ORIGINAL ARTICLE

Hypersensitivity to iodinated contrast media: diagnostic evaluation and re-exposure outcomes

Cristina Coelho, Joana Gomes, Joana Barradas Lopes, Patrícia Barreira, Susana Cadinha, Maria João Sousa, Daniela Malheiro

Department of Allergy and Clinical Immunology, Gaia Espinho Local Health Unit, Vila Nova de Gaia, Portugal

Summary

Background. Iodinated contrast media (ICM) are widely used and generally safe, although hypersensitivity reactions (HSR) may occur. This study aimed to characterize the allergological workup of patients with suspected ICM HSR and evaluate outcomes after re-exposure. **Methods.** We conducted a unicentric retrospective study of patients referred between January 2012 and December 2024 for suspected ICM HSR. Diagnosis was confirmed by suggestive clinical history (CH) with positive skin tests (skin prick, intradermal, and/or patch tests), with or without positive basophil activation test (BAT) or lymphocyte transformation test (LTT), or by a positive drug provocation test (DPT). Diagnosis was considered probable with suggestive CH and positive BAT/LTT, and excluded after negative DPT. Clinical records were reviewed, and patients were contacted to assess re-exposure outcomes. **Results.** A total of 129 patients were included (57% female; mean age 59 ± 15 years); 10% were atopic. Iopromide was the most frequently suspected agent (66%). Reactions were immediate in 67% and non-immediate in 33%, mainly cutaneous (67%). Among those completing the workup (n = 94), immediate HSR was excluded in 40 patients and confirmed in 22 (NPV 77%). Non-immediate HSR was confirmed in 18, considered probable in 3, and excluded in 10; intradermal and patch tests NPV was 44%. Among 40 patients with confirmed HSR, three were re-exposed to the culprit ICM and two reacted. Of 51 patients with excluded HSR, 25 were re-exposed, with one mild reaction. **Conclusions.** CH alone overestimates ICM HSR. Diagnosis relies on skin tests and particularly DPT, which supported exclusion of HSR, when negative.

KEY WORDS

Anaphylaxis; cross-reactivity; drug hypersensitivity; drug provocation test; iodinated contrast media; skin tests.

Impact statement: Allergological workup including drug provocation testing improves diagnostic accuracy in suspected iodinated contrast media hypersensitivity and supports safe re-exposure when hypersensitivity is excluded.

Introduction

Hypersensitivity reactions (HSR) to iodinated contrast media (ICM) are uncommon and usually mild. Severe reactions—including anaphylaxis—are rare (<0.04%) (1-3). HSRs are classified as immediate (within 1-6 hours) or non-immediate. Immediate reactions include urticaria, angioedema, bronchospasm, or anaphylaxis, while non-immediate reactions are typically exanthematous rashes (2,4).

Risk factors for hypersensitivity include a prior history of ICM reaction, other drug allergies, allergic diseases, and family history of ICM hypersensitivity, suggesting a possible genetic predisposition (1,5). Certain ICM agents (e.g., iomeprol, iopromide) are associated with higher rates of hypersensitivity, and non-white patients, younger age, and female sex are also associated with increased risk (5-6).

For patients with prior ICM hypersensitivity, individualized management is recommended, including risk assessment and consideration of alternative ICM agents based on allergy testing, rather than routine premedication with corticosteroids or antihistamines (7). The European Society of Urogenital Radiology also advises referral to an allergist for moderate or severe reactions and recommends switching to an alternative ICM based on allergy evaluation, as cross-reactivity is common and premedication alone is less effective for preventing recurrence (8-10).

Acute management of severe reactions should be guided by clinical severity and follow established emergency protocols. While anaphylaxis requires prompt intramuscular adrenaline as first-line therapy, other acute reactions may be managed with supportive measures such as antihistamines, corticosteroids, and oxygen therapy, as clinically indicated (3-4). Documentation and standardized classification of reaction severity are essential for future risk management (4).

Accurate identification of the culprit agent and selection of a safe alternative is essential, as repeated ICM exposure is often required for ongoing imaging needs.

Skin testing is the cornerstone of allergological evaluation for ICM hypersensitivity. For immediate HSRs (I-HSR), prick and intradermal tests (IDT) are performed, while patch and delayed IDT are used for non-immediate reactions (NI-HSR) (11-16). For NI-HSR, patch testing (PT) is particularly useful, with positive rates around 50% for the culprit ICM (11,14). However, skin test sensitivity is limited, especially for NI-HSR, and negative predictive value (NPV) is suboptimal (e.g., 53% in some series) (11). Cross-reactivity between ICMs is common and unpredictable, needing testing with a panel of agents (9,11).

In vitro assays—including basophil activation test (BAT), specific IgE, mast cell activation, lymphocyte transformation test (LTT), and ELISpot—are available but lack standardization and robust validation

for routine clinical use (17). Their utility is currently adjunctive, not primary, in the diagnostic algorithm.

Prospective studies and meta-analyses demonstrate that a skin test-guided strategy for selecting alternative ICMs significantly reduces recurrence rates of HSRs. In a multicenter prospective study, adherence to an IDT-guided protocol resulted in 85% of patients tolerating re-exposure without adverse reactions, compared to a 53% recurrence rate in those not following the protocol (5). Similar findings are reported in other cohorts, with skin test-negative agents being well tolerated in intravenous provocation tests (15-16). Meta-analytic data support that changing ICM based on allergy evaluation reduces the risk of recurrent immediate hypersensitivity by approximately 61% (10). Drug provocation tests (DPT), when performed with skin test-negative agents, are generally safe and effective for confirming tolerance, even in patients with prior anaphylaxis, though mild cutaneous symptoms may occur (9, 15, 18).

In summary, hypersensitivity to ICM is rare but potentially serious, with management focused on risk stratification, avoidance of culprit agents, and prompt treatment of acute reactions, as supported by consensus statements and international guidelines (11,14-16). The authors aim to characterize a sample of patients with suspected ICM hypersensitivity who were evaluated at a specialized allergy and clinical immunology center.

Methods

Study design

A unicentric, retrospective, observational study with descriptive and inferential analysis was conducted, including patients with a history of HSRs to ICM.

Patients and data collection

Between January 2012 and December 2024, all patients aged ≥18 years referred to the Allergy and Clinical Immunology Department with a suggestive history of a ICM HSR were included. Suspected HSR were classified based on chronology as immediate (within 1-6 hours) or non-immediate (7).

HSRs were classified as follows (7,18):

- Confirmed hypersensitivity: presence of a suggestive clinical history and positive skin tests [skin prick test (SPT 1/1), intradermal test (IDT 1/10 and 1/1 in non-immediate HSR), patch test (PT 1/1)], or a positive drug provocation test (DPT) (19)(20).
- Probable hypersensitivity: suggestive clinical history with positive in vitro tests (lymphocyte transformation test [LTT] or basophil activation test [BAT]) in the absence of confirmatory in vivo tests.
- Excluded hypersensitivity: negative DPT or clinical history consistent with non-allergic adverse drug reactions, or documented subsequent tolerance to the suspected ICM.

All patients underwent a standardized diagnostic approach:

- Detailed clinical history and classification of the reaction (immediate vs non-immediate);
- Skin testing (SPT, IDT, and/or PT).
- In vitro testing (LTT and/or BAT), in selected cases when available, mainly as additional diagnostic tools in patients with contraindications to skin testing or drug provocation testing, or in cases of diagnostic uncertainty. These in vitro tests were used as supportive investigations and not as standalone confirmatory diagnostic tests.
- Drug provocation testing (DPT), when not contraindicated and when previous tests were inconclusive (21).

All diagnostic tests were performed at least 6 weeks after complete resolution of the index reaction (21).

The NPV of skin tests was calculated considering only patients with negative test results who were subsequently re-exposed to iodinated contrast media. The denominator therefore consisted of all test-

negative patients who underwent re-exposure, while the numerator included those who tolerated re-exposure without HSR.

Additionally, patients were contacted and clinical records were reviewed to identify subsequent exposures to ICM and assess the occurrence of new reactions.

Ethics

As part of the standard practice in our allergy clinic all subjects were informed about any risks involved with testing and written informed consent for allergological work-up (ST, in vitro tests and/or DPT) was obtained.

This study was approved by the institutional ethics committee and conducted in accordance with the Declaration of Helsinki of 1964.

Data analysis

Data analysis was performed using Statistical Package for Social Sciences (SPSS) version 28®. Descriptive statistics were used to characterize the sample. Categorical variables were described as absolute and relative frequencies. Normally distributed variables were reported as mean and standard deviation, while non-normally distributed variables were presented as median (minimum and maximum).

Results

A total of 129 patients were included in the study, 57% of whom were female, with a mean age of 59 ± 15 years. The demographic and clinical characteristics are presented in Table I.

Atopy was identified in 10% of participants.

Iopromide was the most frequently suspected ICM (66%), followed by iomeprol (4%). In 22% of cases, the responsible ICM was not identified.

Clinical manifestations were predominantly cutaneous (67%), followed by anaphylaxis (17%), respiratory symptoms (11%), and malaise (5%). HSRs were classified as I-HSR in 67% (n = 87) and NI-HSR in 33% (n = 42) of patients.

Among the 36 patients who did not complete the study or had an inconclusive evaluation, 26 refused or did not attend scheduled procedures. In 3 cases, the suspected drug was unknown, precluding definitive conclusions. In the remaining 7 patients, drug provocation tests (DPT) were performed using alternative agents. The allergological evaluation of these patients is presented in Table II.

Immediate HSRs

Among the 62 patients who completed the full diagnostic workup, hypersensitivity was confirmed in 22 (36%). Most confirmed cases were attributed to iopromide (n = 20). Of these, 11 were confirmed by positive DPT and 9 by positive IDT, including one who also had a positive BAT. Two additional cases were attributed to iomeprol: one confirmed by a positive DPT and the other by positive IDT and BAT.

In 24 patients of 62, IDT were performed with more than one ICM. No patient showed positivity to more than one contrast agent.

Two patients with positive DPT to the suspected agents (iomeprol and iopromide) underwent DPT with alternative agents, iopromide and iomeprol, respectively. The first DPT was positive (Table II).

I-HSR was excluded in 40 patients based on negative DPT results.

The NPV of ID for I-HSR was 77%.

Non-immediate HSR

Among the 31 patients who completed the diagnostic workup, hypersensitivity was confirmed in 18 (58%). Some showed positive results to more than one contrast agent.

Sixteen patients underwent IDT with more than one ICM, and 4 showed positive results to multiple agents (Table III).

Hypersensitivity to iopromide was confirmed in 15 patients: 9 by DPT, 4 by IDT, 1 by both IDT and PT, and one by PT and LTT.

Hypersensitivity to ioversol was confirmed in 3 patients, all by IDT. Two of these also showed positive results to iopromide and iomeprol, while one was additionally positive to iopromide.

Five patients were confirmed to have hypersensitivity to iomeprol (4 by IDT and 1 by DPT).

One patient had hypersensitivity to iodixanol, confirmed by IDT, and also showed positivity to iomeprol. Two patients with confirmed NI-HSRs to iopromide underwent DPT with alternative agents (ioversol and iopromide), both of which were positive (Table II).

NI-HSR was considered probable in 3 patients based on positive LTT results: two to iopromide and one to both iomeprol and ioversol.

NI-HSR were excluded in 10 patients. The NPV of ID and PT for NI-HSR was 44% each.

Diagnostic outcomes in patients with confirmed HSR to ICM are represented in Table IV and V.

Follow-up and re-exposure

In total, 40 patients had confirmed ICM hypersensitivity (24% I-HSR and 20% NI-RSH). Thirteen patients did not undergo further imaging studies requiring contrast administration, whereas 27 underwent subsequent imaging procedures. Among these, 18 underwent non-contrast imaging studies, two received an alternative ICM agent (initial reaction to iopromide, subsequently switched to iomeprol following negative testing), and four received gadolinium-based contrast agents, with no HSR reported. Three were re-exposed to the same ICM. One experienced recurrent anaphylaxis (initial I-HSR),

another developed delayed cervical and oropharyngeal edema (initial NI-HSR), and the third tolerated re-exposure without reaction.

Among the 51 patients in whom hypersensitivity was excluded, 25 were re-exposed to contrast media. Only one developed urticaria and angioedema after iopromide administration, despite an initial I-HSR to ioversol, negative IDT for iopromide and negative DPT for ioversol.

All patients with negative DPT who were re-exposed to the same contrast agent tolerated it without adverse reactions. Notably, 10 patients with excluded hypersensitivity avoided re-exposure despite having a clinical indication for contrast-enhanced imaging.

Discussion and conclusions

The demographic characteristics of our cohort, including a predominance of female patients and a mean age in the mid-50s, are consistent with previously published studies (1,14,22).

In this study, I-HSR were more frequent than NI-HSR, although recent literature suggests an increasing prevalence of NI-HSR over time with maculopapular exanthema being the clinical entity most frequently reported (23).

Hypersensitivity was confirmed in 24% of patients with suspected I-HSR and 20% with NI-HSR. These findings are in line with previous reports, which describe confirmation rates of approximately 10–25% for immediate reactions and 30–70% for non-immediate reactions (2). Similarly, Trautmann et al. reported comparable rates (24%) for both immediate and delayed reactions (15).

The NPV of 77% for IDT in I-HSR and 44% in NI-HSR reveals important limitations of skin tests, particularly in NI-HSR. This variability is well described in the literature, with reported NPV ranging from 53% to over 90%, depending on the population and methodology (11, 24-25). These findings reinforce that negative skin test results do not reliably exclude hypersensitivity, especially in NI-HSR.

Cross-reactivity between different iodinated contrast media was observed only in NI-HSR in our cohort, including cases with positive responses to multiple agents and positive DPT to alternative ICM. This is consistent with previous studies reporting significant rates of cross-reactivity: Doña et al. found that 36% of patients were allergic to multiple ICMs, and Gamboa et al. reported a 22% rate of cross-reactivity between iomeprol and iopamidol (9,11). The underlying mechanisms remain incompletely understood but may be related to shared chemical structures (19). These findings support the need for comprehensive allergological evaluation, including testing with alternative agents.

Re-exposure data further emphasize the clinical relevance of the diagnostic work-up. Among patients in whom hypersensitivity was excluded, re-exposure was generally well tolerated, particularly when a negative DPT had been obtained. No patient with a negative DPT experienced a reaction upon re-exposure, supporting its role as the reference standard. However, one breakthrough reaction occurred

despite negative testing with an alternative ICM, underscoring the limitations of skin tests and the possibility of agent-specific reactions.

Despite negative evaluation, a considerable number of patients avoided re-exposure, highlighting ongoing reluctance among patients and clinicians and the need for improved communication regarding the safety of contrast media after allergological assessment.

This study has some limitations. The high proportion of reactions attributed to iopromide may reflect its frequent use in our center. In addition, the availability of alternative ICM varied over time, which may have limited testing in some patients.

Overall, our findings underscore the importance of a thorough allergological evaluation, including DPT, to guide safe and individualized use of ICM in clinical practice, as clinical history alone may overestimate the diagnosis of ICM HSRs.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

CC: Conceptualization, data curation, methodology, visualization, formal analysis, writing – original draft, writing – review & editing.

JG: Data curation, methodology and visualization.

JBL: Data curation, methodology and visualization.

PB: Data curation, methodology and visualization.

SC: Conceptualization, writing – review & editing.

MJS: Conceptualization, methodology, validation, writing – review & editing.

DM: Conceptualization, methodology, validation, writing – review & editing.

All authors approved the final version to be published.

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Table I. Demographic and clinical characteristics of the study population

Variable	Value
Total patients, (n)	129
Female, %	57%
Mean age ± SD (years)	59 ± 15
Atopy %(n)	10% (13)
Most frequently supected ICM, (%)	Iopromide (66%)
ICM not identified, %(n)	22% (28)
Clinical manifestations	
– Cutaneous, %(n)	67% (85)
– Anaphylaxis, %(n)	17% (22)
– Respiratory symptoms, %(n)	11% (14)
– Malaise, %(n)	5% (6)
Type of HSR (suspected)	
– I-HSR, %(n)	67% (87)
– NI-HSR, %(n)	33% (42)
Patients who complete diagnostic workup, n	93
– Confirmed I-HSR, %(n)	24% (22)
– Confirmed NI-HSR, %(n)	20% (18)

ICM: iodinated contrast media; I-HSR: immediate hypersensitivity reaction; NI-HSR: non immediate hypersensitivity reaction; SD: standard deviation

Table II. Allergological work-up of patients who performed provocation test (gold standard) with an alternative ICM.

Patients (sex/age)	Suspected ICM induced reaction	Reaction timing	ICM used for IDT/result	ICM used in the DPT/ result
F,42	Iopromide	I	Iopromide/ neg	Iomeprol/neg
F,60	Iopromide	I	Iopromide/neg	Iomeprol/neg
M,70	Iopromide	I	Iopromide/ neg	Iomeprol/neg
F,51	Iomeprol	I	Iopromide,iomperol/neg	Iopromide/neg
M,53	Ioversol	NI	Iopromide/ neg	Iopramida/neg
M,62	Iodixanol	NI	Iopromide / neg	Iopromide/neg
F,33	Iobitridol	NI	Iobritidol, ioversol, Iopromide, iomeprol/ neg	Ioversol/neg
F, 19	Iomeprol	I	Iomeprol, Iopromide/ neg	Iomeprol/ pos Iopromide/ neg
M, 69	Iopromide	I	Iopromide/neg	Iopromide/ pos Iomeprol/ neg
F/52	Iopromide	NI	Iopromide,ioversol,iomeprol/neg	Iopromide/pos Iomeprol/neg
M/64	Iopromide	NI	Iopromide,ioversol,iomeprol/neg	Iopromide/pos Ioversol/pos
M/72	Iopromide	NI	Iopromide/pos Iomeprol/neg	Iomeprol/pos

DPT: drug provocation test; F: female; I: immediate; ICM: iodinated contrast media; IDT: intradermal test; M: male; neg: negative; NI: non immediate; pos: positive.

*Table III. Patients with NI-HSR and positive IDT * to different ICM*

IDT	Iopromide	Iomeprol	Iodixanol	Ioversol
Iopromide		I I		I I I
Iomeprol	I I		I	I I
Iodixanol		I		
Ioversol	I I I	I I		

IDT: intradermal test; I: one patient

* All IDT were positive on delayed readings

Table IV. Diagnostic outcomes in patients with confirmed I-HSR to iodinated contrast media

Contrast Agent	Confirmed I-HSR (n)	Diagnostic Method(s)
Iopromide	20	11 DPT+, 9 IDT+ (including 1 BAT+)
Iomeprol	2	1 DPT+, 1 IDT+ & BAT+

DPT: drug provocation test; BAT: basophil activation test; IDT: intradermal test; I-HSR: immediate hypersensitivity reaction; &: and

Table V. Diagnostic outcomes in patients with confirmed NI-HSR to iodinated contrast media

Contrast Agent	Confirmed NI-HSR (n)	Diagnostic Method(s)
Iopromide	15	9 DPT+, 4 IDT+, 1 IDT+ & PT+, 1 PT+ & LTT+
Ioversol	3	3 IDT+
Iomeprol	5	4 IDT+, 1 DPT+
Iodixanol	1	IDT+

DPT: drug provocation test; IDT: intradermal test; LTT: lymphocyte transformation test; NI-HSR: non immediate hypersensitivity reaction; PT: patch test.