JACC: CARDIOVASCULAR INTERVENTIONS VOL. 4, NO. 11, 2011

ISSN 1936-8798/$36.00

PUBLISHED BY ELSEVIER INC.

DOI: 10.1016/j.jcin.2011.10.002

Transcatheter Valve-in-Valve Implantation Using CoreValve Revalving System for Failed Surgical Aortic Bioprostheses

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Objectives The purpose of this study was to evaluate the performance of CoreValve Revalving System (CRS) (Medtronic, Minneapolis, Minnesota) implantation in patients with failed aortic bioprostheses.

Background Transcatheter aortic valve implantation with the CRS is an effective option in high-risk patients with severe aortic stenosis. It may be an option for patients with a failed aortic bioprosthesis, especially when the risk of a surgical redo is deemed prohibitive.

Methods CRS "valve-in-valve" implantation was performed in 25 high-risk patients with a failed bioprosthesis. Their mean age was 82.4 ± 3.2 years. New York Heart Association functional classes III and IV were present in 21 and 4 patients, respectively. The logistic EuroSCORE was 31.5 ± 14.8%, whereas the Society of Thoracic Surgeons score was 8.2 ± 4.2. Patients/prostheses were divided in type A (mainly stenotic, n = 9) and type B (mainly regurgitant, n = 16).

Results The implantation success rate was 100%. In group A, the peak aortic gradient significantly decreased from 77.6 ± 21.6 mm Hg to 34.6 ± 19.4 mm Hg (p = 0.001). In all but 2 patients in group B, no significant regurgitation was observed post-implantation. No patients died during the procedure. At 30 days, there were 3 deaths (12%), 2 myocardial infarctions (8%), and 3 atrioventricular blocks requiring pacemaker implantation (12%). At a mean follow-up of 6 months, there were another death (survival rate of 84%) and a pacemaker implantation (cumulative incidence of 16%). New York Heart Association functional class improved in all patients to I and II.

Conclusions CRS implantation was feasible and effective regardless of the prevalent mode of failure. This finding may significantly affect the treatment of patients with a failed bioprosthesis deemed at a prohibitive risk for surgical redo. (J Am Coll Cardiol Intv 2011;4:1228–34) © 2011 by the American College of Cardiology Foundation

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Manuscript received August 29, 2011; revised manuscript received October 3, 2011, accepted October 5, 2011.

Surgical valve replacement has been the treatment of choice for patients with severe aortic stenosis or regurgitation for decades (1). Aortic prostheses can be basically divided into mechanical or biological, each having specific indications as well as inherent advantages and drawbacks.

Mechanical prostheses, having longer durability, require lifelong oral anticoagulation therapy. On the other hand, bioprostheses, although not requiring prolonged oral anticoagulation therapy, are invariably destined to deteriorate (1).

So far, the treatment of choice for a failed bioprosthesis has been a surgical redo, despite the higher mortality and morbidity compared to the first surgical treatment, as a consequence of comorbidities and technical hurdles (2).

Transcatheter aortic valve implantation (TAVI) is currently considered a valid option for patients with severe aortic stenosis deemed at prohibitive surgical risk to improve survival and quality of life compared with medical therapy (3).

Although neither the CoreValve Revalving System (CRS) (Medtronic, Minneapolis, Minnesota) nor the Edwards SAPIEN Transcatheter (EST) heart valve (Edwards Lifesciences, Irvine, California) have been approved for use in patients with failed aortic bioprostheses, there are reports of successful implantation in patients refused by surgeons for an unreasonable surgical risk (4–9).

We report a multicenter experience with CRS valve-in-valve implantation for a failed aortic bioprosthesis.

Methods

Patients. Valve-in-valve implantation with the CRS for aortic bioprosthesis failure was performed in 25 patients (Table 1) at 8 Italian centers with a high volume of TAVIs. Before the procedure, a thorough evaluation by the heart team, which included cardiologists, interventional cardiologists, anesthesiologists, and cardiac surgeons, was performed to determine surgical eligibility.

Clinical criteria for high risk were considered to be age 75 years and older, coronary artery disease, malignancy, hepatic cirrhosis, frailty, chronic obstructive pulmonary disease, severe pulmonary hypertension, porcelain aorta, low ejection fraction, diabetes, renal failure, and peripheral obstructive artery disease. The logistic EuroSCORE and STS score were calculated.

At the time of enrollment in study, all patients had symptomatic heart failure (New York Heart Association functional classes III and IV) despite intense medical therapy. Echocardiographic criteria for bioprosthesis dysfunction were aortic valve area <1 cm^2 and/or aortic regurgitation grade of 3 or higher.

Once consensus on the therapeutic approach and informed written consent were obtained, evaluation of the patient was performed to select the vascular access and to assess the presence of coronary artery disease. Percutaneous coronary revascularization, when indicated, was performed before TAVI.

Procedure. Implantation of a third-generation 18-F CRS (Medtronic) was performed in all patients. A transfemoral or axillary approach was chosen on the basis of anatomic considerations (vessel diameter, tortuosity, calcification, significant stenosis). General anesthesia or sedation was left to the anesthesiologist's discretion. A temporary pacemaker was placed in all patients in the absence of a previous permanent one. Valvuloplasty during rapid pacing before CRS implantation was optional. Cardiopulmonary support was not used. The CRS size was chosen according to nominal internal diameter of the failed prosthesis.

Transthoracic echocardiography was performed postprocedure and at hospital discharge. Clinical follow-up evaluation was performed at 30 days, 3 and 6 months, and then yearly thereafter.

Double antiplatelet therapy was administered in all patients. Acetylsalicylic acid was continued indefinitely and clopidogrel (75 mg/day) for the next 6 months. For patients previously treated with percutaneous coronary intervention (PCI), dual antiplatelet therapy was continued as planned.

Definitions. Endpoint definitions were according to Valve Academic Research Consortium consensus document criteria (10). Safety and efficacy endpoints were recorded in the hospital, at 30 days, and at last follow-up.

Statistical analysis. Numerical values are expressed as mean ± SD. Continuous variables were compared between groups using the paired *t* test (for normally distributed variables) or the Mann-Whitney *U* test (for non-normally distributed variables). All reported probability values were 2 tailed, and $p < 0.05$ was considered statistically significant. Analyses were performed with the SPSS statistical software package, version 17 (SPSS, Inc., Chicago, Illinois).

Abbreviations and Acronyms

CRS = CoreValve Revalving System

EST = Edwards SAPIEN transcatheter

OA = orifice area

STS = Society of Thoracic Surgeons

TAVI = transcatheter aortic valve implantation

Results

The mean age of the patients was 82.4 ± 3.2 years (10 men, 15 women). The mean logistic EuroSCORE was 31.5 ± 14.8, whereas the mean STS score was 8.2 ± 4.2 (see Tables 1 and 2 for baseline clinical and echocardiographic characteristics). Patients were further characterized according to the cause of failure: predominantly stenosis (group A, n = 9, 36%) and predominantly regurgitation (group B, n = 16, 64%). Eighteen prostheses were stented, 7 were stentless. Among the stentless bioprostheses, the most frequent cause of

JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 4, NO. 11, 2011
NOVEMBER 2011:1228–34

Table 1. Clinical Characteristics at Baseline

Patient #	Age, yrs	Logistic EuroSCORE	STS Score	NYHA Functional Class	COPD	Renal Function, eGFR ml/h	Previous Coronary Revascularization
1	83	62.29	13.9	3	No	25.0	No
2	77	25.78	7.5	3	No	26.7	Yes
3	77	10.06	2.9	3	No	97.2	No
4	82	28.98	10.3	3	No	18.9	No
5	76	38.00	5.2	3	Yes	71.0	No
6	87	31.94	7.3	3	Yes	30.3	Yes
7	81	29.00	11.0	4	No	67.0	No
8	84	31.84	16.3	4	Yes	42.0	No
9	81	11.31	17.4	3	No	39.1	No
10	81	25.73	4.0	3	No	26.6	No
11	86	29.19	10.8	3	No	31.4	No
12	79	23.33	5.5	3	No	37.1	Yes
13	81	21.16	4.9	3	No	69.0	Yes
14	78	29.00	8.5	3	No	73.0	No
15	84	51.00	8.1	3	Yes	26.4	No
16	85	31.80	6.0	3	No	46.7	Yes
17	83	56.10	10.4	3	No	24.9	Yes
18	82	16.00	7.6	3	Yes	30.0	Yes
19	83	57.70	6.0	3	Yes	41.7	No
20	87	29.04	9.7	3	No	44.0	No
21	80	21.30	10.4	4	No	55.0	Yes
22	87	62.00	11.0	3	No	40.0	Yes
23	78	34.00	5.7	3	Yes	38.0	Yes
24	85	44.00	10.0	4	No	35.0	Yes
25	84	41.00	4.1	3	No	42.0	Yes

COPD = chronic obstructive pulmonary disease; eGFR = estimated glomerular filtration rate according to Cockcroft-Gault formula; NYHA = New York Heart Association; STS = Society of Thoracic Surgeons.

failure was regurgitation (6 of 7, 86%), while, among stented, regurgitation was predominant in 10 cases (55%). General anesthesia was chosen in 10 patients and deep sedation in the remaining 15. In 22 patients, a transfemoral approach was used and a left axillary approach in the remaining 3 patients. Surgical access was preferred in 9 patients; a ProStar XL device achieved successful hemostasis in 16 patients.

Balloon valvuloplasty was performed in 8 patients (6 in group A, 2 in group B), post-dilation in 3 patients (2 in group and 1 in group B). CRS 26-mm was implanted in the majority of patients (n = 19, 76%), and no patient needed a second CRS implantation.

Procedural outcome. Valve-in-valve implantation was successful with immediate restoration of satisfactory valve function in all but 1 patient in whom, after CRS implantation in a stentless bioprosthesis (Cryolife 25), an acute left main occlusion occurred that was successfully treated with PCI. No intraprocedural deaths occurred.

Two patients died (8%) during hospitalization. The first patient died of cardiogenic shock due to ostial left main occlusion 48 h after a 26-mm CRS implantation in a Mitraflow 21 stenotic prosthesis. Urgent coronary angiography showed a Mitraflow leaflet overriding the left main ostium, significantly impairing blood flow. Despite prolonged attempts, PCI was not successful. The second patient was urgently admitted with cardiogenic shock due to a severely stenotic Mitraflow 21 and died of multiorgan failure 17 days after a successful CRS implantation. No intraprocedural and periprocedural cerebrovascular events occurred. Three patients (12%) required pacemaker implantation during hospitalization. A third patient died on day 26 post-procedure of acute heart failure (see Table 3 for 30-day follow-up, according to Valve Academic Research Consortium recommendations [10]).

Echocardiographic findings post-TAVI. In group A, the transaortic gradient significantly decreased from 77.6 ± 21.6 mm Hg to 34.6 ± 19.4 mm Hg (p = 0.0004), whereas the valve area increased from 0.5 ± 0.1 to 1.5 ± 0.2 (p = NS). The left ventricular ejection fraction did not significantly change before and after procedure (56.5 ± 12.5 before and 53.5 ± 10 after procedure, p = NS). Post-procedural regurgitation grade was mild in 2 patients (Table 4). Notably, even in group B, the peak transaortic gradient significantly decreased from 36.8 ± 22.4 mm Hg to 20.2 ± 7.2 mm Hg (p = 0.01). Regurgitation grade post-implantation was 0 or 1 in 14 patients (87.5%) compared with

Table 2. Baseline Echocardiographic Characteristics

Valve Type	Stented	Inner Diameter, mm	Mode of Failure, S/R	Peak (Mean) Gradient, mm Hg	AVA, cm^2	R Grade	LVEF, %
Sorin Pericarbon M21	Yes	17	S	65 (48)	0.5	1	30
Mitroflow 21	Yes	17	S	81 (44)	0.4	1	68
Carpentier/Edwards 21	Yes	20	S	91 (57)	0.7	2	64
Carpentier/Edwards 23	Yes	22	S	76 (53)	0.5	1	49
Sorin Pericarbon M23	Yes	19	S	95 (54)	0.6	1	71
St. Jude Toronto 23	No	21	S	116 (60)	0.27	2	55
Mitroflow 21	Yes	17	S	41 (28)	0.5	1	50
Biocor 25	Yes	23	S	73 (39)	0.6	1	63
Carpentier/Edwards 23	Yes	22	S	61 (33)	0.45	1	59
Biocor 25	Yes	23	R	38 (19)	1.1	4	59
Biocor 25	Yes	23	R	15 (6)	1.1	4	46
St. Jude Toronto 23	No	21	R	18 (10)	0.95	3	62
Mosaic 23	Yes	21	R	25 (18)	0.9	4	55
Hancock 23	Yes	21	R	58 (34)	0.9	3	70
Carpentier/Edwards 21	No	20	R	47 (23)	1.09	4	50
Carpentier/Edwards 23	Yes	22	R	65 (36)	1.1	3	70
Biocor 25	Yes	23	R	10 (5)	1.1	4	50
Cryolife 25	No	23	R	22 (14)	1.2	4	60
St. Jude Toronto 23	No	21	R	19 (12)	1	4	70
Cribier 23	Yes	21	R	80 (20)	1.1	4	46
Elan 25	No	23	R	20 (9)	1.2	4	58
Mosaic 23	Yes	21	R	NA	NA	3	35
Mosaic 23	Yes	21	R	65 (35)	NA	4	55
Mitroflow 21	Yes	17	R	NA	NA	4	55
St. Jude Toronto 23	No	21	R	34 (16)	NA	3	45

AVA = aortic valve area; LVEF = left ventricular ejection fraction; NA = not available; R = predominant regurgitation; S = predominant stenosis.

100% of patients having a baseline regurgitation grade of 3 or 4. The ejection fraction did not significantly change (Table 4).

Follow-up. At a mean follow-up of 6 months (median 90 days), there was another death as a result of severe respiratory insufficiency. Pacemaker implantation for a new complete atrioventricular block was also required. There were no additional strokes, myocardial infarcts, major bleeds, or repeat valve interventions (Table 3). Echocardiographic parameters at last follow-up showed a persistent good result after valve implantation (Table 4). New York Heart Association functional class at last follow-up was I and II in all patients (Fig. 1).

Table 3. Clinical Events (See Text for Definitions)

	At 30 Days	Cumulative Event Rate at Last Follow-Up
Death	3(12)	4 (16)
Myocardial infarction	2 (8)	2 (8)
Stroke	0 (0)	0 (0)
New-onset renal failure	1 (4)	1 (4)
Definitive pacemaker	3 (12)	4 (16)

Values are n (%).

Discussion

After the results of the PARTNER trial (3), TAVI can be reasonably considered a valid option in patients with severe aortic stenosis who are deemed at high risk or even unsuitable for surgery to be able to significantly reduce the rate of all-cause mortality, cardiovascular mortality, and repeat hospitalization with respect to medical therapy. All patients in the TAVI arm were treated for a severe stenosis of the native aortic valve by means of EST heart valve implantation. Mortality rates of 5% and 30.7% were observed at 30 days and 1 year, respectively.

Bioprosthetic heart valve durability and the inherent risks of a surgical redo are matters of concern (1,2). Indeed, the latter acted as a spur for the application of TAVI in such an off-label indication, the valve-in-valve technique, which was feasible and effective in some preliminary experience (4–9) as well as reported in a recent publication by Webb et al. (11). Among a population of patients with failed prosthetic heart valves, Webb et al. performed EST heart valve implantation in 10 patients with a failed aortic bioprosthesis and reported encouraging results. Specifically, they observed a 0%

Table 4. Echocardiographic Characteristics at Last Follow-Up

Group	CRS Size	Peak (Mean) Gradient, mm Hg	AVA, cm^2	Regurgitation Grade	LVEF, %
A	26	41 (23)	1.6	0	35
A	26	21 (10)	1.5	0	55
A	26	25 (12)	1.5	0	60
A	26	34 (21)	1.6	0	55
A	26	79 (45)	1.1	2	40
A	26	21 (11)	1.6	0	67
A	26	18 (10)	1.6	0	60
A	26	48 (27)	1.3	2	55
A	29	25 (12)	1.7	0	55
B	26	21 (12)	1.7	2	45
B	26	26 (12)	1.6	0	59
B	26	15 (9)	1.7	0	60
B	26	24 (12)	1.6	0	60
B	29	21 (10)	1.6	1	55
B	26	32 (14)	1.5	1	59
B	29	9 (5)	1.7	0	38
B	26	15 (8)	1.7	1	60
B	29	12 (5)	1.7	0	61
B	29	16 (8)	1.6	0	60
B	26	30 (16)	1.6	1	35
B	26	10 (6)	1.3	0	50
B	29	25 (15)	NA	1	40
B	26	28 (17)	1.7	0	55
B	26	20 (12)	1.7	2	50
B	26	NA	NA	NA	NA

A = mainly stenotic; B = mainly regurgitant; CRS = CoreValve Revalving System; Group = group according to predominant mode of failure; other abbreviations as in Table 2.

mortality rate at 30 days as well as at a median follow-up of 83 days.

A 12.4% mortality rate at 30 days was recently reported by a multicenter real-world registry (12) in which both CRS and EST heart valve devices were used for stenosis of the native aortic valve.

Predictors of early and late mortality in high-risk patients undergoing CRS implantation for severe stenosis of the native aortic valve were thoroughly described by Tamburino et al. (13). They reported 5.4% and 15% mortality rates at 30 days and 1 year, respectively.

In our cohort of CRS valve-in-valve implantation patients, we observed 12% and 16% mortality rates at 30 days and at a mean follow-up of 6 months, respectively. Of note, a 30-day mortality of 12% (n = 3) appears higher than predicted by the STS score that was 8.2 ± 4.2. The latter was developed in 2007 using STS Adult Cardiac Surgery Database records for surgical procedures taking place between January 2002 and December 2006. Operative mortality according to the STS score includes both all deaths occurring during the hospitalization in which the operation was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure unless the cause of death is clearly unrelated to the operation.

It is conceivable that a risk score specifically developed based on data from a surgical population might be insufficient to reliably predict outcomes in a significantly different setting such as CRS valve-in-valve procedures. Moreover, in our cohort, those 3 patients who died after the procedure were deemed inoperable by the surgeon; thus, any risk score based on surgical patients would be difficult to apply.

However, despite the inherent limitations, the STS score and the euroSCORE are still useful tools to approximately quantify the a priori level of risk.

After the encouraging results of the first experiences worldwide, several publications have clarified some aspects of the TAVI procedure. Nonetheless, little is known about specific technical issues when implanting a CRS in a failed bioprosthesis.

From the access site point of view, although EST heart valve implantation was performed in 9 of 10 cases via a transapical approach (11), CRS implantation was feasible by using a less invasive transfemoral or axillary approach, requiring general anesthesia in 40% of the cases.

According to prevalent cause of failure, some procedural steps deserve further discussion. Indeed, for bioprostheses presenting as predominantly regurgitant, pre-dilation seemed unnecessary, even when a significant transvalvular gradient was present. On the other hand, even for mainly stenotic bioprostheses, the need for pre-dilation was debated as being affected by the risk of gross disruption of the bioprosthesis with the subsequent risk of massive regurgitation and/or embolization. Of note, in those cases in which pre-dilation was done, such events did not occur. Similarly, post-dilation should be used only for those patients in whom optimal deployment of the valve was not achieved, thus determining a significant regurgitation or, rarely, a significant transvalvular gradient. As a result of this case-

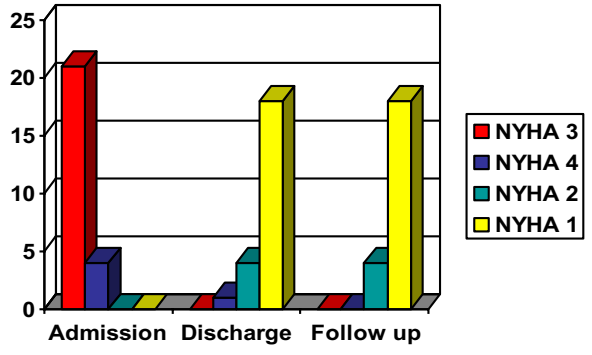

Figure 1. NYHA Functional Class at Admission, Discharge, and Last Follow-Up

New York Heart Association (NYHA) functional class evaluation showing excellent results at a mean 6-month follow-up.

by-case approach, we achieved an adequate orifice area (OA) and residual gradient in all cases. The assessment of the OA was done with both a continuity equation and anatomically; thus, despite inherent limitations of these methods, the calculated OAs of the CRS were consistent with data from the manufacturer. Of note, in some cases, the OA calculated after CRS implantation appeared larger than the theoretical area of the failed bioprosthesis. This is not unexpected with respect to a failed bioprosthesis that might have an inadequate opening of the leaflets.

Similarly, the OA after CRS implantation could also be larger than the OA of a normally functioning bioprosthesis because every type of prosthesis has its own geometry and physiology, both of which determine the excursion of the leaflets and thus the effective OA.

Regardless of the specific model of bioprosthesis, matching the CRS size and the internal diameter of the bioprosthesis is crucially important, although there are only 2 possible sizes of the CRS. Of note, the 26-mm CRS was the correct option in the vast majority of patients in our cohort. Its use was possible even in those bioprostheses with an inner diameter of 17 mm. Specifically, after careful evaluation by the heart team considering the prohibitive surgical risk and the clinical conditions despite intensive medical therapy, implantation of 26-mm CRS was chosen to at least significantly reduce the transvalvular gradient and regurgitation. Of note, an acceptable residual gradient and OA were achieved.

The presence or absence of a radiopaque sewing ring (i.e., a stented or stentless bioprosthesis) also deserve consideration. TAVI for a stented bioprosthesis allows more precise alignment of the CRS frame compared with a stentless prosthesis in which the technique is the same as that for native valves (Fig. 2), although bioprostheses are more often significantly regurgitant and without calcium.

Of note, in our experience, we observed 2 cases of left main coronary artery obstruction. The first immediately after TAVI in a stentless xenograft (Cryolife 25), which was successfully treated with PCI, and the second, 2 days after the procedure in a stented bioprosthesis that led to the exitus of the patient despite the prolonged attempt of PCI (Mitroflow 21, Sorin S.p.A., Milan, Italy).

As previously suggested (14), these are compelling cases confirming the need for an accurate evaluation of the aortic root size, distance between the bioprosthesis and coronary ostia, and the particular characteristics of the bioprosthesis. As such, the Mitraflow poses unique hurdles as being quite tall (13 mm) and having leaflet tissue mounted externally over the stent instead of internally as is usual. In other words, with externally mounted leaflets, in particular if the surgeon opted for a supra-annular position, the valve-in-valve TAVI may lead to the compression of these leaflets against the aortic wall, thus impairing coronary blood flow.

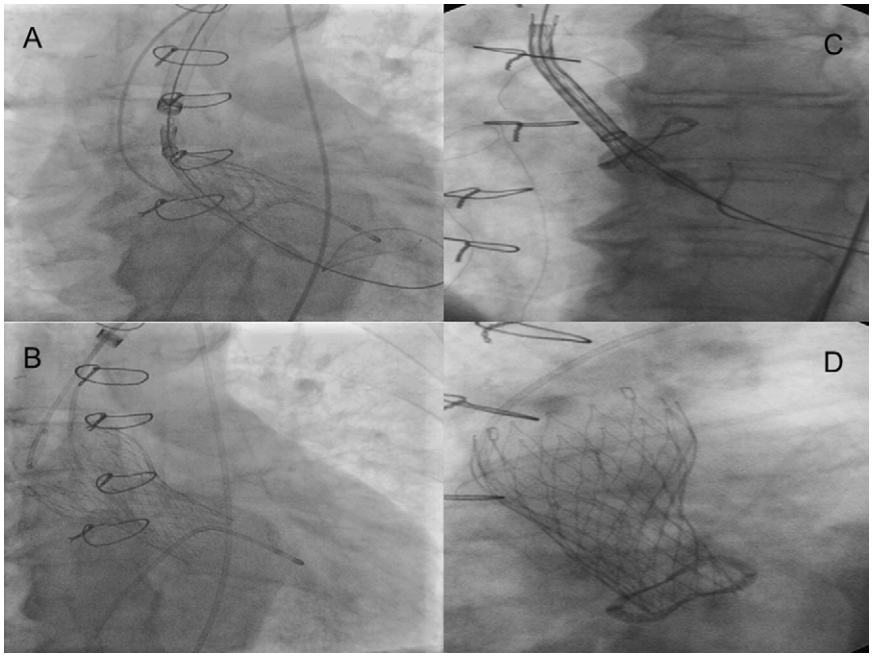

Figure 2. CoreValve Revalving System Deployment in "Stentless" and "Stented" Bioprostheses

Diverse appearance of a "stentless" **(A and B)** compared to a "stented" **(C and D)** bioprosthesis. The "pigtail" catheter **(A)** has positioned in the noncoronary cusp in order to determine the exact position of the aortic valve plane. This manoeuvre is not necessary with a stented bioprosthesis **(C)**, because of the radiopaque sewing ring.

JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 4, NO. 11, 2011
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Electrical disturbances leading to pacemaker implantation are a known drawback of TAVI (15). In our cohort, we observed a 16% rate of pacemaker implantation at 6 months, which is even lower with respect to TAVI for native aortic valve where this percentage can widely vary to as much as 47% (16) with a possible higher risk for CRS compared with the EST heart valve (17). It has been suggested that stented bioprostheses might be at lower risk of electric disturbances being more rigid, thus limiting the compression of the conduction system by the frame of the CRS (8); however, in our cohort, 4 patients received a pacemaker, 2 with a stented bioprosthesis and the other with a stentless one. Thus, it can be presumed that the presence or absence of a sewing ring does not make a difference, but the conduction system is particularly delicate. However, only histopathologic examinations along with electrophysiologic studies might provide insight into this phenomenon.

Study limitations. CRS implantation for a failed aortic bioprosthesis can be reasonably considered an option only in those centers where the learning curve is far completed, and there is a robust experience in the treatment of aortic stenosis in native valves. This should be regarded before advocating a large scale adoption of this technique.

Conclusions

In centers with expertise in CRS-TAVI in native stenotic aortic valves, valve-in-valve implantation for failed aortic bioprostheses is feasible and effective, with good valve performance and symptom improvement persisting at mid-term. Moreover, CRS-TAVI, which was introduced for the treatment of stenotic aortic valves, proved effective, even in those patients with predominantly regurgitant xenografts, meaning that the CRS could be an option in regurgitant aortic valves.

This technique requires a careful evaluation by an expert heart team who should always evaluate the clinical status of the patient as well as the particular anatomy of the aortic root and specific features of the xenograft.

Because aortic bioprostheses differ in a number of technical aspects, inherent long-term performance and durability may significantly vary from one model to another; thus, it is unlikely that the valve-in-valve approach could be completely addressed in future large trials. This creates the further need for sharing experiences and results. To the best of our knowledge, our cohort is the largest in which the CRS was used in the treatment of failed aortic bioprostheses.

Our data could be acknowledged as a proof-of-concept, which may significantly affect the treatment of patients with a failed aortic bioprosthesis, still considered an off-label indication, deemed at prohibitive risk for a surgical redo.

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Key Words: CoreValve Revalving System ■ failed surgical aortic bioprosthesis ■ TAVI.