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## Urgotul® in the management of skin lesions of epidermolysis bullosa. Results of a clinical study

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## INTRODUCTION

Epidermolyses Bullosae (EBs) are genetic and congenital diseases which are due to a permanent defect in the cohesion between the epidermis and the dermis and affect approximately 10 000 patients in France when all forms are taken into account [1-5].

This defect in dermo-epidermal cohesion leads to the formation of areas of skin separation or bullae, which appear either in connection with the slightest degree of trauma or else spontaneously, and also to areas where the buccal, oesophageal and anal mucosae have separated.

Epidermolyses Bullosae are classified into three large groups in accordance with the location of the molecular defect in the skin [6].

Intraepidermal, Junctional or Dystrophic Epidermolyses Bullosae: the skin lesions of this disease can require long-term nursing care, with a skin area to be dressed which sometimes amounts to 70% of the body area of the affected subject [7-9].

Traditional, neutral or impregnated, fatty dressings have been used for many years for covering the skin lesions of epidermolysis bullosa.

Their major drawback is that changing these dressings is frequently painful.

The Urgotul dressing, which combines hydrocolloid and vaseline on a synthetic framework, has demonstrated its efficacy and its acceptability in the treatment of chronic wounds and acute wounds, in particular burns, in several clinical studies [10-11].

Consequently, the aim of this prospective study was therefore to assess the acceptability, the tolerability and the efficacy of this novel dressing in the treatment of skin lesions in patients suffering from epidermolysis bullosa.

## PATIENTS AND METHODS

### 1 – Méthods

A prospective, single-centre, noncomparative Huriet Act clinical trial was set up. This trial was carried out on 20 outpatients who were presenting with the skin lesions of epidermolysis bullosa. The treatment with the Urgotul dressing, on a prechosen lesion, was initiated at the time of the inclusion visit and then monitored, in the case of each recruited patient, whether a minor or an adult, until the lesion had healed or for a maximum period of four weeks.

During the whole of the monitoring period, the treatments given were recorded in a Patient Journal, which was written up each time the dressing was changed (performed by the family or the paramedical personnel).

*Assessments of the following parameters were noted down:*

- Acceptability of Urgotul®, as assessed on the basis of the following parameters: painlessness/painfulness of changing the dressing, ease of applying and removing the dressing, adherence of the dressing to the wound and bleeding on removing the dressing; all these parameters were assessed qualitatively.
- Toleration of the dressing, as assessed by compiling undesirable incidents.

The end-of-study visit (4 weeks) included a clinical assessment as well as a questionnaire on overall acceptability (and the quality of life) as experienced by the patient during the month of monitoring.

### 2 – Patients

11 adults (5 women and 6 men) and 9 children (5 boys and 4 girls) were included.

The adult subjects were aged between 18 and 55 (mean: 29.4 ± 10.0). Their mean weight was 56.8 ± 13.7 kg and their height was 168.6 ± 9.4 cm.The children were aged between 1 and 14 (mean: 5.8 ± 4.8) while their mean weight was 19.4 ± 8.2 kg and their mean height was 108.9 ± 28.9 cm.

### 3 – Features of the epidermolyses

The disease was of the dystrophic type in 13 cases and of the simple type in the other 7 patients.

In the case of the patients presenting with the dystrophic form, associated buccodental, oesophageal and anal lesions were very frequently noted, as were backwardness in height and weight or anomalies of the extremities.

It is to be noted that 6 out of these 13 patients were carriers of the Hal-

lopaucimens form, which is the most serious, of the EB disease, with skin separation rated to be (+++).

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In the case of the other patients, the skin separation was rated to be (+) 8 times (40% of the observations) and (++) for the other 6 cases.

### 4 – Description of the treated lesion

The treated lesion was from 1 to 45 days old (8.8 days on average).

The lesions were located on all parts of the body (upper limb, lower limb, hand, thorax, etc.) with, however, lower limb lesions being predominant (11 out of the 20 lesions).

The large axis of the lesions was between 1 and 10 cm (mean, 3.9 ± 2.2 cm).

The small axis was between 0.7 and 6.0 cm (mean, 2.5 ± 1.4 cm).

## RESULTS

### 1- Analysis

The analysis was descriptive and related to all the patients inclusively. None of the 20 patients included was ignored. 172 treatments in all were performed on these 20 patients, adding up to an accumulated total of 214 days of treatment. The mean period of application was 10.0 days. The dressings were almost always changed daily, with this being linked more to the treatment customs in the case of this disease than to the recommendations for using the dressing (customarily changed every 2 to 4 days depending on the diseases).

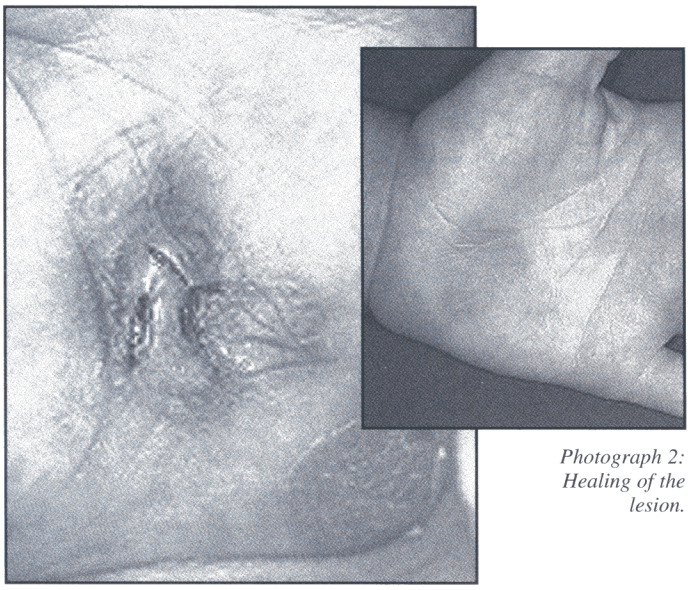
### 2- Acceptability

Documented at each treatment, the assessment of the parameters of acceptability records the following facts:

• a total absence of pain reported for 90% of the treatments performed during the course of the monitoring, with all patients included;

• no premedication was used in more than 90% of the treatments;

• applying the Urgotul® dressing was noted to be very easy or easy in 94% of cases;



*Photograph 1: Lesion on inclusion.*



*Photograph 2: Healing of the lesion.*

• removing the Urgotul® dressing was judged to be very easy or easy in 98% of the treatments performed;

• this removal was performed in the dry in 87% of the treatments, while bathing in 11% of cases and using physiological saline in the remainder of the cases;

• no bleeding was reported on removing the dressing in the case of 88% of the treatments performed;

• no adherence to the wound was observed in the case of 93% of the removals of the Urgotul® dressing;

• the Urgotul® dressing had a tendency to slip (wounds in an inclined position) in the case of 2 patients presenting with a lesion of the lower limb.

### 3- Tolerance

A local and transitory undesirable event was noted in one observation. This was an itching sensation, lasting a few minutes, when the Urgotul® was removed.

The intensity of this local effect was noted as being minimal and did not require any local treatment. The trial dressing was continued and the lesion healed.

### 4- Efficacy

At the time of the 4th week consultation, 19 lesions (95%) had healed and only one had stagnated at the end of the four weeks of monitoring.

All the lesions in the adults had healed and 8 lesions out of 9 had healed in the children.

In the case of the 19 wounds which had healed, the mean period taken for healing was 8.7 days (photographs 1 and 2).

### 5- Quality of life questionnaire (QoL)

This questionnaire was completed, in the presence of the investigator, by all the 20 patients (or their parents) at the time of the four-week visit. The following results were noted:

• 11 patients out of 20 consider that, taken overall, their quality of life has been improved by using Urgotul® in the treatment of their skin lesions;

• 15 patients (75%) found that renewing the dressing was less painful when using Urgotul®; in particular, the reply was an affirmative one in the case of all the 9 children (or parents) and in the case of 6 out of the 11 adult patients;

• 11 patients (61%, on the basis of 18 observations obtained) judged Urgotul® to be more comfortable than the dressings which they were using prior to this study;

• 15 patients (79%, 19 observations obtained) considered that they felt less apprehension at the time dressings were changed when Urgotul®was used; the response was positive in the case of all the children in the study and in the case of 7 out of the 11 adults;

• 19 patients out of the 20 replied in the affirmative to the following question "Would you be willing to have your other wounds treated with Urgotul® in the future?";

• the only negative response to this question comes from the patient whose lesion stagnated under treatment during the trial.

## GENERAL DISCUSSION AND CONCLUSION

This prospective, single-centre, open and uncontrolled study was carried out on 20 patients who were suffering from congenital epidermolysis bullosa and who were presenting with particularly painful skin lesions.

This trial convincingly demonstrated the total acceptability of this dressing in this population, particularly with regard to the lack of pain when changing the dressing.

In parallel, the dressing was extremely well tolerated, with only one adverse local event, which was minor and transitory, being reported over an accumulated 214 days of treatment.

Furthermore, 19 out of the 20 wounds treated had healed by the end of the 4 weeks of monitoring, with a mean period for healing of 8 days. However, this parameter remains of secondary importance since it appears to us to be very difficult to assess rates of healing in epidermolyses bullosae in a "comparative" manner.

In conclusion, the benefit/acceptability ratio of the Urgotul® dressing appeared very highly favourable in the case of this population of patients: this dressing takes a significant place among the nonadhesive dressings which are used for covering the wounds of these patients.

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