REPORT

Folia Cardiologica 2022
vol. 17, no. 2, pages 137–140
DOI: 10.5603/FC.2022.0019

ISSN 2353–7752
e-ISSN 2353–7760

The latest scientific reports in the field of invasive cardiology: Transcatheter Cardiovascular Therapeutics (TCT) Congress, Orlando, November 4–6, 2021

Adrian Bujak, Łukasz Figiel, Jarosław D. Kasprzak

Chair and Department of Cardiology, Medical University of Lodz, Poland

Abstract

During the 3-day TCT Congress in Orlando, the results of several important clinical trials were presented. In this article, 6 studies are presented that were subjectively judged by the authors to be the most important from the perspective of a clinician and an interventionist.

Key words: TCT Congress 2021, clinical trials, mortality, safety, revascularization, aortic stenosis, antiplatelet therapy, atrial fibrillation

Folia Cardiologica 2022; 17, 2: 137–140

The Transcatheter Cardiovascular Therapeutics (TCT) Congress organized by the Cardiovascular Research Foundation (CRF) is considered one of the most important annual events in the broad field of interventional cardiology. The last year's TCT Congress was held in Orlando, Florida on November 4–6, 2021, in the shadow of the COVID-19 pandemics and worldwide public health restrictions, and thus the hybrid form of this event, with some participants present on-site and some participating online, was not surprising. Presentations, discussions, and case reports were carried out simultaneously in several rooms, which allowed choosing between various topics that were of interest for the audience gathered. Of note, online participants were offered free 1-year access to the conference materials. Despite the pandemic limitations, the last year's TCT Congress has been abound with extremely interesting, and sometimes even breakthrough clinical studies which in our opinion will have a major effect on the clinicians' and interventionists' approach to the invasive treatment of various cardiovascular diseases. Below, we present 6 studies presented during the last year's TCT Congress which we considered the most interesting.

The first day of the Congress started with the presentation of the study that was eagerly awaited by invasive cardiologists all over the world due to continuing expansion of innovative low-invasive interventional procedures resulting in a growing overlap of treatments offered by interventional cardiologists and cardiac surgeons. The Fractional Flow Reserve–Guided percutaneous coronary intervention (PCI) as Compared with Coronary Bypass Surgery (FAME) 3 study, simultaneously published in *The New England Journal of Medicine* (NEJM) [1], compared the outcomes of coronary revascularization by PCI and coronary artery bypass grafting (CABG) in patients with multivessel coronary artery disease (CAD). Much hope has been put on the success of the percutaneous strategy, particularly with the previous experience with procedures performed using bare metal stents (BMS), drug-eluting stents (DES), and without lesion selection based on fractional flow reserve (FFR) measurements. Thus, the authors hypothesized that percutaneous coronary revascularization using new generation DES would be non-inferior to surgical revascularization in this patient group during 1-year follow-up. The FAME 3 study was an

Address for correspondence: Adrian Bujak MD, Katedra i Klinika Kardiologii Uniwersytetu Medycznego w Łodzi, Wojewódzki Szpital Specjalistyczny im. Władysława Biegańskiego, ul. Kniaziewicza 1/5, 91–347 Łódź, Poland, e-mail: adbujak93@gmail.com

international multicentre randomized trial that included 1500 patients with multivessel CAD, defined as at least 50% stenoses in at least 3 epicardial vessels without left main coronary artery involvement, who were then randomized in a 1:1 ratio to the study group (n = 757), treated with PCI after the stenosis was confirmed to be haemodynamically significant based on a FFR of ≤ 0.80, or the control group (n = 743) treated with CABG based on the angiographic presentation. The published results were surprising, as during the 12-month follow-up, the primary endpoint of major adverse cardio-cerebrovascular events (MACCE) including all-cause death, myocardial infarction, stroke, and repeated revascularization was not less frequent in the percutaneous coronary revascularization group (10.6%) compared to the surgical group (6.9%), thus not confirming the hypothesis of comparable efficacy of PCI and CABG. The incidence of safety endpoints (major bleeding, acute kidney injury, arrhythmia including atrial fibrillation, and 30-day readmission rate) was significantly higher in the CABG group. Subgroup analysis showed that in patients with coronary lesions at a low level of anatomical complexity, as evidenced by the Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery (SYNTAX) score of < 23, PCI treatment was associated with a lower rate of adverse cardiovascular events compared to surgery (5.5% vs. 8.6%), while in patients with moderately and highly complex coronary lesions (SYNTAX score 23–32 and > 32), surgical treatment was significantly more beneficial, maintaining the status quo in keeping with the current European Society of Cardiology (ESC) guidelines. Future analyses of the FAME 3 study data will allow comparisons of the 2 revascularization methods over a long-term (3- and 5-year) follow-up.

Another presented study was the Angiographic Quantitative Flow Ratio-Guided Coronary Intervention (FAVOR III China) study by Bo Xu et al. [2], published online on the same day in *The Lancet*, evaluating long-term outcomes of PCI of the lesions selected based on quantitative flow ratio (QFR) measurements. The latter procedure is a non-invasive, functional FFR evaluation method based on a 3-dimensional analysis of angiographic images without the need to administer coronary vasodilating agents or introduce an intracoronary catheter. Previous studies showed a comparable diagnostic value of QFR measurements and conventional invasive FFR measurements, the current standard for functional assessment of coronary lesions. The FAVOR III study was a multicentre, blinded, sham-controlled trial with the following inclusion criteria: age > 18 years, stable or unstable CAD, myocardial infarction within 72 hours with at least one coronary lesion with a 50–90% stenosis in a vessel with the reference diameter of at least 2.5 mm by visual (angiographic) assessment. The study group included 3847 patients who were assigned in a 1:1 ratio to the groups with PCI eligibility determined based on standard visual assessment of angiographic lesions or QFR. The primary endpoint were major adverse cardiac events defined as all-cause death, myocardial infarction, or ischemia-driven revascularization at 1-year follow-up. The results turned out to be very promising, with 1-year event rate reduced from 8.8% in the conventional treatment group to 5.8% in the QFR group, mostly due to a lower rate of myocardial infarction in the latter group.

More very interesting studies were reported on the second day. In August 2021, comprehensive guidelines on the management of valvular heart disease were published, and the results presented at TCT 2021 may be considered a sort of extension for this document. According to the current guidelines, transcatheter aortic valve replacement (TAVR) is recommended in older patients (≥ 75 years), those at high surgical risk (STS-PROM/EuroSCORE II risk > 8%), and patients who are deemed unsuitable for the surgery, while other patients may undergo surgical aortic valve replacement (SAVR) or TAVR depending on the individual clinical, anatomical, and procedural characteristics. One of the studies presented at TCT 2021 was a comparison of 5-year outcomes of TAVR versus conventional SAVR in patients with severe symptomatic aortic stenosis at moderate surgical risk based on the Surgical Or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients (SURTAVI) study findings [3]. The SURTAVI study was an international randomized non-inferiority trial designed to compare the efficacy and safety of TAVR and surgical treatment in patients with severe symptomatic aortic stenosis at moderate surgical risk. The principal study findings at 2 years in 1746 patients [4] met the equivalence criteria in terms of safety (all-cause death or disabling stroke) but TAVR was associated with a higher rate of major vascular complications and a higher rate of pacemaker implantation. At 5-year follow-up, the SURTAVI study showed no difference in all-cause deaths and disabling strokes (primary endpoint of the study) between the TAVR and SAVR groups (31.3% vs. 30.8%; hazard ratio [HR] 1.02; 95% confidence interval [CI]: 0.85–1.22). The 2 cohorts did not differ in terms of death, stroke, and myocardial infarction rate. Patients who underwent TAVR required pacemaker implantation more frequently compared to the SAVR group (35.8% vs. 14.5%; p < 0.001). However, post hoc analysis covering the period from 2 to 5 years showed low rates of reintervention (1.0% in the TAVR group vs. 1.3% in the SAVR group; p = 0.60) and hospitalization due to heart failure (12.7% in the TAVR group vs. 12.5% in the SAVR group; p = 0.60) without significant differences between the study arms, a surprising result contrasting with the 2-year study findings that showed higher rates of these events following transcatheter intervention. Echocardiographic evaluation showed that in the TAVR group, the mean aortic gradient at 5 years was lower, and the aortic valve area was much higher (2.2 cm^2 vs. 1.8 cm^2)

compared to the surgical treatment group, with no differences in quality of life indices between the groups. In summary, these results confirm and extend the beneficial results of TAVR in terms of key clinical endpoints up to 5 years after the procedure, with similar transcatheter and surgical treatment outcomes at 2 years.

Another study from the area of valvular heart disease was the 2-year economic analysis from the PARTNER 3 study that compared costs and potential savings related to TAVI or SAVR in a population of patients with severe aortic stenosis at low surgical risk (PARTNER 3: Two-Year Economic Outcomes From a Randomized Trial of TAVR vs. SAVR in Patients at Low Surgical Risk) [5]. The study included 1000 patients with the STS score of < 4% who were then randomized in a 1:1 ratio to SAVR or TAVR, and this analysis focused on the economical aspect. The study showed that the hospitalization cost was 47 196 USD for TAVR and 46 606 USD for SAVR, while the cost of follow-up for up to 2 years after the hospital discharge was lower for TAVR (19 638 USD) compared to SAVR (22 258 USD). In summary, the overall 2-year cost was 66 834 USD for TAVR compared to 68 864 USD for SAVR, a 2030 USD difference. Thus, the cost of TAVR was lower despite much higher cost of the valve prosthesis, which is offset by a shorter duration of hospital stay and a lower cost of the procedure itself. In addition, the cost balance in favour of TAVR may be even higher if the cost of transcathether valve prosthesis is significantly reduced, provided that non-inferior mortality is preserved over a longer term follow-up.

Percutaneous left atrial appendage closure (LAAC) is an established procedure, commonly performed in many cardiac centres in Poland. According to the ESC guidelines on the management of atrial fibrillation, it may be considered to prevent stroke in patients with atrial fibrillation and contraindications to chronic anticoagulation. The Amplatzer Amulet (Abbott Scientific) and the Watchman (Boston Scientific) are the 2 devices best evaluated in clinical studies and mostly commonly employed for the procedure. The study presented on the third day, simultaneously published in the *Circulation*, A Randomized Trial of the Amulet Versus Watchman FLX Devices for Left Atrial Appendage Closure (SWISS-APERO) [6], is the first multicentre, randomized study comparing the Amulet and Watchman FLX devices. The authors randomly assigned 221 patients undergoing LAAC to the procedure using the Amulet (n = 111) or Watchman 2.5 or FLX (n = 110). The primary endpoint included justified crossover to a nonrandomized device during LAAC and residual patency of the left atrial appendage (LAA) identified during coronary computed tomography angiography at 45 days. Secondary endpoints included procedural complication, device-related thrombus, peri-device leak as evidenced by transoesophageal echocardiography (TEE), and clinical outcomes at 45 days. The primary endpoint occurred in 71 (67.6%) patients treated with the Amulet device comparted to 70 (70.0%) patients treated with the Watchman device (risk ratio [RR] 0.97; 95% CI: 0.80–1.16; p = 0.713). Major procedural complications were more common in the Amulet group (9% vs. 2.7%; p = 0.047), relative to higher bleeding rate (7.2% vs. 1.8%). Clinical outcomes at 45 days did not differ significantly between the 2 groups but the rate of incomplete appendage closure (peri-device leak) by TEE at 45 days was higher for the Watchman device (27.5%) compared to the Amulet device (13.7%). These results suggests that both Amulet and Watchman devices may be successfully implanted to nearly all LAAs deemed suitable for both devices, as evaluated by preprocedural TEE.

Antiplatelet agents have an established role in the management of CAD. Currently, a strong trend can be observed for individualization of the duration of dual antiplatelet therapy (DAPT) depending on the patient profile, with multiple possible options. Although platelet inhibition is necessary in CAD, it is not free from complications, including the most important of them — gastrointestinal bleeding. In the multicentre, randomized, placebo-controlled, double blind OPT-PEACE study (Mono-Versus Dual antiplatelet Therapy During 6–12 Months After New Generation Drug-Eluting Stent Implantation), which was simultaneously published in the *Journal of the American College of Cardiology* [7], the authors evaluated the rate and type of gastrointestinal mucosal damage using a magnetically steered endoscopic capsule. The study initially included 1028 patients at low risk of bleeding treated with PCI with stent implantation for chronic or acute coronary syndrome, in whom DAPT with acetylsalicylic acid (ASA) and clopidogrel was continued for 6 months provided certain criteria were met. Following this time, the patients who did not develop a major ischaemic or bleeding event (n = 505), were randomized to 3 groups of treatment continuation for another 6 months: ASA and placebo (n = 168), clopidogrel and placebo (n = 169), or ASA and clopidogrel (n = 168). At 12 months of follow-up, capsule endoscopy was repeated, yielding the following results: the primary endpoint that included gastric or small intestinal damage in the form of erosion, ulceration or bleeding during capsule endoscopy at 6 or 12 months occurred in nearly all patients, with similar rates in the DAPT and single antiplatelet therapy (SAPT) groups (99.2% vs. 94.3%; p = 0.02). The most prevalent form of gastrointestinal damage were erosions (96.9% vs. 93.6%), while ulcerations were less frequent (18.5% vs. 14.4%). Among patients receiving SAPT, the rates of gastrointestinal damage were similar (92.4% vs. 96.2%). In the analysis of a subgroup of patients without mucosal damage during the first 6 months of treatment, gastrointestinal mucosal damage was significantly less frequent among patients receiving SAPT compared to DAPT (68.1%

vs. 95.2%; p = 0.02). The results of this study clearly indicate that nearly all patients receiving antiplatelet agents showed evidence of gastrointestinal mucosal damage, which justifies considering an early switch from DAPT to SAPT, as the latter was associated with a lower bleeding rate and a lower risk of gastrointestinal mucosal damage, with similar effects of ASA and clopidogrel.

References

1. Fearon WF, Zimmermann FM, De Bruyne B, et al. FAME 3 Investigators. Fractional flow reserve-guided PCI as compared with coronary bypass surgery. N Engl J Med. 2022; 386(2): 128–137, doi: 10.1056/NEJMoa2112299, indexed in Pubmed: 34735046.
2. Xu Bo, Tu S, Song L, et al. FAVOR III China study group. Angiographic quantitative flow ratio-guided coronary intervention (FAVOR III China): a multicentre, randomised, sham-controlled trial. Lancet. 2021; 398(10317): 2149–2159, doi: 10.1016/S0140-6736(21)02248-0, indexed in Pubmed: 34742368.
3. Van Mieghem NM. 5-year clinician and echocardiographic outcomes from the randomized SURTAVI trial. Presented at: TCT 2021. Orlando, FL, November 5, 2021.
4. Reardon MJ, Van Mieghem NM, Popma JJ, Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2017; 376(14): 1321–1331, doi: 10.1056/NEJMoa1700456, indexed in Pubmed: 28304219.
5. David J. Cohen, MD, MSc on behalf of the PARTNER 3 Trial Investigators. PARTNER 3: two-year economic outcomes from a randomized trial of TAVR vs. SAVR in patients at low surgical risk. Presented at: TCT 2021. Orlando, FL, November 5, 2021.
6. Galea R, Marco FDe, Meneveau N, et al. Amulet or Watchman Device for Percutaneous Left Atrial Appendage Closure: Primary Results of the SWISS-APERO Randomized Clinical Trial. Circulation. 2022; 145(10): 724–738, doi: 10.1161/circulationaha.121.057859, indexed in Pubmed: 34747186.
7. Han Y, Liao Z, Li Yi, et al. Magnetically controlled capsule endoscopy for assessment of antiplatelet therapy-induced gastrointestinal injury. J Am Coll Cardiol. 2022; 79(2): 116–128, doi: 10.1016/j.jacc.2021.10.028, indexed in Pubmed: 34752902.