INTRODUCTION

Leg ulcers are a painful and costly problem for the community. Venous ulcers are the most common, accounting for 70% to 80% of all cases. Despite recent advances in treatment and the development of new modalities, the current standard of care remains compression therapy, in combination with appropriate moist wound care principles. Debridement is a very important aspect of treatment. It is required in order to remove necrotic tissue, fibrin and slough, and to achieve adequate wound bed preparation. Autolytic as well as enzymatic debridement is used (among others), both methods being well tolerated and easily carried out. Radioactive surgical debridement is also used, but often is not available; it may also cause complications and pain. Hydrocolloidal dressings were first used in wound management in the 1960s and 1970s. The dressings provide the optimal environment for wound healing, i.e. a moist environment, a constant wound temperature and infrequent dressing changes; they can be used on wounds in various stages of healing, especially in wound bed preparation. Gel-forming dressings, which absorb the wound exudate to form a non-adherent gel, accelerate wound healing in a moist environment.

AIM OF THE STUDY

This study compared two different kinds of hydrocolloidal dressings, DuoDERM CGF®-Convatec and Askin® Hydro – Bbrun, containing a polymethylacrylate substance Pyasilk®. Askin® Hydro is a sterile hydro-functional dressing, adhesive, multi-stratified, vegetal substances and CMC based.

MATERIALS AND METHOD

A 28-day randomized, open, controlled, multi-centre trial on patients with venous leg ulcers was carried out, using either hydrocolloidal dressings (HCD) or Askin® Hydro (AG). Throughout the study, all patients used short-stretch compression bandages. The primary efficacy variable was the time period during which the wound bed showed fully granulating tissue: the secondary end-point was the reduction of ulcer size (%). Other aspects considered were pain, oedema, ease of removal, adherence, quantity of exudate, peri-dermal skin aspect and patient comfort. A total of 28 patients with venous leg ulcers entered the study and were treated for 4 weeks. All the ulcers presented a size between 2 and 30 cm². The dressings were changed every 2 or 3 days. Every week a wound assessment was completed, including evaluation of the size and condition of the wound bed and peri-dermal skin and an estimation of all the parameters previously described. A photograph was taken at the beginning, after 2 weeks and at the end of treatment.

RESULTS

The treatment phase has now been completed and the data regarding the ulcers and wound beds are currently being reviewed. The small number of patients included in the analysis was not possible; there are preliminary results. However, the results show a good performance in wound bed preparation for 1 week treatment. The majority of patients had completed the dressing phase at least compared to AG. Absorptivity and ease of removal were similar in both groups, especially regarding pain, oedema or patient comfort. No important side effects were observed.

Especially Pain and oedema have been reported in the qualitative parameters because these two complaints and the exudate have been reported because they are between the patient and the health worker and because between the ulcers, there was a bigger difference and absorption etc. there were not particular difference because they were poorly recorded. Concerning the ulcers the situation is slightly worse for Askin® Hydro group, with a similar result for both. Graphs 4-5.

DuoDERM has a slightly better adherence. There is a greater emission of the exudate, this is only to a slight extent. Graphs 6-7.

In conclusion, we are very positive for Askin® Hydro, without any particular differences. At the beginning of the study, the two groups were slightly different concerning the DuoDERM group, 34.01 cm² in the Askin® Hydro group, the difference thereof. At the end of the study, the reduction of the area of the ulcer was 55% in the DuoDERM group, 58% in the Askin® Hydro group, the difference of 3% does not seem statistically important because of the not perfect initial homogeneity of the two groups. Graphs 2-3.

Concerning the typology of the tissue of the bottom ulcers, there is a slight advantage of this aspect needs to be examined closely in order to outline a future statistical test.

CONCLUSIONS

This study shows that Askin® Hydro is an efficient and safe alternative to DuoDERM for venous leg ulcers. The results indicate that both dressings are easy to apply, quick to be covered with DuoDERM with regard to debridement, but preliminary results indicate differences in the results to be achieved.

Finally we can say that the parameter concerning the typology of the tissular tissue seems to surpass the DuoDERM dressing, needs to be examined closely with the help of statistical test.

BIBLIOGRAPHY

RESULTS

The treatment phase has now been completed and the data regarding the ulcer size and the different compositions of the wound bed are currently being reviewed. The small number of patients included in the study means that statistical analysis was not possible; these are preliminary results.

However, the results show a good performance in wound bed preparation for both groups and at the end of the four-week treatment the majority of patients had completed the debridement phase. The HD showed a slower time of debridement compared to AE; however, ease of removal were similar in both groups, while no differences were detected regarding pain, odour or patient comfort. No important side effects were observed.

Especially:

- Pain and odour have been reported in the qualitative parameters because they are numerically quantifiable; integrity and emission of the exudate have been reported because they are between the most relevant parameters for the patient, the health worker, the type and the health worker and because these there was a larger difference, while between comfort, acceptability, and adhesion of the exudate, there were no particular differences because they were positive for both the dressings.

Concerning the colour there was a slight difference for Askina® Hydro group, while in the pain there was no difference for both.

In any case, we are positive also for Askina® Hydro, without any particular negative evaluation of the patient.

At the beginning of the study, the two groups were slightly different concerning the area of the ulcer (110.49 cm² in the HD group, 14.06 cm² in the Askina® Hydro group; the difference is therefore of about 98%).

At the end of the study, the area of the ulcer was 65% in the HD group and 41% in the Askina® Hydro group. The difference of 24% does not seem statistically important because of the low number of patients in the two groups and because of the poor initial homogeneity of the two groups.

Concerning the morphology of the tissue of the bottom ulcer, there is a slight advantage for Askina® Hydro, but we think that aspect needs to be examined closely in order to outline a datum statistically important.

CONCLUSIONS

This study shows that Askina® Hydro is an efficient and safe alternative to hydrocolloid dressing for the treatment of venous leg ulcers. The results indicated that both dressings are easy to apply and comfortable, Askina® Hydro seems quicker than Duraderm with regard to debridement, but these preliminary data did not allow statistically significant results to be achieved.

Finally, we can say that the parameter concerning the velocity of the morphological tissue reduction, where Askina® Hydro seems to surpass the Duraderm dressing, needs to be examined closely with the next studies.

BIBLIOGRAPHY