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Glycemic control after aortic valve replacement: A retrospective study

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ABSTRACT

Background: Aortic stenosis (AS) is treated through transcatheter aortic valve implantation (TAVI) or surgical aortic valve replacement (SAVR), with diabetes being prevalent among these patients. Inflammation participates in the pathogenesis of AS, and emerging evidence suggests that TAVI may exert anti-inflammatory effects. Given the established link between diabetes and inflammation, we sought to evaluate the impact of aortic valve replacement (AVR) on glycemic control.

Methods: Data from 10,129 consecutive patients undergoing either TAVI or SAVR between January 2010 and January 2022 were analyzed. Of these, 3,783 with diabetes had available pre- and post-procedural glycated hemoglobin (HbA1c) measurements. Analysis of 1,284 individuals with HbA1c $\geq$ 7 % was conducted. Propensity-score matching produced two well-matched cohorts of 266 TAVI and SAVR patients, enabling comparison of periprocedural HbA1c.

Results: In the total cohort (n = 1,284), HbA1c decreased from 8.15 $\pm$ 1.12 to 7.88 $\pm$ 1.38 ($p < 0.001$). After matching, the TAVI group showed a significant reduction from 8.31 $\pm$ 1.31 to 7.86 $\pm$ 1.56 ($p < 0.001$), while a modest decrease from 8.33 $\pm$ 1.33 to 8.15 $\pm$ 1.61 ($p = 0.046$) was observed in SAVR group. The TAVI group showed a trend toward a greater percentage change in HbA1c ($p = 0.051$). Clinically meaningful improvement in HbA1c ($\geq$ 0.3 %) was similar between TAVI (53.1 %) and SAVR (45.6 %) patients (OR = 1.34, 95 % CI 0.93–1.95).

Conclusions: Management of AS through either intervention improved post-procedural glycemia in patients with uncontrolled diabetes. The extent of glycemic improvement was more pronounced with TAVI. Further investigations through controlled and prospective studies could provide more conclusive insights into this matter.

1. Introduction

Degenerative valvular aortic stenosis (AS) is the most common valvular disease in the Western world [1], resulting from the interplay between atherosclerosis and calcification of the aortic leaflets [2]. Currently, aortic valve replacement (AVR) can be performed either via surgical aortic valve replacement (SAVR) or transcatheter aortic valve implantation (TAVI). Inflammation plays a key role in the pathogenesis of AS, where endothelial damage from shear stress permits lipoprotein infiltration, initiating a localized inflammatory response [3]. Immunohistochemistry analyses of degenerated aortic valve leaflets reveals significant evidence of local chronic inflammatory infiltrates [4]. In particular, a strong correlation has been observed between inflammation, calcification severity, and AS progression [4,5].

Diabetes mellitus (DM) is recognized as a significant contributor to the development and progression of AS [2], with approximately one-third of patients undergoing TAVI diagnosed with DM [6]. Insulin resistance is believed to accelerate valvular degeneration through pro-atherosclerotic mechanisms, increased inflammation, and lipid accumulation [7]. The well-documented interplay between DM and inflammation includes insulin resistance documented [8–10], which is strongly linked to chronic inflammation characterized by dysregulated cytokine

Abbreviations: HbA1c, Glycated Hemoglobin; AS, Aortic Stenosis; AVR, Aortic Valve Replacement; DM, Diabetes Mellitus; GLP-1, RA Glucagon-Like Peptide-1 Receptor Agonist; SAVR, Surgical Aortic Valve Replacement; TAVI, Transcatheter Aortic Valve Implantation.

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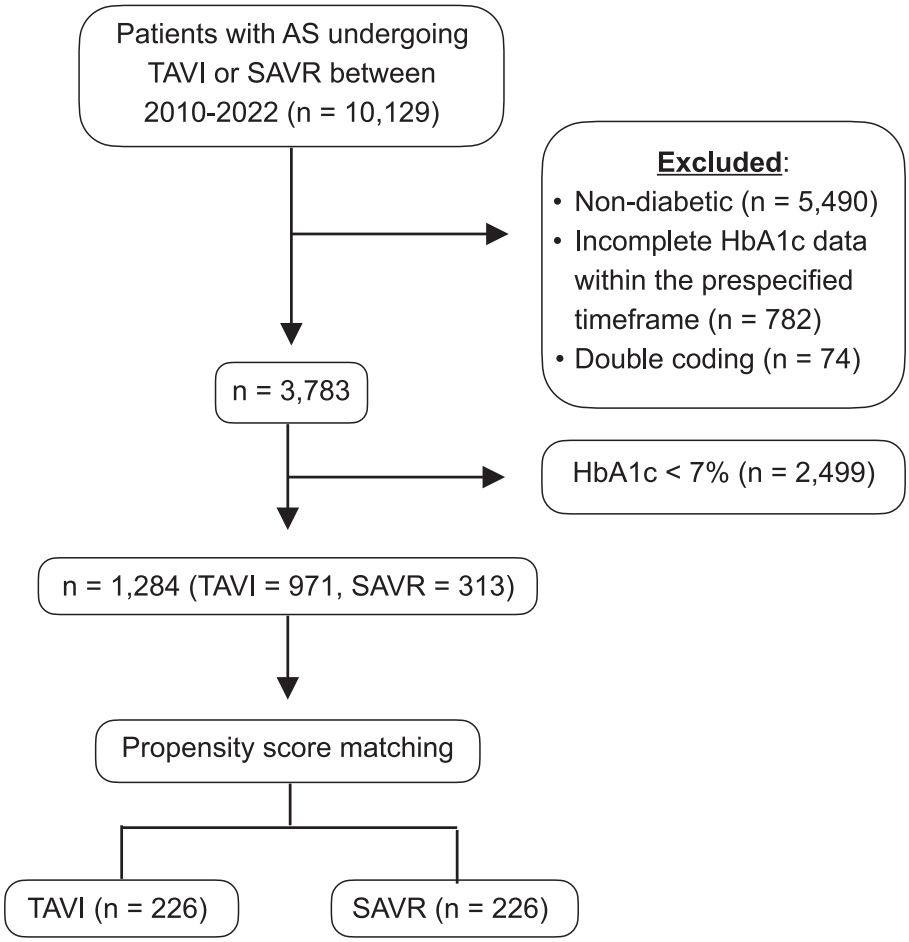

Fig. 1. Flowchart illustrating the inclusion of the study population into the transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) cohorts.

production, elevated acute-phase reactants, and other mediators that trigger a complex inflammatory response [11]. Moreover, increasing evidence indicates that anti-inflammatory therapies can enhance glycemic control, as demonstrated by reductions in glycated hemoglobin (HbA1c) levels [9]. Emerging evidence suggests that TAVI may confer unexpected anti-inflammatory benefits [12]. This hypothesis stems from the high shear stress forces acting on circulating blood cells as they pass through the stenotic valve orifice [13–15]. By improving hemodynamics, the reduction of shear stress forces post-TAVI has been linked to a decrease in various pro-inflammatory markers [12], implying a potential modulation of the inflammatory cascade.

The impact of AVR on glycemic control remains largely unexplored, with no studies to date demonstrating longitudinal changes in glycemic regulation following TAVI or SAVR. Given the established connection between inflammation and DM control, we postulate that these interventions may translate into improved glycemic regulation.

2. Methods

2.1. Study population

We conducted a retrospective analysis of consecutive patients who underwent isolated TAVI or SAVR between January 1, 2010, and January 1, 2022, utilizing data from a large national database. The study was approved by the institutional ethics committee (approval number: 0081–23-CMC) and adhered to the principles of the Declaration of Helsinki. Data collection included baseline demographic, clinical, and laboratory parameters. As HbA1c is the gold standard for evaluating long-term glycemic control, providing an average measure of glycemia over a 2–3 month period, this study assessed HbA1c at two distinct intervals: pre-procedurally, using the most recent measurement within three months prior to the procedure, and post-procedurally, within the timeframe of 3 to 15 months after the procedure. The HbA1c values from the initial three months post-procedure were deliberately excluded to account for potential confounding effects during the "blanking period," allowing for a more accurate evaluation of the impact of the AS intervention.

The inclusion criteria encompassed adult patients (aged 18 years and older) with DM and a confirmed diagnosis of AS who underwent either intervention, with only those having HbA1c measurements available within both prespecified timeframes included. Finally, only patients with poorly controlled DM, defined by HbA1c levels ≥ 7 %, were eligible for inclusion into the final cohort. This criterion was applied due to the inherent difficulty in demonstrating significant improvements in glycemic control within populations that already exhibit relatively well-regulated glycemia [16].

After applying these inclusion criteria and assembling the final patient groups for TAVI and SAVR, propensity-score matching was applied in an attempt to reduce potential bias and facilitate comparison between the two cohorts. Comparative analyses of baseline demographic and clinical characteristics, as well as periprocedural HbA1c levels, were conducted between the two groups. A further subanalysis was performed to identify individuals who achieved a clinically meaningful reduction in HbA1c of 0.3 %, a threshold generally recognized as significant, as it is associated with a notable decrease in the risk of diabetes-related complications [17].

Table 1
Baseline characteristics of the cohort before propensity-score matching.

Patient characteristics	Total (n = 1284)	TAVI (n = 971)	SAVR (n = 313)	p-value
Age, years	76.5 ± 8.5	78.9 ± 7.1	68.9 ± 7.9	<0.001
Gender, female	584 (45.5)	466 (48.0)	118 (37.7)	0.001
Ethnicity, Jewish	1096 (85.4)	855 (88.1)	241 (77.0)	<0.001
Socioeconomic status				
Low	422 (32.9)	293 (30.2)	129 (41.2)	<0.001
Middle	610 (47.5)	476 (49.0)	134 (42.8)	<0.001
High	228 (17.8)	187 (19.3)	41 (13.1)	<0.001
Baseline hemoglobin A1C	8.15 ± 1.1	8.1 ± 1.0	8.4 ± 1.4	<0.001
Chronic renal failure	409 (31.9)	344 (35.5)	65 (20.8)	<0.001
Duration of diabetes mellitus, years	19.4 ± 10.6	20.4 ± 10.7	16.5 ± 9.5	<0.001
Hypertension	1196 (93.1)	910 (93.7	286 (91.4)	0.153
Hyperlipidemia	1261 (98.2)	956 (98.5)	305 (97.4)	0.241
Coronary artery disease	510 (39.7)	419 (43.2)	91 (29.1)	<0.001
Atrial fibrillation	442 (34.4)	340 (35.0)	102 (32.6)	0.432
Cerebrovascular disease	277 (21.6)	213 (21.9)	64 (20.4)	0.578
COPD	186 (14.5)	144 (14.8)	42 (13.4)	0.537
Medications *				
Oral	1089 (84.8)	820 (15.6)	44 (14.1)	0.522
Insulin formulation	626 (48.8)	475 (48.9)	151 (48.2)	0.835
GLP-1 RA	169 (13.2)	121 (12.5)	48 (15.3)	0.191

Data are presented as n (%) or mean ± standard deviation.
Abbreviations: COPD: chronic obstructive pulmonary disease, GLP-1 RA: Glucagon-like peptide-1 receptor agonist, SAVR: surgical aortic valve replacement.
TAVI: transcatheter aortic valve implantation.
Chronic renal failure was defined by glomerular filtration rate less than 60 ml/min.
* Patients can have more than one type of antidiabetic medication.

2.2. Statistical analysis

Categorical variables are presented as numbers and percentages, while continuous variables are expressed as mean ± SD or median and IQR. Baseline demographic and clinical characteristics between the two procedure types were compared using the Chi-square test for categorical variables, and the Independent *t*-test or Mann-Whitney test, as appropriate, for continuous variables. Due to demographic and clinical differences between the two procedure groups, a propensity-score adjusted analysis was performed. A propensity score for each patient was calculated using logistic regression, with the intervention type (TAVI or SAVR) as the dependent variable, and age, gender, ethnicity, socioeconomic status, and comorbidities (chronic renal failure, diabetes duration, prior HbA1c, hypertension, hyperlipidemia, coronary artery disease, atrial fibrillation, cerebrovascular disease, and COPD) as covariates. Pre- and post-matching standardized mean differences (SMD) were calculated to assess balance between the groups. Between-group imbalances were considered minimal if the absolute SMD for a given covariate was less than 10 %. The Wilcoxon signed-rank test was used to compare pre- and post-procedural changes in HbA1c levels, conducted separately for each procedure type. Generalized estimating equations were used to estimate the odds ratio for the association between intervention type and a 0.3 % improvement in HbA1c. The odds ratio, along with the corresponding 95 % confidence interval (CI), is presented. All statistical analyses were performed using IBM SPSS Statistics 28.0 (IBM, New York, NY) and SAS version 9.4. For all analyses, a p-value of less than 0.05 (two-tailed) was considered statistically significant.

3. Results

Over the study period, a total of 10,129 patients underwent one of the two procedures, of which 4,639 (45.8 %) had a pre-existing diagnosis of DM. Among them, 3,783 individuals had complete HbA1c dataset available for analysis, from which a final cohort of 1,284 patients with poorly controlled DM was selected (TAVI = 971, SAVR = 313). Fig. 1 details the inclusion process of the study population into the respective cohorts.

The baseline characteristics of the 1,284 patients with poorly controlled DM are detailed in Table 1. The HbA1c of the total cohort improved from 8.15 ± 1.12 before AS intervention to 7.88 ± 1.38 post-procedurally ($p < 0.001$), as shown in Fig. 2. Next, propensity-score matching resulted in 452 patients, evenly divided 1:1 into TAVI and SAVR groups, producing well-balanced cohorts. The demographic and clinical characteristics of both cohorts are presented in Table 2. The mean age was 71.5 ± 7.1 years (SMD = 0.006), with a predominance of males and baseline HbA1c levels of 8.3 ± 1.3 (SMD = 0). The TAVI group exhibited a slightly higher comorbidity burden, reflected in a greater prevalence of atrial fibrillation (37.2 % vs. 33.2 %, SMD = 0.084) and coronary artery disease (37.6 % vs. 32.7 %, SMD = 0.103).

As illustrated in Fig. 3, both cohorts showed significant improvements in post-procedural HbA1c levels. In the TAVI group, HbA1c levels dropped significantly from 8.31 ± 1.31 to 7.86 ± 1.56 ($p < 0.001$). Similarly, although the SAVR group saw a more modest reduction from 8.33 ± 1.33 to 8.15 ± 1.61, this change also reached statistical significance ($p = 0.046$). The percentage change in HbA1c showed a trend toward being higher in the TAVI group ($p = 0.051$).

Fig. 4 illustrates the post-procedural improvement in HbA1c levels at clinically meaningful thresholds. A reduction of ≥ 0.3 % in HbA1c was

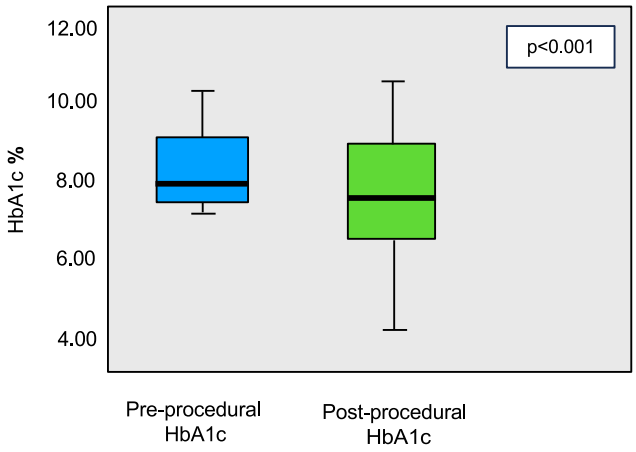

Fig. 2. Changes in glycemic control for the total cohort of patients with glycated hemoglobin (HbA1c) ≥ 7 % undergoing either surgical aortic valve replacement or transcatheter aortic valve implantation for aortic stenosis.

Table 2
Baseline characteristics after propensity-score matching.

After propensity matching			
Patient characteristics	**TAVI (n = 226)**	**SAVR (n = 226)**	**SMD**
Age, years	71.5 ± 7.1	71.5 ± 7.1	0.006
Gender, female	101 (44.7)	90 (40.3)	0.089
Ethnicity, Jewish	45 (19.9)	44 (19.5)	0.010
Socioeconomic status			
Low	87 (38.5)	87 (38.5)	0
Middle	107 (47.3)	101 (44.7)	0.052
High	25 (11.1)	32 (14.2)	−0.093
Baseline hemoglobin A1C	8.3 ± 1.3	8.3 ± 1.3	0
Chronic renal failure	62 (27.4)	58 (25.7)	0.038
Duration of diabetes mellitus, years	17.6 ± 9.4	17.3 ± 9.8	0.031
Hypertension	210 (92.9)	204 (90.3)	0.094
Hyperlipidemia	218 (96.5)	221 (97.8)	−0.078
Coronary artery disease	85 (37.6)	74 (32.7)	0.103
Atrial fibrillation	84 (37.2)	75 (33.2)	0.084
Cerebrovascular disease	54 (23.9)	49 (21.7)	0.052
COPD	38 (16.8)	31 (13.7)	0.086
Medications			
Oral	196 (86.7)	196 (86.7)	0
Insulin formulation	108 (47.8)	109 (48.2)	−0.008
GLP-1 RA	33 (14.6)	32 (14.2)	0.011

Data are presented as n (%) or mean ± standard deviation.
Abbreviations: COPD: chronic obstructive pulmonary disease, GLP-1 RA: Glucagon-like peptide-1 receptor agonist, SAVR: surgical aortic valve replacement, SMD: standardized mean difference.
TAVI: transcatheter aortic valve implantation.
*Patients can have more than one type of antidiabetic medication.
Chronic renal failure was defined by glomerular filtration rate less than 60 ml/min.

observed in 49.3 % (223 out of 452) of the matched cohort, with 53.1 % in the TAVI group and 45.6 % in the SAVR group demonstrating clinically meaningful improvement. However, the difference between the two groups was not statistically significant (OR = 1.34, 95 % CI 0.93–1.95, p = 0.118). TAVI was associated with a greater decrease in HbA1c of ≥ 1 %, with 35 % of patients achieving this reduction compared to 23.9 % in the SAVR group (OR = 1.69, 95 % CI 1.12–2.55, p = 0.013).

4. Discussion

Our study examined the association between resolving AS, through both TAVI and SAVR procedures, and glycemic control. We found that patients with uncontrolled DM and severe AS experienced significant improvements in glycemic regulation following either TAVI or SAVR intervention. The extent of glycemic improvement was more pronounced among patients who underwent TAVI. Although it did not reach statistical significance, there was a trend toward a more clinically significant HbA1c improvement (≥ 0.3 %) in the TAVI group compared to the SAVR group.

DM has surged to epidemic levels globally, with its prevalence continuing to climb [18]. There is a bulk of literature highlights the prognostic implications of diabetes in various cardiovascular conditions, including acute coronary syndrome [19], bypass surgery [20], heart valve operations [21], and TAVI [22]. Furthermore, TAVI patients with poorer glycemic control have been shown to have higher all-cause mortality rates at 1- and 2-year follow-up intervals [21,23,24], and a greater incidence of acute kidney injury [25]. However, to the best of our knowledge, no prior studies have specifically examined the possible impact of AVR on glycemic control. Our findings support the hypothesis that resolving AS improves glycemic control in patients with uncontrolled DM. This assumption is based on previous studies suggesting that AS resolution reduces the expression of proinflammatory markers [12], thereby mitigating systemic inflammation, which may, in turn, contribute to improved glycemic regulation [9].

While the patient populations undergoing SAVR and TAVI are inherently diverse, with notable differences in selection criteria for each procedure [26], we sought to address these disparities through propensity score matching. This approach resulted in relatively comparable baseline characteristics between the two groups. In both cohorts, a statistically significant improvement in glycemia was observed. By focusing on patients with uncontrolled diabetes, defined as pre-procedural HbA1c levels above 7 %, our exclusion criteria strengthened the dataset's integrity, allowing for a more precise evaluation of glycemic control in relation to the interventions. Although a reduction in HbA1c was documented in both cohorts, it is important to recognize that the natural progression of DM, coupled with age-related changes in glucose metabolism, may have partially mitigated this effect. The elderly population, due to hormonal shifts and a more sedentary lifestyle, is prone to greater insulin resistance [27] and an increased disruption of glucose homeostasis [28]. Despite these challenges, glycemic control improved in both groups, with nearly 50 % of the total cohort achieving a clinically meaningful reduction [17]. While these findings do not establish a direct causal relationship, they suggest that the resolution of severe AS may influence glycemic regulation. This is clinically significant, as diabetic complications have an exponential relationship with HbA1c levels [29]. Nevertheless, even with this improvement, the glycemic control remained suboptimal and fell short of the guideline-recommended targets for diabetes management [30].

Our findings indicate a more pronounced improvement in glycemic control among TAVI recipients. This difference may be partly explained by prior research showing that open-heart surgery triggers a significantly greater inflammatory response compared to the percutaneous TAVI approach [31]. Moreover, TAVI patients often experience broader

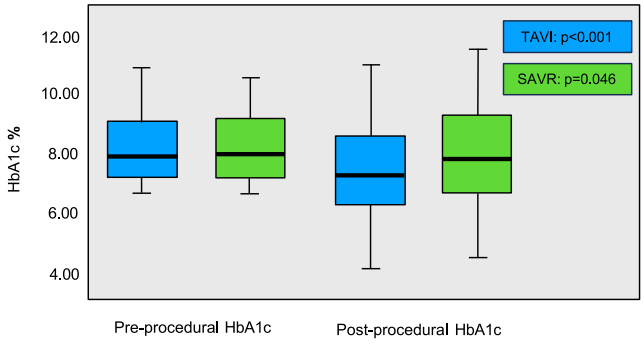

Fig. 3. Glycemic control changes in matched patient groups with hemoglobin A1C (HbA1c) ≥ 7 % undergoing either surgical aortic valve replacement (SAVR) or transcatheter aortic valve implantation (TAVI) for aortic stenosis.

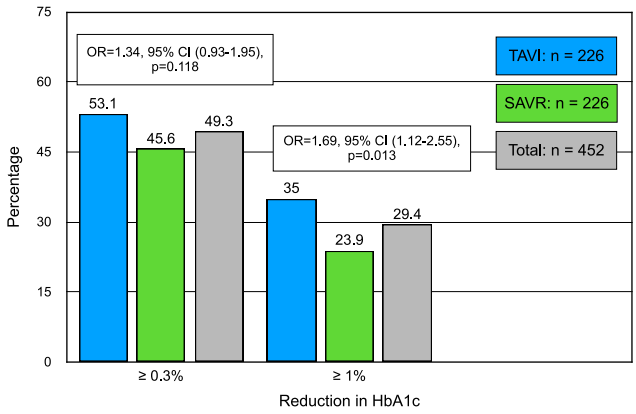

Fig. 4. Comparison of post-procedural HbA1c improvement at clinically meaningful thresholds of the matched cohorts, with data presented as the percentage of subjects. Abbreviations: HbA1c, hemoglobin A1C; TAVI, transcatheter aortic valve implantation; SAVR, surgical aortic valve replacement.

post-procedural benefits, such as better functional status [32], increased 6-minute walk distance [33], improved exercise capacity [34], and enhanced overall quality of life [35]. We believe these collective improvements likely contribute to better glycemic regulation, offering a plausible explanation for the observed differences in post-procedural glycemic outcomes between the two groups.

Several limitations in this observational study are acknowledged. First, inconsistent coding practices across hospitals resulted in technical challenges and the exclusion of a significant number of patients. Second, our reliance on baseline prescription claims to define medication usage, without accounting for dosing or the intensity of anti-diabetic therapies, may not have fully captured changes in treatment during the follow-up period, potentially affecting study outcomes. In addition, while inflammatory markers could have provided further insights, we chose not to include C-reactive protein measurements due to their non-routine use in this clinical context. Finally, TAVI patients may experience a range of broader post-procedural benefits, including improved functional status, which may contribute to better glycemic control. These limitations highlight the need for a prospective study design to capture and evaluate their impact.

In summary, this study, based on real-world clinical data, found that managing severe AS with either TAVI or SAVR led to significant improvement in glycemic control among patients with poorly controlled diabetes. Glycemic control improvement tended to be more pronounced in patients who underwent TAVI. Further investigations through controlled and prospective studies is warrented to provide more conclusive insights.

5. Highlight box

Key findings.

- Management of aortic stenosis, whether surgical or percutaneous, was linked with improved glycemic control in patients with uncontrolled diabetes, with more pronounced improvements observed following TAVI

What is known and what is new?

- Inflammation and diabetes are closely linked, both contributing to the pathogenesis of aortic stenosis, and TAVI has been shown to reduce pro-inflammatory markers.
- In a matched cohort of poorly controlled patients undergoing intervention for aortic stenosis, glycemic control had significantly improved post-procedurally.

What is the implication, and what should change now?

- These findings should be verified in larger prospective studies.

CRediT authorship contribution statement

Yuval Avidan: Writing – review & editing, Writing – original draft, Investigation, Data curation, Conceptualization. **Amir Aker:** Writing – review & editing, Project administration. **Ibrahim Naoum:** Writing – review & editing, Visualization. **Nili Stein:** Methodology, Formal analysis, Data curation. **Sameer Kassem:** Writing – review & editing, Supervision, Conceptualization.

Funding

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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