



**Letter to the Editor** 

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# **Epidural Stem Cell Injection in Treatment of Symptomatic Spinal Stenosis**

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#### **Letter to the Editor**

Spinal Stenosis (SS) involves narrowing of the spinal canal, which extends through the center of the spinal vertebrae. It occurs in the lumbar and cervical portions of the spine and significantly less often in the thoracic portion. The prevalence of SS in the general population is around 11%-16% according to various studies [1]. A certain number of the patients are born with a small spinal canal (developmental SS), but most cases are the result of acquired SS that is more prevalent in the older population. It can often be caused by osteoarthritis of the spine due to the enlargement of facet joints and the formation of bone spurs. Displacement of one vertebra over the other (spondylolisthesis) is another common cause of SS accounting for up to 1/3 of all cases. Another reason for a narrowing of the spinal canal is the thickening of the ligamentum flavum. One more common cause is the bulging or herniation of the discs [2].

SS may cause pressure on the nerve roots that branch out from the spinal cord, which can result in pain, tingling, numbness, muscle fatigue, and if severe, weakness in the legs [3]. The treatment of SS is a difficult task and still poses a serious challenge to the medical community. Initial symptomatic treatment modalities including NSAIDs, various pain medications, physical therapy, and acupuncture are not very effective. Epidural steroid injections are a popular approach to treatment. While it often provides fast relief, the duration is rather short, and repetitive steroid injections may lead to serious complications. Besides, some studies showed that the efficacies of epidural steroid injections are no better than that of the injection of local anesthetics only [4].

Surgical decompression, such as laminectomy (often combined with fusion), carries the possibility of very serious complications. Additionally, it seems that only about 1/3 of patients are satisfied with the results of the surgery. Minimally invasive surgeries, i.e. PILD, MILD, or interspinous spacer devices, are less prone to major

complications, but are not as effective and can be applied only in certain cases of SS [5]. Stem Cell (SC) based treatment is currently approved by the FDA only as a hematopoietic stem cell transplant for certain types of cancer. Despite this, SC therapy has been used fairly often in the last decade for various conditions of the joints. SC augments the repair of dysfunctional, diseased, or injured tissue [6].

Lately, the medical community shows a very significant interest in using Stem Cells (SC) for the treatment of painful diseases of the spine. A more common use has been intradiscal injections for degenerative disc disease. It has also been used for injections in facet joints for osteoarthritis of the spine. There are a couple of reports of epidural injection of SC for herniated or bulging discs [7]. Despite multiple discussions in the medical community about the use of SC for treatment of SS, we found only one published study where a gel containing mesenchymal SC was placed after surgical discectomy [8].

In our practice we perform a significant number of SC injections for different painful conditions of the spine with very promising results. The hUC-MSC (human umbilical cord tissue derived mesenchymal stem cells) used in our clinic are generated from umbilical cord tissue, and are characterized to have standard MSC phenotype according to the International Society for Cellular Therapy criteria. Briefly, the umbilical cord tissue was obtained after full-term deliveries from healthy human donors and were tested negative for infectious agents to meet the eligibility for tissue donation in compliance with Title 21 of the Code of Federal Regulations (21 CFR) part 1271 in the USA. hUC-MSC were isolated and culture expanded from the eligible umbilical cord tissue in a cGMP compliant facility. hUC-MSC suspension was prepared at a concentration of 2 million cells/mL and has been subject to viability, identity, purity and safety testing (sterility, mycoplasma, endotoxin etc.) before release for use in our patients [9].

In light of our positive outcomes, we performed a retrospective review of the cases with SS that were treated with mesenchymal SC epidural injection in the last 10 months. During this time period we treated 16 patients (10 male and 6 female) varying in age from 32 to 86 years old, nine of whom had cervical SS while seven had lumbar SS. Th degree of the narrowing of the canal diameter varied from 9 mm to 4 mm. In our review, the average diameter of the lumbar spinal canal was 7.7 mm, and the cervical spinal canal average diameter was 6.4 mm. Nine patients have more than one level of SS. All patients received a fluoroscopy-controlled epidural injection of 10 million of hUC-MSC (5 cc), and were followed for 60-120 days after the injection. Only two patients reported relief of less than 50%. The average pain relief was 76%. No complications or serious side-effects were observed [10].

Our report has the largest number of patients with SS that were treated with epidural SC injections in the literature. However, it involves only a small group of subjects for a short period of time in a retrospective observation. Considering the very promising results, we suggest that larger prospective studies are needed to fully assess the efficacy of epidural SC for SS [11].

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