What Have We Learned (or Will We Learn) from the REALITY Study

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- Research Grants
  - MDT
- Consultant/Advisory Board
  - Medtronic
  - Alucent Medical
  - SoundBite Medical
  - ROX Medical
  - Abbott Medical
- Royalties/Financial Interest
  - None
- Speaker’s Bureau
  - None
- VIVA Board Member
- I will discuss ‘off-label’ DCB use (outside the US IFU).
What REALITY Will Tell Us:
Validating the “Vessel Preparation” Hypothesis

- DCBs is superior to PTA in TASC II A-B lesions
- Large adjudicated registries report DCB use in complex lesions (long lesions, CTOs and ‘severe’ Ca++) are associated with high rates of provisional stent use
- DCB as a ‘stand alone, leave nothing behind’ technology in ‘real world’ patients is questionable
- REALITY: Is DA “vessel preparation” prior to IN.PACT Admiral DCB use in long, calcified FP lesions safe and effective?
Dr. Ravish Sachar – Raleigh, NC
Dr. Prakash Krishnan – Mt. Sinai, NYC, NY
Dr. Brian DeRubertis, UCLA
Dr. Lawrence Garcia, Boston, MA
Dr. Roger Gammon, Austin, TX
Dr. Michael Scott, Iowa Methodist, IA
Dr. Samir Germanwalla, Longview, TX

Dr. Thomas Zeller, Bad Kroizgen
Dr. Giovanni Torsello, Munster
Dr. Nolte-Esring, Muhlheim
REALITY: The Follow-Up to DEF AR A Hypotheses Generating Trial

- **Pilot RCT** designed to assess the safety/effectiveness of DA followed by a paclitaxel-coated balloon (DA-ART) vs. a DCB alone
  - Small study to detect *trends* in treatment differences between groups
  - Observational investigation of outcomes; not-powered primary one-year outcomes

- **Evaluate the DA-ART hypotheses** to develop further investigational research of this device combination
DEF AR Study Design

General and Angiographic Criteria Assessment

Lesion Severely Calcified*?

Randomization

DAART (n=48)

DCB (n=54)

DAART (n=19)

*Defined as: dense circumferential calcification extending > 5 cm
DEFINITIVE AR at One-Year

Tepe et al. Charing Cross 2017

* includes all patients that received DA+DCB in both randomized and nonrandomized arms
Three Primary Hypotheses of REALITY

• DA + DCB use in long (8-25 cm lesions) moderate-to-severely calcified lesions is safe and effective, reducing the need for provisional stenting, and promoting 12-mo. primary patency.

• A <30% post-DA residual %DS is associated with superior 12-mo primary patency

• The IVUS metric of ‘plaque burden’ post-DA is more sensitive than angiography in predicting 12-mo primary patency
What Angiographic Metrics Are Adjudicated?
REALITY Study: IVUS Sub-Study

Plaque Burden:
An area-based calculation and percentage

\[
\text{Vessel Area: } 4\pi r^2 \\
\text{Lumen Area: } \pi r^2 \\
\text{Plaque Burden (Area)} = 3\pi r^2 \\
\text{Percent: } 75
\]
REALITY:
IVUS Plaque Burden Analysis

Baseline IVUS

Post-DA

Post-DCB
REALITY: IVUS Plaque Burden Analysis

Baseline IVUS  Post-DA  Post-DCB

The Lumen Eccentricity Index: The Directional Atherectomy ‘Foot Print’
**Histomorphologic Assessment of Extracted Tissue**

- Depth:
  - Neointima, IEL, Media, EEL and Adventitia

- Inflammation and Inflammatory Cell Types:
  - Foam cells, macrophages, giant cells, RBCs, lymphocytes

- Stroma:
  - Necrosis, Sclerosis, vascularization, fibrosis, myxomatous

- Other Assessments:
  - Tissue weight, mineralization, cholesterol clefts, osseous metaplasia, medial atrophy

- Histology Core Lab analysis of all tissues extracted

- Dysplastic bone formation

**REALITY**
Sponsored by VIVA
REALITY:

Questions in Need of Answers:

- Is the directional atherectomy + DCB paradigm safe in long moderate-severely calcified lesions?
- How effective is DA in removing calcified atheroma prior to DCB and what can IVUS teach us regarding optimal technique?
- Does a ≤30% %DS post-DA portend a favorable one-year clinical outcome? How is this best assessed?
- What is the appropriate metric to assess ideal vessel prep (residual %DS by angio or luminal gain, residual plaque burden by IVUS)?
THANK-YOU
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