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Transcatheter Aortic Valve Implantation for Pure Severe Native Aortic Valve Regurgitation

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Objectives This study sought to collect data and evaluate the anecdotal use of transcatheter aortic valve implantation (TAVI) in pure native aortic valve regurgitation (NAVR) for patients who were deemed surgically inoperable

Background Data and experience with TAVI in the treatment of patients with pure severe NAVR are limited.

Methods Data on baseline patient characteristics, device and procedure parameters, echocardiographic parameters, and outcomes up to July 2012 were collected retrospectively from 14 centers that have performed TAVI for NAVR.

Results A total of 43 patients underwent TAVI with the CoreValve prosthesis (Medtronic, Minneapolis, Minnesota) at 14 centers (mean age, 75.3 ± 8.8 years; 53% female; mean logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation), 26.9 ± 17.9%; and mean Society of Thoracic Surgeons score, 10.2 ± 5.3%). All patients had severe NAVR on echocardiography without aortic stenosis and 17 patients (39.5%) had the degree of aortic valvular calcification documented on CT or echocardiography. Vascular access was transfemoral (n = 35), subclavian (n = 4), direct aortic (n = 3), and carotid (n = 1). Implantation of a TAVI was performed in 42 patients (97.7%), and 8 patients (18.6%) required a second valve during the index procedure for residual aortic regurgitation. In all patients requiring second valves, valvular calcification was absent (p = 0.014). Post-procedure aortic regurgitation grade I or lower was present in 34 patients (79.1%). At 30 days, the major stroke incidence was 4.7%, and the all-cause mortality rate was 9.3%. At 12 months, the all-cause mortality rate was 21.4% (6 of 28 patients).

Conclusions This registry analysis demonstrates the feasibility and potential procedure difficulties when using TAVI for severe NAVR. Acceptable results may be achieved in carefully selected patients who are deemed too high risk for conventional surgery, but the possibility of requiring 2 valves and leaving residual aortic regurgitation remain important considerations. (J Am Coll Cardiol 2013;61:1577–84) © 2013 by the American College of Cardiology Foundation

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Abbreviations and Acronyms

CT = computed tomography

NAVR = native aortic valve regurgitation

TAVI = transcatheter aortic valve implantation

VARC = Valve Academic Research Consortium

Transcatheter aortic valve implantation (TAVI) has become the standard of care for extreme surgical risk patients with symptomatic severe aortic stenosis and an alternative to open surgery in those deemed high risk. Since the first TAVI procedure was performed in 2002 (1), there has been a growing worldwide experience with TAVI, and with this have come several off-label indications for this technology. Alternative access routes, bicuspid valves, valve-in-valve procedures, and TAVI for intermediate-risk patients are all of increasing interest (2–4).

It is well established that patients with severe aortic regurgitation and symptoms have a poor prognosis (5,6) and should be offered surgical aortic valve replacement (7,8). There are patients with severe aortic regurgitation and at high or extreme surgical risk for whom conventional surgical aortic valve replacement may be unsuitable and who might benefit from transcatheter-based therapy. Until now, there have been limited experience and no collective published data on the use of TAVI for pure severe native aortic valve regurgitation (NAVR) without aortic stenosis.

Methods

Study design. The study was designed as an independent, worldwide, multicenter voluntary registry of patients treated with TAVI for pure severe NAVR using the Medtronic CoreValve (Medtronic, Minneapolis, Minnesota). A total of 43 patients were collected retrospectively and prospectively from 14 centers worldwide.

Data collection. Registry data were collected from participating centers. Data collection was retrospective until December 2011 and prospective from January through July 2012. Data on baseline patient characteristics, device and procedure parameters, echocardiographic parameters, and outcomes up to July 2012 were collected from 14 centers that have performed TAVI for pure severe NAVR. Follow-up data regarding adverse events were censored in July 2012.

Definitions. Pure severe NAVR was defined as severe aortic regurgitation *without* aortic stenosis, and aortic stenosis was defined as a peak aortic jet velocity on continuous wave Doppler of >2.5 m/s (9). Patients with bioprosthetic xenograft, homograft, or autograft regurgitation were not included. Aortic valve calcification was assessed on computed tomography (CT) or transesophageal echocardiography and defined as grade I (none), grade II (mild), grade III (moderate), and grade IV (severe), as previously described (10,11). Procedural success was defined as the successful transcatheter implantation of a functioning aortic valve according to Valve Academic Research Consortium (VARC) criteria (12). Major clinical and safety endpoints were also collected and defined according to VARC criteria.

Patient selection. Patients were selected for TAVI by the heart team at the contributing hospitals. These were real-world patients deemed unsuitable for surgery due to extreme risk. For inclusion in this study, patients had to have severe NAVR without aortic stenosis (i.e., pure, not predominant, aortic regurgitation). Patients who had undergone any previous aortic valve surgery were excluded. Examples of comorbidities that heart teams considered significant enough to make the risk of surgery unacceptable included previous radiotherapy, hostile mediastinum, severe left ventricular dysfunction, previous stroke, significant pulmonary hypertension, and severe pulmonary disease.

Statistical analysis. Categorical variables are expressed as number and percentage, and continuous variables are expressed as mean ± SD. The Mann-Whitney *U* test was used to examine the association between post-procedure aortic regurgitation and death at 30 days. The chi-square and Fisher exact tests were used to find significant associations between aortic valve calcification and need for a second valve. The Fisher exact test was used to examine the association between the need for a second valve and mortality at 30 days. Data were analyzed using the SPSS version 17 (SPSS Inc., Chicago, Illinois), and statistical significance was taken as $p < 0.05$.

Technical aspects. WORKUP. The anatomy in patients with NAVR is often challenging. These patients often have a dilated aortic root, a dilated ascending aorta, and often an elliptical annulus. Figure 1 provides examples from this study of complex aortic anatomy.

There is good evidence that TAVI patients benefit from multimodality imaging during pre-procedure planning before valve sizing and deployment (13–15). In patients with NAVR, pre-procedure transthoracic echocardiography, transesophageal echocardiography, and multislice 3-dimensional CT should be considered mandatory due to the complex nature of these patients. The annulus should be carefully examined, and valve sizing should be according to measurements of the perimeter and area rather than major and minor orthogonal annular diameters. Where aortic calcification is absent, a clear understanding of the surrounding anatomy is vital, especially the ascending aortic diameter and the sinus of Valsalva diameters. When treating patients with aortic stenosis with the CoreValve (Medtronic), 10% to 20% oversizing with respect to the annulus perimeter is recommended when choosing prosthesis size. Although there are no recommendations with respect to device sizing for TAVI in NAVR, the operators in this study adhered to the recommendations for aortic stenosis with the exception of 3 patients in whom oversizing exceeded 20%, as shown in Figure 2.

ACCESS ROUTES. Although transfemoral access was the preferred route at all centers in suitable anatomy, alternative access routes were dependent on the individual center's

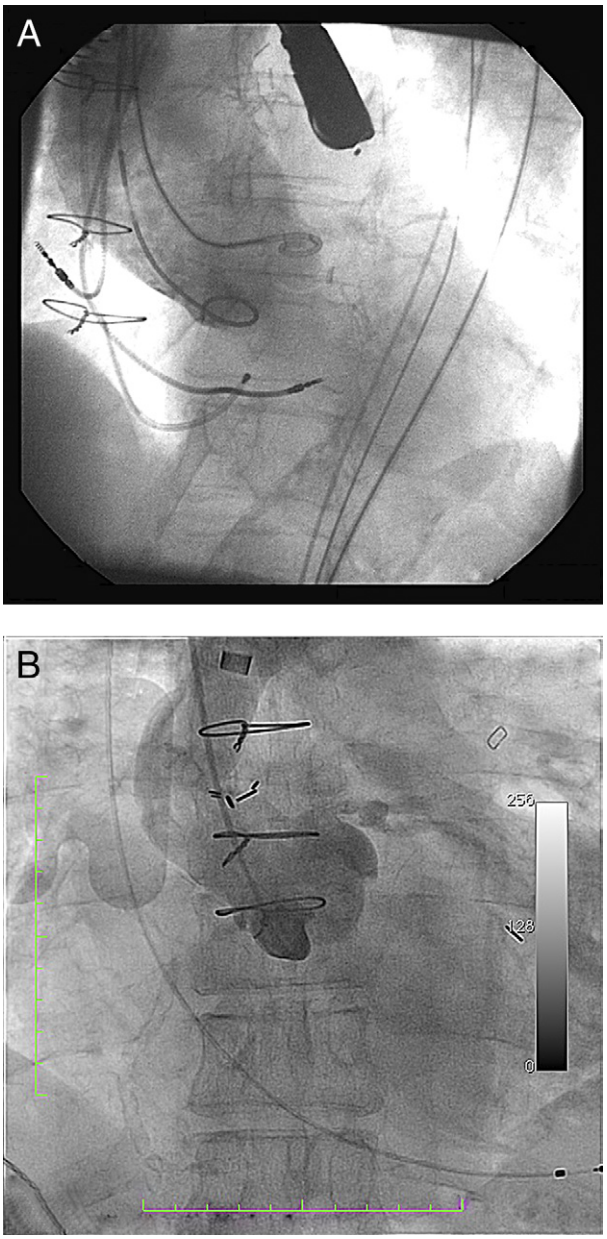

Figure 1 Examples of Complex Aortic Anatomy for Transcatheter Aortic Valve Implantation

(A) A dilated aortic root and ascending aorta as a cause of severe aortic regurgitation. **(B)** Extreme angulation of the ascending aorta in a patient who had valve-sparing ascending aortic surgery for aneurysmal dilation.

expertise and preference, given the patients' individual anatomy. Direct aortic access, subclavian access, and carotid access were all used as alternatives to transfemoral access and were previously described alternative access routes for TAVI (4,16,17).

TAVI for the NAVR procedure. In patients with absent aortic valve calcification, the procedure can be made more difficult by the lack of fluoroscopic landmarks to outline the annulus position and root anatomy. Methods that may assist

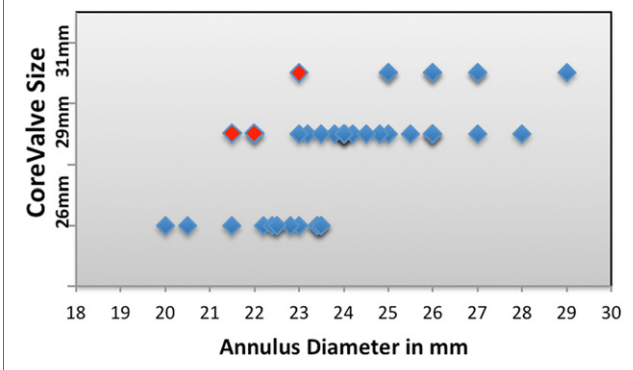

Figure 2 Device Size Versus Annulus Size

Recommended annulus diameter ranges for CoreValve sizing: 20- to 23-mm annulus, 26-mm device; 23- to 27-mm annulus, 29-mm device; 26- to 29-mm annulus, 31-mm device. Note there were 3 patients in whom oversizing above the recommendations for CoreValve sizing were used (shown in **red**).

the procedure include using fixed landmarks in the thoracic anatomy such as sternal wires, pacing wires, and vertebral bodies. Another technique is to use 2 pigtail catheters, as demonstrated in Figure 3. One is placed in the noncoronary sinus, and the other is placed in the left sinus. These techniques can help ensure accurate positioning and reduce large contrast doses from multiple aortograms.

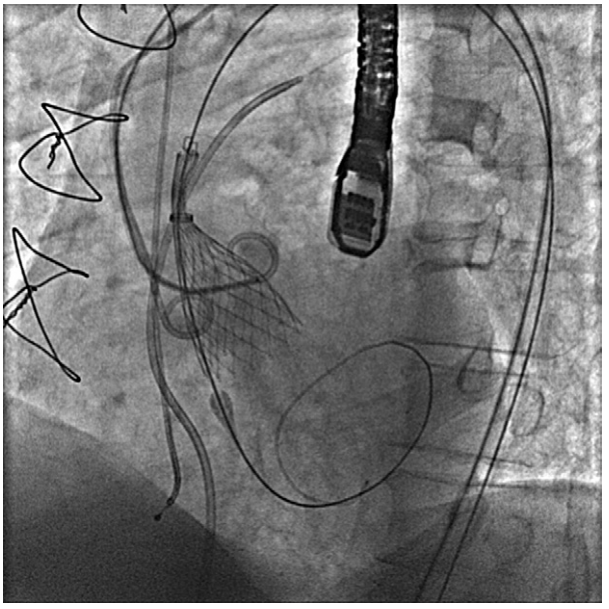

Figure 3 Two-Pigtail Technique

Two pigtails should be placed in the non and left coronary sinuses during the transcatheter aortic valve implantation procedure. This helps to demonstrate the aortic annulus where calcification is absent on fluoroscopy. This 2-pigtail technique may also be useful in limiting the amount of contrast needed for the procedure.

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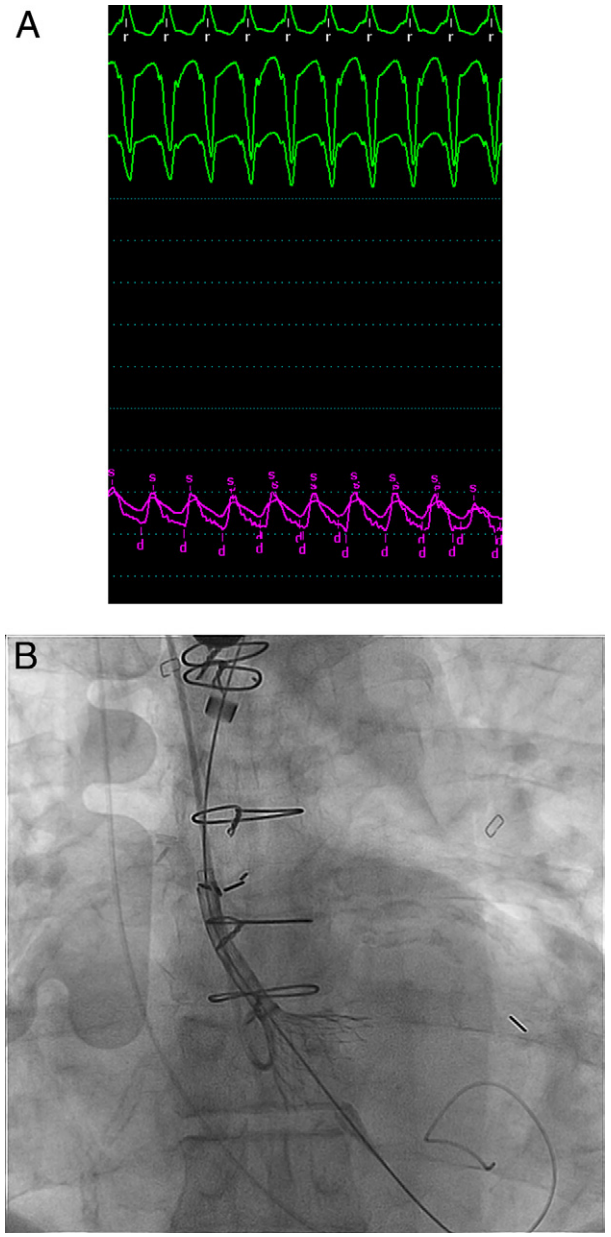

Figure 4 Rapid Ventricular Pacing During Deployment

(A) Rapid pacing reduces regurgitant volume and reduces movement of the prosthesis during deployment. **(B)** Rapid pacing is recommended during the one third to two thirds phase of CoreValve deployment in patients with severe native aortic valve regurgitation.

We recommend the use of rapid pacing (heart rate 150 to 180 beats/min) for the deployment of the CoreValve for severe NAVR. This decreases the regurgitant volume and systolic blood pressure as well as the risk of prosthesis movement. We recommend that this be used at least from one third frame deployment to two thirds frame deployment (Fig. 4). This improves valve stability and reduces sudden movements and risk of valve dislocation during the one third to two thirds phase.

In patients in whom there is significant paravalvular aortic regurgitation after valve deployment, valvuloplasty is unlikely to be of benefit and may lead to valve dislocation toward the aorta. This is due to the fact that unless there is severely calcified anatomy, the CoreValve is invariably fully expanded, and the reason for regurgitation is either suboptimal valve positioning or incorrect initial valve sizing. Where there is residual significant paravalvular regurgitation, a second valve deployed in a valve-in-valve fashion is recommended. This should be performed using a snare to fix the first valve in position (Fig. 5) and prevent ventricular embolization of the first valve, which is a recognized complication of valve-in-valve procedures.

Results

Patient demographics. Forty-three patients underwent TAVI with the Medtronic CoreValve prosthesis in 14 centers from Europe and Israel up to July 2012. Baseline patient characteristics are outlined in Table 1. The mean age of the patients was 75.3 ± 8.8 years, and the majority were female (53%). The prevalence of severe comorbidities was predictably high, with a mean logistic EuroSCORE of 26.9 ± 17.9% and a mean Society of Thoracic Surgeons score of 10.2 ± 5.3%. Each of the 43 patients was deemed unsuitable for surgical aortic valve replacement by a local heart team on the basis of severe comorbidities. The causes of NAVR are outlined in Table 2. The majority were due to degenerative changes in the

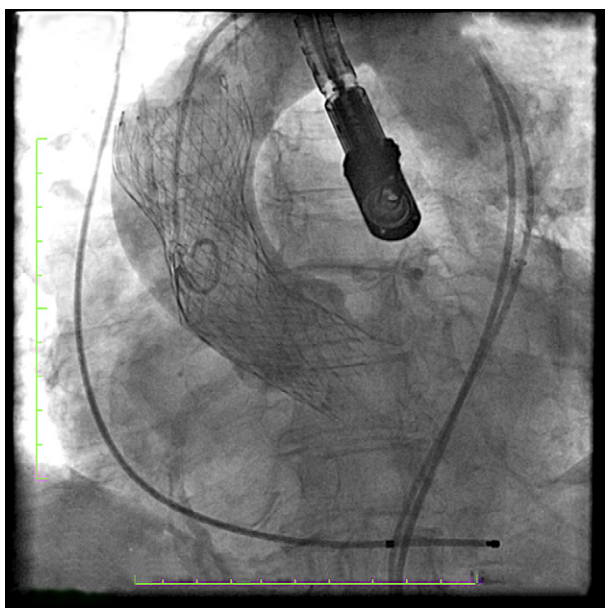

Figure 5 Snare Technique During Valve-in-Valve Transcatheter Aortic Valve Implantation

When implanting a second transcatheter aortic valve implantation device, it is recommended to use a 6-F Amplatz goose neck snare (indicated by arrow, next to pigtail catheter) to fix the first valve in position while performing a valve-in-valve procedure. This technique is used to avoid dislocation and embolization of the first valve into the ventricle.

Table 1 Baseline Characteristics

Age, yrs	75.3 ± 8.8
Female	23 (53)
Diabetes	9 (20.9)
Previous CABG	12 (27.9)
Creatinine, μmol/l	120.9 ± 149.8
GFR, ml/min	44.5 ± 25.3
Chronic renal failure*	9 (20.9)
Previous stroke	9 (20.9)
Hypertension	30 (69.8)
Coronary artery disease	21 (48.8)
Atrial fibrillation	15 (37.2)
Previous myocardial infarction	6 (13.9)
Chronic obstructive pulmonary disease	10 (23.3)
Porcelain aorta	1 (2.3)
NYHA functional class	
II	1 (2.3)
III	29 (67.4)
IV	13 (30.2)
Ascending aortic diameter, mm†	35.9 ± 8.8
Sinus of Valsalva dimension, mm†	32.8 ± 4.9
LVEDD, mm	59.4 ± 13.7
LVESD, mm	41.7 ± 14.4
LV ejection fraction, %	45.5 ± 12.9
Aortic regurgitation grade (echocardiography)	
II	0
III	24 (55.8)
IV	19 (44.2)
Aortic regurgitation grade (angiography)	
II	1 (2.3)
III	22 (51.2)
IV	20 (46.6)
Mitral regurgitation grade	
I or lower	29 (67.4)
II	11 (25.6)
IV	3 (7.0)
Pulmonary hypertension‡	4 (9.3)
Logistic EuroSCORE	26.9 ± 17.9
STS score	10.2 ± 5.3

Values are mean ± SD or n (%). *Chronic renal failure was defined as estimated glomerular filtration rate ≤30 ml (chronic kidney stage 3 or 4). †Ascending aortic and sinus of Valsalva dimensions were obtained either by computed tomography or transesophageal echocardiography, and ascending aortic dimensions in the 4 patients with aortic aneurysm were 65, 53, 41, and 45 mm respectively. ‡Pulmonary hypertension was defined as systolic pulmonary artery pressure >60 mm Hg.

CABG = coronary artery bypass graft; EuroSCORE = European system for cardiac operative risk evaluation; GFR = glomerular filtration rate; LV = left ventricular; LVEDD = left ventricular end-diastolic dimension; LVESD = left ventricular end-systolic dimension; NYHA = New York Heart Association; STS = Society of Thoracic Surgeons.

valve leaflets without root dilation. All patients had severe aortic regurgitation on echocardiography defined by standard criteria (18) without aortic stenosis (which was defined as a peak aortic velocity of >2.5 m/s) and 17 patients (39.5%) had the degree of aortic valvular calcification documented on CT or echocardiography (n = 12, grade II/mild; n = 3, grade III/moderate; n = 1, grade IV/severe) (Table 3). All patients had pure NAVR; those with mixed valve disease were excluded from this study.

Procedural results. The procedure results are outlined in Table 4. All patients had either pre- or intraprocedure transesophageal echocardiography to assess annulus size. Pre-TAVI CT was performed in 19 patients (44.2%). Transfemoral access was used in the majority of patients (n = 35), with 4 patients treated via the subclavian approach, 3 via the direct aortic approach, and 1 via the carotid. The choice of carotid access was at the operator's discretion if other access routes were less favorable due to complex anatomy. The technique used by the operators in this alternative-access carotid case was previously described (16).

Table 2 Mechanism of Aortic Regurgitation

Degenerative	27 (62.8)
Post-endocarditis	6 (14.0)
Aortic aneurysm	4 (9.3)
Aortic valve cusp restriction due to rheumatoid vasculitis, Takayasu's arteritis, unknown	3 (7.0)
Post-radiotherapy	2 (4.7)
Chronic dissection	1 (2.3)

Values are n (%).

Annulus size was calculated by CT (in those who had pre-procedure CT) or transesophageal echocardiography. The mean annulus size was 24 ± 2.3 mm, and a 29-mm prosthesis was most commonly used (29-mm annulus in 22 patients, 26-mm annulus in 14 patients, and 31-mm annulus in 7 patients). Figure 2 shows the relationship between annulus size and the device size chosen for the TAVI procedure. There were 3 patients in whom oversizing of the device exceeded the 20% oversizing according to standard recommendations for valve sizing with respect to annulus diameter. These decisions were made at the operators' discretion when there were perceived concerns regarding paraprosthetic regurgitation or valve migration.

Implantation of a TAVI prosthesis was performed in 42 of 43 patients (97.7%), with 8 patients (18.6%) requiring a second valve during the index procedure for residual aortic regurgitation. In all patients in whom a second valve was needed, aortic valve calcification was absent (p = 0.014) (Fig. 6). Aortic regurgitation of grade I or lower was present post-procedurally in 34 patients (79.1%) (grade II in 7 patients and grade III in 2 patients). Of the 8 patients who required a second valve, 5 had grade II and 1 had grade III aortic regurgitation post-procedure. The remaining 2 patients who required second valves had grade I aortic regurgitation post-procedure. There was no post-procedure grade IV aortic regurgitation and no procedure mortality; however, 1 patient required conversion to open surgery and

Table 3 Aortic Valve Calcification

I (none)	26 (60.5)
II (mild)	13 (30.2)
III (moderate)	3 (7.0)
IV (severe)	1 (2.3)

Values are n (%).

Table 4 Procedural Results

Access	
Transfemoral	35 (81.4)
Subclavian	4 (9.3)
Direct aortic	3 (7.0)
Carotid	1 (2.3)
Implantation of prosthesis	42 (97.7)
Annulus size, mm	24.0 ± 2.3
Prosthesis size, mm	
29	22 (51.2)
26	14 (32.6)
31	7 (16.3)
Valve post-dilation	4 (9.3)
Second valve required	8 (18.6)
Post-procedure AR grade	
I or lower	34 (79.1)
II	7 (16.3)
III	2 (4.7)
New permanent pacemaker	7 (16.3)

Values are n (%) or mean ± SD.
AR = aortic regurgitation.

aortic valve replacement due to residual severe aortic regurgitation post-deployment. Modified RIFLE criteria stage 3 acute kidney injury occurred in 2 patients (4.7%), 1 of whom required long-term renal replacement therapy.

The VARC-defined procedure success for TAVI was 74.4% when grade II or higher residual aortic regurgitation and the need for a second valve were taken into account.

Clinical outcomes. The safety endpoints and clinical outcomes according to the VARC definitions are summarized in Table 5. The 30-day all-cause mortality rate was 9.3% (n = 4) with a cardiovascular mortality rate of 2.3% (n = 1). Major stroke defined according to VARC occurred in 2 patients (4.7%) at 30 days. New conduction abnormalities requiring permanent pacing were present in 5 patients (16.3%). There were major access-related vascular complications in 3 patients (7%), and there were no myocardial infarctions according to the VARC definition. The mean left ventricular ejection fraction improved from 45.5 ± 12% to 49.6 ± 14.2% at 30 days (p = 0.02). The functional class of the patients at baseline and 30 days is outlined in Figure 7. The 12-month all-cause mortality rate was 21.4% (6 of 28 patients), and the cardiovascular mortality rate was 10.7% (n = 3). The need for second valve did not predict mortality at 30 days (p = 0.18), and there was no statisti-

Table 5 Clinical and Safety Outcomes According to VARC*

Mortality	
30-day all-cause	4 (9.3%)
30-day cardiovascular	1 (2.3%)
12 month all-cause	6/28 (21.4)
12-month cardiovascular	3/28 (10.7)
Major stroke (30 days)	2 (4.7)
Major bleeding	8 (18.6)
Acute kidney injury (stage 3)	2 (4.7)
Myocardial infarction	0
Access site complications	6 (14.0)
Major	3 (7.0)
Minor	3 (7.0)
VARC procedure success	32 (74.4)

Values are n (%). *The previously outlined VARC definitions of stroke (minor, modified Rankin Sale score ≤2; major, modified Rankin Scale score ≥2), major bleeding, acute kidney injury (modified RIFLE criteria stage 3), myocardial infarction, major and minor access site complications were used in this analysis.
VARC = Valve Academic Research Consortium.

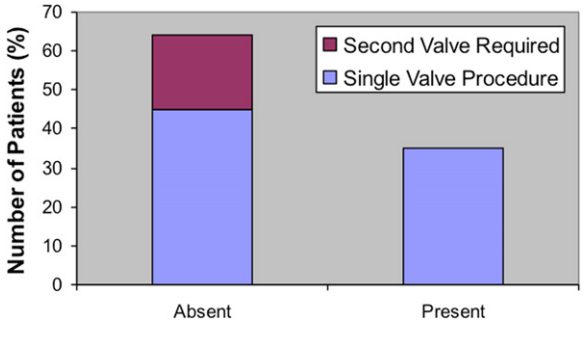

Figure 6 Relationship Between Aortic Valve Calcification and Need for a Second Valve

Eight of 26 patients (31%) without aortic valve calcification required a second valve, whereas none of the 17 patients with calcification (grades II, III, and IV) required second valves to achieve an acceptable result (p = 0.014). This association was statistically significant in chi-square and 2-sided Fisher exact tests.

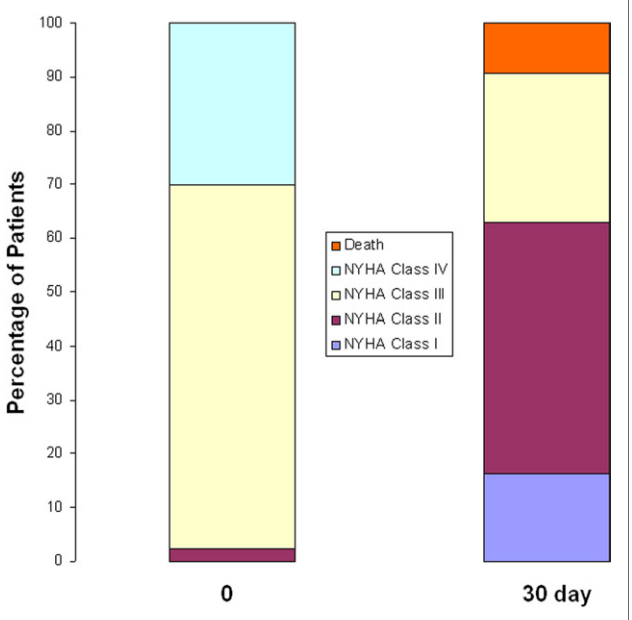

Figure 7 NYHA Functional Status

This figure shows the proportion of patients in each New York Heart Association (NYHA) functional class on the basis of their symptoms at baseline and at 30 days. Note that the majority of patients were in NYHA functional class I or II at 30 days post-procedure.

cally significant association between death at 30 days and post-procedure aortic regurgitation ($p = 0.13$, $z = 1.55$).

Causes of 12-month mortality included perforated gastric ulcer, fatal bleeding after chest tube insertion, progressive cardiac failure and cardiogenic shock, pneumonia, arrhythmia, and a further unwitnessed death due to presumed arrhythmia. Of the 4 patients who had aortic regurgitation due to aortic aneurysm/aneurysmal dilation, 3 of them had died at 6 months (arrhythmia, cardiac failure, and perforated gastric ulcer).

Discussion

TAVI has now become the standard of care for patients with symptomatic severe aortic stenosis who are considered at extreme risk for surgery and an acceptable alternative to surgery for those at high risk (19,20). Many patients with mixed aortic valve disease with severe aortic stenosis and at least moderate aortic regurgitation have been successfully treated with both balloon-expandable and self-expanding TAVI (3,21), but severe NAVR without aortic stenosis is still considered a contraindication to TAVI (22). Furthermore, we were aware that this therapy had been used anecdotally in small numbers of patients in individual centers (23–25). We thought that it was important to collect these data in a registry, which have not, to our knowledge, been reported before.

There are several reasons to explain why TAVI has not been used in large numbers of patients with NAVR. First, population surveys suggest that aortic stenosis is far more prevalent than aortic regurgitation (33.9% vs. 10.4% of patients with single left-sided valvular heart disease), and patients are 4 times more likely to have surgical AVR for aortic stenosis than aortic regurgitation (7,26). Second, although aortic stenosis is predominantly caused by degeneration and calcification of the valve, NAVR is the consequence of diverse etiologies, affecting a younger age group with patients who are very likely to be surgical candidates. Clearly surgery is, and will remain, the gold standard treatment for the overwhelming majority of patients with pure NAVR. Furthermore, involvement of the ascending aorta is present in a proportion of patients, which mandates open surgical treatment (7,8). Finally, patients with aortic regurgitation have a more complex and variable anatomy, making transcatheter therapies more challenging.

The results of this study need to be considered with caution. Implantation of a transcatheter valve was undertaken in 42 of 43 patients. Although this is encouraging and demonstrates feasibility, 8 patients required 2 transcatheter valves, and 9 patients had residual aortic regurgitation that was more than mild. One patient required conversion to open surgery. Thus, VARC-defined success was 74.4%. There was no statistically significant association between the degree of aortic regurgitation post-procedure or need for a second valve and death, but this is likely due to low study numbers.

The issue of residual aortic regurgitation is important. All studies examining the effect of post-TAVI aortic regurgitation have shown that leaving more than grade II aortic regurgitation is associated with worse outcomes, and this is clearly an important factor in younger cohorts of patients.

Stroke rates, vascular complications, bleeding, and mortality compare favorably with published trials and registries for TAVI in the treatment of aortic stenosis, but one would expect this to be so, as patients with pure aortic regurgitation are younger with fewer comorbidities (19,20,26–30). Thus, although these results are encouraging for those patients who are truly ineligible for surgery, surgical valve replacement remains the gold standard for those who can undergo it, even at high risk. Furthermore, there is an increasing number of patients in whom the native aortic valve can be preserved during surgery.

This study has shown a high incidence of the need for a second valve compared with other studies using the same device in the treatment of aortic stenosis (30). Although the need for a second valve is likely to be multifactorial, there was a strong correlation with absent valvular calcification. Absent aortic valve calcification may lead to reduced fixation of the lower part of the valve frame at the annulus during deployment, resulting in malpositioning. This may be further exacerbated by increased movement of the valve prosthesis in the regurgitant jet. Dilation of the aortic root and ascending aorta, which is common in NAVR, may also contribute. This problem may be overcome by valve designs that are fully retrievable and repositionable, and valvular fixation may be improved, even in the absence of calcium with new anatomically oriented valve designs (31,32).

It was apparent, despite small numbers, that patients with an aneurysm of the ascending aorta in this study had a poor response to treatment with TAVI (3 of 4 patients died within 6 months of treatment). This suggests that TAVI is unlikely to alter the prognosis of these patients and that aneurysmal dilation should be considered a contraindication to TAVI in patients with NAVR.

In this study, the operators adhered to valve sizing recommendations with the exception of 3 patients in whom oversizing of the prosthesis exceeded 20% with respect to the native annulus dimension. Although oversizing may be advantageous in NAVR without calcification to prevent dislocation and paravalvular regurgitation, this study was too small to make conclusions or recommendations with respect to valve sizing in these patients. Despite this, when the annulus measurement is on the borderline between 2 valve sizing recommendations, the authors would suggest using the larger of the 2 potential prosthesis choices.

Study limitations. This was a small, predominantly retrospective voluntary registry of a novel indication for transcatheter valve therapy, and we are cautious to draw firm conclusions from these data. There are likely to have been many more patients with severe NAVR who were considered for TAVI but were turned down on the basis of anatomy, difficulties in funding, or reservations on the part of the treating cardiologist, and this should be kept in perspective when considering the use of TAVI for NAVR. We recognize that the assessment of residual aortic regurgitation after TAVI is operator and labo-

ratory dependent. We did not use an independent core laboratory, which would be advantageous in future studies.

Conclusions

This study demonstrates the feasibility and potential procedure difficulties of treating patients with pure severe NAVR without aortic stenosis who have been deemed unsuitable for surgery with TAVI using the Medtronic CoreValve. Despite the variations in causes of valvular regurgitation and complexity of patient anatomy, acceptable results in this high-risk group of patients can be achieved. The possibilities of requiring 2 valves and leaving significant residual aortic regurgitation remain important considerations.

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