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ORIGINAL ARTICLE

CLINICAL EVALUATION OF PREOPERATIVE SKIN PREPARATION WITH AQUEOUS POVIDONE IODINE ONLY AND IN COMBINATION WITH ALCHOLIC CHLORHEXIDINE IN PATIENTS UNDERGOING ELECTIVE AND EMERGENCY SURGERIES

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ABSTRACT: INTRODUCTION: 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 degerming of the skin can be done with antiseptics used for less than one minute which is as effective as five minute scrub with germicidal soap solution followed by painting with antiseptics. **AIMS AND OBJECTIVES:** 1. To evaluate the efficacy of povidone iodine alone and antiseptic agent containing alcoholic chlorhexidine with povidone iodine in preoperative skin preparation by taking swab culture. 2. To compare the rate of postoperative wound infection in both the groups**. METHODS: STUDY DESIGN:** Comparative study conducted on 100 patients in two groups. **STUDY SETTING:** Sri Venkateswara Medical College Tirupathi **SOURCE OF DATA:** 100 Patients (50 in each Group) undergoing elective and emergency surgery admitted in the Department of General Surgery in S.V.R.R. Government General Hospital, Tirupati from 2013 to 2014. **INCLUSION CRITERIA:** 1. Patients undergoing elective & emergency surgery in department of general surgery. 2. Patients with no focus of infection anywhere on the body. 3. Patients irrespective of their age and sex. 4. Patients neither immunocompromised nor on any long term steroids. 5. Patients undergoing mesh repair of hernia are also included. **EXCLUSION CRITERIA:** 1. Immuno compromised patients and patients on long term steroids. 2. Patients with septicemia. 3. Patients suffering from malignancies or undergoing chemotherapy or radiation therapy. 4. Contaminated surgeries in which viscus was opened were excluded from the study. 5. Patients with co-morbid medical conditions like diabetes, hypertension etc. **METHOD OF COLLECTION OF DATA:** In each case preoperatively, detailed history was taken and routine investigations like haemoglobin, total count, differential count, ESR, RBS and chest X-ray, ultrasound were done to rule out any co-morbid conditions, chronic infections or malignancy. Preoperative shaving of the parts was done at the same time on previous evening for all the patients and same antibiotic protocol was followed. The pre-operative skin preparation in each group is done with the respective antiseptic regimen. Group I: Three coats of aqueous povidone iodine IP 5% w/v marketed as Betadine. Group II: Chlorhexidine gluconate 2.5% v/v in 70% propanol followed by two coats of aqueous povidone iodine IP 5% w/v. In both the groups after application of antiseptics, sterile saline swab culture was taken immediately from site of incision and was transferred to microbiology department to determine

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whether microorganisms were left behind and hence to compare the efficacy of both the regimes of skin preparation. Post operatively, 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 to look for any signs of wound infection. 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 $p \leq 0.05$.

KEYWORDS: Skin Preparation, Asepsis, Antisepsis, Antibiotic Sensitivity Test, Wound infection.

INTRODUCTION: 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 degerming of the skin can be done with antiseptics used for less than one minute which is as effective as five minute scrub with germicidal soap solution followed by painting with antiseptics.[1]

Inspite 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 exonerate the other.[2,3,4,5] A confusion still prevails regarding the source of wounds 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. asepsis 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.

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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 case of operators 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.

Despite many advances in the surgical techniques in the past few years, post-operative 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.[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.

IODOPHORS (POVIDONE IODINE): Siggia in 1957 described that povidone-iodine, a complex of polyvinylpyrrolidone and iodine as a water soluble, chemically stable, form of iodine, which is non-irritant to the tissues and does not cause reactions even in patients sensitive to elemental iodine.[11]

Connell et al in 1964 demonstrated povidone-iodine as a highly effective degerming agent which had a rapid lethal effect and was non-injurious to both normal skin and/or open wounds.[12]

CHEMICAL AND ANTIMICROBIAL PROPERTIES OF IODOPHORS:

1. Iodophors are compounds which forms a stable complex of elemental iodine with certain organic carriers such as polyvinylpyrrolidone (PVP).
2. PVP-Iodine is completely soluble in water.
3. PVP-Iodine acts as a reservoir that releases iodine as it is used and ensures that "free" iodine is always available and antimicrobial properties of PVP- Iodine are related to non-complexed freely mobile elemental iodine.
4. There is less skin irritation than with alcoholic iodine tincture but the amount of free iodine is sufficient to retain the advantage of the agent.
5. Gram positive and Gram negative organisms are both sensitive and, inaddition, iodophors are sporicidal.

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DRAWBACKS OF PVP IODINE:

1. Repeated applications are not required but since these agents are water soluble, no protective film is left once rinsed off the skin.
2. The presence of blood or serum protein has been shown to affect adversely the bactericidal activity of the iodophor compounds as well as hexachlorophane.

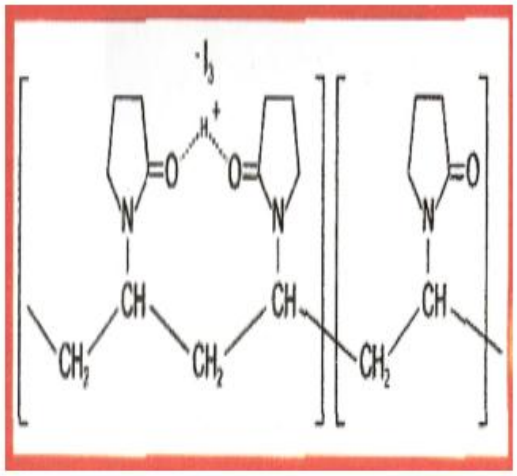

Figure 1: Chemical structure of povidone iodine

Figure 2: Povidone-iodine aqueous solution 5% betadine

CHLORHEXIDINE: The efficacy of 0.5 percent chlorhexidine gluconate in 70 % isopropyl alcohol in sterilizing the skin has been well established in 1960. It was demonstrated that chlorhexidine reduced bacterial colony counts to a greater extent than alcoholic iodine.

Hugo and Longworth (1964) observed that chlorhexidine is rapidly absorbed by bacterial cell and this absorption is accompanied by other cytological changes in the permeability of cell and their optical properties after Davies et al had observed that chlorhexidine exerted its action against wide range of vegetative bacteria both gram positive and gram negative and to lesser extent on spores.[13]

The results of subsequent clinical studies in Great Britain confirmed the broad spectrum of bactericidal activity of this new agent as well as its prolonged effectiveness. Reduction of bacterial skin counts by 80 to 99 percent continued even four hours after initial application. The results of continued preclinical and clinical studies in Great Britain, as well as a comparative study done in the United States have shown chlorhexidine to be significantly superior to hexachlorophane and consistently superior to iodophors.

CHEMICAL AND ANTIMICROBIAL PROPERTIES: Chlorhexidine has a broad spectrum of activity and is bactericidal on contact like the iodophors.

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ADVANTAGES OVER IODOPHORS:

1. A protective film remains on the skin, like hexachlorophane, repeated applications are not required.
2. The bactericidal action is not adversely affected by the presence of blood or serum protein.

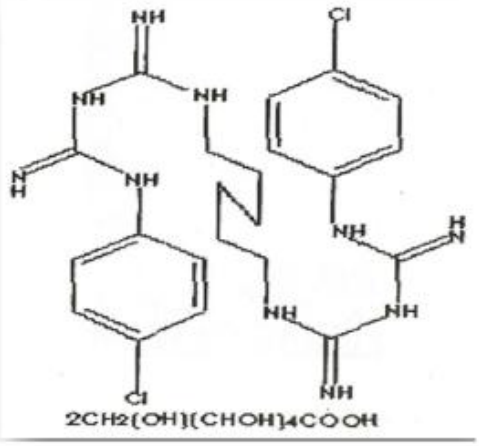

Figure 3: Chemical structure of chlorhexidine gluconate

Figure 4: Germiclean (alcoholic solution of chlorhexidine)

Chlorhexidine is more effective than povidone-iodine in diminishing skin colonization with staphylococci in patients before operation.

T.R. Brown et al (1984) undertook a study to evaluate the different techniques of operative site preparation, and wound infection was the primary evaluation parameter. They concluded that wound infection rates were less with chlorhexidine spray technique (6%) as compared to povidone-iodine scrub or liquid (8.1%).[14]

Kaiser AB et al (1988), undertook a prospective randomized observer-blinded study comparing the ability of preoperative showers with chlorhexidine gluconate, povidone iodine and lotion soap to diminish the staphylococcal skin flora of patients. They concluded that chlorhexidine skin cleanser consistently reduced staphylococcal colony counts whereas use of povidone-iodine inconsistently affected skin flora.[15] Patients prepared with soap solution either had no change or increase in colony counts and hence chlorhexidine was most effective in pre-operative skin preparation.

Garibaldi R.A. et al (1988) studied the impact of preoperative skin disinfection on preventing intraoperative wound contamination. Patients who showered twice with 4% chlorhexidine gluconate had lower mean colony counts of skin bacteria at the surgical incision site in the operating room prior to the final scrub than the patients who showered twice with povidone - iodine solution or medicated bath soap.[16]

Grabsch EA et al., (2004) studied the efficacy of a chlorhexidine in alcohol surgical rub and concluded that chlorhexidine regimen demonstrated excellent bactericidal efficacy throughout an operating list, and was superior to povidone - iodine scrubbing in all aspects. The alcoholic chlorhexidine regimen is simpler and should have wide surgical application.[17]

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Linder N et al., (2004) compared disinfection with 10% povidone - iodine versus 0.5% chlorhexidine gluconate in 70% isopropanol in the neonatal intensive care unit and concluded that the use of 0.5% chlorhexidine gluconate solution in 70% isopropanol as a skin disinfectant is justified in neonatal intensive care units because it is not associated with an increased incidence of infections as opposed to 10% povidone - iodine and is devoid of detrimental effects.[18]

Patrick J. Culligan (2005) concluded that chlorhexidinegluconate was more effective than povidone-iodine in decreasing the bacterial colony counts that were found in the operative field for vaginal hysterectomy.[19]

Julia Langgartner (2004) demonstrated that combined skin disinfection with alcoholic chlorhexidine solution and aqueous povidone-iodine was superior in the prevention of microbial central venous catheters colonization compared to either of regimens alone.[20]

Paocharoen V, Mingmalairak C, ApisarnthanarakA (2009) finally demonstrated that Antiseptic scrub and paint can reduce bacterial colonization and postoperative wound infection. Two forms of antiseptics, povidone-iodine and chlorhexidine, are commonly used in the operating theater. There was a significant reduction of bacterial colonization and wound infection after skin preparation with combination of chlorhexidine and povidone iodine.[21]

AIMS AND OBJECTIVES:

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

METHODOLOGY:

Study Design: Comparative study conducted on 100 patients in two groups.

Study Setting: Sri Venkateswara Medical College Tirupathi.

Source Of Data: 100 Patients (50 in each Group) undergoing elective and emergency surgery admitted in the department of General Surgery in S.V.R.R. Government General Hospital, Tirupati from 2013 - 14.

Inclusion Criteria:

1. Patients undergoing elective and emergency surgery in department of general surgery.
2. Patients with no focus of infection anywhere on the body.
3. Patients irrespective of their age and sex.
4. Patients neither immunocompromised nor on any long term steroids.
5. Patients undergoing mesh repair of hernia are also included.

Exclusion Criteria:

1. Imrnuno compromised patients and patients on long term steroids.
2. Patients with septicemia.
3. Patients suffering from malignancies or undergoing chemotherapy or radiation therapy.
4. Contaminated surgeries in which viscus was opened were excluded from the study.
5. Patients with co-morbid medical conditions like diabetes, hypertension etc.

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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 investigations like haemoglobin, total count, differential count, ESR, RBS and chest X-ray, ultrasound were done to rule out any co-morbid conditions, chronic infections or malignancy. Preoperative shaving of the parts was done at the same time on previous evening for all the patients and same antibiotic protocol was followed. (Ceftriaxone - single dose given intravenously at the time of anesthesia and in minor surgeries, which were done under local anesthesia antibiotics were administered immediately before surgery.) This regime had no effect on transient and resident flora on the intact skin before incision and thus microbial colonization of incision site was only affected by antiseptics used for preoperative skin preparation. The pre-operative skin preparation in each group is done with the respective antiseptic regimen.

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

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 (sterimax) 2.5% v/v in 70% alcohol. (Figure 5)
Step 2: Chlorhexidine containing agent is being spread uniformly and allowed to form a film. (Figure 6)
Step 3: Two coats of aqueous povidone iodine are applied. (Figure 7)

Figure 5- Step 1

Figure 6- Step 2

Figure 7- Step 3

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In both the groups after application of antiseptics, sterile saline swab culture was taken immediately from site of incision (figure 8) 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 8: Sterile Saline Swab Culture Being Taken From Site Of Incision

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- Amoxicillin, Cefotaxime, Ciprofloxacin, Amikacin, Erythromycin.

Post operatively, 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:

- Purulent/ serous discharge from the wound.
- Redness of the surrounding area.
- Pain associated with discharge.
- Increased local temperature.
- Swelling of the surrounding area.

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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.

RESULTS: A total of 100 patients were studied in two groups (50 patients in each group). All the cases were planned for elective and emergency surgery. Cases were selected at random basis irrespective of their age and sex. The patients were from both, rural as well as 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.

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 (yrs)	Group I			Group II			Grand total
	Male	Female	Total	Male	Female	Total	
<20	2	1	3	0	3	3	6
21-30	5	8	13	7	7	14	27
31-40	4	5	9	11	6	17	26
41-50	4	6	10	6	3	9	19
51-60	4	4	8	2	0	2	10
61-70	3	1	4	2	1	3	7
>71	3	0	3	2	0	2	5
Total	**25**	**25**	**50**	**30**	**20**	**50**	**100**

Table 1: Age and sex distribution of subjects

As shown in Table 1, it may be observed that of the 100 subjects studied, there were 50 (50.0%) in the group I and the remaining 50 (50.0%) in the group II.

Study groups	No. of subjects	Mean	SD	95% Confidence Interval for Mean		T value	P Value
				Lower Bound	Upper Bound		
Group I	50	42.22	16.63	2.15	9.91		
Group II	50	38.34	13.65	2.16	9.92	1.275	0.205

Table 2: Descriptive & inferential statistics of age of subjects

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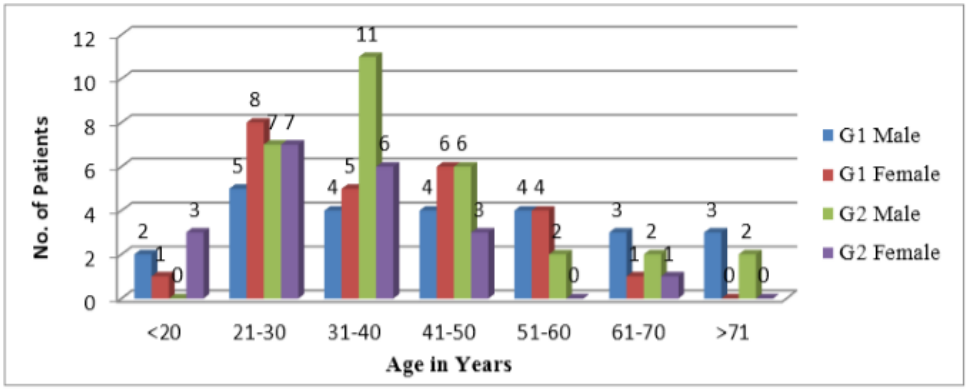
Further it is observed from Table 2 that the mean±SD of the age for group I was 42.22±16.63 and that for group II was 38.34±13.65 years.

Nevertheless, this marginal difference in the age between the two categories were statistically not significant (t=1.275, P=0.205, NS).

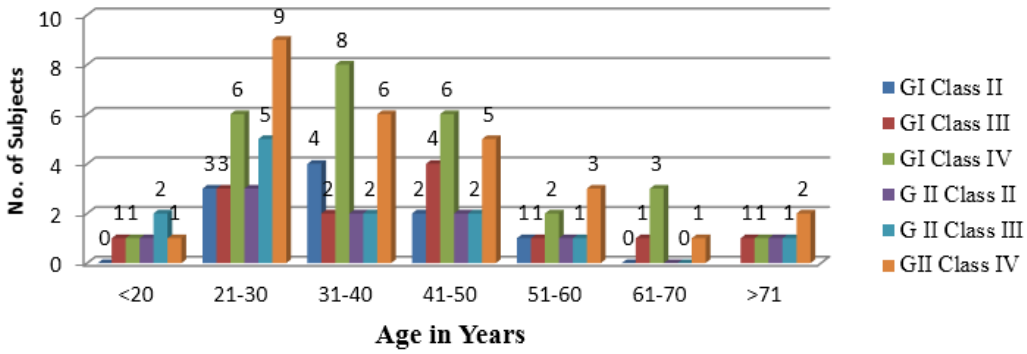


Graph 1: No of Patients in Different Age, Sex Test Groups

SOCIOECONOMIC STATUS: The patients were randomly selected from all the socioeconomic groups.

Age (Yrs)	Group I				Group II				Grand Total
	Class II	Class III	Class IV	Total	Class II	Class III	Class IV	Total	
<20	-	1	1	2	1	2	1	4	6
21-30	3	3	6	12	3	5	9	17	29
31-40	4	2	8	14	2	2	6	10	24
41-50	2	4	6	12	2	2	5	9	21
51-60	1	1	2	4	1	1	3	5	9
61-70	-	1	3	4	-	-	1	1	5
>71	-	1	1	2	1	1	2	4	6
Total	**10**	**13**	**27**	**50**	**10**	**13**	**27**	**50**	**100**

Table 3: Distribution of Socio-Economic Status Based on the age Group



Graph 2: Distribution of Socio-Economic Status Based On the Age Group

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As shown in Table-3, the present study reveals that in both the groups there were 10 patients in class II followed by 13 patients in class III and 27 patients in class IV and there was no difference in the distribution of total number of cases in each class between the two groups.

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 and all the surgeries were elective and emergency.

Diagnosis	Group I		Group II		Total	
	No	%	No	%	No.	%
Mulitinodulargoiter	3	6	3	6	6	6
Solitary nodule-thyroid	1	2	1	2	2	2
B/L Direct inguinal Herina	3	6	3	6	6	6
Lt indirect inguinal hernia	3	6	3	6	6	6
Rt indirect inguinal hernia	3	6	3	6	6	6
Epigastric hernia	1	2	1	2	2	2
Incisional hernia	2	4	2	4	4	4
Paraumblical hernia	1	2	1	2	2	2
Umblical herina	1	2	1	2	2	2
Fibroadenoma Breast	2	4	2	4	4	4
Lipoma	2	4	2	4	4	4
Varicose veins	1	2	1	2	2	2
Undescended testis	1	2	1	2	2	2
Parotid-Pleomorphic adenoma	1	2	1	2	2	2
Acute appendicitis	8	16	8	16	16	16
Obstructed Hernia	6	12	6	12	12	12
Acute Intestinal obstruction	6	12	6	12	12	12
Blunt injury abdomen	4	8	4	8	8	8
Torsion of testis	1	2	1	2	2	2
Total	**50**	**100**	**50**	**100**	**100**	**100**

Table 4: Diagnosis of Subjects

Chi square test χ^2 =7.333, df=18, P=0.999.

Surgery	Group I		Group II		Total	
	No	%	No	%	No	%
Sub-total thyriodectomy	3	6	3	6	6	6
Hemi-thyroidectomy	1	2	1	2	2	2
Lichtenstein mesh repair	6	12	6	12	12	12
Bassini's repair of Inguinal Hernia	3	6	3	6	6	6
Anatomical repair of Epigastric Hernia	1	2	1	2	2	2
Mayo's repair of Umbilical Hernia	2	4	2	4	4	4
Hernioplasty of Incisional Hernia	2	4	2	4	4	4
Excision of fibroadenoma of Breast	2	4	2	4	4	4
Excision of Lipoma	2	4	2	4	4	4
Trendelenberg surgery	1	2	1	2	2	2

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Superficial parotidectomy	1	2	1	2	2	2
Emergency appendicectomy	8	16	8	16	16	16
Herniorrhapy for Obstructed Inguinal Hernia	6	12	6	12	12	12
Adhesiolysis of Acute intestinal obstruction	5	10	5	10	10	10
Sigmoidopexy of Sigmoid volvulus	1	2	1	2	2	2
Mesentric Repair of Blunt injury abdomen	3	6	3	6	6	6
Splenectomy of Blunt injury abdomen	1	2	1	2	2	2
Low Orchidectomy of Torsion of testis	1	2	1	2	2	2
High orchidectomy of Undescended testis	1	2	1	2	2	2
Total	**50**	**100**	**50**	**100**	**100**	**100**

Table 5: Type of surgeries done in both the groups

L - Left; R - Right Chi square test χ^2 =7.778, df=18, P=0.99.

Site of incision		**Group I**		**Group II**		**Total**	
		No	**%**	**No**	**%**	**No.**	**%**
1	Front of ear	1	2	1	2	2	2
2	Front of neck	4	8	4	8	8	8
3	Back of chest wall	1	2	1	2	2	2
4	Breast	2	4	2	4	4	4
5	Upper anterior abdominal wall	2	4	2	4	4	4
6	Anterior abdominal wall	12	24	12	24	24	24
7	Low anterior abdominal wall	25	50	25	50	50	50
8	Ventral aspect of forearm	1	2	1	2	2	2
9	Front of thigh	1	2	1	2	2	2
10	Scrotal	1	2	1	2	2	2
	Total	**50**	**100.00**	**50**	**100.00**	**50**	**100.00**

Table 6: Sites of Incision

Chi square test χ^2 =0.056, df=9, P=1.00

Incision	**Group I**		**Group II**		**Total**	
	No	**%**	**No**	**%**	**No.**	**%**
Lazy S incision	1	2	1	2	2	2
Radial incision	2	4	2	4	4	4
Upper midline	2	4	2	4	4	4
Midline incision	12	24	12	24	24	24
Elliptical incision	1	2	1	2	2	2
Inguinal	16	32	16	32	32	32
Skin fold incision	5	10	5	10	10	10
Transverse incision	3	6	3	6	6	6
Longitudinal incision	1	2	1	2	2	2
Oblique incision	7	14	7	14	14	14
Total	**50**	**100.00**	**50**	**100.00**	**100**	**100.00**

Table 7: Types of incision

Chi square test χ^2 =0.056, df=9, P=1.00.

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It is observed from Table 4-7 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 45mins to 3 hrs and since all the surgeries were elective and emergency, 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 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	44	88	49	98	93	93
Staph. Albus(coagulase -)	3	6	1	2	4	4
Staph. Aureus(coagulase +)	2	4	-	0.00	2	2
Bacillus subtilis	1	2	-	0.00	1	1
Total	**50**	**100**	**50**	**100**	**100**	**100**

Table 8: Microbiological report

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 below (Table 9).

Microbiological report	Group I		Group II		Total	
	No	%	No	%	No.	%
No growth	44	88	49	98	93	93
Growth present	6*	12	1*	2	7	7

Table 9: Comparison of % of cases with positive culture results from site of incision in both the groups

Chi square test χ^2 =3.840, df=1, Fisher's P=0.048.

It was observed from this study (Table 9) that the proportion of cases with growth in Group I was 6(12%) where as in case of Group II was 1 (2%) and this difference in the proportion of patients with growth after skin disinfection between the two groups is found to be statistically significant (χ^2 =3.840, Fisher's P=0.048,S).

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 10.

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		Group 1						Group 2
	Patient No.	**Pt 1**	**Pt2**	**Pt3**	**Pt4**	**Pt5**	**Pt6**	**Pt1**
Anti Bio Gram	**Culture result**	**Staph albus**	**Staph aureus**	**Staph albus**	**Bacillus subtilis**	**Bacillus subtilis**	**Staph albus**	**Staph albus**
	Amoxicillin	S	R	S	S	S	R	S
	cefotaxime	S	R	S	S	S	R	S
	Ciprofloxacin	S	S	S	S	S	S	S
	Amikacin	S	S	S	S	S	S	S
	Erythromycin	S	S	S	S	S	S	S

Table 10: 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 17 shows the cases with different grades of wound infection.

Follow up (Wound Infection Grade)	**Group I**		**Group II**		**Total**	
	No	**%**	**No**	**%**	**No.**	**%**
Grade 0	44	88	49	98	93	93
Ic	1	2	1	2	2	2
IIa	1	2	-	-	1	1
III a	2	4	-	-	2	2
IV	2	2	-	-	2	2
Total	**50**	**100.00**	**50**	**100.00**	**100**	**100.00**

Table 11: Wound Infection Grade During Follow Up Period

Taking all the patients with wound infections together Table 11 can be interpreted as below (Table 12).

Follow up (Wound Infection Grade)	**Group I**		**Group II**		**Total**	
	No	**%**	**No**	**%**	**No.**	**%**
Grade 0	44	88	49	98	93	93
Infected	6*	12	1*	2	7	7
Total	**50**	**100.0**	**50**	**100.0**	**100**	**100.0**

Table 12: Comparison of total number of infected cases in both the groups during follow up period

χ^2 =3.840, Fisher's P=0.048.

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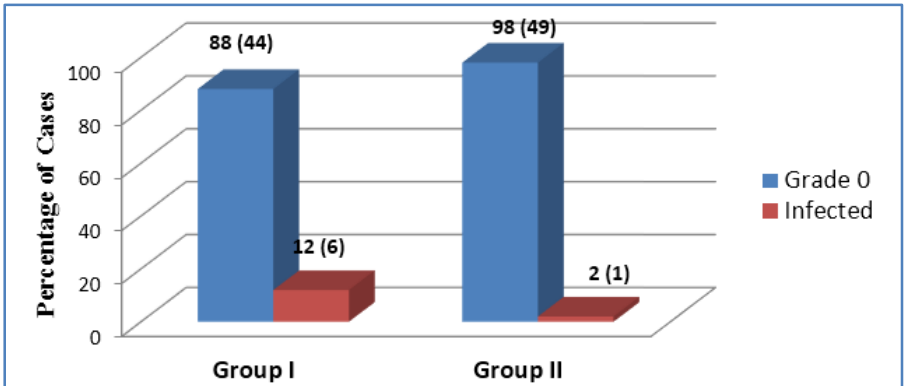

Graph 3: Comparison of total number of infected cases in both the groups during follow up period

Comparison of percentage of cases with wound infection in post-operative follow up period (till suture removal) in both the groups.

It was observed from this study that the proportion of cases infected in Group I was 6(12%) where as in case of Group II was 1(2%) and this difference in the proportion of wound infection rate between the two groups is found to be statistically significant (χ^2 =0.056, Fisher's P=0.048,S).

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 13.

Microbiological report	Group I			Group II		
	No Infection	Infection	Total	No Infection	Infection	Total
No Growth	43	1	44	48	1	49
Growth	1	5	6*	1	0	1*
Total	**44**	**6**	**50**	**49**	**1**	**50**
	χ^2 =32.854, df=1, Fisher's P=0.001;S			χ^2 =24.490, df=1, Fisher's P=0.000;S		

Table 13: Relationship between microbiological report and post-operative wound infection rate

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

Infection: Infection of surgical site in post-operative period (till suture removal). It is noted that out of 6 cases with growth in group I, only 5 had wound infection and the other 1 is ward acquired. Similarly the only infection in group II is 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 14.

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Micro-biological report	Group I			Group II		
	No Infection	Infection	Total	No Infection	Infection	Total
No growth	44	-	44	49	-	49
Growth	1	5*	6	1	0*	1
Total	**45**	**5**	**50**	**50**	**0**	**50**
	χ^2 =32.854, df=1, Fisher's P<0.001;S			χ^2 =24.490, df=1, Fisher's P<0.000;S		

Table 14: Relationship between microbiological report and post-operative wound infection rate after excluding ward infection

This study (Table-14) has revealed that the proportion of infected cases after excluding the ward infection in Group I was 5 where as 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. (χ^2 =32.854, df=1, Fisher's P=0.001;S) (χ^2 =24.490, df=1, Fisher's P=0.000;S)

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 15.

		Group I				
Patient No		**Pt2**	**Pt4**	**Pt5**	**Pt6**	**Pt7**
Wound Infection grade		**IV**	**IlIa**	**IV**	**IlIa**	**Ic**
Culture result		**Staph aureus**	**Bacillus subtilis**	**Bacillus subtilis**	**Staph albus**	**Staph albus**
Antibiogram	Amoxycillin	R	S	S	R	S
	Cefotaxime	R	S	S	S	S
	Ciprofloxacin	S	S	S	S	S
	Amikacin	S	S	S	S	S
	Erythromycin	S	S	S	S	S

Table 15: 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 I.

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Finally, two observations can be made from the above data. First, 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, 5 patients developed wound infection where as in Group II none of the patients developed wound infection. These observations are summarized in Table 16.

Variables	Group I	Group II
Growth	6	1
Infected	5	0

Table 16: Comparison of number of cases with growth and wound infection due to difference in efficacy of antiseptic regimen used in each group

This 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 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.[20] 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.

AGE: Patients were selected irrespective of their age. Comparison of age distribution in the present study and Julia L. study is shown in Table 17.

Authors	Group I(Mean± SD)	Group II(Mean± SD)
Julia L et al.	53.4±17.2	50.5±17.2
Present study	42.22±16.63	38.34±13.65

Table 17: 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 42.22±16.63 and 38.34±13.65 respectively whereas the respective values of Julia et al. study

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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 elective and emergency surgery.

SEX RATIO: Patients were selected irrespective of their sex. Comparison of sex ratio in the present study and Julia L. study is shown in Table 18.

Authors	Group I(Sex ratio=M: F)	Group II(Sex ratio=M: F)
Julia L et al.	35/17=1: 0.49	22/21 = 1: 0.95
Present study	25/25 = 1:1	30/20=1.5:1

Table 18: Comparison of sex ratio of patients in Julia l. and present study

Also, it was observed from this study that the sex ratio of Group I was 1:1 and that of Group II was 1.5:1 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 povidone alone and chlorhexine 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 19.

Authors	Group I	Group II
Julia L et al.	35.3	4.7
Glenn et al.	13.8	3.3
Present study	12	2

Table 19: Various studies showing comparison of colonization rates of site of incision after disinfection with respective antiseptic regimen

As depicted in the above table 12% of patients in Group I 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

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is done with chlorhexidine in combination with povidone iodine as compared to povidone iodine alone.

Table 20 demonstrates 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.

Author	Group I	Group II
Brown et al	8.1%	6.0%
Present study	10%	0%

Table 20: 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 povidine iodine or alcoholic solution of chlorhexidine and it showed that postoperative wound infection rates were less in chlorhexidine group (Group II) (6.0%) than in povidine iodine group (Group I) (8.1%) although this difference was not significant.

The present study compared with post-operative wound infection rates after using povidine iodine alone (Group I) and combination of povidine iodine and alcoholic chlorhexidine (Group II). The wound infection rate in Group I was 10% 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.

A regimen combining alcoholic solution of chlorhexidine 2.5% v/v and aqueous povidine iodine 5% w/v for preoperative skin preparation meets all the qualifications meant for the ideal antiseptic whereas povidine 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.

CONCLUSION: 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 affects the bactericidal activity of povidone iodine but after addition of chlorhexidine the bactericidal activity is not altered.
4. This regimen is non-irritating to skin and side effects of adding chlorhexidine are extremely less.
5. This combination has 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 elective and emergency 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.

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