OptiRAY®

ioversol

Vol. 1

Innovations in **CTAngiography**

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Guerbet
Contrast for Life

Innovations in **CTA**

1– Introduction

CT Angiography (CTA) has been found to have high diagnostic accuracy in the detection of coronary artery disease. However, high effective radiation exposure is a concern[1-4].

Body Mass Index (BMI) is a known factor influencing image quality in CT examinations[1,2]. In particular, in CTA, a higher BMI unfavorably affects contrast-to-noise ratio (CNR) by decreasing arterial attenuation while increasing image noise. To compensate for the latter, adaptation of scanning parameters such as tube voltage and tube current to BMI has been suggested[1].

Several patient and injection related factors, such as BMI ; cardiac output ; contrast volume and iodine concentration of contrast medium (CM) have been identified as having an influence on contrast enhancement[1,3].

As a patient's body weight and the amount of CM are closely related to the degree of contrast enhancement, CM injection protocols should be customized to each patient's morphology. To achieve reproducible contrast enhancement ≥ 300 HU, it is advisable to adjust the amount of administered iodine according to the patient's body weight[4].

1. Tatsugami F et al. Evaluation of a Body Mass Index–Adapted Protocol for Low-Dose 64-MDCT Coronary Angiography with Prospective ECG Triggering. AJR 2009; 192: 635–638.
2. Yoneyama K et al. Influence of image acquisition settings on radiation dose and image quality in coronary angiography by 320-detector volume computed tomography: the CORE 320 pilot experience. Heart International 2012; 7: e11 doi:10.4081/hi.2012.e11.
3. Seehofnerova A et al. Feasibility of low contrast media volume in CT angiography of the aorta. European Journal of Radiology Open 2 (2015) 58–65.
4. Bae K et al. Contrast enhancement in cardiovascular MDCT: effect of body weight, height, body surface area, body mass index, and obesity. AJR 2008; 190: 777–784.

Innovations in CTA

2– Material & Methods

• Image acquisition

All examinations were performed using a GE Healthcare Discovery™ CT 750 HD.

• Patients

Patients underwent 64-slice CTA for suspicion of coronary artery disease.

The patients were divided into two groups:

- Patients < 80 kg were scanned at 100 kVp (group A)
- Patients ≥ 80 kg were scanned at 120 kVp (group B)

• Protocol

Contrast enhancement was achieved by administering 1 cc per kg of ioversol at 350 mg/mL (Opti**RAY**® 350) with a fixed injection time of 13 sec.

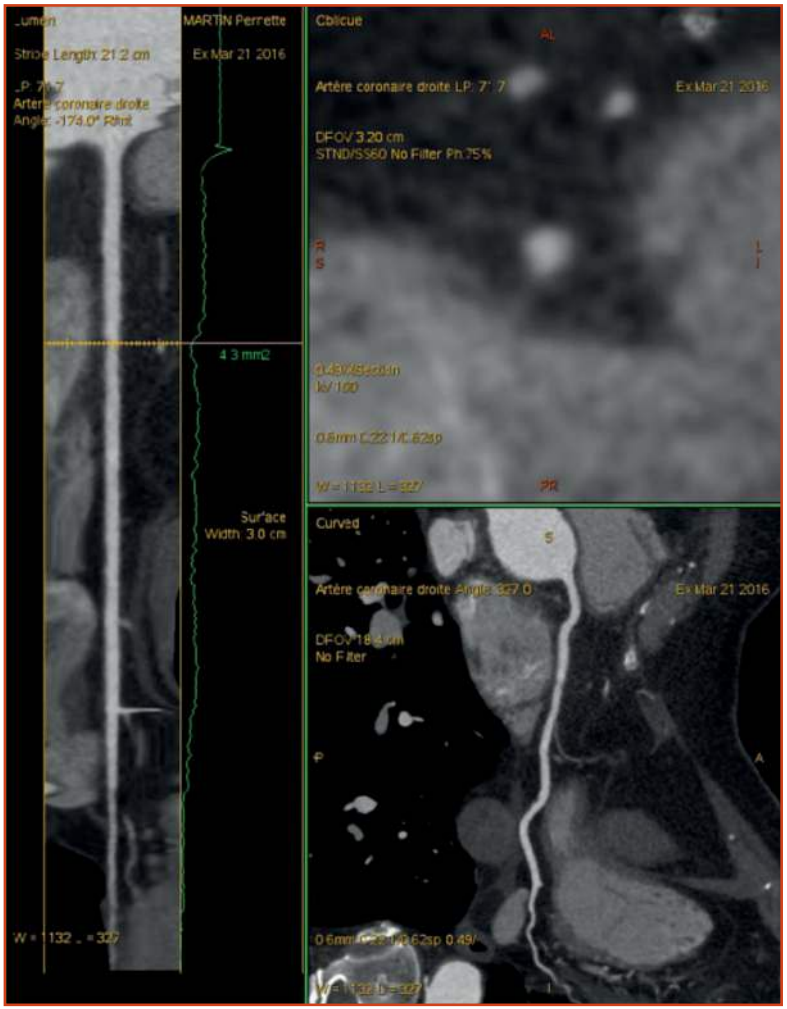
The injection rate was adjusted accordingly.

For example,

- a 65 kg patient would be injected at 5 cc/sec
- a 91 kg patient would be injected at 7 cc/sec.

The maximum injection rate was 8 cc/sec.

Case 1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60 Kg Patient

- 58 years old woman presenting with a typical chest pain
- Coronary CT scan was performed to look for coronary artery disease

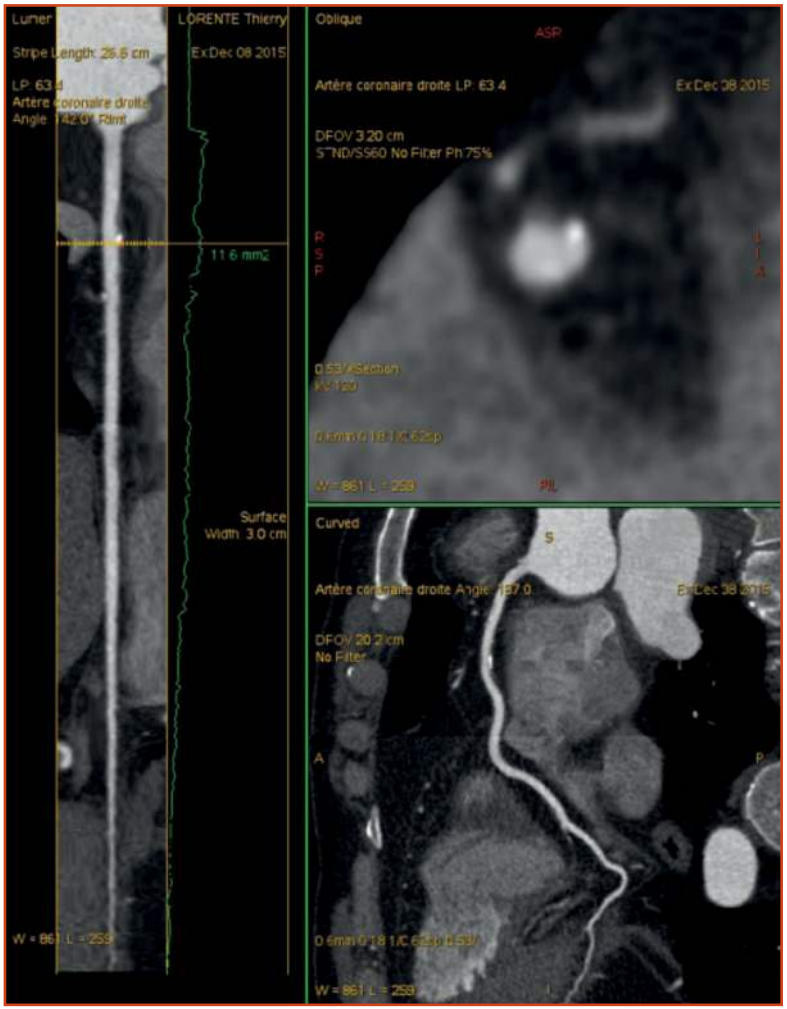
Examination

- 60 cc of Opti**RAY**® 350
- Flow rate 4.6 cc/sec
- 100 kV – 500 mAs
- Aortic enhancement: 650 HU

Diagnosis

- Coronary arteries were found normal

Case 2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DFOV 20.2 cm
No Filter
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W = 861 L = 259

80 Kg Patient

- 65 years old man presenting with multiple cardiovascular risk factors
- Coronary CT scan was performed to look for coronary lesions

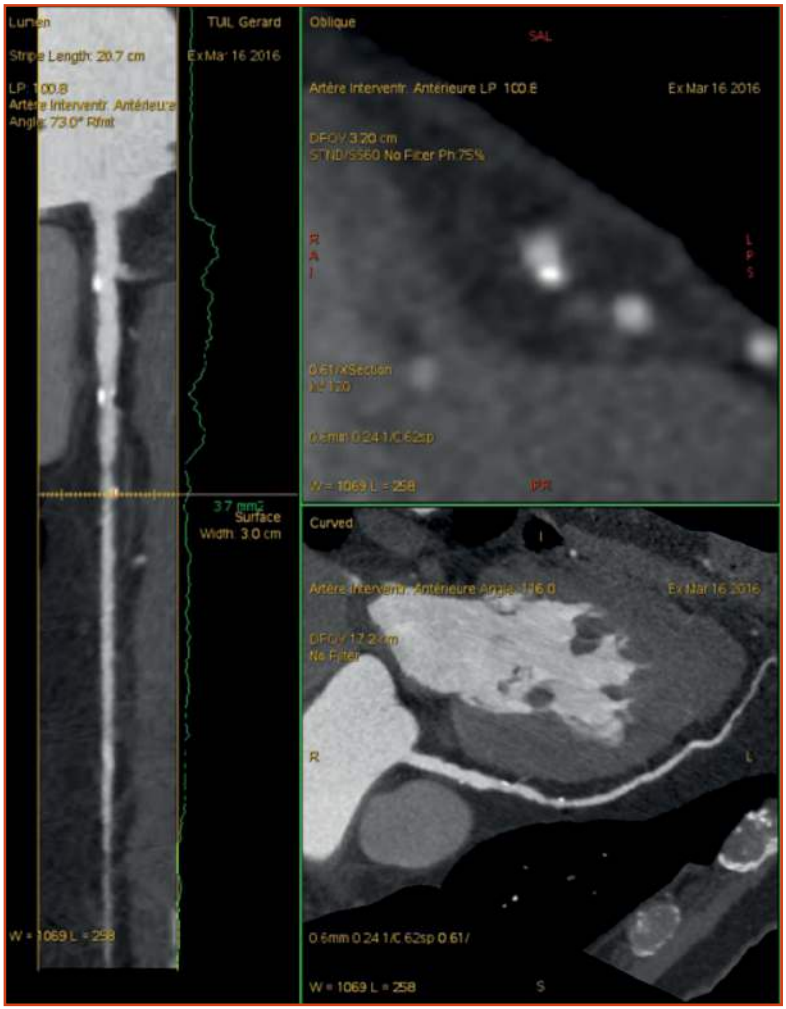
Examination

- 80 cc of Opti**RAY**® 350
- Flow rate 6.2 cc/sec
- 120 kV – 500 mAs
- Aortic enhancement: 515 HU

Diagnosis

Non significant calcified plaque was detected on right coronary artery
No significant stenosis was found

Case 3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98 Kg Patient

- 48 years old man presenting with chest pain during exercise
- Coronary CT scan was requested to look for coronary stenosis as responsible for the symptoms

Examination

- 98 cc of Opti**RAY**® 350
- Flow rate 7.5 cc/sec
- 120 kV – 700 mAs
- Aortic enhancement: 572 HU

Diagnosis

CT scan detected a moderate stenosis: 50% of area reduction at the level of the mid-LAD

4– Conclusion

- For CTA, a BMI-adapted scanning protocol, with the amount of contrast medium adjusted according to the patient's body weight, allows adequate and consistent coronary enhancement (≥300 HU) regardless of BMI.
- A BMI-adapted protocol using ioversol at 350 mg/mL (Opti**RAY**® 350) helps to reduce iodine volume delivery in slim patients and provides adequate coronary enhancement in large patients.


Optiray™ Pharmacy Bulk Package - 300
Optiray™ Pharmacy Bulk Package - 320
Optiray™ Pharmacy Bulk Package - 350
Optiray 300
Optiray 320
Optiray 350

Please refer to the Summary of Product Characteristics before prescribing. **Composition:** OPTIRAY® 240 Ioversol, 509 mg/ml, which is equivalent to 240 mg/ml of elemental iodine. OPTIRAY® 300 Ioversol, 636 mg/ml, which is equivalent to 300 mg/ml of elemental iodine. OPTIRAY® Ioversol, 678 mg/ml, which is equivalent to 320 mg/ml of elemental iodine. OPTIRAY® Ioversol, 741 mg/ml, which is equivalent to 350 mg/ml of elemental iodine. **Indications:** OPTIRAY® non-ionic X-ray contrast medium for injection or infusion. Depending on the preparation, it is indicated for use in cerebral, coronary, peripheral, visceral and renal angiography, in aortography, left ventriculography, venography, intravenous excretory urography and computed tomography (CT) of the head and body. Except for OPTIRAY® 300, safety and effectiveness of OPTIRAY® in children has not yet been established. **Posology and Method of Administration:** The dosage may vary between 1 ml and 150 ml, maximum total dose 250 ml or less. Please refer to the Summary of Product Characteristics for the recommended dosage schedule. **Contraindications:** Proven hypersensitivity to iodine-containing contrast media. Manifest hyperthyroidism. **Special Warnings and Precautions for Use:** As with all other X-ray contrast media, OPTIRAY® may cause anaphylaxis or other manifestations of pseudo-allergic intolerance reactions, e.g. nausea, vomiting, dyspnoea, erythema, urticaria and hypotension. Pretesting cannot be relied upon to predict severe reactions. The thorough assessment of the medical history of the specific patient may be more accurate in predicting potential adverse reactions. A positive history of allergy is not a contraindication, but does require caution. Diagnostic procedures, which involve the use of iodinated intravascular contrast agents, should be performed under the direction of personnel skilled and experienced in the particular procedure to be performed. Serious or fatal reactions have been associated with the administration of iodinated X-ray contrast media. A fully equipped emergency cart, or equivalent supplies and equipment, and personnel competent in recognising and treating adverse reactions of all types should always be available for at least 30 to 60 minutes after administration. Patients with congestive heart failure should be observed for several hours following the procedure to detect delayed haemodynamic disturbances, which may be associated with a transitory increase in the circulating osmotic load. All other patients should be observed for at least one hour after the application, as it has been reported that most of the adverse events occur in this period. The patient should also be informed that allergic reactions may develop up to several days post administration; in such case, a physician should be consulted immediately. Caution must be exercised in patients with severely impaired renal function, combined renal and hepatic disease, anuria, diabetes mellitus, homozygotic sickle cell disease, or monoclonal gammopathy (multiple myeloma, Waldenströms macro-globulinaemia), particularly when large doses are administered. Serious renal effects, including acute renal failure, may occur in these patients. Preparatory dehydration is dangerous and may contribute to acute renal failure. Iodine-containing contrast media may also be hazardous in patients with hyperthyroidism or with autonomous areas of the thyroid gland. In patients with phaeochromocytoma a premedication with alpha-blockers is advisable when the contrast medium is administered intravascularly due to the risk of a hypertensive crisis. Serious neurologic events have been observed following direct injection into cerebral arteries or vessels supplying the spinal cord, or in angiocardiography due to inadvertent filling of the carotids. General anaesthesia may be indicated in selected patients. However, a higher incidence of adverse reactions has been reported in these patients, probably due to the hypotensive effect of the anaesthetic. In angiographic procedures, the possibility of dislodging plaque or damaging or perforating the vessel wall should be considered during catheter manipulation and contrast medium injection. In patients with advanced atherosclerosis, serious hypertension, cardiac decompensation, senility, preceding cerebral thrombosis or embolism, special caution should be exercised. Cardiovascular reactions as bradycardia, rising or falling of blood pressure may occur more often. Angiography should be avoided whenever possible in patients with homocystinuria due to an increased risk of thrombosis and embolism.

Optiray® should be injected with caution to avoid perivascular application. However, significant extravasation of Optiray® may occur especially during the use of power injectors. Generally, it is tolerated without substantial tissue injury applying conservative treatment. However, serious tissue damage (e.g. ulceration) has been reported in isolated cases requiring surgical treatment. **For interactions and specific warnings**, please refer to summary of product characteristics. **Summary of safety profile:** Adverse reactions following the use of Optiray® formulations are generally independent of the dose administered. Usually, they are mild to moderate, of short duration and resolve spontaneously (without treatment). However, even mild adverse reactions may be the first indication of a serious, generalized reaction that can occur rarely after iodinated contrast media. Such serious reactions may be life-threatening and fatal, and usually affect the cardiovascular system. Most adverse drug reactions to Optiray® formulations occur within minutes after administration, however contrast related hypersensitivity reactions may occur with a delay of some hours up to several days. **Adverse reactions may be classified as follows:** Hypersensitivity or anaphylactoid reactions are mostly mild to moderate with symptoms like rash, pruritus, urticaria and rhinitis. However, serious reactions may occur. Serious anaphylactic reactions generally affect the cardiovascular and respiratory system. These may be life-threatening and include anaphylactic shock, cardiac and respiratory arrest, or pulmonary oedema. Fatal cases were reported. Patients with a history of allergic reactions are at increased risk of developing a hypersensitivity reaction. Other type 1 (immediate) reactions include symptoms like nausea and vomiting, skin rashes, dyspnoea, rhinitis, paraesthesia or hypotension. Vasovagal reactions e.g. dizziness or syncope which may be caused either by the contrast medium, or by the procedure. Cardiologic side effects during cardiac catheterisation e.g. angina pectoris, ECG changes, cardiac arrhythmias, conductivity disorders, as well as coronary spasm and thrombosis. Such reactions are very rare and may be caused by the contrast medium or by the procedure. Nephrotoxic reactions in patients with pre-existing renal damage or renal vasopathy, e.g. decrease in renal function with creatinine elevation. These adverse effects are transient in the majority of cases. In single cases, acute renal failure has been observed. Neurotoxic reactions after intra-arterial injection of the contrast medium e.g. visual disorders, disorientation, paralysis, convulsions, or fits. These symptoms are generally transient and abate spontaneously within several hours or days. Patients with pre-existing damage of the blood-brain barrier are at increased risk of developing neurotoxic reactions. Local reactions at the injection site may occur in very rare cases and include rashes, swelling, inflammation and oedema. Such reactions occur probably in most cases due to extravasation of the contrast agent. Extended paravasation may necessitate surgical treatment. Extravasation can cause serious tissue reactions including blistering and skin exfoliation, the extent of which is dependent on the amount and strength of the contrast solution in the tissues.

Marketing Authorization Information: The marketing authorization holder, number and date of approval may differ from one country to another. Volume, presentation and indication may also differ.
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