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Association between transcatheter aortic valve implantation or replacement and mortality, and major adverse events after coronary artery bypass grafting

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ABSTRACT

Background: In recent years, many people are opting for minimally invasive surgery in China. Patients undergoing transcatheter aortic valve implantation or replacement (TAVIR) with previous coronary artery bypass grafting (CABG) have higher risks of death and major complications.

Materials/methods: PubMed and Embase were searched for all comparison studies between TAVIR with and without prior CABG and mortality as a primary outcome, irrespective of surgical risk, to investigate whether patients with prior CABG can undergo TAVIR. Randomized controlled trials and propensity-score-matched cohort studies were eligible for inclusion. The outcomes of interest included 30-day, 6-month, and 1-year mortality and 30-day complications. If significant heterogeneity was found in the random-effects meta-analyses, a sensitivity analysis that individually removed each study was conducted.

Results: Five studies reported results on patients undergoing TAVIR with or without prior CABG. Compared with the non-CABG cohort, the CABG cohort showed no significant difference in the 30-day, 6-month, and 1-year mortality and the 30-day risk of major complications, except life-threatening bleeding. However, for the 30-day risk of life-threatening bleeding, the morbidity of CABG cohort was significantly lower than that of the non-CABG cohort (risk ratio 0.555; 95% confidence interval 0.35–0.85; $P = 0.006$; $I^2 = 0\%$).

Conclusions: Patients with prior CABG can undergo TAVIR. Patients undergoing TAVIR without prior CABG need more attention because of a higher risk of life-threatening bleeding.

1. Introduction

Aortic stenosis (AS) is one of the most common valvular heart diseases in elderly individuals. It always occurs in conjunction with coronary artery disease (CAD) because of the similarities in risk factors and pathogenesis. Severe symptomatic AS carries a poor prognosis. Aortic valve replacement (AVR) is established as a Class I indication for patients with severe AS who are symptomatic or those with impairment of left ventricular function in the absence of symptoms [1]. Until recently, surgical aortic valve replacement was the standard of care in adults with severe symptomatic AS. However, the risks associated with surgical aortic valve replacement (SAVR) increase in elderly patients, those with concomitant severe systolic heart failure or CAD, and those with comorbidities such as cerebrovascular disease, peripheral arterial disease, arrhythmia, chronic kidney disease, chronic respiratory dysfunction, bacterial translocation, and systematic inflammation response syndrome [2–4]. In addition, the mortality rate is higher in high-risk patients undergoing combined SAVR and coronary artery bypass grafting (CABG) than in those undergoing isolated SAVR [5].

In recent years, many people are opting for minimally invasive surgery in China. In addition, the mortality and morbidity rates are much lower than earlier since the introduction of transcatheter aortic valve implantation or replacement (TAVIR) [6]. A systematic review and meta-analysis comparing the effects of transfemoral (TF)-TAVR and SAVR on clinical outcomes, regardless of patient risk, provides more information on the effect of the access route on patient complications [7]. Similarly, the mortality rate is also significantly lower in patients undergoing TAVIR than in those undergoing standard therapy, who cannot

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undergo surgery [8]. Still, many patients die after undergoing TAVIR because of their condition before and after the surgery [9–11].

A surgical history of CAD is one of the most common risk factors for patients undergoing valve implantation or replacement [12–14], especially for patients with prior CABG. Patients with prior CABG undergoing TAVIR have higher risks of death and major complications. However, no definitive conclusions have been drawn from the available data about whether patients with prior CABG should undergo TAVIR and have a similar incidence of complications. This study was performed to evaluate the clinical outcomes of patients with prior CABG undergoing TAVIR. Also, it aimed to show which parts must be checked up more frequently.

2. Materials and methods

A systematic review of the clinical outcomes was performed on patients with or without prior CABG undergoing TAVIR according to the guidelines from the PubMed of Systematic Reviews and the recommendations of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). A computerized search was carried out by two reviewers to identify all relevant studies published in PubMed and Embase databases up to the end of January 10, 2018.

The following search terms were used: TAVI OR TAVR OR "transcatheter aortic valve" AND "Coronary artery bypass." Languages were no limitation, and species were limited to humans only. Citations were screened at the title and abstract levels and retrieved as a full text if they reported the outcome of TAVIR with prior CABG. References of the acquired studies were also searched manually to identify any further relevant studies for the inclusion.

All studies fulfilling the following criteria were included: (1) enrollment for TAVIR based on existing and accepted guidelines; (2) enrolled consecutive patients; (3) adverse events including mortality in patients with prior CABG undergoing TAVIR and other complications; and (4) a follow-up period no less than 30 days. Studies were excluded if any of the following criteria applied: (1) duplicate publication or overlap of patients; (2) abstracts, case reports, review, letter or correspondence, conference presentations, and editorials; (3) mortality of patients undergoing TAVIR not clearly reported or impossible to extract from the published results; and (4) the number of patients with prior CABG less than one fifth of the total population.

Two investigators verified the abstracts and full-text studies independently. The following information was collected: first author, year of publication, region, study design, valve type, inclusion period, sample size, follow-up period, and population baseline characteristics. Cochrane collaboration's tool for assessing the risk of bias was applied for randomized controlled trials or clinical trials and Newcastle–Ottawa Scale 11 was applied for observational studies to assess the methodological quality of studies. Discriminations were resolved by consensus with a third investigator.

The primary endpoint was early and mid-term mortality, including three time points: 30-day, 6-month, and 1-year. The secondary endpoint was 30-day complications from any causes during the follow-up period. If the forest map showed some reports having more weightage than others, it was plotted again after removing these reports to find whether they influenced the overall results.

The data were analyzed using Stata software version 14.0. The risk ratio (RR) with the corresponding 95% confidence interval (CI) was calculated for each endpoint across all studies. A two-sided error of less than 0.05 was considered statistically significant. Heterogeneity of the studies was assessed using Thompson's I^2 test. Significant heterogeneity was present if I^2 was more than 50%. For all the studies with or without I^2 more than 50%, the random-effects model was used for analysis. The origin of heterogeneity was calculated using the meta-regression and subgroup analyses. Sensitivity analysis was performed by deleting one study at a time, and a more than 20% modification of the overall effect was considered significant if a given study was excluded. Publication bias was evaluated using a funnel plot.

3. Results

3.1. Selected studies

Overall, 425 abstracts were identified using the search criteria, and 392 studies underwent a full review (Fig. 1). Of the studies fully reviewed, 377 were excluded: 165 for no propensity matching, 86 for no control arm, 69 case reports, 38 review articles, 14 only abstracts, 3 method papers, and 2 meta-analyses. A total of 15 studies met the final inclusion criteria, of which 6 reported unmatched data and 4 reported duplicate results. The baseline characteristics of the TAVIR studies and patients are reported in Table 1 and Supplementary Table 1, respectively. The data on STS-PROM or EuroScore were also reported in Table S1. In addition, the procedural characteristics of patients are reported in Supplementary Table 2.

3.1.1. Mortality

Four studies, including 4837 patients, reported 30-day mortality. No significant difference was observed in the 30-day mortality (RR 0.943; 95% CI 0.75–1.19; $P = 0.617$; $I^2 = 0\%$) in patients who underwent TAVIR with prior CABG compared with patients without prior CABG (Fig. 2A). Three studies (4.390 patients) reported 6-month mortality. Patients undergoing CABG had the same 6-month risk of mortality as those not undergoing CABG (RR 0.962; 95% CI 0.80–1.15; $P = 0.671$; $I^2 = 0\%$) (Fig. 2B). All five studies, including 4963 patients, showed 1-year mortality. No significant difference was noted in the 1-year mortality (RR 0.942; 95% CI 0.81–1.09; $P = 0.420$; $I^2 = 0\%$) in patients undergoing CABG compared with those without CABG (Fig. 2C). Funnel plots did not indicate publication bias in any of the outcomes (Supporting Information, Fig. S2A–C).

Similarly, the effect on the 30-day, 6-month, and 1-year mortality after removing the study of maximum weightage alone did not show any significant difference between the two groups either (RR 0.902; 95% CI 0.54–1.52; $P = 0.700$; RR 1.030; 95% CI 0.47–2.27; $P = 0.941$; and RR 0.941; 95% CI 0.71–1.25; $P = 0.677$, respectively) (Supporting Information, Fig. S3A–C).

3.1.2. Implantation success

Three studies (4334 patients) reported the cases of implantation success. The risk of implantation success in the CABG cohort was not significantly different compared with that in the non-CABG cohort (RR 0.997; 95% CI 0.98–1.01; $P = 0.595$; $I^2 = 0\%$) (Fig. 2D). Funnel plots did not indicate publication bias in any of the outcomes (Supporting Information, Fig. S2D).

3.1.3. New-onset atrial fibrillation

Two studies (498 patients) reported the 30-day incidence of new atrial fibrillation. The risk of new atrial fibrillation in the CABG cohort was not significantly different compared with that in the non-CABG cohort (RR 0.658; 95% CI 0.23–1.86; $P = 0.430$; $I^2 = 76.8\%$) (Supporting Information, Fig. S1A). Publication bias could not be assessed given the limited number of studies evaluating the new-onset atrial fibrillation.

3.1.4. Acute kidney injury

Two studies (498 patients) reported the 30-day incidence of acute kidney injury. Patients with prior CABG had no significant difference in the 30-day risk of acute kidney injury compared with patients without prior CABG (RR 1.001; 95% CI 0.65–1.54; $P = 0.997$; $I^2 = 0\%$) (Supporting Information, Fig. S1B). Publication bias could not be assessed given the limited number of studies evaluating acute kidney injury.

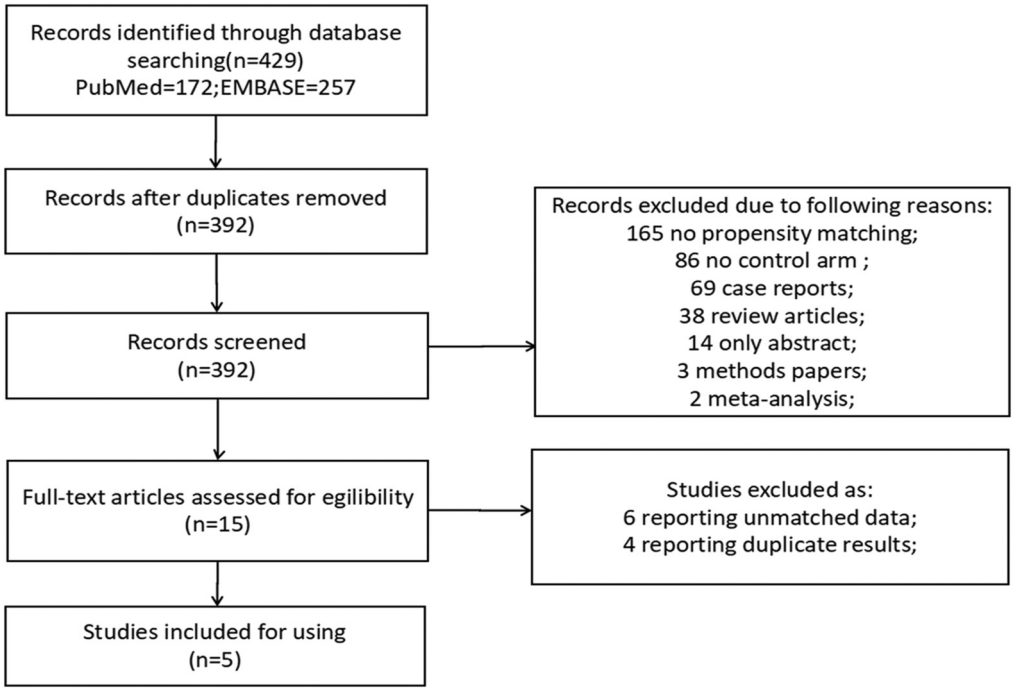


Fig. 1. PRISMA flow diagram showing selection paradigm for inclusion in the analysis.

3.1.5. Myocardial infarction

All 5 studies (4963 patients) also reported the 30-day incidence of myocardial infarction. However, three studies were excluded because no patient developed myocardial infarction. The CABG cohort showed an insignificant difference in the 30-day risk of myocardial infarction compared with the non-CABG cohort (RR 1.942; 95% CI 1.00–3.78; $P = 0.051$; $I^2 = 17\%$) (Supporting Information, Fig. S1C). Publication bias could not be assessed given the limited number of studies evaluating myocardial infarction.

3.1.6. New permanent pacemaker implantation

All 5 studies (4963 patients) reported the 30-day incidence of new permanent pacemaker implantation. No significant difference in the 30-day risk of new permanent pacemaker implantation was observed between patients with and without prior CABG (RR 1.156; 95% CI 0.99–1.36; $P = 0.075$; $I^2 = 0\%$) (Supporting Information, Fig. S1D). The assessment of the funnel plot did not suggest potential publication bias (Supporting Information, Fig. S2E).

Similarly, the effect on new permanent pacemaker implantation after removing the study of maximum weightage alone did not show any significant difference between the two groups (RR 1.201; 95% CI 0.86–1.68; $P = 0.288$) (Supporting Information, Fig. S3D).

3.1.7. Major vascular complications

All 5 studies (4963 patients) reported the 30-day incidence of major vascular complications. No significant difference in the 30-day risk of major vascular complications was found between the CABG and non-CABG cohorts (RR 0.774; 95% CI 0.54–1.02; $P = 0.063$; $I^2 = 0\%$) (Supporting Information, Fig. S1E). The assessment of the funnel plot did not suggest any potential publication bias (Supporting Information, Fig. S2F).

Similarly, the effect on major vascular complications after removing the study of maximum weightage alone did not show any significant difference between the two groups (RR 0.732; 95% CI 0.45–1.19; $P = 0.206$) (Supporting Information, Fig. S3E).

3.1.8. Stroke

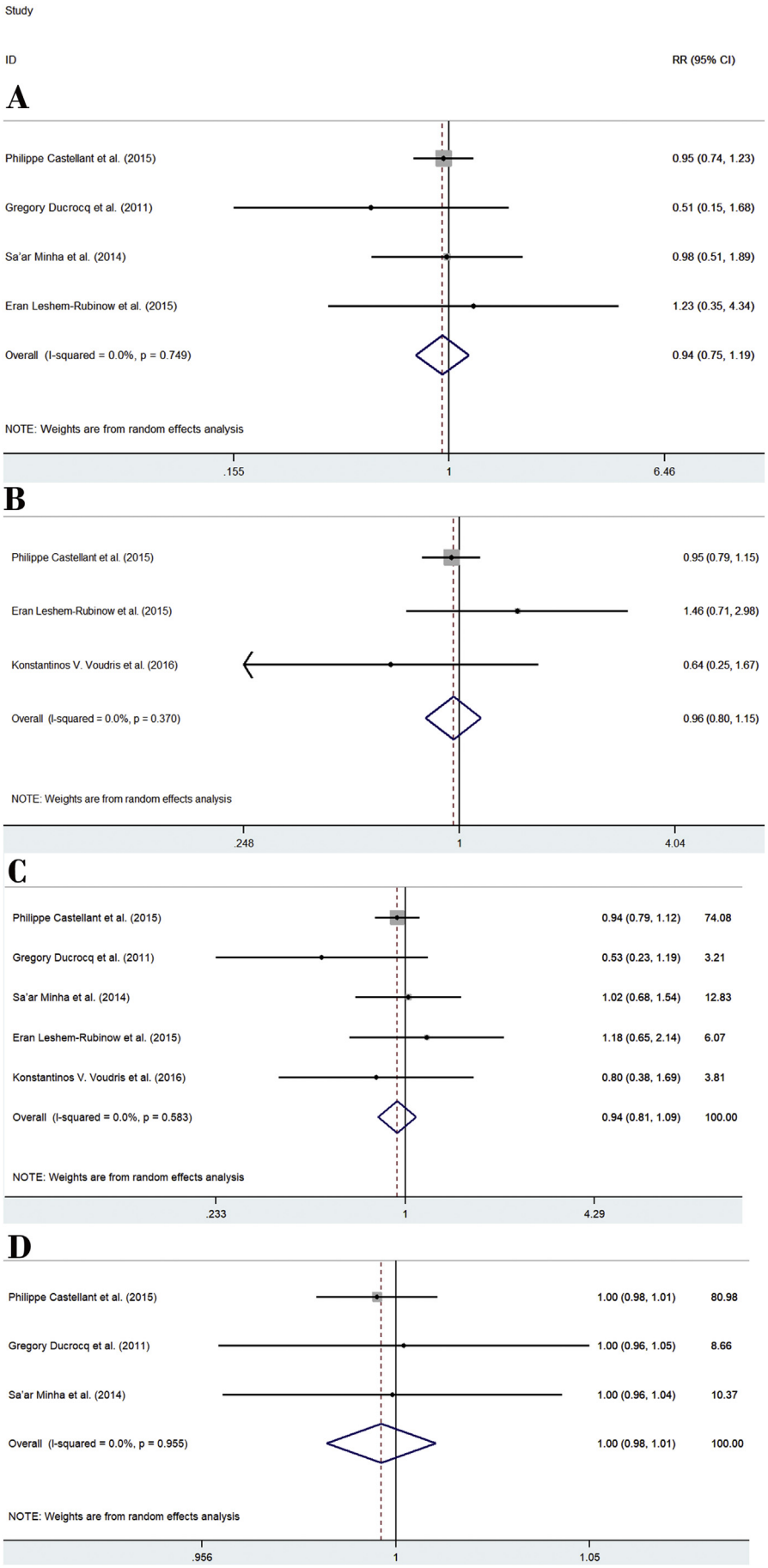
Three studies (4465 patients) reported the 30-day incidence of stroke. No significant differences in the 30-day stroke risk were seen between the two cohorts (RR 0.668; 95% CI 0.40–1.11; $P = 0.122$; $I^2 = 0\%$) (Supporting Information, Fig. S1F). The assessment of the funnel plot did not suggest any potential publication bias (Supporting Information, Fig. S2G).

3.1.9. Life-threatening bleeding

All 5 studies (4963 patients) reported the 30-day incidence of life-threatening bleeding. Significant differences were observed between the two groups (RR 0.555; 95% CI 0.35–0.85; $P = 0.006$; $I^2 = 0\%$) (Fig. 3). The patients who underwent TAVIR after CABG had less chance of developing life-threatening bleeding compared with those without prior CABG. The funnel plots did not indicate publication bias in any of the outcomes (Supporting Information, Fig. S2H).

Table 1
Baseline characteristics of the researches.

Authors	Year of publication	region	Method of operation	Study design	Inclusion period	Following period	Sample size	Clinical size	Quality of study
Philippe Castellant et al. [15]	2015	France	TAVI	Prospective	2010–2011	1	3761	33	Good
Sa'ar Minha et al. [17]	2014	America	TAVI	Prospective	2007–2013	1	372	1	Good
Eran Leshem-Rubinow et al. [18]	2015	Israel	TAVI	Prospective	2009–2014	3.3	515	1	Fair
Konstantinos V. Voudris et al. [19]	2016	America	TAVR	Retrospective	2010–2014	1.5	126	1	Good
Gregory Ducrocq et al. [16]	2012	France	TAVI	Retrospective	2006–2010	2	201	1	Good


Study
ID
RR (95% CI)
A
Philippe Castellant et al. (2015)
0.95 (0.74, 1.23)
Gregory Ducrocq et al. (2011)
0.51 (0.15, 1.68)
Sa'ar Minha et al. (2014)
0.98 (0.51, 1.89)
Eran Leshem-Rubinow et al. (2015)
1.23 (0.35, 4.34)
Overall (I-squared = 0.0%, p = 0.749)
0.94 (0.75, 1.19)
NOTE: Weights are from random effects analysis
.155
1
6.46
B
Philippe Castellant et al. (2015)
0.95 (0.79, 1.15)
Eran Leshem-Rubinow et al. (2015)
1.46 (0.71, 2.98)
Konstantinos V. Voudris et al. (2016)
0.64 (0.25, 1.67)
Overall (I-squared = 0.0%, p = 0.370)
0.96 (0.80, 1.15)
NOTE: Weights are from random effects analysis
.248
1
4.04
C
Philippe Castellant et al. (2015)
0.94 (0.79, 1.12)
74.08
Gregory Ducrocq et al. (2011)
0.53 (0.23, 1.19)
3.21
Sa'ar Minha et al. (2014)
1.02 (0.68, 1.54)
12.83
Eran Leshem-Rubinow et al. (2015)
1.18 (0.65, 2.14)
6.07
Konstantinos V. Voudris et al. (2016)
0.80 (0.38, 1.69)
3.81
Overall (I-squared = 0.0%, p = 0.583)
0.94 (0.81, 1.09)
100.00
NOTE: Weights are from random effects analysis
.233
1
4.29
D
Philippe Castellant et al. (2015)
1.00 (0.98, 1.01)
80.98
Gregory Ducrocq et al. (2011)
1.00 (0.96, 1.05)
8.66
Sa'ar Minha et al. (2014)
1.00 (0.96, 1.04)
10.37
Overall (I-squared = 0.0%, p = 0.955)
1.00 (0.98, 1.01)
100.00
NOTE: Weights are from random effects analysis
.956
1
1.05

3.1.10. Tamponade

Four studies (4837 patients) reported the 30-day incidence of tamponade. No significant difference was found between the two groups (RR 0.779; 95% CI 0.30–2.02; $P = 0.607$; $I^2 = 11\%$) (Supporting Information, Fig. S1G). Publication bias could not be assessed given the limited number of studies evaluating myocardial infarction because two reports showed no development of tamponade in patients with prior CABG.

3.1.11. Sensitivity analysis

No heterogeneity between studies was observed in terms of the 30-day, 6-month, and 1-year mortality and implantation success ($I^2 = 0\%$). For new atrial fibrillation and acute kidney injury, heterogeneity accounted for 0% of variation between effect estimates ($P = 0.430$). However, the limited number of studies reporting the outcome precluded a sensitivity analysis. For myocardial infarction, heterogeneity accounted for 17% of variation between effect estimates ($P = 0.051$). No significant heterogeneity was seen across the 30-day new permanent pacemaker implantation ($I^2 = 0\%$; $P = 0.075$). Besides, no significant heterogeneity was noted in the analysis of major vascular complications ($I^2 = 0\%$; $P = 0.063$). Also, no significant heterogeneity was found in the studies reporting 30-day stroke and tamponade ($I^2 = 0\%$; $P = 0.122$; $I^2 = 11\%$; $P = 0.607$, respectively). No significant heterogeneity was observed in the studies reporting the outcome of the 30-day risk of life-threatening bleeding ($I^2 = 0\%$; $P = 0.006$), but a significant difference was observed between the two groups. Exclusion of any study did not cause significant differences in the risk of life-threatening bleeding among patients undergoing prior CABG.

4. Discussion

For baseline characteristics, the patients with prior CABG indeed had more high-risk features and were mostly younger. In FRANCE 2 [15], patients with previous CABG had significantly different baseline characteristics: younger, with more frequent peripheral vascular disease and diabetes but less COPD, renal dialysis, or pulmonary hypertension. In addition, logistic Euro-SCORE was higher, but this must be interpreted cautiously as history of CABG is included in the calculation. Postoperative mortality rates, however, were 9.2% with and 9.7% without previous CABG, and the overall complication rate was similar in the 2 groups. The same situation happened in the other 4 results [16–19]. The baseline characteristics data between two cohorts are not balanced because the imbalanced baseline characteristics have the same pathogenesis pathway with coronary artery diseases and CABG. However, the data of the surgery procedure and post-operation are always matching. Obviously, the differences of devices and operators in different centers can indeed influence the mortality and complications because they are confounding factors. However, their database quality control was performed by checking data against source documents for 10% of patients in randomly selected centers and quality control of the researches revealed that the confounding variables have been balanced after random allocation or propensity score including the difference of device and the experience of operators. So these results can still be applied to the further studies and these results suggest that TAVIR has the potential to be an attractive option in high-risk patients with severe aortic stenosis and previous CABG.

The 30-day, 6-month, and 1-year mortality indicated no significant correlation between the patients undergoing TAVIR with or without prior CABG and mortality. Castellant et al. [15] enrolled more populations compared with other reports and hence the weightage was high in the forest plot on mortality. Sensitivity analysis was used in the present study, and no significant difference was shown again after removing the aforementioned study. Hence, the preliminary results revealed that prior CABG was a high-risk factor for patients undergoing TAVIR, but it did not influence the mortality. Similar results were also reported for 30-day complications except life-threatening bleeding. However, more studies are still needed to support or challenge this opinion.

In the present study, no significant difference in 30-day complications, except life-threatening bleeding, was observed between the two groups. An 8-year cohort study about AVR with or without concurrent CABG in octogenarians reported same results [20]. Wang et al. reported no significant difference in complications regardless of a history of CABG. However, they showed that a combination of AVR and CABG had higher but acceptable 30-day mortality compared with isolated AVR. The reasons for this were as follows: (1) the report was a single-center retrospective observational study, and the present meta-analysis included observational studies and clinical trials; (2) the difference between AVR and TAVIR; and (3) the difference in condition before and after the operation between surgery and catheterization.

The meta-analysis showed a significant difference in life-threatening bleeding between the two cohorts. This type of severe bleeding was defined as bleeding in a critical organ or bleeding causing death or any overt bleeding requiring packed red blood cell transfusion. In consensus, life-threatening bleeding, also called fatal bleeding, was defined to two types, type a and type b. Type a: probable fatal bleeding; no autopsy or imaging confirmation but clinically suspicious; type b: definite fatal bleeding; overt bleeding or autopsy or imaging confirmation [21]. No significant difference between the two groups was observed in each study; however, the morbidity rate of life-threatening bleeding in all five studies was significantly lower in patients with prior CABG than in those without CABG. In addition, Valve Academic Research Consortium-2 acknowledges the fact that the Bleeding Academic Research Consortium (BARC) convened and established standardized bleeding definitions for patients receiving antithrombotic therapy and undergoing coronary revascularization (PCI or CABG) [21,22]. These professors had reached a consensus that there is a real correlation between CABG and life-threatening bleeding. So the following reasons are most likely to happen in real world due to the results of meta-analysis: (1) more attention was paid by doctors and nurses to the mechanism of anticoagulation and coagulation for patients with prior CABG; (2) patients with prior CABG were treated with some anticoagulation drugs such as heparin, and the dosage of the drugs was tolerated by them; and (3) the anatomical position of coronary vessels changed because of CABG. The trend of life-threatening bleeding changed from no significant difference of all the included articles to significant difference of meta-analysis because changed sample size. Therefore, the results indicated that bleeding might be one of the possible reasons why the mortality rate was acceptable but still high for patients undergoing TAVIR. The report by Ducrocqa et al. [16] showed the maximum differences between the two groups whereas the report by Castellant et al. [15] showed the least differences. This might be because the former was a single-center study whereas the latter was a multicenter clinical trial and closer to the real scenario. Furthermore, it is possible that relevant information was not revealed, thereby requiring detailed investigation. Hence, patients undergoing TAVIR without prior CABG need more attention in terms of life-threatening bleeding.

The present study had many limitations. First, the quality of the meta-analysis was only as good as the quality of the studies being analyzed. The studies by Ducrocq et al. [16] and Voudris et al. [19] were retrospective studies with recollection bias. Second, all studies were included irrespective of many incidences, and the small number

Fig. 2. Mortality and implantation success. (A) Random-effects meta-analysis of the 30-day risk of mortality among patients undergoing TAVIR with or without prior CABG. (B) Random-effects meta-analysis of the 6-month risk of mortality among patients undergoing TAVIR with or without prior CABG. (C) Random-effects meta-analysis of the 1-year risk of mortality among patients undergoing TAVIR with or without prior CABG. (D) Random-effects meta-analysis of the risk of implantation success among patients undergoing TAVIR with or without prior CABG.

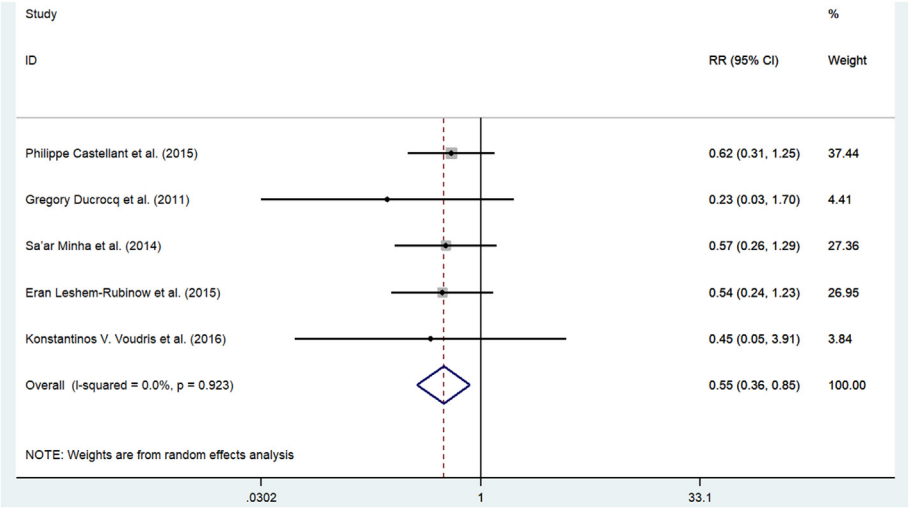


Fig. 3. Random-effects meta-analysis of the 30-day risk of life-threatening bleeding among patients undergoing TAVIR with or without prior CABG.

of studies restricted stratifying outcomes across studies with varying risk. The ratio of patients undergoing TAVIR with and without prior CABG (995 vs. 3968) is near one forth and some bias may exist because of some underlying confounding factors. Besides, the reason why no significant difference was observed in the 30-day risk of myocardial infarction and major vascular complications ($P = 0.051$ and $P = 0.063$, respectively) may be the small number of included studies. Third, the study had a potential for additional bias due to publication bias among the outcomes where significant asymmetry was observed. Finally, the weightage of the study by Castellant et al. [15] was so large that the results could not reveal the role of other data.

Above all, no significant difference in the mortality and complications, except life-threatening bleeding, was found between patients with and without prior CABG if they wanted to undergo TAVIR. The life-threatening bleeding in patients without prior CABG needed the maximum attention. In addition, the findings of the present study can be used as a reference while exploring CAD. Considering the worldwide trend of treating lower-risk patients with TAVIR, further randomized studies are needed to clarify the impact of CAD on TAVIR outcomes.

5. Conclusions

Patients with prior CABG can undergo TAVIR. Patients undergoing TAVIR without prior CABG need more attention because of a higher risk of life-threatening bleeding. Further randomized studies are needed to clarify the impact of CAD, especially the outcomes of prior CABG, on TAVIR.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcha.2018.08.004.

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Disclosures

The authors declare no conflicts of interest.

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