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Adverse cutaneous reaction to diabetic glucose sensors and insulin pumps: irritation contact dermatitis or allergic contact dermatitis?

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Abstract

Background: Adverse cutaneous reaction to diabetes medical devices (glucose sensors and insulin pumps) are described, notably allergic contact dermatitis with isobornyl acrylate and *N,N* dimethylacrylamide as the main allergen.

Objectives: To determine if all adverse cutaneous reaction observed with diabetes medical devices ie Freestyle Libre, Enlite or insulin pumps, referred at our department with suspected allergies are confirmed as allergic contact dermatitis.

Patients and Methods: Fifty-two patients who presented skin reactions to diabetes medical devices were patch tested with the European baseline series, a plastic and glues series, a (meth) acrylates series, a piece of the adhesive part of the device, as well as isobornyl acrylate 0.1% and *N,N* dimethylacrylamide 0.1% pet.

Results: Seventeen patients had no positive reaction to isobornyl acrylate nor to the piece of the adhesive part of the device; 11 of these also tested with *N,N* dimethylacrylamide with negative result. No other relevant allergen was identified.

Conclusion: Some cutaneous reactions, otherwise very similar to those of patients sensitized to isobornyl acrylate, can be explained either by the presence of an untested allergen not yet discovered, or by irritant contact dermatitis. Therefore, European legislation on the full labelling of ingredients by manufacturers, in order to facilitate the identification of allergens and irritants, is imperative.

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

1. Introduction

In the past 5 years, new medical devices appeared on the market to help diabetes patients to monitor their blood glucose levels and insulin injections. These devices are usually combined with a subcutaneous catheter and a transmitter (for blood glucose sensors) or infusion kit (for insulin pumps) applied to the skin by an adhesive patch for a period of 3 to 14 days. Since, some cutaneous adverse reactions have been reported such as infections attributable to subcutaneous catheter insertion, but also irritant contact dermatitis (ICD) with the repeated applications of the adhesive patch. Studies revealed high amount of skin problem in diabetic children and adolescents (1) with 89.5% of skin lesions due to the use of these devices and more than 35% in adults diabetics population (2).

The annular erythematous eruption under the sensors was initially considered as an ICD (3) but the importance of ACD was later confirmed by the identifying isobornyl acrylate (IBOA)(4), *N,N*-dimethylacrylamide (DMAA)(5), but also colophonium (6) and ethyl cyanoacrylate (7, 8) as allergens. Some patients developed skin reactions following the use of these devices who remained completely negative upon patch testing to these allergens, and it is difficult to differentiate between contact allergies and contact irritation.

We herein report on 52 patients with suspected ACD caused by their medical diabetic devices and the final diagnosis proposed after patch tests. It appeared that 17 patients suffering from reactions caused by diabetes medical devices (glucose sensor or infusion insulin set) did not present any relevant sensitization.

2. Patients and methods

From January 2018 to December 2019, 52 patients were patch tested at the Dermatology Department of the Cliniques universitaires Saint-Luc in Brussels. All suffered from cutaneous reactions with a diabetes medical devices such as glucose sensor or infusion insulin set. Out of these 52 patients, 48 were using FreeStyle Libre sensors, 4 Enlite sensors, and 10 insulin infusions sets.

All patients were tested with the European baseline series (Chemotechnique Diagnostics, Vellinge, Sweden and/or Allergeaze, Smartpractice, Phoenix, Arizona), isobornyl acrylate (IBOA) (Sigma-Aldrich (Steinheim, Germany) 0.1% pet. prepared by the hospital pharmacy, with a piece (corresponding to a quarter of the adhesive stuck of the sensor) of the adhesive part of the glucose sensor “as is”, that is, FreeStyle Libre (Abbott Diabetes Care, Witney, Oxfordshire, UK) or Enlite (Medtronic Minimed, Northridge, California), and with a (meth)acrylates and plastic and glues series. Some patients were tested with *N,N*-dimethylacrylamide (DMAA) (purchased from Sigma-Aldrich and prepared by the Department of Occupational and Environmental Dermatology in Malmö) 0.1% pet. The patch tests were fixed on the back using Fixomull stretch (BSN Medical, Hamburg, Germany). Readings were performed on day (D) 2 and D4, according to the ESCD criteria (9).

3. Results

Among the 52 patients included in this study, 35 patients presented a positive reaction to IBOA. Among these 35 patients, 34 had a reaction to FreeStyle Libre and 27 reacted to adhesive part of this medical device. Of these 35 patients, 17 were male and 18 female, with a mean age of 43,0 years (range: 4 to 75).

Among the 52 patients included in this study, 17 presented a negative reaction to IBOA and to the piece of the adhesive part of the medical devices tested. Of the 17 patients, there were only 2 men and 15 women, with a mean age of 41,7 years (range: 3 to 82). All patients had shown annular erythematous reactions under the medical devices, suspected as ACD. Fifteen patients had used the FreeStyle Libre sensor and two others presented reactions to the Enlite sensor. Among these 17 patients, 3 patients presented, in addition, reactions with their infusion insulin set ie, one with Paradigm MiniMed Quick-Set (Medtronic, Minneapolis, Minnesota) and two with ParadigmMiniMed Sure-T (Medtronic).

All these 17 patients had a negative test with IBOA but also with the piece of the adhesive part of the medical devices tested. Eleven patients, also tested with DMAA, did not react positively to this potential culprit allergen. Similarly, all patients were tested with an additional acrylate, as well as a plastic and glue series without any positive reactions. Some patients showed positive reactions to allergens of the European baseline series, notably 3 patients to nickel, 2 patients to hydroperoxides of linalool and 1 patient to colophonium. All patch test results of those 17 patients and demographic data are summarized in **Table 1**.

4. Discussion

Contact dermatitis, that is, skin inflammations caused by external agents, can be divided into irritant contact dermatitis (ICD) and allergic contact dermatitis (ACD). In case of ACD, there is an adaptative immunological process (type IV hypersensitivity reactions according to the Coombs and Gell classification), with the intervention of allergen specific T lymphocytes following contact with an allergenic substance. The production of these specific T cells is carried out during a sensitization phase. This immune response only appears 12 to 72 hours after contact with the allergen. Conversely, ICD is an innate immunological reaction due to contact with a substance having irritating properties (chemical and physical). Lesions appear very quickly, within hours, after contact with the irritant, and could appear after the first exposure with chemical irritant. In this case also, the release of pro-inflammatory cytokines is required but no sensitization phase is necessary. Moreover, some individual susceptibilities could promote ICD, notably a compromised skin barrier integrity such as in xerosis or atopy, but also following an inflammatory response.

Experience suggests that sweating and contact with water accumulating under dressings of a medical device provoke irritation which could in turn promote ACD. Therefore, a detailed history can sometimes help to differentiate between ICD and ACD or at least, identify the provoking factors. However, the time between first symptoms and first use of the sensor does not seem to be different between patients with ACD and patients with suspected ICD. Indeed, it was quite long for the 2 groups. The mean time was 6.3 months (range from 15 days to 29

months) in the group of 17 patients without any reactions, and 7.9 months (range from 15 days to 24 months) in the group of 35 patients sensitized to IBOA.

For several years already, reports of cutaneous complications with medical devices in diabetes patients were published (10). According to a report of Mohd Asarani et al (11), itch and eczema were observed in more than 70% of patients using glucose sensors, and 41% of adult patients consider skin irritation as a reason to stop using glucose sensors (12).

According to a questionnaire study more than 35% of adults diabetics surveyed who had applied a medical device reported skin lesions due to the use of these devices (2). Moreover, another study with diabetic children and adolescents wearing insulin infusion sets, also based on questionnaires, revealed that 89.5% developed skin symptoms, more precisely itching (77.6%), and non-specified eczema (46.2%) (1). Mostly, no distinction between irritant contact dermatitis and allergic contact dermatitis was made.

Initially, reactions were mainly considered as ICD. The causes were the repeated applications at the same site of the sensors' adhesives, but also the worsening of irritation by perspiration and humidity. However, identification of IBOA as a culprit allergen in FreeStyle Libre sensor (4) revealed an important number of cases of ACD, not longer considered as ICD (3). Later, DMAA was reported as another sensitizer in this sensor (5). IBOA was recognized as contact allergen of the year 2020 by the American Society Contact Dermatitis. It has also been integrated as an allergen by the Chemotechnique Diagnostics, which makes it easier to test this on a large-scale. IBOA was also found in other medical devices for diabetic patients, including

the Enlite sensor and Paradigm MiniMed Quick-Set insulin infusion set (13). It should also be noted that in the Enlite sensor, colophonium was found (6) (13).

Most often, reactions due to glucose sensors are characterized by discrete and localized annular erythema and scaling, with edema and well-defined borders. Patients also described itching or burning sensations. In the most severe cases, papulo-vesicular lesions with blistering or oozing were observed and lead the physicians to a diagnosis of ACD. Among the 52 patients herein reported, all presented a very similar clinical picture with an annular, squamous, well-defined itchy erythema under the sensor.

The clinical aspect therefore does not allow a distinction between ICD and ACD, and it is thus important to test in all cases. This was illustrated by figure 1 with two patients with a very similar clinical aspect, one with a sensitization to IBOA, and the other without any positive reaction suggesting an ICD (not to mention the possibility of undiagnosed contact allergy). All patients described progressive worsening, and a decrease in the delay between sensor applications and appearance of the reaction. Thereby, ACD could be regarded more likely than ICD, which is the reason why the patients were tested. However, among the 52 patients tested, 17 did not show any positive reaction to IBOA nor to the adhesive patches of the sensors.

For all these 17 patients, 4 hypotheses have to be considered:

(i.) Firstly, while IBOA was already identified for FreeStyle Libre sensor, DMAA was discovered later (5). Thirteen patients were also tested with DMAA but none of them had a

positive reaction. For the other 4 patients, the substance was missing at the time of the tests. It is therefore possible that DMAA was the culprit allergen in these latter 4 patients. Indeed, sensitization to FreeStyle Libre sensor with a negative reaction to IBOA but positive reaction to DMAA has been described (5).

(ii.) Secondly, it is not excluded that other (s) allergen(s), still unknown to date, are present in the sensor. Whether it is in FreeStyle Libre sensor or in all other medical devices such as Enlite sensor.

(iii.) Thirdly, it is important to remind that a negative reaction to IBOA and to the adhesive part of the devices does not automatically exclude sensitization. Indeed, it has previously been reported that patch testing using a piece of the sensor can provide false-negative reactions (14).

(iv.) Finally, out of these negative tested patients some may suffer from very strong ICD symptoms similar to ACD. Hence, without knowing the complete composition of a product, ICD is a diagnosis of exclusion.

Therefore, it is recommended, in case of suspected ACD to diabetes medical devices, to perform patch testing with (in addition to the European baseline series containing colophonium) IBOA and DMAA, without forgetting to test the adhesive part of the medical device (moistened with a small amount of water if necessary). We propose to also test with the acrylates series, as ethyl-cyanoacrylate has been found in Dexcom Platinum G4 (Dexcom, San Diego, California), but also with the plastics and glues series in order not to miss a sensitization. It was also demonstrated that IBOA was not present in the original adhesives provided by the manufacturer (Adhesive Research, Glen Rock, Pennsylvania) but derived from the plastic part and migrated through the adhesive part of the sensor FreeStyle Libre (14). Among our series of 35 patients

sensitized to IBOA tested with the adhesive part of the sensor (and not the plastic part), only 8 patients (22%) were not positive to these adhesive parts of the sensors. For patients with negative tests, 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 test response. Moreover, patch tests readings at D7 are important for all patients not to miss a delayed reaction. Indeed, delayed reactions are frequent with acrylates. However, unfortunately, it was not possible to perform late readings for all our patients. Patient 11 was positive to colophonium. This patient had only used FreeStyle Libre, for which the manufacturer denied the presence of colophonium (15). Hence, this positive test was not considered to be relevant.

Diabetic medical device manufacturers need to be aware of these risks of irritation and sensitization caused by their products. They should provide appropriate solutions to reduce the incidence of such complications. Once again, these observations highlight the importance of labelling the ingredients contained in medical devices, but also the essential collaboration of manufacturers (16). Indeed, detailed information concerning the ingredients, but also concerning the potential risks of cutaneous complications, would allow better management of patients by clinicians. Legislation concerning labeling obligation does already exist for several years for cosmetics or food, but is still lacking for medical devices. To date, it is really difficult to obtain information about their composition. Chromatographic analyses are always possible but remain time consuming and not very useful if the allergen to look for is unknown.

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The management of such reactions is also complicated. As these devices have revolutionized the management of diabetic patients, and even in case of reactions, patients often want to continue to use them anyway. In case of ICD, the application of an emollient cream or barrier cream may be proposed. However, the UK government website mentions that the application of barrier cream could affect the performance of the device (17). In addition, many patients apply sprays, including the Cavilon (3M Health Care, St. Paul, Minnesota), which contains acrylates but also isooctane, a substance that can also be irritating (18). In the case of ACD, it is recommended to avoid contact with the allergen. Finding a replacement device in this case is difficult as the exact composition is unknown. As IBOA was considered as the main culprit allergen, some manufacturers informed that they have removed it from their products. Notably, Dexom deleted ethyl cyanoacrylate from their devices (19), and recently ANSM (Agence Nationale de Sécurité du médicament et des produits de santé) informed that Abbott had modified one component in the Freestyle Libre sensor, alas, without any detailed information which (20). None of the 52 patients were exposed to the reformulated version of FreeStyle Libre at the time of publication. Recently, a study has shown the effectiveness of application of a steroid (fluticasone propionate) before the insertion of the sensor to prevent skin irritation (21). However, an adverse event associated with topical steroids used continuously and under occlusion is the appearance of skin atrophy. It is also possible to apply a protection with an hydrocolloid blister plaster (22) or film dressing between the skin and the adhesive part of the sensor. However, it should be remembered that some dressings may also contain acrylates or colophonium (23).

Among the patients included in this study, we probably have a selection bias. Indeed, patients were referred to our Department for quite strong symptoms with already suspected ACD. However, we have 32.7% of our tested patients without any positive reaction, suggesting an ICD (alternatively, undiagnosed contact allergy is possible).

5. Conclusion

Sensitization to diabetes medical devices is still a current problem. It is recommended to patch test in order to exclude sensitization to the currently identified allergens IBOA, DMAA, colophonium, or ethyl cyanoacrylate. However, several patients with reactions suspected to be ACD did not test positive, neither with the commercialised or above mentioned allergens, nor with pieces of the adhesive parts of the sensors. This may be due to other culprit allergens having not yet been identified, or a more likely diagnosis of ICD. Irritant contact dermatitis remains a diagnosis of exclusion when all tests are negative. However, this remains always difficult to conclude since the complete composition of such devices is still not known. This highlight the importance and very urgent need of European legislation implementing full labelling of the constituents of medical devices.

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Table 1: Demographic data and patch-tests results of 17 patients with cutaneous reaction to FreeStyle Libre, Enlite and/or insulin pumps without positive reaction to isobornyl acrylate (IBOA) nor to a piece of the adhesive part of the medical device

Patient	Age (years)	Gender	Reaction with medical device		Patch tests D2/D4					
			Glucose Sensor	Insulin infusion set	European baseline series	IBOA 0.1%	DMAA 0.1%	Piece of adhesive of FreeStyle®	(Piece of) adhesive of other medical device	Additional patch tests
1	33	F	Enlite Medtronic	Paradigm MiniMed Quick-Set (Medtronic)	Cobalt -/+	-/-	-/-	-/-	Enlite sensor -/-	MA series: -/- P&G: -/-
2	51	F	Freestyle libre Abbott	No	Sodium metabisulfite -/+	-/-	-/-	-/-	Enlite sensor -/-	MA series: -/- P&G: -/-
3	37	F	Freestyle libre Abbott	No	-/-	-/-	-/-	-/-	Enlite® sensor -/-	MA series: -/- P&G: -/-
4	39	F	Freestyle libre Abbott	Paradigm MiniMed Sure-T (Medtronic)	Paraben mix -/+	-/-	-/-	-/-	Enlite® sensor -/-	MA series: -/- P&G: -/-
5	47	F	Freestyle libre Abbott	No	Thiuram mix +/++ Nickel +/++	-/-	NT	-/-	Enlite sensor -/-	MA series: -/- P&G: -/-
6	82	F	Freestyle libre Abbott	No	Hydroperoxides of linalool -/+	-/-	-/-	-/-	Enlite sensor -/-	MA series: -/- P&G: -/-
7	40	F	Freestyle libre Abbott	No	-/-	-/-	NT	-/-	Enlite sensor -/-	MA series: -/- P&G: -/-
8	60	F	Freestyle libre Abbott	No	-/-	-/-	NT	-/-	Enlite sensor -/-	MA series: -/- P&G: -/-
9	28	F	Freestyle libre Abbott	No	MP +/++	-/-	-/-	-/-	Enlite sensor -/-	MA series: -/- P&G: -/-
10	14	F	Freestyle libre Abbott	No	-/-	-/-	-/-	-/-	Enlite sensor -/-	MA series: -/- P&G: -/-
11	32	M	Freestyle libre Abbott	No	Colophonium -/+	-/-	-/-	-/-	Enlite sensor -/-	MA series: -/- P&G: -/-
12	35	F	Freestyle libre Abbott	No	-/-	-/-	NT	-/-	Enlite sensor -/-	MA series: -/- P&G: -/-
13	54	F	Freestyle libre Abbott	No	Nickel -/+	-/-	-/-	-/-	Enlite sensor -/-	MA series: -/- P&G: -/-

14	55	F	Freestyle libre Abbott	No	-/-	-/-	-/-	-/-	Enlite sensor -/-	MA series: -/- P&G: -/-
15	41	F	Freestyle libre Abbott	No	Nickel ++/+++ Hydroperoxides of linalool - /+	-/-	-/-	-/-	Enlite sensor -/-	MA series: -/- P&G: -/-
16	3	F	Enlite Medtronic	Paradigm MiniMed Sure- T (Medtronic)	-/-	-/-	-/-	-/-	Enlite sensor -/-	MA series: -/-
17	59	M	Freestyle libre Abbott	No	-/-	-/-	-/-	-/-	Enlite sensor -/-	MA series: -/- P&G: -/-

DMMAA, *N,N* dimethylacrylamide; F, female; IBOA, isobornyl acrylate; MA series, (meth)acrylates series; M, male; MP, *Myroxylon pereirae*; P&G series, plastic & glues series; NT, not tested; –, negative; + to +++, positive patch test reaction

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Fig 1. Cutaneous reactions (irritant versus allergic contact dermatitis but with a quite similar clinical presentation) to glucose sensors FreeStyle® Libre: Annular erythema under FreeStyle® Libre with negative reaction to isobornyl acrylate (IBOA) 0,1% (-/-), *N,N* dimethylacrylamide (DMAA) (-/-, and adhesive part of FreeStyle® Libre (-/-) (Day 2/4-reading) suggesting irritant contact dermatitis (not ruled out the possibility of (unresolved) allergic contact dermatitis). (A). Annular erythema under FreeStyle® Libre with sensitization to IBOA (+/+) suggesting allergic contact dermatitis (B)

