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Protocol

Design, methods and rationale for the prevention of postpartum urinary retention study: protocol of a randomized controlled trial

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ABSTRACT

Background: Intrapartum bladder overdistension after neuraxial anesthesia can lead to postpartum urinary retention (PUR) as well as long-term voiding dysfunction. This has not yet been assessed as the primary outcome of a randomized controlled trial.
Methods: Patients in labor planning vaginal delivery will be randomized to continuous (CC) versus intermittent catheterization (IC) after receiving neuraxial anesthesia. The primary outcome is urinary retention within three days postpartum, and prespecified secondary outcomes include voiding dysfunction at 2 and 6 weeks via the UDI-6 questionnaire, positive urine cultures within 2 weeks, and patient and nurse satisfaction. We will explain the rationale, review recruitment and screening processes, and describe the interventions, outcome assessments, and planned statistical analyses.
Conclusions: A feasibility trial of ten percent of the planned study population was performed with excellent recruitment and follow-up retention rates. Reasons for protocol deviation were examined and the protocol adjusted as described. Participants of the larger trial will be randomized between December 2025 and May 2026 with final data collection to occur in May 2026. Analyses and submission of results are planned for winter 2026. The prevention of postpartum urinary retention (P-PURE) trial will provide evidence on how bladder catheterization method affects postpartum urinary retention to guide intrapartum catheterization practices.
Trial Registration: Clinicaltrials.gov NCT07125326.

Keywords: Postpartum urinary retention, Neuraxial anesthesia, Bladder catheterization, Randomized controlled trial, Labor

INTRODUCTION

Neuraxial anesthesia is associated with impaired detrusor contractility and altered afferent bladder sensation, so emptying the bladder with continuous or intermittent catheterization are routinely performed after anesthesia initiation during labor.[1] Intrapartum bladder overdistension can lead to significant bladder detrusor damage and very rarely, bladder rupture, infection, or impaired renal function.[2,3] Recent data suggests rates of postpartum urinary retention reach 10% when both overt and covert retention are included; overt retention is characterized by the inability to void spontaneously at six hours after catheter removal or incomplete emptying, and covert retention is defined by post-void residual (PVR) greater than or equal to 150 cc urine. Both types of retention have been associated with voiding dysfunction up to three years after delivery. Though it is a common occurrence, little evidence exists to guide recommendations to prevent postpartum urinary retention. There are only two published randomized controlled trials comparing rates of PUR with intermittent versus continuous bladder catheterization as a secondary outcome, and the meta-analysis of the only 393 total

laboring patients with epidurals in these studies showed no significant difference in overt PUR between catheterization methods.[4-6]

In addition to the limited data regarding the effects of bladder emptying method on maternal outcomes, few studies have examined patient and provider perspectives on these approaches. The prevention of postpartum urinary retention (P-PURE) randomized controlled trial seeks to fill these evidence gaps.

Objectives

The aims of the P-PURE trial are to evaluate the effect of continuous versus intermittent bladder catheterization on postpartum urinary retention (primary outcome, hypothesized to decrease) and symptomatic urinary tract infection or pyelonephritis (hypothesized to decrease); estimate the effects of catheterization method on longer term voiding dysfunction; and compare patient and nurse satisfaction for the two methods.

METHODS

Study design overview

This is a single center, parallel group, exploratory pilot randomized clinical trial comparing continuous to intermittent bladder catheterization approved by the Institutional Review Board. The trial was registered with ClinicalTrials.gov with identifier NCT07125326. Internal institutional funding was utilized. The authors have no relevant financial conflicts of interest.

Recruitment methods

Inclusion criteria

Patients with term, singleton, living gestations, admitted for labor or induction of labor, and desiring neuraxial anesthesia in labor were included.

Exclusion criteria

Patients under 18 years old, with scheduled external cephalic version or cesarean, and with history of neurogenic bladder or overactive bladder symptoms, or were performing bladder catheterization prior to admission are excluded.

Trained study staff assess initial eligibility by screening medical records of participants admitted to the labor and delivery unit. Eligible participants are approached and asked about their plan for analgesia during labor; if they plan to avoid neuraxial anesthesia they are deemed ineligible and informed at that time.

The study is described in detail and written informed consent is obtained from interested participants.

Sample size calculation

Using recent published data, we estimate a 10% rate in the intermittent catheterization group and 4% rate in the continuous catheterization group.[7,8] To detect this 60% difference with 90% power, the necessary sample size would be 282 patients in two equal groups. To ensure appropriate randomization and protect against loss to follow-up postpartum, we planned to recruit a total of 300 patients per group.

Randomization

Patients are randomized in a 1:1 fashion to receive intermittent catheterization according to current hospital policy or continuous indwelling catheterization after neuraxial placement. The NCI randomization tool was used to make assignments without stratification and assignments were placed into numbered study folders stored in a secure location. After obtaining consent, study staff open the folder, inform the patient and nursing team of their randomization assignment, and ensure comprehension. The group assignment and date are recorded in the randomization log.

Intervention

Following written informed consent and neuraxial anesthesia placement, patients receive either an indwelling bladder catheter or were catheterized according to the established unit protocol (every four hours and if >500 cc are emptied, increasing the frequency by one hour iteratively). The indwelling catheter is removed prior to pushing and patients are catheterized immediately after vaginal delivery if they push longer than one hour. Patients are due to void 6 hours after last catheterization or indwelling catheter removal. If patients have a first void of less than 150 cc or if they have not voided when due, unit staff complete a bladder scan assessment of bladder volume. If the patient fails to void >150 cc and has bladder scan volume greater than or equal to 300 cc, placement of an indwelling catheter is performed. At 24 hours after catheter replacement, a retrograde voiding trial is completed in which 300cc are instilled into the bladder, the catheter is removed, and if <200 cc are voided within thirty minutes, the catheter is replaced. Patient catheter teaching is performed by nursing staff prior to discharge and the patient's obstetrical team is contacted to arrange follow-up for an outpatient voiding trial in five to seven days.

Outcome assessments

Maternal and neonatal outcomes are abstracted from medical records by trained clinical staff. While the patient, nursing team, and delivery providers are not blinded to the catheterization method, the investigator assessing postpartum urinary retention is blinded to the exposure group. This diagnosis is made if within three days postpartum, participants experienced either inability to void spontaneously at six hours after catheter removal or

last catheterization, or a post-void residual volume on bladder ultrasound greater than 150 cc after first micturition. Adherence to existing guidelines for intermittent catheterization frequency is evaluated. The outcomes of symptomatic urinary tract infection and pyelonephritis are also assessed using chart review.

Self-reported voiding symptoms are assessed using the UDI-6 questionnaire which has previously been used in the postpartum population.[9] This questionnaire is administered by telephone or secure patient messaging through the electronic medical record at approximately 2 weeks, 6 weeks, 6 months, and one year postpartum by trained study personnel.

Finally, a survey of nurse and patient satisfaction scores were collected by the nurse present at the time of delivery and this was returned to a secure location.

Statistical analysis

Analyses will be based on the intent-to-treat principle. The primary outcome (proportion of subjects with postpartum urinary retention) and the other categorical variables will be compared across groups using the chi-squared test. Fisher's exact test will be used for variables with that occur <5 times. We will calculate 95% confidence intervals around the differences in proportions and the relative risk of postpartum urinary retention.

Normally distributed variables will be compared using the unpaired t-tests. If variables are not normally distributed, the Mann-Whitney U test will be used to compare groups.

It is anticipated that baseline characteristics will be similar in the two groups given the randomized approach, and because randomization was effective in the pilot trial. If the groups are unbalanced with regards to variables significantly associated with the primary outcome, supplemental analyses will be performed using multivariable logistic regression adjusting for multiple covariates. Tests with $p<0.05$ will be considered statistically significant. Analyses will be performed using statistical package for the social sciences (SPSS).

RESULTS

The P-PURE trial will recruit between December 2025 and May 2026. Abstraction of primary outcomes has a planned completion date of 01 June 2026, and data analysis are planned in winter 2026. Collection of urinary symptom information a year postpartum will conclude spring 2027, and final manuscript preparation of these data is expected fall 2027.

DISCUSSION

While greater than two-thirds of patients in high-income countries choose neuraxial anesthesia during labor and almost all require bladder management, the postpartum effects of catheterization practices are unknown.[10] The P-PURE randomized controlled trial compares continuous to intermittent catheterization to determine the safest bladder emptying method for laboring patients with neuraxial anesthesia. This intervention carries no known additional risk to study patients as they would have received bladder catheterization during labor whether enrolled or not.

CONCLUSION

Intrapartum urinary retention has been repeatedly linked to chronic voiding dysfunction and can require continued follow-up with urologic specialists. Furthermore, this adds notable burden to the existing stress inherent in the postpartum period. Evidence-based preventive measures are needed. Results of this trial will guide catheterization practices to mitigate this significant issue and ultimately improve postpartum health and well-being.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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