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Research Article

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Comparison of the Rate of Wound Infection Post Ankle Open Reduction and Internal Fixation: A Prospective Randomized Control Trial

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Abstract

Method: A prospective study was conducted including 370 patients (mean age: 42, range 18-88 years) undergoing ORIF for ankle fractures. Wound closure was performed according to a standardized protocol (layered with vicryl and nylon), and dressings were applied *via* randomisation with with chlorhexidine 0.5% in alcohol 70% (n=185), or normal opsite® dressing (n=185) and left covered for 14 days. Follow up was performed at two and six weeks in clinic with Southampton scoring sheet filled and normal dressing applied. Statisical analysis comprised Fisher's exact test for comparison of binominal data, and multivariate logistic regression analyses with impaired wound healing or wound infection as the dependent outcome variable and type of dressing, age, gender, smoking and diabetes as independent variables.

Results: The mean age was 43 ± 18.3 years (range 18-88) with 254 females (139 *vs.* 115) and 116 males (46 *vs.* 70) recruited for the ordinary and alcohol groups respectively. At two weeks post-operatively the ordinary *vs.* alcohol dressings group had 24 patients (10 *vs.* 14 p=0.89) with impaired healing, 2 patients (0 *vs.* 2 p=0.995) with delayed healing and no patients with deep infections. At six weeks post-operatively 18 patients (9 *vs.* 9 p=0.97) had impaired healing, 11 patients (5 *vs.* 6 p=0.82) had delayed healing and 5 patients (3 *vs.* 2 p=0.73) had deep infections requiring further orthopaedic intervention.

Conclusions: There is no significant difference in wound outcome scores at two or six weeks between using an alcohol based or ordinary dressing for surgical management of closed ankle fractures.

Keywords: Ankle fractures; Wound healing; Dressings; Infection; Orthopaedics; Trauma

Introduction

Ankle fractures are commonly seen in all age groups making it one of the most frequent clinical presentations to the emergency department often requiring inpatient admissions for further treatment under the guidance of orthopaedic services. The incidence of ankle fractures has been reported at 184 per 100,000 person years and as high as 10% of all fractures [1,2]. Amongst the elderly population, ankle fractures are only outnumbered by those of the hip and wrist; and in the younger population likely represents an even greater proportion of the overall injuries [3,4].

Some of the complications that occur following ankle fracture ORIF include wound complications, pulmonary embolism, below knee amputation, revision surgery, malunion, delayed union or non-union [5]. Wound complications are the most common, and may include wound edge necrosis, wound dehiscence, superficial infection and deep infection or osteomyelitis [6].

Although the rate of infection for clean orthopaedic surgical procedures is relatively low, ranging from 0.5%-6.5% [7,8] it remains the most common complication, with potentially devastating outcomes which can result in repeat debridement, skin flap coverage or even amputation [6-8]. Furthermore, despite foot and ankle surgery being classed as a clean orthopaedic surgical procedure, the local contamination of the region will always be an aspect of foot and ankle surgery that predisposes patients to wound infection [9,10]. This becomes a greater issue when considering the added vulnerability of the foot and ankle region in the context of commonly seen comorbidities which affect the soft tissues; such as poor vascularity, peripheral neuropathy, impaired wound healing states and immunosuppression [6]. While large body of research exists in relation to the risk factors predisposing to postoperative wound infections, there is little or no research into postoperative wound care for ankle fractures.

The majority of evidence-based reports on wound dressings have been published in the plastic surgery and dermatology literature. No study has been done to assess the effect of alcohol-based type of wound dressing in ankle surgeries on superficial wound infection rate [3-5].

Aim

The rate of superficial wound infection post ankle surgery is about 6.5% based on current literature [7,8]. There has been no study done to assess alcohol-based type of dressings.

The aim of this study is to investigate the effect of alcohol based wound dressing on the rate of superficial wound infection post open reduction and internal fixation of closed ankle fractures, and whether our new wound dressing will decrease the infection rate.

Hypothesis

The use of Chlorhexidine 0.5% in alcohol 70% based wound dressing on surgical wounds post ankle open reduction and internal fixation reduces the rate of impaired healing when compared to the use of a conventional opsite™ dressing.

Materials and Methods

A prospective randomised control trial was conducted at two tertiary trauma institutions. Patients undergoing open reduction and internal fixation of ankle for closed fractures (lateral +/- medial incisions) underwent uniform method of wound closure (layered closure, with vicryl and nylon) with wounds covered for fourteen days. Standard antibiotic coverage at induction of surgery with weight-adjusted doses of third generation cephalosporin was administered for all patients.

Patients underwent an informed consent process and were randomised to two groups. Control group wound dressings contained Opsite™ (ordinary dressing) and study group wound dressings contained Chlorhexidine Solution 0.5% in Ethanol 70% soaked gauze covered with Opsite™.

The wound assessment tool was adapted from the Southampton Wound Assessment Score (SWAS), which has been proven in reproducibility and for inter-observer agreement [8]. Scores were recorded for all patients at two and six week postoperative assessments. These were stratified into three subsets to assess for impaired, delayed or deep infection at each time point based on a score from 0-5.

Patient anaesthetic assessment documentation was reviewed and the following data extracted for each subject: Patient age, sex, history of diabetes mellitus, development of postoperative infection, severity of infection, tobacco use.

For the purposes of this study, the patients with alcohol based dressing were defined as the 'study group and the patients with ordinary dressing are defined as the 'control group'.

We performed a priori power analysis for the primary research question regarding deep wound infection with a rate of superficial wound infection of the ankle in the group with ordinary wound dressing is about 6.5% [7,8] based on previous published article; rate of superficial wound infection of the ankle in the group with new wound dressing estimated to be about 1% in order to be clinically significant; the Power was set at 80% and significant level at 95%; the sample size for each paired-sample is 185.

We tested normal distribution of all continuous parameters with the Kolmogorov-Smirnov test. Paired (unpaired) Student's t-test was used for comparison of normally distributed data. The Wilcoxon rank sum test (Mann-Whitney-U-test) was used to compare paired (unpaired) data without normal distribution. Differences between categorical variables were analysed with the Fisher's exact test. Binary logistic regression analysis was performed with deep wound infection (Southhampton wound score >4) as the dependent input variable and age, gender, diabetes, smoking, and type of dressing applied as independent input variables.

Results

185 patients were recruited to the ordinary and alcohol dressing groups over six years from 2012-2018. The mean age was 43 ± 18.3 years (range 18-88) with 254 females (139 *vs.* 115) and 116 males (46 *vs.* 70) recruited for the ordinary and alcohol groups respectively. Independent variables recorded for the groups included diabetes (12 *vs.* 16 p=0.43) and smoking (56 *vs.* 49 p=0.42). Wound incision side was recorded as either medial (28 *vs.* 31) or lateral (157 *vs.* 154).

At two weeks post-operatively the ordinary *vs.* alcohol dressings group had 24 patients (10 *vs.* 14 p=0.89) with impaired healing, 2 patients (0 *vs.* 2 p=0.995) with delayed healing and no patients with deep infections.

At six weeks post-operatively 18 patients (9 *vs.* 9 p=0.97) had impaired healing, 11 patients (5 *vs.* 6 p=0.82) had delayed healing and 5 patients (3 *vs.* 2 p=0.73) had deep infections requiring further orthopaedic intervention (Table 1).

	Patients	2 week SHWS >1	6 week SHWS>1
Total	370	6.48%	4.86%
Female	254	3.24%	3.24%
Male	116	3.24%	1.62%
Smokers	105	5.68%	4.32%
Non-Smokers	265	0.81%	0.54%
Diabetic	28	3.78%	2.43%
Lateral incision	157	6.22%	4.59%
Medial incision	154	0.27%	0.27%

Table 1: Dressing groups.

Logistical regression analysis was used to assess the other independent variables. At six weeks there was a weak association with increased age and deep infection (odds ratio=1.064 p=0.035). None of the other factors reached statistical significance allowing for further assessment of their effects on wound infection post-surgery. No

adverse reactions or toxicity was observed in the alcohol-dressing group (Table 2).

Six week Deep Infection Independent Variable Analysis	Sig. (p-value)	Odds ratio
Gender	0.774	1.448
Age	0.035	1.064
Dressing Type	0.73	0.713
Smoking	1	0.629
Medial/Lateral Wound Site	0.997	0
Diabetes	1	6.655

Table 2: Logistical regression analysis.

Discussion

This study looked at comparing current dressings with a modified alcohol soaked formulation in determining an optimal solution to reducing post-operative wound infections which carry a significant patient burden resulting in loss of function, the need for further surgery or even amputation if untreated [11,12].

Postoperative infection is an inherent risk for all surgical procedures. Postoperative infections are the most common cause of complications in surgical patients and result in an average increase of four days in the hospital [13,14]. The complication rate for clean orthopaedic surgical procedures is relatively low and infection varies from 0% to 12% [15-17]. This was mirrored in our study with a rate of deep infections recorded at 1.3%.

Chlorhexidine gluconate is a commonly used surgical skin preparation chosen for its prolonged action against both gram positive and negative skin commensals, through its disruption of bacterial cell membranes [18,19]. In a study comparing antiseptic surgical scrubs, chlorhexidine gluconate performed significantly better than povidone-iodine in reducing bacterial counts taken immediately after scrubbing, 3 hours and 6 hours later [20]. Furthermore two studies looking at bacterial skin contamination after surgical preparation [21,22] found fewer bacteria on the skin of feet prepared with chlorhexidine gluconate and isopropyl alcohol, when compared with iodine/isopropyl alcohol and chloroxylenol solutions. Cooper et al. [23] evaluated the toxicity of several antimicrobial agents and found povidone-iodine to be significantly more toxic to fibroblasts than other agents ($p<0.05$). Kramer [24] showed a detrimental effect of povidone-iodine on wound healing. Triple antibiotic ointment was shown to increase re-epithelialization by 25% in an animal model. In a prospective, randomized, controlled trial evaluating 426 uncomplicated wounds, the infection rates in the groups treated with bacitracin ointment (six of 109, 5.5%) or triple antibiotic ointment (five of 110, 4.5%) were lower than those in the groups treated with silver sulfadiazine (twelve of ninety-nine, 12.1%) or petroleum (nineteen of 108, 17.6%) ($p=0.0034$) [25]. Broad-spectrum ointments provide occlusion and increase epithelialization while the wound heals [26].

Dressings have minimal impact on a closed wound if the wound is kept clean and not exposed to potential contaminants thru contact with water, soil, mud or other similar vehicles. The dressing should be able to absorb exudate and allow air passage. This study suggests that a medicated dressing may not elute enough into a closed sutured wound to produce any clinical results. Any antibacterial dressing may make a difference on open wounds and would be an avenue for future research.

The greatest strength of this study is that it is the first large multicenter randomized control trial assessing ankle wounds in the context of closed fractures. Weaknesses include non-consecutive patient recruitment resulting in selection bias, assessor variability and inability to blind participants to group allocation.

Conclusion

There is no significant difference in wound outcome scores at two or six weeks between using an alcohol based or ordinary dressing for surgical management of closed ankle fractures. Current surgical practices and advances in sterility have resulted in significantly low rates of postoperative infection as reported in this study.

Conflict of Interest and Funding

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