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Interventional cardiology: a 2023 recap and what to expect in 2024

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The year 2023 was rich in late-breaking trials that covered both the intracoronary and structural domains. These are areas in interventional cardiology where the interest and uptake have expanded steadily across the globe. With respect to intracoronary imaging, four pivotal trials were presented at the European Society of Cardiology Congress. The OCTIVUS trial[1] was an investigator-initiated, prospective, multicentre, randomised, open-label, pragmatic trial conducted at 9 sites in South Korea designed to capture a broad range of patients with various anatomical or clinical characteristics. A total of 2,008 patients were randomised in a 1:1 ratio to undergo either optical coherence tomography (OCT)-guided or intravascular ultrasound (IVUS)-guided percutaneous coronary interventions (PCI) after diagnostic coronary angiography. The primary endpoint was a composite of death from cardiac causes, target vessel myocardial infarction (TVMI), or ischaemia-driven target vessel revascularisation (ID-TVR) at one year, powered for non-inferiority. At one year, the primary endpoint had occurred in 2.5% of patients in the OCT-guided PCI group and in 3.1% in the IVUS-guided PCI group ($p<0.001$).

The OCTOBER Trial was the first adequately powered clinical trial to examine whether routine use of OCT during PCI of complex bifurcation lesions improves clinical outcomes compared to standard practice with angiographic guidance[2]. The primary endpoint was major adverse cardiac events (MACE), a composite of cardiac death, target lesion myocardial infarction (TLMI), or ischaemia-driven TLR at two years. It included a total of 1,201 patients from 38 centres across Europe (600 OCT and 601 angiography only). Left main bifurcation lesions were found in 18.5% of the OCT-guided PCI group and in 19.3% of the angiography-guided group. The primary endpoint of MACE after two years occurred in 10.1% of the OCT arm and 14.1% of the angiography arm ($p=0.035$).

The much-anticipated ILUMIEN IV trial comes at the heels of the ILUMIEN I-III trials, which noted that, compared with angiography, OCT guidance improved procedural success, namely, by greater stent expansion and reduced major malapposition and major dissection. Whether OCT can improve clinical outcomes is unknown and is the question ILUMIEN IV was designed to answer. ILUMIEN IV randomised high-risk patients with one or more high-risk lesions undergoing PCI 1:1 to OCT or angiography guidance. It was powered for a primary imaging endpoint defined as the minimum stent area (MSA) assessed by OCT using a superiority design. It was also powered for a primary clinical endpoint reporting target vessel failure (TVF; cardiac death, TVMI, and ID-TVR) at 2 years with a superiority design. A total of 2,487 patients were randomised: 1,233 to the OCT arm and 1,254 to the angiography-only arm. At 2-year follow-up, the primary imaging endpoint was achieved with an MSA of 5.72±2.04 mm^2 in the OCT group versus 5.36±1.87 mm^2 in the angiography group (p-value<0.001); however, the rate of TVF was not significantly different between the two groups (7.4% in the OCT group and 8.2% in the angiography group; $p=0.45$)[3].

A presented network meta-analysis permitted operators to evaluate the totality of the evidence. The analysis compared the overall effects of intravascular imaging (IVUS and OCT) in improving outcomes

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of the PCI procedure versus angiography, IVUS versus angiography, OCT versus angiography, and IVUS versus OCT. It incorporated 20 randomised trials of intravascular imaging-guided PCI compared with angiography-guided PCI in 12,428 patients with acute and chronic coronary syndromes. Of those, 7,038 were randomly allocated to intravascular imaging guidance and 5,390 patients were randomly allocated to angiography guidance. Patients were followed for a period of between 6 months and 5 years. Intravascular imaging (IVUS or OCT) guidance of PCI resulted in reductions in the primary composite outcome of target lesion failure (TLF) by 31% compared with angiography guidance of PCI. The results of this network meta-analysis emphasise the importance of using intravascular imaging with either OCT or IVUS to optimise stent outcomes and improve the long-term prognosis of patients.

Based on the totality of evidence, PCI guided by intravascular imaging improved procedural success, namely, by achieving higher MSA and reducing adverse cardiac events in patients with complex lesions, especially bifurcation lesions. Whether these trials will prompt a change in the guidelines remains to be seen.

Shifting focus to the structural trials, several were presented at the TCT 2023 conference. The first trial, ALIGN-AR, evaluated a dedicated device for aortic regurgitation (AR). Currently off-label devices have an increased risk of valvular embolisation, migration, or paravalvular leak in patients with pure AR. This study was a single-arm prospective investigation device exemption study assessing the safety and efficacy of the Trilogy transcatheter heart valve system (JenaValve) in patients with symptomatic (New York Heart Association [NYHA] II or greater), moderate to severe, or severe AR (with grade ≥3+ AR) determined by the Heart Team to be at high risk for surgical aortic valve replacement (SAVR). The primary safety endpoint was a composite of all-cause mortality, all stroke, life-threatening/major bleeding, major vascular complications, acute kidney injury (AKI), need for surgery/intervention related to the device, new permanent pacemaker, or ≥moderate paravalvular leak at 30 days. The primary efficacy endpoint was all-cause mortality at 12 months. Overall, 180 patients were enrolled in the ALIGN-AR trial, with 177 undergoing successful implantation of the Trilogy valve (one converted to SAVR, 2 implantations of commercial transcatheter valves). The primary safety endpoint at 30 days occurred in 26.7% of patients, meeting the non-inferiority criteria for the primary endpoint compared to the prespecified performance goal ($p<0.0001$). The primary efficacy endpoint occurred in 7.8% at one year, meeting the non-inferiority criteria for the primary efficacy endpoint ($p<0.0001$). These results are in keeping with the results of real-world consecutive patients with severe AR treated with the Trilogy valve in Germany. This transcatheter heart valve is promising for significant aortic regurgitation in high-risk patients, although a randomised control trial for assessment of clinical outcome is needed.

The 5-year follow-up of the PARTNER 3 Trial showed that the primary endpoint (composite endpoint of death from any cause, stroke, or rehospitalisation) was similar for the two groups, with a rate of 22.8% in the transcatheter aortic valve replacement (TAVR) group and 27.2% in the surgery group ($p=0.07$). The mortality at 5 years was 10.2% versus 9.0% in the TAVR and the surgery group, respectively. No differences were noted for the new permanent pacemaker rate (13.5% vs 10.4%) or regarding stroke (5.8% and 6.4%, [hazard ratio 0.87, 95% confidence interval: 0.51 to 1.48], for TAVR and SAVR, respectively).

The 4-year results of the Evolut Low Risk trial were also reported. The trial indicated that there was a continuing trend towards lower combined rates of all-cause mortality and disabling stroke with TAVR compared with SAVR (10.7% vs 14.1%; $p=0.05$). The absolute difference between the groups rose from 1.8% in favour of TAVR at 2 years to 3.4% at 4 years, demonstrating a sustained benefit of the transcatheter interventions.

In summary, in low-risk patients, balloon-expandable TAVR (SAPIEN 3; Edwards Lifesciences) had the same incidence of the primary endpoint compared to SAVR at 5 years; this was lower at the 1- and 2-year follow-ups, while the Evolut (Medtronic) self-expanding valve continued to have a lower rate of all-cause mortality and disabling stroke compared to SAVR at 4 years. As such, ten-year follow-up is still necessary. At this time, anatomical considerations will ultimately dictate the strategy in low-risk patients who fulfil the inclusion criteria of the published trials. Careful consideration should be given to younger low-risk patients, however, who will require lifetime management of the aortic stenosis.

Finally, the TRISCEND II Pivotal Trial was devised to allow for the analysis of the first 150 patients with significant tricuspid regurgitation (TR) and high surgical risk randomised in the study. At 30 days, the primary composite safety endpoint occurred in 27.4% of the 95 patients treated with transcatheter valve replacement, a rate that compared favourably with historical safety data after tricuspid valve surgery (43.8%). Severe bleeding (10.5%) and the need for permanent pacing (14.7%) were the two most common adverse events. At 6 months, transcatheter tricuspid valve replacement significantly reduced TR, with 98.8% of patients having moderate or less TR compared to just 21.6% who had moderate or less TR with optimal medical therapy. Improvements in quality of life and functional status were superior with transcatheter tricuspid valve replacement. Longer-term data are still awaited for this technology to become a mainstream therapy.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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