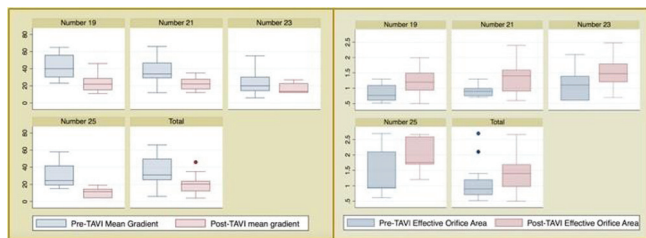


cases (24.4%) and size 25 (ID 21 mm) in 6 cases (13.3%). In relation to angio CT parameters, median of coronary heights were 7 and 7.6 mm (left and right coronary arteries, respectively). 11 patients (24.4%) were treated with Corevalve Revalving System and 34 patients (75.6%) with Evolut R Transcatheter Valve (Medtronic, Minn.). A 23 mm VIV was used for Mitroflow sizes 19, 21 and 23 and was implanted in 38 patients (86.7%). The 6 patients (13.3%) with Mitroflow size 25 were treated with 26 mm VIV. 42 (93.3%) procedures were transfemoral and 3 (6.7%) through a subclavian approach. Postdilatation was performed in 9 cases (20%). Left main coronary artery was protected in 6 cases (13.3%). 46.7% underwent general anesthesia.

There were no coronary occlusions, no deaths and no strokes related to procedure. In the 30 days of follow up, there were 2 deaths (4.4%), both of cardiovascular in origin. According to VARC2 definition, there were 2 major vascular complications (1 femoral occlusion that was treated with a covered stent and a pseudoaneurysm that required surgery) and 3 minor complications. 3 patients required a permanent pacemaker.

Both maximum and mean transvalvular gradients significantly decreased after VIV (from 66.1 ± 28.7 mmHg to 39 ± 14.9 mmHg and from 35.4 ± 16.2 mmHg to 19.5 ± 8.4 mmHg, $p < 0.001$), with higher gradients and lower effective orifice areas as smaller were the surgical valves (figure 1, $p < 0.05$). Significant reduction of the degree of aortic regurgitation was obtained, with absence of aortic regurgitation grade III or IV post TAVI.



Results according to Mitroflow sizes

Conclusions: The results of our pilot study suggest that the treatment of patients suffering Mitroflow SVD with a self expanding percutaneous prosthesis is effective and safe and it could be an alternative treatment for patients with this certain condition.

DIABETES – ASSOCIATED CORONARY ARTERY DISEASE

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Long-term safety and efficacy of the xience everolimus eluting stent in patients at high bleeding risk: a patient-level pooled analysis from four xience post-approval trials

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Background: High bleeding risk patients (HBR) are usually excluded from pre-approval drug-eluting stent trials (DES) due to concerns of increased bleeding risk for prolonged use of dual antiplatelet therapy (DAPT). These patients typically have high risk for ischemic events as well. The treatment of HBR patients in real-world practice remains a dilemma, and the long-term outcomes of these patients are largely unknown.

Purpose: To evaluate long-term ischemic and bleeding outcomes in HBR patients undergoing PCI with everolimus durable polymer DES.

Methods: We performed a patient-level pooled analysis of 4 all-comer real world post-approval trials (XIENCE V USA, XIENCE V Japan, XIENCE V China and XIENCE V India) with a total of 10,502 patients and up to 4-year follow up. HBR patients were identified as meeting ≥ 1 among: age ≥ 75 years, history of major bleeding (MB), prior-stroke, chronic anticoagulant use, renal insufficiency, anemia, or thrombocytopenia. Kaplan-Meier (K-M) estimates were used for time-to-event analyses. Multivariable logistic regression using stepwise selection was performed to determine independent predictors for 4-year mortality and MB.

Results: Of the total pooled population, 3507 patients (33%) presented HBR. Compared with non-HBR patients, HBR patients were older, more often female, and with more co-morbidities, such as diabetes, hypertension, renal insufficiency,

low ejection fraction, prior MI, multivessel disease and prior cardiac intervention. DAPT was used in 78% of HBR patients at 1 year and 40% at 4 years, significantly lower compared with non-HBR patients (85% and 45% at 1 and 4 years, respectively, $p < 0.0001$ for both time points). Four years outcomes are summarized in the Table. HBR was identified as an independent predictor for both mortality and MB. The role of DAPT adherence over time on ischemic-MB events will be presented.

Table 1. Rates of Ischemic and Bleeding Events

	HBR (N=3507)	Non-HBR (N=6995)	HR [95% CI]	P-value
Death	15.9%	3.8%	4.42 [3.79, 5.14]	<0.0001
Cardiac death	7.7%	1.9%	4.31 [3.46, 5.37]	<0.0001
Non-cardiac death	8.8%	2.0%	4.50 [3.65, 5.56]	<0.0001
Myocardial infarction	3.9%	2.3%	1.70 [1.34, 2.16]	<0.0001
Stent thrombosis (ARC definite/probable)	1.5%	0.6%	2.31 [1.51, 3.51]	<0.0001
Major Bleeding (TIMI Major or GUSTO severe)	4.4%	1.6%	2.85 [2.22, 3.67]	<0.0001

Conclusion: In this large pooled patient level analysis, HBR patients are significantly more complex and experience not only higher long-term MB rates but also higher rates of major cardiovascular events, including mortality, than non-HBR patients.

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P2263

Diagnostic performance of quantitative flow ratio in diabetic and non-diabetic patients

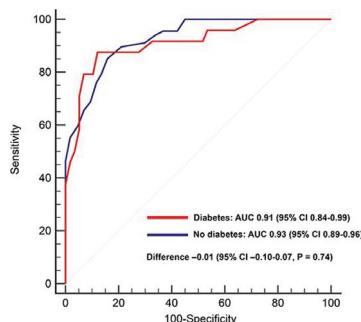
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Background/Introduction: Quantitative flow ratio (QFR) is a newly introduced technique to calculate fractional flow reserve (FFR), without hyperaemia induction or an invasive pressure-wire. The diagnostic performance of QFR could be affected by the presence of microvascular impairment, as QFR computation is based on a predictable hyperaemic response. Because microvascular impairment is highly frequent in diabetic patients, the diagnostic performance of QFR may be suboptimal in this patient population.

Purpose: The purpose of our study was to compare the diagnostic performance of QFR in diabetic and non-diabetic patients.

Methods: Patients who underwent invasive coronary angiography and subsequent invasive FFR measurement within 6 months were included. QFR was determined in all coronary arteries in which invasive FFR was performed, using a dedicated software package. Diagnostic accuracy and the area under the receiver operating characteristic (ROC) curve were determined for QFR, using FFR as the reference standard. QFR and invasive FFR values of ≤ 0.80 were considered significant.

Results: In total, 320 coronary arteries from 66 (25.5%) diabetic and 193 (74.5%) non-diabetic patients were analysed. In a vessel-based analysis, diagnostic accuracy, sensitivity and specificity showed no significant difference between diabetic and non-diabetic patients, 87.8% (95% confidence interval (CI) 78.7%-94.0%) vs. 84.5% (95% CI 79.2%-88.8%) ($P=0.47$), 70.8% (95% CI 48.9%-87.4%) vs. 68.7% (95% CI 56.2%-79.4%) ($P=0.72$) and 94.8% (95% CI 85.6%-98.9%) vs. 90.6% (95% CI 85.3%-94.6%) ($P=0.24$). Moreover, the area under the ROC curve was not significantly different between diabetic and non-diabetic patients, 0.91 (95% CI 0.84-0.99) vs. 0.93 (95% CI 0.89-0.96) ($P=0.74$).



ROC curves for QFR

Conclusion(s): In our study, we showed a good diagnostic performance of QFR which was independent of the presence of diabetes. Future prospective studies are warranted to demonstrate the diagnostic performance of QFR among different subpopulations.

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