Postoperative patient positioning device for improvement of postoperative pain in parturients undergoing cesarean delivery: a randomized controlled trial

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1.0 Background

Postoperative pain has significant short- and long-term implications for parturients undergoing cesarean delivery. Poorly controlled postoperative pain can interfere with the women's ability to care for herself and her newborn in the immediate postoperative period, and can contribute to longer length of hospitalizations [1, 2]. Untreated pain is associated with persistent pain, postpartum depression, and greater opioid use[3].

It is well established that an individualized, multimodal analgesic plan for the management of postoperative pain following cesarean delivery is associated with superior pain relief and decreased opioid consumption[4]. While different institutional guidelines influence general practice patterns, a combination of several medications acting on different receptors has been shown to be effective in decreasing postoperative pain. In 2018, the cesarean section rate in the United States was 31.9%, compared to 20.7% in 1996[5]. As the cesarean delivery rate increases, it is becoming more pertinent to develop and incorporate nonpharmacologic practices for postoperative pain.

The use of abdominal binders as an adjunct to pharmacologic therapy for the management of postoperative pain following major abdominal surgery has previously been discussed in surgical literature[6, 7]. Ossala et al (2020) published a recent meta-analysis of five randomized control trials evaluating the effectiveness of abdominal binders on postoperative pain following midline laparotomy. Their analysis showed significant reduction in postoperative pain on post-op days 1 and 5, though only one of the studies analyzes was from the United States, and the mean patient age was 61 years old[7].

The utility of abdominal support within the Obstetrics literature is both sparse and conflicting. Gillier et al (2016) published the first randomized control trial in the United States studying the use of abdominal binders following antepartum and intrapartum cesarean sections performed via Pfannenstiel incisions. In their study population of 155 women (87 binder vs 68 control), they found no difference in postoperative pain scores on postop days 1 and 2[8]. Gustafson et al (2018) performed a similar, though smaller, study of 56 patients (29 binder vs 27 control), and did report statistically significant lower pain scores in the abdominal binder group ($p= 0.019$)[9]. Of note, these two studies used different metrics to quantify postoperative pain. Neither of these two studies followed patients after hospital discharge, nor did they report on other postoperative complications including venous thromboembolisms or surgical site infections[8, 9].

This paucity of evidence supporting or dissuading the use of postoperative abdominal support following cesarean section for the reduction of postoperative pain leaves important clinical questions unanswered. Additionally, there is an absence of long-term outcomes associated with the use of abdominal support devices. There remains a need for the development and implementation of nonpharmacologic methods for analgesia for women following cesarean sections, along with evidence-based recommendations regarding their use in postoperative patients. The ABBy (G-Squared Medical, Brentwood, TN) is an extended-wear panniculus retractor/tissue stabilizer that is intended for use postoperatively after abdominal procedure. It is placed directly onto patient skin, superior to a transverse incision, and is then used to elevate redundant tissues away from an incision or wound (https://www.gsquaredmedical.com/How-it-Works.html). The ABBy can be removed and replaced by patients and can be used for up to 10 days. This study aims to assess the effect of ABBy use on postoperative pain,

pain medication requirement, and patient satisfaction, when used as a patient-positioning device in women following cesarean delivery.

2.0 Rationale and Specific Aims

Primary Objective: To compare the effects of post-operative patient positioning device, the ABBy, to standard wound dressings on postoperative pain in parturients delivered by cesarean delivery.

Primary Outcome: Postoperative opioid use post cesarean delivery

Secondary Objectives:

- To evaluate subjective pain scores, patient satisfaction, and duration of use of patient positioning device.
- To evaluate surgical complication and costs in groups with and without patient positioning device

3.0 Animal Studies and Previous Human Studies

The utility of abdominal support within the Obstetrics literature is both sparse and conflicting. Gillier et al (2016) published the first randomized control trial in the United States studying the use of abdominal binders following antepartum and intrapartum cesarean sections performed via Pfannenstiel incisions. In their study population of 155 women (87 binder vs 68 control), they found no difference in postoperative pain scores on postop days 1 and 2[8]. Gustafson et al (2018) performed a similar, though smaller, study of 56 patients (29 binder vs 27 control) and did report statistically significant lower pain scores in the abdominal binder group ($p= 0.019$)[9]. Of note, these two studies used different metrics to quantify postoperative pain. Neither of these two studies followed patients after hospital discharge, nor did they report on other postoperative complications including venous thromboembolisms or surgical site infections[8, 9].

4.0 Patient Population and Eligibility

Inclusion criteria:

1. Age $\geq$ 18 years
2. Cesarean delivery
3. <36 hours post-delivery

Exclusion criteria:

1. Vertical skin incision
2. Inability to place device superior to incision
3. Presence of surgical drain
4. Opioid use disorder
5. Chronic opioid use ($\geq$ 14 consecutive days during pregnancy(
6. Allergy to device adhesive
7. Active COVID-19 infection
8. Patient unable to consent

5.0 Enrollment/Randomization

All residents and Labor and Delivery staff will be apprised of the study and appropriate patients with either planned cesarean delivery or those delivered by cesarean delivery within 36 hours will have the opportunity to participate in the trial. The research team will use a daily list of all cesarean deliveries in Epic to identify potentially eligible patients for enrollment. Prior to contacting the patient, the research team member will check with the patient's nurse or care team to discuss eligibility and appropriateness for the study. Notices will also be placed in Labor and Delivery regarding the study. Study personnel will explain the study to the patient and allow ample time for the subject to ask questions related to the study. If the subject consents, she will sign the informed consent document and will be provided with a copy of the consent form prior to randomization.

Patients will be enrolled either during their delivery admission up until 36 hours after delivery. After enrolling, randomization will be performed on the obstetric unit within the first 36 hours postpartum. Participants will be randomized in a 1:1 ratio using permutated blocks of 6. RedCap will be used for randomization, using an uploaded randomization sequence. A member of the study team will access RedCap to complete randomization. The randomization result will be notated with the patient's study number and retained in the research record.

6.0 Study Procedures

Methods: Patients who meet inclusion criteria and undergo cesarean delivery at Vanderbilt University Hospital center will be asked to participate. Informed consent will be obtained during the delivery admission. Enrolled patients will be randomized within the first 36 hours following cesarean delivery. The 36-hour window for randomization will begin at the completion of surgical case, as marked in the Anesthetic Care Record in the EMR.

Patients randomized to the treatment group will have the ABBy device applied by study personnel at the time of randomization, followed by continuation of usual postoperative care. The control group will have postoperative care per usual care.

Cesarean delivery will be performed by patients' surgical team, with surgical technique per surgeon preference. Women in the treatment group will have the ABBy device placed above the incision within 36 hours of cesarean delivery completion. All team members placing the ABBy device will undergo training and demonstrate competence.

Postoperative analgesia will be administered to all participants as per routine guidelines on postpartum. All study patients will receive an electronic survey at 10 days postoperatively and again at 14 days for those continuing to use the ABBy device or opioid medication at the 10-day survey.

Specific medical information regarding pregnancy and delivery will be collected and analyzed from the patients' electronic medical records.

7.0 Risks

A rare risk exists if the patient has an unknown allergy to the adhesive material in the device, though this is estimated at less than one per one million for the silicone-based adhesive used, and per the manufacturer's report, the raw materials used in the silicone roll stock construction (PS-1860) have been analyzed for biocompatibility and found to not cause any adverse effect when used properly (Polymer Science, Monticello, IN).

There is a risk of confidentiality breech in the collection of medical information. All efforts will be made to protect the personal information of the patient by the use of study number assignment and a password-protected database. Any breech in confidentiality will be promptly reported to the Vanderbilt IRB.

8.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

Any adverse events will be reported to the Institutional Review Board in a timely manner as appropriate.

9.0 Study Withdrawal/Discontinuation

Any patient who wishes to withdraw from the study will be allowed to withdraw. Should the patient decide to withdraw from the study, she will notify the principal investigator and her information will be deleted from the study records.

10.0 Statistical Considerations

Sample size: To detect a reduction in pain medication use of 40% using an alpha of 0.05 and a beta of 0.20, 108 patients per group with a total sample of 216 patients will be required. The labor and delivery unit performs about 1400 cesarean deliveries annually; therefore, assuming an 80% eligibility rate and subsequent 50% participation rate, the study would be conducted over a 12-month period.

11.0 Privacy/Confidentiality Issues

Risks to participants are minimized by limiting this prospective study to subjects meeting the inclusion/exclusion criteria. Access to PHI will be limited to the PI and co-investigators. All patients will be de-identified by assignment of a study number. All data collected in this study will be kept electronically in a secure REDCap database. The primary risk in this study involves the disclosure of protected health information. This risk is reasonable, given the above precautions, in relation to the potential benefit to both future patients and society in general by the possibility of reducing the use of pain medication in cesarean patients.

12.0 Follow-up and Record Retention

The study will require 1 year for complete enrollment. Participants will be actively enrolled in the study for the duration of their or delivery admission plus up to 14 days follow-up time. Research records will be retained for up to 6 years.

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