

Technique Features of AF Ablation: What Procedural Features Must A Registry Capture?

FDA View

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FDA's Interests in AF Ablation Registry

- AF registry: Real-world experience in AF ablation
- FDA would like to evaluate the performance of medical products being used in AF ablation procedures
- FDA is interested in comparing the results of pre-market studies with that from AF registry

FDA perspective: Why it is importance to capture procedural features?

- How are the devices being used in the real world?
- Which procedural features affect clinical outcomes?
- Can we explain differences in clinical outcomes between pre-market studies and AF registry based on procedural features?

Procedural features FDA is most interested in:

- Ablation strategy (type of lesion set)
- Imaging modality
- Esophageal monitoring method
- Energy source, ablation catheter type, type of catheter manipulation
- Peri-ablative anticoagulation strategy

Ablation Strategy

- Diversity in clinical practice
 - PV based strategies: Segmental PV isolation, circumferential PV ablation, wide area circumferential ablation, PV antrum isolation ...
 - Non-PV based strategies: Linear ablation, ablation of CFAE, ablation of GP...
- What are the optimal ablation strategies for different types of AF?

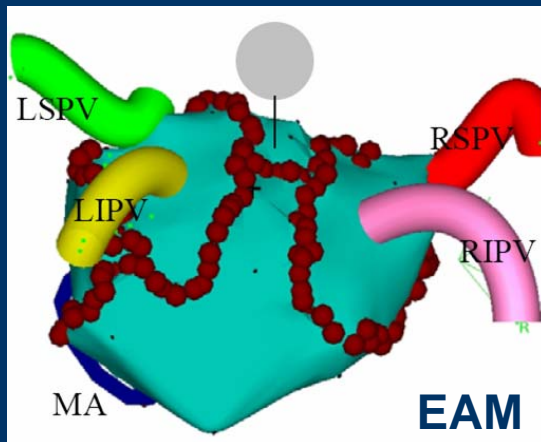
Imaging Modality: Diversity



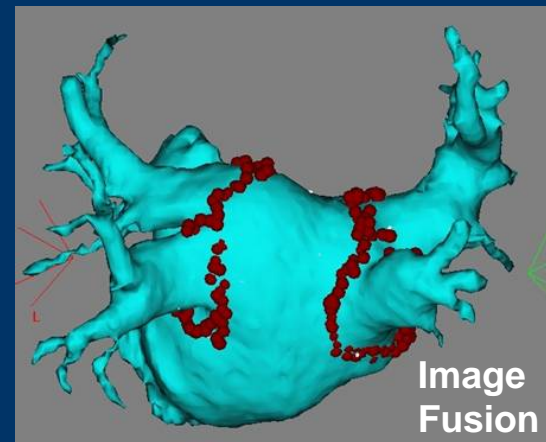
Bella PD, JCE 2009



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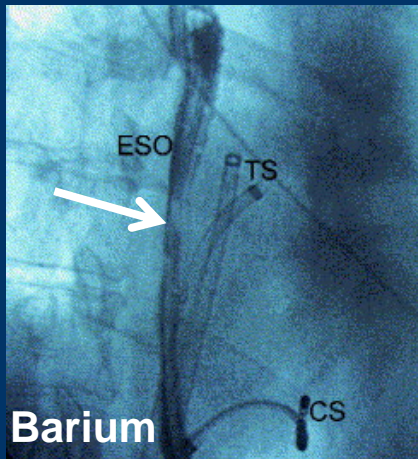


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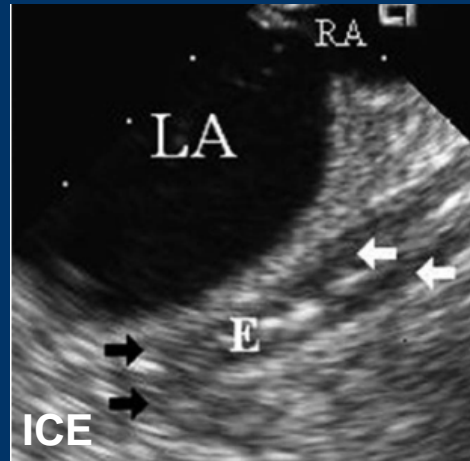
Imaging Modality: FDA Question

- Does the type of imaging used to guide ablation affect clinical outcomes?

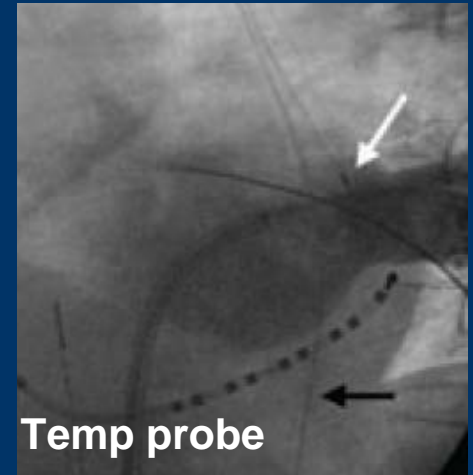
What is the optimal esophageal monitoring method?



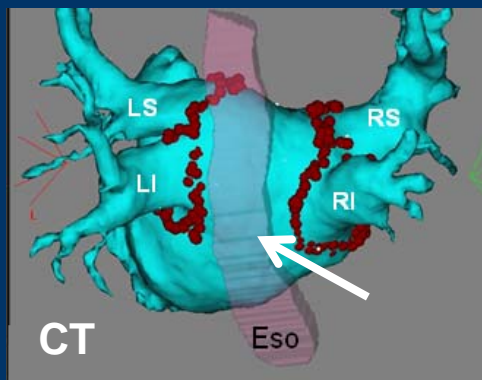
Marine JE, Prog Cardiovasc Dis 2005



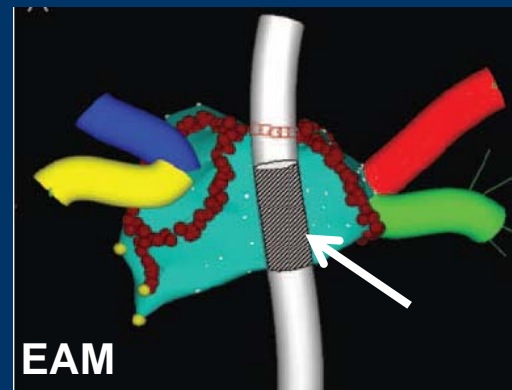
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Energy Source, Ablation Catheter Type and Type of Catheter Manipulation

- Does the risk-benefit profile differ between RF ablation with open irrigation and conventional RF ablation?
- How do devices using alternative energy sources compare to RF ablation devices?
- Does ablation catheter type (single-tip, balloon...) affect clinical outcomes?
- How do the risk-benefit profiles of remote catheter control systems and conventional manual manipulation compare?

Peri-ablative Anticoagulation Strategy

- Anticoagulation protocol varies greatly in:
 - Use of uninterrupted anticoagulation with warfarin
 - Intensity of anticoagulation (different ACT target)
 - Timing of heparinization: prior to first TS, after first TS, or after second TS?
 - ...
- Do differences in anticoagulation protocol affect the rates of thromboembolic events, vascular complications, and temponade?

Summary

- It is important to capture key procedural features in AF ablation registry.
- FDA is most interested in: Ablation strategy, imaging modality, esophageal monitoring method, energy source, ablation catheter type, type of catheter manipulation, and anticoagulation strategy.