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A prospective comparative study of chlorhexidine-alchohol versus povidone-iodine for surgical site antisepsis in clean contaminated surgery

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ABSTRACT:-

Background: Experience with surgical site infection after any surgical procedure is vast and spans generations of surgeons. Worldwide, surgeons use chlorhexidine-alchohol or povidone iodine as pre-operative skin cleansing agent. But it is still unknown that which one is better as there is no recommendation till date and is a topic of major debate among surgeons.

Methods: A hospital based Prospective Comparative Study was undertaken among pre-operative skin swab culture positive patients who have undergone clean-contaminated surgery in a tertiary care hospital of Kolkata to compare between efficacy of Cholorhexidine-Alcohol and Povidone- Iodine as skin cleansing agent for prevention of surgical site infection. All the patients were followed-up for 30 days post-operatively for any evidence of wound infection. If the post-operative wound infection was due to same organism that was present in pre-operative skin swab culture report, then failure of skin cleansing agent was considered. Any specific sensitivity/resistance of any organism to specific skin cleansing agent were also noted.

Results: Among the 90 patients under the study pre-operative antisepsis was found to be successful for 67(74.4%) patients. Cure rate for povidone iodine group (69.4%) was less than Cholorhexidine-alcohol group (80.5%). So, Cholorhexidine-alcohol found to have more strong pre-operative antiseptic action in the study but this difference was not statistically significant (p value-0.229). Regarding specific organism sensitivity, both the agents were also comparable.

Conclusion: Pre-operative skin cleansing plays a vital role in determining the surgical outcome. There is a need to conduct more in depth analytical studies for evaluation of specific sensitivity/resistance of micro- organisms against specific skin cleansing agent for appropriate selection of pre-operative skin cleansing agent to prevent post-operative surgical wound infection.

Key words: Cholorhexidine – Alcohol, Povidine – Iodine, surgical site antisepsis.

Introduction:

Experience with surgical site infection after any surgical procedure is vast and spans generations of surgeons. Knowing the fact that skin is the major source of pathogens responsible for surgical site infection. All the surgeons worldwide use chlorhexidine-alchohol or povidone iodine as preoperative skin cleansing agent. But it is still unknown that which one is better and there is no recommendation till date.

Pre operative skin antisepsis is based on the fact that patient's skin is a significant source of pathogens, so optimization of pre operative skin antisepsis may decrease the post operative surgical site infection. Surgical site infection increases the morbidity, mortality, length of hospital stay and financial burden after surgical procedures. Two major antiseptic agents used worldwide as preoperative skin cleansing agent are chlorhexidine-alchohol and povidone iodine. They both destroy bacterial structural integrity and have been studied extensively, but till date there is no clear cut, published recommendation about the pre operative skin cleansing agent.

OBJECTIVE:

The objective of the study is to observe and compare the efficacy of chlorhexidine-alchohol with that of povidone-iodine for surgical site antisepsis and prevention of post operative surgical site infection in clean contaminated surgeries.

Methods:

Type of Study: Hospital based Prospective Comparative Study.

Study Area: Dept of General Surgery, Institute of Post Graduate Medical Education and Research, SSKM Hospital, Kolkata

Study Population: Patients of either sex who have undergone elective clean contaminated surgeries in the Dept. of General Surgery, IPGME&R, SSKM Hospital, Kolkata during the study period were selected for the study after strict application of exclusion criteria.

Primary Exclusion criteria:

 Patients unwilling to take part/ give consent for that study

- Patients underwent emergency surgeries
- BMI more than 30
- Patients with diabetes mellitus or collagen vascular diseases
- Immunocompromised patients or patients with long standing steroid therapy
- Any ulcer/infected wound near the surgical site
- Any history of skin allergy/contact dermatitis

Secondary exclusion criteria

- Patients with negative pre operative skin swab culture and sensitivity
- Patients ,who were lost to follow-up,
 for example, death within 30 days
 after surgery before the availability of
 post operative wound swab culture
 report, or patients who didn't come in
 follow-up clinic.

STUDY PERIOD: One year (May 2012 – April 2013)

Selection of Study Population:

A total of 368 patients underwent cleancontaminated surgeries in the Main OT Complex of SSKM Hospital, under unit II, Dept of general surgery during the one year study period and 125 of them were excluded after application of primary exclusion criteria. The reasons for exclusion were: **Patients** willing not to participate=6; Diabetic=65; BMI>30=26; Immunocompromised =14; Ulcer/infected wound near surgical site=11; Known skin allergy=3.

After primary exclusion 243 patients were available for the study and were subjected to intervention. The selected patients were line listed according to the hospital register and Povidone-iodine and chlorhexidine alcohol were used alternatively for surgical site antisepsis according to the serial number. Thus 122 patients were given povidone-iodine as pre-operative surgical site cleansing agent and for 121 patients' chlorhexidine were used for the same.

After applying secondary exclusion criteria 153 patients were again excluded from analysis as Pre-operative skin swab culture and sensitivity came negative for 116 patients and 37 pre-operative skin swab positive patients were lost to follow up. So, the final sample size of the study was 90.

Research Instrument and Measurement:

Study Tools:

- A pretested and predesigned
 questionnaire for history taking and
 collection of operative and post-operative
 follow up data.
- Bed Head Ticket (BHT) of the patients
- Pre-operative skin swab culture
- Post-operative surgical site wound swab culture
- Other relevant laboratory investigations

Parameters Studied:

- Body weight and height
- Hemoglobin level
- Blood glucose level
- Duration of surgical procedures
- Pre-operative skin swab
- Post operative surgical site infection
- Post operative wound swab
- Duration of post-operative hospital stay

Study Technique:

questionnaire developed Α was reviewing previous similar studies and different related articles and with help of the questionnaire a thorough history was taken from the patients and after that a number of pre-operative investigations were checked to rule out any co-morbid conditions and patients were enrolled against the inclusion/exclusion criteria of the study. After enrolment, total patients were divided in two random groups, 10% povidone-iodine was used in one group, and chlorhexidine-alchohol was used in another group as pre-surgical antiseptic agent. Antibiotics were fixed in each type of surgical procedures according to the recommended protocol and all the surgeries were performed in the same Operation Theatre to minimize bias. Preoperative skin swab was taken from surgical site before cleansing from every enrolled patient, only the skin swab positive patients were finally included in this study.

All the patients were followed-up for 30 days post-operatively and if there was any surgical site infection; wound swab was again taken and sent for culture. This report was compared with the pre-operative culture report. If the infection was

due to any organism that was not present in previous culture report, then that surgical site infection was not considered as a failure of skin cleansing agent used in that operation. Any specific sensitivity/resistance of any organism to specific skin cleansing agent were noted.

Statistical Analysis:

Data entry and statistical analysis were done using SPSS version 20.0. Descriptive statistics were used primarily to summarize and describe the data to make it more graspable.

For analytical statistics, Chi-square was used where appropriate. For all the statistical tests of significance, p value of <0.05 was considered to reject the null hypothesis.

Then relationship between various factors was studied using univariate & multivariate logistic regression analysis. The final multivariate regression model contained variables which were found significant during univariate analysis.

ETHICAL CONSIDERATIONS:

The Institutional Ethics Committee of IPGME&R, SSKM Hospital, Kolkata reviewed the proposal for ethical consideration and approval was obtained prior to the study.

Written consent was taken from the respondents prior to enroll in the study. The respondents were explained in detail the full description of the research, confidentiality and voluntary participation. They were assured that all data provided by them would be kept confidential and be used only for research or academic purpose. Every received data were treated carefully. Thus, the three principles which need to be followed in any biomedical research i.e. beneficence (an obligation to do no harm by protecting the participants from physical and psychological harm, and preventing them from exploitation), respect of human dignity (full disclosure of the research project and letting the participants decide whether to participate or not in the study) and justice (study participants have the right to be treated equally and fairly in the selection as well as during the course of the study) was considered throughout this study.

RESULTS:

The present hospital based follow up study was undertaken among pre-operative skin swab culture

positive patients who have undergone clean-contaminated surgery in a tertiary care hospital of Kolkata to compare between efficacy of Cholorhexidine-Alcohol and Povidone- Iodine as skin cleansing agent for prevention of surgical site infection. Among the 90 patients under the study povidone Iodine was used as pre-operative skin cleansing agent for 49(54.4%) patients and Cholorhexidine-Alcohol was used for the rest (45.6%).

Majority (60%) of study population belonged to the age group of 40 to 59 years followed by the age group of 20 to 39 years (18.9%). Proportion of two types of pre-operative skin antisepsis differed in different age group but this difference was not statistically significant when association was tested with chi-square test (result not shown). Proportion of male participants (53.3%) slightly outnumbered female in the study and Povidone Iodine was used for pre- operative skin antisepsis

for 56.2% of male and 52.4% of female but Chisquare test revealed no statistically significant difference between type of pre-operative antisepsis and gender (P-Value: 0.715). Open cholecystectomy (25.6%) followed by laparoscopic cholecystectomy was the two most common type of surgery performed among the study population (not shown).

According to International classification of BMI 67.8% of the study population were having normal BMI and 32.2% were pre-obese whereas according to Asian classification of BMI 44.4% of the study population were having normal BMI, 23.3% were overweight and 32.2% were obese. There was no statistically significant difference between type of pre-operative antisepsis and BMI of the study population. Both International and Asian classification of BMI was consistent with the finding.

Table-1: Distribution study population according to pre-operative culture sensitivity finding of skin swab and type of surgical site antisepsis: (n=90)

	Intervention g	Intervention given		
Pre-operative skin culture finding				
	povidone	Cholorhexidine-	Total	
	Iodine	Alcohol		
Staph epidermidis	20(71.4%)	8(28.6%)	28(100%)	
Streptococcus viridians	13(48.1%)	14(51.9%)	27(100%)	
Enterococcus faecalis	7(36.8%)	12(63.2%)	19(100%)	
Staph aureus	3(60.0%)	2(40.0%)	5(100%)	
Streptococcus pyogens	2(100%)	0	2(100%)	
E-coli	5(50%)	5(50%)	10(100%)	
C1 C	177			
Chi-Square Test: Value8.967; df-6; P value-0.	1/5			

^{*}Not mutually exclusive

Majority (38.9%) of the study population found to have serum albumin level within 3.5 to 3.9 gm/dl and 13.3% patients had serum albumin less than 2.9 gm/dl. Duration of surgery for majority (44.4%) of the patients was 1 to 2 hours and a small proportion (5.6%) of patients had undergone surgery which took more than 4 hours time. Preoperative culture sensitivity report of skin swab for majority (31.1%) of the study population was

positive for Staphylococcus epidermidis followed by Streptococcus viridans (30.0%). Around 21.1% and 11.1% patients found to be positive for Enterococcus faecalis and E-coli respectively. But, when comparison was done between the two groups both the groups were found comparable regarding the above mentioned characteristics (Table-1).

Table-2: Distribution study population according to post-operative culture sensitivity finding of wound swab and type of surgical site antisepsis: (n=90)

Culture result after OT	Intervention given	Intervention given				
	povidone Iodine	Cholorhexidine-				
	_	Alcohol				
Staph epidermidis	4(100.0%)	0	4(100%)			
streptococcus Viridans	4(80.0%)	1(20.0%)	5(100%)			
Enterococcus faecalis	6(66.7%)	3(33.3%)	9(100%)			
Staph aureus	4(60.0%)	2(40.0%)	6(100%)			
Streptococcus pyogens	1(100.0%)	0	1(100%)			
Diptheroids	1(100.0%)	0	1(100%)			
E-coli	8(57.1%)	6(42.9%)	14(100%)			
Klebsiella	1(50.0%)	1(50.0%)	2(100%)			
Pseudomonas	2(100.0%)	0	2(100%)			
Negative	28(49.1%)	29(50.9%)	57(100%)			
Chi-Square Test: Value14.714; df-13; P value-0.326						

^{*}Not mutually exclusive

Around 63.3% of the patients with positive preoperative skin swab culture found to negative for post-operative wound swab culture sensitivity. Post-operative culture sensitivity report of wound swab for 15.6% of the study population was positive for E-coli followed by Enterococcus faecalis (10.0%).Culture sensitivity report of 6.6 % and 5.6% patients found to be positive for Staphylococcus aureus and Streptococcus viridans respectively. There was no statistically significant difference in Post-operative culture sensitivity finding of wound swab among two groups of patients (Table-2).

Table-3: Distribution study population according to type of pre-operative skin antisepsis and outcome: (n=90)

	Intervention giv	en		Chi-
Outcome	povidone	Cholorhexidine-	Total	Square
	Iodine	Iodine Alcohol		test
Cured	34(69.4%)	33(80.5%)	67(74.4%)	Value: 1.446
Failed	15(30.4%)	8(19.5%)	23(25.6%)	df: 1
Total	49(100%)	41(100%)	90	P-Value: 0.229



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Among the 90 patients under the study preoperative antisepsis was found to be successful for 67(74.4%) patients. Pre-operative antisepsis was not effective for around one fourth of the study population (Table-3). Cure rate for povidone iodine group (69.4%)was less than Cholorhexidine-alcohol group (80.5%).So. Cholorhexidine-alcohol found to have more strong pre-operative antiseptic action in the study but this difference was also not statistically significant (p value-0.229).

Among the 90 patients under the study, postoperative hospital stay was prolonged than usual
for 17.8% of patients. Around 85.4%

patients of Cholorhexidine-alcohol group
discharged within usual hospital after surgery
whereas 79.6% patients of povidone iodine group
discharged within usual hospital after surgery
(Not shown). This difference was not found to be
statistically significant (p value-0.476).

Table-4: Covariates of outcome- Multivariate logistic regression model: (n=90)

		Outcome variable		0.11	95%Confidence
Independent variable		Cured	Failed	Odds R	Interval
				at i	
				0	
Age in years	Up to 48 years	40	8	2.637	0.824 – 4.275
	More than 48 years(ref)	27	15		
Sex	•		14	1.335	0.417 – 4.275
	Female(ref)	33	9		
BMI	Continuous variable			1.017	0.808 - 1.280
Serum albumin level	Serum albumin level Normal		10	0.786	0.215-2.867
	Hypoalbuminemia(ref)	33	13		
Duration of surgery	Duration of surgery Less than 2 hrs		12	0.488	0.123 – 1.934
	More than 2 hrs(ref)	12	11		
TLC Normal		64	15	0.092	0.019 - 0.432
	Elevated(ref)	3	8		
Method of skin	povidone Iodine	34	15	0.666	0.220 - 2.018
antisepsis	Cholorhexidine- Alcohol(ref)	33	8		

Univariate logistic regression revealed, Patients with age less than 48 years, less (<2 hrs) duration of surgery and normal WBC count found to be protective for failure of pre-operative antisepsis. Gender, BMI, serum albumin level and Hb% found to have no relationship with outcome of

pre-operative antisepsis (not shown). Adjusted logistic regression model identified total WBC count as the only statistically significant covariate for outcome. Normal WBC count of a patient found to be protective for antisepsis failure with

compare to elevated WBC count irrespective of

the type of pre-operative antisepsis (Table-4).

Table-5: Comparison of efficacy of Povidone Iodine and Cholorhexidine – Alcohol as preoperative skin cleansing agent against specific organisms: (n=90)

Organism	Method of pre-	Outcome			Chi-square
	operative	Cured	Failed	Total	test
	skin				
	antisepsis				
I. Staph	povidone Iodine	16(80%)	4(20%)	20(100%)	Value1.867;
epidermid	Cholorhexidine-	8(100.0%)	0	8(100%)	df-1;
is	Alcohol				Pvalue-
	Total	24(85.7%)	4(14.3)	28(100%)	0.172
II.	povidone Iodine	11(84.6%)	2(15.4%)	13(100%)	Value-
Streptoco	Cholorhexidine-	14(100.0%)	0	14(100%)	2.326
ccus	Alcohol				df-1;
viridians	Total	25(92.6%)	2(7.4%)	27(100%)	Pvalue-
					0.127
III.	povidone Iodine	6(85.6%)	1(14.3%)	7(100%)	Value-
Enterococ	Cholorhexidine-	9(75.0%)	3(25.0%)	12(100%)	0.305;
cus	Alcohol				df-1;
faecalis	Total	15(78.9%)	4(21.1%)	19(100%)	P-value-
					0.581
IV.E-coli	povidone Iodine	0	5(100%)	5(100%)	Value-
	Cholorhexidine-	2(40.0%)	3(60.0%)	5(100%)	2.057;
	Alcohol				df-1;
	Total	2(22.2%)	8(77.8%)	10(100%)	P-value-
					0.151
V. Staph	povidone Iodine	0	3(100%)	3(100%)	
aureus	Cholorhexidine-	0	2(100%)	3(100%)	
	Alcohol				
	Total	0	5(100%)	3(100%)	

When both the antiseptic agent were compared for individual micro-organism susceptibility, Povidone Iodine and Cholorhexidine-Alcohol found to be equally effective against Staph epidermidis, Streptococcus Viridans, Enterococcus faecalis and E-coli but both were

found to be totally ineffective g against Staph aureus (Table-5).

DISCUSSION:

Literature review of previous similar studies showed variable findings: some studies found chlorhexidine-alchohol is more effective as pre-operative skin antiseptic agent than povidone-iodine, while some studies showed povidone-iodine and chlorhexidine-alchohol having same efficacy in the means of pre-operative skin antisepsis.

Darouiche et al[1], Noorani et al[2], Paocharoen et al [3], Culligan et al [4], Maki al[5], Lee et al[6] concluded that chlorhexidine-alcohol is more effective skin antiseptic agent than povidone-iodine. Present chlorhexidinestudy finding identified alchohol more effective than povidone-iodine in terms of pre-operative skin antisepsis though the difference was statistically nonsignificant (P-value->0.05). It is probable that, sample size of the current study was not sufficient enough to conclude statistically significant better efficacy of chlorhexidinealcohol over povidone-iodine. On the other hand, none of these studies, pre-operative skin swab was not taken, they have only counted operative/post interventional wound infection as a failure of the specific skin cleansing agent. In present study preoperative

skin swab was taken from surgical site, if this was positive, it was matched with the post operative wound culture report if both reports denoted same bacteria, then only it was noted as failure of specific skin cleansing agent. Surgical site infection can be occurred due to various reasons, the purpose of skin of surgical site cleansing is to decrease the bacterial count present as skin flora, so any infection operatively post should not documented as failure of specific skin cleansing agent. This might have also attributed in the difference in findings with the present study.

Most of these previous studies were conducted in developed countries, this present study was undertaken in a developing, tropical country i.e. India. The sensitivity/resistance pattern of pathogen individual varies any across worldwide. In India, the pathogens are more resistant to antimicrobial agents than the developed countries due mainly: inappropriate antibiotic prescription; inadequate dosage of antibiotics; antibiotics prescribed by non medical persons (over the counter medicine prescription). So, generally, the behaviour of any pathogen to antimicrobial agents is different in developing tropical countries than the western developed countries .so the difference in the finding of this study from previous similar studies was natural. Generally, operation theatre sterility in developing countries differs from the operation theatre sterility of the developed countries that could be also an explanation of difference in the finding.

Some previous studies like Garland et al [7], Kulkarni et al [8], Humar et al [9], Kasuda et al [10], Gupta et al [11], showed similar result as found in that present study. The only study conducted in Tata Memorial Hospital, India by Kulkarni et al [8] showed no difference between chlorhexidine-alchohol and povidone iodine in terms of skin antisepsis that partly validates the present study.

None of the previous studies showed specific sensitivity or resistance of any particular organism to any particular skin antiseptic agent, but in this study it was found that Povidone Iodine and Cholorhexidine-Alcohol were equally effective as pre-operative skin cleansing agent against Staph epidermidis, Streptococcus Viridans, Enterococcus faecalis and E-coli and both of it were found to be totally ineffective as pre-operative skin cleansing against Staph aureus. But theoretically both skin antiseptic agents are highly sensitive for staphylococcus aureus; it due the different may be to sensitivity/resistance pattern of staph aureus in these developing tropical countries. This again indirectly validates finding the conclusion of this present study.

Despite the strong points mentioned above, there were some limitations and possibility of bias in the results. One limitation of this study was, no skin swab was taken intra-operatively, as a portion of skin pathogens are colonized in dermal layer of skin, so they proliferate after skin incision, to minimize this incident all the patients in this study underwent shaving rather than epilation, so that the skin pathogens residing behind the epidermal, layer can come

over the skin surface, so that the pre operative skin swab becomes positive.

Though a wide range of risk factors may also lead to post-operative wound infection except the efficacy of skin cleansing agent it was not possible for the researcher to consider them due to time and resource constrains. The two groups of patients were adjusted for age, sex, BMI, Serum albumin level, Hb%, TLC when comparison of efficacy was done between two types of skin cleansing agent. It is possible that other health related characteristics which were not considered in the study might have confounded the outcome of the study.

In the present study, skin cleansing agent was considered effective when the organism isolated from pre-operative skin swab was absent in post-operative wound swab. But, it is not necessary that, post-operative wound infection will occur by micro-organism present in the skin surface only even in case of clean contaminated surgery. So, it is possible to get re-infection during inta-operative or post-operative period by the same type of organism isolated from pre-operative skin

swab. This might have biased effectiveness of skin cleansing agent to a lower level.

Another limitation of the present study was: only aerobic culture and sensitivity was done in the study for both preoperative skin swab and post operative wound swab. No fungal, anaerobic and mycobacterium culture could be done for resource constrains.

CONCLUSION:

Pre-operative skin cleansing plays a vital role in determining the surgical outcome. In the present study pre-operative skin antisepsis was found was to be ineffective in case of around one fourth of the patients. Cholorhexidine - Alcohol and Povidine -Iodine were equally effective for preventing surgical site infection and normal WBC count of a patient found to be protective for antisepsis failure with compare to elevated WBC count. Regarding specific organism sensitivity, both the agents were equally effective against Staph epidermidis, Streptococcus Viridans, Enterococcus faecalis and E-coli but totally ineffective against Staph aureus. There is a need to conduct more in depth analytical studies for evaluation of specific

sensitivity/resistance of micro- organisms

against specific skin cleansing agent for

appropriate selection of pre-operative skin cleansing agent to prevent post-operative surgical wound infection.

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