Discussant: Ten-Year Clinical Outcomes from a Trial of Three Limus-Eluting Stents With Different Polymer Coatings in Patients with Coronary Artery Disease

Sripal Bangalore, MD, MHA,

Professor of Medicine
Director, Complex Coronary Intervention, Bellevue
Director of Research, Cardiac Catheterization Laboratory
Director, Cardiovascular Outcomes Group
New York University School of Medicine
1st Generation DES: Problems

- Very Late Stent Thrombosis
- Late Acquired Stent Malapposition
- Late Catch up Phenomenon

Räber L et al. Circulation 2011;123:2819-2828
Polymer Related Problems and Solutions

1st Gen Durable Polymer DES

2nd Gen Durable Polymer DES
Biodegrades over decades

Biodegradable Polymer DES
Short-term (Few months)
Mid-term (Few months to yrs)

Polymer-Free DES
Long-term (Few years)

BMS or “BMS like” Stent

BMS
ISAR-TEST-4: 1-year Outcomes

- 2603 patients (~40% ACS, 28% diabetes, 86% MVD)

Conclusions:
These results provide a framework for testing the potential clinical advantage of biodegradable polymer DES over the medium to long term

- BP-DES non-inferior to DP-DES (combined) for the 1 year primary endpoint of TLF

ISAR-TEST-4: 10-year Outcomes

Take Home Message #1

Improvement in stent design can have meaningful impact on hard outcomes including death and/or MI.

Implications for interpretation of trials that used older generation DES/BMS (such as COURAGE/BARI-2D/FREEDOM etc)

1 Bangalore et al. BMJ 2013; 347:f6625
ISAR-TEST-4: 10-year Outcomes

Take Home Message #2

The late clinical benefit of biodegradable polymer DES over 2nd gen DP-DES remains elusive.

Is a higher price tag (in certain health system) for these stents justified?

Take Home Message #3

Although improved, MACE rates continue to accrue beyond 1 year (~3.3%/year) even with 2nd generation DES.

Continued progress in stent or scaffold technology perhaps beyond focus on polymer is warranted.
Persistent Problems with Current Generation DES

2nd Gen Durable Polymer DES
- Polymer - Low grade inflammation
- Drug - Promotion of neo-atherosclerosis
- Metal - Caging of artery

Biodegradable Polymer DES
- Polymer - Inflammation at the time of biodegradation
- Drug - Promotion of neo-atherosclerosis
- Metal - Caging of artery
- Metal - Inflammation due to ion/metal leak

Polymer-Free DES
- Drug - Promotion of neo-atherosclerosis
- Metal - Caging of artery
- Metal - Inflammation due to ion/metal leak
Three Decades of Progress in PCI

Durable Polymer DES

- BMS
- 1st Gen: Thick Strut (>100 µ)
- 2nd Gen: Thin Strut (70-100 µ)

Biodegradable Polymer DES

- 1st Gen: Thin Strut (70-100 µ)
- 2nd Gen: Ultra-Thin Strut (<70 µ)

Comparison:

- Restenosis
  - BMS: ++++
  - 1st Gen: +++
  - 2nd Gen: ++
  - 1st Biodegradable: ++
  - 2nd Biodegradable: +±

- Stent Thrombosis
  - BMS: ++
  - 1st Gen: ++
  - 2nd Gen: +
  - 1st Biodegradable: +
  - 2nd Biodegradable: ±

- Neo-athero
  - BMS: +
  - 1st Gen: ++
  - 2nd Gen: ++
  - 1st Biodegradable: ++
  - 2nd Biodegradable: ++

The Elusive Late Benefit of Biodegradable Polymer Drug Eluting Stents

Running Title: Bangalore et al.; Biodegradable Polymer DES

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