IDEAL Cardiovascular Group

Discussion on 4th May 2017

TAVR – Transcatheter Aortic Valve Replacement

- US entry very late
- Comprehensive register fundamental: only possible with CME ***funding***

Lessons

- Engage early in planning for next devices – mitral
- Iterations of device – evidence/IDEAL Stage depends on type of change
- Outcome measures may change with use in lower risk patients
- Team working vital
- International harmonisation an important aim
- Data linkage a good method for long term FU of cardiovasc devices
- Importance of introducing UDI

ECMO – Extra Corporeal Membrane Oxygenation

- A range of techniques/devices – methods unstable and evolving
- A ***rescue therapy*** applied to patients who are dying
- Many different IDEAL stages simultaneously – typically 2b – need evidence on ***indications***
- Needs mandated international register (***collaborations***)
- Evidence gap – patients who are ***not*** treated missed by registers
- ***Manufacturers' registries***
  - Big potential
  - Reliability
  - Good for label expansion >>>> training for new indication

TEVAR (Thoracic EndoVascular Aortic Repair) for aortic dissections

- One RCT so “Stage 4” but patient selection uncertainties >>> IDEAL 2b
- Collaboration better than little case series (SVS, FDA, industry…)
- Now Stage for some indications but questions still arise
- FDA could draw on other relevant data (use in aneurysms, transections)

…. What about untreated patients?

Practical steps for dissemination and adoption of IDEAL

- ***Start using the name*** – FDA using "IDEAL approach" for ages
- ***Professional Societies*** pivotal. International collaborations.
- ***Journal editors*** must be informed and influenced
- ***Industry***: big companies already use IDEAL approach – need educate small companies
- Need ***money*** for good data collection
- Bring IDEAL influence to bear on ***linking*** electronic records, UDI …