

Efficacy of Systemic Single-dose Diclofenac, Tramadol, and Placebo Immediately after Caesarean Section under Intrathecal Morphine

Kriangsak Kham-im*

Meena Choojai**

Sudarat Luangareeporn**

**Division of Obstetrics and Gynecology*

***Division of Anesthesiology*

Ban Pong Hospital, Ratchaburi

Abstract

Postoperative pain relief after caesarean section delivery under spinal anesthesia can be effectively obtained by intrathecal morphine but its dose-dependent side effects are well recognized. Any techniques that could potentiate the analgesic effects and reduce its unsatisfactory property are of interest. This study was a prospective randomized controlled trial. One hundred fifteen parturients scheduled for elective caesarean section under spinal anesthesia using 0.5% hyperbaric bupivacaine combined 0.2 mg intrathecal morphine were allocated into three groups, each receiving single dose intramuscular diclofenac 75 mg, tramadol 50 mg, or placebo immediately after caesarean section. The aim of this study was to compare the pain-control efficacy of analgesia post operation in the three groups. Mean visual analogue scores of postoperative pain diclofenac was significantly lower than that of placebo at 3-hour postoperative period and significantly lower than tramadol at 3 and 6-hour postoperative periods. Adverse effects including nausea/vomiting, pruritus, and sedation were not different among the three groups.

In conclusion, combination of low dose intrathecal morphine with single-dose intramuscular diclofenac immediately post caesarean section provided better pain control in addition to attenuation of high-dose intrathecal morphine side effects. These benefits would result in early ambulation, comfort, and the ability to care newborns of the patients.

Key words: caesarean section, diclofenac, tramadol, intrathecal morphine

Introduction

Pain is a major problem in surgery including caesarean section of which rate has been increasing and becomes a common surgical procedure nowadays⁽¹⁾.

In Thailand, the rate increased steadily from 15.2 percent in 1990 to 22.4 percent in 1996⁽²⁾ while the World Health Organization recommended caesarean section rate of 15 percent⁽³⁾. In Ban Pong hospital caesarean

section rate is 20.02 percent. The pain after caesarean delivery interferes with patient activities and impacts on motherhood experiences. The provision of optimal analgesia after caesarean section remains a challenge, as satisfactory pain relief must be balanced with the ability of the mother to care her newborn. In fact, pain after caesarean delivery derived three components including incisional pain, deeper muscular pain related to the rectus separation and cramping pain related to postpartum uterine activity⁽⁴⁾. The novel postoperative pain controlled techniques such as patient-controlled analgesia (PCA) and patient-controlled epidural analgesia (PCEA) are expensive and may limit the woman ability to care her baby after delivery because of the sedative and respiratory depressive effect of the opioids⁽⁵⁾ as well as motor blockade due to local anesthetics⁽⁶⁾.

Spinal anesthesia is still popular for caesarean section, especially in Ban Pong hospital, because the technique is easy and produces adequate relaxation of abdominal muscle with little effect on the neonate. However, spinal anesthesia provides insufficient postoperative analgesia; so, additional analgesics are usually required. A single dose of intrathecal morphine decreases post-caesarean opioid analgesic requirement and may reduce or prevent neonatal neurobehavioral depression associated with maternal analgesia⁽⁷⁾.

Excellent postoperative pain relief after caesarean delivery under spinal anesthesia can be obtained with 0.1 - 0.3 mg of subarachnoid morphine, although well known dose-dependent side effects may occur⁽⁸⁾. Therefore, techniques that potentiate the analgesic effects of opioids, allowing for a reduction in their subarachnoid dosage without enhancing their side effects, are of interest. A multimodal approach such as a combination of very small dose of intrathecal morphine in combination with intramuscular diclofenac as the pain control may provide good quality analgesia while reduce drug-related side effects⁽⁹⁾. The combination of

tramadol and diclofenac is more effective for postoperative sensitization and pain after caesarean delivery than two given individually⁽¹⁰⁾. Whereas the main site of action of subarachnoid morphine is the opioid receptors in the substantia gelatinosa of the dorsal horn of the spinal cord, diclofenac has both peripheral and central effects, as it inhibits prostaglandin synthesis and the nonopioid supraspinal noniceptive reflex. Tramadol is another effective postoperative analgesic via its μ -opioid agonist effects and monoaminergic action⁽¹¹⁾.

Although there is a theory of the risk of bleeding by NSAIDs due to decreased platelet function and tocolytic activity, no bleeding side effect were observed in a study⁽¹²⁾. Regarding breast-feeding, it has already been demonstrated that the breast milk of woman treated with diclofenac contains extremely small amounts of the drug, unlikely to represent a hazard to neonates⁽¹³⁾.

In obstetricians' point of view, the effectiveness and satisfaction of post-caesarian section analgesia should not only be pain-control efficacy but also ability of the mother to take care of her newborn.

The aim of this study was to compare the pain-control efficacy of single doses of diclofenac, tramadol and placebo immediately after caesarean section under intrathecal morphine in order to provide a better quality of analgesia in the postoperative caesarian section period.

Methodology

This study was a prospective randomized controlled trial and was approved by Ban Pong hospital Medical Ethics and Research Committee. The first gravidalum pregnant patients scheduled to undergo elective lower segment caesarean section at Department of Obstetric and Gynecology, Ban Pong hospital, Ratchaburi, Thailand between November 2005 and March 2006 were enrolled. Exclusion criteria were

known allergy to diclofenac or tramadol, the American Society of Anesthesiologists (ASA) status > 3, history of peptic ulcer disease or gastrointestinal bleeding, opioid use in last month, liver disease, kidney disease, pre-eclampsia or eclampsia, placenta previa, significant pulmonary disease, or intraoperation complications.

Written informed consent was obtained from each patient. Patients were allocated before surgery into the three groups by using a computerized randomization, each of which received different treatments. Groups 1, received intramuscular diclofenac 75 mg, Groups 2 received intramuscular tramadol 50 mg and Groups 3 received intramuscular placebo of distilled water 2 ml immediately after caesarean section under spinal anesthesia with 15 mg of 0.5% hyperbaric bupivacaine and 0.2 mg intrathecal morphine.

A visual analogue scores (VAS) to assess postoperative pain, nausea, pruritus, and somnolence were explained to each patient before surgery. The VAS is a 10 cm scale with anchor point at 0-10 cm marked no pain and worst possible pain respectively. Modified four point ordinal scales 1-4 were used to assess severity of nausea, pruritus (0= no symptoms, 1=mild symptoms, 2=but not requesting treatment, moderate symptoms, requesting treatment. and 3=symptom persisting despite treatment) and level of sedation (0=awake and alert, 1=drowsy, but responds to verbal stimulus, 2=drowsy, but responds to physical stimulus and 3=unresponsive). Formal assessment of the patients was conducted at 1, 3, 6, 12 and 24 hr after operation.

VAS pain scores were obtained while the patients were at rest, but the patients were encouraged to sit and ambulate at six hours after delivery. In case of VAS pain scores ≥ 6 or patients requesting, additional analgesics were provided. Patients were initially treated with tramadol 50 mg intramuscular, anti-emetic (metoclopramide 50 mg intramuscular) and antipruritic

(chlorpheniramine 10 mg intramuscular). Respiratory depression was recorded according to routine standard postoperative care. The incidence of urinary retention was not studied, as all patients has an indwelling catheter for at least 8 hours after operation. The anesthesiologist who is responsible for administering regional anesthesia and nurse were blinded to the identification of analgesic regimen and were not involved in post operative patient assessment.

An anesthesiologist, who was not subsequently enrolled, prepared the appropriate morphine solution prior to use. The spinal anesthesia and anesthetic management of all patients were standardized. Continuous ECG, noninvasive arterial blood pressure, and O₂ saturation monitors were used before starting anesthesia. Following a fluid preload of 1000 ml of Ringer's acetate solution, dural puncture was performed with the patient in the left-down lateral position in the L3-4 intervertebral space using a 24 G Quinke-type spinal needle, and standard dose of 15 mg of 0.5% hyperbaric bupivacaine combined with preoperative-free morphine 0.2 mg was injected over 60 seconds. The patients were then placed in the supine position with right hip up, and oxygen was supplied by facemask. The operation was started when the sensory block as measured using the loss of cold sensation, had reached the level of T5 and recorded until the end of the operation. All women were observed in the postanaesthetic care room in the delivery suite for a period of 2 hours and thereafter in general postpartum ward, with monitoring of vital signs as for any other routine operation.

The sample size was calculated by Power analysis 0.8 and error $\alpha=0.05$, (Effect size 0.8) were 27 cases per group controlled. So this sample size was designed 40 cases per group or 120 cases in total.

The patients' characteristics (age, weight, height, gestational age) and duration of the operation time among groups were compared by One-Way analysis

of Variance (ANOVA). The comparison of VAS pain score, nausea, puritus, and sedation were performed by the Kruskal- Wallis ANOVA, followed by Mann-Whitney U-testing. Statistical significance was defined when $p < 0.05$.

Results

One hundred twenty patients were enrolled, and 115 completed the study; three patients were excluded because of failed spinal anesthesia whereas the other two patients were excluded because of incomplete data collection : (1 in group tramadol, 2 in group placebo

Table 1 Demographic characteristic data of patients undergoing caesarean section

	Diclofenac (n=38)	Tramadol (n=39)	Placebo (n=38)	p -value
Age (year)	29.3, 6.13 (18 - 42)	28.0, 4.82 (19 - 39)	28.5, 5.25 (17 - 40)	0.590
Weight (kg)	69.8, 11.61 (50 - 97)	69.8, 11.49 (49 - 99)	71.7, 11.09 (52 - 100)	0.698
Height (cm)	155.9, 5.33 (144 - 170)	156.4, 5.51 (147 - 173)	157.0, 5.89 (140 - 170)	0.681
Gestational Age (week)	38.6, 1.23 (36 - 41)	38.7, 1.58 (35 - 44)	38.7, 1.67 (33 - 42)	0.970
Operation time (min)	46.00, 13.15 (27 - 76)	42.6, 15.47 (30 - 62)	43.7, 10.64 (30 - 60)	0.650

remark : data reported in mean, SD (range)

Table 2 VAS of postoperative caesarean section pain

Post-op VA score	Diclofenac n=38	Tramadol n = 39	Placebo n = 38	p value	95% CI
VA score at 1 hr	0.92, 1.48 (0 - 5)	1.46, 1.79 (0 - 6)	0.97, 1.52 (0 - 5)	NS	0.82, 1.42
VA score at 3 hr	0.82, 1.25*, ** (0 - 5)	1.79, 1.69** (0 - 5)	1.47, 1.96 (0 - 6)	< 0.05	0.95, 1.54
VA score at 6 hr	0.87, 1.32** (0 - 5)	1.90, 1.65** (0 - 5)	1.79, 1.73 (0 - 5)	<0.05	1.11, 1.69
VA score at 12 hr	1.26, 1.41 (0 - 5)	1.85, 1.58 (0 - 5)	1.50, 1.52 (0 - 5)	NS	1.26, 1.82
VA score at 24 hr	2.03, 1.62 (0 - 6)	1.79, 1.36 (0 - 5)	1.68, 1.36 (0 - 5)	NS	1.54, 2.10

* $p < 0.05$ when compared with placebo

** $p < 0.05$ when compared between diclofenac and tramadol

NS = Not significant

data reported in mean, SD (range)

and 2 in group diclofenac). Demographic data including age, body weight, height and gestational age revealed no statistical difference among the three groups. Duration of the surgical procedure did not differ among the three groups (Table 1). Sensory level of spinal anesthesia reached the T5 in all patients resulting from painless surgery. Therefore, no intraoperative analgesic supplement was required.

Mean of VAS score post operative caesarean section at 1 hour in the diclofenac group, tramadol and placebo were no different. At 3 hours, the mean VAS score of the diclofenac group was significantly lower than that of the tramadol ($p=0.007$) and the mean VAS score at 6 hours was also significantly lower than those of the tramadol group ($p=0.003$) and the placebo group ($p=0.04$). Repeated evaluations were made at 12 hours and 24 hours after operation showing no differences thereafter among the three groups. (Table 2 and Figure 1).

Other adverse effects including nausea / vomit-

ing pruritus, and sedation (Table 3) were not different among the three groups. No patient experienced respiratory depression.

Discussion

This study showed the data supported the practice of multimodal approach to post-operative analgesia. In previous randomized double-blind study demonstrated the patients who underwent caesarean section under spinal anesthesia experienced less post-operative pain when morphine was added to the intrathecal injection. Interestingly, the present study demonstrated that the combination of small dose of intrathecal morphine with systemic diclofenac improved analgesia compared with either intrathecal morphine alone or in combination with tramadol. Patients in the group that received intrathecal morphine with single-dose diclofenac immediately after caesarean section had significantly lower pain scores than group with placebo at 3-hour post operation as well as

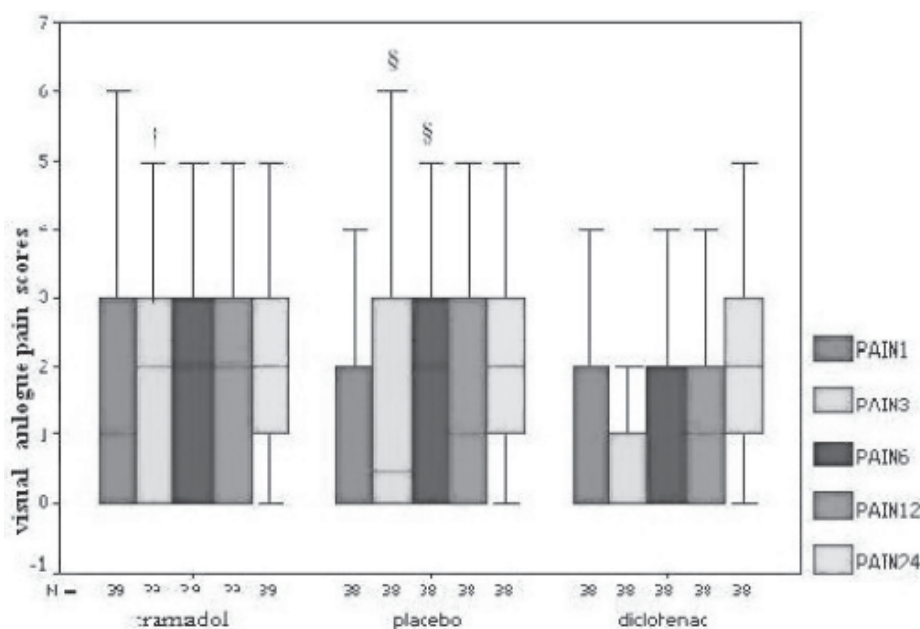


Figure 1 Comparison Visual analogue pain scores (0-10 cm) subclassified according patient group (central bar, median; box area, inter-quartile range). $p<0.05$ vs diclofenac; $p<0.05$ vs diclofenac

Table 3 Postoperative nausea, pruritus and sedation score.

Time (hr)	side effect	Diclofenac n=38	Tramadol n = 39	Placebo n = 38	p value
at 1 hr	nausea	0.47, 1.06	0.23, 0.58	0.61, 1.08	NS
	pruritus	0.29, 0.65	0.46, 0.76	0.55, 1.01	NS
	sedation	0.00, 0.00	0.03, 0.16	0.00, 0.00	NS
at 3 hr	nausea	0.37, 0.88	0.38, 0.75	0.32, 0.74	NS
	pruritus	0.45, 0.86	0.46, 0.64	0.50, 0.80	NS
	sedation	0.00, 0.00	0.03, 0.16	0.00, 0.00	NS
at 6 hr	nausea	0.18, 0.56	0.15, 0.49	0.16, 0.50	NS
	pruritus	0.39, 0.76	0.28, 0.51	0.32, 0.74	NS
	sedation	0.00, 0.00	0.00, 0.00	0.00, 0.00	NS
at 12 hr	nausea	0.05, 0.32	0.00, 0.00	0.03, 0.162	NS
	pruritus	0.32, 0.53	0.15, 0.43	0.16, 0.37	NS
	sedation	0.00, 0.00	0.00, 0.00	0.00, 0.00	NS
at 24 hr	nausea	0.00, 0.00	0.00, 0.00	0.00, 0.000	NS
	pruritus	0.11, 0.31	0.05, 0.22	0.00, 0.00	NS
	sedation	0.00, 0.00	0.03, 0.16	0.00, 0.00	NS

NS = not significant
data reported in mean, SD

the group with tramadol at 3 and 6-hour post operation. Some patients who received only intrathecal morphine demanded additional analgesics for post-caesarean section pain⁽⁹⁾. When different classes of analgesics are administered simultaneously to the same patient the drug can cause competitive, additive, or synergistic effects. In this study and previous study⁽¹⁶⁾, intrathecal morphine and NSAIDs seemed to act synergistically. Small dose of intrathecal morphine combined with intramuscular diclofenac provide excellent postoperative pain control after caesarean delivery.

Diclofenac, a NSAID, is thought to act by inhibiting prostaglandin synthesis, hence its efficacy in post-caesarean analgesia by the reduction of pain from uterine contraction. A central anti-nociceptive effect has also been postulated^(17,18). If NSAID with a short half-life, such as diclofenac⁽¹⁹⁾ is used, repeated doses may be needed.

Tramadol is an effective postoperative analge-

sic^(4,20). Besides α -opioid agonist effect, tramadol has monoaminergic action⁽¹¹⁾ and should be an effective postoperative analgesic medication. However, the results from this study demonstrated the inferior efficacy when compared with diclofenac and did not make any difference from placebo. This might explain by the single dose design in this study was likely to cause the delayed onset of the monoaminergic action. A slower onset of action than morphine has been previously noted. Because all the patients were pregnant, changes in metabolism, analgesic pathway, or sensitivity in pregnancy could also explain the less than expected analgesia with tramadol^(16,10,18).

Spinal hyperbaric bupivacain has been found to have a high incidence of motor block during operation analgesia. In this study no attempt was made to assess the ability of the patients to ambulate. In fact, sensory loss in the lower extremities may have an adverse effect on ambulation⁽³⁾. However, its focus was

on post-caesarean patients to be encouraged to ambulate as early as possible in order to minimize postoperative complications and allow them to care for the newborns.

Pruritus and nausea are the common troublesome side effects of neuraxial opioid administration after caesarean section. Intravenous droperidol⁽²²⁾ has been reported to decrease nausea and pruritus in the first 24 hours after caesarean delivery. In the present study, all groups of patients were not significantly different in the incidence, severity of nausea/vomiting and pruritus. Administration of intrathecal morphine at a dose lower than 0.2 mg might provide similar analgesia but fewer side effects⁽¹⁶⁾.

Post caesarean section patients who use PCA⁽²³⁾ or PCEA with opioids⁽²⁴⁾ may have increased opioid induced somnolence. When continuous epidural block for post-caesarean analgesia is used, local anesthetics may impair the care of the newborn due to motor blockade and respiratory depression by subcutaneous morphine⁽⁶⁾. In the present study, all groups of patients showed no significant difference in sedation and respiratory depression.

In conclusion, combination of low dose intrathecal morphine with single-dose intramuscular diclofenac immediately in post caesarian section provided the better pain control in addition to attenuation of high-dose intrathecal morphine side effect. These benefits would result in early ambulation, satisfactory, and the ability to care for the newborns of the patients.

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บทคัดย่อ ประสิทธิภาพของยาไดโคลฟีแนค ทรามาดอล และยาเปล่า ฉีดเข้ากล้ามเนื้อครั้งเดียวทันทีหลังผ่าตัดคลอดทางหน้าท้องภายใต้การให้ยาระงับปวดมอร์ฟีนทางช่องไขสันหลัง เกรียงศักดิ์ คำอิม*, มีนา ชูใจ**, สударัตน์ เหลืองอารีย์พร**

*กลุ่มงานสูติ-นรีเวชกรรมและวางแผนครอบครัว โรงพยาบาลบ้านโป่ง, **กลุ่มงานวิสัญญี โรงพยาบาลบ้านโป่ง วารสารวิชาการสาธารณสุข 2551; 17:III360-8.

การระงับความรู้สึกด้วยการฉีดยาชาเข้าทางช่องไขสันหลังร่วมกับการให้ยามอร์ฟีน เพื่อการระงับปวดหลังผ่าตัดคลอดทางหน้าท้อง มีประสิทธิภาพดีในการระงับปวด แต่พบผลข้างเคียงขึ้นกับปริมาณของยา เทคนิคต่าง ๆ ที่จะเข้ามามีบทบาทในการลดความเจ็บปวดและผลข้างเคียงจึงเป็นที่น่าสนใจ การศึกษาเชิงทดลองแบบติดตามไปข้างหน้าครั้งนี้ทำในผู้ป่วย 115 คน ที่เข้ารับการผ่าตัดคลอดคลอดทางหน้าท้องแบบไม่ฉุกเฉินภายใต้การระงับความรู้สึกด้วย 0.5% hyperbaric bupivacaine กับ 0.2 mg intrathecal morphine โดยแบ่งผู้ป่วยเป็น 3 กลุ่มให้ยาระงับปวดเข้ากล้ามเนื้อ ดังนี้ 1) ไดโคลฟีแนค 75 mg 2) ทรามาดอล 50 mg และ 3) ยาเปล่า 2 ml ผู้ป่วยได้รับยาตั้งกล่าวทันทีหลังการผ่าตัดคลอดทางหน้าท้องเสร็จ การศึกษาค้นนี้มีวัตถุประสงค์ เพื่อเปรียบเทียบประสิทธิภาพของการระงับปวดหลังผ่าตัดคลอดทางหน้าท้องในผู้ป่วยทั้ง 3 กลุ่ม ผลการทดลองพบว่า ค่าเฉลี่ยของคะแนนความเจ็บปวด ในผู้ป่วยที่ได้รับยาระงับปวดไดโคลฟีแนค มีความแตกต่างกับยาเปล่า อย่างมีนัยสำคัญทางสถิติ ในชั่วโมงที่ 3 และแตกต่างกับทรามาดอล อย่างมีนัยสำคัญทางสถิติในชั่วโมงที่ 3 และ ชั่วโมงที่ 6 หลังผ่าตัด ส่วนผลข้างเคียงในด้านของอาการคลื่นไส้ อาเจียน อาการคัน และอาการง่วงซึม ไม่แตกต่างกันในทั้ง 3 กลุ่ม

การให้ยาระงับปวดมอร์ฟีน ขนาดปริมาณน้อย ร่วมกับการระงับความรู้สึกด้วยการฉีดยาชาทางช่องไขสันหลังและให้ไดโคลฟีแนค ฉีดเข้ากล้ามเนื้อครั้งเดียวทันทีหลังผ่าตัดคลอดทางหน้าท้อง ช่วยระงับปวดหลังผ่าตัดได้ผลดีจึงควรนำมาใช้ เป็นการลดผลข้างเคียงของการที่จะใช้ยา intrathecal morphine ขนาดปริมาณสูง จึงเป็นประโยชน์ช่วยให้ผู้ป่วยสามารถฟื้นฟูสภาพร่างกายได้เร็ว เกิดความรู้สึกสุขสบายและสามารถเลี้ยงดูทารกแรกคลอดได้ต่อไป

คำสำคัญ: ผ่าตัดคลอดทางหน้าท้อง, ไดโคลฟีแนค, ทรามาดอล, ยาระงับปวดมอร์ฟีน