AMERICAN COLLEGE of CARDIOLOGY

The Third DANish Study of Optimal Acute Treatment of Patients with ST-segment Elevation Myocardial Infarction: DEFERred stent implantation in connection with primary PCI - DANAMI-3–DEFER

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References

Contribution To Literature:

The DANAMI-3–DEFER trial suggests that deferred stenting at the time of primary PCI in STEMI patients is not superior for adverse cardiovascular outcomes compared with the conventional practice of immediate stenting.

Description:

The goal of the trial was to compare the utility of deferred versus immediate percutaneous coronary intervention (PCI) in patients presenting with ST-elevation myocardial infarction (STEMI) and referred for primary PCI.

Study Design

Patients in whom the operators could establish Thrombolysis in Myocardial Infarction (TIMI) 2-3 flow without stenting and with minimal acute manipulation or patients presenting with TIMI 2-3 flow were randomized in a 1:1 fashion to stent implantation after 48 hours (n = 603) or immediate stenting per local practices (n = 612).

- Total number of enrollees: 1,215
- Duration of follow-up: 42 months
- Mean patient age: 62 years
- Percentage female: 25%
- Percentage diabetics: 9%

Other salient features/characteristics:

- Infarct location: anterior (45%), inferior (50%)
- Multivessel disease (40%)
- Thrombus aspiration: 61%
- Glycoprotein inhibitor or bivalirudin use: 93%
- TIMI flow 0-1 at presentation: 38%
- No stenting for deferred vs. conventional: 15% vs. 3%
- Median left ventricular ejection fraction (LVEF): 50%

Inclusion criteria:

- STEMI presenting within 12 hours
- Establishment of TIMI 2-3 flow after minimal acute manipulation

Exclusion criteria:

- Known intolerance of contrast media, anticoagulant, or dual antiplatelet therapy
- Unconsciousness or cardiogenic shock
- Stent thrombosis
- Indication for acute coronary artery bypass grafting
- Increased bleeding risk

Principal Findings:

The primary outcome, MACE (all-cause mortality, MI, target vessel revascularization [TVR], hospitalization for congestive heart failure) for deferred vs. immediate stenting: hazard ratio 0.99, 95% confidence interval 0.75-1.29, p = 0.92

Components of the primary outcome (for deferred vs. immediate stenting):

- All-cause mortality: 7% vs. 9%, p = 0.37

- MI: 7% vs. 7%, p = 0.77
- Unplanned TVR: 7% vs. 4%, p = 0.03

Secondary outcomes:

- Median LVEF at 18 months for deferred vs. immediate stenting: 60% vs. 57%, p = 0.04
- Percentage with EF ≤45%: 13% vs. 18%, p = 0.05

Cardiac magnetic resonance (CMR) analysis (n = 510):

- Presence of acute microvascular obstruction: 44% vs. 42%, p = 0.78
- Final infarct size at 3 months: 10% vs. 9% of LV, p = 0.67
- Myocardial salvage index at 3 months: 67% vs. 67% , p = 0.8

Interpretation:

The results of this trial indicate that deferred stenting at the time of primary PCI in STEMI patients is not superior for adverse cardiovascular outcomes compared with immediate stenting (which is conventional practice). In fact, routine deferred stenting was associated with a higher risk of TVR, possibly because stenting at the time of the second procedure at 48 hours was deemed unnecessary in 15% of patients (compared with 3% in the conventional management arm). An improvement in LVEF at 18 months with deferred stenting was observed in a smaller subset that underwent imaging. This is hypothesis generating and cannot easily be explained by the data presented here.

An earlier smaller single-center trial, DEFER-STEMI, had noted an improvement in no-reflow and smaller infarct size at 6 months with a deferred strategy. However, there were several limitations of that trial, including an open-label design. All patients in the deferred arm of that trial were treated with tirofiban in between the two procedures.

References:

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Presented by Dr. Henning Kelbæk at the American College of Cardiology Annual Scientific Session, Chicago, IL, April 3, 2016.

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