Chlorhexidine-alcohol versus povidone-iodine as preoperative skin antisepsis for prevention of Surgical Site Infection in Cesarean Section

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Abstract

Objectives: To compare the efficacy of chlorhexidine-alcohol and povidone-iodine as preoperative antiseptic skin preparation for prevention of Surgical site infection(SSI) after Cesarean Section(CS).

Materials and Methods: A total of 311 eligible women who underwent CS were recruited in the study after fulfilling all the inclusion and exclusion criteria. Patients were randomized into two groups (153 in Chlorhexidine-alcohol Group and 158 in povidone-iodine Group) by computer-generated randomization table. Patients were followed for a period of 30 days in post operative period to monitor for SSI.

Results: The overall rate of SSI was 7%, out of which chlorhexidine-alcohol group had 5.4% and povidone-iodine group had 8.6%. *E.coli*, *K.pneumoniae* and *Acinetobacter baumannii* were the most common organism isolated. *E.coli* was found in 9.5% of the total SSI cases.

Conclusions: The study found that the patients who received chlorhexidine-alcohol as skin antiseptic had less chance of developing SSI than those who received povidone iodine however it did not reach statistical significance.

Introduction

Surgical site infection is the second most common cause of nosocomial infections amongst the hospitalized patients covering about 14%-16% of all nosocomial infections[1]. Post-cesarean complications due to infection has been estimated to occur in 7-20% of patients[2]. Globally, the average rate of CS is approximately 18.6% [3], being the most common major surgery performed among women.

The development of SSI after Cesarean Section results in increased patient morbidity, increased duration of hospital stay due to infection, re-admission, the use of healthcare resources, hospital costs, burden on the mother and other family members or relatives and may also impair mother-child bonding and lactation[4,5]. The rate of infection varies widely according to patient profile depending on several risk factors such as low socioeconomic status, maternal medical disorders, immunosuppression, steroid use, frequent vaginal examination and emergency Cesarean Section[6].

There are many extrinsic factors attributing to SSI which include patient's skin preparation, hand scrubbing techniques, environment of the operating room, processing of instruments and hospital items which are to be used in the operating room[7]. Contamination of the surgical site by endogenous skin commensals or vaginal flora is a fundamental precursor to post-operative SSI after CS. Thus, infections are more of mixed polymicrobial which may include enterococci, gram-negative bacilli, group B streptococci, and anaerobes[8,9].

Hence, choosing correct antiseptic for skin preparation becomes one of the crucial factors for prevention of SSI. Out of the different skin disinfectants available povidone-iodine and chlorhexidine-alcohol are the

most studied as they are active against gram-positive bacteria, gram-negative bacteria, virus, fungi and *Mycobacterium tuberculosis.*

At present, there is no recommendation for a specific skin antiseptic preparation to be used before CS to prevent SSI. In Cochrane Database of systemic review of 2018 on preoperative skin antiseptics for prevention of SSI after CS, it was found that CHG was associated with lower rate of bacterial growth as compared to PVI but the quality of evidence is very low[10].

Hence, this study was conducted to compare the antiseptic efficacy of chlorhexidine-alcohol and povidone-iodine so as to contribute in choosing the best antiseptic solution for preoperative skin preparation in Cesarean section.

Materials And Methods

This study was a Prospective Randomized Controlled Trial, conducted in Department of Obstetrics & Gynaecology, PGIMER, between July,2016 to October,2017.Study was approved by Institutional Ethics Committee(Ethical approval: No. INT/IEC/2017/561,) The trial was registered by Clinical Trials Registry of India .(Registration no. CTRI/2018/05/014294). Written informed consent was obtained from all study participants.

A total number of 311 patients were recruited in consecutive fashion for the study after fulfilling all the inclusion and exclusion criteria (Fig 1)

Inclusion Criteria: All pregnant women undergoing elective or emergency cesarean section irrespective of gestational age at the department of Obstetrics and Gynecology of the institute and consented for the study were included.

Exclusion Criteria: Patient with history of allergy to either of the disinfectants, any skin infection adjacent to the surgery site, severe anemia (Hb < 7gm/dl), h/o fever ≥38ºC on two or more occasions within 1week before CS, pregnant women with features of chorioamnionitis, patients receiving immunosuppressants, heart disease, uncontrolled diabetes mellitus and HIV infection.

Patients were randomized into two groups by computer-generated random number table. Enrolment of the patient was done after the decision for Cesarean section had been made in case of emergency CS and one day prior to surgery for elective cases. Once a patient is enrolled the antiseptic to be used is allotted as per the randomization table. The two groups are:

Group A: Chlorhexidine-alcohol group (2% chlorhexidine-alcohol)

Group B: Povidone-iodine group (10% povidone-iodine)

Signs of SSI for the study protocol were purulent discharge from the incision site, wound dehiscence, localized pain or tenderness, localized swelling; erythema or heat[1]. A stitch abscess alone was not

considered as a sign of SSI.

Pubic hair clipping was done in all the patients. As per routine hospital protocol, prophylactic broad-spectrum antibiotic (Cefazolin 2g i.v.) was given 30-60 minutes prior to skin incision. As per study protocol, under strict aseptic precaution, a skin swab was taken from the surgical site before the application of antiseptic solution and labeled it as **Swab 1**. Then, skin painting with antiseptic solution was started from the planned incision site with gentle pressure and proceeded to the periphery by widening circular motion[11]. Once the desired boundaries or periphery was reached, the sponge was discarded and second painting was started and the same procedure was repeated for 3 times. A waiting period of 3 minutes was allowed after antiseptic application[12]. As per study protocol, under strict aseptic precaution, a second skin swab was taken from the surgical site before incision and labeled it as **Swab 2**. In all the cases rectus sheath closure was done by PDS loop no.1 (Polydioxanone monofilament, delayed absorbable, company ETHICON Inc.) and skin closure was done by mattress suture with Ethilon 2-0 (Monofilament Polyamide black, non absorbable, company Johnson and Johnson Pvt Ltd.).

The skin swabs were sent for culture and sensitivity test to the Department of Microbiology, PGIMER. The microbiologists are blinded about the antiseptic used for each patient.

Details of CS like – either emergency or elective, type of skin incision, duration of surgery, amount of blood loss and need for blood transfusion were recorded. Patients were examined for signs of SSI until discharge from the hospital. As per routine protocol, dressing was done after 48 hours of operation. After discharge, they were followed up either by telephonic contact or OPD visit up to 30 days post-operative period.

For patients who were diagnosed to have SSI within 30 days of post-operative period, a wound swab (**Swab 3**) was taken if there was any discharge from the incision site wound swab was taken and sent for culture and sensitivity test.

Statistical analysis was conducted using IBM SPSS STATISTICS (version 22.0). Sample size of 140 in each group with given percentage of wound infection in two groups in previous studies; 80% power of study and 5% level of significance. All the statistical tests were two-sided and were performed at a significance level of $\alpha=0.05$ (p value). Proportions were compared using Chi square or Fisher's exact test, depending on their applicability for 2 groups.

The outcome measures of the study were:

Primary outcome: Rate of SSI in both the study groups.

Secondary outcome: Organism growth on the swabs taken (Swab 1, 2, and 3).

Result And Discussion

A total of 311 patients were recruited in the study. Out of which 11 were lost to follow up. So, outcome analysis was done on 300 patients(Fig 1).

In this study, we compared the efficacy of chlorhexidine-alcohol and povidone-iodine as skin antiseptic in prevention of SSI after CS. The baseline characteristics of the patients in both the groups are comparable such as age of the patients, period of gestations, BMI, number of days of hospital stay, level of hemoglobin (Table 1). The surgical characteristics in both the groups are comparable such as types of surgery whether elective or emergency, types of anesthesia, types of incision, duration of surgery, amount of blood loss, need for blood transfusion (Table 2).

Primary Outcome: The overall rate of SSI is 7%, chlorhexidine-alcohol group had 5.4% and povidone-iodine group had 8.6% shown in Table 3. Statistical analysis for the test of significance using Pearson Chi-Square gives p=0.271 which is statistically not significant.

Secondary outcome: Among **Swab 1** there were growth of *Enterococcus faecalis* (2 in Group A and 1 in Group B), *E.coli* (1 in Group A) and *P.aeruginosa* (1 in Group B). In **Swab 2**, there was no growth of organism (Table 4). Among **Swab 3** there were growth of *E.coli in 2 patients in* Group A and *K.pneumoniae* and *Acinetobacter baumannii* in group B (Table 5).

In this study, 7% (21 patients) of the study population developed SSI. In the chlorhexidine-alcohol group, the rate of SSI was 5.4% (8 patients) and in the povidone-iodine group, the rate of SSI was 8.6% (13 patients).

The rate of SSI in the study is close to that of the randomized controlled trial by Tuuli MG et al (2016)[8] which was 4% in the chlorhexidine-alcohol group and 7.3% in the povidone-iodine group. The present study is also nearly similar to a systemic review and meta-analysis by Noorani A et al (2010)[13] in clean-contaminated surgery where the rate of SSI was 6.1% in chlorhexidine-alcohol group and 9.8% in povidone-iodine group.

Some other studies have also shown a lower incidence of SSI in the chlorhexidine-alcohol group than povidone-iodine group in non gynaecological surgeries. Darouiche RO et al (2010)[14] conducted a study in patients undergoing clean-contaminated surgery, in which the rate of SSI was 9.5% in chlorhexidine group and 16.1% in povidone-iodine group. In another prospective study conducted by Srinivas A et al (2015)[15] in patients undergoing clean contaminated upper abdominal surgeries, the rate of SSI was 10.8% in chlorhexidine-alcohol group and 17.9% in povidone-iodine group.

However, there are studies which show the rate of SSI in both the chlorhexidine-alcohol group and povidone-iodine group were almost similar. In a randomized study by Menderes G et al (2012)[16], the rate of SSI in CS were almost the same in both the chlorhexidine-alcohol and povidone-iodine groups being 5% and 5.8% respectively. Another randomized trial conducted by Ngai IM et al (2015)[17] in preoperative skin preparation before Cesarean section, there was no significant difference in the rate of SSI in both the chlorhexidine-alcohol group and povidone-iodine groups being 4.5% and 4.6% respectively.

The CAPICA trial, May 2017 found that the rate of SSI in chlorhexidine-alcohol group and the PVI group was almost similar i.e., 6.3% and 7% respectively. It concluded that PVI should still be considered as appropriate antiseptic for Cesarean Section[18].

In this study, organisms such as *Enterococcus faecalis* (2 in Group A and 1 in Group B), *E.coli* (1 in Group A) and *P.aeruginosa* (1 in Group B) are found in culture report of **Swab 1**. However, the culture report of the **Swab 2** of these patients showed no growth of organism. This shows that chlorhexidine-alcohol is effective against *Enterococcus faecalis* and *E.coli.* It also shows that the routine use of povidone-iodine of skin preparation is effective.

The bacterial growth in Swab 3 were *E.coli* (2 in Group A), *K. pneumoniae* and *Acinetobacter baumannii* (1 in Group B as mixed growth). *E.coli* is the commonest bacteria responsible for SSI in this study being 9.5% of total SSI. This is similar to another study from India by Shahane V et al[19] in which it was found that the commonest pathogen isolated in SSI was *E.coli* (31.25%) followed by *P.aeruginosa* (25%) and *S.aureus* (22%). The two patients whose wound swab showed growth of *E.coli* had no history of prolonged rupture of membrane, no history of multiple PV examination or positive urine cultures. Both patients underwent emergency Cesarean section for pathological CTG and placenta previa respectively. SSI is diagnosed during stitch removal on Day 7 and 8 respectively. Hence, the possibility of *E.coli* on culture could be from the ascending infection from genitourinary tract.

Most of the SSI (80.96%) developed after getting discharged from the hospital. They presented mostly with discharge from the wound, pain and swelling of the wound associated with or without fever. There was no need for readmission in any of the cases. But there was increased number of hospital visits for dressing and regular follow up. 19.04% of the SSI cases were diagnosed during hospital stay. Only 2 (9.52%) patients needed prolonged hospital stay. The average duration of hospital stay is 3-4 days.

19 patients (90.5%) developed superficial incisional SSI and 2 patients (9.5%) developed deep incisional SSI (Table 3). There was no organ/space SSI in both the groups in this study .Resuturing was done for one patient (4.76%) with deep incisional SSI for which she needed prolonged hospital stay for 19 days. All other patients with SSI were healed by secondary intention.

Prolonged leakage of membrane and number of PV examination also affects the post operative morbidity after Cesarean section[20–22]. In our study, 2 patients who developed SSI had preterm premature rupture of membrane, the duration of rupture of membrane was >18 hours. Another 2 had term premature rupture of membrane with duration of membrane > 18 hours. Thus, 4 patients (19.06%) of those who developed SSI had prolonged rupture of membrane. The mean number of PV examination in both the groups are similar.

The strength of the study is that it is a prospective randomized controlled trial in a tertiary care institute and swabs from the incision site were taken before and after application of antiseptics. However, the limitation of the study is that it has a relatively small sample size.

Conclusion

The study found that the patients who received chlorhexidine-alcohol as skin antiseptic had less chance of developing SSI than those who received povidone iodine however it did not reach statistical significance.

Since it was a pilot study we recommend to study in larger population.

Declarations

Clinical Trials registration no. CTRI/2018/05/014294

Ethical approval: No. INT/IEC/2017/561, approved by Institutional Ethics Committee, PGIMER, Chandigarh.

Conflict of interest: The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article

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Figures

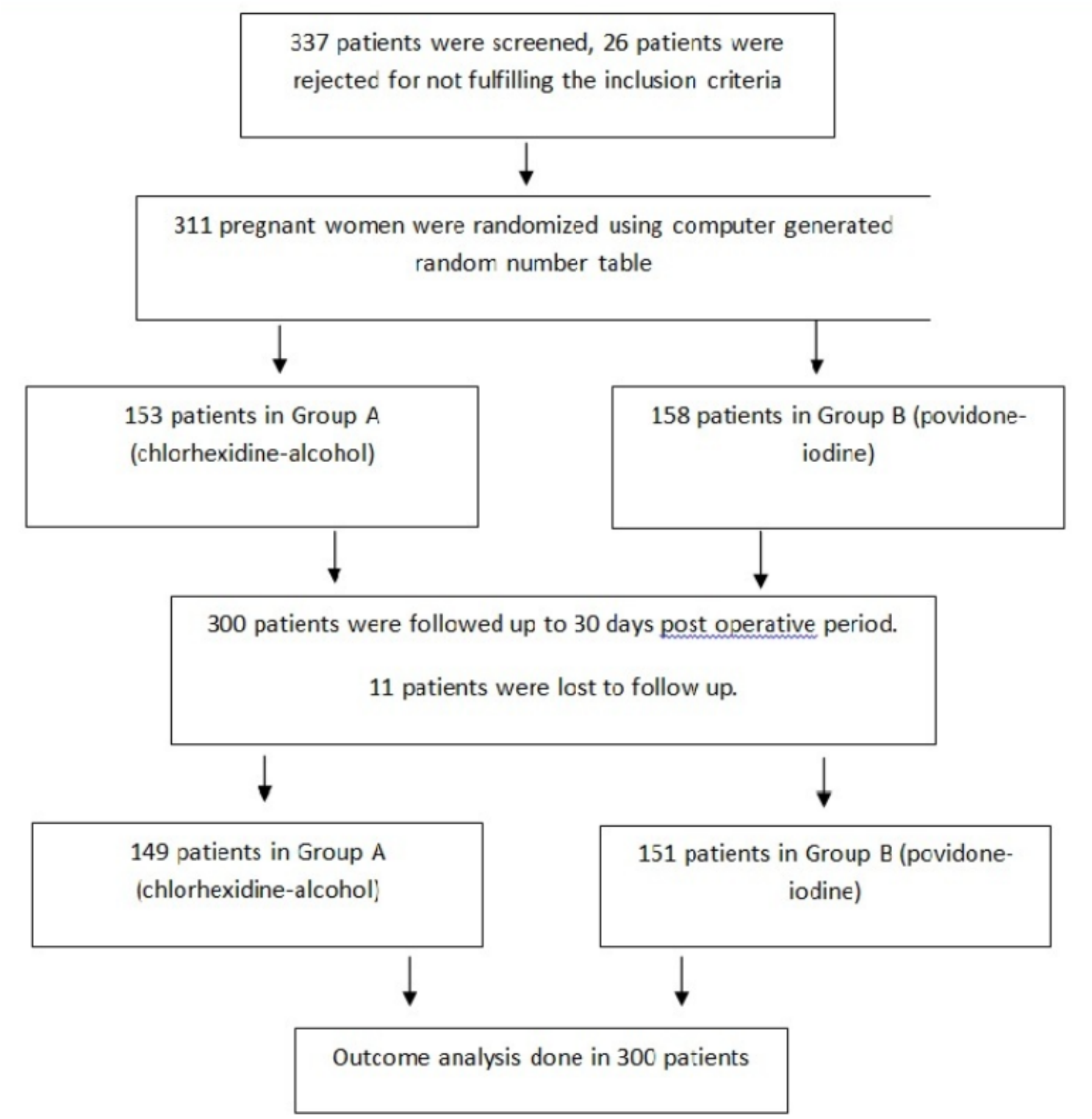

Figure 1

The Consort flow chart Showing patient screening, recruitment, randomization and follow up.