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Review Article

Twelve-Month Clinical Outcomes of Robotic PCI vs Manual PCI: A Systematic Review

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Abstract

Robotic-assisted Percutaneous Coronary Intervention (R-PCI) has been developed to improve procedural precision and reduce operator radiation exposure compared with Manual Percutaneous Coronary Intervention (M-PCI). Although short-term safety and feasibility have been well demonstrated, evidence on 12-month clinical outcomes remains limited. This systematic review evaluated 12-month clinical outcomes of R-PCI versus M-PCI in adult patients with coronary artery disease. Relevant literature published between January 2015 and April 2025 was identified through searches in Scopus, ScienceDirect, PubMed, Cochrane Library, and Google Scholar. Eligible studies directly compared R-PCI and M-PCI and reported 12-month clinical outcomes, including Major Adverse Cardiovascular Events (MACE), Myocardial Infarction (MI), stroke, mortality, and Target Vessel Revascularization (TVR). Four cohort studies were included, involving 915 patients, of whom 334 underwent R-PCI, and 581 underwent M-PCI. At 12 months, MACE rates ranged from 0% to 10.5% after R-PCI and 1.4% to 8.1% after M-PCI. Mortality, MI, and TVR were low and comparable between groups. Although fluoroscopy time varied among studies, procedural success remained high, and adverse events were similar between groups. Studies that utilized Intravascular Ultrasound (IVUS) guidance reported particularly favorable outcomes. Overall, the available observational evidence suggests that R-PCI is associated with 12-month clinical outcomes comparable to those of M-PCI. However, given the limited number of studies, their observational design, and the absence of randomized data, these findings should be interpreted with caution. Further large-scale randomized controlled trials with longer follow-up are warranted to more definitively establish the clinical effectiveness and cost-effectiveness of R-PCI.

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Introduction

Ischemic heart disease remains one of the predominant causes of mortality worldwide and continues to pose a major public health burden.[1–3] In Indonesia, national surveillance such as the RISKESDAS 2018 report consistently identifies ischemic heart disease as one of the main causes of death, driven by rising prevalence of hypertension, diabetes, dyslipidemia, and obesity.[3] As cardiovascular risk factors continue to increase, the demand for safe and effective coronary revascularization strategies remains high.[1–3]

Percutaneous Coronary Intervention (PCI) is a widely utilized treatment for patients with coronary artery disease. Nevertheless, traditional Manual Percutaneous Coronary Intervention (M-PCI) exposes operators to cumulative radiation exposure and significant orthopedic strain from prolonged use of protective lead garments.[4] To address these limitations, Robotic-assisted Percutaneous Coronary Intervention (R-PCI) was introduced, enabling remote manipulation of guidewires and stents from a shielded console. Early clinical experience with robotic platforms such as the CorPath 200 and CorPath GRX demonstrated precise device control and high procedural success.[1-2,5-6] Despite these advantages, its adoption remains gradual due of system costs, longer setup times, and the learning curve required for routine practice.[1-2,6]

Most available evidence regarding R-PCI has focused on short-term procedural outcomes, radiation reduction, and feasibility.[1-2,5-6] Previous meta-analyses have also reported that R-PCI achieves similar safety and efficacy to M-PCI, although data on 12-month and longer-term clinical outcomes remain limited.[7-8] Since events such as restenosis, stent thrombosis, and recurrent ischemia often occur months after the procedure, assessment at 12-month follow-up is clinically important. Additionally, robotic systems significantly reduce operator radiation exposure, representing an important occupational benefit.[4]

Given these considerations, this systematic review aims to summarize and compare the 12-month clinical outcomes of R-PCI and M-PCI in patients with coronary artery disease, focusing on Major Adverse Cardiovascular Events (MACE), Target Vessel Revascularization (TVR), stroke, Myocardial Infarction (MI), and mortality.[1–3,5–8]

Methods

Study Design

The preparation of this systematic review refers to the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020).[9] The primary aim was to compare the 12-month clinical outcomes of R-PCI and M-PCI in adults with coronary artery disease. The review protocol was not registered on PROSPERO.

Search Strategy

A systematic literature search was conducted in Scopus, ScienceDirect, PubMed, Cochrane Library, and Google Scholar to identify relevant studies published between January 2015 and April 2025. The search strategy used predefined keywords combined with Boolean operators as follows: (“robotic percutaneous coronary intervention” OR “R-PCI”) AND (“manual PCI” OR “conventional PCI”) AND (“long-term clinical outcome”). The term “long-term clinical outcome” was included to maximize search sensitivity, as follow-up duration is often described inconsistently across studies. During the screening process, only studies reporting a minimum follow-up duration of 12 months were included in the final analysis. The final literature search was conducted on 18 April 2025. In addition, reference lists of included studies were manually screened (hand-searching) to identify any additional relevant articles.

Eligibility Criteria

Studies were deemed eligible if they: (1) enrolled adult patients (≥18 years old) with coronary artery disease who underwent either R-PCI or M-PCI; (2) reported clinical outcomes with a minimum follow-up of 12 months, including MACE, TVR, MI, stroke, or mortality; and (3) utilized clinically available robotic platforms such as CorPath 200 or CorPath GRX. Studies were excluded if they were single-arm trials, case reports, review articles, meta-analyses, conference abstracts, animal studies, study protocols, or reports limited to procedural outcomes without clinical follow-up.

Study Selection

Titles, abstracts, and full-texts were independently screened by two reviewers using predetermined inclusion and exclusion criteria. Any disagreement between reviewers was resolved through discussion or by consulting a third reviewer. The documentation of the selection process followed the structure of the PRISMA 2020 flow diagram.[9]

Data Extraction

Two reviewers independently extracted relevant data using a standardized data collection sheet. Extracted data included study characteristics, patient demographics, angiographic findings, procedural features, clinical endpoints, and duration of follow-up. Discrepancies between reviewers were resolved through discussion and consensus. When studies reported both unadjusted and propensity score–matched analyses, data from the matched cohorts were preferentially extracted to minimize confounding. Outcomes that were not explicitly reported in the original studies were recorded as Not Reported (NR).

Quality Assessment

The Joanna Briggs Institute (JBI) Critical Appraisal Checklist was applied to assess the potential bias in the cohort studies.[10] Each study was assessed for the clarity of eligibility criteria, the reliability of outcome measurement, the completeness of follow-up, and the management of confounders. The final risk of bias assessment was determined as low, moderate, or high.

Ethical Consideration

Institutional ethical approval or informed consent was not required for this review, as it used previously published data and did not involve any direct human participation.

Data Synthesis

A formal meta-analysis could not be performed due to significant heterogeneity across studies regarding their design, reporting methods, and outcome measures. Instead, findings were summarized narratively and presented using structured tables comparing baseline characteristics, procedural aspects, and 12-month clinical outcomes for R-PCI and M-PCI.

Results

Study Selection

A cumulative total of 4,722 records were found when searching all databases, consisting of 59 from PubMed, 80 from Scopus, 122 from the Cochrane Library, 3,463 from ScienceDirect, and 998 from Google Scholar. After an initial deduplication process that removed 209 entries, 4,513 distinct records proceeded to screening based on their titles and abstracts. Full-text assessment was subsequently performed, and no full-text articles were excluded at this stage. Four studies met all eligibility criteria and were included in the final analysis.[1-2,5-6] The PRISMA 2020 flow diagram visually represents the study selection process (Figure 1).

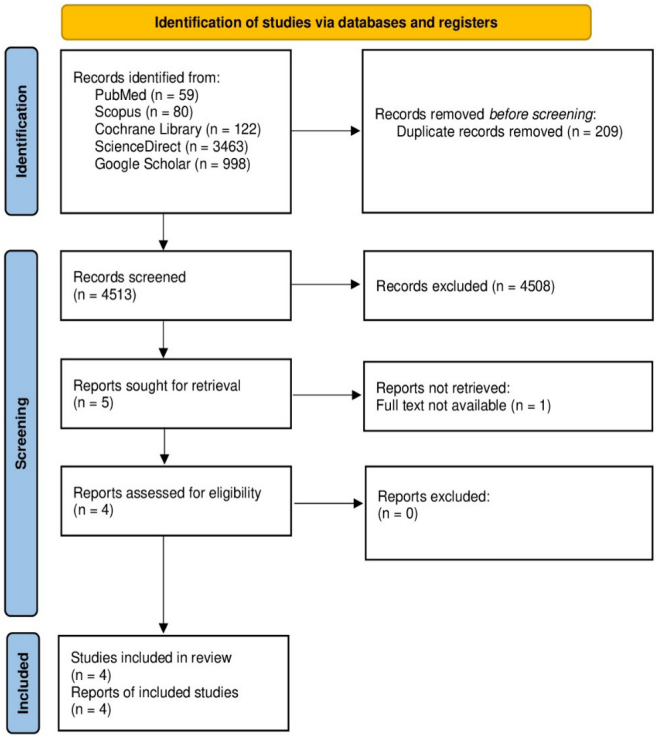

Figure 1. PRISMA flow diagram for study selection in twelve-month clinical outcomes of robotic PCI vs manual PCI: A systematic review.

Study Characteristics

The four included cohort studies were conducted in Germany, Japan, the United States, and a multicenter European setting between 2019 and 2024.[1-2,5-6] Together, these studies evaluated 915 patients, comprising 334 treated with R-PCI and 581 treated with M-PCI. Baseline demographic characteristics, including age, sex, diabetes, and hypertension, were comparable between groups (Table 1). Lesion complexity varied among the included studies. Walters et al.[1] enrolled patients undergoing complex PCI, largely classified as American College of Cardiology (ACC)/American Heart Association (AHA) B2–C lesions, including chronic total occlusions and selected bifurcation lesions. Bay et al.[2] predominantly included patients with complex coronary lesions, also largely classified as ACC/AHA B2–C. In contrast, Wataru et al.[5] analyzed a selected population with less complex coronary anatomy, excluding chronic total occlusions and other high-risk anatomical features. Von zur Mühlen et al.[6] included lesions of moderate complexity, assessed using contemporary lesion classification and scoring systems. All studies employed contemporary robotic platforms (CorPath 200 or CorPath GRX) and drug-eluting stents.

Table 1. Baseline characteristics of included studies.

Study (Year)	Country	Design	Sample size (R-PCI/ M-PCI)	Age, years (mean ± SD or median [IQR])	Male[1] (%)	Hypertension (%)	Diabetes (%)	Lesion complexity[2]	Robotic platform	Follow-up
Wataru et al. (2024)	Japan	Propensity-matched cohort	182 (91/91)	71.5±9.6/ 71.6±11.0	75/74	91/92	47/44	Less complex coronary artery	CorPath GRX	12 months
Walters et al. (2019)	USA	Observational cohort	313 (103/210)	68.1±11.0/ 67.5±12.1	78.3/78.1	95.4/95.1	56/54	Complex PCI	CorPath 200	12 months
von zur Mühlen et al. (2024)	Germany	Observational cohort	140 (70/70)	69.5 (63.0-80.0)/77.0 (68.0-82.0)	77.1/80	71.4/72.9	42.9/35.7	Moderate lesion complexity	CorPath GRX	12 months
Bay et al. (2024)	Multicenter Europe	Registry cohort	280 (70/210)	71.5 (60.2-79.8)/70.6 (62.6-77.8)	72.9/76.2	87.1/87.6	38.6/34.3	Predominantly complex lesions	CorPath GRX	12 months

Data are expressed as mean ± SD, median (IQR) or percentage (%). R-PCI: robotic-assisted PCI; M-PCI: manual PCI; MACE: major adverse cardiac events; TVR: target vessel revascularization. Values were extracted from original studies. (1) Male proportion was derived from reported female data when not explicitly provided in the original study. (2) Lesion complexity was categorized based on lesion characteristics and scoring systems reported in the original studies.

Twelve-Month Clinical Outcomes

At 12 months of follow-up, clinical outcomes were generally similar between R-PCI and M-PCI (Table 2). Walters et al.[1] reported MACE rates of 7.8% for R-PCI and 8.1% for M-PCI. Von zur Mühlen et al.[6] found no MACE events in the robotic group and 1.4% in the manual group. Bay et al.[2] observed slightly higher MACE rates in R-PCI (10.5%) compared with M-PCI (6.5%), while Wataru et al.[5] did not report composite MACE but noted low rates of individual endpoints. Mortality ranged from 0% to 9.6% for R-PCI and 1.4% to 4.8% for M-PCI. MI and stroke were infrequent across studies. TVR rates were low, ranging from 0% to 7.2% for R-PCI and 0% to 7.5% for M-PCI. Overall, no consistent differences in 12-month clinical outcomes were observed between R-PCI and M-PCI across the included studies.[1-2,5-6]

Procedural and Imaging Outcomes

Three of the four included studies reported procedural and imaging outcomes, while Walters et al.[1] did not provide data on fluoroscopy time or contrast use. Among the remaining studies, findings were heterogeneous. Von zur Mühlen et al.[6] and Bay et al.[2] reported longer fluoroscopy durations for R-PCI compared with M-PCI (18.2 min [14.5-26.0] vs 14.5 min [9.5-20.5], and 20.4 min [13.8-27.2] vs 14.4 min [10.4-24.3]). In contrast, Wataru et al.[5] observed shorter fluoroscopy time in robotic procedures (19.5 ± 15.7 vs. 25.9 ± 17.1 min). Contrast use demonstrated similar variability across studies, with statistically significant differences

Table 2. Twelve-month clinical outcomes per study.

Outcome	Wataru 2024 R-PCI	Wataru 2024 M-PCI	Walters 2019 R-PCI	Walters 2019 M-PCI	von zur Mühlen 2024 R-PCI	von zur Mühlen 2024 M-PCI	Bay 2024 R-PCI	Bay 2024 M-PCI
MACE	NR	NR	8/103 (7.8%)	17/210 (8.1%)	0/70 (0.0%)	1/70 (1.4%)	10.5%	6.5%
Mortality	0/91 (0.0%)	3/91 (3.3%)	2/103 (1.9%)	4/210 (1.9%)	2/70 (2.9%)	1/70 (1.4%)	9.6%	4.8%
Myocardial infarction	0/91 (0.0%)	0/91 (0.0%)	3/103 (2.9%)	6/210 (2.9%)	0/70 (0.0%)	0/70 (0.0%)	9.1%	3.5%
Stroke	NR	NR	2/103 (1.9%)	3/210 (1.4%)	NR	NR	2.9%	2.4%
TVR	0/91 (0.0%)	2/91 (2.2%)	1/103 (1.0%)	4/210 (1.9%)	0/70 (0.0%)	0/70 (0.0%)	3.0%	1.5%

Data are expressed as mean ± SD, median (IQR) or percentage (%). R-PCI: robotic-assisted PCI; M-PCI: manual PCI; MACE: major adverse cardiac events; TVR: target vessel revascularizationQR: Interquartile Range; SD: Standard Deviations.. Values were extracted from original studies. (1) Male proportion was derived from reported female data when not explicitly provided in the original study. (2) Lesion complexity was categorized based on lesion characteristics and scoring systems reported in the original studies.

Table 3. Procedural and fluoroscopy outcomes in R-PCI vs M-PCI.

Study	Sample Size (R-PCI/M-PCI)	Procedural Success (% R-PCI / % M-PCI)	Fluoroscopy Time (min, median [IQR] or mean ± SD)	p-Value (Fluoroscopy Time)	Contrast Volume (mL, median [IQR] or mean ± SD)	p-Value (Contrast Volume)
von zur Mühlen et al. (2024)	70 / 70	100 / 94.3	18.2 (14.5-26.0) / 14.5 (9.5-20.5)	0.002	180.0 (140-250) / 160.0 (130-200)	0.041
Bay et al. (2024)	70 / 210	100 / 94.2	20.4 (13.8-27.2) / 14.4 (10.4-24.3)	0.001	144.0 (104.8-188.8) / 145.5 (98.5-190.0)	0.93
Wataru et al. (2024)	91 / 91	100 / 100	19.5 ± 15.7 / 25.9 ± 17.1	< 0.001	70.6±22.6 / 88.4±43.7	<0.001

NR = not reported. p-value < 0.05 considered statistically significant. Data are median (IQR) or mean ± SD. Procedural success was defined as successful stent delivery with <20% residual stenosis and final TIMI 3 flow. R-PCI: robotic-assisted PCI; M-PCI: manual PCI; IQR: Interquartile Range; SD: Standard Deviations.

observed in von zur Mühlen et al. and Wataru et al., but not in Bay et al., being slightly higher in R-PCI in the study by von zur Mühlen, nearly identical in Bay et al., and lower in the robotic arm in the Japanese cohort by Wataru et al. Procedural success was high in all reports (≥94%), and no excess periprocedural complications were reported in robotic cases.

Quality Assessment

We applied the JBI Critical Appraisal Checklist for Cohort Studies to evaluate the methodological quality of all included studies.[10] All four studies[1-2,5-6] achieved a score of 9 out of 10, indicating generally good methodological quality according to the JBI criteria. Minor methodological limitations were mainly related to the observational and non-randomized study designs, particularly regarding control of confounding factors. Across studies, inclusion criteria were clearly defined, outcome measurements were reliable, and a minimum follow-up duration of 12 months was reported. Nevertheless, as all included studies were observational in nature, an inherent risk of selection bias and residual confounding cannot be excluded. Therefore, despite relatively high JBI scores, the overall risk of bias was considered moderate for all included studies (Table 4).

Discussion

Comparison of Twelve-Month Clinical Outcomes

This systematic review suggests that R-PCI is associated with generally comparable 12-month clinical outcomes to M-PCI across the included observational studies. Rates of mortality and major cardiovascular endpoints were broadly similar between the two approaches. However, definitive conclusions regarding equivalence or non-inferiority cannot be established, given the observational nature of the evidence and the limited sample sizes.[1-2,5-6]

Bay et al.[2] reported a numerically higher rate of MACE in the R-PCI group compared with M-PCI (10.5% vs. 6.5%). Although not statistically significant, this finding represents a potential clinical signal. Importantly, the authors attributed this difference primarily to non–target lesion-related and Type 2 MIs occurring during follow-up, suggesting that baseline patient characteristics and residual confounding, rather than procedural factors, may partly explain the observed numerical difference. In contrast, von zur Mühlen et al.[6] reported no MACE or TVR events in the R-PCI group, Walters et al.[1] observed comparable outcomes across all reported clinical endpoints, and Wataru et al.[5] documented

Table 4. Quality assessment of included studies using JBI Checklist for cohort studies.

Study	Checklist Used	Number of Items Fulfilled / Total (10)	Overall Risk of Bias	Quality Rating
Walters et al. (2019)	JBI Cohort Checklist	9 / 10	Moderate	High Quality
von zur Mühlen et al. (2024)	JBI Cohort Checklist	9 / 10	Moderate	High Quality
Bay et al. (2024)	JBI Cohort Checklist	9 / 10	Moderate	High Quality
Wataru et al. (2024)	JBI Cohort Checklist	9 / 10	Moderate	High Quality

Quality assessment based on JBI Checklist for Cohort Studies. All studies were rated as high quality with moderate risk of bias. JBI: Joanna Briggs Institute.

low rates of individual cardiovascular events without reporting a composite MACE outcome. Variability across studies may therefore reflect differences in patient selection, lesion complexity, operator experience, and study design.[1-2,5-6]

These findings are supported by previous systematic reviews and meta-analyses. Jaffar-Karballai et al.[7] and Tripathi et al.[8] demonstrated comparable clinical outcomes and technical success between R-PCI and M-PCI, with no significant differences in MACE. More recently, Łajczak et al.[11] confirmed similar clinical outcomes between both approaches across diverse patient populations. Collectively, the available evidence supports the use of R-PCI as a viable alternative to conventional M-PCI. However, given the predominance of observational data and limited follow-up duration, these findings should be interpreted with caution, and larger prospective studies with longer-term follow-up are needed to better define their clinical impact.[7-8,11]

Procedural Outcomes and Radiation Exposure

The included studies showed some variation in fluoroscopy duration between R-PCI and M-PCI. Von zur Mühlen et al.[6] and Bay et al.[2] reported that robotic procedures tended to take longer, whereas Wataru et al. observed the opposite pattern, with

shorter fluoroscopy time in the robotic group. These differences may relate to operator experience, lesion characteristics, and the types of robotic systems used.[2,4,6] Walters et al.[1] focused mainly on clinical outcomes and did not report procedural data. Even with these variations, procedural success remained high across studies, supporting the safety and feasibility of R-PCI.

Several factors could explain the inconsistent findings. Early experiences with the CorPath system often required more time for system setup and catheter manipulation. With improved operator familiarity and the introduction of newer systems such as the GRX platform, efficiency has increased and fluoroscopy exposure has been reduced.[2,4] Differences in workflow and institutional protocols may also play a role.

Role of Intravascular Imaging

Adjunctive intravascular imaging, particularly Intravascular Ultrasound (IVUS), has been shown to enhance procedural precision during R-PCI. In the study by Wataru et al.,[5] IVUS-guided R-PCI was associated with no reported cardiovascular events at 12-month follow-up. However, this finding should be interpreted in the context of the study's observational design and limited sample size. Evidence from randomized controlled trials in conventional PCI has consistently demonstrated that imaging-guided PCI is associated with reduced rates of MACE, repeat revascularization, and mortality compared with angiography-guided approaches.[12] When integrated with robotic systems, intravascular imaging may facilitate more accurate stent deployment and real-time procedural feedback while maintaining operator safety.[13] Collectively, these findings suggest that the combination of intravascular imaging and robotic technology represents a promising strategy for complex coronary interventions, although further prospective studies are required to confirm its clinical benefit.

Strengths and Limitations

This systematic review followed the PRISMA guidelines[9] and used the JBI checklist[10] to assess study quality, which represents a key methodological strength. However, several limitations should be acknowledged. All included studies were observational and non-randomized, which may introduce selection bias and residual confounding, even though propensity score-matched data were preferentially used when available.[2,5-6] Unmeasured confounders, therefore, cannot be fully excluded. In addition, one potentially relevant study could not be fully assessed due to the unavailability of the full text, which may introduce availability bias. Not all clinical outcomes were consistently reported across studies; some reported only individual endpoints without defining a composite MACE definition, limiting direct comparability. Finally, heterogeneity in outcome definitions and lesion complexity, along with relatively small sample sizes and 12-month follow-up, restrict conclusions regarding longer-term outcomes. Overall, these limitations highlight the need for large, well-designed randomized controlled trials with extended follow-up.

Clinical Implications and Future Directions

R-PCI may represent a feasible and safe alternative to M-PCI, particularly in complex coronary interventions and among operators exposed to high radiation risk. The technology combines procedural precision with occupational safety advantages, making it especially relevant for centers performing high-volume or complex PCI. Integration with intravascular imaging may further enhance accuracy and consistency. Focusing research on large-scale, multicenter RCTs is recommended to verify long-term effects, analyze cost-effectiveness, and clearly outline the ideal patient profile. The continued advancement of robotic and AI-assisted PCI platforms is expected to further refine precision, efficiency, and procedural safety in interventional cardiology.

Conclusion

This systematic review suggests that R-PCI is associated with 12-month clinical outcomes comparable to those of M-PCI, based on available observational evidence. Rates of MACE, TVR, MI, stroke, and mortality were similar between both approaches, although procedural and imaging outcomes varied across studies. Given the limited number of studies, their observational design, and the absence of randomized data, these findings should be interpreted with caution. Overall, robotic-assisted PCI appears to be a feasible and safe alternative to M-PCI in selected settings, and further large, well-designed randomized controlled trials with longer follow-up are needed to more clearly define its clinical effectiveness, cost-effectiveness, and optimal patient selection.

List of Abbreviations

ACC/AHA	American College of Cardiology/ American Heart Association
IQR	Interquartile Range
IVUS	Intravascular Ultrasound

JBI	Joanna Briggs Institute
MACE	Major Adverse Cardiovascular Events
M-PCI	Manual Percutaneous Coronary Intervention
MI	Myocardial Infarction
NR	Not Reported
PCI	Percutaneous Coronary Intervention
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
R-PCI	Robotic-assisted Percutaneous Coronary Intervention
SD	Standard Deviation
TVR	Target Vessel Revascularization

Ethical Clearance

Not applicable.

Publication Approval

All authors consent to the publication of this manuscript.

Authors' Contributions

PAS: Conceived the study, performed the literature search, screened titles, abstracts, and full-text articles, extracted and verified data, assessed study quality, synthesized the findings, drafted and revised the manuscript, and approved the final version; IT: Screened titles and abstracts, critically reviewed the manuscript, and approved the final version. EAP: Screened titles and abstracts, critically reviewed the manuscript, and approved the final version. All authors read and approved the final manuscript.

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Conflict of Interest

None.

Availability of Data and Materials

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Not applicable.

Generative AI and AI-Assisted Technologies in the Writing Process

Authors acknowledge that artificial intelligence (AI) tools were only used to assist in language editing and did not generate or alter the scientific content, analyses, or conclusions presented in this manuscript.

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