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Stoma care products represent a common and previously underreported source of peristomal contact dermatitis

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Abstract

BACKGROUND—Peristomal dermatitis is a common complication for the 700000+ patients in the US with an ostomy. The role of stoma skin care products (SSCP) in peristomal dermatitis is poorly understood.

OBJECTIVE—To evaluate SSCPs as a cause of peristomal dermatitis.

METHODS—Retrospective chart review of patients with peristomal dermatitis at 4 academic hospitals from Jan 2010 to March 2014. Patient demographics, clinical information, and use test and patch test results were documented.

RESULTS—18 patients identified with peristomal dermatitis were tested. The frequency of peristomal contact dermatitis was 12/18. We identified numerous stoma skin care products as triggers of irritant and/or allergic contact dermatitis. The most common stoma skin care product used and/or involved in dermatitis was CavilonTM No Sting Barrier Film.

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CONCLUSIONS—Our data support a paradigm shift where health care workers treating patients with peristomal dermatitis, currently considered a reaction mainly to bodily fluids, must now consider those products used to protect the skin as potential triggers for this disease. Therefore, patients with peristomal dermatitis should be tested to their stoma skin care agents to determine the need for removing or changing these products. Additionally, full ingredient labeling by manufacturers would help identify new allergens and irritants.

Keywords

allergic contact dermatitis; irritant contact dermatitis; patch test; peristomal dermatitis; ostomy; skin barrier; skin care products; stoma

It is estimated that over 700000 patients in the United States are living with a stoma (colostomy, ileostomy, ileal conduit or urostomy).¹ These patients receive regular stoma care in wound ostomy and continence clinics, and complicated cases are referred to the dermatologist for management. Peristomal skin disorders represent the most common post-operative complication in ostomates, the incidence of which ranges from 15–65%.^{2,3} It has been estimated that these events account for more than a third of stoma care clinic visits resulting in a substantial economic burden on the patient and the health care system.² Peristomal skin is constantly exposed to a number of substances including urine, feces, medicaments, ostomy pouch systems, and stoma skin care products such as barrier films and adhesive paste/removers. The above can result in a variety of peristomal events, including physical skin abrasion and/or infections, dermatologic conditions (pyoderma gangrenosum, psoriasis etc.), and contact dermatitis.⁴ Bodily fluids are known to be an important cause of peristomal dermatitis. To protect the peristomal skin, medical professionals recommend applying stoma skin care products designed to prevent peristomal irritation. Because of the presence of known allergens/irritants in peristomal skin products (e.g., fragrances, colophonium), we reasoned that stoma skin care products may represent a previously unappreciated cause of peristomal dermatitis. Allergic contact dermatitis (ACD) has been infrequently reported (0.5–4.7%),^{5–8} but, when present, stoma skin care products are often the cause⁹. The role of these products as irritants is also poorly understood. Most of the evidence in the literature is in the form of case reports and case-series, with no large-scale studies reporting on these events.^{8,10} Herein, we evaluate irritant and allergic etiologies for peristomal dermatitis, and identify commonly used products as culprits.

METHODS

We utilized an Institution Review Board (IRB) approved retrospective chart review of patients with peristomal dermatitis, who were managed by dermatologists at the Memorial Sloan-Kettering Cancer Center (MSKCC), New York-Presbyterian Hospital & Weill Cornell Medical Center (WCMC), Tufts Medical Center, and UMass Memorial Medical Center, during a 4-year period (Jan 2010 – March 2014). In most cases, the status of the peristomal skin lesions was noted clinically and also according to the validated SACSTM (Studio Alterazioni Cutanee Stomali) instrument, which was originally developed by wound ostomy continence nurses and surgeons for objective assessment and classification (online supplemental Figure 1).^{4,11}

Product testing was performed either as a use test or a patch test. In most patients (1–15), the use test was employed, as the products being tested are normally either applied and then occluded under adhesive dressings or are the adhesive dressing itself. For the use test, we identified an area of uninvolved skin of approximately 10cm² to apply the product. If the patient was tested by our staff, the back was chosen. Otherwise, if the patient was unable to come to the office three times in one week and was able to reapply the product to their own skin as instructed, we utilized the arm or abdomen and instructed patients to treat this area as if it were their ostomy site. Stoma skin care products were applied ‘as is’ to accurately mimic the conditions under which the products would be used. Liquid or spray products were applied to dry skin in parallel to changing the ostomy dressing. The site was then covered with adhesive dressing known to not react with the patient’s skin in an attempt to mimic clinical occlusion. Exposure was continued for one week (2 applications) and reactions were then assessed. For those who were able come to the office for all three appointments, our staff photographed and recorded skin findings. For those who were unable to come to all three appointments, if the patient noted a reaction pictures were taken by family or home care nurses. For all patients, sites were examined for epidermal changes including but not limited to erythema, edema, vesiculation, or ulceration. In some instances the brand name of the stoma care product could not be confirmed so the general product category only is listed. All data was recorded in a Microsoft Excel database, and descriptive frequencies were used to summarize the data.

Patients 16–18 were patch tested to stoma care products as follows: ConvaTec™ Sur-fit Natura Stomahesive wafer, Coloplast™ Sensura Wafer, Hollister™ Wafer, Durahesive™ Wafer, Eakin™ material, Hollister™ Adapt Material, Coloplast™ Strip Paste, Coloplast™ Wafer, Hollister™ Adapt Barrier Ring, and Tegaderm was applied as a 2 cm² piece of wafer under paper tape occlusion for 48 h (Patients 16 and 17); Cavilon™ No-Sting Barrier Film was applied as pledget form of the product directly to the skin and covered with tape (Patient 17); or a small amount of ConvaTec™ Stomahesive Protective Powder, Cavilon No-Sting Barrier Film, ConvaTec™ Stomahesive Paste, Adapt stoma powder®, Mupirocin Ointment, Desonide 0.05% Cream, Alkare™ Protective Wipe, StomaCare™ Wipe, or Smith & Nephew™ No-Sting Skin-Prep Wipe was placed on a Finn chamber then allowed to dry and occluded for 48 h (Patients 16 and 18). In all cases areas were examined again 48 h after application of the product and then again 48 h after removal, i.e., at day (D) 4. Regardless of the method of stoma care product testing control patients were not used.

In addition to stoma care product testing, patients were also patch tested to a baseline series, which included either the 80 screening allergens recommended by the North American Contact Dermatitis Group (NACDG) ¹², the NACDG 65 allergen screening series (Patient 16 only), or a modified NACDG standard series (AllergEAZE, Smart Practice® Canada, Calgary, Canada; Dormer Laboratories Inc., Ontario, Canada) along with other supplemental series (Table 1). Allergens were applied to the back with Finn chambers® (Epitest, Tuusula, Finland) on Scanpor® tape (Norgesplaster, Vennesla, Norway) or AllergEAZE patch test chambers (Calgary, Canada). Reactions were graded at D2 or D3 and D4 or D5 using ICDRG criteria. The results presented are those of the final reading day.

RESULTS

Demographics

We identified 54 patients who were treated by a dermatologist for peristomal dermatitis. Clinical data including reactivity patterns for patch test results to a defined allergen (n=10) or testing results to a stoma care product (patch or use testing) (n=18) were available for altogether 18 patients (online supplemental Table 1). The mean age of these 18 patients was 60.4 years (range: 35–87) with 11 males and 7 females. The majority (82%) of patients had a current or prior history of cancer, including colorectal (n=7), genitourinary (n=6), and ovarian (n=2). The ostomy types were as follows: colostomy (n=9), ileostomy (n=3), and ileal conduit diversion (n=6). One patient with an ileostomy also had a wound vacuum-assisted closure. Patients referred to dermatology had ostomies for at least 3 months. Co-existing dermatologic conditions were encountered in 33% of the patients: psoriasis (n=2), lichen sclerosus et atrophicus (n=1), melanoma (n=2), and basal cell carcinoma (n=1).

Clinical Characteristics

The peristomal skin in our patients exhibited a range of clinical reaction patterns: In all cases the peristomal skin was erythematous extending out from the stoma (n=18). In some cases, erosion (n=1) or even ulceration (n=1) of the skin was noted, in some instances vesiculation. In those patients with more chronic dermatitis, lichenification was found. The peristomal regions (quadrants, online supplemental Figure 1) affected at the time of presentation were as follows: all (n=11), right upper (n=2), and right/left lower (n=1 each). Skin reactions were limited to the area around the stoma and did reach the border of the adhesive dressing with rare extension beyond. Patients reported symptoms ranging from pruritus alone to both pain and pruritus. Most of the patients improved with oral antihistamines, topical steroids, avoidance and/or changing of the causative stoma skin care products; in rare instances, oral antibiotics for superinfection were needed.

Skin Testing Results

Overall, the frequency of peristomal contact dermatitis in our patients was 14/18 with 12/18 reacting to a stoma care product and 7/10 to a defined allergen. Of the 15 patients who were use tested to stoma products, 9 (60%) had positive reactions. In those who were patch tested, 25 positive patch test reactions were recorded of which 5 were to a stoma care product; for further details see online supplement Table 1. Regardless of the method of testing used, the patients reported pruritus in association with test reactions. Several patch test reactions to stoma products were irritant bullous reactions (Figure 5, patient 18). In the use test negative patients, an erythematous irritant reaction (IR) to adhesive tape and a doubtful reaction to PDI™ adhesive tape remover pads were recorded but were not counted as positive reactions. The stoma skin care products of relevance in our patients were mainly skin barriers/fillers (e.g. Cavilon™ No-Sting Barrier Film (3M, St. Louis, MN, USA), n=5) (Figure 1–5) that are intended to fill in the unevenness in skin surfaces, help increase the ostomy system wear time, prevent leakage around the stoma, and protect peristomal skin. Adhesive removers (e.g. PDI™ Adhesive Tape Remover Pads, Reliamed, Unisolve, n=6) that are used to remove the adhesive residue from various stoma-related products (ostomy bags, tapes, etc.) were the

other major group of products (Table 1). In addition, products from various manufacturers elicited positive reactions and their ingredients are shown in Table 2.^{13–21}

Seven patients showed positive allergic patch test reactions to one or more potentially relevant agents: colophonium (n=2, tackifier resin), abitol (n=1, dihydroabietyl alcohol balsamic resin, derived from rosin acids), ethyl acrylate (n=1, adhesive), hydroxyethyl methacrylate (n=1, adhesive), cinnamal (n=1, fragrance), Myroxylon pereirae (balsam of Peru, n=1, fragrance marker), benzalkonium chloride (n=1, preservative), fragrance mix I (n=1), glutaraldehyde (n=1, disinfectant), propylene glycol (n=1, humectant), triethanolamine (n=1, pH adjuster), and isophorone diisocyanate (IPDI) (n=1, polyurethane plastics). Positive allergic patch test reactions with unlikely clinical relevance were nickel (n=4, metal), benzoyl peroxide (n=1, bleaching agent, initiator of polymerization), carmine (n=1, coloring pigment), and potassium dichromate (n=1, metal).

DISCUSSION

Previous reports estimated a prevalence of both allergic and irritant peristomal contact dermatitis to an external agent at 0.5–4.7%.^{4–8} Our series was heavily biased by our referral population of recalcitrant peristomal dermatitis and several reactions that were likely irritant reactions; hence, relative frequencies cannot be compared. We identified several stoma skin care products (stoma skin barriers and adhesive removers) as triggers of allergic or irritant contact dermatitis, including severe bullous irritant reactions to a not previously implicated Cavilon™ No-Sting Barrier Film.

The occluded peristomal milieu, along with repeated ostomy bag changes involving skin stripping, mechanical trauma, etc., likely renders the skin vulnerable to contact sensitization or irritation as a result of epidermal barrier disruption.²² In our patients, stoma skin care products were the most common causative agents; however, the specific chemical component of those agents responsible is currently unknown. It would be interesting to test as much as possible with the specific causative agents in appropriate concentrations and vehicles, respectively, to identify between allergy and irritancy. Published literature suggests that the most common allergens causing allergic contact dermatitis in ostomates are epoxy resins (no longer used), Gantrez® copolymers (CHEMPOINT, Bellevue, WA, USA), d-limonene, and (un)known allergens in various stoma skin care products (ostomy pouching systems, skin barriers, adhesive removers).^{8,9,23–28} Gantrez® is a polymethylvinyl ether maleic anhydride copolymer (2 formulations: Gantrez®-425, Gantrez®-335) used in various personal care products, and as an adhesive component in a range of stoma pastes. Our literature review revealed that Gantrez®-425 is a component of Stomahesive® (ConvaTec, Greensboro, NC, USA), Adapt® (Hollister, Libertyville, IL, USA) and Dansac® pastes (Dansac, Kernersville, NC, USA), whereas Gantrez®-335 is an ingredient in Karaya® paste (Hollister, Libertyville, IL, USA).²⁷

Isophorone diisocyanate (IPDI) belongs to the group of (di-)isocyanates, that are used as raw materials in the manufacture of polyurethane plastics.²⁹ Despite its extensive usage, there have been very few reports of contact allergy,^{30,31} with mostly respiratory symptoms gaining attention.³² The cause for the long-standing (~9 months) peristomal dermatitis in our IPDI

positive patient, who was a retired metalworker with an ileal conduit, remains unclear, although potentially IPDI may have been present in the plastic or glue of one of his stoma products. IPDI was not listed on the MSDS sheets.

Marketed as a “hypoallergenic, noncytotoxic liquid,” Cavilon™ No-Sting Barrier Film is a liquid film-forming product that claims to form a waterproof barrier to act as a protective interface against skin irritation from moisture, adhesives, epidermal stripping, friction and seal protective or prescription powder under an ostomy appliance. Contact dermatitis to Cavilon™ No-Sting Barrier Film was relatively common (5 patients), more common than any other stoma skin care product tested in this series. Of those five patients, two had severe bullous reactions to Cavilon™ No-Sting Barrier Film. Given the morphology in these two patients, a severe irritant reaction appears likely. Two patients who reacted to Cavilon™ No-Sting Barrier Film also reacted to colophonium and one reacted to both ethyl acrylate and 2-hydroxyethyl methacrylate all of which are present in many adhesives; however 3M neither confirmed or denied their presence in the Cavilon™ barrier film. It is concerning that a leave-on product meant for direct skin application and improvement of barrier function could cause such a response. This highlights the importance of patch/use testing peristomal dermatitis patients to all of their ostomy products.

Further studies should be focused on detailing patch test results to individual components of stoma skin care products sourced from manufacturers. Prospective studies utilizing high-performance liquid chromatography may also significantly improve the characterization of such allergens. Our study has some limitations. First, the retrospective study design precluded further patch testing with individual components. In many cases evaluation was limited to application of the products on uninvolved skin, since the majority of our cancer patients refused the additional perceived burden of patch testing with its requirement for repeated office visits.

We recommend that health care providers (surgeons, wound ostomy and continence nurses) exercise low thresholds in suspecting peristomal contact dermatitis due to ostomy products, especially when dermatitis does not improve with general stoma care measures (meticulous skin care, proper re-fitting of the appliance) and/or follows a protracted clinical course. The clinical morphology characterized by erythema in the peristomal region involving any or all quadrants does not permit distinction between irritant and allergic reactions, and therefore patch/use testing is helpful. Manufacturers should be required to disclose all ingredients in the product's label and material safety data sheets in order (i) to enable targeted patch testing of constituents, (ii) to avoid recommendation of similar products and (iii) to facilitate selection of safe alternative products. Treatment for peristomal contact dermatitis includes avoidance of the offending product and the use of topical corticosteroid (triamcinolone, clobetasol) spray with oral antihistamines.³³ It is noteworthy that in this patient population, the vehicle in which the topical corticosteroid is administered is critical so that adhesion of the stoma appliances is not impeded.

With the increased use of ostomies as a permanent surgical solution for diseases of the bowel and bladder or as a temporary measure for organ rest, health care professionals can expect peristomal contact dermatitis to become more common. In conclusion, our study

highlights that a view of peristomal dermatitis as simply a reaction of the skin to bodily fluids is incomplete and it is imperative that health care workers consider the stoma care products prescribed to protect the skin as the cause of disease. The causative products we identified appear to mirror those reported in other studies, and our results extend those of other authors. The zealous marketing of a plethora of stoma skin care products, some of which are sources of undisclosed allergens, calls for more stringent regulatory approval standards and allergen labelling on products. Properly trained wound ostomy and continence nurses, patient education, and timely referral to the dermatologist are critical to avoid peristomal complications, reduce clinic visits, and maintain good health-related quality of life in ostomates.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

Peristomal allergic contact dermatitis around the colostomy in a 49-year-old patient who had undergone surgery for a perianal adenocarcinoma. The patient showed reactivity to multiple stoma skin care products: Reliamed adhesive remover wipe (++), Cavilon™ No-Sting Barrier Film (+), and the PDI™ adhesive tape remover pad (++). L1, TV as per the SACS instrument (Patient No. 13)

Figure 2. Peristomal contact dermatitis due to Cavilon™ No-Sting Barrier Film in a 78-year-old bladder cancer survivor. Note the marked erythema and scaling around the stoma (ileal conduit urinary diversion). L1, TV as per the SACS instrument (Patient No. 14)

Figure 3. Peristomal ulcer and dermatitis in a 41 year old male with a history of Crohn's disease and a colostomy. The patient tested positive to ConvatecTM Stomahesive Paste and CavilonTM No-Sting Barrier Film (Patient No. 16).

Figure 4. Positive patch test reaction at the D3 reading to Cavilon™ No-Sting Barrier Film (++) in a 68 year old woman with a history of ulcerative colitis and a colostomy (Patient No. 17).

Figure 5.

A bullous, likely irritant, reaction to Cavilon™ No-Sting Barrier Film at the D3 reading in a 35 year old female with a history of Crohn's disease and an ileostomy. The patient experienced dermatitis at her ostomy site that persisted despite changing to several bags and products (Patient No. 18).

Table 1

Stoma skin care products of relevance in our patients.

No.	Stoma Skin Care Product	Number of Positive reactions	Ingredients (as listed in the MSDS/PDS/SDS) *
Adhesive/Barrier Removers			
1	PDJ™ Adhesive Tape Remover Pad	2	Hydrotreated heavy naphtha (petroleum), Isopropyl esters fatty acids (C14–18), Isopropyl alcohol, Light aliphatic solvent naphtha (petroleum), Xylene
2	ReliaMed® Adhesive Remover Wipes	2	C11–12 Isoparaffin, Petroleum naphtha, Isopropyl alcohol, Isopropyl palmitate, Isopropyl myristate, Isopropyl stearate, Fragrance
3	Uni-Solve® Adhesive Remover	1	Isopropyl Alcohol, C10–11 Isoparaffin, Dipropylene Glycol Methyl Ether, Aloe Extract, Fragrance
4	Hollister Adhesive/Barrier Remover Wipes	1	Stearic Acid, Ethanol, Dimethylsiloxane Cyclic Tetramer, Propylene Glycol Monomethyl Ether, Proprietary Fragrance, Ethyl Acetate, Decahydronaphthalene
5	ConvaTec AllKare® Wipes(barrier/adhesive remover not specified)	1	Barrier Wipes: Dimethyl phthalate, Isopropanolol, Ethyl acetate, Non-hazardous ingredients Adhesive Remover Wipes: D-limonene, Acid treated distillate oil, Balance of ingredients – non hazardous
Skin Barriers/Fillers			
6	Cavilon™ No-Sting Barrier Film	5	Hexamethyldisiloxane, Foam applicator, Isooctane, Acrylate Terpolymer, Polyphenylmethylsiloxane Copolymer
7	Adapt Stoma Adhesive Paste	1	Proprietary Composition
8	ConvaTec Stomahesive® Paste	1	Ethyl alcohol, Butyl alcohol, Balance of ingredients – non hazardous
9	ConvaTec Stomahesive® (product not specified)	1	--
10	ConvaTec Durahesive® (product not specified)	1	--
11	ConvaTec Sur-fit Natura Stomahesive Wafer	1	No MSDS for this product
Others			
12	Adhesive Tape (brand not specified)	1	--

* In some cases, ingredients and/or the % Wt/% Vol may not have been disclosed for proprietary reasons

† first instance in world literature of contact allergy to IPDI, in an ostomate

MSDS, material data safety sheet; PDS, product data sheet; SDS, safety data sheet