

## Artificial Intelligence in Cardiology: General Perspectives and Focus on Interventional Cardiology

### ABSTRACT

Artificial intelligence (AI) is being intensively applied to cardiology, particularly in diagnostics, risk prediction, treatment planning, and invasive procedures. While AI-driven advancements have demonstrated promise, their real-world implementation remains constrained by critical challenges. Current AI applications, such as electrocardiogram interpretation and automated imaging analysis, have improved diagnostic accuracy and workflow efficiency, yet generalizability, regulatory hurdles, and integration into existing clinical workflows remain major obstacles. Algorithmic bias and the lack of explainable AI further complicate widespread adoption, potentially leading to disparities in healthcare outcomes. In interventional cardiology, robotic-assisted percutaneous coronary intervention has emerged as a technological innovation, but comparative clinical evidence supporting its superiority (or even non-inferiority) over conventional approaches is still limited. Additionally, AI-based decision support systems in high-risk cardiovascular procedures require rigorous validation to ensure safety and reliability. Ethical considerations, including patient data security and region-specific regulatory frameworks, also pose significant barriers. Addressing these challenges requires interdisciplinary collaboration, robust external validation, and the development of transparent, interpretable AI models. This review provides a critical appraisal of the current role of AI in cardiology, emphasizing both its potential and its limitations, and outlines future directions to facilitate its responsible integration into clinical practice.

**Keywords:** Artificial intelligence, cardiology, cardiovascular disease, interventional cardiology, machine learning, robotics

*Action is the real measure of intelligence.*

*Napoleon Hill*

### INTRODUCTION

Artificial intelligence (AI) is exerting a growing influence on cardiology, likely contributing to improvements in diagnostic accuracy, predictive analytics, and personalized patient management.<sup>1</sup> Initially, AI applications were restricted to automating apparently simple and routine tasks, such as electrocardiogram (ECG) interpretation.<sup>2</sup> However, the advent of more refined machine learning (ML) algorithms has enabled more sophisticated applications, including advanced image-based diagnostics, complex risk prediction models, and real-time procedural guidance (Figure 1).<sup>3</sup>

Despite these advancements, AI integration into clinical practice remains constrained by several factors, including the need for regulatory approval, extensive validation, and real-world applicability. Indeed, while many AI algorithms and applications demonstrate high performance in retrospective analyses, they encounter challenges in generalizability when applied to diverse patient populations or challenging settings.<sup>4,5</sup> Indeed, in order to ensure robust clinical adoption, external validation in representative cohorts is essential, particularly in interventional cardiology where real-time decision-making and seamless articulation of materials are paramount.



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### INVITED REVIEW

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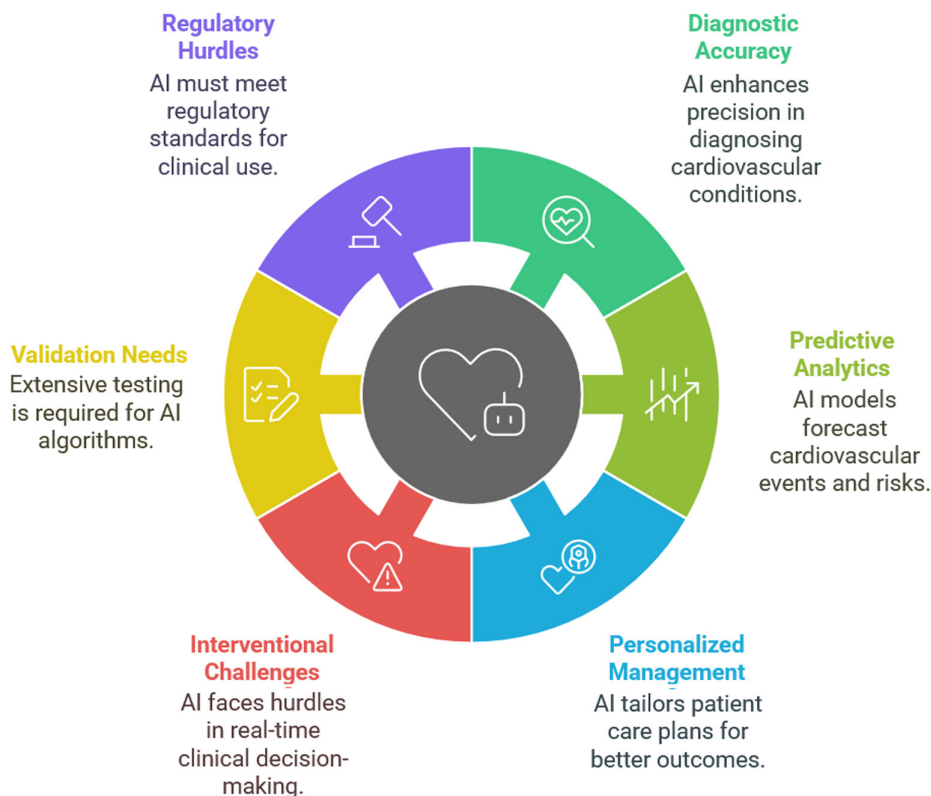
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**Figure 1. Highlights, both positive and negative, of the role of artificial intelligence in cardiology.**

## CORE TECHNOLOGIES AND LEARNING PARADIGMS IN CARDIOLOGY

Several AI-related technologies have significantly impacted cardiology (Table 1; Figure 1).<sup>6</sup> First, ML algorithms have already been employed to analyze complex cardiovascular

### HIGHLIGHTS

- Artificial intelligence in cardiology focuses on enhancing diagnostics, risk prediction, treatment planning, and real-time decision support.
- Artificial intelligence–powered cardiac imaging and robotics may improve diagnostic accuracy and procedural precision, with applications spanning echocardiography, computed tomography, magnetic resonance imaging, and robotic-assisted percutaneous coronary intervention.
- Machine learning and deep learning models could enable personalized medicine by integrating diverse patient data, refining risk stratification, and optimizing individualized treatment strategies, ultimately improving patient outcomes.
- Additional high-quality evidence is, however, sorely needed to appropriately gauge the benefits and risks of artificial intelligence in cardiology. Moreover, ethical, regulatory, and technical challenges remain crucial barriers to the widespread artificial intelligence in cardiology, necessitating interdisciplinary collaboration and standardized frameworks to ensure transparency, fairness, and clinical reliability.

data, enhancing diagnostic accuracy and risk prediction in areas ranging from coronary artery disease to heart failure and arrhythmias (Figure 2).<sup>7,8</sup> Deep learning (DL) architectures have further advanced image and signal analysis in cardiac care, despite increasing analytical complexity and accompanying limits in transparency and explainability.<sup>9</sup>

Different learning paradigms are utilized in cardiology to address diverse challenges.<sup>10</sup> Indeed, supervised learning relies on labeled datasets to train models for specific tasks, such as detecting arrhythmias from ECG data. Unsupervised learning, through clustering techniques or similar approaches that aim at finding insights without external labels or indicators, aids, for instance in patient stratification by identifying patterns without predefined labels.<sup>11-13</sup> Reinforcement learning (RL) has also been explored to optimize clinical decision-making by learning from the outcomes of various treatment strategies.

Hybrid models, which combine elements of ML and DL, have been developed with the specific goal of enabling more complex cardiology applications.<sup>14</sup> These models integrate multiple data sources, including imaging and clinical data, to provide a comprehensive analysis of cardiovascular conditions. Ensemble methods, which aggregate predictions from various models, have been employed to improve predictive accuracy. Such approaches facilitate a more holistic understanding of cardiac conditions, leading to better-informed treatment decisions.

Notably, state-of-the-art AI learning models hold the promise of providing numerous benefits in cardiology at large as well as in interventional cardiology, including enhanced diagnostic

**Table 1. Key Acronyms and Pertinent Definitions**

Acronym	Full Name	Description
AI	Artificial intelligence	Simulation of human intelligence processes by computer systems.
AaaS	AI as a service	Offering AI capabilities through cloud services for healthcare.
ANN	Artificial neural network	Inspired by biological neural networks for pattern recognition.
API	Application programming interface	Allows different software to communicate, crucial for AI integration.
BI	Business intelligence	Tools for data analysis to improve healthcare decisions.
CNN	Convolutional neural network	Specialized for image recognition, crucial for cardiac imaging analysis.
CUDA	Compute unified device architecture	NVIDIA platform for accelerating AI algorithms.
CV	Computer vision	Field of AI focused on enabling machines to interpret and process visual information, essential for medical imaging analysis.
DL	Deep learning	Subset of ML, uses neural networks with many layers for complex data.
DNN	Deep neural network	Multiple layers for complex problem-solving in cardiology.
DT	Decision tree	Simple model for decision-making in patient treatment pathways.
EDW	Enterprise data warehouse	Stores and manages data for AI predictive analytics.
ETL	Extract, transform, load	Prepares data for AI analysis in cardiology.
FL	Federated learning	Trains AI models across decentralized devices, ensuring data privacy.
GAN	Generative adversarial network	Can generate synthetic data for training models without privacy issues.
GBM	Gradient boosting machine	Builds models in stages for risk prediction in cardiology.
GPU	Graphics processing unit	Used for computing to speed up AI model training.
HPC	High performance computing	Powers complex AI computations for data analysis in cardiology.
IoT	Internet of things	Devices like heart monitors feed data for real-time AI analysis.
KNN	K-nearest neighbors	Used for classification and regression in cardiology.
LSTM	Long short-term memory	Good for learning long-term dependencies in heart rate data.
ML	Machine learning	Algorithms learn from data to make predictions or decisions.
MLOps	Machine learning operations	Managing the lifecycle of ML models in clinical settings.
NLP	Natural language processing	Enables understanding of textual medical data or patient interactions.
NN	Neural network	Basic structure for many AI applications in cardiology.
PaaS	Platform as a service	Provides platform for application development without infrastructure management.
PCA	Principal component analysis	Dimensionality reduction technique used to simplify data while preserving its key characteristics, often applied in image processing and genomic studies.
RF	Random forest	Ensemble learning for classification, regression, feature selection.
RL	Reinforcement learning	Area of machine learning where agents learn optimal behavior by interacting with an environment, applied in clinical decision-making and robotics.
RNN	Recurrent neural network	Designed for sequential data like ECG traces, understanding context over time.
SaaS	Software as a service	Delivery model for AI applications in cardiology.
SVM	Support vector machine	Useful in categorizing heart disease risk.
XAI	Explainable AI	AI models designed with transparency, enabling human users to understand the reasoning behind predictions, crucial for trust in healthcare AI.

ECG, electrocardiogram.

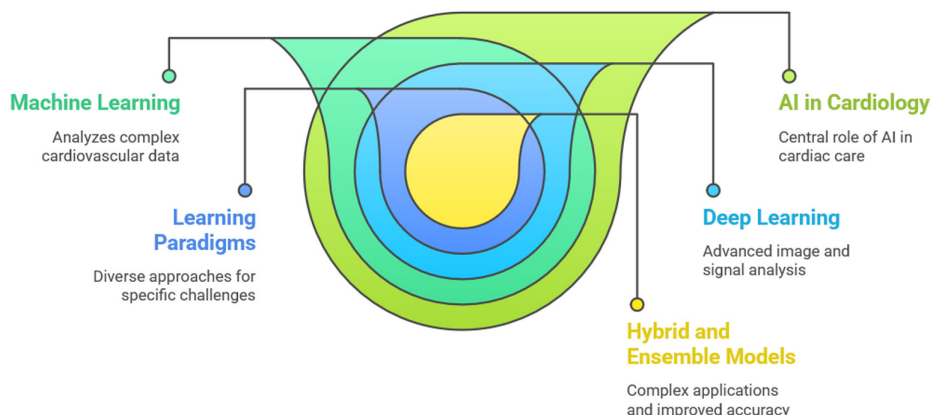
accuracy, personalized outcome prediction, and improved procedural precision (Table 2), with AI-driven tools supporting clinical decision-making, data augmentation, and telemedicine integration, thus facilitating more efficient and accessible care.<sup>15</sup> The reader should, however, be aware that many applications of the above-mentioned AI tools remain untested or proven effective only in selected populations.

### **BIG DATA AND PREPROCESSING FOR ARTIFICIAL INTELLIGENCE IN CARDIOLOGY**

In cardiology, the integration of big data will prove seminal for further advancing patient care and research.<sup>16</sup> Large datasets, combining clinical, imaging, and biomarker data,

enable AI to possibly identify patterns often missed by traditional models, particularly in niche populations like frail young individuals or highly fit elderly patients (Table 3).<sup>17</sup>

Effectiveness of AI relies on high-quality data preprocessing, yet clinical data are often noisy, incomplete, and heterogeneous due to variations in acquisition protocols. Techniques such as normalization, noise reduction, and imputation of missing values improve AI accuracy, as seen in ECG signal filtering for arrhythmia detection.<sup>8</sup> Challenges, however, remain in standardizing and integrating data from diverse healthcare settings, where inconsistent formats hinder AI model generalizability.<sup>18</sup> Privacy concerns are also critical, requiring adherence to regulations like the General Data Protection Regulation



**Figure 2. Overview of artificial intelligence modeling strategies with accompanying cardiovascular applications.**

and the Health Insurance Portability and Accountability Act.<sup>19</sup> Moreover, algorithmic bias remains a concern, as underrepresentation of certain populations can lead to disparities in AI-driven decision-making. External validation across diverse cohorts is essential to ensure equitable application.<sup>20</sup>

**ARTIFICIAL INTELLIGENCE IN CARDIAC IMAGING AND DIAGNOSTICS**

Developments in cardiac imaging include enhancing accuracy, efficiency, and automation of major imaging

modalities, including echocardiography, computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography.<sup>21</sup> Novel AI-powered tools, for instance automate chamber measurements in echocardiography, improving reproducibility and diagnostic precision, achieving performance comparable to expert sonographers (Table 3).<sup>8</sup> In cardiac CT and MRI, AI may quicken image reconstruction, shorten scan times, and enable automated segmentation of cardiac structures for precise anatomical and functional assessment.

**Table 2. Pros and Cons of Artificial Intelligence in Cardiology**

Setting	Pros	Cons
Clinical decision support	Assists in decision-making for complex cases such as severe aortic stenosis and increases detection rate	May lead to reduced clinical judgment and possible issues with the interpretability of AI recommendations
Data augmentation	Enables synthetic data generation for training purposes, improving model robustness	Quality control of synthetic data remains challenging; lack of standardized metrics for evaluating AI-generated data
Diagnostic imaging	Enhances accuracy and efficiency in cardiac imaging interpretation and reduces inter-observer variability	Risk of over-reliance on automated results and potential for algorithmic bias
Drug development	Speeds up identification of drug targets and therapeutic pathways; aids in precision medicine	Requires extensive validation before clinical trials; ethical issues with automated decision-making
ECG analysis	Enables rapid detection of arrhythmias and improves diagnostic accuracy	Requires high-quality data and may miss rare or complex abnormalities
Interventional cardiology	Improves precision in guiding complex procedures (e.g., TAVI, PCI); enhances imaging analysis and lesion assessment	Dependence on AI guidance can reduce operator skill development; high costs of advanced AI-driven systems
Outcome prediction	Provides personalized risk assessment for post-operative and long-term outcomes in congenital heart disease	Generalizability of models may be limited; ethical concerns regarding patient consent and data usage
Outcome prediction	AI models outperform traditional risk stratification in predicting outcomes	Ethical and regulatory challenges; need for robust external validation before clinical adoption
Predictive analytics	Enhances early detection of heart failure and coronary artery disease through pattern recognition	Overfitting risk in predictive models and variability in performance across populations
Telemedicine integration	Expands access to remote cardiac care; reduces healthcare costs and burden on hospitals	Digital divide issues; limited tactile feedback and infrastructure challenges
Wearable technology	Facilitates continuous real-time monitoring of cardiac health and enables early detection of cardiac events	Data privacy concerns and requires patient adherence to device use

AI, artificial intelligence; ECG, electrocardiogram; TAVI, transcatheter aortic valve implantation; PCI, percutaneous coronary intervention.

**Table 3. Recent Landmark Systematic Reviews on Artificial Intelligence in Cardiology**

Focus	First Author, Year	PMID	Studies/Reports	
			Included	Findings
Diagnosis	Panjiyar, 2023	37674942	8	ML-based diagnostic algorithms show high accuracy, but ethical, implementation, and transparency issues are not negligible
	Cuevas-Chávez, 2023	37628438	165	IoT/IoMT technologies can diagnose cardiovascular diseases in real-time, with ensemble techniques obtaining optimal performances
ECG	Oke, 2024	39674006	46	AI technologies for ECG analysis may improve accuracy and diagnosis time, but responsibility issues remain substantial
Imaging	Gonzalez, 2024	39729150	12	Automated TTE analysis appears feasible and reasonably accurate, with a mean bias ranging between 0% and 2.9% for LVEF
	Wang, 2024	39437607	25	DL provides accurate measurements for CAC score data stemming from cardiac CT
Diagnosis	Farhad, 2023	37596521	25	AI methods can be used non-invasively to estimate coronary FFR from angiographic imaging data
Risk prediction	Yan, 2025	39723651	28	Although ML is increasingly being leveraged to predict mortality in HF, predictive performance remains suboptimal
	Sazzad, 2024	38883982	10	AI models have a higher predictive accuracy compared to traditional risk scores in predicting post-TAVR mortality
	Wee, 2024	39347111	11	ML models show promise for risk stratification post-PCI. However, several implementation challenges persist
Robotics	Wagener, 2024	39337024	15	Robotically assisted PCI is feasible and safe in selected patients, and associated with reduced occupational hazard
	Vô, 2023	36852632	24	RMN-guided ablation appears to be safe and effective across a variety of arrhythmia substrates and types of CHD
Telemedicine	Moulaei, 2024	39523670	35	Telemedicine interventions improve BP control, especially when supervised by expert clinicians
Wearable devices	Sinou, 2024	39749057	34	Wearable devices improve BP monitoring and HTN diagnosis and treatment, but standardized protocols are lacking

AI, artificial intelligence; BP, blood pressure; CAC, coronary artery calcification; CHD, congenital heart disease; CT, computed tomography; ECG, electrocardiogram; FFR, fractional flow reserve; HF, heart failure; HTN, hypertension; IoMT, Internet of Medical Things; IoT, Internet of Things; LVEF, left ventricular ejection fraction; ML, machine learning; PCI, percutaneous coronary intervention; RMN, robotic magnetic navigation; TAVR, transcatheter aortic valve replacement; TTE, transthoracic echocardiography.

Despite these advancements, AI-based imaging tools face challenges regarding generalizability, regulatory approval, and integration into clinical workflows. Most poignantly, many algorithms perform well in controlled settings but require external validation in diverse patient populations to ensure broad applicability.<sup>22,23</sup> Moreover, the role of AI in real-world clinical decision-making remains to be fully established, as most studies focus on retrospective datasets rather than prospective validation in randomized trials. Results of ongoing large-scale clinical trials, such as the TRANSFORM (Treating Atherosclerosis In Patients With No Symptoms For Reducing Myocardial Infarction) study, aiming to evaluate the predictive value of AI-based imaging analysis for cardiovascular events in over 7000 patients, are eagerly awaited.<sup>24</sup>

Indeed, while AI holds promise in revolutionizing cardiac imaging, ongoing research must focus on ensuring transparency, reducing bias, and improving real-time interpretability. Future advancements should prioritize externally validated AI models that seamlessly integrate into clinical practice, balancing automation with physician oversight to optimize diagnostic accuracy and patient care.

### PREDICTIVE MODELING AND PERSONALIZED TREATMENT

The clinical translation of improved predictive modeling into personalized decision-making remains a challenge.<sup>5</sup> While ML techniques can identify patterns linked to myocardial infarction, heart failure, and stroke, their reported predictive accuracy rarely translates to real-world settings due to overfitting, biased training data, and poor generalizability.<sup>25</sup>

Similarly, claims on the favorable impact of AI-guided therapy on drug selection and adherence strategies are reassuring, but evidence of benefits over clinician-guided care remains limited.<sup>1,4</sup> Most AI applications in such settings lack prospective validation, struggle with dynamic patient conditions, and are difficult to integrate into routine workflows.

Focusing more attentively on cardiovascular therapeutics, AI-based decision support tools generate automated alerts and inform procedural steps but remain prone to false positives, inappropriate recommendations, and algorithmic bias.<sup>26</sup> In addition, over-reliance on these systems risks introducing medical errors rather than improving outcomes, as well as undermining clinician expertise.

Additional challenges to routine application of AI in cardiology include regulatory uncertainty and lack of transparency/interpretability/explainability. Future efforts should prioritize external validation, bias reduction, and ensuring AI remains a support tool rather than replacing expert judgment.

### ARTIFICIAL INTELLIGENCE APPLICATIONS IN INTERVENTIONAL CARDIOLOGY

Several AI applications have been envisioned in invasive cardiology (Table 4, Table 5, Figure 3).<sup>27-29</sup> Some have targeted the analysis of complex cardiovascular datasets, particularly in detecting ischemic heart disease and characterizing coronary plaque morphology, yet their reliability outside controlled environments remains questionable. While AI-driven image analysis can aid in identifying vulnerable plaques and assessing lesion severity, real-world validation remains limited and often biased toward retrospective datasets.

In the catheterization laboratory, AI-based tools also offer automated image interpretation during angiography and procedural navigation assistance.<sup>27</sup> However, while AI enhances imaging clarity and workflow efficiency, the assumption that AI-driven decision-making can reliably

mimic human clinical judgment is controversial. Training models on historical cases may, however, yield suboptimal recommendations in dynamic, high-risk scenarios where operator experience and real-time adaptation are critical. In addition, the risk of misclassification, overreliance, and potential liability concerns remains largely unaddressed.

Beyond procedural support, AI extends to post-procedural monitoring and rehabilitation, enabling automated risk assessment and early detection of complications.<sup>30</sup> Predictive analytics could optimize post-discharge management, but their integration into standard practice is constrained by poor interpretability, lack of clinician trust, and insufficient regulatory oversight. Without external validation in diverse populations and well-powered prospective studies, the promise of AI enhancing interventional cardiology remains speculative rather than transformative.

### ROBOTICS IN INTERVENTIONAL CARDIOLOGY

Robotic-assisted percutaneous coronary intervention (R-PCI) is an emerging technology in transcatheter therapeutics (Table 6).<sup>29</sup> By allowing interventional cardiologists to manipulate guidewires, catheters, and devices from a

**Table 4. Selected Patents on Artificial Intelligence in Cardiology**

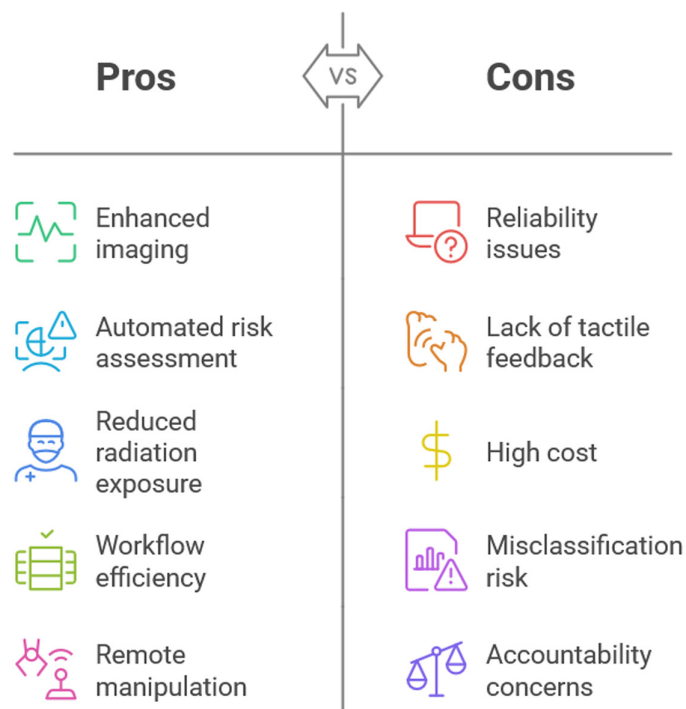
Title of Patent	Patent ID	Focus	Pros	Limitations
AI-based cardiac drug development platform	US 11 567 890 B2	Accelerating cardiac drug discovery using AI simulations	Speeds up development; predicts drug efficacy; reduces costs	Model accuracy limitations; regulatory hurdles
AI-based coronary heart disease diagnostic model	US 11 123 456 B2	Diagnosis of coronary heart disease using AI and genetic data	Combines genetic and clinical data for accurate diagnosis; non-invasive	Requires access to genetic data; potential privacy concerns
AI-based prediction of cardiac events	US 11 345 678 B2	Predicting cardiac events by analyzing patient data with AI	Enables proactive interventions; improves patient outcomes; non-invasive	Potential for false positives/negatives; depends on data accuracy
AI-enhanced cardiac rehabilitation system	US 10 876 543 B2	Personalized cardiac rehabilitation programs using AI	Tailors programs to individual needs; improves adherence; monitors progress	Requires patient compliance; access to technology may be limited
Method and apparatus for detecting atrial fibrillation	US 10 626 830 B2	Detection of atrial fibrillation during blood pressure measurement	Integrates AF detection into routine BP monitoring; enhances early detection; user-friendly	May not detect all arrhythmias; accuracy can be affected by user error
AI-powered cardiac monitoring wearable device	US 11 234 567 B2	Continuous cardiac monitoring using AI algorithms	Real-time monitoring; early anomaly detection; enhances patient engagement	Battery life constraints; data security concerns
AI-powered telecardiology platform	US 11 456 789 B2	Remote analysis of cardiac data using AI	Facilitates timely diagnoses; expands access to care; supports telemedicine	Relies on internet connectivity; potential data privacy issues
AI-driven cardiac imaging analysis system	US 10 987 654 B2	Analysis of cardiac images to detect structural heart diseases	Improves diagnostic precision; assists in early detection; reduces human error	Dependent on image quality; requires large datasets for training
AI-integrated cardiac catheterization system	US 10 765 432 B2	Enhancing precision in cardiac catheterization using AI	Reduces procedural risks; improves accuracy; assists clinicians	High implementation costs; requires specialized training
AI-driven heart failure management tool	US 10 654 321 B2	Managing heart failure by analyzing patient data with AI	Optimizes treatment plans; monitors disease progression; supports decision-making	Data integration challenges; requires continuous data input

AF, atrial fibrillation; AI, artificial intelligence; BP, blood pressure.

**Table 5. Selected Apps Leveraging Artificial Intelligence in Cardiology**

App	Context of Use	Features	Clinical Example
AliveCor KardiaMobile	Personal cardiac monitoring	Portable ECG device that detects atrial fibrillation and normal sinus rhythm; FDA-cleared.	Enables patients to monitor heart rhythms at home, facilitating early detection of arrhythmias.
AliveCor KardiaPro	Remote patient monitoring	AI-driven platform that allows clinicians to monitor patient ECG data remotely, integrating with Kardia devices to track heart health over time.	Facilitates continuous cardiac monitoring for patients with chronic heart conditions, enabling timely interventions when abnormalities are detected.
Anumana	AI-driven cardiac diagnostics	Develops algorithms for early detection of various cardiac conditions using ECG data; validated in numerous peer-reviewed publications.	Assists in early detection of conditions like left ventricular dysfunction, enabling timely intervention.
BioSig PURE EP System	Electrophysiology signal processing	Advanced AI-enhanced platform that improves the clarity of intracardiac signals during electrophysiology procedures.	Assists electrophysiologists in accurately identifying arrhythmias during procedures, potentially improving patient outcomes.
Cardio AI	Cardiac imaging analysis	AI-driven software that analyzes cardiac MRI and CT images to provide quantitative assessments of heart function and structure.	Facilitates precise evaluation of cardiac health, aiding in the diagnosis of conditions such as cardiomyopathies and heart failure.
CardioLogs	ECG analysis and reporting	Cloud-based AI platform that analyzes ECG recordings to detect a wide range of cardiac abnormalities, providing detailed reports for clinicians.	Streamlines the ECG analysis process, enabling faster diagnosis and treatment planning for patients with suspected heart conditions.
CarDS-Plus ECG Platform	Portable and wearable ECG device analysis	Multiplatform AI toolkit facilitates the rapid analysis of single-lead ECGs to detect cardiac abnormalities.	Enables quick detection of arrhythmias using wearable devices.
CathAI	Coronary angiography interpretation	Automated tool uses neural networks to interpret coronary angiograms, increasing standardization and reproducibility in assessing coronary stenosis.	Assists cardiologists in evaluating CAD severity.
CLEW ICU Platform	Intensive care unit monitoring	AI-powered predictive analytics platform that monitors ICU patients, including those with cardiac conditions, to anticipate and prevent clinical deterioration.	Supports healthcare providers in making informed decisions by predicting potential cardiac events in critically ill patients.
EchoMD	Echocardiography interpretation	AI-based platform that assists in the analysis and interpretation of echocardiograms, providing automated measurements and diagnostic suggestions.	Enhances the accuracy and efficiency of echocardiogram assessments, supporting cardiologists in diagnosing heart conditions.
HeartFlow Analysis	Coronary artery disease assessment	Non-invasive AI-powered software that creates a 3D model of coronary arteries from CT scans to evaluate blood flow and blockages.	Provides detailed information on coronary artery disease, aiding in treatment planning without the need for invasive procedures.
Nanox.AI	Medical imaging analysis	AI analyzes routine CT scans to identify asymptomatic chronic conditions in the heart, bones, and liver; FDA-cleared systems.	Assists radiologists in early detection of cardiovascular issues during routine imaging.
Philips AI Cardiac Imaging Solutions	Cardiac imaging diagnostics	AI-enhanced imaging tools improve diagnostic accuracy in cardiac assessments.	Assists in identifying cardiac abnormalities through advanced imaging analysis.
PulseAI	ECG analysis	AI-powered software enhances the detection accuracy of AF in ECG readings.	Improves diagnostic precision in identifying AF compared to traditional algorithms.
Tempus ECG-AF	Clinical risk assessment	AI algorithm analyzes ECG data to identify patients at increased risk of AF.	Supports clinicians in stratifying patients for early AF intervention.

AI, artificial intelligence; AF, atrial fibrillation; CAD, coronary artery disease; CT, computed tomography; ECG, electrocardiogram; FDA, Food and Drug Administration; ICU, intensive care unit; MRI, magnetic resonance imaging.



**Figure 3. Pros and cons of artificial intelligence applications and robotics in interventional cardiology.**

nearby or even remote cockpit, R-PCI could reduce radiation exposure and minimize the risk of injuries to physicians.

While industry-backed studies report high procedural success rates, real-world implementation has revealed several critical limitations. The lack of tactile feedback can impede complex lesion navigation, increasing reliance on operator intuition and imaging modalities. Moreover, system setup times can extend procedures, potentially negating efficiency benefits.<sup>31</sup> Cost is another major barrier, with R-PCI requiring substantial investment in robotic platforms, maintenance, and specialized training—a limiting factor for many hospitals. Patients with complex coronary artery disease (e.g., highly calcific lesions) and those with unstable coronary syndromes (e.g., ST-elevation myocardial infarction complicated by shock) could pose additional and quite significant challenges, for instance for inability to maneuver guidewires efficiently via the robot or delays in setting up the system or switching from R-PCI to manual PCI.

The integration of AI with R-PCI has been proposed to enhance real-time decision support and automate procedural adjustments, but its effectiveness remains largely theoretical. No robust, independent studies confirm AI-driven R-PCI improves outcomes over experienced manual operators.<sup>32</sup> Furthermore, automation raises concerns over accountability—should AI-driven errors lead to complications, who bears responsibility: the physician, the hospital, or the AI developer?

### **ETHICAL, REGULATORY, AND COLLABORATIVE ASPECTS OF ARTIFICIAL INTELLIGENCE IN CARDIOLOGY**

Implementing AI in cardiology introduces several ethical and legal challenges that must be addressed to ensure patient

safety and trust (Figure 4).<sup>33</sup> Concerns regarding patient confidentiality and data security are paramount, as AI systems often require access to sensitive health information (Table 3). Additionally, the potential for algorithmic bias poses risks of unequal treatment outcomes across diverse patient populations. Establishing clear legal frameworks and ethical guidelines is essential to navigate these complexities and promote equitable AI integration in cardiovascular care.

Regulatory oversight remains fragmented and inconsistent, with the European Medicines Agency (EMA), the United States Food and Drug Administration (FDA), and other governing bodies struggling to keep pace with rapid AI advancements.<sup>34</sup> The lack of standardized approval pathways has led to a proliferation of AI tools with variable levels of validation, raising concerns about their safety and efficacy in real-world settings. For example, AI-based arrhythmia detection algorithms have received regulatory clearance based on retrospective datasets, yet prospective trials demonstrating clinical utility remain scarce. Furthermore, the liability of AI-driven decision-making remains legally ambiguous.

The integration of AI into actual cardiology practice requires close collaboration between clinicians, data scientists, bioethicists, and regulators to ensure tools are clinically relevant, transparent, and unbiased.<sup>35</sup> However, current AI development often occurs in industry-driven silos, prioritizing commercial viability over clinical robustness. A lack of physician involvement in AI training and validation has resulted in models that function well in theory but fail to deliver meaningful benefits in real-world practice. Additionally, explainable AI remains an unmet need—clinicians are expected to trust AI-driven recommendations without clear reasoning behind predictions, creating barriers to adoption and accountability.

### **LIMITATIONS, CHALLENGES, AND FUTURE DIRECTIONS**

The adoption of AI in cardiology is hindered by multiple technical, clinical, and ethical challenges that limit its widespread integration into routine practice.<sup>19,36,37</sup> One of the most pressing issues is the lack of standardized protocols for AI implementation, leading to variability in clinical outcomes and poor reproducibility (Table 3).<sup>25,37</sup> Many AI models, despite demonstrating high predictive accuracy in retrospective datasets, fail to generalize when applied to diverse patient populations, partly due to limited external validation.<sup>38</sup> This problem is exacerbated in settings requiring real-time decision-making, such as emergency cardiovascular interventions, where AI-driven recommendations may lack the adaptability and contextual awareness of experienced clinicians.

Another major challenge is algorithmic bias, which arises from imbalanced training datasets that overrepresent certain demographics while underrepresenting others, leading to disparities in AI-guided clinical decisions.<sup>39</sup> Studies have shown that AI-based risk prediction models often underperform in minority populations, potentially exacerbating healthcare inequities.<sup>40</sup> Despite efforts to develop bias detection and correction frameworks, robust solutions remain scarce, limiting the reliability of AI-driven tools in real-world cardiology practice.



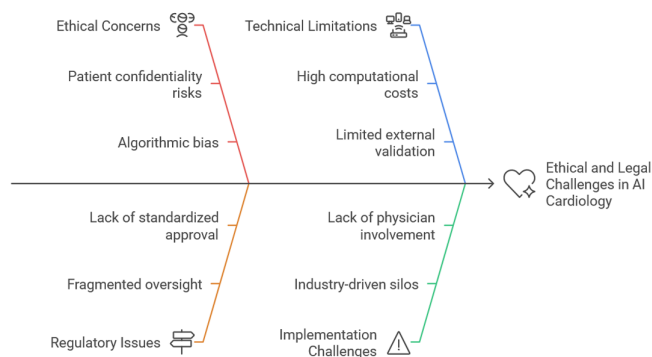
**Table 6. Selected Robotics Systems for Cardiology**

Technology	Context of Use	Features	Clinical Example
Amigo Remote Catheter System by Catheter Precision	Telerobotic interventions	Allows physicians to remotely control catheter movements during cardiac procedures, enhancing precision and reducing radiation exposure.	Utilized in remote catheter navigation during EP procedures.
Cardiodrive Catheter Advancement System by Stereotaxis	Automated catheter manipulation in EP	Intended to automatically advance and retract compatible magnetic EP mapping and ablation catheters when used in conjunction with a Stereotaxis magnetic navigation system.	Enhances procedural efficiency and precision in EP interventions.
CathROB by CathBot	Remote catheter navigation system	Highly compact and versatile remote catheter navigation system is designed to minimize encumbrance and setup time in standard catheterization labs. It features force-sensing mechanisms and intuitive command interfaces.	Enhances precision and safety in catheter-based procedures.
CorPath GRX System by Corindus	Telerobotic interventions	Enables remote performance of coronary procedures, expanding access to specialized care.	Successfully used in remote robotic-assisted PCI, demonstrating the feasibility of telerobotic interventions.
Genesis RMN System by Stereotaxis	Robotic magnetic navigation in EP	AI robotic magnetic navigation system with a tailored responsiveness to physician control, enhancing precision in catheter-based procedures.	Employed in complex EP procedures, improving catheter stability and navigation.
Niobe Magnetic Navigation System by Stereotaxis	Robotic catheter systems in EP	Uses magnetic fields for precise navigation of catheters within the heart, enhancing safety and efficacy of EP procedures.	Employed in complex ablation procedures for arrhythmia treatment, offering improved catheter stability.
Proteus Robotic Guidance System by Neuro-Kinesis	Portable robotic-assisted catheter guidance	Portable robotic-assisted catheter guidance system designed to provide precise catheter manipulation in various interventional procedures.	Aims to improve safety and efficacy in catheter-based interventions.
R-One by Robocath	Robotic-assisted PCI	Assists in the remote navigation, positioning, and delivery of guidewires, balloons, and stents during PCI, improving precision and operator safety.	Achieved 100% clinical success and over 75% reduction in operator radiation exposure in the pilot R-EVOLUTION (R-One Efficiency for PCI Evolution With Robotic Assistance) study.
Sensei X Robotic Catheter System by Hansen Medical	Robotic catheter systems in EP	Provides enhanced control and stability during complex cardiac mapping and ablation procedures, improving the treatment of cardiac arrhythmias.	Utilized in various EP procedures to treat arrhythmias with improved precision.

AI, artificial intelligence; EP, electrophysiology; PCI, percutaneous coronary intervention.

Another critical limitation is the opacity of most complex models, which function as “black boxes” with limited interpretability for clinicians, and this holds even truer when such models are protected by patents or copyright.<sup>41</sup> The lack of

explainable AI (XAI) undermines clinician trust and complicates accountability in medical decision-making. A poignant question commonly comes to mind: if an AI-driven system misguides treatment, who is responsible—the physician, the developer, or the AI system itself? Addressing these concerns requires greater model transparency, clinically interpretable outputs, and regulatory frameworks clarifying liability in AI-assisted decision-making.



**Figure 4. Challenges to the implementation of artificial intelligence in cardiovascular medicine.**

The high computational costs associated with AI model development and deployment present additional barriers to implementation, particularly in resource-limited healthcare settings.<sup>36</sup> While large academic centers and high-volume hospitals may afford AI-driven clinical decision support tools, smaller institutions and underserved regions often lack the infrastructure to integrate these technologies effectively. Additionally, AI-based cardiology tools currently face fragmented regulatory oversight, with inconsistent approval pathways between the FDA, EMA, and other regulatory

bodies.<sup>34</sup> The absence of standardized validation criteria has led to the premature adoption of AI-driven diagnostics and decision support systems without robust prospective trial data confirming their real-world efficacy.

Moving forward, greater emphasis must be placed on prospective validation, ensuring AI models perform reliably across diverse populations and clinical scenarios.<sup>42</sup> Promising avenues for AI include its integration with robotic-assisted interventions, where automation could enhance precision in complex PCI. However, the assumption that AI-driven robotics will outperform human operators remains speculative, necessitating large-scale, independent clinical trials to assess safety and efficacy.

Similarly, AI-powered telemedicine platforms hold the promise of improving remote cardiovascular monitoring and early disease detection, particularly in heart failure management.<sup>30</sup> However, these systems must be rigorously tested to ensure they provide actionable insights without overburdening clinicians with false positives or generating unnecessary interventions. Another area of interest is the potential role of AI in regenerative cardiology, where predictive modeling could aid stem cell therapy optimization and tissue engineering strategies.

### CASE STUDIES AND REAL-WORLD IMPLEMENTATIONS

Artificial Intelligence has been successfully implemented in various real-world cardiology settings, with favorable results in terms of disease prediction, diagnosis, and management.<sup>1,27</sup> For instance, AI-powered diagnostic tools have improved the detection of congenital heart diseases, leading to earlier interventions and better patient outcomes.<sup>43</sup>

Additionally, AI has been integrated into cardiac imaging, assisting in the interpretation of echocardiograms, MRIs, and CT scans.<sup>44</sup> This integration has resulted in more consistent and accurate readings, aiding clinicians in making informed decisions.

Predictive analytics has been employed to forecast cardiovascular risk and guide chronic disease management, but real-world deployment has faced challenges.<sup>33</sup> Indeed, AI-based prediction models for cardiovascular readmissions may appear accurate in the short term or in “bread and butter” patients but prove inaccurate over time without hands-on clinician oversight and expertise when focusing on niche, but actually quite common, patient subgroups.<sup>45</sup>

Indeed, automated imaging analysis by non-experts could enable healthcare providers with limited imaging training to leverage AI for non-invasive diagnostics. For example, AI-assisted lung ultrasound interpretation for heart failure patients allowed general practitioners to detect pulmonary congestion with 80% sensitivity, yet false positives led to unnecessary interventions, demonstrating the need for human validation before AI-generated insights are acted upon.<sup>33</sup>

### CONCLUSION

The increasing integration of AI in cardiovascular medicine is not yet mirrored by evidence of its favorable real-world

impact. While AI-driven tools enhance diagnostics, risk prediction, and interventional procedures, their clinical reliability, generalizability, and cost-effectiveness remain questionable. Most AI models excel in controlled settings but fail in diverse real-world populations, raising concerns about bias, transparency, and accountability. Despite claims of automation and precision, AI often introduces new inefficiencies, misclassifications, and workflow disruptions. The lack of explainability remains a major barrier, as clinicians struggle to trust opaque, algorithm-driven recommendations. Moreover, regulatory inconsistencies and high implementation costs restrict accessibility to AI, disproportionately favoring well-funded institutions. Future progress hinges on rigorous external validation, clear regulatory oversight, and interdisciplinary collaboration. AI should remain a clinical adjunct, not a substitute for human expertise. Without critical evaluation and evidence-based integration, AI risks becoming another overhyped technology with marginal real-world benefit.

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