Effects Of Transforaminal Dilatation By 6F Dilator In Patients With Lumbar Foraminal Stenosis Using Seldinger's Method: A Randomized, Controlled, Double-Blind Trial

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ABSTRACT

Patients with chronic low back pain (with or without radicular pain) may have peri-neural adhesions from mechanical or chemical irritation while they don't have a history of surgery. This might be the source of chronic low back pain. It is now well accepted that those adhesion are attributed to pain associated with patient's motion. When adhesions persist for a long time, they may cause aggravation of neuritis, demylination, a nerve conduction disorders, ectopic neural transmission and neuropathic pain. Conventional neuroplasty may be divided into either chemical or mechanical adhesionolysis using either epiduroscopy or catheter. Chemical neuroplasty have relatively low effect and a high risk for relapse either due to adhesions themselves (which are difficult to remove) or their interference with effective spread of a therapeutic agents to the lesion.Mechanical adhesionolysis has the theoretical advantage that the adhered region around the nerve is separated either with epiduroscopy or directly with a catheter. We used direct dilatation using Seldinger's method and dilator provided in central venous line set (*BALATON®)* to enable relief of spinal stenosis by expanding the space around the nerve in the stenotic intervertebral foramen and injecting steroids with (*HYALASE)* in the area.

INTRODUCTION

patients with chronic low back pain and/or radicular pain may have perineural adhesions due to perineural and neurogenic inflammation from mechanical or chemical irritation, while they don't have any history of surgery [1,2]. Also, a considerable number of patients complaining of pain after spinal surgery reportedly have adhesions and fibrosis in the epidural space [3,4].

It is still unclear whether adhesions or fibrosis constitute the main cause of low back pain or whether adhesions or fibrosis are the direct cause of pain. Considering the reports currently available, although there is less evidence supporting the postulation that adhesions or fibrosis cause pain directly,

it is widely accepted that they are attributed to pain in association with patient's motion [5]. Parke and Watanabe dissected the cadavers of such patients and reported that a number of anterior epidural adhesions, which were not detached even when pulled with threads of about 60 g, were found between L4 and S1. This finding indicates that the adhesions might have been the cause of chronic low back pain [6].

Published reports suggest that the mechanism by which adhesions or fibrosis affect pain may be a disorder of the blood and nutrient supply or repression of the mobility of the dura and dural sleeve. When persisting for a long time, such disorders may cause aggravation of neuritis, demyelination, a nerve conduction disorder, ectopic neural transmission, and, eventually, neuropathic pain [1,6,7,8].

Nonsurgical treatments, such as nerve block, in chronic pain patients with severe adhesions are reported to have a relatively low effect and a high risk for relapse. This may be attributed to the fact that epidural adhesions themselves are difficult to remove through such methods, and also that they interfere with effective spread of a therapeutic agent to the lesion [9]. Epidural injections of steroids may relieve leg pain for weeks to months but do not influence functional status [10,11,12]. If a simple nerve block does not have a sufficient effect in a patient with pain caused by adhesions or stenosis, it is important to confirm whether pain is associated with an adhesion. Once adhesions or stenosis are confirmed as a cause of pain, neuroplasty may be performed to relieve them. Conventional neuroplasty may be divided into either chemical adhesiolysis using hypertonic saline or mechanical adhesiolysis using a catheter. Chemical adhesiolysis is performed by placing a thin catheter at the adhesion site and injecting hypertonic saline. Hypertonic saline has long been used in patients with intractable chronic pain. Although it has recently been used for chemical adhesiolysis, it is unclear whether it actually relieves adhesions, and almost no reports on its effect can be found. A short-term effect of chemical adhesiolysis lasting up to 3 months has been reported [13]. Rather than the hypertonic saline having an adhesion-eliminating effect, however, the analgesic effect of the procedure seems to be associated with a measure of relieved adhesion due to water pressure at the time of the saline injection, dilution of the algesic substances, the hyperosmolar hyperdepolarization of the hypertonic saline, and decreased pain transmission due to highly concentrated chlorine [14,15].

Epiduroscopic adhesiolysis has a reported evidence level of about II-1 over a short term and about III over a long term in patients experiencing pain after spinal surgery [13]. Mechanical adhesiolysis has the theoretical advantage that the adhered region around a nerve is separated with a catheter directly. Mechanical adhesiolysis may be divided into two methods: the epiduroscopic adhesiolysis method, and the adhesiolysis method using a thin catheter without epiduroscopic guidance. Epiduroscopic adhesiolysis enables physicians to see epidural adhesion and inflammation region directly during the procedure. Moreover, it allows for more effective adhesiolysis. A disadvantage of epiduroscopic adhesiolysis, however, is that the thick catheter may cause severe pain and pose risks of nerve damage when procedures are performed in intervertebral foramen with severe

stenosis. When using a thin catheter instead, physician may be unable to eliminate a moderate or severe adhesion due to weakness of the catheter.

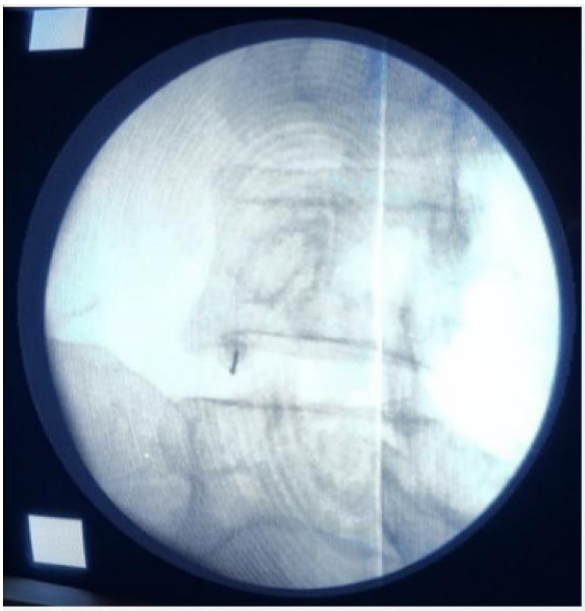
Manchikanti et al. compared the use of an epiduroscope versus a Racz catheter and reported that the duration of effect was shorter in patient who had undergone the Racz catheter procedure. However, the cost-effectiveness was higher in the Racz catheter procedure than in the epiduroscopic procedure [16]. In cases of spinal stenosis, most conventional nonsurgical procedures have shown good short-term analgesic effects; however, functional improvement has not been enough [17,18]. The transforaminal ligament normally covers about 29% of the intervertebral foramen; this does not matter when there is no foraminal stenosis. However, it may exacerbate the foraminal stenosis following progression of degenerative changes [19].

MATERIALS AND METHODS

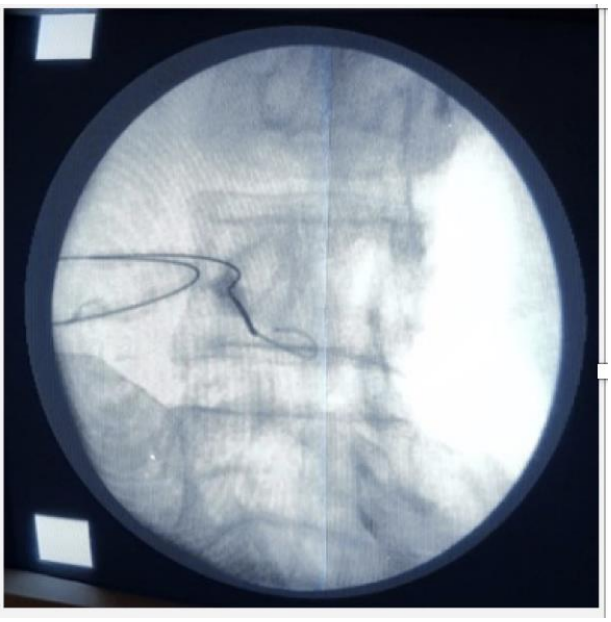
The 56 patients were included with intractable unilateral neural foraminal stenosis divided in two equal groups . We compared two procedures: in the study group, a 6F dilator (provided in central venous line set "*BALTON®"*) was inserted using Seldinger's method into the stenosed neuroforamen, dilatation was performed, and a steroid with hyalase were injected; while in the control group, same procedure was done excluding the dilatation. The pain relief and functional improvement were greater in the group in which dilatation was performed , with effects reported after 1, 3, and 6 months. Response was better and improvement was greater in 3 and 6 months. Data collected and questionnaire variables highly depended on Visual analogue scale (VAS) and Oswestry Low Back Disability Index (ODI) were used. Data were collected and analyzed using double blind study.

RESULTS AND DISCUSSION

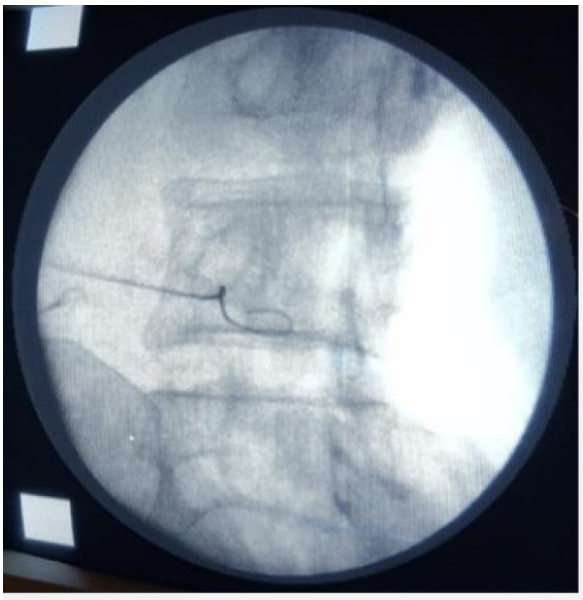
Significant improvement occurred in pain and neurogenic claudication distance in the dilator group during the follow up period after three and six months. The transformational ligament normally covers about 29% of the intervertebral foramen. However, it may exacerbate the foraminal stenosis following progression of degenerative changes. The dilatation may contribute to the expansion of marginal space leaving more space for the nerve in the intervertebral foramen. During data collection, double or event triple blind measures has been followed in that data collectors don't recognize to which group the patient is belonging to, and furthermore, the data analyst has been given data without knowing the group categories or interfering with goals of study or interfering with study outcome.



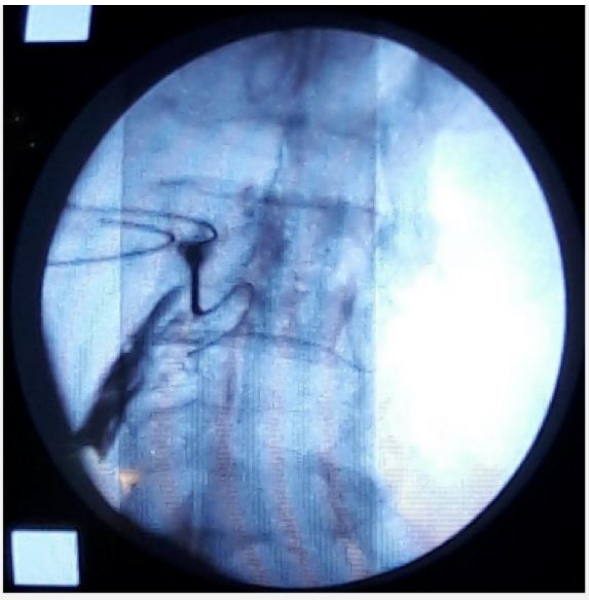
Picture 1: Shows the placing needle in the neuroforamen



Picture 2: Shows the inserting guide wire in the epidural space



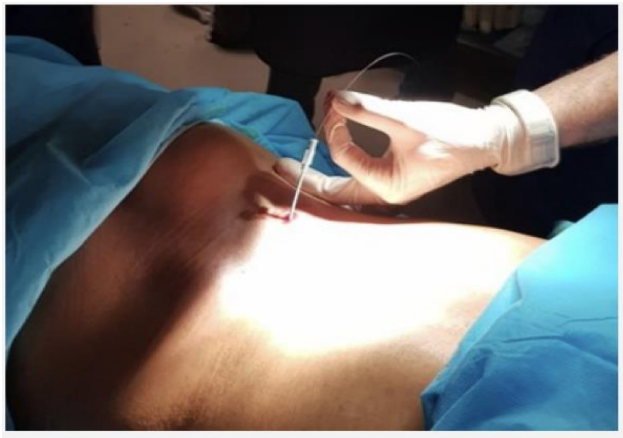
Picture 3: Shows the guide wire in the epidural space.

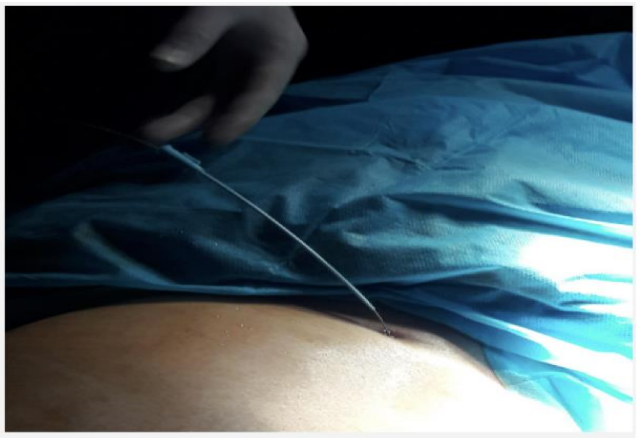


Picture 4: Shows the visualization of nerve root and epidural space with contrast

Picture 5: Shows the visualization of nerve root after dilatation

Picture 6: Shows the insertion of guide-wire using Seldinger's method





Pictures 7 and 8: Shows the inserting dilator and dilating neuroforamen leaving more space for nerve root.

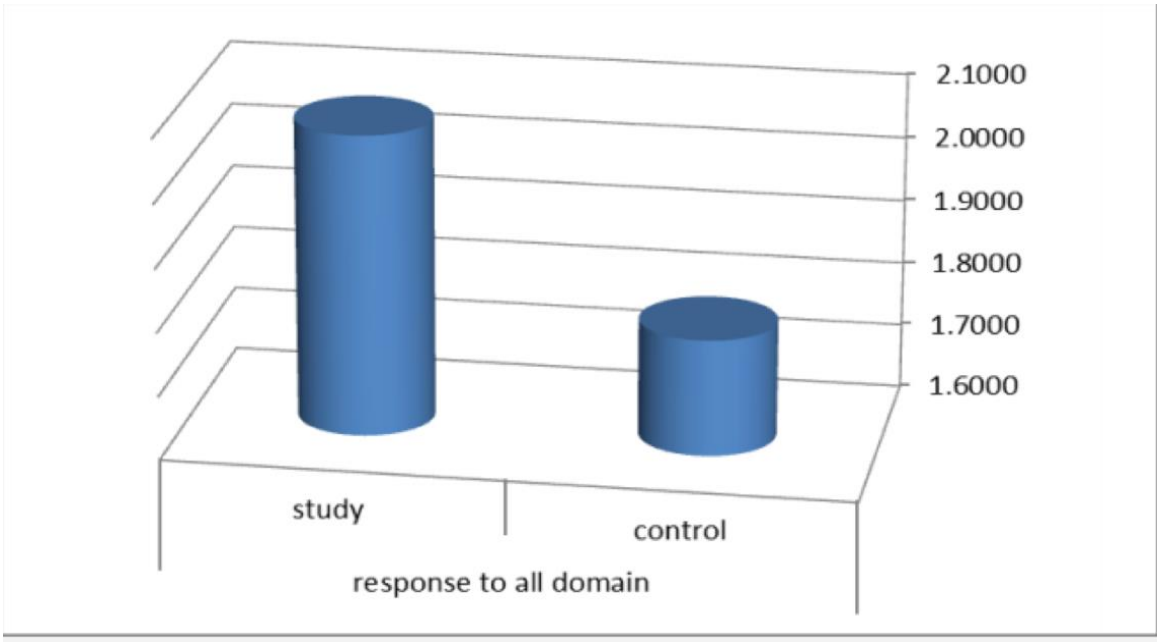


Diagram1: Shows the patient (control and study groups) Response to all domains after one month from the procedure.

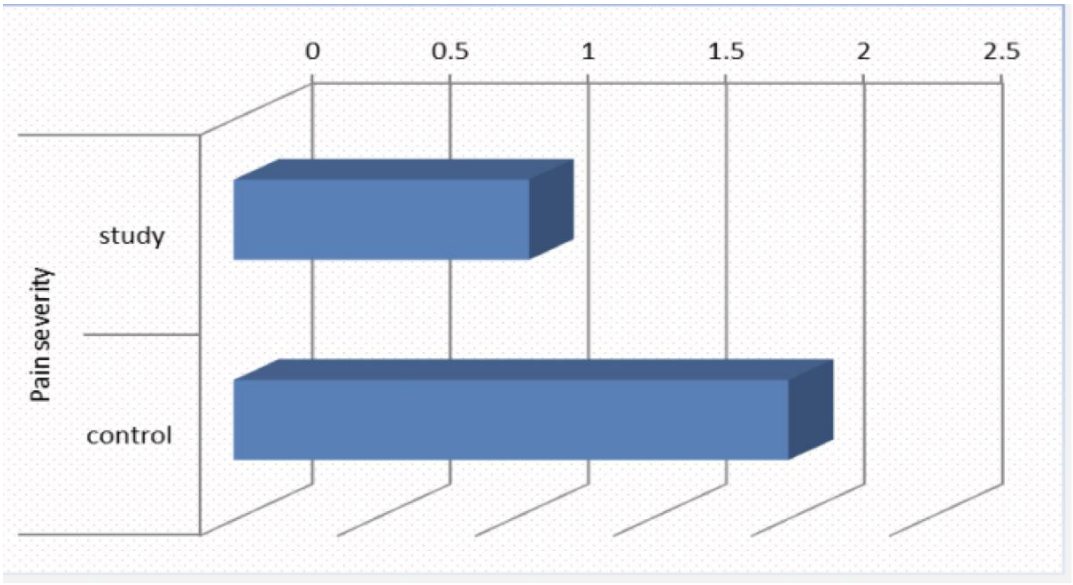


Diagram 2: **Shows pain response in both control and study groups after one month from procedure.**

The surprisingly, the control group (those with just with transforaminal injection of depo steroids together with *HYALASE®* without dilatation) shows better response after 1 month of procedure. This could be due to:-

1. Less interference and less mobilization in control group than study groups. Epidural space is a highly vascular area and performing dilatation in this area may be accompanied by tissue mobilization and post-procedure bleeding that may take more time for better results.
2. Some psychological highlights could not be excluded. Patients have been well explained and informed about details of the procedure and too much worry and stress were noted pre- and post- procedure until given sometime to be reassured.

A further studies and analytic researches may need to be done here to confirm those results and to explore more suggested causes. However, the researchers highly accept and goes with the 1st explanation.

Domain	Mean control	Mean Study	t value	Df	p-value	Significant
Pain severity	1.50	1.14	2.173	54	.034	S
Pain intensity	2.89	1.75	3.930	54	.000	S
Personal care (washing, dressing, etc.)	2.43	1.75	2.367	54	.022	S
Lifting	2.93	2.00	2.931	54	.005	S
Walking	2.21	1.86	1.246	54	.218	N.S
Sitting	2.86	2.04	2.350	54	.022	S
Standing	2.75	1.79	3.368	54	.001	S
Sleeping	2.07	1.63	1.528	54	.132	N.S
Sex life	2.21	1.68	1.889	54	.064	S
Social life	2.11	1.60	1.654	54	.104	S
Travelling	2.50	1.65	2.889	54	.006	S
Over all	2.5964	1.779	2.540	54	.014	S

Table1: Shows significant difference between study and control groups after 3 months from the procedure.

Domain	Mean control	Mean Study	t value	Df	p-value	Significant
Pain severity	2.01	1.07	4.573	54	.000	S
Pain intensity	3.43	2.29	3.339	54	.002	S
Personal care (washing, dressing, etc.)	2.96	2.07	3.003	54	.004	S
Lifting	3.43	2.21	3.791	54	.000	S
Walking	2.61	2.13	1.620	54	.111	N.S
Sitting	3.14	2.18	3.558	54	.001	S
Standing	3.32	2.15	4.700	54	.000	S
Sleeping	2.86	2.12	2.439	54	.018	S
Sex life	2.89	1.96	2.861	54	.006	S
Social life	2.93	2.07	2.745	54	.008	S
Travelling	2.89	2.18	1.976	54	.053	S
Over all	3.0464	2.1293	3.133	54	.003	S

Table 2: Shows significant Difference between Study and Control Groups after six months from procedure

CONCLUSION AND RECOMMENDATIONS

Mechanical dilatation results in significant pain relief and functional improvement in patients with lumbar foraminal stenosis after 3 and 6 months. However, further follow up for longer periods are recommended.

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