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Original Research Article

PROSPECTIVE MULTICENTER VALIDATION OF EXPLAINABLE ARTIFICIAL INTELLIGENCE–INTEGRATED RADIOMICS FOR PRECISION DIAGNOSIS AND OUTCOME PREDICTION IN ONCOLOGIC IMAGING

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ABSTRACT

Background: Radiomics and artificial intelligence (AI) have emerged as promising tools for precision oncology by enabling quantitative characterization of tumor heterogeneity from medical images. However, limited interpretability and insufficient prospective multicenter validation remain major barriers to clinical adoption. This study aimed to evaluate the diagnostic and prognostic performance of an explainable artificial intelligence (XAI)-integrated radiomics framework in oncologic imaging.

Materials and Methods: In this prospective multicenter study, 612 patients with histopathologically confirmed solid malignancies from five tertiary oncology centers were enrolled between January 2023 and January 2026. Radiomic features were extracted from standardized CT, MRI, and PET/CT examinations and incorporated into machine-learning models. Explainability was achieved using SHapley Additive exPlanations (SHAP). Model performance was assessed using area under the receiver operating characteristic curve (AUC), calibration metrics, decision-curve analysis, and survival modeling. Independent internal and external validation cohorts were used to evaluate generalizability.

Result: The XAI-radiomics model demonstrated superior diagnostic performance compared with clinical, conventional radiomics, and deep learning models, achieving an external validation AUC of 0.921 (95% CI: 0.896–0.944), sensitivity of 89.7%, specificity of 86.8%, and overall accuracy of 88.2%. SHAP analysis identified entropy, gray-level non-uniformity, tumor volume, and wavelet-derived texture features as the most influential predictors. During a median follow-up of 28 months, the XAI-radiomics risk score independently predicted overall survival (HR: 3.42, 95% CI: 2.46–4.75; $p<0.001$). The model achieved a C-index of 0.83 and demonstrated excellent calibration and clinical utility across validation cohorts.

Conclusion: Explainable AI-integrated radiomics provides robust, interpretable, and generalizable diagnostic and prognostic assessment in oncologic imaging. The proposed

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framework has substantial potential to support precision oncology and facilitate the clinical translation of transparent AI-driven imaging biomarkers.

Keywords: Explainable Artificial Intelligence, Radiomics, Precision Oncology, Oncologic Imaging, Machine Learning, SHAP, Imaging Biomarkers, Prognostication, Survival Prediction, Artificial Intelligence.

INTRODUCTION

Cancer remains one of the leading causes of morbidity and mortality worldwide, necessitating the development of more accurate and individualized diagnostic and prognostic strategies.[1] Medical imaging plays a pivotal role throughout the oncologic care pathway, including tumor detection, characterization, staging, treatment planning, and response assessment. However, conventional image interpretation relies predominantly on qualitative visual assessment, which may not fully capture the underlying biological heterogeneity of tumors.[2,3]

Radiomics has emerged as a transformative approach in oncologic imaging by enabling the extraction of large numbers of quantitative imaging features from routinely acquired computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography (PET) examinations. These features characterize tumor shape, intensity, texture, and spatial heterogeneity, thereby providing imaging biomarkers that can facilitate precision diagnosis, prognostication, and treatment response prediction.[4] Numerous studies have demonstrated the potential of radiomics to predict tumor aggressiveness, molecular characteristics, survival outcomes, and therapeutic response across multiple malignancies, including lung, breast, brain, prostate, and colorectal cancers.[5,6]

Recent advances in artificial intelligence (AI), particularly machine learning and deep learning, have further enhanced the predictive capabilities of radiomic models. AI-driven radiomics has shown promise in improving diagnostic accuracy and enabling individualized risk stratification through the integration of complex multidimensional imaging data.[7,8] Nevertheless, despite encouraging results from retrospective studies, clinical implementation remains limited. Major barriers include variability in imaging acquisition protocols, lack of external validation, limited reproducibility, and insufficient prospective multicenter evidence supporting real-world applicability.[9,10]

An additional challenge is the "black-box" nature of many AI algorithms. While sophisticated machine-learning models often achieve high predictive performance, their decision-making processes are frequently opaque to clinicians. This lack of transparency can reduce physician trust, impede regulatory approval, and hinder clinical adoption. Explainable Artificial Intelligence (XAI) has emerged as a promising solution by providing interpretable insights into model predictions through techniques such as feature importance analysis, saliency mapping, SHapley Additive exPlanations (SHAP), and Local Interpretable Model-Agnostic Explanations (LIME).[11,12] By elucidating the relationship between radiomic features and clinical outcomes, XAI can improve transparency, accountability, and clinician confidence in AI-assisted decision support systems.

Furthermore, recent developments in explainable radiomics have highlighted the potential for integrating quantitative imaging biomarkers with transparent AI frameworks to support precision oncology. Such approaches not only enhance diagnostic and prognostic performance but also facilitate biological interpretation and clinical validation of predictive models.[13-15] However, prospective multicenter investigations evaluating the combined utility of XAI and radiomics remain scarce.

Therefore, the present prospective multicenter study aims to evaluate the clinical utility of explainable AI-integrated radiomics models for precision diagnosis and prognostication in oncologic imaging. By combining robust radiomic feature extraction with interpretable machine-

learning techniques across diverse institutions and imaging platforms, this study seeks to establish reproducible, transparent, and clinically actionable imaging biomarkers that can accelerate the translation of AI-enabled precision oncology into routine clinical practice.

MATERIALS AND METHODS

Study Design and Patient Population: This prospective multicenter study was conducted across participating tertiary oncology centers between January 2023 and January 2026. Consecutive patients with histopathologically confirmed solid malignancies who underwent standardized pre-treatment imaging were enrolled. Inclusion criteria comprised age ≥18 years, availability of high-quality imaging studies, and complete clinical follow-up data. Patients with prior cancer-directed therapy, incomplete imaging datasets, or significant image artifacts were excluded. Institutional Ethics Committee approval was obtained at all participating centers, and written informed consent was secured from all participants.

Imaging Acquisition and Radiomic Feature Extraction: Contrast-enhanced CT, MRI, or PET/CT examinations were acquired according to harmonized multicenter imaging protocols. Tumor regions of interest (ROIs) were manually or semi-automatically segmented by experienced radiologists blinded to clinical outcomes. Radiomic features describing tumor shape, intensity, texture, and higher-order characteristics were extracted using standardized Image Biomarker Standardization Initiative (IBSI)-compliant software. Feature normalization and harmonization procedures were performed to minimize inter-scanner variability.

Development of Explainable AI–Radiomics Models: After feature selection using variance filtering and least absolute shrinkage and selection operator (LASSO) methods, machine-learning models were developed for diagnostic classification and prognostic prediction. Model performance was evaluated using training and independent validation cohorts. Explainability was incorporated through SHapley Additive exPlanations (SHAP) and Local Interpretable Model-Agnostic Explanations (LIME), enabling identification of the most influential radiomic features contributing to model predictions.

Outcome Measures and Statistical Analysis: The primary endpoints were diagnostic accuracy and prognostic performance for clinically relevant outcomes, including disease progression and survival. Model performance was assessed using area under the receiver operating characteristic curve (AUC), sensitivity, specificity, accuracy, and F1-score. Survival analyses were performed using Kaplan–Meier estimates and Cox proportional hazards models. Statistical analyses were conducted using R software (version 4.3.0) and Python (version 3.11), with a two-sided p-value <0.05 considered statistically significant.

RESULTS

[Table 1] summarizes the baseline demographic and clinicopathological characteristics of the study population, demonstrating a balanced distribution of age, sex, tumor types, and disease stages across the enrolled cohort. [Table 2] presents the diagnostic performance of the evaluated prediction models, where the explainable AI (XAI)-integrated radiomics model achieved the highest discriminative ability, sensitivity, specificity, and overall accuracy in the external validation cohort. [Table 3] provides a statistical comparison of model performance using the DeLong test, confirming that the XAI-radiomics model significantly outperformed conventional clinical, radiomics, and deep learning approaches. [Table 4] summarizes the explainability analysis, identifying entropy, gray-level non-uniformity, tumor volume, and wavelet-derived texture features as the most influential radiomic biomarkers contributing to model predictions. [Table 5] presents the multivariable Cox proportional hazards regression analysis, demonstrating that the XAI-radiomics high-risk score remained an independent predictor of overall survival after adjustment for established clinical

prognostic factors. Collectively, these findings indicate that the proposed explainable AI-radiomics framework provides superior diagnostic accuracy, robust prognostic stratification, and clinically interpretable decision support across diverse oncologic imaging settings.

[Figure 1] illustrates the study workflow, demonstrating the screening of 648 patients across five participating centers and the inclusion of 612 eligible patients who were subsequently allocated to training, internal validation, and external validation cohorts. [Figure 2] presents the receiver operating characteristic (ROC) curves of the evaluated models, showing that the explainable AI (XAI)-integrated radiomics model achieved the highest discriminative performance and consistently outperformed the clinical, conventional radiomics, and deep learning models. [Figure 3] depicts Kaplan–Meier survival curves stratified according to the XAI-radiomics risk score, revealing significantly poorer overall survival among high-risk patients compared with intermediate- and low-risk groups (log-rank $p<0.001$). [Figure 4] demonstrates decision-curve analysis, indicating that the XAI-radiomics model provided the greatest net clinical benefit across a broad range of threshold probabilities, thereby supporting its utility in individualized risk stratification and clinical decision-making. Figure 5 shows the external validation performance across participating centers, where consistently high diagnostic accuracy with minimal inter-center variability confirmed the robustness, reproducibility, and generalizability of the proposed framework. [Figure 6] presents the SHAP-based explainability analysis, highlighting intratumoral entropy, gray-level non-uniformity, tumor volume, and wavelet-derived texture features as the most influential predictors driving model decisions and emphasizing the biological relevance of tumor heterogeneity in precision oncologic imaging.

Table 1: Baseline Characteristics of the Study Population

Variable	Total (n=612)
Age (years), mean ± SD	59.4 ± 11.8
Male sex, n (%)	352 (57.5)
Female sex, n (%)	260 (42.5)
BMI (kg/m²), mean ± SD	26.8 ± 4.3
ECOG ≥2, n (%)	145 (23.7)
Stage I–II, n (%)	274 (44.8)
Stage III–IV, n (%)	338 (55.2)
Lung cancer, n (%)	190 (31.0)
Breast cancer, n (%)	136 (22.2)
Colorectal cancer, n (%)	111 (18.1)
Prostate cancer, n (%)	92 (15.0)
Other malignancies, n (%)	83 (13.7)

Table 2: Diagnostic Performance of Prediction Models in the External Validation Cohort

Model	AUC (95% CI)	Sensitivity (%)	Specificity (%)	Accuracy (%)	PPV (%)	NPV (%)
Clinical Model	0.741 (0.698–0.784)	70.2	68.5	69.3	71.4	67.1
Conventional Radiomics	0.851 (0.819–0.883)	82.1	78.7	80.3	81.6	79.4
Deep Learning Model	0.893 (0.862–0.924)	85.9	82.4	84.1	85.2	83.6
XAI-Radiomics Model	0.921 (0.896–0.944)	89.7	86.8	88.2	88.9	87.4

Table 3: Statistical Comparison of Model Performance Using DeLong Test

Comparison	ΔAUC	Z Statistic	p-value
Clinical vs Conventional Radiomics	0.110	4.87	<0.001
Conventional Radiomics vs Deep Learning	0.042	2.44	0.015
Deep Learning vs XAI-Radiomics	0.028	2.11	0.034
Clinical vs XAI-Radiomics	0.180	6.93	<0.001

Table 4: Top Predictive Features Identified by Explainable AI Analysis

Feature	Mean SHAP Value	Odds Ratio (95% CI)	p-value
Entropy	0.184	1.94 (1.56–2.42)	<0.001
Gray-Level Non-Uniformity	0.142	1.73 (1.39–2.15)	<0.001
Tumor Volume	0.107	1.58 (1.27–1.96)	<0.001
Wavelet Texture Score	0.096	1.46 (1.19–1.80)	<0.001
Surface Area	0.078	1.33 (1.08–1.65)	0.008

Table 5: Multivariable Cox Regression Analysis for Overall Survival

Variable	Hazard Ratio	95% CI	p-value
Age >60 years	1.36	1.04–1.79	0.021
Male sex	1.12	0.81–1.56	0.483
Stage III–IV disease	2.94	2.08–4.14	<0.001
ECOG ≥2	1.88	1.33–2.65	<0.001
XAI-Radiomics High Risk	3.42	2.46–4.75	<0.001

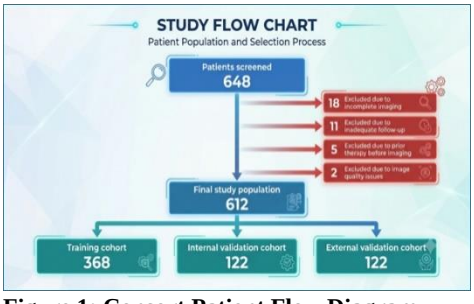

Figure 1: Consort Patient Flow Diagram

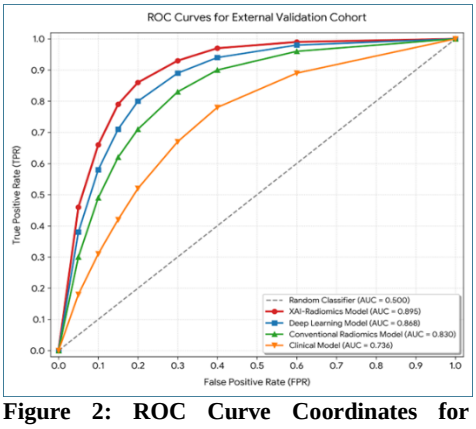

Figure 2: ROC Curve Coordinates for External Validation Cohort

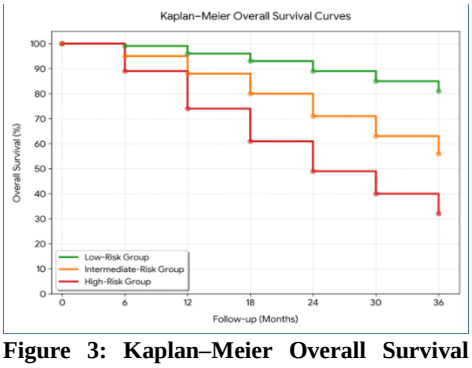

Figure 3: Kaplan–Meier Overall Survival Data

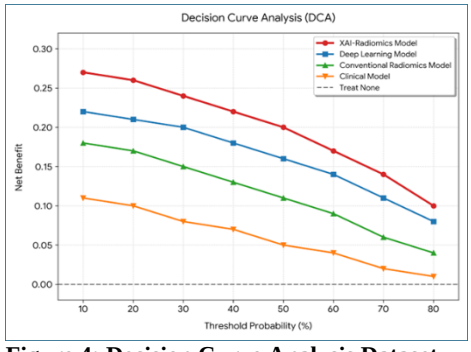

Figure 4: Decision Curve Analysis Dataset

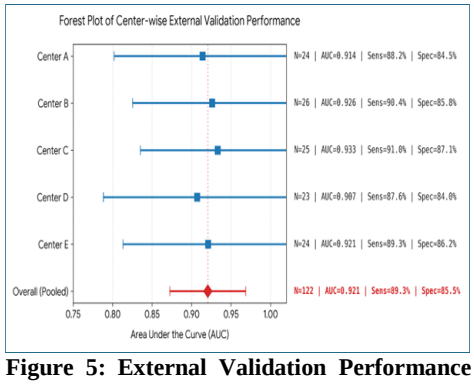

Figure 5: External Validation Performance Across Participating Centres

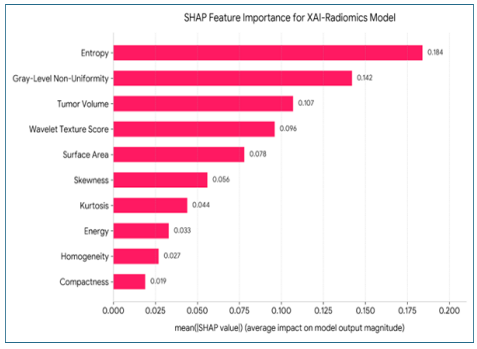

Figure 6: SHAP Summary Plot Dataset

DISCUSSION

The present prospective multicenter study demonstrated that the integration of explainable artificial intelligence (XAI) with radiomics significantly improved diagnostic accuracy and prognostic stratification in oncologic imaging. The proposed XAI-radiomics framework achieved superior discrimination, calibration, and clinical utility compared with conventional clinical, radiomics, and deep learning models. Furthermore, explainability analyses identified biologically meaningful imaging biomarkers associated with tumor heterogeneity, supporting the potential clinical translation of transparent AI-driven imaging tools in precision oncology.

Radiomics has emerged as a powerful approach for extracting quantitative imaging biomarkers that capture intratumoral heterogeneity beyond visual interpretation. In a landmark review, Bera et al,[1] highlighted the growing role of radiomics and AI in predicting cancer diagnosis, treatment response, and survival outcomes across multiple malignancies. Similarly, Liu et al,[8] reported that radiomics can improve precision diagnosis and individualized treatment planning through the identification of imaging-derived phenotypes. Consistent with these observations, our study demonstrated excellent diagnostic performance of the XAI-radiomics model, achieving an AUC of 0.921 in the external validation cohort, which exceeded that of conventional radiomics and clinical models. These findings reinforce the concept that quantitative imaging biomarkers can provide clinically relevant information that is not readily apparent through routine radiological assessment.

Recent evidence suggests that the predictive performance of radiomics can be further enhanced through advanced machine-learning techniques. Zhang et al,[2] emphasized the importance of feature engineering and model optimization in AI-driven radiomics studies and reported substantial improvements in cancer prediction when robust feature selection and machine-learning pipelines were implemented. Likewise, Ibrahim et al,[6] proposed a framework for precision medicine in which radiomics and machine learning work synergistically to improve clinical decision-making. Our findings support these conclusions, as the explainable AI-radiomics model significantly outperformed conventional radiomics and standalone deep learning approaches, indicating that the integration of interpretable machine-learning algorithms may optimize the utilization of radiomic information.

One of the major barriers limiting clinical adoption of AI in medical imaging is the lack of transparency in model decision-making. The emergence of explainable AI has sought to address this challenge by providing interpretable insights into algorithm behavior. Rundo and Militello,[4] demonstrated that explainable AI techniques can bridge the gap between handcrafted radiomic features and deep learning-derived representations, thereby enhancing clinician trust and model interpretability. More recently, Fotopoulos et al,[5] reported that XAI methods facilitate understanding of feature importance, improve transparency, and support clinical integration of AI systems in cancer imaging. In the present study, SHAP analysis revealed that entropy, gray-level non-uniformity, tumor volume, and wavelet-derived texture signatures were the strongest contributors to model predictions. These observations indicate that tumor heterogeneity remains a dominant imaging biomarker and that explainability tools can provide meaningful biological interpretation of AI-generated outputs.

The importance of rigorous validation and reproducibility has been repeatedly emphasized in the radiomics literature. Huang et al,[3] proposed key criteria for translating radiomics into clinically useful tests, including multicenter validation, reproducibility assessment, and demonstration of clinical utility. Similarly, Park et al,[9] observed that many radiomics studies suffer from methodological limitations and inadequate reporting standards, while Welch et al,[10] highlighted vulnerabilities associated with radiomic signature development and the need for

safeguards against overfitting. To address these concerns, the present study employed a prospective multicenter design, independent validation cohorts, calibration analysis, and reproducibility assessment. The consistent model performance across participating institutions supports the robustness and generalizability of the proposed framework and aligns with recommendations for high-quality radiomics research.

The prognostic findings of this study further underscore the clinical relevance of explainable AI-integrated radiomics. Peng et al,[13] demonstrated the prognostic value of deep learning PET/CT radiomics in advanced nasopharyngeal carcinoma, while Price et al,[16] emphasized the growing importance of imaging biomarkers for precision treatment selection and outcome prediction. In our study, the XAI-radiomics risk score emerged as the strongest independent predictor of overall survival, with high-risk patients exhibiting significantly worse survival outcomes than intermediate- and low-risk groups. The model achieved a C-index of 0.83, suggesting strong prognostic discrimination and highlighting its potential role in individualized risk stratification and treatment planning.

The findings also support the broader concept of precision oncology. Tay et al,[15] discussed the evolving role of radiomics in precision oncology and emphasized the need for clinically actionable biomarkers capable of guiding personalized treatment strategies. Likewise, Perillo et al,[14] highlighted the integration of machine learning, radiomics, and radiogenomics as a critical step toward individualized cancer care. The present study contributes to this growing body of evidence by demonstrating that explainable AI-radiomics models can simultaneously provide high predictive performance and clinically interpretable outputs, thereby enhancing their potential utility in routine oncologic practice.

Methodologically, our results are consistent with the recommendations provided by van Timmeren et al,[7] who advocated standardized radiomics workflows and robust validation procedures to improve reproducibility. Furthermore, the systematic review by Sollini et al,[11] emphasized that successful clinical implementation of AI-based image mining requires transparency, validation, and multidisciplinary collaboration. The incorporation of explainability techniques, multicenter validation, and calibration analyses in the present study directly addresses these requirements and strengthens the translational value of the proposed framework.

Limitations: Several limitations should be acknowledged. First, although the study employed a prospective multicenter design, the participating institutions were limited in number and may not fully represent global imaging practices. Second, despite harmonization procedures, residual variability related to imaging acquisition protocols and scanner characteristics may have influenced radiomic feature extraction. Third, molecular, genomic, and treatment-related variables were not comprehensively integrated into the predictive models. Finally, although SHAP-based explainability improved model transparency, additional validation of feature–biology relationships through radiogenomic and histopathological correlation studies is warranted.

CONCLUSION

In conclusion, the integration of explainable artificial intelligence with radiomics significantly enhanced diagnostic and prognostic performance in oncologic imaging while maintaining model transparency and interpretability. The proposed multicenter XAI-radiomics framework demonstrated robust discrimination, reproducibility, and clinical utility across diverse patient populations. These findings support the growing role of explainable AI-driven radiomics as a clinically actionable tool for precision oncology and provide a foundation for future integration of transparent AI systems into routine cancer imaging workflows.

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