Results: Average patient age was 81.2±6.1 years with most patients being in NYHA Class III–IV (76.1%). The transfemoral approach (75%) was the most common route used in 80% of patients. No patients had major bleeding, stage 2 or 3 kidney dysfunction requiring intervention, major vascular complications or repeat procedures for valve-related dysfunction. Secondary end-points were: post-TAVI transaortic gradient reduction; and device success.

Results: Baseline comparison between patients treated with different prostheses revealed no significant demographic and clinical characteristics. Patients treated with DFM had higher safety rates, with respect to MCV and ES (respectively 90.5% vs. 42.9% vs. 57.1%; p=0.004) at 30-day follow up. Post-TAVI transaortic gradient reduction was similar for DFM, MCV and ES subgroups (8.3±3.2 mmHg vs. 5.3±3.7 mmHg vs. 5.6±5.1 mmHg, respectively; p=0.155). Likewise, device success did not differ significantly (100% vs. 95.2% vs. 90.5%, respectively, p=0.21). In the pooled binary logistic regression analysis, DFM prostheses was independent predictor of early safety (DFM vs. MCV: OR 11.2, 95% CI 1.9-66.7, p=0.008; and DFM vs. ES: OR 5.8, 95% CI 1.0-35.7, p=0.05). Some patients with DFM had higher rates of minor complications, likely to make TAVI cheaper. Future trials should prospectively assess the “pathway” costs for both TAVI and conventional surgery, rather than just procedural costs.

TCT-748
First Human Cohort Transcatheter Aortic Valve Implantations Of The Colibri Heart Valve, A Pre-Mounted, Pre-Packaged, Low Profile Ready for Use, Dry Valve In A 1 French Delivery System. Fifteen months of Follow Up

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Background: The purpose of this study was to demonstrate the feasibility and pro- cedural success of the Colibri Transcatheter Aortic Heart Valve. The Colibri Heart valve is the lowest profile (14Fr) first dry valve. It comes completely and sterilized ready for use from the package to the patient. Currently available aortic valves, for surgical or catheter implantation, require rinsing of the chemicals they contain and rinsing of the valve (TAVI cases) before implantation. We describe here the outcome of the first in human cohort of implants of the Colibri Heart Valve up to 15 months of follow up.

Methods: After the initial successful clinical and hemodynamics results of the first Colibri Transcatheter Aortic Valve Implant (CTAVI), we performed, under a compassionate use protocol, four additional consecutive CTAVI patients with severe aortic stenosis who were not surgical candidates. All patients were symptomatic NYHA class 3-4, and had preserved ejection fraction. The five patients’ average aortic valve mean gradient (MG) pre-procedure was 53 mmHg and the average aortic valve area (AVA) of 0.71 cm2. All cases were accessed transapically after surgical exposure of the artery. Balloon aortic valvuloplasty was performed before the CTAVI implantation.

Results: The valve was implanted successful in the orthotopic position in all cases under rapid ventricular pacing and fluoroscopic guidance. The MG dropped to 8.4 mmHg and the AVA increased to 2.2 cm2, there were no transvalvular regurgitations, no need for permanent pacemaker and no stroke. One case had mild paravalvular insufficiency. All patients were discharged home ambulatory. Follow-up for 15 months (n1), 7 months (n2), and 3 months (n3) with excellent clinical outcomes. NYHA 1, no evidence of major adverse events and maintenance of mean gradients of 10 mmHg and AVA of 2.2 cm2.

Conclusions: The Colibri HV implantations, the world’s first pre-package, sterilized, dry valve and ready for use in 14Fr system is feasible and safe. The beneficial clinical and hemodynamic outcomes are persistent up to 15 months with low gradients and large aortic valve area. This low profile valve opens the opportunity to treat patients with small femoral arteries.

TCT-749
Thirty-day results after transcatheter aortic valve implantation with Direct Flow Medical valve compared with Medtronic CoreValve and Edwards Sapien XT valve

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Background: Direct flow medical (DFM) prostheses is a non-metallic, repositionable and retrievable bioprosthetic valve which has never been previously compared with current status of care. In this study we sought to compare the procedural and 30-day outcome after transcatheter aortic valve implantation (TAVI) with three different prostheses: DFM vs. Medtronic Core Valve (MVC) vs. Edwards Sapien XT (ES).

Methods: Twenty-one consecutive patients treated with DFM for severe aortic stenosis were matched to an equal sample of patients undergoing TAVI with MVC and ES (1:1:1 propensity score-matching). Primary end-point was 30-day safety, defined according to the VARC criteria as the composite of all-cause mortality, stroke, life-threatening bleeding, stage 2 or 3 kidney dysfunction requiring intervention, major vascular complications or repeat procedures for valve-related dysfunction. Secondary end-points were: post-TAVI transaortic gradient reduction; and device success.

Results: Baseline comparison between patients treated with different prostheses revealed no significant demographic and clinical characteristics. Patients treated with DFM had higher safety rates, with respect to MVC and ES (respectively 90.5% vs. 42.9% vs. 57.1%; p=0.004) at 30-day follow up. Post-TAVI transaortic gradient reduction was similar for DFM, MVC and ES subgroups (8.3±3.2 mmHg vs. 5.3±3.7 mmHg vs. 5.6±5.1 mmHg, respectively; p=0.155). Likewise, device success did not differ significantly (100% vs. 95.2% vs. 90.5%, respectively, p=0.21). In the pooled binary logistic regression analysis, DFM prostheses was independent predictor of early safety (DFM vs. MCV: OR 11.2, 95% CI 1.9-66.7, p=0.008; and DFM vs. ES: OR 5.8, 95% CI 1.0-35.7, p=0.05). Some patients with DFM had higher rates of minor complications, likely to make TAVI cheaper. Future trials should prospectively assess the “pathway” costs for both TAVI and conventional surgery, rather than just procedural costs.