

Cleansing versus tailored deep debridement, a fresh approach to wound cleansing: an Italian experience

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Objective: To evaluate if cleansing, using a solution containing the antimicrobial polyhexanide and the surfactant betaine (polyhexanide propylbetaine [PP], Prontosan Solution, B. Braun), can aid effective wound bed preparation (WBP).

Method: A solution containing the PP was used in two different treatment regimens. Group A was treated with a single application at different time durations (2, 5, 10 and 15 minutes) to evaluate efficacy in the removal of residues from the wound bed. Group B was treated with PP for 10 minutes, followed by application of an inert dressing, at daily dressing changes for 14 days, to evaluate efficacy of debridement.

Results: A total number of 70 patients took part in the study. In Group A (n=40), after the two and five minute application, no change was

observed. At 10 minutes, an improvement was seen in 4/10 cases and at 15 minutes the improvement was in 5/10 patients. In Group B (n=30), over the 14 days, an improvement in the condition of the tissue, i.e. the wound bed was cleaned and debrided in 73% of cases, was observed. Patients experienced a reduction in pain and no adverse effect or complication was reported. Periwound skin was improved in 29/30 cases, with only one case where the tissue deteriorated, as determined by the presence of maceration.

Conclusion: PP is effective in helping debridement during wound cleansing. Efficacy depends on time of application. However, randomisation and further study is required to confirm these results.

Declaration of interest: The author is a consultant for B. Braun Italy. No involvement or fee was given for the study.

cleansing • debridement • maceration • polyhexanide propylbetaine • wound healing • wound bed preparation

The cleansing of a wound is a routine part of the treatment of both acute and chronic wounds.¹ Cleansing a wound means to deeply clean the skin and the wound bed, removing dead cells and slough. Guidelines and documents have evaluated different methods for wound cleansing.² Andriessen³ talks about cleansing and debridement—the two terms identifying the stages of wound cleansing. They report the results of a retrospective study of polyhexanide propylbetaine solution (PP) versus a saline solution, which showed a statistically significant difference towards the PP in terms of healing and treatment times. Similar results were reported by Bellingeri et al,⁴ where patients were treated with PP or saline. A significant difference was seen between days 0 and 4, using the Bate-Jensen Wound Assessment Tool (BWAT), in favour of PP. The assessment of pain did not show any significant difference between the two groups.

This concept of debridement is well defined in the guidelines proposed by the European Wound Management Association (EWMA):

‘Today, debridement refers to deeply removing adherent, dead or contaminated tissue from a wound and must be

*clearly separated from the act of cleansing, defined as the removal of dirt (loose metabolic waste or foreign material)’.*⁵

The criteria for effective wound bed preparation (WBP)⁶ and that proposed by the TIME concept (tissue, infection/inflammation, moisture balance and edge of wound) have led to a different way of considering wound bed cleansing, with the need to further define the actions necessary to achieve an adequately prepared wound bed. The terms cleansing, antisepsis and debridement tend to overlap, due to a lack of clarity in how they are defined.⁷ The term debridement itself can cause confusion, due to the different methods of debridement, such as sharp debridement⁸ or dressing debridement. In the cleansing phase, options include a pressurised wash from at least 13PPI or whirlpool; both these methods have limitations, due to environmental pollution and time or structural needs,^{9,10} i.e. to effectively use a large volume of water, it is necessary to avoid dispersion and contamination, and to manage increased waste, the disposal of which will need to be carefully and safely managed. Different solutions for wound cleansing are available, which differ by use and features; a summary of their key characteristics and use is listed in Table 1.¹¹

Aim

The idea for this study came from the observation that application times for the cleansing agent PP vary

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Table 1. Solutions used for cleansing

Devices	Effect	Result – indication
Water–saline solution	Mechanical detachment. Inert	Cleansing
Ringer solution	Mechanical detachment. Inert	Cleansing
Hydrogen peroxide	Through effervescence removes debris. Production of oxygen. Tissue damage, algogenic	Cleansing – debridement
Iodopovidine 1%	Antiseptic. Possible tissue damage	Antiseptic
Clorexidine	Antiseptic. Possible tissue damage	Antiseptic
Ipoclorose acid	Antiseptic. Oxidant	Antiseptic
Acidoxidant solution	Reduction of pH. Inactivation of matrix metalloproteinases (MMPs)	Active on pH and microenvironment
Super-oxidised solution	Antiseptic. Oxidant. Low tissue damage	Antiseptic
Polyhexanide propylbetaine	Cationic surfactant with antiseptic activity. Active on biofilm. Removing organic debris. Not irritating and non-sensitizing	Debridement, antiseptic, active on biofilm

among clinicians.^{12–17} Furthermore, in our centre, where PP is extensively applied during cleansing, we have observed different methods of application at dressing change.

We evaluated the activity of a PP cleansing solution at dressing change. We started with the assumption that different durations of application of PP would lead to different effects on the wound bed.¹⁸ We wanted to assess the term ‘tailored deep debridement.’ Tailored related to the time of application, different times determine different effects on the wound bed. Deep debridement is related to a longer time of application and during that time it is possible to be active on deeper layers of slough or non-viable tissue. We also wanted to verify whether the solution showed different activities depending on the time of application. In the first group, we examined a single application for various lengths of time to assess if any changes occurred in the wound bed. In the second group, we evaluated treatment of PP for 10 minutes followed by application of an inert dressing, at

Fig 1. Evolution of the wound bed preparation score Group A (single application)

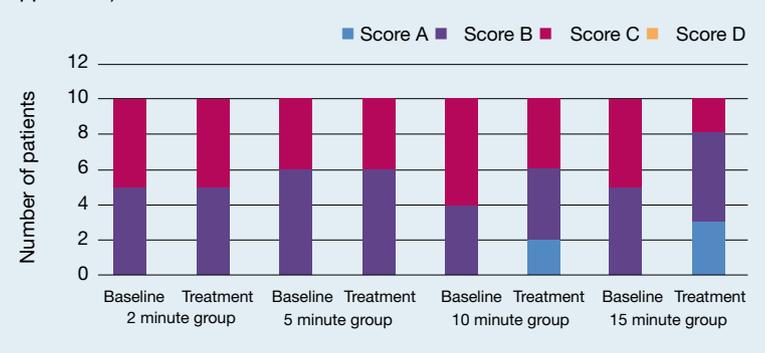


Table 3. Aetiology of wounds in Group A

Aetiology	2 minutes	5 minutes	10 minutes	15 minutes
Venous leg ulcer	6	3	2	5
Arterial leg ulcer	1	2	2	2
Mixed ulcer	2	2	3	1
Pressure ulcer	0	0	1	0
Diabetic foot ulcer	0	1	1	0
Other	1	2	1	2

Fig 2. Venous leg ulcer — by removing the gauze at different times, the amount of removed organic debris and how it is linked to the time exposure of the dressing can be observed



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dressing change, every day for 14 days.

Methods

The PP cleansing solution used in the study (Prontosan Solution, B. Braun, Italy) is composed of two main chemicals:

- Betaine, a surfactant that removes non-vital and foreign tissues, as well as components disrupting biofilm^{19–22}
- Polyhexanide, which acts as a bactericide and antiseptic.^{23,24}

There were two groups of patients observed: Group A received a single application of PP for four different

Table 2. Demographics and aetiology of all patients

	Group A (n=40)	Group B (n=30)
Age, years, medium (range)	75.95 (32–95)	80.53 (52–93)
Males/females, n	14/26	11/19
Aetiology	n	n
Venous leg ulcer	16	10
Arterial leg ulcer	7	4
Mixed ulcer	8	7
Pressure ulcer	1	3
Diabetic foot ulcer	2	2
Other	6	4

durations to evaluate efficacy in the removal of residues from the wound bed. Application times were for a duration of 2, 5, 10 and 15 minutes. A second group of patients, Group B, underwent treatment with PP-soaked gauze for 10 minutes, which was then removed without cleansing, and a non-adherent gauze was applied as a dressing. This was carried out once a day for 14 days.

Table 3. Aetiology of wounds that underwent a change in the wound bed preparation score in Group A when treated for different application times

Aetiology	Number	%
Venous leg ulcer	5/16	31.25
Arterial leg ulcer	1/7	14.28
Mixed ulcer	1/8	12.5
Pressure ulcer	0/1	0
Diabetic foot ulcer	0/2	0
Other	1/6	16.66

Patients were included if they were >18 years old, had a chronic wound (>6 weeks) of defined aetiology, a WBP tissue score of B or C, a WBP exudate score of one or two, and were contaminated or colonised (but had no other level of infection). Exclusion criteria were patients <18 years old, acute wounds, undefined aetiology, neoplastic wounds and allergy to any components in the treatment.

The parameters evaluated during observation were: WBP Score by Falanga;²⁵ wound photographic relief; score of infection by Cutting and Harding,²⁶ which defines 11 parameters to identify local infection—it is considered positive if two or more of the parameters are present. Pain levels were assessed using the visual analogue scale (VAS) score.²⁷ In Group B, periwound skin was also assessed as either normal, damaged, having erythema or macerated.

The cleansing protocols were as follows:

- Group A: removal of dressing and wound evaluation, cleansing with 10ml of PP, photography with digital camera. Application was with soaked cotton gauze, which was then removed at the specified time. To avoid drying out, PP was reapplied every five minutes. The wound was photographed at the final removal of the gauze. The type of dressing applied was evaluated in this group because only the ‘cleansing’ period, during the dressing change, was evaluated.
- Group B: Gauze soaked with PP solution was applied to the wound for 10 minutes, after which the gauze was removed and a non-adherent, secondary dressing was applied, in accordance with the site and the aetiological cause of the wound. On days 0, 7 and 14, photographs were taken with a digital camera, and clinical evaluation of the WBP score and the Cutting and Harding score was performed, along with evaluation of the periwound skin.

Ethical approval was not required, as these procedures are commonly performed during clinical practice. All the patients observed in this study gave written informed consent for the procedure and for the publication of photographs and case details.

Results

For Group A, 10 patients for every time point were enrolled, a total of 40 patients, Table 2 shows their

Fig 3. Evolution of wound bed preparation score (A, B or C) over the course of the two-week treatment with application of the product for 10 minutes at dressing change

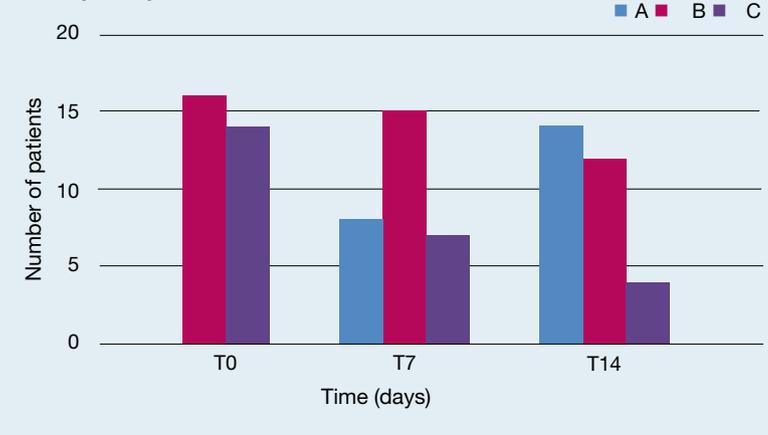


Fig 4. Change in the exudate level, according to the wound bed preparation score, over time



aetiology. For Group B, 30 patients were enrolled. The demographics and aetiology of the wound for both groups is shown in Table 3. No relevant allergy phenomena or side effects were seen in either groups.

Group A: single application

The results are reported in Fig 1. At the two- and five-minute time periods, there are no changes in WBP score when compared with the baseline for the two groups. When treated for 10 minutes, a difference was seen in 4/10 cases, with two reductions in WBP score from C to B and two from B to A (Fig 1). In the group treated for 15 minutes, five variations were noted, with three going from B to A, and two from C to B. Table 3 shows the aetiology of wounds displaying a clinical variation. There were twice as many venous leg ulcers (VLUs) that saw a change in wound status, compared with other known aetiologies; these also account for the highest number of wounds. Fig 2 shows how different effects can be obtained with different contact times.

Group B: 14 days of daily 10 minute applications Figs 3–6 show the collected data. It can be observed how the wound bed (Fig 3) has an improvement of tissues. At the time of the enrolment, 16 cases were classified as B; at the end of the observation, 12 had evolved to A, three remained unchanged and one worsened to C; of the 14 cases classified as C at the time of the enrolment, two evolved to A, nine to B and three remained unchanged. The exudate score (Fig 4) did not change but got a minimal reduction.

Fig 5 shows the infection score of Cutting and Harding data. There were no patients enrolled with a score higher than two and at the end of the observational period there was one case with two positive signs (smelling and increased exudate) while in five cases only one sign was reported (three smelling, one bleeding, one worsening of granulation tissue).

The pain score was evaluated in 26 patients, which showed an average reduction of 47%. We believe this was due to the change in the wound bed. In 20 patients a reduction of pain occurred, in five patients it was unchanged and in one case it worsened (Fig 6). Note two patients had a diabetic neuropathy, one had a paraplegia and one had a traumatic lesion of popliteus nerve; these four patients had no pain and for this reason it is not evaluated.

The parameter of periwound skin was evaluated to assess if the surfactant component would determine any skin damage. However, improvement was observed in 29 out of 30 cases, with the worsening in one wound caused by an increase in exudate, which led to maceration (Fig 7).

Figs 8 and 9 show two cases from Group B. Fig 8 shows Case 22, a 73-year-old female with a VLU of six months' duration. The patient had hypertension and type 2 diabetes, for which she was prescribed an ace inhibitor and insulin. At enrolment, the WBP score was C1 at T0 (Fig 8a), B1 at T7 (Fig 8b), and A1 at T14 (Fig 8c),

Fig 5. Change in the Cutting and Harding infection score (0, 1, 2 or 3) during the observational period

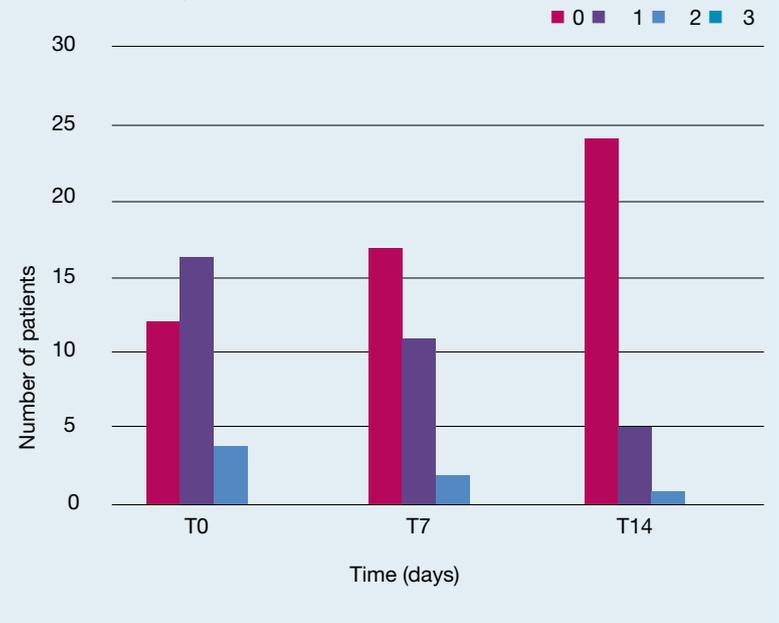
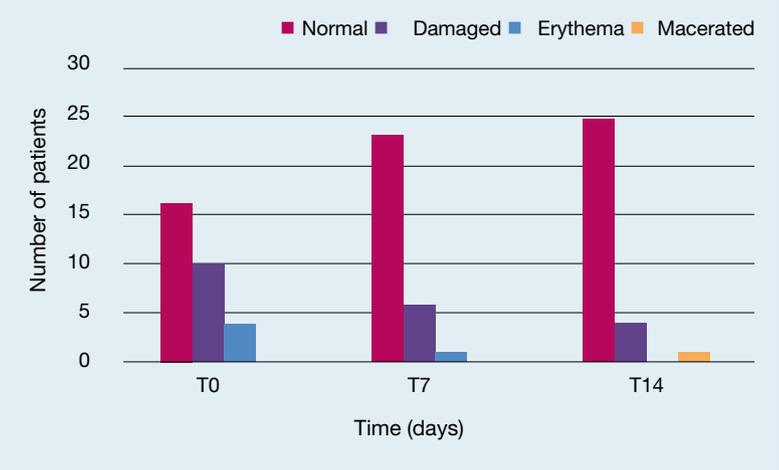


Fig 6. Change in visual analogue scale (VAS) during observational period



Fig 7. Change in periwound skin area during the observation period



demonstrating a strong improvement in the wound.

Fig 9 shows a 69-year-old male with an arterial ulcer of 14 months duration, hypertension, atrial fibrillation, and steatosis, who was an active smoker. The patient

Fig 8. A 73-year-old female with a venous leg ulcer, treated with polyhexanide propylbetaine solution every day at dressing change for 14 days. Wound bed preparation score at baseline day 0 (T0) C1 (a) on day 7 (T7) B1 (b), and day 14 (T14) A1 (c)



Fig 9. A 69-year-old male with an arterial ulcer changes treated with polyhexanide propylbetaine solution every day at dressing change for 14 days. Wound bed preparation score at baseline day 0 (T0) C1 (a) and day 14 (T14) A1 (b)



was on warfarin, furosemide and atenolol. At enrolment, the WBP score was B1 at T0 (Fig 9a) and at A1 at T14 (Fig 9b).

Discussion

The hypothesis was to verify if a solution based on PP could have a specific role in wound cleansing. The two groups were evaluated separately, to confirm the

hypothesis that PP was effective in preparing the wound bed by removing debris, fibrin and slough during dressing changes.

Group A, using a single application, shows how contact duration has a key role; at two and five minutes we can see a simple cleansing effect, with the removal of non-adherent contaminants, such as fibrin and the residue of any dressings used. The effect of applying the product for a longer time nears that of debridement of more adherent debris. From this observation, the term 'tailored deep debridement' was proposed as, dependent on the application time and type of wound, it is possible to see deeper cleansing.

Group B, with an observational period of 14 days, was intended to evaluate the efficiency of the product used in the cleansing phase, along with a secondary, inert dressing. As the product generally performed well, it could be considered effective.

- In terms of tissue, in Group B, an improvement was observed in 23 cases (76.6%), six remained unchanged (20%) and one case worsened (3.33%)
- Exudate levels did not change and was controlled through dressing application, not by cleansing, which aims to remove the debris left by the exudate
- The combination of the undecyl-amidopropyl betaine cationic surfactant with poliesanide results in the removal of non-viable and extracellular tissues with biofilms and a bactericidal and antiseptic activity
- The improvement of periwound skin is linkable to the product's cleansing activity, which favours the removal of abnormal keratinisation and organic residue usually found in the area
- Pain evaluation, undertaken to rule out the possibility that the PP solution could cause increased pain, showed a good tolerability, with a minimal reduction

According to our experience, compared with other solutions, the PP solution is effective not only in cleansing but also in being able to deslough the wound bed, although this is anecdotal evidence and to test this hypothesis requires further study.

Limitations

The study it is not comparative to other solutions. The observational data is interesting, but confirmation of the results with a comparative trial is required. Furthermore, the number of patients in this study is small. A large comparative evaluation is required to support these results.

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Conclusion

Applied PP used to cleanse the wound may be effective in removing soft debris and slough from the wound bed. The result derives from time of single application and duration of treatment. We suggest the definition of 'tailored deep debridement' in the title, to differentiate from the classical definition of debridement. **JWC**

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