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CLINICAL ARTICLE

A randomized controlled trial of abdominal binders for the management of postoperative pain and distress after cesarean delivery

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ABSTRACT

Objective: To determine whether abdominal binders effectively control pain and distress after cesarean delivery. *Methods:* A prospective randomized controlled trial was conducted between April and November, 2014, among women undergoing cesarean delivery (low-transverse skin incision) at two US hospitals. Participants were randomly allocated to either the abdominal binder or control groups on entry to the operating suite. Masking was not possible. Patients in the abdominal binder group were fitted with a device before leaving the operating room and were encouraged to wear it constantly, although breaks were allowed. The primary outcomes were postoperative distress (measured by the Symptom Distress Scale [SDS]) and pain (measured by a visual analog scale [VAS]). Individuals who asked to be removed from the study within 6 hours of surgery were excluded from analyses. *Results:* Analyses included 87 patients in the abdominal binder group and 68 in the control group. The abdominal binder and control groups did not differ in postoperative day 1 VAS (3.1 ± 2.1 vs 3.4 ± 2.3; $P = 0.33$), postoperative day 2 VAS (3.0 ± 1.9 vs 3.8 ± 2.2; $P = 0.16$), postoperative day 1 SDS (21.5 ± 5.4 vs 21.8 ± 5.1; $P = 0.87$), and postoperative day 2 SDS (19.4 ± 4.8 vs 19.9 ± 5.0; $P = 0.53$). *Conclusion:* Postoperative pain and distress scores after cesarean delivery were not affected by abdominal binders.

ClinicalTrials.gov: NCT02129894

1. Introduction

Cesarean delivery is the most frequent major abdominal surgery performed worldwide [1]. In the USA alone, more than 1.25 million such procedures were performed in 2013, accounting for at least 33% of all deliveries [2]. Effective pain management is vital to the postoperative course of all abdominal surgeries. Without adequate pain management, patients are reluctant to ambulate or practice incentive spirometry, both of which are crucial for prevention of thrombotic events and atelectasis [3]. Such reluctance to move after abdominal surgery reflects not only pain, but also fear of injury to the surgical site [3].

Many patients who have undergone abdominal surgery are encouraged to splint their incisions with either their arms or pillows [4]. However, these are only temporary measures and their benefits have not been well defined. Some limited investigations suggest that the use of abdominal compression devices that limit the motion of the abdominal wall might aid the management of pain following major abdominal surgeries [5]. The most common of these devices is composed of elastic material which encircles the abdomen. These devices could also offer additional benefits beyond pain control, including prevention of herniation [6] and wound seroma and/or hematoma [7]. Nevertheless, their use is currently based on physician and patient preferences, with little or no evidence-based supporting data.

Patients who have undergone cesarean delivery also have some unique concerns to consider. Both the hypercoagulable state of pregnancy and the need to care and bond with the newborn in the hours after major abdominal surgery require an alert, mobile, and unstressed mother. Pain control is crucial because the severity of acute pain after delivery—irrespective of the mode of birth—predicts which patients will develop persistent pain and/or postpartum depression [8]. Numerous pharmacological pain control studies have been conducted after cesarean delivery [9], but few investigations have assessed the benefits of nonpharmacological interventions, such as physiotherapy [10]. Although many narcotics are safe to use when breastfeeding, some women prefer to avoid these agents because they believe such use might hinder their ability to care for the newborn or otherwise exert adverse effects on the neonate [11]. Consequently, pain relief after cesarean delivery must be safe and effective, while avoiding adverse maternal or neonatal effects. These requirements make the use of an effective nonpharmacological alternative attractive.

The aim of the present study was to determine whether patients who wear an abdominal binder following cesarean delivery experience less pain and distress than patients who do not wear an abdominal binder.

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2. Materials and methods

A prospective randomized controlled trial was conducted among women aged 18–50 years who underwent cesarean delivery by a low-transverse skin incision at the Bethlehem and Allentown campuses of St. Luke's University Hospital, PA, USA, between April 1 and November 28, 2014. The exclusion criteria were general anesthesia, vertical skin incision, and placement of any postoperative drain. Patients expected to undergo vaginal delivery provided informed consent early in their labor course, thereby allowing participation should emergency cesarean delivery be required. Patients who were scheduled for either a primary or repeat cesarean delivery provided consent on the day of their surgery. Approval for the present study was obtained from the institutional review board of St Luke's University Hospital and Health Network.

Randomization in a 1:1 ratio was completed by a member of the Research Department at St Luke's University Hospital using a computer-generated number table. Opaque envelopes were used to mask allocation to either the treatment group (abdominal binder) or the control group (no abdominal binder) and were drawn when the patient entered the operating suite. The assignment was performed by C.M.G. or J.R.S., or their designee. Masking of group assignment was not possible because of the nature of the intervention.

Demographic data were collected at time of admission and obtained from the medical records of participants. On completion of the cesarean delivery, patients in the abdominal binder group were fitted with a device that was placed low on the abdomen across the incision, before leaving the operating room. The abdominal binder was made of latex-free elastic material with a hook-and-loop adjustable closure system. Patients were encouraged to wear the abdominal binder throughout the day and night; however, they were allowed unmeasured breaks from wearing the device. Patients in the control group were not given any opportunity to wear an abdominal binder.

The primary outcomes were the scores obtained on postoperative days 1 and 2 using the Symptom Distress Scale (SDS) [12] and a visual analog scale (VAS) of pain. The SDS is a validated assessment of distress made up of 13 measures, including pain, nausea, sleep, fatigue, bowel function, concentration, breathing, cough, and outlook. Each measure is given a score of 1–5 by the patient, with high scores indicative of high levels of distress. Thus, the total SDS score ranges from 13 to 65. The SDS score has been used for more than 20 years as a clinical measure in various studies conducted in multiple hospital settings and has a substantial body of literature supporting its reliability and validity [12]. Patients were asked to rate their distress level in the previous 6 hours midmorning using the SDS tool. At the same time, patients reported their postoperative pain levels in the previous 6 hours using the VAS. Patients were instructed to place a mark on a 10-cm line corresponding to the severity of their pain, with 0 cm representing no pain and 10 cm being the worst pain they had experienced.

The secondary outcomes were the quantity of pain medication administered and the change in hemoglobin levels during the postoperative period. The standard pain medications used at St Luke's University Hospital on postoperative days 1 and 2 included ibuprofen, ketorolac, acetaminophen, codeine plus acetaminophen, oxycodone plus acetaminophen, hydrocodone plus acetaminophen, and morphine. The total ibuprofen, ketorolac, acetaminophen, and morphine equivalent doses were calculated for each day. The opioid dose calculator was developed by the Washington State Agency Medical Directors' Group [13]. Hemoglobin levels were measured on postoperative days 1 and 2 by sodium lauryl sulphate method (XE-5000, Sysmex America, Lincolnshire, IL, USA).

A sample size of 160 was deemed to give 80% power to detect a 1.0-cm change in the 10-cm VAS between the two groups. This assumption was based on a standard deviation of 2.2 in the VAS, representing minimal clinical findings between groups. The present study aimed to recruit at least 180 patients to account for loss at follow-up and dropouts.

The data were analyzed using SigmaPlot version 12.5 (Systat Software, San Jose, CA, USA). Individuals who asked to be removed from the study within 6 hours of surgery were excluded from analyses. Measures were compared between groups using the t test, Mann–Whitney U test, or χ^2 test, as appropriate. Adjustments were made for multiple measurements using the Bonferroni correction. $P < 0.05$ was considered statistically significant.

3. Results

Among the 180 patients who were enrolled, 155 were included in the final analysis (87 in the abdominal binder group, 68 in the control group) (Fig. 1). Demographic characteristics were similar between the two groups (Table 1). Overall, 113 (72.9%) participants were white, 27 (17.4%) Hispanic, and 11 (7.1%) African American. No between-group difference was observed in either the number of scheduled cesarean deliveries or the need for cesarean delivery after a trial of labor. In the control group, 62 (91.2%) patients received a morphine sulfate dose in their local anesthesia versus 82 (94.3%) in the abdominal binder group.

The main outcome measures are shown in Table 2. Among all 155 participants, the mean SDS score was 21 on postoperative day 1 and 20 on postoperative day 2. No significant between-group difference was detected in the SDS score on either postoperative day 1 or day 2. No between-group difference was detected in the VAS score on postoperative day 1. By contrast, on postoperative day 2, the score was lower in the abdominal binder group than in the control group ($P = 0.01$); however, statistical significance was not retained after correction for multiple measurements.

A comparison of the pain medications administered to each group is presented in Table 3; no statistically significant between-group differences were observed after correction for multiple measurements. The

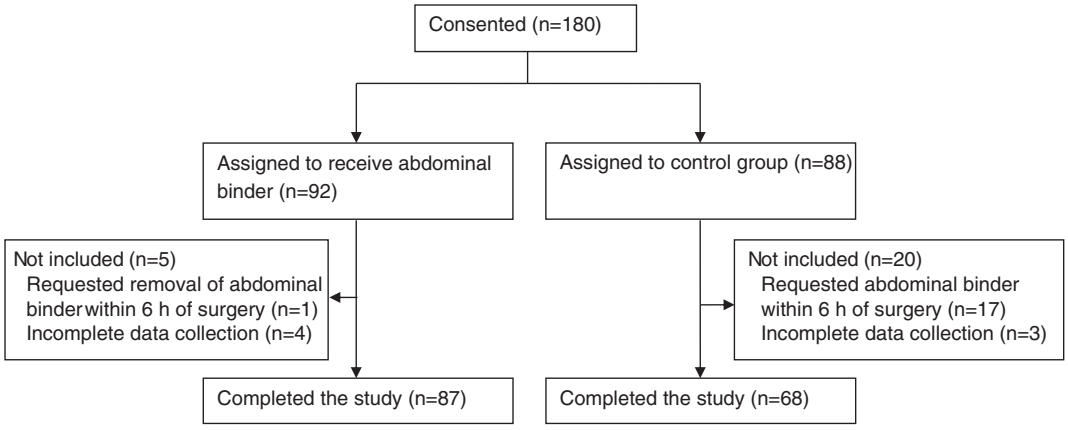

Fig. 1. Study design.

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