Original Research

A PROSPECTIVE RANDOMIZED COMPARATIVE STUDY OF CLONIDINE VERSUS FENTANYL AS ADJUVANTS TO EPIDURAL BUPIVACAINE IN PATIENTS UNDERGOING ELECTIVE LOWER LIMB SURGERIES

Lavanya M. P.[1], Harini Priyadarshini M. S.[2], Amarnath C.[3], Surendra M.[4]
[1]Consultant, Department of Anaesthesiology, K C General Hospital, Malleshwaram, Bengaluru, Karnataka, India.
[2]HOD & Senior Consultant, Department of Anaesthesiology, K C General Hospital, Malleshwaram, Bengaluru, Karnataka, India.
[3]Consultant, Department of Anaesthesiology K C General Hospital, Malleshwaram, Bengaluru, Karnataka, India.
[4]Consultant Anaesthesiologist, Veena Medical Center, Rajajinagar, Bengaluru, Karnataka, India.
Corresponding Author: Harini Priyadarshini M, S.
HOD & Senior Consultant, Department of Anaesthesiology K C General Hospital, Malleshwaram, Bengaluru, Karnataka, India.

ABSTRACT

Background: Epidural adjuvants improve the quality and duration of analgesia while reducing the dose requirement of local anaesthetics. Clonidine and fentanyl are commonly used epidural adjuvants, but their comparative efficacy remains a subject of interest. This study aims to compare the effects of clonidine and fentanyl as adjuvants to epidural bupivacaine in patients undergoing elective lower limb surgeries.

Materials and Methods: This prospective, randomized comparative study was conducted over 18 months and included 60 ASA physical status I and II patients aged 18–60 years undergoing elective lower limb surgeries. Patients were randomly allocated into two groups (n = 30 each). Group BC received 16 mL of 0.5% isobaric bupivacaine with clonidine (1 µg/kg), while Group BF received 16 mL of 0.5% isobaric bupivacaine with fentanyl (0.5 µg/kg). The primary outcomes included onset and duration of sensory and motor block, and secondary outcomes included time to two-segment regression, duration of postoperative analgesia, haemodynamic parameters, sedation score, and adverse effects.

Results: Group BF demonstrated a significantly faster onset of sensory block (6.3 ± 0.79 vs. 11.5 ± 0.82 minutes) and motor block (16.9 ± 1.32 vs. 24.2 ± 1.10 minutes) compared with Group BC ($p < 0.001$). However, Group BC showed significantly prolonged two-segment regression time (268.2 ± 0.38 vs. 109.2 ± 0.27 minutes), duration of sensory block (307.8 ± 0.47 vs. 147.0 ± 0.34 minutes), duration of motor block (292.8 ± 0.42 vs. 133.8 ± 0.35 minutes), and time to first rescue analgesia (307.8 ± 0.47 vs. 207.6 ± 0.34 minutes) ($p < 0.001$ for all comparisons). The incidence of adverse effects, including hypotension, bradycardia, and nausea/vomiting, was comparable between the two groups ($p = 1.000$).

Conclusion: Epidural clonidine (1 µg/kg) as an adjuvant to bupivacaine provided significantly prolonged sensory and motor blockade and longer postoperative analgesia than epidural fentanyl (0.5 µg/kg), without increasing adverse effects. Therefore, clonidine may be considered an effective and safe alternative to fentanyl for epidural anaesthesia in elective lower limb surgeries.

Keywords: Clonidine, Fentanyl, Bupivacaine, Epidural Anaesthesia, Postoperative Analgesia.

INTRODUCTION

Postoperative pain management improves patient satisfaction, speeds up mobilization, shortens hospital stays, and lowers hospital expenses. Reducing the dosage of drugs to minimize adverse effects and give sufficient analgesia is a key objective in the management of postoperative pain.[1]

In lower abdomen and limb procedures, epidural anaesthesia is the most often utilized method for both perioperative surgical anaesthesia and postoperative analgesia.[2,3] The most used medication for postoperative epidural analgesia is bupivacaine.[4] Bupivacaine, a member of the amino amide class of local anaesthetics, is recommended for both peripheral nerve blocks and central neuraxial blockade.[5]

Adjuvants including clonidine, midazolam, fentanyl, and dexmedetomidine are known to increase the efficacy of these local anaesthetics by both strengthening and extending the blockade and lowering the dosage of the anaesthetics.[6,7,8]

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The quality of sensory block is improved, motor blockade is reduced, and a lower dose of local anaesthetic infusion is achievable when opioids are added to epidural local anaesthetics increasing safety and lowering adverse effects.[4] Fentanyl is a synthetic opioid that is strong, short-acting and extremely lipophilic. In neuraxial block it has been frequently utilized as an adjuvant for postoperative analgesia.[1] Fentanyl is 100 times more potent than morphine acting as an agonist at μ-opioid receptors to increase analgesia.[9]

Because of their calming, analgesic, peri-operative sympatholytic, anaesthetic-sparing, and hemodynamic stabilizing qualities, alpha 2-adrenergic receptor agonists have drawn attention.[2] Clonidine is a 200:1 selectivity ratio partial α2 adrenergic agonist that acts centrally. It produces analgesia by blocking voltage-gated Na+ channels and suppressing the production of action potentials in tonic firing dorsal horn neurons. By activating postsynaptic α2 adrenergic receptors in the spinal cord's dorsal horn it causes antinociception. This is similar to the actions of nor-adrenaline which is released from the central nervous system's descending inhibitory pathways. Therefore, when second-order neurons and wide dynamic range neurons in the dorsal horn become less active, the input from peripheral nociceptive Aδ and C fibres is attenuated [10] When given neuraxially clonidine stops nociceptive neurons from firing in response to unpleasant stimuli and stops the release of spinal substance P. The cGMP inhibits the analgesic effect of substance P release.[1]

Although fentanyl is a well-established epidural adjuvant, its use may be associated with opioid-related adverse effects such as nausea, vomiting, pruritus, urinary retention, and respiratory depression. Clonidine, an α2-adrenergic agonist, has emerged as a promising non-opioid alternative that prolongs analgesia while avoiding many opioid-related complications. However, evidence directly comparing epidural clonidine and fentanyl at clinically relevant doses in patients undergoing elective lower limb surgeries remains limited, particularly in the Indian population. Therefore, the present study was undertaken to compare their efficacy and safety when used as adjuvants to epidural bupivacaine.

METHODOLOGY

Over the course of 18 months, 60 patients with ASA grades I and II who were scheduled for elective lower limb procedures between the ages of 18 and 60 participated in comparative two group randomized double blinded clinical research. After ethical clearance from institutional ethical committee and written informed consent, patients were randomly allocated into two groups of 30 each by sealed envelope method. Preoperatively all patients after meeting inclusion and exclusion criteria underwent preanaethetic evaluation and routine laboratory investigations.

On arrival in the operating room, intravenous line was secured with 18G cannula and proloading with Ringer lactate 500ml over 10 minutes was done. Patients were connected to multichannel monitor, and baseline HR, NIBP, ECG and SPO2 were noted. Under aseptic precautions, lumbar epidural space was identified in L3-L4 interspace with loss of resistance technique, epidural catheter was introduced and secured at 3-5cms, and a test dose of 3ml 2% lignocaine with adrenaline was administered. After 4-6 minutes of test dose, epidural drug was administered over a period of 10 minutes depending on drug group allocation:

- Group BC patients were given 16 ml of 0.5% isobaric Inj. Bupivacaine with Inj.Clonidine 1μg/kg
- Group BF patients were given 16 ml of 0.5% isobaric Inj. Bupivacaine with Inj.Fentanyl 0.5μg/kg

Pulse rate, respiration rate, SBP, DBP, MAP, SPO2, and ECG were all continuously monitored. Intraoperative readings were taken every five minutes for the first thirty minutes, then every fifteen minutes for the next two hours, and finally every thirty minutes until rescue analgesia was administered. Intravenous atropine 0.6 mg was used to treat heart rates less than 60 beats per minute. If blood pressure was less than 90 mmHg or less than 20% of the baseline value, extra Ringer's lactate solution was administered intravenously, or if necessary, injectable Mephentermine 6 mg titrated according to blood pressure. Injection to relieve nausea and vomiting IV dose of 0.1 mg/kg of ondansetron was administered.

Following administration of epidural anaesthesia, the following parameters were noted right away:

1. Onset of sensory block
2. Onset of motor block
3. Time for maximum sensory block
4. Duration of the sensory blockade
5. Two segmental dermatomal regression time
6. Duration of motor blockade
7. Sedation score
8. Time to rescue analgesia
9. Adverse events

Modified Bromage score was used to assess motor block. Sedation score was assessed using Ramsay sedation score and patient was considered sedated if score was 4 or more. The VAS score was used to measure analgesia, and the patient was informed about the verbal analogue score preoperatively. The VAS score was taken five minutes prior to the epidural, at the beginning of the procedure, and then every fifteen minutes until the

procedure was finished. Following surgery, VAS was measured every 30 minutes for the first hour, then every hour for the next 12 hours, and finally every 30 minutes for the next 24 hours. Rescue analgesia in the form of an epidural top-up with 8ml of 0.125% isobaric bupivacaine was administered to patients whose verbal VAS score was greater than 3. The main outcome of this trial was when the patient requested the first dose of rescue analgesia.

The R environment version and statistical program SPSS 22.0.3.2.2 were utilized for data analysis, while Microsoft Word and Excel were utilized to create tables, graphs, and other visual aids. The Student t test (two-tailed, independent) was used to assess the significance of research parameters on a continuous scale between two groups (intergroup analysis) on metric parameters. Leven's test was used to assess the homogeneity of variance. The Chi-square/Fisher exact test was used in a non-parametric environment for qualitative data analysis to assess the relevance of study parameters on a categorical scale comparing two or more groups. The Fisher exact test was used when cell samples were very small.

RESULTS

The age distribution of groups BC and BF did not differ significantly (41.73±12.73 vs. 42.87±11.88, p=0.723). The age distribution of groups BC and BF was similar. The sex distribution of groups BC and BF did not differ significantly (p=0.187). The distribution of sex, ASA grade (p=1.0), height (p=0.282), and weight (p=0.282) were all similar in groups BC and BF.

Group BF experienced an early onset of sensory block (6.3 minutes), but group BC experienced a later onset (11.5 minutes). Additionally, group BF experienced an early onset of motor block (16.9 minutes), but group BC experienced a later onset (24.2 minutes). In group BF, both sensory and motor blocks started early and were statistically significant (p<0.001).

In group BF, the maximum sensory block took 11.3 minutes, but in group BC, it took 16.7 minutes. In group BF, the maximum sensory block occurred early and was statistically significant (p<0.001).

Group BC's two-segment regression took 268.2 minutes, while group BF took 109.2 minutes. In group BF, the time to two segment regression was statistically significant (p<0.001) and occurred early.

The sensory block lasted 147 minutes in group BF and 307.8 minutes in group BC. For groups BC and BF, the motor block lasted 292.8 and 133.8 minutes, respectively. Rescue analgesia took 207.6 minutes in group BF and 307.8 minutes in group BC. Group BC experienced longer sensory, motor block, and rescue analgesia durations than group BF; this difference was statistically significant (p<0.001).

Most participants in both groups experienced maximal sensory block at T6, with T6 level sensory block occurring in 80% and 70% of groups BC and BF, respectively. The highest sensory block was at the T8 level in 20% of group BC and 30% of group BF. Even though more members of group BC experienced maximum sensory block at T6, the difference was not statistically significant (p=0.548).

Most subjects in both groups (70% in group BC and 70% in group BF) had a sedation score of 1. 30% of people in groups BF and BC had sedation scores of 2. The sedation scores of groups BC and BF did not differ significantly (p=0.777).

Variables	Group BC	Group BF	Total	P Value
Onset of sensory block (mins)	11.5±0.82	6.3±0.79	8.9±2.74	<0.001**
Onset of motor block (mins)	24.2±1.1	16.9±1.32	20.55±3.87	<0.001**
Time for maximum sensory block(mins)	16.7±1.37	11.3±0.79	14±2.94	<0.001**
Time to two segment regression (mins)	268.2±0.38 (4.47±0.38 hours)	109.2±0.27 (1.82±0.27 hours)	188.4±1.38 (3.14±1.38 hours)	<0.001**
Duration of motor block (mins)	292.8±0.42 (4.88±0.42 hours)	133.8±0.35 (2.23±0.35 hours)	213.6±1.39 (3.56±1.39 hours)	<0.001**
Duration of sensory block (mins)	307.8±0.47 (5.13±0.47 hours)	147±0.34 (2.45±0.34 hours)	227.4±1.41 (3.79±1.41 hours)	<0.001**
Sedation score	1.3±0.47	1.3±0.47	1.3±0.46	1.000
Time for rescue analgesia (mins)	307.8±0.47 (5.13±0.47 hours)	207.6±0.34 (2.46±0.34 hours)	227.4±1.41 (3.79±1.41 hours)	<0.001**

Table 1: Comparison of Study Variables in Two Groups of Patients Studied

Up to 30 minutes after induction, the mean heart rates of the two groups were similar. The change was not statistically significant (p>0.05). Group BC's mean heart rate was lower than group BF's from 30 to 105 minutes following induction. Figure 1 illustrates that this difference was statistically significant (p<0.05)

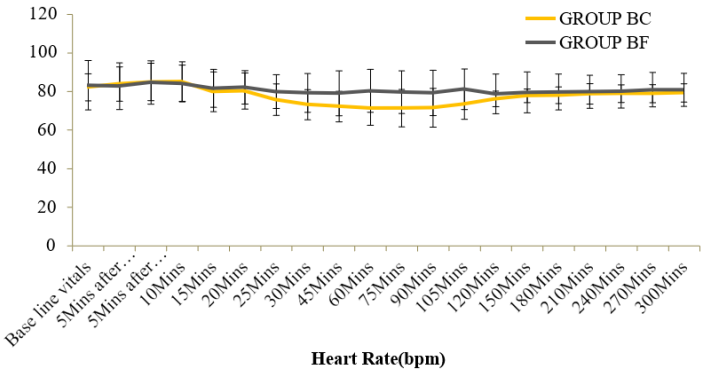

Figure 1: Heart Rate Variation

At baseline, the two groups' mean SBPs were similar to one another. The change was not statistically significant (p>0.05). Group BC's mean SBP was lower than group BF's from 5 to 300 minutes after induction. There was a statistically significant difference (p<0.05). Figure 2

Systolic Blood Pressure (mm Hg)

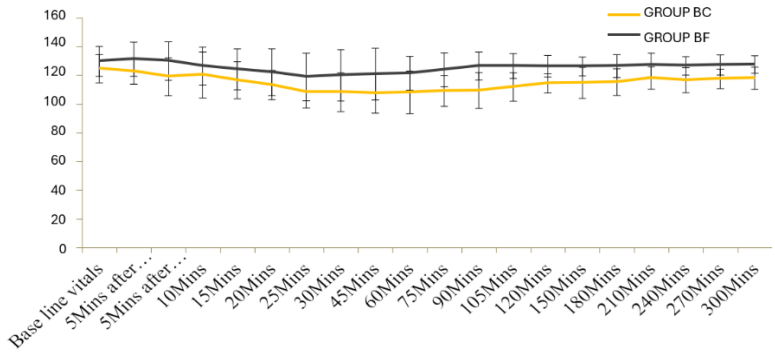

Figure 2: Systolic Blood Pressure Variation

At baseline, the two groups' mean DBPs were similar to one another. The change was not statistically significant (p>0.05). At 5 minutes of induction, 25 minutes after induction, and from 45 minutes to 300 minutes following induction, the mean DBP in group BC was lower than in group BF. There was a statistically significant difference (p<0.05). Figure 3.

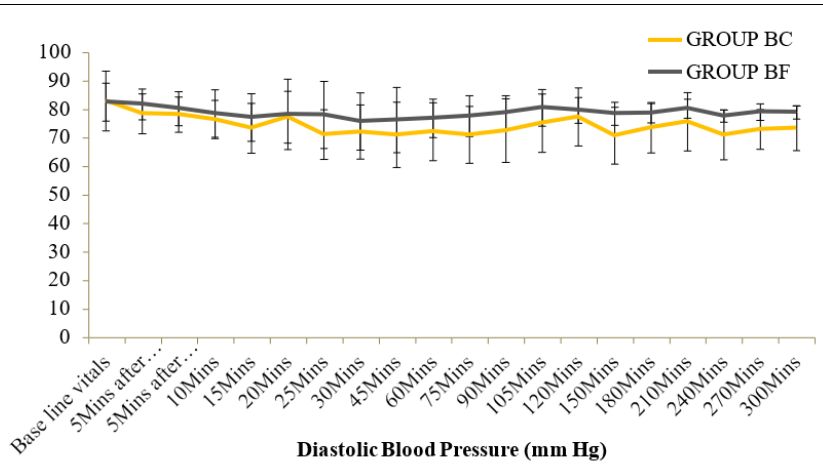

Figure 3: Diastolic Blood Pressure Variation

At baseline, the two groups' mean MAPs were similar to one another. The change was not statistically significant ($p>0.05$). Group BC's mean MAP was lower than group BF's from 5 to 300 minutes after induction. There was a statistically significant difference ($p<0.05$). Figure 4

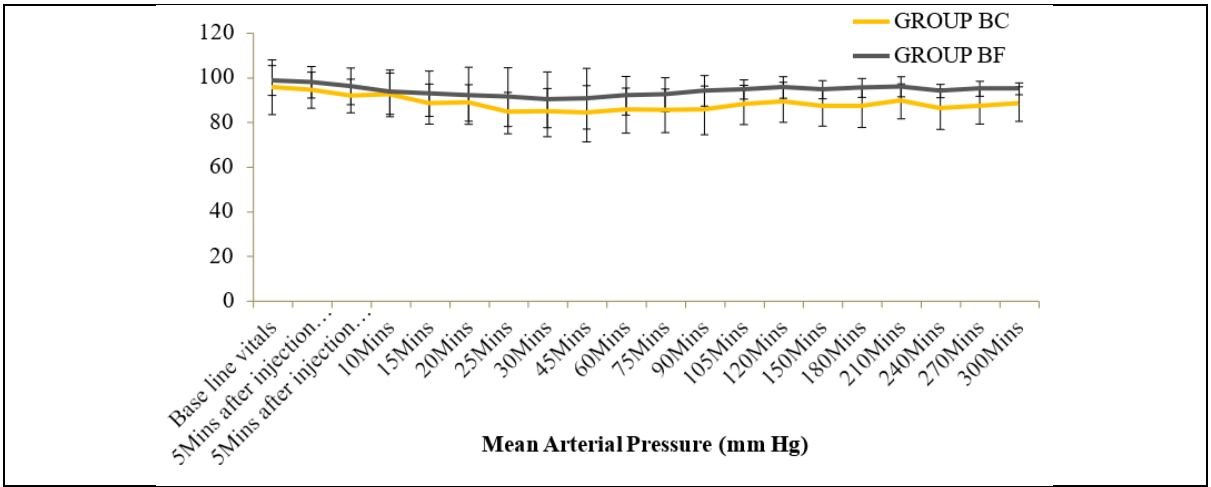

Figure 4: Mean Blood Pressure Variation

The mean saturation in both groups was comparable to each other and was maintained at 99% from induction till 300 mins. Up until 300 minutes after induction, there was no statistically significant difference in the saturation levels of groups BC and BF. Figure 5.

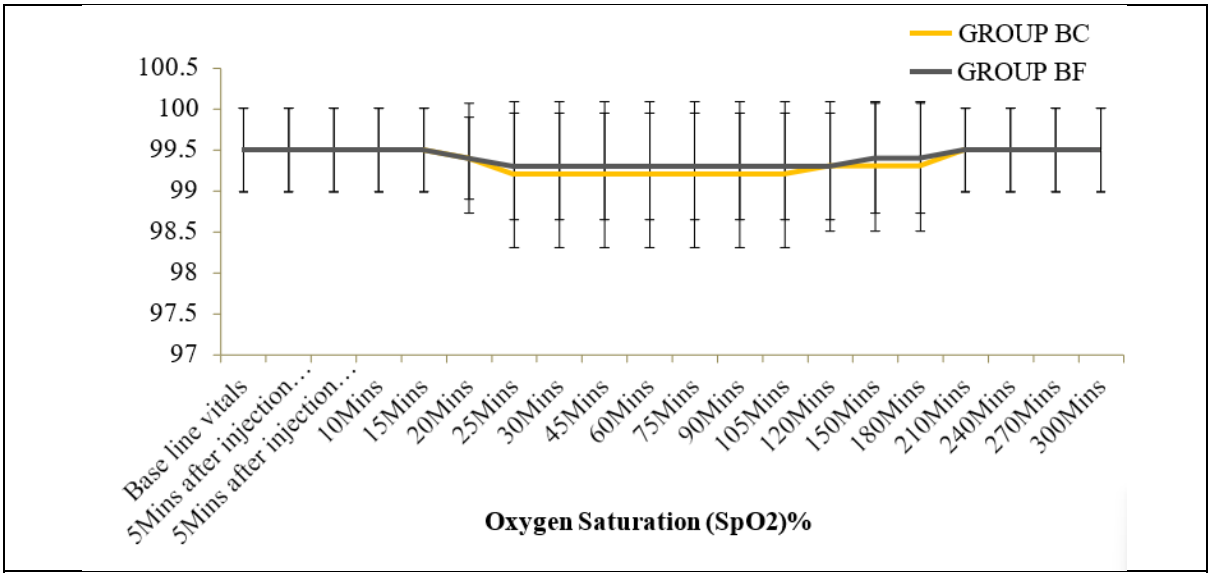

Figure 5: Oxygen Saturation Variation

36.7% of participants in group BC and 33.3% of participants in group BF had side effects. 20% of participants in group BC had hypotension, 20% had bradycardia and 6.7% had nausea and vomiting. 20% of participants in group BF had hypotension, 6.7% had bradycardia and 6.7% had nausea and vomiting. Overall, hypotension was the common side effect (20%) followed by bradycardia (13.3%) then nausea and vomiting (6.7%). There was no significant difference in side effects of group BC and BF ($p=1.000$).

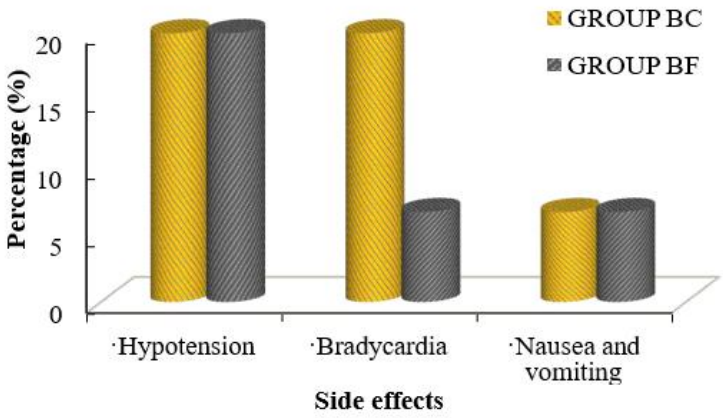

Figure 6: Side Effects - Frequency Distribution in Two Groups of Patients Studied

DISCUSSION

Epidural analgesia offers superior pain relief and early mobilization when a local anaesthetic dose is combined with an adjuvant as opposed to when a local anaesthetic is used alone. Few studies have tried to examine the potential benefits of either combination to evaluate the synergistic effect of these two at lower doses. The quest for the optimal dosage of either an opioid or an alpha-2 blocker as an adjuvant in regional anaesthesia is an ongoing one.

In regional anaesthesia, fentanyl has virtually entirely supplanted conventional opioids like morphine as an adjuvant. Nevertheless, side effects like nausea and vomiting continue to occur to a startling degree of 28-52%, which is extremely uncomfortable for the patient and negates the goal of a quick, uncomplicated recovery.[11-13]

Other drugs, such as α-2 agonists, are being rigorously evaluated as opioid alternatives as adjuvants to neuraxial blocks, with an emphasis on side effects like respiratory depression, nausea, urine retention, and pruritis, because the administration of neuraxial opioids is associated with a variety of negative consequences. Because of their anaesthetic-sparing and hemodynamic-stabilizing properties, alpha-2 agonists may offer an appealing substitute for currently used anaesthetic adjunctive drugs.[14,15] α-2 adrenoreceptor agonists provide analgesia by hyperpolarizing postsynaptic dorsal horn neurons and reducing the release of C-fiber transmitters. The significant analgesic effects of α-2 adrenoreceptor agonists and local anaesthetics are explained by their complimentary actions. The binding of α-2 adrenoreceptor agonists to the motor neurons in the dorsal horn may cause the motor block of local anaesthetics to last longer.

An α2 adrenergic agonist clonidine uses a non-opioid method to generate analgesia. Unlike local anaesthetics, clonidine has no effect on proprioception. Clonidine does not cause respiratory depression, itching, nausea, or vomiting, which are side effects of opioids. When administered epidurally, clonidine's analgesic effectiveness rose. Bradycardia, hypotension, and sedation are possible side effects. Through a non-opioid mechanism, α2 agonists influence the spinal cord's descending noradrenergic pathway, which aids in pain control.[16,17] The analgesic effectiveness, hemodynamics, and adverse effects of clonidine (1µg/kg) and fentanyl (0.5µg/kg) combined with 16ml of 0.5% isobaric bupivacaine were compared in this study. Regarding the mean age distribution (P=0.723), sex distribution (P=0.187), ASA grade distribution (P=1.000), height distribution (P=0.282), and weight distribution (P=0.159) of groups BC and BF, our patients' demographic profiles were similar.

Throughout the course of the trial, the cardio-respiratory parameters stayed constant, confirming the known benefits of α-2 agonists in maintaining a hemodynamically stable perioperative and postoperative phase. The central action of α-2 agonists, which reduces sympathetic outflow and adrenaline release, can explain the reduction in heart rate they generate. When comparing the two groups statistically, there were no discernible changes in the need for vasopressors to maintain stable hemodynamic parameters. However, when compared to the baseline value of the clonidine group, the fentanyl group which in many situations doesn't require any intervention-showed a greater decline in SBP, DBP, and MAP. This was consistent with the research conducted by Ghatak et al.[10]

The results showed that when given as an adjuvant to epidural bupivacaine, clonidine produced longer sensory and motor blocking and postoperative analgesia than fentanyl. Previous studies that used fentanyl and clonidine as an adjuvant to epidural bupivacaine provided support for our study's findings.[18,19]

The highest level of analgesia or sedation score (P=0.777) attained in both groups in our study did not reach statistical significance (P=0.548).

When comparing Group BF to Group BC, we discovered that the onset of sensory and motor blockade was early and statistically significant ($p < 0.001$). The research conducted by Agarwal et al. and others was inconsistent with this.[20] However, our results were consistent with those of Shaikh et al. and others.[2,3]

When comparing Group BF to Group BC, the period for maximum sensory blockade was early and statistically significant ($p < 0.001$). The research conducted by Agarwal et al. and others was inconsistent with this.[20] However, our results were consistent with those of Shaikh et al. and others.[2,3]

Group BF's two-segment regression time was earlier than Group BC's. This was statistically significant ($p < 0.001$). Agarwal et al. and other researchers found similar outcomes.[20]

The Clonidine group fared much better than the Fentanyl group in some postoperative block features, such as the wearing off sensory and motor block and prolonged postoperative analgesia. Agarwal et al. found that the fentanyl group's time to two segmental dermatomal regression and regression to Modified Bromage 1 was considerably shorter than that of the clonidine group similar to this study.

VAS was used to measure the degree of postoperative discomfort and pain alleviation, and analgesia was administered when the VAS was more than 3. The clonidine group's highest VAS score was 5.13±0.47 hours, while the fentanyl group's score was 2.46±0.34 hours. Group BC experienced longer sensory, motor block, and rescue analgesia durations than group BF, and these differences were statistically significant ($p<0.001$). Even though clonidine's extended period of sensory blockade enhanced postoperative pain management, it may not be suitable for nursery procedures since it delays the recovery of motor function. This was consistent with the research conducted by Ghatak et al.[10] Neither group had respiratory depression, most likely because of lower dosage of the drug.

The frequency of side effects, including bradycardia, nausea, vomiting, and hypotension, was comparable and not statistically significant in both groups. Thirty individuals in group BF and thirty percent of participants in group BC experienced adverse effects. In group BC, 20% of patients developed bradycardia and 20% had hypotension. In group BF, hypotension and bradycardia were present in 20% and 6.7% of cases, respectively. The most frequent adverse effect is overall hypotension (20%), which is followed by bradycardia (13.3%). This was consistent with the research conducted by Ghatak et al. [10]

LIMITATIONS

Some of the limitations of the study included small sample size, inclusion of only elective lower limb surgeries and not considering other confounding factors, such as bleeding, tourniquet time and duration of surgery which may affect the hemodynamics and incidence of side effects.

CONCLUSION

Clonidine has emerged as a safe and efficient substitute for fentanyl as an epidural adjuvant, because it offers longer postoperative analgesia and prolonged sensory and motor blockades with less need for post-operative analgesia. Further research is warranted with a larger number of patients with diverse surgeries to establish the role of epidural clonidine.

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