complications, progression of degenerative processes, or a new pathology [4]. The spectrum of abnormalities ranging from purely organic to purely psychological, but in most cases consists of a physiological abnormality complicated by psychological factors [5]. Therefore, FBSS is a complex syndrome that needs a multidisciplinary approach for the assessment and treatment; therapy evaluation is vital for outcome improvement [6].

This study will focus on managing the epidural adhesions and fibrosis that happens as a post-back surgery complication. It has been found that mechanical stimuli are not the only reason for back and lower extremity pain but also can happen due to chemical irritation of the nerve root [7]. Epidural adhesions happen after acute inflammation, and this inflammation results from nucleus pulposus leakage into the epidural space after a tear in the annular fibrosis. Eventually, the epidural adhesions make a pressure on the nerve root [8-11]. Although this epidural fibrosis and adhesions are not painful, they can generate pain as they are trapping the nerve roots, and any movement can put these nerve roots under tension [7,8].

Commonly, epidural injections have been used to treat FBSS under fluoroscopic guide; after that, patients improved due to their anti-inflammatory effect[12,13],Another way for epidural injection has been produced, which is transforaminal with better results treating radicular pain [14, 15]. At the same time, injections by the caudal epidural route give better results regarding pain relief and patient mobility[16,17].

Caudal Epidural injection by a steerable catheter is a useful method, can be achieved percutaneously with local anesthesia infiltration, and it has the ability to reach the target selectively, whether it was herniated disc or adhesions around the nerve root [18]. Usually, adhesions can physically prevent the drugs from contact with the inflamed nerve root; that is why we use the steerable catheter, which can deliver the drug precisely to the target [19].

The objectives of the study are to find out the mode of presentation and success rate of using a steerable epidural catheter to treat 'Failed Back Surgery Syndrome' patients.

METHODS

A case series study was carried out in a private pain clinic in Erbil during a period of one year (From Jan 19 to Jan 20). Fifty cases with FBSS with a history of laminectomy and a history of lumbar spine fixation surgery were included in the study. The exclusion criteria were history of facet joint pain, history of cervical spine fixation, non-operated backache, lumbar tumor spine fixation, pregnancy, addiction, and mental problems.

A questionnaire designed by the researcher was used to collect the following information: age, gender, duration of symptoms in months, pain symptoms (back pain and lower limbs pain), and a history of previous lumbar surgery. Magnetic resonance imaging (MRI) findings that were recorded included the type and location of the herniated disc, number of lesion levels, grade of nerve root compression.

The Visual Analogue Scale (VAS) for back and/or lower limbs pain has been used to evaluate the pain degree, and the Oswestry Disability Index (ODI) was used to evaluate the functional improvement at pretreatment one month and three months after treatment. The VAS represented no pain with 0 and the worst pain with 10. The scoring percentage for the Oswestry low back pain is described in (Table 1). Successful pain relief was defined as a 50% reduction of the VAS, and successful functional improvement was defined as a 50% reduction in ODI.

Table 1. Oswestry Low Back Pain Disability Scores.

0-20%: minimal disability	The patient can cope with most living activities. Usually, no treatment is indicated apart from advice on lifting, sitting, and exercise.
21-40%: moderate disability	The patient experiences more pain and difficulty with sitting, lifting, and standing. Travel and social life are complicated, and they may be disabled from work. However, personal care, sexual activity, and sleeping are not grossly affected, and the patient can usually be managed by conservative means.
41-60%: severe disability	Pain remains the main problem in this group, but activities of daily living are affected. Therefore, these patients require a detailed investigation.
61-80%: crippled	Back pain impinges on all aspects of the patient's life. Positive intervention is required.
81-100 %	These patients are either bed-bound or exaggerating their symptoms.

The Procedure

The patients were admitted to the operating theatre, the vital signs readings were taken, and an IV access was done for the patients. Antibiotic was given according to the protocol and patient's condition. The procedure was done in a prone position with sedation. With the aid of the fluoroscopy, sacral hiatus was visualized to determine the point of entry, sterilization, and draping is done after local anesthesia (1% lidocaine infiltration), the skin incision was made.

A 15-gauge Tuohy needle was inserted into the epidural space through the sacral hiatus. Injection of 2 ml contrast media to confirm that our needle is in the epidural space, also we have to check our needle place to avoid intravascular or subarachnoid needle placement. Now, our Steerable catheter can be inserted after the removal of the needle. Another 2 ml of contrast media was injected with a fluoroscopic guide to visualize the defects by examining the contrast flow into the nerve roots (Fig.1-A). Then the catheter should be positioned so close to the defect and possible area of pain. Thereafter, adhesiolysis was carried out by injecting 20ml of Hyaluronidase 1500IU diluted in 3% hypertonic saline. Then, 20 ml of 1%lidocaine was injected. All these were injected through the catheter. The tip of the steerable catheter can be navigated from outside to do mechanical adhesiolysis inside the epidural space and around the nerve roots. After that, another 2ml of contrast media was injected to visualize the epidural space and the area around the nerve roots. If the contrast media spread is well, that means adhesiolysis is completed (Fig.1-B). Then, non-particulate 80 mg Methylprednisolone was injected through the catheter. Finally, the steerable catheter was removed, the patient was transferred to the monitoring room for 2 hours .After motor and sensory examination, the IV cannula was taken out, and the patient was discharged from the hospital. The patients were asked to visit the clinic for assessment at one month and three-month intervals from the day of the procedure.

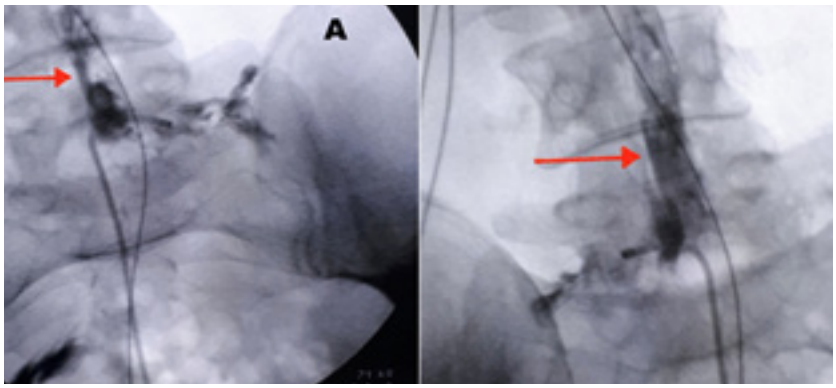

Figure 1. Two AP view fluoroscopic images of the lumbar spine during percutaneous epidural adhesiolysis using a steerable epidural catheter. (A) Before the procedure showing filling defects of contrast medium at the epidural space at L4-5 intervertebral disc level (Red arrow). (B) After the procedure, the contrast agent spread well along with epidural space at L4-5 inter-vertebral disc level (Red arrow).

RESULTS

Fifty patients were included in the study; their mean age ± SD was 49.62 ± 9.05 years. The age range was 32 – 67 years. The median age was 50 years. Table 2 shows that the highest proportion (38%) of the sample aged 50-59 years, and only 18% aged less than 40 years. More than half of the sample (56%) were males. The time since the operation was 8-11 months among 54% of the sample, and it was 12-15 months in 26% of the sample. The most common affected site was the L5-S1 (62%) and L4-L5 (60%), knowing that more than one site was affected in many patients.

It is evident in Table 3 that there was a significant decrease in the mean and median VAS after one month and three months of the intervention ($p < 0.001$). The median VAS was eight before the intervention, decreased to 3 after one month, and 1.5 after three months. The same is for the ODI%, where it is clear that its median decreased from 48% to 22% after one month ($p < 0.001$) and to 13% after three months ($p < 0.001$). The mean difference of the VAS score from the baseline to one month after the intervention was 4.82, and it was 6.82 three months after the intervention, which indicates a decrease in the VAS. However, when comparing the mean of the mentioned difference according to the affected levels, Table 4 shows no significant difference ($p = 0.423$ and $p = 0.316$ after 1 and 3 months), respectively.

The same is for the mean ODI difference, which decreased by 30.44% after one month, and by 48.02% after three months in compared to the baseline value, but there was no significant association with the number of levels ($p = 0.910$ and $p = 0.738$) one and three months after the intervention respectively.

Table 2. Essential characteristics of the studied sample.

	No.	(%)
Age (year)		
< 40	9	(18.0)
40-49	15	(30.0)
50-59	19	(38.0)
≥ 60	7	(14.0)
Gender		
Male	28	(56.0)
Female	22	(44.0)
Time since the operation (months)		
4-7	10	(20.0)
8-11	27	(54.0)
12-15	13	(26.0)
Level of involvement (n = 50*)		
L2-L3	4	(8.0)
L3-L4	12	(24.0)
L4-L5	30	(60.0)
L5-S1	31	(62.0)
Total	**50**	**(100.0)**

***More than one level may be affected.**

Table 3. The VAS and the ODI% were measured before the intervention, one month, and three months after the intervention.

	Mean	(±SD)	Median	Minimum	Maximum	p
VAS Pre	8.38	(±1.07)	8.00	7.00	10.00	
VAS 1 M	3.56	(±0.64)	3.00	3.00	5.00	
VAS 3 M	1.56	(±0.61)	1.50	1.00	3.00	< 0.001*
ODI Pre	61.18	(±8.01)	61.00	48.00	75.00	< 0.001*
ODI 1 M	30.74	(±3.87)	30.50	22.00	41.00	
ODI 3 M	13.16	(±2.93)	13.00	8.00	23.00	< 0.001*
						< 0.001*

***By Wilcoxon signed-rank test comparing with the pre-intervention readings**

Table 4. Parameters of the difference between the pre-intervention reading and the one and three-month readings by the number of levels.

	No. of levels affected	N	Mean	(±SD)	Median	p
Diff. VAS Pre 1Month	One	30	4.97	(±0.81)	5	
	Two	14	4.50	(±1.09)	4	
	Three	5	4.80	(±1.30)	5	
	Four	1	5.00		5	**0.423**
	Total	**50**	**4.82**	**(±0.94)**		
Diff. VAS Pre-3 Months	One	30	6.93	(±0.91)	7	
	Two	14	6.50	(±0.85)	7	
	Three	5	6.80	(±1.30)	7	
	Four	1	8.00		8	**0.316**
	Total	**50**	**6.82**	**(±0.94)**		
Diff. ODI Pre-1 Month	One	30	30.00	(±6.46)	30	
	Two	14	30.86	(±5.79)	29	
	Three	5	31.40	(±4.98)	32	
	Four	1	33.00		33	**0.910**
	Total	**50**	**30.44**	**(±6.00)**		
Diff. ODI Pre-3 Months	One	30	48.07	(±7.77)	49	
	Two	14	47.43	(±5.77)	48	
	Three	5	47.80	(±8.58)	48	
	Four	1	56.00		56	**0.738**
	Total	**50**	**48.02**	**(±7.21)**		

***By Kruskal Wallis test. Diff: Difference between the pre-intervention and one and three months after the intervention. ODI: Oswestry disability index %.**

DISCUSSION

FBSS patients suffer mainly from persistent pain despite conventional medication treatment. They still have continuous pain, limitation of movement, and lower quality of life [20]. The American Pain Society/ American College of Physicians (APS/ACP) guidelines have reported complex benefit-to-harm profiles for medications. With insufficient evidence to recommend one medication over another, the study's time duration was less than two months [21].

Interventional pain physicians may observe better outcomes for individual patients paired with specific procedures. For example, those with epidural fibrosis may respond dramatically to epidural adhesiolysis directed to that level [22]. Epidural Adhesiolysis has been shown to be effective in managing FBSS better than conservative treatments like medications and physiotherapy [19]. Epidural Adhesiolysis is not only effective more than physical therapy, but it is also more effective than caudal epidural steroid injections for the treatment of chronic lower back and leg pain[23], This comes from the ability of the steerable catheter to eliminate adhesions by mechanical effect and also through its steerable soft tip, which can reach our target area and delivers the drug in a reasonable amount and concentration [24].

In our study, the most commonly affected site was the L5-S1 (62%) and L4-L5 (60%), knowing that more than one site was affected in many patients. Chun-Jing et al [22] compared the epidural adhesiolysis with epidural steroid injection in a randomized controlled trial to investigate the efficacy and the feasibility of applying percutaneous lysis of epidural adhesions in failed back surgery syndrome (FBSS). They concluded that patients on epidural lysis reported that the clinical effectiveness rate was 50%. However, for control patients, it was 5.26%, and there was a significant difference between the two groups.

Machikanti et al [25] also compared the epidural adhesiolysis with epidural steroid injection in a randomized equivalence control trial. They found significant pain relief and functional improvement in 82% of the patients in the epidural adhesiolysis (EA) group versus 5% in the epidural steroid injection (ESI) group at the 'one' and 'two' year follow-up ($P < 0.001$).

Lee and Lee [26], compared epidural adhesiolysis (EA) with transforaminal epidural steroid injection (TFESI) in an observational study and concluded that the proportion of successful results was higher for the EA group than for the TFESI group regarding the numerical rating scale and ODI scores at six months.

The same study shows the importance of steerable epidural adhesiolysis in pain relief. Furthermore, it shows a significant decrease of the mean and median VAS after one month and three months of the intervention ($p < 0.001$).

Also, it shows improvement in function and mobility (ODI%), where it is clear that its median decreased from 48% to 22% after one month ($p < 0.001$) and to 8% after three months ($p < 0.001$).

Cho JH et al [27] did a systematic review about the treatment outcomes for patients with FBSS and put a grading for the recommendation level of each treatment for FBSS (Table 5).

Many studies have reported that epidural adhesiolysis is more significant in pain reduction and in functional improvement in contrast to medications and physiotherapy [28, 29]. The efficacy of a steerable catheter for epidural adhesiolysis in comparison to epidural steroid injection was due to the intrinsic features of this catheter in delivering a high amount of steroid, hypertonic saline, and hyaluronidase directly to the target area and also because of its ability to disrupt the adhesions and fibrosis by mechanical navigation[30].

In conclusion, the treatment of FBSS using a steerable epidural catheter with 80 mg Methylprednisolone, hyaluronidase 1500IU, and 3% hypertonic saline for epidural adhesiolysis were effective for pain reduction and functional improvement in patients with chronic lower back and/or leg pain.

This study encourages people to treat FBSS with a steerable catheter for epidural adhesiolysis. However, cost-effectiveness should be considered as this study did not cover economic analysis. Additionally, there is no evidence on whether covering the procedure in routine practice would be economically wise or sustainable.

Ethical Clearance

The Study was approved by the Ethics Committee of the College of Medicine, Hawler Medical University, Kurdistan Region, Iraq (Ethical code number: 08/06/2020- 1/5).

Table 5. Recommendation grade of each treatment for FBSS

Treatment	Outcome	Recommendation
Epidural adhesiolysis	Short term (6-24 months) pain relief and functional improvement	A
Spinal cord stimulation	Mid-term (up to 2-3 years) pain relief and functional improvement	B
Epidural injection	Short-term (up to 2 years) pain relief only	C
Revision surgery	Variable	D

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