

# The use of topical lidocaine/prilocaine cream prior to childhood circumcision under local anesthesia

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## Abstract

A prospective study was conducted to evaluate the efficacy of prior application of topical eutectic mixture of local anesthetics, EMLA, in alleviating the pain associated with infiltration local anesthetic (LA) for circumcision in children and to assess its impact on the outcome. A total of 173 children aged 3–13 years requiring circumcision were randomly assigned to have EMLA or placebo cream applied over the root of the penis 1 h before subcutaneous ring block. A blinded observer rated the pain response on a 10-point visual scale during needle insertion, injection of local anesthetic and circumcision. Children needing conversion to general anesthesia (GA) were counted as failures. A total of 89 and 82 boys were included in the EMLA group and placebo group, respectively. Significantly lower pain scores were recorded for needle puncture in the former group ( $P < 0.001$ ), whilst pain scores for injection and during circumcision were not statistically different between the two groups ( $P = 0.037$  and  $0.138$ , respectively). A total of 88 out of the 89 boys pre-treated with EMLA completed the procedure, whereas seven boys in the placebo group necessitated conversion to GA ( $P = 0.022$ ). The converted cases had higher values for all pain scores and tended to be younger. Therefore, EMLA cream is a useful adjunct to LA for childhood circumcision because it effectively reduces the sharp pain induced by needle puncture. However, careful patient selection is required for a low conversion rate to GA. © 2001 Elsevier Science B.V. All rights reserved.

*Keywords:* EMLA; Local anesthesia; Childhood circumcision

## 1. Introduction

Eutectic mixture of local anesthetics (EMLA) is a eutectic mixture of local anesthetics, lidocaine and prilocaine, suspended in an oil-in-water emulsion (Astra, Sweden). The high concentration of the local anesthetics (LA) stimulates the transdermal spread of the active ingredients, providing effective surface analgesia on intact skin [1]. Over the past few years, a large body of clinical data has been amassed demonstrating clear superiority of EMLA over placebo in reducing acute pain inflicted by a wide variety of medical/surgical procedures on superficial skin surface [2]. An important

area of pediatric practice in which EMLA cream could find wide application is treatment for phimosis. Convincing evidence of its efficacy in this common surgical condition remains meager in the English literature. Effective analgesia has been shown by the cream to permit separation of the preputial adhesions in lieu of circumcision in children [3,4]. EMLA cream has been tried as the sole anesthetic for circumcision in neonates and in old children [5–7]. Even though the procedure was feasible and pain attenuated, significant distress was still evident and the analgesic effect was inferior to either subcutaneous ring block or dorsal penile nerve block [8]. Amid all these uncertainties about its role in circumcision, we set out to determine whether prior application of EMLA significantly reduces the discomfort of infiltrative anesthesia and improves the outcome by a randomised, double-blind, placebo-controlled study.

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## 2. Patients and methods

Children aged 3–13, about to undergo circumcision and assessed to be cooperative enough were offered the choice of general anesthesia (GA) or LA. With informed consent, suitable children of parents who opted for the latter anesthesia were allocated, by drawing lots, to receive either EMLA or a placebo cream. The two creams were indistinguishable. One hour before the anticipated time of circumcision, a thick layer (2 g) of the cream was applied around the root of the penis and a patch of self-adhesive Tegaderm® was placed over the cream to keep it in place. The behavior of the child in the waiting room was subjectively assessed by a single observer; it was described as playful, calm, anxious or crying. Just prior to circumcision, the dressing and cream were removed and the skin was cleansed with aqueous hibitane. Circumcision was performed using a subcutaneous ring block in the usual manner. An independent nurse was assigned specifically to score separately the pain of needle puncture, the pain of local anesthetic injection and the pain during circumcision on a 10-point visual scale with 0 = no pain and 10 = excruciating pain, combined with a pictorial scale based on facial expressions [9,10]. Side effects and complications detected at operation or during follow-up were registered.

## 3. Results

A total of 173 boys with a mean age of 8.8 years (range 3–13 years) were enrolled in the study. They were randomised to one of two groups: (1) pre-treatment with EMLA ( $n = 91$ ); (2) placebo cream ( $n = 82$ ). Two children were subsequently withdrawn from the EMLA group: circumcision could not be performed

because they became very agitated and uncooperative once they saw the injection needle in the operating theatre. The results were analysed statistically by Student's  $t$ -test for paired data or by Chi-squared test of independence as appropriate (Table 1). There were no statistical differences between the two groups in patient's age ( $P = 0.849$ ) ( $t$ -test), weight ( $P = 0.774$ ) ( $t$ -test), pre-treatment emotional status ( $P = 0.337$ ) (Mann-Whitney U test), operative time ( $P = 0.138$ ) (Student  $t$ -test), operating surgeon's experience ( $P = 0.804$ ) (Chi-square test) and the incidence of post-operative edema and hematoma formation.

The mean pain score for needle puncture was significantly lower in the EMLA-treated group compared to the placebo group ( $2.69 \pm 1.72$  versus  $3.82 \pm 1.92$ ;  $P < 0.001$ ). However, statistical differences were not observed in pain scores for infiltration ( $3.46 \pm 2.29$  versus  $4.22 \pm 2.51$ ;  $P = 0.037$ ) and pain scores during circumcision ( $2.37 \pm 2.07$  versus  $2.94 \pm 2.75$ ;  $P = 0.138$ ) (Fig. 1).

LA had to be converted to GA in one boy despite pre-treatment with EMLA, whereas seven boys from the placebo group needed conversion because of pain associated with attempted LA. Thus EMLA appeared to be a useful adjunct to local anesthesia in terms of improved patient compliance (EMLA group 88/89 versus placebo group 75/82;  $P = 0.022$ ) (Mann-Whitney U test).

A total of eight children (one from EMLA group and seven from the placebo group) failed to complete the procedure under LA. No statistical differences were found between this failure group and the 163 successful cases in body weight ( $25.7 \pm 4.5$  Kg versus  $31.2 \pm 10$  kg;  $P = 0.154$ ), experience of the surgeon ( $P = 0.614$ , Mann-Whitney U test) and the pre-procedural behavior ( $P = 0.084$ , Mann-Whitney U test). On the other hand, successful outcome was positively correlated with less pain scores for needle insertion ( $2.8 \pm 1.6$  versus  $7.7 \pm$

Table 1  
Comparison of patient variables between the EMLA-treated group and placebo group<sup>a</sup>

Characteristics	EMLA group ( $n = 89$ )	Placebo group ( $n = 82$ )	P value
Age (month)	106.39 $\pm$ 23.67	105.70 $\pm$ 24.18	$P = 0.849$ ( $t$ -test) <sup>b</sup>
Both weight (kg)	30.63 $\pm$ 10.09	30.20 $\pm$ 9.57	$P = 0.774$ ( $t$ -test) <sup>b</sup>
Operating time (min)	23.56 $\pm$ 7.87	25.62 $\pm$ 8.06	$P = 0.138$ ( $t$ -test) <sup>b</sup>
<i>Pre-procedural behaviour</i>			
Playful	35	21	
Calm	39	52	$P = 0.337$ (Mann-Whitney U test) <sup>b</sup>
Anxious	12	8	
Crying	3	1	
<i>Surgeon's experience</i>			
>4 year	36	31	
>2, <4 year	19	21	$P = 0.804$ ( $\chi^2$ test) <sup>b</sup>
<2 year	34	30	

<sup>a</sup> Plus-minus values are means  $\pm$  SD.

<sup>b</sup> Not significant.

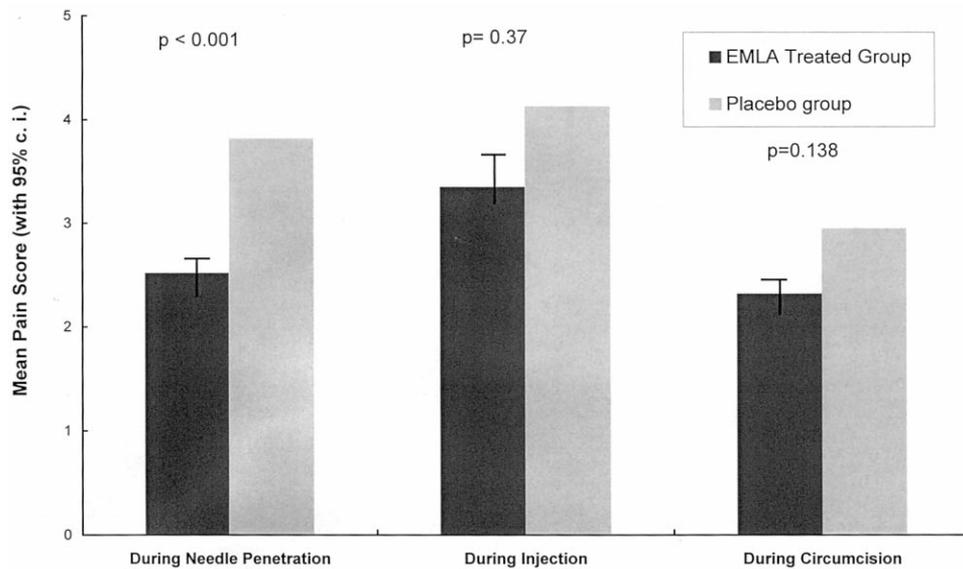


Fig. 1. Comparison of mean pain scores between the EMLA-treated group and placebo group.

1.6;  $P < 0.001$ ), infiltration of local anesthesia ( $3.4 \pm 2.3$  versus  $8.3 \pm 1.5$ ;  $P < 0.001$ ) and during surgery ( $8.5 \pm 1.7$  versus  $2.4 \pm 2.4$ ;  $P < 0.001$ ), as well as older age ( $7.8 \pm 2.0$  years versus  $10.9 \pm 2.1$  years;  $P = 0.044$ ).

No untoward effects from the EMLA, either locally, such as redness and irritation, or generally, such as allergic reaction were reported by either the staff or the parents.

#### 4. Discussion

The recent vogue for day surgery has rekindled interest in loco-regional anesthesia, which is preferred in the day care setting. Childhood circumcision constitutes a significant bulk of work in most day surgery centers. Even though penile nerve block and subcutaneous ring block are highly effective means of controlling pain from circumcision procedure, there remains the discomfort of administering the anesthetic by injection. The latter is a combination of sharp pain caused by needle insertion and duller pain associated with injection of the volume of local anesthetic. The first hurdle for successful circumcision under LA is needle puncture. The present study confirms the previous studies that the EMLA preparation is clinically effective in reducing pain caused by needle puncture at the start of local anesthesia [11–13]. Our results further proved that this salutary effect could be translated into improved outcome in terms of significantly greater proportion of children completing the operation without conversion to general anesthesia.

Controversy still exists as to whether EMLA could effectively ameliorate injection pain. There are controlled studies showing that pain induced by subcuta-

neous and intramuscular injections was reduced by topical EMLA application [13,14], while other studies found EMLA not clinically effective in alleviating pain produced by infiltration of local anesthetics [15,16]. The general feeling has been that EMLA may not penetrate to a sufficient depth to counteract the pain of fluid injection deeper than the skin — this is again borne out by the present study. Nonetheless, the patient compliance appeared better in the EMLA-treated group due to a marked reduction in needle insertion pain.

When the ‘failure cases’ were analysed categorically, it was found that high insertion pain score and high injection pain score were significant factors predicting failure. In addition, patients completing the procedure without conversion to GA were significantly older than the converted cases ( $P = 0.039$ ) — this contrasts with the finding in a previous study that age of child was not a determinant of success and failure of EMLA [17]. Body weight and surgeon’s year of experience were not predictive factors, surprisingly, neither was the observed behavior in the waiting room. In our experience, it is very hard to predict which child would cooperate in the out-patient clinic, or even in the waiting room before actually exposing the child to the operating room and, in particular, the injection needle. Two children originally allocated to the EMLA group became so agitated when they were laid on the operating table and saw the anesthetic-laden syringe that the needle did not have a chance to prick on the skin. If these two cases were included in the EMLA group for statistical analysis of the outcome, the difference in conversion rate between the two groups would not have been statistically significant (three failures out of 91 versus seven failures out of 82,  $P = 0.14$ ). Anecdotal notes in published studies suggest that children with an

intense needle anxiety may not be helped by the application of ELMA [17,18]. Therefore, to improve the 'success rate' with local anesthesia, it would be advisable to test for the psychological response of the child to injection needles in the strange environment of the operating theatre. A further study is under way to determine whether presence of parents in the operating room could allay the anxiety of the child and improve the outcome.

In conclusion, topical application of EMLA cream saves the child from a painful puncture into a sensitive area and is a useful adjunct to local infiltration analgesia for circumcision in a carefully selected group of children.

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