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Prospective randomised controlled trial of nanocrystalline silver dressing versus plain gauze as the initial post-debridement management of military wounds on wound microbiology and healing

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ABSTRACT

Introduction: Recent conflicts have been characterised by the use of improvised explosive devices causing devastating injuries, including heavily contaminated wounds requiring meticulous surgical debridement. After being rendered surgical clean, these wounds are dressed and the patient transferred back to the UK for on-going treatment. A dressing that would prevent wounds from becoming colonised during transit would be desirable. The aim of this study was to establish whether using nanocrystalline silver dressings, as an adjunct to the initial debridement, would positively affect wound microbiology and wound healing compared to standard plain gauze dressings.

Methods: Patients were prospectively randomised to receive either silver dressings, in a nanocrystalline preparation (Acticoat™), or standard of care dressings (plain gauze) following their initial debridement in the field hospital. On repatriation to the UK microbiological swabs were taken from the dressing and the wound, and an odour score recorded. Wounds were followed prospectively and time to wound healing was recorded. Additionally, patient demographic data were recorded, as well as the mechanism of injury and Injury Severity Score.

Results: 76 patients were recruited to the trial between February 2010 and February 2012. 39 received current dressings and 37 received the trial dressings. Eleven patients were not swabbed. There was no difference ($p = 0.1384$, Fishers) in the primary outcome measure of wound colonisation between the treatment arm (14/33) and the control arm (20/32). Similarly time to wound healing was not statistically different ($p = 0.5009$, Mann–Whitney). Wounds in the control group were scored as being significantly more malodorous ($p = 0.002$, Mann–Whitney) than those in the treatment arm.

Conclusions: This is the first randomised controlled trial to report results from an active theatre of war. Performing research under these conditions poses additional challenges to military clinicians. Meticulous debridement of wounds remains the critical determinant in wound healing and infection and this study did not demonstrate a benefit of nanocrystaline silver dressing in respect to preventing wound colonisation or promoting healing, these dressings do however seem to significantly reduce the unpleasant odour commonly associated with battlefield wounds.

Introduction

Recent and ongoing conflicts in the Middle East have been characterised by the insurgents' use of Improvised Explosive Devices (IEDs). These weapons cause devastating injuries, stripping tissue from bone and driving debris deep along fascial planes. The large soft-tissue wounds and traumatic amputations that result are heavily contaminated with soil, vegetation, clothing and other victims' tissue. Due to the high levels of energy-transfer involved, these wounds are seen to evolve for several days after their initial surgery, with further tissue necrosis and requirement for multiple debridements [1]. It is not known whether this wound progression is a peculiarity of the high-energy nature of combat injuries or from the high level of bacterial contamination. For patients facing prolonged transfer from deployed medical facilities, treatments that potentially minimise the degree of bacterial colonisation/infection of wounds between surgical debridements are attractive.

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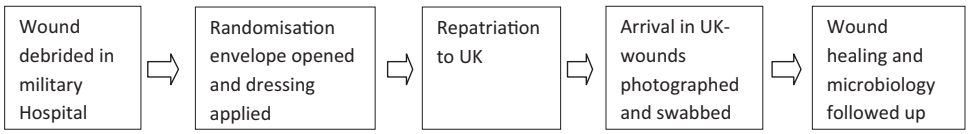

Fig. 1. Phases of trial methodology.

The antimicrobial effects of silver are well established, and dressings designed to elute silver ions have been shown to be effective at reducing bacterial colonisation of wounds [2]. In particular silver dressings are extensively used in the management of burn wounds following surgical excision [3].

This study aims to compare the effect of silver dressings on bacterial colonisation and wound healing and odour compared to standard gauze dressings.

Methods

The study was registered with Ministry of Defence Research Ethics Council (MOD REC) and the Joint Medical Command of the Surgeon General's department, having been approved by the National Research Ethics Service (NRES) (South Birmingham and Solihull). MOD REC issued a consent waiver, as the intervention is a licensed product being used in an approved manner but in a novel environment. The study was therefore registered as a technical evaluation.

All UK casualties who had sustained an injury requiring wound debridement between February 2010 and February 2012 and treated at Camp Bastion Medical Facility in Afghanistan were eligible for inclusion. Cases were excluded if they had an allergy to silver or were injured through non-hostile mechanism i.e. motor vehicle accident. The principal wound in the multiply wounded patient, as determined by the treating surgeon, was the wound randomised in the study. Data including demographics, mechanism of injury, and Injury Severity Score of the patient were collected.

Immediately following the initial surgical debridement, casualties were randomised to have their wounds dressed with either a nanocrystalline silver dressing, Acticoat™ (Smith and Nephew, Hull, UK) i.e. the intervention group, or standard gauze dressing i.e. the control group. Unrestricted randomisation was by means of random number allocation and sealed envelope treatment assignment; on completion of the debridement of the wounds in the field hospital the next envelope would be opened and dressings applied according to the instructions contained within. Surgeons were therefore blinded to which dressing would be applied, as envelopes were not opened until the debridement procedure had been completed. The patient would then be repatriated to the single UK military medical facility according to clinical priorities via the standard military medical evacuation chain. Medical care in all other respects was according to Clinical Guidelines for Operations which, among other protocols, include all patients receiving 1.2 g co-amoxiclav every 8 h (or appropriate alternative in the case of drug allergy).

On arrival in the UK military medical facility the affected limbs were examined with the dressings intact, thus blinding the assessors to the intervention. The wound was ascribed an "odour score" from 1 to 10 by an assessor that had previously attended a standardisation session. The outer surface of the wound dressing was then 'swabbed' with sterile microbiological cotton-tipped swabs and these samples transferred to conventional agar plates and incubated. If bacteria were recovered, the dressings were regarded as colonised. The appearance of wound exudate on the outside of the dressings was also noted as 'strike-through'.

Dressings were then taken down; at this point blinding was no longer possible due to the appearance of the trial dressing. The wound was then swabbed, If bacteria were recovered, the wound was regarded as colonised.

Subsequent wound management was as directed by the clinicians managing the patient and was not influenced by trial participation. Timing of removal of dressings was according to clinical management plan, and not standardised due to the patient's enrolment in the trial.

The final outcome measure was wound healing defined as time to 95% healing of the wound by surface area. This point was chosen as it was felt that at this time the clinical significance of remaining unhealed areas is minimal, however final healing might take longer. The study methodology is summarised in Fig. 1. The primary outcome measure was wound colonisation; secondary outcome measures were dressing colonisation, wound odour and 95% wound healing.

Statistical analysis

Fisher's exact test was used to compare trial arms with respect to bacterial wound colonisation. Odour scores and healing time were treated as a non-parametric and compared using Mann–Whitney *U*-test. Due to the nature of the study and lack of previous data it was not possible to perform a pre-hoc power calculation.

Patients and results

Seventy-six patients were enrolled in the trial between February 2010 and February 2012. Mechanism of injury was blast in 54 cases (71%), gunshot wound in 22 cases (29%). Median ISS score was 10.0 (range 1–45, mean 14.6, SD = 12.0). All but one of the patients was male.

Thirty-nine patients were randomised to receive the standard sterile gauze dressing (control arm) and 37 to receive the activated silver dressing (intervention arm) as shown in Fig. 2. The two arms of the trial were comparable with respect to ISS, mechanism of injury and repatriation delay as shown in Table 1. There was a difference between the mean ages of the patients in the two arms of the trial with the intervention arm being a mean 2.1 years older ($p = 0.0003$).

The primary outcome measure was not measured in 11 of the 76 patients (4 in the intervention group and 7 in the control group) and these cases were excluded from analysis for this outcome measure. There was no difference in the proportion of wounds that bacteria were recovered from in the two trial arms ($p = 0.1384$, Fishers). Bacteria were recovered from 14 of the 33 wound swabs in the treatment group and 20 of the 32 control group swabs as summarised in Table 2.

The secondary outcome measure of dressing colonisation was only collected in 27/37 (73%) in the treatment group and was positive in 10 of these (37%). Dressing swabs were taken from 23/39 (58%) of the control cases and were positive in 13 of these (57%). There was no difference in the proportion of dressings that were colonised in the two treatment arms ($p = 0.2552$, Fisher's exact test). Similar bacteria were collected from the wound and the