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Efficacy of Navi-Cath versus RACZ catheter in management of post laminectomy syndrome: A prospective randomized clinical trial

Eficacia de Navi-Cath versus catéter RACZ en el manejo del síndrome post-laminectomía: Un ensayo clínico prospectivo aleatorizado

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ABSTRACT

Background: Failed back surgery syndrome (FBSS) is a common cause of persistent lumbar and/or radicular pain following spinal surgery, often driven by epidural fibrosis. Percutaneous adhesiolysis (PA) has emerged as an effective treatment, yet the optimal catheter design remains unclear. This study compared the efficacy of the RacZ catheter (non-steerable, smaller caliber) and the Navi-Cath catheter (steerable, larger caliber) in FBSS patients. **Methods:** Sixty patients with FBSS were randomized to receive adhesiolysis using either a RacZ (n = 30) or Navi-Cath (n = 30) catheter. Pain intensity (Numeric Rating Scale, NRS), functional disability (Oswestry Disability Index, ODI), pregabalin use, and complications were assessed at baseline, 1, 3, 6, and 12 months. **Results:** Baseline characteristics were similar between groups. No significant differences were noted in NRS at 1 and 3 months. At 6 and 12 months, the Navi-Cath group reported significantly greater pain reduction ($p = 0.01$, $p = 0.002$). ODI scores improved significantly in both groups, with consistently superior functional recovery in the Navi-Cath group ($p < 0.001$). Pregabalin use decreased in both groups, with lower but non-significant reductions in the Navi-Cath group. Complication rates were comparable. **Conclusion:** Navi-Cath adhesiolysis provided superior long-term pain relief and functional recovery compared with the RacZ catheter, without increased complications. These findings suggest that steerable catheters may offer clinical advantages in FBSS management.

Keywords: Failed back surgery syndrome, epidural fibrosis, percutaneous adhesiolysis, RacZ catheter, Navi-Cath.

RESUMEN

Antecedentes: El síndrome de cirugía fallida de la columna (Failed Back Surgery Syndrome, FBSS) constituye una causa frecuente de dolor lumbar persistente y/o radicular tras la cirugía espinal, generalmente asociado a fibrosis epidural. La adhesiolisis percutánea (AP) ha emergido como una opción terapéutica eficaz; sin embargo, el diseño óptimo del catéter aún no está claramente establecido. El presente estudio tuvo como objetivo comparar la eficacia del catéter de RacZ (no dirigible, de menor calibre) frente al catéter Navi-Cath (dirigible, de mayor calibre) en pacientes con FBSS. **Métodos:** Sesenta pacientes diagnosticados de FBSS fueron aleatorizados para someterse a adhesiolisis mediante catéter de RacZ (n = 30) o catéter Navi-Cath (n = 30). Se evaluaron la intensidad del dolor (Escala Numérica de Valoración, NRS), la discapacidad funcional (Índice de Discapacidad de Oswestry, ODI), el consumo de pregabalina y la incidencia de complicaciones al inicio del estudio y a los 1, 3, 6 y 12 meses de seguimiento. **Resultados:** Las características basales fueron comparables entre ambos grupos. No se observaron diferencias estadísticamente significativas en la NRS a los 1 y 3 meses. Sin embargo, a los 6 y 12 meses, el grupo tratado con Navi-Cath mostró una reducción del dolor significativamente mayor ($p = 0,01$ y $p = 0,002$, respectivamente). Las puntuaciones del ODI mejoraron de forma significativa en ambos grupos, con una

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recuperación funcional consistentemente superior en el grupo Navi-Cath ($p < 0,001$). El consumo de pregabalina disminuyó en ambos grupos, observándose una reducción mayor en el grupo Navi-Cath, aunque sin alcanzar significación estadística. La tasa de complicaciones fue similar en ambos grupos. **Conclusión:** La adhesiolisis realizada con catéter Navi-Cath proporcionó un alivio del dolor a largo plazo y una mejoría funcional superior en comparación con el catéter de Racz, sin incremento en la tasa de complicaciones. Estos hallazgos sugieren que el uso de catéteres dirigibles puede ofrecer ventajas clínicas en el manejo del FBSS.

Palabras clave: Síndrome de cirugía fallida de la columna, fibrosis epidural, adhesiolisis percutánea, catéter de Racz, Navi-Cath.

Introduction

Failed back surgery syndrome (FBSS) is defined as persistent radicular and/or lumbar pain lasting beyond three months following spinal surgery (Barito et al., 2019; Lewik et al., 2023). Its causes are multifactorial, including recurrent disc herniation, retained disc fragments, stenosis, and segmental instability. Among these, epidural fibrosis accounts for 20%-36% of cases and is strongly linked with pain recurrence (Hossieni et al., 2017; Quan et al., 2021). In an observational epiduroscopic study, severe fibrosis was reported in over 80% of FBSS patients, underscoring the importance of addressing adhesions in treatment strategies (Yeo et al., 2024). Patients' with epidural fibrosis not only suffer from pain but also from dysfunction, poor quality of life, and mental illness (Thomson 2013; Rigoard et al., 2015).

Percutaneous adhesiolysis (PA) has been introduced as an interventional technique to mechanically disrupt scar tissue and enhance targeted drug delivery. The Racz catheter is widely used but limited by its smaller caliber and non-steerable design, which may restrict optimal placement. In contrast, the Navi-Cath catheter has a steerable tip and larger caliber, enabling more precise navigation toward affected nerve roots and potentially more effective adhesiolysis and drug administration. This design has been shown in prior studies (e.g., Lee & Lee, 2012) to yield clinically meaningful pain and disability improvements in patients who failed standard epidural injections (Lee & Lee, 2012).

Despite the growing adoption of PA, no randomized controlled trial has directly compared Racz and Navi-Cath catheters in FBSS patients. This study was designed to address this gap.

Hypothesis

We hypothesize that the steerable Navi-Cath catheter achieves more effective mechanical adhesiolysis and targeted drug delivery than the non-steerable Racz catheter, leading to superior pain relief and functional recovery in patients with FBSS. However, complication rate may be higher with Navi-Cath due to its large size.

Aim

This prospective randomized clinical trial aimed to evaluate the efficacy and safety of Navi-Cath versus Racz catheter adhesiolysis in patients with FBSS, with a focus on long-term pain reduction, functional improvement, medication use, and complication rates.

Materials and Methods

Study Design and Ethics

This prospective, randomized, double-blind clinical trial was conducted at Assiut University Hospitals after approval from the Local Ethical Committee (IRB no. 200542) and registration on ClinicalTrials.gov (NCT04779060), at 15th of March 2021, prior to patient enrollment, the principle investigator is SElsawy.

Participants

Eighty-seven patients diagnosed with failed back surgery syndrome (FBSS) were screened; 60 patients met eligibility criteria and completed the study. They were randomly assigned in a 1:1 ratio, to undergo percutaneous adhesiolysis with either a Racz catheter ($n = 30$) or a Navi-Cath catheter ($n = 30$).

Inclusion Criteria: Age ≥ 18 years, persistent or intermittent lower extremity pain with or without low back pain for ≥ 6 months after spinal surgery, pain aggravated by dural tension signs (e.g., forward bending with legs extended), insufficient response to conservative therapy (NSAIDs, muscle relaxants, pregabalin) and epidural steroid injections. Ability to provide informed consent and comply with follow-up.

Exclusion Criteria: Age > 60 years, large contained or sequestered disc herniation, cauda equina syndrome, or compressive radiculopathy, central spinal stenosis, facet joint-related pain, or segmental instability, Uncontrolled psychiatric disorders or major depression, unstable or heavy opioid use, Pregnancy or lactation and Acute illness, active infection, coagulopathy, or anticoagulant therapy (except aspirin).

Randomization and blinding

Randomization was performed using computer-generated blocks of six. Both patients and outcome assessors were blinded to group allocation.

Procedure

A one day -day injection protocol was used for both groups. All procedures were performed under fluoroscopic guidance in the operating room. Patients were placed prone with a pillow under the abdomen to reduce lumbar lordosis. The entry point through the skin, approximately 1 to 2 cm lateral and 2 cm inferior to the sacral hiatus, in the gluteal fold opposite the affected side. After sterile preparation and local infiltration with 1% lidocaine, the introducer needle was advanced via the sacral

hiatus. Proper placement in the epidural space was confirmed with injection of 5 mL radio-opaque dye (Omnipaque®-240).

Racz catheter group

A 16-gauge RX Coude needle® is passed through the described entry point. The needle is advanced to a point below the S3 foramen to prevent S3 nerve root damage. Needle position is confirmed by lateral and anteroposterior fluoroscopic views. After aspiration is negative for blood and cerebrospinal fluid (CSF), epidurogram carried out by 5 -10 mL of iohexol (Omnipaque®-240) is injected under fluoroscopy. The bevel of the needle should face the ventrolateral aspect of the caudal canal on the affected side. Finding the filling defects by examining the contrast flow into the nerve roots is the purpose of the epidurogram. Next, insert a catheter into the scarred area. The ideal Racz epidural catheter is a stainless steel, fluoropolymer-coated, spiral-tipped reinforced Racz Tun-L-Kath-XL® (Epimed International Inc.) is slowly passed through the RX needle to the area of the filling defect or the site of pathology determined by MRI and filling defect. To facilitate steering of the catheter into the desired location, a 15-degree bend is placed at its distal end. Following the positioning of the catheter into the appropriate area adhesiolysis is carried out with 10 ml mixture of normal saline, 2 ml lidocaine 2% and 1500 units of hyaluronidase. Adequate adhesiolysis confirmed by adequate filling of the target nerve roots and the epidural space Figure 1. The catheter was fixed with bio-occlusive dressing and the patient transferred to the recovery room, patients monitored for any potential complications, such as lower limbs weakness. After confirming the absence of any complications, 6 mL of 5% NaCl solution was injected at a rate of 1 mL every 15 minutes for 1.5 hours. This was followed by the injection of 2 mL of 0.9% NaCl solution containing 40 mg of triamcinolone; patients were monitored in the recovery room for any complications. The epidural catheter was removed before discharging the patient.

Navi-Cath group

Adhesiolysis using steering device or video guided catheter (VGC) called NAVI catheter (spinout-v TM video guided catheter, Imedicom co,Ltd. Republic of Korea). The caudal epidural space is entered via a special trocar and introducer under lateral fluoroscopic guidance and confirmed by lateral and A-P fluoroscopic guidance to protect the catheter from kinking. Once the caudal epidural space is identified, 5 ml radio-contrast dye is injected to obtain an epidurogram to identify areas of filling defect. Then, the trocar is removed and the introducer kept in place under fluoroscopic guide. The guide wire was inserted through the introducer in the anterior epidural space under A-P and lateral fluoroscopy, then the NAVI catheter inserted using the guide wire, the handle assembly might be used to hold and direct the catheter from reaching opposite S3 to avoid dural puncture by downward tilt of the catheter tip. The NAVI-Cath is directed under fluoroscopy to the desired adhesions level Figure 2. 5 ml contrast dye injected to detect the filling defect, adhesiolysis was carried out mechanically by the catheter tip using the side ports and pharmacologically by injecting 10 ml mixture of 0.9% normal saline, 2 ml lidocaine 2% and 1,500 units of hyaluronidase. Adequate adhesiolysis confirmed by adequate filling of the target nerve roots and the epidural space. Before catheter removal 2 ml 0.9% normal saline and 40 mg triamcinolone was injected. Catheter removed at the operating room, then patient transferred to the recovery room.

Outcome measures

Primary outcome

Change in pain intensity (Numeric Rating Scale, NRS) at 6 months.

Secondary outcomes

Change in pain intensity (Numeric Rating Scale, NRS) at 1, 3

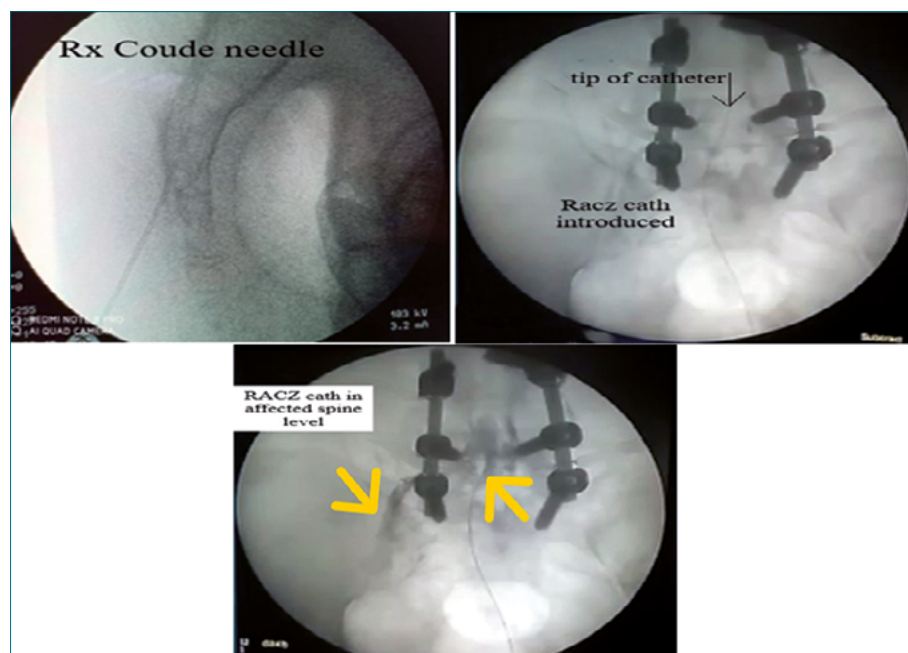


Figure 1. Racz adhesiolysis. Yellow arrows denote filling of the affected nerve root and the epidural space.

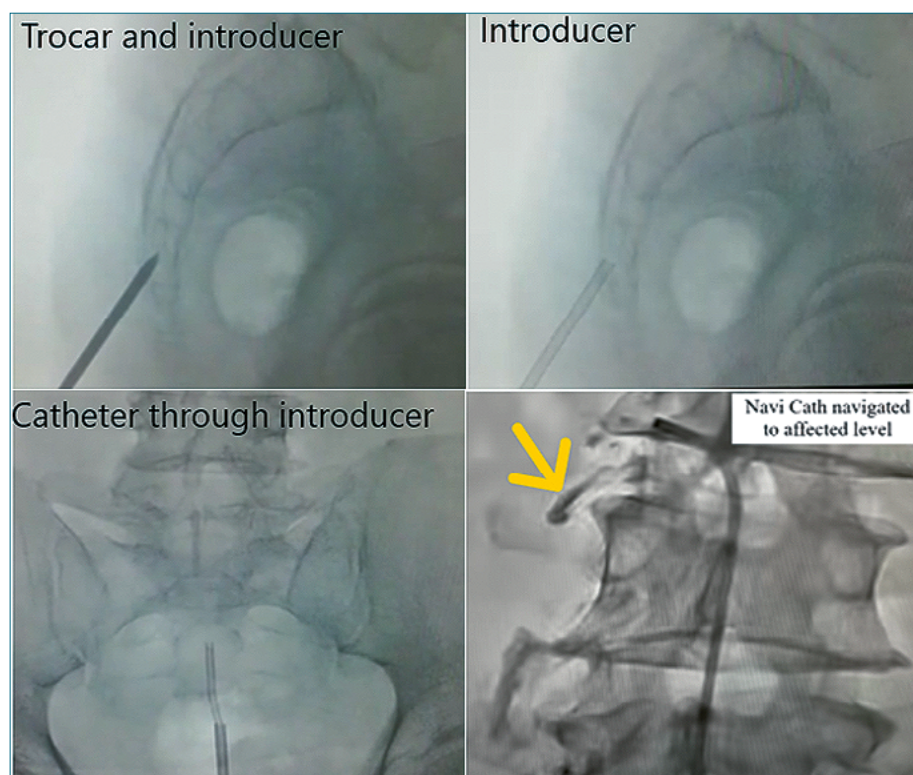


Figure 2. NAVI adhesiolysis. Yellow arrow denotes filling of the affected nerve root.

and 12 months. The changes in Functional disability using the Oswestry Disability Index at 1, 3, 6, and 12 months. Estimate Pregabalin consumption at 3, 6, and 12 months and Adverse events and complications were also recorded.

Sample size calculation

Sample size was calculated using G*Power 3.1, based on a previous study (Choi et al., 2016) reporting a mean VAS score of 3.9 at 6 months post-adhesiolysis. To detect a difference of 1 point in NRS with SD = 1.1, $\alpha = 0.05$, and 90% power, at least 25 patients per group were required. We included 30 per group to account for potential dropouts.

Statistical analysis

Data were analyzed using SPSS version 22. Normality was tested with the Shapiro-Wilk test. One-way ANOVA assessed changes over time within groups. Two-way repeated measures ANOVA evaluated between-group differences across time-points, with Greenhouse-Geisser correction applied when necessary. Post hoc pairwise comparisons were performed using Bonferroni adjustment. Percent improvement in each outcome was calculated as:

for NRS and ODI at 6,9 and 12 months.

A p-value < 0.05 was considered statistically significant.

Results

Patient characteristics

Of the 87 patients enrolled to the study (Figure 3), 60 completed the study (Racz group: 30; Navi-Cath group: 30). Baseline demographic and clinical characteristics were comparable between groups (Table 1).

Pain intensity (NRS)

At baseline, NRS scores did not differ significantly between groups ($p = 0.48$). No significant differences were observed at 1 month ($p = 0.1$) or 3 months ($p = 0.3$). However, the Navi-Cath group showed significantly lower NRS scores at 6 months ($p = 0.01$) and 12 months ($p = 0.002$) compared with the Racz group. Both groups demonstrated significant within-group reductions over time ($p < 0.001$ for each). Pain reduction percentages at 6 and 12 months were significantly greater in the Navi-Cath group (Table 2, Figure 4).

Functional disability (ODI)

ODI scores decreased significantly over time in both groups ($p < 0.001$). The Navi-Cath group consistently demonstrated superior functional recovery compared with the Racz group,

$$\text{Improvement} = \frac{(\text{baseline pre intervention measure} - \text{post intervention measure})}{(\text{baseline preintervention measure})} \times 100$$

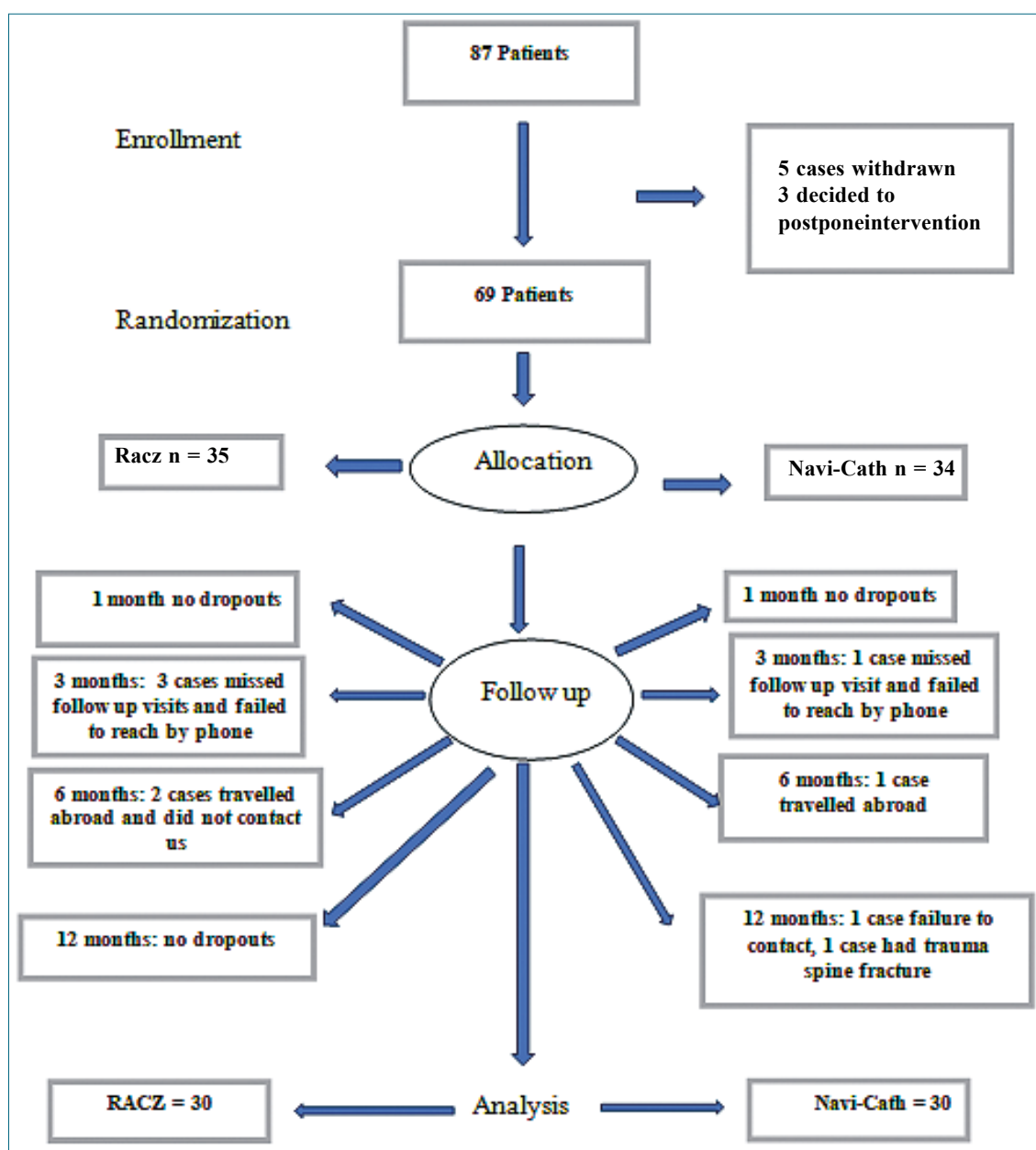


Figure 3. Flow chart.

with significant between-group differences at 3, 6, and 12 months ($p < 0.001$) (Table 4, Figure 5).

Pregabalin consumption

Pregabalin use decreased in both groups compared to baseline. Although consumption was lower in the Navi-Cath group throughout follow-up, the difference was not statistically significant ($p = 0.3$) (Table 5).

Complications

Adverse events were generally mild and comparable between groups. Reported complications included transient

headache ($n = 3$), temporary motor weakness ($n = 2$), catheter-related mechanical issues ($n = 3$ in Racz group only), and coccygodynia ($n = 1$ with NAVI-Cath). No severe complications (e.g., dural puncture, infection, or hematoma) occurred. No statistical difference was recorded regarding the complication rate between both groups (Table 6).

Discussion

Post-laminectomy syndrome, or failed back surgery syndrome (FBSS), affects up to 40% of patients following lumbar surgery and represents a major cause of chronic pain and disability. Epidural fibrosis is the most frequent underlying

Table 1. Demographic and clinical data among the studied groups

		Rac's	Navi	P- value
	Age (years)	49 ± 6	48 ± 7	0.7
Sex	Male	13	14	0.5
	Female	17	16	
	BMI	29 ± 4	30 ± 5	0.6
Number of previous spine surgeries	Once	19/30	18/30	0.8
	Twice	10/30	10/30	
	Triple	1/30	2/30	
Concurrent disease	spondylosis	5/30	4/30	0.5
	DM	5/30	4/30	0.6
	HTN	6/30	6/30	0.5
	Mild	17/30	10/30	0.5
	Moderate	10/30	9/30	
	Severe	2/30	9/30	

Mann-Whitney test for non parametric data; t test for parametric data and Chi Square for categorical data.

Table 2. NRS ratings across the study groups in relation to time

NRS	Pre-intervention	1 M	3 M	6 M	12 M	One way ANOVA	Two-way ANOVA Time*group interaction
Racz	8.9 ± 1	2.2 ± 1.2	2.5 ± 1.4	2.8 ± 1.3	3.2 ± 1	< 0.001	P = 0.05 F = 2.3 df = 3.5
NaviCath	9.1 ± 0.8 0.48	1.5 ± 1.1 0.1	2.2 ± 1.1 0.3	2 ± 0.8 0.01	2.4 ± 0.8 0.002	< 0.001	

Repeated measure analysis with Bonferroni post hoc analysis; One-way ANOVA is used to compare measures in the same group; Two-way ANOVA for measures comparison between both groups.

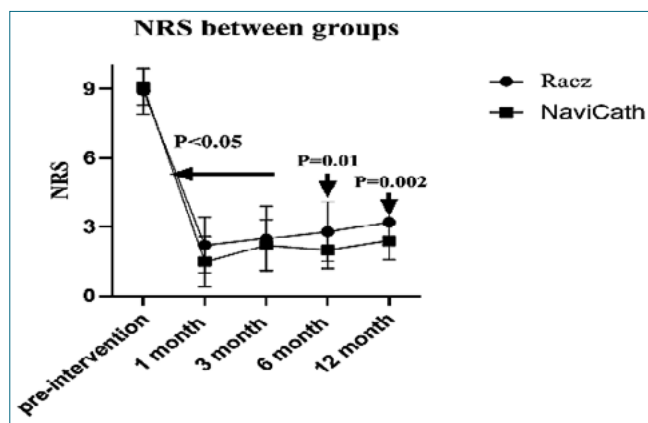


Figure 4. NRS comparison between groups.

mechanism, restricting nerve mobility, impairing neural blood flow, and limiting the spread of epidurally injected medications. These factors make FBSS particularly resistant to conventional therapies, including pharmacological treatment and epidural steroid injections (Manchikanti et al., 2004). There are several mechanisms by which epidural fibrosis can precipitate pain. One is nerve root tethering, which prevents free mobility of the nerve root in the intra-foraminal and epidural spaces with body

movement (Racz et al., 2016). A tethered nerve root is liable to tension, compression, and lack of nutrition. Second is postoperative impaired neural circulation, causing ischemic pain (Kim et al., 2013). Third is venous congestion, which results either from root compression causing outflow obstruction or secondary congestion due to arteriovenous anastomoses or neuroinflammation (Racz et al., 2016 and Kim et al., 2015). However, one other mechanism that could cause FBSS without fibrosis is the presence of the peridural membrane, which is innervated and can become inflamed, particularly in the infra-radicular space (Racz et al., 2016 and Beattie et al., 2000). Two levels of epidural fibrosis were identified by epiduroscopy: dense, resistant fibrous material that was difficult or impossible to penetrate and non-resistant loose or continuous threads and sheets of fibrous material (Bosscher and Heavner 2010). Fibrosis level and the associated vascular changes are correlated to adhesiolysis outcomes (Bosscher and Heavner 2014). These differences could be attributed to the larger size and the steerable mechanism in Navi-Cath, which makes it more effective in dissecting adhesions and fibrosis.

Percutaneous adhesiolysis (PA) has proved effective for the treatment of intractable chronic pain after the failure of conservative management and caudal epidural steroid injections (Kim et al., 2021). However, Patients with spinal stenosis or failed back surgery syndrome have a worse response to epidural steroid injection than do herniated disc patients; this is

Table 3. The Oswestry Disability Index (ODI) between the study groups

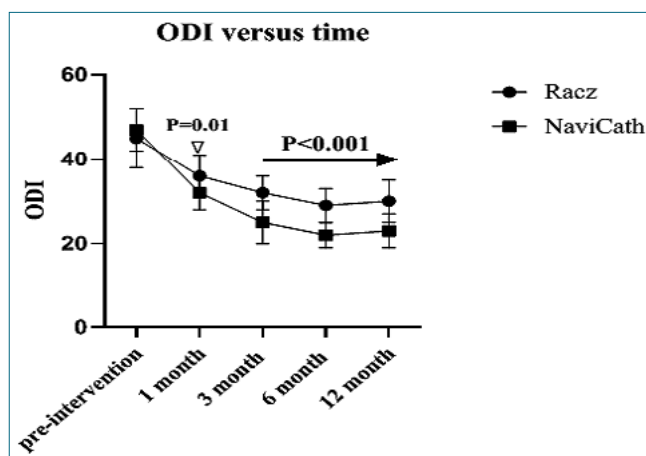
ODI	Pre-intervention	1 M	3 M	6 M	12 M	One way ANOVA	Two-way ANOVA Time * Group interaction
Racz	45 ± 7	36 ± 5	32 ± 4	29 ± 4	30 ± 5	< 0.001	P < 0.001 F = 12 df = 2.5
Navi-Cath	47 ± 5	32 ± 4	25 ± 5	23 ± 4	22 ± 3	< 0.001	
Pos -hoc	0.1	0.01	< 0.001	< 0.001	< 0.001		

Repeated measure analysis with Bonferroni post hoc analysis; One-way ANOVA for comparison between measures in the same group; Two-way ANOVA for measures comparison between both groups

Table 4. Pregabalin consumption between groups

Pregabalin	Pre-intervention	3 M	6 M	12 M	One way ANOVA	Two-way ANOVA Time*Group interaction
Racz	300	60 ± 16	70 ± 28	74 ± 22	> 0.001	P = 0.3 F = 1.2 df = 2.1
Navi	300	56 ± 13	60 ± 30	63 ± 27	> 0.001	
Post hoc	0.2	0.15	0.1			

Repeated measure analysis with Bonferroni post hoc analysis; One-way ANOVA for comparison between measures in the same group; Two-way ANOVA for measures comparison between both groups.

**Figure 5.** ODI comparison between groups.**Table 5. Percent of improvement**

	RACZ	Navicath	P Value
6 months pain reduction	68%	85%	< 0.001
12 months pain reduction	63%	86%	< 0.001
6 months ODI improvement	34%	36%	0.002
12 months ODI improvement	5%	54%	< 0.001

Chi-square test.

because Spinal stenosis and post-spine surgery syndrome are usually associated with irreversible anatomical changes such as epidural fibrosis, scarring, and hypertrophied lateral recess and ligament, which might render the nerve root unresponsive to local steroid application (park et al., 2011; Oh et al., 2019) (Table 3).

Table 6. Procedure complications

		RACZ	Navi	P- value
Treatment complication	Headache	1	2	0.4
	Temporary motor weakness	1	1	1
Catheter related complication	Bending	2	0	0.5
	Blocking	1	0	
	Steering	1	0	
	Coccydynia	0	1	

Mann-Whitney test.

To our knowledge, this trial is the first randomized controlled study directly comparing the Racz and Navi-Cath catheters in FBSS patients. Our results demonstrate that both approaches are effective, but Navi-Cath provided more durable pain relief and superior functional recovery at 6 and 12 months. This is consistent with findings by Lee & Lee (2012) that use of a steerable NaviCath catheter improves outcomes in patients refractory to transforaminal epidural injections.

The high prevalence of epidural fibrosis in previous reports (Lewik et al., 2023; Yeo et al., 2024) underscores the clinical challenge FBSS poses, especially when fibrotic tissue is severe. These reports provide context for our findings that more precise, steerable instrumentation might overcome some limitations posed by extensive adhesions.

Additionally, Quan et al. (2021) demonstrated that outcomes deteriorate with repeated surgical interventions, likely due to worsening fibrosis and adhesions, reinforcing the need for non-surgical interventions that more effectively address epidural fibrosis early. Our study's results with Navi-Cath suggest that better catheter design might offer longer-term relief with fewer repeat procedures.

Strengths of the study

To the best of current knowledge, this is the first randomized controlled trial directly comparing Racz versus Navi-Cath catheters in FBSS. This addresses a real clinical gap, as prior studies focused on single-catheter outcomes rather than head-to-head comparisons. Prospective, randomized, and double-blind design enhances internal validity.

Clinical implications

These findings suggest that while both Racz and Navi-Cath adhesiolysis improve pain and disability in FBSS, the Navi-Cath catheter may represent the preferred technique for long-term management, particularly in patients with extensive epidural fibrosis or difficult-to-access lesions. Importantly, complication rates did not differ between groups, supporting the safety of both techniques.

Study limitations

This trial has several limitations. It was conducted in a single center with a modest sample size, which may limit external validity. Follow-up was limited to 12 months, precluding long-term outcome assessment. The absence of a conservative control group (e.g., epidural steroid injections alone) restricts broader comparative analysis. Pregabalin use was the only measure of pharmacologic need, and additional analgesic metrics or quality-of-life assessments would strengthen the evaluation. Finally, patients were not stratified by fibrosis severity, which could influence treatment response.

Recommendations

Future multicenter randomized trials with larger cohorts and longer follow-up are needed to validate these findings. Incorporating imaging-based fibrosis grading or epiduroscopic classification may help tailor catheter selection. Cost-effective-

ness analyses are warranted to guide resource allocation. Finally, integrating patient-reported outcomes and psychological assessments would provide a more comprehensive view of clinical benefit.

Conclusion

In this randomized clinical trial, both Racz and Navi-Cath catheters improved pain and disability in FBSS patients. However, Navi-Cath produced significantly superior outcomes at 6 and 12 months, with sustained pain relief, functional recovery, and no increase in complication rates. These findings support the use of steerable catheters as a potentially more effective strategy for percutaneous adhesiolysis in FBSS.

Authors contribution: This study was designed by R.A. and S.E. The experiments were performed by R.A., M.A. and S.E. The data were analyzed by R.A. and E.K., and the results were critically examined by all authors. R.H. and S.E. had a primary role in preparing the manuscript, which was edited by E.K. and O.S. All authors have approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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