International Journal of Innovative Technologies in Social Science

e-ISSN: 2544-9435

Operating Publisher
SciFormat Publishing Inc.
ISNI: 0000 0005 1449 8214

2734 17 Avenue SW,
Calgary, Alberta, T3E0A7,
Canada
+15878858911
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ARTICLE TITLE	LOW-DOSE COMPUTED TOMOGRAPHY (LDCT) IN LUNG CANCER SCREENING: EVOLUTION OF CLINICAL EVIDENCE, METHODOLOGY, AND IMPLEMENTATION CHALLENGES
DOI	https://doi.org/10.31435/ijitss.2(50).2026.6028
RECEIVED	16 March 2026
ACCEPTED	24 June 2026
PUBLISHED	30 June 2026
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LOW-DOSE COMPUTED TOMOGRAPHY (LDCT) IN LUNG CANCER SCREENING: EVOLUTION OF CLINICAL EVIDENCE, METHODOLOGY, AND IMPLEMENTATION CHALLENGES

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ABSTRACT

Introduction: Lung cancer is the leading cause of cancer death worldwide, with approximately 1.8 million deaths annually (1,2). Lung cancer is a stage-dependent disease, with the highest rate of long-term survival in those diagnosed with localized disease, especially if amenable to curative resection (1,3). The answer, given in two important RCTs, the NLST (1) and the NELSON trial (2), is that LDCT screening for lung cancer in high risk individuals reduces specific mortality from lung cancer compared with X-ray and no screening. Common implementation of screening has proved very difficult due to high false positive rates, overdiagnosis, and the costs of and burden of diagnostic workup of incidental findings (1,4).
Objective: To summarize evidence on the effectiveness of LDCT screening from clinical trials, and on emerging artificial intelligence (AI) and personalized risk prediction models that could help overcome implementation challenges and improve participant selection (1,5).
Materials and methods: We based our recommendations on a review of the key RCT results, meta-analyzes, and most recent clinical practice guidelines from the US Preventive Services Task Force (USPSTF), American College of Radiology, and International Association for the Study of Lung Cancer, published between 1997 and 2025 (4, 6). A literature search of MEDLINE, PubMed, and the Cochrane Library was performed, reviewing peer-reviewed articles describing screening results, nodule management protocols, and diagnostic performance of deep learning algorithms (4, 7).
Conclusions: Current evidence supports LDCT screening high-risk populations to reduce lung cancer specific mortality by 16% to 24%(2,8). Optimizing risk-based screening through validated models (e.g. PLCOm2012), rather than fixed age and smoking criteria, is important to avoid unnecessary screening, costs, and potential harms(3,5). Screening protocols should prioritize high-risk individuals, regardless of their age or smoking status. Artificial intelligence is another promising development, which can improve the classification of benign and malignant nodules, automate the process of image interpretation, and reduce the work of radiologists (1,5). Global implementation is likely to require the use of standardized reporting (Lung-RADS), smoking cessation programs, and strategies for equitable access to screening (2,5).

KEYWORDS

Lung Cancer, Low-Dose Computed Tomography (LDCT), Cancer Screening, Artificial Intelligence, Risk Prediction Models, Early Detection

CITATION

Jakub Chołast, Maurycy Jabłoński, Laura Kobaka, Wiktoria Łuniewska, Jakub Kacer, Julia Kacer, Jakub Niepokój, Klaudia Jurga, Marta Modrzyk. (2026) Low-Dose Computed Tomography (LDCT) in Lung Cancer Screening: Evolution of Clinical Evidence, Methodology, and Implementation Challenges. *International Journal of Innovative Technologies in Social Science*. 2(50). doi: 10.31435/ijitss.2(50).2026.6028

1. Methods for Diagnosing Lung Cancer

1.1 Low-dose computed tomography (LDCT) is the recommended screening modality for lung cancer in high-risk populations, providing high-resolution cross-sectional images of the thorax (4,5). LDCT can provide highly accurate measurements of nodule size, morphology and growth characteristics facilitating earlier-stage detection of lung cancer, where early-stage cancers (Stage I) can be detected while still curable by surgical resection (1,6). The NLST and NELSON randomized controlled trials have established that yearly LDCT lung cancer screening considerably reduces lung cancer mortality compared to less sensitive screening modalities (1,5).

1.2. Chest X-ray (CXR) and sputum cytology were the first screening tests for lung cancer. Limited sensitivity and specificity(3,4) and no mortality benefit for lung cancer screening (1,3) from the PLCO trial led to abandonment of CXR and sputum cytology as lung cancer screening tests. The sensitivity of CXR is poor for nodules under 1 cm, and the view is often obscured by structures in the mediastinum or heart, and small lesions frequently remain undetected until more advanced stages (4).

1.3 Positron emission tomography (PET) scan with 18F-fluorodeoxyglucose (FDG) is used in the work-up of indeterminate pulmonary nodules and staging of suspected malignancies (2,4). PET scan is of limited use for lesions <15mm in size, Stage I disease, and certain subtypes of adenocarcinoma (2,3), and a negative scan does not exclude malignancy for a population with a high pre-test probability. False-positive FDG uptake may occur in inflammatory and infectious conditions, reducing specificity. Despite these limitations, PET is valuable in detecting unsuspected nodal, or distant, metastases that can considerably alter treatment (2).

1.4 Navigational bronchoscopy and radial EBUS are bronchoscopic methods of obtaining a lung biopsy. They use the airway to navigate to the lesion and obtain a biopsy. They are less likely than CT-guided procedures to get a diagnostic specimen in small peripheral lesions (50% or less for nodules less than or equal to 2 cm in diameter) but are usually safer (2). For example, bronchoscopic approaches may have lower risk of complications such as internal bleeding or a pneumothorax (collapsed lung) than needle-based approaches (2,3).

1.5 CT-guided transthoracic needle biopsy (i.e., fine-needle aspiration [FNA] and core biopsy) is a highly accurate (reported diagnostic yields exceeding 90% in selected studies) method of obtaining cytologic or histologic samples from small or peripheral nodules that are not accessible via the airways (2,4). The diagnostic yield of these techniques is often greater than 90% in the literature (2,9). However, this greater accuracy comes at a cost of a higher risk of complications such as pneumothorax, which along with other minor complications occur at a high rate (2).

1.6 Surgical biopsy may be performed by minimally intrusive video-assisted thoracoscopic surgery (VATS) or robotic-assisted surgery (2). It is the reference standard for definitive histopathological diagnosis of suspicious nodules with confirmed sequential growth when non-surgical, non-intrusive tissue sampling cannot be safely and accurately conducted (2, 4). If the biopsy shows cancer, a definitive resection to cure the cancer (such as a lobectomy) is often performed at the same time (2,4).

1.7 Artificial Intelligence and Computer-Helped Diagnosis CAD systems use deep learning algorithms to assist radiologists in interpreting LDCT scans. The system's intent is to provide a second opinion, with the hope of eliminating human error and missing some small nodules because of fatigue or lapse of attention, and decreasing false-negatives. (1,5) Deep learning tools may analyze "radiomic" features, quantitative characteristics of the tumor that are not visible to the naked eye, to better differentiate between benign and malignant nodules and predict future risk of cancer (1,2).

1.8. Emerging biomarkers and liquid biopsies are being developed to better select patients for imaging and stratify the risk of nodules detected (1,2). Tumor-associated autoantibodies, circulating microRNA, or cell-free DNA (cfDNA) fragments that better detect molecular changes in blood, sputum, or exhaled breath are being tested (1,8). Likewise, airway gene expression assays have been utilized in clinical practice to predict malignancy in individuals with indeterminate nodules, thus avoiding unnecessary intrusive procedures (3,8).

2. Characteristics of chest LDCT in lung cancer screening

2.1 Pros of Chest LDCT in Detecting Lung Cancer

The primary advantage of LDCT screening is the reduction in mortality from lung cancer among people at high risk of lung cancer (1,2). The reduction in lung cancer mortality has been demonstrated by randomized controlled clinical trials, the National Lung Screening Trial (NLST) in the US, and NELSON trial in Europe (20% and 24-26% reduction in lung cancer mortality, respectively) in comparison with chest radiograph or no screening control groups (1,8). These results were confirmed in several meta-analyzes of worldwide trials: the relative mortality reductions amongst trial participants for lung cancer-specific mortality were of the order of 16% to 21% (2,8), and greater in women. Studies have shown a decrease in lung cancer-specific mortality of between 33 and 69% (3,6).

This can lead to a "stage shift" such that lung cancer has been diagnosed at an earlier and more localized stage at which it can be treated (1,2). The increased sensitivity of LDCT compared to standard chest X-ray allows malignant pulmonary nodules smaller than 1 cm to be detected that would otherwise not be found until

symptomatic and more advanced disease has developed (1,4). When compared with usual care, LDCT screening can increase Stage I lung cancer detection by nearly threefold (7). In the general population, approximately 60% of lung cancer is diagnosed only at the advanced distant stage, with 5-year relative survival of 5%. In comparison, with LDCT screening, these cancers are detected at Stage I, with a 5-year survival rate of greater than 75% (5,7).

A meaningful secondary benefit of LDCT is the incidentally acquired information on smoking-related comorbidities (the "Big 3 killers": lung cancer, cardiovascular disease, and COPD) (1,2). The non-oncologic diseases revealed during a baseline LDCT scan include coronary artery calcifications (CAC) for cardiovascular disease, pulmonary emphysema for COPD, and decreased bone density for osteoporosis (1,8). These comorbidities in total account for more deaths than actual lung cancer in those screened (1), but in the case of earlier detection with LDCT, medical interventions can delay disease progression and improve survival (1,2).

In addition, undergoing LCS screening provides that individual with a "teachable moment" that considerably increases the chance of that individual quitting (1,5). Participants in LCS programs are more likely to be interested in smoking cessation treatment and are more likely to successfully quit smoking long-term if their scan is abnormal (3,8). It is believed that integrating smoking cessation programs into LCS workflow can improve cost-effectiveness by 20 to 45% (3). The reduction in mortality is greatest when smoking cessation is combined with regular LDCT screening (3,5).

The effectiveness and precision of LDCT interpretation is continuously increasing with the use of artificial intelligence (AI) and deep learning algorithms (1,2). AI may assist radiologists by automated small nodule detection, eliminating human errors related to fatigue or distractions and decreasing false negative rates (1,8). "Radiomic" analysis can identify differences between benign and malignant lesions better than conventional volumetric radiological analysis, potentially reducing the need for intrusive biopsies (1,8). AI models, including a study using Sybil, can predict a person's lung cancer risk over up to six years from a single scan, allowing for a highly personalized screening approach (1,8). However, evidence remains limited by heterogeneity in training datasets, lack of prospective validation studies, and uncertainty regarding real-world implementation.

2.2 Cons and Limitations of Chest LDCT in Lung Cancer Screening

The most common risk of LDCT screening is a false positive finding, which results in unnecessary additional imaging studies and intrusive testing (1,7). In one of the first and largest randomized trials of LDCT screening (NLST), the rate of false positive findings was as high as 96.4% (1,3) when the threshold diameter of the detected nodule was set at 4 mm. Even with the advent of newer management schemes like Lung-RADS and volumetric assessment (which have improved specificity, with a false positive rate of 1.2% in the NELSON trial) (7), the total number of patients with indeterminate findings remains a burden to the patient and health care system (5). Indeterminate findings also have the potential to lead to a "cascade of tests" including serial CT scans, PET-CTs, and biopsies, leading to increased costs and resource use (1,5).

The main criticism has been that some of these slow-growing tumors would never have caused the person any symptoms or death during his or her lifetime and are therefore overdiagnosed (4,7). Overdiagnosis varies with the length of follow-up after diagnosis and trial design, but in NELSON, the overdiagnosis rate at 11 years was 8.9%. In NLST it ranged from 3.1% to 18.5% (3,7). In trials such as the Danish Lung Cancer Screening Trial (DLCST), overdiagnosis rates as high as 67% have been reported (3,4). While overdiagnosis rates are more favorable at longer follow-up periods, the relative risk of overtreatment, and therefore unnecessary surgery, chemotherapy, or radiation therapy for illness that would have been clinically insignificant, becomes more apparent. (3,7)

All diagnostic procedures done on suspicious nodules carry a risk of complications of the procedure, including the risk of biopsy and surgical resection (4,7). Major complications from intrusive procedures performed on patients without cancer are rare (<1 in 1000). The complication rate is much higher in surgical cases (7) (3). The perioperative mortality in the NLST was 1% in the LDCT group and 0.2% in the control group (6) (3). Possible complications of needle biopsy and bronchoscopy (such as pneumothorax or lung collapse, and internal bleeding) may require hospitalization or additional intrusive procedures (2) (3).

Cumulative radiation exposure from annual LDCT scans and further evaluation may increase the risk for radiation-induced cancers (3) (4). A single LDCT scan carries a low radiation dose of about 1.5 mSv. For over 20-30 years of annual screening, some authorities have said the amassed dose would still be clinically meaningful 18 and that there may be one radiation-induced cancer death per 2500 screened each year. For a

relatively young person at high risk, whose screening could potentially span several decades, this would mean that during that person's lifetime the risk of developing cancer is increased by 1.5% to 5% (3).

SIFs are common in LDCT screening and may result in psychological and financial distress (6,7). Non-LC abnormalities are frequently detected on LDCTs, including coronary artery calcifications (CAC), emphysema or adrenal masses ranging in prevalence from 7.5% to 18% of participants with 4.0 to 45% of screens reporting non-LC abnormalities (7,8). Although some SIFs provide a 'safety net' for other diseases, there is an expensive and clinically unproven work up of these SIFs (2,3), and workup of incidental findings constitutes 46.2% of total screen-based reimbursement (3).

2.3 Costs of Chest LDCT vs. Chest X-Ray in Lung Cancer Screening

While the initial cost of LDCT is much higher than CXR, its greater reduction in mortality renders it cost-effective in high-risk populations for lung cancer. One analysis has attempted to compare the dollar amounts spent per participant in the screening groups of the NLST. LDCT screening costs $1130 USD per participant versus $336 USD for CXR screening (4). The increase cost ($1130 >$300) is justified because the LDCT strategy reduced the lung cancer mortality by 20% compared with the CXR strategy, but the CXR strategy did not achieve a reduction in lung cancer mortality in multiple RCTs (3) (5).

The cost of LDCT screening is mainly driven by the diagnostic workup of indeterminate nodules and SIFs (major incidental findings). As LDCT is much more sensitive than CXR, it also detects more indeterminate findings that require the use of follow-up imaging (PET-CT or serial LDCT) and intrusive procedures (1) (7). In NLST, the cost to evaluate clinically meaningful incidental findings, such as cardiovascular abnormalities and emphysema, was included in the cost-benefit analysis (4), and subsequent studies have shown that incidental findings can be the largest contributor to the cost of screening, accounting for 46.2% of the total reimbursement cost (3).

LDCT screening generally fits within common "willingness-to-pay" thresholds for a health care intervention. The cost of lung cancer screening with LDCT is estimated to be $81,000 USD per QALY for annual screening (3). Several modeling studies have arrived at ICERs ranging from $49,000 to $96,700 per QALY, depending on the screening criteria used (3,5). Applying the standard US threshold of $100,000 per QALY, the additional long-term survival resulting from LDCT offsets the additional short-term cost of LDCT compared with CXR (5).

Costs of screening vary by study internationally depending on definitions, healthcare systems and ways of recruiting individuals for screening. In the UKLS trial in the UK, the cost of screening per participant was £186 GBP. This included the cost of recruitment as well as a single screen (4). One of the largest cost estimations of LDCT screening, the DLCST trial in Denmark, reported an LDCT screen cost of €282 EUR, and annual per-participant costs were €3,756 EUR in the screening group and €3,474 EUR in the control group (4). LDCT is therefore universally more expensive than CXR, but can be optimized by local factors such as standardization of reporting, e.g. Lung-RADS (3,5), or inclusion of smoking cessation programs.

2.4 Optimal Frequency of Chest LDCT Screening by Risk Group

Annual low-dose computed tomography (LDCT) screening is the standard of care for LCS in the high-risk population based on seminal clinical trials and clinical practice guidelines (3) (1). The LDCT screening frequency was driven mainly by NLST findings, which demonstrated a 20% mortality reduction in lung cancer with three rounds of annual LDCT screening (1,5). From this evidence, the USPSTF, the Centers for Medicare & Medicaid Services (CMS), and the American Cancer Society (ACS) recommend that high risk persons (generally 50-80 years old with 20+ pack-year smoking history) undergo yearly LDCT screening until the upper age limit or patients become unable to tolerate curative treatment (1,3). Patient adherence to annual screening is required, as it is shown that a higher percentage of cancers will be detected at earlier stages (8).

For "low-risk" participants with a negative baseline screen, increasing evidence suggests biennial screening may be both safe and effective (5,8). Although NLST participants were screened annually, the European MILD study found no difference in 10-year mortality or interval cancer diagnosis between participants randomly assigned to annual versus biennial screening (1,5,6,10). Other national screening programs outside of the United States in South Korea, Taiwan, China, and Australia have chosen or are planning to use biennial (every two years) screening for their target groups (8). This may be related to a desire to reduce cumulative radiation exposure, cumulative medical costs, and the burden of false-positive findings (2,5).

"Very low-risk" groups are being defined using biomarkers and baseline imaging features (8) (2). Clinical studies have shown that in individuals with a negative baseline scan and low-risk prediction scores based on PLCOm2012 and other models, risk-based screening intervals can be safely extended (8) (2). The ILST results indicated that 2/3 of the participants with very low-risk baseline results (2,8) could safely undergo 24-monthly scanning (surveillance) without negatively affecting the tumor stage at diagnosis (2,8). Likewise, the BioMILD study indicated that participants with a negative baseline LDCT and negative miRNA biomarker test could safely transition to 3-yearly surveillance. The lung cancer incidence was very low (0.8%) after 4 years (2) (8).

Stable or infra-threshold indeterminate nodules may be followed serially for the rate of growth (1) (2). Lung-RADS, a standardized management approach for lung cancer screening, requires that all indeterminate appearances of Categories 3 and 4 that are not definitively abnormal be followed up with LDCT at 3 or 6 months, as opposed to at the next annual screening (1) (5). As a result of this surveillance, "pseudo-incidental" cancers (which are present but too small to be acted upon at the time of baseline screening) are detected as soon as they reach a threshold size or volume doubling time (VDT) indicating malignancy (1,5).

The frequency of screening is likely to become more "risk-based" using AI models and deep learning (8) (2). An example of this is Sybil, which predicts the risk of lung cancer in an individual up to six years in advance using a single baseline scan (1), (8). Such technologies might enable selection of ultra-low risk patients to be screened every few years, and higher-risk patients to be screened every year or every six months (1) (8). Large randomized studies like 4-IN-THE-LUNG-RUN [23] are already evaluating whether these many individualized screening intervals would achieve a similar mortality reduction to annual screening but with the harms of over-screening much reduced (2,8).

3. Lung Cancer Risk Prediction Models and Their Effectiveness

Although there is important lung cancer mortality reduction associated with LDCT LCS, it is associated with a high false-positive rate (up to 96.4%) (9,11). Based on this, a number of prediction models have been developed for the screening population to help to stratify differentiated risk, i.e. distinguishing between malignant versus nonmalignant detected nodules and high-risk individuals who should continue to undergo screening (9,12,13). These models can be categorized into customary multivariable regression models or AI-based deep learning models (9,13).

3.1 Traditional Multivariable Regression Models

Most models use clinical, demographic and radiological information such as the size or density of the nodules to generate a risk estimate (9). The Mayo Clinic model published in 1997, was one of the first established models to predict malignancy in the lung nodules (9). Other common customary models include the PLCOm2012 model, which uses an individual's age, smoking history, race, educational history, and family history of lung cancer to determine the eligibility of individuals for screening (13).

In customary statistics, Lasso regression can be used to fit a sparse model for better interpretability. In a retrospective study, a risk model for Stage I lung cancer was derived with 17 variables, including spiculation, ground-glass opacity (GGO), age, white blood cell count (WBC) and blood urea nitrogen, and a corresponding AUC of 0.93 was reported (14). It was also confirmed that larger nodules are more likely to be suspicious for malignancy and that malignancy is strongly associated with spiculated borders (14).

3.2 Artificial Intelligence and Deep Learning Models

Furthermore, AI-based models, in particular DL-based models, are regarded as promising because they are able to identify complex patterns in imaging data that remain unexplained or unnoticed even by experienced human readers (9,12). Sybil is one example of such a fully validated DL model that predicts lung cancer risk using only one LDCT scan without manual annotations from radiologists (11). Sybil achieved a 1-year AUC of 0.92 on an independent test set from the National Lung Screening Trial (NLST) and is also generalizable to populations in the US and Taiwan (11).

Other AI models have been developed with high diagnostic accuracy (92.46%) in differentiating benign from malignant lesions. Other models, like Sybil, can predict risk up to six years in advance (12) (11). Some AI models can learn clinical risk factors, like duration of smoking, emphysema, and the presence of lung nodules directly from the image (11). Despite excellent discrimination performance, AI models remain vulnerable to dataset shift, spectrum bias, and limited external validation. Furthermore, the black-box nature of deep learning systems may reduce clinician trust and hinder clinical implementation.

3.3 Comparative Effectiveness and Predictive Performance

Multiple systematic reviews and meta-analysis have shown that AI-based models are often better at discriminating between cases than regression models (13) (9). For a pooled analysis of 140 studies, the pooled AUC was 0.82 for AI-based models and 0.73 for regression-based models (13). Direct comparison should be interpreted cautiously because of methodological heterogeneity among studies. However, in LDCT imaging data, the pooled AUC for AI models was 0.85 (13).

Studies in the local population found that the sensitivity of the Chinese Lung Nodules Reporting and Data System (C-Lung-RADS) for lung cancer was higher than the Lung-RADS v2022 international standard (87.1% vs. 63.3%) (12). The application of deep learning algorithms in the China Protocol for the early lung cancer screening program was found to increase the percentage of Stage I lung cancers detected from 46.3% to 65.6% (12).

3.4 Integrated and Multimodal Approaches

The combination of imaging with liquid biopsy based on ctDNA methylation markers may provide the best chance for early detection (12). The LunaCAM-S and LunaCAM-D models produced AUCs of 0.90 and 0.81 for the screening and diagnostic phases, respectively (12). Accordingly, the China Protocol, which is based on 3D thin-layer LDCT reconstruction (Tre-LDCT), AI-assisted diagnosis, and molecular characterization, seeks to provide individualized management for patients (12,15). Prospective validation studies are still required before widespread adoption.

3.5 Challenges and Limitations

Despite the good predictive ability of most models, there is a substantial high risk of bias (ROB) in the way that patients are selected and how non-observed data are handled in the models (13). The Asian and Chinese models have only been internally validated in single-center cohorts and not on a broad international dataset (9). Additionally, deep learning models are often complex and opaque, making it difficult for a clinician to interpret the contribution of each input variable to a high-risk prediction (9,13). Greater standardization of model development and testing in a multi-ethnic cohort will be needed before such models can be considered for use in screening guidelines (9,13).

4. Conclusions

The evidence comes from randomized controlled trials, showing that the use of LDCT screening in high risk individuals reduced lung cancer mortality compared with chest X-ray or no screening (2) (1). Systematic reviews, suggest a reduction in relative lung cancer mortality with a combined estimated effect of approximately 21% reduction in lung cancer mortality (1). Artificial intelligence and deep learning is promising for automated image analysis to reduce radiologist burden and predict risk of lung cancer as far as 6 years into the future. Sybil is a deep learning model that was developed to accomplish these goals (1) (8). In addition, LDCT scans may also opportunistically detect a number of smoking-related comorbidities.

These low screening rates across the breadth of the US population and poor annual screening adherence have impeded the common adoption of this clinically effective intervention, along with the high rate of false positive results that lead to potentially unnecessary intrusive testing (1) (1,3), along with the risk of overdiagnosis(1,4). Measured vascular growth of the nodule, rather than diameter change, reduces false positives and allows for better selection of indeterminate nodules (5) (5,7). Mortality benefit is greatest when screening is used in conjunction with smoking cessation soon after screening(1-3). Future global technological roadmaps addressing tobacco and lung cancer will require universally agreed quality metrics, harmonized performance standards for artificial intelligence and machine learning protocols (8) (2) (3). Additionally, there is a need for further research to refine eligibility criteria for never-smokers who remain high-risk due to familial or environmental exposure(8) (2).

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Receiving funding: not applicable

All authors have read and agreed with the published version of the manuscript
Funding: The article did not receive any funding.
Conflict of Interest Statement: Authors declare no conflicts of interest.
AI: The authors used artificial intelligence-based tools to improve the language quality, grammar, and scientific vocabulary of the manuscript. Following the use of these tools, the authors carefully reviewed and edited the content as needed and take full responsibility for the scientific content of the publication.

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