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Evaluation of percutaneous adhesiolysis for the management of chronic pain due to post spine surgery syndrome

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ABSTRACT

Background: Failed back surgery syndrome (FBSS) is a persistent radicular and/or lumbar pain following spine surgery. Percutaneous adhesiolysis (PA) has proved efficacy for the treatment of intractable chronic pain after failure of conservative management.

Aim: Our research aims to investigate the effectiveness and safety of percutaneous epidural adhesiolysis using RACZ catheter as Numeric rating scale during 6-month duration as a primary outcome and catheter related complication as a secondary outcome among patients suffering chronic leg and low back pain in patients with failed back surgery syndrome.

Methods: 20 patients who were screened diagnosed as FBSS determined by MRI and patient symptoms during enrollment phase completed the study by passing Racz epidural catheter through Racz needle to the region of the filling defect.

Results: High statistically significant difference was found in NRS scores versus time in the study group when analyzed by Friedman test ($P < 0.001$) with 40%, 50%, 58% and 56% improvement in NRS at 2 weeks, 1 month, 3 months and 6 months, respectively.

Conclusion: Racz adhesiolysis is effective in improving pain scores in patients with FBSS after failure of conservative medical therapy.

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FBSS; Adhesiolysis; Racz catheter

1. Introduction

According to the international association for the study of pain, failed back syndrome is known as a persistent pain in spite of spine surgery in the same topographical area [1].

The FBSS has various etiologies; this includes epidural fibrosis, disc reherniation or remnants of disc fragments, acquired stenosis and instability of the spine. The epidural fibrosis accounts for about 20%–30% of cases of FBSS [2].

Different lines of treatment are adopted as a conservative management of this syndrome, it includes physical therapy and medication that aims to improve posture and gait as well as physical function and muscle strength. Oral medication treatment of FBSS is controversial and multimodal. The management involves non-steroidal anti-inflammatory drugs, antiepileptics, antidepressants, oral steroids and opioids [3,4].

Minimally invasive procedures are another line for treatment; it includes epidural steroid injections (ESIs) and epidural injections, these two procedures are the most performed surgery in pain clinics worldwide [5]. There are three primary approaches for administering treatments for radiculopathy; transforaminal, interlaminar or caudally. Radiofrequency ablation is often used to produce long-lasting relief that diagnostic blocks or injections cannot achieve. Spinal cord stimulation has shown potential in managing FBSS. Lysis of adhesions can improve baseline pain scores and drug delivery of ESI, which is done by the delivery of hyaluronidase combined with hypertonic saline into the epidural space. Combining hyaluronidase with steroid may be more efficient and have linger impact than either one solely.

Surgical revision for FBSS may become the only line for treatment of these cases although it is correlated with a high morbidity and low success rates.

Percutaneous adhesiolysis (PA) is a minimally invasive technique, that might be beneficial in the treatment of persistent pain not responding to the previous lines of treatments [6]. The elementary idea behind PA is that introducing a catheter in the ventral epidural space could directly breakdown perineural and/or epidural adhesions, that act as physical barriers to the perineurally administered drugs but also become a reason for neural irritation with subsequent neural inflammation [7].

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Objective of the current research was to assess the effectiveness and safety of percutaneous epidural adhesiolysis using RACZ catheter during 3-month duration in patients with persistent low back and leg pain in failed back surgery syndrome patients.

2. Material and methods

Study design: This is a prospective double-blind multicenter study that was carried out at Assuit University and South-valley university hospitals, Egypt. Twenty out of the 34 patients who were screened diagnosed as FBSS during enrollment phase completed the study, both patient and data collector were blind to the nature of the intervention used. All patients gave an informed consent and must understand how to express Numerical Rating Scale (NRS) before the procedure [8] according pain degree before involvement in the study.

Inclusion criteria: Previous spine surgery of at least 6 months, age≥18, failure of conventional treatment, chronic lower back and/or lower limb radicular pain which failed to respond to fluoroscopically directed epidural injections with at least 6-week post maneuver.

Exclusion criteria: Cauda equina syndrome, compressive radiculopathy, uncontrolled major psychiatric disorders, pregnancy and lactating, patients cannot understand the informed consent and protocol, infection, anti-coagulant or non-aspirin anti-platelet therapy.

The procedure: It is performed under appropriate sterile precautions utilizing fluoroscopy, Racz needle, a water-soluble, nonionic contrast medium and a spring-wire catheter.

- The maneuver applied under standard monitoring with ECG, a pulse oximeter, and NIBP.
- Insertion of intravenous line.
- The patient was in a prone position with a pillow beneath the abdomen to align the lumbar spine, with pointing inward toes.
- Sterilization and drapping the sacral area from the iliac crest to the buttocks.
- The sacral Cornue and the sacral hiatus are palpated with the index finger of the nondominant hand of the operator.
- The entry point via the skin, almost 2 cm inferior and 1 to 2 cm lateral to the sacral hiatus towards the affected side.
- Lidocaine infiltration is applied at the entry point.
- A 16-gauge Racz needle® was passed via the entry point.
- The needle was preceded to a point beneath the S3 foramen to hinder S3 nerve lateral and anteroposterior fluoroscopic views to confirm the targeted affection.
- Once the needle is placed in the epidural space,10 mL of iohexol (Omnipaque®-240) is injected under fluoroscopy after confirmed negativity for blood and cerebrospinal fluid (CSF), a lumbar epidurogram is performed.
- The goal of the epidurogram is to show filling defects through contrast flow into the nerve roots.
- The needle's bevel should face the ventrolateral aspect of the caudal canal on the affected side.
- Next, a catheter is introduced into the scarred region.
- A stainless steel fluoropolymer-coated, spiral-tipped is the ideal Racz epidural catheter reinforced Racz Tun-L-Kath-XL®(Epimed International Inc.). It was slowly passed through the Racz needle to the position of the filling defect or the location of pathology defined by symptoms of patients, MRI, or CT.
- To facilitate steering of the catheter into the desired region, a 15-degree bend is placed at its distal end.
- Following the positioning of the catheter into the appropriate, adhesiolysis is carried out which occur mechanically using the catheter itself.
- After the adhesiolysis had completed, a repeat epidurogram was performed through additional injection of dye.
- Epidural and nerve root filling can be noted when appropriate adhesiolysis is completed.
- Variable doses of local anesthetic of variables doses are injected at this time. The common injected doses include 5–10 mL of 0.25% bupivacaine or 5–10 mL of 2% lidocaine hydrochloride followed by steroid injection. Normal saline was used to flush the catheter.
- The catheter is taped using bio-occlusive dressing after injection; and back to supine position to transfer to the recovery room.

3. Recovery room

- The patient was monitored closely for any remarkable side effects or complications, then removed, and checked for intactness.
- Before ambulation, the wound was examined.
- All parameters permitted ambulation of the patient. I.V. was removed, and the patient returned home with appropriate instructions.

4. Outcome measures

- Primary: Numeric rating scale (NRS) at 2 weeks, 1 month, 3 months and 6 months after intervention.
- Secondary: Catheter-related complications.

Sample size calculation: The sample size was carried out using G Power statistical application version 3.1

based on results of a previous study [9], where mean VAS score was 2.9 in adhesiolysis group 6-month post-intervention, this sample size was evaluated to be able to detect a difference of 1 in NRS at 3-month and 6-month post-intervention. Assuming that the SD = 1.1, and α of 0.05, 19 patients are required to achieve 85% power.

5. Statistical analysis

The statistical analysis for the data in the current study has been carried out using SPSS version 22. Data normality was analyzed by the Shapiro-Wilk test. Data were presented as number, percentage and mean ± SD. Friedman test was used for the analysis of the variance with Tukey post hoc analysis to compare between pre-intervention NRS and follow-up NRS at 2 weeks, 1 month, 3 month and 6 months. Clinical significance if $p > 0.05$. Percent improvement in NRS was calculated as follows (baseline pre-intervention − 2 weeks or 1-month or 3-month or 6-month post-intervention/baseline pre-intervention) x 100 to get the percent of improvement.

6. Results

20 patients out of 34 completed the study. The demographic data of the group presented at Table 1. High statistically significant difference was found in NRS scores versus time in the study group when analyzed by Friedman test ($P < 0.001$) as shown in Table 2 with 40%, 50%, 58% and 56.6% improvement in NRS at 2 weeks, 1 month, 3 months and 6 months, respectively. The reported side effects across the study group as shown in Table 3, there is only one case complaint of headache and one case complaint of temporary motor weakness with complete return of the motor power before discharge. As regards catheter-related complications, only one case of bending the catheter and two cases of blocked catheter were reported, these complications were confronted with replacing the catheter and the procedure was completed. As regards non-catheter-related complication as hypotension and bradycardia of vagal stimulation during procedure, two patients suffered from vagal stimulation complication at the start of the maneuver and were treated with small dose of atropine and ephedrine and continued the maneuver without any other complication.

Figure 1 explains the flow chart of our study.

Table 1. Demographics of the study group.

Demographic data	(mean± SD)
Age (years)	48.2 ± 6.1
Sex F/M ratio	11/9
Weight in kg	84.3 ± 9.87
Height in cm	165.9 ± 7.9
BMI	33±3.6

Note: Number, mean ± SD.

7. Discussion

This research examined the efficacy of RACZ catheter to treat chronic pain after spine surgery and potential complications. The study included 20 patients underwent epidural adhesiolysis, the outcome was NRS 2-week, 1-, 3- and 6-months post-operation. The advantage of epidural adhesiolysis is its ability to place the tip of a soft spring catheter or the fiberoptic endoscope at the targeted lesion site, this allows opening of the perineural space and delivery of the medications to the lesion site providing their anti-inflammatory and neural blockade effects [10].

The American Society of Interventional Pain Physicians in 2003 announced "evidence-based practice guidelines for interventional techniques in the management of chronic spinal pain" [11]. In accordance with our results, Manchikanti et al. revealed that the evidence for lumbar epidural adhesiolysis is fair in treating persistent pain of lower extremity and low back secondary to post-surgery syndrome and spinal stenosis [12]. Epidural adhesion is account for 20–36% of FBSS attributed pain. Post-operative scar formation is normal sequalae of tissue healing surgical incision. Thus, spine interventions could result in fibrous adhesions within the epidural space. These adhesions compress the nerve roots leading to back and leg pain [13,14]. Adhesions theoretically could be

Table 2. Changes in NRS and percent of improvement.

	NRS- pre-intervention	Percent of improvement	P value
baseline mean±SD	6±0.7 CI = 5:6		P <0.001
2-week post-intervention	3.6 ±1 CI = 5.8: 6.3	40%	P1 <0.001
1-month post-intervention	3±0.8 CI = 4: 3	50%	P2 <0.001
3-month post-intervention	2.5 ± 0.8 CI = 3: 2.5	58%	P3< 0.001
6-month post-intervention	2.6±0.8 CI = 2.9: 2	56.6%	P4< 0.001

Note: P = Friedman test comparison between pre-intervention and 2-week post-intervention. Post hoc P2 comparison between pre-intervention and 1-month post-intervention. Post hoc P3 comparison between pre-intervention and 3-month post-intervention. Post hoc P4 comparison between pre-intervention and 6-month post-intervention. SD: Standard deviation of error CI: Confidence interval

Table 3. Complications of intervention.

Complications of intervention		
Treatment complication	Headache	1/20 (5%)
	Temporary motor weakness	1/20 (5%)
Catheter-related complication	bending	1/20 (10%)
	blocking	2/20 (10%)

Note: Number and percentage.

lysed, thus minimizing the pain scores. Adhesiolysis is performed by injecting hyaluronidase in hypertonic saline into the epidural space. The combination of steroid with hyaluronidase may be more efficient and have longer effect than each one alone [15]. This research aimed to estimate the effect of Racz adhesiolysis in patients found in NRS over time in the study group ($P < 0.001$) with 40%, 50%, 58% and 56.6% improvement in NRS at 2 weeks, 1 month, 3 months and 6 months, respectively. Our results regarding efficacy of percutaneous adhesiolysis using Racz catheter are comparable to previous studies. Manchikanti et al. compared the efficacy of percutaneous adhesiolysis compared with caudal epidural steroid injections in a randomized trial included 120 patients, with FBSS, with 24-months follow-up. They reported significant improvement in pain scores at 2 years among 82% of patients in the adhesiolysis group compared to 5% in the group receiving caudal epidural steroid only [16]. Chun et al. investigated the effect of percutaneous caudal adhesiolysis in 92 individuals with FBSS using 4F vascular catheter and stiff guide wire, they documented 50% improvement in adhesiolysis groups versus 5.26% improvement in steroid injection group [17]. Taheri et al. assessed the efficacy of percutaneous epidural adhesiolysis (PEA) in 20 individuals suffered from pain of the low back related to lumber disc herniation using Racz catheter. They reported significant reduction in pain scores and required medications. Pain scores reduced from 95% at three days to 75% at six month [18]. Park et al. studied the effect of

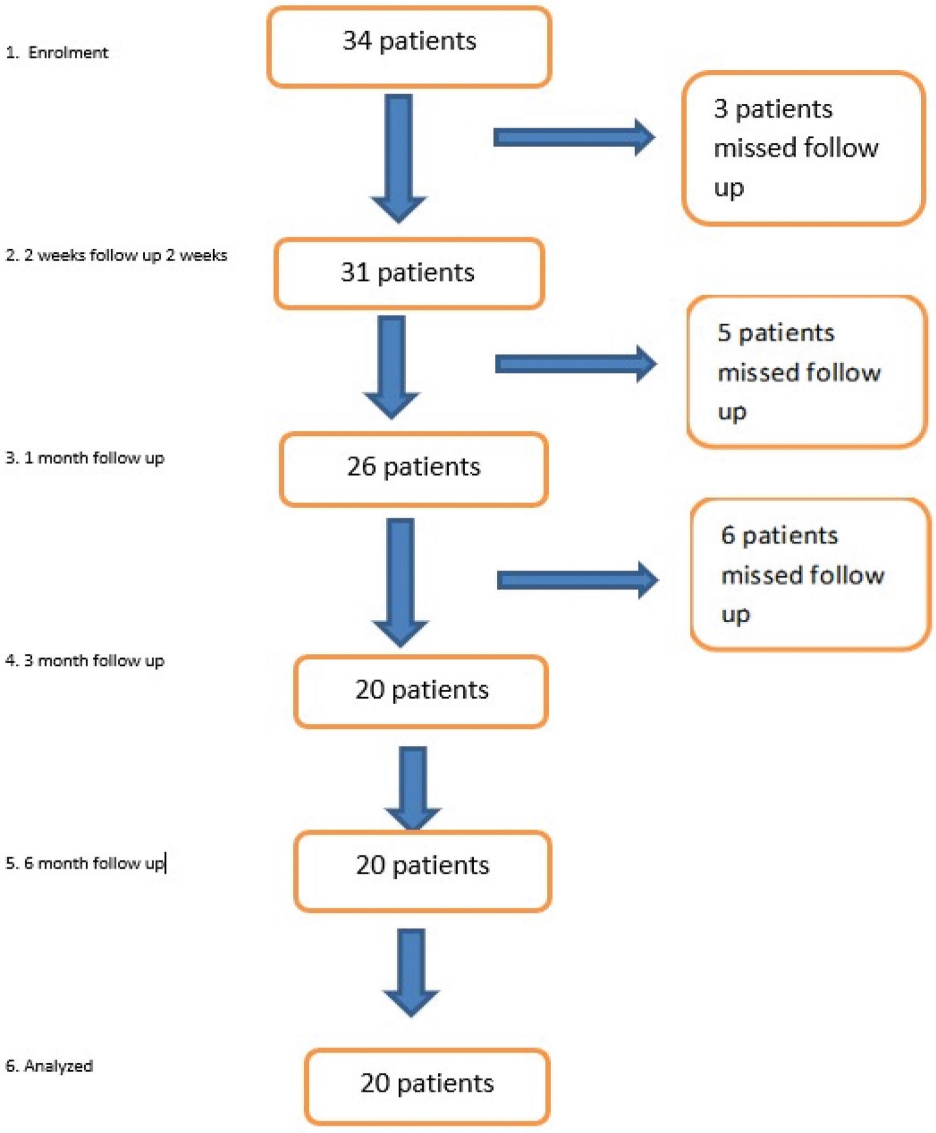

Figure 1. Flow Chart of the Study.

percutaneous adhesiolysis using Racz catheter on 39 patients with central canal stenosis failed to respond to conservative treatment, they reported 71% improvement in Pain scores in 6-month duration [19].

8. Conclusion

PA using RACZ catheter is safe and effective in reducing pain in patients with FBSS refractory to conservative management.

9. Limitations

Sample size was small, short duration of follow-up and absence of control group are the main limitations of the study.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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