THE USE OF A NOVEL DESICCANT AGENT, DEBRICHEM, IN THE TREATMENT OF CHRONIC DIABETIC FOOT ULCERS.

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INTRODUCTION

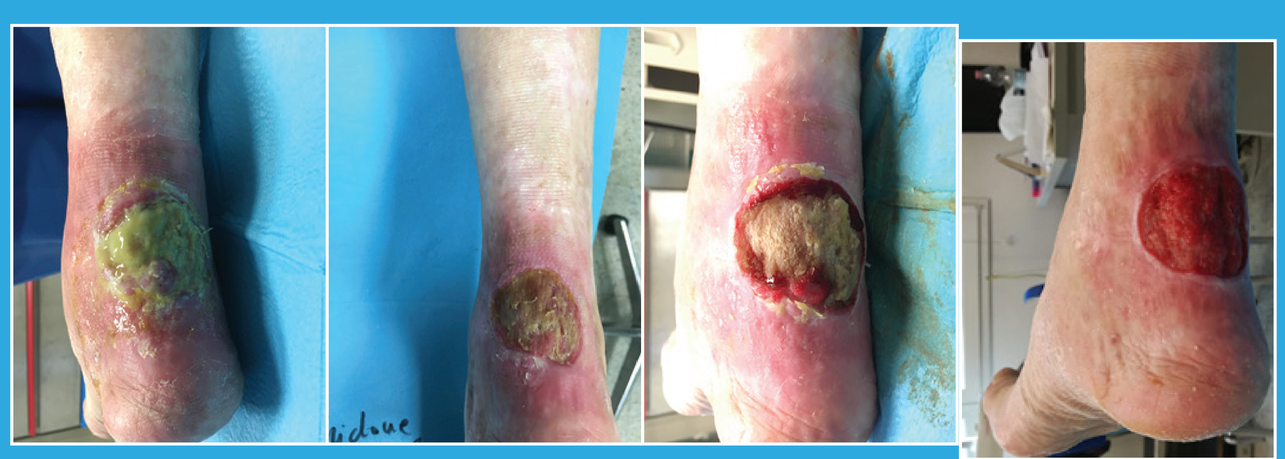
Many diabetic ulcers become chronic even in the presence of a standard adequate treatment. The reasons for chronicization are not fully understood. Among them, biofilm formation than envelopes bacteria in a low replication state is increasingly considered now as a major determinant. Bacteria inside the biofilm are not attackable by the immune system of the patient, or by use of antibiotics, and determine the production of pro-inflammatory proteins (mainly metalloprotease) that halt the healing process.

For these reasons, debridement of the wound bed, with the intentions to remove the biofilm, remains the standard approach to chronic ulcers. However, since the biofilm is not visible to humans' eyes, any form of debridement is indeed a blind procedure with no immediate possibility of checking its effectiveness. Moreover, adequate wound bed debridement requires skilled operators, surgical facilities, it's painful and might lead to bleeding, and it is associated with a significant cost.

Debrichem is a novel topical treatment composed mainly of methane sulfonic acid. It has a powerful affinity with water. When applied on the wound bed, it determines an immediate dissecating effect, thereby destroying any pathogens and denaturating any proteins present. The dissecated material in the wound bed can then be partially washed out with saline. The dissecated material that remains attached to the wound bed can be left and will be autodigested by host macrophages, that will be not more inhibited by the inflammatory proteins. Debrichem does not affect the healthy surrounding skin, due to the low content of water in the external epidermal layer.

CHRONIC HEEL ULCER IN A DIABETIC PATIENT BEFORE AND AFTER DEBRICHEM TREATMENT

FULL GRANULATION WAS REACHED IN 6 WEEKS



RESULTS

20 diabetic patients were included in the study.

The male to female ratio was 18:2. Median age was 59 yrs (range: 45-84).
The wounds were located in the foot (10 patients) and in the leg (10 patients).

In all wounds treated with DEBRICHEM, a progression to full granulation was observed. The median time to reach full granulation was 4 weeks.

SIDE EFFECTS OF TREATMENT:

No serious adverse event was noted. After DEBRICHEM application some patients without concomitant sensory neuropathy experienced a burning sensation that persisted for up to 3 hours.

DISCUSSION

A single application of DEBRICHEM resulted in effective debridement of chronic wounds of diabetic patients. All ulcers proceeded to full granulation without surgical interventions and/or use of advanced medication. DEBRICHEM application was not associated with any serious side effects. This straight-forward treatment can be performed by trained nurses without direct medical supervision. It shows potential for cost reduction of chronic wound management: less reliance on surgical debridement, fewer patients requiring systemic antibiotic administration, and lesser use of expensive advanced medication. These results should be replicated in properly designed larger clinics and also trials.

OBJECTIVE OF THE STUDY

To determine whether a single application of DEBRICHEM on chronic diabetic wound beds could restart the healing process.

PATIENTS AND METHODS

20 diabetic patients with a chronic (> 3 months duration) wound of the foot/leg were enrolled in the study. No patient received a prior debridement procedure. All patients with an ischemic ulcer underwent DEBRICHEM treatment only after an effective procedure of revascularization. No patient had fewer, sepsis, other indications for systemic antibiotic treatment, or a cancer related ulcer.

DEBRICHEM PROTOCOL APPLICATION:

- Dry completely the wound bed with a gauze;
- Apply DEBRICHEM (about 1 ml per 100 cm2) on the wound bed and on the sorrounding healthy skin (about 1-2 cm from the border);
- Leave DEBRICHEM on the wound bed for approximately 30-60 seconds;
- Rinse with plenty of saline;
- Rub with a gauze to remove the detachable material and dry;
- Cover with a fat gauze;
- Use bandage or compression as needed.

Patients were followed weekly. At these visits, wounds were rinsed and cleaned with a sterile gauze, inspected, and covered with a new sterile fat gauze.

The endpoint of the study was progression to 100% of granulation of the wound bed.

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