

A COMPARATIVE STUDY OF LOCAL INFILTRATION OF WOUNDS WITH BUPIVACAINE AND INTRAVENOUS PARACETAMOL AT THE TIME OF INDUCTION FOR POST-OPERATIVE PAIN RELIEF IN PEDIATRIC INGUINAL HERNIOTOMY SURGERIES

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ABSTRACT

Background: Effective postoperative pain control in children is essential to reduce distress, enhance recovery, and prevent complications.

Objectives: To compare the efficacy of local wound infiltration with bupivacaine versus intravenous (IV) paracetamol for early postoperative pain management in children undergoing inguinal herniotomy.

Methods: This double-blind randomized controlled trial included 98 children aged 5–12 years undergoing elective inguinal herniotomy. Participants were randomly assigned into two groups (n=49 each). In the bupivacaine group, 0.25% bupivacaine (prepared by diluting 0.5% solution) was infiltrated into the surgical wound at induction. In the paracetamol group, IV paracetamol was administered at induction. Postoperative pain was assessed using the Face, Legs, Activity, Cry, and Consolability (FLACC) scale at 30 minutes and hourly for 6 hours. Rescue analgesia was administered for FLACC scores ≥ 4 . Data were analyzed using appropriate statistical tests, with $p \leq 0.05$ considered significant.

Results: Of the 98 children, 69.4% were male and 30.6% female, with a mean age of 7.19 ± 1.63 years. The bupivacaine group demonstrated significantly lower FLACC scores at 2, 3, 4, 5, and 6 hours postoperatively ($p < 0.05$). Additional analgesia was required in 6.1% of patients in the bupivacaine group compared to 22.4% in the paracetamol group ($p = 0.021$).

Conclusion: Local wound infiltration with bupivacaine provides superior and prolonged postoperative analgesia compared to IV paracetamol in pediatric inguinal herniotomy, with reduced need for rescue analgesia.

Keywords: Bupivacaine, Paracetamol, FLACC score, Pediatric surgery, inguinal hernia, Postoperative pain.

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INTRODUCTION

Inguinal hernia repair is among the most frequently performed surgical procedures in the pediatric population

worldwide.¹ The condition is primarily congenital and results from the failure of obliteration of the processus vaginalis during late gestation, typically between 36 and 40 weeks.¹ The incidence of pediatric inguinal hernia ranges from 1% to 5% in the general population, with a higher prevalence in preterm infants (9–11%) compared to term neonates (3–5%).² It is more common in males, with a male-to-female ratio of approximately 4:1.² Known risk factors include prematurity, family history, undescended testes, cystic fibrosis, and developmental anomalies of the genitourinary system. Herniotomy remains the standard surgical treatment for pediatric inguinal hernia and is one of the most commonly performed procedures by pediatric surgeons.³ Despite its

routine nature, effective postoperative pain management remains a significant concern. Inadequately controlled pain can lead to delayed recovery, prolonged hospital stay, increased stress response, and dissatisfaction among patients and caregivers.⁴

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage.⁵ Studies suggest that a substantial proportion of hospitalized children experience moderate to severe pain, highlighting the need for effective analgesic strategies.⁶ Various modalities are available for postoperative pain control, including systemic analgesics such as opioids and non-steroidal anti-inflammatory drugs, as well as regional techniques like local anesthetic infiltration.⁷ Each approach has its own benefits and limitations, necessitating careful selection based on efficacy and safety.

Accurate assessment of pain is essential for optimal management, particularly in pediatric patients where communication may be limited. Behavioral pain assessment tools such as the Face, Legs, Activity, Cry, and Consolability (FLACC) scale are widely used and considered reliable for evaluating postoperative pain in young children.^{8,9} Other tools, including the Modified Behavioral Pain Scale (MBPS) and Visual Analogue Scale (VAS), are also utilized, although their applicability varies depending on age and cognitive ability.^{8,10}

Local anesthetic infiltration with agents such as bupivacaine and systemic administration of paracetamol are commonly employed strategies for postoperative analgesia in pediatric herniotomy.^{11, 12} However, there remains variability in clinical practice regarding the most effective and safest approach.

Therefore, the present study aims to compare the efficacy and safety of bupivacaine wound infiltration versus intravenous paracetamol for postoperative pain management in children undergoing inguinal herniotomy. Identifying an optimal analgesic strategy may contribute to improved postoperative outcomes, reduced need for additional analgesia, and enhanced patient comfort.

METHODS

Study Design and Setting: This double-blind randomized controlled trial was conducted at the Department of Pediatric Surgery, Nishter Medical University, Multan, Pakistan, over a period of one year from November 2024 to October 2025.

Sample Size Calculation: The sample size was calculated using previously reported mean FLACC pain scores of 1.53 ± 0.77 in the bupivacaine group and 2.01 ± 0.83 in the paracetamol group. With a power of 80% and a 95% confidence level, the estimated sample size was 88 patients. After accounting for a 10% dropout rate, a total of 98 patients were included, with 49 patients allocated to each group.

Participants: Children aged 5–12 years of either gender undergoing elective inguinal herniotomy were eligible for inclusion. Patients with obstructed hernia, testicular torsion, congenital anomalies, known hypersensitivity to bupivacaine or paracetamol, or those whose guardians declined consent were excluded.

Randomization and Blinding: Participants were randomly allocated into two groups using a simple random sampling technique (lottery method). Allocation concealment was ensured by assigning group distribution through ward nursing staff. Both the patients and the primary investigator were blinded to group allocation throughout the study.

Intervention: All patients underwent standard inguinal herniotomy under general anesthesia.

Group B (Bupivacaine group): Patients received local wound infiltration with 0.5% bupivacaine at a dose of 1 mg/kg, diluted with sterile distilled water to achieve a final concentration of 0.25%, administered at the time of surgical incision.

Group P (Paracetamol group): Patients received intravenous paracetamol at induction of anesthesia as per standard dosing protocols.

Outcome Measures: Postoperative pain was assessed using the Face, Legs, Activity, Cry, and Consolability (FLACC) scale. Pain scores were recorded at 30 minutes postoperatively (baseline), followed by hourly assessments for 6 hours.

The primary outcome was postoperative pain intensity as measured by FLACC score. Secondary outcomes included the requirement for rescue analgesia, defined as administration of additional analgesia when FLACC score ≥ 4 within the first 6 postoperative hours.

Data Collection: Demographic data including age, gender, weight, and height were recorded using a structured proforma. All clinical data, including pain scores and analgesic requirements, were documented by the investigator.

Statistical Analysis: Data were analyzed using Statistical Package for Social Sciences (SPSS), version 26.0. Quantitative variables (age, FLACC score) were expressed as mean $\pm$ standard deviation, while qualitative variables (gender, analgesia requirement) were presented as frequencies and percentages. Comparisons between groups were performed using the independent sample t-test for normally distributed data and the Mann–Whitney U test for non-normally distributed data. The Chi-square test was applied to compare categorical variables, including the requirement for rescue analgesia. A p-value ≤ 0.05 was considered statistically significant.

Ethical Considerations: The study was approved by the Institutional Review Board of Nishter Medical University with reference number 1130/NMU&H dated 20.01.2021. Written informed consent was obtained from the parents or legal guardians of all participants before enrollment.

RESULTS

In a total of 98 children, 68 (69.4%) were male and 30 (30.6%) female. Overall, mean age was noted to be 7.19 ± 1.63 years ranging between 5–11 years. Figure 1 is showing frequency distribution of age among patients.

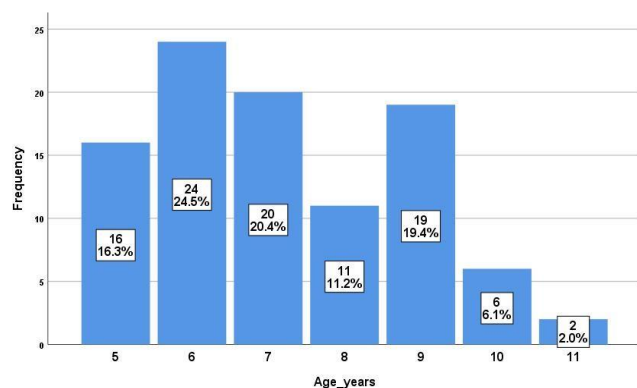


Figure 1: Frequency Distribution of Age among Patients

Age was categorized between 5-8 years and 9-12, and it was noted that 71 (72.4%) children were aged between 5-8 years while remaining 27 (27.6%) were aged between 9-12 years.

The mean body weight was calculated to be 22.22 ± 3.38 kg and the frequency distribution of weight of all the children is shown in figure 2

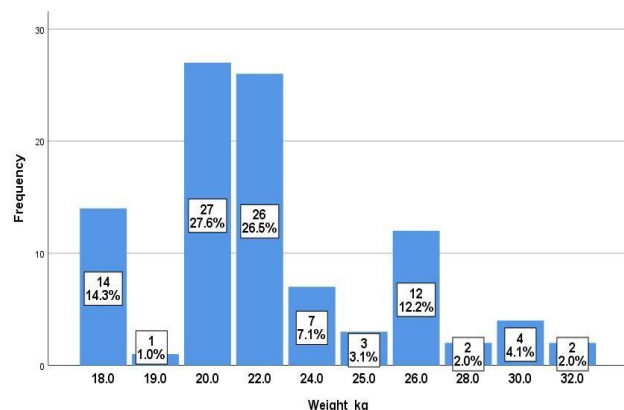


Figure 2: Frequency Distribution of Weight (kg)

The mean overall FLACC score at 30-minutes, 1-hour, 2-hours, 3-hours, 4-hours, 5-hours and 6-hours was recorded to be 5.46 ± 1.09 , 5.03 ± 0.94 , 4.55 ± 0.99 , 4.09 ± 0.95 , 3.36 ± 0.98 , 2.92 ± 0.86 and 2.26 ± 1.07 respectively as shown in figure 4.3.

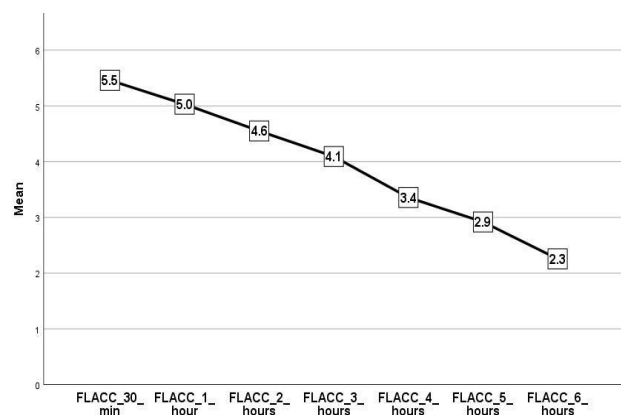


Figure 4.3: Overall FLACC Scores During the Course of the Study

Additional analgesia were required in a total of 14 (14.3%) patients. Distribution of gender in both study groups is shown in table 4.1 and it was noted that 32 (65.3%) patients in Bupivacaine group were male in comparison to 36 (73.5%) in Paracetamol group while 17 (34.7%) patients in Bupivacaine group were female in comparison to 13 (26.5%) in Paracetamol group whereas the difference in terms of gender distribution was not statistically significant in between patients of both study groups ($p=0.381$).

Table 4.1: Comparison of Gender in Study Groups

Gender	Bupivacaine Group (n=49)	Paracetamol Group (n=49)	P-Value
Male	32 (65.3%)	36 (73.5%)	0.381
Female	17 (34.7%)	13 (26.5%)	

The mean age of the patients in Bupivacaine group was 6.96 ± 1.60 years while mean age in Paracetamol group was 7.42 ± 1.64 years. Comparison of mean age in both groups did not show any statistically significant difference ($p=0.162$). Distribution of age groups in both study groups is shown in table 4.2 and it was noted that 35 (71.4%) patients in Bupivacaine group were aged between 5 to 8 years in comparison to 36 (73.5%) in Paracetamol group while 14 (28.6%) patients in Bupivacaine group were aged between 9 to 12 years in comparison to 13 (26.5%) in Paracetamol group whereas the difference in terms of age distribution was not statistically significant in between patients of both study groups ($p=0.821$).

Table 4.2: Comparison of Age Groups

Age (years)	Bupivacaine Group (n=49)	Paracetamol Group (n=49)	P-Value
5-8	35 (71.4%)	36 (73.5%)	0.821
9-12	14 (28.6%)	13 (26.5%)	

The mean body weight of the patients in Bupivacaine group was 21.63 ± 3.11 years while the body weight in Paracetamol group was 22.80 ± 3.56 years. Comparison of the mean body weight in both groups did not show any statistically significant difference ($p=0.086$).

Table 4.3: Comparison of Post-Surgery FLACC Scores in Both Study Groups at Various Intervals

FLACC Scores	Bupivacaine Group (n=49)	Paracetamol Group (n=49)	P-Value
30 minutes	5.45 ± 0.95	5.44 ± 1.22	0.859
1 hours	5.00 ± 0.83	5.06 ± 1.04	0.753
2 hours	4.33 ± 0.83	4.76 ± 1.08	0.031
3 hours	3.90 ± 0.93	4.28 ± 0.95	0.046
4 hours	3.04 ± 0.90	4.28 ± 0.95	0.001
5 hours	2.63 ± 0.84	3.20 ± 0.78	0.001
6 hours	1.90 ± 0.95	2.60 ± 1.07	0.001

Comparison of additional need of post-surgery analgesia showed that 3 (6.1%) patients in Bupivacaine group required additional analgesia in comparison to 11 (22.4%) in Paracetamol group while the

difference was noted to be statistically significant ($p=0.021$) as shown in table-4.6.

Comparison of post-surgery FLACC scores among patients of both study groups at various intervals is shown in table 4.3 and it was noted that post-surgical FLACC scores at 2-hours ($p=0.031$), 3-hours ($p=0.046$), 4-hours ($p=0.001$), 5-hours ($p=0.001$) and 6-hours ($p=0.001$) were statistically significant as patients in Bupivacaine group reported significantly less FLACC scores

Table 4.4: Comparison of Post-Surgery Need for Additional Analgesia in Both Study Groups

Need for Additional Analgesia	Bupivacaine Group (n=49)	Paracetamol Group (n=49)	P-Value
Yes	3 (6.1%)	11 (22.4%)	0.021
No	46 (93.9%)	38 (78.6%)	

DISCUSSION

Effective postoperative pain control is a critical component of pediatric surgical care, particularly in commonly performed procedures such as inguinal herniotomy. The present study demonstrates that local wound infiltration with bupivacaine provides superior postoperative analgesia compared to intravenous paracetamol, as evidenced by lower FLACC scores and reduced requirement for rescue analgesia.

These findings are consistent with previous studies evaluating local anesthetic infiltration in pediatric surgical populations. Hidas et al. demonstrated that continuous incisional infusion of local anesthetics significantly improved postoperative pain control.¹³ Similarly, Sakellaris et al. reported that local anesthetic infiltration reduces postoperative pain and stress response in children undergoing inguinal hernia repair.¹⁴ These studies support the concept that targeting the surgical site directly with local anesthetics provides effective nociceptive blockade.

In the current study, pain assessment was performed using the FLACC scale, which is widely validated for pediatric populations. Merkel et al. originally introduced this tool.¹⁵ and subsequent validation by Nilsson et al. confirmed its reliability across a broader pediatric age group.¹⁶ The consistent use of a validated tool strengthens the internal validity of the present findings.

The reduced need for additional analgesia in the bupivacaine group observed in this study aligns with prior comparative research. Jahromi et al. reported that significantly fewer patients required rescue analgesia following bupivacaine infiltration compared to acetaminophen.¹² Likewise, Ahmad et al. demonstrated superior analgesic efficacy of bupivacaine compared to paracetamol suppositories.³ These findings collectively suggest that local anesthetic infiltration provides more sustained postoperative analgesia.

Other studies have explored combination analgesic strategies. Khasawneh et al. showed that combining bupivacaine infiltration with paracetamol resulted in

better pain control than paracetamol alone,¹⁷ highlighting the benefit of multimodal analgesia. However, even when used alone, bupivacaine infiltration in the present study outperformed intravenous paracetamol, reinforcing its standalone effectiveness.

Comparative studies involving alternative techniques, such as caudal blocks, have shown comparable outcomes. Baird et al., in a meta-analysis, found similar pain scores between caudal blockade and wound infiltration.¹⁸ Likewise, Sethi et al. demonstrated effective analgesia with regional techniques such as caudal and TAP blocks,¹⁹ although these methods require technical expertise and may not always be feasible.

From a practical perspective, local wound infiltration offers several advantages. It is simple, cost-effective, and does not require specialized anesthetic skills, making it particularly suitable for resource-limited settings. Kark et al. and Callesen et al. highlighted the feasibility and safety of local anesthesia techniques in surgical practice.^{20, 22} Although concerns regarding systemic toxicity and wound healing exist, evidence suggests that these risks are minimal when appropriate dosing is used.²¹

The present study has several strengths, including its randomized controlled design, use of a validated pain assessment tool, and direct comparison of two commonly used analgesic modalities.

Limitations: This study has certain limitations. It was a single-center trial with a relatively small sample size, which may limit the generalizability of the findings. Surgeries were performed by multiple surgeons, introducing potential inter-operator variability. Postoperative pain was assessed only for the first 6 hours, thus longer-term analgesic outcomes were not evaluated. Although designed as a double-blind study, the method of allocation may carry a risk of bias. Additionally, secondary outcomes such as time to ambulation, hospital stay, patient/parent satisfaction, and detailed assessment of adverse effects were not systematically analyzed.

CONCLUSION

Local wound infiltration with bupivacaine provides superior and prolonged postoperative analgesia compared to intravenous paracetamol in pediatric inguinal herniotomy. It significantly reduces the requirement for additional analgesia and represents a simple, effective, and practical approach to postoperative pain management.

ETHICAL APPROVAL

Ethical approval of article was granted by the Institutional Review Board of Nishtar Medical University, Multan vide Ref No. 1130/NMU & H, Dated: 20 January, 2021.

AUTHOR'S CONTRIBUTIONS

MH: Conceived idea, design, manuscript writing

MAH: Supervision, critical reviews, manuscript writing

IUK, HI: Data collection & analysis, proof reading, Manuscript writing

ZS: Manuscript writing,

All Authors: Approval of the final version of the manuscript to be published

CONFLICT OF INTEREST

Authors declare no conflict of interest.

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