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1 **Title:** Patient versus allergy specialist interpretation of a negative workup for
2 suspected iodinated contrast media allergy.

3

4 **Authors:** Rik Schrijvers MD PhD^{1,2}, Christine Breynaert MD PhD¹, Jean-Luc Bourrain
5 MD², Pascal Demoly MD PhD^{2,3}, Anca Mirela Chiriac MD PhD^{2,3,*}

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7 ¹ KU Leuven Department of microbiology and clinical immunology, Laboratory of
8 clinical immunology, Leuven, Belgium

9 ² Exploration des Allergies, Département de Pneumologie et Addictologie, Hôpital
10 Arnaud de Villeneuve, University Hospital of Montpellier, France.

11 ³ Equipe EPAR-IPLESP, Sorbonne Université, Paris, France.

12

13 * *Corresponding author:*

14 Dr Anca Mirela CHIRIAC, a-chiriac@chu-montpellier.fr, Allergy Unit, Arnaud de
15 Villeneuve Hospital, University Hospital of Montpellier

16 371, Avenue du Doyen Gaston Giraud, 34295 Montpellier Cedex 5, Montpellier,
17 France, Phone: +33 467336107

18

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20 investigator fellowship Research Foundation Flanders (FWO).

21

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23 work.

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25

26 **Clinical implications:**

27 After a negative ICM drug allergy workup, patients often remained convinced
28 to be allergic or uncertain. Additional patient-perception studies are
29 warranted and may indicate the need for better dissemination of information
30 of drug allergy evaluations towards patients and health care workers.

31

32 *To the editor,*

33 Drug allergy workup aspires to validate or invalidate assumed allergies, identify
34 potential cross-reacting drugs and provide safe alternatives. However, the results
35 obtained and information given by the allergist is not always perceived as such by
36 the patient. Therefore, the label of '*allergy*' often persists for patients despite a
37 negative workup and can result in unnecessary avoidance or unnecessary use of
38 second-line alternatives.

39 In the management of iodinated contrast media (ICM) hypersensitivity reactions
40 (HR), skin testing can be used to identify the subset of truly ICM allergic patients and
41 to provide safe skin-test-negative ICMs for potential re-exposure.

42 Recently, we contacted 597 patients who underwent skin testing for a potential drug
43 hypersensitivity reaction after exposure to iodinated contrast media¹. Using a
44 standardized questionnaire, patients were contacted and questioned whether
45 subsequent exposure to ICM occurred and if this was tolerated. Sixteen of 233
46 (6.9%) patients who were re-exposed experienced reactions, with mostly milder or
47 identical symptoms compared with the initial reaction. No patients with one or more
48 positive skin tests reacted to an identified skin test negative alternative and a
49 stepwise approach was proposed for future evaluation and care for patients with a
50 potential ICM HR.

51 In this work, we evaluated how the result of the allergy workup was perceived by
52 patients and if this was concordant or not with the view of the allergist. Therefore, at
53 the end of the questionnaire, patients were asked whether they considered
54 themselves as '*allergic*' to ICM or not. Only physically contacted patients were
55 included (n=387) and patients with positive skin tests (n=57) or reactions upon re-
56 exposure despite negative skin tests (n=13), or incomplete data (n=18) were
57 excluded, as they could be perceived as '*allergic*', although this would not always
58 corroborate the opinion of the allergist. The study was approved by the local ethical
59 committee.

60 In 299 patients with all negative skin tests, 121 (40.4%) were re-exposed, all
61 uneventfully, and 178 (59.5%) were not re-exposed (Table 1). Patients that were re-
62 exposed (with tolerance) reported '*not to be allergic*' in 92/121 (76.0%) of cases,
63 '*allergic*' in 11/121 (9.1%), and '*uncertain*' in 18/121 (14.9%). Those that were not re-
64 exposed reported '*not to be allergic*' in 57/178 (32.0%) of cases, '*allergic*' in 43/178

65 (24.2%), and 'uncertain' in 78/178 (43.8%). The proportion of patients reporting 'not
66 to be allergic' was higher in the re-exposed versus not re-exposed group (76.0%
67 versus 32.0%, $p < 0.0001$ Chi-square test). This might reflect a change in perception
68 after a tolerated re-exposure although a lower threshold for re-exposure in this
69 subgroup of patients cannot be excluded. The proportion of patients reporting
70 'uncertain' was lower in the re-exposed versus not re-exposed group (14.9% versus
71 43.8%, $p < 0.01$ Chi-square test). However, in total still 54/299 (18.1%) questioned
72 patients were convinced to be 'allergic' despite a negative allergy workup and
73 96/299 (32.1%) remained 'uncertain'.

74 Although skin testing can identify safe alternative(s) for ICM re-exposure and
75 potentially discriminate between allergic and non-allergic ICM HRs, the allergist and
76 patient interpretation is often not well aligned. It is unclear whether more solid
77 information on the negative predictive value of skin testing in ICM HR at the time of
78 the allergy workup in this study would have reduced the number of patients
79 continuing to perceive themselves as 'allergic' or 'uncertain'. However, our study
80 indicates the need for better dissemination of information of the allergy workup
81 towards patients and health care workers.

82 Similar work in penicillin allergy, indicates that the *allergy* label often persists
83 despite a negative workup^{2,3} and that many patients and/or physicians remain
84 reluctant to readminister penicillins despite a negative evaluation⁵. In a survey in
85 patients who underwent a penicillin allergy workup, Gerace et al. observed that
86 12/49 (41%) patients with negative skin tests continued to avoid penicillins either
87 due to personal (42%) or the primary care physician's (58%) concerns³. Picard et al.
88 observed that the parents of 24/170 (18%) children who had negative penicillin skin
89 and provocation testing, refused readministration of penicillins in their children
90 because of fear for a reaction⁴, similar to the 9% of patients considering themselves
91 as allergic despite negative skin tests and a tolerated rechallenge in our work.

92 To our knowledge, this is the first study to evaluate patient interpretation of a ICM
93 drug allergy workup and we would suggest that this is implemented in future work
94 to better evaluate the impact and limitations of the allergy specialist advice.

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Table 1. Patient perception after a negative allergy workup for suspected ICM HR.

Patient perception	Not re-exposed	Re-exposed	Total
	60% (178)	40% (121)	100% (299)
<i>“Allergic”</i>	24 % (43)	9% (11)	18% (54)
<i>“Uncertain”</i>	44% (78)	15% (18)	32% (96)
<i>“Not allergic”</i>	32% (57)	76% (92)	50% (149)