Non-medicated wound dressing as an antimicrobial alternative in wound management

A multicentre study of case observations of secondary healing and chronic wounds by Gerhard Kammerlander et al.
The use of a bacteria binding wound dressing with hydrophobic coating with a fatty acid derivative (dialkylcarbamoyl chloride, DACC) is already well established\textsuperscript{1,7}. Based on the physical principle of hydrophobic interaction, whereby hydrophobic particles aggregate in an aqueous medium and are held together by the surrounding water molecules (Fig. 4), pathogenic wound bacteria bind to the specially impregnated fibres of the wound dressing material. When bacteria or other micro-organisms come into contact with these wound dressings in a moist environment, they are bound to the dressing surface and are removed from the wound when the dressing is changed.

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With this mode of action no substances are released from the dressing into the wound, and the underlying mechanism is purely physical. The bacteria binding effect is of particular interest because it requires no systemic or local antimicrobial agents\textsuperscript{4-6}. Cutisorb\textsuperscript{®} Sorbact\textsuperscript{®} wound dressings from BSN medical are made from fabric impregnated with DACC and are approved as medical devices in wound management for the cleansing and microbial reduction of infected and contaminated, exudating wounds regardless of aetiology. Several case studies have already reported positive results in clinical use\textsuperscript{1-3}.

Study objective

In our multicentre postmarketing surveillance study on 116 patients Cutisorb\textsuperscript{®} Sorbact\textsuperscript{®} was to be used on different kinds of wounds under conditions of daily clinical practice and the course of wound healing was documented. The following aspects were of particular interest:

- Does the treatment lead to a decrease in the signs of perifocal inflammation?
- Can local infections be reduced or eliminated?
- Can a reduction or elimination of soft fibrin layers be detected?
- Is an improvement in the course of wound healing observed during treatment?
- How is the product subjectively tolerated by the patient?
- With what other modern wound management products can Cutisorb\textsuperscript{®} Sorbact\textsuperscript{®} be combined?
- How is the product handling during dressing change?

Method

Secondary healing wounds of widely differing aetiology (Fig. 5) were treated by phased differing aetiology. All users were experienced wound specialists who were briefed on the use and therapeutic indications of the product at the start of the study. They were instructed to use Cutisorb\textsuperscript{®} Sorbact\textsuperscript{®} in combination with the conventional therapeutic interventions in patients with the relevant medical conditions. Especially the secondary dressing and the combination with wound fillers (especially hydrogels) as well as skin care in the peri-wound area were to be chosen appropriate to the wound phase and the type of skin.

The case observations were carried out at four wound centres in Germany, Austria and Switzerland – on an outpatient, partly hospitalized and hospitalized basis – during the period March 2003 to June 2006. The scientific management and monitoring were carried out by G. Kammerlander, Akademie ZWM\textsuperscript{®} - KAMMERLANDER-WFI.

Percentage distribution, n = 116:

- pressure ulcer (10%)
- venous leg ulcer (7%)
- arterial leg ulcer (9%)
- mixed leg ulcer (8%)
- diabetic foot ulcer (22%)
- ulcer of other etiology (3%)
- postinfectious (16%)
- posttraumatic (5%)
- postoperative (18%)
- burn, corrosion (2%)

Fig. 5: Wound aetiology
Apply Cutisorb® Sorbact® directly to the wound

Microbes adhere to Cutisorb® Sorbact® due to hydrophobic interaction ...

... and are removed from the wound when the dressing is changed

Fig. 3: In a moist wound environment, bacteria are bound irreversibly by Cutisorb® Sorbact® and are removed from the wound with every dressing change

Fig. 4: The bacteria binding effect of Cutisorb® Sorbact® is based on the physical principle of hydrophobic interaction. The hydrophobic particles aggregate. The water molecules surround them like a coat and hold them together.

Direct wound contact of the dressing is important for the bacteria binding effect!
Results
A total of 116 patients were documented.
- Mean treatment period: 37 days (4 days – 134 days)
- Mean age: 63 years (27 years – 95 years)
- Mean age of wound at start of treatment: 6 months (1 day – 54 months)
- Sex distribution: 54 women, 62 men
- Recorded dressing changes: 1150
- Mean frequency of dressing change: 2.5/week

Concomitant diseases (percentage distribution):
- Diabetes (39%), PAOD (39%), CVI (9%), hemiplegia (7%), paraplegia (2%), renal insufficiency (3%), heart failure (2%).

Results for infectious events and infection treatment
Based on clinical criteria, a wound was considered infected if typical local signs of infection and signs of systemic infection, if any, were observed. The assessment was performed by users applying the clinical criteria. In 98 (84%) of the 116 documented wounds, a wound infection was diagnosed at the start of treatment. One patient developed a wound infection not previously present during the course of treatment. In no case was there a recurrence of an already curved wound infection.

With reference to the infectious events existing at the beginning of treatment (n = 98), the following outcomes were observed during the course of treatment:
- In 79 patients (81%) the wound infection was successfully treated.
- In 19 cases (19%) the wound infection could not be completely cured until the end of the documented treatment period.

Results for the wound healing process
To evaluate the clinical efficacy of Cutisorb® Sorbact® for its properties as an antimicrobial wound dressing in combination with a secondary dressing, the documented treatment courses and their final outcomes were assigned to the following groups (Fig. 7):
- A course of healing was regarded as "stagnating" if the final outcome exhibited neither a deterioration nor a marked improvement in the wound healing situation compared to the initial situation (7 cases, 6%).
- The wound was classified as "worsened" if the clinical signs of inflammation increased, sloughy layers or necrotic material formed for the first time or the proportion of granulation or epithelial tissue was reduced (1 case, 1%).
- The wound was classified as "improved" if the clinical signs of inflammation were reduced, the wound became clean or an increased amount of granulation or epithelial tissue was observed. Successful cleanup of the wound bed followed by surgical wound closure was also classified as "improved" (84 cases, 72%).
- A course of healing was designated "cured" if the original skin defect showed complete, closed, epithelialised scar formation (24 cases, 21%).

Results for wound pain
The patients’ pain was documented at every dressing change (n=1150) using a visual analogue pain scale extending from 0 (no pain) to 10 (severe pain). This parameter could not be elicited in one patient due to unconsciousness. Pain can occur as a symptom of a wound infection, but can also result from inadequate local treatment. A comparison of the data generated in 115 patients at the beginning and end of the treatment reveals a marked improvement in the pain symptoms during the course of therapy:
- 0 = no pain: 52.2% (beginning), 83.5% (end).
- 1-3 = mild pain: 33% (beginning), 14.8% (end).
- 4-6 = moderate pain: 4.3% (beginning), 0.9% (end).
- 7-10 = severe pain: 10.4% (beginning), 0.9% (end).
Results for patients' subjective perception after applying the wound dressing

Irritant substances or highly absorbent wound dressings can cause unpleasant sensations or pain. Another documented question put to the patients (n=115) concerned subjective sensations directly after applying Cutisorb® Sorbact® at each dressing change (Fig. 8). Only a small proportion of patients (2%) answered this question with "unpleasant". On the other hand, this item was rated as positive for 71% of dressing changes.

Results for product handling

Depending on the medical condition to be treated, the users have various product presentations at their disposal (absorbent pads, swabs, round swabs, ribbon gauzes). Suitable Cutisorb® Sorbact® presentations were chosen according to the different wound situations of the patients (localisation, depth, topography, area, aetiology). At every dressing change, the handling was rated as "very good"/"good"/"satisfactory"/"unsatisfactory". In 98% of cases the rating "good" or "very good" was given. This demonstrates that the users were extremely satisfied with the handling characteristics of Cutisorb® Sorbact® (Fig. 9).

Results for compatibility

During the study period, Cutisorb® Sorbact® was used for phased wound management and combined with other wound dressings. Depending on the degree of exudation, amorphous hydrogels (rated as best type of combination), alginites, hydrocolloids, foam dressings, TenderWet®, film dressings or absorbent compresses were used together with Cutisorb® Sorbact® as needed. Ointment dressings were not used as fatty substances would inhibit the bacteria binding effect. In no single case did the users report intolerance reactions experienced by the patient or undesired interactions between the various products. Cutisorb® Sorbact® did not cause discolouration in the wound area and did not generate any product-specific odour during the course of treatment. If, however, only a dressing pad or swab was selected to dress a low exuding wound, adhesion of Cutisorb® Sorbact® to the wound bed was possible ("incorrect use", inaccurate estimation of wound exudation). The adherence could be released by moistening.

Summary

In the postmarketing surveillance study described, Cutisorb® Sorbact® was tested under conditions of daily use. The documented patient clientele, most of whom had infected, secondary healing wounds, places high demands on local therapy in regard to infection control and wound healing support. Using Cutisorb® Sorbact® in a program of phased wound management, 81% of the initially present wound infections were healed and in 93% of cases there was an improvement in the wound healing situation or a complete cure.

The objectives

- Reduction of signs of perifocal inflammation
- Reduction or elimination of local infections
- Decrease or elimination in soft fibrin deposits
- Improvement in the course of wound healing
- Subjective tolerability by the patient
- Broad compatibility with other modern wound management products
- Easy product handling during dressing change

During the course of a previous study in more than 30 patients performed in the Steiermark region (MD Günther Hirschberger, Wartberg) it was found that wetting the product (also very effective with hydrogel) is important in cases where there is too little wound exudation. Another important aspect to ensure the product efficacy in these cases was to choose a secondary dressing or fixation that kept the wound and wound dressing in a moist condition. This experience helped us to ensure effective product use in the described study.
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