

The comparison between steroid and hypertonic saline 10% with steroid in transforaminal epidural injection in patients with unilateral foraminal stenosis

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ABSTRACT

Background: Chronic radicular low back pain is a common disease that limits patient's daily activity. Epidural steroid injection is becoming the mainstay of therapies for radicular low back pain due to contained bulged disc.

Purpose: To determine the effect of adding hypertonic saline to epidural steroid injections to provide pain relief for chronic radiculopathy back pain secondary to foraminal stenosis.

Methods: In a randomized clinical trial, 50 patients with unilateral radicular low back pain due to unilateral foraminal stenosis were enrolled. Epidural steroid injections were performed using transforaminal approach. In hypertonic saline group 80 mg of triamcinolone plus 2 ml of 10% hypertonic saline, and in control group 80 mg of triamcinolone plus 2 ml of normal saline were injected. Outcome measures were numerical rating scale (NRS), Oswestry disability index, and proportion of responder patients (NRS<3) were measured at baseline, 1, 3, and 6 months post-procedure.

Results: Comparison of pain score between two groups showed that pain score was not significantly different at 1 (p=0.24), 3 (p=0.31) and 6 month (p=0.38). Significant pain relief (NRS<3) in 76% of patients within 1 months. Percent of patient with NRS<3 was 48% and 32% in hypertonic and 40% and 32% in steroid group at 3 and 6 month, respectively.

Conclusion: Hypertonic saline added to steroid did not significantly increase pain relief effect of epidural steroid injection.

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INTRODUCTION

Chronic radicular low back pain is a common disease that limits patient's daily activity¹. Lateral spinal canal stenosis due to contained disc herniation is a common cause of chronic lumbar radicular symptoms^{2,3}. Radicular pain is caused by irritation of the sensory root or dorsal root ganglion of a spinal nerve. The irritation causes ectopic nerve impulses perceived as pain in the distribution of the axon. The pathophysiology is both mechanical stimulation and a cytokine mediated inflammatory reaction at the vicinity of irritating cause such as bulged disc⁴.

Many treatment modalities and techniques, including

surgery and epidural injection, have been used to manage the pain. Surgery is indicated for those patients with progressive neurological deficits or severe pain refractory to conservative measures. The high cost of surgical intervention and numerous adverse effects emphasized on using an alternative of minimal invasive procedures such as epidural injections⁵.

Epidural steroid injection (ESI) is becoming the mainstay of therapies for radicular low back pain due to non-surgical contained bulged disc and foraminal stenosis⁶. ESI is the most widely utilized pain management procedure in the field, their use supported

by tremendous clinical trials and dozens of systematic reviews ⁷. Significant and lasting pain relief can be achieved with transforaminal (TF) approach of epidural steroid injection ^{8,9}. However, despite the extensive literature on the subject, there continues to be considerable controversy surrounding their safety and efficacy.

Recently, Koh wu et al ¹⁰ study showed superior efficacy of hypertonic saline, when added to TF on degenerative lumbar spinal stenosis low back pain and radiculopathy. However, the effect of hypertonic saline injection in ESI has not yet been widely accepted and further studies are required. In this study, we compared epidural steroid injection with and without adding hypertonic saline using TF in controlling unilateral radicular low back pain.

We aimed to determine the effect of adding hypertonic saline to epidural steroid injections to provide superior pain relief for chronic radiculopathy back pain secondary to foraminal stenosis.

MATERIAL AND METHODS

The study was reviewed and approved by the University Review Board and Ethics Committee. Information about trial was given comprehensively both orally and in written form. All patients gave their informed written consents prior to their inclusion in the study.

Patient selection

In a double-blind, randomized, clinical trial, 50 patients with unilateral radicular low back pain due to unilateral foraminal stenosis was enrolled in the study. Patients were randomly allocated into 2 groups by a computer-generated randomization program. Twenty-five patients in the hypertonic group and 25 patients in the control group were assessed.

Inclusion criteria were patients with unilateral radicular pain due to unilateral foraminal stenosis at one level, pain score (NRS)>3, age between 20-60 years age, no history of surgical intervention, no progressive sensory or motor deficit, and MRI indicating paracentral contained disc herniation.

Exclusion criteria were pregnancy, drug abuse,

allergy to local anesthetics, coagulopathy, diabetes, weight loss>10%, neurologic deficits, non-foraminal disc herniation, infection, incontinence, psychological disturbance, seizure.

Transforaminal Procedure

A 22-gauge, 3.5 inch Quincke’s needle was introduced at the level of disc pathology using first an anteroposterior (AP) and, subsequently, an oblique orientation (15-30o) of the fluoroscopy C-arm to achieve the “Scotty Dog” appearance of the lumbar spine and then directed until the needle tip was in the posterior and superior aspect of the intervertebral foramen as checked in the lateral imaging, and in line with the pedicle on AP view.

Hypertonic and steroid epidural injection

After confirmed needle placement in transforaminal approach, in hypertonic saline group 80 mg of triamcinolone plus 2 ml of 10% hypertonic saline, and in control group 80 mg of triamcinolone plus 2 ml of normal saline were injected.

Outcome measurement

Outcome measures were taken at baseline (before procedure), 1, 3, and 6 months post-procedure. The primary outcome measures included pain score using numerical rating scale (NRS). The secondary outcome measures included the Oswestry disability index (ODI), and proportion of responders to ESI by calculating number of patients with NRS<3 to total number of patients in each group.

RESULTS

In a randomized clinical trial, 50 patients with unilateral radicular pain due to foraminal stenosis were included in the study and were randomly assigned to receive hypertonic plus steroid or steroid only.

Age, sex, and BMI were not significantly different between two groups of study. Mean severity of pain prior to TF epidural injection was not significantly different between two groups of study (Table 1).

Table 1. Demographic characteristics of patients.

	Hypertonic Saline+Steroid (n=25)	Steroid (n=25)	p-value
Age (years)	55.4±8.9	56.3±9.4	0.67
Sex (Male/Female)	14/11	16/9	0.56
BMI (kg/m ²)	24.5±4.7	23.7±4.2	0.20
Severity of pain prior to TF (NRS)	7.1±2.5	7.3±3.3	0.78
Duration of pain prior to TF (month)	45.8±8.1	42.6±9.5	0.24
Disability index prior to TF (ODI %)	52.7±8.9%	53.2±9.7%	0.51

TF: transforaminal; BMI: Body mass index; NRS: Numerical rating score; ODI: Oswestry disability index

Disability index of patient prior to TF procedure was not significantly different between two groups of study (Table 1).

Pain and disability

Transforaminal (TF) epidural injection in both groups of steroid and hypertonic saline was effective and provided significant pain relief 1 and 3 months. Pain score was lower at 1 and 3 month after steroid with or without hypertonic compare to baseline; however pain increased at 6 month follows up (Figure 1). Comparison of pain score between two groups showed that pain score was not significantly different at 1($p=0.24$), 3 ($p=0.31$) and 6 ($p=0.38$) month (Figure 1). Therefore, use of hypertonic saline did not extend the duration of significant pain relief (NRS<3) to 6 months compared

with baseline in hypertonic group compare to steroid alone group (Figure 1).

Transforaminal epidural injection with steroid decreased pain score<3 in 72% of patients and injection in steroid with hypertonic saline was effective and provided significant pain relief (NRS<3) in 76% of patients within 1 months. Percent of patient with NRS<3 was 48% and 32% in hypertonic and 40% and 32% in steroid group at 3 and 6 month respectively. Besides, there was no significant differences between two groups at 1, 3 and 6 month after TF injection (Figure 2).

Disability index decreased in 1 and 3 month compare to baseline, however it increased from 3 month to 6 month. Disability index (ODI %) was not significantly different between two groups at 1 ($p=0.42$), 3 ($p=0.29$), and 6 month ($p=0.23$) (Figure 3).

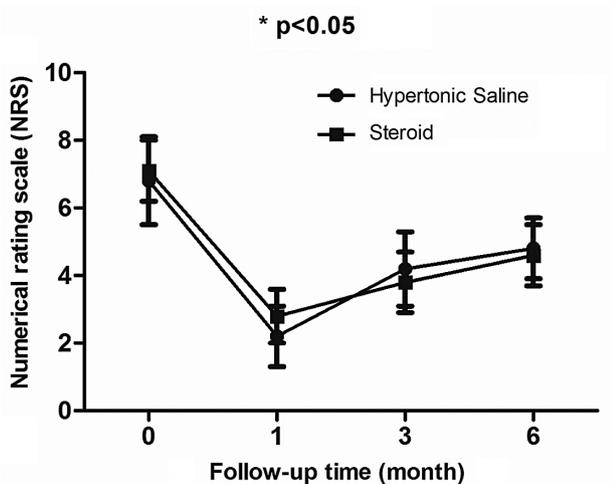


Figure 1. Comparison of pain score between two groups during follow up.

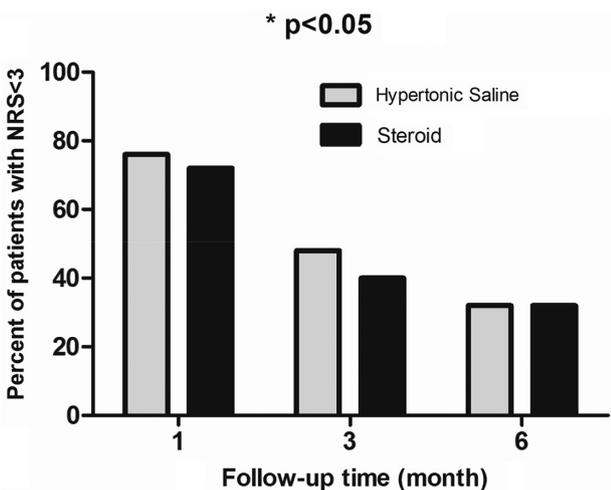


Figure 2. Comparison of proportion (percent) of patient with NRS<3 to total number of patients (25 cases) in each group.

DISCUSSION

In this study we embarked on improvement of effect of ESI by using hypertonic saline as an adjuvant to enhance pain relief. However, we did not observe any significant difference between ESI with or without hypertonic saline.

Although ESI are used extensively in the management of chronic spinal pain, however, evidence is contradictory with continuing debate about the value of ESI in chronic spinal syndromes ¹¹. TF is more often successful in patients without significant compression of the nerve root and, therefore, in whom an inflammatory basis for radicular pain is most likely. In patients with significant compression of the nerve root, the likelihood of benefiting from TF is low. The success rate may be no more than that of a placebo effect, and surgery may be a more appropriate consideration ¹². Low-grade root compression responded

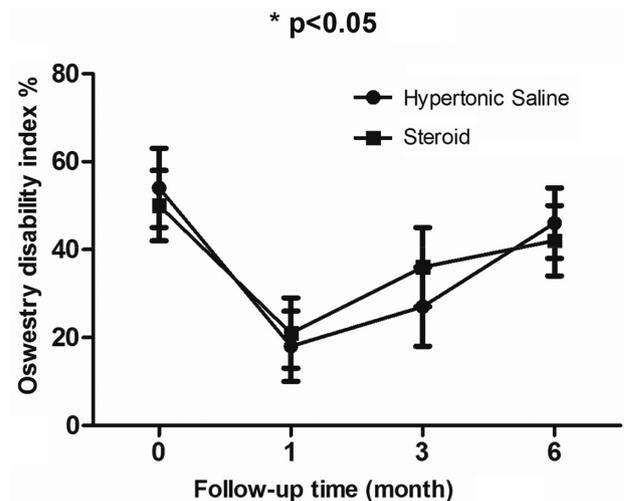


Figure 3. Comparison of disability index (ODI %) between two groups.

more favorably to TF compare to high-grade nerve root compression in previous reports¹³. This emphasizes the importance of patient selection in this study. We included patients with both high and low grade of nerve root compression in radiological images. However, we did not find any significant differences between epidural steroid injection with or without hypertonic saline in pain relief and improvement of clinical disability. Our results could propose that hypertonic may be more effective in high grade nerve root compression or long-lasting nerve compression.

On the other hand, hypertonic saline added to steroid epidural injection effect on pain reduction of foraminal stenosis may be related to its adhesiolysis mechanism that is currently used in post lumbar surgery syndrome and spinal stenosis^{14,15}. Perineural fibrosis could render nerve root hyperesthetic and hypersensitive to compression. Traditionally, steroid injection has been used to treat low back pain and radiculopathy. The addition of hyaluronidase to the injectate has been reported to reduce the degree of fibrosis¹⁶. There is moderate evidence that Epidural lysis of adhesions is more effective than conventional ESI for failed back surgery syndrome, spinal stenosis, and lumbar radiculopathy¹⁷. Epidural lysis of adhesions may directly alleviate pain and facilitate the spread of analgesic substances to area of pain generation. There is a growing body of evidence that suggests it may be effective for spinal stenosis and radicular pain stemming from a herniated disc. The use of hypertonic saline could contribute to the enhanced efficacy of disruption of scar tissue¹⁸.

Significant relief and functional status improvement was seen in 76% of hypertonic saline and 72% of steroid only patients but it decreased to less than 50% of patients at 3 and 6 month. Adding hypertonic saline did not increase duration of pain improvement. Therefore, steroids and hypertonic sodium chloride solution may be an effective management strategy for short term in patients with chronic low back due to foraminal stenosis of paracentral contained disc herniation in consistence with other studies¹⁹. Systematic review showed fair evidence that ESI is moderately effective for short-term (but not long-term) symptom relief²⁰.

In conclusion, hypertonic saline added to steroid did not significantly increase pain relief effect of epidural steroid injection.

REFERENCES

1. Tarulli AW, Raynor EM. Lumbosacral radiculopathy. *Neurol Clin.* 2007;25(2):387-405.
2. Park HJ, Kim SS, Lee SY, Park NH, Rho MH, Hong HP, et al. Clinical correlation of a new MR imaging method for assessing lumbar foraminal stenosis. *AJNR Am J Neuroradiol* 2012;33(5):818-22.
3. Jenis LG, An HS. Spine update. Lumbar foraminal stenosis. *Spine (Phila Pa 1976)* 2000; 25(3):389-94.
4. Govind J. Lumbar radicular pain. *Aust Fam Physcian.* 2004;33(6):409-12.
5. Turner JA, Ersek M, Herron L, Deyo R. Surgery for lumbar spinal stenosis. Attempted meta-analysis of the literature. *Spine (Phila Pa 1976).* 1992;17(1):1-8.
6. Benzon HT. Epidural steroid injections for low back pain and lumbosacral radiculopathy. *Pain* 1986; 24(3):277-95.
7. Manchikanti L, Staats PS, Singh V, Schultz DM, Vilims BD, Jasper JF, et al. Evidence-based practice guidelines for interventional techniques in the management of chronic spinal pain. *Pain Physician.* 2003;6(1):3-81.
8. Botwin KP, Gruber RD, Bouchlas CG, Torres-Ramos FM, Sanelli JT, Freeman ED, et al. Fluoroscopically guided lumbar transformational epidural steroid injections in degenerative lumbar stenosis: an outcome study. *Am J Phys Med Rehabil.* 2002;81(12):898-905.
9. Ghai B, Bansal D, Kay JP, Vadaje KS, Wig J. Transforaminal versus parasagittal interlaminar epidural steroid injection in low back pain with radicular pain: a randomized, double-blind, active-control trial. *Pain Physician.* 2014;17(4):277-90.
10. Koh WU, Choi SS, Park SY, Joo EY, Kim SH, Lee JD, et al. Transforaminal hypertonic saline for the treatment of lumbar lateral canal stenosis: a double-blinded, randomized, active-control trial. *Pain Physician.* 2013;16(3):197-211.
11. Boswell MV, Hansen HC, Trescot AM, Hirsch JA. Epidural steroids in the management of chronic spinal pain and radiculopathy. *Pain Physician.* 2003;6(3):319-34.
12. Jenis LG, An HS. Spine update. Lumbar foraminal stenosis. *Spine (Phila Pa 1976).* 2000;25(3):389-94.
13. Ghahreman A, Bogduk N. Predictors of a favorable response to transforaminal injection of steroids in patients with lumbar radicular pain due to disc herniation. *Pain Med.* 2011;12(6):871-9.
14. Helm Ii S, Benyamin RM, Chopra P, Deer TR, Justiz R. Percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome and spinal stenosis: a systematic review. *Pain Physician.* 2012;15(4):E435-62.
15. Iversen T, Solberg TK, Romner B, Wilsgaard T, Twisk J, Anke A, et al. Effect of caudal epidural steroid or saline injection in chronic lumbar radiculopathy: Multicentre, blinded, randomised controlled trial. *BMJ.* 2011; 343:d5278.
16. Yousef AA, EL-Deen AS, Al-Deeb AE. The role of adding hyaluronidase to fluoroscopically guided caudal steroid and hypertonic saline injection in patients with failed back surgery syndrome: a prospective, double-blinded, randomized study. *Pain Pract.* 2010;10(6):548-53.

17. Lee F, Jamison DE, Hurley RW, Cohen SP. Epidural lysis of adhesions. *Korean J Pain*. 2014;27(1):3-15.
18. Jamison DE, Hsu E, Cohen SP. Epidural adhesiolysis: an evidence-based review. *J Neurosurg Sci*. 2014;58(2):65-76.
19. Manchikanti L, Cash KA, McManus CD, Pampati V. Assessment of effectiveness of percutaneous adhesiolysis in managing chronic low back pain secondary to lumbar central spinal canal stenosis. *Int J Med Sci*. 2013;10(1):50-9.
20. Chou R, Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. *Spine (Phila Pa 1976)*. 2009;34(10):1078-93.