Structural Heart

The Journal of the Heart Team

ISSN: 2474-8706 (Print) 2474-8714 (Online) Journal homepage: https://www.tandfonline.com/loi/ushj20

Transcatheter Aortic Valve Replacement for Failed Surgical Bioprostheses: Insights from the PARTNER II Valve-in-Valve Registry on Utilizing Baseline Computed-Tomographic Assessment

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To cite this article: Danny Dvir, John G. Webb, Philipp Blanke, Jong K. Park, Michael Mack, Philippe Pibarot, Todd Dewey, Howard C. Herrmann, Samir Kapadia, Susheel Kodali, Raj Makkar, Kevin Greason, D. Craig Miller, Augusto Pichard, Lowell Satler, Craig Smith, Rakesh M. Suri, Maria Alu, Jonathon M. White, Martin B. Leon & Jonathon Leipsic (2017) Transcatheter Aortic Valve Replacement for Failed Surgical Bioprostheses: Insights from the PARTNER II Valve-in-Valve Registry on Utilizing Baseline Computed-Tomographic Assessment, Structural Heart, 1:1-2, 34-39, DOI: 10.1080/24748706.2017.1329571

To link to this article: https://doi.org/10.1080/24748706.2017.1329571

STRUCTURAL HEART
2017, VOL. 1, NOS. 1–2, 34–39
https://doi.org/10.1080/24748706.2017.1329571

ORIGINAL RESEARCH

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Transcatheter Aortic Valve Replacement for Failed Surgical Bioprostheses: Insights from the PARTNER II Valve-in-Valve Registry on Utilizing Baseline Computed-Tomographic Assessment

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ABSTRACT

Background: Residual stenosis is a major limitation of transcatheter aortic valve replacement inside failed surgical bioprostheses (valve-in-valve). Our aim was to evaluate whether pre-procedure CT assessment could identify cases at risk for having residual stenosis after the procedure.

Methods: Patients with failed surgical aortic bioprostheses were prospectively enrolled in the multicenter PARTNER II valve-in-valve registry. Core-lab assessment of echocardiographic and CT findings were utilized.

Results: A total of 84 patients that underwent pre-procedural CT were included in the current analysis with a median age of 79.9 ± 9.6 years with 65.5% being male. CT average annulus internal area was 331.64 ± 73.52mm^2. Post SAPIEN XT implantation mean gradient was 17.95 ± 7.59 mmHg and average aortic valve area was 1.06 ± 0.35 cm^2. Small internal annular area per CT was significantly associated with increased gradients in intermediate/large surgical valves (true ID > 20 mm, $p = 0.01$). ROC curve for the evaluation of predictability of CT measured area on post-procedural gradients in intermediate/large surgical valves was high (AUC 0.81). Cutoff of 329 mm^2 had negative predictive value of 95%.

Conclusions: CT-derived annulus area in cases with intermediate and large surgical valves can identify cases at risk for poor hemodynamics after valve-in-valve and influence clinical decision making.

ARTICLE HISTORY Received 29 March 2017; Revised 7 May 2017; Accepted 7 May 2017

KEYWORDS CT; transcatheter aortic valve replacement; valve-in-valve

Introduction

Bioprosthetic tissue valves are increasingly implanted during surgical aortic valve replacements.[1] Structural valve deterioration is a known complication of such implants and as a result patients increasingly present with degenerated bioprostheses. Treatment of patients with failed bioprostheses is challenging. While reoperation is considered the standard of care, these patients are frequently elderly and repeat cardiac surgery carries significant risks.[2,3] Transcatheter aortic valve replacement (TAVR) has become an alternative, less-invasive treatment for high-risk patients with severe symptomatic aortic stenosis.[4,5] Previous reports have demonstrated the feasibility of treating degenerated bioprostheses with transcatheter heart valves inside failed surgical valves (valve-in-valve, VIV).[6,7] Preliminary data from the Valve-in-Valve International Data (VIVID) Registry revealed that although procedural success is achieved in the majority of patients, the procedure includes several safety and efficacy concerns, including elevated post procedural gradients and coronary obstruction.[8]

Over the last decade multidetector computed tomography (MDCT) has asserted itself as an important tool for the assessment of patients prior to TAVR and has been shown to help improve clinical outcomes.[9,10,11] Pre-procedural screening with 3-dimensional MDCT has resulted in a reduction in paravalvular regurgitation and also a more comprehensive evaluation of coronary obstruction risk. The clinical role of MDCT in the advance of transcatheter ViV therapy is less well established. The lack of clinical integration reflects a number of issues including modest understanding as to how to size bioprosthetic valves with CT given the varied structural design. While baseline knowledge of the surgical valve type and design is extremely helpful for Transcatheter Heart Valve (THV) sizing, Surgical Heart Valve (SHV) are often canted and deformed both through the limitations of surgical aortic valve replacement (SAVR) but also over time. Recently,

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a number of groups have begun to look at how to best integrate CT into pre-procedural ViV planning; however, to date, these have largely been supported by expert opinion rather than systematic scientific evaluation and data. Given the paucity of data we sought to determine if pre-procedural CT could predict the risk of elevated post procedural gradients after these procedures, thus allowing for optimal pre-procedural decision-making.

Materials and methods

Study design and patient selection

The Placement of Aortic Transcatheter Valves (PARTNER) II trial is a prospective, multicenter study which enrolled patients with symptomatic severe AS who were either inoperable, high risk or at intermediate risk of operative complications.[14] The current study included a nested registry of patients with degenerated surgical aortic bioprostheses. Only patients at very high risk of complications from re-operative surgery were included. Included patients could have either predominant stenosis, regurgitation or combined stenosis/regurgitation of a surgical bioprosthesis and were required to have a bioprosthesis suitable for VIV treatment with either a 23 mm or 26 mm SAPIEN XT transcatheter heart valve (THV). Severe aortic stenosis was defined as an aortic valve area (AVA) <0.8 cm^2 or indexed AVA <0.5 cm^2/m^2 and a mean gradient >40 mmHg or peak velocity >4 m/s. Patients with at least moderate stenosis and regurgitation were classified as having mixed bioprosthetic failure. Operative risk was determined by heart team evaluation including at least one cardiac surgeon and one interventional cardiologist. Patients were deemed to be at very high risk if the Heart Team considered the risk of surgical mortality or major morbidity to be ≥50%. All patients were presented to a web-based conference call where imaging and clinical data were reviewed by a screening committee and approved prior to implantation. The trial was approved by the Institutional Review Board of all participating sites and written, informed consent was provided by all patients.

Key exclusion criteria were a bioprosthetic valve with a labeled size <21 mm, a second prosthetic valve in any position, more than mild paravalvular regurgitation, extensive unrevascularized coronary artery disease, left ventricular ejection fraction (LVEF) <20%, stroke or transient ischemic attack within 6 months, myocardial infarction within 1 month, upper gastrointestinal bleeding within 3 months, severe renal insufficiency (creatinine >3.0 mg/dL or dialysis dependent) and estimated life expectancy less than 2 years. Patients were excluded in the case of anatomical concerns with a VIV implant, including bioprosthesis instability, perceived risk of THV embolization due to insufficient calcification of a non-stented bioprosthesis or perceived risk of coronary occlusion.

CT assessment

While not mandatory, pre-procedural CT was recommended in all VIV cases. All CT data acquisitions submitted to a central core laboratory (St. Paul's Hospital Cardiac CT Corelab, Vancouver, Canada). Measurements varied based on the structural design of the bioprosthesis. In stented valves with an opaque sewing ring, measurements were performed within and on the outside of the metallic ring. For stentless valves, only a single measurement at the sewing ring/annular plane was done. Additional measurements included the distance from the neo-annular plane to the coronary ostial height and to the sinotubular junction as well as short and long axis of measurements of the sinus of Valsalva and STJ. As well, to assess the risk of coronary occlusion measurement of the Virtual THV to coronary distance (VTC)pre-implantation is becoming part of clinical routine.[12] Images were visually interrogated for both pannus and calcification of the SHV, which were graded qualitatively if present.

Oversight and data management

Clinical assessments were performed at baseline and all subsequent follow-up time points and included formal examination by a neurologist. Serial echocardiographic follow-up was performed immediately following implant (intra-procedural), within 24 hours of hospital discharge and at 30 days. All echocardiography was analyzed independently by an echocardiography core laboratory (Cleveland Clinic, OH). In-hospital and 30-day clinical events were independently adjudicated by a clinical events committee (CEC) for all patients. Non-powered secondary endpoints included major vascular complications, stroke or TIA, acute kidney injury (all VARC criteria), new permanent pacemaker, myocardial infarction and clinical improvements in symptoms (NYHA functional class).

Statistical analysis

All analyses were performed with data from the as-treated patients in the PARTNER II trial, in either the RCT arms or in the NRCA. Small surgical valves were defined as those having true internal diameter (true ID) ≤ 20 mm.[13] Elevated post procedural gradients were defined as those with mean gradients ≥20 mmHg by echocardiographic examination after VIV. Continuous variables are summarized as mean ± SD or as medians and interquartile range, as appropriate, and were compared using Student's *t* test or Mann-Whitney rank sum test accordingly. Categorical variables were compared by the chi-square or the Fisher exact test. A *p*-value of 0.05 was considered statistically significant for all analyses. All statistical analyses were performed using SAS software, version 9.2 (SAS Institute, Cary, North Carolina).

Results

A total of 84 patients were included in the current analysis with a median age of 79.9 ± 9.6 years; 65.5% were male. Patient baseline characteristics are presented in Table 1. Approximately half (49%) of the surgical valves were small (true ID ≤20 mm). Predominant stenosis was the most common mechanism of failure (57.6%) and the vast majority of cases included a stented surgical valve (89.3%). Table 2 presents the pre-procedural CT data: approximately half of the surgical valves (51.3%) were not calcified.

Table 1. Patient characteristics (N = 84).

Patient characteristics	
Age, years	79.9 ± 9.6
Male sex	65.5%
STS score	8.5 ± 4.7
NYHA class III/IV	90.5%
Coronary artery disease	70.2%
Body mass index (kg/m^2)	28.3 ± 6.0
Body surface area (m^2)	1.92 ± 0.27
Previous bypass surgery	57.1%
Chronic obstructive pulmonary disease	31%
Creatinine >2 mg/dL (177 µmol/L)	6%
Atrial fibrillation	41.7%
Permanent pacemaker	28.6%
Porcelain aorta	9.5%
Frailty	23.8%
Diabetes mellitus	21.4%
Hypertension	89.3%
Carotid disease	19%
Valve and procedural characteristics	
Mechanism of failure	
Predominately stenosis	57.6%
Mixed failure	19.3%
Predominately regurgitation	22.9%
Surgical valve label size	
21 mm	22.4%
23–25 mm	63.8%
>25 mm	13.8%
Surgical valve true internal diameter	
≤20 mm	50.8%
>20 mm	49.2%
Implanted transcatheter valve size	
23 mm	60%
26 mm	40%
Procedural access	
Transfemoral	69.5%
Transapical	30.5%

Note. STS, Society of Thoracic Surgery; NYHA, New York Heart Association.

Table 2. Pre-procedural CT analysis (N = 84).

Internal annulus area, mm^2	331.64 ± 73.52
Annulus diameter, mm	
Short	19.13 ± 2.35
Long	20.28 ± 2.69
Mean	19.94 ± 2.38
Sinus diameter, mm	
Short	31.80 ± 4.24
Long	33.52 ± 4.35
Mean	2.85 ± 4.51
Sinotubular junction diameter, mm	
Short	29.65 ± 4.51
Long	30.84 ± 4.63
Mean	30.60 ± 4.66
Sinotubular junction height, mm	18.92 ± 3.75
Valve calcification	
None	51.3%
Mild	27.5%
Moderate/severe	21.3%
Vertical distance from the annulus, mm	
Left coronary	10.6 ± 3.65
Right coronary	12.43 ± 4.27

Average annulus internal area was 332 ± 74m^2. Table 3 includes 30-day clinical outcomes. None of the patients in this cohort died within 30-days. Post implantation mean gradient was 17.95 ± 7.59 mmHg and average aortic valve area was 1.06 ± 0.35cm^2.

Evaluation of echocardiographic results according to surgical valve true ID reveals that small surgical valves have significantly worse hemodynamics than intermediate/large surgical valves (Figure 1 A–D). Figure 2 shows the results of surgical valve internal annulus area per CT according to surgical valve true ID. Although there was a significant correlation in which smaller surgical valves had lower CT measured area (R^2 = 0.33, p < 0.0001), the variability of CT measurements for each surgical valve size was significant: true ID of 19 mm had measured CT area of 273 ± 40 mm^2; 21 mm: 330.6 ± 54.4 mm^2; 23 mm: 373.4 ± 39.1 mm^2. The predictability of CT measured area on elevated post procedural gradients (mean ≥20 mmHg) was not significant in small surgical valves (true ID ≤20 mm, p = 0.066). However, small CT-based measurement was significantly associated with increased gradients in intermediate/large surgical valves (true ID >20 mm, p = 0.01).

Table 3. The 30-day clinical outcomes (N = 84).

All-cause mortality	0%
Major stroke	3.3%
Rehospitalization	3.3%
Coronary obstruction	1.2%
Need for a second transcatheter valve	1.7%
Major bleeding	8.3%
Major vascular complication	1.7%
Pacemaker implantation	1.7%
Acute kidney injury	3.3%
Aortic valve area, cm^2	1.06 ± 0.35
Aortic valve area index, cm^2/m^2	0.56 ± 0.20
AV mean gradient, mmHg	17.95 ± 7.59
AV max. gradient, mmHg	33.65 ± 12.72
LV ejection fraction, %	47.80 ± 13.24
Aortic regurgitation (≥ moderate)	5.8%

Note. AV, aortic valve; LV, left ventricular.

Discriminatory capacity of CT for post-implant elevated gradients was evaluated. ROC curve analysis for the evaluation of the predictability of CT-measured area on post-procedural gradients in intermediate/large surgical valves was high (AUC 0.81). A cutoff of 329 mm^2 had sensitivity of 90%, specificity of 79.2% and negative predictive value of 95% in predicting elevated post-procedural gradients. The risk of poor post-procedural hemodynamics (high gradients and small effective orifice area) differed between the subgroups and was worse in small surgical valves (true ID≤20 mm) and best in intermediate/large surgical valves (true ID>20 mm) with CT-measured area ≥330 mm^2 (3), Figure 3.

Discussion

Poor post-procedural hemodynamics are a significant limitation of aortic VIV procedures. This adverse event is relatively common in these procedures and is considered the Achilles' heel of this approach.[6] Being able to identify patients at risk for elevated post-VIV gradients in advance of the procedure would be very helpful to optimally plan the therapeutic approach during TAVR or refer the patient to conventional redo surgery, in which a surgical valve could be implanted. The current analysis reveals that baseline evaluation of the dimension of the surgical valve may assist in predicting the risk for elevated post-procedural gradients

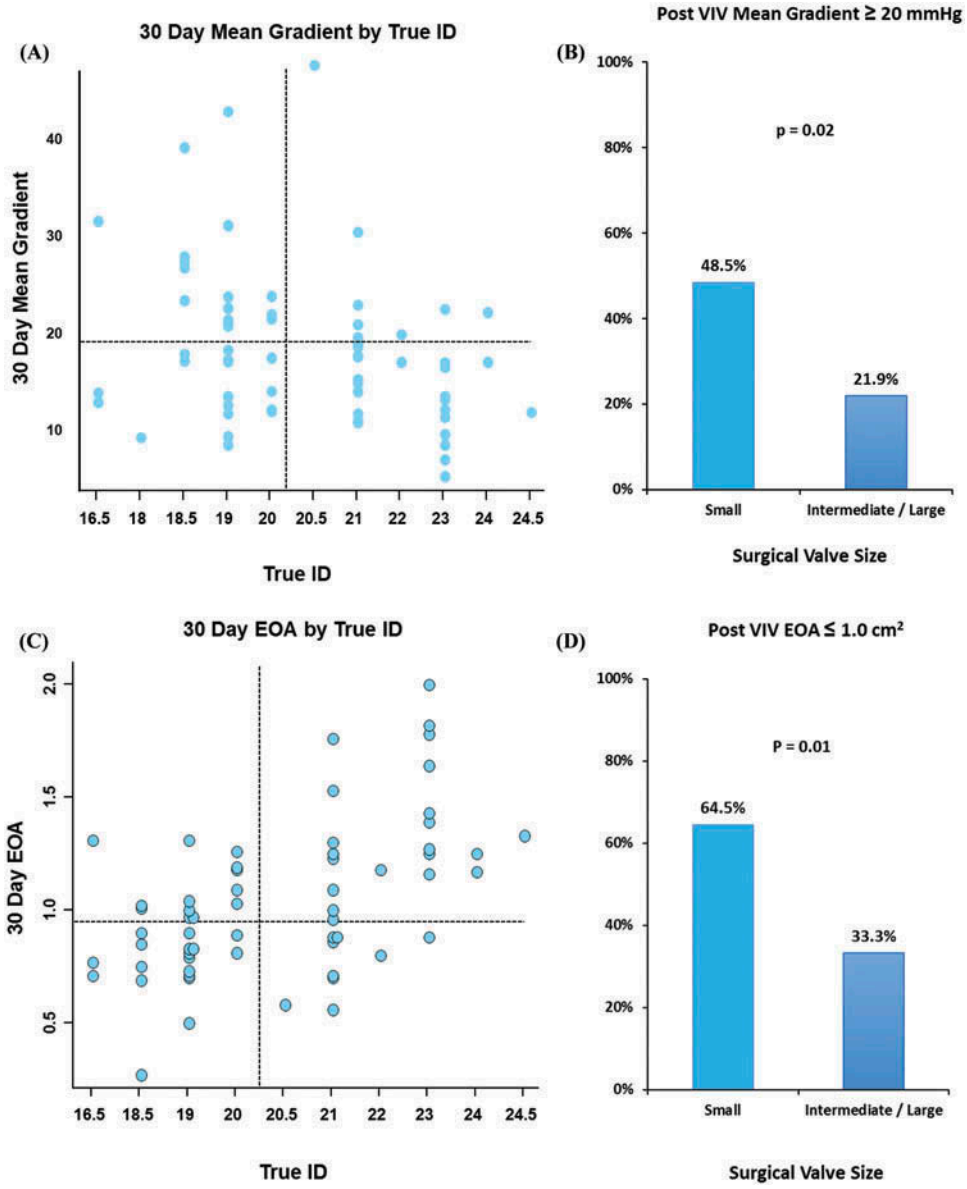

Figure 1. (A) Assessment of 30-day mean post-procedural gradient according to surgical valve true internal diameter. (B) Cases performed in small surgical valves (true ID ≤ 20 mm) had significantly higher rate of elevated post procedural gradients (mean gradient ≥20 mmHg). (C) Assessment of 30-day effective orifice area according to surgical valve true internal diameter. (D) Cases performed in small surgical valves (true ID ≤20 mm) had a significantly higher rate of having a small effective orifice area (<1.0 cm^2).

after VIV and may play an important adjunctive role beyond that evaluating the risk for coronary obstruction.

The VIVID registry has revealed that the risk for elevated post-procedural gradients is significantly related to surgical valve size and procedural issues such as the depth of implant.-[7,14,15] Small and stenotic surgical valves and those implanted with annular level THV devices, especially with deep implantation are associated with a high risk for elevated gradients. Interestingly, the current analysis did not show significant predictability of CT sizing for the risk of poor hemodynamics in small surgical valves. This is probably related to the fact that too many of these cases had poor echocardiographic results: 48.5% had mean gradient ≥20 mmHg and 64.5% had an effective orifice area ≤1.0 cm^2. CT conferred a much greater discriminatory capacity for post-procedural gradients within the intermediate/large surgical valve group (internal diameter >20 mm). In these cases baseline CT area was discriminatory of elevated post-procedural gradients with those baseline area <330 mm^2 exhibiting significantly more likely to exhibit poor post-implant hemodynamics.

CT assessment prior to TAVR is commonly performed to assess the size of the aortic annulus. In contrast, surgical valve dimensions are readily available and CT sizing has not been routinely utilized. However, manufacturers' reported dimensions are not standardized, at times the valve size may not be known, and importantly, the surgical valve may be distorted

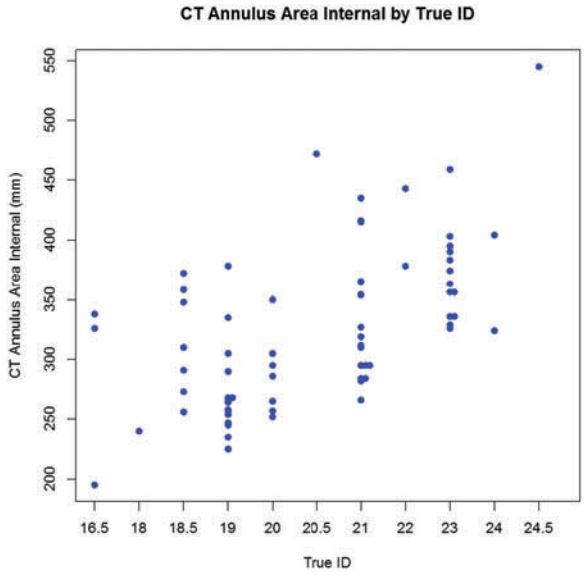

Figure 2. CT-measured internal annulus area according to surgical valve true internal diameter. Although a significant correlation appears ($R^2 = 0.33$; $p < 0.0001$), there is also significant variability in CT results for each surgical valve size.

through both the surgical procedure and over time. This results in the same model and size of surgical valve having different internal areas by CT criteria. In addition, tissue ingrowth and calcification may be important. This data suggests that CT analysis may add value in selected cases.

The current analysis includes several limitations. We were not powered to integrate all the correlates associated with elevated post-procedural gradients, such as the depth of implantation, the size of the implanted SAPIEN XT, and the mechanism of device failure. In addition, the analysis was performed exclusively on balloon-expandable devices. The ability to predict the risk of having poor hemodynamics after VIV may not be similar in self-expandable devices utilized for the treatment of failed aortic surgical valves. Also, while the defined threshold for elevated post-implant gradients used in our study is well established the clinical implications of such post-implant hemodynamics will vary across patient specific clinical and baseline hemodynamic presentations. Finally, while the largest cohort evaluated to date, we are still limited in the spectrum of surgical valves available for analysis which somewhat limits the generalizability of our findings.

Conclusion

In conclusion, residual stenosis is a limitation of aortic VIV, especially when performed in small surgical valves. CT-derived annulus area in cases with intermediate and large surgical valves (true ID >20 mm) can identify cases at risk for poor hemodynamics after VIV (CT area < 330 mm^2) that may influence clinical decision making. This further argues for the importance of optimizing valve internal orifice size at the time of the index surgery with larger surgical implants.

Acknowledgments

The authors wish to thank Rupa Parvataneni, MS (Cardiovascular Research Foundation) for statistical support and Maria Alu, MS (Columbia University) for assistance with manuscript preparation.

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Funding

The PARTNER Trial was funded by Edwards Lifesciences, and the protocol was developed collaboratively by the Sponsor and Executive Committee. The Sponsor was responsible for data collection and monitoring, but the authors had full access to data, and maintained full control over analysis and interpretation of data, writing the report, and the decision to publish.

Disclosure Statements

Dr Dvir is a consultant for Edwards Lifesciences. Dr Webb is a consultant for Edwards Lifesciences and a member of the PARTNER Trial Executive Committee (no direct compensation). Dr Blanke is a consultant for Edwards Lifesciences and provides CT Core Lab services for Edwards Lifescience, Medtronic, Neovasc, GDS, and Tendyne Holdings for which he receives no direct compensation. Dr Mack is a member of the PARTNER Trial Executive Committee (no direct compensation). Dr Pibarot has Core Lab contracts with Edwards Lifesciences for which he receives no direct compensation and is a consultant for St. Jude Medical. Dr Herrmann has received grants from Edwards Lifesciences, St. Jude

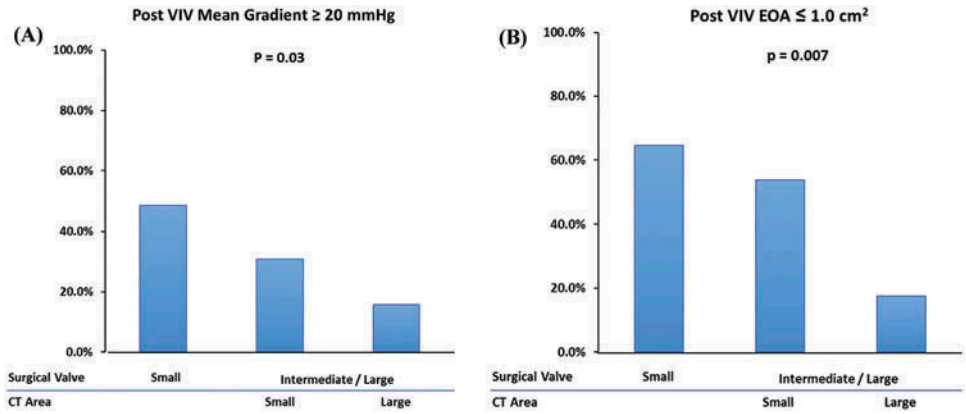

Figure 3. (A) Risk of poor hemodynamics after valve-in-valve was worst in cases performed in small surgical valves and best in those performed in intermediate/large surgical valves with large CT annulus area (≥330 mm^2). (B) CT internal area was considered small with area < 330 mm^2 and large with area ≥ 330 mm^2. Surgical valve was stratified into small (true internal diameter [ID] ≤ 20 mm, intermediate/large (true ID > 20 mm).

Medical, Medtronic, Boston Scientific, Abbott Vascular, Gore, Siemens, Cardiokinetix, and Mitraspan, is a consultant for Edwards Lifesciences and Siemens, and holds equity in Microinterventional Devices. Dr Kodali is a consultant for Edwards Lifesciences and holds equity in Thubrikar Aortic Valve, Inc. Dr Makkar has received grants from Edwards Lifesciences and St. Jude Medical, is a consultant for Abbott Vascular, Cordis, and Medtronic, and holds equity in Entourage Medical. Dr Miller is supported by research grant R01 NHLBI #HL67025, has received consulting fees/honorary from Abbott Vascular, St. Jude Medical, and Medtronic, and is a member of the PARTNER Executive Committee (no direct compensation). Dr Pichard is a consultant for Edwards Lifesciences. Dr Smith is a member of the PARTNER Trial Executive Committee (no direct compensation). Dr Suri is a member of the Clinical Steering Committee at Abbott and St. Jude, consults with Sorin and Abbott, and has a patent application with Sorin. Dr Leon is a member of the PARTNER Trial Executive Committee (no direct compensation). Dr Leipsic (the corresponding author) is a consultant for Edwards Lifesciences and provides CT core lab services for Edwards Lifesciences, Medtronic, Neovasc, GDS, and Tendyne Holdings, for which he receives no direct compensation. The other authors report no potential conflicts of interest to disclose.

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