Original Article

A randomized double-blinded controlled trial comparing ultrasound-guided versus conventional injection for caudal block in children undergoing infra-umbilical surgeries

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Abstract

Background and Aims: Caudal epidural block is widely used in pediatric surgeries to provide intraoperative and postoperative analgesia in infra-umbilical surgeries. The conventional technique involves the risk of multiple punctures and other complications such as dural puncture, vascular puncture, and intraosseous injection.

Material and Methods: Around 106 children aged between 6 months to 10 years belonging to ASA class I-II scheduled for elective infra-umbilical surgeries were included after obtaining written informed consent from parents/guardians. All children were randomized into two groups: ultrasound-guided (Group U) or conventional caudal group (Group C). All were premedicated with oral midazolam and inhalational induction was done with oxygen and 6–8% sevoflurane. Caudal block of 1 mL/kg of 0.125% bupivacaine was administered in both groups. The primary outcome assessed was 1st puncture success rate and the secondary outcomes assessed were number of skin punctures, block performing time, and block success rate.

Results: Group U had a higher first puncture success rate ($P = 0.001$) than Group C (90.6% v/s 64.2%) and was statistically significant. The number of punctures were significantly less ($P = 0.01$) in Group U (1.09 ± 0.295) than Group C (1.45 ± 0.667). Block performing time was significantly higher ($P = 0.0005$) in Group U (53.19 ± 10.97 s) than Group C (30.34 ± 7.34 s). There was no difference in the overall block success rate between the groups (98.1% v/s 100%).

Conclusion: Ultrasound-guided caudal injection increases the first puncture success rate and decreases the number of punctures required compared to conventional caudal block in pediatric infra-umbilical surgeries.

Keywords: 1st puncture success rate, block performing time, caudal block, regional anesthesia, ultrasound

Introduction

Regional anesthetic techniques such as caudal epidural anesthesia decrease the requirement of inhaled anesthetics, attenuate the stress response to surgery, facilitate smooth recovery, and provide good immediate postoperative analgesia with reduced systemic analgesic requirements.[1] A caudal epidural block is a widely used regional anesthetic technique, especially in pediatric surgery. It is safe, reliable, easy to perform, and is very effective in children, especially in infra-umbilical surgeries when combined with general anesthesia. It is one of the most popular techniques in pediatric anesthesia that can be used for intraoperative and postoperative analgesia.

The conventional caudal block involves the insertion of the needle through the skin at an angle of 60–80 degrees till the sacrococcygeal ligament is crossed. Later, the technique involves

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a reduction in the angle of insertion and further advancement of the needle by 2–3 mm till the sacral canal is entered. Complications of caudal epidural block technique involve the risk of multiple needle punctures and other complications such as dural puncture, vascular injury particularly when the needle passes through the sacral canal. Other complications include intraosseous injections, soft tissue bulging, and rarely systemic toxicity.[2]

Using ultrasound before procedure helps in visualizing sacral hiatus, sacrococcygeal ligament, dura mater, epidural space, and also the spread of local anesthetic within the epidural space. Though few early studies have shown this advantage,[3,4] it is currently not known if ultrasound usage improves the 1st puncture success of caudal block in our population. The use of ultrasound also helps in delineating anatomic structures in cases with difficult anatomy or difficulty in palpating bony landmarks. The ultrasonography could also provide information regarding the cephalic spread of injectate during the caudal epidural injection.[4] Ultrasonography was useful in preventing complications e.g., with needle tip visualized in real-time entering into the sacral hiatus by ultrasonography and inadvertently advancing the needle inside sacral hiatus can be prevented.[5,6] Besides, ultrasound has advantages over fluoroscopy in guiding caudal epidural injection because it is easy to learn, radiation-free, and can be virtually used in any clinical setting.[7]

The primary aim of this prospective randomized double-blinded controlled study was to compare 1st puncture success rate of the ultrasound-guided caudal block to conventional caudal block injection in children undergoing infra-umbilical surgeries. The secondary outcomes assessed were blocked performance time, number of skin punctures, block success rate, and complication rate.

Material and Methods

After obtaining written and informed consent from parents/guardians this study was conducted in 106 American Society of Anesthesiologists (ASA) category 1–2 children from February 2019 to July 2019 aged between 6 months and 10 years who underwent elective infra-umbilical surgeries. This study received approval from the institutional ethics committee (Ref: IEC/18/SEP/143/38) and was registered with a clinical trial registry of India (CTRI/2019/02/017421). Children with ASA PS III (American Society of Anesthesiologists Physical Status) and above, infection at the site of caudal injection, any sacral bone abnormalities, bleeding diathesis, allergy to local anesthetics, emergency surgeries, prior neurological or spinal disorders, or unable to provide informed consent were excluded from the study. Patients were premedicated with oral midazolam 0.5 mg/kg, 15–20 min before the procedure.[8] Randomization was done by computer-generated block randomization and divided into 2 groups, Group C (conventional caudal block) and Group U (ultrasound-guided caudal block) [Figure 1]. Parents/guardians were blinded to the mode of caudal block the children were going to receive and anesthesiologists who were collecting the entered data in operating room and anesthesiologists in PACU (post-anesthesia care unit) were also blinded. Patients were monitored with routine preinduction parameters (noninvasive blood pressure, electrocardiography, oxygen saturation, and end-tidal carbon dioxide). Baseline values were recorded and documented.

Anesthesia induction was by inhalation of sevoflurane 6–8% via a face mask. An intravenous line was started. Anesthesia was maintained with 33% O_2: 67% N_2O mixture and sevoflurane reduced to 1–2%. The patient was positioned in the lateral position and a caudal block was performed. All blocks were performed by three senior anesthesiologists who had the experience of more than 10 years both in conventional and ultrasound-guided blocks. Block performing time defined as the time between needle insertions to termination of local anesthetic administration

Under strict aseptic precautions, Group U received ultrasound-guided caudal block, using a high-frequency linear transducer probe 13–6 MHz (SonoSite, Inc., Bothell, WA 98021 USA) which was covered with sterile drape sheet followed by transducer area was covered with 3M Tegaderm adhesive used for dressing. Sacral hiatus was visualized at the level of the sacral cornua. 20–22 gauge jelco needle was inserted by out-of-plane technique and once the position was confirmed transducer moved to in-plane which was held by assistant without a change in position and drug was administered under vision. Under strict aseptic precautions, Group C received a conventional caudal block. Sacral cornua

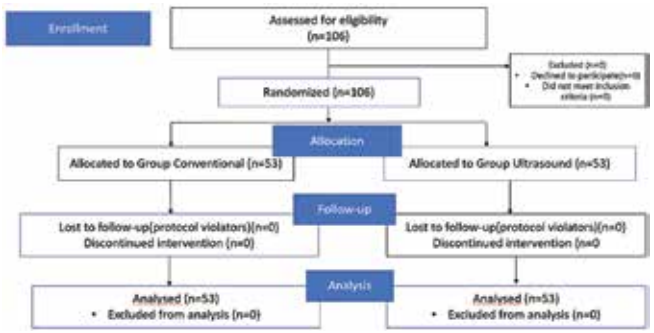

Figure 1: CONSORT flow diagram of study

and sacral hiatus were palpated over the skin. 20–22 gauge jelco needle was inserted at 60–80 degrees angle with the skin surface and was advanced until the sacrococcygeal ligament was passed with a "pop" by the "standard loss of resistance" technique for identification of the caudal space. Then the angle was reduced by 20–30 degrees and the needle was advanced further by 2–3 mm, till the sacral canal was entered. The syringe was aspirated for blood/CSF and once the position was confirmed, the anesthetic drug was administered. About 1 mL/kg of 0.125% bupivacaine was given in the caudal epidural space in both the groups. The surgical incision was made after 10 min of caudal placement. The caudal block was considered to have failed if the patient had an increase in heart rate, an increase in mean arterial pressure, or both of more than 15% compared with baseline during the surgery. In such instances, the patient was treated with 1–2 μg/kg/h of fentanyl throughout the procedure. A successful block was defined as no increase in heart rate or mean arterial pressure above 15% from baseline on skin incision.

The primary outcome was the first puncture success rate which is defined as needle reaching the sacral canal or sacral hiatus with a single orientation on 1st puncture without withdrawal from the skin.

Secondary outcomes measured were number of skin punctures, block performing time, block success rate, and complications. Secondary outcomes also included assessment of pain score in PACU (post-anesthesia care unit) at 30 min using FLACC scale (face, leg, activity, cry, consolability) in 6 months to 3 years children and pain faces scale in 3 to10 years children pain score more than 4 rescue analgesia with inj. fentanyl 1 mcg/kg was given. All the noted data were collected by an anesthetist who was not present during the block procedure.

The sample size was calculated for the primary outcome of the first puncture success rate in the ultrasound group is 80% and in conventional group 63% in the prior study.[9] The other parameters considered for sample size calculation were 80% power of the study and 5% two-sided alpha error. The sample size was calculated to be 53 patients per study group, i.e., a total of 106 patients.

Statistical analysis

The analyses were conducted using the SPSS v21.0 statistical package (SPSS Inc., Chicago, Illinois, United States). A Chi-square test was used for comparing the categorical variable between the groups. Student's *t*-test was used for comparing the normally distributed parameters, and Mann–Whitney U-test was used for comparing the non-normally distributed parameters; $P < 0.05$ was considered statistically significant.

Results

There were no significant differences [Table 1] in age, height, weight, ASA class, or surgery duration [Figure 2], mean blood pressure, heart rate, SpO2 level, and respiratory rate at all measurement times between both the groups. Group U had a higher first puncture success rate than Group C (90.6% v/s 64.2%) and this difference was statistically significant ($P = 0.001$) [Table 2 & Figure 3]. The main number of punctures performed [Table 3] was significantly less ($P = 0.01$) in Group U (1.09 ± 0.295) than Group C (1.45 ± 0.667). Block performing time was significantly higher ($P = 0.0005$) in Group U (53.19 ± 10.97 s) than Group C (30.34 ± 7.34 s) [Table 3]. There was no difference in the overall block success rate between the groups (98.1% v/s 100%) [Table 3]. There were no complications observed in either group. No intraoperative desaturation events, postoperative nausea, and vomiting were observed in both groups.

Discussion

In the present study both groups were comparable in terms of age, sex, weight, ASA physical status, surgery duration, block success rate, heart rate, mean blood pressure, and oxygen saturation.

Table 1: Demographic characteristics

	Group C	Group U	*P*
Age (years) <2 yrs: >2 year-Number of patients	2.68±1.92 21:32	2.72±2.08 22:31	0.917
Male: Female gender Number (percentage)	51 (96.2): 2 (3.8)	47 (88.7): 6 (11.3)	0.270
Weight (kg) <10: >10 kg	13.19±3.99 15:38	12.92±4.34 18:35	0.736
ASA status I: II	49 (92.5): 4 (7.5)	43 (81.1): 10 (18.9)	0.150
Duration of surgery (min)	30.15 (11.08)	31.60 (10.04)	0.481

Values are in mean±SD, number (percentage); analyzed by Student t-test, Chi-square test

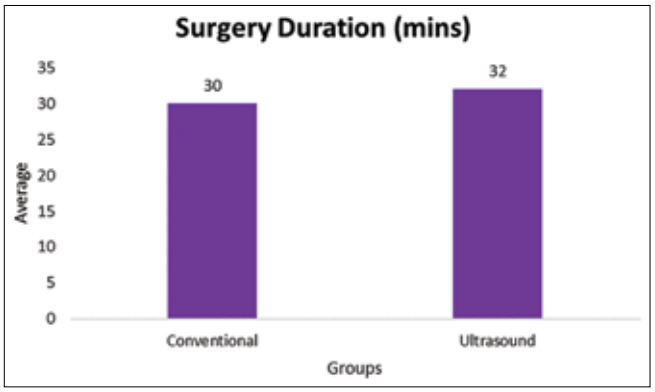

Figure 2: Mean duration of surgery among Group C and Group U

In this study, caudal blocks performed with ultrasound guidance had a higher first puncture success rate [Figure 4] over the conventional method. However, there was no difference in overall block success rate[Figure 5] but the number of punctures required for success in the ultrasound group was lower when compared to the conventional technique. Besides, there were no complications that were observed in both groups.

These results were comparable to the results of a study by Ahiskalioglu *et al.*[9] who found a first puncture success rate of 80% with ultrasound guidance versus 63% with the conventional method. Karaca *et al.*[10] in a similar study showed the first puncture success rate of 90.2% with ultrasound guidance and 66.2% with conventional block. In this study single puncture success was 64.2% in the conventional group compared to the ultrasound group 90.56%. These findings were similar to studies done by Wang *et al.*[11] (73.7% had a single puncture in group C vs 97.7% in group U). In our study subgroup analysis shows the incidence of multiple punctures was more in children above 5 years in the conventional group. Different factors that may contribute to multiple punctures are difficult to palpate sacral hiatus, anatomical variations like the location of sacral hiatus apex.[12] Decreased depth of sacral canal at apex less than 3.7 mm[13] or decrease in length of the sacrococcygeal ligament from apex to baseless than 17.6 mm will also contribute to difficult caudal anesthesia.[12] In conventional caudal block electrical stimulation of needle with 1–10 mA current can cause anal sphincter contraction secondary to stimulation of s2-s4 nerve roots.[14] This technique will be useful for correct needle placement in the sacral canal.

Mean block performing time was 30.34 ± 7.34 s in Group C which was less than the time of 53.19 ± 10.97 s in Group U [Figure 6]. However, we noted that the time with ultrasound guidance was comparatively less than times noted in other

Table 2: Difference in the number of needle punctures between the groups

Number of punctures	Conventional	Ultrasound
1 (%)	34 (64.2)	48 (90.56)
2 (%)	16 (30.18)	4 (7.54)
3 (%)	3 (5.66)	1 (1.88)

Table 3: Success of caudal block

	Group C	Group U	*P*
1st puncture success rate (*n*, %)	34 (64.2)	48 (90.56)	0.001*
Block success rate (*n*, %)	52 (98.1)	53 (100)	1.000
Block performing time (s)	30.34±7.34	53.19±10.97	0.0005*
Mean number of needle punctures	1.45±0.667	1.09±0.295	0.01*

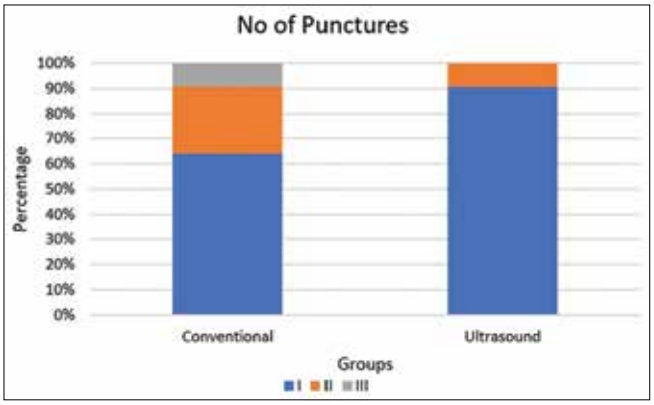

Figure 3: Number of skin punctures done in each patient in Group C and Group U

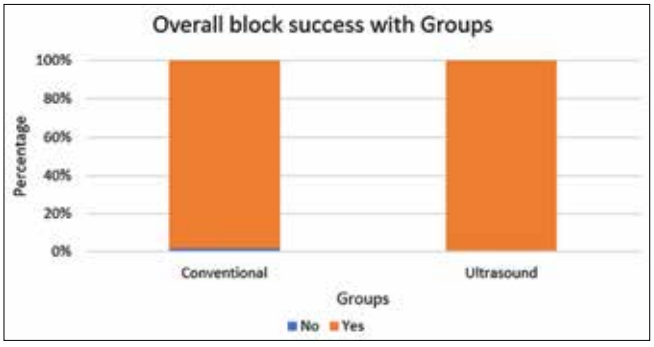

Figure 5: Overall block success rate between the conventional Group C versus ultrasound-guided group U

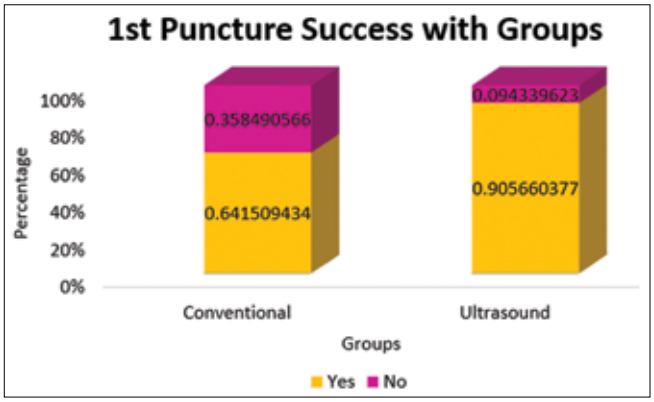

Figure 4: Showing the first puncture success rate between Group C and Group U

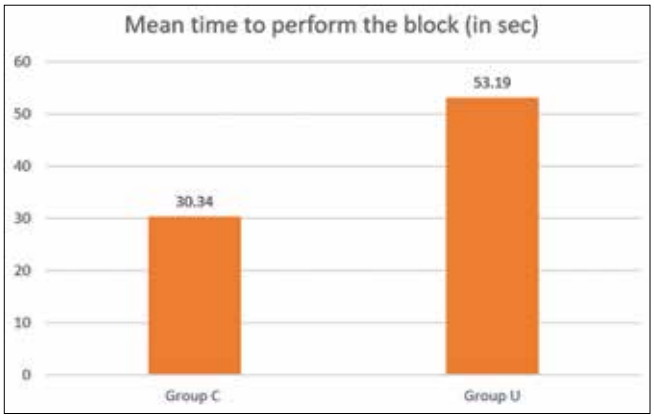

Figure 6: Mean time to perform the caudal block in Group C and Group U

studies like those done by Ahiskalioglu *et al.*[9] (109.9 ± 49.7 s) and Wang *et al.*[11] (145 ± 23 s). Wang *et al.*[11] showed lesser block performing time in the ultrasound-guided caudal block group compared to the conventional group (164 ± 31 s) and the result being statistically significant. Studies were done by Ahiskalioglu *et al.* and Karaca *et al.*[9,10] showed that there was an only marginal difference in the block performing time between both groups and the difference was not statistically significant. One more difference was in the actual time taken to perform the block is different in the above studies. It was varied ranging from a mean of 109.9 s in a study by Ahiskalioglu *et al.* to <10 s in a study done by Karaca *et al.*[9] This significant difference is due to the difference in the definition by the respective authors for the time taken to perform the block.

In a study by Karaca *et al.*, block performing time was defined as the time between the identification of anatomical space to drug injection. In a study by Ahiskalioglu *et al.*, block performing time was defined as the period between the insertion of needle and termination of local anesthetic administration. In a study by Kim *et al.*, the authors defined difficult caudal epidural block as a procedure that took more than 100 s and/or 10 needle passes without withdrawing from the skin. In the present study, due to the routine use of ultrasound in pediatric regional anesthesia block, performance time may be lesser compared to other studies.

The postoperative pain score in children above 3 years yet 30 min in PACU were lower in ultrasound group compared to conventional caudal analgesia group. These findings could be explained by the fact that ultrasound-guided group was monitored spread of drug in caudal epidural space whereas in conventional group distribution of the drug in caudal epidural space was not monitored and two patients had rescue analgesia in a conventional group with pain scores of 5 and 6 which would have caused the increase in pain scale readings. Pain scores at 15 min and 45 min in PACU were comparable in both groups [Tables 4 and 5].

None of the patients in the Group U required rescue analgesia. In ultrasound-guided caudal block angle of needle insertion plays a major role in preventing complications.[15] Optimal angle for needle insertion in ultrasound guided blocks was 20–25° in plane axis parallel to the sacral base. The needle insertion with conventional angle of incidence 60° and then reduction of the angle after entering into sacral canal followed by advancement of the needle by 2–3 mm can lead to complications in caudal analgesia. But in this study complications were not seen in both groups which could be explained by the fact that all the procedures were done by the same three anesthetists who have vast and long experience in pediatric caudal epidural blocks (>10 years) both in conventional and ultrasound-guided techniques.

Table 4: Mean pain score comparison in PACU every 15 min interval up to 45 min in PACU in children below 3 years by FLACC scale

Mean pain score	Conventional group (38)	Ultrasound group (39)	*P*
At 15 min after shifting to PACU	0.58±0.599	0.90±0.59	0.08
At 30 min after shifting to PACU	1.53±0.762	1.00±1.76	0.946
At 45 min after shifting to PACU	0.82±0.69	0.74±0.498	0.45

( ) number of children in each group

Table 5: Mean pain score comparison in PACU every 15 min interval up to 45 min in PACU in children above 3 years by pain faces scale

Mean pain score	Conventional group (15)	Ultrasound group (14)	*P*
At 15 min after shifting to PACU	1.03±0.51	0.97±0.488	0.66
At 30 min after shifting to PACU	2.40±0.58	1.08±0.53	0.03*
At 45 min after shifting to PACU	1.18±0.64	1.11±0.47	0.56

Caudal block under ultrasound guidance could be performed without any complications, including dural puncture,bone contact, or soft tissue bulging. Ultrasound guided caudal block was useful especially in difficult sacral anatomy.

Limitations

Few limitations were observed during the study. Firstly, the duration of motor block in the postoperative period was not considered. Secondly, we only assessed the out-of-the plane technique for skin puncture. Future studies should compare the in-plane and out-of-plane methods for caudal analgesia. Thirdly, we compared the caudal block in children between 6 months and 10 years of age. The performance of the block, however, should be investigated in children weighing <5 kg and aged <6 months. Finally blinding of anesthesiologists who were performing the procedure was not possible.

Conclusion

In conclusion, although the block success rate between groups is not different, the use of ultrasound during the pediatric caudal block procedure reduces the number of punctures required and increases the success rate of the first puncture without any complications.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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