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Allergic contact dermatitis caused by dipropylene glycol diacrylate in the Omnipod® insulin pump

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What's already known about this topic?

- Contact allergy to medical devices (MDs) is a growing clinical problem.
- Isobornyl acrylate is a culprit allergen found in several different MDs in the last years.

What does this study add?

- Dipropylene glycol diacrylate has now for the first time been identified in an MD.
- Evidence in alteration of device content between batches, risking polysensitization among users.

What are the clinical implications of this work?

- Re-analysing MDs is important to find allergens that are present in the MDs from batches that patients react to.

Abstract

Background

Cases of allergic contact dermatitis (ACD) caused by isobornyl acrylate (IBOA) in the Omnipod® insulin pump have previously been reported.

Objectives

We here present three cases of ACD caused by a new allergen in the pump and results from chemical analyses.

Methods

Omnipod® pumps from different batches were analysed by gas chromatography-mass spectrometry. Aimed testing with the department's medical device (MD) series and substances identified in the pump including dipropylene glycol diacrylate (DPGDA) at 0.01% and 0.1% in petrolatum (pet.) was performed. Patch testing also included extracts of the device, the adhesive patch *as is* and allergens from baseline series.

Results

All patients tested positive to 0.1% DPGDA in pet. and two patients also to the concentration 0.01%. DPGDA was found in extracts of the Omnipod® pumps brought by the patients. An Omnipod® pump from an earlier batch contained tripropylene glycol diacrylate, IBOA, *N,N*-dimethylacrylamide, di(ethylene glycol)ethyl ether acrylate (DEGEA) but no DPGDA. One of the patients reacted positively to all these allergens except DEGEA which was not tested.

Conclusions

When suspecting ACD to MDs DPGDA at 0.1% in pet. should be tested. The content of Omnipod® has changed over time. Patch testing with updated test series and relevance assessment of positive reactions is a delicate task. Children, with lifelong use of MDs, risk contracting many allergies with potential cross-allergies. A question should be raised - whether these low molecular weight acrylates should at all be used in devices constantly worn on the skin.

1. Introduction

Allergic contact dermatitis (ACD) is today generally acknowledged as a common cause of adverse skin reactions to insulin pumps and continuous glucose monitoring (CGM) systems. Isobornyl acrylate (IBOA), considered a major culprit allergen, has been the focus of interest for many researchers as well as manufacturers in the last years.¹⁻³ Cases of ACD caused by IBOA in the insulin patch pump Omnipod® (Insulet Corporation, Billerica, Massachusetts) have previously been reported.^{4,5} We here present three cases of ACD caused by a new allergen in the pump, namely dipropylene glycol diacrylate (DPGDA).

2. Patients and methods

2.1 Patients

Case 1

A 40-year-old female with type 1 diabetes (T1D) but with no previous history of atopic eczema was in June 2020 referred to our department, the Department of Occupational and Environmental Dermatology, Skåne University Hospital, Malmö, Sweden (YMDA) due to skin reactions from Omnipod® insulin pump. Severe dry, crusty, annular eczematous patches of different age were seen on the abdomen at previous pump application sites (figure 1). The skin reactions started after 1.5 years of usage (March 2020) but reappeared after only 1 day on subsequent exposures. A hydrocolloid dressing (DuoDERM®) was applied under the pump with no alleviation of the symptoms. A local group III corticosteroid (betamethasone) was used with partial effect. The CGM FreeStyle Libre® (Abbott Diabetes Care, Witney, Oxfordshire, UK) was used since 2016, with minor associated skin reactions.

Case 2

An 8-year-old boy with T1D but no previous record of atopic eczema was referred to our department because of suspected ACD caused by Omnipod®. Eczematous eruptions of different age were seen corresponding to previous locations for the pump. At the site of the last used insulin pump application, a dull red, indurated, scaly patch was seen. The skin reactions started after 7 months of usage (April 2020) but reappeared after only 1 day on subsequent exposures and progressively worsened with each new pump application. For alleviation he alternated the site of application between the abdomen and the gluteal region. A local group III corticosteroid

(mometasone furoate) was tried without any effect. The Dexcom G6® (Dexcom, Inc., San Diego, California) sensor was used with intermittent mild itch at the application site. The FreeStyle Libre® sensor was previously used without associated skin reactions.

Case 3

A 10-year-old boy with T1D but no previous history of atopic eczema was investigated at our department in November 2020, due to suspected ACD caused by Omnipod®. A red, scaly eruption was seen on his left gluteal region corresponding to the latest pump application site. The skin reactions started after 6 months of usage (August 2019) but reappeared after only 1 day on subsequent exposures. When using a local group III corticosteroid (mometasone furoate) before applying the pump the rash appeared first after 2.5 days of usage. He had used the Dexcom G6® sensor for 2 years without associated skin reactions.

Ethical approval

Written consent allowing report of their history and the use of photographs was obtained from the patients (or parents). Patient data are registered, and used with the approval by the Ethical Review Board, Stockholm, Sweden dnr 2020-02190.

2.2. Patch testing

Finn Chambers AQUA® (SmartPractice, Phoenix, Arizona, USA) were used for case 1 and 20 mg of the petrolatum (pet.) test preparations and 15 µl of liquid preparations were applied in the chambers. Case 2 and 3 were tested with IQ Ultimate chambers (Chemotechnique Diagnostics, Vellinge, Sweden). 25 mg of the pet. test preparations and 20 µl of the liquid preparations were applied in these chambers. The tests were occluded on the back for 48 hours. Patch test reading was generally performed on day (D) 3 or 4 and D7. Some substances were added at first reading. These were only patch test read once on D3 or 4. The tests were read and scored according to the ICDRG and ESCD criteria.^{6, 7}

Patch test preparations

All 3 patients were patch tested with an in-house medical device series⁸ supplemented with DPGDA ($\geq 80\%$ CAS No 57472-68-1, TCI Europe N.V., Zwijndrecht, Belgium) tested at 0.01% and 0.1% w/w in pet. Case 2 and 3 were also tested with pet. preparations of 2,2'-methylenebis(6-

tert-butyl-4-methylphenol) monoacrylate at 0.1 and 0.3% w/w respectively.⁹ All patients were tested with separate acetone extracts of i) the adhesive patch removed from the Omnipod® pump and ii) the pump itself. Three different devices from different batches were used, one for each patient. The LOT numbers were L45315 (case 1), L45382 (case 2), and L45659 (case 3). Each material was extracted in an ultrasonic bath for 5 minutes and were thereafter concentrated to a volume of 0.5 ml.¹⁰ All cases were also tested with a small piece of the adhesive patch *as is*.

Case 1 and 3 were tested with the Swedish baseline series and our baseline series for children, respectively. Case 2 was tested only with sesquiterpene lactone mix and colophonium from these series. Case 3 was tested with pet. preparations of di(ethylene glycol) ethyl ether acrylate 0.1% w/w (DEGEA) and tripropylene glycol diacrylate (TPGDA) 0.1% w/w. Case 1 was also tested with the department's extended baseline series as well as ultrasonic bath extracts of the FreeStyle Libre® sensor and patch in acetone, a separate (meth)acrylate series (table 2) and a caine series, where all of these substances except the baseline series were added at the first reading. Chemotechnique Diagnostics provided the patch test preparations unless otherwise stated.⁸ All other test preparations were prepared at our department.

Controls

Twenty-three consecutively patch tested dermatitis patients without known diabetes, volunteered to serve as controls. They were patch tested with DPGDA 0.1% (w/w) and 0.01% (w/w) in pet.

2.3 Chemical analyses

The extracts that were tested in the patients were analysed by gas chromatography – mass spectrometry (GC-MS)¹¹. In addition, from one Omnipod® device (LOTZ00242, expiry date September 2020), provided by the Swedish distributor, separate acetone extracts were prepared from i) the adhesive patch, ii) the plastic housing, and iii) materials from the inside of the device.

3. Results

3.1 Chemical analyses

DPGDA was found in all extracts prepared from the devices brought by the patients, in estimated concentrations corresponding to a total amount of 1-10 µg in both the adhesive patches and in pumps. No IBOA (<0.01 µg/ml) could be detected in any of these extracts.

No DPGDA (<0.03 µg/ml) could be detected in the extracts from the device supplied by the distributor. In the extracts of this device TPGDA, IBOA, *N,N*-dimethylacrylamide (DMAA), and DEGEA were identified but not quantified. TPGDA was mainly found in the extract of the adhesive patch, while the other substances were mainly found in the extracts of the plastic housing and the materials from the inside of the device. TPGDA, DMAA, and DEGEA were not observed in the extracts of the patients' devices.

3.2 Patch test results

Patch test results are summarized in *table 1*. In case 1 strong positive reactions (scored as +++) were seen to DPGDA 0.01% and 0.1% in pet. on reading D 4. Case 1 tested also positively to IBOA and DMAA as well as several other acrylates and to the Omnipod® extracts and the adhesive patch tested *as is* (table 1). Case 2 presented with positive reactions (scored as +) to DPGDA 0.01% and 0.1% in pet. Case 3 tested positive only to the higher concentration (DPGDA 0.1% pet.). Neither IBOA nor DMAA yielded positive reactions in case 2 or 3.

Among controls, no positive reactions were observed to DPGDA 0.01% and 0.1% in pet. (3/3 versus 0/23; $p = 0.0004$; Fisher's exact test, two-sided). No irritant reactions were seen and there were no reported late reactions to this substance.

4. Discussion

In the three cases described above, the time between first symptoms and first use of Omnipod® was at least 6 months, whereas subsequent exposures on nondamaged skin resulted in dermatitis after only 1 day. This temporal relationship is strongly suggestive of sensitization and elicitation of ACD.¹⁰ In the analyses carried out on the devices brought by the patients, DPGDA was found in all extracts, both from the adhesive patches and from the pumps. The total amounts of DPGDA were in the same order of magnitude in both the adhesive patches and the pumps. As far as we know, this is the first report of ACD caused by DPGDA in an MD. DPGDA has previously been implicated in industrial cases of ACD in workers at paint factories and a paint laboratory in Finland and Sweden¹²⁻¹⁴ (although the Finnish cases were not tested with DPGDA as such).¹²

We have in earlier investigations demonstrated the presence of IBOA in extracts of Omnipod® devices.⁴ When reviewing these previous analyses, DPGDA or other acrylates could not be identified. These analyses were however performed using another, less sensitive, GC-MS equipment than the one used for the current analyses.

To get a better understanding from which part of the device that DPGDA originated, further analyses were performed on extracts made from a device provided by the Swedish distributor (from another batch with an earlier expiration date, compared to the devices brought by the patients). Three extracts were made from i) the adhesive patch, ii) the plastic housing, and iii) materials from the inside of the device. Interestingly, no DPGDA was found in any of these extracts. Instead, the analyses showed the presence of TPGDA, IBOA, DEGEA and DMAA. From the results of our analyses it is apparent that the composition of adhesives used in the Omnipod® devices has changed over time and is different in different batches. This highlights the importance of re-analysing MDs to find allergens that are present in the MDs from batches that patients react to. This is also a good example of the difficulties to establish the clinical relevance of positive patch test reactions as substances not found in currently used MDs, may have been used in the same MDs previously.

In case 1 ACD caused by IBOA in the pump was initially suspected based on our previous experiences.⁴ The patient presented with severe contact dermatitis and a strong reaction to IBOA was therefore expected, why the substance was only tested at the lower concentration (0.1% in pet.),^{8, 10} to which a + reaction was observed. Case 1 was also positive to DMAA. The patient used FreeStyle Libre® which earlier has been found to contain both IBOA and DMAA.^{3, 15} Therefore, it could be assumed that she had been sensitized to IBOA and DMAA when using FreeStyle Libre® although she only experienced very mild skin reactions to this device. However, as the analysis of an Omnipod® pump from another batch showed the presence of both IBOA and DMAA, it is also possible that she was sensitized to these substances when using Omnipod®.

Despite IBOA being an acrylate, in most sensitized patients reported in the literature, concomitant positive reactions to other (meth)acrylates have been only occasionally observed. However, in both case 1 in the present study and in previously reported DPGDA-allergic patients^{13, 14} concomitant positive or doubtful reactions to diacrylates such as diethylene glycol diacrylate (DEGDA), TREGDA, and occasionally other acrylates including 1,4-butanediol diacrylate (BUDA), 1,6-hexanediol diacrylate (HDDA) and TPGDA have been seen. Simultaneous positive

reactions to methacrylates have not been as frequently observed. Due to chemical similarities between the acrylates causing positive reactions cross-reactions must be suspected (Table 3.) The high number of suspected cross-reacting substances in case 1 can possibly partly be explained by the extreme positive reaction (++++) to DPGDA. On the other hand, from the chemical analyses we know that one device from an earlier batch (the device provided by the Swedish distributor) than those brought by the patients contained both TPGDA and DEGEA. Case 1 showed a strong reaction to TPGDA but was unfortunately not tested with the DEGEA. The fact that TPGDA may have been present in Omnipod® devices previously used by the patient makes it possible that she was sensitized to TPGDA using Omnipod®. In fact, it is possible that she was primarily sensitized to TPGDA and that the reaction to DPGDA represents a cross-allergic reaction. Furthermore, it cannot be excluded that also other acrylates may have been present in previous Omnipod® batches. Even though tetrahydrofurfuryl acrylate and 2-phenoxyethyl acrylate have not been found in Omnipod® the allergens have previously been identified in other medical devices and primary sensitisation cannot be ruled out^{16, 17}.

Unfortunately, we were not able to obtain DPGDA with a higher purity ($\geq 80\%$), than the one used for test preparations and as a reference in the chemical investigations. However, in the chemical analyses there were no indications of the presence of the other acrylates causing positive reactions in this material. The many simultaneous acrylate reactions in case 1 could also be explained by other sources of exposure to acrylates, but the patient denied skin reactions upon contact with other acrylate-containing products.

As case 2 and 3 were children, aimed testing with only the most important test preparations was performed. Few acrylates were tested why potential cross-allergies are not known. However, the fact that none of the tested acrylates yielded positive reactions can perhaps partly be explained by the weak reactivity seen to DPGDA in these patients. If we would have had access to additional pumps and the ability to perform stronger extracts, DPGDA in the pump might have been concentrated, and positive reactions to the extracts may have been seen¹⁰.

There was no relevant exposure to explain the extreme positive reaction (++++) to caine mix II 10% in pet. or the weak positive reaction (+) to dibucaine hydrochloride 5% seen in case 1.

4.1 Collaboration and transparency regarding MD

As our knowledge on adverse skin reactions to MD increases, more and more cases of ACD caused by different culprit allergens and devices are reported^{3, 4, 11, 15, 18-21}. Cases of contracted contact allergy to culprit allergens in the products should be reported both to the manufacturer and the national Medical Products Agency. Thereby, less allergy-prone devices can hopefully be provided in the future.

In clinics investigating patients with suspected ACD to MD, an updated and accurate knowledge on the composition of the products is necessary. Only then recommendations on alternative products can hopefully be given to patients with known allergy to protect them from re-exposure to their sensitizers. This report illustrates, once again, the great importance of analyzing and re-analyzing MD as the products are not ingredient-labelled and their composition may be changed over time.⁹ However, chemical analyses of the products can only partly, and often with considerable delay, compensate for the lack of information provided by the manufacturers on the composition of the products. Ideally, a bilateral cooperation between manufacturers and investigating clinics with great knowledge in the field, both in developing and evaluating products could reduce the number of cases of ACD. After reports on contact allergy caused by IBOA in MD, producing IBOA-free devices has become a topic of current interest.^{1, 22} Removing known allergens from the products and changing their composition is an important but delicate task. Different glues used in the products can be suspected to contain similar substances. The risk of introducing new potential allergens when changing product composition, further complicated by the time lag from first exposure to the development of ACD, challenges producers in improving their safety assessments of used substances and components in the manufacturing process.

Conclusion

When evaluating patients with suspected ACD to MD, patch testing including DPGDA at concentration 0.1% in pet. is recommended. Individuals sensitized to DPGDA should be further assessed with a relevant (meth)acrylate patch test series.

When adding the risk of cross-allergic reactions, the potential consequences for affected patients contracting DPGDA contact allergy become even greater. Many patients face life-long use of their glucose sensor or insulin pump. Since different products are used over time and the composition of the individual product can be altered, this increases the risk of contracting more and more contact allergies throughout life. For individuals already sensitized there is a substantial risk of renewed

allergen exposure and ACD elicitation as acrylates are widespread in the environment in products such as UV-cured printing inks and lacquers²³, paints and varnishes²⁴ and glues used in MDs or other products²⁵⁻²⁷. There is an urgent need for primary prevention of MD-related contact allergic reactions. The complex chemical nature of the devices underlines the importance of involving toxicologists with skin expertise in device development. Further, the increasing number of cases of MD-related contact allergy raises the question whether potent skin sensitizers – such as low molecular weight acrylates – should at all be part of products permanently worn on the skin.

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Figure Legend

Figure 1. Severe, red eczematous patches of different age corresponding to previous pump application sites (case 1).

Table 1. List of allergens that resulted in positive reactions

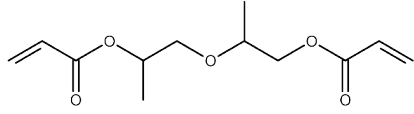
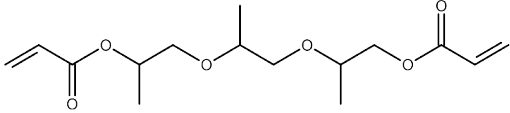
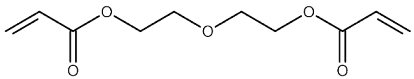
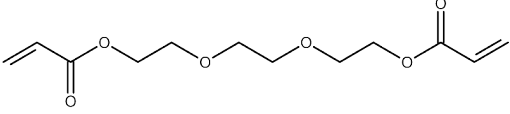
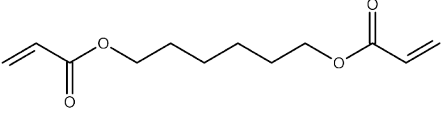
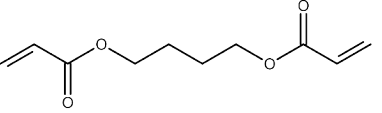
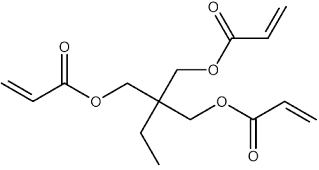
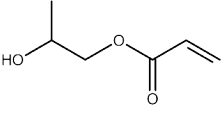
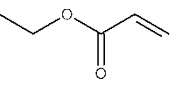
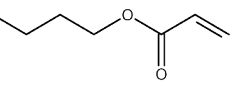
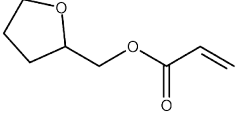
Patch test preparations	Abbreviation	Case 1		Case 2		Case 3	
		D3 or D4	D7	D4	D7	D3	D7
Dipropylene glycol diacrylate 0.01%†	DPGDA	+++	NR	+	+	?+	?+
Dipropylene glycol diacrylate 0.1%†	DPGDA	+++	NR	+	+	+	?+
Medical device series 2020⁸							
1,6-Hexanediol diacrylate 0.1%	HDHA	+++	+	?+	?+	-	-
Isobornyl acrylate 0.1%	IBOA	+	+	-	-	NT‡	NT
2-Phenoxyethyl acrylate 0.1%	PEA	+	?+	-	-	-	-
N,N-dimethylacrylamide 0.1%	DMAA	+	+	-	-	-	-
N,N-dimethylacrylamide 0.3%	DMAA	++	++	-	-	-	-
Tetrahydrofurfuryl acrylate 0.1%	THFA	++	-	-	-	-	-
Ethyl acrylate 0.1%	EA	+	-	-	-	-	-
(Meth)acrylate series† (table 2)							
1,4-Butanediol diacrylate 0.1%	BUDA	+++	NR	NT	NT	NT	NT
Butyl acrylate 0.1%	BA	+	NR	NT	NT	NT	NT
Diethylene glycol diacrylate 0.1%	DEGDA	+++	NR	NT	NT	NT	NT
Hydroxypropyl acrylate 0.1%	HPA	+	NR	NT	NT	NT	NT
Triethylene glycol diacrylate 0.1%	TREGDA	++	NR	NT	NT	NT	NT
Trimethylolpropane triacrylate 0.1%	TMPTA	+	NR	NT	NT	NT	NT
Tripolyethylene glycol diacrylate 0.1%	TPGDA	++	NR	NT	NT	-	-
Own material							
Omnipod® pump acetone extract	-	+	-	-	-	-	-
Omnipod® patch acetone extract	-	+	-	-	-	-	-
A piece of the adhesive patch from Omnipod® tested “as is”	-	+	-	-	-	-	-
Other positive reactions							
Caine mix II 10%	CM II	+++	++	-	-	-	-
Dibucaine hydrochloride 5%†	DH	+	NR	NT	NT	NT	NT

Abbreviations: NR; not read, NT; not tested, †; Substances added at the first reading in case 1, ‡; only the concentration 0.3 % was tested. All substances except acetone extracts were tested in petrolatum.

Table 2. (Meth)acrylate series patch tested in case 1 (positive patch test results are shown in table 1)

Patch test preparations
Ethyl cyanoacrylate 5 %
Bisphenol A glycerolate dimethacrylate 2 %
Triethylene glycol diacrylate 0.1%
Hydroxypropyl methacrylate 2 %
1,4-Butanediol diacrylate 0.1%
Ethylene glycol dimethacrylate 2 %
Methyl methacrylate 2 %
Butyl acrylate 0.1%
Diethylene glycol diacrylate 0.1%
Ethyl methacrylate 2%
Butyl methacrylate 2%
Triethylene glycol dimethacrylate 2%
Trimethylolpropane triacrylate 0.1%
Tetrahydrofurfuryl methacrylate 2%
Hydroxypropyl acrylate 0.1%
1,4-Butanediol dimethacrylate 2%
2,2-bis(4-(2-Methacryl-oxyethoxy)phenyl)propane 2%
Diethylene glycol diacrylate 0.1%
Tripropylene glycol diacrylate 0.1%
Pentaerythritol triacrylate 0.1%
Oligotriacrylate 0.1%
Epoxy acrylate 0.5%
Urethane diacrylate, aromatic 0.05%
<i>N,N'</i> -Methylene-bisacrylamide 1%

All substances were tested in petrolatum.

Name	Molecular structure	Molecular weight	CAS number
Dipropylene glycol diacrylate		242.3	57472-68-1
Tripropylene glycol diacrylate		300.3	42978-66-5
Diethylene glycol diacrylate		214.2	4074-88-8
Triethylene glycol diacrylate		258.3	1680-21-3
1,6-Hexanediol diacrylate		226.3	13048-33-4
1,4-Butanediol diacrylate		198.2	1070-70-8
Trimethylolpropane triacrylate		296.3	15625-89-5
Hydroxypropyl acrylate		130.1	25584-83-2
Ethyl acrylate		100.1	140-88-5
Butyl acrylate		128.2	141-32-2
Tetrahydrofurfuryl acrylate		156.2	2399-48-6

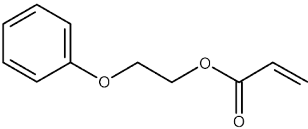
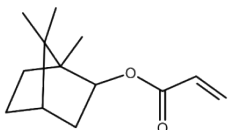
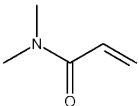
2-Phenoxyethyl acrylate		192.2	48145-04-6
Isobornyl acrylate		208.3	5888-33-5
<i>N,N</i> -dimethylacrylamide		99.1	2680-03-7

Table 3. Structures, molecular weights, and CAS

numbers of acrylates that resulted in positive patch test results in case 1.



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