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THE LONG-TERM EFFECT OF TRANS-SACRAL EPIDUROSCOPIC FORAMINOPLASTY IN INTRACTABLE LUMBAR RADICULOPATHY

ABSTRACT

Introduction: Lumbar radiculopathy is commonly associated with lumbar disc herniation. Epiduroscopy is a method that can be applied in patients who do not benefit from conservative treatment by entering the epidural space with a fiber optic endoscope through the sacral hiatus. We present trans-sacral epiduroscopic foraminoplasty (TSEF) procedure with the Fogarty balloon catheter.

Methods: We collected retrospectively 43 patients who had undergone TSEF between 2013 and 2016. Pain intensity was recorded with visual analogue scale (VAS), and functional outcome was recorded with Oswestry Disability Index (ODI) at preoperative, postoperative 1st, 6th and 12th month follow-ups. Surgery satisfaction was evaluated with Macnab criteria at 1st, 6th and 12th month follow-ups.

Results: There were 27 female (62.8%) and 16 male (37.2%) patients. The mean age of the patients were 70.04 \pm 7.78 years. The mean follow-up period was 15.25 \pm 1.97 months. Preoperative VAS score averages were 6.44 \pm 0.88, decreased to 1.72 \pm 1.34, 3.21 \pm 0.91 and 3.41 \pm 1.17 in postoperative 1st, 6th and 12th month respectively (p<0.0001). The preoperative ODI scores decreased from 71.52 \pm 6.72 to 19.31 \pm 5.49, 27.61 \pm 5.37, 31.31 \pm 7.91 postoperative 1st, 6th and 12th month respectively (p<0.0001). The surgical satisfaction in terms of Macnab criteria were found at 12th month follow up as 60% excellent, 35% good and 5% fair results.

Conclusion: The TSEF procedure is a minimally invasive surgical technique that is easily performed to the patients who are resistant to lumbar radiculopathy, especially those who do not respond to epidural steroid injections, with good long-term results.

Keywords: Lumbar radiculopathy, lumbar disc herniation, trans-sacral epiduroscopic foraminoplasty

Level of Evidence: Retrospective Clinical Study, Level III

INTRODUCTION

Lumbar radiculopathy is commonly associated with lumbar disc herniation, spinal stenosis. and degenerative spondylolisthesis. Disc herniation typically presents with pain in the affected dermatomal area, which is reflected from the back down the leg. In addition, epidural corticosteroid injections (interlaminar, transforaminal or caudal) are highly effective in nerve root compression, which is accompanied by a severe inflammatory response due to herniated nucleus pulposus. In the literature epidural injections also reported pain relief in the mid-term of 55-84% (10,13).

Minimally invasive surgical options for disc decompression are available in

pain resistant to epidural steroids or other injection methods. As opposed to open surgery, by protecting the spinal architecture, these methods include less tissue destruction and procedural complications at lower rates.

Epiduroscopy is an epidural spinal endoscopy system developed for this purpose. A method can be applied in patients who do not benefit from conservative treatment and is used in the treatment of symptomatic disc herniation by entering the epidural space with a fiber optic endoscope through the sacral hiatus. The endoscope was first invented by Adolf Kussmaul in 1868, and in 1958 Hirschowitz introduced a flexible fiberglass endoscope, a milestone for the period of minimally invasive surgery ⁽¹⁹⁾. In principle, Burrman⁽¹⁸⁾ introduced the concept of epiduroscopy in 1931, and Leu et al. reported trans sacral peridural intraductal endoscopy. Rueten et al.⁽¹⁵⁾ reported the clinical application of epiduroscopic assisted laser therapy for postnucletomy syndrome. In 2003, Ruetten and his colleagues performed epiduroscopy in 93 patients⁽¹⁶⁾ and Graziotti in 300 patients with lower back and leg pain⁽¹⁷⁾.

This technique can be used in lumbar pain and lumbar radiculopathies that do not respond to conservative treatments, and can be widely used to perform adhesion-lysis in intractable failed back surgery syndrome⁽⁸⁾. Epiduroscopy is a method of direct visualization of the lumbar epidural lesions and surrounding structures by entering the body through a natural opening called the sacral hiatus. In contrast to the lumbar disc surgery, minimal defects occur in musculoskeletal structures. This flexible epiduroscopy system can be used to diagnose, as well as to reduce disk pressure with laser applications ⁽⁹⁾.

In our study, patients suffering from lumbar radiculopathy and treated with epiduroscopy and foraminoplasty with inflated fogarty balloon at the inferior medial of the exiting root at the foraminal level, and disc pressure reduced with this method called trans-sacral epiduroscopic foraminoplasty (TSEF), were presented.

MATERIAL AND METHODS

Study design and patient population

In our hospital, records of 43 patients who had undergone TSEF between 2013 and 2016 were retrospectively collected. Our study protocol was approved by our hospital ethics committee. Informed consent was obtained from all patients. All patients underwent lumbar spinal MRI and x-rays (radiologic examination) before the procedure and problematic disc levels were recorded. As inclusion criteria, single or double level, back and radicular pain, and patients with lumbar degenerative disc disease, annulus rupture sign -high intensity zone (HIZ)- on MRI imaging and foraminal bulging or protruding lumbar disc herniation. In pre-treatment examinations of the patients, they were found to be straight leg raising test + without neurological deficit. TSEF procedure was carried out on patients who had no pain relief following a 4 week follow up after pharmacotherapy (NSAID) and physical therapy due to back and leg pain, given transforaminal epidural steroid injections or those with recurrent pain. Patients with extruded or sequestered disc herniation, neurological motor deficits, Tarlov cysts, lumbar spinal stenosis or spondylolisthesis, hemorrhagic diathesis, infections or tumor pain have been excluded from the study.

Pain intensity was recorded with visual analogue scale (VAS) and patient's functional outcome with Oswestry disability index (ODI), at preoperative, postoperative 1st, 6th and 12th month follow-ups. Postoperative surgical satisfaction was evaluated according to Macnab criteria, and recorded at 1st, 6th and 12th postoperative months.

All patients were subject to hemodynamic monitoring and intravenous access was established in the prone position in the operating room. Sedation was provided with intravenous midazolam and fentanyl as required. After sterile skin preparation and draping, the appropriate opening of sacral hiatus was identified, and the overlying skin and the underlying ligaments were infiltrated with 1% lidocaine. A vertical 5-10 mm skin incision was made in sacral hiatus and 17 gauge Touhy needle was inserted into the sacrum, guidewires and dilators were placed respectively. A steerable 3.0 mm video-guided catheter (VGC) incorporating epiduroscopes was placed. The position of the VGC in the ventral epidural space was checked under the C-arm scope. The VGC end tip was push forward to the corresponding exiting nerve root foramen. Ventral epidurogram was performed with 1-2 ml of contrast (Figure-1).

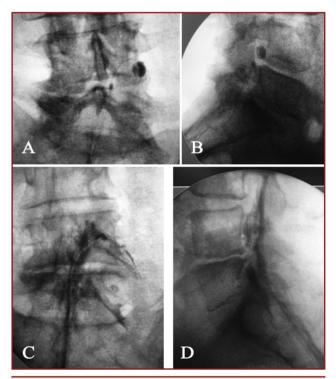


Figure-1. Antero-posterior **(A)** and lateral **(B)** fluoroscopic view, fogarty ballooncatheter are seenin the left L4 foramen. Catheter are placed ventral epidural space, antero-posterior **(C)** and lateral **(D)** epidurogram.

Subsequently, the 2-F fogarty was placed adjacent to the infero-lateral of exiting nerve and foraminal disc, was inflated, carrying out a foramen foraminoplasty by widening the foramen. The root was washed by serum saline irrigation and 1 ml of 40 mg methyl prednisolone acetate was administered. After the procedure was finished, the VGC was removed, the sacral hiatus primer was sutured and the patient was transferred to the recovery room.

We observed dural puncture in 2 patients during surgery, transient mild motor neurologic deficit in postoperative period in 2 patients and mild sensorial neurologic deficit in 4 patients. No complications were observed in the other 35 patients.

Statistical Analysis

Statistical analysis of data was performed using SPSS v.21 for Windows (IBM corp., Armonk, NY, USA). The normally distributed continuous variables are reported as means± standard deviations (P>0.05 in Kolmogorov-Smirnov test or Shapiro-Wilk). The paired T test was used for the comparison of normally distributed data among groups, and the Kruskal-Wallis test was used for non-normally distributed data. The Pearson's correlation coefficient was used to investigate a relationship between the factors. A p value of <0.05 was considered statistically significant.

RESULTS

There were 27 female (62.8%) and 16 male (37.2%) patients in the 43 patients we included between the years of 2013 and 2016, with the mean age of the patients being 70.04 \pm 7.78 years. The mean symptom duration of the patients was 9.58 \pm 1.05 weeks, and the mean follow-up period of the patients was 15.25 \pm 1.97 months. The demographic characteristics of patients are given in Table-1.

Preoperative VAS score averages were 6.44 ± 0.88 , 1.72 ± 1.34 in the first postoperative month, 3.21 ± 0.91 in the 6th month and 3.41 ± 1.17 in the 12th postoperative month, while the decrease in pain intensities was significant at the postoperative 1st, 6th and 12th months (p<0.0001, Figure-2).

When we considered the functional effect of TFSE according to ODI scores, preoperative scores decreased from 71.52 \pm 6.72 to postoperative 1st month 19.31 \pm 5.49, 6th month 27.61 \pm 5.37, 12th month 31.31 \pm 7.91, and there were significant improvement at the postoperative 1st, 6th and 12th months ODI scores (p <0.0001, Figure-3).

The patients treated with TSEF were considered for surgical satisfaction in terms of Macnab criteria at 12th month followup, we found 60% excellent, 35% good and 5% fair results (Figure-4).

Table-1. Demographic factors of the patients (SD: standart deviation)

Age (years, mean± SD)	70.04±7.78
Gender (n, %)	
Male	16 (37.2 %)
Female	27 (62.8 %)
Symtom Duration (weeks, mean± SD)	9.58±1.05
Follow-up (months, mean±SD)	15.25±1.97
Levels (n):	
L4-5	37
L5-S1	30

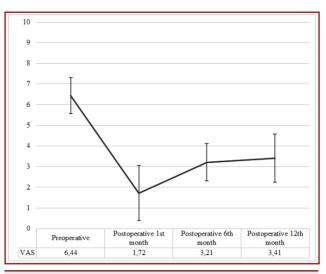


Figure-2. The comparison of preoperative and postoperative Visual Analogue Scale (VAS) scores

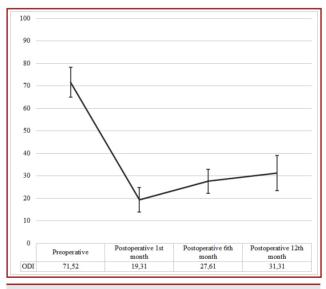
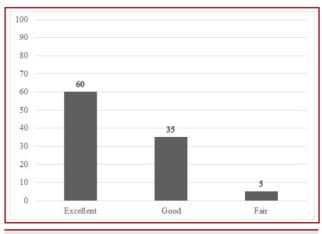
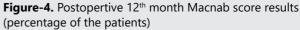


Figure-3. The comparison of preoperative and postoperative Oswestry Disability Index (ODI) scores





DISCUSSION

Low back pain and radiculopathy are a painful condition that disrupts the quality of life. The prevalence of life-long prevalence in individuals is between 54-80%, with an annual prevalence of $15-45\%^{(2,20)}$. Although most of these patients can be treated conservatively, using the epiduroscopy technique in patients who do not respond to conservative treatment, in particular epidural injection techniques, to better visualize the spinal canal and to use some modalities to reduce disc pressure is an alternative method.

Pain formation is a condition that is affected by inflammatory, vascular, biomechanical, and compressive events in addition to the mechanic pressure created by the disc and nucleus pulposus. The nucleus pulposus is a biologically active tissue that triggers a chain of inflammatory type chemical reactions in the degenerative disc disease. Nucleus pulposus is an avascular structure, as well as a tissue that is considered an antigen due to causing a strong inflammatory reaction when making contact with nerve structures. When inflammatory and mechanical reactions develop between the intervertebral disc and posterior longitudinal ligament and nerves, it is thought that back pain and radicular pain is provoked. Along with this, when the nerve is inflamed, it becomes more susceptible to mechanical irritation. The effect of epidural steroid injections on radiculopathies is to clean the mediators released around the nerve, and / or to inhibit secretions, and to block the nociceptive C-fiber connection ^(4,5,7,11).

Transverse sacral epiduroscopic laser applications are widely used in lumbar foraminal disc herniation. It has been used since 1984, when Ascher and Heppner⁽¹⁾ used CO2 and Nd lasers for treatment of lumbar disc hernias for intradiscal pressure reduction. The laser is used for cutting, evaporation, ablation and welding. However, while the Ho: YAG laser is frequently used in trans-sacral endoscopic laser decompression, it damages the annulus.⁽³⁾ Unlike laser treatment methods, the TSEF procedure is thought to reduce radicular symptoms by providing widening in the foramen without destroying the natural shape of the structures in that area. In addition to observing that the mechanical pressure of the catheter balloon shrinks the foraminal discs, we think that pain reduction is a result of serum irrigation around the root creating a washout affect. There is no published literature about the TSEF procedure.

One of the minimally invasive surgical techniques in our study, the epiduroscopy procedure, is a popular treatment modality among spinal surgeons because of its ease of operation, short hospital stay, use of local anesthesia and high efficacy and patient satisfaction⁽⁶⁾. However, the presence of complications in trans sacral endoscopy procedures has not been comparatively investigated and is estimated to be below 10.9%⁽¹⁴⁾. Complications that may develop; Epidural infections can be seen as abscess in very rare cases. Increased intracranial pressure (ICP) can occur with related findings such as headache, nausea, vomiting. It may arise due to the

hydrostatic pressure from the irrigation fluid supplied from the catheter during the TSEF. In addition, increased ICP may cause minor visual changes and may cause more severe visual changes in glaucoma patients. Bolus application of irrigation fluid may cause sudden visual loss as it affects the optic nerve microcirculation. The surgeon should consider these symptoms; reduce the irrigation rate in conditions such as acute onset headache, neck pain. Pneumocephaly is a complication that occurs because of air entrapment in the epidural space. As with irrigation, it arises from the difference between the barometric pressure outside and the epidural space. A sudden onset headache during the procedure may be a symptom, and it is reabsorbed within 1 week. Dural puncture (DP) can usually be seen in the ventral epidural space around the S2 area during epiduroscopy. The thecal SAC endpoint may vary because the DP vary from patient to patient. The end of thecal SAC should be determined from the preoperative MRs before the procedure is started, and great care must be taken in this point as the catheter advances towards the ventral epidural space during the procedure. In addition, as we have seen in 6 patients with TSEF procedure in our series, transient neurological deficits can be seen after balloon foraminoplasty⁽¹²⁾.

There are also limitations of our study. The number of patients is low, and is retrospective in terms of nature, this being the weaknesses of our study. In addition to this, the operation being performed by a single senior surgeon is a strong point of our study. Reliable information related to this technique will be available in randomized, controlled, prospective studies.

CONCLUSION

The TSEF procedure is a minimally invasive surgical technique that is easily performed to the patients who are resistant to lumbar radiculopathy, especially those who do not respond to epidural steroid injections, with good long-term results.

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