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Novel water-based antiseptic lotion demonstrates rapid, broad-spectrum kill compared with alcohol antiseptic

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Summary A novel alcohol-based antiseptic and a novel water-based antiseptic lotion, both with a synergistic combination of antimicrobial ingredients containing 0.2% benzethonium chloride, were evaluated using the standard time-kill method against 25 FDA-specified challenge microorganisms. The purpose of the testing was to determine whether a non-alcohol product could have equivalent rapid and broad-spectrum kill to a traditional alcohol sanitizer.

Both the alcohol- and water-based products showed rapid and broad-spectrum antimicrobial activity. The average 15-s kill was 99.999% of the challenge organism for the alcohol-based antiseptic and 99.971% for the water-based antiseptic. The alcohol-based product demonstrated 100% of peak efficacy (60 s) within the first 15 s, whereas the water-based product showed 99.97%. The novel alcohol-based antiseptic reduced concentrations of 100% of organisms by 99.999%, whereas the water-based antiseptic lotion showed the same reduction for 96% of organisms.

A novel water-based antiseptic product demonstrated equivalent rapid, broad-spectrum antimicrobial activity to an alcohol-based sanitizer and provided additional benefits of reduced irritation, persistent effect, and greater efficacy against common viruses. The combination of rapid, broad-spectrum immediate kill and persistent efficacy against pathogens may have significant clinical benefit in limiting the spread of disease.

Introduction

Alcohol-based hand sanitizers have become the industry standard for waterless hand antisepsis. Products with greater than 60% alcohol are

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currently the only sanitizers recommended for use in hospitals by the CDC [1]. The benefit of alcohol in this concentration is the rapid kill of a broad spectrum of bacteria, including gram-positive and gram-negative bacteria.

However, there are significant intrinsic limitations and drawbacks to the use of alcohol-based sanitizers. Studies have shown that using alcohol-based sanitizers in hospitals is equivalent to handwashing alone but does not result in the hoped-for reduction in hospital-acquired infections (HAI) [2,3], which currently afflict 1 in 20 hospitalized patients and kill nearly 90,000 Americans each year [4]. The most important limitation of alcohol-based sanitizers is the drying effect on the hands, which can reduce hand hygiene compliance. Additional limitations include the lack of persistent activity against pathogens and a relative ineffectiveness against many viruses.

Alcohol-based products dry the hands with repeated use, often leaving the skin of healthcare workers cracked and painful. Multiple studies have demonstrated that even trained healthcare workers follow hand hygiene protocols only 40—50% of the time, in part because of the drying nature of alcohol-based products [5]. Benzethonium chloride (BZT) has been shown to increase moisture levels in the skin with repeated use, whereas every other antimicrobial agent tested was shown to dry the skin [5]. In another dermal irritation study, subjects used a product with 0.2% BZT 100 times daily for five days without reporting any skin irritation [6].

This failure to comply with hand hygiene protocols is clinically relevant because alcohol-based products are only effective until they evaporate, typically approximately 15 s. After this time, hands may become immediately recontaminated if they come in contact with tainted surfaces, as there is no persistent activity. Failures in hand hygiene compliance allows microorganisms to be transmitted to patients and staff.

Finally, alcohol-based sanitizers are largely ineffective against non-enveloped viruses [7], which are a significant cause of disease in healthcare settings and in homes [8]. Non-enveloped viruses include the Norovirus (leading cause of acute gastroenteritis or the ''stomach flu''), rhinoviruses (common colds), rotavirus (severe diarrhea, especially in children), adenoviruses (tonsillitis and conjunctivitis), and Hepatitis A, among others. Studies have shown that 0.2% BZT, as found in the water-based antiseptic lotion evaluated in this study, effectively eliminates more than 99% of HIV, Herpes, and Influenzae viruses on contact [6].

The relative ineffectiveness of alcohol against these viruses has major clinical significance. One of the most studied viruses in clinical settings is Norovirus. In a study using the fingerpads of human volunteers, use of an alcohol-based sanitizer was found to be less effective than rinsing with water alone against Norovirus, reducing its concentration only by 0.14—0.34 log [9]. In a survey of nursing homes, researchers found that facilities that relied on alcohol-based products instead of handwashing were more than six times as likely to have a Norovirus outbreak [10]. Cruise ships, another closed environment where Norovirus is a prevalent pathogen, have averaged 16 outbreaks a year, despite the widespread use of alcohol-based sanitizers [11].

The clinical benefit of a persistent non-alcohol sanitizer has been evaluated in elementary school settings. When students were given access to an alcohol-based product, illness-related absenteeism was decreased by 19% in one study and unaffected in a second [12,13]. In contrast, a quaternary ammonium compound product with persistence, in the same class as BZT, was demonstrated to reduce illness absenteeism by 42% [14].

The purpose of this research is to investigate the rapid and broad-spectrum efficacy of a novel line of alcohol- and water-based antiseptic products containing BZT that seek to address the primary limitations of traditional alcohol-based products. The products tested were an alcohol-based antiseptic (ethanol, 76% (v/v)) and a water-based antiseptic lotion (BZT, 0.2%). Both products have been demonstrated to have persistent activity against gram-positive and gram-negative microorganisms, showing a reduction of at least 97% against transient *Staphylococcus aureus* and *Escherichia coli* 1 h post-application in in vitro testing and reductions of approximately 90% in the same in vitro model 4 h post-application [15]. Both of the antiseptics were also tested using the fingerpad method against the standard Norovirus surrogate, showing a 3.5 log reduction (99.97%) on contact [16].

A water-based, 0.2% BZT antiseptic lotion addresses many of the clinical issues raised by alcohol-based sanitizers. Persistent antimicrobial activity can help prevent recontamination of hands, reduced irritation may increase hand hygiene compliance, and efficacy against common viruses may prevent cross-contamination of viral infections.

This study used an In Vitro Time-Kill protocol to evaluate the test products when challenged with 25 different microorganism species (Microbiologics Inc., St. Cloud, MN) as described in the FDA-Tentative Final Monograph (FDA-TFM) [17]. By evaluating an alcohol-based and a water-based product using the same test and time points, this