

Management for failed back surgery syndrome: three-in-one procedure versus percutaneous spinal fixation alone

Ahmed Abdalla Mohamed** , Atef Kamel Salama^a, Ahmed Essam Salem^b and Ashraf El Gallad^c

^aFaculty of Medicine, Department of Anesthesiology & ICU, Cairo University, Cairo, Egypt

^bFaculty of Medicine, Department of Anesthesiology & ICU, Tanta University, Tanta, Egypt

^cFaculty of Medicine, Department of Neurosurgery, Zagazig University, Zagazig, Egypt

*Corresponding author, email: abdalla2011125@hotmail.com



Objectives: To evaluate the short-term outcome of a 3-in-1 procedure including percutaneous facet radiofrequency, percutaneous spinal fixation and steroid with hyaluronidase enzyme injection versus percutaneous spinal fixation alone for cases with failed back surgery syndrome (FBSS).

Patients and methods: The study included 50 patients who had had previous spinal surgery since a mean duration of 39.7 ± 8.5 months and developed recurrent back pain since a mean duration of 10 ± 2.1 months. Patients were randomly allocated into two groups; group A underwent percutaneous spinal fixation only and group B underwent the 3-in-1 procedure. Outcome was evaluated at the end of six months postoperatively (PO) using a pain numeric rating scale (NRS), the Oswestry Disability Index (ODI) and Odom's criteria for evaluation of surgical outcome with evaluation of patients' satisfaction by outcome.

Results: All patients showed progressive decrease of NRS pain and ODI scores compared with preoperative scores. However, patients in group B showed significantly lower postoperative NRS pain scores and ODI with significantly higher frequency of patients having had > 50% reduction of both scores compared with patients in group A. PO analgesic consumption rate in both groups was significantly lower than the preoperative rate with a significant reduction of mean total scoring compared with preoperative scoring. The frequency of patients who found the provided therapeutic procedure satisfactory and its outcome good-to-excellent was significantly higher among patients in group B compared with group A.

Conclusion: Short-term outcomes of the applied 3-in-1 procedure are promising for improvement of symptoms secondary to FBSS and may ultimately prove to be recommended as the therapeutic modality for such a challenging clinical problem.

Keywords: failed spinal surgery, percutaneous facet radiofrequency, percutaneous spinal fixation

Introduction

Failed back surgery syndrome (FBSS) is the persistence or reappearance of pain after surgery on the spine.¹ Immediate FBSS is defined as persistence, deterioration or recurrence (during hospital stay) of radicular pain and/or sensorimotor deficits and/or sphincter dysfunction after microdiscectomy, which was uneventful from the surgeon's perspective.²

However, FBSS mostly occurs as a chronic pain condition that is a challenging clinical entity with significant impact on the individual and society. Despite advances in surgical technology, the rates of FBSS have not declined and due to the severe pain and disability this syndrome may cause, more radical treatments must be utilised.³

FBSS occurs in 5–40% of patients who undergo back surgery. Epidural scarring is the most common cause of FBSS where fibroplasia ensues due to the fibrin created from the chronic inflammatory process occurring following surgery and is deposited around the nerve root causing damage to the nerve root and restricting blood circulation. Fibroplasia suppresses the mobility of nerve roots, so certain motions trigger pain by stretching the nerve root and extreme fibroplasia limits the diffusion of drugs, thereby reducing the efficacy of drugs injected for treatment.⁴ The lumbar facet joints are responsible for local and referred pain to adjacent areas. Sacroiliac joint pain is also a challenging condition accounting for approximately 20% of cases of chronic lower back pain.⁵

The Dutch Societies of Anesthesiologists, Orthopaedic and Neurosurgical Surgeons documented that when conservative therapies such as pain medication or exercise therapy fail, invasive treatment may be indicated for patients with lumbosacral spinal pain. However, categorisation of low back pain into merely specific or nonspecific gives insufficient insight into the low back pain problem and does not adequately reflect which therapy is effective for the underlying disorder of pain syndrome.⁶

Radiofrequency (RF) neurotomy is one of the advanced pain relief procedures applied to pain with constant and limited distribution. Intended to identify and interrupt the nerves that contribute to chronic pain, the procedure can be used to help patients with chronic (long-lasting) lower back pain and pain related to the degeneration of joints by decreasing pain signals from that specific area. In these cases, RF is the preferred procedure due to its effectiveness over time and lack of complications.⁷ RF neurotomy has been useful for treatment of lumbar facet syndrome and sacroiliac joint pain. Despite gradual loss of efficacy, at 2 years 40% of patients maintained a 50% reduction of pain intensity. Therefore this procedure could be used for treatment of carefully selected patients with chronic lower back pain.⁵

The study aimed to evaluate the short-term outcome of a 3-in-1 procedure including percutaneous facet RF, percutaneous fixation and epidural steroid with hyaluronidase enzyme injection versus percutaneous fixation alone for cases with FBSS.

Patients and methods

This prospective comparative study was conducted at the Neurosurgery and Anaesthesia Departments, Naser Institute, Zagazig University Hospital in conjunction with certain private hospitals. The study protocol was approved by the local ethical committees. Patients fulfilling the inclusion criteria were required to give written full informed consent concerning the method of randomisation between study groups and modalities of management prior to being enrolled in the study.

Patients maintained on rehabilitation medicine for at least six months because of low back pain or lower extremity radiating pain that recurred after spinal surgery and patients who had positive results from controlled diagnostic lumbar facet joint nerve blocks with at least 80% pain relief and the ability to perform previously painful movements were enrolled in the study. Patients were randomised using sealed envelopes chosen by the patients themselves, and allocated into two equal groups: Group A included patients who underwent percutaneous fixation alone and Group B included patients who underwent the 3-in-1 procedure.

Patients with spondylolisthesis, spinal instability or fractures, radicular pain or who had undergone surgical interventions to the lumbar spine within the last three months were excluded from the study. The exclusion criteria also included chronic severe conditions that could interfere with the interpretations of the outcome assessments (subjective not objective criteria), pregnancy or lactation, patients unable to be positioned in the prone position, and patients with a history of adverse reactions to local anaesthetic or steroids.

Anaesthetic technique

All procedures were performed in the operating room under general anaesthesia. General anaesthesia was induced with propofol (2 mg/kg), fentanyl (2 µg/kg), midazolam (0.05 mg/kg), and atracurium (0.5 mg/kg). Anaesthesia was maintained by isoflurane inhalation (1–2%) and fentanyl 1 µg/kg/hour was used as intraoperative analgesia. Heart rate, systolic, diastolic, mean arterial blood pressure (MAP) and oxygen saturation were non-invasively monitored throughout the surgery. Ventilation was controlled and minute ventilation was adjusted to maintain end tidal CO₂ at 35 ± 5 mmHg. Intraoperative neuromuscular block was produced with atracurium. At the end of surgery, atropine sulphate 0.02 mg/kg and neostigmine 0.04 mg/kg were administered intravenously for reversal of muscle relaxation and the trachea was extubated. Following extubation, patients were maintained on supplemental O₂ until awake in the recovery room. Bradycardia and hypotension were defined as heart rate < 60 beat/min, and MAP < 65 mmHg and treated with atropine or ephedrine 5 mg IV, respectively.

Procedural techniques

All procedures were performed in the operating room under fluoroscopy with the patient in the prone position. Applied procedures included the following:

- (A) Percutaneous thermal RF denervation of the median branch of the facet nerve:

Target level was verified with a C-arm at the junction of the transverse process and the base of the superior articular process of the facet joint (FJ). With the C-arm in the oblique position to check needle trajectory and position, an 18-gauge insulated RF needle with 5 mm active tip was inserted through the sterilised skin and docked onto the

target point. After complete recovery from general anaesthesia sensory testing using 50 Hz at 1 V with 1-ms pulse duration to produce pain, pressure, or tingling and motor testing using 2 Hz at 3 V with 1-ms pulse duration were performed without any extremity muscle contraction. Then, a 5-mm active tip electrode was used to create a single lesion at 80°C for 120 s.⁸ (Neurotherm NT 2000, USA)

- (B) Percutaneous screw & rod insertion (Sextant) system:

The use of minimally invasive techniques like the CD Horizon® Sextant™ TM spinal system (Medtronic, Inc., The Netherlands) is better than the traditional lumbar pedicular screw fixation as regards postoperative morbidities. This minimally invasive technique is associated with less tissue trauma, less dissection with concomitantly less postoperative pain and early recovery. It is accomplished by percutaneous insertion of polyaxial screws and pre-contoured rods.⁹

- (C) Interlaminar epidural injection of triamcinolone and hyaluronidase:

A 20-gauge Touhy needle was inserted approximately 2–3 cm so that the needle went into the interspinous ligament. Then, a syringe containing air was attached to the needle and the needle was inserted slowly, 1–2 mm at a time until no resistance was felt. When the location of the needle was identified in the epidural space through the interspinous ligament, 2 ml triamcinolone 40 mg/ml and 1500 IU hyaluronidase were injected.¹⁰

Evaluations of clinical outcome Outcome measures

- (1) Primary outcome:

- Pain severity was assessed using an 11-point numeric rating scale (NRS) with 0 indicates no pain and 10 indicates worst pain imaginable. NRS was chosen as being more practical than the graphic visual analogue scale, easier to understand for most people, and does not need clear vision, paper, and pen.^{11,12} Back pain, leg pain, pain during day and during night were assessed and total NRS pain score was calculated. Pain was assessed preoperatively, immediately prior to hospital discharge and weekly for four weeks postoperatively and then monthly for six months postoperatively in hospital clinics.
- Disability secondary to pain was assessed using the Oswestry Low Back Pain Disability Questionnaire, which is one of the most widely used back-specific disability measurement tools in both clinical work and research.^{13,14} The questionnaire included 10 sections for evaluation of pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and travelling. For each section the total possible score is 5: if the first statement is marked the section score = 0; if the last statement is marked, the score = 5. If all 10 sections are completed the calculated score is 50. The Oswestry Disability Index (ODI) was calculated as follows: patient's score/total possible score multiplied by 100. If one section was missed or not applicable the

total score must be 45 and so on. The ODI scores are grouped into five categories: 0–20 minimal; 20–40 moderate; 40–60 severe disability; 60–80 crippled; and 80–100 indicates that the patient is either bed-bound or exaggerating his or her symptoms.^{14,15}

- The primary outcome measure was at least 50% improvement of NRS and ODI scores.^{16,17}

(2) Secondary outcome:

- Pain medication requirements pre- and post-treatment were recorded using a 0- to 4-point scale with 0: no medication, 1: over-the-counter medications, 2: non-opioid prescription medications, 3: as needed opioid prescription medications, 4: scheduled opioid prescription medications.
- Odom’s criteria include four grades: Excellent: relief of all preoperative symptoms and all abnormal findings were improved; Good: minimal persistence of preoperative symptoms and all abnormal findings were improved or unchanged; Fair: definite relief of some preoperative symptoms, while other symptoms were either unchanged or slightly improved; Poor: all preoperative symptoms and signs were unchanged or exacerbated.¹⁸
- Patients’ satisfaction with the procedure was assessed using four-point scale questionnaire with 4 = very satisfied and 1 = very dissatisfied. Willingness to receive treatment again if pain persists or recurs was checked using a five-point scale questionnaire with 5 = definitely will and 1 = definitely will not.

Statistical analysis

Sample size was calculated using the standard nomogram proposed by Kraemer and Thiemann¹⁹ so as to properly evaluate the primary outcome; considering that the frequency of failed spinal surgery is uncommon, a sample size of > 20 patients was found to be sufficient to detect a difference at the 5% significance level and give the trial 60% power.²⁰ Sample size and power were re-calculated and assured using the Power and Sample Size Calculation Software program provided by the Department of Biostatistics, Vanderbilt University (Nashville, USA).

Obtained data were presented as mean with standard deviation, numbers and percentages. Results were analysed using one-way ANOVA with Bonferroni multiple comparison for inter- and intra-groups comparisons and a chi-square test for non-parametric analysis of numbers and ratios. Statistical analysis was conducted using the SPSS (Version 15, 2006; SPSS Inc., Chicago, IL, USA) for Windows statistical package. A *p*-value < 0.05 was considered statistically significant.

Results

The study included 50 patients, 19 males and 31 females, with a mean age of 60.9 ± 6.3; range: 46–69 years. All patients had recurrent chronic back pain after previous spinal surgery. Details of demographic and clinical data of studied patients as shown in Table 1 were non-significantly (*p* > 0.05) different.

All procedures were completed uneventfully within a mean theatre time of 47.8 ± 11.5; range: 30–78 min; but procedures applied to patients in group B consumed significantly (*p* < 0.05) longer theatre time than for group A. All patients were managed

Table 1: Demographic and clinical data of studied patients

Data	Group A	Group B	
Age (years)	<60 years	8 (32%)	11 (44%)
	>60 years	17 (68%)	14 (56%)
	Mean age	61.4 ± 6.9	60.4 ± 6.3
Gender	Males	10 (40%)	9 (36%)
	Females	15 (60%)	16 (64%)
Weight (kg)	81.3 ± 4.6	82.5 ± 5.2	
Height (cm)	167.8 ± 3.1	168.2 ± 3.3	
BMI (kg/m ²)	28.9 ± 1.6	29.2 ± 1.8	
Duration since previous surgery (months)	38.1 ± 9.5	39.3 ± 10.2	
Duration of pain (months)	9.4 ± 1.8	10.6 ± 2.4	
Affected level	L2–3	2 (8%)	3 (12%)
	L3–4	6 (24%)	9 (36%)
	L4–5	8 (32%)	6 (24%)
	L5-S1	9 (36%)	7 (28%)
Number of affected segments	One segment	7 (28%)	7 (28%)
	Two segments	11 (44%)	9 (36%)
	Three segments	6 (24%)	7 (28%)
	Four segments	1 (4%)	2 (8%)

Notes: Data are presented as numbers and mean ± SD; percentages are in parentheses; BMI = body mass index.

as one-day surgery and were discharged after a mean duration of hospital stay of 6.4 ± 1.6; range: 4–10 h. Patients in group A stayed in hospital for significantly (*p* < 0.05) longer duration than patients in group B (Figure 1).

Throughout six-month follow-up period, all studied patients showed a progressive decrease of NRS pain scores with a significant (*p* < 0.05) difference compared with preoperative scores (Figure 2). Patients who received the 3-in-1 procedure (Group B) showed significantly (*p* < 0.05) less postoperative NRS pain scores compared with patients who received spinal fixation alone (Group A). Twenty-two patients, 14 in group A and 8 in group B, documented decreased NRS pain scores by < 50% with a significantly (*p* < 0.05) higher frequency of patients having a decrease of > 50% and significantly (*p* < 0.05) lower mean total NRS pain score determined at the end of 6 months in group B compared with group A (Table 2).

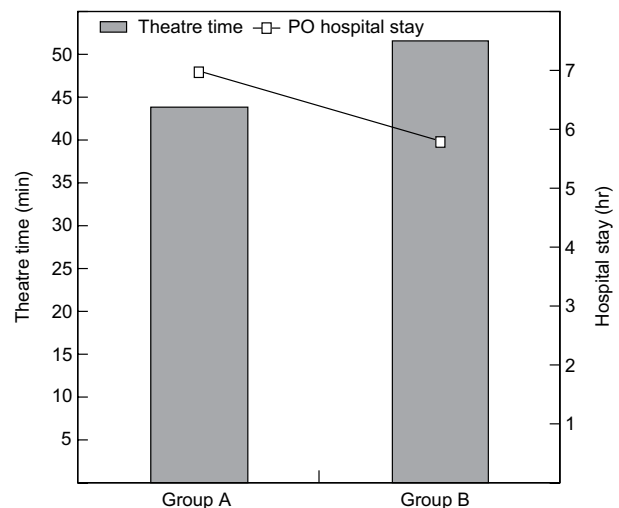


Figure 1: Mean theatre time and postoperative hospital stay of patients in both groups.

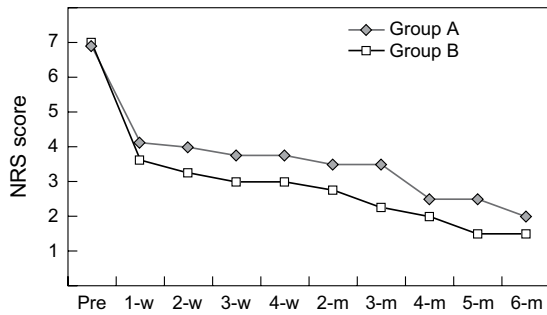


Figure 2: Median total NRS pain score of studied patients determined throughout follow-up period compared with preoperative total score.

Table 2: Mean total NRS and ODI scores of studied patients and frequency of patients showing improvement at end of follow-up

Variable		Group A	Group B
Total NRS score	Mean	Preoperative	6.75 ± 0.8
		End of follow-up	2.3 ± 0.4*
	Frequency of improvement	< 50%	14 (56%)
		> 50%	11 (44%)
ODI score	Mean	Preoperative	33.2 ± 6.1
		End of follow-up	16.5 ± 2.9*
	Frequency of improvement	< 50%	12 (48%)
		> 50%	13 (52%)

Notes: Data are presented as mean ± SD and numbers; percentages are in parentheses.

*Significant difference versus preoperative score.

†Significant difference versus group A.

At the end of six-month follow-up, mean ODI score was significantly ($p < 0.05$) lower compared with the preoperative score in both groups with a significantly ($p < 0.05$) lower score in group B compared with group A. Moreover, 18 patients, 12 in group A and 6 in group B, documented decreased ODI score by < 50% with a significantly ($p < 0.05$) lower frequency in group B compared with group A (see Table 2).

Improvement of pain sensation and disability allowed for a significant ($p < 0.05$) reduction of PO analgesic consumption in both groups compared with preoperative consumption, with a significant ($p < 0.05$) reduction of mean total scoring of received medication compared with preoperative scoring. Moreover, the frequency of patients consuming less PO analgesia was significantly ($p < 0.05$) higher in patients in group B compared with patients in group A with non-significantly ($p > 0.05$) lower mean total scoring of received medication. Twenty-one patients, 15 in group A and 6 in group B, found the relief of preoperative manifestation of pain was poor (6 patients) to fair (15 patients) with significant ($p < 0.05$) difference in favour of group B. Similarly, 18 patients, 11 in group A and 7 in group B, were dissatisfied with their outcome, while other patients were either satisfied or very satisfied with significant ($p < 0.05$) difference in favour of group B (Table 3). Figure 3 shows a flowchart of the participants in the study.

Discussion

The reported PO significant reduction of pain and 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 and handicap after failed back spinal surgery (FBSS). However, the additive effect of adjuvant procedures (the 3-in-1 procedure) was evident and manifested as significantly lower PO pain and ODI scores with significantly lower consumption of PO analgesia than in patients who had spinal fixation alone. Moreover, the frequency of patients who found the 3-in-1 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).

Unfortunately, no previous study has evaluated the outcome of the 3-in-1 procedure; however, the results obtained in the current study go hand in hand with multiple studies that evaluated each procedure separately; for example, Selznick *et al.*²¹ found minimally invasive lumbar interbody fusion by revision surgery is technically feasible and is not associated with more blood loss or neurologic morbidity. Also, Roy *et al.*²² found that transformational epidural steroid significantly reduced pain NRS and disability scores until 12 months after injection. Moreover, Turunen *et al.*²³ examined the long-term outcome of lumbar transpedicular instrumented posterolateral fusion in patients with varied diagnoses and reported the greatest improvement in ODI and pain VAS values was in patients who had degenerative spondylolisthesis with spinal stenosis, followed by patients who had FBSS after one to three laminectomy operations, while the lowest was in patients who had adult isthmic spondylolisthesis, and they concluded that long-term outcomes of lumbar instrumented posterolateral fusion were satisfactory for > 80% of patients.

Helm *et al.*²⁴ 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. Hadziahmetovic *et al.*²⁵ found needle instillation of steroid and lidocaine to be effective in short-term pain control in different painful spine conditions with a statistically significant difference between ODI score and VAS values before procedure and seven days later and concluded that the procedure is a valuable alternative to the classic methods of physical and drug therapy and can also postpone surgical treatment. Hsu *et al.*²⁶ retrospectively studied 115 patients who underwent epidural lysis of adhesions for FBSS or spinal stenosis and reported a modest success rate. Thereafter, Ko *et al.*²⁷ 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.

Kanchiku *et al.*²⁸ suggested that percutaneous RF facet joint denervation is a safe, long-lasting and effective treatment with success rate of 60% at six months after treatment. Also, Spijker-Huiges *et al.*²⁹ found a statistically significant effect of segmental epidural steroid injections on back pain, impairment and disability in acute lumbosacral radicular syndrome and patients from the intervention group were significantly more satisfied with the treatment received than patients from the control group. Moreover, Kim *et al.*³⁰ found that repeated RF neurotomy for lumbar facet joint pain after microscopic discectomy is an effective palliative treatment and provided a mean duration of relief of 9.0 months and > 94% success rate.

Recently, Romero *et al.*³¹ reported short-term pain relief after RF denervation for sacroiliac joint pain with significant progressive decrease of NRS pain score determined at one and six months post-procedure, and long-term pain relief was sustained at 12

Table 3: Patient distribution according to postoperative analgesic consumption, Odom's criteria and satisfaction scoring of surgical outcome in both groups

Items	Score	Group A		Group B	
		Pre	Post	Pre	Post
Postoperative medications	0	0 (0%)	4 (16%)*	0 (0%)	8 (32%)*†
	1	7 (14%)	11 (44%)	6 (24%)	10 (40%)
	2	10 (40%)	8 (32%)	9 (36%)	6 (24%)
	3	6 (24%)	1 (4%)	7 (28%)	1 (4%)
	4	2 (8%)	1 (4%)	3 (12%)	0
	Total score		2.12 ± 0.9	1.28 ± 0.9*	2.28 ± 1
Odom's criteria	Excellent	3 (12%)		6 (24%)*	
	Good	7 (28%)		13 (52%)	
	Fair	10 (40%)		5 (20%)	
	Poor	5 (25%)		1 (4%)	
Satisfaction scoring	Very satisfied	4 (16%)		7 (28%)*	
	Satisfied	10 (40%)		11 (44%)	
	Dissatisfied	9 (36%)		6 (24%)	
	Very dissatisfied	2 (8%)		1 (8%)	

Notes: Data are presented as numbers and mean ± SD; percentages are in parentheses.

*Significant difference versus preoperative score.

†Significant difference versus group A.

and 18 months post-procedure. They concluded that RF denervation of the sacroiliac joint can significantly reduce pain in selected patients with sacroiliac syndrome. McCormick *et al.*³² found function and pain improved by ≥ 50% in 58% and 53% of individuals, respectively, after RF ablation of the medial branch nerves for facet-mediated low back pain with a median reduction in Medication Quantification Scale III score by 3.4 points and the procedure was free of complications.

Van Boxem *et al.*³³ reported six-month clinical success for pulsed RF (PRF) treatment of the dorsal root ganglion for chronic intractable lumbosacral radicular pain of 55.4%, with significant improvement of ODI and the physical component of quality of life questionnaire and a significant reduction in the number of patients on opioids. Thereafter, in 2016, Van Boxem *et al.*³⁴ found that a successful outcome of PRF is more likely in patients aged ≥ 55 years with limited disability and after a positive diagnostic nerve root block, and a combination of all these factors creates a high predictive value.

The current study relied for evaluation of procedural success on reduction of pre-procedural pain severity and disability by > 50 at the end of 6 months' follow-up. In support of this cut-off point for evaluation of procedural success; Avellanal *et al.*¹⁸ defined treatment success as ≥ 50% long-term pain relief maintained during the first year of follow-up. Also, Manchikanti *et al.*³⁵ documented that the summary measure for pain was ≥ 50% reduction of pain in at least 50% of patients, or at least a three-point decrease in pain scores; for disability scores the summary measure was ≥ 50% reduction in disability in at least 40% of

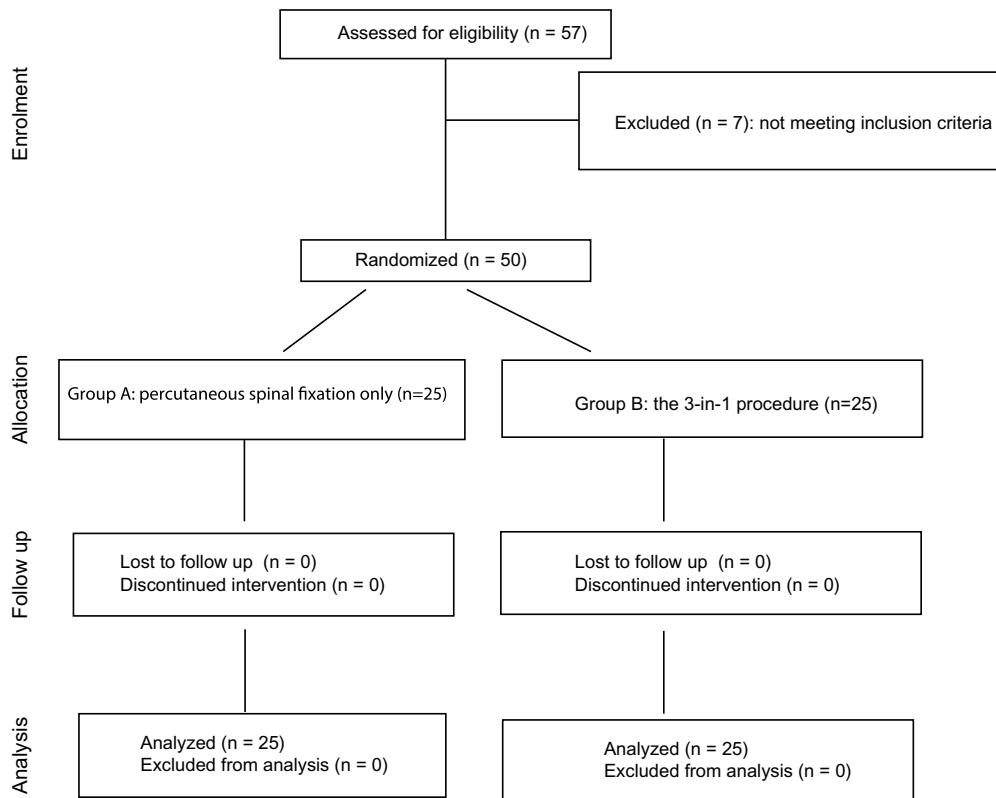


Figure 3: CONSORT Flow participant diagram.

patients or at least a 30-point decrease in disability scores measured on a scale of 0–100.

The superior outcome of the applied 3-in-1 procedure could be attributed to gathering the best for each procedure in one setting, thus improving the short-term outcome of these disabled patients with FBSS. It could therefore be concluded that the applied 3-in-1 procedure is promising for improvement in symptoms secondary to FBSS and may be recommended as the therapeutic modality for such a challenging clinical problem. However, long-term follow-up and wider-scale studies are mandatory for establishment of these outcomes.

ORCID

Ahmed Abdalla Mohamed  <http://orcid.org/0000-0003-1141-1086>

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