

SYSTEMATIC REVIEW

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Investigating the results of transcatheter aortic valve implantation (TAVI) in non-diabetic and diabetic patients: a systematic review and meta-analysis

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Abstract

Background Transcatheter aortic valve implantation (TAVI) has emerged as an effective treatment option for patients with severe aortic stenosis, particularly in those who are not suitable candidates for open-heart surgery. While diabetes is known to be associated with a higher risk of cardiovascular diseases, the impact of diabetes on the outcomes of TAVI remains controversial.

Methods A systematic literature search was conducted across major databases, including PubMed, Web of Science (WOS), and Google Scholar, for studies published in English over the past 20 years, up until July 2024.

Results A total of 10 observational studies were analyzed, revealing that diabetic patients were generally younger than non-diabetic patients. The 30-day mortality rate was lower in non-diabetics (0.03 [0.02–0.04]) compared to diabetics (0.04 [0.03–0.05]). However, the hazard ratio for death beyond 30 days in diabetics was 2.05 (95% CI: 0.91–4.60, $p=0.08$), and at one year, it was 1.04 (95% CI: 0.78–1.39, $p=0.77$), with neither result reaching statistical significance. Meta-regression analysis showed that non-insulin-treated diabetes was significantly associated with an increased risk of acute kidney injury (AKI) compared to non-diabetics, with a log odds ratio (LogOR) of 0.3393 ($p=0.035$) in one analysis and 0.3166 ($p=0.028$) in another, confirming a statistically significant increase in AKI risk.

Conclusions This review highlights that while diabetes slightly increases short-term mortality after TAVI, long-term survival remains comparable to non-diabetic patients. However, non-insulin-treated diabetes significantly raises the risk of acute kidney injury (AKI), emphasizing the need for enhanced renal protection and perioperative management.

Clinical trial number Not applicable.

Keywords Transcatheter aortic valve, Cardiovascular outcomes, Diabetes mellitus, Meta-Analysis

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Background

Severe aortic stenosis (AS) is a life-threatening condition caused by the narrowing of the aortic valve, leading to reduced cardiac output and symptoms like shortness of breath, fatigue, and decreased functional capacity. It develops gradually and often remains asymptomatic for years until the valve becomes critically narrowed. Common symptoms include exertional dyspnea, angina, and syncope, along with fatigue, palpitations, and heart failure signs. In some cases, acute decompensation can occur, leading to pulmonary edema, sudden cardiac death, myocardial ischemia, or cardiogenic shock. Urgent stabilization and, in severe cases, emergent valve intervention (e.g., TAVI) may be required [1, 2].

Echocardiography remains the gold standard for diagnosing and assessing the severity of AS. Key parameters include the aortic valve area (AVA), with severe stenosis defined as $AVA < 1.0 \text{ cm}^2$, and the mean transvalvular gradient, where a value $\geq 40 \text{ mmHg}$ indicates significant obstruction. Additionally, a peak aortic jet velocity $\geq 4.0 \text{ m/s}$ is a hallmark of severe AS. In patients with low-flow, low-gradient AS, the dimensionless index can provide further diagnostic clarity. Incorporating echocardiographic assessment into the clinical evaluation is essential for timely diagnosis and management, guiding treatment decisions such as valve replacement [3, 4].

Aortic valve replacement surgery stands as the predominant therapeutic approach for severe aortic stenosis. Transcatheter aortic valve replacement (TAVR), also called transcatheter aortic valve implantation (TAVI) is a procedure to replace an aortic valve that is narrowed and doesn't open fully. TAVI is minimally invasive, which means it uses smaller incisions than open-heart valve surgery for aortic valve replacement. It may be an option for elderly (age > 75 years), inoperable, and/or high surgical-risk patients who cannot have heart surgery to replace the aortic valve [5–10]. TAVI can help reduce chest pain, shortness of breath and other symptoms of aortic valve stenosis [9].

While TAVI remains a viable option for severe aortic stenosis, research shows that diabetes mellitus (DM) has been associated with significantly worse outcomes after heart valve surgeries emphasizing the importance of tailored management strategies [11]. Insulin resistance (IR) as a key feature of DM, manifesting across various organs such as skeletal muscle, liver, adipose tissue, and the heart. The initiation of hyperglycemia and diabetes frequently follows a preceding period of several years marked by IR. Obesity significantly contributes to this process, establishing a crucial connection between DM and the accrual of fat [12–18]. IR has been found to be associated with elevated risk of CVD [19–21].

Given the increasing prevalence of diabetes and the expanding use of TAVI in treating aortic stenosis, it is

critical to understand how DM influences mortality outcomes post-TAVI. This systematic review aims to consolidate and analyze existing research to provide a clearer picture of the mortality risks associated with TAVI in both diabetic and non-diabetic patients. By addressing the gaps and inconsistencies in current literature, this study seeks to contribute to the development of more personalized care strategies, ultimately improving clinical outcomes for diabetic patients undergoing TAVI.

Methods

This systematic review article was based on the main considerations of preferred reporting items for systematic reviews (PRISMA) [22]. All steps, including searching, initial screening, and the final analysis and data collection, were carried out independently by two authors. Their results were then compared to ensure accuracy and consistency.

Search strategy

A systematic literature search was conducted across major databases, including PubMed, Web of Science (WOS), and Google Scholar, for studies published in English over the past 20 years, up until July 2024. The search was done using the keywords obtained from the MeSH database of medical subject headings and the keywords of other articles published in this field such as “transcatheter aortic valve implantation”, “aortic stenosis”, “diabetes”, “hemoglobin (Hb) A1c” by combining AND and OR operators. For example, one of the search strategies in PubMed presented here: ((“Transcatheter Aortic Valve Implantation”[MeSH] OR “Transcatheter Aortic Valve Replacement”[MeSH] OR “Transcatheter Aortic Valve Implantation” OR “TAVI” OR “Transcatheter Aortic Valve Replacement” OR “TAVR”)) AND ((“Mortality”[MeSH] OR Mortality OR Death)) AND ((“Cardiovascular Diseases/mortality”[MeSH] OR “Cardiovascular Events” OR “Major Adverse Cardiac Events” OR “MACE” OR “Stroke/mortality”[MeSH] OR Stroke OR “Myocardial Infarction/mortality”[MeSH] OR “Myocardial Infarction”)) AND ((“Diabetes Mellitus”[MeSH] OR “Diabetes Mellitus” OR Diabetics OR Non-diabetics OR “Hyperglycemia”[MeSH] OR Hyperglycemia OR “Glycemic Control”))

Eligibility criteria

Eligible studies encompassed observational studies (cohort and cross-sectional). Case reports were excluded from this analysis due to their small sample sizes. The limited number of RCT studies available on this topic further contributed to the exclusion criteria. Also, short papers, conference abstracts, editorial comments, and review studies were excluded although the review ones

were checked from the reference list for more findings. Only studies published in English were considered.

Study selection

After an initial search, duplicate entries, reviews, and articles with unavailable full-texts were systematically excluded. The remaining article records underwent scrutiny based on their titles and abstracts, eliminating those that exhibited an inadequate correlation with the keywords of the current study. Subsequently, the selected full-text articles were thoroughly assessed to ensure they met the predetermined requirements.

Data extraction

By carefully reading the full text of the included studies data were extracted including study characteristics (author, year, country, study design), Patient characteristics (sample size, age, gender, presence of diabetes), reported outcomes including prevalence of 30-day mortality after TAVI, and prevalence of ≥ 1 -year mortality after TAVI.

Quality assessment

Since all the included studies were observational studies, so the qualities of included studies were evaluated using the Newcastle-Ottawa Scale [23], which consists of three major aspects: selection, comparability, and exposure or outcome. A study with 7 or more stars is considered to be high quality.

Statistical method

All statistical analyses were conducted using Stata version 14. Pooled estimates of mortality risk ratios (RR) or odds ratios (OR) with 95% confidence intervals (CI) comparing diabetic and non-diabetic patients were calculated. The heterogeneity across studies was assessed using the I^2 statistic. In cases where heterogeneity was present ($I^2 > 50$ and $p < 0.05$), we utilized a random-effects model to combine the study results. Conversely, in the absence of significant heterogeneity, a fixed-effects model was employed. To evaluate publication bias, we utilized the Egger's regression test and applied the 'trim and fill' method if any significant publication bias was detected. The sensitivity analysis was measured for assessment of the robustness of the combined risk estimates to evaluate whether the low-quality studies would influence the overall result.

Results

Search and study selection

The search process is depicted in Fig. 1. Primary search of PubMed, ISI Web of Science, and Google Scholar electronic database resulted in 313 articles, that after excluding the duplicates, reviews, abstracts, those with unrelated topics, abstracts, or context, non-English articles and articles with not sufficient results finally 10 studies were included. Details and characteristics of the included studies with their summary of results could be found in Table 1. All studies were prospective or retrospective observational study and their quality was checked by Newcastle-Ottawa scales [23], and found to be medium or high quality.

Main analysis

Age

Figure 2 displays a forest plot comparing the age distribution of DM (red dots) and non-DM (blue dots) subjects across multiple studies. The data indicate that the average age in the DM group is consistently lower than that of the non-DM group, highlighting a noticeable age difference between the two populations.

30-day mortality

Figures 3 and 4 showed the rate of 30-day mortality after TAVI procedure in non-DM and DM subjects

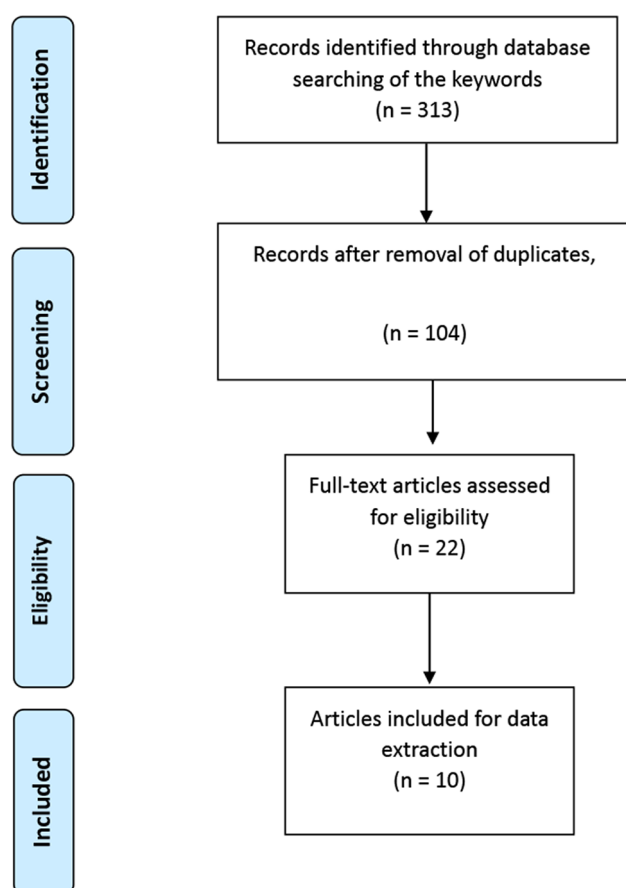


Fig. 1 Flowchart of study selection

Table 1 Characteristics and details of the included studies

Author/Year/Country	Population	Study Design	MACE (non-DM vs. DM)	Other Outcomes
Conrotto et al. 2014 (Italy) [24]	Total: 511 Non-DM: 361 (70.64%) DM: 150 (29.36%)	Prospective multi-center study	No significant differences in bleedings, vascular complications, acute kidney injury, and strokes.	
Abramowitz et al. 2017 (USA) [25]	Total: 47,643 Non-DM: 29,794 (62.52%) DM: 17,849 (37.48%)	Multi-center retrospective observational study	Higher risk of bleeding ($p=0.001$), dialysis (<0.001), and acute kidney injury (<0.001) in DM patients.	DM increases short- and long-term risks of TAVR, especially with insulin dependency.
Lareyre et al. 2019 (France) [26]	Total: 400 Non-DM: 322 (80.5%) DM: 78 (19.5%)	Single-center retrospective observational study	Non-DM: Aortic rupture = 1 (0.3%) DM: 0% $p=0.6222$; Non-DM: Vascular injury = 1.9% DM: 0% $p=0.2245$	Diabetic patients had longer hospital stays, younger age, and higher BMI than non-DM patients.
Dekany et al. 2022 (USA) [27]	Total: 560 Non-DM: 357 (63.75%) DM: 203 (36.25%) Insulin-DM: 53 (9.5%)	Single-center retrospective observational study	1-year mortality ($p=0.323$), 2-year mortality ($p=0.304$), bleeding ($p=0.722$), stroke ($p=0.71$)	Insulin-DM associated with younger age and poorer cardiovascular risk profile ($p=0.009$).
van Nieuwkerk et al. 2022 (USA) [28]	Total: 11,440 Non-DM: 7,890 (69%) DM: 3,550 (31%) Insulin-DM: 314	Multi-center retrospective observational study	Stroke ($p=0.28$), Myocardial infarction ($p=0.21$)	Diabetic patients had younger age, higher BMI, poorer cardiovascular risk profile, and higher mortality trends ($p=0.08$).
Berkovitch et al. 2015 (Israel) [29]	Total: 443 Non-DM: 285 (64%) DM: 158 (36%) Insulin-DM: 44 (28%)	Retrospective observational study	No significant differences in 2-year mortality ($p=0.439$).	Higher prevalence of AKI grade 3 in DM patients ($p=0.032$).
Slingerland et al. 2024 (Netherlands) [30]	Total: 11,819 Non-DM: 9,715 (82.2%) DM: 2,104 (17.8%)	Retrospective observational study	Significant differences in mortality after PCI (OR = 1.68; $p < 0.001$), CABG (OR = 1.35), AVR (OR = 1.5).	Higher mortality for diabetic patients after CABG, TAVI, PCI procedures.
Ayhan et al. 2024 (Turkey) [31]	Total: 552 Non-DM: 338 (70.3%) DM: 164 (29.7%)	Retrospective cohort study	Mortality higher in patients with HbA1c ≥ 6.5 . Independent predictor for long-term mortality.	Higher prevalence of AKI in DM group (2.4% vs. 0%, $p=0.021$).
Khan et al. 2022 (USA) [32]	Total: 135,811 Non-DM: 85,833 (63.2%) DM: 49,978 (36.8%)	Multi-center retrospective observational study	DM patients were older and had higher adjusted risk of mortality, stroke, ARF.	Increased risk of pacemaker requirement and stroke in DM patients.
Mendez-Bailon et al. 2017 (Spain) [33]	Total: 2,141 Non-DM: 1,426 (66.6%) DM: 715 (33.3%)	Retrospective observational study	No significant differences in mortality or hospital stay between DM and non-DM in TAVR patients.	Lower mortality and shorter hospital stay for Type 2 DM patients in S

respectively. The 30-day mortality rates were generally lower in non-DM group.

≥ 1 -year mortality

Figures 5 and 6 showed the rate of ≥ 1 -year mortality after TAVI procedure in non-DM and DM subjects respectively. The ≥ 1 -year mortality rates were generally same in both groups.

Risk ratio

The study results indicated that the hazard ratio for death beyond 30 days in diabetic patients was 2.05 (95% CI: 0.91–4.60) compared to non-diabetics; however, this difference was not statistically significant ($p=0.08$) (Fig. 7). Notably, there was substantial heterogeneity among studies ($I^2 = 97.40\%$). At the one-year mark, the hazard ratio for mortality in the diabetic group was 1.04 (95% CI: 0.78–1.39) compared to non-diabetics, with no statistically significant difference ($p=0.77$) (Fig. 8), and similarly high heterogeneity ($I^2 = 97.42\%$). Overall, while the hazard ratio for mortality was elevated in the diabetic group at both time points, the findings lacked

statistical significance, and study heterogeneity remained considerable.

Meta-Regression results

Non-insulin DM, Insulin-DM, non-DM

Three studies reported the prevalence of acute kidney injury (AKI) in three groups of non-DM, non-insulin DM, and insulin-DM subjects [24, 25, 29]. Results of meta-regression analysis of non-insulin DM vs. non-DM showed that the log odds ratio (LogOR) for AKI in non-insulin-treated diabetes (compared to non-diabetics) is 0.3393 ($p=0.035$), suggesting a statistically significant increase in AKI risk. In terms of insulin-treated subjects, the additional LogOR for insulin-treated diabetes compared to non-insulin-treated diabetes is 0.7487 ($p=0.008$), indicating a significant increase in AKI risk among insulin-treated patients. The regression explains 86% of the variance ($R^2 = 0.860$), suggesting a strong relationship between diabetes severity and AKI risk. The F-statistic ($p=0.00775$) confirms that diabetes treatment status significantly influences AKI rates.

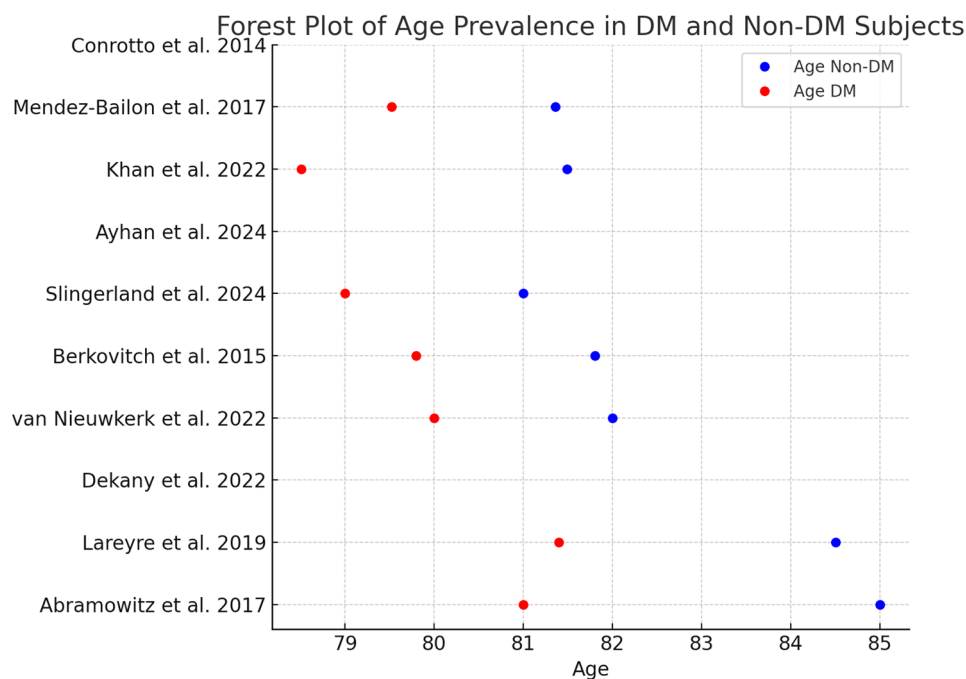


Fig. 2 Forest plot displaying the age distribution in DM (red dots) and non-DM (blue) underwent TAVI

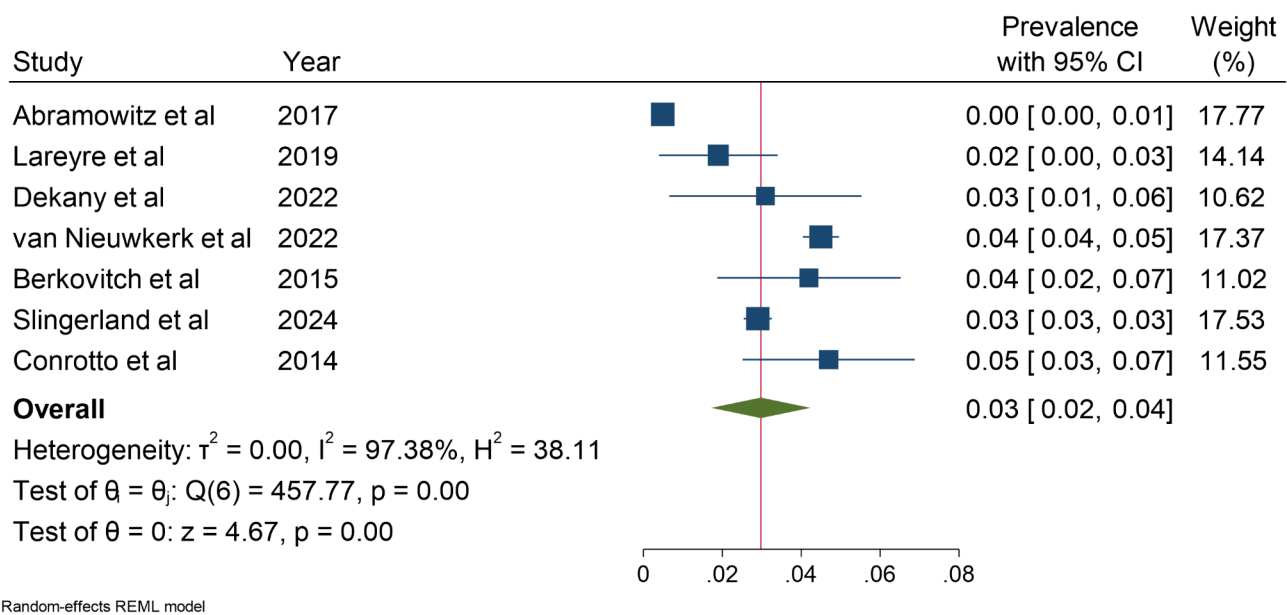


Fig. 3 Rate of 30-day mortality in non-DM subjects underwent TAVI

DM vs. non-DM

Three studies reported the prevalence of AKI in two groups of DM and non-DM subjects. The log odds ratio (LogOR) for AKI in non-insulin-treated diabetes compared to non-diabetics is 0.3166 ($p=0.028$), indicating a statistically significant increase in AKI risk. The model does not explain variability in the data well ($R^2 = 0.000$), suggesting high heterogeneity or limited power due to the small sample size. Despite the small sample size

($n=3$ studies), the effect remains statistically significant ($p=0.028$).

Discussion

This systematic review highlights that while short-term outcomes in TAVI patients are often worse for those with diabetes—particularly insulin-treated diabetes—long-term mortality tends to align between diabetic and non-diabetic groups. Regarding acute kidney injury

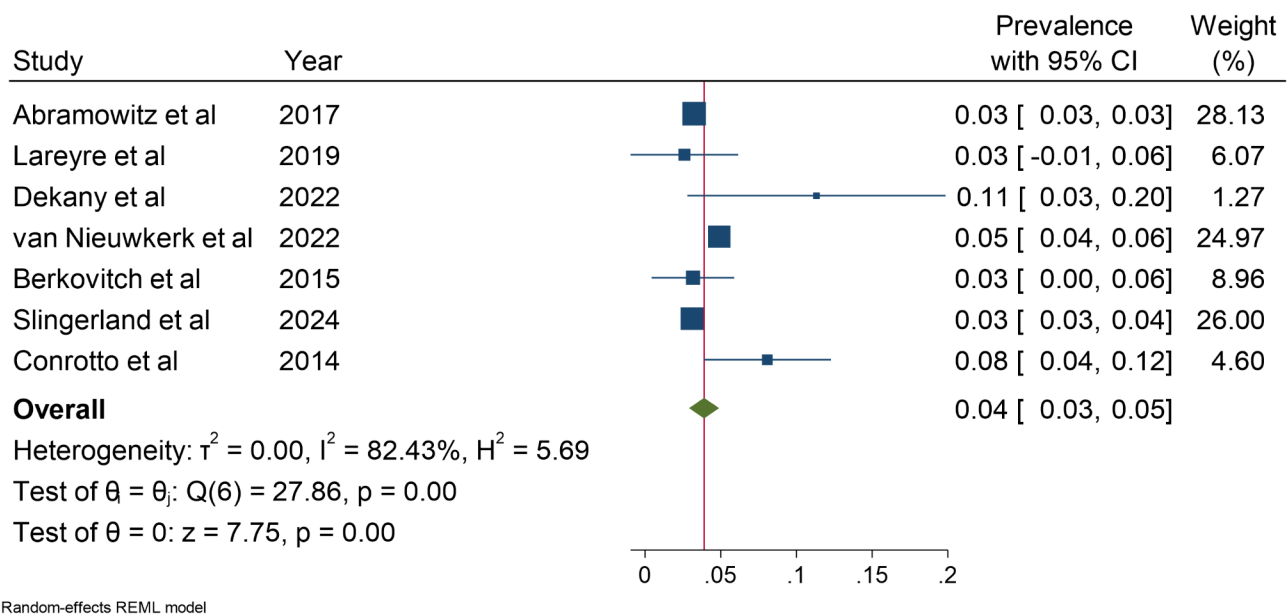


Fig. 4 Rate of 30-day mortality in DM subjects underwent TAVI

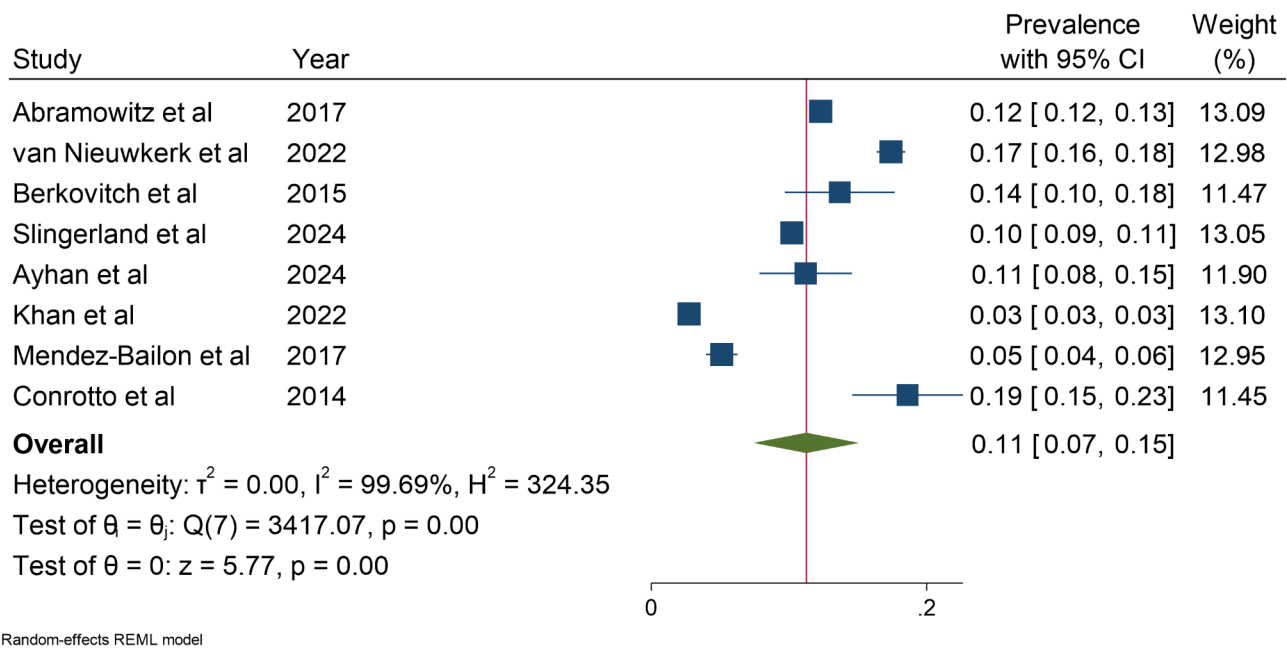


Fig. 5 Rate of ≥ 1 -year mortality in non-DM subjects underwent TAVI

(AKI), the findings indicate that diabetes, especially in insulin-treated patients, is associated with a significantly increased risk of AKI following TAVI. Additionally, non-insulin-treated diabetes also presents a higher AKI risk compared to non-diabetic patients. These results emphasize the need for comprehensive risk stratification and tailored postoperative management strategies to optimize outcomes in diabetic patients undergoing TAVI.

Our analysis of TAVI patients categorized diabetes treatment status into three subgroups: insulin-treated

diabetes, non-insulin-treated diabetes, and non-diabetic patients. Insulin-treated diabetes, indicative of more advanced disease and metabolic dysregulation, is associated with higher rates of complications such as AKI, cardiovascular events, and mortality. Additionally, diabetic TAVI patients often have a higher prevalence of hypertension, chronic kidney disease (CKD), and coronary artery disease (CAD), which may contribute to worse outcomes.

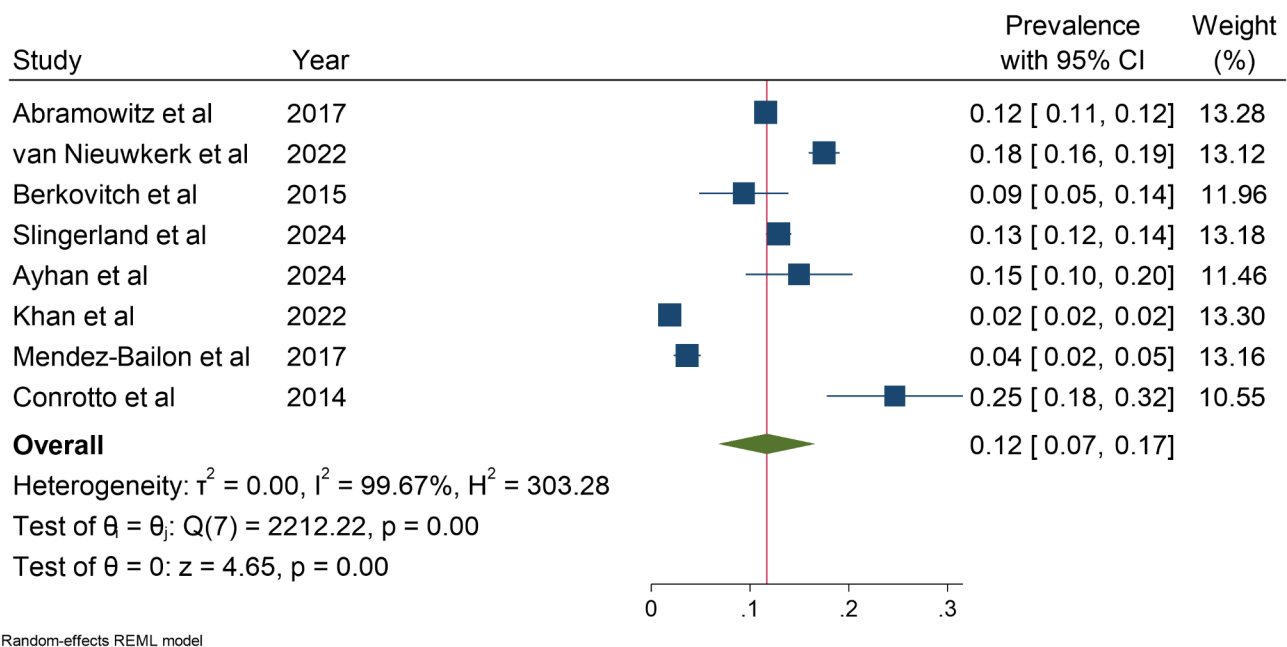


Fig. 6 Rate of ≥ 1-year mortality in DM subjects underwent TAVI

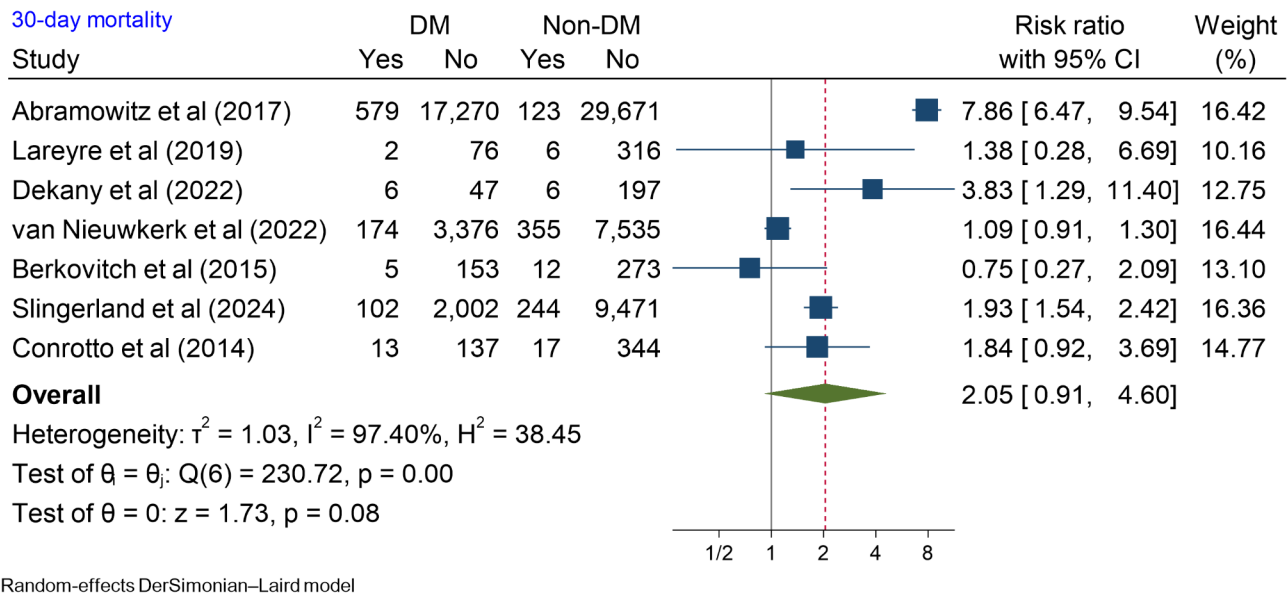


Fig. 7 Hazard ratio for death after 30 days in diabetic and non-diabetic patients

While short-term mortality is elevated in diabetics—especially those requiring insulin—due to metabolic instability and cardiovascular burden, long-term mortality tends to converge between diabetic and non-diabetic groups. This convergence is likely driven by survivorship bias, improved cardiac function post-TAVI, aggressive secondary prevention, and the increasing impact of non-cardiovascular mortality. TAVI itself enhances cardiac performance, which, despite baseline vascular dysfunction in diabetics, contributes to better long-term outcomes.

In a research endeavor encompassing 663 consecutive patients undergoing TAVI, diabetes mellitus independently predicted mortality at 30 days [34]. Patients with diabetes often have coexisting health conditions, such as renal impairment or peripheral vascular disease, which can complicate the TAVI procedure and subsequent recovery. These comorbidities may contribute to a higher likelihood of adverse events within the initial 30 days post-TAVI. In addition, Diabetes is linked to a chronic inflammatory state, and inflammation plays a crucial role in the response to surgical procedures. The inflammatory

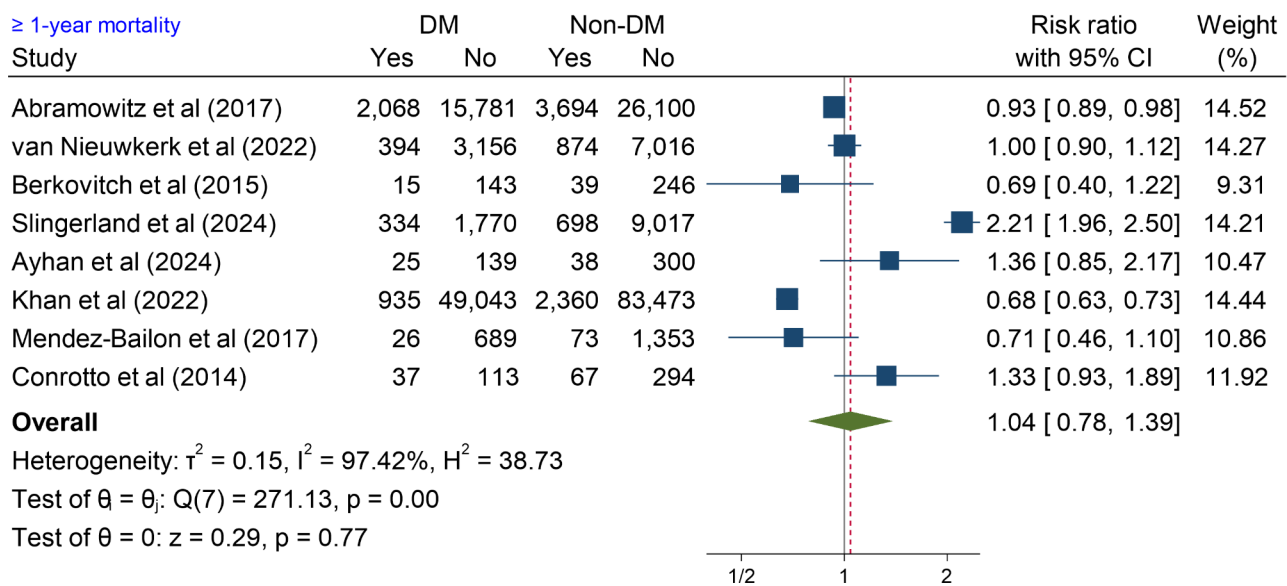


Fig. 8 Hazard ratio for death after 1 year in diabetic and non-diabetic patients

response may be heightened in diabetic patients undergoing TAVI, potentially impacting the healing process and influencing short-term mortality outcomes. Also, diabetes is associated with metabolic imbalances, including insulin resistance and elevated blood sugar levels. These metabolic factors can potentially influence the healing process, immune response, and overall recovery after operation. Contrary to the anticipated impact of the mentioned factors, the collective findings from the gathered studies revealed a surprising outcome. Despite expectations that postoperative results in diabetic patients would be notably worse, the evidence presented in these studies indicated the opposite trend.

In the investigation conducted by van Nieuwkerk et al., all-cause mortality rates exhibited similarity at both 30 days and one year within the unmatched population. After applying propensity score matching to establish 3281 patient-pairs, the mortality rates remained comparable at both 30 days ($p=0.38$) and one year ($p=0.37$). Furthermore, various clinical outcomes including stroke, major bleeding, myocardial infarction, and permanent pacemaker implantation were found to be analogous between diabetic and non-diabetic patients. Although among insulin-treated diabetics ($n=314$), there was a trend towards higher mortality compared to non-insulin-treated diabetics ($p=0.08$), this difference did not achieve statistical significance [28]. In the investigation conducted by Dekany et al., individuals with DM displayed elevated all-cause mortality rates at 30 days, although the disparity at 1 year and 2 years did not reach statistical significance. Furthermore, heightened blood glucose levels falling within the range of 7–11 mmol/L were associated with elevated risks for both 30-day and 2-year mortality.

Each incremental increase of 1 mmol/L in blood glucose was linked to an elevated risk of 30-day mortality [27]. There were no significant differences in other procedural outcomes and complications, including post-TAVI bleeding, the need for emergency cardiac surgery, and the need for permanent pacemaker implantation between DM and non-DM subjects [27]. DM and non-DM patients exhibited comparable pre-operative clinical and anatomical characteristics related to vascular access. They found that the presence of diabetes did not significantly influence procedural characteristics and was not associated with a higher risk of 30-day mortality or vascular events [26].

Study by Basile et al. on 327 hypertensive patients with severe AS undergoing TAVI showed the beneficial effect of renin-angiotensin-aldosterone system (RAAS) inhibition in diabetic patients undergoing TAVI. According to their study baseline treatment with ACEIs/ARBs in hypertensive patients undergoing TAVI is associated with a lower risk of cardiovascular mortality over 2 years, supporting the potential benefit of these drugs. Further trials are needed to validate these findings [35]. This beneficial effect is most likely due to the fact that ACEIs/ARBs improve outcomes in hypertensive AS patients undergoing TAVI by reducing LV pressure overload, preventing fibrosis, improving myocardial oxygen balance, and possibly slowing valve disease progression. Their benefits outweigh the theoretical risks, making them a potentially valuable therapy in this population. However, randomized controlled trials are still needed to confirm these findings.

These findings highlight the need for enhanced pre-operative risk stratification and tailored postoperative care to improve early survival outcomes in diabetic TAVI

patients. A multidisciplinary approach—incorporating preoperative optimization, intraoperative precautions, and postoperative monitoring—is essential for reducing disparities in short-term mortality and improving overall outcomes. Additionally, effective management of diabetes-related cardiovascular and systemic complications is crucial. Future randomized controlled trials are needed to refine these strategies and develop diabetes-specific treatment protocols for TAVI patients.

Limitations

There were only observational studies on this topic. Observational data can be influenced by confounding factors, limiting definitive conclusions about the role of diabetes in short-term outcomes. The exclusion of non-English studies in this systematic review may introduce language bias, potentially limiting the generalizability of the findings. To minimize these biases in future analyses, incorporating non-English studies with the help of translation tools or multilingual reviewers would be beneficial.

Conclusion

While the overall findings suggest a generally similar trend in long-term outcomes between diabetic and non-diabetic patients undergoing TAVI, the nuanced variations in 30-day mortality rates emphasize the importance of continued research and refined risk stratification to enhance our understanding of the complex interplay between diabetes and TAVI outcomes.

Author contributions

AS, and ZT, designed the study, performed the drafting and supervised the whole study. MM, SB, and AS, searched databases, screened articles and extracted data, performed the data analysis and interpretation of data, also wrote the main draft of the manuscript. AA helped in final edition and analysis. ZT, critically revised the manuscript and supervised the meta-analysis. All authors approved the final version of the manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethical statement

This article does not contain any studies with human participants performed by any of the authors.

Competing interests

The authors declare no competing interests.

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