To Study and Compare the Effect of Pre-Operative Skin Preparation with Aqueous Povidone Iodine Only and in Combination with Alcoholic Chlorhexidine on Surgical Site Infection in Tertiary Care Hospital SVRRGGH, Tirupati

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ABSTRACT

BACKGROUND

Even the normal skin of healthy humans usually harbours a rich bacterial flora, which are usually non-pathogenic. But these organisms always have a potential to cause infection of the surgical site. The aim of surgical site preparation with antiseptics is to remove microorganisms harbouring the skin surface to a lower level. Povidine iodine (iodophors) and chlorhexidine are the agents most often used for pre-operative surgical site antisepsis. In this study, we wanted to determine the efficacy of pre-operative skin preparation with aqueous povidone iodine alone and when used in combination with alcoholic chlorhexidine for surgical site asepsis.

METHODS

This is a cross-sectional study. 200 patients (100 in each group) were considered for the study who were undergoing clean elective surgery. Pre-operative preparation of skin in the surgical area was done by the respective antiseptic which was planned accordingly, after such application, sterile saline swab culture was taken immediately from the site of incision during surgery. In the cases which showed growth of organisms, they were isolated from colonies and subjected to gram staining, coagulase test and antibiotic sensitivity test. The organisms thus isolated were identified by their morphological and cultural characteristics and difference in colonization rates were considered as a measure of antiseptic regimen efficacy.

RESULTS

The results showed that, usage of povidine iodine along with alcoholic chlorhexidine is more efficacious and showed significant reduction of colonization rates at the site of incision, in comparison to using povidone iodine alone. Post-operative wound infections were lower, when povidine iodine is used in combination with chlorhexidine is used for pre-operative surgical site preparation.

CONCLUSIONS

Pre-operative skin preparation with the chlorhexidine gluconate 2.5 % v/v in 70 % propanol followed by aqueous povidone-iodine solution is an ideal for broad spectrum asepsis and the post-operative wound infection rate is much lower as compared to povidone iodine alone.

KEYWORDS

Skin Disinfection; Chlorhexidine; Propanol; Povidone-iodine; Bacterial Colonization

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BACKGROUND

Post-operative wound infection is a significant problem although there are many advances in surgical techniques in the last few years. It causes morbidity and prolonged hospitalization. Risk factors for the development of postoperative surgical site infection, which are related to patients were malnutrition, diabetes mellitus, immunosuppression, and some related to surgical procedures. Moynihan (1920) said, "Our bacteriological experiment may conduct with one of the two intentions: 1. All organism are excluded from a wound site. 2. In the wound, all organisms are destroyed by a bactericide applied to wound surface.[1]

- Asepsis and antisepsis are fundamental principles for modern day surgery.
- Asepsis is defined as the exclusion of bacteria from the surgical sites by sterilization of everything employed in it.
- Antisepsis aims at erecting a chemical barrier between the tissue and the possible sources of infection.

Generally, the use of an antibacterial agent should complement aseptic surgery. For which, two most commonly used antiseptics are povidone-iodine and chlorhexidine. When used independently, both are proven to have good antiseptic properties. Now, this study was to test the efficacy of those antiseptics when used in combination.

Aim

To determine the efficacy of pre-operative skin preparation with aqueous povidone iodine alone and when used in combination with alcoholic chlorhexidine for surgical site asepsis.

Objectives

1. To compare the presence of residual bacteria among the study groups.
2. To assess and compare the proportion of postoperative wound infection among the study groups.

METHODS

This cross-sectional study was conducted in Department of General Surgery, S.V.V.R.R.G.G Hospital, Tirupati for a period of one year from March 2019 to April 2020. A total of 200 patients satisfying inclusion criteria were included.

Inclusion Criteria

1. Age 20 -70 years old.
2. Patients undergoing clean elective surgery in department of general surgery who had given written and oral consent.

Exclusion Criteria

1. Patients posted for emergency surgery.
2. Immunocompromised patients.
3. Patients on long term steroids usage.
4. Previous cases of septicemia.
5. Patients with malignancy or taking chemotherapy or radiotherapy.
6. Patients having comorbid medical conditions like diabetes.

Data Collection Procedure

After obtaining institutional ethical clearance bearing a reference number M180110070, this cross-sectional study was planned to be conducted among the patients who got admitted to the study setting to undergo elective surgeries. In each patient, a detailed history about the pre-existing condition was obtained prior to surgery. Routine investigation and chest X-ray were done to look for prior infections or malignancies. 200 patients thus fitting into the inclusion criteria were allocated for the study. The patients thus enrolled for the study were divided into two groups of 100 each by random allocation using lottery method. Same protocol of antibiotics and pre-operative surgical site shaving was followed for all the patients (i.e. Ampicillin and Gentamycin - single dose will be given intravenously just prior to anesthesia in minor surgeries and major surgeries). The pre-operative preparation of the surgical site in each group was done following the respective antiseptic regimen chosen to be performed.

Group I

Scrubbing is done with three coats of aqueous povidone iodine IP 5 % w/v marketed as betadine.

Group II

Antiseptic regimen followed here is two coats of aqueous povidone– iodine IP 5 % w/v followed by single coat of agent containing chlorhexidine gluconate 2.5 % v/v in 70 % propanol.

After performing asepsis of the surgical site, swabs were taken and were subjected to gram stain and culture. The variability in microbial growth rate was considered to measure efficiency of the aforesaid regimen. If any presence of purulent discharge observed in the post-operative period, the samples were collected and sent for pus culture and antibiotic sensitivity tests, and to see whether the causative organisms present preoperatively after skin preparation and the organisms isolated in the postoperative period are same or not. By doing this, an inference can be drawn about the root cause for post-operative wound infection, whether it is due to an incomplete disinfection of the skin or due to the infections acquired in the ward.

Statistical Analysis

The procured data was entered in Ms Excel and the statistical analysis was done using Statistical Package for Social Sciences (SPSS v.21.0). The data was represented as

graphs and tables. Chi square test was done for statistical analysis of results wherever applicable and statistically significant association was considered when $P \leq 0.05$.

RESULTS

In this study, 44.5 % of the cases had hernias, 12 % had goitre, 11 % of cases had varicose veins.

Surgery done	Group A (Betadine) Number (%)	Group B (Betadine + Chlorhexidine) Number (%)	Total
Excision of fibroadenoma	5 (5 %)	7 (7 %)	12 (6 %)
Excision of ganglion	4 (4 %)	4 (4 %)	8 (4 %)
Excision of lipoma	9 (9 %)	7 (7 %)	16 (8 %)
Hemi thyroidectomy	4 (4 %)	6 (6 %)	10 (5 %)
Hernioplasty	4 (4 %)	7 (7 %)	11 (5 %)
Jaboulay procedure	8 (8 %)	5 (5 %)	13 (6.5 %)
Lichenstein hernioplasty	20 (20 %)	20 (20 %)	40 (20 %)
Mesh repair	18 (18 %)	20 (20 %)	38 (19 %)
Near total thyroidectomy	1 (1 %)	0	1 (0.5 %)
Subtotal thyroidectomy	5 (5 %)	1 (1 %)	6 (3 %)
Total thyroidectomy	10 (10 %)	13 (13 %)	23 (11.5 %)
Trendelenburg + Linton	12 (12 %)	10 (10 %)	22 (11 %)
Total	**100 (100 %)**	**100 (100 %)**	**200 (100 %)**

Table 1. Distribution of Study Participants by Surgery Done and Group

Here, no statistically significant difference was observed among the modalities of surgeries performed in both the groups.

Site of Incision	Group A (Betadine) Number (%)	Group B (Betadine+ Chlorhexidine) Number (%)	Total
Anterior abdominal wall	18 (18 %)	20 (20 %)	38 (19 %)
Anterior aspect of forearm	1 (1 %)	1 (1 %)	2 (1 %)
Back of chest	2 (2 %)	1 (1 %)	3 (1.5 %)
Circum-areolar region	5 (5 %)	7 (7 %)	12 (6 %)
Dorsum of hand	3 (3 %)	3 (3 %)	6 (3 %)
Front of the neck	20 (20 %)	20 (20 %)	40 (20 %)
Lateral abdominal wall	2 (2 %)	5 (5 %)	7 (3.5 %)
Lateral aspect of right leg	2 (2 %)	2 (2 %)	4 (2 %)
Lower anterior abdominal wall	20 (20 %)	20 (20 %)	40 (20 %)
Nape of the neck	3 (3 %)	2 (2 %)	5 (2.5 %)
Scrotum	8 (8 %)	5 (5 %)	13 (6.5 %)
Supraclavicular region	2 (2 %)	2 (2 %)	4 (2 %)
Upper limb	12 (12 %)	10 (10 %)	22 (11 %)
Upper part of thigh	2 (2 %)	2 (2 %)	4 (2 %)
Total	**100 (100 %)**	**100 (100 %)**	**200 (100 %)**

Table 2. Distribution of Study Participants Based on the Site of Incision

Residual bacteria	Group A (Betadine) Number (%)	Group B (Betadine+ Chlorhexidine) Number (%)	X^2 - value p-value
Present	15 (15 %)	4 (4 %)	$X^2 = 7.037$ P = 0.008
Absent	85 (85 %)	96 (96 %)	
Total	**100 (100 %)**	**100 (100 %)**	

Table 3. Comparison Based on the Presence of Residual Bacteria

Here, sterile swab cultures were taken from the site of surgical incision after skin disinfection with respective antiseptic regimen chosen to be applied. It was observed that, a positive culture was obtained in 15 % and 4 % of cases disinfected with betadine and betadine + chlorhexidine respectively and a statistically significant dfference has been observed in both the groups.

Wound Infection	Group A (Betadine) Number (%)	Group B (Betadine + Chlorhexidine) Number (%)	X^2 - value P - value
Yes	15 (15 %)	4 (4 %)	$X^2 = 7.037$ P = 0.008
No	85 (85 %)	96 (96 %)	
Total	**100 (100 %)**	**100 (100 %)**	

Table 4. Comparison of the Proportions of Wound Infections

Here, it was observed that the wound infection was present in 15 % and 4 % of cases disinfected with betadine and betadine + chlorhexidine respectively and the difference was found to have a statistically significant difference.

Organism Identified (Residual Bacteria)	Group A (Betadine) Number (%)	Group B (Betadine + Chlorhexidine) Number (%)	Total Number (%)
Bacillus subtilis	7 (46.7 %)	1 (25 %)	8 (42.1 %)
Staphylococcus aureus	3 (20 %)	1 (25 %)	4 (21 %)
Staphylococcus albus	5 (33.3 %)	2 (50 %)	7 (36.9 %)
Total	**15 (100 %)**	**4 (100 %)**	**19 (100 %)**

Table 5. Distribution Based on the Organism Identified in Culture Report from Site of Incision After Surgical Site Disinfection

In the present study, during follow-up, growth was seen in culture report in 15 % of cases from Group A and 4 % of cases from Group B and the difference was found to be statistically significant.

Organism Identified in Postoperative Wound Infections	Group A (Betadine) Number (%)	Group B (Betadine + Chlorhexidine) Number (%)	Total Number (%)
Bacillus subtilis	7 (46.7 %)	1 (25 %)	8 (42.1 %)
Staphylococcus aureus	3 (20 %)	1 (25 %)	4 (21 %)
Staphylococcus albus	5 (33.3 %)	2 (50 %)	7 (36.9 %)
Total	**15 (100 %)**	**4 (100 %)**	**19 (100 %)**

Table 6. Distribution Based on the Organism Identified in Culture Report During Follow-Up

Wound Infection Grade (Follow Up)	Group A (Betadine) Number (%)	Group B (Betadine + Chlorhexidine) Number (%)	Total Number (%)
Grade 0	85 (85 %)	96 (96 %)	181 (90.5 %)
Grade 1	7 (7 %)	1 (1 %)	8 (4 %)
Grade 1 c	1 (1 %)	0	1 (0.5 %)
Grade 2	0	1 (1 %)	1 (0.5 %)
Grade 3	2 (2 %)	1 (1 %)	3 (1.5 %)
Grade 4	5 (5 %)	1 (1 %)	6 (3 %)
Total	**15 (100 %)**	**4 (100 %)**	**19 (100 %)**

Table 7. Distribution Based on the Grade of Wound Infection During the Period of Follow Up

DISCUSSION

Post-operative wound infection is a considerable problem amounting to increased morbidity and prolonged hospitalization in patients undergoing surgery. Risk factors for the development of postoperative wound infection, related to patients are conditions like malnutrition, diabetes mellitus, immunosuppression, and some related to surgical procedures. Among all, the microbial flora present on the patient's own body is most important source of developing

surgical site infections (SSIs). Wound infection is usually seen in 5 % of patients undergoing abdominal surgery, which is presumably caused by the introduction of organisms into the surgical site from the insufficient asepsis done. Thus, a proper skin disinfection is a key strategy to reduce wound infections in the post-operative period.

Many randomized controlled trials done to study effectiveness of various sorts of anti-septic regimens for pre-operative skin disinfection, found that chlorhexidine in an alcoholic solution was found to be more efficacious in reducing colonisation of microorganisms at the site of incision and subsequent post-operative wound infection, in comparison to asepsis done by povidone iodine. In more further studies it was found that the effect of chlorhexidine is more on gram-positive bacteria, especially on coagulase-negative staphylococci.

Julia L et al. stated that, the preoperative surgical site preparation with a combination of PVP-iodine and chlorhexidine was associated with the lowest rate of microbial colonization in the catheter.[2] Similarly, the present study was carried out aiming to prove that pre-operative disinfection with a combination of povidone iodine and chlorhexidine was superior to povidone iodine alone. This study was conducted among 200 cases who were scheduled to undergo clean elective surgeries. Among 100 patients categorised under Group I, the antiseptic regimen considered was three coatings of povidone iodine alone. Whereas, in Group II of the other 100 patients, two coats of aqueous povidone– iodine IP 5 % w/v followed by single coat of agent containing chlorhexidine gluconate 2.5 % v/v in 70 % propanol.

The efficacy of antiseptic regimen employed was compared by-

1. Evaluating the proportion of cases having colonization at the site of incision after undergoing respective antiseptic regimen.
2. Determining the rate of post-operative wound infections, which will be considered as an indicator for inefficient pre-operative asepsis

Age

When observations of this study were compared to the observations made by Julia L et al. age was found to be an independent factor to show any implications on the study results.

Sex Ratio

This study showed that, the gender of the patient did not show any effect on the surgical site asepsis and this result was found to be in consonance with the findings made by Julia L et al.

Authors	Group I (PVP-Iodine)	Group II (PVP-Iodine + Alcoholic Solution of Chlorohexidine)
Julia L et al.[2]	35.3 %	4.7 %
Glenn et al.[3]	13.8 %	3.3 %
Present study	15.0 %	4.0 %

Table. Various Studies Comparing Colonization Rates of Site of Incision After Disinfection with Respective Antiseptic Regimen

Author	PVP – Iodine (Group I)	PVP Iodine + Chlorhexidine or Chlorhexidine Alone (Group II)
Brown et al.[4]	8.1 %	6.0 %
Darouiche et al.[5]	16.1 %	9.5 %
Ranjeet et al.[6]	15.95 %	9.96 %
Sistla et al.[7]	9.5 %	7 %
Present study	15 %	4 %

Table. Depiction of Difference in Post-Operative Wound Infection Rates in Various Studies

This study result showed, that chlorhexidine 2.5 % v/v in 70 % alcohol is nearly an ideal antiseptic than povidine iodine.

Chlorhexidine was thought to be a better antiseptic due to the following factors:

- Its broader antimicrobial properties.
- Its more rapid onset of action than PI and persistence of activity in the presence of body fluids.
- Its nature of leaving a protective film.
- Lower post-operative wound infection rate.
- Significantly less surgical site bacterial growth rate.

Findings from Other Studies:

Takiji Arata et al. compared the alcoholic solution of povidone iodine to aqueous solution of povidone iodine and concluded that significantly higher reduction factors of local resident bacteria were obtained with povidone iodine ethanol solution than with povidone iodine aqueous solution.[8]

Sebben JE concluded that 20 % of resident flora as beyond the reach of surgical scrubs and antiseptics and goal of antiseptic is to remove the transient and pathogenic microorganisms and reduce resident flora.[9]

Jean Davies et al. stated in their study that alcoholic solutions of chlorhexidine, povidone iodine were more efficacious as compared to aqueous solutions and achieved reduction of colony counts up to 99 %.[10]

Patrick J. Culligan et al. have conducted a similar study and concluded that chlorhexidine gluconate has was far more superior bactericidal than povidone iodine, when used for surgical site aspsis.[11]

Summary

This study was conducted among 200 patients to compare 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, which was conducted in Department of General Surgery, S.V.V.R.R.G.G Hospital, Tirupati.

The patients fitting the inclusion criteria were divided into two groups each consisting of 100 patients. The groups were thus allocated irrespective of age and sex, nature of operation or surgical incision. A detailed history and examination was done beforehand and all the necessary investigations were done to rule out any pre-existing infection or malignancy. Patients with pre-existing infections, malignancies, patients with immune compromised status and those posted for emergency surgeries were excluded from the study.

In the first group (Group I), asepis was done using three coats of aqueous povidone iodine IP 5 % w/v.

In second group (Group II), pre-operative skin preparation was done with two coats of aqueous povidone–iodine IP 5% w/v followed by single coat of agent containing chlorhexidine gluconate 2.5 % v/v in 70 % propanol.

After satisfactory pre-operative surgical site preparation, sterile swabs from the site of incision were taken and sent for culture. Microbial colonization of the swabs thus observed as an indicator of asepsis. In group I, it was found that 15 cases out of 100 had bacterial growth. 5 cases were of *staphylococcus albus*, 7 were of bacillus subtilis (opportunistic pathogens) and 3 cases of *staphylococcus aureus* (pathogenic bacteria) were observed. In Group II, 4 cases out of 100 had bacterial growth (2 cases had *staphylococcus albus*, 1 case had bacillus subtilis (both opportunistic pathogens) and 1 case *staphylococcus aureus* (pathogenic bacteria) was grown.). This showed that regime II was more effective in reducing colonization of site of incision (4 % in Group II as compared to 15 % in group I) in comparison to regimen I, in reducing bacterial load at site of incision which was thought to be a potent cause of post-operative wound infections due to translocation of bacteria at the time of incision.

A post-operative follow-up was continued till the time of suture removal to look for any wound site infections. It was found that post-operative wound infections were considerably seen in those cases who had positive bacterial cultures from the site of surgical incision. Using Southampton scoring system, the level of wound infection was assessed. In cases with grade IV infection, samples of pus were sent for culture and antibiotic sensitivity test. This was done to see if the same strains of organisms were seen in the samples collected, be operative and post-operative wound infections. Thus, regimen II was found to be significantly more effective in reducing the rate of post-operative wound infection.

CONCLUSIONS

The observations made from the present study were in support to say that, the 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 following properties:

1. Broader antimicrobial spectrum, when used in combination.
2. Chlorhexidine leaves a protective film which can not be achieved by using povidine iodine alone as it gets rinsed off easily.
3. Bactericidal activity of poviidine iodine was adversely affected by presence of blood or serum protein, but with the addition of chlorhexidine such dampening of bactericidal activity is not seen.
4. This regimen is non-irritatant to skin and side effects are negligible.
5. This has rapid lethal action against both resident and transient flora, especially on staphylococci.
6. Rate of post-operative wound infections is much lower when compared to povidone iodine alone.

Limitations of the Study

1. Study being conducted among a small sample size was a major limiting factor as the duration of the study was limited to 12 months, and controlled parameters are similar. If the parameters were more diverse, the sample size would be much even smaller, and this would have led to poor results.
2. Being a single centred study, a better application of the results observed can not be generalised. To overcome which a multicentre study can be done encompassing a broader spectrum of the population.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.
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