Pilot study comparing Kendall™ AMD antimicrobial foam dressing with ALLEVYN™ Ag hydrocellular antimicrobial dressing in venous leg ulcers

KEY WORDS
- Antimicrobial
- Dressings
- Infection
- Venous leg ulcer

Infection is an important factor that delays wound healing, yet management of wound infection remains clinically challenging. This pilot study compared the clinical effectiveness of two antimicrobial foam dressings – Kendall™ AMD (Covidien; containing polyhexamethylene biguanide) and ALLEVYN™ Ag (Smith & Nephew; containing silver) – in terms of wound size reduction or complete healing of venous leg ulcers. Data analyses were conducted on 32 patients, with 34.38% of ulcers healing or re-epithelialising within the 12-week intervention phase – 63.64% from the Kendall AMD group (*n*=7) and 36.36% (*n*=4) from the ALLEVYN Ag group. Pain reduction was found to be greater in the Kendall AMD arm. Exudate levels were reduced during the study period. There is evidence from this study to suggest that Kendall AMD is as effective as ALLEVYN Ag, a widely used antimicrobial dressing, and is an efficient wound management product for hard-to-heal venous leg ulcers.

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Infection is the single most important independent factor that delays wound healing. Through misuse and overuse antibiotics have been associated with the appearance and rise in resistant (notably methicillin-resistant *Staphylococcus aureus* [MRSA]) and emergent organisms (notably *Clostridium difficile*; European Wound Management Association [EWMA], 2005; Grey and Harding 2006; Robson and Barbul, 2006; Franz et al, 2008; Leaper, 2008; NICE, 2008).

Conversely, antiseptics are not associated with this risk of resistance or emergence, but have been judged by many clinicians to be toxic for open wounds, yet few meaningful clinical trials have measured the value of topical antiseptics in wound care (O'Meara et al, 2001; O'Meara et al, 2008). Although the use of dressings containing silver remains popular, negative reviews on the use of topical silver have been published (Chambers et al, 2007; Vermeulen et al, 2007).

The use of antibiotics is not indicated until there are clinical signs of spreading or invasive infection (i.e. cellulitis or lymphangitis) with systemic signs, or when certain bacteria have been identified, such as β-haemolytic streptococci (EWMA, 2005; Grey and Harding, 2006; Robson and Barbul, 2006; Leaper, 2008; NICE, 2008; World Union of Wound Healing Societies, 2008). However, local infection remains a clinical diagnosis.

Traditionally, iodine-containing compounds (polyvinyl pyrrolidone-iodine and iodophores) and chlorhexidine have been used as irrigants or in antimicrobial dressings to achieve control of bioburden (Leaper and Durani 2008; Durani and Leaper, 2008).

Recognition of the rise in multi-resistant bacteria and over-usage of antibiotics has led to a widespread uptake of silver as an antimicrobial dressing (Leaper, 2006). This has been challenged by some (Chambers et al, 2007; Vermeulen et al, 2007), due to the cytotoxicity of silver dressings, particularly on fibroblasts. The cytotoxicity seen in the laboratory has not been reflected in clinical practice and consensus statements on antibacterials in wound healing state that silver has a place in the wound management armamentarium.

"The primary objective of the study was to compare two foam dressings containing different antiseptics"

POLYHEXAMETHYLENE BIGUANIDE

There are broad-spectrum antiseptics available from the biguanide group, which are presented as antimicrobial products that maintain the optimal moist wound healing environment, control exudate and lead to less pain and odour.

Kendall AMD is one such dressing, containing 0.5% PHMB, and has been found to be useful and cost-effective in preventing surgical site infections (SSIs) after surgery (Penn et al, 2006; Lovelace, 2007; Neitzel, 2007; Johnson and Leak, 2011).

PHMB is not associated with any allergies or toxicities, having been used for more than 40 years as a swimming pool cleaner and active antiseptic ingredient in toothpaste. There appears to be no deterrent to healing in experimental wounds (Davis et al, 2002; Ivins et al, 2009).

Similar to all antiseptics, PHMB works non-specifically on bacterial cell walls, membrane proteins and efflux pumps, cytoplasmic organelles and cell respiratory processes, denatures enzymes and nucleic acid. This probably accounts for the lower rate of resistance found with antiseptics (Gilbert, 2006; Landis et al, 2007).

PHMB has been shown to reduce pain, and reduce bacterial colonisation in chronic wounds (Sibbald et al, 2009); and its successful use has been reported in treating diabetic (Feldman, 2009), venous (Foote, 2009) and compromised arterial ulcers (Herrington, 2009). In the treatment of tracheostomy wound sites, PHMB reduced more bacteria, including MRSA, compared to a control (Motta et al, 2004). In an audit of 19 500 operations, PHMB was found to reduce SSIs by 24%, with a 48% reduction in MRSA infections (Mueller and Krebsbach, 2008).

With the wide introduction of newer technologies for chronic wound management (such as negative pressure therapy and sophisticated debridement instruments) this additional use of wide antibacterial-spectrum antiseptics, such as the biguanides could be a useful addition to the wound care armoury.

AIM

The primary objective of the study was to compare two foam dressings containing different antiseptics – Kendall AMD antimicrobial foam dressing (PHMB) and Allevyn Ag (silver) – in the treatment of hard-to-heal venous leg ulcers in terms of reduction in ulcer size over a 12-week period.

METHOD

Sample

Adult male and female subjects with chronic venous leg ulcers were identified in outpatient wound clinics and invited to attend a research facility. Active wound care agents were not applied for up to 7 days before start of study treatment of a patient and topical antibiotics, antiseptics, enzymatic debridement agents were not used within 7 days prior to randomisation. Medications and therapies which inhibit wound healing (e.g. systemic corticosteroids, antiangiogenics, immunosuppresive agents, chemotherapy, radiotherapy) were not taken by trial patients.

Treatment

The wound bed was irrigated with saline solution and two microbiological swabs of the ulcer bed were taken. Wound fluid samples were collected at each visit.

Following appropriate wound bed preparation, wound specimens for bacteriological culture were obtained using sterile swabs, spatially obtained, from the wound base to allow assessment of microbial diversity across the wound bed. Swabs were transported to a microbiology laboratory and processed the same day. The wound specimens were added to 5 ml of sterile Brain Heart Infusion Broth, vortex mixed and subcultured onto a range of culture media, including blood agar, streptococcal selective agar, cysteine lactose electrolyte deficient agar, anaerobic selective agar, and MRSA selective agar, for quantitative assessment and isolation of pure colonies for identification purposes. Accurate quantification of all potential pathogens including MRSA was assessed using a Don Whitley spiral plater using further dilutions of the original sample. This was undertaken on all specimens taken over the length of the study period so that reduction in bacterial colonisation could be accurately assessed. The bacteria were identified and speciated using conventional techniques.

Depending on randomisation, a Kendall AMD dressing or Allevyn Ag dressing was applied to the ulcer surface. The dressings were kept in place by a retention bandage (Tubifast™, Mölnlycke Health

Care) and covered with a short-stretch compression system.

Procedure

Following fully informed written consent, subjects were randomised to one of the treatment groups using a computer programme.

The study was conducted over a 12-week period or until complete healing occurred (defined as 100% epithelialisation of the target ulcer), whichever occurred sooner. Dressings were changed and the treatment procedure repeated every 3 days (+/– 1 day). Clinical, microbiological, biochemistry, planimetric, and photographic assessments were made at visits to the clinical trial unit on days 0, 7, 14, 28, 56 and 84 (all +/– 1–2 days).

The sixth patient visit marked the end of the study intervention, following 12 weeks of treatment or healing, which may have occurred sooner.

Apart from the difference in the primary wound dressing administered, both groups were subjected to the same treatment procedures.

Wound biochemistry

Filter paper samples were collected and stored at –80˚C and transported to the research laboratory on dry ice. The filter paper samples were stored at –80˚C until wound fluid extraction.

Wound fluid was extracted by incubating each filter paper in 1 ml of phosphate buffered saline (PBS) solution for 2 hours at room temperature on an orbital shaker. Each sample was centrifuged at 2,100 rpm for 10 minutes and the diluted wound fluid (stock solution) was then pipetted, aliquoted and stored at –80˚C until analysis. Total protein analysis was performed in order for meaningful comparisons between samples to be made. The total protein assay used was Micro Lowry, Peterson's modification (Sigma Aldrich).

Wound fluid samples were diluted where necessary and run in duplicate following the assay protocols. For each biological factor, one ELISA was performed, first using an initial wound fluid dilution of 1:10 to determine the optimum dilution factor required. If the majority of samples had measurable levels at this dilution then the remaining samples were analysed. If samples had higher expression than the ELISA measured, they were then diluted further. However, if there was little or no expression at the initial 1:10 dilution then either high sensitivity ELISAs were tried for that factor (if available) or undiluted stock samples were tried.

The final concentration for each biological factor was determined from the standard curve. This was multiplied by the dilution factor to give a final concentration. This value was then divided by the total protein concentration for each sample (mg/ml) to give a final value of ng/mg protein or pg/mg protein for proteinases and cytokines respectively.

Statistical methods

All primary and secondary endpoints were analysed using descriptive statistics. Analysis was blind to group allocation and baseline outcomes were compared between the two groups. Analysis was conducted on the full dataset, based on the intention to treat principle. Primary analysis compared complete healing (as defined by complete epithelialisation without the presence of scab) or reduction in wound size between the groups. Statistical significance levels were set at P=0.05 (for the primary analysis with α=0.05).

Secondary endpoints related to pain experience, odour, exudate, reduction of bacterial burden (a minimum two-log reduction was considered significant – a two-log reduction means the number of organisms is 100 times smaller), development of clinical infection as reported by the clinician, changes in cytokines, growth factors, matrix metalloproteinases (MMPs) and tissue inhibitors of metalloproteinases (TIMPs), tolerability of the dressings, and condition of the wound bed and surrounding skin (all assessed by serial clinical, photography, and planimetry measurements).

Ethics

All necessary permissions were sought from the ethical review committee and local research and development departments. Participation was entirely voluntary and patient care was not affected in any way by their decision to participate or not.

RESULTS

Analyses were conducted on 32 subjects. Sixteen were treated with Kendall AMD antimicrobial foam dressing and 16 with ALLEVYN Ag hydrocellular antimicrobial dressing.

"Clinical, microbiological, biochemistry, planimetric, and photographic assessments were made at visits to the clinical trial unit"

Table 1. Wound duration, location, treatment group and ulcer size at baseline and end of study (week 12)

Patient number	Duration of wound (months)	Location of wound	Treatment group	Wound size (cm^2), week 0	Wound size (cm^2), week 12
001	26	Left medial malleolus	Kendall AMD	2.5	2.9
002	360	Right medial malleolus	Allevyn Ag	3.3	4.6
003	16	Left calf	Kendall AMD	8.4	14.4
004	2	Right gaiter	Allevyn Ag	7.3	0.0
005	240	Right medial malleolus	Kendall AMD	5.8	3.3
006	6	Right ankle	Kendall AMD	3.1	0.4
007	18	Right medial malleolus	Allevyn Ag	3.0	0.1
008	36	Right gaiter	Allevyn Ag	27.4	0.6
010	40	Left gaiter	Kendall AMD	17.9	0.0
011	7	Left medial malleolus	Allevyn Ag	5.8	0.3
012	2	Left gaiter	Kendall AMD	6.5	1.6
013	42	Left medial malleolus	Allevyn Ag	4.3	4.0
014	12	Left medial malleolus	Kendall AMD	2.1	0.0
015	41	Left gaiter	Allevyn Ag	46.5	32.2
016	6	Left gaiter	Kendall AMD	4.0	0.0
017	3	Right ankle	Allevyn Ag	3.6	0.0
019	2	Right lateral malleolus	Kendall AMD	3.1	0.0
020	240	Right gaiter	Allevyn Ag	2.6	0.9
021	39	Left gaiter	Kendall AMD	42.7	25.1
022	4	Right gaiter	Allevyn Ag	2.5	0.0
023	8	Right gaiter	Kendall AMD	3.8	0.0
024	7	Right gaiter	Allevyn Ag	2.1	0.2
025	25	Left medial malleolus	Kendall AMD	10.7	10.7
026	26	Left gaiter	Allevyn Ag	17.2	4.6
027	2	Left medial malleolus	Kendall AMD	4.2	0.0
028	10	Right gaiter	Allevyn Ag	16.9	1.8
029	13	Left medial malleolus	Kendall AMD	2.9	0.3
030	48	Left lateral malleolus	Allevyn Ag	6.5	8.0
031	7	Right gaiter	Kendall AMD	4.4	0.1
032	22	Right medial malleolus	Allevyn Ag	7.9	3.8
033	2	Right gaiter	Allevyn Ag	4.4	0.0
034	36	Left gaiter	Kendall AMD	3.5	0.0

Demographic baseline characteristics

The distribution of baseline demographic data between the subjects was very similar. The mean age of the cohort was 67.69 years (range 42–90 years of age, standard deviation [SD] 13.13) and there was similar proportion of males (53.1%) to females (46.9%). The mean height was 167.72 cm (range 148–191 cm, SD 9.94) and the mean weight was 99.74 kg (range 49 kg–163 kg, SD 28.15).

Ulcer characteristics at baseline (week 0)

The mean surface area measurement of the target ulcer at baseline was 13.37 cm^2 (range 2.1 cm^2–163.4 cm^2, SD 29.17). The mean duration of all target ulcers was 42.13 months (range 2–360 months, SD 80.97); 30 months in the Kendall AMD group and 54.25 months in the ALLEVYN Ag group (*Table 1*). More than two-thirds of the target ulcers (68.8%) were recurrent wounds. The mean ankle-brachial pressure index for the cohort was 1.19 mmHg (range 0.73 mmHg–1.69 mmHg, SD 0.19).

Wound bed appearance

The appearances of the wound bed at baseline are

Table 2. Clinical description of wound bed and surrounding skin by intervention at baseline and end of study (week 12).

Clinical descriptor	Kendall AMD (*n*=16)		Allevyn Ag (*n*=16)	
	Week 0	Week 12	Week 0	Week 12
Wound malodour				
Yes	3	0	1	0
No	13	15	15	15
Slough/necrosis				
0–50%	3	1	3	0
>50%	1	1	2	0
Granulation				
0–50%	13	1	6	8
>50%	3	5	8	3
Exudate				
None	0	8	0	4
Minimal	6	8	3	9
Moderate	8	0	10	2
Heavy	2	0	3	1
Copious	0	0	0	0
Condition of periulcer skin				
Healthy	0	0	0	0
Erythema	16	9	11	5
Maceration	1	0	1	1
Eczematous	14	13	15	13
Other*	16	16	16	16

*The descriptors for "other" periulcer skin conditions included: dry/flaky, haemosiderin, oedema, atrophe blanche, fragile, scarring, lipodermatosclerosis.

outlined in *Table 2*. There were no statistically significant differences in the clinical condition of the ulcers by intervention. The majority of ulcers were not malodorous (87.5%; *n*=28), with 9.38% (*n*=3) of ulcers having slough covering more than half of the wound bed and 34.38% (*n*=11) having granulation tissue covering more than half of the wound bed. Where exudate was present, this was minimal (28.13%; *n*=9) or moderate (56.25%; *n*=18). The periulcer skin was described as erythema in 84.38% (*n*=27) and eczematous in 90.63% (*n*=29).

Primary outcome – healing at week 12

Statistical analysis was carried out on the end of intervention (week 12) data. A chi-squared test value of 0.468 was observed, indicating that there was no statistically significant difference in healing outcome between treatment groups.

Eleven (34.38%) ulcers were classified as healed at 12 weeks; seven (63.64%) from the Kendall AMD group and four (36.36%) from the ALLEVYN Ag group. The majority (84.38%; *n*=27) of ulcers had reduced in area. Five ulcers (15.62%) increased in size (three from the Kendall AMD group and two from the ALLEVYN Ag group; *Table 3*).

Pain

Pain was measured using a self-administered visual analogue scale (VAS) at each treatment visit. Patients were requested to draw a line on the scale that best described the level of pain they had experienced during the previous week. A score of 0 represented no pain and 100 represented worst pain. The mean pain score relating to pain experienced since the last study visit for the whole cohort was 23.78 (range 0–72, SD 22.53) at screening, 21.44 (range 0–70, SD 21.34) at week 0, 18.58 (range 0–84, SD 20.72) at week 1, 13.16 (range 0–52, SD 15.16) at week 2, 10.04 (range 0–52, SD 14.35) at week 4, 11.32 (range 0–65, SD 19.51) at week 8, and 6.22 (range 0–72, SD 15.73) at week 12.

The mean pain score for the Kendall AMD group reduced from 26.44 at week 0 to 10.69 at week 12; and in the ALLEVYN Ag group reduced from 16.44 at week 0 to 1.75 at week 12. Overall pain reduction was greater for those subjects in the Kendall AMD arm, however, mean pain scores indicated little pain or minimal discomfort overall for both groups during the study period.

Microbiology

A total of 23 different bacterial organisms were identified during the study. Eight patients showed more than a two-log decrease in bioburden throughout the study, four from each treatment group. A further eight patients showed more than a one-log decrease in bioburden, five from the Kendall AMD group and three from the ALLEVYN Ag group.

Biochemistry

The biochemical environment of chronic wounds may be studied using tissue samples or wound fluid/wound exudate samples, as were used in this study). Wound fluid sampling is the preferred method as it is less invasive and, therefore, better tolerated by patients (Loffler et al, 2011), but no standardised,

reproducible, or optimum method of chronic wound fluid collection for biochemical analysis has been described to date.

MMPs play important roles in wound healing including the removal of damaged matrix, aiding cell migration and remodelling the new scar matrix, but these are dependent on the rate of MMP synthesis, their activation and the levels of their inhibitors, TIMPs. Synthesis of MMPs and TIMPs is regulated by various growth factors and cytokines (Schultz and Mast, 1999).

The expression of MMPs 1, 2, 3, 8 and 9 and TIMPs 1 and 2 was determined in wound fluid samples. Wound fluid samples were analysed for three cytokines: interleukin-6 (IL-6), tumor necrosis factor alpha (TNF-α), and interleukin-1 beta (IL-1β), as well as five growth factors: transforming growth factor beta-1 (TGF-β1), basic fibroblast growth factor (bFGF), epidermal growth factor (EGF), platelet derived growth factor (PDGF), and vascular endothelial growth factor (VEGF).

Proteinase activity has been shown to be significantly elevated in chronic wound fluid compared to acute wounds (Bullen et al, 1995; Yager et al, 1996). The predominant MMPs observed in wound fluid samples from this study were MMP-8 and MMP-9, with lower levels of MMP-1 and MMP-2. This finding echoes previous studies that have shown MMP-8 to be the predominant collagenase and MMP-9 the predominant gelatinase expressed in chronic wounds (Nwomeh et al, 1999).

In addition to the high levels of proteinases, lower levels of their inhibitors TIMP-1 and TIMP-2 were also observed. This could lead to increased tissue degradation rather than tissue remodelling and, therefore, delayed healing (Bullen et al, 1995).

The cytokines and growth factors that were expressed in high amounts in the samples in this study were IL-6, IL-1β and VEGF with lower levels of TNF-α. Previous studies have found high levels of IL-6, IL-1β and TNF-α in chronic wound fluid with higher levels in wound fluid from nonhealing ulcers when compared to healing ulcers (Harris et al, 1995).

In this study, not all of the biological factors analysed were present in detectable levels in the wound fluid samples and there was a large variation in the levels of each factor expressed, but there were no obvious differences observed between the levels of the studied biological factors with either the treatment group or whether the wound had healed.

Table 3. Primary outcome: Healing outcome at week 12 and percentage change in ulcer area.

Patient number	Treatment group	Healed	% Reduction in ulcer area
001	Kendall AMD	No	–7.4
002	Allevyn Ag	No	–9.5
003	Kendall AMD	No	–132.3
004	Allevyn Ag	Yes	100
005	Kendall AMD	No	28.3
006	Kendall AMD	No	90.9
007	Allevyn Ag	No	97.6
008	Allevyn Ag	No	96.1
010	Kendall AMD	Yes	100
011	Allevyn Ag	No	92.3
012	Kendall AMD	No	64.4
013	Allevyn Ag	No	21.6
014	Kendall AMD	Yes	100
015	Allevyn Ag	No	28.4
016	Kendall AMD	Yes	100
017	Allevyn Ag	Yes	100
019	Kendall AMD	Yes	100
020	Allevyn Ag	No	59.1
021	Kendall AMD	No	39.7
022	Allevyn Ag	Yes	100
023	Kendall AMD	Yes	100
024	Allevyn Ag	No	90.5
025	Kendall AMD	No	–4.9
026	Allevyn Ag	No	62.6
027	Kendall AMD	Yes	100
028	Allevyn Ag	No	90
029	Kendall AMD	No	90.3
030	Allevyn Ag	No	–21.6
031	Kendall AMD	No	98
032	Allevyn Ag	No	42.4
033	Allevyn Ag	Yes	100
034	Kendall AMD	Yes	100

Treatment assessment

Treatment satisfaction and dressing tolerability were recorded by the participants on a VAS where 0 represented not satisfied and 100 represented very satisfied. The mean score for treatment satisfaction across the whole cohort was 87.88 (SD 24.22; mean 90.56 in the Kendall AMD group and 85.19 in the ALLEVYN Ag group). The mean score for dressing tolerability across the whole cohort was 83.69 (SD 25.32), with a mean of 85.69 in the Kendall AMD

"Eleven ulcers were classified as healed at 12 weeks; seven from the Kendall AMD group and four from the ALLEVYN Ag group."

"There was a wide range in the levels of the studied biological factors expressed in each chronic venous ulcer fluid sample."

group and 81.69 in the ALLEVYN Ag group, indicating a high level of treatment satisfaction and dressing tolerability for both dressings.

Assessments of efficacy and tolerance were completed by the investigator using responses from a pre-defined Likert-style list. Efficacy was scored in relation to wound status; the majority of wounds (*n*=13 in Kendall AMD group and *n*=14 in ALLEVYN Ag group) were defined as improving or healed. Tolerance was rated as very good, good tolerance, poor or zero tolerance. The majority of wounds (84%) were rated as very good or good (*n*=14 in Kendall AMD group and *n*=13 in ALLEVYN Ag group), indicating, a high level of efficacy and tolerance for both dressings.

DISCUSSION

One of the aims of this study was to link microbiological and biochemical data with clinical data from patients with chronic venous leg ulcers. It is hard to make comparisons between previously published biochemical studies as even when using the same dressing for wound fluid collection other factors were often not standardised. For example, some studies wash out the wounds before sampling to minimise bacterial contamination. However, this may uncontrollably dilute the wound fluid so much that any biological factor measured may not reflect the actual levels in the wound. Also the length of time a dressing was in place for wound fluid collection, varied from minutes to days. Clearly this would also influence the levels of any biological factors present. No standardised, reproducible or optimum method of chronic wound fluid collection for biochemical analysis has been described to date.

This study used a standardised method for collecting chronic wound fluid, whereby a piece of filter paper was placed onto each chronic venous ulcer, at allocated dressing changes for a set time. The wound fluid, transferred from the venous ulcer, was extracted by incubating the filter paper in a predetermined volume of PBS for a set time. The total protein content was determined for each sample so that comparisons could be made between patients to allow for any difference in the volume of wound fluid within each filter paper. This allowed the concentration of biochemical markers from each sampling to be assessed more accurately.

There was a wide range in the levels of the studied biological factors expressed in each chronic venous ulcer fluid sample. In addition, variations were observed both between and within patients' samples for each factor over the period of the study. This lack of trends or correlation of biochemical markers reflects the lack of correlation of clinical data in progress (healing, static or worsening between the two groups) or to microbiological data which was found in other aspects of the study. It is possible that regression analysis may reveal correlation between biochemical markers and clinical or microbiological data, for example the expression of pro-inflammatory markers may reflect poor clinical progress or increasing microbiological bioburden.

Recognition of the rise in multi-resistant bacteria and over-usage of antibiotics has led to a huge resurgence in the use of silver to treat chronic wounds at risk of infection. However, the debate over the cytotoxicity of silver dressings, particularly on fibroblasts, continues. Zou et al (2013) reported that all silver dressings tested in their study were found to reduce the viability of the diabetic fibroblasts and collagen synthesis and also to change the cell morphology significantly to decrease cell proliferation. These results have reinforced the recent controversy concerning silver dressings, adding to the evidence that silver has significant toxic effects on morphology, proliferation and collagen synthesis of diabetic fibroblasts. Conversely, it should be noted that cytotoxicity seen in the laboratory has not been reflected in clinical practice and consensus statements on antibacterials used in wound healing put forward the view that silver has a place in the wound management armamentarium. However, in light of this debate it is necessary to investigate the availability of more potential and safe options to reduce antibacterial resistance development associated with the management of at-risk wounds.

Due to the small number of participants recruited into this pilot study it was not feasible to conduct detailed statistical analyses. However, descriptive statistics demonstrated that PHMB contained within a foam dressing compared favourably with a comparable silver dressing in all aspects of wound healing and bioburden reduction.

In this study not all of the biological factors analysed were present in detectable levels in the wound fluid samples. This also corresponds with

previous research that has suggested that certain growth factors, e.g. EGF, PDGF and TGF-β, are degraded by the high levels of proteinases present in chronic wound fluid which impacts on the wounds ability to heal (Wlaschek et al, 1997; Yager et al, 1997). There was a large variation in the levels of each factor expressed, but there were no obvious differences observed between the levels of the studied biological factors with either the treatment groups or in healed versus non-healed wounds. No statistical analysis was performed on the data due to the relatively small sample size, the large variation in expression observed and the large number of factors analysed.

Previous studies have looked at either the biochemical characteristics of chronic wound fluid or the wound microbiology. However, to our knowledge, this is the first study to try and link clinical and biochemical data from the same patients. It is hard to know whether the previous gap in the literature is purely down to lack of work in this area or whether it is due to publication bias (Dickerson and Rennie, 2003).

It is recognised that the patient's psychological state is negatively related to wound healing outcomes (Walburn et al, 2009;Vedhara et al, 2010). There is increasing recognition that health-related quality of life (HRQoL) should be included in reviews of new and existing therapies, ensuring that importance is placed on the impact of wound management on the patient. Patients' experiences of living with a chronic wound have been investigated by a number of authors, and a recent consensus document on optimising wellbeing in people living with a chronic wound stated that pain, anxiety, embarrassment associated with wound odour, social life restriction, negative self-image and low self-esteem are among the greatest challenges faced by patients (International Consensus, 2012). Although HRQoL was not formally assessed in this pilot study, data were collected on pain, odour, tolerability, satisfaction and efficacy with the investigated products, and positive outcomes were recorded in all aspects for the studied cohort.

CONCLUSIONS

The results of this small pilot study met the clinical objectives set out in the protocol and provided good evidence to show that Kendall AMD antimicrobial foam dressing had positive healing outcomes for some patients with hard-to-heal venous leg ulcers. The study treatment was well-tolerated by the patients overall, and the level of satisfaction with the treatment was also high.

The aim of this pilot evaluation was to demonstrate whether Kendall™ AMD provided efficient and equivalent wound management when compared to a widely used antimicrobial dressing (ALLEVYN Ag) for hard-to-heal venous leg ulcers. Such small scale evaluations are primarily conducted to determine lack of adverse effects, ease of use and patient tolerability compared to the norm, prior to investing in a larger scale evaluation. It was not intended to demonstrate superiority to existing products.

There is evidence from this study to suggest that Kendall AMD antimicrobial foam dressing is an efficient wound management product for hard-to-heal venous leg ulcers.

Further research is required to explore the incidence of healing on a larger study population and to further explore the efficacy of Kendall AMD antimicrobial foam dressing against other modalities of ulcer care. A cost-effectiveness analyses should be considered for future investigation with particular focus on frequency of dressing change and nature of adverse events. WUK

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