

# Long-Term Mortality Data from BCIS-1:

## A RCT of Elective Balloon Counterpulsation during High-Risk PCI

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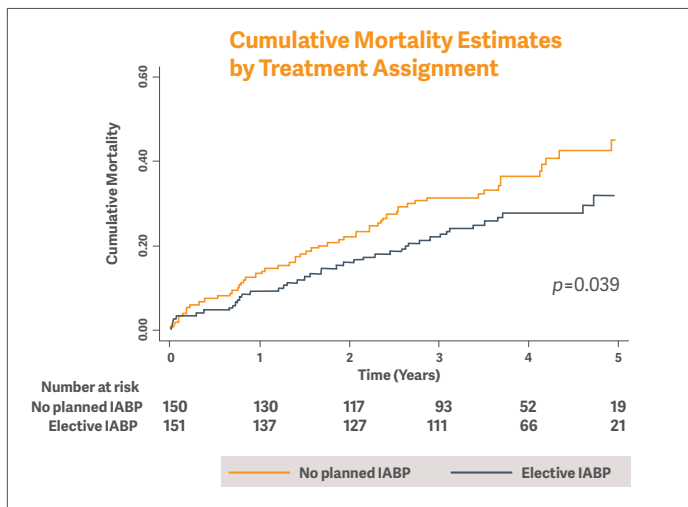
### Introduction

There is conflicting evidence on the utility of elective IABP use during high-risk PCI and no long-term outcome data from randomized trials in this setting. Long-term all-cause mortality rates in elective vs. no planned IABP support is evaluated from the BCIS-1 study.

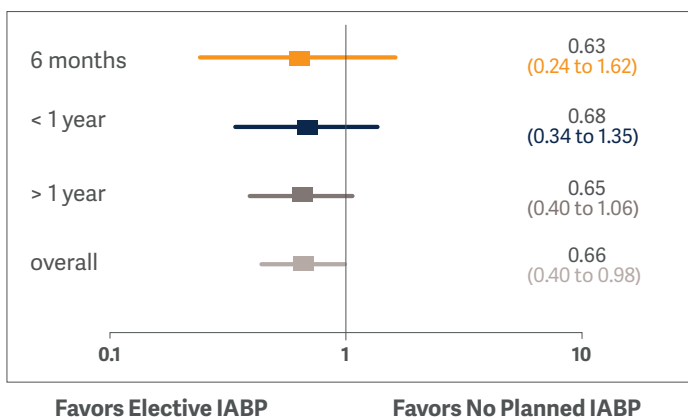
### Methods

- Long-term mortality was assessed on all patients in the BCIS-1 trial
- Mortality data were available for the entire 301 cohort of patients at a median of 51 months from randomization

### Results



- All cause-mortality:
  - 28% in the elective IABP group and 38.7% in the PCI group without planned IABP support ( $p=0.039$ )



## Discussion

- The groups were balanced in terms of baseline characteristics
- Quality, amount of revascularization and other indirect markers of use of devices or drug-eluting stents were also comparable in the 2 groups
- Elective IABP use during PCI was associated with an observed 34% reduction in long-term all-cause mortality
- Hazard ratio at 6 months is essentially similar to the hazard ratio at long-term follow up, which would be consistent with an early treatment effect that is subsequently maintained

## TACTICS Key Takeaways

- In the original BCIS-1 trial complications occurred less frequently with elective IABP group 1.3% vs. no-planned IABP group 10.7% ( $p < .001$ )
  - 12% of the patients assigned to the no planned IABP required emergent insertion primarily due to hypotension
- As seen in this long-term analysis, a reduction in relative risk by one third (34%) would translate to a large, clinically significant treatment effect
- CRISP-AMI also demonstrated a 58% reduction in mortality, shock or heart failure at 6 months post-AMI when IABP was initiated before PCI in patients with large anterior STEMI compared with PCI alone
- This data supports the need for earlier treatment for the high-risk patient

## How to Use

- Become familiar with the positive results of IABP RCT studies and be prepared to discuss with your clinicians
- What has been your experience with complications related to flow devices?
- What risks for the patient cause you to pause before placing a mechanical support device?
- Can you share a case in which IABP was used during high-risk PCI and you had positive outcomes?
- What were the patient's clinical characteristics that factored into selecting IABP?

**TACTICS**

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