# “Off Hours” Versus “On Hours” Presentation in ST-Segment Elevation Myocardial Infarction: Findings from CHAMPION PHOENIX

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## INTRODUCTION

- Several analyses have demonstrated worse outcomes for patients presenting with STEMI during off-hours compared with those presenting during the workday.
- The etiology of this difference is likely multifactorial, including changes in staffing, delays in intervention, and higher procedural complications.
- The vast majority of available data derive from registries with retrospective collection of clinical characteristics and outcomes, while little is available from prospective, randomized trials.
- Comprehensive delineation of relevant outcomes, including stent thrombosis, a feared complication of PCI, is rarely available from large registry data.

## OBJECTIVES

- We sought to determine if off-hours STEMI presentation is associated with worse outcomes in a large, contemporary, international trial.

## METHODS

- **Population**: Subgroup of participants with recent STEMI from CHAMPION PHOENIX, an international, randomized controlled trial of cangrelor during PCI
- **Exposure**: Off-hours PCI was defined by intervention performed during weekdays from 7PM -7AM, weekends, and holidays.
- **Primary efficacy outcome**: Combined outcome of of all-cause death, MI, stent thrombosis, or ischemia-driven revascularization at 48 hours.
- **Primary safety outcome:** GUSTO-defined moderate or severe bleeding.
- **Secondary outcomes**: Individual outcomes that composed the primary outcome.
- **Statistical analysis**: Logistic multivariate regression with propensity scores, constructed using age, randomization arm, region, previous MI, previous PCI, history of diabetes, clopidogrel loading dose, type of anticoagulant, and type of stent.

## RESULTS

### Table 1. Baseline Demographic and Clinical Characteristics According to Time of Presentation

| Characteristic | On-hours Presentation (N=1206) | Off-hours Presentation (N=786) | P-value |
|---|---|---|---|
| Randomization to cangrelor, n (%) | 569 (47.2) | 393 (50.0) | 0.21 |
| Age, y | 61±12 | 60±12 | 0.06 |
| Female, n (%) | 315 (26.1) | 199 (25.3) | 0.69 |
| Region, n (%) | | | <0.0001 |
| • United States | 175 (14.5) | 25 (3.2) | |
| • Other countries | 1031 (85.5) | 761 (96.8) | |
| Comorbidities, n (%) | | | |
| • Diabetes mellitus | 247 (20.5) | 126 (16.1) | 0.01 |
| • Prior myocardial infarction | 153 (12.7) | 78 (9.9) | 0.06 |
| • Prior PCI | 102 (8.5) | 47 (6.0) | 0.04 |
| • Prior CABG surgery | 27 (2.2) | 12 (1.5) | 0.26 |
| • Transient ischemic attack or stroke | 42 (3.5) | 27 (3.4) | 0.94 |
| • Heart failure | 67 (5.6) | 47 (6.0) | 0.69 |
| • Peripheral artery disease | 47 (4.0) | 26 (3.3) | 0.48 |
| Time from earliest symptom to PCI, hr# | 5.98 (3.3, 16.6) | 5.00 (3.1, 9.4) | <0.0001 |
| Time from admission to PCI, min# | 79.8 (42.0, 216.0) | 76.8 (48.0, 144.0) | <0.0001 |
| Site of access, n (%) | | | 0.09 |
| • Femoral | 938 (77.8) | 634 (81.0) | |
| • Radial | 267 (22.2) | 149 (19.0) | |
| Periprocedural medications, n (%) | | | |
| • Clopidogrel loading dose | | | <0.0001 |
| • 300 mg | 381 (31.6) | 354 (45.0) | |
| • 600 mg | 825 (68.4) | 432 (55.0) | |
| • Low molecular weight heparin | 74 (6.1) | 29 (3.7) | 0.02 |
| • Unfractionated heparin | 771 (63.9) | 508 (64.6) | 0.75 |
| • Bivalirudin | 184 (15.3) | 68 (8.7) | <0.0001 |
| • GP IIb/IIIa inhibitor | 133 (11.0) | 83 (10.6) | 0.74 |
| Stent type, n (%) | | | 0.0004 |
| • Only drug eluting stent | 506 (42.0) | 265 (33.7) | |
| • Only bare metal stent | 595 (49.3) | 460 (58.5) | |
| • Both types of stent | 26 (2.2) | 21 (2.7) | |
| • Neither type of stent | 79 (6.6) | 40 (5.1) | |

### Figure 1. Efficacy and Safety Outcomes by Time of Presentation

| | On-hours Presentation | Off-hours Presentation | Adjusted Odds Ratio (95% CI) | P-value |
|---|---|---|---|---|
| **48-hour efficacy outcomes, n (%)** | | | | |
| Primary endpoint* | 41/1205 (3.4) | 24/786 (3.1) | 1.00 (0.57, 1.74) | 0.99 |
| Stent thrombosis | 15/1205 (1.2) | 17/786 (2.2) | 0.57 (0.27, 1.21) | 0.15 |
| Death from any cause | 11/1205 (0.9) | 9/786 (1.2) | 0.89 (0.34, 2.34) | 0.81 |
| Myocardial infarction | 15/1205 (1.2) | 3/786 (0.4) | 2.57 (0.70, 9.44) | 0.16 |
| Ischemia-driven revascularization | 6/1205 (0.5) | 6/786 (0.8) | 0.52 (0.15, 1.76) | 0.29 |
| **30-day efficacy outcomes, n (%)** | | | | |
| Primary endpoint* | 69/1201 (5.8) | 41/786 (5.2) | 0.95 (0.62, 1.47) | 0.83 |
| Stent thrombosis | 24/1201 (2.0) | 25/786 (3.2) | 0.56 (0.30, 1.03) | 0.06 |
| Death from any cause | 32/1201 (2.7) | 21/786 (2.7) | 1.00 (0.55, 1.83) | 0.99 |
| Myocardial infarction | 19/1201 (1.6) | 9/786 (1.1) | 1.04 (0.44, 2.45) | 0.93 |
| Ischemia-driven revascularization | 13/1201 (1.1) | 10/786 (1.3) | 0.61 (0.25, 1.51) | 0.29 |
| **48-hour adverse outcome, n (%)** | | | | |
| GUSTO moderate or severe bleeding | 10/1244 (0.8) | 9/826 (1.2) | 0.51 (0.18, 1.48) | 0.22 |

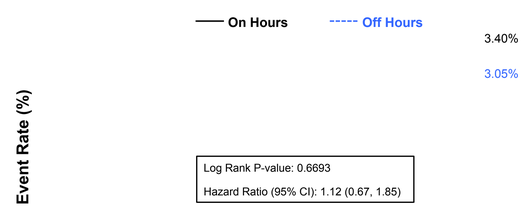
On-hours better  Off-hours better

### Figure 2. Efficacy and Safety Outcomes by Randomization Arm

| | Cangrelor (N=962) | Clopidogrel (N=1030) | Total (N=1992) | OR (95% CI) | P-value | Int. P-value |
|---|---|---|---|---|---|---|
| **48-hour endpoints** | | | | | | |
| Primary endpoint | | | | | | |
| On-hours | 17/568 (3.0) | 24/637 (3.8) | 41/1205 (3.4) | 0.79 (0.42, 1.48) | 0.459 | 0.8373 |
| Off-hours | 10/393 (2.5) | 14/393 (3.6) | 24/786 (3.1) | 0.71 (0.31, 1.61) | 0.407 | |
| Stent thrombosis | | | | | | |
| On-hours | 7/568 (1.2) | 8/637 (1.3) | 15/1205 (1.2) | 0.98 (0.35, 2.72) | 0.9707 | 0.2384 |
| Off-hours | 5/393 (1.3) | 12/393 (3.1) | 17/786 (2.2) | 0.41 (0.14, 1.17) | 0.0861 | |
| Death | | | | | | |
| On-hours | 5/568 (0.9) | 6/637 (0.9) | 11/1205 (0.9) | 0.93 (0.28, 3.08) | 0.9106 | 0.8624 |
| Off-hours | 4/393 (1.0) | 5/393 (1.3) | 9/786 (1.1) | 0.80 (0.21, 2.99) | 0.7374 | |
| Myocardial infarction | | | | | | |
| On-hours | 5/568 (0.9) | 10/637 (1.6) | 15/1205 (1.2) | 0.56 (0.19, 1.64) | 0.2812 | 0.2162 |
| Off-hours | 0/393 (0.0) | 3/393 (0.8) | 3/786 (0.4) | | 0.0827 | |
| IDR | | | | | | |
| On-hours | 3/568 (0.5) | 3/637 (0.5) | 6/1205 (0.5) | 1.12 (0.23, 5.58) | 0.888 | 0.4925 |
| Off-hours | 2/393 (0.5) | 4/393 (1.0) | 6/786 (0.8) | 0.50 (0.09, 2.73) | 0.4124 | |
| **48-hour bleeding** | | | | | | |
| GUSTO moderate or severe bleeding | | | | | | |
| On-hours | 7/585 (1.2) | 3/659 (0.5) | 10/1244 (0.8) | 2.65 (0.68, 10.29) | 0.1439 | 0.4298 |
| Off-hours | 5/415 (1.2) | 4/411 (1.0) | 9/826 (1.1) | 1.24 (0.33, 4.65) | 0.7485 | |

Cangrelor better  Clopidogrel better

### Figure 3. Kaplan-Meier Curves for the Primary Endpoint at 48 Hours




## LIMITATIONS

- The present study question was not pre-specified, hence not specifically powered for these analyses.
- Times to treatment were shorter for off-hours participants, and therefore the similar efficacy and safety outcomes findings observed in this clinical trial may not apply to all STEMI programs.

## CONCLUSIONS

- In a contemporary RCT, we showed that in contrast to findings from several prior studies, time of PCI did not affect STEMI efficacy or safety outcomes.
- These findings are reassuring and suggest that outcomes for STEMI revascularization are not dependent upon timing of presentation.
- Such information is important given that previous studies suggesting a difference in efficacy were retrospective with un-adjudicated outcomes.
- Cangrelor demonstrated consistent benefit regardless of timing of PCI.

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For more details, please find today's study published simultaneously online in *JACC.*

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