Review

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Artificial intelligence and machine learning in thrombosis and hemostasis: a scoping review of clinical and laboratory applications, challenges, and future directions

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Abstract: This scoping review followed the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines to systematically map the current landscape of artificial intelligence (AI) and machine learning (ML) applications in the field of thrombosis and hemostasis (T&H), specifically targeting diagnostic enhancements in clinical and laboratory settings. Utilizing comprehensive searches across MEDLINE, EMBASE, Web of Science, and Scopus (2020–2025), 107 original studies met inclusion criteria and were analyzed. Clinical applications predominantly focused on predictive modelling for venous thromboembolism (VTE), pulmonary embolism (PE), deep vein thrombosis (DVT), anticoagulant management, and disease risk stratification, employing algorithms including neural networks, random forests, and gradient boosting. Laboratory-based AI implementations, though fewer, provided automated quality control, clot detection, and assay interpretation enhancements for potential better decision-making. Significant limitations addressed by the include studies include reliance on retrospective, single-center, small-sample datasets, limited external validation, model interpretability concerns, and integration challenges into clinical workflows. Persistent interdisciplinary disconnect between hemostasis domain experts and AI-ML specialists, compounded by regulatory hurdles, fragmented data, and labor-intensive data labelling processes, was highlighted as a major barrier to broader adoption. Recommendations for future research include developing large, externally validated multicenter datasets, transparent and interpretable ML models, prospective clinical validations, and user-centered integration strategies. Enhancing collaboration between laboratory scientists and AI-ML experts, establishing structured education programs, and creating regulatory frameworks are essential next steps to fully realize the potential of AI for significantly improving diagnostic accuracy, clinical decision-making, and patient management in T&H.

Keywords: artificial intelligence; diagnostics; hematologic diseases; hemostasis; machine learning; thrombosis

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Introduction

The fields of thrombosis and hemostasis (T&H) encompass disorders of blood clotting and bleeding, including thrombotic conditions such as venous thromboembolism (VTE), coagulopathies like disseminated intravascular coagulation (DIC) and heparin-induced thrombocytopenia (HIT), and bleeding disorders such as hemophilia A and B, and von Willebrand disease [1–3].

These conditions are major causes of morbidity and mortality worldwide [4]. For example, VTE (encompassing deep vein thrombosis (DVT) and pulmonary embolism (PE)) is the leading cause of preventable death among hospitalized patients [4]. Accurate and timely diagnosis of T&H

disorders is often challenging – clinical presentations can be subtle or confounded by comorbidities, and laboratory assays are complex, sometimes yielding indeterminate results [5–14]. Traditional diagnostic algorithms (e.g., scoring systems such as the 4Ts for HIT or International Society on Thrombosis and Haemostasis (ISTH) criteria for DIC) are useful but have limitations in sensitivity and specificity [15, 16].

In this context, artificial intelligence (AI) and machine learning (ML) offer new opportunities to enhance diagnostic accuracy and decision-making. AI is a developing field of computer science that focuses on developing models and algorithms capable of performing tasks that otherwise require human intelligence. ML is a subfield of AI that focuses on developing models capable of learning and making predictions or decisions from data, without being explicitly programmed [17].

AI systems excel at recognizing complex patterns in large datasets beyond what conventional statistical methods can parse [1, 18–26]. Over the past decade, AI-ML techniques have been increasingly applied in medicine, including laboratory medicine, to improve patient care through better risk prediction, image interpretation, diagnosis and personalized treatment, recommendations and optimizing workflows [19, 27–36]. In fields such as radiology, cardiology, and oncology, AI algorithms have demonstrated superior performance for certain diagnostic tasks, spurring interest in their adoption.

In T&H, the application of AI-ML is still emerging but gaining traction. Initial studies and reviews suggest that AI approaches can augment both laboratory and clinical aspects of T&H [6, 20, 21, 24, 27, 30, 31, 37–45]. For example, Villacorta et al. leveraged ML techniques, specifically elastic net logistic regression, to develop a risk stratification model for PE. The model integrated D-dimer values, oxygen saturation, and medical history to enhance the accuracy of PE risk assessment and improve imaging efficiency. This approach resulted in more precise and actionable interpretation of D-dimer results and a reduction in the overuse of CT scans [46].

Another recent study by de Laat-Kremers et al. developed a thrombin-driven neural network capable of diagnosing antiphospholipid syndrome (APS) without requiring interruption of anticoagulation therapy. The model utilized thrombin generation curves to accurately identify APS in anticoagulated patients. This example demonstrates how AI, in this case, a neural network can facilitate diagnosis, in complex anticoagulated cases without the need for interrupting anticoagulation, repeating tests and/or using anticoagulant neutralizing procedures (e.g., DOACSTOP), an additional but time-consuming step required for confirming Lupus anticoagulant (LA) [47].

Despite these promising examples, the landscape of AI-ML applications in T&H has not been comprehensively mapped. Prior articles have provided overviews of the topic – for example, a narrative review by Gresele summarized early uses of AI in T&H and discussed future prospects, and Rashidi et al. reviewed ML methods in coagulation and hemostasis research [31, 38]. However, no systematic scoping review has yet synthesized the breadth of evidence across both laboratory and clinical domains of T&H.

The aim of this scoping review is therefore to systematically identify and chart the literature on where, what and how AI and ML have been applied in the field of T&H, specifically focusing on diagnostic applications in clinical and laboratory settings. The review seeks to elucidate the current state of knowledge and highlight gaps and challenges for future research. The review addresses the following key questions:

I. What types of AI-ML techniques have been applied to T&H problems, and how are these models implemented?
II. In what areas of T&H diagnostics are AI-ML models being used? Specifically, what clinical diagnostic tasks (e.g., disease prediction, patient risk stratification, imaging interpretation) and laboratory diagnostic tasks (e.g., assay quality control, pattern recognition in test results, lab optimization) are addressed?
III. What are the limitations, challenges, or risks noted in the literature regarding AI-ML in T&H?
IV. What future directions have been identified to advance the use of AI/ML in T&H?

By answering these questions, the goal is to provide a comprehensive overview of the landscape of AI-ML in T&H, guiding researchers and clinicians on where AI has been beneficial, where improvements are needed, and how future studies can be directed.

Methods

Study design

A scoping review, following established frameworks by Arksey and O'Malley [48] and the enhancements by Levac et al. [49], as well as the latest guidance from the Joanna Briggs Institute (JBI) Manual for Evidence Synthesis [50], was conducted. The reporting of this review adheres to the PRISMA Extension for Scoping Reviews (PRISMA-ScR) checklist [51]. A protocol outlining the review approach was developed *a priori* (internal reference, not publicly

registered) to define the objectives, inclusion criteria, and methods.

Eligibility criteria

Inclusion of literature that met the following criteria: (1) focused on thrombosis and/or hemostasis topics/conditions/abnormalities; (2) involved the application/use of AI-ML techniques for a diagnostic, predictive, prognostics or other similar purpose; (3) original research articles; and (4) published in English in peer-reviewed journals. Emphasis was placed on studies dealing with clinical and/or laboratory-based applications. Exclusion criteria included review articles, conference abstracts without full text, editorials/commentaries, and single-patient case reports, as the focus was on collating evidence from substantive research studies. When multiple papers reported results from the same study population, only the most comprehensive reports were included to avoid duplication.

Information sources and search strategy

A comprehensive literature search was performed. Electronic databases including MEDLINE (via PubMed), EMBASE, Web of Science, and Scopus from 2020 to 2025 was searched. The search strategy combined controlled vocabulary (e.g., MeSH terms) and keywords for two concepts: (a) artificial intelligence and machine learning, and (b) thrombosis/hemostasis. Keywords for AI/ML included “artificial intelligence”, “machine learning”, “deep learning”, “neural network”, “algorithm”, and “natural language processing”. These were paired with T&H terms such as “thrombosis”, “thromboembolism”, “venous thromboembolism”, “pulmonary embolism”, “deep vein thrombosis”, “coagulation”, “hemostasis/haemostasis”, “platelet”, “anticoagulation”, “bleeding disorder”, “DIC (disseminated intravascular coagulation)”, “hemophilia”, “antiphospholipid”, etc. Boolean operators and database-specific syntax were used to ensure a sensitive search. An example MEDLINE search string is provided in the Appendix: Search strategy – it incorporated terms like (“artificial intelligence” OR “machine learning” OR “neural network*” OR “deep learning” OR “algorithm*”) AND (“thrombosis” OR “thromboembolism” OR “coagulation” OR “hemostasis” OR “haemostasis” OR related terms). The reference lists were scanned to included articles and relevant review papers to identify any additional studies missed by the database search. Non-English records were filtered out at the screening stage.

Selection of sources of evidence

All titles and abstracts retrieved from the search were imported into a reference management software EndNote (Clarivate, Philadelphia, USA) and duplicates were removed. The screening process was conducted in two levels by two independent reviewers conducting both title/abstract and full-text screening: (1) Title/abstract screening – these were independently screened and each record’s title and abstract reviewed for potential relevance, applying the eligibility criteria. Studies that clearly did not meet criteria (e.g., unrelated to T&H or not involving AI/ML) were excluded at this stage. If relevance was uncertain from the abstract alone, the citation was carried forward to full-text review to avoid premature exclusion. (2) Full-text screening – these were obtained and independently assessed for eligibility. A standardized form to confirm inclusion or record reasons for exclusion was developed on a Microsoft Excel (Microsoft Corporation, Redmond, USA) spreadsheet. Any uncertainties with studies were resolved through regular discussion/meetings with all authors. A PRISMA flow diagram was created to document the number of records identified, screened, excluded, and ultimately included (Figure 1).

Data charting and extraction

A data charting form was developed to extract key information from each included study (Microsoft excel). The form was pilot tested on a sample of five studies and refined accordingly. Extracted data included: author(s), year of publication, study design, T&H domain or condition addressed, sample size and data sources, description of the AI-ML approach, and the main outcomes or findings. Additionally for laboratorian intended users, how the AI assisted or can potentially assist the field was included. Any comments made on model interpretability, validation, and comparisons to standard of care or traditional methods was also noted.

The studies were categorized into thematic groups to facilitate synthesis. During extraction, it became evident to group applications into two broad categories aligned with the review focus: (1) laboratory applications (studies where the AI was applied to laboratory data or lab processes, such as interpreting test results or images, or improving laboratory diagnostics) and (2) clinical applications (studies where AI was used on clinical patient data for diagnosis, risk prediction, or management decisions in T&H and the intended users were clinicians).

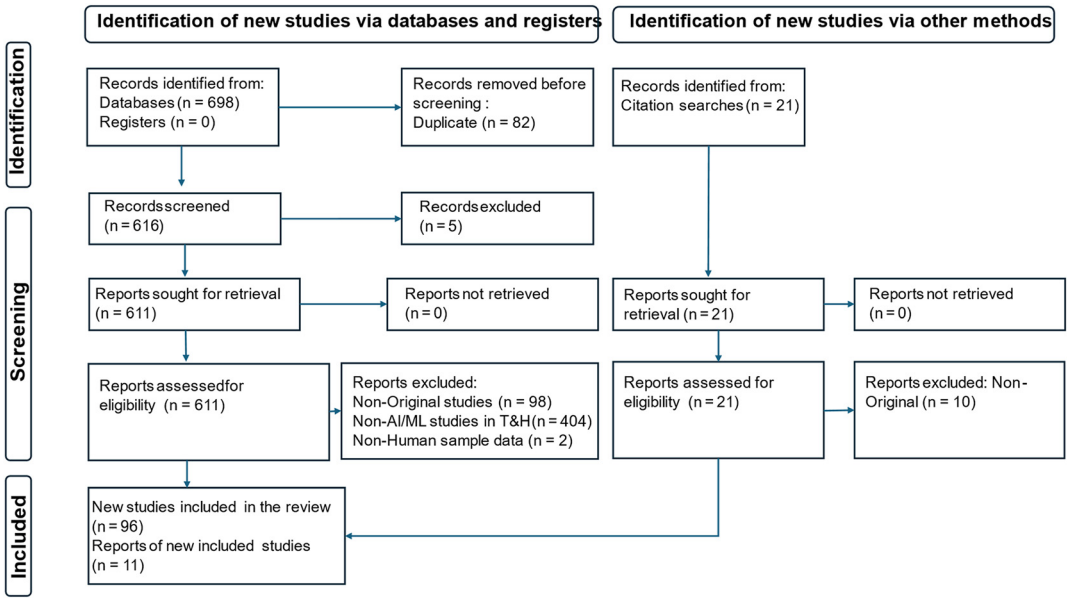

Figure 1: PRISMA-ScR flow diagram of literature search and study selection.

Critical appraisal of individual sources of evidence

Risk of bias assessment of included studies was not applicable to this scoping review as the purpose of this review was to identify and chart the literature on how, where and what AI-ML have been applied in the field of T&H. This is consistent with recommendations in the PRISMA-ScR [51].

Synthesis of results

The results of this scoping review are presented in a structured narrative, addressing each research question and supported by illustrative examples drawn from the included studies as well as a tabulated summary of AL-ML applications in the two domains (lab/clinical).

Overview of included studies

The systematic search identified 719 records (698 from databases and 21 through citation searching). After duplicate removal (n=82) and screening, 611 reports underwent full-text assessment, resulting in 107 studies meeting inclusion criteria (see Figure 1 for PRISMA flow details). Exclusion primarily resulted from non-original research, absence of AI/ML applications in T&H, or non-human studies. Included studies were mostly retrospective observational designs, with a few prospective analyses. Sample sizes varied significantly, from large administrative datasets with hundreds of thousands of patient records to small proof-of-concept studies involving fewer than 100 samples. Studies represented diverse geographical regions, predominantly North America, Europe, and Asia. Studies were categorized into two domains: laboratory applications (summarized in Table 1) and clinical applications (Supplementary Table 1), elaborated further in subsequent sections.

Results

Types of AI-ML techniques applied and their implementation across clinical and laboratory domains

AI-ML techniques applied to T&H include a diverse range of algorithms and data sources. The primary ML techniques identified among the reviewed studies encompass Artificial Neural Networks (ANNs), Support Vector Machines (SVMs), Random Forests (RF), Gradient Boosting algorithms (XGBoost, LightGBM), logistic regression (including Elastic Net Logistic Regression and LASSO), convolutional neural networks (CNNs), and physics-informed neural networks (PINNs). The annual number of such studies has steadily increased from 2020 to 2025, reflecting growing interest in the application of AI-ML in T&H (Supplementary Figure 1). Specific implementations include a study by Villacorta et al. where they developed and internally validated elastic net logistic regression model to predict PE. The model incorporated

Table 1: Laboratory-focused AI-ML applications in thrombosis and Hemostasis.

No.	Reference	Title	Laboratory input	Intended function	AI-ML technique	Laboratory utility and end-user support	Reported limitations
1	Willan et al. [52]	The use of artificial neural network analysis can improve the risk-stratification of patients presenting with suspected deep vein thrombosis	Wells score, D-dimer, ultrasound results	Improves diagnostic triage for suspected DVT without ultrasound	Artificial Neural Network (ANN)	Reduces unnecessary imaging, supports triage in high-volume centers	Limited to structured retrospective dataset; generalizability unclear
2	Villacorta et al. [46]	Machine learning with D-dimer in the risk stratification for pulmonary embolism	D-dimer, oxygen saturation, medical history	Enhances PE risk assessment accuracy and imaging efficiency	Elastic Net Logistic Regression	Improves D-dimer interpretation, reduces overuse of CT scans	Requires external validation
3	Qi et al. [53]	Development and validation of a support vector machine-based nomogram for diagnosis of obstetric antiphospholipid syndrome	Immune, coagulation indices, clinical history	Automates diagnosis of obstetric APS (OAPS)	Support Vector Machine (SVM)	Increases diagnostic confidence in complex autoimmune cases	Sample size limited; external validation needed
4	Fang et al. [54]	Using machine learning to identify clotted specimens in coagulation testing	PT, APTT, TT, Fibrinogen, D-dimer	Detects sample clotting to prevent false test results	Backpropagation Neural Networks (BPNN)	Automate quality control in high-throughput labs	Single-center study; real-time integration challenges. Significant bias in the age distribution
5	Qian et al. [55]	Coagulo-Net: Enhancing the mathematical modeling of blood coagulation	Synthetic and experimental coagulation cascade data	Refines blood coagulation models using sparse/noisy data	Physics-Informed Neural Networks (PINNs)	Supports precision modeling and experimental design	Dependent on model assumptions; not yet clinical-ready
6	Cygert et al. [56]	Platelet-Based Liquid Biopsies through the Lens of Machine Learning	RNA-seq data from tumor-educated platelets (TEPs)	Classifies cancer vs. control using liquid biopsy	CNNs, boosting	Aids non-invasive cancer detection	Complex bioinformatics pipeline; interpretability concerns
7	Zhou et al. [57]	Intelligent classification of platelet aggregates by agonist type	Platelet aggregate images via imaging flow cytometry	Classifies platelet aggregates by triggering agents	Convolutional Neural Network (CNN)	Supports research on thrombosis mechanisms	Not generalizable beyond specific agonists used
8	Hasegawa et al. [58]	Comparative analysis of three ML techniques for SIC progression	DIC scores from day 1 and 3 of ICU stay	Predicts sepsis-induced coagulopathy progression	Random Forest, SVM, Neural Network	Improves early detection of DIC risk using coagulation tests	Retrospective; limited generalizability
9	Cui et al. [59]	An Interpretable Early Dynamic Sequential Predictor for Sepsis-Induced Coagulopathy Progression in the Real-World Using Machine Learning	Real-world sepsis lab data (platelet count, fibrinogen, etc.)	Early detection of SIC and DIC	XGBoost, ODE-RNN	Provides advance warning for critical coagulopathies, expedites testing	Complexity in real-time clinical application
10	Wang et al. [60]	Lupus nephritis or not? A simple and clinically friendly machine learning pipeline to help diagnosis of lupus nephritis	Serum creatinine, urinary RBC count, complement C3, anti-dsDNA antibody levels, eGFR (laboratory data only model)	Diagnoses lupus nephritis among SLE patients	XGBoost, LGB, ANN	Offers a non-invasive, interpretable tool to support clinical and lab-based decision-making in suspected LN	Generalizability of meteorological data not proven

Table 1: (continued)

No.	Reference	Title	Laboratory input	Intended function	AI-ML technique	Laboratory utility and end-user support	Reported limitations
						cases. lab-only model as a "clinically friendly" version	
11	Flamm et al. [61]	Multiscale prediction of platelet function under flow	Calcium signaling assays, microfluidic flow assays	Predicts clot formation under flow	Neural Network + Monte Carlo	Personalized thrombotic risk profiling, thrombosis research	Highly technical setup not widely available
12	de Laat – Kremers et al. [62].	Deciphered coagulation profile to diagnose APS using AI	Thrombin generation data, clotting profiles	Non-invasive APS diagnosis model	Thrombin profile-driven model	Enables APS diagnosis, screening	Requires extensive training datasets
13	de Laat-Kremers et al. [47].	A thrombin-driven neural net diagnoses the antiphospholipid syndrome without the need for interruption of anticoagulation	Thrombin generation curves	APS diagnosis without anticoagulation interruption	Neural Network	Facilitates diagnosis in complex anticoagulated cases without use of DOACSTOP	Needs broader validation
14	Nilius et al. [15].	A machine-learning model for reducing misdiagnosis in heparin-induced thrombocytopenia: A prospective, multicenter, observational study	SRA and immunoassay test result, platelet nadir, UFH, thrombocytopenia timing	Reduces misdiagnosis of heparin-induced thrombocytopenia	ML classifiers (ensemble)	Improves diagnostic precision for HIT testing	Relies on confirmatory SRA tests
15	Li et al. [63]	Blood clot and fibrin recognition method for serum images based on deep learning	Imaging data of clots and fibrin	Automated recognition of clot/fibrin types	Image classification neural networks	Enhances objectivity and throughput in lab tests	Depends on image quality and standardization
16	Guo et al. [64]	Clinical applications of machine learning in the survival prediction and classification of sepsis: coagulation and heparin usage matter	35 blood test variables (e.g., APTT, PT, INR, WBC, lactate, pH, etc.)	Predicts 28-day survival and phenotypes sepsis patients; identifies coagulation-related mortality risks	CNN (7-layer), DCQMFF, K-means Clustering	Enables early prognosis and stratification using routine blood tests; platform supports triage in ICUs and primary care	Retrospective study; performance in small phenotypic clusters was less reliable due to data imbalance
17	Petch et al. [65]	Optimizing warfarin dosing for patients with atrial fibrillation using machine learning	INR (International Normalized Ratio) measurements; warfarin dose-response pairs	To dynamically recommend optimal warfarin dosing to maintain INR in the 2.0–3.0 range and improve clinical outcomes	Batch-Constrained Deep Q-Learning in a semi-Markov Decision Process framework	Provides a digital decision support system that improves TTR (Time in Therapeutic Range) and reduces adverse events across international settings	Retrospective study design; lacks real-world implementation; black-box nature of deep learning; potential overfitting when clinical features were added; requires prospective RCT for validation
18	Yu et al. [66]	A machine learning-based prediction model for sepsis-associated delirium in	Serum creatinine, coagulation screen, platelets, urine output, blood	To predict sepsis-associated acute kidney injury (SA-AKI) up to 48 h in	XGBoost (Extreme Gradient Boosting)	Supports early clinical decision-making by alerting clinicians to high-	Model trained on retrospective data; limited generalizability; needs

Table 1: (continued)

No.	Reference	Title	Laboratory input	Intended function	AI-ML technique	Laboratory utility and end-user support	Reported limitations
		intensive care unit patients with sepsis-associated acute kidney injury	pressure, heart rate, other vital signs and laboratory parameters from ICU patients	advance using patient EHR data		risk patients and potentially guiding preventive interventions. Adaptable ML framework for early prediction of coagulopathy or thrombosis-related complications	prospective validation and real-time clinical testing

ANN, Artificial Neural Network; APS, antiphospholipid syndrome; aPL, antiphospholipid antibody; APTT, activated partial thromboplastin time; BPNN, backpropagation neural network; CNN, Convolutional Neural Network; CT, computed tomography; DCQMFF, dynamic coefficient quantization matrix filtering framework; DIC, disseminated intravascular coagulation; DOACSTOP, direct oral anticoagulant stop reagent; DVT, deep vein thrombosis; EHR, electronic health record; INR, international normalized ratio; ICU, intensive care unit; LASSO, least absolute shrinkage and selection operator; LDA, low dose aspirin; LGB, light gradient boosting; LMWH, low molecular weight heparin; ML, machine learning; ODE-RNN, ordinary differential equation recurrent neural network; OAPS, obstetric antiphospholipid syndrome; PE, pulmonary embolism; PINN, physics-informed neural network; PT, prothrombin time; RCT, randomized controlled trial; RNA-seq, RNA sequencing; SIC, sepsis-induced coagulopathy; SLE, systemic lupus erythematosus; SRA, serotonin release assay; SVM, Support Vector Machine; TEPs, tumor-educated platelets; T&H, thrombosis and hemostasis; TT, thrombin time; TTR, time in therapeutic range; UFH, unfractionated heparin; WBC, white blood cell.

oxygen saturation, prior DVT/PE, immobilization or surgery, alternative diagnosis, and D-dimer. When D-dimer was added, the AUC improved from 0.73 to 0.89 and the Brier score reduced by 14 %. The ML approach outperformed traditional risk scores (Wells, Geneva, PERC) while maintaining a low false-negative rate [46]. ANN outperformed other ML algorithms in predicting DVT among rehabilitation inpatients, using D-dimer levels, bedridden time, Barthel Index, and fibrinogen degradation products as key predictive features [67]; A LASSO logistic regression model was developed to predict first-time postpartum thrombosis in obstetric antiphospholipid syndrome (OAPS) patients without prior thrombotic events, using platelet count, antiphospholipid antibody (aPL) status, and use of low molecular weight heparin (LMWH) or low-dose aspirin (LDA). The model's discriminatory ability was compared to the Adjusted Global Anti-Phospholipid Syndrome Score (aGAPSS), with a significantly higher AUC [0.9181 (95 % CI: 0.8634–0.9728) vs. 0.7848 (95 % CI: 0.6899–0.8796), $p<0.001$], demonstrating superior discrimination, calibration, and clinical utility [68].

Data sources employed in these models range from structured clinical and laboratory measurements such as platelet counts, fibrinogen, prothrombin time (PT), activated partial thromboplastin time (APTT), D-dimer, ultrasound imaging, and thrombin generation curves, to more complex inputs like high-throughput imaging flow cytometry combined with a CNN to develop the intelligent platelet aggregate classifier (iPAC). One study enabled distinguishing platelet aggregates by agonist type based on subtle morphological differences – enabling potential diagnostic and therapeutic applications in thrombotic and inflammatory conditions [57].

The reviewed studies consistently highlight and conclude on the practical implementation of ML to automate diagnostic, prognostic, better risk stratification and management processes, enhance accuracy, reduce unnecessary testing, and support clinical and laboratory decision-making. Despite these advancements, significant limitations are frequently cited, such as the need for external validation, potential overfitting, dependence on retrospective and single-center datasets, interpretability challenges, and real-time integration complexities remain prevalent across many of the applications (summarized in Table 1 and Supplementary Table 1).

Clinical and laboratory domain AI-ML models and applications

In summary, AI-ML applications in T&H diagnostics span both clinical and laboratory domains, with clinical applications currently dominating the landscape. Among the 107 studies included in this scoping review, laboratory-based AI-ML applications comprised only 15.5 % of the studies, primarily focused on automating, optimizing, or enhancing laboratory

diagnostic processes [15, 47, 54, 55, 65]. These systems are intended to assist scientists, laboratory technicians, and other laboratory personnel or can be significantly utilized by laboratories summarized in Table 1. One notable example is the development of a deep reinforcement learning algorithm designed to optimize time in therapeutic range (TTR) for patients receiving warfarin therapy [65]. This approach has the potential to underpin a digital flagging system integrated into laboratory information systems (LIS), automatically comparing patients' PT and international normalized ratio (INR) values against target TTR parameters and fed back to the ML platform for better optimization. Such a system could proactively alert laboratory staff to investigate significant deltas or inconsistencies and simultaneously notify the clinical team through a decision support interface. This could facilitate timely review and adjustment of warfarin dosing or to investigate laboratory instrumentation measurement current validity, improve anticoagulation control, quality control, and enhance clinical outcomes in patients with atrial fibrillation and other conditions in this field that require strict anticoagulant monitoring.

In another study, Hou et al. developed a ML model capable of detecting and identifying clots and fibrin in serum samples, a critical pre-analytical step that is traditionally time-consuming and subject to inter-operator variability [63]. The UNeXt segmentation network was employed to rapidly and accurately segment and classify blood clots and fibrin within serum images, thereby providing a reliable reference for determining the optimal sampling height of the aspiration needle in automated biochemical and immunological analyzers. Importantly, this principle and methodology could be adapted for use in hemostasis laboratories to assess plasma specimens prior to coagulation testing in citrate tubes, the early alert system can offer opportunities to streamline workflows and reduce pre-analytical errors in routine and specialized hemostasis diagnostics. Additionally, Fang et al. demonstrates a proof-of-concept application of ML algorithms in identifying the sample status (clotted/not-clotted) based on the results of coagulation testing. This approach evaluates the sample quality, and it has the potential to facilitate clinical laboratory automation [54].

Conversely, clinical-based ML applications accounted for 84.5 % of reports, primarily intended for clinicians directly involved in point-of-care and clinical decision-making contexts, including doctors, nurses, and other healthcare professionals. Regarding specific diagnostic tasks, predictive modelling represented the largest category, with 67.3 % of the studies aimed at forecasting disease occurrence, progression, or clinical outcomes [69–75]. Diagnostic applications were covered by 10.0 % [76–79]. A further 20.0 % addressed other applications such as risk identification, stratification and screening [7, 10, 67, 80–85], classification [86, 87], optimization [11, 65, 88–90]. Finally, 2.7 % of the studies integrated multiple tasks into a single comprehensive application [88]. Collectively, these sample studies cited from the included studies illustrate the breadth of current AI-ML applications within the field of T&H, emphasizing the predominance of predictive models in clinical settings while highlighting significant opportunities for expanding AI-ML applications within laboratory diagnostics/applications domain.

Study designs, limitations, and challenges

Across the 107 included studies, the majority utilized retrospective data sources. Specifically, 44 % studies were retrospective single-cohort studies, while 27 % were retrospective multi-center or multi-cohort investigations. In contrast, prospective designs were less common, with 8.2 % studies employing prospective single-cohort data and none using prospective multi-center cohorts. Additionally, 9 % of studies combined retrospective and prospective data sources within the same analysis. A smaller subset of 7.3 % of studies relied on simulated or synthetic datasets to train or validate their models. Regarding external validation, 22.7 % of studies reported performing some form of external validation to assess model generalizability beyond the development dataset.

The included studies identified several limitations, challenges, and risks associated with AI-ML applications in T&H. Predominantly, most models were developed using retrospective data, often lacking prospective data collection and prospective real time model optimisation [73, 80, 91]. Many studies were susceptible to overfitting, and some were limited by small sample sizes, increasing the risk of model instability [73, 81, 89, 92]. The "black box" nature of many deep learning approaches frequently constrained interpretability, reducing clinical transparency and acceptance [70, 89]. Additional challenges included imbalanced data distributions and missing values, as well as reliance on datasets derived from ethnically homogenous populations, limiting external validity [72]. Moreover, few studies incorporated multicentre validation, further constraining generalisability. Data and image quality variability, potential biases in feature selection and outcomes, and the high level of technical expertise required for model deployment were also cited as significant barriers. Finally, integrating these AI tools into real-time clinical workflows remains a substantial challenge, underscoring the need for rigorous prospective evaluation and user-centred implementation strategies as

well as ethical and regulatory hurdles. This is summarized in detail in Table 1 and Supplementary Table 1.

Knowledge gaps and future directions cited by prior publications

Across the included studies, several recurring gaps and future directions were identified to advance the use of AI-ML in T&H. The most frequently cited limitation was the lack of external validation in independent cohorts (Table 1, Supplementary Table 1), raising concerns regarding the generalizability of model performance. Many studies relied on retrospective designs and single-center datasets with relatively small sample sizes, often derived from ethnically homogenous populations, which further constrained their applicability across diverse clinical settings, particularly in multiethnic societies. Overfitting and inadequate calibration were also common challenges, alongside issues related to incomplete or imbalanced data and variability in imaging and laboratory data quality. The black-box nature of many deep learning algorithms emerged as a persistent barrier to clinical adoption, with limited interpretability and transparency impeding clinician trust and acceptance, these limitations and challenges have been referred to in previous review articles in one way or another [6, 21, 24, 37, 38, 42–45]. Integration of these tools into existing clinical workflows, laboratory information systems, and electronic health records was frequently highlighted as complex and resource-intensive, requiring substantial technical expertise and infrastructure to implement effectively [37, 42, 56, 61].

To address these limitations, most studies recommended external validation [53] in larger, prospective, multicenter cohorts to improve model robustness and generalizability [66]. Future directions commonly included conducting prospective trials and real-world implementation studies to evaluate clinical impact [59, 65], adherence to AI recommendation groups [17], and effects on patient outcomes. Model refinement and optimization were also prioritized, including incorporating additional clinically relevant variables such as diverse biomarkers, imaging, genetic data, and longitudinal follow-up information [74, 93]. Enhancing model interpretability through explainable AI methods, such as SHAP value analysis [89], feature attribution techniques, and transparent visualizations, was identified as critical to facilitate clinician understanding and trust [56, 89].

Many authors emphasized the importance of integrating AI tools into electronic health records and laboratory information systems [54], including deploying models in “shadow mode” to assess safety prior to live implementation [94]. Expanding training datasets to encompass more diverse populations and mitigating algorithmic bias were also recognized as essential steps towards equitable application [72, 94]. Additionally, several studies advocated for the development of dynamic, real-time prediction models that reflect patients’ evolving clinical status [95], as well as incorporating multimodal data sources to improve predictive accuracy and the use of extensive training data sets [62, 96]. Finally, some investigations highlighted the need to develop user-friendly web-based calculators and bedside tools, alongside evaluating the cost-effectiveness and workflow impact of AI-enabled diagnostic support in routine practice [74].

Discussion

In this scoping review, a broad spectrum of applications of AL-ML in the field of T&H was mapped, with an emphasis on intended users for both the laboratory and clinical domains. The findings illustrate that AI-ML techniques have already started to permeate many areas of T&H: from automating mundane yet critical laboratory tasks, to unraveling complex diagnostic puzzles, to forecasting clinical events and optimizing treatment strategies.

This scoping review highlights the expanding role of AI and ML across the vast field T&H and where it is being or can be utilized. Consistent with trends in broader medical AI, most identified studies leveraged supervised ML algorithms such as neural networks, random forests, and logistic regression to improve predictive accuracy, automate interpretation, and streamline workflows. Laboratory-focused implementations commonly involved image recognition for clot detection, quality control and some research, whereas clinical applications predominantly targeted risk stratification, prediction, diagnosis, and prognostic modelling for conditions such as VTE, PE, and anticoagulation management among many others.

Notably, while model performance metrics were frequently promising (e.g., high AUCs and classification accuracies), external validation was performed in only a minority of studies, raising concerns regarding generalizability. Furthermore, many investigations relied on retrospective single-center cohorts, small sample sizes, or ethnically homogeneous populations, underscoring the persistent risk of bias and overfitting. The interpretability of AI systems, especially deep learning approaches, also remains a central barrier to clinical adoption, as clinicians may be reluctant to trust difficult “black box” models without transparent rationale for predictions. Finally, operational integration of AI tools into laboratory information systems and electronic health records was rarely reported, reflecting substantial translational gaps,

this is more evident for laboratory purposes, the domain that is underdeveloped.

vDespite these limitations, the literature demonstrates AI's clear potential to augment traditional diagnostic pathways. In particular, the capacity to synthesize multidimensional inputs and dynamically recalibrate predictions aligns with the complex pathophysiology of thrombotic and bleeding disorders. Real-world impact, however, remains largely theoretical. To advance from proof-of-concept to standard care, robust prospective multicenter validation, cost-effectiveness analyses against traditional practices, and laboratory-centered implementation studies will be essential.

The slow adoption of AI within the field of T&H, specifically in laboratory diagnostic applications, can be attributed to several intertwined factors. Firstly, there exists a sufficient shortage of domain experts within hemostasis who possess the practical skills and a comprehensive understanding of AI's potential clinical and diagnostic utility, and operational implementation plan. Simultaneously, specialists in computer science, those with a deeper practical understanding of artificial systems, frequently lack a nuanced grasp of the inherent complexities of hemostasis, including the operational constraints, scientific limitations of diagnostic analyzers and the consequent limitations posed by available datasets. This disciplinary disconnect greatly shackles effective interdisciplinary collaboration and thus the integration of AI tools into practical hemostasis workflows.

Compounding this challenge is the inherent dependence of AI-ML model development on high-quality, voluminous datasets, which are frequently unavailable or inaccessible due to stringent ethical considerations, regulatory constraints, and data privacy policies. Researchers often face considerable procedural hurdles, including lengthy ethics approval processes, restricted data-sharing and storage protocols, and rigorous compliance requirements, which collectively impede data availability. Even when data can be accessed, barriers such as incomplete records, limited abnormality/case numbers, fragmented data storage, inconsistent formatting within LIS and EHR, and substantial volumes of unlabeled data requiring labor-intensive manual ground truthing further complicate their utility. Moreover, despite the large volume of EMRs, unique challenges persist, notably issues of inadequate data extraction and labelling methodologies. Each of these factors exacerbates the difficulty of constructing robust and reliable AI datasets suitable for rigorous ML studies.

Additionally, the complexity inherent in selecting appropriate ML algorithms adds yet another layer of difficulty. The choice of optimal algorithms necessitates sophisticated understanding and expertise in both ML methodologies and hemostasis pathophysiology. Such steep learning curves create technical demands that can be daunting even to experienced and seasoned scientist and researchers, further hindering widespread adoption and effective implementation of AI within T&H diagnostics.

Therefore, addressing these multifaceted barriers through targeted interdisciplinary collaborations, streamlined regulatory frameworks, integrated and structured education programs, and improved data standardization practices is paramount to fully realizing and utilizing the potential of AI in significantly enhancing T&H diagnostics and patient management.

Limitations of scoping review

This scoping review is limited by the heterogeneity of the included studies, potential language and publication bias, and the predominance of retrospective models with limited prospective validation. The date range (2020–2025) was selected to capture the most contemporary developments in artificial intelligence and machine learning applications in thrombosis and hemostasis, reflecting the rapid evolution of algorithms, technology in the form of computation and implementation studies during this period. Additionally, laboratory-focused applications were underrepresented and given the rapid pace of AI-ML development, some very recent studies may not have been captured.

Conclusions

In summary, this review underscores that AI-ML are poised to reshape the diagnostic landscape of T&H by enhancing prediction, supporting decision-making, knowledge discovery and translational science and automating laboratory processes. However, widespread clinical translation is contingent upon addressing persistent challenges in data quality and accessibility, model explainability, validation, regulations, and workflow integration. Future research should prioritize the building of large, freely accessible T&H laboratory labelled databases for the development of interpretable, externally validated models embedded within prospective clinical workflows to confirm real-world benefits. Equally important is the establishment of regulatory frameworks, user education, and ongoing monitoring by multidisciplinary teams, including domain expert scientist, to ensure that AI innovations deliver meaningful improvements in patient care within the field of T&H.

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Appendix: Search strategy

Database Searched:

MEDLINE (via PubMed)

Date of Search Conducted:

May 2025

Search Strategy: A comprehensive literature search was performed using both controlled vocabulary (MeSH terms) and free-text keywords. Boolean operators, truncation symbols, and field tags were used to combine concepts relevant to artificial intelligence (AI), machine learning (ML), and hemostasis/thrombosis. The search was restricted to studies published between January 1, 2020, and May 1, 2025, to capture the most recent and relevant developments in the field.

Example Search String (PubMed): ((“artificial intelligence”[MeSH Terms] OR “machine learning”[MeSH Terms] OR “deep learning”[MeSH Terms] OR “artificial intelligence”[Title/Abstract] OR “machine learning”[Title/Abstract] OR “deep learning”[Title/Abstract] OR “neural network*”[Title/Abstract] OR “support vector machine*”[Title/Abstract] OR “random forest*”[Title/Abstract] OR “gradient boosting”[Title/Abstract] OR “ensemble learning”[Title/Abstract] OR “natural language processing”[Title/Abstract]) **AND** (“thrombosis”[MeSH Terms] OR “venous thromboembolism”-[MeSH Terms] OR “pulmonary embolism”[MeSH Terms] OR “deep vein thrombosis”[MeSH Terms] OR “coagulation”[MeSH Terms] OR “hemostasis”[MeSH Terms] OR “hemostasis”[Title/Abstract] OR “thrombosis”[Title/Abstract] OR “thromboembolism”[Title/Abstract] OR “embolism”[Title/Abstract] OR “pulmonary embolism”[Title/Abstract] OR “deep vein thrombosis”[Title/Abstract] OR “coagulation”[Title/Abstract] OR “heparin-induced thrombocytopenia”[Title/Abstract] OR “antiphospholipid syndrome”[Title/Abstract] OR “disseminated intravascular coagulation”[Title/Abstract]))

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