Percutaneous Epidural Neuroplasty (PEN) Using Combination of Hyaluronidase and Hypertonic Saline (NaCl 3%) in Treating Failed Back Surgery Syndrome

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ABSTRACT

Background: Following surgical treatments for low back pain, lower extremity pain or neurologic symptoms would last or recur, this is defined as failed back surgery syndrome (FBSS). FBSS usually occurs in 5 - 40% of these surgical patients. The most common cause is an epidural scar adhesion. Percutaneous epidural neuroplasty is the non-mechanical treatment for this condition. Previously, the use of hyaluronidase and hypertonic saline separately is commonly used for epidurolysis but the combination of hyaluronidase and hypertonic saline 3% has not been explored.

Objective: To investigate the two-year outcomes of percutaneous epidural neuroplasty using a combination of hyaluronidase and hypertonic saline 3% in patients with FBSS.

Methods: Twelve patients who experience low back pain, with or without radiculopathy, who have undergone lumbar spine surgery previously were assigned to the study. Parameters, such as the visual analogue scale scores for the back (VAS-B) and legs (VAS-L), and the Oswestry disability index (ODI), were recorded and compared between pretreatment, 1 week, 1 month, 3 months, 1 year and 2 years follow-up.

Results: For all 12 patients, the postoperative VAS-B, VAS-L, and ODI were significantly different from the preoperative values in all follow-up periods: 1 month, 3 months, 1 year, and 2 years.

Conclusion: Based on this study group, percutaneous epidural neuroplasty using a combination of hyaluronidase and hypertonic saline 3% has a favourable outcome in the 2 years follow-up period.

Keywords: Failed back surgery syndrome, percutaneous epidural neuroplasty, epidurolysis, adhesiolysis, hyaluronidase, hypertonic saline

INTRODUCTION

Chronic low back pain, with or without radiculopathy, is defined as a clinical syndrome of back and leg pain which could be accompanied by neurological deficits such as sensory, reflex, or motor deficits in a nerve root distribution that lasts longer than 12 weeks.1 Definitive treatment for this condition, if a conservative treatment is ineffective, is surgery. Unfortunately, in 5 - 40% of patients that underwent surgery for low back pain, lower extremity pain and other symptoms persist.2,3 These cases are defined as failed back surgery syndrome (FBSS) that can occur due to disc ruptures or disc fragments remaining after surgery, recurrent disc herniation, spinal stenosis, epidural scars, facet joint pain, sacroiliac joint pain, and spinal segment degeneration or instability. In practice, the most common cause is an epidural scar.

In 1986, Gabor B Racz introduced his invention of a special epidural catheter for delivering drugs in the lumbar sacral area and used for percutaneous neuroplasty as a tool for lysis of adhesions.4 The Racz catheter then used worldwide in the early 2000s, primarily for lysis of epidural adhesions to treat lumbosacral radicular and/or low back pain, especially for adhesions after lumbar surgery.5 The technique is minimally invasive under local anaesthesia and easy to perform with proper training. The terms of this technique are commonly known as epidurolysis, adhesiolysis, or percutaneous epidural neuroplasty.

Previous studies on percutaneous epidural neuroplasty showed the effectiveness of adhesiolysis using hyaluronidase and combination or separation with hypertonic saline 10%.6 In another study, relieving pain using local anaesthesia and corticosteroid alone, is less effective for adhesions of FBSS compare to spinal stenosis or mild disc herniation of non-operative patients.7

This study proposes to implement a combination of hyaluronidase enzyme and hypertonic saline for treatment of extremity radiating pain related to spinal adhesions in FBSS cases. To treat fibroplasias and to release bonds between tissues, we chose hyaluronidase that hydrolyzes glucosaminic bonds between hyaluronic acid, a major intercellular substance and connective tissues.8,9 In
this respect, we used adjuvant hypertonic saline 3%, other than standard treatment of hypertonic saline 9%, for synergistic effect with hyaluronidase. The term "adjuvant" for hypertonic saline in this study refers to the facts that some studies of the effects of administering hypertonic saline remain unclear in adhesiolysis treatment. The reason for using hypertonic saline 3% is that the saline solution is commonly available in our operating theatre or wardroom, meanwhile, hypertonic saline 10% is very rare in our country.

**METHODS**

This study was approved by our review board and received informed consent from the patients in the outpatient clinic of the Department of Neurosurgery, Dr. Esnawan Antariksa Airforce Hospital Jakarta. Twelve patients were enrolled in this study. The study included patients who previously underwent any lumbar spine surgeries and currently are diagnosed with FBSS in our outpatient clinic with symptomatic axial back pain, radicular/leg pain or both.

The exclusion criteria included unbearable pain >9 on the visual analogue scale (VAS), pain with VAS scale <4 (leg or back, must be >/= 4), patients who had developed signs of progressive motor weakness or neurologic deficits, allergies to steroids or contrast dyes, coagulopathy, injection of steroids or hyaluronidase, systemic infections, injection site infections, and unstable medical or psychiatric condition.

All patients were clinically assessed with the VAS score for the back (VAS-B) and legs (VAS-L) and Oswestry disability index (ODI). We compared the preoperative and postoperative values (1 month, 3 months, 1 year, 2 years). New MR imaging on the lumbosacral area was performed. Epidurograms were performed in the initial setting during the intervention procedure in the OT.

For the preoperative and long-term postoperative clinical analysis, statistical analysis was performed via a paired t-test. Significant differences between age and clinical outcome, between body mass index (BMI) and clinical outcome, and time from previous surgery to visit OP clinic and clinical outcome were analyzed using Pearson’s correlation analysis. Differences were considered significant at P < 0.05.

**Technique for Percutaneous Epidural Neuroplasty**

The neuroplasty procedure, as described by Gabor B Racz, was performed using a caudal approach with C-arm guided fluoroscopy in the operating theatre. After a 16 gauge RK needle was placed onto the sacral canal via the sacral hiatus under local anaesthesia, 5mL...
of the radiopaque contrast material iohexol (Omnipaque) was injected to confirm epidural placement. Next, a Racz Tun-L-Kath (Epimed, Gloversville, NY) was inserted through the epidural needle and advanced to the anterior part of the lumbar epidural space area. Again, 5 mL of radiopaque contrast material was injected to confirm filling defect under fluoroscopy. The local anaesthetic (5 mL 0.17% bupivacaine) was injected through the catheter followed by 10 mL of 3% saline containing 150U/mL of hyaluronidase (Medilase) and 80 mg methylprednisolone (Depomedrol). The catheter was left in place.

During the following 2 days, 2 mL of 0.17% bupivacaine was injected through the catheter, followed by slow injection of 10 mL 3% saline, 150U/mL of hyaluronidase and 2 mL 0.17% bupivacaine. After the procedure was finished, the catheter was removed.

RESULTS

All 17 patients underwent percutaneous epidural neuroplasty for suggestive adhesion of FBSS between 2014 and 2015 and then follow-up until 2017. There were 5 patients that requested to be removed from the study and 12 patients met our inclusion criteria (8 females, 4 males). The average age is 53 years old, with an average of body mass index (BMI) is 28.3 + 2.6, that means the patients are in mid-age and overweight. The demographic data of the patients are presented in Table 1.

The average time from previous surgery to visit our outpatient clinic is 46.6 ± 28.4 months, that means the majority previous surgeries were done around 4 years before this study but in large variances of age.

The postoperative (1 month, 3 months, 1 year, 2 years follow-up) VAS-B (2.58 + 0.99; 1.58 + 0.66; Table 1 General Characteristics of Patients

<table>
<thead>
<tr>
<th>Demographic Data</th>
<th>Average (± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of patients</td>
<td>12</td>
</tr>
<tr>
<td>Age</td>
<td>53 ± 10</td>
</tr>
<tr>
<td>Gender</td>
<td>Male 4 (33.3%); Female 8 (66.7%)</td>
</tr>
<tr>
<td>Body Mass Index (BMI)</td>
<td>28.3 ± 2.6</td>
</tr>
<tr>
<td>Previous surgery technique</td>
<td>Laminectomy alone 2 (16.6%); Laminectomy with pedicle screw fixation 4 (33.3%); Microdiscectomy 3 (25%); TLIF (cage) 1 (8.3%); PLIF (cage) 1 (8.3%); Microdecompression 1 (8.3%)</td>
</tr>
<tr>
<td>Time from previous surgery to OP visit (months)</td>
<td>46.5 ± 28.3</td>
</tr>
<tr>
<td>Sign and symptoms</td>
<td>Axial back pain 3 (25%); Radicular pain 4 (33.3%); Both 5 (41.7%)</td>
</tr>
</tbody>
</table>

Figure 3 Visual analogue scale (VAS) score for back pain and leg pain in 2 year follow-up

Figure 4 Oswestry Disability Index (ODI) in 2 year follow-up
2.08 + 0.79; 2.41 + 1.08) and VAS-L (2.08 + 1.08; 1.33 + 0.88; 2.33 + 0.78; 2.58 + 0.79) in these cases were significantly decreased from the preoperative values (6.8 + 1.64 and 6.91 + 1.24, respectively; both P < 0.01). In addition, the postoperative (1 month, 3 months, 1 year, 2 years follow-up) ODI (26.33 + 5.69; 22.83 + 3.95; 28.08 + 3.2; 29.41 + 2.50) of our patients was significantly different from the preoperative value (60.08 + 6.17; P < 0.01).

There was a weak correlation between age and all clinical outcomes, but there is a moderate positive correlation between body mass index and ODI outcome. Graphical representations of the clinical scores according to 2 year follow-up are presented in Figure 3 and Figure 4.

DISCUSSION

Doctors and surgeons are interested in pain management studies using diverse materials that can release scar tissues in order to treat adhesion in FBSS. The most common materials are hypertonic saline 10% and hyaluronidase enzyme. It is believed that the addition of therapeutic agents, such as hyaluronidase and hypertonic saline, which suppresses fibroplasia and remove barriers between tissues, would treat adhesion of an epidural scar.6,9

According to a study by Ross et al, every time a scar size increases by 25%, the risk of radiating pain will double.11 If there are extensive epidural scars, the risk of radiating pain will be around 3.2 times higher. On the other hand, releasing the epidural scar could decrease pain by a factor of double or higher. Therefore, hyaluronidase raises our attention as an FBSS treatment because of its involvement in the suppression and decomposition of fibroplasia of tissues and increase drug diffusion.7

In this study, using a combination of 150U/mL hyaluronidase and 10 mL of hypertonic saline 3% three times (in three separate days) significantly decrease VAS score and disability index (ODI). Compared to the previous study, where other authors using hypertonic saline 10%, we use hypertonic saline 3%. Using the combination of hypertonic saline 3%, the clinical outcomes in VAS and ODI score are highly significant for decreasing pain, both back pain and radicular pain.

All follow-ups at 1 month, 3 months, 1 year, and 2 years show good outcomes. Even after 2 years, VAS-B and VAS-L are less than 3 on average. It is also the same result regarding the disability index, all ODI scores are statistically better compared to preoperative ODI scores.

The results of a large study show that epidural lysis of adhesions with hypertonic saline is safe and effective in managing chronic low back and lower extremity pain in patients who failed to respond to other conservative modalities of treatments, including epidural steroid injections.12

LIMITATIONS

Our study has considerable limitations with the lack of patient number followed the study (12 of 17 inclusion patients). More patients are required to be involved in the future for a more trusted success rate.

CONCLUSION

This study used lower hypertonic saline (NaCl 3%) as an adjuvant to hyaluronidase injection to epidural space in percutaneous epidural neuroplasty procedure for suspected adhesions of failed back surgery syndrome (FBSS). Evaluation of VAS-B, VAS-L and ODI pre- and postoperative procedures of neuroplasty showed a significant improvement at 1 month, 3 months, 1 year, and 2 years follow-up. In conclusion, the management of FBSS patients with the suspicion of adhesions and percutaneous epidural neuroplasty using a combination of hyaluronidase and adjuvant hypertonic saline 3%, rather than 10%, has a favourable outcome in the 2 years follow-up.

REFERENCES


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