

Machine Learning-Based Risk Stratification of Procedural and Ischemic Outcomes in Prediabetic Patients Undergoing Chronic Total Occlusion Interventions

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Abstract

Prediabetic patients undergoing percutaneous coronary intervention for chronic total occlusion represent a clinically challenging population with elevated procedural complexity and ambiguous ischemic risk. Traditional regression-based risk models often fail to capture the nonlinear interactions among glycemic status, lesion anatomy, operator technique, and institutional factors. This paper examines the design and deployment of machine learning systems for risk stratification in this setting from a socio-technical and systems perspective. It argues that algorithmic accuracy must be embedded within a broader architecture that includes data governance, interoperable infrastructure, model interpretability, fairness, workflow integration, and longitudinal monitoring. The discussion covers cohort characterization, missing data handling, model selection, validation, deployment, sustainability, and policy implications. A recent national inpatient sample study reporting a paradoxical mortality benefit but increased procedural and ischemic risk in prediabetic chronic total occlusion is considered as an illustration of outcome complexity. The paper highlights structural trade-offs between centralized and federated learning, between model complexity and clinical explainability, and between performance optimization and equity. It concludes that sustainable clinical machine learning systems require robust governance mechanisms, standardized outcome definitions, prospective evaluation, and regulatory alignment to support safe decision-making in interventional cardiology.

Keywords

machine learning; risk stratification; prediabetes; chronic total occlusion; percutaneous coronary intervention; fairness; clinical governance.

1. Introduction

Chronic total occlusion percutaneous coronary intervention remains among the most technically demanding procedures in interventional cardiology. Patients with prediabetes present a particular challenge because chronic hyperglycemia, insulin resistance, and subclinical inflammation may alter vascular biology, plaque composition, and microvascular function, yet these patients do not fall neatly into established diabetic risk categories. As the volume of clinical, angiographic, and laboratory data expands, conventional regression-based risk scores increasingly struggle to represent the conditional dependencies that determine procedural success, ischemic complications, and long-term benefit. Machine learning offers a powerful set of methods for learning complex risk patterns from high-dimensional data, but its value in this clinical context depends on more than predictive performance [1]. The translation of machine learning into routine cardiovascular care requires attention to data

quality, interoperability, safety, fairness, workflow, and governance, all of which shape whether a model becomes a reliable clinical tool or an additional source of operational risk [2].

The broader literature on machine learning in medicine has demonstrated both promise and recurring failures. Models may achieve high discrimination in retrospective datasets while exhibiting serious bias when deployed across heterogeneous populations or institutions [3]. The sources of such failures are often systemic rather than purely algorithmic, including inconsistent coding, missing data, selection effects in registries, and drift in patient demographics or treatment practices [4]. Large publicly available critical care databases have accelerated methodological development, but their scope is not directly transferable to procedural cardiology because they lack detailed angiographic and device-level information [5]. Thus, this paper adopts a systems perspective rather than reporting a single model. It examines how machine learning risk stratification for prediabetic patients undergoing chronic total occlusion interventions should be designed, governed, deployed, and sustained within large cardiovascular care networks. The analysis moves from clinical risk context to data infrastructure, model architecture, fairness, deployment, and policy.

2. Clinical and Systems Context of Chronic Total Occlusion Revascularization in Prediabetes

Chronic total occlusion revascularization is performed to relieve angina, improve left ventricular function, and reduce ischemia, but it carries meaningful risks of coronary perforation, periprocedural myocardial infarction, contrast nephropathy, and radiation injury. Consensus documents and registry studies have established that successful recanalization depends on anatomical features such as occlusion length, calcification, tortuosity, and the availability of collateral flow, as well as operator technique and institutional volume [6]. The decision to intervene in a chronic total occlusion is therefore not solely a clinical judgment; it is embedded in an organizational system involving imaging, device availability, scheduling, and multidisciplinary review. National registry data show substantial variation in procedural success and complication rates, which suggests that risk stratification models must account for institutional and operator factors rather than only patient-level features [7]. Large multicenter registries have further demonstrated that hybrid approaches, including antegrade and retrograde strategies, have improved success rates over time, but they may also introduce new patterns of complications that are not well captured by older risk scores [8]. Meta-analytic evidence indicates that successful recanalization is associated with symptomatic and prognostic benefits, yet residual uncertainty remains about which subgroups benefit most, particularly among individuals with dysglycemia [9].

Prediabetes is a state of abnormal glucose homeostasis that does not meet the diagnostic threshold for diabetes. It is associated with endothelial dysfunction, oxidative stress, and accelerated atherosclerosis, and it is highly prevalent among patients undergoing coronary revascularization. However, the relationship between prediabetes and procedural outcomes is not linear or easily summarized. Some studies have reported that prediabetic patients may have better short-term survival than diabetic patients while still experiencing elevated risks for ischemic and procedural events. This paradox illustrates why machine learning models may be useful: they can integrate continuous glycemic measures, metabolic markers, anatomical complexity, and treatment covariates without requiring the discretization of prediabetes into a simple binary category. Yet the systems challenge is that prediabetes is undercoded in administrative datasets, inconsistently defined across laboratory protocols, and

often treated as a transient state rather than a stable chronic condition. These data limitations have direct implications for model development and deployment.

3. Data Infrastructure and Cohort Characterization

A dependable risk stratification system begins with data infrastructure that supports longitudinal linkage among inpatient, outpatient, laboratory, pharmacy, and procedural records. In cardiovascular and critical care research, harmonized physiological and administrative data have demonstrated the value of reproducible machine learning models, but chronic total occlusion datasets require additional granularity, including detailed angiographic core laboratory variables, device logs, radiation dose, contrast volume, and operator identifiers [5]. The absence of such structured fields in many electronic health record systems necessitates natural language processing of catheterization reports, which introduces further variability and validation burden. From a systems perspective, the trade-off is between depth and breadth: highly curated core laboratory datasets may provide cleaner labels but limited sample size, whereas administrative registries offer broad coverage but less clinical nuance. For prediabetic patients, this trade-off is especially consequential because glycemic status may be incompletely documented in claims data, and outcome definitions may vary between procedural registries and billing codes.

Missing data and measurement error are central structural problems. Multiple imputation using flexible machine learning methods can preserve uncertainty and improve estimate stability relative to simpler single imputation, but the imputation models themselves must be evaluated for bias and calibration [10]. Feature missingness may be informative, especially in prediabetic patients who have less frequent laboratory screening. A systems approach should therefore include explicit missingness indicators and sensitivity analyses across plausible glycemic classifications. Furthermore, predictive model development should follow reporting frameworks such as the Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis statement to ensure that the study design, predictor definitions, and validation strategy are transparent enough for external review [11]. Sample size planning for prediction models requires careful attention to the number of candidate predictors, expected outcome rates, and desired precision, particularly when modeling rare complications in a subgroup such as prediabetic chronic total occlusion patients [12]. Without these elements, retrospective models may be too fragile to support clinical decisions.

4. Machine Learning System Architecture and Risk Model Design

The design of a machine learning system for procedural and ischemic outcome stratification must align analytic objectives with clinical decision points. Pre-procedural models may support patient selection and informed consent, while intra-procedural or post-procedural models may guide hemodynamic support, antithrombotic therapy, and surveillance. These different use cases require different feature availability, latency, and outcome definitions. A responsible development process must begin by specifying the intended clinical action and then define model outputs, decision thresholds, and escalation pathways rather than optimizing a single performance metric in isolation [13]. The translation of machine learning into interventional cardiology also demands evidence of clinical utility beyond discrimination, including the effect on workflow, resource use, and patient-centered outcomes [14]. Standardized definitions for bleeding and ischemic complications are particularly important because model labels derived from heterogeneous adjudication processes can produce misleading risk estimates [15].

A recent national inpatient sample analysis reported a paradoxical mortality benefit but increased procedural and ischemic risk in prediabetic patients with chronic total occlusion [16]. This finding underscores that a single composite outcome may obscure divergent effects across mortality, procedural complications, and ischemic events. In a machine learning architecture, this means the label space should be explicitly decomposed into multiple endpoints, each with its own risk model or a multi-task learning framework that shares representations while preserving outcome-specific calibration. Procedural success, major bleeding, acute kidney injury, periprocedural myocardial infarction, and long-term ischemic events are not interchangeable; predictors may differ in both direction and magnitude across these outcomes.

Algorithmically, gradient-boosted decision trees have become a common baseline in clinical risk modeling because they handle tabular data with mixed variable types, missing values, and nonlinear interactions effectively [17]. They also support interaction detection and variable importance estimation, which can be useful for identifying unexpected predictors of procedural risk in prediabetic chronic total occlusion patients. However, tree ensembles are not inherently interpretable, and clinicians may require local explanations to understand why a particular patient receives a high-risk designation. Post hoc explanation methods such as Shapley additive explanations can decompose a prediction into contributions from individual features, but these explanations must be interpreted as summaries of model behavior rather than causal claims [18]. From a systems perspective, the risk model itself is only one component of a larger architecture that includes feature stores, model registries, prediction services, and audit logs. The choice between a centralized model trained on pooled registry data and a federated approach has major implications for data governance and generalizability.

5. Governance, Fairness, and Interpretability

Governance of machine learning risk stratification in cardiology must address accountability, data stewardship, and algorithmic fairness. Federated learning offers a structural mechanism for training models across institutions without transferring raw patient data, which can reduce privacy risks and support multisite collaboration, but it also introduces challenges in coordinating data schemas, outcome labels, and model updates [19]. Governance frameworks must establish who is responsible for model maintenance, how model performance is reviewed, and what happens when performance deteriorates or a serious adverse event occurs. In prediabetic patients, fairness analyses should evaluate model performance across age, sex, race and ethnicity, renal function, glycemic categories, and institutional settings because risk estimates may be miscalibrated for underrepresented groups even when aggregate performance appears strong [3].

Interpretability is not simply a technical feature; it is a governance requirement that interfaces with patient consent, shared decision-making, and legal accountability. Clinicians must be able to communicate why a model assigns elevated procedural risk to a prediabetic patient and how that risk estimate should influence revascularization strategy. Explainability tools can support this process, but they must be embedded in a workflow that allows clinicians to override or contest model outputs without undermining the value of decision support [18]. Ethical frameworks emphasize that machine learning systems in medicine should be transparent, proportionate, and subject to independent oversight, particularly when they influence invasive procedures or resource allocation [20]. Governance should also include auditability of training data, model versions, and deployment logs so that retrospective investigations can reconstruct why a particular prediction was generated.

6. Deployment, Monitoring, and Sustainability

Deployment of a machine learning model in a catheterization laboratory is a socio-technical intervention, not a software installation. The model must receive timely data from the electronic health record, laboratory systems, and angiographic reporting tools, and it must return risk estimates in a format that fits clinical workflow. Decision support that requires additional manual data entry or interrupts procedural planning is unlikely to be sustained. The system architecture should therefore favor passive integration into existing dashboards and order sets, with clear visual encoding of absolute risks, confidence intervals, and modifiable risk factors. Human factors engineering is essential because clinician trust is shaped by transparency, consistency, and the ability to compare model predictions with clinical judgment. In this context, machine learning models may be most useful when they function as a second opinion rather than a gatekeeper, especially in complex chronic total occlusion cases where operator experience and anatomical judgment remain central.

Longitudinal monitoring is necessary because the performance of risk models can drift as devices, techniques, and patient selection evolve. A deployment system must track data completeness, outcome rates, calibration drift, and subgroup performance over time. When a model is used to support procedural decisions, hospitals should maintain audit logs that link model versions to patient outcomes, enabling postmarket surveillance and root-cause analysis. Sustainability also depends on aligning model development with institutional quality improvement programs and reimbursement mechanisms. If a risk stratification system reduces complications or avoids futile procedures, its value may be realized through lower costs and improved patient experience, but this value must be measured and demonstrated prospectively. Governance frameworks should require prospective validation and continuous monitoring before broad deployment [13]. Federated infrastructure can support distributed monitoring by allowing institutions to share aggregated performance metrics without sharing patient-level data, thereby strengthening external validity while preserving privacy [19].

7. Policy Implications and Future Directions

The policy environment for machine learning in cardiovascular care is evolving rapidly. Regulators and payers increasingly expect evidence of external validity, safety monitoring, and equity before algorithm reimbursement. Risk stratification models for prediabetic chronic total occlusion patients fit within this broader trend because they influence high-cost procedures and invasive decision-making. Policy should encourage the use of standardized data elements for glycemic status, lesion complexity, operator volume, and outcomes because without such standards, cross-institutional benchmarking and algorithmic audits remain difficult. The adoption of common data models and reporting frameworks can support the development of registries that are suitable for machine learning, but these efforts require investment in data governance, semantic interoperability, and workforce training.

Future systems may move beyond static risk scores toward dynamic decision support that incorporates real-time physiological data, computational hemodynamics, and image-derived anatomical features. However, such advances must be accompanied by stronger evidence on clinical utility, patient-centered outcomes, and unintended consequences. The paradox observed in prediabetic chronic total occlusion outcomes indicates that risk models must differentiate between survival, procedural complications, and ischemic events, and they should be calibrated for the specific populations and settings in which they are deployed. Prospective multicenter studies are needed to evaluate whether machine learning-based risk stratification changes patient selection, procedural planning, or longterm outcomes,

complication rates, and long-term survival in this population. Such studies should be embedded in learning health systems that integrate prospective data collection with model refinement. The use of pragmatic trial designs and registry-based randomization may accelerate evidence generation while maintaining real-world relevance [21]. Regulatory bodies should articulate clear expectations for software as a medical device in cardiovascular risk prediction, including requirements for real-world performance monitoring and update pathways. Health technology assessment frameworks also need to evolve to account for the nonstatic nature of machine learning systems, in which retraining and drift correction are part of the product life cycle. Cost effectiveness analyses should include the infrastructure costs of data governance, model maintenance, and clinician training rather than treating algorithms as one-time investments [22].

Policy should also address the risk of widening disparities through differential access to advanced procedural technologies. Prediabetic chronic total occlusion patients are often managed in settings with variable access to intravascular imaging, experienced operators, and hybrid algorithms. A machine learning system that is trained primarily in high-volume academic centers may not perform well in low-resource environments, and it may reinforce existing referral patterns rather than improve equitable access. Fairness audits should therefore be conducted not only with respect to demographic subgroups but also across institutional settings and practice environments. The development of uncertainty quantiles can help clinicians distinguish between high-confidence predictions and cases for which additional imaging or expert consultation is warranted. Model reporting should include performance in clinically relevant subgroups and explicit limitations regarding external transportability [23]. This level of transparency supports trust and enables shared decision-making with patients who face complex trade-offs between procedural risk and ischemic burden.

The integration of machine learning into chronic total occlusion care also raises questions about professional autonomy and liability. Clinicians may be hesitant to adopt algorithmic risk estimates if they fear that deviation from model recommendations will be scrutinized in malpractice proceedings. Legal and policy frameworks should clarify that decision support tools are intended to augment, not replace, clinical judgment, and that the ultimate accountability for procedural decisions remains with the operator and the care team [21]. At the same time, institutions that deploy such systems have a duty to ensure that models are appropriately maintained, that users receive adequate training, and that algorithmic failures are reviewed through structured quality improvement processes. Emerging guidance from cardiovascular societies emphasizes the need for multidisciplinary oversight, including data scientists, outcomes researchers, and patient representatives, to supervise the implementation of artificial intelligence in interventional cardiology [22].

Several research directions are particularly important. First, prospective cohort studies should assess whether prediabetes-specific risk stratification changes revascularization strategy and resource use without increasing inappropriate avoidance of beneficial procedures. Second, external validation across geographically and socioeconomically diverse registries is needed to determine whether models trained on administrative data can be safely applied to procedural registries with more granular anatomical detail. Third, comparative effectiveness studies should evaluate machine learning models against existing clinical scores such as the J-CTO score and PROGRESS-CTO score to determine whether the additional complexity of machine learning yields meaningful gains in discrimination or calibration [24]. Fourth,

qualitative research should examine clinician and patient attitudes toward algorithmic risk stratification in invasive cardiology, because acceptance is shaped by perceived transparency, workflow burden, and trust in the underlying data. Fifth, policy experiments should test models of algorithmic stewardship in which dedicated cardiovascular data science teams review model performance and guide iterative updates. The evaluation of prediction models should follow contemporary methodological standards that emphasize calibration, discrimination, clinical utility, and validation in intended use settings [25].

Finally, the prediabetic population illustrates the broader systems challenge of applying machine learning to conditions that are defined by continuous biomarkers but operationalized as categories. Risk models that treat glycemic status as a static label may miss patients whose metabolic trajectory is evolving. Future architectures should incorporate longitudinal glycemic trajectories, medication use, and lifestyle factors to produce dynamic estimates that can be updated as new data become available. This shift from static risk scores to dynamic risk trajectories aligns with the broader movement toward precision medicine and learning health systems. However, it also magnifies the need for robust data governance, because longitudinal linkage across inpatient and ambulatory settings increases the sensitivity of the data and the complexity of privacy protections. Federated analytics and secure multiparty computation may support such linkage while reducing the risk of reidentification [19]. The governance arrangements must be proportionate to the sensitivity of the data and the potential harms of incorrect predictions.

In conclusion, machine learning-based risk stratification for prediabetic patients undergoing chronic total occlusion interventions holds substantial promise, but its success depends on an integrated approach that spans data infrastructure, model design, governance, deployment, and policy. The technical performance of a model is necessary but insufficient. A system that is accurate in a retrospective registry may fail in clinical practice if it is not interoperable, interpretable, fair, and continuously monitored. The paradoxical outcomes observed in prediabetic chronic total occlusion populations reinforce the need for multiple outcome models rather than a single composite risk score. Sustainable systems require prospective validation, standardized definitions, institutional accountability, and regulatory frameworks that support safe innovation. Interdisciplinary collaboration among cardiologists, data scientists, health informaticians, ethicists, and policymakers will be essential to translate algorithmic advances into meaningful improvements in patient care.

Conclusion

This paper has examined machine learning-based risk stratification for procedural and ischemic outcomes in prediabetic patients undergoing chronic total occlusion interventions from a systems perspective. The central argument is that predictive modeling cannot be isolated from the broader socio-technical infrastructure in which it operates. Data quality, outcome standardization, model interpretation, workflow integration, fairness, and governance all shape the clinical value and safety of risk stratification systems. The paradoxical mortality and morbidity patterns observed in this population highlight the danger of reducing heterogeneous clinical outcomes to a single composite endpoint. A robust architecture should decompose outcomes, support multisite validation, incorporate uncertainty, and enable longitudinal monitoring. The deployment of such systems should be guided by explicit governance frameworks, prospective evaluation, and policy mechanisms that prioritize transparency and equity. Future research should move beyond retrospective model development toward implementation science studies that measure clinical utility, patient-

centered outcomes, and sustainability across diverse care settings. In doing so, the field can advance from promising algorithms to trustworthy decision support tools that genuinely improve the care of patients with complex coronary disease and dysglycemia.

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