



CONCLUSION TA-MVIVR for degenerated bioprostheses can safely be performed in a patient population with a high proportion of cardiogenic shock with favorable clinical outcomes.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

TCT-503

Large Multicenter Evaluation of Clinical Outcomes of Transcatheter Valve-in-Valve Procedures Performed for Failed Mitroflow/Trifecta (externally mounted leaflets) Bioprostheses and Comparison with Conventional Stented Bioprostheses



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BACKGROUND Transcatheter aortic valve-in-valve implantation has become an established therapy for patients with failed surgical aortic bioprostheses. In patients with bioprostheses that have externally mounted leaflets (Mitroflow, Livanova and Trifecta [M/T]), concerns have been raised regarding the risk for coronary obstruction.

METHODS Based on the Valve-in-Valve International Data (VIVID), 1792 patients with a failed stented aortic bioprosthesis were analyzed. M/T bioprostheses have been previously implanted in 467 patients and their baseline characteristics and clinical outcomes were compared to 1325 patients with standard stented bioprostheses. At baseline, patients in the M/T group were older (79.9 ± 7.1 vs. 77.9 ± 9 years, p < 0.001) and were more frequently female gender (53.4 vs. 38.2%, p<0.001), had smaller bioprosthesis label sizes (22.4 ± 1.9 M/T vs. 23.4 ± 2.1 mm others; p < 0.001) and similarly smaller true ID (18.5 ± 1.9 M/T vs. 20 ± 2.2 mm others; p < 0.001). In general, there were no significant differences in procedural details (type of anesthesia, access site, re-dilation, or device malposition) except for a higher percentage of self-expandable devices used in the M/T group (62.1% M/T vs. 50.4% others, p<0.001).

RESULTS Coronary obstruction after valve-in-valve occurred more frequently in the M/T group (4.5% vs. 0.6%; p<0.001). There was greater 30-day mortality in the M/T group (5.4% M/T vs. 3%; p = 0.01). Postprocedural transvalvular gradients were significantly higher in the M/T group (18.8 ± 9.7 vs. 16.7 ± 8.7 mmHg; p < 0.001). There were no further relevant differences in other VARC events including stroke or paravalvular leakage. There was no difference in 1-year survival (log-rank p = 0.46).

CONCLUSION In this large multicenter data collection, transcatheter aortic valve-in-valves in M/T surgical valves were associated with a very significant increased incidence of coronary obstruction, in addition to higher post procedural gradients and early mortality in comparison to conventional stented surgical bioprostheses valve in

valve procedures. However, 1-year mortality did not differ between the groups.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-504

Transcatheter valve-in-valve therapy for degenerated mitral bioprostheses



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BACKGROUND Transcatheter valve-in-valve implantation (mViV) in patients with failing mitral bioprostheses is an emerging alternative for high-risk patients. We evaluated the mean pressure gradient (pmean) after mViV and if stenosis or insufficiency of the bioprosthetic has a differential impact on survival.

METHODS From 06/10-06/17 25 patients received mViV for degeneration of the bioprosthetic mitral valve.

RESULTS Mean patient age was 68.2±14.7 years. Mean logistic Euro-Score was 19.7%±11.7. Twelve (48%) patients were female. The median duration from mitral valve replacement until mViV was 10±3.5years. Fourteen (56%) patients showed a stenosis (MS) of their bioprosthesis (pmean preoperatively 14.1±4.2mmHg), six (24%) an insufficiency (MI) and the remaining five (20%) a combined valve pathology (MC). The majority of the procedures was performed through a transapical access (n=20), one patient received a transatrial access. Since 11/16, we have started to perform all procedures transseptally (n=4). Twenty-four Edwards Sapien valves (Edwards Lifesciences) and one Direct Flow prosthesis (Direct Flow Medical Inc.) were implanted. Periprocedural complications included n=1 conversion to surgical mitral valve replacement for valve migration, n=1 major bleeding from transapical access site, n=1 transient ischemic attack and n=1 valve thrombosis. In three patients a mild valvular and in three patients a mild paravalvular regurgitation was seen post-operatively. After mViV the mean pressure gradient of patients with MS declined to 7.1±4.1mmHg (p=0.001) and in patients with MI or MC to 5.7±2.3mmHg (p=0.04), respectively. 30-day survival was 100% for transapical and non-transapical access. One-year-survival was similar regardless of the mode of bioprosthetic valve failure with 91.7% for MS, 83.3% for MI and 100% for MC (p=n.s.), respectively.

CONCLUSION MViv can be deemed a reasonable therapeutic option for patients with degenerated mitral bioprostheses showing a low complication rate and reasonable survival in high risk patients. Hemodynamic assessment revealed significantly improved pressure gradients and only mild residual regurgitation.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

STEMI AND INCOMPLETE VS COMPLETE REVASCULARIZATION

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TCT-505

Prognostic role of initial and residual SYNTAX SCORE in patients WITH ST-SEGMENT ELEVATION myocardial infarction AFTER primary percutaneous coronary intervention



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BACKGROUND The aim of this study was to investigate the prognostic role of initial and residual severity of coronary atherosclerosis in patients with ST-segment elevation myocardial infarction (STEMI) who underwent primary percutaneous coronary intervention (PCI).

METHODS We recruited 327 consecutive patients with STEMI and multivessel coronary artery disease (MVCAD) who underwent primary PCI. We then assessed the severity of coronary atherosclerosis using coronary angiography and SYNTAX score. All patients were further stratified into two groups: 1) SYNTAX ≤ 22 points (n = 213); 2) SYNTAX ≥ 23 points (n = 114). Out of 327 patients included into initial

analysis, 317 underwent the secondary coronary angiography to assess the residual severity of coronary atherosclerosis after primary PCI. The patients were again divided into two groups: 1) ≤ 8 points ($n = 243$); 2) ≥ 9 points ($n = 74$). Major adverse cardiovascular events within 1 year of follow-up were considered as the study endpoints.

RESULTS Severe coronary atherosclerosis (SYNTAX ≥ 23 points) was significantly associated with a 4.9- and 5.6-fold increased risk of death from all causes and cardiac death, respectively. Moreover, it was significantly associated with a 3.5-, 5-, and 2.4-fold higher risk of MI, stent thrombosis, and combined endpoint, respectively. Higher residual coronary atherosclerosis (SYNTAX ≥ 9 points) was associated with a 3.4-, 2.7, and 2.6-fold higher risk of death from all causes, MI, and repeated non-target vessel revascularization compared to SYNTAX ≤ 8 points.

CONCLUSION Both initial and residual high SYNTAX score are able to predict the risk of major adverse cardiovascular events in patients with STEMI and MVCAD who underwent primary PCI.

CATEGORIES CORONARY: Acute Myocardial Infarction

TCT-506

An updated meta-analysis of randomized trials comparing complete versus culprit-only revascularization in patients undergoing primary percutaneous coronary intervention

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BACKGROUND The optimal management of patients presenting with ST-segment elevation myocardial infarction (STEMI) with concomitant obstructive coronary artery lesions in addition to the culprit lesion is poorly defined. Prior meta-analyses have not comprehensively compared revascularization rates between treatment strategies. We performed an updated meta-analysis of randomized trials comparing complete versus culprit-only revascularization.

METHODS We searched Medline, Embase, the Cochrane Central Register of Controlled Trials (CENTRAL), scientific session abstracts, and relevant websites for randomized trials investigating complete versus culprit-only revascularization in patients with STEMI published or posted between January 1, 2002 and April 30, 2017. The primary endpoint was all-cause death; secondary endpoints were revascularization at follow-up (excluding immediate or staged non-culprit lesion revascularization); cumulative revascularization (a composite of immediate or staged non-culprit revascularization and revascularization at follow-up); and myocardial infarction (MI). We derived odds ratios (OR) or incidence rate ratios (IRR) and calculated risk estimates for the main outcomes according to a random-effects model.

RESULTS 10 trials met the search criteria, randomizing 3,295 patients to complete ($n=1,561$) or culprit-only revascularization ($n=1,734$). All-cause death was similar for patients with complete and culprit-only revascularization (OR 0.81, 95% CI 0.57-1.15, $p=0.31$). Revascularization at follow-up was significantly lower in patients with complete revascularization (OR 0.39, 95% CI 0.32-0.49, $p<0.01$), however cumulative revascularization was significantly higher (IRR 3.98, 95% CI 3.52-4.49, $p<0.01$). Rates of MI were similar in both groups (OR 0.79, 95% CI 0.56-1.10, $p=0.12$).

CONCLUSION In patients randomized to complete or culprit-only revascularization in STEMI, rates of death and MI at follow-up are similar. Although rates of revascularization at follow-up are lower in patients with complete revascularization, cumulative revascularization is higher compared with culprit-only revascularization. Cumulative revascularization rates should also be considered when deciding between treatment strategies in STEMI.

CATEGORIES CORONARY: Acute Myocardial Infarction

TCT-507

Cost utility analysis of complete versus culprit-vessel only percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction in patients with multi-vessel disease

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BACKGROUND Multi-vessel coronary artery disease (MVD) in patients presenting with ST-segment elevation myocardial infarction (STEMI) is associated with poor outcomes. Percutaneous coronary intervention (PCI) of all lesions (complete) as compared with culprit lesion only appears to result in improved long-term outcomes based on recent randomized controlled trial data and meta-analyses. Our objective is to evaluate the cost-utility of complete versus culprit-vessel only PCI strategy.

METHODS Based on a systematic review and meta-analyses of the literature involving 10 RCTs, a model was developed to simulate costs and quality-adjusted life years (QALYs). In the first 12 months, a decision tree framework was used to define different cardiovascular outcomes for STEMI patients receiving either complete or culprit vessel revascularisation. Cost of comparative treatments and follow-up in relation to cardiovascular events were calculated from the UK National health service perspective.

RESULTS Higher procedural costs for complete revascularisation were offset by lower costs for repeat revascularisation, myocardial infarction and angina compared to culprit only patients. An ICER of £6,842 indicates a cost-effective strategy with results that were robust for different variations in the input variables.

CONCLUSION In this cost-utility analysis comparing complete versus culprit only revascularisation in STEMI patients with multi-vessel disease complete revascularisation is likely to be cost-effective. This analysis is based upon modern day NHS costs, quality of life utility data collected and relevant to primary PCI and outcome probabilities based on 9 RCTS comparing complete versus culprit revascularisation and is therefore the most reliable and complete analysis performed to date.

CATEGORIES OTHER: Cost-Effectiveness and Reimbursement Issues

TCT-508

Impact of incomplete revascularization in either diabetic and non-diabetic patients presenting with STEMI and multi-vessel disease

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BACKGROUND Optimal strategy for non-culprit lesion revascularization in patients presenting with ST-segment elevation myocardial infarction (STEMI) and multi-vessel disease remains controversial particularly in diabetic population.

METHODS This is an observational, single-centre study evaluating the impact of incomplete revascularization on clinical outcomes in diabetic and non-diabetic patients presenting with STEMI and multi-vessel disease. Clinical outcomes are reported at one year post primary PCI.

RESULTS A total of 761 patients with a minimum follow up of one year were evaluated. DM was diagnosed in 109 (14.3%) subjects, of whom 40 (36.7%) were on insulin therapy. Diabetes patients had more hypertension (69.7% vs. 37.1%, $p = 0.001$), chronic kidney disease (85.3% vs. 14.7%, $p = 0.001$) and three-vessel disease (29.1% vs. 48.6%, $p = 0.001$). A total of 88 diabetes patients and 472 patients in non-diabetic subgroup ($p = 0.067$) had at least one non-revascularized coronary stenosis after either index culprit only (72.5% vs. 63.8%, $p=0.079$), ad-hoc (11.9% vs. 15.8%, $p = 0.278$) or staged procedure (15.6% vs. 20.4%, $p = 0.243$). At one-year follow-up, incomplete revascularization was associated with higher mortality (13.6% vs. 5.7%, $p = 0.006$), re-infarction (8.0% vs 3.4%, $p = 0.037$) and MACE rates (31.8 vs. 22%, $p = 0.044$) in diabetes patients compared to non-diabetic patients. Complete coronary revascularization was associated with similar survival (4.8% vs. 3.9%, $p = 0.833$) re-infarction rates (0% vs. 1.7% $p = 0.555$) and MACE rate (4.8% vs. 6.1%, $p = 0.827$) in both groups.