Why Registries can be better than RCT’s for Evaluating Vascular Devices

WHERE DO WE STAND?

- In times past, an alert physician would make advances using his power of observation, his five senses, as well as the common one and his clinical judgment.
- These times are over. We live in the era of Evidence-Based Medicine.
- EBM gave rise to “guidelines medicine”, and “cookbook recommendations”.
- EBM promotes the systematic use of RCTs.

ADVANCES IN MEDICINE

- The development of EVAR followed the same path.
- The first EVAR cases were performed by Ukrainian Nicholas Volodos in the late 1980s behind the Iron Curtain.

ADVANCES IN MEDICINE

- The first RCT (EVAR-1) was published in 2005, 14 years later.
**WHERE DO WE GO NEXT?**

- Despite four RCTs conducted to date, uncertainties remain regarding the effectiveness of EVAR in the long term
- New stent grafts have been developed
- They are promoted as more durable

**NEW RANDOMIZED TRIALS?**

- Results may not be applicable to all patients (selection criteria)
- Time required to recruit study participants?
- EVAR Technologies improve, conclusions could be obsolete even before the study publication
- Industry-sponsored RCTs are to be taken with caution, knowing that most negative trials are never published.

**REGISTRIES**

A more realistic way to obtain this information is a large registry with an analysis by propensity score methods

**ADVANTAGES OF REGISTRIES**

- They are based on large cohorts representing the real practice.
- They can be carried out quickly and are cost effective.
- For EVAR, the MEDICARE registries showed similar results to RCTs.

**REGISTRIES - HETEROGENEITY**

Propensity score models to adjust for differences

- **Device heterogeneity**
  - Different technologies: Angioplasty balloons, total occlusion crossing devices
  - Stents: Bare, covered, drug-eluting
- **Patient heterogeneity**
  - Age, risk factors, disease severity, disease location
- **Provider heterogeneity**
  - Variable physician specialty, training, experience
  - Variable treatment option, devices on and off-label use in practice

**REGISTRY CORE DATA**

- **Set of Core Data Elements**
  - Existing registries
  - Industry case report forms
  - UDI (Unique Device Identifier)
- **Data Extraction across Registries and EHR's**
  - SVS, SIR, registries
  - EHRs (Electronic Health Records)
A strategy of active surveillance of a clinical registry identified safety signals with initial alerts occurring within the first 12 months of monitoring.

Resnic FS et al. NEJM 2017

This extensive “real world” clinical data allows the FDA to rapidly approve label extension without the delay of a RCT.

Faris O et al. NEJM 2017

CONCLUSIONS

- Large, prospective, post-market registries are a safer bet than new RCTs to compare evolving vascular devices, even if RCTs will stay and remain necessary in many situations.
- Rigorous, prospective registries with “real world” evaluation can help the physicians to make the appropriate choice of medical devices for their specific patient.