RESEARCH PAPER

Effect of Colchicine Treatment in Primary Percutaneous Coronary Intervention for ST Segment Elevation Myocardial Infarction

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ABSTRACT

Background: Inflammation during primary percutaneous coronary intervention (PCI) has negative outcomes. Colchicine's anti-inflammatory effects may reduce cardiovascular risks in acute myocardial infarction, but evidence post-PCI is limited.

Aim: The efficacy of colchicine therapy in reducing inflammation and adverse ischemic cardiovascular events in patients with ST segment elevation myocardial infarction (STEMI) managed by primary PCI.

Methods: A randomized, controlled patients with STEMI were randomly assigned to the intervention colchicine group in addition to standard therapy versus the other group who received the standard therapy alone. The primary end point was a composite of all death, spontaneous myocardial infarction (MI), resuscitated cardiac arrest, ischemic stroke, ischemia-driven coronary revascularization or hospitalization for unstable angina at 6 months follow up. The secondary end points were components of the primary end point and the group difference in cardiac systolic function by echocardiography from baseline to 1 month after PCI.

Results: A total of 267 patients underwent randomization during February 2022 to February 2024; 89 patients were randomized into the colchicine group, 93 patients in the control groups and 85 patients were excluded. The primary-outcome event was similar between both groups (21 events in colchicine group Vs 26 events in control group, Log Rank test 0.451). The incidence of individual components of the primary outcome appeared to be similar in the two groups. There was no difference in systolic function by echocardiography between the two groups.

Conclusions: The addition of colchicine did not yield a significant benefit in enhancing the outcomes of patients with STEMI at a 6-month follow-up.

Keywords: Colchicine, Primary PCI, STEMI, Cardiovascular events

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INTRODUCTION

Inflammation plays a crucial role in atherosclerosis, leading to acute ischemic issues. In myocardial infarction, decreased blood flow triggers an inflammatory response, activating immune cells and releasing pro-inflammatory cytokines. This inflammation influences post-MI cardiac remodeling, infarct size, and the risk of heart failure [1,2].

Inflammatory activity during PCI increases the risk of myocardial injury. Mechanical stress causes neutrophils to accumulate at damaged sites, worsening inflammation, endothelial function, and microvascular obstruction. Reducing inflammation may help MI patients [3,4].

Colchicine is a cardiovascular treatment with strong anti-inflammatory properties. This affordable oral drug controls inflammation by inhibiting tubulin polymerization and affecting adhesion molecules and the inflammasome pathway [5,6].

Colchicine, added to standard treatment, reduced major cardiovascular events in ACS and stable CAD patients. However, the COPS trial showed no significant outcome improvement after 12 months, and the COLCHICINE-PCI trial indicated that short-term use before PCI didn't lower myocardial injury or cardiac events[7–9].

Therefore, the main objective of the study to test the hypothesis that patients with STEMI who are treated with primary PCI and on low dose colchicine would have significantly lower risk of cardiac events at 6 months.

Patients and Methods

This was an open label controlled interventional study to patients presented with STEMI in Suez Canal university hospitals. Patients were recruited during their index admission with STEMI and primary PCI was performed with the culprit lesion was the occluded artery consistent with the ECG changes.

We excluded patients with known ischemic cardiomyopathy, known hypersensitivity to colchicine, severe renal dysfunction, cardiac arrest or cardiogenic shock as presenting symptoms and history of cardiac bypass surgery (CABG).

Intervention group received a loading dose of 1.0 mg before primary PCI then 0.5 mg once daily in addition to the standard therapy for 1month. Demographic, clinical, echocardiographic, coronary angiographic and laboratory data at admission were gathered and recorded in a computerized database. It contains detailed information regarding the procedure details, lesion characteristics, and periprocedural complications. The left ventricular ejection fraction was assessed by echocardiography before discharge and after 1 month.

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All patients were instructed to maintain their prescribed medications, and a telephone call was performed at 24 h and 3 days after discharge, and those who reported symptoms were instructed to return for assessment. Thereafter, clinical follow up was scheduled at 1, 3, & 6 month of the index procedure unless earlier visits were clinically required.

Ethical consideration

Approval of the ethical institutional committee of Suez Canal University-Ismailia-Egypt was taken before conducting the study. Informed consent was obtained from all individual participants included in the study between February 2022 to February 2024.

All steps of the study were explained to the patients, presented in terms and a form that they could fully understand. This includes any information about the possible benefits and risks to the patient with all its possible complications. All patients knew the potential side effects of colchicine therapy. All personal information was coded as early as possible in data processing and personal information was regarded as confidential.

Procedural Techniques

Percutaneous coronary intervention was performed using 6 F guiding catheters. Rt. radial approach was used as the default, and Lt. radial, Rt femoral accesses were used in some patients if clinically dictated or as per physician preferences. All patients were pretreated with aspirin, in addition to either 600 mg dose of clopidogrel or 180 mg ticagrelor before the procedure. A 3000 IU /kg heparin was given through the radial arterial sheath with a total dose of 70-100 IU/Kg/hour during procedure. A visually estimated diameter stenosis severity of ≥70% for non–left main disease and ≥50% for left main disease has been used to define significant stenosis. Culprit artery was defined by infarct related artery with filling thrombus. Tirofiban was considered for bail-out if there is evidence of no-reflow or a thrombotic complication. Dual antiplatelet therapy (DAPT) consisting of ticagrelor or clopidogrel in addition to aspirin was recommended for 12 months. Quantitative 2D and Doppler echocardiograms were performed before discharge and at 1 month follow up. The study included 2D assessment of left ventricle, assessment of diastolic function and the valves. The assessment of ejection fraction of left ventricle was estimated by M-Mode and visual assessment [10–12].

Study Outcomes, Comorbid Conditions, and Confounders

The primary end point was a composite of all death, spontaneous MI, resuscitated cardiac arrest, ischemic stroke, ischemia- driven coronary revascularization or hospitalization for unstable angina at 6 months follow up.

Secondary end points were individual components of primary outcomes and the group difference in cardiac systolic function by echocardiography from baseline to 1 month after primary PCI.

Statistical analysis

Data was analyzed using the statistical package for the social sciences (version 25.0; SPSS Inc., Chicago, Illinois, USA). Data was expressed as the mean ± SD for continuous variables and as frequency and percentage for categorical variables. Inter-group comparison of categorical variables was done by chi-square statistics or Fisher's exact test, and continuous variables were assessed by Student's t-test. Kaplan-Meier survival curve was constructed, and the log-rank test was used for comparison. For time-to-event analyses, event time was calculated as time from was based on the time from randomization to the first occurrence of any component of the primary composite end point. P value of ≤ 0.05 was considered statistically significant.

Results

A total of 267 primary PCIs were admitted directly from the emergency department with diagnosis of STEMI. We excluded 85 patients; (12 patients with cardiogenic shock, 13 patients presented with aborted cardiac arrest , 9 patients with chronic kidney disease, 3 patients with CABG, 11 patients received thrombolysis, 19 patients refused to participate and 18 patients were loss follow up . The remaining 182 patients were classified into two groups; Colchicine group (89 patients) who received colchicine therapy in addition to standard therapy; Placebo group (93 patients); which received the standard therapy.

Most of our patients were males (80.2%) with a mean age of 57.4± 10.05 years. A total of 6.0% of patients had previous CAD, 45.6% had hypertension, and 47.2% had diabetes mellitus. Both groups were similar in the baseline demographic characteristics **(Table 1)**.

Both groups showed no statistical differences in the laboratory data except for platelet count which, despite being within normal range in both groups, was statistically higher in the colchicine group **(Table 2)**.

Table 1. Baseline Patients' Characteristics

	Colchicine group (n=89)	**Placebo group (n=93)**	**P value**
Age (years)	57.1 ± 10.05	57.72 ± 12.4	0.714
Gender, n (%) Male Female	 74 (83.1) 15 (16.9)	 72 (77.4) 21 (22.6)	0.332
Active smoker, n (%)	48 (53.9)	46 (49.5)	0.721
Old CVS, n (%)	**2**(2.2)	**1**(1.1)	0.346
CAD, n (%)	5 (5.6)	6 (6.5)	0.227
Diabetes, n (%)	38 (42.6)	48 (51.6)	0.119

Hypertension, n (%)	39 (43.8)	44 (46.3)	0.127
BMI (Kg/mm2)	28.16 ± 0.34	24.65 ± 0.25	0.213

Values are n (%) or mean ± 1SD; CVS, cerebrovascular stroke; CAD, coronary artery disease; BMI, body mass index

Table 2. Laboratory data among the studied patients

	Colchicine group (n=89)	**Placebo group (n=93)**	**P value**
Serum creatinine, mg/dL	0.98 ± 0.31	1 ± 0.29	0.552
Serum potassium, mEq/L	3.78 ± 0.38	3.9 ± 0.51	0.095
Serum sodium, mEq/L	136.58 ± 5.93	135.84 ± 3.33	0.340
Hemoglobin, mg/dL	14 ± 1.66	13.97 ± 1.64	0.923
Platelets, /L	251927.71 ± 67669.89	202447.63 ± 109552.83	0.001*
Hemoglobin A1C, %	6.88 ± 2.07	7.11 ± 1.86	0.468
Cholesterol, mg/dL	190.25 ± 45.38	183.69 ± 43.92	0.343
Triglycerides, mg/dL	138.44 ± 80.58	143.15 ± 69.01	0.684
LDL, mg/dL	125.39 ± 40	122.27 ± 41.76	0.858
HDL, mg/dL	41.48 ± 11.26	43.12 ± 13.19	0.737

Values are mean ± 1SD ; LDL, low-density lipoprotein; HDL, high-density lipoprotein

Both groups showed no statistical differences in majority of procedural characteristics **(Table 3)**. The left anterior descending (LAD) was the predominant target vessel for PCI (54%), followed by right coronary artery (RCA) and left circumflex coronary artery (LCX). Single vessel PCI was performed in 78.7% of the procedures, the majority with single stent technique (69.8%) with no intergroup differences. Complete revascularization was significantly higher in the colchicine group. Furthermore, the amount of dye and fluoroscopy time was significantly higher in the colchicine group. There were no statistically significant differences between both groups regarding procedural complications, including arrythmia, cardiac support, no reflow, distal embolization, dissection and side branch occlusion **(Table 4)**. The frequency of no reflow was 11.8% and the use of bailout IC GbIIb/IIIa inhibitors was 22.2% of cases.

Table 3: Angiographic Characteristics among the studied patients

	Colchicine group (n=89)	**Placebo group (n=93)**	**P value**
LM disease, n (%)	2 (2.2)	4 (4.3)	0.406
Three vessel CAD, n (%)	25 (28.0)	23 (24.7)	0.921
Culprit Vessel, n (%) LAD RCA LCX	 54 (60.7) 24 (27.0) 11 (12.3)	 56 (60.2) 25 (26.9) 12 (12.9)	0.494
Dottering only, n (%)	6 (6.7)	3 (3.2)	0.274
Pre-dilation, n (%)	67 (75.3)	64 (68.8)	0.332
Post dilation, n (%)	30 (33.7)	32 (34.4)	0.921
Single vessel PCI, n (%)	76 (85.4)	83 (89.2)	0.496
Two vessel PCI, n (%)	12 (13.5)	10 (10.8)	
One stent, n (%)	67 (75.3)	74 (79.6)	0.417
Two or more stents, n (%)	22 (24.7)	19 (20.4)	
Total stent length/lesion, mm	30.07 ± 9.28	29.50 ± 7.90	0.654
Pressure of stent, atm	13.79 ± 2.34	14.13 ± 2.67	0.361
Thrombus burden ≥ 4 , n (%)	87 (97.7)	90 (96.7)	0.727
Aspiration use, n (%)	2 (2.2)	1 (1.0)	0.492
Culprit bifurcation, n (%)	5 (5.9)	4 (4.7)	0.732
Complete revascularization, n(%)	66 (74.1)	55 (59.1)	0.045*
Ticagrelor use, n (%)	81 (91.0)	79 (86.0)	0.396
Culprit initial TIMI, n (%) TIMI 0 TIMI I	 53 (59.6) 20 (23.8)	 59 (63.4) 14 (16.6)	0.590

Culprit Final TIMI, n (%) TIMI II TIMI III	 5 (2.3) 82 (92.1)	 6 (6.5) 85 (91.4)	0.762
Beta blocker, n (%)	78 (92.8)	81 (96.4)	0.563
Statins, n (%)	88 (98.9)	90 (96.7)	0.489
Amount of Dye (ml)	136.83 ± 45.74	118.46 ± 42.46	0.006 *
Fluoroscopy Time (minute)	15.01 ± 7.303	11.89 ± 4.649	0.001*
Air Kerma, mGy	49782.04 ± 324111.30	30203.18 ± 153284.09	0.683
DAP, Gy·cm2	140780.31 ± 82899.89	121406.04 ± 70933.52	0.092

Values are n (%) or mean ± 1SD; LM, left main; LAD, left anterior descending artery; LCX, left circumflex artery; RCA, right coronary artery; CAD, coronary artery disease; PCI, percutaneous coronary intervention; Kerma, kinetic energy released per unit mass; DAP, dose–area product.

Table 4: Procedural complications among the studied patients

	Colchicine group (n=89)	**Placebo group (n=93)**	**P value**
Cardiac support, n (%)	5 (5.6)	6 (6.5)	0.813
Arrythmia, n (%)	8 (9.0)	11 (11.8)	0.531
Side branch occlusion, n (%)	3 (3.4)	0	0.074
Distal embolization, n (%)	12 (13.5)	11 (11.8)	0.721
Dissection, n (%)	1 (1.1)	3 (3.2)	0.334
No reflow, n (%)	14 (15.7)	10 (10.7)	0.338
IC GPIIb/IIIa inhibitors, n (%)	24 (27.0)	21 (22.6)	0.493

Values are n (%) ; IC, intra coronary use

There were no statistically significant differences between both groups regarding echocardiographic data **(Table 5)**. There was no difference in the left ventricular ejection fraction at pre-discharge and at 1-month follow up between both groups.
The Kaplan-Meier curve was used for the six-month MACE, which is defined as the composite events of cardiovascular death, spontaneous MI, resuscitated cardiac arrest, ischemic stroke, ischemia- driven coronary revascularization or hospitalization for unstable angina. There was no significant difference between both groups (21 events in colchicine group Vs 26 events in placebo group - Log Rank test 0.451- diagram 1) **(Figure 1)**.
There were no reported cases of stroke or resuscitated arrest during the 6-month follow-up. There was no intergroup statistically significant difference regarding all death, myocardial infarction, target vessel revascularization and hospitalization for unstable angina **(Table 6)**.

Table 5: Echocardiography data among the studied patients

	Colchicine group (n=89)	**Placebo group (n=93)**	**P value**
EF at pre-discharge	0.42 ± 0.1	0.40 ± 0.1	0.926
EF at 1-month follow up	0.47 ± 0.08	0.44 ± 0.06	0.906
ESD, mm	35.68 ± 6.4	37.77 ± 7.06	0.533
EDD, mm	51.86 ± 5.97	54.81 ± 5.56	0.743
LA, mm	45.42 ± 5.18	43.95 ± 4.42	0.910
E velocity, cm/s	88.07 ± 19.6	76.7 ± 22.47	0.464
A velocity, cm/s	90.85 ± 94.19	81.11 ± 20.9	0.325
E/e	8.39 ± 2.13	9.87 ± 2.65	0.927

Values are mean ± 1SD; EF; ejection fraction, ESD; end-systolic dimension, EDD; end-diastolic dimension, LA; left atrium

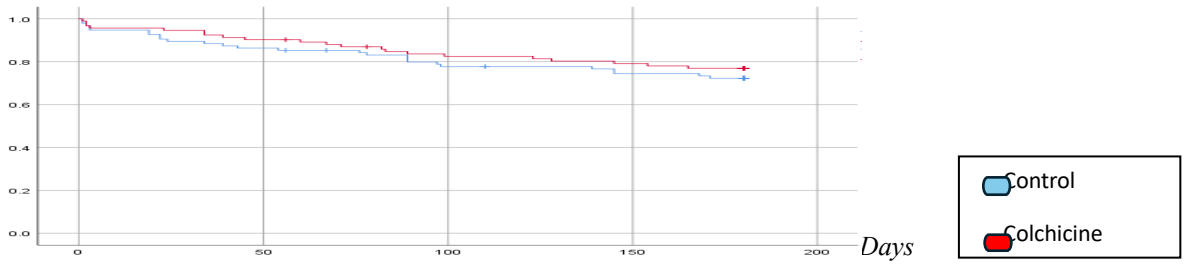

Figure 1: Kaplan-Meier curve with Log Rank test 0.451 indicating primary outcome.

Table 6: Secondary Outcomes among the studied patients

	Colchicine group (n=89)	**Placebo group (n=93)**	**P value**
Death, n (%)	5 (5.6)	7 (7.5)	0.560
Myocardial infarction, n (%)	4 (4.4)	3 (3.2)	0.311
TLR, n (%)	3 (3.3)	2 (2.2)	0.560
Resuscitated arrest, n (%)	0	0	-
Stroke, n (%)	0	0	-
hospitalization for UA, n (%)	11 (12.4)	19 (20.4)	0.079

Values are n (%); TLR; target lesion revascularization, UA; unstable angina

DISCUSSION

The feasibility of colchicine therapy as an adjunct to primary PCI needs careful scrutiny, considering dosing, timing, safety, and drug interactions against benefits.

Our study showed that colchicine administration didn't lower the risk of adverse cardiac events within 6 months follow up. There was no significant difference between both groups for composite events of all death, spontaneous MI, resuscitated cardiac arrest, ischemic stroke, ischemia-driven coronary revascularization or hospitalization for unstable angina. There was no significant difference between both groups regarding individual endpoint components. For procedural characteristics, complete revascularization, the amount of dye and fluoroscopy time were significantly higher in the colchicine group. Both groups received standard medical therapy which includes aspirin, statin, beta blocker and either clopidogrel or ticagrelor.

In agreement with our results, COLCHICINE-PCI randomized trial showed there was also no difference in PCI-related MI or 30-day MACE when a total of 1.8 mg of colchicine was administered before PCI 16. Also agreed with the recently published CLEAR trial, which showed that in patients with acute MI undergoing PCI, daily treatment with colchicine did not reduce MACE at a median follow-up of 3 years compared with placebo[8,13]

In the COPS trial, the investigators found no statistically significant differences between the treatment groups regarding all-cause mortality, cardiovascular death, acute coronary syndromes, or stroke during the initial 12-month follow-up period. However, at the 2-year follow-up, the colchicine group demonstrated a meaningful reduction in the primary endpoint, driven largely by a decrease in urgent revascularization. The study also noted an increase in non-cardiovascular deaths among patients receiving colchicine—an observation that was not seen in our study[14,15].

Similarly, our findings align with the follow-up analysis of the COVERT-MI trial, which showed no meaningful difference between colchicine and placebo groups in the rate of major adverse cardiovascular events at one year. Although that study reported a higher occurrence of left ventricular thrombus in patients receiving colchicine—likely related to larger infarct size—our results did not reveal any difference in thrombosis rates between the colchicine-treated group and the control group[16].

Unlike our findings, the COLCOT trial provided strong evidence for the benefit of once-daily colchicine in patients with a recent ACS event. In COLCOT, individuals treated with colchicine had significantly fewer primary endpoint events, largely due to reductions in stroke and urgent revascularization. However, when hospitalizations for angina-related revascularization were excluded, the decrease in primary endpoint events was no longer statistically significant. In our study, colchicine was administered for only one month, and although hospitalizations for unstable angina were numerically lower in the colchicine group, this difference did not reach statistical significance[7].

In contrast, the LoDoCo2 trial reported a significant reduction in its primary endpoint among patients treated with colchicine. Participants receiving colchicine experienced markedly lower rates of spontaneous myocardial infarction, ischemia-driven coronary revascularization, and cardiovascular mortality. Nonetheless, the study also observed a higher rate of non-cardiovascular deaths in the colchicine group compared with placebo. It is important to note that LoDoCo2 included patients with established coronary artery disease who had been clinically stable for at least six months. In our study, however, only individuals with ST-elevation myocardial

infarction were enrolled, and those with chronic stable coronary disease were specifically excluded [9].

This study was a randomized pilot trial which is limited by a small population size and was not powered to demonstrate differences in long-term clinical end points and, therefore, generalizing these results should be done with caution. This was an open label study with both the researcher and participants were not blinded to their allocation with respect to study drug. The primary outcome of our study was limited to a 6-month follow-up. Majority of population enrolled within the study were male, so it limits the interpretation for women undergoing primary PCI. The lack of inflammatory markers is due to cost constraints and availability. In addition, longer duration or larger doses of colchicine therapy may yield different results.

CONCLUSIONS

Colchicine demonstrated no substantial enhancement in outcomes for patients with ST-Elevation Myocardial Infarction (STEMI) after a six-month follow-up.

List of Abbreviations

ACS	Acute Coronary Syndromes
CABG	Cardiac Bypass Surgery
CAD	Coronary Artery Disease
DAPT	Dual Anti-Platelet Therapy
LAD	Left Anterior Descending Artery
LCX	Left Circumflex Coronary Artery
MACE	Major Adverse Cardiovascular Events
MI	Myocardial Infarction
PCI	Percutaneous Coronary Intervention
RCA	Right Coronary Artery
STEMI	ST Segment Elevation Myocardial Infarction

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