Comparison of the Efficacy of Non-Surgical Treatment by Caudal Epidural Injection versus Oral Prostaglandin E1 Analogue for Management of Lumbar Canal Stenosis

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Abstract

Background: degenerative changes in the spinal canal of the lower back lead to a narrowing condition known as lumbar spinal stenosis (LSS). Lumbar canal stenosis non-surgical therapy options, including caudal epidural injection and oral Prostaglandin E1 analogue, were the focus of this research.

Methods: This randomized clinical trial was conducted on 60 patients with lumbar canal stenosis attending to orthopedic clinic Benha university hospital and Nile Health Insurance Hospital. They were divided into 2 equal groups: Group A treated by caudal epidural injection and Group B treated by oral Prostaglandin E1.

Results: Quality of life (QOL) was shown to be significantly higher in both groups at 3 and 6 months compared to preoperative QOL (P<0.05), and at 6 months compared to QOL at 3 months (P<0.05). At three months, group A had a significantly higher quality of life (QOL) than group B, which was lower than group A [P=0.010]. Both groups showed a significant decrease in VAS from baseline to 3 and 6 months (P 0.05), with the 6-month decrease being even more pronounced than the 3-month decrease. At three months, group B significantly had a lower VAS than group A (P=0.013).

Conclusions: The non-surgical treatment by caudal epidural injection and oral prostaglandin E1 analogue provide a significant improvement in pain, ODI and quality of life during the management of lumbar canal stenosis. Caudal epidural injection provide higher ODI, QOL and higher satisfaction compared to oral prostaglandin E1 analogue, however higher VAS was found in caudal epidural injection.

Keywords: Non-Surgical; Caudal Epidural Injection; Oral; Prostaglandin E1 Analogue; Management; Lumbar Canal Stenosis.

Introduction:

Lumbar spinal stenosis (LSS) is a restriction of the lumbar spinal canal caused by degenerative alterations such spondylolisthesis, facet osteophytes, synovial facet cysts, stretched or herniated disks, and hypertrophy of the ligamentum flavum. Disabilities in male patients aged 50 and up are most commonly caused by LSS [1].

Severe low back pain, pelvis, and limb pain are among the clinical symptoms associated with LSS, which also include fatigue and frailty. Activities that necessitate extension, such as standing or walking, tend to induce pain, which is alleviated by reclining. A typical sign of low back pain is neurogenic claudication, which manifests as weariness and pain after just a short walk [2]. Claudication due to peripheral vascular disease and neurogenic claudication are two different conditions. Since there is a certain amount of space in the spinal canal for neuronal components, flexion helps with neurogenic claudication symptoms [3].

Magnetic resonance imaging (MRI) is the imaging modality of choice for patients with a history and physical evidence suggesting LSS. Spinal canal constriction can be accurately assessed with this noninvasive approach [4]. Physical therapy, lifestyle modifications, oral medication, and epidural injections are among the conservative treatment options for LSS. Operative treatment is provided to patients who experience prolonged and debilitating symptoms or neurologic impairments [5].

A large number of patients undergo epidural injections in the back area. Many pathways go to the epidural area, including those that run caudally, interlaminarly, or transforaminally. When coming from the back, the sacral hiatus is the main landmark. Anatomically, it is the opening at the back of the sacrum where the sacral canal meets the spinal column, usually at the fifth sacral vertebra [6]. There is variation in the volume of corticosteroid solution injected through the sacral hiatus across the respective studies. The epidural space of the final lumbar vertebrae can be filled with a volume of 20 mL, as it seems. The sacral hiatus can be located using any one of a variety of techniques [7]. The nonimage method comprises feeling the depression of the sacral hiatus. The level at which the dura and subarachnoid space terminate is reliably determined by palpating the posterior superior iliac crests. Fluoroscopy and ultrasonography guidance are additional methods for verifying the accurate needle position [8].

As a vasodilator, prostaglandin (PG) E1 enhances blood flow and prevents platelet aggregation. The Prostaglandin E1 analogue was compared to etidolac, an NSAID, in a previous study. After eight weeks, individuals who took the Prostaglandin E1 analogue scored higher on the Standard Form-36 (SF-36) subscales measuring physical function, physical role, physiological pain, vitality, and mental health. Additionally, patients reported additional enhancements in their satisfaction, leg numbness, and walking distance. Nevertheless, the two groups' levels of low back and leg discomfort were not significantly different [9].

LSS may be the result of a multifactorial pathogenesis. When the spinal cord is mechanically compressed, it can lead to a decrease in the blood flow to the brain and other neurological structures. The cytoprotective, antiplatelet, and vasodilator prostaglandin E1 counterpart [10].

The goal of this research was to find out how well prostaglandin E1 analogs taken orally and caudal epidural injections worked as non-surgical treatments for lumbar canal stenosis.

Patients and Methods:

This randomized clinical trial was conducted on 60 patients with lumbar canal stenosis who was treated by non-surgical methods caudal epidural injection versus oral Prostaglandin E1 attending to neurosurgery clinic Benha university hospital .

An informed written consent was obtained from the patient or relatives of the patients. The study was done after approval from the Ethical Committee Benha university Hospitals

This study included male and female patients over the age of 18 who had a history of persistent lower back, buttock, or leg pain along with neurogenic claudication symptoms. The patients had to have central stenosis affecting the level from L3 to S1, a thecal sac less than 80 mm2,

and this condition had to have failed to improve despite long-term nonoperative treatment, including physical therapy and oral medication.

Other potential reasons for discomfort in the lower back and limbs could be hip osteoarthritis, lateral stenosis, facet arthrosis, or listhesis. These factors may influence how the injection reacts. Exclusion criteria included having an allergy to steroids in the past, having a platelet count lower than 75,000/\mL, or having an INR higher than 1.2. **Preoperative assessment:**

A comprehensive history of the patient's complaints, including but not limited to leg paralysis, radicular pain, low back pain, and frigid sensation, was captured. Age, sex, symptoms, pain throughout preoperative period, and medications were among the clinical and demographic variables recorded for every patient. The Oswestry Disability Index (ODI) was used to quantify pain level; higher scores indicated more severe pain. Using the visual analogic score (VAS), secondary outcomes were assessed for low back discomfort. Examinations: MRIs and spine X-rays were conducted in each instance.

Technique:

Group A had peripheral venous catheter insertion and adhered to a standard fasting regimen on the injection day. In the operating room, patients were put in a prone position with a bolster under their sacrum once the monitors were attached. After the necessary cleaning and draping, the sacral hiatus was located by palpation. A further procedure involved injecting 2-3 mL of a 2% lidocaine solution nearby. Following probing of the sacral hiatus' depression, the needle's precise placement was confirmed using an epidurogram, 3 mL of Iohexol, and anteroposterior and lateral fluoroscopic pictures. Inserting the 18-gauge needle at a 45° angle to the epidermis, it was advanced until no resistance was felt. The catheter was connected to an air-filled hypodermic. Air was injected slowly at a rate of approximately 2 mL to verify the accurate placement of the cannula. 80 mg of depo-methylprednisolone injectable into the epidural space. Patients were monitored every two weeks for six weeks.

The Prostaglandin E1 analogue was administered to patients in group B three times daily at a dosage of 5 μg. Efficacy and tolerability of interventions and the evaluation of radicular pain and associated symptoms. Participants who had previously received analgesics, muscle relaxants, anticonvulsants, or methycobalamin were required to undergo a minimum 2-week period of discontinuation prior to commencing the study treatment. For six weeks, the treatment was administered. All forms of pain relief injections and physical therapy were prohibited during the course of the investigation.

Postoperative protocol:

The primary outcome measure in this investigation was the Oswestry Disability Index (ODI) score, which ranged from 0 to 100 points. Indicative of less severe symptoms, lesser scores were used [11]. Patients' degrees of radicular discomfort, chilly sensation in the feet, low back pain (LBP), and limb paralysis were assessed using a visual analog scale (VAS) at each consultation. The VAS was used to measure the level of discomfort in the lower back and leg separately, using a range from 0 (no pain) to 10 (highest pain) [12].

Secondary outcomes included changes in disability, health-related quality of life (QOL) as measured by the SF-36 version 2 score, which ranged from 0 to 100, and subjective satisfaction with each treatment. Patients were monitored every two weeks for approximately six weeks[13].

Statistical analysis:

For the purpose of statistical analysis, we utilized SPSS v26, which was developed by IBM Inc. and is located in Armonk, NY, USA. A two-group comparison was made using an unpaired Student's t-test for the quantitative data, which were given as means and standard deviations (SD). We used statistical tests of analysis of variance (ANOVA) to do repetitive processes looking for variations across many scenarios or periods with the same respondents. Presentation of qualitative variables was done using frequency and percentages (%). When

appropriate, Chi-square or Fisher's exact tests were used to examine the data. Statistical significance was defined as a two-tailed P value less than 0.05.

Results

There was an insignificant difference between both groups regarding age, sex, weigh, height, BMI and duration of surgery. **Table1**

Table 1: Baseline characteristics of the studied groups

		Group A (n=30)	Group B (n=30)	P value
Age (years)		63.57± 7.62	62.43± 7.93	0.575
Sex	**Male**	16 (53%)	19 (63.33%)	0.432
	Female	14 (46.67%)	11 (36.67%)	
Weight (kg)		78.03± 11.56	76.17± 10.13	0.509
Height (min)		1.67± 0.05	1.67± 0.04	1.000
BMI (Kg/m^2)		28.15± 4.85	27.45± 4.3	0.558
Duration of surgery (hrs.)		6.93± 1.55	7.2± 1.42	0.491

Data presented as mean ± SD or frequency (%)., BMI: body mass index

In both groups, VAS was significantly lower at 3 and 6 months compared to baseline (P<0.05) and was significantly lower at 6 months compared to VAS at 3 months (P<0.05). VAS at 3 months was significantly lower in group B compared to group A (P=0.013), with no significant difference between both groups regarding VAS at baseline and after 6 months. **Table 2**

Table 2: Visual analogue scale (VAS) of the studied groups

		Group A (n=30)	Group B (n=30)	P value
VAS	**Baseline**	8.77± 1.33	8.33± 1.09	0.173
	3 months	3.73± 0.91	3.1± 0.99	**0.013***
	6 months	1.93± 0.94	2± 0.98	0.790
	P value within group	**P1<0,001*P2<0,001*, P3<0,001***	**P1<0,001*P2<0,001*, P3<0,001***	

Data presented as mean ± SD., VAS: Visual analogue scale, *: statistically significant different as p value <0.05, P1: p value between baseline and 3 months, P2: p value between baseline and 6 months, P3: p value between 3 and 6 months,

In both groups, ODI was significantly lower at 3 and 6 months compared to preoperative (P<0.05) and was significantly lower at 6 months compared to ODI at 3 months (P<0.05). ODI at 3 months was significantly lower in group A compared to group B (P=0.010), with no significant difference between both groups regarding preoperative ODI and after 6 months. **Table 3**

Table 3: Oswestry Disability Index (ODI) of the studied groups

		Group A (n=30)	Group B (n=30)	P value
ODI	Preoperative	24.8± 3.03	25.43± 3.17	0.432
	3 months	15± 3.06	17.57± 4.34	**0.010***
	6 months	10.93± 3.7	12.33± 4.76	0.177
	P value within group	P1<0,001*P2<0,001*, P3<0,001*	P1<0,001*P2<0,001*, P3<0,001*	

Data presented as mean ± SD., ODI: Oswestry Disability Index, *: statistically significant different as p value <0.05, P1: p value between baseline and 3 months, P2: p value between baseline and 6 months, P3: p value between 3 and 6 months,

In both groups, QOL was significantly increased at 3 and 6 months compared to preoperative QOL (P<0.05) and was significantly increased at 6 months compared to QOL at 3 months (P<0.05). QOL at 3 months was significantly higher in group A compared to group B compared to group A (P=0.010), with no significant difference between both groups at preoperative and at 6 months. **Table 4**

Table 4: Quality of life (QOL) of the studied groups

		Group A (n=30)	Group B (n=30)	P value
QOL	Preoperative	31.27± 6.47	29.57± 6.07	0.298
	3 months	55.17± 10.13	49.5± 5.65	**0.010***
	6 months	74.3± 10.56	69.87± 7.03	0.053
	P value within group	P1<0,001*P2<0,001*, P3<0,001*	P1<0,001*P2<0,001*, P3<0,001*	

Data presented as mean ± SD, QQL: quality of life, *: statistically significant different as p value <0.05, P1: p value between baseline and 3 months, P2: p value between baseline and 6 months, P3: p value between 3 and 6 months,

There was an insignificant difference between both groups regarding satisfaction, despitr being higher in group A. **Table 5**

Table 5: Satisfaction of the studied groups

		Group A (n=30)	Group B (n=30)	P value
Satisfaction	Satisfied	24 (80%)	20 (66.67%)	0.242
	Dissatisfied	6 (20%)	10 (33.33%)	

Data presented as frequency (%).

Discussion

It is estimated that by 2025, more than 64 million seniors would be impacted by LSS, while the exact number of people affected is not yet known. It is not completely clear if LSS is better treated with surgery or nonoperative methods. In spite of this, surgical treatment is linked to a

variety of complications, which can range from 10% to 24%. Epidural injections are often employed to treat LSS, and they have positive long- and short-term results. CEIs were conducted for an extended period of time using anatomical landmarks. In spite of the rarity of CEI complications, Dural puncture and hematoma formation have been documented [14].

Fluoroscopy guidance was implemented to mitigate these complications. Injecting a contrast agent before the procedure produces a picture that looks like a Christmas tree, which helps check that the needle is in the right spot in the epidural space. A major worry in recent years has been radiation exposure, which can affect both patients and healthcare workers. Using ultrasound technology, needle monitoring can be done continuously and in real-time without the need for radiation. In addition, abnormalities in anatomy can be seen by ultrasounds, such a closed sacral hiatus or a sacral canal with an extremely narrow diameter [15].

The results showed that the VAS was significantly lower in both groups between the baseline and the third and sixth months ($P<0.05$), and it was significantly lower between the sixth and third months ($P<0.05$). While there was no statistically significant difference between the two groups at baseline or 6 months, Group B had a significantly lower VAS than Group A after 3 months ($P=0.013$). Not only were the preoperative values significantly higher than the 3 and 6 month ODI values ($P<0.05$), but the 6 month ODI was also significantly lower than the 3 month ODI ($P<0.05$). While neither group's ODI before surgery nor its ODI six months later differed from the other, Group A's ODI at three months was noticeably lower than Group B's ($P=0.010$). When comparing quality of life after 3 and 6 months to quality of life before surgery, both groups demonstrated a significant improvement ($P<0.05$). In comparison to QOL at 3 months, QOL at 6 months showed a significant improvement ($P<0.05$). When comparing the two groups at three months, group A showed far better QOL ($P=0.010$). Between the two groups, however, at six months and before surgery, there was no discernible difference.

Poutoglidou et al [16] whose objective was to evaluate the efficacy of CEIs in the management of LSS. The VAS scores and ODI values of all groups demonstrated a significant improvement both before and one month after the second injection, according to their findings. The beneficial effect of CEIs on LSS is supported by numerous previous publications.

Manchikanti et al [17] reviewed the literature on the efficacy of epidural injections for the management of LSS. The injections given via the caudal route showed success both immediately and over the long term.

Matsudaira et al [18] Findings suggested that limaprost (Prostaglandin E1) would be more effective than etodolac for LSS patients experiencing cauda equina symptoms. The limaprost group achieved significantly better results than the etodolac group on the SF-36 component summaries for physical health (PF, RP, and BP) and mental health (VT and MH). The latter efficacy test found that the limaprost group had better results than the NSAID group in terms of leg numbness, walking distance, patient-reported improvement, and satisfaction. Lumaprost appeared to work better for a subset of patients with less severe symptoms, those who did not experience perineal symptoms such urine disturbance and/or paralysis of the legs when lying down. As one's physical abilities improve due to alleviated symptoms, mental and emotional components undergo a consecutive improvement.

According to the Japanese government, limaprost can be used for "improvement of various ischemic symptoms, such as ulcer, pain, and a feeling of coldness associated with TAO." Among the factors that contributed to its 2001 approval was its claim of helping with "the enhancement of subjective symptoms (pain and numbness of lower legs) and gait ability associated with acquired LSS."

Limaprost was thought by researchers in a phase III study of LSS patients to offer a general improvement from the beginning of the trial to the finish, as well as to increase the drug's overall utility [19]. Overall efficacy included assessed safety problems, while assessment of

overall improvement focused on symptoms (such as leg soreness or paralysis, walking distance).

There are some caveats to this study that need to be considered. The results may not have been as significant because there was no control group to exclude the placebo effect. The small sample size makes it difficult to do a thorough statistical analysis to determine the true difference between the groups. The study's results may be restricted in their generalizability due to the fact that LSS patients exhibit a variety of comorbidities.

Conclusions

The non-surgical treatment by caudal epidural injection and oral prostaglandin E1 analogue provide a significant improvement in pain, ODI and quality of life during the management of lumbar canal stenosis. Caudal epidural injection provide higher ODI, QOL and higher satisfaction compared to oral prostaglandin E1 analogue, however higher VAS was found in caudal epidural injection.

Therefore, larger multicentre cohorts with larger sample size are recommended to validate the current findings.

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