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Comparative Study of Preoperative Skin Preparation with Aqueous Povidone Iodine Only Versus Povidone Iodine in Combination with Chlorhexidine in Clean Elective Surgeries

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Abstract: *The aim of the present study is to evaluate the efficacy of povidone iodine alone and in combination with antiseptic agent containing alcoholic chlorhexidine in preoperative skin preparation by taking swab culture and to compare the rate of postoperative wound infection in both the groups. Patients and methods: This hospital based comparative study includesSixty Patients (Thirty in each Group) with no focus of infection on the body undergoing clean elective surgery at Siddhartha Medical College and General Hospital from 1st July 2017 to28thFebruary 2018. Results: When compared to povidone iodine alone, using a combination of povidone iodine and alcoholic solution of chlorhexidine, wound infections were lesser and the colonization rates of the site of incision were reduced significantly. Hence Preoperative skin preparation with chlorhexidine gluconate 2.5% v/v in 70% propanol followed by aqueous povidone-iodine is an ideal regime as it has a broader antimicrobial spectrum and the rate of postoperative wound infections is much lower as compared to povidone iodine alone.*

Keywords:*Skin disinfection; Chlorhexidine; Propanol; Povidone-iodine; Bacterial colonization.*

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I. Introduction

Despite many advances in the surgical techniques in the past few years, postoperative wound sepsis still remains a major problem. Although only occasionally a cause of mortality, it is a frequent cause of increased morbidity leading to prolonged hospitalization of the patient. Wound infections occur in approximately 5% of patients undergoing major abdominal surgery[1]. Several factors contribute to the development of post-operative wound infections, some relating to the patient and some relating to the procedure itself[2]. Most of the modern achievements in surgery are due to two basic principles i.e. asepsis and antisepsis.

As patients being incapable of complete sterilization, an appropriate procedure should be there for preoperative preparation of skin. Since one cannot resort, as in case of operator's hand to prolonged scrubbing, soaking in germicides etc., one should find chemical agents powerful enough practically to sterilize the skin by local application. Such antibacterial agents must fulfil chemical criteria including spectrum of activity, tissue tolerance, and absence of acquired bacterial resistance. In addition, the antibacterial agent ought to be presented in a formulation appropriate to surgical use.

Many techniques are there for skin preparation before surgery, the commonest being initial scrub with antiseptic soap solution, followed by painting the prepared area with antiseptic paint solution but de-germing of the skin can be done with antiseptics used for less than one minute, which is as effective as a five-minute scrub with germicidal soap solution followed by painting with antiseptics[3]. The two commonly used antiseptics are povidone iodine and chlorhexidine and this study is undertaken to compare the efficiency of povidone iodine alone and in combination with antiseptic agent containing alcohol and chlorhexidine against bacterial flora on the skin of operation site under conditions those encountered in operating rooms.

II. Aims And Objectives

• To evaluate the efficacy of povidone iodine alone and in combination with antiseptic agent containing alcoholic chlorhexidine in preoperative skin preparation by taking swab culture.

• To compare the rate of postoperative wound infection in both the groups.

III. Materials And Methods

3.1 SOURCE OF DATA:This study includes sixty Patients (Thirty in each Group) with no focus of infection on the body undergoing clean elective surgery at Siddhartha Medical College and General Hospital from 1st July 2017 to 28th February 2018.

3.2 STUDY DESIGN AND METHODOLOGY:Hospital based comparative study. All the cases were planned for clean elective surgery. Cases were selected at random irrespective of their age and sex. The patients were from both, rural as well urban background. They belonged to low, middle as well as high socioeconomic groups. Each patient underwent shaving of the parts on the previous night and was requested to take bath with soap and water on the morning of the day of operation and wear properly washed clothes. The nature of operations and therefore site of incisions were variable. The patients were randomly included in either control (group I) or test group (group II) and skin preparation was done with respective antiseptic regimen. A sterile saline swab culture was taken from incision site after skin preparation with respective antiseptic regimen and bacterial isolates were identified.

3.3 INCLUSION CRITERIA:

- Patients between 18 years and 70 years of age
- Patient willing to participate in study and given informed consent

3.4 EXCLUSION CRITERIA:

- Patients with comorbid medical conditions, immunocompromised patients and patients suffering from malignancies
- Patients < 18 years of age
- Patients undergoing clean-contaminated, contaminated and emergency surgeries

IV. Observations And Results

This hospital based comparative study includes Sixty Patients (Thirty in each Group) with no focus of infection on the body undergoing clean elective surgery at Siddhartha Medical College and General Hospital from 1st July 2017 to 28th February 2018.

Table 1: Demographic Profile of Patients in Present Study

AGE (IN YEARS)	GROUP I			GROUP II			GRAND TOTAL
	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	
18-20	2	1	3	0	0	0	3
21-30	0	3	3	3	5	8	11
31-40	4	2	6	2	3	5	11
41-50	3	6	9	7	1	8	17
51-60	3	1	4	3	0	3	7
61-70	3	0	3	3	0	3	6
>70	2	0	2	3	0	3	5
Total	17	13	30	21	9	30	60

Table 2: Distribution of Socio-Economic Status Based on The Age Group

AGE (IN YEARS)	GROUP I				GROUP II			
	CLASS II	CLASS III	CLASS IV	TOTAL	CLASS II	CLASS III	CLASS IV	TOTAL
18-20	2	1	0	3	0	0	0	0
21-30	1	2	0	3	4	4	0	8
31-40	4	2	0	6	1	4	0	5
41-50	4	5	0	9	5	3	0	8
51-60	2	2	0	4	2	1	0	3
61-70	0	1	2	3	1	1	1	3
>70	1	1	0	2	1	1	1	3
Total	14	14	2	30	14	14	2	30

Table 3: Type of Operations Done in Both Groups

OPERATION	GROUP I		GROUP II		TOTAL	
	No.	%	No.	%	No.	%
Anatomical repair of epigastric hernia	2	6.67	1	3.33	3	5.00
Bassini's repair	3	10.00	5	16.67	6	10.00
Lichenstein mesh repair	5	16.67	10	33.33	4	6.67
Mayo's repair	1	3.33	2	6.67	3	5.00
On lay mesh repair	4	13.33	1	3.33	5	8.33
Preperitonial Mesh repair	1	3.33	-	-	1	1.67
L hemithyroidectomy	1	3.33	-	-	1	1.67
R hemithyroidectomy	1	3.33	2	6.67	3	5.00
Subtotal thyroidectomy	2	6.67	-	-	2	3.33
Total Thyroidectomy	2	6.67	2	6.67	4	6.67
Excision of fibroadenoma	1	3.33	1	3.33	2	3.33
Excision of Lipoma	3	10.00	-	-	3	5.00
R orchidopexy L orchidectomy	-	-	1	3.33	1	1.67
Stripping of long saphenous vein with subfascial ligation	-	-	1	3.33	1	1.67
Excision of Ganglion	2	6.67	2	6.67	4	6.67
Excision of Non-infected Sebaceous Cyst	1	3.33	-	-	1	1.67
Hydrocele	1	3.33	2	6.67	3	5.00
Total	30	100	30	100	60	100

Within both the groups, the nature of operations and hence site of incision varied but when compared to each other patients in both the groups underwent same type of surgeries and were randomly divided into either a control group (Group I) or test group (Group II). Duration of surgeries varied from 45 mins to 3 hours and since all the surgeries were clean and elective, the duration of surgeries had no effect on number of cases with positive culture results of swabs taken from site of incision after skin disinfection and as there was no spillage during the surgery, the type of surgery also had no effect on the postoperative wound infection rates.

Table 4: Types of Incisions in Both Groups

TYPE OF INCISION	GROUP I		GROUP II		TOTAL	
	No.	%	No.	%	No.	%
Collar incision	4	13.33	2	6.67	6	10.00
Circumareolar incision	1	3.33	1	3.33	2	3.33
Upper midline	2	6.67	1	3.33	3	5.00
Midline incision	4	13.33	1	3.33	5	8.33
Posterior midline	2	6.67	2	6.67	4	6.67
Elliptical incision	2	6.67	2	6.67	4	6.67
Inguinal	8	26.67	16	53.33	24	40.00
Skin fold incision	1	3.33	-	0.00	1	1.67
Transverse incision	1	3.33	1	3.33	2	3.33
Longitudinal incision	5	16.67	4	6.67	9	15.0
Total	30	100	30	100	60	100

Table 5: Microbiological Report

MICROBE REPORT*	GROUP I		GROUP II		TOTAL	
	No.	%	No.	%	No.	%
No growth	24	80.00	29	96.66	53	88.33
Staph. albus(coagulase -)	3	10.0	1	3.33	4	6.67
Staph. aureus(coagulase +)	1	3.33	-	0.00	1	1.67
Bacillus subtilis	2	6.67	-	0.00	2	3.33
Total	30	100	30	100	60	100

*Culture taken from site of incision after skin disinfection with respective agents.

The proportion of cases with growth in Group I was 6 (20.0%) whereas in case of Group II was 1(3.3%) and this difference in the proportion of patients with growth after skin disinfection between the two groups is found to be statistically significant ($Z=2.01$, $p<0.03$).

Table 6: Culture and Antibiotic Sensitivity Results of Patients with Positive Growth

ANTIBIOGRAM	**GROUP I**						**GROUP II**
Patient No.	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 1
Culture result	Staph albus	Staph aureus	Staph albus	Bacillus subtilis	Bacillus subtilis	Staph albus	Staph albus
Ampicillin	S	R	S	S	S	R	S
Amoxicillin	S	R	S	S	S	S	S
Ciprofloxacin	S	S	S	S	S	S	S
Gentamicin	S	S	S	S	S	S	S
Erythromycin	S	S	S	S	S	S	S

FOLLOW UP

Postoperatively patients were followed up to the time of suture removal (usually 7-10 days) to know the percent of cases who developed wound infections. The grade of wound infection was determined by Southampton wound grading systems.

Table 7: Wound Infection Grade during follow up period

WOUND INFECTION GRADE	GROUP I		GROUP II		TOTAL	
	No.	%	No.	%	No.	%
Grade 0	24	80.0	29	96.7	53	88.3
Ic	1	3.3	1	3.3	2	3.3
II a	1	3.3	-	-	1	1.7
III a	2	6.7	-	-	2	3.3
IV	2	6.7	-	-	2	3.3
Total	30	100	30	100	60	100

It was further observed that most of wound infections in group I occurred in patients who had positive culture results from site of incision and these wound infections were of grade III or grade IV i.e. either serous or purulent discharge was present. None of the group II patients had postoperative wound infection (Grade III and IV). Pus culture and antibiotic sensitivity were done in these patients who developed wound infection.

In Group I where only povidone iodine was used, 6 patients still had microbial colonization of the site of incision whereas in Group II where combination of povidone iodine and chlorhexidine was used, in only 1 patient microorganisms could be cultured from site of incision. Second, in Group I, of the patients with positive culture results from site of incision, 4 patients developed wound infection (Grade III and IV) whereas in Group II none of the patients developed wound infection (Grade III and IV).

V. Discussion

There is now increasing evidence that a higher proportion of surgical site infections may be caused by bacteria introduced into deeper skin structures at the time of incision. Proper skin disinfection might, therefore, be one of the keys to reduce the colonization of site of incision and, thus, preventing the development of subsequent infection. Several randomized, controlled trials investigating different regimens for skin disinfection prior to surgery found chlorhexidine in alcoholic solution more effective in reducing incision site colonization and subsequent wound infection when compared to povidone iodine. This may be explained in part by the greater effect of chlorhexidine on Gram-positive bacteria, especially on coagulase-negative Staphylococci, when compared to other disinfectants.

Julia Langgartner et al[4] conducted a study which showed that skin disinfection with combination of PVP-iodine and propanol/chlorhexidine was associated with the lowest rate of microbial catheter colonization. Similarly this study was done to prove that combination of povidone iodine and propanol/chlorhexidine was superior to povidone iodine alone for preoperative skin disinfection.

Table 8: ComparativeMean Age Distribution of Patients in Julia L. And Present Study

STUDIES	**Group I (Mean ± SD)**	**Group II (Mean ± SD)**
Present study	53.4 ± 17.2	50.5 ± 17.2
Julia L et al. [4]	44.4 ± 18.3	44.2 ± 17.1

It was noticed from this study that the Mean ± SD of age in Group I and Group II was 44.4 ± 18.3 and 44.2 ± 17.1 respectively whereas the respective values of Julia et al.[4] study was 53.4 ± 17.2 and 50.5 ± 17.2, which is higher than the present study but in both the studies, age was not the factor to have any implications on results of the study as all the patients had good immune status, had no co-morbid conditions and were planned for clean elective surgery.

Table 9: Comparison of sex ratio of patients in Julia L. and present study

Authors	Group I (Sex ratio = M :F)	Group II (Sex ratio = M :F)
Julia L et al. [4]	35/17=1: 0.49	22/21 = 1: 0.95
Present study	17/13 = 1: 0.76	21/9 = 1: 0.43

Table 10: Various studies showing comparison of colonization rates of site of incision after disinfection with respective antiseptic regimen

AUTHORS	GROUP I (PVP-IODINE)	GROUP II (PVP-IODINE + ALCOHOLIC SOLUTION OF CHLOROHEXIDINE)
Julia L et al. [4]	35.3	4.7
Glenn et al. [5]	13.8	3.3
Present study	20	3.3

As depicted in the above table 20% of patients in Group I and 3.3% in Group II had colonization of site of incision even after skin disinfection whereas the respective values in Julia L et al[4] study were 35.3% and 4.7% and in Glenn G. et al [5]study, the values were 13.8% and 3.3%. This shows that when compared to povidone iodine alone, using a combination of povidone iodine and alcoholic solution of chlorhexidine, the colonization rates of the site of incision were reduced significantly.

Table 11: Comparative studies showing difference in postoperative wound infection rates

AUTHORS	GROUP I (PVP-IODINE)	GROUP II (PVP-IODINE + ALCOHOLIC SOLUTION OF CHLOROHEXIDINE)
Brown et al[6]	8.1%	6.0%
Present study	13.3%	0%

The study done by Brown et al [6]compared postoperative wound infection rates after using either povidone iodine or alcoholic solution of chlorhexidine and it showed that postoperative wound infection rates were less in chlorhexidine group (Group I) (6.0%) than in povidone iodine group (Group II) (8.1%) although this difference was not significant.

The present study compared postoperative wound infection rates after using either povidone iodine alone (Group I) or a combination of povidone iodine and alcoholic chlorhexidine (Group II). The wound infection rate in Group I was 13.3% and in Group II it was 0% as none of the patient in Group II had wound infection. These rates were calculated after excluding ward acquired infections.

VI. Summary

The result of culture studies showed that in Group I, 6 cases out of 30 had bacterial growth. 3 had staphylococcus albus, 2 had bacillus subtilis (both opportunistic pathogens) and in one case staphylococcus aureus (pathogenic bacteria) was grown. In Group II, only 1 case out of 30 had bacterial growth (staphylococcus albus). This showed that regime II was more effective in reducing colonization of site of incision(3.3% in Group II as compared to 20% in group I). This less effective regimen I in reducing bacterial load at site of incision is a potent cause of postoperative wound infections due to translocation of bacteria at the time of incision.

Postoperatively patients were followed up till the time of suture removal to look for any wound infections. It was seen that postoperative wound infections developed mostly in those cases who had bacteria cultured from site of incision after skin disinfection. Wound infection was graded by Southampton scoring system. In grade IV infection (pus present), pus culture was taken and antibiotic sensitivity test was done and it showed same strain of bacteria which had colonized site of incision.

Although in some cases, surgical site infections also occurred even when there was no growth on culture from site of incision after skin disinfection. These were considered as ward acquired infection. After excluding ward acquired infections, in Group I, 4 patients had postoperative wound infection whereas none of patients in group II had postoperative wound infection. This difference was attributed to difference in efficacy of both the antiseptic regimen thus proving regimen II to be significantly more effective in reducing the rate of postoperative wound infection. (Zero in group II as compared to 13.3% in group I).

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