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PREPARATIVE SKIN PREPARATION AND SURGICAL WOUND INFECTION

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ABSTRACT: BACKGROUND AND OBJECTIVE: It is an established fact now that the normal skin of healthy human beings harbours a rich bacterial flora. Normally considered non-pathogenic, these organisms may be a potential source of infection of the surgical wound. Approximately 20% of the resident flora is beyond the reach of surgical scrubs and antiseptics. The goal of surgical preparation of the skin with antiseptics is to remove transient and pathogenic microorganisms on the skin surface and to reduce the resident flora to a low level. Povidone iodine (Iodophors) and chlorhexidine are most often used antiseptics for pre-operative skin preparation. **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. (2) To compare the rate of postoperative wound infection in both the groups. **METHODS:** One hundred patients (fifty in each group) undergoing clean elective surgery with no focus of infection on the body were included in the study. The pre-operative skin preparation in each group is done with the respective antiseptic regimen. In both the groups after application of antiseptics, sterile saline swab culture was taken immediately from site of incision. In cases which showed growth of organisms, the bacteria isolated were identified by their morphological and cultural characteristics. Grams staining, coagulase test and antibiotic sensitivity test were done wherever necessary and difference in colonization rates was determined as a measure of efficacy of antiseptic regimen. **RESULTS:** The results of the study showed 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. As for the rate of post-operative wound infection, it is also proven that wound infections are also less if the pre-operative skin preparation is done with combination of povidone iodine and alcoholic solution of chlorhexidine as compared to povidone iodine alone. **INTERPRETATION AND CONCLUSION:** 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 post-operative wound infections is much lower as compared to povidone iodine alone.

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

INTRODUCTION: Despite many advances in the surgical techniques in the past years, post-operative wound sepsis still remains a major problem. Although only occasionally a cause of mortality, it is a frequent occur in approximately 5% of patients undergoing major abdominal surgery.¹

In spite of the fact that different studies have been carried out by various workers pointing towards one or another as source of sepsis, yet it is still controversial to indict one and

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exonerate the other.^{2,3,4,5} A confusion still prevails regarding the source of wound sepsis. Hence there is a further need for systematic probe into the minute details of etiology of wound infection.

Several factors contribute to the development of post-operative wound infections, some relating to the patient and some relating to the procedure itself.⁶

A patient, who is undergoing any kind of surgery faces a potential risk of getting infection from his environment – be it the operation theatre or be it the ward. Shooter (1956) and Blower (1960) pointed out the source of post-operative wound infection to be operation theatre and ward respectively.^{3,7} Of course, patient himself cannot be excluded from being a source of infection. Burke (1963) found that in 50% of the operations the strains of staphylococcus aureus isolated were the same as those from patients nose and hence concluded the patient himself to be a source of infection.⁸ Obviously, wound infection in a particular patient may be a result of multiple and diverse factors.

Most of the modern achievements in surgery are due to two basic principles i.e. aspects and antisepsis. The term asepsis and antisepsis denote two policies or methods whereby access of bacteria to wound and its consequent infection is halted. Moynihan (1920) was true when he said, "our bacteriological experiment may be conducted with one of the two intentions:

1. The exclusion of all organisms from the wound.
2. The destruction of all organisms reaching the wound by a bactericide applied to wound surfaces".⁹

Asepsis: Asepsis may be defined as the exclusion of bacteria from the field of surgical procedures by the previous sterilization of everything employed in/ on it.

Antisepsis: Antisepsis aims at erecting a chemical barrier between the tissue and the source of infection. It consists of applying to part of the body a chemical capable of killing or at least inhibiting the growth of bacteria so that even if the bacteria gain access to the body, they will be prevented from attacking it. This is probably the best possible ideal.

It is therefore suggested that the best available standard of aseptic surgery should be complemented by use of an antibacterial agent.

As patients being incapable of complete sterilization, an appropriate procedure should be there for preoperative preparation of skin. Since one cannot resort, as in a 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 fulfill 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.¹⁰

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.

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OBJECTIVES:

1. 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.
2. To compare the rate of postoperative wound infection in both the groups.

METHODOLOGY:

Study Design: This is a comparative study conducted on 100 patients in two groups.

Settings: K.R Hospital, Mysore at Department of General Surgery.

Source of data: 100 patients (50 in each Group) undergoing clean elective surgery with no focus of infection on the body admitted in the department of General Surgery in K.R Hospital, Mysore from 1st January 2011 to 31st August 2012.

Inclusion Criteria:

It includes:

1. Patients undergoing clean elective surgery in department of general surgery. Clean surgery is defined as surgery in which no viscus was opened.
2. Patients with no focus of infection anywhere on the body, afebrile and having normal WBC counts.
3. Patients irrespective of their age and sex.
4. Patients neither immune compromised nor on any long term steroids.
5. Patients undergoing mesh repair of hernia are also included.

Exclusion Criteria:

1. Patients undergoing emergency surgery.
2. Immuno compromised patients and patients on long term steroids.
3. Patients with septicemia and having focus of infection somewhere on the body manifested clinically 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 viscus was opened were excluded from the study.
6. Patients with comorbid medical conditions like diabetes, hypertension etc.

Method of collection of data: This is a comparative study in which patients will be studied in two groups. In each case preoperatively, detailed history was taken and routine investigation like haemoglobin, total count, differential count, ESR, RBS and chest X-ray were done to rule out any acute or chronic infection or malignancy. Preoperative shaving of the parts was done at the same time on previous evening for all the patients the preoperative skin preparation in each group is done with the respective antiseptic regimen.

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Group I: Antiseptic regimen used for preoperative skin preparation is three coats of aqueous povidone iodine IP 5% w/v.

Group II: Antiseptic regimen used is 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 which is shown in the following steps.

Step 1: Single coat of chlorhexidine gluconate 2.5% v/v in 70% alcohol. (Figure 1)



Fig. 1

Figure 1: Chlorhexidine gluconate 2.5% volume in 70% propanol as an antiseptic for preoperative skin preparation.

Step 2: Chlorhexidine containing agent is being spread uniformly and allowed to form a film. (Figure 2)



Fig. 2

Figure 2: Film of chlorhexidine gluconate formed over operative field.

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Step 3: Two coats of aqueous povidone iodine are applied. (Figure 3)



Fig. 3

Figure 3: Povidone iodine as an antiseptic for pre-operative skin preparation.

In both the groups after application of antiseptics, sterile saline swab culture was taken immediately from site of incision (Figure 4) and was transferred to microbiology department to determine whether any microorganisms were left behind and hence to compare the efficacy of both the regimes of skin preparation.

Figure 4: Sterile saline swab culture being taken from site of incision.



Fig. 4

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In the microbiology department, the swabs were inoculated onto blood agar plate, McConkey's agar plates and nutrient broth. Inoculated media were incubated aerobically at 37°C for 24-48 hrs. Nutrient broth was sub cultured if the original plates did not yield organisms. The bacteria isolated were identified by their morphological and cultural characteristics. Grams staining, coagulase test and antibiotic sensitivity test were done wherever necessary and difference in colonization rates was determined as a measure of efficacy of antiseptic regimen. Antibiotic sensitivity test were done to strain the bacteria and this had important implications in knowing whether these strains were responsible in causing infections in post-operative period. Antibiotic testing was done against following antibiotics:

- Cefatoxime
- Amoxicilin
- Ciprofloxacin
- Gentamicin
- Amikacin

Postoperatively, first dressing was done on third postoperative day with aqueous solution of povidone iodine alone and patients were followed up till the time of sutures removal (7-10 days) to look for any signs of wound infection. For example:

If any purulent discharge was seen, pus culture and antibiotic sensitivity tests were done to know whether causative organisms were same which were left behind preoperatively after skin preparation and hence incomplete disinfection was the cause for wound infection or whether the infection was acquired in the ward.

Statistical Analysis: The data collected in the present study is analyzed statistically by computing the descriptive statistics viz., Mean, SD, and percentages. The data is presented in the form of tables and graphs. The difference in mean is tested using z-test and the measures of association between the qualitative variables are assessed using chi-square test. The inference is considered statistically significant whenever $p \leq 0.05$.

RESULTS: The present study was conducted to evaluate comparatively the efficacy of povidone-iodine alone and combination of povidone iodine and alcoholic solution of chlorhexidine for preoperative skin preparation. A total of 100 Patients were studied in two groups (50 patients in each group) from 1st January 2011 to 31st August 2013. 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. 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.

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In no case, in any group, any irritation of skin or any hypersensitivity reaction was observed. No generalized reaction was noted either. No toxicity was observed in any case in either of the groups.

Age and Sex: The patients in both the groups were selected randomly irrespectively of their age and sex. The distribution of age and sex in both the groups is shown in Table 1.

Age group (years)	Group I			Group II			Grand Total
	Male	Female	Total	Male	Female	Total	
<20	2	0	2	1	3	4	6
21-30	7	5	12	9	8	17	29
31-40	6	8	14	7	3	10	24
41-50	5	7	12	8	1	9	21
51-60	2	2	4	3	2	5	9
61-70	2	2	4	1	0	1	5
>71	1	1	2	4	0	4	6
Total	25	25	50	33	17	50	100

Table 1: Age and sex distribution of subjects

As shown in Table 1, it may be observed that of that 100 subjects studied, there were 50 (50%) in the group I and the remaining 50 (50 %) in the group II.

Study groups	No. of subjects	Mean	Standard Deviation	95% Confidence Interval for Mean		t-value	p-value
				Lower Bound	Upper Bound		
Group I	50	40.7	14.4	36.6	44.8	0.66	.51
Group II	50	38.7	15.9	34.2	43.2		

Table 2: Descriptive and inferential statistics of age of subjects

Further it is observed from Table 2 that the mean \pm SD of the age for group I was 40.7 \pm 14.4 and that for group II was 38.7 \pm 15.9 years.

Nevertheless, this marginal difference in the age between the two categories were statistically not significant (t=0.66, p>0.51). Table 7 can be depicted graphically as shown in Figure 5.

Figure 5: Age and sex distribution of Subjects

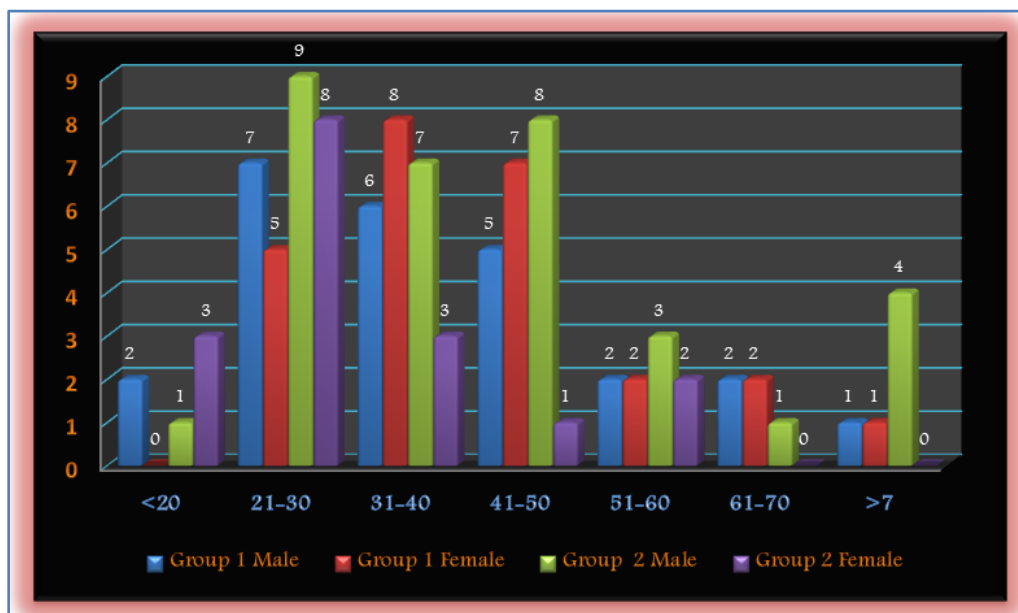


Fig. 5

Nature of operations and site of Incision: The diagnosis and nature of operations were variable and thus site of incisions also varied and incisions were found all over the body. However all the surgeries were clean and elective.

Diagnosis of subjects	Group I		Group II		Total	
	No.	%	No.	%	No.	%
L direct inguinal hernia	1	2	0	0	1	1
R direct inguinal hernia	1	2	0	0	1	1
L indirect inguinal hernia	5	10	7	14	12	12
R indirect inguinal hernia	3	6	8	16	11	11
Femoral hernia, right side	0	0	1	2	1	1
Umbilical hernia	2	4	1	2	1	1
Paraumbilical hernia	1	2	0	0	1	1
Incisional hernia	1	2	1	2	2	2
Epigastric hernia	2	4	2	4	4	4
Solitary nodule L lobe thyroid	4	8	3	6	7	7
Solitary nodule R lobe thyroid	2	4	5	10	7	7
Multinodular goitre	5	10	1	2	6	6
Lipoma over anterior abdominal wall	1	2	0	0	1	1
Lipoma over L forearm	1	2	2	4	3	3
Varicose vein L Lower limb	3	6	1	2	4	4
Varicose vein R lower limb	2	4	0	0	2	2

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Varicocele L side	3	6	1	2	4	4
Fibroadenoma R breast	2	4	2	4	4	4
Fibroadenoma L breast	2	4	1	2	3	3
Gynaecomastia L breast	0	0	1	2	1	1
Hydrocele R side	1	2	2	4	3	3
Hydrocele L side	2	4	0	0	2	2
Epididymal cyst R side	0	0	1	2	1	1
Bronchial cyst R side	0	0	2	4	2	2
Dermoid R forearm	1	2	2	4	3	3
Renal Calculi R side	1	2	0	0	1	1
Pleomorphic adenoma L side	1	2	0	0	1	1
Total	50	100	50	100	100	100

Table 3: Diagnosis of subjects

Chi square test: Z=27.03; df=29; p=0.6; L=Left; R= Right

Figure 6: Diagnosis of Subjects

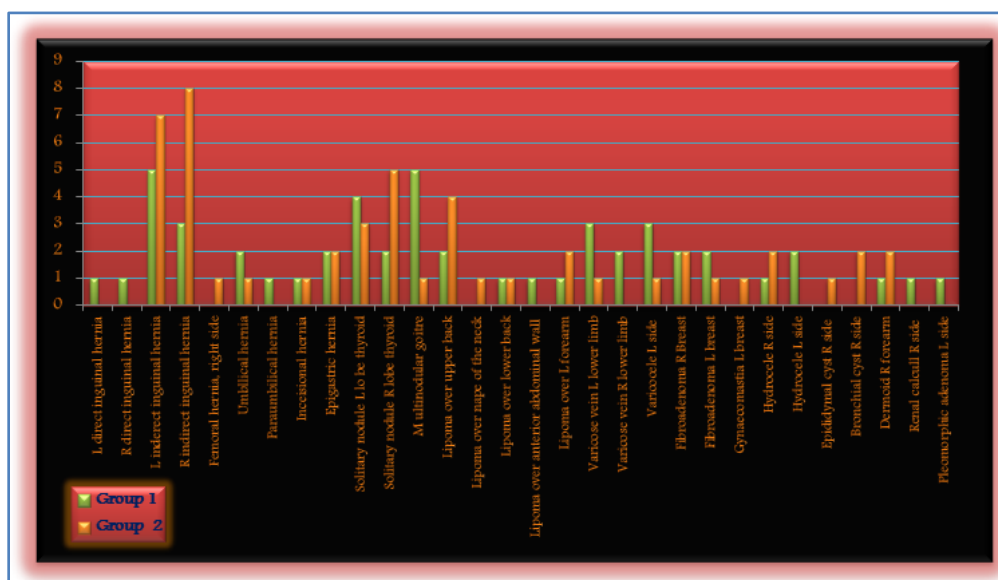


Fig. 6

Operation	Group I		Group II		Total	
	No.	%	No.	%	No.	%
Lichtenstein's mesh repair	10	20	15	30	25	25
L hemithyroidectomy	5	10	3	6	8	8
R hemithyroidectomy	3	6	5	10	8	8
Excision of lipoma	5	10	8	16	13	13
Mesh repair of umbilical hernia	1	2	0	0	1	1

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Mesh repair of incisional hernia	1	2	0	0	1	1
Trendelenburg's procedure	5	10	1	2	6	6
Varicocelectomy	3	6	1	2	4	4
Near total thyroidectomy	2	4	1	2	3	3
Jaboulay's procedure	3	6	2	4	5	5
Excision of gynaecomastia	0	0	1	2	1	1
Excision of epididymal cyst	0	0	1	2	1	1
Excision of bronchial cyst	0	0	2	4	2	2
Anatomical repair of epigastric hernia	1	2	2	4	3	3
Anatomical repair of umbilical hernia	0	0	1	2	1	1
Excision of dermoid cyst	1	2	2	4	3	3
Anatomical repair of incisional hernia	0	0	1	2	1	1
Pyolithotomy	1	2	0	0	1	1
Mesh repair of epigastric hernia	1	2	0	0	1	1
Dunhill procedure	1	2	0	0	1	1
Anatomical repair of paraumbilical hernia	1	2	0	0	1	1
Lotheissen method for femoral hernia	0	0	1	2	1	1
Paratidectomy	1	2	0	0	1	1
Total	50	100	50	100	100	

Table 4: Type of operation done in both the groups

Chi square test: z=22.7; df=24; p=0.53; L=Left; R=Right

Figure 7: Type of operation done in both the groups

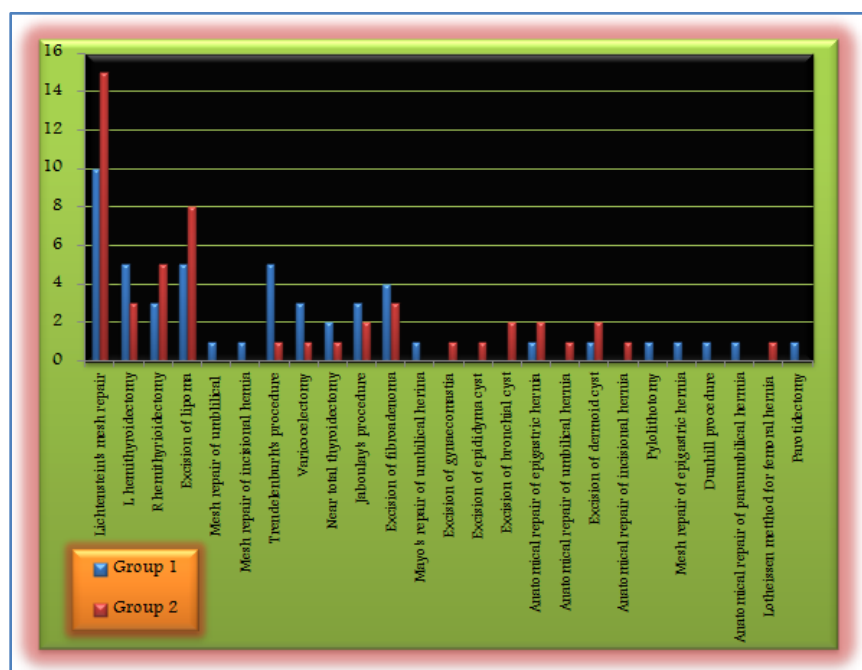


Fig. 7

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Site of incision	Group I		Group II		Total	
	No.	%	No.	%	No.	%
Low anterior abdominal wall	13	26	16	32	29	29
Front of neck	11	22	11	22	22	22
Upper back	2	4	4	8	6	6
Anterior abdominal wall	5	10	4	8	9	9
Upper anterior abdominal wall	1	2	0	0	1	1
Scrotal	3	6	3	6	6	6
Lower back	2	4	1	2	3	3
Front of thigh	5	10	2	4	7	7
Circumareolar	4	8	4	8	8	8
Ventral aspect of right forearm	2	4	3	6	5	5
Ventral aspect of left forearm	1	2	1	2	2	2
Nape of neck	0	0	1	2	1	1
Cheek	1	2	0	0	1	1
Total	50	100	50	100	100	100

Table 5: Sites of incision

Chi square test: $z=5.9$; $df =12$; $p=0.99$

Figure 8: Sites of incision

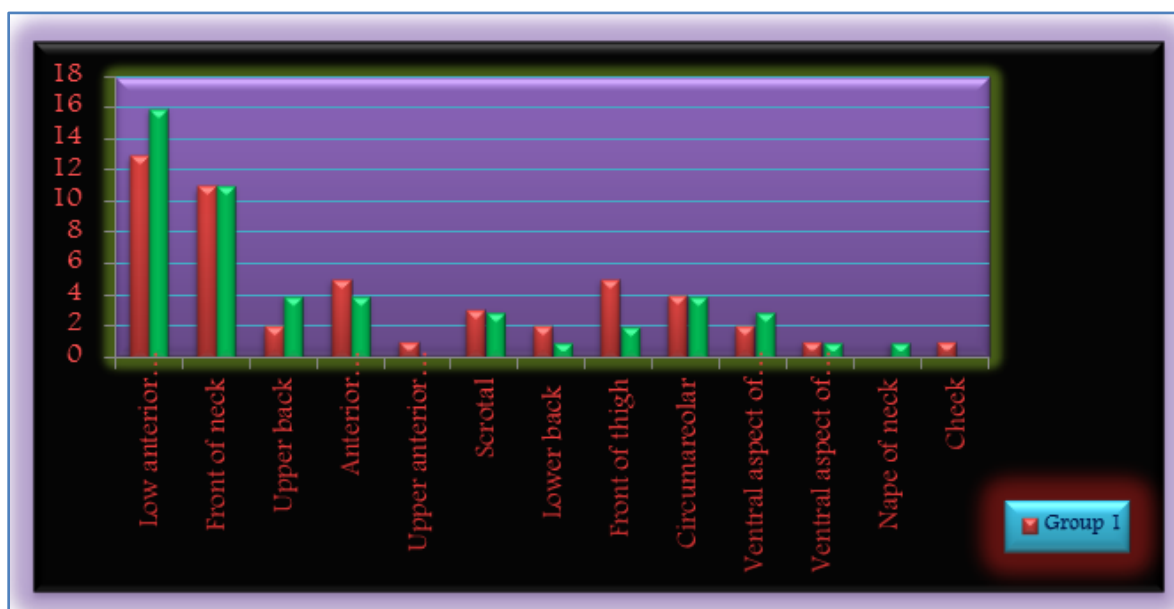


Fig. 8

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Types of incision	Group I		Group II		Total	
	No.	%	No.	%	No.	%
Inguinal	13	26	16	32	29	29
Collar incision	11	22	11	22	22	22
Skin fold incision	3	6	5	10	8	8
Transverse incision	2	4	1	2	3	3
Upper midline	4	8	3	6	7	7
Scrotal	3	6	3	6	6	6
Transverse incision	6	12	3	6	9	9
Circumareolar	4	8	4	8	8	8
Longitudinal	3	6	4	8	7	7
Lazy S incision	1	2	0	0	1	1
Total	50	100	50	100	100	100

Table 6: Types of incision

Chi square test: $z=3.4$; $df=9$; $p=0.9$

Figure 9: Types of incision

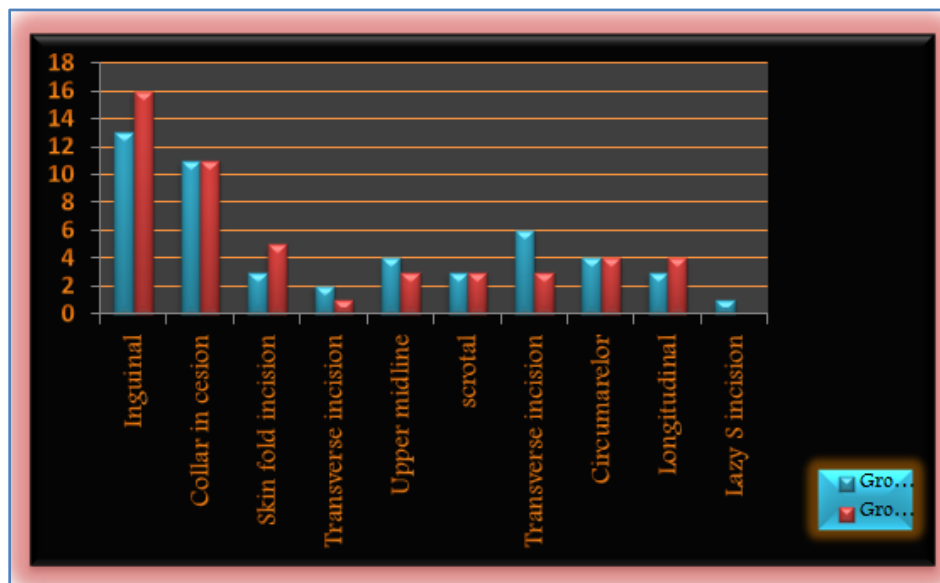


Fig. 9

It is observed from Tables 9-12 that 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

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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 has no effect on the post-operative wound infection rates.

CULTURE RESULTS: Sterile saline swab culture was taken from site of incision after skin disinfection with respective antiseptic regimen to compare the efficacy of both the regimen. In patients with positive culture results, microorganisms were further strained with antibiotic sensitivity test.

Microbiological report	Group I		Group II		Total	
	No.	%	No.	%	No.	%
No growth	45	90	49	98	94	94
Staphylococcus coagulase (-)	4	8	1	2	5	5
Staphylocococcus coagulase (+)	1	2	0	0	1	1
Total	50	100	50	100	100	100

Table 7: Microbiological report

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

Taking all the patients with growth positive (i.e. patients with positive culture results from site of incision after skin disinfection with respective antiseptic regimen) together the above table can be interpreted as shown in Table 8.

Microbiological report	Group I		Group II		Total	
	No.	%	No.	%	No.	%
No growth	45	90	49	98	94	94
Growth Present	5	10	1	2	6	6
Total	50	100	50	100	100	100

Table 8: Comparison of percentage of cases with positive culture results from site on incision in both the groups

Chi square test: $z=4.16$; $df=1$; $p=0.04$

Figure 10: Comparison of percentage of cases with positive culture results from site of incision in both the groups.

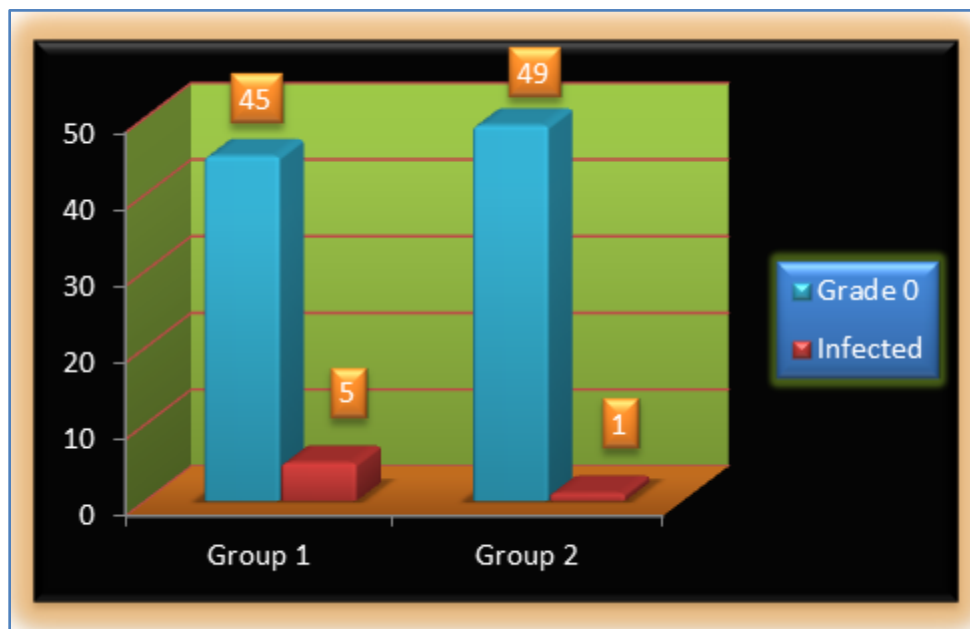


Fig. 10

It was observed from this study (Table 8) that the proportion of cases with growth in Group I was 5 whereas in case of Group II was 1 and this difference in the proportion of patients with growth after skin disinfection between the two groups is found to be statistically significant ($z=4.16$; $p<0.04$).

Culture and antibiotic sensitivity results of the patients with positive growth (from the swabs taken from site of incision after skin preparation with antiseptic) in both the groups is summarized in Table 9.

Antibiogram	Group I				Group II	
	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 1
	Staphylococcus albus	Staphylococcus albus	Staphylococcus albus	Staphylococcus albus	Staphylococcus albus	Staphylococcus albus
Amoxicillin	S	S	S	S	S	S
Cefatoxime	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

Table 9: Culture and antibiotic sensitivity results of the patients with positive growth from the swabs taken from site of incision

Follow up: 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. The grade of wound infection was determined by Southampton wound grading systems. Table 10 shows the cases with different grades of wound infection.

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Follow up (Wound infection grade)	Group I		Group II		Total	
	No.	%	No.	%	No.	%
Grade 0	45	90	49	98	94	94
Ic	1	2	1	2	2	2
IIa	1	2	0	0	1	1
IIIa	1	2	0	0	1	1
IV	2	4	0	0	2	2
Total	50	100	50	100	100	100

Table 10: Wound Infection Grade during follow up period

Taking all the patients with wound infections together Table 16 can be interpreted as shown in Table 11.

Follow up (Wound infection grade)	Group I		Group II		Total	
	No.	%	No.	%	No.	%
Grade 0	45	90	49	98	94	94
Infected	5	10	1	2	6	6
Total	50	100	50	100	100	100

Table 11: Comparison of total number of infected cases in both the groups during follow up period

Z=4.16; p<0.04

Table 17 can be depicted graphically as shown below.

Figure 11: Comparison of total number of infected cases in both the groups during follow up period.

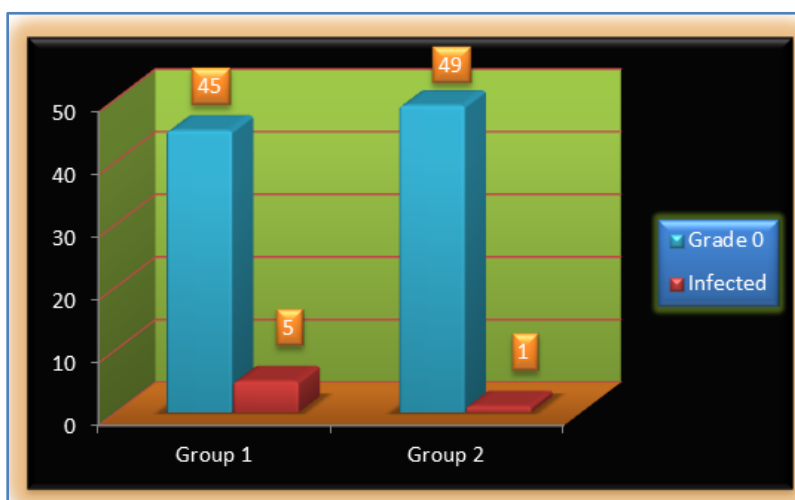


Fig. 11

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It was observed from this study (Tale 17) that the proportion of cases infected in Group I was 5 whereas in case of Group II was 1 and this difference in the proportion of wound infection rate between the two groups is found to be statistically significant ($z=4.16'$ $p<0.04$).

The relation between microbiological result of culture taken from site of incision preoperatively, after skin preparation and wound infection in post-operative follow up period is shown in Table 12.

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
	* $z=15.4$; $df=1$; $p<0.001$			** $z=0.02$; $df=1$; $p=0.8$		

Table 12: Relationship between microbiological report and post-operative wound infection rate

Figure 12: Relationship between microbiological report and post-operative wound infection rate.

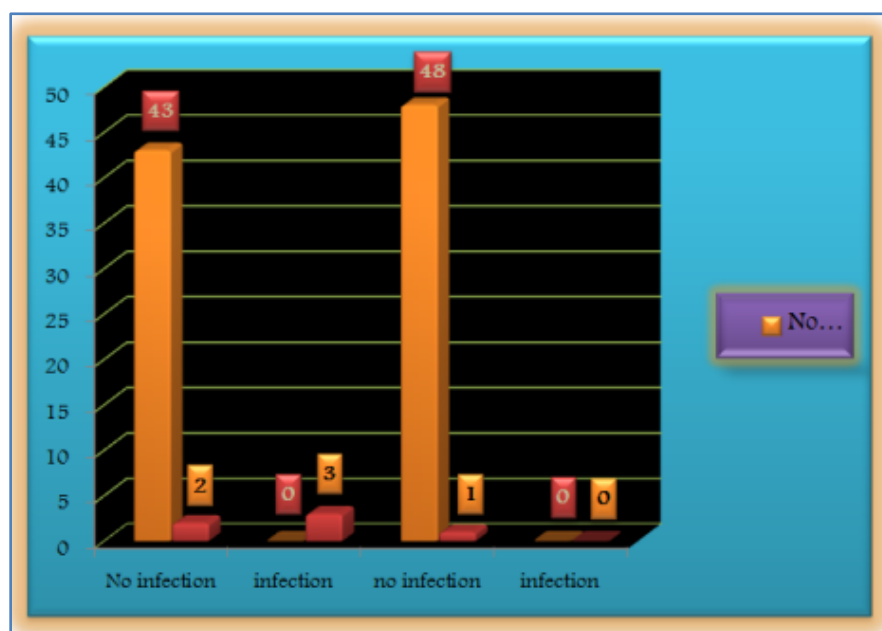


Fig. 12

Figure showing the proportion of patients with (i) no growth and no infection, (ii) growth but no infection, (iii) no growth and infection (ward acquired) and (iv) growth and infection in both the groups.

Note: Growth: Positive culture results from site of incision after skin disinfection.

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Infection: Infection of surgical site in post-operative period (till suture removal).

It is noted from Table 12 that out of 5 cases with growth in group I, only 3 had wound infection and the other 2 were ward acquired. Similarly the only infection in group II was ward acquired. Ward infections were defined as infection occurring in patients with no growth in cultures from site of incision.

The difference in infection rates after excluding ward acquired infections relates directly to the efficacy of antiseptic regimens in respective groups which is shown in Table 13.

Microbiological report	Group I*		Group II**			
	No infection	Infection	Total	No. Infection	Infection	Total
No growth	43	0	43	48	0	48
Growth	2	3*	5	1	0**	1
Total	45	3	48	49	0	49
			*z=27.5;df=1;p<0.001		**0	

Table 13: Relationship between microbiological report and postoperative wound infection rate after excluding ward infection

Figure 13: Relationship between microbiological report and postoperative wound infection rate after excluding ward infection.

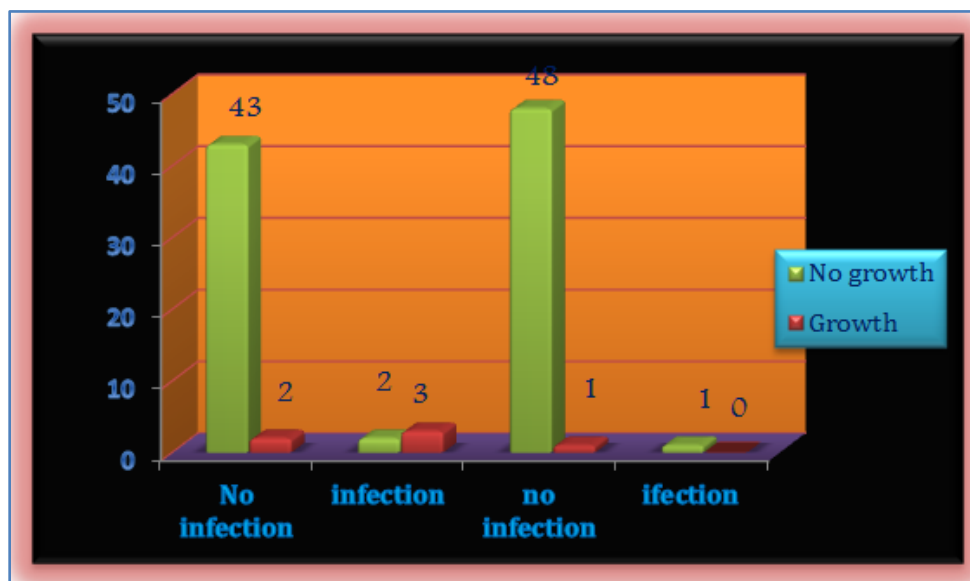


Fig. 13

This study (Table 13) has revealed that the proportion of infected cases after excluding the ward infection in Group I was 3 whereas in case of Group II it was none and this difference in the proportion of infected cases between the two groups is found to be statistically significant.

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Figure showing the difference in proportion of cases with growth and subsequent wound infection after excluding ward acquired infection {designated by (-)} in both the groups. This difference, after excluding ward acquired infections, is directly related to difference in efficacy of antiseptic regimen used in each group.

Note:

Growth: Positive culture results from site of incision after skin disinfection.

Infection: Infection of surgical site in post-operative period (till suture removal).

Ward acquired infection: Patients with no growth but developing infection in post-operative period.

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 infection were of grade III or grade IV i.e., either serous or purulent discharge was present. None of the group II patients had post-operative wound infection. Pus culture and antibiotic sensitivity were done in these patients who developed wound infection. The results of pus culture and antibiotic sensitivity are shown in Table 14.

Antibiogram	Group I		
	Patient 2	Patient 4	Patient 5
	Wound infection Grade IV	Wound infection Grade IIIa	Wound infection Grade IV
	Staphylococcus albus	Staphylococcus albus	Staphylococcus albus
Amoxycillin	S	S	R
Cefatoxime	S	S	S
Ciprofloxacin	S	S	S
Gentamycin	S	S	S
Amikacin	S	S	S

Table 14: Wound infection grade, pus culture result and antibiotic sensitivity report of patients developing post-operative wound infection

These culture and antibiotic sensitivity results showed that the organisms causing infection in the post-operative period were same which were left behind due to less effective antiseptic regimen in group 1.

In view of the above results, in cases who has grade I and grade II surgical site infection with positive culture from site of incision, it was assumed that wound infection was due to ineffective skin disinfection. Incidentally, however, there was no such case.

Finally, two observations can be made from the above data. First, in Group I where only povidone iodine was used, 5 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, 3 patients developed wound infection where as

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in Group II none of the patients developed wound infection. These observations are summarized in Table 21.

Table 21: Comparison of number of cases with growth and wound infection due to difference in efficacy of antiseptic regimen used in each group

Variables	Group I	Group II
Growth	5	1
Infected	3	0

Table 15

Figure 14: Comparison of number of cases with growth and wound infection due to difference in efficacy of antiseptic regimen used in each group.

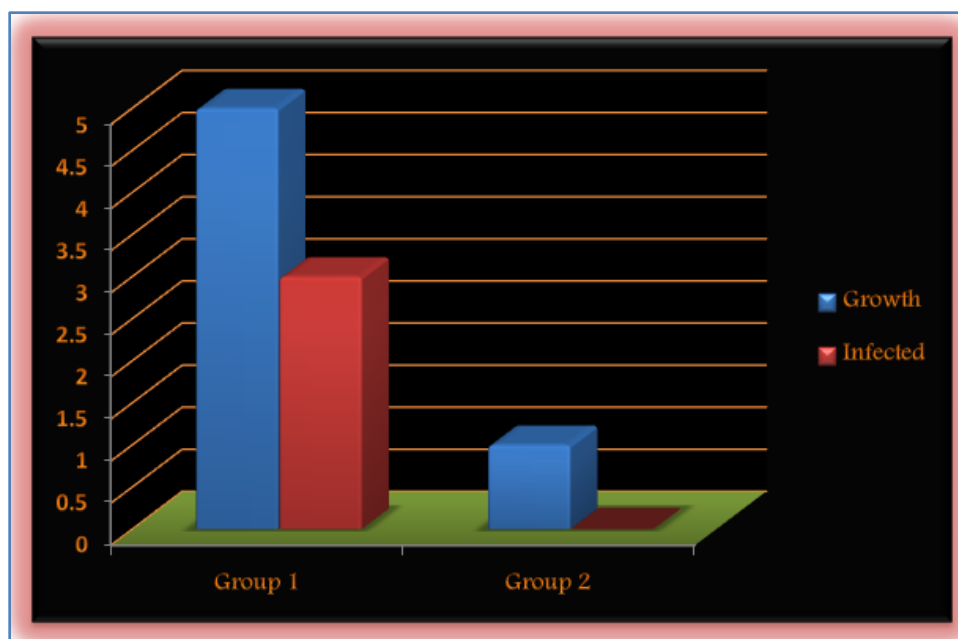


Fig. 14

The difference is due to difference in efficacy between two antiseptic regimen, thereby making regimen in Group II much more clinically and statistically useful in reducing colonization of operative site and also in reducing post-operative wound infections.

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

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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. 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.

This study involved 100 cases which were to undergo clean elective surgeries.

These cases were divided into two groups.

In Group I, antiseptic regimen used for preoperative skin preparation was three coatings of povidone iodine only.

In Group II, antiseptic regimen used for preoperative skin preparation was combination of povidone iodine and alcoholic chlorhexidine.

This study is conducted to compare the efficacy of both the antiseptic regimen by:

1. Evaluating the difference in proportion of cases having colonization of site of incision even after skin disinfection with respective antiseptic regimen.
2. Determining the difference in rate of post-operative wound infections which were related to inefficient skin disinfection preoperatively.

AGE: Patients were selected irrespective of their age. Comparison of age distribution in the present study and Julia L study is shown in Table 22.

Authors	Group I (Mean ± SD)	Group II (Mean ± SD)
Julia L et al	53.4 ± 17.2	50.5 ± 17.2
Present study	40.7 ± 14.4	38.7 ± 15.9

Table 16: Comparative mean age distribution of patients in Julia L. and present study

It was noticed from this study that the Mean ± SD of age in Group I and Group II was 40.7 ± 14.4 and 38.7 ± 15.9 respectively whereas the respective values of Julia L et al. study was 53.4 ± 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 patients had good immune status, had no co-morbid conditions and were planned for clean elective surgery.

SEX RATIO: Patients were selected irrespective of their sex. Comparison of sex ration in the present study and Julia L study is shown in Table 17.

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Authors	Group I (Sex ratio=Male: Female)	Group II (Sex ratio=Male: Female)
Julia L et al	35/7 = 1:0.49	22/21 = 1:0.95
Present study	25/25 = 1:1	33/17 = 1:0.52

Table 17: Comparison of sex ratio of patients in Julia L. and present study

Also, it was observed from this study that the sex ratio (Male: Female ratio) of Group I was 1:1 and that of Group II was 1:0.52 whereas the respective values of Julia L et al. study was 1:0.49 and 1:0.95. It may be seen here that the male to female ratio in the present study in Group I is much higher than Julia et al. Whereas in Group II it was almost 50% less than their study but again the different sex population was not thought to have any effect on the results as all the patients were healthy adults.

CULTURE STUDY RESULTS: Various studies have been undertaken to compare the efficacy of PVP-iodine with chlorhexidine alone or in combination with PVP-iodine. These studies show that addition of chlorhexidine significantly improves the efficacy of antiseptic regimen. The results of our study are consistent with these studies as shown in Table 18.

Authors	Group I (PVP-iodine)	Group II (PVP-iodine + Alcoholic Solution of chlorhexidine)
Julia L et al.	35.3%	4.7%
Glenn G et al.	13.8%	3.3%
Present study	10%	2%

Table 18: Various studies showing comparison of colonization rates of site of incision after disinfection with respective antiseptic regimen

As depicted in the above table 10% of patients in Group 1 and 2% in Group II had colonization of site of incision even after skin disinfection whereas the respective values in Julia L et al. study were 35.3% and 4.7% and in Glenn G et al. 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.

POST OPERATIVE WOUND INFECTION RATES: As for the rate of post-operative wound infection, it is also proven that wound infections are also less if the pre-operative skin preparation is done with either chlorhexidine alone or in combination with povidone iodine as compared to povidone iodine alone.

Table 19 demonstrated the difference in postoperative wound infection rates as a result of difference in efficacy of antiseptic regimen in each group. The present study shows infection rates to be lower in group of patients in whom chlorhexidine was used which is consistent with study done by Brown et al.

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Authors	Group I PVP-iodine	Group II PVP-iodine+ chlorhexidine or chlorhexidine alone)
Brown et al.	8.1%	6.0%
Present study	6%	0

Table 19: Comparative studies showing difference in postoperative wound infection rates

The study done by Brown et al. compared post-operative wound infection rates after using either povidone iodine or alcoholic solution of chlorhexidine and it showed that post-operative 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 post-operative 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 6 % 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.

IDEAL ANTISEPTIC: An ideal skin antiseptic must:

- Fulfil chemical criteria including spectrum of activity, tissue tolerance and absence of acquired bacterial resistance.
- The skin antiseptic should be effective against resident and transient flora.
- It should be effective against all microorganisms.
- It should be capable of being applied quickly and the effect should be sustained at least throughout the operation.
- The antibacterial agent ought to be presented in a formulation appropriate to surgical use.

These characteristics are often claimed for antiseptics but too frequently claims are not borne out by clinical evidence.

A regimen combining alcoholic solution of chlorhexidine 2.5% v/v and aqueous povidone iodine 5% w/v for preoperative skin preparation meets all the qualifications meant for the ideal antiseptic whereas povidone iodine alone is less effective. Chlorhexidine can also be used in most parts of body but needs careful application near eyes and ears as it can be toxic to middle ear on repeated exposures and irritating to eyes when comes in direct contact with the eye.

The results from the present study show that preoperative skin preparation with chlorhexidine gluconate 2.5% v/v in 70% propanol followed by aqueous povidone-iodine is an ideal regime due to the properties mentioned below:

1. It has a broader antimicrobial spectrum than either of them alone.
2. Addition of chlorhexidine leaves a protective film whereas povidone –iodine leaves no film once rinsed off the skin.
3. Presence of blood or serum protein adversely affect the bactericidal activity of povidone iodine but after addition of chlorhexidine the bactericidal activity is not altered.

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4. This regimen is non-irritating to skin and side effects of adding chlorhexidine are extremely less.
5. This combination had rapid lethal action against both transient and resident flora, especially on staphylococci which are more susceptible to chlorhexidine as compared to povidone iodine alone.
6. The rate of post-operative wound infections is much lower as compared to povidone iodine alone.

Therefore it can be safely concluded that this regimen should be followed in preoperative skin preparation in clean elective surgeries. 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.

SUMMARY: The present study was conducted on 100 patients to evaluate comparatively the efficacy of aqueous povidone iodine 5% w/v alone and in combination with chlorhexidine gluconate 2.5% v/v in 70% propanol for pre-operative skin preparation in clean elective surgeries in Department of General Surgery, K. R. Hospital, Mysore.

Patients were randomly divided into two groups of fifty patients each irrespective of their age and sex and detailed history was taken and relevant investigations were done to rule out any focus of infection or malignancy. Patients with comorbid medical conditions, patients undergoing contaminated or emergency surgeries, immune compromised patients and patients suffering from malignancies were excluded from the study. The nature of operation and sites of incision were variable.

In the first group (Group I), antiseptic regimen used for preoperative skin preparation is three coats of aqueous povidone iodine IP 5 % w/v.

In second group (Group II), antiseptic regimen used is 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.

Sterile saline swabs from the site of incision was taken for culture studies after preparation of skin with respective antiseptic regimen to know about colonization of site of incision and in cases with growth, antibiotics sensitivity test was done to strain the organism.

The results of culture studies showed that in Group I, 5 cases out of 50 had bacterial growth. Four had *Staphylococcus albus* and in one case *Staphylococcus aureus* (pathogenic bacteria) was grown. In Group II, only 1 case out of 50 had bacterial growth (*Staphylococcus albus*). This showed that regime II was more effective in reducing colonization of site of incision (2% in Group II as compared to 10% in group I). This less effective regimen I in reducing bacterial load at site of incision is a potent cause of post-operative 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 post-operative 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.

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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, 3 patients had post-operative wound infection whereas none of patients in group II had post-operative 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 post-operative wound infection. (Zero in group II as compared to 6% in group I).

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