



JOURNAL OF EDUCATION, HEALTH AND SPORT

eISSN 2391-8306 · Open Access · Peer-reviewed

apcz.umk.pl/JEHS·Nicolaus Copernicus University in Toruń



Cite as: ŁUNIEWSKA, Wiktoria, SŁAWATYNIEC, Olga, SOBIERAJ, Wiktoria, PAJĄK, Julia, KAMOSIŃSKA, Anna, MAJDA, Antoni and MODRZYK Marta. Weighted Blankets as a Non-Pharmacological Intervention for Sleep, Mental and Neurodevelopmental Disorders: A Narrative Review. *Journal of Education, Health and Sport*. 2026;95:73969. <https://doi.org/10.12775/JEHS.2026.95.73969>

ARTICLE TIMELINE

Received: 04.07.2026 Revised: 26.08.2026
Accepted: 21.09.2026 Published: 21.09.2026

INDEXING & EVALUATION

MEiN points: 40 Unique ID: 246387
Disciplines: Physical culture sciences (Field of medical and health sciences); Health Sciences (Field of medical and health sciences).

The journal has been awarded 40 points in the parametric evaluation by the Polish Ministry of Higher Education and Science (Annex to the announcement of 05.01.2024, No. 32318). Unique Journal Identifier: 201159. Scientific disciplines: Physical culture sciences (Field of medical and health sciences); Health Sciences (Field of medical and health sciences).

Punkty Ministerialne z 2019 – aktualny rok 40 punktów. Załącznik do komunikatu Ministra Szkolnictwa Wyższego i Nauki z dnia 05.01.2024 Lp. 32318. Posiada Unikatowy Identyfikator Czasopisma: 201159. Przypisane dyscypliny naukowe: Nauki o kulturze fizycznej (Dziedzina nauk medycznych i nauk o zdrowiu); Nauki o zdrowiu (Dziedzina nauk medycznych i nauk o zdrowiu). © The Authors 2026.

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Multiparametric Magnetic Resonance Imaging in the Diagnosis of Prostate Cancer. Prostate Fusion Biopsy. Clinically Insignificant Prostate Cancer

Wiktoria Łuniewska, ORCID: <https://orcid.org/0009-0009-5398-422X>

E-mail: wiktoria.lun@gmail.com

1. Medical University of Wrocław, Wrocław, Poland

Olga Sławatyniec, ORCID: <https://orcid.org/0009-0007-0373-1588>

E-mail: olgaslaw2@gmail.com

2. 4th Military Clinical Hospital with Polyclinic, Wrocław, Poland

Wiktoria Sobieraj, ORCID: <https://orcid.org/0009-0007-5412-6302>

E-mail: w.s.sobieraj@gmail.com

3. Lower Silesian Center for Oncology, Pulmonology and Hematology, Wrocław, Poland

Julia Pająk, ORCID: <https://orcid.org/0009-0007-0882-9365>

E-mail: julia.pajak@onet.eu

4. 4th Military Clinical Hospital with Polyclinic, Wrocław, Poland

Anna Kamosińska, ORCID: <https://orcid.org/0009-0005-0718-2112>

E-mail: anna.kamosinska@interia.pl

5. 4th Military Clinical Hospital with Polyclinic, Wrocław, Poland

Antoni Majda, ORCID: <https://orcid.org/0009-0006-4357-513X>

E-mail: antekmajda99@gmail.com

6. Provincial Specialist Hospital in Wrocław, Wrocław, Poland

Marta Modrzyk, ORCID: <https://orcid.org/0009-0003-9590-5602>

E-mail: modrzykmarta@gmail.com

7. Institute of Medical Sciences, Opole, Poland

Corresponding Author

Wiktoria Łuniewska

E-mail: wiktoria.lun@gmail.com

Medical University of Wrocław

Abstract

Background. Prostate cancer diagnosis must balance the early detection of clinically significant disease against the overdiagnosis of indolent tumors. Multiparametric magnetic resonance imaging (mpMRI) has transformed the diagnostic pathway by functioning as a triage test before biopsy and by enabling targeted sampling.

Key words: multiparametric magnetic resonance imaging; prostatic neoplasms; image-guided biopsy; clinically significant prostate cancer; active surveillance

Aim. This narrative review evaluates the role of mpMRI, prostate fusion biopsy, and clinically insignificant prostate cancer in modern prostate cancer diagnostics and management.

Material and methods. A narrative review was prepared using peer-reviewed literature from PubMed and Google Scholar published between 2021 and 2026. Included sources comprised randomized and prospective studies, diagnostic cohorts, systematic reviews, meta-analyses, expert reviews, active surveillance studies, artificial intelligence studies, and health-economic analyses.

Results. Evidence consistently demonstrates that mpMRI improves the detection of clinically significant prostate cancer while reducing unnecessary biopsies and the overdiagnosis of clinically insignificant disease. MRI-targeted biopsy outperforms systematic biopsy for identifying clinically significant tumors, whereas the combined targeted and systematic approach provides the highest overall diagnostic accuracy. Nevertheless, clinically significant MRI-invisible cancers may still occur, highlighting the importance of integrating imaging findings with clinical risk factors. Emerging applications of artificial intelligence and optimized risk stratification may further enhance diagnostic performance.

Conclusions. mpMRI-centered diagnostic pathways reduce unnecessary biopsies and the overdiagnosis of indolent tumors while supporting individualized biopsy and surveillance decisions. Their effectiveness depends on imaging quality, clinical expertise, biopsy technique, patient risk profile, and cost considerations.

Introduction

Prostate cancer develops through a complex interaction of non-modifiable and modifiable risk factors. The strongest established non-modifiable determinants include increasing age, family history, genetic susceptibility, and ethnicity, whereas modifiable factors such as dietary habits,

obesity, alcohol consumption, smoking, and chronic inflammation have also been associated with disease risk [1,2]. Although many of these associations remain under investigation, lifestyle modification represents a promising strategy for primary prevention. In particular, increasing evidence suggests that plant-based dietary patterns may be associated with a lower risk of prostate cancer development and may contribute to improved long-term outcomes [3].

Prostate cancer is among the most common malignancies in men and a major cause of cancer mortality. A contemporary review estimated approximately 1.5 million new diagnoses and almost 400,000 deaths annually, with projections suggesting that the number of new cases may approximately double by 2040 [4]. This burden leads to certain dilemma. Since the number of new cases does not match up with the number of deaths due to prostate cancer, some types of cancer are biologically indolent, whereas a smaller but clinically decisive proportion are aggressive. The aim of modern diagnosis is therefore not the detection of any prostate cancer, but accurate identification of clinically significant prostate cancer while limiting clinically insignificant disease.

In common practice there are several pathways used as screening towards prostate cancer. They are based on prostate-specific antigen (PSA), digital rectal examination, and transrectal ultrasound-guided systematic biopsy has limited specificity and relies on random sampling. PSA-only screening may increase detection of low-risk disease, and recent reviews emphasize the persistent tension between mortality reduction and overdiagnosis [4,5]. Getting to know which type of cancer is actual threat towards patient's life, would significantly change the approach of further treatment. Overdiagnosis matters because it can lead to biopsy-related morbidity, anxiety, and overtreatment with urinary, sexual, or bowel consequences. Contemporary diagnostic strategies emphasize harm minimization, with PSA used as a triage tool for mpMRI and mpMRI as a triage test before biopsy [5].

Clinically significant prostate cancer is most often defined in the reviewed literature as International Society of Urological Pathology (ISUP) grade group 2 or higher, corresponding to Gleason score 3+4 or higher. Clinically insignificant prostate cancer is commonly defined as ISUP grade group 1 or Gleason score 3+3, although tumor volume, cancer core length, and extension beyond the prostate may modify clinical interpretation [6,7].

The aim of this review is to evaluate the role of mpMRI in prostate cancer diagnosis, compare fusion biopsy with systematic biopsy, and critically discuss clinically insignificant prostate cancer and active surveillance using only the supplied 2021-2026 sources.

Research materials and methods

This review was based exclusively on the scientific articles supplied for manuscript preparation. The source set consisted of PubMed and Google Scholar literature from 2021-2026, including randomized and prospective trials, diagnostic cohorts, systematic reviews, meta-analyses, expert panel reviews, active surveillance studies, artificial intelligence studies, and economic analyses.

The conceptual search strategy used combinations of: "multiparametric MRI OR mpMRI" AND "prostate cancer" AND "fusion biopsy"; "MRI-targeted biopsy" AND "systematic biopsy"; "PI-RADS" AND "clinically significant prostate cancer"; "negative mpMRI" AND "prostate biopsy"; "clinically insignificant prostate cancer" AND "overdiagnosis"; "active surveillance" AND "mpMRI"; and "cost-effectiveness" AND "prostate MRI".

Inclusion criteria were peer-reviewed articles from 2021-2026 addressing adult men with suspected or diagnosed prostate cancer and reporting evidence relevant to mpMRI, PI-RADS, MRI-targeted or fusion biopsy, systematic biopsy, negative mpMRI, active surveillance, diagnostic prediction, or cost-effectiveness. Exclusion criteria were sources outside the supplied file set, articles unrelated to diagnosis or monitoring, and publications focused primarily on treatment without diagnostic relevance. Strengths of the selected literature include randomized evidence, contemporary meta-analyses, real-world cohorts, expert reviews, and economic studies. Limitations include heterogeneity in MRI protocols, PI-RADS versions, biopsy route, biopsy thresholds, operator expertise, definitions of clinically significant disease, and reference standards. No pooled statistical analysis was performed.

Research and Discussion

Principles of multiparametric MRI

Multiparametric MRI of the prostate is a powerful tool that brings together anatomical and functional sequences to provide a comprehensive view of the prostate. The T2-weighted imaging sequence offers high-resolution anatomical information, which is crucial for assessing the prostate's zonal anatomy, as well as checking for extraprostatic extension and seminal vesicle invasion. This sequence is particularly useful for identifying lesions in the transition zone. DWI and ADC maps provide functional information related to restricted diffusion, which is associated with cellularity and higher-grade disease [7].

A secondary analysis of the PROMIS trial showed that MRI visibility is influenced by grade and tumor burden. Zones containing Gleason 3+4 cancer, higher-grade cancer, or longer maximum cancer core length had increased odds of MRI visibility, whereas larger prostate volume reduced visibility [8]. The results from this study support the biological rationale for MRI-guided enrichment of biopsy, but on the other hand they explain why small, low-volume, MR-invisible tumors which are still clinically significant, may be missed.

Dynamic contrast-enhanced imaging remains part of mpMRI, although its incremental value is debated. In PI-RADS v2.1, DCE has a limited role, especially in upgrading equivocal peripheral-zone lesions and when T2-weighted or DWI quality is insufficient [9]. PI-RADS standardizes reporting from very low to very high likelihood of clinically significant cancer, but interpretation is still variable. A systematic review comparing PI-RADS v2.1 with v2 found comparable sensitivity and negative predictive value but lower specificity for v2.1 in whole-gland and transition-zone analyses [10].

mpMRI in detection of clinically significant prostate cancer

The major diagnostic value of mpMRI is increased number of diagnoses of clinically significant tumors. Men whose MRI results revealed suspected findings may undergo targeted biopsy, meantime patients with negative MRI results and low clinical risk may avoid immediate biopsy. Principal differences between mp-MRI-led and systemic biopsy-centred pathways were gathered in the Table 1 underneath.

Table 1. Comparison of mpMRI-led pathways and systematic biopsy-centered pathways [8–10]

Diagnostic domain	mpMRI-led / MRI-targeted approach	Systematic biopsy-centered approach	Interpretation
Main purpose	Localize suspicious lesions and enrich biopsy for clinically significant cancer	Random or template sampling of the gland	mpMRI shifts diagnosis from detecting any cancer to detecting relevant cancer
Clinically significant cancer	Higher detection of csPCa in meta-analysis	May miss anterior, apical, or small lesions	Targeting improves efficiency but is not universally sufficient
Clinically insignificant cancer	Lower detection of Gleason 3+3 disease	Higher probability of incidental low-grade detection	MRI pathways reduce overdiagnosis but do not eliminate it
Negative result	PI-RADS 1-2 has high NPV but residual risk remains	Negative biopsy may reflect sampling error	Negative MRI should be risk-adapted
Best current role	Triage, targeting, risk stratification, surveillance	Complementary sampling when MRI or targeting is uncertain	Combined biopsy often maximizes csPCa detection

Negative mpMRI has high but imperfect negative predictive value. The AJR Expert Panel review reported that PI-RADS 1-2 examinations have an approximate negative predictive value of 90% for excluding grade group 2 or higher cancer and an even higher value for grade group 3 or higher disease [11]. Nevertheless, residual risk persists: in a cohort of patients with negative mpMRI who underwent saturation biopsy, clinically significant cancer was found in 11% [12]. Negative MRI should therefore be interpreted with PSA density, family history, genetic risk, clinical stage, and follow-up dynamics.

There is no doubt that MRI-based pathways can reduce unnecessary biopsies and low risk cancer detection [4,5]. There was performed a randomised GÖTEBORG-2 trial, PSA screening followed by MRI and targeted biopsy only reduced detection of clinically insignificant cancer by approximately half compared with a strategy including systematic biopsy, without substantially compromising clinically significant cancer detection. The trial has a major impact because it revealed the fact that over diagnosis is a primary harm, not simply cancer detection as a benefit [6].

MRI-based predictive models may improve patient selection beyond imaging alone. A systematic review found that adding PI-RADS to clinical variables such as age, PSA, prostate volume, PSA density, biopsy status, and family history improved prediction of clinically significant cancer, with most reported AUCs between 0.78 and 0.92 [13]. Another model combining age, PSA density, and PI-RADS v2.1 achieved AUCs of 0.938 in development and 0.914 in external validation [14].

Fusion biopsy vs systematic biopsy

MRI-targeted biopsy is a way to get a more accurate diagnosis by combining MRI and ultrasound images. This can be done in a few ways: by mentally superimposing MRI findings on real-time ultrasound images, using special software to fuse the two, or by doing the biopsy directly inside an MRI machine. A meta-analysis of 26 studies and 5831 patients found that MRI-targeted biopsy detected more clinically significant and high-risk prostate cancer than systematic biopsy and fewer clinically insignificant cancers [15]. A systematic review of targeted biopsy methods similarly emphasized that mpMRI-guided targeting can improve diagnostic accuracy and reduce unnecessary biopsies when applied in appropriate clinical settings [16].

There are no particular guidelines for an optimal targeting technique. On the one hand cognitive biopsy is faster and cheaper for health system but depends heavily on operator experience. Software-assisted fusion supports registration of MRI and ultrasound images but also has its downsides which is requirement of technical proficiency. In-bore biopsy provides direct MRI targeting but it requires significant resources. Comparative meta-analysis found no significant differences in clinically significant or insignificant cancer detection among cognitive targeting, software fusion, and in-bore biopsy [17]. Transperineal cognitive and software-assisted fusion also showed comparable clinically significant cancer detection [18]. Prospective studies

comparing transperineal and transrectal MRI-targeted biopsy found no clear difference in clinically significant cancer detection, although safety and local practice remain relevant [19].

The most important question is whether in regular practice systemic cores can be omitted. The cohort study performed on 867 patients, combined targeted and systemic biopsy detected more clinically significant cancer than any of this method alone. Comparing targeted biopsy to systemic biopsy, both performed alone, the first one detected slightly more clinically significant disease, but the combined approach was most accurate [20]. The other real-live cohort revealed that systemic biopsy detected additional cancers outside target lesions and radical prostatectomy specimens showed mpMRI-negative findings in some cases [21]. The other study reported that omitting MRI-guided fusion biopsy would have missed clinically significant cancer in 11% of patients, whereas omitting systematic biopsy would have missed clinically significant cancer in 6% [22].

A universal targeted-only strategy is therefore not supported. It may be reasonable in selected patients with high-quality imaging, expert operators, prior negative biopsy, or posterior PI-RADS 5 lesions where systematic sampling adds little. Combined biopsy remains attractive in biopsy-naïve men, equivocal lesions, lower PI-RADS scores, large prostates, multifocal disease, or when treatment planning requires information outside the MRI target [23]. Operator experience is also decisive: the added value of systematic biopsy and the frequency of fusion failure decreased as biopsy experience increased [24]. Adequate target sampling is essential, and at least three targeted cores from the index lesion identified the most relevant diagnosis in 97% of patients [25].

Clinically insignificant prostate cancer

Clinically insignificant prostate cancer is an intense discussed topic when it comes to screening and biopsy. One of the most important studies, the GÖTEBORG-2 trial defined each tumour with a result of 3+3 in Gleason score as clinically insignificant and showed that avoiding systematic biopsy in favor of MRI-targeted biopsy only reduced its detection by half [6]. This is clinically meaningful because a low-grade cancer diagnosis may still lead to anxiety, repeated testing, or treatment despite favorable prognosis and the availability of active surveillance.

mpMRI helps reduce overdiagnosis by preventing biopsy in selected low-risk men with negative MRI, directing biopsy toward lesions more likely to contain clinically significant cancer, and supporting surveillance of known low-risk disease. Yet mpMRI does not eliminate overdiagnosis or underdiagnosis. Some MRI-visible Gleason 3+3 tumors may prompt repeated

biopsy or anxiety, whereas some clinically significant tumors remain MRI-invisible [11,19]. PI-RADS 3 lesions are especially challenging because they are common and indeterminate; PSA density, abnormal digital rectal examination, and prostate volume should influence whether biopsy is performed [11]. False positives also arise because benign or premalignant changes can increase MRI visibility, as shown in the PROMIS secondary analysis [8].

Table 2. Features of clinically significant versus clinically insignificant prostate cancer

Feature	Clinically significant prostate cancer	Clinically insignificant prostate cancer
Common biopsy definition	ISUP grade group ≥ 2 ; Gleason score $\geq 3+4$	ISUP grade group 1; Gleason score 3+3
Additional features	May include tumor volume, extraprostatic extension, or greater cancer core length	Usually low-grade, low-volume, organ-confined disease
MRI behavior	More likely visible as grade and cancer core length increase	Often less conspicuous on mpMRI
Clinical implication	Requires risk-adapted treatment discussion or close surveillance	Often suitable for active surveillance
Diagnostic priority	Must be detected accurately	Detection should be minimized when outcomes are unchanged
Controversy	Some low-volume Gleason 3+4 tumors may behave favorably	Some high-volume Gleason 6 tumors may not be trivial

Table summarizes the distinction between clinically significant and clinically insignificant prostate cancer used across the reviewed literature [6,11,12].

Active surveillance

Active surveillance is the most accurate strategy avoiding overtreatment. The most recent reviews emphasize that not all diagnosed prostate cancers require immediate treatment and that for patients with low risk disease, surveillance is preferred approach [4]. Accurate initial

classification is crucial because undergrading may delay treatment for clinically significant cancer, whereas overclassification may deny suitable patients the benefits of surveillance.

mpMRI comes with significant help, because of its significant contribution to surveillance at baseline and during follow-up. At baseline, it can detect occult higher-grade disease that would make surveillance inappropriate. During follow-up, it can identify changes in lesion size, conspicuity, diffusion restriction, or new lesions. There was developed a system PRECISE to standardize MRI reporting. A critical review noted high negative predictive value but low positive predictive value for progression in available studies [26].

MRI cannot replace biopsy in surveillance protocols. A meta-analysis of 15 studies and 2240 patients found pooled sensitivity of approximately 0.59 and specificity of 0.75 for MRI progression during active surveillance [27]. A systematic review of fusion biopsy in active surveillance concluded that systematic and fusion biopsies are complementary; fusion biopsy was more likely to detect significant disease, but it missed 6.4-11% of clinically significant cancers [28]. A 2026 model combining clinical variables and mpMRI-derived radiomic features achieved an AUC of 0.84 for distinguishing rapid progressors from stable cases, suggesting promise for future risk-adapted surveillance [29].

Limitations of mpMRI and fusion biopsy

While mpMRI and fusion biopsy have their benefits, they also have some significant limitations. False negativity is the main limitation of mpMRI. Systemic biopsy may be performed at the patients when PSA density is elevated, family history is positive, or genetic susceptibility is present, even if mpMRI results are negative [11]. The finding of clinically significant cancer in 11% of biopsied men with negative mpMRI illustrates why follow-up triggers and individualized risk assessment are necessary [12].

Also false positive are clinically important. PI-RADS v2.1 may have lower specificity than PI-RADS v2, and qualitative diffusion assessment remains subjective [10]. Inflammation, prostatic intraepithelial neoplasia, and benign stromal or hyperplastic changes can mimic malignancy. PROMIS data showed that prostatic intraepithelial neoplasia increased the odds of zonal MRI visibility in men without cancer, illustrating a mechanism for false-positive MRI [8].

The major downside of fusion biopsy is that it is operator and system dependent. Cognitive fusion requires accurate mental registration, while software fusion requires segmentation, registration, calibration and correction for motion or deformation. In inexperienced operator

hands systemic cores may compensate for targeting failure [24]. Quality assurance, training, and audit are therefore essential elements of MRI-based pathways. These requirements should be viewed as part of the intervention itself, because diagnostic performance depends on the full pathway rather than on the scanner, PI-RADS score, or fusion platform alone.

There are some studies in progress which evaluate artificial intelligence and radionics in reducing inter-reader variability. A fully automated deep learning model performed comparably to radiologists for detecting clinically significant cancer at MRI, while a radiomics systematic review reported good performance without clear superiority over PI-RADS in the limited comparative studies [30,31]. Prospective validation, standardization, and direct comparison with expert readers and risk calculators are still needed.

Cost and availability are other important factors in the discussion of mpMRI. Economic reviews generally support prebiopsy MRI and targeted biopsy as cost-effective compared with systematic TRUS biopsy alone, but most evidence comes from high-income settings [32,33]. A Swedish microsimulation found that MRI with targeted biopsy reduced lifetime biopsy episodes by approximately 40% compared with systematic biopsy alone, although cost-effectiveness varied by strategy [34]. These findings depend on scanner access, radiologist expertise, biopsy platforms, reimbursement, and local patient populations.

Table 3. Advantages and limitations of fusion biopsy [11,12,24]

Aspect	Advantages	Limitations
Diagnostic yield	Enriches sampling for clinically significant lesions	May miss MRI-invisible or out-of-target csPCa
Overdiagnosis	Can reduce detection of Gleason 3+3 disease	Combined biopsy may detect more insignificant disease
Technique options	Cognitive, software-assisted, and in-bore methods allow flexibility	No clearly superior technique across all settings
Treatment planning	Helps localize index lesions and map suspicious regions	Systematic cores may still detect multifocal disease
Quality control	Standardized MRI and adequate target cores improve reliability	Image quality and operator learning curve affect outcomes

Summary

Multiparametric magnetic resonance imaging has become the main tool for diagnosing prostate cancer. This is based on standards set by PI-RADS v2.1 and results from the GÖTEBORG-2 and PRECISION trials. It provides anatomical and functional information through T2-weighted imaging, DWI/ADC, and DCE, interpreted through PI-RADS. MRI-targeted biopsy improves detection of clinically significant and high-risk prostate cancer and reduces detection of Gleason 3+3 disease compared with systematic biopsy. By using mpMRI to guide biopsies, doctors can better detect high-risk prostate cancer and avoid diagnosing cancers that aren't likely to cause problems. This helps solve two big issues: missing cancers that need treatment and treating cancers that aren't a threat. The use of mpMRI has improved the diagnosis process, making it more accurate and reducing unnecessary biopsies.

However, systematic biopsy cannot be abandoned in all patients. Combined targeted and systematic biopsy remains diagnostically strongest in many biopsy-naïve or higher-risk contexts, whereas targeted-only strategies may be appropriate in selected patients with high-quality imaging, experienced operators, and high-suspicion lesions. Negative mpMRI is useful but not absolute reassurance, particularly in men with elevated PSA density or other high-risk features.

Clinically insignificant prostate cancer is a driver of overtreatment, morbidity, cost, and patient anxiety. mpMRI reduces but does not eliminate overdiagnosis. Active surveillance increasingly depends on mpMRI and fusion biopsy, but serial MRI alone is not sufficiently sensitive to replace repeat biopsy. Future directions should include harmonized definitions of clinically significant disease, improved MRI quality control, standardized biopsy reporting, risk calculators incorporating PI-RADS and PSA density, prospective validation of artificial intelligence and radiomics, and cost-effectiveness studies in diverse healthcare systems.

Author Contributions^{[1][2]}_[SEP]

Conceptualization, W.Ł and O.S; methodology, W.S and J.P; formal analysis, A.K and A.M; investigation, W.Ł and M.M; writing original draft preparation, W. Ł and O.S; writing review and editing, J.P; supervision, W.Ł. All authors have read and agreed to the published version of the manuscript.

Funding Statement^{[1][2]}_[SEP]

This research received no external funding.

Institutional Review Board Statement^{[1][2]}_[SEP]

Not applicable.

Informed Consent Statement^{[1][2]}_[SEP]

Not applicable.

Data Availability Statement^{[1][2]}_[SEP]

Data sharing is not applicable to this article.

Acknowledgments^{[1][2]}_[SEP]

The authors would like to thank all individuals and institutions who contributed to the development of this work.

Conflict of Interest Statement^{[1][2]}_[SEP]

The authors declare no conflict of interest

Declaration of the Use of Generative AI and AI-Assisted Technologies in the Writing Process

During the preparation of this work, the author used generative AI tools, including Notebook LM (Google) and ChatGPT (OpenAI), solely for language editing, grammar correction, improvement of readability, and assistance in organizing scientific literature. All scientific interpretation, analysis, and conclusions were performed by the authors, who take full responsibility for the content.

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