ICD Technology - leads, leadless and more

Raffaele Corbisiero MD FACC
Director of Electrophysiology
Deborah Heart & Lung Center

Outline

1- The Problem

2-Issues with traditional therapy

3-An Alternative to traditional therapy
The Problem

Leading Causes of Death in the U.S.

- Septicemia
- Nephritis
- Alzheimer’s Disease
- Influenza/pneumonia
- Diabetes
- Accidents/Injuries
- Chronic lower respiratory diseases
- Cardiovascular disease
- Other cardiac causes
- Sudden cardiac death (SCD)

You must combine deaths from all cancers to outnumber the deaths from SCD each year.

0% 5% 10% 15% 20% 25%

<table>
<thead>
<tr>
<th>Cause</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>All cancers</td>
<td>25%</td>
</tr>
<tr>
<td>Sudden cardiac death</td>
<td>20%</td>
</tr>
<tr>
<td>Other cardiac causes</td>
<td>15%</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>10%</td>
</tr>
<tr>
<td>Chronic lower respiratory diseases</td>
<td>5%</td>
</tr>
<tr>
<td>Influenza/pneumonia</td>
<td>5%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>5%</td>
</tr>
<tr>
<td>Accidents/Injuries</td>
<td>5%</td>
</tr>
<tr>
<td>Alzheimer’s Disease</td>
<td>5%</td>
</tr>
<tr>
<td>Septicemia</td>
<td>5%</td>
</tr>
<tr>
<td>Nephritis</td>
<td>5%</td>
</tr>
<tr>
<td>All causes</td>
<td>20%</td>
</tr>
</tbody>
</table>

Magnitude

- The 5 year mortality of survivors of AMI with LV dysfunction after hospital discharge is > 20%
- SCD accounts for at least 33% of late mortality
- Only 2 to 30% with out-of-hospital cardiac arrest survive

- 42,000 deaths per year from car crashes
  (5-6 times less annual SCD risk but we now have mandated seat belt laws not to mention the cost to all of us and to the Automobile industry for installing them and the authorities for monitoring their use)
- 41,000 deaths per year from breast cancer
  (Mammograms are now the standard of care)
- 7,000 children die from SCD each year
  (Cities across the US are mandating AED’s in schools)

Putting it into Perspective
Prophylactic Therapy

Indications for ICD Therapy

AVID Profile Patients

- AVID = Antiarrhythmics Versus Implantable Defibrillators
- Randomized clinical trial to evaluate ICD versus Class III antiarrhythmic drugs (primarily amiodarone).
- Hypothesis: that one group would achieve significantly lower total mortality rate than the other.
- Patient Profile:
  - Primary VF; or
  - Sustained VT: with syncope; or
  - Sustained VT: symptoms and EF ≤ 40%; or
  - Sustained BP < 80 mm Hg and EF ≤ 40%
- Trial demonstrated 39% reduction in overall mortality for ICD patient.
Causes of SCD in Young People

- HCM: 36%
- Congenital coronary anomalies: 20%
- MVP: 2%
- CAD: 2%
- Other: 8%
- Dilated cardiomyopathy: 3%
- Myocarditis: 3%
- Aortic stenosis: 4%
- Tunnelled LAD: 5%
- Restrictive aorta: 5%
- Mildly increased cardiac mass: 10%
Other Problems

ECG-LQTS

ECG-LQTS
ICD therapy has not reached the ‘tipping point’

Are We Listening?

Heart failure at the crossroads. When medical therapy alone is not enough

**Patient presentation**
- 54-year-old man with hypertension, non-diabetes, and ischemic heart disease
- NYHA class III-IV, LV dysfunction LVEF 0.20, LVED 6.2 cm and LVED 6.2 cm
- Echocardiogram LVEF 6.2 cm and LVFP 0.20
- Native valve, LVSD 6.2 cm and LVEF 0.20
- Echocardiogram LVEF 6.2 cm and LVFP 0.20
- Native valve, LVSD 6.2 cm and LVEF 0.20
- NYHA class III-IV, LVSD 6.2 cm and LVEF 0.20
- Echocardiogram LVEF 6.2 cm and LVFP 0.20
- Native valve, LVSD 6.2 cm and LVEF 0.20

One year later

- NYHA class III-IV, LVSD 6.2 cm and LVEF 0.20
- Echocardiogram LVEF 6.2 cm and LVFP 0.20
- Native valve, LVSD 6.2 cm and LVEF 0.20
- NYHA class III-IV, LVSD 6.2 cm and LVEF 0.20
- Echocardiogram LVEF 6.2 cm and LVFP 0.20
- Native valve, LVSD 6.2 cm and LVEF 0.20

Are We Listening?
Still not Listening??

Incidence of SCD in Specific Populations and Annual SCD Numbers

<table>
<thead>
<tr>
<th>GROUP</th>
<th>Patients with high coronary risk profile</th>
<th>Patients with previous coronary event</th>
<th>Patients with EF &lt; 35%, congestive heart failure</th>
<th>Patients with previous out-of-hospital cardiac arrest</th>
<th>Patients with previous MI, low EF and VT</th>
</tr>
</thead>
<tbody>
<tr>
<td>General population</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of Sudden Deaths</td>
<td>30</td>
<td>25</td>
<td>20</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>Incidence of Sudden Death (% of group)</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>No. of Sudden Deaths Per Year</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Risk Stratification

Under-penetration

Issues?

FEAR will make you dirty your pants
My Issues-Extractions

Well sometimes

How big is the issue?

New and Growing issues with leads

Increased incidence of...

- Infection
- Malfunction
- Redundant leads from upgrades
- Venous occlusion

How big is the issue?

5% Estimated Annual Incidence

- Infection – 1%
  - 2-7% infection rate for replacements/upgrades
  - 50.5% infection rate for new implants

- Malfunction – 2.5%
  - 1.65%-20% annual ICD lead failure based on age

- Occlusion - 0.5%
  - 9-12% of device replacement or upgrade

- Redundant leads – 1%

CXR from EP Referral

Patient referred for erosion of ICD lead

RA lead
- Original RA lead
- Capped pins
- Tunnels R/L

CS lead
- Original CS lead
- Tunnels R/L

What makes Removal Difficult?

Binding scar tissue

Comparative Complication Rates*

*Statistical analysis indicates no significant difference in complication rates between the two groups. Further analysis is needed to determine the exact cause of increased complication rates in the removal group.
RA lead Extracted

Manual Dilator Sheath on ICD Lead

Cook Evolution Gun on ICD lead
Cook Evolution Gun on ICD lead

Post Procedure New Implant

Lead Imperfection

Inappropriate ICD shock due fractured pacing lead (sprint fidelis) we notice noise on the ventricular EGM channel and normal sinus rhythm on the shock can channel and the marker channel showing falsely ventricular fibrillation which led to inappropriate shock.

Recalls –Fidelis, Riata...
Sprint Fidelis® Lead Patient Management Recommendations Update – April 2011

If a Fidelis pace-sense conductor fracture has occurred, we recommend implanting a new high voltage lead, with or without extraction of the Fidelis lead. It is no longer a recommended option to implant a pace-sense lead while maintaining use of the Fidelis high voltage conductor after a Fidelis pace-sense conductor fracture has occurred.

Case Study

Patient Assessment:

- Fever, unknown etiology, with a history of recurrent group B Strep bacteremia treated with IV and oral antibiotics in the past, negative blood culture reported from ER
- Dilated nonischemic cardiomyopathy with preserved ejection fraction
- History of VT with syncopal episodes status post STJ generator and lead replacement in 2012
- Hypertension, controlled
- Depression
- Anxiety
- History of chronic renal insufficiency
- Congenital thrombocytopenia
- History of systemic lupus and internal hemorrhage
- History of diverticulitis
- Splenomegaly
- Anemia
- Thyroid nodule
- Tobacco abuse
Case Study

Patient History

51 y.o. male presents with recurrent infection (Group B Strep bacteremia) referred for system explantation

Past medical history
- Nonischemic cardiomyopathy, congenital thrombocytopenia, colonic polyposis, diverticulosis, depression, history of acute renal failure, obesity (BMI 48), history of lead failure and extraction

Medications
- Coreg 12.5mg p.o. twice daily, doxazosin 2mg p.o. daily, gabapentin 300mg p.o. twice daily, lisinopril 10 mg p.o. daily, sotalol unknown dosage

Device History
- Dual chamber ICD implanted in 2008, full system replacement in 2012, residual RV lead

Transferred in after presenting to community hospital ER stating he started to develop fevers on 1/7/2014

• ER CT showed chest wall abscess without collection of fluid. It also showed splenomegaly, hepatic steatosis, and multiple thyroid nodules.
• Recurrent Strep B bacteremia treated with Rocephin in the past
• TEE Sept 2013 showed no mass or vegetation
Case Study

Femoral Snare

Femoral Snare
Case Study- Now What?
System Extraction
1/16/2014: Full system extraction attempted in the OR; portion of RV lead remaining
1/20/2014: Remaining RV lead segment removed via femoral snare in the EP lab

Now What?-An Alternative

The Other Way

“Everything should be made as simple as possible, but not simpler.”
Albert Einstein
Introduction to the S-ICD™ System

Protection Without Touching the Heart

Subcutaneous ICD Therapy

The S-ICD™ System
• Entirely subcutaneous
• Does not require leads in the heart, leaving the vasculature untouched
• Placed using anatomical landmarks, reducing the need for fluoroscopy at implant
• Sophisticated algorithms provide effective detection and treatment of VT/VF

Design Goals of Subcutaneous ICD Therapy

A new approach

Goals
• To avoid both the short- and long-term complications associated with transvenous leads
• To defibrillate with more uniform voltage gradients, reducing myocardial damage
• To sense activation across the whole heart, improving accuracy for arrhythmia detection
• To provide an option for patient sub-populations for which TV-ICD is not ideal
• To reduce risk of lead failure in young and active patients

Trade-offs
• Larger generator unit and resulting cosmetics.
• Post-shock pacing only
  - no Brady pacing
  - no ATP therapy

Weiss Circulation 2013;128:944–953
Crozier Card Electrophysiol Clinics 2014 submitted
**S-ICD™ System Highlights**

- 80 J (delivered) biphasic shock
- Charge time to 80 J ≤ 10 seconds
- 5.1 year longevity (projected)
- 30 seconds post-shock pacing
- Single electrode connection
- Full featured episode storage

**Implantation of S-ICD™ System**

A predictable implant that relies only on anatomical landmarks

**Ideal Device Placement**
Implanted S-ICD™ Systems
Device location is well accepted by patients

The Subcutaneous Signal
The S-ICD™ System captures high-resolution, morphologically rich signals similar to a surface ECG

Pre-Operative Screening Tool
Pre-implant screening ensures the patient is a good candidate for S-ICD™ System implant and therapy.

- Collect the surface ECG at the intended location of the implanted pulse generator and subcutaneous electrodes.
- Ensure the entire QRS complex and T wave fit within the recommended profile for proper rhythm discrimination by the S-ICD System.
- Verify at least one lead sensing vector is acceptable for at least two postures (supine, standing, optional exercise)
**Sophisticated Rhythm Detection Technology**

*Three far-field sensing vectors*
- Primary, Secondary, Alternate
- Automatic or manual vector selection
- Morphologically rich signal similar to a surface ECG
- Sense electrodes positioned away from large muscle groups
- Maximum flexibility to solve sensing issues non-invasively
  - Sense vector reprogramming

**Therapy Delivery**

*Post-Shock Pacing*
- Transthoracic pacing
- Delivered for up to 30 seconds post-shock
- Demand based pacing @ 50 ppm using 200 mA

**S-ICD System Clinical Evidence**

Growing clinical evidence supports the S-ICD System

*Growing clinical evidence supports the S-ICD System*
**EFFORTLESS Registry**

*Broad Range of Clinical Indications*

Patients with a broad range of cardiac conditions have received the S-ICD™ System

- Ischemic
- Nonischemic VF
- Chronic Kidney
- HCM
- Non ischemic CM
- Congenital
- ATRT

**Broad Range of Body Habitus**

Patients in all age groups and across a broad range of body habitus have received the S-ICD™ System

**S-ICD™ System Implant Post TV-ICD explant**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>EFF * (n=369)</th>
<th>IDE * (n=314)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-ICD implant post TV-ICD explant</td>
<td>35 (15%)</td>
<td>43 (14%)</td>
</tr>
<tr>
<td>TV-ICD explant for infection</td>
<td>34 (62%)</td>
<td>33 (77%)</td>
</tr>
<tr>
<td>Re-infection post S-ICD implant</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>1 yr mortality post S-ICD implant</td>
<td>1 (2.9%)</td>
<td>0</td>
</tr>
</tbody>
</table>

The S-ICD System appears to be a safe and feasible alternative for high risk patients following a TV-ICD extraction

Suitable for a Diverse Patient Population

The S-ICD™ System is an effective solution for a majority of primary and secondary ICD candidates.

- Good option for patients with primary electrical or structural heart disease.

Indications for Use

The S-ICD System is indicated for appropriate antitachycardia therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have:

- Symptomatic bradycardia
- Incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Patient Populations

Patients with a broad range of cardiac conditions have received the S-ICD™ System.

Appropriate Use of the S-ICD™ System

Strong Candidates

- No vascular access
- History of recurrent TV lead infections/fractures
- Renal failure, diabetes, immuno-compromised

Reasonable Candidates

- Young patients with primary electrical problems
- Patients with a primary prevention indication
- Prior VF arrest
- Prosthetic valves

Inappropriate Candidates

- Patients with bradycardia pacing indications
- Need for CRT
- Recurrent monomorphic VT
The S-ICD™ System
• Is entirely subcutaneous
  • Does not require leads in the heart, leaving the vasculature untouched
  • Is placed using anatomical landmarks, removing the requirement for fluoroscopy at implant
  • Provides sophisticated algorithms to detect and treat potentially fatal arrhythmias

The S-ICD System is equipped with sophisticated algorithms for the accurate detection of VT/VF and effective discrimination of AF & SVT:
• 100% of spontaneous VT/VF episodes (119/119) detected and treated\(^a\)
• 0 patients experienced a shock due to AF/SVT discrimination error in
  Conditional Shock (dual) zone\(^a\)

(a) Weiss Circulation 2013;128:944–953

The S-ICD System has over 1300 patients in clinical studies
• 5.5% have received appropriate, life-saving shocks\(^{a,b}\)
• 99.8% sensitivity: 897/899 induced episodes appropriately sensed (IDE)\(^b\)
• Treatment times comparable to TV-ICDs (~20 seconds)\(^{a,b}\)
• 0 lead failures\(^{a,b}\)

The S-ICD System is a suitable therapy solution for a diverse patient population
• Good option for patients with primary electrical or structural heart disease

(a) Weiss Circulation 2013;128:944–953
(b) Lambiase & et al

Case Study

Deborah’s first S-ICD implant

1/22/2014: Successful S-ICD implant
Summary

1 - SCA remains an undertreated problem

2 - Traditional therapy is still the mainstay of treatment but ..........

3 - Subcutaneous therapy is an option

Welcome To The Other Side
Objective
Evaluate the safety and effectiveness of the S-ICD™ System in the treatment of life-threatening ventricular arrhythmias

Design
Prospective, non-randomized, multicenter, single-arm clinical study conducted in the United States, Europe and New Zealand

Enrollment
Began January 2010, concluded May 2011

Primary IDE Effectiveness Endpoint
- Acute induced VF conversion efficacy
  - Induction testing well-established as surrogate for low-occurring spontaneous episodes
  - Hypothesis: Lower Bound of CI 95% > 88%

Primary IDE Safety Endpoint
- 180-day S-ICD™ System complication-free rate
  - Complication-free rates well-established as safety measure for ICDs
  - Hypothesis: Lower Bound of CI 95% > 79%

Patient Distribution Similar to NCDR Registry
- S-ICD™ System IDE Study
  - n = 325 patients
    - Primary Prevention: 79%
    - Secondary Prevention: 21%
  
- NCDR ICD Registry
  - n = 466,023 patients
    - Primary Prevention: 78%
    - Secondary Prevention: 22%
IDE Study Results
Met Both Effectiveness and Safety Endpoints

Effectiveness Endpoints Met
• 100% conversion of induced arrhythmias in evaluable patients

Safety Endpoints Met
• 99% Free from S-ICD™ System complications

Both endpoints met even under worst case sensitivity analysis

Spontaneous VF/VT Episodes
• 119 events in 21 patients
• 100% converted with 80J or spontaneously converted
• 92% first shock conversion efficacy

Complications
• 4.4% perioperative complication rate
• 1 explant for infection (first 1/3 of pts)
• No systemic infection or endocarditis
• No arrhythmic deaths

IDE Clinical Study
Therapy Appropriately Withheld

- Algorithm prevents therapy for VT/VF rhythms that spontaneously terminate prior to discharge.
- Therapy was appropriately withheld in 25 patients with 33 MVT episodes that met criteria to charge.
- No reports of syncope

Ongoing Clinical Studies
Capturing Long-Term S-ICD™ System Performance

EFFORTLESS European Registry

<table>
<thead>
<tr>
<th></th>
<th>US Post Approval Study</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design</strong></td>
<td>Observational, Nonrandomized</td>
</tr>
<tr>
<td><strong>Size</strong></td>
<td>50 centers, 1,000 patients</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td>Europe and New Zealand</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td>30-day complications</td>
</tr>
<tr>
<td></td>
<td>1-year complications</td>
</tr>
<tr>
<td></td>
<td>Inappropriate shocks</td>
</tr>
<tr>
<td></td>
<td>Quality of life</td>
</tr>
<tr>
<td></td>
<td>Hospital personnel</td>
</tr>
<tr>
<td></td>
<td>experience</td>
</tr>
<tr>
<td></td>
<td>Cost effectiveness</td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td>12 months</td>
</tr>
<tr>
<td><strong>Enrollment Status</strong></td>
<td>635 enrolled (Dec 2013)</td>
</tr>
</tbody>
</table>

Weiss Circulation 2013;128:944–953
**Analysis of EFFORTLESS S-ICD™ Registry (n=369) and Danish TV-ICD Registry (n=784)**

Analysis of lead-related complications

- **S-ICD**
  - 1.6%
  - $p < 0.01$

- **TV-ICD**
  - 4.7%
  - $p < 0.05$

- **All complications and observations**
  - 11.5%

---

**Case Study**

**Plan:**

- Continue Recephin started at previous hospital. Infectious Diseases consulted.
- Hypertension well controlled, continue current medications.
- Depression well controlled, continue current medications.
- Given a low-sodium, low cholesterol diet and instructed to stick with diet and exercise for significant weight loss once discharged.
- Patient with anemia but no gross bleeding – monitor H and H.
- History of acute renal insufficiency with creatinine in 2012 of 0.7-0.8. Ordered CMP.
- Patient with congenital thrombocytopenia, platelet count of 88 at ER and no gross bleeding on exam. Continue to monitor.
- Significant GI history, no gross bleeding or pain. Encouraged to lose weight.
- Noted thyroid nodules on CT. TSH ordered and thyroid ultrasound needed after discharge. Needs discussion on smoking cessation.
- Extract the current T-ICD system.

---

**5–ICD™ System Implant Procedure**

- Does not require venous access
- Designed to reduce complications
- Designed to be predictable
- Utilizes anatomical landmarks only
- Does not require fluoroscopy

In one study, 95% of patients were implanted using only anatomical landmarks (no medical imaging).
**Design Goals of Subcutaneous ICD Therapy**

To Overcome Limitations of Transvenous Leads

Anatomical limitations
- Venous access issues

Implant risks
- Pericardial effusion/cardiac tamponade, perforation, pneumothorax, lead dislodgement, endocarditis, systemic infection, death

Lead failure risks
- Inappropriate shock/loss of therapy

Explant risks
- Vessel dissection, perforation or occlusion, valve damage, bleeding, tamponade, systemic infection, death

**Function of the S-ICD™ System**

Straightforward programming and follow-up
**INSIGHT™ Rhythm Discrimination**

- The INSIGHT algorithm identifies and evaluates a heart rhythm rather than individual heartbeats to effectively discriminate VT/VF.
- Studies have shown that the S-ICD™ System’s dual zone programming using the INSIGHT™ algorithm reduces the likelihood of inappropriate shocks.\(^{a,b,c}\)
- Similar to PREPARE Study programming, the INSIGHT algorithm only initiates therapy for longer duration tachyarrhythmias.\(^{c}\)

\(^{a}\) Weiss Circulation 2013; 128: 944–953
\(^{b}\) Olde Nordkamp presentation MP01-5 HRS 2013, Denver CO
\(^{c}\) Olde Nordkamp J Am Coll Cardiol 2012; 60: 1933-1939

**Therapy Delivery**

- **Episodes**
  - Up to 5 shocks per episode @ 80J
  - Up to 128 seconds of S-ECG storage per episode
  - Storage of up to 44 episodes
- **Adaptive Shock Polarity**
  - System remembers the polarity of the last successful shock and automatically selects this shock polarity for the first shock of an episode

**Shock Vector**
- Encompasses the entire left chest
- Tolerant of a wide variety of cardiac sizes/ orientation/hypertrophy

---

---

---
**ICD-HCM Trial**

**Arrhythmias Triggering ICD Intervention**

- VT and VF 14%
- VF only 29%
- VT only 48%
- Bradyarrhythmias = 0

**Background:**

**Objective:** The aim of this study was to assess the performance of a small-diameter high-voltage implantable cardioverter-defibrillator lead.

**Methodology:** The actual turn-on of Sprint Fidelis leads in 340 patients implanted at our center was compared with that of the Sprint Fidelis lead received. The analysis was based on all patients enrolled in the study. The primary outcomes were the incidence of appropriate implantable cardioverter-defibrillator (ICD) shocks, the need for ICD reprogramming, and the occurrence of lead fracture or erosion.

**Results:** The incidence of appropriate ICD shocks was significantly lower in the small-diameter high-voltage lead group compared to the standard-diameter lead group. The need for ICD reprogramming was also lower in the small-diameter lead group. Lead fracture or erosion was observed in some patients in both groups, but the rate was significantly lower in the small-diameter lead group.

**Conclusion:** The small-diameter high-voltage lead appears to be safer than the standard-diameter lead, with a lower incidence of appropriate shocks, reprogramming, and lead fracture or erosion. Further studies are needed to confirm these findings.

---

**HCM**

**Risk Factors:**
- Cardiac arrest/sudden death
- Family history of sudden death
- Marfan syndrome
- Recurrent syncope
- Multiple-reentrant NVs
- Exercise syncope

**ICD**

- Amiodarone (?)

**Risk Levels:**
- Intermediate
- Low
6949 Fidelis Lead

Extraction Recommendations

- Though generally not recommended, consider prophylactic removal –
  - In young active patients
  - At the time of battery change in young patients
  - ???

- Extract the lead at ANY sign of malfunction
  - Impedance rise
  - Noise sensing

SCD in Preserved LVEF

Community-based studies of SCD

  - 714 SCD cases in Multnomah County, OR (2002-2004)
  - Only one-third of the evaluated SCD cases had severe LV dysfunction meeting current criteria for prophylactic ICD implantation
  - “These findings support the aggressive development of alternative screening methods to enhance identification of patients at risk.”

- deVreede-Swagemakers et al (1997)
  - 515 SCD cases in Maastricht, Netherlands (1991-1994)
  - 56.5% of all SCA victims had an LVEF > 30%

Remaining Issues

- Under-penetration in the current primary prevention population
  - Patient identification (education, resources)
  - Patient selection (advanced age, co-morbidities)
  - Reluctance
    - Physician: Is EF the best risk stratifier?, recalls, inappropriate shocks, optimization of pharmacological therapy
    - Patient: psycho-social aspects of ICD, morbidity, recalls
    - Societal: cost-effectiveness, number needed to treat (NNT)

- Identification of high-risk patients who do not meet current primary prevention indications