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Harnessing Artificial Intelligence in Therapeutics: A Paradigm Shift in Pathology and Precision Medicine

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Dear Editor,

Artificial intelligence (AI) is rapidly reshaping contemporary medicine, but its most profound and clinically grounded impact is unfolding within pathology. As the discipline that anchors diagnosis, prognostication, and therapeutic selection, pathology stands at the forefront of AI-driven transformation. Unlike generalized discussions of AI in healthcare, pathology-centered AI directly influences treatment decisions by enhancing diagnostic accuracy, standardization, and interpretability of tissue- and cell-based data (1). When responsibly integrated, AI does not replace the pathologist; rather, it augments expertise, reinforces consistency, and strengthens the bridge between morphologic interpretation and precision therapeutics.

AI in Diagnostic Surgical Pathology: Enhancing Accuracy and Consistency

Surgical pathology has traditionally relied on expert visual interpretation of histologic patterns, a process that is inherently complex and subject to inter- and intra-observer variability. This variability is especially evident in borderline lesions, tumor grading, and assessment of subtle morphologic features that directly influence therapeutic strategies. AI-based deep learning models, particularly convolutional neural networks (CNNs), have demonstrated clinically meaningful performance in addressing these challenges (2). One of the most validated applications of AI in surgical pathology is tumor grading. In prostate carcinoma, AI-assisted Gleason grading systems have shown diagnostic concordance comparable to subspecialty-trained pathologists while significantly reducing interobserver variability. Given that the Gleason grade directly determines treatment selection, which ranges from active surveillance to radical therapy, AI-supported grading enhances confidence and reproducibility in clinical decision-making. Similar advances have been reported in breast carcinoma, where AI tools assist in histologic grading and mitotic count assessment, both of which guide adjuvant therapy decisions (3).

Mitotic figure detection and quantification represent another critical application. Manual mitotic counting is time-consuming and prone to variability, yet it remains integral to grading systems in breast, soft tissue, and neuroendocrine tumors. AI-driven mitotic detection algorithms demonstrate higher sensitivity and consistency compared with manual assessment, enabling pathologists to deliver more standardized prognostic information that directly impacts therapeutic stratification. AI has also shown promise in margin assessment, particularly in oncologic resections. Automated identification of tumor-positive margins on whole-slide images (WSIs) allows rapid screening of large specimens, supporting timely intraoperative or postoperative decisions regarding re-excision, radiation, or systemic therapy (4).

AI in Cytopathology: Risk Stratification and Therapeutic Planning

Cytopathology, characterized by limited material and subtle morphologic cues, is especially well suited for AI-assisted analysis. In cervical cytology, AI-based screening systems have achieved high sensitivity for detecting high-grade squamous intraepithelial lesions, enabling efficient triage and allowing cytopathologists to focus on diagnostically challenging cases. This directly influences patient management by improving early detection and timely intervention. In thyroid fine-needle aspiration cytology, AI models trained on cytomorphologic features have been applied to indeterminate categories (2). By integrating cytologic patterns with molecular correlations, AI-assisted systems aid in risk stratification and support decisions regarding surgery versus surveillance. Such applications reinforce the role of cytopathologists in

guiding personalized management strategies rather than replacing interpretative expertise (5).

AI in Hematopathology: Quantification and Classification

Hematopathology increasingly relies on quantitative assessment and pattern recognition across morphology, immunophenotype, and molecular data. AI-based image analysis tools have been used to quantify blast percentages in bone marrow aspirates, classify lymphoid neoplasms, and assist in the differentiation of acute leukemias (1, 3). These outputs directly inform therapeutic intensity, transplantation eligibility, and targeted therapy selection. By reducing observer variability and providing reproducible quantitative metrics, AI enhances diagnostic confidence in a subspecialty in which treatment regimens are often aggressive and time-sensitive (6, 7).

Biomarker Quantification and Predictive Pathology

Perhaps the most direct link between AI in pathology and therapeutics lies in biomarker assessment. AI-assisted digital image analysis has been extensively validated for immunohistochemical (IHC) scoring of biomarkers such as ER, PR, HER2, Ki-67, and PD-L1 (8). Variability in manual scoring of these markers has long been recognized as a source of inconsistency in treatment selection. Automated PD-L1 scoring algorithms, for example, improve reproducibility and reduce subjective bias, directly influencing eligibility for immune checkpoint inhibitor therapy. Similarly, AI-based Ki-67 quantification provides standardized proliferation indices, aiding prognostication and chemotherapy planning in breast and neuroendocrine tumors (2, 8). In this context, AI serves as a precision tool that strengthens pathology's role in predictive and companion diagnostics.

Pathology-Led AI Discovery: From Morphology to Therapeutic Insight

While AI-driven drug discovery is often discussed broadly, its relevance to pathology lies in AI-enabled morpho-molecular correlation. AI models trained on digitized histopathology can identify subtle architectural and cytologic patterns associated with specific genetic alterations, tumor microenvironment features, or treatment response (4). These insights position pathologists as key contributors to biomarker discovery and patient stratification for targeted therapies and clinical trials. AI-based quantification of tumor-infiltrating lymphocytes and stromal patterns has been associated with immunotherapy response in several solid tumors, reinforcing pathology's central role in guiding precision oncology (5, 9).

Table 1 summarizes key pathology-centered applications of artificial intelligence and their direct therapeutic implications across surgical pathology, cytopathology, and hematopathology. The table highlights how validated AI tools such as tumor grading algorithms, mitotic figure detection, cytology-based risk stratification, blast quantification, and immunohistochemical biomarker scoring enhance diagnostic consistency and reproducibility while preserving pathologist oversight. Importantly, each application listed demonstrates a clear link between AI-assisted interpretation and clinical decision-making, including selection of targeted therapy, immunotherapy eligibility, treatment intensity, and surgical planning. By consolidating these representative use cases, Table 1 underscores the role of AI as a decision-support system embedded within routine pathology workflows, reinforcing its contribution to precision medicine rather than functioning as an autonomous diagnostic entity.

Table 1. Pathology-Centered Applications of Artificial Intelligence and Their Therapeutic Impact

Pathology Domain	AI Application	Clinical Relevance	Impact on Therapeutic Decision-Making
Surgical Pathology	Tumor grading (e.g., prostate, breast)	Improves reproducibility and grading accuracy	Guides selection of surveillance, surgery, and adjuvant therapy
Surgical Pathology	Mitotic figure detection	Standardized proliferation assessment	Influences tumor grade and prognosis
Cytopathology	Cervical cytology screening	High sensitivity for high-grade lesions	Enables early intervention and appropriate triage
Cytopathology	Thyroid FNAC risk stratification	Supports indeterminate category interpretation	Guides surgery versus surveillance
Hematopathology	Blast quantification, leukemia classification	Objective and rapid assessment	Determines treatment intensity and eligibility
Predictive Pathology	IHC quantification (ER, PR, HER2, PD-L1, Ki-67)	Reduces observer variability	Directs targeted therapy and immunotherapy eligibility

Regulatory and Practice Considerations in Pathology-Centered AI

From a regulatory standpoint, AI in pathology is viewed as a decision-support system, not an autonomous diagnostic authority. Regulatory frameworks emphasize validation, transparency, and clinical context, with the pathologist retaining final interpretative responsibility. AI-assisted pathology tools enhance reproducibility and auditability, particularly in high-volume laboratories and

multicenter studies (2, 7). Real-world evidence indicates improvements in turnaround time, workflow efficiency, and diagnostic consistency following AI integration. However, continuous performance monitoring, bias mitigation, and dataset diversity remain essential to ensure safe and equitable deployment (10).

Ethical and Operational Challenges

Despite its considerable promise, the implementation of artificial intelligence in pathology is accompanied by important ethical, technical, and operational challenges that must be addressed to ensure safe and effective clinical adoption. Protection of patient data remains a fundamental concern, as AI systems rely on large volumes of digitized slides and linked clinical information. Robust data governance frameworks, compliance with privacy regulations, secure data storage, and controlled data-sharing practices are essential to prevent misuse and maintain patient confidentiality (4, 7). Another major challenge is the limited explainability of many AI algorithms. "Black-box" models may generate accurate outputs, yet their lack of transparency can hinder pathologists' confidence and accountability, particularly in diagnostically and therapeutically critical cases. Developing explainable AI models that allow users to understand and verify decision pathways is therefore crucial (5).

Operationally, AI tools must integrate seamlessly into existing laboratory information systems and digital pathology workflows. Poor integration can increase workload, disrupt reporting efficiency, and limit adoption. Addressing these challenges requires sustained interdisciplinary collaboration among pathologists, data scientists, informaticians, and regulatory authorities, alongside structured training programs to support responsible and confident AI use (2, 9).

Conclusion

Artificial intelligence represents a transformative force in pathology by strengthening the link between diagnosis and therapy. Through specific, validated applications such as tumor grading, mitotic count automation, biomarker quantification, and margin assessment, AI enhances diagnostic precision while preserving the pathologist's central role. When responsibly implemented, AI functions as an enabling technology that amplifies expertise, supports therapeutic decision-making, and advances precision medicine. The future of AI in therapeutics is not machine-driven diagnosis, but pathologist-led, AI-augmented care.

Declaration of patient consent

The authors certify they have obtained all appropriate patient consent forms. In the form, parents of the patient has given her consent for her images and other clinical information to be reported in the journal. The patient understands that her name and initials will not be published, and due efforts will be made to conceal her identity, but anonymity cannot be guaranteed.

Author Contributions

Both authors contributed equally to the conception, drafting, and final revision of the manuscript.

Conflict of Interest

The authors declared no conflict of interest.

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