

Transcatheter Aortic Valve Implantation for Stenosed and Regurgitant Aortic Valve Bioprostheses

CoreValve for Failed Bioprosthetic Aortic Valve Replacements

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Transcatheter aortic valve implantation is increasingly being used to treat severe aortic stenosis in patients with high operative risk. In an aging population the incidence of aortic stenosis is rising, and increasing numbers of elderly patients are undergoing aortic valve replacement with bioprosthetic valves. Therefore, there is a corresponding increase in prosthetic degeneration. This presents cardiologists with a cohort of patients for whom the risk of re-do aortic valve surgery is prohibitive. We present the first series of such patients with degenerative bioprosthetic stenosis or regurgitation successfully treated with CoreValve (Medtronic, Luxembourg) implantation. (J Am Coll Cardiol 2010;55:97-101) © 2010 by the American College of Cardiology Foundation

Transcatheter aortic valve implantation (TAVI) has entered the mainstream as a viable treatment option for patients with symptomatic, severe aortic stenosis (AS) who are at prohibitively high surgical risk. The initial success in 2002 (1) has been followed by a surge of interest, strengthened by encouraging medium-term results with both the self-expanding CoreValve (Medtronic, Luxembourg) (2,3) and balloon-expandable Edwards Sapien (Edwards Lifesciences, Irvine, California) systems (4,5). Although not initially designed for the purpose, the CoreValve (Medtronic) implant is also an option for patients with a degenerative aortic valve bioprosthesis who would be at high surgical risk from repeat thoracotomy. We present a case series of 4 patients in whom this treatment has been used for failing bioprostheses.

Case Histories

Patient #1. A 76-year-old man underwent isolated aortic valve replacement (AVR) in 1986 for nonrheumatic AS with a 23-mm Carpentier-Edwards valve. During 2007 he became increasingly dyspneic and was found to have severe aortic regurgitation (AR) with moderate AS. His renal function was impaired (creatinine 201 mmol/l, estimated glomerular filtration rate 28 ml/min), and given his resultant

high operative risk score (logistic EuroSCORE 19%), he was referred for TAVI. Transthoracic echocardiography confirmed severe eccentric aortic regurgitation, and the “aortic annulus” measured 21 mm. The procedure was performed under conscious sedation as previously described (6). The right radial artery was cannulated, and a 5-F pigtail catheter was advanced to the aortic root. A 4-F balloon flotation temporary pacing wire was placed via the right internal jugular vein. With the left common femoral approach, the arterial access was prepared for closure with the Prostar (Abbot Vascular Devices, Redwood City, California). The valve was crossed with an Amplatz L1 (Cordis Corp., Miami, Florida) catheter, a hand-curved J-tip Amplatz SuperStiff guidewire (Boston Scientific Corp., Miami, Florida) was coiled in the left ventricle, and an 18-F Cook sheath was introduced over the wire. Without valvular pre-dilation, a 26-mm CoreValve (Medtronic) was introduced and positioned under fluoroscopic guidance, with concurrent pacing at 150 beats/min to limit the effects of aortic regurgitation on valve advancement during deployment. Aortography and hemodynamic monitoring confirmed resolution of the aortic regurgitation (Fig. 1). There was no gradient across the new bioprosthesis on invasive assessment. The femoral access site was closed with the pre-laid ProStar suture pair. A post-procedure echocardiogram the next day showed normal functioning of the supra-annular valve, with a peak flow velocity of 2.7 m/s across it, and trivial aortic regurgitation.

Patient #2. A 66-year-old man underwent AVR in 2001 for symptomatic AS with a 21-mm Mitroflow (Sorin Group

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**Abbreviations
and Acronyms**

AR	= aortic regurgitation
AS	= aortic stenosis
AVR	= aortic valve replacement
LV	= left ventricular/ ventricle
TAVI	= transcatheter aortic valve implantation

Canada, Inc., Burnaby, British Columbia, Canada) bioprosthesis. Echocardiography revealed recurrence of aortic stenosis with regurgitation and significant left ventricular (LV) dilation. Dobutamine stress echo revealed an ejection fraction of 30% with evidence of contractile reserve. The patient was considered by the multi-disciplinary team to be at prohibitively high surgical risk

(logistic EuroSCORE 25%) and was accepted for TAVI. Via the common femoral artery, aortography revealed grade IV AR with a gradient of 100 mm Hg across the valve. A 26-mm CoreValve (Medtronic) device was deployed under rapid ventricular pacing just inferior to the sewing ring of the original bioprosthesis, with resolution of the AR and a transvalvar gradient of 5 mm Hg.

The patient had a diuresis of 4 l over the first 6 h after the procedure and immediately felt much better. On the first post-operative day, he asked to go home but was persuaded to stay for an echocardiogram, which showed some early improvement in LV function (LV velocity time integral rising from 17.4 to 18.8 cm).

At 2-month follow-up he was asymptomatic and walking 4 miles/day. Repeat echocardiography revealed a well-positioned implant and improved hemodynamic parameters with a peak gradient of 50 mm Hg.

Patient #3. An 85-year-old woman was diagnosed with degeneration of her 18-year-old AVR—a flail leaflet causing grade IV AR. Due to her high logistic EuroSCORE of 38%, she was referred for TAVI. Via the femoral approach, a 26-mm CoreValve (Medtronic) implant was deployed into the existing xenograft (Fig. 2) as previously described, with no procedural complications. At 5-month follow-up the patient reported a vast improvement in her quality of life with minimal dyspnea on exertion (New York Heart Association [NYHA] functional class I). A transthoracic echo-

cardiogram showed that the CoreValve (Medtronic) was well-seated with only a mild paraprosthetic leak and a peak velocity of 2.4 m/s.

Patient #4. This patient underwent implantation of a 25-mm Cryolife-O'Brien (Cryolife International, Atlanta, Georgia) bioprosthesis in 2002 for AS. At 84 years of age, she developed degenerative stenosis of her AVR with a gradient of 83 mm Hg and mild AR. Iliac angiography revealed vessels of insufficient caliber to allow a transfemoral approach (Table 1). The multidisciplinary team agreed that TAVI via the left subclavian approach would be her best option.

The procedure was performed under general anesthesia. The left subclavian artery was accessed via a subclavicular surgical cut-down. Introduction of the 18-F St. Jude (St. Jude Medical, St. Paul, Minnesota) sheath required gradual rotation during advancement, because the fit in the subclavian artery was tight. The marker-tip of the sheath dehiscd during introduction and was retrieved with an ENSnare (HATCH Medical, L.L.C., Duluth, Georgia) device (Fig. 3). The 26-mm CoreValve (Medtronic) bioprosthesis was advanced through the tipless sheath and deployed. The skirt remained constrained, but given the decrease in gradient to 50 mm Hg and complicated procedure, it was accepted pending further spontaneous valvular expansion.

Later that evening the patient developed a pale, cold, and pulseless left arm. Emergency subclavian arteriography revealed occlusive subclavian artery dissection. The vessel was approached retrogradely via percutaneous brachial artery access. A 7 × 80 mm LifeStent FlexStar (Edwards Lifesciences) was implanted, and flow restored. After a stormy recovery involving inotropic support and hemofiltration, repeat echocardiography revealed an increase in transvalvular gradient to 70 mm Hg. Therefore, we proceeded to aortic valvuloplasty with a 20-mm BALT (Montmorency, France) balloon. This decreased the trans-aortic gradient from 70 to 30 mm Hg without demonstrable AR (Figs. 3C and 3D). Review at 6 months showed the patient to be well, NYHA functional class II.

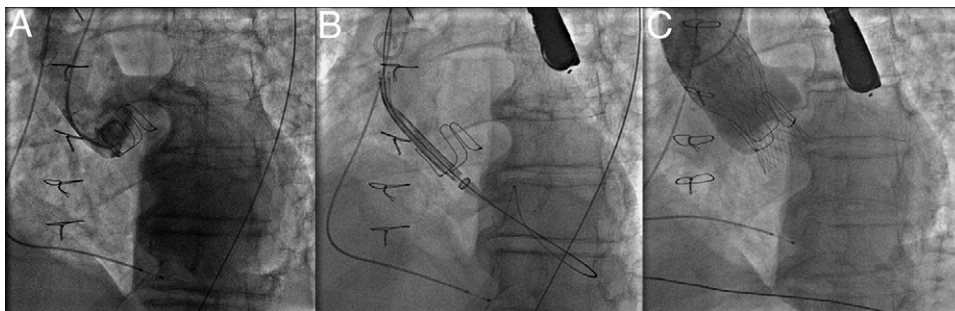


Figure 1. Successful Treatment of AR in a Bioprosthetic Aortic Valve Replacement

(A) Aortography demonstrating aortic regurgitation (AR) of the bioprosthesis. (B) With the bioprosthesis as a target for placement of the CoreValve (Medtronic). (C) Aortography showing the final position of the CoreValve (Medtronic) within the scaffold of the original device without AR.

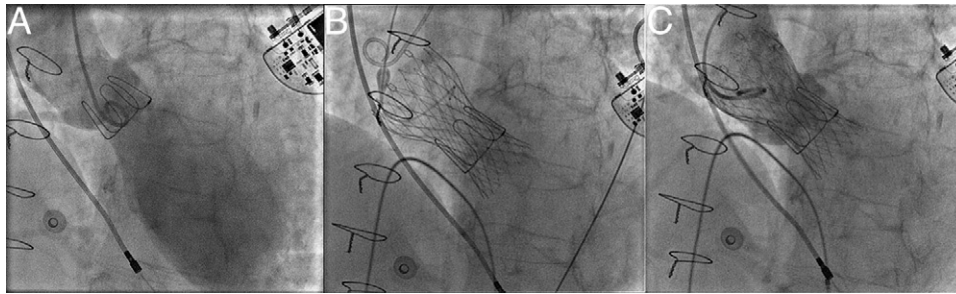


Figure 2 CoreValve Deployment Within a Bioprosthesis

(A) Pre-procedure severe aortic regurgitation (AR). (B) Fully deployed CoreValve (Medtronic) prosthesis with (C) almost complete resolution of the AR.

Echocardiography demonstrated good LV function with a peak gradient across the valve of 29 mm Hg and no AR.

Discussion

Our case series demonstrates that the CoreValve (Medtronic) prosthesis can be safely and effectively deployed in stenotic and regurgitant degenerative surgical aortic valve bioprostheses. Implantation is facilitated by the existing valve structure, and immediate results show good hemodynamic

status with a low transvalvular gradient and no AR. Medium- and long-term results are awaited, but in the meantime, CoreValve (Medtronic) TAVI seems to be an acceptable alternative to re-do surgery for patients with degenerative aortic bioprostheses who are at high perioperative surgical risk.

Aortic stenosis remains the most common valvular complaint in Europe (7,8), and age is a significant contributing factor in its natural history (8). The gold standard for treatment remains surgical AVR (9). The combined effects of an aging population and the prevalence of AS in this cohort have led to increasing numbers of elderly patients being referred for valvular surgery. The valve of choice in these patients is usually a bioprosthetic device, to avoid the need for anticoagulation with its associated complications (10). As a result, there is an increasing prevalence of failing bioprosthetic AVRs. Concurrently, the spectrum of comorbidities in these patients grows more complex, and therefore the risks of re-do surgery increase. Absolute surgical risk for re-do aortic valve operations might be raised by up to 15% compared with initial implants (11,12).

The feasibility of implanting a transcatheter valve into a surgical bioprosthesis was first demonstrated in a pig model in 2007. The investigators used the Cribier-Edwards system to transapically implant 23-mm devices into 5 Carpentier Edwards porcine aortic valve prostheses to good effect (13). A case report of successful treatment of a severely regurgitant aortic valve bioprosthesis with the CoreValve (Medtronic) system has also been described—with retention of good function and no complications at 1-year follow-up (14).

The risks inherent in the TAVI procedure still exist in these patients, as illustrated by the subclavian artery dissection in Patient #4. However, there are some features that make this option attractive. The original bioprosthesis gives a highly visible target for placement of the new implant and offers a scaffold that immediately grips the CoreValve (Medtronic) as it is deployed, facilitating accurate placement of the device. Additionally, the uniform circular sewing ring allows for equal and symmetrical expansion of the skirt of the valve such that paraprosthetic AR is unlikely.

Table 1 Patient Characteristics

	Patient			
	#1	#2	#3	#4
Age (yrs)	76	66	85	84
Sex	M	M	F	F
NYHA functional class	III	IV	III	III
Before procedure				
Creatinine (mmol/l)	233	110	100	129
AV peak gradient (mm Hg)	80	100	50	120
LV ejection fraction (%)	60	30	45	65
AR grade	4	4	4	0
MR grade	1	2	2	0
Rhythm	AF	SR/paced	Paced	SR
Procedural details				
Access gauge	18-F	18-F	18-F	18-F
Pace controlled?	Y	Y	Y	Y
Balloon pre-dilation	N	N	N	N
Implant size	26	26	26	26
After implant				
AR grade	0	0	1	1
AV peak gradient (mm Hg)	39	30	30	35
Post-implant dilation	N	N	N	Y
Final AR grade	0	0	1	1
Post-implant PPM?	N	N/A	N/A	N
Hospital stay (days)	2	2	6	16
Follow-up (months)	2	3	5	6
AR grade	0	1	1	0
AV peak gradient (mm Hg)	27	58	24	29

AF = atrial fibrillation; AR = aortic regurgitation; AV = aortic valve; LV = left ventricular; MR = mitral regurgitation; N/A = not applicable; NYHA = New York Heart Association; PPM = permanent pacemaker; SR = sinus rhythm.

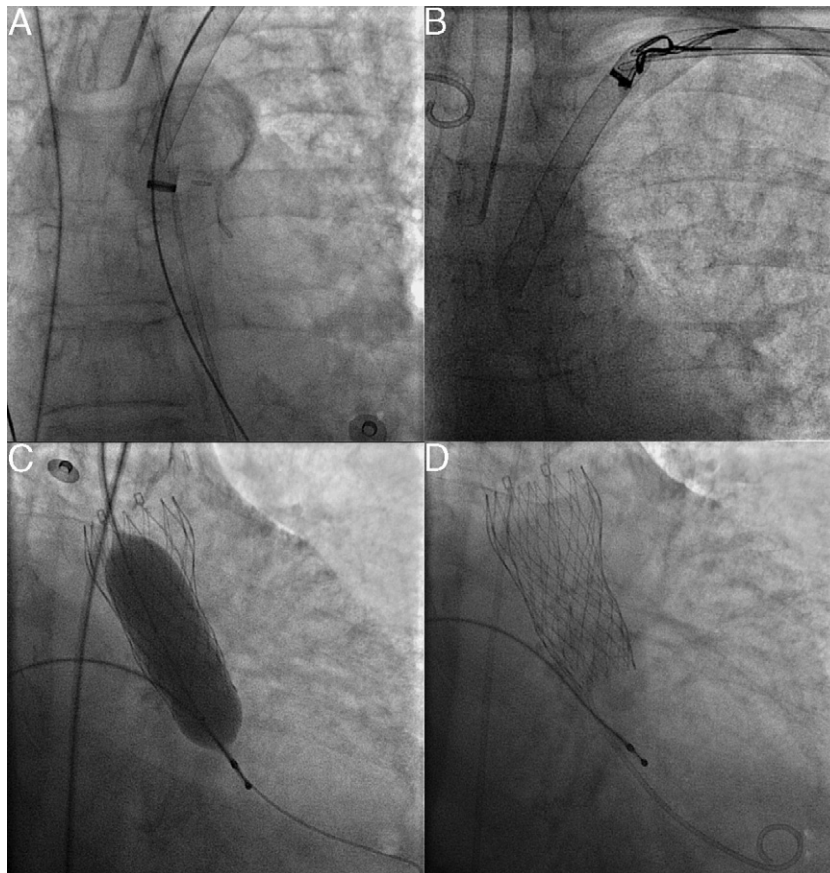


Figure 3 Retrieval of Fractured Sheath-Tip and Post-Implant Valvuloplasty

(A) The detached sheath tip within the ascending aorta, subsequently secured with an ENSnare (HATCH Medical, L.L.C., Duluth, Georgia) device (B). (C) Post-procedural valvuloplasty with a BALT (Montmorency, France) balloon improving the proximal deployment (note the temporary pacing wire within the right ventricle providing pace control). (D) Final position of the CoreValve (Medtronic) device.

Several other aspects of this technique warrant discussion in further detail. Firstly, in native cases, measurement of the aortic annulus is critical to the success of the procedure. In the cases presented, however, it is simply necessary to know the valvular diameter of the previously implanted valve. A 26-mm CoreValve (Medtronic) will be the correct option in the vast majority of cases. It is important to note that internal diameters of <21 mm in the aortic valve implant would be insufficient for CoreValve (Medtronic) implantation, exceeding its design limitations, with a resultant gradient and possible malfunction of the leaflets resulting in a suboptimal outcome.

Second, although native cases require balloon predilation under rapid pacing control, this is not necessary with re-stenotic valves and indeed is likely to be counterproductive for bioprosthetic valves, which might disintegrate with risk of stroke or torrential regurgitation. Patients with severe aortic regurgitation, however, do benefit from pacing at implant both to reduce systolic pressure and to reduce reflux of blood into the LV, which will augment any tendency for the valve to “move forward” into the ventricle on deployment. This pacing rate, however, should aim to

achieve a systolic blood pressure of 100 mm Hg rather than the 40 mm Hg used during balloon dilation and can therefore persist throughout the valve deployment. Currently, tamponade from temporary pacing wires has ironically proved one of the most risk-prone aspects of CoreValve (Medtronic) TAVI cases (15), so the lack of need for a temporary pacing wire in cases without severe AR adds to the safety of the procedure.

The need for permanent pacing after the procedure is a limitation of the CoreValve (Medtronic) system. The registry data suggest a rate of 20% to 25%. In this case series, none of the patients required a permanent pacemaker, presumably because the skirt of the valve is primarily restricted by the sewing ring of the original surgically implanted valve, such that compression of the conduction system is much less likely. Waiting to see whether a pacemaker might be required is a drain on bed-days, and it is advantageous to the patient to be able to mobilize freely on day 1 without significant risk of heart block.

The technique described in this report makes the use of a surgical bioprosthesis rather than a mechanical valve poten-

tially more attractive in patients undergoing conventional valve replacement (16), and already this trend is being observed. However, the resulting internal diameter of the valve decreases with every deployment. This “Russian doll” effect might become more evident in light of successful procedures within both bioprosthetic and TAVI replacements and might serve as an additional driver for the development of valves with smaller diameters. Indeed the longest surviving recipient of the CoreValve (Medtronic) system was also the first to have a “valve-in-valve” procedure, and 3-year follow-up has shown maintenance of clinical status and a well-functioning valve (17). It is notable in our series that the gradients obtained on initial follow-up are not negligible. Although this is unlikely to be important in patients for whom there was no other acceptable surgical alternative, this would not be the case for a patient with a longer life-expectancy. Similarly, if the valvular gradient remains stable over time, this is less of a concern than if the gradient begins to rise with ingrowth of tissue.

The evidence for the use of TAVI is limited, as with any new technology, and consists of mainly of registry data. This can often include the steeper initial learning curve—although impressive procedural success rates of 97% and mortality of 1.5% have recently been reported by a multicenter group (18).

Conclusions

We have confirmed the viability of TAVI in degenerative bioprostheses, both stenotic and regurgitant. Long-term follow up of these patients is required to demonstrate ongoing benefits and limitations of this technique.

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