EPIDUROPLASTY IN FAILED BACK SURGERY SYNDROME WITH AND WITHOUT EPIDUROSCOPY ASSISTANCE

Ahmed F. El Molla, MD, FIPP, PGcert
Professor of Anesthesia & Pain Medicine department. Director of pain relief unit
(Medical Research Institute, Alexandria University, Egypt)
Fellow of Interventional Pain Practice-Texas-USA
Postgraduate Certificate of Pain Management-Cardiff University, UK

Annotation. Epidural fibrosis has been implicated in persistent pain after back surgery. Epiduroplasty is assumed for targeted epidural medication delivery nearby the desired nerve root may result in better pain relief. The primary goal of the current study was to evaluate the efficacy of fluoroscopic guided epiduroplasty with and without epiduroscopy (EDS) in failed back surgery syndrome (FBSS).

FBSS patients were allocated randomly into two groups; the Non-EDS group in whom patients underwent caudal epiduroplasty by fluoroscopic guided insertion of Racz catheter and the EDS group in whom patients underwent caudal epiduroplasty by fluoroscopic guided insertion of Racz catheter assisted with EDS. Pain severity was measured by visual analogue score for chronic radicular leg pain and functional activities were assessed using Waddell and Main score with a follow-up to 6 months whereas, satisfaction was observed at 3 and 6 months.

There was significant reduction in leg pain score (P < 0.001) at 1, 3, and 6 months when compared to the pre-procedure baseline values in both groups. Also there was significant reduction in leg pain score in EDS group (P < 0.001) at 3 and 6 months compared to the Non-EDS group. The function abilities and satisfaction scores showed statistical significant improvement (P < 0.001) at 3 and 6 months in both groups. No complications recorded and side effects were minimal.

Epiduroplasty by fluoroscopic guided insertion of Racz catheter with or without epiduroscopy assistance reduce mono-segmental unilateral radicular leg pain, improve patient functional abilities and satisfaction but with more long term leg pain and functional abilities improvement in epiduroscopic assisted patients, with minimal side effects in FBSS patients.

Key words: epiduroplasty; Racz catheter; epiduroscopy; FBSS.

INTRODUCTION

The painful symptoms in “failed back surgery syndrome” (FBSS) following surgical spinal procedures reflect a combination of pathological processes, such as interruption of blood flow, venous congestion, ischemia, axonal damage and intraneural fibrosis [1; 2]. Epiduroplasty (adhesiolysis) was tried by numerous modalities including invasive and non-invasive techniques. The invasive surgical procedures have proved ineffective in relieving pain in many cases, in addition some complications have been reported [3; 4]. Epidural steroid injection has been one of the “gold standard” in the management of FBSS. Controversy, however, continues its efficacy, with conflicting conclusions found in two systematic reviews [5; 6]. Using fluoroscopy in patients with previous back surgery, epidural steroid injection will spread to reach the level of pathology in only 26% of cases which was attributed to the adhesions which may “shield” the compromised nerve root [7]. Other techniques of epidural injections were used such as forceful epidural injection [8], the use of stainless-steel-tipped catheter (Racz catheter) [9; 10], Transforaminal epiduroplasty [11] and finally epiduroscopy (EDS) which allows more accurate placement of drugs within the epidural space, which may improve the efficacy of epidural steroids in “FBSS” [7; 12].

The hypothesis of the current study was that the targeted epidural medication delivery nearby the desired nerve root after epiduroplasty may result in better pain relief. The primary goal of the current study was
to evaluate the efficacy of epiduroplasty by fluroscopic guided insertion of Racz catheter with and without epiduroscopy on mono-segmental radicular leg pain severity in FBSS patients. The secondary goals were to evaluate functional abilities, satisfaction, and complications.

PATIENTS AND METHODS

This prospective, controlled, double-blind and randomized study was approved by the local ethics committee and the written informed consent was obtained from the patients. Patients were classified as having FBSS [13] who suffered mainly from mono-segmental chronic unilateral radicular leg pain. Patients were randomly allocated, according to a computer randomized table, into two groups. Non-EDS group (control group) in whom they underwent epiduroplasty by fluroscopic guided insertion of Racz catheter without epiduroscopy assistance, whereas, EDS group in whom they underwent fluroscopic guided insertion of Racz catheter with epiduroscopy assistance. Inclusion criteria were as follows: All patients had been undergone discectomy and/or spinal fusion at one or two lumbar disc levels for a persistent lumbar mono-segmental unilateral radicular pain within two years. Magnetic resonance imaging (MRI) with gadolinium for all patients detected the presence of an enhanced granulation tissue adjacent to the targeted nerve root as a suspected reason for such radicular pain. Exclusion criteria were those patients who developed signs of progressive motor disorders or incontinence, had local or systemic infections, coagulation disorders or receiving anticoagulants, cerebrovascular disease, CNS space occupying lesions, glaucoma, malignancy, pregnancy, anatomical abnormalities, language barriers and mental handicaps and patients with multi-segmental pain manifestations. All patients were treated with pregabalin in an oral dose of 300 mg/day. In addition, all other modalities of conservative treatment failed to provide substantial pain relief of at least 6 weeks. Epidural steroid injections in all patients were received at least three times without significant pain relief (≤ 30%). Routine laboratory investigations were assessed (complete blood count, prothrombin and partial thromboplastin time, platelet function studies and bleeding time). All procedures have been performed under fluoroscopy with injection of non-ionic water soluble contrast agent (Ul- travist, Iopromide 240), which was used either for confirmation of proper localization of the needle in caudal epidural space and/or localization of Racz catheter in the sacral canal (Fig. 1) and for epidurography in both study groups to determine the site of scar tissue (a filling defect) and to determine the efficacy of post-procedure epiduroplasty (Fig. 2). On the fluoroscopy table the patient is placed prone with a pillow under the abdomen to straighten the lumbar spine. The procedure was done while the patient was awake and cooperative; under local anaesthesia (lidocaine 1%) and conscious sedation (fentanyl 1 ug.kg-1 and midazolam increments up to 5 mg). The standard ASA monitors for conscious sedation (ECG, SpO2, BP, HR), were used in both groups.

Figure 1. Racz catheter at the level L4—L5 in the epidural space

Figure 2. Epidurography with pelvic leak due to high resistance in the epidural space in FBSS patient
In Non-EDS the sacral area is steriley prepared and draped from the top of the iliac crest to the bottom of the buttocks. Using the sacral cornua as landmarks to locate the hiatus and a flurososcopic guided introduction and advancement of 16 gauge epidural needle into the sacral hiatus in both postero-anterior (PA) and lateral view was performed. Next, a PA view was done to verify needle tip placement toward the affected side. After negative aspiration for blood and CSF, 5 ml of dye was injected in order to exclude vascular, sub-arachoniod or subdural injections to be followed by another 10 ml of dye for epidurography to locate the scar area.

Racz catheter is a stainless steel, fluoropolymer-coated, spiral tipped (RaczTun-L-Kath.) [9; 10]. A Racz catheter is passed through the needle into the filling defect which was predetermined by the epidurography. The bevel of the needle was directed to the ventrolateral aspect of the caudal canal of the affected side either the 7 o’clock position for the left or the 5 o’clock position for the right. Moreover, a nerve stimulator was applied to the metallic distal end of Racz catheter, in order to locate the target nerve by the metallic proximal tip of Racz catheter. After final placement of the catheter and negative aspiration, a test dose of 3 ml of lidocaine with epinephrine followed by 3 to 5 ml of contrast medium (maximum of a total of 20 ml) was injected through the catheter to ensure spread of the dye in the area of the previous filling defect which outlining of the targeted nerve root. Next, 1500 U of hyaluronidase in solution with 10 ml of preservative free (PF) normal saline is injected rapidly. Afterward a mixture of 10 ml of bupivacaine 0.25% and 40 mg of triamcinolone (depot steriod) were injected through the catheter in divided doses after negative aspiration for further lysis of adhesions.

In case of EDS group a 0.8 mm guide wire, introduced through the 16 gauge epidural needle, was directed cranially (Fig. 3). A small incision was made at the introduction site and with the guide in situ, the needle was removed, using Seldinger’s technique by a dilator and introducer sheath. The guide wire and the dilator were then removed. Through the introducer an epidurography in the same manner as in Non-EDS group was done to identify the filling defect to which epiduroscopy was directed. A flexible, 2.7 mm fibre optic endoscope (Karl Storz™, Germany) attached to video-guided camera was introduced into the caudal epidural space. The epidural space was irrigated and distended by infusion of PF saline during the procedure with a total volume infusion not > 100 ml, at rate of not > 30 ml/min and the time from the introduction of EDS was limited to not > 30 minutes. The procedure was stopped whenever the patient reported pressure, paraesthesia, or complains of headache, ear pressure, or severe neck or shoulder pain. The painful nerve root was identified by pain provocation test (gentle mechanical stimulation of the nerve root exactly reproduced the patient’s pain) using the tip of EDS. If EDS showed adhesions, granulation tissue, and/or chronic inflammation at the suspected nerve root (Fig. 4), those would mobilze by means of the tip of EDS.

Figure 3. Guide wire in sacral canal (arrow)

Figure 4. Epiduroscopic views in FBSS patient:
A, a band of epidural adhesion. B, dense granuloma tissue. C, chronic inflammation with swollen nerve root
Then, the Racz catheter was introduced via the port of epiduroscopy, nerve stimulator was used to locate the desired nerve in the same manner as in Non-EDS group. Next, 1500 U of hyaluronidase in solution with 10 ml of PF saline was injected. Afterward a mixture of 10 ml of bupivacaine 0.25% and 40 mg of triamcinolone were injected through the catheter in divided doses after negative aspiration for further lysis of adhesions. When the procedure is completed in both groups, Raczy catheter is secured to the skin with 3-0 silk. Then antibiotic ointment is used at the puncture site and covered with a sterile surgical dressing.

Prophylactic intravenous antibiotic, ceftriaxone 1 g is given daily every 12 hours. Once the patient is taken to the recovery room and vital signs were obtained, 10 ml of the 10% hypertonic saline was infused epidurally over 20 to 30 minutes. The catheter was left in place for 3 days. On the second and third post-procedure days, the catheter is injected once a day with 10 ml of bupivacaine 0.25% after negative aspiration of the catheter. Fifteen minutes later, 10 ml of 10% saline is infused over 20 minutes for patient comfort. On the third day the catheter is removed 10 minutes after the last injection (table 1).

**Table 1**

<table>
<thead>
<tr>
<th>Time of injections</th>
<th>Solution</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day of intervention</td>
<td>X-ray contrast media, 240 mg/ml</td>
<td>20 ml</td>
</tr>
<tr>
<td></td>
<td>Hyaluronidase in normal saline, 150 U/ml</td>
<td>10 ml</td>
</tr>
<tr>
<td></td>
<td>Bupivacaine 0.25% triamcinolone acetate, 4 mg/ml</td>
<td>10 ml</td>
</tr>
<tr>
<td></td>
<td>NaCl, 10% (over 30 minutes)</td>
<td>10 ml</td>
</tr>
<tr>
<td>Postprocedure day 1</td>
<td>Bupivacaine 0.25%</td>
<td>10 ml</td>
</tr>
<tr>
<td></td>
<td>NaCl, 10% (over 10 minutes)</td>
<td>10 ml</td>
</tr>
<tr>
<td>Postprocedure day 2</td>
<td>Bupivacaine, 0.25%</td>
<td>10 ml</td>
</tr>
<tr>
<td></td>
<td>NaCl, 10% (over 10 minutes)</td>
<td>10 ml</td>
</tr>
</tbody>
</table>

Antibiotic ointment was applied to the wound and the sutures were removed. The patients were discharged on the third day. After treatment, patients were instructed to visit the pain clinic for routine assessment every month for 6 months.

**FOLLOW-UP PROTOCOL**

Pain intensity was measured by visual analogue score for mono-segmental radicular leg pain and functional activities were assessed using Waddell and Main score with a follow up period to 6 months whereas, satisfaction was observed at 3 and 6 months.

Each patient underwent standard physical examination and asked to complete a 100-mm VAS questionnaire, in which 0 mm represented no pain and 100 mm the worst imaginable pain, for leg pain (VAS-leg) after first , third and six months. Success was defined as a reduction of VAS-leg of at least 50%. Post-procedure neurological monitoring (sensory and motor) was done to exclude any possibility of accidental subdural/subarachnoid injection, signs of arachnoiditis or other neurologic complications during the follow-up. Medical therapy was continued during the 6 month follow-up period in each patient. If patients developed progressive motor disorders or bladder dysfunction, definitive surgical management would consider. Complications were monitored with each follow-up period. Functional activities were assessed using Waddel and Main score [14]. Briefly; this involves a questionnaire in which one point is awarded for the ability to perform each of the following: heavy lifting, standing, walking, sitting and travelling, all for half an hour; lack of social and sex life restriction; putting on foot wear and sleep disturbance. Zero represents a severe functional restriction, whereas a score of 9 indicates good function. These parameters were checked pre-operatively and at 1, 3, and 6 months.

In addition, a five level satisfaction/dissatisfaction scale (0 = very dissatisfaction, 1 = mild dissatisfaction, 2 = mild satisfaction, 3 = moderate satisfaction and 4 = very satisfaction) was noted at 3 and 6 months after treatment. A single non-treating independent physician or pain nurse, who were blinded to the technique, made all follow up assessment just before the postoperative assessment at 1,3, and 6 months without discussion of the patient about the technique and reported all scores to the treating physician just before the patient’s visit. An epidurography after 6 months for all patients was done to assess the degree of adhesiolysis in a qualitative manner.
STATISTICAL ANALYSIS

Data analysis was performed by SPSS for Windows, version 15. Data were expressed as mean ± SD and number. Nominal non-parametric data were analyzed using Chi-Square test. Parametric data were compared using unpaired t-test. Ordinal non-parametric data were analyzed using Mann-Whitney U-test between groups and Wilcoxon signed rank test in the same group. P-values < 0.05 were considered statistically significant.

RESULTS

There were no patients missed in the follow-up period. Patient’s characteristics and clinical data were comparable in the studied groups (table 2).

In all patients of both groups, VAS-leg pain score was significantly reduced (P < 0.0001) compared to the preoperative values at 1, 3, and 6 months. However, leg pain score in EDS group was significantly reduced (P < 0.001) at 3 and 6 months compared to Non-EDS group (Fig. 5).

<table>
<thead>
<tr>
<th>Patients characteristics and clinical data</th>
<th>Non-EDS (n = 22)</th>
<th>EDS (n = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (M/F)</td>
<td>12/10</td>
<td>9/11</td>
</tr>
<tr>
<td>Age (years)</td>
<td>30 ± 12</td>
<td>35 ± 10</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>150 ± 7</td>
<td>155 ± 3</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>90 ± 5</td>
<td>85 ± 8</td>
</tr>
<tr>
<td>Neurological deficits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Motor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marked</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mild</td>
<td>13</td>
<td>14</td>
</tr>
<tr>
<td>Non</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>Sensory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marked</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Mild</td>
<td>17</td>
<td>14</td>
</tr>
<tr>
<td>Non</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Involved dermatomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L4–5</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>L5–1</td>
<td>12</td>
<td>9</td>
</tr>
</tbody>
</table>

Data are expressed as mean ± SD and number.

Functional activities (Waddel and Main score) showed very poor pre-operative abilities with a baseline of 1.74 ± 1.25 and 1.63 ± 1.33 in Non-EDS group and EDS group, respectively. In the post-procedure, the total function scores showed statistical significant improvement (P < 0.001) when compared to the preoperative values at 1, 3, and 6 months in both groups. However, functional activities were significantly improved (P < 0.05) at 3 and 6 months in EDS group compared to Non-EDS group (Fig. 6).

Figure 5. Leg pain score (individual points are represented as mean ± SD).
* = Significant compared to pre-procedure value,
† = Significant compared to other group.
The five level satisfaction scores in both groups showed statistical significant improvement at 3 and 6 months. However, no statistical significant differences in the satisfaction score between both groups (Fig. 7).

An epidurography after 6 months for all patients was done, there was significant improvement in the distribution of contrast media in 80% of patients in EDS group \( (n = 16) \) compared to 54.6% in the Non-EDS group.
group (n = 12) which means improvement in adhesiolysis in EDS group (P < 0.001).

None of the patients suffered from postoperative neurological deficits during follow up periods. No adverse effects were occurred apart from self-limited low back discomfort few days after the procedure. In EDS group one patient suffered from transient headache, and three patients had fluid leak of saline from the sacral hiatus for two days.

DISCUSSION

FBSS is a poorly defined, heterogeneous disorder consisting of a myriad of surgical and nonsurgical etiologies that encompasses the majority of patients who fail to improve after back surgery [15]. List of causes generally listed are spinal stenosis, disc disruption or retained disc, and perineural fibrosis (14.5%) [16; 17]. Bosscher and Heavner showed that the vast majority of patients who undergo back surgery develop significant epidural fibrosis [18; 19]. Adhesions (fibrosis) surrounding nerve roots may interfere with their nutrition and blood supply and are potent contributors to radicular pain [20]. In disease states, especially with adhesive arachnoiditis, nutrition of the nerve root becomes critical [20; 21]. Impairment of intraneural blood flow is probably the final common pathway leading to abnormalities in nerve conduction and pain generation [20; 21]. It is possible that adhesiolysis reduces pain generation through improvement in nerve root nutrition by removal of obstruction to blood supply and CSF flow [22]. Mechanical adhesiolysis may allow room for the restoration of blood supply and nerve root nutrition, resulting in reversal of nerve dysfunction and pain relief [23]. In the current study the proposed benefits of non-endoscopic and endoscopic epiduroplasty by fluoroscopic guided insertion of Racz catheter, before targeted medication injection was believed to overcome the compliance gradient which may be caused by the adhesions which may “shield” the compromised nerve root. Adhesiolysis is a controversial topic in the treatment of patients with FBSS. Several groups have stressed that lysis of epidural adhesions is an effective therapeutic option [12; 24; 25], whereas others asserted that there is no correlation between therapeutic effect and the degree of lysis of epidural adhesions [26]. In addition, hyaluronidase and NaCl 10% have been used to enhance the effect of lysis of epidural adhesions which was not used in the previous studies [12; 24—26]. Heavner et al. [27], concluded that patients with low back pain and radiculopathy treated with hypertonic saline and hyaluronidase obtained a higher percentage of pain relief and were less likely to require other types of treatments in comparison to patients that received isotonic or hypertonic saline alone. The rationale for use of fluoroscopic-guided insertion of Racz catheter after epidurography relies upon the proper insertion and advancement of the metallic end of Racz catheter (mechanical adhesiolysis) in the area of fibrosis which was assisted with the use of a nerve stimulator to ensure the proper location in the vicinity of the targeted nerve. EDS provided another aid in proper location of the tip of Racz catheter in the area of fibrosis which was manifested in the current study to increase the efficacy of adhesiolysis (mechanical and hydrostatic) as assessed by significant pain relief, improvement in the functional abilities and more satisfaction of patients treated with EDS. In addition, improvements of contrast flow around the targeted nerve by post-procedure epidurography. The main finding of the current study was that the targeted epidural injection via endoscopic fluoroscopic guided insertion of Racz catheter which provides both mechanical and hydrostatic epiduroplasty appeared to achieve better benefits than non-endoscopic fluoroscopic guided insertion Racz catheter which provides only mechanical epiduroplasty. EDS is considered a reliable tool in the diagnosis and removal of fibrosis by both mechanical and hydrostatic techniques [28]. The significant improvement in EDS treated patients might be provided by better adhesiolysis produced by the manipulation of the tip of EDS and/or hydrostatic adhesiolysis which was achieved by the irrigating saline. The former mechanism may result in “wash-out” of inflammatory mediators and mobilization of adhesions which can develop as a result of inflammation around the involved neural tissues [29]. Fibrosis causes leg pain by interfering with the mobility of the dural sleeves of the spinal roots [24]. Lysis of adhesions may play a role in the lasting pain relief which may be achieved by pressure of the irrigation of saline and manipulation of the tip of EDS. As a result of lysis of the adhesions the mobility of the nerve roots may be restored to some extent after EDS. Therefore, the use of EDS which provided both mechanical and hydrostatic adhesiolysis might be responsible for significant pain relief in the third and six months when compared to non EDS treated patients which provided only mechanical adhesiolysis. The significant improvement in the study groups when compared to baseline values may be attributed to effec-
tive adhesiolysis in both groups, and hence targeted medication delivery to the desired nerve. Long-term improvement up to 6 months might be attributed for use of depot steroids, hyaluronidase and NaCl 10% injections “chemical adhesiolysis” in the post-procedure three days protocol. Steroids reduce inflammatory oedema of the injured nerve root and therefore improve intraneural blood flow [7]. Hyaluronidase and NaCl 10% have been used to enhance the effect of lysis of epidural adhesions [11; 12]. The effectiveness of adhesiolysis in both groups was documented by epidurography after 6 months which showed qualitative improvement in EDS treated patients manifested by flow of the contrast along the path of the targeted nerve in most cases. Multi-centre studies, large sample size and long term follow up may be needed to make the results more reliable.

In conclusion, Epiduroplasty by fluoroscopic guided insertion of Racz catheter via epiduroscopy is more effective in reduction of mono-segmental unilateral radicular leg pain and improvement of functional abilities with good satisfaction and minimal side effects in FBSS.

REFERENCES


