AJNR

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This information is current as of August 12, 2025.

AJNR Am J Neuroradiol 1983, 4 (3) 312-313
http://www.ajnr.org/content/4/3/312

Comparison of Radiographic Quality and Adverse Reactions in Myelography with Iopamidol and Metrizamide

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A randomized double-blind study was conducted to compare the radiographic quality and adverse reactions in myelography of the two nonionic water-soluble contrast media, iopamidol and metrizamide. A total of 46 myelograms were obtained, 28 with iopamidol and 18 with metrizamide. Untoward reactions consisted of nausea, headaches, back and leg pain, neuropsychiatric findings, and urinary retention. Iopamidol caused no reactions in 20 of the 28 cases, while metrizamide caused no reactions in only three of 18 cases. Film quality evaluation showed 22 of the 28 studies with iopamidol were judged excellent, whereas only 11 of the 18 metrizamide studies were judged excellent. The results of this study suggest that iopamidol produces better quality studies with fewer and milder adverse reactions than metrizamide.

This randomized double-blind study was conducted to compare the radiographic quality and adverse reactions of the two nonionic water-soluble contrast media, iopamidol and metrizamide, in myelography. The use of water-soluble contrast media for myelography was proposed by Almen [1] in 1969. The first nonionic medium introduced for clinical use was metrizamide. Metrizamide was found to give better visualization of nerve roots and sleeves than Pantopaque [2] and also showed low neurotoxicity [3]. Clinical use of metrizamide has not revealed serious, permanent reactions to the drug, although seizures and acute mental changes have been found [4–6].

A new water-soluble contrast agent, iopamidol, has been introduced for myelography. Iopamidol was initially formulated by Bracco Industria Chemica of Milan, Italy, and is currently being developed by the Squibb Institute. The development and physicochemical properties of iopamidol have been reported by Pitre and Felder [7], and several papers on the clinical use of iopamidol have been published [8–10]. We report our findings when iopamidol and metrizamide were compared for adverse reactions and radiographic quality.

Materials and Methods

In this study 46 myelograms were obtained, 28 with iopamidol and 18 with metrizamide. Patient selection was entirely at random. All male patients and nonpregnant females over 18 years of age who required lumbar myelography, thoracic myelography, cervical myelography, total columnar myelography, CT cisternography, or CT ventriculography were asked to participate. Every patient was fully informed of the experimental nature of iopamidol. Reasons for exclusion from the study included: pregnancy; planned surgery within 24 hrs; hypersensitivity to iodine compounds; spinal puncture within the past month; bloody cerebrospinal fluid; increased intracranial pressure or suspicion of intracranial tumor; abscess or hematoma; medication with agents that lower the seizure threshold; or a history of convulsive disorders, multiple sclerosis, psychosis, alcoholism, or drug abuse.

Each patient selected had a complete medical history taken within 5 days before the study, and underwent a thorough physical and neurologic examination before and after the myelogram. A nurse obtained vital signs before drug administration and at 15 min, 30 min, and 1, 4, 8, 24, and 72 hr after administration. The nurse interviewed each patient within 6 hr after the procedure and at 24, 48, and 72 hr postmyelography, noting any adverse reactions. A complete laboratory profile was also taken on each patient before and after myelography.

In this study, all myelograms were obtained by lumbar puncture. Each patient was randomly assigned either metrizamide or iopamidol, and the contrast medium used was unknown to the neuroradiologist performing the study. Each patient was premedicated with 120 mg intramuscular phenobarbital, and 15 ml of contrast medium was used in every case, except for one ventriculogram in which 5 ml was used. The concentration was the same for each medium for each region of the spine examined. In the thoracic and lumbar regions 200 mg/dl iodine was used, and in the cervical area 300 mg/dl iodine was used. Patients were put in a head-up supine position for at least the first 8 hr after the procedure and then in a horizontal position for another 16 hours.

In addition to studying the adverse reactions produced by each contrast medium, the radiographic quality of each study was evaluated by two experienced neuroradiologists who were unaware of the medium used. Particular attention was paid to contrast density discrimination and how well the nerve roots and sleeves were visualized. Studies were graded as excellent, good, fair, or poor.

Results

Untoward reactions consisted of nausea, headaches, back and leg pain, neuropsychiatric findings, and retention of urine. The neuropsychiatric findings included dizziness, confusion, and/or hallucinations. No seizures occurred with either contrast medium.

Table 1 lists the incidence of adverse reactions, and summarizes the overall results of untoward reactions for each drug. It should be noted that patients given iopamidol did complain of nausea and

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AJNR 4:312–313, May/June 1983 0195-6108/83/0403-0312 $00.00 © American Roentgen Ray Society

TABLE 1: **Incidence of Adverse Reactions**

	Iopamidol (of 28)	Metrizamide (of 18)
Nausea	1	10
Headache	7	9
Pain	0	3
Neuropsychiatric	0	6
Urine retention	0	2

Note.—Overall incidence of adverse reactions was eight of 28 for iopamidol and 15 of 18 for metrizamide. Chi-square test showed these figures on adverse reactions to be significant at the $p < 0.001$ level.

TABLE 2: **Overall Results of Film Quality Ratings**

	Iopamidol	Metrizamine
Excellent	22	11
Good	3	5
Fair	0	1
Poor	0	1
Totals	25*	18

Note.—Chi-square test showed the grouped data to be significantly different at the $p = 0.05$–0.1 level.

* Three studies excluded for reasons not relevant to the comparison.

headaches but did not complain of pain, neuropsychiatric findings, or retention of urine. The chi-square test showed these data to be significantly different at the $p < 0.001$ level.

In addition to studying adverse reactions, the radiographic quality of each study was also judged. Table 2 summarizes the results of those findings. Three iopamidol studies were eliminated from the quality evaluation for radiographic technical reasons. The chi-square test showed the grouped data to be significantly different at the $p = 0.05$ to $p = 0.1$ level.

Discussion

Headaches were the most frequent adverse reaction. Seven of the 28 patients given iopamidol complained of headaches, as did nine of the 18 patients given metrizamide. This finding is in agreement with a prior report [8] listing headache as the most frequent side effect when the use of iopamidol and metrizamide in myelography was compared. The severity of the headaches also differed according to which contrast medium was used. Each headache was classified as mild, moderate, or severe. Four of the seven headaches of patients using iopamidol were judged to be mild, three were moderate. In contrast, three of the nine headaches using metrizamide were mild and six were moderate, requiring medication. The mildness of the reactions with iopamidol has been previously reported [10].

In addition to the lesser severity of the headaches this study also found an absence of neuropsychiatric problems with iopamidol. None of the patients studied with iopamidol was found to have these reactions, while six of the patients given metrizamide had one or more of these side effects. Other studies have documented the lack of neuropsychiatric findings when iopamidol was used [8, 11].

This study also found a very low frequency of pain and nausea associated with iopamidol. Pain was experienced by three patients given metrizamide and no patients receiving iopamidol. Ten of the 18 patients receiving metrizamide experienced nausea, while only one of 28 iopamidol cases had this side effect. Metrizamide also accounted for the two cases of retention of urine.

Iopamidol images were judged excellent in 22 of 25 cases, as against 11 of 18 for metrizamide. Iopamidol gave better contrast density discrimination as well as equal or better visualization of nerve roots and sleeves when compared with metrizamide. It should also be noted that iopamidol is stable in solution and does not need to be reconstituted. Our findings suggest that iopamidol produces better quality myelographic studies than metrizamide, and that adverse reactions to iopamidol are fewer and milder than those associated with the use of metrizamide.

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