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Comparison of Chlorhexidine Mechanical Scrub and Alcohol-Based Paints for Foot Antisepsis

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ABSTRACT

Introduction: Previous studies have demonstrated the difficulty in eliminating bacteria from surgical sites on the foot. Chlorhexidine, previously shown to be effective for surgical preparation of the foot, is now available in an alcohol-based preparation solution. However, mechanical cleaning of the web spaces has been shown to improve the effectiveness of surgical preparation agents. This study compares two chlorhexidine products—one is applied with a mechanical scrub, and the other is an applicator containing alcohol-based paint.
Methods: Thirty-four patients in a dialysis center were enrolled. Subjects' feet were randomized. One side was prepared with 2% chlorhexidine solution, and the other side with alcohol-based 2% chlorhexidine paint in a disposable applicator. The subjects' feet were covered for 1 hour. Culture swabs sampled the hallux nail fold and the first web space.
Results: Bacteria grew on culture specimens obtained from 2 of the subjects prepared with chlorhexidine preparation solution. No bacteria grew on specimens obtained from the alcohol-based chlorhexidine applicator. There was no significant difference (p=0.25) between the alcohol-based chlorhexidine paint or the mechanical preparation with chlorhexidine solution.
Discussion: Mechanical cleaning of the foot is not necessary for the use of chlorhexidine in preparing a foot for surgery. An applicator containing chlorhexidine and alcohol is an effective technique for preparing the foot for surgery.
Level of Evidence: II; Therapeutic prospective study.
Keywords: Surgical skin preparation; Chlorhexidine; Surgical site infection.

INTRODUCTION

The high infection rate associated with foot surgery has spawned a number of studies examining the most effective techniques for eliminating bacteria prior to surgery. Comparisons of different preparation solutions including providone iodine, chlorhexidine, para-chloro-meta-xylenol, triclosan, hexachlorophene, normal propyl alcohol, ethanol, and isopropyl alcohol have demonstrated chlorhexidine gluconate solution to be the single most effective preparation solution [1,2]. The technique for preparation has also been examined. It was shown that mechanical cleaning between the toes enhanced the effectiveness of the surgical

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preparation [3]. Recently, chlorhexidine has become available in a disposable applicator in an alcohol base. This material has been examined and found to be more effective than other alcohol-based paint surgical preparations (4). The purpose of this study was to compare the mechanical scrub technique utilizing chlorhexidine with the no-scrub chlorhexidine alcohol paint-based technique to verify noninferiority of the paint-based technique.

MATERIALS & METHODS

Many of the previous studies examining surgical preparation of the foot have been accomplished in the surgical theater introducing a number of uncontrolled variables, such as the length of the procedure, the use of preoperative antibiotics, and breaks in sterile technique. This study was planned to eliminate these variables. Patients undergoing dialysis were selected as a study population. These individuals are constantly exposed to the health care system and the problematic organisms associated with health care settings. A high proportion of these individuals are diabetic with an associated increased preoperative infection risk. We theorized these individuals would pose a worst case challenge for the surgical preparation of the foot.

Prior to enrolling patients, approval was obtained from both the university institutional review board and the dialysis center review board. A power analysis was performed to determine the number of subjects. A population of 35 patients was determined to have a 90% chance of identifying differences previously observed between the proposed preparation methods with significance set to 5% (p=0.05) [3].

Patients undergoing dialysis were approached to participate in the study. No compensation was offered for participation. Exclusion criteria included active infection, wounds or ulcers on either foot, recent exposure to antibiotics, previous lower extremity amputations, and less than 1 hour remaining in the dialysis treatment. Risks and benefits were explained to the subjects. Informed consent was obtained from the participants.

Each subject serves as both control and test to provide a direct comparison in techniques. The materials used are approved by the Food and Drug Administration for surgical skin preparation. A computer-generated random sequence determined the foot to be prepared with chlorhexidine mechanical scrub and the foot to be prepared by chlorhexidine alcohol paint applicator. The chlorhexidine preparation solution (Dyna-Hex 2, Chlorhexidine gluconate 2%; Xttrium Laboratories; Chicago, IL) was used with a 4 minute soft sponge scrub with attention to cleaning between toes with a back-and-forth motion. The foot was blotted dry with a sterile towel and covered with an impervious sterile stockinet. The chlorhexidine alcohol applicator preparation solution (ChloraPrep™, Chlorhexidine gluconate 2% w/v & isopropyl alcohol 70% v/v 26 ml Medi-Flex; Leawood, KS) was used to apply a single coat of solution to the foot. No effort was made to scrub between the toes or the nail fold, but care was taken to insure these surfaces were coated with the chlorhexidine solution. The foot was allowed to dry and then placed into the impervious sterile stockinet. The feet were left covered with the stockinet for 1 hour. After 1 hour, the feet were uncovered. Cotton swabs were used to sample the nail fold of the hallux

and the first web space. The subject's feet were cleaned with 70% isopropyl alcohol to remove residual agent.

The cultural swabs were immediately transferred to the laboratory where each swab was inoculated to a sheep blood agar, chocolate agar, and anaerobic blood agar plate. All culture media was supplied by Becton Dickinson and Company (Sparks, MD). The aerobic culture plates were incubated in 5% CO_2 atmosphere at 35 degrees. A blood agar plate containing *Staphylococcus aureus* was used for the growth control. The plates were read for growth at 24 and 48 hours. A final report was issued following the 48 hour reading. The anaerobic plates were incubated in an anaerobic chamber at 35 degrees. The chamber contained anaerobic condition indicator and plate inoculated with *Bacteroides fragilus* as the growth control. These plates were read at 48 and 96 hours. A final report was issued following the last reading. All plates were read by a laboratory technologist (ASCP). If any growth was detected, the culture was considered positive and was given a grading of rare, few, moderate, or heavy growth. Temperature of the incubators and refrigerator was monitored daily.

RESULTS

A total of 34 subjects were enrolled for a total of 68 feet. No subject withdrew from the study. There were no adverse reactions during the study. The study population included 24 (71%) diabetes and 3 subjects (95) with a history of previous foot infection or ulcer requiring medical treatment. The subjects with a history of previous foot infections were all diabetics.

There were 2 positive cultures in the chlorhexidine preparation solution arm. Both cultures were positive for *Staphylococcus epidermidis*. There were no positive cultures in the alcohol chlorhexidine applicator arm. Both subjects with positive cultures after preparing the foot were diabetics. None of the patients with a history of previous infections had a positive culture after surgical preparation of the foot.

There was 1 patient who was noted to have extremely poor hygiene. While scrubbing the foot with the chlorhexidine preparation solution, a large amount of loose material was removed from between the toes. No effort was made to remove all material with the chlorhexidine applicator while preparing the contralateral foot. Care was taken to insure that all surfaces in the interdigital area were coated. When the samples were collected, there was debris visible on the culture swab in the applicator-prepared foot but not on the swab in the mechanically scrubbed foot. There was no growth in either sample.

The results were evaluated by Fischer exact test. A p-value to 0.05 was considered statistically significant. Calculations were made utilizing OpenEpi [5]. There was no statistically significant difference ($p=0.25$) in the rate of positive cultures between the 2 preparation methods. The very small positive culture results (6%) for the chlorhexidine was on the low end of previous studies.

DISCUSSION

There have been a number of studies examining the relative advantages of surgical preparation techniques for the foot. Chlorhexidine has consistently been shown to be

the most effective agent for eliminating skin flora on the foot [1,4-9]. Mechanical preparation has been shown to reduce the recolonization of skin flora, but has also been thought to allow bacteria in deeper skin structures to migrate to the surface [3,10]. This study compared 2 surgical preparation methods utilizing chlorhexidine. The surgical scrub technique utilized a soap solution containing chlorhexidine with the mechanical action of scrubbing between the toes. The applicator technique used an alcohol-based paint containing the same concentration of chlorhexidine in a single-use applicator.

This study was designed to eliminate many of the variables associated with surgery. The preparation was done by a single individual, eliminating variable technique by surgical staff. There was no cross-contamination due to breaks in sterile technique during the course of the surgical procedure. The subjects were not on antibiotics. The time from preparation to culture was carefully controlled. There was no blood or other fluids to remove or inactivate the preparation agents. The feet were matched pairs with no host or exposure differences. The sampling technique was identical in all patients. The control offered by being outside the operating theater is also the study's primary weakness, since the subjects were not in actual surgical situations.

In setting up this study, we initially were concerned that the results of the surgical preparation solutions would be confounded by contamination from the environment of the dialysis center. The subjects were in street attire. No surgical gowns or masks were utilized during the study. We expected the short exposure period, the time the foot was not covered by the stockinet, would limit the contamination from the surrounding environment. The low culture-positive results would seem to indicate that contamination from the environment was not an issue.

Many previous studies examining chlorhexidine in foot surgery reported higher positive-culture rates. Ostrander reported 30% growth in patients prepared with the chlorhexidine applicator [4]. In that study, the samples were taken immediately after the patient had been draped for surgery. Bibbo reported 38% growth immediately after a chlorhexidine scrub followed by alcohol [6]. The early use of the alcohol would have removed the chlorhexidine. The longer exposure of chlorhexidine on the subject's feet may have allowed the material sufficient time to eliminate the bacteria despite its rapid (20 seconds) effectiveness [11].

Other studies have shown similar results. Brooks reported a 20.8% culture-positive rate without mechanical cleaning between the toes and a 7.7% rate when the web spaces were scrubbed [3]. That study used a protocol of providone-iodine as a first scrub and chlorhexidine gluconate 0.5% in 70% methylated spirit. The samples were taken after surgery. The length of surgery was not specified. Their results with scrub very closely match ours (6%) with a similar mechanical cleaning of the web space. The higher results (30%) without scrubbing despite a similar chlorhexidine and alcohol paint may be related to lower concentration of chlorhexidine in their study. Goucher reported a 5% positive growth with a chlorhexidine surgical scrub [1]. The preparation method in Goucher's study matched the technique in Bibbo's article [6]. The difference was Goucher sampled at the end of the surgical case and the swab was moistened in sterile saline. Surgical time ranged from 13 to 138 minutes. The large discrepancy in findings is surprising

given the similar techniques between Goucher and Bibbo [1,6]. There have been issues with wet sampling swabs [9]. Goucher, however, cleaned the foot with alcohol reducing the likelihood of an inhibiting agent on the culture swabs. Both Brooks and Goucher's results for a chlorhexidine scrub indicate that our results are not inconsistent outliers.

We had intended to determine if diabetes made it more difficult to eradicate skin bacteria. While both subjects with positive cultures after preparation were diabetic, the low number of positive cultures prevents us from drawing any conclusions. No subject with a history of foot infection or ulcer in the past had positive cultures. Again, the low number of positive cultures makes this information interesting but posesses insufficient power to allow any definitive conclusions.

The purpose of this study was to determine if the elimination of the mechanical part of the surgical preparation hampered the elimination of bacteria from sites on the foot. Brooks and Lilly speculated that the scrubbing action might indeed be detrimental due to the damage to the epithelium and exposure of bacteria in the deeper skin layers [3,10]. The mechanical action of shaving the surgical sites has been shown to cause microabrasions and raise the surgical site infection rates [12]. However, Brooks' study showed that the mechanical action reduced the bacterial recolonization of the foot during surgery. We observed a higher but not significant positive culture rate in feet prepared with mechanical scrubbing of the web space. The results of this study indicate that the alcohol-based chlorhexidine applicator is as effective as the mechanical scrub with chlorhexidine preparation solution for elimination of bacteria from the surface of the foot based on cultures obtained 1 hour after preparation.

The true effectiveness of a surgical preparation would require a carefully randomized controlled study. As was demonstrated by the numbers in this case, a large number of subjects would be required to achieve the necessary power. This would require a multicenter study. Sampling studies, such as this report, serve as an approximation to clinical outcomes research.

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