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First-in-Man Transfemoral Transcatheter Aortic Valve Replacement With the 29 mm Edwards SAPIEN XT Valve

Melanie Freeman,[1] MBBS, Josep Rodés-Cabau,[2] MD, Marina Urena,[2] MD, Robert DeLarochelliere,[2] MD, Eric Dumont,[2] MD, Jean-Bernard Masson,[3] MD, Alexander B. Willson,[1] MBBS, MPH, Ronald K. Binder,[1] MD, Stefan Toggweiler,[1] MD, Jonathon Leipsic,[1] MD, David A. Wood,[1] MD, and John G. Webb,[1*] MD

Objectives: To demonstrate the feasibility of transfemoral transcatheter aortic valve replacement (TAVR) with the 29 mm Edwards SAPIEN XT valve and Novaflex™ + delivery system through a 20F expandable sheath (eSheath™, Edwards Lifesciences, USA). In addition, to describe the use of the Novaflex + delivery system and expandable sheath. **Background:** TAVR has undergone significant advances in device technology resulting in smaller profile sheaths and delivery systems, allowing transfemoral delivery of a 29 mm valve. **Methods:** Twelve patients underwent transfemoral TAVR with the 29 mm Edwards SAPIEN XT valve and Novaflex + delivery system through a 20F expandable sheath. Baseline clinical and procedural characteristics are evaluated. In-hospital and 30-day outcomes are reported according to Valve Academic Research Consortium criteria. **Results:** All patients were male with a mean aortic annulus diameter of 25.0 ± 1.1 mm and 25.9 ± 1.2 mm, on transesophageal echocardiography and multidetector computerized tomography, respectively. Mean iliofemoral minimal luminal diameter (MLD) was 8.0 ± 0.8 mm. Successful deployment of the valve occurred in 11 out of 12 patients. Valve embolization occurred in one patient. Aortic valve area increased from 0.7 ± 0.2 to 2.0 ± 0.5 cm^2 ($P < 0.001$). There were two major vascular complications; however, there were no in-hospital or 30-day neurological events, need for pacemaker insertion, or mortality. **Conclusions:** Transfemoral TAVR with the 29 mm Edwards SAPIEN XT valve and Novaflex + delivery system through a 20F expandable sheath was feasible with acceptable short-term outcomes. © 2012 Wiley Periodicals, Inc.

Key words: aortic valve stenosis; heart valve prosthesis; prosthesis design; heart valve prosthesis implantation; bioprosthesis

BACKGROUND

Transcatheter aortic valve replacement (TAVR) has emerged as a treatment option in patients with severe symptomatic aortic stenosis at high risk or not eligible for conventional aortic valve replacement [1,2].

Since its advent, significant developments have been made in device technology, resulting in smaller profile sheaths and delivery systems [3]. This has led to a significant reduction in vascular complications [4], and has expanded the number of patients eligible for the transfemoral approach who would otherwise have been excluded due to small vessel diameter.

Currently, the Edwards SAPIEN XT THV™ (Edwards Lifesciences, USA) is manufactured in 20 mm, 23 mm, 26 mm, and 29 mm external diameters. The 20 mm valve is compatible with the NovaFlex transarterial delivery system and has been utilized in Canada and Japan [5]. A 29 mm valve delivery system

[1]Department of Cardiology, St. Paul's Hospital, University of British Columbia, Vancouver, Canada
[2]Department of Cardiology, Quebec Heart and Lung Institute, Laval University, Quebec, Canada
[3]Department of Cardiology, Montreal University Hospital Center, Quebec, Canada

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*Correspondence to: John G. Webb, MD, St. Paul's Hospital, 1081 Burrard Street, Vancouver, BC, Canada V6Z 1Y6.
E-mail: john.webb@vch.ca

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is available in Canada and Europe, but only by transapical approach [6].

We describe the initial experience with the 29 mm SAPIEN XT valve implanted using a new transfemoral delivery and expandable sheath system (Novaflex+™ and eSheath™, Edwards Lifesciences, USA).

METHODS

Twelve patients with severe symptomatic aortic stenosis, who were considered high surgical risk, underwent transfemoral TAVR using the 29 mm Novaflex + delivery system via a 20F eSheath. The procedures were performed at three centers in Canada (St Paul's Hospital, Vancouver, Quebec Heart and Lung Institute, Quebec, and Montreal University Hospital Center, Quebec) between October 2011 and January 2012. Eligible patients had annulus diameters of 24–27 mm, as determined by transesophageal echocardiography (TEE), with an iliofemoral minimum artery luminal diameter (MLD) of 7 mm, measured on angiography or multidetector computerized tomography (MDCT). All patients provided written informed consent.

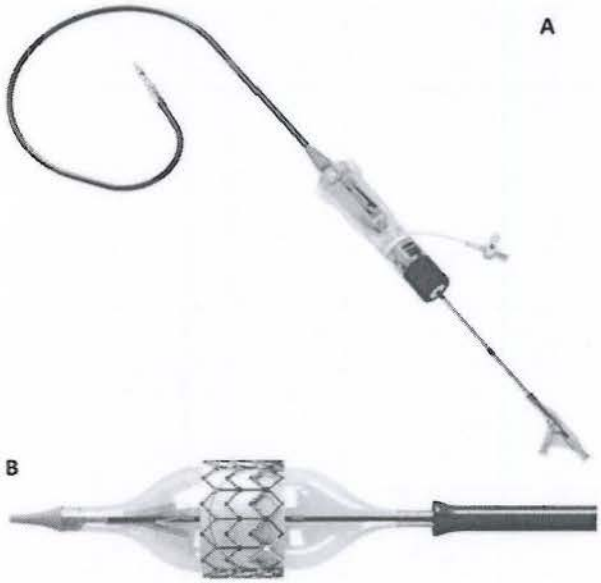

Fig. 1. (A) Novaflex + delivery system, (B) distal end of novaflex + delivery system with expanded valve. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

Novaflex +

The Novaflex delivery system was developed to allow for a reduction in sheath size when compared with the earlier generation Retroflex system [3]. The Novaflex + delivery system (Fig. 1) is an adaptation of this with a 360° flex tip design providing tighter balloon shaft support, while its balloon tip has been shortened to minimize the likelihood of left ventricular injury. The delivery system includes a handle with a rotating thumb wheel for articulation of the catheter, a tapered distal tip to facilitate crossing the native valve, and a balloon catheter for deployment of the valve. The handle contains an indicator that shows the amount of catheter deflection, a valve alignment wheel for fine adjustment of the transcatheter heart valve (THV) during valve alignment, a press and release button that enables movement between handle positions, and a flush port to flush the flex catheter. A stylet is included within the guidewire lumen of the delivery system to maintain lumen patency during the crimping process. The balloon catheter has radiopaque valve alignment markers defining the valve alignment position and the working length of the balloon. A radiopaque double marker proximal to the balloon indicates the flex catheter position during deployment.

eSheath

The eSheath is an expandable sheath that allows for transient sheath expansion during valve delivery

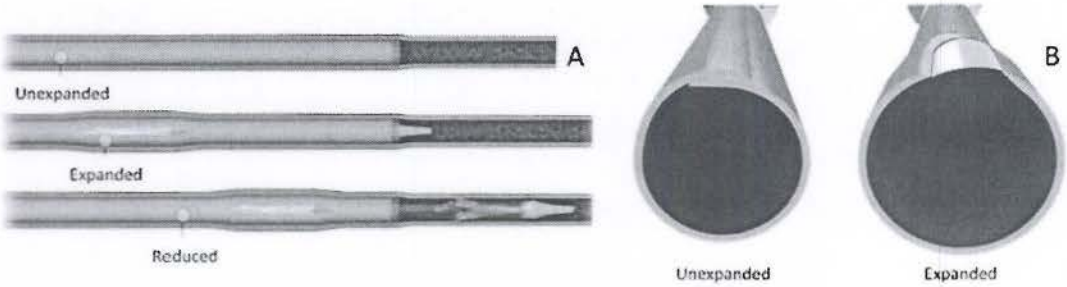

Fig. 2. Edwards eSheath. (A) As the valve/delivery device is advanced through the sheath, the expansion seam opens to accommodate the outer diameter of the device and then recoils to a reduced profile once the valve has passed through. (B) Unexpanded and expanded eSheath. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

TABLE I. Comparison of Sheath Sizes and SFAR Ratios

Parameter		16F eSheath	18F eSheath	20F eSheath	22F RF3 sheath	24F RF3 sheath
Recommended valve	SAPIEN XT	20 mm 23 mm	26 mm	29 mm	–	–
	SAPIEN	–	–	–	23 mm	26 mm
Sheath ID	Unexpanded	16F	18F	20F	22F	24F
Sheath OD	Unexpanded	6.7	7.2	8	8.4	9.2
	Expanded with valve	8.9	8.9	9.9	–	–
Recommended minimum artery diameter		6	6.5	7	7	8
Sheath OD/Vessel ID (SFAR)	Unexpanded	1.12	1.11	1.14	1.2	1.15
	Expanded with valve	1.48	1.37	1.41	–	–

SFAR: sheath to femoral artery ratio based on recommended minimum artery diameter, ID: Internal diameter, OD: Outer diameter.

(Fig. 2). The sheath is introduced in its low profile configuration reducing the potential for arterial injury. The sheath transiently expands to allow passage of the valve. As the valve passes the sheath recoils to its lower profile diameter. The eSheath is available in 16F, 18F, and 20F unexpanded internal diameters with 6.7 mm, 7.2 mm, and 8.0 mm unexpanded outer diameters respectively (Table I). The maximum temporary expanded internal diameter of the eSheath is 8.9 mm for sizes 16F and 18F and 9.9 mm for size 20F. All sheaths have a working length of 36 cm.

Edwards SAPIEN XT Valve

The 29 mm SAPIEN XT valve consists of bovine pericardial leaflets, a cobalt-chromium frame and a sealing cuff on the inflow aspect of the stent to prevent paravalvular regurgitation. The current manufacturer's recommendations are to base device selection on two-dimensional long axis TEE measurements of the aortic annulus. The 20 mm SAPIEN XT is recommended for use in patients with annulus diameters of 17–19 mm, the 23 mm SAPIEN XT valve is recommended for use in those with annulus diameters of 18–22 mm, while the 26 mm SAPIEN XT is recommended in those with annulus diameters of 21–25 mm. The 29 mm SAPIEN XT valve has been recommended for use in patients with annulus diameters of 24–27 mm. However many groups, including our own, are moving towards 3-dimensional annular sizing utilizing MDCT. Recommendations for MDCT sizing are still in development [7,8].

Once fully deployed, the valve heights are measured at 13.5 mm, 14.3 mm, 17.2 mm, and 19.1 mm for the 20, 23, 26, and 29 mm valves, respectively (Fig. 3).

Procedural Details

The TAVR procedure has been described elsewhere in detail [9]. Briefly, all procedures were performed under general anesthesia with TEE guidance. The eSheath, with the introducer, is inserted over a guidewire into the common femoral artery, after femoral access is achieved. When introducing the sheath, the expansion seam is oriented toward the posterior wall of the artery being accessed and the sheath is inserted into the vessel in its unexpanded state. The introducer is then removed leaving the sheath in place. Following balloon aortic valvuloplasty, the 29 mm SAPIEN XT valve mounted on the Novaflex + delivery system is inserted into the sheath hub, protected by a loader which is retracted after the valve has passed through it. The Novaflex + delivery catheter is passed through the eSheath into the descending aorta, where adjustments are made to align the valve on the balloon catheter. The delivery catheter tip is then flexed to facilitate passage through the aortic arch and stenotic native valve. Once positioned, using TEE and angiographic guidance, the valve is deployed during rapid ventricular pacing. Once the delivery system is retrieved, the femoral access site is closed utilizing previously inserted percutaneous sutures (ProGlide™, Abbott Vascular, Abbott Park, IL) or by surgical closure.

All patients underwent transthoracic echocardiography prior to discharge. In-hospital and 30-day outcomes are reported according to Valve Academic Research Consortium criteria [10].

Statistics

Continuous variables are described as mean ± the standard deviation, while categorical variables are described with numbers and percentages. Means were compared using two tailed paired Students T test; P values of <0.05 were considered statistically significant.

RESULTS

Baseline Characteristics

Baseline clinical characteristics are listed in Table II. All patients were male with a mean height and weight of 1.7 ± 0.1 m and 77.8 ± 13.1 kg. The mean aortic annulus diameter on TEE was 25.0 ± 1.1 mm. All patients underwent preprocedural MDCT with contrast revealing a MDCT derived mean annular diameter of

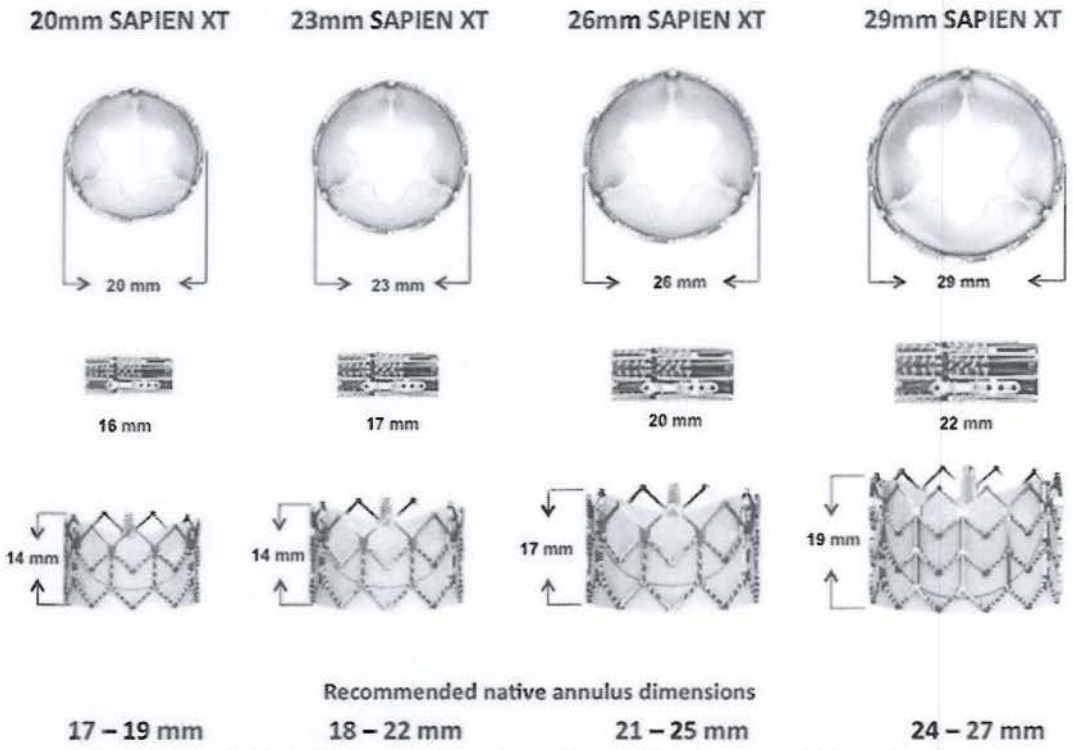

Fig. 3. Edwards SAPIEN XT valve dimensions with associated recommended annulus diameters. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

TABLE II. Baseline Characteristics

Baseline characteristics	$n = 12$
Age (years)	84.7 ± 4.9
Male	12 (100%)
Diabetes	5 (42%)
Height (m)	1.7 ± 0.1
Weight (kg)	77.8 ± 13.1
Prior CABG	3 (25%)
COPD	3 (25%)
Prior pacemaker	1 (8%)
Frailty	5 (42%)
Porcelain aorta	0 (0%)
STS PROM (%)	5.8 ± 2.7
NYHA class pre TAVR	
Class I	1 (8%)
Class II	0 (0%)
Class III	9 (75%)
Class IV	2 (17%)
GFR (ml/min)	67.9 ± 26.0
Mean TEE aortic annulus diameter (mm)	25.2 ± 1.1
Mean MDCT aortic annulus diameter	25.9 ±1.2
Mean AVA (cm^2)	0.7 ± 0.2
Mean trans aortic gradient (mm Hg)	46.7 ± 17.3
LVEF (%)	44.2 ± 14.3
Moderately-severe or severe mitral regurgitation	0 (0%)

CABG: coronary artery bypass grafting, COPD: chronic obstructive airways disease, STS PROM: Society of Thoracic Surgeons predicted risk of mortality, NYHA: New York Heart Association, TAVR: transcatheter aortic valve replacement, GFR: glomerular filtration rate, TEE: transesophageal echocardiography, MDCT: multidetector computerized tomography, AVA: aortic valve area, LVEF: left ventricular ejection fraction.

25.9 ± 1.2 mm and a mean annulus area of 5.6 ± 0.3 cm^2. Mean iliofemoral MLD was 8.0 ± 0.9 mm.

Procedural Outcomes

Insertion of the 20F eSheath, passage of the Novaflex + delivery system through the expandable sheath and across the arch, positioning of the 29 mm SAPIEN XT valve, removal of the delivery system, and vascular closure was successful in all patients. Procedural details are shown in Table III.

Successful deployment of the valve occurred in 11 out of 12 patients (Fig. 4). Valve embolization occurred in one patient (case 1). The valve was redeployed in the transverse aorta, with no clinical sequelae. It is unclear as to the cause of embolization, however a 29 mm SAPIEN XT was successfully implanted 2 months later utilizing a transapical approach to reduce the risk of ventricular movement during deployment.

A periaortic hematoma was suspected in one patient (case 8) on TEE immediately following valve implantation (Fig. 5). This was subsequently confirmed on MDCT. There were no sequelae.

Cardiac tamponade occurred in one patient due to wire perforation of the left ventricle. A pericardial

TABLE III. Procedural Details

Case number		1	2	3	4	5	6	7	8	9	10	11	12	Mean ± SD
Annulus diameter (mm)	TEE	24	24	25	26	24	26	27	26	24.5	25	23	25	25.0 ± 1.1
	TTE	25	26	24	25	24	25	24	22	-	21	-	-	
	MDCT	26.4	26.5	25.9	27.4	25.5	26.5	25.5	23.5	24.5	27.8	27	25.3	25.9 ± 1.2
Annulus area cm^2	MDCT	-	5.7	5.4	-	5.4	5.6	5.3	5.0	5.4	6.2	6.7	-	5.6 ± 0.5
Access site	Side	Right	Right	Left	Right	Right	Left	Right	Right	Right	Right	Right	Right	
	MLD (mm)	7.1	7.5	8	9	8.5	6.8	7.6	7.5	8	9.7	8.2	8	8.0 ± 0.8
	Vessel calcification	0	2	2	1	0	0	1	1	1	0	0	1	
	Vessel Tortuousity	1	2	1	0	2	0	1	1	2	2	1	1	
	Percutaneous closure	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	No	
	Closure device	Proglide	Proglide	Proglide	Perclose	Proglide	Proglide	NA	Proglide	NA	Proglide	NA	NA	
SFAR	Unexpanded	1.13	1.07	1.00	0.89	0.94	1.18	1.05	1.07	1.00	0.82	0.98	1.0	1.0 ± 0.1
	Expanded	1.39	1.32	1.24	1.10	1.16	1.46	1.30	1.32	1.24	1.02	1.21	1.24	1.3 ± 0.1

TEE = transesophageal echocardiography; TTE = transthoracic echocardiography; MDCT = multidetector computed tomography; MLD = minimal luminal diameter; Vessel calcification was graded as none = 0, mild=1(some calcification), moderate=2 (the course of the artery can be seen without injection of contrast dye), or severe = 3 (heavily calcified iliofemoral arteries); Vessel tortuosity was graded as none = 0, minimal = 1, moderate = 2, or severe = 3; SFAR = Sheath to Femoral Artery Ratio.

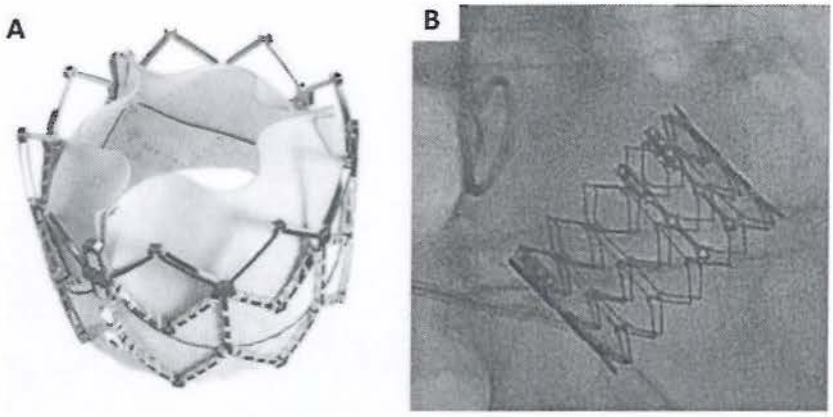

Fig. 4. A: Edwards SAPIEN XT valve. B: 29 mm SAPIEN XT following successful deployment. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

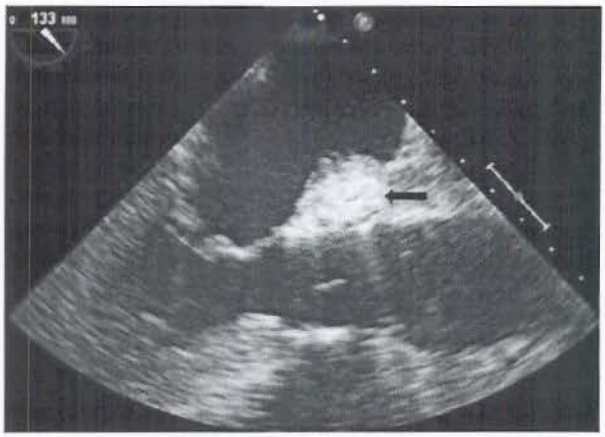

Fig. 5. Periaortc hematoma as seen on TTE following deployment of the 29 mm SAPIEN XT.

effusion without tamponade was noted on TEE prior to crossing the native valve with the nosecone and valve prosthesis. The 29 mm SAPIEN XT was successfully implanted; however during valve positioning the patient became hypotensive and pericardiocentesis was performed immediately after valve implantation. Despite successful pericardiocentesis and good hemodynamics, bleeding persisted and a surgical intervention was required. A small perforation at the level of the apex was identified and successfully repaired. The patient was discharged home well 5 days postoperatively.

Outcomes

At discharge and 30 days, there were no strokes, need for pacemaker insertion, or deaths (Table IV). There were two major vascular complications; wire

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