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Impact of Changing Sterile Glove at the Time of Wound Closure to Reduce Surgical Site Infection in Women Undergoing Elective Cesarean Section; a Prospective Randomized Controlled Clinical Trial

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Abstract

Objective: Surgical site infections (SSIs) among surgical patients are the most common nosocomial infection, accounting for 38 percent. It is estimated that SSIs develop in 2 to 5 percent of the more than 30 million patients undergoing surgical procedures each year. We aimed to assess the impact of changing sterile gloves at the time of wound closure to reduce SSI in women undergoing elective cesarean section (CS).

Patients and Methods: The study was done from February 2023 to July 2023 at Ain Shams University Hospital. 220 Women were randomly distributed and blindly allocated into two groups. Group A (operative glove changing group "n=110"), Group B (usual care group "n=110"). Postoperative febrile morbidity, cellulitis, need for antibiotics for skin- or wound-related infection, and endometritis were compared between study groups.

Results: Postoperative wound complications were statistically significantly higher among cases not subject to a change of sterile gloves, 28.0% vs. 9.8%. On the other hand, no differences were noted between study groups regarding operative duration 61.39 ± 7.76 vs. 59.35 ± 8.11 minutes.

Conclusion: Changing sterile gloves at the time of wound closure reduces surgical site infection and associated morbidity in women undergoing elective CS.

Key words: Changing Glove, Surgical Site Infection, Cesarean Section

Introduction

CS is the most common major operation performed worldwide. In daily obstetric practice. It accounts for up to 60% of all births in some countries[1].

A previous study reported that Egypt has the third

highest CS rate (54%) in the world and lacks a standard classification system to analyze CS rates[2], following the Do-minican Republic (56.4 percent) and Brazil (55.6 percent). Within the Arab region, rates of CS are far higher in Egypt than in any other Arab country[3].

In another study, the CS rate in Egypt was estimated at 55.1%, the highest rate was 67.8% in Behira, and the lowest was 49.0% in Assiut. In most governorates, the CS rate was higher in rural than urban areas, but the difference was insignificant. High CS rates were significantly related to higher social class and fewer children (≤ 3)[4].

The percentage of "unjustified" cesarean deliveries has exceeded 62 percent of total deliveries in Egypt, many of which could have been done naturally. In August 2022, the Central Agency for Public Mobilization and Statistics (CAPMAS) reported a noticeable increase in C-sections in recent years. CAPMAS found that C-sections increased to 72 percent of all deliveries in 2021, up from 52 percent in 2014. The agency also found that C-sections in rural areas increased to 84 percent of all deliveries in 2021, up from 70.6 percent in 2014[6].

One of the most serious complications after CS is wound complication it varies from 3 to 30%[6].

It may be infectious as SSI or non-infectious as hematoma, seroma, and wound separation. These complications cause increased hospital stays or readmission also, maternal morbidity and cost are increased[7].

SSIs are a common cause of healthcare-associated infection. The United States Centers for Disease Control and Prevention (CDC) has developed criteria defining SSI as an infection related to an operative procedure that occurs at or near the surgical incision within 30 days or 90 days if prosthetic material is implanted at surgery. SSIs are often localized to the incision site (superficial/deep incisional SSI) but can also extend into deep tissues[8].

There were numerous recommendations for SSI prevention efforts in recent World Health Organization (WHO) guidelines. However, most of these interventions were not well-supported by high-quality evidence[9].

The WHO recommendations for change of gloves at the time of fascial closure were identified as the priority recommendations. Three studies have been published to date, all suggesting a benefit. However, the evidence for SSI reduction with glove change before fascial closure is limited, consisting primarily of small RCTs with a high risk of bias[10].

Due to the poor evidence database, the CDC, WHO, and NICE guidelines do not recommend changing gloves as part of routine care. The 2017 WHO Guidelines on SSI Reduction Practice executive summary indicates that well-designed RCTs would be requested because there is no direct proof of the usefulness of sterile surgical gloves changing before wound closure[11].

The CDC Healthcare-associated infection (HAI) prevalence survey found 110,800 SSIs associated with inpatient surgeries in 2015. SSI is the most costly HAI type with an estimated annual cost of $3.3 billion, and extends hospital length of stay by 9.7 days, with hospitalization costs increasing by more than $20,000 per admission[12].

We aimed to assess the impact of changing sterile gloves at the time of wound closure to reduce SSI in women undergoing elective cesarean section (CS).

Patients and Methods

This prospective randomized controlled clinical trial was conducted at the delivery operative theatre, Obstetrics and Gynecology Department, Faculty of Medicine, Ain Shams University Maternity Hospitals from February 2023 to July 2023. The study gained ethical committee approval from the Faculty of Medicine Ain Shams University (FMASU MS 61/2023).

The study was registered in the PAN-African clinical trial registry. Patients' informed consent was obtained before enrolling in the study, after which the clinical research's nature, scope, and possible consequences were explained.

The inclusion criteria included pregnant women aged 20-35 years; non-obese with body mass index (BMI) < 30 kg/m2 with term pregnancy ≥ 37 weeks +0 days; singleton and viable fetuses were enrolled.

The exclusion criteria were obese women with body mass index (BMI) ≥ 30 kg/m2, anemic women with hemoglobin level < 10.5 g/dl, immuno-compromised women with medical disorders with pregnancy as diabetes mellitus, hypertension, cardiac, hepatic, or renal disorders, with anticipated pelvic adhesions as cases with a history of endometriosis, pelvic inflammatory diseases or more than previous 3 CSs, multifetal pregnancy, emergency CS, with antepartum hemorrhage (placenta previa or placenta accrete spectrum disorder), obstetric cases with increased risk of infection as premature rupture of membranes (PROMs), and woman who refused to participate in the study or write consent.

Randomization and allocation: Systematic random sampling was used, and women who fulfilled the inclusion criteria were randomly assigned to either group. Two hundred twenty opaque envelopes were numbered serially, and in each envelope, the corresponding letter, which denoted the allocated group, was placed according to the randomization table. Then, all envelopes were closed and put in one box. Randomization was done using a computer-generated randomization sheet using MedCalc © version[13].

The primary outcome was the incidence of SSSI, which included wound seroma, wound infection, and skin separation.

The secondary outcomes were febrile morbidity, cellulitis, the prescription of antibiotics, period of hospital stay, and cost.

Sample Size Justification

Using the EPI Info 7 software for sample size calculation, with a power of 80% and an alpha error of 0.05, and based on the study by Hameed et al. in 2020, the anticipated incidence of wound infection in the intervention group is 5%, and 18.8% in the control group [13]. A sample size of 100 women per group was necessary to detect the difference between the two groups. To account for an expected 10% loss of follow-up, the sample size was increased to 110 women per group. Group A, the intra-operative glove changing group, involves surgeons replacing their outer surgical gloves with new sterile gloves just before abdominal closure. Meanwhile, Group B, the usual care group, entails the surgeon not changing gloves before abdominal closure.

Study procedure

The data were collected in a case report form. All patients received appropriate pre-operative antibiotics in the form of cephazolin, "1st-generation cephalosporin" (Zinol®, 1 g, vial, PHARCO INTERNATIONAL, Egypt) 30 minutes before skin incision and 12 hours postoperative, betadine (povidone-iodine 10%) skin prep, except where allergies prohibited.

Vaginal preparation and cesarean delivery techniques were at the discretion of the attending surgeon.

Abdominal closure was considered to begin with the closure of the peritoneum if performed; otherwise, with the closure of the abdominal fascia.

The change of gloves was before skin closure, which was done using Vicryl (polyglactin 910), "an absorbable, synthetic, braided suture, manufactured by Ethicon Inc., a subsidiary of Johnson and Johnson, 2/0 or 3/0 with a noncutting curved needle.

All women were discharged on the same home treatment (Augmentin®, Amoxicillin/Clavulanic acid, 1 g, tablet, GlaxoSmithKline GSK, Egypt), metronidazole and proper analgesics.

The patient was given wound dressing instructions (keep it dry and clean).

All women were advised to come for a follow-up visit one week post-operative, then they were called on their phone after three weeks for a second follow-up and assessment of the incidence of SSI

Statistical Methods

Recorded data were analyzed using the statistical package for social sciences, version 23.0 (SPSS Inc., Chicago, Illinois, USA). Numerical parametric variables were described as means and standard deviations, and categorical variables as numbers and percentages. Independent t-test was used to compare quantitative variables, whereas paired Student's t-test was used to analyze differences between two independent groups. For parametric data (SD < 50% mean), the significance level was set at 0.05.

Results

Table 1 shows the demographic and baseline criteria: age, parity, number of CS, BMI, and operative time. The median number of CS in both groups was 2, reflecting the high rate of CS in Egypt. The mean duration of CS was 60 minutes which is relatively high as we are training hospital. There is no statistically significant difference between groups regarding the demographic and clinical criteria between the studied groups.

As regards the complications of surgical site infections after one week, table 2 shows a statistically significant higher frequency of wound hematoma (28 vs. 10 patients) in the usual care group than in the intra-operative glove-changing group, with a p-value (p=0.002). At the same time, there were no complications of wound seroma, wound infection, skin separation of at least 1cm, or other incisional abnormalities after one week, with a p-value (p>0.05).

As regards the complications of surgical site infections after three weeks, table 3 shows a statistically significant higher frequency of Wound Seroma, Wound hematoma, and Wound infection in the usual care group than in the intra-operative glove-changing group (28 vs. 10 patients), with a p-value (p=0.002). At the same time, there were no complications of skin separation of at least 1cm and other incisional abnormalities after three weeks, with a p-value (p>0.05).

Table 1. Comparison between Group A and Group B according to Baseline characteristics. Comparison between Group A and Group B according to Baseline characteristics

Baseline characteristics	Group A (n=102)	Group B (n=100)	Test value	P-value
Age (years)				
Mean±SD	29.50±5.64	29.11±5.95	0.25	0.618
Range	19-44	19-41		
Parity				
Median (IQR)	2 (1-3)	2 (1-3)	1.689	0.195
Range	0-6	0-6		
Number of CS				
Median (IQR)	2 (1-3)	2 (1-3)	0.610	0.436
Range	1-4	1-6		
BMI				
Mean±SD	22.17±2.27	21.58±2.35	3.589	0.059
Range	18-25	18-25		
Operation duration (hrs)				
Mean±SD	61.39±7.76	59.35±8.11	3.650	0.057
Range	35-90	35-78		

Table 2. Comparison between Group A and Group B according to complication after one week

Follow up after one week	Group A (n=102)		Group B (n=100)		RR (95% C.I.)	P-value
	No.	%	No.	%		
Wound Seroma	0	0.0%	0	0.0%	0.000	1.000
Wound hematoma	10	9.8%	28	28.0%	2.86 (1.47-5.57)	0.002*
Wound infection	0	0.0%	0	0.0%	0.000	1.000
Skin separation of at least 1cm	0	0.0%	0	0.0%	0.000	1.000
Other incisional abnormalities	0	0.0%	0	0.0%	0.000	1.000

Table 4 shows the secondary outcomes (Febrile morbidity in the form of mild Fever, Cellulitis, prescription of antibiotics for the skin, Endometritis, Period of hospital stay, and cost). There was a statistically significantly higher frequency of febrile morbidity (mild fever), cellulitis, and antibiotic prescriptions for the skin in the usual care group than in the intra-operative glove changing group, with a p-value (p=0.002).

Table 5 shows the secondary outcomes (Febrile morbidity in the form of mild Fever, Cellulitis, prescription of antibiotics for the skin, Endometritis, Period of hospital stay, and cost). There was no complications after three weeks of secondary outcomes, with a p-value (p>0.05).

Table 6 shows the risk in the Usual Care group, 28% (28/100), and in the Intra-Operative Glove Changing Group, 9.8% (10/102). The relative risk for postoperative wound complications was 2.86 (0.28/0.098) with a 95% confidence interval ranging from 1.47 to 5.57; the z-statistic is 3.082, and the associated P-value is 0.002. The conclusion is that there is a 2.86-fold increased risk in the women in the Usual Care Group than in the Intra-Operative Glove Changing Group, and this statistically significant (P=0.002) and number needed to treat (NNT) was 5.50 and 95% C.I. (3.49 to 12.97).

Discussion

Our Results and their interpretation

This study revealed that postoperative wound

Table 3. Comparison between Group A and Group B according to complication after 3 weeks

Follow up after 3 weeks	Group A (n=102)		Group B (n=100)		RR (95% C.I.)	P-value
	No.	%	No.	%		
Wound Seroma	10	9.8%	28	28.0%	2.86 (1.47-5.57)	0.002*
Wound hematoma	10	9.8%	28	28.0%	2.86 (1.47-5.57)	0.002*
Wound infection	10	9.8%	28	28.0%	2.86 (1.47-5.57)	0.002*
Skin separation of at least 1cm	0	0.0%	0	0.0%	0.000	1.000
Other incisional abnormalities	0	0.0%	0	0.0%	0.000	1.000

Table 4. Comparison between Group A and Group B according to secondary outcome after 1 week

Follow up after 1 week	Group A (n=102)		Group B (n=100)		RR (95% C.I.)	P-value
	No.	%	No.	%		
Febrile morbidity (Mild Fever)	10	9.8%	28	28.0%	2.86 (1.47-5.57)	0.002*
Cellulitis	10	9.8%	28	28.0%	2.86 (1.47-5.57)	0.002*
Prescription of antibiotics for a skin	10	9.8%	28	28.0%	2.86 (1.47-5.57)	0.002*
Endometritis	0	0.0%	0	0.0%	0.000	1.000
Period of hospital stay	0	0.0%	0	0.0%	0.000	1.000
Cost	0	0.0%	0	0.0%	0.000	1.000

Table 5. Comparison between Group A and Group B according to secondary outcome after 3 weeks

Follow up after 3 weeks	Group A (n=102)		Group B (n=100)		RR (95% C.I.)	P-value
	No.	%	No.	%		
Febrile morbidity	0	0.0%	0	0.0%	0.000	1.000
Cellulitis	0	0.0%	0	0.0%	0.000	1.000
Prescription of antibiotics for a skin (Stop Treatment)	10/10	100%	28/28	100%	0.000	1.000
Endometritis	0	0.0%	0	0.0%	0.000	1.000
Period of hospital stay	0	0.0%	0	0.0%	0.000	1.000
Cost	0	0.0%	0	0.0%	0.000	1.000

complications were statistically significantly higher among cases not subject to a change of sterile gloves, 28.0% vs. 9.8%. On the other hand, no differences were noted between study groups regarding operative duration 61.39 ± 7.76 vs. 59.35 ± 8.11 minutes.

In this study, three weeks after the operation, wound seroma (28.0% vs. 9.8%.), hematoma (28.0% vs. 9.8%), and infection (28.0% vs. 9.8%) were statistically significantly higher among cases not subject to change of sterile gloves, with p-value (p=0.002). On the other hand, no differences were noted between study groups regarding postoperative skin separation and other incisional abnormalities, with a p-value (p>0.05)

Also, one week after the operation, febrile morbidity (28.0% vs. 9.8%.), cellulitis (28.0% vs. 9.8%), and need for antibiotics for skin- or wound-related infection (28.0% vs. 9.8%), were statistically significantly higher among cases no subjected to change of sterile gloves with p-value (p=0.002). On the other hand, no differences were noted between study groups regarding endometritis, period of hospital stay, and cost, with p-value (p>0.05).

Comparison of our results to other studies

Ismail et al., 2022 investigated the clinical effect of post-cesarean section wound complications after changing surgical gloves. It was a retrospective study that included 200 pregnant women undergoing elective CS at El Hussein Hospital. Their results were similar to the current study reporting that changing gloves during C-S was linked to a lower risk of infection at the incisional surgical site and reduced postoperative febrile morbidity[14].

The NIHR Global Health Research Unit on Global Surgery 2022 agreed with this study and reported that changing gloves and sterile instruments before fascial closure in abdominal surgery is a low-cost and straightforward intraoperative intervention that reduces SSI[15].

Also, Narice et al. 2021 reported that changing gloves after delivery of the placenta during a cesarean section is associated with a significant reduction in the incidence of post-surgical wound complications compared with keeping the same gloves throughout the surgery[16].

Rattanakanokchai et al. 2021 conducted a systematic review and meta-analysis to assess associations between changing gloves during cesarean section (CS) and postoperative infection. They reported that changing gloves during CS was associated with a de-

Table 6. Comparison between Group A and Group B according to Postoperative wound complications

Postoperative wound complications	Group A		Group B		RR (95% C.I.)	P-value
	No.	%	No.	%		
Yes	10	9.8%	28	28.0%	2.86	0.002*
No	92	90.2%	72	72.0%	(1.47-5.57)	
Total	102	100.0%	100	100.0%		

creased risk of incisional SSI. Still, changing gloves did not alter the risks of postoperative endometritis and febrile morbidity[17].

Also, Hameed et al. 2020 compared the outcome of changing gloves intra-operatively by the entire team versus standard practice (no changing gloves) during a cesarean section. The results were similar to the current study. They reported that adopting changing gloves by the entire team during a cesarean section showed better outcomes in terms of wound infection and febrile morbidity compared to no changing glove practice[13].

This study's results were comparable to those of a few other reported studies in terms of reduced postoperative wound infection[18-20].

Yet another study concluded that under standard surgical circumstances, surgeries done without changing gloves are time-and cost-effective compared to surgeries performed with changing gloves during surgery, with similar surgical and functional outcomes. According to them, cautious use of surgical gloves is a patient-and environment-friendly decision, thus reducing the hospital's biomedical waste load[21].

Scrafford et al. (2018) agreed with us and reported that changing the intra-operative glove before abdominal closure during cesarean section significantly reduced the incidence of post-operative wound complications. Intraoperative glove changing significantly decreased composite wound complications from 13.6% in the control group to 6.4% in the intervention group. Similar to our study, the median surgical time was 64 min in the control group and 66 min in the glove-change group with no significant difference (p = 0.26) [22]. Against us, 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). In the same line with us, fewer participants in the glove-change group experienced febrile morbidity compared to controls.

Three studies compared the incidence of wound infective complications when changing gloves. The glove-changing groups had significantly lower incidences of wound infective complications[16, 22-23].

Further subgroup analysis showed that changing gloves after delivery of the placenta but not before was associated with a lower incidence of wound infective complications[16,23].

The studies on endometritis after changing gloves during a CS did not show a significant change in the incidence of endometritis. Subgroup analysis based on the timing of the intervention also did not statistically affect the incidence of endometritis[16].

Three studies compared the incidence of febrile morbidity in 744 women based on whether gloves were changed during the CS or not[16, 22-23]. The distribution of participants between the intervention and control groups was similar. No statistically significant differences were identified on postoperative febrile morbidity regardless of whether the gloves were changed before and/or after delivery of the placenta.

This finding is consistent with previous studies that evaluated infection prevention bundles for CS and found that changing gloves intraoperatively after delivery of the placenta, when assessed in conjunction with other interventions such as chlorhexidine preparation, perioperative antibiotics, and removal of the placenta by gentle traction might reduce the incidence of SSI[24-25].

Our results differ from Cernadas et al. (1998)[16], who did not find the outcome statistically significant due to several causes, such as different study methodologies, outcomes, sample size, different medical conditions, gestational age of studied cases at the time of enrollment, different sterilization techniques, different protocols of antibiotics taken, and infection control measures.

Other specialties, like Urology and Colorectal, however, have not found any statistically significant differences in postoperative infective complications

after changing gloves. We think this may be due to intrinsic differences in the surgical nature of CS compared with other operations[22,26].

Even though the pathophysiology of SSI following CS remains to be fully elucidated, we hypothesized that changing gloves intraoperatively may be more effective in containing infection at a local rather than at a systemic level because it reduces contamination of the wound with commensal flora from the vagina during surgery. Postoperative low-grade febrile episodes, on the other hand, are not necessarily infective and might represent a physiological response to surgery[27].

This would explain why changing gloves during CS may not be as effective at reducing postoperative fever as it is for wound complications. Endometritis may also be less affected by intraoperative changing of gloves because its strongest risk factors tend to occur in the antenatal period and during labor (vaginal dysbiosis, prolonged rupture of membranes, multiple vaginal examinations) Olsen et al., 2010. Therefore, interventions carried out during delivery, such as intraoperative changing of gloves, may have missed the window of opportunity[28].

Clinical implications of the study: We encourage all obstetricians to change their surgical gloves before suturing the skin in CS in order to decrease the postoperative infection morbidities.

Strengths and limitations of the study: Our research's strengths are appropriate methodology, proper randomization and broad inclusion criteria making the results potentially applicable to most cesarean sections in clinical practice.

The study has limitations, including the relatively small number of patients, lack of blinding of surgeons, no record of glove changes, and its single institution design, which may limit its applicability to other hospital settings or patient populations.

Recommendations for further studies: Before this recommendation can be implemented in current clinical practice, larger numbers of patients and well-powered studies are needed to assess the limitations and cost-effectiveness of changing sterile gloves.

Conclusion: changing sterile gloves at the time of wound closure reduces surgical site infection and associated morbidity in women undergoing elective CS.

Authors Contributions

All authors jointly contributed to the conception and design of the study.

Mustafa M. Abbas: Design of the study, helped in review of literature, revision of results and data analysis , writing the manuscript and submission to journal

Alaa El-Din H. El-Feky; design of the study , revision of review of literature and revision of manuscript

Fatma H. Abd El-Aal: registration of trial, obtaining ethical committee approval, reviewed the literature, shared in collection of Data, patient recruitment , design of the study , revision of review of literature and revision of manuscript , Design of the study, helped in review of literature, revision of results and data analysis and contributed in writing the manuscript.

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Study registration

The study was registered in the Pan-African Clinical Trial

Disclosure of Interest

The authors declare no conflict of interest.

Ethics Approval

Following local regulations, the protocol gained

ethical and research approval from the Faculty of Medicine Ain Shams University FMASU S 61/2023.

Informed Consent

All patients have signed informed consents after explaining the whole procedure.

We Confirm that all methods were performed according to the relevant guidelinesand regulations according to the Declaration of Helsinki.

Data Sharing

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

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Not applicable.

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