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ORIGINAL ARTICLE

A comparative study of clonidine and dexmedetomidine as an adjuvant to levobupivacaine for caudal analgesia in children undergoing below umbilical surgeries: A randomized double-blind controlled trial

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SUMMARY

Objectives: Dexmedetomidine and clonidine have been studied separately as adjuvants with levobupivacaine, but there is no literature comparing the two drugs for caudal anesthesia in children. We compared the analgesic efficacy and adverse effects of clonidine and dexmedetomidine as adjuvants to levobupivacaine for caudal analgesia in children undergoing infraumbilical surgeries.

Methods: In this prospective randomized study, 100 pediatric patients (3 to 8 years) of either sex, scheduled for infraumbilical surgery, were randomly allocated to two equal groups in a double-blind manner. After induction of anesthesia using a standard technique, caudal anesthesia was administered using 0.2% levobupivacaine (1 ml/kg) with either 1 µg/kg dexmedetomidine (Group A) or 1 µg/kg clonidine (Group B). Hemodynamic parameters, motor block, degree of sedation, postoperative analgesia, use of rescue analgesics, and side effects were evaluated for 24 hours.

Results: The mean duration of analgesia in Group A (12.7±2.4 h) was higher than in Group B (10.6±2.2 h), which was statistically significant (p=0.000). The mean duration of sedation was higher in Group A, although it was statistically insignificant. Hemodynamic parameters were comparable in the two groups. No significant side effects were observed in the groups.

Conclusion: Dexmedetomidine (1 µg/kg) added to 0.2% levobupivacaine (1 ml/kg) for caudal block provides prolonged analgesia with better sedation scores when compared to clonidine (1 µg/kg) with 0.2% levobupivacaine (1 ml/kg) for below umbilical surgeries in pediatric patients, without increasing the incidence of adverse effects. Hence, we would recommend the use of 1 µg/kg dexmedetomidine as an adjuvant to 0.2% levobupivacaine.

Keywords: Analgesia; anesthesia; caudal; child; clonidine; dexmedetomidine; hemodynamics; levobupivacaine.

Introduction

Caudal analgesia, combined with general anesthesia, is the most common, safe, and reliable technique for analgesia in pediatric patients undergoing below umbilical surgeries. While excellent pain relief, minimal side effects, and high patient satisfaction are advantages, the short duration after a single injection is the main disadvantage.[1]

Caudal block can be practiced by a single-shot injection or as a continuous infusion through a caudal epidural catheter.[2] Levobupivacaine is equally efficacious as bupivacaine but has a superior pharmacokinetic profile, as it is much safer regarding reduced cardiotoxicity and neurotoxicity.[3]

Various adjuvants such as tramadol, ketamine, ephedrine, morphine, clonidine, fentanyl, and dexmedeto-

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midine with local anesthetics have been investigated to extend the duration of postoperative analgesia.[4,5]

Clonidine is a mixed alpha-1 and alpha-2 adrenoceptor agonist with a predominant alpha-2 action. It provides better perioperative hemodynamic stability and good quality intraoperative and prolonged postoperative analgesia with minimal side effects. Dexmedetomidine is a more potent sedative than clonidine, but patients remain easily aroused. This aspect, combined with the minimal influence on respiration, makes dexmedetomidine an interesting alternative to clonidine.[6]

Multiple studies have compared clonidine and dexmedetomidine with local anesthetics like bupivacaine and ropivacaine. There are studies comparing clonidine and dexmedetomidine separately with other adjuvants when added to levobupivacaine in the pediatric population. However, to our knowledge, there is a lack of data comparing clonidine and dexmedetomidine as adjuvants with levobupivacaine for caudal analgesia in pediatric patients. This study was designed to compare the analgesic efficacy and side effects of dexmedetomidine and clonidine when added to levobupivacaine for caudal analgesia in children, with the primary outcome as the duration of analgesia. The secondary outcomes were sedation scores, sedation time, hemodynamic parameters, pain scores in the first 24 hours, and complications in the two groups.

Materials and Methods

Ethics approval for this study was obtained from the Institutional Ethics Committee (F.1/IEC/CNBC/ 05/01/2020/4224), and the study was registered with the Clinical Trial Registry of India (CTRI/2020/06/025684). After obtaining written and informed consent from the patient's relatives, 100 American Society of Anesthesiologists physical status (ASA PS) 1 and 2 children aged 3 to 8 years, scheduled for elective below umbilical surgery, were prospectively enrolled in the study. The study was conducted in accordance with the Helsinki Declaration.

Patients with any history of developmental delay/mental retardation, spine and central nervous system anomalies, contraindications to regional anesthesia, history of allergy to drugs used in the study, known bleeding disorders, and infection at the injection site were excluded from the study.

The study population of 100 patients was randomly allocated into two groups by the draw of lots, with 50 patients in each group. The anesthesiologist who picked up the lots and prepared the drugs in a secluded place in a sterile manner was not a part of the study. The medication was handed over to and administered by another anesthesiologist blinded to the combination of drugs prepared in the syringe. The subjects, their parents or guardians, and the health care personnel providing direct patient care and assessing outcomes were blinded to the study.

In the operation theatre, a multi-parameter monitor was attached, and baseline values were recorded for arterial oxygen saturation (SpO_2), pulse rate (PR), respiratory rate (RR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and electrocardiogram (ECG). Anesthesia was induced with a standard inhalational technique using sevoflurane 8% with 100% O_2 in spontaneous ventilation. After securing a peripheral intravenous (i.v.) access, fentanyl 1µg/kg and propofol 2–3 mg/kg were injected. After that, the airway was secured with an appropriately sized laryngeal mask airway, and sevoflurane concentration was reduced to 2%, with O_2 and N_2O at 50% each for maintenance of anesthesia.

After that, patients were placed in a lateral position. Under all aseptic precautions, a single-dose caudal epidural injection was performed as per the group assigned using a 23-gauge hypodermic needle and the loss of resistance technique.

GROUP A received 0.2% levobupivacaine (1ml/kg) with 1µg/kg dexmedetomidine in 0.5 ml normal saline, and GROUP B received 0.2% levobupivacaine (1ml/kg) with 1µg/kg clonidine in 0.5 ml normal saline, with a maximum volume of 20 ml for both groups.

The time of the caudal block was recorded, and surgery was allowed to start 10 minutes after the caudal injection. No other analgesics, sedatives, or narcotics were used intraoperatively. Continuous monitoring of vital parameters was done intraoperatively. Vitals were recorded every 5 minutes for the first 20 minutes after performing the block and thereafter every 10 minutes until the completion of surgery. At the

end of the surgery, all anesthetic gases were discontinued, and the LMA was removed after adequate spontaneous breathing efforts were returned. The occurrence of intraoperative hypotension (fall in SBP >20% from baseline) and bradycardia (HR <60 bpm) was recorded and treated with a bolus of i.v. fluid and atropine (20 µg/kg every 2–5 minutes).

After surgery, patients were shifted to the Post Anesthesia Care Unit (PACU) for further observation and monitoring. Postoperatively, pain scores were assessed using the Wong-Baker pain scale (WBS), motor block using the Modified Bromage score (MBS), and the degree of sedation using Ramsay Agitation Sedation Score (RASS) were evaluated at 0 minutes, 30 minutes, 1 hour, 1.5 hours, 2 hours, 4 hours, and 8 hours. Duration of postoperative sedation was deemed from the time to extubation until the Ramsay sedation score was 2 or less. Motor block was evaluated until the MBS became '0'. The pain was assessed until the requirement of the first rescue analgesic (or 8 hours, whichever was longer), after which the study was considered over for that patient. All patients were also monitored for vital parameters, the occurrence of postoperative desaturation (SpO_2 <90%), hypotension (fall in SBP >20% from baseline), bradycardia (HR <60/minutes), postoperative nausea vomiting, urinary retention, and apnea. Patients complaining of pain at the surgical site or WBS of 4 or more were given i.v. paracetamol 15 mg/kg as a rescue analgesic. If the pain persisted after half an hour, syrup ibuprofen 6 mg/kg was given (after ensuring full recovery from anesthesia). The rescue analgesic requirement within one hour in the postoperative room was considered a failure of the caudal block, and the child was excluded from the study. Serious adverse events (if any) were to be managed per the protocol.

The primary outcome measure was the time to first use of rescue analgesic from arrival in the recovery room. The secondary outcome measures were pain scores, motor block, sedation scores, and adverse events such as postoperative nausea and vomiting (PONV), desaturation, urinary retention, and apnea.

Pain severity was measured using the WBS for 24 hours.[7] Postoperative sedation was evaluated on a 6-point RASS ranging from 1 to 6.[8] The duration of sedation was defined as the time from extubation until the RASS was 2 or less.

Statistical Analysis

The sample size was determined by using the time to requirement of the first rescue analgesic to compare the effectiveness of the study drugs between the two groups. Based on previous studies[9] to detect a difference of 1 hour in the time to the requirement of the first rescue analgesic (duration of analgesia) between the two groups, a sample size of 47 patients per group was considered necessary to detect statistical significance with an effect size of 0.67 at alpha 0.05 and power of 90%. So, we decided to recruit 50 patients in each group.

Statistical analysis was performed using the SPSS program for Windows, version 17.0 (SPSS, Chicago, Illinois). Continuous variables were presented as mean±SD, and categorical variables were presented as absolute numbers and percentages. Data was checked for normality before statistical analysis. Normally distributed continuous (quantitative) variables like duration of surgery and analgesia, hemodynamic parameters, age, weight, pain scores, and sedation scores were compared using the unpaired t-test. Categorical (qualitative) variables like gender and postoperative complications were analyzed using the chi-square test. Data that was not normally distributed, like Bromage score, was analyzed using the Whitney U test. A p-value of <0.05 was considered statistically significant.

Results

This randomized comparative double-blind trial was performed on 100 children (50 in each group) once they satisfied the inclusion criteria and informed consent was obtained. 120 patients were assessed for eligibility, out of which 8 were excluded as their parents declined to participate, 12 were excluded based on exclusion criteria, and finally, 100 were recruited for the study. All recruited patients received the allocated intervention and completed the study (Fig. 1). Subject characteristics and intraoperative clinical profiles were comparable among the study groups (Table 1).

The two groups showed no statistically significant differences in hemodynamic parameters (PR, SBP, and DBP) (Fig. 2, 3). The SpO_2 at baseline or over the intraoperative and postoperative period was comparable between the groups.

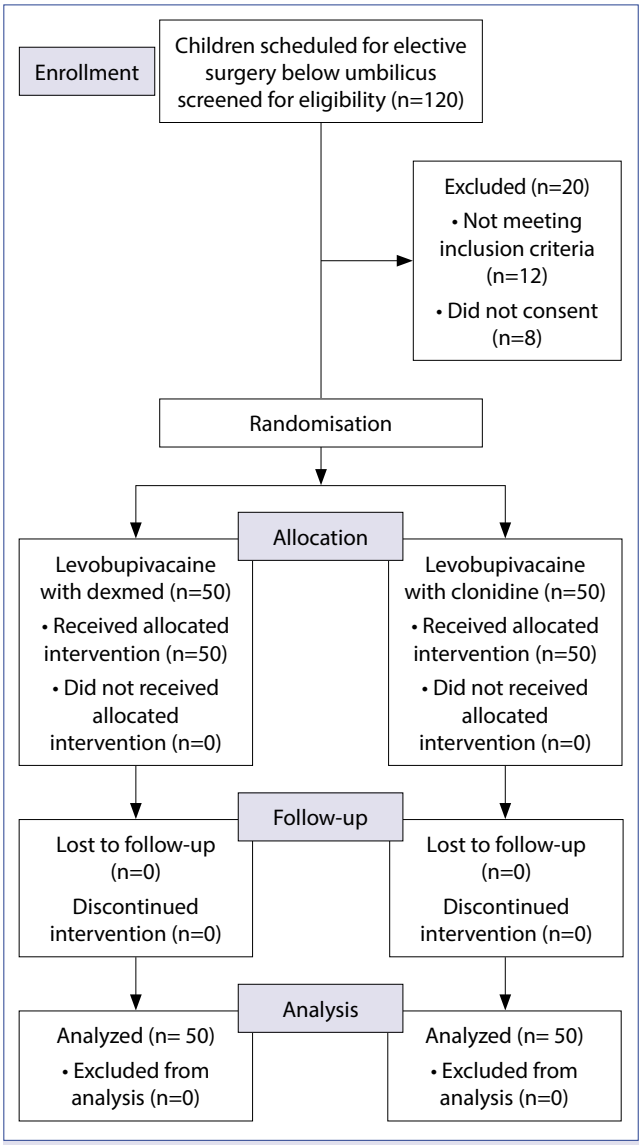

Figure 1. Consort diagram.

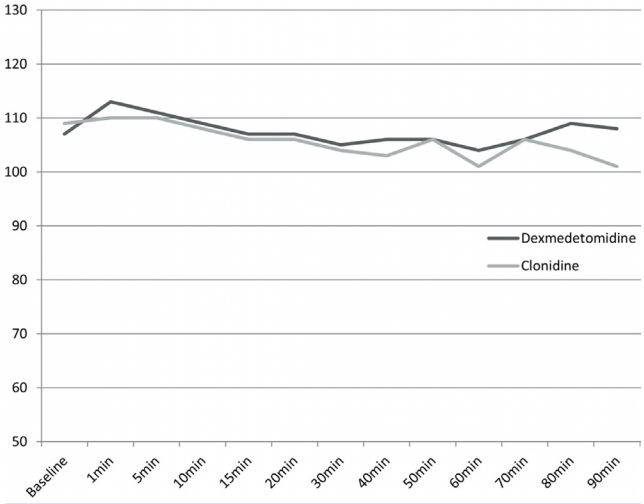

Figure 2. Figure comparing the mean intra-operative heart rates between patients in the dexmedetomidine and clonidine groups over time.

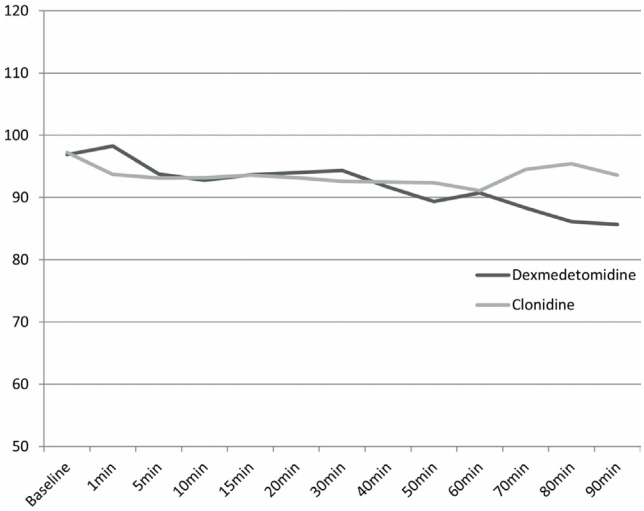

Figure 3. Figure comparing the mean intra-operative systolic blood pressures between patients in the dexmedetomidine and clonidine groups over time.

The mean duration of analgesia in the dexmedetomidine group was significantly higher (12.70±2.41 h) than for clonidine (10.64±2.23 h); p=0.001 (Table 1).

In both groups, the number of patients requiring i.v. fluid boluses for hypotension at 15 minutes (3 vs. 4), 20 minutes (4 vs. 4), and 30 minutes (2 vs. 1) in the intraoperative period were similar in Groups A and B, respectively.

The mean pain score assessed by the Wong-Baker pain scale was not statistically significant during the first four hours of the postoperative period, but it was lower in Group A compared to Group B at 4 hours (2.50±0.50 vs. 2.92±0.27; p<0.001) and 8 hours (2.80±0.40 vs. 2.93±0.25; p=0.05). The pain scores remained comparable at the rest of the time points during the 24-hour postoperative observation period.

The comparison showed no statistically significant differences in the mean Modified Bromage Scale scores between the two groups during the immediate postoperative period (0 minutes and 30 minutes; p=0.84 and 0.28). However, at 1 and 1.5 hours, the scores were significantly higher in the clonidine group (p<0.001) (Table 2).

A comparison of the mean Ramsay Sedation Score revealed no statistically significant differences between the two groups during the immediate postoperative period. The mean duration of sedation was longer in the dexmedetomidine group than in the clonidine group (128.60±72.06 vs. 117±73.05 minutes). However, the difference was statistically insignificant (p=0.42). PONV was observed in 3 pa-

Table 1. Demographic data, mean duration of analgesia and sedation, and incidence of PONV

	Group A (dexmedetomidine) Mean (SD)	Group B (clonidine) Mean (SD)	p
Age (years)	5.3 (1.52)	5.6 (1.74)	0.360
Weight (kg)	13.63 (6.87)	13.55 (6.03)	0.948
Height (inches)	46.14 (6.26)	45.59 (5.91)	0.654
Gender (M/F)	40/10	32/18	0.075
Duration of surgery (minutes)	56.80 (15.31)	59.40 (17.66)	0.433
Duration of analgesia (hours)	12.70 (2.41)	10.64 (2.23)	0.0001*
Mean duration of sedation (minutes)	128.60 (72.06)	117 (73.05)	0.426
PONV, n (%)	3 (6%)	4 (8%)	0.70

*: Statistically significant (p<0.05); PONV: Postoperative nausea and vomiting; SD: Standard deviation; M: Male; F: Female.

Table 2. Modified Bromage Scale scores and Wong-Baker Scale scores over time

	Group A (dexmedetomidine)	Group B (clonidine)	p
Modified Bromage Scale, Median (Min–Max)			
0 hr	1 (0–1)	1 (0–1)	0.84
0.5 hr	0 (0–1)	0 (0–1)	0.28
1 hr	0 (0–1)	0 (0–1)	0.78
1.5 hr	0 (0–1)	0 (0–1)	0.77
Wong-Baker Scale, Mean (SD)			
0 hr	2.48 (0.5)	2.52 (0.50)	0.69
0.5 hr	2.44 (0.5)	2.52 (0.50)	0.42
1 hr	2.54 (0.50)	2.64 (0.53)	0.33
1.5 hr	2.50 (0.51)	2.48 (0.50)	0.84
2 hr	2.52 (0.50)	2.40 (0.49)	0.23
4 hr	2.5 (0.50)	2.9 (0.27)	0.00*
8 hr	2.8 (0.40)	2.93 (0.25)	0.05

*: Statistically significant (p<0.05); SD: Standard deviation; Min: Minimum; Max: Maximum.

tients in Group A and 4 in Group B (p=0.70). None of the patients in any group experienced hypotension, bradycardia, respiratory depression, desaturation, apnea, or urinary retention in the postoperative period (Table 1).

Discussion

Caudal dexmedetomidine and clonidine have been studied separately with levobupivacaine in children, where they have been shown to increase the duration of postoperative analgesia.[10–12] We compared the analgesic efficacy of clonidine and dexmedetomidine as adjuvants to 0.2% levobupivacaine in children undergoing infraumbilical surgeries.

Armitage's formula for caudal block recommends bupivacaine 0.5 ml/kg for a lumbosacral block, 1 ml/kg for a thoracolumbar block, and 1.25 ml/kg for a mid-thoracic block. Since we had patients undergoing all types of below umbilical surgeries requiring blockade of thoracolumbar dermatomes (up to T10) for our study, a volume of 1 ml/kg was chosen.[13]

Ivani et al.[14] studied levobupivacaine in various concentrations of 0.125%, 0.2%, and 0.25%. They observed a dose-response relationship both with regard to the median duration of postoperative analgesia (0.125%, 60 min; 0.20%, 118 min; and 0.25%, 158 min) and the number of patients with evidence of early postoperative motor blockade (0.125%, 0

patients; 0.20%, 4 patients; and 0.25%, 8 patients). Though the 0.125% concentration was associated with significantly less early motor blockade, it resulted in a shorter duration of postoperative analgesia. Based on these results, we used 0.2% levobupivacaine for caudal blockade in children.

The main finding of the present study is that a caudal injection of a combination of levobupivacaine with dexmedetomidine 1 µg/kg significantly provides a longer duration of postoperative analgesia compared to levobupivacaine with clonidine 1 µg/kg. This difference in the duration of analgesia can be attributed to the more selective action of dexmedetomidine on alpha-2a adrenoceptors responsible for the hypnotic and analgesic effects of these drugs.[15]

The findings of our study were similar to the study conducted by Jinjil et al.[16] and Mavuri et al.,[17] who studied the analgesic efficacy of caudal clonidine (1 µg/kg) and dexmedetomidine (1 µg/kg) as adjuvants to 0.2% ropivacaine in pediatric patients. They also found that the duration of postoperative analgesia was significantly longer in the dexmedetomidine group compared to the clonidine group. Previous studies by Al Maghawry et al.,[18] Ahuja et al.,[19] and Nasr and Abdelhamid[20] have demonstrated attenuated neuroendocrine stress responses by adding clonidine and dexmedetomidine to the local anesthetic for caudal block. The serum cortisol levels were decreased in the clonidine and dexmedetomidine groups compared to control, with the lowest levels reported in the dexmedetomidine group, further reiterating its more potent analgesic effect.[18]

The mean pain score assessed by the Wong-Baker pain scale was not significantly different during the first 4 hours postoperatively, but it was lower in Group A at 4 hours and 8 hours compared to Group B. This may be due to improved and more prolonged analgesia with dexmedetomidine than clonidine. Al Maghawry et al.[18] similarly reported a comparable pain score between clonidine and dexmedetomidine groups until postoperative 6 hours, after which the scores were significantly lower in the dexmedetomidine group.

We found a higher duration of sedation in the patients who received dexmedetomidine (128.60±72.06 minutes) than those who received clonidine (117.00±73.05 minutes), although the difference was not statistically significant. In the present study, 72% of the patients in the dexmedetomidine group had Ramsay scores of 3 or 4 at the end of 90 minutes compared to 54% in the clonidine group. The longer duration of sedation and better sedation scores at 90 minutes in the dexmedetomidine group can be attributed to its more selective and potent agonist action on supraspinal alpha-2a receptors mediating hypnosis. Similar studies conducted by Mavuri et al.[17] and Reddy and Gangadharaiah showed a significantly prolonged duration of sedation with clonidine and dexmedetomidine compared to plain ropivacaine, with dexmedetomidine documenting the most extended duration of sedation.

Both the groups were also compared for motor blockade postoperatively using the Modified Bromage score.

Immediately after arrival in the recovery room, 46% of patients in Group A and 48% in Group B had a Modified Bromage score of 0, which increased to 74% of patients in Group A and 64% in Group B at 30 minutes. At 120 minutes and beyond, none of the patients showed residual motor blockade, and the score among all patients was 0. So, the p-value could not be calculated. Ivani et al.[21] reported 25% motor block at wake-up following levobupivacaine 0.2% caudal anesthesia compared with 16% with 0.2% ropivacaine. Gupta et al.[22] reported 60% motor block at wake-up following 0.2% bupivacaine compared with 0.25% levobupivacaine, but in both groups, the incidence decreased to less than 7% at 3 hours.

Clonidine and dexmedetomidine are alpha-2 agonists that induce sympatholysis by stimulation of the prejunctional inhibitory alpha-2 receptors, with subsequent decrease in norepinephrine release and are known to cause adverse effects such as hypotension and bradycardia due to an uninhibited increase in parasympathetic tone.[23] In our study, hemodynamic parameters were comparable in both groups at various intervals. However, 4 cases in each group required i.v. fluid boluses, and the parameters returned to normal within 20 to 30 minutes of the caudal injection. El Shamaa et al.[5] studied dexmedetomidine's effect with bupivacaine in the caudal

block and found no significant changes in the hemodynamics with dexmedetomidine compared to bupivacaine alone.

There was a significantly higher mean pulse rate during the first 2 hours in the postoperative period in the clonidine group compared to the dexmedetomidine group. However, the patients were comfortable and pain-free during this interval. This observation during a particular interval can be due to better analgesia and sedation provided by dexmedetomidine.

The groups had no significant difference in the incidence of nausea, vomiting, or urinary retention. No episodes of clinically significant respiratory depression or desaturation were identified. A similar conclusion was drawn from the studies conducted by Gupta and Pratap[22] and Neogi et al.[23] They all observed that adding caudal clonidine and dexmedetomidine in similar doses significantly prolonged the duration of analgesia without an increase in the incidence of adverse effects.[24]

Conclusion

Dexmedetomidine (1 µg/kg), when added to levobupivacaine (0.2%), provides a longer duration of analgesia with better sedation scores as compared to clonidine (1 µg/kg) for below umbilical surgeries in pediatric patients, without increasing the incidence of adverse effects.

Ethics Committee Approval: The Chacha Nehru Bal Chikitsalya Children Hospital Ethics Committee granted approval for this study (date: 05.05.2020, number: F.1/IEC/CNBC/05/01/2020/4224).

Informed Consent: A consent form was obtained from each patient before participating in the study.

Conflict of Interest: The authors declare that there is no conflict of interest.

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