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Efficacy of povidone iodine and alcohol-chlorhexidine gluconate antiseptic solutions in patients undergoing Orthopaedic Surgery

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Abstract
Introduction: Surgical site infection is a well-known and relatively common complication of orthopaedic surgeries. Despite the dreaded effects, there's no common agreed protocol at most of the Hospitals in India. Since the patient's skin is a major source of pathogens that cause surgical-site infection, proper optimization of preoperative skin antisepsis may decrease postoperative infections.
Objective: To compare the effect of 10% povidone iodine and 70% ethyl alcohol-0.5% chlorhexidine gluconate antiseptic solutions on lowering bacterial load pre operatively in patients undergoing Orthopaedic Surgery at Ruby Hall Clinic.
Methodology: It was a randomized controlled trial, done at Department of Orthopaedics, Ruby Hall Clinic. A total of 44 consecutive patients undergoing orthopaedic surgery in the month of March, 2019 were recruited into the study and randomized to receive one of two antiseptic solutions (10% Povidine-iodine or Chlorhexidine gluconate 0.5% with ethyl alcohol 70%). Swabs were taken from incision site and analyzed via qualitative and quantitative analysis before and after skin preparation.
Results: The proportion of positive culture was significantly higher in the Povidone iodine group (28.6%) than in the Ethyl alcohol-chlorehxidine gluconate group (4.5%) (p=0.035). 70% Ethyl-Alcohol-0.5% chlorhexidine gluconate solution is more effective than 10% Povidone iodine in Ankle region (p-0.013). Age, sex, type of ward (Private, Semi Private or General) and the duration of hospital stay do not influence efficacy of either 10% Povidone iodine or 70% Ethyl-alcohol-0.5% chlorhexidine gluconate solutions.
Conclusion: We suggest that alcohol-based formulation (Eg 0.5% chlorhexidine gluconate-70% ethyl alcohol) be used for skin preparation in Orthopaedic surgery as it is superior to Povidone Iodine.

Keywords: Surgical site infections, chlorhexidine, povidone iodine, preoperative, skin preparation

Introduction

The introduction of skin antiseptic solution in the 1860s revolutionized the surgical treatment of patients by decreasing the incidence of postoperative infections, previously a common and feared occurrence [1]. Despite the implementation of preoperative preventive measures, which include skin cleansing with povidone–iodine, surgical-site infection occurs in 300,000 to 500,000 patients who undergo surgery in the United States each year [2, 3], and this creates a need for proper preventive measures of post-operative infection. Surgical site infection related to orthopaedic surgeries at Ruby Hall Clinic has been observed to be relatively low as compared to the national average. Despite the observed low infection rate, Ruby Hall Clinic has no standard protocol on optimum type of antiseptic solution. Lack of protocol on optimum method and type of antiseptic solution may be one of possible contributing factor of observed Surgical site infection, and a presence of one may be helpful in being utilized by other hospitals to achieve the low infection rate that Ruby Hall Clinic currently has. Moreover, even the CDC has not issued a recommendation as to which antiseptics should be used preoperatively to prevent postoperative surgical-site infection in the 27 million operations performed annually in the United States [4].

Normal skin flora such as *Staphylococcus aureus* and coagulase-negative *staphylococcus* Spp, are common causes of surgical-site infections after orthopaedic surgery [1]. Patients' skin at the operation site is routinely prepared with antiseptic solutions in the operating theatre before

surgical incisions is made. Skin preparation with an antiseptic aims to reduce the number of microorganisms present on the skin, and hence reduce the risk that the surgical wound will become infected [1].

It was of benefit to know the comparison efficacy of 70% Ethyl-alcohol-0.5% Chlorhexidine gluconate and 10% Povidone iodine antiseptic skin solutions on reduction of bacterial load in Orthopaedic surgeries and influence of some patient and hospital facors, findings that would be useful in making decision on optimum type and method of antiseptic solution.

Materials and Methods

Fourty four patients (13 female, 31 male, mean (SD) age 37.2 (±17.6) years) undergoing orthopaedic surgery during March 2019, were enrolled in this prospective randomized study. Of the 44 operations, 21 involved thigh incisions, 11 Hip, 4 ankle, 4 forearm, 2 arm, 1 elbow and 1 leg.

Subjects were excluded if they had current open wounds, active infection, a history of antiseptic use immediately before taken to theatre, no implant. Subjects were randomized via generation of random number blocks to be prepared with either 10% povidone iodine (n=22) or 70% alcohol-0.5% chlorhexidine gluconate (n=22). A single reviewer did all the pre-operative skin preparations to avoid bias. A sterile cotton wool was used to apply the solution using paint technique. Swab was taken after 3 min to give adequate contact and dry time, placed in a transport media and then taken to bacteriology laboratory for culture and quantitative analysis. All swabs were handled by a dedicated bacteriologist.

The pre-preparation swabs were diluted to 1:120 and 1:480, the post-preparation swabs were neat and diluted to 1:120. The sample plated onto a blood agar Petri dish for aerobic growth, then positive culture was recorded and quantified by counting the number of colony forming unit. All subjects gave written informed consent. Microbiologist was blinded regarding to which intervention group the swabs were taken from.

Statistical analysis

Using formula for comparing two proportions, a power analysis indicated that a sample size of 22 patients in each group (A total of 44 patients) would provide 80% power to detect a significant difference ($p<0.05$), between antiseptic solutions and groups, with regard to the proportion of positive cultures of specimens obtained from each site.

Quantification of organisms were presented for means and SD using the Student's t-test to identify factors that statistically affect the ability of antiseptic solution to lower bacteria load. P-values at two tailed level of significance of 0.05 were presented. Two-sample Wilcoxon rank-sum (Mann-Whitney) used for normality and skewness of the data respectively was used to reject the null hypothesis. The data entry screen was designed using EPI-DATA (3.1) then exported to STATA (13.0) for data cleaning and analysis.

Results

Majority of participants were from General Wards (50% for 10% povidone iodine and 72.7% for 70% ethyl alcohol-0.5% chlorhexidine gluconate groups) and most of them had surgeries involving thigh incision (50% for 10% povidone iodine and 45.5% for 70% ethyl alcohol-0.5% chlorhexidine gluconate groups). The mean (SD) duration of hospital stay was 09.6 (±11.6) in days.

No significant difference in age, sex, duration of hospital stays or site of admission was demonstrable between the two groups. 70% Ethyl alcohol-0.5% chlorhexidine gluconate was superior than povidone iodine regard to bacteria inhibition in ankle region related surgical incisions (p=0.013).

The commonest bacteria isolate before and after application of antiseptic solutions in both groups were coagulase negative *Staphylococcus* Spp.

Table 1: Illustrates total number of positive cultures before and after application of antiseptic solution in each group of intervention.

	Positive (%)	Negative (%)	P value
	Culture results before antiseptic solution		
Povidone Iodine	21 (95.5)	1 (4.5)	*N/A
Alcohol-chlorhexidine gluconate	22 (100)	0	
	Culture results after antiseptic solution		
Povidone Iodine	6 (28.6)	15 (71.4)	0.035
Alcohol-chlorhexidine gluconate	1 (4.5)	21 (95.5)	

*N/A Not applicable

Table 2: Illustrates bacterial species identified in the post preparation cultures.

	Frequency (43)	Percentage
Bacteria isolates before application of antiseptic solution		
Acinetobacter Spp	1	2.3
Bacillus Spp	1	2.3
Beta Haemolytic Colonies	1	2.3
Gram Negative Rods	1	2.3
Gram Positive Cocci-Dnase Negative	1	2.3
Gram Positive Cocci-Msa Negative	2	4.7
Gram Positive Cocci-Msa Positive	1	2.3
Micrococcus Spp	4	9.2
Staphylococcus Aureus	1	2.3
Coagulase negative Staphylococcus Spp	30	69.9
Bacteria isolates after application of antiseptic solution		
Povidone iodine		
Coagulase negative Staphylococcus Spp	6	100
Alcohol-chlorhexidine gluconate		
Coagulase negative Staphylococcus Spp	1	100

Discussion

Our findings demonstrate that most participants were young, majority recruited from General Wards with high male to female ratio and that there was moderate duration of hospital stay. Other similar studies demonstrated a relatively older population with high female to male ratio [5, 6].

The observed variation could be because this study involved mainly trauma patients from road traffic accidents which normally affect young active men, unlike comparable studies which involved degenerative shoulder conditions and foot deformities [5, 6].

We have also shown that there is no significant difference in reduction of bacteria load between the two groups of intervention with regard to age and sex. Other similar studies documented similar findings [5, 6]. Contrary to these findings, it has been found that distribution and concentration of normal flora vary significantly with age and sex [7, 8, 9].

We are in the opinion that this difference could be due to the fact that current study involved only one population group (young adult) with less variation. In addition to this, surgical incisions involved mainly extremities which has skin with relatively low metabolism and secretion, unlike the observed variation with sex which is mainly accounted by skin with high metabolism and active secretions [8, 9].

Furthermore, we have found that site of admission and duration of hospital stay have no effect on efficacy of the two solutions. This is contrary to the fact that some other studies demonstrated that site of admission and duration of hospital stay significantly affect skin colonization [10, 11, 12].

In addition to this, the observed variation in comparable studies involved mainly immune compromised patients admitted in ICU unlike this study which involved relatively immune competent, trauma patients from road traffic accident [11, 12].

Our study demonstrate that ankle region incisions have relatively high number of bacteria loads in which bacteria growth inhibition was superior by 70% ethyl alcohol-0.5% chlorhexidine gluconate than 10% povidone iodine. It has also shown that rate of positive culture was high in the 10% povidone iodine group than 70% ethyl alcohol-0.5% chlorhexidine gluconate group. Similar findings have been demonstrated with other studies [5, 6].

Presence of high concentration of microorganisms in ankle related surgical incisions is due to conducive environment which favour more growth of normal flora [13, 14, 15]. Possible explanation for superiority of 70% ethyl alcohol-0.5% chlorhexidine gluconate could be due to additive effect of the two solutions. We have also found that coagulase negative *Staphylococcus* Spp is the common isolates before and after application of antiseptic solution. This is in line to the fact coagulase negative *Staphylococcus* Spp is one of the commonest normal flora distributed throughout different body parts [15, 16, 17]. Furthermore, clinically, these findings account to the fact that coagulase negative *Staphylococcus* Spp is one of the common isolates in Orthopaedic surgeries related surgical site infection [3]

Although both the antiseptic preparations we studied possess broad-spectrum antimicrobial activity [18], the superior clinical protection provided by chlorhexidine-alcohol is probably related to its more rapid action, persistent activity despite exposure to bodily fluids, and residual effect [19]. The superior clinical efficacy of chlorhexidine–alcohol in our study correlates well with previous microbiologic studies showing that chlorhexidine-based antiseptic preparations are more effective than iodine-containing solutions in reducing the bacterial concentration in the operative field for vaginal hysterectomy [20] and foot-and-ankle surgery [21, 22]. Although the use of flammable alcohol-based products in the operating room poses the risk, though small, of fire or chemical skin burn, no such adverse events occurred in this study or the other studies that we have referred to or come to know about [20, 21, 22].

Conclusion

Preoperative cleansing of the patient's skin with chlorhexidine-alcohol is superior to cleansing with povidone-iodine for preventing surgical-site infection in Orthopaedic Surgery.

Funding

None

Conflict of Interest

None

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