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COLCHICINE IN CARDIOVASCULAR MEDICINE

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ABSTRACT: Colchicine, a centuries-old anti-inflammatory agent derived from the autumn crocus, has garnered renewed interest in cardiovascular medicine due to its unique pharmacological properties. This review examines the evolution, clinical applications, and controversies surrounding colchicine in cardiovascular care. Beginning with a historical overview, the authors delve into its pharmacokinetics and pharmacodynamics, emphasizing its inhibition of microtubule assembly and reduction of neutrophil and inflammasome activation. The authors elucidated its molecular mechanisms, highlighting its anti-inflammatory effects and role in reducing atherosclerosis, plaque instability, and thrombotic events. Clinical applications are extensively reviewed, showcasing colchicine's efficacy in preventing recurrent cardiovascular events after myocardial infarction, mitigating inflammation, and reducing the incidence of atrial fibrillation. Strategies for monitoring efficacy and safety, including key biomarkers predicting patient response, are explored. Pivotal trials, such as COLCOT, LoDoCo2, COPS, and COP-AF, are analyzed, demonstrating significant reductions in adverse cardiovascular events and highlighting colchicine's emerging role in the management of hypertension. Despite its therapeutic promise, controversies persist regarding colchicine's efficacy in perioperative atrial fibrillation and its side effects, such as diarrhea and lipid profile alterations. These debates are scrutinized, along with considerations for specific populations, particularly those with renal and liver disease. The review also discusses colchicine's impact on various organ systems, underscoring the need for cautious use in vulnerable populations. In conclusion, this review presents colchicine as a versatile therapeutic agent with significant potential in cardiovascular disease management. However, its narrow therapeutic window and varying effects across different organ systems necessitate careful patient selection and monitoring to optimize clinical benefits and minimize risks.

INTRODUCTION: Colchicine, a natural alkaloid derived from the autumn crocus plant (*Colchicum autumnale*), has been recognized for its potent anti-inflammatory properties since ancient Egypt and Greece, where it was used to treat rheumatism and gout^{1, 2}. Its effectiveness in alleviating joint pain and inflammation made it a valuable therapeutic agent long before modern medicine.

By the 19th century, colchicine was formally isolated and incorporated into Western medicine, becoming a standard treatment for acute gout attacks^{3, 4}. Over time, the understanding of colchicine's mechanisms has evolved, leading to its application in more advanced clinical settings.

Its primary action involves inhibiting microtubule polymerization by binding to tubulin, which disrupts cellular processes dependent on microtubules⁵. This mechanism underlies colchicine's anti-inflammatory effects, particularly through the inhibition of neutrophil motility and activity. By preventing neutrophil migration to inflamed sites, colchicine reduces the local

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inflammatory response, alleviating pain and swelling. This characteristic was vital in traditional gout treatment and has spurred interest in broader applications today ⁶.

Relevance to Modern Cardiovascular Diseases:

Recently, colchicine has emerged as a promising agent in cardiovascular medicine, especially in conditions where inflammation is a critical factor. Cardiovascular disease (CVD), including coronary artery disease and heart failure, remains a leading cause of morbidity and mortality globally ^{6, 7}. The role of inflammation in CVD progression has become increasingly recognized, leading to new strategies focusing on anti-inflammatory therapies ⁷. Colchicine's potential in cardiovascular disease management first gained attention in the context of pericarditis. When used alongside nonsteroidal anti-inflammatory drugs (NSAIDs), colchicine effectively reduced recurrence rates of pericarditis. Its use has since expanded to various cardiovascular conditions driven by inflammation ⁸.

Recent clinical trials, such as the COLCOT (Colchicine Cardiovascular Outcomes Trial) and LoDoCo2 (Low-Dose Colchicine 2), have provided strong evidence supporting its efficacy in reducing the risk of major adverse cardiovascular events in patients with a history of coronary artery disease ^{9, 10}. These studies demonstrated colchicine's role in secondary prevention, showing significant reductions in myocardial infarction, stroke, and the need for coronary revascularization ^{11, 12, 13}.

Other trials, like the COPS (Colchicine for Prevention of Secondary Cardiovascular Events) and the COP-AF (Colchicine for the Prevention of Perioperative Atrial Fibrillation), further highlighted its potential, although debates regarding its efficacy and safety in various patient populations persist ^{20, 21, 22, 23}. The growing body of evidence has also raised interest in applying colchicine to other cardiovascular conditions. In atrial fibrillation, for instance, the drug's ability to modulate inflammation might aid in reducing postoperative atrial fibrillation incidence, potentially decreasing complications associated with this common arrhythmia ^{14, 15, 16}. Moreover, its use in hypertensive patients is being explored due to its potential to attenuate vascular inflammation, thus improving blood pressure control and reducing end-organ damage ^{17, 18, 19}.

Objectives and Scope of the Review: Given the evolving role of colchicine in cardiovascular medicine, this review aims to provide a comprehensive analysis of its cardiovascular evolution ^{24, 25}. It will delve into the pharmacology and mechanism of action of colchicine, elucidating how its anti-inflammatory properties translate to clinical benefits in cardiovascular conditions ²⁶⁻²⁸. Additionally, it will analyze the pathophysiology behind colchicine's beneficial effects, examining how its action on inflammation modulates cardiovascular disease progression ^{29, 30}.

We will explore clinical applications and monitoring strategies, particularly focusing on practical considerations for clinicians implementing colchicine therapy. This includes understanding biomarkers predictive of patient response, optimal dosing strategies, and safety monitoring ³¹.

A significant portion of this review will focus on major clinical trials that have shaped the current understanding of colchicine's cardiovascular potential ^{32, 33}. The COLCOT and LoDoCo2 trials, among others, will be reviewed to underscore how colchicine has proven effective in reducing adverse cardiovascular outcomes ^{12, 22}. Simultaneously, we will address the controversies and challenges that persist, particularly regarding safety concerns like gastrointestinal side effects and their impact on lipid profile ³⁴.

Lastly, we will consider colchicine's impact across various organ systems. While the cardiovascular system is the primary focus, it's crucial to understand how the drug's action might affect other systems like the kidneys, liver, and brain ²⁹.

By compiling the latest evidence and insights, this review will present a nuanced view of colchicine's evolving role in cardiovascular medicine, providing a valuable resource for researchers, clinicians, and policymakers ³⁰⁻³⁵. To conclude, recommendations for future research directions and clinical practice, aiming to bridge knowledge gaps and enhance the practical utility of colchicine in cardiovascular disease management, are discussed ^{36, 37}.

For the literature review, publications up to May 2025 were included in the study. Bibliographic databases were searched (MEDLINE/PubMed, EMBASE, Google Scholar, BioMed Central, the

Cochrane Collaboration Database of Randomized Trials, Scopus, ClinicalTrials.gov) using the search terms 'colchicine' AND 'cardiovascular disease' OR 'coronary artery disease' OR 'stroke' OR 'pericarditis' OR 'atrial fibrillation' OR 'atherosclerosis' OR 'heart failure' OR 'Low dose aspirin'. The research was restricted to the English language ¹¹. Titles and abstracts of all studies were independently screened by the authors, while potentially eligible studies were appraised as full text. The reference list includes the most relevant papers ¹².

MATERIALS AND METHODS:

Search Strategy: For this comprehensive review of colchicine's evolution in cardiovascular applications, an exhaustive literature search was conducted using several bibliographic databases, including MEDLINE/PubMed, EMBASE, Google Scholar, BioMed Central, the Cochrane Collaboration Database of Randomized Trials, Scopus, and ClinicalTrials.gov. The search was performed using a combination of keywords and MeSH terms tailored to capture the broad spectrum of colchicine's cardiovascular effects. Key search terms used included "colchicine," "cardiovascular diseases," "coronary artery disease," "stroke," "pericarditis," "atrial fibrillation," "atherosclerosis," "heart failure," and "low dose aspirin." Boolean operators (AND, OR) were utilized to refine the search results.

Inclusion and Exclusion Criteria: Studies included in this review were selected based on several criteria:

- **Language:** Only articles published in English were considered.
- **Publication Date:** The scope was limited to studies published up to May 2025 to ensure the inclusion of the most recent and relevant data.
- **Study Type:** Randomized controlled trials, observational studies, systematic reviews, and meta-analyses were included. Editorials, commentaries, and case reports were excluded.
- **Focus:** Only studies that explicitly discussed the cardiovascular effects of colchicine, either as a primary or secondary outcome, were included.

Study Selection: The initial search yielded a substantial number of records. Titles and abstracts were first screened independently by two reviewers to assess relevance. Discrepancies were resolved through discussion or by consulting a third reviewer. Full texts of potentially eligible studies were then retrieved and further assessed against the inclusion criteria. The reference lists of these articles were also examined to identify additional studies that may have been missed in the initial database search.

Quality Assessment: The quality of the included studies was assessed using appropriate tools based on the study design. Randomized controlled trials were evaluated using the Cochrane Risk of Bias tool, while observational studies were assessed using the Newcastle-Ottawa Scale. This assessment helped in identifying studies with high methodological quality for inclusion in the review.

Synthesis of Results: Data from included studies were synthesized qualitatively, given the heterogeneity in study designs and outcomes measured. The synthesis focused on summarizing the therapeutic roles of colchicine in various cardiovascular conditions, its pharmacological properties, and the clinical evidence supporting its use. Key controversies and gaps in the current research were highlighted to provide a balanced view of the available evidence.

Ethical Considerations: This review did not involve primary human or animal subjects and relied solely on publicly available published data. Therefore, ethical approval was not required. However, all data handling followed ethical practices for secondary data analysis, ensuring the integrity of the reported findings.

Pharmacology and Mechanism of Action:

TABLE 1: PHARMACOLOGICAL PROPERTIES OF COLCHICINE

Property	Details
Absorption	Rapidly absorbed in the gastrointestinal tract.
Bioavailability	Variable (ranges from 24% to 88%)
Metabolism	Metabolized via CYP3A4 enzymes
Excretion	Primarily via feces, partly in urine
Half-life	Approximately 26-31 hours (steady state)
Mechanism of Action	Inhibits microtubule polymerization, reducing inflammation

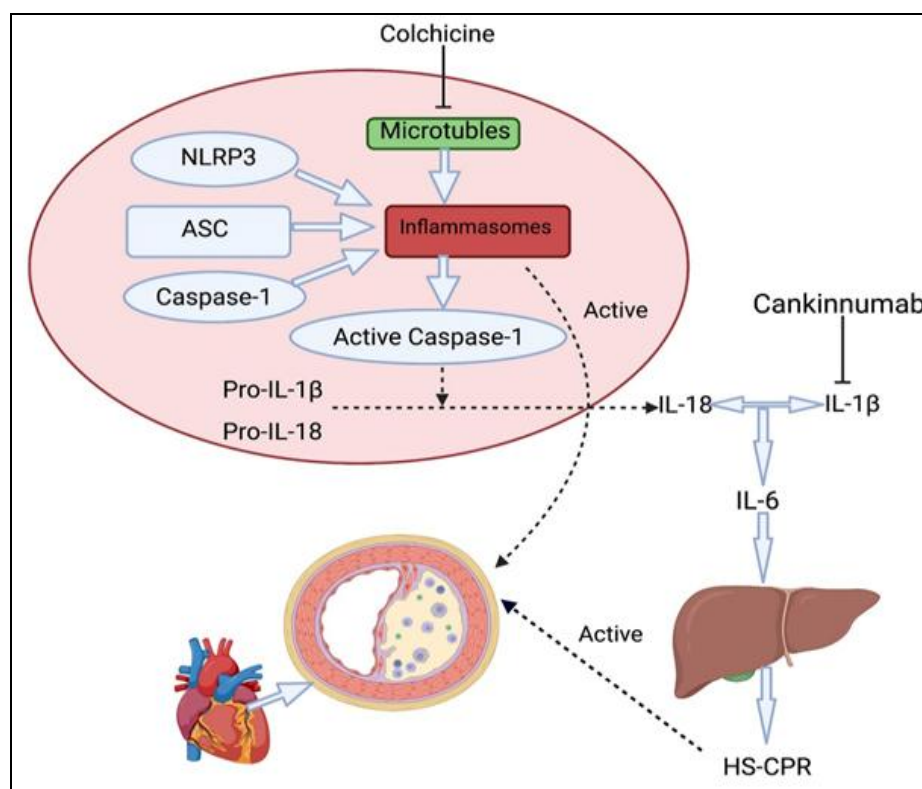


FIG. 1: MECHANISM OF ACTION OF COLCHICINE IN CARDIOVASCULAR DISEASES

Pharmacokinetics and Pharmacodynamics:

Colchicine, an alkaloid from the *Colchicum autumnale* plant, is rapidly absorbed *via* the gastrointestinal tract after oral administration. Its bioavailability ranges between 24% and 88% due to interindividual variability. Once absorbed, the drug is widely distributed throughout the body, particularly in leukocytes, spleen, kidneys, and liver, reflecting its affinity for cells active in the inflammatory process³⁸.

Colchicine binds extensively to plasma proteins, with an elimination half-life typically ranging from 26 to 31 hours. Metabolism occurs mainly in the liver through CYP3A4, and colchicine is a substrate for P-glycoprotein. Consequently, drugs inhibiting either CYP3A4 or P-glycoprotein can significantly increase colchicine exposure, raising the risk of toxicity. The drug is excreted through both biliary and renal pathways. Impairment in either system, such as chronic liver or kidney disease, necessitates dosage adjustments to minimize adverse effects.

Molecular Mechanisms in Cardiovascular Effects: The therapeutic efficacy of colchicine in cardiovascular conditions hinges on its ability to bind tubulin, inhibiting microtubule polymerization

^{17, 23}. This disruption of microtubule dynamics impairs various cellular functions, especially in leukocytes, limiting their mobility and reducing their ability to release pro-inflammatory mediators. In cardiovascular disease, where inflammation is a central driver, these effects of colchicine are particularly beneficial²⁴⁻²⁶.

Colchicine also inhibits the assembly of the NLRP3 inflammasome, a multiprotein complex involved in the production of pro-inflammatory cytokines like interleukin-1 β (IL-1 β). Activation of this inflammasome is linked to the progression of coronary artery disease and other cardiovascular conditions. By preventing NLRP3 assembly, colchicine reduces the release of IL-1 β and other cytokines, thereby attenuating vascular inflammation and its downstream effects.

In addition, colchicine has been shown to inhibit platelet aggregation, which may contribute to its protective effects against atherothrombosis. The drug's ability to reduce neutrophil-platelet interactions further helps stabilize atherosclerotic plaques and prevent adverse cardiovascular events.

Role in Inflammation Modulation: Colchicine's primary role in inflammation modulation revolves

around its capacity to inhibit neutrophil chemotaxis and activity. Neutrophils are central players in the acute inflammatory response and significantly contribute to atherosclerotic plaque destabilization. By limiting neutrophil migration to inflamed vascular sites, colchicine reduces plaque vulnerability and mitigates the risk of rupture, a primary trigger for acute coronary syndrome. Furthermore, the inhibition of the NLRP3 inflammasome is crucial in chronic cardiovascular inflammation. IL-1 β , a cytokine driving the production of other pro-inflammatory mediators like IL-6 and tumor necrosis factor-alpha (TNF- α), is significantly reduced when the NLRP3 inflammasome is inhibited. This comprehensive suppression of the inflammatory cascade by colchicine diminishes systemic inflammation, closely linked to the pathogenesis of atherosclerosis and other cardiovascular diseases. Overall, colchicine's broad-spectrum anti-inflammatory effects, combined with its favorable pharmacokinetic profile, make it a promising agent in cardiovascular disease management. Targeting inflammation at both the cellular and molecular levels disrupts the pathophysiological processes leading to adverse cardiovascular outcomes.

Pathophysiology and Cardiovascular Implications:

Impact on Atherosclerosis and Plaque Stabilization: Colchicine's impact on atherosclerosis centers on its ability to modulate the inflammatory response that drives the disease process. Chronic inflammation plays a pivotal role in atherosclerotic plaque formation and progression. By impeding the migration and activity of neutrophils and other leukocytes at the site of vascular injury, colchicine reduces the inflammatory burden, thereby slowing the development of atherosclerotic plaques. Moreover, colchicine contributes to plaque stabilization by inhibiting the NLRP3 inflammasome, reducing the secretion of interleukin-1 β (IL-1 β) and other cytokines that exacerbate inflammation and promote plaque vulnerability. With a more stable plaque, the risk of rupture is diminished, mitigating the potential for acute coronary syndromes, a major precipitating event for myocardial infarction.

Anti-Inflammatory Effects in Cardiac Tissues: Beyond its influence on atherosclerosis, colchicine

exerts potent anti-inflammatory effects directly within cardiac tissues. In conditions like myocarditis and pericarditis, inflammation causes significant tissue damage that compromises cardiac function. By reducing neutrophil infiltration and downregulating cytokine production, colchicine diminishes the inflammatory injury, thereby preserving myocardial integrity. In acute pericarditis, colchicine has become a mainstay of treatment due to its effectiveness in reducing recurrence rates. Attenuating pericardial inflammation limits complications like pericardial effusion and constrictive pericarditis. In myocarditis, colchicine's ability to suppress the cellular immune response can help reduce the extent of myocardial damage.

Influence on Thrombotic Events and Platelet Aggregation: Colchicine's influence extends to the prevention of thrombotic events by interfering with the platelet-vascular interaction that leads to thrombus formation. The drug inhibits platelet activation and aggregation, which are critical steps in the development of arterial thrombosis. This effect is particularly relevant in conditions like acute coronary syndrome, where thrombosis often complicates atherosclerotic plaque rupture.

Additionally, colchicine reduces the interaction between neutrophils and platelets, further preventing the formation of platelet-neutrophil aggregates that contribute to thrombotic complications. By limiting this interaction, colchicine helps prevent the propagation of thrombosis in patients with existing cardiovascular disease. In sum, the pathophysiological implications of colchicine in cardiovascular health are multifaceted. Its ability to stabilize atherosclerotic plaques, mitigate cardiac inflammation, and prevent thrombotic events underlines its potential as a cornerstone therapy in the management of cardiovascular conditions³⁴. These effects position colchicine as a versatile and promising therapeutic agent across a spectrum of cardiovascular diseases³⁵.

Clinical Applications and Monitoring:

Current Clinical Applications in Cardiovascular Medicine: Colchicine's applications in cardiovascular medicine have expanded significantly, driven by emerging evidence that

underscores its benefits beyond traditional anti-gout therapy. Historically used for gout and familial Mediterranean fever, it has now become an important adjunctive treatment in various cardiovascular diseases ³⁸.

Acute and Recurrent Pericarditis: Colchicine has revolutionized the management of acute and recurrent pericarditis. Studies have shown that colchicine, when added to nonsteroidal anti-inflammatory drugs (NSAIDs), significantly reduces the risk of recurrence by dampening the inflammatory cascade that drives the disease ²¹. The Colchicine for Recurrent Pericarditis (CORE) trial and Colchicine for Acute Pericarditis (COPE) trial highlighted colchicine's ability to lower recurrence rates and lessen symptoms in acute cases ^{30, 35}.

Post-Pericardiotomy Syndrome: After cardiac surgery, post-pericardiotomy syndrome frequently manifests as pericardial inflammation, which can lead to pericardial effusion and tamponade. Colchicine is effective in this setting as well, reducing the incidence and severity of symptoms.³¹ The Colchicine for the Prevention of the Post-Pericardiotomy Syndrome (COPPS) trial demonstrated that patients receiving colchicine had significantly lower rates of the syndrome, illustrating its preventive role ^{36, 37}.

Acute Coronary Syndromes: The anti-inflammatory action of colchicine is also beneficial in patients with acute coronary syndromes (ACS) ³². In the Colchicine Cardiovascular Outcomes Trial (COLCOT), colchicine reduced the risk of major adverse cardiovascular events, including recurrent myocardial infarction, stroke, and urgent revascularization in patients who had recently experienced an ACS. These results underscore its role as an adjunctive therapy to established treatments like aspirin and statins ³⁸.

Atherosclerosis and Secondary Prevention: Beyond acute settings, colchicine plays a role in reducing inflammation associated with atherosclerosis ^{12, 22}. The Low-Dose Colchicine (LoDoCo2) trial showed that low-dose colchicine significantly lowered the incidence of cardiovascular events in patients with chronic coronary artery disease. Its ability to stabilize atherosclerotic plaques by reducing inflammation

positions it as a valuable agent for secondary prevention ³⁸.

Atrial Fibrillation (AF): Colchicine may also prevent atrial fibrillation after cardiac surgery. Inflammation is a key contributor to postoperative AF, and small-scale trials like COP-AF have indicated colchicine's efficacy in reducing the incidence of this arrhythmia. More evidence is required, but preliminary data is promising.

Monitoring Strategies for Efficacy and Safety: Given the diverse clinical applications of colchicine, effective monitoring is crucial for ensuring efficacy and safety ⁸.

Therapeutic Response: Assess clinical outcomes such as symptom reduction in pericarditis and decreased major adverse cardiovascular events in coronary artery disease. Objective measures like reduced CRP levels and imaging studies can confirm therapeutic benefits ^{21, 29}.

Adverse Effects: Monitor for gastrointestinal disturbances (diarrhea, nausea, abdominal pain), particularly in older patients or those with renal impairment. Routine blood counts can detect rare hematological side effects like leukopenia or pancytopenia³¹.

Drug Interactions: Colchicine is metabolized by CYP3A4 and P-glycoprotein. Caution is needed with co-administered drugs that inhibit these pathways, such as clarithromycin or antifungals, which can increase colchicine levels and toxicity risk ³².

Renal and Hepatic Function: Regularly monitor kidney and liver function, especially in long-term therapy or patients with pre-existing conditions, to avoid increased risk of toxicity³³.

Biomarkers for Predicting Patient Response: Identifying reliable biomarkers can enhance personalized colchicine therapy by predicting patient response and minimizing adverse effects.

Inflammatory Markers: CRP and ESR levels can indicate systemic inflammation and colchicine's anti-inflammatory efficacy. Elevated baseline levels may predict a favorable response in

conditions like pericarditis and coronary artery disease.

Genetic Markers: Polymorphisms in drug-metabolizing enzymes or transporters (e.g., ABCB1 gene) may affect colchicine pharmacokinetics and toxicity.

Lipoprotein Markers: Colchicine may reduce LDL cholesterol in some patients. Monitoring lipid levels can assess their secondary cardiovascular benefits.

Cardiac-Specific Markers: Cardiac troponins and natriuretic peptides may predict therapeutic response and prognosis, particularly in myocardial inflammation or ischemic heart disease.

In summary, colchicine’s applications in cardiovascular medicine are extensive and evolving. Effective monitoring and the use of biomarkers are essential to maximize benefits and minimize risks. Colchicine remains a cornerstone therapy for various cardiovascular conditions.

Trials and Clinical Studies: The clinical landscape of colchicine in cardiovascular medicine has been shaped by numerous pivotal trials, each shedding light on its potential benefits and limitations. Here’s a concise look at the significant clinical studies:

COLCOT Trial: The Colchicine Cardiovascular Outcomes Trial (COLCOT) demonstrated colchicine’s efficacy in reducing cardiovascular events in post-myocardial infarction patients. Involving over 4,000 participants, the trial found that daily low-dose colchicine (0.5 mg) significantly reduced the incidence of major adverse cardiovascular events, including urgent revascularization and stroke. Colchicine’s anti-inflammatory properties were crucial in stabilizing atherosclerotic plaques, thereby reducing the risk of subsequent cardiovascular events ^{14, 16}. The COLCOT trial solidified colchicine’s role in secondary prevention following an acute coronary syndrome ^{17, 19}.

LoDoCo2 Trial: The Low-Dose Colchicine 2 (LoDoCo2) trial built upon the findings of the earlier LoDoCo study, focusing on chronic coronary disease. This randomized, double-blind trial evaluated over 5,000 patients and revealed that low-dose colchicine significantly reduced the composite endpoint of cardiovascular death, myocardial infarction, and ischemic stroke^{14,15}. These findings reinforced colchicine's role as an effective adjunct in patients with stable coronary artery disease and as a preventative measure against future cardiovascular events ^{16, 19}.

COPS and COP-AF Trials:

COPS Trial: The Colchicine in Patients with Acute Coronary Syndrome (COPS) trial explored the effect of colchicine in reducing major adverse cardiovascular events in patients with recent acute coronary syndromes. Although the trial did not achieve statistical significance in its primary endpoint, it highlighted potential benefits in reducing certain endpoints, underscoring the need for further research ^{24, 25}.

COP-AF Trial: The Colchicine for the Prevention of Postoperative Atrial Fibrillation (COP-AF) trial examined colchicine's role in preventing atrial fibrillation after cardiac surgery. Postoperative atrial fibrillation is a common complication with significant morbidity. COP-AF demonstrated that colchicine significantly reduced the incidence of postoperative atrial fibrillation, providing strong support for its use in this context ^{26, 28}.

Colchicine Hypertension Trial: The Colchicine Hypertension Trial investigated whether colchicine could exert an antihypertensive effect through its anti-inflammatory action. This smaller-scale study found modest improvements in blood pressure levels among hypertensive patients receiving colchicine compared to controls. While the primary outcomes weren't dramatic, the trial provided initial data suggesting that inflammation plays a role in hypertension and that colchicine could be part of a broader management strategy.

TABLE 2: CARDIOVASCULAR TRIALS EVALUATING COLCHICINE EFFICACY

Trial Name	Patient Population	Key Findings
COLCOT	Post-MI patients	Reduced CV death, MI, and stroke
LoDoCo2	Chronic CAD patients	Reduced CV death, MI, stroke, ischemia
COP-AF	Thoracic surgery patients	No significant reduction in AF

COPS	Cardiac surgery patients	Reduced postoperative AF incidence
Colchicine Hypertension Trial	Hypertensive patients	Evaluating anti-inflammatory effects

Analysis of Trial Data:

Efficacy Across Trials: Colchicine consistently demonstrates anti-inflammatory benefits, reducing cardiovascular events across various conditions and patient populations. This efficacy is evident in both acute and chronic settings.

Safety Profile: Colchicine generally has a consistent safety profile, with gastrointestinal side effects being common but typically mild. Rare occurrences of myopathy and blood disorders highlight the need for careful patient selection and monitoring.

Implications for Practice: The evidence supports colchicine as a valuable adjunct to standard care in cardiovascular disease, particularly for patients at high risk for recurrent ischemic events or postoperative atrial fibrillation. Its affordability and oral administration enhance its practicality.

Future Research: Questions remain regarding optimal dosing, therapy duration, and patient selection. Future studies should focus on long-term safety and efficacy, as well as strategies for monitoring and minimizing adverse effects.

TABLE 3: TRIALS IN PATIENTS WITH ACUTE PERICARDITIS, RECURRENT CARDITIS, POSTPERICARDIOTOMY SYNDROME

Research Title	Study Type	Participants	Treatment	Control Group	Key Measure	Colchicine Outcome	Significant Side Effects
Acute Pericarditis							
COPE (Imazio et al., 2005)	Forward-looking, randomized, non-blinded	Patients with acute pericarditis (n=120)	Colchicine (1.0-2.0 mg day one; then 0.5-1.0 mg/day for three months)	Standard treatment	Recurrence rate over 18 months	10.7% vs. 32.3%; P=0.004	Digestive intolerance (8.3%)
ICAP (Imazio et al., 2013)	Forward-looking, randomized, double-blind, placebo-controlled	Patients with acute pericarditis (n=240)	Colchicine (0.5 mg twice daily for 3 months for those >70 kg; 0.5 mg daily for ≤70 kg)	Placebo	Persistent or recurrent pericarditis at 18 months	16.7% vs. 37.5%; P<0.001; Relative Risk Reduction (R) 0.56 (CI, 0.30–0.72)	None
Sambola et al., 2019	Forward-looking, randomized, non-blinded	Acute pericarditis (n=110)	Colchicine (1 mg twice daily for 3 months for >70 kg; 0.5 mg twice daily for ≤70 kg)	Standard therapy	Recurrence rate over 24 months	10.9% vs. 13.5%; P=0.34; Hazard Ratio (HR) 1.53 (CI, 0.7–3.4)	Digestive intolerance (13.5%)
Recurrent Pericarditis							
CORE (Imazio et al., 2005)	Forward-looking, randomized, non-blinded	Recurring pericarditis (n=83)	Colchicine (1.0-2.0 mg on day one; 0.5-1.0 mg/day for six months)	Standard therapy	Recurrence rate over 20 months	24% vs. 50.6%; P=0.02	Digestive intolerance (7%)
CORP (Imazio et al., 2011)	Forward-looking, randomized, double-blind, placebo-controlled	Recurring pericarditis (n=120)	Colchicine (1.0-2.0 mg on day one; 0.5-1.0 mg/day for six months)	Standard therapy	Recurrence rate over 18 months	24% vs. 55%; P<0.001; Absolute Risk Reduction (ARR) 0.31 (CI, 0.13–0.46); R 0.56 (CI, 0.27–0.73)	Digestive intolerance (7%)
CORP-2 (Imazio et al., 2014)	Forward-looking, randomized,	Recurring pericarditis (n=240)	Colchicine (0.5 mg twice daily for six months)	Standard therapy	Recurrence rate over 18 months	21.6% vs. 42.5%; P=0.0009;	Digestive intolerance (7.5%);

	double-blind, placebo- controlled		for those >70 kg; 0.5 mg daily for ≤70 kg)			Relative Risk (RR) 0.49 (CI, 0.24– 0.65)	Liver toxicity (2.5%)
Post-pericardiotomy Syndrome							
Finkelstein et al., 2002	Forward- looking, randomized, double-blind, placebo- controlled	Cardiac surgery patients (n=163)	Colchicine (1.5 mg daily starting from day three post- op for one month)	Placebo	Post- pericardiotomy syndrome (PPS) at 3 months	10.6% vs. 21.9%; P<0.135	Not reported
COPPS (Imazio et al., 2010)	Forward- looking, randomized, double-blind, placebo- controlled	Cardiac surgery patients (n=336)	Colchicine (1 mg twice daily on day one, then 0.5 mg twice daily for one month from post-op day 3, reduced dose for ≤70 kg)	Placebo	PPS at 12 months	8.9% vs. 21.1%; P=0.002; R 0.579 (CI, 0.273-0.756)	Digestive intolerance (8.9%)
COPPS-2 (Imazio et al., 2014)	Forward- looking, randomized, double-blind, placebo- controlled	Cardiac surgery patients (n=360)	Colchicine (0.5 mg twice daily for 48-72 hours pre-op until one- month post-op; 0.5 mg daily for <70 kg)	Placebo	PPS over 3 months	19.4% vs. 29.4%; Absolute difference 10% (CI, 1.1- 8.7%)	Digestive intolerance (14.4%)

Notes: ARR: Absolute risk reduction; HR: Hazard ratio; POD: Postoperative day; PPS: Post pericardiotomy syndrome; RR: Relative risk; RR: Relative risk reduction. Remark: Significant adverse events include those found to be higher compared to the control group or those considered clinically relevant.

TABLE 4: TRIALS IN PATIENTS WITH POSTOPERATIVE ATRIAL FIBRILLATION AND POST-PULMONARY VEIN ISOLATION ATRIAL FIBRILLATION

Research Title	Study Type	Participants	Treatment	Control Group	Key Measure	Colchicine Outcome	Significant Side Effects
Postoperative Atrial Fibrillation							
COPPS (Imazio et al., 2011)	Prospective, randomized, double-blind, placebo- controlled	Patients undergoing any cardiac surgery (n=336)	Colchicine (1 mg twice daily from day 3 post-op, followed by 0.5 mg twice daily for a month; reduced dose for ≤70 kg)	Placebo	Post-op AF over one month	12% vs. 22%; P=0.021; R 0.45 (CI, 0.34-0.94)	Digestive intolerance (9.5%)
COPPS-2 (Imazio et al., 2014)	Prospective, randomized, double-blind, placebo- controlled	Patients undergoing any cardiac surgery (n=360)	Colchicine (0.5 mg twice daily or 0.5 mg daily for <70 kg, 48-72 hours pre-op, then one month post-op)	Placebo	PPS (Postoperative AF secondary outcome) at 3 months	33.9% vs. 41.7%; absolute difference 7.8% (CI, - 2.2% to 17.6%)	Digestive intolerance (14.4%)
Sarzaeem et al., 2014	Prospective, randomized, double-blind, placebo-	Patients undergoing coronary artery bypass	Colchicine (1 mg twice daily for two doses pre-op, then	Placebo	Post-op AF at six months	14.8% vs. 30.6%; P=0.006	Not reported

	controlled	surgery (n=216)	0.5 mg twice daily for five days)				
Zarpelon et al., 2016	Prospective, randomized, open-label	Patients undergoing elective coronary artery bypass surgery (n=140)	Colchicine (1 mg twice daily pre-op, then 0.5 mg twice daily until discharge)	No colchicine	Post-op AF at discharge	7.04% vs. 13.04%; P=0.271; OR 0.46 (CI, -0.53 to 0.81)	Not reported
END-AF Trial (Tabbalat et al., 2020)	Prospective, randomized, open-label, placebo-controlled	Patients undergoing elective cardiac surgery (n=152)	Colchicine (1 mg once, 12-24 hours pre-op, then 0.5 mg daily until discharge)	Placebo (12-24 hours pre-op, then daily until discharge)	Post-op AF at discharge	16% vs. 18.3%; P=0.88; OR 0.85 (CI, 0.37-1.99)	Digestive intolerance (2.4%)
Post-Pulmonary Vein Isolation Atrial Fibrillation							
Deftereos et al., 2012	Prospective, randomized, double-blind, placebo-controlled	Patients undergoing pulmonary vein isolation (n=161)	Colchicine (0.5 mg twice daily from day one post-procedure for three months)	Placebo	Post-procedure AF over three months	16% vs. 33.5%; P=0.01; OR 0.38 (CI, 0.18-0.80)	Digestive intolerance (8.6%)
Deftereos et al., 2014	Prospective, randomized, double-blind, placebo-controlled	Patients undergoing pulmonary vein isolation (n=223)	Colchicine (0.5 mg twice daily from day one post-procedure for three months)	Placebo	Post-procedure AF over 15 months	31.1% vs. 49.5%; P=0.01; R 0.37; OR 0.46 (CI, 0.26-0.81)	Digestive intolerance (9.7%)

Notes: OR: Odds ratio; PPS: Post Pericardiotomy syndrome; RR: Relative risk reduction.

TABLE 5: TRIALS ON PATIENTS WITH STABLE CORONARY ARTERY DISEASE, ACUTE CORONARY SYNDROME, AND ACUTE MYOCARDIAL INFARCTION

Research Title	Study Type	Participants	Treatment	Control Group	Key Measure	Colchicine Outcome	Significant Side Effects
Stable Coronary Artery Disease							
LoDoCoTrial (Nidorf et al., 2013)	Prospective, randomized, observer-blinded, open-label	Stable CAD (n=532)	Colchicine (0.5 mg daily until study conclusion)	Conventional therapy	Combined measure of ACS, out-of-hospital cardiac arrest, or non-cardio-embolic ischemic stroke at a median of 3 years follow-up	5.3% vs. 16%; P < 0.001; HR 0.33 (CI, 0.18-0.59)	Gastrointestinal intolerance (2.5%), myalgia (0.9%), myositis (1 case)
LoDoCo2 Trial (Nidorf et al., 2020)	Prospective, randomized, double-blind, placebo-controlled	Stable CAD (n=5522)	Colchicine (0.5 mg daily until study conclusion)	Placebo	Composite of CV death, spontaneous MI, ischemic stroke, or ischemia-driven coronary revascularization at a median of 28.6 months follow-up	6.8% vs. 9.6%; P < 0.001; HR 0.69 (CI, 0.57-0.83)	Noncardiovascular deaths (1.9%; HR 1.51 [CI, 0.99-2.31]), myalgia [‡] (21.2%), gastrointestinal intolerance (15.4% in run-in period)
Acute Coronary Syndrome							
COPS Trial (Tong et al., 2020)	Prospective, randomized, double-blind, placebo-controlled	Patients hospitalized for ACS (n=795)	Colchicine (0.5 mg twice daily for the first month, then 0.5	Placebo	Composite of all-cause mortality, ACS, urgent unplanned revascularization, and non-cardio-	6.1% vs. 9.5%; P=0.09; HR 0.65 (CI, 0.38-1.09)	Total deaths (8 vs. 1; P=0.017), non cardiovascular deaths (5 vs. 0; P=0.024)

Myocardial Injury Reduction (Mewton et al., 2021)	Phase 2, prospective, randomized, double-blind, placebo-controlled	ACS (n=194)	mg daily for 11 months) Colchicine (2 mg bolus followed by 0.5 mg twice daily for 5 days)	Placebo	embolic ischemic stroke at 12 months Infarct size measured by CMR at 5 days	Mean of 26 g (IQR 16-44) vs. 28.4 g (IQR 14-40); P=0.87	LV thrombus (22.2% vs. 7.4%; P=0.01), gastrointestinal intolerance (34.4% vs. 10.1%; P=0.0001)
After Myocardial Infarction							
COLCOT Trial (Tardif et al., 2019)	Prospective, randomized, double-blind, placebo-controlled	Acute MI within 30 days (n=4745)	Colchicine (0.5 mg daily until study conclusion)	Placebo	Composite of death from CV causes, resuscitated cardiac arrest, MI, stroke, or urgent angina hospitalization leading to coronary revascularization over a median of 22.6 months	5.5% vs. 7.1%; P=0.02; HR 0.77 (CI, 0.61-0.96)	Pneumonia (0.9% vs. 0.4%; P=0.03)

TABLE 6: TRIALS ON PATIENTS WITH PERCUTANEOUS CORONARY INTERVENTION

Research Title	Study Type	Participants	Treatment	Control Group	Key Measure	Colchicine Outcome	Significant Side Effects
Percutaneous Coronary Intervention							
O'Keefe et al., 1992: Ineffectiveness of Colchicine in Preventing Restenosis After Coronary Angioplasty	Prospective, randomized, double-blind, placebo-controlled	PTCA (n=130)	Colchicine (0.6 mg twice daily for the duration of the study)	Placebo	Restenosis at 6 months	46% vs. 45%; not statistically significant	Gastrointestinal intolerance (28%)
Freed et al., 1995: Combination Therapy of Lovastatin, Enalapril, and Colchicine Doesn't Prevent Restenosis After PTCA	Prospective, open-label	PTCA (n=50)	Colchicine (0.6 mg twice daily) + Lovastatin (20 mg daily) + Enalapril (2.5-10 mg twice daily, titrated to SBP >100 mmHg) + Aspirin (81 mg daily)	N/A	Late loss of lumen diameter at 16 weeks	0.5 mm ± 0.8 mm†	Gastrointestinal intolerance (18%)
Deftereos et al., 2013: Colchicine Treatment to Prevent Bare-Metal Stent Restenosis in Diabetic Patients	Prospective, randomized, double-blind, placebo-controlled	BMS PCI for diabetic patients (n=196)	Colchicine (0.5 mg twice daily)	Placebo	Angio-ISR and IVUS-ISR at 6 months	Angio-ISR: 16% vs. 33%, P=0.007; OR 0.38 (CI, 0.18-0.79); IVUS-ISR: 24% vs. 43%, P=0.006; OR 0.42 (CI, 0.22-0.81)	Gastrointestinal intolerance (16% vs. 7%, P=0.058)
Shah et al., 2020: Acute Colchicine Administration Before PCI - COLCHICINE-PCI Trial	Prospective, randomized, double-blind, placebo-controlled	ACS or stable CAD PCI (n=400)	Colchicine (1.2 mg pre-PCI, 0.6 mg post-PCI)	Placebo	PCI-related myocardial injury at 6-8 and 22-24 hours post-PCI	57.3% vs. 64.2%, P=0.19	Gastrointestinal intolerance (9.3% vs. 3.2%, P=0.001)

Cole et al., 2021: Colchicine to Prevent Periprocedural Myocardial Injury in PCI - COPE-PCI Pilot Trial	Prospective, randomized, double-blind, placebo-controlled	NSTEMI or stable angina (n=75)	Colchicine (1 mg, then 0.5 mg an hour later, 6-24 hours pre-procedure)	Placebo	Periprocedural MI; Secondary measures: Major and minor periprocedural myocardial injury at 24 hours post-PCI	No periprocedural MI occurred in either group; Minor: 58% vs. 85%, P=0.01; Major: 31% vs. 54%, P=0.04	None
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Notes: HR: Hazard ratio; PTCA: Percutaneous transluminal coronary angioplasty; ACS: Acute coronary syndrome; NSTEMI: Non-ST-elevation myocardial infarction; CAD: Coronary artery disease; PCI: Percutaneous coronary intervention; ISR: In-stent restenosis.

TABLE 7: TRIALS ON PATIENTS WITH ATRIAL FIBRILLATION, CORONARY ARTERY DISEASE, AND CEREBROVASCULAR DISEASE

Research Title	Study Type	Target Population	Treatment	Primary Outcome	Planned Follow-Up	Country
Atrial Fibrillation						
COP-AF (Colchicine for the Prevention of Perioperative Atrial Fibrillation) - NCT03310125	Phase 3, prospective, randomized, double-blind	Patients undergoing major thoracic surgery (n=2800)	Colchicine 0.5 mg BID for 10 days	Perioperative atrial fibrillation (POAF)	14 days	Canada
COCS (Colchicine in Cardiac Surgery) - NCT04224545	Phase 4, prospective, randomized, double-blind	CABG or AVR patients (n=1000)	Colchicine 1 mg daily before surgery, and for 2-5 days post-surgery	Perioperative atrial fibrillation (POAF)	7 days	Russia
IMPROVE-PVI Pilot (Impact of Short-Course Colchicine vs. Placebo After Pulmonary Vein Isolation) - NCT04160117	Phase 3, prospective, randomized, double-blind	RFA PVI (n=200)	Colchicine 0.6 mg BID for 10 days	AF recurrence	2 years	Canada
Coronary Artery Disease						
CLEAR SYNERGY (Colchicine and Spironolactone in MI/SYNERGY Stent Registry) - NCT03048825	Phase 3, prospective, randomized, blinded, double-dummy, 2×2 factorial design	STEMI or NSTEMI post-PCI (n=7000)	Colchicine 0.5 mg BID + Spironolactone 25 mg daily, SYNERGY Bioabsorbable Polymer Drug-Eluting Stent	Major adverse cardiovascular events (MACE)	1 year	New York, USA
COLCARDIO-ACS (Colchicine Effects on Cardiovascular Outcomes in ACS) - ACTRN12616000400460	Prospective, randomized, double-blind, placebo-controlled	ACS + hs-CRP >2 mg/L, 4-6 weeks post-event (n=3000)	Colchicine 0.5 mg daily for 3 years	Cardiac events	3 years	Australia
Effect of Colchicine in Patients with Myocardial Infarction - NCT04218786	Phase 2, prospective, randomized, double-blind	ACS (n=800)	Colchicine 0.5 mg daily for 3 months	MACE	3 months	Pakistan
PCI ORCA (Oral Colchicine in Argentina to Prevent Restenosis) - NCT04382443	Phase 4, prospective, randomized, open-label	PCI (n=450)	Colchicine 0.5 mg BID for 3 months + BMS or DES	MACE	1 year	Argentina
Cerebrovascular Disease						
CONVINCE (Colchicine for Prevention of Vascular	Phase 3, prospective,	Stroke/TIA (n=2623)	Conventional treatment +	MACE	60 months	Ireland

Inflammation in Noncardio Embolic Stroke) - NCT02898610 CASPER (Colchicine After Stroke to Prevent Event Recurrence) - Registration ID TBD	randomized, open-label Prospective, randomized, double-blind, placebo-controlled	Stroke/TIA + hs-CRP >2 mg/L, 4-6 weeks post-event (n=unknown)	Colchicine 0.5 mg daily for 60 months Conventional treatment + Colchicine 0.5 mg daily for 60 months	MACE	TBD	Australia
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The trials collectively indicate that colchicine holds significant potential for cardiovascular disease management, supporting it's evolving role from a historical gout remedy to a modern anti-inflammatory cornerstone in cardiovascular therapy.

Controversies and Debates:

TABLE 8: CONTROVERSIES AND CURRENT RESEARCH GAPS

Controversy	Discussion
Long-Term Safety	Limited long-term data on potential cumulative toxicity
Adverse Impact on Lipid Profiles	Conflicting evidence on colchicine's effect on cholesterol levels
Efficacy in Perioperative AF	Mixed trial outcomes raise questions about perioperative benefits.
Drug Interactions	Risk of toxicity when combined with CYP3A4 or P-glycoprotein inhibitors

Efficacy Concerns in Perioperative Atrial Fibrillation: Perioperative atrial fibrillation (AF) presents a significant challenge in cardiovascular medicine, with ongoing debates about colchicine’s efficacy for its management. The COP-AF trial showed promising results, indicating a reduction in postoperative AF due to colchicine's anti-inflammatory effects. However, conflicting data from other studies complicate the assessment of colchicine's true efficacy. Some trials have shown limited or no benefit, attributed to varying study designs, patient populations, dosing regimens, and surgical procedures.

The divergence in outcomes has sparked a discussion about the broader applicability of colchicine in preventing perioperative AF. Factors influencing these mixed results include differences in patient inflammatory states, surgery types (e.g., cardiac vs. non-cardiac), and the baseline cardiovascular risk profile of the participants. To clarify its role, more rigorous and large-scale

randomized controlled trials are needed. These studies should aim to identify specific patient subgroups and surgical scenarios where colchicine might offer the most benefit.

Side Effects Including Diarrhoea and Lipid Profile Changes: Despite its potential benefits, colchicine is not without drawbacks, especially concerning gastrointestinal side effects. Diarrhea is one of the most frequently reported adverse events, often dose-dependent, leading to patient non-compliance or discontinuation. Gastrointestinal issues can sometimes be mitigated by adjusting the dose or timing of administration.

Beyond gastrointestinal effects, concerns have arisen about colchicine's impact on lipid metabolism. Studies have reported changes in lipid profiles, such as increased LDL cholesterol and decreased HDL cholesterol, complicating its use in patients already at high cardiovascular risk. While these changes are not uniformly observed across all patients, they underscore the need for careful monitoring.

Additionally, colchicine can induce myopathy and neutropenia, particularly when used with other medications like statins or macrolide antibiotics. These risks necessitate careful patient selection, dose adjustments, and comprehensive monitoring to ensure safety and minimize adverse outcomes ²⁹.

Considerations for Specific Populations (Renal, Liver Disease): Colchicine's narrow therapeutic window requires extra caution when prescribing it to patients with pre-existing renal or hepatic impairment. In individuals with renal dysfunction, colchicine clearance is significantly reduced, increasing systemic exposure and the risk of toxicity. Similarly, in patients with liver disease, impaired metabolism can lead to accumulation and enhanced adverse effects. This pharmacokinetic profile necessitates careful dosing adjustments and

frequent monitoring. Patients with end-stage renal disease or significant hepatic impairment are often excluded from colchicine trials due to their higher risk of severe adverse effects, like myopathy, rhabdomyolysis, and neutropenia. Clinical experience and evidence in these groups are limited, leaving clinicians to rely on pharmacologic principles and small-scale studies.

In light of these factors, dose adjustments or alternative therapies may be warranted for patients with severe renal or hepatic impairment. Healthcare professionals must balance potential benefits against risks in these populations and consider additional factors like drug-drug interactions and comorbidities that may affect the overall treatment plan. These controversies and debates reflect colchicine’s complex pharmacological profile and varied impact on different patient populations. A personalized approach, guided by ongoing research, is crucial to optimizing its use. Further studies are essential to define its role in perioperative AF and better understand its side effects and safety in specific populations. Comprehensive clinical monitoring, patient education, and evidence-based practice are necessary when integrating colchicine into modern cardiovascular treatment strategies.

Effects on Various Organ Systems:

TABLE 9: COLCHICINE'S ADVERSE EFFECTS ON DIFFERENT ORGAN SYSTEMS

Organ System	Adverse Effects
Gastrointestinal	Diarrhea, nausea, vomiting, abdominal pain
Neuromuscular	Myopathy, rhabdomyolysis
Hematologic	Bone marrow suppression, anemia
Dermatologic	Rash, alopecia
Hepatic	Hepatotoxicity

Cardiovascular System: Colchicine’s anti-inflammatory properties make it a promising therapeutic agent for cardiovascular diseases. By inhibiting microtubule assembly and reducing the activation of neutrophils and inflammasomes, colchicine attenuates inflammation, which plays a significant role in atherosclerosis and myocardial infarction. Trials like COLCOT and LoDoCo2 have documented colchicine's potential to stabilize atherosclerotic plaques and limit cardiac inflammation, showing a reduction in cardiovascular events. However, the long-term

effects of colchicine on the cardiovascular system require further investigation, particularly in patients with pre-existing cardiovascular conditions.

Central Nervous System (Brain): Research into colchicine's effects on the central nervous system (CNS) is still emerging. Colchicine can cross the blood-brain barrier and affect microtubule stability, which may have implications for neuroinflammation. In rodent models, colchicine-induced cognitive impairment has been linked to neurotoxicity, potentially contributing to oxidative stress and neurodegenerative processes. However, these findings have not been fully confirmed in humans. Further research is necessary to elucidate its precise effects on the CNS and determine whether it may exacerbate or alleviate neuroinflammatory conditions.

Renal System: Colchicine's narrow therapeutic index is particularly significant for renal health. The drug is largely excreted via the kidneys, and impaired renal function can lead to increased serum concentrations and a higher risk of adverse effects. Colchicine nephrotoxicity, though rare, has been reported and can manifest as acute renal failure, especially in patients with existing kidney disease. Consequently, dose adjustments and frequent monitoring are essential when prescribing colchicine to patients with renal impairment. Despite these concerns, colchicine may have a protective role in reducing renal inflammation associated with gout and some autoimmune conditions.

Liver: The hepatic metabolism of colchicine makes liver function a critical consideration. In cases of liver impairment, colchicine may accumulate to toxic levels, increasing the risk of side effects. Hepatotoxicity is rare but possible, particularly in patients with pre-existing liver disease. Liver injury typically presents as elevated transaminase levels. Despite the potential risks, colchicine has shown benefits in liver conditions involving inflammation, such as non-alcoholic fatty liver disease (NAFLD) and cirrhosis. Clinicians should closely monitor liver enzymes and adjust doses in patients with liver dysfunction.

Vessels and Circulation: Colchicine's anti-inflammatory and anti-thrombotic properties extend

to its effects on the vascular system. The drug reduces the expression of adhesion molecules on endothelial cells and inhibits platelet activation, thereby decreasing platelet aggregation and subsequent thrombus formation. These mechanisms can potentially reduce the risk of venous thromboembolism and improve outcomes in inflammatory vasculitis. However, colchicine's impact on circulation requires careful patient monitoring due to its potential to interact with medications like anticoagulants, increasing the risk of bleeding ²⁰.

TABLE 10: COMPARISON OF CLINICAL OUTCOMES ACROSS COLCHICINE TRIALS

Outcome	COLCOT	LoDoCo2	COPS	COP-AF
CV Death Reduction (%)	1.8	1.5	N/A	N/A
Myocardial Infarction (%)	3.4	3.1	N/A	N/A
Stroke Reduction (%)	0.8	1.0	N/A	N/A
Perioperative AF Reduction	N/A	N/A	Significant	Not significant

In summary, colchicine's effects on various organ systems highlight the importance of a nuanced understanding of its pharmacokinetics and pharmacodynamics. While offering significant therapeutic benefits, particularly in cardiovascular diseases, its use should be tailored carefully to each patient's clinical profile to minimize adverse effects and maximize efficacy.

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