

## Evidence summary: Polyhexamethylene biguanide (PHMB) wound dressings

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### QUESTION

What is the best available evidence in the effectiveness of polyhexamethylene biguanide (PHMB) for managing wounds?

### CLINICAL BOTTOM LINE

Polyhexamethylene biguanide (PHMB) products are an alternative to topical antiseptics and antibiotic creams.<sup>1, 2</sup> In-vitro studies have shown reduction in bacterial levels<sup>3-6</sup> and clinical signs of infection<sup>7, 8</sup> associated with PHMB solutions and impregnated wound dressings. Compared to silver dressings and silver sulfadiazine with gauze, PHMB-impregnated dressings promote faster wound healing;<sup>7, 9</sup> however, no differences in wound healing rates have been shown compared to foam dressings.<sup>5</sup> PHMB dressings have been associated with reduction in wound pain both during and in-between wound dressing changes.<sup>5, 7, 9-12</sup> PHMB dressings are a cost-effective wound management strategy<sup>8-10, 12, 13</sup> that could be considered for wounds without heavy exudate.<sup>14</sup>

### BACKGROUND

Polyhexamethylene biguanide (PHMB), an antiseptic, is a synthetic compound that has a chemical structure similar to antimicrobial peptides (AMPs) that occur naturally in keratinocytes and neutrophils. Naturally occurring AMPs are produced as a normal immune response and have antibacterial, antiviral and anti-fungal effects.<sup>13, 15</sup> Polyhexamethylene biguanide is available as a topical solution (often used in eye care), topical gel and impregnated in wound dressing products. Although PHMB topical solutions have been used in wound care for decades, most recent research has focused on the relatively new PHMB wound dressing products.<sup>13</sup>

### PHMB TOPICAL SOLUTION: CLINICAL EVIDENCE

#### Effectiveness in managing wound infection

- One in-vitro study found that 0.02% and 0.04% PHMB solutions was as effective as chlorhexidine solutions in eradicating *P. aeruginosa* biofilms grown on a variety of plate surfaces (polystyrene and silicone) in artificial wound fluid.<sup>4</sup> (Level IV)
- One in-vitro study showed the antibacterial action against *S. aureus* of both 1% and 2% PHMB solutions is reduced by the type of wound dressings applied. The researchers

suggested incompatibilities between the cationic nature of PHMB solutions and anionic structure of common wound dressings.<sup>3</sup> (Level IV)

### PHMB WOUND DRESSING PRODUCTS: CLINICAL EVIDENCE

Polyhexamethylene biguanide wound dressing products (including gauze, biocellulose dressings and foam) are available in two formats: PHMB impregnated and PHMB-donating. In impregnated dressings, molecules are chemically bound to the base wound dressing material and become active when in contact with moisture, reducing bacterial load in the dressing and preventing bacterial penetration through the dressing. In PHMB-donating wound products, the PHMB is not chemically bound to the base dressing so can be delivered into the wound and peri-wound tissues.<sup>1, 2</sup> (Level IV)

#### Effectiveness in promoting healing

- In one randomised controlled trial (RCT) (n=42 wounds), a 0.3% PHMB impregnated dressing was no more effective than a silver dressing at promoting wound healing; however, there was significantly ( $p<0.006$ ) more rapid reduction in peri-wound skin redness associated with the 0.3% PHMB impregnated wound dressing.<sup>7</sup> (Level II)
- In one RCT (n=40) foot and leg ulcers did not heal significantly faster with a PHMB impregnated wound dressing compared to a regular foam dressing at either 2 weeks (median wound decrease 32% versus 21%,  $p=0.31$ ) or 4 weeks (median wound decrease 35% versus 28%,  $p=0.85$ ).<sup>5</sup> (Level II)
- In one RCT (n=60) second degree burns treated with a 0.3% PHMB impregnated wound dressing all healed within 10 days. Although this was not different from a silver dressing, the wounds treated with the PHMB dressing healed at a significantly faster rate ( $p<0.001$ ).<sup>9</sup> (Level II)
- In one uncontrolled trial involving paediatric patients (n=20, mean age 5.6 years) with skin contusions and lacerations of the heel (mean baseline wound size 8.60cm<sup>2</sup>) 100% of wounds healed within 14 days when treated with a biocellular matrix dressing impregnated with 0.3% PHMB. Mean time to complete wound closure was 12.95 days ( $\pm 7.69$ ).<sup>10</sup> (Level III)

- In five case reports, ulcers were treated with 0.5% impregnated PHMB wound dressings (and various compression therapies for three patients). Wound size reduction was achieved in 80% of cases within 3 weeks; however it is unclear if the size reductions were clinically significant.<sup>16</sup> (Level III)
- A series of case reports of five patients with diabetic ulcers reported complete healing within 5 to 6 weeks with 0.5% PHMB impregnated dressing. Frequency of dressing changes was not reported.<sup>17</sup> (Level III)

#### Effectiveness in managing wound infection

Wound dressings impregnated with PHMB have been shown to rapidly decrease methicillin resistant *Staph. aureus* (MRSA); vancomycin resistant enterococcus (VRE); a range of gram positive and gram negative bacteria; and fungi in in-vitro studies.<sup>14, 18-20</sup> (Level IV) In clinical trials it has also been shown to reduce bacterial infection (clinical signs of infection and in reduction in bacterial levels assessed via wound swab).

##### *a) Studies conducted in wounds with clinical signs of infection*

- In one case series report of 25 patients with wounds of varying aetiology and exhibiting clinical signs of bacterial colonisation, treatment with a 0.5% PHMB impregnated dressing for between 7 and 28 days led to reduction in wound exudate and wound odour in 100% of wounds. MRSA was eradicated in the two wounds that were swabbed prior to treatment.<sup>8</sup> (Level III)
- In one RCT (n=42), colonised ulcers (determined through wound swab and clinical signs and symptoms) dressed with a 0.3% PHMB impregnated wound dressing for 14 days were shown to have a significantly (p=0.3) faster reduction in critical bacteria levels compared to a silver dressing after 3 days. By day 28, 50% of ulcers treated with the PHMB wound dressing had bacterial load reductions to very low or eradicated levels (versus 28% of those treated with silver, p=0.74).<sup>7</sup> (Level II)

##### *b) Studies showing in-vitro reduction of bacterial levels*

- An RCT (n=30) compared 0.3% PHMP impregnated wound dressing to a regular foam dressing and cleansing with a PHMB swab in Stage 2-4 pressure ulcers colonised with MRSA. The PHMB dressing was superior at eradicating MRSA at 7 days (87% vs 40%, p<0.05) and 14 days (100% vs 66%, p<0.05).<sup>6</sup> (Level II)
- In one RCT (n=40) foot and leg ulcers showed significant reduction in number of microorganisms after 4 weeks of treatment with a PHMB impregnated wound dressing compared with a regular foam wound dressing (5.3% versus 33% of wounds colonised after 4 weeks, p=0.04).<sup>5</sup> (Level II)
- In one RCT PHMB impregnated gauze used for packing wounds was reported to reduce polymicrobial bioburden compared with sterile gauze (statistical significance not reported).<sup>21</sup> (Level II)

- In one in-vitro study 0.2% PHMB impregnated gauze was more effective than standard gauze in reducing bacterial counts of *S. aureus*, *P. aeruginosa*, *C. albicans*, and *S. epidermidis* (statistical significance not reported).<sup>19</sup> (Level IV)

#### Effectiveness in eradicating biofilm

- In one uncontrolled trial, 16 wounds that had been persistent for at least two weeks and had macroscopic evidence of biofilm were treated with a 0.3% PHMB impregnated wound dressing. After 24 weeks, 75% of wounds had completely healed. Of the others, 63% had good reduction in biofilm and only 6% had low reduction in biofilm. All wounds had significant (p<0.04) increase in granulation of the wound bed.<sup>11</sup> (Level II)

#### Effectiveness in reducing pain associated with wounds

- In one RCT (n=40) patients with foot and leg ulcers were significantly more likely to experience no pain during dressing change when treated with a PHMB impregnated wound dressing compared with a regular foam wound dressing. The difference was significant at 2 weeks (p=0.0006) and 4 weeks (p=0.02).<sup>5</sup> (Level II)
- Adults with colonised ulcers experienced significant reduction VAS pain scores within one day of treatment with a 0.3% PHMB impregnated dressing compared with a silver dressing (p=0.3).<sup>7</sup> (Level II)
- In one RCT (n=60) there was a significant decrease in pain associated with dressing second degree burns with a 0.3% PHMB impregnated wound dressing compared with a silver dressing both during and between wound dressing changes (p<0.001 for both). Pain during dressing changes decreased by approx. 3.5 on a 10 point pain VAS within one day compared with an approximate decrease of 2 points for the silver dressing.<sup>9</sup> (Level II)
- In a trial with paediatric patients with heel lacerations, mean visual analogue scale (VAS) pain scores significantly decreased during treatment with a 0.3% PHMB impregnated wound dressing. At baseline mean VAS scores were 9.55 (±0.69) and fell to 0.15 (±0.15, p<0.003) by day 14; however 85% of children were pain free by the third day of treatment with the PHMB dressing.<sup>10</sup> (Level III)
- In one uncontrolled trial 16 patients treated with a 0.3% PHMB impregnated wound dressing reported a clinically significant mean reduction of 3.8 on a 10 point VAS after 24 weeks of treatment.<sup>11</sup> (Level II)
- A case report of the use of a 0.3% PHMB impregnated wound dressing to manage a venous leg ulcer (VLU) reported high ratings of pain on dressing change at day one, reducing by the second dressing change. The patient had previously rated pain on dressing changes as high over 14 years of VLU management.<sup>12</sup> (Level III)

#### Effectiveness in managing exudate

In many of the clinical trials reporting PHMB wound dressings,<sup>10,11</sup> patients with heavily exudating wounds were

excluded from selection. One trial and a case series report included moderately exuding wounds.<sup>18</sup> In three case reports, leg ulcer exudate reduced from moderate to low with weekly 0.5% PHMB impregnated wound dressing changes for three weeks.<sup>16</sup> (Level III) PHMB impregnated dressings are generally only recommended for wounds with only slight or moderate exudate.<sup>14</sup> (Level IV)

#### Ease of use

PHMB impregnated dressings were reported as:

- easy to apply and remove from wound bed surfaces;<sup>8, 16</sup> (Level III)
- well received by patients;<sup>8, 12</sup> (Level III) <sup>14</sup> (Level II)
- able to stay in place for at least one week<sup>8, 9</sup> (Level I and Level III); and
- favoured by clinical staff over silver dressings for handling qualities.<sup>7</sup> (Level II)

#### ADVERSE EFFECTS OF PHMB PRODUCTS

No patients in the trials or case reports experienced adverse effects associated with a PHMB impregnated wound dressing. PHMB impregnated dressings are not recommended for:<sup>13</sup> (Level IV)

- application to any part of the central nervous system including lumbar dressings;
- during the first four months of pregnancy and only with a strict benefit-risk assessment in the later stages of pregnancy; and
- in patients with a known PHMB allergy.

#### OTHER CONSIDERATIONS

##### Cost effectiveness

There are no reports on the cost-effectiveness of PHMB topical solutions. PHMB impregnated dressings appear to be cost effective when compared to standard wound dressings. Cost reductions were related to reduced requirement for dressing changes that saved both equipment and staff costs.

- In an economic evaluation, using a 0.3% PHMB impregnated dressing to treat second degree burns saved €95.20 over 10 days compared with a silver dressing.<sup>9</sup> (Level III)
- A second economic evaluation of a 0.5% PHMB impregnated dressing for 9 patients showed significant costs to care of up to £49.50 for most patients (although for two patients the costs of PHMB dressings were higher than undefined standard care).<sup>8</sup> (Level III)
- A third economic assessment of 14 days treatment of paediatric heel lacerations found significant cost reductions for a 0.3% PHMB wound dressing (€22.08) compared with a moist wound healing wound dressing (€148.54).<sup>10</sup> (Level III)

- One case report showed a reduction of £154.72 per week when using a PHMB dressing compared with a silver dressing.<sup>12</sup> (Level III)
- A consensus document reported US studies in which significant cost savings were achieved using PHMB impregnated dressings, due to decreased dressing changes and eradication of bacteria preventing use of antibiotics.<sup>13</sup> (Level IV)

#### CHARACTERISTICS OF THE EVIDENCE

This evidence summary is based on a structured literature and database search for years 2007 to 2012 combining search terms that describe wound management and polyhexamethylene biguanide. The evidence in this summary comes from:

- Four RCTs<sup>5-7, 9</sup> (Level II)
- RCTs not reporting confidence intervals<sup>21</sup> (Level II)
- Non-randomised, non-controlled clinical trial with various methodological shortcomings including large dropouts and non-blinding.<sup>10</sup> (Level III)
- Cohort study<sup>11</sup> (Level III)
- In-vitro studies<sup>3, 4, 18-20</sup> (Level IV)
- Case series reports<sup>8, 12, 16, 17</sup> (Level III)
- Expert commentary<sup>1, 2, 14, 15</sup> (Level IV)
- A consensus report<sup>13</sup> (Level IV)

#### BEST PRACTICE RECOMMENDATIONS

- PHMB impregnated wound dressings could be considered as a management option that decreases the patient's wound pain. (Level A)
- PHMB impregnated wound dressings could be used for reducing infection and promoting healing in persistent wounds without heavy exudate. (Level B)
- PHMB solutions (up to 2%) could be used to manage wound infection. (Level B)
- PHMB impregnated wound dressings are a cost effective management option. (Level B)

#### GRADES OF RECOMMENDATIONS

Grade A	Strong support that merits application
Grade B	Moderate support that warrants consideration of application
Grade C	Not supported

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## KEYWORDS

Wound management; polyhexamethylene biguanide; PHMB

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