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Prophylactic Negative Pressure Wound Therapy with the Medela Invia Motion at Cesarean Delivery: a Pilot Study

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Abstract

Objective: To assess patient centered outcomes associated with use of the Medela INVIA Motion prophylactic negative pressure wound therapy (NPWT) system at cesarean delivery.

Methods: This was a single arm trial including patients undergoing scheduled or unscheduled cesarean delivery at or greater than 23 weeks' gestation. Patients unwilling to provide consent, unavailable for follow up or with a contraindication use of prophylactic NPWT were excluded. Consented patients had the Medela INVIA Motion prophylactic NPWT system placed and secured after skin closure. The device was removed at discharge (typically postoperative day 3-4). Patient reported outcomes were pain scores on a scale of 0 (no pain) to 10 (worst pain) and patient satisfaction scores on a scale of 0 (completely dissatisfied) to 10 (completely satisfied) at discharge and postoperative day 30. Other outcomes were a composite of wound complication including wound infection, would separation, seroma, antibiotics prescribed for presumed surgical site infection within 30 days, and occurrence of adverse skin reactions potentially related use of prophylactic NPWT.

Results: A total of 20 patients undergoing cesarean delivery were included. The average body mass index at delivery was 37 kg/m^2. All patients had routine infection prevention measures. Nearly all patients had a Pfannenstiel incision skin incision. Pain scores were generally low at the time of discharge (median score 2.5 [IQR 1, 5]) and near 0 by postoperative day 30 (median 0 [IQR 0, 1]). Patients were very satisfied with their experience using the Medela INVIA Motion prophylactic NPWT at discharge (median score 10 [IQR 8.5, 10]) and postoperative day 30 (median score 10 [IQR 10, 10]). There was no wound complication or adverse skin reaction.

Conclusion: Use of the Medela INVIA Motion prophylactic NPWT after cesarean delivery was associated with low pain, high satisfaction and no increase in adverse skin reactions. (ClinicalTrials.gov#NCT04365452)

Keywords: Medela INVIA Motion prophylactic negative pressure wound therapy; cesarean delivery

Introduction

Cesarean delivery is the most common major surgical procedure among women in the United States. In 2022, 32.2% (1.2 million) of the 3.66 million births in the United States were by cesarean[1]. Despite significant advances in the use of antiseptics, prophylactic antibiotics, and sterile surgical technique, surgical site infection remains a significant cause of morbidity after

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cesarean[2,3]. In addition to the patient-level impact, surgical site infections increase hospital length of stay and escalate costs at least two-fold at the health care system level[4]. Obesity (body mass index [BMI] ≥30 kg/m^2) complicates over 33% of pregnancies, and exacerbates the problem of surgical site infections after cesarean[5]. Obese women are more likely than non-obese women to deliver by cesarean and are also at a higher risk for surgical site infections[6-9]. Several studies demonstrate a dose-response relationship between increasing BMI and surgical site infections after cesarean[8,10]. Therefore, additional interventions are needed to reduce surgical site infections after cesarean.

Prophylactic negative pressure wound therapy with closed, portable, single use, battery powered systems were cleared by the FDA for prophylactic application after wound closure at the time of surgery. The most common systems are the Prevena and PICO systems. While they have been shown to be beneficial in other types of surgical procedures, data on their effectiveness at cesarean are mixed[11-13]. More recently the Medela INVIA Motion prophylactic negative pressure wound therapy (NPWT) system was introduced into clinical care.

We conducted this pilot study with the objective of assessing patient centered outcomes associated with use of the Medela INVIA Motion NPWT system at cesarean delivery.

Study Design and Methods

This was a single arm pilot trial conducted between March and August 2020 at Indiana University Health Methodist Hospital and Eskenazi Hospital in Indianapolis, Indiana. Patients undergoing scheduled or unscheduled cesarean delivery at or greater than 23 weeks' gestation were included. We excluded patients unwilling or unable to provide consent, not availability for postoperative follow-up or with a contraindication to NPWT including pre-existing infection around incision site, bleeding disorder, therapeutic anticoagulation, allergy to any component of the dressing (e.g., silver, silicone, adhesive tape) or prior irradiated skin irradiation.

The Medela INVIA Motion prophylactic NPWT system consists of a charcoal foam, manufactured using a reticulated polyether and polyurethane hydrophobic material, a FitPad suction interface with a Quick-connector which connects the foam to the pump, a transparent film and a compact regulated pump. All components are packaged together and sterilized using ethylene oxide. The Invia Foam Dressing Kit is available in four sizes: Small, Medium, Large and X-Large. Consented patients had the Medela INVIA Motion prophylactic NPWT system placed and secured after skin closure and connected to the pump (Figure 1). The pump was then activated to achieve a negative pressure of -125 mmHg.

Figure 1: Medela INVIA Motion prophylactic negative pressure wound therapy system

Participants were monitored daily until discharge from the hospital. The device was removed on the day of discharge, (typically postoperative day 3 - 4). If the patient remained hospitalized for more than 7 days, the device was removed on postoperative day 7. Patients were educated about the signs and symptoms of infection and other wound complications and encouraged to call their provider if those occurred. Participants were contacted by telephone around 30 days after delivery to assess whether they had symptoms of surgical site infection and whether they had had a physician office visit or emergency department visit or hospital readmission for wound complications. Medical records were obtained from physician office and emergency department visits, and hospital admissions, to determine the diagnosis at each postoperative visit or readmission. Patient demographics, antepartum, intrapartum, intraoperative and postpartum course were extracted from medical record. Data were abstracted by research staff.

The study outcomes were patient centered outcomes including pain scores on a scale of 0 (no pain) to 10 (worst pain) and patient satisfaction scores on a scale of 0 (completely dissatisfied) to 10 (completely satisfied) at discharge (typically postoperative day 3 - 4). and postoperative day 30. We also assessed an efficacy outcome, defined as a composite of wound complication including wound infection, would separation, seroma, antibiotics prescribed for presumed surgical site infection within 30 days. Wound complications were defined according to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network criteria[14]. Safety outcomes included occurrence of adverse skin reactions potentially related use of prophylactic NPWT including skin blistering, allergic reaction, and wound bleeding.

Descriptive statistics was used for analysis, with percentages and proportions reported. As a pilot study, a convenience sample size of 20 was chosen; no formal sample size estimation was performed.

Kuuseg RN, et al., Obstet Gynecol Res 2023
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Results

A total of 20 patients undergoing cesarean delivery consented and were included. In all, 14 (70%) participants were Caucasian and 6 (30%) were black. The average body mass index at delivery was 37 kg/m^2. All patients had preoperative antibiotic prophylaxis and skin preparation with chlorhexidine- or iodine-alcohol and 7 (35%) had vaginal cleansing. Nearly all patients had a Pfannenstiel incision skin incision (Table 1). Nine (45%) participants had subcutaneous tissue depth>2 cm and 8 (40%) had subcutaneous tissue closure with suture. All participants had subcuticular skin closure with suture; none were closed with staples.

Table 1: Baseline and Operative Characteristics

	N=20
Ethnicity	
Hispanic	1 (5)
Non-Hispanic	19 (95)
Race	
African American	6 (30)
Caucasian	14 (70)
Government insurance	10 (50)
Pre-pregnancy Body Mass Index, Kg/m^2	33.6 (27.6, 36.6)
Delivery Body Mass Index, Kg/m^2	37.0 (32.5, 41.3)
Smoking	4 (20)
Chronic Hypertension	1 (5)
Diabetes	1 (5)
Gestational age	39 (37.1, 39.1)
Prior cesarean	11 (55)
Chorioamnionitis	1 (5)
Antibiotic prophylaxis	20 (100)
Ancef	16 (80)
Azithromycin	1 (5)
Skin prep	20 (100)
Vaginal prep	7 (35)
Pfannenstiel incision	19 (95)
Subcutaneous tissue depth>2 cm	9 (45)
Subcutaneous closure	8 (40)
Subcuticular Skin closure	20 (100)
Estimated blood loss (ml)	821 (470, 1019)

Data presented as n (%) or median (interquartile range [IQR])

Table 2: Patient Outcomes

	N=20
Pain at discharge (0,10)	2.5 (1, 5)
Pain at postoperative day 30 (0, 10)	0 (0, 1)
Satisfaction at discharge (0,10)	10 (8.5, 10)
Satisfaction at postoperative day 30 (0, 10)	10 (10, 10)
Composite wound complications	0
Adverse skin reactions	0
Physician office or Emergency Room Visit for Wound Concerns	0

Median (interquartile range [IQR])

Pain scores were generally low at the time of discharge (median score 2.5 [IQR 1, 5]) and almost 0 by postoperative day 30 (median 0 [IQR 0, 1]). Patients were highly satisfied with their experience using the Medela INVIA Motion prophylactic NPWT at discharge (median score 10 [IQR 8.5, 10]) and postoperative day 30 (median score 10 [IQR 10, 10]) (Table 2). There were no wound complications or adverse skin reactions in any of the participants.

Discussion

This study was conducted to assess patient centered outcomes associated with use of the Medela INVIA Motion prophylactic NPWT system at cesarean delivery. In this single arm pilot trial, use of the Medela INVIA Motion prophylactic NPWT after cesarean delivery was associated with low pain and high satisfaction. There were no cases of wound complications or adverse skin reactions.

Experimental evidence suggests that prophylactic NPWT reduces bacterial contamination, edema, and exudates, increases microvascular blood flow, and promotes granulation tissue by inducing mechanical stress that promotes cell growth[15-18]. Coincidentally the increased risk of surgical site infections in obese women is thought to be in part due to increased thickness of the subcutaneous space that allows accumulation of exudate, increases lateral tension on the wound edges, promotes growth of bacteria, and leads to wound infection and breakdown[19]. Therefore, it is anticipated that prophylactic NPWT would be particularly effective in this population.

Prior studies on the effectiveness of prophylactic NPWT after cesarean delivery have been mixed with some meta-analyses concluding that there is evidence of benefit in reducing infections while others did not[11-13]. One study notably reported a reduction in pain and a 30% decrease in total opioid use[20].

This was a prospective study in which patients were closely followed to ascertain outcomes. To our knowledge, this is the first study of the Medela INVIA Motion prophylactic NPWT at cesarean delivery. We focused on patient centered outcomes which are often neglected in studies of this nature. The positive patient experience and the non-occurrence of any wound complications or adverse skin reactions are reassuring. Limitations of the study include the small sample size which may have contributed to the non-occurrence of any wound complications or adverse events. Another limitation is the absence of a control group in this

pilot study, which precludes definitive conclusions about the INVIA Motion prophylactic NPWT system.

In conclusion, among obese women undergoing cesarean delivery, use of the Medela INVIA Motion prophylactic NPWT was associated with low pain and high satisfaction. Although the sample size is modest, the non-occurrence of wound complications or adverse skin reactions is reassuring. A larger trial with a control group and powered to detect differences in wound complications is needed to define the role of the Medela INVIA Motion prophylactic NPWT at cesarean delivery.

Declarations

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