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Randomised comparison of two skin preparation methods in foot and ankle surgery

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ABSTRACT

Background: Foot and ankle surgery has an increased incidence of post-operative surgical site infections. The aim of this study was to examine the efficacy and efficiency of an alternative method of surgical site preparation for foot and ankle surgery.
Method: Fifty-one volunteers were recruited for this study which compared standard gauze painting using 2% chlorhexidine with 70% alcohol to immersion of the foot and ankle in a non-sterile bag filled with 60 mL of the same solution and rubbing all skin surfaces (bag immersion method). Each method was applied to different feet of each volunteer in a randomised order. Commercially available impression agar slides were used to measure bacteria colony-forming-unit (CFU) counts from four areas of each foot after allowing the preparation to dry. Outcomes included CFU count and preparation time.
Result: There was no difference between the methods in terms of CFU count (0 total CFU vs. 1). Preparation time was significantly shorter for the bag immersion method (63.98 s vs. 67.98 s). Two-side 90% confidence intervals (2.03–6.00) for the difference in means of preparation time demonstrated equivalence using a margin of ±20%.
Conclusions: The bag immersion method is a valid alternative, equivalent in preparation timing and the elimination of transient skin flora when using 2% Chlorhexidine with 70% alcohol.

1. Introduction

Surgical site infections (SSIs) following an invasive surgical procedure can cause significant morbidity and mortality along with substantial economic costs [1,2]. The financial burden of SSIs, whilst mainly attributed to the extended length of stay in hospital [3], is associated with loss of individual functionality and productivity, further adding to the hardship associated with SSIs. In Australia, SSIs are associated with an estimated economic cost of $53 million AUD per year, with over 21,000 cases annually [3].

Orthopaedic surgeries of the foot and ankle have been shown to be associated with higher infection rate than other areas of the body, internationally reported to vary between 0.5 and 6.5% [2,4,5]. Many factors affect the incidence of SSIs associated with foot and ankle surgery. These include the morphology of the foot, the fact that it is often enclosed in a moist and warm environment, and its resident organisms. All play a role in the infection rates as reported by previous studies [1,4,6,7]. Many studies have evaluated the impact of skin preparation solutions and techniques [7–9] on the flora of the foot, and several of these have demonstrated the difficulty of completely eliminating bacteria, particularly from the forefoot [8–10].

A meta-analysis conducted by Yammine and Harvey 2013, identified there was no conclusive superiority in different skin preparation methods [1]. The methods examined included preoperative washing with antiseptic agent and intraoperative sterile brush scrubbing of the foot and ankle area. No studies have examined preoperative skin preparation using an unsterile bag filled with antiseptic solution wrapped around the foot and ankle to rub all skin surfaces with antiseptic (the bag immersion method) and compared this method to the traditional antiseptic method by painting all skin surfaces with a gauze swab on Rampleys forceps.

This novel method is becoming the method of choice for many foot and ankle specialist surgeons over the traditional painting preparation, but it has only been evaluated for the preoperative preparation prior to hand surgery and not for foot and ankle

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surgery. Two separate groups, Incoll et al. and Chou et al. [11,12] have separately demonstrated significant improvements in reduction in either positive bacterial culture growth [11] or in preparation time [12], when using this novel method for preoperative skin preparation in hand surgery.

The aim of this study was to demonstrate that skin preparation of the foot and ankle with the bag immersion method is as efficient and effective at elimination of surface skin flora, when compared to the traditional painting method. It was hypothesised that the bag immersion technique will be equivalent to that of the standard painting method in both efficiency and effectiveness.

2. Methods

This study was approved by a regional ethics committee. Fifty-one adult volunteers were recruited through the outpatient clinic and ward at a major metropolitan teaching hospital. The inclusion criteria were having both feet with 5 toes on each, and having the ability to give informed consent. Volunteers with the following conditions were excluded from the study; a history of systemic antibiotics within the last 2 weeks or lower limb surgery within the last 30 days, gross foot or ankle deformity, open wounds below the knee, active infection, and allergy to chlorhexidine. Upon consenting to participate in the study, the volunteers were randomly assigned into one of two preparation groups, by opening an assignment envelope. Participants assigned to Group A underwent timed bag immersion preparation of the right foot and ankle followed by the standard painting technique on the left foot. Group B followed the exact same preparation techniques with exception to the left foot being immersed and the right foot painted. Relevant baseline characteristics of all volunteers were recorded on demographic study sheets.

Both procedural groups followed the standard technique currently being used during surgery as this allows for clinical validity. No special instructions for bathing or showering was given before the foot and ankle preparation, and all volunteers followed their usual personal hygiene routine on the day of study. All foot preparations were performed by the same investigator and bacteriological samplings were performed by two investigators.

2.1. Randomisation procedure

Randomisation of assignments was determined by permuted blocks using a computer generated random number sequence. There was a 1:1 randomisation in this study. Volunteers were enrolled sequentially as they become available. Randomisation of trial participants was achieved using a permuted block randomisation design. A block size of 4 was used in conjunction with a random number sequence to create a master list for preparation allocation. The use of permutation blocks assured that the assignment of preparation techniques was balanced. Fifty-two envelopes containing 26 assignments to Group A and 26 assignments to Group B were made available at the start of the study. An envelope was sequentially selected once the informed consent was obtained from the recruited subject and opened to determine the assignment. The envelopes were sealed, so there was no way of differentiating the two assignments without opening the envelope.

2.2. Bag immersion technique

100 mL of 2% chlorhexidine in 70% alcohol solution (Orion Laboratories T/A Perrigo Australia, Sydney, AUS) in a non-sterile clear plastic bag measuring 610 mm wide × 615 mm deep (Fig. 1A) was used. The subjects' lower leg was positioned over the edge of the bed so the lower limb below the knee was not in contact with any surface (Fig. 1B). The antiseptic solution was agitated in the bag to coat the interior surface (Fig. 1C). A timer was started when the bag was pulled over the foot and the antiseptic solution came in contact with the subject's skin. The bag filled with the chlorhexidine solution was then pulled over the foot so that the forefoot became submerged in the solution at one corner of the bag. All of the forefoot, including between the toes in the webspaces, was rubbed with the chlorhexidine solution (Fig. 1D). The knee was then extended so the investigator could rest the plantar aspect of the foot on their thigh and work the bulk of the fluid more

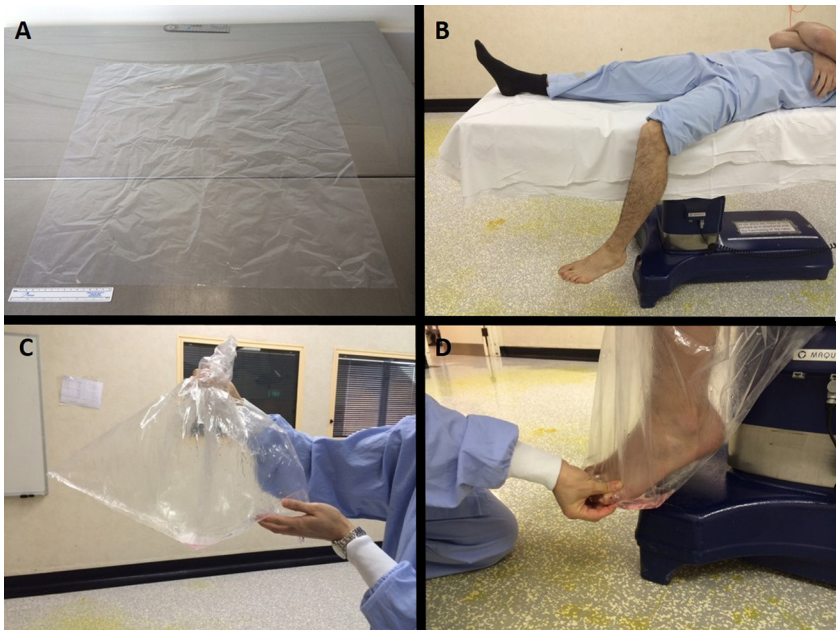

Fig. 1. The initial steps of the bag immersion technique on the lower limb. (A) The non-sterile clear plastic bag, measuring 610 mm × 615 mm. (B) Patient lies supine with the treatment leg positioned over the edge of the bed. (C) The clear plastic bag filled with chlorhexidine solution. The bag is agitated to ensure that the chlorhexidine solution coats all internal surfaces. (D) Illustrates the chlorhexidine solution massaged into the forefoot, toes and webspaces.