

A RANDOMIZED TRIAL COMPARATIVE STUDY OF THE IMPACT OF ADDING CLONIDINE TO BUPIVACAINE AND USING BUPIVACAINE ALONE FOR AXILLARY BRACHIAL PLEXUS BLOCK

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ABSTRACT

Background

Numbing a specific nerve or a group of nerves with a shot of medicine is an essential part of anesthesia. Especially people who cannot bear general anesthesia during a procedure or suffer from hemodynamic instability consider peripheral nerve blockade as a primary substitute. Clonidine is an antihypertensive drug (α_2 agonist) when used as an adjuvant to bupivacaine (a powerful local anesthetic), it may increase the period of blocks. This study aims to compare and evaluate the adjuvant effect of clonidine with bupivacaine and solo bupivacaine for "axillary brachial plexus block".

Methods

A randomized, controlled, prospective study was conducted involving 60 participants undergoing hand or forearm surgeries. Participants were divided into two groups: Group 1 received clonidine (0.8 ml, 120 μ g) + normal saline (0.2 ml) + bupivacaine (25 ml, 0.5%), and Group 2 received normal saline (1 ml) + bupivacaine (25 ml, 0.5%). The onset time and duration of motor and sensory blocks were recorded.

Results

Group 1 had a significantly faster onset of nerve block and a longer duration of motor (440.5 ± 42.28 min vs. 198.43 ± 27.96 min) and sensory blocks (339.57 ± 40.82 min vs. 212.83 ± 35.25 min) compared to Group 2. These differences were statistically significant ($p < 0.001$). No major side effects were observed in either group.

Conclusion

This study clearly shows that the effect of adjuvant clonidine fastens the onset of nerve blockade and also gives a longer duration of analgesic effect to the patients without producing any major side effects.

Recommendation

Based on the findings, the study recommends using clonidine as an adjuvant to bupivacaine for axillary brachial plexus blocks in clinical practice, especially in cases where prolonged anesthesia and analgesia are desired, and minimal side effects are essential.

Keywords: Hemodynamic Instability, Peripheral Nerve Blockade, Adjuvant Clonidine, Bupivacaine, Nerve Block Duration.

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INTRODUCTION

"Brachial plexus block" is an important medical procedure that involves the numbing of a specific nerve or a group of nerves with a shot of medicine which we generally refer to as regional nerve block anesthesia [1]. It is also considered as an essential part of anesthesia. People who cannot bear general anesthesia during a procedure or suffer from hemodynamic instability consider peripheral nerve blockade as a primary substitute [2, 3].

Both intraoperative anesthesia and extended duration of analgesic effect can be achieved by brachial plexus block without any significant side effects [4]. A large number of

adjuvants have been investigated to increase the effectiveness and lower the side effects of local anesthetics [5]. On the other hand, clonidine is an antihypertensive α_2 agonist that imitates the effect of norepinephrine hormone and in turn, can be used as an additive to bupivacaine (a powerful local anesthetic) to prolong the duration of peripheral nerve blockades [6]. Clonidine acts as a powerful sedative by stimulating independently the central and peripheral sympathetic terminals of the nerves. It also activates the α_2 -receptors in the CNS hence lowering its activity in the SNS [7]. The dose-dependent side effects of clonidine include low blood pressure, sedation, and bradyarrhythmia. The scope

of this study is to compare and evaluate the adjuvant effects of clonidine to bupivacaine with solo bupivacaine for "axillary brachial plexus block".

MATERIALS AND METHODS

Study design

Page | 2 It was a randomized, controlled, prospective study.

Study setting

The study was conducted in the Department of Anaesthesiology, Patna Medical College & Hospital, Patna, Bihar, India. The study duration was 180 days (March 2024 to August 2024).

Study size

A total of 60 patients were involved in the study. The participants were divided into 2 groups with the help of a computer-generated random number table with 30 patients per group. All the patients were involved in the study with their consent.

Inclusion criteria

Participants 18 years or older than those who were to undertake a hand or forearm operation were selected for the study.

Exclusion criteria

Participants who were on medication with psychotropic drugs, Patients with chronic analgesic treatment, Participants who had undergone complexity for "axillary brachial plexus block", Previous history of psychological, nervous disorder, cardiac disorder, renal disease or liver disease, or alcohol abuse and also pregnant or breastfeeding women were all precluded from the study.

Intervention

The pre-anesthetic check-up was done for all patients. No premedication or sedation was advised. The participants were also explained about the "linear visual analog scale system" (0 to 10cm) which is used for the investigation of pain in which 0 indicates "no pain" and 10 indicates "un-tolerated pain".

Two different anesthetists were involved in the preparation of the drug and performing the block. Then the participants were segregated into 2 groups with 30 patients per group. The patients in 1st group were given 0.8 ml of (120µg) clonidine + 0.2 ml of normal saline + 25 ml of Bupivacaine (0.5%). The patients in the 2nd group were given 1 ml of normal saline + 25 ml of Bupivacaine (0.5%). Well-experienced and trained anesthesiologists were appointed to perform the block. The appropriate observations were then recorded by them. The surgical room was standard monitored. The heart rate, BP, and levels of oxygen saturation were all tracked throughout the procedure. "Axillary brachial plexus block" was conducted with a single injection technique. The process was carried out on patients in a "supine position". In a sterile environment, after examining the axillary artery the needle of the nerve stimulator was injected and the solution of the drug was pushed in according to the group of patients segregated into two. Now the needle was taken out of the artery. The arm was maintained in an elevated position over a pillow for 30 minutes before the surgery. The patient's sedation, motor, and sensory block were all monitored every 5min.

Statistical evaluation was done using the "Unpaired students test" and the calculations were done by "SPSS V11". The observations were denoted as mean ± Standard deviation. The statistically significant value of p was <0.005.

RESULTS

The selected 60 patients who were to undertake a hand or forearm operation were included in the study. The participants were segregated into two groups with 30 persons per group. The participants in 1st group were given 0.8 ml of (120µg) clonidine + 0.2 ml of normal saline + 25 ml of Bupivacaine (0.5%). The patients in the 2nd group were given 1 ml of normal saline + 25 ml of Bupivacaine (0.5%).

The patient's baseline characteristics like age, gender, height, weight, BMI, and period of surgery are all tabulated in Table 1. No notable differences between the baseline characteristics of the patients in group I and group II was observed.

Table 1: Baseline characteristics of bupivacaine clonidine group and bupivacaine group

| Baseline Characteristic | Bupivacaine Clonidinegroup | Bupivacaine group | Value of P |
|-----------------------------|----------------------------|-------------------|------------|
| Age in years | 41.28±8.34 | 40.34+10.56 | >0.005 |
| Sex (Male/Female) | 14/16 | 16/14 | >0.005 |
| Height in Centimeter | 164.7±11.47 | 163.9±9.86 | >0.005 |
| Weight in Kilogram | 58.5±7.76 | 57.8±8.93 | >0.005 |
| BMI in kg/m ² | | | |
| Surgery duration in minutes | 110.5+14.37 | 115.8+13.66 | >0.005 |

The time profile and duration of the nerve block (Motor and sensory) are listed in Table 2. From these observations, it is distinct that in bupivacaine clonidine group patients the inception of the motor nerve block was 8.82 minutes faster than the patients in the bupivacaine group and also the period of motor nerve block was notably longer in group I (440.5±42.28 min) than group II (198.43±27.96 min). The value of p was found to be

<0.001. The inception of the sensory nerve was quicker in the bupivacaine clonidine group than in bupivacaine group patients. Also, the period of sensory nerve block was notably longer in the bupivacaine clonidine group (339.57±40.82 min) than in the bupivacaine group (212.83±35.25 min). The value of p was found to be <0.001.

Table 2: Time profile of sensory and motor blocks in group and group II

| Baseline Characteristic | Group I | Group II | p-value |
|--|--------------|--------------|---------|
| Inception of motor nerveBlock in minutes | 10.22±1.36 | 19.5±1.92 | < 0.001 |
| Period of motor nerve Block in minutes | 440.5±42.28 | 198.43±27.96 | < 0.001 |
| Inception of sensory nerveBlock in minutes | 5.47±0.92 | 8.8±0.85 | < 0.001 |
| Time of sensory nerveBlock in minutes | 339.57±40.82 | 212.83±35.25 | < 0.001 |

The inception of the surgical block was quicker in the bupivacaine clonidine group (12.7±1.38 min) than in bupivacaine group II (21.84±2.56 min) patients. Also, the period of sedative effect was significantly longer in group I (718.7±40.7 min) than in group II (512.9 ± 32.8 min). The value of p was found to be <0.001. The Drug reactions of the participants in both groups were tabulated

in Table 3. The values show that there were no noticeable differences in the participant's BP, heart rate, and levels of oxygen saturation. However, the sedative effect was quite more in the bupivacaine clonidine group than the bupivacaine group. This finding was also statistically significant.

Table 3: Drug reaction profile between group I and group II

| Adverse effects | Group I | Group II | p-value |
|--|-----------|----------|---------|
| Heart rate (<45 Min) | 2 | 0 | >0.005 |
| Hypotension (decrease of mean arterial BP) | 11 | 9 | >0.005 |
| Oxygen Saturation level <90% | 0 | 0 | >0.005 |
| Sedation Score | 2.76±0.79 | 1.7±0.68 | - |
| Post Operative Weakness | 2 | 0 | >0.005 |

DISCUSSION

This study revealed that the inception of the motor nerve was quicker in the bupivacaine clonidine group than the patients in the bupivacaine group and also the period of motor block was notably longer in group I. These findings of the current study correlate with the studies of Bernard et al [8] and Chakraborty S et al [9] as they observed quick inception of motor block in group I (Bupivacaine clonidine group) than the group II (bupivacaine group). Since clonidine acts directly on the nerve fiber receptors to produce the analgesic effect [10, 11]. Clonidine is proven to increase the period of nerve block particularly axillary plexus block [12, 13]. The effect of clonidine is higher when injected through perineural administration than intramuscularly since it acts on the local neurons directly [14, 15].

The current study researched the technique of brachial plexus block using local anesthetics. These local

anesthetics spread throughout the area differently depending on various block techniques [16, 17]. Although the mechanism of clonidine is still not distinct, various types of research show the prolongation of clonidine in the "axillary brachial plexus block". [18, 19, 20].

Generalizability

The findings of this study are most applicable to patients undergoing hand or forearm surgeries who are candidates for axillary brachial plexus block. However, since the study was conducted in a single tertiary care hospital, the results may not be universally applicable to all healthcare settings or patient populations. The results are likely valid for similar surgical procedures, but further research across diverse geographic locations and with larger sample sizes would enhance the external validity and applicability of these findings. The use of clonidine as an adjuvant could be extended to other nerve blocks, but specific clinical

conditions and patient comorbidities may affect outcomes and should be considered.

CONCLUSION

These findings depict that the effect of adjuvant clonidine fastens the onset of nerve blockade and also gives a longer duration of analgesic effect to the patients without producing any major side effects. Hence, in conclusion, clonidine as an adjuvant to bupivacaine in the "axillary brachial plexus block" has a significant mechanism.

Limitation

This trial faced certain limitations. The sample size of 60 participants, although adequate for the scope of the study, limits the power of the findings, and larger studies may be needed to confirm the results. The trial was conducted at a single center, which may introduce institutional bias, and the results may not reflect variations in clinical practices across other institutions. Additionally, the subjective nature of pain measurement using the Visual Analogue Scale (VAS) may have introduced imprecision.

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