

# **Colchicine for Post-operative Pericardial Effusion (POPE):**

## **The Post-Operative Pericardial Effusion-2 (POPE-2) Study.**

### **A Multicenter, double-blind, randomized Trial**

P. Meurin<sup>1</sup>, S. Lelay-Kubas, B. Pierre, H. Pereira,  
B. Pavy, MC. Iliou, JL. Bussiere, H. Weber , JP. Beugin,  
T. Farrokhi, A Bellemain-Appaix, L. Briota, JY. Tabet,  
for the French Society of Cardiology.

(1) Les Grands Prés; Villeneuve Saint Denis, France



# Disclosures

- ✓ Concerning this study: no conflict of interest
  - All the authors/investigators worked for free
  - Main funding source: French Society of Cardiology
  - Mayoly-Spindler company provided the study's drug and placebo
  
- ✓ Other relationships with pharmaceutical companies:
  - Consultant for Servier
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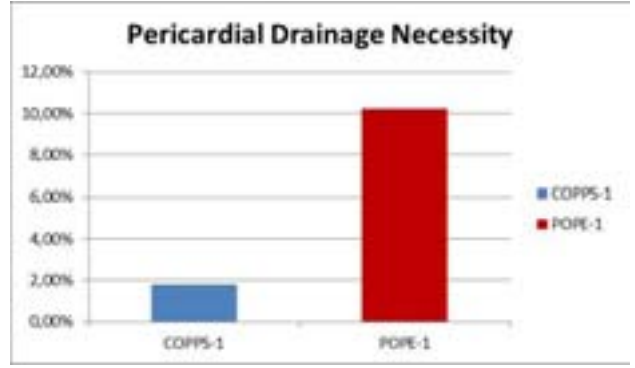
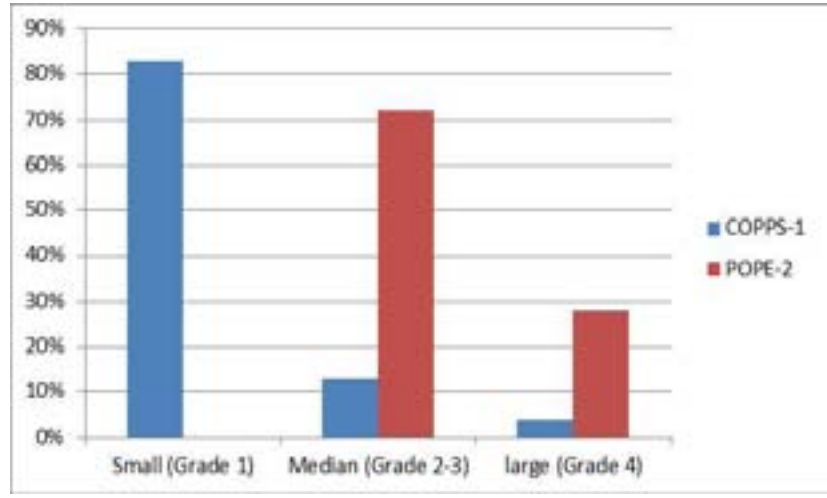
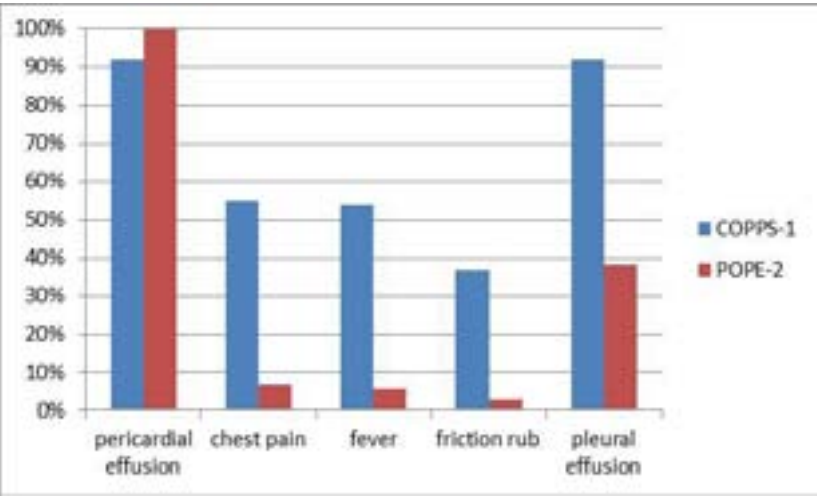
# Background: Post Operative Pericardial Diseases after day 7: PPS(post pericardiotomy syndrom) and POPEs are very different

Symptoms:

PPS: yes  
POPEs:

Effusions:

PPS: no or small  
POPEs: yes, larger



**To sum-up:**

- PPS: acute pericarditis but low Tamponade Risk
- POPEs: initially asymptomatic but high Tamponade Risk

1- Meurin et al. POPE-1 Study. Ann Intern Med 2010. 2- Imazio et al. COPPS-1 Study. Eur Heart J 2010. 3- Imazio et al Am J Cardiol. 2011

# POPE-2 Study: methods (1)

- ✓ **Objective:** to assess whether colchicine was effective in reducing post operative pericardial effusion (POPE) volume.
- ✓ **Design:** multicenter, randomized, double-blind, placebo-controlled study
- ✓ **Setting:** Ten post operative cardiac rehabilitation centers (POCRC).
- ✓ **Patients:** 197 patients at high risk of tamponade: i.e with a POPE of Grade 2,3 or 4.
- ✓ **Treatment administration:** 14 days (colchicine or placebo)  
- Pts > 70 kg followed by a colchicine or placebo dose of 1 mg daily  
- Pts < 70 kg 1 mg per day without a loading dose

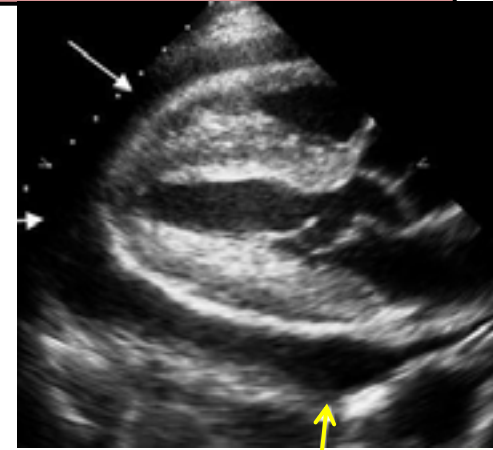
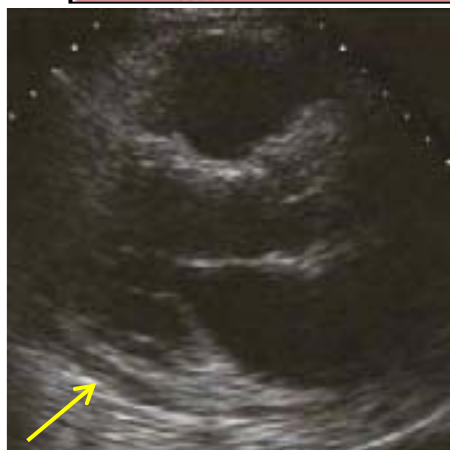


# Methods (2): why did we include only patients with Grade 2,3 or 4 POPEs ?

## Echocardiographic classification 1, 2

Grade at Day 15 (8-29)	Loculated	Circumferential	Estimated Late Tamponade Risk at Day 30
0	0	0	0
1- Small	< 10 mm	0	0
2-Moderate	10-14 mm	< 10 mm	2-7%
3-Medium	15-19 mm	10-14 mm	15%
4-Large	≥ 20 mm	≥ 15 mm	25-45%

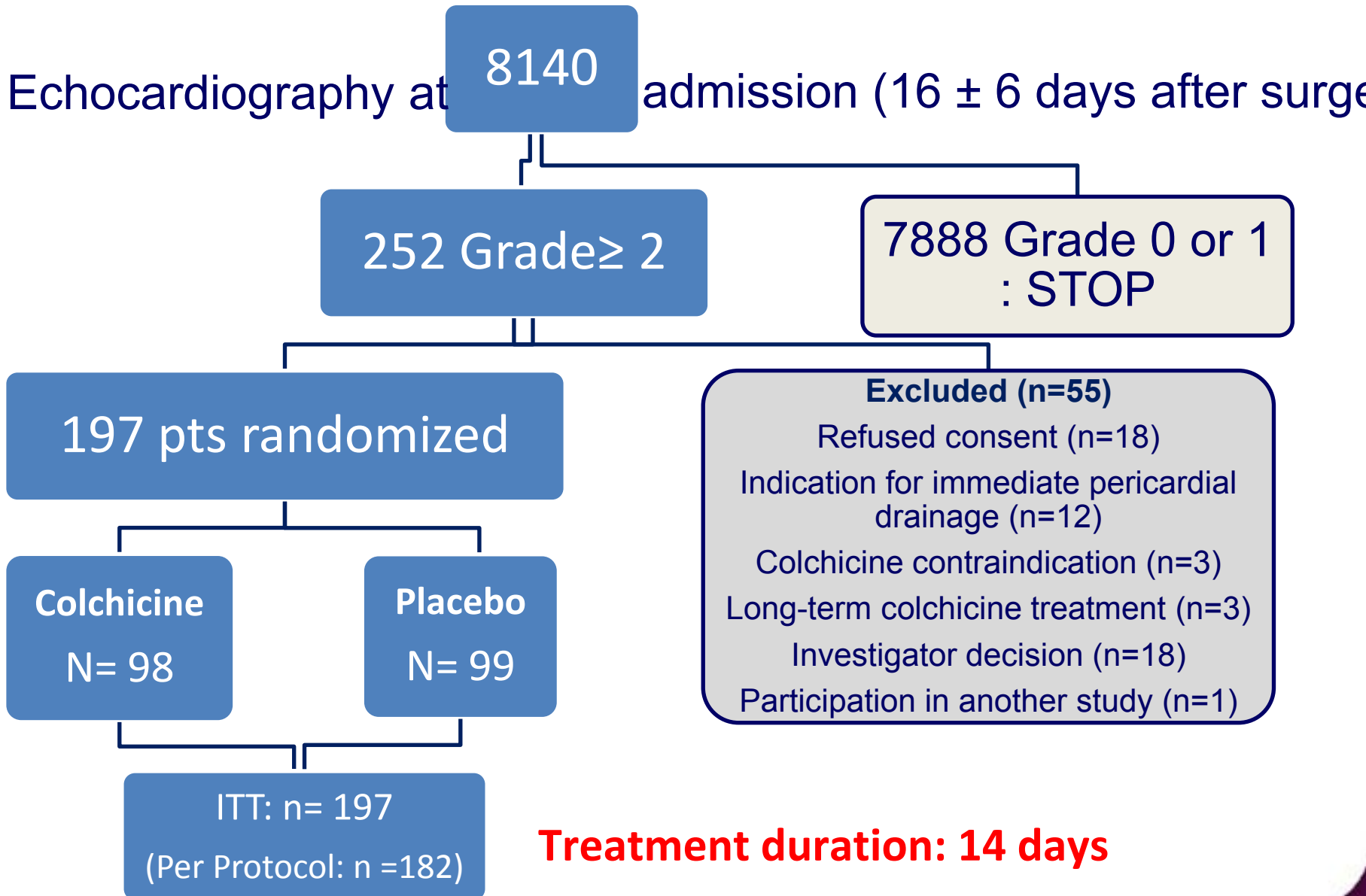
} = 10%



1- Meurin P, Weber H, Renaud N et al. Chest 2004;125:2182-87. 2- Meurin et al. POPE-1 Study. Ann Intern Med 2010

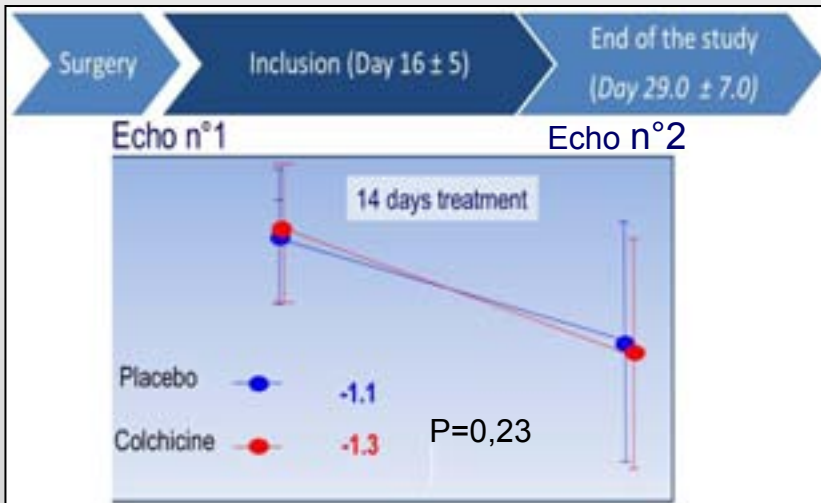


# From April 2011 to March 2013

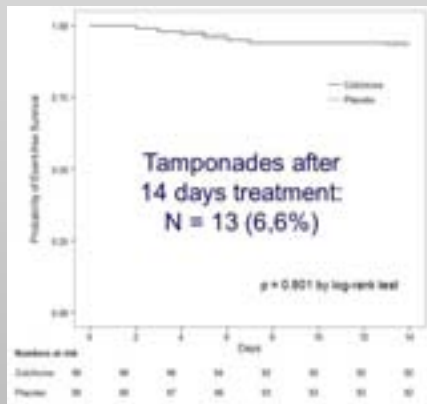


# Results

**Primary Endpoint:  
Mean Pericardial Effusion Grade Decrease**



**Secondary Endpoint: Cardiac Tamponades**



# Conclusion

**Moderate to large persisting (> 7 days) post-operative pericardial effusion:  
What does this study add?**

- 1°) High risk patients: 11,5 % reoperation within 6 months:
  - 6.6 % tamponades in the 2 following weeks
  - Another 5 % will require pericardial drainages within 6 months
- 2°) Colchicine administration seems to be useless

