ACUTE REACTIONS TO UROGRAPHIC CONTRAST MEDIUM*

INCIDENCE, CLINICAL CHARACTERISTICS AND RELATIONSHIP TO HISTORY OF HYPERSENSITIVITY STATES

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ACUTE reactions to the intravenous injection of iodinated contrast medium for excretory urography pose a hazard familiar to most physicians. The clinical characteristics and incidence of reactions to these agents have been documented in the medical literature by Ochsner and his associates,[3,7-9] Ansell[1] and others.[5,6,11,12] But in spite of the availability of this large body of detailed information, differences of opinion, confusion and misunderstanding persist as regards the relative incidence of acute reactions in large patient populations, their significance in specific clinical settings and their relationship to pre-existing "hypersensitivity" or "allergic" states.

It is the purpose of this study to add to the body of available data observations on the incidence and clinical characteristics of reactions to urographic contrast medium in a large, uniform series of patients and to explore the relationship between a history of "allergy" and acute reaction to contrast medium.

METHOD

The study group consisted of 32,964 consecutive outpatients at the Mayo Clinic who were referred to the Department of Diagnostic Roentgenology for excretory urography during a 27 month period. Included were 15,594 males and 17,370 females who ranged in age from infancy to 91 years. No patient on whom excretory urography was undertaken was excluded from the study.

The first 9,934 consecutive patients were studied to determine what relationship exists between a history of known or suspected allergy or hypersensitivity and acute reactions to urographic contrast medium.

Prior to injection of contrast material, each patient in this group was questioned in detail on the following relevant points and the data tabulated:

1. Presence or absence of a history of "allergy" or "hypersensitivity."
2. Specific allergen or allergens if known (*i.e.*, pollens, foods, drugs, iodides, urographic medium, etc.).
3. Clinical characteristics of previous hypersensitivity response if known (*i.e.*, hives, asthma, nausea and vomiting, hay fever, etc.).

Among the remaining 23,030 patients in the study, detailed historical data relating to past history of allergy or hypersensitivity were obtained prior to injection but were tabulated for analysis only in those patients who developed acute reactions. Reactions in all 32,964 patients were recorded as to clinical characteristics, severity and treatment for later analysis.

TECHNIQUE OF EXAMINATION

All patients were examined in a single radiologic facility under highly uniform conditions. The contrast medium used in all examinations was a mixture of sodium and meglumine diatrizoate 69 per cent (Reno-

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vist-Squibb). A routine intravenous test dose of approximately 1 ml. of this medium was employed. The dose administered ranged from as little as 1 ml. test dose only to as much as 150 ml. Standard doses in children ranged from 10 ml. to 30 ml. depending on age and weight. In adults, a standard dose of 30 ml. was used for most patients with known or suspected urologic disease, and a dose of 50 ml. was employed for patients studied because of hypertension and some large patients with suspected urologic disease. Larger doses ranging to 150 ml. were used on a routine basis in patients with chemical evidence of depressed renal function. In an occasional patient, failure of adequate venopuncture or extravascular extravasation of contrast medium during injection resulted in administration of doses under 30 ml.

DEFINITIONS

The response of patients to injection of contrast medium was tabulated in one of 3 categories:

1. No clinically significant response.
2. Minor side effects.
3. Acute reactions.

For the purpose of this study, certain arbitrary definitions were necessary. Patients considered to have *no clinically significant response* include those with no symptoms from injection as well as those who experienced mild transient symptoms which appeared to be the result of normal physiologic effects of injection of the contrast medium itself and were judged to be of no clinical significance. These included mild hot flush, metallic taste in the mouth, mild sense of nausea without retching or vomiting, "peculiar" sensation over the body, tingling in the face or extremities and pain in the arm associated with extravasation of contrast medium. It is worthy of note that one or more of these minor symptoms were experienced by most patients.

Similar symptoms were recorded as *minor side effects*, when unusually prominent or severe. For example, nausea with retching or vomiting was recorded as a minor side effect as was pain in the arm associated with venospasm.

Acute reactions were defined as symptoms and signs considered to be true idiosyncratic responses to contrast medium. These included urticaria in all its forms, mucous membrane and cutaneous edema, bronchospasm, convulsions, hypotension, shock, cardiac arrest and death.

RESULTS

INCIDENCE AND CLINICAL CHARACTERISTICS

The incidence of reactions and the types encountered are tabulated in Table 1.

No clinically significant response was recorded in 30,713 patients (93.2 per cent).

Minor side effects were observed in 1,683 patients (5.1 per cent). These included nausea with retching and vomiting in 1,626; a strong but transient hot flushing or sense of warmth, either alone or with nausea and vomiting, in 37; subjective complaint of "faintness" not found to be associated with hypotension in 7; cough associated with transient "fullness" in the throat and flushing in 7; and pain in the arm secondary to venospasm but not the result of extravasation in 6. No patient in this group with minor side effects required treatment and all symptoms were transient.

Acute reactions were recorded in 568 (1.72 per cent) of the 32,964 patients. The reaction developed during the injection or

TABLE 1

REACTIONS
INCIDENCE AMONG 32,964 PATIENTS

Type	No.	Per Cent
None	30,713	93.2
Minor side effects	1,683	5.1
Acute reactions total	568	1.72
Dermal	476	1.44
Nasal and mucosal	41	0.12
Cardiovascular	24	0.07
Respiratory	16	0.05
Neurologic	3	0.01
Other	8	0.02

within 5 to 10 minutes after completion of the injection in all patients but 2. In these the reaction developed within 1 hour of injection. No examples of delayed reactions to injection of contrast medium were recognized but no special effort was made to identify reactions of this type.

The clinical characteristics of acute reactions are tabulated in Table II. While more than one symptom was recorded in a large number of patients, it was necessary to oversimplify the analysis and tabulate reactions by the predominant symptom or sign. Three hundred thirty-four were classified as mild, 204 as moderate and 30 as severe.

Dermal reactions were present in 476 with hives the dominant finding in 444 and a diffuse erythematous rash in 32. Hives varied in extent from solitary to generalized and were accompanied by itching and in severe cases by moderate cutaneous edema.

TABLE II

CLINICAL CHARACTERISTICS
568 ACUTE REACTIONS

Type	Severity		
	Mild	Moderate	Severe
Dermal (476)			
Hives	271	170	3
Erythema	10	21	1
Nasal; mucosal (41)			
Periorbital edema	13	6	
Sneezing, congestion	17		
Angioedema			5
Cardiovascular (24)			
Syncope	8		
Shock			15
Cardiac arrest			1
Respiratory (16)			
Asthma	5	3	1
Laryngeal	6		1
Neurologic (3)			
Grand mal seizure			3
Other (8)	4	4	

(Erythematous rash associated with cardiovascular symptoms is discussed below.)

Nasal and mucosal symptoms were observed in 41. Of these, periorbital edema with or without itching of the eyes was most frequent with 19 examples recorded. Nasal congestion with sneezing and rhinitis was present in 17 and angioneurotic edema with severe diffuse swelling of the skin and mucous membranes in 5.

Cardiovascular reactions were encountered in 24 (Table III). These were of 3 types: syncope associated with transient hypotension in 8; hypotension (shock) accompanied by a diffuse erythematous rash in 15; and cardiovascular collapse with cardiac arrest and death in 1.

Respiratory symptoms developed in 16. These included symptoms of bronchospasm or bronchial asthma in 9 and episodes of laryngeal edema with signs of airway obstruction of mild to moderate severity in 7.

Neurologic symptoms were seen in 3. All were grand mal seizures not accompanied by other signs or symptoms.

Miscellaneous other symptoms thought to represent idiosyncratic reactions were seen in 8 patients. In 3, shaking chills accompanied by diarrhea and profuse sweating developed within one hour of injection. These symptoms were terminated by injection of antihistamine and epinephrine on an empiric basis. In 3, parotid swelling developed within minutes of injection. In 2 marked restlessness with severe nausea and vomiting were observed and a single patient developed profuse sweating with no other recognizable symptoms.

TABLE III

CARDIOVASCULAR REACTIONS

Syncope	
No treatment	8
Shock with erythema	
Moderate—not hospitalized	5
Severe—hospitalized	10
Cardiac arrest	
Death	1

SEVERE REACTIONS

Reactions classified as severe occurred in 30 patients (Table IV). They occurred at a rate of about 1 for each 1,100 patients examined and represented 5 per cent of the total number of acute reactions in this series. Only about one-third appeared life threatening at the time they occurred, but 1 of these proved fatal in spite of prompt and vigorous treatment.

Fifteen patients with reactions classified as severe developed a diffuse erythematous rash accompanied by hypotension as the major symptoms. Bradycardia (pulse 30 to 40/min.) accompanied the hypotension in 9 and tachycardia in 6. The reaction appeared within 3 to 5 minutes after injection of medium in all cases. It was preceded by nausea and vomiting and the patients almost invariably lost consciousness. Airway obstruction due to relaxation of the tongue developed in 6. Many patients had urinary and fecal incontinence during the episode. Neither myocardial infarction nor cardiac arrest was observed in this series but subsequently, we have seen an acute myocardial infarction develop in several patients with this syndrome.

The cutaneous rash which accompanied these reactions was diffuse, of moderate to severe intensity, and usually accompanied by perioral palor. Neither bronchospasm nor pulmonary edema was observed.

Each of the patients with this syndrome required vigorous treatment. All recovered within 30 minutes to 2 hours. In 5, the recovery was so prompt and complete that the patient was dismissed from the Radiologic Department after a period of rest. Ten patients with more severe reactions, or reactions which cleared more slowly, were hospitalized for overnight observation, but all recovered with no residual effects.

Five patients developed angioneurotic edema with diffuse mucocutaneous swelling over the entire body. Hives or cutaneous erythema accompanied the edema in all patients and 1 patient had associated parotid swelling. None was accompanied by bronchospasm or cardiovascular symptoms and all responded promptly to treatment with epinephrine and hydrocortisone. No late sequelae were noted.

TABLE IV

SEVERE REACTIONS TO UROGRAPHIC MEDIUM

Type	Patients
Shock with erythema	15
Angioneurotic edema	5
Hives or erythematous rash	4
Generalized convulsion	3
Asthma	1
Laryngospasm	1
Cardiovascular collapse with cardiac arrest and death	1
Total	30

Severe hives or cutaneous rash was present in 4 patients. One was accompanied by mild bronchospasm with moderate wheezing. The remainder had associated mucocutaneous edema, pruritus and rhinitis. All responded promptly to treatment. None required hospitalization.

Three patients developed grand mal seizures not accompanied by other signs or symptoms suggestive of idiosyncratic response to the contrast agent. Two of these patients had a history of similar seizures and were on anticonvulsive therapy. The third patient had no prior history of convulsive disorder and when last seen had had no repetition of seizures. No specific treatment was given to these patients. All 3 were hospitalized for observation and completion of medical evaluation.

One patient developed a severe asthmatic attack relieved by aminophyllin and one acute laryngeal edema with mild cyanosis, dyspnea and hives relieved by epinephrine.

Cardiovascular collapse with cardiac arrest and death occurred once. The patient was a 52 year old male studied for complaints suggesting urinary outlet obstruction from enlarged prostate. Moderate nausea and retching occurred early during the injection and injection was temporarily interrupted until these symptoms subsided. The reaction developed precipitously im-

mediately after the injection was completed. It consisted of loss of consciousness, apnea and cardiac arrest with deepening cyanosis. Immediate resuscitative measures were undertaken. The airway was opened, cardiac massage instituted, and appropriate drug therapy was underway within 2 to 3 minutes of onset. The therapy was effective and the patient regained consciousness, but on arousal was panic stricken and pulled out his airway and intravenous needles. Subsequently, difficulty was encountered reestablishing his airway and in administration of intravenous drugs. Cardiac arrest recurred and in spite of the availability and use of all appropriate resuscitative techniques, he died.

RELATIONSHIP OF DOSE TO REACTION

The relationship of dose to reaction is seen in Table v.

The test dose alone induced nausea and vomiting in 28 and acute reactions in 9 patients. The acute reactions were mild in 3, moderate in 4 and severe in 2. One of the severe reactions was a grand mal seizure and the other severe generalized erythematous rash. In all 28 patients who experienced nausea and vomiting the examination was continued with injection of the full dose of contrast medium after the initial symptoms subsided. The nausea and vomiting recurred in only 6 of these and subsided promptly after injection was completed. In 6 of 9 patients with acute reactions to the test dose, the examination was terminated but in 3, all of whom had mild to moderate hives, the injection was completed following administration of intramuscular antihistamine because of the importance of the clinical problem under study. No further reaction developed in any of these patients.

With doses under 30 ml., minor side effects were recorded in 4.1 per cent; with doses of 30 ml., in 5.0 per cent; and with doses of 50 ml., in 5.3 per cent. With doses of 30 to 50 ml., acute reactions were recorded in 1.67 and 1.73 per cent, respectively, with no apparent difference in the relative incidence of mild, moderate and severe reactions with these doses. The number of reactions recorded in patients receiving doses under 30 ml. or over 50 ml. is small and the calculated incidence rates of doubtful statistical significance.

TABLE V

RELATIONSHIP OF DOSE TO REACTION

	Patients	Minor Side Effects		Acute Reaction				
Dose (ml.)	No.	No.	Per Cent	Mild	Moderate	Severe	Total No.	Per Cent
1 (test)	32,968	28	0.09	3	4	2	9	0.03
<30	823	33	4.1	9	3	0	12	1.5
30	21,168	1,043	5.0	205	129	20	354	1.67
50	10,626	562	5.3	111	65	8	184	1.73
>50	247	13	5.3	4	2	0	6	2.4
Unknown	37	4	11.0	2	1	0	3	7.8
	Total	1,683	5.1	334	204	30	568	1.72

RELATIONSHIP OF HISTORY OF ALLERGY TO ACUTE REACTION

Nine thousand, nine hundred thirty-four patients were studied with specific reference to the relationship between a history of allergy or hypersensitivity and the occurrence of reactions (Table VI): 7,445 (75 per cent) gave no allergic history (negative history); 2,489 (25 per cent) reported symptoms which the patient thought or had been told represented an allergic or hypersensitivity state (positive history). On close scrutiny many of these complaints are not true "allergies." For example, many patients reported symptoms of nausea and vomiting associated with injection of narcotic drugs for pain relief as "allergies." However, the data as recorded accurately represent the incidence of a history of "allergy" as obtained from the patient in day to day practice.

Three hundred forty-five (4.6 per cent) of the patients with a negative history experienced mild side effects consisting primarily of nausea and vomiting during examination and 89 (1.2 per cent) developed acute reactions. One hundred sixty-six (6.9 per cent) patients with a positive history developed minor side effects and 74 (3.0 per cent) developed acute reactions.

Table VII relates the incidence of reactions to a number of common allergens and types of allergic response claimed by patients. It is, of course, usual to find patients with multiple allergies. In this analysis, major allergens or types of symptoms are tabulated separately and cause a discrepancy between the total number of patients reporting "allergies" in this series (2,489) and the number of patients listed by type of "allergic" history in this table (2,815). Acute reactions were associated with a history of asthma in 6 per cent; hay fever in 4 per cent; hives of unknown cause in 7 per cent; miscellaneous food allergies in 6 per cent; seafood allergy in 6 per cent; inorganic iodides in 13 per cent; and previous reaction to injection of urographic contrast medium in 20 per cent. Among 1,854 other "allergic" states were 1,374 patients with sensitivity to drugs such as penicillin, tetracycline, chloromycetin, sulfa, morphine, codeine, aspirin and 480 with sensitivity to a wide variety of other substances. The incidence of reactions in these patients was 2 per cent, which is less than twice the incidence expected in the patients who reported no history of "allergy."

Of special interest were 121 patients who claimed sensitivity to a previous injection of iodinated contrast medium for excretory urography. On careful questioning or review of the recorded history prior to injection, it was determined that 66 had had reactions consisting of hives, orbital edema, nasal congestion, mild asthma or other mild forms of acute reaction. The remaining 55 patients had had episodes of nausea and vomiting which they or their physician had interpreted as a reaction. In many instances these patients had been advised never to have urography again. No patient who gave a clear history of previous severe reaction such as hypotension, severe asthma or severe hives was examined again in this series. Forty-three of the 121 patients were

TABLE VI

INCIDENCE OF HISTORY OF ALLERGY AND REACTIONS
(9,934 Patients)

Allergic History	No. of Patients	Minor Side Effects		Acute Reactions	
		No.	Per Cent	No.	Per Cent
Negative	7,445	345	4.6	89	1.2
Positive	2,489	166	6.9	74	3.0

TABLE VII

INCIDENCE OF REACTIONS RELATED TO TYPE OF ALLERGIC HISTORY*

Allergy Reported by Patient	No. of Patients	Patients with Reactions	
		No.	Per Cent
Asthma	140	9	6
Hay fever	316	13	4
Hives (unknown cause)	69	5	7
Food allergy	212	12	6
Seafood	64	4	6
Urographic contrast medium	121	24	20
Iodine (iodide)	39	5	13
Other†	1854	37	2

* Many patients reported multiple allergies. These are tabulated separately and cause a discrepancy between total number of patients reporting allergies in this series (2,489) and the number of patients listed here by type of allergic history.

† Primarily sensitivity to antibiotics, sulfa drugs and narcotics, but includes many other drugs and substances.

premedicated with antihistamine prior to examination. None reacted to the intravenous test dose.

Among the 55 patients with a history of nausea and vomiting only 1 developed a reaction. This consisted of mild hives. Of the 66 patients with a definite history of hives or other reaction, 23 (35 per cent) developed an acute reaction to examination in this study. Reactions in these patients consisted of hives in 22 and mild asthma in 1. The hives ranged from a single hive to moderate generalized hives. A diffuse, mild erythematous rash accompanied hives in 3 patients and mild periorbital edema in 1 patient. Nineteen of the patients who developed a reaction had been premedicated.

COMMENT AND CONCLUSIONS

Acute reactions to injection of urographic contrast medium remain one of the most vexing problems faced by any physician who does excretory urography in his day to day practice. Minor side effects were recorded in 5.1 per cent of this series and acute reactions in 1.72 per cent. The vast majority of these reactions were temporarily unpleasant but limited in duration and severity and did not represent a serious threat to the patient. Severe reactions on the other hand, developed in 0.09 per cent of the patients (1 of each 1,100 examined) and the severity of their symptoms made prompt and vigorous treatment necessary. One-third appeared life threatening and 1 patient died.

Much of the difficulty encountered in dealing with reactions results from the fact that they cannot be predicted by any known means and attempts at prevention by premedication have not proved effective in reduction of the incidence of severe reactions or death.[1,9]

In this series all patients had a preliminary intravenous test dose. Nine had a positive response in the form of an acute reaction to the test dose, 2 of which were severe. In the remaining 559 patients with acute reactions, the test dose gave no hint that a reaction would occur. Thus, the results in this study confirm the opinion of many authors: that the intravenous test dose is of no value in prediction of reactions; that it is potentially hazardous to the patient; and that its continued use cannot be justified on medical grounds. It follows then that as no medical justification for pretesting exists, likewise no medico-legal justification exists and pretesting should be abandoned.

The association between a history of "allergy" and acute reactions to contrast medium was investigated to gain further insight into the nature and extent of this association. The incidence of reactions in patients with a history of "allergy" was 2.5 times that in patients who claimed no such history (3.0 per cent as compared with 1.2 per cent). When specific types of allergic responses or allergens are considered (Table VII), it is evident that in the presence of asthma, hay fever, hives of unknown etiology, certain food allergies, sensitivity to urographic contrast medium and iodides, there is a substantial increase in incidence

of reactions but that among other common allergic or hypersensitivity states the increase is minor. The type and severity of reactions among patients with a history of allergy was not tabulated separately for inclusion in this report but was observed to be essentially the same as for patients with no history of allergy. Only 4 (13 per cent) of the 30 severe reactions occurred among patients with a history of allergy, whereas allergy was claimed by 25 per cent of patients.

Twenty-three of 66 (35 per cent) patients with prior reaction to urographic contrast medium and 1 of 55 (1.8 per cent) with a prior "reaction" consisting of severe nausea and vomiting developed reactions when re-examined. No reaction in this group was more severe than the previously recorded reaction or reactions and in most instances was identical in clinical characteristics. In contrast to the observations of Ansell[1] we have not encountered a patient in whom a second, third or even fourth reaction was more severe than the initial reaction. Thus, there is no evidence in this series or in our over-all experience outside this study that would suggest an increase in sensitivity to contrast medium with repeat examination.

A striking feature of reactions in a given patient with known sensitivity to urographic contrast medium was the inconstancy with which reactions occur from examination to examination. Five patients in this group had had multiple urographic examinations (as many as 6) since their first reaction. Each experienced reactions with some but not all subsequent examinations even when the contrast medium and the dose were unchanged. In a typical example, a patient with a history of 6 previous examinations had experienced hives on his face on 3 occasions and no hives on 3. He was premedicated with antihistamine for only 2 of the 6 examinations and both times developed mild hives. On examination during this study, no reaction developed.

We concluded, as have others,[4,10] that neither a history of specific allergy nor a history of prior mild to moderate reaction from injections of contrast medium is a contraindication to excretory urography. Thus, we believe that these patients should not be denied examination by excretory urography when sound medical indications for its use exist.

SUMMARY

Thirty-two thousand, nine hundred sixty-four consecutive patients were studied with reference to the incidence and clinical characteristics of reactions to a single urographic contrast medium. Mild side effects were recorded in 5.1 per cent and acute reactions in 1.72 per cent. Severe reactions occurred in 0.09 per cent with 1 death from cardiac arrest.

Acute reactions are unpredictable on the basis of history or any known pretesting technique. Pretesting itself is hazardous and gives a false sense of security to both physician and patient. As a consequence of these facts, it is evident that the presently available pretesting techniques serve no useful purpose and should be abandoned.

The first 9,934 patients were studied with special reference to an association between a history of "allergy" or "hypersensitivity" and acute reactions. Reactions were 2.5 times (3.0 per cent as compared to 1.2 per cent) more frequent in patients with a positive history of "allergy." No increase in severity of reactions was noted. With a history of prior mild to moderate reaction to urographic contrast medium, reactions occurred in 20 per cent. No evidence of increasing sensitivity with repeated use was found.

It is concluded that neither a positive history of previous "allergy" nor previous mild to moderate reaction from contrast medium is a contraindication to excretory urography.

Acute life threatening reactions, although very rare, can occur unexpectedly in any patient, at any time. The radiologic team doing excretory urography must be well trained in their recognition and treat-

ment. Emergency equipment, adequate to cope with any reaction,[2] must be on hand and available for immediate use in every radiologic suite where excretory urography is done.

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