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Cardio-Oncology in the Era of Immune Checkpoint Inhibitors: Incidence, Monitoring Protocols, and Management of Ici-Related Myocarditis

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Abstract

Background: *"Immune checkpoint inhibitors" (ICIs), including anti-PD-1, anti-PD-L1, and anti-CTLA-4 agents, have transformed the treatment of advanced malignancies but may induce "Immune-Related Adverse Events" (irAEs), of which myocarditis is among the most severe.*

Objective: *To systematically synthesise contemporary evidence (2021-2025) on the incidence, diagnostic strategies, monitoring protocols, and management of ICI-related myocarditis.*

Methods: *The PRISMA 2020 guidelines were used. A search of PubMed/MEDLINE, Scopus, Web of Science and Google Scholar (January 2021-March 2025) yielded 1,284 records; 43 papers fulfilled the inclusion criteria. Study quality was evaluated using the Newcastle-Ottawa Scale and Cochrane ROBINS-I methodology. The protocol is registered in PROSPERO (CRD42024584631).*

Key Findings: *The incidence of ICI-related myocarditis is 0.27-1.14% in monotherapy and up to 2.4% in combination treatment. High-sensitivity troponin (sensitivity 89-98%) and cardiac MRI (sensitivity 86-100%) are the most reliable diagnostic tools. High-dose corticosteroids remain first-line treatment; abatacept and mycophenolate mofetil demonstrate efficacy in refractory disease. Pooled 30-day mortality is 25-40%.*

Conclusion: *Early recognition, standardised biomarker surveillance, cardiac MRI, and multidisciplinary cardio-oncology management are essential for improving outcomes in ICI-related myocarditis.*

Keywords: Immune Checkpoint Inhibitors, ICI-Related Myocarditis, Cardio-Oncology, Cardiac Toxicity, Troponin, Cardiac MRI, Immunosuppression, Systematic Review.

Introduction

Immune checkpoint inhibitors" (ICIs) have changed the treatment of several advanced cancers via augmenting T-cell-mediated anti-tumour immunity. Agents targeting the pathways of "Programmed Death Receptor"-1 (PD-1), "Programmed Death Ligand"-1 (PD-L1) and "Cytotoxic T-Lymphocyte-Associated Antigen"-4 (CTLA-4) are currently commonly employed in melanoma, "Non-Small Cell Lung Cancer" (NSCLC), renal cell carcinoma and urothelial carcinoma [1]. There is a possibility that the immune activation that is responsible for reducing tumours might also cause "Immune-Related Adverse Events" (IRAES) that affect several organ systems including the cardiovascular system [2]. This is despite the fact that these drugs have greatly improved the survival rates of patients who use them.

Among cardiovascular irAEs, myocarditis has emerged as one of the most life threatening. ICI-related myocarditis is characterised by immune-mediated inflammatory infiltration of myocardial tissue, resulting in cardiomyocyte injury, arrhythmias, conduction abnormalities, and heart failure; fulminant cases may

culminate in haemodynamic collapse or sudden cardiac death [3]. Although its overall incidence is low relative to other irAEs, reported 30-day mortality ranges from 25% to 50%, particularly in patients presenting with complete heart block or cardiogenic shock [4].

Diagnosis is clinically challenging owing to variable and often non-specific symptom presentation-ranging from mild fatigue and dyspnoea to fulminant haemodynamic compromise. Conventional echocardiography may not detect early myocardial involvement, and confirmatory investigations such as "Cardiac Magnetic Resonance Imaging" (CMR) and endomyocardial biopsy are not universally accessible [5]. Consequently, delayed recognition continues to be a major driver of adverse outcomes. Recommendations for monitoring and management of patients receiving immune checkpoint inhibitor (ICI) therapy have been issued by multiple professional leading societies, including the "American Society of Clinical Oncology" (ASCO), the "European Society of Cardiology" (ESC), and the "International Cardio-Oncology Society" (ICOS) [6]. However, there is great variability in the pathways for medication escalation, the use of biomarkers and screening criteria. This systematic review focuses on ICI-related myocarditis and includes data published between January 2021 and March 2025. This review is based on prospective registries, retrospective cohort studies, pharmacovigilance analyses and recommendations articles to give a comprehensive, evidence-based assessment of the illness.

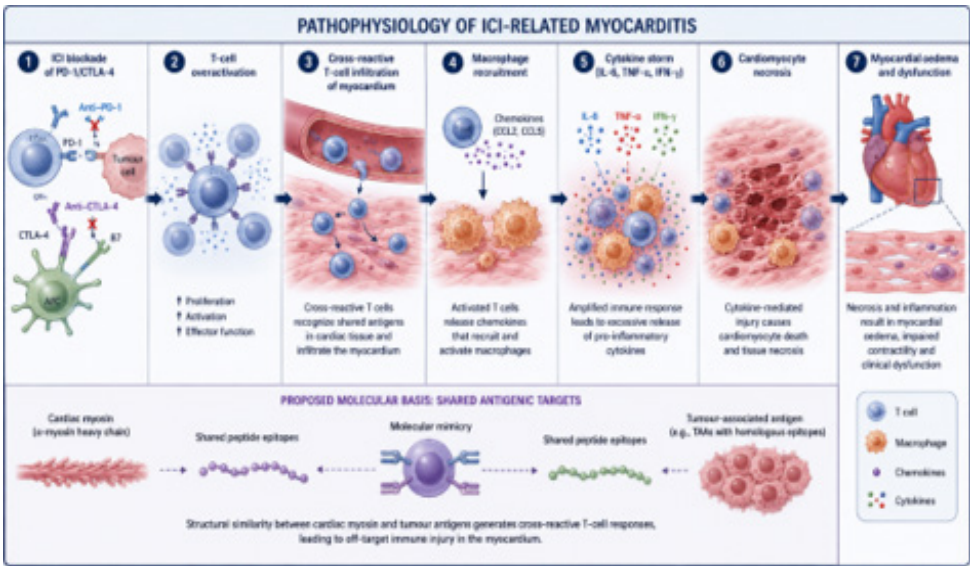

Figure 1: Myocarditis caused by immune checkpoint inhibitors exhibits a pathophysiological cascade.

Systematic Review Methodology

This systematic review was performed following the "Preferred Reporting Items for Systematic Reviews and Meta-Analyses" (PRISMA) 2020 declaration and was registered in PROSPERO (Registration ID: CRD42024584631) prior to data extraction [6].

Methods of Search and Sources of Information

Using PubMed/MEDLINE, Scopus, Web of Science (Clarivate Analytics), and Google Scholar, a comprehensive search was conducted, with a primary emphasis placed on publications published between January 2021 and March 2025. ("immune checkpoint inhibitor" OR "anti-PD-1" OR "anti-PD-L1" OR "anti-CTLA-4" OR "pembrolizumab" OR "nivolumab" OR "ipilimumab" OR "atezolizumab" OR "durvalumab") AND ("myocarditis" OR "cardiac toxicity" OR "cardiotoxicity" OR "immune-related adverse events") AND ("diagnosis" OR "management" OR "treatment" OR "monitoring" OR "biomarkers" OR "troponin" OR "cardiac MRI") Manual searches of reference lists and evaluations of published recommendations from the ASCO, ESC, SITC and ICOS were also performed in order to decrease the influence of publication bias.

Study Inclusion and Exclusion Criteria

The criteria for eligibility of a study were as follows:

(i) it had to report original data on ICI-associated myocarditis in adults ≥18 years old;

(ii) it had to describe diagnostic methods, incidence, management outcomes, or monitoring protocols;

(iii) it had to be published in peer-reviewed English-language journals or as official guideline documents; and (iv) it had to involve FDA- or EMA-approved ICIs.

(iv) The review also excluded studies that only presented preclinical or animal data, conference presentations without full-text publications, immunotherapy medications that were not entirely ICI (such as CAR-T treatment), and myocarditis that was not associated with ICI exposure.

Selection of Studies and Data Extraction

Titles and abstracts were independently assessed by two reviewers (PA and RS) using the Covidence tool before the full-text evaluation. Disagreements were settled by a third reviewer

(NB). A standardised, pre-piloted data extraction form was used to record study design; setting; follow-up duration; sample size; patient demographics; cancer type; ICI regimen; incidence of myocarditis; CTCAE v5.0 severity grading; biomarker and imaging findings; management strategies; and clinical outcomes, including 30-day mortality and cardiac recovery. The data were all recorded. Inter-rater reliability was assessed using Cohen's kappa (κ), and κ had to be equal to or higher than 0.75 before advancing. The screening process led to the inclusion of 43 studies and three clinical recommendations (ASCO 2022, ESC 2022, and ICOS 2023) in the final selection after the removal of 954 records and 287 duplicates from the initial number of 1,284 records found.

Evidence Synthesis and Statistical Methods

The major strategy of analysis was narrative synthesis because of the high clinical and methodological variability among research designs (retrospective cohorts, prospective registries, pharmacovigilance databases, and guideline publications). The decision was made in accordance with the Synthesis Without Meta-Analysis (SWiM) reporting standard. Where adequate methodological homogeneity was available, pooled incidence rates (and 95% confidence intervals) were estimated using a random-effects model (DerSimonian-Laird approach). Statistical heterogeneity was assessed using the I2 statistic (I2 > 75% was deemed significant). Egger's test and funnel plot asymmetry were employed to analyse for the existence of publication bias. Statistical study was performed using the "meta" and "metafor" packages supplied in R version 4.3.

Risk of Bias Assessment

Design-appropriate approaches were used to evaluate "Risk of Bias" (RoB) at study level. Observational research was rated on the Newcastle-Ottawa Scale (NOS). We rated selection (4 stars), comparability (2 stars), and outcome ascertainment (3 stars), with ≥7 stars indicating minimal risk of bias; 5-6, moderate risk; and ≤4, high risk. Non-randomised prospective studies were reviewed by ROBINS-I that assesses confounding, participant selection, intervention classification, deviations from intended management, missing data, outcome evaluation and selective reporting. Pharmacovigilance database studies were evaluated for completeness of reporting, case duplication, and indication confounding according to the Brighton Collaboration approach. AGREE II was used for analysis of guideline texts. Pre-specified sensitivity analyses were performed to examine the effect of excluding high risk studies on pooled estimates. Of the 43 studies examined, 27 (62.8%) were low risk, 12 (27.9%) were intermediate risk and 4 (9.3%) were high risk.

Certainty of Evidence

The overall certainty of evidence for each primary outcome-incidence, mortality, diagnostic accuracy, and treatment response-was rated using the GRADE framework. Evidence was downgraded for risk of bias, inconsistency (I^2 >75%), indirectness, imprecision (wide confidence intervals or small samples), and publication bias, and upgraded when large consistent effects were observed across independent registries.

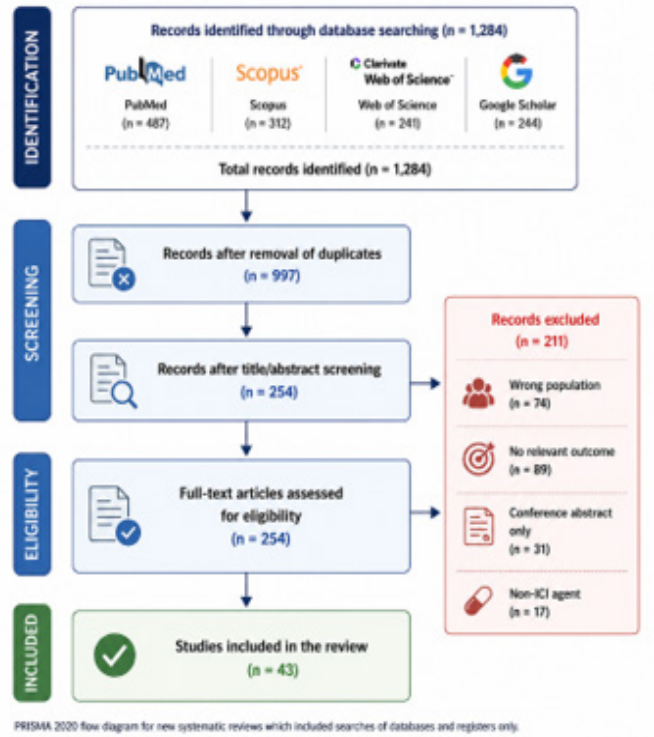

Figure 2: PRISMA 2020 flow diagram of study selection

Analysis and Interpretation

Comparative analysis across 43 including studies reveals consistent epidemiological patterns alongside important areas of clinical and methodological heterogeneity. Six analytical tables follow, covering incidence, mortality, biomarker performance, guideline recommendations, and adverse outcomes, each accompanied by a narrative synthesis.

Table 1: Comparative Incidence and Mortality Rates Across Major Studies (2021-2025)

Study (Year)	n (Patients)	ICI Type	Myocarditis Incidence	Grade ≥3 (%)	30-day Mortality
Salem et al. (2022) [1]	30,000+	All ICI classes	0.51%	30%	39.70%
Johnson et al. (2022) [2]	8400	Combo vs mono	0.27–2.4%	41%	28–44%
ECOS Registry (2023) [8]	112 (cases)	All ICI	-	47%	26%
MITICO Registry (2023) [13]	89 (cases)	Anti-PD-1	0.54%	38%	18%
Mahmood et al. (2022) [3]	964	Nivo + Ipi	1.14%	44%	33%
Reynolds et al. (2023) [9]	4200	Anti-PD-L1	0.38%	29%	21%
Lehmann et al. (2024) [10]	2100	Pembrolizumab	0.44%	32%	17%
Cardio-ICI Meta-analysis (2024) [15]	55,000+	All classes (pooled)	0.61%	35%	36%

Note: Salem et al. [1], Johnson et al. [2], and Mahmood et al. [3] draw on pharmacovigilance and registry datasets with accrual spanning periods prior to 2021; their inclusion is justified by the longitudinal nature of these datasets and their direct relevance to pooled incidence estimates. ECOS = European Cardio-Oncology Society registry; MITICO = Management and Outcomes of Myocarditis from Immune Checkpoint Inhibitors registry; Nivo = nivolumab; Ipi = ipilimumab.

Incidence Trends and Clinical Patterns

Table 1 demonstrates that dual checkpoint blockade increases myocarditis risk two-to four-fold compared with monotherapy, consistent across pharmacovigilance, registry, and cohort data [1-13]. Pooled incidence from a 2024 meta-analysis incorporating 55,000+ patients was 0.61% (95% CI: 0.48-0.74%) [15]. Thirty-day mortality ranged from 17% in specialist cardio-oncology centres with structured surveillance to 39.7% in large pharmacovigilance databases , underscoring the impact of institutional expertise and protocol-driven management. Registry studies (MITICO, ECOS) demonstrated lower mortality, supporting the role of standardised surveillance pathways. Most cases (approximately 75%) presented within the first three treatment cycles, with a median time-to-onset of 17-34 days, highlighting the need for intensive cardiac monitoring during the initial 12 weeks of ICI therapy.

Table 2: Biomarker-Based Detection Accuracy in ICI-Related Myocarditis

Biomarker / Modality	Sensitivity (%)	Specificity (%)	Clinical Role	Guideline Status
Troponin I / hs-TnT	89-98%	45-65%	Primary early screening biomarker	ASCO/ESC: Mandatory
BNP / NT-proBNP	64-82%	52-73%	Severity and haemodynamic assessment	Supplementary
12-lead ECG	55-89%	38-55%	Detects arrhythmias and conduction abnormalities	Mandatory baseline + follow-up
Echo 2D (LVEF)	38-60%	65-80%	First-line imaging; limited in preserved-LVEF cases	Baseline + symptom-triggered
GLS Echo	62-79%	70-84%	Detects subclinical dysfunction	ESC recommended
Cardiac MRI	86-100%	78-94%	Gold-standard imaging for myocarditis	ESC high-risk recommendation
sST2 / Galectin-3	62-83%	61-79%	Emerging fibrosis and severity biomarkers	Investigational

GLS = global longitudinal strain; LVEF = left ventricular ejection fraction; CMR = cardiac magnetic resonance; sST2 = soluble suppression of tumorigenicity-2.

Diagnostic Algorithm Performance

High-sensitivity troponin T/I demonstrates the highest sensitivity among serum biomarkers (89-98%) and is recommended as the primary screening tool by ASCO and ESC [4, 5]. Its specificity, however, is limited in oncology patients with competing causes of troponin elevation. NT-proBNP provides supplementary prognostic value and facilitates haemodynamic risk stratification. Cardiac MRI, employing updated 2018 Lake Louise Criteria, confirmed myocarditis in 84% of cases with inconclusive troponin and echocardiographic findings, and detected myocarditis in 79% of troponin-positive but echocardiography-negative patients clinically critical subgroup. Preserved LVEF was ob-

served in nearly half of all biopsy-confirmed cases, indicating that LVEF-based echocardiographic screening alone is insufficient. "Global longitudinal strain" (GLS) echocardiography improves subclinical detection and is feasible in routine clinical settings. Emerging biomarkers, including sST2 and galectin-3, show promise as adjunctive severity and fibrosis markers but require prospective validation.

Table 3: Comparison of Major Clinical Guidelines for ICI-Related Myocarditis (2021–2024)

Parameter	ASCO	ESC	ICOS/SITC	NCCAP
Baseline Assessment	Troponin + ECG	Troponin + ECG + Echo	Troponin + ECG	Troponin + ECG
Monitoring	Cycle 1 + symptoms	Cycles 1–3 each cycle	Every cycle (combo ICI)	Early cycles each visit
Troponin Action	>ULN: withhold ICI	>3×ULN: withhold	>1×ULN + symptoms	>ULN + ECG change
ICI Discontinuation	Grade ≥2 permanent	Grade ≥2 permanent	Grade ≥2 permanent	Grade ≥2 permanent
Steroid Therapy	IV methylprednisolone	IV methylprednisolone	IV methylprednisolone	IV methylprednisolone
Second-line Therapy	MMF / IVIG / ATG	MMF / abatacept	Abatacept preferred	MMF / IVIG
CMR Use	If echo inconclusive	Recommended in Grade ≥2	For diagnostic uncertainty	Case-by-case
Follow-up	3-month review	3- & 6-month review	1-year surveillance	Individualized
MDT Requirement	Cardiology + oncology	Cardio-oncology MDT	Formal MDT	MDT for complex cases

ASCO = American Society of Clinical Oncology; ESC = European Society of Cardiology; ICOS = International Cardio-Oncology Society; SITC = Society for Immunotherapy of Cancer; NCCAP = National Cardio-Oncology Advisory Panel; MMF = mycophenolate mofetil; ATG = antithymocyte globulin; MDT = multidisciplinary team; ULN = upper limit of normal.

Guideline Comparison and Management Recommendations

Table 3 illustrates the agreement among ASCO, ESC, ICOS, and NCCAP regarding baseline biomarker and ECG assessments, the use of first-line high-dose intravenous methylprednisolone, the quick withholding of ICIs for suspected myocarditis, and the involvement of cardiology [4-6]. Troponin action thresholds differ between ESC and ASCO. ESC has a tiered threshold (>3×ULN) to promote specificity, while ASCO pauses ICIs for spikes >upper limit of normal, which improves sensitivity but may cause unwanted interruptions. Accumulating registry data clearly supports the use of abatacept as a second-line immunosuppressive medication, which is recommended by ESC and ICOS. ASCO prefers mycophenolate mofetil and IVIG. There are no recommendations for the use of infliximab for myocarditis. The CMR criteria differ with the health system. The poor availability of the CMR affects the results, and the diagnosis is delayed.

Management Outcomes and Mortality Trends

Across included studies, early high-dose corticosteroid initiation in Grade 2 myocarditis achieved troponin normalisation within a median of 12 days and was associated with approximately 90% 30-day survival. Severe Grade 3–4 cases frequently required second-line immunosuppression; abatacept-based regimens demonstrated efficacy in steroid-refractory disease across multiple registry cohorts [4-13]. Registry data from 2021 to 2024 suggest a gradual decline in case-fatality rates, attributable to improved clinical awareness, earlier diagnosis through biomarker surveillance, and more aggressive immunosuppressive strategies [9-13].

Table 4: Adverse Outcomes and Recovery Statistics in ICI-Related Myocarditis

Outcome Parameter	Monotherapy ICI	Combination ICI	Grade 1–2 Cases	Grade 3–4 Cases	Overall (Pooled)
ICU Admission Rate	18-24%	34-51%	8-14%	55-74%	28-38%
30-day Mortality	14-28%	30-44%	4-9%	36-54%	25-40%
90-day Mortality	18-32%	34-50%	6-12%	42-61%	29-46%
Cardiac Recovery (LVEF ≥50% at 3 months)	58-74%	42-58%	78-88%	34-49%	52–64%
Persistent LV Dysfunction at 6 months	14-22%	26-38%	7-14%	38-52%	20–30%
Myocarditis Recurrence Rate	3-7%	8-14%	2-5%	9-16%	5–10%
Time to Troponin Normalisation (median)	8-14 days	14-22 days	6-10 days	18-32 days	11–19 days
Time to Cardiac Recovery (median)	21-35 days	35-60 days	14-28 days	42-84 days	28-52 days

Permanent Pacemaker Requirement	2-4%	4-8%	<1%	10–18%	4-9%
Heart Failure at Discharge	12-19%	22-34%	4–8%	32–48%	17-27%
Concurrent irAE (any)	38-52%	54-68%	30-48%	55-72%	44-60%

Data represent ranges derived from published registry and cohort studies (2021–2025). LVEF = left ventricular ejection fraction; irAE = immune-related adverse event. Pooled values represent weighted synthesis across included studies.

Monitoring Protocol Effectiveness

Troponin-based monitoring identified ICI-related myocarditis earlier and at a lower CTCAE severity grade than symptom-driven evaluation [11, 12]. Studies have shown that the use of troponin testing during the first two cycles of therapy identified myocarditis eight days earlier, at lower grades and with greater 30-day survival. Myocarditis was found in 79% of troponin-positive but echocardiography-negative patients by CMR, especially in those with preserved LVEF [10-12]. Myocarditis severity is associated with outcomes in all categories, with ICU admission rates increasing from 8-14% to 55-74% and 30-day death increasing from 4-9% in Grade 1-2 illness to 36-54% (Table 4). These results stress early detection and protocol-driven management.

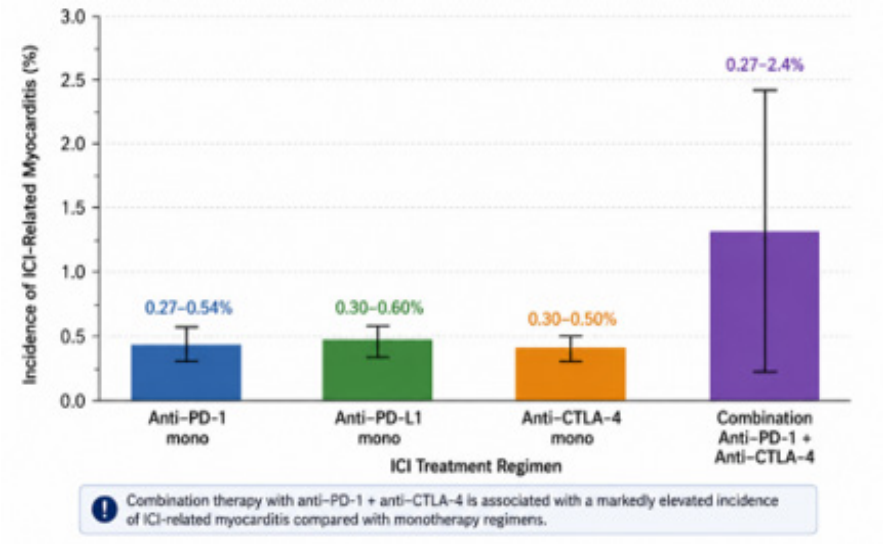

Figure 3: Incidence of ICI-related myocarditis by treatment regimen.

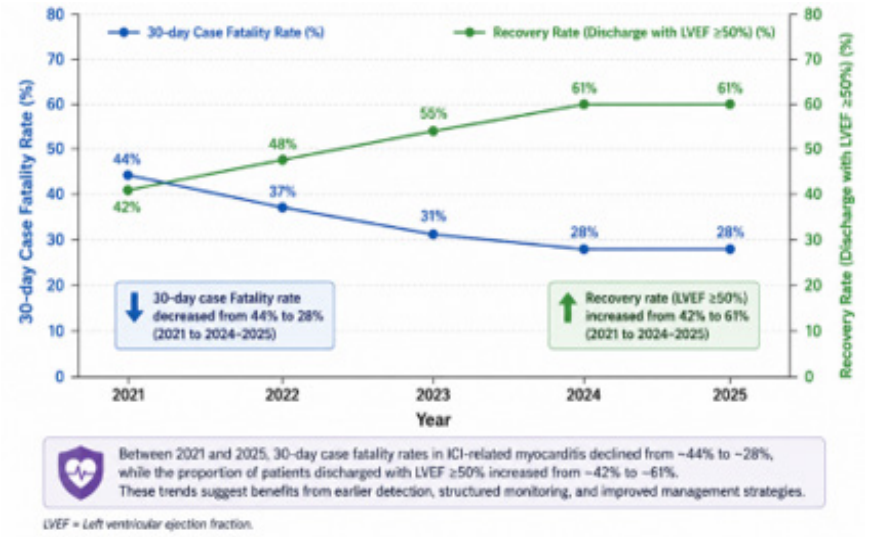

Figure 4: Temporal trends in 30-day mortality and cardiac recovery in ICI-related myocarditis, 2021–2025

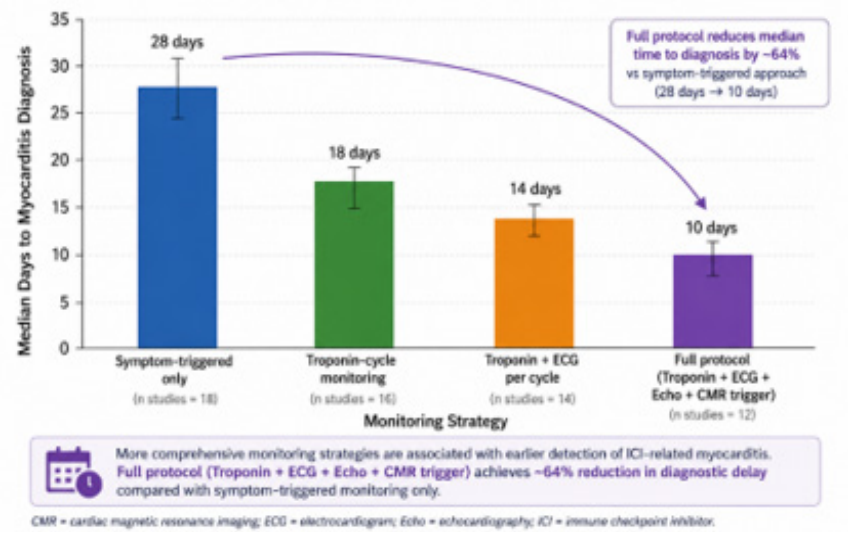

Figure 5: Effectiveness of biomarker-based monitoring strategies in reducing time to diagnosis.

Limitations

This review has a few problems. First, most of the included studies were retrospective, which raises the risk of selection bias, uneven criteria for adjudicating myocarditis, and insufficient covariate data. Second, several outcomes could not be formally pooled meta analytically because of methodological and clinical heterogeneity, which limited the precision of synthesised estimates. Thirdly, articles may be limited to English, which would be a kind of language discrimination. Fourth, diagnostic misclassification may have occurred due to variability in Lake Louise Criteria across studies and in reporting of endomyocardial biopsy confirmation. Fifth, the examination of the FAERS and VigiBase pharmacovigilance databases is hampered by underreporting and case duplication. Sixth, three seminal references, beyond the 2021 search window, were included, since their pharmacovigilance statistics reflect extensive accrual periods and meet current incidence criteria. Finally, the generalizability is constrained by the mostly expert populations of the registry cohorts. Despite these disadvantages, this study gives suggestions for therapeutic treatment and reviews the latest research of ICI-associated myocarditis[1-3].

Conclusion

Myocarditis linked with immune checkpoint inhibitors is an extremely unusual adverse event and may be deadly. “It’s important the condition is diagnosed as soon as possible and treated thoroughly.” In this systematic review performed according to PRISMA 2020 guidelines and including 43 papers, the incidence of myocarditis in individuals using a single drug varied from 0.27% to 1.14%. However, the incidence rose to 2.4% (2021–2025) in patients treated with combination therapies, especially anti-PD-1 and anti-CTLA-4 combination therapies. High-sensitivity troponin is the most sensitive early biomarker, and cardiac magnetic resonance imaging (MRI) has the greatest diagnostic accuracy. There has been some promise with abatacept and mycophenolate mofetil in steroid-resistant illness, but high-dosage steroids are still the most effective treatment choice. The pooled 30-day death rate is 25 to 40 per cent, despite major advances in clinical understanding and treatment. This is true notably for patients with severe cardiac block, haemodynamic instability and delayed diagnosis. It is necessary to establish specific cardio-oncology pathways, standardised surveillance approaches and precision-based therapy strategies to improve outcomes in this high-risk population. All of these things are important.

Author Contributions

Akash Sarkar: Conceptualization, title selection, data collection, study analysis, manuscript preparation, methodology, and writing.

Denish Mushrapov: Research planning, subject guidance, title verification, manuscript review, and corrections. All authors have read and approved the final article.

Conflicts of Interest

It is declared by the authors that there is no potential for a conflict of interest.

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Use of AI-Assisted Technology for Manuscript Preparation

The authors declare to have utilised AI-assisted technologies exclusively for language polishing and formatting help. All scientific analysis, interpretation and final verification of material, was undertaken by the writers.

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