Sjournals
Scientific Journal of Medical Science (2014) 3(7) 331-336
ISSN 2322-5025
doi: 10.14196/sjms.v3.i7.1521

Contents lists available at Sjournals
Scientific Journal of Medical Science
Journal homepage: www.Sjournals.com

Original article

Is it worth to give steroid in caudal epidural injections? A prospective randomized controlled study

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ARTICLE INFO

Article history:
Received 09 July 2014
Accepted 14 July 2014
Available online 28 July 2014

Keywords:
low back pain
lumbar disc herniation
caudal epidural
steroids

ABSTRACT

Background: Epidural injection, besides surgical decompression, is now one of the most common modality of treatment in lumbar disc herniation who doesn't responds to conservative therapy. The main aim of our study was to evaluate the role of fluoroscopically guided caudal epidural injection with or without steroids in patients of one or two level lumbar disc herniation. Material and methods: Two groups were made group N and group S. Each patient in group S received 2 ml (80 mg) of methyl prednisolone mixed with 10 ml of lignocaine (2%) and diluted in 18 ml of normal saline and group N received 10 ml of lignocaine (2%) with 20 ml of normal saline. A total of 3 caudal epidural injections were given to each patient at an interval of 3 weeks. All patients were prospectively assessed with examination of straight leg raising, visual analogue scale pain scores and Oswestry Disability Scale at 1, 3, 6, 9, 12 month interval. Results: No statistically significant differences were observed in the baseline scores between the 2 groups. At follow up, Pain scores, ODI and SLR changed significantly from baseline in both groups, with no significant differences between the two groups except at the 1 month where decrease in VAS and ODI Score was significantly more in group S. No patient reported any major immediate or late complication(s) following caudal epidural injection. Conclusion: Normal saline or saline mixed with steroid provides same benefit at long term but at one month steroid group patients showed more

relief as compared to saline group.

1. Introduction

Back pain is now a major issue of significance in health science. Every individual feels backache at least once in his/her entire life time. Hult (1954) estimated that up to 80% of people are affected by this symptom at some time in their lives. The prevalence rate of low back pain in a number of studies ranged from 22% to 65% in one year and the lifetime prevalence ranged from 11% to 84% (Walker, 2000).

Lumbar disc herniation and spinal canal stenosis are two of the most common causes of backache and radicular pain in all age group people irrespective of socioeconomic status. In the absence of cauda equine syndrome, the initial treatment is non operative, with approximately 50-60% of patients reporting satisfactory improvement after conservative care (Weinstein et al., 2006). Epidural steroids in combination with local anaesthetics or normal saline besides surgical decompression is now one of the most common modality of treatment in lumbar disc herniation patients who don't responds to conservative therapy. The main mechanism behind backache is inflammation that is caused by biochemical factors alone or in association with mechanical deformation of lumbar tissues resulting in vascular compromise and neurotoxicity (Takahashi et al., 2003; Mullerman et al., 2006).

Based on these facts epidural steroids may have a role in these patients. Epidural injections can be performed by three approaches; interlaminar, transforaminal and caudal. The main aim of our study was to evaluate the role of fluoroscopically guided caudal epidural steroids or normal saline injection in patients of one or two level lumbar disc herniation with cord compression and radiculopathy.

2. Materials and methods

The study was conducted in tertiary care hospital from May 2011 to April 2013 (24 months). One hundred twenty patients from 18 to 60 years with clinical and radiological (MRI) diagnosis of lumbar disc herniation with backache and radiculopathy, who failed to respond to conservative therapy for duration of 6 weeks and denied the proposed surgical intervention, were included in the study. All patients had a positive straight leg raising test and no patient had any neurological deficit. The exclusion criteria included patients with prior back surgery, impending cauda equine syndrome or with cauda equine syndrome, back or leg pain due to other aetiologies (e.g. spinal fracture, metastasis, neuropathy, vascular claudication or neurogenic claudication), pregnancy, breast feeding status or medical disorders like bleeding diathesis, uncontrolled diabetes, connective tissue disorders, excessive smoking and severe COPD.

The cases enrolled in the study were planned for treatment with epidural injections through the caudal route and they were randomly allocated in to two groups. The group N patients received 10 ml of lignocaine (2%) diluted in 20 ml of normal saline and group S patients received 2 ml of methyl prednisolone (80 mg) mixed with 10 ml of lignocaine (2%) and diluted in 18 ml of normal saline. A total of 3 caudal epidural injections were given at an interval of 3 week irrespective of previous epidural injection effect. Detailed information about the type of the procedure and the possible side effects and complications was given to each patient. Written informed consent was obtained from patients before inclusion in the study. A specialist who was blinded to the chemical nature of drug, performed the caudal epidural procedures in a sterile operating room equipped with resuscitative and monitoring equipment, using fluoroscopy. A 50 ml syringe containing the treatment drug was prepared by an independent investigator who was not involved in the management of the patients and thus, the study was double-blinded. Patient was made to lie in the prone position with intravenous access and was monitored appropriately. After sterile preparation, entry point was made with 20 Gauge spinal needle at sacral hiatus after local anaesthetic infiltration under C –arm guidance in both anterior-posterior and lateral view and the assigned solution was injected slowly. After the procedure, patients were observed in post operative room for one hour and were discharged thereafter. After three injections, patients were followed at 1, 3, 6, 9 and 12 months. All patients were prospectively assessed with clinical examination, a neurological examination which included documentation

of motor strength on a scale of 0 to 5 (with 5 indicating normal strength). The visual analogue scale (VAS) pain score at 1, 3, 6, 9 and 12 month intervals for assessment of current back and lower extremity pain was used and was compared with initial values. Any decrement in the VAS pain scores of more than two scales was considered to be significant. An Oswestry Disability Scale (ODI) was employed to quantitate the level of function (on a 0 to 50-point scale, in which a higher score represented greater disability) and significant improvement and function was described as at least a 40% reduction in ODI. The straight leg raising test was also performed. All the cases were screened for any complications during the study period. The patients were given NSAIDs as rescue medications on an as and when needed basis.

2.1. Sample size

The sample size was calculated based on significant pain relief considering a 0.05 two-sided significance level, a power of 80%, and an allocation ratio of 1:1, 50 participants in each group were estimated. The data were analyzed by using the statistical software SPSS, version 17.0. The categorical data was analyzed by using the x2 test, while the continuous variables were analyzed by using the Student t-test and repeated ANOVA wherever required. The results were presented as median (range) and number (percentage) for continuous variables. A P-value < 0.05 was considered as statistically significant and P values < 0.001 as highly significant.

3. Results

Two patients in group S were excluded from the trial due to blinding failures. A further six patients (4 patients in group N and 2 in group S) were enrolled for surgery prior to 3 months follow-up. 5 patients(2 in group N and 3 in group S) at 6 weeks and 3(1 in group N and 2 in group S) patients at 3 months didn't attend for review follow up. So, these patients were excluded from the study.

Therefore at 1 year data was available for 104 patients. There was no difference in demographic profile between the two groups.

Table 1
Demographic Profiles Values were expressed as number and percentage or mean ±SD as appropriate.

	GROUP N(n = 53)	GROUP S(n = 51)	P value
AGE(yr)	44.9 ± 4.7	47.2 ± 4.9	.35(NS)
SEX(M/F)	38:15	40:11	.57(NS)
Height(cm)	168 ± 8.6	166.4 ± 8.8	.37(NS)
Weight(kg)	68.2 ± 9.2	69.8 ± 9.1	.26(NS)

No statistically significant differences were observed in the baseline scores between the 2 groups. The mean baseline VAS values were 7.5 ± 1.03 and 7.6 ± 1.05 for patients in N and S group respectively. The mean baseline ODI value before epidural injection was 62.9 ± 7.9 for patients in N group, while the respective score for patients in group S was 62.9 ± 8.5 (p>.05). The baseline lasegue angle in group N and group S was 42.3 ± 11.8 and 41 ± 12.8, respectively.

Table 2
Baseline and Final Values of Clinical Parameters in Both Groups along with Their P Values..

		Baseline(0 month)	At 12 month	P value
VAS score	GROUP N (n =53)	7.5 ± 1.03	1.55 ±. 59	< .01 (ES)
	GROUP S (n =51)	7.6 ± 1.05	1.6 ± .6	< .01 (ES)
	GROUP N (n =53)	62.9 ± 7.8	38.2 ± 4.03	< .01 (ES)
ODI	GROUP S (n =51)	62.9 ± 8.5	36.3 ± 5.4	< .01 (ES)
	GROUP N (n =53)	42.3 ± 11.8	66.8 ± 5.04	< .01 (ES)
Lasegue angle	GROUP S (n =51)	41 ± 12.8	65.8 ± 5.3	< .01 (ES)

At follow up period, pain scores were 4.8 ±.1, 4.0 ± .8, 2.6 ± .64, 1.6 ± .59 for group N and were 5.01 ± .12, 4.13 ± .8, 2.7 ± .70, 1.63 ± .6 for group S, Lasegue angle was 53.16 ± 7.7, 58.7 ± 7.0, 62.7 ± 8.4, 66.83 ± 5.0 for

group N and was 53.7 ± 8.6, 59.33 ± 7.5, 63.11 ± 7.7, 65.83 ± 5.3 for group S and ODI scale was 57.3 ± 8.73,43.5 ± 8.54,40.1 ± 5.7,38.2± 7.8 for group N and was 54.2 ± 8.54, 41.7 ± 7.54, 39.5 ± 6.03 ,36.2 ± 6.8 for group S at 1, 6, 9 and 12 month respectively that was changed significantly from baseline in both groups but with no significant differences between the groups (Figure 1, 2 and 3). We have also observed that at 1 month follow up 68% patients of group S observed a significant decrease in VAS but only 35% patient in group N ($P < .05$). But at 1 year follow up, this value increased to 87% patient in group S and 80% patients in group N ($P > .05$).

No patient reported any major immediate or late complication following caudal epidural Injection. Out of all injection procedures, there was feeling of dizziness during eleven injections(6 in group N, 5 in group S) however, their blood pressure and pulse rate were normal in all cases. None reported any lower limb dysfunction in terms of loss of sensation and/or reduced motor power, or bladder and bowel dysfunction.

4. Discussion

There have been various studies conducted to evaluate the role of steroids for chronic back pain via interlaminar (Gelalis 2009), transforaminal (Karppinen 2001) or caudal (Sayegh et al 2009, Iversen 2011) epidural route and to find out whether addition of steroid has any extra advantage.

As we have gone through the literature where multiple authors have evaluated accurate needle placement for caudal epidural injections with or without fluoroscopic guidance showing incorrect needle placement in 20% to 38% of patients(Stitz et al 1999, Manchikanti et al 2004). Also the volume which has been used in previous studies varied from 10ml to 30 ml (Manchikanti et al 2008, Iversen 2011). As Trotter ((1947)) concluded that sacral canal volume varied between 12 to 65 ml with 32 ml as mean. Rabinovitch DL et al (2009) done a systematic review and their preliminary results suggest 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. The hypothesis behind is that this high volume injectate displaces the dura forward and inward, producing a stretch of the nerve roots that leads to lysis of fibrous tissue (Rabinovitch 2009).This may be one reason that higher volumes can give increased benefit.

So we planned this study to use the fluoroscopically guided caudal epidural injection with 30 ml volume in the patient of lumbar disc herniation and also to evaluate the role of steroid in epidural injections with this higher volume.

Our study has demonstrated that caudal epidural injections with or without steroid for lumbar disc herniation pain result in significant decrease in VAS, improvement in ODI scale as well as improvement in Lasegue angle at long term follow up (Figure 1, 2, 3 respectively).

FIG.1 SHOWING VAS SCORE

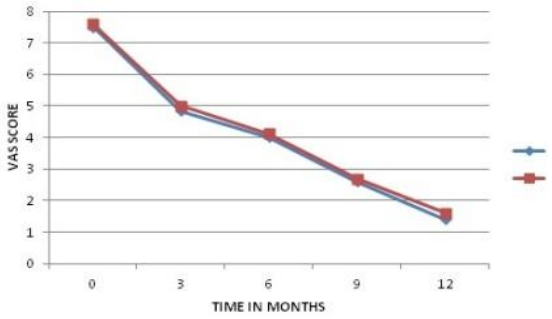


Figure 2 :Showing Lasegue Angle

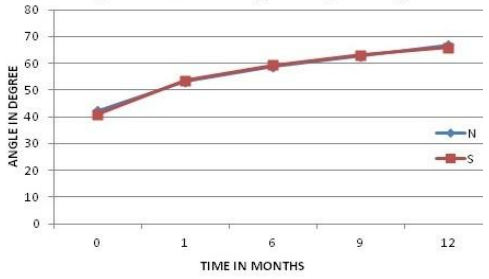
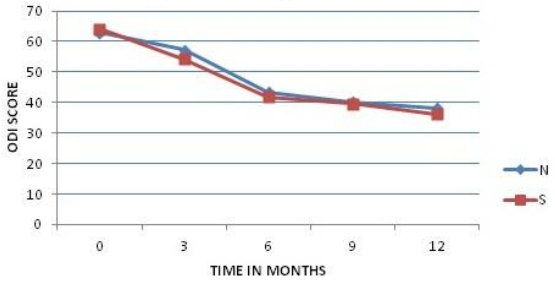


Fig 3:Showing ODI Score



Same result were observed by Manchikanti L et al. (2008) who reported that significant pain relief (≥ 50%) in 79% to 81% of the patients with significant improvement in functional status (40% or greater reduction in Oswestry scores) in 83% to 91% of the patients at the end of one-year follow-up with no significant differences noted with or without steroids. Sayegh et al. (2009) and Iversen T et al. (2011) also observed the same as they compared the caudal epidural steroid with normal saline and concluded that steroid results early benefit but in long term results are almost same.

In our study we observed that at 1 month follow up 68% patient of group S observed a significant decrease in VAS but only 35% patient in group N (P <0 .05). But at 1 year follow up, this value increased to 87% patient in group S and 80% patient in group N (P >0.05). Same results were obtained by Karpinnen et al (2001) who observed that peri-radicular infiltration of corticosteroids for sciatica produces a short-term benefit in terms of improvement in leg pain. This study found that leg pain improved at 2 weeks by 45% in the steroid group when compared with 24% in the saline group, but at 3, 6 months and 1 year after the injection there was no treatment effect of steroids over saline (Figure 1, 2, 3)

The mechanism of action of epidurally administered steroid and local anaesthetic injections is still not well understood. It has been found that corticosteroids reduce inflammation by inhibiting either the synthesis or release of a number of pro-inflammatory mediators (Flower et al 1979, Byrod et al 2000). And the local anaesthetics provide short- to long-term symptomatic relief by suppression of nociceptive discharge, the block of axonal transport of the sympathetic reflex arch, the block of sensitization, and anti-inflammatory effect (Mao et al., 2000).

In our study we have observed that the significant improvement of SLR and ODI was observed in both the groups at follow up period but the difference between the groups was not significantly different (Figure 2). Javed S et al. (2008) also observed that caudal epidural steroid injection result in significant improvement in SLR.

5. Conclusion

Normal saline or saline mixed with steroid provides same benefit at long term but at one month steroid group patients showed more relief as compared to saline group. The limitation of our study is that we have used higher volumes as compared to previous studies but their results are comparable to our study. But since we have also observed that some patients felt dizziness which was not reported in previous studies, so further studies are required regarding safe volume of drug to be used in caudal epidural injections.

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