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Efficacy and safety of colchicine in patients with myocardial infarction: a systematic review and meta-analysis

Muhammad Furqan Saleem,[1] Tuba Ashraf,[2] Ahmed Mekki,[3] Usama Siddique,[4] Muhammad Usama Javed,[4] Chaudhry Bilal Rauf,[5] Chaudhary Hammad Jamil,[6] Azaz Ali Shah,[7] Muhammad Usman Haider,[8] Salman Ahsan,[9] Mohammad Ebad Ur Rehman,[10] Huzaifa Ahmad Cheema,[11] Bilawal Nadeem,[12] Raheel Ahmed[13]

[1]Department of Cardiology, Loma Linda University Medical Center, CA, USA; [2]Department of Medicine, Nishtar Medical University, Multan, Pakistan; [3]Department of Medicine, Alshifa Hospital, Gaza, Palestine; [4]Department of Medicine, Faisalabad Medical University, Pakistan; [5]Department of Critical Care, Poonch Medical College, Rawalakot, Pakistan; [6]Department of Cardiac Surgery, Punjab Institute of Cardiology, Lahore, Pakistan; [7]Department of Medicine, Saidu Teaching Hospital, Swat, Pakistan; [8]Department of Medicine, Geisinger Health System, Wilkes-Barre, PA, USA; [9]Department of Internal Medicine, University of Illinois College of Medicine-Peoria, IL, USA; [10]Department of Medicine, Rawalpindi Medical University, Pakistan; [11]Department of Medicine, King Edward Medical University, Lahore, Pakistan; [12]Department of Internal Medicine, Boston Medical Center, Boston, MA, USA; [13]National Heart & Lung Institute, Imperial College London, UK

Correspondence: Mohammad Ebad Ur Rehman, Department of Medicine, Rawalpindi Medical University, Rawalpindi, Pakistan, 46000.
Tel.: +923365367865. E-mail: ebadrehman.rehman@gmail.com

Contributions: Muhammad Furqan Saleem: conception of the study, methodology design, and initial drafting of the manuscript. Tuba Ashraf: literature search, screening of articles, and data extraction. Ahmed Mekki: data collection, quality assessment of studies, and manuscript editing. Usama Siddique: literature search, data analysis, and drafting of results. Muhammad Usama Javed: methodology design, data interpretation, and critical revision of the manuscript. Chaudhry Bilal Rauf: data extraction, reference management, and manuscript formatting.

Chaudhary Hammad Jamil: statistical analysis, preparation of tables and figures, and results interpretation. Azaz Ali Shah: screening of articles, data charting, and drafting of results. Muhammad Usman Haider: data verification, critical review of methodology, and manuscript editing. Salman Ahsan: manuscript writing, proofreading, and editing. Mohammad Ebad Ur Rehman: conceptual guidance, data synthesis, and critical review of discussion. Huzaifa Ahmad Cheema: data interpretation, drafting of discussion, and final editing. Bilawal Nadeem, Raheel Ahmed: supervision, critical revision for intellectual content, and approval of the final manuscript. All the authors have read and approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

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Abstract

Colchicine is an anti-inflammatory drug that has emerged as a potential treatment option following myocardial infarction (MI). This meta-analysis assesses the efficacy and safety of colchicine in patients following an MI. A comprehensive literature search was performed using the Cochrane Library, ClinicalTrials.gov, Embase, and MEDLINE, covering studies from their inception to December 2025. RevMan was used to perform a random-effects meta-analysis, and forest plots were used to visualize pooled estimates. The Mantel-Haenszel method was applied to analyze dichotomous outcomes. Nine randomized control trials (RCTs) were included in this meta-analysis, including 13,834 patients. The analysis revealed that there was no statistically significant difference between colchicine and placebo groups in all-cause mortality [relative risk (RR)=0.93, confidence interval (CI)=0.78-1.11], cardiac death (RR=0.95, CI=0.73-1.22), MI (RR=0.82, CI=0.67-1.00), stroke (RR=0.64, CI=0.26-1.58), adverse events (RR=1.01, CI=0.85-1.21), serious adverse events (RR=0.96, CI=0.87-1.05), serious gastrointestinal adverse events (RR=1.35, CI=0.94-1.95), and serious infections (RR=1.00, CI=0.62-1.62). However, there was an increased risk of diarrhea in people with colchicine compared to the placebo (RR=2.12, CI=1.35-3.32). This meta-analysis demonstrates that colchicine following an MI does not have a significant impact on cardiovascular events or major adverse events other than an increased risk of diarrhea. There is a need for more comprehensive RCTs with longer follow-up times to fully comprehend the potential cardiovascular benefits of colchicine.

Key words: myocardial infarction, colchicine, coronary artery disease, acute coronary syndrome.

Introduction

Coronary artery disease is the leading cause of mortality and morbidity worldwide, with the National Health Interview Survey 2015 data reporting more than 100,000 mortalities being attributed to myocardial infarction (MI) [1]. Inflammation is a crucial contributor to the pathophysiology of MI, with evidence suggesting patients with MI show elevated inflammatory markers more commonly than elevated low density lipoprotein cholesterol (LDL-C). Furthermore, in MI patients on high intensity statin, elevated C-reactive protein is more accurate in predicting a subsequent MI compared to LDL-C [2,3].

Colchicine was initially used as an anti-inflammatory drug in the management of gout, with its usage expanding to include other inflammatory conditions such as familial Mediterranean fever and pericarditis. Colchicine has anti-inflammatory effects because it reduces tubulin and leucocyte activities, along with the secretion of cytokines that contain inflammation [4]. Colchicine can lead to amelioration of systemic inflammation, for example, through reducing concentrations of high-sensitivity C-reactive protein, which is a major marker of systemic inflammation [5]. The American College of Cardiology/American Heart Association guidelines only recommend prophylactic use of colchicine for the treatment of pericarditis after myocardial infarction [6]. However, recent evidence highlights the potential role of colchicine in preventing recurrent MI and improving mortality in this population. In the Low-Dose Colchicine (LoDoCo) trial, colchicine was found to significantly reduce risk of cardiovascular events in patients with stable coronary artery disease [7].

Previous meta-analyses have demonstrated significant improvement in clinical outcomes with colchicine in patients with MI. A meta-analysis by Younas et al., which included 7161 patients, reported that colchicine significantly reduces the risk of adverse cardiovascular events and hospitalization urgency, but increases gastrointestinal adverse events and does not affect mortality [8]. However, new data on more than seven thousand patients was recently published in the CLEAR trial [9]. Therefore, we undertook a systematic review and meta-analysis to assess the efficacy and safety of colchicine in patients with MI.

Materials and Methods

Our meta-analysis was performed according to the guidelines presented in the Cochrane Handbook for Systematic Reviews of Interventions and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA). Our protocol is registered with PROSPERO (CRD420261327522).

Data sources and searches

The Cochrane Central Register of Controlled Trials, MEDLINE, Embase, and ClinicalTrials.gov were used to perform a thorough electronic search from their inception to December 2025. Reference list of included studies and similar systematic reviews were also screened to identify further pertinent studies. Medical Subject Heading (MeSH) terms and keywords for 'Colchicine' and 'Myocardial Infarction' were used.

Eligibility criteria

Randomized controlled trials (RCTs) assessing the efficacy and safety of colchicine in patients with MI were included. Parameters for exclusion comprised of any study designs other than RCTs, such as quasi-randomized trials, observational studies or studies conducted on animals. No language or data restrictions were applied.

Study selection and data extraction

Articles retrieved by the literature search were imported onto Rayyan and duplicates were removed. Titles and abstracts of all references were screened. Full-texts of pertinent articles were compared against the eligibility criteria by two authors independently (T.A. and U.S.). Any discrepancies over the selection of studies were settled by a third author (M.E.U.R.).

Relevant data was extracted onto a pre-piloted Excel Spreadsheet which included author name, publication year, country name, sample size, study design, mean age, gender, hypertension, diabetes, heart failure, prior MI, prior percutaneous coronary interventions (PCI), prior stroke, colchicine regimen used (dose, duration, and frequency) and outcomes.

Outcomes

The primary outcomes were all-cause mortality and cardiac death while secondary outcomes are MI, stroke, adverse events, serious adverse events, serious gastrointestinal adverse events, diarrhea and serious infections.

Risk of bias assessment

The risk of bias in the included studies was evaluated using the revised Cochrane risk of bias tool for randomized trials. RoB 2.0 assesses bias in five domains: (1) bias resulting from the randomization process; (2) bias due to deviations from intended interventions; (3) bias due to missing outcome data; (4) bias in the measurement of the outcome; and (5) bias in the selection of the reported result. Two investigators evaluated the risk of bias for each included study as either high, low or some concerns of bias (C.B.R. and M.U.J). Any discrepancies regarding the risk of bias assessment were settled by a senior investigator (M.E.U.R.).

Data synthesis

Review Manager (RevMan, Version 5.4) software was used to conduct all meta-analyses. The Mantel-Haenszel method was used for dichotomous outcomes. Risk ratios (RRs) and corresponding 95% confidence interval (CI) were extracted. A random effects model was used. Forest plots were constructed to visually represent the pooled analyses, and to assess the statistical heterogeneity, the Higgins I^2 statistic were evaluated. Leave-one-out sensitivity analyses were undertaken. Egger's test was performed to assess publication bias.

Results

Search strategy

The initial database search retrieved 1273 results. After removal of 83 duplicates, 1190 articles were included in screening. Finally, 9 RCTs were included in our meta-analysis [9-17]. The study selection process is summarized in Figure 1.

Study characteristics

Nine RCTs are included in our meta-analysis. Two studies were conducted in France [10,15], one in Iran [11], one in Australia [14], one in fourteen different countries [9], and one in twelve countries [17]. Overall, these RCTs included 13,834 patients with acute MI, with 6901 patients receiving colchicine and 6935 receiving placebo. All studies compared oral colchicine with placebo. Dosage ranged from 0.5mg to 1mg. The detailed study characteristics are depicted in *Supplementary Table 1*.

Risk of bias assessment

The revised Cochrane Risk of Bias (Rob 2.0) tool was used to determine the risk of bias in our selected studies. Six studies were at low risk of bias, 2 studies had some concerns due to issues in intended interventions and selection of reported results, and only 1 study had high risk of bias due to issue in missing outcome data. *Supplementary Figure 1* demonstrates the quality assessment of selected studies.

Meta-analysis of primary outcomes

All-cause mortality

Six out of 9 studies reported all-cause mortality [9,11-13,16,17]. The analysis revealed that there was no statistically significant difference in all-cause mortality rates between colchicine and placebo groups (RR= 0.93, CI= 0.78-1.11, P-value= 0.44). No heterogeneity was recorded (I^2= 0%) (Figure 2). Leave-one-out sensitivity analyses demonstrated similar findings to primary analysis. Egger's test suggested potential publication bias (P=0.0008).

Cardiac death

Four out of 9 studies reported cardiac deaths in both groups [9,11,12,17]. Our analysis revealed that the use of colchicine in acute MI patients did not reduce the risk of cardiac death compared to placebo (RR= 0.95, CI= 0.73-1.22, P-value= 0.66). The level of heterogeneity recorded was low (I^2= 8%) (Figure 3). Leave-one-out sensitivity analyses demonstrated similar findings to primary analysis. Egger's test did not indicate significant publication bias (P=0.38).

Meta-analysis of secondary outcomes

Myocardial infarction

Eight studies reported data on MI [9-12,14-17]. Meta-analysis demonstrated a trend toward MI reduction with colchicine compared to placebo (RR = 0.82, 95% CI 0.67-1.00, P = 0.05), reflecting an 18% relative risk reduction that narrowly missed conventional statistical significance. The level of heterogeneity recorded was low (I^2= 10%) (*Supplementary Figure 2*). Leave-one-out sensitivity analyses demonstrated similar findings to primary analysis. Egger's test indicated significant potential publication bias (P = 0.0001).

Stroke

Five studies out of 9 reported stroke in both groups [9,12,15-17]. No statistically significant difference in stroke rates between colchicine and placebo groups were noted (RR=0.64, CI= 0.26-1.58, P-value= 0.33). A moderate level of heterogeneity was recorded (I^2= 62%) (*Supplementary Figure 3*). Leave-one-out sensitivity analyses demonstrated similar findings to primary analysis. Egger's test did not indicate significant publication bias (P = 0.13).

Adverse events

Six studies reported the incidence of adverse events [9-12,14,17]. Statistical analysis revealed that the use of colchicine did not reduce the risk of adverse events compared to placebo (RR= 1.01, CI= 0.85-1.21, P-value= 0.90). A moderate level of heterogeneity was noted (I^2= 62%) (*Supplementary Figure 4*). Leave-one-out sensitivity analyses demonstrated similar findings to primary analysis. Egger's test indicated significant potential publication bias (P = 0.0001).

Serious adverse events

Five studies reported serious adverse events [9,10,12,15,17]. No statistically significant difference in serious adverse events between colchicine and placebo groups was noted during analysis (RR=0.96, CI= 0.87-1.05, P-value= 0.38). No heterogeneity was noted (I^2=0%) (*Supplementary Figure 5*). Leave-one-out sensitivity analyses demonstrated similar findings to primary analysis. Egger's test indicated significant potential publication bias (P = 0.004).

Serious gastrointestinal adverse events

Seven studies reported serious gastrointestinal adverse events [9,10,11,14-17]. The statistical analysis revealed that the use of colchicine did not decrease serious adverse events compared to the placebo (RR=1.35, CI= 0.94-1.95, P-value= 0.10). Moderate level of heterogeneity was noted (I^2=47%) (*Supplementary Figure 6*). Leave-one-out sensitivity analyses demonstrated similar findings to primary analysis. Egger's test indicated significant potential publication bias (P = 0.0001).

Diarrhea

Six out of 9 studies reported diarrhea [9,10,11,13,15,17]. Our statistical analysis demonstrated that the use of colchicine increased the risk of diarrhea compared to the placebo (RR=2.12, CI=1.35-3.32, P-value= 0.001). The level of heterogeneity recorded was high (I^2=87%) (*Supplementary Figure 7*). Leave-one-out sensitivity analyses demonstrated similar findings to primary analysis. Egger's test indicated significant potential publication bias (P = 0.0001).

Serious infections

Only 3 studies reported serious infections [9,15,17]. Analysis revealed that that the colchicine and the control group were comparable in terms of serious infections (RR= 1.00, CI= 0.62-1.62, P-value= 1.00). The level of heterogeneity recorded was moderate (I^2=59%) (*Supplementary Figure 8*). Leave-one-out sensitivity analyses demonstrated similar findings to primary analysis. Egger's test did not indicate significant publication bias (P = 0.31).

Discussion

This meta-analysis of 9 RCTs involving 13,834 patients found that colchicine has no significant impact on all-cause mortality, cardiac death, recurrent MI, stroke, adverse events, serious adverse events, serious gastrointestinal adverse event, or serious infections. However, it was linked to an increased risk of diarrhea.

Recent studies have shown that colchicine is a viable anti-inflammatory treatment for coronary artery disease (CAD) [18]. Since inflammation is a key component of atherosclerosis and acute coronary events, researchers have conducted studies to explore its role as a supplement to

standard medical therapy. Patients who are diagnosed with chronic coronary artery disease and those rehabilitating from acute coronary syndrome have received a lot of attention. Colchicine is found to possess anti-inflammatory properties as it interferes with microtubule assembly, which hinders immune cell adhesion, motility, and cytokine production. It reduces neutrophil-endothelial interactions by downregulating E-selectin and inhibits the NLRP3 inflammasome. NLRP3 inflammasome is a major contributor to atherosclerotic inflammation. These processes imply that by reducing the inflammatory response linked to the advancement of coronary artery disease, colchicine may have cardioprotective advantages [19]. In one trial, acute coronary syndrome patients treated with low-dose colchicine for a year showed positive changes in the composition of coronary plaque on CT angiography [20].

The broader context of inflammation-targeted cardiovascular therapy supports this rationale. The CANTOS trial established proof of concept that selective inhibition of the interleukin-1β pathway with canakinumab significantly reduces recurrent cardiovascular events independently of lipid lowering, confirming inflammation as a therapeutic target in atherosclerotic disease. Building on this, the COLCOT trial demonstrated that low-dose colchicine initiated shortly after MI significantly reduced the risk of ischemic cardiovascular events, while LoDoCo2 extended these findings to patients with chronic coronary disease, showing a significant reduction in cardiovascular events with long-term colchicine use. Taken together, these trials establish a consistent mechanistic and clinical framework within which our findings should be interpreted. The trend toward MI reduction observed in our meta-analysis (RR = 0.82, 95% CI 0.67-1.00, P = 0.05) is directionally aligned with these results, and the absence of a statistically significant effect on mortality endpoints may reflect differences in follow-up duration, patient selection.

Colchicine may have an impact on thrombosis in addition to inflammation. According to some data, it lessens platelet activation and interactions with monocytes and neutrophils. Due to this, colchicine helps to close the gap between clot formation and inflammation [21].

Our meta-analysis found no statistically significant reduction in all-cause mortality, cardiac death, or recurrent MI with colchicine following MI, though the trend observed for recurrent MI (RR = 0.82, 95% CI 0.67-1.00, P = 0.05) suggests a possible modest benefit that warrants cautious interpretation. These findings are consistent with the meta-analysis by Diaz-Arocutipa et al. (2021), which pooled 6 RCTs comprising 6,005 patients and similarly found no significant

effect on hard clinical endpoints [22]. However, another analysis by Tardif et al. (2019) included 4,745 patients from 6 different RCTs. Their results show that low dose colchicine is able to significantly reduce the risk of ischemic cardiovascular events [17]. Our meta-analysis includes a recent RCT conducted by Jolly et al. (2024) which included 7062 patients from 14 different countries [9]. This RCT significantly increased the total patient population compared to prior meta-analysis. Colchicine use did not significantly lower cardiac death or all-cause mortality according to the pooled analysis. The data shows low heterogeneity which indicates consistent study results.

There was no significant difference in the incidence of stroke between the colchicine and placebo groups. The meta-analysis conducted by Tardif et al. (2019) mentions that colchicine can significantly reduce the risk of ischemic cardiovascular events. However, it does not specifically mention stroke [17]. The findings of Diaz-Arocutipa et al. (2021) show no significant reduction in stroke which are consistent with the results of our meta-analysis [22]. There is moderate heterogeneity which shows that there is some variability among the studies. Colchicine is an anti-inflammatory drug, and inflammation is an important factor when it comes to stroke. By preventing microtubule polymerization, colchicine can lower the activity of inflammatory cytokines. These cytokines play a major role in the development of thrombus and atherosclerosis. There is formation of thrombus in cerebral arteries during ischemic stroke which triggers inflammation [23].

Overall adverse events and serious adverse events showed no significant difference between colchicine and placebo group. There was a trend toward an increased risk of serious gastrointestinal (GI) events, but it is not statistically significant. Our meta-analysis indicates that there is an increased risk of diarrhea compared to the placebo. These findings are consistent with the meta-analysis conducted by Tardif et al. (2019) and Diaz-Arocutipa et al. (2021) [22]. Colchicine impacts cellular functions by preventing microtubule polymerization. This mechanism of action can cause GI symptoms like diarrhea, nausea, and vomiting. It interferes with the normal function of cells in the gastrointestinal tract, especially in the intestinal lining [24]. The risk of serious infections remained unchanged, indicating that colchicine does not impair immune function in patients who are post-MI.

There is an absence of significant cardiovascular benefits or mortality in this study. This indicates the possibility that colchicine is not a generally effective treatment approach for people who have had an MI. Colchicine has anti-inflammatory qualities, suggestive of possible plaque stabilization and a decrease in thrombo-inflammatory processes. However, the findings of this meta-analysis do not support a significant impact on major cardiovascular events. The extensive use of colchicine in post-MI patients may be restricted due to the increased risk of diarrhea. The GI side effects are usually modest and treatable but there is a possibility that patient adherence may be decreased long-term.

By using a significantly larger sample size, our meta-analysis builds upon the studies conducted earlier. This makes it possible to evaluate evidence more precisely and to properly assess heterogeneity. Our study was able to guarantee a more understandable interpretation of the findings by using this certainty to guide our conclusions. This approach improves our results and sets our study apart from earlier research.

It is important to take into consideration several limitations when interpreting these results. The moderate heterogeneity in stroke and adverse event outcomes demonstrates variability in research populations and methods. There is a need for more comprehensive randomized controlled trials with longer follow-up times to fully comprehend the potential cardiovascular benefits of colchicine. Additionally, the timing of colchicine initiation following MI was inconsistently reported across studies, precluding subgroup analyses based on treatment timing. Lastly, because we did not have access to individual patient-level data, our meta-analysis is based on aggregate-level data.

Conclusions

This meta-analysis of 9 RCTs involving 13,834 patients found that current evidence does not demonstrate a statistically significant reduction in all-cause mortality, cardiac death, recurrent MI, stroke, or serious adverse events with colchicine in post-MI patients, though a borderline reduction in recurrent MI warrants cautious consideration. Colchicine was associated with an increased risk of diarrhea. These findings should not be interpreted as conclusive evidence of inefficacy; rather, they reflect the limitations of currently available data, including variability in follow-up duration and patient populations. Further large-scale RCTs are needed to clarify the

role of colchicine in post-MI care and identify subgroups that may derive meaningful clinical benefit.

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Online supplementary material

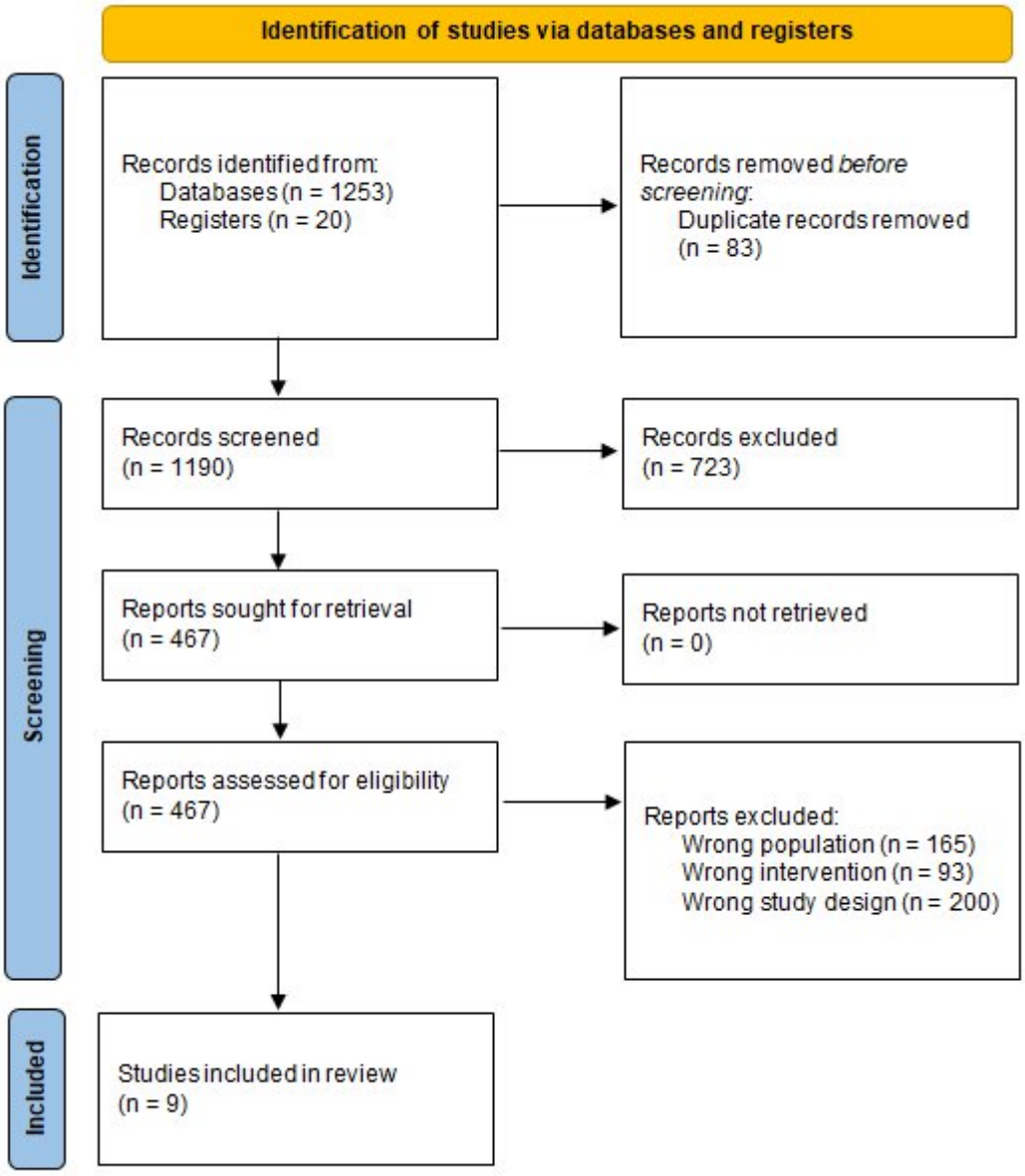

Figure 1. PRISMA flowchart.

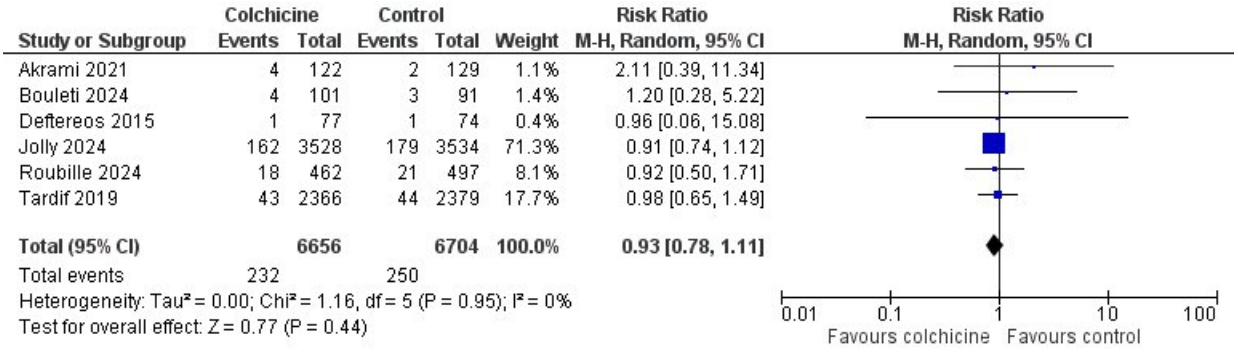

Figure 2. Forest plot of all-cause mortality.

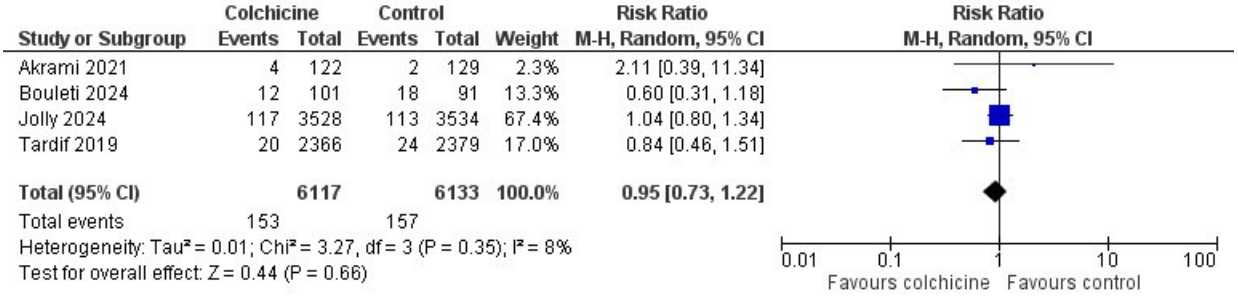

Figure 3. Forest plot of cardiac death.