

Original Research Article

Effectiveness and cost-utility of lumbar facet joint blocks using bupivacaine with and without steroid in the treatment of chronic low back pain in adults

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ABSTRACT

Background: Chronic low back pain (LBP) causes lot of pain and suffering thus contributing to frequent and increased cost and burden on health-care-facilities. In United Kingdom, it has been estimated that economic cost of LBP pain is around £12.3B per annum. It is also associated with increased incidence of depression, anxiety. These morbidities also lead to increased costs for patient. To study effectiveness and cost-utility of lumbar facet joint blocks using bupivacaine with and without steroid in the treatment of chronic LBP in adults.

Methods: Hospital-based randomized comparative study was carried out among 100 adult cases of chronic LBP. They were randomly assigned as 50 cases treated with bupivacaine without steroids and 50 cases treated with bupivacaine with steroids. Modified Oswestry disability index was used to assess functional improvement and visual analogue scale to assess pain score. Patient data was used to assess cost-utility.

Results: Patients in group-II were significantly older, had more pain duration than group-I. Incidence of repeat procedure required was more in group-I compared to group-II ($p < 0.05$). The functional level in both groups was comparable ($p > 0.05$) at baseline. At one, three, six and twelve months, it improved more significantly in group-II compared to group-I ($p < 0.05$). At baseline, pain score was significantly more in group-II compared to group-I ($p < 0.05$). But, at one, three, six and twelve months, it was significantly lesser in group-II compared to group-I ($p < 0.05$). Patients in both groups were comparable for physician cost and facility cost. But total number of procedures and average number of treatments per patient were lesser in group-II compared to group-I.

Conclusions: Thus, we conclude that bupivacaine with steroids is not only effective in relief of pain and returning normal functionality, but also cost-effective compared to bupivacaine without steroid in adult patients with chronic LBP.

Keywords: Efficacy, Pain, Steroids

INTRODUCTION

Chronic low back pain (LBP) in the adults may be due to lumbosacral facet joint issues. Prevalence of this kind of chronic low back pain varies from 15% to 45%.^{1,2} The chronic low back pain in the adults due to syndrome related to the lumbar facet is controversial. Some say that it is due to the lumbar facet syndrome while others say that the lumbar facet syndrome has no role in the chronic low

back pain.^{3,4} Similarly, the controversy exists with regard to its treatment modalities. Mainly there are three types of treatment modalities. Intra-articular injections, medial branch blocks and neurolysis of medial branches. Among these, the intra articular injections are found to have long term benefit to the patients.^{3,5} But the benefits of the other two modalities are doubtful. Chronic LBP causes lot of pain and suffering thus contributing to frequent and increased cost and burden on the health care facilities. In

the United Kingdom, it has been estimated that the economic cost of the chronic low back pain is around £12.3B per annum. It is also associated with increased incidence of depression, anxiety in the patients. These morbidities also lead to increased costs for the patient.^{6,7} Lumbar facet joints have encapsulated nerve endings. Medial branch nerves have medial branches which supply to these facet joints. Any part of facet joints like fibrous capsule, synovial membrane etc. if affected can lead to chronic low back pain in the adults.⁸

Intra articular injections in the facet joint are common treatment modality used to treat chronic low back pain in the adults. There are also other methods as mentioned above which not very well proven. Usually, a steroid is injected with a local anesthetic in the facet joint.⁹ With this background, present study was carried out to study the effectiveness and cost-utility of lumbar facet joint blocks using bupivacaine with and without steroid in the treatment of chronic low back pain in adults.

METHODS

This was a single center, hospital based, randomized comparative study carried out at a tertiary care facility among adult patients having chronic low back pain over a period of two years. Institutional Ethics Committee permission was obtained. Written informed consent was taken from all the patients included in the present study.

Adult patients of either gender with chronic low back pain of at least three months duration, with or without sciatica, were included in the present study. Those with radiculopathy, claudication, low back pain due to rheumatoid etiology, congenital deformity, traumatic deformity, fracture of spine, underwent surgery of spine, treated with systematic steroids, having high blood sugar levels which are not under control, allergic to any drugs especially anesthetics, pregnancy and not willing to come for follow-up were excluded from the present study.

During the study period, it was possible to recruit a total of 100 cases with chronic low back pain with above mentioned eligibility criteria. These cases were randomly allocated into two groups. Computer generated random numbers were used to allocate the patients into two groups. Group I patients were given bupivacaine but steroid was not combined. Group II patients were given bupivacaine with steroids. All patients were followed for a total period of one year. They were asked to come for the follow-up at one, three, six and twelve months from the date of first treatment which was considered at baseline.

Once the patient was allocated to group, his/her baseline details were recorded in the pre-designed, semi-structured study questionnaire. Pain was assessed with the help of visual analogue scale (VAS) which is a 10-point scale. The patient was shown the scale and was asked to grade his/her current pain level. Once, the patient indicated, we recorded the same for that particular patient. Functional assessment

was carried out with the help of modified Oswestry disability index (MODI). For cost utility analysis, all relevant details were enquired for and noted down.

All patients underwent magnetic resonance imaging scan (MRI) of spine using 1.5T magnet. The patients were asked to lie down in supine position, with extended lower limbs. Multichannel spine dedicated coil was used. The MRI was done using the standard guidelines and protocol. Czervionke classification was used for grading the facet joint inflammation on MRI.¹⁰ No edema was graded as zero. When edema was limited to only joint capsule it was graded as one. When edema extended beyond joint capsule but not more than 50%, it was graded as grade two. When it involved more than 50% of peripheral area, it was graded as grade three. When it extended into intervertebral foramen and other parts, it was graded as grade four.

All patients were treated with facet joint injection using standard techniques and appropriate guidelines were followed. The patient was asked to be in the prone position. The site was cleaned thoroughly for asepsis. The C-arm was positioned in such a way that facet joint can be visualized properly. Lidocaine 0.5% in small quantity was used to anesthetize the local area. 22-gauge lumbar puncture needle was used and it was introduced in the facet joint till the resistance. Then the group I patients were given bupivacaine without steroids and the group II patients received bupivacaine with steroids.

The data was entered in the Microsoft excel worksheet and later exported to SPSS statistical software version 22. Chi square test or the Fischer exact test was used to compare the proportions in two groups. Independent samples t test was used to compare the mean values in two groups. P value less than 0.05 was considered as statistically significant.

RESULTS

Patients in the group II were significantly older compared to the group I patients. At the same time, the patients from the group II had more pain duration compared to group I patients. These differences were found to be statistically significant ($p < 0.05$). However, both the group were comparable for sex distribution ($p > 0.05$) (Table 1). For patients with group, I who received the bupivacaine but no steroids, the incidence of repeat procedure required was 40% compared to only 6% in group II who received steroids along with bupivacaine. This difference was found out to be statistically significant ($p < 0.05$) (Table 2).

The functional level in both the groups was comparable ($p > 0.05$) at baseline. At one, three, six and twelve months, the functional level improved more significantly in group II patients compared to group I patients ($p < 0.05$). At baseline, the pain score was significantly more in the steroid group compared to the non-steroid group ($p < 0.05$). But, at one, three, six and twelve months, it was significantly lesser in group II patients compared to group

I patients ($p<0.05$) (Table 3). Table 4 shows the cost utility of bupivacaine with steroids compared to bupivacaine without steroids. Patients in both the groups were comparable for physical cost and facility cost. But total

number of procedures and average number of treatments per patient were lesser in group II patients compared to the group I patients.

Table 1: Comparison of demographic profile in two groups.

Demographics	Group I (Bupivacaine without steroids)	Group II (Bupivacaine with steroids)	P value
Age (in years)	44.84±14.95	51.92±13.88	0.016
Pain duration in months	4.5±1.8	9.4±4.3	0.0001
Sex	Female	21 (42%)	0.316
	Male	29 (58%)	
		24 (48%)	

Table 2: Comparison of efficacy of bupivacaine with steroids in terms of repeat procedures required.

Repeat procedure required	Group I (Bupivacaine without steroids)	Group II (Bupivacaine with steroids)	P value
Yes	20 (40%)	3 (6%)	0.0001
No	30 (60%)	47 (94%)	

Table 3: Comparison of function and pain in two groups.

Variables		Group I (Bupivacaine without steroids)	Group II (Bupivacaine with steroids)	P value
Function (MODI)*	Baseline	27.28±3.65	27.7±4.45	0.608
	At one month	19.92±8.66	12.7±5.01	0.0001
	At 3 months	11.88±5.65	9.12±1.82	0.001
	At 6 months	8.72±2.79	7.02±2.59	0.002
	At 12 months	8.02±3.24	6.64±2.88	0.027
Pain scores	Baseline	8.24±0.59	8.66±0.65	0.001
	At 1 month	5.66±2.25	3.32±1.28	0.0001
	At 3 months	3.22±1.75	2.0±0.83	0.0001
	At 6 months	2.28±1.29	1.32±0.98	0.0001
	At 12 months	2.04±1.32	1.38±1.02	0.006

*Modified Oswestry Disability Index

Table 4: Comparison of cost-utility in two groups.

Variables	Group I (Bupivacaine without steroids)	Group II (Bupivacaine with steroids)
Total number of procedures	50	50
Average number of treatments per patient	1.4	1.06
Physician cost (INR)	8000	8000
Facility cost (INR)	12000	12000
Total procedures	1400000	1060000

DISCUSSION

Patients in the group II were significantly older compared to the group I patients. At the same time, the patients from the group II had more pain duration compared to group I patients. These differences were found to be statistically significant ($p<0.05$). However, both the group were comparable for sex distribution ($p>0.05$). For patients with group, I who received the bupivacaine but no steroids, the incidence of repeat procedure required was 40% compared to only 6% in group II who received steroids along with

bupivacaine. This difference was found out to be statistically significant. ($p<0.05$). The functional level in both the groups was comparable ($p>0.05$). At one, three, six and twelve months, the functional level improved more significantly in group II patients compared to group I patients ($p<0.05$). At baseline, the pain score was significantly more in the steroid group compared to the non-steroid group ($p<0.05$). But, at one, three, six and twelve months, it was significantly lesser in group II patients compared to group I patients ($p<0.05$). Patients in both the groups were comparable for physician cost and

facility cost. But total number of procedures and average number of treatments per patient were lesser in group II patients compared to the group I patients. Additional costs of repeated travelling and overnight stay with miscellaneous expenses were more with Group 1 pts (which were not calculated).

Manchikanti L et al, carried out a randomized clinical trial (RCT) among 84 case who were randomized in two groups in which first group were given sarapin and local anesthetic injection while group two patients were given methyl prednisolone in addition to what group one received. The authors concluded that “medical branch block with sarapin and local anesthetic was cost effective whether you add steroid or not. However, in the present study, we found that the addition of steroid was actually cost effective.”¹¹

Cohen et al, conducted a RCT in which they randomized 229 cases in three groups.¹² First group was given steroid with bupivacaine in the form of intra articular facet injections. Second group was given the blocks of medial branch while the third group was given the saline. At the end of one month all the three groups were comparable for reduction in the pain score. Positive blocks were significantly more in the medial branch group and also in the intra articular group compared to the control group. Again, the pain score was comparable in the three groups after the radiofrequency ablation at the end of three months. The authors concluded that facet blocks were not therapeutic. Probably the facet blocks indicate the prognosis after radiofrequency ablation.

Boswell et al, evaluated the effectiveness of different types of facet joint intervention in the treatment and management of chronic low back pain.¹³ For this, they carried out a systematic review. They observed that facet joint injections for cervical intra articular, there is limited evidence. In case of lumbar intra articular, there is moderate evidence for pain relief in the short term and in the long term. The authors concluded that for facet joint injections is evidence ranged from moderate to limited. For medial branch blocks, the range of evidence was from moderate.

Manchikanti et al, carried out a cost utility analysis of lumbar facet joint nerve blocks in patients with chronic low back pain.¹⁴ They found that over a period of two year, the patients had undergone around 5.6 procedures on an average. The mean relief during this period was about 82.8 weeks. The cost for the procedures over a period of one year was 2654.08 USD. The total cost which included the indirect cost and drugs with multiplication stood at 4432 USD. The authors concluded that the procedure was cost effective.

CONCLUSION

Thus, we conclude that bupivacaine with steroids is not only effective in relief of pain and returning normal

functionality, but also cost-effective compared to bupivacaine without steroid in adult patients with chronic low back pain.

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