

Gadolinium-Based Coronary Angiography in Patients with Contraindication for Iodinated X-Ray Contrast Medium: A Word of Caution

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Background: In coronary angiography, the use of contrast agents containing iodine still defines the gold standard. In patients with contraindications for iodine exposition, gadolinium has been considered to be a safe alternative to standard iodinated contrast medium for coronary angiography. The aim of the present study was to assess the safety and technical quality of gadolinium-based coronary angiography.

Methods: Nineteen consecutive patients with contraindication to iodinated contrast medium underwent gadolinium-based coronary angiography. Contraindications included previous anaphylactic shock or severe allergic reaction to iodinated contrast medium ($n = 13$) or thyrotoxicosis ($n = 6$). Gadolinium was diluted 1:1 with sodium chloride before application. Patients were clinically observed for potential side effects, and renal function was assessed by determination of creatinine values and calculation of creatinine clearance in pre- and postprocedural blood samples. Image quality was evaluated by two independent observers, and classified into three different categories (grade 1, high diagnostic quality; grade 2, moderate diagnostic quality; and grade 3, poor quality).

Results: During angiography, a mean of 32.6 ± 10.9 mL (range 10–45 mL) gadolinium was used. No patient developed a significant impairment of renal function within 24 hours after the examination (mean creatinine value preprocedural: 1.12 ± 0.15 mg/dL, postprocedural: 6 hours 1.15 ± 0.18 mg/dL, 24 hours 1.13 ± 0.16 mg/dL) (baseline vs. 6 hours $P = 0.23$, baseline vs. 24 hours $P = 0.66$, 6 hours vs. 24 hours $P = 0.12$) (mean creatinine clearance preprocedural: 73.8 ± 18 mg/dL, postprocedural: 6 hours 71.7 ± 16.8 mg/dL, 24 hours 73.2 ± 17.8 mg/dL) (baseline vs. 6 hours $P = 0.2$, baseline vs. 24 hours $P = 0.71$, 6 hours vs. 24 hours $P = 0.21$). Four patients (21%) suffered severe complications due to gadolinium application, such as malignant cardiac arrhythmias ($n = 3$) and hemodynamic decompensation ($n = 1$). Image quality was generally reduced in comparison to iodine contrast coronary angiography, but was adequate for diagnostic purposes (13 patients [68.4%] had reasonably good picture contrast [grade 2.1 ± 0.3]; in 6 patients [31.6%], image quality was satisfactory [grade 2.6 ± 0.13]). Opacification of distal vessels as compared to proximal segments was remarkably reduced.

Conclusions: Gadolinium-based coronary angiography is a potential alternative technique in patients with allergy to iodinated contrast medium or thyrotoxicosis with reduced, but acceptable, image quality for diagnostic purposes. Nevertheless, possible life-threatening side effects and complications have to be considered. (J Intervent Cardiol 2008;*:1–8)

Introduction

Coronary angiography still defines the gold standard for diagnosis of coronary artery disease. The

use of iodinated X-ray contrast medium, however, may result in serious complications, such as deterioration of renal function or anaphylactoid reaction.¹ Recently, gadolinium has been considered as an alternative to obviate the risks of conventional X-ray contrast medium.^{2,3} Gadolinium is a nonionic contrast medium with an osmolality of 789 mOsm/kg, and is currently approved for intravenous use in magnetic resonance imaging (MRI) (Omniscan Package Insert,

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Amersham Health, Princeton, NJ).^{4,5} In addition, several cases of intra-arterial gadolinium application for different angiographic visualizations, such as the aorta, lower extremities, and renal, cerebral, and carotid arteries, have been described.⁶⁻⁹ Furthermore, gadolinium has even successfully been used for coronary angiography.¹⁰⁻¹⁴ For a long period of time, there was a lack of information with regard to the intra-arterial application of gadolinium during angiography in patients with chronic renal insufficiency, especially concerning the dosage, which is higher as in magnetic resonance angiography.¹⁵ Briguori et al. investigated creatinine levels in patients with chronic renal insufficiency after gadolinium-based coronary angiography in comparison with iodinated contrast medium-based coronary angiography, and considered gadolinium as a nephrotoxic contrast medium.¹⁶

Until now, no data have been available in terms of gadolinium as a contrast medium in coronary angiography in a larger group of consecutive patients. The aim of the present study was to assess the safety and the effectiveness of gadolinium as contrast medium in coronary angiography in respect to possible side effects, the impact on renal function, and achievable image quality.

Materials and Methods

Study Objectives. Coronary angiography was performed in 19 consecutive patients (12 men, average age 62 ± 9 years) using gadolinium for opacification. Indications for coronary angiography were stable angina ($n = 14$) or unstable angina ($n = 5$); indications for applying gadolinium were manifest hyperthyroidism ($n = 6$) or previous severe allergic reaction with anaphylactic shock after the application of iodine despite cortisone (250 mg prednisolone intravenous) ($n = 13$).

Experimental Design.

Clinical reactions and safety. Patient reactions due to gadolinium and angiographic picture quality were assessed. Comorbid conditions, indication for coronary angiography, and the amount of contrast medium were registered. In all patients, renal function was assessed by determination of creatinine values in preprocedural and postprocedural blood samples, 6 and 24 hours after gadolinium application, corresponding to the publication of Seyon et al., who assessed the efficacy of N-acetylcysteine in decreasing the incidence of contrast-induced renal dysfunction after contrast agent exposition.¹⁷ Furthermore, creatinine clearance was

calculated by using the Cockcroft-Gault formula. Acute renal failure was defined as either an increase in serum creatinine of 0.5 mg/dL or 25% of baseline parameter or the need for dialysis. The patients' electrocardiogram (ECG) was continuously monitored during and after angiography, and clinical reactions were monitored.

Image quality. In all patients, gadolinium was diluted 1:1 with sodium chloride. All the studies were performed on the same imaging equipment, with the same size catheters (6-French) and identical contrast medium power injection (7 mL in the left coronary artery, 6 mL in the right coronary artery). Since there exist no standard components for the assessment of image quality of coronary vessels in angiography, we determined conventional iodinated contrast medium (Ultravist^(R), Schering, Berlin) as reference. Contrast imaging due to gadolinium was compared with a standard coronary angiography of a patient not belonging to this group, where iodinated contrast medium was utilized. We distinguished between three possible grades of image contrast quality, from good (grade 1 conforming to iodinated contrast medium) to moderate (grade 2) to poor (grade 3) (Fig. 1). Angiographic picture quality was evaluated by two independent, blinded observers.

Statistical Analysis. Values are reported as mean $\pm$ standard deviation (SD). Renal laboratory data were analyzed using paired *t*-test for comparing categorical variables. All tests of significance were 2-tailed, and significance was defined at the 0.05 level or below.

In order to define correlation between patient body mass index (BMI) and image quality, a Pearson's linear correlation test was performed. A 2-tailed probability value below 0.05 was considered significant.

Results

Baseline Parameters. Demographic characteristics of all patients are shown in Table 1. During angiography, a mean of 32.6 ± 10.9 mL (range 10–45 mL) gadolinium was applied, which is equivalent to a mean dosage of 0.23 ± 0.08 mmol/kg body weight, being clearly under the limit of 0.4 mmol/kg body weight. In two patients (10%), diagnostic evaluation was expanded by using intravascular ultrasound (IVUS). Therapeutic intervention by coronary stenting was necessary in two cases (10%), both guided by IVUS before and after coronary stenting.

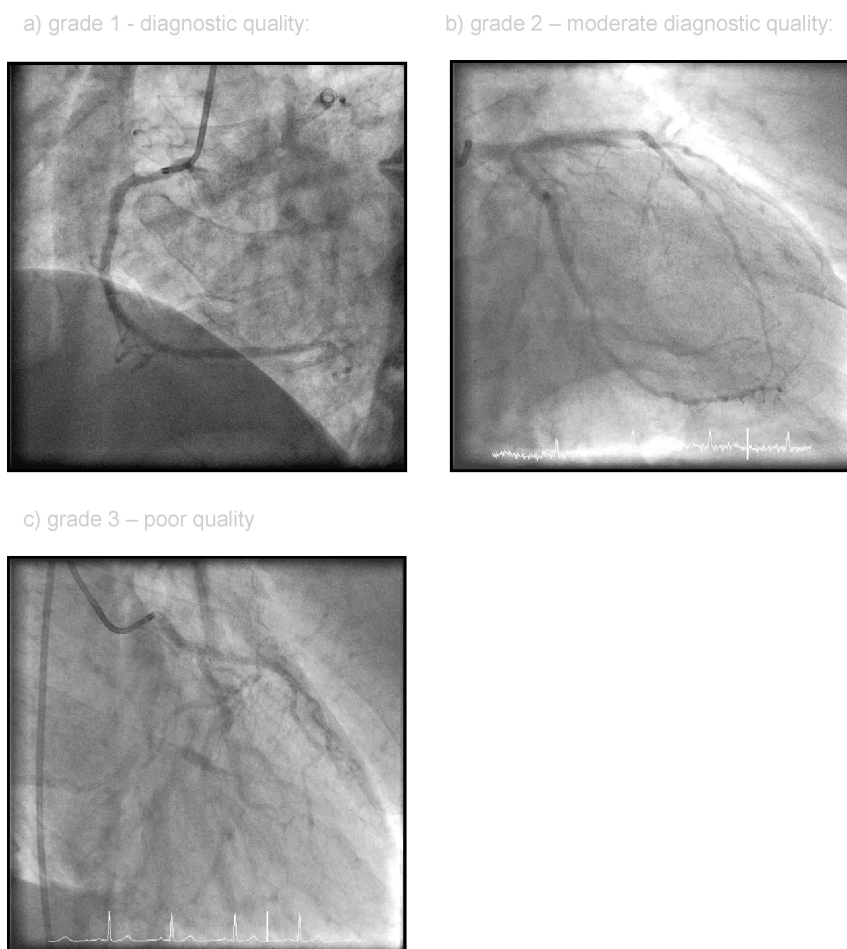


Figure 1. Coronary angiogram based on gadolinium with three different image qualities.

Clinical Reactions and Safety.

Side effects and complications. Four out of 19 patients (21%) suffered severe life-threatening complications after coronary injection of gadolinium in

terms of malignant ventricular cardiac arrhythmias (Table 2).

The first patient was a 69-year-old man (78 kg) with history of severe allergic reaction to iodinated contrast medium who was referred to our hospital for treatment of coronary artery disease. Coronary angiography was performed using a total of 40 mL gadolinium. After coronary injection, the patient suffered self-limiting

Table 1. Patient Demographics

Characteristics	Patients (n = 19)
Male	12 (63.2%)
Age (years)	62.2 ± 9.2
Height (cm)	172.1 ± 6
Weight (kg)	76.9 ± 7.6
Adiposity (BMI > 30 kg/m ²)	12 (63.2%)
Arterial hypertension (systolic blood pressure > 140 mmHg)	18 (94.7%)
Diabetes mellitus	5 (26.3%)
Hypercholesterolemia	19 (100%)
History of smoking	6 (31.6%)

Table 2. Patient Reactions due to Gadolinium

	Patients (n = 19)
Allergic reaction	3 (15.8%)
Itching	1 (5.3%)
Nausea	1 (5.3%)
ECG alterations, e.g., ventricular fibrillation	3 (15.8%)
Blood pressure reaction, e.g., severe hypotension	1 (5.3%)

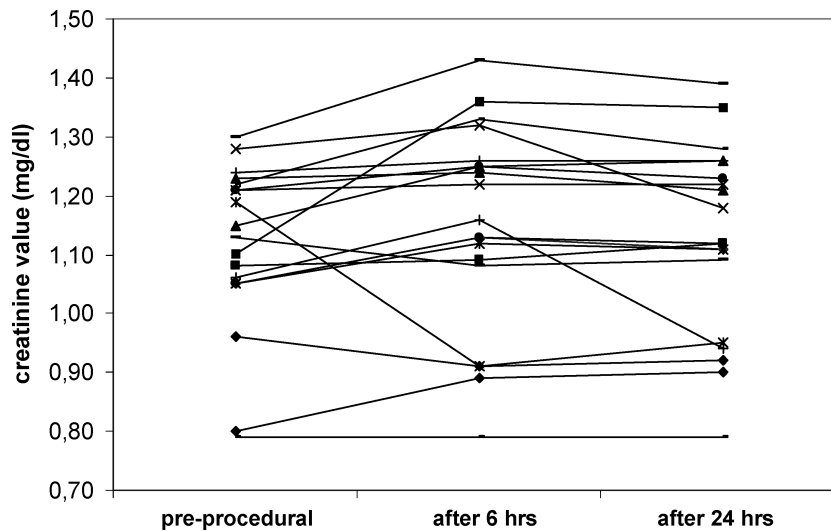


Figure 2. Serum creatinine values before and after intracoronary application of gadolinium.

ventricular tachycardia for approximately 5 seconds. As this phenomenon has not been described before when using iodinated contrast medium, the rest of the examination was performed using iopromide as contrast agent diluted 1:1 with 0.9% sodium chloride without any further complication; the electrolytes were normal in this patient. Coronary vessels showed no significant stenoses, and the patient was discharged 2 days later without any further complications.

The next two cases were of two women who presented with unstable angina, and had a history of severe allergic reactions to iodinated contrast medium. Therefore, coronary angiography was conducted with gadolinium. After the first injection into the right coronary artery, the patients developed ventricular fibrillation, which had to be terminated by defibrillation with 200 J. The patients were stabilized, and the procedure was continued with iodinated Ultravist® after administration of 250 mg corticoid and 150 mg antihistamine. Coronary angiography revealed less than 50% luminal narrowing of the left coronary artery. Patients were discharged 24 hours later without further complications.

In all three of these cases, there were no signs of coronary artery occlusion by the catheter before coronary injection due to the fact that catheter pressure did not decrease at any time during examination.

The last case was of a 66-year-old woman (77 kg) with suspected coronary artery disease and a history of allergic reaction to iodinated contrast medium who was undergoing an abdominal computed tomography.

After gadolinium was injected into the left coronary artery, the patient developed intense hypotension (systolic blood pressure decreased from 135 mmHg to 70 mmHg), bradycardia, nausea, and dizziness. The patient was treated successfully, and recovered after administration of atropine and metoclopramid. For the rest of the examination, gadolinium was diluted 2:1 with 0.9% sodium chloride. The patient remained stable, and coronary angiography showed no stenoses of the coronary arteries.

Renal function. In all patients, no laboratory abnormalities occurred postprocedurally, and no thyroid dysfunction was observed. No patient developed a significant impairment of renal function within 24 hours after the examination (mean creatinine value preprocedural: 1.12 ± 0.15 mg/dL, postprocedural: 6 hours 1.15 ± 0.18 mg/dL, 24 hours 1.13 ± 0.16 mg/dL) (baseline vs. 6 hours $P = 0.23$, baseline vs. 24 hours $P = 0.66$, 6 hours vs. 24 hours $P = 0.12$) (Fig. 2) (mean creatinine clearance preprocedural: 73.8 ± 18 mg/dL, postprocedural: 6 hours 71.7 ± 16.8 mg/dL, 24 hours 73.2 ± 17.8 mg/dL) (baseline vs. 6 hours $P = 0.2$, baseline vs. 24 hours $P = 0.71$, 6 hours vs. 24 hours $P = 0.21$) (Fig. 3) (Table 3). In patients with known preinterventional compensated renal insufficiency ($n = 3$, 15.8%), creatinine values remained constant after gadolinium application (creatinine value preprocedural: 1.76 ± 0.6 mg/dL, postprocedural: 6 hours 1.53 ± 0.67 mg/dL, 24 hours 1.56 ± 0.7 mg/dL). All patients were discharged without any consequential loss.

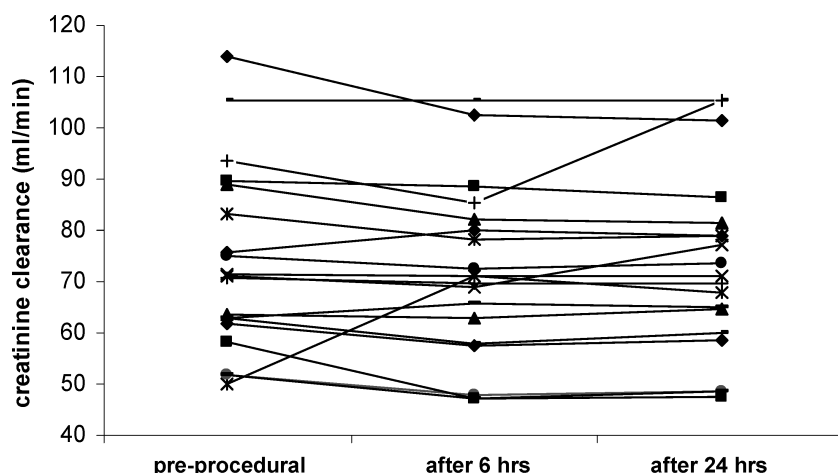


Figure 3. Creatinine clearance before and after intracoronary application of gadolinium.

Image Quality. Image quality by using gadolinium was generally reduced in comparison to iodine contrast coronary angiography, but was adequate for diagnostic purposes. Thirteen patients (68.4%) had reasonably good picture contrast (grade 2.1 ± 0.3); in the other six patients (31.6%), image quality was satisfactory (grade 2.6 ± 0.13). Opacification of distal vessels as compared to proximal segments was considerably diminished. Generally, body habitus does affect image quality, but in this study, the variation in image quality was not weight based (Fig. 4). According to Pearson's linear correlation test, patient BMI showed no correlation with image quality ($r = -0.1261$, 95% confidence interval [CI] -0.5490 – 0.3481 , $P = 0.6068$). If angio-

graphic image quality due to iodinated contrast agents is defined as grade 1, this study demonstrates a remarkably reduced picture contrast when using gadolinium as contrast medium for diagnostic purposes.

Discussion

Arrhythmias and Vascular Collapse. In the present study, we were able to demonstrate that the use of gadolinium is a potential alternative technique in diagnostic coronary angiography, although some severe side effects have to be reported. In our study, 4 of 19 patients (21%) developed potentially life-threatening cardiac arrhythmias after gadolinium injection into the coronary arteries, requiring defibrillation or medical emergency therapy. However, in the past, gadolinium has been successfully used for coronary angiography.^{10–14} So far, no serious side effects have been reported.¹⁵ Allergic reactions to iodinated contrast medium are a major side effect of coronary angiography. Adverse reactions range from mild inconvenience, such as itching, nausea, or vomiting, to life-threatening emergencies, such as dyspnea, shock, or cardiopulmonary arrest.¹⁸ Allergic reactions to a contrast agent can be either an anaphylactoid reaction or a chemotoxic one. An anaphylactoid reaction would be caused by activation of the kinin system; a chemotoxic reaction would be caused by the hydrophobicity and hyperosmolality of the contrast medium.¹⁹ So far, the literature describes headache (3%), nausea and vomiting (1–3%), and slight hypocalcemia as main side effects

Table 3. No Postprocedural Impairment of Renal Function

Creatinine values preprocedural (mg/dL)	1.12 $\pm$ 0.15	
Creatinine values postprocedural 6 hours (mg/dL)	1.15 $\pm$ 0.18	$P = 0.23^*$
Creatinine values postprocedural 24 hours (mg/dL)	1.13 $\pm$ 0.16	$P = 0.66^\dagger$
Creatinine clearance preprocedural (mL/min)	73.8 $\pm$ 18.0	
Creatinine clearance postprocedural 6 hours (mL/min)	71.7 $\pm$ 16.8	$P = 0.20^*$
Creatinine clearance postprocedural 24 hours (mL/min)	73.2 $\pm$ 17.7	$P = 0.71^\dagger$

* P value 0 hours versus 6 hours; $^\dagger P$ value 0 hours versus 24 hours; paired Student's t -test.

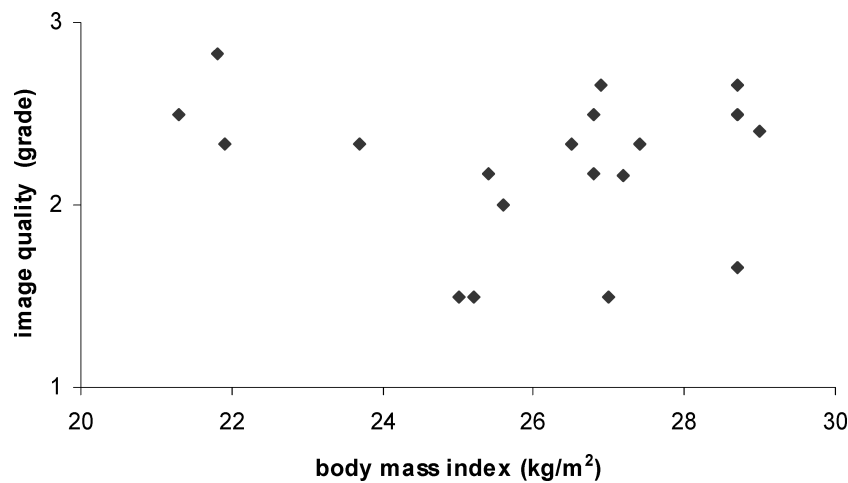


Figure 4. Correlation between patient body mass index (BMI) and image quality.

of gadolinium when applied intra-arterially.²⁰ One major side effect is a hemodynamic or arrhythmic effect when gadolinium is injected into the coronary artery. The pathophysiology of this phenomenon remains unclear; one possible explanation is that the osmolality of gadolinium is about 700 mOsm/kg, which is more than double the physiological level. The incidence of critical life-threatening side effects with gadolinium has been reported to be one-tenth of that for iodinated contrast medium.^{21,22}

Renal Function. In the present study, we did not see any significant impairment of renal function within the 24 hours after contrast agent exposition, which confirms earlier studies.^{22–25} Since we measured serum creatinine and derived creatinine clearance over a 24-hour period, we are unable to make a certain statement on further development of renal function. However, in a randomized trial, Seyon et al. assessed the efficacy of N-acetylcysteine in decreasing the incidence of contrast-induced renal dysfunction, and found no difference in serum creatinine or creatinine clearance at 24 hours or at 48 hours after contrast agent exposition between the treatment and control groups.¹⁷

With a gadolinium application between 15 and 45 mL per coronary angiography, dosages were clearly below this critical concentration of 0.4 mmol/kg. Compared to conventional iodinated contrast medium, gadolinium can be eliminated almost completely out of the human body by renal dialysis. Gadolinium is eliminated by urinary excretion via glomerular filtration.¹⁴ At normal renal function, half-life period is 77 minutes; at renal impairment (creatinine clear-

ance ≤ 20 mL/min) half-life period is prolonged up to 30 hours.^{14,15} Currently published issues report a strong association between gadolinium-based contrast agents and nephrogenic fibrosing dermatopathy/nephrogenic systemic fibrosis, but, so far, no case has occurred after intra-arterial application for coronary angiography.²⁶ Acute renal failure can occur when gadolinium is applied in high doses. Giozzet et al. report two cases of acute renal insufficiency caused by high doses of gadolinium (dosage 0.6 and 0.9 mmol/kg).^{23,25,27}

However, in a retrospective, single-center study, Sam et al. demonstrated the safety of gadolinium: after application of contrast medium, acute renal failure occurred in 7 of 195 (3.5%) patients with chronic renal insufficiency. In patients with normal creatinine levels, no impairment of renal function occurred.²⁵ Therefore, it is important not to exceed the limit of 0.4 mmol/kg body weight; the safety dose is ≤ 40 –70 mL at one examination per patient.^{22–24}

Image Quality and Issues of Dilution. Our results demonstrate a reduced, but acceptable, image quality when used for diagnostic coronary angiography. In recently published studies, angiographic imaging of peripheral vessels by using gadolinium as contrast medium was of good quality.^{19,28–31} However, there remain controversial opinions concerning image quality after application of gadolinium in cardiac catheterization procedures. Intra-arterial gadolinium is difficult to visualize with fluoroscopy because of the high flow rates, as well as the limits of the recommended total dose.⁸ Sarkis et al. reported good image quality with gadolinium, although the contrast appears

better with an iodine solution because of its higher concentration.¹¹ Furthermore, without higher application dosage, neither a left ventricle angiography nor a complex coronary intervention is possible. The missing angiography of the left ventricle can be balanced by alternative diagnostic methods like echocardiography or cardiac MRI. Dilution with sodium chloride could be a solution, thereby worsening the image quality. Smaller amounts of nondiluted gadolinium would be an option for better angiography, thereby possibly increasing the risk of arrhythmia. Therefore, it is questionable if invasive gadolinium-based coronary angiography has clear advantages over current MRI angiography for detecting significant proximal coronary vessel disease in this group of patients.

Discussion of Cost. The usage of gadolinium is connected with an increased expense. Fifty milliliters of a conventional iodinated contrast medium cost approximately 10 euros; the corresponding amount of gadolinium costs 150 euros.

Study Limitations. This study is limited by its small number of patients and a missing control group. In most of the patients with known allergic reaction due to iodinated contrast medium, coronary angiography can be performed when corticoids and antihistamines are applied before. The patient group with severe allergic reactions despite this medical pretreatment, and requiring a different diagnostic approach, is very small. However, the number of patients included is representative, since a novel approach in coronary angiography and an off-label use of gadolinium has been applied in necessary and routine cardiac diagnostics.

Conclusion

Coronary angiography with gadolinium-based contrast medium is a potential alternative technique in patients with allergy to iodinated contrast medium with acceptable image quality for diagnostic purposes, but one has to consider the possible life-threatening side effects. These seem more infrequent when gadolinium is diluted 1:1 with sodium chloride, thereby impairing image quality. A further disadvantage, next to raised costs, is the limited applicable amount of gadolinium, which limits the possibility of complex coronary interventions. Therefore, intra-arterial gadolinium used for coronary angiography is of limited clinical applicability.

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