



ORIGINAL ARTICLE

Comparison of chlorhexidine alcohol versus povidone iodine alcohol for pre-operative skin preparation in cesarean section to reduce the rate of surgical site infection.

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Article Citation: Zahid T, Akram A, Irshad S, Ishaq B, Fatima A, Kousar S. Comparison of chlorhexidine alcohol versus povidone iodine alcohol for pre-operative skin preparation in cesarean section to reduce the rate of surgical site infection. Professional Med J 2025; 32(03):329-336. <https://doi.org/10.29309/TPMJ/2025.32.03.8778>

ABSTRACT... Objective: To compare the efficacy of chlorhexidine alcohol versus povidone iodine alcohol for pre-operative skin preparation in cesarean section to lower the rate of surgical site infection (SSI). **Study Design:** Randomized Controlled Trial. **Setting:** Gynaecology and Obstetrics Department Pakistan Institute of Medical Sciences, Islamabad. **Period:** July 2022 to December 2022. **Methods:** The study was conducted on a total of 360 patients booked for cesarean section presenting in Gynaecology & Obstetrics outpatient department PIMS who fulfilled the inclusion criteria. Two groups (A & B) were made and patients were randomly divided into the groups. In Group A, patients received chlorhexidine alcohol for pre-operative skin preparation and group B received povidone iodine alcohol for the same purpose. Post cesarean section patients were kept hospitalized for one week to observe for signs of surgical site infection and after discharge they were followed up for 30 days on weekly basis or as and when they develop symptoms of surgical wound infection. **Results:** Mean age of mothers in both groups remained to be 34.55 ± 6.76 . Overall mean duration of cesarean sections remained to be 39.59 ± 5.85 minutes. Out of total 360 patients, 26 (7.2%) patients developed surgical site infection. Among them chlorhexidine alcohol group had 6 cases (23.1%) of SSI while there were 20 cases (76.9%) of SSI in Povidone Iodine group making it a statistically significant difference (p -value = 0.004). There was 20% frequency of infection among mothers having history of diabetes while 6.3% were those having no history of diabetes and difference is statistically significant. **Conclusion:** Chlorhexidine Alcohol is more effective in reducing the surgical site infection as pre-operative skin preparation solution in cesarean section as compared to the povidone iodine alcohol. History of diabetes among mothers was a significant risk factor for occurrence of SSI while obesity, parity, duration of surgery and age were not found out as risk factors in this study. Most of the infection occurred within ten days after cesarean section in present study.

Key words: Cesarean Section, Chlorhexidine Alcohol, Povidone Iodine, Surgical Site Infection.

INTRODUCTION

One of the commonest obstetrical procedure being performed worldwide is cesarean section with a rising trend in both developing and developed countries as shown by the latest surveys.¹ The average rate of cesarean section (CS) is around 18.6% globally, making it the most frequent major surgical procedure performed in females and post op complications following cesarean sections are also on rise as expected.² Surgical site infection (SSI) is one of the post op complication, with global incidence ranging from 3% to 15%.³

Surgical site infections are the post-operative infections affecting either skin, tissue or organ and is a major contributor to economic burden on health care facilities. Although steps are taken to reduce its incidence i.e. making and implementing infection control mechanisms, improvisation of surgical techniques, antibiotics cover pre and post-operatively, devising better sterilization methods.⁴ Regardless of all this, it remains one the commonest hospital acquired infection causing prolongation of patients' hospital stay resulting in considerable morbidity and even death of the patients. SSI is associated with a mortality rate of 3%.⁵

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Article received on:

12/11/2024

Accepted for publication:

16/01/2025

Hence, patient outcome can be improved by preventing or curtailing the incidence of SSI and this will also considerably lessen financial burden on health care system.⁶

Main source of pathogens that cause surgical-site infection is derived from the skin. With use of skin antisepsis before surgery it is possible to reduce post-operative infections and this include either using Povidone-Iodine- Alcohol and chlorhexidine alcohol. Povidone-iodine comes under category of broad-spectrum antiseptic solution and is used extensively as topical application for prevention and treatment of wound infection. Chlorhexidine alcohol belongs to antiseptic and antibacterial agent group. It either kills the bacteria or halts its growth so in short it has both bactericidal and bacteriostatic qualities.⁴ Irony is that regardless of using preoperative preventive measures, surgical-site infections still occur making pre-operative skin preparation a debatable topic to know which one among above-mentioned is the best antiseptic solution choice.⁷ Meta analyses and international guidelines that are available differ regarding most efficacious preoperative skin antiseptic solution and its concentration.⁵

Kesani et al. in 2019 discovered that the efficiency of chlorhexidine group in treatment of surgical site infections among Indian population was statistically significant as compared to the povidone-iodine group (6.95% vs. 14.28% respectively; p value=0.005).⁸ Albezrah NA found a difference in SSI between chlorhexidine alcohol group and povidone iodine group that is statistically significant (4.3% vs. 7.7%; p -value = 0.014) in Saudi population.⁹ But Aworinde et al. in 2019 found that there was no statistically significant difference between the chlorhexidine-alcohol group and the povidone iodine group (12.2% vs 15.1%; p -value=0.26) when studied regarding incidence of surgical site infections among Nigerian population.¹⁰ So to find out the appropriate choice of antiseptic solution for pre-operative skin preparation is of extreme clinical importance, as it can notably reduce the morbidity of patients and can curtail healthcare costs related with SSIs in patients undergoing cesarean sections and elective gynecological

surgery.

Keeping in view the contradictory results shown in afore-mentioned studies regarding efficacy of chlorhexidine alcohol versus povidone iodine solution in preventing SSIs and lack of local published data especially in obstetrics & gynaecological procedures, there is a need to conduct this study in our population. Therefore, the aim of this study is to identify the antiseptic solution with maximum efficacy in reducing SSIs in cesarean section by comparing both antiseptic solutions. The solution showing more efficacy can be then used in skin preparation in patients undergoing caesarian section as this will improve patients' outcome by reducing incidence of surgical site infections.

METHODS

This study is a Randomized Controlled Trial conducted from July 2022 till December 2022 in the Department of Gynaecology and Obstetrics, Pakistan Institute of Medical Sciences, Islamabad. Approval was taken from ethical review committee of the hospital (F.1-1/2015/ERB/SZAMBU/763-28-04-21) before starting the study. Sample was drawn by using Consecutive Non-probability Sampling. Following was inclusion criteria of the study i.e. Pregnant women in the range of 18-45 years of age and who were at the appropriate gestational week to undergo cesarean section. Whereas the exclusion criteria was as follows: patients who are allergic to chlorhexidine, povidone iodine or alcohol, who took steroid for a period of > 2weeks in past 2 months, or those having skin infection next to operation site. Also, pregnant women with abnormal placentation (previa/ accrete), diagnosis of chorioamnionitis, urogenital tract infection within the time period of 2 weeks of delivery or with history of auto-immune diseases were excluded. The patients who were unable to undergo follow-up till 30 days postoperatively or having active bacterial infection at the time of informed consent (except for viral hepatitis) were also excluded from the study. Surgical site infections were defined as per operational definition i.e. infections that occur 30 days after surgery with no implant.

With 80% power of test and 95% significance level, while considering expected effectiveness of chlorhexidine alcohol and povidone iodine alcohol as 10.43% vs. 3.07% respectively¹¹, a total sample size of 360 pregnant women is calculated. So, 360 patients presenting in the outpatient department of Gynea and Obs PIMS, Islamabad who fulfilled the inclusion criteria and not tallying with the exclusion criteria were included in the study after taking written informed consent from each patient. Afterwards using lottery method these pregnant women were randomly divided into two groups A & B with 180 patients in each group. Patients in Group A received Chlorhexidine alcohol that was 2% chlorhexidine gluconate and 70% isopropyl alcohol for pre-operative skin preparation in cesarean section while women included in Group-B received Povidone iodine-alcohol (10% povidone-iodine and then surgical spirit) for this purpose.

Pre-operatively all patients were evaluated with complete history, general physical and obstetric examination, and complete blood count and relevant biochemical tests. Patients in both groups received Intravenous antibiotics i.e. 1g Ceftriaxone as per protocol. After surgery, patients' vital signs were checked and surgical site was examined for the signs of infection at least once a day during the first week while patient is admitted, and upon discharge, weekly follow up was done for the 30 days or as and when symptoms of wound infection developed. In patients who developed surgical site infection, pertinent blood tests and microbiological samples from infected skin area were sent for culture and sensitivity.

Data was noted down on designated proforma along with the record of demographic details of the patients. To eliminate bias, antiseptic solutions were supplied from the same medical store. Subsequently data was entered and analyzed on SPSS version 25. For interpretation of numerical data i.e. age, parity, body mass index and duration of surgery, Mean \pm SD and range was used. While data related to categorical variables i.e. history of diabetes and efficacy of the treatment were presented as frequency and percentage. For comparison of efficacy between

the two groups Chi-Square test was applied taking p-value < 0.05 as statistically significant. Data was stratified for age, parity, duration of surgery and history of diabetes.

RESULTS

From total 360 pregnant women who went through cesarean section, 180 in each group i.e. Chlorhexidine Alcohol group and Povidone Iodine group, data was gathered and analyzed. Mean age of the participants appeared to be 34.55 ± 6.76 years with minor difference in both groups. Mean parity of pregnant women included in the study was 2.51 ± 0.87 with no major difference noted in both groups. Overall mean BMI of study participants remained to be 29.53 ± 1.11 kg/m².

Among pregnant women who were part of this study, percentage of women with history of diabetes in two groups was also noted and it's found out that 25 (6.9%) women out of 360 had history of diabetes. Among them, group A (chlorhexidine alcohol group) had 12/25 (48.0%) cases while Group B (Povidone Iodine group) had rest of 52% diabetic case as presented in Table-I.

Duration of surgery also noted and mean duration of the cesarean section overall calculated to be 39.59 ± 5.85 minutes with no notable difference between two groups as shown in Table-II.

Timing of occurrence of SSI post cesarean section was also noted. No case developed infection during hospital stay and at the time of discharge while 18/26 (69.2%) cases had infection at 10 days post operatively while remaining 30.8% cases exhibited infection after follow up of 30 day yet the calculated p-value=0.622 showed that difference is not significant statistically.

Efficacy of both solutions was determined on the basis of occurrence of SSIs in pregnant women belonging to both groups. Among total 360 pregnant women, 26 (7.2%) developed surgical site infection out of which 20/26 (76.9%) cases belonged to povidone Iodine group (Group B) and only 6 cases (23.1%) were from chlorhexidine alcohol group (Group A). Overall chlorhexidine

alcohol group had 6/180 (3.34%) cases of surgical site infection compared to 20/180 (11.11%) cases of SSIs in Povidone Iodine group making this difference statistically significant indicated by p -value=0.004 when Chi-square test was applied as shown in Table-III.

Statistically significant difference was noted when stratification of SSI was done with history of diabetes that shows a 20% frequency of infection among mothers with history of diabetes as compared to 6.3% in those who are not diabetic as presented in Table IV.

Age of pregnant women was stratified with SSI and frequency of 5.2% infections was observed in age group of 18-35 years of age while 8.2% infections were found in age group of >36 years though the difference is not significant statistically

insignificant. Stratification of SSI with body mass index (BMI) showed 7.7% infections among overweight group and 6.3% among obese group however the difference was not significant statistically. Parity of pregnant women was also stratified with SSI. A frequency of SSI in 1-2 parity group remained 8.2% which was higher when compared to parity of >3 yet this difference is not significant statistically.

DISCUSSION

The efficacy of different methods and materials on reducing the rates of surgical site infections was studied by many researchers. Research is carried out mostly in general surgery with a few studies exploring the use of chlorhexidine in reducing surgical site infections in cesarean sections and gynecological surgeries.¹²

History of Diabetes In Pregnant Women	Groups				Total	
	Group A (Chlorhexidine Alcohol group)		Group B (Povidone Iodine group)			
	N	%	n	%	N	%
Present	12	48.0	13	52	25	6.9
Absent	168	51.1	167	49.9	335	93.1

Table-I. Distribution of pregnant women with h/o Diabetes among Groups A&B

Groups	Duration of Cesarean Section	
	Mean (Minutes)	Standard Deviation (+ SD)
Group A (Chlorhexidine Alcohol)	39.26	5.83
Group B (Povidone Iodine)	39.92	5.86
Over all	39.59	5.85

Table-II. Mean duration of cesarean section among both groups

Occurrence of Surgical Site Infection (SSI)	Groups				Total	
	Group A (Chlorhexidine Alcohol group)		Group B (Povidone Iodine group)			
	N	%	N	%	N	%
Absent	174	52.1	160	47.9	334	92.8
Present	6	23.1	20	76.9	26	7.2

Table-III. Distribution of surgical site infection occurrence among groups
Chi-Square value: 8.125 p-value: 0.004

History of Diabetes among pregnant women	Surgical Site Infection				Total	
	No		Yes			
	n	%	N	%	N	%
Present	20	80.0	5	20.0	25	6.9
Absent	314	93.7	21	6.3	335	93.1

Table-IV. Stratification of surgical skin infection with history of diabetes in pregnant women
Chi-Square =6.546 p-value = 0.011

There is scarcity of local data on this important issue and the one available local study deals with general surgery patients with no study done in obstetrics/ gynaecology patients.¹³ The use of perioperative antibiotic as prophylaxis has shown to reduce infection rates in patients undergoing surgery.¹⁴ Alongside antibiotics, pre-operative skin preparation also holds important place in reducing SSIs. Different antiseptic solutions are used for this purpose. Iodine has been well known as an efficacious broad-spectrum antiseptic solution that is active against bacteria, yeasts, molds, fungi, viruses and protozoans.¹⁵ Chlorhexidine is a chemical antiseptic that exhibits both bacteriostatic and bactericidal properties. Though both the solutions show broad-spectrum germicidal properties, it has been a topic for research since long that which among two is better. Chlorhexidine-alcohol may be due to its swift and steady activity is proposed as effective protection.¹⁵ Moreover, it is inexpensive and safer making it a preferred choice of health care staff.¹⁶

In current study SSI was observed in total 26 (7.2%) patients out of which 20 patients (76.9%) belonged to Povidone-Iodine group and 6 patients belonged to Chlorhexidine Alcohol Group. Overall chlorhexidine alcohol group had 6/180 (3.34%) cases of SSI while Povidone Iodine group has 20/180 (11.11%) cases of SSI and when both were compared the difference is statistically significant as exhibited by p -value = 0.004. Findings of this study are similar to the study which showed statistically significant result between two groups. The SSI's rate for the 10% povidone-iodine protocol was 10.4% versus 3.07% for the 2% chlorhexidine protocol making it statistically significant (p -value = 0.08).¹² The rate of long hospital stay, was significantly higher for patients cleaned with 10% povidone-iodine protocol compared with patients scrubbed with 2% chlorhexidine protocol i.e. 16.5% and 6.7%, respectively (p -value = 0.021). Moreover, emergency visits after cesarean section was significantly higher for the povidone-iodine protocol group compared with the chlorhexidine protocol group, 9.2% and 3.07%, respectively as shown by p -value = 0.0058.¹²

Luwang et al. carried out a study comparing the efficacy of chlorhexidine–alcohol with povidone–iodine as preoperative antiseptic skin preparation for prevention of SSI post cesarean section. 311 women who underwent CS were recruited in the study. Patients were randomized into two groups and were followed for a period of 30 days post operatively to check for SSI. The rate of SSI in the chlorhexidine–alcohol group is 5.4% and that of the povidone–iodine group is 8.6%.² The findings are comparable with the present results though significance was not reported. Similarly, the above study followed the patients after a month while present study has 1st follow up after 10 days of discharge and second follow up was after a month. The time of occurrence of SSI after cesarean section was also noted. Majority of patients showed infection 10 days post operatively.

A systematic review and metaanalysis done by Bai et al. comparing the effectiveness of chlorhexidine and povidone–iodine in preventing surgical site infections revealed that chlorhexidine seems to be more effective than povidone–iodine in reducing the overall rate of surgical site infections.¹⁷ Another metaanalysis conducted by Jalalzadeh et al. provides evidence for a beneficial role of all different chlorhexidine in alcohol concentrations and particularly 2.0–2.5% chlorhexidine in alcohol as compared with iodine for SSIs prevention in patients going through a surgical procedure.¹⁸ One more meta-analysis included 20 studies that investigated the effects of chlorhexidine and povidone-iodine on the incidence of SSI. The results indicate that compared to povidone-iodine, chlorhexidine is more effective in preventing overall, superficial, and deep SSIs. One randomized controlled study involving 311 cases of post-caesarean section SSIs showed that while chlorhexidine had a better preventive effect compared to povidone-iodine, but the difference was not statistically significant.⁵ A Cochrane review done including 13 individually-randomized controlled trials (RCTs), with a total of 6938 women who underwent cesarean section. Six were conducted in the America and the rest in France, India, Egypt, Denmark, Nigeria, Indonesia and South Africa. Most of the evidence

found was of comparatively poor quality, making it difficult to be confident of findings. Though evidence proposed that in women who had their skin prepared using chlorhexidine, there is possibly a minor reduction in the incidence of surgical site infection compared to those in whom povidone iodine was used but to approve these findings authors suggested for further good quality trials.¹⁹ At the University Clinical Center of Kosovo, a prospective observational cohort study involving 325 women who underwent C-sections was conducted. Each woman was followed for 30-postoperative days. The high occurrence rate of SSIs after C-sections in this study points towards importance of infection control especially surgical site infections.²⁰ The mean time of occurrence of SSIs after surgery was discovered in another study and it was 10.3 ± 5.7 postoperative day, minimum 4 days and maximum 25. These findings are much similar with present study.²¹

Stratification of data in our study showed that 20 % SSI presented in mothers having history of diabetes as compared to 6.3% in those having no history of diabetes and difference is statistically significant (p -value = <0.05). Findings are consistent with a study reported the 41375 cesarean deliveries performed during the study period, with 3.7% were complicated with SSI. Following independent risk factors for SSI were identified by using multivariable regression model i.e. gestational diabetes mellitus, previous cesarean section, obesity, hypertensive disorders, premature rupture of membranes and recurrent pregnancy losses by using a multivariable regression model²², as similarly in our study history of diabetes mellitus was a significant risk factor for SSIs.

CONCLUSION

Chlorhexidine Alcohol as pre-operative skin preparation solution is more effective in reducing surgical site infections as compared to the povidone iodine as evident by the statistically significant results of our study. In this study, age, parity, BMI and duration of surgery are not detected as risk factors however history of diabetes is a significant risk factor for occurrence

of SSIs.

Strength of the study

There is scarcity of local data regarding efficacious antiseptic solution to reduce surgical site infections especially in patients of Obstetrics and Gynaecology. This study proposes an efficacious pre-operative skin preparation antiseptic solution for reduction in surgical site infections post cesarean section in Pakistani women. As in today's world cesarean section is one of the commonest surgical procedure performed in women, a reduction in SSIs can lead to improvement in patients' outcome & satisfaction and can help in reduction of financial burden caused by SSIs.

LIMITATIONS

The study is conducted in one center with small sample size. Therefore, it is essential to conduct Multicentric studies with larger sample size to validate the aforementioned conclusions and for making evidence based local guidelines regarding pre-operative skin preparation to reduce incidence of surgical site infections.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

SOURCE OF FUNDING

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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


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2	Ayesha Akram	Drafting of article & critically revising of draft.	
3	Samina Irshad	Data analysis & interpretation.	
4	Benish Ishaq	Critical revision of data.	
5	Ambreen Fatima	Data collection.	
6	Shermeen Kousar	Proof reading.	