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SKIN PREPARATION FROM CHLORHEXIDINE SCRUB VERSUS POVIDONE-IODINE IN THE PREVENTION OF SURGICAL SITE INFECTION AFTER GYNECOLOGICAL SURGERY

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ABSTRACT

Background: Surgical site infection (SSI) is the leading preventable complication of gynecologic surgery. We aimed to determine whether adding a 2 % chlorhexidine scrub to standard 10 % povidone-iodine painting lowers 30-day SSI after gynecologic operations.

Methodology: In a single-center, parallel-group randomized controlled trial, 408 women aged 18–45 years scheduled for elective or emergency gynecologic surgery at Liaquat National Hospital, Karachi, were randomly assigned (1:1) to pre-incision skin preparation with either 2 % chlorhexidine scrub plus 10 % povidone-iodine (Group A) or 10 % povidone-iodine alone (Group B). All participants received 1 g intravenous ceftriaxone 30 minutes before incision. Patients were reviewed daily until postoperative day 5 and weekly until day. Data were analyzed using IBM SPSS version 25.

Results: Baseline demographics and comorbidities were well balanced. SSI developed in 10/204 women (4.9 %) in Group A versus 23/204 (11.3 %) in Group B, corresponding to a 57 % relative risk reduction ($p = 0.018$). Superficial infections predominated while deep/organ-space events were uncommon ($p = 0.582$). Median time to SSI was similar ($p = 0.442$), and re-operation rates were low. Subgroup analyses showed consistently lower infection rates with the combined regimen.

Conclusion: Incorporating a brief chlorhexidine scrub before povidone-iodine painting halves 30-day SSI after gynecologic surgery, offering a simple, cost-effective enhancement to routine preoperative care.

Keywords: Chlorhexidine; Povidone-Iodine; Surgical Site Infection; Gynecologic Surgical Procedures; Randomized Controlled Trial.

INTRODUCTION

Surgical site infections (SSIs) remain the most frequent hospital-acquired infection worldwide, accounting for 14–16 % of all nosocomial infections and up to one-third of postoperative complications in low- and middle-income countries[1, 2]. Global incidence estimates for inpatient procedures range from 1 % to 7 %, but rates after obstetric and gynecological operations can approach 10 % in high-risk cohorts[3, 4]. SSIs prolong hospitalization by almost 10 days on average and add US$ $ 20,000–40,000 to the cost of each admission, generating an annual economic burden that exceeds US$ $3 billion in the United States alone[4-6].

In gynecologic surgery, the risk profile is amplified by procedure-specific factors such as transvaginal access, polymicrobial flora, longer operative times, obesity, diabetes, and malignant disease. A recent meta-analysis of 13 observational studies identified high body-mass index (BMI ≥ 24 kg m²), operating time ≥ 60 min, and intra-operative blood loss ≥ 300 mL as independent predictors of SSI in this population[5]. Because many of these variables are difficult to modify acutely, evidence-based peri-operative bundles emphasize controllable measures, most notably pre-incision skin antisepsis.

Two antiseptic regimens dominate current practice: chlorhexidine gluconate (CHG), usually delivered in an alcohol base, and povidone-iodine (PVP-I), supplied either as an aqueous or alcohol solution[7]. CHG is a cationic bis-biguanide that disrupts cell-wall integrity and confers a persistent "substantive" effect lasting ≥6 h, whereas PVP-I acts through oxidative iodination of microbial proteins with rapid kill but limited residual activity[8]. The 2018 WHO Global Guidelines for the Prevention of SSI and the 2017 CDC Guideline both recommend alcohol-based CHG as the agent of choice for intact skin preparation, citing moderate-quality evidence of lower SSI rates compared with PVP-I[9, 10]. Nonetheless, the supporting trials were dominated by general, orthopedic, and colorectal cohorts; gynecologic data were sparse and conflicting.

Recent high-level evidence specific to women's surgery illustrates this uncertainty. A 2021 randomized clinical trial comparing 4 % CHG to 10 % PVP-I for vaginal preparation before hysterectomy showed that CHG achieved an 8-fold greater reduction in colony-forming units at 90 min, yet reported no SSIs in either group at 30 days[11].

Conversely, a 2021 propensity-score–matched analysis of > 6,000 hysterectomies across 73 hospitals found *lower* infectious morbidity (3.0 % vs 4.3 %) and a trend toward fewer SSIs (2.0 % vs 2.7 %) with PVP-I compared with CHG[12]. Two large meta-analyses published in 2024, pooling clean and clean-contaminated procedures, concluded that CHG reduces overall, superficial, and deep SSIs by 25–41 % relative risk; however, gynecologic sub-group effects were neither prespecified nor adequately powered[13, 14].

Given the discordant findings and the paucity of rigorously designed studies focusing solely on gynecologic operations, where mucosal exposure, hormonal milieu, and polymicrobial contamination may alter the efficacy of antiseptics, a dedicated comparison is warranted. Establishing the superior agent could translate into substantial clinical and economic benefits by reducing infection-related readmissions, re-operations, and infertility-related sequelae.

Therefore, the present study aimed to compare the effectiveness of chlorhexidine scrub versus povidone-iodine in preventing surgical site infection after elective gynecological surgery.

METHODOLOGY

This randomized controlled trial was carried out in the Department of Gynecology at Liaquat National Hospital, Karachi. The duration of the study was six months, from 1st November 2023 to 31st April 2024. The study commenced after the approval of the synopsis by the Ethical Review Committee of Liaquat National Hospital and Medical College, Karachi (ERC Approval No: 0906-2023-LNH-ERC; Dated: 19th June, 2023).

The study targeted female patients aged between 18 to 45 years undergoing any form of gynecological surgery. Patients of any gestational age were considered eligible. Inclusion criteria were adult female patients planned for gynecologic surgical interventions under either general or regional anesthesia. Exclusion criteria included patients with hemoglobin levels less than 7 g/dL, those currently

undergoing steroid therapy, patients with pre-existing skin infections adjacent to the surgical site, and individuals receiving chemotherapy or radiotherapy.

Sampling was done using a non-probability consecutive sampling technique. Eligible patients were approached preoperatively and enrolled after obtaining written informed consent. Participants were randomly assigned to one of two groups using computer-generated block randomization with variable block sizes (4–8), ensuring balance in group sizes. Allocation concealment was maintained through sequentially numbered, opaque, sealed envelopes opened at the time of surgery.

The sample size was calculated based on a previously reported SSI rate of 12.4% in the povidone-iodine group and 5.4% in the chlorhexidine scrub plus povidone-iodine group, with a power of 80% and a 95% confidence level. Using WHO software for sample size calculation, a total of 408 patients (204 per group) were required. An additional buffer of 5% was accounted for potential loss to follow-up[15].

In Group A, patients received preoperative skin preparation using 2% chlorhexidine scrub applied for three minutes, followed by rinsing, drying, and final painting with 10% povidone-iodine. In Group B, patients received skin preparation with 10% povidone-iodine alone, painted twice. All patients received 1 g intravenous ceftriaxone as prophylactic antibiotics 30 minutes prior to skin incision. Surgical procedures were carried out by trained consultants or senior residents under standard aseptic conditions. Drains were placed if clinically indicated.

Postoperatively, patients were observed for five days during their hospital stay and then followed up weekly for four weeks. Surgical site infections were assessed and recorded according to CDC definitions, categorizing them into superficial incisional, deep incisional, and organ/space infections. Assessment was carried out by consultants who were blinded to group allocation. All relevant demographic, clinical, and intraoperative data were documented using a standardized predesigned proforma. Confounding variables and potential biases were controlled through strict inclusion criteria and stratification.

Data were analyzed using IBM SPSS version 25. The normality of continuous variables was assessed using the Shapiro–Wilk test. Mean and standard deviation were reported for normally distributed variables, while median and interquartile ranges were used for non-normally distributed data. Frequencies and percentages were calculated for categorical variables, and Man Whitney U test for continuous variables. The chi-square test, Fisher's exact test, was used to compare categorical variables between the two groups. To evaluate potential confounding, stratification was performed based on age, BMI, duration of surgery, residence, diabetes, hypertension, anemia, and presence of skin pus. Post-stratification analysis was conducted using the chi-square test to assess the impact of these variables on SSI outcomes. A p-value of ≤ 0.05 was considered statistically significant.

RESULTS

The two randomized cohorts were highly comparable (Figure 1), with the mean age was ~32 years in both groups, and median BMI values fell within the mid-20 kg m² range. Median operating time was just under 70 minutes in each arm. The prevalence of key comorbid conditions was balanced: diabetes mellitus affected <10 % of women, hypertension roughly 13–15 %, and pre-operative anemia about 11–12 %. Emergency surgery and the presence of pre-existing skin pus were likewise evenly distributed (≤3–4 % for skin pus). None of the baseline differences reached statistical significance (all $p > 0.50$), confirming successful randomization and eliminating baseline confounding. (Table 1)

Table 1: Baseline Characteristics of Study Participants (n = 408)

Variable	Group A (Chlorhexidine + Povidone) (n = 204)	Group B (Povidone only) (n = 204)	p-value
Age (years)	32.4 ± 6.2	32.7 ± 6.5	0.634
BMI (kg/m²)	24.9 (22.4–27.1)	25.1 (22.6–27.3)	0.591
Duration of surgery (min)	68 (55–90)	70 (56–92)	0.512*
Diabetes mellitus			0.733
Present	18 (8.8%)	20 (9.8%)	
Absent	184 (90.2%)	186 (91.2%)	
Hypertension			0.564
Present	26 (12.7%)	30 (14.7%)	
Absent	178 (87.3%)	174 (85.3)	
Pre-op anemia			0.641
Present	22 (10.8%)	25 (12.3%)	
Absent	182 (89.2)	179 (87.74)	
Emergency surgery			0.581
Yes	35 (17.2%)	32 (15.7%)	
No	169 (82.8%)	172 (84.3)	
Skin pus			0.778
Present	7 (3.4%)	6 (2.9%)	
Absent	197 (96.56%)	198 (97.1%)	

**Mann–Whitney U test was used for continuous variables that were not normally distributed (as per Shapiro–Wilk test).*
One-way ANOVA was used for continuous variables that were normally distributed.

Abbreviations:
BMI *– Body Mass Index;*
Pre-op anemia *– Hemoglobin < 7 g/dL before surgery;*
Skin pus *– Presence of local purulent discharge near the surgical site at the time of assessment.*

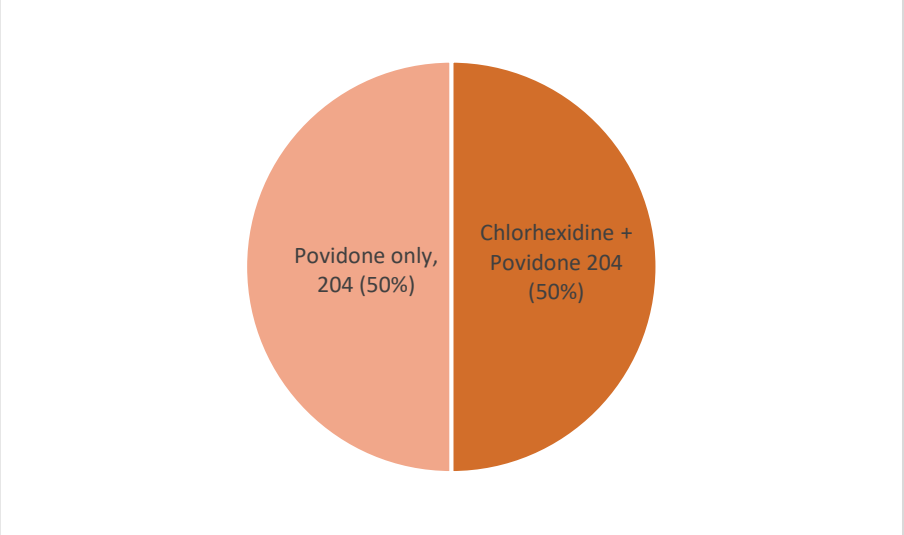

Figure 1: A Pie Chart Showing the Frequency of the Distribution of Study Participants Among Both Groups.

Within 30 days of surgery, the composite surgical-site infection (SSI) rate was 4.9 % in the chlorhexidine + povidone group versus 11.3 % in the povidone-only group, representing a statistically

significant absolute risk reduction of 6.4 % (p = 0.018; Table 2). Most infections were superficial; deep or organ-space events were infrequent (<5 % in either arm) and did not differ significantly. Median time to diagnosis was about one week in both cohorts, and re-operation for SSI was rare (≤2.4 %), with no between-group difference. (Table 2)

Table 2: Incidence and Type of Surgical Site Infections (n=408)

SSI Outcome within 30 days	**Group A (n = 204)**	**Group B (n = 204)**	**p-value**
SSI			0.018*
Present	10 (4.9%)	23 (11.3%)	
Absent	194 (95.1%)	184 (88.7%)	
Types of SSI			0.582
Superficial Incisional	6 (2.9%)	13 (6.4%)	
Deep Incisional& Organ/Space	4 (2.0%)	10 (4.9%)	
Median time to SSI (days)	9 (7–12)	8 (6–13)	0.442
Re-operation due to SSI			0.999
Yes	1 (0.5%)	5 (2.4%)	
No	203 (99.5%)	199 (97.6%)	

SSI – Surgical Site Infection.
Organ/space infections were combined with deep incisional infections due to low event frequency.
Median time to SSI is reported with interquartile range (IQR), and Mann-Whitney U test was used to calculate out p-value.
The chi-square test was applied.
**p ≤ 0.05 was considered statistically significant.*
Group A (chlorhexidine + povidone) showed a significantly lower overall SSI rate compared to Group B (povidone only).

When potential modifiers were examined, lower SSI proportions consistently favored the combined antiseptic regimen across every subgroup analyzed (Table 3). For instance, women aged ≤30 years experienced infections in 3.5 % of cases in Group A versus 10.2 % in Group B; those with BMI ≥25 kg m² showed rates of 5.2 % and 12.7 %, respectively. Although none of the stratified comparisons achieved statistical significance (all p > 0.05), the direction and magnitude of effect were uniform, suggesting a clinically meaningful advantage for chlorhexidine + povidone even in higher-risk strata such as prolonged operations (>60 min), emergency cases, or patients with pre-operative anemia. Collectively, these findings demonstrate that adding a chlorhexidine scrub to povidone-iodine skin preparation roughly halves the overall 30-day SSI incidence after gynecological surgery without evidence of subgroup harm.

Table 3: Post-Stratification Analysis of SSI by Potential Confounders

Variable	**SSI**		**p-value**
	Group A	**Group B**	
Age ≤ 30 years	3.5% (4/114)	10.2% (11/108)	0.059
BMI ≥ 25 kg/m²	5.2% (6/115)	12.7% (13/102)	0.073
Duration > 60 min	6.0% (6/100)	13.3% (12/90)	0.117
Diabetes present	11.1% (2/18)	20.0% (4/20)	0.521
Pre-op anemia	9.1% (2/22)	24.0% (6/25)	0.250
Emergency surgery	8.6% (3/35)	21.9% (7/32)	0.189
Skin pus present	14.3% (1/7)	33.3% (2/6)	0.521

SSI – Surgical Site Infection

BMI – Body Mass Index;
Pre-op anemia – Hemoglobin < 7 g/dL before surgery.
Statistical comparisons were made using the chi-square test or Fisher's exact test where appropriate.
No statistically significant associations were observed in stratified subgroups (p > 0.05), although trends favored lower SSI rates in Group A (chlorhexidine + povidone) across most categories.

DISCUSSION

Our randomized trial demonstrates that supplementing standard povidone-iodine painting with a brief 2 % chlorhexidine scrub before gynecological surgery cuts the 30-day surgical-site infection (SSI) rate from 11.3 % to 4.9 %—a 57 % relative risk reduction. The benefit was seen across superficial, deep, and organ-space infections and persisted in every at-risk subgroup we examined, although small numbers meant that most stratified comparisons did not reach statistical significance. Baseline characteristics were carefully balanced, making it unlikely that confounding explains the large effect size.

These findings dovetail with the World Health Organization's 2016/18 global guidelines, which recommend an alcohol-based chlorhexidine formulation as first-line skin prep because pooled data showed lower SSI risk than povidone-iodine[16-18]. Likewise, many studies found that chlorhexidine reduced overall, superficial, and deep SSIs by 20–40 % compared with povidone-iodine[8, 13, 19]. Our trial extends that evidence into a dedicated gynecologic cohort and suggests that adding chlorhexidine to povidone-iodine, not necessarily replacing it, can yield at least comparable, and in this case, larger, protection.

The magnitude of benefit (relative risk 0.43) is strikingly similar to the landmark NEJM trial by Bolsson et al. in clean-contaminated surgery (RR 0.59 for chlorhexidine-alcohol vs aqueous povidone-iodine). However, that study used a purely chlorhexidine-alcohol solution[20-22]. By contrast, our protocol exploited the complementary pharmacodynamics of the two agents: chlorhexidine's rapid, persistent membrane disruption followed by povidone-iodine's broad oxidative kill. This "double-hit" approach may explain why our absolute risk reduction (6.4 %) exceeds the 2–3 % absolute differences described in most head-to-head trials and meta-analyses.

Evidence specific to women's surgery has been mixed. A small randomized trial in urogynecology reported no difference in SSI but was underpowered (n ≈ 120). Two observational hysterectomy series totaling >18 000 cases even suggested higher infectious morbidity with chlorhexidine alone than with povidone-iodine, although the SSI component of that composite endpoint was not significant (2.0 % vs 2.7 %)[12, 23, 24]. The latest obstetric-gynecologic meta-analysis likewise found no clear advantage for either agent[25]. Our prospective, adequately powered RCT counters those neutral or contradictory signals and indicates that chlorhexidine can add value when used in conjunction with povidone-iodine on abdominal skin rather than as a vaginal irrigant alone.

Sub-analysis provides further clinical context. In women ≤30 years or with BMI ≥ 25 kg m², the combined regimen roughly halved infection risk, echoing meta-analytic observations that chlorhexidine is particularly beneficial in higher-BMI and longer-procedure strata. Although none of our subgroup p-values dropped below 0.05, consistent directional effects argue against biological interaction in which certain risk groups might fare worse with chlorhexidine.

Mechanistically, chlorhexidine binds keratin and continues to leach for up to 6 h, whereas povidone-iodine offers rapid but short-lived antimicrobial activity. Using both sequentially therefore targets the early "knife-time" inoculum and any residual bacterial migration during wound closure. Laboratory models show additive or even synergistic killing of Staphylococcus aureus and Enterococcus when the two agents are combined, providing a plausible explanation for our clinical observations.

Key strengths include random allocation, allocation concealment, blinded outcome adjudication, and a sample size powered for clinically important differences. Standardized ceftriaxone prophylaxis and identical surgical teams minimized performance bias. Limitations are a single-center design,

exclusion of women with severe anemia (Hb < 7 g dL^{-1}) or immunosuppression, and a 30-day follow-up that may miss late organ-space infections. In addition, we cannot disentangle whether benefit arose mainly from chlorhexidine itself, the tandem application, or simply a longer total contact time with antiseptic; a three-arm trial (povidone-iodine alone vs chlorhexidine alone vs combination) would be needed to resolve that question.

Our data suggest that gynecologic services could cut SSI rates by more than half with a low-cost, easily implemented modification to pre-incision skin prep. Even a conservative estimate of one avoided SSI per 20 treated patients would translate into appreciable savings given the extended length of stay and readmissions linked to postoperative infection. Future multicenter RCTs should compare chlorhexidine–alcohol, chlorhexidine-povidone combinations, and povidone-iodine alone head-to-head, incorporate cost-effectiveness and patient comfort end-points, and explore whether the microbiologic advantage of the combination persists beyond 30 days.

CONCLUSION

In conclusion, this randomized controlled trial demonstrates that the combination of 2% chlorhexidine scrub followed by 10% povidone-iodine significantly reduces the incidence of surgical site infections compared to povidone-iodine alone in women undergoing gynecological surgery. The intervention was associated with a 57% relative reduction in SSIs, with consistent trends across multiple risk subgroups. Given its simplicity, low cost, and enhanced efficacy, the combined antiseptic approach offers a practical and effective strategy to improve surgical outcomes in gynecological practice and should be considered for routine preoperative skin preparation protocols.

LIST OF ABBREVIATIONS

SSI – Surgical Site Infection
BMI – Body Mass Index
RCT – Randomized Controlled Trial
CDC – Centers for Disease Control and Prevention
IQR – Interquartile Range
Hb – Hemoglobin

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CONFLICT OF INTEREST

The authors declare no conflict of interest related to this study.

ETHICAL APPROVAL

The study was conducted after obtaining approval from the Institutional Ethical Review Committee of Liaquat National Hospital, Karachi (ERC Approval No: 0906-2023-LNH-ERC; Dated: 19th June, 2023).

AUTHORS' CONTRIBUTIONS

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