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Negative pressure wound therapy system in extremely obese women after cesarean delivery compared with standard dressing*

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ABSTRACT

Objective: Data regarding the use of the negative pressure wound therapy (NPWT) system in extremely obese women (body mass index [BMI] ≥ 50 kg/m²) undergoing cesarean delivery are limited. We sought to examine the rate of wound complications in extremely obese women according to postcesarean dressings (NPWT [PICO, Smith & Nephew, St. Petersburg, FL] versus standard dressings).

Study design: This was a retrospective cohort study of all extremely obese women (BMI ≥ 50 kg/m²) at 23 weeks' gestation or greater who underwent cesarean delivery at an academic teaching hospital in Washington, DC, between January 2009 and September 2017. During this period, a PICO Single Use NPWT system was used at our institution. Women who missed a postpartum follow-up were excluded. Since 2014, Medstar Washington Hospital Center recommended the use of a PICO Single Use NPWT system for extremely obese women at the time of delivery. However, the ultimate decision to use the NPWT was made by attending physicians, considering the cost of the device and the risk of wound complication. Our primary outcome was a composite of cellulitis, hematoma/seroma, and wound dehiscence. Coarsened exact matching with k-to-k solution was performed using BMI, rupture of membranes, and labor.

Results: Of 179 extremely obese women, 73 (40.8%) and 106 (59.2%) received NPWT and standard dressings, respectively; 61 women who received NPWT were matched to 61 women who received standard dressings. The rates of the primary outcome in the unmatched cohort were similar between women who received NPWT and those who received standard dressings (20.6 versus 16.0%; $p = .44$). The rates of primary outcome remained similar between women who received NPWT and those who received standard dressings after matching (18.0 versus 18.0%; $p = 1.00$).

Conclusion: In extremely obese women undergoing cesarean delivery, prophylactic PICO NPWT was not associated with a decreased risk of the primary outcome compared with standard dressings. A large prospective randomized controlled trial would be useful to answer if NPWT is beneficial for extremely obese women.

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Introduction

Surgical site infections and wound complications (wound hematoma/seroma and dehiscence) are one of the most common complications after cesarean delivery [1,2]. Surgical site infections and wound complications are associated with increased maternal morbidity and mortality, resulting in prolonged hospital stays and undue burdens to the health care system [3–5]. Extreme obesity (body mass index [BMI] ≥ 50 kg/m²) is a well-known risk factor for surgical site infections and wound complications after cesarean delivery [6–8].

Negative pressure wound therapy (NPWT) is a closed, sealed system that applies negative pressure

to the wound surface, which promotes wound healing by removing exudates, approximating the wound edges, and reducing bacterial contamination. In non-obstetric surgeries, NPWT has been shown to decrease the rate of surgical site infection, seroma or hematoma formation, and reoperation rates [9,10]. However, good quality data are lacking in extremely obese women undergoing cesarean delivery. Recently, two meta-analyses of obese women undergoing cesarean delivery showed contradicting results (one showing no significant difference in a composite outcome [surgical site infection, hematoma, seroma, or wound dehiscence] and another showing 50% decrease in surgical

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site infection) [11,12]. Both meta-analyses included the use of two different NPWT systems (Prevena; KCL USA, San Antonio, TX, and PICO; Smith & Nephew, St. Petersburg, FL). These two meta-analyses did not specifically examine extremely obese women. As NPWT is not without additional cost (approximately \$257 per device [13]), a cohort study comparing NPWT and standard dressing is clinically relevant in determining if these devices are applicable in obstetrical surgery. The aim of our study was to compare the rate of wound complication between NPWT system and a standard dressing in extremely obese women undergoing cesarean delivery.

Materials and methods

This was a retrospective cohort study of all extremely obese women ($\text{BMI} \geq 50 \text{ kg/m}^2$) at 23 weeks' gestation or greater who underwent cesarean delivery at Medstar Washington Hospital Center, an academic teaching hospital in Washington, DC, between January 2009 and September 2017. During this period, a PICO Single Use NPWT system was used at our institution. Women who missed a postpartum follow-up were excluded. An electronic medical record was used to identify women who underwent cesarean delivery. The first author (TK) conducted a chart review to obtain the data from the outpatient, inpatient, and anesthesia record. MedStar Institutional Review Board approved this study.

Since 2014, Medstar Washington Hospital Center recommended the use of a PICO Single Use NPWT system for extremely obese women at the time of delivery. However, the ultimate decision to use the NPWT was made by attending physicians, considering the cost of the device and the risk of wound complication. The PICO Single Use NPWT system maintains negative pressure at $80 \pm 20 \text{ mmHg}$ [14]. Exudate is absorbed and evaporated through the outer film without collecting fluid in a canister. The PICO Single Use NPWT system does not contain an alarm system as well as an antimicrobial coating. The PICO Single Use NPWT system was placed over the closed skin incision and removed on postpartum day 7. For standard dressing, a TELFA nonadhesive dressing with a 3M Tegaderm transparent film adhesive dressing or pressure dressing was used. Typically, a cesarean delivery was performed by an attending physician and a resident physician. At Medstar Washington Hospital Center, antibiotics were given intravenously within 1 h before skin incision. The 2-g dose of cefazolin was usually given, but a 3-g dose was considered by attending

physicians. Since December 2016, intravenous azithromycin 500 mg was administered to all women undergoing cesarean delivery. Skin preparation was conducted using povidone iodine or chlorhexidine gluconate.

Maternal demographics that were evaluated included age, parity, multiple gestation, gestational age, number of prior cesarean deliveries, race/ethnicity, BMI at the time of admission, smoking, alcohol use, illicit drug use, maternal comorbidities including diabetes (pregestational and gestational diabetes), chronic hypertension, and pregnancy-associated hypertensive disease (gestational hypertension, preeclampsia, hemolysis, elevated liver enzyme, low platelet [HELLP] syndrome, and eclampsia), and human immunodeficiency virus. Labor and delivery outcomes that were evaluated included emergency cesarean delivery, skin incision type, skin closure type, length of operation, and labor information (labor [cervical dilation $\geq 4 \text{ cm}$ in the setting of contraction], second stage of labor, rupture of membranes, duration of rupture of membranes, and chorioamnionitis). BMI was obtained at the time of admission to labor and delivery. Emergency cesarean delivery was defined as an emergent cesarean delivery where skin preparation was not completed. Indications for cesarean delivery were also evaluated. Chorioamnionitis was defined as fever at least 38.0°C plus fetal tachycardia (>160 beats per min) or purulent fluid from cervical os.

Our primary outcome was defined as a composite wound complication including cellulitis, hematoma/seroma, and wound dehiscence ($>1 \text{ cm}$) within 6 weeks after cesarean delivery. Secondary outcomes included deep wound infection, endometritis, and other severe infections (abdominopelvic abscess and blood culture confirmed sepsis). Cellulitis was defined as an infection of the skin or subcutaneous tissue with at least one of the following: purulent discharge, organisms isolated from the incision, or erythema/induration/tenderness. Hematoma/seroma was defined as collections of blood or serum (wound dehiscence was not required for the diagnosis) [15]. Deep wound infection was defined as an infection of deep soft tissues with at least one of the following: purulent discharge, spontaneous dehiscence, or evidence of abscesses [15]. Endometritis was defined as the presence of at least two of the following: fever ($>38.0^\circ\text{C}$), abdominal pain, uterine tenderness, or purulent drainage from the uterus [15]. Abdominopelvic abscess was confirmed by radiologic findings. These outcomes were obtained by chart review of outpatient, inpatient, and anesthesia record.

Descriptive statistics were calculated for all study variables. Chi-square test, Fisher's exact test, or Wilcoxon rank-sum test were performed. To account for the potential demographic change, we performed coarsened exact matching with k-to-k solution based on predefined factors including body mass index (kg/m^2), rupture of membranes, and labor [16]. These factors were chosen because these were known risk factors for surgical site infections [17]. The coarsened exact matching coarsens each variable into substantively meaningful groups, exact match on these coarsened data, and then only retain the original uncoarsened values in the matched data. We used coarsened exact matching over other techniques such as Mahalanobis distance or the propensity score because other methods require multiple iterations and rematching [16]. All statistical analyses were performed using Stata/IC 15.1 (StataCorp, College Station, TX).

Results

We identified 417 extremely obese women who underwent a cesarean delivery between January 2009 and September 2017. Two hundred thirty-eight women were excluded due to loss of follow-up. Of 179 women remained, 73 (40.8%) and 106 (59.2%) received the PICO Single Use NPWT and standard dressings, respectively; 61 women who received the PICO Single Use NPWT were matched to 61 women who received standard dressings. Demographic and labor and delivery data are presented in Table 1. In the unmatched cohort, women receiving the PICO Single Use NPWT were more likely to be older and have higher BMI compared to women receiving standard dressing ($p < .05$). In the matched cohort, women receiving the PICO Single Use NPWT were more likely to be older compared to women receiving standard dressing ($p < .001$).

Wound complication according to type of dressing is presented in Table 2. In the unmatched cohort, women receiving the PICO Single Use NPWT compared to those receiving standard dressings had similar rates of the primary outcome (20.6 versus 16.0%; $p = .44$) but had higher rates of deep wound infection (5.5 versus 0%; $p = .02$). In the matched cohort, women receiving the PICO Single Use NPWT compared to those receiving standard dressings had similar rates of the primary outcome (18.0 versus 18.0%; $p = 1.00$) but had higher rates of hematoma/seroma (11.5 versus 1.6%; $p = .03$).

Discussion

In this cohort of extremely obese women who underwent cesarean delivery, we found that the PICO Single Use NPWT was not associated with decreased odds of wound complications compared to standard dressings.

Extreme obesity is a known risk factor for wound infection after cesarean delivery [6,8]. Conner et al. in 2014 reported extreme obesity was associated with a threefold increase in wound complication [6]. Higher BMI is associated with an increased risk for wound complications after cesarean delivery, and women with BMI $50 \text{ kg}/\text{m}^2$ or higher are at the greatest risk for morbidity [6,8]. The effect of NPWT has not been examined in an extremely obese population. NPWT is thought to accelerate wound healing by removing exudates, increasing blood flow, and stimulation of granulation tissue [18]. In nonobstetric surgeries, NPWT was found to be associated with a decreased risk of wound complication [9,10,19]. However, in women undergoing cesarean delivery, studies examining the efficacy of NPWT have shown conflicting results [12,13]. Smid et al. in 2017 reported a meta-analysis of five randomized controlled trials (RCT), showing no difference in a composite outcome (surgical site infection, seroma, hematoma, and wound dehiscence) between NPWT and standard dressing [12]. Whereas Yu et al. in 2018 reported a meta-analysis of six RCTs and three cohort studies, showing a significant decrease in surgical site infection by 55% associated with NPWT compared with standard dressing [13]. However, both meta-analyses were heterogeneous in their inclusion criteria in regards to BMI range and type of NPWT. There are no trials that compare the two most common NPWT systems (Prevena [KCL USA, San Antonio, TX] and PICO [Smith & Nephew, St. Peterburg, FL]). In our study, we examined the effect of a PICO Single Use NPWT system. The lack of differences in our study may be because we only examined the PICO Single Use NPWT.

A NPWT system is not without additional cost. Echebri et al. in 2015 reported the additional cost of prophylactic NPWT was \$257 compared with standard dressing [13]. Based on their data, at a wound complication rate of 18%, the rate must be reduced to less than 5% for NPWT to be cost-effective. In our cohort, the rate of wound complication was 16–18% with standard dressings and 18–21% with the PICO Single Use NPWT, suggesting that the PICO Single Use NPWT may not be cost-effective in our cohort.

Our study has multiple strengths. Our data were derived from a chart review of outpatient, inpatient, and anesthesia record. Therefore, we believe that our

Table 1. Demographics and labor and delivery outcomes.

	Unmatched			Matched		
	Standard dressing (<i>n</i> = 106)	NPWT (<i>n</i> = 73)	<i>p</i> -value	Standard dressing (<i>n</i> = 61)	NPWT (<i>n</i> = 61)	<i>p</i> -value
Maternal age, mean (SD)	27.5 (5.9)	30.8 (4.9)	<.001	27.5 (5.8)	30.9 (5.2)	<.001
Parity, median (10–90th)	1 (0; 3)	1 (0; 3)	.37	1 (0; 3)	1 (0; 3)	.77
Multiple gestation	4 (3.8)	5 (6.9)	.36	3 (4.9)	4 (6.6)	.70
Number of previous cesarean, median (10–90th)	0 (0; 2)	1 (0; 2)	.90	1 (0; 2)	0 (0; 2)	.37
Race/ethnicity			.07			.07
Non-Hispanic White	3 (2.8)	1 (1.4)		2 (3.3)	1 (1.6)	
Non-Hispanic Black	101 (95.3)	65 (89.0)		59 (96.7)	55 (90.2)	
Hispanic	1 (0.9)	6 (8.2)		0 (0)	5 (8.2)	
Asian	1 (0.9)	0 (0)		0 (0)	0 (0)	
Other	0 (0)	1 (1.4)		0 (0)	0 (0)	
Body mass index, median (10–90th)	52.8 (50.3; 66.7)	55 (50.8; 66.8)	.02	53.8 (50.8; 65.8)	54.1 (50.5; 65)	.60
Gestational age, median (10–90th)	38.9 (35; 40.7)	38.4 (35.1; 40.3)	.46	38.9 (36.1; 41)	38.4 (35.1; 40.4)	.62
Smoking	3 (2.8)	3 (4.1)	.64	2 (3.3)	2 (3.3)	1.00
Illicit drug use	3 (2.8)	3 (4.1)	.64	2 (3.3)	2 (3.3)	1.00
Pregestational diabetes	10 (9.4)	9 (12.3)	.54	7 (11.5)	6 (9.8)	.77
Gestational diabetes	11 (10.4)	5 (6.9)	.42	7 (11.5)	3 (4.9)	.19
Chronic hypertension	26 (24.5)	28 (38.4)	.05	13 (21.3)	23 (37.7)	.05
Pregnancy associated hypertension	39 (36.8)	25 (34.3)	.73	19 (31.2)	22 (36.1)	.57
HIV	3 (2.8)	1 (1.4)	.52	2 (3.3)	1 (1.6)	.56
Skin incision			.69			.57
Pfannenstiel	96 (90.6)	69 (94.5)		55 (90.2)	57 (93.4)	
Joel-Cohen	1 (0.9)	2 (2.7)		0 (0)	1 (1.6)	
High transverse skin incision	4 (3.8)	1 (1.4)		2 (3.3)	1 (1.6)	
Vertical incision	5 (4.7)	1 (1.4)		4 (6.6)	2 (3.3)	
Staple skin closure	69 (65.1)	37 (50.7)	.05	41 (67.2)	31 (50.8)	.07
Labor (cervix ≥ 4 cm + contraction)	48 (45.3)	27 (37.0)	.27	21 (34.4)	21 (34.4)	1.00
Second stage	3 (2.8)	4 (5.5)	.37	1 (1.6)	3 (4.9)	.31
Rupture of membranes	48 (45.3)	24 (32.9)	.10	21 (34.4)	21 (34.4)	1.00
Chorioamnionitis	3 (2.8)	1 (1.4)	.52	3 (4.9)	1 (1.6)	.31

HIV: human immunodeficiency virus; NPWT: negative pressure wound therapy; SD: standard deviation. Number shown as *n* (%) unless otherwise specified.

Table 2. Wound complication according to type of dressing in women with BMI 50 kg/m² or higher.

	Unmatched			Matched		
	Standard dressing (<i>n</i> = 106)	NPWT (<i>n</i> = 73)	<i>p</i> -value	Standard dressing (<i>n</i> = 61)	NPWT (<i>n</i> = 61)	<i>p</i> -value
Primary outcome	17 (16.0)	15 (20.6)	.44	11 (18.0)	11 (18.0)	1.00
Cellulitis	9 (8.5)	7 (9.6)	.80	7 (11.5)	5 (8.2)	.54
Hematoma or seroma	4 (3.8)	7 (9.6)	.11	1 (1.6)	7 (11.5)	.03
Wound dehiscence	13 (12.3)	12 (16.4)	.43	9 (14.8)	10 (16.4)	.80
Deep wound infection	0 (0)	4 (5.5)	.02	0 (0)	3 (4.9)	.08
Endometritis	7 (6.6)	2 (2.7)	.25	5 (8.2)	1 (1.6)	.09
Severe infections	0 (0)	2 (2.7)	.09	0 (0)	1 (1.6)	.32

CI: confidence interval; NPWT: negative pressure wound therapy. Number shown as *n* (%) unless otherwise specified.

data are accurate. The definitions of surgical site infections and wound complications were based on objective clinical data, decreasing the likelihood of overestimation. Coarsened exact matching was used to account for potential demographic differences.

Our study is not without limitations. Our study was conducted in a single institution where the majority of patients are high-risk Non-Hispanic black. Since 2014, Medstar Washington Hospital Center recommended the use of a PICO Single Use NPWT system for

extremely obese women at the time of delivery although the ultimate decision to use the PICO Single Use NPWT was made by attending physicians. As a result, rates of the use of the PICO Single Use NPWT were 6% (6/101) and 86% (67/78) before the recommendation (2009–2013) and after the recommendation (2014–2017), respectively. It is possible that baseline demographics were different between women who received the PICO Single Use NPWT and those who did not, which would result in a selection bias. To account for the possible bias, we performed coarsened exact matching. In addition, demographics were similar between women who delivered before the recommendation (2009–2013) and those who delivered after the recommendation (2014–2017; data not shown). There was no difference in wound complication before and after the recommendation (17.8 versus 18.0%; $p = .98$). Two-third of women were excluded due to loss of follow-up, which may be a cause of selection bias. However, women who received the PICO Single Use NPWT compared to those who did not have similar postpartum follow-up rates (41 versus 43%; $p = .68$). Women who had postpartum follow-up compared to those who missed were more likely to be younger, more likely to have pregestational diabetes and chronic hypertension, and were less likely to have unknown race and smoking habit (data not shown) although other demographics were similar.

In summary, the PICO Single Use NPWT system was not associated with decreased odds of wound complication in extremely obese women. In our cohort, we only used PICO Single Use NPWT system. Therefore, the effectiveness of other NPWT systems such as PREVENA remains unknown. Adequately powered RCTs would be useful to assess the effect and clinical utility of NPWT on wound complication in extremely obese women after cesarean delivery.

Disclosure statement

The authors do not have conflict of interest.

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