

The efficacy of 2% Lidocaine gel in pain relieving of episiotomy: A double-blind randomized trial

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ABSTRACT

Objective: Episiotomy is the most common obstetric surgical and discomfort and pain is a common experience for all women exposed to episiotomy. This study was performed to investigate the efficacy of lidocaine gel 2% in pain relieving after episiotomy.

Methodology: In a randomized, double-blind, placebo-controlled trial, 150 women who had episiotomy were selected and received 5cc lidocaine gel 2% or a placebo every four hours after episiotomy repair. Then pain ratings were recorded before the administration of the drugs and at 6 and 12 hour after the first dose, according to a numerical rating scale. Data were analyzed using the unpaired t- test, and the Pearson (χ^2) test. A P value of less than .05 was considered statistically significant.

Results: Women using lidocaine gel had lower average pain scores, although this only reached statistical significance at 12 hours after delivery ($p=0.009$). Mean pain score at this time was 2.63 ± 2.01 in lidocaine group and 3.6 ± 2.4 in placebo group. Also there was a significant difference between two group in consumption of analgesia in postpartum ($P=0.034$). There weren't any adverse effect with lidocaine gel uses.

Conclusions: This study suggested that lidocaine gel is a safe and simple drug that may be effective for episiotomy pain relief on first day of postpartum.

KEY WORDS: Lidocaine, Pain, Episiotomy.

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INTRODUCTION

Episiotomy is the most common obstetric procedure discomfort and pain is a common experience for all women exposed to episiotomy.¹ In past hundred years, episiotomy rates has decreased in many countries by more than 30 percent while in developing countries including Asian countries it is more than 90 percent.² This surgical procedure is largely utilized about more than 60 percent In Italy and 62.5 percent in America.^{3,4} In Iran also this procedure is used very largely and in a study in Tehran the episiotomy rate was about 88 percent.⁵

Complications of after episiotomy repair are perineal pain, irritation, edema and post coital pain. Perineal pain is the most maternal complaint.⁶ Post partum hemorrhage and urine retention are physical problems due to perineal pain. Also perineal pain affects early maternal - newborn contact and care of newborn later.⁷

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Perineal pain has been found to be most common and severe on the first day after delivery, with a shift toward less pain with increasing time.⁸ About 92-97 percent of women experiences perineal pain on the first day of postpartum.^{9,10} An estimated 20-25% of women continue to experience distress and discomfort for up to two weeks after birth and 10% of women suffer pain in the three months after childbirth.¹¹ Factors that may influence the severity of pain experienced include type of delivery, use of epidural analgesia, degree of perineal trauma, and type of suture material, neonatal birth weight and prolonged second stage.^{8,11,12}

Pain related to episiotomy and laceration in the immediate postpartum period has been traditionally treated with oral medications including nonsteroidals like ibuprofen, intravenous narcotics, epidural narcotics and local anesthetic spray. Other local measures include hazel compresses and warm sitz baths.¹² The application of local anesthetic preparations is uncommon, although they are inexpensive and easy to use.⁸ Lidocaine gel is a local anesthetic its application on the perineum in the second stage of labor has been shown to lessen pain perception in the immediate postpartum period. The advantages of using topical lidocaine include its localized action with negligible systemic absorption, ease of administration, and self-application by the patient.¹²

Several studies have highlighted the treatments available. Randomized, placebo-controlled trials conducted by Harrison and Brennan found a single dose of lignocaine 5 percent spray to be more effective in an aqueous rather than alcohol base and more effective than cinchocaine 2 percent for post episiotomy pain. They also found that aqueous lignocaine 5 percent spray was comparable to a single dose of mefenamic acid in terms of analgesic effect, each showing a significant improvement compared with the placebo. However, lignocaine proved to be faster acting and lasted approximately 3 to 4 hours.^{13,14}

In a randomized, double-blind, placebo-controlled trial Minassian and et al found topical application of 5% lidocaine ointment was not effective in relieving episiotomy or perineal laceration pain.¹²

A double-blind placebo controlled trial was conducted in a regional teaching hospital in the north-west of England. One hundred forty nine women who had sustained a first- or second-degree tear were received lignocaine gel or placebo. This study suggested that lignocaine gel may be effective on the second postpartum day.⁸

Results in a study in Iran showed that lidocaine gel was effective in relieving episiotomy pain at two hours

after delivery.¹⁵ Considering pain relief is a priority in post partum cares, we conducted this study to evaluate the efficacy of lidocaine gel in pain relieving of episiotomy or Perineal laceration.

METHODOLOGY

This randomized, placebo-controlled, double-blind study was conducted at the shabihkhani hospital affiliated with Kashan University of Medical Sciences in Iran. The study period extended from February to July 2007. Primiparous and multiparous women who had delivered vaginally with an episiotomy were recruited to the study. Exclusion criteria were history of adverse reactions to local anesthetics or lidocaine, cardiac disease, class C diabetes or more on the White classification, postpartum hemorrhage, and manual removal of placenta, instrumental delivery and neurological disease affecting the lower extremities.

Sample size calculations were based on the pilot study which found a mean Numerical Rating Scale (0-10) of 4.5 with standard deviation of 2.15. To detect a clinically significant reduction in pain scores from 4.5 to 3.5 (with a similar standard deviation), it was necessary to recruit 74 women to each trial arm (5% level of significance with 80% power).

Randomization was performed using a random number table. Each number on the table had a corresponding labeled lidocaine or placebo gel in the pharmacy. When a patient signed the consent, the ward midwife chooses the number on the random number table and sent them to the pharmacy where the corresponding gel was held. Patients and medical personnel, including the investigators, were blinded to the type of drug. Patients were randomized to receive either 2% lidocaine gel ($n_1=75$) or placebo gel ($n_2=75$). The placebo was a lubricating gel. Women were instructed to apply 5 ml of gel on the perineum and furchett every 4 hours up to 12 hours after delivery. The primary outcome was perineal pain at 6 hours post delivery and Secondary outcomes were perineal pain at 12 hours post delivery. The severity of Pain rated on a numerical rating scale from 0 (no pain) to 10 (worst pain ever) before the administration of the drugs and at 6 and 12 hour after the first dose. Ethical approval for the study was gained from university ethics committee. All patients signed an informed consent after delivery and before entering in the study.

Analysis of data was performed using the SPSS statistical package. Data were analyzed using the unpaired t- test, and the Pearson (χ^2) test. A *P* value of less than .05 was considered statistically significant.

RESULTS

During the study period, 450 women who gave birth at the shabihkhani hospital need to suture during childbirth due to episiotomy. Of the 250 women approached to participate in the study, while one hundred declined to join. All 150 women were included in the analysis, with 75 randomized to receive lidocaine gel and 75 to receive placebo. Study outcome data were available for 100% of women at 6 and 12 hours after birth.

The lidocaine and placebo groups were similar with respect to maternal age, parity, gestational age, nationality, educational level, neonatal birth weight, infant sex, type of episiotomy, duration of second stage of labor, labor induction and consumption of pethedin in labor (Table-I).

Results of the pain score analysis for the two groups are presented in Table-II and show that the mean and SD of pain score before drug uses in lidocaine and

placebo group was 3.3 ± 1.81 and 2.9 ± 2.03 respectively and there weren't any statistical differences between two groups ($P=0.22$). The mean and SD of pain score at 6 hours in lidocaine and placebo groups was 2.8 ± 1.7 and 3.2 ± 2.5 respectively but there wasn't any statistical differences between two groups ($P=0.23$). The mean and SD of pain score at 12 hours in lidocaine and placebo groups was 2.6 ± 2.01 and 3.6 ± 2.4 respectively and there was statistical differences between two groups ($P=0.009$).

In placebo group use of additional analgesia was more than lidocaine group, respectively 20% and 8% and there was a significant difference between two group in consumption of analgesia in postpartum ($P=0.034$). There weren't any adverse effect with lidocaine gel uses.

DISCUSSION

In this study the use of 2% lidocaine gel was shown more effective than placebo for perineal pain relief at 6 hours after delivery. However, a statistically significant benefit in terms of pain relief was found at 12 hours after delivery. Also there was a significant difference between two groups in consumption of analgesia in postpartum. No side effects were reported by women in the lidocaine group.

Collins et al used 2% lidocaine gel during the second stage of labor and showed that there was decreased pain perception in the immediate postpartum period.¹⁶ Harrison and Brennan's studies showed that 5% lignocaine spray was effective for the immediate relief of post episiotomy pain.¹³ Another study showed that use of 2% lidocaine gel at 30, 60, 90 and 120 minutes after episiotomy repair was effective for pain relief.¹⁵ Others showed that there wasn't any statistical differences between the mean of pain score in 2% lidocaine gel and 2% lidocaine injection groups, immediately, 30 and 60 minutes after episiotomy repair. They concluded that lidocaine gel is an effective method for pain relief after episiotomy.¹⁷ Minassian et al found that 5% lidocaine ointment wasn't effective for episiotomy pain in the first day of postpartum.¹²

Table I: Patient and perinatal characteristics.

Patient characteristics	Lidocaine	Placebo	P value
Maternal age (y)	24.5 ± 4.47	24.7 ± 5	NS
Gestational age (wk)	39.2 ± 1.4	39.3 ± 1.3	NS
Neonatal Birth Weight (gr)	3309 ± 442	3204 ± 453	NS
Second stage length (h)	0.81 ± 0.2	0.75 ± 0.1	NS
Parity			
Nullipara	46 (61.3%)	45 (60%)	NS
Multipara	29 (38.7%)	30 (40%)	
Education			
Under diploma	64 (85.3%)	62 (82.7%)	NS
Higher	11 (14.7%)	13 (17.3%)	
Nationality			
Iranian	65 (86.7%)	65 (86.7%)	NS
Afghan	10 (13.3%)	10 (13.3%)	
Type of episiotomy			
Mediolateral	63 (96.9%)	65 (98.5%)	NS
Median	2 (3.1%)	1 (1.5%)	
Infant Sex			
Boy	40 (53.3%)	35 (46.7%)	NS
Girl	38 (50.7)	37 (49.3%)	
Labor Induction			
Yes	50 (66.6%)	56 (74.7%)	NS
No	25 (33.4%)	19 (25.3%)	
Pethedin Consumption			
Yes	54 (72%)	56 (74.7%)	NS
No	21 (28%)	19 (25.3%)	

Table-II: Pain Score Analysis.

Pain score	Lidocaine (n=75)	Placebo (n=75)	P. value
Before Administration, Mean (SD)	3.3 ± 1.81	2.9 ± 2.03	NS
At 6 hr, Mean (SD)	2.8 ± 1.8	3.2 ± 2.5	NS
At 12 hr, Mean (SD)	2.63 ± 2.01	3.6 ± 2.4	0.009

Our findings are different from other researches. There may be several reasons for this, most importantly the difference in the eligibility criteria (such as parity), type of drug (such as spray or ointment) and timing of the intervention. For example in corkill et al research participants had perineal laceration and were between 24 and 72 hours post delivery⁸ and in Minassian et al study participants were between 24 and 48 hours post delivery and used 5% lidocaine ointment.¹² Inomidvar study participant was Primiparous and evaluated at 30,60,90 and 120 minutes after delivery.¹⁵

CONCLUSION

Our findings showed that lidocaine gel is more effective than a placebo in pain relieving due to episiotomy or second degree laceration, although this difference only reached statistical significance at 12 hours after delivery. Therefore lidocaine gel is a safe and simple drug that may be effective for episiotomy and laceration pain relief in first day of postpartum.

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REFERENCES

1. Cunningham FG, Gant NF, Leveno KJ, Gilstrap LC, Hauth JC, Wenstrom KD. Williams Obstetrics. (22th Ed), New York: McGraw-Hill. 2005: 435.
2. Abedian Z, Navabi Rigi Sh, Dadgar S, Esmaili H. Comparing the Effect of Colling Gel Pads and Ice Pack, after Episiotomy, on the Intensity of Perineal Pain. Iranian J Obstet Gynecol 2007;10(2):79-86.
3. Fyनेface-Ogan S, Mato CN, Enyindah CE. Postpartum Perineal Pain in Primiparous Women: A Comparison of Two Local Anaesthetic Agents. Nigerian J Medicine 2006;15(1):77-80.
4. Facchinetti F, Casini ML, Costabile L, Malavasi B, Unfer V. Diclofenac pyrrolidine versus Ketoprofen for the relief of pain from episiotomy: A randomized controlled trial. Acta Obstetrica Gynecologica Scandinavica 2005;84:951-955.
5. Rezazadeh A, Ghafari V. The prevalence of episiotomy and its adverse effects in Mirza Khochak Khan Hospital. Abstract Book of 3Th congress of obstetrics and gynecology. Tehran: Iran University of Medical Science Press 1997: 68.
6. Mahomad K, Grant A, Ashurst H, James D. The south mead perineal suture study: A randomized comparison of suture material and suturing techniques for repair of perineal trauma. Br J Obstet Gynecol 1989;96:1272-1280.
7. Henderson C, Macdonald S. Mayes' Midwifery. Edinburgh: Bailliere Tindall 2004:479-491.
8. Corkill A, Lavender T, Walkinshaw SA, Alfievic Z. Reducing postnatal pain from perineal tears by using lignocaine gel: A double-blind randomized trial. Birth 2001;28:22-27.
9. Macarthur AJ, Macarthur C. Incidence, severity, and determinants of perineal pain after vaginal delivery: A prospective cohort study. American J Obstet Gynecol 2004;191(4):1199-1204.
10. Andrews V, Thakar R, Sultan A, Jones P. Evaluation of postpartum perineal pain and dyspareunia- A prospective study European J Obstet Gynecol Reprod Biol 2008;137(2):152-156.
11. Dodd JM, Hedayati H, Pearce E, Hotham N, Crowther CA. Rectal analgesia for the relief of perineal pain after childbirth: A randomised controlled trial of diclofenac suppositories. Br J Obstet Gynecol 2004;111:1059-1064.
12. Minassian V, Jazayeri A, Prien S, Timmons RL, Stumbo K. Randomized trial of lidocaine ointment versus placebo for the treatment of postpartum perineal pain. Obstet Gynecol 2002;100:1239-1243.
13. Harrison RF, Brennan M. Evaluation of two local anesthetic sprays for the relief of post episiotomy pain. Curr Med Res Opin 1987;10:364-369.
14. Harrison RF, Brennan M. Comparisons of two formulations of lignocaine spray with mefenamic acid in the relief of post episiotomy pain: A placebo controlled study. Curr Med Res Opin 1987;10:375-379.
15. Omidwar SH, MirMohammali M. The efficacy of lidocaine gel on post episiotomy pain. Asrar J 2003;10:53-57.
16. Collins MK, Porter KB, Brook E, Johnson L, Williams M, Jevitt CM. Vulvar application of lidocaine for pain relief in spontaneous vaginal delivery. Obstet Gynecol 1994;84:335-337.
17. Seyedi Alavi GH, Kordi M, Yari F. Comparison between 2% lidocaine gel and 2% lidocaine injection on perineal pain during episiotomy. The Iranian J Obstetrics and Gynecology 1999;1:46-50.