

QUALITY IMPROVEMENT STUDY

Continuous wound infusion catheter as part of a multimodal analgesia regimen for post-Caesarean delivery pain: a quality improvement impact study

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Abstract

Background: The role of continuous wound infusion catheters as part of a multimodal analgesia strategy after Caesarean delivery is unclear. We introduced continuous wound infusion catheters to our multimodal analgesia regimen to evaluate the impact on analgesic outcomes after Caesarean delivery.

Methods: After institutional review board (IRB) approval, a 4-month practice change was instituted as a quality improvement initiative. In addition to multimodal analgesia, continuous wound infusion catheters for up to 3 days were offered on alternate weeks for all women undergoing Caesarean deliveries. The primary outcome was postoperative in-hospital opioid consumption. Secondary outcomes were static and dynamic pain scores at 24 and 72 h, time until first analgesic request, opioid-related side-effects, length of stay, satisfaction (0–100%), and continuous wound infusion catheter-related complications.

Results: All women scheduled for Caesarean delivery ($n=139$) in the 4-month period were included in the analysis, with 70 women receiving continuous wound infusion catheters, and 69 in the control group. Opioid consumption (continuous wound infusion catheter group 11.3 [7.5–61.9] mg morphine equivalents vs control group 30.0 [11.3–48.8] mg morphine equivalents), pain scores (except 24 h resting pain scores which were higher in the control group 2 [1–3] vs 1.5 [0–3] in the continuous wound infusion catheters group; $P=0.05$), side-effects, length of stay, and complications were similar between groups. Satisfaction scores at 24 h were higher with continuous wound infusion catheters (100% [91–100%] vs 90% [86–100%]; $P=0.003$) with no differences at 72 h. One patient demonstrated symptoms of systemic local anaesthetic toxicity which resolved without significant harm.

Conclusions: The addition of continuous wound infusion catheters to a multimodal analgesia regimen for post-Caesarean delivery pain management demonstrated minimal clinically significant analgesic benefits. Future studies are needed to explore the use of continuous wound infusion catheters in populations that may benefit most from this intervention.

Keywords: local anaesthetic; opioid usage; practice change; quality improvement; wound infusion

Caesarean delivery is the most frequently performed inpatient surgical procedure worldwide. Of the 3.7 million births per year within the USA, approximately one-third are performed

via Caesarean delivery.¹ Pain after Caesarean delivery is a leading concern for women,² and acute postoperative pain can impact recovery, increase opioid use, and progress to

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chronic pain.^{3,4} Effective post-Caesarean delivery pain management can optimise maternal neonatal bonding, breastfeeding, improve patient satisfaction, and enhance overall quality of recovery.⁵ Multimodal management strategies involving intrathecal morphine, scheduled acetaminophen, and non-steroidal anti-inflammatory drugs (NSAIDs), are recommended and endorsed by professional societies to optimise postoperative pain outcomes related to Caesarean delivery.^{6–10} However, even with these multimodal analgesic strategies, many women still require opioids for breakthrough pain.^{11–13}

Peripheral local anaesthetic surgical wound infusions, especially continuous wound infusions (CWI) have been shown to reduce opioid consumption and pain after Caesarean delivery.^{14–18} However, these studies did not utilise optimal multimodal analgesic strategies. Thus, there are limited data to determine analgesic benefits of CWI in the setting of optimal analgesic strategies that include intrathecal morphine, scheduled acetaminophen, and NSAIDs.

The primary aim of this quality improvement project was to determine if adding CWI to a multimodal analgesic regimen of neuraxial morphine, scheduled acetaminophen, and ibuprofen reduced in-hospital opioid consumption after Caesarean delivery. We hypothesised that this intervention would reduce opioid consumption and pain scores, and increase maternal satisfaction.

Methods

After institutional review board (IRB) approval at Stanford University (IRB#60600), we conducted a single-centre quality improvement initiative over a 4-month period (between September and December 2020) on the Labor and Delivery Unit at Lucile Packard Children's Hospital, Stanford. Our institution is an academic, Level 4, referral centre with an annual Caesarean delivery rate of 31%.

All women scheduled for Caesarean deliveries during the quality improvement period were included. No patients were excluded based on personal, medical, or surgical criteria. The standard anaesthesia technique for scheduled Caesarean delivery at our institution includes either spinal or combined spinal epidural anaesthesia with hyperbaric bupivacaine (10–12 mg), and intrathecal opioids (fentanyl 15 µg and morphine 100 µg). In the absence of contraindications, all women receive acetaminophen (1 g i.v. after delivery in the operating room, then 650 mg orally every 6 h) and NSAIDs (ketorolac 30 mg i.v. after delivery in the operating room, then ibuprofen 600 mg every 6 h) throughout their hospital stay. Breakthrough pain (assessed by nurses using verbal numerical rating scale for pain [NRS] with 0 representing 'no pain' and 10 representing 'worst pain possible') is managed with oxycodone as required, based on a standardised 4 hourly protocol (2.5 mg if reported NRS is 1–4, with the option of another 2.5 mg 1 h later if required) or 5 mg if NRS is 5–10 (with the option of another 5 mg 1 h later if required).

During the quality improvement project period, continuous wound catheters (On-Q system: PM020- Catheter Extension Kit and CB04-OnQ 40mL Select-A-Flow pump) were offered to all women undergoing scheduled Caesarean deliveries on an alternate week schedule (patients delivering on week 1 were offered CWI, week 2 not offered CWI, week 3 CWI and so forth). CWI were inserted subcutaneously by the surgical team, above or below the fascia (as per surgeon preference), before wound closure. Presurgical clinical care consent was obtained by the

surgeon in which the risks and benefits were discussed. A continuous infusion of bupivacaine 0.5% was administered at 4 ml h⁻¹ for 72 h. Wound catheters were discontinued before 72 h either upon patient request or in the event of earlier hospital discharge. Wound catheters were removed by the anaesthesiologist before hospital discharge. Patients were seen by an anaesthesiologist for standard post-anaesthesia care follow-up at 24 h (standard care) and 72 h (CWI patients) after Caesarean delivery. During these evaluations, participants were asked questions about their pain experiences and side-effects associated with post-Caesarean pain management. We collected the following variables from all women during the project period: personal characteristics, obstetric and medical history, pain scores, opioid consumption, related side-effects, length of stay, and complications from the electronic medical records and anaesthesiology follow-up visits.

The primary outcome for this quality improvement analysis was inpatient postpartum opioid consumption (milligram morphine equivalents; MME). Secondary outcomes included static and dynamic pain scores (at 24 and 72 h post-delivery), length of hospital stay (in hours from delivery), time until first opioid request (hours after delivery), opioid use in 0–24, >24–48, and >48–72 h periods, maternal satisfaction (0–100%), nausea (0–10 NRS), vomiting (yes/no), pruritus (0–10), and wound catheter-related complications (haematoma, leakage, and local anaesthetic systemic toxicity). We hypothesised that CWI added to our standard multimodal analgesic protocol would reduce opioid consumption, and improve pain scores and maternal satisfaction.

Statistical analysis

Based on a review of previous studies, we determined that a sample size of 70 per study group would be appropriate for this project to demonstrate a difference in the primary outcome of opioid consumption.¹⁹ Accounting for dropouts, this sample size would be sufficient to demonstrate a 33% difference in MME of opioid analgesic consumption in the inpatient post-operative period (power 0.8, alpha 0.05, two-sided Student's *t*-test).^{12,20} With a delivery volume of ~4750 deliveries per year, we planned to conduct the project over a 4-month period. All tests used a two-sided *P*-value 0.05 (type I error). Data are presented as median (inter-quartile range, IQR) or *n* (%). The Wilcoxon rank sum test was used to compare continuous variable and uncorrected χ^2 test or Fishers' exact test was used to compare the frequencies of categorical variables. Analyses were performed with STATA version 14.0 (StataCorp, College Station, TX, USA). Oxycodone was converted to MME, with oral oxycodone 1 mg considered equal to 1.5 mg MME.²¹

Results

All women scheduled for Caesarean delivery in the 4-month period were included. Seventy patients underwent Caesarean delivery with CWI catheters placed, compared with 69 who did not have CWI placed. The average length of infusion in the CWI group was 61.1 (15.4) h. Within the CWI group, 15 had the catheter placed above the fascia and 55 had the catheter placed below the fascia. Patient and obstetric data are summarised in Table 1.

The median (IQR) in-hospital opioid consumption was 11.3 (7.5–61.9) MME in CWI vs 30.0 (11.3–48.8) MME in the control group (*P*=0.18; Fig 1). Thirty-six out of seventy (51%) women in

the CWI group required opioids during their post-partum hospitalisation compared with 40 of 69 (58%) in the control group ($P=0.49$). There was no difference between the two groups in opioid usage at the 0–24 h (CWI group 7.5 [3.8–19.7] MME, control group 15 [7.5–22.5] MME) ($P=0.13$), >24–48 h (CWI group 15 [7.5–30] MME, control group 11.25 [7.5–22.5] MME) ($P=0.37$), and >48–72 h (CWI group 20.6 [7.5–31] MME, control group 7.5 [7.5–30] MME) ($P=0.22$) post-Caesarean delivery time periods (Fig 1). There was no difference in the proportion of patients requiring postoperative opioids between CWI catheters placed above (seven of 15 used opioids) and below the fascia (29/55 used opioids) ($P=0.77$); with 26.3 (7.5–30.0) MME used in above the fascia group compared with 11.3 (7.5–71.3) MME in the below fascia group ($P=0.67$). After removal of the CWI catheter, 13 (18.6%) patients in the CWI group subsequently required opioids.

No significant differences in static or dynamic pain scores were demonstrable during the study period (Fig 2). Median 24 h pain scores at rest were lower at 1.5 (0–3) in the CWI group compared with 2 (1–3) in the control group ($P=0.05$; Fig 2).

Table 1 Characteristics of patients included in practice change initiative. There were no significant differences between groups. Values are presented as median (range) or *n*. For the optional pre-Caesarean questionnaire, not all patients responded to the questions. BMI, body mass index; CD, Caesarean delivery; CWI, continuous wound infusion; NRS, verbal numerical rating scale for pain.

| Characteristics | CWI group (n=70) | Control group (N=69) |
|---|---------------------------|---------------------------|
| Age, yr | 36.5 (range 22–44) | 35 (range 21–42) |
| BMI, kg/m ² | 29.1 (range 23.8–58.2) | 30.7 (range 21.2–52.7) |
| Previous birth | | |
| Vaginal | 6 | 0 |
| Caesarean delivery | 40 | 32 |
| Current fertility status | | |
| Gravida status | 2 (2–3) | 2 (2–3) |
| Parity | 1 (0–1) | 1 (0–1) |
| Multiple gestation | 0 | 0 |
| Practice type | | |
| Academic | 27 | 18 |
| Private | 30 | 24 |
| Community | 11 | 17 |
| Optional pre-Caesarean questionnaire | n=63 | n=47 |
| Currently using opioid medications | 0 | 0 |
| How much pain do you anticipate you will have after your CD? (0–10 NRS) | 5 (4–8) | 5 (4–7) |
| How much pain medication do you anticipate you will need after your CD? (0–10 NRS, 0 'none', and 10 'lots') | 5 (4–7) | 5 (4–7) |
| If you had a previous CD, did you experience severe pain with it? (Yes/No) (%) | 14/26 (54) | 10/22 (45) |

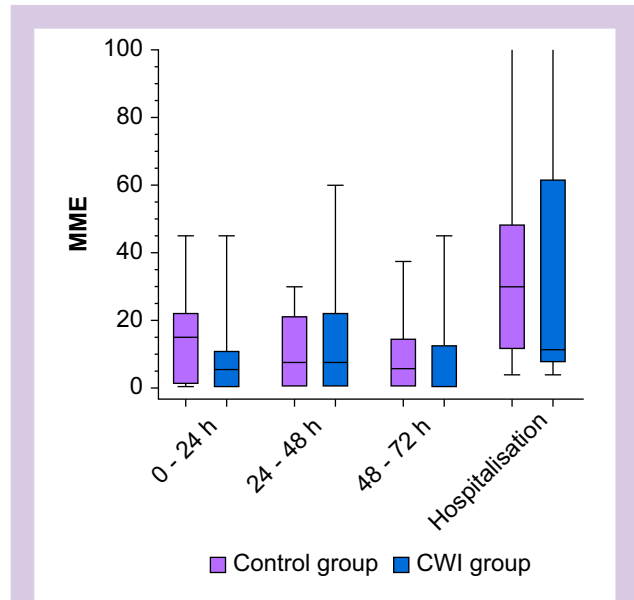


Fig 1. Box and whisker plot representing opioid usage during hospitalisation. In the CWI group, 36 of 70 patients required a median (inter-quartile range) in-hospital opioid consumption of 11.3 (7.5–61.9) MME compared with 40 of 69 patients in the control group that required a median of 30.0 (11.3–48.8) MME. There was no statistical difference between the two groups at any of the time periods: 0–24 h, >24–48 h, >48–72 h, and entire hospitalisation. CWI, continuous wound infusion; MME, milligram morphine equivalents

Median dynamic pain scores were 3.5 (2.5–5) in the CWI group and 4 (3–5) in the control group ($P=0.38$; Fig 2). At 72 h (or at discharge if sooner), the CWI group median static pain scores at rest were 1 (0–2) compared with 2 (0–3) in the control group ($P=0.18$; Fig 2). Median pain with movement at 72 h was 3 (2–4) in the CWI group and 3 (2–4) in the control group ($P=0.94$; Fig 2). During hospitalisation, the median peak pain score was 5.5 (3–7) for CWI group compared with 6 (4–7) for the control group ($P=0.26$). There was no difference in time to first opioid usage post-Caesarean delivery (CWI group 15.9 [2.8–26.9] h compared with control group at 4.4 [2.1–25.0] h), ($P=0.19$, Fig 3).

No significant differences were demonstrable at 24 or 72 h for nausea, vomiting, or pruritus. During the first 24 h post-delivery, in the CWI group, nine of 70 individuals reported nausea (7 [5–8] NRS rating) compared with 11 of 69 (5 [1–5] NRS rating) in the control group ($P=0.44$). For those individuals experiencing nausea, mean vomiting episodes reported in the first 24 h post-delivery were 2 (0–3) in the CWI group compared with 2 (1–2) vomiting episodes in the control group ($P=0.48$). A total of 32 of 70 in the CWI group reported pruritus (NRS rating of 4 [3–6.5]) compared with 33 of 69 women in the control group (NRS rating of 4 [3–6], $P=0.80$) in the first 24 h. At 72 h, one individual in the CWI group reported nausea without emesis compared with two individuals in the control group who reported nausea without emesis. There was no pruritus noted at 72 h.

Median satisfaction at 24 h postpartum was 100% (91–100%) in the CWI group compared with 90% (86–100%) in the control group ($P=0.003$). Satisfaction at 72 h in the CWI

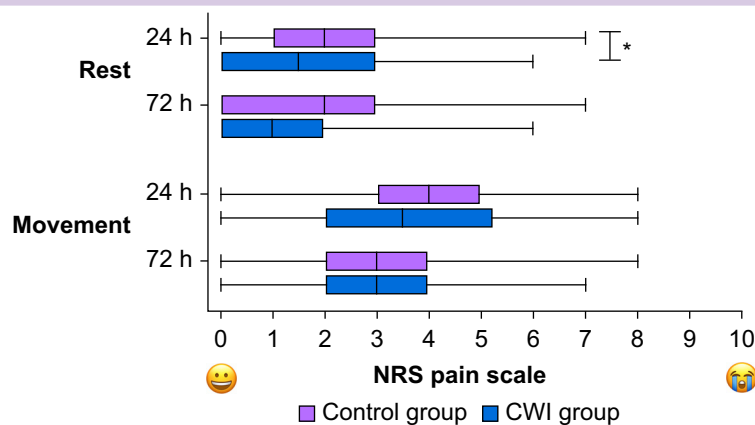


Fig 2. Box and whisker plot of self-reported NRS pain scores with rest and movement post-delivery at 24 and 72 h. A significant difference was noted at 24 h at rest between the control group and CWI group ($P=0.05$, Wilcoxon rank-sum test). CWI, continuous wound infusion; NRS, verbal numerical rating scale for pain 0–10, with 0=no pain and 10=worse pain imaginable.

group was 100% (90–100%) and 100% (90–100%) in the control group ($P=0.41$). The mean length of hospital stay in the CWI group was 77 (72–98) h compared with 75 (55–93) h for the control group ($P=0.07$).

The most frequently reported complication in the CWI group was leakage from the incision site or inadvertent removal of the catheter as a result of wound dressing change. There was a single report of a patient with perioral numbness at 24–48 h after catheter placement that was related to a

technical error with the infusion pump being set at 12 ml h⁻¹ not 4 ml h⁻¹, that resolved when the infusion rate was corrected.

Discussion

The addition of a CWI to a multimodal analgesia regimen (intrathecal opioid and scheduled acetaminophen and ibuprofen) for post caesarean delivery pain management did not reduce in-hospital opioid consumption (our primary outcome), but did improve 24 h static pain and maternal satisfaction scores, without adjustment for multiple comparisons. Previous studies exploring peripheral local anaesthetic surgical wound infusions have shown reduction in opioid consumption and pain after Caesarean delivery.^{14–18} However, these studies did not utilise concurrent optimal multimodal analgesic strategies and in particular did not include intrathecal morphine with wound catheters. Our study highlights the importance of assessing the impact of additional analgesic modalities in the setting of optimal multimodal analgesia rather than in isolation.

Our findings are consistent with other local anaesthetic techniques such as transversus abdominis plane and quadratus lumborum blocks for Caesarean delivery analgesia. Regional local anaesthetic blocks only provide significant opioid sparing and pain reduction when intrathecal morphine is not utilised for Caesarean delivery.^{22,23} The lack of analgesic benefit in the setting of multimodal analgesia is likely because of diminishing analgesic effect size when good baseline analgesia is provided. Comprehensive multimodal management strategies involving intrathecal morphine, scheduled acetaminophen and NSAIDs, are recommended and endorsed by professional societies to optimise postoperative pain outcomes related to Caesarean delivery.^{6–8,24} The routine use of CWI is associated with medication and device costs, wound leakage (if sited subcutaneously), and potential risk of local anaesthetic toxicity (as one of our cases demonstrated). The lack of significant differences in opioid consumption between groups in this study supports the use of currently

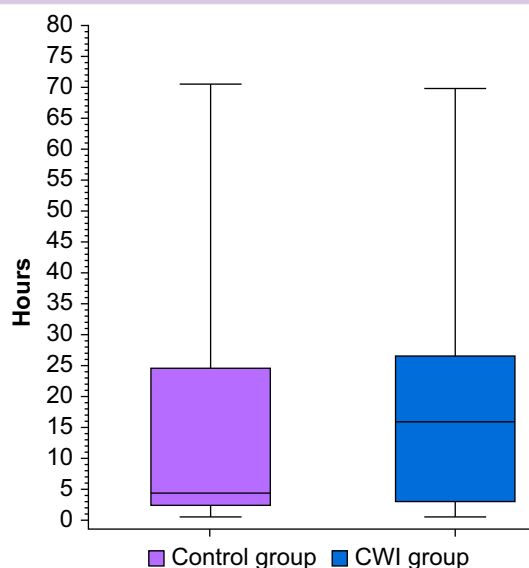


Fig 3. Box and whisker plot representing time to first opioid of the CWI group and control group. There was no difference between the two groups with the CWI group median time to first opioid consumption [15.9 [2.8–26.9] h] compared with the control group [4.4 [2.1–25.0] h]. CWI, continuous wound infusion.

recommended multimodal strategies without CWI. However, CWI and regional local anaesthetic techniques may be beneficial to patients at risk of severe pain or identified as having greater analgesic requirements.²⁴

Future studies need to address if a personalised approach that offers CWI to patients identified to be at higher risk for severe pain would offer benefit, or if CWI routinely offered to patients with chronic pain or opioid use disorder improve analgesic outcomes.

We did not find a significant difference in analgesic efficacy between CWI insertion above and below the fascia. However, only 15 patients had the catheter placed above the fascia, compared with 55 with the catheter placed below the fascia, so the study was underpowered to detect differences between these sub-groups. Subfascial placement of CWI has been shown to reduce opioid consumption and improve pain after Caesarean delivery. An additional benefit of subfascial placement is less leakage of local anaesthetic which can interfere with wound assessment.^{14,25} These known additional benefits of subfascial placement may have impacted practice at our institution; despite not dictating the site of CWI placement, three out of four obstetricians inserted the catheter below the fascia.

This quality improvement intervention had several potential limitations. The dose of local anaesthetic (bupivacaine 0.5%, 4 ml h⁻¹) was empiric and based on our department's experience with CWI. Although there are limited data for the optimal local anaesthetic dosing strategy for CWI, we acknowledge that different drugs (e.g. lidocaine or ropivacaine) may have impacted outcomes. Further investigations may be warranted to determine optimal type, doses, and concentrations of local anaesthetics for CWI. This project relied on clinically collected variables on a diverse patient population, with broad inclusion criteria to maximise generalisability and determine the 'real-world' impact of adding CWI into clinical practice. This analytic approach has advantages over randomised controlled trials that limit generalisability and impact routine pain management with strict study protocols. We acknowledge that certain confounders (e.g. using CWI both above and below the fascia) may have increased heterogeneity and impacted results. However, as noted above, we did not find differences between above and below fascia groups. Similarly, we did not mandate the length of time the CWI remained *in situ*, the duration of infusion was dictated by routine discharge practices. While this may have impacted results, the average length of infusion in the CWI group of 61 h is likely to have impacted opioid consumption if differences did exist.

In summary, the addition of CWI to a comprehensive multimodal analgesia regimen (intrathecal opioid and scheduled acetaminophen and ibuprofen) for post-Caesarean delivery pain management did not demonstrate significant differences in opioid consumption but did improve 24 hour static pain and maternal satisfaction scores. Based on these quality improvement findings, we no longer routinely add CWI to our standard multimodal analgesic protocol. Future studies are needed to determine if a personalised approach that offers CWI to patients identified to be at higher risk for severe pain (e.g. chronic pain or opioid use disorder) would offer benefit from CWI.

Author's contributions

Study design: CF, PS, BC, ER, ES, DH, NG

Data collection: CF, PS, BC, ER, ES, DH

Data analysis: CF, NG

Write-up of the manuscript: CF, PS, BC, ER, NG

Approve the final version of manuscript: all authors.

Declarations of interest

The authors declare that they have no conflicts of interest.

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