A STUDY OF COMPARATIVE EVALUATION OF PREOPERATIVE SKIN PREPARATION WITH CHLORHEXIDINE-ALCOHOL VERSUS POVIDONE-IODINE IN PREVENTION OF SURGICAL SITE INFECTIONS

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ABSTRACT

BACKGROUND
Surgical site infections is a dangerous condition posing a heavy burden on the patient and social health system. The use of preoperative skin preparation by effective antiseptic plays an important role in reducing postoperative wound infections. Hence, the present study was undertaken to compare and evaluate the efficacy of 2% chlorhexidine-alcohol versus 5% povidone-iodine in abdominal surgeries for prevention of SSI.

MATERIALS AND METHODS
The present one year randomised controlled trial was conducted in the Department of General Surgery, Government Rajaji Hospital, Madurai, over a period from 2014 to 2015 on 120 patients undergoing elective abdominal surgeries. The patients were divided into two groups by computer randomisation that is Group A (chlorhexidine-alcohol group) and Group B (povidone-iodine group). The surgical wounds were examined for any infections present.

RESULTS
Most of the patients were males in both the groups (73.33% and 61.67% in group A and B, respectively). Half of the patients (50%) in both the groups had chronic appendicitis. The mean duration of surgery in group A was 44.66 ± 5.86 minutes, and in group B, it was 45.00 ± 6.24 minutes. Staphylococcus aureus (1.67% in group A and 10% in group B) was the most common organism isolated after skin preparation. After the application of antiseptic agents, there was reduction of bacterial colonisation in both the groups, but significant reduction was seen in chlorhexidine group. In group A, two patients had superficial SSIs vs. 14 patients in group B (p=0.001). The mean length of hospital stay in group A was significantly less (7.20 ± 1.10 vs. 8.67 ± 3.17).

CONCLUSION
Preoperative skin cleansing with chlorhexidine significantly reduces risk of postoperative SSIs and colonisation of bacteria in clean abdominal surgeries.

KEYWORDS
Antiseptic Skin Preparation, Chlorhexidine-Alcohol, Lower Abdominal Surgeries, Povidone-Iodine, Surgical Site Infection.


BACKGROUND
Despite many advances in the surgical techniques in the past few years, postoperative wound sepsis still remains a major problem. Although, only occasionally a cause of mortality, it is a frequent cause of increased morbidity leading to prolonged hospitalisation of the patient. Surgical site infections occur in approximately 5-6% of patients undergoing major procedures and minor surgeries. 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 exonerate the other. A confusion still prevails regarding the source of wounds sepsis. Hence, there is a further need for systematic probe into the minute details of aetiology of wound infection. Contributing factors to the development of postoperative wound infections related to procedures and patients itself. 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. Shooter¹ (1956) and Blower² (1960) pointed out the source of postoperative wound infection to be operation theatre and wards, respectively, of course, patient himself cannot be excluded from being a source of infection.
Burke³ (1963) found that in 50% of the operations, the strains of staphylococcus aureus isolated were the same as those from patient's nose and hence concluded the patient himself to be a source of infection. Obviously, wound infection in a particular patient maybe 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. Moynihan⁴ (1920) was true when he said, "Our bacteriological experiment maybe 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".

Asepsis- Asepsis maybe defined as the exclusion of bacteria from the field of surgical procedures by the previous sterilisation 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 surgeries should be complemented by use of an antimicrobial agent.

As patients being incapable of complete sterilisation, an appropriate procedure should be there for preoperative preparation of skin. Since one cannot resort, as in case of operator's hand to prolonged scrubbing, soaking in germicides, etc., one should find chemical agents powerful enough practically to sterilise 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 alcohol and 5% povidone-iodine and chlorhexidine and this study is undertaken to compare the efficiency of 2% chlorhexidine-alcohol and 5% povidone-iodine and chlorhexidine-alcohol against bacterial flora on the skin of operation site under conditions those encountered in operating rooms.

OBJECTIVES
• To compare the efficacy of 2% chlorhexidine-alcohol versus 5% povidone-iodine for preoperative skin preparation in preventing surgical site infection in elective clean surgeries.
• To study the incidence of surgical site infection in patient undergoing elective clean surgeries.

To identify the organism causing surgical site infections and to detect the sensitive antibiotic to treat the infection.
• Statistical analysis of the gathered data.

MATERIALS AND METHODS
Study Design: This is a comparative study conducted on 120 patients in two groups.
Settings: Government Rajaji Hospital, Madurai, at Department of General Surgery.
Source of Data- 120 patients (60 in each group) undergoing clean elective.
Surgery with no focus of infection on the body admitted in the Department of General Surgery in Government Rajaji Hospital, Madurai, from 2014 to 2015.

Inclusion Criteria
• Patient older than 18 years.
• Patients undergoing clean elective surgery in the Department of General Surgery.
• Duration of surgery 30 to 90 minutes.

Exclusion Criteria
• Patients undergoing emergency surgery.
• Immuno compromised patients (HIV).
• Patients on long-term steroids.
• Patients with sepsis and having focus of infection somewhere on the body manifested clinically by fever and increased total and differential counts.
• Patients with diabetes mellitus.
• Patients with history of allergy to study agents.

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.

Group A- Antiseptic regimen used for preoperative skin preparation is single coat of 2% chlorhexidine-alcohol, 2% in 70% isopropyl alcohol

Group B- Antiseptic regimen used is three coats of agent containing 5% povidone-iodine.

If infections developed in postoperative period, antibiotic testing was done against following antibiotics-
• Cefotaxime.
• Amoxicillin.
• 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 suture.
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 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.

RESULTS

The present one year randomised controlled trial was conducted in the Department of General Surgery, Madurai Medical College, Madurai, over a period from 2014 to 2015 on 120 patients undergoing abdominal surgeries. The patients were divided into two groups by computer randomisation that is:

- Group A – Chlorhexidine-alcohol group.
- Group B – Povidone-Iodine group.

The data obtained was tabulated on Microsoft excel spreadsheet and analysed by rates, ratios and percentages.

Statistical Analysis

The data collected in the present study is analysed 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≤0.05.

<table>
<thead>
<tr>
<th>Group A (n=60)</th>
<th>Group B (n=60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>No. %</td>
<td>No. %</td>
</tr>
<tr>
<td>Male</td>
<td>44 73.33</td>
</tr>
<tr>
<td>Female</td>
<td>16 26.67</td>
</tr>
<tr>
<td>Total</td>
<td>60 100.00</td>
</tr>
</tbody>
</table>

Table 1. Sex Distribution

\[ x^2 = 1.861, \ p = 0.172 \]

In the present study, most of the patients were males in both the groups (73.33% in group A and 61.67% in group B). The male-to-female ratio in group A was 2.75:1, and in group B, it was 1.60:1 suggesting both the groups were comparable.

<table>
<thead>
<tr>
<th>Age Groups (Year)</th>
<th>Group A (n=60)</th>
<th>Group B (n=60)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Percentage</td>
</tr>
<tr>
<td>&lt;20</td>
<td>6</td>
<td>10.00</td>
</tr>
<tr>
<td>21 to 30</td>
<td>18</td>
<td>30.00</td>
</tr>
<tr>
<td>31 to 40</td>
<td>10</td>
<td>16.67</td>
</tr>
<tr>
<td>41 to 50</td>
<td>9</td>
<td>15.00</td>
</tr>
<tr>
<td>51 to 60</td>
<td>8</td>
<td>13.33</td>
</tr>
<tr>
<td>&gt;61</td>
<td>9</td>
<td>15.00</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.00</td>
</tr>
</tbody>
</table>

\[ x^2 = 2.954, \ p = 0.707 \]

Table 2. Age Distribution

In this study, the most common age group among patients in group A was 21 to 30 years (30%), and in group B, it was 31 to 40 years (23.33%). The mean age in group A was 39.88 ± 18.53 years with range being 11 to 92 years, and in group B, mean age was 39.15 ± 16.39 years with range being 10 to 77 years suggesting that in both the groups the age was comparable.

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Group A (n=60)</th>
<th>Group B (n=60)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Percentage</td>
</tr>
<tr>
<td>Cholelithiasis</td>
<td>30</td>
<td>50.00</td>
</tr>
<tr>
<td>Inguinal hernia</td>
<td>29</td>
<td>48.33</td>
</tr>
<tr>
<td>Umbilical hernia</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Epigastric hernia</td>
<td>1</td>
<td>1.67</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.00</td>
</tr>
</tbody>
</table>

\[ x^2 = 4.043, \ p = 0.132 \]

Table 3. Diagnosis
In the present study, 50% of the patients in both the groups had chronic appendicitis. Inguinal hernia was diagnosed in 48.33% of patients in group A and 40% in group B and umbilical hernia was diagnosed in 10% of patients in group B. The epigastric hernia was diagnosed in 1.67% in group A.

In this study, each 50% of patients in both the groups underwent meshplasty and open cholecystectomy.

In this study, the duration of surgery was between 30 to 45 minutes in 70% of patients in group A and 68.33% in group B. In the remaining patients (30% in group A; 31.67% in group B) had duration of surgery between 46 to 60 minutes. The mean duration of surgery in group A was 44.66 ± 5.86 minutes, and in group B, it was 45.00 ± 6.24 minutes.

In the present study, on postoperative day three, five and seven inspection findings revealed significantly high rate of infection in group B (23.33%) compared to group A (3.33%) (p=0.001).

<table>
<thead>
<tr>
<th>Duration (Minutes)</th>
<th>Group A (n=60)</th>
<th>Group B (n=60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>Percentage</td>
<td>Number</td>
</tr>
<tr>
<td>30 to 45</td>
<td>42 70.00</td>
<td>41 66.67</td>
</tr>
<tr>
<td>46 to 60</td>
<td>18 30.00</td>
<td>19 33.33</td>
</tr>
<tr>
<td>Total</td>
<td>60 100.00</td>
<td>60 100.00</td>
</tr>
</tbody>
</table>

\[ \chi^2=0.390 \]  
\( p=0.843 \)
In this study, among the patients who had SSIs, the microbiological examination revealed E. coli as the organism (3.33%) present in chlorhexidine group. In povidone-iodine group, 16.66% of the patients had infection due to Staph aureus followed by E. coli 6.6%.

Table 8. Surgical Site Infections

<table>
<thead>
<tr>
<th>Infection</th>
<th>Group A (n=60)</th>
<th>Group B (n=60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>2</td>
<td>14</td>
</tr>
<tr>
<td>Negative</td>
<td>58</td>
<td>46</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>60</td>
</tr>
</tbody>
</table>

χ²=10.385 \( p=0.001 \)

Table 9. Type of Surgical Site Infections

In the present study in group A, 3.33% patients had superficial SSIs compared to 23.33% in group B and this difference was statistically significant (\( p=0.001 \)).

Table 10. Hospital stay

In this study, majority (96.67%) of the patients in group A had hospital stay upto seven days and 3.33% patients required hospital stay between 8 to 14 days. In group B, 76.67% patients had hospital stay upto seven days followed by 13.33% of patients between 8 to 14 days and 10% of patients more than 14 days. This difference was statistically significant (\( p=0.001 \)). The mean length of hospital stay in group A was 7.20 ± 1.10 days, whereas in group B, it was 8.67 ± 3.17 days.
DISCUSSION

Although considerable progress has been made in understanding the cause and prevention of surgical site infections during the past 100 years, postoperative wound infections (incisional and deep) remain a leading cause of infections, especially in developing countries.

Most SSIs are potentially preventable as their occurrence usually depends on contamination of an incision during surgery with the patient’s own endogenous organisms. Later contamination with exogenous organisms is less common. In both cases, however, the establishment of an infection relates to the amount and pathogenicity of the microorganisms present and the adequacy of patients host response in turn related to their comorbidity.

Among surgical patients, SSIs are the most common nosocomial infection accounting for about a third of all such infections. In most studies, about two thirds of these can be classified as superficial incisional, while the remaining involve either organs or spaces entered during surgery or deep incisional SSIs. On average, having an SSI, increases a patient’s hospital stay by 7-10 days with organ/space and deep incisional SSIs accounting for the longest stays and highest costs.

In the present study, most of the patients were males in both the groups (66.60% in group A and 70% in group B). The male-to-female ratio in group A was 2.75:1, and in group B, it was 1.60:1. The most common age group among patients in group A was 31 to 30 years (30%), and in group B, it was 51 to 60 years (23.33%). The mean age in group A was 50.02 ± 12.02 years, and in group B, it was 46.51 ± 14.61 years. These findings suggest both the groups were comparable in demographic characteristics.

A similar study was done to compare the efficacy of the reduction of bacterial colonisation and surgical wound infection using chlorhexidine and povidone-iodine antiseptic skin preparations in general surgery patients. The patients were divided into two groups. Group 1 included 250 patients (122 females, 138 males) was the povidone-iodine group and group 2 (250 patients, 91 females and 159 males) was the chlorhexidine group. The mean age in group A was 56.2 years (20-79) in group 1 and 50.5 years (18-78) in group 2. There was no significant statistical difference of the age between the two groups (p-value = 0.27).

In the present study, half of the patients (50%) in both the groups had cholelithiasis, whereas inguinal hernia was diagnosed in 48.33% of patients in group A and 40% in group B. Cases of umbilical hernia were diagnosed in 10% of patients in group B only and epigastric hernia was diagnosed in 1.7% in group A only. Based on the diagnosis, half of the patients in both the groups (50%) underwent meshplasty and laparoscopic cholecystectomy.

Overall, the duration of surgery ranged between 30 to 60 minutes and it was between 30 to 45 minutes in 70% of patients in group A and 68.30% in group B. However, 30% in group A and 31.70% in group B had duration of surgery between 46 to 60 minutes. The mean duration of surgery in group A was 44.66 ± 5.86 minutes, and in group B, it was 45.00 ± 6.24 minutes.

A similar study had reported the average operation time as 1.43 hours (40 mins. to 3 hours) in povidone-iodine and 1.45 hours (45 mins. to 3 hours) in chlorhexidine group (p=0.93).

In the present study, risk factors for development of surgical site infection except preoperative skin preparation using two different antiseptic agents was controlled. There was no significant statistical difference of the risk factors between the two groups of the sample patients such as age, operative time, wound classification or underlying host factors. Surgeries were performed in both the groups under the same standard guidelines.

Most of the early surgical complications are septic, which include abscess and wound infection. Wound infection is common, but is nearly always confined to the subcutaneous tissues and responds promptly to wound drainage, which is accomplished by reopening the skin incision. Wound infection predisposes the patient to wound dehiscence.

After skin preparation, Staphylococcus aureus in group A and 10% group B) was the commonest organism isolated. After the application of antiseptic agents, there was reduction of bacterial colonisation in both the groups, but significant reduction was seen in chlorhexidine group (p <.001).

In the present study, on postoperative day three, five and seven inspection findings revealed significantly high rate of infection in group B (23.33% versus 3.33%; p=0.001). In the present study in group A, two patients of inguinal hernia had superficial SSIs compared to 14 patients in group B. (seven patients=inguinal hernia, seven patients=chronic appendicitis) and this difference was statistically significant (p=0.001). In the patients having SSIs, the wound was laid open and secondary suturing was undertaken subsequently once the wound was clean.

These findings were similar to the results of a study done in Thailand. The study reported as wound infection decreased from 3.2% to 2% after chlorhexidine skin preparation and the organisms found in the culture specimen included Streptococcus epidermidis, Staphylococcus aureus, Streptococcus species and Enterococcus species. The bacterial colonisations reduced significantly after skin preparations in all types of organisms. The authors also suggested other disadvantages of using povidone-iodine are hypersensitivity and colour staining. The study recommended, chlorhexidine antiseptic should be the first consideration for preoperative skin preparation.

Another randomised controlled trial was conducted on patients undergoing clean-contaminated surgery in six hospitals to preoperative skin preparation with either chlorhexidine-alcohol scrub or povidone-iodine scrub and paint. The primary outcome was any surgical site infection within 30 days after surgery. Secondary outcomes included individual types of surgical site infections. A total of 849 subjects (409 in the chlorhexidine-alcohol group and 440 in the povidone-iodine group) qualified for the intention to treat analysis. The overall rate of surgical site infection was significantly lower in the chlorhexidine-alcohol group than in the povidone-iodine group (9.5% vs. 16.1%; p=0.004;
Chlorhexidine-alcohol was significantly more protective than povidone-iodine against both superficial incisional infections (4.2% vs. 8.6%, p=0.008) and deep incisional infections (1% vs. 3%, p=0.05), but not against organ-space infections (4.4% vs. 4.5%). The study concluded that preoperative cleansing of the patient’s skin with chlorhexidine-alcohol is superior to cleansing with povidone-iodine for preventing surgical site infection after clean-contaminated surgery.

In a randomised study, the application of chlorhexidine-alcohol reduced the risk of surgical site infection by 41% as compared with the most common practice in the United States of using aqueous povidone-iodine.

In this study, among the patients with who has SSIs, the microbiological examination revealed E. coli as the organism (3.33%) present in chlorhexidine-iodine group. In povidone-iodine group (16.6%) of the patients had infection due to Staph aureus followed by E. coli (6.6%).

In the present study, majority (96.70%) of the patients in group A had duration of hospital stay upto seven days and 3.30% patients required hospital stay between 8 to 14 days. In group B, 76.70% patients had hospital stay upto seven days followed by 13.30% of patients between 8 to 14 days and 10% of patients more than 14 days suggesting significantly prolonged length of hospital stay in group B. (p=0.001). The mean length of hospital stay in group A was 7.20 ± 1.10 days, whereas in group B, it was 8.67 ± 3.17 days and this difference was statistically significant. Though the patients who had no SSIs were fit for discharge on third or fourth postoperative day, they insisted to stay in hospital till suture removal, which was undertaken on postoperative day seven as they were coming from far off places and remote villages.

Overall, the present study showed that preoperative skin cleansing with chlorhexidine-alcohol significantly reduced the rate of postoperative SSIs. However, the choice of preoperative surgical site antisepsis remains controversial and surgeons have long debated the choice of skin preparation.

The limitations of the present study were smaller sample size and risk factors for SSIs in abdominal surgeries such as age, obesity, associated comorbid conditions such as diabetes mellitus, hypertension and immunocompromised patients were not taken into consideration. Hence, further studies with larger sample considering these risk factors would explore outcomes of SSIs using skin antiseptics with chlorhexidine-alcohol.

**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.

A regimen combining alcoholic solution of 2% chlorhexidine with 70% isopropyl alcohol 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. 2% chlorhexidine with 70% isopropyl alcohol 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.

**Summary**

The present study was conducted on 120 patients to evaluate comparatively the efficacy 2% chlorhexidine in 70% isopropyl alcohol and 5% povidone-iodine for preoperative skin preparation in clean elective surgeries in Department of General Surgery, Government Rajaji Hospital, Madurai.

Patients were randomly divided into two groups of 60 patients each and patient 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, immunocompromised 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 A), antiseptic regimen used for preoperative skin preparation is containing 2% chlorhexidine gluconate in 70% isopropyl alcohol.

In second group (Group B), antiseptic regimen used is containing 5% povidone-iodine. Postoperatively, patients were followed up till the time of suture removal to look for any wound infections. It was seen that postoperative wound infections developed mostly in those cases who had bacteria cultured from site of incision after skin disinfection. Wound infection was graded by Southampton scoring system. In grade IV infection (pus present), pus culture was taken and antibiotic sensitivity test was done and it showed same strain of bacteria, which had colonised site of incision.

**CONCLUSION**

The results from the present study show that preoperative skin preparation with chlorhexidine gluconate 2% in 70% isopropyl alcohol vs. 5% povidone-iodine.

1. It has a broader antimicrobial spectrum than either of them alone.
2. Addition of chlorhexidine-alcohol 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-alcohol, the bactericidal activity is not altered.
4. This regimen is non-irritating to skin and side effects of adding chlorhexidine-alcohol 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-alcohol as compared to povidone-iodine alone.
6. The rate of postoperative 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 topical skin preparation in clean elective surgeries. Since, the superiority of this regimen was proved in reducing incision site colonisation and postoperative surgical wound infection, it is prudent to use this regimen in clean surgical procedures.

REFERENCES