Wound bed preparation: a case series using polyhexanide and betaine solution and gel—a UK perspective

Objective: The burden of wound care within the NHS is estimated at a cost of £5.3 billion per year and is set to rise annually by 30%. This case series describes the results of using polyhexanide (PHMB) and betaine wound irrigation solution and gels (Prontosan, B.Braun Medical Ltd., UK) across the UK in hard-to-heal (also described as chronic) wounds up to 20 years' duration, with an observation period of greater than one month. Over half of the hard-to-heal wounds were healed and vast improvements to all other wounds were observed. Improvements to wound bed condition were reported as early as two days after commencing initial treatment, with decreases in malodour, exudate, slough and pain reported across the case series. In addition to wound bed improvements, a reduction in dressing change frequency of 55% was observed in hard-to-heal wounds under the new treatment regime.
Declaration of interest: DMC is employed by B. Braun and LA and JS received consulting fees from B. Braun. There are no further conflicts of interest

biofilm • chronic • hard-to-heal wounds • PHMB • polyhexanide • Prontosan • wound cleansing • wound bed preparation

Resources associated with managing hard-to-heal (also described as chronic) wounds are substantially greater than those associated with managing other wounds, with 20% more practice nurse visits and 104% more community nurse visits reported for patients with these wounds.[1] The average annual cost of managing hard-to-heal wounds is reported at 135% compared with wounds that healed within one year,[1] and this is expected to rise by a third over the next decade.[2]

Hard-to-heal wounds can provide an ideal environment for the creation of biofilm.[3] Biofilm is associated with chronic inflammation,[4] increased slough and exudate,[5] as well as increased microbial tolerance to antimicrobials and antibiotic therapy.[6] A recent meta-analysis on the prevalence of biofilms in hard-to-heal wounds has reported a presence of biofilm in 78.2% of hard-to-heal wounds (95% CI 61.6–89.0%; p=0.002).[7] As such, all hard-to-heal wounds that have not responded to standard care are considered to have biofilms as an underlying cause of delayed healing.[8,9] Recent wound biofilm consensus statements focus on cleansing as a strategy to address biofilms and recommends routine cleansing and disruption of biofilm at each dressing change.[9]

Prontosan (B.Braun Medical Ltd., UK) wound irrigation solution and gels, contain polyhexanide (PHMB) and betaine surfactant. These ingredients work in combination to disrupt and remove biofilm, as well as aid the removal of debris and slough.[10,11] Research studies have demonstrated significantly higher efficacy of PHMB and betaine irrigation solution and gels compared with normal saline for improving wound condition, reducing inflammatory signs and accelerating the healing of hard-to-heal wounds.[11–13] Use of this cleansing system is therefore of interest to the wound care community.

Aim

We review and combine the results of multiple case studies in the UK into a case series to evaluate outcomes, and provide an overview of the effectiveness of PHMB and betaine wound irrigation solution and gels in hard-to-heal wounds.

Methods

Case studies from within the UK, where PHMB and betaine wound irrigation solution and gels were used for wound bed preparation, were collated. Inclusion criteria were use of PHMB and betaine wound irrigation solution alone (application of a 'soak' with PHMB and betaine solution, applied to the wound at dressing change), or PHMB and betaine irrigation solution used in addition to PHMB and betaine gel (wound soak with additional application of PHMB and betaine gel to the wound to remain in situ between dressing changes) used on hard-to-heal wounds or complex wounds.

Soak times with cleansing solution varied according to wound condition, with the majority stating 5–10 minutes. Wounds were classified as hard-to-heal or complex if they were determined as chronic or complex by the original case study author, were of >6 weeks in duration,[14] and/or were presenting with signs of complications (infection, suspected biofilm or necrosis identified).[15] Exclusion criteria were acute/non-complex

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Table 1. Proportion of wounds with treatment duration of >1 month, healed by treatment time for all wounds and treatment groups

	All wounds >1 month treatment (n=23)		Irrigation solution >1 month treatment (n=4)		Irrigation solution and gel >1 month treatment (n=19)	
Treatment duration	Healed	Cumulative healed	Healed	Cumulative healed	Healed	Cumulative healed
2 months	6 (26.1%)	6 (26.1%)	0 (0.0%)	0 (0.0%)	6 (31.6%)	6 (31.6%)
3 months	3 (13.0%)	9 (39.1%)	1 (25.0%)	1 (25.0%)	2 (10.5%)	8 (42.1%)
6 months	2 (8.7%)	11 (47.8%)	1 (25.0%)	2 (50.0%)	1 (5.2%)	9 (47.4%)
10 months	1 (4.3%)	12 (52.2%)	0 (0.0%)	2 (50.0%)	1 (5.2%)	10 (52.6%)

wounds, wound pathway without primary data, insufficient data, burns and primary focus of debridement pad use.

Case studies were assigned to two treatment groups:

- Solution group—PHMB and betaine irrigation solution alone
- Solution and gel group—PHMB and betaine irrigation solution in addition to PHMB and betaine gel.

The proportion of wounds achieving partial healing in the two treatment groups, and as an entire cohort, were assessed. Impact on complete wound healing was analysed for wounds treated for >1 month. All other measurements were analysed by the whole cohort

Wound and patient characteristics were reported where available:

- Number of patients and wounds
- Type of wound
- Previous treatment history
- Age of wound
- Wound details (malodour, exudate, slough and size)
- Pain level (analgesia use)
- Dressing change details
- Duration of new treatment
- Patient quality of life.

Results

There were 35 case studies, complying with eligibility criteria available for analysis; 11 further case studies were excluded: six for use of a debridement pad as a primary treatment, three covering a biofilm pathway, one covering burn wounds and one due to lack of detail. The remaining 24 case studies, comprised of 52 hard-to-heal wounds from 50 patients, were included in the final analysis. Solution and gel were used on 36 wounds; the remaining 16 wounds used solution alone. PHMB and betaine treatment was initiated for multiple reasons including: long duration of wound (> 1 month, n=20; > 3 months, n=15); failure to heal due to infection (n=14), postperative/trauma complications including dehisced wounds (n=7) and wounds described as 'complicated with healing by secondary intention' (n=38). Multiple reasons were often cited. Duration of case studies ranged from nine days to 10 months. Treatment was followed to complete wound healing for 12 (23%) wounds; for all other case studies (77%) the reason for ending observation was not documented.

Wound healing

Considering the hard-to-heal/complex nature of wounds in these case studies, a treatment duration of <1 month was determined to be unlikely to result in

Table 2. Wound area, treatment duration and type of wound for wounds with area measured (n=8)

Wound area before treatment	Wound duration	Wound type	Treatment group	Wound area after treatment	Treatment duration	Wound area reduction
65cm^2	7 months	Leg ulcer	Solution	0cm^2	6 months	100%
35cm^2	7 months	Leg ulcer	Solution	0cm^2	3 months	100%
38cm^2	6 months	Infected leg ulcer	Solution and gel	16cm^2	3.5 months	58%
15cm^2	>1 year	Leg ulcer	Solution	14cm^2	1 month	7%
49cm^2	5 months	Leg ulcer	Solution and gel	3cm^2	5 months	94%
120cm^2	3 months	Buttock wound	Solution	2cm^2	3 months	98%
Full leg circumference x 8–17cm long	2 weeks	Leg cellulitis	Solution and gel	0cm^2	3 months	100%
300cm^2	Unknown	Category IV infected pressure ulcer	Solution and gel	157cm^2	6 days	48%

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complete healing; case studies with treatment <1 month were excluded from analysis for complete healing. Case studies where treatment duration surpassed one month (23 wounds) were analysed. Of these 23 wounds, 12 (52%) resulted in complete wound healing, of which 10 (83%) were treated with solution and gel, and two (17%) were treated with solution alone. The majority (26.1%) of healed wounds were healed within two months. Completely healed wounds are summarised in Table 1.

Of the remaining 11(48%) wounds not reported as healed, the health professionals described eight as demonstrating improvements and wound size reduction. The remaining three wounds had no further details pertaining to healing progress.

Wound area

Wound area was reported for only eight of the 52 wounds; all wounds measured demonstrated reduced size following treatment, with >90% reduction observed in five (63%) of the eight wounds within 3–6 months and a mean wound size reduction of 75.6% observed (Table 2). Wound area reduction was calculated as wound area at the end of treatment, expressed as a percentage of initial wound area.

Initial improvements

Description of initial signs of wound improvement were documented for 33 wounds (63%); for other wounds, only endpoint data was available. The earliest initial improvements were observed within two days in the solution and gel group and reported within four weeks in the solution only group. Overall, for both treatment groups, initial wound improvements were observed within one week for 19% of all wounds (10/52); and by week four, 63% of wounds (33/52) had demonstrated some initial improvement in wound bed condition (Fig 1).

Pain score

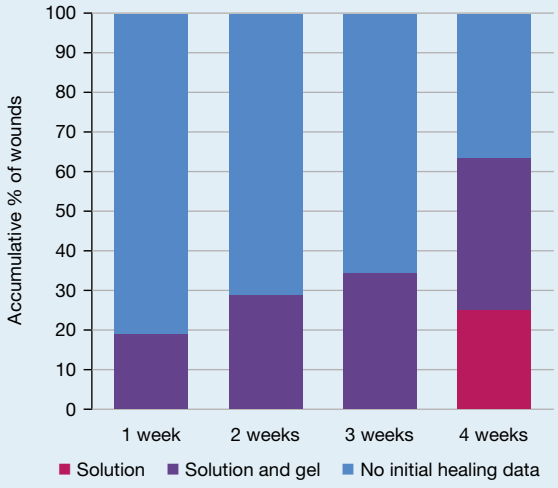
Pain was recorded either directly, via a numeric pain score or binary pain status, or indirectly, by use of pain medication. Before beginning PHMB and betaine treatment, pain was reported for 21 wounds. Reduction in pain was reported for 18/21 painful wounds (86%); two of which reported being pain-free. There were two patients, previously unable to tolerate compression for leg ulcers, able to initiate compression, three wounds (14%) were not followed up, and one wound (5%) reported an increase in pain and stopped treatment.

Pain medication was taken by eight patients, including paracetamol, cocodamol, morphine, codydramol, ibuprofen, fentanyl lozenges, diclofenac and oxycodone. On follow-up, four patients had reduced their pain medication, two of which had stopped taking any pain medication during the case study.

Malodour, excessive exudate and slough

Initially, malodour was reported in six wounds; five were followed up, all reporting improvements.

Fig 1. Accumulative percentage of wounds with initial healing (expressed by treatment group) and those with no data on initial healing



Malodour was reduced in two wounds (33%) and resolved in three wounds (50%).

The presence of excessive exudate was described in 20 wounds (38%) at the start of the new treatment. In some cases, additional details were recorded describing exudate: one wound was described as 'purulent'; one as 'green'; one as 'medium'; three as 'high', and one wound as 'heavy'. Exudate was followed up for all 20 wounds; all reported reduced exudate; in 10 out of 20 wounds (50%), exudate was fully resolved by the study end (Fig 2). Reduction in exudate was described by health professionals in two wounds as 'immediate' and 'rapid'; reductions were noted as early as after two days of treatments for two wounds, and after one week of treatment for one wound.

Fig 2. Outcomes of wound condition after treatment expresses as percentage of wounds displaying issue initially (overall results).

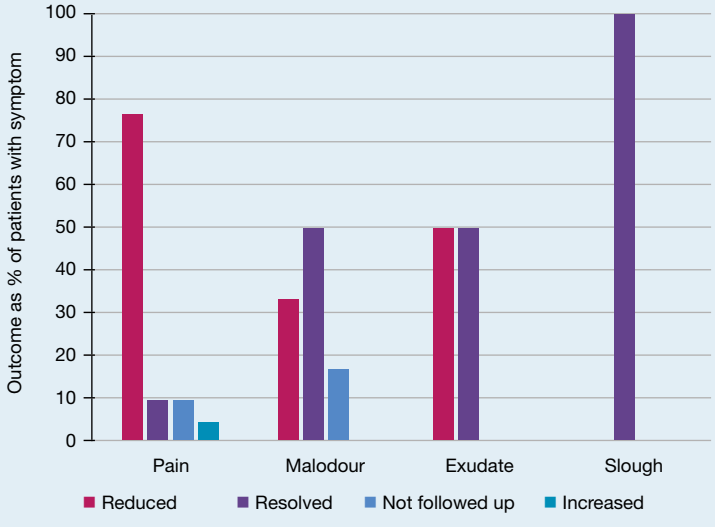


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Table 3. Changes to dressing frequency over time after treatment with polyhexanide and betaine (both treatment groups) and calculated impact of reduced dressing change on dressing use and visits

Initial dressing change frequency	New dressing change frequency	Length of treatment before change	Calculated % reduction in dressing changes
3x/week	2x/week	2 weeks	33
Daily	Weekly	4 weeks	86
3x/week	2x/week	20 days	33
Daily	3x/week	2 weeks	57
Daily	Alternate days	Few weeks*	50
Daily	2x/week	2 days	71

*Described as 'few weeks' in case study

Slough was present initially for 16 wounds (31%), and described in seven wounds as: '100% slough' (n=2); 'thick' (n=2); '40% slough' (n=1); 'large' (n=1) and 'sticky' (n=1). Presence of slough alone was noted for nine cases. Slough was removed from all (100%) initially sloughy wounds treated with PHMB and betaine (Fig 2).

Dressing changes

Frequency of dressing changes was documented for 14 wounds (27%). Of these, 13 wounds were within the solution and gel group and one was within the solution-only group. Initially, six wounds were dressed daily; three were dressed on alternate days; three were dressed three times per week and two wounds were dressed twice per week. Before treatment with PHMB and betaine, dressings were changed on average 4.68 times per week (standard deviation, SD: 2.14).

How often dressings were changed was followed up for six wounds, all were reduced (33–86%); with a mean reduction of 55% in dressing change frequency overall. Table 3 demonstrates that a reduction in dressing changes was observed as early as after two days of PHMB and betaine treatment. After treatment, dressing changes were reduced to 2.25 times per week (SD: 0.88). This reduction was observed on average after 16.5 days (SD: 8.8).

Patient quality of life

Comments relating to improved patient QoL after PHMB and betaine treatment were recorded by 10 patients (20% of all patients). Improvements with mobility during the course of treatment was noted for seven patients, with one patient starting swimming again and another was mobile enough to attend clinic for appointments rather than home visits. Psychological improvements were also noted for patients, with recorded comments including: 'morale improved'; 'able to attend first social occasion in five years'; 'the ability to resume normal social activities'; 'able to go on holiday abroad' and 'able to engage in family life'.

Discussion

It is well acknowledged that the majority of hard-to-heal wounds contain a bacterial biofilm that is recognised as a leading factor in delayed healing.[16] Guidance states that for any hard-to-heal wound not reduced in size by >40% after four weeks, it is to be assumed that biofilm is the underlying cause, and should be treated accordingly by treating the biofilm through active cleansing and reducing biofilm reformation.[8,17–19] Biofilms are highly resistant to standard cleansing with saline and tap water,[20] whereas PHMB and betaine have been described in wound care guidelines as antibiofilm agents capable of reducing biofilm by combined actions of a surfactant and an antimicrobial.[8,17,20] This case series sought to discuss the impact of treatment with active cleansing with PHMB and betaine agents on hard-to-heal complicated wounds.

Wound healing and wound size

Within the UK, 39% of all wounds are not healed within one year, and these non-healed wounds cost substantially more than healed wounds.[1] In the previously hard-to-heal/complex wounds in this case series, improvement was observed in the majority of the wounds, with full healing observed in over half of those treated with PHMB and betaine for >1 month. The case series data is in alignment with previous large cohort analyses, demonstrating most complete wound healing occurring between 2–4 months after treatment with PHMB and betaine.[21,22] Other large (953 patients) retrospective studies reported wound healing occurring in 80% of hard-to-heal wounds, after treatment with PHMB and betaine solution and gel.[23]

A limitation of the case series presented here is that it is not possible to assess what may have happened to the wounds had standard (saline) treatment continued. However, a randomised controlled trial (RCT) comparing PHMB and betaine gel with saline demonstrated a significant reduction in mean wound size ($p=0.013$) and percentage reduction in wound size ($p<0.001$) in the PHMB and betaine group after two weeks.[24] With unhealed wounds costing 135% more than healed wounds,[1] the progression of over half of hard-to-heal wounds to fully healed may offer economic benefits in the reduction of the burden of wound care that warrant further investigation.

Initial improvements

A previous RCT, comparing saline with PHMB and betaine treatment in 289 patients for 28 days, reported significantly quicker reduction in wound size and inflammatory signs in the PHMB and betaine group.[12] In addition, a case series evaluation of PHMB and betaine in the UK of hard-to-heal wounds demonstrated dramatic improvement in 70% of patients within three weeks.[25] In this review, we found that initial improvements in wounds were observed as early as two days after treatment with PHMB and betaine gel and solution, and as early as four weeks when using solution

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alone. All initial improvements were seen within four weeks of starting cleansing with PHMB and betaine treatment. Considering the complexities of, and previous delayed healing in, the wounds in these case studies, the rapid improvements observed support improvements reported in literature.

Pain score

Patients with hard-to-heal wounds often experience pain; between 37.5%[26] and 63%[27] of patients with leg ulcers report pain. Similar results were observed in this case series, in which pain was reduced for the majority of patients, improving QoL. The gold standard treatment for venous leg ulcers is compression therapy.[28] Patients, previously reported as being unable to tolerate compression, were able to begin compression treatment following cleansing with PHMB and betaine, which helped resolve their pain. Furthermore, an 80% reduction in patient pain has been reported, in hard-to-heal wounds, following PHMB and betaine treatment, compared with baseline saline treatment.[13] In addition, 77% of patients reported reduced pain within 31 days of PHMB and betaine treatment,[29] and in other case series, all patients with hard-to-heal wounds reported pain reduction with PHMB and betaine treatment.[13,30]

Reducing pain can have a direct impact on patients' QoL. Hard-to-heal wounds can prevent patients from leaving home or walking due to pain, despite taking analgesia.[25] The impact of the level of pain medication taken should also be considered. Indeed, in the current study, all patients taking pain medication had their prescription reduced and half stopped taking any pain medication at all.

Malodour, excessive exudate, necrosis, slough and patient quality of life

Biofilm within a hard-to-heal wound can be responsible for and contribute to increased slough,[5] higher amounts of exudate,[31] inflammation due to prolonged host immune response,[32–34] signs of clinical infection,[8] increase bacterial load,[18] increased tolerance of microbes to antimicrobials and antibiotic therapy,[6,35] all of which can lead to a delay in wound healing.

In this study, exudate, malodour and slough were all improved with most fully resolved after treatment with PHMB and betaine, indicating underlying causes such as biofilm or infection were resolved. The wound bed improvements reported in this study are in alignment with findings of other studies[12,13,23,25,29,36] as well as with RCTs.[24] Additionally, the introduction of PHMB and betaine irrigation solution and gel as standard practice, for treatment of all wounds in one UK NHS trust, reduced healthcare-associated infections and surgical site infections (SSI) by 92%,[37] since the change in practice. Wound bed improvements, with PHMB and betaine, have been observed previously,[12,13] demonstrating reduced wound area, inflammatory signals[12] and more rapid wound healing, compared with standard treatment (saline).[11,12]

Dressing changes

Greater demands are being made on community nursing because of an ageing population, complex care provision and desire for care at home.[38] This study found dressing change frequency to be reduced, on average, by 55%. These results align with a recent large scale observational study, in which dressing change frequency was reduced within 60 days of treatment with PHMB and betaine gel,[13] as well as in other case series where daily dressing changes were reduced to alternate days after a few weeks.[25] With district nurse visits and extra dressings accounting for over 69% of the additional cost of unhealed wounds,[39] a reduction of 55% in dressing change frequency may reduce the need for such frequent district nurse visits and/or outpatient appointments over the course of treatment of a wound. While data is unavailable for hard-to-heal wounds, reduction in district nurse visits of 25% for hard-to-heal surgical wounds has been calculated to save £7258–7432 per wound.[39] Similar savings could be expected with reduced nurse visits for other hard-to-heal wounds.

Limitations

Data collection in wound care is acknowledged to be difficult. Case studies can be inconsistent and lacking in detail. Such inconsistencies were found in the case studies here and we acknowledge that not all case studies could be included for all analyses. Case studies in wound care tend to have a bias to include the most difficult wounds, possibly due to historical practices of new innovations being tried on the most difficult wounds to 'see if it works'. Indeed, in this case series, the authors observed large wounds with wound areas up to 300cm^2 which had been unhealed for up to 20 years, being selected as trial wounds. The duration of treatment in this case series was not consistent and the reason for writing up the study at the time point allocated was not clear, with many wounds still undergoing treatment and in many cases wounds treated for <1 month. The authors would recommend observation of a broader use of PHMB and betaine wound irrigation solution and gel covering all hard-to-heal wounds, to fully understand the impact of changing wound cleansing practice from saline to use of an active wound cleansing agent as part of effective wound bed preparation.

Conclusion

Hard-to-heal wounds can take many months or years to heal, resulting in a huge economic burden to the NHS and much patient discomfort. In this study, hard-to-heal wounds of up to 20 years' duration were observed during a period of treatment with PHMB and betaine irrigation solution and gels, and demonstrated improvements in the wound bed (exudate, malodour and slough) which may account for improved healing.

Data indicates that PHMB and betaine solutions and gels would be beneficial to reduce wound healing

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duration, and may have a potential positive economic impact in terms of a 55% reduction in dressing change frequency observed in this study; intervention studies looking at the impact of all hard-to-heal wounds are advised, to fully understand lifetime value and system benefits for the wider health economy. **JWC**

Reflective questions

- How many hard-to-heal wounds do you see in your practice? Are there common characteristics to these wounds?
- What processes are currently in place to review wounds and prevent them becoming hard-to heal wounds?
- How does the treatment process alter for these wounds and would you do anything differently?

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