Emerging medical device allergens - an update from a clinical perspective

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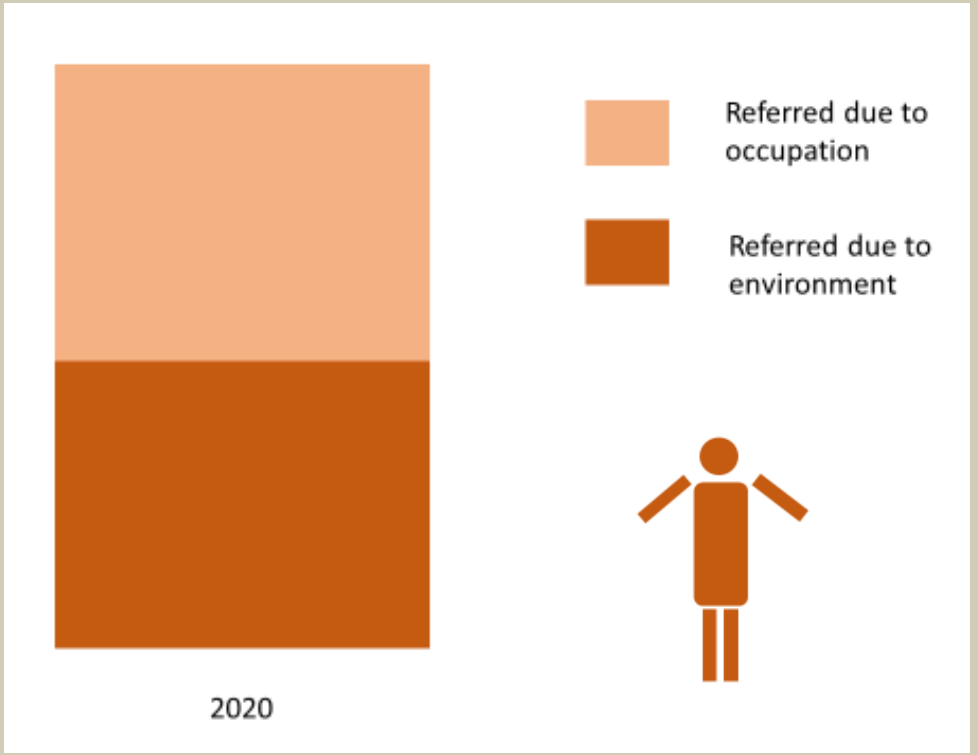
Department of Occupational and Environmental Dermatology
Skåne University Hospital, Malmö, Sweden

- Emerging allergens and related exposures
- Contact allergy to medical adhesive tapes within the military forces
- Clinical implications of medical device-related contact allergies
- How can we learn from the past to develop safer products in the future?

The Department of Occupational and Environmental Dermatology in Malmö is referral center for individuals where an *exogenous aetiology* to skin/mucosal problems is suspected. The clinic annually investigates around 1000 individuals.



Population in the region (SSR) 2 million



Population referred about 1000/year
All ages-also children

In the last 10 years – increasing number of patients referred due to suspected contact allergy to MDs
Today – around 10% of those referred due to a skin disease that is suspected to be caused by an environmental (non-occupational) exposure are medical device (MD)-related

Possible environmental exposure



Possible MD-related skin problem

There is an increasing exposure to MDs in the population

They are used in all parts of our healthcare sector

They are also used for personal care and to facilitate our daily life

Many MDs are bought over the counter and recommendation on use is limited, social media might spread “off-label” use to a larger group than originally intended

Localised adverse skin reactions

- Many patients are referred due to contact dermatitis – a localised dermatitis where the individual is exposed to for example a MD
- Contact dermatitis may be caused by:

  Contact allergy – allergic contact dermatitis

  Skin irritation – irritant contact dermatitis

  A combination of the factors above

How are the patients investigated?

Contact allergy is diagnosed by patch testing



Patch test/epicutanous test

a standardized provocation test

The substances suspected to cause contact allergy are put under occlusion on the back for 48 hours

If the patient is allergic to a substance this will evoke an eczematous reaction at the test site, graded on D3 and D7

The degree of inflammation decides the patient´s reactivity to the allergen

Patch testing

Own material,
Selected test substances

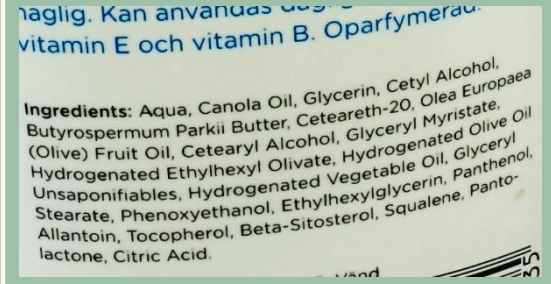
Other patch test series

Extended baseline series

Swedish baseline series

What to patch test?

Relevance assessment of found allergies


vitamin E och vitamin B. Oparfymerad.

Ingredients: Aqua, Canola Oil, Glycerin, Cetyl Alcohol, Butyrospermum Parkii Butter, Ceteareth-20, Olea Europaea (Olive) Fruit Oil, Cetearyl Alcohol, Glyceryl Myristate, Hydrogenated Ethylhexyl Olivate, Hydrogenated Olive Oil Unsaponifiables, Hydrogenated Vegetable Oil, Glyceryl Stearate, Phenoxyethanol, Ethylhexylglycerin, Panthenol, Allantoin, Tocopherol, Beta-Sitosterol, Squalene, Panto-lactone, Citric Acid.

Ingredient declaration

Safety data sheets

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Patch testing

What to patch test?

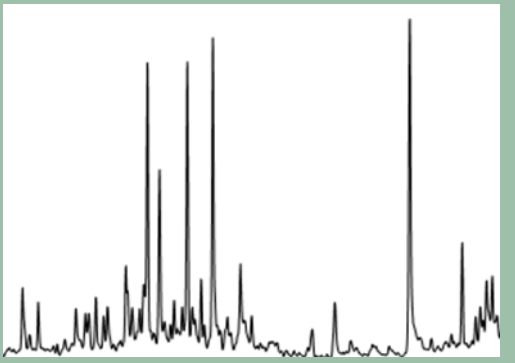
Own material,
Selected test substances

Other patch test series

Extended baseline series

Swedish baseline series

Relevance assessment of found allergies



Chemical analysis

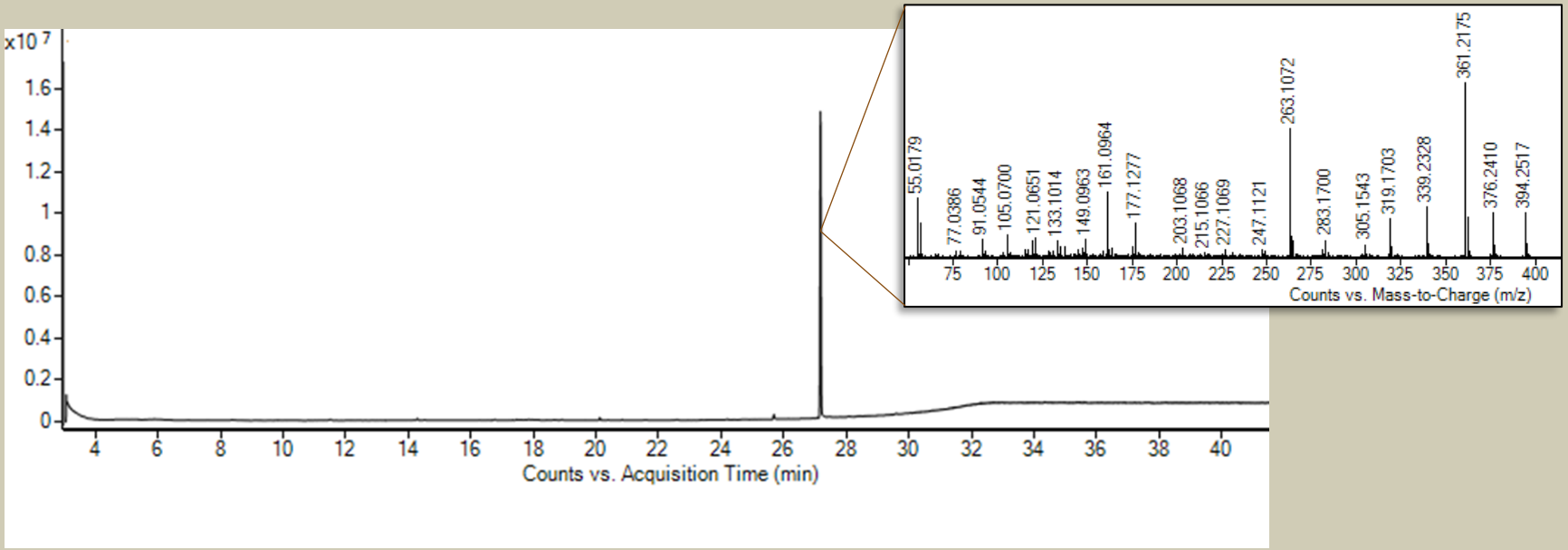
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Challenges in investigations of suspected ACD to MDs

- No commercially available test series
- Lack of information on device content
- MD content may change over time without notification to prescribers or users

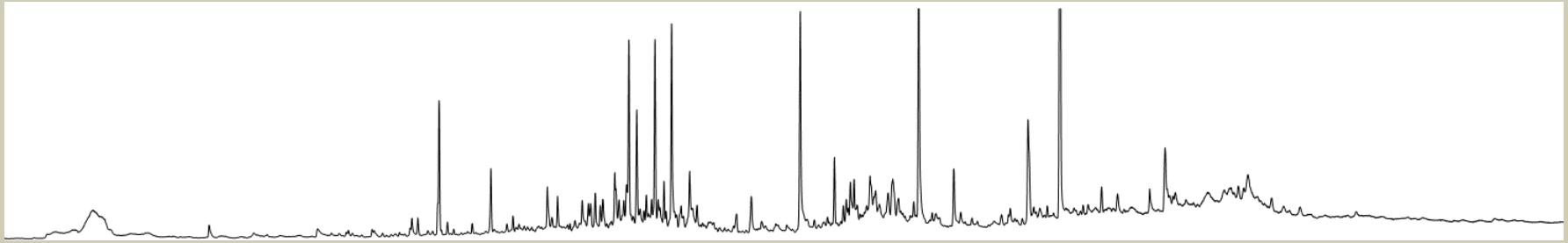
Gas Chromatography – Mass Spectrometry (GC-MS)



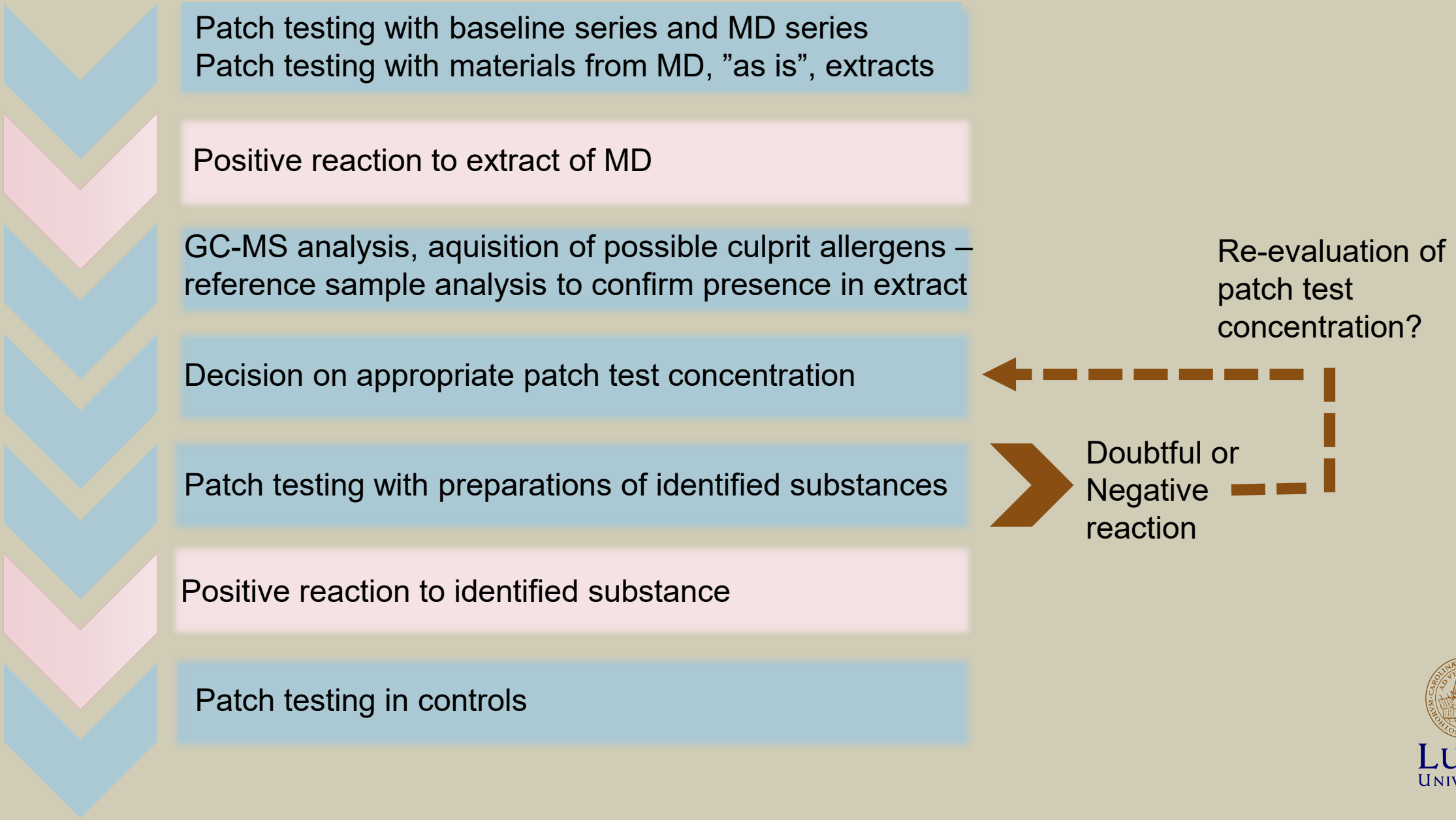


The mass spectrum may be compared with reference spectra in databases for identification of substances. Standard sample confirms identity.

If sample is completely unknown, fragmentation pattern can provide information about structure (groups, bonds) of the analysed molecule.



Diagnostic process in Malmö to establish contact allergy to a new MD allergen

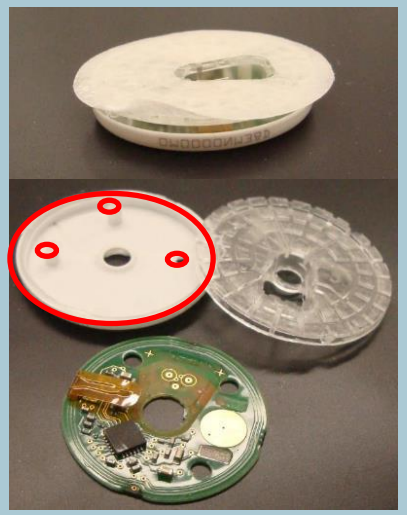


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In what part of the device is the culprit allergen found?

sensor housing

Isobornyl acrylate (IBOA) in sensor housing adhesive – spreading to other parts



Herman A *et al*. *Contact Dermatitis* 2017: **77**: 367-373.

adhesive patch

2,2′-methylenebis (6-*tert*-butyl-4-methyl-phenol) monoacrylate (MBPA)

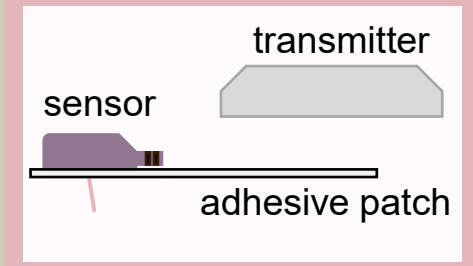
Svedman *et al*. Contact Dermatitis. 2021;84:439-446

Colophonium derivatives

Mowitz *et al*. Contact Dermatitis. 2024; 90: 495-500.

sensor transmitter

1,6-hexanediol diacrylate (HDDA) was found in the sensor transmitter, which initially had not been patch tested or analysed



Persad et al. Contact Dermatitis. 2023; 89(4): 303-305.

Prevalence of contact allergy to diabetes MD allergens
In those referred for CA investigation

Adults with suspected contact allergy patch tested at YMDA* *October 2017 - October 2020*

70.4% allergic to MD series



*The Department of Occupational and Environmental Dermatology, Skåne University Hospital, Malmö, Sweden

Prevalence of contact allergy to diabetes MD allergens

Among adults with type 1 diabetes using sensor/pump



Study on contact allergy to MDs for individuals with diabetes

All adult patients with type 1 diabetes (n=1943) attending two outpatient diabetes clinics in southern Sweden were asked to participate in a questionnaire (n=667) and patch test study (n=204).

Prevalence of skin rash



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https://doi.org/10.1177/19322968251336261

Sage Journals

Original Article

A Cross-Sectional Study Demonstrating a High Prevalence of Skin Rash to Diabetes Medical Devices: An Underestimated Problem

Josefin Ulriksdotter, MD, Thanisorn Sukakul, MD, PhD, Magnus Bruze, MD, PhD, Nils Hamnerius, MD, PhD, Martin Mowitz, PhD, and Cecilia Svedman, MD, PhD

1943 adults with type 1 diabetes invited

667 responded to the questionnaire

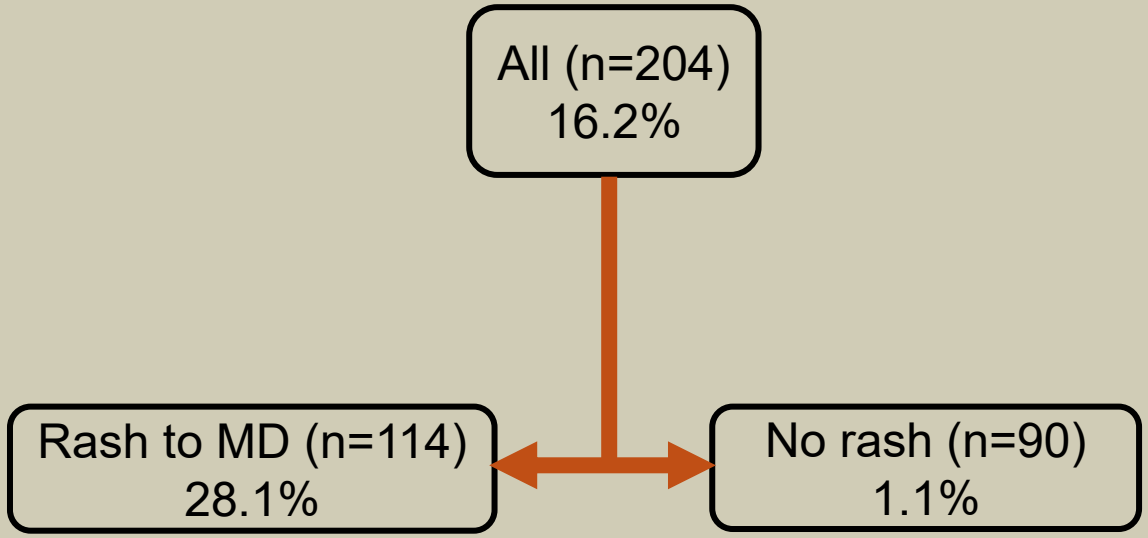
Prevalence of skin rash to

CGM: 42.1% Insulin pump: 44.9%

Less than 5% of those with skin rash had been patch tested prior to this study.

Prevalence of contact allergy to MD allergen[a]

204 of the respondents in the questionnaire study were patch tested



[a]Allergen i CGM/insulin pump = allergens that have been identified in a diabetes MD and caused contact allergy among users

Top 5 medical device-allergens

Table 9. The five allergens found in diabetes MDs with highest contact allergy prevalences in the individuals with diabetes.

		Rash to diabetes MDs	
Patch test preparation	**All (n=204)**	**Yes (n=114)**	**No (n=90)**
Isobornyl acrylate 0.3% pet.	20 (9.8%)	19 (16.7%)	1 (1.1%)
Isobornyl acrylate 0.1% pet.	11 (5.4%)	10 (8.8%)	0
***N,N*-Dimethylacrylamide 0.3% pet.**	10 (4.9%)	10 (8.8%)	0
2-Hydroxyethyl acrylate 0.1% pet.	7 (3.4%)	7 (6.1%)	0
Dicyclohexylmethane-4,4′-diisocyanate 1.0% pet.	6 (2.9%)	6 (5.3%)	0
1,6-hexanediol diacrylate	4 (2.0%)	4 (3.5%)	0

MD, medical device; n, number; pet., petrolatum.

https://lucris.lub.lu.se/ws/portalfiles/portal/241471968/Avhandling_Josefin_Ulriksdotter_LUCRIS.pdf

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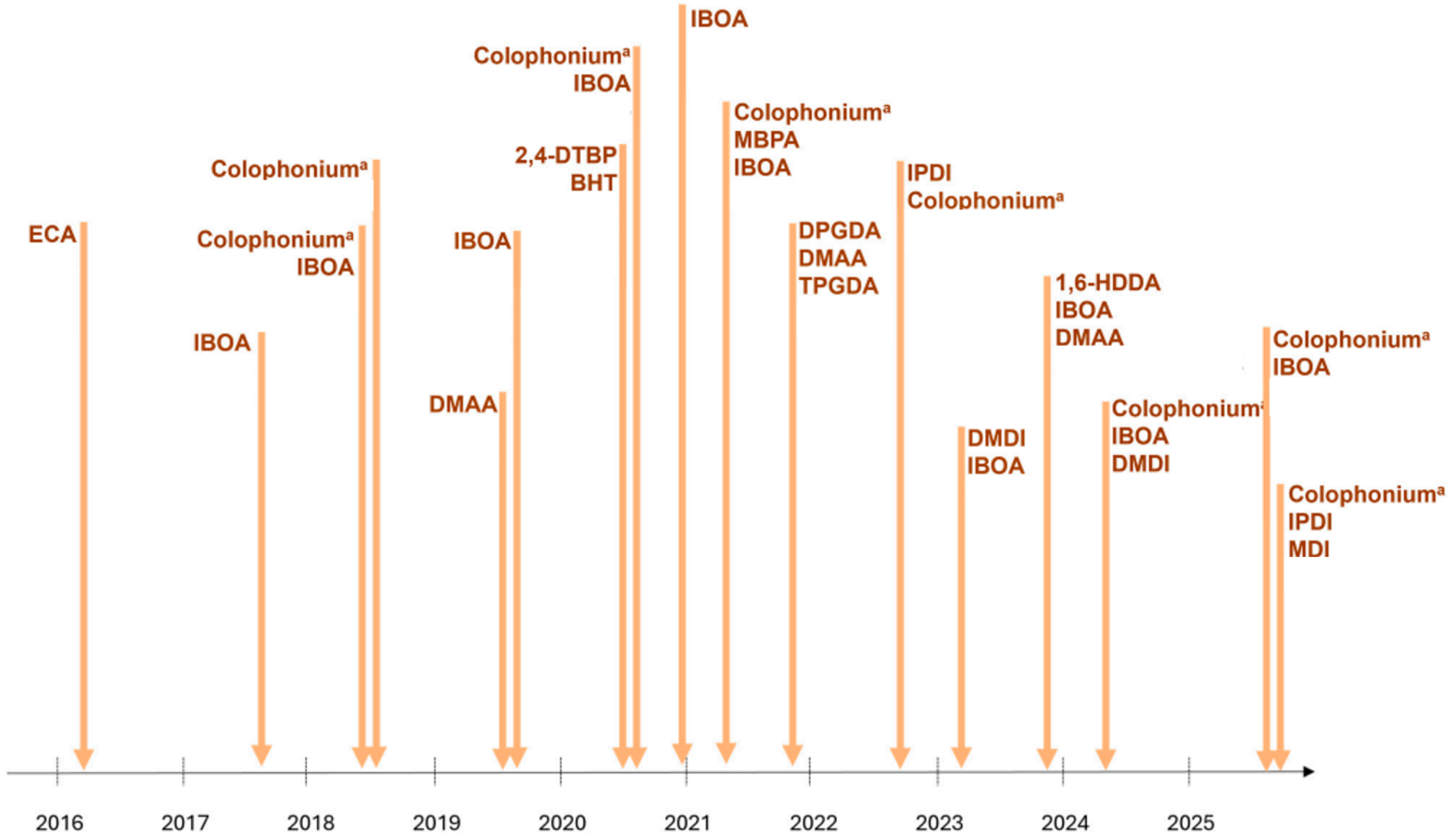


Figure 6a. Timeline with allergens reported to be present in diabetes medical devices 2016-2025[b].

Occupational allergic contact dermatitis induced by adhesives used for prevention of chafing in the military forces—A case report

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KEYWORDS: case report, colophony, contact allergy, medical device, occupational allergic contact dermatitis

Occupational dermatitis in the army has been reported previously.[1,2] In this case report the use of adhesives for primary prevention of chafing of the feet caused severe allergic contact dermatitis.

CASE REPORT

A male conscript, 24-years-old, was referred for suspected occupational contact dermatitis.

The patient gave written informed consent to publication of the case report and photos.

The conscript had rhinoconjunctivitis, atopic dermatitis, otherwise healthy. In the armed forces, he worked as a driver and excavator operator. He had no previous work or leisure experience with electronics, medical devices (MDs), or wood.

In 2021, the armed forces prepared a prolonged march. To prevent chafing,[1,2] the conscripts were recommended to apply adhesives on their feet. Taping of the feet has been used for decades within the armed forces but is also recommended on social media. During the exercise, the patient developed dermatitis with blistering on both feet localized in the region where the feet were taped (Figures 1–3). The dermatitis reappeared when the same procedure of taping was performed at next extended march. After this, the tape was considered the possible culprit agent and therefore avoided. At referral post-inflammatory lesions could still be seen on the ankles and dorsum aspect of the feet.

The patient had prior to his time in the army not experienced skin problems with adhesives or bandaid. Two different brands, Optiplaste®-C (Essity, BSN Medical SAS, Vibraye, France) and Strappal® (Essity, BSN Medical SAS) had been used.

26 recruits within the Swedish Armed Forces were investigated

- 77% CA to used adhesive tape
- 61% CA to colophony



ORIGINAL REPORT

Colophonium-related Allergic Contact Dermatitis Caused by Medical Adhesive Tape Used to Prevent Skin Lesions in Soldiers

Nils HAMNERIUS[1], Jakob DAHLIN[1], Magnus BRUZE[1], Kristina NILSSON[2], Thanisorn SUKAKUL[1] and Cecilia SVEDMAN[1]
[1]Department of Occupational and Environmental Dermatology, Lund University, Skåne University Hospital, Malmö and [2]Department of Current Operations, Army Command, Swedish Armed Forces, Sweden

Medical adhesive tapes are commonly recommended for the prevention of friction blisters during hiking and military marches. The aim of this paper is to report on the results of investigations into an outbreak of tape-related foot dermatitis in 26 military conscripts following continuous use of medical adhesive tapes for several days during a field exercise. Patch tests were performed using baseline series and aimed testing was performed with colophonium-related substances and different medical adhesive tapes. Contact allergy to the adhesive tapes used was found in 20 (77%) subjects, and contact allergy to colophonium in 16 (61%). Chemical analysis detected colophonium-related substances in the culprit tapes. Compared with consecutive dermatitis patients investigated at our Department of Occupational and Environmental Dermatology in the previous 10 years, conscripts with colophonium allergy had increased odds ratios for concomitant contact allergy to phenol formaldehyde resins and fragrance substances including hydroperoxides of limonene and linalool. The results show that prolonged use of medical adhesive tapes on intact skin carries a high risk for allergic contact dermatitis. Prior to their introduction on the market, medical devices should be assessed for possible side-effects.

Key words: allergic contact dermatitis; colophonium; contact allergy; medical device; military personnel; occupational dermatitis.

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DOI: 10.2340/actadv.v103.18428

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SIGNIFICANCE

Adhesive tapes can be used for the prevention of friction blisters. However, this report shows that long-term use of adhesive tape over many days is an obvious risk for the development of contact allergy to substances in the adhesive, which may lead to severe foot dermatitis. This also carries a risk of future skin disease, as these substances are not only used in adhesive tapes, but also in professional life and in dental care procedures. This demonstrates that, prior to their introduction, medical devices should be assessed for possible side-effects.

The use of adhesives on the skin can cause allergic contact dermatitis, a well-known side-effect of medical adhesive bandages and, more recently, of medical devices applied on the skin (1, 2). Among the allergens most commonly reported to cause allergic contact dermatitis to adhesives are colophonium and colophonium-related substances, rubber additives, and acrylates (1). The use of sports tapes, including medical adhesive tapes, has become increasingly popular for the treatment and prevention of exercise-related friction blisters (3–5), and is often advocated on internet sites and social media (5–7). To date, reports of allergic contact dermatitis caused by these products are rare (8–10).

This paper reports occupational allergic contact dermatitis caused by the use of medical adhesive tapes. In March 2022, a 24-year-old conscript, referred from military healthcare, was investigated at the Department of Occupational and Environmental Dermatology, Lund University, Skåne University Hospital, Malmö, Sweden because of severe foot dermatitis. Patch testing identified multiple contact allergies, including allergy to a medical adhesive tape. The tape had been used for the prevention of blisters when marching and the patient's history indicated that sensitization had most likely happened after entering the military service. The results of the investigation have been reported elsewhere (11), and caused us to inform the military health authorities. This led to the investigation of an outbreak of foot dermatitis in conscripts at another military unit in Sweden. During a field training exercise (manoeuvre) at the end of the summer of 2021 many conscripts, who had used medical adhesive tape for prevention of blisters, had developed foot dermatitis. The tape had been applied on intact skin prior to the exercise and there was a temporal association between the occurrence of dermatitis and use of medical adhesive tape for several days. The aim of this paper is to report the results of the patch test investigations in this group of conscripts.

METHODS

Subjects

In cooperation with the Occupational Health Care of the Swedish Armed Forces conscripts who had experienced foot dermatitis were investigated by the Department of Occupational and Environ-

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How are these product used and advertised for in our society?

Implications for individuals with MD related contact allergies

- Itch, discomfort, sometimes oozing skin reactions
- Need to change MD more often
- Stop using MD
- May react when exposed to the allergen
    - in alternative MDs containing the same allergen(s)
    - in other types of MDs
    - in other products (work related/non-work related)

Ulriksdotter et al. Contact Dermatitis. 2020; 83: 301–309.

Occupational ACD

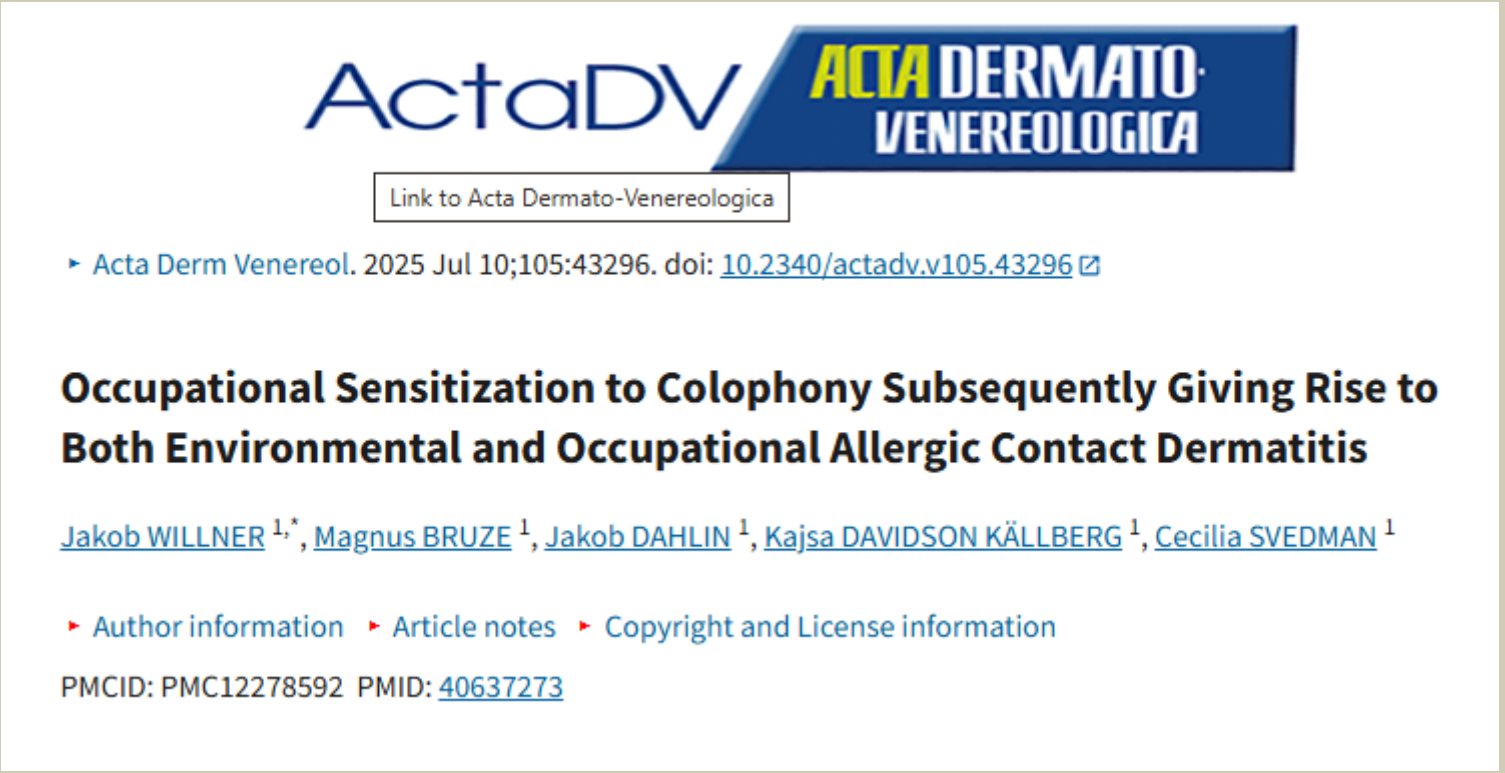


25-year-old male grounds maintenance worker

Blistering due to medical adhesives as a conscript

Later developed severe hand dermatitis after constructing a pine wood fence

ACD upon re-exposure outside MDs



20-year-old woman
Blisters under tape used to prevent shafting –
per oral corticosteroids and quit her military service
Thereafter developed ACD to artificial leather boots

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CONTACT DERMATITIS

CONTACT POINTS | Open Access

Vulvar contact dermatitis caused by sensitization to colophonium in a patient with type 1 diabetes

Giuseppina Salzano, Francesca Galletta, Lucia Caminiti, Paolina Lonia, Vittoria Donia, Giovanni B. Pajno, Stefano Passanisi, Fortunato Lombardo

First published: 01 April 2021 | https://doi.org/10.1111/cod.13851 | VIEW METRICS

13-year-old girl, ACD to colophonium-containing CGM and thereafter a colophinium-containing sanitary pad

ACD upon re-exposure in other MDs

CONTACT DERMATITIS

Contact Dermatitis homepage

CONTACT POINT | Full Access

Allergic contact dermatitis from a disposable blood pressure cuff containing isobornyl acrylate and 2-phenoxyethyl acrylate

Hélène Renaudin, Anne-Sophie Darrigade, Ella Dendooven, Kenn Foubert, Olivier Aerts, Brigitte Milpied

First published: 15 December 2020 | https://doi.org/10.1111/cod.13761 | VIEW METRICS

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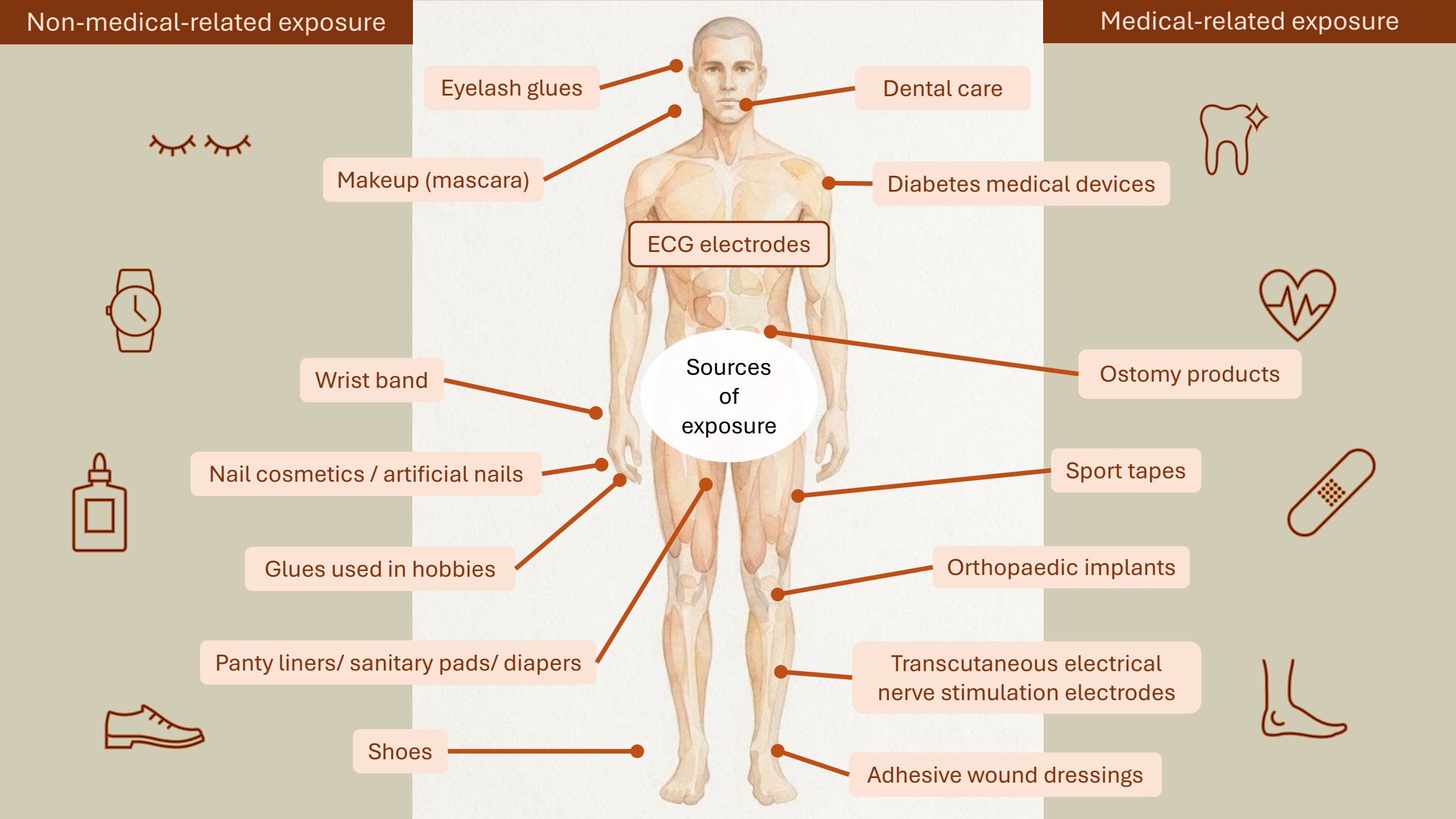
CASE REPORT

A 14-year-old boy with type 1 diabetes mellitus had developed several episodes of allergic contact dermatitis (ACD) at the skin contact sites of a disposable blood pressure cuff (Philips, Amsterdam, The Netherlands) (Figure 1A,B), in 2018 and 2019, when he had been hospitalized because of diabetic ketoacidosis. The dermatitis had always occurred within a few hours following the application of the device. Before in 2017, he had been using the FreeStyle Libre glucose sensor (Abbott Diabetes Care, Witney, Oxfordshire, UK) which, after 3 months, had resulted in ACD, forcing the patient to rely again on finger pricks to monitor his glycaemia. His history revealed no other previous skin problems associated with the use of adhesives, wound dressings, nor any other medical device. When he was referred to our

14-year-old boy with type 1 diabetes
ACD to glucose sensor and then
to blood pressure cuff containing the same culprit allergen

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Non-medical-related exposure
Medical-related exposure
Eyelash glues
Dental care
Makeup (mascara)
Diabetes medical devices
ECG electrodes
Sources of exposure
Wrist band
Ostomy products
Nail cosmetics / artificial nails
Sport tapes
Glues used in hobbies
Orthopaedic implants
Panty liners/ sanitary pads/ diapers
Transcutaneous electrical nerve stimulation electrodes
Shoes
Adhesive wound dressings

Summary and conclusion

Skin rash and contact allergy to CGM and insulin pumps is common and have a negative impact on those affected

Chemical analyses are needed to identify allergens in the products, and patch test with allergens that the medical device users are exposed to and for relevance assessments of allergies found

The content of the devices changes over time

The problem is underdiagnosed and underreported*



The problem is underdiagnosed and underreported

*To medical products agencies, manufacturers and in scientific reports

Wish list for the future

Considering the number of users that need and want to use MDs throughout life, improved primary- and secondary prevention are called for.

How can this be achieved?

- **Primary prevention** – better primary toxicological evaluation of the products *to reduce the prevalence of contact allergy*
- **Secondary prevention** – better information on device content to improve diagnostics of MD-related allergies and *protect those sensitised from re-exposure*



www.pexels.com


Thank you!