Egyptian Journal of Anaesthesia

ISSN: (Print) 1110-1849 (Online) Journal homepage: https://www.tandfonline.com/loi/teja20

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To cite this article: Ahmed M. Aref, Maher Fawzy, Waleed Hamimy & Mae Shawky (2011) The effectiveness of volume versus concentration of the epidural steroid injections through transforaminal approach, Egyptian Journal of Anaesthesia, 27:1, 61-65, DOI: 10.1016/j.egja.2011.01.004

To link to this article: https://doi.org/10.1016/j.egja.2011.01.004

Published online: 17 May 2019.

Egyptian Journal of Anaesthesia (2011) **27**, 61–65

Egyptian Society of Anesthesiologists

Egyptian Journal of Anaesthesia

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Research Article

The effectiveness of volume versus concentration of the epidural steroid injections through transforaminal approach

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Received 2 December 2010; revised 15 January 2011; accepted 16 January 2011
Available online 12 February 2011

KEYWORDS

Transforaminal;
Epidural steroids;
Back pain

Abstract *Background:* The use of transforaminal epidural injections under fluoroscopy guarantees the proper delivery of steroids to the target site with the least volume. The aim of this study was to compare the effects of different volumes of epidural steroid injections for treatment of sciatica through transforaminal approach.

Methods: 60 ASA I–II patients complaining of unilateral radiculopathy were divided randomly into three equal groups (group A–C), to be given transforaminal injection under fluoroscopy. All patients received a mixture of (80 mg methylprednisolone acetate + 1 ml contrast dye of Omnipaque 300) plus 1 ml of 0.5% bupivacaine (group A), or 2 ml of 0.5% bupivacaine (group B), or 3 ml of 0.5% bupivacaine (group C).

Results: There was significant reduction in the (VAS) score, at 60 minutes (group A 2.3 ± 1.1, group B 2.7 ± 0.8 and group C 3 ± 0.8 $p < 0.01$). Patients in group A had significantly lower VAS score (3.9 ± 1) in relation to the groups B VAS score (4.7 ± 1.1) and C (5 ± 1.1) two weeks after the injection ($p < 0.01$).

In group A, sixteen patients showed a significant reduction in the frequency of analgesic intake in the follow up period, while eleven patients reduced the frequency of analgesic intake during the 2

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Peer review under responsibility of Egyptian Society of Anesthesiologists.
doi:10.1016/j.egja.2011.01.004

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weeks follow up period, in group B. As for group C, twelve patients remained on the same frequency of analgesic intake following injection. Patients in group A showed significant reduction in the need for surgery.

Conclusion: Patients receiving a low volume and high concentration of corticosteroid via transforaminal epidural approach for the treatment of symptomatic lumbar disc herniation or spinal stenosis had significantly better short-term pain improvement, and less incidence of need for surgical intervention, than patients who were treated with a diluted solution of corticosteroid.

1. Introduction

The purpose of an epidural steroid injection is to deliver corticosteroid close to the site of pathology, presumably onto an inflamed nerve root, this is based on the principle that the corticosteroid injected into the epidural space will have higher local concentrations over an inflamed nerve root and will be more effective than a steroid administered either orally or by intramuscular injection [1].

One of the major concerns about epidural steroids is that their true efficiency might not be evident in clinical trials because the injectate fails to reach the desired target. Thus, the importance of transforaminal epidural injections under fluoroscopy will guarantees the proper delivery of steroids to the target site with the least volume, and fulfilling the aim of reaching the primary site of pathology (ventral and lateral epidural space), compared to interlaminar and caudal approaches. Since pain generators are located anteriorly in the epidural space, ventral epidural spread is the reasonable target for placement of antiinflammatory medications [2–4].

There is no agreement on how epidural steroids injection therapy should be done with respect to the volume and mass. In addition, the methods used for epidural injections vary with different physicians, and no standard for the performance of this procedure has been defined. Positive results from epidural steroids vary from 20% to 95% and may depend on route of injection [3,4]. We hypothesis that a higher concentration which is delivered directly to the inflamed roots may have more therapeutic effect than more diluted cortisone solution. In spite of, the fact that it may have wider spread in the epidural space.

The aim of this study was to compare the effects of different volumes of epidural steroid injections for treatment of sciatica through transforaminal approach.

2. Patients and methods

After approval from the Local Ethical Committee and written informed consent, 60 ASA I–II patients were divided randomly into three equal groups (group A–C) using the closed envelope method. All patients had a thorough initial physical examination by the spine surgeon and the diagnosis of degenerative lumbar disc herniation or foraminal spinal stenosis was confirmed by magnetic resonance imaging.

2.1. Inclusion criteria

Unilateral distribution of radicular pain, all patients should have completed an anti-inflammatory course of medication and physical therapy for at least six weeks without adequate benefit; both the patient and the treating surgeon have agreed that operative treatment would have been the next indicated step, after a trial of epidural steroid injection.

2.2. Exclusion criteria

All patients who had had a previous spine operation, trauma, cauda equina syndrome, a progressive neurological or a motor deficit, a neoplastic or infectious etiology, multiple disc lesions, coagulation defect and a history of an adverse reaction to corticosteroids or local anesthetics.

All patients lied prone, sterile preparation was performed with alcohol followed by Betadine (povidone–iodine) solution. Local superficial anesthesia (1% lidocaine using a 25-gauge needle), was injected into the skin at the lateral edge and slightly inferior to the corresponding transverse processes. With fluoroscopic guidance, a 22-gauge spinal needle was then advanced toward the junction between the transverse processes and the superior articulating process till it passed beneath the base of the appropriate pedicle. The final position of the tip of the needle was at the 6-O'clock position of the pedicle on the antero posterior plane and the 12-O'clock position of the foramen on the lateral plane. This target region is described as the safe triangle which is bounded by the pedicle superiorly, the lateral border of the vertebral body laterally, and the outer margin of the spinal nerve medially [5–7].

When bloody tap occurred, the needle was repositioned to obtain negative aspiration. To confirm the correct position of the needle tip 0.5–1 ml of contrast dye Omnipaque 300 was injected to demonstrate the flow around the nerve root. After negative aspiration of fluid or blood the steroid mixture was given and then one ml contrast dye was injected and X-ray image was taken (AP & lateral) to assess the spread of the contrast.

Once appropriate needle placement had been confirmed by injecting 0.5–1 ml of contrast dye, all patients received a mixture of (80 mg methylprednisolone acetate + 1 ml contrast dye of Omnipaque 300 to display the distribution of the injectant in the epidural space) plus 1 ml of 0.5% bupivacaine (group A), or two milliliters of 0.5% bupivacaine (group B), or 3 ml of 0.5% bupivacaine (group C).

X-ray images were taken after a contrast dye injection to demonstrate the distribution within the epidural space, showing the number of segments over which the injectate had spread. The contrast flow pattern was considered non-selective where the dye spread to cover more than two nerve roots, and/or crossed to the contralateral side. Using ***Visual Analogue Scale*** (***VAS: 0–10***), all patients were asked to report the degree of pain, before injection, 1 h after and after

2 weeks for follow up. Pain scores were taken by a nurse that was blinded to the procedure. Six weeks after the injection, a follow up evaluation was performed in person or by telephone. The procedure was considered a failure if, the patient showed no improvement after 2 weeks and demanded a surgery. However; patients who showed partial improvement were allowed up to 3 injections, with a minimum of 2 weeks apart, using the former technique. The analgesic intake was recorded 24 h after injection and 14 days following injection, patients showing unchanged frequency of analgesic intake before and after injection with a request for surgery were considered to have a failed procedure.

3. Statistics

Statistical analysis was done using SPSS 16 program. Continuous data was expressed as mean ± SD, for comparison of parametric data one-way analysis of variance was applied. ***Post hoc*** Student-Neuman-Keuls and Tukeys tests were used to indicate which of the comparisons achieve statistical significance, for nonparametric data Kruskal–Wallis analysis was applied. Chi-squared test was used for nominal data, Fisher exact test was used for any values 5 or less. A P value <0.05 was considered significant.

4. Results

There were no significant differences between groups with regard to any of the demographic data and levels of disease Table 1.

Pre-injection visual analogue scale (VAS) score showed non significant difference between the 3 groups, however, there was significant reduction in the (VAS) score, at 60 min (group A 2.3 ± 1.1, Group B 2.7 ± 0.8 and group C 3 ± 0.8 $p < 0.01$) Table 2.

Patients in group A had significantly lower VAS score (3.9 ± 1) in relation to the groups B VAS score (4.7 ± 1.1) and C (5 ± 1.1) 2 weeks after the injection ($p < 0.01$) Table 2.

In group A, sixteen patients showed a statistically significant reduction in the frequency of analgesic intake in the follow up period ($p < 0.05$) Table 2, while eleven patients reduced the frequency of analgesic intake during the 2 weeks follow up period, in group B. As for group C, twelve patients remained on the same frequency of analgesic intake following injection.

Group A showed a significantly lower number of patients (two) who decided to undergo surgery compared to 5 patients in group B and 9 patients in group C ($p < 0.05$). Group A also showed a significantly higher number of patients (twelve) who were satisfied with a single injection throughout the 6 weeks follow up period, compared to 8 in group B and only 5 patients in group C ($p < 0.05$) (Table 3).

Concerning the contrast flow pattern, initial use of 0.5 ml of contrast dye (Omnipaque 300) to confirm the needle position is considered selective to nerve root. However, the 3 groups were non-selective following injection of 2.5–4.5 ml of steroid, dye and local anesthetic mixture, for the injectate spread to more than 2 nerve roots and even crossed to the contralateral side, there were no significant difference between the 3 groups. In group A, fifteen patients showed non-selectivity, group B, eighteen patients showed non-selectivity, as for C all the cases showed no selectivity to nerve root.

Of the sixty patients in our study; none showed dural puncture, however two patients complained of transient headache following the injection, which resolved within 24 h. Only one patient suffered a vasovagal attack. Intravascular placement of the needle during the epidural injection has occurred in ten of the patients irrelevant to groups. The incidence of complications was irrelevant to the group of patients. During our short term follow up, none of the patients showed complications related to epidural administration of corticosteroids.

Table 1 Demographic data and levels of disease.

	Group A ($n = 20$)	Group B ($n = 20$)	Group C ($n = 20$)
Age	49(15)	51(16)	45(12)
Weight (kilograms)	74(6)	76(8.5)	74(9)
Sex (female/male)	11/9	10/10	12/8
Disc level (*patients number*)			
L3–L4	11	10	9
L4–L5	9	10	11

Presented as mean (SD) or number.

Table 2 Showing visual analogue scale (VAS) and analgesic intake.

	Group A ($n = 20$)	Group B ($n = 20$)	Group C ($n = 20$)
VAS mean (*SD*)			
Pre-injection	6.5(0.8)	6(0.7)	7(0.5)
60 min	2.3(1.1)*	2.7(0.8)	3(0.8)
2 weeks	3.9(1)*	4.7(1.1)	5(1.1)
Analgesic intake 14 days (*number of patients*)			
Decreased	16*	11	8
Unchanged	4	9	12

$p < 0.01$ within same group.
* $p < 0.05$ between group A, B and C.

Table 3 Showing number of injections, patients who had surgery done and contrast flow pattern.

	Group A ($n = 20$)	Group B ($n = 20$)	Group C ($n = 20$)
Injection (*number of patients*)			
Single injection	12*	8	5
Two injections	6	9	6
Three injections	2	3	9
Surgery (*number of patients*)			
Yes	2*	5	9
No	18	15	11
Contrast flow pattern (>2 roots and/or crossing to other side)	15	18	20

* $p < 0.05$ between group A, B and C.

5. Discussion

In our study we were able to prove that a higher concentration of corticosteroids (small volumes) directly delivered to the inflamed roots through a transforaminal approach, had a more therapeutic effect than diluted solutions (large volumes) for treatment of sciatica, in spite of the fact that it may have wider spread in the epidural space.

This may be explained by the presumption that injection of higher concentrations of corticosteroids in a smaller volume mixture, is considered therapeutically "selective" because it can deliver the concentrated medication to an anatomical spinal segment or nerve root that correlates closely with the patient's clinical and radiographic examinations. The higher the volume the more the likeliness of injectate dispersion and spread to the upper or lower spinal segments or nerve roots and/or contralateral spread to the opposite side, thus losing the therapeutic selectivity.

The most important finding was that 90% of the patients who received high concentration corticosteroids in group A didn't require surgery versus 75% and 55% for high volume groups B and C, respectively, after the 6 weeks follow up period. The analgesic intake in the form of anti-inflammatory drugs for the high concentration group was significantly reduced after 2 weeks and continued throughout the 6 weeks follow up period, while in the high volume groups many patients either remained on the same frequency of anti-inflammatory intake before injection or resorted to surgery.

Our study supports that of Schaufele et al. [8] which also stated that 90% of the patients injected with a high concentration mixture of 1 ml of 80 mg methylprednisolone acetate and 1 ml of lidocaine 2%, were satisfied with the injections and didn't require surgery later. In another study by Kabatas et al. [9] where a mixture of (0.5 ml 0.5% bupivacaine + 1 ml 40 mg methylprednisolone + 1 ml Omnipaque 300 dye) were injected, results showed that 67% of the cases didn't need surgery. Although a high concentration mixture was injected, the percentage of patients asking for surgery here was higher than ours, maybe because most of their patients suffered from spinal stenosis which doesn't improve significantly following TFESI. In a randomized controlled trial (RCT) by Riew et al. [10] a mixture composed of 1 ml of 0.25% bupivacaine and 6 mg of betamethasone in 1 ml was injected, 75% of the patients decided not to have an operation post-injection, the difference between their results and ours may be due to the use of betamethasone acetate instead of methylprednisolone. This is proved in a study by Noe and Haynsworth [11] showing that the aqueous steroid betamethasone is not an effective alternative to the commonly used methylprednisolone (Depo-Medrol) when injected epidurally in patients with lumbar pain. The study also shows that the anti-inflammatory effect of a depo-steroid can be greater than a non-depo steroid, even at equipotent doses. This should be an important factor to consider when reviewing epidural steroid outcome studies, where the type of steroid might affect results as much as other variables such as route of administration, volume of injectate, or use of fluoroscopy.

As for other studies which looked at the outcome of transforaminal epidural steroid injection; Vad et al. [12] transforaminally injected a total volume of 1.5 ml betamethasone acetate (9 mg) + 1.5 ml of 2% preservative free xylocaine, with an outcome of 85% of patients not reverting to surgery, in a study by Lutz et al. [13], with 1.5 ml of 2% xylocaine and 1.5 ml 9 mg of betamethasone acetate injected a successful outcome with no surgery was reported by 52 of the 69 patients (only 75.4%) at an average follow-up of 80 weeks (range 28–144 weeks). On the contrary, in a study by Weiner and Fraser [14] 28 patients with severe radiculopathy secondary to herniation of lumbar disks were treated by transforaminal steroid injection, using a large volume of injectate 2 ml of 1% lidocaine combined with 2 ml of betamethasone. The authors showed that 22 of the 28 patients improved dramatically, with sustained long term relief lasting for 3 years. In their studies 89% of the patients didn't request for surgery, while in our study, only 55% of the patients from group C with the large volume injectate didn't require surgery, this difference was presumably because their cases had a lower VAS score than ours pre-injection.

Another study by Botwin et al. [15] involving the injection of a solution of 2 ml of 1% xylocaine + 2 ml (12 mg) betamethasone acetate revealed the following, 61.8% of their patients didn't consider surgery in a short term follow up of 2 months. While our study also showed a significant improvement in the VAS score in the 2 weeks follow up period concerning group A in comparison with groups B and C.

The study by Schaufele et al. [8], also gave VAS score results similar to our study as there was a statistically significant improvement in the VAS scores from before the injection (VAS mean 5.9) to VAS after injection in the follow up period (VAS mean 3.2, $p < 0.01$), in our study it was 6(0.8) before versus 3.9(1) 2 weeks after injection, both studies were done for patients injected with a high concentration steroid/local anesthetic mixture (2 ml).

As for the number of injections 45% of Schaufele's [8] cases were satisfied with a single injection compared to 60% of our group A patients. In groups B and C only 40% and 25%, respectively were satisfied with a single injection in our study.

Transforaminal epidural injections of anesthetic and corticosteroids are generally safe with a reported minor complication rate of 9.6% in the lumbar spine [16].

Considering procedural complications, of our 60 patients there was no incidence of infection, dural puncture or complications related to epidural injection of corticosteroids. However post injection headache occurred in 3% of our patients, vasovagal attack had a 1.6% incidence and intravascular placement of the needle 17%.

In a study by Botwin et al. [16] complications were reported including transient headaches in 3.1% and vasovagal reaction in 0.3%. Furman et al. [17] reported an overall rate of intravascular injection of 11.2% compared to 8.3% in our study. Manchikanti et al. [18] reported intravenous placement of the needle in 22% of the procedures, and the same incidence of headaches as our study of 3%. In a prospective study by Lee et al. [19], 87 fluoroscopically guided injections, the incidence of intravascular injections during lumbosacral transforaminal ESIs as determined by digital subtraction fluoroscopic guidance was 23% overall.

The limitations of our study: First, the follow-up interval for pain improvement was short (only 6 weeks). However, it is commonly agreed that epidural steroid injections are particularly helpful for pain control in the first weeks after the injection.

Second, the sample size was relatively small plus the strict inclusion/exclusion criteria that were enrolled. This eliminated a large proportion of patients typically seen by pain interventionalists. Our goal was to limit the study to a certain group of patients to increase our results validity.

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