

Original Research Article

Effect of Oral Premedication on Sub Arachnoid Block for Elective Lower Limb Surgeries

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ABSTRACT

Objectives: To study the effect of premedication with oral clonidine on spinal anaesthesia with 0.5% hyperbaric bupivacaine.

Method: 61 patients posted for elective lower limb surgeries were included in this study. They were randomly divided into 2 groups, Group 1 (OC) 30 patients received oral clonidine 2.5 mcg/kg prior to spinal anaesthesia with 3cc of 0.5 % hyperbaric bupivacaine. Group 2(C) 31 patients received plain 3 cc of 0.5 % hyperbaric bupivacaine.

Statistical Methods: The statistical analysis was done using SPSS software Version 15. The analysis done included Mean and standard deviation, Fisher Exact test for association and Mann-Whitney U tests.

Results: The age and weight distribution were similar in the two groups. The onset of motor blockade was seen to occur earlier in the intervention group compared to the control group (p=0.002).Moderate sedation was observed in all patients that received oral clonidine. There was a statistical significance between the two groups with respect to postoperative analgesia. The oral clonidine group showed a more stable haemodynamic profile in the postoperative period.

Conclusion: Premedication with 2.5 mcg/kg of oral clonidine prior to spinal anaesthesia provides better postoperative analgesia, earlier onset of motor blockade and more sedation as compared to hyperbaric bupivacaine, with stable hemodynamics.

Key words: oral clonidine, spinal anaesthesia, bupivacaine, postoperative analgesia

INTRODUCTION

Neuraxial blockade, spinal anaesthesia in particular, is a very popular procedure performed for lower abdominal, lower limb, urological and gynaecological surgeries.

Spinal anaesthesia was first administered by August Bier in 1898. ⁽¹⁾ The practice of neuraxial blockade has seen numerous advances since then. Intrathecal Bupivacaine is the most commonly used drug in day to day practice as it provides longer duration of anaesthesia and is four times more potent compared to its precursor lignocaine.⁽²⁾

In order to decrease the adverse effects associated with high doses of a single local anaesthetic agent, neuraxial adjuvants were advocated. In addition to their dose sparing effects, neuraxial adjuvants are also used to reduce the latency of onset, improve the quality ,prolong the duration of neural blockade and intra operative and postoperative analgesia.

Common neuraxial adjuvants include opioids, sodium bicarbonate (NaHCO3), vasoconstrictors, alpha-2 adrenoceptor agonists, cholinergic agonists, N-methyl-daspartate (NMDA) antagonists and γ aminobutyric acid (GABA) receptor agonists. ⁽²⁾

Clonidine is a centrally acting partial alpha-2 adrenoceptor agonist. Its analgesic effect is said to be mediated by binding postsynaptic alpha-2 receptors (G-protein coupled inhibitory receptors) in the dorsal horn of the spinal cord, resulting in its antinociceptive action. ⁽³⁾

Clonidine has many routes of administration- intrathecal, oral, intramuscular, intradermal, intravenous and epidural. ⁽⁴⁾

Oral clonidine is a cheaper and simpler alternative to the other routes of administration. Clonidine is rapidly absorbed orally with a peak action between 60-90 minutes. This makes it effective as premedication. ⁽⁵⁾ However, controversies surround the postoperative analgesic effect of oral clonidine. ^(6,7)

Aims and objectives:

To study the effects of oral clonidine as a premedication prior to administering spinal anaesthesia with 0.5% hyperbaric bupivacaine.

MATERIALS AND METHODS

A double blind randomised study was conducted on 61 consenting adult inpatients who are posted for lower limb surgery, under spinal anaesthesia, between the age group of 18-65 years with ASA physical status 1 and 2 were enrolled in the study. Exclusion criteria included pregnancy, known sensitivity to clonidine and bradycardia.

A detailed pre anaesthetic evaluation was done and patients were made familiar with the 10 point Visual Analogue scale. Basic laboratory data, ECG, Chest X-ray and any other relevant investigation needed were reviewed. Informed consent was taken.

All patients were kept nil per oral for 8 hours with pre medication of Tab Ranitidine 150 mg orally 12 hours before surgery.

Patients were randomly allotted into two groups by Anaesthesiologist 1 who decided whether to premedicate the patient with oral clonidine 2.5 mcg/kg or not, that is whether the patient belonged to Group OC (oral clonidine) or Group C (control).

Randomization – Lottery method.

Anesthesiologist 1 prepared one box containing 61 chits all of the same color.30 of

Group OC and 31 of Group C.

Each chit described the drug to be given (3cc of 0.5% hyperbaric bupivacaine) with either 0.5 cc of preservative free clonidine or 2.5mcg/kg of oral clonidine.

Group 1 (OC)- 2.5 mcg/kg of oral clonidine followed by spinal anaesthesia with 3 cc of 0.5 % hyperbaric bupivacaine

Group 2 (C)- 3 cc of 0.5 % hyperbaric bupivacaine

Half hour before the procedure, intravenous access was secured and patients were preloaded with 1000ml Ringer's Lactate solution.

In operating room, non invasive blood pressure, pulse-oximeter, ECG monitors were placed. Baseline SPO2, heart rate, ECG recorded.

Spinal block was administered in the L3-L4 subarachnoid space using a 23G Quincke Babcock spinal needle. Free flow of cerebrospinal fluid was ascertained before injecting the drug.

Sensory block was evaluated by pinprick and motor blockade by Bromage scale.

Intra operatively, non-invasive blood pressure monitoring was done at 0, 2, 5 and every 5 minutes thereafter. Continuous heart rate and SPO2 monitoring was performed. Any fall in BP and heart rate, complaints such as nausea, vomiting or pruritus was recorded, treated and time of occurrence noted. Sedation was assessed by University of Michigan Sedation Scale (UMSS)

Further assessment was done in the postoperative room by Anaesthesiologist 2

Total

blinded to the study groups. Duration of analgesia by Visual Analogue Scale every 20 mins for the first hour and every hour thereafter, Time to requirement for rescue analgesic, Heart rate, Blood pressure, oxygen saturation and incidence of postoperative nausea and vomiting.

Statistical analysis:

The statistical analysis was done using SPSS software. The analysis done included Mean and standard deviation, Fisher Exact test for association and Mann-Whitney U tests.

RESULTS

The two groups were similar in terms of age, weight and gender distribution.

| Table 1: Mean age and weight in the two groups | | | | | | | |
|--|--------------|-------|--------------------|----|-------|--------------------|--|
| | Grou | р | | | | | |
| | Oral Control | | | | | | |
| | Ν | Mean | Standard Deviation | Ν | Mean | Standard Deviation | |
| Age (Years) | 30 | 36.23 | 9.67 | 31 | 42.52 | 14.22 | |
| Weight (kg) | 30 | 54.83 | 5.75 | 31 | 57.00 | 7.51 | |

| (g) | 30 | 54.65 | 5.75 | 31 | 57.00 | 7.51 |
|-----|-------|---------|-------------------|-----------------|----------|------|
| | | | | | | |
| | | Table 2 | : Gender distribu | ution in the tw | o groups | |
| | Gende | r | Group | | Total | |
| | | | Oral | Control | | |
| | Male | | 16 | 17 | 33 | |
| | | | 53.3% | 54.8% | 54.1% | |
| | Femal | e | 14 | 14 | 28 | |
| | | | 46.7% | 45.2% | 45.9% | |

| Table | Time of onset of | f motor blockade |
|-------|------------------------------------|------------------|
| | | |

31

100.0%

61

100.0%

30

100.0%

| | | | Group | | Total | | |
|------------------|---------|----------------|--------|---------|--------|--|--|
| | | | Oral | Control | | | |
| Time of onset of | 2 - 2.9 | Count | 1 | 4 | 5 | | |
| motor blockade | | % within Group | 3.3% | 12.9% | 8.2% | | |
| | 3 – 3.9 | Count | 21 | 8 | 29 | | |
| | | % within Group | 70.0% | 25.8% | 47.5% | | |
| | 4 and | Count | 8 | 19 | 27 | | |
| | above | % within Group | 26.7% | 61.3% | 44.3% | | |
| Total | | Count | 30 | 31 | 61 | | |
| | | % within Group | 100.0% | 100.0% | 100.0% | | |

Table 4:Time of onset of sensory blockade

| | | | Group | | Total |
|------------------|---------|----------------|--------|---------|--------|
| | | | Oral | Control | |
| Time of onset of | 2 - 2.9 | Count | 24 | 20 | 44 |
| sensory blockade | | % within Group | 80.0% | 64.5% | 72.1% |
| | 3 and | Count | 6 | 11 | 17 |
| | above | % within Group | 20.0% | 35.5% | 27.9% |
| Total | | Count | 30 | 31 | 61 |
| | | % within Group | 100.0% | 100.0% | 100.0% |

| Table 5 | : Degree of sedation | between the two grou | ps |
|---------|----------------------|----------------------|----|
| | | Group | To |

| | | | Group | | Total |
|----------|---|----------------|--------|---------|--------|
| | | | Oral | Control | |
| Sedation | 0 | Count | 0 | 31 | 31 |
| | | % within Group | .0% | 100.0% | 50.8% |
| | 1 | Count | 12 | 0 | 12 |
| | | % within Group | 40.0% | .0% | 19.7% |
| | 2 | Count | 18 | 0 | 18 |
| | | % within Group | 60.0% | .0% | 29.5% |
| Total | | Count | 30 | 31 | 61 |
| | | % within Group | 100.0% | 100.0% | 100.0% |

Table 6: Duration of postoperative analgesia between the two groups

| | | Duration | Duration of Analgesia | | | | | |
|-------|---------|----------|------------------------|----------|--------------|--|--|--|
| | | Median | Median First Third 95% | | | | | |
| | | | Quartile | Quartile | confidence | | | |
| | | | | | interval for | | | |
| | | | | | median | | | |
| Group | Oral | 280 | 250 | 300 | (270, 289) | | | |
| | Control | 240 | 200 | 280 | (215, 270) | | | |



Graph 1: Bar diagram showing the time of onset of motor blockade



Graph 2: Box plot representing duration of postoperative analgesia between the two groups



Graph 3: Postoperative pulse rate



Graph 4: Postoperative systolic blood pressure





| VAS | | Group | | | | |
|-------------|---|-------|--------|-------|--------|--|
| | | Oral | Oral | | | |
| | | Count | % | Count | % | |
| 0 minutes | 0 | 30 | 100.0% | 31 | 100.0% | |
| 10 minutes | 0 | 30 | 100.0% | 31 | 100.0% | |
| | 1 | 0 | .0% | 0 | .0% | |
| 20 minutes | 0 | 30 | 100.0% | 30 | 96.8% | |
| | 1 | 0 | .0% | 1 | 3.2% | |
| | 2 | 0 | .0% | 0 | .0% | |
| 40 minutes | 0 | 29 | 96.7% | 30 | 96.8% | |
| | 1 | 1 | 3.3% | 1 | 3.2% | |
| | 2 | 0 | .0% | 0 | .0% | |
| 60 minutes | 0 | 27 | 90.0% | 29 | 93.5% | |
| | 1 | 2 | 6.7% | 1 | 3.2% | |
| | 2 | 1 | 3.3% | 1 | 3.2% | |
| 90 minutes | 0 | 25 | 83.3% | 17 | 54.8% | |
| | 1 | 4 | 13.3% | 13 | 41.9% | |
| | 2 | 0 | .0% | 1 | 3.2% | |
| | 3 | 1 | 3.3% | 0 | .0% | |
| 120 minutes | 0 | 4 | 13.3% | 4 | 12.9% | |
| | 1 | 17 | 56.7% | 16 | 51.6% | |
| | 2 | 8 | 26.7% | 7 | 22.6% | |
| | 3 | 1 | 3.3% | 4 | 12.9% | |
| 180 minutes | 0 | 0 | .0% | 0 | .0% | |
| | 1 | 6 | 20.0% | 4 | 12.9% | |
| | 2 | 12 | 40.0% | 11 | 35.5% | |
| | 3 | 11 | 36.7% | 9 | 29.0% | |
| | 4 | 1 | 3.3% | 7 | 22.6% | |

Table 7: VAS scores in the postoperative period

The VAS score was < 4 in both groups during the first 120 minutes in the postoperative period. At the 180min time interval, 1 patient from group 1(OC) (3.3%) and 7 patients from Group 2(C) (22.6%) experienced a VAS >4 and were administered the rescue analgesic.

DISCUSSION

The study shows there exists significant association between the groups and time of onset of motor blockade (p value = 0.002) but no significant association between the groups and time of onset of sensory blockade (p value = 0.255). (*Table 3 and 4; Graph 1*)This is, in part, similar to the findings of Dziubdziela W et al., ⁽⁸⁾ who stated that oral clonidine has no effect on the onset of both motor and sensory blockade.

All patients in Group 1(OC) experienced some degree of sedation-Mild sedation (40%) and moderate sedation (60%), whereas none of the patients in Group 2 (C) experienced any sedation.

(*Table5*) This is similar to the findings of Ezri et el., ⁽⁶⁾ who concluded that all the patients experienced anxiolysis and sedation after administration of oral clonidine.

The test showed that there exists significant difference in the average duration of analgesia among the two groups (pvalue =0.015). (*Table6;Graph 2*) These similar findings were seen in studies conducted by Montazeri et al., ⁽⁹⁾ and Codi et al., ⁽¹⁰⁾ who concluded that oral clonidine given 90 mins and 2 hours before spinal anaesthesia, respectively, prolonged both the sensory and motor blockade There was no statistical significance between the groups with respect to the VAS scores.(*Table 7*)

The pulse rate and blood pressure were comparable in the two group during the intraoperative period. In the postoperative period, Group 1(OC) showed a more stable haemodynamic profile, whereas Group 2 (C) exhibited a steady rise in the pulse rate, systolic and diastolic blood pressures. (*Graph3,4,5*) These findings were also observed by Liu SS et al., ⁽⁷⁾ who documented that patients receiving oral clonidine did not experience any hypotension or bradycardia in the perioperative period.

CONCLUSION

Based on the findings of the study, we can conclude that premedication with oral clonidine provides earlier onset of motor blockade, longer duration of postoperative analgesia, moderate sedation, with a stable haemodynamic profile in the postoperative period, thus making it a useful adjuvant to sub arachnoid blockade.

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