Original Article

The Use of Levobupivacaine With or Without Ketorolac in Post Cesarean Pain Management: A Randomized Double-blinded Control Trial

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Background: Cesarean delivery is the most common operative procedure among women of reproductive age. Post-cesarean pain is chief among the major problems in parturients. An effective analgesia is required for adequate postoperative pain management.

Objective: To determine the effectiveness in postoperative pain reduction of levobupivacaine usage compared to its combination with ketorolac via local infiltration postoperatively in participants who underwent cesarean delivery under spinal anesthesia.

Materials and Methods: Pregnant women between 18 and 40 years of age who underwent cesarean delivery at Thammasat University Hospital were enrolled. The participants were randomly allocated into two groups; the study and control groups received local surgical wound infiltration of 50 mg of levobupivacaine (0.5%) with or without 30 mg of ketorolac at the end of surgical wound closure, respectively. After the operation, the visual analog scale (VAS) was recorded at 1, 2, 4, 8, 12, 18 and 24 hours. Demographic data, additional opioid requirements in the first 24 hours postoperative and adverse effects were also recorded.

Results: A total of 160 parturients were recruited, consisting of 80 cases in each group. Both groups were comparable in demographic data. Mean postoperative pain in the study group was significantly lower than the control group within the first 24 hours post-surgery. Overall meperidine requirement during the first 24 hours and adverse side effects in the study and control groups were comparable.

Conclusion: Combined ketorolac with levobupivacaine significantly decreased post-cesarean pain in the first 24 hours compared to the use of only levobupivacaine.

Keywords: Ketorolac, Levobupivacaine, Cesarean delivery, Pain

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Cesarean delivery is the most common operative procedure among women of reproductive age by an increasingly high rate[1]. Postoperative pain is an important problem that precludes early ambulation and lactation. An effective analgesia is required for adequate pain control in post cesarean mothers. When medication is prescribed in lactating parturient, the doctor should be concerned about its side effects on breastfeeding and the possibility of drug transfer via breast milk to the newborn [2].

Postoperative pain reduction can be performed using many different strategies such as the use of opioids, anti-inflammatory analgesia, nerve blocks or adjunctive techniques. Local wound infiltration with anesthetic agent is a simple and effective procedure in postoperative pain reduction[3]. Adequate pain management minimizes the amount of analgesic used, lessens the side effects of analgesics and improves quality of life outcomes for the patient[4,5].

Opioids have traditionally been the choice of medication for postoperative pain control after cesarean delivery. Their side effects include nausea, vomiting, constipation, urinary retention and respiratory depression[6].

In the 1940's, amide analgesics such as lidocaine, were introduced for pain management. Lidocaine has a short acting effect. As a result, newer amide analgesia has since been introduced with differing side effects[7].

Levobupivacaine is a long acting-local anesthetic agent member of the amide group of anesthetics. It was introduced in 1960, and was later used in post cesarean delivery pain management[8]. Pharmacodynamics of levobupivacaine is similar to its starting molecule, namely bupivacaine, and exerts pharmacological action via peripheral

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neurotransmission blockage. However, levobupivacaine has lower cardiovascular and central nervous system toxicity than bupivacaine[9,10]. The duration of action depends on the dosage and the anesthetic technique. Analgesic duration of wound infiltration with long acting-local anesthetic agent is 4 to 8 hours[3].

Nonsteroidal anti-inflammatory drugs (NSAIDs) have been introduced for postoperative analgesia since 1970. Their mechanism of action is the inhibition of cyclooxygenase (COX) enzymes resulting in prostaglandin synthesis inhibition. NSAIDs show both anti-inflammatory activity and analgesic effects[11].

Ketorolac is a member of the NSAIDs group which had been approved by American Academy of Pediatrics for safe use in lactating women[12,13]. It has both COX-1 and COX-2 inhibitory effects. Ketorolac can be administered orally, intravenously or intramuscularly. Subcutaneous infiltration can also be used but the pharmacodynamic and pharmacokinetic properties are not well understood at present[12]. Combination of NSAIDs and anesthetic agents for postoperative pain management has been successfully used i.e., in obstetric and orthopedic surgery[4,11].

Currently, there are many different materials for postoperative pain reduction such as opioids and NSAIDs via different routes, including oral, intravenous, intramuscular and local infiltration. Optimal pain management can effectively mitigate postoperative pain.

Currently, there is still limited information about the effectiveness of combination local levobupivacaine and ketorolac for reducing post-cesarean pain. Therefore, the aim of this study was to determine the effectiveness in pain reduction of levobupivacaine usage compared to its combination with ketorolac via local surgical wound infiltration postoperatively in participants who underwent cesarean delivery under neuraxial anesthesia.

Materials and Methods

The presented study was a prospective double-blind randomized controlled trial and approved by the Ethics Committee of the Faculty of Medicine, Thammasat University (MTU-EC-OB-1-016/61) (TCTR20180626001). It was conducted at Thammasat University Hospital between July and December 2018. This prospective randomized-controlled trial was reported according to CONSORT statement style.

Pregnant women aged between 18 and 40 years who had indications for cesarean delivery during the periods of study were enrolled. The exclusion criteria included body mass index (BMI) >40 kg/m^2, hypovolemic shock, hypersensitivity to ketorolac or local anesthetic agents, history of cardiovascular disease, renal disease, hepatic disease, coagulopathy, active peptic ulcer disease, history of chronic pain, current long term pain medication and a refusal to undergo the investigation.

Written informed consent was signed by each participant after thorough counseling. The participants were randomly assigned into two groups using a computer-generated table of random numbers. The generated numbers were kept in sealed opaque envelopes. An envelope was picked and opened in the operating room by the scrub nurse in each case.

During preoperative period, visual analogue scale (VAS) (0 = no pain, 10 = worst pain) was introduced to all patients. In the operating room, stats including blood pressure, pulse, respiratory rate, electrocardiography and pulse oximetry were monitored noninvasively.

The standard method of anesthesia in this study was a neuraxial regional block (spinal anesthesia). Ten milligrams of 0.5 percent preparation of bupivacaine in hyperbaric solution with the addition of 0.2 mg morphine hydrochloride was used as standard of neuraxial regional block in this study. The anesthesiologist and their co-workers took responsibility for this procedure.

The parturients were randomly divided into two groups, decided by the result of sealed opaque envelope choice. The parturients, attending obstetricians, anesthesiologists and attending nurses were all blinded to the study. The sealed envelopes determined the medications prepared and administered by the anesthesiologist. The study group received local infiltration with a combination of 50 mg levobupivacaine (10 ml in 0.5% solution) plus 30 mg ketorolac (Ketolac®, ATB Thailand). The control group received a local infiltration of 50 mg levobupivacaine (10 ml in 0.5% solution) plus 1 ml of 0.9% normal saline. After completion of anterior rectal sheath repair, medication was administered via subcutaneous infiltration in tissue surrounding the surgery site prior to closing.

All participants in this study received the hospital standard for preoperative and postoperative care including vital sign monitoring, intravenous fluid and intravenous oxytocin infusion.

Demographic data of the participants included age, BMI, occupation, education, any underlying disease, history of cesarean section, parity, gestational age, operative time, postoperative blood loss and fetal birth weight were all compared.

The primary outcome was the level of postoperative pain. It was determined at 1, 2, 4, 8, 12, 18 and 24 hours after surgery by using visual analog scale (VAS). Each patient was evaluated and interviewed by an attending postoperative nurse who was blind to the patient's study or control status. The patient's VAS score was recorded during the postoperative protocol. Meperidine was an adjuvant analgesic medication used in postoperative cases who requested additional analgesic medication.

The secondary outcomes included the total dosage of opioids (meperidine) given upon request within 24 hours after surgery, time for the first additional opioid requirement and the possible side effects of drug used, namely, nausea, vomiting, tachycardia, respiratory depression, drug allergy, postpartum hemorrhage, renal insufficiency, hepatitis or gastrointestinal disturbance were also recorded.

The sample size was calculated by using software G*Power version 3.1.7[14]. The alpha and beta errors were

both set at 0.05. The total sample size was 160 cases which were then divided to 80 cases in each arm.

The data was analyzed using the Statistical Package for the Social Sciences (SPSS Inc, Chicago, IL, USA) for Windows version 17. Categorical data as analyzed by using Chi-square test. Continuous data were analyzed by using mean, Mann-Whitney U test and unpaired t-test. The *p*-value less than 0.05 was considered statistically significant.

Results

One hundred and sixty parturients were recruited in the current study. They were randomly assigned into study and control groups as represented in Figure 1.

The control and study groups each consisted of 80 cases. Mean age of participants were comparable. Half of all cases were nulliparous. History of cesarean delivery was found in about one-third of the cases. Most cases had no underlying disease, however, some cases were associated with diseases including diabetes mellitus, hypertension, dyslipidemia, thyroid disease, and asthma. Both groups had no statistical significance in demographic data, namely, BMI, underlying disease, cesarean delivery history and mean gestational age. The maternal outcomes in terms of operative time and estimated blood loss were not significantly different. The neonatal outcomes in terms of fetal birth weight were comparable as shown in Table 1.

Postoperative pain in the study group was significantly lower than the control group within the first 24 hours after surgery. Mean visual analog scale in the study and control groups at 1, 2, 4, 8, 12, 18 and 24 hours were 0.72/1.00, 0.99/1.86, 2.91/3.99, 3.19/4.70, 3.96/4.81, 4.19/5.00 and 4.31/5.00 respectively, as represented in Figure 2.

Overall meperidine requirements during the first 24 hours in the study and control groups did not differ to statistical significance. The median time for the first additional opioid requirement after surgery in the study and control groups were not significant difference as represented in Table 2.

Nausea and vomiting were the major adverse effects

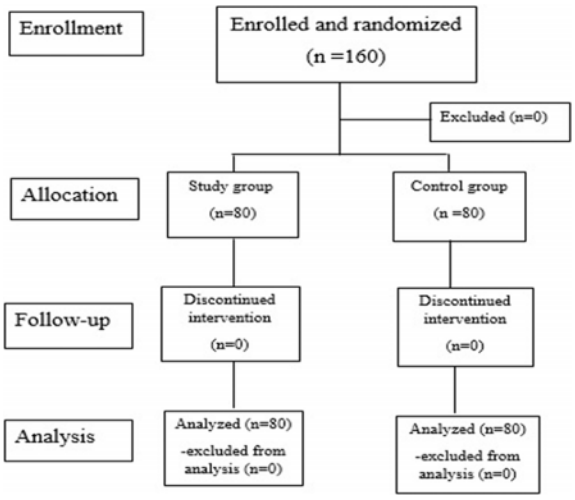

Figure 1. Participant flow diagram, Study group: ketorolac plus levobupivacaine, Control group: levobupivacaine.

Table 1. Demographic data of participants

	Control (n = 80)	Study (n = 80)	*p*-value
Age (year)*	29.8±4.99	28.9±4.66	0.274
BMI (kg/m^2)*	28.7±4.85	29.2±4.50	0.468
Occupation**			0.205
Employee	46 (57.50)	37 (46.25)	
Non-employee	34 (42.50)	43 (53.75)	
Education**			0.901
Under graduated	54 (67.50)	54 (67.50)	
Bachelor	26 (32.50)	26 (32.50)	
Underlying disease**			0.443
Yes	2 (2.50)	5 (6.25)	
No	78 (97.50)	75 (93.75)	
History of C/S**	25 (31.25)	23 (28.75)	0.732
Parity**			0.875
Nulliparous	39 (48.75)	40 (50.00)	
Multiparous	41 (51.25)	40 (50.00)	
Gestational age (days)*	267.3±13.20	269.3±28.54	0.580
Operative time (min)*	43.5±9.68	44.8±9.09	0.351
EBL (ml)*	420.0±171.11	433.8±166.46	0.607
Fetal birth weight (g)*	3,084.1±547.21	3,252.2±549.60	0.054

BMI = body mass index, C/S = cesarean section, EBL = estimated blood loss
* Mean ± SD, ** n (%)

in the present study. It was found at percentage of 21.25 in the study and 13.75 in the control group with no statistical difference.

Discussion

The present study compared the effectiveness of local levobupivacaine wound infiltration with and without ketorolac in postoperative pain control after cesarean delivery. All subjects in this study underwent cesarean delivery under neuraxial anesthesia. The results revealed that patients with combined local levobupivacaine and ketorolac wound infiltration reported better effect in pain reduction than those received only levobupivacaine. The analgesic effects of the combination treatment persisted until 24 hours after surgery. However, additional opioid requirements in the patients were comparable in both groups.

Effective postoperative pain control could improve the quality of life of patients[15]. Opioids were traditionally used for postoperative pain control. Their side effects were of major concern, especially respiratory depression[6]. Local anesthetic agents within the amide group, such as levobupivacaine, were used for opioid dose reduction in postoperative cases[9]. The study of Jolly et al reported that continuous subfascial infiltration with levobupivacaine via elastomeric infusion pump for 48 hours after cesarean section under spinal anesthesia decreased postoperative pain, opioids consumption and facilitated breastfeeding, however it also increased nurse workload for changing wound dressings[1].

According to literature, systemic NSAIDs administration was introduced to replace or reduce patient's postoperative opioid requirement. Local NSAIDs administration was reported to be effective in postoperative pain control while its mechanism is still unknown[12].

A study by Carvalho et al[11] from the USA reported that the adjuvant of ketorolac in anesthetic medication protocol enhanced analgesic effects. Carvalho's study was conducted in post-cesarean delivery cases. Subcutaneous instillation of bupivacaine and ketorolac around surgical wound was reported to be more effective in pain control and reduced opioid consumption in the first 48 hours post-operation compared to those who received only bupivacaine. The present study also reported that the combination of levobupivacaine and ketorolac had significantly lower pain scores than in those that received only levobupivacaine. The route of administration in this study was a single shot local wound infiltration while that of Carvalho was a continuous local instillation in the first 48 hours after the operation. Outcomes of the present study were measured by VAS and additional opioid consumption while Carvalho's study were recorded as VAS, additional opioid consumption and local inflammatory cytokines in wound exudate such as interleukin-6 and interleukin-10 measurements. Rescue opioid in Carvalho's and the present study were morphine and meperidine, respectively. Carvalho et al suggested that the administration of NSAIDs into surgical wound may be an alternative choice in pain control to reduce systemic opioid dosage. The result of his work supported the results of the current study in pain reduction.

Hayden et al[16] from Sweden reported that the combination of ropivacaine and ketorolac showed better pain relief outcomes and lower rescue morphine requirements than that of saline infiltration with intravenous ketorolac. Hayden's study was conducted in subjects who underwent open abdominal hysterectomy and the study drug was infiltrated in the operating site. Both Hayden's and the present study used local infiltration of anesthetic agents, namely ropivacaine and levobupivacaine, respectively. The result of the present study offered similar results to Hayden's work, that the combination of ketorolac and amide anesthetic agents offered a better pain score reduction when used with standard pain management protocol. However, the rescue opioid was not different in the present study.

Recently, Kovacec et al[17] from Slovenia reported 48 hours continuous in-wound infusion with levobupivacaine and ketorolac after cesarean section under spinal anesthesia, the combination significantly lowered the pain score during movement in the first 36 hours post-operation and provided greater opioid-sparing effects during the first 48 hours than the use of levobupivacaine alone. The rescue opioid in Kovacec's and the present study were piritramide and meperidine, respectively. Comparison of the present study to the previous literature was illustrated in Table 3.

The present study revealed that combined levobupivacaine and ketorolac infiltration lowered the pain score for as long as 24 hours after surgery. The duration of long-acting local anesthetic infiltration is known to be around 4 to 8 hours[3], but the duration of subcutaneous ketorolac action is not well established[12]. The current study showed no significant difference in rescue opioid requirement between the two groups which was different from Carvalho's and Kovacec's study. This may be due to the difference in infusion techniques. In this study a local infiltration technique was used however, continuous local infusion technique was used in Carvalho's and Kovacec's study.

A strength of this study was the use of a randomized double-blind control trial, which minimized confounding factors. All participants underwent cesarean section via low midline incision that was the most widely done in clinical practice among hospitals in Thailand.

Limitations of this study included the effect of neuraxial anesthesia that was effective and lasted longer than expectations compared to general anesthesia. However, it was inappropriate to conduct this study by general anesthesia. Further study with a greater number of participants who underwent cesarean section under emergency circumstances (general anesthesia is indicated) might be conducted in the near future.

In conclusion, the local subcutaneous injection of levobupivacaine and ketorolac combination was more effective in postoperative pain control than the use of only levobupivacaine. The additional opioid requirement in both groups was comparable. Multimodality of anesthetic agents, namely neuraxial anesthesia adjunct with local anesthetic agent and NSAIDs combination would be the treatment of choice

for postoperative pain control. Our result, compared to the literature, suggested that local instillation of levobupivacaine and ketorolac cocktail might result in reduction of postoperative pain.

Conclusion

Combined ketorolac with levobupivacaine significantly decreased postoperative pain after cesarean delivery compared to the use of only levobupivacaine. The additional opioid requirement showed no difference between the two groups.

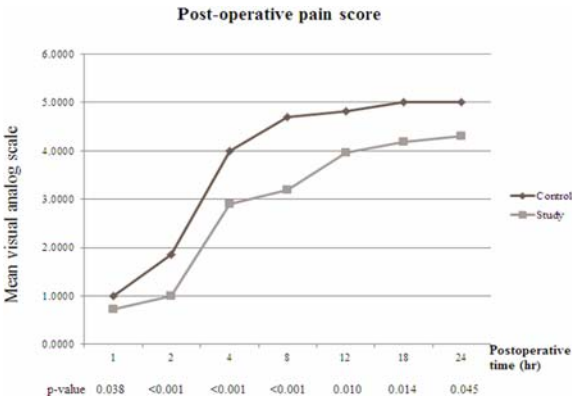

Figure 2. Post-operative pain score during the first 24 hours after operation. Study: levobupivacaine+ ketorolac group, Control: levobupivacaine group.

What is already known on this topic?

Post-cesarean pain is the most common problem. Its reduction can be performed using many different strategies such as the use of opioids, anti-inflammatory analgesia, nerve blocks or adjunctive technique. Opioids are traditional used for pain relief. Additional of NSAIDs and local anesthetic agent are subject of interest. Subcutaneous infiltration of NSAIDs can also be used but its pharmacodynamics and pharmacokinetic are not currently understood.

What this study adds?

Combined ketorolac with levobupivacaine significantly decreased post cesarean pain in the first 24 hours after operation without any serious side effects.

Acknowledgements

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Potential conflicts of interest

The authors declare no conflicts of interest.

Table 2. Additional analgesic used and side effects

	Control (n = 80)	Study (n = 80)	*p*-value
Additional meperidine (mg)*	0 (40)	0 (25)	0.159
Time to request mepiridine (hr)*	0 (6)	0 (8)	0.710
Side effect			
Nausea/vomiting**	11 (13.75)	17 (21.25)	0.214

* Median (interquartile range), ** n (%)

Table 3. Comparing of local combined levobupivacaine and NSAIDs infiltration

Study	Carvalho[11]	Hayden[16]	Kovacec[17]	Present
Years	2013	2017	2018	2018
Country	USA	Sweden	Slovenia	Thailand
Anesthesia	SA/IF	GA/LIA,IV	SA/IF	SA/LIA
Operation	C/S	TAH	C/S	C/S
Type of study	RCT	RCT	RCT	RCT
Postoperative observational period (hr)	48	24	48	24
Number of participants	60	59	59	160
Postoperative pain reduction	IE	IE	IE	IE
Additional analgesic used	D	D	D	ND

GA = general anesthesia, SA = spinal anesthesia, IF = local infusion, LIA = local infiltrative anesthesia, IV = intravenous analgesia, C/S = cesarean section, TAH = total abdominal hysterectomy, RCT = randomized controlled-trial, IE = increased efficacy, D = decreased, ND = not decreased

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เปรียบเทียบประสิทธิภาพของการฉีดยาลีโวบิวพิวาเคนเทียบกับคีโตโรแลคและลีโวบิวพิวาเคนบริเวณแผลผ่าตัดเพื่อระงับความเจ็บปวดหลังผ่าตัดคลอดบุตร: โดยวิธีการแบบสุ่มมีการควบคุมและอำพรางสองฝ่าย

รุ่งฤดี วงษ์ศรี, คมสันติ์ สุวรรณฤกษ์, เด่นศักดิ์ พงศ์โรจน์เผ่า, อธิตา จันทเสนานนท์, อาทิตยา สิงห์วงษา, จรรยา ภัทรอาชาชัย, กรณ์กาญจน์ ภมรประวัติธนะ

ภูมิหลัง: การผ่าคลอดบุตรเป็นการผ่าตัดที่พบบ่อยในสตรีวัยเจริญพันธุ์ โดยหลังผ่าตัดจะมีปัญหาตามมาคือ อาการปวดแผลหลังการผ่าตัด การให้การลดปวดที่เหมาะสมและเพียงพอจะช่วยลดความทุกข์ทรมานจากการผ่าตัด

วัตถุประสงค์: ศึกษาประสิทธิภาพของการระงับความเจ็บปวดหลังการผ่าตัดคลอดบุตรโดยนำยากลุ่มต้านการอักเสบที่ไม่ใช่สเตียรอยด์และลีโวบิวพิวาเคนมาใช้แบบฉีดเฉพาะที่บริเวณแผลผ่าตัดเพื่อการระงับปวด

วัสดุและวิธีการ: ผู้เข้าร่วมวิจัยคือสตรีตั้งครรภ์อายุระหว่าง 18 ถึง 40 ปีที่มารับการผ่าตัดคลอดบุตร ณ โรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ โดยจะถูกคัดเลือกชนิดแบบเดาสุ่มและแบ่งเป็น 2 กลุ่มจำนวนเท่ากัน โดยกลุ่มศึกษาได้รับการฉีดยาลีโวบิวพิวาเคน 50 มิลลิกรัมผสมกับยาคีโตโรแลค 30 มิลลิกรัม ส่วนกลุ่มควบคุมได้รับยาลีโวบิวพิวาเคน 50 มิลลิกรัมแบบไม่ผสมยาคีโตโรแลค ฉีดบริเวณชั้นเนื้อเยื่อใต้ผิวหนังรอบแผลก่อนเย็บปิดแผลผ่าตัด จากนั้นทำการเก็บข้อมูลคะแนนความปวดแผลที่ 1, 2, 4, 8, 12, 18 และ 24 ชั่วโมงหลังการผ่าตัด โดยใช้วิช่วล อนาล็อก สเกล ปริมาณยาฉีดแก้ปวดกลุ่มโอปีออยด์แบบฉีดที่ผู้ป่วยขอเพิ่มใน 24 ชั่วโมงแรกหลังการผ่าตัด และผลข้างเคียงหรือภาวะแทรกซ้อนที่เกิดขึ้น

ผลการศึกษา: จากผู้เข้าร่วมวิจัยทั้งสิ้นจำนวน 160 คนในทั้งสองกลุ่มกลุ่มละ 80 คนพบว่าไม่มีความแตกต่างกันในด้านลักษณะของข้อมูลพื้นฐานและข้อมูลทางคลินิก ค่าเฉลี่ยคะแนนความปวดแผลหลังการผ่าตัดของกลุ่มศึกษามีค่าน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติที่ 1, 2, 4, 8, 12, 18 และ 24 ชั่วโมงหลังผ่าตัด ปริมาณยาฉีดแก้ปวดกลุ่มโอพิออยด์ที่ขอเพิ่มใน 24 ชั่วโมงแรกหลังการผ่าตัด และผลข้างเคียงหรือภาวะแทรกซ้อนที่พบในทั้งสองกลุ่มไม่แตกต่างกัน

สรุป: การฉีดยาคีโตโรแลคผสมกับยาลีโวบิวพิวาเคนบริเวณแผลผ่าตัดช่วยระงับความปวดแผลใน 24 ชั่งโมงแรกหลังผ่าตัดคลอดบุตรได้อย่างมีนัยสำคัญทางสถิติ เมื่อเทียบกับการได้รับยาลีโวบิวพิวาเคนเพียงอย่างเดียว