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Clinical evaluation of preoperative skin preparation with aqueous povidone-iodine alone and in combination with alcoholic chlorhexidine in patients undergoing elective surgery

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Abstract
Introduction: Adequate pre-operative skin preparation helps in reducing the SSIs and this study is undertaken to compare the efficacy of povidone-iodine alone and in combination with chlorhexidine.
Aims and Objectives: To evaluate the efficacy of povidone-iodine alone and in combination with an antiseptic agent containing alcoholic chlorhexidine on preoperative skin preparation.
Methodology: This is an observational study in which 100 patients admitted for elective clean surgery in Dr. PSIMS & RF during the period of 2 years from November 2019 – October 2021 studied in two groups where preoperative skin preparation is done using povidone-iodine alone and in combination with alcoholic chlorhexidine.
Results and Conclusion: There are 5 patients in group-1 and 1 in group-2 who has positive culture after skin disinfection. There were 5 cases in group-1 and 1 in group-2 who developed SSIs. This study show that chlorhexidine followed by povidone-iodine is effective when compared with povidone-iodine alone.

Keywords: Povidone-iodine, chlorhexidine, asepsis, SSI, skin preparation

Introduction

Skin is the primary barrier against bacterial invasion. Following a skin incision, microorganisms of the standard skin flora may contaminate exposed tissues and cause an SSI. Despite many recent advances in surgical techniques in the past few years, post-operative wound sepsis remains a significant problem. SSIs are associated with longer hospital and intensive care unit stays, increased readmission to hospital after discharge, and a two-fold increase in mortality. Many factors contribute to the development of post-operative wound infections, some relating to the patient and some relating to the procedure itself [1]. The terms asepsis and antisepsis denote two policies whereby access to a wound and its consequent infection is halted. Moynihan [2] (1920) conducted his bacteriological experiment with one of the two intentions: 1. The exclusion of all organisms from the wound; 2. The destruction of all micro-organisms reaching the wound by a bactericide applied to the wound surface. Preoperative skin antisepsis has been proven to rapidly reduce local microorganism counts in the operational field. Of many techniques for skin preparation before surgery, initially with antiseptic soap solution, followed by painting the prepared area with sterile paint solution is most common. Degerming of the skin done with antiseptics used for less than a minute is as effective as a five-minute scrub with a germicidal soap solution followed by painting with antiseptics [3]. Commonly used agents for skin antisepsis are chlorhexidine gluconate (CHX) or povidone-iodine (PVP-I). The 2017 Centre for Disease Control and Prevention Guideline for Prevention of SSIs recommends, with high-quality evidence, the use of intraoperative skin preparation with an alcohol-based antiseptic agent; however, due to a lack of conclusive randomized controlled trials (RCTs), no specific antiseptic agent is endorsed [4]. Other institutions, such as Health Protection Scotland and the Canadian Patient Safety Institute, recommend the use of CHX [5, 6]. These recommendations are based on the remanent effect against bacterial regrowth and thus prolonged activity that can be attributed to CHX [7, 8]. Furthermore, CHX remains activated in the presence of organic fluids such as blood or pus, in contrast to iodophors, which become inactivated [9]. This study is undertaken to compare the efficacy of povidone-iodine alone and in combination with alcoholic chlorhexidine

against bacterial flora on the skin of the operation site under conditions, encountered in operating rooms.

Aim and Objectives

1. To evaluate the efficacy of povidone-iodine alone and in combination with an antiseptic agent containing alcoholic chlorhexidine on preoperative skin preparation by taking swab culture.
2. To compare the rate of postoperative wound infection in both groups.

Inclusion criteria

1. Patients of all age groups undergoing elective surgery in the Department of General Surgery with a clean wound.

Exclusion criteria

1. Patients undergoing emergency surgery.
2. Immunocompromised patients and patients on long-term steroids.
3. Patients with septicemia and having a focus of infection somewhere on the body manifested clinically with fever and increased total and differential counts.
4. Patients suffering from malignancies or undergoing chemotherapy or radiation therapy.
5. Clean contaminated and contaminated surgeries in which viscous was opened were excluded from the study.
6. Patients with comorbid medical conditions like diabetes, hypertension, etc.

Methodology

This is an observational study in which 100 patients admitted for elective clean surgery in the Department of General surgery of Dr. Pinnamaneni Siddhartha Institute of Medical Sciences and Research Foundation during the period of 2 years from November 2019 – October 2021 will be studied in two groups. Cases were selected at random irrespective of each case preoperatively, shaving of the parts was done at the same time on the previous evening for all the patients. The preoperative skin preparation in each group is done with the respective antiseptic regimen. For Group-1 antiseptic regimen used is three coats of aqueous povidone-iodine IP 5% w/v. For Group-2 antiseptic regimen used is a single coat of agent containing chlorhexidine gluconate 2.5% v/v in 70% propanol followed by two coats of aqueous povidone-iodine IP 5% w/v. The pre-operative antibiotic used is Cefotaxime 1 gram I.V given following a test dose; one hour prior to incision. A sterile saline swab culture & sensitivity is done from the site of incision immediately in both the groups. This had important implications in knowing whether these strains were responsible for causing infections in the post-operative period. Statistical analysis was performed using SPSS Statistics V22.0. Results were represented with frequencies and percentages. The Chi-square test and Fischer exact test were applied to find significance. $P < 0.05$ was considered statistically significant.

Results

A total of 100 patients who were planned for clean elective surgery were studied in two groups (50 in each group). The Mean (SD) value of the age for group-1 was 40.7 ± 14.4 and that for group-2 was 38.7 ± 15.9 years and the difference is not statistically significant. There were 58 males (Group I - 25; Group II – 33) and 42 females (Group I - 25; Group II –27). Duration of surgeries varied from 45 minutes to 3 hours and since all the surgeries were clean and elective, the duration of surgery has no effect on the number of cases with positive culture swabs. There are 5 patients in group-1 and 1 patient in group-2 who had positive culture which is found to be statistically significant. The culture and antibiotic sensitivity results of the patients with growth in both groups are summarised in table-5. Post-operatively patients were followed up to the time of suture removal (usually 7-10 days) to know the percent of cases who developed wound infections. There were 5 cases in group-1 and 1 case in group-2 who developed postoperative wound infections. It is noted that out of 5 cases with growth in group-1, only 3 had post-operative wound infection and the other 2 were ward acquired. Similarly, the only infection in group-2 is ward acquired

Table 1: Age distribution

Age group	Group I		Group II		Total
	No. of cases	Percentage	No. of cases	Percentage	
<20	2	4%	4	8%	6
21-30	12	24%	17	34%	29
31-40	14	28%	10	20%	24
41-50	12	24%	9	18%	21
51-60	4	8%	5	10%	9
61-70	4	8%	1	2%	5
>70	2	4%	4	8%	6
	50		50		100

Table 2: Gender distribution

Gender	Group I		Group II		Total
	No. of cases	Percentage	No. of cases	Percentage	
Male	25	50%	33	66%	58
Female	25	50%	17	34%	42
	50		50		100

Table 3: Nature of operations

Diagnosis of subjects	Group I		Group II		Total	
	Number	Percentage	Number	Percentage	Number	Percentage
Excision	14	28%	16	32%	30	60%
Excision Biopsy	5	10%	-	-	5	10%
Hemithyroidectomy	1	2%	-	-	1	2%
Hernioplasty	17	34%	23	46%	40	80%
Superficial Parotidectomy	1	2%	1	2%	2	4%
Total Thyroidectomy	6	12%	4	8%	10	20%
Trendelenburg Procedure	6	12%	6	12%	12	24%
Total	50		50		100	

Table 4: Culture report

Microbiology report	Group I		Group II		Total	
	Number	Percentage	Number	Percentage	Number	Percentage
No growth	45	90%	49	98%	94	94%
Growth present	5	10%	1	2%	6	6%
Total	50		50		100	

Table 5: Sensitivity report

Antibiogram	Group I					Group II
	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 1
	S. epidermidis	*S. aureus*	*S. epidermidis*	*S. epidermidis*	*S. epidermidis*	*S. epidermidis*
Amoxicillin	S	S	S	S	S	S
Cefotaxime	S	S	S	S	S	S
Ciprofloxacin	S	S	S	S	S	S
Gentamycin	S	S	S	S	S	S
Amikacin	S	S	S	S	S	S

*S = Sensitive

Table 6: Relationship between Microbiological report and post-operative wound infection rate

Microbiological report	Group I			Group II		
	No infection	Infection	Total	No infection	Infection	Total
No Growth	43	2#	45	48	1#	49
Growth	2	3*	5	1	0*	1
Total	45	5	50	49	1	50
	Chi-Square =15.4; $p < 0.001$ & Fisher's Exact value			Chi-Square =0.02; p=0.8 & Fisher's Exact value		

***** - Post-operative infections with Positive culture report
# - Ward infections

Table 7: Sensitivity report of post-operative infections with positive culture report

Antibiogram	Group I		
	Patient 2	Patient 3	Patient 5
	S. aureus	*S. epidermidis*	*S. epidermidis*
Amoxicillin	S	S	S
Cefotaxime	S	S	S
Ciprofloxacin	S	S	S
Gentamycin	S	S	S
Amikacin	S	S	S

Discussion

The use of PVP-iodine in surgeries dates to 1955. Chlorhexidine gluconate with its increased efficiency has been recently made available all over as an antiseptic and disinfectant. In this study, we compared the efficacy of povidone-iodine alone and in combination with alcoholic chlorhexidine in elective clean surgeries for the prevention of surgical site infections. The present study was done on 100 patients who were to undergo elective clean cases in the Department of General Surgery, Dr. PSIMS & RF with the aims of evaluating the efficacy of povidone-iodine alone and in combination with an antiseptic agent containing alcoholic chlorhexidine on preoperative skin preparation, and to compare the rate of postoperative wound infections in both the groups. The present study has 10% in group-1 and 2% in group-2 had colonization of site of incision even after skin disinfection whereas the respective values in Julia L *et al.* [10] studies were 35.3% and 4.7% and in Ajay *et al.* [11] study were 20.8% and 3.3% This shows that when compared to povidone-iodine alone, using a combination of povidone-iodine and an alcoholic solution of chlorhexidine, the colonization rates of the sites of incision were reduced significantly. The rate of postoperative wound infections (after excluding ward infections) in group-1 is 6% and of group-2 is 0% whereas the respective values in Brown *et al.* [12] studies were 8.1% and 6.0%, Ajay *et al.* [11] studies were 13.3% and 0%. The difference in the results was not that significant in studies done by Park *et al.* [13], Sistla *et al.* [14], and Paocharoen *et al.* [15]. The results from the present study show that pre-operative skin preparation using chlorhexidine gluconate 2.5% v/v in 70%propanol followed by aqueous povidone-iodine 5% w/v is effective when compared with aqueous povidone-iodine alone. The limitations of our study include convenient sample size and lack of diversity in patients, as it is a single-center study.

Conclusion

Despite many recent advances in surgical techniques in the past few years, post-operative wound sepsis remains a significant problem. There is now an increase in evidence that a high proportion of SSIs is caused by bacterial access into deeper skin structures during skin incision. Therefore, proper skin antiseptics might be one of the keys to reducing the colonization of the site of incision and thus reducing the incidence of subsequent infection. The present study confirms the superiority of povidone-iodine in combination with alcoholic chlorhexidine over povidone-iodine alone in pre-operative skin preparation and warrants recommendation of it as a preferred antiseptic in skin preparation for elective clean surgery. Since the superiority of this regimen was proved in decreasing incision site colonization and postoperative wound infection, it is prudent to use this regimen in contaminated and emergency surgeries. However, further studies are needed to explore the comparative efficacy of these agents in a larger number of patients with clinically relevant endpoints.

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