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Original Research Article

A prospective study to evaluate the efficacies of low volume and high volume caudal epidural steroid injections in the treatment of lumbar degenerative disc disease

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ABSTRACT

Background: To evaluate the efficacy of low volume corticosteroid injections in the treatment of radiculopathy associated with lumbar degenerative diseases by comparing with that of conventional high-volume injection and appreciate the advantages of the technique. Study was a prospective comparative study. Setting was the operating room.
Methods: 52 patients, they were randomized into two groups. Among them, 27 had undergone caudal epidural steroid injection (CESI) with low volume and 25 with high volume injections of triamcinolone. Intervention of the study was caudal epidural steroid injection (CESI) to all patients in both groups. Low volume group received 5 ml and high-volume group received 15 ml diluted triamcinolone solution. They were evaluated with the visual analog scale, Oswestry low back disability questionnaire, short form 12, relief of claudication and neurological disability.
Results: There was no statistically significant difference in the clinical improvement between the two groups. However, there are definite distinct advantages of low volume injection such as lesser pain at injection site and no complications that warrant admission.
Conclusions: The low volume technique of CESI is superior to the traditional high-volume technique in this study. Despite earlier concepts that low volume injections failed to penetrate the proximal epidural spaces, present study conclusively proved that it is superior to high volume injections.

Keywords: Caudal epidural steroid injection, High volume injections, Low volume injections, Oswestry low back pain disability questionnaire, Radiculopathy, Triamcinolone, Visual analog score

INTRODUCTION

Back pain is an affliction that affects a substantial proportion of the entire population, at some point of time in their lives. A significant percentage of back pain cases can be grouped as predominantly neuropathic.[1] One of the frequently used non operative treatment modalities for radiculopathy is epidural steroid injections (ESI), which have been used for several years.[2] Study shows epidural steroid injections are very commonly method of spinal pain management intervention modality in United States.[3] CESI was used for the control of sciatica symptoms earlier.[4] It is one of the most frequently performed pain procedures in the treatment of lumbar degenerative disc disease. CESI is the easiest among the three routes into the epidural space with the lowest risk of inadvertent puncture of the dura.[5] This gains its popularity; however high-volume solution is recommended due to the belief that it does not reach the lower lumbar nerve roots otherwise.[5] The dosage and route of administration of this

drug have been a matter of debate. Current study intends to shed light on this condition and the use of low volume injections for the radiculopathy associated with degenerative lumbar disc disease. Their null hypothesis is that patients who had low volume corticosteroid CESI in the treatment of radiculopathy associated with lumbar degenerative diseases have the same efficacy as those treated with high volume injection.

METHODS

The study was a prospective comparative study of patients who presented in their unit with lumbar radicular pain. Between January 2014 and April 2015, 52 patients underwent CESI with 80 mg of triamcinolone. Of these, 27 patients (51.92%) received low volume injections (5ml: which includes 2ml triamcinolone - each ml is 40 mg, diluted in 3 ml normal saline). Of the remaining 25 patients (48.07%) received high volume injection (15ml: which includes 2ml triamcinolone - each ml is 40 mg diluted in 13 ml normal saline). All patients were given single dose of injection. They were matched for age, Oswestry disability index (ODI) and VAS. A statistician blinded to the outcome measured, did this selection.

Inclusion Criteria

Adult patients (aged 25-60), capable of providing consent and complying with the outcome instruments who had pain of appropriate quality radiating to the lower limb irrespective of neurological signs and demonstration of disc degeneration by MRI.

Exclusion Criteria

Patients with severe motor deficit, uncontrolled diabetes mellitus, bleeding disorders, previous surgery at the affected segmental level, segmental instability, pregnancy, recent infection, spinal deformities, cardiac failure and patients with red flag signs. Patients were not excluded based on duration of pain alone.

After thorough clinical, general and spinal examination patients were followed up with x-rays and MRI of the lumbosacral spine. Once the diagnosis of degenerative disc herniation made they were counseled and worked up for caudal epidural injection. Figure 1 provides an outline of the study design.

Before proceeding to the procedure, patients were also specifically evaluated for duration of symptoms, neurological deficits and claudication distance. After randomization, both groups were injected in the major operation theatre as per the standard protocols, by a single surgeon with the aid of fluoroscopy.

Patients in both groups received oral antibiotic prophylaxis for 3 days. All were subject to standard preoperative optimization and postoperative care. All were encouraged to do the physiotherapy and core muscle strengthening exercises when they can afford to do it. They were evaluated with the visual analog scale at 15 minutes after injection, at discharge, 3 weeks, 6 weeks and 3 months post injection. They were also evaluated with the oswestry low back disability questionnaire and SF 12 at 3 months.

Statistical Analysis

The outcome data was analyzed by a Bio statistician using the SPSS Statistics version II.

RESULTS

The group demographics, including the accuracy of matching of both groups are shown in Table 1. Both groups were comparable with no significant differences in patient sex, BMI, average duration of symptoms at the time of admission. We found that higher proportion of patients in the low volume group experienced improvement of symptoms (80% versus 51.7% in terms of pain relief in the neurological deficits group) but to prove this, a study with a larger sample size needs to be conducted.

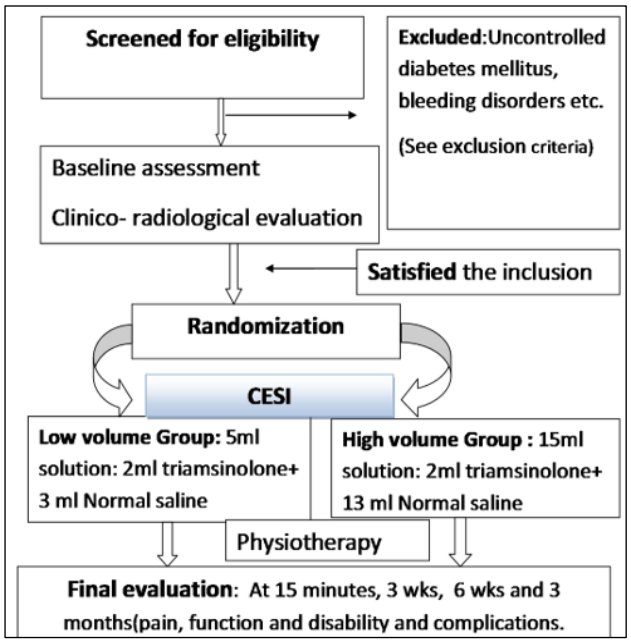

Figure 1: Outline of the study design.

The low volume group shows significant improvement in those with neurogenic claudication (76.4% versus 57.1%). We compared the number of patients getting relief at three months for both groups based on the level of disc herniation and found no significant difference in relief based on it are shown in Table 2.

Hence, we observed that low volume injections were as effective as high volume even in treating multilevel disc herniations as well. To establish a relationship between the level of disease and the volume of injectate, a larger

study needs to be devised. The outcome based on the ODI and VAS is summarized in Table 3. In the low volume group 88.88% (24/27) of patients at 6 weeks and 74 % (20/27) of patients at 3 months had significant improvement of VAS (p value 0.001 and 0.010). Similarly, in the high-volume counterpart 80 % (22/25) of patients at 6 weeks and 84 %(21/25) of patients had good improvement of VAS (p value 0.001 and 0.008).

We performed the paired t-test to analyze the results. The ODI was compared at the first visit and during the visit at third month. In the low volume group, 23 out of 27 patients (85.18%) had an improvement of the score and the paired t-test showed a p-value of 0.02 which is significant statistically. In the high-volume group, 22 out of 25 patients (88%) had an improvement of the score and the paired t-test showed a p-value of 0.03 which is also statistically significant.

Table 1: Demographic characteristics (data and results) of two groups.

Variable	High volume injections	Low volume injections
No. of patients	25	27
Sex ratio (male/female)	9/14	11/16
Average duration of symptoms	20.6 months	30 months
Mean BMI[1]	26.14 kg/m2	29.71 kg/m2
Ratio of obese patients with sciatica experiencing relief at 3 months	7/13 (53.8%)	4/7 (57.14%)
Ratio of patients with neurological deficits experiencing relief at 3 months	8/14 (57.1%)	12/15 (80%)
Ratio of patients with single level disease with relief at 3 months	7/9 (77.7%)	7/9 (77.7%)
Ratio of patients with multi-level disease with relief at 3 months	12/16 (75%)	15/18 (83.3%)
Ratio of patients with claudication experiencing relief at 3 months	8/14 (57.1%)	13/17 (76.4%)

Table 2: Outcome measures of both groups for multilevel and single level lumbar disc disease.

	Single level disease (all patients had L4-L5 disease)		Multilevel disc disease	
	Number of patients	Number of patients with relief at 3 months	Number of patients	Number of patients with relief at 3 months
Low volume	9	7	18	15
High volume	9	7	16	12

Table 3. P value for paired t-test for Oswestry low back disability score (OSW) and visual analog score(VAS).

Variable	P value for high volume	P value for low volume
OSW at first visit and 3 m	0.03 significant	0.02 significant
VAS at first visit and 15 minutes	0.692 Not significant	0.004 significant
VAS at first visit and discharge	0.015	0.001
VAS at first visit and 3 weeks	0.001	0.001
VAS at first visit and 6 weeks	0.001	0.001
VAS at first visit and 3 months	0.010	0.008

The study analyzed the complication also and found, 7.4% of patients (2/27) in low volume group had mild pain at the injection site till 15 minutes (p value 0.004) where as 32% of patients (8/25) in high volume group had significant pain at the injection site till 15 minutes (p value 0.692) and it was persisted for one hour in 3 patients (12%).

None of the patients in both groups had any infection at the injection site. One of the patients in the high-volume group had developed a short episode of cardiac arrest immediately after the injection and the patient was revived by their intervention specialist. We assumed it might be because of the unbearable dural stretch pain he suffered immediately followed the injection. Interestingly none of their patients in the low volume group had similar untoward complication because of pain. All patients in the low volume group were discharged after 4

hours of observation but the high-volume group was admitted for 24 hours because of similar anticipated problems. None of them where required any surgical intervention.

DISCUSSION

Low back pain usually arises from any damage/degenerative changes in the intervertebral discs, facet joints, spinal nerves and dural tissue.[6] Intervertebral disc degeneration and herniated discs are the common causes among them. Though the exact mechanism is still not certain, studies indicate due to a combination of mechanical compression and inflammatory response to the spinal nerve root follows the protrusion of nucleus pulposus.[7] The extent of nerve root mechanical compression/irritation is responsible for radicular pain and low back pain is not clear.[5] In general, sciatica (radicular pain) is most-likely due to nerve root mechanical compression.[5] Epidural steroid injections are found effective for the radicular pain than back-dominant pain, which is likely to be due to facet syndrome, or muscular pain.[7] The corticosteroids provide pain relief by inhibition of pro-inflammatory mediators and by causing a decreased sensitivity of nerve roots to the inflammatory irritants).[8,9] Of the three routes of epidural steroid injections available the superiority of one route over the others is controversial.[8] Each One has its own merits and demerits. Administration of saline along with steroid can exert an analgesic effect via the washout of the extradural inflammatory cytokines and the adhesiolysis of scar tissue is the logic behind dilution in normal saline.[10,11]

The study obtained a sample of size of 52 patients, which is comparable to that by Revel et al with a sample size of 60 patients who did a similar study.[12] In the series by Bogduk et al, they found that a volume of 10 ml would reach the L5 segment and 15ml would reach the L4 segment.[13] But in this study, they found a respectable number of patients with multilevel disc disease have good benefits from both 5ml and 15ml injections. Manchikanti et al concluded that increasing the volume of injectate to greater than 10 ml does not seem to increase filling pattern.[9,14,15] Present study supports his theory with clinical results. The work of Schaufele et al also showed that injection of a mixture of 1 ml of 80 ml methyl prednisolone and 1 ml of 2% lignocaine showed that the injection of a lower volume resulted in lesser pain.[16] They used the interlaminar approach for injection. No prospective study has been devised before current study which compares the efficacies in previously non-operated disc herniations. There have been no earlier studies regarding the severity of pain at the injection site that is caused due to conventional high-volume injection. This can be postulated due to the sudden distension and increase of pressure inside the epidural space. This pain has been examined in current study and was a common complaint of the high-volume group of patients. We observed a distinct advantage of low volume injection that is associated with lesser pain. High volume injections are theoretically associated with vascular extravasations. This coupled with the pain at injection site lead us to admit all patients for a minimum of 12 hours.[17] This is the justification for the 24 hours' admission of the high-volume group. All patients with low volume injections were comfortable within 2 hours of injection and did not warrant admission. Low volume injections can administer higher concentrations of corticosteroid to the epidural spaces. This may directly be the reason why there is an earlier onset of relief in patients who received low volume injections.

Current study could not definitively establish the duration of effect of these injections as even after 3 months of follow up there was statistically significant pain relief for both groups in all three scales. However, theoretically the maximum duration of action of triamcinolone has been found to be within 2 months, their finding may not be biologically plausible. The explanation for this is that the natural course of the disease, takes the patient through a series of spontaneous aggravation and relief of sciatica. This supplemented with post injection physiotherapy in the form of back strengthening exercises may help the patient obtain a longer duration of pain relief.

In current study, we found no complications that were noted by the previous authors, except for one patient in the high-volume group with short episode of cardiac arrest. We attribute the fact that one surgeon performing these injections coupled with thorough evaluation before the procedure for medical illnesses and careful asepsis to be the reason for their very low complication rate. During current study, no patients demanded surgery for radicular pain, after the injection in both groups.

Limitations of this study was the small sample size of current study is a drawback. Hence, we recommend formulation of larger studies, so that the results can be confirmed at a larger scale.

CONCLUSION

The low volume technique of CESI is superior to the traditional high-volume technique of CESI in the current study. Low volume injections were associated with lesser pain at the injection site immediately after injection which is a well-known complication of the conventional high-volume injections. Because of this, there is little need for hospital admission in those patients receiving low volume injections. Despite earlier concepts that low volume injections failed to penetrate the proximal epidural spaces, current study conclusively proved that low volume injections as effective as high-volume injections in doing this by delivering high concentrations in the proximal epidural spaces. We therefore recommend the routine use of low volume caudal epidural steroid injections for radiculopathy associated with lumbar degenerative disc disease. A much larger series would be required to establish these results at a larger scale.

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