

# A comparative study of ultrasound-guided caudal block versus anatomical landmark-based caudal block in pediatric patients undergoing infra-umbilical surgeries



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## ABSTRACT

**Background:** Pain is an unpleasant sensory and emotional experience that can lead to a variety of potentially negative sequelae in any age group. Thus, efficient and optimum pain management is essential. Optimum post-operative pain management is crucial for preventing adverse sequelae in the post-operative period. Caudal epidural block is a commonly performed regional anesthetic technique for maintaining intra- and post-operative analgesia for pediatric patients undergoing lower abdominal, urogenital, and lower limb surgeries. **Aims and Objectives:** This study was done to compare the success rate and complications between ultrasound (USG) and landmark-guided caudal epidural analgesia in infra-umbilical surgeries in children aged more than 1 month–<12 years. **Materials and Methods:** A total of 150 subjects were randomly allocated into two equal groups (each of 75 patients). Double blinding was done. Both the groups were compared for procedural time, occurrences of subcutaneous swelling, hemorrhagic tap, dural puncture, requirement of intraoperative fentanyl as rescue analgesia, and post-operative analgesia by revised Face, Legs, Activity, Cry, Consolability and Visual Analog Scale score. **Results:** USG-guided caudal block had significantly higher ( $P < 0.001$ ) procedure time (mean  $\pm$  standard deviation procedure time =  $11.6 \pm 1.6$ ), significantly lower ( $P = 0.003$ ) incidence of subcutaneous swelling, and significantly lower ( $P = 0.012$ ) requirement of fentanyl. Post-operative pain was comparable. **Conclusion:** USG-guided caudal block was more time-consuming ( $P < 0.001$ ) but with a higher success rate and subcutaneous swelling ( $P = 0.003$ ) occurred less.

**Key words:** Caudal block; Ultrasound-guided caudal block; Landmark-guided caudal block; Pain relief for infraumbilical surgery; Pediatric post-operative analgesia

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## INTRODUCTION

Pain is an unpleasant sensory and emotional experience that can lead to a variety of potentially negative sequelae even in children. Thus, it is necessary to develop strategies to manage post-operative pain in the most effective and optimal way.

Meredith Campbell in 1933 first described caudal analgesia in connection with urologic surgical procedures in children. It is now a common regional anesthetic technique for effective pain relief in the pediatric population undergoing lower abdominal, urogenital, and lower limb surgeries.

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Caudal epidural block (CEB) obviates the need for systemic analgesics, reduces the risk of opioid associated respiratory depression and ensures better hemodynamic stability as well as recovery, along with achieving effective intra- and post-operative analgesia.

Now, with the advent of portable ultrasound machines, it is becoming popular to administer CEB in children with more success rate and less occurrence of local anesthetic systemic toxicity.<sup>1</sup>

With this background, the present study was aimed primarily to compare the success rate and complications between ultrasound (USG) and landmark-guided caudal epidural analgesia in infra-umbilical surgeries in children aged more than 1 month–<12 years.

Furthermore, the procedural time, rate of procedural complications, post-operative analgesia, and requirement of fentanyl as a rescue analgesic were compared as secondary objectives.

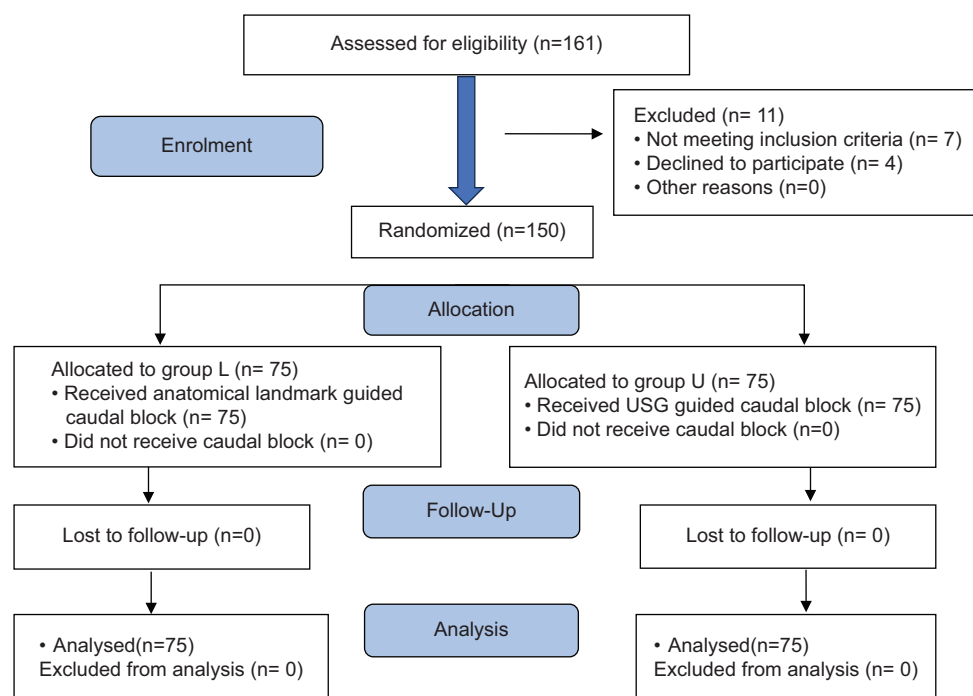
### Aims and objectives

Primary objective was to compare success rates between two groups by analyzing the intraoperative requirement of opioid analgesia.

Secondary objectives were, to compare the procedural time, procedural complication rate and postoperative analgesia.

## MATERIALS AND METHODS

The study was approved by the Institutional Ethics Committee and CTRI registration was done (ICTRI/2022/02/040291). Informed consents for participating in this study was obtained from the parents or legal guardians of the child, after meeting the inclusion criteria. A total of 150 subjects, aged more than 1 month–12 years, posted for infra-umbilical surgery in our institute, who were not in the exclusion criteria, were taken up for our study. They were randomly allocated into two groups (each of 75 patients) using the sealed envelope technique, group U (for patients receiving the block under USG guidance) and L (for patients receiving the block by landmark guidance). Total procedure was based on CONSORT 2010 guideline (Figure 1). One experienced (consultant) anesthesiologist agreed and performed the CEB either by standard technique or by USG guidance after induction of general anesthesia with intermittent positive pressure ventilation. The following study variables were compared – age, sex, American Society of Anesthesiologists (ASA) grading, types of surgery, procedural time, occurrences of subcutaneous swelling, hemorrhagic tap, dural puncture, requirement of intraoperative fentanyl as rescue analgesic and post-operative analgesia by revised Face, Legs, Activity, Cry, Consolability (FLACC) and Visual Analog Scale (VAS) score. It was a double-blinded parallel group randomized controlled study. The time and place of study were orthopedics OT, pediatric surgery OT, and trauma care OT of a tertiary care hospital and medical college, from March 2021 to September 2022. Study population: patients



**Figure 1:** CONSORT 2010 flow diagram

more than 1 month–12 years of age, of ASA physical status I and II, undergoing elective infra-umbilical surgeries.

### Inclusion criteria

The inclusion criteria were as follows – Patients belonging to either sex, of age more than 1 month–<12 years, of ASA physical status I and II, and scheduled to undergo various elective infra-umbilical surgeries, and who gave consent to undergo the study.

### Exclusion criteria

Following were the exclusion criteria – patients aged either <1 month or more than 12 years, refusal from parents to give consent for the procedure, patients having meningomyelocele or other spinal canal defects, with evidence of peripheral neuropathy, neurological deficit or motor weakness, with significant cardiac, respiratory, hepatic or renal disorders or any other uncontrolled systemic illness, bleeding diatheses, history of allergy to amide local anesthetics, infection at the site of needle insertion, history of seizures and syndromic patients.

### Calculating sample size

The sample size for this study was calculated based on the proportion of successful caudal blocks as the primary outcome measure. Considering the confidence level 95%, with a difference of 15% in between groups (population proportion), with 95% power and 5% probability of type 1 error and two-sided testing, and assuming population size as 600 within the study period (pooled data from register), the estimated sample size was 148 for this study.

The formula used  $n = (n \times Z^2 \times P \times [1 - P]) / (e^2 \times [n - 1] + Z^2 \times P \times [1 - P])$ , where  $n$  is the sample size,  $n$  is the population size,  $Z$  is the Z-score corresponding to the desired confidence level,  $P$  is the estimated proportion of the population that possesses the characteristic of interest, and  $e$  is the margin of error.

Sample size calculation was done with nMaster 2.0 (Department of Biostatistics, Christiana Medical College, Vellore; 2011) software.

### Statistical analysis plan

The data were entered in a Microsoft Excel spreadsheet, and the final analysis was done using Statistical Package for Social Sciences software, IBM manufacturer, Chicago, USA, version 21.0. Categorical variables were presented in the form of number and percentage, and quantitative variables were presented as the means  $\pm$  standard deviation (SD) and median with 25<sup>th</sup> and 75<sup>th</sup> percentiles, interquartile range (IQR). The data normality was checked using the Kolmogorov–Smirnov test, where  $P < 0.05$  denoted lack of normality in the data. As all of the quantitative variables lacked normal distribution,

**Table 1: Comparison of age between patients undergoing ultrasound-guided caudal block and anatomical landmark-based caudal block**

| Age in years | Procedure                            |                                 | Total   | P-value*           |
|--------------|--------------------------------------|---------------------------------|---------|--------------------|
|              | Landmark-guided (n=75)<br>Number (%) | USG-guided (n=75)<br>Number (%) |         |                    |
| 0–7          | 42 (56)                              | 39 (52)                         | 81 (54) | 0.623 <sup>†</sup> |
| 8–12         | 33 (44)                              | 36 (48)                         | 69 (46) |                    |

\*Chi-square test, <sup>†</sup>Not significant, USG: Ultrasound

**Table 2: Comparison of gender among patients undergoing ultrasound-guided caudal block and anatomical landmark-based caudal block**

| Gender | Procedure                            |                                 | Total      | P-value*           |
|--------|--------------------------------------|---------------------------------|------------|--------------------|
|        | Landmark-guided (n=75)<br>Number (%) | USG-guided (n=75)<br>Number (%) |            |                    |
| Male   | 63 (84)                              | 65 (86.7)                       | 128 (85.3) | 0.644 <sup>†</sup> |
| Female | 12 (16)                              | 10 (13.3)                       | 22 (14.7)  |                    |

\*Chi-square test, <sup>†</sup>Not significant, USG: Ultrasound

**Table 3: Comparative analysis of ASA grades among patients undergoing ultrasound-guided caudal block and anatomical landmark-based caudal block**

| ASA grade | Procedure                            |                                 | Total      | P-value*           |
|-----------|--------------------------------------|---------------------------------|------------|--------------------|
|           | Landmark-guided (n=75)<br>Number (%) | USG-guided (n=75)<br>Number (%) |            |                    |
| I         | 27 (36)                              | 19 (25.3)                       | 46 (30.7)  | 0.157 <sup>†</sup> |
| II        | 48 (64)                              | 56 (74.7)                       | 104 (69.3) |                    |

\*Chi-square test, <sup>†</sup>Not significant, USG: Ultrasound, ASA: American Society of Anesthesiologists

Mann–Whitney U test was used to identify differences in the distribution of those variables in landmark-guided and USG-guided caudal block groups. The difference in qualitative variables between landmark-guided and USG-guided caudal block groups was analyzed using the Chi-square test. Fisher's Exact test was used if any cell value was  $< 5$ . For statistical significance,  $P < 0.05$  was considered significant.

## RESULTS

Both groups were compared for demographic characteristics, ASA grading, and the type of surgery done on them. Both groups were compared on different study objective parameters, such as procedure time, incidence of subcutaneous swelling, fentanyl requirement,

post-operative pain score (revised FLACC score for 1 month–7 years, and VAS score for 7 years–12 years of age), and the results were as follows.

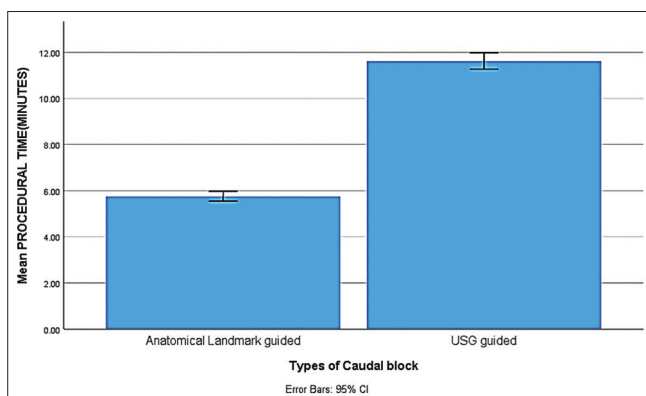
- Tables 1, 2, 3 and 4 shows that, both the groups were comparable in terms of age, sex, ASA grade and type of surgery done.
- Table 5 and Figure 2 shows that, USG-guided caudal block had higher procedure time ( $11.6 \pm 1.6$  sec, Mean $\pm$ SD) than anatomical landmark guided caudal block ( $5.8 \pm 0.9$  sec, Mean $\pm$ SD) which was statistically significant too ( $P < 0.001$ ).
- Table 6 and Figure 3 shows that USG-guided caudal block had significantly lower ( $P = 0.003$ ) incidence of subcutaneous swelling (6.7%) than anatomical landmark-guided caudal block (24%).
- Table 7 and Figure 4 shows less fentanyl requirement in USG guided block group ( $P = 0.012$ ). Other complications like hemorrhage, CSF aspiration did not occur in any patient.
- Post-operative pain was measured by revised Face, legs, activity, cry, consolability score (FLACC score) in patients aged 1 month –7 years and the VAS ( Visual analogue

scale) score in patients aged 8–12 years. From Table 8 and Figure 5, it is evident that no differences were found in both groups on post operative pain measurement when pain was assessed by revised FLACC score ( $P = 0.317$ ). Same results are seen from Table 9 and Figure 6. Both groups were comparable on post operative pain scoring when done by VAS too ( $P = 0.914$ ).

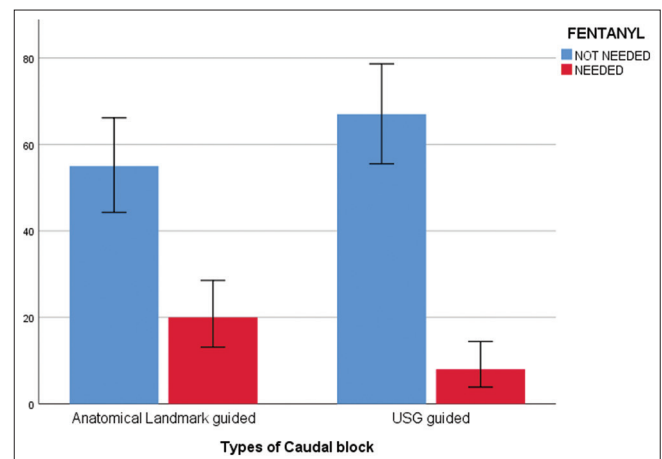
## DISCUSSION

CEB offers an excellent method of perioperative pain management in infra-umbilical surgeries. As mentioned previously, the aim of this study was to assess the effect of using real-time USG during the placement of the block. In this section, a brief discussion is being done on the study outcomes, keeping in view the existing literature regarding the same topic.

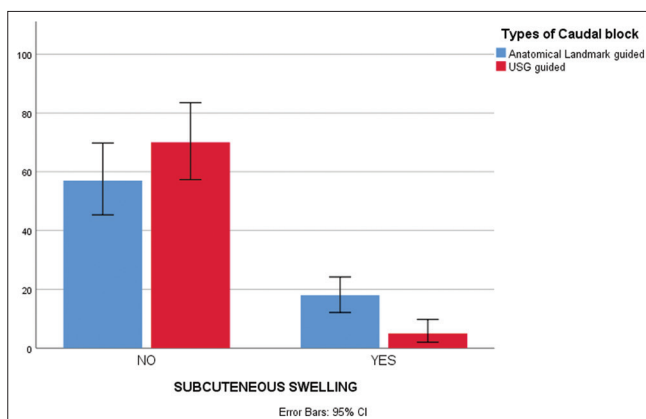
Nanjundaswamy et al.,<sup>2</sup> in their study, randomly allocated 124 children into two equal groups (landmark-guided and USG-guided), which revealed that on average, USG-guided



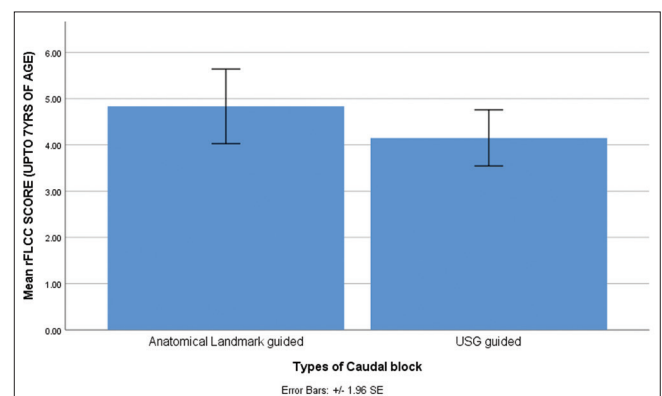
**Figure 2:** Comparative analysis of procedure time among patients receiving ultrasound-guided caudal block and anatomical landmark-based caudal block



**Figure 4:** Comparative analysis of the requirement of fentanyl among patients undergoing ultrasound-guided and anatomical landmark-based caudal block



**Figure 3:** Comparative analysis of incidence of subcutaneous swelling among patients receiving ultrasound-guided and anatomical landmark-based caudal block



**Figure 5:** Comparison of post-operative pain (revised Face, Legs, Activity, Cry, Consolability Score) in patients aged 0–7 years undergoing ultrasound-guided and anatomical landmark-based caudal block (n=81)

**Table 4: Comparison of type of surgery among patients undergoing ultrasound-guided caudal block and anatomical landmark-based caudal block**

| Type of surgery | Procedure                            |                                 | Total     | P-value*           |
|-----------------|--------------------------------------|---------------------------------|-----------|--------------------|
|                 | Landmark-guided (n=75)<br>Number (%) | USG-guided (n=75)<br>Number (%) |           |                    |
| Duhamel         | 2 (2.7)                              | 3 (4.0)                         | 5 (3.3)   | 0.051 <sup>†</sup> |
| Hernioplasty    | 24 (32.0)                            | 41 (54.7)                       | 65 (43.3) |                    |
| Orchidopexy     | 10 (13.3)                            | 3 (4.0)                         | 13 (8.7)  |                    |
| PSARP           | 7 (9.3)                              | 3 (4.0)                         | 10 (6.7)  |                    |
| STSG            | 5 (6.7)                              | 5 (6.7)                         | 10 (6.7)  |                    |
| Urethroplasty   | 27 (36)                              | 20 (26.7)                       | 47 (31.3) |                    |

\*Chi-square test, <sup>†</sup>Not significant, USG: Ultrasound, PSARP: Posterior Sagittal Anorectoplasty, STSG: Split-thickness skin

**Table 5: Comparison of procedure time among patients receiving anatomical landmark-based caudal block and ultrasound-guided caudal block**

| Procedure time (Minutes) | Procedure                            |                                 | Total      | P-value*            |
|--------------------------|--------------------------------------|---------------------------------|------------|---------------------|
|                          | Landmark-guided (n=75)<br>Number (%) | USG-guided (n=75)<br>Number (%) |            |                     |
| Mean±standard deviation  | 5.8±0.9                              | 11.6±1.6                        | 8.7±3.2    | <0.001 <sup>†</sup> |
| Median (IQR)             | 6 (5,6)                              | 11 (11,12)                      | 8.5 (6,11) |                     |
| Range                    | 4,8                                  | 9, 16                           | 4,16       |                     |

\*Mann-Whitney U Test as Kolmogorov-Smirnov test  $P<0.005$ , <sup>†</sup>Statistically significant, USG: Ultrasound, IQR: Interquartile range

**Table 6: Comparison of incidence of subcutaneous swelling among patients receiving ultrasound-guided and anatomical landmark-based caudal block**

| Subcutaneous swelling | Procedure                            |                                 | Total (n=150)<br>Number (%) | P-value*           |
|-----------------------|--------------------------------------|---------------------------------|-----------------------------|--------------------|
|                       | Landmark-guided (n=75)<br>Number (%) | USG-guided (n=75)<br>Number (%) |                             |                    |
| Yes                   | 18 (24)                              | 5 (6.7)                         | 23 (15.3)                   | 0.003 <sup>†</sup> |
| No                    | 57 (76)                              | 70 (93.3)                       | 127 (84.7)                  |                    |

\*Chi-square test, <sup>†</sup>Statistically significant, USG: Ultrasound

CEB took 7.71 min, whereas landmark-guided block took 5.94 min, and this difference in procedural time was statistically significant ( $P=0.003$ ).

Our analysis observed no differences in outcome based on sociodemographic patterns, ASA status, and types of

**Table 7: Comparative analysis of the requirement of Fentanyl among patients undergoing ultrasound-guided and anatomical landmark-based caudal block**

| Requirement of fentanyl | Procedure                            |                                 | Total (n=150)<br>Number (%) | P-value*           |
|-------------------------|--------------------------------------|---------------------------------|-----------------------------|--------------------|
|                         | Landmark-guided (n=75)<br>Number (%) | USG-guided (n=75)<br>Number (%) |                             |                    |
| No                      | 55 (73.3)                            | 67 (89.3)                       | 122 (81.3)                  | 0.012 <sup>†</sup> |
| Yes                     | 20 (26.7)                            | 8 (10.7)                        | 28 (18.7)                   |                    |

\*Chi-square test, <sup>†</sup>Statistically significant, USG: Ultrasound

**Table 8: Comparison of post-operative pain (revised FLACC score) in patients aged 0–7 years undergoing USG-guided and anatomical landmark-based caudal block (n=81)**

| Revised FLACC score     | Procedure                            |                                 | Total (n=81)<br>Number (%) | P-value* |
|-------------------------|--------------------------------------|---------------------------------|----------------------------|----------|
|                         | Landmark-guided (n=42)<br>Number (%) | USG-guided (n=39)<br>Number (%) |                            |          |
| Mean±standard deviation | 4.8±2.7                              | 4.1±1.98                        | 4.5±2.4                    | 0.317    |
| Median (IQR):           | 4 (3, 7)                             | 4 (2, 5)                        | 4 (3, 5)                   |          |
| Range:                  | 1, 10                                | 2, 9                            | 1, 10                      |          |

\*Mann-Whitney U Test as Kolmogorov-Smirnov test  $P<0.05$ . USG: Ultrasound, FLACC: Face, Legs, Activity, Cry, Consolability, IQR: Interquartile range

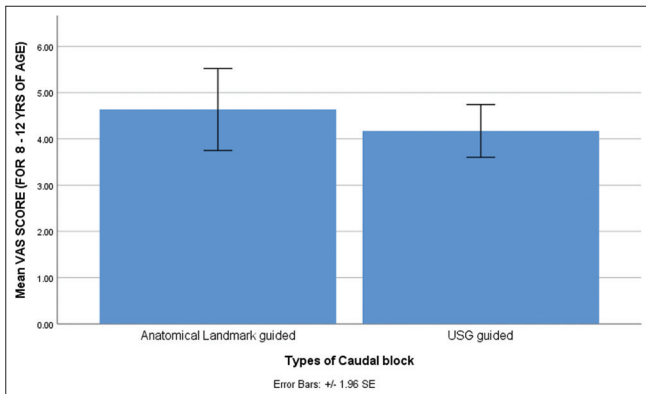
**Table 9: Comparison of post-operative pain (VAS score) in patients aged 8–12 years undergoing USG-guided and anatomical landmark-based caudal block (n=81)**

| VAS score               | Procedure                            |                                 | Total (n=69)<br>Number (%) | P-value* |
|-------------------------|--------------------------------------|---------------------------------|----------------------------|----------|
|                         | Landmark-guided (n=33)<br>Number (%) | USG-guided (n=36)<br>Number (%) |                            |          |
| Mean±standard deviation | 4.6±2.6                              | 4.2±1.7                         | 4.4±2.2                    | 0.914    |
| Median (IQR)            | 4 (2, 7)                             | 4 (3, 5)                        | 4 (3, 5)                   |          |
| Range                   | 1, 10                                | 2, 9                            | 1, 10                      |          |

\*Mann-Whitney U Test as Kolmogorov-Smirnov test  $P<0.05$ . VAS: Visual Analog Scale, USG: Ultrasound

surgery involved. The median (IQR) time to reach epidural space was 105.5 (297.0) s in the landmark-guided group and 143.0 (150) s in the USG-guided group ( $P=0.407$ ) in the study by Mital et al.,<sup>3</sup> in 2021.

In the present study, USG-guided caudal block had significantly higher ( $P<0.001$ ) procedure time (mean±SD procedure time=11.6±1.6) than anatomical landmark guided caudal block (mean±SD procedure time=5.8±0.9).



**Figure 6:** Comparison of post-operative pain (Visual Analog Scale score) in patients aged 8–12 years undergoing ultrasound-guided and anatomical landmark-based caudal block (n=81)

Riaz et al. concluded in their study that the success rate was higher in the USG group (95%) as compared to the landmark technique ( $P=0.000$ ).<sup>4</sup>

In our study, the analysis showed similar findings. USG-guided caudal block had significantly lower ( $P=0.012$ ) requirement of fentanyl (10.7%) than anatomical landmark-guided caudal block (26.7%).

A systematic review and meta-analysis by Jain et al. stated that the incidence of vascular puncture and subcutaneous injection was significantly less in the USG-guided group as compared to the landmark technique. Dural puncture was seen in only one patient in the landmark technique. There were no other reported complications, such as intravascular injection, neural damage, hematoma, anaphylaxis, or local anesthetic toxicity.<sup>5</sup>

Similar findings were also seen in a study by Ahiskalioglu et al. Rates of vascular puncture and subcutaneous bulging were higher in the landmark-guided group.<sup>1</sup>

However, in our study, we observed no incidence of either hemorrhagic tap or dual puncture during the procedure. There was an incidence of subcutaneous swelling, which was more common in the group (L). USG-guided caudal block had significantly lower ( $P=0.003$ ) incidence of subcutaneous swelling (6.7%) than anatomical landmark-guided caudal block (24%).

#### Limitations of the study

As real-time ultrasound is a newer technique, the duration of procedure might have been influenced in group U (USG guided group).

Post-operative pain assessment was done using rFLACC and VAS score, both of which require an unbiased response from the patient. But, emergence reaction due to sevoflurane may explain the upscaling of rFLACC score in some of the children.

## CONCLUSION

This study was done to evaluate the influence of using real-time USG during the placement of CEB in pediatric patients undergoing various infra-umbilical surgeries. It may be concluded that, although more time-consuming, USG-guided CEB has a higher success rate and significantly fewer occurrences of complications and thus offering us a better way of perioperative pain management.

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**Authors' Contributions:**

**SH**- Primary investigator, definition of intellectual content, literature survey, prepared first draft of manuscript, implementation of study protocol, data collection, data analysis, and initial preparation of manuscript; **AR**- Literature survey, defining study design and protocol, drafting manuscript, editing and revision, preparing the article, and submission; **PM**- Review manuscript; **MM**- Concept, design, design of study and making clinical protocol, manuscript preparation, editing, and manuscript revision; **AL**- Review manuscript.

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