Review paper

Evolution of radiological imaging and AI in medical imaging

Magdalena Wiacek, Anna Adam, Igor Z. Zubrzycki

Kazimierz Pulaski University of Technology and Humanities in Radom, Faculty of Medical Sciences and Health Sciences, Radom, Poland

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Abstract

This review explores the evolution of radiological imaging – from early X-rays to modern computed tomography, magnetic resonance imaging, ultrasound, and positron emission tomography – and the growing role of artificial intelligence in medical diagnostics. Focusing on head and neck cancer, parotid gland tumors, and thyroid nodules, it highlights how machine learning (ML) and deep learning (DL) techniques, including convolutional neural networks (CNNs), radiomics, and texture analysis, enhance tumor detection, classification, and prognosis. AI models often outperform traditional methods in accuracy and consistency, yet challenges persist. These include small and retrospective study cohorts, limited data standardization, and regulatory constraints under GDPR and MDR. The review emphasizes the importance of data interoperability via DICOM and HL7 standards to support broader AI adoption. Despite current limitations, artificial imaging holds transformative potential in radiological diagnostics. Its successful clinical integration depends on rigorous study design, transparent validation, and adherence to ethical and legal standards to ensure reliability, safety, and patient trust in AI-driven healthcare.

Introduction

November 8, 1895, was a landmark day in the history of radiology [1]. Following Roentgen's discovery of X-rays in 1896, Magie discovered fluoroscopy, which was, in simple words, an extension of the X-ray technique [2]. After a few decades, Vallebona invented conventional tomography [2]. The theoretical foundations of computed tomography [3] allowed the first commercial computed tomography (CT) in 1971. Currently, a 320-row spiral CT machine has been built, changing the technical standard of medical imaging [3].

In 1942, Dussik reported an initial experiment on the application of ultrasound in medicine [4]. Compared to imaging techniques, ultrasound provided clear images of the soft tissues and underlying anatomy [5].

The early artificial imaging (AI) was a primitive system that emulated human decisions [6]. The first application of AI in the health and medical sciences dates back to the 1960s, when PubMed from the National Library of Medicine appeared as an essential digital information resource [7]. Recently, artificial neural networks (ANN) have become a popular approach, acting similarly to the human brain and capable of learning and making decisions [4].

In medical practice, a variety of imaging techniques, including computed tomography (CT), magnetic resonance imaging (MR), ultrasound (US), and positron emission tomography (PET), are used to analyze the regions of the head and neck to present a patient with a good medical diagnosis. Among the most commonly used mathematical techniques for image reconstruction is filtered back projection (FBP), a relatively simple and computationally efficient method that performs well under "standard" conditions. However, its performance is diminished, providing higher noise and more artifacts for low doses of radiation and larger patients [8].

The shortcomings of FBP can be overcome by model-based iterative reconstruction (MBIR), a fully iterative reconstruction technique. It is a very computationally demanding image reconstruction (IR) method that allows significant improvements in noise reduction and artifact reduction [7]. However, due to the high computation requirements, it has limited availability in clinical applications [9]. Thus, a hybrid iterative reconstruction (HIR) method was developed to overcome the computational burden, comprising iterations in the sinogram domain, one back projection, and iterations in the image domain [10]. This method is computationally less demanding than MBIR but cannot reduce noise and artifacts. This remarkable expansion of artificial intelligence in medical imaging reflects the significant interest in this area. Given the diverse applications of AI in medical and health sciences, this review focuses on particular applications of AI in radiology, with an emphasis on image analysis of specific anatomical regions of the human body.

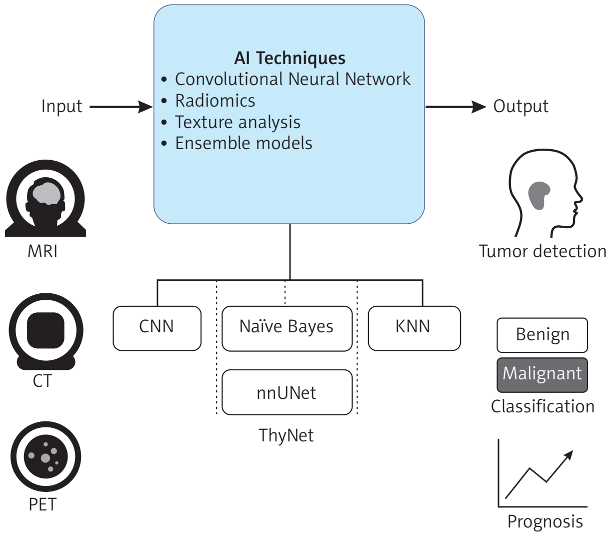

Figure 1. AI techniques and head and neck cancer imaging

AI analysis of medical imaging of the head and neck

AI techniques and head and neck cancer imaging were presented in Figure 1.

MRI image acquisition

Head and neck cancer (HNC) is the sixth [9] or seventh [9] most common type of cancer worldwide. HNCs encompass a wide range of squamous cell carcinomas (SCCs), which develop from the epithelial lining in areas of the oral cavity, the sinonasal region, the pharynx, the larynx, and the salivary glands [11]. Most cancers are diagnosed without a clinically evident antecedent premalignant lesion at advanced stages [11], leading to significantly reduced survival rates, even with curative treatment. Key risk factors include tobacco use, excessive alcohol consumption, areca nuts, exposure to gamma and ultraviolet radiation, a family history of cancer, and aging [12]. Furthermore, the human papillomavirus (HPV) and Epstein–Barr virus (EBV) are associated with the onset of oropharyngeal and nasopharyngeal SCC [13].

HNC standard diagnosis is based on imaging techniques, such as CT, magnetic resonance imaging, PET analysis, clinical examination, histopathological analysis, and molecular testing [7]. In recent years, CNNs outperformed other modes and radiologists in the accuracy of interpreting CT, MRI, and PET [14–17] of, among others, the head and neck region.

Although the use of AI in head and neck image analysis has become increasingly popular, the recent study by Giannitto *et al.* [18] showed that only 66% of radiologists had any AI experience, and most AI users work in an academic environment.

Nevertheless, AI has made its way through and become an essential tool for easy and error-proof diagnosis. Therefore, of the 23 key studies [19] on the application of AI in radiomics, diagnosis, and outcomes of HNC patients, four were selected to highlight the problem.

Thus, Ramkumar *et al.* [20] investigated whether MRI texture analysis could differentiate sinonasal inverted papilloma from squamous cell carcinoma. Using a machine learning model, comprising five established texture analysis algorithms utilized in a region of interest (ROI) from the largest cross-section of the tumor using MRI data from 46 patients (24 inverted papilloma, 22 squamous cell carcinoma), 89.1% accuracy in classifying tumors was achieved. Romeo *et al.* [21] investigated whether radiomic machine learning – using the following database: 40 patients (21 M, mean age = 69 ±14 years), of which 33 with oral cavity squamous cell carcinoma (OC) and 7 with oropharyngeal squamous cell carcinoma (OP/OPSCC) – employing texture analysis features of primary tumor lesions on CT scans, could predict tumor grade and nodal status of squamous cell carcinoma. For tumor grade classification, the highest precision of 92.9% was achieved using Naive Bayes (NB) and the bagging of NB and K-Nearest Neighbors (KNN). The best results for the area under the curve exceeding 0.900 were obtained with NB, KNN, and the boosting of J48. Wang *et al.* [22] developed a T category prediction radiomics (TCPR) model to predict the T category (T3 vs. T4) in advanced laryngeal cancer. The resulting model significantly improved the prediction accuracy of the T category (AUC = 0.892) compared to radiologist assessment alone (AUC = 0.775). Mukherjee *et al.* [23] in their study, encompassing The Cancer Genome Atlas (TCGA) HNSCC cohort – tumors from the oral cavity (n = 172 out of 279), oropharynx (n = 33 out of 279), and laryngeal sites (n = 72 out of 279) where male patients consisted of (n = 203 out of 279) [24], and Stanford HNSCC cohort (n = 1000, male n = 700) – and aimed to determine the performance of radiomic features on CT to predict histopathological features of tumor grade, extracapsular spread, perineural invasion, lymphovascular invasion, and human papillomavirus status in head and neck squamous cell carcinoma (HNSCC).

We performed unsupervised analysis using hierarchical clustering with Euclidean distance to cluster features and patients which demonstrated a moderate ability to predict studied features, with a mean area under the receiver operating characteristic curve (AUC-ROC) of 0.75 for tumor grade, 0.64 for perineural invasion, 0.69 for lymphovascular invasion, 0.77 for extracapsular spread, and 0.71 for human papillomavirus status. The study concluded that radiomic CT models have the potential to predict characteristics typically identified in the pathologic assessment of HNSCC. The prediction of the treatment outcome of HNSCC patients is a derivative of the accurate evaluation of lymph node status in cervical cancer [25]. However, current AI technology employed in image analysis of HNSCC is subject to an error of 20% [26–29]. This observation outlines the primary problem with AI-driven image analysis: the lack of comprehensive data sets. Small numbers and retrospective data often limit the scope of such studies. AI models can enhance the prediction of treatment outcomes. However, the need for more comprehensive studies is a significant limitation.

Zhang *et al*. [30] performed an MRI detection of parotid glands using the DL model to identify and segment parotid gland tumors (PGT) automatically. This study achieved a precision, sensitivity, and specificity of 98.2%, 100%, and 97.7%, respectively. The employed model utilized nnUNet and a PG-specific post-processing technique, trained on T1-weighted images (T1WI) from 311 patients and fat-suppressed T2-weighted images (FS-T2WI) from 257 patients, employing five-fold cross-validation. Thus, the results of this study ascertained that the deep learning model may achieve impressive performance metrics.

A study on the classification of parotid gland tumors by multimodal MRI and DL employing a two-dimensional convolutional neural network (Unet) showed that the model could classify Warthin tumor and pleomorphic adenoma tumor but not malignant tumor [31].

The concise table of the aforementioned study is shown in Table 1.

Ultrasound image acquisition

Parotid gland tumors account for about 5% of head and neck tumors. The most common include pleomorphic adenomas and Warthin tumors. Currently, the effectiveness of distinguishing between benign and malignant forms is limited. To overcome this obstacle, He *et al*. [32] studied three types of machine learning models, i.e., clinical models, US models, and ultrasound-based ensemble machine learning (USEML) models. The result of this study showed that the USEML model surpassed other DL models. However, the most significant differences were observed between USEML and physician experience.

Additional evidence for the usability of DL in the diagnosis of parotid gland tumors was delivered by the study of Wang *et al*. [33], which showed its remarkable effectiveness in distinguishing between benign parotid gland tumors (BPGT) and malignant parotid gland tumors (MPGT), thus underscoring DL's potential as a valuable tool in clinical decision-making.

A high incidence rate of thyroid cancer (3.4 per 100,000 in men and 11.5 per 100,000 in women) requires a diagnostic tool to enhance the objectivity of the evaluation of the risk of thyroid cancer nodules. From the thirty studies performed from 2012 to 2022, evidence has been drawn that AI increases the diagnostic accuracy of thyroid cancer [34]. Moreover, standardized mathematical algorithms significantly limit interobserver variability and can offer a second opinion for an analysis hindered by a radiologist's limited expertise.

The study performed by Peng *et al*. [35] confirmed this observation. The aforementioned study exposed the area under the receiver operating characteristic curve (AUC-ROC) for an accurate diagnosis using ThyNet – a system developed on images acquired at

Table 1. Summary of key studies on AI applications in head and neck cancer (HNC) radiomics

Study	Modality	Algorithm	*N*	AUC/Sensitivity/Specificity	Limitations
Ramkumar *et al.* [20]	MRI Texture Analysis	Machine Learning (5 algorithms)	46 patients (24 IP, 22 SCC)	89.1% accuracy	Small sample size
Romeo *et al.* [21]	CT Radiomics	Naive Bayes (NB), KNN, J48 Boosting	40 patients (21 M)	92.9% precision for tumor grade	Limited sample size (only 7 OP SCC patients)
Wang *et al.* [22]	Radiomics (CT)	Radiomics Model (TCPR)	N/A	AUC 0.892 (T3 vs. T4)	Limited generalizability due to model-specific focus
Mukherjee *et al.* [23]	CT Radiomics	Hierarchical Clustering	279 patients (203 M)	AUCs: 0.75 (tumor grade), 0.64 (perineural invasion)	Moderate prediction accuracy
Zhang *et al.* [30]	MRI Detection (Parotid)	Deep Learning (nnUNet, PG-specific post-processing)	311 (T1WI), 257 (FS-T2WI)	Sensitivity: 100%, Specificity: 97.7%	The model may not generalize across all tumor types
Chang *et al.* [31]	MRI (Multimodal)	Convolutional Neural Network (Unet)	N/A	Not reported for malignant tumors	Inability to classify malignant tumors

Table 2. Summary of key studies on AI applications in diagnosis of parotid gland and thyroid tumors

Study	Modality	Algorithm	*N*	AUC/Sensitivity/Specificity	Limitations
He *et al.* [32]	Ultrasound-based Ensemble ML (USEML)	USEML, Clinical, US models	546	USEML surpassed other DL models, with a significant difference in physician experience	The retrospective nature of the cohort
Wang *et al.* [33]	Deep Learning (DL)	Deep Learning Model	251	Remarkable effectiveness in distinguishing benign and malignant tumors	Small number of cases
Sorrenti *et al.* [34]	AI (Various Models)	Various AI models	30 studies (2012–2022)	Increased diagnostic accuracy, AI surpasses radiologists	Interobserver variability
Peng *et al.* [35]	AI (ThyNet)	ThyNet System	8339	AUC-ROC surpassing radiologists	The diverse prevalence of thyroid nodules
Barczyński *et al.* [36]	AI (S-Detect)	S-Detect	Various studies	Sensitivity and specificity have been confirmed in various studies	Limited specificity in some studies
Choi *et al.* [37]	AI (S-Detect)	S-Detect	Various studies	Sensitivity similar to radiologists, lower specificity	Lower specificity and AUC compared to radiologists
Gitto *et al.* [38]	AI (S-Detect)	S-Detect	Various studies	Higher malignancy sensitivity than physicians	Higher sensitivity, lower specificity
Han *et al.* [39]	AI (S-Detect)	S-Detect	372	High consistency in segmentation	Performance of the system might differ in a general population
Kim *et al.* [40]	AI (S-Detect)	S-Detect	Various studies	Sensitivity is higher than that of radiologists, but the specificity	Lower specificity
Reverter *et al.* [41]	AI (AmCAD-UT)	AmCAD-UT	300	Lower specificity, lower AUC	Lower specificity, lower AUC
Koios-DS [42]	AI (Koios-DS)	Koios-DS	N/A	Higher malignancy sensitivity	Requires further validation in clinical settings
Medo-Thyroid [43]	AI (Medo-Thyroid)	Medo-Thyroid	N/A	Highly consistent with radiologists in measurement extraction	Limited clinical validation

the First Affiliated Hospital of Sun Yat-sen University, Guangzhou, and the Sun Yat-sen University Cancer Center, Guangzhou, China – surpassing those observed for radiologists.

Among AI tools that have received FDA approval for classifying thyroid nodule cancer, S-Detect 2, AmCAD-UT, Koios-DS, and Medo-Thyroid can be distinguished. Among the models mentioned, the applicability of S-Detect was confirmed by the set of studies [36–40].

An analysis of the performance accuracy of the AmCAD-UT tool showed that it provides sensitivity analogous to that of the radiologist but with lower specificity and lower area under the curve (AUC) [41]. Koios-DS performs with a higher malignancy sensitivity than physicians [42]. Medo-Thyroid automatically segmenting the thyroid and thyroid nodules is highly consistent with experienced radiologists in extracting thyroid nodule measurements [43] A comprehensive review of artificial intelligence-based approaches for the diagnosis of parotid and thyroid neoplasms is shown in Table 2.

Challenges of AI in the analysis of the head and neck

Mäkitie *et al.* [44] indicted that at present, the studies on the applications of AI in the diagnosis of head and neck cancer can be divided into the five key themes: (1) identification of precancerous and cancerous lesions on histopathological slides; (2) predicting the histopathological characteristics of lesions based on imaging; (3) prognostics; (4) extracting pathological information from imaging; and (5) applications within radiation oncology. From the perspective of the presented study, the latter three are the focus for further development of AI-supported medical image acquisition and analysis. The outlined applications of AI image analysis of head and neck cancer outline the current technological and methodological deficiencies in the clinical application of artificial intelligence.

Nevertheless, of the multiple applications of AI in analyzing head and neck cancer, such an approach has several limitations. Among the most important factors hindering the current clinical application of AI are the standardization of data collection, variation in image acquisition, and AI model development.

In the landscape of healthcare, the integration of AI into the analysis of head and neck medical imaging presents both remarkable opportunities and formidable challenges. However, the intersection of AI and medical regulations, such as the General Data Protection Regulation (GDPR) and Medical Device Regulation (MDR), brings additional complexity to AI implementation and utilization.

Thus, AI's capacity to rapidly analyze vast amounts of data contributes to early diagnosis and better patient management. However, as the technology evolves, the legal and regulatory frameworks that govern medical AI and imaging technologies must also advance to ensure safety, efficacy, and ethical use [45, 46].

A major challenge in the applications of AI within the healthcare sector stems from the "black box" nature of these systems. A degree of opaqueness surrounding how AI systems arrive at specific decisions or diagnoses renders it difficult for providers to understand and trust these technologies [47, 48]. Such a lack of transparency poses significant issues regarding accountability and liability, particularly when errors occur in clinical settings [49, 50]. Such complications highlight the necessity for clear regulatory guidelines that will not only ensure patient safety but also provide mechanisms for accountability.

Moreover, data privacy is a critical concern, especially under the GDPR, which mandates stringent protections for personal data throughout the European Union. The interaction of AI with regulated data raises questions about data sharing and usage, particularly when sensitive health-related data is involved [45, 51]. Therefore, developers and medical institutions must navigate these regulations carefully to avoid breaches that could lead to substantial legal penalties. Besides that, proper consent for data utilization must be systematically obtained, complicating the training of AI systems that depend on diverse datasets for optimal performance [52, 53].

The regulatory landscape is further complicated by the presence of multiple governing bodies, such as the Federal Drug Administration/Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in the EU. AI medical devices may not fit neatly into the traditional categories established for conventional medical devices [45, 54, 55]. With guidelines evolving rapidly, regulatory bodies are tasked with keeping pace, requiring ongoing dialogue between developers, healthcare providers, and regulators to create harmonized systems [56, 57].

The Medical Device Regulation (MDR) is another crucial aspect to consider in integrating AI-based technologies in healthcare. The MDR has introduced more stringent requirements for clinical evaluation, emphasizing clinical data quality and post-market surveillance to mitigate potential risks associated with AI systems [58, 59]. Compliance with these regulations demands a significant understanding of both the technical aspects of AI systems and the frameworks governing them. Companies may face high costs related to regulatory compliance, potentially stifling innovation and the rapid deployment of beneficial technologies [59, 60].

Moreover, for AI systems to function effectively and be integrated seamlessly into clinical workflows, data standardization plays a pivotal role. Two key standards that are crucial for the efficient use of AI in radiology are DICOM (Digital Imaging and Communications in Medicine) and HL7 (Health Level 7). These standards ensure interoperability between different systems, enhancing the exchange of medical data, improving AI model performance, and ensuring patient safety.

Within this framework, DICOM is critical and provides a standard for transmitting, storing, and sharing images and associated data. This standard enables interoperability among various imaging devices and systems, facilitating seamless communication across healthcare organizations [61, 62]. The harmonization of medical imaging data across DICOM protocols can support AI research in radiology by providing comprehensive datasets that allow for the development of more accurate and generalizable AI models. Additionally, it encourages collaboration among institutions by enabling federated learning, which includes the training of AI models on distributed data while preserving patient privacy [62, 63].

HL7 encompasses messaging standards for the exchange, integration, and sharing of electronic health information. By implementing HL7 standards, clinicians can ensure that AI systems receive real-time data generated by various healthcare applications, ultimately leading to more informed AI-assisted decision-making processes [62, 64]. Standardized data structures provided by HL7 can help address compatibility issues arising from disparate health information systems, ensuring smoother transitions during patient data workflows and enabling efficient utilization of AI applications in clinical settings [62, 64].

Harmonizing DICOM and HL7 standards requires not only technical adjustments but also cultural shifts within healthcare organizations. Stakeholders must cultivate a collaborative mindset, which often necessitates overcoming resistance to change and addressing fears related to data sharing, such as privacy concerns and competitive pressures [63, 65].

Conclusions

To evaluate the methodological quality and risk of bias of the diagnostic accuracy studies included in this review, we employed the QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies 2) tool. This framework assesses four domains: Patient Selection, Index Test, Reference Standard, and Flow and Timing, each rated for risk of bias. Additionally, the first three domains were assessed for concerns regarding applicability to the review question.

Among the studies focusing on the use of artificial intelligence in head and neck cancer (HNC) imaging, Ramkumar *et al.* and Romeo *et al.* [20, 21] present notable concern regarding patient selection, due to their limited sample sizes and narrowly defined populations. Furthermore, both studies had high applicability concerns, as the patient cohorts may not adequately represent the broader clinical spectrum of HNC.

Wang *et al.* [33] showed unclear risk of bias in patient selection due to limited reporting of recruitment strategies, and its model-specific focus restricted its generalizability. Mukherjee *et al.* [23] had a comparatively lower risk of bias across domains, benefiting from the use of large, well-established cohorts (TCGA and Stanford) and a structured analytical pipeline. The strongest methodological rigor was demonstrated by Zhang *et al.* [30], whose study employed large training and testing datasets, cross-validation, and clearly documented DL model architecture, resulting in low risk across all domains.

Conversely, Chang *et al.* [31] presented limitations in both reference standard and applicability due to its inability to reliably classify malignant parotid tumors, raising concerns about the model's utility in clinical diagnostic pathways.

In the second group of studies focused on parotid and thyroid tumor diagnosis, He *et al.* [32] and Wang *et al.* [22] used retrospective data and relatively small patient cohorts, leading to a high risk of selection bias and limited external validity. The models themselves were generally well described, with a low risk associated with the index test domain.

The ThyNet study by Peng *et al.* [35], which included over 8,000 patients from multiple centers, was the most robust in terms of design and generalizability, achieving a low risk across all QUADAS-2 domains. In contrast, the review by Sorrenti *et al.* [34] aggregated findings from 30 studies with considerable heterogeneity in both model architecture and reference standards, resulting in high concerns across multiple domains, especially applicability and reference standards.

For FDA-approved tools such as S-Detect, AmCAD-UT, Koios-DS, and Medo-Thyroid, the available validation studies were generally of moderate quality. Most had clear definitions of index tests but lacked detailed reporting on patient recruitment and the temporal relationship between image acquisition and diagnosis.

Overall, the quality of diagnostic accuracy studies assessing AI applications in head and neck and endocrine imaging is heterogeneous. Common limitations include retrospective study designs, small and non-representative sample sizes, and incomplete reporting of patient selection criteria and temporal alignment between tests and reference standards. While some models – particularly those trained on large, multicenter datasets with prospective designs – show promising performance and robust methodology, others require further validation to ensure reliability, reproducibility, and clinical applicability. These findings underscore the importance of rigorous study design and transparent reporting in future AI research, particularly in light of evolving regulatory requirements and the need for trustworthy clinical decision support systems.

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Conflict of interest

The authors declare no conflict of interest.

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Address for correspondence

Magdalena Wiacek
Faculty of Medical Sciences
and Health Sciences
Kazimierz Pulaski
University of Technology
and Humanities
Radom, Poland
E-mail: m.wiacek@urad.edu.pl

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