Closed Incision Negative Pressure Therapy in Obese Patients Undergoing Caesarean Delivery: A Randomized Controlled Trial

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ARTICLE SYNOPSIS

INTRODUCTION

In the U.S., close to a third of all babies are born via Caesarean delivery,[1] making this procedure the most common surgery in the country. About 2-7% of such deliveries result in surgical site occurrences (SSOs) that raise the risk of infection, complicate recovery, and incur extra costs.[2,3] Maternal obesity (BMI > 30) is a key risk factor for post-Caesarean wound morbidity.[4,5]

Evidence from previous studies suggests that closed incision negative pressure therapy (ciNPT) may decrease the rate of postoperative infection and wound dehiscence.[6] This study sought to compare clinical outcomes in obese women who received ciNPT or standard-of-care (SOC) dressings following Caesarean delivery.

METHODS

Study design

This single-center post-marketing RCT enrolled 92 patients from Duke University Medical Center between 2012 and 2014. Subjects were ≥ 18 years old and had a BMI of ≥ 35 at the time of delivery. Women with skin, systemic, or chorioamniotic infections and those at high risk for anesthesia were excluded from participation.

Protocol

Participating clinicians used standard techniques to prepare subjects for the operation, perform it, and close the wounds. All women received preoperative antibiotics and post-operative pain medications as required (not standardized in the protocol). The peritoneum was left open and the adipose tissue was sutured if thicker than 2 cm. Once the closed wounds passed inspection, patients were randomized 1:1 to ciNPT and SOC groups.

Women in the ciNPT group received a sterile "peel-and-place" multilayer dressing over the closed incision. The dressing's tubing was then connected to a negative pressure unit that delivered -125 mmHg of continuous pressure to the dressing for 5 to 7 days and removed exudates. Women in the SOC group had their wounds dressed with Steri-Strips (Trademark of 3M Health Care, St. Paul, MN) sterile gauze, and Tegaderm (Trademark of 3M Health Care, St. Paul, MN) for 1-2 days. Subjects without complications were discharged from hospital 3-4 days postoperatively.

Endpoints

The primary endpoint was the presence of one or more postoperative SSOs (counted as one event per affected patient, regardless of the number of SSOs in that patient). These SSOs included inflammatory responses, prolonged drainage, fluid collection, dehiscence, and surgical site infections. A standardized wound-scoring system minimized bias. The secondary endpoint was the use of surgical interventions such as antimicrobials, surgical drainage, incision packing, adjunctive negative pressure therapy, debridement, and reoperation. Supplementary endpoints included postoperative pain scores ≥ 2 (Baker Faces Scale) at rest and with pressure. Medication use was also recorded.

Patient characteristics

Collected data included age, BMI, gestational age at delivery, and first vs repeat Caesarean section

CHARACTERISTIC	ciNPT (N = 46)	SOC (N = 46)	OVERALL
Mean age	30.4	29.7	30.0
Mean BMI	46.3	46.8	46.5
African American	29 (63%)	35 (76.1%)	64 (69.6%)
Caucasian	17 (37.0%)	10 (21.7%)	29.3%
Other (American Indian or Hispanic/Latino)	3 (6.5%)	3 (6.5%)	6 (6.5%)
First Caesarean	11 (23.9%)	15 (32.6%)	26 (28.3%)
Mean gestational age at delivery	38.1	37.9	38.0
Diabetes	8 (17.4%)	8 (17.4%)	16 (17.4%)
Mean incision length (cm)	16.3	16.3	16.3

TABLE 1. Patient characteristics in the intention-to-treat (ITT) population*

**Abbreviated version of the table in the original journal article*

(Table 1). The study population included ethnic groups described as African American, Caucasian, American Indian and Hispanic/Latino. Other than the higher proportion of African American subjects in the SOC group than the ciNPT group, patient characteristics were similar in the two groups.

RESULTS

Pain results are reported for the intention-to-treat (ITT) population (n = 96); all other results pertain to the per-protocol population (n = 92). Per-protocol results were analyzed using SAS version 9.2.

As detailed in Table 2, the ciNPT group had a 63% relative reduction in patients with SSOs compared to the SOC group, though the difference did not reach statistical significance. In terms of specific SSOs, the ciNPT group had:

- Fewer cases of fluid collection (1 vs 4, $p = 0.36$)
- Fewer cases of dehiscence (1 vs 5, $p = 0.20$)
- Fewer cases of surgical incision intervention (1 vs 6, $p = 0.11$)

CHARACTERISTIC (PER-PROTOCOL GROUP)	ciNPT (N = 39)	SOC (N = 43)	*P* VALUE
SSO (any)	2 (5.1%)	7 (16.3%)	0.16
Unanticipated local inflammatory response	0 (0%)	0 (0%)	n/a
Prolonged drainage	0 (0%)	0 (0%)	n/a
Fluid collection (seroma, hematoma, abscess)	1 (2.6%)	4 (9.3%)	0.36
Dehiscence	1 (2.6%)	5 (11.6%)	0.20
Surgical incision intervention (any)	1 (2.6%)	6 (14.0%)	0.11
Surgical site infection	1 (2.6%)	4 (9.3%)	0.36
Characteristic (ITT group)	ciNPT (n = 46)	SOC (n = 46)	*P* value
Postoperative pain at rest (any level of pain)	20 (43.5%)	39 (84.8%)	< 0.001
Postoperative pain with pressure applied	25 (54.3%)	42 (91.3%)	< 0.001

TABLE 2. Surgical site occurrences (SSOs) and complications

The ciNPT group had a significantly lower rate of postoperative pain at rest (43.5 vs. 84.8%, $p < 0.001$) and with pressure (54.3 vs 91.3%, $p < 0.001$). Total narcotic use was 30% lower in the ciNPT group than the SOC group ($p = 0.036$), while acetaminophen and NSAID use did not differ significantly between the groups.

DISCUSSION

This study demonstrated that, compared to the standard of care for women undergoing Caesarean deliveries, ciNPT is associated with a significant reduction in postoperative pain and with a trend toward reduced wound complications.

The reduction in incisional pain in the ciNPT group, corroborated by a lower use of narcotic medications, has significant implications, given that ineffective pain relief may affect breastfeeding and bonding as well as increasing the risk of thromboembolism.[7,8] While not statistically significant, the reduction in SSOs with ciNPT is also clinically relevant due to the substantial morbidity and costs of surgical site infections (a component of the primary outcome).

Previous investigations of post-Caesarean ciNPT have yielded mixed results. One case-control study found no reduction in surgical site infections with ciNPT compared to historical controls.[9] In contrast, a prospective case-control study found a significant 70% reduction in wound complications with ciNPT versus historical controls,[10] and a study of obese women yielded no postoperative complications in the ci-NPT-treated group (vs 10% in the control group).[11]

This study adds to the body of evidence regarding ciNPT following Caesarean delivery. There is a need for further, more strongly powered studies to examine the impact of ciNPT in risk-diverse obstetric populations.

REFERENCES:

1. Centers for Disease Control and Prevention. Births—Method of delivery. Available at: http://www.cdc.gov/nchs/fastats/delivery.htm

2. Edwards J R, Peterson K D, Mu Y et al. National Healthcare Safety Network (NHSN) report: data summary for 2006 through 2008, issued December 2009. *Am J Infect Control* 2009;37:783–805.

3. Perlow J H, Morgan M A, Montgomery D et al. Perinatal outcome in pregnancy complicated by massive obesity. *Am J Obstet Gynecol* 1992;167:958–962.

4. Alanis MC, Villers MS, Law TL et al. Complications of cesarean delivery in the massively obese parturient. *Am J Obstet Gynecol* 2010;203:2710–2712.

5. Olsen MA, Butler AM, Willers DM et al. Risk factors for surgical site infection after low transverse cesarean section. *Infect Control Hosp Epidemiol* 2008;2906:477–484.

6. Stannard JP, Volgas DA, McGwin G et al. Incisional negative pressure wound therapy after high-risk lower extremity fractures. *J Orthop Trauma* 2012;26:37–42.

7. Gadsden J, Hart S, Santos AC. Post-cesarean delivery analgesia. *Anesth Analg* 2005;101(5 Suppl):S62–S69.

8. Woods AB, Crist B, Kowalewski S et al. A cross-sectional analysis of the effect of patient-controlled epidural analgesia versus patient controlled analgesia on postcesarean pain and breastfeeding. *J Obstet Gynecol* Neonatal Nurs 2012;41:339–346.

9. Gibbs C, Orth T, Gerkovich M et al. Traditional dressing compared with an external negative pressure system in preventing wound complications. *Obstet Gynecol* 2014;123:145S.

10. Swift SH, Zimmerman MB, Hardy-Fairbanks AJ. Effect of single-use negative pressure wound therapy on postcesarean infections and wound complications for high-risk patients. *J Reprod Med* 2015;60:211–218.

11. Mark KS, Alger L, Terplan M. Incisional negative pressure therapy to prevent wound complications following cesarean section in morbidly obese women: a pilot study. *Surg Innov* 2014;21:345–349.