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ORIGINAL RESEARCH

To study the effect of epidural bupivacaine versus epidural bupivacaine and clonidine for post-operative analgesia in a tertiary care hospital: comparative study

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ABSTRACT

Introduction: Postoperative pain remains a significant concern despite advancements in surgical and anesthetic techniques. Effective postoperative analgesia improves patient outcomes and accelerates recovery. Conventional local anaesthetics like Bupivacaine provide a limited duration of analgesia. Epidural opioids, though effective, are associated with adverse effects. Clonidine, an alpha-2 adrenergic agonist, has shown promise as an adjunct for prolonging analgesia without significant respiratory depression.

Aims and Objectives:

1. To assess the effect of clonidine as an adjunct to Bupivacaine on the onset of sensory blockade after epidural injection.
2. To evaluate the incidence of adverse effects with epidural clonidine.
3. To determine the duration and efficacy of analgesia when clonidine is combined with epidural Bupivacaine.

Materials and Methods: A randomized controlled study was conducted on patients undergoing surgery under epidural anaesthesia. Patients were divided into groups receiving either Bupivacaine alone or Bupivacaine with Clonidine. Standardized methods were used to assess the onset and duration of sensory blockade, pain scores and to monitor for adverse effects. **Results:** Addition of clonidine to Bupivacaine resulted in faster onset of sensory blockade, significantly prolonged duration of analgesia and reduced postoperative pain scores. The incidence of major adverse effects was low, with mild sedation and dry mouth being the most common. **Conclusion:** Epidural clonidine as an adjunct to Bupivacaine enhances the quality and duration of postoperative analgesia with minimal side effects, making it a valuable option for postoperative pain management.

Key words: Postoperative pain, epidural analgesia, clonidine, bupivacaine, sensory blockade, adverse effects

INTRODUCTION

One of the most crucial areas of anaesthesia is postoperative pain control [1]. Postoperative pain is an acute pain that starts with surgical trauma and ends with tissue healing. Despite advances in knowledge, skill, and sophisticated. Technology that characterizes most aspects of modern surgical treatment, many patients continue to experience considerable discomfort during the postoperative period [2].

Various modalities have been tried for the management of postoperative pain, out of which epidural opioids are an established and accepted technique [3]. Effective postoperative pain management results in early mobilisation and a decrease in the immediate complications-infectious, neurological, cardiovascular, and thrombo-embolic sequelae produced by immobility. This promotes early surgical rehabilitation, shortens hospital stays, lowers hospital expenses, and improves patient satisfaction [4].

Pain alleviation is the main indicator of an analgesic regimen's effectiveness. It is crucial to understand that pain scores are frequently assessed while the patient is

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at rest, which makes it difficult to find methods that successfully relieve dynamic pain and enable patients to move and cough [4].

An epidural analgesic approach that effectively relieves pain, has few adverse effects, and increases patient satisfaction is excellent for major surgeries [5]. Opioids, ketamine, clonidine, benzodiazepines, and other substances can be added to epidural infusions to increase analgesia while reducing adverse effects. Epidural analgesia with continuous infusion of the analgesic drugs through the epidural catheter is widely regarded as a superior technique in providing prolonged duration of postoperative pain relief after elective surgery [6].

This study was planned to identify the effect of epidural Bupivacaine versus epidural Bupivacaine and clonidine for post-operative analgesia.

AIMS AND OBJECTIVES

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MATERIALS AND METHODS

Hospital Based prospective, randomized, controlled study was conducted on patients undergoing surgery under epidural anesthesia after obtaining ethical clearance.

STUDY TYPE: Prospective Randomized control study.

STUDY PERIOD: April 2023 to April 2024.

STUDY AREA: Dept. of Anaesthesiology, King George Hospital and Andhra Medical College Visakhapatnam and Government Hospital and Medical College, Vizianagaram

STUDY SUBJECTS: Adult patients of the age group 30-75 years scheduled for abdominal, obstetrical, gynaecological, and orthopedic surgeries under epidural anaesthesia.

METHOD OF COLLECTION OF DATA

SAMPLE SIZE: A clinical study of 70 cases of ASA grade I & II between the age group 30-75 years undergoing abdominal, gynaecological, and orthopedic surgeries under epidural anaesthesia.

INCLUSION CRITERIA: ASA grade I and II, aged 30-75 years, who give informed, valid consent, and Patients scheduled for abdominal, gynaecological, and orthopedic surgeries.

EXCLUSION CRITERIA: Poorly controlled hypertension, angina, congestive cardiac failure, Atrial fibrillation, arrhythmias, Patient with coagulation abnormalities, Weight >95kg, Age> 75 years, ASA grade III and IV, and with contraindications to regional anaesthesia, Patients on tricyclic anti-depressants, alpha-2 adrenergic agonists or opioids.

METHODOLOGY

PRE-ANAESTHETIC EVALUATION

- Patients were assessed the day before surgery with detailed history, examination, and routine labs.
- ECG (for >40 years) and chest X-ray (if indicated) were performed.
- The procedure and Visual Analogue Scale (VAS) for pain were explained; written consent was obtained.

PREMEDICATION

- Diazepam 5-10 mg orally the night before surgery.
- Patients fasted for 8 hours preoperatively.

ANAESTHESIA AND TECHNIQUE

All surgeries performed under epidural anaesthesia using 0.5% Bupivacaine. Standard monitors (NIBP, pulse oximetry, ECG) applied; IV access secured. Epidural space identified at L2-L3 using an 18G TOUHY needle and loss of resistance to air technique. 18G PORTEX catheter inserted; test dose of lignocaine with adrenaline given. After confirming correct placement, 0.5% Bupivacaine administered. No intraoperative narcotics used.

POSTOPERATIVE ANALGESIA ALLOCATION

At first pain complaint (VAS >4), patients were randomized to:

GROUP B: 0.125% Bupivacaine 10 ml (n=35)

GROUP B+C: 0.125% Bupivacaine 9 ml + clonidine 150 µg (1 ml) (n=35).

STATISTICAL ANALYSIS

Frequency distribution and percentages were used to describe quantitative variables. Student's t-test analysed continuous data, and possible significance has been determined, considering it statistically significant if it's $p<0.05$% level of significance.

RESULTS

The study included a total of 70 patients of aged between 30 and 75 years with ASA physical classifications I or II. Group B consisted of 35 patients who received 0.125% Bupivacaine alone, while Group B+C included 35 patients who received 0.125% Bupivacaine plus 150 µg clonidine. These patients were randomly assigned to two equal groups, with 18 men and 17 women in each group, resulting in equal gender distribution. Depending on the type of

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surgery, patients were selected from three departments. The largest percentage of patients came from orthopaedic surgeries, accounting for 54.3% in Group B and 48.6% in Group B+C. General surgical cases constituted 14.3% of Group B and 20% of Group B+C, whereas gynaecological surgeries represented 31.4% in both groups.

Table 1: Onset of analgesia among the two groups

Group	Onset of Analgesia (min)	t-value	P-value
B (Bupivacaine)	16 ± 3.34	4.1	<0.001
B+C(Bupivacaine + Clonidine)	12.7 ± 0.87		

The mean time of onset of analgesia in group B was 16+/-3.34 (S.D) minutes. The mean time of onset of analgesia· in group B+C was 12.7+/-0.87(S.D) minutes. The Statistical analysis by Student's unpaired t-test showed that the time of onset of analgesia in group-B+C was significantly less when compared to group B (t=4.1).

Table 2: Incidence of side effects

Side effects	Group B	Group B+C
Nausea/Vomiting	5(14%)	4(11 %)
Shivering	3(9%)	0
Dry Mouth	0	7(20%)
Urinary Retention	2(6%)	2(6%)
Hypotension	0	0
Bradycardia	0	0
Respiratory Depression	0	0
Pruritis	0	0

it is observed that the incidence of nausea and vomiting was similar in both groups (14%in Group B as compared to 11% in Group B+C). 3 patients in Group B out of 35 had incidence of shivering (9%) while no shivering was observed in Group B+C. Drymouth was observed in 7 patients (20%) and was significantly higher in Group B+C than Group B. Incidence of urinary retention was similar in both groups. No incidence of bradycardia, hypotension or respiratory depression was observed in either groups.

Table 3: The duration and efficacy of analgesiaamong groups

Parameter	Group B (Bupivacaine only)	Group B+C (Bupivacaine + Clonidine)	t-value	Significance
Onset of Analgesia (min)	16.0 ± 3.34	12.7 ± 0.87	4.1	0.002*
Request for First Analgesia (min)	134.9± 31.4	237.8± 42.6	11.06	<0.001
Duration of Analgesia (min)	118.6 ± 29.29	225.1 ± 45.74	11.62	<0.001

The duration of analgesia was significantly longer in the clonidine group (225.1 minutes) compared to the control group (118.6 minutes). Analgesic efficacy was better in the clonidine group, with most patients reporting "good to excellent" pain relief.

Table 4: Visual Analogue Score-Group B (Bupivacaine only)

Postoperative Timing	VAS 4	VAS 3	VAS 2	VAS 1	Patients with Pain (%)
0 min	35	0	0	0	0%
15 min	17	1	13	4	0%
30 min	0	0	16	19	0%
45 min	0	1	21	13	0%
60 min	2	10	23	0	2 (5.7%)
90 min	1	23	9	0	3 (8.6%)
2 hr	10	21	1	0	13 (35%)
2.5 hr	13	9	0	0	26 (75%)
3 hr	7	2	0	0	33 (95%)
3.5 hr	2	0	0	0	35 (100%)

Table 4, the action of Bupivacaine on the post-operative patients was very minima, 2(5.7%) patients experienced pain in 60 mins duration.

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Table 5: Visual Analogue Score-Group B+C (Bupivacaine + Clonidine)

Postoperative Timing	VAS 4	VAS 3	VAS 2	VAS 1	Patients with Pain (%)
0 min	35	0	0	0	0%
15 min	0	7	21	7	0%
30 min	0	0	0	35	0%
45 min	0	0	0	35	0%
60 min	0	0	0	35	0%
90 min	0	0	6	29	0%
2 hr	0	1	18	16	0%
2.5 hr	0	2	27	6	0%
3 hr	2	7	23	3	2 (5.7%)
3.5 hr	4	17	11	1	6 (16%)
4 hr	18	6	5	0	24 (65%)
5 hr	6	5	0	0	30 (86%)
6 hr	5	0	0	0	35 (100%)

Table 5, illustrate that Group B+C experienced delayed and less intense postoperative pain compared to Group B, indicating improved analgesia with the addition of clonidine.

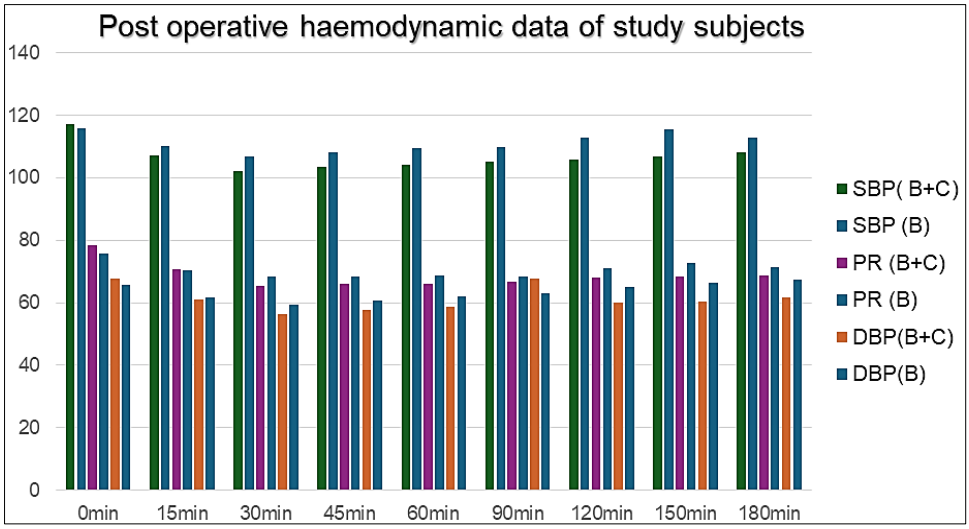

Figure 1: Haemodynamic stability of the study subjects among the groups

The bar chart compares the effects of spinal anesthesia using Bupivacaine alone (B) versus Bupivacaine combined with clonidine (B+C) on systolic blood pressure (SBP), pulse rate (PR), and diastolic blood pressure (DBP) over 180 minutes. At the start (0 min), all three parameters, PR, and DBP, are higher in the B+C group compared to the B group. Over time, both groups show a gradual decrease in these values, reaching their lowest around 60-90 minutes, after which the values either stabilize or show a slight increase. Throughout the observation period, the B+C group consistently maintains higher SBP, PR, and DBP compared to the B group.

DISCUSSION

Postoperative pain is a complex experience combining nociceptive sensations from tissue injury and the emotional suffering it causes [7]. Surgical trauma triggers the release of inflammatory mediators like histamine, activating fine C-and A-fibers in the spinal cord's dorsal horn (lamina I and II), which play a key role in transmitting pain signals. Effective pain control is essential because poorly managed postoperative pain impairs recovery by reducing lung function (leading to atelectasis and hypoxemia), increasing sympathetic activity that causes vasoconstriction and a hypercoagulable state (raising the risk of deep vein thrombosis), and elevating catecholamines that increase cardiac workload and risk of arrhythmias or ischemia [8, 9].

Additionally, pain induces a catabolic state that delays wound healing and suppresses immunity, while also decreasing gastrointestinal motility and circulation, further slowing recovery. Epidural anaesthesia works by delivering local anaesthetics to the epidural space, blocking nerve impulses from small nociceptive fibres and sympathetic nerves, thereby providing effective analgesia [10, 5, 11].

Managing postoperative pain effectively helps reduce complications, speeds recovery, and improves overall patient outcomes.

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In The present study indicates that the mean time of onset of analgesia in group B was 16 ± 3.34 (S.D.) minutes, while in group B+C, it was 12.7 ± 0.87 (S.D.) minutes, and this difference was statistically significant. This means patients receiving Bupivacaine plus clonidine experience pain relief faster than those receiving Bupivacaine alone. Such findings align with studies showing that combined spinal-epidural or additive techniques generally produce quicker onset of sensory block compared to single-agent spinal or epidural anesthesia[11].

The statistical significance confirms this difference is unlikely due to chance, showing a true enhancement of analgesic onset by Clonidine. Our results align with the study conducted by Bonnet *et al*., [12] which found that the onset of analgesia in both clonidine groups occurred within 15 minutes. Additionally, in a study by Agarwal *et al*., [1] the onset of sensory block with B+C was noted to be 9.53 minutes.

In the present study, it is observed that Nausea and vomiting occurred similarly in both groups (14% in Group B vs. 11% in Group B+C). Shivering was seen in 9% of Group B but was absent in Group B+C. Dry mouth was significantly higher in Group B+C (20%). Urinary retention was similar in both groups. No bradycardia, hypotension, or respiratory depression was observed.

VAS was used in the current study to measure post-operative pain alleviation. When asked to rate their level of pain on a scale at the time of their first prescription, patients' responses were found to be negligible across all groups. In the present study, Group B+C experienced delayed and less intense postoperative pain compared to Group B, indicating improved analgesia with the addition of clonidine, which aligns with the study done by Agarwal *et al*., [1] And Jyothi *et al*., [12] Group BC experienced significantly less pain compared to Group B($p < 0.05$).

Table 6: Comparing results of other studies

Study	Adjuvant	Analgesic Duration	Pain Scores	Side Effects
Present study	Clonidine	Prolonged	Lower VAS	Minimal
Agrawal *et al*.,	Clonidine	Prolonged	Lower VAS	Minimal
Jyothi *et al*.,	Clonidine	Prolonged	Lower VAS	Acceptable sedation
Prakash *et al*.,	Midazolam	Prolonged	Lower VAS	Nonsignificant

CONCLUSION

This randomised controlled research shows that postoperative pain management is greatly enhanced when clonidine is added to epidural Bupivacaine. Compared to Bupivacaine alone, patients who received Bupivacaine plus clonidine reported improved overall pain reduction with a quicker onset and longer duration of analgesia. Only mild drowsiness and dry mouth were more common with clonidine, and the incidence of serious side effects was modest in both groups. Throughout, haemodynamic stability was preserved. To improve the quality and duration of postoperative analgesia, clonidine is a safe and efficient addition to epidural Bupivacaine.

CONFLICT OF INTEREST: No.

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