Postpartum Non-pharmacologic Pain Management – Randomized Controlled Trial

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Objective

To examine whether use of an abdominal binder for postpartum patients after vaginal delivery can effectively manage their pain and reduce the need for pharmacologic analgesics

Aims

1. To determine whether use of an abdominal binder on postpartum days zero and one will result in decreased patient pain as measured by pain scores on a visual analog scale of one to ten
2. To determine whether use of an abdominal binder for postpartum patients will reduce the quantity of non-narcotic pain medications given on postpartum day zero and one
3. To determine whether use of an abdominal binder for postpartum patients will reduce the quantity of narcotic pain medications given on postpartum day zero and one

Hypothesis

Use of an abdominal binder postpartum after a vaginal delivery will be associated with lower pain scores and reduced need for pharmacologic analgesics.

Background

A significant part of postpartum care involves management of patients' pain and discomfort. Etiologies of this pain include perineal pain, incisional pain, uterine involution pain, and pelvic girdle and lower back pain. Postpartum pain management primarily focuses on the former three types of pain: perineal, incisional and uterine involution. In a review of the management of postpartum pain, Eshkevari et al[1] discuss several well-established pain management strategies employed for postpartum patients, including ibuprofen and other NSAIDs for uterine involution pain and inflammation; local anesthetics for perineal lacerations or episiotomies; warm or cold compresses for perineal pain; and opioids for post-operative or poorly controlled postpartum pain.

Data regarding management of pelvic girdle and lower back pain is scarce and the limited literature available primarily focus on the pregnant patient. Different proposed treatment or management strategies

during pregnancy include physical therapy, targeted exercises, acupuncture, NSAIDS and opioids[3]. Approximately 25% of postpartum women endorse pelvic girdle and/or lower back pain[2], and these types of pain can persist for as long as several weeks to 1-2 years after delivery[3]. Therefore, management remains key for the postpartum patient as well. The proposed pathophysiology behind pelvic girdle pain and lower back pain in the context of pregnancy is widening of the pubic symphysis and increased laxity in the sacro-iliac joints (SIJ) secondary to both biomechanical shear forces of increased weight bearing and elevated levels of relaxin, a polypeptide hormone that increase laxity of ligaments[3]. A prospective study investigating the impact of abdomino-pelvic belts at different positions on the laxity of the SIJ found that use of the abdomino-pelvic belt significantly decreased mobility of the SIJ[4]. Additionally, pelvic belts or abdominal binders may help provide stability to muscles of the abdomen, back and spine[4,5].

Studies investigating the use of abdominal binders for pain management in post-operative patients following both cesarean section and gynecologic surgery have had mixed results. A randomized control trial examining impact of abdominal binders on patient reported pain and symptom distress found no significant difference in pain on post-operative days one and two, and the difference in distress on post-operative day two was no longer statistically significant after correction for multiple measures[6]. Another study involving gynecologic surgery patients randomized to abdominal binder or control groups found that there was no overall significant difference in morphine use or pain scale between the groups, and the benefits were limited to a significant effect on post-operative ambulation for a subset of patients with highest risk of complications: patients > 50 years, cancer patients, and those with vertical incision. In contrast, a more recent randomized controlled trial assessing abdominal binders following cesarean delivery found that pain and symptom distress scores were significantly lower at all time points in comparison to a control group[7].

A common theme in the current literature regarding postpartum pain management is the need for more research[1,3,7]. In light of the current opioid abuse epidemic, which affects approximately 2.1 million people and the U.S Department of Health and Human Services declared a public health emergency in 2017[8], there is a renewed emphasis utilizing non-opioid methods on pain control. As a primary source of pain in the postpartum period is associated with musculoskeletal pelvic discomfort, the use of a supportive abdomino-pelvic belt may be a non-pharmacologic modality that could reduce pain and decrease narcotic requirements in postpartum patients. No studies to our knowledge have directly assessed the effectiveness of abdominal binders on pain management in postpartum patients. This study aims to examine how use of an abdominal binder might impact postpartum pain, and the use of pharmacologic analgesia following vaginal delivery.

Protocol

- Recruitment
    - We will evaluate patients admitted to Labor and Delivery for potential participants in our study based on the inclusion and exclusion criteria outlined below. If appropriate to approach, eligible potential participants will be approached in their labor and delivery room prior to delivery. If interested in participation, the Informed Consent document will be presented and explained in the room to ensure privacy.

- Inclusion Criteria
    - 18 years of age and older
    - Pregnant
    - Admitted to labor and delivery
    - Anticipated spontaneous vaginal delivery
    - Informed consent obtained

- Exclusion Criteria
    - Documented chronic pain condition
    - Chronic narcotic use or Maternal Abstinence Treatment
    - UDS positive for opiates on admission
    - Trial of labor after cesarean
    - Lack of sufficient English proficiency to obtain informed consent
    - Cesarean section or operative vaginal delivery

- Subject Informed Consent
    - Informed consent process will take place at the Berry Women's Center at Miami Valley Hospital
    - Written and signed consent will be obtained in English.

- Plans of obtaining informed consent:
    - Potential eligible participants will be approached in the labor and delivery room to ensure privacy. The research assistant will provide and discuss an informed consent form with

the participant. The informed consent form will describe the project goals, length and rational, as well as the types of PHI that will be collected. All participants who agree to participate in the study will sign the informed consent form. All participants will be provided with a copy of the signed consent form.

- Study design & procedures
    - After signing informed consent, participants will be assigned to the intervention or control group via block randomization
    - Those participants in the standard of care group will receive routine postpartum care
    - Those participants in the intervention group will receive an abdominal binder in addition to routine postpartum care
        - Determination of appropriate binder size will be based on a visual assessment of the patient's abdominal circumference
    - Nursing staff will evaluate participant's pain level using a visual analog scale of 1-10 a minimum of every 4 hours. Patient reported pain score and pain location will be recorded in the participant's electronic medical record. These processes do not deviate from current standards of care and documentation.
    - Additional non-pharmacologic pain relief measures utilized by patients will be documented on the data collection sheet attached to the patient's chart. These measures include heating pad, ice pack, and tucks pads
    - All medications received will be documented in the electronic medical record per usual documentation protocols
    - Nursing staff will document compliance of patient for wearing the abdominal binder, making notes when the binder was removed and if/when it was put back on.

- Sample Size Estimation & Data Analysis Plan
    - Sample size was estimated using G*Power. In order to detect a difference between groups on pain scores and use of pain medications, we will need to enroll 65 patients per group. This will enable us to detect a moderate difference (i.e., medium effect size) between the groups with a power = 80% and p at <0.05. We will enroll an additional 10 patients to account for dropouts for a total N=140.

    - The two groups will be compared for 1. reported pain scores (assessed by nursing staff and documented in the EMR) and for 2. pain medications used (morphine equivalent as

recorded in the MAR) for the duration of patients' hospital stay. Repeated measures analysis of variance will be used to determine differences between the groups over time.

- Data collection plan
    - Prospective data collection with hard copy data entry form that includes PHI for participant identification, basic demographic information, delivery information (see separate document), non-pharmacologic pain relief measures used
    - Electronic medical record review for: pain scores, pain location, medications received
        - Pain score immediately postpartum
        - Pain scores on PPD#0 and PPD#1
        - Patient reported pain locations
        - Quantity of non-narcotic pain medication received on PPD#0 and PPD#1
        - Quantity of narcotic pain medication received on PPD#0 and PPD#1
        - Compliance wearing the abdominal binder

- Risks
    - Allergic reaction to fabric of abdominal binder
    - Skin irritation
    - Increased discomfort or pain with use of abdominal binder

- Mitigation of risks
    - If participants experience an allergic reaction or skin irritation from the abdominal binder they will offered symptomatic treatment. Participants in the experimental arm will be encouraged to keep the abdominal binders in place for 24 hours postpartum, but will be permitted to remove the abdominal binder at any time should they find it causing irritation, increased pain or any other adverse reaction.

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