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Comparison of the Efficacy of Chlorhexidine Gluconate versus Povidone Iodine as Preoperative Skin Preparation for the Prevention of Surgical SiteInfections

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Objectives: To compare the efficacy of chlorhexidine–alcohol and povidone–iodine as preoperative antiseptic skin preparation for prevention of surgical site infection (SSI)
Materials and methods: A total of 311 eligible Patient who underwentSurgery were recruited in the study after fulfilling all the eligibility and exclusion criteria. Patients were randomized into two groups (153 in chlorhexidine–alcohol group and 158 in povidone–iodine group) by a computer-generated randomization table. Patients were followed for a period of 30 days in postoperative period to monitor for SSI.
Results: The rate of SSI in the chlorhexidine–alcohol group is 5.4% and that of the povidone–iodine group is 8.6%.
E. coli, K. pneumoniae, and Acinetobacter baumannii were the most common organisms isolated. E. coli was found in9.5% of the total SSI cases.
Conclusions: The study found that the patients who received chlorhexidine–alcohol as skin antiseptic had less chance of developing SSI than those who received povidone–iodine; however, it did not reach a statistical significance.

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I. Introduction

Surgical site infections (SSIs) are one of the mostimportant causes of healthcare-associated infections (HCAIs). Infections that occur in the wound created by an invasive surgical procedure are generally referred as surgical site infections (SSIs). SSIs most commonly occur 5 to 6 days postoperatively but may develop sooner or later than that. Approximately 80-90% of all postoperative infection occurs within 30 days after the operative procedure.[1]

Survelliance of Surgical site infection Surveillance of SSI provides data that can both inform and influence practice to minimise the riskof SSI, as well as communicate more clearly therisks of infection to patients.[2] Surveillance wasfirst recognised as an important tool in reducingrates of infection in the 1980s.[3]

Since some SSIs may take many days to develop, evidence of infection may not become apparent until after the patient has been discharged from hospital. Surveillance focused on detecting SSI during the inpatient stay is thus likely to underestimate the true rate of SSI, a problem that is exacerbated by the increasing trend towards shorter lengths of postoperative hospital stay and day surgery.[4] Therefore, systems that enable casesof SSI to be identified after discharge from hospital enhance the value of surveillance. However, there are a number of practical difficulties in reliably identifying SSI in community settings and methods that systematically and accurately identify SSI are required if valid comparisons of rates are to be made.[5]

SSIs are associated with considerable morbidity and it has been reported that over one-third of postoperative deaths are related, at least in part, to SSI[6]. However, it is important to recognize that SSIs can range from a relatively trivial wound discharge with no other complications to a life- threatening condition. Other clinical outcomes of SSIs include poor scars that are cosmetically unacceptable, such as those that are spreading, hypertrophic or keloid, persistent pain and itching, restriction of movement particularly when over joints and a significant impact on emotional wellbeing.[7]

Postsurgical infection leads to increased length of postoperative hospital stay, drastically escalated expense, higher rates of hospital readmission, and jeopardized health outcomes. There are numerous risk factors contributing to the development of SSIs related to patient, environment and the treatment being provided. Most important source of developing SSIs is patient's own microbial flora. Strict antisepsis of surgical site and optimization of pre-operative antisepsis may decrease the incidence of SSIs. The prevention of an SSI is easier, more economical and more feasible than treating an established SSI. As SSIs are usually polymicrobial in nature, prophylactic antibiotics cover is of no use; moreover there is risk of emergence of antibiotic resistance. Preoperative skin preparation of the surgical site using appropriate antiseptic products is

one of the important interventions to prevent SSIs.[8]

Any chemical agent for microbial reduction of the skin ideally kills all skin organisms, is nontoxic and hypoallergenic, does not result in significant systemic resorption, has residual activity, and is safe for repetitive use as Antiseptic. Antisepticsare split into 2 major types: iodine/iodophor & chlorhexidine.

Iodine-based surgical antiseptics (PovidoneIodine-PI) are effective against a wide range ofgram-positive and -negative organisms (includingmethicillin-resistant *Staphylococcus aureus* [MRSA]) as well as tubercle bacillus, fungi andviruses. Systemic absorption of iodine can occurand in rare cases has led to iodine toxicosis anddeath; care should thus be taken when using this preparation in especially high-risk populations such as severe burn victims and new-borns. Chlorhexidine Gluconate (CHG) is commerciallyavailable in aqueous or alcohol formulations, andhas broad activity against gram-positive and gram- negative bacteria, anaerobes, yeasts, and some lipid-enveloped viruses, although fungal coverageis reduced when compared with iodophor.[9] Aqueous-based iodophors such as povidone- iodine (PI) contain iodine complexed with a solubilizing agent that allows for the release of free iodine when in solution. Iodine acts in an antiseptic fashion by destroying microbial proteins and DNA A second product, aqueous-based chlorhex- idine gluconate (CHG), works by disrupting bacterial cell membranes. CHG has more sustained antimicrobial activity and is more resistant to neutralization by blood products than the iodophors.[10,11]

The aim of this study to compare efficacy of Povidone Iodine and Chlorhexidine Gluconate with help of sterile saline swab culture (in terms of colony type & morphology and colonization rates) of SSIs

II. Material And Method

All patients undergoing elective surgeries with clean & clean contaminated surgical wound within study duration (six months) in Dept. of Surgery, JLNMCH BHAGALPUR, fulfilling eligibility criteria were included in the study. **Inclusion Criteria**

1. Patients undergoing elective surgery with clean & clean contaminated surgical wound 2. Patients of all ages, sex & socio economic status. 3. Patients not having any focus of infection at the time of inclusion in study

Exclusion Criteria

1. Allergy to any type of skin preparations 2. Infection at or adjacent to surgery site 3. If patient is unable to stay in hospital for required study duration 4. Emergency surgery 5. Immunocompromised patients and patients on steroids 6. Patients with septicemia and systemic illness 7. Malignancies or undergoing chemo & radiotherapy. 8. Contaminated & dirty surgeries in which viscous was opened were excluded from THEMSTUDY.

Procedure of Data Collection

After admission, informed written consent was obtained from patients fulfilling the inclusion criteria. A short case history was recorded and thorough physical examination was conducted on each patient to establish proper diagnosis and to know about the presence of the risk factors regarding surgical site infection. Only very essential investigations were performed urgently for taking correct decision about the management. Strict aseptic precautions were followed duringthe operation. Meticulous techniques were practiced as far as possible. The operation procedure and related preoperative factors wereobserved directly and recorded in the data collection sheet instantly.

During the postoperative period all the patientswas closely monitored everyday up to the discharge of the patient from the hospital. If any symptom or sign of infection appear during this period then details were recorded in the form of site involved, type of SSI, presence of discharge if any, rise in local temperature, induration if any and its size. If any collection of pus identified it was drained out and sent for culture and sensitivity test. Proper antibiotic were given toevery patient both pre- operative and post- operative periods. Appropriate management was given to each of the patients of surgical site infection. Antibiotic were changed where necessary after getting the report of culture and sensitivity test. Postoperative events were recorded in the data sheet during every day follow up till discharge of patient. After completing the collection of data was compiled in a systematic way.

Patients were randomly divided in Group I(Povidone-iodine) & Group II (Chlorhexidine) each group having equal number of patients undergoing elective clean & clean-contaminated surgeries. The pre operative skin preparation is done with povidone iodine IP 5% w/v marketed as Betadine in group-I & chlorhexidine gluconate 5%v/v in aqueous base in group II. In both the groupssterile saline swab culture were taken from the incision site pre-painting as well as post-painting. In cases where culture is positive antibioticsensitivity is done along with morphological characteristics and differences in colonization rates were determined as a measure of efficacy of antiseptic regimen.

III. Results

In present study observed that maximum number of patients 36 (43.90%) were observed in 31 to 50 years of age in group I and maximum number of patients 50 (42.37%) were observed in 31-50 years of age in group II. Mean age of subjects was

41.18 years (table 1) and the most common surgery was cholecystectomy (31.70%), (37.28%) followed by inguinal hernioplasty (21.95%), (16.10%) in group I and group II respectively (table 2).

In this study observed that the maximum number of patients65 (79.26%) in group I and 117 (99.16%) patients in group II were stayed 5-10 days followed by 17(20.73%) patients stayed more than 10 days in group I and only 1 (0.84%) cases stayed less than 5 days after surgery in group II (table 3).

In this study showing bacterial growth prepaintingin povidone iodine group & chlorhexidine group as 81.70% & 99.15% respectively, which is statistically insignificant in chi square test 17.07& P-value was 0.461 (table 4) and bacterial growth in postpainting the group I & group II as 4.8% & 1.7% respectively, which is statistically significant in chi square test 10.37 & P-value was

0.043. No growth of organism shown in 78 (95.12%), 116 (98.30%) patients in group I and group II respectively (table 5). The objective symptoms of SSIs, where as all symptoms present in 3 patients in group I and only 1 patients have allsymptoms in group II.

IV. Discussion

The pre operative skin preparation is done with povidone iodine IP 5% w/v marketed as Betadine in group-I & chlorhexidine gluconate 5% v/v in aqueous base in group II. In both the groups sterile saline swab culture were taken from the incision site pre-painting as well as post-painting. In cases where culture is positive antibiotic sensitivity is done along with morphological characteristics anddifferences in colonization rates were determined as a measure of efficacy of antiseptic regimen. It was noticed from this study that the Mean of age in Group I and Group II was 40.68 years and

41.25 years respectively whereas the respectivevalues of Patrick JC, Kari K, Miles M and Blackwell L et al[12] study was 53.4 years, which is higher than the present study but in both the studies, age was not the factor to have any implications on results of the study as all patients had good immune status, had Comorbid conditions and were planned for clean electivesurgery.

There are numerous risk factors contributing to the development of SSIs related to patient, environment and the treatment being provided. Nutrition of the patient play important role in wound healing and recovery of the patient. Most important source of developing SSIs is patient's own microbial flora. Strict antisepsis of surgical site and optimization of pre-operative antisepsis may decrease the incidence of SSIs. The prevention of an SSI is easier, more economical and more feasible than treating an established SSI. In present study most common surgery was cholecystectomy (31.70%) followed by inguinal hernia (21.95%) in group I and in group II, mostlysurgery was cholecystectomy (37.28%) followed by inguinal hernioplasty (16.10%) and appendi- cectomy (15.25%). There is now increasing evidence that a higher proportion of surgical siteinfections may be caused by bacteria introduced into deeper skin structures at the time of incision. Proper skin disinfection might be one of the most important factor 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 foundchlorhexidine in aqueous solution more effective in reducing incision site colonization and subsequent wound infection when compared to povidone iodine.[13] Most SSIs are superficial, but even so they contribute greatly to the morbidity and mortality associated with surgery[14,15]. Estimating the cost of SSIs has proved to be difficult but many studies agree that additional bed occupancy is the most significant factor In this study maximum number of patients 182(91%) stayed 5-10 days after surgery in bothgroup followed by 17 (20.73%) patients stayedmore than 10 days in group I and only 1(0.84%)patient stayed less than 5 days after surgery ingroup II. Similar result (8±2 day post operatively)was found in a study by Matin ASMR (1981).[16] Haddad V and Macon WLN (1980)[17] showed in their studies that theoccurrence of woundinfection was on an average of 6.8 post-operative days which was also similar to that of ours (5.33-6.33).The time of appearance of wound infectionin majority of the cases (6 to10 days) indicatesthat the source of infection was not from the operation theatre, rather from patients'surroundings like, patients' ward, attendance etc. Our result showing bacterial growth in preoperative period in povidone iodine group 81.70% while in chlorhexidine group 99.15% which is statistically insignificant P-0.461. Surgical site infection in recent times is a significant cause in the morbidity of the patientleading to delay in the hospital stay. Proper skindisinfection however plays a vital rol inreduction or surgical site infections.

The microbiological report during the time ofpostoperative period, showing bacterial growth in PI group 4.8% while in CHG group 1.7% which is statistically significant (P-0.043).

Connell et al in 1964[18] demonstrated povidone- iodine as a highly effective degerming agent which had a rapid lethal effect and was noninjurious to both normal skin and/or open wounds. Hugo and Longworth

(1964)[19] observed that chlorhexidine is rapidly absorbed by bacterial cell.
A study by Ranjeet et al (2013)[20] showed that surgical site infection in chlorhexidine group was 9.96% & that of povidone-iodine was 15.95%. Darouiche et al (2010)[21] found chlorhexidine group 9.5% is better than povidone-iodine group 16.1%.
Ingli et al (2010)[22] done a meta-analysis of variousRCT's comparing chlorhexidine with iodine for preoperative skin antisepsis revealed that chlorhexidine was associated with significant fewer surgical site infections along with reduction in the cost of antisepsis.
Grabsch EA et al (2004)[23], suggested excellentbactericidal efficacy of chlorhexidine over povidone iodine. T.R. Brown et al (1984)[24]concluded that wound infection rates were lesswith chlorhexidine spray technique (6%) as compared to povidone iodine scrub or liquid (8.1%).
Paocharoen V et al (2009)[25] concluded that bacterial colonization and postoperative surgical wound infection were significantly reduced in the chlorhexidine group than in povidone iodinegroup.
In this study showed the objective symptoms maximum occur in group I (3.6%) as compare to group II (1.6%). These rates were calculated after excluding ward acquired infections.
The study done by Brown et al. (1984)[24] compared post-operative wound infection rates after using either povidone iodine or aqueous solution of chlorhexidine and it showed that post- operative wound infection rates were less in chlorhexidine group (Group I) (6.0%) than in povidone iodine group (Group II) . Chlorhexidine can also be used in most parts of body but needs careful application near eyes and ears as it can be toxic to middle ear on repeated exposures and irritating to eyes when comes in direct contact with the eye.
The results of the present study shows chlorhexidine gluconate 5% v/v in aqueous solution is nearly an ideal antiseptic due to:

- Broader antimicrobial spectrum than povidone iodine.
- It leaves a protective film where as povidone-iodine leaves no film.
- Rate of post-operative wound infections are much lower than povidone-iodine.
- Bacterial colonization is also significantly less than povidone-iodine.
- It has more rapid onset of action than PI and persistent activity in the presence of body fluids.

V. Conclusion

Surgical site infections determine the final outcome of an operation apart from the morbidity and mortality they cause. Though surgical care is very important to prevent wound infection, butsome pre and post operative steps can reduce post operative wound infections also. Hence it can be safely concluded that chlorhexidine aquaous should be followed in preoperative skin preparation in clean & clean contaminated electivesurgeries. Since the efficacy of this regimen was proved in reduction in incision site colonization and postoperative wound infection, it is prudent touse this regimen in contaminated and emergency surgeries.

chlorhexidine aquaous was associated with reduced risk of postoperative SSI in clean and clean-contaminated surgery when compared to Povidone Iodine. Further studies should evaluate the effectiveness of CHG versus PI in reducingSSI across contaminated surgery.

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