International Journal of Obstetric Anesthesia (2015) **24**, 210–216
0959-289X/$ - see front matter © 2015 Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.ijoa.2015.03.006

ORIGINAL ARTICLE

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Scheduled acetaminophen with as-needed opioids compared to as-needed acetaminophen plus opioids for post-cesarean pain management

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ABSTRACT
Background: Combination opioid-acetaminophen drugs are commonly used for pain management after cesarean delivery. The aim of this study was to determine if scheduled acetaminophen decreases opioid use compared to as-needed combination acetaminophen-opioid administration.
Methods: We performed a retrospective chart review of women who underwent cesarean delivery before and after a clinical practice change. All patients received spinal anesthesia containing intrathecal morphine 200 μg and scheduled non-steroidal anti-inflammatory drugs for 48 h postoperatively. The first group (As-Needed Group, n=120) received combination oral opioid-acetaminophen analgesics as needed for breakthrough pain. The second group (Scheduled Group, n=120) received oral acetaminophen 650 mg every 6 h for 48 h postoperatively with oral oxycodone administered as needed for breakthrough pain. The primary outcome was opioid use, measured in intravenous morphine mg equivalents, in the first 48 h postoperatively.
Results: The Scheduled Group used 9.1 ± 2.1 mg (95% CI 5.0–13.2) fewer intravenous morphine equivalents than the As-Needed Group (P <0.0001) over the study period. Fewer patients in the Scheduled Group exceeded acetaminophen 3 g daily compared to the As-Needed Group (P=0.008). Pain scores were similar between study groups.
Conclusions: After cesarean delivery, scheduled acetaminophen results in decreased opioid use and more consistent acetaminophen intake compared to acetaminophen administered as needed via combination acetaminophen-opioid analgesics, without compromising analgesia.
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Keywords: Acetaminophen; Cesarean section; Multimodal analgesia; Postoperative analgesia; Opioids

Introduction

Ideal post-cesarean delivery pain management provides analgesia with minimal side effects for both mother and infant. Postoperative multimodal pain management regimens often include oral opioid-acetaminophen combination drugs.[1–3] Although opioids are frequently prescribed after cesarean delivery, they may result in maternal side effects that include sedation, nausea, vomiting, pruritus and constipation.[4,5] Opioids transfer to breast milk and adverse effects on breastfed infants, such as sedation and respiratory depression, have been reported.[6–11]

Administering opioids and acetaminophen separately has several potential advantages. First, acetaminophen can be administered on a scheduled basis, which may improve postoperative analgesia and decrease postoperative opioid use and opioid-related side effects.[12] Second, the daily acetaminophen dose can be monitored to avoid excessive dosing in patients with high analgesic requirements. The impact of uncoupling opioids and acetaminophen on post-cesarean delivery analgesia has not been studied.

The aim of this retrospective study was to compare scheduled acetaminophen plus as-needed opioids for breakthrough pain after cesarean delivery with as-needed administration of opioid-acetaminophen combination drugs. The primary outcome was opioid use. We hypothesized that scheduled acetaminophen would decrease opioid use compared to as-needed combination opioid-acetaminophen administration while providing comparable postoperative analgesia.

Methods

A retrospective review of electronic records of cesarean deliveries before and after a change in pain management

Accepted March 2015
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regimen was made. Stanford University Institutional Review Board (IRB) approval was given. The IRB did not require written consent as patient information was de-identified during data collection. The change in pain management regimen was made in response to the recommendation by McNeil-PPC Consumer Healthcare (manufacturer of Tylenol®, paracetamol) of a maximum dose of 3 g daily in the USA.[13] The voluntary reduction in maximum daily dose by McNeil was to reduce the risk of liver injury associated with Tylenol. In the USA, it has been estimated that 20% of acute liver failure may be attributed to accidental excessive ingestion of acetaminophen.[14] Combination oral opioid-acetaminophen analgesics were replaced with scheduled acetaminophen and as-needed oral oxycodone for breakthrough pain management after cesarean delivery.

Inclusion criteria were cesarean delivery, a spinal or combined spinal-epidural for intraoperative anesthesia, term pregnancy (37–42 weeks of gestation), and maternal age $\geqslant$18 years. Patients were excluded if they were participating in another study, did not receive our standard intrathecal anesthetic, were transferred to the intensive care unit, were not prescribed postoperative analgesia according to our pre- or post-change standard protocols, or were diagnosed with chorioamnionitis (the latter because their pain scores may have been affected by a concurrent infection in addition to post-surgical pain).

The postoperative pain management protocol changed on March 25, 2012. Sequential electronic operative records for cesarean deliveries at Lucile Packard Children's Hospital were opened from March 24, 2012 back to January 2012 until 120 pre-protocol change patients that met study criteria (the As-Needed Group) had been obtained. In a similar way, electronic operative records from the end of July until the beginning of September 2012 and January through February 2013 were opened until 120 post-protocol change patients (the Scheduled Group) were obtained. The data collection periods were chosen to allow a four-month familiarization period after the change in regimen; the gap in the post-protocol collection period was for logistic reasons.

The spinal anesthetic consisted of preservative-free hyperbaric bupivacaine 12 mg, fentanyl 10 μg and morphine 200 μg. All patients received a non-steroidal anti-inflammatory drug (NSAID) every 6 h for 48 h after surgery. They were given oral ibuprofen 600 mg if they tolerated oral intake, otherwise they were given intravenous ketorolac 15 mg until they were able to switch to oral ibuprofen. In addition to scheduled NSAIDs, all the Scheduled Group patients were given oral acetaminophen 650 mg every 6 h for 48 h after surgery.

Breakthrough pain was treated in the following ways for the two groups. In the As-Needed Group, patients were given combined opioid-acetaminophen tablets. The prescribed tablet was based on obstetrician preference and was either hydrocodone 5 mg with acetaminophen 325 mg (Vicodin®, AbbVie Inc., North Chicago, IL, USA) or oxycodone 5 mg with acetaminophen 500 mg (Percocet®, Endo Pharmaceuticals Inc., Chadds Ford, PA, USA). In the Scheduled Group, breakthrough pain was treated with 5 mg oxycodone tablets. The algorithm for treating breakthrough pain was the same for both groups. Patients were asked to rate their pain on a 0–10 verbal pain score (VPS, where 0=no pain and 10=worst pain imaginable):

- If the VPS was $\leqslant$4 and the patient wanted treatment, they were given 1 tablet.
- If the VPS was >4, they were given two tablets.
- Patients were allowed up to 10 mg oral opioid every 4 h.
- If pain control was inadequate with oral medications or a patient was unable to tolerate an oral medication for breakthrough pain, intravenous morphine boluses of 4 mg were offered every 10 min with a maximum of 20 mg in 6 h or 32 mg in 24 h.
- Morphine or hydromorphone was administered via intravenous patient-controlled analgesia (PCA) if intravenous morphine boluses did not control pain.

Nursing staff elicited the VPS as part of normal clinical care. Patients were always asked to rate their pain before receiving as-needed analgesics. However, there was no protocol to dictate when or how often a patient was asked to rate their pain. Respiratory rate was checked hourly for 16 h after surgery. A pulse oximeter was used if patients were evaluated to be at risk of respiratory depression (e.g. morbid obesity, obstructive sleep apnea, receiving intravenous opioids).

Postoperative nausea and vomiting (PONV) was treated with intravenous ondansetron or metoclopramide. Pruritus was treated with nalbuphine 2.5 mg, naloxone 100 μg or diphenhydramine 25 mg, repeated as needed. Respiratory depression was treated with supplemental oxygen and naloxone as needed. Side effect treatment was based on patient-reported symptoms, standard analgesic protocol, and nurses' clinical judgment.

Demographics, medications used, time to first opioid use after surgery, VPS, time from the end of surgery until discharge and treatment (medication or oxygen) for side effects (PONV, pruritus, respiratory depression) were obtained from the electronic operative record and electronic patient chart. Analgesic and VPS data were collected in 24-h increments: postoperative hours <24 and postoperative hours $\geqslant$24 to <48. Opioids were quantified in intravenous morphine equivalents where 20 mg oral oxycodone or hydrocodone was equivalent to intravenous morphine 10 mg.[15] All opioid data were double-checked by one investigator (ARV). Maximum,

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