

COMPARATIVE STUDY ON POST-OPERATIVE ANALGESIA IN LOWER LIMB ARTHROPLASTIES WITH CONTINUOUS EPIDURAL INFUSION OF 0.125% BUPIVACAINE AND TWO DIFFERENT NARCOTIC ANALGESICS FENTANYL AND SUFENTANILRajeev Dwivedi¹, Nimisha Mishra², Sudhakar Dwivedi³**HOW TO CITE THIS ARTICLE:**

Rajeev Dwivedi, Nimisha Mishra, Sudhakar Dwivedi. "Comparative Study on Post-Operative Analgesia in Lower Limb Arthroplasties with Continuous Epidural Infusion of 0.125% Bupivacaine and Two Different Narcotic Analgesics Fentanyl and Sufentanil". Journal of Evolution of Medical and Dental Sciences 2015; Vol. 4, Issue 16, February 23; Page: 2746-2751, DOI: 10.14260/jemds/2015/394

ABSTRACT: Present study was carried out to compare and evaluate the effect of fentanyl and sufentanil in combination of bupivacaine on postoperative pain relief and possible side effects if any in patients operated for hip and knee arthroplasties. We randomly selected sixty patients of ASA grade I - III of age 18 to 75 years divided in to two groups. Group -I Received 2.5 µg/ml fentanyl along with 0.125% bupivacaine as a continuous epidural infusion at the rate of 5 ml/hr up to 48 hr after the surgery. Group-II Received 0.25 µg/ml sufentanil along with 0.125% bupivacaine as a continuous epidural infusion at the rate of 5 ml/hr up to 48 hr after the surgery. Analgesia was assessed by Visual analogue scale and motor block if any by Bromage scale. Haemodynamics and respiratory parameters were recorded and side effects if any were noted. In group I mean VAS score during rest was 27.0 +/-4.8 and mean VAS score during movement was 33.5 +/-4.9 in group II mean VAS score during rest was 20.8 +/-4.9 and mean VAS score during movement was 27.7 +/-5.2. The dynamic pain VAS score showed a statistically significant difference between two groups. haemodynamics parameters were similar in both groups. Thus group II patients received sufentanil along with 0.125% bupivacaine had better post-operative analgesia during movement as well as at rest without respiratory depression or significant side effects.

KEYWORDS: Epidural Anesthesia, Spinal anesthesia, fentanyl, sufentanil, postoperative pain, postoperative analgesia.

AIMS AND OBJECTIVES:

1. To study the efficacy of post-operative pain relief in patients operated for hip and knee arthroplasties using 2.5 µg/ml fentanyl and 0.25 µg/ml concentration of Sufentanil along with 0.125% bupivacaine solution as a concentration epidural infusion at a constant rate of 5 ml/hour.
2. Comparison of opioid induced side effects in both the groups i.e.
3. Assessment for haemodynamic disturbances if any.

METHODS: This study was conducted after approval of institution ethics committee and after obtaining written informed consent from patients. We selected 60 patients undergoing lower extremity joint replacement surgeries of ASA grade I-III of age 18 to 75 years having weight 40-100 kgs. Sixty patients were randomly divided into two groups of 30 each.

Group-I Received 2.5 µg/ml fentanyl along with 0.125% bupivacaine as a continuous epidural infusion at the rate of 5 ml/hr up to 48 hr after the surgery.

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Group-II Received 0.25 µg/ml sufentanil along with 0.125% bupivacaine as a continuous epidural infusion at the rate of 5 ml/hr up to 48 hr after the surgery.

Patient having co-existing severe cardiovascular or respiratory illness or any contraindication to central neuraxial block were excluded from the study.

All patients were kept nil orally for 6 hours, after taking the patients in O.T. baseline vitals are recorded. A wide bore I.V. access was established after preloading the patients with 500ml of lactated ringer's solution, epidural puncture was performed with 16 gauge combined spinal epidural set at lumbar region of L3-L4 intervertebral space. Epidural space identification was done with "Loss of resistance" to air technique. after the administration of spinal drug, A 16 gauge catheter was inserted cephalad 4-6 cm into the epidural space and tested with 3ml lignocaine 2% and adrenaline 1:200000 to exclude intravascular or intrathecal position of catheter. Technical complications in relation to epidural puncture or insertion of catheter were recorded.

During the postoperative course, the performer of the study went and monitored the patients 4th hourly for pain, general condition and side effects if any. The aim was to achieve a dynamic pain score (pain on movement) of 40 or less on a visual analog scale (VAS), with zero representing no pain and 100 being the worst pain possible. Drug dosage was only limited by side effects such as sedation, respiratory depression, nausea, or pruritus. If there was any doubt concerning the correct position of the epidural catheter, 5 ml of Bupivacaine 0.25% was administered. If an adequate analgesic effect (VAS #40) could not be achieved, it was assumed that the epidural catheter was not in situ; the patient was excluded from the study and was provided with parenteral opioids or NSAIDs for pain relief.

48 hours after the surgery, the infusion was terminated, the epidural catheter was removed, and patients were treated according to the intensity of the pain with IV Tramadol, or NSAIDs. An independent investigator recorded all of the study data at the initiation of epidural infusion at 4,8,16,24,32,40 and 48 hours. The quality of pain control was judged according to the dynamic VAS score and the demand for additional bolus doses or other analgesic medication. The following side effects of Bupivacaine and Sufentanil were examined: motor block [Bromage scores 0: normal motor function; 1 or greater: reduced motor function], respiratory depression (1: normal respiratory rate, 2: respiratory rate 8–12 breaths/min, 3: respiratory rate, 8 breaths/min), sedation (0: awake patient looks around; 1: tired, sleepy, patient easy to wake up, when spoken to; 2: asleep, can easily be woken by a light glabellar tap; 3: coma, sedated, a sluggish response–too deep), nausea (yes or no), emesis (yes or no), and pruritus (yes or no). Demographic variables, medical history, preoperative physical status, intraoperative medication, duration of general anaesthesia, blood loss, volume replacement, fluid balance, and transfusions were recorded in a standardized protocol for further analysis.

Observations were tabulated and statistical analysis was carried out by using student unpaired T test, Mann Whitney and Chi-square test. P value <0.05 was taken to be statistically significant.

RESULTS: There was no significant difference between the groups with respect to demographic data and ASA status. (Tables I - II).

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PARAMETERS	GROUP I	GROUP II
No. of patients	30	30
(a) Age (in years)		
Mean	53.23	57.5
SD	11.7	11.0
Range	18-75	32-75
(b) Weight (in kgs)		
Mean	63.6	64.6
Range	45-85	41-80
(c) Sex (%)		
Male	16	14
Female	14	16

TABLE I: DEMOGRAPHIC PROFILE OF PATIENTS

P value for age: 0.2942; P value for weight: 0.62 P value for sex: 0.8.

P value for age and weight has been calculated by using unpaired t test and p value for sex by chi square test.

ASA Grade	Group I		Group II	
	No. of patients	Percentage (%)	No. of patients	Percentage (%)
I	17	56.7	16	53.3
II	13	43.33	14	46.7
III	0	0.0	0	0.0
Total	30	100	30	100

Table II: PROFILE OF ASA (American Society of Anesthesiologists) GRADE IN BOTH THE GROUPS

To compare both the groups, Mann- Whitney test was employed, and the two tailed p value obtained was 0.8, considered statistically not significant. Hence both the groups were comparable in terms of ASA status.

The quality of the analgesic corresponded to the aim of the study to achieve dynamic pain VAS score of 40 or less. The mean VAS score during rest in group I was 27.0 ± 4.8 and in group - II mean VAS score during rest is 20.8 ± 4.9 data analyzed with Mann Whitney test $p < 0.0001$, Statistically significant. Group - II patients had better post-operative analgesia, during rest as compared to group - I patients(table III).

Post-operative Duration (hours)	Group I			Group II			test	P value	Significance
	Mean	SD	Range	Mean	SD	Range			
0	11.7	7.8	0-40	10.0	6.4	0-40	MW	0.3231	NS

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4	21.5	6.5	0-40	15.2	7.1	0-40	MW	0.0009	Significant
8	27.0	4.8	0-40	20.8	4.9	0-40	MW	<0.0001	Significant
16	25.3	3.9	0-40	19.5	5.5	0-40	MW	<0.0001	Significant
24	20.1	5.5	0-40	14.5	5.0	0-40	MW	<0.0001	Significant
32	18.7	3.7	0-40	12.2	5.0	0-40	MW	<0.0001	Significant
40	17.4	3.6	0-40	9.5	6.9	0-40	MW	<0.0001	Significant
48	16.2	4.1	0-40	6.3	5.9	0-40	MW	<0.0001	Significant

Table III: COMPARISON OF EFFICACY OF ANALGESIA IN BOTH THE GROUPS DURING REST VAS SCORE AT REST

The mean VAS score during movement in group - I was 33.5 ± 4.9 and is group II mean VAS score during movement was 27.7 ± 5.2 , data analyzed with Mann Whitney test $p < 0.05$ statistically significant. Group II patients had better post-operative analgesia during movement as compared to group I patients. (Table IV)

Post-operative Duration(hours)	Group I			Group II			test	P value	Significance
	Mean	SD	Range	Mean	SD	Range			
0	15.7	8.8	0-40	16.5	8.5	0-40	MW	0.5578	NS
4	27.8	8.9	0-40	23.8	7.73	0-40	MW	0.03	Significant
8	33.5	4.9	0-40	27.7	5.2	0-40	MW	0.0002	Significant
16	30.0	5.4	0-40	24.5	5.9	0-40	MW	0.001	Significant
24	29.2	5.7	0-40	19.3	5.2	0-40	MW	<0.0001	Significant
32	26.5	5.1	0-40	16.7	4.4	0-40	MW	<0.0001	Significant
40	24.3	5.3	0-40	13.3	5.0	0-40	MW	<0.0001	Significant
48	23.0	5.2	0-40	9.7	5.9	0-40	MW	<0.0001	Significant

Table IV: COMPARISON OF EFFICACY OF ANALGESIA IN BOTH THE GROUPS DURING LIMB MOVEMENT VAS SCORE WITH MOVEMENT

The difference in post-operative mean pulse rate, mean systolic and mean diastolic blood pressure at different time intervals was well within the clinically accepted normal values.

There was significant motor blockade only during the initial 4 hours after the surgery presumably due to the residual intraoperative neuraxial blockade. Immediately after the surgery, the mean bromage score of both the groups were between 1.0 - 1.4, which decreased to 0.5 - 0.4 in next 4 hours. This data was analyzed using Mann Whitney test and p value of 0.1114 was obtained, statistically not significant.

Six patients experienced nausea in group -I compared to 7 patients in group-II rescue analgesia was required in 5 patients in group-I, but was needed only in 2 patients in group- II.

DISCUSSION: Arthroplasties are commonly performed surgeries worldwide. Because of the large amount of bone handling in these procedures all patients experience severe excruciating pain in the first 48 hours after the arthroplasties. Apart from the psychological point of view, severe pain also leads to restriction of early physiotherapy, which is crucial for joint function.

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Lumbar epidural analgesia is a common modality for pain relief following hip or knee replacements. It provides better pain relief than other postoperative analgesic modalities with minimal systemic side effects. Epidural analgesia can be given either as intermittent boluses or as a continuous infusion.

In this study the regimen of a continuous epidural infusion of 60µg sufentanil in 240ml (0.25 µg/ml) of bupivacaine 0.125% at a rate of 5ml/hrs during the first 48 hours after arthroplasties provide better pain relief during rest and during movement as compared with 600 µg fentanyl in 240ml (2.5 µg/ml) of bupivacaine, in this study the efficacy of pain was measured both during rest and during movement shows after the surgery in group I the mean VAS score during rest was 27.0 ± 4.8 and the mean Vas score during movement was 33.5 ± 4.9 in group II the mean VAS score during rest was 20.8 ± 4.9 and mean VAS score during movement was 27.7 ± 5.2 .

Sundra Kempa et al⁽¹⁾ conducted a study on postoperative analgesia for total hip replacement patients using continuous epidural infusion of ropivacaine 0.1% with and without sufentanil, fifteen patients in each group received either an epidural infusion of 0.1% ropivacaine with 1µg/ml sufentanil (R1S) or 0.1% ropivacaine without sufentanil (R) at a rate of 5-9ml/hr. All patients had access to IV piritramide via a patient- controlled analgesia device. The R1S group consumed six times less piritramide over a 48 hrs infusion period than the R groups (median 12.7 vs 75.0mg: $p < 0.001$). Motor block was negligible for the study duration in both groups.

Alida A. broekemo et al⁽²⁾ studies postoperative analgesia with continuous epidural sufentanil and bupivacaine in 614 patients undergoing abdominal surgery, all patients recieved continuous infusion of 50 µg sufentanil in 50 ml of 0.125% bupivacaine at a rate of 6-10 ml/hr. VAS score of less than 30mm was considered satisfactory and 91-94% of patients obtained satisfactory analgesia which was comparable to the results in our study.

Bertini et al,⁽³⁾ 1995 studied post-operative analgesia in 50 total hip replacement patients, all patient received combined spinal epidural anaesthesia (intrathecal bupivacaine 15.8 +/- 0.6mg) then 24 h PCEA bupivacaine 0.125% morphine 40 µg/ml, 1ml bolus, 10min lockout, 25ml/4h max and 3 ml/h infusion. The mean VAS score was 15, which was similar to our results

Our study confirms previous clinical studies, that adding opioids to epidural local anaesthetic improves postoperative pain management.^(1,2,3)

In most clinical studies the efficacy of pain relief was only assessed in patients at rest. Recent studies have focused on pain relief during mobilization and coughing. Two studies^(4,5) demonstrated that postoperative analgesia by an opioid bupivacaine combination was significantly better during mobilization and coughing than by an epidural opioid alone.

Early respiratory depression i.e. within five to ten minutes after epidural administration of sufentanil has been described after a bolus dose of 50 µg^(5,6), but no prospective study is available addressing respiratory depressions in large number of patients after continuous infusion of sufentanil, fentanyl and a local anaesthetic through epidural. In this study, we did not encounter any significant episode of respiratory depression and both the groups had mean respiratory rate 13 ± 1 with in clinical range.

Bupivacaine in large bolus doses can leads to hypotension due to suppression of sympathetic ganglia. But when given in low concentration as continuous infusion 5ml/hr there would not be any haemodynamic changes.

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Motor blockade with a concentration of 0.125% bupivacaine is negligible, but it may not provide satisfactory post-operative analgesia in arthroplasties itself. Low concentrations will block only preganglionic sympathetic fibers, in this study we found that sufentanil and fentanyl acts synergistically with 0.125% bupivacaine and increases the efficiency of postoperative analgesia. The incidence of side effects like nausea, vomiting, pruritus was of no clinical significance.

CONCLUSION: Thus we conclude that continuous epidural infusion of Sufentanil- Bupivacaine combination provides good to excellent post-operative pain relief and can be routinely employed in patients posted for lower limb arthroplasties

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