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Case Review

Effectiveness of Percutaneous Adhesiolysis with Hypertonic Saline Neurolysis in Refractory Spinal Stenosis

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The increasing proportion of elderly patients, coupled with increasing longevity, causes the problem of lumbosacral pain secondary to spinal stenosis of the lumbar spine to be an important issue. Symptoms of spinal stenosis are caused by entrapment and compression of intraspinal vascular and nervous structures; which may lead to inactivity, loss of productivity, and potential loss of independence, particularly in the elderly. Surgical decompression is considered as the natural treatment. However, the results of surgical treatments have been mixed. Results of conservative treatment are also not encouraging. While the effectiveness of caudal epidural blocks for lumbar canal stenosis was positive, the effectiveness of interlaminar epidural steroid injections showed no beneficial effects on symptomatology of spinal stenosis.

Percutaneous epidural adhesiolysis with hypertonic saline neurolysis has been studied in patients with refractory low back pain secondary to post lumbar laminectomy syndrome, as well as spinal stenosis. The specific role of adhesiolysis and hypertonic saline neurolysis in the management of refractory low back and lower extremity pain secondary to spinal stenosis has not been studied.

This retrospective evaluation included 18 patients derived from a total sample of 239 patients undergoing adhesiolysis and hypertonic saline neurolysis over a period of 3 years. The results showed significant improvement with reduction of pain; with improvement of physical health, mental health, and functional status. Improvement in psychological status was also noted, with decrease in narcotic intake.

Epidural adhesiolysis with hypertonic saline neurolysis is a safe and probably effective modality of treatment in managing symptomatic moderate to severe lumbar spinal canal stenosis.

Keywords: Spinal stenosis, lumbar degenerative disc disease, neurogenic claudication, adhesiolysis, hypertonic saline neurolysis

Stenosis of the lumbar spinal canal is a major cause of disability and lost productivity (1-6). The increasing proportion of elderly patients, coupled with increasing longevity, causes the problem of lumbosacral pain secondary to spinal canal stenosis of the lumbar spine to be an important issue in today's healthcare (1-11). It can lead to inactivity, loss of productivity and potential loss of independence, particularly in the elderly (1, 2, 5). It is a treatable condition with or without surgical intervention.

Symptoms of spinal stenosis are caused by entrapment and compression of intraspinal vascular and nervous structures (12). Lumbar spinal stenosis has been known for more than a hundred years, but for a long time it was regarded as the "forgotten spinal disease" (12). However, lumbar spinal canal stenosis now is an accepted clinical entity. The space in the vertebral is limited, usually because of progressive degenerative changes and sometimes in combination with a congential narrow bony canal. Symptoms and signs are related to the limited canal space. Surgical decompression is considered as the natural treatment, and the results of this were reported in several publications (12-29). In a meta-analysis by Turner et al (6), successful results after surgical treatment were reported for 26% to 100% of subjects, with a mean follow-up of less than 4 years. Herno et al (30), in contrast, reported good surgical results for 68% of patients after a mean follow-up of 12 years. Johnsson et al (18), in a study comparing surgically and conservatively treated patients for symptomatic spinal stenosis, reported that 60% of the patients treated surgically improved and 25% deteriorated; whereas, of the conservatively treated patients, 30% improved and 60% were unchanged. Johnsson et al (31) also studied the natural

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course of spinal stenosis and found that, after a mean observation of 49 months, the symptoms of spinal stenosis were unchanged in 70%, improved in 15% and worse in 15% of the patients. Jønsson et al (23), in a prospective study, evaluated 105 consecutive patients who underwent surgical decompression for lumbar spinal stenosis. They reported that, during the follow-up period, 5%, or 19, patients underwent reoperation. Excellent results were reported by 67% at 4 months, 63% at 2 years, and 52% at 5-year follow-up. Katz et al (26), in a retrospective review and prospective follow-up of 88 patients 7 to 10 years after decompressive surgery for spinal stenosis, reported a reoperation rate of 23% and severe back pain in 33% of the patients. In addition, 53% of the patients were unable to walk two blocks. However, 75% were satisfied with the results of the surgery. Katz et al (27) in a prospective observational study of 199 patients with degenerative lumbar spinal stenosis, reported a decrease of the proportion of patients with severe pain from 81% before surgery to 31% by 2 years afterward.

Over time it also has been reported that many patients did well conservatively without surgery (12, 31-37). However, controlled clinical studies comparing conservative and surgical treatment are rare, and few studies deal with long-term results (6, 17). Amundsen et al (12), in a cohort of 100 patients with symptomatic lumbar spinal stenosis, selected 19 patients with severe symptoms for surgical treatment and 50 patients with moderate symptoms for conservative treatment; 31 patients were randomized between the conservative (N = 18) and surgical (N = 13) treatment groups. After a period of 4 years, excellent or fair results were found in half the patients selected for conservative treatment and in four fifths of the patients selected for surgery. They concluded that the outcome was most favorable for surgical treatment. They also concluded that an initial conservative approach seems advisable for many patients because those with an unsatisfactory result can be treated surgically later with a good outcome. However, none of the publications have addressed the role of conservative or nonsurgical treatment after failure of surgical treatment. There are no specific reports describing the effectiveness of spinal cord stimulation or implantable intrathecal drug administration systems in the management of symptomatic spinal stenosis before or after surgery. Ciocon et al (38) studied the effectiveness of caudal epidural blocks for elderly patients with lumbar canal stenosis. In this descriptive, prospective study they showed significant pain reduction for up to 10 months. However, Fukusaki et al (39), in evaluating the effectiveness of interlaminar epidural steroid injections, showed that no beneficial effects on pseudoclaudication associated with spinal canal stenosis were noted as compared with local anesthetic alone or normal saline.

Percutaneous epidural adhesiolysis with hypertonic saline neurolysis has been utilized in patients with refractory low back pain not only secondary to postlumbar laminectomy syndrome, but also secondary to spinal stenosis. It is not known if epidural fibrosis is present in symptomatic patients with spinal stenosis who have not had previous surgical intervention. It is well known that there is obstruction. The clinical effectiveness of percutaneous adhesiolysis was evaluated in two randomized, controlled trials (40, 41) and multiple retrospective evaluations (42-44). These studies have shown adhesiolysis with hypertonic neurolysis to be a clinically effective and cost-effective modality of treatment for refractory low back pain secondary to various causes, including postlumbar laminectomy syndrome. However, the specific role of adhesiolysis with hypertonic saline neurolysis in the management of refractory low back and lower extremity pain secondary to spinal stenosis has not been studied. This case study was undertaken to evaluate the clinical efficacy and cost-effectiveness of this modality of treatment for patients suffering with refractory symptomatology secondary to spinal stenosis nonresponsive to fluoroscopically directed caudal or transforaminal epidural steroid injections.

METHODS

This retrospective evaluation included all patients diagnosed with moderate to severe lumbar canal spinal stenosis who underwent adhesiolysis with hypertonic saline neurolysis over a period of 3 years . From a total of 239 patients undergoing adhesiolysis with hypertonic saline neurolysis between January 1998 and December 2000, all patients with a magnetic resonance imaging (MRI) diagnosis of moderate to severe lumbar spinal stenosis were identified. All charts were reviewed, and patients were contacted by a physician who was not involved in the treatment of these patients. The survey provided a minimum time interval of 1 year between treatment and evaluation and a maximum interval of 3 ½ years.

The evaluation included patient characteristics of age, gender, duration of pain in years, height, weight, body mass index, mode of onset of pain, and history of surgical intervention. All procedures were performed under fluoroscopy in an ambulatory surgery setting in sterile operating rooms by one physician. The procedure was performed

Table 1. *Patient characteristics*

Number of patients		N= 18
Gender	Men	39% (7)
	Women	61% (11)
Age (yrs.)	Mean + SEM	64.1 + 3.79
	> 65	56% (10)
Weight (lbs)	Range	127 - 300
	Mean + SEM	186 + 10.58
Height (inches)	Range	59 - 75
	Mean + SEM	67.3 + 1.06
Mode of onset of pain	Nontraumatic or gradual onset	67% (12)
	Related to an incident	33% (6)
Duration of pain (years)	Range	0.5 - 40
	Mean + SEM	10.5 + 2.85
Previous surgical intervention		56% (10)

by obtaining access to the epidural space with an RK-needle® and Racz®-catheter (EpiMed International Inc., Gloverville, NY). Various drugs injected included contrast of variable amounts, normal saline 0 to 10 mL, lidocaine 2% preservative free 5 mL, 10% sodium chloride solution 6 mL, and betamethasone 6 mg.

Overall quality and duration of pain relief were noted at each follow-up visit. Along with this, psychological status, medication intake, and complications were also monitored. A quality of pain relief of 50% or greater was considered as significant.

Data were recorded on a database using Microsoft® or Access®. The SPSS Version 9.0 statistical package was used to generate the frequency tables, and the chi-squared statistic was used to test the significance between pretreatment and posttreatment variables. Paired t-test was used to compare the pre-and posttreatment overall health status. Results were considered statistically significant if the p value was less than 0.05.

RESULTS

A total of 23 patients had the diagnosis of moderate to severe spinal stenosis, derived from 239 patients undergoing adhesiolysis and hypertonic saline neurolysis. Since five patients were lost to follow-up, they were not included in the analysis; thus, 18 patients were evaluated. Patient characteristics are shown in Table 1. Table 2 illustrates details of multiple procedures, with 100% of the patients undergoing 1 procedure, which decreased to 56% of patients with 4 procedures to 6% for 8 to 10 procedures. Table 3 illustrates comparison of significant relief, which was defined as greater than 50% with each injection, ranging from 4.8 + 0.71 weeks with the first injection to 9.9 + 1.3 with the second injection to 9.7 + 1.09 weeks with the third injection to 24 + 14.75 weeks with the fourth injection.

Table 2. *Details of multiple procedures*

Multiple procedures	Number	Percent
One	18	100%
Two	16	89%
Three	15	83%
Four	10	56%
Five	5	28%
Six	3	17%
Seven	2	11%
Eight	1	6%
Nine	1	6%
Ten	1	6%

Table 3. *Comparison significant relief (>50%) with each injection in weeks*

Injection number	Mean + SEM	Range
One	4.8 + 0.71 (18)	0 - 9
Two	9.9 + 1.30 (16)	3 - 26
Three	9.7 + 1.09 (15)	0 - 17
Four	24.0 + 14.75 (10)	0 - 156
Five	9.8 + 1.24 (5)	6 - 13
Six	10.3 + 1.44 (3)	9 - 13
Seven	11.0 + 2.0 (2)	9 - 13
Eight	13.0 (1)	-
Nine	13.0 (1)	-
Ten	13.0 (1)	-
Average	10.7 + 2.12	0 - 156

The range of relief for various injections was 0 to 156 weeks, whereas average relief was 10.7 + 2.12 weeks.

Fig. 1 depicts cumulative significant relief with one to three injections, which was 89% at 1 month and 3 months, declining to 61% at 6 months. Fig. 2 shows cumulative significant relief with 1 to 10 injections, which was shown to be 89% at 1 month and 3 months, 72% at 6 months, 17% at 12 months, and 11% at 2 years.

Comparison of overall health status before and after the treatment as depicted in Table 4 showed significant improvement with reduction of pain; and improvement of physical health, mental health, and functional status. Psychological status of the patients pre- and posttreatment periods with evaluation of depression, generalized anxiety

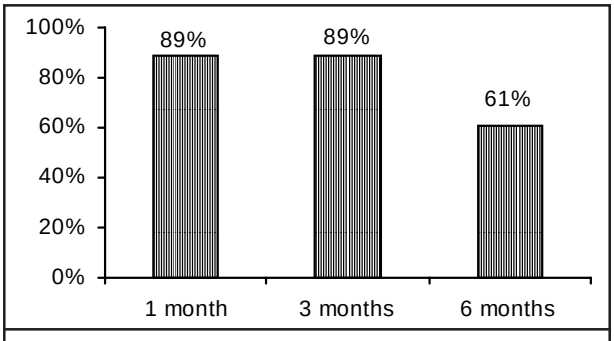

Fig. 1. Cumulative relief (>50%) with 1-3 injections

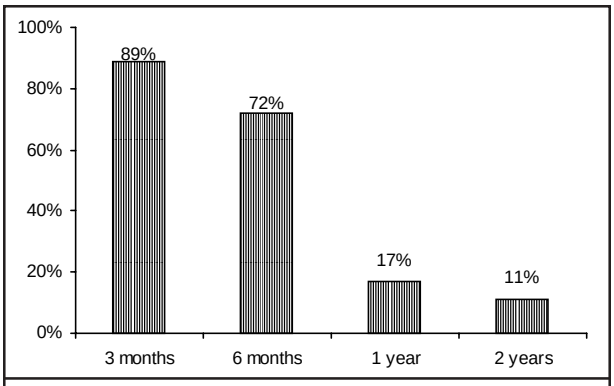

Fig. 2. Cumulative relief (>50%) with 1 to 10 injections

disorder, somatization disorder and symptom magnification, showed significant change with generalized anxiety disorder (Table 5). However, somatization disorder and symptom magnification were seen in 22% of patients prior to treatment and in 0% of the patients after treatment, even though there was no significant difference noted. Similarly, comparison of narcotic intake in pre- and posttreatment periods showed significant decrease in heavy intake of narcotics and in an increase in patients taking no narcotics or taking mild to moderate doses of narcotics, as shown in Table 6.

DISCUSSION

Spinal stenosis is a progressive disease. The term implies nondiscogenic compression of the cauda equina, provoking a symptom complex including low back pain; leg pain; numbness; weakness; and, specifically, pseudoclaudication. It is most commonly seen in men, even though women are involved more commonly with degenerative spondylolisthesis and rheumatoid arthritis. Neurogenic claudication is usually bilateral and is reported as pain or weakness in the muscles of the thighs and calves provoked

Table 4. *Comparison of overall health status pre- and posttreatment periods*

	Pre	Post
Average pain	7.3 + 0.28	3.5* + 0.31
Physical health	4.7 + 0.34	6.4* + 0.26
Mental health	4.6 + 0.33	6.3* + 0.31
Functional status	2.8 + 0.19	5.1* + 0.24

* Indicates significant difference between pre- and posttreatment values

Table 5. *Psychological status of the patients pre- and posttreatment*

	Pre	Post
Depression	67% (12)	44% (8)
Generalized anxiety disorder	61% (11)	22%* (4)
Somatization disorder	22% (4)	0% #
Symptom magnification	22% (4)	0% #

* P=0.041; # P=0.051

by both standing and walking, and relieved within minutes by sitting or lying down (20, 45-48). Patients also often report an accompanying numbness that may be described as a rubbery sensation, or pins and needles (45). In spinal stenosis, typically, the symptoms involve both lower extremities (46); in contrast to other cauda equina diseases, which produce sphincter differences (49). Stenosis seldom produces sphincter disturbances and, when present, sphincter disturbances are very subtle. In true vascular claudication, by contrast, muscle pain is cramping, has no paresthetic quality and is provoked by walking and relieved by standing. Spinal stenosis may be associated with epidural fibrosis, which is an inflammatory reaction of the arachnoid, a fine, nonvascular and elastic tissue enveloping the CNS (50). There are many possible etiologies of epidural fibrosis, including an annular tear, hematoma, infection, surgical trauma, or intrathecal contrast media (51-53). Lumbar epidural fibrosis may be found in the three compartments of the epidural space (50). While dorsal epidural scar tissue is formed by resorption of surgical hematoma (54); ventral epidural scar tissue is formed by ventral defects in the disc (50); lateral epidural scar tissue is formed by lateral disc defects, facet overgrowth and neural foraminal stenosis, etc., (55).

Lane (56) was the first to recognize and describe symptoms of lumbar canal stenosis and its surgical treatment in 1893 in London. His patient had a well-defined cauda equina syndrome and complained of difficult gait and weakness of her back and insecurity of her legs. The descriptions of neurogenic claudication and its relief by forward flexion were presented in 1889 (57) and 1911 (13). Even though congenital narrowing of the spinal canal has long been proposed, various contributing factors to lumbar stenosis include degenerative changes with hypertrophy of facet joints, or ligamentum flavum, degenerative spondylolisthesis, scoliosis, osteophytes; rheumatoid arthritis, and Paget's disease of bone, achondroplasia and fluorosis. Common causes are congenital, degenerative changes, and rheumatoid arthritis. These patients present with few physical findings. Radiographic imaging is an important adjunct to clinical examination for confirming the presence and levels of stenosis (2, 3, 5, 58). The various tests utilized in the diagnosis of spinal canal stenosis normally include myelograms, computed tomography (CT) scans, and MRIs, but also include electromyelography. Myelography is considered as the gold standard for the diagnosis of lumbar canal stenosis and is considered essential specifically when laminectomy is considered (46, 59, 60). However, MRI also has been shown to have an accuracy of 75% to 85% in diagnosis (61). Its false-positive rate for diagnosing stenosis in asymptomatic people varies from 7% to 21% (62, 63). Even though CT scans are considered as the leading diagnostic test, CT results have shown to be positive in 9% of asymptomatic "normal" subjects with spinal stenosis (64). In addition to providing false-positive results, CT scans also have been criticized for technical difficulty and false-negative results (65-68). Grading of stenosis using plain CTs is purely subjective (1).

Table 6. *Comparison of narcotic intake in pre- and pos treatment periods*

	Pre	Post
None	0%	11% (2)
Mild	22% (4)	39% (7)
Moderate	11% (2)	44% (8)
Heavy	67% (12)	6%* (1)

* Indicates significant difference

Intrathecal saline was used to relieve pain in cancer patients by Ventrafridda and Spreafico (68). Multiple studies have been published that applied epidural adhesiolysis with hypertonic saline neurolysis for management of refractory low back and lower extremity pain that fails to respond to other modalities of treatments. The evidence of the effectiveness of percutaneous lysis of adhesions with hypertonic saline neurolysis has been moderate, with both the 1-day and 3-day techniques.

The results of this study show that epidural lysis of adhesions with hypertonic saline neurolysis is effective in managing symptomatic moderate to severe lumbar canal stenosis nonresponsive to fluoroscopically directed epidural steroid injections. This study shows that significant pain relief was seen with each injection, except in two patients who failed to receive significant pain relief. The study shows significant relief at 1 month, 3 months, and 6 months

with one to three injections, with 89% of the patients reporting good relief at 1 and 3 months, and 61% at 6 months. Similarly, with 1 to 10 injections, 89% of patients reported good relief at 1 and 3 months, 72% of the patients at 6 months, 17% at 12 months and 11% at 2 years. Comparison of overall health status pre- and posttreatment shows significant improvement; not only with average pain, but also with physical health, mental health, and functional status. While psychological status with depression showed no significant change, generalized anxiety disorder was significantly reduced after the treatment. Somatization disorder and symptom magnification also were not present in any patients after treatment, yet this failed to reach statistical significance. Narcotic intake was reduced, with 11% of the patients receiving no narcotics posttreatment compared to 0% prior to treatment; and heavy narcotic usage, which was 63% prior to treatment, decreased to 5% posttreatment.

This study may be criticized for its retrospective nature. While retrospective analysis is not considered as valuable as results from randomized, controlled, prospective trials, it should be pointed out that prospective studies also have serious limitations, with small numbers of patients and high costs. Since spinal stenosis is not a common condition treated and only a small number of patients receive adhesiolysis, it would be extremely difficult to conduct a prospective, randomized study for this purpose. An advantage of this retrospective survey is its ability to select from a large database, even though final numbers were fairly small. In an analysis of various investigations, Concato et al (69) found that well-designed observational studies do not systematically overestimate the magnitude of effects of treatments as compared with those in randomized, controlled trials on the same topic, after analysis of numerous reports for five clinical topics. Ioannidis et al (70) also compared the evidence of treatment effects in randomized and nonrandomized studies. They showed very good correlation between the summary parts ratios of randomized and nonrandomized studies. While they showed that heterogenicity was frequent among randomized trials (23%), they also found that it was very frequent among non-randomized studies (41%).

CONCLUSION

Epidural adhesiolysis with hypertonic saline neurolysis is potentially an effective modality of treatment in managing symptomatic moderate to severe lumbar canal stenosis that fails to respond to fluoroscopically directed caudal epidural steroid injections and other modalities of treatment. This technique is effective in providing significant pain relief, improving functional status, and overall psychological status, and reducing narcotic intake. The treatment also improved the patients state of anxiety, somatization, and symptom magnification. Hence, it is concluded that epidural adhesiolysis performed on a single-day basis is safe and probably an effective modality of treatment in managing symptomatic moderate to severe lumbar canal spinal stenosis.

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