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Short and Long-Term Safety & Efficacy Outcomes for Afib Ablation: Reaching Consensus on Definition(s) & Data Capture

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Introduction

- Is this the right time for an AF ablation registry?
  - No precipitating events (e.g., serious public health concerns)
  - Pre-market studies for AF-specific technologies ongoing
  - Only one device approval for AF in the U.S.
  - CABANA just beginning

Safety

- Industry-sponsored pre-market safety & effectiveness studies
  - Size limitations
- Utility of an AF ablation registry
  - Assess risk of infrequent adverse events
  - Composite ablation-related safety endpoint
    - E.g. pulmonary vein stenosis, phrenic nerve injury, atrio-esophageal fistula, stroke and other serious adverse events that may be attributable to AF ablation
- Data available to manufacturers for MDR reporting obligations

Effectiveness

- Should this registry collect effectiveness outcomes?
- Registry model is observational, not interventional
- Numerous variations in:
  - Technique, lesion sets – not standardized
  - Devices used
  - Physician experience
  - Monitoring of patients' rhythm during follow-up
  - Length and location of follow-up
  - Use of AADs post-ablation
  - Frequency of repeat ablation

  → All impact effectiveness outcomes
- Registry not the right study design to assess effectiveness

Monitoring for AF Recurrence

- Detection of AF recurrence largely dependant on intensity of rhythm monitoring
- Expense and complexity of rigorous rhythm monitoring
- Outside the scope of a registry?

Draft ACC Case Report Form & Metrics

- Extensive data collection on draft CRF – 9 dense pages
- AF recurrence post-ablation – effectiveness endpoint

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Conclusions

- Is this the right time for an AF ablation registry?
- Focus on safety outcomes
- Effectiveness outcomes should be evaluated in prospective clinical trials

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