



ORIGINAL ARTICLE

Comparative study between Racz technique alone and Racz with radiofrequency in the management of failed back surgery syndrome

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ABSTRACT

Background: Failed Back Surgery Syndrome refers to patients with sustained pain post spinal surgery for back pain. Racz and colleagues described the technique which involves epidurography, adhesiolysis, and injection of hyaluronidase, 10% sodium chloride and bupivacaine on day 1. The technique of Radiofrequency ablation uses high-frequency current which produce tissue coagulation due to heat. The procedure used radio wave, applied through a percutaneous probe which generate thermal lesion in the nerve. **Patients and methods :** This study was conducted on 60 Failed Back Surgery Syndrome patients classified into two groups each of 30 patients. FBSS treated by Racz technique (group I) and the other group (II) treated by Racz plus radiofrequency. **Results:** VAS score and Oswestry score used to assess both techniques daily for a week then weekly for a month, then monthly for 6 months, we found that both techniques showed statistically non-significant difference before the procedure, but showed a statistically highly significant difference between both groups after the techniques. There is a reduction of VAS score from a mean of 6.2 to 3.87 in group (I) and a reduction from 6.03 to 2.7 in group (II). There is a reduction of Oswestry score from a mean of 57.2 to 40.6 in group (I) and a reduction from 57.03 to 32.47 in group (II). **Conclusion:** Using radiofrequency with Racz catheter adhesiolysis gives better results than using Racz catheter alone in cases with failed back surgery syndrome.

Keywords: failed back surgery syndrome, ;pain, Racz; radiofrequency.

INTRODUCTION

Failed Back Surgery Syndrome refers to patients with sustained pain after spinal surgery for back or leg pain [1,2]. Epidural lysis of adhesions is a procedure which treat chronic low back pain in patients which didn't respond to medical treatments [3,4].

The technique described by Racz [5]. include epidurography, and injection of hyaluronidase 10% sodium chloride and bupivacaine, on day 1. The Racz technique requires the catheter to stay in place for three days, with injections of hypertonic sodium chloride solution bupivacaine and occur on days 2 and 3 [6]. the technique of Radiofrequency ablation (RFA) is that uses high-frequency current to produce tissue coagulation and heat (7). It involves the use of radio wave, applied through

a percutaneous probe to generate heat, and create a lesion in a spinal sensory nerve [8,9].

The Oswestry Disability Index is important tool researchers and disability evaluators use to measure a patient's permanent functional disability [10]. The test is considered the 'gold standard' of low back functional outcome evaluation [11]. Visual analogue scale (VAS) is a subjective measure of pain intensity range from (0) no pain to (10) worst pain [12].

The aim of this study is comparing between using Racz catheter alone and using Racz catheter with radiofrequency to control pain and disability in patient with failed back surgery syndrome.

PATIENTS AND METHODS

The work has been carried out in accordance with The Code of Ethics of the World Medical

Association (Declaration of Helsinki) for studies involving humans.

After obtaining approval from Institutional Review Board (IRB) then a written informed consent obtained from patients, we conducted this prospective randomized comparative study on adult patients from 30-60 years old of both sexes who are admitted to Pain Management Unit in Zagazig University Hospitals.

a) Group (I) (Racz alone): Formed of thirty patients of failed back surgery syndrome (FBSS) were managed by Racz technique alone.

b) Group (II) (Racz with radiofrequency): Formed of thirty patients of FBSS managed by Racz technique with pulsed radiofrequency to affected nerve roots and thermal radiofrequency to medial branches of affected facet.

Inclusion criteria:

- Both sexes.
- BMI 25-30 kg/m²
- Age between thirty and sixty years.
- Admitted to interventional pain management.
- Ability to perform a written informed consent.
- Patient suffering from persistent pain after recurrent lumbar.
- Spine surgery operated within more than six months.

Exclusion criteria:

- Patient refusal.
- Surgery was operated less than six months.
- Contraindication to perform the proper technique e.g. coagulopathy and skin infection
- Uncooperative patients..

Data of collection:

From all patients, the following data were collected:

- Name.
- Age.
- Medical and past history.
- Body mass index.
- Diagnosis and pathology (recurrent and persistent pain after recurrent back surgery). Level of pathology (L3-L4 and L5-S1).

Visual Analogue Scale (VAS) score and Oswestry disability score were applied to both

groups before the intervention. Both scales were applied daily for one week, then weekly for one month, then monthly for six months.

Technique:

- collection of data done by full history.
- Basic clinical examination through inspection, palpation of the back and provocative tests like straight leg test, straight leg test variant and femoral stretch test, also through neurological examination that consists of motor examination clinically, sensory examination clinically and reflex examination.
- After history taking and clinical examination, standard monitoring was applied to patient (noninvasive arterial blood pressure monitoring, pulse oximetry, and electrocardiography).
- Baseline vital signs; collection of Blood pressure (systolic, diastolic and mean), heart rate, respiratory rate and oxygen saturation (SpO₂) were done

Group I:

In operation room, insertion of an intravenous 18G venous cannula was done, then patient was lied in prone position with a pillow placed under the abdomen (to correct the lumbar lordosis) and a pillow under the ankles (for patient comfort). then the patient was asked to put his or her toes together and heels apart (to relax gluteal muscles and facilitates identification of sacral hiatus).

Conscious sedation was given to the patient with fentanyl (20-50 µg), midazolam (3-10 mg) and propofol if needed. then sterile preparation done and draping, the sacral hiatus was identified through palpation just caudal to sacral cornu or with fluoroscopic guidance.

Subcutaneously the Local anesthetic drug was given one inch laterally and 2 inches caudally to the sacral hiatus on the side opposite to the documented radiculopathy. The skin is pierced with an 16-gauge, Racz needle (Epimed International, Inc., Johnstown, NY) (figure 1) at 45 degree angle guided by fluoroscopy, so when the needle pass the hiatus, we change the angle of the needle was to 30 degrees and then confirmation of the correct placement of the needle in the epidural space

done , we injected 10 ml of omnipaque (GE Healthcare [Shanghai] Co, Ltd, Shanghai, China) through the needle but after negative aspiration so the spread of the contrast was visualized.

Then the opening of the needle turned ventral laterally, then insert Racz catheter 19-gauge (Epimed International, Inc., Johnstown, NY) with a bend 2.5 cm from the tip of the catheter and at a 30-degree angle .

The tip of the catheter is advanced toward the ventral lateral epidural space of the desired level under continuous AP-fluoroscopic guidance . then we injected 2 to 3 ml additional contrast through the catheter under real-time fluoroscopy to identify the (scarred in) nerve root. then we injected 1500 µg of hyaluronidase dissolved in 10 ml of preservative-free 10% saline slowly through the catheter.

The visualization of the scarred in nerve root was noticed. Then, 10 ml of bupivacaine and steroid 40-80 mg of Depo-medrol injected through catheter. Under continuous fluoroscopic guidance the needle was removed. The catheter sutured with the skin using non-absorbable suture then we coated the skin with sterile dressing. On the second and third day 10 ml of bupivacaine 0.25%, then 10 ml of hypertonic saline 10% was injected after negative aspiration through Racz catheter (Figure 2).

The catheter secured to the skin using non-absorbable suture and the skin then coated with sterile dressing. On the second and third day 10 ml of bupivacaine 0.25%, then 10 ml of hypertonic saline 10% are injected after negative aspiration.

The catheter was removed in the third day under complete aseptic condition.

Group II:

In operation room, the same steps done to take patients as in group (I) plus radiofrequency technique as follow:

The radiofrequency cannula-curved, 10 cm (NeuroTherm, 600 Research Drive, Suite 1 Wilmington, MA 0188 USA) was inserted in the direction of the radiation beam. While the

cannula was still located in the superficial layers, the direction was connected so that the cannula appeared as a point on the screen.

Then the cannula was inserted carefully further until in the lateral view ,the point was located in the middle on the intervertebral foramen

Then The stylet of the needle removed and exchanged with the radiofrequency probe. we connected the probe to the radiofrequency generator (Figure 3) (Neurotherm NT 1100, Massachusetts, MA, USA). The impedance (300-500 Ohm) was checked, and thereafter the sensory threshold. The patient felt tingling at a voltage of < 0.5 V(if he was awake not sedated).

Contraction of the muscle was innervated by the nerve root stimulated at 0.7-1 Hz. Thereafter, a pulsed current (routinely 20 ms current and 480 ms without current) was applied for 120 seconds with an output of 45 V, during the procedure, the temperature at the tip of the electrode might not surpass 42°C and thermal temperature of 80°C for 60 seconds on the medial branches supplying the affected facets if there was dominant back pain more than lower limb pain.

In the case, we fail to introduce the Racz catheter due to severe epidural adhesions, it will be excluded from the study.

Complications that may occur during the technique are , in group (I) eg , bending of the tip of the needle, shearing of the catheter, misplacement of the catheter, blocking of the catheter, blood aspiration and bleeding in the epidural space, hypotension, migration of the catheter, paresthesia, headache and infection but in group (II) eg, local edema and numbness of skin covering the area treated, muscle spasm, infection to skin, bending of the tip of the radiofrequency needle, plus complication of Racz catheter like in group (I)

Treatment after the intervention:

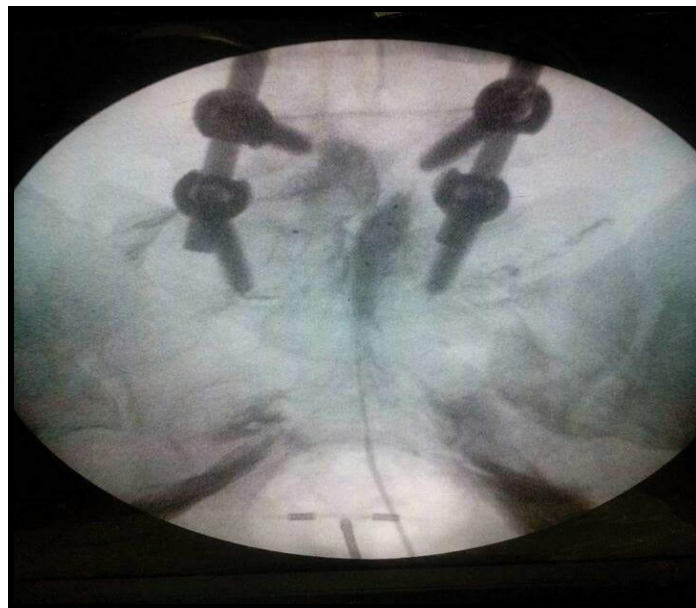
All patients were given antibiotics (Ciprofloxacin 500 mg/12 hours for 5 days), analgesics (diclofenac sodium 75 mg / 12 hours intramuscular injection for one week), gastric

protective as (Omeprazole 20 mg / 12 hours before meals orally for one week) muscle relaxant (baclofen 10 mg / 12 hours orally) .

All patients were informed that a transient increase in a radicular pain may occur in the first 7 days.



Figure (1) : Showing Racz needle



Figure(2): Antero-Posterior view showing dye spread through L5 foramen after adhesiolysis in case of FBSS in group (I).

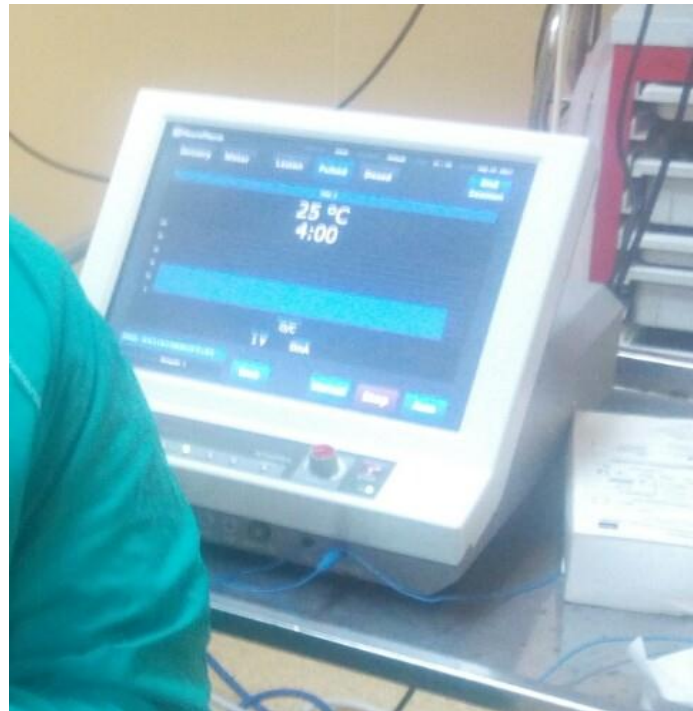


Figure (3): Radiofrequency apparatus used for pulsed radiofrequency ablation for patients with FBSS used in group (II).

Statistical analysis

Data were collected in a master sheet, coded , entered and analyzed using EPI-INFO and Excel 2013 program from Microsoft Corporation.

Quantitative data were expressed as the mean \pm SD , and qualitative data were expressed as absolute frequencies (number) & relative frequencies (percentage). the following tests were used to test differences for significance difference and association of qualitative variable by Chi square test (χ^2). Differences between quantitative independent groups were tested by t-test , paired by paired t-test, correlation by Pearson's correlation (r).

For all above mentioned data, the threshold of significance was fixed at 5% level student t-test (t) and the propability (p value): p-value of < 0.05 was considered statistically significant (S) , p value of ≥ 0.05 was considered statistically insignificant (NS), P value of < 0.01 indicates highly significant results and P value of < 0.001 indicates very highly significant results.

RESULTS

There was no significant difference between Racz only and Racz with radiofrequency

regarding mean blood pressure,heart rate,respiratory rate and Spo2 intraoperative and postoperative ($p > 0.05$) (table1)

VAS score was matched in the first week and first month in the two groups ,but Racz with radiofrequency was highly significantly lower after 2nd 3rd month, 4th month, 5th month and 6th month ($p < 0.001$) (table 2).

Oswestry score was matched in the first week and the first month but Racz with radiofrequency was highly significantly lower after 2nd ,3rd month,, 4th month,5th month and 6th month ($p < 0.001$) (table 3).

There was a high significant change in assessment using both scores but more in the second group ($p < 0.001$) (table 4).

Edema and spasm was significantly higher in 2nd group but bleeding and hypotension were significantly associated with Racz only group(table 5)

There was no significant difference regarding need for additional analgesia postoperative between the two studied groups ($p > 0.05$) (table 6).

Table (1): Socio-demographic characteristics of the study group:

Variable	case group (24)	
Age (years):		
mean ± SD	34.6±9.37	
(Range)	(18-53)	
median	35	
	NO	%
Sex		
Male	16	66.7%
Female	8	33.3%

Table (2): Perforation size in the study group:

Variable	The case group(24)	
perforation size (mm):		
mean ± SD	1.39±0.44	
(Range)	(0.5-2)	
Median	1.35	
	NO	%
perforation size		
0.5-1 cm	6	25.0%
1-2 cm	18	75.0%

Table (3): Causes of septal perforation:

Variable	NO(24)	%
Septal surgery	19	79.2%
Excessive cauterization	4	16.7%
Blunt trauma	1	4.2%

Table (4): Symptoms of nasal perforation:

Symptoms	NO (24)	%
Crusting	23	95.8%
Nasal obstruction	23	95.8%
Epistaxis	13	54.2%
Pain	1	4.2%
Whistling	1	4.2%
Headache	1	4.2%
Nasal discharge	1	4.2%

Table (5): Success rate in the study group:

Success rate	NO(24)	%
Successes cases	23	95.8%
Failed cases	1	4.2%

DISCUSSION

This study was conducted on 60 Failed Back Surgery Syndrome (FBSS) patients classified into two groups each of 30 patients. FBSS treated by Racz technique (group I) and the other group (II) treated by Racz plus radiofrequency. The two groups were matched in age and sex ($P > 0.05$) and the disease duration in both groups were statistically non-significant. SBP, DBP, HR and RR were statistically non-significant ($P > 0.05$).

In this study VAS score and Oswestry score were used to assess both techniques, we found that both techniques showed statistically non-significant difference before the procedure ($P > 0.05$), while on the other hand they showed a statistically highly significant difference between both groups after the techniques ($P < 0.001$). There is a reduction of VAS score from a mean of 6.2 to 3.87 in group (I) and a reduction from 6.03 to 2.7 in group (II). Also, there is a reduction of Oswestry score from a mean of 57.2 to 40.6 in group (I) and a reduction from 57.03 to 32.47 in group (II).

This indicates that Racz technique with radiofrequency is more reliable and effective technique on relieving pain of FBSS than Racz alone technique.

Terao et al. [13] concluded that a combination of epidural spinal cord stimulation plus radiofrequency is a very effective as a treatment for severe FBSS and has longer duration of pain relief than spinal cord stimulation. This is concordant with our finding that RF adds a benefit to the management of FBSS.

Bellini and Barbieri [14] treated the cases of low back pain due to many causes; one of them is scarring in the epidural space. The success rate of epidural steroid injections in dealing with epidural fibrosis has been reported to be

59% and 58% at one and two years, considering 4 and 5 procedures during this period. Significant pain relief in 90% of patients at one month, 80% at 3 months, 56% at 6 months, and 48% at 12 months .

In acute or subacute cases of lumbosacral radicular pain under the L3 level, transforaminal corticosteroid administration is recommended. In chronic lumbosacral radicular pain, pulsed radiofrequency treatment at the level of the spinal ganglion done. But, cases with refractory lumbosacral radicular pain, adhesiolysis and epiduoscapy can be considered. But, in patients with a therapy-resistant radicular pain in the context of an FBSS, spinal cord stimulation is recommended in a study design .

The reported postoperative (PO) significant reduction of pain and Oswestry Disability Index (ODI) in conjunction with a significant reduction of analgesic consumption points to the appropriateness of a percutaneous spinal fixation procedure alone for management of pain after FBSS. The frequency of patients who found the radiofrequency in conjunction with Racz procedure excellent-to-good and its outcome satisfactory (76% and 72%, respectively) was significantly higher compared with percutaneous spinal fixation procedure alone (40% and 56%, respectively) [15].

The results obtained in the current study go hand in hand with multiple studies that evaluated each procedure separately.

Helm et al. [16] conducted a systemic review for studies that evaluated the effectiveness of percutaneous adhesiolysis in the treatment of refractory low back and leg pain due to post-lumbar surgery syndrome and reported fair results for its effectiveness. Percutaneous adhesolysis was preferred by placing the

catheter into the tissue plane at the ventrolateral aspect of the foramen so that medication can be injected. Pain relief at least 50% and functional improvement of at least 40% were the primary outcome measures. Percutaneous adhesiolysis may be considered as a first line of treatment for chronic refractory low back and lower extremity pain.

Hadziahmetovic et al. [17] the study included 35 patients had lumbar or cervical radiculopathy. Selective nerve root block and facet block have been performed by needle instillation of steroid and local anaesthesia (lidocaine and celestone) under X-ray visualization by C-arm depending on clinical findings and MRI. Cases were evaluated by pre- and post-VAS and Oswestry Disability Index (ODI). There was statistically significant difference between the value of ODI score before the procedure and 7 days later. The difference was also statistically significant in VAS value.

Hsu et al. [18] retrospective study in 115 patients who underwent epidural Lysis Of Adhesions (LOA) for FBSS (n = 104) or spinal stenosis (N = 11) between 2004 and 2007. Overall 48.7% of patients experienced a positive outcome, using hyaluronidase did not correlate with outcomes in the univariate analysis. So, using hyaluronidase that increase risks and costs did not improve outcome in this study. This is against our study. Thereafter, **Ko et al.** [19] found that recurrence of pain within 2-4 weeks after selective nerve root block can be reduced when hyaluronidase is added to the routine block regimen. This supports our study.

Kanchiku et al. [20] aimed to study the effectiveness of percutaneous radiofrequency neurotomy of facet joints by monitoring Compound Muscle Action Potentials (CMAPs) of the multifidus muscle group as objective index of treatment efficacy. Results suggested that percutaneous radiofrequency facet joint denervation is a safe, long-lasting and effective treatment for chronic facet joint pain .

CONCLUSION

Using radiofrequency with Racz catheter adhesiolysis gives better results than using Racz catheter alone in cases with failed back surgery.

Conflict of Interest: No any financial or personal relationships with other people or organizations that could inappropriately influence the current study.

Financial Disclosures: No any specific financial interests, relationship and affiliations relevant to the subject of the manuscript.

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