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Indications: The Edwards SAPIEN XT transcatheter heart valve (THV) systems are indicated for use in pediatric and adult patients with a dysfunctional, non-compliant right ventricular outflow tract (RVOT) conduit with a clinical indication for intervention and: pulmonary regurgitation ≥ moderate and/or mean RVOT gradient ≥ 35 mmHg.

Contraindications: The THV and delivery systems are contraindicated in patients with inability to tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. Assessment for coronary compression risk prior to valve implantation is essential to prevent the risk of severe patient harm. Incorrect sizing of the THV may lead to paravalvular leak, migration, embolization and/or RVOT rupture. Accelerated deterioration of the THV may occur in patients with an altered calcium metabolism. Prior to delivery, the THV must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. THV leaflets mishandled or damaged during any part of the procedure will require replacement of the THV. Do not use the THV if the tamper evident seal is broken, the storage solution does not completely cover the THV, the temperature indicator has been activated, the THV is damaged, or the expiration date has elapsed. Do not mishandle the NovaFlex+ delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g. kinked or stretched), or the expiration date has elapsed. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Patient injury could occur if the delivery system is not un-flexed prior to removal. Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. THV recipients should be maintained on anticoagulant/antiplatelet therapy as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution, rinse solutions, or to the THV.

Precautions: Safety, effectiveness, and durability of the THV have not been established for implantation within a previously placed surgical or transcatheter pulmonic valve. Long-term durability has not been established for the THV. Regular medical follow-up is advised to evaluate THV performance. Glutaraldehyde may cause irritation of the skin, eyes, nose and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, immediately flush the affected area with water and seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Material Safety Data Sheet available from Edwards Lifesciences. Patient anatomy should be evaluated to prevent the risk of access that would preclude the delivery and deployment of the device. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: Echocardiographic evidence of intracardiac mass, thrombus, or vegetation; a known hypersensitivity or contraindication to aspirin, heparin or sensitivity to contrast media, which cannot be adequately premedicated; pregnancy; and patients under the age of 10 years.

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Indications: The Edwards crimper is indicated for use in preparing the Edwards SAPIEN XT transcatheter heart valve for implantation.

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Precautions: For special considerations associated with the use of this device prior to THV implantation, refer to the SAPIEN XT transcatheter heart valve Instructions for Use.

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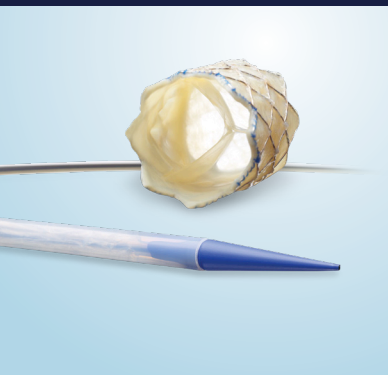
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Contraindications

None known

Warnings/Precautions/Side Effects

- **DO NOT implant in the aortic or mitral position. Pre-clinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations.**

- DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22 Fr size introducer, or if there is significant obstruction of the central veins.

- DO NOT use if there are clinical or biological signs of infection including active endocarditis. Standard medical and surgical care should be strongly considered in these circumstances.

- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.

- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.

- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.

- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice.

Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, blistering, or peeling of skin, pain, swelling, or bruising at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: stent fracture*, stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

*The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions for Use provided with the product or available on http://manuals.medtronic.com.

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Important Labeling Information
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Indications

The Melody™ TPV is indicated for use in patients with the following clinical conditions:

- Patients with regurgitant prosthetic right ventricular outflow tract (RVOT) conduits or bioprostheses with a clinical indication for invasive or surgical intervention, OR

- Patients with stenotic prosthetic RVOT conduits or bioprostheses where the risk of worsening regurgitation is a relative contraindication to balloon dilatation or stenting

Contraindications

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath

- Implantation of the TPV in the left heart

- RVOT unfavorable for good stent anchorage

- Severe RVOT obstruction, which cannot be dilated by balloon

- Obstruction of the central veins

- Clinical or biological signs of infection

- Active endocarditis

- Known allergy to aspirin or heparin

- Pregnancy

Potential Complications/Adverse Events: Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, pain, swelling or bruising at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: stent fracture*, stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

*The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

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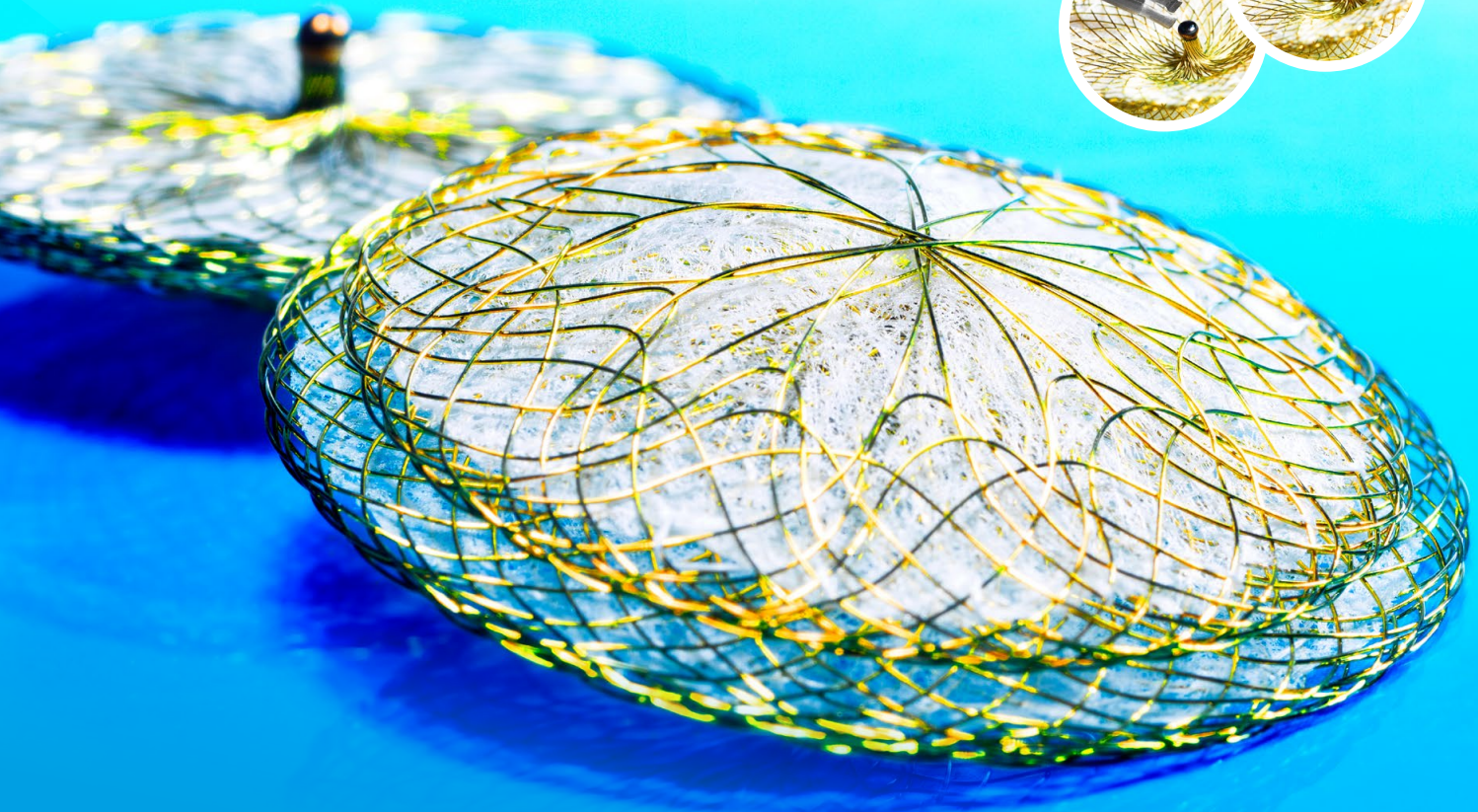
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Towards "Primary" TAVI: Transcatheter Aortic Valve Implantation without Computerised Tomography, Transoesophageal Echocardiography or General Anaesthesia

Does Retrospective Data Provide Support for the Concept?

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Abstract

Background: In the elective setting, advanced adjunctive technology is appropriately used to aid TAVI. However, extensive pre-procedural work-up may not be possible in an acute setting.

Methods: We examined retrospective data from early TAVI practice to inform the concept of "primary" acute TAVI. Data was examined from two UK TAVI centres (2007-2012) prior to routine use of computerised tomography (CT). 30-day and 1 year clinical outcomes were assessed. Mortality tracking was obtained as of December 2012.

Results: 384 underwent TAVI at the two sites during this period. Patients were aged 81.4±7.0 years. 46.3% were male. Logistic EuroSCORE was 19.2±11.6. Peak aortic valve gradient and aortic valve area were 79.7±25.2mmHg and 0.62±0.20cm2 respectively. Aortic annular size was assessed by transthoracic echo (TTE; 73.4%) or transoesophageal echo (TOE; 24.5%) and was 23.1±2.4mm. Iliofemoral assessment was by invasive contrast angiography (99.5%). Procedures were performed under local anaesthetic (39.1%), local anaesthetic and anaesthetic sedation (46.0%), or general anaesthesia (14.9%). Device implantation was predominantly with the CoreValve self-expanding prosthesis (87.7%), via the femoral approach (90.7%). Procedural imaging was TTE (85%), TOE (3.4%), or none (11.6%). Device implantation success rate was 96.1%. Procedural complications included death (0.8%) and emergency valve-in-valve implantation (3.1%). Aortic regurgitation ≥grade2 (moderate/severe) was observed in 12.5%. Mortality rates were 9.3%, (30-day) and 15.2% (one-year).

Conclusion: A minimalist approach to TAVI does not offer contemporary levels of procedural success. A 95% success rate may be considered acceptable in emergency or urgent settings. A self-expanding prosthesis may be particularly suited to this clinical scenario.

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Introduction

Aortic stenosis affects 5% of people over the age of 75 years [1]. Left untreated, prognosis is poor. Trans-catheter aortic valve implantation (TAVI) has become an established treatment for patients with

severe symptomatic aortic stenosis who are at an intermediate or high risk for surgery [2, 3].

Patient selection remains fundamental to achieving successful outcomes with TAVI. A key step in the selection process is systematic anatomical work-up from access site to implantation site using multi-modality imaging. The most important aspect of anatomical screening involves assessment of the aortic valvular complex and the peripheral arterial vasculature, allowing identification of the optimal prosthesis size and the most appropriate access route. In the elective setting, multi-slice computed tomography (MSCT) of the aortic valve complex, aorta, and iliofemoral vessels is the gold standard assessment [4]. General anesthesia (GA) is usually required when transesophageal echocardiography (TEE) is used, both for the comfort of the patient and to maintain a secure airway [5].

However, patients with severe aortic stenosis may present as urgent or emergency cases and be unable to undergo standard investigations due to clinical instability or renal dysfunction. Balloon aortic valvuloplasty "bridging" to TAVI may be used but is not low-risk in this setting [6]. The use of emergency TAVI is increasing [7-11].

During the early use of TAVI, computed tomography (CT) pre-assessment was not routine. We used retrospective data to analyze whether a minimalist approach to TAVI, with minimal use of CT, TEE, and GA, could yield reasonable TAVI outcomes and thus whether this approach could be appropriately used in urgent or emergency settings as "primary" TAVI.

Materials and Methods

Patient Population

The study population comprised 384 consecutive patients from two high-volume centers (Brighton and Belfast) in the United Kingdom over a 5-year period (2007–2012). Patients were assessed using iliofemoral angiography and TTE. MSCT or TEE was used in only a minority of cases during this period. Valve sizing was based on a combination of TTE annular measurements (which provide an anteroposterior measurement) and the aortogram (which provides a lateral measurement). The optimal implant was derived from aortography starting in the anterior-posterior/

caudal 15° projection, adjusting according to the initial image. A self-expanding CoreValve prosthesis was used in most cases, and the degree of oversizing was at the discretion of the operators.

All TAVI case data were entered prospectively into local dedicated databases based on a predetermined dataset agreed upon by the Society for Cardiothoracic Surgery in Great Britain and Ireland and the British Cardiovascular Intervention Society. This included information on patient demographics, risk factors, and outcome measures. Data consistency was assured by internal audit undertaken independently. Peri-procedural and post-procedural complications were reported according to definitions defined within the national dataset at the time [5]. All data were cross-checked prior to uploading to the Central Cardiac Audit Database. Mortality tracking was obtained via the Medical Research Information Service for the English cohort and via the General Register Office of Northern Ireland for the Northern Irish cohort. Mortality tracking was successful in 100% of cases.

Endpoints

The primary endpoint of the study was all-cause mortality assessed at 30 days and 1 year. The secondary endpoint was in-hospital major adverse cardiovascular events (MACE), defined as a composite of in-hospital death, myocardial infarction, and stroke.

Definitions

Device success was defined as implantation of a single functioning prosthetic valve within the aortic annulus, with stable hemodynamics, absence of severe paravalvular aortic regurgitation, and no peri-procedural mortality or conversion to emergency open valve surgery. Safety and efficacy endpoints were defined using Valve Academic Research Consortium (VARC) definitions [7].

Statistical Analysis

Categorical data are presented as percentages, and comparisons between groups were performed using Chi-square tests. Continuous data are presented as mean ± standard deviation (SD) or median (interquartile range), and comparisons between groups were performed with two-sample t-tests. Time-to-event data analysis was performed using Cox propor-

tional hazards models. A Kaplan-Meier survival curve was drawn to assess differences between groups for time-to-event data. Analyses were performed using Stata 10.1 (StataCorp, College Station, TX, USA).

Results

Patient Demographics and Pre-Procedural Characteristics

Baseline demographics including risk factors are shown in Table 1. Patients were aged 81.4 ± 7.0 years, and 46.3% were male. Mean logistic EuroSCORE was 19.2 ± 11.0. Approximately one-quarter of patients (28.8%) had significant coronary artery disease involving at least one epicardial coronary artery, 15.8% had extensive aortic calcification, and mean creatinine was 127.7 ± 80 mmol^{-1}.

TAVI was indicated for significant aortic stenosis in 90.3% of cases, aortic regurgitation in 4.7%, and mixed aortic valve disease in 5.0%. "Valve-in-valve" due to previous surgical bio-prosthesis failure represented 5.7% of cases, and 1.8% of cases were for true bicuspid valve stenosis (Table 2).

Pre-procedural assessment of the aortic valve complex, including annular measurement, was made by TTE (73.4%), TEE (24.5%), or MSCT (0.5%). Mean annular diameter in the overall patient cohort was 23.1 ± 2.4 mm. Mean peak aortic gradient was 79.7 ± 25.2 mmHg, and mean valve area was 0.62 ± 0.20 cm^2 (Table 2). Analysis of vessel diameter, tortuosity, and calcification was made by iliofemoral angiography (99.5%) or MSCT (0.5%; Table 2).

With regard to procedural anesthesia, GA was used in 14.9% of cases, usually for "surgical" approaches to TAVI. Most procedures were performed under local anesthesia (lignocaine 1%) with either intravenous paracetamol (39.1%) or conscious sedation (remifentanil/propofol; 46%).

Peri-Procedural Characteristics

Peri-procedural characteristics are shown in Table 2. Most patients (87.7%) underwent TAVI using the self-expanding CoreValve prosthesis (Medtronic CoreValve System, Medtronic, Luxembourg). Procedures were performed via the retrograde transfemoral (90.7%), subclavian (4.9%), axillary (0.5%), direct aortic (2.3%), or trans-apical approach (1.3%). Other

Table 1. Patient demographics

Characteristic		TAVI N=384
Age yr (mean±SD)		81.4 ±7.0 (384)
Male sex (%) no./total no.		46.3 (177/382)
Height cm (mean±SD)		165±9.3
Weight kg (mean±SD)		74.1±15.2 (382)
Caucasian		99.4 (382/384)
Logistic EuroSCORE (mean±SD)		
NYHA class (%) no./total no.		
	II	9.9 (38/383)
	II	66.3 (254/383)
	IV	22.5 (86/383)
Coronary artery disease (%) no./total no.		
	Left main stem	2.4 (9/381)
	1 vessel with diameter stenosis >50%	13.1 (50/382)
	2 vessel with diameter stenosis >50%	7.3 (28/382)
	3 vessel with diameter stenosis >50%	6.0 (23/382)
Extensive calcification of the acending aorta (%) no./total no.		15.8 (60/380)
Previous myocardial infarction (%) no./total no.		23.8 (91/383)
Previous intervention (%) no./total no.		
	Coronary artery bypass surgery	21.7 (83/382)
	Surgical valve replacement	6.5 (25/382)
	Other operation requring opening of the pericardium	1.8 (7/382)
	Percutaneous coronary intervention	24.0 (92/383)
	Balloon aortic valvuloplasty	10.2 (39/384)
Diabetes disease (%) no./total no.		21.4 (82/383)
Pulmonary disease (%) no./total no.		
	Asthma	19.3 (74/383)
	Chronic obstructive pulmonary disease	3.7 (14/383)
Neurological disease (%) no./total no.		
	Transient ischaemic attack	4.7 (18/384)
	Cerebrovascular accident	8.9 (34/384)
	Other neurological condition	3.9 (15/384)
Peripheral vascular disease (%) no./total no.		25.5 (97/380)
Permenant pacemaker (%) no./total no.		
	Pre TAVI prophylaxis	6.0 (23/383)
	Previous PPM insertion	3.4 (13/383)
Atrial fibrillation (%) no./total no.		18.8 (72/383)
Creatinine (mean±SD)		127.7±80.0 (378)

NYHA = New York Heart Association; TAVI = Transcatheter aortic valve implantation; PPM = Permanent pacemaker

Table 2. Pre-procedural characteristics.

Pre-procedural characteristics	TAVI N=384
Heart team meeting (%) no./total no.	100 (384/384)
Primary reason for TAVI (%) no./total no.	
High risk for surgical AVR	65.0 (249/383)
Formally turned down for surgical AVR	30.6 (117/383)
Patient refused surgical AVR	4.4 (17/383)
Aortic valve aetiology (%) no./total no.	
Degenerative	89.8 (344/383)
Rheumatic	2.3 (9/383)
Failed bioprosthesis	5.7 (22/383)
Bicuspid	1.8 (7/383)
Aortic valve pathology (%) no./total no.	
Stenosis	90.3 (346/383)
Regurgitation	4.7 (18/383)
Mixed	5.0 (19/383)
Pre-procedural assessment of the aortic valve complex	
Aortic annular measurement method (%) no./total no.	
TTE	73.4 (281/383)
TOE	24.5 (94.383)
Contrast aortography	1.6 (6/383)
CT with valve perimetry	0.5 (2/383)
Aortic valve measurements (mean±SD)	
Aortic valve area - cm2	0.62±0.2 (380)
Peak aortic valve gradient - mmHg	79.7±25.17 (382)
Aortic annular diameter - mm	23.1±2.4 (381)
Left ventricular function (%) no./total no.	
Good 50-60	79.8 (305/382)
Moderate 30-50	14.9 (57/382)
Poor <30	5.2 (20/382)
Pulmonary hypertension (%) no./total no.	
PA systolic >60mmHg	13.0 (50/384)
Pre-procedural assessment of the illiofemoral vessels	
Contrast illiofemoral angiography	99.5 (383/381)
CT	0.5 (2/383)
Anaesthesia	
Local anaesthetic and IV paracetmaol	39.1 (150/383)
Local anaesthetic and conscious sedation	46.0 (176/383)
General anaesthesia	14.9 (57/383)

AVR = aortic valve replacement; TTE = transthoracic echocardiogram; TOE = transoesophageal echocardiogram
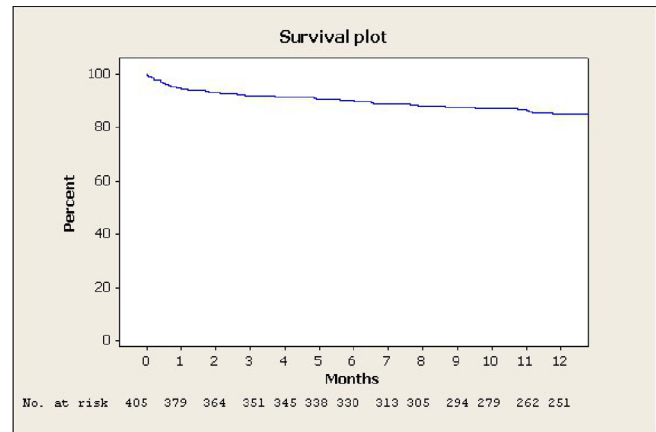
Figure 1. Kaplan-Meier survival curve for all patients to 1 year.

valve systems used were the Edwards Sapien (Edwards Life Science, Irvine, CA, USA) in 7.3% of cases and the Portico valve (St. Jude Medical, Minneapolis, MN, USA) in 5.0% of cases. Most (86%) patients underwent percutaneous pre-closure using the Prostar vascular closure system (Perclose Inc., Menlo Park, CA, USA).

Implantation was performed under contrast aortography (100%) with or without additional TTE (85%). Peri-procedural TEE was utilized in 3.4% of cases. Post-procedure para-valvular aortic regurgitation was assessed using hemodynamics, TTE, and contrast aortography.

Device Success and Complications

Device implantation success was achieved in 96.1% of cases (Table 4). Three patients (0.8%) died intra-procedure. Twelve patients (3.1%) required emergency second valve implantation at the time of the index procedure for on-table severe paravalvular aortic regurgitation (PAR). No patient required conversion to emergency open valve surgery. Five patients (1.3%) required subsequent "valve-in-valve" implantation as a separate procedure.

In-hospital complications are detailed in Table 4. In-hospital MACE rate was 6.0%. The incidences of stroke and myocardial infarction were 2.0% and 0.3%, respectively. Post-procedural aortic regurgitation grade by fluoroscopic aortography was 0 (37.3%), 1 (45.6%), 2 (12%), or >2 (0.8%). Post-procedure aortic regurgitation grade by TTE was zero (36.2%), mild (52.2%), moderate (10%), or severe (0.5%). VARC-de-

Table 3. Pre-procedural characteristics.

Characteristics	TAVI N=384
Delivery approach	
Retrograde trans-femoral	90.7 (348/384)
Axillary	0.5 (2/384)
Subclavian	4.9 (19/384)
Trans-apical	1.3 (5/384)
Direct aortic	2.3 (9/384)
Delivery sheath size	
16g	0.5 (2/384)
18g	97.4 (374/384)
>20g	0.5 (2/384)
Valve manufacturer	
Medtronic CoreValve	87.7 (336/383)
Edwards Sapien	7.3 (28/383)
St Jude Portico	5.0 (19/383)
Valve Size (mm)	
23mm	6.8 (26/384)
26mm	45.8 (176/384
29mm	40.4 (155/384)
31mm	4.9 (19/384)
BAV prior to TAVI insertion	
Yes	85.2 (327/384)
No	14.6 (56/384)
BAV sizes (mm)	
18	8.8 (34/384)
20	21.3 (82/384)
22	36.7 (141/384)
25	14.3 (55/384)
26	2.1 (8/384)
28	0.8 (3/384)
Peri-procedural imaging - (%) no./total no.	
Contrast Aortography	100 (383/383)
Additional TTE	85.6 (328/383)
Additional TOE	3.4 (13/383)
No additional imaging	11.6 (42/383)
Post procedure aortic regurgitation by TTE	
0 (None)	36.2 (138)
I (Mild)	52.2 (199/381)
II (Moderate)	10 (38/381)
III (Severe)	0.5 (2/381)

Table 3 (cont.). Pre-procedural characteristics.

Characteristics	TAVI N=384
Post procedure aortic regurgitation by fluroscopy	
0 (None)	37.3 (140//381
I Mild)	45.6 (171/381
II (Moderate)	12 (45/381
III (Severe)	0.8 (3/381
Vascular closure technique	
Surgical closure	12.8 (49/384)
Pre-closure percutaneous device closure	80.0 (307/384)
Manuel pressure	5.2 (20/384)
Surgical closure and pre-closure percutaneous device closure	1.3 (5/384)
Median total volume of contrast administered (IQR) mls	180 (20-400)

TTE = transthoracic echocardiogram; TOE = transoesophageal echocardiogram

fined major and minor bleeding was seen in 3.7% and 5.8% of patients, respectively.

A few (3.4%) patients had a pre-existing permanent pacemaker. Some (6.0%) underwent pre-procedure pacing due to known right bundle branch block (overall rate 20.3%), and 14.3% required post-procedure in-hospital permanent pacing.

30-Day and 1-Year Mortality

Mortality at 30 days was 9.3%. Mortality at 1 year was 15.2% (n = 45/296). A Kaplan-Meier survival curve for the entire patient cohort is shown in Figure 1.

Discussion

This study reports a large consecutive and all-inclusive historical series of patients who underwent TAVI with first-generation self-expanding devices. This series is unique in that it captures every TAVI case performed at two high-volume centers that systematically used a minimalist approach before MSCT became the imaging gold standard. It includes the entire "learning curve" and early experience from these centers, with robust short and long-term follow-up achieved in 100% of patients.

Table 4. Success rate and complications.

	TAVI N=384
Device success	
(%) no./total no.	96.1(369/384)
On table death (%) no./total no.	0.8 (3/384)
Emergency on table valve in valve implantation for severe AR (%) no./total no.	3.1(12/384)
Conversion to emergency open valve surgery	
(%) no./total no.	0.0 (0/383)
In Hospital MACE (In hospital death/MI/CVA)	
(%) no./total no.	5.8 (23/384)
Post procedural VARC defined complications (30-day)	
Myocardial infarction (%) no./total no.	0.3 (1/383)
CVA/TIA (%) no./total no.	2.0 (8/383)
Device embolization (%) no./total no.	0.3 (1/383)
Tamponade (%) no./total no.	2.1 (8/384)
Conduction abnormality requiring pacing (%) no./total no.	14.3 (55/384)
AR>2+ moderate/severe - TTE (%) no./total no.	10.5 (40/381)
AR>2+ moderate/severe - angiographic (%) no./total no.	12.8 (48/381)
Major and minor vascular access site injury (%) no./total no.	3.7 (14/383)
Major and minor bleeding (%) no./total no.	6.1 (23/377)
Haemofiltration/dialysis (%) no./total no.	1.0 (4/380)
Subsequent valve in valve implantation (%) no./total no.	1.3 (5/384)
Death (%) no./total no.	
30 day (%) no./total no.	9.3 (36/384)
1 year (%) no./total no.	15.2 (45/296)

CVA = cerebrovascular accident; TIA = transient ischaemic attack; AR = aortic regurgitation; TTE = transthoracic echocardiogram

Principle Findings

Within our patient cohort, 30-day mortality was 9.3%. This is comparable to rates in other historical registries: 7.1% in the UK TAVI registry [12], 10.4% in the Canadian registry [13], 8.5% in the SOURCE registry [14], 12.7% in the FRANCE registry [15], and 8.2% in the German registry [16]. Our all-comer results are also similar to those achieved in the randomized

PARTNER B (5.0%) [17] and PARTNER A (5.2%) [18] cohorts. Our 1-year mortality was 15.8%, which is comparable to rates in the overall UK TAVI registry, in which mortality was 21.4% at 1 year and 26.3% at 2 years [12].

While we do not advocate "routine use" of this technique, this minimalist method may represent an option for patients who present in an urgent or emergency setting. Our data suggest that reasonable results can be obtained using this strategy. Indeed, one might hope for improved results now that repositionable self-expanding prostheses are available.

Potential Roles for Primary TAVI

Bridging the acute aortic stenosis patient with balloon aortic valvuloplasty is often undertaken in the absence of full assessment, but this strategy is not ideal. While it may stabilize an acutely unwell patient, balloon aortic valvuloplasty is not a low-risk procedure. Contemporary data from the UK registry suggest a procedural complication rate of 6.3%, comprising death (2.4%), blood transfusion ≥ 2 U (1.2%), cardiac tamponade (1.0%), stroke (1.0%), vascular surgical repair (1.0%), coronary embolism (0.5%), and permanent pacemaker (0.2%). In this registry, mortality was 13.8% at 30 days and 36.3% at 12 months [6]. Furthermore, if primary TAVI is performed at the time of index admission, there would be no need for a second intervention, limiting patient risk and overall cost.

Two small-volume single-center studies support this idea. Landes et al. recently reported 27 cases of urgent TAVI in patients admitted with refractory and persistent heart failure despite optimal medical therapy. Patients were more likely to be frail and have higher Society of Thoracic Surgeons score or EuroSCORE. Pre-procedural assessment used fewer imaging modalities, yet implantation success remained high and reached 96.3%, with no difference in rate of peri-procedural complications (VARC-2) compared with that among 342 elective patients. The patient groups had similar 30-day mortality rates and MACE [10].

Frecker et al. reported outcomes from 27 patients who underwent emergency TAVI presenting with cardiogenic shock due to acutely decompensated aortic stenosis. Three patients died within 72 hours of successful valve deployment, and a further six died within 1 month, giving a 30-day mortality of 33.3%,

which was significantly higher than that for electively treated patients (7.7%, $P < 0.0001$). Estimated 1-year survival was 59.3% in emergency and 82.7% in electively treated patients ($P = 0.0009$) [11].

Valve Type

Our data suggest that a self-expanding prosthesis may have advantages. First, current iterations are 14-F, which may be advantageous if no iliofemoral imaging has been performed. Second, minimizing rapid pacing make be useful if there are concerns about hemodynamic stability. Third, the risk of annular rupture from over-sizing is rare with self-expanding versus balloon-expandable valves, which are more dependent on accurate annular sizing as well as the degree and extent of calcification. Finally, if treating a failed surgical bioprosthesis, there is the advantage of supra-annular valve function and lower post-procedural gradients with self-expanding valves. The latest iteration also offers the advantage of being repositionable.

Limited Pre- and Peri-Procedural Imaging

One major concern with primary TAVI is the limited use of pre- and peri-procedural imaging, which plays a pivotal role in planning. MSCT is now considered the gold standard for pre-procedural TAVI assessment, and expert consensus guidelines exist on CT imaging prior to TAVI [4]. MSCT has several advantages over TTE and fluoroscopy-based staging techniques. These include a "single test assessment" of the vascular access site and the aortic valve complex and more accurate annular sizing and assessment of the aorta, which may impact the degree of post-procedural aortic regurgitation and the ability to predict appropriate fluoroscopic implant projections.

Echocardiography, by contrast, tends only to identify the antero-posterior diameter of the aortic annulus, which is smaller on average than the lateral-to-lateral aortic annular diameter. With a self-expanding prosthesis (as used in most patients in this study), allowance can be made for potential discrepancies and appropriate up-sizing when measurements are borderline. Irrespective, a retrospective study by Mylotte et al. found that CT-based annular analysis revealed incorrect CoreValve size selection by TTE in up to 50% of patients [19].

Paravalvular Aortic Regurgitation

There is now clear data to suggest that the precision of the annular measurement may impact the degree of PAR seen post-implant [20]. PAR ≥ 2+ (moderate to severe) is an independent predictor of short- and long-term mortality [21]. Therefore, minimizing PAR post-TAVI is important. In this series using a minimalist approach, 12.5% of patients exhibited PAR > 2+. This rate would need to be reduced if primary TAVI is to become a useful tool. Repositionable valves should prove valuable in this respect.

GA or Sedation

From a procedural aspect, limited use of TEE allows for conscious sedation rather than GA, which is associated with shorter implant time, decreased stay in the intensive care unit, and faster discharge from the hospital [22, 23].

Durand et al. undertook TAVI using the Edwards Sapien XT prosthesis in 151 consecutive patients using local anesthesia and fluoroscopy only. Conversion to GA was required in 3.3% of patients and was related to complications. Device success was similar to that in our series (95.4% vs. 96.1%), with similar 30-day mortality (6.6% vs. 9.3%) [24].

Cost-Effectiveness

TAVI is a cost-effective treatment. Cost per life-year gained is well within accepted values for commonly used cardiovascular technologies irrespective of geography and definition [25]. Primary TAVI should further impact cost-effectiveness as it limits the patient to one definitive treatment episode. Attizani et al. reported the use of a minimally invasive strategy in an elective population, defined as local anesthesia with or without conscious sedation, performed in the catheter lab without TEE guidance. They found this strategy to be cost-effective, with a cost saving of $16,000 per case compared with standard care [26].

Conclusion

A minimalist approach to TAVI does not offer contemporary levels of procedural success, but a 95% success rate may be considered acceptable in emergency or urgent settings. A self-expanding prosthesis may be particularly suited to this clinical scenario.

Conflict of Interest

DHS, MS, GM, and J-CL are proctors for Medtronic CoreValve.

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Transcatheter Aortic Valve Replacement in Transposition of the Great Arteries Following Arterial Switch Operation

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Abstract

Transcatheter aortic valve replacement (TAVR) for the treatment of congenital heart disease has been mostly limited to patients with bicuspid aortic valve stenosis. We present a case of a 19 year old Jehovah's witness patient with D-Transposition of the great arteries (D-TGA) who underwent an arterial switch operation, followed by a valve sparing aortic root repair with a hemashield graft, who later developed severe aortic valve regurgitation and successfully underwent a transcatheter aortic valve replacement (TAVR) with the Edwards Sapien-3 valve.

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Key Words

Introduction

The minimally invasive technique of transcatheter aortic valve replacement (TAVR) may be ideal for the growing population of adult congenital heart disease (ACHD) patients, many of whom may be at increased risk of adverse events associated with surgical valve replacement. TAVR has had limited application in the ACHD population to this point, mostly utilized for the treatment of bicuspid aortic valve (BAV) stenosis or valve-in-valve replacement of dysfunctional aortic bioprostheses. Aortic stenosis or aortic regurgitation (AR) in ACHD patients may be due to isolated valvular abnormality such as BAV or as a component of additional congenital anomalies such as hypoplastic left heart syndrome. Both aortic stenosis and AR can occur following aortic valve repair or replacement with bioprostheses, homografts, or pulmonary autografts as in the Ross procedure or in arterial switch operations. We herein present a case of TAVR in an ACHD patient with D-transposition of the great arteries (D-TGA) post status arterial switch and subsequent valve sparing aortic root repair with resultant severe AR.

Case Presentation

A 19-year-old woman of Jehovah's Witness faith with D-TGA, membranous ventricular septal defect, and subpulmonic stenosis underwent a right modified Blalock-Taussig-Thomas shunt and Blalock-Hanlon atrial septectomy at 1 year of age; arterial switch operation, sub-pulmonic stenosis resection, and atri-

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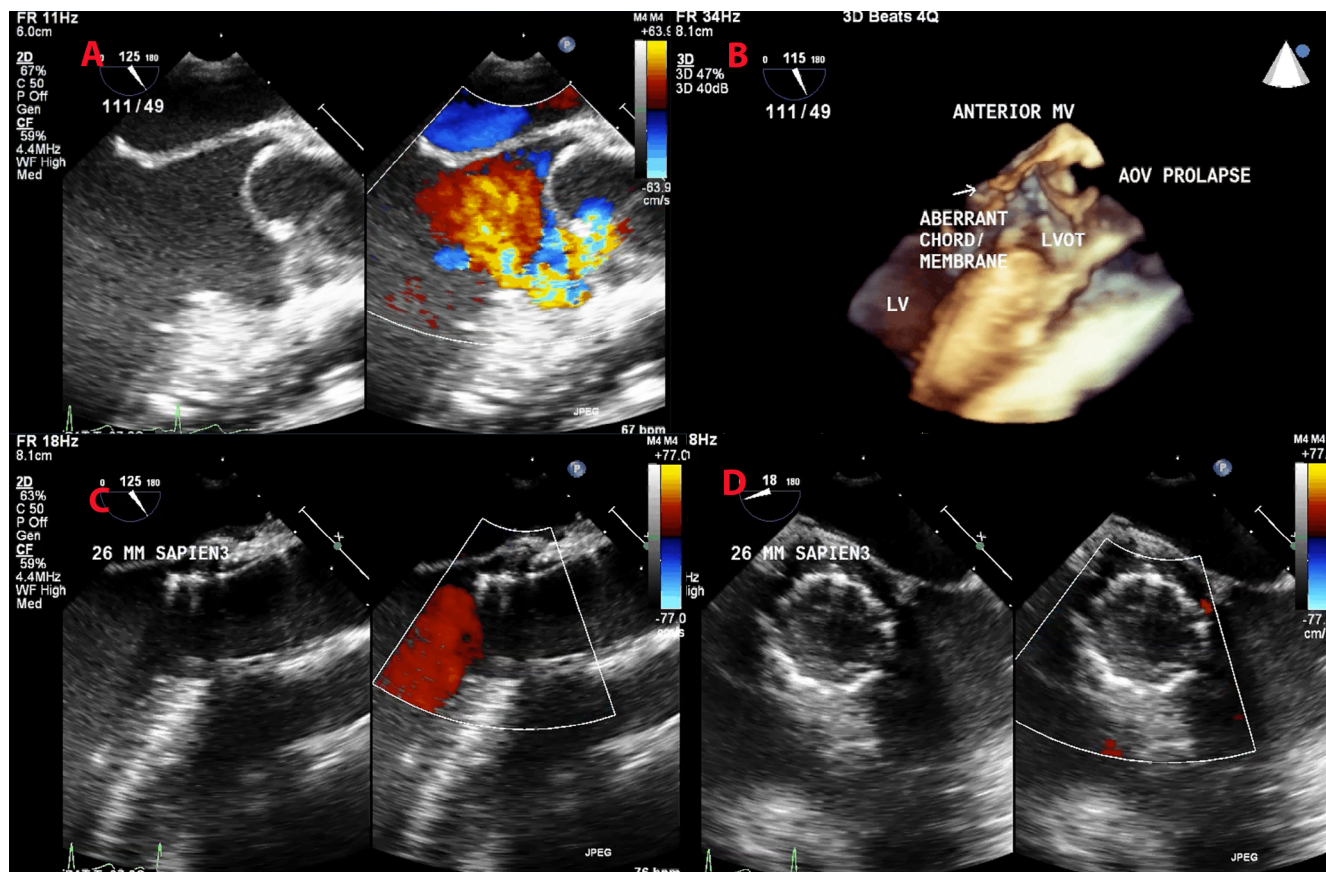
Figure 1. Transesophageal echocardiography (TEE) of transcatheter aortic valve replacement (TAVR) in D-transposition of the great arteries (D-TGA) status post arterial switch with a valve sparing root repair using a hemashield graft and repair of severe aortic regurgitation using a 26-mm Edwards Sapien-3 valve. *Panel A*. TEE two-dimensional (2D) long axis view of the aortic valve demonstrating left coronary cusp prolapse and severe regurgitation. *Panel B*. TEE three-dimensional (3D) long axis view of the aortic valve demonstrating left coronary cusp prolapse and aberrant chord in the left ventricular outflow tract. *Panel C*. TEE 2D long axis view of the aortic valve status post deployment of a 26-mm Sapien-3 valve with no residual regurgitation and trace perivalvular regurgitation. *Panel D*. TEE 2D short axis view of the aortic valve status post deployment of a 26-mm Sapien-3 valve with no residual regurgitation and trace perivalvular regurgitation.
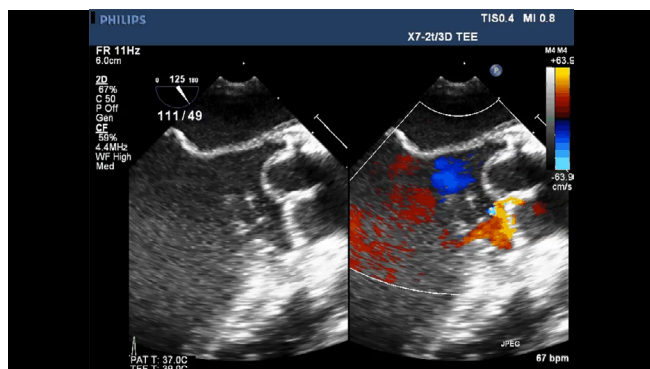
Video 1. TEE 2D long axis view of the aortic valve with color compare showing the prolapsing aortic valve leaflet and severe regurgitation. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.01.

Video 2. TEE 3D view of the aortic valve prolapse and aberrant chord. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.02.

Figure 2. Angiography of transcatheter aortic valve replacement in D-TGA status post arterial switch with a valve sparing root repair using a hemashield graft and repair of severe aortic regurgitation with a 26-mm Edwards Sapien-3 valve. *Panel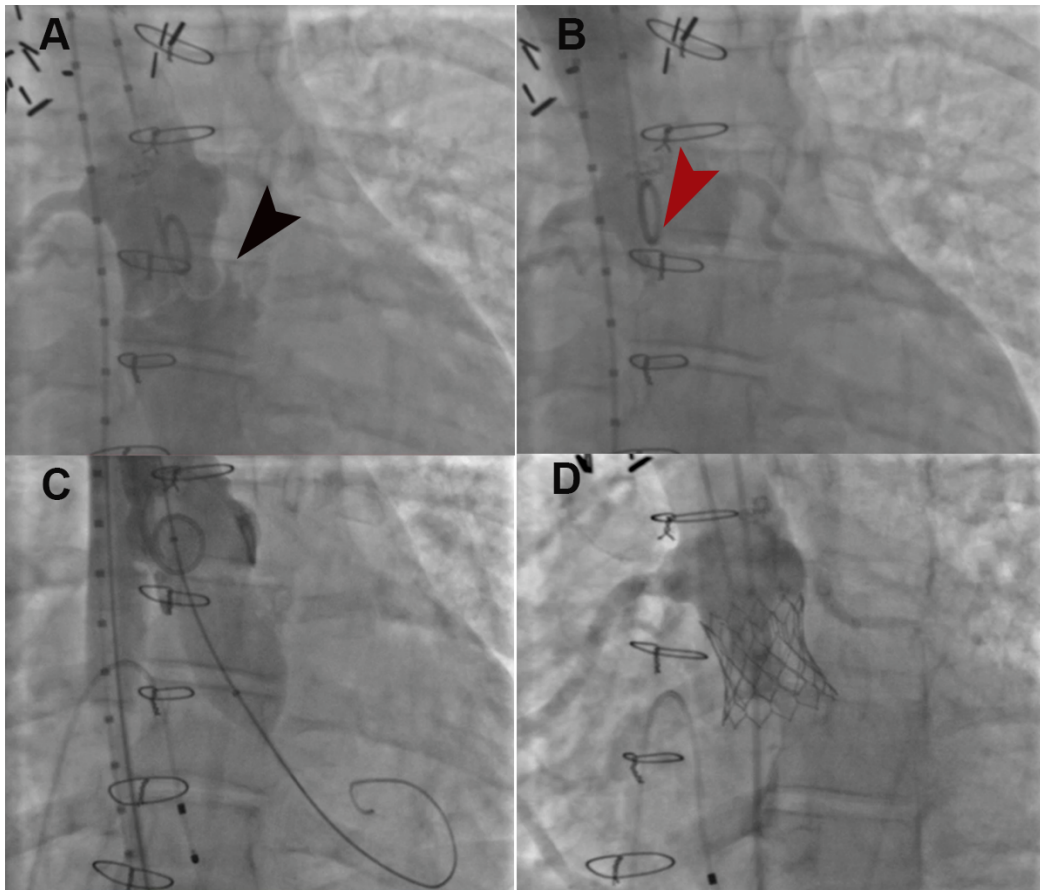 A.* Aortic root angiogram demonstrating the severely regurgitant valve with opacification of the left ventricle and re-implanted coronary arteries at a safe height from the aortic valve annulus (**black arrow** marks the aortic valve leaflets). *Panel B.* The aortic valve in an open position (**red arrow**). *Panel C.* Balloon sizing of the aortic valve annulus and aortic valve angioplasty with a waist measuring 19–21 mm. *Panel D.* Aortic root angiogram status post 26-mm Edwards Sapien-3 valve deployment with no residual regurgitation, no perivalvular regurgitation, and normal coronary artery flow.
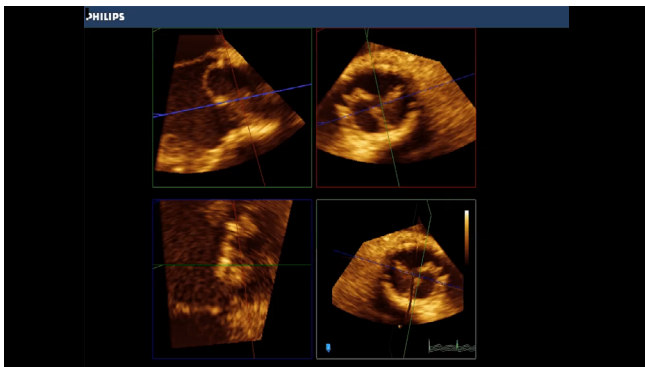
Video 3. TEE 3D views of the aortic valve demonstrating the left coronary cusp prolapse; views also used for annular dimensions. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.03.

al and ventricular septal defect closure at 2 years of age; and valve-sparing aortic root replacement with a 22-mm Hemashield graft and subaortic membrane resection at 15 years of age. The last operation was complicated by cognitive injury and memory loss, and her recovery was protracted. She subsequently developed symptomatic severe AR. Because of her refusal to receive blood transfusions due to her Jehovah's Witness faith and history of three surgeries, two median sternotomies, and post-operative cognitive injury, she was considered high risk for repeat surgical intervention and was referred for off-label use of TAVR.

Procedure

Pre-procedural electrocardiography-gated cardiac computed tomographic angiography (CTA) showed the valve annular dimensions to be $21 \times 20 \times 23$ mm, adequate clearance of the coronary ostia to the annulus, and no aortic valve or ascending aortic calcification. Abdominal/pelvic CTA demonstrated adequate femoral arterial size for a transfemoral valve replacement approach without significant tortuosity.

The procedure was performed under general anesthesia. Intra-procedural transesophageal echocardiography (TEE) showed severe eccentric aortic regurgitation due to malcoaptation of the aortic valve leaflets and prominent prolapse of the left coronary cusp leaflet (Figure 1; Videos 1, 2, 3, and 4). There was a false chord extending from the anterior mitral valve leaflet to the left ventricular outflow tract without functional obstruction (Video 2). The aortic valve annulus measured $20 \times 20 \times 21$ mm by TEE, mostly consistent with the CTA annular dimensions. Aortic root angiograms (Figure 2; Video 5) showed severe AR and patent re-implanted coronary arteries without evidence of atherosclerotic disease with a distance from the valve level of 27–30 mm and minimal concern for coronary obstruction. A 23 mm $\times$ 4 cm balloon was used to perform balloon sizing with rapid ventricular pacing at 180 bpm; the waist on the balloon was noted to be 21 mm. A 26-mm Edwards Sapien-3 valve (Edwards LifeSciences, Irvine, CA, USA) was prepped and mounted onto the Commander delivery system in the usual manner and advanced into the 14-F sheath, and the valve was assembled in the descending aorta. Once across the valve, aortic angiography was performed to ensure appropriate position of the Sapien valve. Rapid pacing at 180 bpm was initiated, and the valve was deployed using the nominal volume of 23 ml (Video 6). Aortic root angiography was performed, which demonstrated a competent aortic valve (Figure 2; Video 7). Post-deployment TEE showed a well-positioned 26-mm Edwards Sapien-3 valve with trace perivalvular regurgitation at the left coronary cusp region and no central regurgitation (Figure 1; Videos 8 and 9). The delivery sheath was pulled and perclose sutures were deployed; however, right iliac angiography revealed that the right femoral artery was occluded at the site of the perclose su-
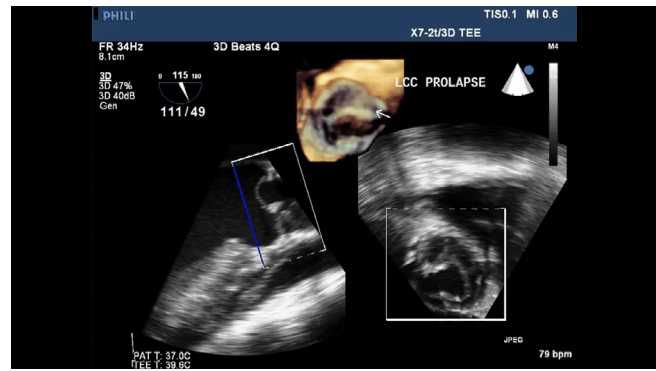
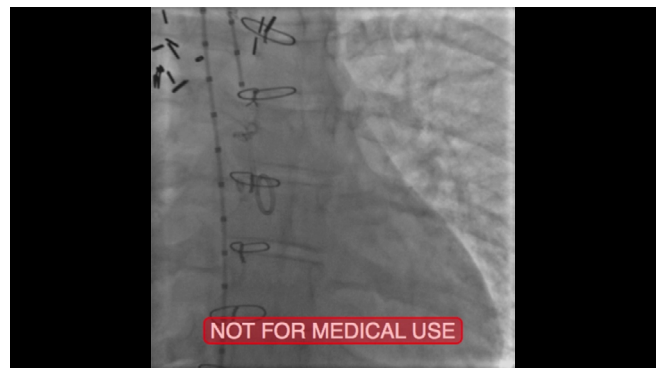**Video 4.** TEE 2 and 3D views of the aortic valve showing the left coronary cusp prolapse. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.04.

Video 5. Baseline aortic root angiogram demonstrating the severely regurgitant aortic valve and that the re-implanted coronary arteries were at a safe height from the aortic annulus. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.05.
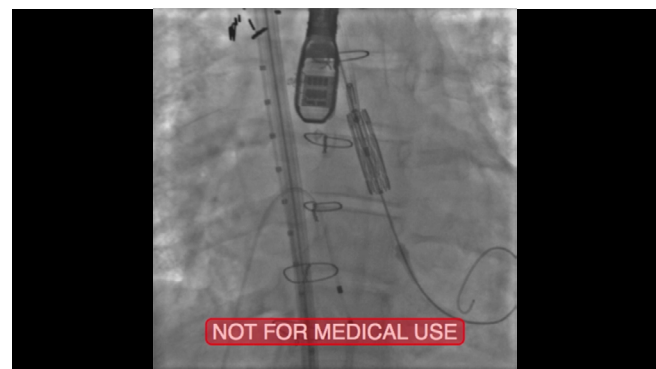
Video 6. Deployment of a 26-mm Sapien-3 valve with aortic root angiogram prior to deployment and rapid pacing during deployment. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.06.
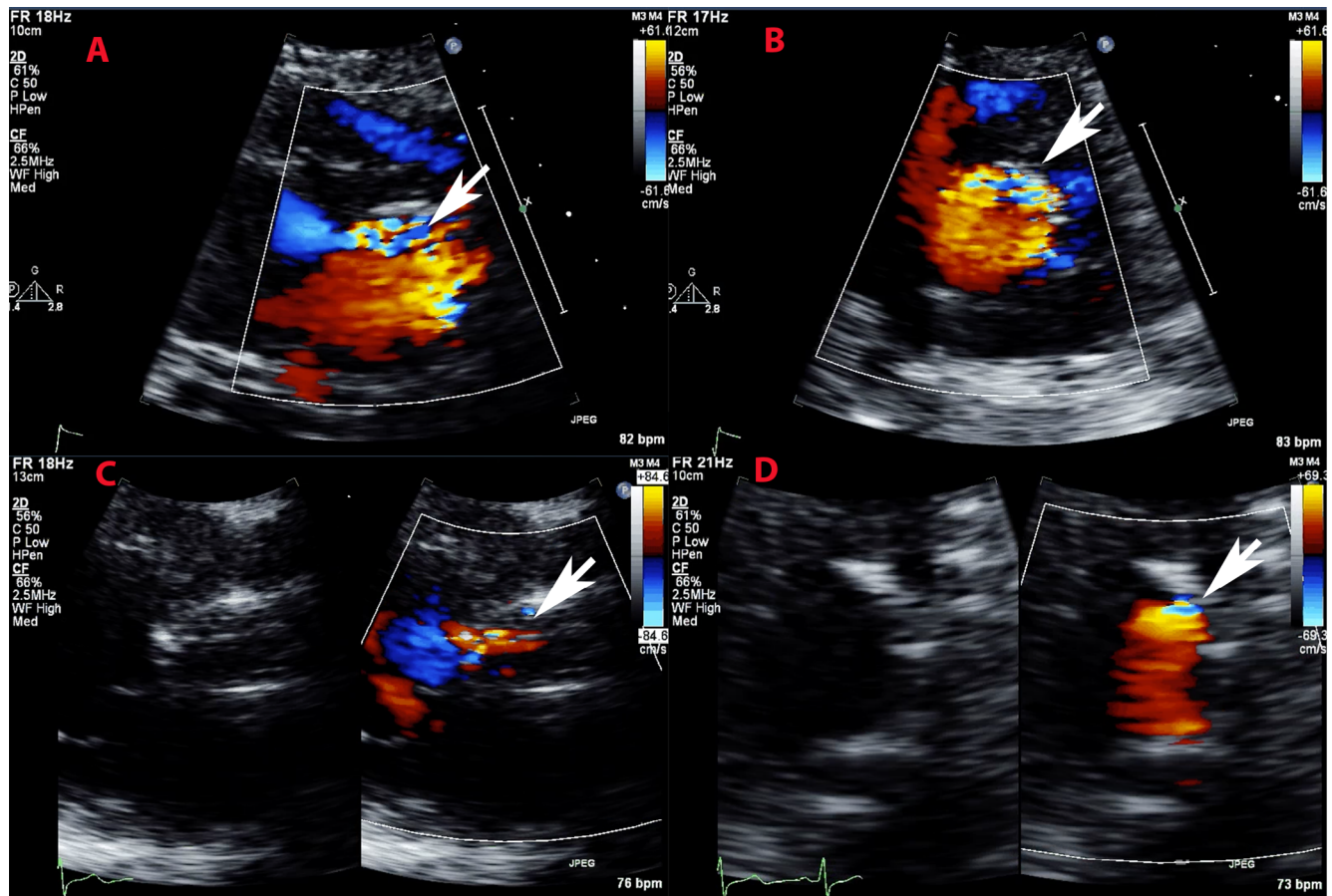
Figure 3. Transthoracic echocardiography (TTE) post-initial procedure and post-dilation of the aortic prosthesis. *Panel A.* TTE 2D long axis view of the aortic valve prosthesis with color Doppler demonstrating perivalvular regurgitation (**white arrow**). *Panel B.* TTE 2D short axis view of the aortic valve prosthesis with color Doppler demonstrating perivalvular regurgitation (**white arrow**). *Panel C.* TTE 2D long axis view of the aortic valve prosthesis with color Doppler demonstrating reduced perivalvular regurgitation post dilation (**white arrow**). *Panel D.* TTE 2D short axis view of the aortic valve prosthesis with color Doppler demonstrating reduced perivalvular regurgitation post dilation (**white arrow**).
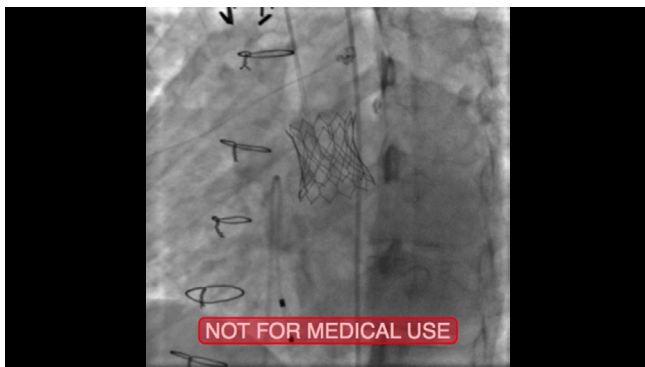
Video 7. Post-valve deployment aortic root angiogram demonstrating no residual aortic regurgitation or perivalvular regurgitation and normal coronary artery flow. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.07.
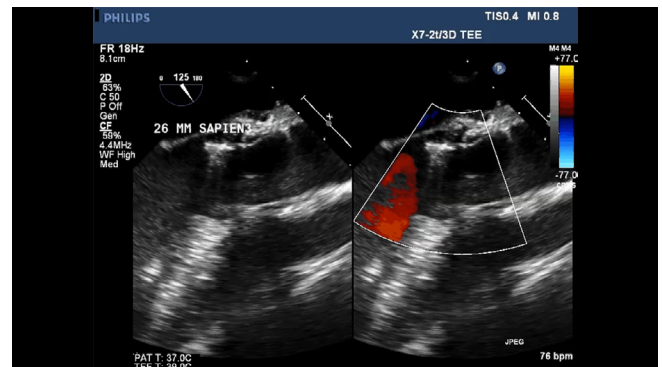
Video 8. TEE 2D long axis view of the aortic valve status post deployment of the Sapien-3 valve. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.08.
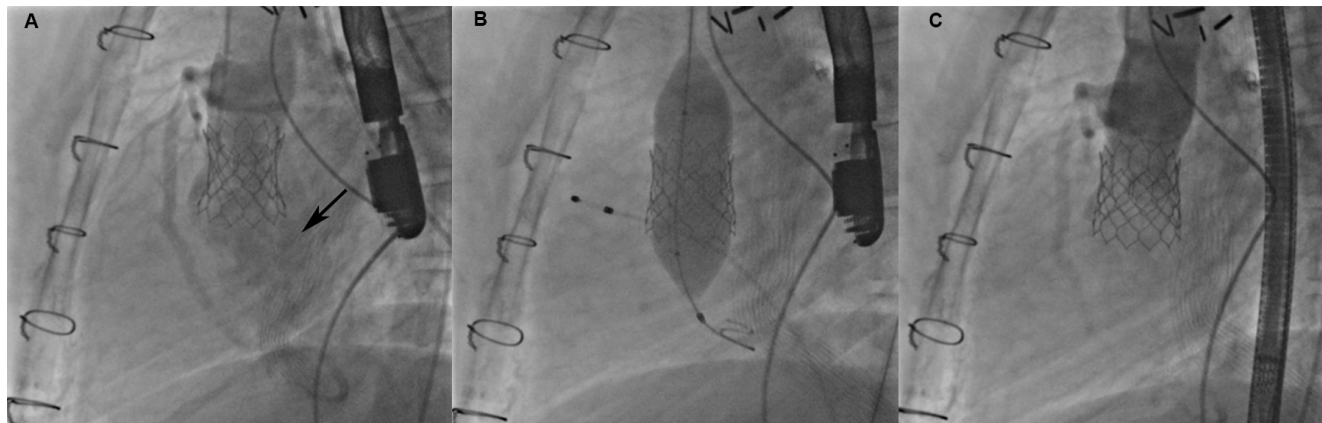
Figure 4. Angiography and angioplasty of the transcatheter aortic valve 10 months post-initial procedure. *Panel A.* Aortic root angiogram in the lateral projection demonstrating downward migration of the transcatheter valve of approximately 4–5 mm with severe perivalvular regurgitation (**black arrow**). *Panel B.* Angioplasty of the transcatheter Sapien 3 valve using a 24-mm VIDA balloon resolving the residual waist. Note the transvenous pacemaker in the right ventricle. *Panel C.* Post-angioplasty aortic root angiogram in the lateral projection demonstrating only mild residual perivalvular regurgitation.
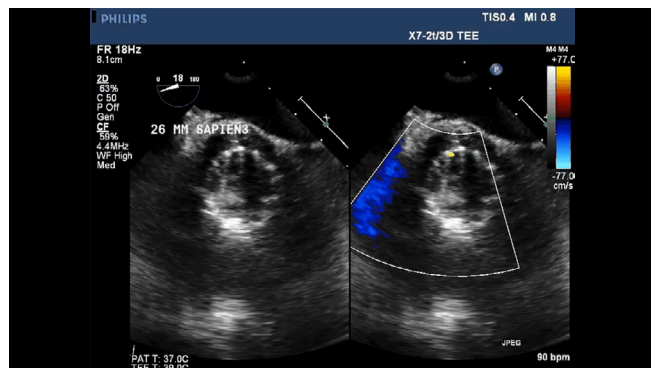
Video 9. TEE 2D short axis view of the aortic valve status post deployment of the Sapien-3 valve. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.09.
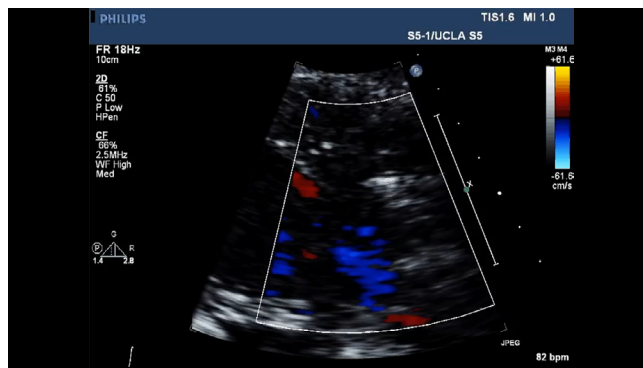
Video 10. TTE 2D long axis view of the aortic valve upon follow-up after the procedure demonstrating progressive perivalvular regurgitation. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.10.

tures. Surgical cutdown and open repair of the right femoral artery were performed with a good final result and return of normal peripheral pulses.

The patient was monitored in the surgical intensive care unit. Her B-natriuretic peptide level decreased from 121 pg/ml pre-procedure to 39 pg/ml. Her post-operative echocardiogram showed no evidence of central or perivalvular regurgitation. She was started on aspirin and clopidogrel and discharged on postoperative day 2. On initial clinic follow-up within 1 month post-procedure, she reported minimal improvement in her exertional symptoms, and her echocardiogram showed progressive perivalvular regurgitation (Figure 3; Videos 10 and 11). In

the next few months following the initial TAVR, the patient reported worsening exertional symptoms. Given the perivalvular AR, she was brought back to the cardiac catheterization laboratory. Cineangiography demonstrated slight downward migration of the aortic prosthesis with evidence of severe perivalvular regurgitation (Figure 4; Video 12). This was hypothesized to be due to inadequate post-dilation of the Sapien valve in a patient with primary AR. A 24-mm Vida balloon (BARD Peripheral Vascular, Tempe, AZ, USA) was used to perform high-pressure dilation, which resulted in improved valve apposition to the walls of the hemashield graft and resolution of the perivalvular AR (Figure 4; Videos 13 and 14). The patient toler-

Video 11. TTE 2D short axis view of the aortic valve upon follow-up after the procedure demonstrating progressive perivalvular regurgitation. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.11.

Video 13. Balloon dilation of the Sapien 3 valve using a 24-mm VIDA balloon. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.13.
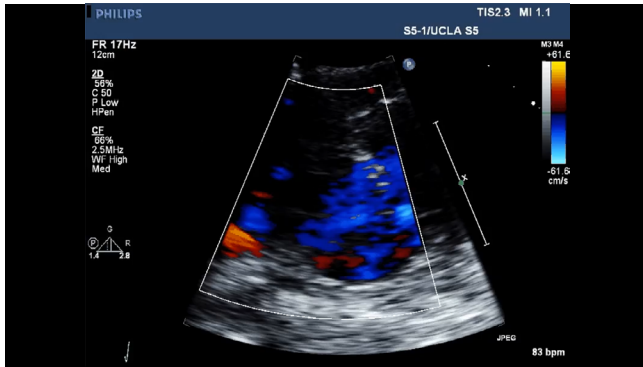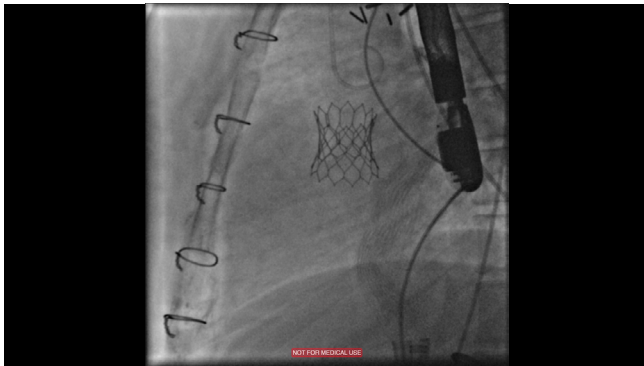

Video 12. Aortic root angiogram in the lateral projection 10 months post-initial valve deployment demonstrating downward migration of the valve and severe perivalvular regurgitation. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.12.

Video 14. Aortic root angiogram post-dilation demonstrating better apposition of the Sapien 3 valve and only mild residual perivalvular regurgitation. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.14.

ated the procedure well, and follow-up echocardiography 4 months post-procedure demonstrated mild perivalvular regurgitation and stable valve position (Figure 3; Videos 15 and 16).

Discussion

TAVR in the ACHD population has been mostly limited to patients with calcific stenotic BAV. Initially, some studies showed a higher risk of perivalvular regurgitation in BAV TAVR with earlier generation valves including the CoreValve (Medtronic Inc, Minneapolis, MN, USA) and Sapien XT (Edwards Lifesciences) [1]. In later studies, however, this risk was mitigated with the use of newer generation valves such as the Lotus (Boston Scientific, Marlborough, MA, USA) and Sa-

pien-3 (Edwards Lifesciences), which have a sealing system that decreases perivalvular regurgitation [2]. Nevertheless, the use of TAVR in the ACHD population has been scant, and many patients present with predominant AR without calcification. The present case illustrates the benefits and potential pitfalls of TAVR in an ACHD patient with primary AR. Although the hemashield graft served as an anchor for valve deployment well below the coronary artery buttons, there was evidence of gradual downward migration and development of severe perivalvular regurgitation despite initial valve placement at nominal balloon volume, indicating a potential role for deployment at greater than nominal volumes and the importance of adequate post-dilation. Several newer generation transcatheter valves are currently in preclinical or ear-
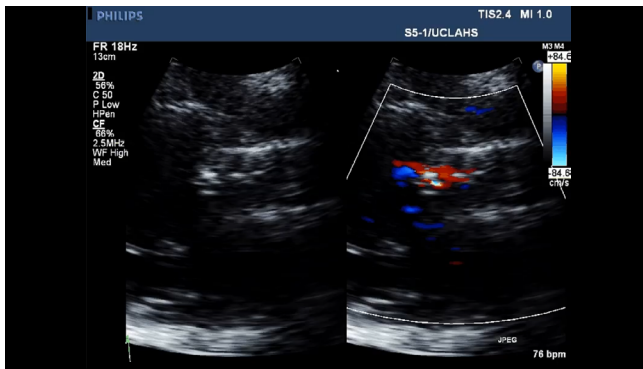
Video 15. TTE 2D long axis view of the aortic valve post-dilation demonstrating reduction in perivalvular regurgitation. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.15.
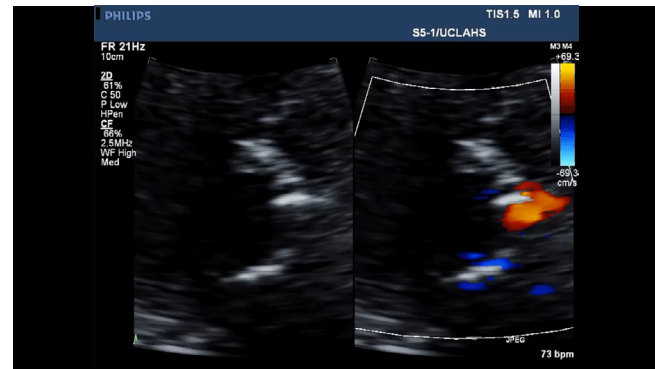
Video 16. TTE 2D short axis view of the aortic valve post-dilation demonstrating reduction in the perivalvular regurgitation. View supplemental video at https://doi.org/10.12945/j.jshd.2018.042.17.vid.16.

ly clinical testing for the treatment of primary AR and are equipped with an anchoring system that serves to stably and accurately position the valves in patients with predominant AR to prevent the migration and resultant perivalvular regurgitation seen in this study [3, 4]. These new platforms will expand the use of TAVR in ACHD patients to further decrease the need for repeat surgeries in this patient population. To our knowledge, this is the first published case of transcatheter deployment of an Edwards Sapien-3 valve in the aortic position in a patient with D-TGA post status arterial switch with predominant AR.

In conclusion, TAVR in patients with congenital heart disease and pulmonary conduit or bioprosthetic valve dysfunction has become the new standard of care. These minimally invasive and effective tech-

niques have allowed for a reduction in the number of open cardiac surgeries needed over the lifetime of a CHD patient. Advances in technology are increasing the applications of TAVR in lesions that were previously only surgically treated. TAVR in ACHD patients with predominant AR is a new frontier, and the use of the newer-generation valves may prove promising.

Conflict of Interest

The authors have no conflict of interest relevant to this publication.

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Evolution of Approach to Right Ventricular Outflow Tract Stenting in Infants ≤ 2Kgs

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Abstract

Surgical palliation or repair of symptomatic Tetralogy of Fallot in the neonatal period is associated with a relatively high mortality rate. Stenting of the right ventricular outflow tract is a newer procedure that has evolved to allow its performance in low birth weight neonates. In this case series, we describe the evolution of our approach to right ventricular outflow tract stent implantation in neonates weighing < 2 kg.

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Key Words

Congenital heart disease • Cardiac catheterisation • Tetralogy of Fallot • Low birth weight

Introduction

Surgical palliation or repair of symptomatic Tetralogy of Fallot (ToF) in the neonatal period is associated with a relatively high mortality rate. A large contemporary database of over 3,000 patients reports 6.2% mortality associated with palliative modified Blalock-Taussig-Thomas (BTT) shunt and 7.8% mortality for primary neonatal repair [1]. Thus, in many centers, alternative palliative options for promoting pulmonary arterial blood flow and growth have been evaluated, including stenting of the arterial duct [2], pulmonary balloon valvuloplasty [3], and, more recently, stenting of the right ventricular outflow tract (RVOT) [4-10]. Pulmonary balloon valvu-loplasty has not gained widespread acceptance, as subvalvar muscular obstruction has been shown to be unresponsive to ballooning alone; however, in some substrates with predominant valvar obstruction, this option remains [11-13]. RVOT stenting was initially described by Gibbs et al. [4]; however, a larger, more contemporary series of 52 patients reported by Stumper et al. [5] demonstrated excellent outcomes. The authors concluded that RVOT stenting is a viable first-line treatment option for selected patients with severe RVOT obstruction as an alternative to systemic-to-pulmonary artery shunting procedures and for whom early complete repair carries significant additional risk or complexity. Only one patient in this cohort weighed < 2 kg. Despite significant advancements in stent design and profile to support stent delivery in low birth weight (LBW) infants, this cohort of patients remains a challenge, with a recent report suggesting a procedural mortality of 12% associated with interventions in infants < 2 kg [14].

In the past 4 years, we have placed 58 RVOT stents in 53 patients, with 4 patients weighing ≤ 2 kg. Initially, we pursued a percutaneous approach in all patients; however, we have now moved to a perventricular approach through a small subxiphoid incision for patients < 2 kg. This approach provides a more direct route to the RVOT and possibly lessens the likelihood of hemodynamic instability induced by splinting the tricuspid valve. This report outlines these cases and

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the learning curve associated with RVOT stenting in LBW infants.

Case Presentation

Case 1

An ex-36-week male infant weighing 1.9 kg was diagnosed soon after birth with ToF. There was failure to pass meconium, and a diagnosis of Hirschsprungs disease required a defunctioning colostomy. Due to progressive cyanosis, the infant was taken to the catheter laboratory in the second week of life and underwent RVOT stenting with a 4 × 12-mm coronary stent (Boston Scientific, Marlborough, MA, USA). There was severe RVOT narrowing (Figure 1) that was crossed with a 0.014″ BMW wire (Abbot Vascular, Clonmel, Ireland) through a 4-F angled Terumo catheter (Terumo Europe NV, Leuven, Belgium) positioned in the RVOT. Further angiography was possible through a Tuohy-Borst placed on the catheter over the wire. Stent position was confirmed with the use of transthoracic echocardiography (TTE). The infant tolerated the procedure well with no hemodynamic instability following placement of the coronary wire in the distal right pulmonary artery. Oxygen saturation improved from mid-70% to mid-90%. The infant required further dilation of the stent at 3 months with a 6 × 20-mm balloon (Boston Scientific, Marlborough, MA, USA) and underwent uncomplicated complete surgical repair at 6 months.

Case 2

An ex-30 + 3-week male infant with a birth weight of 1.18 kg and an antenatal diagnosis of ToF became progressively cyanosed over the first 4 weeks of life. Despite administration of oxygen and propranolol for hypercyanotic spells, the patient remained symptomatic and was listed for urgent RVOT stenting at 4 weeks of age weighing 1.6 kg. The RVOT was crossed with a 0.014″ BMW wire, and a 4 × 12-mm coronary stent was placed across the RVOT. Repeat angiography suggested residual infundibular muscle proximal to the RVOT stent. With advancement of a second stent, the initial stent milked distally into the main pulmonary artery. It was not possible to advance the second stent into a suitable position, and on removal through the sheath, the stent embolized off the

balloon into the right atrium. The stent was retrieved with an Amplatz goose neck snare (Covidien, Plymouth, MN, USA) and removed. Subsequently, a third 4 × 12-mm stent was advanced to the RVOT, covering the infundibular muscle, and was successful in alleviating the obstruction. The patient recovered well from the procedure without any sequelae.

At 8 weeks of age, weighing 2.2 kg, the patient re-presented with hypercyanotic spells, and echocardiography suggested muscle beneath the previously placed stents. Initial angiography confirmed the wedge of muscle. The stents were crossed with a 0.014″ GrandSlam wire (Asahi Intecc, Osaka, Japan) and a 5 × 12-mm Formula 414 stent (Cook Medical, Bloomington, IN, USA) was placed in a good position. Final angiography and echocardiography suggested that the residual muscle bundle was fully covered by the stent.

Further subsequent desaturations led to a right modified BTT shunt at 10 weeks of age and subsequent complete repair at 26 weeks, weighing 5.3 kg.

Case 3

An ex-35 + 4 week male infant with a birth weight of 1.52 kg was diagnosed with ToF with severe RVOT obstruction following birth and was commenced on propranolol and prostaglandin. Clinical features were suggestive of Cornelia de Lange syndrome. At day 21 of life, weighing 1.84 kg, the patient developed progressive cyanosis despite prostaglandin therapy with a TTE, confirming progressive restriction of the ductus arteriosus. Following a multi-disciplinary team discussion, he was brought to the cardiac catheterization laboratory at 23 days of age for an urgent RVOT stent. The RVOT was crossed with a 0.018″ Terumo wire through a 4-F non-tapered angled Terumo catheter. The Terumo wire was exchanged for a 0.014″ GrandSlam wire, which led to significant hypotension thought to be secondary to splinting of the tricuspid valve. Some improvement was seen with the administration of adrenaline and withdrawal of the 4-F catheter. A 4.5 × 13-mm coronary stent was deployed under TTE guidance across the RVOT. This stent migrated proximally with balloon withdrawal, and attempts to manipulate it back into position with a balloon were unsuccessful. A further 4.5 × 18-mm coronary stent was advanced to stabilize the first stent; however,
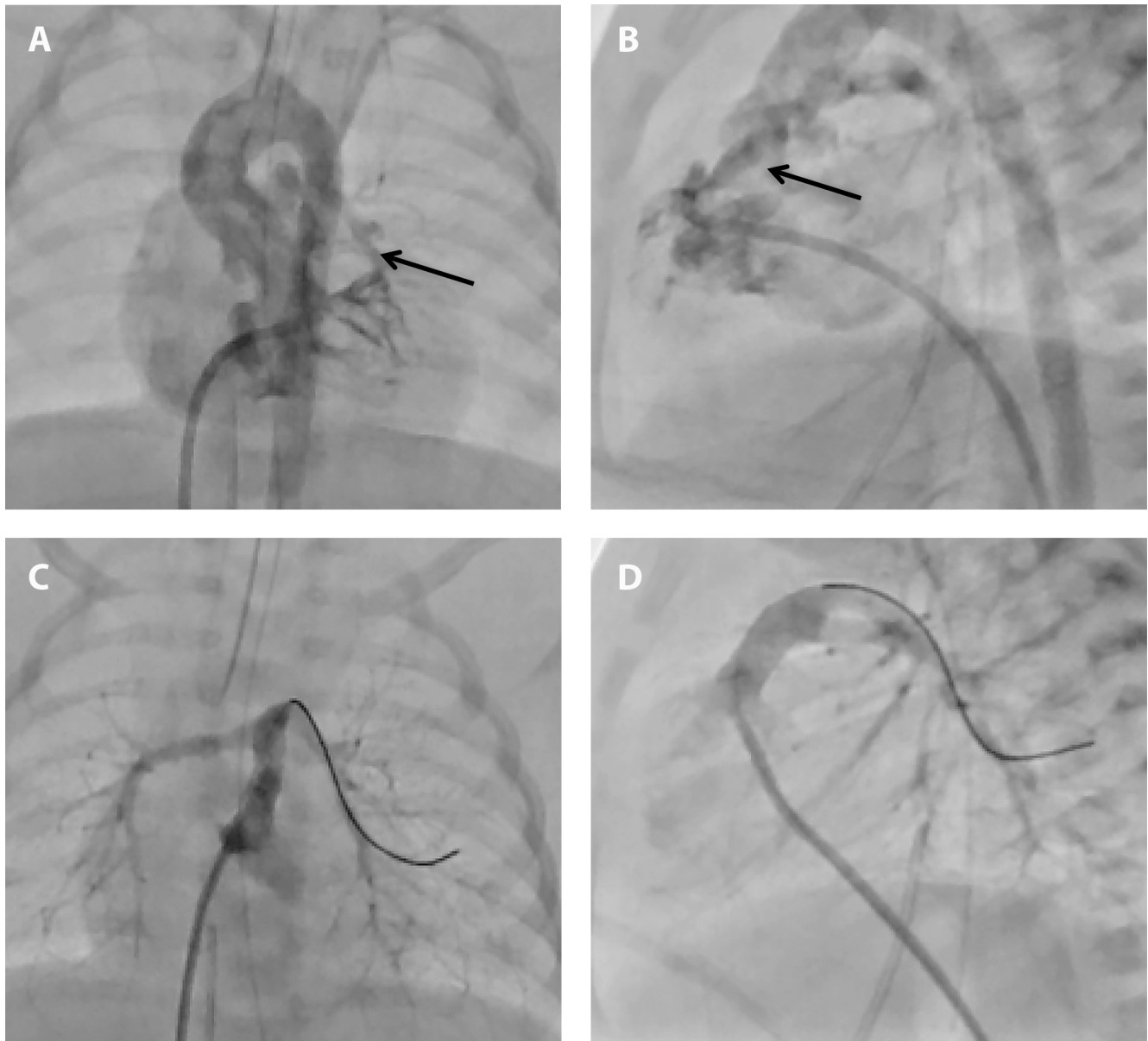
Figure 1. *Panels A and B*. Initial right ventricle angiogram demonstrating severely hypoplastic RVOT in both *(Panel A)* frontal and *(Panel B)* lateral planes (**black arrows**). *Panels C and D*. Repeat angiography following placement of a 4-mm coronary stent in the RVOT demonstrating *(Panel C)* improved filling of the pulmonary arteries and *(Panel D)* a more patent RVOT.

upon deployment it too migrated proximally into the right ventricle. The patient was stable initially, but further attempts to reposition the stents into the RVOT were unsuccessful and led to the patient becoming hypotensive and acidotic.

After the patient stabilized, a decision was made to perform a sternotomy and attempt to retrieve the stents through a 9-F sheath inserted into the right ventricle. Through this, an Amplatz Goose Neck Snare was advanced into the right ventricle; however, attempts to snare the embolized stents led to damage to the right ventricular myocardium. The patient was emergently placed on cardio-pulmonary bypass (CPB) with retrieval of the stent and a modified systemic-to-pulmonary artery shunt performed. Despite this, the patient subsequently could not be weaned

from CPB due to severe biventricular dysfunction. He was felt to be too small for extracorporeal support and did not survive weaning of CPB.

Case 4

An ex-36 + 4-week infant with an antenatal diagnosis of ToF was born with a weight of 2 kg. He had the associated features of right undescended testes, hypospadias, micrognathia, butterfly vertebrae, and transient hyperinsulinemia.

The patient was listed for insertion of a RVOT stent on day 12 of life due to worsening oxygen saturation requiring re-commencement of prostaglandin to keep baseline saturation above 70%. On this occasion, initial right ventricle angiography was performed using a right femoral venous approach (Figure 2A and 2B). Similar to the third case, placement of a coronary wire across the tricuspid valve led to hypotension; therefore, on this occasion, a decision was made to revert to a subxiphoid approach to minimize hemodynamic instability. Through a small subxiphoid incision, a 5-F sheath was placed through the anterior surface of the right ventricle (Figure 2C). Following sheath angiography, a 0.014" BMW wire was placed in the distal right pulmonary artery through a 4-F Terumo catheter, and a 5 × 16-mm Formula 414 stent was deployed in a good position. Oxygen saturation increased to low 90%.

The patient had an uncomplicated post-operative course and recovered well. Ten weeks following the initial procedure, weighing 3.14 kg, he underwent uncomplicated implantation of a further 6 × 20-mm Formula 414 stent via the right femoral vein for progressive cyanosis secondary to muscle hypertrophy proximal to the RVOT stent. He subsequently underwent an uncomplicated full surgical repair at 5 months, weighing 5 kg.

Discussion

Despite significant advances in neonatal CPB, the mortality for symptomatic neonates with a diagnosis of ToF weighing < 2 kg has been reported as high as 49% [15]. This reflects the difficulties of CPB in this age group, with infants having smaller circulating blood volumes, higher oxygen consumption rates, and highly reactive pulmonary vascular beds. In ad-

dition, infants have labile thermoregulation and immature organ systems with multiple implications for ischemic tolerance and inflammatory response [16]. However, despite these difficulties, adopting a watch-and-grow approach has not been shown to improve outcomes [17, 18].

The unpredictability of pulmonary balloon valvuloplasty combined with the high mortality of both modified BTT shunt placement and primary repair signaled the need for an alternative palliation option—the RVOT stent. Since the initial report in 1997, numerous case series have reported on the use of RVOT stents in the palliation of ToF patients [4-10]. These mainly involved patients weighing > 2.5 kg.

In this series, we describe the evolution of our approach to insertion of an RVOT stent in ToF patients weighing ≤ 2 kg. In four patients, we performed RVOT stenting to facilitate somatic and pulmonary artery growth to an adequate size suitable for primary repair. Previous reports demonstrate that mortality associated with early primary repair is highest in neonates with small pulmonary arteries (i.e., Nakata index < 150 mm/m^2) [19].

We have fine-tuned our approach to obviate the need for a long sheath to deliver the stent, which assists the approach in smaller infants; however, the potential hemodynamic instability seen with a stiff coronary wire across the tricuspid valve may limit even this approach. Following the relative ease of stent delivery in the initial case, we felt that that a coronary stent could be delivered without much difficulty. Lower profile and shorter length stents appeared to course through the smaller heart more easily. However, our second case highlighted the difficulties that can arise with percutaneous stent insertion, particularly ensuring adequate stent length without the availability of a long sheath, and the challenges with crossing a pre-existing stent in the RVOT. In the third case, hemodynamic instability required rapid stent deployment that ultimately led to stent migration. This case highlights the limited room for error and intolerance to stent manipulation within small hearts. In the fourth case, a hybrid perventricular approach via a subxiphoid incision was performed. This perventricular approach was previously described as a viable option in LBW neonates [10] and in this case allowed the infant to grow to successful neonatal repair.
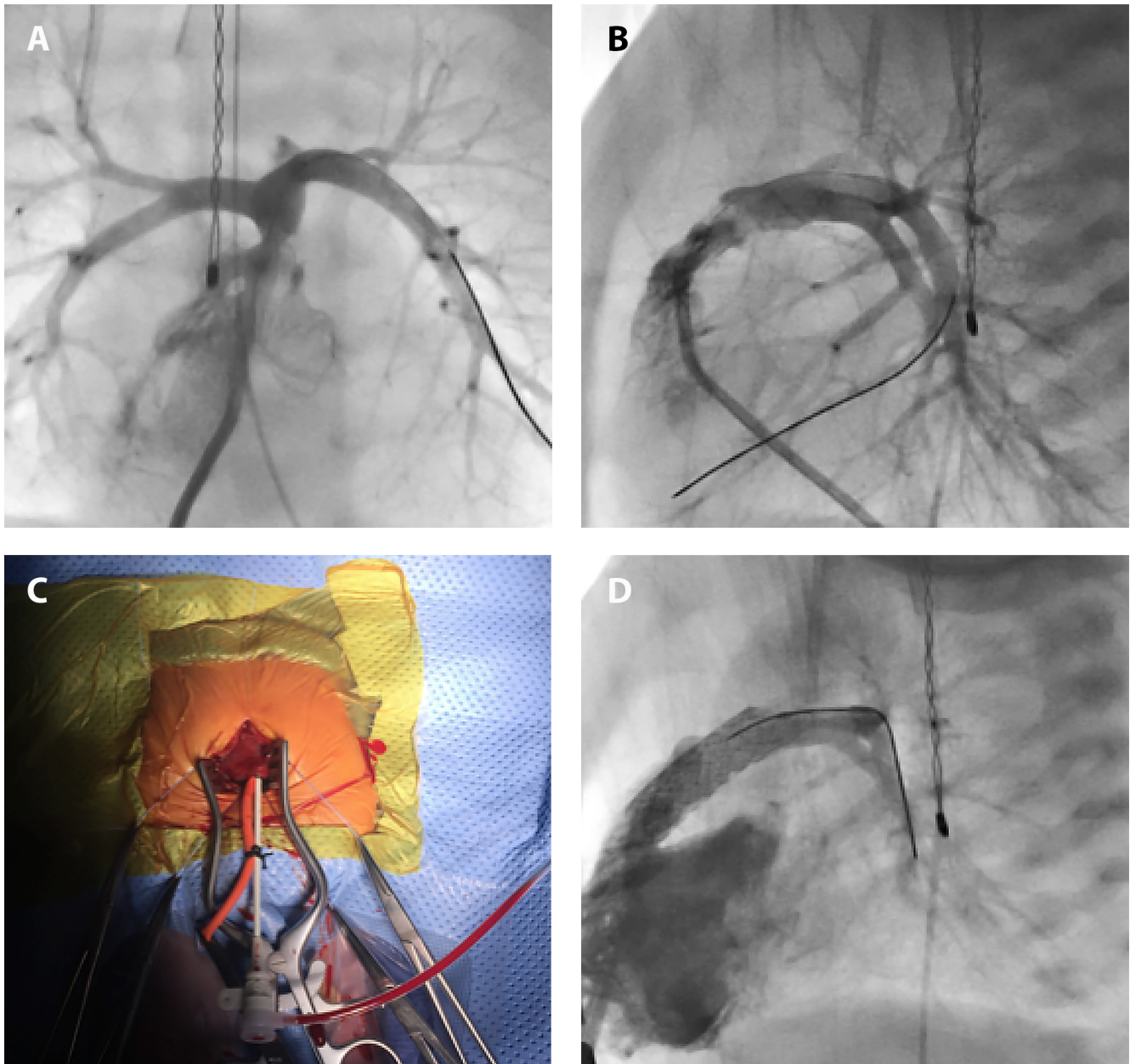
Figure 2. *Panels A and B.* Initial right ventricle angiogram demonstrating RVOT and pulmonary valve narrowing in both *(Panel A)* frontal and *(Panel B)* lateral planes. *Panel C.* 5-F short sheath paced through a small subxiphoid incision. *Panel D.* Right ventricle angiogram following stenting of the RVOT with a 5 × 16-mm stent.

Ultimately, these cases reflect a learning curve with RVOT stenting in infants weighing < 2 kg. Although an uncomplicated outcome is possible with a standard transcutaneous approach, the margins of error are small, and complications are poorly tolerated. We believe a hybrid approach through a small subxiphoid incision provides the most direct route to the RVOT in small infants and reduces hemodynamic instability, which may allow time to assess stent position adequately.

In conclusion, this case series highlights the evolution of an approach to RVOT stenting in infants weighing < 2 kg. Although a successful outcome with a transcutaneous approach is possible, complications

may occur and are poorly tolerated. We feel a hybrid approach provides the most direct route to the RVOT with the least hemodynamic instability, providing concurrent angiography through the delivery sheath to facilitate optimal stent position. This small (n = 4) case series may not provide sufficient experience to support a perventricular approach as first-line for all infants ≤ 2 kg requiring RVOT stenting. However, early conversion to this approach should be considered in those infants who do not tolerate attempts at percutaneous stent delivery.

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Conflict of Interest

The authors have no conflict of interest relevant to this publication.

Comment on this Article or Ask a Question

LAA CSI Focus Abstracts

LAA CSI Focus – November 17-18, 2017

THE VALUE OF 3D PRINTING FOR LAAO DEVICE SIZING

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Background: Percutaneous left atrial appendage occlusion (LAAo) is an alternative approach to medical therapy to prevent atrial fibrillation (AF) mediated stroke, in patients with a high stroke risk and contraindication for long-term oral anticoagulation. Despite an increasing rate of successful implantations, correct sizing and optimal device positioning remain a challenge. 3D printing has capability to create a highly accurate model of any structure and may be a useful approach for entire LAA anatomy, optimizing device size testing before LAAo..

Aim: To explore the usefulness of 3D printed LAA models to predict adequate sizing and risk of peri-device leaks or malposition post LAAo in a large patient cohort.

Methods: 70 consecutive patients (CHA_2DS_2-Vasc score=4.5±1.5) with a LAAo procedure with Amulet™(St. Jude Medical, St Paul, MN, USA) and a pre- and post-procedure cardiac CT, were included in three institutions between Feb 2014 and Mars 2017. A clinical follow-up was effective for 17±10 months. Cavity segmentation was performed automatically based on CT Dicom data and manually adjusted to include the entire left atrium, then converted to a STL file and 3D printed with high resolution 50microns.

Results: Larges peri-device leaks >5mm occurred in 33% of patients. A mismatch between the model predicted size and the device used was a major predictor of peri-device leaks (AUC=0.85) with Predictive Positive Value (PPV)=82% and NPV=89% compared with CT sizing and TEE sizing (AUC=0.58 and 0.57, respectively p<0.001). Two cerebral ischemic events occurred and four silent devices-related thrombi located in patients with an off-axis prosthesis. An off-axis positioning was observed in 24% of patients. Predictive factors were a large
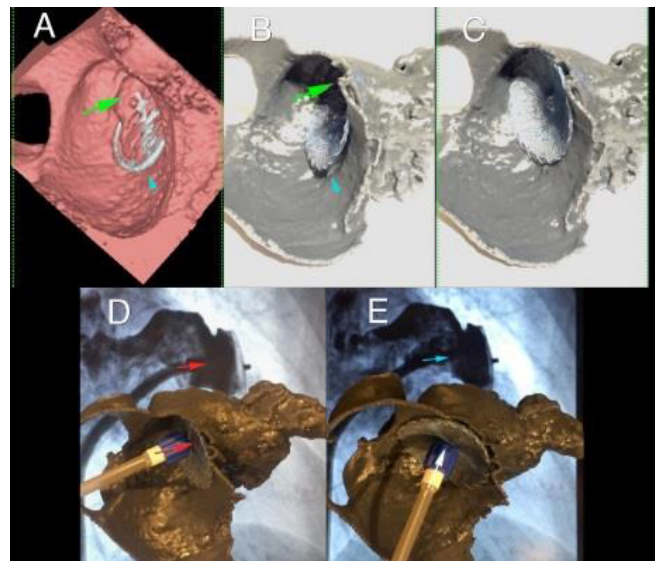
Figure 1. *Panel A.* Device-related thrombus (**green arrow**) in a patient with an off-axis prothesis leading to a cul-de-sac between the disc and the large pulmonary ridge. In addition, note a gap between the disc and LA ostium (**small arrow**). *Panels B, C, D, and E.* Device predicted positions with regard to the sheath orientation in a printed model. *Panel B.* Off-axis device predicted by the printed model. *Panel D.* In vitro printed model superimposed on a cineangiographic view: improper alignment between LAA ostium axis with the sheath (**red arrow**). *Panels C & E.* Optimal device sealing using a the printed model and a larger size with an adequate sheath orientation (**blue arrow**)

pulmonary vein ridge and an inadequate transseptal site puncture. Complications rate was correlated with the mismatch between size used and printed model: odds ratio of 4.1 (1.5-12.7; p=0.01).

Conclusion: 3D-printed patient-specific LA model allow more accurate sizing than TEE and CT measurements. It permits a pivotal training, device testing and evaluation of optimal trans-septal puncture site with potentially important implications in minimizing procedure-related complications.

LEFT ATRIAL APPENDAGE CLOSURE WITH A NOVEL DEVICE: INITIAL EXPERIENCE AND MID-TERM FOLLOW-UP FROM A SINGLE CENTER

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Background: Left atrial appendage (LAA) closure is considered an effective option in patients with non-valvular atrial fibrillation (NVAF) and contraindications to long-term oral anticoagulant (OAC) therapy. However, there are some concerns about safety of currently available devices.

Objective: Our aim is to provide an initial assessment on safety and efficacy of the novel LAA closure Ultraseal device in patients with NVAF and contraindications to long-term OAC therapy.

Methods: Thirteen consecutive patients with NVAF undergoing Ultraseal device implantation between July 2016 and April 2017 were included. All patients performed transesophageal echocardiography and computed tomography angiography prior to LAA closure.

Results: Procedural success was achieved in all patients except one who experienced incorrect device deployment but with complete LAA closure. Procedure duration halved from first to last procedure performed. No adverse events, including pericardial effusion, were observed during index hospitalization. At mean follow-up (166±80 days) all patients were alive and free from major bleedings and ischaemic strokes.

Conclusion: Our results suggest that the Ultraseal device is a safe and feasible option for LAA occlusion. Notably, the learning curve in this single-center experience was fast, paralleled by extremely low complication rates. These results should be considered hypothesis generating and larger studies are mandatory.

ACUTE EMBOLISATION OF WATCHMAN PLUG ONTO AORTIC BIOPROSTHESIS FOLLOWED BY SUCCESSFUL PERCUTANEOUS REMOVAL

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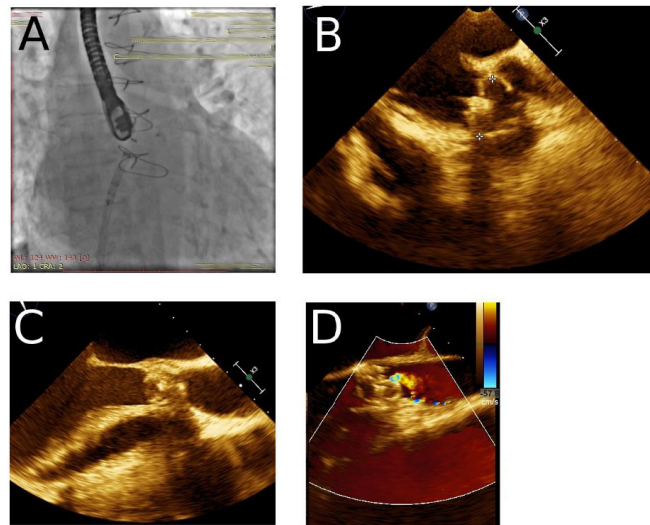
Figure 1. *Panel A.* Watchmann Device placed in LAA. *Panel B.* Confirmation of correct placement in TEE. *Panel C.* Device embolising aortic bioprosthesis. *Panel D.* Doppler showing residual flow through the device during reanimation.

History, Physical and Indication For Intervention: Our patient was an 80-year old woman who underwent implantation of aortic bioprosthesis (Shellhigh 27) 8 years earlier due to severe aortic stenosis. She suffered from chronic kidney disease (stage G3a), hypertension and paroxysmal atrial fibrillation, but no coronary artery disease. She had history of multiple severe bleedings from the lower digestive tract during oral anticoagulation with with rivaroxaban.

Intervention: The procedure initially went with no complications using sedative drugs only and no general anesthesia. Patients' LAA had "chicken wing" morphology and the maximum width of ostium was 14,1mm measured in TEE during the procedure. Initially a Watchman 27mm was used, but it had to be switched to a Watchman 21mm because of excessive protrusion. Correct localization of the Watchman device was confirmed in scopy and TEE, as shown on (Fig.1, panel A and B, respectively) as well as by tug test with 9% device compression (19/21mm). Color doppler showed no significant peri-device flow. A few minutes after the procedure was finished, while the patient was still in the cath lab, there was a cardiac arrest with pulseless electrical activity. Immediately we begun resuscitation and reintroduced the TEE probe. The echo image showed embolisation of the plug on the aortic bioprosthesis with almost complete obstruction of flow as shown on (Fig 1. panel C). During heart massage only a very small jet of flow across the plug was observed as shown on (Fig 1. panel D). Resuscitation was continued according to the ERC guidelines. Six minutes after arrest VF was observed and patient was defibrillated once with 200J successfully. Position of the device and lack of sufficient flow through aortic valve required immediate intervention.

Meanwhile, a EN Snare vascular loop 6x10 was introduced using a 11F Cordis vascular scaffold in left femoral artery. The loop was protruded through bioprosthesis valves and we succeeded in catching the device and moving it down to the abdominal aorta. Soon after

removing it from the prosthesis, ROSC was observed. Afterwards, using a 18x30 loop and 16F scaffold, device was removed completely. Time from embolisation and cardiac arrest to ROSC was about 30 minutes. The device was snared during heart massage, which was continued without any interruptions for the whole period of cardiac arrest. This might have contributed to survival. The patient was discharged week later with no neurological losses.

Learning Points of the Procedure: We suspect that the morphology of chicken wing might have caused the device to only have limited area of contact with LAA walls, as can be observed on Fig 1.B. Even though the compression was within the desired range, outer parts of the device didn't expand fully because the volume of LAA was not proportional to the ostium size. The difficult anatomy of LAA can increase the risk of device migration. Further studies are needed to evaluate the relation between various LAA morphologies and risk of device embolisation.

PREOPERATIVE WATCHMAN AND AMPLATZER AMULET OCCLUDER SIZING BY CARTO XP

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Background: Cardiac closure systems are used to manage anatomical anomalies and malformations of the heart and the associated pathological effects. In patients suffering from atrial fibrillation (AF) left atrial appendage (LAA) is the main source for thrombus formation and embolization. Currently, to select a particular LAA occluder size, several dimensions from fluoroscopy and TEE imaging have to be measured intraoperatively, depending on the chosen make and model.

Objective: The aim is to enable a precise preoperative determination of individual LAA occluder size using the CARTOMERGE image integration tool which is a feature of the CARTO XP electro-anatomical mapping system.

Methods: We compared conventional intraoperative fluoroscopy and/or TEE guided selection of LAA occluders with preoperative CARTOMERGE selection in 40 consecutive patients (24 m, 16 f, age: 69.6±8.5 years) receiving Watchman (n=22) or Amplatzer Amulet (n=18) devices. CHA$_2$DS$_2$-VASc Score was 3.6±1.9 and HAS-BLED-Score was 3.4±1.2. LAA-morphologies were Chicken Wing (50.0%), Cauliflower (25.0%), Windsock (17.5%) and Cactus (5.0%). During implantation 11 of the patients (27.5%) were in AF. Routine cardiac CT scans were imported into CARTOMERGE for segmentation of the left atrium. The resulting volume images (VI) and slice images (SI) were adjusted in their three dimensional orientation to fit the manufacturer's sizing recommendations. Subsequently, the match between pre- and intraoperative sizing was compared with the actually implanted device size.

Results: In the Watchman group, preoperative VI corresponded with 43.6% (7/16) and SI with 40.0% (8/20), while intraoperative fluoroscopy corresponded with 12.5% (2/16) and TEE with 30.0% (6/20) of all actually implanted devices. According to clinical routine an aberration of one size is commonly used. After including one additional size to the estimation, VI corresponded with 87.5% (14/16), SI with 90.0% (18/20), while fluoroscopy corresponded with 87.5% (14/16) and TEE with 75.0% (15/20) of all actually implanted occluders. The remaining were selected empirically.

In the Amplatzer Amulet group, preoperative VI corresponded with 50.0% (8/16) and SI with 44.4% (8/18), while intraoperative fluoroscopy corresponded with 61.1% (11/18) of all actually implanted devices. According to clinical routine an aberration of one size is commonly used. After including one additional size to the estimation, VI corresponded with 68.8% (11/16), SI with 83.3% (15/18), while fluoroscopy corresponded with 100.0% (18/18) of all actually implanted occluders. The remaining were selected empirically. Postoperatively in the Amplatzer group, one embolization and two dislocations occurred were observed and one patient died during follow-up.

Conclusion: In the 40 consecutive patients, preoperative utilisation of CARTOMERGE was found to be feasible and more accurate than conventional intraoperative fluoroscopy and/or TEE based sizing of Watchman occluders but less precise for the Amplatzer Amulet system. Larger studies have to be done.
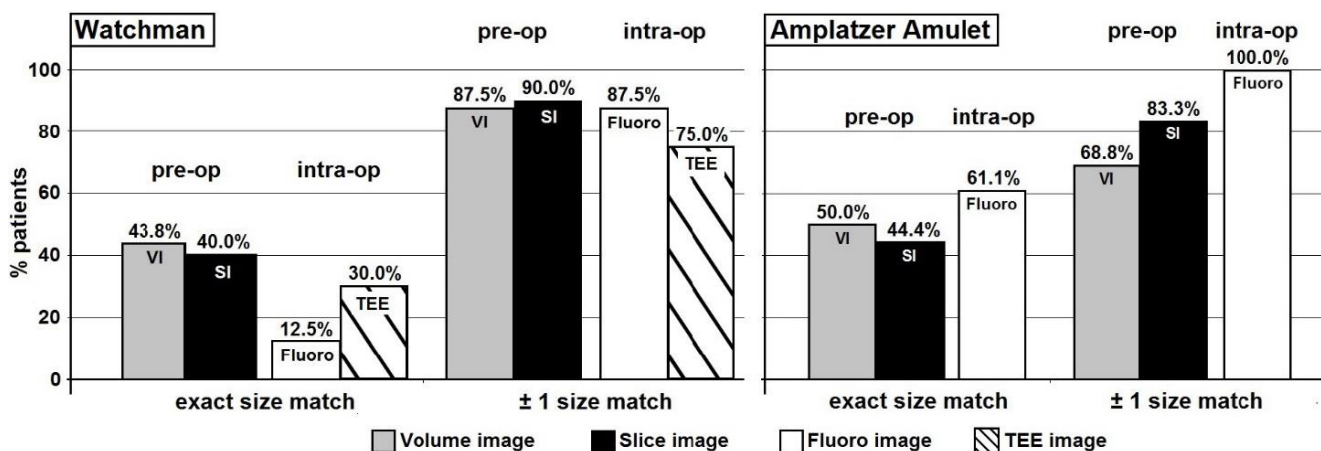
LATE PERFORATION OF THE LAA 4 MONTHS AFTER OCCLUDER IMPLANTATION. REASON FOR OR CAUSED BY A RESUSCITATION?

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History and Physical: A 75-years old male with atrial fibrillation, a CHADS VASc Score of 4 and a HAS BLED Score of 4 was referred for an interventional closure of the left atrial appendage (LAA). The intervention was successful with an SJM® Amulet 18 mm device (panel 1). Nearly 4 months later the patient expressed acute dyspnoea and some minutes later had to be resuscitated. Pulseless electrical activity was documented by the rescue team. With ongoing thoracic compressions and application of catecholamines ROSC occurred after 10 minutes and the patient could be transported to a hospital. Ultrasound revealed a pericardial tamponade and a drainage tube was installed. Over the next hour two liters of blood were drained and conventional methods of stabilizing the coagulation did not stop the bleeding. In preparation of cardiac surgery a coronary angiogram was performed (panel 2). It revealed active leakage of contrast agent in the proximal circumflex artery and the patient was transferred to the cardiac surgery department. Intra-operatively a perforation of the tissue at the basis of the LAA close to the left main coronary artery was discovered. The occluder was excised through the opened left, and the LAA was closed by endocardial sutures. After that two sutures were used to seal another lesion at the LAA basis which stopped the bleeding.

Discussion: In review of the clinical information it remains unclear whether a primary perforation of the LAA led to the cardiac arrest. Since there were more than one laceration of the LAA it seems also possible that the thoracic compressions led to the perforation and consecutive pericardial tamponade. In the literature there are several reported cases of an early perforation of the pulmonary artery by an LAA occlusion device leading to cardiac tamponade. To our knowledge this is the first reported case of a potential late lazeration of the circumflex artery by an LAA occluder.

Imaging: Panel 1: TOE of the implantation, Panel 2: Coronary angiogram.

Indication for Intervention: Pericardial tamponade due to a perforation of the LAA by the occluder with suspected lazeration of the circumflex artery.

Intervention: Pericardiocentesis and introduction of a pig tail drainage catheter. Surgical removal of the occluder and closure of the LAA basis by suture.

Learning Points of the Procedure: Check early for cardiac tamponade after LAA occlusion even when the procedure has been performed more than 3 months earlier, i.e. after an unexplained resuscitation.

3D MULTIMODAL IMAGE FUSION FRAMEWORK FOR LAA CLOSURE PROCEDURE

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Background: The left atrial appendage (LAA) is the main site responsible of thrombus formation in patients with non-valvular atrial fibrillation (NVAF). Oral anticoagulant therapy is the gold standard treatment to prevent cardioembolic events. In patients with NVAF and contraindications to the anticoagulation therapy, percutaneous LAA closure is a strategy to reduce the cardioembolic risk. This procedure is particularly challenging because of LAA anatomical complexity.

Objective: The aim of this study was trifold: to develop a multimodal-image-fusion technique in order to support the procedure's planning and execution; to assess the feasibility of LAA anatomical and functional characterization by a multimodal approach based on LAA 3D surface models and to develop an automatic tool able to quantify morphological parameters.

Methods: Three different imaging modalities were involved in this study: pre-operative ECG-gated cardiac CT, pre- and intra-operative 3D echocardiography (transesophageal echocardiography TEE or intracardiac echocardiography ICE) and intra-operative angiography (XA). LAA 3D models were generated using the volumetric CT and US acquisitions; for both CT and US datasets, multiple models were created, one for each of the ten phases in which the cardiac cycle was divided. A custom software was developed to register these models with US and angiographic images, through an algorithm based on the use of RAO/LAO and CRA/CAU C-arm rotation angles and on the identification of anatomical reperi. This algorithm was applied for all cardiac phases, allowing a dynamic spatial fusion. LAA anatomical and functional parameters was measured directly from 3D US and CT models: LAA volume (V-LAA) and ostium area (AO-LAA) were calculated for each cardiac phase and LAA ejection fraction (LAA-EF) in a full cardiac cycle was measured for the LAA motility evaluation. The 3D models-based-method for LAA parameters extraction was validated on 10 CT datasets from patients scheduled for percutaneous LAA closure procedure, availing the Simpson's method at present the gold standard technique. The agreement between methods was assessed by paired t-test.

Results: This study has demonstrated the feasibility to fuse 3D LAA US and CT models with XA and 3D US images, without the use of dedicated commercial platform. The measurements extracted with our 3D-models-based-method has presented a high correlation with respect to the gold-standard technique (LA diastolic phase: V-LAA=10.61±5.17 cm³ vs 10.55±4.88 cm³, p=0.8319; AO-LAA=4.80±1.66 cm² vs 4.77±1.53 cm2, p=0.5045; LA systolic phase: V-LAA= 7.51 ± 4.85 cm3 vs 7.46 ± 4.71 cm³ , p=0.7693; AO-LAA= 3.78 ± 1.72 cm² vs 3.79 ± 1.69 cm², p=0.8227; LAA-EF=33±16% vs 33±16%, p=0.9993).

Conclusion: The image-fusion techniques allow combining complementary information for improving the visualization of the patterns of interest and the procedure's planning and execution. By image-fusion is possible to take advantage of both the higher temporal resolution of the echocardiographic images and the greater anatomical accuracy of the CT models. Moreover, the use of 3D models in the registration procedure allows exploiting them for the LAA anatomical and functional characterization, for biomechanical simulation and for 3D printing in support of pre-operative planning. The multimodal-image-fusion overcomes the limitations of the standard image-techniques routinely used in cathlab.

SIMULTANEOUS PERCUTANEOUS CLOSURE OF LEFT ATRIAL APPENDAGE AND PATENT FORAMEN OVALE

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Hospital Fundacao Francisco Costantini; Cardiology Department; Interventional Cardiology

History: L.J.R, male, 69 yo, admitted with history of dyslipidemia, inferior limb venous insufficiency & several atrial fibrillation episodes. Echocardiography showed no thrombus in left atrium, left atrial appendage (LAA) with favorable anatomy to closure, and the presence of patent foramen ovale (PFO) with right to left shunt detected by saline microbubbles.

Images:

Indication With CHADS and CHA2DS2-VASC scores 1, oral anticoagulaion become among the indications. Because of clinical reasons and patient preference, percutaneous closure of the LAA and the PFO was performed.
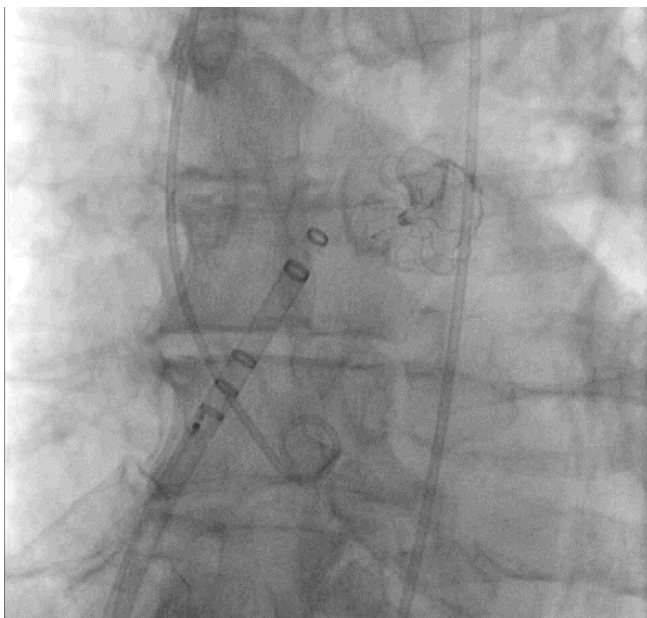

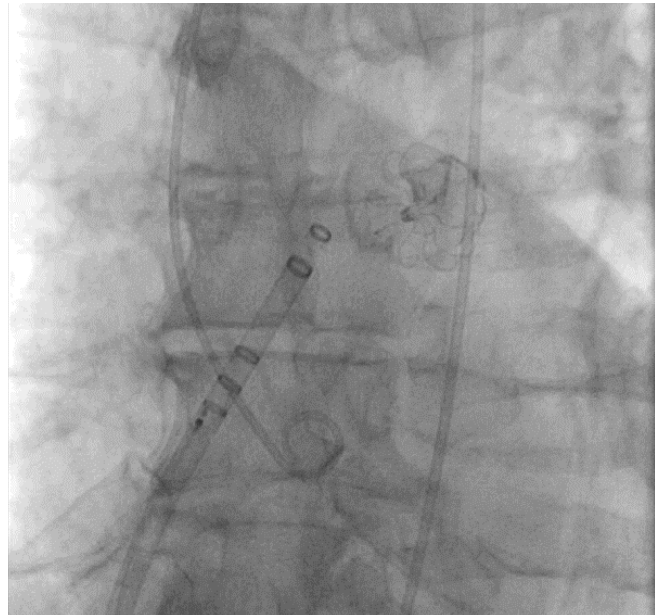**Figure 1.** Delivering Watchman 27 device.

Figure 2. Delivering Amplatzer 25 PFO occluder.

Intervention: LAA closure was carried out under fluoroscopy and Transesophageal echocardiography (TEE). A multipurpose (MP) catheter was placed in the left atrium through the PFO. Using a 0,35 stiff wire, the MP was changed for a dedicated 14 Fr delivery catheter. LAA Angiography was performed using a pigtail through de delivery system. After measurements by fluoroscopy & TEE, a 27 Watchman device was released closing the LAA. Using the same delivery system, a 25 amplatzer PFO device was implanted confirming its size, position and stability. Doppler and saline microbubbles showed no shunt. The patient was discharged the following day. Oral anticoagulation was used and changed to ASA and Clopidogrel after 6 months.

Learning Point-Conclusion: LAA Percutaneous closure is at present a treatment option in stroke prevention settings. Also PFO closure is recommended when risk of paradoxical embolism exist. The case shows that it is possible to perform both percutaneous procedures simultaneously.

VIRTUAL HAEMODYNAMIC STUDY ON DIFFERENT LEFT ATRIAL APPENDAGE MORPHOLOGIES

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Background: Around 90% of thrombi leading to stroke in patients with non-valvular atrial fibrillation are originated in the left atrial

appendage (LAA). The evaluation of LAA morphologies in haemodynamic terms may shed some light on the role of this structure in the cardiovascular system and the effect of its occlusion.

<u>Objective:</u> The main objective of this virtual study was to evaluate some haemodynamics parameters in different patient-specific LA/LAA morphologies to identify characteristics potentially related to a high risk of thrombus formation.

<u>Methods:</u> Eleven patient-specific morphologies provided by the Cardiovascular Center in Aalst, Belgium were studied. From 3D rotational angiography images, left atria (LA) and LAA geometries were extracted and processed to create volumetric meshes. The Computational Fluid Dynamic (CFD) method was used to simulate blood flow in the atrium. Simulations were run using a laminar, Newtonian and incompressible flow hypothesis. All walls were simulated rigid replicating the worst AF scenario (e.g. chronic AF), when atrial contraction is not possible anymore. At the inlets (pulmonary veins) a time-varying blood flow function was applied following literature data. At the mitral valve a constant pressure of 8 mmHg was imposed during the diastolic phase. In systole, the mitral valve was closed, behaving like a wall.

<u>Results:</u> LAA morphology parameters and indices characterizing blood flow were jointly analysed. For instance, we computed the endothelial cell activation (ECAP) parameter, which is the ratio of the oscillatory shear index (OSI) and the time average wall shear stress (TAWSS), since it estimates the thrombogenic susceptibility of the LA/LAA walls. In addition, includes the $CHA_2DS_2\_VASc$ score to relate the risk of stroke with the computed haemodynamics and morphological indices. The ECAP distribution in LA during one cardiac cycle in the studied cases shows The higher values of ECAP are located on the LAA.

<u>Conclusion:</u> Despite the limitations of virtual models of biological processes such as thrombogenesis, this study offers a potential tool to better understand the relation of LAA morphologies and haemodynamic parameters.

FATAL LATE ISCHEMIC STROKE ON A POORLY ENDOTHELIALIZED WATCHMAN LEFT ATRIAL APPENDAGE OCCLUSION DEVICE

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<u>History:</u> A 77-year-old female with a significant past medical history for immune thrombocytopenic purpura, hypothyroidism, and hypertension was being treated for persistent atrial fibrillation with a CHA2DS2-VASc score of 3 (points for hypertension, age, and sex). Initially the patient was anticoagulated with warfarin until 2013 when she experienced a left hemorrhagic bursitis with an INR of 2.8. The patient's anticoagulation was changed to the direct oral anticoagulant rivaroxaban until 2015 when this was changed to apixaban following a lower gastrointestinal bleed. The patient tolerated this well until April 2016 when a Watchman® left atrial appendage (LAA) occlusion device was implanted.

<u>Indication for Intervention:</u> Multiple major bleeding episodes while on anticoagulation.

<u>Intervention:</u> In April 2016 under transesophageal echocardiography (TEE) guidance a 24mm Watchman® device was implanted into the LAA with adequate positioning and no peri-device leakage. Following the procedure, dual antiplatelet therapy (DAPT) including aspirin and clopidogrel was initiated. However, in May 2016 she presented to hospital with hemorrhoidal bleeding so her DAPT was changed to warfarin with an INR target of 2.0-3.0. Unfortunately, the INR was subtherapeutic for the first 5 weeks resulting in a TEE confirmed thrombus overlying the device in June 2016. After extensive discussion, the INR target was increased to 2.5-3.0 and low dose aspirin was initiated. TEE in September 2016 showed thrombus resolution whereby warfarin was discontinued in December 2016. In April 2017, the patient was admitted to the intensive care unit with altered level of consciousness, decompensated septic shock, and hypoxemic respiratory failure with a TEE confirmed device thrombus. Brain MRI showed small acute infarcts involving multiple vascular territories. The patient passed away peacefully in the presence of her family after withdrawing physiologic support. Autopsy showed multiple cerebral and cerebellar infarcts and micro-infarcts associated with fibrin thrombi, and cardiac examination showed a poorly endothelialized Watchman® device with a dislodged thrombus in the left atrium. The final cause of death was determined to be septic shock and multiple thromboembolic events.

<u>Learning Points of the Procedure:</u> We report the late complication of ischemic stroke due to thrombus formation on an incompletely endothelialized Watchman® device 1 year after implantation. This case suggests that the endothelialization process of this device is not fully understood and may be inhibited by early subtherapeutic anticoagulation and thrombus formation. In summary, complete endothelialization is crucial in preventing long-term ischemic stroke, and patients with early anticoagulation or device complications may require additional follow-up to prevent this fatal late complication.

PANNUS FORMATION AFTER LAA OCCLUDER DISLOGEMENT AS A RARE COMPLICATION

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Republican Scientific and Practical Center "Cardiology"; Heart Rhythm Department; Minsk City
Pannus formation after laa occluder dislogement as a rare complication

<u>History and Physical:</u> 75 years old female patient was admitted to the hospital in October 2016. Clinical diagnosis: Permanent normosystolic atrial fibrillation. CTI ablation (2011), VVIR pacemaker implantation (2011), DDDR pacemaker re-implantation (2013), arterial hypertension 2-nd degree, risk 4. Diabetes Mellitus, type 2. Pulmonary hypertension. Obesity 2 degree. CHA2DS2-VASc score 5. Patient was taking warfarin and having labile INR.

<u>Imaging and Intervention:</u> Due to high risk of stroke and labile INR on warfarin the patient underwent Left Atrial Appendage Occluder (LAAO) implantation. During the procedure LAA angiography was performed. Entrance of LAA was measured in different positions:

RAO 30, CRAN 15 – 23.4 mm; RAO 30, CAUD 15 – 24.2 mm. Amplatzer Cardiac Plug 26 mm was selected for implantation. LAAO implantation was successfully performed. Traction test was negative. LAAO position stable. The second day after LAAO implantation trans-esophageal Echo was performed and revealed no abnormalities. The patient was discharged on the 3-d day after the procedure. Rivaroxaban was prescribed for 3 months. At 3-month follow–up TEE was performed. The Patient had dislodgement of a disk-part of the occluder into distal direction of the appendage. The upper part of the disk slept under the ridge. Pannus formation is currently registered above the disk at previous disk position, so that it was covering the main part of the ridge. We could describe triangle formation which is formed by the disk surface, pannus and the ridge (Pic. 1). The patient was switched to warfarin aiming INR about 2,5-3,0. At 6-month follow–up TEE was performed. This diagnostic revealed thrombus formation on LAAO disk surface in size of 1,46*0,41cm (Pic. 2). The pannus was not visualized anymore. Warfarin dose was increased, aiming INR about 3,0. At 9-month follow-up no more thrombotic masses were verified. The patient was recommended to continue intake of Rivaroxaban.

Learning Points of the Procedure: Pannus formation is a rare additional complication phenomenon after LAA occluder disk dislodgement. Pannus is a substrate for further thrombus development. In order to prevent LAAO dislocation it is important to choose the right size of the device, to be sure not to put the device too deep into LAA. Achieve stable position of the occluder is always important. Adequate anticoagulation after LAAO implantation should not be underestimated.

THE INTRAOPERATIVE ROLE OF RT3DTEE FOR TRANSSEPTAL PUNCTURE: CHALLENGING CASES

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Background: Access to the left atrium (LA) for several interventional procedures is obtained by transseptal puncture that permits direct passage to the LA via the interatrial septum (IAS) and systemic venous system. Careful knowledge of anatomy of IAS and its anatomical variations (thickened, aneurysmal, previous procedures, presence of PFO) is important for the success of the procedure and the safety of the patient.

Methods: RT3DTEE permits good images of IAS and correct evaluation of the distance from aorta and left atrium walls; may be useful in patients with unusual anatomy of interatrial septum such as lipomatous hypertrophy (LH) and very small surface of fossa ovalis (FO) (Panel A) to reach exactly the right point to puncture and to see the tenting of the fossa by the catheter tip. In patients with congenital heart disease who have undergone surgical or percutaneous repair, access from the RA to the LA could be challenging and the use of

RT3DTEE con be very helpful for the procedure. A case of previous ASD closure with Amplatzer device n.22 (PANEL B) in which is possible to see the close relationship between the device, the aortic root and the roof of LA. Clearly to access the LA without puncturing the transseptal device is possible only in the inferior part of IAS just below the device through the adjacent native septum. 3DTEE imaging facilitates the procedure by providing in one single view detailed pictures of the targets in relation to each other. Congenital corrected transposition (cGTA) in situs viscerum inversus is a rare cardiac malformation characterized by the combination of discordant atrio-ventricular and ventriculo-arterial connections (PANEL C). The great arteries are parallel to each other. By far the most important structure to avoid puncturing is in our case the pulmonary trunk due to its close position with IAS.
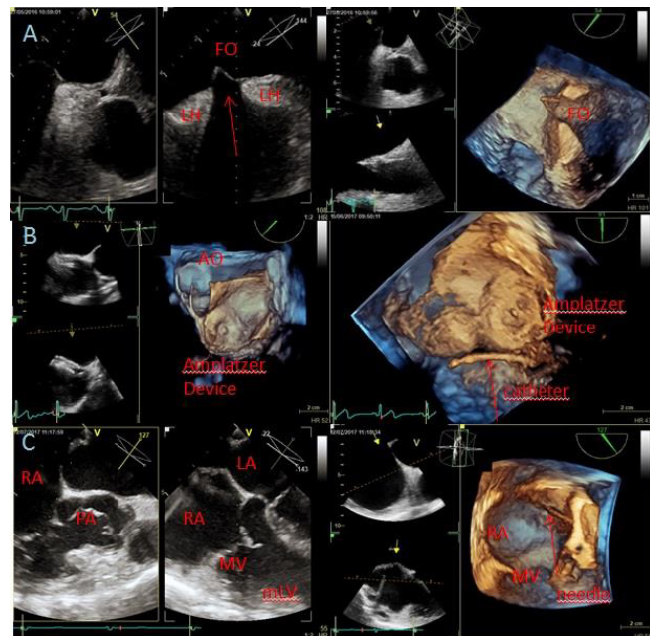

Figure 1.

Conclusions: Performing transseptal puncture the role of RT3DTEE is an added value showing anatomical images in multiple perspective, even more if complex congenital heart disease or previous percutaneous repair are present.

LEFT ATRIAL APPENDAGE OCCLUSION FOR STROKE PREVENTION IN PATIENTS WITH VALVULAR ATRIAL FIBRILLATION

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Cliniques Universitaires Saint-Luc

Background: Left atrial appendage occlusion (LAAO) is a valuable therapy for stroke prevention among patients with non valvular atrial fibrillation (NVAF).

Objective: The aim of the present study was to evaluate the feasibility and the safety of LAAO in patients with valvular atrial fibrillation (VAF).

Methods and Results: Among 85 consecutive patients undergoing LAAO in our center since 2009, 10 of them had prior valvular surgery (2 surgical bioprostheses, 2 TAVI and 6 valve repairs) at a median time of 1520 days. At baseline, the CHA2DS2-VASc score was significantly higher in patients with VAF (group 1 ; 5.6 ± 2.1) than in those with NVAF (group 2 ; 4.7 ± 1.4, p=0 .04), but the HASBLED was similar between groups 1 and 2 (3.8 ± 1.4 vs 3.4 ± 1.1 respectively, p=0.17). There were no difference in procedural success (100 vs 97%) nor in the rate of periprocedural major adverse events (1 migration successfully snared in group 1 vs 2 tamponades treated successfully by pericardiocentesis in group 2). At follow-up (median time 312 vs 330 days respectively, p=NS), overall survival was 80% in group 1 vs 89% in group 2 (p= 0.33) with no death procedure- nor device-related; the rate of additional adverse events was similarly low between groups 1 and 2 : major bleedings (2 vs 3, p=0.10) and ischemic strokes (0 vs 3, p=1).

Conclusion: Our data suggest that LAAO for stroke prevention is feasible and safe among patients with valvular atrial fibrillation, at mid term follow-up.

TRANSCATHETER LEFT ATRIAL APPENDAGE OCCLUSION USING DIFFERENT DEVICES IN THE REAL LIFE: RESULTS OF THE BELGIAN REGISTRY

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Objectives: This study aimed at assessing the safety and efficacy at mid-term follow-up of left atrial appendage occlusion using different devices, in the real life in Belgium.

Methods and Results: Between June 2009 and November 2016, 457 consecutive patients (63% males, 75±12 yrs, CHA2DS2-VASc 4±0.6, HASBLED 3.5±0.7) undergoing left atrial appendage occlusion in 21 centers, were included in the study. Technical success was 97.1%. There were 19 periprocedural major adverse events (4.1%) including three death (0.6%), nine tamponnades (1.9%), four major bleedings (0.8%) and two device embolizations (0.4%). The procedural outcome was similar between patients implanted with the Watchman device (N = 139) and those treated with the ACP/Amulet prosthesis (N = 318).

Among patients successfully implanted with a complete follow-up (672 patient-years, median follow-up 1273 days), the actual annual stroke rate was 1.2%, lower than the expected stroke risk (4%, 70%

reduction). The observed bleeding rate was 2%, while the calculated risk was 3.7% (46% reduction).

Kaplan-Meier analysis showed a similar overall survival (91±3% and 87±4% versus 93±2% and 87±3% ; p = 0.35) and event-free survival (88±3% and 80±5% versus 92±2% and 84±3% ; p = 0.17) at 1 and 2 years, for the Watchman versus the ACP/Amulet groups of patients, respectively.

At last follow-up, 90% of patients were left untreated by any anticoagulants: medication was limited to aspirin in 65% or to nothing in 5.7% of cases.

Conclusions: The data of the Belgian left atrial appendage occlusion registry suggest that the procedure is safe and effective in a real world setting, to prevent atrial fibrillation-related thromboembolism at mid-term follow-up, using either the Watchman or the ACP/Amulet device.

PERCUTANEOUS CLOSURE OF LAA IN A PATIENTE WITH COR TRIATRIATUM

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Background: Cor triatriatum(CTT)is a rare congenital heart disease (incidence 0,1-0,4%) in which the left atrium is divided into parts by a fibromuscular membrane. The postero-superior portion receives venous blood, whereas the anterior-inferior part is in contact with mitral valve, fossa ovalis and left atrial appendage (LAA). The membrane is attached laterally to the junction of the left upper pulmonary vein and LAA, medially to the interatrial septum above the fossa ovalis. CTT could be associated with other cardiac defects for example LSVC, ASD or anomalous venous return. This type of disease can be very severe in infancy mimic mitral stenosis or have a late presentations related to other cardiac conditions such as mitral regurgitation or atrial fibrillation (AF).

History: We report a case of a patients (woman, 47 years) with CTT with large unrestrictive communications between the two chambers and small ostium secundum atrial septal defect. She was referred to our echolab for evaluation for LAA percutaneous closure as a bearer of permanent AF and Cooley's disease (CHA2-DS2-VASC:2, HAS-BLED:4). The latter condition is an absolute contraindication for oral anticoagulation.

Imaging: RT2D/3D TEE clearly shows the absence of clots, the LAA anatomy: cauliflower like, the anatomical relationships between the membrane and surrounding structures and the interatrial septum in detail.

Indication for intervention: we decides to use the Watchman device (n.21, Boston Scientific) for the presence of the membrane just above
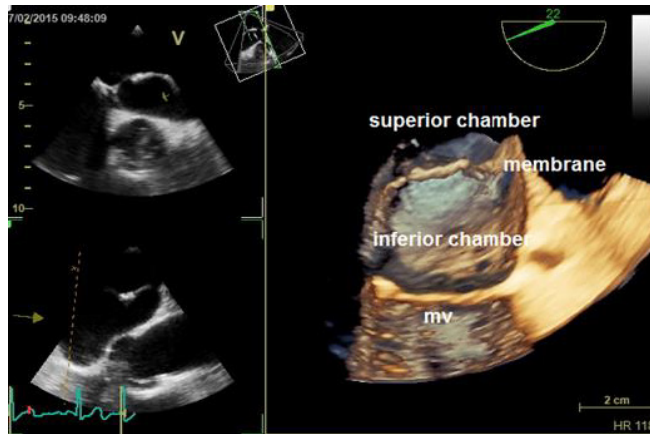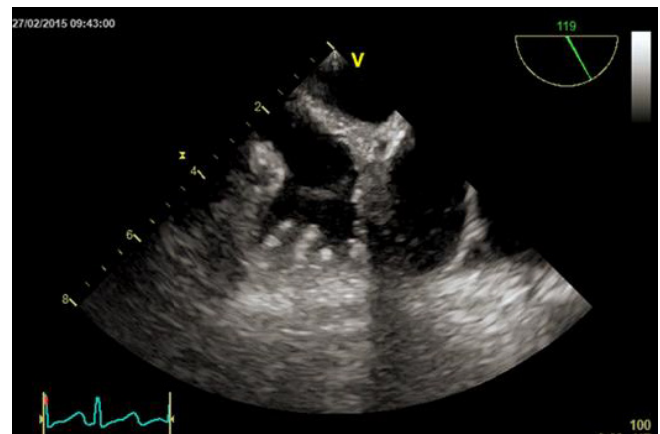
Figure 1.

Figure 2. The membrane arising from the IAS just above the small ASD.

Figure 3. The anatomical relationship between LAA, membrane and LAA.

the LAA. We decided not to cross the interatrial septum through the ASD but to perform the transseptal puncture in a more postero-inferior position in the IAS below the membrane.

Figure 4. LAA with "cauliflower" morphology, no evidence of clots.
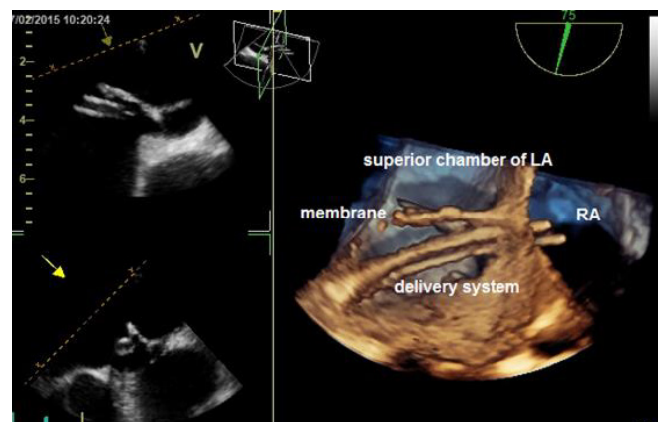
Figure 5. The passage of the delivery system below the membrane, towards the LAA.

Figure 6. The Watchman device allocated in LAA just below the membrane.

Conclusions: In our case the decision to close the LAA was very helpful for the patient with Cooley's disease and absolute contraindication for anticoagulation. The 3D findings help us to guide the

percutaneous approach of LAA closure in each step: the passage of the delivery system through the interatrial sepum, the right positioning of the device in LAA and the relationship with the membrane.

NO ANTIPLATELET THERAPY FOLLOWING LEFT ATRIAL APPENDAGE CLOSURE IN PATIENTS WITH VERY HIGH BLEEDING RISK

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Background: LAA percutaneous closure (LAAC) has been proposed and validated as an effective and safe treatment in patients with atrial fibrillation (AF) and contra-indication to anticoagulant therapy. Optimal post procedural antithrombotic medication and its duration is still under debate, as the bleeding risk needs to be balanced against the risk of device thrombus formation and thromboembolic complications. Many different antiplatelet regimens after LAAC have been proposed :1) 6 months DAPT + lifelong ASA, 2) 3 months DAPT + lifelong ASA, 3) 6 weeks DAPT + lifelong ASA, 4) Single ASA lifelong. Nevertheless in very high risk bleeding patients the requirement of lifelong single antiplatelet therapy remains the main limitation, as recent data showed similar bleeding rates in patients treated with ASA to those treated with oral anticoagulant. In clinical practice about 6% of patients have no antithrombotic therapy post LACC, due to high bleeding annual rates.

Objective: To investigate the long-term outcome of patients undergoing LAAC followed by no antiplatelet therapy.

Methods: This is an ongoing, observational, retrospective, nonrandomized, multicenter registry. All patients treated with LAA percutaneous occlusion with ACP/AMULET, between 2012 and 2016, that have suspended any antiplatelet therapy due to clinical conditions, will be included. At least 1 year of follow-up will be required.

Patients with no antiplatelet therapy at follow up will be compared to patients with patients who maintain either single or dual antiplatelet therapy. Additionally, the efficacy of this new antithrombotic strategy will be evaluated by comparing the rate of embolic and bleeding events at follow-up in the study population with the event rate predicted by the patients' CHA2DS2-VASc and HAS-BLED scores, respectively.

Conclusion: Aim of this study is to prove the feasibility and safety of LAAC in a subsets of AF patients at very high bleeding risk unsuitable for lifelong sin.

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CSI Africa Abstracts

CSI Africa – December 1-2, 2017

LARGE PATENT DUCTUS ARTERIOSUS AND SEVERE PULMONARY VALVE STENOSIS

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History: 06 years old female patient, Body weight 22kg. Systolic and continuous murmurs since birth. Pediatric cardiology assessment at the age of one year. Follow up with repeated airways infections that indicated percutaneous P.D.A. closure and Pulmonary valvuloplasty.

Physical Examination: Systolic murmur on the pulmonary auscultation focuGrade 4-5/6 and continuous murmur under the left subclavian

E.C.G: Right axis deviation, Biventricular hypertrophy.

T.T.E: Biventricular hypertrophy. Good systolic function. Severe pulmonary valve stenosis (dysplasic valve, doming shape, post stenotic dilatation, transvalvular gradient 100mmHg, annulus 18mm of diameter. Right ventricular systolic pressure 110mmHg.

Confluent pulmonary artery branches. Fluximetry in the pulmonary artery compatible with large Patent Ductus Arterious 6mm of diameter.

Angiography: Profile view severe pulmonary valve stenosis, post stenotic dilatation, annulus 20mm. Patent ductus arteriosus, 6mm diameter.

Intended Procedure: Percutaneous Pulmonary Valvuloplasty and Transcatheter closure of PDA using an Amplatzer ductus occluder type I.

Learning Points: Challenges with the pulmonary valvuloplasty associated with PDA.

DEVELOPING A CARDIO-SURGICAL CENTER IN CENTRAL AFRICA: THE CAMEROON EXPERIENCE

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Objective: To create awareness and stimulate the zeal to develop cardio-surgical centres in low income countries.

Background: Within the M.E.C.C.A (Monetary and Economic Community of Central Africa) zone, cardiovascular health is a major asset. The Shisong Cardiac Centre in Cameroon has over the past seven years assisted many clients to regain lost hopes.

Method: A retrospective review of patients who underwent percutaneous interventions, pacemaker implantations and cardiac surgery from January 2010 to June 2017.

Results: Total performance and respective monthly (30-day) mortality rate: Cardiac Catheterizations, diagnostic and interventions: (459), mortality rate (0.002%). Pacemaker implantations: (155), mortality rate (0.007%).Cardiac Surgery: (643), intra-operative mortality rate(0.004%).

Discussion: Late presentation at procedures and financial hardship on the part of the population, availability of consumables, human resources, and technical difficulties are amongst the factors that have characterized our experience.

Conclusion: Cardio-surgical centres are possible in low income countries. Challenges are bound to occur but through a collaborative approach, sustainability may be assured. Patient education and a safe sociopolitical atmosphere play vital roles.

SHORT AND INTERMEDIATE TERM SAFETY AND EFFICACY OF PERCUTANEOUS DEVICE CLOSURE FOR SECUNDUM ATRIAL SEPTAL DEFECTS USING OCCLUTECH FIGULLA OCCLUDER N

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Background: Transcatheter closure has become the method of choice for most patients with secundum ASD. Although the Occlutech device may have some advantageous characteristics there is a paucity of data on outcomes after the use of this relatively new device.

Objectives: To investigate the safety, effectiveness & hemodynamic effects of percutaneous atrial septal defect (ASD) closure using the Occlutech® devices in a prospective trial.

Methods: Observational, single arm study including 111 patients who underwent ASD closure between October 2013 and December 2015. Device performance, immediate, short and intermediate-term outcomes were assessed.

Results: Median age and ASD size were 7.8 years (8 months–59 years) and 16.5 mm (4.8–38 mm) respectively. Deficient or absent retro-aortic rim was observed in 30 patients (27%). All patients had dilated right side chambers. Pulmonary artery systolic pressure > 35 mmHg was observed in 57 (51%) patients who had significantly larger ASDs (p=0.009) and larger RV lengths (p=0.006). Implantation of Occlutech device (mean size of 19.4±8 mm) with successful closure was reported in 95.5%. Closure success was linked to larger IVC rims (p = 0.009). An IVC rim ≥ 7.2 mm is 97.1% sensitive, while IVC rim ≥ 11.2 mm is 100 % specific for closure success. Median follow-up of 6 months was obtained in all patients. Successful closure lead to significant regression of RV & pulmonary artery dimensions at 1, 3 & 6-months follow up (p<0.001).

Conclusions: Transcatheter closure of secundum ASDs using the Occlutech septal Occluder is safe, and effective in children, adolescents, and adults. The device performed well in a wide range of anatomical scenarios resulting in excellent short and intermediate-term outcomes. Sufficient IVC rim is the most important factor in predicting successful closure.

SHORT AND INTERMEDIATE TERM SAFETY AND EFFICACY OF PERCUTANEOUS DEVICE CLOSURE HEART SURGERY FOR CONGENITAL HEART DISEASE IN RABAT'S PEDIATRIC HOSPITAL

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Background: We aim to report the results of our experience in pediatric closed heart surgery for congenital heart disease in Rabat's pediatric hospital, in a country that suffers from a lack of a strong health infrastructure.

Methods: We conducted a retrospective study of patients that underwent palliative or corrective surgery for congenital heart disease in Rabat's pediatric hospital, in a period of 27 months, from 25 June 2014 to 12 September 2016.

Results: The mean age of our patients (n=62) was 2 years 8 months. 62% were infants, below X months old. Patent ductus arteriosus was the most frequent non-cyanotic lesion while tetralogy of Fallot was the most frequent cyanotic heart disease. Four patients had congenital dysrhythmia. 35 palliative procedures were performed (12 modified Blalock Taussig shunts, 13 pulmonary arterial bandings) while 33 were curative (24 ligations of patent ductus arteriosus, 6 Crafoord interventions and 3 ligations of double aortic arches). 4 patients underwent epicardial permanent pacing. The short-term (mortality rate was 8%, mainly in the group that underwent palliative procedures (a ratio of 4 to 1). Hemodynamic instability was by far the most frequent early complication whereas nosocomial infection was the most reported complication in the medium term. In the longer term, one death was reported a year after surgery in a patient who underwent a BT shunt. One case of residual hypertension was reported in our oldest patient that underwent a Crafoord intervention. 38% of the patients were lost to follow up while the control was satisfying for 62% of them. Three of the patients that underwent a Blalock Taussig shunt for a ToF have had a corrective surgery; 2 of them in private structures and one in Rabat's children hospital during a surgical mission by a Swiss team. The patients that underwent PA banding are still waiting for corrective surgery.

Conclusion: Congenital heart disease is still under-diagnosed and undertreated in our country. Our results are encouraging despite the lack of infrastructure and the complexity of the heart disease treated. Our country remains in need of specialized centers with multidisciplinary teams and expert physicians.

BALLOON MITRAL VALVOTOMY IN A PATIENT WITH SITUS INVERSUS DEXTROCARDIA

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Ain Shams university Cairo, Egypt

Background: A 20 years old female with history of rheumatic fever at the age of 10.Three years ago, she started to note progressive shortness of breath on moderate effort followed by paroxysmal nocturnal dyspnoea and orthopnoea.

On Examination: Pulse =80/ min. regular with good volume, equal on both sides, well felt peripherally and without special character BP=120/80 mmHg. Normal jugular venous pressure no leg oedema. Liver was felt 2cm below the left costal margin. Apex was in the right fifth space inside the mid clavicular line with slapping character. Auscultation revealed accentuated S1, loud P2+Opening snap+mid diastolic rumble at the apex.

Echo showed Dextrocardia +Situs inversus, Mitral stenosis with mitral valve area (MVA) =1cm^2 by planimetry without mitral regurgitation (MR).Wilkins score =8/16,Rifaie score=2/12.TEE revealed free left atrial appendage(LAA)+thin atrial septum. Balloon mitral valvotomy (BMV) was planned.

Technical challenges: 1-Right or let femoral vein access. Reverse the fluroscopy screen or not 3-Left atrial and atrial septal orientation 4. Expected difficult crossing of the mitral valve

Technique: Right femoral vein and artery puncture were done. (BMV) was done using the transvenous transseptal approach. Inoue balloon technique was undertaken using 24-26 mm balloon diameter. Technical tips will be discussed during the presentation.

Result: (BMV) was successfully done without significant complications. Left atrial pressure dropped from 25 to 14 mmHg. Pulmonary artery mean pressure dropped from 40 to 20 mmHg Post (BMV) echo showed: Mitral valve area= 1.9 cm² by planimetry. Mean Doppler gradient=5 mmHg .Moderate mitral regurgitation.

Conclusion: Association of rheumatic mitral stenosis and dextrocardia with situs inversus is very rare. Only few cases were reported in the English literature where (BMV) was done. Despite technical difficulties, (BMV) could still be done in the hands of experienced operators.

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