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Effect of intra-operative glove-changing during cesarean section on post-operative complications: A randomized controlled trial

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Abstract

Purpose—To compare the rates of wound related complications among women undergoing a cesarean section when the surgical team used intra-operative glove changing versus usual care.

Methods—All women undergoing a cesarean section at a single, county hospital were randomized to usual care or intra-operative glove-changing prior to abdominal closure. Participants were randomized at the time of decision for cesarean section; surgeons were not blinded to randomization arm. The primary outcome was any wound related complication, including wound hematoma, seroma, skin separation of at least 1cm, wound infection, or other incisional abnormality requiring treatment within 8 weeks of surgery. To detect a reduction in the primary outcome from 17% in the control group to 9% in the intervention group with 80% power, a total of 554 women (277 per group) were required. Secondary outcomes included other infectious complications including endometritis and other superficial or deep soft tissue infections.

Results—From August 2015 to November 2016, 277 women were randomized to usual care and 276 women were randomized to intra-operative glove changing. The two groups were well-balanced in terms of demographic data, comorbid conditions and surgical characteristics. Intra-operative glove changing led to a significant decrease in composite wound complications from 13.6% in the control group to 6.4% in the intervention group ($p=0.008$).

Conclusion—Intra-operative glove changing prior to abdominal closure during cesarean section significantly reduced the incidence of post-operative wound complications.

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Ethical approval:

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Author Contributions:

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This article does not contain any studies with animals performed by any of the authors.

Keywords

Obstetrics; Cesarean section; Gloves; Wound; Infection; Complications

Introduction

Cesarean section is the most commonly performed major abdominal surgery in the United States and almost one third of births in the US are cesarean deliveries [1]. While cesarean delivery is usually an uncomplicated procedure, up to 20% of patients can experience a complication following cesarean delivery with infectious complications being the most common [2]. Several studies have tested new interventions that attempt to decrease these infectious complications including pre-operative bathing, appropriate use of pre-operative antibiotics, type of pre-operative scrub utilized, hair clipping, vaginal cleansing, maintaining intra-operative normothermia, closure of subcuticular skin and type of skin closure [3].

There is evidence that normal vaginal flora contributes to post-operative infectious morbidity when introduced to the abdominal cavity during a cesarean delivery; Yancey et al. proposed that surgeons' gloves may contribute to this contamination [4]. Moreover, data suggest that reducing the burden of transferred vaginal bacteria may reduce infection rates [5].

The effect that glove changing during a procedure might have on infectious complications has been studied both as a single intervention and as part of a surgical bundle or closing tray in colorectal, gynecologic oncologic and urologic procedures with mixed results [6,7]. There have been two previous randomized controlled trials looking at infectious morbidities following cesarean section when surgeons change their gloves during the procedure, also with mixed results. The purpose of this study was to evaluate whether surgeons' glove-changing during cesarean section decreases rates of post-operative composite wound complications compared to current standard of care.

Methods

This was a prospective, randomized controlled trial enrolling women who underwent cesarean section for any indication at HealthPartners Regions Hospital in St. Paul, Minnesota between August 2015 and November 2016. The protocol was approved by the HealthPartners Institutional Review Board, which decided to waive the need for patient informed consent. They argued that because intra-operative glove changing is itself an intervention that could be both a routine part of surgery at the surgeon's discretion, and unknown to patients under normal circumstances during any other surgery, that the intervention was felt to be so innocuous as to not require consent. The study was registered on clinicaltrials.gov (NCT02907892).

Women were eligible for participation if they were undergoing cesarean section of a singleton pregnancy for any indication at Regions Hospital. The only exclusion criteria were non-singleton pregnancies and emergency procedure. Patients were included in the study if study eligibility criteria were met at the time that cesarean section was decided as the route

of delivery by patient and provider. Patients were unaware of their participation in this study. Patients were randomized using a simple computer generated sequence 1:1 to either usual care or to the glove change group. The randomization allocation was concealed in an opaque sealed envelope and was only opened in the operating room by the circulating nurse prior to skin incision. All patients received appropriate pre-operative antibiotics, chlorohexidine skin prep except where allergies prohibited, and hair clipping as indicated. Vaginal preparation and cesarean delivery techniques were at the discretion of the attending surgeon.

In the glove change group, the surgical team including all surgeons, surgical assists and scrub technicians replaced their outer surgical gloves with a new pair of sterile gloves just prior to abdominal closure. Abdominal closure was considered to begin with closure of the peritoneum, if performed, otherwise with closure of the abdominal fascia. We decided to change gloves prior to abdominal closure and not after delivery of the placenta due to safety concerns. Because after delivery of the placenta the hysterotomy is still open and bleeding, we felt that it was not prudent to take the time to change gloves at this time as it was likely to increase blood loss for the procedure. Further, we felt it best to change our gloves once the direct access to the genitourinary tract (via the hysterotomy) was closed.

Demographic, comorbid conditions and surgical variables were collected (Table 1). The primary outcome for the study was a composite endpoint of any wound complication occurring within eight weeks following delivery as used in similar studies [8,9]. These wound complications included wound seroma, wound hematoma, wound infection, skin separation of at least 1cm, or other incisional abnormality requiring a bedside procedure to treat or coded as a wound-related complication in the electronic medical record. Secondary outcomes included febrile morbidity (defined as temperature > 100.4 degrees Fahrenheit prior to hospital discharge), cellulitis, prescription of antibiotics for a skin- or wound-related infection, endometritis, and composite infectious complications (defined as the occurrence of at least one of endometritis, cellulitis, or wound infection). Outcome data were collected from the electronic medical record (EMR) by an investigator unaware of the subject's intervention assignment. Outcomes for all subjects were considered only within the eight weeks following delivery, and excluded breast, perineal, or non-gynecologic complications. Patients who did not have an examination documented in the medical record within eight weeks following delivery were considered lost to follow up as we did not have consent to contact patients.

Based on previous research and experience with the study population, the rate of any complication in this population at the time of study initiation was assumed to be 20%, and a reduction by 50% was presumed to be clinically meaningful, resulting in an initial planned sample size of 398 individuals. However, given the wide range of complication rates reported in the literature, a planned review of the complication rate in the first 100 enrolled control patients was decided upon a priori to allow for an expansion of the sample size if needed due to lower than anticipated complication rates. This blind review was conducted December 2015 among the 108 controls enrolled to date. The rate of any complication in the initial control sample was 17%. We therefore recalculated the sample size based on this complication rate and increased the planned sample size to 554 (277 per group) to achieve 80% power to detect an approximate 50% reduction (9%) in the intervention group as

statistically significantly different from the control group (17%) using a two-sided Z test with pooled variance and a significance level of 0.05.

Demographic and clinical characteristics were summarized and analyzed by randomized group using chi-squared tests for categorical data and t-tests and Wilcoxon Rank-Sum tests for continuous data. Comparisons of the rates of any wound or infection complication by randomized group were conducted using chi-squared tests and Fisher's Exact tests, following an intention-to-treat analysis. Data were analyzed with and without the second delivery for four patients who delivered twice during the study timeframe; no significant differences were noted and therefore all data points were included. An additional analysis was conducted using logistic regression to assess the effect of vaginal preparation, a potential confounding variable which was not balanced between randomized groups, on the estimate of the intervention on the primary outcome; odds ratios (ORs) and 95% confidence intervals (CIs) are presented. Data were analyzed in SAS 9.4 (Cary, NC) and p values < 0.05 were considered statistically significant.

Results

From April 2015 to November 2016, a total of 554 women were eligible for this trial; 553 were randomized (277 to the usual care group and 276 to the glove-changing group; Figure 1). One patient was excluded from the final analysis as she did not meet eligibility criteria due to the emergent nature of her cesarean section. The two groups were well-balanced in terms of demographic variables, comorbid conditions and surgical variables (Table 1). Specifically, women were approximately 31 years old, almost half had a previous cesarean section, about a third were in labor at the time of index cesarean section, and the median gestational age at randomization was 39 weeks. The median surgical time was 64 minutes in the control group and 66 minutes in the glove-change group ($p=0.26$), and median estimated blood loss was 800 cc in the control group compared to 900 cc in the glove-change group ($p=0.13$). One notable difference between groups was that only 10.5% ($n=29$) of patients in the control group compared to 20.3% ($n=56$) of patients in the glove-change group received a vaginal preparation prior to their cesarean section ($p=0.001$). Among the 553 participants who were randomized, 87.9% had at least one examination available in the EMR within 8 weeks following delivery and were therefore included in the final analysis of the primary endpoint. Those with follow-up data available were similar to those who did not, except they were older (29.1 ± 5.8 vs. 30.8 ± 5.2 years; $p=0.02$).

In the intention to treat analysis, there was a statistically significant difference between the rate of composite wound complications between the control group (13.6%) and the glove-change group (6.4%, $p=0.008$; Table 2). Following adjustment for vaginal preparation, the estimate of the effect of the intervention changed very little (unadjusted OR=0.42 (95% CI: 0.22, 0.79), $p=0.007$ versus adjusted OR 0.43 (95% CI: 0.23, 0.81), $p=0.009$), suggesting that the difference in vaginal preparation between the two groups did not confound study results.

Of the individual wound complications in the composite endpoint considered, skin separation demonstrated the largest difference between groups (6.8% compared to 2.1%, $p=$

0.01). None of the other wound-related or infectious secondary outcomes were statistically significant on their own. Fewer participants in the glove-change group experienced febrile morbidity compared to controls, however this difference was not statistically significant (3.0% vs 5.6%; $p=0.15$).

Discussion

Intraoperative glove changing prior to abdominal closure during cesarean section decreased occurrence of composite wound complications. While we did not find significant differences between any of the individual variables with the exception of skin separation, taken as a composite this could have a large impact on the burden of wound complications following cesarean delivery.

Our results are consistent with a previous small randomized controlled trial in which women were assigned to either usual care or glove changing after delivery of the placenta [10]. In this study, they showed a significant reduction in wound infections (25% to 5.5%) associated with glove changing.

A second randomized study of 228 women undergoing cesarean delivery in which the primary outcome was rate of endometritis did not show a benefit to intra-operative glove changing (17.7% vs 15.7%; [11]). This difference is likely due to the extremely low rates of endometritis and inadequate power in this relatively small study.

There have been several studies conducting among women undergoing cesarean sections evaluating the use of a surgical bundle, however none of these included glove changing, in order to reduce the rates of surgical site infection (SSI). A meta-analysis showed that implementing these bundles can lead to decreased SSI [3]. Several studies have looked at the role of introduction of a SSI reduction bundle to reduce surgical site infections in other specialties [7]. All of these studies have included glove changing as part of the bundle and all have shown an improvement in the rates of SSI with the introduction of the bundle. Interestingly, when glove changing was studied in colorectal, gynecologic oncology and urologic procedures as a single intervention outside of the bundle in a randomized trial, it was not shown to improve SSI [6]. The difference in results between this study and ours is likely due to the differences in surgical procedures between these services and cesarean sections.

Strengths of this study include the large sample size, randomized design, and broad inclusion criteria making the results potentially applicable to most cesarean sections in clinical practice. There are limitations to this study. First, was the lack of blinding of the surgeons, some of whom were responsible for the choice of vaginal preparation and performing post-operative examinations on these patients. Second, there was no control and record of whether the surgeons and other staff completed the glove change in the medical record,, though the final analysis was conducted using intention to treat methods as opposed to actual use. Finally, this study is limited by its single institution design and might not be applicable to other types of hospital settings or patient populations.

In summary, we found that the act of the surgical team changing their gloves prior to closure of the abdomen during a cesarean section led to significantly reduced rates of composite wound complications. Based on these results, we recommend considering this adding this intervention as a routine part of an obstetrician's surgical practice, and encourage its adoption into surgical bundles for this population.

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Figure 1.
CONSORT diagram of participant enrollment and allocation.

Table 1

Participant characteristics.

Variable	Control			Glove Change		
	N	Mean (SD)		N	Mean (SD)	p-value
Age, years	277	30.7 (5.3)		276	30.6 (5.4)	0.75
BMI, kg/m ²	277	33.8 (6.7)		276	34.5 (1.4)	0.25
	N	%		N	%	p-value
Prior C-section	151	54.5		143	51.8	0.52
No	126	45.5		133	48.2	
Yes						
DM/GDM						0.27
No	236	85.2		244	88.4	
Yes	41	14.8		32	11.6	
In Labor						0.27
No	184	66.4		171	62.0	
Yes	93	33.6		105	38.0	
Membranes Ruptured						0.52
No	168	60.7		160	58.0	
Yes	109	39.4		116	42.0	
Chorioamnionitis						0.31
No	271	97.8		266	96.4	
Yes	6	2.2		10	3.6	
Wound Vacuum Applied						0.80
No	232	83.8		229	83.0	
Yes	45	16.3		47	17.0	
Vaginal Preparation						0.001
No	248	89.5		220	79.7	
Yes	29	10.5		56	20.3	
	N	Median (Min, Max)		N	Median (Min, Max)	p-value

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Variable	Control		Glove Change		p-value
	N	Mean (SD)	N	Mean (SD)	
Parity, median (range)	277	2 (1, 8)	276	2 (1, 9)	0.69
Gestational Age, weeks	277	39 (31, 42)	276	39 (34, 43)	0.10
Surgical Time, minutes	277	64 (25, 162)	276	66 (31, 150)	0.26
Estimated Blood Loss	277	800 (500, 3500)	276	900 (500, 3050)	0.13

Table 2

Outcomes (among 486 with follow-up)

	Control		Glove Change		p-value
	N	%	N	%	
Primary Outcome	34	13.6	15	6.4	0.008
Wound Composite					
Secondary Outcomes					
Seroma	8	3.2	4	1.7	0.38
Hematoma	3	1.2	2	0.9	1.00
Separation	17	6.8	5	2.1	0.01
Other Wound Complication	6	2.4	1	0.4	0.12
Wound Infection *	14	5.6	8	3.4	0.28
Infection Composite	28	11.2	27	11.4	0.93
Skin Infection	15	6.0	14	5.9	0.97
Endometritis	10	4.0	7	3.0	0.54
Wound Infection *	14	5.6	8	3.4	0.28
Febrile morbidity	15	5.6	7	3.0	0.15

* Same outcome included in both composite endpoints

Table 3
Adjusted odds ratios and p-values for subgroups with and without vaginal preparation

Primary Outcome	Control		Glove Change		Unadjusted		Adjusted	
	N	%	N	%	Odds Ratio (95% CI)	p-value	Odds Ratio (95% CI)	p-value
Wound Composite	34	13.6	15	6.4	0.42 (0.22, 0.79)	0.007	0.43 (0.23, 0.81)	0.009