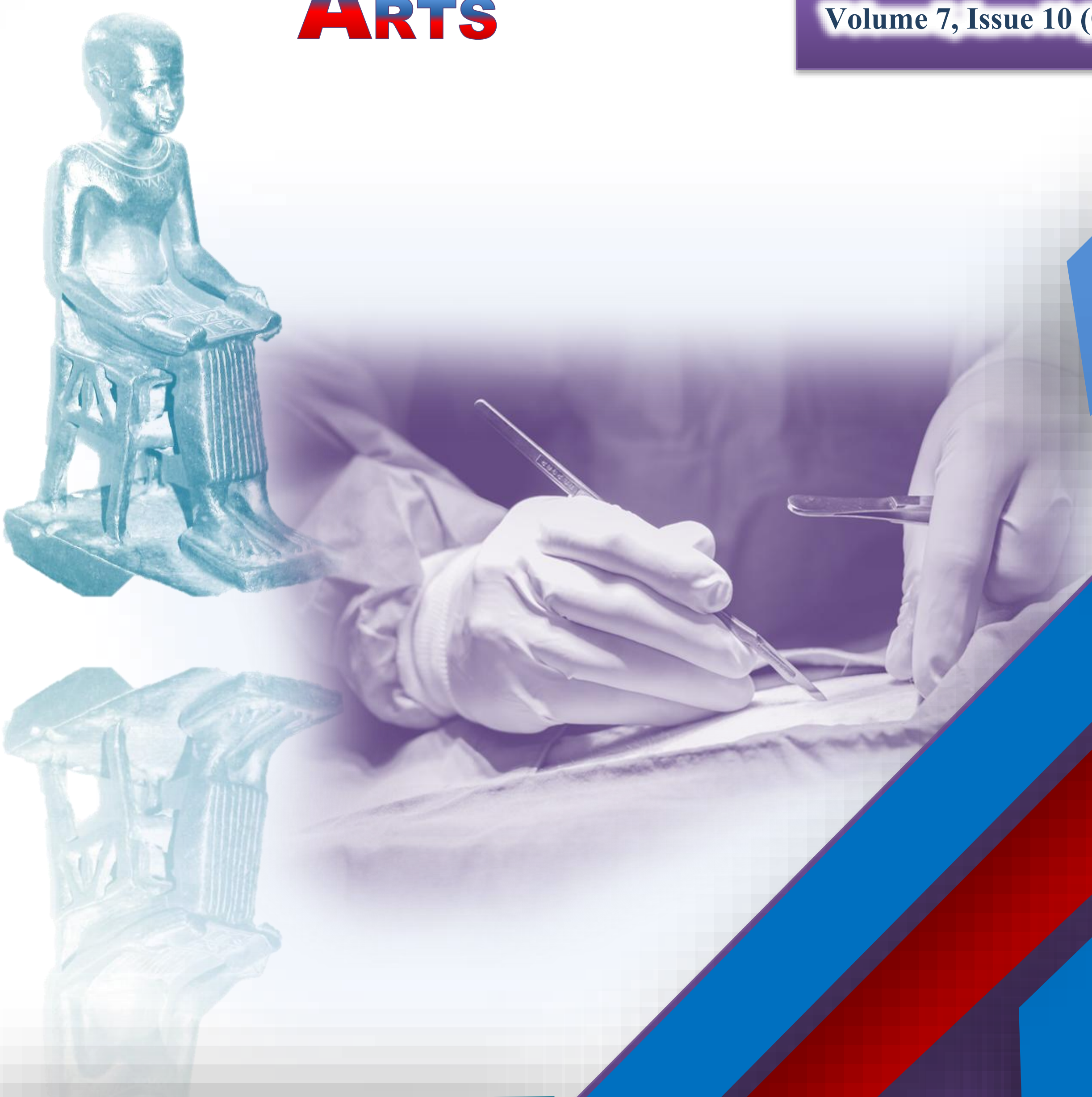
IJMA

International Journal of Medical Arts

Volume 7, Issue 10 (October 2025)



http://ijma.journals.ekb.eg/

P-ISSN: 2636-4174

E-ISSN: 2682-3780

Available online on Journal Website
https://ijma.journals.ekb.eg
Main Subject [Orthopedic Surgery]

Original Article

Laparoscopic versus Ultrasound-Guided Transversus Abdominis Plane Block versus Laparoscopic Intraperitoneal Instillation of Local Anesthetic in Pediatrics Undergoing Inguinal Hernia Repair: A randomized Controlled Trial

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Abstract

Article information

Received: 22-06-2025

Accepted: 09-08-2025

DOI: 10.21608/ijma.2025.396789.2203

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Citation: Ibrahim AM, Bakr DM, Abo Mostafa AII, Elhaddad AA, Abdallah MK, Abdelwahab EH, Helal RA. Laparoscopic versus Ultrasound-Guided Transversus Abdominis Plane Block versus Laparoscopic Intraperitoneal Instillation of Local Anesthetic in Pediatrics Undergoing Inguinal Hernia Repair: A randomized Controlled Trial. IJMA 2025 Oct; 7 [10]: 6169-6174. doi: 10.21608/ijma.2025.396789.2203

Background: Significant pain and discomfort post inguinal hernia repairing surgeries are often reported in surgical units concerning pediatrics. In this trial, we compared the analgesic effects of ultrasound-guided transversus abdominis plane block [UTAPB], laparoscopic guided transversus abdominis plane block [LTAPB], and laparoscopic intraperitoneal instillation [IPIN] of local anesthetic [LA] for pediatrics undergoing laparoscopic inguinal hernia repair [LIHR].

Patients and Methods: This randomized trial included 66 pediatrics aged between two months and seven years and planned for LIHR. They were divided into three equal groups: a control group received UTAPB, a second group received LTAPB, and a third group received IPIN of LA into the peritoneal cavity. Each block was administered using a standardized dose of 1 ml/kg bupivacaine 0.25% with 20 mL maximum volume. The primary outcome was pethidine consumption in the first 24 hours after surgery.

Results: UTAPB and LTAPB groups had significantly lower total pethidine consumption compared to the IPIN of LA group [$p < 0.001$], with a significantly longer time to first rescue analgesia [$p < 0.001$]. Pain scores at 2, 4, and 6 hours after surgery were significantly lower in the UTAPB and LTAPB groups than in the IPIN of LA group [$p < 0.05$]. No significant variances were noted in postoperative pain scores, time to rescue analgesia, and overall pethidine consumption between the UTAPB and LTAPB groups.

Conclusion: In children undergoing LIHR, both UTAPB and LTAPB were found to be more effective than IPIN of LA in decreasing pain scores, delaying the need for rescue analgesia, and decreasing overall opioid use during the initial 24 hours after operation, with comparable analgesic effect between UTAPB and LTAPB.

Keywords: Inguinal Hernia; Laparoscopic; Intraperitoneal Instillation; Pediatric; Transversus Abdominis Plane Block.

INTRODUCTION

Significant discomfort and pain post repairing surgeries of inguinal hernia are often reported in surgical units concerning pediatrics, considering the fact that these procedures are quite common. The abdominal wall incision pain arises from nerves coursing through the transversus abdominis plane [TAP] between transversus abdominis and internal oblique muscles [1].

Analgesics such as non-steroidal anti-inflammatory drugs [NSAIDs], opioids, local wound infiltration, and nerve blocks are utilized to treat pain in a multimodal fashion following inguinal hernia surgery. Parental satisfaction, psychological distress, and recovery are all positively impacted by effective analgesia following operation [2].

One regional anesthetic method that blocks abdominal neuronal afferents is the ultrasound-guided transversus abdominis plane block [UTAPB] [3, 4]. In operations related to the lower abdomen, it has shown to be a trustworthy and efficient method of handling pain following surgery [5]. The ultrasound guidance has made it possible to put needles with more accuracy than before to ensure accurate targeting of the TAP [6].

The laparoscopic-guided transversus abdominis plane block [LTAPB] precisely injects anesthetic under visual guidance camera, improving accuracy over ultrasonography technique [7].

Intraperitoneal instillation [IPIN] of local anesthetic [LA] was recently suggested as a viable alternative for managing pain following laparoscopic surgery; it led to lower postoperative pain scores and rare serious adverse effects, but this technique is not used widely in pediatrics [8, 9].

The aim of this study was to compare the analgesic profile of LTAPB, UTAPB and laparoscopic IPIN of LA in pediatric laparoscopic inguinal hernia repair [LIHR]. The primary outcome was the first day's pethidine consumption. The secondary outcomes were postoperative pain scores, time to the first analgesic request, and side effects.

PATIENTS AND METHODS

A double-blind, controlled study with a random design was performed on 66 children, with ages ranging from two months to seven years of both genders, with American Society of Anesthesiologists [ASA] physical status I and II planned for elective LIHR. After receiving ethical approval from the Ethical Review Board of Tanta University Hospitals, Egypt [approval code: 36264PR352/9/23] and registering the study on clinicaltrials.gov [registration number: NCT06098105], the research was conducted from October 2023 to April 2024. Prior to enrollment, the legal guardians of all participating pediatric patients provided written informed consent.

Exclusion criteria were a history of allergies to local anesthetics, hepatic or renal dysfunction, prior inguinal surgery, or contraindications to regional nerve blocks [sacral structure anomalies, conditions causing excessive bleeding, or infection surrounding the injection].

Randomization and blindness:

A computer-generated randomization process allocated participants in a 1:1:1 ratio to three parallel groups. Group UTAPB [as an active control group], group LTAPB, and group IPIN of LA. Parents didn't know the group assignment of their kids. An anesthetist who had no further role in intraoperative anesthetic management or postoperative evaluation of the study outcomes performed the UTAPB on all patients in this group. Two skilled surgeons performed the operations and applied both LTAPB and laparoscopic IPIN of LA after gas insufflation. The surgeons had no role in outcomes assessment. The intraoperative data such as hypotension and/or bradycardia were recorded by an investigator who was not allowed to know the type of the block given. Also, postoperative outcomes were evaluated and recorded by an anesthetist who was blinded to the group assignment and didn't have any role in intraoperative anesthetic management.

Before group allocation, all participants underwent a comprehensive evaluation, which included medical history, clinical examination, and laboratory investigation.

Standard ASA monitoring, which included pulse oximetry, electrocardiogram [ECG], non-invasive arterial blood pressure [NIBP], capnography, and temperature probe was applied for intraoperative monitoring.

Anesthesia was induced via inhalation of 4-6% sevoflurane in 100% oxygen delivered through a facemask. Following the loss of consciousness, sevoflurane concentration was reduced to 2-3% to facilitate intravenous cannula placement. Endotracheal intubation [ETT] was performed based on the child's age after giving IV 0.25mg/kg atracurium. The blocks were performed using an aseptic technique using 1 ml/kg of 0.25% bupivacaine with a maximum amount of 20 mL.

UTAPB:

After positioning the linear high-frequency ultrasound probe transversely midway between the iliac crest and costal border, the anterolateral abdominal wall was investigated. Under ultrasonographic guidance, the transversus abdominis, internal obliques, and external obliques muscles were located. Lateral tracing of the fascial planes helped identify structures by moving the probe towards the rectus sheath. Inserting a needle anteriorly and guiding it into the fascial plane among the internal oblique, and transversus abdominis muscles as well, with the tip of the needle at the mid-axillary line, was done using an in-plane approach. When the aspiration was negative, to ensure that the needle was positioned correctly, 1 ml of saline was injected. Then, 0.5ml/kg of 0.25% bupivacaine was given on each side [total 1 ml/kg with a maximum amount of 20 mL].

LTAPB:

Under direct visual guidance of a laparoscopic camera after insufflation, the surgeon inserted a needle midway between the iliac crest and costal margin at the mid-axillary line on either side until experiencing a distinct "pop" sensation. The correct placement was verified by observing the internal bulge sign described by Doyle, which manifests as an inward protrusion of the transversus abdominis muscle and peritoneum upon injection of the LA solution

[0.5ml/kg of 0.25% bupivacaine in each side with a maximum amount of 20 mL] [10].

LAP-assisted IPIN:

Pneumoperitoneum was established using non-humidified and non-heated carbon dioxide [CO_2] with an intra-abdominal pressure maintained around 10-12 mmHg. After the initial CO_2 insufflation, LA [1 ml/kg 0.25% bupivacaine with a maximum amount of 20 mL] was instilled towards the undersurface of the diaphragm via the umbilical port.

Following surgical completion, sevoflurane administration was stopped. Then the ETT was removed after reversal of muscle relaxant, and the patients were transferred to the post-anesthesia care unit [PACU].

Pain after the operation was evaluated at specific intervals: 30 minutes after surgery and subsequently at 2, 4, 6, 12, 18, and 24 hours using the Face, Legs, Activity, Cry, Consolability [FLACC] scale [11], ranging from 0 [indicating no pain] to 10 [representing the worst possible pain]. Routine analgesia on the first day for all patients consisted of IV paracetamol [15 mg/kg] every 8 hours. In cases where the FLACC score exceeded 3, rescue analgesia was provided with pethidine [0.5 mg/kg]. The pethidine dose was calculated on body weight and was only given for FLACC scores > 3, which reflected moderate to severe pain intensity. The time of first rescue analgesia and the total pethidine consumption in 1st 24h postoperative were documented.

Adverse events were carefully monitored and addressed: hypotension was treated through intravenous fluid administration; bradycardia was managed with 0.01-0.02 mg/kg atropine IV, and respiratory depression [an SpO_2 level below 92% requiring oxygen supplementation].

The study's primary outcome was the cumulative pethidine consumption during the initial 24-hour period following the surgical procedure. Secondary outcome measures encompassed post-operative pain assessments, the elapsed time before requiring rescue analgesia, and the incidence of adverse events.

Sample Size Calculation:

The determination of the required sample size was carried out using the G*Power 3.1.9.2 software application developed by the University of Kiel, Germany. A pilot study was conducted, enrolling five patients per group, and revealed a mean [± SD] total pethidine consumption within the first 24 hours postoperatively of 9.4 ± 4.35 mg in Group UTAPB, 10.5 ± 4.64 mg in Group LTAPB, and 14.8 ± 3.83 mg in Group IPIN. Based on these pilot results, a sample size of 19 patients per group was determined, considering an effect size of 0.546, a group ratio of 1:1:1, a 95% confidence limit, and 95% power. To account for potential participant dropout, an additional three patients were recruited for each group, leading to a total of 22 individuals for each group as the sample size.

Statistical analysis:

The statistical analyses were conducted using SPSS version 27 software [IBM©, Chicago, IL, USA]. The normality of the data distribution was evaluated through Shapiro-Wilk tests and visual inspection of histograms. Normally distributed continuous variables were presented as mean ± standard deviation, and comparisons were made using one-way ANOVA with the post Hoc Tukey test for pairwise comparisons. Non-normally distributed continuous variables were reported as median [interquartile range], and comparisons were made by Kruskal-Wallis test with Mann- Whitney U test for pairwise comparisons. Also, the mean difference and the median difference in certain variables between each two groups, with the corresponding 95% confidence interval [CI], were calculated for better validation of our results.

To calculate CI for the difference in means, t test was used, while the Hodges-Lehmann estimator was used to calculate the CI for the median difference in FLACC scores between each two groups. Bonferroni correction was done to obtain the adjusted [corrected] p value for multiple comparisons by multiplying the p value by the number of comparisons. So, all reported p values are corrected, and p values less than 0.05 were considered statistically significant. Categorical variables were presented as frequencies and percentages, and the Chi-square test was utilized for their analysis.

RESULTS

Out of 84 patients initially screened for eligibility, 11 were found ineligible, and seven parents declined participation. A total of 66 patients were divided into three equal groups, with 22 individuals in each. They were then monitored for data collection and subsequent statistical analysis [Figure 1].

The three groups were similar in terms of baseline demographics and surgery length [Table 1].

No significant FLACC score differences among groups at 30 min, 18 hr., and 24 hr. However, at 2, 4, and 6 hr postoperative, the UTAPB and LTAPB groups showed significantly lower FLACC scores than IPIN of LA group [$p < 0.05$]. At 12hr. after surgery, only the UTAPB group had significantly lower median FLACC score values than the IPIN of LA group, p value < 0.001 [Table 2].

The UTAPB and LTAPB groups had significantly lower total pethidine consumption compared to the IPIN of LA group [$p < 0.001$], with a significantly longer time to first rescue analgesia [$p < 0.001$]. No significant difference between UTAPB and LTAPB groups in time to first rescue analgesia and total 24-hour pethidine consumption [p= 0.462 and 0.224, respectively] [Table 3].

The occurrence of hypotensive episodes and bradycardia did not exhibit a statistically significant variation across the three study groups. Moreover, none of the participants from any of the groups developed respiratory depression [Table 4].

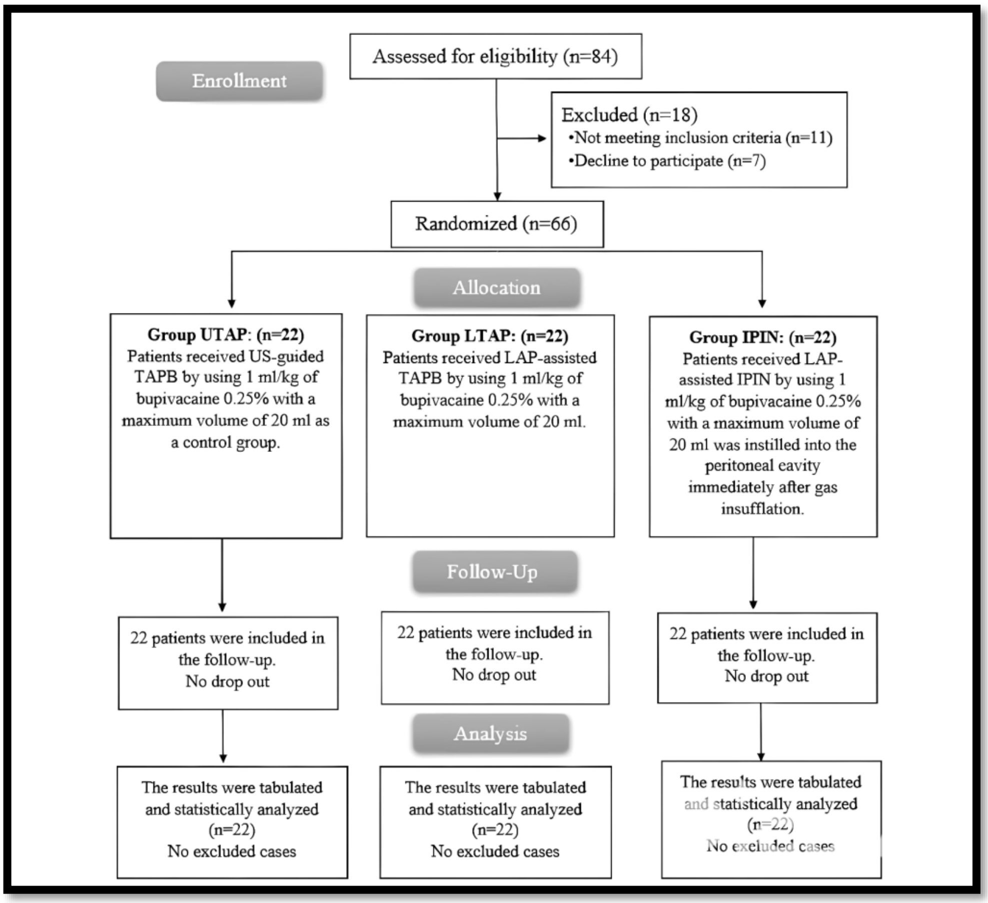

Figure [1]: CONSORT flowchart of the enrolled patients. UTAP: ultrasound transversus abdominis plane block, LTAP: Laparoscopic transversus abdominis plane block, IPIN: intraperitoneal instillation

Table [1]: Demographic data and duration of surgery of the studied groups

		Group UTAP [n=22]	Group LTAP [n=22]	Group IPIN [n=22]	P value
Age [years]		3.3 ± 1.7	3.1 ± 1.78	3.7 ± 1.86	0.497
Weight [kg]		15.7 ± 4.33	14.9 ± 4.44	16.3 ± 3.94	0.546
Sex	**Male**	20 [90.91%]	20 [90.91%]	19 [86.36%]	0.852
	Female	2 [9.09%]	2 [9.09%]	3 [13.64%]	
ASA physical state	**I**	18 [81.82%]	16 [72.73%]	17 [77.27%]	0.772
	II	4 [18.18%]	6 [27.27%]	5 [22.73%]	
Duration of surgery [min]		45.7 ± 10.5	41.6 ± 11.27	47.3 ± 10.77	0.209

Data are presented as mean ± SD or frequency [%], ASA: American society of anesthesiologists.

Table [2]: FLACC score of the studied groups

	Group UTAP [n=22]	Group LTAP [n=22]	Group IPIN [n=22]	Bonferroni test	Median difference [95%CI]
30min	0 [0 - 1]	0.5[0 - 1]	0.5 [0 - 1]		# -0.5 [-0.81: -0.19]; ## -0.5 [-0.81: -0.19]; ### 0 [-0.31: 0.31]
2h	1 [1 - 1]	1 [1 - 1.75]	2 [2 - 3]	B1=2.406; B2<0.001 B3<0.001	# 0 [-0.27: 0.27]; ## -1 [-1.85: -0.15] ### -1.25 [-2.1: -0.4]
4h	2 [1 - 3]	2 [1 - 2]	3 [2 - 4.5]	B1=1.686; B2=0.045 B3=0.009	# 0 [-0.46: 0.46]; ## -1 [-1.83: -0.17] ### -2.5 [-3.26: -1.74]
6h	2 [1 - 3]	1.5 [1 - 2]	3.5 [2 - 6]	B1=0.936; B2=0.027 B3<0.001	# 0.5 [0: 1]; ## -1.5 [-2.55: -0.45] ### -4 [-5.03: -2.97]
12h	2 [1 - 4]	3 [2.25 - 3]	3.5 [3 - 6]	B1=0.48; B2<0.001 B3=0.12	# -1 [-1.76: -0.24]; ## -1.5 [-2.46: -0.54] ### -3 [-3.8: -2.2]
18h	3 [2.25 - 4]	3 [3 - 4]	4 [3 - 5]		# 0 [-0.65: 0.65]; ## -1 [-1.74: -0.26] ### -1 [-1.65: -0.35]
24h	3 [2.25 – 4.75]	4 [3 - 5]	4 [3 - 5]		# -1 [-1.85: -0.15]; ## -1 [-1.89: -0.11]; ### 0 [-0.81: 0.81]

Data are presented as median [IQR], P1: P value between Group UTAP and Group LTAP, P2: P value between Group UTAP and Group IPIN, P3: P value between Group LTAP and Group IPIN. FLACC: Face, Legs, Activity, Cry, Consolability. # Median difference [95%CI] between Group UTAP and Group LTAP, ## Median difference [95%CI] between Group UTAP and Group IPIN, ### Median difference [95%CI] between Group LTAP and Group IPIN, B1: Bonferroni test between Group UTAP and Group LTAP, B2: Bonferroni test between Group UTAP and Group IPIN, B3: Bonferroni test between Group LTAP and Group IPIN.

Table [3]: Time of first rescue analgesia and total pethidine consumption in 1st 24h postoperative of the studied groups

	Group UTAP [n=22]	Group LTAP [n=22]	Group IPIN [n=22]	Bonferroni test	Mean difference [95%CI]
Time of first rescue analgesia [h]	10.3 ± 1.45	9.4 ± 1.56	4.2 ± 1.56	B1=0.462; B2<0.001 B3<0.001	# 0.864 [-0.24 to 1.97] ; ## 6.091 [4.99 to 7.20] ### 5.227 [4.12 to 6.33]
24h total pethidine dose [mg]	14 ± 6.12	15.4 ± 4.47	23.9 ± 7.92	B1=0.224; B2<0.001 B3<0.001	# -1.409 [-5.99 to 3.17]; ## -9.909 [-14.49 to -5.33] ### -8.500 [-13.08 to -3.92]

Data are presented as mean ± SD. P1: P value between Group UTAP and Group LTAP, P2: P value between Group UTAP and Group IPIN, P3: P value between Group LTAP and Group IPIN. # Mean difference [95%CI] between Group UTAP and Group LTAP, ## Mean difference [95%CI] between Group UTAP and Group IPIN, ### Mean difference [95%CI] between Group LTAP and Group IPIN, B1: Bonferroni test between Group UTAP and Group LTAP, B2: Bonferroni test between Group UTAP and Group IPIN, B3: Bonferroni test between Group LTAP and Group IPIN.

Table [4]: Adverse events in the studied groups

	Group UTAP [n=22]	Group LTAP [n=22]	Group IPIN [n=22]	P value
Hypotension	3 [13.64%]	5 [22.73%]	6 [27.27%]	0.530
Bradycardia	2 [9.09%]	3 [13.64%]	5 [22.73%]	0.438
Respiratory depression	0 [0%]	0 [0%]	0 [0%]	---

Data is presented as frequency [%].

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DISCUSSION

Repairing an inguinal hernia is a frequent approach in pediatric day-surgery units, but it is known to induce significant postoperative pain and discomfort [12]. Laparoscopic surgery itself can contribute to pain through several mechanisms, including incisional discomfort, stretching and inflammation of the viscera-peritoneum, and shoulder pain caused by irritation of the diaphragm from residual carbon dioxide insufflation [13].

The study results explained that both the UTAPB and LTAPB groups had considerably reduced pain ratings compared to the IPIN group at 2, 4, and 6 hours after the surgery, with a substantial delay of rescue analgesia and decreased opioid use generally on the first postoperative day. Multiple studies provide evidence for the effectiveness of UTAPB in managing pain. **Li *et al.*** [14] illustrated that UTAPB significantly reduced pain scores and lung collapse in pediatric laparoscopic surgeries. Furthermore, **Mekawy *et al.*** [15] showed that UTAPB had significantly reduced pain scores compared to caudal block in inguinal hernia repair surgery. Moreover, **Abu Elyazed *et al.*** [16] showed that UTAPB significantly reduced pain in children having elective inguinal hernia repairs performed via open surgery compared to the control group.

The present study showed that UTAPB and LTAPB groups had similar analgesic effects regarding pain intensity, time to rescue analgesia, and total opioid consumption that are corroborated by previous studies. **Sahap *et al.*** [17] reported no significant differences in opioid consumption or pain scores between UTAPB and LTAPB in patients undergoing cholecystectomy. Similarly, **Diyaolu *et al.*** [18] observed no significant differences in pain scores or time to first rescue analgesia in children receiving UTAPB or LTAPB for laparoscopic procedures. These findings suggest that both UTAPB and LTAPB may be viable options for postoperative pain management, with the choice potentially influenced by anatomical considerations or surgeon preference. Moreover, **Wong *et al.*** [19] found that there was no statistically significant difference between LTAPB and UTAPB in postoperative rescue analgesic consumption or pain levels among patients who underwent colorectal surgery. However, our findings regarding comparable analgesic efficacy between UTAPB and LTAPB differ from those reported by **Zaghiyan *et al.*** [20]. In their study, the LTAPB appeared to be more effective for pain management and reducing opioid requirements at 24 hours postoperatively. This discrepancy may be attributable to variations in study design, such as the volume of local anesthetic used or the inclusion of epinephrine in the LTAPB block compared to our protocol.

In the present study, both UTAPB and LTAPB provided superior analgesic quality compared to IPIN of LA. Supporting our findings, **Elkabarity *et al.*** [21] indicated that the UTAPB group exhibited significantly reduced pain levels and overall opioid use throughout the first 24-hour period after the surgical procedure than the IPIN group in laparoscopic hysterectomy patients. The possible reason for the inadequate effects of IPIN compared to other groups may be that local anesthetics would probably gravitate toward the posterior peritoneal wall, thus not having a significant effect on actual nerves in the peritoneum. Despite the relatively short half-life of bupivacaine [around 4 hours], the other two blocks provided prolonged analgesic effects. This could be explained by the fact that the fascial plane between the internal oblique and transversus abdominis muscles is a potential space with confined borders and low vascularity in comparison to the intraperitoneal space. This allowed direct action on the nerves with minimal systemic absorption.

Our study faced certain **limitations**, being a single-centric with a relatively modest sample size. Also, we didn't include a placebo-control group in our study from a practical point of view, and we didn't assess the local anesthetic plasma levels to know the risk of anesthetic toxicity. Moreover, pain evaluation in pediatric population is still a challenge, as the FLACC scale depends on behaviors, which makes it unable to distinguish between pain-related and non-pain-related behaviors. We recommend more research to assess the impact of different adjuvant agents, dosages, and concentrations used in these blocks, as well as to explore the efficacy of varying block techniques across other surgical procedures.

Conclusions: In children undergoing LIHR, both UTAPB and LTAPB were found to be more effective than IPIN of LA in decreasing pain scores, delaying the need for rescue analgesia, and decreasing overall opioid use, with comparable analgesic effects between UTAP and LTAP.

Financial and Non-Financial Relationships and Activities of interest: None.

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International Journal of Medical Arts

Volume 7, Issue 10 (October 2025)

http://ijma.journals.ekb.eg/

P-ISSN: 2636-4174

E-ISSN: 2682-3780