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SYNTAX III Revolution Trial

SYNTAX III Revolution: non-invasive Heart Team assessment of multivessel coronary disease with coronary CT angiography

At the dawn of a new era in non-invasive decision making

Paris, France, 22 May 2018. Results from the innovative SYNTAX III Revolution trial underline the effectiveness of evolving non-invasive algorithms for Heart Team decision making using state-of-the-art imaging.

“Designed to better understand the Heart Team decision-making process itself, the SYNTAX III Revolution clinical trial was distinctive among clinical trials in that, rather than randomising the patient, it was the doctors themselves who were randomised – in this case, the Heart Team – in order to understand more completely the present and future role of non-invasive assessments in deciding and planning revascularisation strategies”.

- Professor Patrick W. Serruys, study chairman

The SYNTAX III Revolution trial was specifically designed to provide evidence in decision making by randomising two Heart Teams in six participating international centres. These teams, composed of a surgeon, an interventional cardiologist and a radiologist, considered the treatment of 223 patients over an 18-month period.

Each of the two Heart Teams was presented with the same patient and asked to plan a procedure, answering such questions as ..... Which vessel(s) need to be revascularised? How many bypasses are needed? How many stents should be used? The primary goal was to assess the treatment decision - whether it was decided, based on the information received, to go with either surgery (CABG) or PCI.

Heart Team A had to make their decision on whether to perform revascularisation with either PCI or surgery using information received strictly from non-invasive means - multislice coronary computed tomography angiography (MSCT) from a GE Revolution multislice CT scan with fractional flow reserve (FFR) CT assessment (HeartFlow).
Heart Team B needed to make the same decision but using only conventional cine-angiography.

The Cohen’s kappa statistic was employed to indicate the level of agreement between the two Heart Teams in terms of their treatment decision – in this case to use either CABG or PCI – based on the MSCT-first assessment or angiography-first evaluation.

“We were looking at the concordance of judgement and the concordance of opinion in the planning of the procedure and discovered that the Cohen’s kappa statistic was very high – 0.82 – which can be called an almost perfect assessment/agreement. It showed good agreement as well in terms of the number of bypasses, how many stents should be used and the location in the coronary circulation”.

“We were amazed,” Prof. Serruys continued, “to hear participating surgeons telling us that they could see more things on the GE Revolution multislice scan than using conventional angiography”, pointing to a near future when “cine-angiography could be dispensed with completely and only the non-invasive multislice scans used” for procedural evaluation.

In the initial trial, in order to ensure patient safety, the actual procedure remained “virtual”. After each blinded Heart Team made its decision and planned for surgery or PCI – and before the actual intervention took place – the different Teams were unblinded and provided with all the information acquired by both the MSCT-first assessment and angiography-first examination before actually continuing with the procedure. In January 2018, preparing for the next step, a meeting was organised with the surgeons of the six centres where they were presented with randomised cases and asked if they could plan an operation using the GE multislice scan alone. “To our surprise,” Prof. Serruys said, “there was a very high feeling of ‘feasibility’ among the surgeons” to do this and so the next phase, planned for 2018-2019, will be a first-in-man trial asking surgeons to treat 100 patients based on multislice CT scan alone without looking at coronary angiography.

“In the next five to ten years, with its increasing accuracy, I think we are going to see the new generation of multislice CT scans replacing conventional cine-angiography. For interventional cardiologists this is a bonus, allowing them to have the image before bringing the patient to the cath lab and being able to make a decision concerning
whether it is a one-vessel or multivessel disease. If it is clearly one-vessel disease, there is no reason to consider surgery, but, when you know in advance that it is a multivessel disease, you can immediately discuss with the surgeon based on the non-invasive imaging alone and go immediately to the operating room or the interventional suite to perform the intervention”.

“So this can be seen as promising a real change in our practice – it will take time and it will take multiple trials, but the impetus is there to go in this direction. It is clearly the beginning of a trend we will see in the next few years”.

- Professor Patrick W. Serruys

**Key points**

- **SYNTAX III Revolution trial**: For the first time randomised the Heart Teams and not the patient for the assessment of agreement between conventional angiography and coronary CTA.

- Angiography-first algorithm vs. MSCT-first algorithm
  - High-definition GE Revolution™ CT
  - HeartFlow FFR-CT

- **223 patients**

- **6 international centres:**
  - Universitair Ziekenhuis Brussel, Brussels, Belgium
  - Centro Cardiologico Monzino, I.R.C.C.S., University of Milan, Milan, Italy
  - Centre Cardiologique du Nord, Saint Denis, France
  - Centre Hospitalier Universitaire de Nancy, Nancy, France
  - University Hospital Zurich, Zurich, Switzerland
  - Friedrich-Schiller-Universität Jena, Jena, Germany.

- **Core Lab**: Cardialysis, Rotterdam, the Netherlands

- **Funding**
The SYNTAX III trial is an investigator-driven study sponsored by the European Cardiovascular Research Institute (ECRI). For this study, the ECRI received research grants from GE Healthcare and HeartFlow Inc.
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CORRESPONDING SESSION
EuroPCR 2018 session: Tuesday 22 May - Main Arena 12:20-14:00 (presentation 13:35-13:45)

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