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# Epidural clonidine for post operative analgesia in lower limb orthopedic surgeries

# <sup>1</sup>Dr. Cherukuri Kaushik MBBS, <sup>2</sup>Dr. Mary Samuel MBBS, MD, <sup>3</sup>Dr. Balkees Beevi.N MBBS, <sup>4</sup>Dr.Vishnu Teja MBBS, <sup>5</sup>Dr. Naveen Kumar MBBS

<sup>1</sup>Junior Resident 3, <sup>3</sup>Junior Resident 2, <sup>4,5</sup> Junior Resident 1, <sup>2</sup>Professor Dept of Anaesthesiology Dr.D.Y.Patil Vidhyapeeth (Deemed University)

# \*Corresponding Author: Dr. Cherukuri Kaushik MBBS

Flat 103, Aster 4, sukwani campus Yaswhantrao mansion Pimpri chinchwad Pune Maharashtra

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#### ABSTRACT

*BACKGROUND &AIM*: Regional anaesthesia has always been the safe, cost effective approach and the technique of choice for providing post operative analgesia. Combined spinal–epidural (CSE) anaesthesia offers the advantage of both spinal and epidural anaesthesia.

*METHODS:* A Prospective, randomized, placebo-controlled, double blinded study was carried out on 60 patients belonging to ASA (American Society of Anesthesiologists) I and II grades, between 20-60years of either gender, posted for lower limb orthopaedic surgeries under (CSE). Divided into two equal groups: Group C (STUDY) [epidural clonidine 150mcg diluted to 5ml in normal saline + intrathecal 0.5% hyperbaric bupivacaine, 15mg (3ml)].Group S (CONTROL) [epidural 5ml of normal saline + intrathecal 0.5% hyperbaric bupivacaine, 15mg (3ml)]. Demographic, hemodynamic, Sensory & motor block characteristics, analgesia and sedation score were assessed and compared using appropriate standard methods.

*RESULTS:* The demographic profile, duration of the surgery and diastolic blood pressure were comparable with non significant Pvalues. The onset of sensory analgesia : group[C]- 34.43 seconds group[S]-48.2 seconds, Pvalue of <0.001.), Time of Bromage 3 (group[C]-51.37 seconds, group[S]-66.3,Pvalue of <0.001) Time of Peak sensory block (group[C]- 4.33 minutes, group[S]- 5.43 minutes, Pvalue of <0.001) were noted to be significantly early in study-group, while the time to 2 segment regression (Group [C] -191.5 minutes, group[S] 100.33 minutes, Pvalue<0.001),duration of motor block (Group[C]- 288.17 minutes ,group[S] -190.83 minutes, Pvalue <0.001) the time to rescue analgesia (group[C]-349.17 minutes group[S] -200.17 minutes, Pvalue of <0.001) were significantly longer in study group epidural clonidine. The VAS SCORE lower in the group[c] while the sedation score was lower in group[s]. Heart rate and systolic blood pressure was significantly low in study group.

*CONCLUSION:* Administration of epidural clonidine provides faster onset of action, prolonged blockade and excellent post operative analgesia without any significant adverse effects

Keywords: Combined spinal epidural anaesthesia, clonidine, bupivacaine, Visual Analaogue scale, Ramsay Sedation score

# INTRODUCTION "For all the happiness mankind can gain is not in pleasure, but rest from pain."

John Dryden

The International Association for the study of pain defines pain as "an unpleasant, sensory and emotional experience associated with actual or potential tissue damage or described in terms of such

damage".<sup>[1][2]</sup> Alleviating pain is one of the fundamental duties of an anesthesiologist. Modern anaesthesia relieves pain not only during surgery, but also during the postoperative period which increases the patient's quality of life, with faster recovery thereby minimizing treatment costs. Combined spinal-epidural (CSE) anaesthesia offers a safe and inexpensive technique with the advantage of both spinal and epidural anaesthesia. It provides faster onset of surgical anaesthesia and prolongs the duration of post-operative pain relief.<sup>[1]</sup> Epidural analgesia was earlier limited to the use of local anaesthetics for relieving post operative pain. Then opioids were used as adjuvants but Unfortunately, opioids produce certain side effects such as respiratory depression, nausea, urinary retention, pruritus and patients may develop tolerance to their analgesic effects.<sup>[2][3][4]</sup> there are other receptor specific agents exist which when administered epidurally or into the intrathecal space relieves pain in both animals and humans. Clonidine, an alpha2 adrenergic agonist used ideally as an oral formulation for the treatment of hypertension can produce analgesia when applied near the spinal cord.<sup>[2]</sup> Clonidine hydrochloride is an imidazoline derivative. The anti nociceptive property of Clonidine is by means of an opioid sparing mechanism as it directly and postsynaptic stimulates pre alpha 2adrenoceptors in the dorsal horn gray matter of the spinal cord, thereby inhibiting the release of nociceptive neurotransmitters<sup>[5-6]</sup> Although clonidine provides heightened and long standing analgesia, these effects do not produce satisfactory anesthesia, sufficient for surgery. Hence, clonidine has been used only as an adjunct to local anesthetics. At low doses, epidural clonidine increases the efficiency, decreases the dose of anaesthetic agent and offers a more efficient haemodynamic course during anaesthesia.<sup>[6-</sup>

Thus the present study has been undertaken to evaluate the efficacy of epidural clonidine for post operative analgesia in a combined spinal-epidural technique.

# MATERIAL AND METHODS:

2.1.Study Design: A Prospective, randomized, placebo-controlled, double blinded study was undertaken in department of Anaesthesiology and Critical Care, Padmashree Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pimpri,

Pune- 411018 for a period of 1.5 years. The sample size was calculated using the values of onset of sensory block - mean and standard deviation (SD) of clonidine and saline group were 37.83  $\pm$  8.58 and  $50.33 \pm 8.80$  respectively.<sup>[1]</sup> Entering these values in the WINPEPI software(version 11.65) the calculated sample size was 16 (8 in each group). However the study enrolled a larger sample size of 60 (30 in each group) for better validation of results. After obtaining institutional ethics committee approval, study was carried out on randomly selected 60 patients belonging to ASA (American Society of Anesthesiologists) I and II grades, aged between 20 and 60 of either gender, posted for lower limb orthopaedic surgeries under combined spinalepidural anesthesia (CSE)

2.2: Preanaesthetic Evaluation: Pre operative visit was done on the day prior to surgery and detailed history and complaints were noted. General and systemic examination of cardiovascular, respiratory and central nervous system was done. Routine laboratory investigations were done. Patients were explained about the procedure that they would undergo, about the nature and purpose of the study. A written and informed consent was obtained from each patient.

*Exclusion Criteria:* Patients posted for emergency procedures and for whom central neuro axial block is contra indicated and those with major neurological, cardiac, respiratory, metabolic, renal, hepatic disease, coagulation abnormality or with known allergies to the study drugs were all excluded from the study.

Baseline vitals were recorded 2.3: Induction: for all the patients and were preloaded with 10ml/kg of Ringer's lactate and maintained on IV fluids throughout the surgery. Under strict aseptic precautions in sitting position, the epidural space was identified at L2–L3 inter-vertebral space with an 18 G Tuohy needle using loss of resistance technique, and a 20 G epidural catheter was advanced into the epidural space.Correct placement of epidural catheter was verified by injecting a test dose of 3ml of lignocaine (2%) adrenaline (1:2,00,000).The with drug administered for induction of anaesthesia will determine the groups for the study.Sixty(60) patients were divided randomly into two equal groups:

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- Group C (STUDY) 30 cases received injection clonidine 150 mcg, diluted to 5 ml in normal saline (NS) via epidural catheter 10 min prior to Sub Arachnoid block (SAB).
- Group S (CONTROL) 30 cases received 5 ml NS 10 min before Sub Arachnoid block (SAB).

Hyperbaric bupivacaine 0.5%, 15mg (3 ml) was given intrathecally to both the groups at L3–L4 intervertebral space using 26G Quincke babcock needle for SAB.

2.4:Monitoring: 2.4.1) Sensory Block was assessed bilaterally using loss of sensation to pinprick with the help of a short hypodermic needle along the mid clavicular line.2.4.2) Motor blockade was assessed using MODIFIED BROMAGE SCALE<sup>[8]</sup>

- 0: No motor block;
- 1: Inability to raise extended legs;
- 2: Inability to flex knees;
- 3: Inability to flex ankle joint.

Surgery commenced once the sensory block attained a level of T10 dermatome. In this study, onset of sensory block was defined as the time taken to achieve loss of sensation to pinprick at L1 dermatome level following SAB. Time taken to achieve Bromage 3 following SAB was defined as the onset of motor block. Time taken for two segment regression of sensory block was noted, and time taken for motor block to recede from Bromage 3 to Bromage 0 was recorded as the duration of motor block. 2.4.3) Hemodynamics moniotoring: Basal heart rate (HR), respiratory rate (RR), non-invasive arterial blood pressure (NIABP) and oxygen saturation were recorded before placement of epidural catheter and every 5 min till the end of surgery.2.4.4) Side effects: Patients were observed for any discomfort, nausea, vomiting, shivering, pain, hypotension, bradycardia and other sideeffects.2.4.5)Sedation: Intra and post-operative sedation was assessed using RAMSAY SEDATION SCORE.<sup>[9]</sup>

- 1.Anxious or restless or both
- 2.Co-operative, oriented and tranquil
- 3.Responding to commands

• 4.Asleep, brisk response to light, glabellar tap or auditory stimuli,

- 5.Asleep, sluggish response
- 6.Asleep, unarousable.

2.4.6) Assessment Of Pain: The duration of analgesia was considered based on the time of onset of sensory block at L1 till the time patient complained of pain. Pain was assessed using VISUAL ANALOGUE SCALE (VAS)<sup>[10]</sup>

- 0: No pain
- 2–4: Mild pain
- 5–7: Moderate pain
- 8–10: Worst pain.

NOTE: During the postoperative period rescue analgesic, injection Diclofenac 75mg i.m. stat was given when the patient requests for an analgesic or VAS >7. Subsequent rescue analgesics were given if the patient had a pain score of 5 or more than 5. Time of administration of the rescue analgesic was noted and chart was maintained.Sedation score, VAS and haemodynamic parameters were observed at 30min, 3rd. 4th. and 1st. 2nd. 5th 6hrs postoperatively.Patients were monitored for analgesia, for 24 hrs post operatively. Epidural catheter was removed after 48 hours under all aseptic precautions, after checking the patency and intact blue tip of the catheter.

STATISTICAL ANALYSIS: Data was collected, compiled and tabulated. The statistical analysis was done by using parametric test and final interpretation by using 'Z' test (standard normal variant) with 95 % level of significance. Quantitative data was analyzed by **Student't' test**. Qualitative data was analysis by **Chi square test**.

**RESULTS;** All the 60 patients enrolled completed the study.

4.1 *Demographic Profile:* The demographic profile of the patients were Comparable with non significant p values for age, gender and ASA Grades.

4.2.*Time Intervals In Anaesthesia:* Table 1& Graph 1Sensory and motor blockade characteristics of study group clonidine were significantly efficient over the control group saline.

4.3. Hemodynamic Characteristics: 4.3.1). Evaluation of heart rate: Graph:2The heart rate measured intraoperatively and post operatively at  $\frac{1}{2}$  hr, 1, 2, 3, 4,5 and 6 hours with p values of 0.016, 0.033, 0.042, 0.035, 0.001, 0.026, 0.036, 0.049 respectively were significantly low in the study group while The baseline values were non significant with a mean of  $71.2 \pm 12.84$  in study group and  $70.26 \pm 11.33$  in control group with a P value of 0.766. This is due to sympatholytic effect of clonidine leading to lower heart rate values.4.3.2). Evaluation of systolic blood pressure: Graph:3.The SBP was measured at baseline, intra-operatively and post operatively at  $\frac{1}{2}$ hr, 1, 2, 3, 4, 5 and 6 hours. The baseline values were non significant with a P value 0.715. At rest of the time points these were significantly low in the study group with values of 0.009. р 0.015,0.010,0.018,P<0.001,0.001,0.005,0.006 respectively. This is due to anti-hypertensive effect of clonidine leading lower SBP to values.4.3C). Evaluation of diastolic blood pressure: The DBP was measured at baseline, intra-operatively and post operatively at  $\frac{1}{2}$  hr, 1, 2, 3, 4, 5 and 6 hours. All the values at all the time points were nonsignificant.

4.4.Side Effects: There was one case of hypotension in study group and 2 instances of bradycardia. There were no adverse events seen at all in the control group.

4.5.Sedation Score Comparision: Table:2The post-op sedation scores were significantly lower in the control-group at  $\frac{1}{2}$  hr, 1, 2 and 3 hours subsequent to surgery. However, these were non significant at 4<sup>th</sup> hour, 5<sup>th</sup> hour and 6<sup>th</sup> hour subsequent to the surgery. This is explained by fall in levels of clonidine corresponding with its half life.

4.6 Pain :4.6.1) Visual Analogue Scale (VAS)score comparison: Table:3The VAS scores were evaluated post operatively at  $\frac{1}{2}$  hr, 1, 2, 3, 4, 5 and 6 hours subsequent to the surgery. All the values were significantly lower in the study group. There was gradual increase in the mean VAS scores. This is due to weaning effect of the anaesthesia. The lower values in the study group can be due to analgesic effect of the clonidine. Also, the half life of clonidine explains the gradual increase in the mean VAS scores though these were lesser than the control group.4.6.2) Mean doses of rescue analgesia: The mean doses of rescue analgesia were 2.33 & 3.37 with SD of 0.48 & 0.56 in the study group control group respectively. Significantly lesser mean doses of rescue analgesia in study group with a P value of <0.001.

#### **DISCUSSION:**

Pain is an inevitable component of the postoperative period. It is a sense of damage, hurt, fear, and punishment to the patient. Pain being a subjective phenomenon is perceived only by the sufferer. Post operative pain is associated with adverse outcomes such as patient discomfort, longer duration of hospital stays, exposure to analgesic drugs and their associated adverse events. Postoperative pain management aims at providing a subjective comfort to the patient by inhibiting pain. Epidural analgesia is a safe technique for post operative pain relief and equivalent to traditional analgesic methods.<sup>[11]</sup>With epidural analgesia patient can be mobilized early and can resume activities quickly as compared to parenteral opioids <sup>[12]</sup>. Clonidine is a selective partial alpha 2 adrenoreceptor agonist. It is known to potentiate both the sensory and motor block of local anaesthetics. Clonidine is rapidly and extensively absorbed into the spinal cerebrospinal fluid compartment after epidural administration, with concentrations peaking 30-60 min after injection and coincides with near maximal analgesia. After epidural administration, clonidine produces peak concentrations in arterial blood within 10 min and venous blood within 30-45 min. As the side effects, such as sedation, hypotension or bradycardia, are at least partly related to systemic absorption, the route that provides the best balance between analgesia and side effects is more acceptable. The results of our study are discussed below.

*5.1: Demographic Profile: The* ASA grades, age and gender were comparable with non significant p values.

5.2. sensory and motor blockade characteristics: **Table 1 and Graph 1 TIME INTERVALS OF ANAESTHESIA**: The onset of *SENSORY ANALGESIA* [C-34.43/S-48.2seconds] P value <0.001, *TIME OF BROMAGE* 3 [C-51.37/S-66.3]P value <0.001, The *TIME OF PEAK SENSORY BLOCK* [C-4.33/S5.43 minutes]P value <0.001) were noted to be significantly early in Group C, while the *TIME TO 2 SEGMENT REGRESSION* [C-191.5/S-

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100.33 minutes, Pvalue<0.001), DURATION OF MOTOR **BLOCK** [C-288.17/S-190.83 minutes]Pvalue <0.001) and the TIME TO RESCUE [C-349.17/S-ANALGESIA 200.17minutes]Pvalue<0.001) were significantly longer in Group C.In 2020 a study by Arora P et al. <sup>[13]</sup> in patients undergoing lower limb and lower abdominal surgeries use of clonidine was associated with prolonged duration of analgesia when compared to bupivacaine alone but was not associated with significant differences in onset of sensory and motor blockade. However, it was associated with longer duration of motor blockade. But in our study even onset of sensory blockade was earlier with clonidine group.

5.3 Hemodynamics: Heart Rate: The heart rate was measured at baseline, intra-operatively and post operatively at <sup>1</sup>/<sub>2</sub> hr, 1, 2, 3, 4, 5 and 6 hours. The baseline values were non significant with a P value 0.766. At rest of the time points these were significantly low in the study group as observed from Graph 2. This is due to sympatholytic effect of clonidine leading to lower heart rate values. Clonidine is also known to blunt rise in heart rate due to intravenous atropine explaining its property of [15] SYSTOLIC BLOOD reducing heart rate. PRESSURE AND DIASTOLIC BLOOD PRESSURE : The SBP was measured at baseline, intra-operatively and post operatively at  $\frac{1}{2}$  hr, 1, 2, 3, 4, 5 and 6 hours. The baseline values were non significant with a P value 0.715 as observed from Graph 3. At rest of the time points these were significantly low in the study group. The DBP was measured at baseline, intraoperatively and post operatively at 1/2 hr, 1 hour, 2 hour, 3 hour, 4 hour, 5 hour and 6 hour. All the values at all the time points were non-significant. This is due to anti-hypertensive effect of clonidine leading to lower SBP values. <sup>[16,17]</sup> Clonidine is a centrally acting anti-hypertensive.

5.4:Visual Analogue Scale: The Visual Analogue Scale (VAS) scores were evaluated post operatively at ½ hr, 1, 2, 3, 4, 5 and 6 hours subsequent to the surgery. All the values were significantly lower in the study group as observed from **TABLE 3**.There was gradual increase in the mean VAS scores. This is due to weaning effect of the anaesthesia. The lower values in the study group can be due to analgesic effect of the clonidine. Also, the half life of clonidine explains the gradual increase in the mean VAS scores though these were lesser than the control group. The mean doses of rescue analgesia were 2.33 in study group and 3.37 in the control group. Significantly lesser mean doses of rescue analgesia in study group with a P value of <0.001. **Jahangiri M et al.** <sup>[14]</sup> in 1994 **noted** that use of epidural clonidine can be associated with reduction in phantom pain after major lower limb amputation surgeries. **Huang YS et al.** <sup>[15]</sup> in 2007 noted that optimal amount epidural clonidine for post operative pain after total knee arthroplasty in a solution of ropivacaine and morphine is 1 mcg/ml which is different from our study which used only clonidine.

5.5: Sedation Scores: The postoperative sedation scores were significantly lower in the control group at  $\frac{1}{2}$  hr, 1, 2 and 3 hours subsequent to the surgery. However, these were non significant at 4<sup>th</sup> hour, 5<sup>th</sup> hour and 6<sup>th</sup> hour subsequent to the surgery as observed from Table 2. This is explained by fall in levels of clonidine corresponding with its half life. Huang YS et al. <sup>[15]</sup> in 2007, in a study noted that clonidine in a dose of 4.0 mcg/mL as patient controlled epidural analgesia leads to severe sedation and prolonged sensory and motor block in patients undergoing total knee arthroplasty. As compared with above quoted study the dose of epidural clonidine used in our study was significantly low only 150mcg but had sedation score higher than control in the early post operative hours.

5.6:Adverse Events: No serious or life threatening adverse drug reactions were noted in the study. There was one case of hypotension in study group and 2 instances of bradycardia. however these effects were transient and didn't require any prompt intervention. Hypotension and bradycardia are known adverse events associated with use of clonidine. The results of our study are in concordance with commonly observed side effects of clonidine and those of bupivacaine. No significant trends can be observed with the available data.

### CONCLUSION:

1. In the epidural clonidine group there was early onset of sensory analgesia, Bromage 3 and time to peak sensory analgesia.

2. The duration of motor block, two segment regression and time to first rescue analgesia

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was longer in the patients who received Anesthesiology 1996;85:655-74.

epidural clonidine.

3. The total number of rescue analgesics required in the postoperative period was substantially less in patients who received epidural clonidine compared to the patients in the control group.

4. There were no serious adverse events noted in the study group which required prompt intervention.

Based on our study it is concluded that Epidural Clonidine can be a useful adjuvant to the regular anaesthetic technique in lower limb orthopaedic surgeries. However, we propose conducting similar studies with a larger sample size and with varied patient groups for further conclusive evidence.

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### **TABLES AND GRAPHS**

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	Study-g	roup	Control-group			
	Mean	S.D	Mean	S.D	P value	Inference
						Significantly
Onset of sensory block						early in study
(sec)-L1	34.43	4.92	48.20	4.60	P<0.001	group
						Significantly
						early in study
Time of Bromage 3 (sec)	51.37	4.75	66.30	7.17	P<0.001	group
						Significantly
Time to peak sensory						early in study
block-T10(min)	4.33	0.61	5.43	0.50	P<0.001	group
						Significantly
Time to 2 segment						longer in study
regression (min)	191.50	20.14	100.33	7.76	P<0.001	group
Duration of surgery						
(mins)	122.10	33.51	124.00	39.62	0.84176	Non significant
						Significantly
Duration of motor block						longer in study
(min)	288.17	16.58	190.83	13.00	P<0.001	group
						Significantly
Time to first rescue						longer in study
analgesia (mins)	349.17	19.44	200.17	17.44	P<0.001	group
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#### **Table 1: TIME INTERVALS IN ANAESTHESIA**

Evaluation of onset, duration of anaesthesia, time to surgery, time to rescue analgesia



Graph 1: Bar diagram showing the onset, duration of anaesthesia, time to surgery, time to rescue analgesia



Graph 2: Bar diagram showing heart rate in both the groups





#### **Table 2: Sedation scores**

	Study g	roup	Control group			
Sedation score						
(Post-OP)	Mean	SD	Mean	SD	P value	Inference
						Significantly lower in
30 min	2.30	0.47	1.23	0.43	P<0.001	Control
						Significantly lower in
1 hr	2.30	0.47	1.10	0.31	P<0.001	Control
						Significantly lower in
2 hr	2.27	0.45	1.23	0.43	P<0.001	Control
						Significantly lower in
3hr	2.33	0.48	1.30	0.47	P<0.001	Control
4hr	1.23	0.43	1.20	0.41	0.76	Non significant
5hr	1.23	0.50	1.20	0.41	0.78	Non significant
6hr	1.37	0.61	1.20	0.41	0.22	Non significant

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The above shows postoperative sedation scores.

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	Study gro	oup	Control group			
VAS Score/Post OP	Mean	SD	Mean	SD	P value	Inference
30 min	1.07	0.25	1.40	0.50	P<0.001	Significantly lower in Study group
1 hr	1.27	0.45	2.03	0.81	P<0.001	Significantly lower in Study group
2 hr	2.07	0.25	3.20	0.61	P<0.001	Significantly lower in Study group
3hr	2.23	0.43	6.03	0.81	P<0.001	Significantly lower in Study group
4hr	6.03	1.22	6.93	0.37	P<0.001	Significantly lower in Study group
5hr	7.23	0.77	7.67	0.48	0.01	Significantly lower in Study group
6hr	7.27	0.58	7.77	0.43	P<0.001	Significantly lower in Study group

### Table 3: Visual Analogue Scale score comparison

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