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EFFECTIVENESS AND LONG-TERM OUTCOMES OF CAUDAL EPIDURAL STEROID INJECTIONS USING THE LOSS OF RESISTANCE TECHNIQUE IN FAILED BACK SURGERY SYNDROME

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Abstract

Failed back surgery syndrome (FBSS) is a complicated disorder that is characterized by continued pain after spinal surgery, which has a great impact on the quality of life of patients. The study was a retrospective evaluation of the short- and long-term outcomes of caudal epidural steroid injections (CESI) using Loss of Resistance (LOR) technique in 75 FBSS cases who were receiving CESI at Ratchaburi Hospital January 2014 through December 2018. Visual Analog Scale (VAS), Oswestry Disability Index (ODI) and Patient Satisfaction Score (PSS) were used to measure the outcome at the baseline, and follow-up (3, 6, 12, 18 and 24 months). The outcomes showed that there was a great improvement in pain, disability, and patient satisfaction with benefits extending to two years. Another point presented by the study is that patient-reported outcomes should be taken into account when evaluating the efficacy of CESI. The findings indicate that CESI is an effective, safe, and practical option of treatment to maintain FBSS, especially to patients who have failed to respond to conservative therapies.

Keywords: Failed back surgery syndrome, Epidural steroid injection, Loss of Resistance technique, Patient satisfaction, Chronic pain

INTRODUCTION

Failed back surgery syndrome (FBSS) is a controversial and even debilitating problem that involves persistent or recurrent pain after having a spinal surgery that greatly impacts the quality of life of a patient. The history of the condition is not simple and the lack of the standardized diagnostic criteria makes the treatment difficult. Patients with FBSS can also have lower back pain, pain in the legs or both and this causes difficulties in doing the daily activities and causes emotional distress.1 FBSS can be treated by use of conservative therapy, interventional therapy and surgical therapy with some degree of success. Although there is always a chance of surgery, a surgery procedure has its own risks and is more expensive, and may not be more effective than non-surgical procedures in treating chronic back and leg pain under fluoroscopic or ultrasound guidance.6 Previous studies have shown that CESI is capable of providing effective treatments with respect to chronic back and leg pain, though not better than non-surgical treatments.7,8 The proposed study is, therefore, a retrospective one in the evaluation of the short-term and long-term outcomes of CESI via the LOR technique in FBSS patients with 18G Tuohy needle, where the patients are to receive a drug combination of 80 mg/2 ml of triamcinolone and 18 ml of normal saline.

METHODS

It is a retrospective type of study having 75 participants of FBSS who have had CESI at Ratchaburi Hospital between January 2014 and December 2018 and conducted by one orthopedic specialist. In a previous study, 88 people with FBSS were recruited however 13 of them refused to continue CESI within the first six months and eight of them chose surgery. Everyone together with their families reduced their physical activities following CESI. After the process, the subjects were left on non-surgical therapy. The Ratchaburi hospital human research ethics committee approved the study and the approval number (COA-RBHEC 051/2023). Everything was done as an inpatient.

Inclusion Criteria:

The study included patients aged between 20 and 90 years old with lower back pain, unilateral pain, or bilateral leg pain, persistent pain in spite of a history of failed back surgery, failure of non-surgery with more than eight weeks of treatment, MRI verification of the cause of FBSS and a VAS score of 8 and PSS score of 3 at baseline.

Exclusion Criteria:
Those patients whose neurological symptoms were severe or progressive, or whose lower back and leg pain were due to specific causes (e.g., tumors, infections, trauma), comorbid conditions contraindicating the use of CESI (e.g., bleeding disorders, dementia, epilepsy, allergies to steroids), pregnant women, active infections, and those who have already received CESI at least once were not included.

Sample Size Determination:
Results in previous research to determine mean VAS at one year follow-up: One year VAS mean = 4.82, standard deviation (SD) = 0.78, pre-injection VAS mean = 7.11, effect = 0.2, significance = 0.05, power = 0.8, two tailed. The sample of 128 participants obtained with the help of G Power was determined on the basis of the prior researches that examined VAS scores at the one-year follow-up.

Data Collection:
We measured VAS scores, ODI and PSS in the pre-intervention time, and at 3, 6, 12, 18 and 24 months after the procedure. The medical records were selected to provide patient demographics, clinical characteristics, MRI results, and outcome measures. Failure was the presence of VAS greater than five, ODI greater than forty, and PSS less than five. VAS is a numerical scale that would measure the intensity of lower back pain or leg pain at 0 (no pain) to 10 (worst pain). ODI is a self-administered questionnaire on the level of disability during daily activities because of lower back or leg pain and the scores vary between 0 (no disability) and 100% (maximum disability). The PSS is a numerical measure of patient satisfaction, a scale that goes between 0 (unsatisfied) and 10 (completely satisfied). The statistical analysis was done with Stata 18.0 MP software. Mean plus SD was used to present continuous variables whereas mean and frequency were used to present categorical variables. A paired t-test was used to compare pre and post-intervention outcomes, and the significance level was taken as $p<0.05$.

CESI Procedure:
The CESI process was performed in the operating room in the state of strict aseptic conditions. The patient was put in the prone position with the pillows to support the chest and the pelvis. Surface anatomy was used to palpate the sacral cornua, which is an anatomical landmark to the insertion of the needle into the sacral hiatus. The injection area was washed and covered with a gown after which a local anesthetic (2% xylocaine without adrenaline, 5 CC) was applied. Monitored anesthesia was used to carry out CESI to promote the safety of the patient and reduce severe outcomes. A Tuohy needle (18G) was then inserted into the sacral hiatus at an angle of 15 degrees and the needle will be advanced until the sacrococcygeal ligament is met, which is an indication of the epidural space. Aspiration was then done to be sure that the needle has not accidently punctured either a blood vessel or the space of the cerebrospinal fluid. The Loss of Resistance (LOR) procedure was used to make sure that the needle was correctly placed in epidural space. The next step involved the addition of 4 CC of air by the needle. The surrounding tissues responded to the probe by resistances that were first met but then suddenly faded or ceased on entering the epidural space where the pressure was less. This reflected that the needle was at the right place in the epidural space (Figure 2). After checking the location of the needles, a solution (triamcinolone 80 mg/2 ml and 18 ml of normal saline) was gradually injected into the epidural area (Figure 3). Even distribution and the possibility of complications are minimized with this injection mix. Close observation was done after injecting the patient to check whether he had any severe adverse reactions. They were admitted to spend one day at the hospital and then discharged with the follow-up appointments thereafter.

RESULTS

Table 1: Characteristic and Clinical Data of Patients.

Characteristic	N (%)
Demographic Data	
Age (in years)	47.25 ± 11.92
BMI (kg/m²)	28.43 ± 4.12
Duration of symptoms before CESI (weeks)	14.75 ± 5.33
Gender (Male: Female)	28:47
Procedure time (minutes)	5.85 ± 2.14
Signs and Symptoms	
Low back pain only	2 (2.67)
Low back pain with	73 (97.33)
Right sciatica	14 (18.67)
Left sciatica	21 (28.00)

Bilateral sciatica	40 (53.33)
MRI Finding	
Recurrent disc herniation	38 (50.67)
Adjacent instability	26 (34.67)
Fibrosis	11 (14.67)
Associated Disease	
Hypertension	39 (52.00)
Dyslipidemia	31 (41.33)
Diabetes mellitus	21 (28.00)
Smoking	13 (17.33)
Alcohol intake	17 (22.67)

Table 2: Occupation Distribution.

Occupations	N (%)
Farmer	18 (24.00)
Business	22 (29.33)
Government officer	9 (12.00)
Maid	8 (10.67)
Unemployed	6 (8.00)
Labourers	7 (9.33)
Other	4 (5.33)

The researchers completed the demographic and clinical data of 75 patients who received CESI in case of failed back surgery syndrome (FBSS). The mean age of the patients was 47.25 years and the standard deviation was 11.92 years. The average BMI was 28.43 kg/m 2, which meant that the group of patients was slightly overweight. The mean period of symptoms before CESI was 14.75 weeks with some variation (SD = 5.33). The gender of the patients showed that most of them were female, with female patients being 47 and males being 28. The CESI procedure time was fairly fast with an average of 5.85 minutes (SD= 2.14) and can be considered an effective treatment regimen. Regarding the symptoms, most patients (97.33) had low back pain with sciatica whereas 2.67 had low back pain alone. The sciatica distribution was as follows; 18.67% right-side sciatica, 28% left-sided sciatica, and 53.33% bilateral sciatica. MRI results revealed that recurrent disc herniation was the most frequent cause, which existed in 50.67% of patients and was followed by adjacent instability (34.67) and fibrosis (14.67). This fact underlines the phenomenon of the complexity of FBSS, which frequently entails a multiplicity of underlying pathologies. The patient population had associated diseases and was mostly affected by hypertension 52 percent, dyslipidemia 41.33 percent and diabetes mellitus 28 percent. Patients with 17.33 and 22.67 percent had smoking and alcohol usage respectively. Such comorbid disorders can affect the results of CESI, which should be taken into account when working with FBSS patients. The distribution of the patients occupation is provided in Table 2. The biggest portion of the patients were engaged in business (29.33%) and then farmers (24%) and government officers (12%). Other significant percentages of the sample were maid services (10.67) and laborers (9.33). Fewer percent of the patients were unemployed (8%), and those who claimed to be part of other occupations (5.33). This work information will help in the determination of the socioeconomic status and lifestyle of the study participants which may be associated with the occurrence of FBSS and its outcomes of treatment.

DICUSSION

Other previous research works on CESI have provided different criteria on whether it is a success or failure based on the data or literature. Chaudhary et al. evaluated the outcomes based on numeric pain rating scale, ODI, straight leg raise (SLR), and modified Schober test. Adiya et al. compared CESI results using ODI and VAS pain score. When defining failure as a VAS score 5 or above, the patients who did not improve at 3, 6, 12, 18 and 24 months were 34, 12, 5, 3, 5, and 4 respectively in our study. Nonetheless, in the case of failure involving both VAS 5 and ODI 40 the failure rates were 2, 2, 2, 2, 2, and 1. The method is valuable because it puts the right standards in determining failure of treatment. We have also added the PSS to determine patient satisfaction, which is important in outcome measurement. It is important that the patient satisfaction with the treatment process or treatment outcome be properly evaluated and reported. This paper understands failure as VAS >5, ODI >40 and PSS <5 where two patients have not improved according to this criterion. The increased level of patient satisfaction (when compared to the previous) is a substantial one since CESI plays a significant role in pain relief and functional improvement which is a significant advantage to health and well-being. It emphasizes the need to take patient-reported outcomes into account, which include PSS, disability, and pain. In comparison to the past researches which have demonstrated the effectiveness of CESI in the short run in treating FBSS,

the research presently contributes novel information as the effects could last as long as two years. This study proves that CESI may be beneficial to patients who do not respond to conservative interventions effectively, who may be considered at significant risk of surgery, or who need a less invasive approach. Nevertheless, pain management experts have yet to agree on the kind, amount, frequency, and overall amount of injections, as well as the same of other interventions. It is not completely known what therapeutic actions of steroids occur in FBSS, but the anti-inflammatory and immunomodulatory effects are probable to be involved. These mechanisms still need to be studied and CESI protocols optimized through further research. The needle and medication used are the most important parts in CESI procedures. Here, the Tuohy needle was 18G. The Tuohy needle with its blunt tip and a mild curve helps to enter the epidural space atraumatically and minimizes the possibility of dural puncture. The triamcinolone mixture was 80 mg/2 ml in normal saline 18 ml and this mixture is CESI mixture that aids in reducing the tissue trauma and makes it easy to inject. Triamcinolone, an effective corticosteroid, which has anti-inflammatory and immunomodulatory effects, is appropriate in the FBSS, where inflammation has a major role. The Tuohy needle combined with triamcinolone/saline solution was probably the cause of the prolonged effectiveness of CESI in the present study. Even with the use of ultrasound to guide the epidural space, Chen et al. have demonstrated LOR technique with the use of air in order to confirm successful penetration of the epidural space in FBSS. Stitz et al. recorded that, 74.1 percent of patients were successfully needle placed on the primary attempt with a combination of anatomical landmarks and palpable air over the sacrum indicating successful injection in 91.3 percent of attempts which means that LOR is as effective as fluoroscopic guidance. Our research is based on these results and evidently proves that CESI using the LOR technique is safe and effective in the blind case, without imaging guidance. CESI when guided by ultrasound or fluoroscopic is associated with extra technical equipment and can lead to complications due to contrast media. The major and long-lasting changes in pain (reduction of VAS by 74.49 percent), disability (reduction of ODI by 56.09 percent), and patient satisfaction (an increase in PSS by 75.76 percent) up to the two-year follow-up indicate the possibility of CESI with LOR technique as a successful intervention in FBSS. Especially remarkable are the constant satisfaction levels of patients and the increase in PSS. Pain treatment and CESI are regarded as sources of positive treatment results and better health. Patient-reported outcome such as the PSS should be an important consideration when assessing the efficacy of therapy as should more traditional measures of pain and disability. The study illustrates that CESI on the LOR technique is a feasible safe method of managing FBSS to a maximum of two years. The long-term positive outcomes in pain, disability, and patient satisfaction indicate that CESI has the potential of managing FBSS in the long term. Steroids anti-inflammatory effects provide important mechanisms in the treatment of FBSS, and CESI treatment protocols are to be researched in order to perfect the guidelines. This paper highlights the two-year follow-up as it demonstrates that sustained CESI injections can be effective in the reduction of pain and enhancement of functions in the long-run of patients with FBSS. But the long term use of corticosteroids may cause some severe side effects such as osteoporosis, adrenal suppression and predisposition to infection. Hence, the extension of CESI to triamcinolone after 24 months of administration should be a well-thought issue. The fact that the hypertension and dyslipidemia occur more frequently in the less favorable during CESI outcomes implies that these factors might affect the treatment outcomes. The fact that cases of diabetes are increasing in these patients should receive additional research on the possible effects it may have in the treatment outcomes. The reason is that the incidence of smoking and alcohol use in the less responsive group is low, and as such, these factors might not be significant contributors to treatment failure. Surprisingly, patients with occupations that required a lot of physical activity and movement like farming performed poorly, as their job may have affected the recovery and management of pain once the procedure has been done. The strengths of our study are a thorough evaluation across time points and taking into account comorbidities that can influence the outcomes of treatment.

CONCLUSION

The paper shows that caudal epidural steroid injections (CESI) with the use of the Loss of Resistance (LOR) method is effective and safe to treat the failed back surgery syndrome (FBSS). The findings suggest that CESI yields considerable and permanent pain, disability and patient satisfaction outcomes and benefits up to two years. The 18G Tuohy needle, as well as the collaboration of triamcinolone and normal saline have added success to the procedure, reducing the amount of tissue trauma and enhancing the precision of the epidural space penetration. We found that the use of patient-reported outcomes, including the Patient Satisfaction Score (PSS), with the traditional ones like the Visual Analog Scale (VAS) and the Oswestry Disability Index (ODI) would help to assess the effect of CESI on patient satisfaction in all aspects. Although the study suggests the use of CESI as an effective treatment intervention in patients with FBSS who did not respond to conservative treatment methods or who are at high risk of surgery, more research is necessary in order to streamline treatment regimens such as the nature, dosage, frequency, and quantity of injections. Moreover, there is the issue of the long-term risks, including osteoporosis and adrenal suppression, which should be taken into consideration. The results also indicate that comorbidity factors such as hypertension, dyslipidemia, and diabetes might also have a bearing on the results of CESI and hence there is the need to examine the effect of these conditions on the treatment

outcomes. All in all, CESI using LOR technique provides an encouraging and less invasive option of managing FBSS and long-term patient outcomes.

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