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**Original Research Article**

# Efficacy of chlorhexidine gluconate in reducing surgical site infections after emergency caesarean delivery: a randomized controlled trial

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## ABSTRACT

**Background:** Caesarean delivery (CD) is a major, life-saving surgical procedure, with emergency CDs posing a greater risk for Surgical Site Infections (SSIs) due to compromised preoperative preparation. SSIs are common hospital-acquired infections, significantly increasing morbidity and healthcare costs. Preoperative skin antisepsis is critical for SSI prevention, with recent evidence suggesting Chlorhexidine Gluconate (CG) may be superior to Povidone Iodine (PI). This study was done to compare the efficacy of CG versus PI for skin antisepsis before emergency CD at AIIMS Bhubaneswar.

**Methods:** This was a parallel-arm, single-blinded, randomized controlled trial. Four hundred and fifty women undergoing emergency CD were randomized to receive either CG or PI for preoperative skin antisepsis. Participants were observed for 30 days duration postoperatively to assess the primary outcome of SSI development. Secondary outcomes included hospital stay, re-suturing, readmission, and pyrexia. Statistical analysis involved Chi-square, Fisher's exact, and Wilcoxon-Mann-Whitney U tests.

**Results:** SSI occurred in 1.8% (4/225) of the CG group and 6.2% (14/225) of the PI group, a statistically significant difference ($p = 0.016$). Most SSIs were superficial, with no significant difference in type between groups. No significant differences were found in secondary outcomes. Higher BMI was significantly associated with SSI in both groups, and prolonged surgery duration in the CG group.

**Conclusions:** CG significantly reduced SSI incidence compared to PI in emergency CD. This supports CG's superior antiseptic properties and suggests its use can effectively mitigate SSI risk in this high-risk population.

**Keywords:** Antiseptic, Caesarean delivery, Hospital-acquired infection, Randomized controlled trial, Surgical site infection

## INTRODUCTION

Caesarean delivery (CD), defined as the birth of the fetus via laparotomy and hysterotomy, holds a pivotal role in global maternal health.[1] It is recognized as the most frequently performed major life-saving surgical procedure for pregnant women worldwide, with reported rates varying significantly from 6% to 27.2%.[2] This surgical intervention is broadly categorized based on urgency: elective and emergency deliveries. An elective CD is a planned procedure, typically undertaken for medical indications that have manifested before or during pregnancy, ideally after 39 weeks of gestation.[3] Conversely, an Emergency CD is necessitated by an immediate and critical threat to the life of either the fetus or the woman, demanding rapid intervention.[4]

The decision to delivery interval (DDI) depends on the gravity of the indication and a DDI of 15 minutes has been

achieved in cases such as cord prolapse, whereas a DDI of around 30 minutes is recommended in cases of fetal compromise.[4-6] A shorter DDI although necessary for survival of both mother and fetus, leads to compromising on pre-operative preparation, infection control and therefore emergency procedures are also theoretically at higher risk of leading to post-operative infections.

Surgical Site Infections (SSIs) are defined as "infections occurring up to 30 days after surgery (or up to one year after surgery in patients receiving implants) and affecting either the incision or deep tissue at the operation site".[7] SSIs complicates 2-5% of all surgical procedures and 5 to 12% of CDs. SSIs are the commonest hospital acquired infections accounting for about 14-16%.[8-11] Emergency CD predisposes women to develop SSI as compared to Elective CD.[12] Many studies have showed that occurrence of SSI following CD depends on many factors like - maternal age, weight, educational status, antenatal care(ANC), anaemia, medical illness, duration of labour prior CD, number of vaginal examinations, premature rupture of membranes, skin antisepsis, emergency surgery, surgical techniques, operating time and the amount of blood loss during the surgery.[13,14] Evidence showed that most of the SSI often occurs between 5$^{th}$ and 10$^{th}$ postoperative days following CD.[15] The most common organism isolated is Staphylococcus aureus, accounting for 20-30% of SSI.[9] It remains a substantial cause of morbidity, prolonged hospitalization, requirement of re-suturing, re-admission, increased medical costs and maternal death.[16]

As per World Health Organization (WHO), Centers for Disease Control and Prevention (CDC) and National Institute for Health and Care Excellence (NICE) guidelines stated that "preoperative skin antisepsis is one of the most critical factors and an important intervention to prevent postoperative SSI" as patients own skin microbial flora is the important source of pathogens causing SSI.[17-19] Skin preparation by antiseptic solution, traditionally done by PI, before CD is paramount for SSI prevention.[20] However recent Randomized controlled trials (RCT) showed Chlorhexidine (CG) being superior to PI having a higher affinity for skin binding, higher antibacterial activity with prolonged residual effects with less incidence of SSI.[21] Evidence from Nigeria states that CG vaginal cleansing significantly reduced post-caesarean endometritis**,** though not all showed significant impact on SSIs. A network meta-analysis ranked 2% alcohol-based CG as most effective for SSI prevention, closely followed by alcohol-based povidone-iodine. Despite some variability, the overall trend points to CG as a slightly more effective antiseptic, though both agents remain clinically acceptable for caesarean section antisepsis. Furthermore, there are no published randomized studies to conclude the best skin antiseptic in preventing SSIs which are common in Emergency CDs.[22-24] This study was done to assess the impact of skin antisepsis by CG compared with PI before an emergency CD for the prevention of SSI in a tertiary healthcare setting.

## METHODS

A parallel arm, single blinded, randomized controlled study was conducted where one arm was given CG and the other arm was given PI as a skin antiseptic in women undergoing emergency CD. As the interventions involved application of two distinct antiseptics, blinding of only the participants was possible. A simple randomization was performed using a computer-generated random number sequence. Allocation concealment was performed using sequentially numbered opaque sealed envelopes to randomize participants across the two arms.

The trial was conducted in the Obstetrics and Gynecology department of a government run tertiary care hospital, All India Institute of Medical Sciences (AIIMS) Bhubaneshwar, India. Women undergoing Emergency CD were included with the study duration of 14 months from June 2020 to August 2021. Antenatal women of more than equal to 34 weeks of gestational age were included while those denying consent, diagnosed with chorioamnionitis, pyelonephritis, urinary tract infection, mastitis and skin lesions adjacent to operative site were excluded from the study. The sample size was calculated by assuming a baseline rate of SSI of 16%, on the basis of a prior study conducted by Darouiche et al.[25] Anticipating a clinically significant reduction of SSI by 50% in the CG group than in the PI group, we estimated that the study needed to enrol 876 participants, 438 in each group, to have 80% power to detect a significant difference in the rates of SSI between the 2 groups, at a two-tailed alpha level of 0.05 or less.

However, the recruitment was restricted to 450 participants due to COVID pandemic. The intervention arms included Chlorhexidine Gluconate IP (Indian Pharmacopoeia) equivalent to 0.5% weight/volume (w/v) of CG and Isopropyl Alcohol 70% volume/volume (v/v) purified water IP in one arm and PI 10% w/v in the other arm. Preoperative prophylactic antibiotics were administered according to the hospital policy. For women in the CG group, skin preparation was done by centrifugal scrubbing motion for 30 seconds if incision site was dry and 2 minutes if incision site was moist, starting from the area of the intended incision extending upward towards the sub costal margin to the midaxillary line and down to the middle of the thigh. The drying time was for 3 minutes. For women in the PI group, application was done by 2 step scrub followed by painting and then left to dry for 3 minutes before draping the area and commencing the surgery. The drying time of PI (10 minutes) was longer than to CG (3 minutes).

A total of the 460 patients were recruited where 230 were assigned to PI group and 230 to CG group using the randomised sequence. Five patients from each group were lost to follow up therefore data from 450 participants (225 each in PI and CG group) were analysed according to per protocol analysis. Figure 1 depicts the Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the trial.

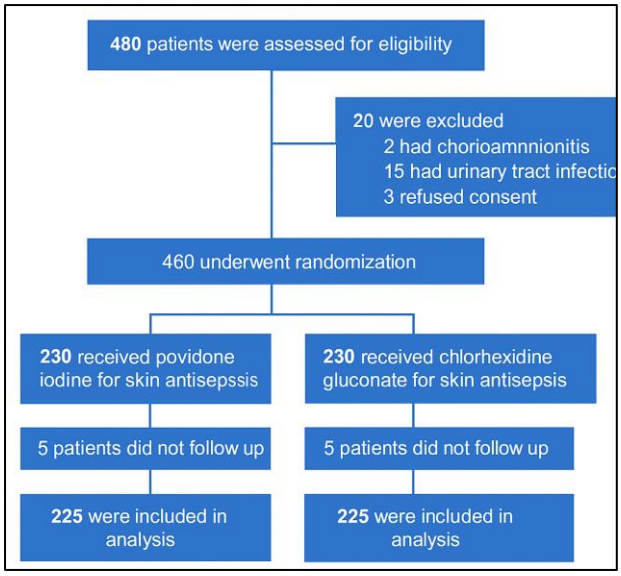


**Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the trial.**

Antenatal women at ≥34 weeks gestational age undergoing Emergency CD in the Department of Obstetrics and Gynaecology of AIIMS, Bhubaneswar and willing to be a part of the study, were given the Patient Information Sheet (PIS) in English and Odia languages. At recruitment, detailed history including age, gravida, parity, pre-pregnancy Body Mass Index (BMI), gestational age at the time of surgery, medical illness, labour and surgery related variables such as spontaneous or induced labour, duration of labour, prolonged duration of rupture of membranes (<18hours or >/18hours), number of vaginal examinations (<5 or >/5), indication of CD, type of skin incision (Pfannenstiel or vertical incision), duration the surgery (<1hour or >/ 1hour), amount of blood loss during surgery (<500ml or >/500ml) and skin closure technique (Mattress or subcuticular sutures) were recorded. As a part of routine evaluation, complete blood count, coagulation profile, kidney and liver function tests, serology, thyroid profile and random blood sugars, urine routine microscopy and cultures were also performed. The intervention was given as per the randomised sequence. All women were followed up after 48hours, 1week and 1month after CD as per CDC guidelines. During the follow up, thorough examination of wound was done for any symptoms or signs of SSI, wound swab was sent for culture and sensitivity if any discharge from wound. Patients with pyrexia, separated wound edges, deep SSIs were admitted for daily dressing, antibiotics were given as per wound swab culture and sensitivity report and re-suturing was done in relevant cases.

The primary outcome was development of SSI within 30 days after CD. The principal investigator, unaware of the study-group assignments, verified the diagnosis of SSI which was made by treating physician. Secondary outcomes were duration of hospital stay, requirement of re-suturing, readmission resulting from infection and pyrexia.

Data of all participants was collected and entered using Microsoft Excel 2019. An intention-to-treat approach was used for the analysis of the trial data. The baseline characteristics between the two groups were compared using Wilcoxon-Mann-Whitney U test for continuous variables and Fisher's exact test or Chi square test for categorical variables. The proportions of patients who developed SSI in the two study groups was estimated and compared using Chi square test. The secondary outcomes were compared using the Fisher's exact test and t-test. Fisher's exact test was also used to compare the bacterial growth across the study groups.

The study protocol was approved by the Institutional Ethics Committee (IEC) of AIIMS Bhubaneswar with Ref Number: IEC/AIIMS BBSR/PG Thesis/2019-20/109**.** All procedures were conducted according to the ethical standards of the institutional research committee. A written informed consent was obtained from all participants prior to enrolment. This trial was prospectively registered with the Clinical Trials Registry of India (CTRI)**:** CTRI/2020/06/025722.

## RESULTS

A total of 460 participants were recruited and randomly assigned to the two groups, of which 230 participants received CG and 230 received PI. At baseline (Table 1), both groups were statistically comparable across a wide range of clinical and demographic variables, including BMI, maternal age, gestational age at delivery, booking status, and comorbidities such as anaemia, hypertension, and diabetes. There were also no significant differences in labour onset, duration of surgery, blood loss, and skin closure technique.

**Table 1: Characteristics of the study participants at baseline (n=450).**

| Characteristic | Povidone iodine (n=225), N (%) | Chlorhexidine gluconate (n=225), N (%) | P value |
|---|---|---|---|
| **Maternal age (years)*** | 27.34±4.63 | 26.99±5.05 | 0.171[1] |
| **Gestational age at CD (weeks)*** | 38.07±1.93 | 37.98±1.76 | 0.412[1] |
| **BMI (Kg/m²) *** | 23.33±1.42 | 23.26±1.43 | 0.646[1] |
| **Booking status**** | | | |
| Booked | 63 (28.0) | 70 (31.1) | 0.470[3] |
| Un-booked | 162 (72.0) | 155 (68.9) | |

Continued.

| Characteristic | Povidone iodine (n=225), N (%) | Chlorhexidine gluconate (n=225), N (%) | P value |
|---|---|---|---|
| Anemia** | 90 (40) | 75 (33.3) | 0.523[2] |
| Hypertensive disorders of pregnancy** | 42 (18.6) | 45 (20) | 0.884[3] |
| Diabetes mellitus** | 15 (6.7) | 27 (12) | 0.083[2] |
| **Onset of labor**** | | | |
| Spontaneous | 169 (75.1) | 152 (67.6) | 0.151[3] |
| Induced | 29 (12.9) | 43 (19.1) | |
| Not in labor | 27 (12.0) | 30 (13.3) | |
| Prolonged labor** | 13 (5.8) | 22 (9.8) | 0.113[3] |
| **Number of PV examinations**** | | | |
| <5 | 204 (90.7) | 193 (85.8) | 0.108[3] |
| >5 | 21 (9.3) | 32 (14.2) | |
| Prolonged rupture of membranes** | 3 (1.3) | 7 (3.1) | 0.201[3] |
| **Indication for CD**** | | | |
| Fetal distress | 99 (44.0) | 85 (37.8) | 0.598[3] |
| Previous CS not willing for TOLAC | 44 (19.6) | 45 (20.0) | |
| Failed induction | 11 (4.9) | 24 (10.7) | |
| Severe pre-eclampsia/eclampsia | 13 (5.8) | 20 (8.9) | |
| Non progress of labor | 11 (4.9) | 13 (5.8) | |
| Breech presentation (primigravida) | 10 (4.4) | 8 (3.6) | |
| Early features of obstruction | 8 (3.6) | 6 (2.7) | |
| Scar tenderness | 8 (3.6) | 6 (2.7) | |
| Cephalopelvic disproportion | 6 (2.7) | 5 (2.2) | |
| Obstructed labor | 3 (1.3) | 6 (2.7) | |
| Placenta previa | 4 (1.8) | 2 (0.9) | |
| Contracted pelvis | 2 (0.9) | 2 (0.9) | |
| Transverse lie | 2 (0.9) | 2 (0.9) | |
| Twin gestation-first twin breach | 3 (1.3) | 1 (0.4) | |
| Compound presentation | 1 (0.4) | 0 (0.0) | |
| **Skin incision**** | | | 1.000[2] |
| Transverse | 223 (99.6) | 224 (99.6) | |
| Vertical | 1 (0.4) | 1 (0.4) | |
| Duration of surgery (minutes)* | 64.63±14.70 | 65.86±17.09 | 0.571[1] |
| **Blood loss**** | | | 0.455[3] |
| <500 mL | 66 (29.5) | 73 (32.7) | |
| >500 mL | 158 (70.5) | 150 (67.3) | |
| **Skin closure technique**** | | | |
| Mattress | 117 (52.0) | 115 (51.1) | 0.850[3] |
| Subcuticular | 108 (48.0) | 110 (48.9) | |

Statistical tests used - [1]Wilcoxon-Mann-Whitney U Test, [2]Fisher's Exact Test, [3]Chi-Squared Test. *Mean±SD, **Frequency (percentage)

**Table 2: Comparing SSI between PI and CG groups (overall) (n=450).**

| SSI | Povidone iodine (n=225), N (%) | Chlorhexidine (n=225), N (%) | P value |
|---|---|---|---|
| **Overall** | | | |
| Present | 14 (6.2) | 4 (1.8) | 0.016[1] |
| Absent | 211 (93.8) | 221 (98.2) | |
| Superficial SSI | 13 (5.8) | 3 (1.3) | 0.405[1] |
| Deep SSI | 1 (0.4) | 1 (0.4) | |
| **At 48 hours** | | | |
| Present | 1 (0.4) | 0 | 1.000[2] |
| Absent | 224 (99.6) | 225 (100) | |
| **At one week** | | | |
| Present | 11 (4.9) | 3 (1.3) | 0.030[1] |
| Absent | 214 (95.1) | 222 (98.7) | |

Continued.

| SSI | Povidone iodine (n=225), N (%) | Chlorhexidine (n=225), N (%) | P value |
|---|---|---|---|
| **At one month** | | | |
| Present | 2 (0.9) | 1 (0.4) | 1.000[2] |
| Absent | 223 (99.1) | 224 (99.6) | |

Statistical tests used - [1]Chi-Squared Test, [2]Fisher's Exact Test

A total of 4 patients (1.8%) in the CG group and 14 (6.2%) in the PI group developed SSI. This difference was found to be statistically significant on chi-square test. ($\chi 2$=5.787, p=0.016), depicted in Table 2. Among the total 18 SSI recorded in the study, most were superficial infections, comprising 92.9% (13 of 14) in the PI group and 75% (3 of 4) in the CG group. Deep SSIs were rare, with only 1 case (7.1%) in the povidone group and 1 case (25%) in the CG group. There was no significant difference between groups in the type of SSI (p=0.405).

There was one SSI diagnosed at 48 hours in the PI group and none in the CG group. The difference was not found to be statistically significant at p=1.000. There were 11(4.9%) SSIs diagnosed in PI group and 3 (1.3%) SSIs diagnosed in CG group within one week. This difference was found to be statistically significant (p=0.030). There were two (0.9%) SSIs diagnosed in PI group and one (0.4%) SSIs diagnosed in CG group within one month. This difference was not statistically significant (p=1.000).

Gaping of wound edges was noted in four cases of SSI (28.6%) in PI group and one case of SSI (25%) in CG group (Table 3). The difference was not found to be statistically significant. There were no statistical differences between patients randomly assigned to the CG group and those randomly assigned to the PI group with respect to rates of duration of hospital stay, requirement of re-suturing, readmission resulting from infection and pyrexia. Culture specimens were collected from all 18 patients with SSI, of which 16 (88%) showed positive bacterial growth. Both culture-negative cases (2/18; 7%) were from the PI group, while all CG group patients had positive cultures. There was no statistically significant difference between groups ($\chi^2$=0.643, p=1.000).

**Table 3: Secondary outcomes in SSI patients between PI and CG Groups (n=18).**

| Outcomes | Povidone iodine (n=14), N (%) | Chlorhexidine (n=4), N (%) | P value |
|---|---|---|---|
| **Wound gaping** | 4 (28.6) | 1 (25.0) | 1.000[1] |
| **Hospital stay (days)*** | 9.55±4.61 | 11.00±4.58 | 0.658[2] |
| **Re-suturing**** | 4 (28.6) | 1 (25.0) | 1.000[1] |
| **Readmission due to infection**** | 2 (14.3) | 0 (0.0) | 1.000[1] |
| **Pyrexia**** | 2 (14.3) | 0 (0.0) | 1.000[1] |
| **Wound culture** | | | |
| Positive | 12 (85.7) | 4 (100) | 1.000[1] |
| Negative | 2 (14.3) | 0 | |

[1]Fisher's Exact Test, [2]t-test, *Mean±SD, **Frequency (percentage)

**Table 4: Characteristics between participants with and without SSI in PI Group (n=225).**

| Parameters | SSI Yes (n=14), N (%) | SSI No (n=211), N (%) | P value |
|---|---|---|---|
| **Maternal age (years)*** | 28.86±4.20 | 27.24±4.64 | 0.218[1] |
| **Gestational age at delivery (weeks)*** | 37.67±1.57 | 38.10±1.96 | 0.278[1] |
| **BMI (Kg/m²)*** | 24.03±1.08 | 23.28±1.43 | 0.060[1] |
| **BMI**** | | | |
| 18.5-22.9 Kg/m² | 1 (7.1) | 67 (32.4) | 0.048[2] |
| 23.0-24.9 Kg/m² | 10 (71.4) | 127 (61.4) | |
| 25.0-29.9 Kg/m² | 3 (21.4) | 12 (5.8) | |
| 30.0-34.9 Kg/m² | 0 (0.0) | 1 (0.5) | |
| **Booking status**** | | | |
| Booked | 3 (21.4) | 60 (28.4) | 0.762[2] |
| Un-booked | 11 (78.6) | 151 (71.6) | |
| **Anemia**** | | | 0.096[2] |
| Absent | 7 (50.0) | 128 (60.7) | |
| Mild | 5 (35.7) | 47 (22.3) | |
| Moderate | 1 (7.1) | 35 (16.6) | |
| Severe | 1 (7.1) | 1 (0.5) | |
| **Hypertensive disorders of pregnancy**** | | | |
| Absent | 11 (78.6) | 172 (81.5) | 0.590[2] |

Continued.

| Parameters | SSI Yes (n=14), N (%) | SSI No (n=211), N (%) | P value |
|---|---|---|---|
| Gestational hypertension | 2 (14.3) | 15 (7.1) | |
| Chronic hypertension | 1 (7.1) | 9 (4.3) | |
| Pre-eclampsia | 0 (0.0) | 9 (4.3) | |
| Eclampsia | 0 (0.0) | 6 (2.8) | |
| **Diabetes mellitus**** | | | |
| Absent | 12 (85.7) | 198 (93.8) | 0.175[2] |
| Gestational diabetes mellitus on medical nutritional therapy | 1 (7.1) | 8 (3.8) | |
| Overt diabetes mellitus | 1 (7.1) | 2 (0.9) | |
| Gestational diabetes mellitus on insulin | 0 (0.0) | 3 (1.4) | |
| **Onset of labor**** | | | |
| Spontaneous | 10 (71.4) | 159 (75.4) | 0.719[2] |
| Induced | 2 (14.3) | 27 (12.8) | |
| Not in labor | 2 (14.3) | 25 (11.8) | |
| Prolonged labor (yes)** | 1 (7.1) | 12 (5.7) | 0.576[2] |
| **Number of PV examinations**** | | | |
| <5 | 13 (92.9) | 191 (90.5) | 1.000[2] |
| >5 | 1 (7.1) | 20 (9.5) | |
| Prolonged rupture of membranes** | 0 (0.0) | 3 (1.4) | 1.000[2] |
| **Skin incision**** | | | |
| Transverse | 13 (92.9) | 210 (100.0) | 0.062[2] |
| Vertical | 1 (7.1) | 0 (0.0) | |
| Duration of surgery (minutes)* | 78.57±32.37 | 63.71±12.33 | 0.070[1] |
| **Blood loss**** | | | |
| <500 mL | 3 (21.4) | 63 (30.0) | 0.763[2] |
| >500 mL | 11 (78.6) | 147 (70.0) | |
| **Skin closure**** | | | |
| Mattress | 10 (71.4) | 107 (50.7) | 0.133[3] |
| Subcuticular | 4 (28.6) | 104 (49.3) | |

[a]Significant at p<0.05, [1]Wilcoxon-Mann-Whitney U Test, [2]Fisher's Exact Test, [3]Chi-Square Test, *Mean±SD, **Frequency (percentage)

**Table 5: Characteristics between participants with and without SSI in CG Group (n=225).**

| Parameters | SSI Yes (n=4), N (%) | SSI No (n=221), N (%) | P value |
|---|---|---|---|
| **Maternal age (years)*** | 26.75±4.11 | 27.00±5.07 | 0.957[1] |
| **Gestational age at delivery (weeks)*** | 37.18±1.99 | 37.99±1.76 | 0.362[1] |
| **BMI (Kg/m²)*** | 25.85±2.11 | 23.21±1.38 | 0.015[1] |
| **BMI**** | | | |
| 18.5-22.9 Kg/m² | 0 (0.0) | 77 (35.2) | 0.003[2] |
| 23.0-24.9 Kg/m² | 1 (25.0) | 124 (56.6) | |
| 25.0-29.9 Kg/m² | 3 (75.0) | 18 (8.2) | |
| 30.0-34.9 Kg/m² | 0 (0.0) | 0 (0.0) | |
| **Anemia** | | | |
| Absent | 1 (25.0) | 149 (67.4) | 0.122[2] |
| Mild | 2 (50.0) | 42 (19.0) | |
| Moderate | 1 (25.0) | 29 (13.1) | |
| Severe | 0 (0.0) | 1 (0.5) | |
| **Hypertensive disorders of pregnancy** | | | |
| Absent | 3 (75.0) | 177 (80.1) | 0.593[2] |
| Gestational hypertension | 1 (25.0) | 14 (6.3) | |
| Chronic hypertension | 0 (0.0) | 14 (6.3) | |
| Pre-eclampsia | 0 (0.0) | 8 (3.6) | |
| Eclampsia | 0 (0.0) | 8 (3.6) | |
| **Diabetes mellitus** | | | |
| Absent | 4 (100.0) | 194 (87.8) | 1.000[2] |

Continued.

| Parameters | SSI Yes (n=4), N (%) | SSI No (n=221), N (%) | P value |
|---|---|---|---|
| Gestational diabetes mellitus on medical nutritional therapy | 0 (0.0) | 19 (8.6) | |
| Overt diabetes mellitus | 0 (0.0) | 7 (3.2) | |
| Gestational diabetes mellitus on insulin | 0 (0.0) | 1 (0.5) | |
| **Onset of labor**** | | | |
| Spontaneous | 4 (100.0) | 148 (67.0) | 0.763[2] |
| Induced | 0 (0.0) | 43 (19.5) | |
| Not in labor | 0 (0.0) | 30 (13.6) | |
| Prolonged labor (yes)** | 1 (25.0) | 21 (9.5) | 0.339[2] |
| **Number of PV examinations**** | | | |
| <5 | 3 (75.0) | 190 (86.0) | 0.461[2] |
| >5 | 1 (25.0) | 31 (14.0) | |
| Prolonged rupture of membranes** | 1 (25.0) | 6 (2.7) | 0.120[2] |
| **Skin incision**** | | | |
| Transverse | 4 (100.0) | 220 (99.5) | 1.000[2] |
| Vertical | 0 (0.0) | 1 (0.5) | |
| Duration of surgery (minutes)*[a] | 86.25±22.87 | 65.49±16.81 | 0.010[1] |
| **Blood loss**** | | | |
| <500 mL | 1 (25.0) | 72 (32.9) | 1.000[2] |
| >500 mL | 3 (75.0) | 147 (67.1) | |
| **Skin closure**** | | | |
| Mattress | 4 (100.0) | 111 (50.2) | 0.122[2] |
| Subcuticular | 0 (0.0) | 110 (49.8) | |

[a]Significant at p<0.05, [1]Wilcoxon-Mann-Whitney U Test, [2]Fisher's Exact Test, *Mean±SD, **Frequency (percentage)

In the PI group for skin antisepsis, a significant association was found between the development of SSI and higher BMI (p=0.048). No other parameters were found significantly associated with SSI in the PI group (Table 4).

In CG group for skin antisepsis (Table 5), there was a significant association between the development of SSI and higher BMI (p=0.003) and duration of surgery of 86.25±22.87 minutes in those who developed SSI vs 65.49±16.81 minutes in those who did not develop SSI (p=0.010).

## DISCUSSION

The current randomized controlled trial assessed the effectiveness of CG compared to PI as a preoperative skin antiseptic in preventing SSI in women undergoing emergency caesarean delivery. Our study demonstrated a significantly lower incidence of SSI in the CG group (1.8%) compared to the PI group (6.2%), suggesting that CG is more effective in preventing postoperative wound infections in this high-risk population. There was no statistically significant difference between the groups for secondary outcomes such as duration of hospital stay, need for re-suturing, or readmission due to infection, likely owing to the overall low incidence of SSI in both groups. Literature has concluded that emergency surgery itself is a risk factor for the development of SSI compared to electives due of non-optimization of patient general condition and co-morbidities.[12,26] However, especially in emergency CD, factors like prolonged rupture of membranes, prolonged labour prior to CD, multiple per vaginal examinations further increase the risk of SSI development.[27,28] Therefore, women undergoing emergency CD are especially at higher risk of developing SSI compared to other emergency surgical procedures.

Further, evidence also states that two thirds of SSIs are confined to the incision, therefore skin antisepsis before surgery especially in emergency surgeries results in significant clinical benefit. This study recruited participants who underwent emergency CD which itself is a risk factor for the development of SSI. The results showcased that factors like obesity, anaemia, duration of the surgery, skin closure technique were significantly associated with SSI, in either antiseptic groups, which was similar to the other studies. However, factors like booking status, prolonged rupture of the membranes, prolonged labour, multiple per vaginal examinations and amount of blood loss during surgery were not significantly associated with the development of SSI compared to the other studies which showed significant risk. This could have resulted from a low proportion of SSI in the study sample.[27,29,30]

Adeyemo et al conducted a randomized trial where vaginal cleansing with 0.3% CG significantly reduced postoperative endometritis compared to saline (5.0% vs. 13.3%, p=0.042). However, it did not reduce SSI or post-op fever.[22] Nnagbo et al looked at the impact of vaginal cleansing with CG, finding a notable reduction in post-caesarean endometritis, even when standard antibiotics were used. CG vaginal cleansing shows promise as an effective adjunct to antibiotics for reducing uterine infections post-C-section.[23] Ghele et al analysed 9 RCTs

(4 antiseptic regimens) and concluded that 2% CG in alcohol had the highest likelihood of preventing SSIs, followed by alcohol-based povidone-iodine. However, the differences were modest, and credible intervals overlapped.[24]

The results of this trial are similar with those of the prior studies that demonstrated the superiority of CG based antiseptics over Iodine-based antiseptics for the prevention of SSI. The superiority of chlorhexidine-based solution is probably related to its more rapid onset of action, persistent activity despite exposure to bodily fluids and residual effect.[21]

The strength of this study includes that it is a common medical problem encountered by almost all healthcare professionals. Prevention of SSI is a pressing need and this study evaluates a simple intervention to avoid the same. There is a paucity of randomized controlled trials evaluating the efficacy of CG based antiseptic preparations vs PI for skin antisepsis prior to emergency CD. It adds to the limited pre-existing evidence in a prospective manner. The assessment for outcomes was objective, hence, removing any bias and obviating the need for further blinding.

This study has a few limitations like low sample size due to restricted recruitment during COVID-19 pandemic, giving a low proportion of SSI in the study sample. This limited occurrence also reduced the statistical power to detect meaningful differences in the secondary outcome parameters. SSIs are not specific only to emergency CD, hence, similar intervention in elective CDs warrant exploration.

## CONCLUSION

This randomized controlled trial specifically evaluated the antiseptic efficacy in emergency CDs. CG significantly reduced SSI incidence compared to PI, aligns with its known properties including, more rapid onset of action, persistent activity despite exposure to bodily fluids, and residual effect. While the majority of SSIs were superficial in both groups, there was no statistically significant difference in the type of SSI (superficial vs. deep) between the two antiseptic agents. The study found no significant differences in secondary outcomes such as duration of hospital stay, requirement for re-suturing, readmission due to infection, or pyrexia, likely due to the overall low SSI incidence in the study population. The results suggest that optimizing skin antisepsis with CG offers a simple yet effective intervention to mitigate SSI risk in emergency caesarean deliveries.

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