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Standardized Antimicrobial Efficacy Testing of Wound Antimicrobials is required to Accurately Simulate Efficacy in Humans

Richard Streips*

Department of Medicine and Microbiology, Texas Tech University Health Sciences Center, Lubbock, USA

Introduction

Standardized Antimicrobial Efficacy Testing of Wound Antimicrobials Is Required to Accurately Simulate Efficacy in Humans Current standards does not sufficiently recognise the impact of the wound microenvironment on antimicrobial agent efficacy. To address this, solutions containing octenidine/phenoxyethanol, polyhexanide, povidone-iodine and sodiumhypochloride acid were subjected to standard-based or modified peptide-based challenges and compared to a simulated clinical reference containing human acute or chronic wound exudate. A quantitative suspension method was used to compare antimicrobial efficacy against S. aureus and P. aeruginosa. Bland-Altman analysis was used to investigate method agreement. Depending on the class and concentration of agent and challenge, different substances and challenges produced disparate results. Highly concentrated antiseptics maintained high efficacy in the face of complex challenges, whereas chlorine-based irrigation solutions had a significantly reduced antimicrobial effect. The composition of the challenge substance was found to be more important than pure concentration. Antimicrobial irrigation solutions and local antiseptics play an important role in the treatment of infection, colonisation and biofilm burden in acute and chronic wounds.

Description

The advancement of modern antimicrobial agents in wound management has helped to reduce the overall occurrence and severity of infectious wound complications. With biofilm burdening approximately of chronic wounds and postoperative wound infection rates still ranging up to 30% depending on type of surgery and location best informed and ideally evidence-based local treatment is critical. For clinicians to provide the best local antimicrobial treatment, antiseptic agents' efficacy dynamics, risk-benefit profiles and potential confounding factors must be investigated. These baseline data promote informed decisions and the use of antimicrobial agents in the appropriate indications. As a result, national and international In European countries, the standard has become the de facto standard. However, the standard has several flaws that have prompted recent debates about its feasibility for comprehensive and sufficient baseline testing in agents, specifically for the indication as a wound antimicrobial. First, the standard was not created with wounds in mind, but rather with intact skin antisepsis and the efficacy of antiseptic surgical hand disinfection in mind. Furthermore, within different test settings are possible, resulting in diverging results of a single tested substance and classifying it as more or less antimicrobial effective. Furthermore, relevant wound-specific challenges such as biofilm formation, local compromise of regenerative cells in a chronic wound and interference with the substance's efficacy are not addressed [1-3].

This results in incoherent reports and unclear efficacy profiles for antimicrobial agents intended for wound irrigation or antisepsis, as well as inaccurate translation into subsequent evidence-building steps for clinical recommendations. Furthermore, it raises the question of which test conditions best reflect the clinical setting of a challenging wound micro-environment, as well as the relevant demand for close-to-reality test scenarios and challenge substances. To answer this question, various potential simulated test settings, challenge substances and conditions must be considered. Previously, some studies addressed this by investigating the feasibility of several potential challenge substances (including bovine albumin and sheep erythrocytes), which led to the current standards Human material, on the other hand, has only recently been used as a challenge substance and comparator. Clinicians rely on the efficacy profiles of antimicrobial substances, solutions and dressings obtained as part of the product approval process for the indicated use as skin and wound antiseptics in everyday clinical practise. However, there is no universal standard for evaluating the antimicrobial product category "wound irrigation solutions and topical antiseptics." As a result, for antimicrobial efficacy evaluation and product approval in Europe, manufacturers and researchers primarily rely on This standard is intended for the use of chemical disinfectants and antiseptics on surfaces or intact skin (products for surgical and/or hand disinfection and/or washing). As a result, the standards' test conditions are not intended to reflect the clinical use of substances in acute or chronic wounds, nor in wound cavities [4].

Overall, these findings suggest that modified peptide-based challenge conditions represent and reflect the physiological interaction and efficacy of wound irrigation solutions better than standard challenge conditions. As a result, this modified peptide challenge could be defined as a prescribed baseline challenge condition in a future revised specific set of standards tailored to the group "antimicrobial wound irrigation solutions and antiseptics." Naturally, the addition of peptides in standardised challenge procedures does not reflect the complex interactions and challenges within the wound-microenvironment. Nonetheless, it represents a simplified approach that presents superior standards in reflecting and approximating reality when compared to the current established standards, as demonstrated by the degree of agreement with the comparison standard reflected To summarise, the more closely a test method for evaluating efficacy profiles is adapted to the subsequent field of application, the more reliable a statement about its efficacy in practise can be made. The current established standards for antimicrobial wound solutions do not adequately meet these criteria for all categories of antimicrobial irrigation solutions and antiseptics. As demonstrated here, current challenge conditions in standards, which are intended to simulate, significantly underestimate or overestimate the efficacy of a whole class of wound antimicrobials when compared to a human wound exudate reference standard. As a result, it is necessary to create new standards for wound specific antimicrobial irrigation solutions and antiseptics or to develop and implement adapted standardised test conditions in accredited laboratories [5].

***Address for Correspondence:** Richard Streips, Department of Medicine and Microbiology, Texas Tech University Health Sciences Center, Lubbock, USA, E-mail: richardstrips554@edu.in*

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Conclusion

As a result, relevant "close to reality" wound micro-environmental influences and interactions, as well as specific considerations regarding active agents in substances, should be considered. As a first step, the broad inclusion of the performed protein/peptide modification in the modified peptide-challenge into standardised testing should be considered, as it demonstrated significantly better agreement with results obtained under simulated physiological wound conditions This would allow for the testing of a substance's or solution's antimicrobial potential in a more realistic artificial wound micro-environment.

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