

DIABETIC FOOT INFECTION CONTROLLED BY IMMUNOMODULATING HYDROGEL CONTAINING 65% GLYCERINE

J.A.J. VANDEPUTTE RN, MA, CNS. & L.G.M. GRYSOEN RN, MA, CNS ; C.N.C. Clinical Nursing Consulting, Woundcare dept. Bruges, Belgium, Europe. (diabetes/E/96)

Introduction

It is generally admitted that diabetic patients are much more susceptible to infections in all wounds. Since nearly all wounds are contaminated, we can assume the presence of bacteria (contamination) in diabetic wounds. It has been established that said bacteria are not attacked properly, which may result in a faster proliferation and, consequently, result in an infection. In the literature¹ some possibilities are pointed out to explain why the treatment of diabetic wounds is often more difficult than other chronic wounds.

1. The normal infection reaction would be further disturbed by a poor vascular response.
2. The normal granulocyte migration would be delayed.
3. Chemotaxis (attraction of cells by chemical substances) would develop less effectively in case of hyperglycaemia.
4. The same hyperglycaemia would reduce the granulocytes phagocytosis capacity.



Picture 1

Diabetic foot wound from 76 year old lady. She had previous amputations of toes. The wound had been treated with dry gauze and was infected. The Yellow film which is still visible is from a frequently prescribed local antiseptic Rivanol. This wound has been treated with Elasto-Gel for 7 days and one can already see that the infection has gone. The surrounding skin is softened and the wound is already healing.

Everyone who is dealing with diabetic wounds should take care of infection prevention. The clinical signs are not so clear, and sometimes things are going bad before the patient or the caregiver have noticed something.

According to Laing² the appearance of infections in diabetic foot wounds can often be explained by a lack of appropriate care, repeated trauma/pressure and a combination of these factors. Infection of diabetic feet occurs frequently and, according to Laing again, it is of vital importance to the patient that the infection be quickly diagnosed and efficiently treated.

Diabetic patients must be careful not to incur even small wounds. Very soon after the integrity of the skin in the lower extremities is damaged, the wound will be colonised by a series of micro-organisms. When an infection appears, it will generally be multi-microbial. During the treatment of a diabetic foot wound it is essential for the wound to be treated adequately in order to prevent serious infections. Proper absorption of wound exudate and expert debridement of the necrotic wound tissue reduces³ the initial infection considerably.

As wound care professionals we are looking for a dressing that helps us dealing with the presence of bacteria in diabetic wounds, since this is the major problem. Therefore we conducted a clinical trial with a promising glycerine based hydrogel.



Picture 2

Wound completely covered with an 10 by 10 cm Elasto-Gel sheet. Since the dressing acts like a pressure relieving mattress the patient is able to walk in her shoe without serious discomfort. This dressing is secured with a stretch bandage. In the beginning of the treatment the cavity was filled with Ca-Alginates and then the dressing was opened every 2 days for changing the alginate dressing but the same Elasto-gel was reapplied for about 8 days.

ELASTO-GEL: special dressing for diabetic foot wounds ?

Summarising the data above, we found that an ideal dressing for diabetic foot wounds needs to have the following characteristics:

- * smooth and slightly pressure-relieving, in and around the wound;
- * capable of keeping the wound moist, although not soaking wet;
- * a strong bacteriostatic action;
- * able to remain on the wound for a long time and sufficiently strong to resist the pressure resulting from walking while wearing a shoe;

- * does not disturb the wound bed when removed;
- * able to keep the growth factors supplied in place, i.e. on the wound bed;
- * able to modulate serious infectious reactions.



Picture 3

The same foot after 2 months treatment with Elasto-Gel. Notice the excellent condition of the surrounding skin. Due to the glycerine the epidermal layers are in optimal condition and contributing to a faster epithelialization. The skin is also better protected against pressure and is easy to inspect for other small wounds and early signs of inflammation or infection. This picture shows the wound after debridement of the soft callus. The dressing is at this stage changed every 7 days.

In our search for such a dressing, our preliminary investigations indicated one approach the requirements. The dressing is called Elasto-gel and consists of 65% glycerine, 17.5% water and 17.5% polyacrylamide. The rate healing of the wound is not inhibited. The durability of the gel allows the dressing to easily remain in place for seven days whilst the patient keeps walking on it. Another aspect is its strong bacteriological action, due to its high glycerine contents⁴. We know from other findings⁵ that hydrogel absorbs the wound exudate, but when doing so it concentrates the growth factors and the valuable proteins in the wound site. Thus, a layer forms, like a thin film, which can be found on the wound. This means that the dressing does not take away from the wound the valuable material produced in the wound, but that, to the contrary, it keeps them concentrated at the very place where they are most needed.⁶

When we now return to the specific situation of a diabetic foot wound, we think that the use of Elasto-Gel could reduce the risk of infection drastically. Indeed, in other wounds the bacteria which are present in the wound and even the most feared bacteria will not be able to proliferate any further. Therefore, we proposed that the same would be true for the diabetic ulcers. We also proposed that the glycerine would soften the callus, which usually appears around such wounds. As for the dressing itself, it would bring about the necessary pressure suppression when it is placed on and around the wound. In order to proof the usefulness of this hydrogel dressing a clinical trial was conducted.



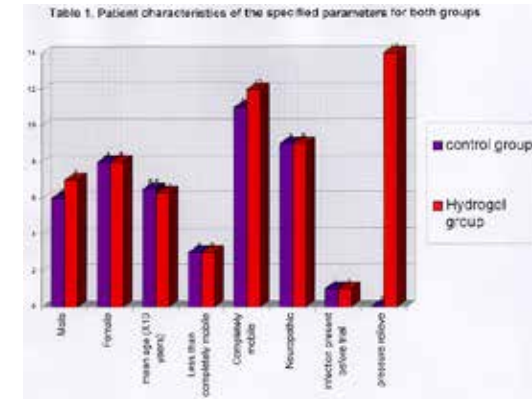
Picture 4

Wound after 2.5 months of treatment. Only a small wound is left. Inside the wound is epithelialized. Some callus is still present. The condition of the surrounding skin is still excellent. Two weeks after this picture was taken the wound was completely healed and no further treatment was necessary. During the whole treatment no antiseptics or antibiotic treatment has been used. There were no signs of infection present during the treatment with Elasto-Gel.

Clinical Trial (dry gauze treatment versus moist hydrogel treatment)

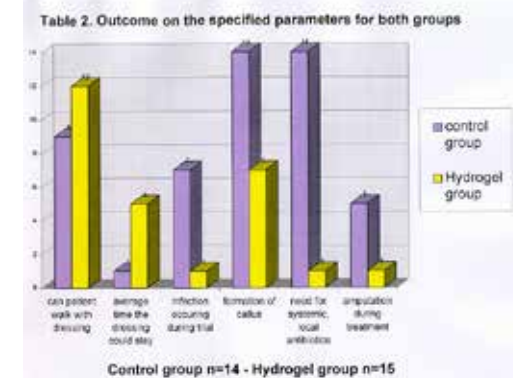
Method: Fifteen patients with diabetic foot ulcers were treated with the hydrogel dressing and cleansed with a dermal wound cleanser. The control group (n=14) was treated with a dry gauze and the wounds were treated twice a day and irrigated with chlorhexidine 0,05% solution. Patients were allocated to treatment groups according to a pre-prepared randomisation listing. If the patient was a diabetic and had a wound on his feet (neuropathic or not) they were taken into the trial. Necrotic, infected wounds and patients who already had been amputated a toe were not excluded. Only the patients who were under a systemic antibiotic regime were excluded from the trial.

Before starting treatment, all patients received information on the purpose of the study and gave a written consent. At each dressing change, the state of the ulcer and surrounding skin was assessed and the nurse also observed the ease of removal and application of the dressing. The wounds were photographed every four weeks. At the end but also during of the trial, the patients were interviewed about the comfort of the dressing and whether there was any pain on removal.



The parameters we did look for were:

- pressure relieve
- can the patient walk again with the dressing on the wound
- average time the dressing could stay on the wound
- infection ratio
- need for other dressings
- nursing labour time
- formation of callus
- need for systemic, local antibiotics or local antiseptic creams
- overall wound healing, especially amputation during treatment



Results: One patient of the control group died. One patient had a wound on both legs. Therefore the number of legs treated was 30 (15 in each group). Table one shows the patient characteristics of the two groups.

Since the hydrogel dressing is a thick layer of elastic polymer-glycerine gel it relieves the pressure of the wound and the surrounding area. Even when the patient wants to walk in his shoes this hydrogel works as a preventive cushion. This preventive action is very important especially in the patient with neuropathy. The hydrogel dressing was able to stay on the wound for over 5 days. The treatment with gauze, creams and other dressings must be changed at least once a day. The use of the hydrogel reduces nursing labour time significantly. In contrast to other dressings like hydrocolloids, one can lift the hydrogel to inspect the wound and then re-apply the same dressing, if it is not saturated.

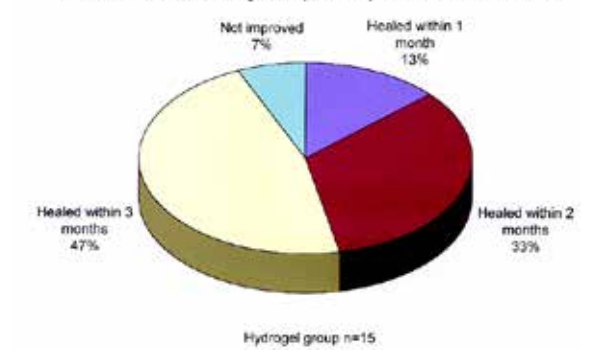
Only in one patient in the experimental group an infection was seen, while in the control group 7 patients suffered from an infection ($\alpha < 0.01$). Formation of callus is a classic experience in the treatment of diabetic foot ulcers. We found that the glycerine hydrogel did soften the callus so that its formation did slow down and if present it was easy to remove.

As for the need for antibiotics and local antiseptic creams almost all patients in the control group did use antiseptic creams. In addition, 6 of them were given systemic antibiotics ($\alpha < 0.0001$).

In the experimental group only one patient was given systemic antibiotics. No antiseptic creams were used in the experimental group. Five patients from the control group lost one or more toes.

The overall healing in the experimental group was significantly better than the ones in the control group ($\alpha < 0.05$). Of those ulcers which healed there was no difference in the two groups.

Table 3. Overall healing time ($\alpha < 0.05$) HYDROGEL GROUP

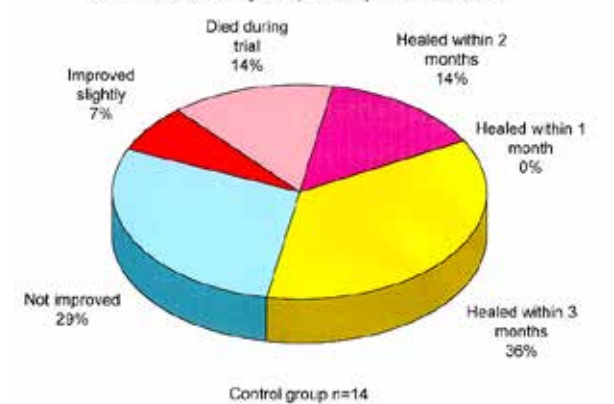


Discussion

In the control group the most frequent used dressing was gauze and Betadine cream. In the experimental group we used in the cavities always a Alginate dressing.

We tried also to fill the cavity with a piece of the hydrogel, but this could only stay for one day. When using Alginates we could leave the it for over 5 days, which was determined by the amount of exudate produced by the wound. We always fill dead spaces, otherwise they dry out the wound and bacteria can proliferate causing infection. Dead spaces are deadly! The removal of callus was easy in the hydrogel group. Patient comfort was better with Elasto-Gel. Elasto-Gel does not decrease the overall healing time when compared to non infected standard treated (moist) wounds. When using an antiseptic cream we believe that they do more harm than good because some of these products have the tendency to dry out the surface of the wound, which results in the formation of a dry crust on the wound surface. In this dry crust bacteria can survive easily and since the wound healing in diabetic patients is impaired this creams are often causing infections in our experiences. The hydrogel dressing consisting of 65% glycerine is strongly bacteriostatic and this is the only reasonable explanation why we see almost no infection in the experimental group.

Table 4. Overall healing time ($\alpha < 0.05$) CONTROL GROUP



Conclusion

We believe that the glycerine hydrogel is a major contribution to the treatment of diabetic foot ulcers.

References

- 1 De Heus-van Putten, M., Meysen, J.C., Wijma, J., en van Rossum, K. Diabetische voet. In: *WCS Wondenboek*, edited by Blanken-Spindler J., Leiden: WCS, 1995, p. 1-12.
- 2 Laing, P.: DIABETIC FOOT ULCERS. The American Journal of Surgery: 167, NO 1A (Suppl), 31S-36S (1994).
- 3 Lipsky, B., R. Pecoraro and S. Larson: OUTPATIENTS MANAGEMENT OF UNCOMPLICATED LOWER EXTREMITY INFECTIONS IN DIABETIC PATIENTS. Arch Intern Med: 150, 790-797 (1990).
- 4 Hoekstra, H. ELASTOGEL AND TREATMENT OF SKIN DISORDERS, 1996, proceedings Fourth European -African Elasto-Gel distributor's meeting, Enkopingem Lidingö, Seden, not published rapport.
- 5 Mertz P.M., Davis, S.C., Oliveira, M.F., Eaglstein, W.H., EFFECT OF ELASTO-GEL ON PSEUDOMONAS AERUGINOSA PROLIFERATION IN BURN WOUNDS, 1995, not published rapport.
- 6 Jonkman, M.F., Bruin, P., Hoeksma, E.A., Nieuwenhuis, P., Klase, H.J., Pennings, A.J., and Molenaar, I.A. A CLOT-INDUCING WOUND COVERING WITH HIGH VAPOR PERMEABILITY: ENHANCING EFFECTS ON EPIDERMAL WOUND HEALING IN PARTIAL-THICKNESS WOUNDS IN GUINEA PIGS. Surgery, 104; 537-545, 1988.