



***Short and Long Term Safety
& Efficacy Outcomes For AF
Ablation: Reaching
Consensus on Definition and
Data Capture***

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Short and Long Term Safety and Efficacy Outcomes For AF Ablation

Complications: vascular complications, pericardial effusion, tamponade, significant PV stenosis, atrial-esophageal fistula, chest pain, pulmonary edema, stroke, death and others.

No issue on definitions

Major Complications: those resulting in permanent injury or death, requiring intervention, prolonged the hospitalization, or necessitating re-hospitalization

Issues with detection:

Detection of PV stenosis requires routine CT/MRI scan which are not reimbursed in every state.

Acute complications are easier to capture since the patients are hospitalized.

Chronic complications depend on the placement of a system designed to collect this information (data base).

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Primordial Version of a Registry: we have created a consortium of Centers (presently 8) performing the same procedure, collecting the same information prospectively, using the same follow up protocol to assess efficacy.

This requires dedicated staff to care for the patients, manually enter the data, ensure regular follow up testing, manage and analyze the data base (**Atrial Fibrillation Center**).

Presently many centers, including academic setting, do not collect the data prospectively and do not have a consistent follow up protocol

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Potential issues: Electronic Medical Record helps transferring information relative to the hospital stay into the data base. These are not available in every hospital.

Unlike a hospital or academic center based model, in a practice, the follow up is done in the office settings which are logistically separated.

This would require additional resources to capture the data and ensure the quality of the information.

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Acute Outcomes:

Depend on the procedural endpoints. The consensus statement suggests isolation but not all operators follow the recommendation.

Till more uniformity exists in procedural strategies a registry needs to capture the type of procedure performed by the operator.

Many centers also assess for the presence of additional triggers with infusion of isoproterenol at high doses. This needs to be captured together with the sites of these extra foci.

In longstanding AF, organization to atrial tachycardia or termination of AF with ablation needs to be recorded.

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- **Long term outcomes:** success should be established after a blanking period of 2 to 3 months
- Any arrhythmia after the blanking period should be considered a recurrence but should be labeled (atrial fibrillation, atrial tachycardia, atrial flutter, others).
- The easiest endpoint is freedom from documented AF/AT/Aflutter longer than???
- However, patients with recurrence could still be significantly improved
- It is important to capture success with one procedure, as well as success with two or more ablations
- Success with and without drugs should be separated.
- It is important to realize that presently success depends on the procedure performed and on the skill, and experience of the operator

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- **How do we establish long term outcomes?**
- Monitoring modalities: Holters from 24 hours to 21 days, event recorders, loop recorders, implantable monitors, other implanted devices.
- The consensus statement considers adequate a minimum of 24 hour holters every 3 to 6 months for 1 or 2 years. However, many centers still rely only on symptomatic recurrences.
- Our protocol has included event recorders for 5 months, and 7 day holters every three months for the first year, and twice a year for the second year.
- We need to hold surgical procedure outcomes to the same standard.

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- Is this monitoring enough?
- Should we consider implantable devices in everybody?
- Should we individualized monitoring based on patient symptoms?
- Is it possible to discontinue coumadin even in high risk patients?
- What is the long term impact of extensive ablation strategies on left atrial mechanical function?
- What is the best minimal ablation scheme for patient with longstanding AF?
- Does a “successful ablation” impact on mortality?