Circulatory Systems Devices Panel of the Medical Devices Advisory Committee, FDA

ACC Testimony

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What we heard

- RCT, Registries, meta-analysis
- Definitions are a problem
- Event rates are low
- Studies are under powered
- ST DES/BMS essentially comparable to 1 year
- > 1 year signal for increased ST- ? For how long
- Thienopyridines – good but for how long
- Off label use- there is not a good BMS group for comparison- have not really compared to CABG

Late ST for DES is Multifactorial

- Patient compliance issues
- Lesion types
  - Ostial
  - Bifurcation lesions
  - Prior brachytherapy
- Patient specific characteristics
  - Resistance
  - Hypersensitivity
  - Low EF
  - Renal failure
  - Diabetes

What we also know

- The occurrence of late events in non target vessel events occurs more often than late events in target vessels after the first year
- Both BMS/DES are hugh improvements over POBA
- Data hysteria
  - .05   5 times > .01

What we also know

- The occurrence of non target vessel events is greater than late target events after the first year.

- Both BMS/DES are a hugh improvement over POBA

- Data hysteria
  - .05   5 times   > .01
  - .005   5 times   >.001

What we also know

- The occurrence of non target vessel events is greater than late target events after the first year
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  - .0005   5 times   > .0001

What is needed

- Short-term strategies for current DES
    - Reiteration of patient selection: best treatment - medical, PCI or CABG
    - Reiteration of the approved indications for DES and the limited information for non-approved indications and late events
    - Recommendations on duration of anti-platelet therapy
    - Strategies to improve patient compliance
    - Education of all healthcare personnel on need to continue anti-platelet agents among patients with DES

What is needed

- Near term strategy
  - Better define patient selection - particularly off label
  - Informed consent - medical, PCI, CABG
  - Risk/benefit discussion
  - Carefully look at what we know and don't know
  - Design trials to find out best therapy

What is needed

- Longitudinal database
    - Unique patient identifier
    - Common data standards
    - Independent funding – consideration for surcharge on devices and pharmaceuticals or similar strategy
    - Built on platform similar to STS and ACC databases – 7.5 Million patient records
    - ACC NCDR database is considering longitudinal data collection

What is the pay back

- Most exciting issue to discuss at this meeting
- It will benefit more patients than anything we have discussed so far
- Positive data collection will provide more useful information than negative data
- Unique patient identifier is essential for EHR and fulfillment of quality potential
- Beyond the scope of this panel – Not really
- We need longitudinal data on devices, pharmaceuticals and procedures