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CRT-700.34 Short-Term Outcomes Among Aortic Valve Stenosis Patients Undergoing Impella-Supported High-Risk Percutaneous Coronary Intervention

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CRT-700.3

The Association Between Gender and Complication of the Transcatheter Aortic Valve Replacement by the Difference of the Type of Valve

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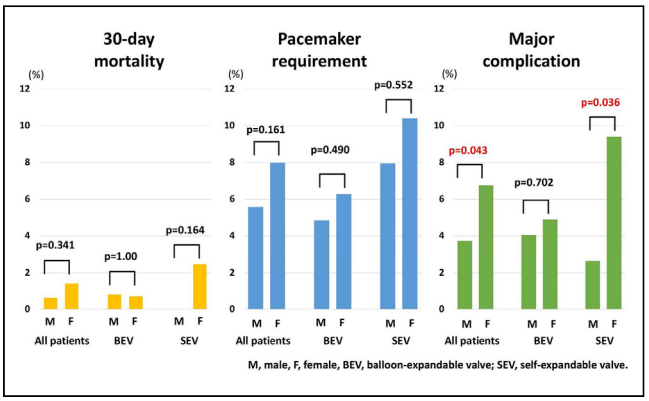
BACKGROUND According to the previous studies, the procedural complication on transcatheter aortic valve replacement (TAVR) were more common in females than males. However, the difference of those outcomes between types of valve, have not been fully elucidated. Therefore, we aimed to evaluate the impact of gender on TAVR complications between self and balloon-expandable valve.

METHODS A cohort of 971 patients, who underwent a TAVR procedure in our institution between January 2016 and September 2021, were included and retrospectively analyzed. Patients were divided into self-expandable valve (SEV: n=315) and balloon-expandable valve (BEV: n=656) group according to the type of a TAVR valve. We evaluated the proportion of short-term mortality (within 30 days), pacemaker requirement, and major complications (which was defined as composite occurrence of cardiac arrest, stroke, myocardial infarction, major bleeding, and unplanned vascular surgery/intervention).

RESULTS Female gender is more common in the SEV group than in the BEV group (64.1% vs. 43.6%: p<0.0001), while there is no significant difference in the prevalence of hypertension (93.3% vs. 90.6%, p=0.138), diabetes mellitus (33.0% vs. 35.4%, p=0.470), current smoker (4.1% vs. 2.4%, p=0.161), hemodialysis (3.5% vs. 5.2%, p=0.259), and STS score (5.4±3.6 vs. 5.7±4.6, p=0.288) between 2 groups. Females had a higher rate of complications in all categories, however, only vascular complications in the SEV group showed a significant difference (Figure).

CONCLUSION Complications were more common in females in all categories, but only vascular complications were proven to be significantly higher mainly in the SEV group. Particular attention should be given to access choices in females undergoing TAVR.



CRT-700.33

Performance and Use of the Evolut FX Transcatheter Aortic Valve System: Results From the Evolut FX Limited Market Release Clinical Survey

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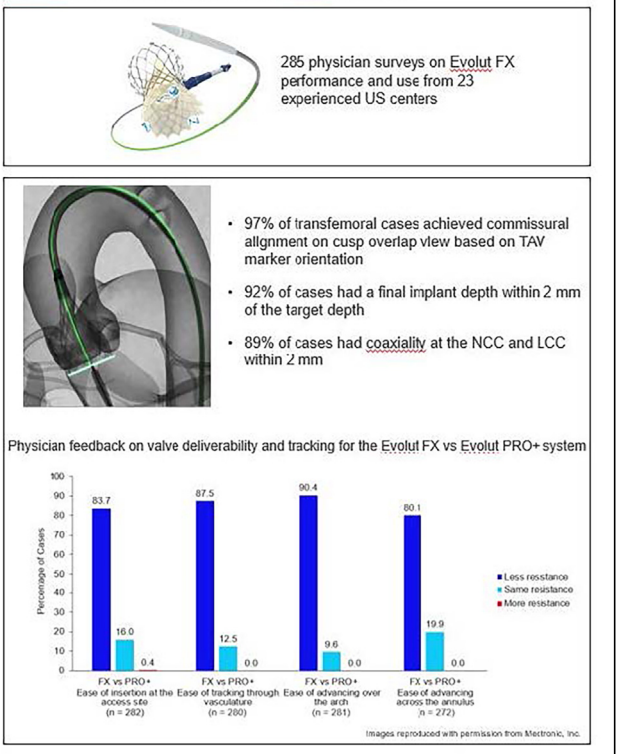
BACKGROUND The next generation supra-annular, self-expanding Evolut FX transcatheter aortic valve (TAV) system (Medtronic, Minneapolis, MN) has been redesigned to improve deliverability, trackability, and deployment accuracy. Enhancements include a more tapered catheter tip and flexible catheter shaft, single-spine delivery system, optimized deployment stability layer, and 3 radiopaque commissural markers on the TAV frame. The impact of these enhancements has not been evaluated.

METHODS Physician feedback was obtained between Jun 24 - Aug 12, 2022 at 23 experienced US centers using a benchmark survey that compared Evolut FX to the predicate PRO+ system. Descriptive statistics were summarized.

RESULTS A total of 285 surveys (1/case) were collected. Evolut FX valves (23 mm, 5%; 26 mm, 25%; 29 mm, 47%; 34 mm, 23%) were implanted via transfemoral (TF) access in 98% of cases. Guidewires used included the Confida (19%), Safari (42%), and Lunderquist (38%). The cusp-overlap (CO) technique was used in 87% of cases. Commissural alignment at the CO view based on TAV marker orientation was achieved in 97% of TF cases. Final implant depth at the noncoronary cusp (NCC) averaged 3.0±1.7 mm. Implant accuracy, defined as absolute difference in target minus final implant depth at the NCC, was 0.9±1.1 mm; 92% of cases had a final implant depth ≤2 mm of the target depth. Coaxiality at the NCC and LCC was ≤2 mm in 89% of cases. Most physicians noted better deliverability and tracking with Evolut FX compared to the PRO+ system (Figure).

CONCLUSION Survey results from experienced Evolut TAVR teams using Evolut FX demonstrated improved deliverability, tracking, coaxiality, and deployment accuracy compared to PRO+. A high (>95%) rate of commissural alignment was achieved, which may facilitate future coronary access.

Figure. Clinical survey results of physician feedback on valve deliverability, tracking, coaxiality, and deployment accuracy for the Evolut FX system



CRT-700.34

Short-Term Outcomes Among Aortic Valve Stenosis Patients Undergoing Impella-Supported High-Risk Percutaneous Coronary Intervention

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BACKGROUND Among patients undergoing percutaneous coronary intervention (PCI), severe aortic stenosis (AS) is associated with an increased risk of adverse outcomes. Although the use of mechanical circulatory support with Impella has been shown to improve 90-day outcomes in patients undergoing high-risk PCI (HRPCI), there is little information about the safety of this approach in pts with severe AS. We, therefore, sought to evaluate the efficacy and safety outcomes of Impella-supported HRPCI among patients with varying severity of AS.

METHODS We studied patients enrolled in PROTECT III—a multicenter study of patients undergoing Impella-supported HRPCI. Patients were classified according to the severity of AS: none/trivial, mild, moderate, and severe. The primary outcome was the rate of major adverse cardiac and cerebrovascular events (MACCE) at 90 days, defined as the composite of all-cause death, MI, stroke/ TIA, and revascularization. Secondary outcomes included in-hospital PCI-related complications, stroke/TIA, and vascular complications requiring surgery.

RESULTS Of 596 patients with echocardiographic data, 490 had no/trivial AS, and 34, 27, and 45 had mild, moderate, or severe AS, respectively. Patients with AS were older, less likely to have diabetes, more likely to have left main disease, and had higher left ventricular ejection fractions (Table). Severely calcified lesions and the use of atherectomy were more frequent among patients with moderate or severe AS. There were no differences in rates of PCI-related complications, stroke/TIA, 30-day MACCE, or 90-day MACCE according to AS severity. Rates of transfusion were higher among patients with AS—regardless of severity.

CONCLUSION Among patients undergoing Impella-supported HRPCI, PCI-related complications and 90-day outcomes did not differ based on AS status or severity.

Table. Baseline Characteristics, In-Hospital, and 90-day Outcomes according to AS Severity

	No/trivial AS(n=490)	Mild AS(n=34)	Moderate AS(n=27)	Severe AS(n=45)	P value
Baseline and Procedural Characteristics					
Age (years)	69.7 ± 11.0	77.4 ± 8.9	79.8 ± 9.8	79.1 ± 10.3	<0.0001
Sex, male	71.8%	82.4%	74.1%	62.2%	0.26
Hypertension	87.8%	94.1%	100.0%	95.6%	0.07
Diabetes mellitus	60.7%	55.9%	44.4%	33.3%	0.002
Chronic kidney disease	28.1%	36.4%	33.3%	38.6%	0.37
Peripheral vascular disease	19.5%	17.6%	29.6%	19.0%	0.62
Prior Stroke/Transient ischemic attack	17.0%	21.2%	25.9%	15.9%	0.62
Congestive heart failure	57.6%	67.6%	57.7%	60.0%	0.71
Left ventricular ejection fraction, %	34.0 ± 14.9	41.0 ± 17.8	40.3 ± 18.4	41.9 ± 15.8	0.0003
Acute coronary syndrome	58.7%	57.1%	50.0%	32.6%	0.01
3 vessel coronary artery disease	59.0%	64.7%	59.3%	48.9%	0.51
Left main disease	57.6%	79.4%	66.7%	70.5%	0.03
Number of treated lesions at the index procedure	2.6 ± 1.5	2.6 ± 1.7	2.3 ± 1.4	2.4 ± 1.3	0.44
Severely calcified lesions	51.1%*	50.0%*	74.5%*	58.3%*	0.006
Atherectomy use	54.1%	68.0%	91.3%	72.7%	0.0009
Procedural and In-hospital Outcomes					
PCI related complication‡	2.7%	0%	3.7%	0%	0.17
Stroke/TIA	1.4%	0%	0%	0%	0.67
Severe heart failure requiring IV inotrope, ultra-filtration or MCS	0.4%	0%	0%	0%	0.93
Anemia requiring transfusion	5.9%	14.7%	14.8%	13.3%	0.03
Vascular complication requiring surgery	0.8%	0%	7.4%	0%	0.007
Primary Outcomes (KM analysis)					
30-day MACCE†	10.1%	13.8%	3.7%	4.9%	0.39
90-day MACCE†	14.6%	17.7%	3.7%	7.4%	0.32

‡PCI related complications defined as composite of no reflow, abrupt closure, dissection, distal embolus, and perforation. †MACCE is defined as the composite of all-cause death, myocardial infarction, stroke/transient ischemic attack, and revascularization.

CRT-700.35

Echocardiographic Transprosthetic Gradients After Implantation of Contemporary Transcatheter Valves in Patients With Small Annuli- From TAVI-SMALL 2 Registry

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