Study title :
DOCTORS : Does Optical Coherence Tomography Optimise Results of Stenting ?

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Disclosures :

- Research Support : Bayer HealthCare, Bristol-Myers Squibb, Daiichi-Sankyo, Boerhinger Pfizer
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- Scientific Advisory Board : Bristol-Myers Squibb

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Declaration of Interest

- Research contracts (Bayer
- BMS
- Daiichi-Sankyo
- Boehringer
- Pfizer)
- Consulting/Royalties/Owner/ Stockholder of a healthcare company (Bayer
- Pfizer
- St Jude Medical
- Edwards)
- Others (Scientific Advisory Board BMS)

Background

- OCT offers potential advantages over angiography :
  - To identify plaque morphologies associated with worse prognosis [1-3] in ACS pts
  - To assess postprocedural results that cannot be seen by angiography (optimal lesion coverage, stent expansion or apposition) with a view to further optimizing outcomes[2–6]
- Additional information yielded by OCT imaging during PCI impacts on physician decision-making in two-thirds of cases [6].
- It remains to be investigated whether the use of additional interventions prompted by OCT findings will translate into a benefit in procedural outcome.
- In this setting, randomized data investigating the utility of OCT over angiography alone to guide PCI are lacking [7-8], specifically in patients with NSTE-ACS.

[1]Niccoli G et al. Eur Heart J. 2015;36:1377-1384. [2]Vergallo R et al. Am Heart J. 2014;167:59-67. [3]Porto I et al. Circ Cardiovasc Interv. 2012;5:89-96,S81-86. [4]Prati F et al. EuroIntervention. 2012;8:823-829. [5]Prati F et al. JACC Cardiovasc Imaging. 2015;8:1297-1305. [6]Wijns W et al. Eur Heart J. 2015;36:3346-3355. [7]Waksman R et al. Eur Heart J. 2015;36:3356-3358. [8]Sawlani NN et al. JACC Cardiovasc Imaging. 2015;8:1306-1308.

Study Design & Aim of the Study

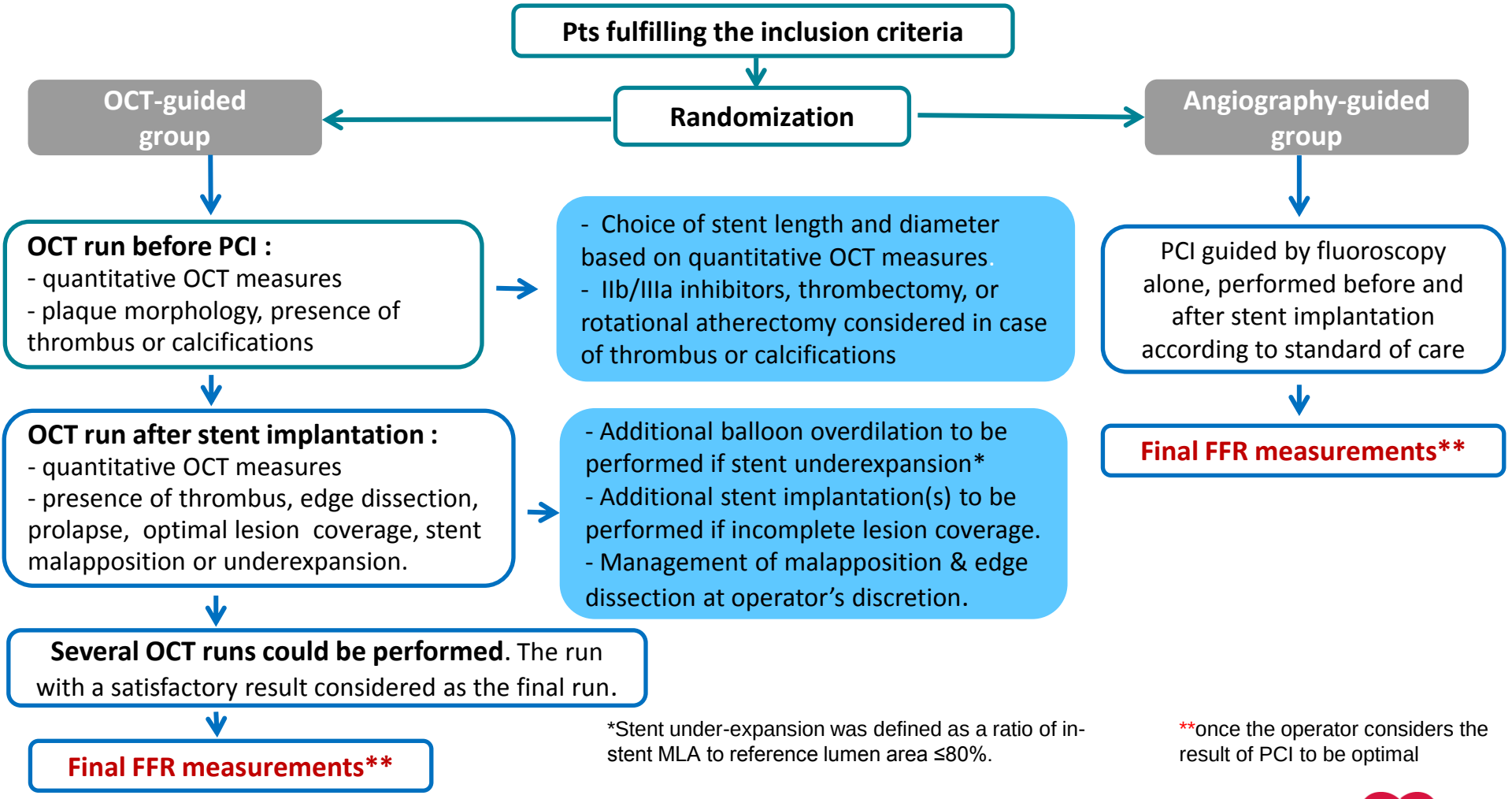
Study Design (previously published Am Heart J 2014;168:175-181.)

- Randomized, prospective, multicenter, open label trial (NCT01743274)
- Performed in 9 hospitals in France

The DOCTORS study aimed to evaluate :

- whether the use of OCT during PCI would provide useful clinical information beyond that obtained by angiography alone
- whether this information would modify physician decision-making
- and impact on the functional result of angioplasty as assessed by fractional flow reserve (FFR) measured after stent implantation in a lesion responsible for NSTE-ACS.

Flow Chart



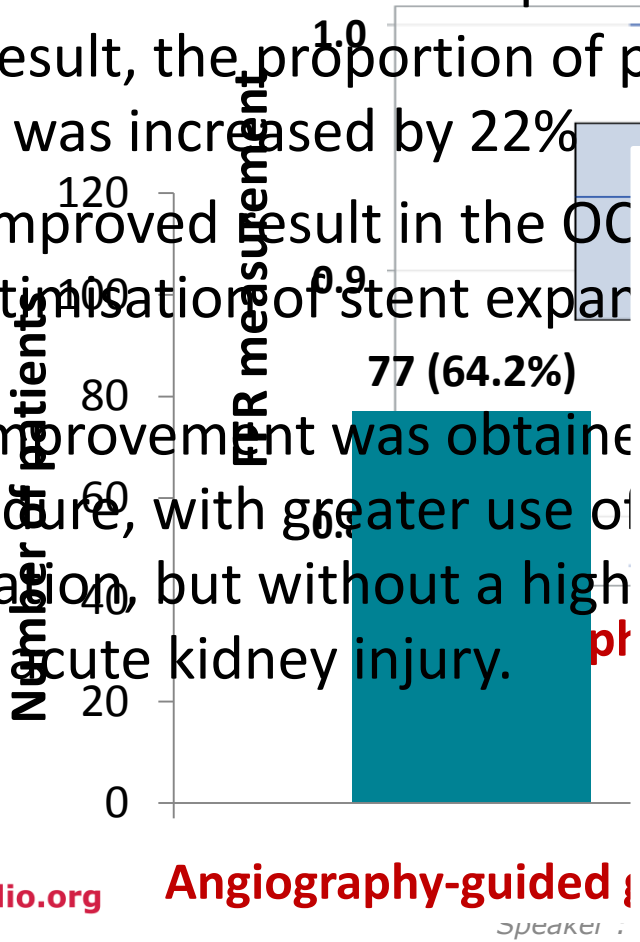
*Stent under-expansion was defined as a ratio of in-stent MLA to reference lumen area ≤80%.

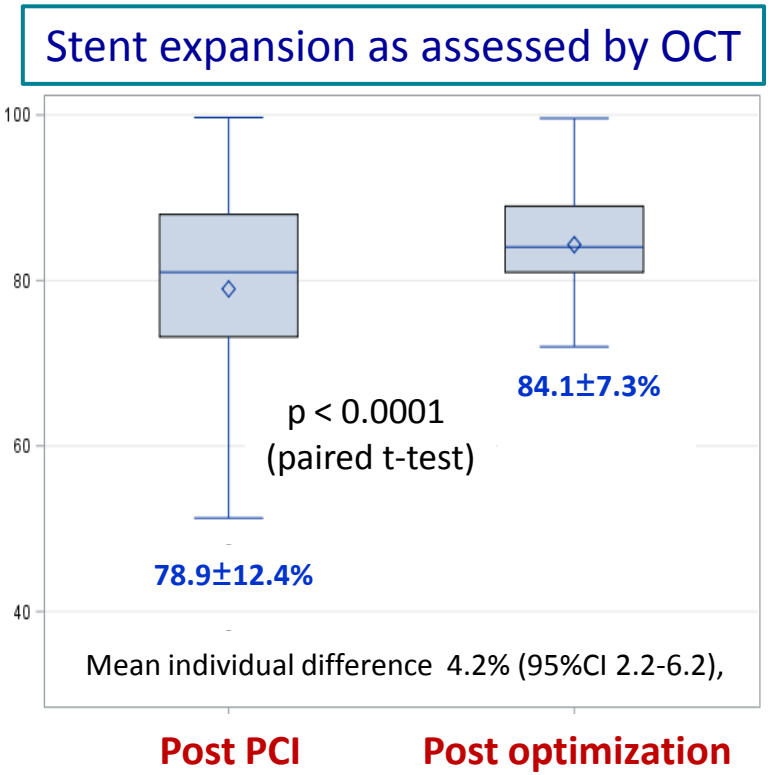
**once the operator considers the result of PCI to be optimal

Speaker : N. Meneveau

Results

- FFR was significantly improved in the OCT-guided group
- Optimization of the PCI procedure based on OCT findings was performed in 50% of patients in the OCT group
- As a result, the proportion of patients with post-PCI FFR >0.90 was increased by 22%
- This improved result in the OC by optimisation of stent expar
- The improvement was obtaine procedure, with greater use of irradiation, but without a high MI or acute kidney injury.





Conclusion

- DOCTORS is the 1st RDZ trial to investigate the use of OCT on top of angiographic guidance during PCI in patients with ACS.
- OCT provided useful information beyond that obtained by angiography alone.
- The OCT findings impacted directly on physician decision-making, leading to a change in procedural strategy in half of cases, and was associated with higher FFR at the end of the procedure than PCI guided by fluoroscopy alone.
- This improvement was driven mainly by optimization of stent expansion.
- The benefit was obtained at the cost of a longer procedure with higher fluoroscopy time and more contrast medium, but without an increase in peri-procedural MI or kidney dysfunction.
- Additional prospective studies with clinical endpoints are required before considering incorporating OCT guidance for standard use in patients with ACS.

Optical Coherence Tomography to Optimize Results of Percutaneous Coronary Intervention in Patients with Non–ST-Elevation Acute Coronary Syndrome

Results of the Multicenter, Randomized DOCTORS (Does Optical Coherence Tomography Optimize Results of Stenting) Study

Editorial, see p XXX

BACKGROUND: No randomized study has investigated the value of optical coherence tomography (OCT) in optimizing the results of percutaneous coronary intervention (PCI) for non–ST-segment elevation acute coronary syndromes.

METHODS: We conducted a multicenter, randomized study involving 240 patients with non–ST-segment elevation acute coronary syndromes to compare OCT-guided PCI (use of OCT pre- and post-PCI; OCT-guided group) to fluoroscopy-guided PCI (angiography-guided group). The primary end point was the functional result of PCI assessed by the measure of post PCI fractional flow reserve. Secondary end points included procedural complications and type 4a periprocedural myocardial infarction. Safety was assessed by the rate of acute kidney injury.

RESULTS: OCT use led to a change in procedural strategy in 50% of the patients in the OCT-guided group. The primary end point was improved in the OCT-guided group, with a significantly higher fractional flow reserve value (0.94±0.04 versus 0.92±0.05, *P*=0.005) compared with the angiography-guided group. There was no significant difference in the rate of type 4a

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