Original Article

Comparison of Wound Infiltration of Lidocaine with and without Ketorolac on Episiotomy Wound for Pain Management: A Randomized Double-Blinded Controlled Trial

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Background: Episiotomy is performed in almost all spontaneous vaginal deliveries in Thailand. It is known to cause moderate postpartum pain which has a negative effect on maternal quality of life. Lidocaine is used for relieving pain during the suturing. Local anesthesia and NSAIDs such as ketorolac, are often used in many pain relieving procedures with positive results. The purpose of this study is to investigate the pain reducing efficacy of combination of ketorolac and lidocaine during episiotomy comparing with lidocaine alone.

Materials and Methods: Two hundred and forty healthy singleton parturients who had undergone spontaneous vaginal delivery at the delivery room of Thammasat University Hospital were recruited. Participants were randomly assigned into two groups using systemic random sampling. The allocation was assigned in sealed envelopes. First half is ketorolac group receiving 1% lidocaine with 0.3% ketorolac (10 ml consisted of 100 mg and 30 mg of lidocaine and ketorolac tromethamine, respectively). Lidocaine group received 1% lidocaine. Primary outcomes were pain score assessed immediately after birth 2, 6 and 24 hours postpartum by visual analog scale (VAS). Postpartum complications were evaluated for secondary outcome.

Results: No statistical differences in demographic data and clinical characteristics were found in both study and control groups. Mean VAS of the study group was statistically lower than that of the control group after perineal repair (3.32 vs. 4.43; $p<0.001$), 2 hours (3.08 vs. 4.08; $p<0.001$) and 6 hours postpartum (2.52 vs. 3.63; $p<0.001$), respectively. Four cases in each group had postpartum hemorrhage. No case underwent peripartum hysterectomy.

Conclusion: Infiltration of ketorolac with lidocaine on episiotomy wound significantly reduced pain after perineal repair, 2 hours and 6 hours postpartum compared with lidocaine alone. No significant differences in side effects and postpartum complication were reported in both groups.

Keywords: Ketorolac, Lidocaine, Episiotomy, Local infiltration analgesia

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Episiotomy is a surgical procedure during the second stage of vaginal delivery to widen the vaginal outlet[1]. Although it is not routinely performed during vaginal delivery worldwide[2], it is performed in almost all spontaneous vaginal deliveries in Thailand. Episiotomy is known to cause moderate postpartum pain which has a negative effect on patient's quality of life[3]. Local anesthesia, lidocaine, is normally used for pain relieving during episiotomy and repairing[1].

Nonsteroidal anti-inflammatory drugs (NSAIDs) are typically used to reduce pain and inflammation[4]. By inhibiting cyclooxygenase enzymes, NSAIDs consequently causes a decline in prostaglandins, which are the compounds responsible for pain and inflammation.

Ketorolac tromethamine, is a rapid acting NSAIDs used for short term relief of moderate to severe pain[5]. It does not has opioid side effect. It is beneficial for obstetrical use because it does not cause respiratory distress or decrease milk production in postpartum women[5]. It can be administered intravenously, intramuscularly, or local infiltration.

Local anesthetic agents and NSAIDs, widely practiced in subcutaneous infiltration especially surgical incision[6], have been comfortably used, saved, and conserved the financial cost[5]. Even through there are many orthopedic surgery literatures demonstrated[6-8], there is no study of local infiltration of NSAIDs in relieving pain in episiotomy wound.

The purpose of the present study is to investigate efficacy of a combination of ketorolac and lidocaine in pain reduction during episiotomy compared with the use of only

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lidocaine. Primary outcomes are analgesic efficacy and the side effect of the treatment. Postpartum complication are then evaluated for secondary outcome.

Materials and Methods

This randomized double-blind controlled trial was approved by the Ethic Committee, Faculty of Medicine, Thammasat University, MTU-EC-OB-1-024/61.

The participants were recruited from healthy singleton parturients aged equal and more than 18 years old who had undergone spontaneous vaginal delivery at the delivery room of Thammasat University Hospital between March to August 2018. All subjects received thorough counseling before providing their informed consents. Exclusion criteria contain participants with first or forth degree of episiotomy wounds, median episiotomy wounds, participants with fetal anomaly, an underlying history of cardiovascular or renal disease, active use of anticoagulants, history of active peptic ulcers, disease or hypersensitivity to NSAIDs or local anesthetic agent. Patient demographics, age, body mass index (BMI), occupation, education, incomes, duration of the first stage of labor, type and degree of the episiotomy wound, episiotomy length, amount of lidocaine use, additional analgesia, time of episiotomy wound repair, baby birth weight (BBW), and estimated blood loss (EBL) were collected.

The sample size in this study derived from the standard deviation between study and control group (SD = 0.9) from Perret's literature[6], which used ketorolac as a local injection. An alpha and beta value of 0.05 and 0. 2 were used respectively. One hundred and twenty cases are required per group. Participants were randomly assigned into two groups using systemic random sampling. The allocation was assigned by sealed envelopes.

Local anesthetic agent in the study group was a combination of ketorolac tromethamine (Ketorac®, ATB, Thailand) with lidocaine. Medications used by both groups were prepared by a registered nurse at the delivery room. The 10 ml combination of ketorolac with lidocaine consisted of 5 ml of 2% lidocaine, 1 ml of ketorolac tromethamine (30 mg) and 4 ml of normal saline (NSS). Finally, the study group received 1% of lidocaine and 0.3% of ketorolac. The patients in control group received 10 ml of 1% lidocaine (as routine used at Thammasat University Hospital) for local infiltration. If the episiotomy wound is larger than the regular length, the additional dose of anesthetic agent was added for operator's requirement per protocol. The total volume of anesthetic agent was also recorded. Medications for both control and study group were indistinguishable from one another by the patients. All patients and health care providers involved in labor and delivery, as well as data collection were all masked from participant allocation process.

All participants underwent local anesthetic infiltration before performing episiotomy. Additional infiltration was given during episiotomy wound repair. The participants pain score were assessed immediately after birth, after perineal repair and 2, 6 and 24 hours postpartum. Visual analog scale (VAS) represented pain, with a 0 representing no pain and a 10 representing worst possible pain, was introduced to the patients. The amount of 500 mg of acetaminophen tablets that participants asked for during the 24 hours postpartum was recorded. Possible side effects, i.e., nausea, vomiting, itching, respiratory depression, and allergic reactions were also recorded. Data was analyzed by using the Statistical Package for the Social Science (SPSS Inc, Chicago, IL USA) for window version 23. Continuous data was analyzed by using mean and unpair t-test. Chi-square test was used for categorical data. Level of statistical significance was set at *p*-valve less than 0.05.

Results

Our study and control groups each consisted of 120 cases. Mean age and gestational age of both groups were 28 years old and 38 weeks, respectively. Both groups showed no statistical difference in demographic data as represented in Table 1. Two thirds of cases in both groups are multiparity. Mean BMI of both groups is 26 kg/m^2. More than half of both groups are in low risk category. We defined moderate to high risk as overt diabetes mellitus, gestational diabetes mellitus, chronic hypertension, preeclampsia, anemia, and advanced maternal age.

There was no statistical difference in clinical labor characteristics between study and control group (Table 2). Majority of episiotomy performed were right side and second degree laceration. Both groups had equal mean episiotomy wound length of 3.6 cm. The number of requested 500 mg paracetamol in the ketorolac study group was less than that of the control group (n = 19 and 29 respectively) with no statistical difference. Mean BBW was 3,000 gm in both groups.

Mean VAS of the study group was statistically less than that of the control group after perineal repair, 2 hours and 6 hours postpartum respectively.

Figure 1 and Table 3 represented the VAS of control and study groups. After immediate delivery and 24 hours postpartum, both groups showed equal pain level. After perineal repaired, 2 hours and 6 hours postpartum, VAS of ketorolac group were significantly lower than control group (3.32 vs. 4.43, 3.08 vs. 4.08, 2.52 vs. 3.63, respectively).

Additional analgesics, ketorolac side effects, estimated blood loss, and postpartum hemorrhage in the study and control groups had no statistical differences. Four cases in each group had postpartum hemorrhage with EBL loss of more than 500 ml due to uterine atony. No case underwent peripartum hysterectomy.

Discussion

Ketorolac is a non-selective cyclooxygenase inhibitor (COX). It inhibits the conversion of arachidonic acid to prostaglandin by inhibiting COX-2. Episiotomy and surgical incision can up regulate tissue inflammation via COX-2 pathway[4,5]. Lidocaine is an amine compound that inhibits pain neurotransmission process. The combination of ketorolac and lidocaine could result in a synergistic effect in pain control.

Characteristic data of the study and control groups

Table 1. Demographic character of participants in control (lidocaine) group and study (lidocaine plus ketorolac) group

	Lidocaine (n = 120)	Lidocaine + Ketorolac (n = 120)	*p*-value
Age (years)*	28±5.6	28.8±6.0	0.42
Parity**			0.43
Nulliparous	52.0 (43.3)	46.0 (38.3)	
Multiparous	68.0 (56.7)	74.0 (61.7)	
GA (days)*	268.9±9.6	267.4±12.5	0.24
BW (kg)*	66.8±10.6	66.2±9.9	0.56
HT (cm)*	158.3±4.7	157.7±5.2	0.58
BMI (kg/m^2)*	26.6±3.8	26.6±3.8	0.83
ANC risk**			0.38
None	69.0 (57.5)	77.0 (64.2)	
GDM/overt DM	6.0 (5.0	3.0 (2.5)	
CHT/preeclampsia	1.0 (0.8)	3.0 (2.5)	
Anemia	0.0 (0.0)	1.0 (0.8)	
Other	44.0 (36.7)	36.0 (30.0)	
Education**			0.51
High school or less	75.0 (62.5)	84.0 (70.0)	
Under graduated	19.0 (15.8)	20.0 (16.7)	
Bachelor	26.0 (21.7)	16.0 (13.3)	
Occupation**			0.07
Government officer	11.0 (9.2)	9.0 (7.5)	
Employee	64.0 (53.3)	82.0 (68.3)	
Own business	14.0 (11.7)	13.0 (10.8)	
Other	31.0 (25.8)	16.0 (13.4)	
Income (Baht)**			0.51
≤15,000	82.0 (68.3)	90.0 (75.0)	
15,001 to 30,000	31.0 (25.9)	24.0 (20.0)	
≥30,001	7.0 (5.8)	6.0 (5.0)	

* mean ± SD (standard deviation), ** n (%)
GA = Gestational age, BW = body weight, HT = height, BMI = body mass index, ANC = Antenatal care, GDM = Gestational diabetes mellitus, CHT = Chronic hypertension

in the present study was similar. Patients who received lidocaine and ketorolac via local infiltration experienced less episiotomy pain than people in control group at the beginning phase. The pain score of both groups were equally reported at 24 hours postpartum measurement. Ketorolac has half life of 5 hours. This might explain the same pain scores in both groups at 24 hours afterthought fact that ketorolac effect had worn off.

Reuben and his coworkers' report on ambulatory hand surgery revealed that ketorolac and lidocaine combination increased efficacy of intravenous regional anesthesia (IVRA)[7]. Lidocaine or lidocaine plus ketorolac were administrated by local infiltration for analgesia augmentation. The participants who received ketorolac for adjuvant analgesic treatment had better pain relief than control group. The surgical site of the present study was in perineal area. Both hand and perineal area have numerous nerve and blood supplies. Our results supported Reuben's work (Table 4).

The study by Reinhart and his colleagues reported that the combination of ketorolac and lidocaine could relieve pain and prolong time of the first pain reported[8]. Patients in Reinhart study underwent ankle surgery. VAS score and time of the first reported pain were primary endpoint in the present study. Ketorolac treated group showed a better pain relief and longer time of the first pain reported than the control group. Both Reinhart and our study showed that ketorolac could augment the pain relief effect of lidocaine.

Kardash conducted his work in herniorrhaphy cases. Both local infiltration at surgical site or subcutaneous injection of ketorolac could relief pain equally[9]. Ketorolac could augment pain relief by lidocaine in all routes of administration.

Cansino and coworkers reported the efficacy of ketorolac and lidocaine in paracervical block during first trimester surgical abortion[10]. The combination of ketorolac and lidocaine showed better pain control than that of lidocaine alone during cervical dilatation in the therapeutic abortion. His work showed that ketorolac could augment pain relief from visceral pain pathway.

In orthopedic surgery that required tourniquet application, ischemic pain after opening tourniquet was studied by Sayfi et al[11]. Intravenous ketorolac with lidocaine during IVRA resulted in longer mean of analgesic duration compared to that of lidocaine alone (4. 4 and 0.2 hours,

Table 2. Clinical characteristics of labor in control (lidocaine) group and study (lidocaine plus ketorolac) group

	Lidocaine (n = 120)	Lidocaine + Ketorolac (n = 120)	*p*-value
First stage (mins)*	520.2±269.6	531.8±281.5	0.83
Second stage (mins)	15.2±11.5	15.3±11.1	0.99
Site**			0.15
Right	118.0 (98.3)	114.0 (95.0)	
Left	2.0 (1.7)	6.0 (5.0)	
Degree**			0.70
Second	117.0 (97.5)	116.0 (96.7)	
Third	3.0 (2.5)	4.0 (3.3)	
Length (cm)*			
Inner	3.6±1.4	3.7±1.2	0.34
Outer	3.6±1.1	3.7±1.2	0.70
Medication (ml)*	9.2±2.9	8.8±2.2	0.08
Sutured time (mins)*	19.4±8.1	20.2±9.6	0.66
BW (gm)*	3,054.4±347.3	3,073.9±404.3	0.08
EBL (ml)*	194.2±129.2	198.3±124.7	0.83
Additional paracetamol (mg)*	100.0±205.2	108.3±283.9	0.36
Side effect**	0.0 (0.0)	1.0 (0.8)	0.32
PPH**	4.0 (3.3)	4.0 (3.3)	1.00

* mean ± SD (standard deviation), ** n (%)
First stage = duration of first stage of labor, Second stage = duration of second stage of labor, Site = site of mediolateral episiotomy wound type, Degree = degree of laceration of episiotomy wound, Length = episiotomy wound length, BW = birth weight, EBL = estimated blood loss, PPH = postpartum hemorrhage

Table 3. Comparison of pain score in control (lidocaine) group and study (lidocaine plus ketorolac) group

Pain score (VAS)	Lidocaine* (n = 120)	Lidocaine + Ketorolac* (n = 120)	*p*-value	NNT
Immediate			0.32	
Mild to moderate	95 (79.2)	101 (84.2)		
Severe	25 (20.8)	19 (15.8)		
Finish			0.03	0.10
Mild to moderate	103 (85.8)	113 (94.2)		
Severe	17 (14.2)	7 (5.8)		
2 hours			0.02	0.13
Mild to moderate	110 (91.3)	118 (98.3)		
Severe	10 (8.3)	2 (1.7)		
6 hours			0.03	0.14
Mild to moderate	111 (92.5)	118 (98.3)		
Severe	9 (7.5)	2 (1.7)		
24 hours			1.00	
Mild to moderate	119 (99.2)	119 (99.2)		
Severe	1 (0.8)	1 (0.8)		

* n (%)
Mild = pain score 0 to 3, Moderate = pain score 4 to 6, Severe = pain score 7 to 10, VAS = Visual analog scale, Immediate = after delivery immediately, Finish = after sutured, NNT = numbers needed to treat

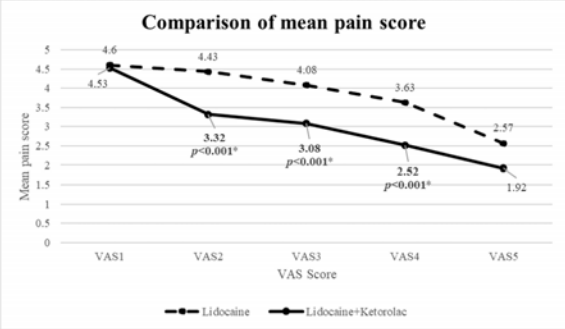
respectively).

The strength of the current study was double-blinded randomized control. Pain from the episiotomy procedure was evaluated by standardized observer who did not know medication assignment. Study of pain from episiotomy was rarely reported in Western countries. Episiotomy was not the common procedure before vaginal birth in nulliparous women in Caucasian parturients. The study of Hopkins and their colleagues reported that the Asian populations had twice higher risk of third and fourth degree perineal tear during parturition than Caucasian patients[12]. Pain from episiotomy parturient kept them away from more

active roles with their babies in the early post labor hours. Fear and stress, especially of perineal pain, were reported to interfere with lactation[13]. The use of ketorolac in conjunction with lidocaine could possibly allow a better mother-newborn bonding and breastfeeding experience. Early ambulation is a result from painless or minimal episiotomy pain. Both early ambulatory and ease of lactation would improve mother-newborn experience in their early days.

Pain reduction strategy should be initiated in both vaginal and cesarean deliveries. Reducing episiotomy pain could reduce fear and stress in parturient, allowing early ambulatory, easy lactation, and increment of breastfeeding success rate.

Our study demonstrated the significant pain relief from episiotomy among parturient who received ketorolac and lidocaine combination via local infiltration. There was no serious side effects or adverse drug events in the present study.



VAS1 = after delivery, VAS2 = after sutured, VAS3 = 2 hours postpartum, VAS4 = 6 hours postpartum, VAS5 = 24 hours postpartum, * = statistically significant

Figure 1. Comparison of mean pain score.

Conclusion

Infiltration of ketorolac with lidocaine on episiotomy wound significantly reduced pain after perineal repair, 2 hours and 6 hours postpartum compared with lidocaine alone. No statistically significant difference in side effects and postpartum complications were reported in both group.

What is already known on this topic?

An episiotomy is a surgical procedure where the perineum is incised during the second stage of vaginal delivery, to widen the vaginal outlet. Episiotomy is known to causes a moderate postpartum pain which has a negative effect on patient's quality of life. Local anesthesia, lidocaine is normally used for pain relieving during episiotomy and repairing. Ketorolac tromethamine, is a rapid acting NSAIDs used for short term relief of moderate to severe pain. Local anesthetic agents and NSAIDs, widely practiced in subcutaneous infiltrative analgesia especially surgical incision, have been comfortably used, saved and conserved the financial cost.

What this study adds?

Ketorolac and lidocaine combination via local infiltration significantly reduce episiotomy pain and had no serious side effects or adverse drug events.

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Potential conflicts of interest

The authors declare no conflicts of interest.

Table 4. Comparison of ketorolac efficacy in control (lidocaine) group and study (lidocaine plus ketorolac) group

	Reuben	Reinhart	Kardash	Cansino	Seyfi	Khwanwong
Year	1996	2000	2005	2009	2017	2018
Procedure	Hand Sx	Podiatric Sx	Herniorrhaphy	Abortion	Arm Sx	Episiotomy
Route	L	AB	L/SC	PB	IVRA	L
Study/Control	K/N	K/NSS	K/K	K/NSS	K/N	K/N
Lidocaine	L	L	L	L	IV	L
ml (%)	5 (1)	17 (2)	19 (1)	18 (1)	20 (1)	20 (1)
Ketorolac	L	L	L/SC	L	IV	L
Dose (mg)	60	80	30	30	20	60
Number	60	79	40	50	40	240
Result	IE	IE	ND	IE	IE	IE
Relative risk						
Adverse effects						
Major				2		
Minor				1		

Sx = surgery, L = local infiltration, AB = ankle block, SC = subcutaneous injection, PB = paracervical block, IVRA = intravenous regional anesthesia, K = ketorolac, N = none, NSS = normal saline, IE = increase efficacy, ND = no difference

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เปรียบเทียบการฉีดยาคีโตโรแลคผสมยาลิโดเคนเข้าแผลฝีเย็บหลังคลอดปกติเทียบกับกลุ่มที่ได้ยาลิโดเคนอย่างเดียวเพื่อระงับความเจ็บปวด: การศึกษาแบบปิดสองด้านชนิดสุ่มแบบมีกลุ่มควบคุม

วรดา ขวัญวงษ์, อธิตา จันทเสนานนท์, เด่นศักดิ์ พงศ์โรจน์เผ่า, สวรรยา เบ็ญจหงษ์, กรณ์กาญจน์ ภมรประวัติธนะ, คมสันติ์ สุวรรณฤกษ์

ภูมิหลัง: การตัดฝีเย็บเป็นหัตถการที่กระทำบ่อยในการคลอดปกติในประเทศไทย ซึ่งก่อให้เกิดความเจ็บปวดและมีผลกระทบทางด้านลบต่อคุณภาพชีวิตของมารดาหลังคลอด การเย็บซ่อมแซมฝีเย็บภายหลังคลอดมักใช้ยาลิโดเคนฉีดเฉพาะที่ การฉีดผสมยากลุ่มระงับการอักเสบที่ไม่ใช่สเตียรอยด์ เช่น ยาคีโตโรแลค สามารถลดความเจ็บปวดจากหัตถการได้ผลดีในหลายประเทศ จุดประสงค์ของการศึกษาครั้งนี้เพื่อศึกษาประสิทธิภาพของยาคีโตโลแรคผสมยาลิโดเคนในการระงับความเจ็บปวดจากการตัดฝีเย็บเทียบกับยาลิโดเคนอย่างเดียว

วัสดุและวิธีการ: สตรีตั้งครรภ์เดี่ยวที่มีสุขภาพดี 240 คน ที่มาคลอดปกติ ณ ห้องคลอด โรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ ถูกคัดเลือกชนิดแบบเดาสุ่มและแบ่งกลุ่มเป็นจำนวนเท่ากัน กลุ่มศึกษาได้รับยาคีโตโรแลคความเข้มข้น ร้อยละ 0.3 ผสมยาลิโดเคนความเข้มข้น ร้อยละ 1 ฉีดที่แผลฝีเย็บหลังคลอดเทียบกับกลุ่มควบคุมที่ใช้ยาลิโดเคนความเข้ม ร้อยละ 1 เพียงอย่างเดียว ผลการศึกษาหลักประกอบด้วยคะแนนความเจ็บปวดทันทีหลังคลอด 2, 6 และ 24 ชั่วโมงหลังคลอดโดยใช้ วิช่วล อนาล็อก สเกลส ข้อแทรกซ้อนหลังการคลอดจัดเป็นผลการศึกษารอง

ผลการศึกษา: ไม่พบความแตกต่างของข้อมูลพื้นฐานและคลินิกของทั้งกลุ่มศึกษาและกลุ่มควบคุมค่าเฉลี่ยวิช่วล อนาล็อก สเกลสของกลุ่มศึกษาน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติภายหลังเย็บฝีเย็บแล้วเสร็จ, 2 ชั่วโมง และ 6 ชั่วโมงหลังคลอด (3.32/4.43, 3.08/4.08, 2.52/3.63) ตามลำดับ พบผู้ป่วยตกเลือดหลังคลอดจำนวนกลุ่มละ ๔ คน ไม่มีผู้ป่วยรายใดได้รับการตัดมดลูกหลังคลอด

สรุป: การฉีดยาลิโดเคนผสมยาคีโตโรแลคขณะเย็บซ่อมแซมฝีเย็บลดความเจ็บปวดอย่างมีนัยสำคัญทางสถิติ ภายหลังซ่อมแซมแล้วเสร็จ, 2 ชั่วโมง และ 6 ชั่วโมงหลังคลอด