Short Term Assessment of Efficacy and Safety Using Rac'z catheter in Percutaneous Adhesiolysis for Management of Chronic Post spine surgery syndrome pain

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Abstract

Background: Failed back surgery syndrome (FBSS) is a persistent radicular and/or lumbar pain post spine surgery. Percutaneous adhesiolysis (PA) has proved efficacy for treating intractable chronic pain following the failure of non-surgical management.
Objectives: our research is the short-term evaluation of the efficacy of percutaneous epidural adhesiolysis using Racz catheter in improving pain scores in leg and low back pain in failed back surgery syndrome patients.
Patients and methods: 20 patients diagnosed with FBSS completed the study, determined by pre-interventional MRI underwent adhesiolysis by introducing Racz epidural catheter through an RK needle to the level of the pathology.
Results: 20 patients diagnosed with FBSS failed to respond to medical treatment undergone caudal epidural adhesiolysis using RACZ catheter. Remarkable difference was found in NRS when comparing the scores pre-intervention and 2 weeks after the intervention; P<0.001, also high statistical difference was detected when comparing the baseline pain scores with 1 month, 3 months scores; P<0.001. Friedman test displayed a high significant variance in NRS scores versus time (P< 0.001).
Conclusion: Racz adhesiolysis is an effective intervention in improving pain scores in patients with FBSS.

Keywords: FBSS; Adhesiolysis; Racz catheter.

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Introduction

Failed back surgery syndrome (FBSS) is typically characterized by persistent radicular and/or lumbar low pain following spine procedure. Typically, persistence is the presence of pain for longer than three months, indicating that the pain has become chronic. **(Brito-Garcia et al., 2019)**. Consequently, FBBS has multiple reasons that have been reported and observed in all patients, such as pressure on the nerve root due to disc re-herniation or retained disc fragment, acquired stenosis, epidural fibrosis وand segmental instability. However, 20% to 36% of FBSS are caused by the degenerative illness epidural fibrosis. Percutaneous adhesiolysis is a quite new technique, where the lysis of scar fibers can be occurred mechanically through various percutaneous modalities such as the intromission of catheters as Rac'z catheter which can be introduced through the skin by the help of fluoroscopy control to reach the targeted level to break up perineural/epidural adhesions **(Baber and Erdek, 2016).**

The approach toward FBSS include conventional management consisting of physical therapy and medication that aims to optimize posture and gait and as well as improving physical function and strength of the muscle **(Delitto et al., 2015; Keller et al., 2004)**. The oral pharmaceutical therapy of FBSS is increasingly controversial and multimodal. In addition to antiepileptics, nonsteroidal anti-inflammatory medications, oral corticosteroids, antidepressants, and opioids, including injections, surgical alternatives are available as a last resort. Other techniques include minimally invasive procedures like as epidural injections. Epidural steroid injections (ESIs) are the most common therapy implemented in clinics of pain worldwide **(Manchikanti, 2004)**. These can be delivered by interlaminar, transforaminal, or caudal routes and are suggested for the treatment of symptoms of radiculopathy. Also, radiofrequency ablation of nerves is frequently utilized to provide long-lasting comfort that cannot be achieved with a diagnostic block or therapeutic injection. By increasing the extent of the lesion, it is possible to target the intended nerve. Stimulation of the spinal cord (SCS) is another therapy method that has demonstrated enormous promise in the management of FBSS. Adhesions can be practically lysed, enhancing pain scores at baseline and medication distribution of the epidural steroid injection. Typically, the epidural space is injected with hyaluronidase and hypertonic saline to lyse adhesions. The combination of hyaluronidase with steroids may have more efficacy and a longer period of impact than either one alone. Finally, surgical revision for FBSS is associated with increased morbidity with correspondingly low success rates **(Baber and Erdek, 2016)**.

The current study aims to estimate the short-term evaluation of the efficiency of percutaneous epidural adhesiolysis using a Racz catheter in improving pain scores among patients suffering chronic leg and low back pain in patients with failed back surgery syndrome.

Patients and Methods

Study design: This was a prospective double-blind multicenter study conducted at Assuit University and Qena University Hospitals at South Valley University with the agreement of the local ethics council (SVU-MED-AIP029-2-20-6-46) Twenty patients

identified with FBSS during the study's enrollment phase were followed to completion; however, neither the patient nor the data collector were aware of the nature of the intervention employed.

Inclusion criteria: Patients with lumbar surgery of at least 6 months, age ≥ 18, history of intermittent or persistent functionally-limiting lower limb radicular pain exacerbated by "Dural tug" (noted while the patient is sitting on the exam table with stretched out, bended forward legs, bringing on the back pain) without or with pain of the low back of at least 6 months following the failure of conservative pharmacological therapy in most patients encompassing muscle relaxants (magnesium sulphate, tizanidine), non-steroidal anti-inflammatory drug group and pregabalin, persistent low back pain and/or lower limb radicular pain which didn't respond or poorly responded to fluoroscopically-directed epidural injections with at least 6 weeks after the last epidural steroid injection, and Patients who are competent to understand the study protocol and provide voluntary, written informed consent and participate in outcome measurements.

Exclusion criteria: age > 60 years of age, cauda equina syndrome, huge contained or sequestered herniation, central spinal stenosis after surgery, compressive radiculopathy, and facet joints as sole pain generators, heavy or unstable opioid usage, uncontrolled major depression or psychiatric diseases, uncontrolled or acute medical illness, pregnant or lactating women, patients incapable to realize the protocol and informed consent, infection, anti-coagulant therapy, non-aspirin antiplatelet therapy. **(Fig.1)** explains the flow chart of our study.

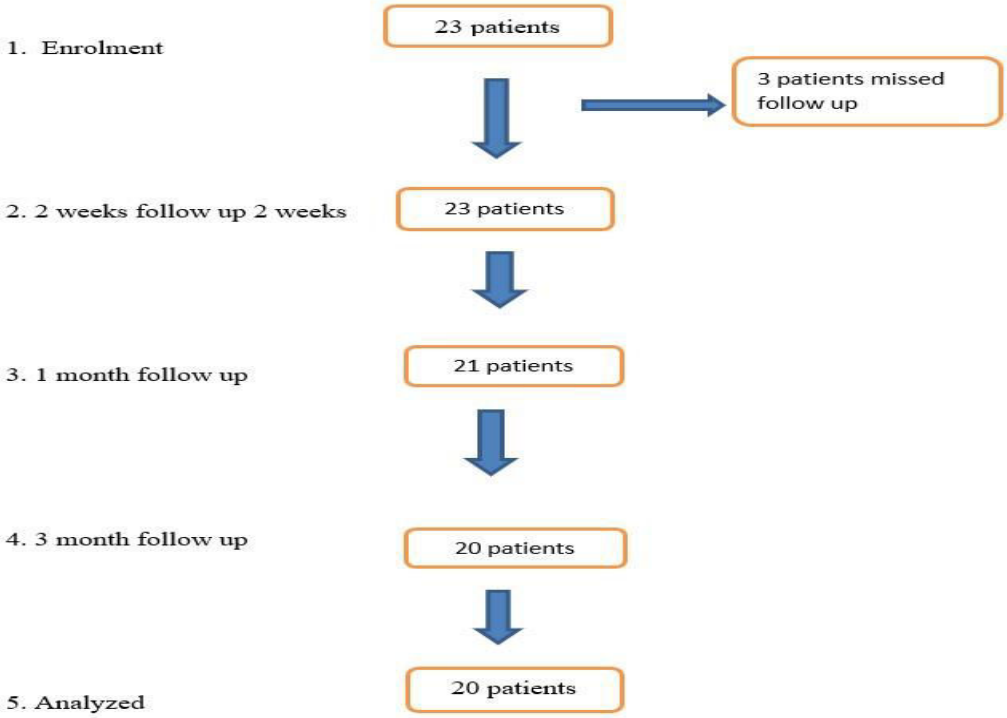

Fig.1.The study's flow Chart

Outcome measures: Primary: difference in a numeric rating scale (NRS) at one month and three months after the intervention**.** Secondary: adverse outcome profile of complications and adverse effects.

The procedure: was carried out in a disinfected operating room in proper sterilized precautions utilizing fluoroscopic guidance, a Racz needle, A water-soluble, nonionic contrast medium, and a spring-wire catheter.

- The patient was positioned in a prone posture and a pillow beneath the abdomen to make the lumbar spine straight, with the toes pointing inward.
- Intravenous access is initiated.
- Monitors, including an ECG, pulse oximeter, and NIBP, are applied.
- The sacral region is set using a sterilized tool and draped from the iliac crest to the buttocks.
- Using the index finger of the non-dominant hand, the sacral Cornue and sacral hiatus are palpated.
- The skin entrance site is almost 1-2 centimeters laterally and 2 centimeters inferior to the sacral hiatus in the gluteal fold on the unaffected side.
- A local anaesthetic, such as lidocaine, is injected at the point of entry.
- A 16-gauge Racz needle® is introduced via the entrance point of interest.
- The needle was progressed below the S3 foramen to prohibit damage to the S3 nerve root.
- Lateral and anteroposterior fluoroscopic guided appearance confirms clearly.
- 10 mL of iohexol (Omnipaque®-240) is injected under fluoroscopy following negative cerebrospinal fluid (CSF) and blood aspiration.
- Once it is determined that the needle placement is in the epidural area, a lumbar epidurogram is carried out using 2 to 5 mL of contrast.
- Direct the needle‘s bevel toward the ventrolateral aspect of the caudal canal on the afflicted side.
- The goal of the epidurogram is fluoroscopic imaging of the filling deficiencies by analyzing contrast flow into the nerve roots. Next, a catheter is inserted into the scarred region.
- The optimal Racz epidural catheter is fluoropolymer-coated stainless steel, spiral-tipped Racz Tun-L-Kath-XL®(Epimed International Inc.) that is progressively introduced through the RK needle to the location of pathology or the filling defect, as confirmed by CT, MRI, or patient complaints.
- A 15-degree bend is put at the distal end of the catheter to aid its navigation to the desired level.
- Adhesiolysis is approved either mechanically by the catheter itself or chemically by neurolytic medications such as hyaluronic acid with local anaesthetics, after the implantation of the catheter at the intended level.
- Following the attainment of adhesiolysis, a second epidurogram is performed by injecting more contrast.
- When adhesiolysis is complete. Both the epidural space and nerve root will be determined. Injectable doses of local anaesthetic are administered at this time. 5-10 mL of lidocaine hydrochloride (2%) or 5-10 mL of bupivacaine (0.25%) are commonly administered.

- The catheter is taped with bio-occlusive bandage, upon finishing the injection, and the patient is positioned supine and moved to the recovery room.

Recovery Room

- The patient is meticulously observed for any side effects or significant complications.
- If the patient showed goo pain relief with no motor impairment, with no complications, neurolysis using hypertonic saline is performed with varied dosages of 10% sodium chloride solution through injection. An infusion pump or repeated injections of 2- 3 mL, ranging from 6-10 mL in total, can be used to perform hypertonic neurolysis, which is then followed by steroid injection. A normal saline is used to flush and flooded the catheter, then examined for intactness.
- The entry point is also examined at this time.
- The patient is ambulated if parameters are acceptable. Remove the I.V. access appropriately, the appropriate instruction must be cleared before the patient is discharged home.

Statistical Analysis

The statistical analysis for the data in the current study has been done by 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 and 3 months. Clinical significance if $p < 0.05$.

Results

20 patients diagnosed with FBSS failed to respond to medical treatment undergoing caudal epidural adhesiolysis using RACZ catheter. The demographics are reported in (**Table.1**).

Table 1: Demographic data

Demographics	**(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**

Number, mean ±SD.

(**Table.2**) shows the number of spine surgeries done before adhesiolysis and the concurrent diseases such as DM, HTN and spondylosis.

Table 2: Clinical criteria of the patients

Clinical criteria of the patients		
Number of previous spine surgeries	**Once**	13/20 (65%)
	Twice	6/20 (30%)
	Triple	1/20 (5%)
Concurrent disease	**spondylosis**	5/20 (25%)
	DM	5/20 (25%)
	HTN	6/20 (30%)

Number and percentage

Considerable variation was detected in NRS when comparing the scores pre-intervention and 2 weeks after the intervention; P<0.001, also high statistical difference was detected when comparing the baseline pain scores with 1-month scores ; P<0.001 and a high statistically significant difference was detecting when comparing of numerical rate scale at 3 months ; p< 0.001, (**Table.3**).

Table 3. Changes in NRS pain ratings in relation to time.

Variables	NRS-preintervention	P value
baseline	6 ± 0.7 CI=6: 5	P < 0.001
2-week post-intervention	3.6 ±1 5.8: 6.3	P1 <0.001
1-month post-intervention	3±0.8 4: 3	P2 <0.001
3-month post-intervention	2.6±0.7 2.9: 2.3	P3 <0.001

P = Friedman test comparison between preintervention and 2 weeks postintervention. Post hoc P1 comparison before and 2 weeks after-intervention. Post hoc P2 comparing between pre-intervention and 1 month. Post hoc P3 comparison between pre-intervention and 3 months after-intervention.

The reported side effects across the study group (**Table.4**) there is only one case complaint of headache, 2 cases with suspected dural puncture by the spread of dye and one case complaint of temporary motor weakness and these patients underwent strict follow-up for about 4 hours with complete return of motor power before discharge. As regards catheter-related complications only 2 cases of bending the catheter and one case of the blocked catheter were reported.

Table 4. Complications of intervention

Treatment complication	**Headache**	1/20 (5%)
	Suspected Dural puncture	2/20 (10%)
	Temporary motor weakness	1/20 (5%)
	infection	
Catheter-related complication	**bending**	2/20 (10%)
	blocking	1/20 (5%)
	steering	0/20
	coccydynia	0/20

Number and percentage

Discussion

The outcomes of this research support that percutaneous adhesiolysis with Racz catheter is effective in reducing pain scores in patients with previous lumbar spine surgeries following unsuccessful response to conservative medical treatment. The benefits of adhesiolysis are related to the ability to dissolve adhesions, and the ability to deliver drugs (local anaesthetics, steroids, and hypertonic sodium chloride solution) to target affected sites **(Boswell et al., 2007)**. Corticosteroids could reduce inflammation by blocking the production of pro-inflammatory mediators **(Lee et**

al.,1998). Local anaesthetics could provide symptomatic relief depending on many mechanisms, such as blockage of nociceptive discharge, anti-inflammatory impact, sympathetic de-sensitization, and blockade of neuronal pain transport **(Cassuto et al., 2006)**. As regards, the 10% hypertonic sodium chloride solution has could yield analgesia and adhesiolysis **(Racz et al., 2008)**.

The current findings are concurrent with the findings of previous researches that evaluated the effect of epidural adhesiolysis in different causes of refractory low back pain **(Gerdesmeyer et al., 2005; Veihelmann et al., 2006)**. Systematic reviews also discussed the role of percutaneous adhesiolysis in post-lumbar surgery syndrome and spinal stenosis and reported fair evidence in these cases **(Helm et al.,2012)**. Furthermore, they reported that complications from adhesiolysis are low, minimal, and self-limited **(Manchikanti et al., 2008)**. However, in another study, the authors concluded that there was potent proof for the use of adhesiolysis for post-lower lumbar laminectomy syndrome **(Epter et al., 2009)**. In an earlier study by Gerdesmeyer et al., they strongly supported using epidural adhesiolysis for managing persistent lumbar radicular pain after failed back surgery or post disc protrusion.

The American Society of Interventional Pain Physicians 2003 documented "evidence-based practice guidelines for interventional techniques in the management of chronic spinal pain" **(Boswell et al., 2007)**. These protocols recommended that either a three-day protocol and two interventions each year or a one-day methodology and four interventions per year can be used to perform the epidural adhesiolysis operation. There are few numbers of studies on percutaneous epidural adhesiolysis for the management of lower back pain with or without radiculopathy in cases of FBSS.

The limitation of this study is the short-term follow-up, further studies with longer follow-up times are recommended.

Conclusion

In conclusion, percutaneous adhesiolysis using Racz catheter is efficient for the management of persistent back pain in FBSS refractory to conventional conservative management.

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