target lesion failure [6.2% vs 5.3% HR 1.12 (0.80 - 1.58) I^2=0%], target lesion revascularization [4.9% vs 3.4% HR 1.40 (0.93 - 2.10) I^2=15%], target vessel failure [8.2% vs 6.1% HR 1.24 (0.75 - 2.04) I^2=0%], target vessel myocardial infarction [1.1% vs 1.8% HR 0.73(0.19 - 2.90) I^2=62%], and stent thrombosis [0.4% vs 0.6% HR 0.85 (0.27 - 2.62) I^2=0%]. There was no difference in the 2-year outcomes: Cardiac death [2.9% vs 2.0% HR 1.43 (0.77 - 2.66) I^2=0%], target lesion failure [7.8% vs 6.4% HR 1.22 (0.85 - 1.74) I^2=0%], and target vessel revascularization [5.4% vs 3.9% HR 1.39(0.89 - 2.19) I^2=0%].

CONCLUSION The COMBO DTS showed no difference in 1- and 2-year clinical outcomes compared to standard DES. There is a need for further studies to identify the subgroups that may benefit from this stent over standard DES.

500.04

Clinical Outcomes of the COBRA Polyzene-F Coronary Stent System for Percutaneous Coronary Intervention in Acute Coronary Syndromes

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BACKGROUND The COBRA-Polyzene-F (PzF) (CeloNova Biosciences, SanFransisco, Texas) is a novel coronary stent with PzF nano-coating. Preclinical studies have shown that PzF has a low surface thrombogenicity and is known to have anti-inflammatory, bacterial resistant, and pro-healing properties.

METHODS Between April 2017 and March 2018, out of a total of 7317 patients from the ACC-NCDR registry for patients who underwent percutaneous coronary intervention (PCI) at 5 large hospitals, 137 received COBRA-PzF stents. Patients were grouped based on coronary artery disease (CAD) presentation into 2 groups: acute coronary syndrome (ACS) (n=47) and non-acute coronary syndrome (non-ACS) (n=90). Both groups were compared for various in-hospital clinical outcomes post PCI with COBRA-PzF stents.

RESULTS Of 137 patients who received a COBRA-PzF stent, 4.26% of patients in the ACS group had myocardial infarction as compared to 2.22% in the non-ACS group (p=0.60) (Table 1). Similarly, cardiogenic shock (8.51% vs 2.22%, p=0.18) and post-procedural bleeding (6.38% vs 1.11%, p=0.11) were non-significantly higher in the ACS group as compared to non-ACS group. Patients in the ACS group had non-significantly higher in-hospital mortality (4.26%), pericardial tamponade (2.13%), and dialysis requirement (4.26%), while no such events occurred in the non-ACS group.

CONCLUSION PCI with COBRA-PzF stent showed no difference in in-hospital outcomes between the groups. The COBRA-PzF stent can be used safely with both ACS and non-ACS patients. Further clinical trials should be conducted to investigate safety and efficacy of the COBRA-PzF stent in patients with variable CAD presentation.

Table 1

Cobra-PzF	Acute Coronary Syndrome (n=47)	Non- Acute Coronary Syndrome (n=90)	p-value
Death (n,%)	2 (4.26%)	0	0.11
Myocardial Infarction (n,%)	2 (4.26%)	2 (2.22%)	0.6
Cardiogenic shock (n,%)	4 (8.51%)	2 (2.22%)	0.18
Tamponade (n,%)	1 (2.13%)	0	0.34
Dialysis requirement (n,%)	2 (4.26%)	0	0.11
Post-procedure bleeding (n,%)	3 (6.38%)	1 (1.11%)	0.11

EMERGING DEVICES & INNOVATIVE THERAPIES

500.05

Comparison Between Fractional Flow Reserve (FFR) vs. Computational Fractional Flow Reserve Derived from Three-dimensional Intravascular Ultrasound ($IVUS_{FR}$) and Quantitative Flow Ratio (QFR).

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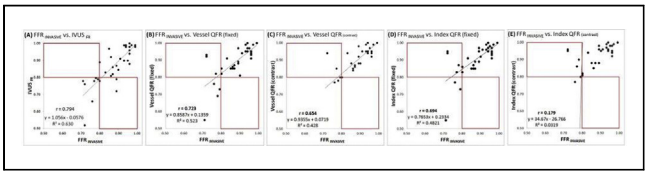
BACKGROUND The determination of the ischemic status of a coronary artery by wireless physiologic assessment derived from angiography has been validated and approved in the US. However, the use of plain angiography quantitative variables does not add much to the physiology data since it has low correlation with fractional flow reserve (FFR) and predicts clinical outcomes poorly. Recently, a gray scale intravascular ultrasound (IVUS) derived physiology method ($IVUS_{FR}$) was developed and showed a good correlation with invasive FFR by combining the geometric advantages of IVUS with physiology. The aim of this study is to assess the coefficient of correlation (R) of invasive FFR compared to $IVUS_{FR}$ and quantitative flow ratio (QFR).

METHODS Stable coronary artery disease (CAD) patients with intermediate lesions (i.e. 40-80% of diameter stenosis) were assessed by angiography and IVUS. QFR was derived from the angiography images, and $IVUS_{FR}$ was derived from quantitative IVUS data using computational fluid dynamics. Coefficient of correlation (R) was used in this report.

RESULTS Twenty-four patients with 34 lesions were included in the analysis. The $IVUS_{FR}$, invasive FFR, Vessel QFR fixed flow (vQFRf), and Vessel QFR contrast flow (vQFRc) values varied from 0.52 to 1.00, 0.71 to 0.99, 0.55 to 1.00, and 0.34 to 1.00, respectively. The coefficient of correlation (R) of FFR vs. $IVUS_{FR}$ was 0.79; FFR vs. vQFRf was 0.72; FFR vs. vQFRc was 0.65 (Figure).



CONCLUSION Compared to invasive FFR, $IVUS_{FR}$ and vQFRf showed a similar coefficient of correlation and were better than vQFR contrast flow.

500.06

Adverse Events and Modes of Failure Related to Impella RP: A Retrospective Analysis of the Manufacturer and User Facility Device Experience (MAUDE) Database

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BACKGROUND Right ventricular (RV) mechanical circulatory support remains an important adjunctive therapy for RV failure refractory to medical therapy. Impella RP (Abiomed, Danvers, MA) is approved for providing temporary RV support for patients with acute right heart failure or decompensation following acute myocardial infarction or after major cardiac surgery. Robust data on the most commonly reported complications and failure modes for the Impella RP is lacking. We analyzed the post-marketing surveillance data from the Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database to assess these endpoints.

METHODS The MAUDE database was queried from July 1, 2008, through July 31, 2018, for Impella devices by searching for the following event types: “injury”, “malfunction”, “death”, and “other”. After excluding left ventricular Impella devices and incomplete reports, 35 Impella RP device reports were included in the final analysis.

RESULTS In cases of reported complications, Impella RP was placed most commonly for RV failure developing in postcardiotomy patients (20%) followed by myocardial infarction with cardiogenic shock (14.2%) and post left ventricular assist device placement (11.4%). The most commonly reported complications were bleeding (42.9%) and vascular complications (22.8%). The modes of failure included damage or fracture of the device elements (34.2%); thrombus, or clot in the system (17.1%); and device detachment (8.6%). Table 1 and Table 2 provide a complete list of complications and modes of failure respectively.

CONCLUSIONS Findings from the MAUDE database highlight the failure modes of the Impella RP device that should be addressed in order to improve the device performance and obtain improved clinical outcomes when utilized for RV failure.