week 52. Hospitalization due to worsening HF was significantly reduced with FCM compared with placebo.

The secondary end points of self-reported Patient Global Assessment (PGA) score and NYHA class improved early and were sustained at week 52. The odds ratio for PGA was >1 at week 6 and week 52 with FCM vs placebo (P=.29 and P=.001, respectively). The odds ratio for change in NYHA class was >1 at week 6 and week 52 (P=.067 and P<.001, respectively).

Dr Ponikowski concluded that treatment of iron deficiency with FCM in symptomatic HF patients resulted in sustained improvement in functional capacity, symptoms, and quality of life and resulted in a reduction in HF hospitalizations.

POPE-2: No Benefit With Colchicine to Reduce Persistent Postoperative Pericardial Effusion

Written by Mary Mosley

Postoperative pericardial effusion (POPE) is present within the first 7 days after cardiac surgery in 50% to 80% of patients, and the risk for early cardiac tamponade ranges from 0.5% to 1%. There is no drug that can treat this local hemorrhagic complication, stated Philippe Meurin, MD, Les Grands Prés, Villeneuve Saint Denis, France. From day 8, patients with POPE are at risk for persistence of the effusion, with the risk for tamponade dependent on its size. Although nonsteroidal anti-inflammatory drugs do not reduce persistent POPE, it is unknown whether the anti-inflammatory drug colchicine (COL) might be effective. COL has been shown to be effective in treating other pericardial conditions, including acute pericarditis [Imazio M et al. *N Engl J Med.* 2013] and postpericardiotomy syndrome [Imazio M et al. *Eur Heart J.* 2010].

The Colchicine Treatment for Post-operative Pericardial Effusion [POPE-2; NCT01266694] was a double-blind, placebo-controlled study to evaluate whether COL could reduce the volume of POPE. Conducted at 10 cardiac rehabilitation centers in France, the trial randomized 197 patients with moderate to large pericardial effusion (ie, grades II, III, and IV) on admission echocardiography (8 to 30 days after surgery) to a 14-day treatment course of placebo (n=99) or COL (n=99). The dose of COL was adjusted according to patient weight; all patients received 1 mg/day, except those who weighed ≥70 kg, who received an additional 1 mg on day 1. The primary end point was the change in mean pericardial effusion grade (MPEG) in the COL arm relative to placebo.

The patients has a mean age of 65 years, and most were men, 89% and 84% of the placebo and COL groups, respectively. At baseline, both groups were similar for the proportion of patients with grade II, III, and IV effusions and for MPEG.

Table 1. Primary End Point of Decrease in Mean Pericardial Effusion Grade

	Placebo Group	Colchicine Group	Mean Change (95% CI)	*P* Value
Baseline	2.9 ± 0.8	3.0 ± 0.8	NA	NA
Final	1.8 ± 1.3	1.7 ± 1.2	NA	NA
Change	−1.1 ± 1.3	−1.3 ± 1.3	−0.19 (−0.55 to 0.16)	.23

NA, not applicable.

The difference in the reduction of MPEG between the arms was not significant (Table 1).

Development of cardiac tamponade after 14 days of treatment did not significantly differ (log-rank P=.801) between the arms; neither did the requirement for pericardial drainage within 6 months (log-rank P=.202). The proportion of patients who had a ≥1-MPEG decrease was nonsignificant between the arms (67% and 74% of the placebo and COL groups, respectively; P=.27), as was the presence of atrial fibrillation at the end of the study (12% and 15%, respectively; P=.51). The reductions in the width of the echo-free space were similar at –4.7 and –5.8 mm in the placebo and COL groups, respectively (P=.23).

Furthermore, no difference was found with COL in any of the prespecified subgroups, including C-reactive protein level ≥30 mg/L and receiving an oral anticoagulant or in the per protocol analysis.

The POPE-2 study confirmed that a moderate to large POPE persisting >7 days is a serious condition, with cardiac tamponade occurring in 13 patients (6.6%) and pericardial drainage within 6 months occurring in 22 patients (11.2%) across both arms. COL did not provide any benefit either by echocardiography or on clinical events.

COPPS-2: Colchicine Reduced PPS in Cardiac Surgery Patients

Written by Mary Mosley

Colchicine (COL) administered perioperatively in patients undergoing cardiac surgery reduced the incidence of the primary end point of postpericardiotomy syndrome (PPS) compared with placebo. Secondary end points of postoperative atrial fibrillation (POAF) and postoperative pleural and pericardial effusions were not significantly reduced in an investigator-initiated,