

Table 2: Patient Satisfaction and Pain Assessment

	Staples (N=114)	Sutures (N=113)	P value
Pain level (1=least, 10=most)	2 [1, 3]	2 [1, 3]	.71
Wound appearance satisfaction (1=least, 10=most)	10 [9, 10]	10 [9, 10]	.99
Concern about wound healing (1=least, 10=most)	1 [1, 2]	1 [1, 2]	.22
Would you have same closure again?			
Yes	98 (83.1)	108 (93.9)	.01
No	20 (16.9)	7 (6.1)	

Data were analyzed with Mann-Whitney U and χ^2 tests, where applicable
Data are presented as median [interquartile range] or n (%)

38 Pfannenstiel vs. vertical skin incision for cesarean delivery in women with class III obesity: a randomized clinical trial

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OBJECTIVE: Given lack of Level I evidence, there is equipoise regarding the optimal type of skin incision for morbidly obese women undergoing cesarean delivery (CD). Our objective was to compare Pfannenstiel versus vertical incision for the prevention of wound complications after CD in women with class III obesity.

STUDY DESIGN: We performed a two-center, comparative effectiveness, randomized clinical trial (RCT) that included women GA \geq 24 weeks with body mass index \geq 40 kg/m² undergoing CD (NCT01897376). Exclusion criteria were fetal demise, clinical chorioamnionitis, and rupture of membranes $>$ 18 hours. Immediately before CD, women were randomized in a 1:1 ratio to either Pfannenstiel or midline vertical incision. The primary outcome was a composite that included any of the following: surgical site infection (superficial, deep, or organ/space), cellulitis, seroma/hematoma or separation up to 6 weeks postpartum. Secondary outcomes are described in Table 1. In order to detect a 50% difference in the primary outcome between groups (27% to 13.5%), sample size calculation estimated need for 135 women per group ($\alpha = 0.05$, power 80%). We planned study enrollment for a defined period of time due to feasibility and thus recognized the potential for not reaching this sample size. Therefore, we planned to conduct (in addition to traditional frequentist analysis) a Bayesian analysis to estimate the probability of treatment benefit (i.e.: probability that one incision prevents wound complications better than the other). A priori, we decided that probability of treatment benefit \geq 60% for either incision type to be convincing evidence to pursue a larger RCT.

RESULTS: From 10/2013 to 6/2017, 648 eligible women were approached, 228 (35%) agreed to participate in the RCT, and 91/228 (40%) were randomized. Complete data to 6 weeks follow-up was available for 87% (n=79). We found no differences in primary or secondary outcomes (Table 1). Bayesian analysis revealed a 58% probability that Pfannenstiel had lower primary outcome rate than vertical incision.



CONCLUSION: To our knowledge, this is the first published RCT to compare skin incision types for obese women undergoing CD. Our trial suggests there are no major differences in wound outcomes based on Pfannenstiel vs. vertical skin incision. The utility of a larger RCT to address this clinical question is limited.

Table 1. Outcomes by skin incision type and relative risk of select outcome with vertical skin incision

Outcome	Pfannenstiel N=43	Vertical N=38	RR (95%CI)	P value
Primary outcome ^a	8 (18.6%)	8 (21.1%)	1.13 (0.47-2.72)	0.78
2 week composite outcome ^b	5 (10.4%)	8 (20%)	1.92 (0.68-5.40)	0.22
Non low transverse hysterotomy	2 (5%)	2 (5%)	1.13 (0.17-7.65)	0.90
Operative time, minutes	63 (52-79)	66 (58-83)		0.98
Estimated blood loss (mL)	800 (700-1000)	1000 (812-1000)		0.75
Post-operative LOS	3.2 \pm 1	3.5 \pm 4.1		0.71
Hospital readmission	2 (5%)	1 (3%)	0.57 (0.05-6.00)	0.64

Data expressed as n (%), mean \pm SD, and median (interquartile range).

^a For primary outcome, we included women who had 6 week follow-up (n=79) and women who developed the composite outcome prior to completing 6 week follow up (n=2, total n=81).

^b Defined as composite outcome with same components as primary outcome, among those with 2 week follow up: Pfannenstiel n = 48, vertical n = 40.

39 One-step vs two-step screening for gestational diabetes: a randomized controlled trial

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OBJECTIVE: To assess the incidence of gestational diabetes mellitus (GDM) using the International Association of Diabetes in Pregnancy Study Group (IADPSG) criteria (one-step approach) compared to the American College of Obstetrics and Gynecology (ACOG) criteria (two-step approach) for the diagnosis of GDM.

STUDY DESIGN: This is a prospective randomized controlled trial of women presenting for GDM screening. Patients were randomized into universal screening with either the one-step approach—a 2-hour 75g oral glucose tolerance test (OGTT as defined by IADPSG, thresholds 92mg/dl, 180mg/dl, 153 mg/dl), or with the two-step approach—a 50 glucose challenge test (GCT, threshold 135mg/dl) followed by a diagnostic 3-hour 100 g test (OGTT, as defined by Carpenter and Coustan and endorsed by ACOG, thresholds 95mg/dl, 180 mg/dl, 155mg/dl, 140mg/dl). Diagnosis of GDM required the presence of one abnormal value with the one-step approach, and two abnormal values on the second part of the two-step approach. The primary outcome was incidence of GDM.

RESULTS: A total of 249 women were included in the trial. Of those, 123 were randomized into the one-step approach (2-hour 75g OGTT, IADPSG) and 126 into the two-step approach (1 hour GCT followed by 3 hour 100g OGTT, ACOG). GDM was diagnosed in 10 women (8.1%) in the one-step group, and 7 women (5.5%) in the two-step group (p=0.42). There was no significant difference in the rate of preeclampsia, cesarean section rate, macrosomia, shoulder dystocia, or neonatal hypoglycemia between both groups (figure). There was a significant increase in neonatal hyperbilirubinemia with the one-step approach screening (p=0.04).

CONCLUSION: GDM screening with the one-step approach did not significantly increase the incidence of GDM compared with the two-step approach.

