
ATLAS S-ICD
Avoid Transvenous Leads in Appropriate Subjects S-ICD

Rationale

- The transvenous lead is the least reliable component of the ICD system and may lead to the premature revision of the system in 2-20% of patients during the typical lifespan of an ICD generator.
- Many of these revisions and associated complications could be avoided in a lead that was not placed in the vasculature or heart.
- Younger patients under-represented in ICD trials
- Canada has a strong history of ICD clinical trials, and registries of patients with inherited heart rhythm disorders

Complication	Estimated Rate	Source
Early avoidable, lead-related complications		
Pneumothorax/hemothorax	1.5%	SIMPLE trial, Pacemaker meta-analysis, ICES ICD registry
Cardiac perforation, effusion, tamponade, pericarditis	1.0%	SIMPLE trial, ICD meta-analysis
Lead dislodgement, loss of sensing/pacing	3.0%	Pacemaker meta-analysis, clinical estimate, ICD meta-analysis
New, severe tricuspid insufficiency	3%	Sadreddini cohort
Ipsilateral upper extremity DVT	0.3%	Clinical estimate
Need to revise dialysis access	0.2%	Clinical estimate
Total	8%	
Other early complications		
Death	0.6%	SIMPLE trial
Myocardial Infarction	0.1%	SIMPLE trial
Stroke	0.2%	SIMPLE trial
Significant wound hematoma	2.3%	SIMPLE trial
Device-related infection	1.3%	SIMPLE trial, Pacemaker meta-analysis. Clinical estimate
Total	4.5%	

Inclusion Criteria

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Patient must satisfy any ONE of the following two criteria:

1. Patient is ≥ 18-60 years old AND has a standard indication for ICD;

OR

2. Patient is ≥ 18 years old has a standard indication for ICD AND has any one of the following present:
   - An inherited arrhythmia syndrome (i.e. Long QT, Brugada, ARVC, hypertrophic or dilated cardiomyopathy, early repolarization syndrome, etc.)
   - Prior pacemaker or ICD removal for infection
   - Need for hemodialysis
   - Prior heart valve surgery (repair or replacement)
   - Chronic obstructive pulmonary disease (with FEV1 <1.5L)

Exclusion Criteria

- Mechanical tricuspid valve
- Fontan repair
- Presence of an intra-cardiac shunt
- Known lack of upper extremity venous access
- Need for cardiac pacing for bradycardia indication
- Clinical indication for biventricular pacing
- PR interval >240msec
- Patients with permanent pacemaker
- Patients unwilling to provide informed consent or comply with follow-up
- Pregnant at time of enrollment and implant
- Patients who currently have a ventricular assist device (i.e. LVAD)

Primary Objective

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To show that the use of an S-ICD reduces the rate of perioperative complications, measured at 6 months following implant.

Secondary Objective

1. To show that the S-ICD is associated with fewer long-term device-related complications.
2. To show that the S-ICD has a similar effectiveness for the treatment of ventricular arrhythmias and is associated with a similar risk of failed appropriate ICD shock and/or arrhythmic death.

Primary Outcome

The primary safety endpoint will be measure at 6months following ICD implantation, and will be a composite of lead-related perioperative complications, including:

- Hemothorax or pneumothorax
- Cardiac perforation, tamponade, pericardial effusion or pericarditis
- Lead dislodgement or loss of pacing/sensing requiring revision
- New moderate-severe or severe tricuspid insufficiency (3+ or 4+)
- Ipsilateral upper extremity deep venous thrombosis

A secondary 6-month safety composite will include the following, in addition to the above complications:

- Device-related infection requiring surgical revision
- Significant wound hematoma (requiring evacuation or interruption of oral anticoagulation)
- Myocardial infarction
- Stroke
- Death

Secondary Outcome

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Safety

a) Late (>6 months post-operative) and
b) Total device-related complications, including:
   - Lead dislodgement or fracture, or loss of adequate sensing or pacing
   - Device-related infection; Pericarditis or pericardial effusion
   - New moderate-severe or severe tricuspid insufficiency (3+ or 4+)
   - Ipsilateral upper extremity deep venous thrombosis
   - Need to revise dialysis access or need to revise ICD or lead for any reason
   - Non-systemic embolism
   - Wound dehiscence or disjunction
   - Allergic reaction to ICD

Efficacy

- Occurance of failed appropriate shock or arrhythmic death
- Hospital, emergency department or clinic visits as a result of:
  a. ICD therapy (Shocks or ATP, both appropriate or inappropriate)
  b. Device-related complications
  c. Arrhythmia
  d. Heart failure
- Any inappropriate shock
- All-cause mortality
- Health Economics
- Patient acceptance and quality of life