International Journal of Research in Orthopaedics
*Bamroongshawgasame T. Int J Res Orthop. 2024 Nov;10(6):1111-1116*
http://www.ijoro.org

DOI: https://dx.doi.org/10.18203/issn.2455-4510.IntJResOrthop20242655

**Original Research Article**

# Long-term outcomes of caudal epidural steroid injection in failed back surgery syndrome patients with loss of resistance technique

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**Received:** 18 August 2024
**Accepted:** 03 September 2024

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## ABSTRACT

**Background:** Failed back surgery syndrome (FBSS) is a complicated issue with various treatment approaches. This retrospective study assesses the success and safety of caudal epidural steroid injection (CESI) in FBSS patients utilizing the loss of resistance (LOR) strategy, focusing on long-term outcomes lasting up to two years.
**Methods:** The 75 FBSS patients had CESI with triamcinolone and normal saline under local anesthesia. The visual analog score (VAS), Oswestry disability index (ODI), and patient satisfaction score (PSS) were measured at pre-intervention and 3, 6, 12, 18, and 24 months following the procedure.
**Result:** Majority of patients (57.33%) reported bilateral sciatica, with recurrent disc herniation (54.67%) being the most prevalent MRI finding. Significant improvements ($p<0.001$) in VAS, ODI, and PSS scores were seen in all subsequent periods. Furthermore, no significant issues reported, demonstrating the safety and effectiveness of CESI with LOR.
**Conclusions:** CESI with the LOR technique is helpful treatment in FBSS at three, six, twelve, eighteen, and twenty-four months. It is easy to perform, less technically demanding, has low complications, and lower costs than surgery. A CESI may offer an alternative approach to managing FBSS for short-term and long-term outcomes.

**Keywords:** Caudal epidural injection, FBSS, Spine surgery, LOR technique, Epidural steroid injection, Long-term outcome

## INTRODUCTION

Failed back surgery syndrome (FBSS) is a debatable and occasionally severe sickness characterized by incurable or recurring pain later than spinal surgery that has significant results on a patient's quality of life. The history is difficult to understand, and the lack of defined diagnostic criteria complicates therapy. Patients with FBSS might have low back pain, leg pain, or both, which impairs their ability to function and induces psychological stress.[1]

FBSS treatment includes conservative, interventional, and surgical procedures, each of which has varying degrees of effectiveness. Physical therapy and medication are typical conservative therapies that provide temporary relief.[2,3] Surgery is still possible but involves inherent risks and more significant expenses and may not result in better results than nonoperative treatments.[6] Prior studies have demonstrated the effectiveness of CESI in chronic back and leg pain under fluoroscopy or ultrasound guidance.[7,8] However, CESI performance in FBSS for extended outcomes has limited results. Therefore, this retrospective study aims to assess the short-term and long-term outcomes of CESI with the LOR technique in FBSS patients by using an 18G Tuohy needle, which deployed, along with a drug combination of triamcinolone 80 mg/2 ml and 18 ml of normal saline.

## METHODS

This is a retrospective study. 75 FBSS patients who underwent CESI in Ratchaburi hospital from January 2014 to December 2018 by a single orthopedist were enrolled. In an early study, 88 patients who suffered from FBSS

were registered, and 13 patients refused to continue CESI in the early six months; eight patients underwent surgery. All patients with relatives practiced decreasing their activities after CESI. After the procedure, the patients continued non-operative treatment. The Ratchaburi hospital human research ethics committee has approved this study, and the ethical number is (COA-RBHEC 051/2023). All interventions were performed on an inpatient basis.

***Inclusion criteria***

Patients with age 20 to 90 years, pain in the lower back, unilateral or bilateral legs, persists despite a history of failed back surgery, failure of nonoperative treatment more than eight weeks, MRI confirmation of the cause of FBSS and VAS score ≥8 and PSS score ≤3 at baseline were included in study.

***Exclusion criteria***

Patients with severe neurological symptoms or progressive deficits, specific disorders causing low back and leg pain (e.g., tumor, infection, trauma), comorbidities contraindicating CESI (e.g., bleeding disorder, dementia, epilepsy, steroid allergy), pregnancy, active infection, follow-up duration less than 24 months, inadequate medical records and CESI more than one time were excluded.

***Sample size determination***

Data from the prior studies evaluated mean VAS scores at one-year follow-up:[9] One-year VAS mean (posttreatment)=4.82, standard deviation (SD)=0.78, pre-injection VAS mean=7.11, effect size=0.2, significance level=0.05, power=0.8, two-tailed test. The sample size was 128 patients, calculated using G Power based on prior studies evaluating mean VAS scores at one-year follow-up.

***Data collection***

We recorded VAS scores, ODI, and PSS for the preintervention period and 3, 6, 12, 18, and 24 months post-procedure. The patient demographics, clinical characteristics, MRI findings, and outcome measures were obtained from medical records. VAS exceeded five, ODI exceeded forty, and PSS less than five, which was a failure. The VAS is a numerical score that points to the severity of lower back or leg pain. The score is usually between 0 and 10, with zero indicating no symptom and ten suggesting the worst symptom.

The ODI is a self-administered questionnaire that computes a percentage score representing an individual's degree of function (disability) in daily tasks while recovering from lower back or leg pain. Each question had six statements that scored from 0 to 5. The lowest disability appears as a zero, while the maximum disability is represented by a five. 0% seem to have no disability. However, 100% means the most significant level of disability. The PSS is a numerical assessment of patients' satisfaction. The score is normally between 0 and 10, with zero suggesting unsatisfaction and ten indicating complete satisfaction.[10]

We use Stata 18.0 MP software for statistical analysis.

The continuous variables were demonstrated as mean±SD. The category variables were expressed as mean and frequency. Pre-and post-intervention measures of outcomes were compared using a paired t test. Statistical significance was calculated at $p<0.05$.

***CESI procedure***

The CESI procedure was done in the operating room under strict, clean, and sterile conditions. Figure 1 shows the standard set of equipment. The patient was prone with pillows supporting the chest and pelvis. The sacral cornua, the anatomical marker for needle entry into the sacral hiatus, was palpated using surface anatomy. Following cleaning and draping the injection site, a local anesthetic (2% xylocaine without adrenaline, 5 CC) was administered. Under a monitorial anesthetic, CESI was performed to ensure patient safety and any serious outcomes. A Tuohy needle number 18G was carefully introduced into the sacral hiatus at a 15-degree angle. It was advancing the needle until the sacrococcygeal ligament felt like it was proposing the epidural space.

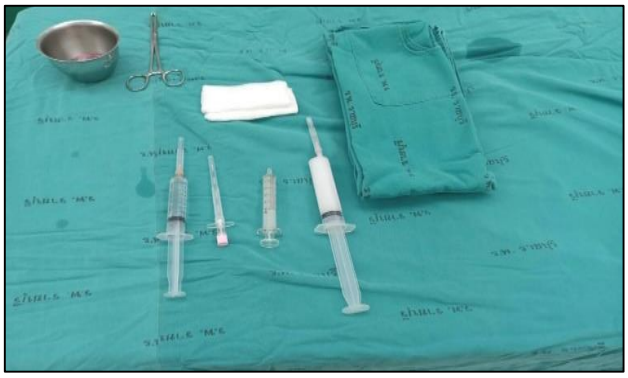

**Figure 1: Standard equipment set and triamcinolone 80 mg/2 ml. mixed with 18 ml. of normal saline solution for CESI.**

Aspiration was then performed to assert that the needle would not, by error, penetrate a blood vessel or the cerebrospinal fluid area. The LOR technique was employed to guarantee accurate needle position in the epidural space. Then, 4 CC of air was gently injected through the needle. Initially, resistance would be pressure within the surrounding tissues. However, the resistance suddenly dissipated or was erased upon entering the epidural space with lower pressure. This event meant that the position of the needle tip was adequate within the epidural area (Figure 2). Once the confirmation of needle placement was sufficient, the mixture (triamcinolone 80

mg/2 ml mixed with 18 ml normal saline) was slowly restored into the epidural space (Figure 3). The injection mixture provides distribution and lowers the likelihood of problems. The patient was observed entirely post-injection to ensure none of the worst reactions. They were rested in the hospital for one day before being discharged and follow-up appointments according to the schedule.

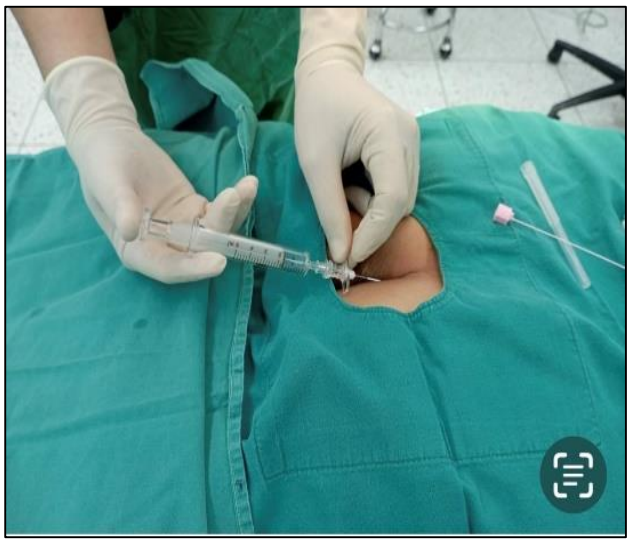

**Figure 2: Demonstrate the LOR technique by gently introducing 4 CC of air freely.**

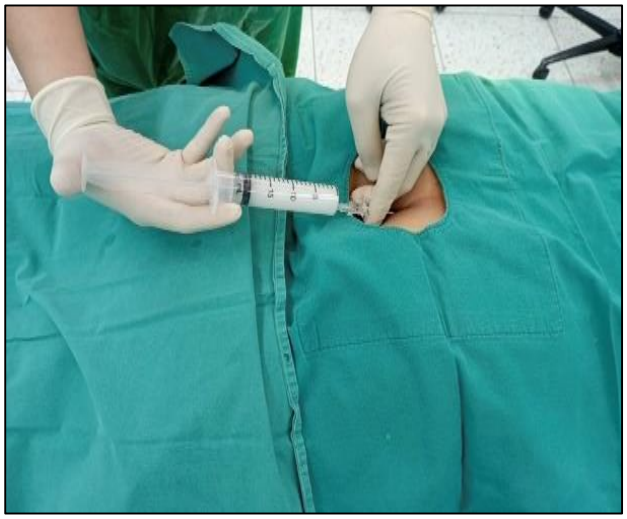

**Figure 3: Injection of triamcinolone 80 mg/2 ml mixed with 18 ml of normal saline solution.**

## RESULTS

Seventy-five patients (mean age 50.35±13.51 years) met the inclusion criteria. The most common magnetic resonance imaging (MRI) finding was recurrent disc herniation (54.67%), followed by adjacent instability (32.00%) and fibrosis (13.33%). Signs and symptoms initially showed that most patients had combined lower back pain and radicular leg pain (98.67%); only one had lower back pain (1.33%).

The female was 51, and the male was 24. Hypertension, dyslipidemia, and diabetes mellitus were 36 (48.00%), 34 (45.33%) and 23 (30.67%) (Table 1).

Table 2 shows the distribution of occupations: farmer (28.00%) followed by business (26.67%) and government officer (14.67%).

Table 3 illustrates the changes in mean VAS, ODI, and PSS scores over time.

Statistical analysis demonstrated that pain levels (lower back and leg), disability, and patient satisfaction showed marked improvement at every subsequent assessment compared to the baseline measurements. These improvements were statistically significant ($p<0.001$).

Failure incidence was 2.67%, and all were female with adjacent segment instability. Her jobs were farmers. Table 4 demonstrates number of CESI failures at different time points. One patient failed at 3 months, and one at 6 months.

**Table 1: Characteristic and clinical data of patients.**

| Characteristic | N (%) |
|---|---|
| **Demographic data** | |
| Age (in years) | 50.35±13.51 |
| BMI (kg/m$^2$) | 27.17±3.08 |
| Duration of symptoms before CESI (weeks) | 13.25±4.45 |
| Gender (Male: female) | 24:51 |
| Procedure time (minutes) | 6.32±2.08 |
| **Sign and symptom** | |
| Low back pain only | 1 (1.33) |
| Low back pain with | 74 (98.67) |
| Right sciatica | 12 (16.00) |
| Left sciatica | 19 (25.33) |
| Bilateral sciatica | 43 (57.33) |
| **MRI finding** | |
| Recurrent disc herniation | 41 (54.67) |
| Adjacent instability | 24 (32.00) |
| Fibrosis | 10 (13.33) |
| **Associated disease** | |
| Hypertension | 36 (48.00) |
| Dyslipidemia | 34 (45.33) |
| Diabetes mellitus | 23 (30.67) |
| Smoking | 12 (16.00) |
| Alcohol intake | 15 (20.00) |

**Table 2: Occupation distribution.**

| Occupations | N (%) |
|---|---|
| **Farmer** | 21 (28.00) |
| **Business** | 20 (26.67) |
| **Government officer** | 11 (14.67) |
| **Maid** | 10 (13.33) |
| **Unemployed** | 7 (9.33) |
| **Labourers** | 4 (5.33) |
| **Other** | 2 (2.67) |

**Table 3: Outcome measures at different time points.**

| Outcome measure | Baseline | 3 months | 6 months | 12 months | 18 months | 24 months |
|---|---|---|---|---|---|---|
| **VAS** | 9.77±0.42 | 4.36±1.35 | 2.59±1.53 | 2.15±1.75 | 2.28±1.90 | 2.55±2.12 |
| **ODI** | 55.75±9.08 | 34.77±11.18 | 27.01±11.92 | 23.73±12.21 | 23.55±12.64 | 25.12±13.07 |
| **PSS** | 0.37±0.71 | 7.48±1.52 | 8.00±1.60 | 7.87±1.84 | 7.88±1.95 | 7.77±2 |

**Table 4: Number of failures to CESI at different time points.**

| Outcomes | 3 months | 6 months | 12 months | 18 months | 24 months |
|---|---|---|---|---|---|
| **VAS** | 8 | 10 | 12 | 13 | 13 |
| **ODI** | 8 | 9 | 9 | 10 | 10 |
| **PSS** | 1 | 2 | 2 | 2 | 2 |

## DISCUSSION

Prior studies of CESI used the criteria of failure or success, depending on their literature or data population. Chaudhary et al reported the numeric pain rating scale, ODI, straight leg raise (SLR), and modified Schober test in their outcome measures. Adiya et al evaluated the results of CESI by measuring ache scores on ODI and VAS.[9] In our study, when the failure group was classified by only VAS≥5, the number of patients who failed to intervene at 3, 6, 12, 18, and 24 months were 34, 12, 5, 3, 5, and 4. When the failure group included VAS≥5 and ODI≥40, the number of patients who failed to intervention at 3, 6, 12, 18, and 24 months were 2, 2, 2, 2, 2, and 1. This is important because it appropriately uses criteria to determine treatment failure groups. We applied the PSS to include the failure criterion. It is always necessary and proper to carefully calculate and report on patient satisfaction with either outcome or process.[10,11] This study applied VAS exceeding five, ODI exceeding forty, and PSS less than five, which was a failure. Two patients failed CESI because of this criterion. The elevated patient satisfaction rate is significant. The positive effects of CESI on pain relief and functional improvement contribute to the benefit of the treatment and health. It underlines the importance of considering patient-reported outcomes, such as PSS, disability, and pain. The results of this study are compared with past studies that demonstrate the effectiveness of CESI in the short term for FBSS.[6-9] However, this study goes further, pointing out that the benefits might last up to two years. This research approves how CESI might be advantageous for patients who have failed to demonstrate a satisfactory response to conservative management, are at high risk for surgery, or would like a less invasive procedure. There is no consensus among the interventional pain management specialists concerning type, dosage, frequency, total number of injections, or other interventions. The therapeutic effects of steroids in FBSS are not fully understood; anti-inflammatory of corticosteroids and immunomodulatory properties are likely contributors.[12,13] Further research is needed to elucidate these mechanisms and optimize CESI protocols for FBSS.

The choice of needle and medication combination is crucial in CESI procedures. In this study, an 18G Tuohy needle was employed. With a blunt angle and a slight curve, the Tuohy needle's design facilitates atraumatic entry into the epidural space and reduces the risk of dural puncture.

The CESI uses 80 mg/2 ml of triamcinolone and 18 ml of normal saline through the 18 G gauge, which is the proper ease injection and minimization of tissue trauma. While a powerful corticosteroid with anti-inflammatory and immunomodulatory properties, triamcinolone is suitable for FBSS, in which inflammation plays a major role. The Tuohy needle and the specific triamcinolone/saline solution may improve the extended success of CESI in this investigation. Chen et al demonstrated the LOR technique using air to indicate successful epidural space penetration in FBSS, even when using ultrasound guidance.[7] According to Stitz et al reported that successful placement of the needle on the first attempt occurred in 74.1% of the patients; the combination of these two signs of anatomical landmarks and no palpable air subcutaneously over the sacrum predicted a successful injection in 91.3% of attempts and showed the effectiveness of blind LOR compared to fluoroscopy guidance.[17] The results of our study build upon these findings by demonstrating the safety and efficacy of CESI with the LOR technique in a blind approach without imaging guidance. Using an ultrasound guide and fluoroscope guide for CESI is a technical demand and needs more setting equipment. The complications of contrast media were reported with these techniques. The significant and sustained improvements in pain (74.49% reduction in VAS), disability (56.09% reduction in ODI), and patient satisfaction (75.76% improvement in PSS) observed up to two years after procedure underscore the potential of CESI with LOR as a valuable treatment option for FBSS patients. The beneficial patient satisfaction rates and the constant PSS ratings are particularly remarkable. Pain relief and CESI contribute to positive treatment outcomes and improve overall healthiness. When assessing therapy efficacy, outcomes reported by patients, such as the PSS, must be carefully weighed against traditional pain and impaired asset measures. This research shows that CESI,

using the LOR technique, is both practical and safe for treating FBSS for up to two years. Improvements in pain, disability, and patient satisfaction even two years after the intervention suggest that CESI can successfully control FBSS.

Their anti-inflammatory properties offer the mechanisms of steroids in FBSS treatment, and CESI guidelines for FBSS treatment need to be studied for more research. This study stresses two years after the intervention period. According to research, ongoing CESI injections may benefit from the reduction of pain in the long term and functional improvement for FBSS patients. However, it is critical to understand that prolonged corticosteroid treatment has serious symptoms such as osteoporosis, adrenal suppression, and increased susceptibility to infection. As a result, the choice to continue CESI with triamcinolone after 24 months should be observed.[13,14] The high-frequency hypertension and dyslipidemia in the group with inferior CESI results show a link between these diseases and decreased treatment effectiveness. The increase in the class of diabetes in that group warrants further questioning into its potential influence on outcomes from treatment. The low incidence of smoking and alcohol use in the less responsive group shows that these features may not play a substantial role in treatment failure in this patient population. Patients who have failed the CESI are farmers. Their occupation might be connected to farming's physically demanding nature, which could influence recovery and pain management following the procedure.

Our study's strengths include a full assessment of outcomes over a variety of timelines and the inclusion of related comorbidities.

### *Limitations*

This retrospective study has limited power on potentially confounding variables and biases. The definition of failure based solely on baseline VAS, ODI, and PSS might not capture the full spectrum of treatment outcomes. The small sample size can restrict the fault of generalizability, especially within the failure group and without a control group; the observed gains are mainly ascribed to the CESI technique. Further studies to explore the relationship between CESI and treatment outcomes would include a comparison group and consider a wide definition of failure that encompasses outcomes in the long term and measurement of a patient's quality of life. Additionally, exploring potential comorbidities and their influence on treatment outcomes could help identify factors that might increase risk of failure, even with CESI. Further study is needed to determine the proper timing and frequency of CESI in FBSS. While our study demonstrated significant outcomes at all follow-ups, the endurance of these benefits and the need for frequent injections are demonstrably unknown. Future studies should evaluate the long-term outcomes of CESI and explore the most appropriate treatment procedures to maximize patient outcomes.

## CONCLUSION

This retrospective study proves the effectiveness of CESI with the LOR technique in FBSS patients up to two years post-procedure. Pain, disability, and satisfaction improved conspicuously and sustainably. Further refinement of injection techniques and investigation of the underlying mechanisms of action are needed to maximize the therapeutic effects of CESI with the LOR technique in FBSS.

## ACKNOWLEDGEMENTS

The author would like to thank Dr. Oramon Bamroongshawgasame for assisting with the data analysis.

*Funding: No funding sources*
*Conflict of interest: None declared*
*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Bamroongshawgasame T. Long-term outcomes of caudal epidural steroid injection in failed back surgery syndrome patients with loss of resistance technique. Int J Res Orthop 2024;10:1111-6.