Impact of a quality improvement intervention based on Enhanced Recovery After Surgery guidelines for cesarean delivery: an observational prospective study.

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Abstract

Objective: To assess whether the non-placement or early removal of urinary catheter (Ucath) could improve the recovery of patients undergoing cesarean delivery (CD). Moreover, we assessed the impact of neuraxial morphine in this study population. Design: Prospective cohort Setting: Hospital Clínic of Barcelona. Sample Patients undergoing CD Methods: Prospective cohort over a 10-month period. Main outcomes measures: Surgical time (ST), time to first spontaneous micturition (FSM), need for intermittent catheterization (Icath), time to first solid oral intake (FOI), time to mobilization (Tmob) and time to hospital discharge (THD). Results. Among 290 patients, those without or who had Ucath removed early (first 6h) displayed significantly shorter times to: FSM, FOI, Tmob and THD. Urinary retention (21.9 % vs 8.9 %, $p = 0.004$) and intermitent catheterization (39.7 % vs 19.6 %, $p < 0.001$) were more frequent when Ucath was not placed. Using morphine did not significantly increase postoperative times. Urinary retention was significantly higher when morphine was used in spinal anesthesia (8.7 % vs 21.8 %, $p = 0.049$). No differences were found in terms of nausea, vomiting and pruritus. Morphine was associated with better pain control at 6 and 12 h at rest. Conclusions. Not using or removing Ucath early had a positive impact on the postoperative care of CD. Neuraxial morphine was appropriate and safe and should be considered a first-line analgesic in CD.

TITLE PAGE

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Impact of a quality improvement intervention based on Enhanced Recovery After Surgery guidelines for cesarean delivery: an observational prospective study.

Short title: Multidisciplinary quality improvement intervention for cesarean delivery.

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Structured Abstract

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Results . Among 290 patients, those without or who had Ucath removed early (first 6h) displayed significantly shorter times to: FSM, FOI, Tmob and THD. Urinary retention (21.9 % vs 8.9 %, $p = 0.004$) and intermitent catheterization (39.7 % vs 19.6 %, $p < 0.001$) were more frequent when Ucath was not placed. Using morphine did not significantly increase postoperative times. Urinary retention was significantly higher when morphine was used in spinal anesthesia (8.7 % vs 21.8 %, $p = 0.049$). No differences were found in terms of nausea, vomiting and pruritus. Morphine was associated with better pain control at 6 and 12 h at rest.

Conclusions . Not using or removing Ucath early had a positive impact on the postoperative care of CD. Neuraxial morphine was appropriate and safe and should be considered a first-line analgesic in CD.

Fundings. This study did not receive financial support.

Keywords Enhanced recovery after surgery, urinary catheter, cesarean delivery, morphine, neuraxial anesthesia.

Tweetable abstract: Not using or removing urinary catheters early had a positive impact on the care of cesarean delivery patients

MAIN TEXT

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Introduction

Cesarean delivery (CD) is an extended practice worldwide. The rate of CD continues to increase mainly due to maternal factors such as advanced maternal age and subsequent increased maternal comorbidities, maternal preferences and having a previous CD(1). Therefore, numerous efforts have been made to optimize perioperative care among these patients(2,3). Enhanced Recovery After Surgery (ERAS) guidelines for CD have created a pathway for postoperative care(2). Specific issues include early feeding, nausea and vomiting prevention, accurate postoperative analgesia, early mobilization and urinary drainage among others(2,4). The

best practice regarding postoperative care of women undergoing CD remains a multidisciplinary challenge involving obstetricians, anesthesiologists and midwives(2,4).

The insertion of a urinary catheter (UC) is a preoperative measure to prevent iatrogenic damage of the urinary bladder. Traditionally retained for up to 12-24 h after the procedure, it allows an objective and easy assessment of urinary output volume and color and reduces postpartum urinary retention. However, there is no strong evidence supporting the prolonged use of UC(5). Moreover, the systematic use of UC has been associated with a higher incidence of urinary tract infection, delayed mobilization time and a longer hospital stay(6,7). ERAS protocols recommend a removal of the UC within 6 h after the surgery but evidence is still lacking (2). The advantages and disadvantages of the non-use of UC and the early or delayed removal of it remains controversial, even though the latest evidence suggest that early removal might be beneficial(5).

Another trending focus of the ERAS protocol for CD is to optimize pain management, since a good pain control has been demonstrated to accelerate patient recovery. Neuraxial anesthesia is the recommended modality for CD by the American Society of Anesthesiologists, with spinal anesthesia being the most common technique for elective CD(3). Neuraxial opioids provide an optimal analgesia in these patients(6,7). Hydrophilic opioids such as morphine provide a longer length of action than lipophilic opioids such as fentanyl, which is mainly used for intraoperative anesthesia(7). The optimal dose of intrathecal morphine is still uncertain, and ranges between 50 and 200 μg (7). Side effects like nausea, vomiting and pruritus should not be overlooked, and may increase with escalating doses(7).

The objective of this study was to assess whether the non-placement or early removal of UC could improve the recovery of patients undergoing CD. Moreover, we aimed to evaluate the impact of the perioperative use of morphine and its adverse secondary effects in our study population.

Methods

An observational prospective study was conducted over a 10-month period in the context of the implementation of a best practice CD protocol in the Maternity Unit at Hospital Clínic of Barcelona. Patients giving birth via CD (elective, intrapartum and urgent CD) were included.

Anesthetic protocol:

* In elective or urgent CD in patients without an epidural catheter, intradural anesthesia with local anesthetic was used together with 10 to 20 μg of fentanyl with or without morphine (50 to 100 μg).

* In intrapartum CD in patients carrying an epidural catheter local anesthetic was administered through the catheter with or without the administration of 2 to 3 mg of morphine via epidural at the end of surgery.

* Patients undergoing CD under general anesthesia were excluded.

Urinary catheter criteria:

* UC was inserted in all urgent CD, when technical difficulties were anticipated according to obstetric criteria (previous CD or abdominal surgery, full cervix dilatation CD) or when there was a high risk of postpartum hemorrhage (multifetal gestations, large for gestational age fetus). In the other cases, surgery was performed without UC.

* We defined an early removal of UC when it was removed within the first 6 h following CD. If the patient was unable to achieve spontaneous micturition 6 h after removal of the UC or when urinary retention was suspected, intermittent catheterization was performed. Those cases requiring a control of the urinary output such as women with preeclampsia, surgical bladder lesion or postpartum hemorrhage were excluded from the study.

Demographic data and surgical information including surgical times were collected, as well as time to UC removal, time to first spontaneous micturition, need for intermittent catheterization, time to first solid oral intake, time to mobilization after CD (defined as the lapse of time from surgery until sitting on a chair)

and time to hospital discharge. Surgical complications such as uterine atony, urinary bladder injury and postpartum hemorrhage were collected.

We also recorded data regarding anesthetic modality (intradural versus epidural), use and doses of morphine and opioid-related complications (urinary retention, pruritus, nausea and vomiting). Numeric pain rating scale (NPRS) at 6 and 12 h after the surgery, both at rest and upon movement, was also registered.

The study protocol underwent Institutional Review Board approval [code HCB/2021/0409]. Data were analyzed using Stata vs15.

Results

From May 2020 to February 2021, 290 patients were recruited. Demographic data described by groups are shown in Table 1. Differences in gestational age and body mass index, although statistically significant, bear a low impact due to the number of patients recruited. In contrast, difference in previous CD and parity, as well as the type of CD, can be explained due to our UC protocol, as a previous intervention is an indication for UC placement. The same can be said for emergent CD.

Obstetric outcomes

Surgical time was significantly shorter in patients who did not have a UC inserted (46.1 min [IC95% 43.4 – 48.8] vs 51.1 min [IC95% 49.4 – 52.8], p = 0.005), being the mean time difference 5.0 min [IC95% 1.5 – 8.4].

Figure 1 and Table 2 display time to first micturition, time to mobilization, time to first oral intake and time to hospital discharge. When comparing those patients who underwent CD with no UC placed or when it was early removed (before 6 h after the surgery) to those with a later removal, time to first micturition after surgery, time to first oral intake and time to hospital discharge were significantly shorter in the first group ($p < 0.001$, $p < 0.001$ and $p = 0.032$, respectively). Time to mobilization, was shorter in the first group, although not being significantly different between groups ($p = 0.068$).

When comparing those patients with no UC with those with UC placed, regardless its time of removal, no differences in the occurrence of uterine atony ($p = 0.976$) were observed. Moreover, no bladder lesions were recorded in either group. Urinary retention was more frequently observed in patients in which UC was not placed compared to those patients in which it was placed (21.9 % [IC95% 11.7 – 32.0] vs 8.9 % [IC95% 5.2 – 12.6], p = 0.004) and consequently intermittent catheterization was also more frequent in the first group (39.7 % [IC95% 27.6 – 51.8] vs 19.6 % [IC95% 14.4 – 24.7], $p < 0.001$).

Anesthetic outcomes

Epidural anesthesia was used in 120 (41.4 %) patients, and spinal anesthesia in the remaining 170 (58.6 %). Data regarding morphine use are shown in Table 3. In 225 patients (77.6 %) morphine was used, of which 124 (72,9 %) was intradural and 101 (84.9 %) was epidural. Mean morphine dose was 58.0 µg (SD 16.6) in spinal anesthesia and 3 mg (SD 0.7) in epidural anesthesia. The use of morphine did not significantly change the time to first micturition (10.9 h [IC95% 9.4 – 12.4] vs 12.2 h [IC95% 11.3 – 13.2], p = 0.170), the time to mobilization (11.2 h [IC95% 9.8 – 12.6] vs 11.1 h [IC95% 8.8 – 13.3], p = 0.944) and the time to oral intake (7.5 h [IC95% 6.2 – 8.7] vs 7.4 h [IC95% 6.6 – 8.2], p = 0.949) compared to when no morphine was administered. This effect remained unchanged when adjusting by modality of anesthesia, spinal or epidural.

Regarding morphine adverse effects, the use of morphine did not increase the incidence of nausea and vomiting (10.9 % [IC95% 3.3 – 18.6] vs 8.5 % [IC95% 4.8 – 12.1], p = 0.546), pruritus (3.1 % [IC95% 0 – 7.34] vs 3.1 % [IC95% 0.8 – 5.4], p = 1.000) and urine retention (16.9 % [IC95% 7.8 – 26.0] vs 26.2 % [IC95% 20.5 – 32.0], p = 0.123).

When adjusting for the modality of neuraxial anesthesia, urinary retention was significantly higher when morphine was used in spinal anesthesia (8.7 % [IC95% 0.5 – 16.8] vs 21.8 % [IC95% 14.5 – 29.0], p = 0.049), but no differences were found with the use of morphine when epidural anesthesia was performed (36.8 %

[IC95% 15.2 – 58.5] vs 31.7 % [IC95% 22.6 – 40.8], p = 0.660). The incidence of nausea, vomiting and pruritus was not significantly different when adjusting for the modality of neuraxial anesthesia.

Finally, the administration of morphine was significantly associated with a better pain control at 6 and 12 h at rest: NRS 3.0 [IC95% 2.4 – 3.6] vs 2.3 [IC95% 2.1 – 2.5] (p = 0.013) and NRS 2.5 [IC95% 2.0 – 3.0] vs 2,0 [IC95% 1.7 – 2.2], (p = 0.043), respectively. Regarding pain at mobilization, we found no difference at 6 nor at 12 h: NRS 3.5 [IC95% 2.6 – 4.4] vs 3.3 [IC95% 3.0 – 3.5], (p = 0.540) and NRS 3.8 [IC95% 3.2 – 4.3] vs 3.4 [IC95% 3.1 – 3.7], (p = 0.308), respectively. When assessing pain control according the type of neuraxial anesthesia, spinal anesthesia showed better control both at 6 h at rest and at movement ($p < 0.001$ and p = 0.031 respectively) (Figure 2).

Discussion

Main findings

According to these results, the option of not using a UC for a CD when the above-mentioned criteria are met was a safe procedure in our context. No increase in surgical or postsurgical complications was observed. Until now, few studies have assessed the non-use of UC. Although no severe complications occurred, an increased incidence of urinary retention was observed in our study. A cautious selection of those candidate patients for UC non-use and a better assessment of urinary retention should optimize this approach. High maternal BMI, urgent procedures or anticipated technical difficulties should be indicators for the use of UC in CD. Moreover, the use of bedside ultrasound for assessing the residual vesical volume was demonstrated to be reliable and to decrease the necessity of intermittent catheterization (10).

Patients with non-use of UC or its early removal achieved first micturition after CD significantly faster than those who had a delayed UC removal. We found that not using a UC or removing it early could lead to a prompter hospital discharge, compared to the delayed removal group. Although this might be related to the fact that women who needed a UC were more likely to experience complications in the postpartum period, these findings are consistent with published data and updated ERAS guidelines(2).

Not inserting a UC decreased CD surgical time, but this difference did not appear to be clinically relevant. Procedure duration differences were discreet probably due to the fact that this analysis was made during a protocol implementation process, when surgeons were still becoming accostumed to operating without UC. The fact that the surgical team was not always the same may be also a cause of bias in surgical times.

Autonomous patient mobilization and oral post operative feeding are known to be negatively affected when patients have invasive devices, such as a UC. This fact agrees with the findings of our study, since time to first mobilization was shorter when a UC was not used or when it was early removed. Concerning time to first oral intake, although statistically significant, it did not represent a relevant clinical difference between groups, probably because hunger is not affected by the placement of a UC. No studies have evaluated this correlation between the use of UC and early oral feeding before. Although, more research is needed to confirm these findings, the use of UC would not delay oral feeding after surgery.

The use of neuraxial morphine as postoperative analgesia is widely implemented in our institution at the specific doses that are usually recommended in the literature for CD (2,6,7). At these doses, adverse events are rarely reported (6,7). This is consistent with our findings, as we did not see an increased tendency in pruritus, nausea, or vomiting. A slightly higher incidence of urinary retention in those patients having a CD under spinal anesthesia with morphine was observed but this fact did not increase the time to first micturition, mobilization and oral intake.

Regarding pain control, overall NPRS indicated an adequate analgesia, with the mean NPRS being less than 3 at rest and less than 4 at movement in all cases. Interestingly, in patients who underwent spinal anesthesia, the addition of morphine improved NPRS at 6 h both at rest and at movement by at least 1 point, a statistically significant difference (Figure 2). Even though the literature reports that 2 to 3 mg of morphine administered epidurally is equivalent to 50 to 100 μg administered in spinal anesthesia (6), we did not see the same grade of improvement when administering these doses through epidural catheter after fetal

extraction. The main difference of spinal administration with respect to epidural administration lies in the duration of the clinical effect, the speed of redistribution towards the brain centers and the mechanism by which the drug reaches these centers. Morphine is an opioid that, when deposited in the intrathecal space at doses of 100 to 200 µg, produces analgesia that can last up to 24h(8). It is important to point out that due the special physiological changes in the obstetric population, an intrathecal dose not higher than 100 µg is recommended. In addition, it should not be forgotten that the use of fentanyl to optimize analgesia during CD also achieves an analgesic effect with a variable but shorter duration than morphine (9). Because of this, we use a lower dose of morphine (50 to 100 µg) and we still achieved significantly and clinically better pain control without increasing adverse morphine effects.

All these findings should be taking cautiously as we did not take other factors into consideration including previous interventions, either CD or surgeries.

Interpretation

Due to the increase in the rate of CD (1), efforts to optimize perioperative care in these patients are imperative. A more appropriate postoperative care of these patients can improve their recovery including early mobilization, reduction in the time of the first spontaneous micturition and early feeding. All of these can contribute to an early discharge from the hospital, thus improving the quality of care, the quality perceived by the mother and her family, and the optimization of resources. Moreover, achieving an improved CD recovery could help support breastfeeding (11).

The proper functioning of protocols and healthcare pathways depends on multidisciplinary care, and the case of CD is no different. The implementation of this protocol based on ERAS guidelines opens the door to further studies in our hospital. New fields to explore include evaluating the use of ultrasound by nurses in order to measure the urinary bladder volume, randomized trial on the use of morphine by anesthesiologist and a future study conducted by obstetricians assesing the variables that influence the time to first oral intake.

Strengths and limitations

Even though our findings indicate a tendency to improvement in the postoperative management of patients undergoing CD when UC is not used or is removed early, the study is not without limitations. Data was collected prospectively in the setting of the implementation of a best practice protocol, so there was no randomization of the patients. Even though early removal of the UC was encouraged, some patients had the UC removed later than 6 h after surgery. his group of patients was considerably smaller than the others, which is also a limitation when comparing it to the other groups.It is important to mention in this regard that the groups had modest differences as stated above and as shown in Table 1. Regarding morphine use, anaesthesiologists delivering care to CD patients were the ones to decide whether or not they administered this drug , as well as the dosage. Taking all this into consideration, our results should be interpreted as exploratory findings, which might promote further studies and protocols enhancing early mobilization and discharge in those patients in which UC can be avoided, as well as the early removal in patients who require a UC.

Conclusions

Close multidisciplinary teamwork is essential for improving the quality of patient care, promoting rapid and satisfactory recovery, and thus achieving the objectives set out in the ERAS protocol.

The non-use of UC when surgical conditions allow it or its early removal have a positive impact on postoperative care of CD patients. Neuraxial morphine for analgesia in these patients is a good and safe option.

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DISCLOSURE OF INTERESTS

The authors report no conflict of interest.

CONTRIBUTION TO AUTHORSHIP

Conceptualization and design: EM, MM, MSD, OCT, AP.

Data collection: MM, OCT.

Drafting of first manuscript: OCT, MSD.

Data analyses: OCT

Data interpretation: EM, MM, MSD, OCT, AP.

Critical revision of the manuscript: EM, MM, AP.

Supervision: TB, ISM, PG, IG, JMP.

All authors confirm that they had full access to all the data in the study and accept responsibility to submit for publication.

DETAILS OF ETHICAL APPROVAL

The study protocol underwent Institutional Review Board approval [code HCB/2021/0409].

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FIGURE LEGENDS

Figure 1. Postoperative times comparison by groups.

Comparison of (**A**) time to first micturition ($p < 0.001$), (**B**) time to first oral intake ($p < 0.001$), (**C**) time to first mobilization ($p < 0.001$) and (**D**) time to hospital discharge ($p = 0.002$), shown as mean and IC95%.

UC: urinary catheter.

Figure 2. Postoperative pain numeric rating score by morphine use.

Comparison of pain scores by type of neuraxial anesthesia and morphine use, at 6 and 12 h, both at rest and at mobilization.

NPRS: numeric pain rating scale.

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