

COMPARISON OF PERSIST™ ANTISEPTIC ACTIVITY UNDER OPSITE™ IV3000 OR GAUZE DRESSINGS

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Abstract: Persist™, an antiseptic solution, was evaluated to determine recolonization under either OpSite™ IV3000 (polyurethane dressing) or standard gauze dressings at 24, 48, and 72 hours. There were no significant differences in the bacterial recolonization rates between the dressings with either antiseptic treatment. The Persist™ solution has been shown to be efficacious with a short application time and dries quickly which may result in better compliance with catheter site preparation protocols.

INTRODUCTION

One of the major sources of catheter-related infections is from the bacteria present on the skin of the subject. The INTRAVENOUS NURSING STANDARDS OF PRACTICE (1990) developed by the Intravenous Nursing Society (INS) addresses this issue of catheter-site antisepsis. These guidelines recommend that a catheter insertion site be aseptically cleansed with an antimicrobial solution prior to cannula insertion. Antimicrobial solutions that may be used include tincture of iodine (1% -2%), iodophor, isopropyl alcohol (IPA), or chlorhexidine (CHG). The solution is to be applied in a circular motion starting at the intended puncture site, working outward, and allowed to air dry completely. When 70% IPA is used, it is to be applied with friction for a minimum of 30 seconds or until the applicator is visually clean. A common practice for preparation of IV sites is that they are cleansed with IPA followed by a povidone-iodine (iodophor) (PVP-I) solution.

In response to clinician and patient needs, a site-preparation solution was formulated that (1) was expected to be as effective as currently marketed catheter-site antiseptic solutions, (2) dried rapidly, and (3) could be done in a single step. This product is called Persist™. It is similar to PVP-I which is an aqueous solution of polyvinylpyrrolidone polymer complexed with iodine. However, Persist™ is dissolved in 70% ethanol as the carrier.

Previous studies have demonstrated that the antiseptic activity of Persist™ is similar to a regimen of PVP-I and IPA, either agent alone, or chlorhexidine for up to 120 hours. The Persist™ solution, which has been shown to be effective with a 30-second application time, dries quickly which may result in better compliance with catheter-site preparation protocols.

The study reported here is a continuation of our evaluation of Persist™. The objective of this study was to compare the antiseptic activity of Persist™ to PVP-I under OpSite™ IV3000 and gauze dressings. The activity was demonstrated by the failure to recover large numbers of viable bacteria from treated skin surfaces. Gauze dressings are traditionally changed every 48 hours. This study tested the treated and untreated skin at 24, 48, and 72 hours. Two untreated skin controls have been included since it has been postulated that polyurethane dressings remove a proportion of the normal skin flora that is present on untreated skin. Also, gauze may allow more rapid sublimation of the iodine from the skin surface and/or inactivation of iodine by reaction with skin proteins. This would result in a more rapid loss of the residual iodine activity under gauze.

MATERIALS AND METHODS

The antiseptic activities of Persist™ and PVP-I under OpSite™ IV3000 and gauze dressings were compared at 24, 48, and 72 hour intervals. The Persist™ solution was applied for 30 seconds. The positive control PVP-I was applied for one minute. All solutions were allowed to air dry before covering with the appropriate dressing.

SUBJECTS

After obtaining Institutional Review Board approval, subjects were recruited. Subjects were given instructions, both verbal and written, about all procedures to be followed during their participation in the test. Subjects were given test kits which contained soap, shampoo, and antiperspirant to be used throughout the study. Written informed consent was obtained from each subject. All subjects were questioned about past reactions to antiseptics and disinfectants (particularly iodine) and to dressing materials. If any symptoms of a sensitivity or reaction to the treatment became apparent at any time during the study period, the treatment of that volunteer would have been discontinued.

The sample size was based on data from Maibach and Aly, (1981), Noble (1981), and Bruch (1983). Human subjects have been shown to have a large range in the number of recoverable bacteria on the skin of their arms. One-hundred aerobic bacteria per cm² was chosen to be the minimum acceptable count for this evaluation based on several studies cited in these publications. Subjects were screened twice prior to participating in this study to determine that they had an average of 10² or more recoverable bacteria per cm² of skin surface on their arms.

The first two weeks of the study were designated as the Pre-Test Period. During this time subjects were to refrain from the use of soaps, shampoos, *etc.* which contained antibacterial agents. This interval was designed to stabilize the bacterial skin flora. During the second week of the study, bacterial counts were obtained two times from all subjects. Counts were not taken on consecutive days. Samples were collected following the procedure outlined under Microbiological Methods. The Treatment Period began when the skin sites were aseptically cleansed with the antiseptic solutions and ended when the last site was sampled.

TEST AND CONTROL ANTISEPTIC MATERIALS

The test material was Persist™, a patented formulation of povidone-iodine in an alcohol carrier, prepackaged with 3-inch swabstick applicators, one per package. The test material was supplied by Becton Dickinson.

The positive control antiseptic solution PVP-I (NDC 052380-1201-4) was obtained from Aplicare (Branford, CT). It was supplied as single-swabstick applicators packaged with the antiseptic solution.

PROCEDURES

Sampling Method

Treatment sites were designated on each arm of the subject. Positive control sites and test areas were assigned according to a randomization scheme. Each site represented a different treatment exposure for a time interval of 24, 48, or 72 hours.

To attempt to duplicate actual “as used” conditions, the Persist™ solution was applied by scrubbing the area in a circular motion for 30 seconds. The positive control site was treated by scrubbing with PVP-I swabstick in a circular motion for 1 minute. All sites were allowed to dry before covering with either the OpSite™ IV3000 or a standard 2” x 2” gauze dressing. At the time specified by the randomization scheme, each site was sampled using the scrub-cup technique described below.

Microbiological Methods

Quantitative cultures were obtained by the detergent scrub technique of Williamson and Kligman (1965). Briefly, a sterile scrubbing cup (5.07 cm², internal area) was held firmly to the skin. Three (3) ml of wash solution (Trypticase Soy Broth, BBL, Cockeysville, MD) containing the neutralizer (0.1% sodium thiosulfate and 1% Tween 80) were pipetted in and the area scrubbed with moderated pressure for two minutes using a sterile Teflon policeman. The wash fluid was aspirated, replaced with 3 ml of fresh solution, and the scrub repeated. The two washes were pooled, and aliquots were plated in triplicate by a spread-plate method on Trypticase Soy Agar (containing 1.0% Tween-80 and 0.1% sodium thiosulfate). After 72 ± 4 hours aerobic incubation at 35° ± 2°C, colonies were counted and viable cells in the original sample calculated by standard methods (Richardson, 1985). The average number of microorganisms recovered per square centimeter of skin was determined and reported. The adequacy and effectiveness of the neutralizer system was also tested to demonstrate that there was no effect on the growth of the microorganisms.

EVALUATIONS

The data were analyzed in the following manner. Since the combinations of treatment/dressing changed from day to day, the analysis of this data followed a two-pronged approach. First, only the 24-hour data was analyzed with all 6 combinations. Second, all three times were analyzed together using the 4 subsetted combinations.

A two-way analysis of variance (ANOVA) was used to evaluate the results of the first 24-hour data. The two factors were subject and antimicrobial/dressing method. Subject was considered a random factor while antimicrobial/dressing was considered a fixed factor.

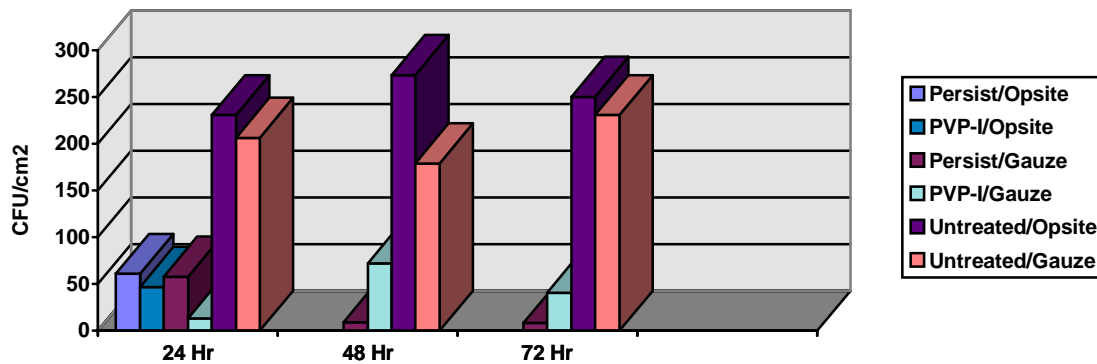
A three-way analysis of variance (ANOVA) was used to evaluate the results over time. The three factors were subject, time, and antimicrobial/dressing method. Subject was considered a random factor while the other two were considered as fixed factors. A square root transformation of the data was necessary in order to satisfy the assumption of a normally distributed and homogeneous error term. Since the three replicate cultures described above were not true replications of the treatment combination, they were averaged and the analysis performed on the average CFU. This resulted in one observation per treatment combination per subject. The three-factor interaction was assumed to be zero and was used as the random error term in the analysis. The analysis was done at the 0.05 level of significance.

The Persist™ product was considered to be as effective as a standard catheter site antiseptic agent if the number of bacteria recovered from the Persist™ treatment sites was not higher than the levels obtained from the positive control site.

RESULTS

The results of the control and test site samplings are represented in Figure 1. As can be seen in this figure, the Persist™/Opsite™ IV3000 sites had a bacterial recovery similar to the PVP-I/Opsite™ IV3000 sites. Also, the Persist™/gauze sites had a bacterial recovery similar to the PVP-I/gauze sites. In this study there was no significant difference between the treatment/dressing groups ($p=0.4454$). The differences that were seen were between the treatment/dressing groups and the untreated control sites. The 72-hour time period had no effect on the recolonization rate in this study.

Figure 1. Mean bacterial counts (CFU/cm² of skin) from the test sites of 8 subjects. Each subject received all treatments/dressings for the 24-hour interval; treatment/gauze with untreated/dressings was evaluated at 48 and 72 hours. The Persist™/dressing and PVP-I/dressing groups were not significantly different from each other.



DISCUSSION

Within the limits of this study, both the Persist™ and PVP-I, catheter site-preparation solutions had the same level of antisepsis under either an OpSite™ IV3000 or a standard gauze dressing.

This study was conducted with a limited number of subjects (8). These individuals were not restricted with regard to their activity. In some instances, the dressing began to peel away from the site and had to be secured with additional tape. Some of those sites may have been contaminated from surrounding skin or the environment.

This study was conducted with healthy subjects with no known immune deficiencies or underlying diseases. Furthermore, the sites to be sampled were required to be intact skin. A patient who requires vascular access for therapy is not always completely healthy, and the presence of a catheter precludes an intact skin site. Recognizing these factors, further study should be conducted with hospitalized patients to determine whether the actual in-use performance of the Persist™ is as we found it to be in healthy subjects.

As stated in earlier studies, a controlled clinical trial with hospitalized patients would be the most desirable method of testing Persist™. Dr. Dennis Maki compared colonization and catheter sepsis under gauze, polyurethane, and iodophor-transparent dressings (Maki, *et. al.*, 1987). The cutaneous colonization under all the dressings was low and comparable. Catheter-related infection (≥ 15 CFU) did not differ significantly with the dressing comparison.

In summary, this study has demonstrated that the comparison of Persist™ catheter-site preparation solution under OpSite™ IV3000 or gauze dressings has antibacterial activity which is similar to PVP-I solution under OpSite™ IV3000 or standard gauze dressings. In contrast to aqueous PVP-I solutions, the Persist™ solution dries quickly and has a short (30-second) application time. That property may increase compliance with catheter insertion site-preparation protocols and, in turn, may result in better patient care.

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