



**ORIGINAL RESEARCH PAPER**

**Anesthesiology**

**EVALUATION OF THE EFFECTIVENESS OF EPIDURAL ROPIVACAINE 0.1%, WITH TRAMADOL , BUPRENORPHINE AND FENTANYL IN LOW BACK PAIN.**

**KEY WORDS:** Conservative Treatment, Low Back Pain, Methodology, Randomized Controlled Trials, Systematic Review

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**ABSTRACT**

**Aim:** To compare the efficacy of 0.1% Ropivacaine with Tramadol, Buprenorphine and Fentanyl for relief of low back pain and sciatica, its effect on vital parameters and any side effects.

**Method:** 90 patients belonging to ASA grade 1 and 2 were allocated into 3 groups. Group A received Tramadol 50 mg, Group B received Buprenorphine 0.1 mg and Group C fentanyl 20 micrograms. The patient were observed pre block, then at 1 hr, 4 hr. (at discharge), 24hr then 1 week and 6 weeks after block. The assessment of pain was done using Visual analogue scale. The data was tabulated and statistically analyzed using student paired "t-test".

**Result:** In cases of sciatica results were excellent (71.42%) after 1 and 6 weeks, while in patient with PID it was 58.22%. In patient with sacral canal stenosis there was no relief in pain. In all the 3 groups of analgesics, pain relief was statistically and clinically significant after 1 hour of epidural injection.

**Conclusion:** We concluded from the study that extradural medication through epidural route in the treatment of low back pain proved to be of great success in various etiological factors. It is one of the best non-surgical, semi-invasive methods available. The use of adjuvants like Tramadol, Buprenorphine and fentanyl increased the efficacy of analgesia.

**INTRODUCTION**

The effect of chronic low back pain on our society is enormous, in terms of both human suffering and cost. Many treatments have been advocated, but few have been rigorously tested in controlled trials. Low back pain is defined as an acute, subacute, or chronic discomfort localized to the anatomic area below the posterior ribs and above the lower margins of the buttock. Low back pain is second only to the common cold as the most common affliction of mankind. The lifetime prevalence of back pain exceeds 70% in most industrialized countries.

Low back pain (LBP) is one of the most prevalent medical problems in society today. In addition to the profound effect LBP can have on patients, it has an exceedingly high societal cost. Although most acute episodes of back pain will ultimately resolve, this condition will become chronic for many. Those with chronic LBP are a challenge to treat. Nonetheless, with a better understanding of the underlying patho physiology and treatment options, our management of these patients is gradually improving. Conservative therapy remains the mainstay treatment of chronic LBP.

The impact of low back pain (LBP) on society has been evaluated by a number of studies. The National Health and Nutrition Examination Survey II demonstrated the prevalence of back pain lasting more than 2 weeks to be 16% for persons aged between 25 and 74 years. The small percentage of patients who do not recover and progress to chronic LBP, defined as having duration more than 12 weeks, accounts for the greatest costs. Therefore, the most effective treatments are aimed at reducing recovery time and preventing the progression from acute to chronic pain.

Low back pain is the commonest problem in adult and elderly population visiting pain clinic. In majority of cases the cause is Idiopathic followed by PID. The aim of present study was to draw attention to the value of epidural injection using local anesthetic along with tramadol, buprenorphine and fentanyl as adjuvant.

**OBSERVATIONS**

The present study is based on observation recorded in 90 patients of low-back pain who were administered 0.1% Ropivacaine with tramadol, buprenorphine and fentanyl by epidural injection. The study was carried out in the department of Anesthesiology NSCB Medical College Jabalpur.

**TABLE NO. 1 SHOWING DRUG DISTRIBUTION**

Group	No. of Patients	Drug distribution	Dose
A	30	Tramadol HC 1	50 mg
B	30	Buprenorphine HC 1	0.1 mg
C	30	Fentanyl	20 micrograms

Study covered 90 patients of both sex in the age group 21-60 years. These patients were randomly divided into three groups of 30 each. Group A received Tramadol HC 1 50 mg. Group B received 0.1 mg Buprenorphine HC1 and Group C received fentanyl 20 micrograms mixed in 0.1% Ropivacaine 10cc.

**TABLE NO. 2 NATURE OF RESULTS THE BASIS OF CLINICAL DIAGNOSIS**

Diagnosis	No.	Result of Therapy				P Value
		Excellent	Good	Fair	Poor	
PID	34	19 (55.88%)	7 (20.58%)	5 (14.7%)	2 (5.88%)	Significant
Spondylolisthesis	6	-	5 (75%)	1 (25%)	-	significant
Sciatica	24	15 (71.42%)	6 (21.42%)	3 (7.14%)	-	significant
Spondylosis	8	-	6 (75%)	2 (25%)	-	Not significant
Sacral canal stenosis	4	-	-	-	4 (100%)	Not significant
Operated case of PID	4	2 (50%)	2 (50%)	-	-	Not significant

Table showing results of therapy.

**TABLE NO. 3 GRADATION OF RESPONSE**

Response	Tramadol HC 1		Buprenorphine HC 1		Fentanyl	
	No.	%	No.	%	No.	%
Excellent	14	45	9	30	15	50
Good	9	30	11	36.7	10	35
Fair	4	10	6	20	3	10
Poor	3	15	4	13.33	2	5

Gradation of response was done based on subjective pain relief, after epidural injection. Most of the patients showed excellent response to the therapy.

**TABLE NO. 4 RESULT AT FOLLOW-UP**

Result	Tramadol HC1		Buprenorphine HC1		Fentanyl		P Value
	No.	%	No.	%	No.	%	
Cured	11	45%	14	55%	14	45%	Significant
Relieved	11	45%	10	35%	10	40%	Significant
Unrelieved	8	10%	6	10%	6	15%	Not significant

**TABLE NO. 5 SHOWING SIDE EFFECTS**

Side effect	Tramadol HC1	Buprenorphine HC1	Fentanyl	P Value
No side effect	19 (75%)	14 (55%)	19 (70%)	NS
Sedation	07 (15%)	08 (25%)	06 (20%)	NS
Nausea	04 (10%)	06(15%)	05 (10%)	NS
Vomiting	-	-	-	NS
Dysphoria	-	-	-	NS
Dizziness	-	-	-	NS
Drynes of mouth	-	2 (5%)	-	NS
Urinary retention	-	-	-	NS

For categorical data chi-square test was applied. A P value of 0.05 or less was considered statistically significant

**RESULTS**

Study covered 90 patients of both sex in the age group 21-60 years. These patients were randomly divided into three groups of 30 each with male predominance in all groups. Group A received Tramadol HC1 50 mg. Group B received 0.1 mg Buprenorphine HCl and Group C received fentanyl 20 micrograms mixed in 0.1% Ropivacaine 10cc through epidural route. Gradation of response was done based on subjective pain relief, after epidural injection. Most of the patients showed excellent response to the therapy.

Observation recorded showed maximum number of patients with PID (34 Patients, 50.66%) showing excellent results in 44.11% while sciatica patients showed excellent results 57.14% cases after 20 minutes. Poor results in patients of sacral-canal stenosis. 10 points VAS was used to assess the pain relief in the study. No significant pain relief was found immediately following epidural injection while statistically significant pain relief was seen after 20 minutes which persisted thereafter. No statistically significant changes in pulse rate, respiratory rate and blood pressure in all the three groups.

**Group A:-** A this group 45% patients were considered to be cured while in 45% patients the signs and symptoms were relieved for a short period of time & in 10% cases the condition did not show any improvement.

**Group B:-** Permanent relief was observed in 55% cases while temporary relief was seen 35% cases no relief was noticed in 10% patients.

**Group C:-** in this group 45% of patient were thought to be cured with some relief in signs and symptoms in 40% cases. While 15% cases was labelled to be not benefited from the therapy

**STATISTICAL ANALYSIS:**

Statistical analysis was done using Stata 11 software. A descriptive analysis was done on all variables to obtain a frequency distribution. The mean + SD and ranges were calculated for quantitative variables. For continuous variables descriptive

statistics (mean and standard deviations) were computed. Continuous variables were compared by the Student t test. Proportions were analyzed with the chi-square test. Demographic characteristics, hemodynamic parameters data was analyzed statistically. For categorical data chi-square test was applied. P value of 0.05 or less was considered statistically significant.

**DISCUSSION**

Regional analgesia provides superior quality of pain relief after surgery and avoids many of the side effects of conventional narcotic analgesics. Epidural blockade using lipophilic opioids has advantages of better pain relief, minimal central nervous system depression, minimal somatic and visceral pain and abolition of the reflex muscle spasm. Observations of natural history and epidemiology suggest that low-back pain should be a benign, self-limiting condition that low back-disability as opposed to pain is a relatively recent Western epidemic, and that the role of medicine in that epidemic must be critically examined.

Rest is the commonest treatment prescribed after analgesics but is based on a doubtful rationale, and there is little evidence of any lasting benefit. To achieve the goal of treating patients rather than spines, we must approach low-back disability as an illness rather than low-back pain as a purely physical disease. We must distinguish pain as a purely the symptoms and signs of distress and illness behavior from those of physical disease, and nominal from substantive diagnoses. Many treatment options for acute and chronic low back pain are available, but little is known about the optimal treatment strategy. A rating system was used to assess the strength of the evidence, based on the methodologic quality of the randomized controlled trials, the relevance of the outcome measures, and the consistency of the results. Management must change from a negative philosophy of rest for pain to more active restoration of function. Only a new model and understanding of illness by physicians and patients alike makes real change possible Rosenstiel AK, Keefe FJ studied the use of coping strategies in chronic low back pain patients, its relationship to patient characteristics and current adjustment. Cognitive and behavioral pain coping strategies were assessed by means of questionnaire in a sample of 61 chronic low back pain patients. Data analysis indicated that the questionnaire was internally reliable. While patients reported using a variety of coping strategies, certain strategies were used frequently whereas others were rarely used. Three factors: (a) Cognitive Coping and Suppression, (b) Helplessness and (c) Diverting Attention or Praying, accounted for a large proportion of variance in questionnaire responses. These 3 factors were found to be predictive of measures of behavioral and emotional adjustment to chronic pain above and beyond what may be predicted on the basis of patient history variables (length of continuous pain, disability status and number of pain surgeries) and the tendency of patients to somaticize. Each of the 3 coping factors was related to specific measures of adjustment to chronic pain. [1]

Epidural steroid injections are the most commonly used procedures to manage chronic low back pain in interventional pain management settings. Approaches available to access the epidural space in the lumbosacral spine include the interlaminar, transforaminal, and caudal. The overall effectiveness of epidural steroid injections has been highly variable. Waddell G. et al developed a new clinical model for the treatment of low-back pain as there was increasing concern about low-back disability and its current medical management, this analysis attempts to construct a new theoretic framework for treatment. This model is used to compare rest and active rehabilitation for low-back pain. [2]

Van Tulder MW et al studied conservative treatment of acute and chronic nonspecific low back pain they did and a systematic review of randomized controlled trials of the most common interventions. Objectives was to assess the effectiveness of the most common conservative types of treatment for patients with acute and chronic nonspecific low back pain Various methodologic flaws were identified. Strong evidence was found for the effectiveness of muscle relaxants and nonsteroidal anti-inflammatory drugs and the ineffectiveness of exercise therapy for acute low back pain;

strong evidence also was found for the effectiveness of manipulation, back schools, and exercise therapy for chronic low back pain, especially for short-term effects. They concluded that the quality of the design, execution, and reporting of randomized controlled trials should be improved, to establish strong evidence for the effectiveness of the various therapeutic interventions for acute and chronic low back pain. [3]

SSekiguchi M et al clarified the anatomic variations of the sacral hiatus using the bony landmarks of the sacrum for improving the reliability of caudal epidural block (CEB). The CEB has been widely used for the diagnosis and treatment of lumbar spinal disorders. Benzon HT used epidural steroid injections for low back pain and lumbosacral radiculopathy. Non-surgical treatments of back pain may have prolonged and lasting benefit. Epidural steroid injections are one of the non-operative managements of back pain. These injections are recommended in patients with signs and symptoms of nerve root irritation. Relief of pain is attributed to the anti-inflammatory effect of the steroid. Patients with acute radiculopathy have better response compared to patients with chronic symptoms. Improvement may not be noted until 6 days after the injection. [4, 5]

Koes BW, Scholten RJ et al studied efficacy of epidural steroid injections for low-back pain and sciatica and did a systematic review of randomized clinical trials. Overall, 6 studies indicated that the epidural steroid injection was more effective than the reference treatment and 6 reported it to be no better or worse than the reference treatment. The benefits of epidural steroid injections, if any, seem to be of short duration only. Future research efforts are warranted, but more attention should be paid to the methods of the trials. Manchikanti L, Pampati V et al injected caudal epidural injections with sarapin or steroids in chronic low back pain. Results showed that there was significant improvement in patients receiving caudal epidural injections, with a decrease in pain associated with improved physical, functional and mental status; and decreased narcotic intake combined with return to work. In conclusion, caudal epidural injections with steroids or Sarasin are an effective modality of treatment in managing chronic, persistent low back pain that fails to respond to conservative modalities of treatments and is also negative for facet joint pain. The treatment is not only effective clinically but also is cost effective. [6, 7]

Govindarajan R, Bakalova T et al studied the role of epidural buprenorphine in management of pain in multiple rib fractures. Pain from multiple rib fractures may affect pulmonary function, morbidity, and length of stay in the intensive care units. This study describes some clinical characteristics of epidural buprenorphine, a lipophilic and partial opiate agonist with a higher  $\mu$  receptor affinity than morphine, in combating the pain in multiple rib fractures. The authors found a significant improvement in ventilatory function tests during the 1st, 2nd, and 3rd day after epidural analgesia when compared with the preanalgesia levels. So to conclude epidurally introduced narcotic, like buprenorphine in saline, has been found to be effective in our study to achieve adequate analgesia in treatment of patients with multiple rib fractures. [8]

Shah FR, Halbe AR et al studied Improvement in postoperative pain relief by the addition of midazolam to an intrathecal injection of buprenorphine and bupivacaine. This study compared the efficacy of the addition of midazolam to a mixture of buprenorphine and bupivacaine used for spinal anaesthesia. The authors concluded that intrathecal midazolam 2 mg improves the quality and duration of postoperative pain relief afforded by intrathecal buprenorphine and bupivacaine. Similar studies were done by Last AR, Hulbert K et al who did work on chronic low back pain and its evaluation and management. Gore M et al studied the burden of chronic low back pain and its clinical comorbidities, treatment patterns, and health care costs in usual care settings. [9, 10, 11]

When coming to some unconventional treatments of low back pain Chrubasik S et al did treatment of low back pain exacerbations with willow bark extract. Herbal medicines are

widely used for the treatment of pain, although there is not much information on their effectiveness. This study was designed to evaluate the effectiveness of willow (*Salix*) bark extract, which is widely used in Europe, for the treatment of low back pain. Willow bark extract may be a useful and safe treatment for low back pain. [12]

Turkey G, Goren Steal did a comparison of lumbar epidural tramadol and lumbar epidural morphine for pain relief after thoracotomy. The purpose of this study was to compare lumbar epidural morphine and lumbar epidural tramadol with respect to onset and duration of analgesia, analgesic efficacy, and drug-related side effects after muscle-sparing thoracotomy. The study revealed that the quality of analgesia achieved with repeated doses of lumbar epidural tramadol after muscle-sparing thoracotomy is comparable to that achieved with repeated doses of lumbar epidural morphine. Compared with morphine, lumbar epidural tramadol results in less sedation and a less-pronounced decrease in oxygenation. [13, 14]

Manchikanti L et al studied effectiveness of lumbar facet joint nerve blocks in chronic low back pain. Lumbar facet joints have been implicated as the source of chronic pain in 15% to 45% of patients with chronic low back pain. Various therapeutic techniques including intraarticular injections, medial branch blocks, and radiofrequency neurotomy of lumbar facet joint nerves have been described in the alleviation of chronic low back pain of facet joint origin. The authors did a randomized clinical trial and derived a conclusion that this study demonstrate that medial branch blocks with local anesthetic and Sarasin, with or without steroids, are a cost effective modality of treatment, resulting in improvement in pain status, physical status, psychological status, functional status and return to work. Similar work was also done by Flor H, Turk DC on etiological theories and treatments for chronic back pain by somatic models and interventions. [15, 16]

Mehta Y et al did a comparative study on lumbar versus thoracic epidural buprenorphine for postoperative analgesia following coronary artery bypass graft surgery. Devilkin AE, Vijay an R et al did work on epidural tramadol for postoperative pain relief. [17, 18]

Zenz M. studied epidural opiates for the treatment of cancer pain whereas Pergolizzi J, Böger RH et al studied opioids and the management of chronic severe pain in the elderly and then gave a consensus statement of an International Expert Panel with focus on the six clinically most often used World Health Organization Step III opioids (buprenorphine, fentanyl, hydromorphone, methadone, morphine, oxycodone).

## CONCLUSION

[A]The use of opioids in cancer pain: The criteria for selecting analgesics for pain treatment in the elderly include, but are not limited to, overall efficacy, overall side-effect profile, onset of action, drug interactions, abuse potential, and practical issues, such as cost and availability of the drug, as well as the severity and type of pain (nociceptive, acute/chronic, etc.). At any given time, the order of choice in the decision-making process can change. This consensus is based on evidence-based literature (extended data are not included and chronic, extended-release opioids are not covered). There are various driving factors relating to prescribing medication, including availability of the compound and cost, which may, at times, be the main driving factor. Therefore, comorbidities—including cancer and noncancer pain, osteoarthritis, rheumatoid arthritis, and post herpetic neuralgia—and patient functional status need to be taken carefully into account when addressing pain in the elderly.

World Health Organization step III opioids are the mainstay of pain treatment for cancer patients and morphine has been the most commonly used for decades. In general, high level evidence data (Ib or IIb) exist, although many studies have included only few patients. Based on these studies, all opioids are considered effective in cancer pain management (although parts of cancer

pain are not or only partially opioid sensitive), but no well-designed specific studies in the elderly cancer patient are available. Of the 2 opioids that are available in transdermal formulation—fentanyl and buprenorphine—fentanyl is the most investigated, but based on the published data both seem to be effective, with low toxicity and good tolerability profiles, especially at low doses.

[B]The use of opioids in noncancer-related pain: Evidence is growing that opioids are efficacious in noncancer pain (treatment data mostly level Ib or IIb), but need individual dose titration and consideration of the respective tolerability profiles. This strikes a balance between the evidence-based medicine and anecdotal experience. Factual recommendations and expert opinion both have a value when applying guidelines in clinical practice.

[C]The use of opioids in neuropathic pain: The role of opioids in neuropathic pain has been under debate in the past but is nowadays more and more accepted; however, higher opioid doses are often needed for neuropathic pain than for nociceptive pain. Most of the treatment data are level II or III, and suggest that incorporation of opioids earlier on might be beneficial. Buprenorphine shows a distinct benefit in improving neuropathic pain symptoms, which is considered a result of its specific pharmacological profile. [19, 20]

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