Research Article

Comparison of Efficacy of Lignocaine Jelly versus Lignocaine Injection during Perineum Repair in Normal Vaginal Delivery

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Abstract

Background: Normal vaginal delivery is frequently associated with perineal trauma that can be iatrogenic (episiotomy) or spontaneous. Episiotomy is the most common surgical procedure in obstetrics being performed in approximately 20% of deliveries

Objective: To compare the efficacy of lignocaine Jelly versus lignocaine injection during perineum repair after episiotomy in normal vaginal delivery.

Methods: This study was carried out at Department of Obstetrics & Gynecology, Shalamar Hospital, Lahore during September 2020 - Feb 2021. For this randomized control trial, a total of 160 women fulfilling selection criteria were recruited for study from labour room. Informed consent was obtained from each case. Women were then segregated in group A& B and treatment was randomly allotted using lottery method, while in group A 2% lignocaine Jelly was applied on their perineum during active phase of labour at 8-9 cm cervical dilatation, before estimated time of one hour pre delivery. Women in group B were administered 10 ml of 1% lignocaine injection locally at the proposed site of episiotomy just before crowning.

Results: The average ages of the cases among Group-A i.e. Lignocaine Jelly group and Lignocaine injection group (group-B) was 26.20 ± 3.32 years and 26.46 ±3.47 years respectively. The mean gestational age in Lignocaine Jelly group was 38.65 ± 0.90 weeks and in Lignocaine injection group was 38.67 ± 0.87 weeks. The mean BMI in Lignocaine Jelly and injection group was 26.70 ± 1.39 and 26.46 ± 2.20 respectively. Average pain score observed in Lignocaine Jelly was 3.58±1.06, whereas in Lignocaine injection group was 4.39 ± 1.26. There was statistically significant difference in average pain scores as the mean pain score in the Lignocaine Jelly group was lower compared with Lignocaine injection group (p-value≤ 0.001). In Lignocaine Jelly group 77(96.2%) females were satisfied while in Lignocaine injection group 68(85%) cases were satisfied, higher satisfaction rate was seen in lignocaine Jelly group, p-value (0.015)

Conclusion: Women to whom lignocaine Jelly was applied before episiotomy had less mean VAS Pain Score and higher satisfaction rate during perineal repair than women who were given lignocaine injection for perineal repair. So lignocaine Jelly can be used as a good alternative of local infiltration of lignocaine injection, in term of less pain, less adverse effects and more patient satisfaction during perineal repair of birth process.

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Keywords | Vaginal delivery, Episiotomy, lignocaine Jelly, lignocaine injection, Pain, satisfaction.

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Introduction

Normal vaginal delivery is frequently associated with perineal trauma that can be iatrogenic (epi-siotomy) or spontaneous.[1] Episiotomy is the most common surgical procedure in obstetrics

being performed in approximately 20% of deliveries. Literature shows episiotomy performed during second stage of labour to facilitate delivery of presenting part of fetus is asso-ciated with significant maternal discomfort in immediate as well as in late post partum period in the form of super-ficial dysparnuea and chronic discomfort in perineal area.[2,3,4] The study of pain relief during episiotomy repair is yet lacking and looking for an ideal analgesia as it is a common belief by health care professionals and community that pain during episiotomy and perineal repair is an unavoidable component of labour which mother has to bear. Every woman has fear of pain during labour especially of episiotomy being performed during 2nd stage of the labor is among commonest reasons of increasing cesarean section rate due to maternal wish to avoid pain of episiotomy and perineal repair. Several methods have been used to achieve analgesia and alleviate pain during second stage of labour and to perform episiotomy and for perineal repair like epidural analgesia, saddle block, Pudendal block, and local infiltration of 1% lidocaine. Some non-pharmacological methods have also been used for pain relief in second stage of labour and to perform episiotomy and repair like application of hot or cold massage at perineal area but are usually inadequate.[5,6,7] Epidural analgesia is not available in every setting, needs highly skilled person to administer it and very close maternal and fetal monitoring during labour. Moreover if a patient has already epidural, the dose is needed to be topped up before the episiotomy and it has its own pros and cons. Pudendal block is although an effective method of analgesia, however it is technically difficult to administer, requiring long needle to infiltrate 10 ml of either 0.5% bupivacaine or 1% lidocaine. More expertise is required for administration of Pudendal block with accurate knowledge of local anatomy and is associated with risk of vaginal injury, failure of block and formation of vaginal hematoma. Another traditional method is local infiltration by 10ml of lignocaine 1% injected into the area of episiotomy. Local infiltration is also associated with local discomfort, needle prick pain and local swelling at area of infiltration causing difficulties in skin to skin approximation of perineal injury. So new non invasive methods are being in search to reduce maternal discomfort during perineal repair which are easier to administer. Local application of lignocaine gel is already being in use in different modalities of medicine as well as in few studies it has been used as an alternative of local infiltrate for perineal repair with controversial results.[3,10,13] Moreover no study has already been done on local population regarding this mode of analgesia for perineal repair. Given the scarcity of available local literature, we aim to compare outcomes of lignocaine Jelly compared to lignocaine injection for perineum repair among females who underwent normal vaginal delivery (NVD) in our population in terms of mean pain score degree of patient satisfaction and adverse effects.

Methods

This Study was done at Department of Obstetrics & Gynecology, Shalamar Hospital, Lahore during September 2020 - Feb 2021. For this randomized control trial, a total of 160 women fulfilling selection criteria were recruited for study from labour room. Sample size of 160 cases; 80 cases in each group is calculated with 80% power of test, 5% level of significance and taking expected percentage of satisfaction i.e. 94% with lignocaine cream and 78% with lignocaine injection during perineum repair in normal vaginal delivery.[14]

Women in age category of 18-40 years and gestational age above 37 weeks as well as primigravida who underwent NVD with perineal repair after episiotomy were included. Women with twin pregnancy, presenting with full dilatation at time of presentation and obese females (BMI>30 kg/m^2) were excluded from the study. Data was collected after taking approval letter from the Institutional Review Board (IRB) of mentioned above hospital and informed consent from all patients. After taking basic demographics of patients e.g. age, parity, BMI, gestational age etc., the women were then segregated in group A & B and treatment was randomly allotted using lottery method, while in group A 2% lignocaine Jelly was applied on their perineum during active phase of labour at 8-9 cm cervical dilatation, before estimated time of one hour pre delivery. In group B, just before crowning perineal infiltration of 10ml of 1% lignocaine injection was done. Then females were followed-up till delivery. Episiotomy was performed in both groups and repaired by researcher herself/ post graduate trainee. Women were observed for pain and discomfort during perineal repair and after 2 hours of delivery, females were asked for perineal pain by using visual analog scale (VAS) ranging from 1-10,

where 1 indicates minimum and 10 worst possible pain experienced by the patient.

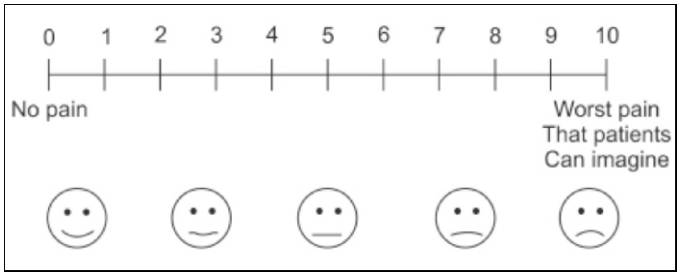

Figure 1: *Visual Analog Scale*

Then females were shifted in post-delivery wards and were followed-up there for 12 hours. After 12 hours, they were asked at the time of discharge for satisfaction of procedure. Satisfaction was labeled if both of the following conditions are fulfilled:

a. I will prefer to opt same in the future if need arises.

b. I recommend it as a preferred method to others as well.

SPSS v. 21.0 was used for purpose of data entry and analysis. Mean and standard deviation was applied for numeric data e.g. age, gestational age, BMI etc. whereas frequency and percentages were given for categorical data eg. Gender and satisfaction. Independent sample t-test was used to compare mean pain scores and chi-square test was used for association of satisfaction among the groups. Stratification for age, parity, gestational age, education and BMI was done and post-stratified chi square test was used taking p-value <0.05 as significant.

Results

The average ages found among cases in Lignocaine Jelly group and Lignocaine injection group was 26.20 ± 3.32 years and 26.46 ±3.47 years. Moreover, the average gestational age in Lignocaine Jelly group was 38.65 ± 0.90 weeks and in Lignocaine injection group was 38.67 ± 0.87 weeks. The mean BMI in Lignocaine Jelly and injection group was 26.70 ± 1.39 and 26.46 ± 2.20 respectively. So both groups were similar in all their demographic features like age, gestational age, BMI and parity. The mean pain in Lignocaine Jelly group was 3.58 ± 1.06 and in Lignocaine injection group was 4.39 ± 1.26. The mean pain was significantly lower in Lignocaine Jelly when compared with Lignocaine injection, p-value ≤ 0.001. In Lignocaine Jelly group 77 (96.2%) females were satisfied while in Lignocaine group 68(85%) cases were satisfied, the Statistically higher satisfaction level was found in lignocaine Jelly group, p-value = 0.015.

Table 1: *Demographic Features*

	Lignocaine Cream	Lignocaine Injection
Mean Age	26.20 ± 3.32 years	26.46 ±3.47 years
Mean Gest Age	38.65 ± 0.90 weeks	38.67 ± 0.87 weeks.
Mean BMI	26.70 ± 1.39 Kg/m^2	26.46 ± 2.20 Kg/m^2

Table 2: *Descriptive statistics of pain (VAS) in both groups*

	Study groups	Mean	S.D	Min	Max
VAS Pain Score	Lignocaine Cream (n=80)	3.58	1.06	2	7
	Lignocaine Injection (n=80)	4.39	1.26	2	8
	Total (n=160)	3.98	1.23	2	8

• t-test = -4.41 , p-value<0.001

Table 3: *Comparison of satisfaction of subjects in both groups*

		Study groups		Total
		Lignocaine Cream	Lignocaine Injection	
Satisfaction	Yes	77(96.2%)	68(85.0%)	145(90.6%)
	No	3(3.8%)	12(15.0%)	15(9.4%)
Total		80(100.0%)	80(100.0%)	160(100.0%)

• Chi-square test = 5.95, p-value = 0.015

Discussion

Pain and discomfort in perineal area resulting from episiotomy is one of the most common unpleasant experiences of women undergoing vaginal birth. Since long time analgesia being given to perform and repair episiotomy is by local infiltration of lignocaine/lidocaine at the site of episiotomy just before crowning of presenting part. At the injection site local anesthetics act by blocking nerve conduction by blocking sodium channel which are involved in depolarization and conduction of nerve impulse and hence cause temporary loss of sensory sensation. Perineal infiltration of local anesthetics causes needle prick pain, burning sensations and tissue swelling that can cause difficulty in correct identification of anatomical structures and wound approximation.[8,9] It

can lead to suboptimal and unsightly repair of tissues being cut during episiotomy. Recent there is an emergence of using topical aneasthesia available as ointments and gel replacing local injections to provide local anesthesia. These modes of aneasthesia gives instant pain relief by acting upon the peripheral sensory nerves as well as the tissues around these.[10] These are being used in different modalities of medicine to provide effective local anesthetic effect with minimal or almost no systemic absorption. So topical applications are being safe, easy to use and effective.[11] EMLA is a Lidocaine prilocaine Jelly which is an oil/water emulsion which has an oil phase consisting of mixture of 2.5% prilocainein and 2.5% lidocaine a ratio of 1:1 by weight. Analgesic effect produced by EMLA is achieved after an hour of application of topical application of gel. Maximum analgesic effect is seen with up to 120 minutes of application. Absorption from genital mucosa is rapid with onset of action within 5-10 minutes. Use of EMLA in minor gynecological procedures as, intrauterine device/Mirena insertion, hysterosalpingography for tubal pregnancy and office hysteroscopy has been studied extensively with proved analgesic effect, but only a few studies are available in literature regarding its use in perineal trauma repair and these have conflicting results.[12] Few studies have shown it to be a good substitute to perineal infiltration of inject able anesthetics.[13] Use of topical products such as sprays, gels, creams and ointments has been reported by other medical specialties as good alternatives to injectable anesthetics. Several benefits of using topical anesthetic agents are that they have a local effect without significant systemic absorption, ease of use, and they can be used by the patient herself.[15]

A randomized clinical trial was conducted by Duhan et al on 100 primigravida women divided in two groups (50 in each group) at term with singleton healthy pregnancies.[14] One group was administered with 10ml of 1% lignocaine just before crowning, at the perineal infiltration whereas the other group received application of topical Jelly on perineum at the 8 to 9 cm cervical dilatation at the time of labour and well before crowning. Like ours, VAS scale was used in this study too and was assessed using independent sample t-test for mean difference in pain, and chi square was used for assessment of patient satisfaction and the need for additional analgesia . This study showed that average pain score for 1st group was 4.14±1.0 and for the 2nd group was 4.3±1.28 with an insignificant statistical difference i.e. p=0.4878. Additional analgesia was required in 18% of women from 1st and 26 % from 2nd group with another insignificant association (p=0.46). Moreover, in group 1, 78% and in group 2, 94% women were satisfied with used agent (p=0.04).[15] Hence Duhan et al concluded that due to inadequate skin penetration EMLA Jelly was lesser effective on the perineal musculature compared to local lignocaine therefore, requiring more analgesia in 2nd group. They concluded that for the repair of episiotomy EMLA Jelly has a comparable efficacy to local infiltration of lignocaine injection. EMLA is shown to have good tolerability against needle prick fear and anxiety and is deemed safe, easy to use and has higher satisfaction.[6] Another study conducted by Kargar R at al.[16] showed that mean pain score was 4.1±2.5 with lignocaine ointment and 4.3±2.2 with lignocaine injection (p=0.730), satisfaction was achieved in 95% women with lignocaine ointment and 91% with lignocaine injection (p=0.681).[7] In current study we found that the mean pain in Lignocaine Jelly was 3.58±1.06 and in Lignocaine injection group was 4.39 ±1.26. The mean pain was significantly lower in Lignocaine Jelly when compared with Lignocaine injection, p-value ≤ 0.001. Moreover in current study in Lignocaine Jelly group 77(96.2%) females were satisfied while in Lignocaine injection group 68(85%) cases were satisfied, hence there was more satisfaction rate in lignocaine Jelly group statistically i.e. p-value= 0.015. The current study is novel in our local body of knowledge where both these drugs have been compared In our study two patients in lignocaine injection group developed local edema and one complained of light headedness and dizziness, however none of the patient showed adverse effects like difficult breathing, ringing in ear or chest pain etc .While no adverse effect was observed in group B who received lignocaine local topical lignocaine gel .

Conclusion

Women who were given lignocaine Jelly had less mean pain score and higher satisfaction during perineum repair after episiotomy in normal vaginal delivery as compare to lignocaine injection.

Ethical Approval: The Institutional review board approved the study vide letter No. Ref: SMDC-

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

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Authors' Contribution:

SF: Concept, design and execution of study,
SR: Supervised all activities of study, revising manuscript and final approval
ST: Methodology and discussion writing,
MR: Data analysis and interpretation, revised the manuscript critically, proof reading
DM: Concept, design and execution of study,
MU: Concept, design and execution of study,

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