VACUTEX™ capillary action dressing: a multicentre, randomized trial

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Abstract

This article describes a preliminary study comparing the effect of VACUTEX™ capillary action wound dressing vs standard protocol for the treatment of sloughy and necrotic wounds. The study was carried out over a period of 5 months. Randomization was computer generated and batches of trial numbers and dressing allocation were delivered to each of the three study sites, sealed in opaque envelopes to ensure blinding of allocation. A total of 35 patient participants were recruited (17 VACUTEX™, 14 standard protocol, three withdrew, one died). All participants gave their consent to enter the study. All participants were assessed and photographs were taken on days 1, 8, 15, 22 and 29. Nursing assessments of size, site, depth, severity, tissue type of wound and causation were collected, as were demographic factors including mental status, primary/associated medical history, weight, height, and ethnic origin.

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The demand for wound care products is growing rapidly because of demographic and technological changes (Roberts, 1998). Increasing numbers of clinical trials are now performed in order to produce clinical evidence for products. The evidence should be subjected to rigorous evaluation, including cost implications of the treatment and the healing time to the end point. Cost-effective management of wounds is a complex matter and should focus on not only short-term costs of healing, but also the long-term costs (Roberts, 1998).

DEBRIDEMENT

Debridement is defined as the removal of devitalized or contaminated tissue, which is adjacent to a traumatic or infected lesion, until the surrounding healthy tissue is exposed. This may also include the removal of foreign material that has become embedded in the wound (*Dorland's Electronic Medical Dictionary*, 1998). Debridement is necessary in order to allow the wound to be fully assessed and graded (Vowden and Vowden, 1999). It must not be seen in isolation but regarded as one element in the healing process (Fowler and Van Rijswijk, 1995). In some wounds, rehydration and debridement may be considered inappropriate and should therefore be used only after careful wound and patient assessment (Vowden and Vowden, 1999).

Chronic wounds contain devitalized tissue which is referred to as slough and eschar. Any eschar covering the wound needs to be debrided to prevent bacterial infection and to promote optimal wound healing (Miller 1996; Thomas et al, 1999). With necrotic wounds, if surgical debridement is not an option, the aim of treatment is to rehydrate and soften tissue and promote autolytic debridement (Thomas, 1990).

The optimum environment for the natural wound healing process to be activated is warm, moist and non-toxic (Winter, 1975; Thomas, 1990). Drying out the wound will cause all the healing processes to cease (Miller and Collier, 1996). When wounds are left exposed to the air or dressed with traditional gauze dressing (which leads to wound drying), the healing rate is decreased by 40% when compared to a moist wound where epidermal resurfacing takes place rapidly (Eaglstein, 1985).

There are distinct advantages of moist wound healing for the patient (Field and Kerstein, 1994). There is less pain because the wound is immersed in the natural body fluids and there are fewer infections as dry eschar may harbour microorganisms (Field and Kerstein, 1994). Trauma on dressing change will also be reduced as dressings will not adhere to moist wounds. In addition, there will be a decreased rate of microorganism transmission when changing dressings because there will be less airborne dispersal of dried fragments of wound tissue. Autolytic debridement occurs more effectively in a moist environment and the majority of dressings require water for the hydrolysis of proteins (Davis et al, 1992).

The criteria for the ideal dressing are listed in *Table 1*. There is a huge range of dressing products currently on the market. This can be confusing for the nurse when trying to decide which product to use.

VACUTEX™

VACUTEX™, which is manufactured by Protex Capillary Dressings Ltd, is a three-layer polyester filament and polycotton dressing. These three layers work together using capillary action. The outer layer in contact with the wound is able to lift and transport necrotic and sloughy tissue. The middle layer prevents 'strike-through' by allowing wound exudate to move into and wick laterally across the fabric rather than leaving the exudate at the wound surface. The outer layer of the dressing away from the wound draws the exudate from the saturated middle layer. This has the potential to reduce the risk of infection by removing harmful bacteria and maceration of the wound. Also, the low-adherent fused outer layers prevent any microfibres shredding onto the wound. *VACUTEX*™ is non-interactive, non-impregnated and suitable for most wounds, both acute and chronic (Deeth and Pain, 2001).

Table 1. Criteria of the ideal dressing

Ensures that the wound remains moist with exudate but is not macerated
Ensures that the wound remains free of clinical infection and excessive slough
Allows gaseous exchange
Keeps the wound free of toxic chemicals, particles or fibres
Keeps the wound at optimum temperature and pH for healing
Ensures that the wound is undisturbed by frequent dressing changes

Source: Thomas (1990)

Table 2. Standard dressing protocol

Primary dressing	Larvae therapy Hydrocolloids Hydrogel	One of these may be used but may require a secondary dressing
Secondary or primary	Hydrocellular foam Hydrophilic foam Hydrocolloids Hydropolymer	One of these can be used in isolation or in combination
Infected	Antibacterial Antiseptics	If signs of infection are present one of these may be used with a secondary dressing
Secondary or securing	Films Tape Bandage Non-adherent Skin protection spray/wipe	On all wounds as appropriate

AIMS OF THE STUDY

The aims of this study were:

- To examine the efficacy of *VACUTEX*™ on wounds meeting the eligible criteria against standard protocol
- To determine the rate of debridement of *VACUTEX*™ when compared with standard protocol
- To examine the economic cost of using *VACUTEX*™ when compared with standard protocol.

METHODOLOGY

A comparative study method was used to examine *VACUTEX*™ wound dressing (the trial dressing) *vs* standard dressing protocol (*Table 2*) for the debridement of any wounds with necrotic and sloughy tissue. The trial dressing was new to all the three sites in the study (an acute teaching hospital, a district general hospital and nursing homes). Therefore, nursing staff received training in the action and use of the trial dressing before commencement of the study to ensure sufficient knowledge, skill and competence in use of the product.

Randomization was computer generated and batches of trial numbers and dressing allocation were delivered to each of the study sites, sealed in opaque envelopes to ensure blinding of allocation. The aim was to recruit 20 patients to each group in total to ensure that at least 40 patients (20 trial dressing and 20 standard protocol) completed the study from across the three sites over the study period.

Statistical power analysis carried out before commencement of the study indicated that a total of 30 patients in each group would give approximately 9% power to detect a 10% difference between the trial dressing and standard dressings. Most trials are powered to 60%; therefore, this patient group size was suitable for detection of an approximately 30% difference between dressing types. The study was designed as a pilot to identify the appropriate size of a future definitive trial.

The following data were collected:

- All participants were assessed for a maximum of 4 weeks or until complete debridement had been achieved, whichever occurred first. Wounds were photographed on days 1, 8, 15, 22 and 29

- Predisposing factors that caused the wound as well as the current dressing in use before commencement into the trial
- Assessment of size, site, depth, severity, signs of debridement and condition of surrounding skin
- Demographic factors, mental status, primary/associated medical history, weight and height, ethnic origin
- Patient completion date/withdrawal and reason (if appropriate).

Before commencement of the study the protocol ethics approval was obtained from the relevant local research ethics committee for each of the study sites.

On identification of an appropriate wound type, i.e. necrotic or sloughy, the research nurse was notified to screen and recruit patients. Written consent was obtained which included permission to take weekly photographs and subsequently to publish/use for education purposes. Upon consent, participants were randomly allocated to either the experimental or control group.

Patient eligibility criteria

The patient eligibility criteria were:

- Patients with established necrotic/sloughy wounds that may/may not be clinically infected
- Wound size >20 mm x 20 mm
- Patients aged 18 years and over
- Patients expected to stay in the care setting at least 8 days following entry to the trial or receiving ongoing treatment in outpatients
- Patients who had given consent, or relatives who had witnessed assent, to enter the trial, including photographic assessment.

Patient exclusion criteria

The patient exclusion criteria were:

- Patients previously recruited to this trial
- Patients involved in any other research study that may influence wound management
- Patient sensitivity to trial dressing or standard protocol post-entry into the trial
- Patients whose condition changes such that normal treatment is compromised
- Moribund patients, i.e. those likely to die before wound healing could occur
- Patients deemed unsuitable by the medical clinician responsible for their care and treatment.

PRELIMINARY RESULTS

Thirty-five patients were recruited to the trial of which four withdrew/died leaving 31 fully completed. This allowed 17 trial dressing-treated wounds and 14 standard protocol-treated wounds to be assessed. The average number of days spent in the trial was 18.8 trial dressing *vs* 14.8 standard protocol. However, one trial dressing participant was followed for 62 days. This skewed the results and so, after exclusion of this outlier, the adjusted number of days spent in the trial was trial dressing 16.1 *vs* standard protocol 14.8 (*Table 3*).

Statistical analysis by *t*-test ($t = 1.02$, $P = 0.32$ and $t = 0.414$, $P = 0.68$; see *Table 3*) and rank sum test (sum of ranks = 196 and cut off for $P = 0.05$ is <183) found no statistically significant difference between wound treatment time for participants in either group.

All wounds were visually assessed and a 'nursing judgment' of healing at the time of trial exit was made. This judgment was based on the size and improvement of slough/debridement of devitalized tissue (*Figures 1, 2* and *3*). The findings are shown in *Table 4*. Statistical analysis by χ^2 test gave a test statistic of 5.23 indicating a significant difference ($P = 0.022$). This suggests that the 76.5% improvement for trial dressing-treated patients was significantly better than the 35.7% improvement for standard protocol-treated patients.

Table 3. Duration of wound observation

	Mean	SD	*n*	Statistical evaluation of VACUTEX™ *vs* standard protocol
VACUTEX™	18.82	14.25	17	$t = 1.02/P = 0.32$
VACUTEX™ (after exclusion of outlier)	16.12	9.2	16	$t = 0.414/P = 0.68$
Standard protocol	14.78	8.5	14	

Table 4. Visual assessment of wound improvement ($\chi^2 = 5.23$, $P = 0.022$)

	Improved	No Improvement	Total
VACUTEX™	13 (76.5%)	4 (23.5%)	17
Other	5 (35.7%)	9 (64.3%)	14
Total	18	13	31

KEY POINTS

- Cost-effective management of wounds is a complex matter and should focus on not only short-term costs of healing but also long-term costs.
- In some wounds rehydration and debridement may be considered inappropriate and should therefore be used only after careful wound and patient assessment.
- *VACUTEX™* is a three-layer filament and cotton dressing. These three layers work together using capillary action.
- *VACUTEX™* capillary action dressing is non-interactive, non-impregnated and suitable for the majority of wounds, both acute and chronic.

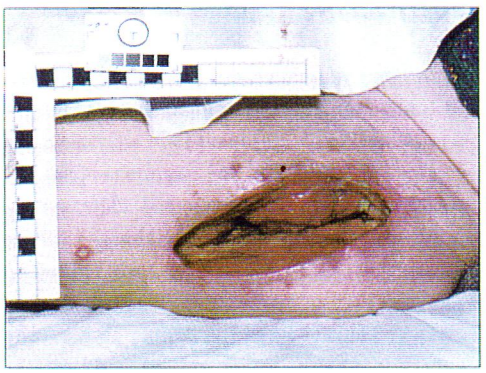

Figure 1. Patient's hip wound 1 week after treatment with the trial dressing.

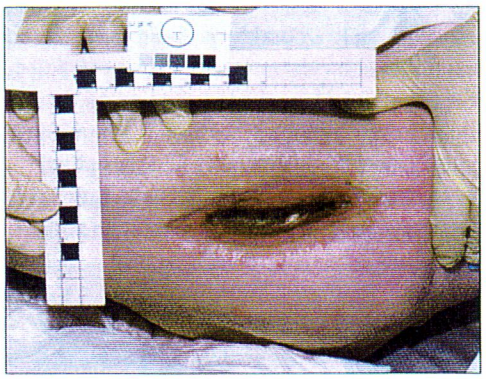

Figure 2. Patient's hip wound 2 weeks after treatment with the trial dressing.

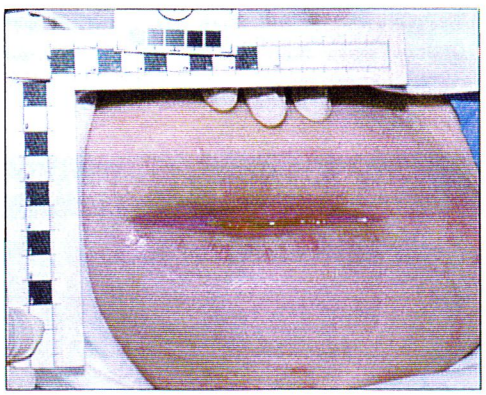

Figure 2. Patient's hip wound 3 weeks after treatment with the trial dressing.

STATISTICAL ANALYSIS

Further data analysis of the completed trial will be undertaken over the next few months to examine the demographic and clinical characteristics of the patients recruited, and to look at wound healing velocities. It is also planned to examine in more detail the differences between trial dressing and standard protocol dressings in terms of exudate management and cost-economics.

SUMMARY

This article presents an outline of the methodology of a recently completed small-scale, multicentred, randomized control trial. It provides initial evidence of significant reported improvement in visual assessment of the trial dressing (capillary action wound dressing) over standard protocol (76.5% *vs* 35.7% improvement). This suggests that the trial dressing may be a useful new treatment for dealing with sloughy, devitalized and exudating wounds.

Further studies will be carried out to explore this in more detail and to investigate more fully the cost implications of successfully healing patients' wounds. BJN

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