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Using Urgotul dressing for the management of epidermolysis bullosa skin lesions

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Objective: To evaluate the acceptability, tolerance and efficacy of Urgotul wound dressing in the management of epidermolysis bullosa (EB) skin lesions.

- Method: This was an open-label uncontrolled clinical trial involving 20 patients (11 adults and nine children) with EB simplex or dystrophic EB. Patients were selected from the register of EB patients at the investigating centre and included if they presented with at least one skin lesion requiring management with a non-adherent wound dressing. Lesions were treated with the study dressing for a maximum of four weeks. All dressing changes, wound parameters, pain and effect on quality of life were recorded.

- Results: All patients completed the trial. Nineteen out of 20 wounds healed within 8.7 +/- 8.5 days. Overall, 11 patients (55%) considered that their quality of life had improved following use of the dressing, which was also reported to be pain free and 'very easy' or 'easy' to remove at most dressing changes. Nineteen out of 20 patients stated that they would use the study dressing to manage their lesions in future.

- Conclusion: This study confirmed the very good acceptability and efficacy of Urgotul in the treatment of skin lesions in patients with EB.

- Declaration of interest: This study was sponsored by Laboratoires Urgo (Dijon, France).

Epidermolysis bullosa (EB) is a heterogeneous group of rare, inherited skin diseases characterised by recurring painful skin lesions, often precipitated by minor trauma resulting in dermo-epidermal separation or split. Treatment for this family of 23 genetic skin disorders is mainly supportive as there is as yet no radical and effective therapy for them.1

Severe forms of EB may involve the eyes, oral mucosa and the oesophagus; some may produce scarring and deformities in the extremities. There are three major forms of EB, depending on the level of cleavage in the skin (Box 1).

In patients with EB, wound healing is impaired by multiple factors including:

- Foreign bodies such as dressing residue

- Bacteria

- Nutritional deficiencies

- Tissue anoxia

- Ageing2

- Glucocorticoids.

In addition, pain at dressing removal is a major issue, particularly for children.3,4

To limit any additional risk of trauma, wounds should be covered with a non-adherent dressing, such as petrolatum-impregnated gauze, hydrogel, silicone or an absorbent foam silicone covered with a non-adherent pad and secured with soft, roller gauze bandages (non-adherent and atraumatic upon removal) and elastic tubular dressings.5-7

Clinical trials on Urgotul (Laboratoires Urgo), a lipidocolloid dressing, have demonstrated its acceptability and efficacy in children and adults8 with a wide range of acute wounds (superficial burns, abrasions, traumatic wounds) and chronic wounds (leg ulcers, pressure ulcers, dehisced wounds)9-14 and in a very large observational study.15

The characteristics of this dressing (Box 2), specifically pain-free removal, appear to be congruent with the treatment of skin lesions in patients with EB.

A clinical trial was therefore conducted to evaluate the acceptability and efficacy of Urgotul (the study dressing) in EB patients who were familiar with the evaluation of topical treatments for their skin lesions.

Method

Study design

This was an open single-centre prospective non- randomised clinical trial conducted on patients with EB. Thirty potential participants were identified from a register of diagnosed cases of EB and were sent a letter inviting them to participate in the study; 20 agreed. The study procedure was outlined to them and written consent obtained.

Inclusion criteria

- Children aged =12 months or adults

- Patients with at least one current skin lesion less than 300cm2 in size that required topical treatment and protection with a simple greasy wound dressing.

Exclusion criteria

- Known hypersensitivity to carboxymethylcellulose

- A clinically infected wound

- Squamous cell carcinoma

- Current participation in another clinical trial.

Study protocol

At the inclusion visit the patients' sex, age, EB category, age at disease onset, and main medical and surgical history were recorded.

If multiple lesions were present, the one that best met the inclusion criteria was selected as the target lesion and its largest and smallest axes were measured. Lesion history and previous topical treatments given were noted.

Lesions were photographed after cleansing with a saline solution.

The patient, family or a private nurse performed the dressing changes and wound cleansing. Patients completed a diary after each dressing change in which they recorded:

- Method of dressing removal (simple removal, removal after soaking the dressing or after bathing)

- Overall ease of removal (very easy/easy/difficult)

- Presence of odour (none/mild/severe)

- Any wound bleeding (none/mild/severe)

- Global evaluation of dressing adherence to the wound bed (none/mild/severe)

- Ease of dressing application (very easy, easy, difficult)

- Presence of dressing-induced pruritus, exudate leakage or any other local adverse event such as bleeding, overgranulation or infection. Patients were very familiar with these types of wounds, so would be able to recognise if there was a problem in the wound bed. However, they were asked to call the investigating centre or at least visit their GP if a local adverse event occurred during the study.

At each dressing change pain was recorded using a study-specific four-item verbal scale: none/mild to moderate/severe/very severe.

If pain was present, its intensity was measured using a 100mm visual analogue scale (VAS) in adults and children aged six years or more - a 100mm line with a continuum of 0 (no pain) to 100 (worst imaginable pain). Children under three years had their pain rated by their parents; those aged three to six years used a VAS scale

with faces.

After a maximum of four weeks of treatment, patients were seen at the investigating centre at Saint Louis Hospital. The investigators documented the wound status, photographs and any local or systemic adverse events that had occurred, based on the patients' or parents' diary.

This information was recorded during the study period only, so no pre-study scores are available.

At week 4, patients were asked a series of questions relating to quality-of-life parameters using a study-specific quality-of-life tool (Box 3); parents of the youngest children in the study based their answers on their experience of managing these recurrent wounds. Again, no pre-study comparative data were recorded. Development of this tool was based on the authors' own experience.

Patients were also asked about their general experience of using the study dressing.

Statistical methods
The descriptive statistical analysis was performed on an intention-to-treat basis for both the principal (acceptability of the dressing and its effect on quality of life) and secondary outcome measures (healing time and tolerance). It considered all patients included in the trial.

Ethics
The Versailles Ethics Committee (France) approved the study protocol and patient information sheet, and the study was conducted in compliance with good clinical practice. Written informed consent was obtained from the adult patients, or from both parents before their children were enrolled.

Results
Patients' characteristics
Over a five-month period, 20 patients (11 adults and nine children) were included. Their main baseline characteristics are given in Table 1.

Disease onset occurred within the first year of life in 18/20 patients (90%) and at three and eight years in the remaining two.

Thirteen patients (65%) had dystrophic EB (DEB), with three to six clinical manifestations of the disease (peri-oral lesions, oesophageal lesions, anal lesions, extremity deformities, ocular lesions and delayed development).

The target lesion had been present for between one and 45 days (mean: 8.8 +/- 12.1 days). The mean largest and smallest axes were 3.9 +/- 2.2cm and 2.5 +/- 1.4cm respectively.

In 10 patients a previous dressing had been used on the target lesion (simple gauze in five cases and a petrolatum gauze or non-adherent dressing in the remaining five). These lesions were mainly located on the lower limbs (55%) or on the hands (15%); other locations were the upper limb, chest, foot or neck.

In the remaining 10 patients, the target lesions were new, so no dressing or only gauze had been used on them.

No patients were lost to follow-up and none interrupted treatment with the study dressing before the fourth week for any reason other than healing.

Primary outcomes: acceptability of the dressing and quality of life
Overall, 11 patients (55%; seven adults and four children) considered that their quality of life had improved with the use of Urgotul dressing.

- Dressing application - This was regarded by patients as easy or very easy in 94.5% of the dressing changes

- Dressing-change time - Seven patients (35%; three adults, four children) considered that this took less time than with their previous dressing; nine (45%; five adults and four children) thought it took a similar amount of time; four (20%; three adults and one child) thought it took more time.

- Dressing removal - This was regarded as 'easy' or 'very easy' in 98% of changes and as 'difficult' only once in one patient and twice in another. Dry dressing removal was performed in 87.2% of the recorded changes; 12.7% were soaked with saline

- Odour - A mild transitory odour was noticed during 19 changes in five patients

- Bleeding and adherence - Mild bleeding was reported in 18 changes in five patients and strong adherence of the study dressing to the wound was reported twice in only one patient

- Adverse events - Two patients (one adult and one child) reported pruritus once between two dressing changes. One patient reported exudate leakage during four inter-dressing changes.

- Pain - A total of 152 dressing changes were documented in the patient diaries. In 87% of cases, analgesia was not required before dressing changes. The remaining 13% only required paracetamol. Ninety-one per cent of the dressing changes were reported to be pain free; of the remainder, 9% were rated as mild to moderate.

In adults, only one patient reported pain at dressing changes (mild to moderate pain in four consecutive dressing changes); the mean VAS score was 5mm.

In children, pain was rated as severe at only one dressing change in one patient and as mild to moderate at eight changes (only two were given a premedication) in three patients. The highest VAS score recorded in the paediatric population was 24mm.

Fifteen subjects (75%; six adults and nine children) stated that dressing changes were less painful with the study dressing than with their usual wound dressing.

Characteristics of the dressing changes are given in Table 2.

Secondary outcomes: healing time and tolerance
- Healing time - Healing was obtained within 8.7 +/- 8.5 days on average (range: 1-36 days). At the final visit 19/20 wounds had healed; the exception was in a 14-year-old girl with DEB whose lesion, which had been present for 1.5 months before inclusion, was considered by the investigator to be stagnating, despite the clear reduction in wound size (50%). This result is similar to her previous experiences with dressings and was thought to be due to the nature of her disease, hallopausiemens EB, the most serious form of DEB.

Ten of the 20 patients considered that healing times were shorter with the study dressing. Two thought they were longer than achieved with their previous dressing. The remaining eight patients thought they were the same.

- Comfort - Fifteen patients considered the study dressing more comfortable than their usual dressing. Before dressing changes, most adults and all children felt less apprehensive about the procedure than they had with their usual dressing. Nineteen out of 20 patients (95%) said they would use the study dressing again if necessary.

The study dressing was never considered as troublesome as their usual dressing in terms of daily activities by either the adults or children.

Discussion
This open-label uncontrolled clinical trial was conducted in an EB referral centre in France, and involved 20 adults and children already known to the medical investigator. All these patients (or the children's parents) were familiar with the local care of their EB skin lesions.

As these recurrent skins lesions heal spontaneously, the main objective was to evaluate the acceptability of the study dressing in this frail population, particularly in terms of pain at dressing change and effect on quality of life.

Most patients had participated in previous dressing studies and were familiar with the procedures and how to complete the report files. While this trial was not controlled and the sample was relatively small, the clinical relevance of the observations obtained can be viewed with confidence, given the very low prevalence of this genetic disease in France (3000-5000 patients).

No active drug is yet available for the topical treatment of EB skin lesions,16 and while tissue- engineered skin has appeared to give encouraging results in terms of healing rates and absence of adverse effects,1,17 it is not routinely used.

Patients with EB therefore require a non-adherent dressing to avoid trauma and bleeding on removal. In this study, the acceptability and efficacy of the study dressing were considered very good. No patients were withdrawn from the study and none discontinued its use. Application was regarded as easy or very easy by both adult patients and parents.

Patients were instructed to report pain during each dressing change, and various tools were used, depending on the patient's age, to evaluate the pain level. This was regarded as important as pain is often one of the most disturbing factors during dressing change.3 Unexpectedly, pain did not appear to be a problem in this sample,

which probably accounts for the high level of satisfaction with the study dressing - 19 out of 20 patients confirmed they will treat new skin lesions with it.

However, one of the most important nursing considerations is to educate individuals and their families about proper wound care, products and different dressing techniques18 and to promote the development of new modern dressings adapted to these EB skin lesions.

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Authors
C. Blanchet-Bardon, MD, Dermatologist, Department of Dermatology, Saint Louis Hospital, Paris, France; S. Bohbot, MD, Medical Director, Laboratoires Urgo, Chenove, France. Email: claudine.blanchet-bardon@sls.ap-hop-paris.fr

Table 1. Baseline characteristics of the patients

	Adults (n=11)	Children (n=9)	Total (n=20)
Sex (M/F)	6/5	5/4	11/9 (55%/45%)
Weight (kg):			
Mean ± SD	56.8 ± 13.7	19.4 ± 8.2	
(range)	(39–77)	(9–30)	
Height (cm):			
Mean ± SD	168.6 ± 9.4	108.9 ± 28.9	
(range)	(154–185)	(78–155)	
Age (years):			
Mean ± SD	29.4 ± 10.0	5.8 ± 4.8	
median (range)	29.9 (18.0–55.00)	3.0 (1.0–14.0)	
EB category:			
• EBS	2	5	7 (35%)
• DEB	9	4	13 (75%)
Duration of target wound (days):			
• EBS			
Mean ± SD	16.0 ± 19.8	1.8 ± 0.4	
median (range)	16.0 (2–30)	2.0 (1–2)	8.8 ± 12.1
• DEB			3.0 (1–45)
Mean ± SD	5.1 ± 4.0	22.0 ± 19.1	
median (range)	3.0 (1–12)	20.0 (3–45)	
Wound size (cm):			
• Largest axis			
Mean ± SD	4.4 ± 2.7	3.3 ± 1.2	3.9 ± 2.2
median (range)	4.0 (1.0–10.0)	3.5 (1.0–4.5)	3.8 (1.0–10.0)
• Smallest axis			
Mean ± SD	3.0 ± 1.6	1.9 ± 0.7	2.5 ± 1.4
median (range)	3.0 (0.7–6.0)	2.0 (1.0–3.0)	2.0 (0.7–6.0)
Location:			
• Lower limb	7	4	11 (55%)
• Hand	1	2	3 (15%)
• Upper limb	1	1	2 (10%)
• Chest	1	1	2 (10%)
• Other locations	1	1	2 (10%)

EBS = epidermolysis bullosa simplex; DEB = dystrophic epidermolysis bullosa

Table 2. Characteristics of the dressing changes (according to patients)

	Adults	Children	Total no. of dressing changes
Dressing removal:	(n=78)	(n=72)	(n=150)
• Very easy	64	63	127 (85%)
• Easy	13	7	20 (13%)
• Difficult	1	2	3 (2%)
Odour:	(n=78)	(n=72)	(n=150)
• None	64	67	131 (87%)
• Mild	14	5	19 (13%)
• Severe	0	0	0 (0%)
Bleeding:	(n=78)	(n=72)	(n=150)
• None	75	57	132 (88%)
• Mild	3	15	18 (12%)
• Severe	0	0	0 (0%)
Dressing adherence:	(n=77)	(n=70)	(n=147)
• None	73	64	137 (93%)
• Mild	4	4	8 (5%)
• Strong	0	2	2 (1%)
Dressing application:	(n=73)	(n=72)	(n=145)
• Very easy	38	62	100 (69%)
• Easy	29	8	37 (25%)
• Difficult	6	2	8 (5%)
Pain:	(n=77)	(n=71)	(n=148)*
• None	73	62	135 (91%)
• Mild to moderate	4	8	12 (8%)
• Severe	0	1	1 (1%)
• Very severe	0	0	0 (0%)

*Data are missing for four dressing changes

n = number of recorded changes in the patient's report file

Box 1. The three main types of epidermolysis bullosa

Epidermolysis bullosa simplex (EBS)

A group of autosomal dominant skin diseases characterised by blistering caused by mechanical stress-induced degeneration of basal epidermal cells. The major subtypes of EBS are disorders of the basal epidermal keratins, keratin 5 (K5) and keratin 14 (K14)[19]

Dystrophic epidermolysis bullosa (DEB)

Recessive dystrophic epidermolysis bullosa (RDEB) is a severe, inherited, autosomal disease characterised by dermolytic blister formation. Anomalies of collagen VII are responsible for the disease[20]

Junctional epidermolysis bullosa (JEB)

Junctional epidermolysis bullosa with the split in the pars lucida[21]

Box 2. The study dressing

Urgotul is a non-occlusive, lipidocolloid dressing made of a 100% polyester net composed of a flexible continuous yarn impregnated with hydrocolloid particles and vaseline

Use of Urgotul in this study

Patients were supplied with 10 x 10cm dressings. Wounds were cleansed with saline and the dressing was applied so that it covered the entire wound area (more than one dressing was used where required). Simple gauze was used as a secondary dressing and secured with a fixation bandage

The care protocol recommended that the study dressing be changed every three to four days but patients were free to change the dressing according to their own practice

Box 3. Patient questionnaire completed at visit on week 4

1 Overall, did your quality of life improve when using the Urgotul dressing? (Yes/No)

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2 Overall, regarding the Urgotul dressing:

- Did your dressing changes take less, the same or more time than with your usual dressing?
- Did you find the ease of use of this dressing better, similar or worse than with your usual wound dressing?
- Did you feel that dressing changes with Urgotul were less painful than with your usual dressing? (Yes/No)

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3 Regarding the healing rate of your wound when using Urgotul, did you feel it was quicker, similar or slower when compared with your experience with your usual dressing?

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4 Did you find the Urgotul dressing more, less or as comfortable as your usual dressing?

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5 When using Urgotul dressing, did you feel less, similar or more fear at the time of dressing changes?

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6 Based on your experience with Urgotul, will you be ready to use it again if necessary? (Yes/No)