Reducing the effective radiation dose and the amount of contrast medium in CTA of the abdominal aorta

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Primary Objective: Is it possible to reduce the effective radiation dose and reduce the amount of contrast medium used in CTAs for patients, without losing image quality, using a reduced tube voltage protocol (80 kV) or CARE kV scanning protocol…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON36968

Source
ToetsingOnline

Brief title
Radiation dose and contrast reduction in CTA

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Bloodvessel deviations

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Voor dit onderzoek is geen extra geld nodig. Het zijn onderzoeken die voor de patient al ingepland staan.

Intervention

Keyword: Bolus reduction, Contrast medium, CTA, Effective radiation dose

Outcome measures

Primary outcome

The amount of Hounsfield Units (HU) measured in the aorta at 30 positions from

the celiac trunk to the iliac arteries in both groups.

Secondary outcome

• The uniformity of the attenuation values of both protocols.

• The clinical usefulness of the scans determined by 3 radiologists and scored

at a scale from 1 to 5.

• The effective radiation dose of the scans for both protocols

• The contrast-to-noise-ratio of the scans for both protocols

• The Signal tot noise ratio of the scans for both protocols

Study description

Background summary

Since the introduction of MDCT technology, CT angiography (CTA) has become a standard tool for the evaluation of disease of the aorta and its major branches. CTA permits the selective visualization of vascular structures after the IV injection of contrast material and the reconstruction of 3D images. As the use of MDCT has become routine in clinical practice, concerns have been raised regarding radiation exposure.
The current literature assumes a small but not negligible risk for radiation induced cancer from CT examinations. Therefore, reducing the radiation dose from CT has become an important issue. Various techniques and patient-based strategies have focused on reducing the radiation dose delivered during CT studies.
Numerous methods have been evaluated for radiation dose reduction during CTA including the use of a lower tube voltage. Lowering the tube voltage represents an important radiation reduction approach because the radiation dose varies

with the square of the tube voltage. Sigal-Cinqualbre et al were the first to hypothesize that low-kilovoltage scanning may facilitate the reduction in iodine load by increasing the vasculature enhancement due to the lower effective energy more closely approximating the k edge of iodine (33 kV). By approximating the k edge of iodine, a low-tube voltage computed tomographic technique increases the x-ray absorption of iodine by facilitating photoelectric interactions compared with Compton scattering effects. This technique can substantially increase the contrast enhancement of vascular and parenchymal structures while simultaneously reducing radiation dose to the patient.
Low tube voltage CTA of the body with 100 keV or 80 keV represents the most commonly applied technique for radiation dose reduction, with savings ranging from 20% to 50% when compared to the conventional protocol employing 120 keV. With this approach, the increased contrast between the arterial system and the surrounding tissue at the lower tube voltage offsets the greater image noise.
The amount of contrast medium injected in a patient is of concern because of the risk of complications, especially contrast induced nephropathy (CIN). CIN is defined as acute kidney injury caused by exposure to intravascular iodinated contrast medium, resulting in a decrease in the glomerular filtration rate. CIN is the third leading cause of all hospital-acquired renal insufficiency and is associated with increased long-term mortality.
The amount of contrast medium can be redused, using a test bolus prior to the scan bolus. The test bolus is used to synchronize the data acquisition with the arrival of contrast material in the abdominal aorta.

Study objective

Primary Objective: Is it possible to reduce the effective radiation dose and reduce the amount of contrast medium used in CTAs for patients, without losing image quality, using a reduced tube voltage protocol (80 kV) or CARE kV scanning protocol compared to patients, who are scanned with the conventional scanning protocol of 120 kV and 100 ml contrast medium?

Study design

Intervention study, Technical Efficacy study.

Intervention

Randomly, 15 Patients are assigned to undergo the CARE kV protocol using the Combined Applications to Reduce Exposure (CARE kV) tool of Siemens, CARE kV automatically suggest kV and effective mAs to optimize the contrast-to-noise-ratio (CNR) of the image while limiting the applied effective radiation dose. The system*s proposal is based on the attenuation as measured in the topogram and the user defined acquisition type (non-contrast, bone, soft tissue, vascular).

The remaining 15 patients are assigned to undergo the low voltage protocol which scans the patients with the dual-source CT technique at a voltage of 80 kV and 140 kV instead of the single source CT at a voltage of 120 kV. When the image quality of the 80 kV scans would be insufficient the 140 kV scans can be used for diagnostic purpose.
The scans of the 30 patients mentioned above will be compared with 15 patients scanned in a previous study using conventional settings; a tube current of 120 kV and 100 ml contrast medium [9].
In our previous study we used a test bolus reduction protocol with a test bolus of 10 mL contrast medium (ioversol 350, 350 mg iodine per milliliter; Optiray 350, Tyco Health care, Mansfield, Mass) to synchronize the data acquisition with the arrival of contrast material in the abdominal aorta. The test bolus was followed by a bolus injection of 40 mL of undiluted contrast medium (ioversol 350) and the a saline chasing bolus of 20 mL at 4 mL/sec. With this study we will use the same test bolus reduction protocol only the injected volume is a mixture of 1:1 contrast medium and saline. This results in a total contrast medium injection of 25 mL, which means a 50% reduction in iodine load compared to our previous study and even a 75% reduction in iodine load when compared to the conventional CTA protocol which uses 100 mL of contrast medium.

Study burden and risks

There is no risk that the scans of patients undergoing the low tube voltage or CARE kV protocol will be of less quality. The low tube voltage is associated by a dual energy scan of 140 kV, which is performed with a second x-ray tube. The total amount of radiation dose of the 80 kV and 140 kV scan is comparable to a normal 120 kV scan.
There is however a risk in the reduction of contrast material. When the reduction is too large, the image quality will not be sufficient. If this occurs a new scan will be made immediately after the first scan, so the patient doesn*t have to come back. This scan will be made with the multiphasic injection method and with the use of a test bolus. When this is done the total amount of contrast used for this patient will be 75 ml, which is still less than 100 ml used in clinical practice. However this will be 3 times the amount of contrast material used in patients were the image will be sufficient the first time. Also the second scan will increase the radiation exposure about 5-11 mSv.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Referred for CTA of the abdominal aorta according to clinical indications
- Mentally competent
- Signed informed consent
- >= 18 years
- Kidney function >= 60 GFR

Exclusion criteria

- < 18 years
- Mentally incompetent
- Kidney function < 60 GFR
- Allergy contrast medium
- Known arrhythmias or other heart disorders
- Pregnancy or lactation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	30-10-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL41889.028.12