Original Article

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Chlorhexidine-alcohol versus Povidone-iodine plus Alcohol as Preoperative Antiseptic for Prevention of Surgical Site Infection in Caesarean Section: A Randomised Controlled Trial

Obstetrics and Gynaecology Section

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ABSTRACT

Introduction: Caesarean Section (CS) is one of the most commonly performed surgical procedures worldwide, with its incidence steadily increasing. Surgical Site Infection (SSI) remains a significant complication, impacting maternal recovery and healthcare costs.

Aim: To evaluate the efficacy of chlorhexidine-alcohol versus Povidone-Iodine (PI) plus alcohol in preventing SSI in patients undergoing CS.

Materials and Methods: This Randomised Controlled Trial (RCT) was conducted in the Department of Obstetrics and Gynaecology from April 2024 to April 2025 at a tertiary care centre, Shri B.M. Patil Medical Hospital and Research Centre, Bijapur, Karnataka, India. A total of 208 pregnant women undergoing CS were enrolled and randomly assigned to two groups: Group A received preoperative skin preparation with chlorhexidine-alcohol, while Group B received PI followed by surgical spirit. Postoperative wound assessment was conducted on day 2, and wounds were cleaned and dressed using sterile Sterizone (a transparent film dressing with a silver lining). Follow-up inspections occurred on day 5, day 7, or at discharge whichever was later. In cases of wound discharge, swabs were sent for culture and sensitivity. Outcomes assessed included incidence of SSI, wound discharge, and need for additional interventions. Statistical analysis was conducted using John's Macintosh Project (JMP)-Statistical Analysis System (SAS) software version 17. Continuous variables were compared using the independent t-test, and categorical data using the Chi-square test. A p-value<0.05 was considered statistically significant.

Results: The incidence of superficial SSI was significantly lower in the chlorhexidine group compared to the PI group (1.0% vs. 8.7%, p-value=0.018). Similarly, deep infections were less frequent in the chlorhexidine group (1.9% vs. 2.9%, p-value=0.018). There was no significant difference between groups regarding the types of organisms isolated (p=0.0966). *Staphylococcus aureus* was the most commonly isolated pathogen (1.9% in both groups).

Conclusion: Chlorhexidine-alcohol demonstrated superior efficacy in reducing SSI compared to PI in patients undergoing CS. The present finding supports the use of chlorhexidine-alcohol as the preferred preoperative antiseptic for caesarean deliveries.

Keywords: Antiseptic efficacy, Caesarean wound infection, Postoperative wound care

INTRODUCTION

The CS is a very commonly performed surgical procedure worldwide, with its global rate steadily increasing, currently averaging around 18.6% [1]. A significant complication following CS is the development of SSI, which can lead to prolonged hospital stays, increased patient morbidity, re-admissions, heightened healthcare resource utilisation, and escalated hospital costs [2,3]. The SSIs are a major cause of both morbidity and mortality in patients undergoing CS, highlighting the need for effective preventive measures [2,4].

Optimising aseptic techniques in the preoperative phase, particularly through proper skin antisepsis, has been shown to reduce the risk of postoperative complications [1]. The choice of antiseptic for preoperative skin preparation is a critical factor in minimising the incidence of SSI. Among the most commonly studied antiseptics are PI and chlorhexidine alcohol [5,6].

The SSI is defined as an infection that occurs at the surgical site within 30 days following the procedure. SSIs are categorised into organ/space and incisional infections. Incisional SSIs are further classified into superficial and deep [7,8].

Existing studies have compared various preoperative skin antiseptic agents, notably chlorhexidine-based solutions and PI, with several meta-analyses suggesting that chlorhexidine may be more effective in reducing SSI rates, particularly in clean-contaminated surgeries [9-11]. However, the evidence remains inconclusive for caesarean deliveries, where factors such as amniotic fluid contamination and maternal co-morbidities pose unique infection risks [12]. Additionally, studies often vary in terms of antiseptic concentrations, application techniques, and patient populations, making it difficult to establish a standardised protocol.

A significant gap in the literature is the lack of consistent data focusing specifically on CSs in low and middle-income settings, where SSI rates tend to be higher due to limited resources and infection control practices. Furthermore, limited data exist on the microbial spectrum of SSIs in this patient group, which is essential for guiding empirical antibiotic therapy.

The present study aimed to assess the efficacy of chlorhexidine-based antiseptic protocols compared to PI protocols in reducing the incidence of SSI among patients undergoing caesarean deliveries. Additionally, the study will examine the organism growth in wound

swabs taken from the surgical site to determine the microbial profile associated with these infections.

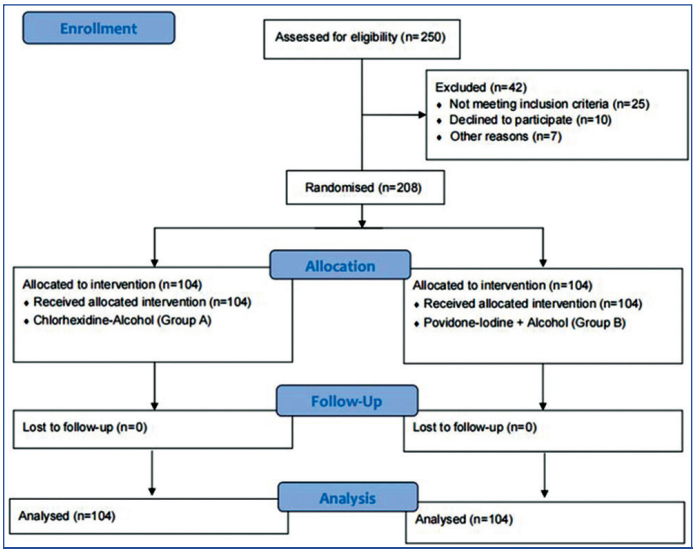
The novelty of present study lies in its dual approach assessing both clinical outcomes and microbiological findings- within the specific context of caesarean deliveries. The findings are expected to contribute to evidence-based recommendations for optimal antiseptic practices in obstetric surgery, with significant clinical relevance in improving maternal outcomes and guiding targeted antimicrobial stewardship.

MATERIALS AND METHODS

The present RCT was conducted in the Department of Obstetrics and Gynaecology at Shri B.M. Patil Medical Hospital and Research Centre, Bijapur, Karnataka, India, from April 2024 to April 2025. The study was registered prospectively with the Clinical Trials Registry of India (CTRI/2024/05/067268) and received ethical clearance from the Institutional Ethics Committee (Approval No BLDE(DU)/IEC/865/2022-23, dated 10 April 2023).

Inclusion and Exclusion criteria: Eligible participants were pregnant women aged 18 years or older undergoing caesarean delivery, either elective or emergency. Exclusion criteria included women with Premature Rupture of Membranes (PROM), overt diabetes mellitus or gestational diabetes, severe anaemia (haemoglobin <8 g/dL), abdominal skin lesions, concurrent systemic infections such as urinary tract infections or febrile illness (temperature >98.5°F), prolonged labour, drug allergies, history of prior wound infection, or immunocompromised status.

Sample size calculation: The sample size was determined based on an anticipated difference in *Escherichia coli* culture positivity between the two groups- 42.1% in the chlorhexidine-alcohol group and 26.8% in the PI group [1]. Using the formula $n = \{(Z\alpha+Z\beta)^2\times 2pq\}/(MD)^2$, where $Z\alpha=1.96$ for a 5% significance level, $Z\beta=0.84$ for 80% power, p=average of the two proportions (34.45), q=100-p (65.55), and MD=15.3%, the required sample size was calculated to be 104 participants in each group, totalling 208. No dropouts occurred during the study period; all 208 participants completed the trial and were included in the final analysis [Table/Fig-1].



[Table/Fig-1]: Consolidated Standards of Reporting Trails (CONSORT) flow diagram.

Study Procedure

Participants were randomised in a 1:1 ratio using computer-generated random numbers into two groups. Allocation concealment was maintained using sequentially numbered opaque sealed envelopes. This was a single-blinded study while patients were aware of the antiseptic used, the outcome assessors (those evaluating wound status postoperatively) were blinded to group allocation to reduce bias.

In Group A (intervention group), preoperative skin preparation was performed using gauze soaked in 2% chlorhexidine solution combined with 70% isopropyl alcohol. Scrubbing was done in a centrifugal motion from the subcostal region to the mid-axillary and mid-thigh areas, repeated twice, and the area was dried with sterile gauze. Final painting with the same solution was carried out in the operating theatre. In Group B (control group), the skin was prepared with 10% PI, followed by painting with surgical spirit (70% alcohol), following the same technique as in Group A.

Both groups received preoperative antibiotics consisting of ceftriaxone 1g intravenous (i.v.) and metronidazole 100 mg i.v. Postoperatively, a transparent silver-lined film dressing (Sterizone) was applied to the surgical site. The wound was first inspected on postoperative day 2, cleaned with surgical spirit, and redressed. Further evaluations were conducted on day 5, day 7, or at discharge-whichever occurred later. In cases of wound discharge, swabs were collected and sent for culture and sensitivity testing, and additional wound care was administered as required. All participants received postoperative antibiotics including ceftriaxone 1g i.v. twice daily and metronidazole 100 mg i.v. thrice daily for 48 hours, followed by oral cefixime twice daily for five days.

The primary outcome assessed was the incidence of SSI, defined in accordance with Centres for Disease Control and Prevention (CDC) guidelines [12]. Secondary outcomes included the type of wound healing, culture positivity, and the type of isolated organisms. A healthy wound was defined as one with no discharge, erythema, or gaping. An unhealthy wound was characterised by mild erythema, serous discharge, or minimal gaping without pus. A superficial SSI involved only the skin and subcutaneous tissues, often with purulent discharge or positive cultures, while deep SSI extended to the fascial or muscular layers, often associated with systemic signs and wound dehiscence.

STATISTICAL ANALYSIS

Data were compiled using Microsoft Excel and analysed with JMP-SAS (v17). Continuous variables such as maternal age, gestational age at delivery, duration of surgery, and hospital stay were summarised using mean±standard deviation and compared between groups using the Independent t-test. Categorical variables, including wound status, infection rates, organism isolation, and requirement for secondary suturing, were presented as frequencies and percentages and analysed using the Chi-square test. A p-value of <0.05 was considered statistically significant.

RESULTS

The baseline characteristics, including age, gestational age, duration of surgery, and duration of hospital stay, were statistically comparable between the two groups, confirming that both cohorts were similar at the start of the study and any differences in outcomes are less likely due to baseline variability [Table/Fig-2].

Characteristics	Group A (Chlorhexidine) (n=104) (Mean±SD)	Group B (Povidone Iodine) (n=104) (Mean±SD)	p-value
Age (years)	25.08±4.027	25.25±4.339	0.97
Gestational age (weeks)	38.313±1.179	38.42±0.946	0.87
Duration of surgery (minutes)	65.57±13.694	69.56±15.02	0.07
Duration of stay (days)	5.27±4.027	6.37±4.337	0.90

[Table/Fig-2]: Baseline characteristics of patients in the study groups.
Independent t-test was used

A significantly higher proportion of healthy wounds was observed on Day 7 in the Group A (97.10%) compared to the Group B (88.50%), with a p-value of 0.029, indicating better postoperative wound condition with chlorhexidine [Table/Fig-3].

Superficial SSI was substantially lower in the Group A (1.00%) than in the Group B (8.70%), with a significant p-value of 0.018, suggesting chlorhexidine was more effective in preventing superficial infections [Table/Fig-4].

Day 7 wound	Group A (Chlorhexidine) (n=104)	Group B PI (N=104)	Total (N=208)
Healthy	101 (97.10%)	92 (88.50%)	193 (92.80%)
Unhealthy	3 (2.90%)	12 (11.50%)	15 (7.20%)
Total	104 (100%)	104 (100%)	208 (100%)
Chi-square value	5.820		
p-value	0.029		

[Table/Fig-3]: Wound healing on day 7.
Values presented as n (%)

SSI	Group A (Chlorhexidine) (n=104)	Group B PI (n=104)	Total (N=208)
Healthy	101 (97.10%)	92 (88.50%)	193 (92.80%)
Superficial	1 (1.00%)	9 (8.70%)	10 (4.80%)
Deep	2 (1.90%)	3 (2.90%)	5 (2.40%)
Total	104 (100%)	104 (100%)	208 (100%)
Chi-square value	7.187		
p-value	0.018		

[Table/Fig-4]: SSI according to CDC.
Values presented as n (%)

The difference in organism isolation patterns was not statistically significant (p-value=0.0966), implying no meaningful difference in microbial profile between groups [Table/Fig-5].

Organism	Group A (Chlorhexidine) (n=104)	Group B (Povidone Iodine) (n=104)	Total (N=208)
Staphylococcus aureus	2 (1.90%)	2 (1.90%)	4 (1.90%)
Acinetobacter baumanii	0	1 (1.00%)	1 (0.50%)
Klebsiella pneumonia	0	1 (1.00%)	1 (0.50%)
Sterile	1 (1.00%)	8 (7.69%)	9 (4.32%)
Non infected wounds	101 (97.10%)	92 (88.50%)	193 (92.78%)
Total	104 (100%)	104 (100%)	208 (100%)
Chi-square value	7.8641		
p-value	0.0966		

[Table/Fig-5]: Organism isolated.
Values presented as n (%)

Fewer patients required secondary suturing in Group A (1.00%) compared to Group B (4.80%) (p-value=0.212), indicating a trend favouring chlorhexidine, though without strong statistical support [Table/Fig-6].

Secondary suturing	Group A (Chlorhexidine) (n=104)	Group B (Povidone Iodine) (n=104)	Total (N=208)
No	103 (99.00%)	99 (95.20%)	202 (97.10%)
Yes	1 (1.00%)	5 (4.80%)	6 (2.90%)
Total	104 (100%)	104 (100%)	208 (100%)
Chi-square value	2.746		
p-value	0.212		

[Table/Fig-6]: Secondary suturing.
Values presented as n (%)

DISCUSSION

The current study demonstrates a lower likelihood of developing an SSI in the chlorhexidine group compared to the PI group. These findings are consistent with recent research, such as a RCT conducted by Luwang AL et al., which found chlorhexidine to be a more effective antiseptic than PI, with infection rates of 5.4% versus 8.6%, respectively (p=0.276) [6]. Similarly, the RCT by Tuuli MG et al., revealed a significant difference in SSI rates between the chlorhexidine-alcohol group (4.0%) and the PI group (7.3%), with a p-value of 0.02 [8]. The present study corroborates these findings, showing a lower SSI rate in the chlorhexidine group (2.90% vs. 11.50%; p=0.02).

Menderes G et al., found that SSI rates in both groups were almost identical, at 5% and 5.8%, respectively [7]. This discrepancy could be due to differences in sample size, patient demographics, or the clinical setting, which highlights the variability in findings across studies.

In the present study, the rate of superficial SSIs was 4.80%, while the deep SSI rate was 2.40%, with a statistically significant p-value of 0.018. These findings align with a meta-analysis by Wang P et al., which revealed that patients treated with chlorhexidine had a lower incidence of SSIs as compared to those receiving PI disinfection (3.75% vs. 6.26%, p<0.001) [9]. Also, deep SSIs were less frequent in the chlorhexidine group (1.9% vs. 2.9%). The present findings are comparable to those of Kesani VP et al., who reported lower rates of deep SSI in the Chlorhexidine group (1.46% vs. 4.18%, p=0.04) [1]. No adverse reactions were reported in the present study, indicating that both antiseptics are generally safe and effective.

The most common organism found in both groups was *Staphylococcus aureus* accounting for 1.9%, whereas Kesani VP et al., reported *E. coli* as the most common organism in their study accounting for 31.66% of SSIs [1]. Similarly, Luwang AL et al., reported *E. coli* as the commonest organism isolated in 9.5% of total SSI cases [6].

Taken together, these findings suggest that chlorhexidine offers a superior benefit in reducing superficial SSIs and promoting wound healing compared to PI. In a meta-analysis by Bai D et al., Chlorhexidine exhibited statistically lower rates of overall SSIs, superficial SSIs and deep SSIs compared to povidone-iodine. (p-value <0.001 in all the SSIs) [13].

Given its proven efficacy, safety profile, chlorhexidine should be considered the antiseptic of choice for preoperative skin preparation, especially in procedures with high infection risk such as caesarean deliveries. To enhance the robustness and generalisability, larger multicenter RCTs should be undertaken to minimise institutional bias and improve statistical power. Future studies should stratify patient groups based on key variables such as American Society of Anaesthesiology (ASA) classification, Body Mass Index (BMI), diabetic status, and type of surgery, to enable more refined and accurate comparisons. Incorporating detailed microbiological profiling, including resistance patterns, would provide valuable insights for targeted antibiotic prophylaxis.

Limitation(s)

The present study, despite its clinical relevance and randomised design, presents several limitations that may affect the interpretation and generalisability of its findings. The relatively small sample size limits statistical power, particularly for detecting less frequent outcomes such as deep SSIs or rare adverse events. Being a single-centre study, it is subject to institutional bias and may not reflect practices or outcomes in other healthcare settings. Furthermore, the study lacked a detailed microbiological analysis, omitting insights into pathogen spectrum or resistance patterns. Potential confounding factors, such as variation in surgical techniques, intraoperative contamination control, and wound care practices, were not standardised or adjusted for.

CONCLUSION(S)

The present study demonstrates that the use of chlorhexidine-alcohol as a skin antiseptic significantly reduces the likelihood of SSIs compared to PI. A detailed analysis of the results from both groups revealed that chlorhexidine-alcohol led to a markedly lower rate of SSIs overall when compared to PI. These findings suggest that chlorhexidine-alcohol may be a more effective choice for preventing SSIs in surgical settings.

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