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Research Article

Topical Lidocaine- Prilocaine Cream Versus Lignocaine Infiltration For Episiotomy Repair: A Randomized Clinical Trial

Nirmala Duhan, Ritu Nandal

Department of Obstetrics and Gynecology, Pt B D Sharma Post Graduate Institute of Medical Sciences, Rohtak, Haryana, India

Correspondence

Professor Nirmala Duhan
8-UH, Medical Campus,
Pt B D Sharma PGIMS,
Rohtak-124001
Haryana, India
Tell: +91 9896016348
Email: nkadian@gmail.com

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Abstract

Purpose: To investige effect of the topical route of administration of the anesthetic agent (lidocaine-prilocaine cream-EMLA) in comparison to the conventional perineal infiltration of lignocaine for episiotomy suturing.

Methods: In a randomized clinical trial 100 primigravid women with singleton healthy pregnancies at term were randomly allocated into two groups. Group 1(50 women) received 10 ml of 1% lignocaine for perineal infiltration at the time of crowning while 50 women of Group 2 had EMLA cream application on the perineum at 8-9 cm of cervical dilatation during labor.After repair of episiotomy, pain scores (on VAS), need for additional analgesia and patient satisfaction was recorded and analyzed by unpaired t-test and Chi-square tests.

Results: The mean pain score was 4.14±1.0 for group 1 and 4.3±1.28 for group 2 (p=0.4878). Nine (18%) women of group 1 and 13 (26%) of group 2 (p=0.46) required additional analgesia. Thirty nine (78%) women of group 1 and 47 (94%) of group 2 expressed satisfaction with the anaesthetic agent used (p=0.04).

Conclusion: EMLA cream may be less active on the perineal muscular layers than local infiltration of lignocaine due to limited penetration beneath the skin which could account for higher requirement of additional analgesia in group 2 of the study. The cream is a safe, highly satisfactory and easy-to-use agent with comparable efficacy to local lignocaine perineal infiltration for episiotomy repair and is better tolerated on account of reduced needle anxiety and painful injections.

Introduction

Episiotomy is the most frequent operation in obstetrics and is commonly done under local anaesthetic infiltration of the perineum[1]. The local anaesthetic (LA) agents act by reversibly blocking nerve conduction at or near their site of application thereby causing temporary loss of sensation in the limited area. However, the insertion of the needle not only causes pain but at times may also result in burning sensation, distortion of the surgical site by edema and accidental intravascular administration. Small amounts of the anaesthetic agents are also thought to reach the fetus[2].The clinical syndrome of LA fetal intoxication was first described by Sinclair et al in 1965 and includes total arrest of spontaneous respiration, hypotonia, seizures and cardiac symptoms such as bradycardia or ventricular tachycardia at or shortly after birth[3].

Efforts have been made to find effective, easy to use and safe alternatives to the use of injectable lignocaine for repair of episiotomy. Topical anaesthetics have a localized action, negligible systemic absorption, painless and easy application and do not cause oedema at the surgical site that may distort the wound margins. Topical formulations like ointments and sprays have been tried for paediatric, dermatologic and gynaecologic minor procedures. However, in the context of perineal trauma in general and episiotomy in particular, only a few studies are available in literature and these too have yielded conflicting results[4,5]. Moreover most of these trials ecaluated post-episiotomy pain rather than pain during suturing. A mixture of 2.5% lidocaine and 2.5% prilocaine has been used as a topical anaesthetic for minor dermatological surgical procedures in the past.

This study was planned to compare the efficacy of topical lidocaine-prilocaine cream (EMLA) and lignocaine (1%) infiltration in alleviating pain during episiotomy suturing.

Methods

The study was conducted on 100 patients admitted to the labour ward in the Department of Obstetrics & Gynecology of a tertiary care centre of North India from October 2010 to October 2011. Primigravid women with singleton live term pregnancy

with cephalic presentation in the first stage of labour were included in the study after approval by the Institutional Ethical Committee and obtaining an informed consent. Those with known allergy to lignocaine, altered mental status, local perineal infection, request for epidural analgesia, hepatic disorders and glucose-6 phosphate dehydrogenase (G6PD) deficiency were excluded from the study. Out of the 144 women assessed for eligibility, 116 women were counseled and 100 (86.20%) agreed to participate (Figure 2). The enrolled women were divided into two groups by simple randomization with a 1:1 allocation ratio. The allocation treatment was written on cards that were sealed in sequentially numbered, opaque and stapled envelopes. The envelopes were opened at the time of allocation after the enrolled participants had completed all baseline assessments.

Group I comprised 50 women who received 10 ml of 1% lignocaine for perineal infiltration at the time of crowning while 50 women of Group II had EMLA cream application on the perineum at 8-9 cm of cervical dilatation during labor, approximately one hour before the expected time of birth. EMLA, a eutectic mixture, is composed of Lidocaine-25 mg, Prilocaine-25 mg, Arlactone 289 -19 mg, Carbopol-10 mg, Sodium hydroxide to make a pH of 9.6 mg and purified water to produce l gram. Five grams of this cream was applied as a thick layer (about 2 g/ 10 cm^2 area) to the intact surface of the perineum and covered with an occlusive dressing (Figure 1).

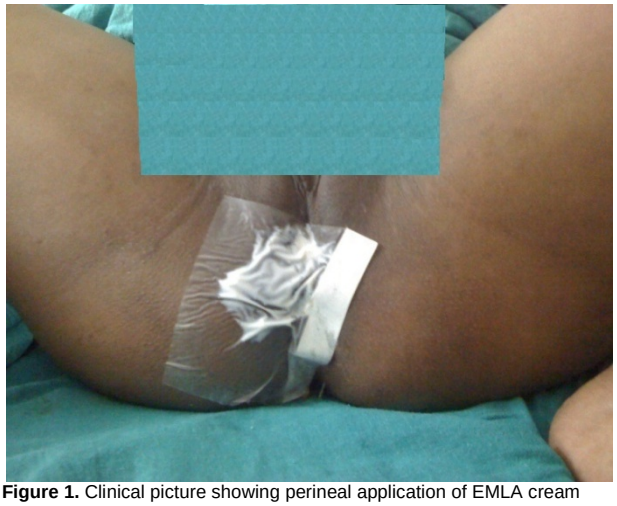

Figure 1. Clinical picture showing perineal application of EMLA cream with occlusive dressing.

At the time of crowning, the occlusive dressing and any residue of the cream was removed and episiotomy was given. The request for additional anaesthetic agent (10 ml of 1% lignocaine solution for both groups) was honoured and recorded for both groups. After repair of episiotomy, each patient was asked to grade the severity of pain during perineal repair on a 10 cm Visual Analog Scale (VAS). The far left was labelled 'No pain at all' and the far right was labelled as 'severe uncontrolled pain'. The subject was asked to make a vertical mark on this line reflecting the severity of pain. The numeric score was derived by measuring the distance in millimetres from the far left of the VAS line to the mark made by the subject. It was predefined that patients with VAS pain scores of 30 mm or less were categorised as having mild pain; those with scores of 70 mm or more as having severe pain and those between 31 mm to 69 mm as moderate pain. The overall satisfaction of the patients with the use of anaesthetic agent was also documented. Pain score during episiotomy repair was the primary outcome of the study. Secondary outcome measures included the need for additional anaesthetic agent and overall satisfaction of patients. The data was analyzed by unpaired t –test and Chi-Square tests.

Results

The two groups were similar for baseline characteristics and obstetric outcomes as depicted in Table1.

Episiotomy was performed in all the patients of the study. The mean application to delivery interval time in Group II was in the range of 33-70 minutes with the mean being 48.02±11.64 minutes. All women had normal vaginal deliveries and the episiotomy was repaired in 3 layers (mucosa, muscles and skin) by chromic catgut 0 suture on round body (vaginal mucosa and muscles) and cutting needles (for perineal skin). The pain scores during perineal repair are depicted in Table 2.

The mean pain scores in the study were comparable for both groups (4.14±1.0 for group I and 4.3±1.28 for group II; p=0.4878, 95%CI=0.6159,0.2959). Forty nine (98%) women of each group had pain score of 6 or lower i.e experienced mild to moderate pain during perineal suturing. The proportion of women who required additional analgesia was also comparable in the two groups [9 (18%) women in group I and 13 (26%) in group II (p=0.46)]. Thirty nine (78%) women of group I and 47 (94%) of group II expressed satisfaction with the anaesthetic agent used, the difference being statistically significant [p=0.04, relative risk (RR)=1.2 (95% CI:1.02-1.40); NNT=6.2 (95% CI:3.4-37)].

Table 1. Patient demographics and obstetric outcomes in the lignocaine (Group I) and EMLA(Group II) groups of the study.

Variable	Group I (Lignocaine) (n=50)	Group II (EMLA) (n=50)	p-value
Mean age (years)	22.1±1.5	22.1±1.5	0.86
Parity	1	1	-
Literacy	42 (84%)	46 (92%)	0.43
Gestational age(weeks)	38.9±1.04	38.9±1.27	0.93
Haemoglobin (gm%)	9.47±1.0	9.2±1.07	0.19
Complications during pregnancy	14(28%)	12(24%)	0.81
Birth Weight (kg)	2.6±0.34	2.7±0.38	0.15
One minute APGAR Score ≥	49(98%)	48(96%)	0.55

Table 2. Pain scores, additional analgesic requirement and patient satisfaction in the study

Pain Score	Group I (lignocaine) (n=50)	Group II (EMLA) (n=50)	p-value
0-3(Mild)	12(24%)	14(28%)	0.819
4-6(Mod)	37(74%)	35(70%)	0.823
7-10(Severe)	01(2%)	01(2%)	1
Mean pain score ± SD	4.14±1.0	4.3±1.28	0.48
Additional analgesia	9 (18%)	13 (26%)	0.46
Patient satisfaction	39 (78%)	47 (94%)	0.04

Discussion

This trial has compared the effectiveness of topical lidocaine-prilocaine cream (EMLA) and lignocaine (1%) infiltration in alleviating pain during episiotomy repair. Only one study has compared the two drugs for pain relief during this procedure[6]. Franchi et al carried out a randomised controlled trial in which the effectiveness of topically applied lidocaine-prilocaine (EMLA) cream was compared to that of the local anaesthetic mepivacaine (1%) infiltration in 61 women with either an episiotomy or perineal laceration for providing pain relief during perineal suturing. Women of the EMLA group had a mean pain score of 1.7±2.4 in comparison to 3.9± 2.4 (p=0.0002) in the mepivacaine group of the study. The authors concluded that EMLA cream is an effective and satisfactory alternative to local anaesthetic infiltration during perineal repair[6].

EMLA cream provides analgesia by the release of two amide anesthetics, lidocaine and prilocaine into the epidermal and dermal layers before penetrating the underlying muscles. Inhibition of inward flow of sodium ions through the nerve membranes hampers the conduction of nerve potential along the neurons. The duration of action of the cream is dependent on the dose and duration of contact with skin under the occlusive dressing, with improved pain scores noted with increased application time[7]. Depth of anaesthesia depends on contact time and the effect reaches a maximal depth of 3 mm after a 60-minute application and 5 mm after a 120-minute application[6]. As the mean application-to-delivery interval was 48.02±11.64 minutes and the maximum time of cream application in the present study was 70 minutes, the maximum penetration of 5 mm was unlikely to have been reached. For this reason, EMLA cream may be less active on the perineal muscular layers than local infiltration of lignocaine. This lack of deep penetration may have contributed to the clinically insignificant but higher requirement of additional analgesia in group II of the study. Of those women who required additional analgesia, more women from group II exhibited satisfaction after the additional lignocaine infiltration suggesting reduced needle anxiety and pain at the time of infiltration in this study.

Typically, for the topical anaesthetic creams, the systemic blood levels achieved are well below the concentrations that cause toxicity. If 60 g of EMLA cream is placed on a 400-cm^2 area for 4 hours, the peak blood levels of lidocaine and prilocaine will be 1/20th and 1/36th of the toxicity level, respectively[6]. Methemoglobinemia may occur in infants younger than 3 months of age who have been exposed to high doses of EMLA cream for prolonged periods[8]. However, young adults, those with G6PD deficiency and those on oxidizing drugs like antimalarials and sulfonamides may also be at increased risk of development of methaemoglobinemia with use of EMLA cream[9]. Mild and transient localized reactions, generally in the form of blanching and erythema consequent upon peripheral vasoconstriction have been reported after treatment with EMLA cream, but no serious reactions were ascribed to the cream in various studies. Overdose of the infiltrated local anaesthetic, usually caused by inadvertent intravascular injection may result in nausea, vomiting, dizziness, cardiovascular collapse and neurotoxicity. A molded head in the occipitoposterior position may predispose to inadvertent direct injection of the local anesthetic agent directly into fetal scalp[10]. In this trial, there were no intrapartum or postpartum complications including nausea, dizziness, local irritation, itching and redness, postpartum hemorrhage or any neonatal transfer to intensive care.

Conclusion

EMLA cream appears to be a safe, highly satisfactory and easy-to-use agent with comparable efficacy to local lignocaine perineal infiltration for episiotomy repair. The agent is better tolerated as it reduces needle anxiety and painful injections. Although low numbers in the study are a limitation, the authors suggest larger randomized trials with sample sizes of more than 384 cases (considering an average 40% rate of episiotomy in India and an allowable error of 5%).

Conflict of interests: The authors declare no conflict of interest.

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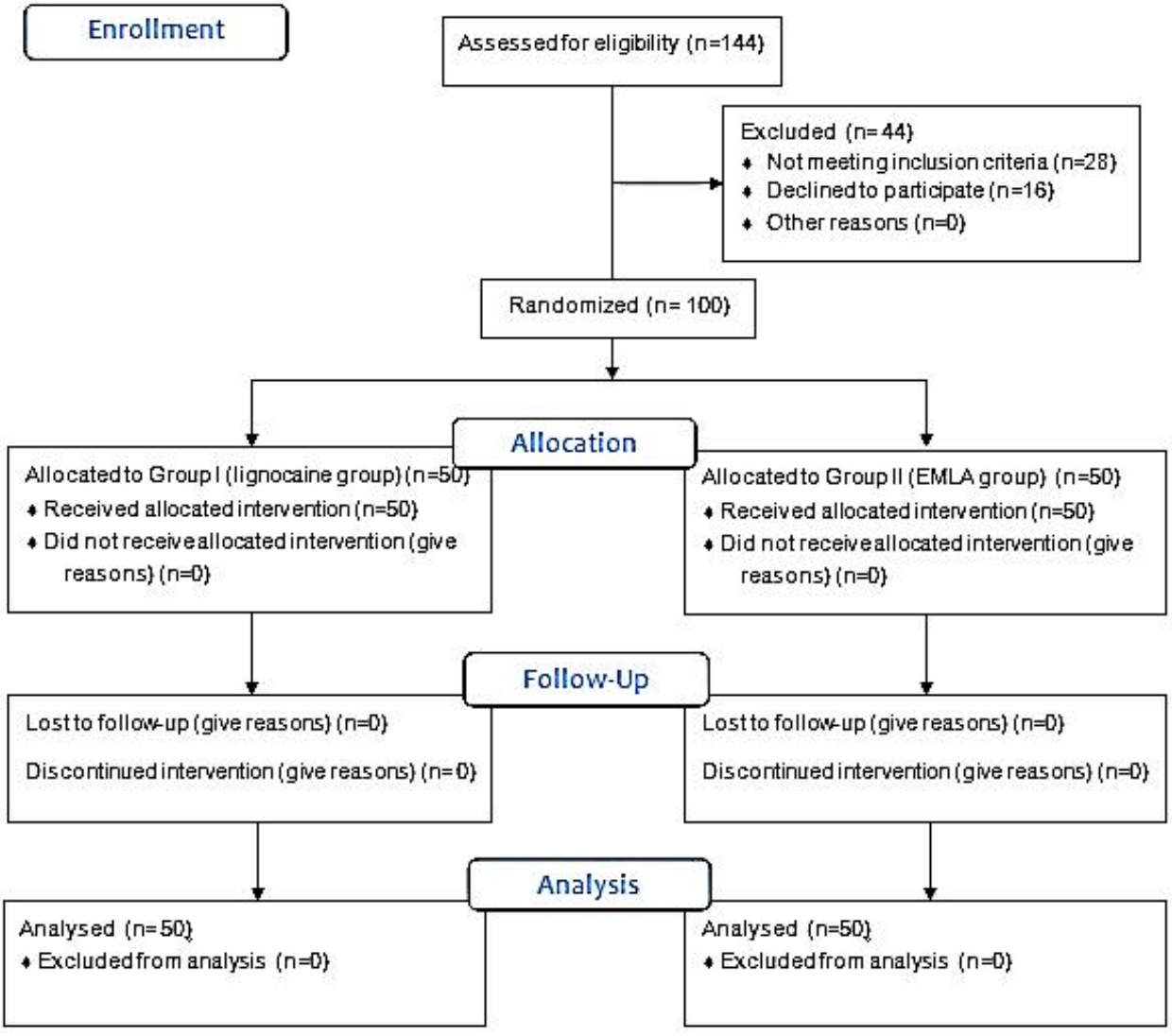

Figure 2. CONSORT 2010 Flow Diagram: topical lidocaine- prilocaine cream versus lignocaine infiltration for episiotomy repair