Four year follow up of SYNTAX trial; optimal revascularization strategy in patients with three vessel disease and/or left main disease. Holmes D, Cannon LA, Stathla E, et al. TCT 2011 Presentation.

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Background: The Syntax trial was designed to compare contemporary surgical and percutaneous techniques in patients with three vessel and/or left main disease. Syntax trial used a scoring system based on coronary angiogram which quantifies lesion complexity. Based on this score patients were classified into 3 groups, those with score <22 (low-risk), 23–32 (intermediate-risk) and ≥33 (high-risk).

Methods: A total of 1800 patients with de novo three vessel and/or left main disease were randomised 1:1 to coronary artery bypass grafts (CABG) or percutaneous coronary intervention (PCI) with taxus express paclitaxel eluting stent. Design was a prospective randomised one involving 85 centres worldwide. Primary end point was a composite of major adverse cardiac and cerebrovascular events; MACCE (death from any cause, stroke, myocardial infarction [MI], or repeat revascularization).

Results: At 1 year PCI failed to meet the prespecified margin of non-inferiority against CABG, after the primary end point of major adverse cardiac and cerebrovascular events (MACCE) occurred significantly more in the PCI arm than in the CABG arm, driven predominantly by a higher rate of repeat procedures in the PCI arm. For the harder end points of death, stroke and MI rates were identical between the two. This trend continued in the 2- and 3-years results.

Four-year follow-up results of SYNTAX have shown a continuing failure of non-inferiority of PCI compared to CABG. The results have made it clear that even in the so called intermediate-risk group (Syntax score 22–32) CABG is superior to PCI. This is not only driven by an increased rate of repeat procedures in the PCI group but by a difference in hard end points of death, MI, and cerebrovascular accidents (14.9% for CABG vs 17.3% for PCI). As expected, the rate of revascularization was significantly lower in the CABG arm (10.9% vs 20.7%).

Conclusion: Four-year MACCE rates in the overall randomised cohort were significantly higher for PCI than CABG. There was a significant increase of cardiac death, MI and repeat revascularisation in PCI vs CABG-treated patients. However, composite safety (death/stroke/MI) remains not significantly different between arms at 4 years ($P=0.07$). MACCE rates at 4 years were not significantly different for patients with a low baseline SYNTAX Score; for patients with intermediate or high SYNTAX scores, MACCE was increased at 4 years in patients treated with PCI. The 4-years SYNTAX results suggest that PCI may be an acceptable alternative revascularisation method to CABG when treating patients with less complex (lower SYNTAX score) disease including lunar module (LM) disease.

Perspective

The CABG as compared to first generation paclitaxel eluting stent is the preferred method of revascularisation in triple vessel disease with complex anatomy. In less complex anatomy with low syntax score, PCI is an acceptable alternative. The results with new generation stents like everolimus eluting stents (Xiance V/Promus) which have lower major adverse cardiac events (MACE) could be different.

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Radial Vs Femoral (RIVAL) trial for coronary angiography and intervention in patients with acute coronary syndromes.

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Background: It has become clear in a number of recent trials that bleeding following a percutaneous coronary intervention (PCI) is as major a risk factor for subsequent mortality as a myocardial infarction (MI) and this risk has been seen to persist even after 1 year after the procedure. This has prompted an intense interest in promotion of so-called “bleeding avoiding strategies”. One of the potential bleeding avoiding strategies is a shift of vascular access site from femoral to radial. This has been shown in smaller studies to be associated with less bleeding but with concern about its feasibility in different clinical situations where speed is an essence. This trial was designed to compare the use of two vascular access sites in the setting of acute coronary syndromes (ACS).

Design and methods:

- The Radial Vs femoral access for coronary intervention (RIVAL) trial was a randomised, parallel group, multicentre trial. Patients with ACS were randomly assigned (1:1) to radial or femoral artery access.
- The trial assessed the impact of the vascular access site on a quadruple primary end point of a composite of death, MI, stroke, and non-CABG (coronary artery bypass grafts) related major bleeding at 30-days. The individual components of the quadruple formed the major secondary end points.
- As it is widely accepted that there is a prominent learning curve for performing a radial PCI, it was deemed necessary that the participants involved in the trial be comfortable with both routes and should have had performed at least 50 radial PCIs in the preceding year.

Concomitant medications:

- All the patients were required to be receiving all the current guideline directed medications. Consequently 99.3% were on aspirin, and 96% on clopidogrel. Amongst the adjuvant anti-thrombotic therapy 33% received unfractionated heparin, 3% received bivalirudin, and 10.9% received fondaparinux; GpIIb-IIIa inhibitors were given to 25% of patients.

Principle findings:

- A total of 7021 patients were enrolled, 3507 to radial access and 3514 to femoral access.
- About 28% presented with ST-segment elevation myocardial infarction (STEMI), 22% had diabetes, and 67% underwent PCI, while 8% underwent CABG.
- The success rates were similar and high in both the arms (95.3%). The operators were fairly high volume and trained with a median annual PCI rate of 300 out of which approximately 40% were radial PCIs.
- The first important finding was a relatively high cross-over rate. The rate was 7.6% in the radial arm compared to 2% in the femoral arm and this difference was statistically significant ($P < 0.0001$).
- There was no difference in the primary quadruple end point of death, MI, stroke, and non-CABG related major bleeding (3.7% for radial vs 4% for femoral access).
- The secondary end point of death, MI, or stroke were similar in the two arms (3.2% vs 3.2%).
- As there was a very high interest in the safety end point of bleeding it was analysed in detail. There was no difference in bleeding if non-CABG major bleeding was taken as a whole (0.7% for radial vs 0.9% for femoral). However, as expected major vascular access site complications (1.4% vs 3.7%; $P < 0.0001$) and AClITY non-CABG major bleeding (1.9% vs 4.5%, $P < 0.0001$) were significantly lower in the radial access arm.
- Another area of concern with the radial access is the speed. The study showed no significant difference in the overall PCI time between the two arms (35 minutes vs 34 minutes). However, the total fluoroscopy time was significantly different between the two (9.3 minutes vs 8 minutes, $P < 0.0001$).
- The most significant parameter where radial access scored impressively over femoral access was patient satisfaction. Patient preferred access site for next procedure was almost twice as high with radial access (90% vs 49%, $P < 0.0001$).

Interpretation

Where do the results of this study leave us? The results are fairly predictable. In experienced hands both sites lead to high and equal success rates. There is no increase in the total procedure time with radial access although there is a significant increase in total fluoroscopy time making cumulative radiation exposure an important safety issue for operators who opt for a very high or exclusive radial practice over a prolonged period of time. Although overall bleeding is same but vascular site bleeding is an important issue and radial access clearly establishes its superiority over femoral access. The issue which probably will drive the future increase in use of radial access as shown in this study is patient satisfaction. There is a substantial difference of having to lie down for hours with pressure and sheaths in areas which may be discomforting and embarrassing for many patients and being able to move about immediately with a small band tied to the arm.

Perspective

Like many other “this or that” situations the message here is also “this and that rather than this or that”. Interventional cardiologists should become proficient in both the accesses and select the access on an individual basis keeping in mind the speed, bleeding risk and of course the patient preference. Contrary to the expectation that radial route will be safer for patients, this study failed to show increased safety for radial route. The main reason for this is that the non-access bleeds were nearly equal in both the arms. This shows that our search for further means of reducing bleeding complications should continue.

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1. **Rivaroxaban in patients with a recent acute coronary syndrome.** Mega JL, Braunwald E, Wiviott SD, ATLAS ACS 2–TIMI 51 Investigators. N Engl J Med 2012;366:9–19. doi: 10.1016/S0019-4832(12)60037-6

Background: Acute coronary syndromes (ACS) arise from coronary atherosclerosis with superimposed thrombosis. Since factor Xa plays a central role in thrombosis, the inhibition of factor Xa with low-dose rivaroxaban might improve cardiovascular outcomes in patients with a recent ACS.