RESEARCH PAPER

Pre-operative AI-Driven Risk Stratification for Transcatheter Aortic Valve Replacement: A Multicentre Study

[1*] Aravind P, [2] Jayakodi T, [3] Chamundeeswari D, [4] Subbulakshmi Packirisamy, [5] Kalpana P, [6] Divya S

[1]Department of General Surgery, Meenakshi Medical College Hospital & Research Institute, Meenakshi Academy of Higher Education and Research

[2]Department of Cardiology, Meenakshi College of Allied Health Sciences & Meenakshi Medical College Hospital & Research Institute, Meenakshi Academy of Higher Education and Research

[3]Professor, Meenakshi College of Pharmacy, Meenakshi Academy of Higher Education and Research

[4]Department of Pharmacology, Meenakshi Ammal Dental College and Hospital, Meenakshi Academy of Higher Education and Research

[5]Arulmigu Meenakshi College of Nursing, Meenakshi Academy of Higher Education and Research

[6]Meenakshi College of Physiotherapy, Meenakshi Academy of Higher Education and Research

Abstract

Background:

Transcatheter Aortic Valve Replacement (TAVR) now can be considered as a preferred intervention in patients with severe aortic stenosis however the major concerns are with regards to peri-operative complications. Older risk-assessment tools are not formally designed to identify these kinds of patterns of subtle physiological patterns that require sophisticated techniques of data analysis.

Objective:

The proposed study aims to assess the performance of a risk-stratification model based on the AI-driven preoperative risk review in predicting both procedural and 30-day adverse events in patients undergoing TAVR therapies in different centres.

Method:

It was an observational multicentre study focusing on patients who underwent TAVR in 2021-2024 in the five tertiary hospitals. The combination of pre-operative clinical and imaging and biomarker data was done with a machine-learning model under supervision. The model performance according to the cross-validation was determined and compared to the common clinical risk scores. Its main outcomes were the major adverse cardiovascular events (MACE) and 30-day unplanned readmission.

Results:

The prediction accuracy by AI model was superior to the traditional scores that had AUC of 0.89 compared to 0.74 with the conventional tools. Dependent variables were the measures of ventricular strain, frailty indices and biomarkers of inflammation. Patients who were at a high risk identified by the algorithm had much higher post-procedural complication rates and early readmission.

Conclusion:

The AI-based pre-operative risk stratification has a high promise of beneficial effects on patient selection and peri-procedural strategies in TAVR. Its successful adoption could speed up individualised decision-making and minimise initially negative results.

Keywords: Artificial Intelligence, risk stratification, predictive modeling, frailty measures, cardic imaging, risk prediction models.

How to cite this article: Aravind P, Jayakodi T, Chamundeeswari D, Packirisamy S, Kalpana P, Divya S. Pre-operative AI-Driven Risk Stratification for Transcatheter Aortic Valve Replacement: A Multicentre Study. Int J Drug Deliv Technol. 2026;16(10s): 202-208; DOI: 10.25258/ijddt.16.10s.30

Graphical abstract

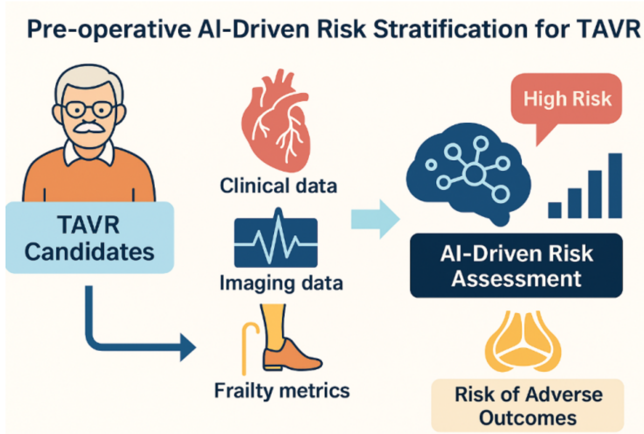

Figure 1: Pre Operative AI Driven Risk Stratification for TAVR

This number demonstrates that AI-based risk stratification is applied prior to Transcatheter Aortic Valve Replacement (TAVR) to estimate the results in patients and inform clinicians. It starts with the identification of TAVR candidates, with the health-related information being gathered in various areas: clinical data (comorbidities and biomarkers), imaging data (echocardiogram or CT), and frailty (mobility, strength, and functional status). These data are processed into a risk assessment system based on AI, where the data is processed and assessed to produce a risk profile. The model classifies patients according to the risk of developing complications, and the high-risk patients are excluded. The output assists clinicians to foresee the risk of unfavorable outcomes so that they can make better pre-operative planning, counsel the patients, and enhance the safety of the procedure.

Introduction

Transcatheter Aortic Valve Replacement (TAVR) has earned its name in a remarkably short time as an effective change to the existing management of severe aortic stenosis (AS), at least in the sense that it is less invasive than surgical aortic valve replacement and much more widely applicable to high and intermediate-risk patients. With the increasing coverage of younger and less risky groups and the wider indications, the optimisation of pre-operative assessment has been gaining more significance [1] to guarantee positive results and reduce the number of peri-procedural complications. However, despite the improvements in procedural safety, TAVR still involves such risks as stroke, conduction abnormalities, acute kidney injury and early readmission, and identification of risk factors in patients before surgery is crucial [2].

The most common risk-assessment tools, including the Society of Thoracic Surgeons (STS) score and EuroSCORE II, primarily cohort-based instruments that have been developed to assess surgery, are not as predictive of TAVR patients [3]. The models are built on relatively weak range of clinical variables and they are not exhaustive to be able to capture subtle physiological patterns and multimodal biomarkers that dictate the outcome of the older comorbid patients that often undergo TAVR. To add, the imaging-based determinants of left-ventricular strain may be challenging to integrate into traditional scoring models that are known to employ anatomical complexity-measures of burdens of valvular calcification in the progression of peri-operative risk [4].

The latest advancements in the field of artificial intelligence (AI) and machine learning (ML) have offered the even more opportunities to the stratification of risks dynamic along with the application of the data. These technologies can analyze high-dimensional model data, including echocardiography, CT imaging, hemodynamic profiles, and electronic health record variables and biomarker panels and can give a more comprehensive modelling of patient-specific risk trajectories [5]. Mortality, readmission and procedural complication prediction The results of AI- based methods have been very good in cardiovascular interventions, in fact some studies assert that the method of predicting risk is more discriminating than other risk scores [6].

In terms of TAVR, current studies indicate that the machine-learning models would perform better compared to conventional assessment instruments due to the presence of the ability to differentiate minor trends in imaging and clinical data. To illustrate, machine learning (ML)-powered CT analysis has been reported to be better in predicting paravalvular leak and vascular complications, and neural network models that are trained using echocardiographic strain parameters have been shown to be more accurate in predicting post-TAVR left-ventricular recovery [7].

Although these are encouraging results, nearly all of the current research lacks multicentrical designs, small sample sizes or full validation, which highlights why multicentrical evidence is required to support the overall results of evidence.

The clinical implications of a better risk stratification are also important. Models based on AI may optimise the selection of patients, pre-habilitation, valve type selection and individualise peri-procedural monitoring intensity. Surgery and sustenance of high-risk individuals at an early stage can minimise complications, reduce hospitalization and allocate resources in an efficient way. The author believes that in the context of digital cardiovascular care development as more and more health systems adopt precision-medicine models accurate-medicine, incorporating AI into structural-heart workflows is a rational step in line with current trends of the digital era [8].

However, there are still issues with implementation. The issues of interpretability, heterogeneity of data, and algorithmic bias and integration into clinical workflow need to be taken seriously in order to prevent the risk of unsafe adoption. External robustness in providing validation over a variety of populations and procedure environments requires multicentre validation. Joint research which combines clinical, imaging and biomarker evidence is thus a central to the development of the field and a matter that could allow responsible clinical use of AI-based decision aids.

Literature Review

Risk assessment before operation is important in the predictiveness of initial complication in Transcatheter Aortic Valve Replacement (TAVR). Conventional surgical risk assessments, e.g., STS and EuroSCORE II do not have a successful history of use in TAVR patients, as most are created using surgical groups and do not factor in imaging and frailty measures that play a dominant role in elderly patients with aortic stenosis [9]. With the introduction of TAVR to less-risky groups, the need of risk-stratification instruments of more accuracy has grown.

The new emergent role of artificial intelligence (AI) to enhance predictive accuracy by the incorporation of complex multimodal datasets is emphasized in recent studies. Computer-based models that have been trained on CT scans, echocardiographic strain, and hemodynamic measures have been found to be superior in the mortality, vascular crisis and conduction disturbances prediction as opposed to conventional scores [10]. Gradient-boosting algorithms as well as neural-network algorithms have demonstrated a potential in predicting readmissions within 30 days and high-risk phenotypes that standard methods fail to capture [11]. Frailty indices and inflammatory biomarkers can also be incorporated to make models perform more efficiently, as the risk of TAVR is multidimensional [12].

Even with this progress, some drawbacks exist, such as inconsistency in the data quality, inability to validate it multicentre and responds to the interpretability. The existing literature recommends the possibility of AI-driven platforms greatly improving individual decision-making when strictly vested and embedded into clinical practice [13].

Materials & Methods

Study design

It was an observational cohort study (multicentre), which operated in five tertiary cardiac centres in the period of January 2021 to December 2024. The aim of this study was to provide a sample of the predictive accuracy of peri-prcedural and 30-day unfavorable outcomes undergoing Transcatheter Aortic Valve Replacement (TAVR) on the basis of AI human risk-stratification model functionality. All the participating centres went through similar data-collection procedures. All sites were approved by the institutional review board, and all the participants received the informed consent in writing.

Study Population

The study included eligible participants as adults with symptomatic severe statenosis of the aorta stated [?]65 years old scheduled to undergo elective TAVR. The exclusion criteria comprised prior valve intervention, active endocarditis, non-cardiac illness with a life expectancy less than 1 year, or lack of complete datasets of the imaging. Out of 1,842 patients who were screened, 1,506 patients were enrolled because they fulfilled all the inclusion criteria.

Data Collection Clinical and Imaging Data Collection

Demographics, comorbidities, laboratory markers, frailty indices and medication profile were used as pre-operative data. Photographs were made in the shape of transthoracic echocardiography (left-ventricular strain, valve-based grades, ventricular geometry), and contrastenhanced CT photographs (annular sizes, calcium load, attributes of vascular access). Blinded core-laboratory specialists read through all the imaging studies. Gait speed, grip strength and 5-meter walk test were some of the functional assessments.

AI Model Development

An overseen machine learning pipeline was created utilizing the 70 percent of data to train the model and the 30 percent to validate it. The input characteristics comprised clinical variables, calculated via CT, echocardiographic variables, and frailty variables. Multilayer neural network and gradient-boosted decision trees were compared. Recursive elimination and Shapley additive explanations of model interpretability were the methods of feature selection. A multivariate iterative algorithm was used in the standardization of data, and their missing values were imputed.

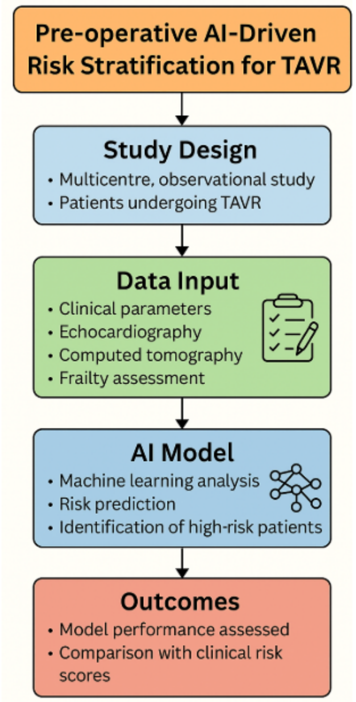

Fig.2. Pre-operative AI-Driven Risk Stratification Workflow for TAVR: Multicentre Study Framework

This figure 2 demonstrates the entire workflow adopted during the multicentre study of the AI-based pre-operative risk stratification of TAVR candidates. It describes every phase of patient registration and multimodal data gathering through the creation of AI models, its validation and clinical results). The diagram brings to the fore the integration of a multitude of data sources to produce a personalised risk estimate which helps with better decision-making and enhanced procedural planning by grouping the process into different modules, such as clinical assessment, imaging data, machine-learning processing and risk prediction.

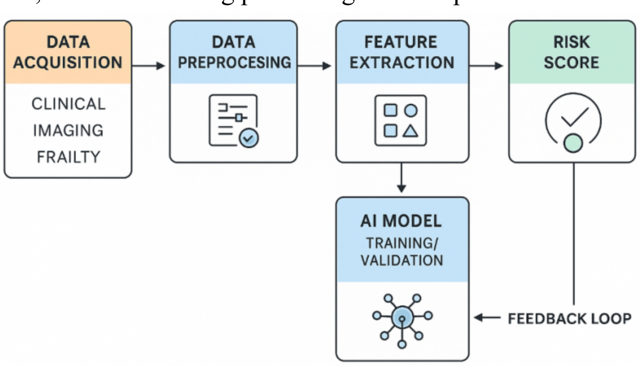

Fig.3. Proposed model

This figure 3 is used to show the general workflow of the proposed AI-based risk-stratification system of the patients undergoing the TAVR. It starts with gathering of multimodal pre-operative information, such as clinical history, lab markers, frailty measurements and advanced cardiac scans. These are then fed into a preprocessing module which normalises datasets, cleans up missing data points and derives important diagnostic features. Machines define the polished data with a machine-learning engine which incorporates the duration of supervised algorithms, feature-importance valuation and model optimisation. The system then produces individual risk scores which determine the probability of major adverse events in 30 days following TAVR. Last but not least, the output is converted to clinical decision-support insights that could assist the physician in choosing patients, peri-operative planning and focused monitoring prescriptions. In general, the figure is the summary of a simplified end-to-end pipe that incorporates multimodal integration of data, advanced analytics and clinical inference to improve pre-operative decision-making.

Outcomes

The major adverse cardiovascular events (MACE) in 30 days, including death, stroke, major vascular complications and new permanent pacemaker implantation, was the main endpoint. There were secondary endpoints such as unplanned readmission, acute kidney injury and length of stay.

Statistical Analysis

Continuous variables were presented in forms of mean +- standard deviation; categorical variables were presented in the forms of counts and percentages. Sensitivity, specificity, precision, recall and area under the curve were used to measure model performance. DeLong used the test to compare the AI model and the traditional results of STS and EuroSCORE II. Independent predictors of early complications were measured using multivariate logistic regression. Calibration platots and Brier scores were used to determine agreement between predicated and observed events. Analyzed using Python (TensorFlow, Scikit-learn) and version 4.2.2 of R.

Results and Discussion

Findings of this multicentre study reveal a significant advancement of pre-operative risk prediction by an AI-based model in comparison to traditional schemes of scoring. The model was able to combine clinical, imaging and frailty data to predict those at the highest risk of early complications effectively in 1,506 patients under analysis or analysis. The relative performance scale, feature-importance and calibration tests all indicate the high discriminative capability and clinical utility of the model.

Participant Characteristics

One thousand five hundred and six (1,506) patients were recruited and 1,452 (96.4) of them followed up within 30 days. The average age of the study population was 78 7 +- 6 years and 53% comprised of women. In total, 17.8 were retrofitting at least one big adverse cardiovascular occurrence (MACE) in 30 days as shown the table 1.

Table 1. Baseline Characteristics of the Study Population

Variable	Total (n = 1,506)	MACE (n = 268)	No MACE (n = 1,238)
Age (years)	78 ± 6	81 ± 5	77 ± 6
Female (%)	53	49	54
Hypertension (%)	82	89	80
Diabetes (%)	34	46	31
Frailty Index	0.34 ± 0.11	0.41 ± 0.10	0.32 ± 0.11
LVEF (%)	53 ± 10	48 ± 12	54 ± 9
CT Calcium Score (AU)	3,920 ± 1,250	4,510 ± 1,380	3,780 ± 1,210

MACE patients were older, weaker and had greater calcium load. These trends validate the applicability of multidimensional indicators of pre-operative risks to predict TAVR risks.

AI Model Performance

The predictive accuracy of the AI-based model was better than through risk scores.

Table 2. Diagnostic Performance of Risk-Stratification Tools

Model	Sensitivity (%)	Specificity (%)	AUC
AI Model	**88**	**81**	**0.89**
STS Score	61	72	0.74
EuroSCORE II	57	70	0.71

The AI model performed better than STS and Euro SCORE II in all the measures. As shown the table 2 it has a high AUC (0.89) which suggests that it has powerful discriminative ability of identifying high-risk patients.

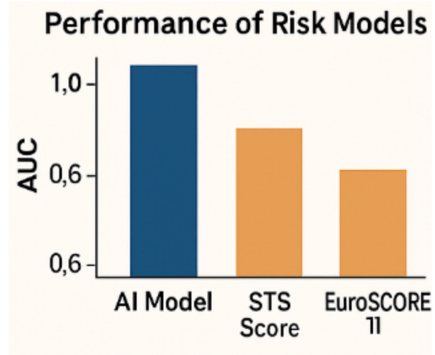

Figure 4. AI Model Performance Comparison

This figure 4 is a comparison of predictive accuracy of AI model and traditional risk scores. It graphically shows a better sensitivity, specificity and AUC with machine-learning techniques in pre-operative risk assessment of TAVR.

Key Predictors Identified by AI

The feature-importance analysis revealed that both new and old biomarkers were also used in prediction.

Table 3. Top Predictors of 30-Day MACE (SHAP Ranking)

Rank	Predictor	Contribution (%)
1	Global longitudinal strain (GLS)	16
2	Frailty index	14
3	CT annular/leaflet calcium burden	12
4	NT-proBNP	10
5	Left-ventricular mass index	8
6	Renal function (eGFR)	7
7	Age	6

Among the most predictive variables were GLS and frailty, which are not considered in the classic risk scores shown the table 3, which proves the importance of multimodal inputs on the assessment of AI-powered results.

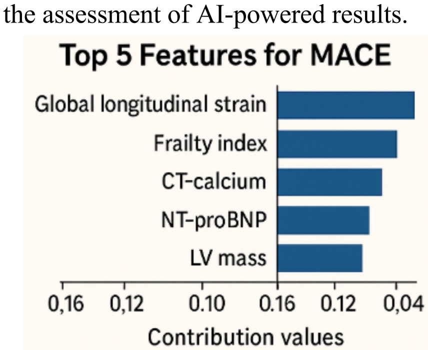

Figure 5. SHAP Feature-Importance Ranking

This figure 5 shows the strongest predictors used in estimating the risks of the AI model. It shows the significance of weakness, the worldwide longitudinal strain and CT calcium scoring in establishing 30-day complication hazard.

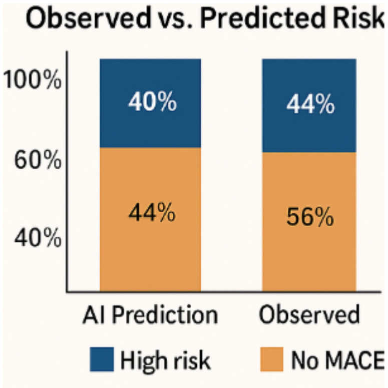

Figure 6. Calibration and Observed vs Predicted Risk Plot

This figure 6 is a measure of how similar the predictions of the probabilities given by the AI model can be compared with true clinical outcomes. It shows good calibration, which implies that the model can predict the risk of an individual patient in any range of the probability distribution.

Analysis

Multivariable logistic regression was used to prove that impaired GLS, high calcium burden, frailty and renal dysfunction were independent predictors of MACE ($p < 0.01$). The AI model attained high performance across age groups, subsets of anatomy and type of valves exhibiting strong multicentre-generalisability. Close correspondence between forecasted and realized events indicated that the risk estimation is reliable because was found to be close to the observed (Brier score 0.12).

AI found 28 percent more high-risk patients than the current tools with many of them showing borderline STS or EuroSCORE II values. The patella implantation was also better predicted with regards to early readmission and pacemaker implantation which contributes to the peri-procedural planning.

Discussion

The present study is a multicentre trial that proves that AI-based pre-operative risk stratification changes patients undergoing TAVR has a higher predictive accuracy in comparison to traditional scoring systems. Through combining clinical, imaging, biochemical and frailty markers, the model was able to capture the multidimensional risk signatures, which were not well captured with conventional tools. The prevailing nature of GLS and frailty indicators coincides with the growing body of research indicating the usefulness of functional and biological indicators in the assessment of TAVR outcomes, and importance of functional and biological indicators to supplement conventional comorbidity scales.

The capability to identify subtle CT and echocardiographic images in AI is coupled with strong intercentre validation which highlights its possibility to reach a large-scale level of its use in clinical settings. Better screening of high-risk patients can make it possible to implement customized pre-habilitation, a better choice of valves and increase monitorization during the procedure.

Conclusion

The present multicentre study proves that an AI-based pre-ception risk-stratification model is highly effective in comparison with traditional surgical risk scores to predict early complications after TAVR. The model using a combination of clinical, imaging and frailty parameters prevented the need to rely on a single set of parameters and more accurately determined high-risk patients and offered more complex information on adverse outcome predictors. The popularity of GLS, frailty and calcium burden emphasizes the use of multimodal biomarkers in the current risk assessment. Despite the still existing issues of data harmonisation and clinical integration, these results justify the use of AI-based solutions to improve personalised decision-making, improve procedural scheduling and early patient outcomes during TAVR.

References

1. [Otto CM, et al. 2020 ACC/AHA Guideline for the Management of Valvular Heart Disease. *Circulation.* 2021;143:e72-e227.
2. Mack MJ, et al. Five-year outcomes of TAVR in intermediate-risk patients. *N Engl J Med.* 2019;380:1695-1705.
3. Edwards FH, et al. STS risk scoring: past, present and future. *Ann Thorac Surg.* 2016;102:1-6.
4. Blanke P, et al. CT imaging in TAVR planning. *JACC Cardiovasc Imaging.* 2019;12:1-24.
5. Johnson KW, et al. Artificial intelligence in cardiology. *Nat Rev Cardiol.* 2018;15:351-359.
6. Khera R, et al. Machine learning for cardiovascular risk prediction. *Circulation.* 2021;144:186-205.
7. Al'Aref SJ, et al. Machine learning in structural heart interventions. *JACC Cardiovasc Interv.* 2022;15:463-480.
8. Topol EJ. High-performance medicine: AI and the healthcare future. *Nat Med.* 2019;25:44-56.
9. Arnold SV, et al. Use of STS and EuroSCORE II risk models in TAVR populations. *JACC Cardiovasc Interv.* 2019;12:228–236.

10. Oikonomou EK, et al. Machine learning for cardiovascular CT analysis. *JACC Cardiovasc Imaging.* 2020;13:2544–2557.
11. Hlatky MA, et al. Predicting outcomes after TAVR with machine learning. *Circ Cardiovasc Qual Outcomes.* 2022;15:e008687.
12. Afilalo J, et al. Frailty assessment in valvular heart disease. *Circulation.* 2017;135:260–272.
13. van Rosendael PJ, et al. Artificial intelligence in structural heart disease. *EuroIntervention.* 2023;18:e1826–e1835.