PHMB: Does it have a role in wound care?

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ABSTRACT

Polyhexamethylene biguanide (PHMB) is a broad spectrum antimicrobial agent. Used widely within Europe and the US in a myriad of applications from swimming pools to contact lens solutions. However its use as a topical application for wound care has not been widely adopted – especially within the UK. A literature clinical evaluation was conducted in accordance with the Medical Device Directive and database results were screened and abridged based on GHTF quality criteria. The resulting clinical information was extracted and reviewed.

The evidence demonstrates PHMB to have excellent bacteriocidal properties whilst offering very low toxicity in humans, does not causes skin sensitivity in normal concentrations. Furthermore there is no evidence of bacterial resistance, and is highly biocompatible. It was clear that PHMB offers an excellent tool to clinicians in both preventing and treating infected wounds.

Background

Chronic wounds

- Cost the NHS around £3bn every year, Affect 200,000 individuals at any one time.
- Bacterial colonisation are both complex and controversial.
- Once bacterial colonisation is established, wound healing is significantly reduced, or halted exacerbating the pain, discomfort and reduced quality of life for patients.

Polyhexamethylene biguanide (PHMB) is a cationic biocide which binds to negatively charged phosphate groups of bacterial phospholipid walls. This in turn disrupts the membrane, causing cytoplasmic shedding and cell death. However due to this selection and similarity to our own Antimicrobial Peptides (AMPs) means it leaves mammalian cells intact.

Used extensively for over 60 years, PHMB is used in

- contact lens solutions,
- swimming pools,
- wound irrigation solutions,
- eye washes in the treatment of acanthamoeba keratitis.

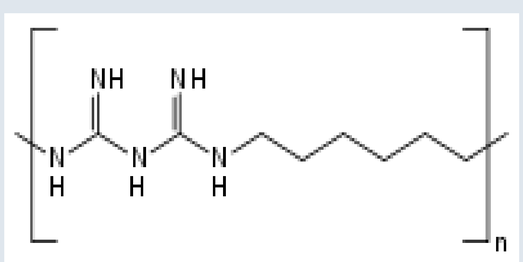

Image1: PHMB structure

Methods

A literature clinical evaluation was conducted in accordance with EU Directive 93/42/EEC (medical device directive), and guidelines from MEDDEV and Global Harmonisation Task Force (GHTF).

A literature search review plan was created detailing:

- Database selection
- Search terms (for each database)
- Characteristics
  - must contain PHMB,
  - delivery vehicle (e.g. foam, cellulose or gauze)
  - used in wound care (any aetiology)

An exclusion criterion was then defined to shortlist potential literature. Using three phases below:

- **Phase 1**: Review title only
- **Phase 2**: Review abstract
- **Phase 3**: Review full text; Extract data

Papers undergoing phase 3 were scored based on the quality and relevance using the GHTF scoring system. An example of the data extraction form is shown below (table1)

APPENDIX V: COPIES OF ACCEPTED LITERATURE

Source	Author	Title	Journal	D	A	P	R	Total	Status	Performance / Safety	Device	Use	Patient #	Outcome Assessment
Google Scholar	Alb-las, J.	Clinical evaluation of a PHMBimpregnated biocellulose dressing on paediatric lacerations	*journal of wound care*	1	1	2	1	5	Included	Performance / Safety	Suprazorb X + PHMB	lacerations	20	Twenty children (mean age 5.6 years (±1.33) were recruited into the study and included in the analysis. The mean baseline wound area was 8.60cm2 (±6.57). The mean time to complete wound closure was 12.95 days (±7.69) with a mean total of 4.70 visits (±1.56). The mean VAS pain score was 9.55 (±0.69), compared with 0.15 (± 0.37) on day 14 (p<0.003). At the second visit (after 3 days) 17 of the 20 children were reported to be free of pain. No cases of local infection were noted. Conclusion: The dressing was found to be child and parent friendly. The evaluation also showed that it was well tolerated and achieved good healing outcome. It has now been incorporated into the clinic's treatment protocol for these wounds.
EBSCO	Faby	Bacterial decontamination of surgical wounds treated with Lavasept®	*International Journal Of Hygiene And Environmental Health*	3	3	1	1	8	Included	performance	Lavasept	various	50	The aim of the present study was to answer some outstanding microbiological questions on the clinical value of the novel antiseptic Lavasept®. The results obtained confirm the following issues: In the management of surgically radically debrided but still bacterially contaminated soft tissue wounds Lavasept® can lead to faster and significant reduction of microorganisms on wound surfaces in comparison with Ringer solution. Application of the novel antiseptic Lavasept® to bacterially contaminated soft tissue wounds does not lead to the impairment of wound healing described after use of older antiseptics. In this double-blind evaluation 0.2% Lavasept® solution was significantly better rated in regards to tissue compatibility than Ringer solution. The qualitative and quantitative microbiological investigations indicate the good antimicrobial action of Lavasept® treatment in comparison to control treatment with Ringer's solution. It is concluded that Lavasept® combines antiseptic action with good tissue compatibility

Table 1: Example of literature data extraction

Results

The largest search results came from Google Scholar with 3290 articles from the initial search, and 78 from EBSCOhost (which included PubMed, CINHAL etc.).

Table 2 shows the proportion of search results making it to phase 3.
Table 3 shows the results of the phase reviews shown as a 100% stacked bar chart

Database	Phase 3	Actual
EBSCOhost	46%	n=36/78
Google Scholar	3%	n=86/3290
MHRA/MAUDE	0%	n=0/2
Cochrane	0%	n=0/1
NHS CRN/CT	6%	n=1/18
BSI	0%	n=0/20

Table 2: Proportion of articles making it to phase 3 review.

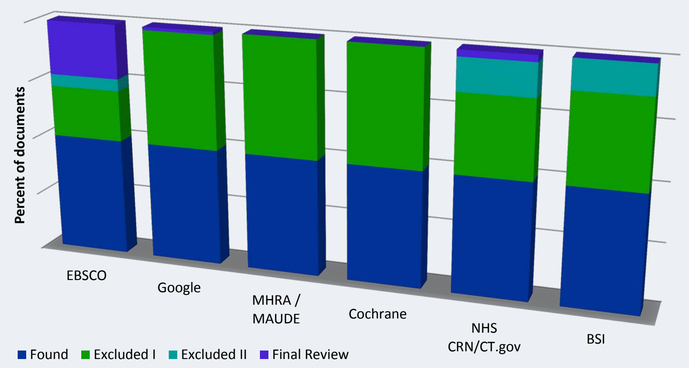

Table 3: Results of literature screen (100% stacked)

Conclusion

A number of key conclusions can be drawn from the systematic review of current literature, as it relates to PHMB in wound care.

- PHMB has been in use for 60 years within Europe & US
- Similarity with antimicrobial peptides means it kills bacteria leaving mammalian cells intact
- Effective on bacteria, viruses, fungi, yeasts.
- No evidence of bacterial resistance
- Very low toxicity
- Non-sensitising
- Highly biocompatible (outperforms chlorhexidine, iodine, triclosan, silver)

Based on all the information in the current literature, and the absence of any adverse events reported, it would be sensible to conclude that PHMB offers a safe alternative to current topical therapies.

- PHMB offers an opportunity to incorporate a new method of bacterial control which has been proven to be safe, efficient and cost effective.
- Useful in both the treatment and prevention of wound colonisation.
- The use of PHMB in wound dressings provides huge benefits to patients, and provides clinicians with an effective tool.

Declaration of interest:
The author is employed by Brightwake Ltd, as Head of Quality & Regulatory Affairs. Brightwake Ltd, is part of Advancis Medical, an innovative wound care design and manufacturing company.