OBSTETRICS

Effect of using silver nylon dressings to prevent superficial surgical site infection after cesarean delivery: a randomized clinical trial

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BACKGROUND: Surgical site infections are associated with significant healthcare cost and burden. Silver-impregnated dressings have been associated with a decrease in surgical site infections in select populations, but it is unknown whether the benefit can be observed after cesarean deliveries.

OBJECTIVE: We sought to evaluate the impact of silver nylon dressings in reducing superficial surgical site infections after cesarean delivery.

MATERIALS AND METHODS: A blinded randomized clinical trial of women undergoing scheduled or unscheduled cesarean delivery at a single site was conducted. Women were recruited for participation from September 2013 to June 2016. Women with vertical skin incisions were excluded. Enrolled participants were randomized to silver nylon dressing or an identical-appearing gauze wound dressing. Wounds were evaluated in the outpatient office at 1 week and 6 weeks after delivery. The primary outcome was superficial surgical site infection as defined by Centers for Disease Control criteria at any time within the first 6 weeks after cesarean delivery. A sample size of 330 per group (n = 660) was planned to compare the 2 arms. Data were analyzed using the χ^2, Fisher exact test, Student *t* test, Mann–Whitney *U* test, and logistic regression where appropriate, and a value of $P < .05$ was considered significant.

RESULTS: Among the 657 participants, overall, the primary outcome was similar between the 2 groups (4.6% in the silver nylon group vs 4.2% in the gauze group, $P = .96$). Women allocated to silver nylon, when compared to those who were allocated to gauze, had similar rates of superficial surgical site infection within 1 week (1.2% vs 0.9%) and within 6 weeks (4.6% vs 4.2%) after delivery ($P > .99$). The 2 groups were similar in age (30.9 ± 5.6 vs 31.0 ± 5.5 years, $P = .95$), body mass index (36.2 ± 8.7 vs 35.3 ± 8.2 kg/m^2, $P = .19$), pregestational diabetes (6.2% vs 3.4%, $P = .14$), gestational diabetes (7.9% vs 7.3%, $P = .88$), cesarean delivery after labor (31.9% vs 31.1%, $P = .86$), presence of chorioamnionitis (5.2% vs 2.1% $P = .06$), and operative time (56.4 ± 20.6 vs 55.9 ± 17 minutes, $P = .69$). After adjusting for clinical and sociodemographic confounding variables, current smoking (adjusted odds ratio, 4.9; 95% confidence interval, 1.8–13.4) body mass index ≥40 kg/m^2 (adjusted odds ratio, 3.08; 95% confidence interval, 1.3–6.8), and surgery length (minutes) (adjusted odds ratio, 1.02; 95% confidence interval, 1.002–1.04), but not use of gauze dressing, were associated with superficial surgical site infections.

CONCLUSION: Among women undergoing cesarean delivery, silver nylon dressing was not more effective than gauze in reducing the risk of superficial surgical site infections.

Key words: cesarean, obesity, prophylactic antibiotics, silver nylon dressing, superficial surgical site infection, wound infection

In the United States in 2015, 1.3 million cesarean deliveries were performed, accounting for 32% of all deliveries.[1] The rate of postoperative surgical site infection (SSI) after cesarean delivery is between 3% and 18%.[2–4] Affected women are more likely to need a prolonged hospitalization, hospital readmission, reoperation, and additional antibiotic therapy.[5–7] It is estimated that each SSI adds $3,400–$3,700 to the healthcare costs.[6] Given the burden in morbidity and cost, there is a heightened focus on reduction of SSI in association with cesarean delivery.[8]

Silver has been used for centuries to reduce infection secondary to its antimicrobial properties.[9] Krieger et al described silver as a metal that is relatively inert and poorly absorbed by cells. When it is exposed to a wound, it ionizes and becomes highly reactive to proteins and cell membranes.[10] It has been shown to interact with structural proteins and DNA, inhibiting bacterial replications and causing fatal structural changes within bacterial cell walls.[11] Prospective and retrospective studies in other specialties such as colorectal surgery and orthopedic surgery demonstrating a decreased rate of SSI with use of silver dressings have resulted in an interest in its use for cesarean wounds.[11–14] The existing published data on the use of silver dressings after cesarean deliveries is limited to 1 retrospective review.[11]

The objective of this study was to evaluate the effectiveness of a silver nylon wound dressing in preventing superficial SSI. We conducted a prospective, randomized study directly comparing this dressing with standard gauze dressings in participants undergoing cesarean delivery. We hypothesized that use of the silver nylon dressing would be associated with a decreased rate of superficial SSI after cesarean delivery.

Materials and Methods

This study was designed as a parallel blind randomized clinical trial at a single tertiary referral center. The institutional review board approved the trial protocol.

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AJOG at a Glance

Why was this study conducted?

Silver dressing have been associated with a reduction in surgical site infections in the orthopedic and colorectal literature. We sought to evaluate the impact of silver dressing on superficial surgical site infections after cesarean delivery.

Key findings

The rate of superficial surgical site infection was similar between the 2 groups. Maternal body mass index and operative time were the 2 predictors of superficial surgical site infection.

What does this add to what is known?

Silver nylon dressings when compared to gauze are not associated with a reduction of superficial surgical site infection after cesarean delivery.

The study was registered in ClinicalTrials.gov (NCT01697748). Argentum Medical provided partial funding for the study but did not participate in the design, conduct or reporting of the trial. An independent data and safety monitoring board oversaw the trial.

Women who were ≥36 weeks' gestation and receiving care at any of 3 obstetric (OB) sites were recruited between September 2013 and June 2016, and follow up visits were completed in August 2016 after the sample size was achieved. The recruitment sites were the University of South Florida (USF) Health outpatient obstetric clinic, the TGH Genesis at Health Park outpatient clinic, and the obstetric unit at Tampa General Hospital (TGH).

Women were included if they met all of these inclusion criteria: 1) age 18 years or older, 2) undergoing a scheduled or unscheduled cesarean delivery, 3) primary or repeat cesarean deliveries, 4) transverse (Pfannenstiel) skin incision, and 5) willingness and ability to provide written informed consent in English or Spanish.

Women were excluded if they met the following exclusion criteria: 1) patients did not receive routine prophylactic dose of antibiotics in the operating room, 2) skin incisions other than Pfannenstiel, 3) uterine incisions other than low transverse, and 4) patients with known or discovered allergies to silver or nylon.

The participants were randomized in a 1:1 ratio to 1 of 2 arms: silver nylon dressing or an identical-appearing gauze pad covering their cesarean delivery incision. All dressings were placed in the operating room after the completion of the procedure and after the surgeons left the operating room. The operating physician, the postpartum provider, and research staff were blinded to the study group.

Silver nylon dressing

The saline-treated silver nylon dressing was applied in the operating room over the cesarean delivery incision after the procedure was completed. It was saline treated again and re-dressed every 12 hours for the first 48 hours by the postpartum nurses according to Silver Nylon instructions. The dressing was replaced on postoperative day 2 with a saline-treated silver nylon island (silver-treated dressing with adhesive around it) that would remain on the incision through postoperative week 1. Traditional follow-up care was rendered.

Gauze pad (standard)

The gauze pad was applied in the operating room over the cesarean delivery incision after the procedure was completed. On postoperative day 2, the gauze pad was changed by the postpartum nurses. A second gauze dressing was placed over the scar, and a transparent film adhesive was applied around it to secure it to the skin. It remained on the incision through postoperative week 1. Outside the study, physicians varied in their duration of maintaining the dressing, but for study purposes it standardized to 1 week allowing comparability to the silver dressing–treated group. Caregiver blinding was therefore maintained. Otherwise, traditional follow-up care was rendered.

At the 1 week postoperative visit, the medical assistant in the clinician's office removed the dressing in the absence of the provider to reduce assessment bias.

Allocation

A computer-generated, stratified, mixed block randomization sequence was developed by an independent statistician (K.D.) and the assignments were placed into opaque envelopes. The sealed envelopes were stored in a secure designated area within Labor and Delivery's Operating Room at Tampa General Hospital. Once the cesarean delivery was completed, an envelope was selected from the next sequentially numbered envelope and the number on the envelope was recorded on a study sheet. The surgery date and the patient's study identification number were documented in the surgery log. The randomization envelope was opened once the primary surgeon left the operating room. The designated dressing was applied to the wound, and the selected envelopes were brought to the University of South Florida Obstetrics/Gynecology Department Research Office.

Research coordinators arranged the follow-up visits for continued incision inspection on postoperative weeks 1 and 6. A total of 20 attending physicians from the department of obstetrics and gynecology agreed to participate, along with 20 University of South Florida obstetrics and gynecology residents.

All standard procedures were followed, including preoperative antibiotics and chlorhexidine alcohol skin preparation. The prophylactic antibiotic of choice administered by Tampa General Hospital Anesthesia Department prior to cesarean delivery is cefazolin. For those patients allergic to penicillin, clindamycin (first choice) or vancomycin was used as an alternative during the time period of the study. Per hospital protocol, the antibiotic was administered by the anesthesia team upon completion of a spinal or epidural and

preceding administration of general anesthesia.

Data collection

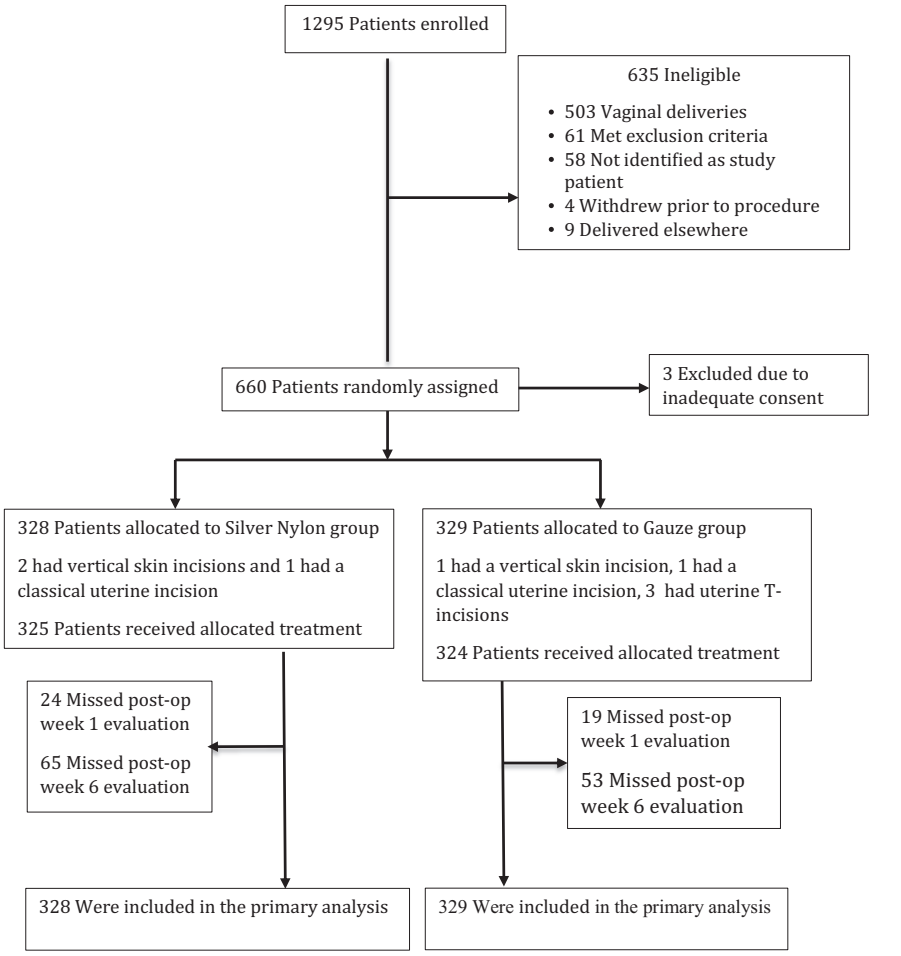
Ascertainment of primary outcome

The primary outcome was superficial SSI detected at any time within the first 6 weeks after delivery.

A superficial SSI was defined using the Centers for Disease Control and Prevention definition. To meet criteria, these infections had to involve only skin and subcutaneous tissue of the incision, and the patient had to have at least one of the following: 1) purulent drainage from the superficial incision; 2) organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision; 3) at least 1 of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, and superficial incision deliberately opened by surgeon, and culture positive or not cultured (a culture-negative finding does not meet this criterion); and 4) diagnosis of superficial incisional SSI by the surgeon or attending physician.[15]

The participants were evaluated in the outpatient clinic at 1 and 6 weeks postoperatively and were given a $15.00 gift card to a local grocery store as compensation for their time. Information was obtained about their interval health. The trained healthcare providers in the outpatient clinics evaluated the wounds. The medical records from USF and Tampa General Hospital were reviewed for each patient by trained research coordinators. This included the review of prenatal records and postpartum visits performed at USF and TGH Genesis at Health Park clinic, along with the inpatient admission documentation at Tampa General Hospital where the cesarean delivery was performed. We reviewed both scheduled and unscheduled visits. Tampa General Hospital also employed active surveillance for SSI through the Infection Control department, which included reciprocal communication with local hospitals and emergency rooms to document SSI among women who delivered at TGH. Each month, TGH received reports about superficial SSI treated at area hospitals among women who had their surgery at TGH. We reviewed this database to identify additional cases of superficial SSI among our study participants. This information was in addition to the inquiries made during the 1-week and 6-week postoperative visits. Data collected in the study included patient characteristics, medical comorbidities, obstetric history, index (current) delivery, evaluation of incisions on postoperative week 1, and again at 6 weeks. Data were reviewed by 2 members of the research team (L.O and D.N.) for verification, and a random sample of charts was reviewed for accuracy. Charts were reviewed again by 2 members of the research team (L.O. and D.N.) if there were missing values.

FIGURE 1
Randomization and follow-up of study participants



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Statistical analysis

At the time of the study design, the Tampa General Hospital superficial SSI rate was 15%, which was within the range reported in the literature. We determined that a sample size of 600 patients would provide a power of 80% to detect a 50% absolute reduction (15% vs 7.5%) in superficial SSI at a 2-sided $\alpha = 0.05$. This reduction was similar to the reduction demonstrated in a randomized clinical trial of silver dressing to reduce SSI after colorectal surgery.[13] Assuming an approximate 10% dropout loss to follow-up rate, the total sample size was adjusted to 660.

All analyses were conducted according to intention-to-treat principle. We used the χ^2 or Fisher exact tests to analyze categorical variables and the Student *t* test for continuous variables. Relative risks and 95% confidence intervals were calculated for outcomes. Adjusted odds ratios and 95% confidence intervals were calculated from multivariate logistic regression models to relate potential confounding variables to the development of a superficial SSI. The variables with at least a borderline association ($P \leq .10$) were then included in a multiple logistic regression model to verify which was independently associated with the outcome of interest. Adjustment covariates included body mass index (BMI) $\geq$40 kg/m^2, smoking, chorioamnionitis, preelampsia, duration of surgery, and preoperative hemoglobin. Model fit was assessed with the Hosmer−Lemeshow goodness-of-fit test. A multiple imputation analysis was performed with no difference in the results. A P value $<.05$ was considered statistically significant. A planned interim analysis was conducted when 50% of the patients had been randomized.

The protocol will be made available upon request for up to 36 months after publication. Individual patient-level data will not be made available.

Results

During the study period, 1295 patients were enrolled in the study. A total of 635 patients were excluded prior to randomization. The most common reason for not being randomized was that the patient had a vaginal delivery. In all, 328 patients were randomly assigned to receive the silver nylon dressing, whereas 329 received the gauze dressing. A total of 657 women were included in the intention-to-treat analysis (Figure 1). Six women developed an allergic reaction to the adhesive tape placed around dressing (3 in the silver dressing group and 3 in the gauze group).

All of the patients except for 11 (3 in the silver dressing group and 8 in the gauze group) received their assigned intervention. A similar number of participants in each group (49 [15.9%] in the silver dressing group and 49 [15.6%] in the gauze group) were lost to follow-up. There were no significant differences between the 2 groups in baseline characteristics (Table 1). Participants in the 2 groups were similar in age, race/ethnicity, and BMI. The women allocated to the silver nylon group were less likely to smoke (4.9% vs 9.8%, $P = .02$) and were more likely to be diagnosed with preeclampsia (6.3% vs 2.5%, $P = .02$) (Table 1).

Overall, the most common indication for the cesarean delivery was an elective repeat cesarean delivery (57.0%). Women who were allocated to the silver nylon dressing group were similar to the comparative gauze group in indications for delivery, operative time, use of suture for skin closure, and use of chlorhexidine for skin preparation, but they had a lower preoperative hemoglobin (11.2 ± 1.3 vs 11.5 ± 1.3 g/dL, $P = .003$) (Table 2).

A total of 15 participants (4.6%) in the silver dressing group and 14 (4.2%) in the gauze group received a diagnosis of superficial SSI (relative risk, 0.99; 95% confidence interval [CI], 0.96−1.028) (Table 3). After adjusting for confounding variables, current smoking (adjusted odds ratio [aOR], 4.9; 95% CI, 1.8−13.4), BMI $\geq$40 kg/m^2 (aOR, 3.08; 95% CI, 1.3−6.8), and

TABLE 1
Characteristics of the patients at baseline

Characteristic	Silver dressing (n = 328)	Gauze (n = 329)
Age (y)	30.9 ± 5.6	31.0 ± 5.5
Ethnic group		
Hispanic	74 (22.6)	74 (22.6)
Race		
Black	85 (26)	74 (22.6)
White	226 (69.1)	227 (70.0)
Asian	8 (2.4)	9 (2.8)
Body mass index (kg/m^2)	36.2 ± 8.7	35.3 ± 8.2
BMI ≥ 40 kg/m^2	98 (29.9)	75 (22.8)
BMI ≥ 50 kg/m^2	29 (8.8)	20 (6.1)
Commercial insurance	182 (55.5)	177 (53.7)
Nulliparous	102 (31.1)	104 (31.6)
Diabetes mellitus		
Pregestational	20 (6.2)	11 (3.4)
Gestational	26 (7.9)	24 (7.3)
Chronic hypertension	59 (18.0)	49 (15.0)
Smoking during pregnancy[a]	16 (4.9)	32 (9.8)
Positive for group B streptococcus	103 (31.9)	94 (28.9)
Gestational age (wk)	38.6 ± 1.9	38.5 ± 1.8
<37 wk at delivery	32 (9.8)	36 (10.9)
Prior cesarean delivery	197 (60.2)	191 (58.6)
Preeclampsia[a]	20 (6.2)	8 (2.5)
Chorioamnionitis	17 (5.2)	7 (2.1)

Data are presented as n (%) or mean ± SD.

BMI, body mass index.

[a] $P < .05$.

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TABLE 2
Characteristics of cesarean procedures

Characteristic	Silver dressing (n =328)	Gauze (n =329)	*P* value
Primary indication for cesarean delivery			.68
Failure to progress	47 (14.5)	41 (12.6)	
Nonreassuring fetal heart tracing	12 (3.7)	18 (5.5)	
Elective repeat procedure	188 (57.8)	186 (57.2)	
Malpresentation	26 (8.0)	33 (10.2)	
Cesarean delivery after labor	104(31.9)	101(31.1)	.86
Receipt of standard antibiotic prophylaxis	300 (91.5)	299 (91.7)	
Skin closure method			.75
Staples	18 (5.6)	16(4.9)	
Suture	300 (93.8)	297 (93.1)	
Glue	3 (0.9)	6 (1.8)	
Skin preparation			
Chlorhexidine-alcohol	315 (96.0)	315 (96.3)	1.0
Vaginal preparation	105 (32.1)	111 (33.9)	.67
Surgery length (min)	56.4 ± 20.6	55.9 ± 17.5	.69
Preoperative hemoglobin (g/dL)	11.2 ± 1.3	11.5 ± 1.3	.003
Blood loss (mL)	733 ± 258	719 ± 236	.46

Data are presented as n (%) or mean ± SD.

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surgery length (minutes) (aOR, 1.02; 95% CI, 1.002−1.04), but not use of gauze dressing, were associated with superficial SSI.

Comment

Principal findings

In our study, the use of silver nylon dressing after cesarean delivery failed to prevent superficial SSI. After adjusting for confounding variables, BMI, tobacco use, and surgery length were the factors predictive of superficial SSI. To date, this is the largest randomized trial, to our knowledge, that addresses the effectiveness of a silver nylon dressing in lowering the superficial SSI rate of patients undergoing cesarean delivery (searched in PubMed and clinicaltrials.gov using the terms cesarean, silver, and dressing).

Clinical implications

A recent focus on surgical technique and postoperative management of cesarean wounds has yielded some promising results in the prevention of SSI. These efforts have included the addition of azithromycin to broaden the spectrum of prophylaxis and the use of chlorhexidine for skin preparation.[2,16,17] However, the rates of SSI remain higher than desired. The superficial SSI rate in our study was lower than anticipated. During the study period, Tampa General Hospital implemented several concurrent measures, which aimed at lowering the superficial SSI rate in obstetrics. These changes included the following: transitioning from staple use to sutures for skin closure; improving use and documentation of prophylactic antibiotics; betadine vaginal preparation for ruptured membranes and nonemergent cases; clipping rather than shaving; use of chlorhexidine wipes preoperatively and postoperatively; chlorhexidine-alcohol skin preparation for all nonemergent cases; closure of subcutaneous tissue >2 cm in depth; surgical times <60 minutes; blood loss <1 L; and use of ultraviolet light disinfection in the operating room daily.[18,19] These changes are in line with the heightened effort nationwide to identify evidence-based methods to reduce cesarean delivery−associated infections.[18] The measures were successful but also affected our study results.

The findings of our study indicate that obese women remain at high risk for superficial SSI after cesarean deliveries, despite following evidence-based measures to reduce SSI. In our study, the use of a silver nylon dressing did not mitigate this risk. Recognizing the need for other solutions in this at-risk group, Valent et al found that a course of oral cephalexin and metronidazole in obese women for 48 hours after cesarean delivery decreased the superficial SSI rate within 30 days after delivery[20]; however, this study has not been replicated. Furthermore, additional studies are needed to examine the mechanisms contributing to the higher superficial SSI rate among obese women in an effort to identify interventions. One theory proposes that the moisture in the pannus of obese women predisposes to wound infections. In this scenario, an "ideal dressing" that would provide a protective role under appropriately moist conditions stimulating cellular regeneration would theoretically be beneficial.[21] The silver nylon dressing is reported to work in a similar fashion. The manufacturers state that the silver-treated dressing in the presence of moisture allows silver ions to dissociate from the metallic surface and diffuse into the wound. This action is theorized to provide antimicrobial protection with a reservoir of continuous release of silver ions enhancing epithelial migration.[21] Although we failed to detect a difference, several clinical studies have been performed using silver dressings in the treatment of a variety of acute and chronic wounds and have been more promising.[11,13,21,22] Findings in other investigations indicate that there may be a difference in skin microbiotia in obese women that may contribute to the predisposition to superficial SSI.[23]

TABLE 3
Primary composite outcome and its components

Outcome	Silver dressing (n = 328)	Gauze (n = 329)	Relative risk (95% CI)
Primary composite outcome			
Wound infection			
Superficial	15 (4.6)	14 (4.2)	0.96 (0.44–1.96)
Deep wound infection	0	0	—
Endometritis	5 (1.5)	0	—
Wound hematoma	5 (1.5)	5 (1.5)	0.99 (0.53–1.86)
Wound seroma	10	8	0.89 (0.58–1.36)
Wound separation	4 (1.2)	7 (2.1)	3 (0.63–3.02)

CI, confidence interval.
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Our findings of an association between operative time and superficial SSI are in line with previous studies.[24,25] Other post–cesarean delivery maternal infection risk factors include women of black race/ethnicity, a nontransverse uterine incision, duration of membrane rupture >6 hours, and surgery duration >49 minutes.[26] As we move forward to identify ways to improve outcomes, we are reminded that operative time is 1 of the few modifiable risk factors for superficial SSI.

Strengths and weaknesses

When examining the data, there are a few caveats to consider. Some patients who had previously used silver nylon dressing declined study participation for fear that they might be randomized to the gauze dressing arm. Consenting occurred mainly in the clinical office. Despite measures to alert the research staff to the patients' participation in the study, some consented patients were missed and failed to be randomized. This typically occurred with patients who underwent a multiple-day induction of labor involving multiple shifts of care providers. We excluded women with vertical skin incisions, precluding any comment on the usefulness in this high-risk category of patients. In addition, although physicians were blinded to the study group allocation, the nurses during the delivery hospitalization were not. However, as none of the superficial SSI occurred during the delivery hospitalization, it is not likely to have affected the diagnosis of the primary outcome. Moreover, we had a higher than anticipated loss to follow-up rate, which could have contributed to a lower detection rate of the primary outcome. Finally, measures implemented by the hospital resulted in a substantially lower superficial SSI rate than what was used for study planning.

Despite this lower rate, our findings are important. The gains observed with use of silver dressings in the colorectal and orthopedic literature may be more difficult to ascertain in the obstetric population. With lower rates of the outcome of interest, a study of silver dressing would require a larger sample size. For the eventual rate of the outcomes of interest, we would have needed 1083 women in each arm to detect a 50% reduction in superficial SSI for a given baseline superficial SSI rate of 4.2%. Also, the continued use of these dressings has significant cost implications. Our local cost for a silver nylon dressing is substantially higher than the cost of the gauze dressing ($26.82 vs $1.85 per dressing). We should be reluctant to implement expensive interventions without evidence of the efficacy or cost-effectiveness. The results of our study indicate that the added cost of the silver dressing in order to reduce SSI is not beneficial for the reduction of SSI.

Conclusion with future research implications

In our study, a silver nylon dressing failed to show benefit in preventing superficial surgical site infection. Routine use for the prevention of superficial SSI should be discouraged prior to well-designed trials demonstrating efficacy in obstetric surgeries. ■

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