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Accepted Date : 26-Feb-2012
Article type : Original Article

THE RELEVANCE OF PATCH TESTING IN PERISTOMAL DERMATITIS

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Funding: None

Conflicts of Interest: None declared

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What's already known about this topic?

Positive patch test reactions have been the subject of 25 case reports over the last 30 years

No consistently relevant allergens, apart from Gantrez resins in adhesive paste accessories, have been described.

What does this study add?

An description of patch testing in the context of a population of stoma patients, including suggested patch test series

Common allergens usually from cleansers or deodorisers are the most frequently seen

Components of medical adhesive tape in stoma appliances appear to be an emerging source of skin reactions

Abstract:

Introduction: Skin disorders are a common problem for ostomates resulting in more than a third of visits to a stoma nurse. Irritant reactions, particularly irritant contact dermatitis are the most frequently seen accounting for more than 50% of problems in some studies. We report our experience in patch testing for peristomal dermatitis.

Methods: All patients were identified from our database of the skin-stoma clinic. Results of patch testing to various chemicals was performed and results analysed.

Results: From a total of 850 stoma patients in the combined clinic, 149 patients were patch tested. Only 7 patients (4.7%) had positive reactions of current, proven relevance, none of which was related to constituents of the stoma appliances themselves. The majority of the relevant allergens were preservatives and fragrances.

Conclusion: The symptoms and clinical appearances of allergic contact dermatitis and irritant contact dermatitis are similar in the occluded peri-stomal environment and are therefore difficult to distinguish on clinical grounds alone. Allergy is a relatively infrequent cause of peristomal dermatitis despite the continual exposure of skin to the components of cleansers, medicaments, other accessories and the stoma bag systems themselves.

Introduction:

Skin disorders are a common problem for ostomates resulting in more than a third of visits to a stoma nurse ¹. Irritant reactions, particularly irritant contact dermatitis (ICD) are the most frequently seen accounting for more than 50% of problems in some studies². This is not surprising when one considers that stoma formation results in the unnatural apposition of bowel with abdominal skin which, unlike urogenital or anal epithelium, is not adapted to the occlusion or repeated contamination with urine or faeces. Stripping of the skin on removal and application of appliances also contributes to disturbance of barrier function³. These features of the occluded peristomal skin environment intuitively would also enhance the possibility of allergic contact dermatitis. Appliance manufacturers endeavour to minimize these risks by employing materials with a low potential for irritation or allergy in systems designed to avoid trauma, undue wetness and to maintain skin pH between 4 and 5.5.

Modern stoma appliances consist of a plastic pouch, typically laminated thermoplastic (vinyl and polyethylene) and attached to an adhesive skin barrier by means of a firm thermoplastic ring. Colostomy bags are often one piece, closed pouches that are removed and disposed of when full. For ileostomies and colostomies of the ascending colon bags may be either drainable by means of a re-sealable flap or a two-piece systems where the barrier remains on the skin for 1-3 days and the pouches are changed when full which can be several times per day. Urostomy bags are mostly one-piece appliances with a nylon tap for drainage purposes. Most stoma bags have an additional, skin coloured, fabric cover and may also incorporate a carbon

filter system for any gases passed. There is a range of skin barriers, the commonest being a hydrocolloid composed of food grade materials. These are polyisobutylene (PIB) which provides “dry tack” adhesion to the skin and a mixture of carboxymethylcellulose and fruit pectins which serve to preserve the acidic pH of the skin and to absorb water thereby maintaining the dry-skin adhesion. The polymer’s adhesion is not optimal until warmed so most barriers incorporate an immediate adhesive tackifier on the surface, traditionally rosin based (pentaerythritol ester of rosin) but increasingly entirely synthetic hydrocarbon materials are used. To increase flexibility fibres such as cotton may be added to the hydrocolloid to provide a cross-linking effect. Newer polymer systems such as styrene-isoprene-styrene (SIS) in place of PIB also provide flexibility by cross-linking. Some recently introduced products employ alginate-based barriers whilst the older karaya systems are used relatively infrequently nowadays. Many barriers employ an adhesive tape border for added security against detachment of the bag. These adhesive tapes are similar to other medical dressings and contain acrylate adhesive systems. A range of accessory products such as additional adhesive lotions (containing acrylates), wipes, deodorizers, adhesive removers, skin cleansers, and antiperspirants is available increasing the potential for exposure of the peristomal skin to irritants or allergens.

We have previously reported the results of patch testing in stoma patients with suspected ACD to stoma materials as part of a cohort study² where only one of 65 cases had proven contact allergy (to a stoma deodoriser). We herein report our findings from all stoma patients patch tested from 1998-2011.

Materials and Methods:

The first 65 patients patch tested represented all patients with otherwise unexplained dermatitis, identified from a cohort study of 525 cases. Preliminary findings on these cases have been reported before as part of that study². In the subsequent 11 years we have run monthly stoma dermatology clinics that receive referrals nationwide from dermatologists, general practitioners, stoma nurses and surgeons as well as providing open access to old patients.

The approach to skin disease around stomas is similar to that at other special sites eg vulval dermatoses. A general medical history and examination is undertaken and all

those presenting with rashes are screened for infection with swabs for microbiological examination. Dermatophyte infection is occasionally seen and scrapings are taken from any flaking rashes to look for fungal elements. The patient is also observed changing their appliance. The appliance type, all accessories or medicaments coming into contact with the skin are recorded and any potentially harmful techniques such as excessive scrubbing of the skin can be identified. Irritant dermatitis caused by repeated leakage of urine or faeces onto the skin is usually obvious and responds rapidly to appliance adjustments to prevent leaks. Pre-existing or coincidental skin disease eg psoriasis and dermatitis elsewhere that might represent secondary generalisation are noted. In some cases dermatitis is clearly located in an area of skin continually in contact with a distinct portion of the appliance e.g. a tape border, suggesting a contact reaction. In these cases the patient is referred directly for patch testing and undergoes a use test. Patch testing & use testing is also considered in any cases not responding to interventions including appliance adjustments to prevent leaks or where an inflammatory rash remains unexplained despite other investigations or a primary dermatosis such as suspected psoriasis persists despite appropriate therapy. Effectively all patients with persistent or recurrent dermatitis, where leakage causing irritant dermatitis was excluded were invited for further investigation by patch testing. Patch testing was performed using our own extended Manchester standard battery, the patient's own products and our own stoma series testing (table 1). This series of stoma appliance, accessories and medicament components was constructed using information kindly disclosed by the major stoma products manufacturers and with materials supplied free from (ISP Europe, BASF UK, Dansac UK, Hollister incorporated, Convatec, AH Shaw Ltd, Medlogix global and Salts UK). Where separate ingredients could not be sourced the product was applied "as is". Patients also undertook a use test. This involved applying a stoma bag together with accessories

such as additional hydrocolloid washers to the non-stoma side of the abdomen. The appliances were changed at the same time as that on their stoma. The test was continued for 5–7 days. The initial 65 patients from the cohort study all underwent prick testing to cotton, pectin, latex, gelatine, carboxy methyl cellulose, polyacrylamide and polyisobutylate. This was subsequently abandoned as there were no positive results.

Results:

The proportions of patients in the original cohort study presenting with each of a variety of dermatoses has been reported elsewhere². We have since attended more than 850 new ostomy patients in our clinics. During this subsequent 11 years the proportions of the disorders seen in the clinic have changed a little as a result of more complex tertiary referrals; infections (11%), primary dermatoses e.g. psoriasis or eczema (19%), defined irritant papular reactions e.g. chronic papillomatous dermatitis (12%), pyoderma gangrenosum (17%), nicorandil-associated ulcers (2%), other rare dermatoses eg lichen sclerosus (2%), non-stoma related e.g. extra-intestinal Crohn's disease (5%), irritant dermatitis related to faecal urine or physical irritation 18%, unexplained dermatitis 13% (results presented at the European Council of Enterostomal Therapists conference in Bologna, June 14th 2011).

A total of 149 patients have been patch tested. There were 53 positive reactions. Only 7 patients had positive reactions of current, proven relevance (table 2a), none of which was related to constituents of the stoma appliances themselves (one had 2 reactions). All 7 patients also reacted to the relevant products (wipes and lotions tested "as is"; deodorisers diluted to 1% in petrolatum). In each case the peristomal dermatitis settled on avoidance of materials containing the allergen. The first 65 patients tested were drawn from the cohort study population of 142 subjects and only 1 had a relevant

positive reaction representing a prevalence of ACD of 0.7%. This patient was sensitive to oak moss absolute (*Evernia prunastri*) and the deodorising product he was using that contained it. The other patient who was sensitive to a fragranced deodoriser specifically reacted to cinnamal. Both patients were using their deodorising preparation inappropriately, allowing significant skin contact instead of placing a few drops in the bag itself as per the package instructions.

Three patients had positive reactions to components of cleansing wipes that are intended to remove the adhesive debris that is left when removing a bag. These included propylene glycol (2 cases) and Isopropyl alcohol (propan-2-ol). All three patients reported a definite improvement in the peri-stomal dermatitis following discontinuation and substitution of the wipes with ones which did not contain either allergen.

Two patients were sensitive to Methylchloroisothiazolinone/ methylisothiazolinone (MCI/MI) found as a biocide in wet-wipes and wet toilet tissue (figure 1). One of these patients was also sensitive to formaldehyde and the formaldehyde-releasing biocide bronopol (2-bromo-2-nitropropane-1, 3-diol) which was a declared ingredient of a deodorising spray she used intermittently. Avoidance of these materials resulted in complete resolution of the peristomal dermatitis in each case.

We found two patients with positive results of past relevance to chlorocresol which is present in a proprietary skin gel that both patients had stopped using already as they had suspected it to be the cause of their peri-stomal dermatitis.

Twenty of the 43 other reactions were considered to be not relevant because there was no evidence of any exposure of the peristomal skin to these materials (see table2b). It is possible, however that they were of past relevance not recalled by the patient, particularly Gantrez which is the second most frequently reported stoma allergen to date and PVP/VA copolymers (present in some adhesive dressings or pastes), the skin barrier wipe Cavilon™ and 2-ethylhexyl acrylate which is a declared ingredient of some adhesive retention strips used to secure stoma bag wafers.

The epoxy resin reactions may also have been of previous relevance but no epoxy material was demonstrable on chemical analysis of the stoma appliances used in each case (analysis by Magnus Bruze. Malmo University Hospital Sweden).

Similarly diamino diphenyl methane was not demonstrable by HPLC in any of the 3 relevant appliances tested. (Michael Taylor, principal scientist, Hollister Inc. Libertyville, Chicago II USA). Butanediol dimethacrylate was tested for by Bert Bjorkner Department of Occupational and environmental dermatology, University of Malmo Sweden and was not demonstrable in the suspected appliance.

Three patients had strong reactions to colophony (rosin). Rosin-based tackifiers have been used to increase the initial adhesion of hydrocolloid skin barriers. Five potentially relevant stoma appliances were tested for the presence of the rosin materials abietic acid, dehydroabietic acid and the stable oxidation product 7-oxodehydroabietic acid using HPLC (Ann-Therese Karlberg, Professor Dermatochemistry and Skin Allergy, Department of Chemistry, University of Gothenburg. Sweden) and no rosin materials were detected. However one of the rosin sensitive patients was patch tested because of a severe reaction to a batch of stoma bag skin barriers; she also had a positive use test. Unfortunately she discarded the bags after we told her of our suspicion that they were the cause of her dermatitis so we were not able to test them for allergenic rosin materials.

Gelatin was not considered a true reaction as the patient's reaction cleared spontaneously prior to patch testing and had no further problems despite continuing to use the same appliance. Furthermore, we were unable to provoke the dermatitis with the use test on the uninvolved skin of the abdomen.

Most manufacturers were happy to share information about ingredients, however we were unable to get any information about the acrylic monomers used in the "medical grade" adhesive or "multipolymer" used for tape borders and adhesive strips. Many appliance manufacturers use ready made material from an international supplier of medical acrylic adhesive systems who refused to divulge the information but did say that monomer levels fell to undetectable (less than 40ppm) before the product was finished. This meant that for the other 5 acrylates (table 2b) we have been unable to reliably ascertain the relevance so far, although in 2 cases (Bis GMA & Methyl methacrylate) changing to a different appliance without adhesive fabric borders did not improve the dermatitis which was then presumed to be irritant. In the other cases use tests were positive suggesting that further investigation is warranted.

Apart from the use test results detailed above the only other significantly positive one was an elderly woman who was negative on patch-testing but who reacted to a new batch of hydrocolloid washers. She did not however react to other batches of the same product. The ultimate cause was never identified as she had discarded the box of washers and the manufacturers found no problems with any other patients using them.

Discussion:

It is not surprising, given the nature of the peristomal environment that when skin problems occur many patients and health professionals consider that allergy has played the most important role. This assumption possibly also stems from the number of individual case reports in the medical literature describing contact allergy to components of stoma appliances or their accessories. When one considers that over 1.5 million people in the UK and USA alone use stoma appliances on a daily basis, the number of allergic reactions reported over the last 30 years could be regarded as reassuringly small. All but two of these 25 cases^{4, 5} has been comprehensively reviewed by Martin et al in 2005⁶.

The most frequently reported allergen group are epoxy resins⁷⁻¹⁰ representing over one third of all reports of ACD associated with ostomies although to our knowledge they are now no longer used in any stoma appliances marketed in Europe, America or Australasia (personal communication all major appliance manufacturers). Gantrez® copolymers are the next most frequently reported allergens (4 cases)^{5, 6, 11, 12}. These are used as adhesive components in a range of pastes employed to fill irregularities in the skin before applying a stoma bag thereby enhancing the wet adhesion of the appliance to the skin (Gantrez ES 425 or 225 depending on the manufacturer). This range of PMV/MA copolymers (poly methyl vinyl ether/maleic anhydride) is widely used in other applications such as hair styling foams, toothpastes and denture fixatives so that sensitisation may also in some cases have occurred via exposure at sites other than the stoma. Patients sensitive to Gantrez, however they may have been sensitised, are advised to avoid the relevant adhesive pastes in future.

Limonene (2 cases)¹³ and the racemate dipentene continue to be used in some stoma adhesive remover wipes, the other principal ingredients being polydimethylsiloxanes

although we have not had any patients react to adhesive remover wipes or releasing sprays. The remaining 10 cases of ACD in the literature are individual reports of reactions to rubber materials (3 cases)^{14, 15}, fragrance materials in deodorisers (2 cases)^{2, 16}, lanolin in a cream¹⁵, Benzotriazole (UV absorber) in a laminated vinyl bag⁴, karaya sealing ring¹⁷, Abitol in adhesive paste¹⁸ and the food grade hydrocolloid component PIB¹⁹.

We have herein presented our own findings which bring the number of reported cases to 32 since 1978. In our series of patients the relevant positive reactions are to common sensitizers such as fragrances and preservatives in deodorisers (5 cases) rather than to components of the appliance systems themselves. One patient was sensitive to isopropyl alcohol used in a barrier wipe as a solvent. This lower aliphatic alcohol has recently been shown to be a more common sensitizer than previously thought²⁰. Two patients were sensitive to propylene glycol which is present in several types of wet cleansing wipes as a humectant.

We were able to discount many of the remaining reactions as not responsible for the dermatitis observed either because there was no evidence of relevant exposure or because chemical analysis failed to demonstrate the material. Although not proven these other allergies are all of potential relevance to materials used peristomally and some, such as the reactions to Gantrez or epoxy resin systems, may well have developed from exposure in the past. Furthermore the information obtained is useful so that future exposure is avoided. The acrylate monomers remain the group where there is still some doubt as to possible relevance. This warrants further investigation not least because the details of the composition of the adhesive tapes are not revealed by the suppliers. This is one reason why we have kept a wide range of acrylic adhesive components on our stoma patch test series to date. The acrylates represent 14 of the

54 positive reactions and we are currently re-analysing products for possible sources.

Diaminodiphenylmethane is probably of historical significance in relation to epoxy systems previously employed by some stoma appliance manufacturers, however it may also be employed in the synthesis of some medical grade thermoplastic polymers such as PEEK (polyether ether ketone) although we have not found a relevance to stoma appliances and have dropped it from our series.

Regularly reviewing our results as well as communicating with appliance manufacturers has however allowed us to modify our stoma series over the years for most allergen groups (table1). For example, although we screen for latex sensitivity we no longer undertake prick tests to natural rubber unless indicated because it is no longer present in appliances to our knowledge. Our aim is clearly to produce a patch test series that picks up as many relevant positive reactions as possible and without testing to unnecessary materials. This exercise indicates that we should continue to test for the common allergens particularly fragrance materials, preservatives and other excipients of cleansers and wet wipes as well as the copolymers (Gantrez, PVP). From reviewing the literature and communication with the manufacturers we aim to add to the series, limonene, benzotriazole and propyl gallate an antioxidant in some newer peristomal skin moisturising lotions. The continued use of modified-rosin tackifiers indicates that we should also include pentaerythritol ester of hydrogenated rosin ^{21, 22}

Conclusion:

The symptoms and clinical appearances of ACD and ICD are similar in the occluded peri-stomal environment and are therefore difficult to distinguish on clinical grounds alone. Allergy compared to faecal or urine irritation is a relatively infrequent cause of peristomal dermatitis despite the continual exposure of skin to the components of

cleansers, medicaments, other accessories and the stoma bag systems themselves.

Nevertheless patch testing is an essential investigation for those with persistent peristomal inflammation in order to identify the small cohort with a relevant allergy who will be helped by avoidance advice.

Our Recommendations for who should undergo allergy testing;

In addition to those stoma patients with a clear localisation of dermatitis suggesting contact sensitivity, patch testing should also be considered for all cases with dermatitis which is not clearly related to faecal, urine or physical irritation, to infections or primary skin disorders such as psoriasis. We also recommend patch testing for all patients with persistent rashes unresponsive to appropriate interventions whatever the original diagnosis. In addition to the standard series and our stoma series (table 1) we patch test to the patients own materials in particular the hydrocolloid or other barrier, any tape border separately, a piece of the bag itself including any cover fabric and any other material in contact with the skin eg, adhesive pastes, extra hydrocolloid rings or adhesive strips. We suggest that all patients where contact sensitivity is considered should also undertake a use test (figure 2), whereby a stoma bag together with all accessories such as any hydrocolloid washers, washing materials, barrier lotions, tapes or pastes are applied to the non-stoma side of the abdomen. The appliances etc are changed at the same time and in exactly the same way as that on their stoma. The test should be continued for 7 days as late reactions may occur in our experience. Any significant reactions may indicate a sensitivity to a component of the patients appliance regimen even in the presence of negative patch testing such that further investigation may be indicated including liaison with the product manufacturers and even analysis of the appliance materials.

Table 1: Our own stoma series

No.	Chemical	No.	Chemical
1	Cinnamyl Alcohol	20	1,6-Hexanediol Diacrylate
2	Cinnamaldehyde	21	Tetrahydrofurfuryl Methacrylate
3	Eugenol	22	Tetraethyleneglycol Dimethacrylate
4	Alpha-Amyl-Cinnamaldehyde	23	N,N-dimethylaminoethyl Methacrylate
5	Hydroxycitronellal	24	Ethyl Cyanoacrylate
6	Geraniol	25	Diazolidinyl Urea
7	Isoeugenol	26	Propylene Glycol 20% in aqueous
8	Oak Moss Absolute	27	Chlorhexidine Digluconate 0.5% in Aqueous
9	Sorbitan Sesquioleate	28	2-Ethylhexyl Acrylate 0.1% in petrolatum
10	Methyl Methacrylate	29	Isopropyl 10% in aqueous
11	n-Butyl Methacrylate	30	Cetrimide 0.1% in aqueous
12	2-Hydroxypropyl Methacrylate	31	Polyvinyl pyrrolidone 1% aqueous
13	2-Hydroxyethyl Methacrylate	32	Gantrez ES225/Gantrez ES425
14	Ethyleneglycol Dimethacrylate	33	Cavilon foam applicator
15	Triethyleneglycol Dimethacrylate	34	Karaya 10% in aqueous
16	1,4-Butanediol Dimethacrylate	35	Benzoyl Peroxide
17	Urethane Dimethacrylate	36	Benzotriazole 1% pet.
18	BIS-MA (bisphenol A dimethacrylate)	37	d-Limonene 10% pet.
19	BIS-GMA (bisphenol A glycerolate dimethacrylate)	38	Propyl gallate 1% pet

Cavilon® barrier wipes contain siloxanes and acrylic terpolymer (vinyl chloride/ ethylacetate/ hydroxylpropyl acrylate)

Povidone iodine has been changed to PVP (K 30; Kollidon® BASF) as false positive, irritant reactions are common to povidone iodine²³

Our updated stoma series will include limonene, benzotriazole and propyl gallate. Pentaerythritol ester of hydrogenated rosin²⁴ is not readily available for patch testing but we are currently sourcing it and it will be included if reports from manufacturers confirm that it is still used as a tackifier

The first 65 patients were also tested to gelatine, cotton fibre, PIB, sodium carboxymethylcellulose, polyacrylamide, polysiloxane (adhesive remover spray as is), hydrocarbon tackifier resin and PVP-VA copolymer. These were dropped because no reactions were found and the materials considered to be largely inert. Nonetheless if the patient has a positive use test or reacts to pieces of their appliance systems we endeavour to obtain sample of these chemical components from the relevant manufacturers for further testing. There may, for example be contaminated batches of otherwise innocuous materials such as pib¹⁹.

Table 2a: Relevant allergens found in our cohort with breakdown of their relevance

Relevant allergen	Allergen past-relevance	Source	Number of patients
Propylene glycol		Skin wipes	2
Isopropyl alcohol		Skin wipes	1
Cinnamal		Stoma deodoriser	1
Oak Moss, evernia prunastri		Stoma deodoriser	1
MCI/MI		Skin wipes	2
Bronopol		Deodorisers	1
	chlorocresol	Stoma skin gel	2

Table 2b Positive allergens of unproven relevance

Allergen	Possible relevance	Unlikely to be relevant	Number of patients
Epoxy resins	Possibly of relevance to older appliance systems		3
Formaldehyde*		No source identified	3
Rosin derivatives*	Possibly relevant to older appliance systems tackifiers		2
Fragrance		No source identified	3
Oak moss absolute (Evernia prunestri)		No source identified	1
Cinnamal		No source identified	1
Wool alcohols		No source identified	1
Gelatine		No source identified	1
Lyril (Hydroxyisohexyl 3-cyclohexene carboxaldehyde)		No source identified	1
Cinnamaldehyde		No source identified	1
PVP/VA copolymer	Medical adhesive and dressing systems		1
Nickel		No source identified	3
Cobalt chloride		No source identified	1
Cavilon™ foam applicator	Patient did not recall using this barrier preparation		1
Gantrez ES425		Possibly sensitised from non-stoma products	1
Diaminodiphenylmethane*		No source identified	1
Balsam of Peru		No source identified	1
Quinoline mix		No source identified	1
Diazolidinyl urea	Possible exposure from cleansing materials		2
Ethyl hydroxyacrylate	The acrylates are all of potential relevance as they may be components of adhesive systems. Research into this is ongoing		1
Bis GMA	⁶³		2
Methyl methacrylate	⁶³		1
Butanediol dimethacrylate*	⁶³		3
1, 6 hexanediol diacrylate	⁶³		2
2 hydroxyethyl methacrylate	⁶³		2
Triethyleneglycol diacrylate	⁶³		1
2-ethylhexyl acrylate	Used in some adhesive “retention” strips		2

***Chemicals not found following analysis of the appliances.**

Legends

Figure 1. A 57 year old woman sensitive to MCI/MI present in moist cleansing wipes.

Figure 2 . A 63 year old woman with a positive use test suggesting sensitivity to a component of the tape border of her appliance. Investigation of potentially allergenic adhesive ingredients, in particular the acrylates is ongoing

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