

# Angiographic Sub-study of the TOTAL trial: a randomized trial of manual thrombectomy during PCI for STEMI

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on behalf of the TOTAL Investigators

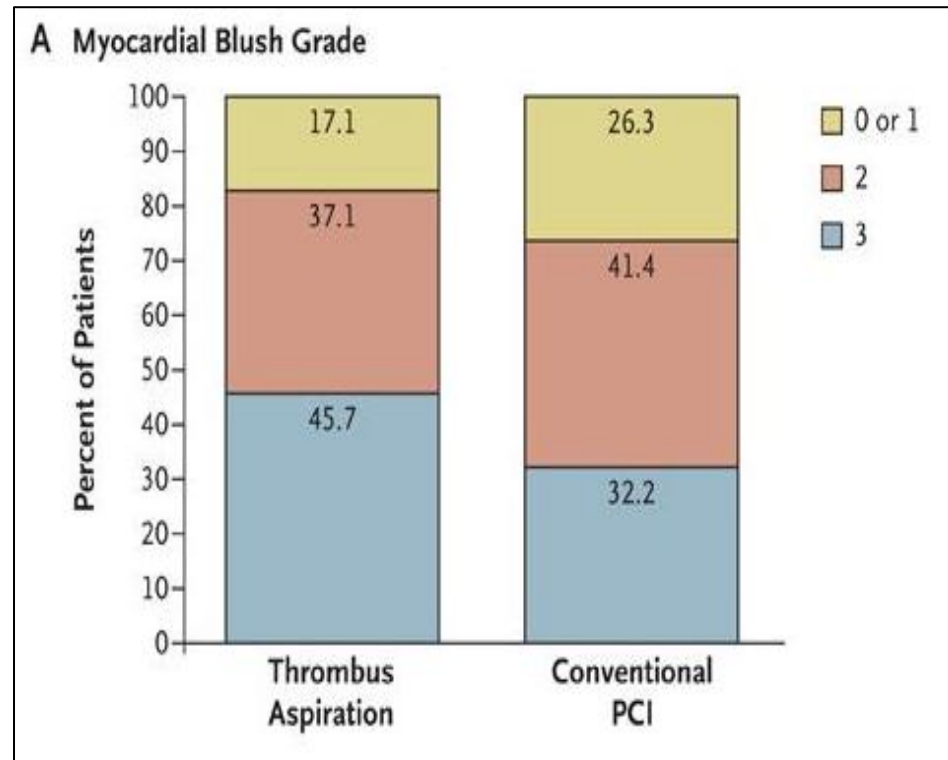
# Disclosures

TOTAL trial was funded by:

- Canadian Institutes of Health Research
- Canadian Network and Centre for Trials Internationally (CANNeCTIN)
- Medtronic Inc.

# Background

- Myocardial blush grade has been shown to predict mortality after primary percutaneous coronary intervention (PPCI)<sup>1</sup>
- Small trials have shown improvement in myocardial blush grade with manual thrombectomy<sup>2</sup>



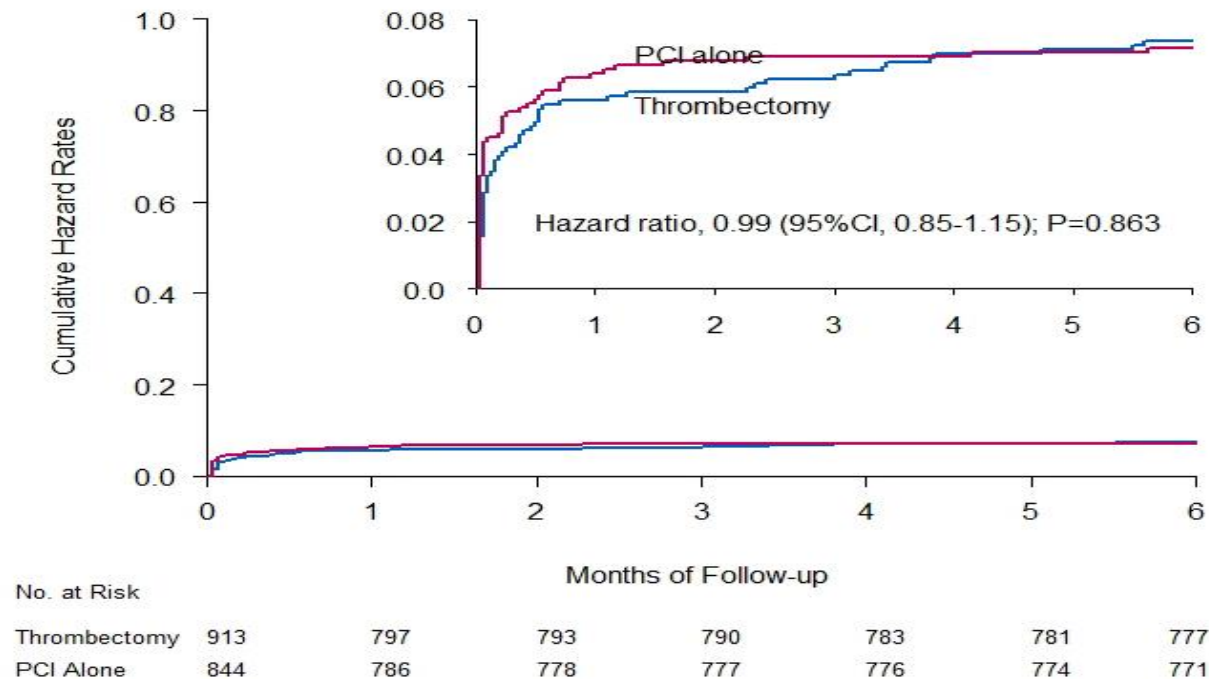
Svilaas T et al. N Engl J Med 2008;358:557-567.

1. Van 't Hof AW *et al* Circulation 1998; 97(23):2302-2306
2. Svilaas T *et al* NEJM 2008; 358 (96): 557-567

# Background

- The TOTAL trial is an international, prospective randomized (multicenter) trial of manual thrombus aspiration (using the Export<sup>®</sup> catheter, Medtronic CardioVascular, Santa Rosa, CA) in STEMI patients versus PPCI alone

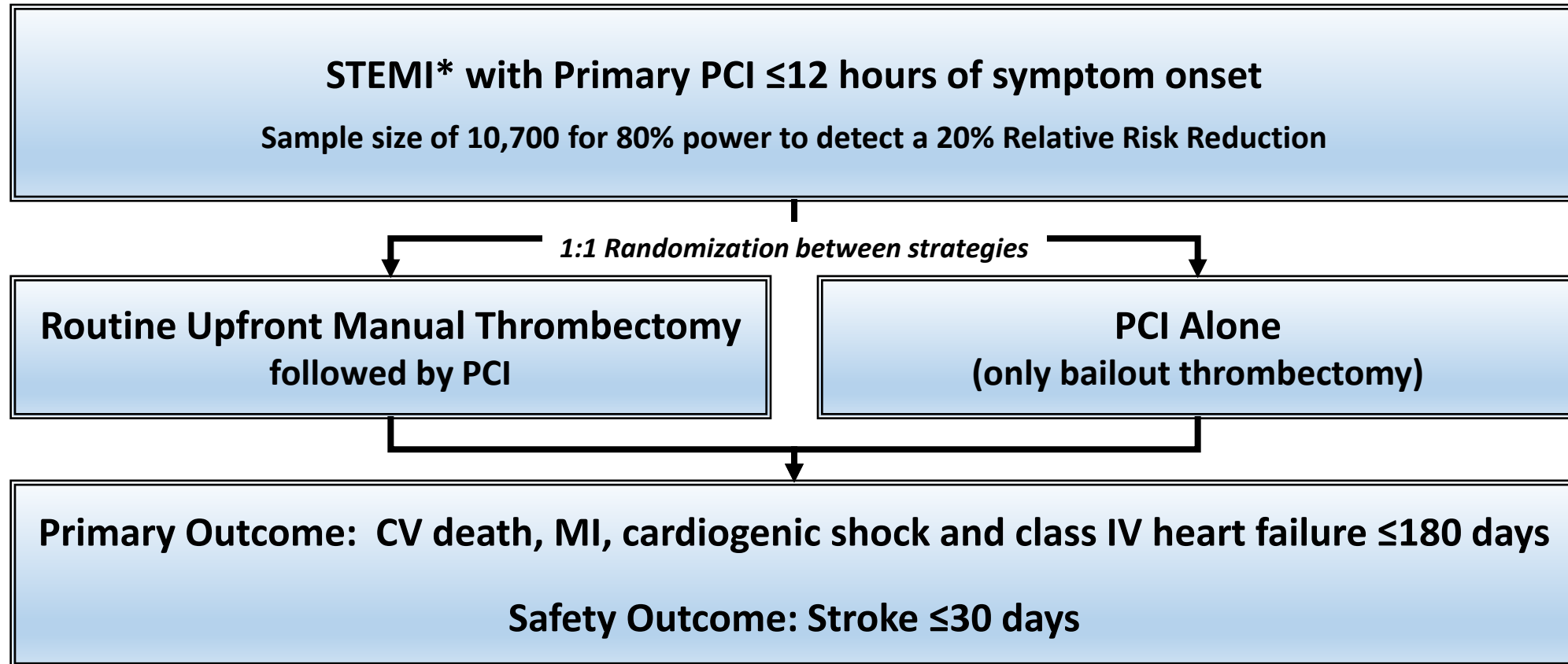
**TOTAL demonstrated no benefit to routine aspiration in patients undergoing PPCI for STEMI**



# Study Questions

- 1) Does manual thrombectomy compared to PCI alone impact:
  - Myocardial blush grade 0/1
  - Final TIMI flow
  - Distal embolization and other angiographic complications
- 2) Are these angiographic outcomes associated with mortality?

# The TOTAL Trial Study Design



**Bailout Thrombectomy allowed if PCI alone strategy fails:**

- Persistent TIMI 0 or 1 flow with large thrombus after balloon pre-dilatation
  - Persistent large thrombus after stent deployment at target lesion

# Methods

- The sub-study randomly selected 1610 patients (791 thrombectomy, 819 PCI only) from the TOTAL cohort (80% power to detect 25% RR reduction MBG 0 or 1 for manual thrombectomy)
- Angiographic parameters were blinded to treatment assignment at the angiographic core lab (Peter Munk Cardiac Centre, Toronto, Canada)

# Primary Outcome

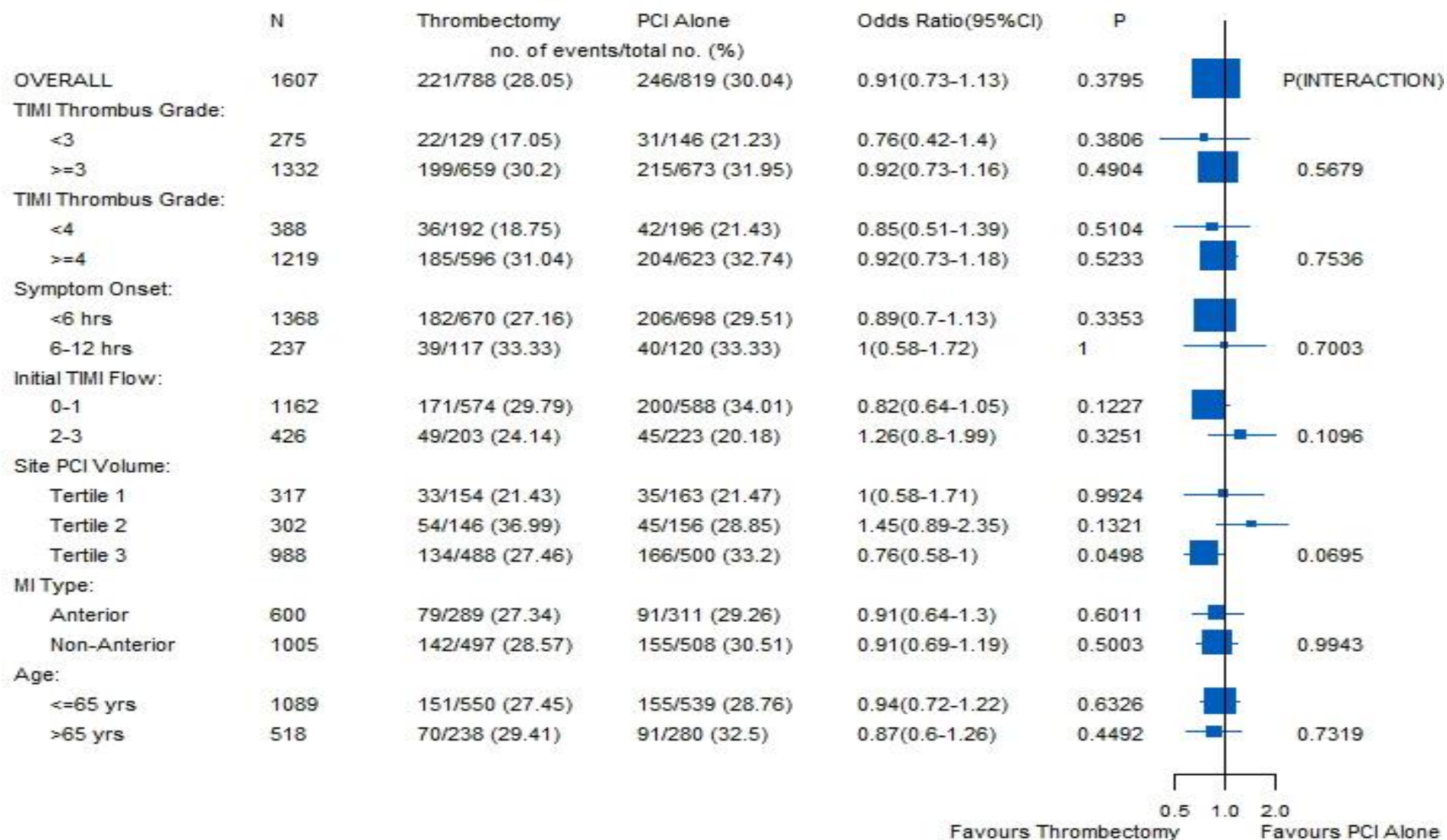
	<b>Thrombectomy (N=791) (%)</b>	<b>PCI alone (N=819) (%)</b>	<b>p value</b>
<b>Myocardial Blush Grade 0,1</b>	<b>221 (28%)</b>	<b>246 (30%)</b>	<b>0.38</b>
<b>Myocardial Blush Grade 2,3</b>	<b>567 (72%)</b>	<b>573 (70%)</b>	<b>0.38</b>
<b>Post PCI TIMI Flow 0</b>	<b>9 (1.1%)</b>	<b>6 (0.7%)</b>	<b>0.4</b>
<b>Post PCI TIMI Flow 1</b>	<b>11 (1.4%)</b>	<b>10 (1.2%)</b>	<b>0.76</b>
<b>Post PCI TIMI Flow 2</b>	<b>59(7.5%)</b>	<b>70 (8.5%)</b>	<b>0.42</b>
<b>Post PCI TIMI Flow 3</b>	<b>712 (90%)</b>	<b>733 (89.5%)</b>	<b>0.73</b>



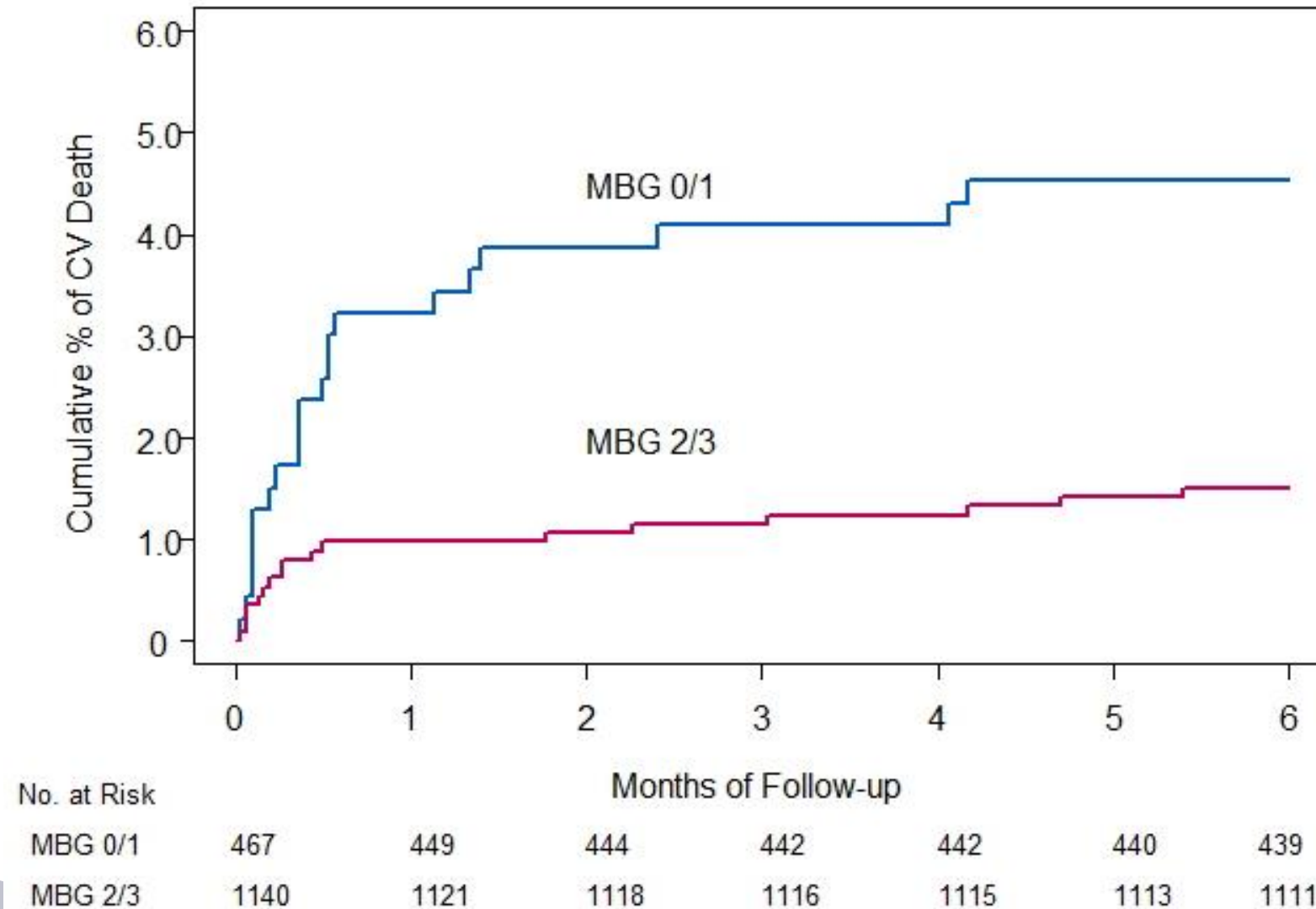
# Secondary Outcomes

	<b>Thrombectomy (N=791) (%)</b>	<b>PCI alone (N=819) (%)</b>	<b>p value</b>
<b>PPCI Complications</b>	<b>94 (11.9%)</b>	<b>126 (15.5%)</b>	<b>0.04</b>
<b>Distal Embolization</b>	<b>56 (7.1%)</b>	<b>87 (10.7%)</b>	<b>0.01</b>
<b>Abrupt IRA Closure</b>	<b>7 (0.9%)</b>	<b>1 (0.1%)</b>	<b>0.02</b>
<b>Perforation</b>	<b>4 (0.5%)</b>	<b>5 (0.6%)</b>	<b>0.78</b>
<b>Dissection</b>	<b>26 (3.3%)</b>	<b>22 (2.7%)</b>	<b>0.48</b>
<b>IRA Sidebranch Closure</b>	<b>7 (0.9%)</b>	<b>9 (1.1%)</b>	<b>0.66</b>
<b>Thrombus Formation</b>	<b>6 (0.8%)</b>	<b>6 (0.7%)</b>	<b>0.95</b>
<b>Transient No-reflow</b>	<b>14 (1.8%)</b>	<b>11 (1.3)</b>	<b>0.49</b>
<b>Left Main Dissection</b>	<b>1 (0.1%)</b>	<b>0 (0 %)</b>	<b>-</b>

# Subgroup Analysis for MBG 0/1

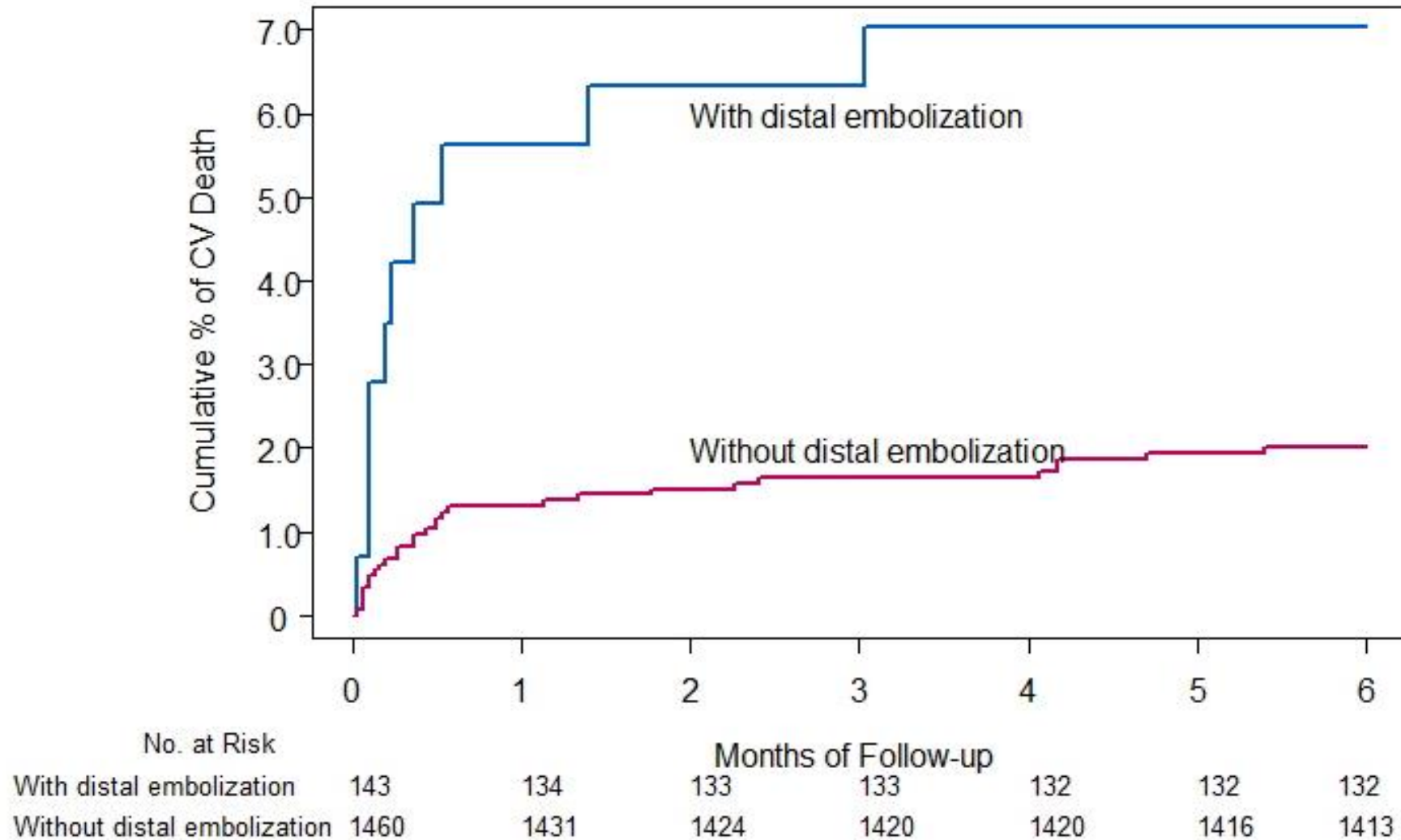


# Myocardial Blush Grade and Mortality



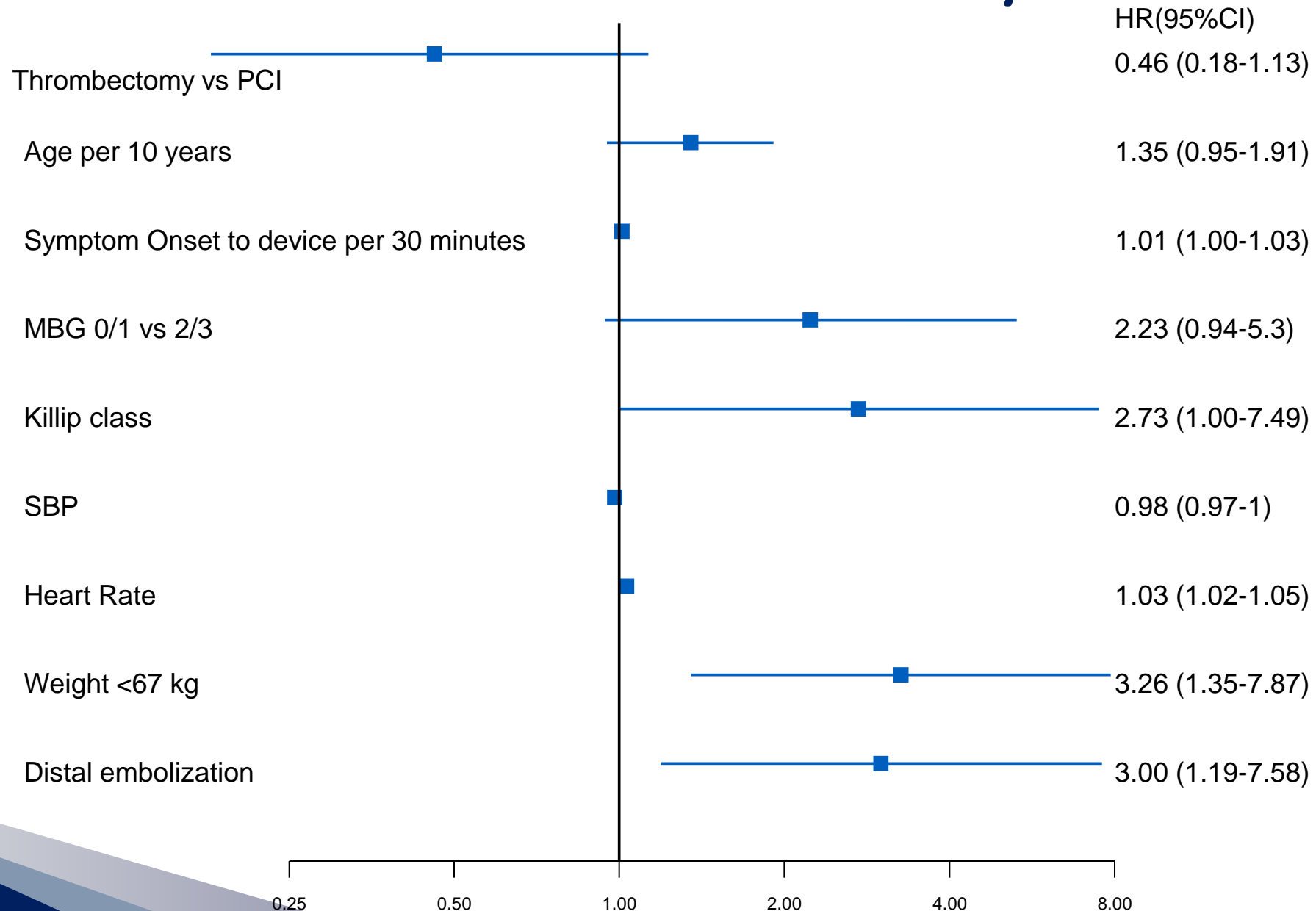
**HR 2.84**  
(95%CI 1.23-6.54)  
P=0.01

# Distal Embolization and Mortality



**HR 3.63**  
(95%CI 1.77-7.46)  
P=0.01

# Independent Predictors of Mortality



# Conclusions

- **Routine thrombectomy did not result in an improvement in final myocardial blush or TIMI Flow following PPCI for STEMI**
- **Routine thrombectomy reduced angiographic distal embolization**
- **Distal embolization was independently associated with mortality in multivariable analysis**
- **distal embolization is an important surrogate endpoint which is less subjective than blush and should be considered in future trials evaluating therapies for STEMI management**