

Ibuprofen Versus Acetaminophen for the Relief of Perineal Pain After Childbirth: A Randomized Controlled Trial

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Objectives: To evaluate efficacy of ibuprofen compared with acetaminophen for relief of perineal pain after childbirth, side effects of ibuprofen compared with acetaminophen and patient satisfaction in treatment between the 2 groups

Material and Method: A total of 210 women who gave birth by spontaneous vaginal delivery with mediolateral episiotomy between June 2006 and November 2006 were randomly assigned to receive either ibuprofen (400 mg) (n = 106) or acetaminophen (1000 mg) (n = 104), both given orally when suturing was completed. Pain ratings were recorded before the treatment and at 1, 2, 3 and 4 hours after the treatment on a 10-cm visual analogue scale. Side effects and patient satisfaction were assessed at 24 hours.

Results: Pain in the ibuprofen group was considerably more reduced than the acetaminophen group at 1 hour of treatment (mean pain rating 2.18 vs. 2.88, respectively; $p < 0.003$). Even though, at 2, 3 and 4 hours of treatment ibuprofen seemed to give more relief of pain than acetaminophen, they did not reach statistically significant differences (mean pain rating; at 2 hour: 1.59 vs. 1.97, $p = 0.093$; at 3 hour: 1.08 vs. 1.31, $p = 0.183$; and at 4 hour: 0.69 vs. 0.85, $p = 0.169$; respectively). There were no side effects and no significant differences in overall patient satisfaction between the two groups.

Conclusion: Ibuprofen was consistently better than acetaminophen at 1 hour after treatment for relief of perineal pain after childbirth without any side effects. After 2 hours, ibuprofen and acetaminophen had similar analgesic properties.

Keywords: Episiotomy, Perineal pain, Ibuprofen, Acetaminophen

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Perineal pain from episiotomy is a common problem following vaginal birth. It not only impacts on the physical and mental functioning of the woman, but also decreases the success for the mother to breastfeed, her ability to care for her new baby, mobility, urinary and fecal incontinence. These effects may be detrimental to the experiences of motherhood. Although the use of episiotomy is often debated, it remains a common practice in Thailand

There are numerous treatments for perineal pain relief in clinical practice including pharmacological and non-pharmacological applications.

Nonpharmacological methods of pain management such as application of heat or sitz baths are often inadequate. Acetaminophen is the most common analgesic used for mild perineal pain. For moderate to severe pain, a variety of drugs have been used including opioid, non-opioid and combination of both. Very few of these are free of side effects.

Nonsteroidal anti-inflammatory drugs (NSAIDs) are widely used for moderate to severe pain in clinical practice. However, there is insufficient evidence to assess the benefits and harms of orally administered NSAIDs for perineal pain relief after childbirth. Compared with other NSAIDs, ibuprofen has a similar efficacy and fewer adverse side effects. Ibuprofen inhibits prostaglandin synthesis, which is thought to sensitize pain receptors to the effects of

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pain mediators, such as bradykinin, acetylcholine and histamine. Ibuprofen is the only NSAIDs used commonly for a long time in pregnancy. The infant's weight adjusted dose is estimated 0.0008% of the mother's dose. The American Academy of Pediatrics classifies ibuprofen as compatible with breast feeding⁽¹⁾. Ibuprofen has been found to be effective in the management of pain after episiotomy, without associated side effects. However, studies comparing ibuprofen with acetaminophen for perineal pain relief after delivery have been limited with conflicting results which may be due to small sample sizes, short observation periods, lack of standardized or validated pain assessment, omission of side effects, and of patient preference. In the authors' institution, standing orders for the management of postpartum pain include perineal light care twice a day and acetaminophen 2 tablets (1000 mg) every 4 hours prn for pain. The particular choices for analgesia have not been rigorously studied.

The main purpose of the present study was to evaluate the efficacy of ibuprofen compared with acetaminophen for relief of perineal pain after childbirth. The secondary objectives were to evaluate side effects of ibuprofen compared with acetaminophen and to evaluate patient satisfaction in treatment between the two groups.

Material and Method

Term pregnant women were recruited from the delivery room of King Chulalongkorn Memorial Hospital between June 2006 and November 2006. Women with mediolateral episiotomy without a third- or fourth-degree tear after a normal uncomplicated delivery who had not used any analgesic drugs within 4 hours preceding the study were eligible for the present study. Exclusion criteria included allergy to either study drug, a history of drug dependence, regular use of analgesic drugs before or during pregnancy, and any medical condition known to be potentially exacerbated by acetaminophen or NSAIDs, including a history of gastrointestinal ulcer or bleeding, significant renal or liver impairment and asthma. Women with postpartum hemorrhage or any other major postpartum complications were also excluded.

Ethical approval for the present study was obtained from the Research and Ethical Committee of the Faculty of Medicine, Chulalongkorn University.

Mediolateral episiotomies and repairs were performed by residents in all cases using the standard procedures under local anesthesia⁽²⁾. After assessment for eligibility, women were recruited in the delivery room

by a resident or one of the investigators. Written informed consent was obtained after perineal repair. Then the eligible women were randomly allocated to receive either ibuprofen or acetaminophen orally by stratified random sampling technique. Each treatment pack contained ibuprofen (400 mg) 1 tablet and ranitidine (150 mg) 1 tablet or acetaminophen (500 mg) 2 tablets wrapped in foil.

All women were asked to give pain score by visual analogue scale before ibuprofen or acetaminophen taken and at 1, 2, 3 and 4 hours after treatment. Patients were allowed to use a supplemental analgesic after 4-hour evaluation as a rescue drug.

The primary outcome for the present study was severity of pain, rated on a 10-cm visual analogue scale from 0 ("no pain") to 10 ("worst pain ever"). An initial rating was recorded before the subject took the first dose of analgesia and at 1, 2, 3 and 4 hours after the first dose by one of the investigators.

The secondary outcomes were evaluated for side effects, including nausea, vomiting, stomach pain, indigestion, disorientation and dizziness and maternal satisfaction with relief of perineal pain between the two groups after 24 hours of treatment. The subjects were asked to indicate their overall level of satisfaction with their study drug on a 10-cm visual analogue scale ranging from 0 ("very dissatisfied") to 10 ("very satisfied").

All the data were collected and analyzed by one of the investigators who were blinded to group assignment using the SPSS statistical package. Demographic and clinical characteristics were compared between the groups using analysis of variance and Chi-square test. Categorical variables, such as presence of side effects were compared between the groups using Chi-square test and continuous variables, such as sequential measures on visual analogue pain scales and overall satisfaction as measures on visual analogue scales were compared between the groups using Student's t-test. P-value < 0.05 was considered statistical significance.

Results

Two hundred and ten women were enrolled in the present trial, with 106 randomized to receive ibuprofen and 104 to receive acetaminophen. The two treatment groups were similar in demographic data and clinical features (Table 1).

The severity of perineal pain did not differ at the time before the treatment between the ibuprofen and acetaminophen groups. Ibuprofen was consistently

Table 1. Maternal demographics and clinical features

Variables	Treatment groups		p-value
	Ibuprofen n = 106	Acetaminophen n = 104	
Maternal age (years)	25.75 (4.18)	26.68 (4.36)	0.110
Gestational age (days)	269.44 (7.70)	269.70 (7.82)	0.810
Length of labor (minutes)	724.44 (150.02)	732.68 (165.18)	0.705
Birth weight (kg)	2976.89 (247.66)	2997.69 (257.92)	0.552
Parity	1.48 (0.63)	1.63 (0.68)	0.094
Degree of perineal tear	0.61 (0.86)	0.66 (0.83)	0.669

Data were presented as mean (SD)

Table 2. Mean ratings (SD) of pain intensity

Variables	Treatment groups		p-value
	Ibuprofen n = 106	Acetaminophen n = 104	
Pain rating			
Before taking analgesia	4.13 (2.14)	3.85 (2.26)	0.349
1 h after taking analgesia	2.18 (1.44)	2.88 (1.97)	0.003
2 h after taking analgesia	1.59 (1.28)	1.97 (1.89)	0.093
3 h after taking analgesia	1.08 (0.97)	1.31 (1.49)	0.183
4 h after taking analgesia	0.69 (0.69)	0.85 (0.94)	0.169
Satisfaction	8.04 (1.24)	7.93 (1.34)	0.557

better for perineal pain relief than acetaminophen at one hour after treatment (mean ratings (SD) of pain intensity 2.18 (1.4) vs. 2.88 (1.97), respectively; $p < 0.003$) but no differences in mean ratings of pain intensity were shown at 2, 3 and 4 hours, respectively (Table 2).

There were no statistically significant differences in patient satisfaction between the ibuprofen and acetaminophen groups (mean ratings (SD) of patient satisfaction 8.04 (1.24) vs. 7.93(1.34), respectively, $p = 0.59$).

No side effects of the two drugs were detected in either groups.

Discussion

Factors that may influence the severity of perineal pain include mode of birth, type of suture material and perineal repair technique, in the present study the authors had controlled for these confounders. This clinical trial demonstrates that ibuprofen 400 mg and acetaminophen 1000 mg administered as single oral doses are effective analgesic agents in relieving postpartum episiotomy pain. It is unethical to use placebo

as a control. Ibuprofen 400 mg was found to provide significantly more analgesia than acetaminophen 1000 mg at 1 hour after episiotomy. Even though, at 2, 3 and 4 hours of treatment ibuprofen seemed to give more relief of pain than acetaminophen, they did not reach statistically significant differences. This explanation may be due to, in both the treatment groups the authors included only mild or moderate pain because the exclusion criteria in the present study were assisted vaginal deliveries such as forceps extraction and vacuum extraction and third or fourth perineal tears. It has been found that ibuprofen had a more rapid onset of action and a more prolonged duration of action than acetaminophen. Most studies found that ibuprofen was more effective than acetaminophen in reducing the moderate to severe pain. The present findings confirm other studies demonstrating the analgesic efficacy of ibuprofen when used in the treatment of postpartum episiotomy pain.

Schachtel et al⁽³⁾ have reported the results of the comparisons of the single-dose ibuprofen 400 mg, acetaminophen 1000 mg and placebo in the relief of

postpartum episiotomy pain. Their study showed that both active agents were effective compared with placebo and ibuprofen was more effective than acetaminophen with reduction of pain by more than 50%.

Peter et al⁽⁴⁾ have compared ibuprofen and acetaminophen with codeine for the treatment of perineal pain after childbirth. They found that the two analgesics had similar analgesic properties in the first 24 hours post partum with mean pain rating 3.4 and 3.3, respectively.

Behotas et al⁽⁵⁾ have studied the relief of post-episiotomy pain by comparing a single dose of 400 mg of ibuprofen, 1 g of acetaminophen and placebo. The study showed that ibuprofen was more effective after 1 hour than the other two groups.

In the present study the authors prescribed ibuprofen as a single oral dose therefore, we found no adverse effects. The side effects which have been reported when used as multiple doses are nausea (4.5%), vomiting (2.8%), stomach pain (9.2%), indigestion (8.9%), dizziness (25.2%), and disorientation (8.1%).

The women in both of the present study groups did not differ in their expression of satisfaction. The present finding is consistent with the study of Peter et al⁽⁴⁾.

The strengths of the present study include use of a randomized, controlled trial, several measures of pain intensity, measurement of a variety of side effects and measurement of patient satisfaction. The present study may be useful for the future study about the new NSAIDs such as parecoxib and etoricoxib for perineal pain relief.

In conclusion, ibuprofen was consistently better than acetaminophen at 1 hour after treatment for relief of perineal pain after childbirth without any side effects. After 2 hours, ibuprofen and acetaminophen had similar analgesic properties.

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การศึกษาการใช้ยา ibuprofen เปรียบเทียบกับยา acetaminophen ในการลดความเจ็บปวดของแผลฝีเย็บภายหลังการคลอดบุตร

รุ่งทิวา กมลเดชเดชา, เขื่อน ต้นนิรันดร

วัตถุประสงค์: เพื่อศึกษาเปรียบเทียบประสิทธิภาพการใช้ ibuprofen 400 มิลลิกรัม และ acetaminophen ในการลดความเจ็บปวดของแผลฝีเย็บ ภายหลังการคลอดบุตร

วัสดุและวิธีการ: รูปแบบการศึกษาเป็นแบบสุ่มตัวอย่าง โดยหญิงตั้งครรภ์ที่กำหนดที่คลอดบุตรทางช่องคลอด และได้รับการตัดฝีเย็บด้านข้าง ในช่วงเวลาระหว่าง มิถุนายน พ.ศ. 2549 และพฤศจิกายน พ.ศ. 2549 ทั้งหมด 210 คน สุ่มเพื่อรับยา ibuprofen 400 มิลลิกรัม ($n = 106$) หรือ acetaminophen 1000 มิลลิกรัม ($n = 104$) โดยทั้ง 2 กลุ่มได้รับยาหลังจากเย็บแผลเสร็จเรียบร้อยแล้ว มีการเก็บข้อมูลระดับความปวดตั้งแต่ก่อนได้รับยา ชั่วโมงที่ 1, 2, 3 และ 4 หลังการได้รับยา โดยใช้ "10-cm visual analogue scale" ประเมินผลข้างเคียงและระดับความพึงพอใจของผู้ป่วยที่ 24 ชั่วโมง

ผลการศึกษา: ประสิทธิภาพในการลดความเจ็บปวดของแผลฝีเย็บ ภายหลังการคลอดบุตรในกลุ่มที่ได้รับ ibuprofen ดีกว่าในกลุ่มที่ได้รับ acetaminophen ที่ 1 ชั่วโมงของการให้ยา (ค่าเฉลี่ยของระดับความเจ็บปวด 2.18 และ 2.88 ตามลำดับ, $p < 0.003$) ถึงแม้ว่าในชั่วโมงที่ 2, 3 และ 4 ของการให้ยา Ibuprofen ให้ผลในการลดปวดได้ดีกว่า acetaminophen แต่ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติ (ค่าเฉลี่ยของระดับความเจ็บปวด; ที่ 2 ชั่วโมง: 1.59 และ 1.97, $p = 0.093$; ที่ 3 ชั่วโมง: 1.08 และ 1.31, $p = 0.183$; และที่ 4 ชั่วโมง: 0.69 และ 0.85, $p = 0.169$; ตามลำดับ) ไม่พบผลข้างเคียง และไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติของความพึงพอใจของผู้ป่วยระหว่าง 2 กลุ่ม

สรุป: Ibuprofen มีประสิทธิภาพในการลดความเจ็บปวดของแผลฝีเย็บ ภายหลังการคลอดบุตรได้ดีกว่า acetaminophen ที่ 1 ชั่วโมงแรกหลังการให้ยา โดยปราศจากผลข้างเคียง แต่ให้ผลไม่ต่างกันที่หลัง 2 ชั่วโมงของการให้ยา
