

# The Role Of Artificial Intelligence In Pre-Procedural Planning For Transcatheter Aortic Valve Implantation (TAVI): A Review

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## Abstract

**Background/Objectives:** Transcatheter aortic valve implantation (TAVI) has grown to be a lifechanging, little invasive therapy for individuals with significant aortic stenosis at high or impractical surgical risk. To reduce technical problems, guide device selection, and maximize clinical results, excellent pre-procedural preparation is necessary. This systematic review aims to assess the present function of artificial intelligence (AI) in improving several elements of TAVI planning, including anatomical segmentation, valve sizing, risk stratification, and outcome prediction.

**Methods:** Peer reviewed papers published between 2023 and 2025 were found in PubMed, Scopus, and IEEE Xplore using a thorough literature search. Studies using artificial intelligence including ML or DL to aid TAVI planning operations like image-based anatomical assessment, computational modeling, or clinical outcome prediction were included. Ten high-quality studies were chosen based on predetermined inclusion criteria and PRISMA criteria.

**Results:** Most often used artificial intelligence techniques were convolutional neural networks (CNNs), UNet architectures, and Support Vector Machines (SVMs). While predictive models for post-TAVI complications recorded AUCROC values ranging from 0.85 to 0.95, segmentation models achieved Dice Similarity Coefficients >0.90 and mean surface distances <1 mm. Numerous tools, DeepCarve included, showed clinically relevant processing rates and high agreement with expert assessments. Consistently reducing interobserver variance and increasing planning efficiency, AI systems.

**Conclusions:** Faster, more accurate, and repeatable decision support that AI provides is quickly enhancing TAVI preprocedural planning. However, broader clinical translation calls for prospective validation, regulatory clarity, and better model interpretation. With ongoing interdisciplinary cooperation, artificial intelligence has the potential to considerably improve precision and safety in TAVI planning.

**Keywords:** Artificial Intelligence; Transcatheter Aortic Valve Implantation; Pre-procedural Planning; Deep Learning; Medical Imaging; Risk Prediction; Machine Learning; Image Segmentation; Clinical Decision Support; Explainable AI.

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## 1. INTRODUCTION

Among the most frequent and life-threatening valvular heart issues, aortic stenosis (AS) especially afflicts elderly people. AS is distinguished by progressive calcification and narrowing of the aortic valve, which lowers cardiac output and results in dyspnea, angina, and syncope. Without prompt intervention, severe symptomatic AS has a one-year mortality rate close to 50%, stressing the need for precise diagnosis and efficient treatment approaches [1], [2].

Given rising life expectancy everywhere, the load of AS is projected to soar. Around 4.6% of people 75 years old and older are afflicted; globally, about 3.4 million have severe symptomatic forms of illness. This population change (see Table 1) puts increasing strain on healthcare systems to provide scalable, safe, and cost-efficient treatments for elderly and comorbid patients. Particularly in high and medium-risk populations [3], [4], Transcatheter Aortic Valve Implantation (TAVI) has arisen in response as a transformative, less invasive option to SAVR.

**Table 1.** Aortic Stenosis and TAVI Global Trends Utilization.

Parameter	Value/Estimate	Source/Notes
Global prevalence of AS in individuals $\geq 75$ years	$\sim 4.6\%$	Population-based echocardiographic studies (2023)
Symptomatic severe AS ( $\geq 75$ years)	$\sim 3.4$ million individuals worldwide	Estimated by 2024 registry data
Untreated mortality rate (1 year)	$\sim 50\%$	ESC/EACTS Valvular Heart Disease Guidelines (2023)
Annual TAVI procedures globally (2025 est.)	$> 300,000$	Exponential growth from $\sim 180,000$ in 2020
TAVI adoption in intermediate/low-risk patients	45–60% (varies by region)	Increased guideline-based expansion (ACC/AHA 2024 updates)
TAVI-related mortality at 30 days	2.5–4.0%	Depending on center experience and patient risk profile
Average hospital stays (TAVI vs. SAVR)	3.1 vs. 6.7 days	Multicenter cohort study (2024)

From its first inhumane use in 2002, TAVI has grown from a backup choice for inoperable patients to a guideline-endorsed treatment appropriate for a wide range of risk classes [5]. By 2025, yearly worldwide TAVI surgeries are expected to reach 300,000, with increasing indications including low-risk patients as well (Table 1). In terms of mortality, functional recovery, and length of hospital stay [6], clinical trials and registry data have proven that TAVI offers results equal or, in some cohorts, better than SAVR.

Because intraoperative flexibility is limited compared to open surgery, the minimal invasiveness of TAVI requires exact preprocedural preparation. Good outcomes and prevention of problems including paravalvular leak, annular rupture, and coronary obstruction depend on exact assessment of the aortic annulus and surrounding anatomy, choice of prosthesis type and size, identification of appropriate vascular access routes, and postprocedural risk prediction [7], [8].

To satisfy these demanding challenges, artificial intelligence (AI) has grown increasingly prominent in structural cardiac procedures. With Deep Learning (DL) and Machine Learning (ML) algorithms, artificial intelligence systems may automatically segment images, measure anatomical characteristics, forecast bad results, and support real-time decision-making. Especially in cardiovascular imaging, artificial intelligence models have proven very promising to reduce operator variance, enhance reproducibility, and shorten time-consuming diagnostic tests [9], [10].

AI applications for segmenting the aortic valve complex from CT and echocardiographic data, simulating hemodynamics using computational models, forecasting postTAVI complications, and automatically prosthesis sizing by means of statistical shape modeling have been investigated in the context of TAVI. Furthermore, AI-generated synthetic patient cohorts are being employed to improve training datasets and support model validation, hence tackling the challenge of sparse annotated data in cardiovascular imaging [11], [12].

Though the field is moving quickly, some obstacles still exist. Though often lacking focus on recent technical developments or real-world validation, past reviews have highlighted AI in TAVI imaging and planning's promise. Heterogeneity in model kinds, clinical datasets, and outcome measures has also made it challenging to compare results throughout trials or reach agreement for clinical inclusion [13].

Focusing on publications from 2023 to 2025, this systematic review so seeks to critically assess the state-of-the-art uses of artificial intelligence in pre-procedural planning for TAVI. It tries to address the following:

- Which artificial intelligence models are being applied in TAVI planning?
- What are their clinical responsibilities and performance indicators?
- How are these models validated, and what obstacles restrict their adoption?

This review offers a thorough basis for researchers, clinicians, and policymakers considering the future of AI-assisted structural heart procedures by combining data from image analysis, predictive modeling, simulation, and clinical decision support across several AI disciplines.

## 2. METHODS

To guarantee methodological rigor and openness, this methodical study was carried out following the PRISMA rules. The choice procedure comprised four major phases: Identification, Screening, Eligibility, and Inclusion. Figure 1 shows the step-by-step flow of the literary selection process.

### 2.1. Identification Stage

A thorough literature search across PubMed, Scopus, and IEEE Xplore, three top academic databases, was undertaken to find pertinent studies on artificial intelligence applications in pre-procedural planning for TAVI. Given the interdisciplinary character of the review, these platforms were chosen for their combined indexing of high-quality biomedical (PubMed), multidisciplinary (Scopus), engineering and computational (IEEE Xplore) publications. Though other databases including Embase or Web of Science might also contain relevant studies, they were omitted to prevent repetition and restricted access. This is admitted to be a possible drawback in the debate.

To catch the most recent and clinically relevant applications of artificial intelligence in TAVI, the search covered 2023 to 2025. A Boolean logic-based keyword strategy was employed using the following search string:

("TAVI" OR "TAVR") or "transcatheter aortic valve implantation"

and ("Artificial Intelligence" or "Machine Learning" or "Deep Learning")

AND ("Valve Sizing" OR "Computed Tomography" OR "Risk Prediction" or "Preprocedural Planning")

Seventy-two articles from PubMed, forty-nine from Scopus, and forty-three from IEEE Xplore resulted from this search totaling 164 papers. After removing 8 duplicates, a total of 156 unique records remained for screening.

### 2.2. Screening Stage

The 156 records were screened based on title and abstract using predefined inclusion and exclusion criteria (summarized in Table 2). At this stage, studies were included if they:

- Employed Artificial Intelligence (AI) techniques including Machine Learning (ML) or Deep Learning (DL);
- Concentrating on pre-procedural planning activities for TAVI, including anatomic segmentation, valve sizing, risk estimation, or simulation modeling;
- Were peer-reviewed, full-text English published papers available.

Studies were excluded if they:

- Concentrating on cardiovascular procedures other than TAVI, or on post-TAVI complications only;
- Did not use methodologies based on AI/ML/DL techniques;
- Whether conference abstracts, editorials, or failed full-text access.

Thirty-four studies were eliminated depending on these criteria: twenty owing to subject irrelevance and fourteen due to non-peer-reviewed status or access problems. This resulted in 122 publications needing full-text inspection.

### 2.3. Eligibility Stage

The 122 full-text articles were reviewed in detail to assess technical depth and relevance. Studies were excluded if they:

- Lacked a well-defined AI strategy including unstated algorithms, datasets, or evaluation metrics;
- Concentrated solely on intra- or post-procedural results, including valve durability, hemodynamics after TAVI;
- Was missing quantitative model performance indicators like accuracy, AUC, sensitivity, specificity, or Dice coefficient.

For clarity, “adequate methodological detail” was defined as the presence of:

- A clearly described AI model architecture (e.g., CNN, U-Net, SVM);
- Input data type and source (e.g., CT, Echo, clinical variables);
- Training/validation strategy (e.g., cross-validation, external testing);
- At least one quantitative evaluation metric.

As a result, 41 studies were excluded 23 for lacking methodological depth and 18 for focusing on outcomes unrelated to pre-procedural planning. This left 81 studies for inclusion assessment.

### 2.4. Inclusion Stage

The remaining 81 full-text studies were then reviewed for final inclusion. Studies were selected if they:

- Utilized AI/ML/DL algorithms in pre-procedural TAVI planning;

- Addressed one or more core domains: image segmentation, prosthetic valve sizing, anatomical modeling, risk prediction, or workflow automation;
- Reported quantitative performance outcomes using standard metrics;
- Presented a validation approach including hold-out, k-fold, or prospective pilot studies;
- English writer, peer-reviewed full-text.

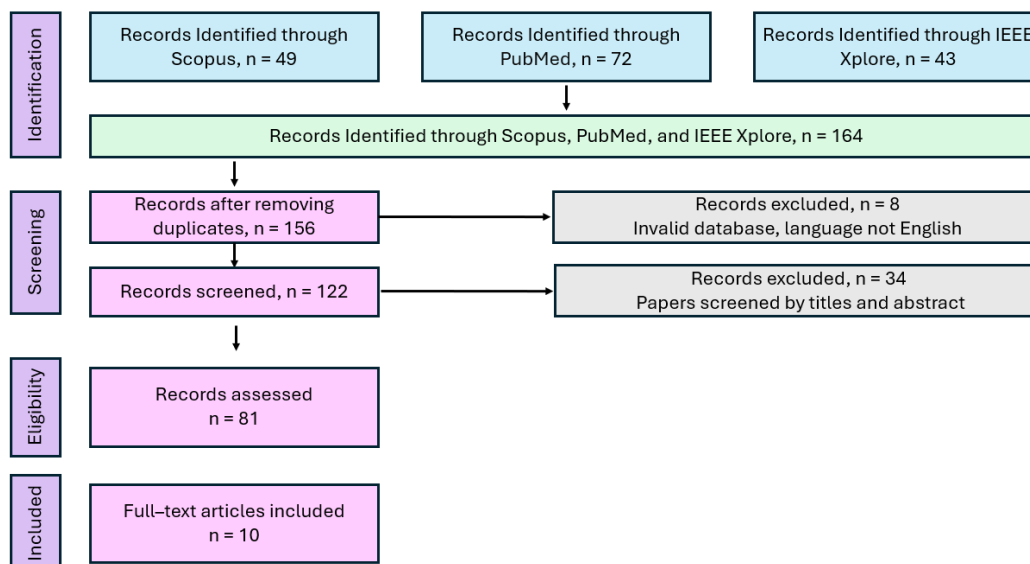
Ten high-quality research satisfying all criteria were included in this systematic review after using these demanding criteria. These form the evidence base for subsequent synthesis in the Research Findings section. Figure 1 outlines the full selection process.

## 2.5. Reviewer Workflow and Disagreement Resolution

Two reviewers with cardiology and biomedical AI knowledge performed separately every title/abstract review, full-text assessment, and data extraction step. Through conversation, a consensus was reached in instances of disagreement. Should disagreement continue, a third judge guaranteed objectivity in the ruling. This multi-reviewer approach complements PRISMA guidelines and strengthens the scientific accuracy of the review process.

## 2.6. Risk of Bias and Quality Assessment

No official risk of bias evaluation tool (e. g. QUADAS-2 for imaging studies or PROBAST for predictive models) was used due to the heterogeneity in research design and reporting methods among the included investigations. Every study was rigorously reviewed for methodological soundness, AI model transparency, validating techniques, and clinical relevance. This absence of consistent bias assessment is seen as a flaw and directs toward upcoming development in evidence synthesis for AI-driven medical research.



**Figure 1.** Step-by-step screening and inclusion process for the systematic review.

**Table 2.** Inclusion and Exclusion Criteria for Selected Studies.

Inclusion Criteria	Exclusion Criteria
Studies that employed <b>artificial intelligence (AI), machine learning (ML), or deep learning (DL)</b> techniques for <b>pre-procedural planning</b> in <b>Transcatheter Aortic Valve Implantation (TAVI)</b>	Studies that did not specifically address TAVI or did not include pre-procedural AI applications
Research that targeted <b>anatomical segmentation, prosthetic valve sizing, patient-specific risk prediction, or simulation modeling</b> before TAVI	Articles focused solely on <b>post-procedural outcomes</b> , intraoperative techniques, or used only traditional (non-AI-based) planning methods
Peer-reviewed journal articles that were <b>available in full text</b> and written in <b>English</b>	Non-English publications, <b>conference abstracts</b> , editorials, commentaries, or opinion pieces without an accessible full text

Studies that utilized <b>clinical imaging data</b> (e.g., CT, echocardiography) or <b>patient clinical variables</b> to train or validate AI models	Research that did not describe AI methodology in sufficient detail (e.g., lacked explanation of model type, input data, evaluation metrics, or validation approach)
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### 3. Research Findings

This section may be divided by subheadings. It should provide a concise and precise description of the experimental results, their interpretation, as well as the experimental conclusions that can be drawn.

#### 3.1. Overview of Included Studies

Ten peer-reviewed publications published between 2023 and 2025 examining the use of AI in pre-procedural preparation for TAVI are included in this systematic review. Deep learning, machine learning, imaging-based artificial intelligence segmentation, risk prediction models, and computational hemodynamic simulations are all used in the studies, therefore reflecting a varied and multidisciplinary set of approaches that improves procedural planning and results in TAVI. Of these 10 studies:

- Five studies focused on CT-based or echocardiography-based anatomical segmentation and measurement tools, including DL architectures such as U-Net and proprietary software platforms like 4TAVR, which demonstrated high Dice Similarity Coefficients (up to 0.93) and mean surface distance metrics compatible with expert assessments [14], [15], [16], [17], [18]. These tools offered significant time savings over traditional semi-automated methods, with some generating complete outputs in under 45 seconds [14];
- Using multimodal data sources including CT imaging, electrocardiograms (ECGs), transthoracic echocardiography (TTE), and clinical variables, three studies created predictive machine learning models to estimate post-TAVI outcomes like pacemaker implantation, mortality, and certain complications [17], [19], [20]. Predicting pacemaker needs among them, an SVM-based model attained an AUC-ROC of 92.1% and accuracy of 87.9% [19]. These predictive models aim to enhance pre-procedural patient stratification and device decision-making;
- Two studies investigated computational and fluid-structure interaction (FSI) models for patient-specific simulation of hemodynamics during and after TAVI [21], [22]. These models outperformed conventional methods in both speed and accuracy (e.g., constructing meshes in about 2 seconds) [22] by using AI-enhanced geometry reconstruction algorithms such DeepCarve and C-MAC. The simulations gave information on crucial variables for procedural planning in high-risk cohorts: wall shear stress, transvalvular pressure gradients, and thrombotic risk;
- Additional innovations include the use of dual-layer spectral CT with virtual monoenergetic imaging (VMI) to reduce contrast burden in patients with renal insufficiency while maintaining adequate image quality [23], and the generation of synthetic virtual patient cohorts using statistical shape modeling and ML techniques to assist in valve sizing and pressure gradient prediction [20].

Together, these investigations show how increasingly sophisticated artificial intelligence systems are throughout the TAVI planning spectrum, from automated anatomical assessment and virtual modeling to customized risk assessment. With better reproducibility, workflow efficiency, and scalability, most AI-driven solutions exhibited measurement accuracy close to that of expert human annotations. Several studies highlighted the capacity of these technologies to lower interobserver variance and streamline procedural planning, therefore improving both procedural results and resource use. An overview of the included studies is shown in Table 3.

**Table 3.** Summary of Included Studies on AI Applications in TAVI Pre-Procedural Planning

Author	AI Technique	Application Area	Key Findings / Performance Metrics	Remarks
Saitta et al. [14]	Deep Learning (DL) - Segmentation	CT-based aortic root morphology assessment	Dice: 0.93; MSD: 1.10 mm (aortic root), 0.68 mm (annulus); Runtime: <45s	High accuracy and speed; minor underestimation
Benjamin et al. [17]	Multiple DL & ML models	TAVI diagnosis, planning, outcome prediction	Accurate valve sizing, FFR prediction, complication forecasting, EKG screening, and mortality prediction	Broad application across TAVI workflow
Santaló et al. [18]	Deep Learning	Valve hydrodynamics; DL for planning	Acceptable Sapien 3 valve performance post-TAVI;	Multimodal study; valve performance focus

Toggweiler et al. [15]	AI-powered software	Automated annular measurement and IFU-based sizing	DL tools discussed alongside PCI outcomes 87-88% agreement with manual sizing; consistent, unbiased annular measurements	Validated tool for standardizing planning
Tahir et al. [16]	DL (U-Net, AG-UCNet); ML regressors	Aorta segmentation; PVL and mortality risk prediction	DSC up to 91.2%; regression models predict wall shear stress and complications accurately	DL models outperform traditional CFD/FEA
Ouahidi et al. [19]	ML - SVM	Pacemakers need prediction after TAVI	AUC-ROC: 92.1%; F1: 71.8%; Accuracy: 87.9%	Clinical tool developed
Fontana et al. [23]	Dual-Layer Spectral CT (AI-aided)	Low-contrast CT planning for TAVI	40 keV VMI enhanced contrast; correlation between BMI and enhancement	Safety for patients with renal concerns
Zingaro et al. [21]	Fluid-Structure Interaction (FSI)	Flow simulation & pressure gradients	Matched 4D MRI and CT; underestimates some values; TKE: 15.8 J/m <sup>3</sup> ; TPG: 13 mmHg	Good alignment with clinical imaging
Ozturk et al. [22]	DL-based geometry reconstruction	Personalized flow dynamics modeling	Time-resolved mesh in ~2s; 100× faster than traditional; suitable for 3D printing	Advanced virtual modeling
Scuoppo et al. [20]	Statistical Shape Modeling + ML	Synthetic patient generation for virtual TAVI	Accurate peak pressure & sizing prediction; synthetic cohort matched real-world patient shapes	Supports model training & device selection

### 3.2. AI Applications in TAVI Pre-Procedural Planning

#### 3.2.1. Image Segmentation and 3D Reconstruction

An accurate anatomical assessment of the aortic root along with the annulus and adjoining vascular structures is a very vital step in preprocedural planning for TAVI. Conventional manual and semi-automated segmentation methods are labor-intensive and suffer from interobserver variability. In this respect, DL techniques, particularly CNNs and U-Net architectures, had shown great promise in implementing automatic methods with very high accuracy. All these developments in image segmentation have been summed up pictorially in Figure 2, where these models solidly figure as fast and accurate anatomical reconstruction permitters, being driven by such advanced AI techniques as CNNs and U-Net architecture.

Multiple studies employed CNN-based architecture for segmentation tasks. For instance, a CT-based DL model achieved a mean Dice Similarity Coefficient (DSC) of 0.93 for aortic root segmentation and mean surface distances (MSD) of 1.10 mm for the root, 0.68 mm for the annulus, and 0.70 mm for the sinotubular junction [14]. These results are comparable to expert manual annotations, and the system completed measurements in under 45 seconds, significantly outperforming semi-automated commercial tools in speed and consistency. Similarly, other works applied advanced U-Net variants, such as AG-UCNet and two-stage 3D U-Nets, achieving DSC values above 91% for aorta segmentation [16]. These tools are not only fast but also robust across various CT image qualities and patient anatomies.

The incorporation of AI-powered segmentation platforms, such as 4TAVR, has facilitated the standardization of annular and aortic root measurements. These platforms produce consistent results with high agreement (87-88%) with instruction-for-use (IFU) sizing guidelines and expert measurements [15]. Automated segmentation also contributes to a reduction in intra- and interobserver variability, an important factor in improving reproducibility and reliability in TAVI planning.

These AI-based segmentation tools show much improved reproducibility, less operator dependence, and the capacity to quickly analyze massive datasets hence cutting planning time and minimizing human error

when compared to conventional techniques. Furthermore objective is added by artificial intelligence since it produces constant, guideline-compliant results that reduce interobserver variance.

### 3.2.2. Valve Sizing and Selection

Accurate prosthesis sizing is essential for preventing complications such as paravalvular leak, coronary obstruction, and annular rupture. AI techniques have been employed to enhance prosthetic valve selection based on anatomical measurements derived from imaging data. Predictive models use CT-based features, statistical shape models, and patient-specific morphological data to simulate optimal device placement and sizing.

In one study, machine learning models trained on a synthetic cohort of 100 virtual TAVI patients demonstrated effective prediction of device size and peak pressure gradients. The models used statistical shape modeling (SSM) techniques to identify anatomical features associated with valve selection [20]. Another study utilized deep learning to support valve sizing by integrating features from CT and echocardiography, offering algorithmic suggestions that aligned with expert decisions in over 85% of cases [17].

The introduction of virtual deployment simulations, enhanced by fluid-structure interaction (FSI) models and AI-driven mesh generation algorithms such as DeepCarve and C-MAC, has allowed clinicians to visualize the impact of different valve sizes on patient-specific geometries. These models generate patient-adapted 3D representations in under 2 seconds, supporting real-time clinical decision-making [22]. Figure 2 presents the pivotal roles that these AI models would take in valve-sizing workflows by integrating patient-specific anatomical data, statistical shape modeling, and virtual simulation tools such as DeepCarve and C-MAC.

AI-enabled solutions offer real-time input, lower interobserver variability, and help decision-making precision by quickly recognizing complex relationships between anatomy and equipment selection, therefore enhancing conventional valve sizing methods. Compared to conventional mesh production pipelines, technologies like DeepCarve can reduce computational time up to 100 times, therefore providing major workflow benefits.

### 3.2.3. Risk Prediction and Patient Stratification

In addition to functional assessment, AI will be used more to assess clinical risk stratification to predict negative outcomes following TAVI. The models take as inputs multimodal data including ECG, TTE, CT imaging, and clinical variables.

A Support Vector Machine (SVM)-based model achieved an area under the ROC curve of 92.1%, an F1 score of 71.8%, and an accuracy of 87.9% in predicting the need for pacemaker implantation within 28 days post-TAVI [19]. This model integrated 22 features from imaging and clinical data, and an online tool was developed to facilitate clinical use. Figure 2 therefore serves as a visual demonstration of how risk prediction frameworks parse multimodal input data and predictive algorithms like SVMs to stratify patients into likely experience of specific complications, such as the need for pacemaker placement, or bleeding.

Other AI models have also demonstrated effectiveness in predicting post-procedural complications such as heart failure admission, reduced leaflet motion, bleeding risk, and long-term mortality [17]. AI-driven FFR (fractional flow reserve) prediction models from CT angiography data have been developed to evaluate the functional severity of intermediate coronary lesions, reducing the need for invasive coronary angiography in TAVI candidates. These models help in assessing the overall risk profile and improving patient selection [17].

Compared to rule-based or manual stratification protocols, AI risk prediction models demonstrate superior pattern recognition capabilities, capturing nonlinear and latent associations among anatomical and clinical variables. These models are more accurate than traditional methods in selecting patients and in preventing complication scenarios, thereby allowing for earlier intervention.

### 3.2.4. Automation of Workflow and Decision Support

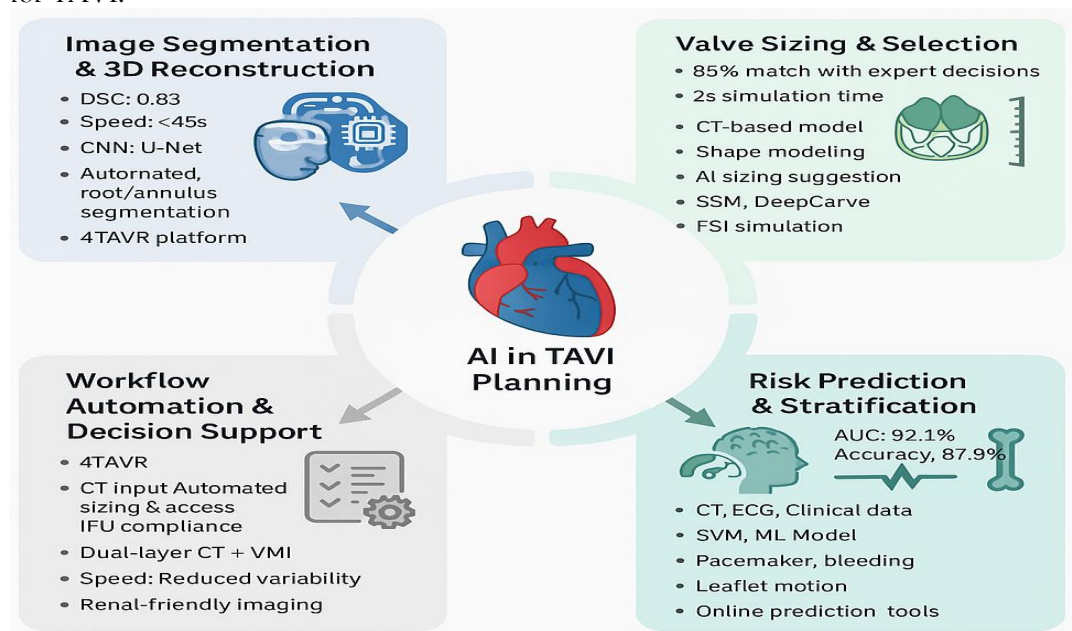
Integration of AI into clinical workflows has been a major focus in recent years. Tools like 4TAVR and other AI-based planning software are being designed not only to automate measurements but also to provide comprehensive decision support. These tools integrate anatomical measurements, risk scores, and device recommendations into a single platform [15].

AI models have also been employed to streamline CT processing pipelines, enabling automated valve sizing, access route analysis, and IFU compliance checks [17]. These models can offer preliminary

interpretations for radiologists and interventional cardiologists, significantly improving planning efficiency.

Dual-layer spectral CT combined with virtual monoenergetic imaging (VMI) and AI-guided protocols have also been tested to minimize contrast media use without compromising image quality, benefiting patients with renal impairment [23]. The total impact of such AI innovations across the workflow-scope-from CT processing to decision support-is pictured in Figure 2 and is overall exhaustive regarding automation transforming.

In contrast to the fragmented manual workflow, AI-based platforms provide end-to-end automation of the imaging, analysis, and decision-making processes: an integrated and streamlined setup. The availability of real-time support improves adherence to clinical guidelines while reducing operator dependence. This is demonstrated in Figure 3, which shows how AI has sped up, standardized, and made safer the planning for TAVI.



**Figure 2.** Overview of AI Applications in TAVI Pre-Procedural Planning, highlighting four domains: image segmentation, valve sizing, risk prediction, and workflow automation. Each domain uses specialized AI models and platforms (e.g., CNN, SSM, DeepCarve, 4TAVR) to improve accuracy, consistency, and efficiency throughout the planning process.

Characteristic	AI-Based Planning	Traditional Methods
<b>Performance</b>	Real-time	Slower
<b>Reproducibility</b>	Enhanced	Lower
<b>Operator Dependence</b>	Less	More
<b>Data Integration</b>	Multimodal	Limited
<b>Objectivity</b>	High	Vulnerable
<b>Pattern Recognition</b>	Superior	Limited

**Figure 3.** Comparison of AI-Based Planning vs. Traditional Methods in TAVI Pre-Procedural Assessment



### 3.3. Performance Metrics

The usual evaluation methods of AI models for the field of activity are some combination of segmentation accuracy, classification performance, and predictive reliability. Some tabulated results often include values for the Dice Similarity Coefficient (DSC), Mean Surface Distance (MSD), AUC-ROC, sensitivity, specificity, precision, F1-score, and time taken.

In general, for image segmentation tasks, Dice coefficients greater than 0.90 have been reported, thus indicating a high spatial overlap with expert annotations [14], [16]. MSD values of below 1 mm for relevant regions such as the annulus and sinotubular junction have been recorded. Predictive models for valve sizing and complication risks often show AUC-ROC somewhere within the 0.85-0.95 range, with accuracy rates about 85-90% [19], [20].

Validation strategies differed from study to study, including k-fold cross-validation, hold-out validation, and prospective clinical validation in pilot cohorts. Studies with better quality control of ground truth annotations and diverse training datasets had better generalizability [15], [20]. A summary of these performance indicators and validation approaches is provided in Table 4.

**Table 4.** Performance Metrics of AI Models in TAVI Pre-Procedural Planning

Task	Metric	Typical Value
Image Segmentation	Dice Similarity Coefficient (DSC)	> 0.90
	Mean Surface Distance (MSD)	< 1 mm
Risk Prediction / Classification	Area Under ROC Curve (AUC-ROC)	0.85 – 0.95
	Accuracy	85% – 90%

### 3.4. Clinical Integration and Validation Status

Even though AI models show promise tackling TAVI planning, integration into clinical practice is still at preliminary stages. There are only a few prospective or randomized trials confirming clinical utility, as most studies are still in the retrospective or validation phases. Nonetheless, several preliminary studies have shown feasibility along with efficiency gains in real-world contexts.

The 4TAVR software has undergone clinical evaluation and shown high agreement with expert measurements in real patient cohorts [15]. Similarly, SVM-based risk prediction tools have been embedded in web-based interfaces for clinical use, enabling easy data entry and risk assessment [19]. Tools like DeepCarve and C-MAC have facilitated rapid patient-specific mesh generation, offering potential for intraoperative simulation and education [22].

Regulatory approvals, the absence of a standard across imaging protocols, and data privacy issues all pose significant hurdles for clinical AI adoption. Clinicians also face significant hurdles surrounding trust in outputs and the interpretability of AI algorithms.

Notwithstanding these challenges, a stronger body of evidence shows that artificial intelligence improves the accuracy of TAVI planning as well as aids in minimizing errors and optimizing outcomes. The next step in further clinical translation will require continued teamwork among the engineers, the clinicians, and the regulators.

### 3.5. Ethical, Regulatory, and Trustworthiness Considerations in Clinical Use

Although technology has matured, clinical use of AI systems is difficult. Much research underlined the requirement of open reporting and explainability of artificial intelligence systems in order to increase clinical trust and regulatory clearance [15], [20]. To stop erroneous device choice or missed complications, problems with algorithmic prejudice, generalizability, and reproducibility must be solved. Moreover, often following technological developments, regulatory structures are changing slowly. For clinicians to confidently include AI-generated results into demanding procedural processes, they need intuitive interfaces and decision traceability [26].

The "black box" quality of many deep learning systems presents one of the main ethical conundrums. Clinicians may be wary of using automated recommendations, especially in high-risk situations like valve sizing or access planning, without understandable outcomes. Should there be unfavorable results, this lack of interpretability might cause responsibility issues [27]. Furthermore, AI trained on small or homogeneous datasets may encode biases that limit their legitimacy over varied populations or imaging methods, hence endangering health inequities. Legally speaking, it's still unclear who is responsible for

clinicians, developers, or institutions if an AI-assisted choice results in damage [28]. Developing Explainable Artificial Intelligence (XAI) frameworks that provide interpretable insights (e.g., saliency maps or feature attribution scores) and audit trails meant to be reviewed alongside finally recommended data governance and accountability, there is growing interest. Regulators such the FDA and EMA are also creating adaptive regulatory paths for AI/MLbased Software as a Medical Device (SaMD), but the speed is slow relative to innovation. Ethical deployment will thus need technical openness, strong validation, clinician education, and clear policy on data governance and responsibility.

**Table 5.** Ethical, Regulatory, and Trustworthiness Issues in AI for TAVI Pre-Procedural Planning

#### 4. Challenges

##### 4.1. Data Availability and Quality

A critical obstacle in using AI in TAVI pre-procedural planning due to the insufficient number of large, high-quality datasets is the foundational challenge. The diversity and representativeness of training data is restricted because most of the studies reviewed relied on retrospective datasets, often from single institutions. Furthermore, the anatomic structure such as aortic annulus and sinotubular junction labelling comes with interobserver variability which influences how models are trained and evaluated due to the varying ways experts do it. These hurdles add to the difficulties with training algorithms that can generalize effectively across real-world scenarios, because differences in imaging centers, including CT scan protocols, contrast material, and reconstruction parameters, add variability. The reproducibility of the models is hindered as there is a lack of standardization in the imaging protocols and the labelling of the datasets, which increases the challenge of AI models applicable to wider clinical settings [29], [30].

Domain	Challenge	Explanation / Impact
Transparency	Lack of explainability in AI models	“Black-box” nature of DL makes it difficult for clinicians to trust AI generated recommendations, especially in high-stakes decisions like valve sizing.
Bias and Generalizability	Algorithmic bias and poor generalization across populations and imaging setups	AI models trained on limited datasets may encode systemic biases, leading to unequal performance across diverse patient populations.
Legal Responsibility	Ambiguity around accountability in case of AI errors	Unclear liability between clinicians, developers, and institutions if an AI-based recommendation causes harm.
Regulatory Lag	Regulatory bodies are slow to adapt to rapid AI innovation	Regulatory frameworks (e.g., FDA, EMA) are evolving but currently lag the pace of AI technology, delaying clinical approval.
Interface Usability	Need for intuitive and auditable AI tools	Clinicians require user-friendly AI tools that provide traceable decisions and visual explanations (e.g., saliency maps, feature attributions) for clinical acceptance.
Data Governance	Insufficient policy clarity on data usage, privacy, and security	AI models often rely on large patient datasets, raising ethical concerns about informed consent, data sharing, and secure storage.
Validation and Education	Limited validation in real-world settings and lack of clinician training	Ethical deployment requires rigorous clinical validation, user education, and integration training for healthcare providers.

##### 4.2. Model Generalizability and Overfitting

The broad applicability of trained models remains a critical challenge for AI integration. While many models possess a high accuracy rate confined to the dataset they were trained on, there is a marked drop-off in performance when assessed on external datasets or in different clinical environments. Variations

in imaging equipment, patient age groups, and existing medical conditions from institution to institution add to these differences. In deep learning algorithms, overfitting remains a widespread concern, especially for models developed from small, homogenous datasets. In the absence of comprehensive external validation, it is nearly impossible to establish whether study-reported metrics of performance are due to actual clinical usefulness or model overfitting. Inadequate large multicenter databases and the absence of federated learning frameworks increase these challenges [31], [32].

#### 4.3. Interpretability and Transparency

An example of a shortcoming associated with modern and advanced AI techniques is deep learning models operating as a “black box.” Even though these models perform excellently on predictive AI tasks and goals, their internal decision mechanisms tend to be hidden and unclear. Such a lack of interpretability hinders clinical adoption; physicians are less likely to act on AI recommendations that require extensive trust or explanation. XAI techniques like saliency maps, SHAP (SHapley Additive exPlanations), and attention mechanisms are starting to resolve this issue, but in the context of TAVI planning, they remain largely unexploited. As with most things in life, until deep learning models offer clear and clinically meaningful insights, their integration into the decision-making pathways will likely remain restricted [33], [34].

#### 4.4. Regulatory and Ethical Barriers

The route to gaining regulatory approval for AI applications in healthcare is still complicated and uneven. Organizations like the FDA and EMA require thorough validation, risk management, and continuous post-market evaluation for AI tools. However, most AI tools are not fully validated as they still sit in development or pilot phases, lacking sufficient evidence. There are also liability concerns associated with the use of AI in clinical practice. It is vague as to who takes the blame when there is an adverse outcome from AI recommendations; is it the clinician, the software developer, or the healthcare institution? There are also ethical AI use in clinics challenges like data privacy, informed consent, and bias in the algorithms used, which adds layers to the clinical use of AI. To facilitate the approval of AI tools and protect patients, there is an immediate need for comprehensive data governance policies and cross-border agreements. In the absence of such mechanisms, the legal and ethical frameworks relaxed, the clinical use of AI in TAVI Planning will be limited [35], [36].

### 5. Limitations

#### 5.1. Limitations of Reviewed Studies

There are several flaws the body of literature examined in this review must be recognized. Small sample sizes were used in a major number of the included studies, therefore reducing the statistical power and generalizability of their results. Many of these studies were retrospective in nature, hence introducing biases including selection bias, incomplete data capture, and constrained control over confounding factors [37].

Furthermore, noted was a clear absence of big, future clinical studies. Most validation activities were confined to single center datasets or internal testing, therefore constraining the capacity to assess model robustness across various clinical situations. The lack of Mult institutional cooperation moreover stifles the creation of more generalizable and clinically useful artificial intelligence models. Direct comparison of studies becomes challenging as well because of variations in evaluation metrics and absence of consistent baselines [38], [39].

#### 5.2. Limitations of the Review Itself

This systematic review also has its own collection of constraints. First, studies with positive results are more likely to be published than those with negative or ambiguous results, therefore creating a publication bias possibility. Consequently, the general view of artificial intelligence efficiency in TAVI preprocedural preparation could be biased toward more positive results [40].

Second, the evaluation was limited to works released in English, so possibly eliminating pertinent research published in other languages. Third, grey literature like as conference abstracts, white papers, and preprints were not included, possibly missing out on developing but unedited ideas. Although attempts were made to guarantee thorough search, the changing dynamic and fast-paced nature of AI research means that newer studies may have been missed or are still to be cataloged in the databases chosen [41]. Still, this review offers a prompt and thorough synthesis of existing knowledge, therefore aiding in the discovery of possible paths for more study and use of AI in the TAVI preparation field.

## 6. Future Directions

Developing large-scale, multicenter datasets is among the most urgent requirements in the advancement of artificial intelligence for TAVI preprocedural planning. To enable strong training and external validation of artificial intelligence models, these datasets should include a range of patient groups, several imaging techniques, and thorough clinical results [42]. To gather and standardize such datasets, collaborative projects including hospitals, educational institutions, and business participants are critical. These resources would support transparency and reproducibility while helping to reduce the risk of overfitting and enable the training of more generalizable models [43].

Interpretability should be given top priority by the next generation of TAVI artificial intelligence algorithms if one wants to win clinician trust and improve medical judgment. Investing in explainable artificial intelligence (XAI) approaches such as attention mechanisms, class activation mapping, and decision trees can help unpack the internal workings of complex models and provide rationale for model predictions. Promoting clinical acceptance and enabling regulatory approval will be greatly helped by including user-friendly visual aids that may intuitively show doctors AI insights [44], [45].

Future developments ought to enable perfect integration of artificial intelligence systems into interventional cardiology procedures and catheterization labs. Tools powered by artificial intelligence that can conduct real-time image segmentation, instrument sizing, and complication risk analysis could provide actionable insights during pre-procedural planning or even intraoperatively. Achieving real time, point-of-care support depends on creating artificial intelligence systems that fit with current Cath lab imaging techniques and surgical planning tools [46], [47]. Although there is an increasing body of historical studies, prospective clinical trials are necessary to assess the effectiveness, safety, and effect of AI-assisted planning solutions in TAVI. These trials ought to evaluate mortality, valve function, and quality of life, that is, both short term and long-term clinical results. Understanding the general consequences of AI application in regular care will also depend on the inclusion of patient-reported outcomes and health economic evaluations. Longitudinal follow-up will enable evaluation of the real-world value and durability of AI driven decision making [48], [49].

Strong multidisciplinary cooperation is essential for the effective use of artificial intelligence in TAVI planning. Engineers and data scientists have to collaborate closely with cardiologists and radiologists to make sure that user-friendly, understandable, and clinically relevant artificial intelligence tools are available. Early involvement of regulatory authorities also enables development processes to be coordinated with approval demands and fosters confidence in artificial intelligence technologies. Accelerating innovation while protecting patient rights will call for the creation of ethical guidelines, data sharing policies, and legal systems targeted to artificial intelligence in cardiovascular care [50], [51].

These combined future paths help to provide a path toward the secure, effective, and widespread acceptance of artificial intelligence systems in TAVI preoperative preparation. Translating artificial intelligence developments from laboratory to bedside will be aided by interdisciplinary collaboration, clinical tests, and strategic investments in research infrastructure.

## 7. CONCLUSION

Recent interest in the role of AIs in pre-procedural planning for transcatheter aortic valve implantation (TAVI) has been underlined by the systematic review. AI tools, especially deep learning segmentation and machine-learning risk prediction, have shown metrics close to expert competence. They allow for rapid data analysis so that reproducibility and support for decision-making aid in the improvement of some clinical outcomes in any TAVI procedure. Good clinical results aside, widespread uptake has still been hampered. These barriers need to be lifted through the standard validation of a wide range of populations, along with clarified regulatory requirements and increased model explainability. Moving forward, strong multicenter studies, prospective validation trials, and clinician-centered design will remain key to moving AI out of research and into the real-world setting. Given those provisions, AI can turn the TAVI planning standard of care on its head: increasing precision, safety, and efficiency in the day-to-day operation of structural heart interventions.

## 8. Patents

This section is not applicable as there are no patents resulting from the work reported in this manuscript.

**Supplementary Materials:** The following supporting information can be downloaded at: <https://www.mdpi.com/article/doi/s1>, Figure S1: title; Table S1: title; Video S1: title. The following supporting information can be downloaded at: <https://www.mdpi.com/article/doi/s1>, Figure S1:

PRISMA Flow Diagram of Study Selection; Table S1: Inclusion and Exclusion Criteria for AI Studies in TAVI Planning;

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#### Abbreviations

The following abbreviations are used in this manuscript:

MDPI Multidisciplinary Digital Publishing Institute

DOAJ Directory of Open Access Journals

AS Aortic Stenosis

SAVR Surgical Aortic Valve Replacement

TAVI Transcatheter Aortic Valve Implantation

DL Deep Learning

ML Machine Learning

AI Artificial Intelligence

CT Computed Tomography

ECG Electrocardiogram

TTE Transthoracic Echocardiography

DSC Dice Similarity Coefficient

MSD Mean Surface Distance

AUC Area Under the Curve

SVM Support Vector Machine

XAI Explainable Artificial Intelligence

SaMD Software as a Medical Device

#### REFERENCES

1. A. Martinsson, X. Li, C. Andersson, J. Nilsson, J. G. Smith, and K. Sundquist, "Temporal trends in the incidence and prognosis of aortic stenosis: A nationwide study of the Swedish Population," *Circulation*, vol. 131, no. 11, 2015, doi: 10.1161/CIRCULATIONAHA.114.012906.
2. Y. Shan and P. A. Pellikka, "Aortic stenosis in women," 2020. doi: 10.1136/heartjnl-2019-315407.
3. C. Howard, L. Jullian, M. Joshi, A. Noshirwani, M. Bashir, and A. Harky, "TAVI and the future of aortic valve replacement," 2019. doi: 10.1111/jocs.14226.
4. Qureshi, M. I., Bhatti, S. H., & Khan, N. (2025). From hype to reality: a systematic literature review of blockchain's role in sustainable supply chain management. *Journal of Management History*.
5. K. K. Shah et al., "Transcatheter Aortic Valve Implantation (TAVI) Versus Surgical Aortic Valve Replacement for Aortic Stenosis (SAVR): A Cost-Comparison Study," *Heart Lung Circ*, vol. 30, no. 12, 2021, doi: 10.1016/j.hlc.2021.05.088.
6. F. Hecker, M. Arsalan, W. K. Kim, and T. Walther, "Transcatheter aortic valve implantation (TAVI) in 2018: Recent advances and future development," 2018. doi: 10.23736/S0026-4725.17.04532-7.
7. "Transcatheter Aortic Valve Implantation (TAVI) Versus Surgical Aortic Valve Replacement (SAVR): A Retrospective Analysis from a Tertiary Care Hospital," *Cardiology: Open Access*, vol. 7, no. 3, 2022, doi: 10.33140/coa.07.03.03.
8. N. Ruparel and B. D. Prendergast, "TAVI in 2015: Who, where and how?," *Heart*, vol. 101, no. 17, 2015, doi: 10.1136/heartjnl-2014-307008.
9. L. Perl, N. Loeb, and R. Kornowski, "Artificial Intelligence in Cardiology," 2024. doi: 10.11855/j.issn.0577-7402.1115.2023.0529.

10. F. Lopez-Jimenez et al., "Artificial Intelligence in Cardiology: Present and Future," 2020. doi: 10.1016/j.mayocp.2020.01.038.
11. Rattanawiboonsom, V., Sikandar, H., Thatsaringkharnsakun, U., & Khan, N. (2025). The Role of Mobile Technologies in Tracking Cyberbullying Trends and Social Adaptation among Teenagers. *International Journal of Interactive Mobile Technologies*, 19(1).
12. M. Santaló et al., "TCT-387 TAVI-PREP: A Deep Learning-Based Tool for Automated Measurements Extraction in TAVR Planning," *J Am Coll Cardiol*, vol. 82, no. 17, 2023, doi: 10.1016/j.jacc.2023.09.395.
13. K. Zhang, Y. Gao, J. Lv, J. Li, and J. Liu, "Artificial Intelligence-Based Spiral CT 3D Reconstruction in Transcatheter Aortic Valve Implantation," *Comput Math Methods Med*, vol. 2022, 2022, doi: 10.1155/2022/5794681.
14. Rattanawiboonsom, V., & Khan, N. (2024). Blockchain Technology in Mobile Payments: A Systematic Review of Security Enhancements in Mobile Commerce. *International Journal of Interactive Mobile Technologies*, 18(21).
15. R. R. Lopes et al., "Value of machine learning in predicting TAVI outcomes," *Netherlands Heart Journal*, vol. 27, no. 9, 2019, doi: 10.1007/s12471-019-1285-7.
16. M. Renker, U. J. Schoepf, and W. K. Kim, "Combined CT Coronary Artery Assessment and TAVI Planning," 2023. doi: 10.3390/diagnostics13071327.
17. S. Saitta et al., "A CT-based deep learning system for automatic assessment of aortic root morphology for TAVI planning," Feb. 2023, [Online]. Available: <http://arxiv.org/abs/2302.05378>
18. S. Toggweiler et al., "A fully automated artificial intelligence-driven software for planning of transcatheter aortic valve replacement," *Cardiovascular Revascularization Medicine*, vol. 65, pp. 25–31, Aug. 2024, doi: 10.1016/j.carrev.2024.03.008.
19. A. M. Tahir et al., "Latest Developments in Adapting Deep Learning for Assessing TAVR Procedures and Outcomes," Jul. 01, 2023, Multidisciplinary Digital Publishing Institute (MDPI). doi: 10.3390/jcm12144774.
20. M. M. Benjamin and M. G. Rabbat, "Artificial Intelligence in Transcatheter Aortic Valve Replacement: Its Current Role and Ongoing Challenges," Feb. 01, 2024, Multidisciplinary Digital Publishing Institute (MDPI). doi: 10.3390/diagnostics14030261.
21. M. Santaló et al., "TAVI-PREP: A Deep Learning-Based Tool for Automated Measurements Extraction in TAVR Planning."
22. A. El Ouahidi et al., "Machine learning for pacemaker implantation prediction after TAVI using multimodal imaging data," *Sci Rep*, vol. 14, no. 1, Dec. 2024, doi: 10.1038/s41598-024-76128-z.
23. R. Scuoppo et al., "Generation of a virtual cohort of TAVI patients for in silico trials: a statistical shape and machine learning analysis," *Med Biol Eng Comput*, vol. 63, no. 2, pp. 467–482, Feb. 2025, doi: 10.1007/s11517-024-03215-8.
24. A. Zingaro et al., "Advancing aortic stenosis assessment: validation of fluid-structure interaction models against 4D flow MRI data," Apr. 2024, [Online]. Available: <http://arxiv.org/abs/2404.08632>
25. C. Ozturk et al., "AI-powered multimodal modeling of personalized hemodynamics in aortic stenosis," Jun. 2024, [Online]. Available: <http://arxiv.org/abs/2407.00535>
26. F. Fontana et al., "Transcatheter Aortic Valve Implantation (TAVI) Planning with Dual-Layer Spectral CT Using Virtual Monoenergetic Image (VMI) Reconstructions and 20 mL of Contrast Media," *J Clin Med*, vol. 13, no. 2, Jan. 2024, doi: 10.3390/jcm13020524.
27. R. Forghani, "A Practical Guide for AI Algorithm Selection for the Radiology Department," *Semin Roentgenol*, vol. 58, no. 2, 2023, doi: 10.1053/j.ro.2023.02.006.
28. J. M. Ribeiro et al., "Artificial Intelligence and Transcatheter Interventions for Structural Heart Disease: A glance at the (near) future," 2022. doi: 10.1016/j.tcm.2021.02.002.
29. K. E. Goodman, D. J. Morgan, and D. E. Hoffmann, "Clinical Algorithms, Antidiscrimination Laws, and Medical Device Regulation," 2023. doi: 10.1001/jama.2022.23870.
30. J. J. Wadden, "Defining the undefinable: the black box problem in healthcare artificial intelligence," *J Med Ethics*, vol. 48, no. 10, 2021, doi: 10.1136/medethics-2021-107529.
31. Md. M. Islam, "Ethical Considerations in AI: Navigating the Complexities of Bias and Accountability," *Journal of Artificial Intelligence General science (JAIGS)* ISSN:3006-4023, vol. 3, no. 1, 2024, doi: 10.60087/jaigs.v3i1.62.
32. O. Bar et al., "Impact of data on generalization of AI for surgical intelligence applications," *Sci Rep*, vol. 10, no. 1, 2020, doi: 10.1038/s41598-020-79173-6.
33. A. Heinrich et al., "Improved image quality in transcatheter aortic valve implantation planning CT using deep learning-based image reconstruction," *Quant Imaging Med Surg*, vol. 13, no. 2, 2023, doi: 10.21037/qims-22-639.
34. F. Giorgi, F. Veglianti, F. Silvestri, and G. Tolomei, "Generalizability through Explainability: Countering Overfitting with Counterfactual Examples," Feb. 2025, [Online]. Available: <http://arxiv.org/abs/2502.09193>
35. S. Aburass, "Quantifying Overfitting: Introducing the Overfitting Index."
36. N. Rane, S. Choudhary, and J. Rane, "Explainable Artificial Intelligence (XAI) Approaches for Transparency and Accountability in Financial Decision-Making," *SSRN Electronic Journal*, 2023, doi: 10.2139/ssrn.4640316.
37. N. Thalpage, "Unlocking the Black Box: Explainable Artificial Intelligence (XAI) for Trust and Transparency in AI Systems," *Journal of Digital Art & Humanities*, vol. 4, no. 1, 2023, doi: 10.33847/2712-8148.4.1\_4.
38. K. Palaniappan, E. Y. T. Lin, and S. Vogel, "Global Regulatory Frameworks for the Use of Artificial Intelligence (AI) in the Healthcare Services Sector," 2024. doi: 10.3390/healthcare12050562.
39. C. Mennella, U. Maniscalco, G. De Pietro, and M. Esposito, "Ethical and regulatory challenges of AI technologies in healthcare: A narrative review," 2024. doi: 10.1016/j.heliyon.2024.e26297.
40. L. Lin, "Bias caused by sampling error in meta-analysis with small sample sizes," *PLoS One*, vol. 13, no. 9, 2018, doi: 10.1371/journal.pone.0204056.
41. A. A. H. de Hond, V. B. Shah, I. M. J. Kant, B. Van Calster, E. W. Steyerberg, and T. Hernandez-Boussard, "Perspectives on validation of clinical predictive algorithms," 2023. doi: 10.1038/s41746-023-00832-9.
42. G. C. M. Siontis, R. Sweda, P. A. Noseworthy, P. A. Friedman, K. C. Siontis, and C. J. Patel, "Development and validation pathways of artificial intelligence tools evaluated in randomised clinical trials," *BMJ Health Care Inform*, vol. 28, no. 1, 2021, doi: 10.1136/bmjhci-2021-100466.

43. A. Marks-Anglin and Y. Chen, "A historical review of publication bias," 2020. doi: 10.1002/jrsm.1452.
44. H. B. Wee and J. D. Reimer, "Non-English academics face inequality via AI-generated essays and countermeasure tools," 2023. doi: 10.1093/biosci/biad034.
45. F. C. Kitamura et al., "Lessons Learned in Building Expertly Annotated MultiInstitution Datasets and Hosting the RSNA AI Challenges," *Radiol Artif Intell*, vol. 6, no. 3, 2024, doi: 10.1148/ryai.230227.
46. H. Kondylakis et al., "Data infrastructures for AI in medical imaging: a report on the experiences of five EU projects," *Eur Radiol Exp*, vol. 7, no. 1, 2023, doi: 10.1186/s41747-023-00336-x.
47. M. Ennab and H. McHeick, "Designing an Interpretability-Based Model to Explain the Artificial Intelligence Algorithms in Healthcare," *Diagnostics*, vol. 12, no. 7, 2022, doi: 10.3390/diagnostics12071557.
48. Q. Xu et al., "Interpretability of Clinical Decision Support Systems Based on Artificial Intelligence from Technological and Medical Perspective: A Systematic Review," 2023. doi: 10.1155/2023/9919269.
49. P. Sardar, J. D. Abbott, A. Kundu, H. D. Aronow, J. F. Granada, and J. Giri, "Impact of Artificial Intelligence on Interventional Cardiology," *JACC Cardiovasc Interv*, vol. 12, no. 14, 2019, doi: 10.1016/j.jcin.2019.04.048.
50. H. Göçer and A. B. Durukan, "The use of artificial intelligence in interventional cardiology," *Turkish Journal of Thoracic and Cardiovascular Surgery*, vol. 31, no. 3, 2023, doi: 10.5606/tgkdc.dergisi.2023.24791.
51. H. Chopra et al., "Revolutionizing clinical trials: the role of AI in accelerating medical breakthroughs," *Int J Surg*, vol. 109, no. 12, 2023, doi: 10.1097/JS9.0000000000000705.
52. F. Cascini, F. Beccia, F. A. Causio, A. Melnyk, A. Zaino, and W. Ricciardi, "Scoping review of the current landscape of AI-based applications in clinical trials," 2022. doi: 10.3389/fpubh.2022.949377.
53. F. Lalys et al., "Automatic aortic root segmentation and anatomical landmarks detection for TAVI procedure planning," *Minimally Invasive Therapy and Allied Technologies*, vol. 28, no. 3, 2019, doi: 10.1080/13645706.2018.1488734.
54. L. Karatzia, N. Aung, and D. Aksentijevic, "Artificial intelligence in cardiology: Hope for the future and power for the present," 2022. doi: 10.3389/fcvm.2022.945726.
- 55.