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Clinical Survey on Adverse Reactions of Iodinated Contrast Media
—Interim Report—

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ヨード造影剤の副作用に関する臨床調査
（中間報告）
—123,060例の分析—

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Introduction

This study consisted of a comprehensive survey to evaluate adverse reactions to iodinated contrast media. It included comparisons of ionic and non-ionic low osmolar contrast media at a time of changes from a generation of the former to a generation of the latter.

Material and Method

From September 1986 to April 1987 we collected data concerning 123,060 cases examined in 196 hospitals throughout Japan. For several reasons, 3,439 cases were excluded from analyses. Only prpcedures involving the intravenous administration of contrast media were studied.

Severity of reactions	ADR No. (%)		Odds rate of non-ionic to ionic (95% confidence limit)
	Ionic CM 77,040 cases	Non-ionic CM 42,581 csses	
generalized	10,429 (13.54)	1,789 (4.2)	0.28 ** (0.27~0.29)
severe a)	344 (0.45)	41 (0.10)	0.21 ** (0.16~0.29)
very severe b)	38 (0.05)	3 (0.01)	0.14 ** (0.05~0.39)
death	※(1) (0.001)	※(1) (0.002)	1.81 NS (0.12~27.79)

a) Severe adverse reactions included : facial edema, rigor/tremor, dyspnea, sudden drop in blood pressure, cardiac arrest and loss of consiousness.
b) Very severe adverse reactions : severe adverse reactions requiring anesthesiologist's help or hospitalization.
※ causal relation unknown under investigation.
(Odds rate and 95% confidence limit according to generalized Mantel-Haenszel's method)
{ **: $\alpha < 0.01$ / NS: $\alpha > 0.05$

Fig. 1 Over-all frequency and severity of adverse reactions (ADR) to contrast meida.

Reactions to pretesting	Ionic CM			Non-ionic CM		
	Total No.	ADR No. (%)	Severe ADR No.(%)	Total No.	ADR No. (%)	Severe ADR No. (%)
Positive	487	238 (48.87)	11 (2.26)	244	47 (19.26)	0 (0)
Negative	60,907	8,061 (13.23)	262 (0.43)	30,339	1,263 (4.16)	30 (0.099)
Unknown	67	16 (23.88)	1 (1.49)	39	3 (7.69)	0 (0)
No response	1,836	—	—	1,049	—	—

Fig. 2 Frequency of adverse reactions (ADR) to contrast media related to whether pretest was positive.

History of previous reactions	Ionic CM			Non-ionic CM		
	Total No.	ARD No. (%)	Severe ADR No.(%)	Total No.	ARD No. (%)	Severe ADR No.(%)
Yes	2,962	1,335 (45.07)	44 (1.49)	3,166	390 (12.32)	9 (0.28)
No	32,620	3,105 (9.52)	79 (0.24)	17,445	533 (3.06)	13 (0.07)
Unknown	571	123 (21.54)	6 (1.05)	382	21 (5.50)	0 (0)
No response	1,623	—	—	974	—	—

Fig. 3 Frequency of adverse reactions (ADR); correlation of history of previous adverse reactions and current reactions to contrast media.

History of allergy	Ionic CM			Non-ionic CM		
	Total No.	ADR No. (%)	Severe ADR No. (%)	Total No.	ADR No. (%)	Severe ADR No.(%)
Yes	6,096	1,474 (24.18)	72 (1.18)	4,048	354 (8.75)	8 (0.20)
No	66,708	8,356 (12.53)	252 (0.38)	36,219	1,338 (3.69)	31 (0.09)
Unknown	3,848	533 (13.85)	16 (0.42)	2,094	88 (4.20)	2 (0.10)
No response	388	—	—	220	—	—

Fig. 4 Frequency of adverse reactions (ADR) to contrast media; effect of history of allergy.

Results

There was an over-all rate of adverse reactions of 13.5% for the ionic contrast media and a rate of 4.2% for non-ionic low osmolar contrast media (Fig. 1).

One death occurred in each group related to the media, but the causal relationships are unknown and still under investigation.

Among those who had positive reactions to test dose, there were tendencies for higher rates of adverse reactions.

Among positive test individuals adverse reactions were observed in 234 (48.9%) of 487 persons who recieved the ionic contrast media and in 47 (19.3%) of 244 who received nonionic contrast media (Fig. 2).

The effect of histories of previous reactions was demonstrated. For both ionic and non-ionic contrast media, previous reactors were liable to have other kinds of adverse reactions and hypersensitivities (Fig. 3).

HIstories of allergy had a definite correlations with higher rates of adverse reactions, even when non-ionic low osmolar contrast media were used. The allergies investigated in this study included atopy, asthma, pollenosis, drugs and foods.

Discussion

The frequency of such adverse reactions varies with reported series[1)2)]. In the present study, the rate was 13.5% for ionic and 4.2% for non-ionic contrast media. The rate may range from 5 to 15%.

The introduction of low osmolar iodine contrast media obviously minimized the rate of adverse reactions.

From a clinical standpoint it is generally agreed that allerviation of pain at the time of injection of the contrast media greatly facilitates the radiological examinations. Sogn et al (1987)[3] reported that comparison of iohexol and ionic monomeric contrast media disclosed the rate of adverse reactions to be about 3.5 times less using iohexol than ionic monomers.

We are also of this opinion.

Conclusion

The over-all rate of adverse reactions were 13.5% among 77,040 persons who received ionic contrast media and 4.2% among 42,581 who received non-ionic low osmolar contrast media. Crude data are currently available and investigations are now in progress.

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