Research Study Protocol

Title: Duration of urinary catheterization following cesarean deliveries under neuraxial anesthesia: a prospective cohort study

Abbreviated Title: DUCC Study

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Site: British Columbia (BC) Women's Hospital, Vancouver, Canada

Background:

In cesarean deliveries (CD), indwelling urinary catheters are routinely inserted to aid in bladder emptying while patient mobility is restricted (1). These catheters typically remain in place during the immediate postpartum period due to suppression of spontaneous urination caused by the administration of neuraxial anesthetics and opioids. With a recent emphasis on enhanced recovery, the Society of Obstetric Anesthesia and Perinatology (SOAP) guidelines recommend that urinary catheters be removed within 6 to 12 hours postpartum to facilitate optimal recovery (2).We conducted a quality improvement project at BC Women's (BCW) Hospital and found the median [IQR] time to urinary catheter removal after spinal (n= 97) and epidural (n = 52) anesthesia were 19.0 [16.7-20.6] and 19.4 [16.5 – 23.4] hours (3). Despite patients regaining hip flexion and mobility, catheters at BCW were frequently left in place beyond the SOAP-recommended guidelines. We also found that factors affecting removal included catheter insertion timing, patient condition, shift changes, and notably, patient anxiety.

Postpartum anxiety affects 9.9%–20.7% of women in the first year and can impact recovery, especially following CD (4-6). Postpartum anxiety has been measured using the State Trait Anxiety Inventory (STAI-S) and is validated in the immediate postpartum period (7, 8). The STAI-S scale measures the respondents current state of anxiety by using terms that evaluate subjective feelings of worry, apprehension, concern, and nervousness; in general, asking them how they feel in the current moment (9). The STAI-S questionnaire takes approximately 5 minutes to complete. The scoring is 20-37 to indicate low anxiety, 38-44 to indicate moderate anxiety, and 45-80 to indicate high anxiety. Patients with heightened anxiety may be apprehensive about recovery following CD. In particular, pain during mobilization is an anxiety-provoking event that was often elicited as a reason why catheter removal was delayed during an internal audit. This study will aim to elucidate this further.

Study aim and objectives:

The primary objective of this study is to examine the relationship between the duration of urinary catheterization in postpartum patients who underwent a CD under neuraxial anesthesia and the STAI-S scores. We would also like to explore the relationship between the duration of urinary catheterization and cultural factors associated with nursing practice.

Hypothesis:
We hypothesize that there will be a significant correlation between the duration of urinary catheterization in patients following CD under neuraxial anesthesia postpartum and STAI-S scores.

Study design and methodology:
This will be a prospective cohort study in postpartum patients who underwent a CD under neuraxial anesthesia at BCW.

Primary outcome:
1. Correlation between duration of urinary catheterization and STAI-S score.

Secondary outcomes:
1. Association between duration of urinary catheterization and timing of delivery.
2. Association between duration of urinary catheterization with neuraxial technique and opioid dose.
3. Nursing perception on the barriers to early urinary catheter removal.

Inclusion criteria:
- Patients ≥19 years of age.
- Undergoing cesarean delivery (elective or emergent) at BC Women's Hospital.
- Neuraxial anesthesia as their primary mode of anesthesia (spinal, epidural, combined spinal-epidural, dural-puncture epidural).
- In-patient status at 24 (+/- 8) hours.
- Self-reported proficiency in speaking and reading English.

Exclusion criteria:
- Refusal to participate.
- Inability to provide informed consent.
- Other surgery (i.e. cervical cerclage) or delivery modes (i.e. operative vaginal delivery).
- De novo general anesthetic, or patients who had a conversion from neuraxial to a general anesthetic.
- Communication from patient's nurse indicating that it is not appropriate to approach due to distressing birth experience and/or outcome.

Withdrawal criteria:
- Withdrawal of consent at any time.

Recruitment:

This study will be based at BCW located in Vancouver. It is standard clinical care for patients to be moved to the postpartum wards (Arbutus, Dogwood, Rabbit, and Cedar) once they are discharged from the Post-Anesthesia Care Unit (PACU), following their CD. Once patients are assigned a bed in the postpartum wards, they are assigned a nurse who will be responsible for their care while they are an in-patient in the hospital. Nursing staff at BCW work 12 hour shifts (7:00 AM – 7:00 PM or 7:00 PM to 7:00 AM). The patients' urinary catheter will be taken out by one of the nursing staff who is assigned to the patient at the time of catheter removal.

While the patient is in PACU, the Letter of Invitation (LOI) (Appendix 1) will be given to every eligible patient by the PACU nursing staff. This gives the patient time to read over the LOI before a member of the research team approaches the patient in the postpartum wards. Research staff will have printed copies of the LOI in a binder in PACU for the nursing staff to distribute to each patient who had a cesarean delivery.

Each morning, research staff will review the list of patients who underwent a CD and compile their own list. Subsequently, they will screen the patients to confirm their eligibility. The eligibility assessment will be done in paper format through a simple screening handout. If the patient and/or nurse does not consent to participate, the eligibility assessment with be kept in a binder. Once the list of eligible patients is finalized, research staff will document the time of urinary catheter insertion for the CD and add 16 hours to this time (indicating when the urinary catheter should be removed). After, research staff will have two lists created: 1) patients who have had their catheter removed ≤ 16 hours since insertion, and 2) patients who have had their catheter removed > 16 hours *or* still have their catheter in past 16 hours.

If patients fall under list 1 it is considered within the normal range of catheter removal at BCW; thus, recruitment and data collection from nursing staff is not required. If patients fall under list 2 it is considered outside the normal range of catheter removal at BCW; thus, recruitment and data collection from nursing staff is required.

Using these two lists, the research staff will follow a different method of recruitment and data collection for each patient (see Figure 1 for reference). For list 1, only patients will be approached. For list 2, research staff must first approach the nurse assigned to the patient. Once recruitment and data collection for the nurse is complete, the patient from list 2 can be approached. If the patients for whom the nursing data collection is already complete decline to participate in the study, the nursing data will be kept as it will be used to address the third secondary outcome.

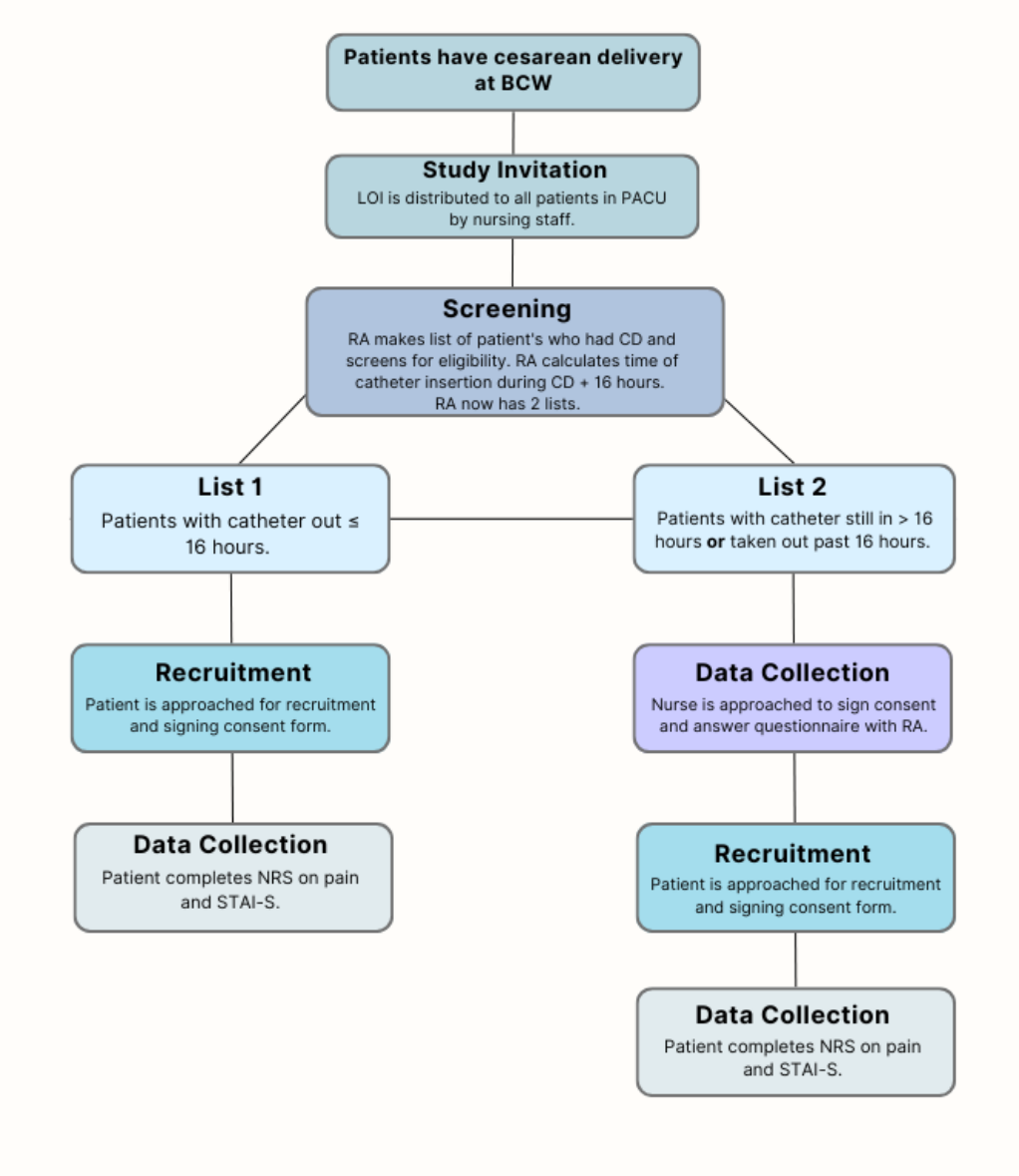

Figure 1: Study procedure flow diagram. Abbreviations: BC Women's Hospital (BCW), Letter of Invitation (LOI), Post Anesthesia Care Unit (PACU), Cesarean Delivery (CD), research assistant (RA), numeric rating scale (NRS), State Trait Anxiety Inventory (STAI-S).

Nurse recruitment:

Once patients from list 2 are identified, the research team will write down which nurse should be approached prior to approaching the patient. Once the research staff locate the postpartum nurse in the wards, they will approach the nurse about the study and hand them the Nurse Participant Information and Consent Form (Appendix 2) to read and sign. If the nurse is busy at the time of approach, research staff will work with the nurse to find a suitable time to address any questions and get informed consent.

Investigators will educate nursing staff about the study directly by attending several nursing rounds, which occur daily at 11:00 AM, to present the study to as many post-partum nurses as possible. Additionally, nursing staff in all postpartum wards will be notified of the study through the standard hospital procedures using the Program Utilization form and approval of the research and clinical units.

Patient recruitment:
Prior to the research team approaching eligible patients, we will discuss this with the ward nurse or obstetric provider (if applicable) to ask the patient for permission to approach. With patient permission, a member of the research team will visit the patient in-person for recruitment. Upon approach, research staff will ensure it is an appropriate time for the patient to discuss the study. If the patient is interested, we will provide a thorough discussion about the details of the study (e.g. why the study is being carried out and how it will affect care if patient chooses to participate) and any questions will be addressed. At this time, the patient will receive a Participant Informed Consent Form (Appendix 3) to review and sign and a paper copy of Patient Resources (Appendix 4) for patient's to self-refer if they wish regarding anxiety and postpartum recovery and care.

Those responsible for approaching participants will be trained in the study protocol and procedures by the research team. They will also complete necessary training modules (privacy, ethical conduct of research) in TCPS-2. Students and research staff will be supervised through regular meetings with the study team.

Data collection:
Nurse data collection:
Once the nurse has signed their consent to participate in the study, research staff will work with the nurse to fill out the Nurse Data Collection Sheet (Appendix 5). To ensure that the data collected by nurses is not lost, research staff will complete the questionnaire with the nurse and communicate the questions and subsequent options verbally or by showing the nurse the options for responses. This is feasible as the questionnaire should take approximately 2 minutes to complete. The questionnaire will require the nurse to identify factors that influenced their decision to remove the catheter when they did, by checking 'yes' or 'no' for each statement.

Patient data collection:
After obtaining written informed consent, enrolled patients will be asked to fill out a questionnaire on paper regarding their feelings of anxiety, using the STAI-S, and questions about their experience of pain (Appendix 6). This should take the patient approximately 5-8 minutes to complete.

All patient participants will be recommended to contact the Pacific Postpartum Support Society, the BC Mental Health Line, or Health Link BC if they have any concerns about their STAI-S scores.

- Pacific Postpartum Support Society offers telephone and text support by counsellors with extensive training in perinatal mental health.
- BC Mental Health Line is the crisis centre of BC and offer immediate, confidential support and follow-up 24/7 by phone and online.

- Health Link BC provides a health services navigator and can link callers to a registered nurse, dietitian, exercise professional or pharmacist.

Participants will be advised that this is not a diagnosis and that they should contact their health care provider with any concerns. This information will be provided to all participants during the consent process, prior to starting questionnaires, after completion of questionnaires, and for instances in which patient's request study data.).

CST data collection:
Finally, once the patient has been discharged from the hospital, research staff will use CST to fill in the remaining data to be collected. The information collected from CST will be inputted using the CST Data Collection Sheet (Appendix 7). This data collection sheet will be completed for all patients who have been recruited into the study (patients from list 1 and list 2).

Data to be collected from CST Cerner:
- Participant demographics including age and ethnicity.
- Participant obstetric information including mode of delivery, gravida, time and date of delivery, mode of anesthesia, and bromage scores.
- Urinary catheter information including time and date of catheter insertion, time and date of first independent assist/ambulation, time and date of catheter removal, and incidence of urinary re-catheterization.

Sample size calculation and statistical analyses:
Power calculation cannot be reliably determined for correlation analysis. The sample size selection is therefore guided by prior studies. A group of 296 mothers was surveyed with the STAI questionnaire before they were discharged to assess how their anxiety changed during the first month after giving birth (7). Data from a sample size of 235 postpartum patients at the perinatal hospital in Greece was used to determine the strength of the correlation between state anxiety and primiparity, admission to the NICU, and negative experience of labour (8). Figueiredo ad Conde (10) published a study assessing anxiety and depression symptoms in women and men from early pregnancy to three-months postpartum, using a sample of 260 Portuguese couples. Fairbrother and colleagues (11) published a study assessing the prevalence and incidence of perinatal anxiety disorders among women experiencing a medically complicated pregnancy by asking 310 women to complete postnatal screening measures for anxiety.

Assuming the lower bound of the correlation coeffficent of 0.2, a type 1 error of 0.05 and 80% power, approximately 194 patients would be required. Taken into account the sample size of prior studies listed above, including our preliminary quality improvement project on duration of urinary catheterization in spinal versus epidural anesthesia (3), along with potential missing data and attrition, we aim to recruit a total of 300 patients.

All demographic, obstetric, and anesthetic factors will be analyzed by descriptive statistics. The primary outcome will be analyzed using Pearson correlation coefficients. The first two secondary

outcomes will be analyzed using multivariable regression model. The third secondary outcome will be analyzed using descriptive statistics for the dichotomous response and thematic analysis for the open ended responses.

Data management:
De-identified patient and nursing data will only be collected by members of the research team using paper data collection forms. For patients and nurses, there will be a data collection form that is handed to the participant upon their consent to participate in the study. The third data collection form will be entered by a member of the research team through accessing the patient's electronic health records via CST Cerner. The recorded information is part of standard clinical care. The relationship while accessing patient charts in CST will be described as 'researcher'. Only information pertinent to the study will be retained on study data collection spreadsheets, which will be stored in an encrypted file on a computer. Patient files will not be checked out of health records. No confidential information that is not specified in the REB process will be taken from patient records. Once collated, the data will then be entered into a password protected Microsoft Excel spreadsheet on a password protected computer in the locked Research Assistant's office. The research team will analyze the de-identified dataset.

Patients will be identified on all study documents only by their unique study number, which will be matched to any identifying information in the official study files. This mode of data retention ensures a minimal risk of confidentiality breach, as any identifiable information will be kept separate from their confidential questionnaires.

All research records will be maintained and stored for 15 years as per C.05.012 (4) of the Canada's Food and Drugs Act and Regulations following publication of the study and then destroyed using the hospital's privacy and confidentiality shredding service.

This study will be registered online with http://www.clinicaltrials.gov/.

The results will be written up and submitted for presentation at medical conferences and publication in a medical journal so that we can disseminate the findings within the medical community. This may help us to better understand patient's postpartum health and recovery.

We will permit and facilitate all study related monitoring, audits, IRB/IEC review, and regulatory inspection(s), and provide direct access to source data/documents.

Risks and benefits:
Risks
This is a non-interventional study, therefore the risk to patients is minimal. Involvement in the consenting part of the study is entirely voluntary and not consenting will have no impact on the care which is given to patients.

It is understandable that if a participant is experiencing anxiety or pain during their recovery, and then are asked about it later, even if voluntarily wanting to do so, may experience psychological distress. If during the course of the study, the participant raises any questions regarding their anxiety scores or pain, the research staff will ask the patient if they would like us to inform their

direct care team of concerns regarding their anxiety and/or pain. The role of the research staff will be to simply relay this information to the patient's direct care team. We will not be involved in clinical care. Each patient will be given a list of resources specific to anxiety and postpartum care and recovery at the end of their own copy of the Informed Consent Form. This is for them to self-refer if they wish.

Participants will be given as much time as they feel necessary during the consent process. The patient will be provided 7 pages of information about the study, and they will be informed that the study team member will check back later as agreed by the participant to allow them to read through the information before deciding to participate. Study staff will complete thorough research training to ensure they are well prepared to identify and mitigate any risks associated with the study. They will have received training on the study protocol and procedures, including the consent process, data security and sensitive topics. They will also receive virtual training of privacy and the ethical conduct of research (TCPS-2).

Benefits

This study aims to enhance our understanding of the factors contributing to the prolonged use of urinary catheters beyond the recommended duration. It will also evaluate the potential impact of patient anxiety on this matter. The findings will offer valuable insights for researchers, healthcare providers, and nursing staff, enabling them to deliver improved care to patients during the postpartum period.

If participants ask to receive study data (specifically STAI-S scores) they will obtain information that may be useful to better understand their postpartum health and recovery. This information may be used by participants to seek care from healthcare providers when appropriate.

Feasibility:

At BC Women's Hospital, approximately 48 cesarean deliveries under neuraxial anesthesia are preformed each week. Assuming a 70% recruitment rate and recruitment to only occur during weekdays because of working hours of the research team, a total of 23 patients will be recruited per week. Additionally, since the research lead (Ms. Aislynn Sharrock) will have several research projects to work on at one time; limiting her capacity to recruit for this study; we estimate approximately 26 weeks will be required to complete this study.

Financial cost:

Funding will be provided by the Department of Anesthesia at BC Women's Hospital.

Disclosure:

Nothing to disclose.

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