Obesity: *Original Research*

Closed Incision Negative Pressure Therapy in Morbidly Obese Women Undergoing Cesarean Delivery

A Randomized Controlled Trial

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OBJECTIVE: To evaluate the efficacy of incisional negative pressure wound therapy in the prevention of postoperative wound morbidity in women with class III obesity undergoing cesarean delivery.

METHODS: In an open label randomized controlled trial, women admitted for delivery with class III obesity (body mass index 40 or higher) measured within 2 weeks of admission for delivery were offered participation in the study. They were consented either in the outpatient maternal–fetal medicine specialty clinic, during admission to labor and delivery and before a decision to perform cesarean delivery, or in the preoperative area of the hospital before scheduled cesarean delivery. Exclusion criteria included anticoagulation therapy, human immunodeficiency virus infection, and silver or acrylic allergy. Those who ultimately underwent cesarean delivery were randomized to standard surgical dressing or incisional negative pressure wound therapy dressing. The primary outcome was wound morbidity. Preplanned secondary outcomes included characteristics of composite wound morbidity, and hospital, emergency room, and clinic utilization. The sample size estimate required randomization of 440 women to detect a 50% decrease in composite outcome.

RESULTS: Between January 1, 2015, and July 31, 2016, 850 women were screened and 677 women with class III obesity were enrolled. Of these, 441 underwent cesarean delivery and were subsequently randomized (219 to standard dressing and 222 to incisional negative pressure wound therapy). The primary outcome, overall composite wound morbidity rate, was 18%. This was not different between the two cohorts (incisional negative pressure wound therapy 17% vs standard dressing 19%, relative risk 0.9 [95% CI 0.5–1.4]).

CONCLUSION: Prophylactic incisional negative pressure wound therapy use did not reduce postoperative wound morbidity when compared with a standard surgical dressing in women with class III obesity.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, NCT02289157.

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The prevalence of obesity is at an all-time high in the United States, and the obesity rate among women is 40%, with 9.8% of women having class III obesity (body mass index [BMI, calculated as weight in kilograms divided by height in meters squared] 40 or higher) in 2014; the prevalence of age adjusted

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women having class III obesity in 2005 was 7.6%.[1] As a result, obesity is a frequent and severe comorbidity of pregnancy. Data from our institution show that more than half of women are obese when they initially present for prenatal care.[2]

Surgical site infections are the most common of all hospital-acquired infections and account for 20% of infections in hospitalized patients with up to 300,000 occurring annually in the United States. It is estimated that these infections account for $3.5–10 billion in annual health care expenditures.[3] With increasing cesarean delivery rates in obese women, the rate of postoperative complications subsequently increases; specifically, infectious complications.[4,5]

In an attempt to reduce postcesarean delivery wound morbidity, closed incision negative pressure therapy dressings have been introduced into practice.[6] Hyldig et al[7] have identified and described decreased wound infection and seroma in multiple types of surgery including orthopedic, median sternotomy, abdominal wounds, and breast reductions in her meta-analysis. The proposed mechanism of action of these surgical dressings is a combination of increased lymphatic drainage of tissue edema, reduction of lateral tension to decrease dehiscence rates, and optimization of the wound environment.[6,8,9] Whether or not incisional negative pressure wound therapy reduces wound morbidity is an important question for obstetricians and patients. Data from large trials are needed to validate its efficacy.[10]

METHODS

This was a pragmatic, open label randomized controlled trial (RCT) of closed incision negative pressure therapy in morbidly obese women undergoing cesarean delivery to determine effectiveness in the prevention of postoperative wound morbidity. The study was approved by the Institutional Review Board at the University of Texas Southwestern Medical Center and registered through ClinicalTrials.gov (NCT02289157). Study devices were provided by Kinetic Concepts Incorporated. Women with class III obesity (BMI 40 or higher) who underwent cesarean delivery at Parkland Health & Hospital System in Dallas, Texas, between January 1, 2015, and July 31, 2016, were eligible to participate. Women on anticoagulation therapy, with human immunodeficiency virus infection, or with a silver or acrylic allergy were excluded.

Obese gravid women (class III obesity) in our hospital system (measured within 2 weeks of admission for delivery) were assessed for study eligibility and offered participation. They were identified and consented in the outpatient maternal–fetal medicine clinic, in the hospital during antepartum hospitalization, in the preoperative area before scheduled cesarean delivery, and before indication for cesarean delivery at the beginning of labor (including scheduled inductions). If the decision was made to proceed with cesarean delivery (cesarean births were performed for obstetric indications), enrolled women were randomized using block randomization. The allocation was stratified for the presence of labor. A computer-generated random sequence was used for each of the strata using randomized blocks of sizes 4, 6, 8, and 10. Participants were randomized to either a standard surgical dressing (Telfa Adhesive Island Dressing 4×10 inches and Steri-Strips) or incisional negative pressure wound therapy on completion of surgery. All surgeons and providers were blinded to treatment allocation before the placement of a standard dressing or incisional negative pressure wound therapy device.

All women received infection-prevention measures. These include prophylactic preoperative antibiotics of two grams of cefazolin (unless a penicillin allergy was noted, in which gentamycin and clindamycin were administered) within 60 minutes of skin incision, pubic hair shaving, as well as an abdominal skin preparation of 2% chlorhexidine gluconate–70% isopropyl alcohol solution. In addition, all scheduled cesarean deliveries were given a 4% chlorhexidine gluconate wash to be used before presenting for surgery. In laboring and patients with ruptured membranes, group B streptococcus prophylaxis was used according to hospital practices.[11] No preoperative vaginal preparation was used.

Intraoperative incision measurements were obtained for all study participants including skin incision length and the subcutaneous tissue depth at the deepest location along the incision using a sterile marked surgical pen. Subcutaneous tissue was closed with 3-0 plain gut if depth was greater than 2 cm. The skin was approximated with subcuticular 4-0 Vicryl or staples (1 Proximate Plus MD 35 Regular). After skin closure, the surgical dressing was applied according to the assigned randomization. The standard surgical dressing included reinforced adhesive skin closures as well as a gauze adhesive bandage. Those randomized to the incisional negative pressure wound therapy dressing received the Prevena Incision Management System which was placed according to the manufacturer's protocol. This is a single use, disposable vacuum system. The dressing is impregnated with ionic silver, which acts to reduce bacterial colonization and is attached to a battery-operated suction system that

provides 125 mm Hg of continuous suction pressure to remove excess exudate from the incision into a 45 mL canister.

Women were followed daily until hospital discharge. The standard group had their dressings removed per routine, usually on postoperative day 1. On the day of discharge, all study participants received an additional incisional examination by study personnel. Those randomized to incisional negative pressure wound therapy had their surgical dressing removed at this time, unless premature removal was indicated or requested by the primary obstetric care team. All participants were appointed to a 2-week postpartum appointment to examine the incision site and were contacted by telephone 30–60 days after delivery to assess whether they had a surgical-site complication and whether additional emergency department or clinic visits were necessary. Additionally, a patient satisfaction questionnaire was administered. Medical records were reviewed for emergency department visits, additional clinic visits, and hospital readmissions and reoperation. Demographic information, obstetric and medical history, and details of the operative procedure were obtained.

Kinetics Concept Incorporated donated incisional negative pressure wound therapy devices for the study and provided initial in-service on use and trouble shooting. They did not pay for any other clinical services for these patients. All clinical work was done under the protocol approved as a Departmental investigation with Departmental funding. Kinetics Concept Incorporated had minimal input into this manuscript and did not censor the presentation of our findings.

The primary outcome was wound complication defined as wound disruption or wound infection (cellulitis was included). A wound disruption was defined as the partial or complete opening of the deep subcutaneous space (dehiscence–underlying causes include seroma, hematoma), not to include only superficial skin separation. Surgical site infection required antibiotics and wound care and required physician diagnosis conforming to Centers for Disease Control and Prevention guidelines concerning surgical site infection.[12] Cellulitis required antibiotics and follow-up. Secondary outcomes were length of postoperative hospital stay, readmission length of stay, number of emergency department visits, and number of additional clinic visits for wound complications.

The sample size was estimated assuming a 20% baseline rate of surgical-site complications in women with class III obesity based on an observational pilot study at our institution. It was estimated that 440 women would have to be enrolled (220 in each group)

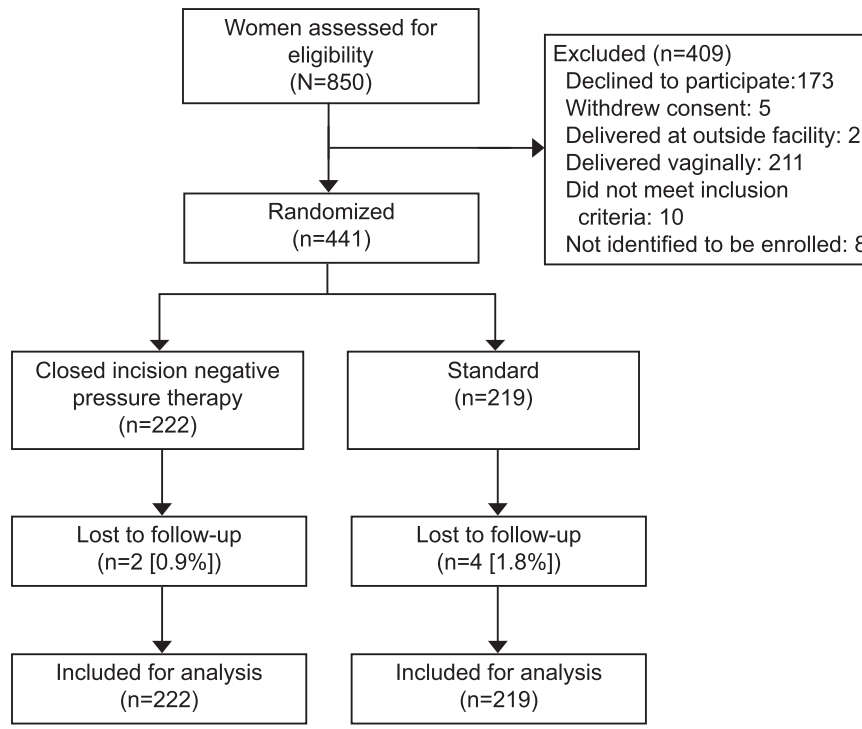

Fig. 1. Enrollment and randomization of study participants.

Hussamy. Negative Pressure Wound Therapy in Obese Women. Obstet Gynecol 2019.

Table 1. Baseline Maternal Characteristics

Characteristic	iNPWT (n=222)	Standard (n=219)
Maternal age (y)	29.1±6.1	30.3±6.1
Gestational age at delivery (wk)	38.6±1.9	38.7±4.5
Race		
Black	56 (25)	60 (27)
Hispanic	151 (68)	146 (67)
White	15 (7)	13 (6)
Parity		
0	55 (25)	42 (19)
1	64 (29)	68 (31)
2	62 (28)	57 (26)
More than 2	41 (18)	52 (24)
BMI at delivery (kg/m^2)	46.6±6.0	45.8±5.8
Tobacco use	18 (8)	15 (7)
Chronic hypertension	40 (18)	36 (16)
Diabetes	36 (16)	24 (11)

iNPWT, incisional negative pressure wound therapy; BMI, body mass index.
Data are mean±SD or n (%).
There were no significant differences between the two study groups in any baseline characteristics.

Table 2. Obstetric and Surgical Characteristics

Characteristic	iNPWT (n=222)	Standard (n=219)	P*
Type of cesarean delivery			.18
Primary	95 (43)	80 (37)	
Repeat	127 (57)	139 (63)	
Cesarean delivery priority			.99
Scheduled	72 (32)	72 (33)	
Urgent	141 (64)	138 (63)	
Emergent	9 (4)	9 (4)	
Length of surgery (min)	84 (70, 103)	80 (64, 99)	.13
Estimated blood loss (mL)	1,000 (1,000, 1,250)	1,000 (1,000, 1,250)	.08
Incision type			.29
Pfannenstiel	52 (23)	61 (28)	
Vertical midline	170 (77)	158 (72)	
Skin closure			.38
Staples	12 (5)	8 (4)	
Suture	210 (95)	211 (96)	
Subcutaneous tissue depth (cm)	5.5±1.7	5.3±1.8	.19
No. of subcutaneous layers closed	3 (2, 4)	3 (2, 4)	.67
Incision length (cm)	14.5±2.5	14.6±2.9	.74
Labor	44 (20)	32 (15)	.17
Induction	47 (21)	43 (20)	.81
Rupture of membranes	78 (35)	65 (30)	.37
Length (h)	11.7±6.7	13.0±10.2	
Chorioamnionitis	15 (7)	12 (5)	.58

iNPWT, incisional negative pressure wound therapy.
Data are n (%), median (Q1, Q3), or mean±SD unless otherwise specified.
* Calculated based on Pearson χ^2, Student *t*-test, and Wilcoxon rank sum test.

to have 80% power to detect a 50% difference in the rate of postoperative wound morbidity in the incisional negative pressure wound therapy group (at a two-sided alpha level of 0.05).

Student's *t*-test, Pearson χ^2 test, and Wilcoxon rank sum tests were used to evaluate continuous normal data, categorical data, and nonparametric data, respectively. Incidence and relative risks (RRs) are used to describe the primary composite outcome (wound morbidity), and to detect interaction a Mantel Haenszel test of homogeneity was used.

Results were analyzed using the intention-to-treat principle. For randomization, patients were separated into two strata by whether or not they were in labor. A randomization schedule for each of the strata (labor vs no labor) was computer generated by randomized blocks of size 4, 6, 8, and 10. The assignments were placed in opaque envelopes sequenced by the randomization schedules to be opened at the time of randomization. DM generated the allocation sequence.

RESULTS

Between January 1, 2015, and July 31, 2016, 850 women with class III obesity were screened and 677 women were enrolled (Fig. 1). A total of 441 women underwent cesarean delivery and were randomized to receive either a standard surgical dressing (219 women) or an incisional negative pressure wound therapy device (222 women). Six women were lost to follow-up after initial hospital discharge (two in the incisional negative pressure wound therapy group and four in the standard group). All randomized women were analyzed using an intention-to-treat basis. There were no significant differences in the baseline maternal characteristics between the two groups, including BMI at delivery (Table 1). There were also no significant differences in surgery characteristics between the two groups (Table 2).

Overall wound morbidity for the entire cohort was 18% (n=79). Thirty-seven women (17%) in the incisional negative pressure wound therapy group (n=222) and 42 women (19%) in the standard group (n=219) developed postoperative wound morbidity (RR 0.9; 95% CI 0.5–1.4; *P*=.54) (Table 3). Twenty-eight women had prolonged postoperative hospitalizations greater than 5 days: 14 (n=222) in the incisional negative pressure wound therapy group and 14 (n=219) in the standard group. Twelve women in the incisional negative pressure wound therapy

Table 3. Classification of Wound Morbidity

Wound Classification	iNPWT (n=37)	Standard (n=42)	RR (95% CI)
Dehiscence	4 (11)	1 (2)	3.9 (0.4–194.3)
Cellulitis	12 (32)	16 (38)	0.7 (0.3–1.7)
SSI			0.8 (0.4–1.5)
Superficial incisional SSI	20 (54)	25 (61)	—
Deep incisional SSI	0 (0)	0 (0)	—
Organ space SSI	1 (3)	0 (0)	—

iNPWT, incisional negative pressure wound therapy; RR, relative risk; SSI, surgical site infection.
Data are n (%) unless otherwise specified.
P value calculated based on Pearson χ^2 test.

group compared with nine in the standard group were readmitted for wound concerns. A total of 72 women required the use of antimicrobials postoperatively (33 in the incisional negative pressure wound therapy group and 39 in the standard group). There were 24 women requiring reoperation in the entire cohort (14 in the incisional negative pressure wound therapy group and 10 in the standard dressing group). None of these individual outcomes were significantly different (Table 4).

Overall median postoperative length of stay for both groups was 3 days. Other secondary outcomes, including median readmission length of stay (16 days in incisional negative pressure wound therapy group compared with 21 days in the standard group, *P*=.59), number of emergency department visits, and the number of additional clinic visits for wound concerns were not significantly different between the treatment groups. Characteristics of these wounds are listed in Table 5.

Table 4. Overall Wound Morbidity and Its Components

Outcome	iNPWT (n=222)	Standard (n=219)	RR (95% CI)
Primary composite outcome	37 (17)	42 (19)	0.9 (0.5–1.4)
Prolonged hospitalization*	14 (0)	14 (2)	1.0 (0.4–2.2)
Readmission	12 (5)	9 (4)	1.3 (0.5–3.5)
Antimicrobial use†	33 (15)	39 (18)	0.8 (0.5–1.4)
Reoperation‡	14 (6)	10 (5)	1.4 (0.6–3.5)

iNPWT, incisional negative pressure wound therapy; RR, relative risk.
Data are n (%) unless otherwise specified.
P values calculated based on Pearson χ^2 test.
* Prolonged hospitalization was longer than 5 postoperative days (greater than the 99th percentile).
† Antibiotic use for wound morbidity. All women received prophylactic antibiotics before cesarean delivery (cefazolin 2 g intravenously). The use of antibiotics for chorioamnionitis was not included.
‡ Reoperation included incision and drainage, extirpation, or both.

Wound complications were further classified based on the Centers for Disease Control and Prevention's National Healthcare Safety Network definitions for surgical site infections. Superficial incisional infections accounted for the majority of wound complications and occurred in 25 women (61%) in the standard group and 20 women (54%) in the incisional negative pressure wound therapy group (*P*=.31). There were no deep incisional infections in either group. One woman in the incisional negative pressure wound therapy group developed an organ space infection and required reoperation and hysterectomy. The groups also did not significantly differ in rates of dehiscence or cellulitis.

A post hoc subgroup analysis was performed to estimate the relative effect of incisional negative pressure wound therapy compared with standard dressing on the risk of wound morbidity in each subgroup. No interaction in the treatment effect of incisional negative pressure wound therapy was detected in any of the specified subgroups, which included type of cesarean delivery, skin incision type, rupture of membranes, labor, skin-closure type, chronic hypertension, diabetes, and chorioamnionitis (Table 6).

Sixty-three women (28%) who received the incisional negative pressure wound therapy dressing experienced either skin maceration or bullae formation, either along the dressing edge or in the umbilicus. No cases of superinfection of these areas of skin compromise were noted.

A total of 397 (90%) women were successfully evaluated in clinic at their 2-week follow-up visit and 411 women (93%) were successfully contacted by telephone at least 30 and 60 days postoperatively to assess for wound morbidity and to complete a brief patient satisfaction survey (Table 7). Women who received the incisional negative pressure wound therapy dressing were as satisfied with their wound healing as the standard group (89% vs 92%, respectively).

DISCUSSION

In this pragmatic trial, we examined the effectiveness of closed incision negative pressure therapy dressing in the prevention of postoperative wound morbidity. Our pragmatic trial has this focus: an

Table 5. Secondary Outcomes

Outcome	iNPWT (n=222)	Standard (n=219)	*P**
Postoperative length of stay (d)	3 (3, 4)	3 (3, 4)	.54
Readmission length of stay (d)	16 (9, 22)	21 (11, 25)	.59
ED visits			.83
1	30 (14)	28 (13)	
2	2 (1)	1 (0)	
Additional clinic visits			.48
1	15 (7)	15 (7)	
2	4 (2)	6 (3)	
3	5 (2)	2 (1)	
4	1 (0)	4 (2)	
5	1 (0)	0 (0)	

iNPWT, incisional negative pressure wound therapy; ED, emergency department.
Data are n (%) or median (Q1, Q3) unless otherwise specified.
*Calculated based on Wilcoxon rank sum test and Pearson χ^2 test.

intent to enroll a population relevant to the decision in practice and representative of the patients or populations and clinical settings for whom the decision is relevant. First, the use of incisional negative pressure wound therapy did not reduce the frequency of postoperative wound morbidity in morbidly obese women undergoing cesarean delivery by at least 50%. Second, there were no patient subgroups that showed a trend toward a benefit in decreasing wound morbidity with incisional negative pressure wound therapy use.

There are limited data on the use of incisional negative pressure wound therapy in obstetrics including retrospective reviews (Gibbs C, Orth T, Gerkovich M, Heitmann E, Parrish M, Lu G. Traditional dressing compared with an external negative pressure system in preventing wound complications [abstract]. Obstet Gynecol 2014;123:145S.),[13,14] prospective trials comparing historic controls,[15] and small pilot studies (Ruhstaller K, Downes K, Chandrasekaran S, Elovitz MA, Srinivas S, Durnwald C. PROphylactic wound VACuum therapy after cesarean section to prevent wound complications in the obese population: a randomized controlled trial (The ProVac Study) [abstract]. Am J Obstet Gynecol 2017;1:S34. and Tuuli MG, Martin S, Stout MJ, Steiner HL, Harper LM, Longo S, et al. Pilot randomized trial of prophylactic negative wound therapy in obese women after cesarean delivery [abstract]. Am J Obstet

Table 6. Risk of Wound Morbidity in Subgroups Stratified by Treatment Group

Subgroup	iNPWT	Standard	RR (95% CI)	*P* for Interaction*
Type of cesarean delivery				.68
Scheduled	12/72	12/72	1.0 (0.5–2.0)	
Unscheduled	25/150	30/147	0.8 (0.5–1.3)	
Incision type				.27
Pfannenstiel	3/52	8/61	0.4 (0.1–1.6)	
Vertical midline	34/170	34/158	0.9 (0.6–1.4)	
Rupture of membranes				.55
Yes	15/78	17/65	0.7 (0.4–1.4)	
No	22/144	25/154	0.9 (0.6–1.6)	
Labor (spontaneous or induced)				.49
Yes	15/91	17/75	0.7 (0.4–1.4)	
No	22/131	25/144	1.0 (0.6–1.6)	
Skin closure				.64
Staples	4/12	4/8	0.7 (0.2–1.9)	
Suture	33/210	38/211	0.9 (0.6–1.3)	
Chronic hypertension				.92
Yes	8/40	8/36	0.9 (0.4–2.1)	
No	29/182	34/183	0.9 (0.5–1.3)	
Diabetes				.22
Yes	5/36	7/24	0.5 (0.2–1.3)	
No	32/186	35/195	1.0 (0.6–1.5)	
Chorioamnionitis				
Yes	4/15	3/12	1.1 (0.3–3.9)	.74
No	33/207	39/207	0.8 (0.6–1.3)	

iNPWT, incisional negative pressure wound therapy; RR, relative risk.
Data are n/N unless otherwise specified.
*Calculated by the Mantel-Haenszel test of homogeneity. $P<.20$ is considered significant.

Table 7. Patient Satisfaction Survey Results

	iNPWT (n=210)	Standard (n=201)	*P*
"Dressing interfered with feeding infant"	12 (6)	14 (7)	.60
"Dressing interfered with caring for infant"	21 (10)	13 (7)	.19
"I would use this dressing again"	187 (89)	185 (92)	.30
"I was satisfied with wound healing"	192 (91)	188 (94)	.42

iNPWT, incisional negative pressure wound therapy.
Data are n (%) unless otherwise specified.

Gynecol 2017;1:S245.).[16] Two independent groups presented pilot RCTs comparing incisional negative pressure wound therapy with standard dressings in obese women (BMI 30 or higher) after cesarean delivery and found no reduction in wound morbidity (Ruhstaller et al, Am J Obstet Gynecol 2017, S34, and Tuuli et al, Am J Obstet Gynecol 2017, S245). These negative findings have been attributed to the lack of appropriate power and concluded that larger, more adequately-powered studies are feasible and needed.[17,18] A more recent RCT reported no benefit; however, the trial was prematurely halted owing to futility (enrollment was slow, and interim calculation of incidence of surgical site infection in the standard and trial groups suggested that a significant result could not be reached at the a priori sample size decided).[19] Given the heterogeneity of the literature to date, it is not surprising that two separate meta-analyses have been published with conflicting conclusions on the efficacy of incisional negative pressure wound therapy after cesarean deliveries.[20,21]

This is the first adequately-powered, and fully conducted RCT comparing incisional negative pressure wound therapy dressing to a standard dressing to address efficacy in preventing postcesarean delivery wound morbidity in women with class III obesity (PubMed was searched from inception through May 31, 2019, using terms "cesarean delivery, closed incision, negative pressure therapy"). Rising obesity and cesarean delivery rates leading to increased postcesarean delivery morbidity is widely recognized.[4,5] The impetus to decrease wound morbidity coupled with compelling data on the use of incisional negative pressure wound therapy in nonobstetric surgical specialties has led many to adopt the prophylactic placement of these dressings.[22] Some have rationalized this use further by creating theoretic cost-effective models that show an additional economic benefit in those deemed at high risk for surgical site infections.[23–25] However, the premature adoption of incisional negative pressure wound therapy without clear evidence on its benefit in the obstetric population is concerning, and it is of primary importance to justify use with evidence of clinical benefit rather than theoretic economic benefit.[10]

Recently, Hyldig et al completed a multiinstitutional trial with incisional negative pressure wound therapy in which surgical site infection in cesarean deliveries, not wound complications, was the specific outcome measure. The trial was powered to detect a 50% difference in surgical site infection and found this benefit with use of incisional negative pressure wound therapy compared with standard surgical dressing (4.6–9.2%, RR 0.5 [95% CI 0.3–0.84]).[7] We note our findings for incisional negative pressure wound therapy compared with standard surgical dressing were 9.5% vs 11.4% (RR 0.8 [95% CI 0.8–1.5]). We were not adequately powered to look at a 50% difference in the rate of surgical site infection. Further, Hyldig et al[26] found the use of incisional negative pressure wound therapy to be dominant over standard surgical dressing in preventing surgical site infections using data from their trial in a cost effectiveness analysis.

Our trial has some limitations. Incisional negative pressure wound therapy dressings were removed at time of hospital discharge rather than when the battery life ceased (192 hours). This shortened use could attribute to the negative findings of the study. However, removal was conducted in accord with the manufacturer's recommendation which is for use for 2–7 days with removal by a medical professional. Although many studies of obesity in pregnancy use prepregnancy BMI, we elected to use maternal weight within 1–2 weeks of admission to calculate BMI (either in the maternal–fetal medicine subspecialty clinic or labor and delivery) as this takes into account weight gain during pregnancy and has a more direct effect on cesarean delivery difficulty and associated postoperative complications and may more accurately predict cesarean delivery risk.[27] All surgeons and providers were blinded to treatment allocation before the placement of a standard dressing or incisional negative pressure wound therapy device. It was difficult to enforce blinding after this time owing to the physical presence of the incisional negative pressure wound therapy device and clinician or surgeon involvement in follow-up. Bias at this

stage of the evaluation was possible. Finally, our study population consists predominantly of Hispanic women in a public hospital setting, and our results may not be generalizable to other obstetric populations.

Despite this, our study has some strengths as well. We found a 19% wound complication rate in the standard dressing group which is consistent with the rate we used to power the study (20%). The acceptance rate of the study was 80%, despite a lack of compensation for participation. The study design was pragmatic–we did not exclude certain types of cesarean deliveries, presence of labor, ruptured membranes, chorioamnionitis, or diabetes. Only 1.4% of patients were lost to follow-up, with no postoperative contact possible after initial hospital discharge. Additionally, our study protocol allowed inspection of every incision after incisional negative pressure wound therapy removal, allowing documentation of adverse skin reactions to the dressing Howell et al reported a 63% blistering rate with incisional negative pressure wound therapy use after knee arthroplasty,[28] this complication has been reported elsewhere in the surgical literature.[7] We found similar skin reactions, but not as frequently (28% of women who received incisional negative pressure wound therapy). No complications arose from these blisters and they were not noted at the 2-week follow-up visit. This blistering was not seen in standard dressings.

In summary, the use of a closed incision negative pressure wound therapy device compared with a standard dressing did not significantly lower the wound complication rate in morbidly obese women undergoing cesarean delivery.

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Authors' Data Sharing Statement

Will individual participant data be available (including data dictionaries)? *No.*

What data in particular will be shared? *None.*

What other documents will be available? *None.*

When will data be available (start and end dates)? *The data are available in this manuscript and at ClinicalTrials.gov; NCT02289157.*

By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? *Not applicable.*

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