ISSN- O: 2458 - 868X, ISSN–P: 2458 – 8687
Index Copernicus Value: 68 . 16
PubMed - National Library of Medicine - ID: 101731606

International Journal of Medical Science and Innovative Research (IJMSIR)
IJMSIR : A Medical Publication Hub
Available Online at: www.ijmsir.com
Volume – 5, Issue –2, April - 2020, Page No. : 209 - 216

Effects and Outcome of Epidural Steroids for Low Back Pain

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Citation this Article: Dr. Jain Prerana, Dr. Singh Prabhanjan, "Effects and Outcome of Epidural Steroids for Low Back Pain", IJMSIR- April - 2020, Vol – 5, Issue -2, P. No. 209 – 216.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Chronic Low back pain (LBP) is a clinical syndrome of back and leg pain accompanied by sensory, reflex or motor deficits in a nerve root distribution lasting for more than 12 weeks. Epidural steroids injection (ESI) with local anaesthetic with or without adjuvents is administered into epidural space to relieve such pain. From the previous study results and hypothesis, we decided to conduct double blind randomized controlled study on " Effects and outcome of epidural steroid injection for low back pain" using triamcinolone acetate 80 mg and methylprednisolone 80 mg with 0.0625% bupivacaine.

Materials and method: After obtaining the ethical committee approval and following all the institutional protocols, patients of age between 18-70 years and body mass index 18-30kg/m^2 with recurrent episodes of back pain more than 4 weeks were included in this double blind, randomized, comparative study. All the patients were divided randomly into 2 groups of 25 patients each using block randomization sequence by paper chit selection method as per the drugs administered: **Group T (n=25)** received Triamcinolone 80 mg+0.0625% bupivacaine and **Group M (n=25) received** Methylprednisolone 80 mg+0.0625% bupivacaine. Epidural injection was given through midline approach under fluoroscopic guidance. Subsequent injections were given at an interval of 21 days, maximum being three injections. At each visit , pain and functional disability was monitored using the **10 point visual analog scale** and **Oswestry disability index** respectively. Information on use of analgesics and complications, if any was also recorded.

Observation: The pain relief was observed in both the groups and the scores were better in both the groups over the follow up period. Disability improvement was observed in both the groups significantly over the time post procedure but the difference was comparable in both groups. The use of analgesics decreased in both the groups significantly and the patient response was satisfactory.

Conclusion: Triamcinolone and methylprednisolone are equally effective as epidural steroid for the management of chronic low back pain with no significant short and long term complications.

Keywords: Low back pain, Epidural steroids injection, Triamcinolone, Methylprednisolone.

Introduction

Chronic Low back pain (LBP) is defined as a clinical syndrome of back and leg pain accompanied by

sensory, reflex or motor deficits in a nerve root distribution lasting for more than 12 weeks.[1] The origin of chronic back pain is often assumed to be degenerative conditions of the spine; however, controlled studies have indicated minimal or nonexistent correlation between clinical symptoms and radiological signs of degeneration. Inflammatory arthropathy, metabolic bone conditions, and fibromyalgia are the other causes of chronic spine-related pain conditions.[2]

Treatment of LBP is a multimodal approach. Initially LBP is treated conservatively with NSAIDS, antidepressants, anticonvulsants, oral and epidural steroids, transcutaneous electrical nerve stimulation (TENS), tractions, ultrasound and physiotherapy modalities. [3]

Epidural steroids injection (ESI) is injection of costicosteroids mixed with local anaesthetic with or without adjuvents administered into epidural space to relieve pain of spinal origin. Rationale behind use of corticosteroids is supposed to be suppression of biochemical factors of inflammation leading to reduction in soft tissue swelling, oedema, pressure, adhesions and slow regression of disc herniation.

ESI are always recommended in conjuction with a formal physical therapy program such as a dynamic spine stabilization programs which include spine mobility and strengthening exercises and postural and dynamic body mechanics training.[1,4,5]

From the previous study results and hypothesis, we decided to conduct double blind randomized controlled study on " Effects and outcome of epidural steroid injection for low back pain" using triamcinolone acetate 80 mg and methylprednisolone 80 mg with 0.0625% bupivacaine.

Materials and Methods

After obtaining the ethical committee approval and following all the institutional protocols, patients of age between 18-70 years and body mass index 18-30kg/m^2 with recurrent episodes of back pain more than 4 weeks were included in this double blind, randomized, comparative study after obtaining the informed and written consent.

Patients allergic to local anaesthetic agent, antibiotics or radiographic dyes, having coagulopathies, pregnant women and having structural spinal deformities were excluded from the study.

Pre procedure evaluation included complete history, detailed examination and investigations. Onset, duration, intensity, characteristic of pain, aggravating and relieving factors was noted. Past history, current medications and present VAS score was also noted. The nerve root irritation and radicular pain was assessesd using the straight leg raising test (SLRT). The functional status was evaluated using the Oswestry Disability Index (ODI) and Brief Pain Inventry (BPI) before and after the procedure. Presence and absence of paraspinal muscle spasm was documented. Motor and sensory deficits were also recorded. The diagnosis was confirmed on the basis of Magnetic resonance imaging (MRI) which was also correlated clinically and the level was confirmed.

All the patients were divided randomly into 2 groups of 25 patients each using block randomization sequence by paper chit selection method as per the drugs administered:

- Group T (n=25) received Triamcinolone 80 mg+0.0625% bupivacaine
- Group M (n=25) received Methylprednisolone 80 mg+0.0625% bupivacaine

Informed and written consent for the procedure was

taken in the patient's language. Patient was checked for vital parameters (Pulse, NIBP, Temperature, respiratory rate) and taken to the procedure room. Patients were given either lateral or prone position on the table. Targeted lumbar area was properly prepared with betadine solution and spirit. Proper draping was done. Target level was localized and correct level identified in anteroposterior(AP) and lateral view under fluoroscope. Inj.2% lignocaine 2ml was given at the injection site with 24G hypodermic needle.

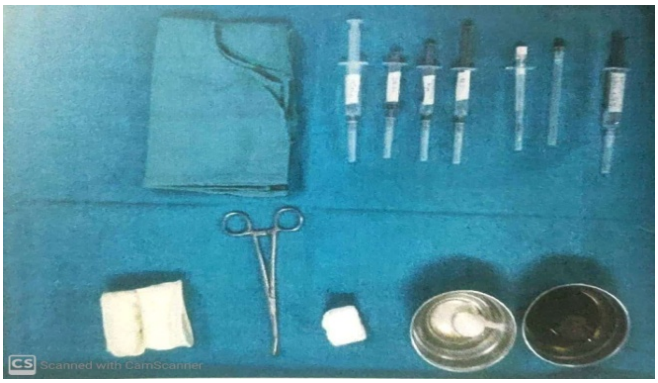

Figure 1: Preparation of the procedure.

A midline approach is used through the space between the lamina of vertebrae. The structures piecered by the epidural needle are skin, subcutaneous tissue, paraspinal muscles and lastly ligamentum flavum. The loss of resistance to fluid (LORF) technique was used for the placement of the Tuohy needle in the dorsal epidural space. Correct placement of the needle was confirmed by inj. Iohexol dye spread under fluoroscopy. Patients were then given the steroid preparation according to the assigned group with local anaesthetic agent. After the completion of the procedure the patients were shifted to recovery room and observed for 30 minutes. On discharge, the patient were instructed with DO'S and DON'T'S protocol. 2nd injection was repeated 21 days after the 1st injection and the 3rd was given 21 days after the 2nd injection. At each visit , pain and functional disability was monitored using the **10 point visual analog scale**(0-10 point scale) and **Oswestry disability index**(0-20%-minimal disability,21-40%-moderate disability,41-60%-severe disability,61-80%-crippled,81-100%-bed ridden) respectively. Information on use of analgesics and NSAIDS was also recorded on individual's cards.

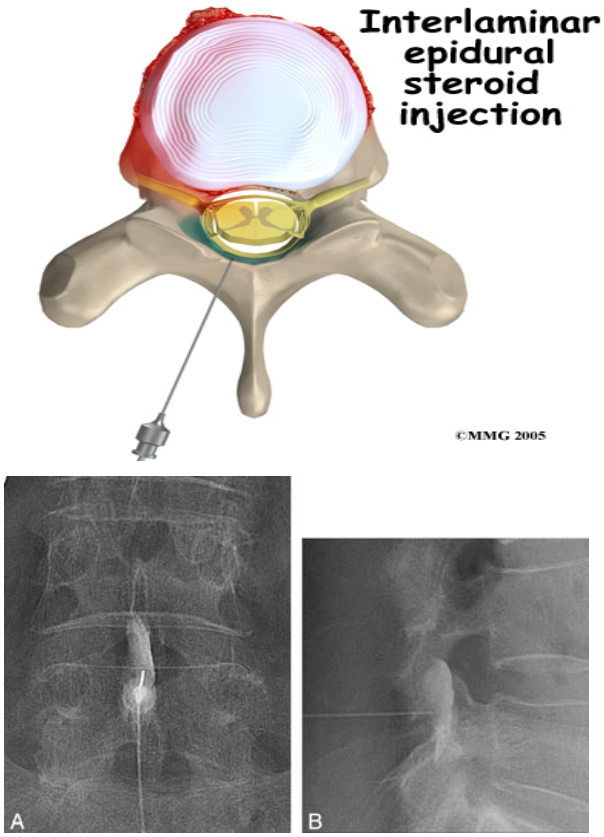

Figure 2: Epidural steroid injection and fluoroscopic images.

Patients were observed for immediate temporary complications like lightheadedness, nausea, increased radicular pain, non specific headache, vasovagal reaction and paraplegia, pain during injection and also for late complications related to corticosteroids.

Stastical analysis was performed to compare the efficacy of the two steroids using student 't' test and p value < 0.05 was considered significant.

Observation and Results

The two groups were comparable with respect to age, gender, and body mass index.

Table 1: Demographic Data

	Group T(N=25)	Group M(N=25)	P Value
Age (Years)	46.68 ± 11.48	45.68 ± 11.65	0.7612
Gender(M:F)	19:6	13:12	
Body Mass Index(Kg/M^2)	22.63 ± 2.67	23.81 ± 2.04	0.0855

Table 2: Level of Injection

Level Of Injection	Group T(N=25)	Group M(N=25)
L1-L2	-	-
L2-L3	-	1 (4%)
L3-L4	4 (16%)	2 (8%)
L4-L5	15 (60%)	16 (64%)
L5-S1	6 (24%)	6 (24%)

Table no. 2 shows that maximum patients had L4-L5 disc involved and this was the commonest level at which the procedure was performed probably this being the weight bearing point in the spinal column.

Table 3: Visual Analog Score

Vas	Group T(N=25)	Group M(N=25)	P Value
Average Last Week	3.44±0.57	3.48±0.57	0.8051
Last 24 Hours	4.04±0.72	4±0.28	0.7986
Pre Procedure	4.12±0.58	4.16±0.46	0.7882
Post Procedure	1.92±0.48	1.56±0.75	0.2574
1st Follow UP	2.08±0.86	1.92±0.68	0.4691
2nd Follow UP	1.92±0.89	1.52±0.75	0.0922
3rd Follow Up	1.48±0.57	1.32±0.54	0.3134
3rd Month	1.48±0.57	1.16±0.46	0.0338 *

Table no.3 and fig no. 3 presents the VAS score in both the groups. The pre procedure VAS score and in the last 24 hours was significantly higher but was comparable in both the groups ($p<0.05$). VAS score improved post procedure and was better during the first, second and third follow up in both the groups. During the 3rd month follow up the VAS score was significantly better in Group M ($p=0.0338$) when compared to Group T.

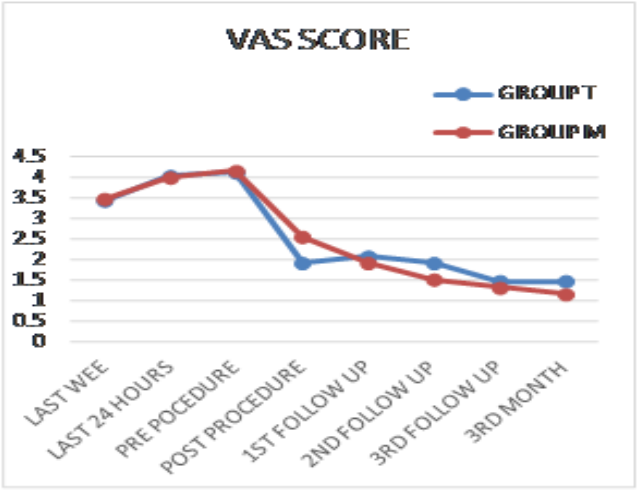

Figure 3: VAS score

Table 4: Oswestry disability index (ODI)

ODI	Group T(N=25)	Group M(N=25)	P Value
Pre Procedure	11.36±3.23	11.44±2.29	0.92
Post Procedure	7.76±2.62	9.48±7.61	0.2906

1st Follow Up	6.92±2.46	7.24±2.12	0.6245
2nd Follow Up	6.08±2.17	6.56±2.06	0.4264
3rd Follow Up	5.4±2.26	5.76±2.14	0.5657
3rd Month	5.12±2.14	5.2±1.67	0.8835

Figure 4: ODI

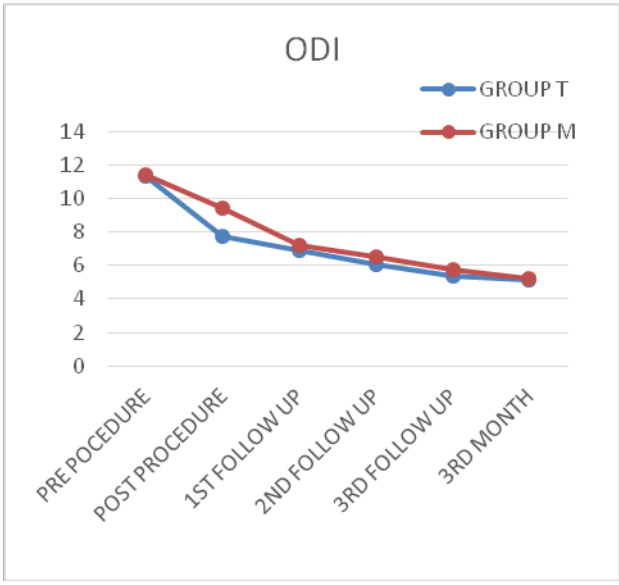

Table no. 4 and fig no. 3 compares the ODI scores among the groups. Most of the subjects presented with moderate disability in both the groups and the pre procedural ODI score was comparable among the groups (p=0.92).The post procedure ODI score improved in both groups but the difference was insignificant among the groups at 1st,2nd,3rd follow up and 3rd month.

Table 5: Medication Use

Medication Use (No. Of Tablets Per Day)	Group T	Group M	P Value
Pre Pocedure	1.88±0.32	2±0	0.4153
3 Weeks	1.25±0.43	1.2±0.4	0.6722
6 Weeks	1.15±0.36	1.25±0.43	0.3771
9 Weeks	1±0	1.2±0.4	0.2797
12 Weeks	1.16±0.37	1.33±0.47	0.1618

Table no. 5 shows the consumption of analgesic medications pre and post intervention. The consumption of tablet brufen was significantly higher in both the groups and the difference was comparable (p=0.4153). The use of the analgesics decreased significantly in the post intervention period in both the groups at 3, 6, 9 weeks and 3rd month.

Table 6: Complications

Complications	Group T(N=25)	Group M(N=25)
Electrifying Shock Like Feeling	8 (32%)	12 (48%)
Pain On Injection	5 (20%)	13 (56%)
Allergic Reactions	-	-
Corticosteroid Related	-	-

The table no. 6 shows that there were no long term corticosteroid related complications. Acute complications like electrifying shock like sensation and pain on injection were seen in both the groups.

Discussion

Epidural steroid injections have been used for decades in the management of low back pain. It is minimally invasive and effective treatment modality[6]. The first reported use of epidural steroid was in 1952 by Robecchi and Capra.[7]

Epidural steroid injection following epidurography (fluoroscopic guidance) is found to be superior to the blind technique[6,8]. Ultrasonography have also been attempted to confirm the drug placement via LESI[6]. There are several types of steroid being used for epidural injection like hydrocortisone, betamethasone, triamcinolone and methylprednisolone.

We conducted this study with an objective to compare the efficacy of methylprednisolone and triamcinolone in chronic low back pain through epidural route.

The steroids are known for its anti inflammatory properties, stabilization of neural membranes, suppresses the ectopic neural discharge and may also have anaesthetic effect on unmyelinated C nociceptive fibres[5,6,7,9]. Methylprednisolone has an intermediate duration of action and its sodium retaining potency is half of cortisol and anti inflammatory potency is five times. The preservative benzyl alcohol is neuro toxic increasing the chance of meningitis and arachnoiditis[6]. Triamcinolone is also an intermediate acting drug with similar anti inflammatory potency as methylprednisolone but lacks the sodium retaining capacity. It is less soluble and remains in the suspension for longer period at the injection site as compared to methylprednisolone and this has been a proposed mechanism for increased local effects[6]. Since,steroids remain in situ for approximately two weeks ,this is logically the minimum time period to assess the patient's response and to administer a repeat injection.

The pre and post procedure VAS score was assessed. The VAS score before the procedure was higher in both the groups but there was no statistical difference among the groups. VAS score immediately after the procedure and in the subsequent follow ups improved significantly in both the groups but was significant in Group M at follow up of 3rd month. The result in our study is supported by **Huda N et al[10]** in 2010. They deduced from a study of 70 subjects that methylprednisolone achieved better pain relief and improved VAS scores when compared to triamcinolone in long term.

The functional assessment was done by Oswestry disability index. Most subjects in both the groups presented with moderate disability. The ODI scores were higher but comparable in both the groups before the procedure. The ODI scores were much better after the procedure and in all the follow ups upto 3rd month in both the groups but the difference was insignificant. The results correlated with the findings of **Koes BW et al[11] in 1995 and Huda N et al in 2010.**

The consumption of analgesic medication was assessed to evaluate the efficacy of ESI. The use of analgesic medication was significantly reduced in both the groups compared to pre intervention at 3,6,9 weeks and at 3rd month. This could be associated with the anti inflammatory properties of the steroids. This finding in our study was consistent with the study of **Datta R and Upadhyay KK 2010[6]** who compared methylprednisolone, dexamethasone, triamcinolone with bupivacaine through caudal route in LBP patients and found the consumption of analgesic medications decreased in the all the three steroids.

No chronic complications occurred during the study but the pain on injection was significantly higher in Group

M which may be attributed to the particulate nature of methylprednisolone.

Limitations of the study

1. Follow up was done only for 3 months
2. The sample size is small
3. Lack of control group
4. Since the patients were sent home we could not monitor whether the subjects took any other modalities of treatment for LBP

Conclusion

The pain relief was observed in both the groups and the scores were better in both the groups over the follow up period. The pain relief was significantly better with methylprednisolone at 3 months post procedure. Disability improvement (ODI SCORE, brief pain inventory) was observed in both the groups significantly over the time post procedure but the difference was comparable in both groups. The use of analgesics decreased in both the groups significantly and the patient response was satisfactory. No major acute or chronic complications were observed but pain on injection was significant with methylprednisolone.

Hence, triamcinolone and methylprednisolone are equally effective as epidural steroid for the management of chronic low back pain with no significant short and long term complications.

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