A Comparative Study between Efficacies of Povidone-Iodine (10%) Solution Versus Alcohol Based Solution Hygienium as Skin Antiseptic

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Abstract
Background and Objectives: Skin asepsis is a crucial measure for preventing infectious complications of central neuraxial block, i.e. meningitis. The aim of this study was to comparative evaluation of effectiveness of some conventional surgical antiseptic solutions and to identify the most effective one.

Material and Methods: Effectiveness of Hygienium was compared with Povidone-iodine (10% Betadine) as skin antiseptic prior to administration of central neuraxial block. Two rounds of sampling were conducted, one before application of antiseptic solution and the second after skin preparation with antiseptic solution. Colonies were counted after 48 hours of aerobic incubation at 37°C. All counts were conducted twice. Positive cultures were identified and their frequencies were compared. Data were summarized using descriptive statistical methods. Comparison of counts between groups was performed.

Results: Out of 131 samples, positive culture in Hygienium as compared to Povidone-iodine (4.6% v 6.2%) is statistically not significant showing equal efficacy. Staph. aureus, Staph epidermidis, Streptococcus, Diptheroids are most common organisms isolated in both the groups for testing the antiseptic efficacy.

Conclusions: Povidone-iodine and Hygienium are equally effective as antiseptic. Hygienium can preferably used in situations where lesser time is required for preparation of skin prior to administration of central neuraxial block and when patient positioning is difficult.

Keywords: Povidone-iodine, Alcohol-based Solutions, Hygienium, Skin asepsis,

Introduction
Skin asepsis is one of the major concern in central neuraxial block to prevent the most serious complication i.e, meningitis[¹]. The incidence of infectious complications with epidural catheters is very low. However, when it occurs, it can have disastrous implications for patients[²]. The most appropriate and safe antiseptic solution for skin asepsis in central neuraxial block remains controversial till now. The ideal antiseptic agent should be effective against a wide range of microorganisms, exert a long term effect and
should have minimum toxic effect on skin. There are conflicting reports regarding preferred agent for cutaneous antisepsis but among the commonly used solutions are 10% aqueous solution of Povidone-iodine, 2% chlorhexidene in alcohol, isopropyl alcohol. Some studies shown that povidone iodine and chlorohexidine may cause chemical meningitis at a dose of as less as 0.1 ml of solution into CSF. Isopropyl alcohol due to less drying time maintains asepsis, but does not have residual effect as needed in placing epidural catheter. The Hygenium contains isopropyl alcohol, 1-propanol and mecteronium ethylsulfate that provides skin asepsis and residual effect due to mecteronium ethylsulfate. Our primary aim therefore was to compare the efficacy of these agents for cutaneous antisepsis. This study was done to compare the efficacy of povidone iodine with Hygenium as skin antiseptics in OT setting.

Materials & Methods;
This observational study was undertaken in Ortho OT VIMSAR in time period from September 2017 to November 2017. Basing on previous study by Kadam R et al[5], the sample size calculated to be 61 in each group considering power of 80 and alfa error of 5 %. Considering drop outs in the study sample size was taken as 70 in each group. 140 patients posted for surgery under spinal anaesthesia were enrolled into this study. Four participants having local skin disease were excluded. There was also no absolute or relative contra indications to spinal anaesthesia. The patients were randomly allocated into two groups of 68 each i.e. Group P for povidone iodine and Group H for Hygenium. Out of these, 3 patients in group P & 2 patients in group H were discarded due to culture contamination. Hence total patients in Group P & Group H were 65 & 66 respectively as shown in the flow diagram below.

The first sample was taken using sterile swab sticks from 1 square inch area near the site of spinal anaesthesia before the application of study-antiseptic solution. The second sample was taken with sterile swab from same area from center to periphery in a circular fashion after skin preparation. A contact time of 3 minutes in group P and 30 sec in group H was allowed after skin preparation. The swabs were sealed inside the labelled test tubes and sent to dept of microbiology for culture. Swabs were inoculated on sterile agar plates and incubated for 48 hours at 37°C. A colony count was done at the end of 48 hours and results were documented. The microbiologist conducting the culture of the specimen was unaware of the study antiseptic solution.
Results
The base line characteristics are comparable in this study as shown in the table 1.

Table 1. Demographic profiles of both group

| Group Characteristics | Male : female | Mean of Age | S.D of Age | Mean of Height | S.D of Height |
|-----------------------|---------------|-------------|------------|---------------|---------------|
| Group-P               | 34:31         | 34.18       | 10.06      | 63.21         | 3.049         |
| Group-H               | 37:29         | 35.00       | 8.733      | 63.54         | 2.851         |

The mean age & height of Group P & Group H are shown in figure 1.

In this study, the skin swabs taken before application of antiseptics showed growth of skin commensals and some of other organisms like Staph aureus, Staph epidermidis, Streptococcus, Diptheroids as shown in the table 2 & Figure 2.

Table 2 Skin commensals of both groups before application of antiseptics

| Micro organisms     | Group P |          | Group H |          |
|---------------------|---------|----------|---------|----------|
|                     | Number  | Percentage| Number  | Percentage|
| Staph aureus        | 37      | 56.9     | 41      | 62.1     |
| Staph epidemidis    | 31      | 47.6     | 28      | 42.4     |
| Streptococcus       | 21      | 32.3     | 18      | 27.3     |
| Diptheroids         | 8       | 12.3     | 11      | 16.6     |
| Total               | 65      | 100      | 66      | 100      |

Figure 1

Figure 2 Skin commensals of both groups
After 48 hr incubation, number of growth of bacterial flora that was found in either of the groups are shown in table 3 & Figure 3.

**Table 3 growth of bacterial flora after application of antiseptics**

| Culture growth | Group P | Group H |
|----------------|---------|---------|
| Positive cultures | 4 (6.2%) | 3 (4.6%)|
| Negative cultures | 61 (93.8%) | 63 (95.4%)|
| Total          | 65 (100%) | 66 (100%)|

**Figure 3** growth of bacterial flora after application of antiseptics

In this study, test statistic is chi square distribution with 1 degrees of freedom at 5% level of significance, for two tailed test the critical value is 3.841 which is much higher than the computed value. Therefore, we cannot reject the null hypothesis at 5% level of significance.

**Discussion**

Povidone iodine is the most commonly used skin antiseptic for years. Povidone-iodine exerts its antiseptic properties in two ways, first it substitutes the covalently bound hydrogen groups such as -OH, -NH, -SH, or -CH groups. Second, povidone is an iodophor and it reacts with the oxygen containing functional groups. Free iodine determines the bactericidal activity; total iodine determines the ability to kill bacteria. Iodine solutions have rapid, broad-spectrum antimicrobial activity against bacteria, viruses, and fungi. It quickly penetrates micro-organisms and attacks nucleotides, fatty acids and thiol groups. It inhibits protein synthesis by oxidizing the thiol group. But it has the drawback that it has longer contact period of about 2-3 minutes and some studies showed that it may cause chemical meningitis on intrathecal injection. This longer duration of contact period may not be beneficial in case of orthopedic surgeries like hip fracture, fracture neck of femur, femur fracture etc in which there is difficulty in patient positioning and also it is painful for the patient to remain in that position for long time. Hygenium on the other hand takes lesser contact time and is equally effective. So it can be used in those patients safely. It can also be used as skin antiseptics before intravenous cannulation, intramuscular injection and central neuraxial blockade. Hygenium contains 2-propanolol, 1-propanolol and macetronium ethyl sulphate as ingredients. The new CDC guideline on hand hygiene has indicated that the efficacy of alcohols is superior to many other active agents such as chlorhexidine gluconate or povidone iodine, also on the resident hand flora. Alcohol without the addition of non-volatile agents such as quaternary ammonium...
compounds or chlorohexidine gluconate are regarded to have no sustained efficacy\textsuperscript{12}. Alcohol-based hand rubs have been shown to have a better antimicrobial efficacy on both the transient and resident hand flora\textsuperscript{11,13}. It has been shown earlier that ethanol at a concentration of 60\% is far less effective against the resident hand flora than ethanol at 80\% or more\textsuperscript{14,15}. Kulkarni A et al observed no differences between 2\% chlorhexidine and 10\% povidone-iodine for skin disinfection in regard to costs, efficacy or side-effects\textsuperscript{8}. Kareem SAMA et al observed alcohol-based hand rub significantly reduces the bacterial colony counts compared with standard surgical scrub\textsuperscript{7}. Most patients’ swabs led to bacterial growth before but not after application of either antiseptic solution, indicating equal efficacy. Limitations of our study that we have not taken anaerobic microorganism culture into consideration.

**Conclusion:**

Povidone iodine and Hygenium are equally effective as antiseptic. Both the antiseptics spare spores. Both can be used as an alternative to each other. Hygenium can preferably used in situations where lesser time is required for preparation of skin prior to administration of central neuraxial block and when patient positioning is difficult.

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