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Research Article

Resilia Inspiris® Valve in Modern Times: A Useful Alternative in Younger Patients with Severe Aortic Valve Stenosis with Anticipation for Future Valve-in-Valve Transcatheter Aortic Valve Implantation?

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Keywords: Aortic valve replacement; Inspiris resilia; Structural valve degeneration; Survival

Abstract

Introduction: The outcome of the Inspiris Resilia valve implanted in aortic position is investigated with respect to its hemodynamic properties and durability. In case of structural valve degeneration, its design would allow valve-in-valve transcatheter aortic valve implantation.

Methods: The PubMed database was consulted for last 5 years with the search term: "inspiris resilia aortic valve". Exclusion criteria were not the IR valve under study, reviews, letters to the editor, use in pulmonary position and editorials. Case reports and in vitro studies were included as a separate category.

Results: Fifty-six papers were identified, of which 28 were retained. These included eleven comparative studies, ten single arm studies, with a follow-up to 5 years with one extension to 7 years, three *in vitro* studies, and four case reports as proof-of-concept for the valve-in-valve transcatheter aortic valve implantation approach. Age and risk scores of the investigated population are low in most series. Thirty-day outcomes, including complication rates and hemodynamic profile, are satisfactory for the Inspiris Resilia as well as for the conventional valves. This applies also for the mid-and-long-term results.

Conclusion: There is cautious optimism for the Inspiris Resilia valve for its durability and there is proof of concept for a possible valve-in-valve transcatheter aortic valve implantation in case of valve degeneration, but problems caused by calcification of a degenerated Inspiris Resilia valve should be considered.

Introduction

The rate of aortic valve stenosis increases with age and has a dismal prognosis once this condition becomes symptomatic. Aortic valve replacement has the potential to restore the patients' life expectancy. The choice between a mechanical and biological valve prosthesis is a matter for debate. The need for anticoagulation with its bleeding risk versus the risk for structural valve degeneration (SVD) are important issues in this debate. Although the use of mechanical heart valves (MHV) is recommended in patients under 60 years of age, the percentage of biological heart valves (BHV) implanted in this age category is increasing rapidly. The inconvenience of anticoagulation treatment with its inherent bleeding risk as well as the longer durability of more recently developed BHV and the potential option for valve-in-valve transcatheter aortic valve implantation (VIV-TAVI), are the main drivers in this trend. The improved durability of BHV remains doubtful in younger patients, who also have a long-life expectancy [1]. One propensity score match analysis (PSM) based on a register of patients aged between 50 and 69 years, and who received surgical aortic valve replacement

(SAVR) showed that patients receiving MHV had better long-term survival, but with a similar stroke rate. Patients who received a BHV had a lower risk for major bleeding but a higher reoperation rate [2]. An older randomized controlled trial of patients aged between 55 and 70 years indicated that thromboembolism, bleeding, endocarditis, and survival at 13 years was comparable between patients with MHV and BHV, but that valve failure and reoperation rate were higher after implantation of a BHV [3]. The importance of this treatment policy increased with the observation that the implantation of BHV increased over time [4] and was much higher compared to MHV implantation [5]. Recent series confirmed that, after propensity score matching (PSM), mortality rates at 1, 5 and 15 years were comparable between patients receiving BHV and MHV [4,6]. However, better survival after implantation of MHV was observed in patients younger than 60 years [5]. Another meta-analysis revealed a more complex relationship between age and survival: the overall survival was similar between the compared arms for patients <50 years old but was significantly increased in the MHV arm for patients 50-70 years old and significantly increased in the BHV arm for patients >70 years old [7]. Stroke rates between both groups did not differ significantly in one series (6,7) but were borderline higher in another series [4]. Major bleeding was significantly more observed in the MHV group [4,7]. A high reoperation rate was confirmed in patients who received BHV [4,6,7]. and this event was more than three times higher after 15 years of follow-up [6]. The Inspiris Resilia (IR) has two innovative features. First, the valve incorporates novel VFit technology. This design allows for a controlled and predictable expansion during future VIV-TAVI procedures, when patients are older and usually have higher surgical risk. It shares the internally mounted leaflet design with the Carpentier-Edwards (CE) Perimount valves. Second, the valve tissues were treated to slow calcification and improve durability by dehydration and reduction of the lipid content. Its dry storage allows easier handling and eliminates the need of rinsing before implantation. The transport of the valve would be less costly and may give it longer shelf life. This valve received a European CE mark in 2016 and was approved by the FDA in 2017.

Methods

The PubMed database was searched for the last 5 years with the MeSH terms: "Inspiris Resilia aortic valve". Exclusion criteria were not the IR valve under study (n = 1), redundant publications (n = 1), reviews (n = 4) or letters to the editor (n = 2), because these papers are not sources of new data. Implants in pulmonary (n = 6) or mitral position (n = 2) and papers dealing with other issues such as mode of aortotomy, use of composite grafts, and contra-indications for MHV (n = 12), were also excluded for analysis. Case reports describing VIV-TAVI and *in vitro* studies with respect to durability by accelerated wear testing and to feasibility of VIV-TAVI in IR were included for their relevance. Going through the reference list of and included series resulted in the inclusion of one additional paper.

Results

Initially, fifty-six papers were identified, of which 28 were retained. Eleven manuscripts dealt with comparative studies with an outcome up to 5 years. Ten single arm studies had a follow-up to 5 years with one extension to 7 years. Three papers dealt with *in vitro* studies. Additionally, four case reports served as proof-of-concept. One duplicate publication was omitted from this review because of redundancy. Another manuscript was included after a secondary reference. This article was an extension to seven years follow-up of the existing COMMENCE trial. The six papers studying the pulmonary position of the study valve were not included in the formal analysis but were commented on because of off-label use of the IR valve and of the poor postoperative results.

The IR valve was tested in vitro through accelerated wear testing. Three 21-mm and three 23-mm valves underwent one billion cycles simulated, which is considered as an equivalent of 25 years. There was no significant reduction in mean effective orifice areas (EOA) compared to control devices which did not undergo this procedure. The flow characteristics were also comparable. One billion cycles are considered 5 times longer than the standard requirement for a tissue valve as stipulated in International Standards Organization 5840-2:2015 [8]. A second two billion cycle test, considered as equivalent to 50 years simulated in vitro durability, also showed that there was an adequate hemodynamic performance. The valves showed no signs of gross damage [9]. Even in case of SVD of the IR valve, the Vfit technology would allow a non-surgical approach to replace the degenerated valve. The possibility of fracturing degenerated aortic valve prostheses could improve the functionality after TAVI. The design of the IR allowed the enlargement of the stent diameter. This resulted in improved leaflet kinematics of the transcatheter heart valves as valve-in-valve concept: there was an *in vitro* fluoroscopic visible enlargement of 2 mm of the stent diameters, while the EOA and mean transvalvular gradient (TVG) did not decrease significantly. There was no pin wheeling effect. These findings could have important consequences in small-sized biological surgical valve prostheses [10].

Eleven series were identified which compared the IR valve with control valves, such as Carpentier-Edwards and Avalus [11-21] and one manuscript dealt with gender differences [22]. These results can be seen in Table 1. Eight of these series used a PSM analysis, one paper provided nationwide data with economic impact [13], another did not provide raw data of clinical outcomes, but related patient-valve prosthesis mismatch to postoperative mortality [21], and a third series studied postoperative thrombocytopenia [15]. The included series had sufficient quality if rated by the Newcastle-Ottawa

Table 1: Comparative series with 30-day outcomes (significant differences in bold type).

Reference	Valve	N	Age (y)	Risk Score (%)	ACC (min)	CPB (min)	Mortality (%)	m-TVG (mm Hg)
Bartus 2023 [11]	IR	556	75 ± 6	**STS 2.6 ± 2.0**	-	-	-	-
	CE	556	76 ± 4	**STS 5.0 ± 1.6**	-	-	-	-
Bernard 2023[12]	IR	217	69 ± 7	1.9	70	91	2.8	**10**
	CE	217	70 ± 7	2.5	78	98	2.3	**14**
Brown 2025 [13]	IR	6298	**65 ± 10**	Elix 6.4 ± 2.5	-	-	3.1	-
	Other	11846	**69 ± 10**	Elix 6.4 ± 2.5	-	-	3.4	-
Chiariello 2023 [14]	IR	74	**57**	**STS 3.5**	85	117	**1.0**	12
	Avalus	74	**75**	**STS 9.3**	89	117	**3.0**	13
D'Alonso 2024 [15]	IR	70	**65 ± 7**	-	-	-	1.4	-
	CE	74	**69 ± 8**	-	-	-	**0**	-
D'Onofrio 2024[16]	IR	605	**60**	**STS 0.9**	**82**	**107**	**0.5**	**10**
	Intuity	1688	**75**	**STS 1.9**	**62**	**91**	**1.8**	**10**
	CE	296	**72**	**STS 0.9**	**105**	**135**	**2.4**	**13**
Francica 2023[17]	IR	122	57 ± 9	ES 2.7 ± 2.4	89 ± 34	114 ± 40	**0**	11.3 ± 3.5
	CE	122	58 ± 11	ES 2.7 ± 2.4	84 ± 31	101 ± 40	**0**	11.9 ± 5.4
Maeda 2023 [18]	IR	66	74 ± 8	-	108 ± 35	152 ± 149	1.5	10.9 ± 3.9
	CE	66	73 ± 6	-	95 ± 24	138 ± 35	**0**	11.9 ± 3.5
Narita 2025 [19]	IR	79	75	ES 2.0	103	139	**0**	10.7
	CE	79	74	ES 2.4	95	132	**1.3**	11.5
Saiydoun 2025 [20]	IR	52	62 ± 5	ES 1.6 ± 2.1	-	-	-	11.0 ± 3.4
	Avalus	52	66 ± 4	ES 1.6 ± 1.9	-	-	-	10.6 ± 2.9
Zierer 2024 [22]	IR male	433	59 ± 10	ES 1.6 ± 1.7	75 ± 25	104 ± 39	-	-
	IR female	243	59 ± 10	ES 2.4 ± 3.0	72 ± 26	102 ± 38	-	-

ACC: Aortic Cross-Clamp (minutes); CPB: Cardiopulmonary Bypass (minutes); CE: Carpentier-Edwards; Elix: Elixhauser score; Fem: Female IR: Inspiris Resilia; Mal: Male; m-TVG: mean Transvalvular Gradient at Discharge (mm Hg); Mort: Mortdality (as %), N: Number. Significant Differences: Indicated in bold.

scale. Using the PMS analytical method, representation and selection of patients of the exposed cohort (i. e., those which receive the IR valve) and the controls (patients receiving the conventional valve), as well as the ascertainment of exposure were present in the series. The outcome of interest was not present at the start of the studies, and its assessment was based on medical records. The PSM analysis made the experimental cohort comparable to the control group. The adequacy of outcome, however, was incomplete, which can be derived from the empty spaces in tables one and two. Continuous results are mostly presented as mean +/- SD in the tables. In other series, the median value is presented as sole value.

Table 1 shows that the mean ages and risk scores were not significantly different in most series. These risk scores mostly indicated a low operative risk except in two series [11,14]. In one series, the predicted STS score overestimated the observed mortality rate in both arms [14]. This was most pronounced in the control arm, with a high median age. The observed mortality remained under 3.5% and close to the corresponding risk score. There was a wide variation in aortic cross-clamp time and in cardiopulmonary bypass time. In most series, the postoperative mean TVG of the IR valve was slightly lower compared to the conventional device. Eight of the eleven series showed mid-term results at two [12,14,22] three (17-20) and five years [11]. These results are visible in Table 2. None of the comparative series had a follow-up exceeding five years. Paravalvular leaks and regurgitation across the IR or the conventional valve exceeded in none of the series at the level of 2% at an early or mid-term time. Consequently, none of these differences are clinically relevant. The rate of SVD of the IR valve remained below 1.5% in all series, even at 5 years [14]. LVMI regression was better after Avalus implantation [14]. The rate of postoperative implantation of a permanent pacemaker implantation at any time remained below 5% and survival was high for both conventional and IR valve, without significant differences.

Ten single-arm series were retained. The short-term outcomes are shown in Table 3 [23-33]. One of these series was extended to a follow-up of 7 years [27]. The age in these series varied, but the risk scores, with the observed 30-day mortality rates, were mostly low. The surgical times varied considerably. In only one series, a more than mild regurgitation rate of 6.2 was documented [28]. The postoperative mean TVG corresponded with the findings in the comparative series.

Eight of the single-arm series, shown in Table 4, had a mid-term follow-up varying between one and five years [23-26,29-32], while two of these series were limited to short-term outcomes [28,33]. Of these series, only two had a five-year follow-up [26, 30]. One of these was a part of the COMMENCE trial, which has been extended to 7 years, and was published as a separate report [27]. The trial started with 689 patients, of whom 512 completed the 5-year follow-up. Of these, 225 patients agreed for further follow-up and 195 patients completed the follow-up at 7 years. Their mean age was 65+/-11 years, with a corresponding low mean risk score of 2.1+/-2.1%. Mean TVG (9.4+/-4.5 mmHg) and effective orifice area (1.8+/-0.6 cm^2) remained stable at 7 years. The SVD rate was 0.7% and reoperation rate was 2.8%, mostly for prosthetic

Table 2: comparative series with long-term outcome.

Reference	Valve	FU (y)	Regurg (%)	m-TVG (mm Hg)	SVD (%)	PVE (%)	PPM (%)	Survival (%)
Bartus 2023 [11]	IR	5	-	-	**1.0**	-	-	-
	CS	-	-	-	**4.8**	-	-	-
Bernard 2023 [12]	IR	2	-	**11.1 ± 0.5**	-	-	-	94
	CS	-	-	**12.3 ± 0.5**	-	-	-	91
Chiariello 2023 [14]	IR	2	0	12	0	0	3	93
	Avalus	-	0	13	0	0	5	96
Francica 2023 [17]	IR	3	0	-	-	-	3.3	-
	CS	-	0	-	-	-	1.6	-
Maeda 2023 [18]	IR	3	0	-	0	-	0	95.2
	CS	-	1.7	-	0	-	0	95.2
Narita 2025 [19]	IR	3	-	10.7–11.3	-	-	-	93.8
	CS	-	-	11.5–12.1	-	-	-	95.4
Saiydoun 2025 [20]	IR	3	1.9	12.9 ± 3.7	0	-	3.8	100
	Avalus	-	0.0	12.9 ± 3.6	0	-	3.8	98.1
Zierer 2024 [22]	IR (male)	2	1.2	-	0.5	1.0	4.8	96.2
	IR (female)	-	0.4	-	1.4	1.0	4.6	96.3

FU: Follow-up; m-TVG: mean Transvalvular Gradient (mm Hg); PVE: Prosthetic Valve Endocarditis (%); PPM: Permanent Pacemaker Overall (%); Regurg: Regurgitation more than mild at any time (%); SVD: Structural Valve Degeneration (%); Surv: Survival (%), M: Male patients; F: Female patients. Significant Differences: Indicated in bold

Table 3: single arm series with 30-day outcomes.

Reference	N	Age (y)	Risk Score (%)	ACC (min)	CPB (min)	Mortality (%)	m-TVG (mm Hg)
Ahmad 2021 [23]	100	56 ± 9	ES 5.8 ± 6.4	41 ± 17	79 ± 38	0.0	10.6 ± 2.6
Ahmad 2022 [24]	154	57 ± 10	ES 3.4 ± 1.8	58 ± 23	92 ± 32	2.1	9.5 ± 3.3
Bakhtiary 2023 [25]	556	63 ± 9	ES 2.2 ± 2.5	75 ± 29	111 ± 44	1.4	11.2 ± 4.9
Bavaria 2023 [26]	689	67 ± 12	STS 2.0 ± 1.8	-	-	1.2	5–13 (size dep.)
Berry 2024 [28]	81	67 ± 9	-	-	-	-	6.8 ± 2.4
Fukunaga 2022 [29]	29	75 ± 5	-	125 ± 36	177 ± 42	3.4	10.2 ± 3.5
Fukunaga 2025 [30]	60	73 ± 6	-	118 ± 35	165 ± 46	1.9	10.3 ± 3.5
Meuris 2023 [31]	421	54 ± 7	ES 1.5 ± 1.6	74 ± 25	96 ± 34	0.7	11.7
Porto 2023 [32]	487	58 ± 12	ES 4.8 ± 7.9	86 ± 34	113 ± 50	1.6	9.0
Useini 2021 [33]	80	61 ± 8	ES 3.6 ± 2.4	64 ± 17	89 ± 19	2.5	10.2 ± 4.1

ACC: Aortic Cross-Clamp (minutes); CPB: Cardiopulmonary Bypass (minutes); CE: Carpentier-Edwards; Fem: Female IR: Inspiris Resilia; Mal: Male; m-TVG: mean Transvalvular Gradient at Discharge (mm Hg); Mort: Mortality (as %); N: Number

Table 4: Single arm series with long-term follow-up.

Reference	FU (y)	Regurg (%)	m-TVG (mm Hg)	SVD (%)	PVE (%)	PPM (%)	Survival (%)
Ahmad 2021 [23]	1	0	11.5 ± 2.3	0	-	1.0	100
Ahmad 2022 [24]	3	0	13.9 ± 5.9	0	0.6	-	87.7
Bakhtiary 2026 [25]	3	0.5	11.9	3.2	4.0	6.5	91.0
Bavaria 2023 [26]	5	0.5	11.5 ± 6.0	0	-	-	89.0
Fukunaga 2022 [29]	2	0	11.2 ± 3.3	0	0	0	96.6
Fukunaga 2025 [30]	5	0	10.2 ± 2.7	0	0	0	97.4
Meuris 2023 [31]	1	1.7	12.6 ± 5.3	0	-	3.8	98.3
Porto 2023 [32]	1	1.6	9.0	0	2.1	5.5	96.4

FU: Follow-up; m-TVG: mean Transvalvular Gradient (mm Hg); NS: Not Stated; PVE: Prosthetic Valve Endocarditis (%); PPM: Permanent Pacemaker Overall (%); Regurg: Regurgitation more than mild at any time (%); SVD: Structural Valve Degeneration (%); Surv: Survival (%).

valve endocarditis. At 7 years, no or only trivial paravalvular leak was observed in 99.3% of the patients. For freedom of more than mild transvalvular regurgitation, this was 96.2%. Freedom of mortality was 85.4% [27].

Only four case reports of VIV-TAVI in a degenerated IR valve were identified. All four patients needed chronic hemodialysis and had a high surgical risk [34-37]. This indicates that the Resilia tissue is not durable in patients with end-stage renal disease. These case reports showed proof-of-concept for the procedure, by choosing a larger valve size than the original implant. In one elderly patient with a degenerated 21-mm IR valve, a successful urgent trans-carotid VIV-TAVI was performed with a 23-mm Sapien 3 Ultra Resilia device. Fluoroscopic confirmation of partial valve ring expansion at the VFit zone was demonstrated after post-dilation using the same balloon. Post procedural TTE showed a mean TVG of 15 mmHg with trivial paravalvular regurgitation. Pre- and post procedural CT scans showed an expansion of the IR valve of 2 millimeters [34]. An insufficient dilatation with indentation at the ring of the IR valve was documented in another patient. This might be due to calcification in the valve cusp as this tissue might interfere with the opening of the IR ring. The hemodynamic improvement was sufficient, and this outcome was still visible after one year [35].

Discussion

Bovine pericardial valves have been used extensively and worldwide in the past decades [38]. The use of these valves increased overtime [4,5], which is also illustrated by our own early [39] and later [40] experience. The hemodynamic stability of the internally mounted Carpentier-Edwards valves was proven by numerous studies. It also demonstrated superiority over many other biological valves in terms of durability. Two externally mounted valve prostheses, Trifecta and Mitroflow valves, had a larger EOA because of their design. Despite their good hemodynamic profile, both valves showed a higher rate of SVD and of reoperation [41,42]. The overall risk for SVD was high, especially if the prosthesis was of small size and if the follow-up exceeded 5 years. The anti-calcification treatment seemed unable to prevent early degeneration [43-45]. A meta-analysis showed that valve reintervention rate and all-cause mortality were higher with externally mounted valves, compared to internally mounted leaflet designed valves, which were mostly of Carpentier-Edwards series [46]. The significant mechanical abrasion observed in the commissural region of externally mounted valves could be caused by repeated leaflet-to-stent contact, resulting in early SVD. The increased reoperation rate could contribute to an increased mortality rate. The externally mounted leaflet design could also result in an increased risk for coronary obstruction in case of VIV-TAVI [46]. The newer-generation IR builds on the proven design of the Carpentier-Edwards Magna Ease valve, which would allow safe VIV-TAVI because of its lower profile and lower risk for coronary obstruction. This valve is assembled from RESILIA-tissue with anti-calcification properties. This is achieved by a stable and irreversible capping which eliminates free glutaraldehyde residuals which bind calcium. The tissue is also glycerolized, enabling easier transport, dry storage and handling of the valve, without the need for rinsing [38]. The IR valve is also equipped with V-Fit stent technology, which is potentially useful for future VIV-TAVI procedures with larger size aortic valve [38], without the risk imposed by an externally mounted design. However, only one *in vitro* study [10]. and four case reports [34-37], are currently identified to demonstrate the feasibility of this approach. Moreover, in all the four cases, patients were under hemodialysis. End stage renal disease is associated with premature calcific degeneration of bioprosthetic heart valves and increasing the rate of SVD [47]. A CT-scan confirmed that the stent size increased by two millimeters after VIV-TAVI [34].

Most of the included series used PSM analysis to compare the IR with the control valve. This quasi-experimental statistical method reduced confounding factors in observational studies and balanced the confounders between both patient groups. The probability of treatment assignment was based on observed characteristics, whereby subjects with similar scores were paired. The mean age of the included series varied but remained on or above the lower end of what is deemed appropriate for implanting BHV. The risk scores and the corresponding 30-day mortality rates were low for most of the series, except in two reports, where there was a significantly lower risk score of the patients receiving the IR study valve [11-14]. However, the risk score overestimated the observed mortality by 2.5% for the IR study valve and by more than 6% for the control valve [14]. A more modest overestimation of the risk was observed by two other series [17-19]. In four single arm series [23,24,32,33]. an overestimation of the observed mortality of more than 1% was recorded. In two single-arm series, the mean risk score was above 4% ([23,32]. The surgical times varied, reflecting the complexity of the surgical procedure. In several series, additional procedures such as CABG were performed in at least 40% of the patients [12,13,17,25,27,29-33]. The effect of an additional procedure on the outcome was not investigated. However, our own experience demonstrated a significant but limited effect of adding CABG to SAVR on survival [48]. There is reason to assume that adding a CABG would not affect the hemodynamic outcome of the valve prosthesis. For this reason, an additional procedure does not seem to have major implications for the choice concerning the use of the IR valve. The hemodynamics in terms of mean TVG and EOA for the IR valve and the conventional valves were comparable at 30-days and remained stable throughout the follow-up. The rate of SVD of the IR valve remained low, but most comparative [12,14,17-20,22] and single-arm series [23-25,29,31,32] had a follow-up of one to three years. This duration seems too short to draw definitive conclusions. The results of the included single-arm series matched those of the comparative series in every aspect. The results of the COMMENCE trial were extended to 7 years showing an excellent outcome with a low rate for SVD, for valve regurgitation of any type and for reoperation. However, the study valves were implanted in 689 patients, but only 225 patients re-consented after 5 years and data at seven years were obtained in 195 patients [27]. This outcome could become the benchmark for future surgical and transcatheter prostheses, but these results should be interpreted with caution and need confirmation. One small series of 81 patients focused also on the intravalvular leak of the IR valve. Perioperative mild leaks were common and unique to the IR valve. The exact mechanism is unclear. Given the high frequency of this postoperative finding, it is essential that intraoperative echocardiographers can distinguish clinically insignificant leaks from relevant regurgitation, based on origin, severity, and direction of the observed jets, thereby providing appropriate recommendations for surgeons [28]. In one series, thrombocytopenia was less present after implantation of the IR valve, compared to conventional valves. In absence of other clinical events such as bleeding and reoperation rates, this seems less relevant [15]. The rate of patient-prosthesis mismatch was low in IR valves [32] and even lower compared to Carpentier-Edward valves [18]. However, the consistency between predicted and measured mismatch was low for IR compared to Carpentier-Edward valves, especially in smaller sizes [21]. The reduction of the left ventricular mass index with the IR valve was adequate [29], but inferior in comparison with the Avalus valve [14].

The IR valve has been approved by the FDA for the aortic position only. The implantation in pulmonary position in patients with congenital heart disease was considered off label. The hemodynamic results after implantation as a composite graft were comparable to those obtained with the Carpentier-Edward valve. However, when the IR valve was implanted in the native right ventricle outflow tract, there was an early onset of mild valve regurgitation [49]. Progress to moderate and severe regurgitation was observed in another series. The design of the valve might not be suitable for such low-pressure conditions [50-52]. Distortion of the valve and its angular position might be crucial [53], and caution is warranted, even after initially favorable results [54]. In case of failure of the IR valve, a transcatheter procedure could offer a solution [55]. The scarcity of robust data about the IR valve in the pulmonary position remains concerning.

The limitations are those of the included retrospective series. Some of these series are relatively small, and do not register all possible outcomes. PMS analysis aims to reduce the effect of confounders, but the method cannot adjust for variables which are not included in the model and therefore remain undetected. Potential examples are surgical techniques, the effect of additional procedures such as CABG and the individual experience of the surgeon. Another limitation of this review is the simplicity of the search terms. This allows for a broad sweep through the literature database, but with the risk of missing important articles. This risk has been minimized by searching through the references of the articles included. The most important limitation of the included series is the short duration of the follow-up, which does not allow the predict long-term durability of the IR valve. Furthermore, the valve size with its impact on hemodynamics and durability was studied in some series, but not considered in the current analysis.

Conclusion

We can conclude from these series that the technical success rate for IR is high. The rates of patient-prosthesis mismatch, need for reoperation, endocarditis, and paravalvular leak are comparable to the results of the conventional valves. The hemodynamic profile of IR is not inferior compared to the conventional valve and SVD does not occur more often. The follow-up, however, is limited and too short to draw definitive conclusions about possible SVD. The fate of the externally mounted Trifecta and Mitroflow valves serves as cautionary tale in this respect. Vfit technology allows expansion of the IR valve in patients in whom VIV-TAVI could become necessary. An increase of two millimeters has been demonstrated. These cases deliver a proof-of-concept for this approach, but the presence of calcification might hamper its expansion. In younger patients, a redo-SAVR might be considered instead of VIV-TAVI. The latter procedure seems preferable for older and frail patients with a high surgical risk. Especially for younger patients, the heart team should devise a comprehensive management plan beyond 10 or 15 years after the index procedure, since many of these patients are expected to outlive their valve prosthesis. Patient preference plays an increasingly important role in decision making [38]. Future data with respect to the durability of novel bio prosthesis such as the IR valve and the results of VIV-TAVI will influence such long-term treatment strategies of aortic valve stenosis. The risk of coronary obstruction during these procedures must be considered for each surgically implanted valve [56,57]. For these reasons, a detailed registry for VIV-TAVI for a degenerated IR valve is needed.

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