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Social Science Journal

A Comparative Clinical Study Of Bupivacaine 0.25% With Clonidine And Ropivacaine 0.25% With Clonidine In Paediatric Caudal Block For Below Umblical Surgery

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Abstract

Background: Pain Is "An Unpleasant Sensory And Emotional Experience Related With Present Or Potential Tissue Damage Or Described In Terms Of Such Damage," According To The International Association For The Study Of Pain (IASP). Due To The Belief That Children Do Not Perceive Pain, Do Not React To Or Recall Unpleasant Events, They Have Received Inadequate Treatment For Pain And Painful Treatments. Hence There Was An Unfortunate Tendency To Ignore The Need For Analgesia During Painful Procedures And Even During And After Surgery. This Prompted The Current Research, Which Aimed To Examine The Duration Of Analgesia After Administering Equivalent Volumes Of Bupivacaine And Ropivacaine With Clonidine As An Adjuvant For Paediatric Caudal Block And Evaluate Their Safety And Effectiveness. This Prospective Open Label Observational Study Was Conducted After Getting Permission From The Institutional Ethics Committee. The Study Was Done At Anaesthesiology Department Co-Operation From The Department Of Paediatric Surgery Of A Tertiary Teaching Care Hospital Of Eastern India For A Period Of 2 Years. 60 Children, Satisfying The Inclusion Criteria Were Divided Into Two Groups Consisting Of 30 Each. GROUP I Received 0.25% Bupivacaine 0.5ml/Kg+ 1 µg/Kg Clonidine, Whereas GROUP II Received 0.25% Ropivacaine 0.5ml/Kg+ 1 µg/

Results: The Difference In Duration Of Analgesia Between The Two Groups Is Statistically Significant (P<0.001).

Conclusions: 0.25% A Combination Of 0.5ml/Kg Bupivacaine And 1microgram/Kg Clonidine Is Preferable To 0.25% Bupivacaine Alone. Short Surgical Procedures, Such As A Circumcision, Can Be Managed With Ropivacaine 0.5 Ml/Kg And Clonidine 1 Microgram/Kg.

Keywords: - Bupivacaine, Clonidine, Pain, Post operative analgesia, Ropivacaine

Background

Pain is "an unpleasant sensory and emotional experience related with present or potential tissue damage or described in terms of such damage," according to the International Association for the Study of Pain (IASP). [1.] Due to the belief that children do not perceive pain, do not react to or recall unpleasant events, they have received inadequate treatment for pain and painful treatments. Hence there was an unfortunate tendency to ignore the need for analgesia during painful procedures and even during and after surgery.[2,3] Since the anaesthesiologist, you want to make sure your patient is comfortable after surgery, as any discomfort they experience will only make their parents more concerned. There are a number of approaches that have been tried and shown to be at least somewhat effective in relieving pain in children. Regional anesthetic treatments allow for a quicker return to awareness and more efficient postoperative pain management with less sedation[4] than would be achievable with general anesthesia alone. The caudal epidural block is one of the most popular and often used regional blocks in paediatric anesthesia[5].This method may be used in conjunction with general anesthesia to provide intraoperative and postoperative analgesia for individuals having brief surgical operations below the umbilicus[6]. Pediatric caudal block has been achieved using a variety of long-acting local anesthetics. Long-acting amide local anesthetics are used for paediatric caudal block, and they include bupivacaine (in dosages ranging from 0.15% to 0.5%) and ropivacaine (in concentrations ranging from 0.2% to 0.75%). The consequent deep motor block and systemic toxicity are minimized when the concentration and dosage of local anesthetics are decreased. The primary disadvantage of single-shot caudal block is its relatively short duration of action, even with long-acting local anesthetics like Bupivacaine and Ropivacaine[5]. Good post-operative analgesia is required to prevent the youngster from feeling pain after surgery. Adjuvants such as opiates [8, 9, 10], midazolam [11], ketamine [12], neostigmine [13], clonidine [14], and others have been used to delay the need for epidural catheter implantation and increase the effectiveness of local anesthetics during and after surgery. The strength and duration of analgesia produced by the alpha 2 adrenergic agonist clonidine vary depending on the amount taken[16]. In children with caudal block, it is often administered as an adjuvant at a dosage between 1 and 3 milligrams per kilogram of body weight. Clonidine enhances intra- and postoperative analgesia while lessening local anesthetic toxicity when used with local anesthetics such lignocaine, bupivacaine, and ropivacaine in a caudal block. This prompted the current research, which aimed to examine the duration of analgesia after administering equivalent volumes of Bupivacaine and Ropivacaine with Clonidine as an adjuvant for paediatric caudal block and evaluate their safety and effectiveness.

Hence this study was conducted with a purpose to assess the efficacy, safety, and analgesic duration of subcutaneous injections of the efficient analgesics Bupivacaine and Ropivacaine in caudal block-affected children.

Methods

After obtaining permission from the Institutional Ethics Committee, the study was conducted in Anaesthesiology department in association with the department of Paediatric Surgery of a tertiary teaching care hospital of Eastern India for a period of 2 years.

Children between 1 to 6 years, planned for circumcision with American society of Anesthesiologists (ASA) physical status-I were included in the study. Patient with body weight > 20 kilograms (kgs), bleeding diathesis, infection at the site of block, spine abnormalities, allergic to local anaesthetics, recent history of aspirin or any other anti-inflammatory drugs and children with pre-existing systemic disease were excluded from the study.

60 children, satisfying the inclusion criteria were divided into two groups consisting of 30 each. GROUP I received 0.25% Bupivacaine 0.5ml/kg+ 1 µg/kg Clonidine, whereas GROUP II received 0.25% Ropivacaine 0.5ml/kg+ 1 µg/kg Clonidine. Children were admitted and a thorough preoperative evaluation was done which included a detailed history taking, general physical and systemic examination and laboratory investigations. Parents gave a written informed consent after being explained the procedure, advantages and its consequences in their own language. Basal vital parameters like heart rate, blood pressure and Oxygen saturation were recorded after connecting the child with Philips V24E monitor. Injection (Inj.) Glycopyrolate 0.005- 0.008 mg/kg IV and Inj. Midazolam 0.03mg/kg IV was given as premedication. Patients were induced with Ketamine 2mg/kg IV and maintained on spontaneous ventilation with Oxygen, Nitrous Oxide and Sevoflurane by using the Jackson Rees circuit. Rhe child was put in the left lateral position and under aseptic precautions the sacral hiatus was identified. The loss of resistance technique was used to identify the caudal epidural space and the drug was deposited after confirming negative aspiration for blood and CSF. Intraoperatively the onset of action and duration of surgery were noted. The onset of action is defined as the time in minutes between local anaesthetic injection and the absence of gross movements or absence of significant increase in heart rate on application of the mechanical stimulus. Heart rate, blood pressure and SPO_2 were recorded before and after induction and every 5 mins thereafter till the surgery was over. Any rescue doses of Sevoflurane if needed was noted. Post-operatively the vital parameters were recorded every 15 mins and also the duration of sedation, duration of analgesia, any complications were noted. The duration of analgesia is defined as the time of onset of analgesia to the time of appreciation of pain. This was assessed by using the subjective pain scale in children more than 3years of age who can verbally express pain and observational pain scale for rest of the children who cannot verbally express pain. If the child complained of pain or if the pain score is >/=3 the child received Paracetamol suppository 15mg/kg as a rescue analgesic. Sedation was assessed using the Sedation score where the duration of sedation is defined as the time from the onset of analgesia to spontaneous eye opening (sedation score<1) and motor block was assessed by Modified Bromage scale.

Statistical Analysis

Descriptive statistical analysis was done in this study by using SPSS version 21.0. Continuous measurements were presented as mean±SD and categorical measurements as Number (%). Significance is assessed at 5 % level of significance. Student t test (two tailed, independent) was used to determine the significance on continuous scale between two groups and Chi-square/ Fisher Exact test was used to determine the significance of study parameters on categorical scale between two or more groups. Mann Whitney U test has been used to find the significance of SPO_2 between two groups.

Results

The total number of children included in the study were 60.

30 children in group I and 30 children in group II.

As shown in figure 1, there was no significant difference in the age distribution of the children between the two groups.($p>0.05$). The mean age of patients studied in group I and group II was 3.72±1.61 years and 3.40±1.60 years. There was no significant difference in the age distribution of the children between the two groups.($p>0.05$). The mean weight of patients studied in group I and group II was 13.46±3.35 kgs and 13.26±3.66kgs.

There was no significant difference in the weight distribution of the children between the two groups.($p>0.05$)

As shown in figure 2, the mean onset of action in group I was 7.06±0.69mins and in group II was 6.5±0.73mins. The mean duration of surgery in group I was 26.83±4.04mins and in group II was 26.33±3.45mins. There was no significant difference in duration of surgery between both the groups with $p>0.5$. The mean duration of sedation in group I and group II was 139.12±14.22mins and 136.66±13.21mins respectively. The difference in duration of sedation between both the groups is not significant statically with $p>0.05$. In our study in group I, the shortest duration of analgesia was 405mins, longest was 555mins and the mean duration of analgesia being 477.5±39.01mins, whereas in group II the shortest duration of analgesia was 390mins, longest was 490mins and the mean being 437±23.21mins.

The difference in duration of analgesia between the two groups is statistically significant ($p<0.001$).

Among the 60 children studied, only one case (3.3%) in group I had retention of urine for >12hrs.

There was no significant difference in the Systolic, Diastolic and mean arterial blood pressure (MAP) between both the groups at 0 min and in subsequent measurement at 5 mins interval till 30 mins ($p>0.05$ at each measurement) as shown in figure 3 and 4.

There was no significant difference in the Oxygen saturation (SPO_2) between both the groups at 0 min and in subsequent measurement at 5 mins interval till 30 mins ($p>0.05$ at each measurement) as shown in figure 5. The basal SPO_2 in group I was 100±0 % and in group II was 99.96±0.18%. After 30mins it was 99.9±0.18% and 100% respectively.

The difference in haemodynamic parameters post-operatively was not statically significant. ($p>0.05$).

Discussion

To anesthetize the sacral dermatomes, Armitage EN15 recommended using 0.5ml/kg of 0.25 percent Bupivacaine and 0.25 percent Ropivacaine; however, our analysis revealed no evidence that using a greater volume of the same local anesthetic dose lengthened the duration of caudal blockade. Alpha 2 adrenergic agonists, such as clonidine and prednisolone, are often used as adjuvants to prolong the effect of local anesthetics. Both groups in our research were given an adjuvant dosage of clonidine (1 microgram per kilogram). In a 2005 research by

Upadhyay et al.[16] including 50 children undergoing elective lower abdominal and lower limb procedures, it was shown that the addition of clonidine to 0.75ml/kg of caudally administered 0.25% bupivacaine significantly extended the duration of analgesia. In a group of 60 young people treated ureteral reimplantation, the analgesic, adverse effect, and rehabilitation profiles of ropivacaine 0.2%, caudal clonidine, hydromorphone, and morphine were prospectively examined by Vetter TR et al[17] in 2007. Despite having equal analgesic effects to caudal hydromorphone or morphine, clonidine caused much less postoperative nausea, vomiting, and itching. When combined with Bupivacaine, Clonidine increases the duration of caudal analgesia, as was shown by Archna et al.[26] in 2009. K U Adate et al.[18] came to the conclusion that the addition of Clonidine to 0.1% ropivacaine gives similar quality and duration of analgesia as that of 0.2% ropivacaine and Clonidine, without causing a significant degree of post-operative sedation. They did this by comparing the effectiveness and safety of 0.2% ropivacaine and 0.1% ropivacaine with the addition of Clonidine 2microgram/kg. While locating the caudal epidural space in children less than 7 years old is simple, it becomes increasingly difficult as the child ages as the sacral gap closes and the sacral vertebrae fuse[19]. Children as young as one and as old as six were enrolled in our research. Rates of failure were found to be rather high in children older than seven years old, according to research published by Bernard et al.[19] in 1989. Caudal blocking during ureteral reimplantation procedures was the subject of research by Vetter TR et al.[17] in 2007. The study's participants' children varied in age from six months to six years. Finding the caudal epidural space in older children is more difficult than in younger children because the sacral hiatus narrows and the sacral vertebrae fuse[19] as a kid grows older. Our study included newborns and young children (aged 1 to 6 years). In this study, kids under the weight of 20 kg were taken into account. Constant et al.[14] looked at the efficacy of caudal obstruction in children under 25 kg in 1998. An increased dose of local anesthetic is needed when body mass grows, which might result in a greater cephalad distribution of the medication and a more profound blockage. [19] Children weighing fewer than 20 kg were included in this research. Our research found that the average time to action for group I was 7.1 minutes, whereas for group II it was 6.5 minutes. The minimum activation time was 5 minutes and the maximum was 9 minutes. This closely resembles the time at which effects began to be seen in a 2004 study by Locatelli et al. Analgesic effect start was shown to be 8 minutes after caudal administration of Bupivacaine 0.25 percent and Levobupivacaine 0.25 percent, and 7 minutes after caudal administration of Ropivacaine 0.25 percent, according to a 2004 research by Locatelli et al.[20]. Before having anaesthesia induced with 2 milligrammes of propofol and 2 milligrammes of fentanyl, all of the children received 0.5 milligrammes of midazolam per kilogramme of body weight.The kids' airways were managed using a face mask or laryngeal mask airway intubation. 1998 G. In a double-blind study, Ivani et al.[21] provided 245 kids aged 1 to 10 years who were undergoing elective minor surgery 1 ml/kg of 0.25 percent Bupivacaine or 0.2 percent Ropivacaine as a single caudal extradural injection. Anesthesia was induced using Halothane or Sevoflurane and Propofol after an oral dose of midazolam was given, and it was kept going with Sevoflurane or Isoflurane and oxygen while the patient breathed on their own. 0.2% Ropivacaine 1ml/kg took 9.7 minutes to take effect, whereas 0.25% Bupivacaine 1ml/kg took 10.4 minutes. According to Ivani et al.[22]'s findings from 2000, caudal Ropivacaine's 0.2 percent onset of action took 10 minutes to take effect without an adjuvant, but just 9 minutes with Clonidine 2g/kg. They were premedicated with oral midazolam before being induced and kept on Sevoflurane, Oxygen, and Nitrous Oxide-facilitated spontaneous ventilation. Children's caudal injection of 0.25 percent Levobupivacaine and 0.25 percent Ropivacaine was studied in 2000 by Astulo M, Disma N, and Arena C[23]. Sevoflurane, oxygen, and air were used via a laryngeal mask airway to intubate and monitor the children. Mean time to block onset was 8.2+/-2.2min with Levobupivacaine and 8.5+/-3min with Ropivacaine. When used with a local anesthetic, adjuvants speed up the

process by which the anesthetic takes effect. Our research found that the average time to action for group I was 7.1 minutes, whereas for group II it was 6.5 minutes. The minimum activation time was 5 minutes and the maximum was 9 minutes. This closely resembles the time at which effects began to be seen in a 2004 study by Locatelli et al. Different local anesthetics have variable concentrations, and these differences affect how long the analgesia lasts. The duration of analgesia after receiving Ropivacaine or Bupivacaine has been observed to be comparable in some trials, and to be greater in others. Similar to adults, the duration of the patient's pain-free period is extended when Clonidine is combined with other local anaesthetics in paediatric caudal block. For group I in our study, the lowest analgesia duration was 390 minutes, the longest was 490 minutes, and the mean was 437.0±23.21 minutes. For group II, the shortest analgesia duration was 405 minutes, the longest was 555 minutes. The caudal analgesia duration with 0.25 percent Bupivacaine 1 milliliter per kilogram was determined by Lee et al.[24] to be 312 minutes, whereas the caudal analgesia duration with 2 milligrams per kilogram of clonidine was 588 minutes. All of the kids in this trial were premedicated with 0.2 milligrams per kilogram of body weight of intramuscular morphine, which may have affected how long the analgesia lasted. The average duration of analgesia was 987 minutes in 1994, according to study by Samir et al.[25], when clonidine 1g/kg was administered as an adjuvant to 0.25 percent bupivacaine 1ml/kg, as opposed to 460 minutes when bupivacaine 0.25 percent 1ml/kg was used alone. The extended analgesia these patients felt may have been caused by premedicating them with 0.3 mg/kg of oral diazepam before thiopentone induction and halothane maintenance". Hansen et al.[5] discovered that the time to first analgesic dose after caudal deposition of the medicine was 450 minutes when clonidine 2g/kg was administered as an adjuvant to 0.25 percent Bupivacaine 0.5ml/kg. In contrast, using just half the dosage of Clonidine that they used, we found that the analgesia lasted just as long. 50 children undergoing elective lower abdominal and lower limb surgeries were the subjects of a 2005 research by Upadhyay et al.[16] that examined the effects of caudally given 0.25 percent Bupivacaine 0.75ml/kg alone and in combination with low dose Clonidine 1g/kg. In the Clonidine group, pain relief lasted for 10.3 hours. In contrast, our research shows that, regardless of the Clonidine dosage, analgesia wears off more quickly. Analgesia lasted for 270 minutes in those given 0.25 percent Bupivacaine 0.75 milliliters per kilogram (ml/kg), and 615 minutes in those given 2 milligrams per kilogram (mcg) of clonidine as an adjuvant (Archna et al., 2009). It's possible that the discrepancy in determining the length of time analgesia was effective in this research is due to the fact that pain was evaluated by parents. In 2010, S.J. Bajwa et al. investigated the effectiveness of lower abdominal surgeries in children with caudal 0.25 percent Ropivacaine and 0.25 percent Ropivacaine mixed with 2 micrograms per kilogram of body weight. They were each administered an oral dose of 0.3 mg of midazolam per kilogram of body weight as a premedication. The average duration of sedation in the Ropivacaine group was 2.68+/-0.56 hours, while it was 2.86+/-0.52 hours in the Ropivacaine plus Clonidine group. This is similar to our study, which utilized 1 microgram of Clonidine per kilogram of body weight. The average duration of anesthesia for individuals who got caudal Clonidine 2g/kg as an adjuvant was 546 minutes, compared to 348 minutes for those who received plain Bupivacaine 0.25% 1ml/kg. Oral Trimeprazine and intramuscular morphine (IM morphine) may have contributed to the prolonged sedation seen in these individuals. The parents acknowledged that their kid seemed more at ease after sedation, and they did not view this as a negative consequence. The concentration of local anesthetics administered determines the extent to which motor function is blocked. Ropivacaine, like other amide local anesthetics, generates motor blockage, although at a milder level. Analgesia and minimal to moderate motor blockage are side effects of a 0.25 percent solution of bupivacaine and ropivacaine. According to the Modified Bromage scale, we found no indication of motor blockage in either group, which is comparable with the 1998 results of G.Ivani et al. [21] who compared Ropivacaine 0.2 percent and Bupivacaine 0.25 percent

for caudal analgesia in children. Hansen et al.[5] did not find any evidence of motor blockage when they administered 0.25 percent Bupivacaine at a rate of 0.5 milliliter per kilogram, in conjunction with 2 micrograms of clonidine per kilogram. When comparing Bupivacaine alone to Bupivacaine with Clonidine 2microgram/kg, Archna et al.26 found no evidence of motor blockage in either group in 2009. K. When U adate et al. [18] evaluated 0.1% and 0.2% Ropivacaine in 2011, they found no difference in residual blocking between the two groups. Clonidine lowers heart rate and blood pressure via blocking alpha 2 receptors. Baseline mean heart rates were 129+/- 9.16/min and 132.72+/-11.86/min in groups I and II, respectively, in our research. The mean heart rates for Group I patients at the end of surgery were 105.16+/-7.44/min and for Group II patients they were 105.25+/-6.36/min, showing a slight drop in heart rate of up to 15% throughout. While there was no discernible change in SBP or DBP from one group to the other, we did see an increase in haemodynamic parameters when a kid was in pain. Children administered caudal Bupivacaine alone or in combination with Clonidine 1g/kg or 2g/kg had a substantial reduction in heart rate of up to 20% and mean arterial pressure of up to 10%, according to a study conducted in 1998. Caudal Bupivacaine, combined with Clonidine 1.5 mg/kg and 0.75 mg/kg, considerably decreased heart rate and systolic arterial pressure, according to Constant et al.[14] in 1998. In 2010 S J Bajwa et al[25] observed vomiting as side effect in those given caudal clonidine2µg/kg and Ropivacaine 0.25%.

.Conclusions

Analgesia persisted for 477.5±39.01 minutes in group I, and only 437±23.21 minutes in group II ($p<0.001$). A rescue dosage of 15mg/kg of Paracetamol suppository was administered when a child complained of pain or had a pain/discomfort score of >=3. We have identified one occurrence of urine retention in group I (3.3%). Hence 0.25% a combination of 0.5ml/kg Bupivacaine and 1microgram/kg Clonidine is preferable to 0.25% Bupivacaine alone. Short surgical procedures, such as a circumcision, can be managed with Ropivacaine 0.5 ml/kg and Clonidine 1 microgram/kg.

Declarations

Ethics approval and consent to participate: Prior approval from the institutional ethics committee of S.C.B. Medical College and hospital was taken. (No: 399 dted 14.10.2020)

Consent for publication: Not applicable

Availability of data and material: All data and materials are available with corresponding author in excel sheet.

Competing interests: Nil

Funding: There was No funding for the conducting this study.

Authors' contribution: Dr. Elisha Paikray collected all the data and coordinated with the clinical department. Dr. Anima Rout wrote the manuscript. Dr. Vedvyas Mishra and Dr. Kallol Kumar Jena overall supervised the conducting of the study. Dr. Elisha Paikray additionally responsible for the stastical analysis undertaken in the study.

Acknowledgements: Not applicable

List Of Abbreviations

IASP	International Association for the Study of Pain
ASA	American society of Anesthesiologists
Inj	Injection
Hrs	Hours
Mins	Minutes
IM	Intramuscular
BP	Blood Pressure
MAP	Mean Arterial Blood Pressure
SPO_2	Oxygen Saturation

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Figures/ Legends:

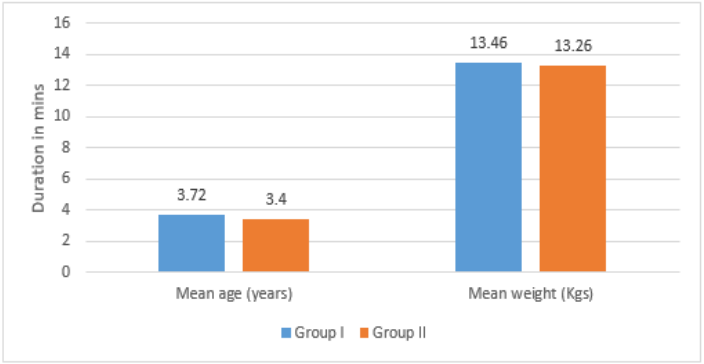

Figure1: *Demographic details of the study population*

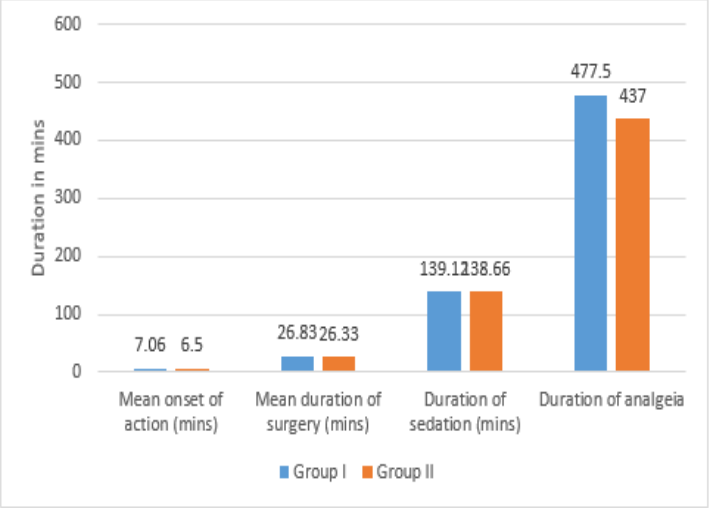

Figure 2: *Intra operative parameters between both groups.*

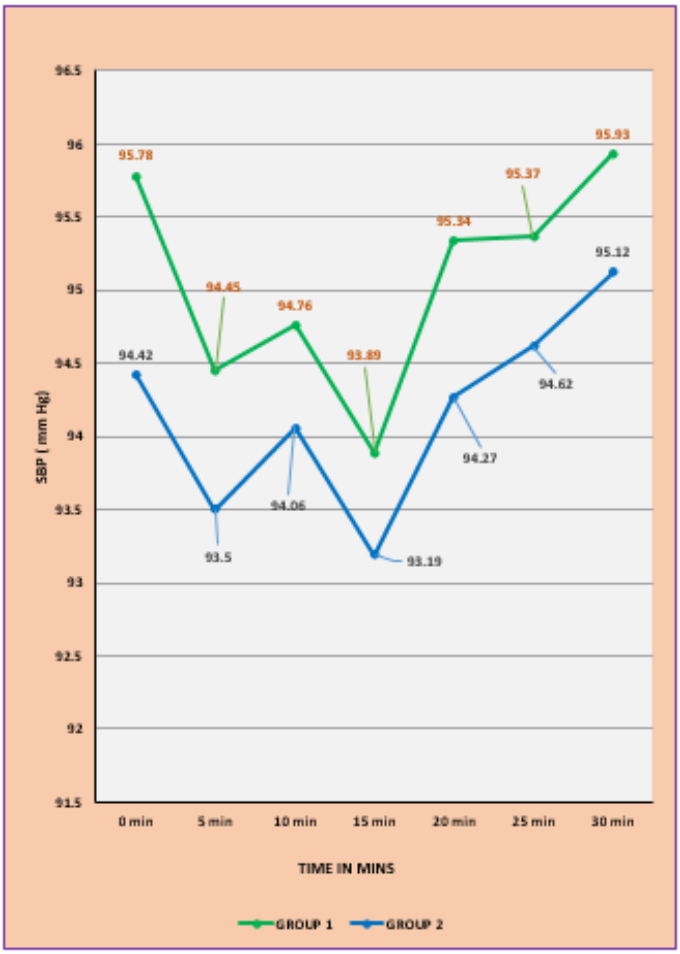

Figure 3: *Variations in intra-operative Systolic BP in both groups.*

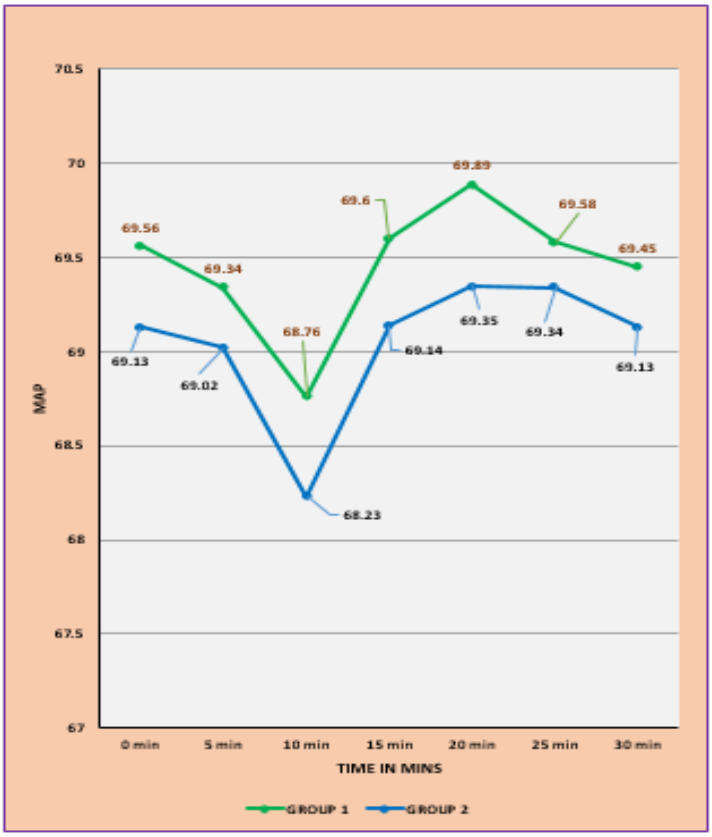

Figure 4: *Variations in intra-operative MAP in both groups.*

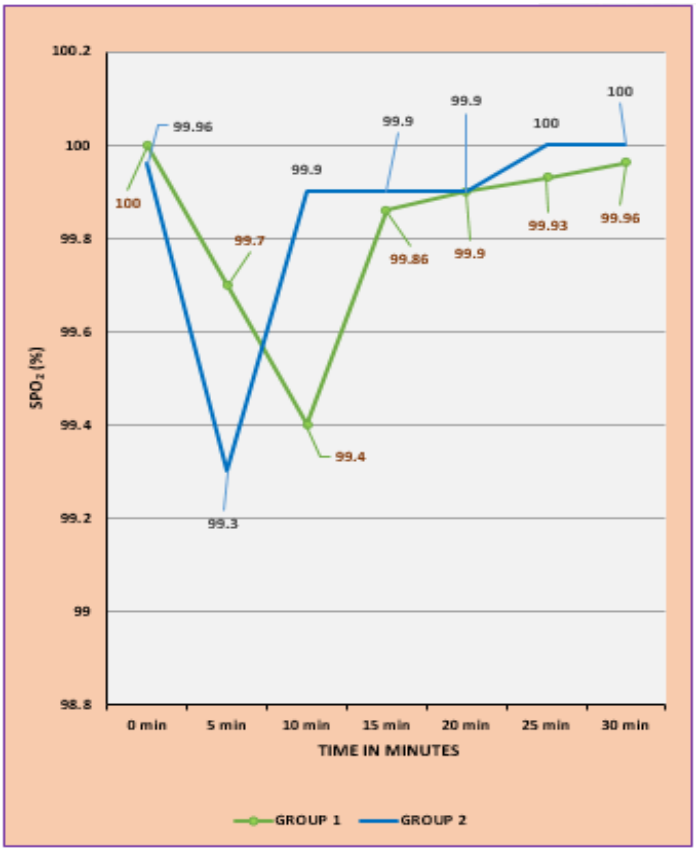

Figure 5: *Variations in intra-operative SPO_2 in both groups.*