Original Article

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

Pawanna P, MD[1], Chanthasenanont A, MD[1], Pongrojpaw D, MD[1], Limpivest U, MD[1], Pattaraarchachai J, PhD[2], Suwannarurk K, MD[1]

[1] Department of Obstetrics and Gynecology, Faculty of Medicine, Thammasat University, Pathumthani, Thailand
[2] Chulabhorn International College of Medicine, Thammasat University, Pathumthani, Thailand

Background: Episiotomy was a surgical procedure at external genitalia for widening of the vaginal outlet during labor. It is known to cause postpartum perineal pain and may have effects on quality of life.

Objective: The present study aimed to compare the analgesic effect of dexamethasone with lidocaine and lidocaine infiltration alone during episiotomy. The primary and secondary outcomes were the analgesic efficacy and postpartum analgesic rescue, respectively.

Materials and Methods: Three hundred and sixty healthy singletons parturient who spontaneously delivered at Thammasat University Hospital were recruited. Participants were randomly assigned into two groups using systemic random sampling. Local infiltration of dexamethasone (4 mg) with lidocaine hydrochloride (100 mg) and lidocaine hydrochloride alone was performed in study and control group, respectively. Pain score was assessed by numerical rating scale and recorded immediately after delivery and after perineal repair, then again at 2-, 6- and 24-hours postpartum. The primary outcome was analgesic efficacy represented by postpartum pain scores. The amount of postpartum acetaminophen consumption and postpartum complications were evaluated for secondary outcome.

Results: Both study and control group had comparable demographic and clinical characters. Pain score by numerical rating scale (NRS) of the study group was statistical lower than the control group at immediate after episiotomy wound repairing and 2 hours postpartum. Both groups had equal pain intensity until 24 hours postpartum. Analgesic rescue during the first 24 hours after delivery in the study group was lower than the control group (p = 0.025). There was no report of wound infection and serious side effect.

Conclusion: Local infiltration of dexamethasone plus lidocaine before performing episiotomy gave a significant pain relief immediately after perineal repair, 2 hours postpartum and decreased analgesic rescue requirement.

Keywords: Dexamethasone, Lidocaine, Episiotomy, Pain

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Episiotomy is a surgical incision of the perineum and the posterior vaginal wall to enlarge the vaginal opening for delivery. Adequate exposure of vaginal introitus is essential for vaginal surgery. Schuchardt incision is performed for widening of the vaginal outlet during vaginal surgery while episiotomy is performed for vaginal delivery[1].

Episiotomy is commonly performed in parturient in Southeast Asia region especially in the first delivery. The episiotomy rate in Thailand, Philippines, USA and Australia were 91, 64, 25 and 17 percent, respectively[2]. A high episiotomy incidence in Southeast Asia was assumed to be from difference of anatomy, physiology and culture between Asians and Caucasians. However, the perinatal outcome between two groups is not significantly different[2].

Pain from episiotomy was often described as moderate pain. Local anesthetic infiltration was adequate and widely practiced during episiotomy and repairing. Corticosteroid had synergistic effect with anesthetic agent for pain relief due to its anti-inflammatory effect which is known to be from inhibition of phospholipase; thus, suppressing the prostaglandin formation[3,4]. In addition, corticosteroid also decreased vascular permeability and reduced surrounding tissues swelling[4].

Dexamethasone was one of the long acting synthetic corticosteroids that ubiquitously used for pain relief. It could be administered via intravenous, intramuscular, oral, and local routes. Combination of dexamethasone and anesthetic agent

Correspondence to:
Chantasenanont A.
Department of Obstetrics and Gynecology, Thammasat University Hospital, 99/209, Moo 18, Khlongnueng, Khlongluang, Pathumthani 12120, Thailand.
Phone: +66-2-9269343, **Fax:** +66-2-9269485
E-mail: dr.athita@gmail.com

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resulted in excellent pain relief with minimal side effects[3].

The present study aimed to compare the analgesic effect of dexamethasone combination with lidocaine and lidocaine infiltration alone during episiotomy. The primary and secondary outcome were the analgesic efficacy and postpartum analgesic rescue, respectively.

Materials and Methods

The present study was approved by the Ethic Committee, Faculty of Medicine, Thammasat University, MTU-EC-OB-1-208/61. The study was registered at www.clinicaltrials.in.th (No. TCTR20190609002)

Singleton pregnant women aged more than or equal 18 years old who had vaginal delivery at Thammasat University Hospital between July to September 2019 were included in this randomized double-blind controlled trial study. The exclusion criteria was participants with chronic renal or liver disease, immunocompromised, overt diabetes mellitus, allergy to corticosteroid or local anesthesia drugs and intrapartum fever. Parturient with first, fourth degree, and median episiotomy wounds were also excluded from the study.

Sample size was calculated based on previous data from Evaristo-Mendez G et al that studying efficacy of local ropivacaine comparing to combination of local ropivacaine and dexamethasone[5]. The sample size giving the statistical difference was 168 cases per group. Ten percent addition for data loss, so the sample size was 180 cases per group.

After the participants were informed of study process, legal inform consents were obtained. A total of 360 participants who met the specified criteria were enrolled. The patients were randomized into 2 groups; the study group whom received local infiltration of 4 mg of dexamethasone in combination with 1% lidocaine and the control group whom received only 1% lidocaine. The participants were 180 cases in each group. The patient demographic data that was collected included age, body mass index (BMI), occupation, education, level of income, duration of the first and second stage of labor, type and degree of the episiotomy wound, episiotomy length, amount of medication use, additional analgesia, time of episiotomy wound repair, baby birth weight (BBW), and estimated blood loss (EBL).

The anesthetic drugs for both groups were prepared by registered nurse and similar visually appear as a clear solution. For the study group, 2 ml (8 mg) of dexamethasone was mixed with 10 ml of 2% lidocaine hydrochloride which was equal to 200 mg of the mentioned drug. Eight milliliters of normal saline (NSS) was then added, therefore giving us the total volume of 20 ml and was later divided into two portions, 10 ml each which consisted of 4 mg dexamethasone and 100 mg lidocaine. In the control group, patients were administered with 10 ml of 1% lidocaine hydrochloride. The concentration of lidocaine was 100 mg equally in both groups. In case of a large episiotomy wound, an optimal dose of anesthetic agent was adjusted for doctor's requirement. All patients and health care providers involved in labor and delivery, as well as data collector were masked from the participant allocation process.

The local anesthesia infiltrated prior to the episiotomy and additional doses were added during the repair of the perineal wound. The total dose of drug administered was recorded. The patients' pain scores were assessed by numerical rating scale (NRS) ranging from 0, representing no pain, to 10, representing the worst possible pain. The pain score was recorded immediately after delivery and after perineal repair, then again at 2-, 6-, and 24-hours postpartum.

After delivery, the patients were transferred to postpartum ward and received the same postpartum pain management. Acetaminophen was prescribed in both groups if patients required additional analgesic drug. The amount of acetaminophen consumption within 24 hours postpartum was also recorded. The primary outcome was analgesic efficacy represented by postpartum pain scores. The secondary outcome was the amount of postpartum acetaminophen consumption and postpartum complications. The authors also recorded any adverse events during hospital stay, including allergic reaction, respiratory depression, nausea and vomiting. The incidence of surgical site infection was recorded by retrospective follow-up at postpartum clinic. The data was analyzed by using statistical packet for the social science (SPSS Inc, Chicago, IL USA) for Windows version 23. The independent sample t-test or Chi-square were used as appropriate conditions. The statistical significance was defined as *p*-value less than 0.05.

Results

Three hundred and sixty pregnant women who met the eligibility criteria and delivered at Thammasat University Hospital were enrolled in the present study as presented in Figure 1.

Mean age of participants in this study was 28.7 years old. Half of the cases (158/360) were nulliparous. Mean gestational age of both groups was 38 completed weeks. Three quarter of cases had no underlying disease. One-third of cases had education level of bachelor's degree or higher. Two-third of participants were employees from government and private sectors. Eighty percent of participants had monthly income more than 15,000 baht. Both groups of participants have comparable demographic characters as shown in Table 1.

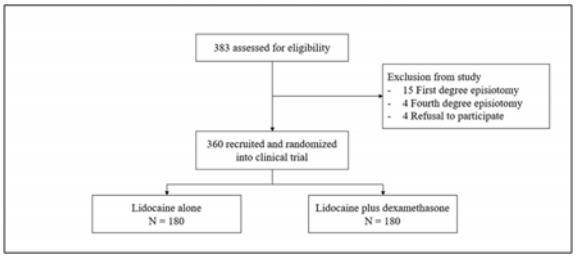

Figure 1. Flow chart of participants' progress through the study.

Table 1. Demographic character of participants

	Control (n = 180)	Study (n = 180)	*p*-value
Age (years)*	28.3±6.0	29.1±6.1	0.21
Parity**			0.40
Nulliparous	83 (46.1)	75 (41.7)	
Multiparous	97 (53.9)	105 (58.3)	
GA (weeks)*	38.5±1.5	38.5±1.6	0.61
BW (kg)*	67.0±10.6	67.2±10.0	0.92
HT (cm)*	158.6±5.4	158.4±5.7	0.71
BMI (kg/m^2)*	26.6±3.8	26.7±3.9	0.82
ANC risk**			0.93
None	132 (73.3)	136 (75.6)	
GDM	15 (8.3)	7 (3.9)	
CHT/preeclampsia	2 (1.1)	8 (4.4)	
AMA	31 (17.2)	29 (16.1)	
Education**			0.90
Primary school or less	27 (15.0)	24 (13.3)	
High school	95 (52.8)	99 (55.0)	
Bachelor's degree	38 (21.1)	41 (22.8)	
Master's degree	20 (11.1)	16 (8.9)	
Occupation**			0.92
Housewife	20 (11.1)	23 (12.8)	
Government officer	16 (8.9)	14 (7.8)	
Employee	103 (57.2)	101 (56.0)	
Own business	23 (12.8)	19 (10.6)	
Other	18 (10.0)	23 (12.8)	
Income (baht)**			0.94
<15,000	35 (19.4)	38 (21.1)	
15,000 to 30,000	93 (51.7)	86 (47.8)	
>30,000	52 (28.9)	56 (31.1)	

* mean ± SD (standard deviation), ** n (%)
Control = lidocaine, Study = lidocaine + dexamethasone
GA = gestational age, BW = body weight, HT = height, BMI = body mass index, ANC = antenatal care, GDM = gestational diabetes mellitus, CHT = chronic hypertension, AMA = advance maternal age

Both groups have comparable first stage of labor duration. Second stage of labor duration in both groups was around 15 minutes without statistical difference. Most of the episiotomy wounds were classified as second degree wound. Episiotomy wound length, anesthetic dosage, episiotomy repairing time, fetal and maternal outcomes were comparable as presented in Table 2.

Pain score by numerical rating scale (NRS) for both groups were equal at the beginning of the episiotomy wound repairing. NRS of the study group (lidocaine, in combination with dexamethasone) was statistically lower than the control group at the time of immediate and 2 hours postpartum. After 2 hours of delivery, both groups had equal pain intensity until 24 hours as represented in Table 3 and Figure 2. Analgesic rescue during the first 24 hours after delivery in the study group was lower than the control group ($p = 0.025$).

There was no report of side effect of anesthetic agent or any other medication in the present study.

There were only two and five cases of immediate postpartum hemorrhage in the control and study group, respectively ($p = 0.253$). All seven cases received only uterotonic agents without blood transfusion or hysterectomy.

Discussion

The results found in the present study demonstrated that addition of dexamethasone to lidocaine produced higher potency of analgesia than lidocaine alone in patients who undergo episiotomy for vaginal delivery immediately after perineal repair and 2 hours postpartum. However, pain score at 6 and 24 hours postpartum is not different between two groups. This can be explained by the short duration of action of lidocaine that only persisted for 2 hours[6]. The usage of acetaminophen within 24 hours postpartum is significantly lower in the study group which the combination of lidocaine and dexamethasone is being used. There were many studies of local dexamethasone infiltration in oral mucosa, which composed of stratified squamous epithelium and enrich blood supply similar to vaginal epithelium, shown higher efficacy than anesthetic agents alone[7-10]. A previous monograph by Brucoli et al[11] reported that intralesional administration was the most efficient method compared to intravenous and oral route. Therefore, local injection route would be the administration of choice.

Dexamethasone was also used as a synergist to anesthetic agents in orthopedic surgery. Studies of Sharma M et al and Bhattacharjee et al demonstrated superior quality and prolonged the duration of postoperative analgesia without significant side effects[12,13].

In minimal invasive surgery or minor operations with a small surgical incision sites, dexamethasone also had excellent efficacy for pain control. There were studies of adding dexamethasone to anesthetic agents in endoscopic nasal surgery[14] and laparoscopic cholecystectomy[15] shown lower pain scores and additional analgesia requirements in dexamethasone group. An episiotomy wound was also classified as small surgical incision and dexamethasone usage resulted in a similar manner as mentioned above.

Refer to studies of the impact of dexamethasone on the incidence of surgical site infection[16,17] and nausea vomiting prophylaxis[18]. There were no increased risk of surgical site infection with a single dose of dexamethasone (4 to 8 mg) as well as providing prophylaxis of nausea and vomiting. Likewise, the present study corresponds to the aforementioned evidence.

The strengths of the present study are that the study was conducted as a double-blind randomized control trial. The number of participants in the present study was more than other studies. Dexamethasone was cheap, ubiquitous used and available in all hospital in Thailand.

Conclusion

The use of dexamethasone combined with lidocaine intralesional before performing episiotomy results in a significant pain relief immediately after perineal repair and 2

Table 2. Clinical characteristics of labor

	Control (n = 180)	Study (n = 180)	*p*-value
First stage (mins)*	503.0±252.6	534.1±264.5	0.26
Second stage (mins)*	14.7±10.7	15.1±10.2	0.68
Episiotomy degree**			0.59
Second	174 (96.7)	172 (95.6)	
Third	6 (3.3)	8 (4.4)	
Length (cm)*			
Inner	3.8±1.6	4.0±1.3	0.25
Outer	4.0±0.8	4.1±1.1	0.37
0.1% Lidocaine usage (ml)*	9.2±2.8	9.4±2.1	0.55
Sutured time (mins)*	19.5±7.6	21.2±10. 5	0.07
BBW (gm)*	3,075.7±352.3	3,060.2±383.6	0.69
EBL (ml)*	188.1±110.8	194.2±123.0	0.62
PPH**	2 (1.1)	5 (2.8)	0.25

* mean ± SD (standard deviation), ** n (%)
Control = lidocaine, Study = lidocaine + dexamethasone
First stage = duration of first stage of labor, Second stage = duration of second stage of labor, Length = episiotomy wound length, BBW = baby birth weight, EBL = estimated blood loss, PPH = postpartum hemorrhage

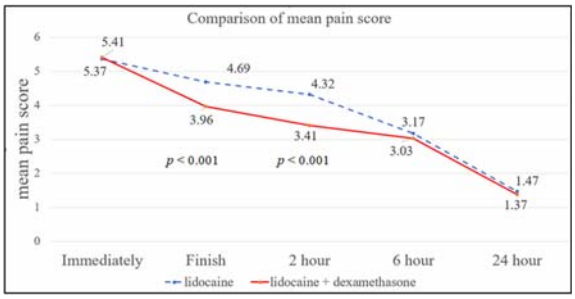

Figure 2. Comparison of mean pain score between study (lidocaine plus dexamethasone) and control (lidocaine) group.

hours postpartum. The usage of acetaminophen within 24 hours postpartum is significantly lower in the study group. Also, there is no report of side effect, especially wound infection, in this study.

What is already known on this topic?

Episiotomy was a surgical procedure at external genitalia for widening of the vaginal outlet during labor. It was commonly performed in parturient in Southeast Asia. Episiotomy caused moderate pain that could be relief by local anesthetic infiltration. Dexamethasone had synergistic effect with anesthetics agent.

What this study adds?

Local infiltration of dexamethasone plus lidocaine before performing episiotomy gave a significant pain relief immediately after perineal repair and 2 hours postpartum. It decreased analgesic rescue requirement within 24 hours postpartum. There was no report of wound infection and serious side effect. Combination of dexamethasone and lidocaine resulted in excellent pain relief with minimal side effects.

Table 3. Comparison of primary outcome and secondary outcome

	Control (n = 180)	Study (n = 180)	*p*-value
Primary outcome (NRS)*			
Immediate	5.37±2.11	5.41±1.78	0.87
Finish	4.69±1.65	3.96±1.33	<0.05
2 hours	4.32±1.64	3.41±0.99	<0.05
6 hours	3.17±1.14	3.03±0.99	0.20
24 hours	1.47±1.19	1.37±1.07	0.38
Secondary outcome**			
Acetaminophen use (n, %)			0.03
None	129 (71.7)	152(84.5)	
500 mg	44 (24.4)	24 (13.3)	
1,000 mg	7 (3.9)	4 (2.2)	

* mean ± standard deviation (SD), ** n (%)
Control = lidocaine, Study = lidocaine + dexamethasone
NRS = numerical rating scale, Immediate = after delivery immediately, Finish = after perineal repair, 2 hours = at 2 hours after delivery, 6 hours = at 6 hours after delivery, 24 hours = at 24 hours after delivery

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Potential conflicts of interest

The authors declare no conflicts of interest.

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เปรียบเทียบการฉีดยาเดกซาเมทาโซนผสมยาลิโดเคน เข้าแผลฝีเย็บหลังคลอดปกติ เทียบกับกลุ่มที่ได้ยาลิโดเคนอย่างเดียวเพื่อระงับความเจ็บปวด: การศึกษาแบบปิดสองด้านชนิดสุ่มแบบมีกลุ่มควบคุม

ปริวัตร ปะวรรณะ, อธิตา จันทเสนานนท์, เด่นศักดิ์ พงศ์โรจน์เผ่า, อุรวี ลิมปีเวศน์, จรรยา ภัทรอาชาชัย, คมสันติ์ สุวรรณฤกษ์

ภูมิหลัง: การตัดบริเวณฝีเย็บเป็นหัตถการเพื่อขยายปากทางช่องคลอดในระหว่างกระบวนการคลอด จุดประสงค์ของการศึกษาครั้งนี้ เพื่อเปรียบเทียบประสิทธิผลของการระงับปวดระหว่างยาเดกซาเมทาโซนร่วมกับยาลิโดเคน เทียบกับยาลิโดเคนเพียงอย่างเดียว โดยการฉีดบริเวณฝีเย็บ ผลลัพธ์ของการศึกษาคือประสิทธิภาพในการระงับปวด และความต้องการยาระงับปวดเพิ่มเติมหลังคลอดตามลำดับ

วัตถุประสงค์: เพื่อเปรียบเทียบประสิทธิผลของการระงับปวดระหว่างยาเดกซาเมทาโซนร่วมกับยาลิโดเคน เทียบกับยาลิโดเคนเพียงอย่างเดียวโดยการฉีดบริเวณฝีเย็บ ผลลัพธ์ของการศึกษาคือประสิทธิภาพในการระงับปวด และความต้องการยาระงับปวดเพิ่มเติมหลังคลอดตามลำดับ

วัสดุและวิธีการ: สตรีตั้งครรภ์เดี่ยวสุขภาพดี จำนวน 360 ราย ที่มาคลอดบุตร ณ โรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ ผู้เข้าร่วมการศึกษาถูกแบ่งเป็นสองกลุ่มโดยวิธีการสุ่มแบบปกปิด โดยกลุ่มศึกษาได้รับการฉีดยาเดกซาเมทาโซน 4 มิลลิกรัม ร่วมกับลิโดเคน 100 มิลลิกรัม ในขณะที่กลุ่มควบคุมได้รับยาลิโดเคน 100 มิลลิกรัมเพียงอย่างดียว ระดับความเจ็บปวดบันทึกเป็นคะแนนระดับความเจ็บปวดแบบตัวเลขภายหลังคลอดทันที ภายหลังเย็บซ่อมแซมฝีเย็บเรียบร้อยหลังคลอดบุตร 2 ชั่วโมง, 6 ชั่วโมง และ 24 ชั่วโมง ตามลำดับ ผลลัพธ์คือประสิทธิภาพในการลดปวดของยาและปริมาณยาแก้ปวดที่ได้รับภายใน 24 ชั่วโมงหลังคลอดบุตร รวมถึงภาวะแทรกซ้อน

ผลการศึกษา: ข้อมูลพื้นฐานของผู้เข้าร่วมการศึกษาทั้งสองกลุ่มไม่มีความแตกต่างกัน คะแนนความเจ็บปวดหลังคลอดบุตรทันทีของทั้งสองกลุ่มไม่แตกต่างกัน คะแนนความเจ็บปวดในกลุ่มศึกษาน้อยกว่าในกลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ ที่ระยะเวลาหลังเย็บซ่อมแซมแผลฝีเย็บเรียบร้อย และ 2 ชั่วโมงหลังคลอดบุตร หลังจากนั้นผู้เข้ารับการศึกษาทั้งสองกลุ่มมีระดับความเจ็บปวดหลังคลอดเท่ากันใน 24 ชั่วโมงหลังคลอด ความต้องการยาระงับปวดเพิ่มเติมใน 24 ชั่วโมงแรกของกลุ่มศึกษาน้อยกว่าในกลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติไม่พบแผลติดเชื้อหรือภาวะแทรกซ้อนที่รุนแรงในการศึกษาครั้งนี้

สรุป: การใช้ยาเดกซาเมทาโซนร่วมกับยาลิโดเคนฉีดบริเวณที่จะตัดแผลฝีเย็บ สามารถลดระดับความปวดในช่วงระยะเวลาหลังจากเย็บแผลเสร็จจนกระทั่ง 2 ชั่วโมงแรกหลังคลอดบุตรได้ดีกว่าการใช้ยาลิโดเคนเพียงอย่างเดียว และลดการใช้ยาแก้ปวดภายใน 24 ชั่วโมงแรกได้อย่างมีนัยสำคัญทางสถิติ