

CLONIDINE AND DEXMEDETOMIDINE AS ADJUVANTS TO CAUDAL BUPIVACAINE FOR POSTOPERATIVE ANALGESIA IN CHILDREN UNDERGOING INFRAUMBILICAL SURGERY: A THREE-ARM RANDOMIZED CONTROLLED STUDY

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ABSTRACT

Background: Single-shot caudal bupivacaine provides effective analgesia for paediatric infraumbilical surgeries, but its duration is limited. α_2 -Adrenergic agonists may prolong duration of caudal analgesia when used as adjuvants.

Objective: To compare the analgesic efficacy and safety of clonidine and dexmedetomidine added to caudal bupivacaine.

Materials and Methods: This prospective, single blind, randomised controlled study included 90 children aged 1–10 years, with American Society of Anesthesiologists physical status I or II, undergoing elective infraumbilical, perineal, or lower-limb surgery. Participants were allocated equally in 3 groups to receive caudal 0.25% bupivacaine 1 mL/kg with either normal saline (Group B), or clonidine 1 μ g/kg (Group BC), or dexmedetomidine 1 μ g/kg (Group BD). The primary outcome was the duration of postoperative analgesia, secondary outcomes included postoperative pain score (FLACC Face, Legs, Activity, Cry, and Consolability scores), rescue analgesic requirements during the first 24 hours, haemodynamic changes and adverse effects.

Results: Baseline demographic and operative characteristics were comparable among the groups. The mean duration of postoperative analgesia was 329.0 ± 60.4 minutes in Group B, 606.7 ± 88.6 minutes in Group BC, and 834.3 ± 141.9 minutes in Group BD ($p < 0.001$). All pairwise comparisons were significant ($p < 0.001$). The mean number of rescue analgesic doses required during the first 24 hours was 3.10 ± 0.55 , 2.17 ± 0.59 , and 1.53 ± 0.63 in Groups B, BC, and BD, respectively ($p < 0.001$), with significant differences between each pair of groups. Postoperative pain scores were generally lower with both adjuvants during the early postoperative period, with dexmedetomidine providing greater pain reduction at several assessment points. No significant between-group differences were observed in intraoperative or postoperative haemodynamic and respiratory variables. The incidence of nausea and vomiting was also comparable among the groups.

Conclusion: Adding clonidine or dexmedetomidine at 1 mcg/kg to caudal 0.25% bupivacaine prolonged postoperative analgesia and reduced rescue analgesic requirements compared with bupivacaine alone. Dexmedetomidine provided longer analgesia and lower rescue analgesic requirements than clonidine without a significant changes in haemodynamic variables or observed adverse effects.

KEYWORDS: Bupivacaine; Caudal block; Clonidine; Dexmedetomidine; Paediatric Analgesia; Postoperative Pain.

INTRODUCTION

Postoperative pain is common in children and requires timely recognition and treatment.¹ Its assessment can be difficult because crying and restlessness may also result from fear, hunger, or anxiety.² Inadequately treated pain may cause adverse physiological responses, disturb sleep and feeding, delay recovery, and increase sensitivity to later painful experiences.^{3,4} Effective analgesia is therefore an important part of paediatric anaesthetic care.² Although systemic opioids provide effective pain relief, repeated administration may cause sedation, nausea, vomiting, and respiratory depression.⁵ A multimodal approach that includes regional anaesthesia can improve postoperative analgesia while reducing systemic opioid and general anaesthetic requirements.^{6,7}

Caudal epidural block is commonly used in children undergoing infraumbilical, perineal, urological, and lower-limb procedures.⁸ The technique is relatively simple and provides reliable intraoperative and early postoperative analgesia.⁹ Bupivacaine is widely used for single-shot caudal block, but its analgesic effect usually lasts for only four to six hours.¹⁰ Caudal catheterisation can extend the duration of analgesia but is technically more demanding and carries a risk of infection.¹¹ Several adjuvants have therefore been studied as a means of prolonging analgesia after a single caudal injection.

Opioids, ketamine, neostigmine, midazolam, clonidine, and dexmedetomidine have been administered with caudal local anaesthetics. Some of these drugs are associated with adverse effects such as respiratory depression, nausea, vomiting, pruritus, urinary retention, and excessive sedation.¹¹⁻¹³

Clonidine and dexmedetomidine are α_2 -adrenergic receptor agonists that produce analgesic and sedative effects with little respiratory depression. Their analgesic action is mediated mainly through α_2 -adrenoceptors in the dorsal horn of the spinal cord and supraspinal pathways involved in pain modulation.¹⁴⁻¹⁶ Both drugs, however, may cause bradycardia, hypotension, and sedation. Their haemodynamic effects and safety must therefore be considered alongside their analgesic efficacy.

Clonidine has been used as an adjuvant in neuraxial and peripheral nerve blocks and can prolong the analgesic effect of bupivacaine.¹⁷⁻²¹ Dexmedetomidine has approximately eightfold greater affinity for α_2 -adrenergic receptors than clonidine and greater selectivity for the α_2A receptor subtype associated with analgesia and sedation.¹⁸ El-Hennawy et al.²² reported that clonidine and dexmedetomidine at 2 $\mu\text{g/kg}$ prolonged caudal bupivacaine analgesia compared with bupivacaine alone, without a significant difference between the two adjuvants. Dexmedetomidine at 1 $\mu\text{g/kg}$ has also been reported to prolong caudal analgesia in children without increasing adverse effects.⁴

Although both clonidine and dexmedetomidine prolong caudal analgesia, evidence regarding their relative efficacy and safety at a dose of 1 $\mu\text{g/kg}$ remains limited. This study therefore compared caudal 0.25% bupivacaine alone with bupivacaine combined with clonidine 1 $\mu\text{g/kg}$ or dexmedetomidine 1 $\mu\text{g/kg}$ in children undergoing elective infraumbilical surgery. The primary outcome was the duration of postoperative analgesia. Secondary outcomes included postoperative pain scores, rescue analgesic requirements, haemodynamic changes, and adverse effects.

MATERIALS AND METHODS

This Hospital based single centre, single-blinded, three Arm, randomized controlled study was conducted in the Department of Anesthesiology at Santokba Durlabhji Memorial Hospital, Jaipur, from August 2016 to May 2017.

The study population comprised children aged 1–10 years of either sex, with American Society of Anesthesiologists physical status I or II, who were scheduled for elective infraumbilical, perineal, or lower-limb surgery.

Children with ASA physical status III or IV, known allergy to the study drugs, developmental delay, sacral spine abnormalities, infection at the injection site, coagulation abnormalities, haematological, neurological disease or severe renal or hepatic derangement were excluded. Children receiving anticoagulants, antipsychotic drugs, tricyclic antidepressants, α_2 -adrenergic agonists or β -blockers were also excluded.

The sample size of 21 children in each group was calculated with 80% power and an α error of 0.05 to detect a minimum between-group difference of 30 minutes in the duration of postoperative analgesia, assuming a standard deviation of 34 minutes, as reported by El-Hennawy et al.²² The final sample size was increased to 30 participants in each group to accommodate attrition and improve precision, resulting in a total sample size of 90 participants.

An independent statistician generated the allocation sequence using computer-generated permuted-block randomization with a block size of six. Treatment assignments were placed in sequentially numbered, opaque, sealed envelopes and kept inaccessible to the investigators responsible for participant enrolment. After a participant had been enrolled, the next envelope in sequence was opened immediately before preparation of the study medication, thereby concealing allocation until assignment.

The 90 enrolled participants were allocated in a 1:1:1 ratio to three study groups, with 30 participants in each group. Group B received a caudal injection of 0.25% bupivacaine 1 mL/kg combined with 1 mL of 0.9% normal saline. Group BC received a caudal injection of 0.25% bupivacaine 1 mL/kg combined with clonidine 1 $\mu\text{g/kg}$ diluted in 1 mL of 0.9% normal saline. Group BD received a caudal injection of 0.25% bupivacaine 1 mL/kg combined with dexmedetomidine 1 $\mu\text{g/kg}$ diluted in 1 mL of 0.9% normal saline.

The study was conducted after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from parents/guardians of all participating children, and assent was obtained from the children who were above 7 years of age before enrolment in the study. Participation was voluntary and confidentiality of the information collected was maintained throughout the study.

METHODOLOGY

A preanaesthetic assessment was performed on the day before surgery and the children were kept fasting as per guidelines before the procedure that is 6 hours for light meal and formula milk, 4 hours for breast milk and 2 hours for clear liquids. Intravenous access was established and standard monitoring comprising electrocardiography, pulse oximetry, and noninvasive blood pressure measurement was instituted. Isolyte-P was administered at a maintenance rate of 4 mL/kg/h. Intravenous glycopyrrolate 0.005 mg/kg, fentanyl 2 $\mu\text{g/kg}$, and ondansetron 0.1 mg/kg were administered before induction. General anaesthesia was induced with propofol 2.5 mg/kg and orotracheal intubation was facilitated with succinylcholine 2 mg/kg. Anaesthesia was maintained with oxygen, sevoflurane and atracurium.

After induction of general anaesthesia, the child was placed in the left lateral position. Under aseptic precautions, the sacral hiatus was identified using anatomical landmarks, and the caudal epidural space was accessed using a 25 G short bevelled needle introduced at 45° angle to skin and advanced till a “click” is felt as the sacrococcygeal ligament is pierced, following which the needle was made parallel to skin and advanced 1-2 mm in cephalad direction. Before injection, careful aspiration was performed to exclude the presence of blood or cerebrospinal fluid. The solution was administered slowly while monitoring for subcutaneous swelling, resistance to injection or haemodynamic evidence of intravascular administration. The procedure was performed by an anaesthesiologist with experience in paediatric regional anaesthesia. The number of attempts was recorded, with a new skin puncture considered a separate attempt.

Surgery commenced fifteen minutes after administration of the caudal block. A caudal block was considered inadequate if heart rate or systolic blood pressure increased by more than 20% from the pre-incision value following surgical stimulation despite an adequate depth of general anaesthesia. In such cases, intravenous fentanyl 1 µg/kg was administered. A block requiring intraoperative rescue analgesia was classified as failed. Participants with failed blocks were excluded from the study.

Heart rate, systolic, diastolic and mean arterial pressure and peripheral oxygen saturation were recorded before induction, immediately after administration of the caudal block, at skin incision and every 10 minutes until completion of surgery. Hypotension was defined as a reduction in mean arterial pressure of more than 30% from the preinduction baseline and was treated initially with an intravenous crystalloid bolus of 10 mL/kg; persistent hypotension was treated with intravenous noradrenaline infusion at 0.1 µg/kg/min. Bradycardia was defined as a reduction in heart rate of more than 30% from the preinduction baseline and was treated with intravenous atropine 0.01 mg/kg. After extubation, patients were transferred to the post anaesthesia care unit and monitored continuously for 2 hours. Heart rate, blood pressure, respiratory rate, oxygen saturation, pain intensity, sedation, nausea, vomiting, pruritus, urinary retention, motor weakness, hypotension, bradycardia, and respiratory depression were assessed. After transfer to the ward, observations were continued for 24 hours.

Postoperative analgesia was defined as the interval between administration of the caudal block and the first dose of rescue analgesia. Pain intensity was assessed using the Face, Legs, Activity, Cry, and Consolability scale (FLACC) on arrival in the postanaesthesia care unit and at 1, 2, 4, 6, 8, 10, 12, 14, 16, 18, and 24 hours after recovery from anaesthesia. Intravenous paracetamol 15 mg/kg was administered when the FLACC score exceeded 4. If required paracetamol was repeated at intervals of at least 6 hours, without exceeding a total dose of 60 mg/kg during the first 24 hours.

Statistical analysis

Statistical analysis was performed using SPSS version 23.0. Continuous variables were expressed as mean ± standard deviation and compared among the three groups using one-way analysis of variance. When the overall test was significant, pairwise comparisons were performed using Tukey's honestly significant difference post-hoc test. Categorical variables were presented as number (percentage) and compared using the chi-square test or Fisher's exact test. All tests were two-sided, and a p value <0.05 was considered statistically significant.

RESULTS

[Table-1] Baseline demographic and operative characteristics were similar across the three-study group. The overall mean age was 5.39 ± 3.12 years, and the mean body weight was 17.46 ± 6.18 kg. Of the 90 participants, 63 (70.0%) were male and 27 (30.0%) were female. Implant removal was the most frequently performed procedure, accounting for 21 (23.3%) operations, followed by herniotomy in 19 (21.1%) and orchiopexy in 16 (17.8%) participants. The mean duration of surgery was 53.3 ± 12.5 minutes. No statistically significant differences were observed among the groups in age, weight, sex distribution, type of surgery or duration of surgery ($p > 0.05$).

[Table-2] The mean duration of postoperative analgesia differed significantly among the three groups ($p < 0.001$). Analgesia lasted significantly longer in Group BC than in Group B and in Group BD than in both Groups B and BC. The mean number of rescue analgesic doses required during the first 24 hours also differed significantly among the groups ($p < 0.001$). Group BD required the fewest rescue doses, followed by Group BC and Group B, with all pairwise comparisons reaching statistical significance. Postoperative FLACC scores differed significantly among the groups at 1, 2, 4, 6, 8, 10, and 14 hours. Compared with Group B, FLACC scores were significantly lower in Groups BC and BD at 1, 2, 4, and 6 hours. At 6 hours, Group BD also had a significantly lower score than Group BC. At 8 hours, Group BD had significantly lower scores than both other groups, whereas Group BC had a significantly higher score than Group B. At 10 hours, a significant difference was observed only between Groups B and BD, with a lower score in Group BD. At 14 hours, Group BD had a significantly lower score than Group BC. No significant differences were observed among the groups at 12, 16, 18, or 24 hours.

[Figure-1] Postoperative complications were infrequent and showed no significant difference among the three groups ($p = 0.956$). Nausea occurred in 9 (10.0%) participants, while vomiting occurred in 4 (4.4%). No postoperative complication was observed in 77 (85.6%) participants.

[Figure-2] Intraoperative heart rate decreased gradually after induction in all three groups, with no significant between-group differences at any recorded time point (all $p > 0.05$). A similar temporal pattern was observed for mean arterial pressure, which decreased during the first 30 minutes and subsequently increased; however, values

remained comparable among the groups throughout the intraoperative period (all $p>0.05$). Peripheral oxygen saturation and end-tidal carbon dioxide remained stable, with no significant differences among the groups at any intraoperative assessment (all $p>0.05$).

During the postoperative period, heart rate and mean arterial pressure initially decreased and subsequently returned towards baseline values in all groups. Respiratory rate remained stable throughout the 24-hour observation period. No significant between-group differences were observed in postoperative heart rate, mean arterial pressure, or respiratory rate at any assessed time point (all $p>0.05$). These findings indicate that the three caudal regimens had comparable perioperative haemodynamic and respiratory profiles.

DISCUSSION

This randomised controlled study compared caudal 0.25% bupivacaine alone with bupivacaine combined with clonidine or dexmedetomidine at 1 $\mu\text{g/kg}$ in children undergoing elective infraumbilical, perineal, or lower-limb surgery. Both adjuvants prolonged postoperative analgesia and reduced rescue analgesic requirements. Dexmedetomidine produced a longer duration of analgesia and a lower 24-hour rescue analgesic requirement than clonidine. Postoperative pain scores also differed during the early postoperative period. No significant between-group differences were observed in haemodynamic or respiratory variables or in the recorded postoperative adverse events.

The mean duration of postoperative analgesia was 329.0 ± 60.4 minutes with bupivacaine alone, 606.7 ± 88.6 minutes with clonidine, and 834.3 ± 141.9 minutes with dexmedetomidine. All pairwise comparisons were statistically significant. These findings indicate that both α_2 -adrenergic agonists prolonged the analgesic effect of caudal bupivacaine and that dexmedetomidine provided a longer effect than clonidine at the studied dose.

The benefit of clonidine is consistent with the findings of Jamali et al¹⁷ who reported that clonidine 1 $\mu\text{g/kg}$ prolonged analgesia when added to caudal 0.25% bupivacaine. Similar findings were reported by Parameswari et al¹⁰. The effect of dexmedetomidine is also consistent with Goyal et al²³ who reported a longer duration of analgesia with dexmedetomidine 1 $\mu\text{g/kg}$ and bupivacaine than with bupivacaine alone. Saadawy et al²⁴ likewise observed prolonged analgesia when dexmedetomidine 1 $\mu\text{g/kg}$ was added to caudal bupivacaine.

El-Hennawy et al²² found that both clonidine and dexmedetomidine prolonged caudal analgesia compared with bupivacaine alone, with longer median analgesia in the dexmedetomidine group. Ganeshnavar et al²⁵ reported a longer duration of analgesia with bupivacaine–dexmedetomidine than with bupivacaine–clonidine. Raval et al²⁶ also reported longer analgesia with dexmedetomidine 1 $\mu\text{g/kg}$ than with clonidine 1 $\mu\text{g/kg}$. Differences in the absolute duration of analgesia across these studies may reflect variation in patient age, surgical procedures, anaesthetic protocols, local-anaesthetic regimens, pain-assessment schedules, and criteria for rescue analgesia.

The number of rescue analgesic doses required during the first 24 hours was lowest with dexmedetomidine, followed by clonidine and bupivacaine alone. This finding supports the observed differences in the duration of analgesia and is consistent with the reports of Raval et al²⁶ and Ganeshnavar et al²⁵. Postoperative FLACC scores differed among the groups at several assessment points. Scores were generally lower during the early postoperative period in the adjuvant groups. The pattern at later assessments, may partly reflect the administration of rescue paracetamol, because treatment given in response to pain can reduce subsequent scores and complicate comparisons at fixed time points. The duration of analgesia and cumulative rescue requirement therefore provide more direct measures of the treatment effect than isolated later FLACC scores.

Heart rate and mean arterial pressure changed over time after induction and surgery, but no significant between-group differences were detected at any time point. These observations are consistent with reports by El-Hennawy et al²², Anand et al²⁷, Parameswari et al¹⁰ and Saadawy et al²⁴ who found no significant haemodynamic differences after adding clonidine or dexmedetomidine to caudal local anaesthetic. Respiratory rate, oxygen saturation, and end-tidal carbon dioxide also remained comparable among the groups, consistent with the findings reported by Upadhyay et al²⁸ and Goyal et al²³.

Postoperative adverse events were infrequent. Nausea and vomiting did not differ significantly among the groups, and no clinically significant postoperative respiratory depression, hypotension, bradycardia, pruritus, or urinary retention was recorded. Because of lower sample size, current study therefore cannot exclude clinically important differences in rare complications.

This study has several limitations. It was conducted at a single centre with 30 participants per group, which limits the precision of safety estimates and may restrict generalisability. The study was single-blinded, and incomplete blinding could have influenced postoperative assessment or treatment decisions. Sedation was not measured using a validated scale, although it is a relevant adverse effect of α_2 -adrenergic agonists. Postoperative pain was assessed at predetermined intervals, and rescue analgesia may have influenced later FLACC scores.

CONCLUSION

In children undergoing elective infraumbilical surgery, the addition of clonidine or dexmedetomidine at 1 $\mu\text{g/kg}$ to caudal 0.25% bupivacaine prolonged postoperative analgesia and reduced rescue analgesic requirements compared with bupivacaine alone. Dexmedetomidine produced a longer duration of analgesia and lower 24-hour rescue analgesic requirements than clonidine. No significant between-group differences were observed in

haemodynamic variables or recorded adverse effects. At the doses studied, dexmedetomidine provided more effective postoperative analgesia than clonidine as an adjuvant to caudal bupivacaine.

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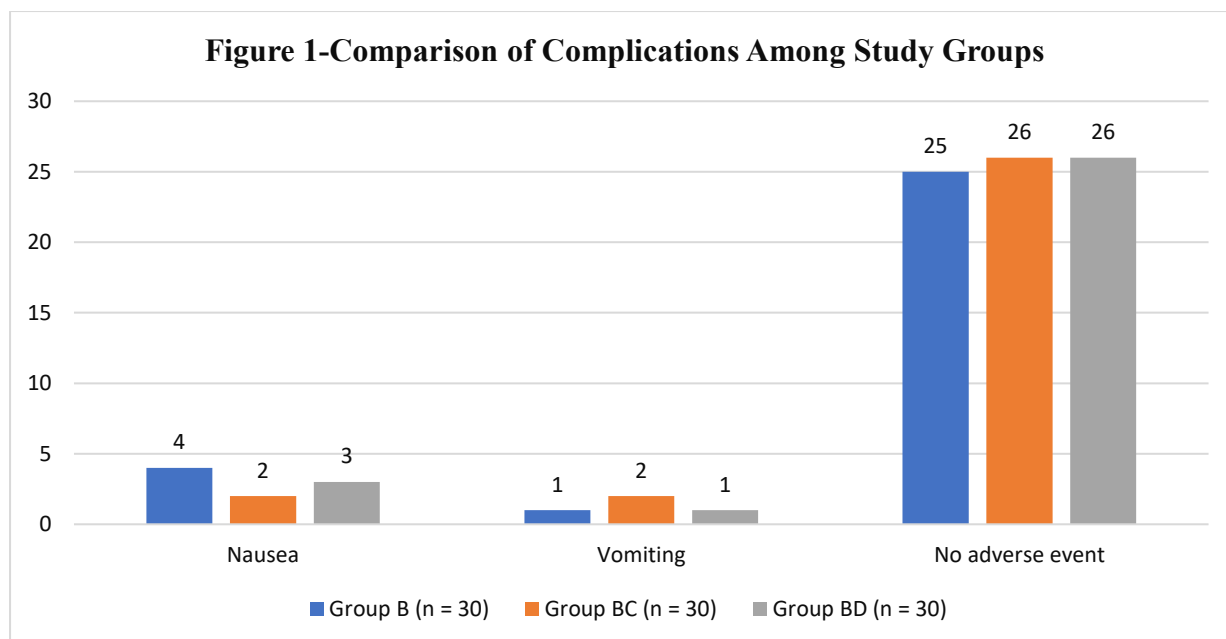
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Table 1. Baseline demographic and operative characteristics of the study participants

Characteristic		Group B (n = 30)	Group BC (n = 30)	Group BD (n = 30)	Total (N = 90)	p value
Age (years)		5.20 ± 3.23	5.27 ± 3.50	5.70 ± 2.65	5.39 ± 3.12	0.801
Weight (kg)		17.20 ± 6.63	17.43 ± 6.87	17.73 ± 5.09	17.46 ± 6.18	0.946
Sex	Female	9 (30.0)	10 (33.3)	8 (26.7)	27 (30.0)	0.853
	Male	21 (70.0)	20 (66.7)	22 (73.3)	63 (70.0)	
Type of surgery	Fixation	2 (6.7)	2 (6.7)	1 (3.3)	5 (5.6)	1.000
	Herniotomy	6 (20.0)	6 (20.0)	7 (23.3)	19 (21.1)	
	Hydrocele surgery	2 (6.7)	2 (6.7)	3 (10.0)	7 (7.8)	
	IR	7 (23.3)	7 (23.3)	7 (23.3)	21 (23.3)	
	Orchiopexy	5 (16.7)	6 (20.0)	5 (16.7)	16 (17.8)	
	SSG	1 (3.3)	1 (3.3)	1 (3.3)	3 (3.3)	
	STR	5 (16.7)	4 (13.3)	5 (16.7)	14 (15.6)	
	Tenotomy	2 (6.7)	2 (6.7)	1 (3.3)	5 (5.6)	
Duration of surgery (min)		55.0 ± 12.3	52.7 ± 14.6	52.3 ± 10.7	53.3 ± 12.5	0.673

Table 2- Comparison of postoperative analgesic outcomes and FLACC pain scores among the study groups

Outcome	Group B (n = 30)	Group BC (n = 30)	Group BD (n = 30)	ANOVA p value	Significant Tukey comparisons
Duration of analgesia, min	329.0 ± 60.4	606.7 ± 88.6	834.3 ± 141.9	<0.001	BC > B; BD > B; BD > BC
Rescue analgesic doses during 24 h	3.10 ± 0.55	2.17 ± 0.59	1.53 ± 0.63	<0.001	B > BC; B > BD; BC > BD
FLACC Score					
0 min	0	0	0	—	—
1 h	0.27 ± 0.45	0.07 ± 0.25	0.03 ± 0.18	0.009	B > BC; B > BD
2 h	1.03 ± 1.10	0.33 ± 0.48	0	<0.001	B > BC; B > BD
4 h	3.00 ± 1.66	0.67 ± 0.61	0.17 ± 0.38	<0.001	B > BC; B > BD
6 h	2.63 ± 1.40	1.27 ± 1.00	0.10 ± 0.31	<0.001	B > BC; B > BD; BC > BD
8 h	2.07 ± 0.94	2.87 ± 1.63	0.77 ± 0.90	<0.001	BC > B; B > BD; BC > BD
10 h	2.83 ± 1.12	2.30 ± 1.56	1.67 ± 1.54	0.009	B > BD
12 h	2.70 ± 1.09	2.33 ± 1.35	2.03 ± 1.59	0.167	None
14 h	2.76 ± 1.19	3.20 ± 0.85	2.23 ± 1.43	0.008	BC > BD
16 h	2.97 ± 1.10	3.03 ± 0.72	2.60 ± 1.04	0.182	None
18 h	2.93 ± 0.87	3.27 ± 1.00	2.97 ± 0.85	0.291	None
24 h	3.77 ± 0.86	3.37 ± 0.61	3.47 ± 0.86	0.128	None



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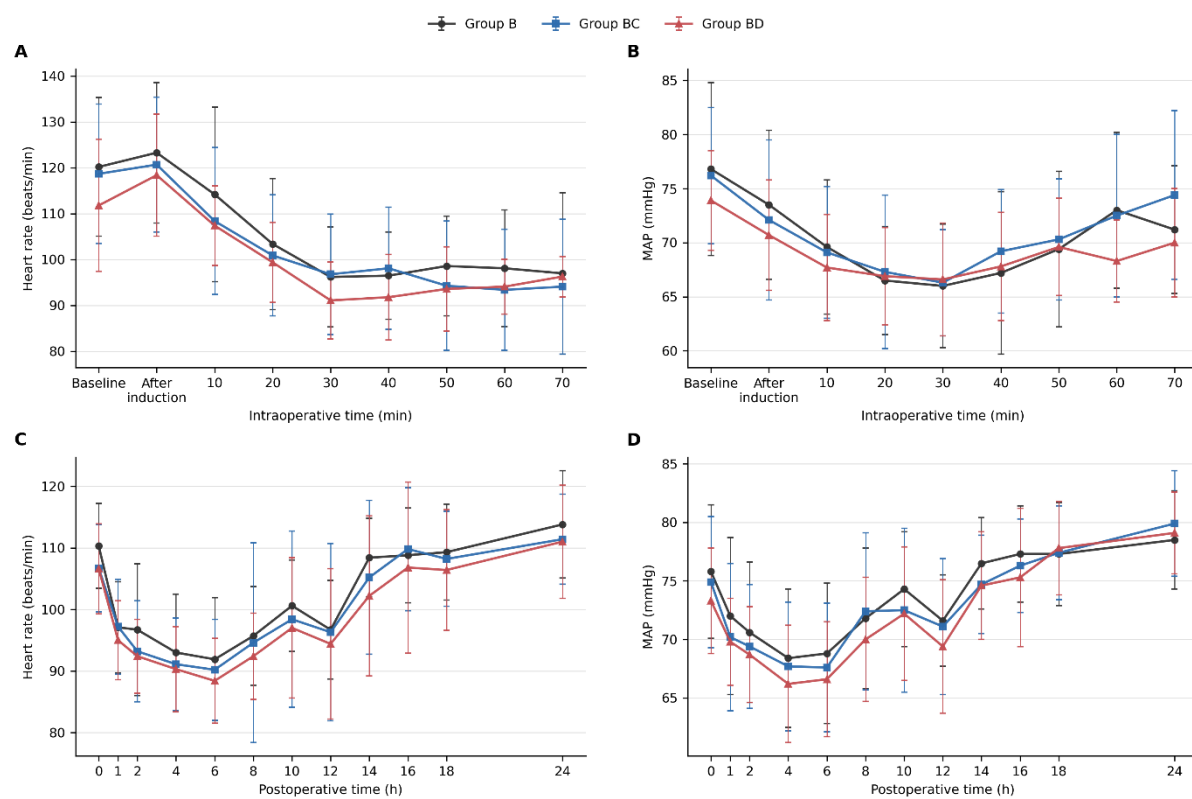


Figure 2- Perioperative heart rate and mean arterial pressure. (Panels A and B show intraoperative heart rate and mean arterial pressure, respectively, at baseline, after induction, and at 10-minute intervals thereafter. Panels C and D show postoperative heart rate and mean arterial pressure, respectively, from arrival in the postanesthesia care unit to 24 hours after surgery)