EFFECTS OF CAUDAL EPIDURAL STEROID INJECTION FOR LOW BACK PAIN AND SCIATICA

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ABSTRACT

Objective: To evaluate the short term effects of high volume of injectate containing local anesthetics and steroids as compared to low volume injectate of the same drugs and the need for repetition as a means of treatment for patients suffering from severe chronic low backache (LBP) and sciatica.

Study Design: Quasi experimental study, interventional.

Place and Duration of Study: Department of Anaesthesia, Combined Military Hospital (CMH) Peshawar and CMH Gujranwala from Jun 2008 to Jun 2013.

Material and Methods: This quasi experimental double blind study was carried out in the department of Anaesthesia, CMH Peshawar and CMH Gujranwala from Jun 2008 to Jun 2013. A total of 100 patients were distributed into two equal groups A and B according to inclusion and exclusion criteria. All the patients were clinically examined along with basic investigations. After confirming the epidural space 80 milligram (2ml) of methyl prednisolone mixed either with 0.25% bupivacaine, 0.2 ml/kg in group A or 0.125% bupivacaine, 0.4 ml/kg in group B was injected into the caudal epidural space.

Results: Clinical evaluation was performed at the time of enrolment (visit 1), after 2 weeks (visit 2), 6 weeks (visit 3), 3 months (visit 4) and 6 months (visit 5). On visit 5 i.e. 6 months after the start of the study the total patients in group A and B were 43 and 41 respectively. According to Denis Pain Scale 23 patients (53%) in group A and 26 patients (63%) in group B showed improvement (*p* value <0.05). According to MacNab's criteria 33 patients (77%) in group A and 35 patients (85%) in groups B showed improvement (*p* value <0.05). Regarding weekly intake of medicines 12 patients (27.9%) in group A and 16 patients (39.0%) in group B, had 50% reduction in their weekly intake of pain killers (*p* value <0.05). In group B the number of patients showing improvement was 4 more than group A which was statistically significant (*p* value 0.041).

The incidence of hypotension after the injections was 4 (2.76%) in group A and 7 (5.03%) in group B (*p* value <0.05). None of the patients in group A but 4 patients (2.88%) in group B (*p* value <0.05) had difficulty in voiding urine after two hours. All the complications were self-limiting and settled without any morbidity or need for hospitalization.

Conclusions: Caudal epidural steroid injections 0.2 ml/kg as well as 0.4 ml/kg show significant improvement in patients with low backache un-responsive to conservative measures alone. High volume injectate is more effective as compared to low volume but there is significantly increased risk of complications like hypotension and difficulty in voiding urine.

Keywords: Bupivacaine, Caudal Epidural, Low Back Pain, Sciatica, Steroids, Volumes.

INTRODUCTION

Low back pain is the most frequent cause of limitation of activity in people younger than 45 years and one of the common reasons for seeking medical advice. It accounts for 15% of all sick leaves in developed countries and thus is of great socio-economic importance[1]. Even though chronic low back pain (LBP) is currently estimated to affect around 15% of the US population, identifying its actual cause(s) can be an extremely difficult task. Lumbar disc

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herniation seems to be one of the most frequent causes of LBP, nevertheless it is well known that many patients, complaining of LBP as well as of radiating leg pain suggesting sciatica, did not show lumbar disc herniation in magnetic resonance imaging (MRI) and computed tomography[2]. There is emerging evidence suggesting that this "paradox" may be attributed to the fact that nerve root compression is not sufficient by itself to cause nerve root pain[3] since painful radiculopathy may be the end-result of a local chemical contribution from injured tissue[4,5]. A positive straight leg raising (SLR) test is not considered as a diagnostic or prognostic criteria since it is well accepted that degenerative changes do not necessarily correlate with pain generation[6].

Treating patients suffering from LBP is challenging and this is probably why so many treatment modalities, ranging from simple conservative measures to use of nonsteroidal anti inflammatory drugs, epidural local anaesthetics alone or in combination with various drugs including long acting steroids, ozone therapy, intradiscal electro thermal therapy (IDET) and different surgical interventions along with comprehensive rehabilitation programmes are being practised with varying results[7-13].

Ever since its introduction[14] the efficacy of caudal epidural injection (CEI) for managing low backache and sciatica, has been controversial. Attempts have been made to improve its success rate by combining it with bilateral psoas block[15] or injecting the drugs through lumbar route (inter laminar or transformational approaches) with or without image intensifier guidance[16]. Literature moderately supports the use of CEI containing steroid preparations for the long-term relief of patients suffering from chronic LBP, even though there is a lack of relevant well-designed randomized, controlled studies[17]. The actual effect(s) if any and the mode(s) of action of CEI with or without steroids on patients with chronic LBP, remain more or less unknown[18]. However these are low risk interventions and have the advantage of simplicity, cost effectiveness, minimal invasion and early relief of symptoms[19]. They reduce the need for narcotics and can avoid operative interventions for a period of up to five years. It is also a method of crisis intervention and prognosis indicator, thereby meaning that they are more effective in acute and severe forms of radiculopathy[20]. The total volume of injectate, preparations, dose and interval for repetition of steroids to be used is debatable however studies have shown that 80% of the time 10 ml of injectate volume will reach the L4-5 inter space[21].

The objective of this study was to evaluate the short term effects of high volume of injectate containing local anaesthetics and steroids as compared to low volume injectate of the same drugs and the need for repetition as a means of treatment for patients suffering from severe chronic LBP and sciatica.

MATERIAL AND METHODS

This quasi experimental double blind study was carried out in the Department of Anaesthesia, Combined Military Hospital (CMH) Peshawar and Gujranwala from Jun 2008 to Jun 2013. After our institution's ethical committee's approval, one hundred adult male as well as female patients, willing to undergo the study and to co-operate for follow up with low back pain (Denis pain scale 3 to 5) for a period of at least 1 month (with or without unilateral or bilateral sciatica) not responding well to conservative pain control measures were included and divided into two equal groups A and B by a coin flipping technique. All the patients were referred from medical and surgical out patient departments.

Patients having, infection at the site of injection, cancer, allergy to steroids or anesthetics, non controlled diabetes mellitus or hypertension, obesity (BMI>30), clotting disorder, urinary or faecal incontinence, severe claudication on walking, suffering from psychosomatic diseases were excluded.

Following screening an informed consent was obtained and the patients were enrolled (visit 1). They were distributed into two groups A and B, fifty patients in each, by a coin flipping

technique. All the patients were clinically examined after taking detailed history keeping in mind inclusion and exclusion criteria along with basic investigations like complete blood count, urine routine examination and ECG if indicated.

At the start of the procedure a 20 gauge intravenous cannula was passed and Hartmans' solution (7ml/kg) infusion was started along with SpO_2 and Non Invasive blood pressure (NIBP) monitoring. The procedure was performed in main operation theatre fully equipped with resuscitation facilities. Patients were placed in prone position with a wedge-shaped pillow under the hips to tilt the pelvis and bring the sacral hiatus into greater prominence. The sacrococcygeal area was prepared using an iodine-based antiseptic solution. Sterile-gloved middle finger of the non dominant hand was used to locate the tip of the coccyx through palpation. A skin wheal was raised with 2-3 ml 1% lignocaine with adrenaline (1:4000) i.e. 0.0005% at the level of proximal interphalyngeal joint by using a 24-gauge needle with 3ml syringe for local infiltration. A 21-gauge x 1½" needle in non-obese patients and a 23-gauge x 89 mm Quinke spinal needle (due to its low cost as compared toughy's needle) for obese patients was used for localization of caudal epidural space. After the feeling of a click, loss of resistance, negative aspiration for CSF or blood, 80 milligram (2 ml) of methyl prednisolone mixed either with 0.25% bupivacaine, 0.2 ml/kg in group A or 0.125% bupivacaine, 0.4 ml/kg in group B was injected into the caudal epidural space, while waiting to hear a wooshing sound with stethoscope over the sacrum. Following CEI, each patient remained at the outpatient clinic for a period of two hours until he/she felt physically and psychologically fit to be discharged. Patients were allowed to receive tab diclofenac sodium 50 mg along with tab paracetamol 500 mg on as required basis up to maximum of 3 tab of each a day. The patients complaining of severe or constant pain were given inj ketorolac 30 mg and inj tramadol 100 mg if required. Clinical evaluations were performed at the time of enrolment (visit 1), after 2 weeks (visit 2), 6 weeks (visit 3), 3 months (visit 4) and 6 months (visit 5).

Denis pain scale, MacNab's criteria, 50% reduction in weekly intake of pain killers and complications like hypotension (>10% fall in MAP), bradycardia (<60 per min), nausea/ vomiting, headache, difficulty in voiding after two hour, spinal anaesthesia and paraesthesia etc, were recorded in the proforma by another anaesthetist blinded of the groups.

The patients were evaluated on subsequent visits and were given 2nd and 3rd injections at visit 3 and 4 according to the protocol. Denis pain scale of less than three, excellent and good daily living activities level, according to MacNab's criteria and 50% reduction in weekly intake of supplemental pain analgesics were considered as the improvement criteria. The patients not showing improvement on 2nd visit were subjected to magnetic radio imaging (MRI) of lumbosacral spine. Among them, the patients who were considered appropriate candidates and willing for surgery were excluded from the study and managed by the neurosurgeon subsequently.

Data were recorded and analysed statistically on statistical package for the social sciences (SPSS) version 20. Results were analysed statistically by comparing the values in both groups. Mean and standard deviation were calculated for age and weight. Frequencies were calculated for gender. For Denis pain scale, MacNabs criteria and 50% reduction in medicine, paired t-test was applied for intra group comparison and independent t-test was applied to compare group A with group B. A *p* value of <0.05 was considered as significant.

RESULTS

There were 50 patients in each of the two groups A and B. Male to female ratio was 33:17 in group A whereas in group B it was 36:14. In group A and B the mean ages were 46.92 ± 11.82 and 48.44 ± 10.64 years respectively (*p*-value 0.747) and the mean weights were 79.48 ± 16.14 kg and 76.12 ± 13.15 kg respectively (*p* value 0.747) table-I. On visit 1, none of the patients had

any pain or minimal pain on Denis pain scale and excellent or good functional status on MacNab's criteria in both of the groups.

On visit 2, 21 patients (42%) in group A and 28 patients (56%) in group B showed improvement (*p* value <0.05). Although in group B the number of patients showing improvement was 7 more than group A but the difference was not statistically significant (*p* value 0.981) fig-1. According to MacNab's criteria 29 patients (58%) in group A and 28 patients (56%) in group B showed improvement (*p* value< 0.05). In group A the number of patients showing improvement was 1 (2%) which was more than group B but not statistically significant (*p* value 0.371) fig-2. Fourteen patients (28%) in group A and 23 patients (46%) in group B showed 50% reduction in their weekly intake of analgesics (*p* value <0.05). In group B the number of patients showing improvement was 9 (18%) which was more than group A and was also statistically significant (*p* value 0.002) fig-3.

On visit 3, 23 patients (47%) in group A and 30 patients (65%) in group B showed improvement (*p* value <0.05). Although in group B the number of patients showing improvement was 7 more than group A but the difference was not statistically significant (*p* value 0.111). According to MacNab's criteria 29 patients (59%) in group A and 30 patients (65%) in group B showed improvement (*p* value <0.05). Although in group B the number of patients showing improvement was 1 more than group A but it was not statistically significant (*p* value 0.881). Twenty one patients (42%) in group A and 26 patients (57%) in group B showed 50% reduction in their weekly intake of analgesics (*p* value <0.05). Although in group B the number of patients showing improvement was 5 more than group A but the difference was not statistically significant (*p* value 0.904).

On visit 4, 22 patients (48%) in group A and 28 patients (65%) in group B showed improvement (*p* value <0.05). Although in group B the number of patients showing improvement was 6 more than group A but the difference was not statistically significant (*p* value 0.501). According to MacNab's criteria 29 patients (60%) in group A and 36 patients (84%) in group B showed improvement (*p* value <0.05). Although in group B the number of patients showing

Table-I: Demographic data.

	Group A	Group B
Mean Age	49.92 ± 11.82	48.44 ± 10.64
Mean Weight	79.48 ± 16.14	76.12 ± 13.15
Male / Female Ratio	33 / 17	36 / 14

Table-II: Incidence of complications.

Complications	Group A	Group B
Hypotension	4 (2.76%)	7 (5.03%)
Headache	2 (1.38%)	4 (2.88%)
Nausea Vomitting	3 (1.38%)	6 (4.32%)
Urinary Retention	0%	4 (2.88%)
Total procedures	145	131

Table-III: Denis pain scale.

P1	No pain
P2	Minimal pain
P3	Moderate pain
P4	Severe pain
P5	Constant pain

improvement was 7 more than group A but it was not statistically significant (*p* value 0.759). Fifteen patients (30%) in group A and 18 patients (36%) in group B (*p* value <0.05) showed 50% but the difference was not statistically significant (*p* value 0.093).

During visit 3 and onward, 7 patients (14%) in group A and 9 patients (18%) in group B were

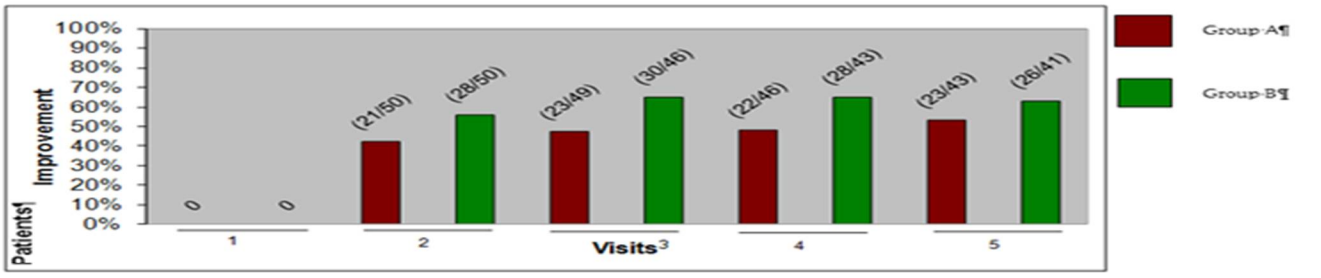

Figure-1: Improvement in denis pain scale.

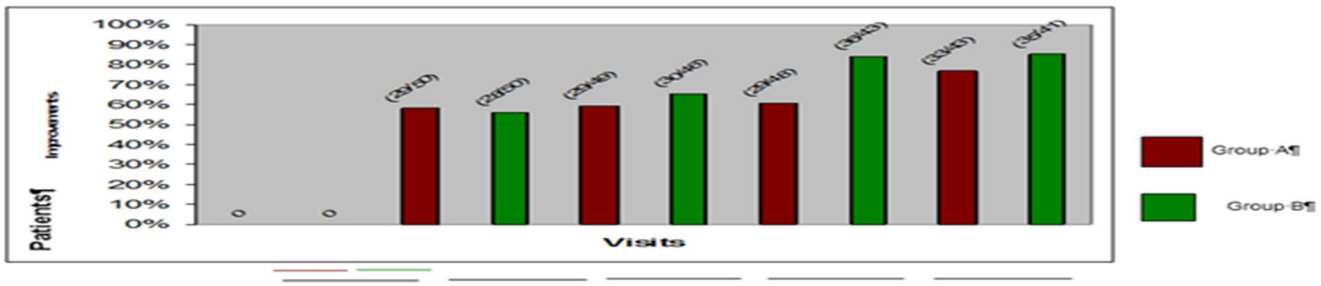

Figure-2: Improvement according to MacNabs' criteria.

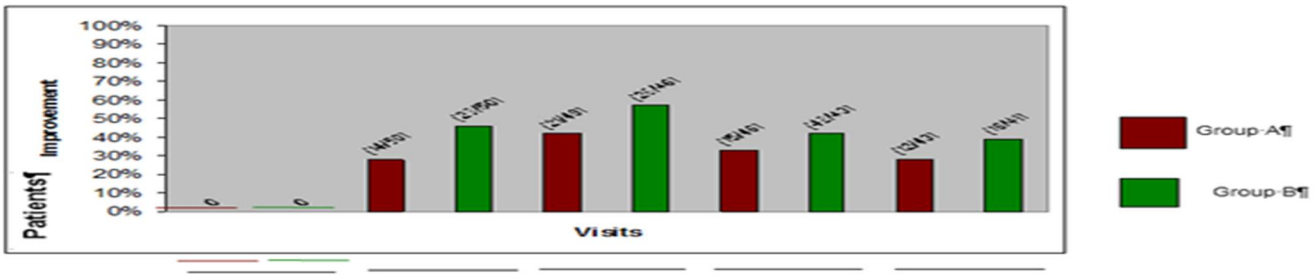

Figure-3: 50% reduction of medicine.

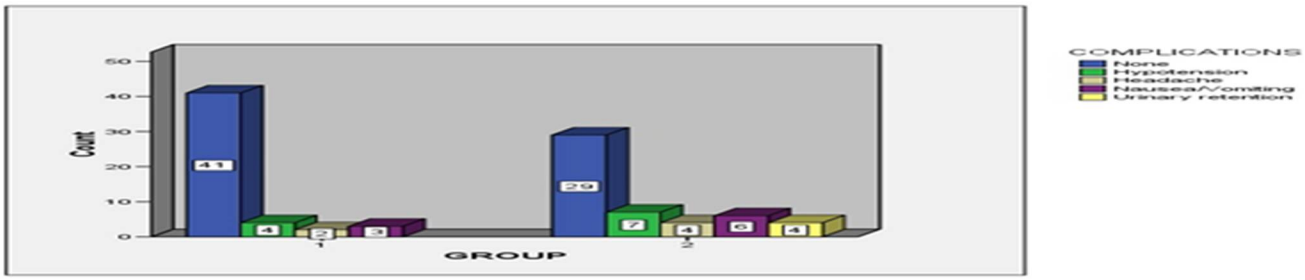

Figure-4: Incidence of complications.

reduction in their weekly intake of analgesics. Although in group B the number of patients showing improvement was 3 more than group A excluded till the final visit as they either underwent neurosurgical interventions or did not come for follow up.

On visit 5 i.e. 6 months after the start of the study the total patients in group A and B were 43 and 41 respectively. According to Denis Pain Scale 23 patients (53%) in group A and 26 patients (63%) in group B showed improvement (*p* value <0.05). Although in group B the number of patients showing improvement was 3 more than group A but the difference was not statistically significant (*p*-value 0.975). According to MacNab's criteria 33 patients (77%) in group A and 35 patients (85%) in groups B showed improvement (*p* value <0.05). Although in group B the number of patients showing improvement was 2 more than group A but it was not statistically significant (*p* value 0.822). Regarding weekly intake of medicines 12 patients (27.9%) in group A and 16 patients (39.0%) in group B (*p*-value <0.05) had 50% reduction in their weekly intake of pain killers. In group B the number of patients showing improvement was 4 more than group A which was statistically significant (*p* value 0.041)

The incidence of hypotension after the injections was 4 (2.76%) in group A and 7 (5.03%) in group B (*p* value <0.05) for which another 7ml/kg Hartmans solution was infused rapidly. In group A 2 (1.38%) patients and 4 (2.8%) in group B (*p* value 0.093) complained of nausea and vomiting for which inj. Metclopramide (maxolon) 10 mg IV was given. Three patients (1.38%) in group A and 6 patients (4.32%) in group B (*p*-value 0.036) complained of headache for which tab. Paracetamol 1000mg was given orally. None of the patients in group A but 4 patients (2.88%) in group B (*p* value <0.05) had difficulty in voiding urine after two hours table-II and fig-4. All the complications were self-limiting and settled without any morbidity or need for hospitalization.

DISCUSSION

Our results are comparable to the study of Manchikanti et al[21] who included 62 patients, and compared caudal epidural steroid injections with Sarapin and have demonstrated significant relief in 71% and 65% of the patients at 1 month, 67% and 65% at 3 months, and 47% and 41% at 6 months, in group I and group-II, respectively. Similarly Fare et al[22] have compared caudal epidural Betamethasone with distilled water for injection and have demonstrated that symptoms improved in 132 patients (72.1%) following CEI.

Botwin et al[23] have performed fluoroscopically guided caudal epidural injections on 34 patients with bilateral radicular pain from lumbar spinal stenosis and have shown that sixty-five percent of patients at 6 weeks, 62% at 6 months, and 54% at 12 months had a successful outcome. Our study results are in concordance with Rabinovitch et al[24] who have suggested a positive correlation between larger volumes of fluid injected in the epidural space and greater relief of radicular leg pain and/or low back pain by reviewing the existing literature. In another study Javed et al have concluded that CESI injections are safe and effective mode of treatment of low back pain in patients of lumbar disc herniation. It provides pain free period to enable the patient for physiotherapy, which helps in early recovery. The treatment is not only effective clinically but also cost effective[25].

A meta analysis by Watts and Silagy[26] on ESI showed that the chance of short term success was more than 75% which lasted up to 60 days. Spaccarelli[27] extensively reviewed case reports, of retrospective and prospective studies on the use of lumbar and caudal ESI. They concluded that this treatment was more effective in patients with certain lower extremity radicular pain syndromes. There are multiple factors including anatomical factors, medical comorbidities and psychological factors which may strongly influence the patient outcome and also determine the success of non surgical treatment. Myofacial pain syndrome, facet and sacroiliac joint arthritis often produce pain that radiates into the lower extremity and they are unlikely to respond to this form of therapy.

CONCLUSION

The results of our study show that caudal epidural steroid injections 0.2 ml/kg as well as

0.4 ml/ kg show significant improvement in patients with low backache un-responsive to conservative measures alone. High volume injectate is more effective as compared to low volume but at the cost of significantly increased risk of complications like hypotension and difficulty in voiding urine.

CONFLICT OF INTEREST

The authors of this study reported no conflict of interest.

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