HHS Public Access

Author manuscript

Pediatr Dermatol. Author manuscript; available in PMC 2016 October 25.

Published in final edited form as:

Pediatr Dermatol. 2015 ; 32(5): 628–634. doi:10.1111/pde.12486.

An Evaluation of Treatments for Pruritus in Epidermolysis Bullosa

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Abstract

Background—Pruritus is a common complication in patients with epidermolysis bullosa (EB) and can be problematic. Objective data about the treatments used by EB patients for pruritus have not been reported and recommendations are limited.

Objective—To quantitatively determine which treatments have been used by EB patients for pruritus and to evaluate the perceived effectiveness of these treatments in pruritus relief.

Methods—A questionnaire was developed to evaluate which treatments and therapies have been used for pruritus in patients of all ages and types of EB. Questions about bathing products, moisturizers, topical products, oral medications, dressings, and alternative therapies were included. A 5-point Likert scale (-2=relieves itch a lot, -1=relieves itch a little, 0=no change, 1=increases itch a little, 2=increases itch a lot) was used to evaluate the perceived effectiveness of different treatments on pruritus relief. Patients from seven North American EB centers were invited to participate.

Results—Greasy ointments (53.4%), lotions (45.2%), creams (40.4%), and oral hydroxyzine (39.0%) were the most frequently used treatments for pruritus. Treatments that were used

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Financial Disclosure: All authors have no financial relationships relevant to this article to disclose.

Conflict of Interest: All authors have no conflict of interest.

frequently and perceived to be the most effective included creams (mean=-1.1), topical prescription corticosteroids (mean=-1.0), oils (mean=-0.9), oral hydroxyzine (mean=-0.9), topical diphenhydramine (mean=-0.9), and vaporizing rub (menthol/camphor/eucalyptus) (mean=-0.9). Patients that used creams (p=0.05) or lotions (p=0.04) more often experienced significantly less pruritus. Systemic opioids (mean=0.3), adherent bandages (mean=0.3), and bleach baths (mean=0.2) slightly increased pruritus.

Conclusions—Randomized-controlled trials of therapies will be necessary to develop evidence-based recommendations for control of pruritus in EB patients.

Keywords

Pruritus; itch; treatments; epidermolysis bullosa; recessive dystrophic epidermolysis bullosa; dominant dystrophic epidermolysis bullosa; junctional epidermolysis bullosa; epidermolysis bullosa simplex

Introduction

Epidermolysis bullosa (EB) is a group of rare, inherited disorders that cause skin fragility. Main EB subtypes include dystrophic EB, junctional EB, and EB simplex.[1] Patients with EB can experience many complex, chronic problems including pain from blisters, erosions, and scarring of the skin that can involve the hands, feet, mouth, eyes, and esophagus, as well as secondary complications including failure to thrive, nutritional deficiencies, cancer, and anemia.[2]

We recently reported that pruritus is common in EB patients and can be problematic.[3] While there are suggestions for the management of pruritus in EB patients, objective data about the treatment of pruritus in EB patients limited.[4, 5] The purpose of this study was to quantitatively determine which treatments and therapies have been used by EB patients for pruritus and to evaluate the perceived effectiveness of these treatments in pruritus relief.

Methods

Patient Selection

The Epidermolysis Bullosa Clinical Research Consortium (EBCRC) was formed to create a North American database for the clinical characterization of EB. EB patients who presented to an EBCRC center were given the opportunity to enroll in a longitudinal database. Approval for the EBCRC was obtained by the Institutional Review Board at each participating institution. All patients enrolled in the EBCRC and, as appropriate, their parents, signed written informed assent/consent to be contacted for future studies.

The institutional Review Board at the Stanford University School of Medicine approved the pruritus study protocol. Informed consent/assent for participation in the questionnaire was obtained from all participants.

EB patients from seven EBCRC centers were invited to participate in this questionnaire (N = 145). EB patients not enrolled in the EBCRC but who previously had requested to be contacted for participation in research studies were also sent an invitation (N=51).

Information about the study was available on the Stanford University EB website.[6] An additional 20 EB patients contacted us expressing interest in the questionnaire and were sent an invitation. All participation was voluntary, and English-speaking patients of any age with a diagnosis of EB were included. The questionnaire was available for completion during a ten-week period.

Study Protocol

The questionnaire was created and data was collected and stored using the Research Electronic Data Capture application (REDCap) hosted at the Stanford Center for Clinical Informatics (Stanford, CA). REDCap is a secure, web-based application designed to support data capture for research studies.[7] A link to the questionnaire was sent via e-mail to participants. Participants without access to email had the option to complete the questionnaire by phone. Patients 12 years or older were asked to complete the questionnaire alone. Patients younger than 12 years old either completed the questionnaire with a caregiver, or the caregiver completed the questionnaire on their behalf. Reminder emails were sent to participants who did not respond. Attempts were made to call all participants who did not respond in order to confirm email addresses and receipt of the questionnaire.

Questionnaire

The treatment section of the questionnaire (Supplement I) was developed based on recommendations and reports for pruritus in EB and other dermatologic conditions.[4, 5, 8] Additional questions were included based on clinical experience with EB patients.

Information about demographics, EB diagnosis, and self-reported EB severity was obtained. Questions about bleach baths, pool salts, moisturizers, topical products, oral medications, dressings, and complementary/alternative therapies were included. A 5-point Likert scale (-2=relieves itch a lot, -1=relieves itch a little, 0=no change, 1=increases itch a little, 2=increases itch a lot) was used to evaluate the perceived effectiveness of treatments on pruritus relief, and treatment frequency was obtained (1=never, 2=rarely, 3=sometimes, 4=often, 5=always). Options to include additional information were provided. Response to each question was not mandatory.

Statistical Analysis

Descriptive statistics, including percentages of total responses were calculated. Overall scores consisting of the averages of responses based on the 5-point Likert scale were tabulated and were fitted into a generalized linear model and Cochran-Armitage trend tests. All tests were two-sided, and statistical significance was set at $P < 0.05$ for all analyses. Analyses were conducted using SAS version 9.4 (SAS Institute Inc, Cary, NC).

Results

Demographics

Of the 216 questionnaires sent, 146 questionnaires were completed and included in the analysis (response rate=68%). Demographics and distribution by EB type are shown in Table I.

Bathing Products

Twenty-three percent and 37% of participants used pool salts and bleach in baths, respectively (Table II). While pool salts helped relieve pruritus, bleach baths slightly increased pruritus. There was no relationship between frequency of pool salt usage and the degree of pruritus relief (p= 0.72). Four participants additionally stated using oatmeal baths for pruritus relief.

Moisturizers

Eighty-one percent of participants used a moisturizer. Creams provided the greatest relief from pruritus, followed by oils, greasy ointments, and lotions (Table II). Patients who used creams (p=0.05) or lotions (p=0.04) more frequently experienced less pruritus than patients who used either less often.

Topical products

Sixty-one percent of participants used a topical product for pruritus. Prescription topical corticosteroids, topical diphenhydramine, and vaporizing rub (menthol/camphor/eucalyptus) were used frequently and provided the most relief from pruritus (Table III). Pimecrolimus and menthol/camphor were used by fewer patients but were perceived to relieve pruritus.

Oral Medications

Oral medications that were frequently used and surveyed to be most effective at relieving pruritus included hydroxyzine, corticosteroids, cetirizine, diphenhydramine, and gabapentin (Table IV). The effects of other medications used for pain and sleep on pruritus relief are shown in Table IV. Opioids slightly increased pruritus.

Dressings

Seventy-six percent of participants reported using dressings. The effects of different dressings on pruritus are shown in Table V. Dressings impregnated with petrolatum or silver were frequently used and perceived to relieve pruritus. Hydrogels and dressings impregnated with 3% bismuth tribromophenate/petrolatum were also perceived to relieve pruritus but were used less frequently. Adhesive bandages increased pruritus (mean= 0.3) and were used most commonly by patients with recessive dystrophic EB (N=8) and dominant dystrophic EB (N=6).

Complementary/alternative methods

Fourteen percent of participants used a complementary or alternative method to help relieve pruritus. The reported effect of these therapies on pruritus is shown in Table VI. Patients additionally stated using ice packs (N=12), distraction (N=7), and music (N=4) for pruritus relief.

Discussion

The results of this study objectively demonstrate that EB patients use a variety of treatment modalities for pruritus. Although many different treatments were surveyed, a specific treatment with consistent and sustained benefit for pruritus relief was not identified.

Bathing Products

The exposure of open wounds to water while bathing can be very painful and can increase pruritus in some EB patients.[3] It is unclear if this increase in pruritus is secondary to stress or pain. The use of anxiolytics such as benzodiazepines may be recommended for pruritus secondary to anticipated stressors such as bathing. While pool salts and oatmeal baths have been recommended anecdotally for pain while bathing, both decreased pruritus in EB patients.[5] The mechanism of pain and pruritus reduction is unclear.

In contrast to pool salts, bleach baths slightly increased pruritus. Bleach baths are recommended to decrease the bacterial burden and secondary skin infections.[4] In studies with patients with atopic dermatitis, bleach baths caused itching and stinging in a small number of patients that resolved after the bleach was washed off.[9, 10] All EB patients with chronic wounds have been found to carry *staphylococcus aureus,* and 75% of EB patients without chronic wounds colonize the pathogen.[11] In contrast, only about 30% of the general population colonize *staphylococcus aureus*.[12] Therefore, given the higher risk of secondary skin infections in EB patients, decreasing the bacterial burden with bleach may outweigh the temporary pruritus.

Moisturizers

Moisturizers can provide a protective film over the skin and help to maintain a defensive barrier effect and hydration.[13, 14] Dry skin may facilitate the entry of irritants and increase the propensity of secondary skin infections.[13] In EB patients, dry skin and infected wounds were shown to be more pruritic than non-wounded skin.[3] An emphasis on compliance and generous application of moisturizers may be necessary since EB patients who used a cream or lotion more often reported significantly less pruritus than patients who used these moisturizers less frequently.

Topical products

Corticosteroids were effective in decreasing pruritus. However, long-term use of either topical or oral corticosteroids is associated with the risk of suppression of the hypothalamic-pituitary-axis and can occur with greater frequency in children.[14] Oversight is recommended with long-term use of mid to ultra-potent topical steroids.

Topical antihistamines also helped decrease pruritus. Recently, topical antihistamines such as diphenhydramine have been shown to result in anti-inflammatory activity by stimulating epidermal differentiation, leading to thickened cornified envelopes, and by enhancing epidermal lipid synthesis and secretion.[15] In addition to these effects, topical formulations may have a higher bioavailability in the skin than systemic comparisons resulting in greater

pruritus relief.[15] However, topical antihistamines can be a possible cause of contact dermatitis in susceptible individuals and therefore, should be used with caution.[16, 17]

Other topical products that relieved pruritus included vaporizing rub (menthol/camphor/eucalyptus oil) and products containing menthol/camphor and menthol/pramoxine. Topical menthol decreases pruritus by its action on the TRPM8 channel. This channel is activated by menthol and cold stimuli and produces a cooling sensation that reduces pruritus.[8, 18]

Pimecrolimus was perceived to decrease pruritus but was used by a few patients. There is a report of the use of tacrolimus, a calcineurin inhibitor, for pruritus in EB pruriginosa but future investigations for its use in other forms of EB are necessary.[19]

Oral medications

Oral antihistamines were the most common oral medications used for pruritus. Although systemic antihistamines decreased pruritus in EB patients, it is unclear if the decrease in pruritus is secondary to its central sedating proprieties. Both sedating and non-sedating anti-histamines decreased pruritus to a modest degree. Patients with difficulty sleeping because of pruritus may consider an oral sedative to improve sleep.

The mechanism of action of gabapentin in pruritus relief is unclear. It has been shown to decrease pruritus in patients with chronic kidney disease and burn injuries and also has been used as an analgesic for an infant with EB.[8, 20, 21] Other medications used for pain including acetaminophen and non-steroidal anti-inflammatory drugs only slightly decreased pruritus, in comparison to opioids, which increased pruritus.

Dressings

Dressings that were most commonly used included foam and gauze dressings, which had little to no effect on pruritus relief. Dressings impregnated with either petrolatum or 3% bismuth tribromophenate/petrolatum may decrease pruritus by adding moisture to the skin. Although only used by two patients, hydrogel dressings helped decrease pruritus. Hydrogel dressings are recommended for painful wounds and contain insoluble polymers that expand in water and hydrate wounds.[4] It is surprising that some RDEB patients are using adhesive bandages. These bandages are highly adherent to the skin and are likely to cause irritation, skin trauma upon removal, and pruritus in EB patients.

Complementary/alternative methods

A limited number of patients reported using alternative methods for pruritus relief. These methods may be useful by helping patients to focus less on pruritus and develop coping or distraction strategies when faced with the symptom.

Limitations

A limitation of the study included that all findings were based on self and caregiver-assisted reports. Participants may not have recognized the names of all of the medications included in the questionnaire or have known the names of all of their medications. To minimize confusion, caregivers were asked to help patients complete the questionnaire and precise

information about the dose and duration of treatment was not obtained. In addition, we were not able to determine the perceived effectiveness of treatments that were not commonly used or were not included in the questionnaire.

The results of this study indicate that EB patients have used many different treatments and therapies for the management of pruritus. Although treatments that were perceived to be most effective in pruritus relief were identified, we did not identify any specific treatments with exceptional benefit. Based on the results of this study, systematic, controlled evaluations to identify the most effective therapies for pruritus are necessary.

Acknowledgments

We would like to thank the Agnes Varis Charitable Trust, the Epidermolysis Bullosa Medical Research Foundation, and the Jackson Gabriel Silver Foundation for funding this study. The project described was supported by the National Center for Research Resources and the National Center for Advancing Translational Sciences, National Institutes of Health, through grant UL1 RR025744. The content is solely the responsibility of the authors and does not necessarily represent the official views of the funding sources.

Funding Sources: Funding for this project was provided by the Agnes Varis Charitable Trust. Funding for the EBCRC was provided by the Epidermolysis Bullosa Medical Research Foundation and the Jackson Gabriel Silver Foundation. REDCap is funded by Grant UL1 RR025744 from National Institute of Health/National Center of Research Resources.

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Abbreviations

EB	Epidermolysis Bullosa
EBCRC	Epidermolysis Bullosa Clinical Research Consortium
REDCap	Research Electronic Data Capture Application

Table I

Subject Demographics (N=146)

	N (%)
Participant	
Patient	90 (61.6)
Caregiver for patient	36 (24.7)
Patient with caregiver	20 (13.7)
Male	73 (50.0)
Female	73 (50.0)
Patient age, mean (range)	22.3 (0-67)
Epidermolysis bullosa type and subtype	
Dystrophic	97 (66.4)
Recessive	77 (79.4)
Dominant	14 (14.4)
Unknown	6 (6.2)
Junctional	14 (9.6)
Non-Herlitz	8 (57.1)
Unknown	6 (42.9)
Simplex	31 (21.2)
Dowling-Meara	7 (22.6)
Weber-Cockayne	8 (25.8)
Unknown	16 (51.6)
Unknown	4 (2.7)
Epidermolysis bullosa disease severity	
Mild	38 (26.2)
Moderate	69 (47.6)
Severe	38 (26.2)

Table II

Bathing Products and Moisturizers (N=146)

	N (%)	Effect on Pruritus[1] (SD)
Bathing Products:		
Pool salts	34 (23.3)	-0.7 (0.8)
Bleach	54 (37.0)	0.2 (0.9)
Moisturizers:		
Creams	59 (40.4)	-1.1 (0.7)
Oils	39 (26.7)	-0.9 (0.8)
Greasy ointments	78 (53.4)	-0.8 (0.9)
Lotions	66 (45.2)	-0.8 (0.7)

[1] -2=Relieves itch a lot, -1=Relieves itch a little, 0=No change, 1=Increases itch a little, 2=Increases itch a lot

Table III

Topical Products (N=146)

	N (%)	Effect on Pruritus[1] (SD)
Pimecrolimus	3 (2.1)	-1.3 (0.6)
Prescription corticosteroids	28 (19.2)	-1.0 (0.8)
Menthol/camphor	7 (4.8)	-1.0 (0.6)
Diphenhydramine	27 (18.5)	-0.9 (0.6)
Vaporizing rub (menthol/camphor/eucalyptus oil)	16 (11.0)	-0.9 (0.9)
Hydrocortisone 0.5 or 1%	44 (30.1)	-0.8 (0.6)
Silver sulfadiazine	16 (11.0)	-0.7 (0.8)
Pramoxine	3 (2.1)	-0.7 (0.6)
Calamine	18 (12.3)	-0.6 (0.6)
Menthol/pramoxine	14 (9.6)	-0.6 (0.5)
Benzocaine	12 (8.2)	-0.4 (0.5)
Antibacterial honey	17 (11.6)	-0.1 (0.6)
Doxepin 5% cream	1 (0.7)	0
Tacrolimus	1 (0.7)	0

Table IV

Oral Medications (N=146)

	N (%)	Effect on Pruritus[1] (SD)
For Pruritus:		
Hydroxyzine	57 (39.0)	-0.9 (0.8)
Doxepin	9 (6.2)	-0.9 (0.6)
Oral corticosteroids	15 (10.3)	-0.8 (0.9)
Cetirizine	27 (18.5)	-0.7 (0.7)
Ondansetron	12 (8.2)	-0.7 (0.7)
Benzodiazepines	12 (8.2)	-0.7 (0.7)
Diphenhydramine	48 (32.9)	-0.6 (0.7)
Gabapentin	24 (16.4)	-0.5 (0.6)
Amitryptyline	5 (3.4)	-0.4 (0.5)
Loratadine	18 (12.3)	-0.3 (0.6)
Selective serotonin reuptake inhibitor	6 (4.1)	-0.3 (0.5)
Chlorpheniramine	3 (2.1)	-0.3 (0.6)
Fexofenadine	10 (6.8)	-0.1 (0.3)
Cyproheptadine	7 (4.5)	-0.1 (0.4)
Desloratadine	2 (1.4)	0.0 (0.0)
Mirtazapine	4 (2.7)	0.3 (0.5)
For Pain:		
Ketamine	2 (1.4)	-0.5 (0.7)
Non-steroidal anti-inflammatory drug	65 (44.5)	-0.3 (0.5)
Acetaminophen	69 (47.3)	-0.2 (0.6)
Opioids	55 (37.7)	0.3 (1.1)
For Sleep:		
Zolpidem	8 (5.5)	-0.8 (1.4)
Trazadone	4 (2.7)	-0.8 (0.5)
Over-the counter sleep aids	11 (7.5)	-0.5 (1.0)
Ramelteon	1 (0.7)	-1.0
Zaleplon	1 (0.7)	0

[1] -2=Relieves itch a lot, -1=Relieves itch a little, 0=No change, 1=Increases itch a little, 2=Increases itch a lot

Table V

Dressings[1] (N=146)

	N (%)	Effect on Pruritus[2] (SD)
Hydrogel dressing	2 (1.4)	-1.5 (0.7)
Petrolatum dressing	39 (26.7)	-0.6 (0.8)
3% bismuth tribromophenate/petrolatum dressing	12 (8.2)	-0.6 (0.9)
Silver dressing	32 (22.0)	-0.5 (0.8)
Foam dressing	95 (65.1)	-0.2 (0.9)
Silicone dressing	51 (34.9)	-0.1 (0.7)
Gauze	62 (42.5)	0.0 (0.7)
Retention Gauze	57 (39.0)	0.1 (0.8)
Non-adherent gauze	39 (26.7)	0.1 (0.6)
Adhesive bandage	21 (14.4)	0.3 (0.8)
Hydrofiber dressing	4 (2.7)	0.3 (1.3)

[1] See Supplement 1, question 52 for examples

[2] -2=Relieves itch a lot, -1=Relieves itch a little, 0=No change, 1=Increases itch a little, 2=Increases itch a lot

Table VI
Complementary/alternative methods (N=146)

	N (%)	Effect on Pruritus[1] (SD)
Acupuncture	1 (0.7)	-1.0
Mindfulness	9 (6.2)	-0.8 (0.4)
Yoga	4 (2.7)	-0.8 (0.5)
Biofeedback	2 (1.4)	-0.5 (0.7)
Meditation	6 (4.1)	-0.3 (0.5)
Cognitive behavioral therapy	3 (2.1)	-0.3 (0.6)
Aromatherapy	3 (2.1)	-0.3 (0.6)
Support groups	2 (1.4)	0 (0)
Hypnosis	1 (0.7)	0

[1] -2=Relieves itch a lot, -1=Relieves itch a little, 0=No change, 1=Increases itch a little, 2=Increases itch a lot