Methods and results: A total of 470 patients, aged 83.4±6.4years, logistic Euroscore 21.9±12.3, undergoing TAVI with the Edwards valve were evaluated. PD was performed using the balloon delivery system when significant paravalvular AR was identified. The diameter of the valve was measured from cine acquisition at 3 different levels. PD was performed in 49 patients (10.4%) with grade 2, 3 or 4 AR in 42.1%, 55.3%, and 2.6%, respectively. After PD, a reduction of at least 1 degree of AR was achieved in 81.5% of cases (residual AR grade 2, 3 and 4 in 36.8%, 10.5%, and 0%, respectively). A significant increase in the prosthesis diameter was observed at the 3 valve levels (AbsoluteΔ3.5%-5.4%, $p<0.01$). For the 23mm valve, mid level of valve increased from 23.0±0.4 to 24.1±0.5mm ($p<0.01$) and for the 26mm, from 25.2±0.9 to 26.6±0.9mm ($p<0.01$). Occurrence of annulus rupture (4.2 vs 1.7%, p=0.24), cerebrovascular accidents (2.6 vs 2.4%, p=0.63), need for new pacemaker (8.3 vs 4.3%, p=0.31) and 30-day composite endpoint (25.5 vs 21.3%, p=0.50) were similar between PD and non PD group.
Conclusions: PD for the treatment of significant paravalvular leak after Edwards valve implantation is associated with a significant increase in valve diameter and decrease by at least one AR grade in 81.5% of cases. This promising approach may improve long-term outcome and warrants further investigation.

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Predictors of mortality following corevalve transcatheter aortic valve implantation: results from the ADVANCE study

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Purpose: Transcatheter aortic valve implantation (TAVI) is considered standard of care in patients at extreme risk of surgical aortic valve implantation, and as an alternative to surgery in those considered high risk. However, despite the high frequency of TAVI data being regularly reported in the literature, little evidence exists on predictors of survival.
Methods: The CoreValve ADVANCE study enrolled 1015 "real-world" patients at 44 centers in 12 countries in Western Europe, Asia and South America. Baseline characteristics include mean age, 81.1±6.4 years, 51% female, logistic EuroSCORE, 19.4±12.3%. All primary endpoint-related events were fully adjudicated according to VARC definitions by an independent Clinical Events Committee. A univariate Cox regression model was used to evaluate potential predictors of all-cause mortality at 1 year. Statistically significant variables with a P value$\leq$0.05 from the univariate analysis were included in the multivariate analysis.
Results: All-cause mortality at 1 year was 17.9%. Univariate analyses revealed several significant predictors of 1-year mortality; cerebrovascular disease, peripheral vascular disease; baseline serum creatinine, EuroSCORE, LVEF $\leq$50%, and mean AV gradient; major vascular complications, life-threatening bleeding, Stage III acute kidney injury (AKI), and discharge moderate/severe aortic regurgitation (AR); however after multivariate analysis only Stage III AKI (0.6% of patients) (HR, 9.91[95% CI, 3.76, 26.09], $P<0.001$), and discharge moderate/severe AR (16.0% of patients) (HR, 1.64 [1.03, 2.61], P=0.04) were significant.
Conclusions: In our study AKI was a rare event, but like other TAVI trials was found to be a positive predictor of mortality. The ADVANCE Study showed that the CoreValve System is associated with low mortality rates at 1 year, impacted only by post-procedural moderate to severe AR and Stage III AKI.

2588 | BEDSIDE
The DISCOVER CE Trial: multicenter prospective trial of the direct flow medical transcatheter aortic valve

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Background: The 18F Direct Flow Medical transcatheter aortic valve system is a next generation technology that has the potential to improve the outcome of TAVR. This design has conformable sealing rings which minimizes paravalvular aortic regurgitation (AR) and permits full assessment of valve performance prior to permanent implantation.
Objectives: The DISCOVER Trial is a prospective, multicenter, non-randomized CE evaluation of the safety and performance of the Direct Flow Medical Percutaneous Aortic Valve 18F System for the treatment of severe aortic stenosis in patients considered ineligible for surgery or at high risk for surgical complications.
Methods: Patients were required to have a logistic EuroScore $\geq$ 20 or other high surgical risk features not reflected by the logistic EuroSCORE. Patients were reviewed by an independent Patient Review Committee consisting of cardiac surgeons and interventional cardiologists. Acute procedural, 6 and 12 month clinical and echocardiographic VARC defined outcomes are assessed. All echocardiographic and angiographic data are evaluated by an independent core laboratory (Medstar) and adverse events adjudicated by an independent clinical event committee.
Results: At the time of abstract submission, 50 patients have been enrolled in the CE cohort. The average age was 84±5 (range of 71 to 94) years. The baseline logistic EuroSCORE was 27±12% (range: 2 – 55%) and STS score was 11.3±10.3%. Other baseline characteristics included: LVEF = 55.4±10%, 50% with CAD, 15% prior CABG, and 29% with CKD. A 25mm valve was used in 48% and 27 mm in 52%. There was 98% freedom from all cause mortality at 30 days. VARC defined 30 day patient safety freedom from events was 91% and device success was 97%. Core lab assessment of post procedure echocardiograms demonstrated 97% mild or less paravalvular AR and a mean gradient of 11.4±5.2 mmHg. 82% of the patients were reported in NYHA Class I/II at 30 days. The complete 6 month and available 12 month clinical and echocardiographic data will be presented.
Conclusions: The Direct Flow Medical Transcatheter Aortic Valve System provides excellent acute and midterm results including virtual elimination of aortic regurgitation. This technology has the potential to provide next generation clinical outcomes. The complete 6 month and available 12 month hemodynamic and clinical data will be available at the time of presentation.

RAPID FIRE – EVERYTHING ABOUT STENTING

2589 | BENCH
Prolonged clopidogrel use improves clinical outcomes following drug eluting but not bare metal stent implantation

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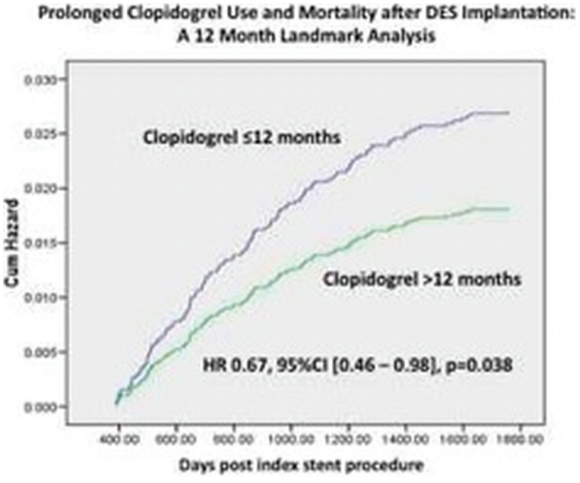
Purpose: Current guidelines recommend clopidogrel for 6-12 months following drug eluting stent (DES) implantation. The role of clopidogrel beyond 12 months is unclear.
Methods: We linked hospital administrative, community pharmacy and cardiac revascularization data to determine clopidogrel use and outcomes for all patients receiving a coronary stent in British Columbia 2004 - 2006 with follow-up to 5 years. Cox proportional hazard regression analysis was performed to determine the effect of prolonged clopidogrel use (>12 months) on outcomes. Patients who died $\leq$12 months from index stent placement were excluded.
Results: 15,629 patients were included in the study. Of 3,599 patients who received at least 1 DES and 12030 patients who received only bare metal stents (BMS), 1326 (37%) and 2121 (18%) respectively filled a prescription for clopidogrel >12 months from the index procedure. The mean duration of clopidogrel prescription in patients who received clopidogrel >12 months was 406±35 days in the DES group and 407±37 days in the BMS group, compared with 217±115 days ($p<0.0001$) and 117±116 days ($p<0.0001$) respectively for those who did not. Compared with $\leq$12 months clopidogrel, prolonged clopidogrel use was associated with a reduction in mortality (HR 0.67, 95% CI [0.46–0.98], p=0.038), mortality and readmission for myocardial infarction combined (HR 0.70, 95% CI [0.54–0.92], p=0.01) and an indication of a reduction in readmission for myocardial infarction alone (HR 0.70, 95% CI [0.49–1.00], p=0.051) in patients treated with DES, but not with BMS alone.



Conclusions: In contrast to BMS, clopidogrel use beyond 12 months following DES implantation was associated with improved clinical outcomes. Our data support a longer duration of clopidogrel therapy for patients treated with DES.