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Efficacy and Tolerance of Caudal Epidural Injection. A Retrospective Study of 201 Patients

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Abstract

Objective: Sacrococcygeal epidural (SE) injection is indicated for the relief of lumbo sciatic pain, but is not regularly performed in daily practice. The objective of this study was to evaluate the efficacy and tolerance of SE injections.

Design: Retrospective study with a questionnaire sent to patients who underwent the procedure between January 2007 and September 2012.

Results: A total of 558 patients (202 men: 36%) underwent the procedure. 57 were excluded from the study (28 for an incorrect postal address, 15 because they had died, 7 because no injection was administered, 5 for cognitive impairment and 2 who refused to respond).

Among the 201 respondents (201/501: 40.1%), 53% (n=107) reported an improvement in pain, 64% in less than 5 days after the procedure (68/107), with pain relief lasting for over 6 months in 63% (65/104). 87 patients reported an improvement in walking (87/192: 45%) and in quality of life. Considering that all non-responders had an injection failure, we obtained 19% of success in our sample of 558 patients. The injection was well tolerated by 85% of patients (162/190). 37% of patients (72/194) experienced pain during the procedure, with a mean VAS pain score of 6.8 ± 2.5 mm. 53% (102/191) would agree to have a new injection.

Conclusion: Sacrococcygeal epidural injection provided pain relief in more than half of patients and the procedure was well tolerated. This procedure merits a more prominent place in the management of symptomatic lumbar canal stenosis.

Keywords: Epidural fibrosis; Lumbo sciatic pain; Sciatica

Introduction

Caudal sacrococcygeal epidural (SE) Injection was the first epidural injection technique. Initially described in 1901, it did not come into widespread practice until 1925, when Viner used it to treat sciatica [1-3]. It is indicated in rheumatology for the treatment of sciatic pain due to constitutional or acquired lumbar canal stenosis, mainly caused by arthritis or postoperative epidural fibrosis.

Several studies have reported that the technique is effective, although results are discordant. Ciocon described positive short and long term outcomes, with pain relief lasting from 4 to 10 months [4]. Revel found significant short term pain relief in 49% of treated patients compared to 19% of controls, but no long term effect on chronic nerve root pain from postoperative lumbar spinal fibrosis [5]. Helsa described short term success and a long term effect of three SE injections of bupivacaine and depo-methylprednisolone for chronic lower back pain and sciatica in 69 patients, 36 of whom had undergone disc hernia surgery [6]. Conversely, Meaded did not find any short or long term improvement in 47 patients with lower back pain following posterior lumbar laminectomy who received three large volume SE injections (20 mL saline and 125 mg prednisolone acetate) once monthly for three months [7].

As for all injections, the adverse effects include a risk of infection, particularly because the injection site is in the gluteal fold. However, a review of the literature found only one case of infection [8]. Several authors have reported a 6-9% rate of venous injection of contrast agent during fluoroscopic guidance [9-11], causing flush, allergic reactions, vagal malaise or Tachon's syndrome [12]. There are also adverse effects linked to the use of corticosteroids, the most common being decompensation of diabetes, hot flushes, and sleep disturbance.

Despite evidence in the literature supporting the efficacy of the procedure, its actual practice rates vary, probably due to uncertainty as to its efficacy in a given patient and particularly to concern about adverse effects, and also because the ventral decubitus position is uncomfortable for the patient. Furthermore, a recent literature review recommended avoiding this type of injection, because of a lack of clinical evidence for the success rates of epidural injection in the management of lower back pain and sciatica [13].

The aim of this study was to evaluate patients' views on the efficacy and tolerance of caudal sacrococcygeal epidural injections via a questionnaire sent to all patients who underwent this procedure for lumbar sciatica between January 2007 and September 2012 in the Clermont-Ferrand Hospital Rheumatology Department.

Materials and Methods

Ethics committee

This study received a favorable opinion from the Ethics Committee of the Rhône-Alpes Auvergne interregional clinical investigation centers on 20-Sept-2012. All the patients were informed that information concerning this study would be submitted for publication.

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Inclusion of participants

All patients who received a SE injection for the treatment of lumbar sciatica between January 2007 and September 2012 were included. The medical procedure coding system from the I2000 program ("AFLB007") was used to obtain the patient list and contact details of patients who had undergone the procedure performed as an outpatient in the day hospital or whilst conventionally hospitalized in the Gabriel Montpied University Hospital Rheumatology Department in Clermont-Ferrand. We therefore obtained the name of each patients and their corresponding address to send them the questionnaire and the consent form.

Patients who received more than one injection during the period 2007-2012 were only included once. They were asked to give the reasons for having undergone the procedure more than once (previous injections were effective, a new attempt after a failure, spinal surgery contraindicated or refused).

Technical procedure

Patients were positioned in the ventral decubitus position with their head between their arms, with a pillow under their hips to better identify the sacral foramen. After thorough disinfection, a mixture of 125 mg (5 mL) of prednisolone acetate (Hydrocortancyl®) and 25-30 mL of saline was injected into the sacral foramen with a needle 21 G and 50 mm length. No ultrasonographic or radiographic guidance was used. Our appropriate technique (without sonographic guidance) that would allow a higher likelihood to inject fluids into the lumbar spinal canal was to insert the needle into the sacral and lumbar canal via insertion of the needle midline between the 2 cornua sacralia (with special internal rotated positioning of the thighs with heels outward rotated). Once in the canal the needle can be pushed forward for about 5 cm and then inject. A local anesthetic such as ropivacaine (Naropeine®) could be previously injected subcutaneously in advance, although this anesthetic was not routinely used before 2011. After the injection, the patient had to remain horizontal for approximately an hour to monitor for any signs of intolerance.

This procedure is taught and performed in the Clermont-Ferrand Hospital Rheumatology Department. All injections were administered using this method, with some variations, such as differences in the volume injected due to the operator's usual practice and the patient's tolerance. We only used an anatomical landmark without ultrasound or radiological guidance to assess the exact site for the injection.

Questionnaire

A questionnaire was sent to the patient's home address by post, for completion by the patient him/herself and to be returned in the enclosed postage-paid envelope. The following data were collected: Patient name. If the patient wished to remain anonymous, this section could be left blank. The date of birth allowed the patient's current age and the age at the time of the procedure to be calculated.

Efficacy of the injection, with the aid of numeric scales assessing pain, walking speed and quality of life. Success of the SE injection was defined by a "yes" answer to the question "Did the injection relieve/improve your pain?"

The visual analog scale (VAS scale) was used to assess the effectiveness of the injection on pain, walking speed and quality of life separately. The degree of improvement was ranked on a scale from 0 (no improvement) to 10 (total relief). The VAS scale was in millimeters (mm).

Tolerance of the procedure: the patient was asked to report any pain during the procedure and any adverse effects experienced after the procedure. The procedure was well tolerated if the patient answered "yes" to the question "Did you tolerate the procedure well?" The pain during the procedure was assessed using a VAS scale in mm and ranked from 0 (no pain) to 10 (maximal pain). Patients who took anticoagulant drugs were also included. Aspirin with a daily dose less than 100 mg/day was continued with no particular precaution. On the contrary, all the patients with other anticoagulants drugs were hospitalized in Rheumatology department. Injection was made after stopping anticoagulant treatments and patients were monitored the three days after.

The patient was also asked if he/she would agree to a new injection if asked by the General Practitioner or Rheumatologist. The patient could give the reason for a yes or no answer: previous injections were effective, previous injections failed or were poorly tolerated.

Statistical analysis

Data were expressed as the numbers of patients and percentages for qualitative variables and mean and standard deviation values for quantitative variables. For percentages, the denominator corresponded to the number of available data, i.e. to the total number of respondents minus missing data. The Student t test was used to compare the mean VAS pain score between groups. A two-tailed probability of $p<0.05$ was considered to be statistically significant. The statistical analysis was performed on R software, version 2.14.2.

Results

Response to the questionnaire

A total of 558 questionnaires were sent out. Most of the potential participants were women (n=356: 63.8%) and average age at the time of the procedure was 69.8 ± 13.4 years old. 157 questionnaires concerned procedures done in 2007, 129 in 2008, 59 in 2009, 59 in 2010, 63 in 2011 and 90 in 2012. The date of the procedure was unknown for one person. Fifty-seven patients were excluded (28 due to an incorrect postal address, 15 because they had died, 7 because no injection was actually given, and inclusion was due to errors in the computer coding system, 5 for inability to respond due to cognitive impairment, and 2 who refused) (Figure 1). Of the 501 potential patients, we obtained a total of 201 respondents (201/501: 40.1%).

Characteristics of respondents

Out of 201 respondents, eight respondents wished to remain anonymous and their patient characteristics are therefore not available. The respondents were mainly women (126/193: 65.3%) with an average age at the time of the procedure of 69.8 ± 12.5 years old and a current average age of 73.2 ± 12.4 years old. Thirty-five injections were performed in 2007, 31 in 2008, 25 in 2009, 24 in 2010, 36 in 2011 and 42 in 2012. 118 respondents had only one injection, 42 had two, 23 had three and 11 had more than three. The main reasons for having more than one injection were efficacy of the previous ones (n=29), failure of a previous attempt (n=28), medical contra-indication (n=8) or patient refusal for spinal surgery (n=20).

Efficacy of the injection

On pain: Of the 201 respondents, 53% (n=107) reported an improvement in pain, with most patients experiencing pain reduction within 5 days after the injection (68/107: 64%), which lasted for more than 6 months in 63% (65/104), and for more than one year in 36.5% (38/104). Three patients reported an improvement in pain but

did not complete the subsequent questions relating to details of this improvement. Of the 107 patients who reported pain relief, improvement lasted no more than one month in 22 patients. Fourteen patients had immediate improvement and twenty-eight patients improved within 3 days, with the improvement lasting for 6 months (n=6), 1 year (n=2) or longer (n=14). The percentage pain score improvement rate remained stable over time. The highest success rate was found for 2008 (64.5%) and the lowest for 2007 (42.8%). Improvement was found to be more common in men (40/66: 60%) than in women (64/126: 50.8%). An age of between 60 and 70 years old at diagnosis was associated with a lower success rate (31.4%), and there were no differences in the improvement rates in other age groups, notably >80 years old (Table 1).

On other features: Walking improved in 45% of patients (87/192, with a mean improvement on the numeric scale of 6.3 ± 2.1 mm. Seventy-two patients reported an increase in walking distance which was moderate in 33, considerable for 21 and complete improvement in 4. Of the 87 patients (87/190: 45%) who reported an improvement in quality of life, 40 described considerable or complete improvement.

Tolerance

The procedure was well tolerated by 162 patients (162/190: 85%). Hot flushes occurred in 29 patients, hypertensive episodes in 8 and malaise in 5 patients. Twenty-seven patients (27/201: 13.4%) had diabetes, of whom 6 patients experienced an increase in blood glucose requiring introduction of insulin therapy in 2 patients and increased insulin doses in 1 patient.

Pain during the procedure was reported by 72 patients (72/194: 37%); the mean VAS pain score was 6.8 ± 2.5 mm. The procedure pain score did not differ for the 39 patients in whom the injection was effective (6.86 ± 2.32 mm) and the 33 patients in whom it was ineffective (6.75 ± 2.78 mm) (p=0.86). From 2011 onwards ropivacaine, a local anesthetic, was used routinely whereas prior to this, it was only given occasionally. Before 2011, procedure pain was reported by 43/115 patients (37%) compared to 25/78 (32%) after 2011, with a slightly higher but not significantly different pain score (7.07 ± 2.42 mm before 2011 compared to 6.39 ± 2.84 mm after 2011; p=0.36).

122 patients did not experience pain during the injection and had a mean procedure pain score of 1.58 ± 1.68 mm. Forty-nine of these injections were performed after 2011.

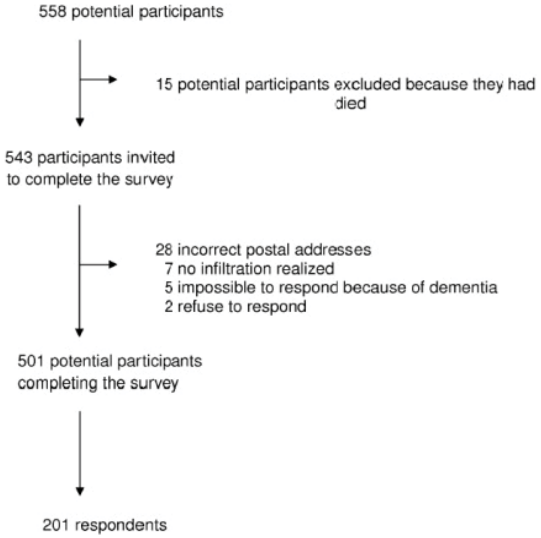

Figure 1: Flow chart of participants in the study.

Characteristics	Percentage of patients reporting improvement	Mean improvement in improved patients
Year of procedure		
2012	25/42 (59.5 %)	6.17 ± 1.66
2011	18/36 (50.0 %)	7.00 ± 1.88
2010	15/24 (62.5 %)	6.00 ± 3.18
2009	12/25 (48.0 %)	6.50 ± 2.11
2008	20/31 (64.5 %)	6.00 ± 2.45
2007	15/35 (42.8 %)	6.31 ± 2.18
Gender		
Female	64/126 (50.8 %)	6.52 ± 2.38
Male	40/66 (60.0 %)	6.08 ± 1.83
Age at procedure		
> 80 years old	24/42 (31.0 %)	5.55 ± 2.32
70-80 years old	35/70 (50.0 %)	6.16 ± 2.50
60-70 years old	22/70 (31.4 %)	7.09 ± 2.73
< 60 years old	24/40 (58.5 %)	6.58 ± 1.71
Values expressed as mean ± standard deviation. Mean improvement in pain is reported by the patient using a numeric scale from 0 (no improvement) to 10 (total improvement).		

Table 1: Percentage of respondents reporting an improvement in pain according to year of procedure, age at time of procedure, and gender.

53% of the patients (102/191) would agree to have another injection if recommended by their Rheumatologist: 55 without hesitation, 21 with apprehension and 27 only because it was necessary. The 89 patients who would not want another injection cited lack of efficacy (n=65) and procedure pain (n=26) as their main reasons.

Discussion

Patients who received a SE injection between 2007 and September 2012 were invited to answer a questionnaire on the efficacy and tolerance of the procedure. The success rate for pain relief was 53% for the 201 respondents. Tolerance was good for 85% of the respondents and more than half would agree to another injection if recommended by their Doctor or Rheumatologist, including 25% who would accept without hesitation.

Pain relief was achieved in the short term but also, and more importantly, over the long term. Of the 107 patients who reported improvement, only 22 improved for one month or less, whereas all of the others reported improvement for at least 3 months and 38 for over 1 year. These findings are consistent with those of Ciocon [4] and Helsa et al. [6], who reported long term improvement after a series of three SE injections. In our study, improvement lasted for at least 6 months in 36 patients and for more than 1 year in 28 patients among the 60 patients who received a single injection.

The success rate for pain relief was generally stable over the period 2007 to 2012, although curiously was lower in the 60-70 year-old age group than in the other age groups (31% compared to 50-59%). We have no clear explanation for this. There were slightly more women in this age group (77% compared to 71% for 70-80 years old, 69% for >80 years old and 59% for <60 years old), and our findings indicated a higher success rate in men than in women. Another, possibly more convincing explanation, can be found in the study by Manchikanti et al. showing that SE was most effective in a specific group of patients, those with little lower back pain and primarily leg pain [14]. We cannot rule out the possibility that patients in the 60-70 year old age group had lower back pain than in the other age groups, although unfortunately, we could not collect these data in this study.

The VAS score for pain during the procedure was >6 mm in 72

patients. Surprisingly, the routine use of ropivacaine since 2011 did not lead to a marked reduction in pain scores, which fell from 7.1 to 6.4 mm, a difference which was not statistically significant. Likewise, we did not find a large reduction in the percentage of patients reporting pain during the procedure before and after 2011 (32% compared to 37%). Conversely, from our perspective as interventionists, ropivacaine made the procedure easier, faster and more comfortable. This difference is due to the purely subjective nature of pain assessment. Nevertheless, this was a retrospective study asking patients to assess the pain they felt during a procedure which could have been performed up to 5 years prior to the assessment. Somanchi et al. point out that ropivacaine should be used with caution following a case of paraplegia during a SCH injection [15], but no neurological complications were reported from our 201 respondents in the questionnaire. The pain occurring during the procedure might be explained by the fact that it was performed using only clinical landmarks. Several studies describe the advantage of radioscopic or ultrasound guidance for correct positioning of the needle [16-20]. We speculate that this may also lead to higher success rates. Lee et al. reported excellent short term and good long term responses in 216 patients who received fluoroscopy-guided injections [21].

Six of the 27 patients with diabetes reported an increase in their blood glucose levels requiring introduction of insulin therapy in 2 cases and an increased insulin dose in 1 case. These findings are in line with those of Zufferey et al. who found no increase in blood glucose levels after an epidural steroid injection in 5 diabetic patients [22]. On the other hand, the studies by Even and Gonzales [23,24] tend to suggest caution as hyperglycemia occurred after the epidural injection in 30 and 12 diabetic patients in these studies, respectively. Although not strictly required, we feel it would be prudent to closely monitor blood glucose levels in diabetic patients receiving SCH injections and to perform the procedure in the hospital if blood glucose monitoring cannot be done at home.

Our study has several limitations. Firstly, it is based on a retrospective questionnaire asking patients details about a procedure that could have been performed up to 5 years earlier. There is also no control group available in this kind of retrospective study. This can reduce the reliability of data such as the severity of pain experienced during the procedure at the time. A prospective study with pain assessment immediately after the procedure would provide a better evaluation of the advantages of the use of ropivacaine.

The data are subjective, which can also be considered a limitation due to their limited robustness. Furthermore, pain and quality of life assessments, which are clinically relevant parameters in lumbar radiculopathies, are by definition subjective. A new cohort study with a prospective assessment of pain and walking speed with more objective measurements, such as the 6-minute walking test, would provide a better assessment of the efficacy of SE injections.

The response rate to the 501 questionnaires was 40%, which corresponded to a panel of 200 patients. Data are missing from 300 patients who underwent the procedure. We cannot exclude the possibility that these patients did not respond because their injection provided no pain relief. The 53% improvement in pain after caudal epidural injection may therefore be overestimated. However, using the worst case scenario (that non-respondents had no improvement after the injection) the success rate would still be 21% (107/501).

Another limitation is that the interventionist is not known. In our department, the procedure is performed by both senior Rheumatologists and Interns, and we cannot exclude the role of operator experience, particularly as this procedure is highly technical and requires manual dexterity. It is possible that less experienced operators might have achieved a lower pain relief success rate. However, this should be considered in light of a report by Price showing that the success rate of the injection decreased with operator experience (OR 0.34; 95% 0.17-0.72) [25]. This implies that experience is needed to perform the procedure but is not in itself sufficient to guarantee success and that the procedure needs to be performed regularly in order to achieve a high success rate. On the other hand, Issa et al. found that patient satisfaction differed depending on the operator: patients reported a poor experience when Residents performed the injection as compared to Senior Attending Physicians, although both patient groups were satisfied with the procedure [26]. Another limitation of the procedure is the lack of radiological or ultrasound guidance and therefore we did not assess the accuracy of the site of the injection. We cannot exclude the possibility that the SE injection was less effective than it could have been had we used imaging guidance. Such guidance could have enabled us to achieve even better results.

This original study emphasizes the benefits of caudal epidural injection. This injection improved pain in over half of the patients and was well tolerated. This procedure should be more widely used in the treatment of symptomatic lumbar canal stenosis but also of lumbar disc herniation, especially in light of recent findings demonstrating favorable cost-effectiveness and a good cost-utility ratio [27].

Conflict of Interest

There are no current external funding sources for this study and no financial support or conflict of interest for all authors.

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Author Contributions

Injections: SM, MC, MV, ZT, AT

Study conception and design: SM, JJD, MS

Data collection: SM

Data analysis: SM

Manuscript writing: SM, MC, MV, ZT, AT, SMG, JJD, MS

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