Prognostic Significance of Hypoalbuminemia in Transcatheter Aortic Valve Implantation Patients: A Systematic Review and Meta Analysis of Diagnostic Test Accuracy

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Abstract

Background:
Calcific aortic stenosis is common in older adults, and TAVR has expanded treatment to patients with high comorbidity and frailty. Serum albumin is an inexpensive marker that reflects inflammation, nutrition, and physiologic reserve, but its prognostic performance in TAVR needs clearer quantification.

Methods:
We performed a PRISMA/PRISMA-DTA–guided systematic review and diagnostic test accuracy meta-analysis of studies evaluating pre-procedural hypoalbuminemia in adults undergoing TAVR/TAVI. PubMed, Embase, and Scopus were searched from inception to 18 January 2026. Hierarchical models were used to pool sensitivity and specificity for 30-day mortality, and a random-effects model pooled hazard ratios for time-to-event mortality. Risk of bias was assessed using PROBAST.

Result:
Ten studies met inclusion criteria. Definitions of hypoalbuminemia varied (most commonly <3.3–3.5 g/dL). For predicting 30-day mortality, pooled sensitivity was 47.7% (95% CI 35.5–59.9) and pooled specificity was 76.0% (95% CI 62.9–89.2), indicating better rule-in than rule-out performance. Across studies reporting time-to-event outcomes, hypoalbuminemia was associated with higher mortality (pooled HR 1.15, 95% CI 1.03–1.29). PROBAST ratings were generally low risk for participants, predictors, and outcomes, with some concerns in the analysis domain.

Conclusions:
Pre-procedural hypoalbuminemia is a practical risk marker in TAVR patients, showing moderate specificity for early mortality and a consistent association with worse survival, supporting its use in peri-procedural risk stratification.

Introduction

Calcific aortic stenosis (AS) is an increasingly common, life-limiting disease in older adults and a major driver of heart-failure symptoms, syncope, and reduced functional capacity.[1] Population data

suggest that among people older than 75 years, AS is present in roughly 12% and severe AS in about 3–4%, making it one of the most frequent clinically significant valve diseases in contemporary practice.[2] Once severe AS becomes symptomatic, prognosis deteriorates rapidly without valve replacement.

Transcatheter aortic valve implantation/replacement (TAVI/TAVR) has transformed management by providing a less invasive alternative to surgical aortic valve replacement, expanding treatment access for elderly and comorbid patients.[3] Procedure volumes have grown dramatically, with >100,000 TAVR procedures in the U.S. in 2023 and estimates around 200,000 procedures globally each year, reflecting broad adoption across health systems.[4,5] Contemporary outcomes are generally favorable yet clinically meaningful early and late adverse events still occur, particularly in patients with frailty, inflammation, renal dysfunction, or limited physiologic reserve. In this context, readily available biomarkers that capture "biologic risk" beyond traditional surgical scores could meaningfully inform Heart Team decision-making and peri-procedural optimization.[6]

Serum albumin is an inexpensive, routinely measured marker that integrates nutritional status, systemic inflammation, hepatic synthetic function, and overall frailty. Hypoalbuminemia is common in older hospitalized cohorts, reported as high as 90% in some geriatric inpatient populations, and remains frequent in other contemporary inpatient samples, supporting its plausibility as a pragmatic risk signal rather than a rare finding.[7,8] Therefore, this study aims to systematically review the evidence and perform a meta-analysis of diagnostic test accuracy to determine whether pre-procedural hypoalbuminemia predicts adverse outcomes after TAVI, including short-term and follow-up mortality and clinically relevant complications, and to clarify how albumin thresholds might be used to strengthen peri-TAVI risk stratification and guide clinically actionable optimization.

Material And Methods

This systematic review and meta-analysis was designed and reported in accordance with the PRISMA 2020 statement and the PRISMA extension for diagnostic test accuracy (PRISMA-DTA).[9] A prespecified methods plan guided the processes of literature searching, study selection, data extraction, and synthesis. No external funding was received for this work.

The clinical question was framed using a PICO approach. The population comprised adult patients with severe aortic stenosis undergoing TAVI or TAVR. The index test was pre-procedural hypoalbuminemia, defined according to each study's prespecified albumin threshold and measured prior to the TAVI procedure. The comparator was normal albumin status or the higher albumin category as defined by the study. Outcomes included clinically relevant post-TAVI endpoints, with priority given to all-cause mortality at 30 days and at the longest available follow-up; additional endpoints were included when consistently reported, such as acute kidney injury, major bleeding, stroke, vascular complications, and rehospitalization. For the diagnostic test accuracy framework, the occurrence of the clinical endpoint within the specified follow-up interval served as the reference standard, and hypoalbuminemia was treated as a binary prognostic "test" for that event.

A systematic search was conducted in PubMed, Embase, and Scopus from database inception to 18 January 2026. Search strategies combined controlled vocabulary and free-text keywords related to transcatheter aortic valve implantation or replacement and albumin (including terms such as "TAVI," "TAVR," "transcatheter aortic valve," "albumin," and "hypoalbuminemia"), along with outcome-related terms (including "mortality," "outcome," "prognosis," and "complications"). Reference lists of included studies and relevant reviews were screened to identify additional eligible studies. Eligible reports included randomized trials, prospective or retrospective cohort studies, and registry-based analyses that enrolled adult

TAVI/TAVR patients, measured baseline serum albumin prior to the procedure, and reported a defined hypoalbuminemia threshold or albumin-stratified groups together with at least one eligible post-procedural endpoint. Studies were excluded if they were case reports, small case series, reviews, editorials, or conference abstracts lacking sufficient data; if they did not allow extraction or derivation of albumin-defined outcome data; or if they were duplicates or overlapping cohorts, in which case the most complete and/or most recent report was retained.

All authors independently screened titles and abstracts followed by full-text review against the eligibility criteria. All authors also independently performed data extraction using a standardized form, capturing study design and setting, patient baseline characteristics and comorbidities, procedural details, timing and definition of albumin measurement and hypoalbuminemia cut-off, follow-up duration, and endpoint definitions. Any disagreements at any stage were resolved through discussion until consensus was reached. For diagnostic test accuracy synthesis, data were extracted or derived to form 2×2 contingency tables for each endpoint and timepoint using hypoalbuminemia as the index test, classifying patients as true positives, false positives, false negatives, or true negatives based on whether the endpoint occurred during follow-up. When multiple albumin thresholds were presented, the primary threshold prespecified by the study was preferentially used for the main analysis, and alternative thresholds were considered in sensitivity analyses when feasible.

Risk of bias was assessed independently by all authors using the PROBAST (Prediction model Risk Of Bias ASsessment Tool), evaluating the domains of participants, predictors, outcome, and analysis, with discrepancies resolved through discussion. These assessments were used to inform sensitivity analyses, including analyses restricted to studies judged to have lower risk of bias by PROBAST criteria.

Statistical analyses were conducted in RStudio using R, specifically R version 4.5.2 and RStudio 2026.01 (Apple Blossom; 2026.01.0+392). A meta-analysis of diagnostic test accuracy was performed to estimate pooled prognostic performance of hypoalbuminemia for each binary endpoint. Summary sensitivity and specificity were obtained using hierarchical models appropriate for DTA, with results displayed using hierarchical summary receiver operating characteristic (HSROC) methods. Additionally, we pooled Hazard Ratios (HR) to evaluate the prognostic impact of hypoalbuminemia on time-to-event outcomes. These prognostic effect sizes were synthesized using a random-effects model to account for anticipated between-study heterogeneity. The between-study variance was estimated using the DerSimonian-Laird estimator. Furthermore, 95% confidence intervals and test statistics were computed using the Wald-type method. The primary implementation used the mada package (version 0.5.12) for DTA/HSROC modeling, with additional analyses and visualizations supported, when required, by metafor (version 4.8-0) and meta (version 8.2-1). Clinical and methodological heterogeneity was examined by considering differences in hypoalbuminemia definitions and thresholds, timing of albumin measurement, baseline risk profiles, valve era, and follow-up horizons.

Result

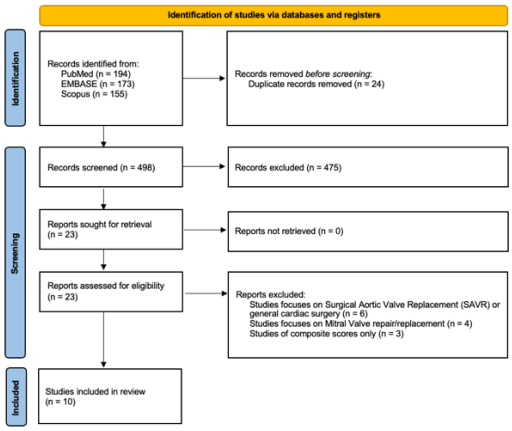

Figure 1. PRISMA diagram.

As summarized in the PRISMA flow diagram, we identified 522 records across PubMed (n = 194), EMBASE (n = 173), and Scopus (n = 155). After removing duplicates (n = 24), we screened 498 records and excluded 475 at the title/abstract stage, leaving 23 reports to retrieve—none were missing (n = 0). We then assessed 23 full texts for eligibility and excluded 13 for clear reasons: the focus was on surgical aortic valve replacement (SAVR) or general cardiac surgery (n = 6), mitral valve repair/replacement (n = 4), or reporting composite scores only (n = 3). In the end, 10 studies met the criteria and were included in the review (Figure 1).[10–19]

Table 1. Characteristics, Mortality Outcomes, and Key Findings of Included Studies

Author, Year	Country	Study Design	n (Sample Size)	Mean Age (Years)	Male (%)	Follow-up	Low Albumin Cut-off / Definition	Key Findings
Bogdan et al. (2016)	Israel	Retrospective cohort	150	81	39	25 months	≤ 4 g/dL (Mean: 3.67 ± 0.29)	Low baseline albumin was an independent predictor of long-term mortality, with a significant survival difference between low and normal albumin groups.
Chauhan et al. (2016)	USA	Retrospective cohort	342	81.8	47.7	14.9 months	< 3.5 g/dL	Hypoalbuminemia was strongly associated with increased 1-year mortality and bleeding events, serving as a valuable marker for frailty in TAVR patients.
Green et al. (2015)	USA	Prospective cohort	244	86	51	12 months	Per 0.1 g/dL decrease < 3.5 g/dL	Pre-procedure albumin levels independently predicted 1-year mortality, with lower levels associated with significantly higher risk of death.
Grossman et al. (2017)	Israel	Retrospective study	426	83.8	45	12 months	4 g/dL	Adding serum albumin to the TAVR risk score significantly improved the prediction of 1-year mortality compared to using the risk score alone.
Hermiller et al. (2016)	USA	Retrospective cohort	3687	83.3	53.7	12 months	< 3.3 g/dL	Hypoalbuminemia was a powerful independent predictor of both 30-day and 1-year mortality, outperforming BMI as a prognostic marker.
Kappetein et al. (2012)	USA	Prospective cohort	159	86	50	12 months	3.8 g/dL (Quartiles); Per 0.1 g/dL decrease < 3.5 g/dL	Lower baseline albumin levels were significantly associated with increased all-cause mortality at 1 year after TAVR.
Koifman et al. (2015)	USA	Retrospective cohort	476	84	83	12 months	Per 0.1 g/dL decrease < 3.5 g/dL	Hypoalbuminemia was independently associated with increased 1-year mortality and acute kidney injury following TAVR.
Osnabrugge et al. (2015)	USA	Retrospective cohort	471	84	49.1	12 months	< 3.3 g/dL	Preoperative anemia and low albumin were identified as simple, independent prognostic markers for early and late mortality after TAVR.
Rodriguez-Pascual et al. (2016)	Spain	Prospective cohort	109	83	42.2	24.5 months	Per 0.1 g/dL decrease < 3.3 g/dL	Low serum albumin was a significant predictor of mortality in elderly patients undergoing TAVR, reflecting nutritional and inflammatory status.
Yamamoto et al. (2017)	Japan	Prospective cohort	1215	84.4	29.7	12 months	< 3.5 g/dL	Hypoalbuminemia was consistently associated with higher mortality risk at 30 days and 1 year, regardless of the transcatheter approach used.

Across the included TAVR/TAVI studies, baseline serum albumin showed up again and again as a simple but meaningful prognostic marker: patients with hypoalbuminemia (most often defined around < 3.3–3.5 g/dL, with some studies using ≤ 4.0 g/dL or modeling risk per 0.1 g/dL decrease) consistently had worse survival and higher adverse-event risk after the procedure. The evidence came from a mix of retrospective and prospective cohorts across several countries (including the USA, Israel, Spain, and Japan), with sample sizes ranging from just over a hundred patients to several thousand and follow-up typically around 12 months (and up to 25 months in one study). While the exact outcome windows varied, the overall message was consistent: lower pre-procedure albumin independently predicted higher 30-day and/or 1-year mortality, and in some cohorts it also tracked with complications like bleeding events or acute kidney injury. One study even showed that adding albumin to an existing TAVR risk score improved prediction compared with the risk score alone, reinforcing the idea that albumin can add clinically useful information beyond standard variables (Table 1).

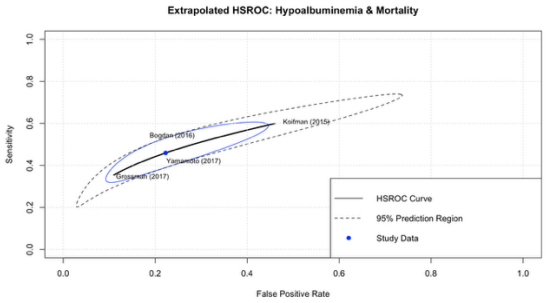

Figure 2. HSROC of low blood albumin level predicting mortality within 30 days.

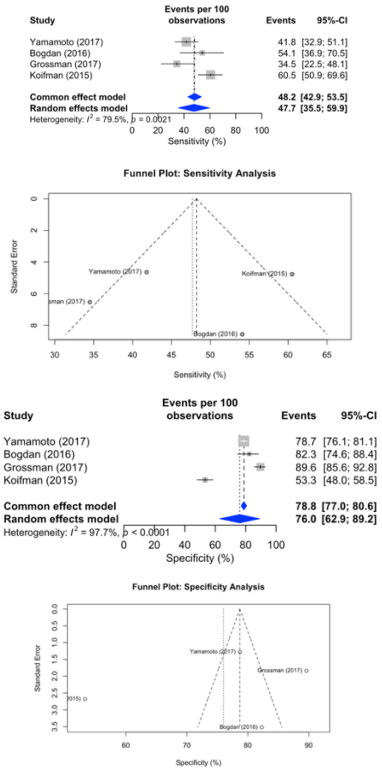

Figure 3. Meta-analysis for sensitivity and specificity.

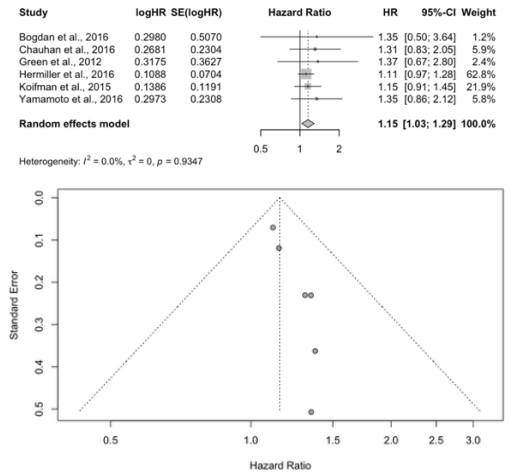

Figure 4. Meta-analysis of pooled HR for each reported study.

Across the diagnostic test accuracy meta-analysis, low serum albumin showed moderate sensitivity for identifying 30-day mortality after TAVR, with a random-effects pooled sensitivity of 47.7% (95% CI 35.5–59.9) (Figure 3). In contrast, specificity was higher, with a random-effects pooled specificity of 76.0% (95% CI 62.9–89.2), suggesting low albumin is better at "ruling in" higher risk than it is at catching every event (Figure 3). The HSROC plot visually matches this pattern, with study points clustering around modest sensitivity and moderate-to-good specificity and a fairly wide prediction region (Figure 2). When we pooled time-to-event data, hypoalbuminemia was associated with significantly worse survival, with a random-effects pooled hazard ratio (HR) of 1.15 (95% CI 1.03–1.29) (Figure 4).

Overall, PROBAST suggested low risk of bias across most domains, with Participants, Predictors, and Outcome consistently rated low risk for all included studies (Table 2). The main concern was the Analysis domain, which was rated high risk in Bogdan (2016), Green (2015), Kappetein (2012), and Rodríguez-Pascual (2016).

Table 2. PROBAST risk of bias

Study	Participants	Predictors	Outcome	Analysis	Overall
Bogdan et al. (2016)	Low	Low	Low	High	High
Chauhan et al. (2016)	Low	Low	Low	Low	Low
Goldfarb et al. (2017)	Low	Low	Low	Low	Low
Green et al. (2015)	Low	Low	Low	High	High
Grossman et al. (2017)	Low	Low	Low	Low	Low
Hermiller et al. (2016)	Low	Low	Low	Low	Low
Kappetein et al. (2012)	Low	Low	Low	High	High
Koifman et al. (2015)	Low	Low	Low	Low	Low
Osnabrugge et al. (2015)	Low	Low	Low	Low	Low
Rodríguez-Pascual et al. (2016)	Low	Low	Low	High	High
Yamamoto et al. (2017)	Low	Low	Low	Low	Low

Discussion

Hypoalbuminemia came through as a consistent, clinically meaningful risk signal in TAVR patients, and the direction of the association fits what we see at the bedside: lower baseline albumin tracked with higher short- and longer-term mortality, with a modest but statistically significant pooled increase in risk (HR 1.15, 95% CI 1.03–1.29). Albumin is not simply a "nutrition number." In older, high-comorbidity TAVR populations, it often reflects the combined burden of systemic inflammation, catabolic stress, hepatic congestion, renal loss, and overall physiologic reserve.[20,21] In that sense, low albumin functions as a global marker of vulnerability, exactly the kind of baseline fragility that can shape outcomes after a major hemodynamic intervention.[22]

There are also several cardiology-based mechanisms that plausibly connect low albumin to worse post-TAVR outcomes. Reduced oncotic pressure can promote interstitial edema and worsen pulmonary congestion, which matters in patients with limited diastolic reserve or borderline volume status where small shifts

can precipitate heart failure symptoms.[23] Hypoalbuminemia also tends to cluster with chronic inflammation and endothelial dysfunction, which may impair microvascular perfusion and recovery, and it correlates with higher susceptibility to acute kidney injury, particularly relevant around contrast exposure, peri-procedural hypotension, and medication changes.[24] Finally, low albumin often travels with sarcopenia and frailty, which can blunt the ability to mobilize, rehabilitate, and compensate after the physiologic stress of TAVR even when the valve result itself is excellent.

The diagnostic accuracy results help clarify how to use albumin clinically: low albumin had moderate specificity but limited sensitivity for predicting early mortality (pooled specificity 76.0% [62.9–89.2] vs pooled sensitivity 47.7% [35.5–59.9]). Practically, that means hypoalbuminemia shouldn't be treated as a screening tool to "rule out" risk, but when it is present it does add weight to a higher-risk phenotype. This aligns with the idea that many early adverse outcomes can occur without low albumin (e.g., procedural complications), but low albumin identifies a subset with reduced reserve who may be less able to tolerate peri-procedural stress and more prone to downstream decompensation.[25,26] In real-world workflows, albumin can be used as a simple flag to prompt deeper frailty assessment, tighter congestion/volume evaluation, renal protection planning, and more deliberate post-procedure monitoring and rehab planning.[26]

Limitations of this work are important. Most included studies were observational, albumin thresholds and measurement timing varied, and there was meaningful between-study heterogeneity in the diagnostic accuracy analyses, likely reflecting differences in populations, comorbidity burden, and how outcomes were defined and adjusted for. Only a small number of studies contributed to some pooled estimates, which makes the results more sensitive to individual study effects and reduces confidence in publication-bias assessments. While overall risk of bias was generally low in several domains, multiple studies had higher concerns related to analysis methods, raising the possibility of residual confounding or inconsistent covariate handling. Also, albumin is influenced by non-cardiac factors (infection, liver disease, malignancy, protein-losing states), so it may partly proxy broader illness severity rather than serving as a direct causal driver.

Conclusion

Baseline albumin appears to be a practical, low-cost marker that adds meaningful prognostic information in TAVR patients: hypoalbuminemia is associated with higher mortality risk and has enough specificity to be clinically useful for risk stratification. The most actionable takeaway is to treat low albumin as a "high-risk alert" that should trigger a more comprehensive evaluation of frailty, congestion, renal/hepatic reserve, and inflammatory/nutritional status, rather than using it in isolation. Future studies should standardize albumin cutoffs and timing, test incremental value over established TAVR risk tools in prospective cohorts, and—most importantly.

Acknowledgment

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Author's Statement

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