

Evaluating a dressing impregnated with polyhexamethylene biguanide

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Aims: To evaluate a new polyhexamethylene biguanide (PHMB) foam dressing for inclusion in the specialist dressing section of a trust's wound management formulary. **Methods:** Kendall™ AMD (Covidien) antimicrobial foam dressing's use was reviewed through a retrospective evaluation of patients who had been treated with the dressing. Data was collected from the medical and nursing notes of 25 patients. **Results:** All 25 patients showed improved healing outcomes, with nine patients achieving complete closure during the evaluation period. No adverse incidents were noted. **Conclusions:** The foam dressing impregnated with 0.5% PHMB featured in this article performed well in the evaluation. The dressing was acceptable to both clinicians and patients and demonstrated a potential cost-saving. **Conflict of interest:** None.

KEY WORDS

Wound Infection
Antimicrobial dressings
Product evaluation
Polyhexamethylene biguanide (PHMB)

The prevention and effective management of wound infection is always a high priority for clinicians. Over the past decade there has been a change in practice whereby the use of topical antimicrobial agents has become widespread. The indiscriminate use of antibiotics is now discouraged because of the associated risks of the development of resistant organisms (Kingsley et al, 2006; Leaper, 2010; Best Practice Statement, 2011), and concerns that fewer new effective agents will be available in the future (Conley and Johnson, 2005).

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In support of this change in practice, File and Carter (2010) reviewed the available evidence and suggested that the 'early, judicious' use of antimicrobial dressings may reduce the bacterial

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burden in the wound, although they acknowledged that there are no controlled studies to support this theory. Despite this lack of evidence, the use of antimicrobial dressings is now established as an infection prevention and control strategy in wound management and, to date, dressings impregnated with silver; honey and iodine have all been used effectively (Fife and Carter, 2010).

One function of a specialist wound care service is to evaluate new products as they become available, and to recommend whether they should be included in a wound care formulary. This responsibility includes reviewing new antimicrobial wound care products for general use in an organisation where

there is a risk of wound infection. The mode of action, efficacy and the risk of toxicity should also be considered, in addition to the properties of the carrier dressing. The wound care team also has to consider the cost impact of a new product on the overall dressing budget, the aim being to contain or reduce the current expenditure without compromising patient outcomes.

Polyhexamethylene biguanide (PHMB) is a synthetic compound, similar to naturally occurring antimicrobial peptides (AMPs) (Kingsley, 2009), which has become used in wound dressings, including non-adherent products, gauze, drains and intravenous sponges (Moore and Gray, 2007). This 25-patient evaluation looked at the effectiveness of a foam dressing with PHMB.

PHMB: resistance and toxicity

When considering a new technology or dressing for inclusion in the trust wound management formulary, the wound care service, in conjunction with the trust wound management group, will initially undertake a literature review. This includes looking for evidence to support the claims of efficacy against a wide range of bacterial species, information with regards to toxicity, the speed of action and the potential for resistance.

A review of the literature on PHMB identifies it as an antiseptic with a broad spectrum of activity, able to act on multiple target sites within the bacteria and presenting a low risk of generating resistance mechanisms (Gilbert, 2006). As an antimicrobial agent, PHMB has a long history of use spanning 60 years in applications such as disinfection solutions for contact lenses (Larkin et al, 1992), swimming pool cleaners and baby wipes, and is widely used in the food industry, although it has only recently been introduced into wound care products. Despite this widespread use, there are no reports of bacteria acquiring resistance to PHMB (Gilliver, 2009).

Bacteria can develop resistance to antibacterial agents through a variety of mechanisms. The concentration of an antimicrobial agent, such as PHMB, within a bacterial cell is controlled by the permeability of the membrane that surrounds the cell and which regulates influx and efflux (Mahamoud et al, 2007). In order to protect themselves against harmful substances, some bacteria employ an 'efflux pump mechanism', whereby molecules of the agent are evacuated from the cell before they can become effective (Tenover, 2006).

The mode of action of PHMB, as well as its target sites on the bacteria, suggest that the development of resistance is highly unlikely (Hübner and Kramer, 2010). It consists of positively charged molecules that are attracted and bind to the negatively charged bacterial cell membranes. These molecules disrupt the bacterial cell membrane and the cytoplasmic contents are expelled, killing the cell (Gilbert, 2006). As PHMB works on the bacterial membrane rather than inside the cell itself, the efflux pump mechanism cannot be employed by the cell as a defence.

The effectiveness of PHMB against common pathogens found in wounds was also considered in a review of the literature provided by the manufacturer, although the evidence for this was limited to *in*

vitro studies (Shah et al, 2009). When using standard methods employed in testing antimicrobial agents, PHMB was effective against a number of pathogens including *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli* and *Candida albicans* (Shah et al, 2009).

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Antiseptic dressings and clinical practice

As a result of its longevity as a safe antiseptic, for example, in contact lens solution, and its mode of action, particularly its ability to act on multiple target sites within the bacteria and presenting a low risk of generating resistance mechanisms, the wound care service at the authors' trust were interested in undertaking a product evaluation of a PHMB wound care product, Kendall™ AMD antimicrobial foam dressing (Covidien). The manufacturers describe the carrier foam as comprising an outer open-cell foam surface, which is designed to facilitate exudate absorption, and a denser inner core designed to retain fluid. Exudate is absorbed into the dressing, allowing the PHMB within the dressing to act upon the bacteria.

At the time of this evaluation there was little published data on the Kendall AMD antimicrobial foam dressing, although an *in vitro* study has examined the antimicrobial efficacy of the dressing against a standard foam in a challenge assay test using *Staphylococcus aureus*, including Metcillin-resistant *S. aureus* (MRSA), *Pseudomonas aeruginosa*, vancomycin-resistant enterococcus (VRE), *Candida albicans*, *Staphylococcus epidermidis*, *Enterococcus faecalis*, and *Escherichia coli*. The results suggested that the presence of PHMB could reduce the microbial count more than 99.9% when compared to a standard foam product (Shah et al, 2009).

Kendall AMD antimicrobial foam dressing was also compared to other commercially available antimicrobial foam and non-foam dressings *in vitro* using clinically relevant organisms (MRSA, VRE, and *P. aeruginosa*). The results indicated that under test conditions, Kendall AMD antimicrobial foam dressing sustained a >3-log reduction in all three organisms for seven days (McGhee and Shah, 2009).

Clinical studies undertaken on this dressing suggest, therefore, that it may have the potential to be an effective bacterial barrier as well as being acceptable to patients. In particular, Sibbald et al (2009) demonstrated a decrease in superficial bacteria and a statistically significant reduction in pain ($p=0.0225$ at four weeks). In a double-blind randomised controlled pilot study conducted on 40 patients with leg and foot ulcers, where Kendall AMD antimicrobial foam dressing was compared to a standard foam product, a reduction in pain was noted (Sibbald et al, 2009). This was also reported in further studies (Hagelstein and Harding, 2009; Keast et al, 2009) and is an important consideration when patient comfort is required to maintain concordance with a dressing.

Method

A small ($n=50$) prospective product evaluation of Kendall AMD antimicrobial foam dressing was undertaken within the authors' trust when the product initially became available and, while the dressing improved healing outcomes, it was applied only to inpatients. As the use of the dressing increased, due to the successful evaluation on inpatients, so did the requirement to use it on outpatients where care was shared with the community nursing services.

When the decision was made for a formulary inclusion, the use of Kendall AMD antimicrobial foam dressings by community staff was reviewed through a retrospective evaluation of patients. Data was collected from the medical and nursing notes of 25 patients who had attended on an outpatient basis and who were also

Table 1
Wound aetiologies seen in the study

Acute wounds		Chronic wounds	
Failure-to-heal surgical wounds	8	Leg/foot ulcer (non-diabetic)	10
Excision/surgery in 'at-risk' wound	3	Foot ulcer (diabetic)	2
Prior/after skin grafting	2		
Total	13		12

treated by community nurses. This was a convenience sample of patients who were followed up by the wound care service for the period of the evaluation.

Information on patients who were discharged from the outpatient services or lost to follow-up before the end of the evaluation was discounted. As the dressing was a new product, the views of the patients and those of the staff treating them were collated. The patient population was reflective of those treated in any busy wound care clinic. There was a wide variety in the ages of those treated (15 male and 10 female) ranging between 18–92 years. There was also a number of different wound aetiologies (Table 1), although the common factor in all of the wounds, as assessed by the clinician, was that they required an antimicrobial dressing.

Doncaster and Bassetlaw Hospitals Foundation NHS Trust operates a strict policy preventing the indiscriminate use of topical antimicrobial dressings, which reflects national recommendations (Best Practice Statement, 2011). While specific honey, silver and iodine products are listed on the trust's formulary, the

wound care guidelines suggest that they should be used for a period of two weeks before the wound is reassessed. If the wound is not improving, the treatment is not reapplied. Long-term use is discouraged and only recommended in patients who are considered to be at 'high risk' of infection. The use of Kendall AMD antimicrobial foam dressing within the evaluation was subject to the recommendations made in the guidelines.

After a full patient and wound assessment by a member of the wound care service, Kendall AMD antimicrobial foam dressing was applied to each wound. All wounds were assessed as requiring an antimicrobial dressing based on the clinical signs and symptoms, i.e. inflammation, including redness, heat and pain (Cutting and Harding, 1994; European Wound Management Association [EWMA], 2006; World Union of Wound Healing Societies [WUWHS], 2008).

In 18 patients, the wounds were described as 'heavily colonised', whereas five were considered to be 'locally infected' or 'critically colonised'. Two

patients had wounds that were not progressing and swab results confirmed that MRSA was present, although there were no patients with a systemic infection that required antibiotic therapy.

In 12 patients, wound odour was also recorded.

Results

Clinical outcomes

The length of time in which Kendall AMD antimicrobial foam dressing was used varied from seven to 28 days, depending on the patient's infection status and wound progression.

A review of the wound outcomes demonstrated that:

- ▶▶ Nine wounds had progressed to healing
- ▶▶ In the remaining 16 patients, there was an overall reduction in devitalised tissue and a recorded improvement in the condition of the wound bed
- ▶▶ In the two patients with MRSA present in their wound, repeat wound swab results were negative and the wounds improved
- ▶▶ In all patients, the level of exudate reduced at the end of the evaluation. It was recorded as 'low' in 15 patients and described as 'moderate' in one case
- ▶▶ Only one patient was noted as having wound odour at the end of the evaluation
- ▶▶ No new infections were recorded.

User opinion

As part of the evaluation, clinicians and patients were asked for their opinion when using Kendall AMD antimicrobial foam dressing, with the following results:

Table 2
The comparative weekly cost by patient

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9
Standard care	£80.20	£80.20	£80.20	£80.20	£31.36	£58.20	£30.40	£56.76	£37.84
Revised care	£30.62	£30.62	£61.24	£61.24	£61.24	£30.62	£30.62	£30.62	£30.62
Budgetary impact	£49.58	£49.58	£18.96	£18.96	-£29.88	£27.58	-£0.22	-£26.14	£7.22

- ▶▶ When used on 24 patients, the dressing was rated as 'easy' or 'very easy' to apply and remove
- ▶▶ Only one patient reported the dressing to have stuck to the wound, which may have been related to a low level of exudate
- ▶▶ Twenty-four patients reported the overall comfort of the dressing to be 'good' or 'very good'.

Budgetary implications

The primary aim of the study was to evaluate how Kendall AMD antimicrobial foam dressing had performed when used in an uncontrolled environment, both as a bacterial barrier and in reducing bioburden in heavily colonised and locally infected wounds. However, cost is always a major consideration and, therefore, it was also useful to observe how the product was applied in clinical practice and whether introducing it would incur any additional expenditure.

The fact that nine of the patients' wounds healed during the course of the evaluation provided an opportunity to undertake a simple health economic analysis to identify any cost benefits (Drummond et al, 2005). A comparative cost analysis of treatment for the two approaches, i.e. before and after the use of Kendall AMD antimicrobial foam dressing was undertaken, although this was a conservative analysis since it did not include any cost-savings arising from an improved healing rate, as this would have represented an additional benefit. The treatments were recorded as 'actual' costs, which were calculated from each patient episode and included the cost of both the dressings and also the nursing time, based on the frequency of dressing changes.

As these patients were treated as outpatients, the cost of nursing care was calculated using the Personal Social Services Research Unit (PSSRU, 2009; www.pssru.ac.uk) system, with the price of dressings taken from the 2010 *Drug Tariff* (May).

Information from the patients' notes identified that a number of different dressings had been used before the evaluation, ranging from silver or iodine

dressings with a secondary foam dressing, to foam-only being used as a primary dressing. The frequency of dressing change was weekly or twice-weekly. *Table 2* demonstrates the comparative weekly cost by patient. It identifies that when treating these nine patients, £1 67.92 per week was saved by using Kendall AMD antimicrobial foam dressing instead of the original regimen. The care costs of two of the patients was higher when using the Kendall AMD antimicrobial foam dressing, but it should be noted that as these wounds were not improving with previous treatments, the overall cost may have eventually been higher anyway.

The evidence on the use of PHMB suggests it is a safe and effective antimicrobial agent (Motta and Trigilia, 2005; Moore and Gray, 2007) and, when impregnated into a foam dressing, can provide an alternative to silver, iodine and honey when attempting to prevent and manage wound infection.

Discussion

Nurses in clinical practice have to base their choice of dressings on the best available evidence, and assess the risk of using the product against the possibility of favourable healing outcomes. They have a professional responsibility to use antimicrobial agents sensibly, using the most appropriate product for each clinical situation.

The evidence on the use of PHMB suggests it is a safe and effective antimicrobial agent (Motta and Trigilia, 2005; Moore and Gray, 2007) and, when impregnated into a foam dressing, can provide an alternative to silver, iodine and honey when attempting to prevent and manage wound infection.

It is important that clinicians who manage patients with complex wounds have access to a range of effective antimicrobial dressings. This small evaluation suggests that Kendall AMD antimicrobial foam dressing impregnated

with 0.5% PHMB can be a useful addition to wound care formularies. In the authors' trust, it is now used with other antimicrobial dressings and, as a result, the trust's overall expenditure on this class of dressings continues to reduce.

Conclusion

The foam dressing impregnated with 0.5% PHMB featured in this article performed well in the evaluation. All of the wounds improved, with nine patients progressing to healing, and the dressing was acceptable to both clinicians and patients. It also demonstrated a potential cost-saving.

The authors recognise that this is a small-scale study undertaken in an uncontrolled environment and that a larger, more controlled evaluation would have to be performed to produce more accurate and scientific outcomes.

However, in a clinical situation, there is not always the time or resources to perform sophisticated research and, therefore, small-scale product evaluations can be useful in deciding whether to include products on a trust's wound care formulary. **WUK**

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Key points

- ▶▶ The prevention and effective management of wound infection is a high priority for clinicians.
- ▶▶ One function of a specialist wound care service is to evaluate new products as they become available and to recommend whether they should be included in a wound care formulary.
- ▶▶ PHMB is an antiseptic with a broad spectrum of activity, able to act on multiple target sites within the bacteria, presenting a low risk of generating resistance mechanisms.
- ▶▶ Nurses have a professional responsibility to use antimicrobial agents sensibly, using the most appropriate product for each clinical situation.
- ▶▶ Nurses in clinical practice have to base their choice of dressings on the best available evidence, and assess the risk of using the product against the possibility of favourable healing outcomes.

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