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Chlorhexidine (2.5%)–alcohol versus povidone-iodine (10%) alcohol for surgical site antisepsis in cesarean section in a tertiary care hospital – A prospective observational and analytical study

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ABSTRACT

Background: Rising trends of cesarean section globally demand identification of most suitable pre-operative antiseptic agent to minimize surgical site infections (SSI) and its consequences. **Aims and Objectives:** The aims of this study were to determine, compare, and analyze SSI developing following the use of chlorhexidine (2.5%)–alcohol and povidone-iodine (10%) alcohol as pre-operative antiseptic agents in cesarean section. **Materials and Methods:** A prospective, observational, and analytical study was conducted in a tertiary care center for 1 year, where 300 women receiving pre-cesarean surgical site antisepsis with chlorhexidine (2.5%)–alcohol were compared with another 300 receiving povidone-iodine (10%) alcohol. **Results:** The two study groups were compared in terms of various sociodemographic and clinical parameters which might act as confounding factors and were found to be similar. As compared to women receiving povidone-iodine (10%) alcohol, women receiving chlorhexidine (2.5%)–alcohol had significantly lesser incidence of overall ($P<0.001$), superficial ($P<0.001$), and deep ($P<0.05$) SSI, infections developing at 48 h–5 days ($P<0.001$) and at 5 days–30 days ($P<0.05$). There was no significant difference among the two groups with respect to wound swab culture reports and post-SSI inflammatory markers. As compared to the povidone-iodine group, in the chlorhexidine group, a significantly ($P<0.05$) greater percentage healed with meager dressing and a significantly ($P<0.05$) lesser percentage required secondary suturing and readmissions and had a significantly ($P<0.05$) lesser mean duration of hospital stay. **Conclusion:** Chlorhexidine (2.5%)–alcohol appears to be a better pre-operative surgical site anti-septic agent than povidone-iodine (10%) alcohol in cesarean section.

Key words: Chlorhexidine; Povidone-iodine; Skin antiseptic agent; Surgical site infections

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INTRODUCTION

Cesarean delivery is a major obstetrical surgical procedure aiming to save the lives of mothers and babies, but surgical site infections (SSI) is one of its common complications (incidence 3–15%).[1]

At present, the global rate of cesarean sections is more than one in five (21%) of all births and will probably reach one-third (29%) of all deliveries by 2030 and this will lead to further rise in SSI.[2] Delayed healing leads to poor cosmetic outcome.[3] Post-cesarean surgical cosmesis was a neglected issue in the past but with growing awareness, the

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most suitable pre-operative surgical site anti-septic agent must be used to minimize SSIs. Furthermore, post-cesarean SSI increases maternal morbidity and is frustrating for the mother trying to recover and simultaneously taking care of the newborn.[1] It prolongs maternal hospital stay and is a burden to health care economy.[4] This study, conducted in a tertiary care center in a developing country like India, aims to establish a pre-operative antiseptic agent of choice for diminishing the magnitude of such problems.

Aims and objectives

The primary objective of this study is to determine and compare the incidence of SSIs with the use of chlorhexidine (2.5%)–alcohol skin antiseptic agent and povidone-iodine (10%) skin antiseptic agent for pre-operative skin preparation in cesarean section. The secondary objective is to determine, compare, and analyze the various aspects of SSI – such as type of SSI (whether superficial or deep), time taken to develop, associated microbiological agents, laboratory parameters, management protocols adopted, mean duration of hospital stay, and re-admissions in the two study populations.

MATERIALS AND METHODS

It is a prospective, observational, and analytical study conducted in a tertiary care hospital for 1 year (February 2020–February 2021). Ethical clearance was obtained from the Institutional Ethics Committee and written informed consent was obtained from all mothers included in the study.

Antenatal mothers admitted and undergoing lower segment cesarean section (LSCS) in the Obstetrics and Gynecology Department in the hospital during the study period were included in the study.

Patients with history of known hypersensitivity to chlorhexidine, iodine, iodophore, or having evidence of pre-existing local infection (at or adjacent to operative site) or systemic infections (other than COVID-19) or with severe immunodeficiency (e.g., AIDS and Cancer) or connective tissue disorders or with the previous abdominal surgeries with mid-line incisions or those who ultimately had obstetric hysterectomy were excluded from the study. Based on a study by Kesani VP et al.,[5] sample size was calculated as-

$$N = \frac{[\,Z_{\propto}\sqrt{2\,\bar{P}\left(1-\bar{P}\right)} + Z_{\beta}\sqrt{\left\{P_1\left(1-P_1\right)+P_2\left(1-P_2\right)\right\}}\,]^2}{\left(P_1-P_2\right)^2}$$

Where,

Z_{α} is a constant = 1.96

Z_{β} is a constant = 0.84

$$\bar{P} = \frac{(P_1 + P_2)}{2}$$

P_1=Incidence of SSI with use of povidone-iodine skin antiseptic agent in the mother study=0.14

P_2=Incidence of SSI with the use of chlorhexidine–alcohol skin antiseptic agent in the mother study=0.07

Calculating thus, we get, N=300 in each study group.

Thus, total 600 antenatal mothers admitted and undergoing LSCS in this institution during the study period and meeting the exclusion criteria were included in the study. Based on various literature, sociodemographic variables having influence on SSI which might act as confounding factors in our study such as maternal age,[1] (body mass index in kg/m^2),[6] residence (urban/rural),[1] socioeconomic status[7] (as per Modified Kuppuswamy scale), and maternal educational qualification,[6] were compared between the two study groups for optimization. Similarly, as studied by many researchers, clinical parameters likely to have influence on SSI and thus confound our study results, were studied among the two groups for optimization and they were – gravida,[6] period of gestation,[8] number of antenatal visits,[8] and maternal comorbidities (Hypertensive disorder of pregnancy,[6] Diabetes Mellitus,[6] Anemia[9]), presence/absence of COVID-19,[10] previous abdominal surgeries (including cesarean section),[1] duration of trial of labor (if any) before surgery,[11] premature rupture of membrane (if any) and its duration,[11] number of per vagina examinations,[1] type of cesarean section (whether emergency or elective),[6] skin incision length,[4] suturing technique and suturing material used,[12] and duration of surgery.[13]

According to NICE guidelines,[14] there is recommendation for both chlorhexidine (2%)–alcohol solution and povidone-iodine (10%) alcohol as pre-operative surgical site antiseptic agent.

Chlorhexidine destroys the bacterial cell membranes, leading to leakage of cellular contents and causes coagulation of cellular contents.[15] On the other hand, the exact mechanism of action of iodine though unknown, it has been postulated that iodine reacts with amino acids and fatty acids in the bacteria and thus destroys their cellular structures and enzymes.[15]

Both chlorhexidine–alcohol and povidone-iodine are available for surgical site preparation in our hospital. The choice of surgical site antiseptic to be used is at the surgeon's discretion. The 300 patients in each group were

allocated by observing the consecutive patients receiving either chlorhexidine (2.5%)–alcohol or povidone-iodine (10%) alcohol skin antiseptic agent before surgery and meeting the inclusion and exclusion criteria during the study period.

SSI is defined by the Centre for Disease Control and Prevention as an infection occurring within 30 days from the operative procedure and it divides SSIs into incisional SSI and organ/space SSI. Incisional SSI is further divided into superficial incisional, involving the skin and subcutaneous tissue, and deep incisional SSI, involving fascial and muscle layers.[16]

The outcomes studied among the two groups are the incidence of SSI (overall), superficial SSI, deep SSI, as well as incidence of SSI developing at <48 h, at 48 h–5 days and at 5 days–30 days. Furthermore, after development of SSI, the investigation results such as microbiological flora associated with the SSI and laboratory parameters (C-reactive protein [CRP], total leucocyte count [TLC], and neutrophil percentage) and management protocol adopted for the SSI (whether conservatively managed by regular dressing or required secondary suturing), mean duration of hospital stay, and number of re-admissions were compared.

Data collection was from history, physical examination, laboratory investigations, and management methods adopted.[5] All mothers who underwent cesarean section received pre-operative prophylactic intravenous 1 g Ceftriaxone.[14] Patients received pre-operative surgical site preparation with either chlorhexidine–alcohol or povidone-iodine in a widening circular motion starting from the planned skin incision site and this process was repeated a 2nd time. Postoperatively, first dressing of the wound site was done after 48 h as per standard protocol, followed by observation and regular dressing till discharge. Patients with healthy wounds were discharged on the 5th post-operative day (after removal of non-absorbable stitches or with stitches *in situ* in case of subcuticular sutures) and were followed up in the OPD (out patients' department) after 30 post-operative days or in between, if, any complication arose. For patients who developed signs and symptoms of surgical site infection, wound swab was sent for culture and sensitivity, blood was sent for levels of CRP, TLC, and differential leucocyte count to note for neutrophil percentage. Broad spectrum antibiotics were empirically started and later modified as per culture-sensitivity reports. While some SSI healed with regular dressing, some of the infections required secondary suturing. Patients who were given secondary sutures were discharged the following day and were followed up in the OPD after 14 days for stitch removal. If anyone developed SSI after discharge (on 5th post-operative day), they were re-admitted and were managed similarly as those who developed SSI prior to 5 days.

Continuous variables were analyzed by Student's t-test or Mann–Whitney U-test depending on distribution. Categorical data were analyzed by Chi-square test or Fischer's exact test as appropriate. $P<0.05$ was considered statistically significant and values <0.001 were considered as statistically highly significant. Statistical analysis was done by Med Calc version 18.11 (Mariakarke Belgium: MedCalc software 2012).

RESULTS

In Table 1, sociodemographic and clinical parameters likely to act as confounding factors in the study have been compared and optimized between the two groups.

In Figure 1 The outcome variables of the two study groups have been demonstrated in a flow chart.

In Table 2, the outcome parameters have been compared. The incidence of SSI-overall, superficial incisional type, deep incisional type, as well as incidence of SSI developing between 48 h–5 days and 5 days–30 days were significantly ($P<0.05$) more in the povidone-iodine group than in the chlorhexidine group.

The surgical wound swab on culture showed that the percentage of infections due to Staphylococcus (both methicillin resistant and methicillin sensitive), *Escherichia coli*, and Pseudomonas are more in the povidone-iodine group than in the chlorhexidine group but with non-significant P value. The percentage of Klebsiella and no growth are however more in the chlorhexidine group than in the povidone-iodine group but with non-significant P value. Mean CRP, TLC and neutrophil percentage, though raised and comparatively more in povidone-iodine group than in chlorhexidine group, differences were not significant.

The percentage of patients healing with dressing was significantly ($P<0.05$) more in the chlorhexidine group than in the povidone-iodine group and the percentage of patients requiring secondary suturing was significantly ($P<0.05$) more in the povidone-iodine group than in the chlorhexidine group. The mean duration of hospital stay and incidence of re-admissions was significantly ($P<0.05$) more in the povidone-iodine group than in the chlorhexidine group.

DISCUSSION

This study was performed with the aim of comparing the efficacy of the two widely used antiseptic agents – chlorhexidine

Table 1: Distribution of the study population according to sociodemographic profile and clinical factors

Parameters	Chlorhexidine–alcohol (n=300)	Povidone-iodine (n=300)	P value
Mean age (in years)±SD	21.64±4.06	21.26±3.81	0.238
Mean BMI (kg/m^2)±SD	20.56±1.04	20.48±1.31	0.408
Residence			
Urban	135 (45%)	139 (46.33%)	0.743
Rural	165 (55%)	161 (53.67%)	
Socioeconomic status			
Upper	12 (4%)	16 (5.33%)	0.065
Upper middle	35 (11.67%)	29 (9.67%)	
Lower middle	106 (35.33%)	96 (32%)	
Upper lower	96 (32%)	125 (41.67%)	
Lower	51 (17%)	34 (11.33%)	
Maternal educational status			
No schooling	24 (8%)	12 (4%)	0.094
Primary (till class 4)	39 (13%)	44 (14.67%)	
Secondary (till class 10)	115 (38.33%)	138 (46%)	
Higher secondary (till class 12)	72 (24%)	67 (22.33%)	
Graduate	50 (16.67%)	39 (13%)	
Gravida			
Primigravida	143 (47.67%)	147 (49.00%)	0.744
Multigravida	157 (52.33%)	153 (51.00%)	
Period of gestation (at delivery)			
Preterm (<37 weeks)	44 (14.67%)	48 (16%)	0.717
Term (37-42 weeks) (including early-, full-, and late-term)	246 (82%)	239 (79.67%)	
Post-term (>42 weeks)	10 (3.33%)	13 (4.33%)	
Number of antenatal visits			
<4 visits	124 (41.33%)	135 (45%)	0.365
>4 visits	176 (58.67%)	165 (55%)	
Glycemic status			
Overt diabetes mellitus	4 (1.33%)	3 (1%)	0.856
Gestational diabetes mellitus	11 (3.67%)	13 (4.33%)	
Euglycemic	285 (95%)	284 (94.67%)	
Hypertensive disorders of pregnancy			
Chronic hypertension	7 (2.33%)	8 (2.67%)	0.984
Gestational hypertension	12 (4%)	14 (4.67%)	
Pre-eclampsia	15 (5%)	16 (5.33%)	
Eclampsia	5 (1.67%)	4 (1.33%)	
Normotension	261 (87%)	258 (86%)	
Blood hemoglobin status			
No anemia	143 (47.67%)	144 (48%)	0.973
Mild anemia	146 (48.67%)	147 (49%)	
Moderate anemia	10 (3.33%)	8 (2.67%)	
Severe anemia	1 (0.33%)	1 (0.33%)	
COVID-19 status			
Positive	8 (2.67%)	6 (2%)	0.589
Negative	292 (97.33%)	294 (98%)	
Prevalence of previous abdominal surgeries (including ceserean sections)			
Previous surgeries present	109 (36.33%)	111 (37%)	0.865
No previous surgery	191 (63.67%)	189 (63%)	
Duration of labor before cesarean section			
<12 h	253 (84.33%)	256 (85.33%)	0.733
>12 h	47 (15.67%)	44 (14.67%)	
Duration of premature rupture of membrane (PROM) (IF ANY)			
No prom	268 (89.33%)	264 (84%)	0.742
Prom for <18 h	29 (9.67%)	31 (10.33%)	
Prom for >12 h	3 (1%)	5 (1.67%)	
Number of per vaginal Examinations before cesarean section			
<4 times	188 (62.67%)	184 (61.33%)	0.737
>4 times	112 (37.33%)	116 (38.67%)	
Emergency versus elective Cesarean section			
Emergency	279 (93%)	282 (94%)	0.619
Elective	21 (7%)	18 (6%)	

(Contd...)

Table 1: *(Continued)*

Parameters	Chlorhexidine–alcohol (n=300)	Povidone-iodine (n=300)	P value
Length of skin incision			
<0.166 m	147 (49%)	158 (52.67%)	0.369
>0.166 m	153 (51%)	142 (47.33%)	
Suturing technique and suture Material used			
Mattress suturing with ethilon monofilament	146 (48.67%)	152 (50.67%)	0.624
Subcutaneous suturing with vicryl rapide	154 (51.33%)	148 (49.33%)	
Mean duration of cesarean section (in min±SD)	54.41±15.53	54.22±12.06	0.867

The quantitative variables are tabulated as Mean±Standard Deviation (SD) and p value has been calculated using Unpaired Student's t-Test. Categorical variables are tabulated as frequency (percentage) and p value has been calculated using Chi-square test

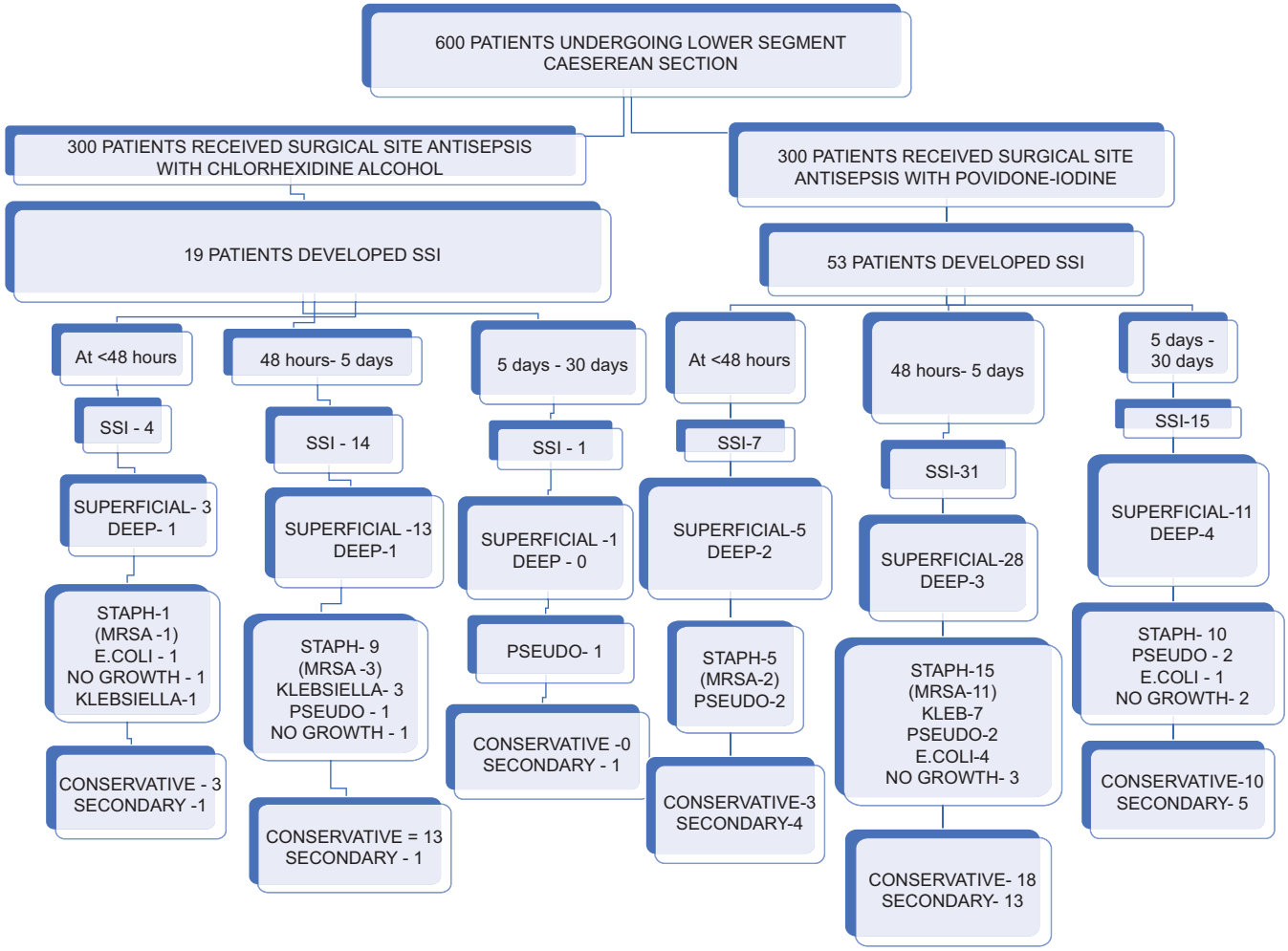

Figure 1: Flowchart depicting the outcome variables among the two study groups

(2.5%)–alcohol and povidone-iodine (10%) – alcohol in surgical site antisepsis with 300 study population in each of the two study groups.

With respect to sociodemographic profile, the two study populations were found to be similar.

Other clinical parameters likely to influence surgical site infection rates were also studied and the two groups were found to be similar with respect to such confounding factors.

A significantly lesser percentage of the study population of chlorhexidine–alcohol group [19 (6.33%)] developed SSI as compared to the povidone-iodine group [53 (17.67%)] with a P<0.001. Similar results showing chlorhexidine to be more efficient than povidone-iodine have been found in studies by Kesani VP et al., (6.95% vs. 14.28%,

Table 2: Comparison of the outcome parameters between the two study population

Parameters		Chlorhexidine–alcohol (n=300)		Povidone-iodine (n=300)		P value
		NO SSI	SSI	NO SSI	SSI	
Incidence of surgical site infection		281 (93.67%)	19 (6.33%)	247 (82.34%)	53 (17.67%)	<0.0001
Incidence of SSI according to time taken to develop	<48 h	4 (1.33%)		7 (2.33%)		0.361
	48 h–5 days	14 (4.67%)		31 (10.33%)		0.009
	5 days–30 days	1 (0.33%)		15 (5.0%)		<0.001
Incidence of SSI based on type	Superficial incisional SSI	17 (5.67%)		44 (14.67%)		<0.001
	Deep incisional SSI	2 (0.67%)		9 (3%)		0.033
	Organ/space SSI	0 (0%)		0 (0%)		-
Micro-0rganisms on wound swab culture	Staphylococcus	-	10 (52.63%)	-	30 (56.60%)	0.922
	a. Methicillin sensitive		a. 6 (31.58%)		a. 17 (32.08%)	
	b. Methicillin resistant		b. 4 (21.05%)		b. 13 (24.53%)	
	Escherichia coli	-	1 (5.26%)	-	5 (9.43%)	
	Pseudomonas	-	2 (10.53%)	-	6 (11.32%)	
	No growth	-	2 (10.53%)	-	5 (9.43%)	
	Klebsiella	-	4 (21.05%)	-	7 (13.20%)	
Laboratory parameters following development of SSI	Mean C-reactive protein±SD	-	10.37±1.32	-	11.02±1.40	0.083
	Mean total leucocyte count±SD	-	16982.39±1748.49		17018.14±1588.83	0.935
	Mean neutrophil percentage±SD	-	77.89±1.17	-	78.08±1.56	0.630
Treatment procedure adapted	Conservative management	-	16 (84.21%)	-	31 (58.49%)	0.045
	Secondary suturing	-	3 (15.79%)	-	22 (41.51%)	0.045
Mean hospital stay (In days±SD)		-	6.1579±0.393	-	6.9623±1.42	0.018
Number of re-admissions		-	1 (5.26%)	-	15 (28.30%)	0.040

Categorical variables are tabulated as frequency (percentage) and p value has been calculated using Chi-Square test. The quantitative variables are tabulated as mean±standard deviation (SD) and p value has been calculated using unpaired student's t-test

P=0.05),[5] and a randomized control trial by Tuuli et al., (4.0% vs. 7.3%, P=0.02).[17] However, chlorhexidine and povidone-iodine were found to be similar in efficacy in studies by Elshamy et al., (3.7% vs. 4.6%, P=0.35)[18] and Springel et al., in the CAPICA trial (6.3% vs. 7.0%, P=0.38).[19] However, in both the above studies, results were not significant (P>0.05). In a recent RCT conducted in India by Luwang et al., chlorhexidine was found to be a better antiseptic agent than povidone-iodine (5.4% vs. 8.6%, P=0.276).[20]

A greater percentage of SSI developed in the povidone-iodine group as compared to the chlorhexidine group with significant P<0.05 in the period of 48 h–5 days (4.67% vs. 10.33%, P=0.009) and 5 days–30 days (0.33% vs. 5.0%, P<0.001) and with non-significant P<48 h postoperatively (1.33% vs. 2.33%, P=0.361). In a study by Kesani VP et al.,[5] more percentage of SSI developed in the povidone-iodine group than in the chlorhexidine group at 48 h–1 week (5.12% vs. 10.80%, P=0.014) and in ≤1 week post-operative period with significant P values (5.86% vs. 11.49%, P=0.018) but with non-significant P value in 8 days–30 days follow-up period (1.09% vs. 2.78%, P=0.15).

A significantly greater percentage of patients in the povidone-iodine group as compared to chlorhexidine group developed both superficial incisional [44 (14.67%) vs. 17(5.67%); P<0.001] and deep incisional SSIs [9 (3%) vs. 2 (0.67%); P=0.033]. This was similar to studies by Kesani VP et al.,[5] In a study by Darouiche et al., they showed that the incidence of SSI with chlorhexidine gluconate 2%+Isopropyl alcohol 70% is lesser (33 out of 409 subjects with 17 having superficial, 4 having deep, and 18 having organ space infection postoperatively) than that with povidone-iodine (71 out of 440 subjects, with 38 having superficial, 13 having deep and 20 having organ space infections postoperatively) (RR=0.59, 95% CI=0.41–0.05) (P=0.004).[21]

The wound swab cultures showed no significant result difference among the SSIs of the two study groups and this was similar to studies by Kesani VP et al.,[5] The most common organism associated with both of our study groups were *Staphylococcus aureus* [mostly methicillin sensitive (31.58% vs. 32.08%), though quite a few were methicillin resistant (21.05% vs. 24.53%)] while in the study by Kesani VP et al,[5] *E. coli* was found to be the most common organism (42.10% vs. 26.82%). However, in the Indian study conducted by Luwang et al.,[20] *E. coli* (31.25%) was found to be the most commonly isolated organism from post-cesarean SSI. They also showed that chlorhexidine is effective against *Enterococcus faecalis* and *E. coli*. The difference in the associated microflora in the

different studies is probably based on the local nosocomial microflora.

A study by Shen et al., [22] has shown that CRP, TLC, and neutrophil percentage are useful indicators of SSI. In the two study groups, these parameters were found to be raised from baseline and comparatively more in the povidone-iodine group than in the chlorhexidine group, but differences were non-significant. Such parameters are raised based on the body's intrinsic defense mechanism and were thus found not to be influenced by the extrinsic antiseptic agent used.

SSIs may be managed conservatively or surgically with secondary suturing.[20] In the study by Luwang et al., the average duration of hospital stay was 3–4 days with only 1 patient (4.67%) requiring resuturing, while the rest of the patients healed with secondary intention.[20] However, in that study, no comparison was made between the two study groups regarding mode of treatment after the development of SSI. In our study, in the chlorhexidine group as compared to the povidone-iodine group, a significantly greater percentage was managed with dressing alone (84.21% vs. 58.49%, P=0.045) and a significantly lesser percentage required secondary suturing (15.79% vs. 41.51%, P=0.045).

Researches showed that length of hospital stay[23] and readmissions[24] were significantly associated with SSIs. In our study, the mean duration of hospital stay was 6–7 days with a significant difference between the two groups (chlorhexidine vs. povidone-iodine – 6.1579±0.393 vs. 6.9623±1.42, P=0.018). One patient (5.26%) in the chlorhexidine group required readmission while 15 patients (28.30%) in the povidone-iodine group required readmission with a significant difference between the two groups (P=0.040).

Limitations of the study

The limitation of the study is that some more factors which might confound the results of the study like expertise of surgeon performing the cesarean section, subcutaneous tissue thickness, and certain wound classification systems which might help to understand the SSIs better have not been considered. Another drawback is that, pre-operative skin swab for analysis of skin microflora was not performed. Furthermore, results might be biased, because data are collected in a tertiary care hospital, and hence, the actual rural picture might not be reflected.

CONCLUSION

Thus, analyzing the results in the two groups, we found that on using chlorhexidine alcohol for surgical site antisepsis, the rate of SSI – overall, superficial incisional, deep incisional, and also SSI developing at 48 h–5 days and even up to 30 days postoperatively was significantly lesser than on using povidone-iodine. Furthermore, significantly greater percentage of SSIs in the chlorhexidine group healed with conservative management with meager dressing and significantly lesser percentage required secondary suturing, readmissions and had a significantly lesser hospital stay. Thus, chlorhexidine alcohol was found to have a better overall effect in preventing SSI, and hence, a better effect on cosmesis, maternal physical, and mental well-being and also on healthcare cost. Thus, chlorhexidine (2.5%)–alcohol appears to be a better pre-operative surgical site anti-septic agent than povidone-iodine (10%) alcohol for prevention of SSI.

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