

The Effect of Metoclopramide Addition to Lidocaine on Pain of Patients with Grades II and III Post-Episiotomy Repair

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ABSTRACT

Introduction: Episiotomy is the most common procedure used for dilatation of the vaginal opening for giving birth. Although episiotomy is associated with benefits for the mother, it may lead to short term and long term disabilities, including postpartum perineal pain that is secondary to perineal tearing.

Aim: The aim of this study was to investigate the effect of subcutaneous lidocaine compared with lidocaine and metoclopramide on pain after episiotomy.

Materials and Methods: In this clinical trial study, the patients (83 for control group and 83 for case group) with episiotomy Grades II and III were enrolled and were asked to express their postpartum episiotomy pain as a number, from zero (no pain) to 10 (severest pain) Visual Analogue Scale (VAS score) at 0, 30 minute, 1 hour, 2 hour, 4 hour, 6 hour and 12 hour postpartum. Patients at the second stage of labour (crowning) were assigned

to two groups: In the control group, 5 cc lidocaine 2% and in the case group, 5 cc lidocaine + 10 mg metoclopramide was injected for episiotomy. Then, the pain score was compared between the two groups. The data were analyzed by t-test and chi-square test with software SPSS version 20.0.

Results: Mean age of the women was 23.19±0.46 years in the control group and 23.96±0.58 years in the case group with no significant difference between the two groups ($p < 0.05$). The mean pain score in the control group was 3.54±0.71 and in the case group 2.93±0.91 at 30 minutes after the injection, with a statistically significant difference. At other intervals, postnatal pain scores in the case group was lower than those of the control group ($p < 0.05$).

Conclusion: Injection of metoclopramide with lidocaine is more effective than lidocaine alone for relieving the pain after episiotomy.

Keywords: Perineal pain, Plazil, Visual analogue scale (VAS)

INTRODUCTION

Episiotomy is a surgical incision for dilatation of the vagina entry to deliver the infant. The most common types of episiotomy are midline or mediolateral [1]. Mothers' fear of vaginal delivery, postpartum perineal pain, prolapse, and change in perineal anatomy that causes fecal incontinence lead to tendency toward elective caesarean section [2]. Lidocaine is a local, intermediate acting anaesthetic of amino acids with a moderate power, which is used for local anaesthesia with the maximum infiltration dose of 300 mg and duration of action 30-60 minutes [3]. Metoclopramide is a gastrointestinal stimulant and is used mainly as an antiemetic drug [4].

VAS is a tool to assess pain after painful procedures. According to this scale, the patient's pain score as the most severe pain as 10 and no pain as zero. This tool is to measure specifications or attitude towards pain subjectively. The evidence indicates that VAS is more expressive than discrete scales and can represent the real pain more efficiently [3-5].

Labour pain is one of the worst pain ever experienced by human [6]. A major cause of caesarean section is fear of labour pain and painful procedures such as episiotomy [7]. The efforts to manage and control post-episiotomy pain are made for various purposes [8]. Currently, lidocaine is normally used as an anaesthetic to repair episiotomy and also used in labour [5]. As metoclopramide has been demonstrated to exert analgesic effect and is administered intravenously, orally or subcutaneously after surgery [9-11], it can be used to control the pain due to episiotomy.

In the light of the postsurgical and analgesic effect of IV metoclopramide which has been already studied and demonstrated partially efficient, and the importance of vaginal delivery promotion described above, this study was conducted to compare the effect of

metoclopramide alongside lidocaine on pain relief after episiotomy repair with that of lidocaine alone which is being used routinely.

MATERIALS AND METHODS

This study was conducted between 21 April, 2014 and 22 July, 2014. In this double-blind clinical trial study, 166 patients (83 for control group and 83 for case group) referring to Hajar Hospital for childbirth and having episiotomy Grades II and III were enrolled and the necessary explanations regarding the procedures at delivery (the drugs injection in episiotomy) were given to them. For all the patients, labour induction or augmentation was done under the supervision of a gynaecologist to facilitate labour if necessary.

All the patients were given enema at the beginning of hospitalization and the urine was evacuated during delivery using Foley catheter. The episiotomy was mediolateral for all the patients. The patients with the tears beyond episiotomy were excluded as these tears are considered confounding. The inclusion criteria were nulliparity, term cephalic delivery with no previous problem, and episiotomy Grade II or III.

The exclusion criteria were tears of vagina, episiotomy or around the urethra beyond the episiotomy, use of vacuum and forceps at delivery, labour at Foley stage, susceptibility to plazil or developing plazil-induced extrapyramidal complications, withdrawal from study at any steps of the study and episiotomy Grade IV or I. If they filled out the written consent form, they were included into the study. The control group was administered with 5 cc lidocaine 2% + 2 cc distilled water. The case group was administered with 5 cc lidocaine 2% + 20 mg plazil. The administration was similar in the two groups.

For all the patients, mefenamic acid was orally administered to control uterine contractions, but the pain of episiotomy site was

exclusively investigated in this study, and the patients did not receive any analgesics in the following steps of the study.

The gynaecologist prepared and gave the anaesthetic to a gynaecology resident who was assigned to collect specimen from all the patients and recorded their names. Both the patients and the gynaecology resident were blinded to the administered drug till the completion of the study.

The patients who were found with exclusion criteria during the study were replaced with new patients to reach to the required sample size. In case and control groups, three and five patients had episiotomy Grade III, respectively. Other patients had episiotomy Grade II.

From case and control groups, seven and 10 patients were found with exclusion criteria, respectively. These patients were replaced with new patients with inclusion criteria.

The patients were asked to express their postpartum episiotomy pain as a number, and hence represent their status of pain from zero (representing no pain) to 10 (representing the most severe pain) (VAS score) at 0, 30 minute, 1 hour, 2 hour, 4 hour, 6 hour and 12 hour after childbirth.

The patients were transferred to flat delivery in the second stage of labour (crowning). In the control group, lidocaine 2% was subcutaneously injected and in the case group, 5 cc lidocaine 2%+10 mg metoclopramide was injected for episiotomy. After the completion of tears repair, the patients were asked to fill out a questionnaire for measurement of pulse rate, pain and blood pressure at the above intervals.

STATISTICAL ANALYSIS

The data on both groups were recorded and analyzed by the SPSS 16. Chi-square and t-test were used to compare the data of the two groups.

RESULTS

In this study, the mean age of the women was 23.19±0.46 years in the control group and 23.96±0.58 in the case group with no significant difference ($p<0.05$). Therefore, the two groups were matched for age [Table/Fig-1].

In this study, the pain score decreased in both case and control groups over time (at 0, 30 minute, 1 hour, 2 hour, 4 hour, 6 hour and 12 hour after childbirth) ($p<0.05$). In other words, both drugs contributed to relieving the pain and the pain relief increased overtime.

In addition, the comparison of pain scores at the intervals between the two groups indicated that the pain scores were significantly lower in the case group than the control group at all the intervals after delivery ($p<0.05$) [Table/Fig-2].

In this study, the mean systolic and diastolic blood pressure decreased in the women of both case and control groups at the intervals ($p<0.05$). In other words, both drugs contributed to decreasing the blood pressure. In addition, the comparison of pain scores at the studied intervals between the two groups indicated that the blood pressure (systolic and diastolic) reduced significantly in the case group compared to that of the control group at all the intervals after delivery ($p<0.05$) [Table/Fig-3].

The mean heart rate decreased in both case and control groups at the intervals ($p<0.05$). In other words, both drugs contributed to decreasing the heart rate and returning it to the normal level. In addition, the comparison of heart rate at the studied intervals between the two groups indicated that the heart rate was significantly lower in the case group than the control group at all intervals after delivery ($p<0.05$). This can be due to further reduction of pain [Table/Fig-4].

In addition, the mean one and five minute Apgar score was 7±0.5 and 9±0.5 respectively for born infants in this study and mean respiratory

rate of the women (14±2) breaths per minute at the studied intervals was not different between the two groups of study.

No patients were reported to develop complications, including erythema, wheal, dizziness, drowsiness, and vertigo and extrapyramidal complications.

DISCUSSION

Since several studies have been conducted to investigate pain control and analgesic effects of subcutaneous administration of metoclopramide, and lidocaine at episiotomy site. Therefore, in this study we investigated metoclopramide addition to lidocaine to increase analgesic effect.

Groups	Mean (Standard Deviation) Age (Year)	p-value
Control (lidocaine injection)	23.19±0.46	0.302
Case (lidocaine+metoclopramide injection)	23.96±0.58	

[Table/Fig-1]: Age of participants in the two groups.

A study investigated the intradermal injection of lidocaine and epinephrine in 96 women for spontaneous repairs of tears at delivery and found that the effect of combined local anaesthetic and vasoconstrictors was more remarkable [3].

Safavi M et al., study indicated that addition of 10 mg metoclopramide to lidocaine for intravenous local anaesthesia caused relief of intraoperative pain and reduction in postoperative analgesic use until 24 hours after the surgical procedure in the patients with trauma [4], which is consistent with the present study.

Pain Scores at Different Postpartum Intervals	Control Group (Lidocaine Injection, n:80)	Case Group (Lidocaine + Metoclopramide Injection, n:80)	p-value*
Immediately after childbirth	0.71±3.97	0.92±3.68	0.035
30 minute after childbirth	0.71±3.54	0.91±2.93	≤0.001
1 hour after childbirth	0.79±3.09	0.72±2.41	≤0.001
2 hours after childbirth	0.76±2.54	0.66±2.13	≤0.001
4 hours after childbirth	0.56±2.14	0.62±1.76	≤0.001
6 hours after childbirth	0.67±1.89	0.48±1.35	≤0.001
12 hours after childbirth	0.61±1.46	0.50±1.14	≤0.001
p-value**	≤0.001	≤0.001	

[Table/Fig-2]: Determination and comparison of pain scores at different postpartum intervals in the two groups of study.

*Mann-Whitney test, ** Friedman test

Fujii Y et al., investigated the effect of IV injection of propofol, and lidocaine + metoclopramide in 90 patients, and demonstrated that combined injection of lidocaine and metoclopramide had greater effect than lidocaine alone on pain relief ($p<0.05$) [9].

This may indicate that simultaneous administration of lidocaine and metoclopramide can be associated with fewer drug interactions. Fujii Y et al., compared the effects of IV propofol and lidocaine + metoclopramide on postoperative pain relief, and demonstrated greater therapeutic effect of lidocaine + metoclopramide. Moreover, Fujii Y et al., reported that combined lidocaine and metoclopramide had no drug interaction [10].

Gibbs RD et al., studied the effect of metoclopramide alongside morphine after tubal ligation surgery through laparoscopic method to decrease the administration of morphine in patients and demonstrated that preoperative metoclopramide administration caused decrease in postsurgical opioid use [11].

Turan A et al., reported lidocaine local injection as a simple, cost-effective and reliable approach to local anaesthesia in minor emergency surgeries [12].

In addition, some studies have shown lidocaine alone to be an inappropriate anaesthetic in emergency because of certain reasons such as slow onset of sensory and motor block, poor muscle relaxation, local anaesthetic toxicity, tourniquet pain and short duration of postoperative pain [13,14].

Blood Pressure at Different Postpartum Intervals	Systolic Blood Pressure		p-value*	Diastolic Blood Pressure		p-value*
	Control Group	Case Group		Control Group	Case Group	
Immediately after childbirth	5.49±111.06.	107.13±6.97	≤0.001	7.01±68.67	6.75±65.75	≤0.006
30 minutes after childbirth	5.61±110.38	6.82±106.25	≤0.001	5.95±68.31	6.33±65.19	≤0.001
1 hour after childbirth	6.10±107.31	5.49±103.69	≤0.001	5.95±65.81	5.06±63.06	≤0.001
2 hours after childbirth	5.26±105.25	4.96±102.69	≤0.001	4.95±64.13	4.74±61.94	≤0.001
4 hours after childbirth	5.39±104.75	4.57±102.44	≤0.003	4.68±63.69	3.97±61.69	≤0.001
6 hours after childbirth	5.30±141.9	102.13±4.55	≤0.007	4.85±63.56	4.15±61.81	≤0.007
12 hours after childbirth	5.16±103.56	4.21±101.75	≤0.014	4.79±63.13	3.79±61.31	≤0.003
p-value**	≤0.001	≤0.001		≤0.001	≤0.001	

[Table/Fig-3]: Determination and comparison of blood pressure at different postpartum intervals in the two groups of study.

*Mann-Whitney test, ** Friedman test

Blood Pressure at Different Postpartum Intervals	Control Group (Lidocaine Injection, n: 80)	Case Group (Lidocaine + Metoclopramide Injection, n:80)	p-value*
Immediately after childbirth	3.57±85.19	4.53±82.94	≤0.002
30 minute after childbirth	3.53±84.25	4.28±82.66	≤0.017
1 hour after childbirth	3.40±82.99	3.59±81.34	≤0.001
2 hours after childbirth	3.05±81.95	3.50±80.66	≤0.001
4 hours after childbirth	3.01±80.99	2.99±79.64	≤0.002
6 hours after childbirth	2.83±80.40	2.88±78.94	≤0.001
12 hours after childbirth	2.81±79.89	3.51±78.11	≤0.001
p-value **	≤0.001	≤0.001	

[Table/Fig-4]: Determination and comparison of heart rate at different postpartum intervals in the two groups of study.

*Mann-Whitney test, ** Friedman test

In some studies, addition of certain drugs like tramadol, opioids, muscle relaxants, dexmedetomidine and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) to parenteral lidocaine have been recommended to enhance the quality of blocks, prolongation of analgesia after the procedures and relief of tourniquet pain [15]. Analgesic effect of metoclopramide has been recently investigated. Metoclopramide which is known as an antiemetic agent can exert a weak local anaesthetic effect [16].

The findings of the present study suggested that pain relieved in both control (lidocaine injection) and case (lidocaine injection alongside metoclopramide) groups over time ($p < 0.05$); in other words, both drugs were effective in relieving pain and the effect increased over time.

The results of the present study indicated that, the pain scores were significantly lower in the group administered with lidocaine alongside metoclopramide than the control group (who were injected with lidocaine) at all the intervals after delivery ($p < 0.05$). For example, the mean pain score in the control group (lidocaine injection) was 3.54 ± 0.71 and in the case group 2.93 ± 0.91 , 1/2 hour after injection, with a statistically significant difference.

In a study, the potential mechanism of the analgesic effect of metoclopramide was reversible blocking of the stimulation path of peripheral nerves through affecting neuron's stimulative membrane [17]. Liaw WJ et al., compared the pain-relieving effects of IV metoclopramide and lidocaine in propofol injection and demonstrated that both drugs had similar effects on pain control. Moreover, they indicated that metoclopramide effect on pain relief was comparable to axetil flurbiprofen [17]. In another study, IV metoclopramide considerably relieved the pain compared to placebo in nasogastric tube insertion [18]. The analgesic effect of metoclopramide on renal colic has been confirmed, as well [19].

In another study by Pang WW et al., study, the effect of IV injection of tramadol or metoclopramide was compared with placebo in 10 volunteer patients. Each patient was injected with 0.5 cc tramadol, 5 mg metoclopramide, 5 mg lidocaine and 0.5 ml normal saline at separate anterior forearm surfaces. The findings demonstrated

reduction in the sense of tactile, cold and pinprick was similar 15 minutes after injection of tramadol + metoclopramide and lidocaine 1% ($p < 0.1$) [20].

The present study indicated that the blood pressure (systolic and diastolic) reduced significantly in the group administered with lidocaine + metoclopramide compared with the control group (lidocaine alone) at all postpartum intervals ($p < 0.05$).

Altogether, administration of both lidocaine and metoclopramide is more effective in relieving the pain after episiotomy than lidocaine alone.

In the light of the importance of vaginal delivery promotion and the results of this study, it is recommended to relieve the pain after episiotomy with metoclopramide injection alongside lidocaine. In addition, further research is needed to investigate the side effects of the combination of these two drugs.

LIMITATION

The limitations of this study were that all of the participants were nulliparous, some of women discharged after delivery with consent before the completion of the study and replacement with new samples, some women did not volunteer to participate in the study. This study was double-blind, and that only one person did sampling.

CONCLUSION

Based on the results of this study, subcutaneous injection of metoclopramide and lidocaine is effective in reducing postpartum episiotomy pain ($p < 0.05$).

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Date of Submission: **Dec 19, 2015**

Date of Peer Review: **Jan 08, 2016**

Date of Acceptance: **Jun 07, 2016**

Date of Publishing: **Apr 01, 2017**

FINANCIAL OR OTHER COMPETING INTERESTS: None.