Original Article

# Effect of different volumes of bupivacaine 0.25% caudal blocks on cardiac index measured by electrical cardiometry in children undergoing elective lower abdominal surgeries: A randomised controlled trial

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## ABSTRACT

**Background and Aims:** Studies assessing caudal block's effects on children's cardiac output are scarce. We aimed to estimate the effects of the caudal block using different volumes of plain bupivacaine 0.25% on the cardiac index assessed by electrical cardiometry. **Methods:** Children aged 1–8 years undergoing minor lower abdominal surgeries were randomly assigned to one of three equal groups: The 0.8 group received general anaesthesia (GA) along with caudal block with 0.8 mL/kg of bupivacaine 0.25%, the 1.2 group received GA along with caudal block with 1.2 mL/kg of bupivacaine 0.25%, and the control group received GA only. The primary outcome was the percentage of change in the cardiac index from the baseline 10 minutes after the caudal block. Continuous variables were analysed using the ANOVA test, while categorical data was analysed using a chi-squared test with the significance level set at $P < 0.05$. **Results:** The mean percentage of change of cardiac index from baseline 10 minutes after caudal block was significantly lower in the 0.8 and 1.2 groups (−11.4 (standard deviation (SD): 12.5%) and −17.1 (SD: 15.5%), respectively) compared to the control group (−0.7 (SD: 11.5%), ($P = 0.007$ and $P = 0.0001$). Mean differences were −11 (0.8 vs control, 95% confidence interval (CI): −18.7, −3.3%, and −15.2 (1.2 vs control, 95% CI: −23, −7.5%). **Conclusion:** The cardiac index progressively decreased with the increase in the volume of the caudal block with plain bupivacaine at 0.25% compared to the baseline. However, this decrease was not clinically significant, suggesting that the cardiac index remained within an acceptable range after the caudal block. Nevertheless, caution is warranted due to the increased incidence of hypotension with increasing volumes of plain local anaesthetics in the caudal block.

**Keywords:** Anaesthesia, bupivacaine, cardiac index, cardiac output, caudal block, children, hypotension, regional anaesthesia

## INTRODUCTION

Caudal block is a commonly performed regional block in paediatric anaesthesia because it is safe and provides adequate perioperative analgesia for infra-umbilical and lower-limb procedures.[1,2] The cardiovascular effects of neuraxial blocks tend to be less pronounced in children than in adults for several reasons. One key factor is the lower systemic



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vascular resistance (SVR) in children, which allows for greater vasodilation without a significant drop in blood pressure.[3] Additionally, children typically have a higher baseline heart rate and a relatively higher cardiac output (CO), enabling them to maintain stable blood pressure despite changes in vascular tone induced by the block.[4]

A caudal block uses a wide range of doses depending on the desired dermatomal level, which can range from 0.5 mL/kg up to 1.25 mL/kg, consistent with the Armitage regimen.[1,5] Studies assessing the effects and safety of different volumes of caudal blocks on CO are scarce and show conflicting results due to the different volumes, additives of the local anaesthetics used, and different methods for measuring the CO.[6–10]

Electrical cardiometry (EC) estimates CO by using skin electrodes to measure changes in thoracic electrical bioimpedance during the cardiac cycle. It has emerged as a new non-invasive tool for assessing CO with reasonable accuracy in adult and paediatric anaesthesia.[11]

The primary objective of the current study was to estimate the effects of the caudal block using two different volumes of plain bupivacaine 0.25% on the cardiac index (CI) 10 minutes after the caudal block, as assessed by EC. The secondary objectives were the intraoperative changes in heart rate, mean arterial pressure, and the incidence of complications of caudal block. We hypothesised that caudal block using different volumes of plain bupivacaine 0.25% would decrease the cardiac index in children undergoing lower abdominal surgeries.

## METHODS

This randomised controlled trial adheres to the principles of the Helsinki Declaration 1975, as revised in 2013, and Good Clinical Practice guidelines. Written informed consent was obtained from all participant guardians before enrolment to participate in the study and use of the patient data for research and educational purposes. The study was conducted between November 2021 and June 2022 at Cairo University Hospital after approval of the Research Ethics Committee, Faculty of Medicine, Cairo University (vide approval number MS-445-2021, dated 20 October 2021). The study was registered before patient enrolment at the clinicaltrials.gov registry system (NCT05133687, dated 24 November 2021). The study included 96 children aged 1–8 years, American Society of Anesthesiologists's physical status (ASA) I and II undergoing elective lower abdominal surgeries. Patients with coagulation disorders [Platelets $\leq$50,000 mm$^3$ and/or international normalised ratio >1.5]; patients with suspected or proven allergy to local anaesthetics, rash, or signs of infection at the injection site; body mass index $\geq$95$^{th}$ percentile for the age; patients whose parents refused to participate; and patients scheduled for laparoscopic surgeries were excluded from the study.

Recruited children were randomly assigned using a computer-generated sequence (https://www.randomizer.org). Concealment was achieved using sequentially numbered opaque envelopes allocating patients into three equal study groups: 0.8 group to receive general anaesthesia (GA) and caudal block with 0.8 mL/kg of bupivacaine 0.25%, 1.2 group to receive GA and caudal block with 1.2 mL/kg of bupivacaine 0.25%, and control group to receive GA with local infiltration of the wound or transversus abdominis plane block at the end of the procedure. The concealed envelopes were opened after induction of anaesthesia by a senior anaesthesia resident (who was not involved in data collection but had performed more than 50 caudal blocks), who was responsible for preparing and conducting the caudal block for the caudal groups as instructed.

Upon arrival at the operating room, electrocardiography (ECG), a non-invasive blood pressure monitor, and a pulse oximeter were applied, and baseline measurements were recorded. An EC device (ICON®; Cardiotonic, Osypka; Berlin, Germany) was applied to the child through four ECG electrodes at the following sites: forehead, the left side of the neck, left mid-axillary line at the level of the xiphoid process, and left thigh. Patient gender, height, and weight were entered into the device, which was set to estimate the measured parameters at a 20-beat moving average recorded every 10 seconds. Baseline EC parameters (cardiac index, stroke index (SI), and SVR) were recorded by averaging three sets of data over 30 seconds by an anaesthesia resident who was not included in the anaesthetic management. If the child was not cooperative, inhalational induction of anaesthesia using titration of sevoflurane (3%–8%) in oxygen air 60% mixture until the child was sedated and baseline EC parameters were recorded.

After securing an intravenous (IV) line, all children were anaesthetised using IV propofol 2 mg/kg, fentanyl

1 μg/kg, and atracurium 0.5 mg/kg to facilitate tracheal intubation. Anaesthesia was maintained using 1.5% isoflurane and IV atracurium 0.1 mg/kg top-ups every 30 minutes. All children received a loading dose of IV 10 mL/kg of lactated ringer solution over 10 minutes after induction of anaesthesia, and fluids were maintained on 4 mL/kg/h of lactated ringer solution.

Children in the caudal groups were positioned on their right side, and a 22-gauge needle was inserted blindly into the caudal epidural space after antiseptic preparation of the skin. Plain bupivacaine 0.25% at a dose of 0.8 mL/kg and 1.2 mL/kg (without exceeding a maximum of 2.5 mg/kg) was slowly injected into the caudal space. After repositioning the children into a supine position, a 10-minute steady-state period without surgical stimulation was permitted, during which multiple sets of measurements were obtained every 2 minutes and surgery was started after this period. Caudal success was defined as a heart rate (HR) and/or mean arterial pressure (MAP) increase of no more than 20% from baseline parameters to surgical incision without additional analgesics or anaesthetics. Patients with caudal failure were excluded from the study.

After the start of surgery, EC measurements were obtained 15, 20, and 30 minutes after the induction of anaesthesia. The control group had their EC measurements after the induction of anaesthesia at the same time points as the corresponding caudal groups.

The primary outcome of the study was the percentage of change of the cardiac index from the baseline measurement (CI 0) after 10 minutes of successful caudal block (CI 10) calculated as [(CI 10 - CI 0)/(CI 0) *100]. Secondary outcomes included EC absolute values: cardiac index, SI, and SVR measured every 2 minutes for 10 minutes after induction of anaesthesia. Then, at 15, 20 and 30 minutes, HR and MAP were measured at the same time points of the corresponding EC values, along with the incidence of side effects and complications: caudal block failure, bradycardia (HR <60/min), hypotension (MAP <20% of the baseline), and local anaesthesia systemic toxicity.

The sample size was calculated using G*Power-3.1 software. A pilot study was done on 10 patients (5 patients each in the 0.8 and 1.2 groups), and the mean cardiac index 10 minutes after a successful caudal block was lower than the baseline cardiac index by 9.8% [standard deviation (SD: 12%)] and 12.2% (SD: 11.8%), respectively. Assuming no change in the cardiac index in the control group and using a common SD of 12%, we calculated 84 patients (28 patients in each group) by using a one-way analysis of variance (ANOVA) test to have a study power of 95% and an alpha error of 0.05%. The sample size was increased to 96 patients (32 in each group) to compensate for the possible dropouts.

Data were analysed using the Statistical Package of Social Science Software program, version 25 (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.). Continuous variables (HR, MAP, cardiac index, SI, and SVR) were tested for normality by using the Shapiro–Wilk test, presented as mean (SD) or median (quartiles), and analysed using ANOVA or Kruskal–Wallis test as appropriate. All categorical data (block failure, bradycardia, and hypotension) were analysed using the chi-squared or Fisher's exact test as appropriate and shown as percentages and absolute numbers of cases. Repeated measures variables (HR, MAP, cardiac index, SI, and SVR) were analysed using a two-way (ANOVA) test. Post-hoc pairwise comparison was performed using the Bonferroni test. A $P$ value $< 0.05$ was considered statistically significant.

## RESULTS

Ninety-six patients were randomised in the current trial. Two patients were excluded from the 0.8 group due to failed caudal block, and 94 patients were available for the final analysis [Figure 1].

The demographic data, baseline haemodynamics, and cardiometry parameters among the three groups were comparable [Table 1].

The mean percentage of change in the cardiac index from baseline 10 minutes after a caudal block was significantly lower in the 0.8 and 1.2 groups (−11.4 (SD: 12.5%) and −17.1 (SD: 15.5%), respectively) compared to the control group (−0.7 (SD: 11.5%), ($P$ = 0.007 and $P$ = 0.0001). Mean differences were −11 (0.8 vs control, 95% confidence interval (CI): −18.7, −3.3%, and −15.2 (1.2 vs control, 95% CI: −23, −7.5%). The significant decrease in the cardiac index from the baseline measurements continued for up to 30 minutes after induction of anaesthesia compared to the control group [Figure 2].

The absolute values of the cardiac index showed a significant drop over all the time points in the 0.8

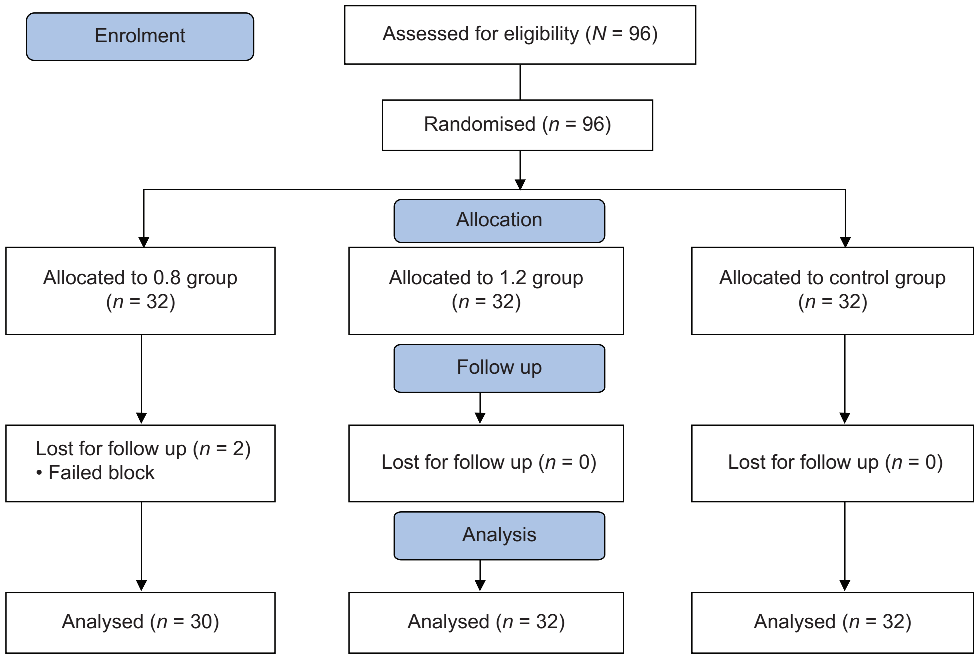


**Figure 1:** Flow diagram showing patient enrolment and analysis

**Table 1: Patient demographics and baseline characteristics**

| | 0.8 group (*n*=30) | 1.2 group (*n*=32) | Control group (*n*=32) |
|---|---|---|---|
| Age (years) | 3 (1–8) | 4 (1–8) | 4 (1–8) |
| Weight (kg) | 15 (10–35) | 17 (10–27) | 17 (12–25) |
| Length (cm) | 90 (78–137) | 108 (75–129) | 107 (82–129) |
| Gender (male) n (%) | 28 (93.3%) | 27 (84.4%) | 26 (81.2%) |
| Surgery: | | | |
| • General | 22 (73.3%) | 18 (56.2%) | 27 (84.4%) |
| • Urosurgery | 8 (26.7%) | 14 (43.8%) | 5 (15.6%) |
| Fasting (hours) | 8.7 (2.1) | 9.3 (2.1) | 9.4 (2.1) |
| Duration of operation (minutes) | 70.7 (16.9) | 72 (14.9) | 76.7 (13.4) |
| Baseline heart rate (beat/min) | 136.3 (22) | 125.8 (20) | 128.1 (18.8) |
| Baseline mean arterial pressure (mmHg) | 62.9 (11.7) | 64 (8.8) | 63.9 (9.3) |
| Baseline CI (L/min/$m^2$) | 5.5 (0.9) | 5.7 (0.7) | 5.3 (0.9) |
| Baseline SI (mL/min/$m^2$) | 42.6 (10.5) | 45.5 (8.1) | 42.4 (8.4) |
| Baseline SVRI (Dyne.sec.$m^2$.$cm^2$) | 2200 (1153.7) | 1933 (1024.5) | 2069.5 (990.2) |

Data are expressed as mean (standard deviation), frequency (percentage), or median (Q1 - Q3). Q1=first quartile, Q3=third quartile, CI=cardiac index, SI=stroke index, SVRI=systemic vascular resistance index

and 1.2 groups compared to their initial baseline readings. The cardiac index values of the 1.2 group were significantly lower compared to the control group 15 minutes after the caudal block [Figure 3].

SVR was comparable between the three groups except at 30 minutes after caudal block, when it was significantly higher in the 0.8 and 1.2 groups compared to the control group.

The heart rates of the 0.8 and 1.2 groups were significantly lower than the baseline at most of the time points. The mean arterial pressure significantly decreased after 8 minutes and persisted for up to 30 minutes of the caudal block in the 0.8 and 1.2 groups compared to the baseline readings [Figure 4].

Two (2.1%) of the patients had a failed caudal block failure, which was reported in the 0.8 group only. The intraoperative bradycardia was comparable between the three groups, while the 1.2 group had significantly more intraoperative episodes of hypotension compared to the 0.8 group and control group [20 (62.5%), 10 (33.3%), and 6 (18.8%), respectively; $P = 0.001$].

## DISCUSSION

We observed a significant reduction in the cardiac index 10 minutes after the caudal block compared to the baseline measurement. This reduction was more pronounced with increasing volumes of the caudal block, indicating a dose-dependent effect on CO.

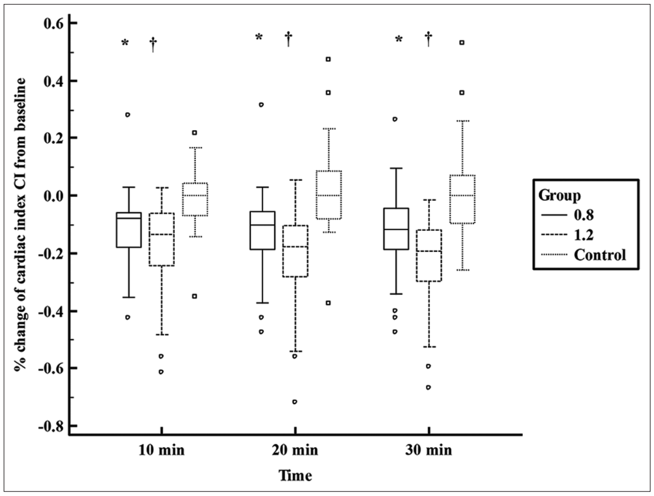


**Figure 2:** Change in the cardiac index from the baseline measurements. * denotes significance between the 0.8 group and control group, † denotes significance between the 1.2 group and control group. CI = cardiac index

The absolute values of the cardiac index decreased significantly within a few minutes after the caudal block and persisted for up to 30 minutes. Despite the statistically significant drop in cardiac index, it is important to note that all measured cardiac index values remained within the predicted clinical range for cardiometry.

The decrease in CO following a caudal block has been mainly attributed to the reduction in SVR due to the vasodilatory effects of the local anaesthetic, causing a decrease in the venous return and reduction of the CO. However, in the current study, this mechanism cannot fully explain the reduction in the cardiac index because we reported a non-significant change in the SI and an increase in SVR to compensate for the drop in the CO. The decrease in CO after a caudal block might be due to complex interactions involving the venous return, cardiac contractility, and autonomic regulation.

In the current study, we propose that the main mechanism for the decreased cardiac index was the

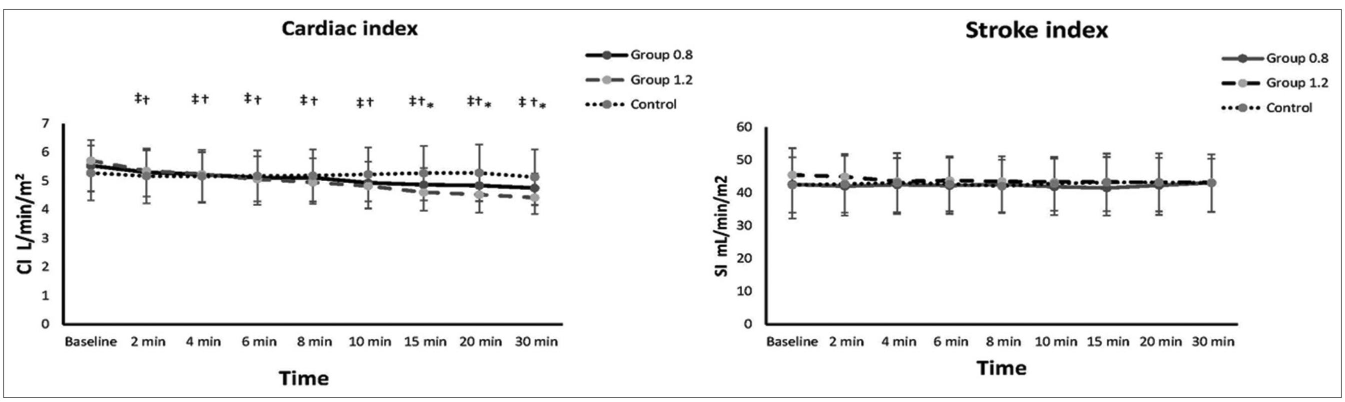


**Figure 3:** Intraoperative cardiac index and stroke index of the three groups. * denotes significance between the 1.2 group and control group, † denotes significance compared to the baseline reading within the 0.8 group, ‡ denotes significance compared to the baseline reading within the 1.2 group

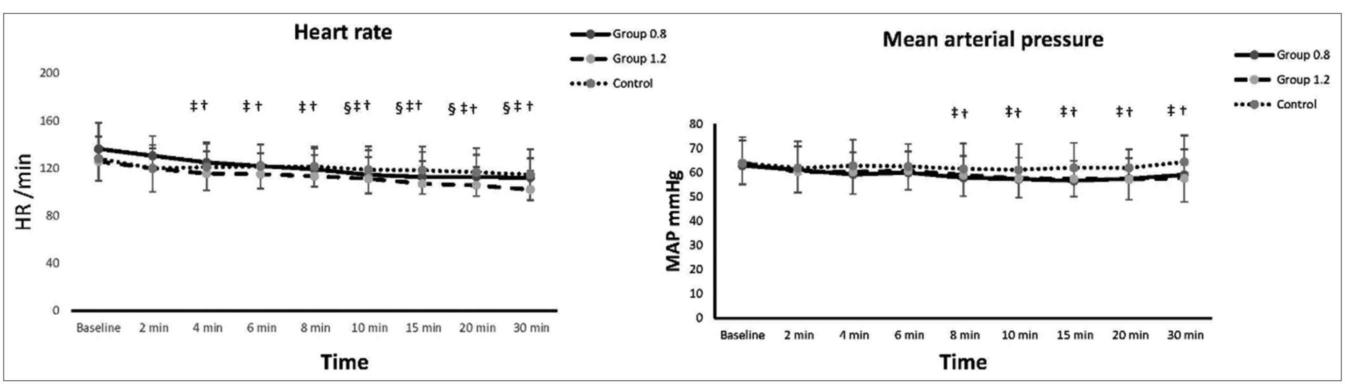


**Figure 4:** Intraoperative heart rate and mean arterial pressure of the three groups. † denotes significance compared to the baseline reading within the 0.8 group, ‡ denotes significance compared to the baseline reading within the 1.2 group, § denotes significance compared to the baseline reading within the control group

impairment of autonomic regulation, which resulted in decreased heart rate and, to a lesser extent, cardiac contractility. These mechanisms could explain the significant drop in the cardiac index without comparable changes in the SI, denoting that the main effect on the cardiac index was primarily related to the change in the heart rate.

The gold-standard thermodilution technique for measuring CO is technically difficult in paediatrics. Different semi-invasive and non-invasive tools for CO monitoring, such as oesophageal Doppler and transthoracic echocardiography, have previously been used in the paediatric population.[6,10] EC has emerged as a new non-invasive tool for assessing CO with fair accuracy and precision in adult and paediatric anaesthesia. While its performance may be comparable to the standard thermodilution method, it should not be considered a replacement for this established technique. Instead, it offers a viable alternative for real-time CO monitoring in clinical practice, particularly when non-invasive measurements are preferred.[11,12]

A single retrospective study by Liu *et al*.[7] included 40 children to study the effect of adding adrenaline to different types, volumes, and concentrations of local anaesthetics on haemodynamic parameters measured by EC. They reported a significant increase in CO in the local anaesthesia with the adrenaline group compared to the plain local anaesthesia, which showed a non-significant decrease in CO over time. The different types and concentrations of the local anaesthetics used in this study could have minimised the magnitude of this effect on cardiac index in the plain local anaesthetic group, unlike our study that used fixed concentration and volume of the local anaesthetic in each group. Moreover, the increased stroke volume and CO in the adrenaline group could prove the theory that the effect of the local anaesthetic on the cardiac index is directly related to the changes in the autonomic nervous system caused by the local anaesthetic or its additives. Adding adrenaline to the caudal block in children has been previously shown to increase the stroke volume and the CO measured by oesophageal Doppler compared to plain local anaesthetics, which could confirm that the inotropic effects are directly mediated by the beta receptors' effects of the systemically absorbed adrenaline.[9,13,14]

In line with our results, Siriboon *et al*.[15] explored the effect of the caudal block using plain bupivacaine 0.25% on three age groups of children by using an ultrasonic CO monitor. The authors reported a significant drop in CO and HR in the three groups, with a non-significant increase in the SVR, especially in older children.

The vasodilatation of the relatively small blood vessels of the lower limbs after caudal anaesthesia may be counteracted by the compensatory reflex vasoconstriction of the upper limb vessels, which could explain the paradoxical increase in the measured total SVR after caudal anaesthesia. Moreover, the SVR is inversely proportional to the CO; therefore, the increase in SVR may be interpreted as a compensatory mechanism for the decrease in the CO.

Unlike most previous studies on the caudal block in children, hypotension was reported in up to 2/3 of patients in the 1.2 group. The increased incidence of hypotension in the current study could be explained by the significant vasodilation, which may contribute to a reduction in blood pressure caused by the higher volume of caudal anaesthesia.[1]

Furthermore, there is no clear definition of hypotension in children.[16–18] Hypotension was defined too liberally (>20% of the baseline measurement), which may also explain the higher incidence of hypotension recorded in the 1.2 group of the current study.

We compared the effects of increasing volumes of caudal block on CO, as measured by EC, to a control group to eliminate GA's possible effects on haemodynamics. The study had some limitations: it was a single-centre study, no central line was inserted for ethical reasons, and central venous pressure was assumed to be zero. Additionally, measurements were taken for only 30 minutes after the caudal block; however, we attempted to mitigate the potential effects of surgical stress on the measured parameters.

## CONCLUSION

The cardiac index progressively decreased with the increase in the volume of the caudal block with plain bupivacaine at 0.25% compared to the baseline. However, this decrease is not clinically significant, suggesting that the cardiac index remained within an acceptable range after the caudal block. Nevertheless, caution is warranted due to the increased incidence of hypotension with increasing volumes of plain local anaesthetics in the caudal block.

### Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' Institution policy.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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