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Research Article

Ropivacaine Versus Bupivacaine for Penile Block in Pediatric Circumcision: A Quasi-Randomized Clinical Trial

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ABSTRACT

Background: Circumcision is one of the most frequently performed pediatric surgeries. Effective perioperative analgesia is essential to minimize pain, reduce stress responses, and facilitate early recovery. This study aimed to compare the analgesic efficacy, hemodynamic effects, and recovery outcomes of ropivacaine versus bupivacaine in penile nerve block among children undergoing circumcision.

Methods: In this quasi-randomized clinical trial conducted at Bahrami Children's Hospital (Tehran, Iran) from November 2024 to January 2025, 66 male children aged 3 months to 3 years (ASA I–II) scheduled for elective circumcision were consecutively enrolled. Based on sequential allocation, participants received either 0.2% ropivacaine (Group R) or 0.25% bupivacaine (Group B) at 0.2 mL/kg for dorsal penile block. Hemodynamic parameters were recorded at key perioperative time points. Pain was assessed using the FLACC scale, and recovery time and fentanyl consumption were documented.

Results: Group R demonstrated significantly lower heart rates and higher systolic blood pressure at post-induction, post-incision, and end-of-surgery time points ($p < 0.05$). The need for intraoperative fentanyl was lower in group B (24.2% vs. 66.7%, $p < 0.001$), while postoperative FLACC scores were lower in Group R ($p = 0.024$). Recovery time was significantly shorter in the ropivacaine group ($p < 0.001$). No adverse events occurred.

Conclusion: Both drugs (ropivacaine and bupivacaine) were safe and effective. Ropivacaine provided better analgesia and faster postoperative recovery, while bupivacaine reduced intraoperative opioid use. These findings suggest that drugs should be selected based on individual clinical preferences.

Introduction

Due to cultural norms and medical indications, circumcision is one of the most frequently performed minor surgical procedures in pediatric practice, especially in Muslim-majority populations in the Middle East and certain global healthcare settings [1]. In order to minimize postoperative pain, lessen stress-related hormonal reactions, and promote early mobilization in this population, it is critical to provide effective perioperative analgesia [2]. Long-term effects, such as increased nociceptive sensitivity and possible

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effects on neurodevelopment, have also been linked to inadequate pain management during infancy [3].

For analgesia during penile surgeries, peripheral nerve blocks, particularly penile blocks, offer a targeted, efficient, and generally safe method [4]. Penile blocks are especially appealing in short ambulatory procedures because they are less invasive, have fewer systemic effects, and maintain motor function when compared to caudal epidural techniques [5]. Penile nerve blocks also lower the risk of hemodynamic instability and widespread sympathetic blockade in infants and toddlers due to their anatomical specificity [6].

Long-acting amide-type local anesthetics like ropivacaine and bupivacaine are frequently used in pediatric regional anesthesia. Both substances work by reversibly blocking sodium channels in nerve membranes, which prevents sensory transmission and action potential propagation [7].

Due to its immature hepatic metabolism and decreased plasma protein binding, bupivacaine, traditionally regarded as the gold standard for regional blocks, carries a higher risk of cardiotoxicity and neurotoxicity, especially in neonates and infants [8-9]. A more recent enantiomerically pure drug called ropivacaine was created to offer a similar sensory blockade with a better safety profile [10].

Compared to bupivacaine, ropivacaine exhibits lower affinity for myocardial sodium channels and decreased lipid solubility, which results in a lower risk of harmful cardiovascular events like arrhythmias and hypotension [11]. According to a number of studies, ropivacaine has a comparable or marginally shorter analgesic duration than bupivacaine, but it also has less motor blockade and more stable hemodynamic parameters [12-14].

Such hemodynamic stability is clinically significant in pediatric populations, particularly in infants undergoing circumcision, because this age group is more sensitive to changes in autonomic tone and systemic vascular resistance [15].

Even though both agents are being used more frequently in pediatric regional blocks, there is still little and conflicting research on their relative safety and effectiveness in the context of penile block. Few studies have solely examined the use of ropivacaine and bupivacaine in penile nerve blocks for circumcision, an area of significant clinical significance given the procedure's frequency and the need for the best possible pain management in preverbal children [16]. However, some have assessed these drugs in caudal or peripheral blocks for lower abdominal surgeries. Furthermore, there are few studies that specifically evaluate postoperative pain profiles and perioperative hemodynamic changes over long periods of time (up to 24 hours) in this population.

Consequently, the current study sought to evaluate the analgesic efficacy and hemodynamic outcomes of ropivacaine compared to bupivacaine in penile block for infants and toddlers undergoing elective circumcision. This study employs a quasi-randomized design and integrates validated pain assessment and hemodynamic monitoring at various perioperative intervals to furnish evidence for anesthetic selection in pediatric minor urologic surgeries.

Methods

Design and setting

This quasi-randomized clinical trial was conducted at Bahrami Children's Hospital, Tehran, from November 1, 2024, to January 31, 2025. The study employed a quasi-experimental allocation approach, in which participants were enrolled using a consecutive sampling and numbered sequentially from 1 to 66 upon admission to the operating room. Based on this numerical order, those with odd numbers received ropivacaine, and those with even numbers received bupivacaine, resulting in an alternating, non-randomized allocation pattern. Anesthesia management and data collection were integrated into routine clinical care without interference from the research team. Outcome assessments were conducted prospectively, from the time of penile block administration until transfer from the recovery room.

Participants and Sample Size

Sixty-six male children, aged 3 months to 3 years, classified as American Society of Anesthesiologists (ASA) physical status I or II, and scheduled for elective circumcision surgery under general anesthesia with a penile block, were enrolled consecutively. Informed written consent was obtained from the parents or legal guardians after a thorough explanation of the study protocol.

Eligible participants were those without any history of hypersensitivity to amide-type local anesthetics, without congenital genitourinary anomalies, and free from significant systemic diseases. A priori power analysis was used to determine the sample size, which resulted in 33 patients per group, assuming a medium effect size (Cohen's $d = 0.5$), $\alpha = 0.05$, and power = 0.8.

Based on their numerical order of enrollment, participants were divided into two groups:

- Group B (n = 33): 0.2 mL/kg of 0.25% bupivacaine (without epinephrine) was administered.
- Group R (n = 33): 0.2 mL/kg of 0.2% ropivacaine (without epinephrine) was administered.

A skilled pediatric anesthesiologist used a 23G short-bevel needle to perform all blocks under sterile conditions after intravenous induction of anesthesia with 8% sevoflurane (via Mapleson F circuit), propofol (2 mg/kg), and laryngeal mask airway (LMA) insertion.

Throughout the process, isoflurane in oxygen was used to maintain anesthesia. All 66 participants completed the study and were included in the final analysis.

Instruments

Pain was measured at 1, 4, 8, and 24 hours after the block using the Face, Legs, Activity, Cry, Consolability (FLACC) scale (0–10) [17].

Using calibrated multiparameter monitors, heart rate (HR), peripheral oxygen saturation (SpO_2), systolic and diastolic blood pressure (SBP and DBP), and post-induction, post-incision, end of surgery, and every 15 minutes during recovery were measured.

Trained observers who were blind to group assignment recorded all pain and hemodynamic assessments. If FLACC scores were higher than 4, rescue analgesia with intravenous fentanyl (1 µg/kg) was given. The total fentanyl consumption and time to emergence were also documented.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA). Normality of data distribution was tested using the Shapiro–Wilk test. Continuous variables were analyzed with an independent-samples t-test or Mann–Whitney U test, as appropriate.

Repeated measures ANOVA with Greenhouse–Geisser correction was used to evaluate intra-group changes over time. Categorical variables were compared using the chi-square test or Fisher's exact test. Missing data were handled using the last observation carried forward (LOCF) approach. Statistical significance was defined as a P value < 0.05.

Ethical Considerations

This research has an ethics confirmation from the Tehran University of Medical Sciences ethics committee, with the code IR.TUMS.SPH.REC.1403.295. The study adhered to the Declaration of Helsinki. Written informed consent was obtained from parents or legal guardians.

Results

Demographic and baseline characteristics of the 66 enrolled patients are summarized in (Table 1). There were no significant differences between Group B (Bupivacaine) and Group R (Ropivacaine) in mean age (1.52 ± 0.66 vs. 3.55 ± 2.22 years, respectively; $p = 0.082$) or weight (9.85 ± 3.38 vs. 15.97 ± 8.93 kg; $p = 0.094$) (Table 1). Hemodynamic outcomes are detailed in (Table 2) and illustrated in (Figure 1,2). While systolic blood pressure was consistently higher in Group R at these intervals ($p < 0.05$), Group R showed significantly lower heart rates post-induction, post-incision, and at the end of surgery when compared to Group B ($p < 0.01$) (Table 2, Figure 1). Throughout the perioperative period, the groups' diastolic blood pressure and SpO_2 stayed similar. Intraoperative fentanyl requirement was significantly lower in Group B than in Group R (24.2% vs. 66.7%; $p < 0.001$). Analgesic requirements in the recovery unit were not significantly different (Group B 9.1% vs. Group R 0%; $p = 0.078$). When the FLACC scale was used to measure postoperative pain one hour after the block, Group R scored lower than Group B (1.12 ± 0.33 vs. 1.55 ± 1.00; $p = 0.024$) (Table 3). Additionally, recovery time was significantly shorter for the ropivacaine cohort (23.48 ± 6.31 min vs. 30.00 ± 0.00 min; $p < 0.001$) (Table 3). No major adverse events were observed in either group, underscoring the favorable safety profiles of both anesthetics.

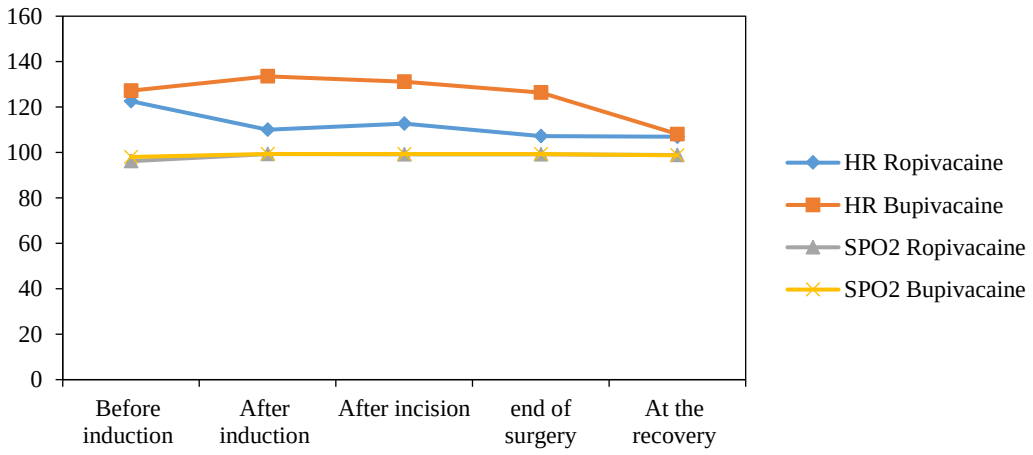

Figure 1- Trend lines between groups for heart rate and SpO_2 over predefined time points

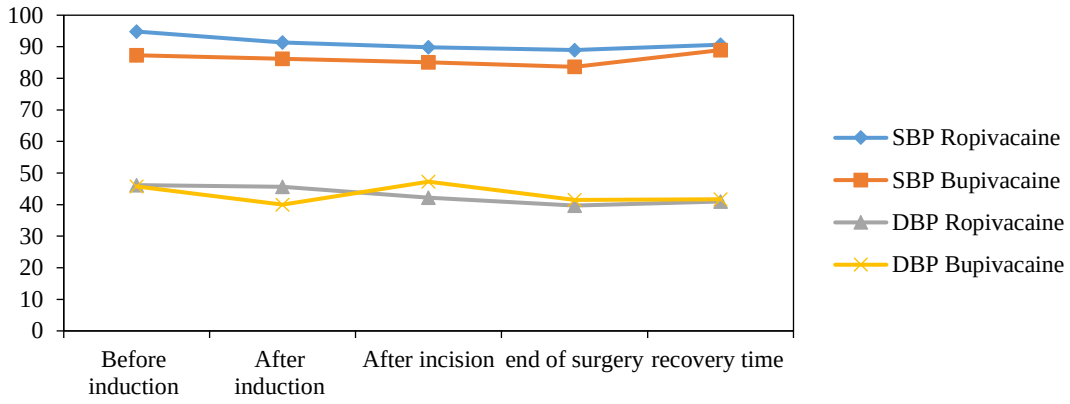

Figure 2- Trend lines between groups for SBP and DBP over predefined time points

Table 1- parameters and socio-demographic findings in the results of two groups

Patient Characteristics	Ropivacaine (n=33) Mean± SD	Bupivacaine (n=33) Mean± SD
Age	3.55 ± 2.22	1.52± 0.66
Weight	15.97 ± 8.93	9.85 ± 3.38
ASA (I/II)	(27/6) (81.8% / 18.2%)	(30/3) (90.9% / 9.1%)

Table 2- The variables of Ropivacaine and Bupivacaine at the different time

Groups type		Ropivacaine (n=33) Mean± SD	Bupivacaine (n=33) Mean± SD	P value
Pre induction	HR	122.58±17.02	127.28±12.92	0.812
	SBP	84.82±13.95	87.27±4.52	0.095
	DBP	46.18±12.05	45.76±11.46	0.881
	SPO_2	98.18±15.50	98.03±1.07	0.493
Post induction	HR	110.09±16.89	133.52±10.93	0.000
	SBP	91.36±12.37	86.18±4.77	0.028
	DBP	45.64±13.03	40.00±10.60	0.073
	SPO_2	99.30±0.81	99.36±0.82	0.764
Postsurgical incision	HR	112.73±18.97	131.09±9.89	0.000
	SBP	89.88±10.14	85.06±4.99	0.017
	DBP	42.18±10.91	47.27±7.61	0.032
	SPO_2	99.18±1.04	99.00±0.36	0.753
At the end of surgery	HR	107.18±13.06	126.42±10.75	0.006
	SBP	88.97±7.85	83.64±4.88	0.002
	DBP	39.70±8.96	41.52±6.18	0.341
	SPO_2	99.15±0.90	99.27±0.91	0.590
At the recovery time	HR	106.94±14.11	108.12±9.06	0.352
	SBP	90.61±9.82	88.94±4.96	0.189
	DBP	40.94±9.01	41.67±12.16	0.468
	SPO_2	98.85±0.87	98.70±0.98	0.510

Table 3- FLACC score with the Recovery time variables between the Ropivacaine and Bupivacaine groups

Patient Characteristics	Ropivacaine (n=33) Mean± SD	Bupivacaine (n=33) Mean± SD	P value
FLACC score	1.12 ± 0.331	1.55± 1.00	0.024
Recovery time	23.48 ± 6.31	30.00 ± 0.00	0.000

Discussion

This quasi-randomized clinical trial demonstrated that while both ropivacaine and bupivacaine provided effective and safe anesthesia for pediatric penile block, ropivacaine was associated with greater hemodynamic stability, lower postoperative pain scores, and shorter recovery time, whereas bupivacaine resulted in reduced intraoperative opioid requirements. Indeed, pediatric regional anesthesia trials generally report similar hemodynamic stability with both amide agents. For example, Chipde et al. found virtually no difference in

heart rate or blood pressure in children receiving caudal ropivacaine versus bupivacaine [18].

Similarly, a recent pediatric caudal study noted that neither group experienced significant hypotension or bradycardia, and oxygen saturation remained >97% throughout [19]. These findings align with systematic reviews concluding that long-acting local anesthetics (ropivacaine, bupivacaine, and levobupivacaine) are equivalent in clinical efficacy for pediatric analgesia, while ropivacaine tends to have the lowest cardiotoxicity profile [10,20]. In our trial, the slightly higher systolic pressure with ropivacaine may reflect its reduced vasodilatory effect, consistent with its lower lipophilicity and less negative inotropic action.

Crucially, there was no clinical instability resulting from these slight variations in SBP and HR. Overall, both local anesthetics gave children under anesthesia outstanding hemodynamic stability, supporting the idea that ropivacaine is a safer option with less cardiovascular depression.

Ropivacaine provided superior postoperative analgesia, as evidenced by significantly lower FLACC scores at one hour, even though intraoperative fentanyl use was lower in the bupivacaine group, possibly because of its quicker onset. These results are consistent with earlier pediatric research showing comparable or marginally longer-lasting ropivacaine-induced pain relief [10].

Furthermore, ropivacaine's reduced propensity for motor block, which promotes faster emergence and discharge readiness, is probably the reason for its shorter recovery time. Overall, both medications offered sufficient analgesia, with ropivacaine exhibiting benefits in terms of comfort and quick recovery.

Despite the fact that this study's conclusions are clinically applicable and grounded in sound methodology, some limitations should be taken into account. Generalizability may be limited by the study's small sample size and quasi-randomized design.

Other restrictions include assessor blinding and the absence of pharmacokinetic data. To confirm these results and investigate the effects of adjuncts or different concentrations on block quality and duration, more randomized controlled trials with larger cohorts and stratified age groups are required.

Conclusion

Ropivacaine and bupivacaine provided both effective analgesia and hemodynamic stability in children undergoing penile block. Both drugs were safe and effective. Ropivacaine provided better analgesia and faster postoperative recovery, while bupivacaine reduced intraoperative opioid use. These findings suggest that drugs should be selected based on individual clinical preferences.

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