Ring block with levobupivacaine 0.25% and paracetamol vs. paracetamol alone in children submitted to three different surgical techniques of circumcision: A prospective randomized study

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ABSTRACT

Background: circumcision in children is a painful procedure. We aim compare the intraoperative and postoperative efficacy of three different surgical procedures of the ring block using levobupivacaine 0.25% combined with rectal paracetamol as opposed to rectal paracetamol alone. **Methods:** the study included 106 boys scheduled to undergo circumcision. The patients were randomly assigned within two groups to receive either ring block with levobupivacaine 0.25% and rectal paracetamol 30 mg/kg, or rectal paracetamol 30 mg/kg alone. The following surgical procedures were performed: sutureless proctoplasty, preputial plasty, and conventional circumcision. The efficacy of intraoperative analgesia was estimated on the basis of increases in heart rate and mean arterial pressure. Postoperatively, children were assessed for pain, pain-free (PF) period, and the total doses of analgesics administered during hospitalization, on the day after discharge, and on the first and second postoperative days. **Results:** all children remained stable during anesthesia. Postoperatively, the mean pain score did not show statistical differences between the groups. Children who received combined analgesia had a longer PF period ($P < 0.001$). However, the total doses of paracetamol administered during the observational period showed no differences. Children undergoing sutureless prepuceplasty received lower doses of paracetamol postoperatively ($P < 0.001$). **Conclusion:** subcutaneous ring block either with levobupivacaine 0.25% plus rectal paracetamol or rectal paracetamol alone provides adequate intraoperative and postoperative analgesia in circumcised children. However, combined analgesia allows a longer PF period. The need for less analgesic administration in children undergoing sutureless prepuceplasty could mean that the circumcision techniques might be a mitigating factor in terms of pain.

Key words: *Circumcision, levobupivacaine, paracetamol*

INTRODUCTION

Male conventional circumcision (CC) is one of the oldest and commonest operations in the male child.[1] Although simple and easy to perform, it is associated with considerable pain[2] and carries the risk of complications such as bleeding, sepsis, urethrocutaneous fistula, meatal stenosis, and other less common complications.[3]

The traditional modalities of pain control in CC rely on strategies provided either by topical analgesics[4] or systemic administration of nonsteroidal anti-inflammatory drugs such as paracetamol, and opioid analgesics.[2] However, over the past few decades, the use of local anesthetic techniques has become an important tool in pain management throughout the perioperative period. Such techniques include caudal epidural block,[5] dorsal penile nerve block (DPNB) with or without ultrasound guidance, subpubic penile block,[6] subcutaneous ring block (SCRB),[7] and pudendal nerve block.[8] These techniques have diminished the need for opioid analgesics and prolonged the pain-free (PF) postoperative period.

Access this article online	
Quick Response Code:	Website: www.saudija.org
	DOI: 10.4103/1658-354X.125936

However, trials and studies in the literature have yet to determine the optimal analgesic method.[9]

Surgical alternative techniques of CC, such as wound closure with tissue glue[10] and prepuceplasty techniques,[11,12] have been proposed to reduce morbidity associated with complications of CC, some of these techniques have been found to be less painful.[10,12]

In this prospective randomized study, we evaluated the intraoperative and postoperative efficacy of combined analgesia provided by SCRB with levobupivacaine 0.25% in conjunction with paracetamol, against analgesia provided by paracetamol alone, in children submitted to three different surgical techniques of circumcision. We hypothesized that combined analgesia would have better results than those presented by a single intervention. Furthermore, we investigated the impact of each surgical technique on postoperative pain.

METHODS

Having obtained hospital ethical committee approval and parental consent, we enrolled 106 ASA Grade I-II boys in the study, all of whom were scheduled for elective circumcision (ages ranging from 2 to12 years). Exclusion criteria included a severe systemic disease, neurological and bleeding diseases, and a previous unsuccessful circumcision.

No premedication was given to the children. General anesthesia was induced with atropine 0.01 mg/kg, propofol 3 mg/kg, and fentanyl 1 mg/kg intravenously. Rocuronium, 0.8 mg/kg, was used as required to facilitate a laryngeal mask of the appropriate size to be put in place. Anesthesia was maintained with sevoflurane and O_2/N_2O. During anesthesia, children were monitored for mean arterial pressure (MAP), heart rate (HR), peripheral oxygen saturation (SPO_2), and capnography.

Following induction of anesthesia and before the start of surgery, the children were randomized into two groups, by the closed-envelope technique. Group A (53 patients) received SCRB with 0.25% levobupivacaine (0.5% levobupivacaine diluted in normal saline, Chirocaine®, Abbott Laboratories, Ltd) with a dose of 0.1 ml/kg (total dose 0.5 mg/kg) injected around the base of the penis[7] plus rectal paracetamol of 30 mg/kg; group B (53 patients, control group) received a paracetamol suppository of 30 mg/kg.

One of the following surgical techniques of circumcision was performed: sutureless prepuceplasty (SPP),[11] preputial plasty (PP),[12] and CC. The SPP technique was carried out by cutting the phimotic ring in its dorsal surface longitudinally. The wound was covered with a steroid cream and left to heal in a second intention without sutures. The PP was performed by a dorsal incision in the phimotic prepuce with transverse skin closure of the wound. The CC was carried out by excision of the foreskin with a scalpel, a clamp, hemostasis with bipolar diathermy, and re-approximation of the skin edges. Vicryl®, 4/0 Rapid, ETHICON was used for wound closure in the PP and CC techniques. At the end of surgery, all wounds were covered with petroleum gauze, which was removed after the first passage of urine.

Intraoperative protocol

The efficacy of intraoperative analgesia was estimated on the basis of gross movements or changes in HR and MAP, after surgery stimulus. Increases ≥20% of the first values were documented and considered as signs of inadequate analgesia. At the end of surgery, the children were transferred to the recovery room (RR). The duration of anesthesia, surgery, and the administration of any supplemental analgesia was recorded.

Postoperative protocol

The time from the termination of general anesthesia to the time the children had the first analgesic administration was defined as the pain-free (PF) period.

In the RR, the children were observed by a nurse (ST) blinded to which groups the children belonged to and the surgical technique in question, for the following: Pain scores, need for analgesia, post-anesthetic, and surgical complications. The behavioral FLACC Pain Scale was used to assess postoperative pain [Table 1].[13] Values ≥5 were considered as an indication for intravenous tramadol (1 mg/kg) administration. To avoid misinterpretations, the pain score was evaluated after the children were able to communicate. All doses of supplemental analgesia were recorded. The time from the children's transfer to the RR up to the time they were fully awake and ready to be taken on to the ward was defined as RR stay (RRS) and was recorded accordingly.

Once on the ward, the children were observed for six hours for pain, post-anesthetic, and post-surgical complications. FLACC pain score was recorded on admission, and every 60 minutes thereafter by an independent observer (DS). Any supplemental analgesic administration (oral or rectal paracetamol 20 mg/kg) was recorded. Patients were discharged when they had stable vital signs, could tolerate oral fluids, and had passed urine. The time up to discharge was recorded, and defined as Ward Stay (WS). The parents were instructed to record the total doses of analgesics (paracetamol 20 mg/kg orally or per rectum) on the day after discharge and the first and second postoperative day. Email or telephone

Table 1: The FLACC pain scale

	Scoring		
Categories	**0**	**1**	**2**
Face	No particular expression or smile	Occasional grimace or frown, withdrawn disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaint
Consol ability	Content, relaxed	Reassured by occasional touching, hugging or talking to, dissuactible	Difficulty to consol or comfort

communication with parents was undertaken by one of the contributors of the study (NZ).

Data collection

The following data were collected: (a) patients' demographics, that is, age, weight, the group to which they were assigned, the HR, and MAP intraoperatively, the type of the surgical technique performed, the mean duration of anesthesia and surgery and any supplemental analgesic administration given under general anesthesia; (b) the mean RRS and WS; (c) the observed values of FLACC pain score during RRS and WS; (d) the mean PF period between groups and surgical techniques; (e) the total doses of paracetamol given on the ward, on the day of surgery after discharge, and on the first and second postoperative days; and (f) complications due to general anesthesia, levobupivacaine, SCRB, and surgery.

Statistical analysis

The statistical analysis was performed with the SPSS, version 12.00 (SPSS Inc, Chicago, IL). Categorical data were presented as mean ± SD, as indicated. Comparisons between the two study groups and surgical techniques were performed using the T-independent test for independent samples, the Chi-Square test, and one-way ANOVA, as appropriate. The results were considered to be statistically significant, when the *p*-value was greater than 0.05.

RESULTS

The mean age of patients was 6.9 ± 2.6 years (range 2-14 years). There was a normal distribution of age and weight between groups [Table 2]. Thirty nine (36.8%) patients underwent SPP, 34 (32.1%) PP, and 33 (31.1%) CC. The mean duration of anesthesia (Group A: 27.02 ± 1.1 min, group B: 26.6 ± 1.2 min, respectively) and surgery (Group A: 18.74 ± 1.24 min, Group B: 18.32 ± 1.25 min, respectively) between groups was almost equal. During anesthesia, the vital signs of children of both groups were stable, without an increase in HR and MAP ≥20% of the initial values. The intraoperative findings are shown in Table 2. There were no statistical differences between groups regarding the mean RRS (32.9 ± 1.4 min and 35.7 ± 1.1 min, respectively), and the mean FLACC pain score in the RR (0.87 ± 0.75 and 1.19 ± 0.63 respectively). No supplemental analgesia was administered.

Table 2: Patients characteristics and intraoperative data. The data are expressed as mean±SD, and numbers

Variable	Group A	Group B	*P* value
Number of patients	53	53	NS*
Age (yrs)	7.15 ± 2.47	6.43 ± 2.27	NS
Weight	25.6 ± 0.6	7.6 ± 2.25	NS
HR (bpm)	75.0 ± 8.37	74.6 ± 9.19	NS
MAP (mmHg)	70.2 ± 5.07	68.2 ± 5.73	NS
SPO_2 (%)	98.2 ± 0.81	97.72 ± 0.72	NS
Surgical technique			
SPP**	21	18	NS
PP†	16	18	NS
CC‡	16	17	NS
Duration of anesthesia (min)	27.02 ± 1.1	26.6 ± 1.2	NS
Operating time (min)	18.74 ± 1.24	18.32 ± 1.25	NS

NS*: Nonstatistical significant, SPP**: Sutureless prepuceplasty, PP†:Preputial plasty, CC‡: Conventional circumcision

The mean duration of WS did not show statistical differences between the two groups (Group A: 7.05 ± 0.65 h and Group B: 6.88 ± 0.64 h, respectively) [Table 3]. The mean FLACC pain score in the ward patients of group A was lower than that recorded for group B, although without statistical significance: 3.45 ± 0.94 (range 2-6) and 3.63 ± 2.02 (range 3-7), respectively. The combined treatment group had a longer PF period than controls (5.47 ± 0.5 h vs. 4.47 ± 0.66 h, $P < 0.001$). Twenty-seven (51%) patients from Group A and 25 (47.1%) from Group B did not report supplemental analgesia during WS. In

Table 3: Primary postoperative outcome findings. The data are expressed as mean±SD, range, and numbers

Variable	Group A (n:53)	Group B (n:53)	*P* value
RR*			
Mean RR stay (min)	32.45±4.34 (25-40)	34.06±4.81 (25-45)	NS
Mean FLACC pain score	1.55±1.10 (0-3)	1.74±0.78 (0-4)	NS
Fentanyl administration	0/53 pts	0/53 pts	NS
WS**			
Mean WS (h)	6.19±0.0.39 (6-7)	6.28±0.46 (6-7)	NS
Total mean FLACC pain score	3.45±0.94 (range 2-6)	3.63±2.02 (range 3-7)	NS
Pain-free period (h)	5.47±0.5 (5-6)	4.47±0.66 (4.6)	<0.001
Patients receiving paracetamol			
-In the Ward			
One dose	26(53)	28(53)	NS
-On the day after discharge			
One dose	4(53)	6(53)	NS
Two doses	1(53)	1/53	NS
- first postoperative day			
One dose	1(53)	1(53)	NS
- second postoperative day			
One dose	0(53)	1(53)	NS
Total	33	38	NS

*Recovery Room, **Ward Stay

Group A, the first analgesic administration was noted at 5 h (17 patients), and in Group B at 4 h (9 patients). Notably, the longer PF period was observed in patients submitted to the SPP technique (5.18 ± 0.56 h vs. 4.81 ± 0.52 h and 4.5 ± 0.56 h of PP and CC techniques, (*P*:0.006, and $P < 0.001$, respectively), irrespective of the group [Figure 1].

The total dose of paracetamol during WS, on the day after discharge, and on the first and second postoperative days, showed no statistical differences between the groups [Table 3]. It is worth noting that children undergoing SPP received a lower total dose of paracetamol as compared to those submitted the other two techniques ($P < 0.001$) [Table 4].

Levobupivacaine was well tolerated by the children in this study. Postoperative nausea and vomiting (PONV) affected 4 (7.5%) patients in Group A and 2 (3.8%) in Group B. Two patients (3.8%) in

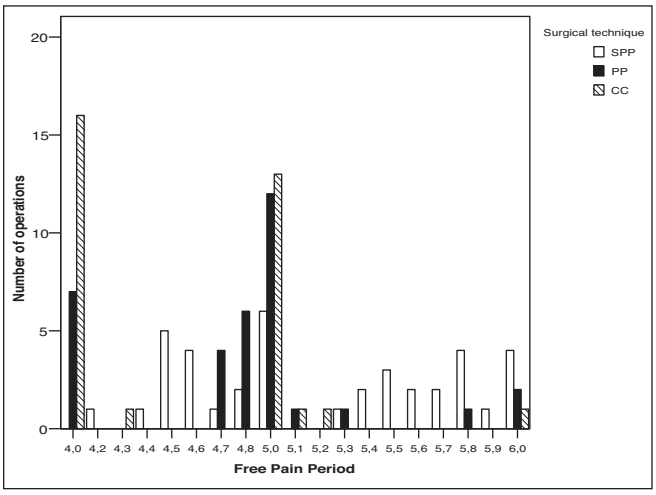

Figure 1: Pain-free period between patients submitted to SPP, PP, and CC

Table 4: Total doses of postoperatively administered paracetamol between surgical techniques

Variable	Surgical technique				
Total dose of paracetamol	SPP	PP	CC	Total	*P* value
None	32	14	6	52	
One dose	7	20	25	52	<0.001
Two doses	0	0	2	2	
Total	39	34	33	106	

Group A showed insignificant edema in the region of the SCRB. Circumcision complications included mild oozing noted in 8/106 (7.54%) patients, 50% of whom had been submitted to the CC technique [Table 5].

DISCUSSION

The results of this study demonstrated that SCRB with levobupivacaine 0.25% combined with paracetamol, or paracetamol on its own, produce effective intraoperative and postoperative analgesia in children undergoing circumcision. However, the combined treated group displayed a longer PF period postoperatively, with lower pain scores. Furthermore, the SPP operation seemed to be less painful when compared to PP and CC techniques in terms of the total postoperative analgesic administration of paracetamol.

Among regional anesthetic methods, the caudal penile block and DPNB emerge as the most commonly used techniques.[14] However, the potential complications observed with caudal anesthesia, such as motor block, delayed first micturation, nausea, and vomiting,[2] and those seen with DPNB, such as local hematoma and

Table 5: Incidence of complications between groups and surgical techniques

Variable	Group A	Group B	*P* value
POVN* and SCRB** complications			
POVN	4	2	NS
Edema (insignificant)	2		
Postoperative surgical complications			
Oozing (SPP#/PP¤/CC¥)	1/1/3	0/2/1	NS

*POVN: postoperative nausea, vomiting, **SCRB: subcutaneous ring block, #SPP: sutureless prepuceplasty, ¤PP: preputial plasty, ¥CC: conventional circumcision

edema, systemic toxic effects due to absorption of the local anesthetic, and gangrene of the skin of the glans penis,[15] may expose children to hazardous consequences. Broadman *et al*.,[7] in 1987, introduced the SCRB of the penis as an alternative regional analgesic method for children undergoing circumcision. They noted that the block was easy to perform, and was effective and safe without complications at the site of injection. Although Holder *et al*.[16] reported that the SCRB had an unacceptable failure rate when compared with the subpubic penile block, most authors agree that the SCRB is an effective and safe anesthetic technique.[17-19] Our results are consistent with these findings.

Levobupivacaine is the pure S(−)-enantiomer of racemic bupivacaine. It is a long-acting anesthetic agent, with the onset of action ≤15 min with various anesthetic techniques, lasting 6.5-17 h depending on the regional block, and causing less toxic side effects to the central nervous and cardiovascular systems than bupivacaine.[20] Clinical studies have demonstrated that the use of levobupivacaine 0.25% alone, whether used with the caudal block, DPNB or SCRB technique, provided adequate postoperative analgesia in children undergoing circumcision.[19,21,22] In this study, SCRB with levobupivacaine 0.25% plus paracetamol provided adequate intraoperative analgesia. Postoperatively, the first analgesic request was noted at 5 h, and 51% of the patients did not require additional analgesia.

Paracetamol is the most commonly used antipyretic and mild analgesic agent for children.[23] Its analgesic effect is thought to be related directly to its concentration.[24] Anderson *et al*.[25] found that adequate plasma analgesic concentration of paracetamol should be 10 mg/l, provided by a loading dose of oral paracetamol 40 mg/kg preoperatively in children undergoing tonsillectomy. However, the exact analgesic dose of rectal paracetamol has not yet been established.[25] Lee[26] proposed a loading dose of 30-40 mg/kg of rectal paracetamol and 15 mg/kg thereafter. Sayed *et al*.[2] found that a high dose (40 mg/kg) of rectal acetaminophen (paracetamol) in children undergoing circumcision provided analgesic results that were comparable with those of caudal block with bupivacaine 0.25%, and better than those of EMLA cream. Although they did not measure plasma levels of paracetamol, they suggested that delayed absorption of paracetamol is responsible for adequate postoperative analgesia. Birmingham *et al*.[27] investigated the 24-h pharmacokinetics of rectal acetaminophen (paracetamol) and speculated that factors such as the temperature of the rectal canal, the presence of stools, and composition of the suppository may influence in the absorption of paracetamol. Interestingly, the results of our study showed that a dose of rectal paracetamol 30 mg/kg alone intraoperatively sustained a satisfactory analgesia during WS in 47.1% of the patients.

Postoperative pain in children undergoing CC is severe during the first 2 h.[28] The persistence of pain thereafter in 29 (27.3%) of the patients in this study could mean that other reasons, and not the surgical trauma *per se*, might be implicated. Elemen *et al*.[10] noted that the postoperative pain duration in children submitted to CC was significantly lower compared to those undergoing wound approximation with sutures. One possible explanation could be the traction effect of the sutures caused by contact with the clothes.[10] In our study, however, this correlation was not confirmed in parents or older children.

Complications from the SCRB included an insignificant edema at the site of injection, confirming previous results[7,19] concerning the safety of the technique. Mild oozing was seen in 9 (8.48%) patients from both groups (0.94%, 4.24%, and 3.18% for SPP, PP, and CC respectively, in both groups). This percentage of complications does not exceed those reported in other studies.[3]

SCRB with levobupivacaine 0.25% plus rectal paracetamol and rectal paracetamol alone provide adequate intraoperative and postoperative analgesia in circumcised children. However, the combined analgesia has a longer PF period than paracetamol alone. Nonetheless, the analgesics requirements postoperatively between groups showed no statistical differences. The need for more analgesic administration in children submitted to CC could mean that circumcision techniques might be associated with pain. This study is not without its limitations; the number of patients is small, and measurements of serum concentration of paracetamol are not available. More studies including a larger number of patients and less painful surgical techniques are required, and plasma levels of paracetamol need to be determined to confirm our findings.

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How to cite this article: Zavras N, Tsamoudaki S, Christianakis E, Schizas D, Pikoulis E, Kyritsi H, *et al*. Ring block with levobupivacaine 0.25% and paracetamol vs. paracetamol alone in children submitted to three different surgical techniques of circumcision: A prospective randomized study. Saudi J Anaesth 2014;8:45-50.
Source of Support: Nil, **Conflict of Interest:** None.