MI contact allergy in Croatia: epidemiology and course of disease following patch testing

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ABSTRACT

Background. Methylisothiazolinone (MI) has caused an epidemic of contact allergy in Europe documented with data from many countries, but no studies from Croatia exist. Also data is lacking on severity of MI disease, impact on quality of life and prognosis.

Objectives. To determine the frequency of MI contact allergy among Croatian dermatitis patients, identify causative exposures, qualify impact of disease and study prognosis.

Methods. Data was collected for consecutive dermatitis patients with MI contact allergy during one year patch tested in a University Hospital Center in Zagreb, Croatia.

Results. MI contact allergy was diagnosed in 13.2% of 798 tested patients. Most frequent dermatitis locations were the hands (76%) and face (61%). In 89.3% of patients the MI contact allergy was found to be of current relevance. Dishwashing liquids, laundry detergents and shampoos were most frequently responsible for the dermatitis. A considerable severity and impact on daily living of disease was found at first consultation with a statistically significant decrease in both at follow-up 3 months following patch testing.

Conclusions. An exceptionally high rate of contact allergy to MI was found. The severity of MI allergic contact dermatitis and impact on daily living documents the need for prevention.

Key words: methylisothiazolinone, patch test, education, exposure, follow up

INTRODUCTION

Methylisothiazolinone (MI) has recently been added to the European baseline series (1). An unprecedented rise in MI contact allergy has been seen primarily due to stay-on cosmetic products, but also other exposures such as paints and soaps (2-5). Data has been collected from many countries, but not from Croatia, where patch testing with MI has been performed since March 2015. Many studies on MI contact allergy have been published in recent years, but none of these has included severity assessments, impact on quality of life or prognosis. The aim of the study was to identify current and causative exposures to MI in Croatian patients with MI allergy, qualify reaction patterns and course of disease.

PATIENTS AND METHODS

Consecutive dermatitis patients who were patch tested in the Department of Dermatology and Venereology, University Hospital Center Zagreb between 2 November 2015 and 3 November 2016, were eligible for inclusion in the study, provided they were diagnosed with contact allergy to MI (see below). At inclusion, basic characteristics of the patients such as sex, age, occupation, site of dermatitis, history of atopic dermatitis, previous patch test results, and onset of dermatitis were documented. Furthermore, the dermatologist graded the severity of the dermatitis on a visual analogue scale (VAS) from 0 (no dermatitis) to 100 (very severe dermatitis), in terms of a physician's global assessment. Patients were asked to indicate how much their skin disease had influenced their daily life negatively by thinking of the past week on a VAS scale from 0 (no influence) to 100 (could not be worse), that is, to provide the patient's own global assessment.

All patients were patch tested with the baseline series (Imunološki zavod, Zagreb, Croatia; and Chemotechnique, Vellinge, Sweden) using 8 mm Finn Chambers® (Epitest, Tuusula, Finland) on Scanpor tape® (Norgesplaster, Vennesla, Norway) applied to the upper back and left in place for 2 days. A micropipette was used to apply 15 µl of each MI 0.2% aq. and MI/MCI 0.01% aq. to the filter paper in a Finn Chamber. Patches were read at day (D)2, D3 and D7 according to the ESCD guideline on patch testing (6). A positive response was defined as a +, ++ or +++ reaction.

On D7 patients with a positive reaction to MI 0.2% were asked to bring all their cosmetics, cleaning products and other types of relevant products, also from work place. It was recorded if MI or MCI/MI were present in any of these products. In case one or more of these products were the cause of the current dermatitis, more details about these products were retrieved. Further it was recorded whether the patients had experienced symptoms in newly painted rooms. A follow-up visit about 3 months after patch testing was made, where patients and physicians were asked again to give their global assessment concerning severity of dermatitis and negative influence of dermatitis on daily living, respectively, in a fashion identical to the initial visit.

Data were recorded anonymously in an online documentation system (SoSci survey; https://www.soscisurvey.de) and processed and analyzed using the statistical software package R (version 3.4.2, https://r-project.org). Besides descriptive statistics, the Wilcoxon signed-rank test was used for pre/post comparison of VAS score for severity and impact of disease. A *p*-value of < 0.05 was considered significant.

RESULTS

In total 798 patients (198 males and 600 females) were tested to the baseline series. Of these, 51 (6.4%) were positive to MCI/MI (1.4% males, and 5% females) and 105 (13.2%) to MI (2.1% males and 11.0% females). Forty (5%) patients were positive both to MI and MCI/MI, and 116 (14.5%) patients were positive either to MCI/MI or MI respectively.

Out of the 105 patients who were positive to MI 75 patients [11 (14.7%) males and 64 (85.3%) females] were included in the study. Median age was 42 years. Main occupations were office workers (n=20), student/pensioners (n=12) and housewives (n=4). Five were unemployed, three were hairdressers/beauticians and only one was painter. In total 22 patients did not want to participate in the study, and 8 patients did not show up after 3 months and did not reply to phone calls and/or letters.

Eleven patients had atopic dermatitis, current (9) and/or past (5). The onset of disease was in 48 (69%) cases between 2013 and 2016, most (n=23) in 2015. Only 3 (4%) had a known contact allergy to MI and/or MI/MCI previously proven by patch testing. In total 69 (92%) patients had ongoing dermatitis at the first consultation; location was in 76% (n=57) the hands, in 61% (n=46) the face, including 51% (n=38) with periorbital involvement. In 42 (56%) patients, three or more anatomical sites (with the categorization chosen) were affected. In the remaining 33 patients, the most common combinations were hands and arms (n=11), hands and feet, and neck and periorbital (n=2 each). In total 18 (24%) of patients had experienced airborne symptoms mainly dermatitis (n=15), but also rhinitis (n=3); asthma-like symptoms (n=1) and/or conjunctivitis (n=2) was reported.

Exposures

According to the documentation of products to which the patients had been exposed, 71 were exposed to products containing MI (between 1 product, in 16 patients, to 11 products, in 2 patients; the mean number of products was 3.8). Exposure to products containing MCI/MI was noted in 57 patients (between 1 in 19 patients to 11 products in one patient, mean number of products 2.4). Exposure to privately used products was by far dominating, with a share of 89 % (n=67) and a mean number of products of 3.4, while occupationally used products were documented in just 27% of patients (n=20). The main product groups in the context of private exposure were wet wipes, liquid soaps, shampoos, bath and shower gels and hand creams (Table 1). Additionally, liquid laundry detergents (n=21) and fabric softeners (n=14) were frequently identified to contain MI or MCI/MI.

Product type	**Number of products with:**		**Used in Private life**	**Used occupationally**
	MI	**MCI/MI**		
Creams/Lotions				
-body	3	3	2	0
-face	7	4	6	0
-eyes	3	1	2	0
-hands	16	10	14	1
-feet	1	0	1	0
Sunscreens	3	1	3	0
Self-tanning	0	0	0	0
Deodorant				
-spray	3	2	2	0
-roll-on/stick	5	5	6	1
Make-up				
-face masks	3	2	2	1
-eye make-up	2	0	1	0
-tinted bases	0	0	0	0
-make-up remover	9	4	9	1
Wet wipes	34	24	31	6
Hairstyling				
-gels/mousse	3	2	3	0
-sprays	2	1	2	0
Nail care	0	0	0	0
Mouths washes	0	0	0	0
Rinse-of cosmetics				
-liquid soap	27	20	24	6
-bath/shower gel	20	13	18	0
-shampoo	27	20	22	0
-conditioner	3	3	3	0

Shaving products	1	0	1	0
Cleaning agents	23	17	21	7
Household cleaning spray	17	11	17	4
Dishwashing liquid	23	14	21	2
Paints	4	3	3	0
Glues	1	0	1	1
Cutting oils	1	0	0	1

Table 1: Number of products containing MI or MCI/MI and used by the patients (determined from ingredient labelling, materials safety data sheets, contact to manufacturer or chemical analysis)

Current relevance

In 67 of 75 (89.3%) patients the MI contact allergy was found to be of current relevance. Products were identified, which had caused or contributed to the current dermatitis. On average 2.87 products were given per patient as responsible for the dermatitis. The most frequent types of product found relevant were dishwashing liquids (36%), laundry detergents and shampoo (34.7% each) (Table 2).

	Number	In % of all relevant products
Dishwashing liquid	27	36
Laundry detergent	26	34.7
Shampoo	26	34.7
Wet wipes	23	30.7
Fabric softener	19	25.3
Cleaning agent	15	20
Shower gel	10	13.3
Liquid soap	8	10.7
Hand cream	7	9.3
Wall paint	4	5.3
Face cream	4	5.3

Conditioner	3	4
Roll-on deodorant	3	4
Make up remover	2	2.7

Table 2: The most frequent types of product found relevant for the current dermatitis.

Severity, QoL and course of disease

Severity was assessed by the physician at the first consultation, when patch testing was planned using a VAS from 0 (no dermatitis) to 100 (very severe dermatitis) and again at a follow-up visit at least 3 months following patch testing. At the first consultation the severity was median 40 with 30 and 80 as quartiles; range 5 to 100. At the follow-up visit the severity VAS was median 5 with 0 and 17.5 as quartiles; range 0 to 70. This is illustrated in figure 1. The improvement in severity was statistically significant (p<0.001 by Wilcoxon signed-rank test).

At the same points in time the patients were asked to indicate how much their skin disease had influenced their daily life negatively by thinking of the past week on a VAS scale from 0 (no influence) to 100 (could not be worse). At their first consultation the negative impact was scored to 100 as a median with 70 and 100 as quartiles; range 15 to 100. At the follow-up visit the negative impact was scored to 5 points as median, with 0 and 20 as quartiles; range 0-100. This is illustrated in figure 2 and the improvement was statistically significant (p<0.001 by Wilcoxon signed-rank test).

Twelve patients (16%) had to take sick-leave due to their MI contact allergy, 2 (2.7%) was admitted to hospital for treatment and for 4 patients (5.3%) the MI allergy had occupational consequences resulting in job loss or job change.

DISCUSSION

This is the first study which has examined the prevalence of MI contact allergy in Croatia. The results were exceptional. In total 13.2% of consecutively patch tested patients had contact allergy to MI, defined by a positive patch test. In comparison 6.0% of consecutively patch tested patients from 8 European countries had a positive patch test to MI in 2015, with a top range of 13.0% in Finland in a special center for occupational skin disease (7). In previous investigations from 2013 in individual countries high rates were found in Portugal with 10.9% positive patch test reactions to MI (8) 11.1% on The British Isles (9) and 13.2% in Finland (10). If the number of patients having positive patch test reactions to the mixture MI/MCI are added to those with MI reactions, one in five patients in Croatia are allergic to isothiazolinones, which are permitted in cosmetic products. In the current investigation most reactions were caused by consumer products. This is also reflected in that many more females than males were allergic to MI (2.1% males; 11.0% females), which is also seen in other populations (11).

The cases identified in Croatia were in the majority (69%) incident cases with on-set within the past 3 years reflecting an on-going epidemic. In a study from Leeds (12) trends of MI contact allergy were followed from 2008 to 2015. Even though a decreasing prevalence to both MI and MCI/MI were seen after 2013, where the first recommendation to ban MI in cosmetic products from the Scientific Committee on Consumer Safety was given (13), 11 out of 16 cases (69%) had their first symptoms after 2013 (12). In the European multicenter study mentioned above 68% (86/126) of patients also developed symptoms after 2013 (7). In this study from Croatia the most frequent types of product found relevant to the dermatitis (causative) were dishwashing liquids (36%), laundry detergents and shampoo (34.7% each). Wet wipes as stay-on cosmetics (30.7%) were among the top ranking causative products,

which is interesting as wet wipes were implicated in the first cases reported on MI contact allergy from cosmetics (14). Hand and facial creams accounted for 9.3% and 5.3% of causative products, which may show a beginning effect of the announced ban in stay-on cosmetic products (15); fully implemented by 17. February 2017, from which date stay-on cosmetics containing MI must not be sold any more in Europe. There is a changing pattern in product types causing MI contact allergy from stay-on cosmetics to wash-off and house hold products. In a recent Swiss market survey of 1948 consumer products it was shown that only 7.6% of all cosmetic products were found to contain isothiazolinone. Shampoo was the product category with the highest percentage of isothiazolinones (33.8%), followed by shower gel (13.3%) and wet wipes (11.6%) (16). A higher percentage of detergents (42.7%) than of cosmetics were found to contain isothiazolinones, most often benzisothiazolinone (BIT) in 31.2% and MI in 31.1%, followed by MCI (9.9%). High concentrations were particularly found in detergents (16). These results connect well with the patterns of causative products in the current investigation.

In total 18 (24%) of patients had experienced airborne symptoms mainly dermatitis (n=15), but also rhinitis; asthma-like symptoms and/or conjunctivitis was reported. Isothiazolinones are used in many water-based paints (17,18). MI was found 55/60 (91.7%) of paints bought in five different European countries in concentrations up to 142 ppm (18). MI is volatile and can be found for weeks in indoor air after indoor decorating has been done (19). Airborne contact dermatitis and airway symptoms in MI allergic individuals have been reported in children and adults from many countries (2,4,7). There seems to be no effective solution in place for this severe problem.

This is one of the few studies investigating the course of disease, impact on daily living and the potential positive effects of being patch tested and informed about relevant allergy (20,21,23-25), in this case to MI. A major impact of contact allergy to MI was documented. The patients scored the negative impact of their skin disease at the first consultation as 'could not be worse', corresponding to median 100 on a VAS from 0-100. At the same time the dermatologist assessed the severity of the skin disease on a VAS as median 40 with 30 and 80 as quartiles, on a 0-100 scale. The many sources of MI exposures contribute to the severe state of disease in these patients as well as hidden exposure from products, where there is no ingredient labelling requirement (22). The study also showed a clear benefit of diagnosing MI allergy by patch testing, informing patients on how to avoid exposures and treatment.

At the follow-up visit after 3 months the negative impact of disease was scored to 5 points as median by the patients and so was severity of disease assessed by the dermatologists.

In an English study follow-up was made 2 months after patch testing, it was demonstrated that patients confirmed as having contact allergy showed a subsequent improvement in eczema severity and an improvement in quality of life (21). A clinical follow-up study on 105 formaldehyde allergic patients showed by examination that patients' dermatitis had generally improved from their first visit to the department (20 ?). It was also seen that patients who paid attention to their allergy had statistically significantly fewer eruptions than those who did not (20). In another study from US showed that allergic contact dermatitis had an appreciable effect on quality of life, especially when it affected the hands, the face, or was occupationally related (reference ?). It was shown that outcomes in patients with allergic contact dermatitis were improved by early diagnosis (23). In UK an audit on the value of patch testing was done from the patients' perspective. It showed that patch testing

was beneficial, especially for those with allergic contact dermatitis. Patients' knowledge of the results was good but education could be improved (24). In our study only patients with positive patch tests to MI were included however in a study from US following up 431 patients with suspected allergic contact dermatitis, there was significantly better improvement in each of quality of life among patch tested subjects compared with non-patch-tested subjects (25).

During this epidemic many people in the European population has become sensitized. The big hurdle is that many of these probably do not have access to dermatology care and patch testing. It has been estimated that 15-38% of patients with allergic contact dermatitis in Germany (26) and 20%-30% in Denmark (27), are seen by a dermatologist and relevantly patch tested. These countries have free access to health care services, so the situation in some other countries may be much worse. This mean that patch test data show the tip of the iceberg and a large pool of individuals are sensitized but not diagnosed with contact allergy e. g. to MI and cannot benefit from advice and labelling. They will continue to have symptoms unless other preventive actions are launched such as restrictions or bans of the substance.

In conclusion the severity of MI allergic contact dermatitis and impact on daily living documents the need for prevention.

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Questionnaire on MI-allergy and exposures: Patient form (A)

To be filled in for each patient with contact dermatitis at their first consultation

Patient initials…… Date……

Sex □ male Age in years……..
□ female Occupation…….

Job title (ISCO-08 #): .....(.....)
Start of job: ...../ ...../ ..... End of job: ...../ ...../ ..... or ongoing [ ]

Specific tasks: .....

Contact materials: [.....] [.....] [.....]] [.....] (use ESSCA catalogue)

Protective measures: .....

Severity[1]

Physicians Global Assessment (VAS).

How severe is the current dermatitis?

0 100
|----------|
No dermatitis Very severe

Quality of Life[1]**, (ask the patient set a mark on the line)**

Patients own global assessment.

How much does your skin disease influence you daily life/quality of life negatively?
Think about the past week.

0 100
|----------|
No influence It could not be worse

Localisation of Dermatitis

Present dermatitis	□
Hands	□
Arms	□
Trunk	□
Neck	□
Eyes	□
Scalp	□
Face(rest)	□
Legs	□
Feet	□
Genital/ano area	□

	yes	no
Atopic dermatitis, presently	□	□
Atopic dermatitis, previously	□	□

if yes, age of debut of AD _____

	yes	no
Previously patch tested:	□	□

year_____

	yes	no
Known positive to MI or MI/MCI:	□	□

[1] This information should be filled in ***at the first consultation***, not after dermatitis has subsided when the patch test is performed

No present dermatitis ☐
Onset of present dermatitis: month_____ year_____

Patient form (B) p.1:
only for patients with a positive reaction (at least +) to MI

Patient initials…… Date……

Patch test results: (only record if positive at -at least one reading)

	Current test reaction			
Test preparation	**D2**	**D3/ 4**	**D5/ 7**	**Comments**
Methylisothiazolinone 0.2%				
MCI/MI 0.02%				
Fragrance mix I				
Fragrance mix II/HICC				
Balsam of Peru				
Formaldehyde				
Quaternium 15				
Parabens				
Nickel				
Chromium				
Cobalt				
Others from baseline series :				

(+++, ++, + allergic reaction; IR irritant reaction; (+) or ? doubtful reaction)

Comments:_____

_____

Patient form (B) p.2

Patient initials……

Table X.: Number of products brought in by the patients in the different categories

Products used by the patient containing MI or MCI/MI (determined from ingredient labelling, MSDS (incl. internet), contact to manufacturer or chemical analysis)

Product type	Number of products with: MI	MCI/MI	Used in Private life	Used occupationally
Creams/Lotions				
-body				
-face				
-eyes				
-hands				
-feet				
Sunscreens				
Self-tanning				
Deodorant				
-spray				
-roll-on/stick				
Make-up				
-face masks				
-eye make-up				
-tinted bases				
-make-up remover				
Wet wipes				
Hairstyling				
-gels/mousse				
-sprays				
Nail care				
Mouths washes				
Rinse-of cosmetics				
-liquid soap				
-bath/shower gel				
-shampoo				
-conditioner				
Shaving products				
Cleaning agents				
Household cleaning spray				
Dishwashing liquid				
Paints				
Glues				
Cutting oils				
Others (write which):				

Patient form (B) p.3 **Patient initials……**

Current relevance: If you judge any of the above products to have caused or contributed to the (current) dermatitis. Please give more details her:

Product type	name	producer	Comments eg. Batch no.

Airborne exposures?

Reacted in newly painted rooms? Yes □ No□
If yes:
With dermatitis □
With rhinitis □
With asthma(like) symptoms□
With conjunctivitis □

Reacted to other airborne exposure? Yes □ No□
If yes:
Type of exposure:_____

Reaction type:
With dermatitis □
With rhinitis □
With asthma(like) symptoms□
With conjunctivitis □

Questionnaire on MI-allergy and exposures: Clinic form (C)

Study started: _____/_____/_____ Study ended_____/_____/_____

Number of patients tested with MI in total:
……..

Number of females tested: ……..

Number of males tested: …….

Patient follow-up form (D) p.1: only for patients with MI allergy

Patient initials…… date:…….

Follow-up time:…… **months**
(time since patch testing eg. 3 months)

Severity
Physicians Global Assessment (VAS) :

0 100
|----------|
No dermatitis Very severe

Quality of Life, (ask the patient set a mark on the line)
Patients own global assessment.
How much does your skin disease influence you daily life/quality of life negatively? Think about the past week.

0 100
|----------|
No influence It could not be worse

Consequences from MI contact allergy
[ ] Sick-leave if yes how many weeks the last year due to (MI)dermatitis…….
[ ] In-patient treatment
[ ] Job change
[ ] Job loss and unemployed

Other relevant information:

_____