Original Article

Value of Hyaluronidase in Steroid Caudal Epidural Injection with High Volume Normal Saline for Failed Back Syndrome

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ABSTRACT

Background: Management of low back pain after spinal surgeries is one of the most challenging problems in pain medicine. Re-surgery must be considered, however, re-surgery is complex and costly. The rationale for use of hyaluronidase in patients with failed back syndrome (FBS) relies upon its reported ability to disrupt epidural adhesions. Objective: Evaluate the efficacy of adding hyaluronic acid to steroids and high volume normal saline by caudal epidural injection. Patients & Methods: Forty patients with failed back syndrome after lumbar spinal surgery were included in this prospective randomized study to evaluate the efficacy of adding hyaluronic acid to steroids by caudal epidural injection of high volume saline. Group A was injected with local anesthetics and steroids only while in group B, hyaluronidase was added. Results: Group A included fifteen males (75 %) and five females (25%). The mean age was forty years with a range of twenty four to twenty nine. In group B, there were fourteen males (70 %) and six females (30 %). The mean age was thirty eight with a range of 27 to 60. The mean body mass index (BMI) was 26.75 with a range of 24 to 30 for Group A, while it was 26.6 with a range of 24 to 29 in group B. The mean duration of symptoms in group A was seven and half months with a range of 3 to16 months while in group B the mean duration of symptoms was 8.2 months with a range of 2 to 18 months. In our study there was improvement of Visual analogue scale (VAS) in both groups at one month and six months however the mean VAS was higher in Group B than Group A. In group A the mean VAS decreased from 7.5 before the procedure to 3.15 and 1.89 at one month and after six months post procedure respectively. In group B the mean VAS decreased from 7.6 before the procedure to2.25and 1.5 at one month and after six months post procedure. Conclusion: Addition of hyaluronidase increases efficacy of epidural injection by decreasing pain on the short and long term. It increases patient satisfaction and is safe with minimal adverse effect.

INTRODUCTION

Management of low back pain after spinal surgeries is one of the most challenging problems in pain medicine. Although the exact incidence is not known, it is estimated to be as high as 68%.1 The incidence of failed back syndrome (FBS) is up to 40%, where patient presents with recurrent and persistent pain with or without radiculopathy in spite of successful disc related spine surgery mostly due to epidural fibrosis may account for as much as 20% to 36% of cases of FBS.2 Re-surgery must be considered however it is complex, costly and with increased risk of complications.3

Fibrous tissue in the epidural space may adhere to the dura mater and nerve roots. This causes a mechanical tethering of the nerve roots or the dura, which may contribute to chronic low back and lower extremity pain in a significant subset of patients.4

Scar formation can physically prevent direct application of medication to nerves or affected areas.5 Among the non surgical interventions in managing chronic persistent pain of post lumbar surgery syndrome, epidural steroid injections and percutaneous adhesiolysis with or without hypertonic saline are most commonly used.6-7 The evidence for transforaminal epidural steroid injections and serial caudal epidural steroid injections in managing lumbar radicular pain with FBS is strong for short-term and moderate for long-term reliefs.8

The rationale for use of hyaluronidase in patients with FBSs relies upon its ability to disrupt epidural adhesions. The addition of hyaluronidase to fluoroscopically guided caudal steroid injection in patients with FBS increases the efficacy as assessed by long-term pain relief and improved range of motion of the lumbar spine.9

Several studies have evaluated the role of hyaluronidase in epidural injection in failed back syndrome, however more studies are needed to confirm these findings. Our study aims to add more evidence to the role its use on both a short and long term.

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PATIENTS AND METHODS

In a thirty-six-months period, forty patients with failed back syndrome after lumbar spinal surgery were included in this prospective randomized trial to evaluate the efficacy of adding hyaluronic acid to steroids and high volume normal saline by caudal epidural injection. Any patient with a clear indication for re-surgery was excluded from the trial and referred for surgery. Patients included had tried proper medical treatment and physiotherapy and still had complaints with a pain score above five on visual analogue score (VAS). Demographic information, complete history taking and neurological examination were done and documented. Pre-operative MRI was done for all cases and informed consents were taken. Pre-operative visual analogue score were documented for all cases. Patients were randomized by simple randomization to 2 groups: Group A was injected with local anesthetics and steroids only while in group B, hyaluronidase was added. In both groups, high volume (25 ml) normal saline was injected. All procedures were done in an operating room with adequate sterilization. Patients were put in prone position with a pillow beneath the pelvis. Identification of entry point was done both clinically and with the aid of lateral fluoroscopy. The cutaneous entry site was infiltrated with lidocaine 2%. An 18-gauge Tuohy needle was inserted into the sacral hiatus (B BRAUN, Meisungen AG, Düsseldorf, Germany). Needle position was confirmed using fluoroscopy both in the lateral and antero-posterior plan.

After negative aspiration of blood or cerebrospinal fluid (CSF), 5 mL of water-soluble contrast medium iopromide (Ultravist 300, Schering AG, Berlin, Germany) was injected to verify the needle position in the caudal epidural space (Fig. 1 &2). Caudal injection into the epidural space of a mixture of 10 mL of 0.25% bupivacaine solution, 80 mg of methylprednisolone and 25 ml of normal saline at room temperature were injected in group A. Hyaluronidase was added in group B.

Post-operative complications, if any, were documented. Post-operative pain assessment with the same scores was done after one month and after six months.

RESULTS

In our series, group A included fifteen males (75%) and five females (25%). The mean age was forty years with a range of twenty four to fifty nine. In group B, there were fourteen males (70 %) and six females (30 %). The mean age was thirty eight with a range of twenty seven to sixty.

The mean BMI was 26.75 with a range of 24 to 30 for group A while it was 26.6 with a range of 24 to 30 in groups B.

The median duration of symptoms in group A was seven and half months with a range of three to sixteen months, while in group B the mean duration of symptoms was eight months with a range of two to eighteen months. In group A, the visual analogue score median was 7.5 with a range of six to nine. In group B, the visual analogue score median was 7.6 with a range of six to nine (Table 1). Two of patients (10%) suffered from slight discomfort in the form of back pain after the procedure. There was no recorded complication in both groups. Pain improved after injection in both groups (Table 1).

Table 1: Pre and post procedure visual analogue score in both groups

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<thead>
<tr>
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<th>Group A</th>
<th>Group B</th>
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<tbody>
<tr>
<td>Pre VAS</td>
<td>7.5</td>
<td>7.6</td>
</tr>
<tr>
<td>VAS at 1 Month</td>
<td>3.15</td>
<td>2.25</td>
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<tr>
<td>VAS after 6 Month</td>
<td>1.89</td>
<td>1.5</td>
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</tbody>
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DISCUSSION

Management of low back pain after spinal surgeries is one of the most challenging problems in pain medicine causing significant psychological and economic burden related to surgical outcomes and after treatment for disabling back pain. Although the exact incidence is not known, it is estimated to be from 40%, to as high as 68%, where patient presents with recurrent and persistent pain with or without radiculopathy in spite of successful disc related spine surgery.

Re-surgery must be considered and magnetic resonance scanning and dynamic X-rays of the lumbosacral spine are needed to differentiate epidural fibrosis from other amendable surgical causes. These include residual disc herniation, foraminal stenosis, instability or new lateral disc prolapse.

However, re-surgery is complex, costly and with increased risk of complications. The result of re-surgery is poor with recurrence of pain in 55% of cases with the possibility of epidural fibrosis causing recurrent radicular pain. Experimental studies have shown electrophysiological evidence of neurologic disturbances caused by peridural scar formation and abnormal dorsal root ganglion response.

Among the interventions in managing chronic persistent pain of post lumbar surgery syndrome is epidural steroid injections and percutaneous adhesiolysis with or without hypertonic saline.

The evidence for epidural steroid injections either transforaminally or caudally in managing lumbar radicular pain with FBSS is strong for short-term and moderate for long-term reliefs.

In this study, there was no difference in demographic data of patients in both groups regarding the age, sex. In this series, the mean BMI was 26.6 in group B and was 26.75 in group A, compared to Yousef series where the BMI mean was from 27.7 to 27.7. The
mean duration of complaints was 8.2 with a range of 2 to 19 in group B and 7.5 range 3 to 16 in group. In comparison to other studies, as in Youssef’s series et al, which had a mean duration of symptoms mean of 9.4 to 10.1, while Rahimzadeh stated 7.1 to 8 in his study.

The rationale for use of hyaluronidase in patients with FBSS relies upon its purported ability to disrupt epidural adhesions. Its primary action is to depolymerize hyaluronic acid and, to some extent, chondroitin-4 and chondroitin-6 sulfate. Hyaluronidase disrupts the proteoglycan ground substance, thus accelerating the diffusion of injected substances. Epidurally administered hyaluronidase presumably disrupts the ground substance found in the epidural adhesions. The dura, which is composed of collagen, elastin, and surface fibroblast, is preserved.

In our study there was improvement of VAS in both groups at one month, six months. However the mean VAS was higher in Group B than Group A. The mean VAS in group A decreased from 7.5 before the procedure to 3.15 and 1.89 at one month and after six months post procedure respectively. In group B the mean VAS decreased from 7.6 before the procedure to 2.25 and 1.5, at one month and after six months post procedure.

Rahimzadeh concluded that patients with low back pain due to failed back syndrome had significantly lower pain scores and patient satisfactions when adding hyaluronidase to steroids rather than using steroids alone. He stated that adding hyaluronidase to the epidural injections was effective in the management of chronic low back pain in patients with failed back surgery syndrome.

Yousef concluded in his prospective double-blind study that addition of hyaluronidase 1500 IU to fluoroscopic guided caudal steroid with 3% of 30 ml hypertonic saline, which provides long term pain relief in FBS. Steroids have membrane stabilizing action resulting in inhibition of ectopic discharge along with anti-inflammatory action. Kulkarni also concluded that epidural normal saline with addition of hyaluronidase, triamcencolone and local anesthetic to produce volumetric adhesiolysis provided 90% pain relief for >6 months with improved quality of life.

In this study we used normal saline similarly to Kulkarni and Heavner. Both also added hyaluronidase to their injections. Kulkarni et al used cold (2°C) 0.9% normal saline not hypertonic saline. It was at 2 degrees centigrade to enhance the analgesic effects by depressing pain carrying C fiber conduction.

Using 0.9% normal saline is equally effective and 10% hypertonic saline can cause hypertension, tachycardia with raised intracranial pressure and pulmonary edema.

However, other studies concluded that patients with low back pain and radiculopathy treated with hypertonic saline (on the basis that hypertonic saline decreases cell edema and pressure on the nerve) 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. Manchikanti reported that non endoscopic epidural administration of corticosteroids and hypertonic saline is a safe and cost-effective procedure for relieving chronic intractable pain in post laminectomy patients who fail to respond to other modalities of treatment. He reported significant improvement in patients suffering from chronic low back pain after receiving local anesthetic, hypertonic saline, and steroids. He claimed that they were less likely to require repeat treatments for the 1-year follow-up period.

In this study, high volume 30 ml of saline was used to cause hydrostatic neurolysis similar to Yousef and Kulkunari. They inject high volume of saline in an attempt to mechanically disrupt the fibrotic scar and to get the benefit of its anesthetic effect. They preferred it to avoid the adverse effect of injecting 10% hypertonic saline which included elevated CSF pressure, tachycardia, hypertension, and pulmonary edema. In current study, a single injection instead of 3 separate injections was used to avoid the difficulty of three injections and to decrease the cost. This was similar to the findings of Yousef, who used 3% hypertonic saline instead of 10% hypertonic saline and Manchikanti. In their study they used hypertonic saline rather than normal saline. They also stated that the use...
of a single injection is as effective as multiple injections. Of the first six months, one patient (5%) needed re injection in group A after one month and improved after six months. Patients were re injected with the same injectables as in their original group.

The addition of hyaluronidase to fluoroscopically guided caudal steroid and hypertonic saline injection in patients with FBS increases the efficacy as assessed by long-term pain relief and improved range of motion of the lumbar spine. There were no complications in our series but four patients (10%) had back discomfort during or after the procedure. Their back discomfort resolved within one week.

CONCLUSION

The use of steroids in association with high volume normal saline to promote neurolysis through caudal epidural injections is effective in patients with failed back surgery syndrome. The addition of hyaluronidase increases efficacy by decreasing pain in addition to increased patient satisfaction on both the short and long-term assessment. It is safe with minimal adverse effect.

Disclosure:
The authors have no personal, financial or institutional interest in any of the drugs, materials, or devices described in this article.

REFERENCES