

Postoperative Analgesia for Circumcision in Children: A Comparative Study of Caudal Block versus High Dose Rectal Acetaminophen or EMLA Cream

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Abstract: Background: Analgesia for circumcision in children is considered essential by the American Academy of pediatrics to minimize the postoperative discomfort and pain. **Objectives:** We compared efficacy of caudal epidural bupivacaine analgesia versus high dose rectal acetaminophen (40mg/kg b.wt) or topical application of Eutetic mixture of the local anesthetics lidocain and prilocain (EMLA[®] cream) in children undergoing circumcision. **Methods:** Sixty ASA I children aged 6 weeks-3 yr undergoing circumcision were randomized to receive either single dose of 2-4gm of topical EMLA[®] cream (Astra Pharma Inc. Sweden) 1h prior to procedure (group I), 40 mg/kg b.wt rectal acetaminophen (group II) or caudal epidural 1mg/kg b.wt of 0.25% bupivacaine (group III). The study drug was administrated in the groups (II) and (III) immediately after induction of general anesthesia. All children were assessed for the post operative pain intensity with the FLACC pain scale for five categories (F) Face, (L) Legs, (A) Activity, (C) Cry, and (C) Consol ability, time to first supplemental analgesia (oral acetaminophen), frequency of analgesic used and any adverse events during the first 24hrs. **Results:** Total FLACC pain score was significantly decreased, together with significant reduction in the percentages of children required postoperative analgesia in both caudal bupivacaine and rectal acetaminophen groups when compared to the EMLA[®] group. However no difference was observed in pain scores, frequency of used analgesia or time to first rescue analgesia between caudal epidural or rectal acetaminophen group. Postoperative undesirable effects were comparable in all groups. **Conclusions:** High dose rectal acetaminophen (40 mg/kg) provides adequate post-circumcision analgesia in pediatrics comparable to caudal block and superior to topical EMLA[®] cream. It is a useful alternative to caudal block as it is easier administer and appears safe.

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Key words: analgesic, caudal block, circumcision, rectal acetaminophen, EMLA cream.

1. Introduction

Circumcision is a painful intervention that is frequently performed in pediatric surgery. It is generally performed under general anesthesia in order to eliminate fear and anxiety. Ideal method of postoperative analgesia after circumcision requires very low complications rates and high success rates⁽¹⁾. Analgesia may be obtained through various techniques, these methods include administration of opioids, administration of non-steroidal anti-inflammatory drugs such as acetaminophen and the use of regional anesthetic techniques, such as topical local anesthetic cream and caudal anesthesia and analgesia. Each of these techniques has their advantages and disadvantages, and they have proved efficacy when compared with placebo. Some of these methods have compared to determine if one is superior with respect to pain control or adverse effects⁽²⁾. Caudal blockade is the most popular regional anesthetic technique used in children as it is cheap, easy, and effective method as a post operative analgesia and as an anesthetic technique⁽³⁾. Acetaminophen has gained wide acceptance as a simple and safe antipyretic and analgesic in children. It is often administrated rectally preoperatively to provide analgesia or antipyresis to infant and children for whom the oral rout is not an option. Perioperative use

of high-dose rectal acetaminophen (40-45 mg/kg b.wt) has been recommended by many authors⁽⁴⁻⁶⁾. The use of this route might prove ideal for the perioperative setting as the slower rate of absorption could provide a prolonged analgesic effect during recovery.

Aim of the work:

The purpose of this study was to compare the effects of caudal epidural analgesia with that of high dose rectal acetaminophen or EMLA[®] cream in children undergoing circumcision.

2. Patients and Methods:

The study was approved by the local ethics committee, and a written informed parental consent was obtained for each subject. We studied 60 boys, ASA physical status I-aged 6 weeks-3yr undergoing elective day circumcision surgery in pediatric hospital Assiut University in this prospective, comparative study. They were randomized into 3 groups. Patients were excluded if they had sever systemic disease, preexisting neurological or obvious spinal disease, bleeding diathesis, history of seizure disorder, a known allergy to any of the study drugs or if they had received paracetamole 24 hrs prior to the time of surgery.

A 22-gauge intravenous catheter was inserted into a small vein on the dorsum of the hand in the premedication room and I.V fluid (3-5 ml/kg b.wt/h) was administered but no premedication was given.

Inhalational induction of anesthesia was done with a face mask using sevoflurane in oxygen. Sevoflurane was used for maintenance. After induction, a laryngeal mask, appropriate to the children's age and weight, was put in place.

Patients were randomized by the closed-envelope technique into 3 groups of 20 patients each.

Group I:

In which the parents were instructed to apply 2-4 grams of EMLA[®] cream on the shaft of the penis and 1cm around its base one hour prior to the appointed time for circumcision. In order to avoid absorption of the EMLA[®] cream into the disposable diaper, parents were instructed to apply a 20 × 20 cm piece of household plastic wrap on the inside of the disposable diaper over the penis (the same manouvre done for the other 2 groups to blind the observer).

Group II:

The patients were randomized to receive 40 mg/kg acetaminophen per rectum immediately after induction of anesthesia. Adminstrated doses were combinations of uncut rectal suppositories (120,200,350, or 500mg) to approximate the target dose.

Group III:

Patients received a caudal block using a 22G needle in the lateral decubitus position, with 1mg/kg of 0.25% bupivacain with a maximum volume of 20mg immediately after induction of anesthesia

After caudal block the anesthesiologist placed an adhesive strip over the needle puncture. (The patients in the other two groups had an adhesive strip placed on the skin superficial to the caudal space to "blind" the observers). Intraoperatively heart rate, respiratory rate, blood pressure and oxygen saturation were monitored. At the end of the surgery, inhalational agent was discontinued and after recovery from general anesthesia the patient was shifted to PACU (Postanaesthetic Care Unite) and his vitals, pain and side effects (nausea, vomiting, agitation, bleeding, penile hematoma, motor weakness, and urinary retension) were observed and recorded every 15 minutes for 30 minutes. Then the children were transferred to wards where they observed and recorded for the same parameters hourly for the first 12 hours and every 2 hours for another 12 hours. The time at which first analgesia received (was measured from recovery to first analgesic time) and total number of analgesia in 24 hours were recorded. Postoperative pain was scored using the pediatric observational FLACC pain scale with its 0-10 score range for five categories (F) face, (L) Legs, (A) Activity, (C) Cry, and (C) Consol ability.⁽⁷⁾

The FLACC Pain Scale

CATEGORIES	SCORING		
	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 complaints
CONSOLABILITY	Content, relaxed	Reassured by occasional touching, hugging or talking to, distractible	Difficulty to console or comfort

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Figure 1. The presently applied FLACC observational pediatric postoperative pain scale⁽⁷⁾

If the patient's FLACC pain scale score was noted at any time to be three or more, acetaminophen 10-15 mg/kg orally was administered and recorded. Also motor weakness was assessed on wakening by inability

of the child to withdraw his leg on response to painful stimulation of leg and feet after 3 hours from recovery from general anesthesia.

Statistical analysis:

Data of the study are expressed as mean \pm (SD) median (range) and number (%) as appropriated. Comparison between the three studied groups are done using analysis of variance (ANOVA) or Kruskal-Wallis test as appropriate. P value $<$ 0.05 was considered statistically significant.

3. Results:

There were no difference among groups in age, weight, heart rate (HR), mean arterial blood pressure (MAP), peripheral oxygen saturation (spo₂) and duration of surgery or general anesthesia during the study period. None of the patients showed hypotension, bradycardia or decreased O₂ saturation more than the clinically acceptable rang ($p >$ 0.05, Table 1). On evaluation of the FLACC pain scores within the three groups, a significant decrease in pain scores was found. However, a comparison of the total FLACC pain score measurements of the three different groups revealed a significant increase of the FLACC score in the EMLA

group as compared to both other groups while there was no significant difference in comparing the rectal acetaminophen group and the caudal block group. The first analgesic demand time was significantly shorter ($P <$ 0.05) in the EMLA group (320 ± 11 min) as compared to rectal acetaminophen group (480 ± 23 min) or caudal block group (491 ± 18 min) while it did not differ between the later two groups. A significantly larger percentage of patients in the EMLA group also required supplementary systemic analgesics throughout the 24h examination period (Table 2).

No major complication (oedema, hematoma, postoperative agitation or urinary retention) was seen in any of the three groups also no severe bleeding occurred during surgery.

Patients in the EMLA group experienced less post operative nausea and vomiting as seen only in 2 patients compared to 4 patients in both other two groups however this was not statistically significant. Motor weakness showed in only 1 patients in the caudal group (Table 3).

Table 1. Patient demographic and intraoperative clinical Data

Variable	EMLA cream group (n=20)	Rectal Acetaminophen group (n=20)	Caudal block group (n = 20)
Age (mo)	16.5 \pm 13.3	17.1 \pm 15.0	16.2 \pm 14.1
Weight (kg)	12.6 \pm 4.2	11.1 \pm 5.5	11.8 \pm 6.1
Heart rate (bpm)	123 \pm 10	125 \pm 7	126 \pm 9
MAP (mmHg)	80.6 \pm 4.3	79.4 \pm 6.2	81.3 \pm 5.4
Spo ₂	98-100	97-100	97-99
Duration of surgery (min)	23 \pm 7	21 \pm 8	21 \pm 7
Duration of GA (min)	25 \pm 5	23 \pm 4	25 \pm 3

MAP = mean arterial blood pressure, GA = general anesthesia, spo₂ = peripheral oxygen saturation.

Data are mean \pm SE or range.

Table 2. Postoperative total FLACC Score, time to first analgesic request, Frequency of Supplemental analgesia /24hrs

Variable	EMLA cream group (n=20)	Rectal Acetaminophen group (n=20)	Caudal block group (n = 20)
Total FLACC Score	1.9 \pm 0.05 ^{■*}	0.9 \pm 0.03	0.8 \pm 0.04
Time to first analgesic request (min)	320 \pm 11 ^{■*}	480 \pm 23	491 \pm 18
Frequency of supplemental analgesia /24hrs			
No	0 ^{■*}	10 (50%)	11 (55%)
1	9 (45) ^{■*}	5 (25%)	6 (30%)
2	7 (35%) ^{■*}	4 (20%)	3 (15%)
3	4 (20%) ^{■*}	1 (5%)	0

* $P <$ 0.05 versus the Acetaminophen group mean \pm SE or frequency (%)

■ $P <$ 0.05 versus the caudal block group Data are

Table 3. Incidence of adverse effects

Variable	EMLA cream group (n=20)	Rectal Acetaminophen group (n=20)	Caudal block group (n = 20)
Nausea and vomiting	2 (10%)	4 (20%)	4 (20%)
Urinary retention	-	-	-
Motor weakness	-	-	1 (5%)

Data are n (%).

4. Discussion:

In this study, caudal epidural analgesia given intraoperatively to patients undergoing circumcision did not demonstrate improved analgesia compared to rectal acetaminophen while both of these methods had significantly better post-operative analgesia compared with topical EMLA cream.

All patients in the three groups exhibited adequate postoperative analgesia as judged by the decreased FLACC pain scale and increased the time to first required analgesia which was (320 + 11 min), (480 + 23 min), (491 + 18 min) for the EMLA group, acetaminophen and caudal group respectively.

An important goal of modern anesthesia is not only to provide balanced anesthesia but also to provide quality control of postoperative analgesia. Ease of performance and reliability make caudal block the most commonly performed block in children⁽³⁾. This is in agreement with our results that showed no significant difference in the duration of general anesthesia or hemodynamic in the three studied groups. Caudal administration of bupivacaine is a widespread regional analgesic technique for intra and postoperative analgesia during infra-umbilical surgeries in children. However its problem include prolonged time to micturition⁽⁸⁾, lower limb motor block, and an increased potential for local anesthetic toxicity.

The use of bupivacaine for pediatric analgesia for circumcision was reported in many studies performed on children older than 1 year. A study by Choi et al.⁽⁹⁾ compared the use of topical EMLA cream with bupivacaine in randomized placebo-controlled manner and concluded that, despite no difference in the score obtained using a pain scale between the two groups, bupivacaine dorsal penile nerve block (DPNB) resulted in significantly longer analgesia. A second study by Margetts⁽¹⁰⁾ compared bupivacaine in DPNB with caudal bupivacaine with ketamine in 60 boys and reported no immediate adverse effects.

Our results are in agreement with Jamali et al.⁽¹¹⁾ who reported that the duration of analgesia with 0.25% caudal bupivacaine was 460 + 439 min. In addition Luze et al.⁽¹²⁾ found that only 21% of children, given 0.18% bupivacaine caudally did not require any supplementary analgesics and that the mean duration of caudal analgesia was 2.7hrs.

Contrary to our results Gunduz et al.⁽¹³⁾ showed that bupivacaine 0.25% provided satisfactory analgesia without supplementary analgesics for 24hrs following caudal block.

Difference in the surgical procedures performed, method of pain scoring, bupivacaine dose and volume and calculation of analgesia time possibly account for this discrepancy.

Acetaminophen 40mg/kg rectally in our study produced similar analgesia postoperatively as caudal bupivacaine. Of all of the non-steroidal anti-

inflammatory drugs available we chose rectal acetaminophen because it is easily administered and is a potent analgesic. The dose of acetaminophen was chosen based on the study by several investigators who have suggested using higher dose when administering acetaminophen by the rectal route in children because of the delayed absorption^(4-6,14,15) However we did not measure the plasma level of acetaminophen to determine the target serum concentration needed for the analgesic efficacy.

A topical application of eutectic mixture of the local anesthetics, lidocaine and prilocaine (EMLA[®] cream) had achieved considerable popularity for its ability to diminish pain associated with circumcision, while less effective than local blocks it provides safe and effective analgesia⁽⁹⁾. In a review of Cochrane Database⁽¹⁶⁾, however, its use was not shown to have any special advantage over other analgesic techniques with proven efficacy such as caudal block or regional nerve block which is in agreement with our results that demonstrated an increased in the FLACC pain scale together with increased percentages of children required postoperative analgesia due to short time to first analgesia in EMLA group.

We did not observe any serious adverse effects and our minor complication rate was small and comparable in the three studied groups.

Also our results was in agreement with the Cyna and Middleton Cochrane Database review⁽²⁾ who concluded that no difference were seen between caudal and rectal or intravenous analgesia in the need for rescue analgesia or any other outcomes (2 trials, 162 boys).

Some potential limitations of our study was the relatively small number of patients in the group (20 patients) and it is possible that the FLACC pain scale was not sensitive enough to discern relevant differences in postoperative pain intensity between the caudal and acetaminophen groups. However it has been validated for children from 2 month to 7 years.

Conclusion:

We conclude that both caudal epidural block and 40mg/kg rectal acetaminophen provide comparable and more effective, techniques for post operative analgesia in children undergoing circumcision under general anesthesia than topical EMLA cream with a very small incidence of adverse effects. A single large dose of inexpensive rectal acetaminophen (40 mg/kg) may be preferable to caudal block in children old enough to walk due to possibility of temporary leg weakness after caudal block.

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