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THERAPEUTIC INTERVENTIONAL PROCEDURES FOLLOWING FAILED BACK SURGERY; IS IT WORTH IT?

Therapeutic Interventional Procedures following Failed Back Surgery; Is It Worth it?

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Abstract

Background Data: Treatment of failed back surgery syndrome (FBSS) is challenging to any spine surgeon or pain specialist.

Purpose: The study aims to evaluate pain and functional outcome in response to lumbar spine interventional procedures in failed back.

Study Design: Prospective non-randomized clinical case study.

Patients and methods: Between Jan 2013 to Jan 2016, 35 patients with FBSS were included. Every patient was subjected to history taking, physical examination, and diagnostic imaging. Patients received a fluoroscopy guided lumbar spine procedures according to the failed back cause. A visual analog scale (VAS) for pain intensity, and Oswestry Disability index (ODI) were completed before the intervention maneuverand continued for one year during follow up. Patients were prepared for another intervention or surgery if he didn't respond to the maneuver according to the case.

Results: Patients were predominately females (62.9%) with a mean age of 39.74±12.37 years. Clinical and radiological finding revealed; 31.4% canal or foraminal stenosis, 25.8% facet arthropathy, 17.2% epidural scar, 14.3% recurrent disc, and 11.3% degenerative sacroilitis. After intervention procedure, and during 12 months follow up, one way ANOVA test was significant with P=0.001 for both VAS and ODI. Multivariate logistic regression analysis for both VAS and ODI after one year revealed that proper diagnosis and intervention maneuver were the independent factors that affect both

with P value (0.001, 0.002), and (0.001, 0.018) respectively. Only 22.9% of cases end up with surgery during this year.

Conclusion: Intervention procedures in FBSS can improve pain scale and functional outcome in most cases up to one year. Surgery should be the last line of therapy when the case is indicated. (2016ESJ117)

Keywords: Failed back surgery syndrome, therapeutic interventional, lumbar spine

Introduction

Failed back surgery syndrome (FBSS) or post lumbar surgery syndrome are terms used to explain unsatisfactory outcome after lumbar spine surgery.[3] FBSS can be defined as persistent or recurring low back pain, with or without sciatica following one or more lumbar surgeries.[35] The rate of the FBSS increased in the last two decades despite of the advances in surgical technology.[14,22] A recent systemic literature review of discectomies for lumbar disc herniation demonstrates that 5%–36% of patients after 2 years had FBSS below the age of 70 years.[1,31] Another retrospective cohort study of 35,558 patients in South Korea, who underwent lumber disc surgery, the re-operation rate after 5 years was 13.4%.[20]

Epidural fibrosis after lumbar surgery is a progressive disease associated with radicular pain and unfavorable outcomes. Epidural scar usually developed in response to tissue damage, mainly nucleus pulposus, or hematoma during surgery.[32] Typically, the degenerative changes progresses overtime to development either central or foraminal spinal stenosis due to facet joint or disc degeneration, or segment instability.[1] Stenosis can also be initiated or exacerbated by epidural adhesions.[26] Ddegenerative changes can be accelerated in the adjacent segments after fusion surgeries. Fusion to the sacrum may hasten the development of sacroiliac joint (SIJ) disease.[1,2]

There is no consensus about the best treatment for failed back syndrome, but there are general agreement to try conservative therapy first unless the patient had sever incapacitating radiculopathy, instability, or progressive neurological impairments.[1,22] Surgical revision for FBSS is associated with a high morbidity and lower success rate.[1,3]

Lumbar injection of analgesia and steroids are commonly used, by interventional pain specialists, to improve back pain or sciatica associated with FBSS. The duration of analgesia ranges from 1-12 months.[14] Epidural steroid injection procedures are commonly used. It can be administered primarily by three approaches: transforaminal, interlaminar, or caudally to alleviate radicular pain. A recent meta-analysis study found that one third to one half of patients can avoid spine surgery in short term with epidural steroid injection.[4]

Injection of the facet jointsand SIJ are common maneuver used for back pain associated with degenerated facet or SIJ after back surgery.[1,21] when surgery failed to improve pain, radiofrequency ablation (RFA) of the lumbar facet or SIJ are often used. Pain relief can be extended from 6 months up to 2 years.[1,28]

The aim of this study was to assess the quality of pain relief and functional outcome in response to therapeutic interventional procedures for the lumbar spine in FBSS.

Patients and Methods

This prospective evaluation of therapeutic Interventional lumbar spine procedures under fluoroscopy was undertaken in Suez Canal University Hospital, in Ismailia, and in

El-Mebarra health insurance hospital, in Port Said, Egypt. From Jan 2013 to Jan 2016, 35 patients attending the neurosurgery outpatient clinic were included in this study. All patients received at least 6 months of conservative treatment before the procedure. It consisted of analgesics, anti-inflammatory drugs, and/or physical therapy. Potential advantages and disadvantages of the maneuver were explained, and a written consent was signedbyevery patient.

FBSS patients following spinal canal stenosis and/or disc herniation surgery of ≥18 years old, with back and/or leg pain of significant VAS (≥5), and at least a 40% decrease on ODI[35] were included in this study. Uuncontrolled psychological disorders patients, severe or progressive neurological deficit, addiction, local anesthetic allergies, skin infections, severe cardiopulmonary disease, uncontrolled diabetes, morbid obesity, exogenous steroid application restriction, coagulation disorders, pregnancy, workers' compensation claims, multiple and overlapping complaints involving concomitant hip osteoarthritis, and segment instability associated with high failure rate were excluded from our study.

The assessment included demographic data of age, gender, weight, and previous back surgery. All Patients had complete neurological examination. The distribution of back pain and radicular pain were further assessed in conjunction with MRI or CT findings. The recurrence of disc compression, epidural fibrosis, facet arthropathy changes, and SIJ degeneration were confirmed by the results of the image. Dynamic x-ray films were done in every case to assess stability. Before the intervention maneuver, visual analog scale (VAS),[27] and Oswestry disability index (ODI)[11] were fulfilled by enrolled patients. Questionnaire wererepeated at 2 weeks, 6 months, and 12 months after the procedures.

In degenerative facet disease, pain distribution was categorized according to the level of the facet joint affection. Therapeutic medial branch block for facet arthropathy was done. The needles were inserted in the medial branch location.[12] Two to four facets medial branches would be injected according to the case. We used to do therapeutic instead of diagnostic block for the patient benefit. If the injection was successful, the patient can be planned for repeated sessions, or he was candidate for RFA of the facet medial branch if he had narrow time window for free pain. In patient with SIJ pain, injection was prepared in ordinary fashion. The joint could be injected along or in association with S1medial branch in most cases.

The level and cause of neural compression and radiculopathy after surgery (disc herniation, spinal canal stenosis, or scar formation) were recorded. Caudal epidural blocks was used for cases of extensive epidural fibrosis, or stenosis. (Figure 1A) Transforaminal blocks were administered for those with disc herniation and isolated radicular pain. At least two radicular nerves were injected. (Figure 1A-D) At least 50% pain relief on the VAS was considered clinically significant.[5]

The procedure and technique of treatment were determined by using guidelines based on European tests, and practices for the treatment of chronic back pain described in previous work by the same institute.[6,12]

In patient with sever anxiety, intravenous administration of midazolam 2mg and fentanyl 100 mcg were used. In all cases, fluoroscopy guidance was used. Local anesthetic agents used for injection were lidocaine 1% or bupivacaine HCL 0.5% along with steroids (80 mg triamcinolone). For epidural injection, injection

3-5 ml of nonionic contrast media Omnipaque (iohexol 300 mg) was used to perform an epidurogram, so the injection localization of the roots was clarified. After injection maneuver, all patients transferred to the Peri-Anesthesia Care Unit for monitoring vital signs, pain levels, and possible neurological adverse events for 60-90 minutes. They were then discharged home with instruction not to work for 24 hours.[14]

Evaluation of complications included headache, nausea, vomiting, bleeding, swelling, pain, fever with meningitis and arachnoiditis, numbness, weakness were reported by the patients.[35]

All patients were re-assessed for the location, intensity, and the nature of low back pain and radicular pain in regular follow up. Patients with no response or no improvement to all previous treatments were assessed for surgery.

Statistical Analyses:

The collected data were collected and analyzed by Statistical Package for Social Science (SPSS) version 20. Parametric data for each variable was presented in mean ± SD. Categorical numeric data were analyzed using chi square test. One way ANOVA test was used for assessment of regression of pain (VAS) and improvement of the function (ODI) during follow up. A multivariate regression model including age, diagnosis, type of spine intervention, was constructed to identify the factors that may have contributed to a favorable outcome. P value less than 0.05 was considered significant.

Results

A total of 35 patients were enrolled in the study, patient characteristics and demographic data are illustrated in (Table 1) including age and gender. Patients were predominately females (62.9%) with a mean age of 39.74±12.37 years. Diagnosis was categorized according to patients' clinical and radiological data. (Table 2) All patients had back pain and sciatica with predominant sciatica in 48.6%. Only two patients (5.4%) experienced previous two back surgeries.L4/5 was the most commonly affected level in 48.6%. Central and foraminal stenosis together with residual disc was account for 45.7% of cases, followed by facet arthropathy 25.7%.

Type of spine intervention was illustrated in table 3. Transforaminal epidural injections were done in 34.3% of cases, followed by medial branch block in 25.7% of cases; 8.6% of them needed further RFA of the medial branch. Failure of the technique that mandated surgical intervention was reported in 22.9% of cases, and 17.2% of them due to recurrent disc or canal stenosis. (Table 4)

The pre-procedural VAS mean ranged from (6-9) with a mean of 7.09. The post-procedural VAS score ranged from 2 to 5 with a mean of 3.66, and after one year VAS score was ranged from 2 to 5 with mean 3.54. One-way ANOVA for VAS analysis pre procedure and during follow up was significant, with P=0.001. It was noticed that VAS mean was much less recoded after 6 months comparatively to 2 weeks after the intervention maneuver denoting that some patient had more intervention (2nd injection, or surgery for those patient with no response after first maneuver). (Table 5) The pre-procedural ODI ranged from 20 to 50 with a mean of 30.11. The post-procedural ODI ranged from 14 to 24 with a mean of 19.20. After one year, ODI was ranged from 18-24 with mean 22.34. Functional outcome (ODI) was improved significantly with P=0.001. (Table 5)

Analysis of a multivariate logistic regression for VAS after one year as indicator of pain outcome revealed that age, accurate diagnosis, proper intervention maneuver, and further

intervention if needed were independent factors affecting the pain outcome. (Figure 2A) For ODI analysis after one year, only age, accurate diagnosis, and intervention maneuver were the independent factors that affecting the outcome. (Figure 2B)The only explanation for that is more accuracy of ODI rather than subjective VAS score for verification of the outcome. Also, second intervention (injection, RFA, or even surgery) could decrease the pain, but much less affecting the daily life activity of the failed back patient. (Table 6) We had two patients with inadvertent subarachnoid injection, prolonged sensory motor block up to 6 hours in epidural injection.

Table 1. Patients Characteristics.

Characteristic		Value
No. of Patients		35 (100%)
Sex	Male Female	13 (37.1%) 22 (62.9%)
Age		39.74±12.37
Co-morbidity	Co-morbidity Hypertension Diabetes mellitus Hypertension &Diabetes mellitus Smoke	13 (37.1%) 4 (11.4%) 4 (11.4%) 1 (2.9%) 4 (11.4%)
Clinical	Back &leg pain Back pain Leg pain uni or bilateral Sacroiliac pain	12 (34.3%) 2 (5.7%) 17 (48.6%) 4 (11.4%)
Previous Surgery	1 2	33 (94.6) 2 (5.4%)
Level of surgery	L3-4 L4-5 L3-5 L5-S1 L4-S1	3 (8.9%) 17 (48.6%) 2 (5.4%) 7 (20%) 6 (17.1%)

Table 2. Diagnosis of Patients Who Underwent Intervention and Type of Intervention.

Diagnosis	No. (%)
Facet arthropathy	9 (25.7%)
Spinal Canal Stenosis	5 (14.3%)
Single Level Foraminal Stenosis	6 (17.1%)
Sacroilitis	4 (11.4%)
Epidural Scar	6 (17.1%)
Residual Post Surgical Disc	5 (14.3%)

Table 3. Diagnosis of Patients Who Underwent Intervention.

Intervention Maneuver	No. (%)
Medial branch blocks	9 (25.7%)
Sacroiliac joint blocks	4 (11.4%)
Transforaminal epidural injections	12 (34.3%)
Epidural injection	10 (28.6%)

Table 4. Patient Needed Additional Maneuvers.

Maneuver	No. (%)
1 Injection	12 (34.3%)
2 Injection	12 (34.3%)
1 Injection + RFA	3 (8.6%)
1 Injection + Discectomy	5 (14.3%)
1 Injection + Laminotomy	2 (5.7%)
1 Injection + PLIF augmented fixation	1 (2.9%)

Table 5. Comparison of Mean VAS and ODI in Each Group.

VAS	(No.=35)	ODI	(N=35)
Pre injection	7.09±1.12	Pre injection	30.11±10.76
After 2 weeks	3.66±1.26	After 2 weeks	19.20±5.34
After 6 months	3.17±0.92	After 6 months	21.26±4.60
After 1year	3.54±1.09	After 1year	22.34±4.43
Significance	0.001	Significance	0.001

Values are mean±standard deviation, VAS: Visual analog scale, ODI: Oswestry disability index. *One-way ANOVA.

Table 6. Multivariate Logistic Regression Analysis of Factors Associated with a Favorable Response in VAS and ODI After One Year.

VAS after one year	P value	ODI after 1 year	P value
Age	0.016	Age	0.010
Diagnosis	0.001*	Diagnosis	0.018
Intervention	0.002*	Intervention	0.001*
Maneuver	0.005*	Maneuver	0.260

Multivariate analysis for VAS after one year as dependent variable with R square 0.699 and adjusted R square 0.590. ANOVA is sig. P=0.001. Multivariate analysis for ODI after one year as dependent variable with R square 0. 665 and adjusted R square 0.442 ANOVA is sig. P=0.001.

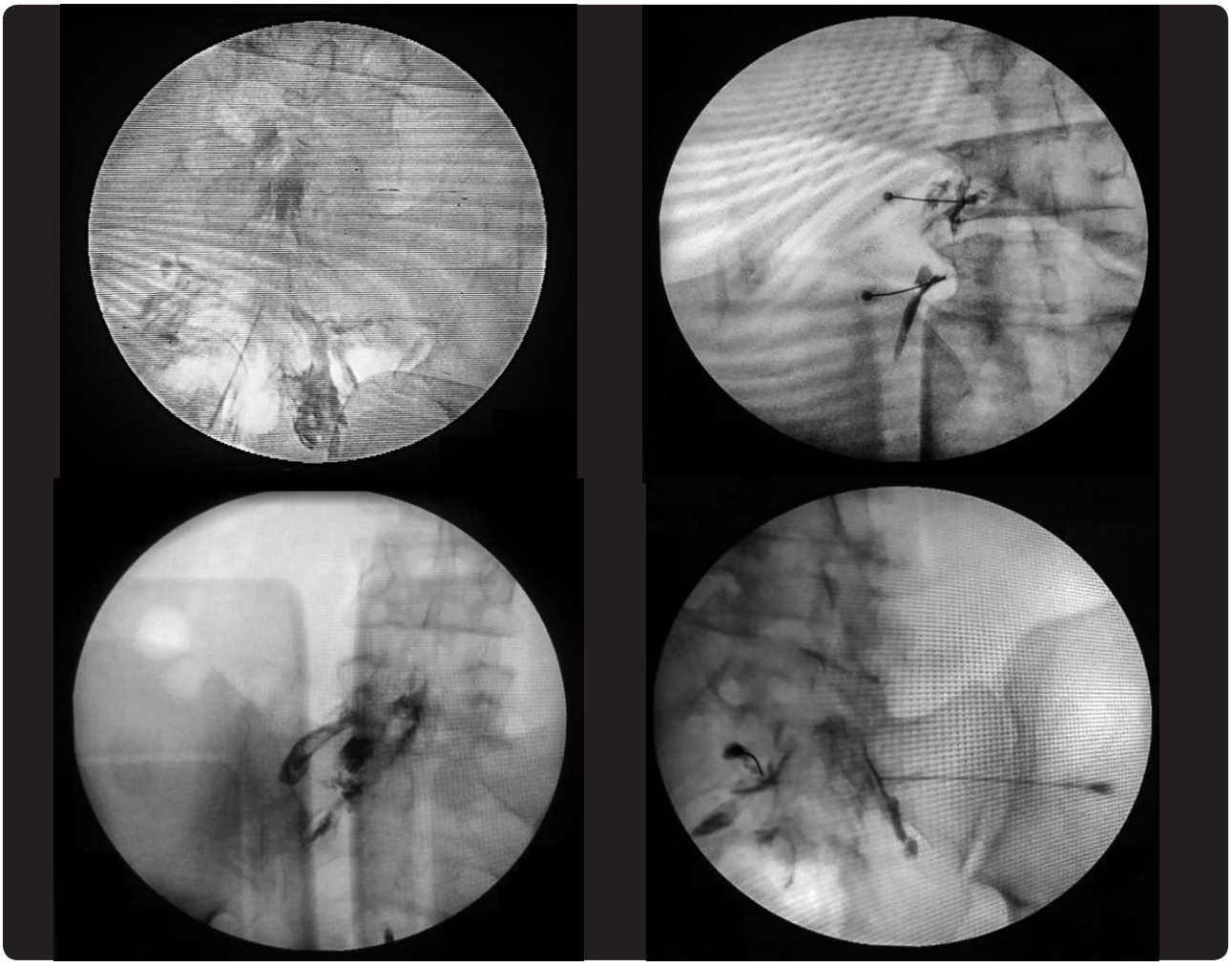

Figure 1. Fluoroscopic images of different epidural injection modalities after injection of the contrast; A) Caudal epidural injection contrast (noticed the needle extended into L5/S1 disc). Patient had lamintomy L5/S1. B) Pre (L4 root) and post ganglionic (L5 root) injection after L4/5 fenestration discectomies. C) Edematous and swollen L5 roots found during injection. Patient had laminotomy L3/4, and 4/5. D) Incomplete stain of the right S1 root comparative to the left one. Patient had bilateral sciatica after L5/S1 fenestration discectomy. The patient had residual disc that mandate re-surgery on the right one.

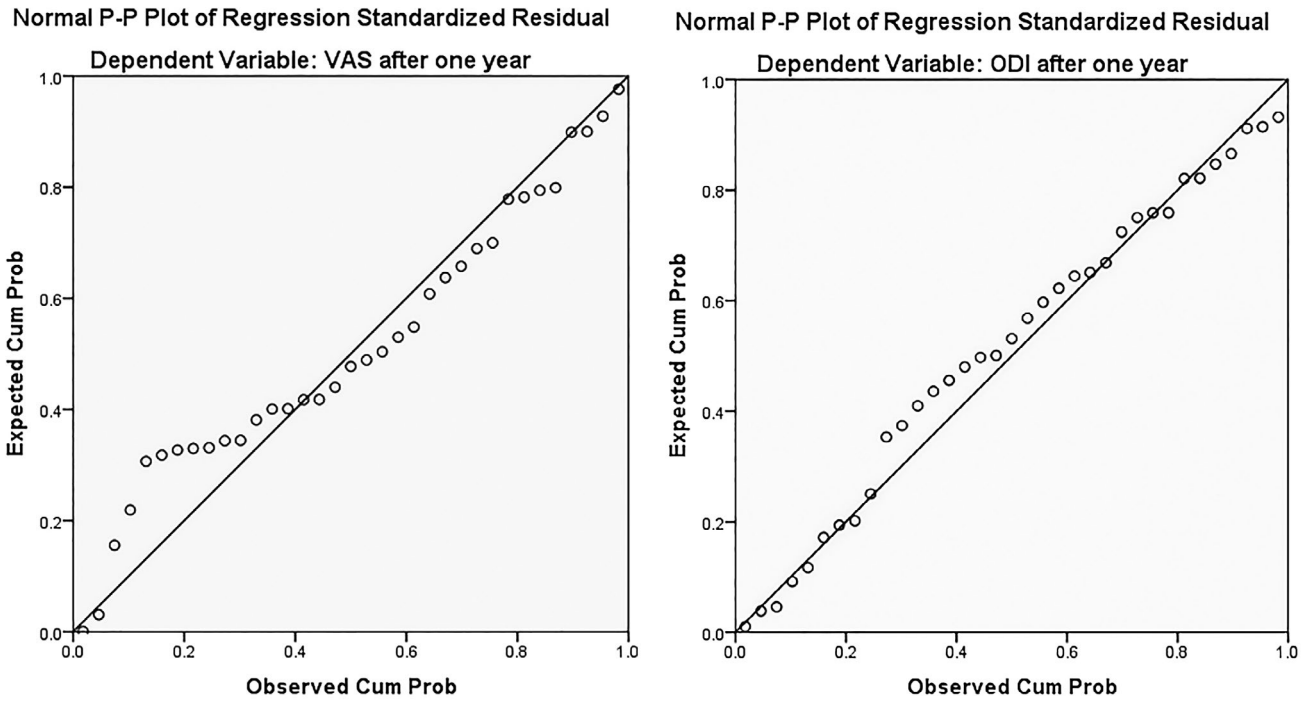

Figure 2. Multivariate regression analysis for VAS a (A) and ODI (B) after one year of intervention

Discussion

Recurrence of the back pain after surgery is caused by many factors. Many patients assumed that incomplete primary surgery is usually the case. But in fact, pain may result from aging process of the lumbar spine or new onset of spine pathology.[1]

In order to manage FBSS, etiology should be determined first. As in this study, with other, the most common causes of FBSS are degenerative facet changes and associated spinal stenosis, herniated disc, and epidural fibrosis.[35] Surgical revision for FBSS is associated with low success rate and high morbidity.[1,2] According to such statement, many alternate methods had been tried.[14,19,29,35]

Epidural fibrosis after surgery is a common causes of FBSS, it is often refractory to surgical management.[14,32] Causes of epidural fibrosis include the surgeon's rough manipulation of tissue during surgery, bleeding, dural tears, and irritation from mechanical instability.[16,35] During operation, the nucleus material leak into the epidural spaces, it generates chemical inflammation, which causes a significant degree of fibrosis and sciatica.[14,21]

Scar tissue causes lumbar roots adhesion and entrapment which leads to FBSS. Such scar prevent progress of the injection therapy in the vicinity of the surgical site, and also an accurate replacement of the needle is very difficult due to anatomical changes.[17] Steroid, and recently hyaluonidase that suppresses fibroplasia and remove barriers between tissues, had some promising result to treat scar tissue.[14,19] The therapeutic benefit of steroid also is attributed to relieving the inflammation secondary to mechanical or chemical nerve root irritation.[35] Some patients presented with neuropathic pain instead of nociceptive one. This probably attributed to sensitization of the dorsal horn of the spinal cord during surgery which prevent the recovery by any mean.[9] There are three

main approaches for epidural steroid injection; interlaminar (midline and paramedian), transforaminal, and caudal epidural.[17] In radicular pain, transforaminal epidural is preferred than any other administration root due to proximity to the target tissue, and spread into the anterior epidural where the herniated disc is mostly affected.[4,12,14] Interlaminar epidural injection was evidence level II for short term relieve, and level III (weak) for long term relief. However, strong evidence for treatment for patient with FBSS is still lacking[29] In one study, Jevulder et al,[18] experienced good result when he used transforaminal approach instead of caudal epidural injection. In this study, the total epidural injection (transforaminal epidural injection, and caudal epidural injection) was 22 patients (62.9%). After one year, 7 (20%) patients needed surgical intervention, and 6 patients (17.2%) had spinal stenosis, recurrent, or retained disc.

Epidural steroid injections have been use for treatment of radicular pain secondary to residual disc or development of spinal stenosis after surgery.[10,14,17] A randomized double blind study by Manchikankti et al,[25] evaluated caudal epidural injection in FBSS. The study showed 60% to 70% of patients achieved (50%) significant pain relief during the first year, and 40% to 55% of them exhibited significant improvement of function. Such difference between pain and function outcome was found in our study. After 6 months, the mean VAS was 3.17, which was less that the initial 3.66, and after one year management 3.54. In comparative to ODI which was steady increase during 6 month (21.26), and 1 year (22.34) respectively. Gharibo et al,[13] used transforaminal approach for FBSS and found the same results. During transforaminal intervention, the injection site is dorsal, but the steroid spread into the ventral aspect by diffusion, it doesn't spread to the other side due to dorsal median epidural septum. With extensive scar, or advanced foraminal stenosis, it block ventral diffusion of the drug.[10,19,35] For such case, mechanical adhesiolysis by percutaneous epiduroscopy recently shown promising results.[1,3,26]

Facet joint arthropathy is another cause of back pain. It was proved that those degenerative changes can develop regardless of the type of surgery.[5,24,28] In this study with others, patient showed significant improvement after therapeutic injection of the medial branches.[24,30] Only three patients (8.6%) needed further RFA for the nerve. Gofeld et al,[15] showed long-term improvements of facet joint pain with RFA after diagnostic block. While Cohen et al,[8] found such maneuver had no influence on the patient outcomes for those with previous back surgery.

However, many studies demonstrate lengthy of injection pain relieve up to 6 months.[3,7,12,24] Repeated injection in this study showed no side effect and avoid the patient from excessive oral NSAID intake. Facet joints had two technique for injection either intra-articular or medial branch, but the efficacy of the former has not been proven.[12,17,33] In a study of SIJ intervention after failed back, Maigneet al,[23] found a 50% reduction in pain using VAS scale. In FBSS, SIJ pain ranges from 16 % up to 63% in some studies.

A multivariate regression analysis revealed that proper diagnosis and intervention technique can improve pain (VAS), and function outcome (ODI) after one year. Also, second intervention can improve pain more than function outcome, and surgery sometimes needed when patient failed on percutaneous injection.

In this series, we found small complication including inadvertent subarachnoid injection, prolonged sensory motor block up to 6 hours

in epidural injection. Some complication had been reported using these maneuver include; dural penetration with CSF leakage, and patient developed headache, nausea, vomiting. Infection causes meningitis and arachnoiditis. Steroid myopathy or salt and water retention also had been reported.[12,34,35]

This study is limited because of small number of patients, FBSS of various etiologies, surgical intervention in some cases. However, the study analysis using of fluoroscopic intervention of different FBSS causes found promising result that decreased the need for surgical intervention. However, a comparative study with homogenous, large number of cases and long term follow up is recommended.

Conclusion

FBSS are challenging cases with limited guidelines regarding patient management. The present study pointed out the importance of intervention technique in improving the outcome of patients with FBSS. It has a positive impact on minimizing the pain score; improve the function outcome and patient satisfaction. Surgery should be reserved for highly indicated cases. Future randomized controlled trials are warranted to further verify this finding.

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الملخص العربي

الإجراءات التدخلية العلاجية للعمود الفقري القطني في حالات الاخفاق الجراحى للظهر؛ هل تصلح للاستخدام؟

البيانات الخلفيه: علاج متلازمة الاخفاق الجراحى للفقرات القطنية (متلازمة ف ب س س) يشكل تحديا لأي جراح في العمود الفقري أو متخصص في الألم.

الغرض: وتهدف الدراسة إلى تقييم الألم، والنتيجة الوظيفية استجابة للإجراءات التدخلية العلاجية في العمود الفقري القطني في حالات الاخفاق الجراحى للظهر.

تصميم الدراسه: دراسة سريرية غير عشوائية

المرضى والطرق: بين يناير ٢٠١٣ إلى يناير ٢٠١٦، تم تضمين ٣٥ مريضا يعانون من متلازمة (ف ب س س). وقد تعرض كل مريض لأخذ التاريخ المرضى، والفحص البدني، والتصوير التشخيصي. تلقى المرضى إجراءات الحقن الموجهة بالاشعة للعمود الفقري القطني وفقا لسبب الاخفاق الجراحى. تم الانتهاء من مقياس التناظر البصري (ف ا س) لشدة الألم، ومؤشر أوزويستري للإعاقة (أ د ي) قبل الاجراء التداخلى. واستمر التقييم لمدة سنة واحدة أثناء المتابعة. تم إعداد المرضى لاجراء تداخلى اخر أو جراحة أخرى إذا لم يستجب للحقن الموجه لكل حالة على حدى.

النتائج: كان المرضى في الغالب إناث (٦٢,٩٪) مع متوسط عمر ٣٩,٧٤ ± ١٢,٣٧ سنة. واتضح بالكشف السريري والإشعاعي ان ٣١,٤٪ من المرضى يعانون من ضيق بالقناة العصبية, ٢٥,٨٪ يعانون من اعتلال الوجه المفصلى للفقرات، ١٧,٢٪ يعانون من تليف فوق الام الجافية، ١٤,٣٪ يعانون من ارتداد القرص المتكرر، و ١١,٣٪ يعانون من خشونة بالمفصل العجزى عند التقائه بالحوض. وكانت النتيجة بعد الإجراء التدخلى، وخلال المتابعة فى ١٢ شهر، كان اختبار الطريق الاحادى (أ ن وف ا) ذو دلالة احصائية كبيرة (ب =0.001) لكل من (ف ا س) و (أ د ي). كشف تحليل الانحدار اللوجستي متعدد المتغيرات لكل من (ف ا س) و (أ د ي) بعد سنة واحدة أن التشخيص المناسب والاجراء التداخلى كانت عوامل مستقلة تؤثر على المتغيرين (ف ا س) و (أ د ي) بقيمة P= (0.001-0.002) و (0.001-0.018) على التوالي. وان ٢٢,٩٪ من الحالات احتاجت الى تدخل جراحي خلال هذا العام.

الاستنتاج: ان إجراءات العلاج التدخلى في متلازمة (FBSS) يمكن أن تحسن من مقياس الألم والنتيجة الوظيفية في معظم الحالات لمدة تصل إلى سنة واحدة .يجب أن يكون التدخل الجراحى هو العلاج الأخيرفى حالة فشل العلاج التداخلى.