International Journal of Cardiology 287 (2019) 53–58

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Self-expanding transcatheter aortic valve implantation for degenerated Mitroflow bioprosthesis: Early outcomes

Isaac Pascual [a,b,c], Pablo Avanzas [a,b,c,*,1], Daniel Hernández-Vaquero [a,b], Rocío Díaz [a,b], Raquel del Valle [a], Remigio Padrón [a], Rebeca Lorca [a], Victor León [a], María Martín [a,b], Fernando Alfonso [d,e], César Morís [a,b,c]

[a] Heart Area, Hospital Universitario Central de Asturias, Oviedo, Spain
[b] Instituto de Investigación Sanitaria del Principado de Asturias (ISPA), Oviedo, Spain
[c] University of Oviedo, Spain
[d] Department of Cardiology, Hospital Universitario de la Princesa, Madrid, Spain
[e] Instituto de Investigación Sanitaria Princesa (IIS-IP), Spain

ARTICLE INFO

Article history:
Received 19 April 2018
Received in revised form 23 December 2018
Accepted 28 January 2019
Available online 1 February 2019

Keywords:
TAVI
Mitroflow
Valve in valve
Structural valve deterioration
Aortic stenosis
Bioprosthetic valves

ABSTRACT

Background: The aim of this study was to assess the safety and effectiveness of valve in valve (VIV) TAVI with the autoexpandable valve, specifically in patients with failed Mitroflow (MF) bioprosthetic aortic valves.
Methods: Pilot, single center, observational and prospective study that included 45 consecutive patients with symptomatic failed MF bioprosthetic aortic valve, referred for VIV TAVI. The safety primary endpoint was a composite of early events at 30 days, defined by VARC-2 criteria. The efficacy primary endpoint was the device success (no procedural mortality, correct positioning of a single prosthetic heart valve into the proper anatomical location and absence of moderate/severe prosthetic aortic valve regurgitation). We also analysed patient-prosthesis mismatch (PPM) parameters.
Results: Between March 2012 to December 2017, 45 symptomatic patients (age 79.9 ± 6.5 years) with degenerated MF valves (numbers 19: 33.3%; 21: 28.9%; 23: 24.4%; 25: 13.3%) underwent CoreValve (n = 11) or Evolut R (n = 34) implantation (23 and 26 mm sizes). The STS predicted risk of mortality was 6.3 ± 6.3%. The safety primary endpoint occurred in 4 patients (8.8%). The efficacy endpoint was present in all patients (100%). There were no coronary occlusions or procedural deaths. The number of patients with any degree of PPM raised from 51.1% (pre-TAVI) to 60% (post-TAVI).
Conclusions: Self-expanding TAVI for degenerated MF bioprosthesis has favourable early outcomes. The VIV procedure has provided an important gateway to avoiding high-risk redo surgery and is now a potential option for MF failed surgically aortic implanted valves.

1. Introduction

Degenerative aortic stenosis is the most frequent heart valve disease in developed countries and aortic valve replacement is one of the most frequently performed procedures in cardiac surgery departments. Biological prostheses account for >50% of all surgically implanted prosthetic valves in current use [1]. The main concern of surgical biological valves is their limited durability and predisposition to structural valve deterioration (SVD).

In this context, transcatheter aortic valve implantation (TAVI) has emerged as an alternative therapeutic option to repeated surgery for treating aortic SVD [2,3]. Recently, transcatheter valve-in-valve (VIV) implantation for the treatment of degenerated aortic bioprosthesis has been proved feasible after Heart Team evaluation [4,5]. Both careful patient selection and procedural planning are essential to achieve successful outcomes [4,6–8]. Nevertheless, there are still some concerns regarding its safety. There are some registries and case series that have reported the short-term outcomes and complication rates of patients treated with transcatheter VIV implantation for failed surgical bioprosthetic aortic valves. However, these studies are heterogeneous, including both different kinds of degenerated valves and different types of prosthesis used for the VIV procedure [7–10].

On the other hand, there is controversy in the literature regarding Mitroflow SVD pattern. The Mitroflow (MF) bovine pericardial prosthesis valve (Sorin Group Inc., Mitroflow Division; Vancouver, Canada) is commonly used in Spain and has been implanted in >100,000 patients throughout the world [11]. Recent evidence suggests that this valve is more prone to early SVD than initially expected [11,12]. In a recent

* Corresponding author at: Cardiac Catheterization Laboratories, Hospital Universitario Central de Asturias, Avda de Roma S/N, 33011 Oviedo, Spain.
E-mail address: avanzas@secardiologia.es (P. Avanzas).
[1] This author takes the responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

https://doi.org/10.1016/j.ijcard.2019.01.094
0167-5273/

study from our group, 15.8% of the MF prostheses showed data of SVD 8 years after implantation [13]. Moreover, the MF prosthesis raises special concerns for VIV therapies due to its specific design. This prosthesis was designed for a supraanular functioning, with long valves sutured outside the stent. These factors may predispose to an increased risk of coronary occlusion. Interestingly, 42% of the patients complicated with coronary occlusion from the global VIV registry had a MF valve [14].

The aim of this study was to assess the safety and effectiveness of VIV TAVI with the autoexpandable valve, specifically in patients with failed MF bioprosthetic aortic valves.

2. Methods

2.1. Design and population

Since 2007, 471 patients underwent TAVI in our center. All patients referred for TAVI in our institution were evaluated and followed-up by experienced interventional cardiologists in a specific TAVI outpatient clinic, according to guidelines and systematic protocols. All patients were carefully evaluated by a multidisciplinary Heart Team. This is a pilot, single center, observational and prospective study that included 45 consecutive patients with symptomatic failed MF bioprosthetic aortic valve, referred for interventional treatment, from March 2012 to December 2017. During study recruitment period, 70 patients were treated with open heart surgery at our institution due to Mitroflow SVD. In the very early experience (first 14 cases), anatomic evaluation was performed by echocardiogram and angiography. Routine computed tomography evaluation was incorporated in the protocol in June 2014. Informed consent was obtained from each patient and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki, as reflected in a priori approval by the institution's human research committee.

2.2. Computed tomography evaluation

ECG-gating contrast-enhanced multislice computed tomography (CT) was performed prospectively, according to a systematic protocol, by the same TAVI evaluation team, with an experience of >300 studies. All quantitative parameters collected were reported in millimetres (mm) and included a) right and left coronary height; b) sinus of Valsalva diameters and c) distance from the virtual surgical valve ring (VSVR) to each coronary ostia (VSVR distance, right and left). The VSVR is a virtual ring with diameter equal to inner diameter of the surgical valve, superimposed on the sinus of Valsalva at the level of each coronary artery take-off. The qualitative parameters studied included presence and patency of coronary bypass grafts.

2.3. Valve-in-valve TAVI procedure

Implantation was carried out in the cardiac catheterization laboratory under general anesthesia or local anesthesia and deep sedation, according to anesthesiologist's preferences. All patients received prophylactic antibiotic coverage with cephalosporins, except those allergic to beta-lactams, who received vancomycin. Vascular access was femoral in the vast majority of cases, being the procedure entirely percutaneous. In 3 cases (due to excessive calcification, twisted arteries or atherosclerosis of the iliofemoral region, or when the diameter of the iliac/femoral arteries was <6 mm) a subclavian/axillar access was preferred, although involving open surgery. TAVI size was chosen, in pannus absence, according to the implanted Mitroflow size: number 23 in case of Mitroflow 19, 21 and 23 mm sizes and number 26 in case of Mitroflow 25 mm size. When the procedure was performed by transfemoral approach, it was completed by percutaneous closure of both femoral arteries. The femoral artery through which the device was implanted was closed using a previously implanted PROSTAR XL® device and the contralateral femoral artery was closed using PERCLOSE® or ANGIOSEAL®. When access was subclavian, the artery was surgically exposed and then punctured using the Seldinger technique, and the following procedure was identical to that used for femoral access. Finally, the artery was surgically closed.

Coronary protection was carried out according to first operator criteria. As a general rule, a high support angioplasty wire was inserted into the left main in those cases that left coronary height was below or equal to 6 mm (Supplemental Fig. 1, Videos 1 and 2, n = 8 cases).

2.4. Primary endpoints

The safety primary endpoint was a composite of early events at 30 days, defined by VARC-2 criteria [all-cause mortality, stroke, life-threatening bleeding, acute kidney injury (AKI) stage 2 or 3, coronary artery obstruction requiring intervention, major vascular complication, valve-related dysfunction requiring repeat procedure such as balloon valvuloplasty, TAVR, or SAVR] [15].

The efficacy primary endpoint was device success (absence of procedural mortality and correct positioning of a single prosthetic heart valve into the proper anatomical location and no moderate/severe prosthetic valve aortic regurgitation).

2.5. Secondary endpoint

Secondary endpoints were the analysis of patient-prosthesis mismatch (PPM) parameters and prosthetic valvular effective area. PPM for aortic valve prostheses was defined as an indexed effective orifice area ≤0.85 cm^2/m^2. Severe PPM was defined as an indexed effective orifice area ≤0.65 cm^2/m^2 [16].

2.6. Study variables

Study variables were included in a specifically designed database. All patients were evaluated prospectively, according to a structured predefined protocol, in the specific TAVI outpatient clinic before the procedure and with scheduled follow-up.

Clinical follow-up related variables were documented following VARC-2 criteria [15]:

- Mortality: all-cause mortality during the follow-up.
- Cardiovascular mortality: mortality defined by at least one of these criteria: every death due to cardiac cause, unexpected or with unknown death cause, death related to any procedure complication or treatment of any complication of the procedure and death due to vascular but non-coronary cause.
- Prosthesis failure/dysfunction: we took into consideration the definitions of the consensus statement for SVD [16]. Severe haemodynamic SVD was defined by any of the following situations: mean transprosthetic gradient >40 mm Hg; mean transprosthetic gradient >20 mm Hg change from baseline; or severe intra-prosthetic aortic regurgitation, new or worsening (>2+/4+) from baseline. All cases of SVD were evaluated by 2 experienced echocardiographers, independent from the study.
- Severe PPM: indexed area 0.65 cm^2/m^2

2.7. Follow-up

Follow up was performed by clinical visit at the TAVI outpatient clinic or by phone call. There were no losses in the follow-up.

2.8. Statistical analysis

Results for normally distributed continuous variables are expressed as the mean value + standard deviation, and continuous variables with non-normal distribution are presented as median values (interquartile intervals). Analysis of normality of the continuous variables was performed with the Kolmogorov-Smirnov test. Logistic regression was used to assess the univariate associations between continuous baseline characteristics and the combined endpoint, and χ^2 testing was used for discrete variables. Differences were considered to be statistically significant if the null hypothesis could be rejected with 95% confidence. The SPSS 20.0 statistical software package (SPSS Inc., Chicago, IL, USA) and STATA 14 (STATA Corp. LP, USA) were used for all calculations.

3. Results

3.1. Population and angio-CT parameters

During the inclusion period, 45 consecutive patients with MF SVD were treated with VIV in our center. Main characteristics of the sample are shown in Table 1. Mean age was 79.9 ± 6.5 years, 23 were male (51.1%). STS score was 6.3 ± 6.3, logistic EuroScore was 24.7 ± 17% and 82% of the patients were in NYHA III–IV/IV. The prosthesis failure was due to stenosis in 28.9% of the cases, regurgitation in 35.6% and mixed in 35.6%. Mitroflow size was 19 [manufacturer internal diameter (ID) of 15.4 mm] in 15 cases (33.3%), size 21 (ID 17.4 mm) in 13 cases (28.9%), size 23 (ID 19 mm) in 11 cases (24.4%) and size 25 (ID 21 mm) in 6 cases (13.3%). Table 1 shows angio-CT parameters.

3.2. Procedure

Procedure characteristics are shown in Table 2. Eleven patients (24.4%) were treated with Corevalve Revalving System and 34 patients (75.6%) with Evolut R Transcatheter Valve (TV) (Medtronic, Minn.). A 23 mm valve was used for MF sizes 19, 21 and 23 mm and was implanted in 38 patients (86.7%). The remaining 6 patients (13.3%) with MF size 25 were treated with 26 mm valves. Most procedures were transfemoral (n = 42, 93.3%), only 3 of them (6.7%) were performed through a subclavian approach. Postdilatation was performed in 9 cases (20%). Left main coronary artery was protected in 8 cases (17.8%).

Table 1
Basal clinical characteristics (n = 45).

Age, years (range)	79.9 ± 6.5
Male gender, n (%)	23 (51.1)
Body mass index, kg/m^2	27.2 ± 3.5
STS score, %	6.3 ± 6.3
Logistic EuroSCORE, %	24.7 ± 17
EuroSCORE II, %	7.7 ± 3.9
Functional class at SVD diagnosis, n (%)	
– NYHA I/IV	0 (0)
– NYHA II/IV	8 (17.8)
– NYHA III/IV	27 (60)
– NYHA IV/IV	10 (22.2)
Chronic kidney failure, n (%)	19 (42.2)
LVEF < 50%, n (%)	13 (28.9)
Mitroflow bioprosthesis sizes	
– No. 19	15 (33.3)
– No. 21	13 (28.9)
– No. 23	11 (24.4)
– No. 25	6 (13.3)
Cardiovascular risk factors	
Diabetes mellitus, n (%)	12 (26.7)
Dyslipidemia, n (%)	17 (37.8)
Arterial hypertension, n (%)	25 (55.6)
Smoking habit, n (%)	5 (11.1)
Cardiovascular history	
Extracardiac arteriopathy, n (%)	3 (6.7)
Prior AMI, n (%)	6 (13.3)
Prior stroke, n (%)	4 (8.9)
Pacemaker implantation, n (%)	8 (17.8)
Prior coronary revascularization, n (%)	13 (26.6)
Parameters of degenerated Mitroflow bioprosthesis	
Typo of degeneration	
– Stenosis	13 (28.9)
– Regurgitation	16 (35.6)
– Mixed	16 (35.6)
Peak gradient, mm Hg	66.1 ± 28.7
Mean gradient, mm Hg	35.4 ± 16.2
Aortic regurgitation (grade III–IV), n (%)	31 (68.9)
LVEF, %	55.5 ± 13.3

Time from valvular surgery to degeneration (n = 45)

	≤5 years (n = 4)	5 to 10 years (n = 38)	>10 years (n = 3)
Stenosis, n (%)	2 (4.4)	10 (22.2)	1 (2.2)
Regurgitation, n (%)	0 (0)	16 (35.55)	0 (0)
Mixed, n (%)	2 (4.4)	12 (26.6)	2 (4.4)

Angio-computed tomography parameters

Left coronary sinus width, mm	29.8 ± 7.8
Right coronary sinus width, mm	29.7 ± 5.5
Left coronary height, mm	7.6 ± 5.3
Right coronary height, mm	8.5 ± 6.1
Left VSVR (mm)	4.8 ± 2.7
Right VSVR (mm)	5.6 ± 2.6

Data are expressed as mean + standard deviation for normally distributed data, median (interquartile range) for non-normally distributed data, and number (%) for categorical variables. AMI: acute myocardial infarction. EuroSCORE: European System for Cardiac Operative Risk Evaluation. STS SCORE: Society of Thoracic Surgeons SCORE. NYHA: New York Heart Association. LVEF: Left Ventricular Ejection Fraction. SVD: structural valve deterioration. VSVR: virtual surgical valve ring.

3.3. Safety primary outcome

There were no coronary occlusions, no procedural deaths and no strokes. In the 30 days of follow up, there were 2 deaths (4.4%), both of cardiovascular in origin. The first patient was an 84 year old male, with associated severe pulmonary hypertension and right ventricular failure, who underwent an emergent procedure due to cardiogenic shock and died 6 days afterwards due to refractory heart failure. The second one was a 85 year old woman with pulmonary hypertension and chronic renal failure who underwent an elective vascular surgery and suffered a cardiac arrest 27 days after TAVI procedure. According to VARC2 definition [15], there were 2 major vascular complications (one femoral occlusion that was treated with success, using a covered stent and a pseudoaneurysm that required surgery) and 3 minor complications. One patient suffered an episode of transient diplopia suggestive of transient ischemic attack and 3 patients required a permanent pacemaker.

Table 2
Procedure, functional evaluation and prosthesis patient mismatch (PPM) parameters.

Procedure	
Devices	
– Corevalve, n (%)	11 (24.4)
– Evolut R, n (%)	34 (75.6)
Valve sizes	
– 23 mm, n (%)	39 (86.7)
– 26 mm, n (%)	6 (13.3)
Vascular access	
– Right femoral, n (%)	39 (86.7)
– Left femoral, n (%)	3 (6.7)
– Left axillar, n (%)	3 (6.7)
Pacemaker post TAVI, n (%)	3 (6.7)
General anesthesia, n (%)	21 (46.7)
Peak to peak post TAVI gradient, mm Hg	14.4 ± 7.8
Postdilatation, n (%)	9 (20)
Left main coronary artery protection, n (%)	8 (17.8)

Functional evaluation (transtoracic echocardiogram)

	Pre TAVI	Post TAVI	*p* value
Peak gradient, mm Hg	66.1 ± 28.7	39 ± 14.9	0.001
Mean gradient, mm Hg	35.4 ± 16.2	19.5 ± 8.4	0.001
Effective area, cm^2	0.98 ± 0.4	1.42 ± 0.5	0.001
LVEF, %	55.5 ± 13.3	54.2 ± 11.5	0.057
Aortic regurgitation > grade II, n (%)	31 (68.9)	0 (0)	0.001

PPM parameters

	Post valvular surgery	Post TAVI
Mismatch, n (%)	23 (51.1)	27 (60)
Moderate PPM, n (%)	14 (31.1)	14 (31.1)
Severe PPM, n (%)	9 (20)	13 (28.9)

Data are expressed as mean + standard deviation for continuous variables and number (%) for categorical variables. LVEF: Left Ventricular Ejection Fraction. PPM: patient-prosthesis mismatch. TAVI: transcatheter aortic valve implantation.

3.4. Efficacy primary outcome

The efficacy endpoint was present in all patients and a significant reduction of the degree of aortic regurgitation was obtained with the procedure (Table 2, $p < 0.05$). Both maximum and mean transvalvular gradients significantly decreased (from 66.1 ± 28.7 mm Hg to 39 ± 14.9 mm Hg and from 35.4 ± 16.2 mm Hg to 19.5 ± 8.4 mm Hg, $p \leq 0.001$), with higher gradients as smaller were the surgical valves (Fig. 1, $p < 0.05$).

3.5. Secondary outcomes

Before the procedure, 51.1% of the patients referred for TAVI had some degree of PPM. Afterwards, this number raised to 60% (Table 2). Fig. 2 shows prosthetic valvular effective orifice area. After the procedure, valvular effective orifice area was higher across all different sizes of the MF valves treated ($p < 0.05$).

4. Discussion

This is the first study systematically assessing the value of a self-expanding aortic valve prosthesis implantation in patients with MF SVD. The main finding of our study was that this strategy is safe and effective in the treatment of these challenging patients.

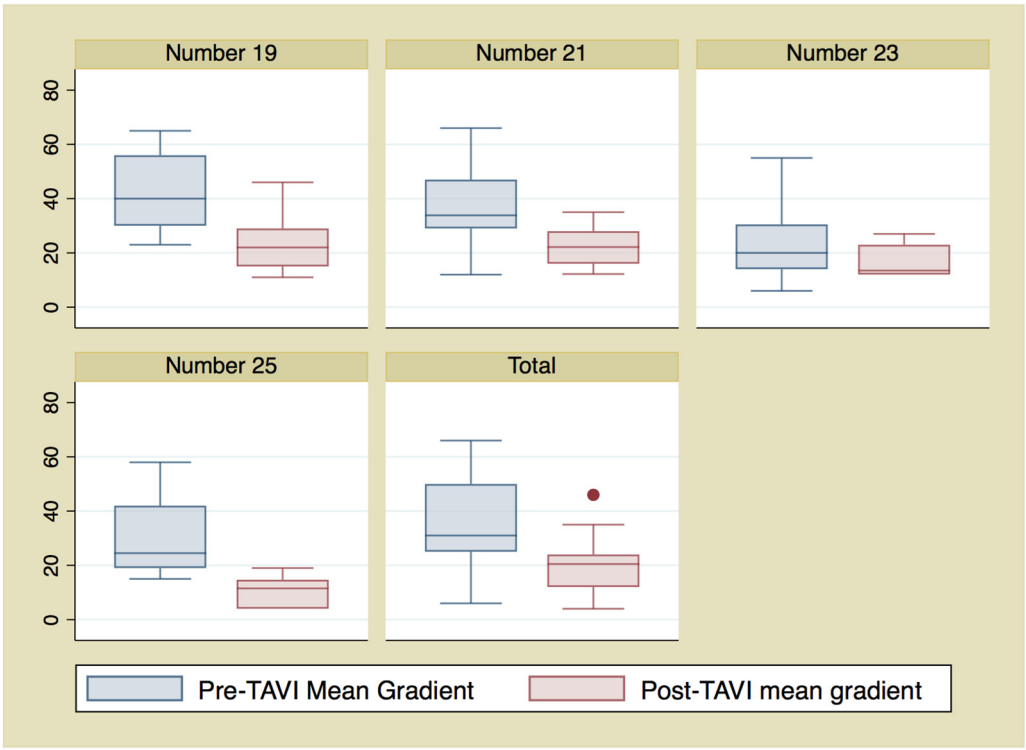

Fig. 1. Pre and post TAVI mean transvalvular gradients distribution according to MF sizes.

We took advantage of a large cohort of patients treated in our hospital with the MF aortic valve and previous findings of our group, reporting the real rate of long-term degeneration of this prosthesis (15.8% at 8 years) when evaluated according to a competitive risk model [17]. Considering this background, we designed this prospective registry to evaluate the percutaneous treatment for prosthetic degeneration of the MF valve. Percutaneous procedures were performed with the Corevalve self-expanding prosthesis and with its subsequent Evolut R valve evolution (Medtronic Minn). One of the strengths of this registry is that all patients had the same degenerated prosthesis and all of them were treated with the same type of percutaneous valve. Therefore, the results of this homogeneous cohort can be

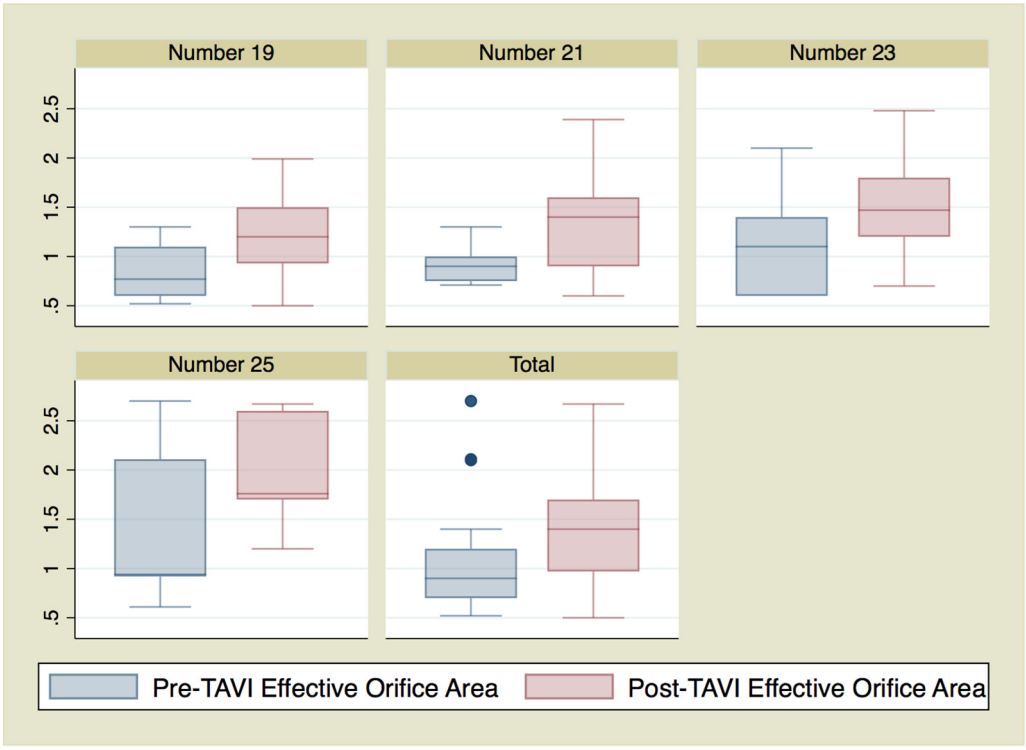

Fig. 2. Pre and post TAVI effective orifice areas distribution according to MF sizes.

analysed without the additional confusion related to the different types of valves implicated in other previous registries [14,18]. Moreover, to the best of our knowledge, this is the largest series reported to date, regarding percutaneous treatment with self-expanding prostheses of degenerated MF prostheses.

The highest rates of valve degeneration in our cohort were found between 5 and 10 years after aortic valve replacement surgery. Valve degeneration occurred in similar proportions in each of the possible ways: stenosis, regurgitation or mixed mechanism.

There were no deaths during implantation and the 30-day survival rate was high (96%). These results confirm the safety of VIV in the Mitroflow bioprosthesis, according to those reported for SVD in other biological valves. Nonetheless, when evaluating the safety of the VIV procedure, besides those described for conventional TAVI procedures, three additional aspects should be considered: coronary occlusion, malapposition, and the persistence of high transvalvular gradients [14,18].

Coronary obstruction is one of the most feared VIV complications. The risk in this procedure is considered higher than that of TAVI in a native valve. In the largest series, a 3.5% incidence was reported. Moreover, this risk is believed to be even higher in bioprostheses with leaflets outside the stent [17–19]. However, despite MF valve fulfills all these risk factors, in our cohort there were no coronary obstructions. The coronary ostia height, especially that of the ostium of the left main, and the virtual transcatheter valve-to-coronary ostia distance are known to be determinant factors. Recently, it has been reported that every millimetre of increase in height is associated with a significant decrease in coronary occlusion risk [19,20]. Therefore, in our series, all ostia heights were carefully measured. At this point, it is remarkable our high rate of success and lack of coronary complications compared to previous published studies. The Mitroflow valve has been designed for improved hemodynamic performance. Doenst et al. suggest, however, that the majority of this hemodynamic advantage by design is lost by a "defensive" sizing strategy [21]. We can hypothesize that the Mitroflow valves were originally downsized. If so, the large sinuses of Valsalva could have protected the patients in our series.

The absence of malapposition in our cohort could be explained by the meticulous selection of the prosthesis size. Besides, the expertise of our group achieved with this type of prosthesis may also explain the results. The procedure was successful in all patients. The reference of the MF stent in fluoroscopy was crucial to ensure the height of the TAVI implant, closely related to the degree of residual regurgitation [23]. An implant's depth <5 mm has been considered a predictor of better hemodynamic outcome.

On the other hand, discretely elevated residual transvalvular gradients are relatively frequent, not only after TAVI, but also after surgical valve replacement [24–27]. However, VIV post-procedure transvalvular gradients are higher than in the TAVI over a native valve, being more frequent with expandable balloon valves compared to self-expanding prostheses. The average residual gradient reported for VIV is around 16 mm Hg [28,29]. Both small-sized biological valves and the use balloon-expandable valves may be considered associated factors with residual valve gradient [18,30]. Nonetheless, little is known about the behaviour of residual gradients after VIV in the MF bioprosthesis [31]. Our data are consistent with those in the literature, as shown by the residual mean gradient of 19 mm Hg. Moreover, our series have a high percentage of small valves (87% with internal diameters ≤ 20 mm) compared to other series that range from 20 to 50% [17,18,20,32]. A recent statement on the management of valvular disease claimed that an anticipated hemodynamic improvement could only be achieved in the larger-sized prosthesis [4]. However, our data showed that, at least in the MF prosthesis, the improvement could be reached in all sizes.

Of particular interest to post-TAVI functional valve evaluation is the PPM documentation. In this regard, an adequate evaluation of the functional results of the surgical biological prosthesis after its implantation is essential. It is considered a related factor to survival and early prosthetic valvular degeneration [17,33–35]. This is particularly important for MF valves, as the presence of PPM can be over 40% [36]. Severe PPM rates in VIV have been estimated around 30% of the cases [18]. Recently, Pibarot et al. [30] reported that patients with pre-existing severe PPM were more likely to have a surgical prosthesis ≤21 mm compared with those who did not have severe mismatch. Those patients receiving a balloon-expandable valve had higher residual valve gradients. Moreover, an independent association between pre-existing PPM and increased mortality after VIV was found [30]. In our series, the existence of severe postoperative PPM was observed in 9 patients (20%) and after VIV, this percentage increased to 28.9% (13 patients). All patients with severe PPM after TAVI had MF sizes with internal diameter ≤ 20 mm (10 patients with a size 19 mm, 2 patients with a size 21 mm and 1 patient with a size 23 mm). The presence of PPM after TAVI should be evaluated with caution, on a case-by-case basis, regardless of the gradients reduction or post-TAVI valvular insufficiency [14,18]. However, there is limited experience regarding the fracture of the prosthetic surgical ring by inflating a balloon before or after TAVI [37,38]. The presence of PPM post-TAVI has been related to a worse long-term prognosis and a more rapid prosthetic degeneration.

Finally, complete AV block seems less frequent in VIV procedures. This could be explained because of the surgical annulus, especially in self-expanding valves, that may protect against the pressure that the device exerts on the ventricular septum. Our data showed a low percentage (6.7%) of pacemaker implantation due to high grade AV block. Although higher percentages (9%) have been reported in smaller series, our data are consistent with recently published series with self-expanding prostheses [31,39].

4.1. Limitations

This is a single center study with a relatively limited sample size. In spite of this clear limitation, to date, this is the largest cohort of MF degenerated aortic valves treated with a self-expanding prosthesis.

5. Conclusions

Self-expanding TAVI for degenerated MF bioprosthesis has favourable early outcomes. The valve-in-valve procedure has provided an important gateway to avoiding high-risk redo surgery and is now a potential option for MF degenerated surgically aortic implanted valves.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2019.01.094.

Conflict of interests

Dr. Cesar Moris is Medtronic Proctor.

The other authors report no conflict of interests.

References

[1] J.M. Brown, S.M. O'Brien, C. Wu, J.A. Sikora, B.P. Griffith, J.S. Gammie, Isolated aortic valve replacement in North America comprising 108,687 patients in 10 years: changes in risks, valve types, and outcomes in the Society of Thoracic Surgeons National Database, J. Thorac. Cardiovasc. Surg. 137 (1) (2009) 82–90.
[2] M. Maganti, V. Rao, S. Armstrong, C.M. Feindel, H.E. Scully, T.E. David, Redo valvular surgery in elderly patients, Ann. Thorac. Surg. 87 (2) (2009) 521–525.
[3] S. Leontyev, M.A. Borger, P. Davierwala, T. Walther, S. Lehmann, J. Kempfert, et al., Redo aortic valve surgery: early and late outcomes, Ann. Thorac. Surg. 91 (4) (2011) 1120–1126.
[4] R.A. Nishimura, C.M. Otto, R.O. Bonow, B.A. Carabello, J.P. Erwin 3rd, L.A. Fleisher, et al., 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, J. Am. Coll. Cardiol. 70 (2) (2017) 252–289.
[5] R.A. Nishimura, P.T. O'Gara, R.O. Bonow, Guidelines update on indications for transcatheter aortic valve replacement, JAMA Cardiol. 2 (9) (2017) 1036–1037.
[6] H. Baumgartner, V. Falk, J.J. Bax, M. De Bonis, C. Hamm, P.J. Holm, et al., 2017 ESC/EACTS Guidelines for the management of valvular heart disease, Eur. Heart J. 38 (36) (2017) 2739–2791.
[7] E.M. Tuzcu, S.R. Kapadia, L.G. Svensson, Valve in valve: another milestone for transcatheter valve therapy, Circulation 126 (19) (2012) 2280–2282.

[8] R. Gurvitch, A. Cheung, J. Ye, D.A. Wood, A.B. Willson, S. Toggweiler, et al., Transcatheter valve-in-valve implantation for failed surgical bioprosthetic valves, J. Am. Coll. Cardiol. 58 (21) (2011) 2196–2209.
[9] V. Bapat, K.N. Asrress, Transcatheter valve-in-valve implantation for failing prosthetic valves, EuroIntervention 10 (8) (2014) 900–902.
[10] N.B. Hamid, O.K. Khalique, M.J. Monaghan, S.K. Kodali, D. Dvir, V.N. Bapat, et al., Transcatheter valve implantation in failed surgically inserted bioprosthesis: review and practical guide to echocardiographic imaging in valve-in-valve procedures, JACC Cardiovasc. Imaging 8 (8) (2015) 960–979.
[11] T. Senage, T. Le Tourneau, Y. Foucher, S. Pattier, C. Cueff, M. Michel, et al., Early structural valve deterioration of Mitroflow aortic bioprosthesis: mode, incidence, and impact on outcome in a large cohort of patients, Circulation 130 (23) (2014) 2012–2020.
[12] V. Joshi, K. Prosser, D. Richens, Early prosthetic valve degeneration with Mitroflow aortic valves: determination of incidence and risk factors, Interact. Cardiovasc. Thorac. Surg. 19 (1) (2014) 36–40.
[13] R. Diaz, D. Hernandez-Vaquero, J. Silva, C. Moris, Early structural valve deterioration of the Mitroflow aortic bioprosthesis: will the new anticalcification treatment change anything? Response, Rev. Esp. Cardiol. 70 (12) (2017) 1153.
[14] D. Dvir, J. Webb, S. Brecker, S. Bleiziffer, D. Hildick-Smith, A. Colombo, et al., Transcatheter aortic valve replacement for degenerative bioprosthetic surgical valves: results from the global valve-in-valve registry, Circulation 126 (19) (2012) 2335–2344.
[15] A.P. Kappetein, S.J. Head, P. Genereux, N. Piazza, N.M. van Mieghem, E.H. Blackstone, et al., Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document, Eur. Heart J. 33 (19) (2012) 2403–2418.
[16] D. Capodanno, A.S. Petronio, B. Prendergast, H. Eltchaninoff, A. Vahanian, T. Modine, et al., Standardized definitions of structural deterioration and valve failure in assessing long-term durability of transcatheter and surgical aortic bioprosthetic valves: a consensus statement from the European Association of Percutaneous Cardiovascular Interventions (EAPCI) endorsed by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS), Eur. Heart J. 38 (45) (2017) 3382–3390.
[17] R. Diaz, D. Hernandez-Vaquero, J. Silva, I. Pascual, J.M. de la Hera, V. Leon, et al., Real structural valve deterioration of the Mitroflow aortic prosthesis: competing risk analysis, Rev. Esp. Cardiol. 70 (12) (2017) 1074–1081.
[18] D. Dvir, J.G. Webb, S. Bleiziffer, M. Pasic, R. Waksman, S. Kodali, et al., Transcatheter aortic valve implantation in failed bioprosthetic surgical valves, JAMA 312 (2) (2014) 162–170.
[19] H.B. Ribeiro, J. Rodes-Cabau, P. Blanke, J. Leipsic, J. Kwan Park, V. Bapat, et al., Incidence, predictors, and clinical outcomes of coronary obstruction following transcatheter aortic valve replacement for degenerative bioprosthetic surgical valves: insights from the VIVID registry, Eur. Heart J. 39 (8) (2018) 687–695.
[20] D. Dvir, J. Leipsic, P. Blanke, H.B. Ribeiro, R. Kornowski, A. Pichard, et al., Coronary obstruction in transcatheter aortic valve-in-valve implantation: preprocedural evaluation, device selection, protection, and treatment, Circ. Cardiovasc. Interv. 8 (1) (2015).
[21] T. Doenst, P.A. Amorim, N. Al-Alam, S. Lehmann, C. Mukherjee, G. Faerber, Where is the common sense in aortic valve replacement? A review of hemodynamics and sizing of stented tissue valves, J. Thorac. Cardiovasc. Surg. 142 (5) (2011 Nov) 1180–1187.
[23] M. Simonato, J. Webb, R. Kornowski, A. Vahanian, C. Frerker, H. Nissen, et al., Transcatheter replacement of failed bioprosthetic valves: large multicenter assessment of the effect of implantation depth on hemodynamics after aortic valve-in-valve, Circ. Cardiovasc. Interv. 9 (6) (2016).
[24] P. Avanzas, I. Pascual, A.J. Munoz-Garcia, J. Segura, J.H. Alonso-Briales, J. Suarez de Lezo, et al., Long-term follow-up of patients with severe aortic stenosis treated with a self-expanding prosthesis, Rev. Esp. Cardiol. 70 (4) (2017) 247–253.
[25] E.P. van der Straaten, L.M. Rademakers, A.H. van Straten, S. Houterman, M.E. Tan, M.A. Soliman Hamad, Mid-term haemodynamic and clinical results after aortic valve replacement using the Freedom Solo stentless bioprosthesis versus the Carpentier Edwards Perimount stented bioprosthesis, Eur. J. Cardiothorac. Surg. 49 (4) (2016) 1174–1180.
[26] M. Barbanti, A.S. Petronio, F. Ettori, A. Latib, F. Bedogni, F. De Marco, et al., 5-year outcomes after transcatheter aortic valve implantation with CoreValve prosthesis, JACC Cardiovasc. Interv. 8 (8) (2015) 1084–1091.
[27] P. Avanzas, A.J. Munoz-Garcia, J. Segura, M. Pan, J.H. Alonso-Briales, I. Lozano, et al., Percutaneous implantation of the CoreValve self-expanding aortic valve prosthesis in patients with severe aortic stenosis: early experience in Spain, Rev. Esp. Cardiol. 63 (2) (2010) 141–148.
[28] D. Dvir, J.G. Webb, Transcatheter aortic valve-in-valve implantation for patients with degenerative surgical bioprosthetic valves, Circ. J. 79 (4) (2015) 695–703.
[29] K. Milburn, V. Bapat, M. Thomas, Valve-in-valve implantations: is this the new standard for degenerated bioprostheses? Review of the literature, Clin. Res. Cardiol. 103 (6) (2014) 417–429.
[30] P. Pibarot, M. Simonato, M. Barbanti, A. Linke, R. Kornowski, T. Rudolph, et al., Impact of pre-existing prosthesis-patient mismatch on survival following aortic valve-in-valve procedures, JACC Cardiovasc. Interv. 11 (2) (2018) 133–141.
[31] M. Adamo, C. Fiorina, S. Curello, G. Chizzola, E. Pezzotti, E. Gavazzi, et al., Self-expanding transcatheter aortic valve implantation for degenerated small Mitroflow bioprosthesis: early and midterm outcomes, EuroIntervention 13 (9) (2017) e1032–e1039.
[32] S. Alnasser, A.N. Cheema, M. Simonato, M. Barbanti, J. Edwards, R. Kornowski, et al., Matched comparison of self-expanding transcatheter heart valves for the treatment of failed aortic surgical bioprosthesis: insights from the valve-in-valve international data registry (VIVID), Circ. Cardiovasc. Interv. 10 (4) (2017).
[33] D. Hernandez-Vaquero, J.M. Garcia, R. Diaz, D. Calvo, Z. Khalpey, E. Hernandez, et al., Moderate patient-prosthesis mismatch predicts cardiac events and advanced functional class in young and middle-aged patients undergoing surgery due to severe aortic stenosis, J. Card. Surg. 29 (2) (2014) 127–133.
[34] S.J. Head, M.M. Mokhles, R.L. Osnabrugge, P. Pibarot, M.J. Mack, J.J. Takkenberg, et al., The impact of prosthesis-patient mismatch on long-term survival after aortic valve replacement: a systematic review and meta-analysis of 34 observational studies comprising 27 186 patients with 133 141 patient-years, Eur. Heart J. 33 (12) (2012) 1518–1529.
[35] V. Dayan, G. Vignolo, G. Soca, J.J. Paganini, D. Brusich, P. Pibarot, Predictors and outcomes of prosthesis-patient mismatch after aortic valve replacement, JACC Cardiovasc. Imaging 9 (8) (2016) 924–933.
[36] D. Hernandez-Vaquero, R. Diaz, I. Pascual, J. Rozado, J.M. De la Hera, V. Leon, et al., The prevalence of patient-prosthesis mismatch can be reduced using the trifecta aortic prosthesis, Ann. Thorac. Surg. 105 (1) (2018) 144–151.
[37] D. Tanase, J. Grohmann, S. Schubert, F. Uhlemann, A. Eicken, P. Ewert, Cracking the ring of Edwards Perimount bioprosthesis with ultrahigh pressure balloons prior to transcatheter valve in valve implantation, Int. J. Cardiol. 176 (3) (2014) 1048–1049.
[38] J.E. Nielsen-Kudsk, E.H. Christiansen, C.J. Terkelsen, B.L. Norgaard, K.T. Jensen, L.R. Krusell, et al., Fracturing the ring of small Mitroflow bioprostheses by high-pressure balloon predilatation in transcatheter aortic valve-in-valve implantation, Circ. Cardiovasc. Interv. 8 (8) (2015), e002667.
[39] S.L.W. Sang, T. Beute, J. Heiser, D. Berkompas, J. Fanning, W. Merhi, Early outcomes for valve-in-valve transcatheter aortic valve replacement in degenerative freestyle bioprostheses, Semin. Thorac. Cardiovasc. Surg. 30 (3) (2018) 262–268.