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Caudal Epidurography and Therapeutic Steroid Injection in Failed Back Surgery Syndrome (FBSS): A Database Review

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Keywords: Failed back surgery syndrome; Spinal pain; Epidural steroid injection; Caudal epidurography.

Abstract

Background: The role of caudal epidurography and epidural steroid injections in FBSS in low-middle-income countries remains unknown. Failed Back Surgery Syndrome (FBSS) is a chronic pain condition with a significant impact on quality of life. It affects about 5 to 40% of patients who undergo spinal surgery. This retrospective study evaluates the effect of epidural steroid injection using caudal epidurography on pain (static and dynamic) and on functional improvement, mood, and sleep.

Methods: Patients with chronic low back pain and a diagnosis of FBSS and subsequent admission who underwent caudal epidurography with catheter insertion technique between July 2010 and June 2020 were included. Data was retrieved from Pain Management Clinic System (PMCS). A data extraction form was designed to extract pain scores at rest and activity on a numeric rating scale (0-10), sleep, mood, and routine activities at the time of initial presentation and after caudal epidurography.

Results: A total of 73 FBSS patients were included in this study. The mean (SD) patient age was 53. 49 (± 16) years with 85% (n=62) of patients had a history of lumbar spine surgery. A significant difference was observed between the pain scores, after the caudal epidural steroid injection, on rest (p-value <0.001) and activity (p-value < 0.001). Significant (<0.001) improvement was reported in mood and sleep (<0.001). Overall, 79% of patients felt improvement inperforming routine activities after the procedure.

Conclusion: This study found a significant role of epidural steroids using caudal epidurography in alleviating chronic back pain and improving sleep, mood, and routine activities. However, there is a need for further prospective clinical trials to determine the definitive role of epidural steroids in FBSS management and for their incorporation into clinical guidelines.

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Introduction

About 80% of the adult population experience Lower Back Pain (LBP) at some point in their lives, making it a global health concern [1]. The prevalence among the Pakistani population is 40.6%, which is less than other countries in the South Asian counties, it is double what is noted in India [2]. Differential diagnosis of LBP patients with problems of the spine includes disc prolapse, degeneration, inflammation, infection, stenosis, and metastatic involvement or with a failed back surgery syndrome [3].

Failed Back Surgery Syndrome (FBSS) is a chronic pain condition with a significant impact on quality of life [4]. It affects about 5 to 40% of patients who undergo spinal surgery [5]. The International Society for the Study of Pain defines FBSS as "lumbar spinal pain of unknown origin either persisting despite the surgical intervention or appearing after surgical intervention for spinal pain originally in the same topographical location" [6]. The risk is higher in patients who have undergone multiple back surgeries as surgery itself may induce spinal stenosis, instability, epidural fibrosis, or disrupt adjacent discs which may exacerbate existing symptoms or cause new symptoms [7-9].

Management of chronic pain due to FBSS is a real challenge because of the long-suffering and loss of functional activities. The first line of treatment includes conservative management with medications like Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), opioids, anticonvulsants, and antidepressants with physical rehabilitation to facilitate neuroadaptation and developing tolerance [10,11]. Interventional pain management procedure is reserved for patients who do not respond well to medication and physical therapy [12].

The choice of pain interventional procedure for FBSS is based on the underlying etiology of pain and the presence of radiological findings. For FBSS due to facet joint deformity, procedures like radiofrequency ablation of medial branch blocks can be performed while adhesiolysis may be an effective option for FBSS secondary to epidural fibrosis [13]. More generally, the use of epidural steroid injections has been shown to influence pain reduction for FBSS resulting from multiple pathologies including disc prolapse, spinal stenosis as well as epidural fibrosis [14]. However, the quality of evidence supporting these findings is generally moderate to low which warrants a need to explore this treatment option in further detail [13].

During the management plan for FBSS, several factors must be taken into consideration to choose the most appropriate treatment option with the goal of improving the patient's pain and quality of life. Although the role of epidural steroids for FBSS-related back pain has shown promising results, the literature is limited to the developed world with uncertainties in the quality of evidence [13]. Furthermore, limited literature is available regarding the use of epidural steroids for patients with FBBS in Low to Middle-Income Countries (LMIC) particularly using the caudal epidurography technique. Given the low cost and easy availability of steroids in an LMIC like Pakistan, the use of epidural steroid injections as standard management can reduce treatment costs for FBSS in the country. Therefore, the primary objective of this study was to evaluate the effect of epidural steroid injection using caudal epidurography on static and dynamic pain scores. The secondary objective was to evaluate the effect of a Caudal Epidural Steroid Injection (CESI) on functional improvement, mood, and sleep.

Methods

This retrospective data base review was conducted after approval from the Institutional Ethical Review Committee (ERC-2020-4818-11143) of a quaternary care hospital. Patients with low back pain and a diagnosis of FBSS who underwent caudal epidurography with catheter insertion technique and steroid injections between July 2010 and June 2020 were included in the study.

Caudal epidurography with catheter insertion techniques is performed in patients presenting with FBSS. The procedure is performed in a prone position under fluoroscopy after local anaesthesia to the puncture site. A Tuohy needle is inserted into the caudal canal through the sacral hiatus and the catheter is inserted through the epidural needle. The following epidurography is used to confirm the cephalad flow of the dye to the targeted vertebral level. Once the spread of dye is confirmed, a mixture of local anaesthetic and steroid is injected into the epidural space near the target area.

For this study, patient data were retrieved from the hospital's pain management software program called Pain Management Clinic System (PMCS). Medical records of all patients who were presented to the pain clinic with low back pain and underwent caudal epidurography with catheter insertion technique were included. Patients with incomplete data and lost to follow-up after intervention were excluded.

A data extraction form was designed to extract patients' demographic data, pain score at rest and activity using a Numeric rating scale (NRS), sleep, mood, and routine activities at the time of initial presentation in the pain clinic and after caudal epidural steroid administration. Patient-reported pain scores were attained using NRS ranging from 0, corresponding to no pain, to 10 corresponding to the worse possible pain [15]. To ensure patient confidentiality, a log number was assigned to the included patients and all extracted data were anonymised.

Data analysis

Data collected were analyzed by using IBM SPSS (Statistical Package for Social Science) statistical software version 19. Frequency, percentage, mean with standard deviation and median with Interquartile Range (IQR) were calculated for the variables. The Wilcoxon signed-rank test was applied to the pain scores on activity and rest before and after the procedure. McNemar's test was applied to determine whether the proportion of participants who had disturbed mood and sleep before the caudal epidural steroid injection improved after the treatment.

Upon completion of the study, the electronic data was kept password protected whereas hard copies were kept in a locked cupboard in the research cell as per the University policy.

Results

A total of 73 FBSS patients who underwent caudal epidurography were included in this study. Male: female ratio was 29: 44 (39.7: 60.3%). The mean (SD) patient age was 53. 49 (± 16) years while the mean BMI (kg/m^2) was 30.1 ± 5.4.Sixty-two patients had a history of one spinal surgery while the remaining 11 had undergone 2 back surgeries before presenting to our pain clinic. The reported duration of back pain was variable with 40 % suffering for one year, followed by 29% reports for 5 years (**Table 1**). Forty patients did not have any comorbidities while 22 (30.1%) had hypertension, 16 (21.9%) diabetes mellitus, and 9 (12.3%) cardiovascular diseases and other comorbidities.

Table 1: Quantitative and qualitative demographic variables.

Quantitative variables	Mean ± SD[a]
Age (years)	53.49 ± 16
BMI (kg/m^2)	30.1 ± 5.4
Categorical variables	**Frequency (%)**
Gender	
Male	29 (39.7%)
Female	44 (60.3%)
No. of back surgeries performed	
One	62 (84.9%)
Two	11 (15.1%)
Pharmacological treatment tried	
Yes	73 (100%)
No	0
Pain duration	
Less than 1 year	36 (49.3%)
1 to 5 years	21 (28.8%)
5 to 10 years	3 (4.1%)
More than 10 years	13 (17.8%)
SD = standard deviation	

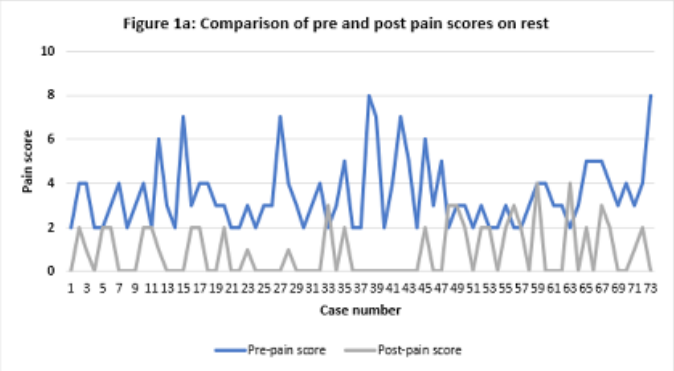
Before undergoing the caudal epidural procedure, patients reported a median (IQR) NRS pain score of 6 (3) on activity and 3 (2) on rest. After the caudal epidurography and steroid injection, the pain scores on activity were reported as 3 (2) and on rest were 0 (2). Statistically significant difference was observed between the pain scores, before and after the injection on activity (p-value < 0.001) and rest (p-value < 0.001). The average pain score decreased by 50% on activity and 100% on rest post-intervention. (**Figures 1a and 1b**).

Before caudal steroid administration, 42 (57.5%) patients reported disturbed mood. Post-treatment, a significant (<0.001) improvement was reported in the mood in 28 (38.4%) patients. Similarly, almost two-thirds (n=44) of patients reported disturbed sleep before the treatment. After the procedure, significant improvement (<0.001) in 30 patients was reported in their sleep (**Table 2**).

Significant improvement was also observed in functional activity after the treatment. Before the treatment, 12 (16.4%) patients could not walk, 42 (57.5%) had limited activity, 13 (17.8%) were mildly disturbed and 6 (8.2%) were active with pain. After the treatment, 3 (4.1%) were fully active, 55 (75.3%) considered themselves improved and 15 (20.5%) thought that no changes occurred.

Table 2: Pre and post treatment comparison of mood and sleep.

Categories	Pre-treatment (n=73)		Post-treatment (n=73)		Positive change	Negative change	p-value[c]
	Yes	No	Yes	No			
Mood	42 (57.5%)	31 (42.5%)	16 (21.9%)	57 (78.1%)	28 (38.4%)	2 (2.7%)	< 0.001
Sleep	44 (60.3%)	29 (39.7%)	14 (19.2%)	59 (80.8%)	30 (41.1%)	0	< 0.001
McNemar test							



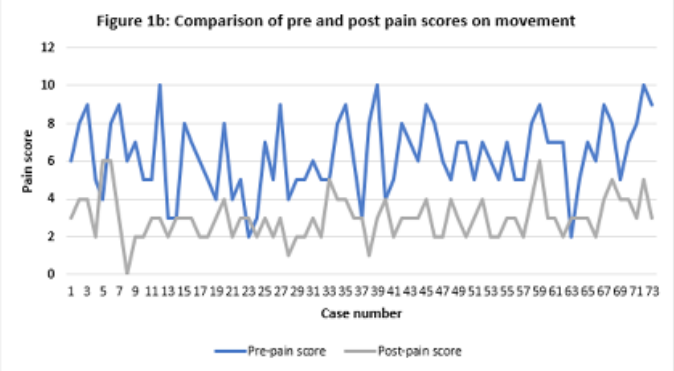


Figure 1: Comparison of pain scores before and after caudal epidural steroids on rest **(1a)** and movement **(1b)**.

Discussion

In this study, the efficacy of caudal epidural steroids administration, through a caudal epidural catheter was evaluated for pain and quality of life in patients with FBSS. Seventy-three patients with FBSS underwent caudal epidurography and steroid injections with a significant improvement in pain after the procedure on rest and activity. This finding is consistent with that of Manc-hikankti et al [16] who evaluated the efficacy of caudal epidural injections, with and without steroids, in patients who had persistent back and/or leg pain 6 months post-surgery and had failed to respond to conservative management. The randomized double-blinded trial found that more than 50% of patients achieved significant pain relief over a period of 1 year with no significant difference between the steroid and non-steroid groups. A 1-year follow-up showed that 56% of patients who received only lidocaine experienced significant pain relief, while 61% of patients who received steroids had significant relief in pain [16].

In current practice, the surgeons, physicians, and pain specialists experience an overwhelming burden of patients with FBSS. Patients with FBSS experience persistent back and/or leg pain despite undergoing spinal surgery like discectomy, laminectomy, or fusion [17]. Concomitantly, pain in this population may arise after surgery. The back pain in FBSS may be accompanied by referred or radiating pain to the lower limbs [18]. Overall, the pain in FBSS not only affects patients' quality of life and well-being but also causes a significant financial burden

on the family as well as the healthcare system, particularly in under-resourced settings like in LMICs [19]. As the prevalence of chronic back pain continues to rise, the rate of lumbar surgeries will also be on a rising trend. With a high failure rate of such procedures, the likelihood of increased prevalence of FBSS is also expected [20-22]. This increasing burden of FBSS warrants the need for a thorough understanding of the condition and increased knowledge of the effective management options by clinicians.

Management of patients with FBSS mainly focuses on chronic back pain. The goal is to start management conservatively and move towards more aggressive options if conservative management does not provide effective pain relief. The failure rates with revision surgery are high and therefore minimally invasive interventional procedures must be considered for pain management [19]. Epidural injections with long-acting steroids have been commonly used to treat LBP. Although the mechanism of action of steroids for pain alleviation has not been fully understood yet, the anti-inflammatory nature, attributed to the reduced production of prostaglandins and phospholipases, may have a role [23,24]. The effectiveness of epidural steroids for FBSS has not yet been determined due to limited and contrasting evidence [13].

The efficacy of epidural injections in FBSS is complicated by factors like anatomical abnormalities, instrumentation and scar tissue formation that pose difficulty for accurate needle placement. Additionally, blind epidural injections especially in patients with past surgeries have a high risk of Duralpuncture [25]. In ourcenter, epidural steroid injection was performed using a caudal epidural approach with catheter insertion under fluoroscopic guidance to minimize the risk of complications and enable adequate and effective administration of steroids. The literature supports the use of imaging modalities to prevent Duralpuncture during drug administration [25].

In this study improvement in sleep, mood, and routine activity with epidural steroids were observed. Of the 42 patients with poor mood before the procedure, more than 50% (n=28) showed improvement in mood. Similarly, 30 out of the 44 patients who had poor sleep before the caudal epidural steroid injection showed significant improvement in sleep after the intervention. It has been found that individuals with chronic pain often experience sleeping difficulties and low moods which poorly impact their quality of life [26]. Therefore, it can be speculated that improvement in pain may also positively affect sleep and mood. This relationship was also noticed in the study arm where patients with significant improvement in pain also experienced an improvement in sleep and mood. Almost 80% of patients also showed functional improvement in routine activities after the procedure. This finding is much higher than the current reported for epidural steroids where around 40% to55% of patients exhibited significant functional improvement after the procedure [16].

This study was limited by retrospective data which prevented direct patient interaction and exploration of patient experience of the procedure and the long-term effectiveness of the intervention. The observational study design, with a lack of a placebo group, raises questions about comparative effectiveness with other epidural injections. The single Centre sample also limits the wide generalization of the outcomes. Despite these limitations, this study provides valuable information about the effectiveness of caudal epidural steroids with a catheter using caudal epidurography for treating FBSS. It also encourages the need for further prospective clinical trials, to establish the definite role of steroids in alleviating symptoms of FBSS and for its incorporation into clinical guidelines and practice.

Conclusion

It was found that there is a positive role of caudal epidural steroids using caudal epidurography in alleviating pain in patients with FBSS and improving sleep, mood, and routine activities in limited resource settings. However, there is a need for prospective clinical trials to determine the definitive role of caudal epidurography and epidural steroids injection in FBSS management. The development and implementation of regional clinical guidelines is future perspectives.

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Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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Data statement

The data used for this study is with the Principal Investigator and is an institutional property, can be provided upon reasonable request.

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