INTRODUCTION

Lumbar spinal stenosis (LSS) is a condition characterized by narrowing of the lumbar spinal canal due to degenerative changes, such as facet osteophytes, synovial facet cysts, spondylolisthesis, bulging or herniated disks, and hypertrophy of the ligamentum flavum. LSS is a common cause of disability in patients, usually men, more than 50 years old.1

Clinical symptoms related to LSS range from fatigue and weakness to severe low back pain and pain to the buttocks and the legs. Pain increases with activities that involve extension, such as walking or standing and is relieved with sitting. A patient with LSS usually complains of discomfort and tiredness after walking a short distance (neurogenic claudication).2 It is important to differentiate neurogenic claudication from claudication caused by peripheral vascular disease. Flexion improves symptoms in neurogenic claudication, as it increases the limited area available in the spinal canal for the neural elements.3

In patients with a history and physical findings consistent with LSS, magnetic resonance imaging (MRI) is the imaging modality of choice. It is a noninvasive technique that can reliably evaluate the presence of narrowing of the spinal canal.4 Conservative treatment modalities for LSS include oral medication, physical therapy, lifestyle modifications,5 and epidural injections. Operative treatment is reserved for patients with persistent, debilitating symptoms or neurologic deficits.6

Lumbar epidural injections are very popular in everyday clinical practice. The epidural space is accessible by caudal, inter-laminar, or transforaminal route.7 For the caudal approach, the main anatomical landmark is the sacral hiatus, which corresponds to the posterior caudal opening at the end of the sacral canal, usually located at the fifth sacral vertebra. The volume of corticosteroid solution injected through the sacral hiatus varies among the studies. It appears that a volume of 20 mL is sufficient to fill the epidural space up the last lumbar vertebrae.8 There are several methods available for the identification of the sacral hiatus. The nonimage technique involves palpation of the depression of the sacral hiatus. Palpation of the posterior superior iliac crests is a reliable method for identifying the level where the termination of the dura and the subarachnoid space occurs. Other methods to confirm proper needle position include fluoroscopy and ultrasonography guidance.9

The purpose of this study is to compare the efficacy of caudal epidural injections (CEIs) performed with a...
nonimage, ultrasonography-, or fluoroscopy-guided technique in patients suffering from LSS.

**METHODS**

**Study Design and Setting**

The prospective, randomized study was conducted in a 1-year period (December 2018 to January 2020). The study protocol was approved by the Institutional Review Board (IRB approval code: 992/30-11-2018) and informed written consent was taken from all the patients.

**Inclusion and Exclusion Criteria**

The study included patients of both genders, older than 18 years old, with a history of chronic low back, buttock, or leg pain and symptoms of neurogenic claudication that failed to improve despite prolonged nonoperative treatment, including oral medication and physical therapy. Only patients with central stenosis, affecting L3 to S1 level, with a thecal sac less than 80 mm², confirmed by MRI, were included in the study. Patients with possible alternative sources for low back pain or extremity pain that could affect the response to an injection, such as hip osteoarthritis, lateral
stenosis, facet arthrosis, and listhesis were identified and excluded from the study. Patients with a history of allergy to steroids and with an absolute platelet count below 75,000 per cubic millimeter or an International Normalized Ratio (INR) higher than 1.2 were also excluded.

**Allocation to Groups**

The patients were randomly allocated to 1 of the 3 groups according to a computer-generated random table. The patients in group N (n = 15) underwent CEI with the nonimage technique, the patients in group U (n = 15) received injection using ultrasonography guidance, and patients in group F (n = 15) using fluoroscopy guidance (Fig. 1). All the injections were performed by the same orthopaedic surgeon.

Patients were admitted to the hospital 1 day prior to the day the injection was due. A detailed history was taken and a neurologic examination was performed to all patients. Laboratory tests, including a complete blood count and a coagulation panel, were obtained. The day that the injection was scheduled, a peripheral venous catheter was placed and a standard fasting protocol was followed. In the operating room, after attaching monitors, patients were placed in prone position with pelvis supported by a pillow. After proper disinfection and draping, sacral hiatus was identified by palpation and local infiltration with 2-3 mL of 2% lidocaine was done.

In group N, after palpation of the depression of the sacral hiatus, an 18-gauge needle was inserted at an angle of 45° to the skin and was advanced until a loss of resistance was felt. A syringe filled with air was attached to the needle. Slow injection of approximately 2 mL of air was performed to confirm proper needle placement. In group U, the GE Logiq 200 PRO ultrasound machine was used. A linear transducer (linear probe 9 MHz) was placed longitudinally to the vertebral axis in order to visualize the sacral hiatus (Fig. 2). In group F, proper position of the needle was confirmed with anteroposterior and lateral fluoroscopic images and with an epidurogram using 3 mL of Iohexol (Fig. 3). The solution used for caudal blockade consisted of 12 mg betamethasone and 4 mg ropivacaine dissolved in 20 mL normal saline. Patients were monitored for 4 h after the CEI for any possible complication and were discharged the same day. After a 30-day interval, they received a second injection with the same technique.

**Type of Outcome Measures**

This study compared the 3 techniques regarding clinical effectiveness (reduction of Visual Analogue Scale [VAS] score) and the functional improvement (reduction of Oswestry Disability Index [ODI]). The VAS score is a pain-rating scale, based on self-reported measures of symptoms, that ranges from 0, which represents “no pain,” to 10, which corresponds to the “worst pain.” The ODI value is an index derived from the Oswestry Low Back Pain Questionnaire that is considered the gold standard of low back functional outcome tools. The questionnaire is designed to give
information as to how low back or leg pain affects the activities of daily living. Each question is scored on a scale of 0 to 5, with 0 indicating the least amount of disability and 5 the most severe disability. The scores are then summed and multiplied by 2 to obtain the index. In the present study, VAS scores and ODI values were recorded before the CEIs and 1 month after the second injection. The inter-views and the evaluation of the patients before and after the procedures were performed by an independent researcher. Also, the duration of each procedure was recorded by the monitor attached to the patient. The procedure times for each group were recorded and compared.

Statistics

The primary analysis of power was the pain relief. A minimal difference of 0.9 in VAS score was set based on previous studies. Data from a previous study indicated that patients typically reported a change of 2.957 points (standard deviation [SD] = 1.698) on the VAS score at 1 month post steroid injections. With an SD of the VAS of 1.698 and a mean difference of 0.9, an effect size of 0.53 was calculated. With an alpha value of 0.05 and a power of study at 80%, a sample size of 13 for each group was obtained. Taking into account a 20% loss in follow-up, 15 patients per group were included. Continuous variables were given as mean ± SD and nominal variables were expressed as number of cases. The Shapiro–Wilks test was used to determine whether data were normally distributed. Analysis of variance and Tukey post hoc test were used to compare mean VAS scores and ODI values among the groups. Paired samples t-tests were used for intragroup comparisons, pre- and post-treatment. A p-value of < 0.05 was considered to be statistically significant. The data were entered into an Excel sheet and were analyzed using Jamovi software version 1.1.9.

RESULTS

This monocentric study evaluated 45 patients, randomly allocated to 3 groups. All patients completed their treatment and their follow-up interviews. The mean age of the patients in the N group was 72.4 ± 10.4, in the U group 72.8 ± 8.03, and in the F group 69.1 ± 11.2 years old, and there were no significant differences (F[2, 27.38] = 0.55, p = 0.581). As far as the sex is concerned, there were no statistically significant differences between the groups (χ² = 4.82, df = 2, p = 0.09). Baseline VAS scores had no significant differences among the groups (F[2, 42] = 0.01, p = 0.987), while in the pre-injection ODI values there was a statistically significant overall difference (F[2, 42] = 4.11, p = 0.022), with the U group exhibiting the significantly higher score compared to N group (p = 0.035) (Table 1).

Mean VAS scores and mean ODI values improved 1 month after the injections compared to baseline values (Fig. 4). All the patients had significant pain relief and reported functional improvement in their daily activities. In particular, there was a statistically significant difference in the VAS score pre- and postinjection in all the groups (N group t[14] = 5.27, p < 0.001; U group t[14] = 4, p < 0.001; and F group t[14] = 5.99, p < 0.001). A statistically significant improvement in the ODI values was also observed.
in all the groups (N group t[14] = 4.32, p < 0.001; U group t[14] = 4.51, p < 0.001; and F group t[14] = 4.22, p < 0.001). However, the intergroup difference in mean VAS score and ODI value before and after CEIs was not statistically significant (F[2, 42] = 0.18, p = 0.836 and F[2, 42] = 0.84, p = 0.438).

The mean time of the procedure was 14.65 ± 2.43 for the N group, 15.78 ± 1.26 for the U group, and 16.68 ± 2.05 for the F group. Although, the mean duration of the procedure was higher in the F group, the differences were not statistically significant (F[2, 25.8] = 3, p = 0.067).

With regard to complications, 1 patient from the N group reported a transient headache and 1 patient from the F group experienced facial flushing. No major complications occurred.

DISCUSSION

The exact prevalence of LSS is unknown; however, it is estimated that more than 64 million elderly adults will be affected by the year 2025.12 It is not clear whether surgical or nonoperative treatment is more effective in the treatment of LSS.13 Nevertheless, surgical treatment is associated with several complications, ranging from 10% to 24%.6 Epidural injections are widely used for the treatment of LSS with good short- and long-term outcomes.14

For many years CEIs were performed utilizing anatomical landmarks. Although the complications of CEIs are rare, hematoma formation and dural puncture have been observed.15 Fluoroscopy guidance was introduced to eliminate those complications. Furthermore, prior injection of a contrast agent produces a Christmas tree-like image and confirms proper needle placement in the epidural space.16 Radiation exposure of both the patient and the personnel is a major concern lately.17 Ultrasonography offers real-time and continuous monitoring of the needle while being radiation free.18 Additionally, anatomical variations, such as a closed sacral hiatus or a very small diameter of the sacral canal, can be detected using an ultrasound.19

In the present study, we tried to detect the success rate of CEIs in terms of pain relief and functional improvement in patients suffering from LSS using 3 different techniques, the classic nonimage technique, by palpation of proper landmarks, and the ultrasonography-guided and fluoroscopy-guided techniques. It must be pointed out that all the injections were administered by the same orthopedic surgeon who is very familiar with the procedure. Statistical analysis of VAS scores and ODI values before and 1 month after the second injection showed a significant improvement in all the groups. Multiple previous publications support the

Figure 4. (a and b) Functional improvement after caudal epidural injections. (a) VAS score, (b) ODI value. Each column represents a mean (standard deviation) (n = 15). VAS = Visual Analogue Scale; ODI = Oswestry Disability Index; N = nonimage; U = ultrasonography; F = fluoroscopy.
In conclusion, CEI is a safe and effective modality for the management of LSS. It provides excellent short-term outcomes. Nonimage, ultrasonography-guided, and fluoroscopy-guided CEIs are similarly effective in terms of pain relief and functional improvement.

Disclosure Statement
The authors have no conflicts of interest to disclose.

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Author Contributions
Frideriki Poutoglidou, MD, performed the CEIs, collected the data, and wrote the manuscript. Dimitrios Metaxiotis, MD, PhD, conceived the original idea and designed the randomized clinical trial. Angelo V Vasiliadis, MD, PhD, participated in the study design and acquisition and analysis of the data. Dimitrios Avlonos, MD, contributed to the interpretation of the results. Anastasios Mpeletsiotis, MD, PhD, supervised the project. All authors provided critical feedback and helped shape the final manuscript.

References

Table 1. General characteristics of the patients

<table>
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<tr>
<th>Parameters</th>
<th>Group N</th>
<th>Group U</th>
<th>Group F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>72.4 ± 10.4</td>
<td>72.8 ± 6.03</td>
<td>69.1 ± 11.2</td>
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<tr>
<td>Sex (male-female)</td>
<td>10.5</td>
<td>4.11</td>
<td>7.8</td>
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<td>VAS preinjection</td>
<td>5.4 ± 2.38</td>
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<td>5.4 ± 2.61</td>
<td>0.987</td>
</tr>
<tr>
<td>ODI preinjection</td>
<td>36.5 ± 11.7</td>
<td>50.2 ± 19</td>
<td>37.6 ± 11.4</td>
<td>0.022</td>
</tr>
</tbody>
</table>

VAS = Visual Analogue Scale; ODI = Oswestry Disability Index; N = nonimage; U = ultrasonography; F = fluoroscopy. The data are presented as mean±/ standard deviation.

beneficial effect of CEIs for LSS. Manchikanti et al conducted a systematic review to assess the outcomes of epidural injections for the treatment of LSS. A short- and long-term efficacy was shown for the injections administered by the caudal route.

Inter-group comparisons showed that there was no statistically significant difference in the VAS score and ODI value improvement among the groups. Although imaging modalities facilitate the procedure, 1 month after the injections, patients from the nonimage group had similar improvement. Also, there were no significant differences between the U and F groups. The time of the procedure was slightly higher in the F group, followed by the U group. The use of imaging modalities increased the overall procedure time, but not in a statistically significant manner. An orthopedic surgeon who is familiar with the procedure, could opt to use the nonimage technique, since it is faster. On the other hand, ultrasonography and fluoroscopy provide a confirmation of the correct needle placement in the epidural space. As far as the complications are concerned, dural pricking, transient headache, hematoma formation, infection, facial flushing, and vasovagal reaction have been reported. In the present study, 1 patient from the nonimage group reported a transient headache and a patient from the fluoroscopy group experienced facial flushing. There were no major complications regardless of the injection method.

The present study had some limitations. First, all the CEIs were conducted by the same physician, who is very familiar with the procedure, limiting the generalization of the results. Secondly, the use of analgesics before or after the CEIs was not recorded. It is possible that analgesic use might have influenced the VAS scores and ODI values. Finally, although study subjects were selected based on their symptoms and very specific MRI findings, indicative of LSS, and patients with other degenerative diseases were excluded, there could have been some heterogeneity among them. No anatomical variations were found among the 45 patients included in the study. The presence of anatomical variations could have altered the results. Additional studies may be required to improve and confirm the results of the present study.


