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Evaluation of the radiation dose delivered to patients and staff during endovascular repair of aortic aneurysm in new generation imaging suites with image fusion guidance

Submission date
30/10/2017

Recruitment status
No longer recruiting

Registration date
08/11/2017

Overall study status
Completed

Last Edited
17/01/2020

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Imaging systems have evolved to facilitate aortic aneuryms endovascular repairs (EVAR) (a surgery to repair a widened area in the large artery that carries from the heart to the stomach, pelvis and legs). The latest hybrid rooms have advanced imaging applications, such as contrast enhanced Cone Beam Computed Tomography (ceCBCT, 3D images acquired through a C-arm rotation around the patient), and pre-operative Computed Tomography Angiography (CTA) images fusion with live fluoroscopy (continuous x-ray imaging) to provide a “3D roadmap”. This helps navigate through the aorta navigation and increases accuracy of endograft implantation (a tube covered in mesh placed in the aorta to help blood pulse through it). Despite the current widespread of these new imaging applications, little has been published on their impact on radiation exposure. Radiation effects are cumulative and put patients at risk of radiation injuries after exposure. However, clinical staff regularly exposed to radiation during everyday fluoroscopy-directed procedures is exposed to an increased incidence of stochastic injuries (chance or random injuries). Published evidence suggests that repeated injections of contrast media contribute to the development of lifelong nephropathy (kidney disease or damage). It has been demonstrated in a study conducted in a single center EVAR performed under fusion guidance in a hybrid room following the ALARA (as low as reasonably achievable) principles allowed significant reduction of radiation exposure and contrast media volume. The aim of this study is to evaluate if such dose and contrast volume reduction can also be observed in a study with more than one centres.

Who can participate?
Adults aged 18 to 99 years old who are undergoing EVAR with a bifurcated endograft in the hybrid room with fusion imaging guidance.

What does the study involve?
Aortic centers record data for all consecutive patients undergoing endovascular aneurysm repair (EVAR) with a bifurcated endograft. All centers followed the As Low As Reasonable Achievable

(ALARA) principles during EVAR. The same dose protocol was used in every center (for both fluoroscopy and angiography). Radiation doses are evaluated through two validated parameters: The Dose-Area product and the Cumulative Air-Kerma that are provided by the imaging systems. All systems internal dosimeters calibration are checked by the hybrid room manufacturer prior to patient inclusion.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
1. Heart of England NHS Foundation Trust (UK)
2. Aortic Center, Institut Coeur-Poumon (France)
3. Royal Oldham Hospital (UK)
4. Maimonides Medical Center (USA)
5. CHU Rangueil (France)
6. Takai Hospital (Japan)

When is the study starting and how long is it expected to run for?
October 2015 to October 2017

Who is funding the study?
Lille University Aortic Centre (France)

Who is the main contact?
Professor Stephan Haulon

Contact information

Type(s)
Scientific

Contact name
Prof Stephan Haulon

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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
REVAR2017

Study information

Scientific Title
Fusion Imaging-Guided EVAR Reduces Radiation - Results from a prospective multicentric study

Acronym
REVAR

Study objectives
Use of fusion imaging (between fluoroscopy and preoperative angioCT-scan) and strong appliance to the radiation protection principles in a modern hybrid room seemed to be associated with a radiation dose reduction during aortic endovascular repair in a previously published monocentric study (DOI: 10.1016/j.ejvs.2014.05.026).
The purpose of this study is to evaluate if similar results could also be observed in a multicentric study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
CERAR Ethical Committee of the French Aesthesiologist Society, 20/02/2016, ref: IRB 00010254--2015023

Study design
Prospective multicentre observational multicentric study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Radiation effects

Interventions
This study is a prospective multicentric observational study. Six high volume aortic centers record data for all consecutive patients undergoing endovascular aneurysm repair (EVAR) with a bifurcated endograft.

All centers followed the As Low As Reasonable Achievable (ALARA) principles during EVAR. The same dose protocol is used in every center (for both fluoroscopy and angiography). Every case is performed using 2d/3d fusion with aortic volume rendering generated from the preoperative high resolution computed tomography angiography (CTA). Accuracy of the registration is adjusted with dynamic registration if required. Completion angiography, to assess technical success at the end of each procedure, is performed with a standard 2-dimension (2D) short angiography. All procedures are carried out by experienced operators under general or locoregional anesthesia.

Radiation doses are evaluated through two validated parameters in the literature: The Dose-Area product (DAP, in Gy.cm²) and the Cumulative Air-Kerma (CAK, in mGy), that were provided by the imaging systems. All systems internal dosimeters calibration are checked by the hybrid room manufacturer prior to patient inclusion.

Written consent is obtained for all patients prior to enrollment.

Intervention Type
Procedure/Surgery

Primary outcome measure
Dose-Area Product (DAP, in Gy.cm²) is measured using the internal dosimeter of the imaging equipment at the end of each procedure.

Secondary outcome measures
1. Cumulative Air-Kerma (CAK, in mGy) is measured using the internal dosimeter of the imaging equipment at the end of each procedure
2. Fluoroscopy Time (FT, min) is measured using the imaging equipment at the end of each procedure.
3. Duration of fusion imaging preparation (defined as time spent on the workstation from the start of the aorta analysis protocol to the launch of the fusion software) measured using a chronometer and reported by the investigators at the beginning of each procedure.
4. Duration of fusion imaging registration (time spent from the start of the bone registration to the switch from the bone mask to the vascular mask) measured using a chronometer and reported by the investigators at the beginning of each procedure.
5. Total Contrast Media Volume (cc) is measured manually by reporting the total volume of contrast medium injected to the patient during the case at the end of each procedure

Overall study start date
01/10/2015

Completion date
31/10/2017

Eligibility

Key inclusion criteria

1. All consecutive patients undergoing endovascular aneurysm repair (EVAR) with a bifurcated endograft in the hybrid room with fusion imaging guidance
2. Aged 18 to 99 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Patients treated in emergency
2. Patients with planned additionnal procedures (hypogastric embolization or iliac branch for the graft for example)
3. Patients refusing enrollment
4. Patients under the age of 18 yo or not able to give their consent

Date of first enrolment
01/02/2016

Date of final enrolment
30/11/2016

Locations

Countries of recruitment
England

France

Japan

United Kingdom

United States of America

Study participating centre
Institut Coeur-Poumon
Aortic Center
Lille

France
59000

Study participating centre
Heart of England NHS Foundation Trust
Birmingham
United Kingdom
B9 5SS

Study participating centre
Royal Oldham Hospital
Manchester
United Kingdom
OL1 2JH

Study participating centre
Maimonides Medical Center
New York
United States of America
NY 11219

Study participating centre
CHU Rangueil
Toulouse
France
31400

Study participating centre
Takai Hospital
Toki
Japan
509-5301

Sponsor information

Organisation
Centre Hospitalier Regional et Universitaire de Lille

Sponsor details
Vascular Surgery Department
CHRU Lille – Hôpital Cardiologique
1, Blvd du Pr Jules Leclercq
Lille
France
59037

Sponsor type
Hospital/treatment centre

Website
http://www.chru-lille.fr/

ROR
https://ror.org/02ppyfa04

Funder(s)

Funder type
University/education

Funder Name
Lille University Aortic Centre

Results and Publications

Publication and dissemination plan
The authors consider submission to the Annals of Surgery Journal by the 31/12/2017. Both study protocol and statistical analysis plan can be shared if requested.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from S. Haulon, Aortic Centre, Department of Aortic and Vascular Surgery, Hôpital Marie Lannelongue, Le Plessis-Robinson, INSERM UMR_S 999, Univerité Paris Sud, France (email: s.haulon@ccml.fr)

IPD sharing plan summary
Available on request

Study outputs
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/09/2018	Yes	No