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Contact dermatitis caused by glucose sensors in diabetic children

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Abstract

Background: Allergic contact dermatitis caused by glucose sensors has been recently described in diabetes, mostly in adult patients. Isobornyl acrylate and *N-N* dimethylacrylamide are the potent causative agents.

Objectives: To describe a children population with contact dermatitis caused by glucose sensors, determine the causative allergen, and assess the prevalence of isobornyl acrylate (IBOA) sensitization.

Patients and Methods: Overall, 12 children with a reaction to medical devices, either glucose sensors or insulin sets, were patch tested with the European baseline series, glues and rubber, (meth) acrylates series, and with piece of the adhesive part of the glucose sensor FreeStyle® Libre. Isobornyl acrylate at 0.1% was applied for patch tests in 11 patients, and *N-N* dimethylacrylamide in two. Some patients were tested with adhesive parts of the infusion set.

Results: Overall, 10 children reacted to the adhesive part of the sensor FreeStyle® Libre, and 10 children were IBOA-sensitized. One patient turned out to be negative in all patch tests.

Conclusion: Allergic contact dermatitis caused by glucose sensors is, thus, common in the pediatric diabetic patient population. Like in the adult patient population, IBOA was revealed to be the culprit allergen with an 83.3% sensitization rate in children exhibiting adverse cutaneous reactions caused by FreeStyle® Libre.

Key words: FreeStyle® Libre, allergic contact dermatitis, glucose sensor, diabetes mellitus, isobornyl acrylate, acrylate, adhesives, medical device, pediatric

Introduction

Type 1 diabetes mellitus has been shown to affect about 5% of all diabetes patients, occurring mostly in childhood, adolescence, or early adulthood. It is characterized by an insulin deficiency, and these patients are, therefore, insulin-dependent and require daily injections of insulin or an insulin pump. Since the introduction of medical devices like glucose sensors and, in particular, insulin pumps onto the market, the management of Type 1 diabetes has been significantly improved. Indeed, glucose sensors, such as FreeStyle® Libre (Abbott Diabetes Care, Chicago, Illinois, USA), Enlite® (Medtronic Minimed, Northridge, CA, USA), or Dexcom® (Dexcom, San Diego,CA, USA), reduce the risk of hypoglycemia (1). Moreover, insulin pumps have proven to improve the patients' quality of life. Nevertheless, since their introduction, several cutaneous undesirable events have been reported, such as infections, hematomas, irritant contact dermatitis (ICD), as well as allergic contact dermatitis (ACD) (2-4). Several ACD cases have been reported with IBOA, an acrylate derivative, identified as the culprit allergen (5). *N*-*N*-dimethylacrylamide (DMAA) has also been implicated (6). Additionally, unexpected co-sensitization with plant derivatives like sesquiterpene lactones has been described (7). We herein reported on 12 Belgian children with suspected ACD caused by their medical diabetic devices and identified the allergens involved.

Patients and methods

i. Patients

Overall, 12 patients, less than 18 years of age, were included in the study. All suffered from diabetes mellitus Type I and presented a cutaneous reaction under their glucose sensor or insulin infusion set, suspected to be an ACD. All patients were using

Freestyle® Libre and none of them were using the 2nd generation of the sensor (FreeStyle® Libre 2) with Bluetooth connection and hypo or hyperglycemia alarm.

ii. Patch tests

With the agreement of their parents, patch tests were performed between January 2016 and July 2019 at the Dermatology Department of the Cliniques universitaires Saint-Luc. All children were tested with the European baseline series (Chemotechnique, Vellinge, Sweden and/or Allergeaze®, Smartpractice, Phoenix, AZ), isobornyl acrylate (IBOA) (Sigma-Aldrich (Steinheim, Germany), diluted to 0.1% in petrolatum (pet) by the Saint-Luc hospital pharmacy, with N,N-dimethylacrylamide (DMAA) (purchased from Sigma-Aldrich and prepared by the Department of Occupational and Environmental Dermatology in Malmö) diluted to 0.1% in pet., with a piece of the adhesive part of glucose sensor (corresponding to a quarter of the adhesive stuck to the sensor), and with (meth)acrylates and plastic & glues series. Some children were patch tested with the three components of the sesquiterpenes lactones mix (SLM): eight with costunolide and dehydrocostus lactone purchased from Sigma-Aldrich (Steinheim, Germany) and prepared by the Saint-Luc hospital pharmacy (0.1% in pet); nine with alantolactone (0.1% in pet). The patch tests were fixed on the children's back using Fixomull® stretch (BSN Medical, Hamburg, Germany). Readings were performed on Days (D) 2 and 4, according to the ESCD criteria (8).

Results

Of the 12 children included in this study, eight were girls and four were boys, with a mean age of 11.5 years (range: 4 to 17). All patients had exhibited a reaction to FreeStyle® Libre, while two patients also presented an ACD caused by another glucose sensor, Enlite® (Patients 3 and 12) or Dexcom G4® (Patient 12). Some patients also presented a reaction

when wearing the infusion set of an insulin pump, such as Paradigm® MiniMed Sure-T® (Patients 4 and 12) or Paradigm® MiniMed Quick-Set® (Medtronic Minimed, Northridge, CA, USA) (Patient 2). Only Patient 4 was tested with a piece of the adhesive part of the infusion set and presented a positive reaction to it.

Of the 12 patients, 10 tested positively to the adhesive part of the glucose sensor FreeStyle® Libre, while 10 out of the 11 tested using IBOA 0.1% exhibited a positive reaction. One participant (Patient 6) displayed a negative reaction to the piece of the adhesive part of FreeStyle® Libre, yet a positive IBOA patch-test D2/D4 +/+. Another participant (Patient 1) was not tested using IBOA and DMAA, but tested positively to a piece of the FreeStyle® Libre adhesive. Yet another participant (Patient 11) tested negatively to both IBOA and the glucose sensor FreeStyle® Libre adhesive.

Of the 12 patients, one tested positively to compositae mix, and five to "sesquiterpene lactone mix" (SLM). Of these patients, eight were texted using costunolide and dehydrocostus lactone, and nine using alantolactone. Among these, two participants reacted positively to costunolide (with severe reactions (++) for both), one reacted to dehydrocostus lactone, and one reacted to alantolactone.

Several positive patch tests reactions were observed with the acrylates series, such as patient 5 with a positive reaction to hydroxypropyl methacrylate (HPMA), patient 9 with a positive reaction to ethylacrylate and hydroxyethylacrylate, and patient 12 with a positive reaction to butyl acrylate. All patch test results and demographic data have been summarized in **Table 1**.

Discussion

Type 1 diabetes is an insulin-dependent condition, requiring accurate knowledge of blood glucose levels to properly inject appropriate insulin units. Medical devices like glucose sensors have significantly improved glycemic control, along with the quality of life of these

patients, who no longer have to perform daily finger pricking. Moreover, insulin pumps have proven to provide better living comfort for these patients. However, some patients have developed skin reactions under the adhesives of the medical devices designed for diabetic patients. Several studies have revealed that the allergens involved like IBOA and *N-N* dimethylacrylamide (DMAA) were detected within the sensors and insulin pumps, migrated through the adhesives sticking to the skin. It has been demonstrated that the sensor FreeStyle® Libre, the sensor Enlite®, and some Medtronic® insulin pumps contain IBOA and DMAA (5, 6, 9). It was also demonstrated that IBOA was not present in the original adhesives provided by the manufacturer (Adhesive Research Glen Rock, PA, US). Indeed, patients sensitized to IBOA, did not reacted to the original adhesives provided by the manufacturer, confirming the hypothesis of a migration of IBOA trough the adhesive (10). The occlusion and sweating probably increase this phenomenon.

Note that patient 12 presented a positive reaction to colophonium. Passanisi et al. (11) described ACD from the glucose sensor Enlite® caused by colophonium, the presence of which was confirmed by the manufacturer. Moreover, some gas chromatography-mass spectrometry (GC-MS) analysis reveal and confirm the presence of methyldehydroabietate, which indicates the use of colophonium in this device (9). The positive reaction in patient 12 was probably due to previous use and therefore sensitization to the sensor Enlite®.

Several children suffering from dermatitis on the area where the glucose sensor was affixed, which was suspected to be an ACD to these medical devices, were referred for patch testing to our department. All patients except one were tested with IBOA. Concerning the patient who was not IBOA-tested, it must be recalled that IBOA was not yet known to be a causative allergen at the time the patient was tested. Regarding DMAA, only two patients were tested with this allergen, as the agent has only recently been described as potential

causative agent. Of all the IBOA-tested children, only one (Patient 11) did not present a positive reaction. Ten of the 12 children with glucose sensor reactions were found to be sensitized to IBOA. Of note, this sensitization rate proved to be perfectly in line with the one reported by Hyry and al. (12).

All patients were patch tested with a piece of the adhesive part of the sensors with only two of them exhibiting negative reactions. In one of these cases (Patient 7), a positive reaction to IBOA enabled us to establish the diagnosis of ACD to IBOA. In the second case (Patient 11), however, the IBOA and DMAA were tested negatively. For this latter case, either an irritant contact dermatitis (ICD) with the adhesive patch of the sensor applied for a long time (>14 days) on the skin or an ACD with a false negative reaction to the adhesive part of the sensor could be discussed.

It has previously been reported that patch testing using the piece of the sensor can provide false negative reactions (10). In this patient (patient 11) displaying a negative reaction to IBOA, DMAA, and a piece of the sensor, the clinical reaction under the sensor was an eczematous annular reaction with a progressive worsening. The patient reported that these reactions occurred more and more quickly, with a progressive decrease in the delay between sensor applications and dermatitis development, which is more suggestive of an ACD rather than an ICD. It has been recommended to perform patch tests using acetone extracts made from the different parts of the sensor, in an effort to increase the patch testing responses. While two allergens (IBOA and DMAA) had already been identified for FreeStyle® Libre, we cannot exclude that other allergens, still unknown to date, are present within the sensor. This observation emphasizes the relevance of a good collaboration with the manufacturers who should be invited to provide all of the ingredients contained in the medical device, in particular to facilitate the management of these patients with suspected ACD despite negative patch test results.

Moreover, only three patients presented positive reactions to four different acrylates, butyl acrylate, ethyl acrylate, hyrdoxyethyacrylate, and hydroxypropyl methacrylate, respectively. Given the absence of any positivity to the same patch test acrylates in these patients, there is no evidence for cross-reactivity. This observation rather suggests that concomitant reactions, known as co-sensitizations, are more likely to be present than cross-reactions. Sensitization to these acrylates in these children could also be explained by any past contact with these acrylates. The absence of cross-reactivity between IBOA and other acrylates has already been suggested. The special branched structure of IBOA may also prevent cross reactivity's to other acrylates. Currently, IBOA is not included in the (meth)acrylate series. At this time, there is no recommendation from the European Society of Contact Dermatitis and the European Environmental and Contact Dermatitis Research Group about inclusion of IBOA in a specific series. In Germany, IBOA 0,1% was included to the plastics and glues series according the recommendation of the German Contact Allergy Group (Deutsche Kontaktallergie Gruppe; http://dkg.ivdk.org/). In order not to miss any acrylate sensitization, we recommend IBOA 0.1% be included in (meth)acrylates series. While IBOA has been described in medical devices, it seems important to us to test it routinely every time an ACD to adhesives/glues is suspected, without missing new sources of sensitization. As IBOA is present in multiple medical devices for diabetes patients, we suspect it to be similarly employed in other medical devices or sources.

Possible cross-reactions between IBOA and SLM have been previously reported (7). In this previous paper, we observed that 62.26% patients sensitized to IBOA tested positively to SLM, contained in the European baseline series. These patients reported no relevant exposition and/or reactions to sesquiterpenes lactones or plant derivatives such as via cosmetics with plants. This was unexpected while the prevalence rate of sensitization to SL

(based on the SLM patch tests) observed in European patch-test clinics ranges from 0.1 to 2.0% (13, 14). In order to better understand this co-sensitization, several analyses were performed, including patch tests with all the component of the SLM. In the present study, 5/12 (41.7%) children were positive to SLM, three patients were tested with the three components of SLM (alantolactone, costunolide, and dehydrocostus lactone). Of these, one patient presented positive reactions to alantolactone and costunolide, one to costunolide, and the other one to dehydrocostus lactone. Therefore, 2/3 of patients sensitized to SLM reacted with a strong reactivity (++) to costunolide. The co-sensitization rate is thus stable without to date any further explanation of this phenomenon. The two most likely hypotheses remain a co-sensitization, rather than cross-reactivity but also the possible presence of a common precursor for IBOA and lactones, such as camphene (7).

The FreeStyle® Libre was employed in all cohort patients as first-line. Other sensors, such as Enlite® and Dexcom®, were proposed as second-line sensors for two patients who could no longer wear the FreeStyle® due to dermatitis. The glucose sensor Enlite® was proposed in one case following patch testing that revealed sensitization to IBOA (Patient 3), and in the second patient, it was proposed before the patch tests were carried out (Patient 12). In both cases, the wearing of the Enlite® was not tolerated, given that a dermatitis against this other sensor occurred very quickly, requiring stopping its wearing. Later on, chromatographic analyses revealed the presence of IBOA in the Enlite® glucose sensor (9). Moreover, one patient (Patient 12) presented a positive reaction to butyl acrylate. Of note is that this patient wore a Dexcom® G4 in November 2018 and exhibited an eczematous reaction after a few days. Ethyl cyanoacrylate has been reported to be a potent allergen present in Dexcom® G4 (15, 16). Since August 15, 2016, the manufacturer has been using a heatstaking thermal process that eliminates the ethyl cyanoacrylate from this sensor, owing to the high number of

ACDs reported (17). Possible cross-reactions between two octyl-cyanoacrylate an ethyl-cyanoacrylate have similarly been described, as well as simultaneous positive reactions to octyl cyanoacrylate and butyl acrylate (18, 19).

It must also be mentioned that the large number of patients wearing a FreeStyle® Libre is due to the patients' preference because of the ease of its use, but in addition, due to the doctors' prescribing habits. Indeed, these were the first sensors to be reimbursed on the Belgian market. Concerning Dexcom®, its reimbursement was made possible at the end of 2018. In Belgium, the Enlite sensors are not fully reimbursed according to the reimbursement convention, but require a supplement to be paid by the patient, which renders them less attractive from a financial perspective. In Belgium, FreeStyle® Libre thus remains the first-line sensor prescribed for diabetic patients. At Cliniques universitaires Saint-Luc, since the establishment of the diabetic convention for children, 215 young diabetics have been using the FreeStyle® Libre sensor, 20 Dexcom®, and six Enlite®. Among these 215 children, 12 underwent patch tests for suspected ACD, of whom 11 turned out to be positive to IBOA. The Patients 3 and 12 were not included in the convention from Cliniques universitaires Saint-Luc. This observation means that 4.2% (9/215) of diabetes children followed-up in the Cliniques universitaires Saint-Luc and who were wearing a glucose sensor FreeStyle® Libre were sensitized to IBOA. According to the French governmental agency *Agence Nationale de Sécurité du Médicament et des Produits de Santé* (ANSM), the rate of cutaneous adverse events has increased from 0.2% in Mai 2018 to 0.4% in June 2018 (20). This figure appears to be underestimated, given that many patients and parents of children with cutaneous reactions did not report these reactions to their endocrinologists nor check among forums in an effort to find alternatives, such as application of spray, hydrocolloid dressing (21) between the sensors and the skin, and others. Only patients with severe cutaneous adverse reactions have brought this to their endocrinologist's attention, whereas numerous other children did not undergo the

patch tests because of the multiple appointments required. According to pediatric endocrinologist estimations, about 20% of children exhibit reactions to the glucose sensor. In Finland, while the prevalence of ACD due to FreeStyle® Libre has been estimated at 0.7%, this figure was found underestimated by Hyry and al. , owing to the absence of patch tests being conducted in some patients (12).

Moreover, the time between the first symptoms of ACD and the first use of the sensor was quite long. Indeed, the mean time was 6,3 months (range from 2 to 16 months). Note also, that the number of days between application of the sensor and appearance of the cutaneous reaction range from 2 to 7 days.

Conclusion

Several ACD cases caused by medical devices, glucose sensor, or infusion insulin sets have been described in diabetes patients, and in particular, children suffering from Type 1 diabetes, with a significant impact on their quality of life, already affected by their diabetes. Overall, 83.3% of children with adverse cutaneous reactions to FreeSyle® Libre and who were patch tested, and an estimated 4.2% of all diabetes children wearing a FreeSyle® Libre were found to be sensitized to IBOA. It is, thus, recommended that IBOA 0.1%, DMAA 0.1%, and an adhesive patch piece of the sensor should be tested in all children presenting a reaction caused by diabetic medical devices. We also recommend IBOA 0.1% be included in the acrylate series. As IBOA contained in several medical devices has been described as a potent allergen, it appears crucial to test this agent in every suspicious case of ACD due to adhesives or glues in order to avoid missing any new source of sensitization. With the commercialization of new devices, and in an effort to facilitate patient care and provide appropriate recommendations, we strongly advise that strict regulatory use regarding medical device labeling be implemented.

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Table 1: Demographic data and patch-tests results of 12 children with cutaneous reaction to FreeStyle® Libre

Patient	Age (years)	Gender	Reaction with medical device		Onset of the dermatitis (months) following FreeStyle® Libre use	Patch tests D2/D4				
			Glucose sensor	Insulin infusion set		European baseline series	Isobornyl acrylates 0.1% (IBOA)	(Piece of) adhesive of FreeStyle®	(Piece of) adhesive of other medical device	Additional patch tests
1	9	M	Freestyle® Libre	No	3	-/-	NT	+/+	NT	MA series: -/- P&G: Abitol +/++, Hydroquinone +/++
2	12	F	Freestyle® Libre	Paradigm® MiniMed Quick-Set® (Medtronic)	3	MP -/+ SLM ++/++ Tixocortol pivalate +/+ FMI +/+ PG +/+ BIT +/?	+++/+++	+/++	Enlite® sensor -/- Dexcom® G4 -/-	MA series: negative P&G: Epoxy resin cycloaliphatic +/+
3	12	M	Freestyle® Libre Enlite®	No	6	SLM +/+	+/+	+/+	Enlite® sensor -/- Decom® G4 -/-	MA series: negative P&G: negative
4	4	F	Freestyle® Libre	Paradigm® MiniMed Sure-T® (Medtronic)	10	-/-	+/+	+/+	Enlite® sensor +/+ infusion set Paradigm® MiniMed Sure-T® -/+	MA series: negative P&G: negative Plants: negative
5	13	F	Freestyle® Libre	No	11	-/-	+/+	-/+	Enlite® sensor -/-	MA series: HPMA -/(+) P&G: negative Plants: achilla millefolium -/(+) tanacetum vulgare -/(+) SLM decomposition: dehydrocostus lactone +/+
6	12	F	Freestyle® Libre	No	2	-/-	+/+	-/-	Enlite® sensor -/-	MA series: negative P&G: negative Plants: negative SLM decomposition: negative
7	4	M	Freestyle® Libre	No	11	SML -/+	++/++	+/++	Enlite® sensor -/-	MA series: negative P&G: negative Plants: negative SLM decomposition: costunolide +/++

8	15	F	Freestyle® Libre	no	5,5	-/-	++/++	+/++	Enlite® sensor -/-	MA series: negative P&G: negative Plants: negative SLM decomposition: negative
9	17	F	Freestyle® Libre	no	16	-/-	+/++	-/+	Enlite® sensor -/-	MA series: ethylacrylate -/++; hydroxyethylacrylate -/++ P&G: negative Plants: negative SLM decomposition: negative
10	15	F	Freestyle® Libre	no	3	SLM ++/++	+++/++	++/++	Enlite® sensor -/-	MA series: negative P&G: negative, Plants: negative SLM decomposition: costunolide +++/++; alantolactone -/+
11	14	F	Freestyle® Libre	no	2	-/-	-/-	-/-	Enlite® sensor -/-	MA series: negative P&G: negative Plants: negative SLM decomposition: negative DMAA -/-
12	11	M	Freestyle libre ® Dexcom® G4 Enlite®	Paradigm® MiniMed Sure-T® (Medtronic)	3	Colofonium ++/++ SLM ++/++ Compositae mix -/++ Propylene glycol -/+	++/++	++/++	Enlite® sensor -/-	MA series: butyl acrylate -/++ P&G: negative Plants: negative SLM decomposition: negative DMAA -/-

BIT, benzisothiazolinone; DMAA, *N-N* dimethylacrylamide; F, female; FM, fragrance mix; HPMA, Hydoxypropyl methacrylate; M, male ; MP, Myroxylon pereirae; PG, Propylene Glycol; P&G series, plastic & glues series; NT, not tested ; SLM, Sesquiterpene lactone mix; −, negative; ?+, doubtful, + to +++, positive patch test reaction

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