A Randomized Controlled Trial of use versus non-use of bladder catheterization in elective cesarean delivery

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Background

Delivery by Cesarean section (CS) is one of the most commonly performed surgeries in the world. Advantages of CS are well described, however it is a major surgery that presents complications including those involving the urinary system. Currently it is common practice to place an indwelling bladder catheter prior to CS. Although the current recommendation published in the ERAS guideline is to remove indwelling catheters immediately post operatively, it is typical that they are left in for upwards of 24 hours (1). Indwelling foley catheters are associated with higher rates of urinary tract infection (UTI), post-operative pain, and prolonged postoperative hospitalization (2). There is evidence to suggest that omitting the use of indwelling catheters during CS could reduce these risks which could significantly benefit patients in their post-partum recovery (3).

A Cochrane review completed in 2014 on this subject included only three randomized controlled trials comparing use versus non-use of indwelling bladder catheter in CS. UTI was significantly reduced in non-catheterized groups in both studies who assessed for bacteriuria (3,4). In one study, patient ambulation, first postoperative voiding time, and duration in hospital were all significantly less in the non-catheterized group, however this study had significant heterogeneity in their groups particularly involving regional versus general anesthetic (3). A common reason for routine bladder catheterization is the idea that it reduces bladder injury by increasing visualization of the lower uterine segment, however interestingly there were no bladder injuries described across evaluated studies in the non-catheterized groups (3,4,5). So far, limitations mainly in methodology and sample size in previous work have made it difficult to provide sound clinical recommendations when it comes to non-use of routine bladder catheterization. Our hope is to conduct a randomized controlled trial at the Foothills

Medical Centre that focuses on sound methodology and clear outcomes to build on the existing evidence on this topic.

Primary Research Question

To investigate the impact of routine bladder catheterization in uncomplicated CS on hospitalization time (readiness to discharge), time to ambulation, urinary retention, development of UTI, prevention of bladder injury, operating time, and patient satisfaction.

Study Design

This would be a randomized controlled trial conducted on the labour and delivery and post-partum unit at a large academic site (Foothills Medical Centre) in Calgary, Alberta. Study recruitment of patients awaiting delivery via CS would occur either in participating prenatal clinics in Calgary or in obstetrical triage by a trained nurse research assistant. Participants would be randomized into either a catheterized or non-catheterized group prior to their scheduled elective CS. Allocation concealment will be ensured by using either a central computer generator for randomization if funding permits, otherwise sealed, opaque, and sequenced envelopes will be used. Since we anticipate potential differences in patients with increasing parity, randomization will be stratified by parity and blocked to prevent imbalance in treatment groups.

Patients placed in the catheterized group will have an indwelling catheter placed after anesthetic has been administered. It would be removed at 12 hours post CS by postpartum nursing staff. Participants in the non-catheterized group would be encouraged to empty their bladders just prior to transfer to the operating room where they will undergo surgery without an indwelling catheter. If there is an intraoperative decision to place an indwelling catheter, the reason for doing so will be recorded on the post-operative survey described below. Due to the nature of this study design, blinding of either party is not feasible. Inclusion criteria are women who are 18 years of age or older with a singleton pregnancy presenting for an elective primary or repeat CS. Exclusion criteria include diagnosis of abnormal placentation including placenta previa, vasa previa, or suspected invasive disease.

The primary outcome will be time at readiness for discharge post-surgery. Secondary outcomes will include time to ambulation, incidence of urinary retention, incidence of UTI requiring antibiotics in the first 4 weeks postpartum, incidence of bladder injury in surgery, operating time, and patient satisfaction as measured by the Maternal Satisfaction for Caesarean Section questionnaire (MSCS).

Urinary retention will be defined based on a patient's inability to spontaneously void requiring either -and-out catheterization or placement of an indwelling catheter during the postoperative course. The data for postoperative time at readiness for discharge as well as ambulation time will be collected via a form that will be distributed to the postpartum nursing team. It will be important to ensure that the time at clinical *readiness* for discharge be recorded, as there are many variables (such as waiting on prescriptions) that could act as confounders to the actual time to discharge. The operating surgeon will provide data on intraoperative observations and complications. This will be collected via an electronic post-operative questionnaire using free software such as Qualtrics. This will be used to identify

intraoperative difficulties and complications such as bladder injury, bladder distension, difficulty with hysterotomy or bladder avoidance during surgery, and the clinical decision to place indwelling catheter either intraoperatively or immediately postoperatively. If the surgeon decides at any point during the surgery to place an indwelling catheter, intention to treat analysis will be upheld and those participants will to be analyzed according to their original group.

The MSCS is a validated 22-item questionnaire developed initially as an efficient tool for evaluating maternal satisfaction in women undergoing CS under regional anesthesia (6). This will also include a visual analogue scale (VAS) for simple maternal satisfaction. This scale was recommended in a large comparative review published in BMC as a short option for patient satisfaction specific to maternity care with high reliability, and good construct validity. This will be completed by the patient prior to discharge

Statistical Analysis

The primary outcomes are hospitalization time, time to ambulation, urinary retention, development of UTI, prevention of bladder injury, and patient satisfaction. For many of these baseline estimates for a sample size calculation are not available. However, based on data from FMC the average length of stay post CS is 2.1 days. Converting this to hours and assuming a power of 80% and setting alpha at .05 a sample 30 subjects would provide 80% power to detect a 50% difference in length of stay. A sample of 128 would have adequate power to detect a difference in LOS of 25%. We aim to recruit 140 individuals. Currently FMC performs between 62-100 elective CS per month (2022-march 23 data). Therefore, with even a modest recruitment rate we should easily recruit sufficient patients. Time to discharge, time to ambulation and patient satisfaction (VAR) will be analysed with a comparison of means after appropriate transformations. A t-test will be used to assess statistical significance. Bivariate data such as urinary retention, UTI and bladder injury will be described as rates and statistical significance assessed with a Fisher's exact test.

Risks and Benefits

The benefits of the proposed study are the gathering of information that could help guide clinical practice with regards to the use of bladder catheterization in uncomplicated cesarean delivery. While evidence exists, there are significant issues with methodology that make the results difficult to interpret. Based on previous literature, the largest risk to participants is the need for intraoperative catheterization based on the surgeon's discretion after abdominal entry. Precaution to maintain a sterile environment in this case would be taken.

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