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Valve-in-Valve Transcatheter Aortic Valve Replacement Versus Redo Surgical Aortic Valve Replacement

An Updated Meta-Analysis

Michel Pompeu B.O. Sá, MD, MSc, PhD,[a] Jef Van den Eynde, BSc,[b,c] Matheus Simonato, MD,[d] Luiz Rafael P. Cavalcanti, MD,[a] Ilias P. Doulamis, MD, PhD,[e] Viktoria Weixler, MD, PhD,[f] Polydoros N. Kampaktsis, MD,[g] Michele Gallo, MD,[h] Pietro L. Laforgia, MD,[i] Konstantin Zhigalov, MD, PhD,[j] Arjang Ruhparwar, MD, PhD, CHM,[j] Alexander Weymann, MD, MHBA, PhD,[j] Philippe Pibarot, DMV, PhD,[k,l] Marie-Annick Clavel, DVM, PhD[k,l]

ABSTRACT

OBJECTIVES The aim of this study was to evaluate early results of valve-in-valve (ViV) transcatheter aortic valve replacement (TAVR) versus redo surgical aortic valve replacement (SAVR) for structural valve degeneration (SVD).

BACKGROUND ViV TAVR has been increasingly used for SVD, but it remains unknown whether it produces better or at least comparable results as redo SAVR.

METHODS Observational studies comparing ViV TAVR and redo SAVR were identified in a systematic search of published research. Random-effects meta-analysis was performed, comparing clinical outcomes between the 2 groups.

RESULTS Twelve publications including a total of 16,207 patients (ViV TAVR, n = 8,048; redo SAVR, n = 8,159) were included from studies published from 2015 to 2020. In the pooled analysis, ViV TAVR was associated with lower rates of 30-day mortality overall (odds ratio [OR]: 0.52; 95% confidence interval [CI]: 0.39 to 0.68; $p < 0.001$) and for matched populations (OR: 0.419; 95% CI: 0.278 to 0.632; $p = 0.003$), major bleeding (OR 0.48; 95% CI: 0.28 to 0.80; $p = 0.013$), as well as with shorter hospital stay (OR: −3.30; 95% CI: −4.52 to −2.08; $p < 0.001$). In contrast, ViV TAVR was associated with higher rates of severe patient-prosthesis mismatch (OR: 4.63; 95% CI: 3.05 to 7.03; $p < 0.001$). The search revealed an important lack of comparative studies with long-term results.

CONCLUSIONS ViV TAVR is a valuable option in the treatment of patients with SVD because of its lower incidence of post-operative complications and better early survival compared with redo SAVR. However, ViV TAVR is associated with higher rates of myocardial infarction and severe patient-prosthesis mismatch. (J Am Coll Cardiol Intv 2021;14:211–20)

From the [a]Division of Cardiovascular Surgery of Pronto Socorro Cardiológico de Pernambuco-PROCAPE, University of Pernambuco-UPE, Recife, Brazil; [b]Department of Cardiovascular Diseases, Research Unit of Cardiac Surgery, University Hospitals Leuven, Leuven, Belgium; [c]Department of Cardiovascular Sciences, KU Leuven, Leuven, Belgium; [d]Division of Cardiac Surgery, Escola Paulista de Medicina-UNIFESP, São Paulo, Brazil; [e]Department of Cardiac Surgery, Boston Children's Hospital, Harvard Medical School, Boston, Massachusetts, USA; [f]German Heart Center, Berlin, Germany; [g]NYU Langone Medical Center, New York, New York, USA; [h]Department of Cardiac Surgery, Cardiocentro Ticino, Lugano, Switzerland; [i]I.R.C.C.S. Policlinico San Donato, San Donato Milanese, Milan, Italy; [j]Department of Thoracic and Cardiovascular Surgery, West German Heart and Vascular Center Essen, University Hospital of Essen, University Duisburg-Essen, Essen, Germany; [k]Centre de Recherche de l'Institut Universitaire de Cardiologie et de Pneumologie de Québec, Québec City, Québec, Canada; and the [l]Department of Medicine, Faculty of Medicine, Université Laval, Québec City, Québec, Canada.

The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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ABBREVIATIONS AND ACRONYMS

CI = confidence interval

OR = odds ratio

PPM = patient-prosthesis mismatch

PVL = paravalvular leak

SAVR = surgical aortic valve replacement

SVD = structural valve degeneration

TAVR = transcatheter aortic valve replacement

ViV = valve-in-valve

Valve-in-valve (ViV) transcatheter aortic valve replacement (TAVR) in patients with bioprosthetic surgical structural valve degeneration (SVD) arose as an alternative to conventional redo surgical aortic valve replacement (SAVR) (1). As ViV TAVR is less invasive in comparison with redo SAVR, it is expected to reduce complications and mortality in patients with prosthetic SVD who are at high surgical risk. Although some observational studies have shown the feasibility of ViV TAVR, there are currently no randomized controlled trials comparing it with redo SAVR. Our objective in this study was to perform a systematic review with meta-analysis to appraise the current scenario and compare outcomes between ViV TAVR and redo SAVR.

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METHODS

ELIGIBILITY CRITERIA, DATABASES, AND SEARCH STRATEGY. We followed the internationally recognized Meta-Analyses of Observational Studies in Epidemiology protocol (2). Using the population, interventions, comparison, outcome, and study design strategy, studies were included if the following criteria were fulfilled: 1) the population comprised patients with prosthetic aortic SVD; 2) there was an intervention group undergoing ViV TAVR; 3) there was a control group undergoing redo SAVR; 4) outcomes studied included any of the following: 30-day mortality, 1-year mortality, myocardial infarction, stroke, acute kidney injury requiring dialysis, permanent pacemaker implantation, major vascular complication, major bleeding, moderate-to-severe paravalvular leak (PVL), severe patient-prosthesis mismatch (PPM), hospital length of stay, and 30-day readmission; and 5) studies were observational in nature.

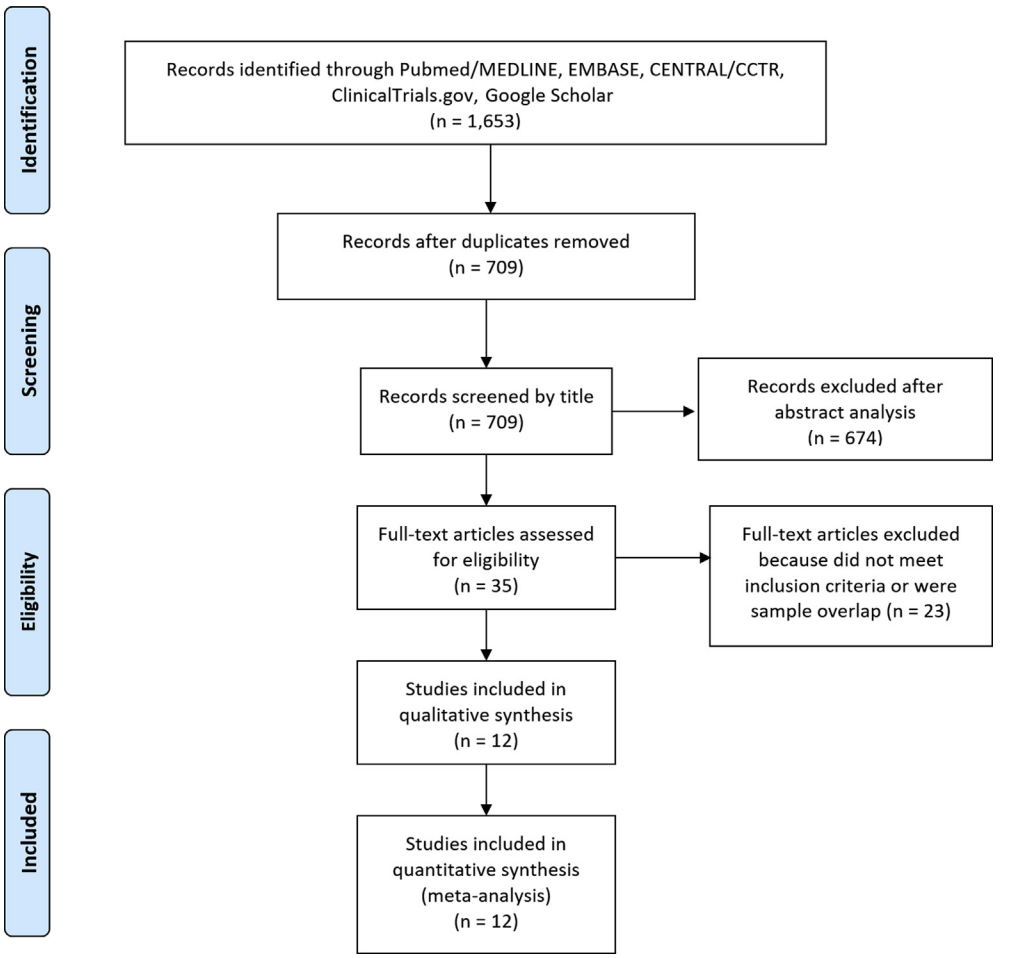
The following sources were searched for papers meeting our inclusion criteria and published until July 31, 2020: PubMed/MEDLINE, Embase, the Cochrane Controlled Trials Register, ClinicalTrials.gov, Google Scholar, and the reference lists of relevant papers. We searched for the following terms: "transcatheter aortic valve replacement," "TAVR," "transcatheter aortic valve implantation," "TAVI," "redo surgical aortic valve replacement," "redo-SAVR," "reoperation," "reoperative," "valve-in-valve," "ViV," "ViV-TAVI," "ViV-TAVR," "structural valve deterioration," "structural valve degeneration," "failed bioprosthesis," and "failed bioprosthetic valves." The following steps were taken for study selection: 1) identification of titles of records through database search; 2) removal of duplicates; 3) screening and selection of abstracts; 4) assessment for eligibility through full-text papers; and 5) final inclusion in study. Studies were selected by 2 independent reviewers. When there was disagreement, a third reviewer made the decision to include or exclude the study. Ethical approval was not applicable for this study, as it consisted of a systematic review and meta-analysis.

ENDPOINTS, RISK FOR BIAS, AND STATISTICAL ANALYSIS. The primary endpoint of the study was 30-day mortality. The secondary endpoints were 1-year mortality, myocardial infarction, stroke, acute kidney injury requiring dialysis, permanent pacemaker implantation, major vascular complication, major bleeding, PVL, severe post-procedural PPM, 30-day readmission, and mean length of hospital stay (days). For studies reporting interquartile ranges, the mean was estimated using a validated formula (3).

The Risk of Bias in Non-Randomized Studies of Interventions tool was systematically used to assess included studies for risk for bias (4). The papers and their characteristics were classified into five groups: A (low risk for bias), B (moderate risk for bias), C (serious risk for bias), D (critical risk for bias), or E (no information/unclear). Two independent reviewers assessed risk for bias. When there was disagreement, a third reviewer checked the data and made the final decision.

Odds ratios (ORs) with 95% confidence intervals (CIs) and p values for the crude endpoints were calculated. For other comparative data, differences in means with 95% CIs and p values were considered. Forest plots were created to represent clinical outcomes. Chi-square and I^2 tests were performed for assessment of statistical heterogeneity (5). The OR and differences in means were combined across the studies using 2 random-effects models: a Mantel-Haenszel method and an inverse-variance method (6). To assess the publication bias, a funnel plot was generated for each outcome, statistically assessed by Begg and Mazumdar's test (7) and Egger's test (8). As a sensitivity analysis, we analyzed the primary endpoint (30-day mortality) including only studies with propensity-matched comparisons, as this method helps control confounders in nonrandomized studies. A 2-tailed p value <0.05 was considered to indicate statistical significance. All analyses were completed with R version 3.6.3 (R Foundation for Statistical Computing, Vienna, Austria).

FIGURE 1 Flow Diagram of Studies Included in Data Search



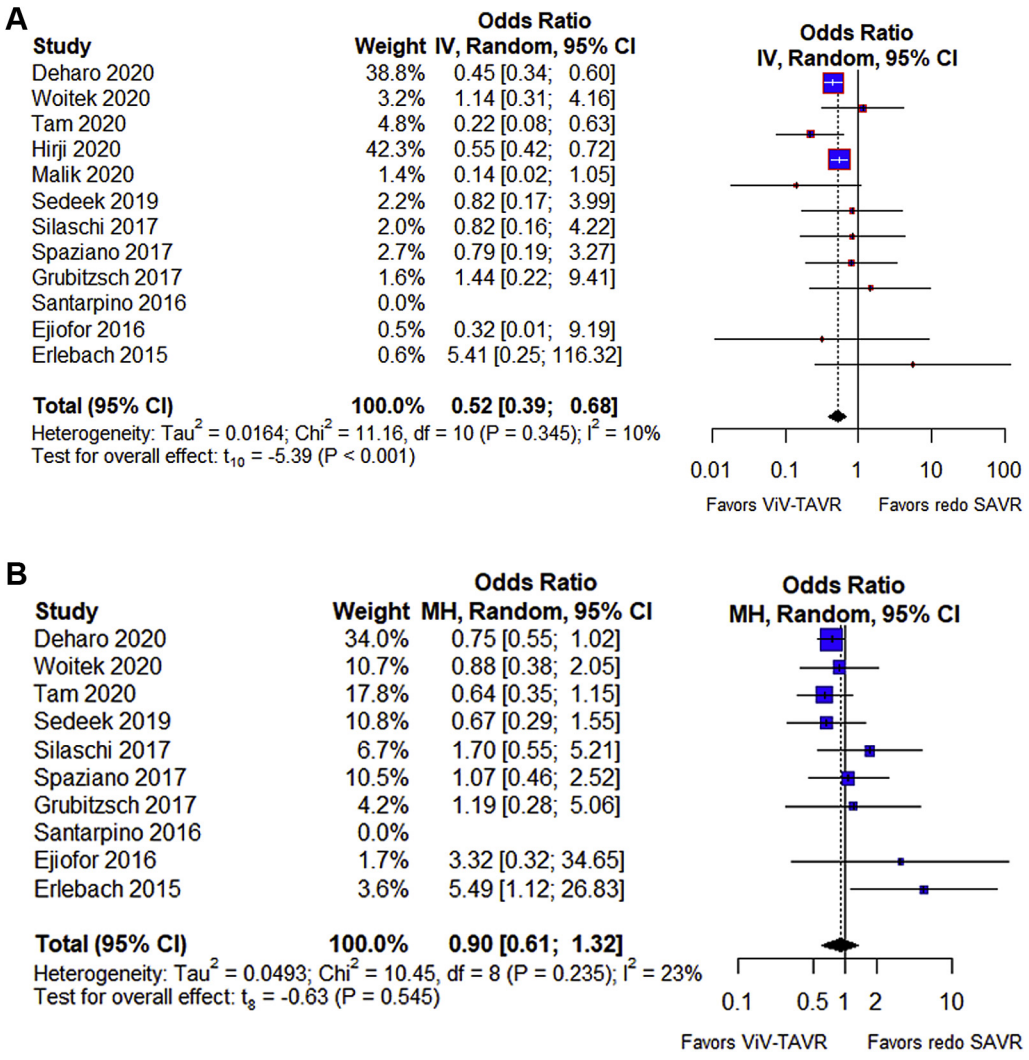
CCTR = Cochrane Controlled Trials Register.

RESULTS

STUDY SELECTION AND CHARACTERISTICS. A total of 1,653 citations were identified, of which 35 studies were potentially relevant and retrieved as full text. Twelve studies (9-20) fulfilled our eligibility criteria (**Figure 1**). Characteristics of each study and their patients are shown in Supplemental Tables S1 to S6. A total of 16,207 patients (ViV TAVR, 8,048 patients; redo SAVR, 8,159 patients) were included from studies published from September 2015 to July 2020. Six studies were nonrandomized observational studies with matched populations. We observed that in most of the studies, the patients in the ViV TAVR group were older, with higher frequencies of diabetes, chronic obstructive pulmonary disease, atrial fibrillation, renal failure, coronary artery disease, and history of coronary artery bypass graft and with higher Society of Thoracic Surgeons scores and European System for Cardiac Operative Risk Evaluation scores in comparison with their redo SAVR counterparts. The overall internal validity of the analysis was considered moderate to high risk for bias, mostly because of confounding caused by the differences in the unmatched populations (Supplemental Table S7).

CLINICAL ENDPOINTS. Mortality. The overall OR for 30-day mortality showed a statistically significant difference favoring ViV TAVR versus redo SAVR (random-effects model: OR: 0.52; 95% CI: 0.39 to 0.68; $p < 0.001$ (**Figure 2A**). There was evidence of low heterogeneity of treatment effect among the studies for 30-day mortality. However, for 1-year mortality there was no statistically significant difference in the risk for mortality in the ViV TAVR group

FIGURE 2 Forest Plots for 30-Day and 1-Year Mortality



Pooled odds ratio and conclusions plot for **(A)** 30-day mortality and **(B)** 1-year mortality. CI = confidence interval; MH = Mantel-Haenszel; SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement; ViV = valve-in-valve.

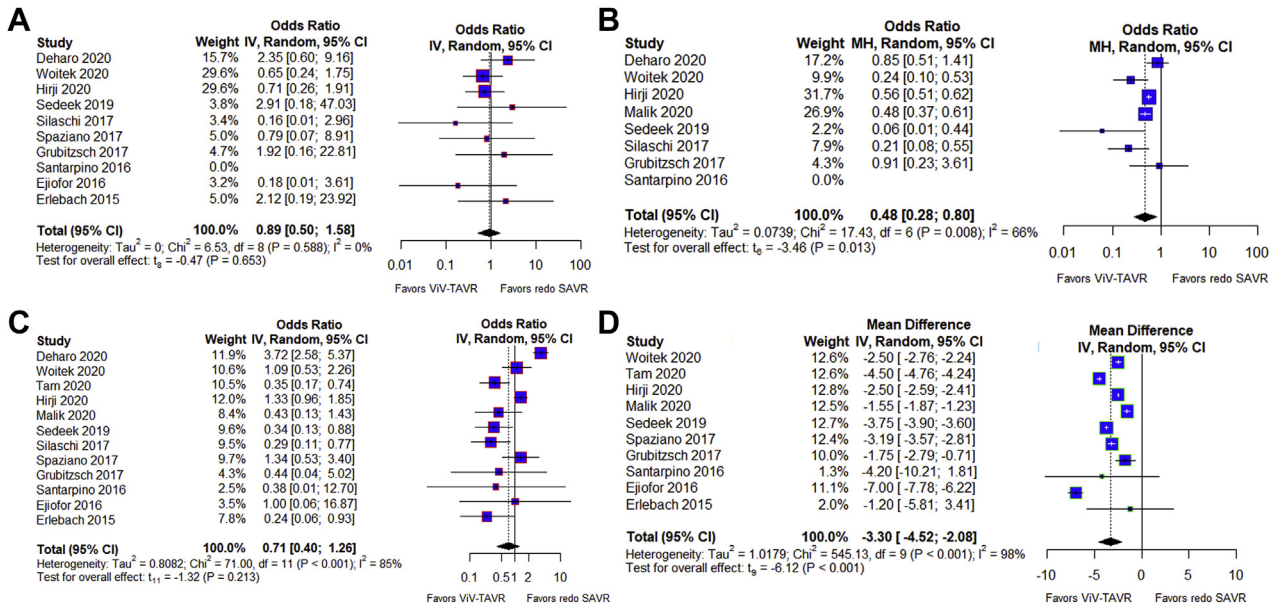
(random-effects model: OR: 0.90; 95% CI: 0.61 to 1.32; p = 0.545 (Figure 2B), with low risk for heterogeneity.

Complications. Rates of complications differed between treatment modalities. ViV TAVR was favored by a lower risk for major bleeding (random-effects model: OR: 0.48; 95% CI: 0.28 to 0.80; p = 0.013), and length of hospital stay (random-effects model: absolute difference −3.30 days; 95% CI: −4.52 to −2.08; p < 0.001). Heterogeneity was high for all of these findings. Figure 3 includes Forest plots with some patient-relevant outcomes.

ViV TAVR was outperformed by redo SAVR in the risk for severe post-procedural PPM (random-effects model: OR: 4.63; 95% CI: 3.05 to 7.03; p < 0.001), with low evidence of heterogeneity. These are summarized in Figure 4. Finally, no significant differences for stroke, permanent pacemaker implantation, myocardial infarction, acute kidney injury requiring dialysis, major vascular complications, PVL, and 30-day readmission were found (Supplemental Figure S1).

RISK FOR BIAS ACROSS STUDIES. Funnel plot analysis (Supplemental Figures S2 and S3) did not disclose

FIGURE 3 Forest Plots for Stroke, Major Bleeding, Permanent Pacemaker Implantation, and Length of Hospital Stay



Pooled odds ratio and conclusions plot for **(A)** stroke, **(B)** major bleeding, **(C)** permanent pacemaker implantation, and **(D)** length of hospital stay. IV = inverse variance; other abbreviations as in Figure 2.

any asymmetry around the axis for the treatment effect in any of the studied outcomes, except for 30-day readmission. Consequently, publication bias related to most of the outcomes is unlikely.

SENSITIVITY ANALYSIS WITH MATCHED POPULATIONS. The OR for 30-day mortality in the ViV TAVR group compared with the redo SAVR group in each study with matched populations is reported in Figure 5. Six studies reported data on 9,098 matched patients. There was evidence of low heterogeneity of treatment effect among the studies with matched populations for 30-day mortality. There was a statistically significant difference between ViV TAVR and redo SAVR in 30-day mortality among matched patients (random-effects model: OR: 0.419; 95% CI: 0.278 to 0.632; p = 0.003).

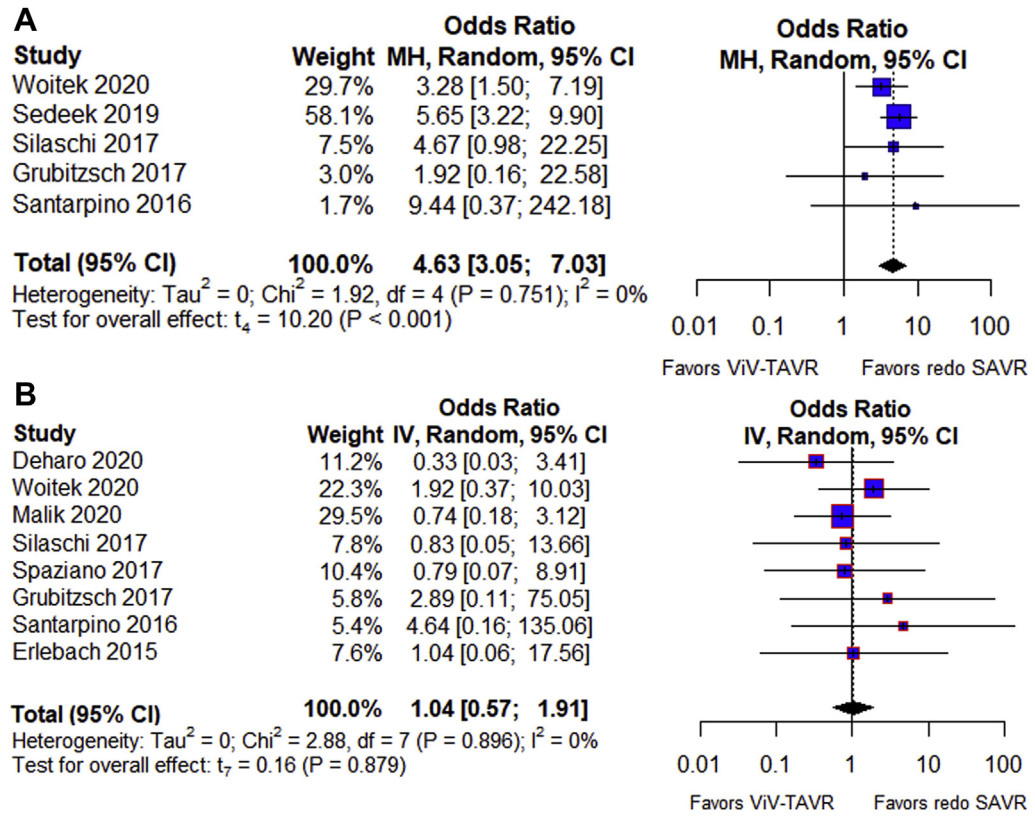
DISCUSSION

In this large systematic review and meta-analysis including 12 comparative studies of ViV TAVR and redo SAVR, we demonstrate that ViV TAVR was associated with lower rates of 30-day mortality (overall and for matched populations), and major bleeding, as well as with shorter hospital stay. Additionally, we observed no statistically significant difference in the risk for 1-year mortality. In contrast, redo SAVR was associated with lower rates of severe post-procedural PPM (Central Illustration).

With recent trends showing an increase in bioprosthetic surgical valve use (21), the number of patients requiring reintervention is also expected to grow. In this setting, ViV TAVR has become a feasible and safe option, especially for the frail and highly comorbid elderly population, in light of the non-negligible risk for morbidity and mortality of redo SAVR. Despite promising early results, long-term outcomes and direct comparison with redo SAVR are still needed.

One could expect that because of the higher preoperative risk profile and higher rate of comorbidities (higher age, higher risk scores, etc.) among the ViV TAVR population, this would lead to worse early post-operative outcomes in this group. However, the ViV-TAVR group outperformed conventional redo-SAVR patients on 30-day mortality, with no difference for mortality at 1 year. Additionally, this higher risk profile did not translate into significant differences in 1-year mortality, stroke, myocardial infarction, 30-day readmission rate, acute kidney injury requiring dialysis, and major vascular complications. These findings highlight the importance of

FIGURE 4 Forest Plots for Severe Patient-Prosthesis Mismatch and Myocardial Infarction



Pooled odds ratio and conclusions plot for **(A)** severe patient-prosthesis mismatch and **(B)** myocardial infarction. Abbreviations as in Figure 2.

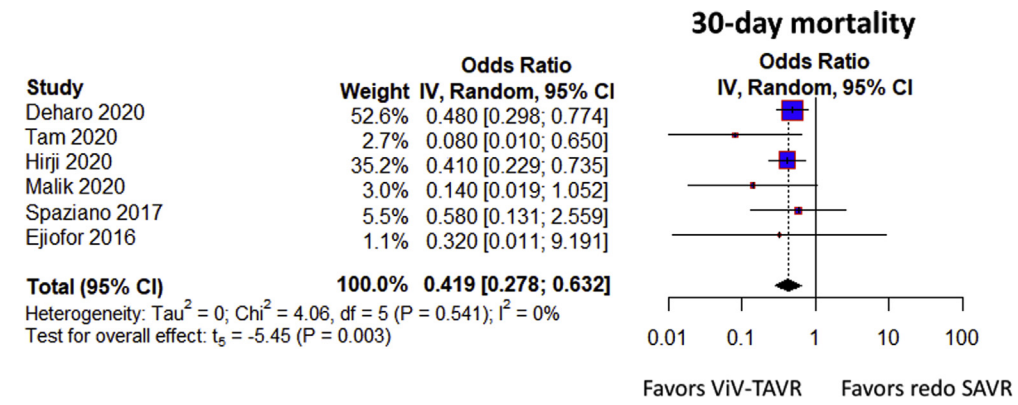
ViV TAVR in a properly selected population that requires a less invasive procedure.

In the largest nationwide study comparing ViV TAVR versus redo SAVR published to date, Hirji et al. (13) used the U.S. National Readmissions Database to identify more than 3,000 American adult patients with degenerated bioprosthetic aortic valves who underwent either VIV TAVR or isolated redo SAVR. After propensity score matching, VIV TAVR appeared to confer an advantage over redo SAVR in terms of 30-day mortality, 30-day morbidity, bleeding complications, and a shorter length of hospital stay. These results were confirmed in our meta-analysis. However, the investigators did not make any statements regarding the differences in PPM rates between the 2 groups. Moreover, because of the nature of the database, longer follow-up was not available.

Our results show a significantly higher risk for severe PPM in patients undergoing ViV TAVR versus redo SAVR. Although the incidences of severe PPM in large cohorts from the Society of Thoracic Surgeons/American College of Cardiology TVT (Transcatheter Valve Therapy) Registry seem to be similar after native TAVR or SAVR (11% and 12%, respectively) (22,23), ViV TAVR has been identified as a predictor of severe PPM (22), whereas redo SAVR has not (24). This is consistent with our findings and likely reflects the surgical restoration of the native aortic valve annular size in patients with failed bioprostheses, which is not an option during ViV TAVR.

In contrast, the clinical significance of severe PPM lies in its association with increased mortality and heart failure hospitalizations, which has been well documented in several large studies in both TAVR and SAVR patients (22,23,25). However, a large study including only ViV TAVR patients demonstrated that although severe post-procedural PPM was present in one-quarter of procedures, it was not associated with 1-year mortality (26). In light of this, the clinical impact of severe PPM in ViV TAVR patients was not

FIGURE 5 Sensitivity Analysis (Matched Populations)



Pooled odds ratio and conclusions plot for 30-day mortality. Abbreviations as in Figures 2 and 3.

immediately reflected in our results; on the contrary, we have found decreased 30-day mortality in patients undergoing ViV TAVR versus redo SAVR. Follow-up times in the included studies are short, and one possible explanation for the difference in mortality could be that the peri-operative mortality after redo SAVR is significantly higher compared with ViV TAVR in patients with similar comorbidities.

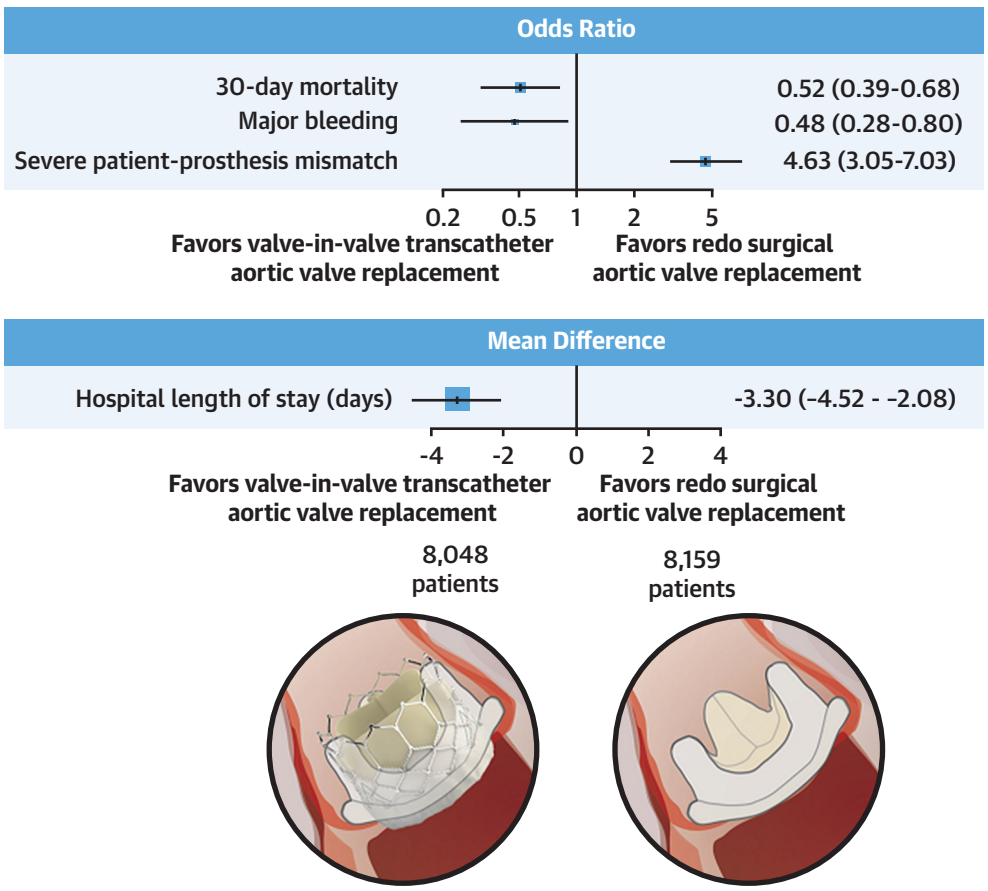
The causes of severe PPM are multiple. Some cases of severe PPM are due to pre-ViV factors, such as a small surgical valve, a stented surgical valve, or stenosis as the mechanism of failure (27). Others are related to procedural characteristics, including the choice of the transcatheter device (as an intra-annular device may be more prone to PPM) and the depth of implantation (27). Finally, some post-procedural situations may mimic PPM and lead to elevated gradients, including leaflet thrombosis and valve degeneration (27). Indeed, a study-level meta-analysis does not provide the granularity to analyze all of these factors in conjunction. However, techniques such as optimal transcatheter heart valve positioning and bioprosthetic valve fracturing (28,29) may be used to reduce the odds of severe post-procedural PPM, especially in patients at high risk for this complication who are not good surgical candidates. The long-term effects of severe post-procedural PPM in ViV TAVR durability are unknown.

In the present analysis, permanent pacemaker implantation was not more common in the redo SAVR population in comparison with the ViV TAVR patients. It has been shown that pacemaker need is associated with longer hospital stay, increased costs, increased rehospitalization risk, and worse survival (30–32). Patients requiring reintervention are typically fragile, and this frailty extends to the conduction system. One of the possible explanations comes from the failed surgical valve itself, which might protect the conduction system from impingement by the transcatheter device by buffering expansion. Prior evidence suggests that this risk may be further reduced by optimal transcatheter valve implantation (27).

There are limited long-term data on ViV TAVR, with no head-to-head studies comparing long-term outcomes of ViV TAVR with those of redo SAVR. Recently, however, a multicenter study with 1,006 ViV TAVR patients was published (33). The investigators found an 8-year survival rate of only 38%, which was also significantly lower in patients with small bioprostheses. Small bioprostheses are a key predictor of pre-procedural severe PPM, which has been associated with higher 1-year mortality (34) and was also associated with a higher risk for reintervention in the long-term ViV TAVR study. Therefore, heart teams may consider patients with small surgical valves as high risk for poor outcomes with ViV TAVR, and conventional redo SAVR may be a more appealing option in some of these cases. Surgeons may also consider annular enlargement in the index SAVR, which has shown good results (35). Durability should be a key focus of future studies comparing ViV TAVR with redo SAVR.

Our study has shown no advantage for redo SAVR regarding the incidence of myocardial infarction. Coronary obstruction is always a feared complication in ViV TAVR. In a large study of ViV TAVR patients, the rate of coronary obstruction in a

CENTRAL ILLUSTRATION **ViV-TAVR Is Associated With Lower Rates of 30-Day Mortality, and Major Bleeding, But Higher Rates of Severe Patient-Prosthesis Mismatch**



Sá, M.P.B.O. et al. J Am Coll Cardiol Intv. 2021;14(2):211-20.

typical procedure is approximately 2% (36). However, there are several risk factors, such as specific types of surgical valve, that may increase the rate of this complication to as high as 6.4%. Coronary obstruction is potentially deadly, leading to approximately 50% 30-day mortality. Operators planning ViV TAVR procedures should take full advantage of imaging strategies to predict risk (37) and may consider procedures such as leaflet tearing in high-risk cases (38).

It should not be neglected, though, that the choice of intervention must be individualized upon meticulous assessment of clinical characteristics and technical aspects by a multidisciplinary heart team. For instance, ViV TAVR may be the norm in high-risk patients with comorbidities, whereas redo SAVR may be preferred in patients with unfavorable anatomy. Additionally, there will always be contraindications and clinical scenarios in which surgical treatment would be the clear-cut first choice, such as patients with endocarditis or predominant PVL due to surgical valve ring dehiscence.

STUDY LIMITATIONS. Although this study provides compelling evidence regarding the role of ViV TAVR for patients with failing bioprostheses compared with the current standard of care, which is redo SAVR, there are some points that merit consideration when interpreting these findings. A clustered analysis according to the type of the implanted biological valve and the mechanism of failure (stenosis, regurgitation, or mixed) was deferred because of lack of individual patient data.

The field of reintervention on failing valves is still emerging. Thus, long-term comparative follow-up data are not available. Most studies included described follow-up durations <5 years, which does not allow one to draw any conclusions on long-term outcomes or prosthesis durability. The heterogeneity of the 2 groups (older, higher risk patients in the ViV TAVR group compared with redo SAVR) further complicates the process of comparing their outcomes. Most studies tried to correct for these confounders using propensity score matching. Nevertheless, randomized clinical trials will be needed to build a more robust model of comparison.

CONCLUSIONS

ViV TAVR is a valuable option in the treatment of degenerated aortic bioprosthesis, especially in patients with high operative risk due to a lower incidence of peri-operative complications and better early survival compared with redo SAVR. In contrast, redo-SAVR might still be the preferable option in young patients with low surgical risk and long life expectancy, especially with small bioprosthetic valves, to avoid the long-term complications of elevated residual aortic transvalvular gradients due to PPM. Long-term follow-up is needed to better evaluate and compare these 2 treatments.

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Dr. Pibarot has echocardiography Core Laboratory contracts with Edwards Lifesciences, for which he receives no direct compensation. Dr. Clavel has computed tomography Core Laboratory contract with Edwards Lifesciences, for which she receives no direct compensation and received research grant from Medtronic. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

ADDRESS FOR CORRESPONDENCE: Dr. Michel Pompeu B.O. Sá, Division of Cardiovascular Surgery of Pronto Socorro Cardiológico de Pernambuco-PROCAPE, Rua dos Palmares, s/n-Santo Amaro, Recife, Pernambuco 74970-240, Brazil. E-mail: michel_pompeu@yahoo.com.br.

PERSPECTIVES

WHAT IS KNOWN? ViV TAVR has been increasingly used for SVD. To date, no randomized controlled trials comparing it with redo SAVR have been conducted.

WHAT IS NEW? This meta-analysis, including 16,207 patients from 12 studies, revealed that ViV TAVR was associated with lower rates of 30-day mortality, and major bleeding, as well as with shorter hospital stay. In contrast, higher rates of severe PPM were observed with ViV TAVR.

WHAT IS NEXT? A randomized trial is required to generate more conclusive results about the comparison between ViV TAVR and redo SAVR. In the meantime, ViV TAVR can be considered a valuable option in the treatment of SVD because of its lower incidence of post-operative complications and lower mortality rates.

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KEY WORDS aortic valve, meta-analysis, structural valve degeneration, surgical aortic valve replacement, transcatheter aortic valve replacement

APPENDIX For supplemental tables and figures, please see the online version of this paper.