Experience report

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Experiences with the use of polyhexanide-containing wound products in the management of chronic wounds – results of a methodical and retrospective analysis of 953 patients

Erfahrungen mit dem Einsatz polihexanidhaltiger Wundprodukte bei der Versorgung chronischer Wunden – Ergebnisse einer systematischen retrospektiven Untersuchung an 953 Patienten

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Summary

Since the end of 2004 the Municipal Hospital Bielefeld Mitte (North Rhine-Westphalia) has been using special wound products for the treatment of chronic wounds: a wound irrigation solution containing betaine surfactant and PHMB (poly[hexamethylene-biguanide]), and a PHMB-containing wound gel. Two and a half years after the introduction of these products the wound healing processes of 953 patients and compatibility of PHMB with different wound dressings were documented and evaluated. On the basis of the analysed data and good practical experience it was decided to continue with the use of these products.

Key words

Wound management, wound irrigation, wound gel, wound dressings, decontamination

Zusammenfassung

Das Städtische Klinikum Bielefeld Mitte setzt seit Ende 2004 routinemäßig spezielle Wundprodukte für die Behandlung chronischer Wunden ein: eine betain- und polihexanidhaltige Wundspüllösung und ein polihexanidhaltiges Wundgel. Nach zweieinhalb Jahren wurden im Rahmen der klinischen Anwendung die Heilungsverläufe von 953 Patienten und die Kompatibilität der polihexanidhaltigen Präparate mit verschiedenen Wundauflagen dokumentiert und ausgewertet. Aufgrund der positiven Daten und Erfahrungen wurde entschieden, die Produkte weiter einzusetzen.

Schlüsselwörter

Wundversorgung, Wundspülung, Wundgel, Wundauflagen, Dekontamination

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Introduction

The Municipal Hospitals Bielefeld make up a maximum care facility and together have 940 beds. In 1996, to standardise decubitus prophylaxis and therapy in the hospitals a *Wound Management Work* Group was formed, from which *Central Wound Management* has developed. It reports directly to the nursing care management, and responsibility for the medical care lies with the Medical Superintendent of the Clinic for General Internal Medicine, Endocrinology, Diabetology and Pneumology. The main focuses of *Central Wound Management* are a diabetological podiatry outpatient clinic and internal wound management (care of patients with acute and chronic wounds on the wards, decubitus and bed management and podology).

The concept of wound bed preparation developed by Falanga [1] and Sibbald [2] formed the basis of the *Wound Management Work Group* for the standardisation of prophylaxis and therapy. With their approach to therapy old views on the causes of chronic wounds were revised. These assumed that chronic wounds are really only poorly healing acute wounds in which the healing process has stopped at an early stage. Treatment must consequently only eliminate the disturbing factor in order to bring the wound into the healing process. Falanga and Sibbald rejected this view, maintaining that chronic wounds are by no means wrongly treated acute wounds, but rather that they are an independent entity that does not occur naturally, e.g. in animals. Consequently, in the course of their evolution, human beings had no possibility of developing a successful strategy against wounds becoming chronic. The objective of wound bed preparation is to promote the formation of stable granulation tissue. An essential component of wound bed preparation is gently cleansing by means of irrigation, if necessary supported by surgical debridement. The efficacy of modern wound dressings should be increased through optimal preparation of the wound bed. The maximum benefit for the patient is only achieved if time is invested in wound bed optimisation.

Thorough and gentle cleansing is an important prerequisite for the healing course of chronic wounds [3]. Wound coating forms a favourable substrate for the growth of bacteria and creates in the wound an environment for oxidative stress [4], which in turn is a disturbing factor for the microcirculation in the proximity of the wound [5]. A lasting

deficiency of the oxygen supply and nutrient supply prevents the formation of granulation tissue and thus prolongs the healing process.

Wound cleansing in wound care can be carried out routinely by means of irrigation. In practice, sterile medicinal products or special wound irrigation solutions are frequently used. According to the RKI[1] recommendations “Prevention of infection in residential care homes” [6], the use of unfiltered tap water is obsolete. There, in section 6.4.1, it is stated: *Only sterile solutions may be used* f*or the irrigation of wounds*. As medical services such as the care of wounds must, in accordance with § 135a of the SGB[2], be of *the quality advised by experts*, the decision to use unfiltered tap water can also have legal relevance [7].

Wound coating is made up mainly of non-vital tissue components, fibrin coatings and more or less dried-on exudate. In amount, denatured proteins (fibrin coatings, collagen) predominate, and in addition lipoproteins and lipids (secreted from cell membranes), nucleic acids (from cell nuclei and ribosomes) and carbohydrates (hyaluronic acid) are present. Outside their natural environment many of these substances lose their natural three-dimensional form, they denaturate. When this happens they generally lose their solubility in aqueous solutions. The use of wound irrigation solutions with the addition of wash-active substances (surfactants, PEG[3]) is intended to increase the solubility of the wound coating and improve the cleansing effect [8]. In every thorough cleansing, bacteria and immune cells such as granulocytes and macrophages are removed from the wound together with the wound coating. As a result, the oxidative stress potential in the wound is reduced.

Patients and methods

Question

We asked how the healing processes of chronic and poorly healing wounds are assessed after the introduction of special polyhexanide-containing wound products, and

[1] Robert Koch Institute
[2] Civil Code
[3] Polyethylene glycol

whether the result justifies the additional expenditure. The wounds were routinely moistened and cleansed with the wound irrigation solution at every change of dressing. Depending on the state of the wound, a wound gel was also applied or the tamponade was soaked in wound irrigation solution. We documented the compatibility of the polyhexanide-containing wound preparations with different wound coverings.

Patients

The patient recruitment for this retrospective study took place by means of setting qualifying dates: 01.01.2005 and 31.03.2007. All patients who were receiving treatment in our outpatient wound clinic between the qualifying dates were recruited. For the evaluation, only those patients for whom there were complete records of their treatment were included. In total there were 953 patients – 571 women and 382 men – with a mean age of more than 65 years. The predominant condition was diabetic foot syndrome (62 %), with two out of three wounds being infected at the time of the history being taken. In all, the rate of wound infections was 41 %. The spectrum of pathogens covered the typical wound micro-organisms. Among the Gram-positive micro-organisms *Staphylococcus epidermidis* and *Staphylococcus aureus* predominated, among the Gram-negative micro-organisms *Escherichia coli* and *Pseudomonas aeruginosa*. Resistance to antibiotics was often seen for beta-lactam penicillin, oxacillin and ampicillin and for the aminoglycoside gentamicin.

Wound care

After the history of the wound has been ascertained, for every patient a wound care standard is established, which is subsequently adjusted according to the amount of exudate from the wound. The following were newly included in this care standard:

- routine irrigation of the wound (Prontosan®, B. Braun Melsungen AG) at every dressing change (objective: clean wound on visual inspection) and
- the additional application of a wound gel (Prontosan® Wound Gel, B. Braun Melsungen AG) if there was no or only moderate exudation, the amount being dependent on the depth and area of the wound, or the additional moistening of a tamponade with the wound irrigation solution (objective: filling of the wound to the level of the surrounding intact skin).

Depending on wound size, hydrofibre or foam dressing coverings in the standard sizes 5 x 5, 10 x 10, 15 x 15 or 20 x 30 cm were used. Deep or undermined wounds were treated with appropriate tamponades. If there was a very large amount of exudate a sterile absorptive compress was used as a secondary covering, the state of the area surrounding the wound being taken into consideration in each case (e.g. non-adhesive foam dressings in cases of skin irritation).

When discharged or transferred, each patient received a treatment recommendation for the physician continuing treatment or the care facility or outpatient care service. There were a few re-referrals for plastic surgery cover, but none on account of an infection or re-infection.

Wound evaluation

The wounds were to be classified reliably and without problem; a simple classification into three classes was therefore carried out:

- *Healing:* A wound was classified as healed if the original defect was stably and completely closed (formation of epithelium).
- *Improvement:* A wound was classified as improved if the wound size had decreased by at least 25 % in relation to the original size.
- *No improvement:* The wound did not meet either of the above criteria.

Wound infection: All chronic wounds are contaminated with bacteria. If there were signs of local inflammation (redness, pain, heat, oedema) or systemic signs of infection (increase in CRP[4], accelerated ESR[5], leucocytosis, fever) the wound was classified as infected. Swabs for confirmation were not carried out in all cases. Heavily soiled wounds and wounds of patients with compromised immune defence (e.g. tumour therapy) and diabetes were classified as being at risk of infection and observed particularly carefully.

[4] C-reactive protein)
[5] Erythrocyte sedimentation rate)

Evaluation of the patient documentation

The degree of wound cleansing achieved, the moistening of the wound and the skin compatibility of the polyhexanide-containing wound preparations were evaluated; in addition, the compatibility of the polyhexanide-containing products with different wound coverings was examined. By questioning the patients the wound odour and tolerability of the combination therapy were also evaluated. The practicability of the wound irrigation and application of the gel were evaluated by the users.

The following data documented in the patient documentation were recorded:

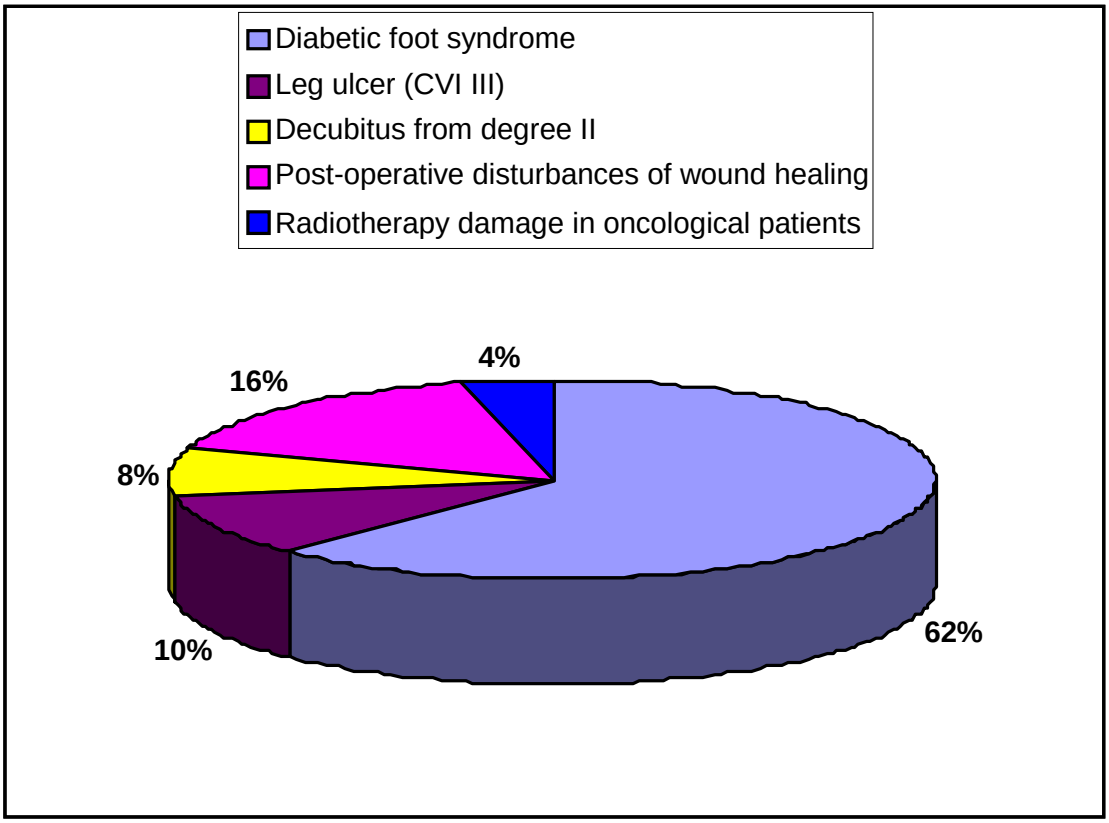
- Gender
- Type of chronic or poorly healing wound
    - venous leg ulcer
    - decubitus
    - ulcer in diabetic foot syndrome
    - ulcer due to arterial disease
    - reaction to radiotherapy
- Evaluation of wound cleansing and course of healing
    - atraumatic cleansing
    - loosening of wound coatings and visual cleanliness after irrigation
    - autolytic wound cleansing after use of the gel
    - reduction in wound size
- Frequency of skin irritation
    - redness / irritation
    - allergic reactions (e.g. detachment of epidermis)
- Compatibility with wound coverings
    - structural stability of the covering (e.g. detachment of foam)
    - stability, integrity of the covering
- Frequency of wound infections
- Evaluation by the patients
    - wound odour
    - pain
    - tolerability

- Evaluation by the user (practicability)
    - simple, rapid, problems during use
    - faulty use, cause

Results of the evaluation

Almost two thirds of all patients (62 %) were treated on account of diabetic foot syndrome. Ten per cent of the patients were treated on account of a leg ulcer (CVI stage III) and 8 % of the patients were treated for decubitus of grade II or higher. In 16 % of the patients post-operative disturbances of wound healing had to be treated, 4 % had reactions to radiotherapy following oncological treatment (Fig. 1).

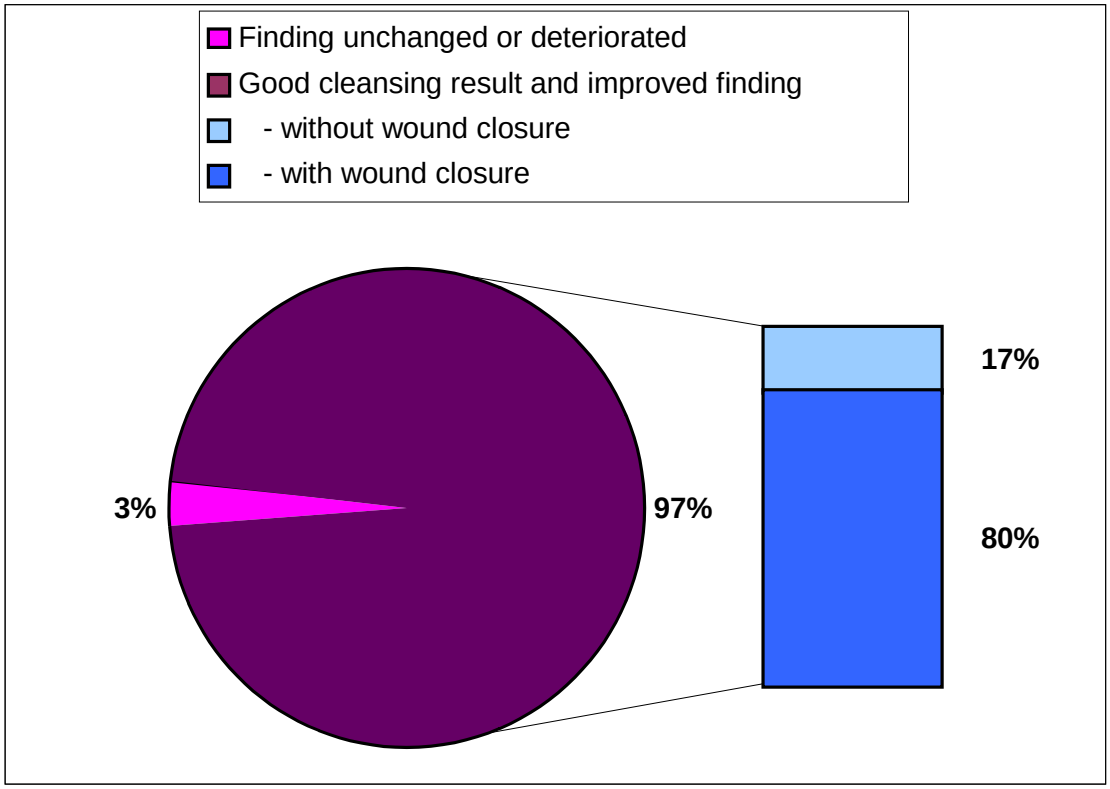
Figure 1: Cause of wound (n=953 patients)



The cleansing effect of the wound irrigation solution and of the supportive removal of non-vital tissue components (autolytic wound cleansing) by the gel were evaluated separately after the irrigation or at the next dressing change. For the evaluation the total effect was taken into consideration. A good irrigation result by means of the solution and promotion of autolysis by the gel were always a sign of a favourable healing process. Wounds that did not improve with the combination therapy of wound irrigation solution and wound gel or in which there was a deterioration were not evaluated with regard to cleansing effect. In the case of these wounds, in the opinion of the angiologist no

improvement was possible. In 80 % of the wounds wound closure could be achieved with the combination therapy (Fig. 2). In all cases, at the beginning of treatment wound and wound surroundings could be gently and effectively cleansed with the combined use of wound irrigation solution and wound gel.

Figure 2: Progress of the wounds (n=953 patients)



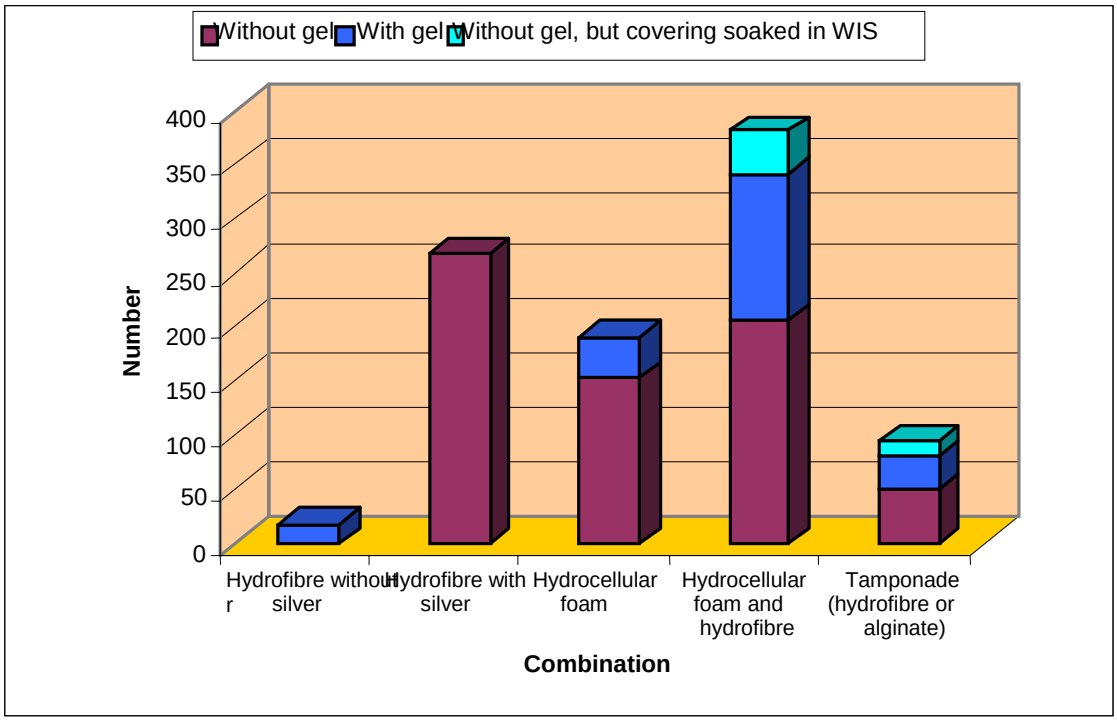
The Prontosan® Wound Gel, in accordance with the directions, was used for moistening only in cases of the absence of exudation or only moderate exudation. The moistening behaviour was predominantly evaluated as good, irrespective of the cause of the wound, only in a few cases as adequate.

Wound coverings were used as compresses or tamponades. For severely discharging wounds hydrofibre (sodium carboxymethylcellulose) with and without silver (Aquacel® and Aquacel® Ag, ConvaTec) and an alginate (e.g. Trionic®, Johnson & Johnson) were used. To absorb smaller amounts of wound fluid a hydrocellular foam dressing (e.g. Mepilex® or Mepilex® Border, Mölnlycke) was used. The wounds were moistened and cleansed with Prontosan® Wound Irrigation Solution (B. Braun Melsungen). Prontosan®

Wound Gel was also used in combination with hydrofibre or alginate tamponades, but not with silver-containing products.

The combination of wound gel with different wound coverings is common practice today. The evaluation of compatibility was carried out purely macroscopically on the basis of any changes in the structure or integrity of the wound coverings or discolourations. Evidence of incompatibility could not be established in any combination, although the wound gel was combined most frequently with hydrocellular wound compresses. No remains of dressing materials were found in the wound, and there were also no adherences of the wound covering to the wound. No skin irritations were observed.

Figure 3: Combination of different hydroactive wound coverings with betaine- and polyhexanide-containing wound products (gel or irrigation solution).
Consideration is given here to the primary or longest treatment phase of the wound (WIS: wound irrigation solution).

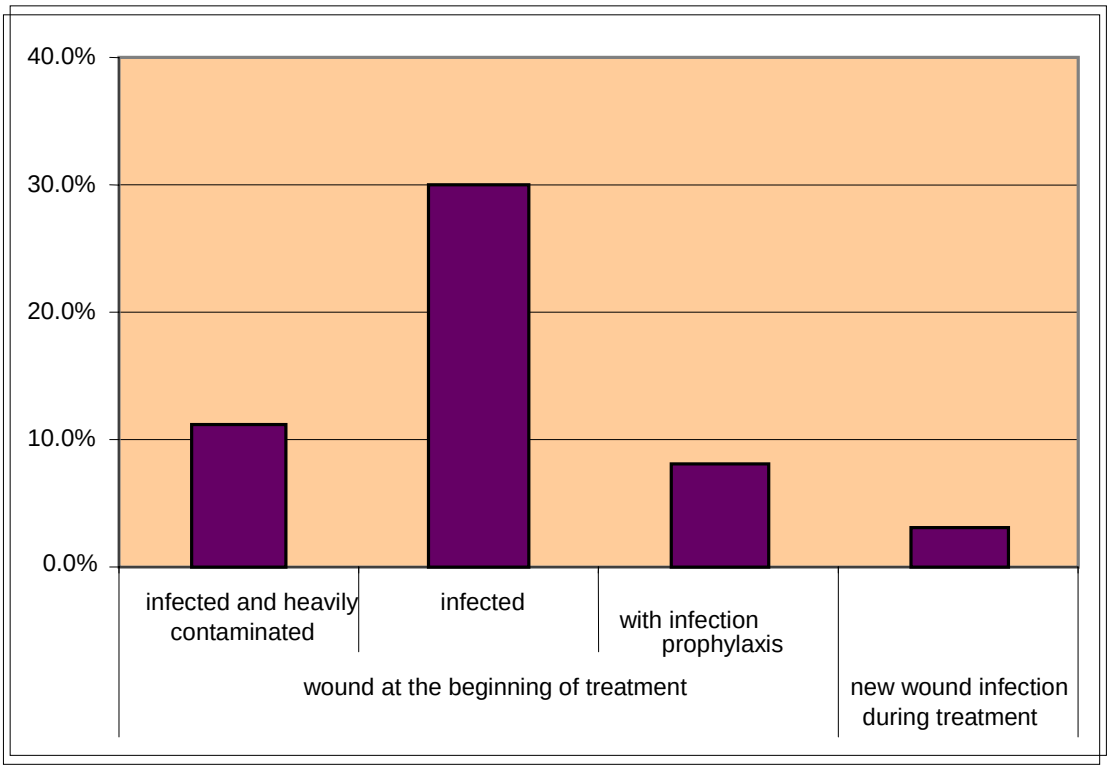


At the beginning of treatment 41 % of the patients (391 out of 953) had a wound infection, 11 % (105 out of 953) had heavily contaminated wounds. These patients were given systemic antibiotics in addition to the combination therapy with wound gel and wound irrigation solution. In a further 8 %, for safety reasons infection prophylaxis was carried out at the beginning of treatment. Swabs were taken from wounds with existing

infections and wounds with suspected infections. After a week, when swabs were taken again, a clear reduction in the pathogenic micro-organisms was found.

Infections in diabetic foot syndrome were markedly common – two thirds of these patients came to us with existing wound infections. On treatment, the wound infections persisted only for a short time (maximum five days). In 29 cases (3 %) a first or renewed wound infection developed after the beginning of treatment. Before the use of the combination therapy with wound gel and wound irrigation solution this proportion was approximately 40 %.

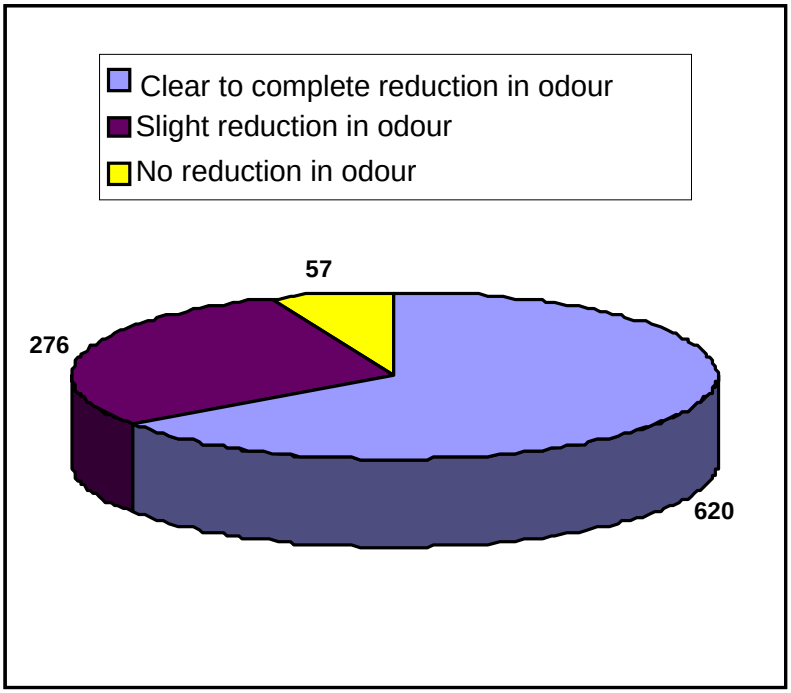
Figure 4: Frequency of wound infections at and after the beginning of treatment (n=953 patients)



Evaluation of the nature and intensity of odour from the wound by the patient (Fig. 5) is a highly subjective criterion, but one that plays a major role for patient compliance. Almost two thirds of the patients (620 out of 953) found a great to complete reduction or improvement in odour. Dressings that can smell unpleasant after being applied (e.g. hydrocolloid dressings) were not used.

Both wound irrigation solution and wound gel were very well tolerated. Only 1 % of the treated patients reported a slight burning sensation; 99 % had no pain or discomfort. Forty per cent of the patients reported a slight pleasant cooling effect, at least at times.

Figure 5: Evaluation by the patients of the reduction in odour



Discussion

Chronic wounds constitute a major problem both medically and socially. Adequate treatment of such wounds requires a high degree of co-operation and integration between all those involved. The cause of incorrect and inadequate therapies, which are often encountered in the treatment of chronic wounds, lies in insufficient to poor understanding of the pathophysiological processes that lead to wounds becoming chronic. In addition, outside hospital the treatment of chronic wounds is greatly restricted by low reimbursement rates. The approaches to therapy therefore differ greatly and often appear arbitrary. Consequently, chronic wounds were and still are an experimental area.

In 1996 the clinics of the Municipal Hospitals Bielefeld gGmbH decided to change this situation and as the first action to standardise decubitus prophylaxis and therapy. Various specialist disciplines were included from the outset, and the project was under the direct control of the medical and nursing management. On the basis of the concept of wound bed preparation described by Falanga [1] and Sibbald [2], a *Wound Management Work Group* drew up standardised prophylaxis and therapy recommendations that were developed further by *Central Wound Management* and established for all chronic and poorly healing wounds. At the end of 2004 it was decided to routinely moisten and cleanse these wounds with a polyhexanide-containing wound irrigation solution and, if the state of the wound permitted it, also to apply a polyhexanide-containing wound gel. With the introduction of this treatment concept (“combination therapy”) the number of wound infections fell considerably and the times to healing improved. We therefore decided to document and report the changes that took place.

By means of setting qualifying dates we have evaluated the fully documented courses of 953 wounds. In 80 % of cases wound closure could be achieved, 3 % of the wounds showed no improvement with our treatment or they deteriorated. 62 % of the wounds were due to diabetic foot syndrome, post-operative disturbances of wound healing were present in 16 % of the cases and pressure ulcers from grade II upwards were present in 8 % of the cases. The distribution frequency of the wound types lies in the particular situation of the Municipal Hospitals Bielefeld. As a maximum care facility with a Clinic

for Plastic, Reconstruction and Aesthetic Surgery – Hand Surgery, the hospital is a regional centre for complicated surgical cases with poorly healing wounds. The patients with pressure ulcers came mainly from the Geriatric Clinic and the Haematology and Oncology Clinic and had disturbed healing processes as a result of their multimorbidity or primary disease.

Every chronic wound is colonised with bacteria, and it is an essential aim of modern wound treatment to reduce the bacterial load in order, among other things, to keep the risk of an infection low. In this respect the combination therapy with the polyhexanide-containing wound preparations proved to be particularly effective. The wound infection rate after the beginning of treatment fell from over 40 % to 3 %, and the use of topical antibiotics became completely unnecessary. In cases of acute infections, after thorough cleansing with wound irrigation solution a dressing with a silver-containing wound covering was applied and therapy was initiated with systemic administration of antibiotics. Within five days the acute infection phase had ended in all cases, but the systemic antibiotic therapy was continued and the course completed in each case.

The great reduction in wound infections can be explained by a synergistic effect of betaine (an amphoteric surfactant) and polyhexanide in the wound irrigation solution and wound gel. Betaine has a solubilising and wetting effect [8]. Bacteria can thus be sealed in micelles and the penetration of polyhexanide into the wound tissue is facilitated. It must be assumed that the observed improvement in the healing courses is directly connected with this, for bacterial substances activate and increase inflammatory reactions and prolong the phase of inflammation [9]. In cases of chronic leg ulcer a high number of bacteria (more precisely, colony-forming units, CFU) on the base of the wound correlate with poor wound healing [10]. It is certainly not possible, and also not necessary, to eliminate all bacteria from a wound, but a target of considerably less than 10^5 CFU per gram tissue/wound coating is reported [11].

The betaine- and polyhexanide-containing wound products were compatible with all wound coverings used. Neither discolourations nor changes in structure were recorded. *In vitro*, polyhexanide showed a stabilising effect on wound coverings of collagen sponge that were exposed to enzymatic attack by collagenase [12]. The intervals between dressing changes, especially for the wounds in diabetic foot syndrome, could

be extended. It was seen that with the “combination therapy” a daily dressing change was no longer necessary, even for critical wounds; instead, the normal rhythm of three times per week was sufficient.

The patients evaluated the treatment with the polyhexanide-containing wound products as well tolerated and painless in 99 % of cases, and almost two thirds reported that the wound odour had considerably improved. In no case did treatment with the mentioned wound products have to be discontinued. The patients’ quality of life was increased, they felt better and their compliance was improved. Local irritation (irritation or cumulative toxic or contact allergy conditions) was not observed in any of the cases. We attribute this to the consistent use of adequate coverings adapted to the wound phase and to the strict adherence to the intervals between dressing changes. The handling of the products was classified by nursing staff and doctors as unproblematical.

In addition to the phase-adapted wound therapy, all necessary examinations and therapeutic measures were carried out. The general therapeutic measures included the optimisation of the diabetic metabolism and relief of pressure. The special measures after examination of vascular status by means of imaging diagnostic measures included the restoration of peripheral arterial blood supply in diabetic foot syndrome by means of conventional measures (e.g. PTA) or vascular surgery (e.g. bypass surgery). In addition, an improvement in the venous situation was achieved by compression therapy in the case of leg ulcer and relief of pressure through positioning in the case of decubitus. In the case of large-area wounds, plastic surgery covering was carried out after elimination of the infection and, if necessary, use of vacuum-assisted closure therapy (VAC therapy).

Conclusion

At the Municipal Hospital Bielefeld, poorly healing and chronic wounds have routinely been treated with betaine- and polyhexanide-containing wound products. The wounds are cleansed and moistened at each dressing change with the wound irrigation solution, and, if the amount of exudate permits, the wound gel is also applied or the tamponade is soaked with wound irrigation solution. When silver-containing wound coverings are used, the wound gel is not applied. This treatment scheme was able to be integrated into our wound preparation concept without any problem. As a result, the wound

infection rate is today 3 %, and 80 % of the wounds heal to wound closure. Additional costs of this approach to treatment are compensated by the less frequent use of antibiotics and by longer intervals between dressing changes in the case of critical wounds. The patients evaluate the treatment as painless, tolerable and with a reduction in odour. The betaine- and polyhexanide-containing wound products are fully compatible with the wound coverings used.

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