Management of indwelling labor epidural catheters and pain during cesarean delivery: a prospective single-center patient-reported outcome study

IRB number 025-604

Document date: 12/16/2025

IRB Protocol Template

Title: Management of indwelling labor epidural catheters and pain during cesarean delivery: a prospective single-center patient-reported outcome study

Investigators:
Principal investigator: Michael Hofkamp, M.D.

Background & Significance

Two previous prospective studies have reported an association between pain during cesarean delivery (PDCD) and top up of an indwelling labor epidural catheter as the primary anesthetic technique.[1,2] A propensity matched retrospective cohort study reported that patients who had indwelling labor epidural catheters removed were 4.3 times more likely to not require additional anesthetic medication during their cesarean delivery.[3] The incidence of patient reported pain during cesarean delivery when removal of an indwelling labor epidural catheter is compared to top up of an indwelling labor epidural catheter is unknown. We hypothesize that patients who have removal of their indwelling labor epidural catheters followed by successful neuraxial anesthesia will have a lower incidence of pain during cesarean delivery compared to patients who had top up of their indwelling labor epidural catheters.

Study Question/Hypothesis & Specific Aims

Study Purpose/Question

The purpose of this study is to determine the incidence of patient-reported pain during cesarean delivery among patients who had removal of their labor epidural catheter followed by successful neuraxial anesthesia and patients who had top up of their indwelling labor epidural catheter for cesarean delivery.

Specific Aims

Primary aim: determine if there is a difference in patient-reported pain during cesarean delivery among patients who had removal of their labor epidural catheter followed by successful neuraxial anesthesia and patients who had top up of their indwelling labor epidural catheter for cesarean delivery.

Secondary aim: determine the incidence of dyspnea and upper extremity weakness delivery among patients who had removal of their labor epidural catheter followed by successful neuraxial anesthesia and patients who had top up of their indwelling labor epidural catheter for cesarean delivery.

Study Design

This is a prospective survey-based observational study.

Study Population/Subject Selection

Patients will be identified as potential study participants if they have a cesarean delivery at Baylor Scott & White Medical Center-Temple from January 1, 2026 through December 31, 2025. If they meet inclusion criteria then they will be asked if they would consent to participate in the study

Inclusion Criteria:
-ages 18-50 years
-had cesarean delivery at Baylor Scott & White Medical Center from January 1, 2026 through December 31, 2026
-Fluent in the English language (our catastrophizing survey is validated in English language only)
-Can provide their own consent
-Identifies as Black or African American only, Hispanic, or White or Caucasian only
-had administration of local anesthetic through indwelling labor epidural or removal of indwelling labor epidural followed by single injection spinal or combined spinal epidural

Exclusion Criteria:
-less than 18 years old, older than 50 years old
-had cesarean delivery at Baylor Scott & White Medical Center before January 1, 2026 or after December 31, 2026
-Employee of Baylor Scott & White Health labor and delivery unit
-Student of a school that performs clinical rotations at Baylor Scott & White Medical Center-Temple
-Incarcerated at the time of study enrollment
-Underwent scheduled cesarean hysterectomy
-Underwent cesarean delivery with general anesthesia as either the primary anesthetic technique or had conversion to general anesthesia because of failure of neuraxial anesthesia
-Admitted to the intensive care unit immediately following cesarean delivery
-Did not have intrathecal morphine or intrathecal fentanyl if receiving spinal anesthesia
-Had anesthesia for an attempted external cephalic version within 24 hours of cesarean delivery

Study Procedures

Study procedures for individual visits/interventions and/or interactions

The operating room log will be examined to determine potential subjects who had cesarean deliveries. The electronic medical records of each potential subject will be examined to determine if they meet inclusion criteria. If the potential subject does not meet inclusion criteria, the reason why the subject was excluded will be documented. If the subject meets inclusion criteria, the subject will be approached at the bedside between 24-72 hours after wound closure and invited to participate in the study. Subjects

agreeing to participate will complete the informed consent process and then complete a four-item questionnaire and a catastrophizing questionnaire. A study investigator will then enter survey data into REDCap along with data from the electronic medical record. A study investigator will then extract the data onto an Excel spreadsheet for analysis.

Informed Consent Process

Each potential subject will be approached at the bedside, given a brief description of the study, and will be asked to participate. Those wishing to participate will read and complete an informed consent document indicating that they agree to participate in the study. The subjects will be given a copy of their signed informed consent document.

Blinding

The study design does not involve blinding of the subjects.

Data Collection Details

An Excel spreadsheet will be used to collect data for every patient who has a cesarean delivery during the study period and the following data will be collected: date of cesarean delivery, medical record number, whether the subject met inclusion criteria, why the subject did not meet inclusion criteria (if applicable), whether the subject was approached by a study investigator to participate in the study, whether the subject agreed to participate in the study, whether the subject completed the study, whether all data was entered into REDCap, and comments.

For subjects who completed the study, the following data will be entered into REDCap: medical record number, date and time of informed consent, responses from the four-question questionnaire, responses from the Catastrophizing questionnaire, time and date of questionnaire completion, race, age, height, weight, BMI, gravidity, parity, gestational age, multiple gestation, history of cesarean delivery, history of depression, history of anxiety, obstetric indication for admission, whether labor epidural catheter was replaced during labor, last labor epidural technique, training of operator who placed last labor epidural catheter, number of physician-administered boluses during labor for last labor epidural catheter, date/time last labor epidural catheter placed, date/time entering operating room, date/time skin incision, date/time wound closure, ACOG indication for cesarean delivery, urgency of cesarean delivery, whether epidural catheter was activated or removed, local anesthetic used to dose epidural catheter, whether fentanyl was administered through epidural catheter within 60 minutes of skin incision, outcome of the new neuraxial anesthetic technique, dose of spinal bupivacaine, whether fentanyl 15 mcg and morphine 150 mcg were added to spinal anesthetic, other intrathecal doses of fentanyl and morphine (if applicable), whether local anesthetic was administered through the epidural catheter after CSE placement, whether additional anesthetic medications were administered, total dose of intravenous fentanyl, total dose of intravenous morphine, total dose of intravenous hydromorphone, total dose of intravenous dexmedetomidine, total dose of intravenous ketamine, total dose of intravenous propofol, total dose of intravenous midazolam, whether inhaled nitrous oxide was administered, quantitative blood loss, whether neonate was admitted to NICU, and adverse events.

Data Protection & Confidentiality

The subject accrual log will be stored in a password protected file saved on a network drive and only key study personnel will have access to it. The written surveys will be stored in a locked office. Data will be entered by key study personnel into REDCap. Data will be extracted by key study personnel onto a password-protected Excel spreadsheet stored on a network drive. Paper and electronic data will be retained for a period of three years after study completion. Paper data will be destroyed by insertion into a hospital receptacle designated for secure documents to be shredded by a contractor. Electronic data will be destroyed by deletion by a study investigator.

Data Analysis

Descriptive statistics will be used to describe characteristics of the sample collected. Frequencies and percentages will be used to describe categorical variables, while means and standard deviations (or medians and ranges when appropriate) will be used to describe continuous variables. A chi-square test (or Fisherâ€™s exact test when low cell counts are present) for categorical variables and a two sample t-test (or Wilcoxon-Rank-Sum test when data is not normal) will be used to test for associations in bivariate comparisons. A multivariate logistic regression will be performed with variables of interest to predict which variables predict pain during cesarean delivery. We will use the followiing variables in the multivariate logistic regression independent of the bivariate analysis: results from catastrophizing survey, number of physician administered rescue analgesia boluses during labor, urgency category of cesarean delivery, whether labor epidural catheter was removed or a top up dose was administered, and operative time. We will add variables from the bivariate analysis that have a p value of less than 0.2 to the multivariate logistic regression. We will adjust the multivariate logistic regression model as needed to address potential co-linearity and quasi-separation of variables. Statistical significance will be determined at a level of 0.05.

Risks & Benefits

The physical, psychological, social, legal, and economic risks to subjects are low due to the prospective questionnaire study design and our security procedures in place to prevent unintentional disclosure of data. All data will be de-identified prior to presentation or publication. There is no direct benefit to subjects. Future patients may benefit from the results of this study due to increased understanding of what variables predict pain during cesarean delivery. The overall risk to benefit ratio is low.

References

1. Litman J, Bates R, Lindheim SR, Sharpe EE, Ehrig JC, Hofkamp MP. Patient and clinical characteristics associated with pain during cesarean delivery: a prospective single-center patient-reported outcome study.Int J Obstet Anesth. 2025;61:104324
2. Sanchez J, Prabhu R, Guglielminotti J, Landau R. Pain during cesarean delivery: A patient-related prospective observational study assessing the incidence and risk factors for intraoperative pain and intravenous medication administration.*Anaesth Crit Care Pain Med*. 2024;43(1):101310
3. Shepherd B, Sharpe EE, Hammonds K, Hofkamp MP. A comparison of anesthetic outcomes between activation and removal of epidural catheters for patients who

underwent unscheduled intrapartum cesarean delivery. Proc (Bayl Univ Med Cent). 2023;36(4):473-477