Indications The Protecta™ XT CRT-D system is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular tachyarrhythmias and for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class II/III) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration. Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive Pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmias in ICD indicated patients with atrial septal lead placement and an ICD indication.

The Protecta DR and VR system is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular tachyarrhythmias in patients with NYHA Functional Class II/III heart failure. The Protecta DR is also indicated for use in the above patients with atrial tachyarrhythmias, or those patients who are at a significant risk of developing atrial tachyarrhythmias. Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive Pacing (PMOP) are indicated for the Prevention of Suppression of Atrial Tachyarrhythmias in ICD indicated patients with atrial septal lead placement and an ICD indication. Additional Protecta XT DR System Notes: The ICD features of the device function the same as other approved Medtronic market released ICDs. Due to the addition of the OptiVol® diagnostic feature, the device indications are limited to the NYHA Functional Class II/III heart failure patients who do not have fluid retention related symptoms due to heart failure. The use of the device has not been demonstrated to decrease the morbidity related to atrial tachyarrhythmias. The effectiveness of high frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 17%, and in terminating device classified atrial fibrillation (AF) was found to be 16.9%, in the VTAI patient population studied. The effectiveness of high frequency burst pacing (atrial 10 Hz Burst therapy) in terminating device classified atrial fibrillation (AF) was found to be 36.8%. The clinical value of the OptiVol® fluid monitoring diagnostic feature has not been assessed in those patients who do not have fluid retention related symptoms due to heart failure. Changes in a patient's disease and/or medications may alter the efficacy of the device's programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transvenous defibrillation paddles directly over the device. Additionally, for CRT-ICDs, certain programming and device operations may not provide cardiac synchronization. Potential Complications: Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate tachyarrhythmia episodes, acceleration of ventricular tachycardia, and surgical complications such as hematomas, infection, inflammation, and thrombosis. See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call 1(800) 328-2518 and/or consult Medtronic’s website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.
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<td>2008</td>
<td>Mark DB</td>
<td>QoL</td>
<td>39</td>
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Introduction

For the past 20 years, Medtronic has been the leader in developing and implementing technology and programming recommendations to reduce shocks. Protecta™ ICD and CRT-D systems are the latest to lead the industry toward devices that shock only true VT/VF.

This guide will serve as a resource for evidence-based decision making to reduce unnecessary and inappropriate shocks. All of these findings from this literature were utilized to develop SmartShock Technology – six new exclusive algorithms that discriminate true lethal arrhythmias from other arrhythmic and nonarrhythmic events.

Section I – Clinical Need

In the past 20 years, many trials have demonstrated the mortality benefits of ICDs. However, these trials also showed a high incidence of unnecessary and inappropriate shocks. According to Dr. Sweeney, “Strategies to minimize shocks may further improve survival in ICD patients.” This section includes studies that highlight the potential mortality benefit of shock reduction and the incidence of shocks observed in these studies.

Appropriate Evaluation and Treatment of Heart Failure Patients after Implantable Cardioverter-Defibrillator Discharge

Summary
Multiple clinical trials support the use of ICDs for prevention of sudden cardiac death in patients with heart failure. Unfortunately, several complicating issues have arisen from the universal use of ICDs in HF patients. An estimated 21% of HF patients who receive an ICD for primary prevention will experience an appropriate shock within 1 to 3 years of implant, and one-third of patients will experience an inappropriate shock. An ICD shock is associated with a 2- to 5-fold increase in mortality, with the most common cause being progressive HF.

Authors
Mishkin JD, Saxonhouse SJ, Woo GW, et al.

Source

Study Type
Review paper of existing studies (AVID, MADIT-II, DEFINITE, SCD-HeFT).

Design
Data from approximately 6,000 patients enrolled in several clinical trials was examined.

Objectives
This review describes an evidence-based, multidisciplinary strategy for evaluating and managing HF patients who receive an ICD shock, with special emphasis on aggressive monitoring to reduce future shocks and HF events.

Key Results
• An estimated 21% of HF patients who receive an ICD for primary prevention will experience an appropriate shock within 1 to 3 years of implant, and one-third of patients will experience an inappropriate shock.
• An ICD shock is associated with a 2- to 5-fold increase in mortality, with the most common cause being progressive HF.

Conclusion
ICD therapy is now part of standard medical care to reduce the risk of sudden cardiac death in HF patients. Although ≥ 60% of patients who receive an ICD for primary prevention will not receive an ICD shock over the first several years, many will receive appropriate and inappropriate shocks that are associated with an increase in HF event risk. Appropriate evaluation of the HF patient after an ICD shock is required to identify the cause and reduce the incidence of future shocks. Heart failure surveillance strategies need to be developed as patients continue to avoid sudden cardiac death while increasing their risk of heart failure events after an ICD shock.

Clinical Implications
Shock reduction is important to HF patients because both appropriate and inappropriate shocks can be associated with an increase in HF events.

Key takeaway:
Up to 21% of HF patients receive inappropriate shocks.

Study Supports Lifesaving Benefits of Implantable Defibrillation Devices

Summary
Researchers with the ALTITUDE, an observational study of 47,032 patients with ICDs and 38,967 patients with CRT-Ds documented 3-year survival rates of 96% and 89%, respectively – levels that exceed those reported from earlier pivotal studies. Five-year survival rates in ALTITUDE were 92% for patients with ICDs and 78% for those with CRT-Ds.

Authors
Mitka M.

Source

Study Type
Retrospective analysis of LATITUDE database.

Design
The researchers looked at all patients enrolled in LATITUDE, a remote monitoring program from Boston Scientific that allows individuals with implantable devices to be followed up from their homes. The monitoring records, in turn, provide a large database that has proven useful for research. An independent panel analyzed the data from 1,272 shocks.

Objectives
To evaluate the lifesaving benefits of ICDs.

Key Results
• Any inappropriate first shock from the devices (which occurred for 35.5% of patients with ICDs and 34.5% of patients with CRT-Ds over a 5-year period) was associated with a mortality risk that was at least 2.2 times that of patients who never received a shock.
• This increased risk translated into a 5-year survival rate of 91.8% for patients with ICDs who received a shock compared with 93% for those with ICDs who did not receive shocks.
• Among patients with CRT-Ds, the survival rate over 3.5 years was 75.6% for those who had received a shock compared with 80% for those who had not.

Conclusions
The inappropriate first-shock rate seen in ALTITUDE was similar to the levels of 30% to 45% seen in other studies. Regardless of the issue of appropriateness, a shock has clinical implications, serving as a marker for increased mortality risk.

Clinical Implications
Shock reduction is an important part of the management of ICD patients.

Key takeaway:
35% of patients received an inappropriate shock at 5 years for all causes.
**Summary**

ICD shocks for VF save lives when no other therapy type is effective. However, recent evidence indicates an association between shocks and increased mortality risk. The objective of the study was to determine whether shocks or ATP are associated with increased patient mortality. Shocked VA episodes, but not ATP-terminated episodes, are associated with increased mortality risk. Shocked patients have a substantially higher VA episode burden and poorer survival compared with ATP-only treated patients.

**Authors**

Sweeney MO, Sherfesee L, DeGroot PJ, Wathen MS, Wilkoff BL.

**Source**


**Study Type**

Review of existing studies.

**Design**

Retrospective analysis of four trials incorporating ATP to reduce shocks – PainFREE Rx, PainFREE Rx II, EMPIRIC, and PREPARE – in 2,135 patients with a total of 5,376 spontaneous episodes and 10.8 months’ mean follow-up. An iterative statistical modeling process was employed to uncouple the effect of the arrhythmia from the delivered therapy (after adjusting for baseline predictors by including baseline characteristics), episode type (VT, FVT, VF), and therapy type (shocks or ATP).

**Objectives**

To determine whether shocks or ATP are associated with increased patient mortality.

**Key Results**

- Patients with shocked ventricular arrhythmias (VA) had 20% increased mortality risk per shocked episode, while ATP-terminated VA was not associated with higher mortality risk.
- Patients who died had 5 to 6 times more ventricular arrhythmias than survivors. Inappropriate shocks were not associated with increased risk of death. ATP had a very high efficacy, terminating 80% of all treated VA episodes.

**Conclusion**

Shocked VA episodes, but not ATP-terminated episodes, are associated with increased mortality risk. Shocked patients have a substantially higher VA episode burden and poorer survival compared with ATP-only treated patients.

**Clinical Implications**

- Strategies to minimize shocks may further improve survival in ICD patients.
- Strategies and technologies to reduce shocks and arrhythmia burden should be adopted.
- 96% of episodes should be targeted with ATP therapy first in order to effectively treat VAs.

**Key takeaway:**

Shocks are associated with increased mortality risk.
Prognostic Importance of Defibrillator Shocks in Patients with Heart Failure

Summary
Patients with heart failure who receive an implantable cardioverter defibrillator (ICD) for primary prevention (i.e., prevention of a first life-threatening arrhythmic event) may later receive therapeutic shocks from the ICD. Information about long-term prognosis after ICD therapy in such patients is limited. Among patients with heart failure in whom an ICD is implanted for primary prevention, those who receive shocks for any arrhythmia have a substantially higher risk of death than similar patients who do not receive such shocks.

Authors
Poole JE, Johnson GW, Hellkamp AS, et al.

Source

Study Type
Review paper of SCD-HeFT data.

Design
811 patients from the SCD-HeFT trial were implanted with an ICD. The relationship of ICD-shock therapy to death from any cause was examined.

Objectives
To assess the long-term prognostic significance of both appropriate and inappropriate ICD shocks in SCD-HeFT.

Key Results
- Those who receive shocks for any arrhythmia have a substantially higher risk of death than similar patients who do not receive such shocks.

Conclusions
Inappropriate shocks in the MADIT-II study, occurred in 83 (11.5%) of the 719 MADIT-II ICD patients and constituted 31.2% of all shock episodes. Smoking, atrial fibrillation, diastolic hypertension, and prior appropriate shocks occurred in and constituted an increased chance of inappropriate shock. Inappropriate shock occurrence was associated with increased mortality. Coupled with potential effects on quality of life, this association with increased mortality heightens the importance of efforts to reduce the occurrence of inappropriate shocks.

Clinical Implications
Shock reduction is important, as shown in a cohort of patients from the MADIT-II trial. Every means available should be utilized in order to decrease shocks as much as possible.

Key takeaway:
MADIT-II – 31% inappropriate shocks. In primary prevention patients, inappropriate shocks are associated with an increased mortality risk (no causal relationship) after 5 years.

The graph below shows that an appropriate shock, as compared with no appropriate shock, was associated with a risk that was increased by a factor of more than 5, and an inappropriate shock, as compared with no inappropriate shock, was associated with a near doubling of the risk of death.

<table>
<thead>
<tr>
<th>Shock type</th>
<th>Hazard ratio for death (95% CI)</th>
<th>P-Value</th>
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</thead>
<tbody>
<tr>
<td>≥ 1 app vs. no app</td>
<td>5.68 (3.97-8.12)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>≥ 1 inapp vs. no inapp</td>
<td>1.98 (1.29-3.05)</td>
<td>0.002</td>
</tr>
<tr>
<td>Both shock types vs. no shock</td>
<td>11.27 (6.70-18.94)</td>
<td>&lt; 0.001</td>
</tr>
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</table>

The graph below shows the adjusted hazard ratios for the risk of death according to the number of appropriate or inappropriate shocks. One appropriate shock was associated with a risk of death that was increased by a factor of approximately 4, whereas a second appropriate shock was associated with a further significant increase by a factor of 2.

<table>
<thead>
<tr>
<th>Shock type</th>
<th>Hazard ratio for death (95% CI)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 app vs. no app</td>
<td>3.98 (2.52-6.30)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>≥ 2 apps vs. no app</td>
<td>8.23 (4.64-14.59)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>≥ 2 apps plus 1 inapp vs. no shock</td>
<td>15.89 (7.42-34.02)</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>
Conclusions

Among patients with heart failure in whom an ICD is implanted for primary prevention, those who receive shocks for any arrhythmia have a substantially higher risk of death than similar patients who do not receive such shocks.

Clinical Implications

Shock reduction can improve survival in ICD patients. Therefore, every effort should be made to decrease both appropriate and inappropriate shocks whenever possible.

Key takeaway:
In primary prevention HF patients, shocks are associated with an increased risk of mortality.

Necessity for Surgical Revision of Defibrillator Leads Implanted Long-Term: Causes and Management

Summary

Defibrillator lead malfunction is a potential long-term complication in patients with an implantable cardioverter defibrillator (ICD). The aim of this study was to determine the incidence and causes of lead malfunction necessitating surgical revision and to evaluate two approaches to treat lead malfunction. ICD lead malfunction necessitating surgical revision becomes a clinically relevant problem in 2.5% of ICD recipients within 5 years. In selected cases, simple implantation of an additional pace/sense lead is feasible. Regardless of the chosen approach, the incidence of recurrent ICD lead-related problems after lead revision is 8-fold higher in this population.

Authors

Source

Study Type
Retrospective analysis.

Design
We included 1,317 consecutive patients with an ICD implanted at three European centers between 1993 and 2004. The types and causes of lead malfunction were recorded. If the integrity of the high-voltage part of the lead could be ascertained, an additional pace/sense lead was implanted. Otherwise, the patients received a new ICD lead.

Objectives
To determine the incidence and causes of lead malfunction necessitating surgical revision and to evaluate two approaches to treat lead malfunction.

Key Results
- At 5 years, the cumulative incidence was 2.5% (95% confidence interval, 1.5 to 3.6)
- Lead malfunction resulted in inappropriate ICD therapies in 76% of the cases
- Implantation of a pace/sense lead was feasible in 63%
- Both lead revision strategies were similar with regard to lead malfunction recurrence (P = 0.8). However, the cumulative incidence of recurrence was high (20% at 5 years; 95% confidence interval, 1.7 to 37.7).

Conclusions
ICD lead malfunction necessitating surgical revision becomes a clinically relevant problem in 2.5% of ICD recipients within 5 years. In selected cases, simple implantation of an additional pace/sense lead is feasible. Regardless of the chosen approach, the incidence of recurrent ICD lead-related problems after lead revision is 8-fold higher in this population.

Clinical Implications
ICD leads malfunction for many different reasons and across all companies. It is important to utilize all strategies available in order to identify these issues prior to the patient receiving any inappropriate shocks.

Key takeaway:
ICD lead malfunction becomes clinically relevant in 2.5% of ICD recipients within 5 years.
Section II – Clinical Proof

SmartShock technology dramatically reduces the incidence of inappropriate shocks while maintaining sensitivity.\(^1\,^2\) It includes six exclusive algorithms that discriminate true lethal arrhythmias from other arrhythmic and nonarrhythmic events.

This section highlights the studies that have shown how the revolutionary algorithms in Protecta can reduce shocks. It also provides an overview of studies that have shown the benefits of some of our other algorithms.

\(^1\) Virtual ICD: A Model to Evaluate Shock Reduction Strategies. Presented at HRS 2010 (P03-125).
\(^2\) Protecta Clinical Study, Medtronic data on file.
Virtual ICD: Combining Shock Reduction Strategies to Enhance ICD Therapy: A Role for Computer Modeling

**Summary**
While the implantable cardioverter defibrillator (ICD) can reduce mortality, inappropriate ICD shocks remain a limitation. Randomized trials provide evidence of efficacy, but they are not always practical. Computer models provide an alternative approach, and are particularly useful when evaluating multiple interventions. A computer model was developed using clinical data and validated in a separate large ICD dataset (EMPIRIC). After validation, the model was applied to 736 real adjudicated clinical episodes from the ICD arm of the SCD-HeFT. Computer modeling is able to predict the results of a known clinical trial and demonstrate that shock reduction strategies have the potential to significantly reduce inappropriate and unnecessary ICD shocks versus the mandated programming used in SCD-HeFT.

**Authors**
Volosin KJ, Exner DV, Wathen MS, Sherfesee L, Scinicariello AP, Gillberg JM.

**Source**
Online. October 11, 2010

**Study Type**
Computer model.

**Design**
Step 1: A computer model was developed using the shock reduction feature implementation hierarchy (modeled after Protecta SmartShock) and statistical distributions of device performance derived from prior clinical ICD studies.

Step 2: Portions of the model were validated in a separate large ICD dataset (EMPIRIC).

Step 3: The model was then applied to 736 real adjudicated clinical episodes from the ICD arm of the SCD-HeFT.

- The computer model was repeated 10,000 times for each episode in order to generate a robust estimated range of shock avoidance performance.

**Objectives**
The purpose of this study was to develop a computer model to predict the performance of existing and new shock reduction technology and strategies without the expense and complexity of clinical trials.

**Key Results**
1. Number of Patients Shocked:
   - Overall modeled VF sensitivity: 99.2%.
   - At 5 years, percentage of patients receiving inappropriate shocks from the dual chamber model was 8.4% versus 23.5% in the original study.

2. Number of Episodes Shocked:
   - Shocks for SVT episodes decreased from 131 episodes to 12 episodes (NID of 18/24).

**Conclusion**
This model was able to hypothetically demonstrate a significant reduction in shocks. In this analysis, a combination of shock reduction strategies reduced both the calculated proportion of patients receiving shocks and the total shock burden. No single approach to shock reduction was sufficient to eliminate all types of unnecessary and inappropriate shocks.

**Clinical Implications**
The new shock reduction algorithms in Protecta can decrease inappropriate shocks by 82% while still maintaining safety.

**Key takeaways:**
- A carefully adjudicated dataset, along with a robust validation and statistical methods, ensured the validity of the model.
- In a primary prevention cohort programmed with a single detection zone with rate cutoff of 188 bpm and new shock reduction strategies, 97.6% of patients were predicted to be free of inappropriate shocks at 1 year and 91.6% at 5 years.

---

Time Course and Characterization of Defibrillator Shocks Using a Virtual ICD Model

**Summary**
ICD therapy reduces mortality from VT/VF, but shocks for non-VT/VF events are common. We assessed the potential benefit of shock reduction methods using data from the SCD-HeFT trial. Reasons for shocks varied over time. Shock-avoidance methods, in combination, have the potential to eliminate > 80% of nonessential shocks in primary prevention ICD recipients.

**Authors**
Exner DV, Wathen MS, Volosin KJ, Sherfesee L, Scinicariello AP, Gillberg JM.

**Source**
HRS Conference 2010.

**Study Type**
A Virtual ICD decision model using data from SCD-HeFT.

**Design**
A Virtual ICD decision analysis model was developed and validated. It combines algorithms to avoid shocks via enhanced detection (SVT, oversensing, and noise) with ATP.

**Objectives**
To assess the potential benefit of shock reduction methods using data from SCD-HeFT.

**Key Results**
- Forty-four percent (44%) of the included shocks were for episodes adjudicated to be non-VT/VF.
- These inappropriate shocks were decreased by 82% using the Virtual ICD algorithms.
- The shock reduction methods were effective throughout follow-up.

**Conclusion**
Reason for shocks varied over time. Shock-avoidance methods, in combination, have the potential to eliminate > 80% of inappropriate shocks in primary prevention ICD patients.

**Clinical Implications**
The use of enhanced detection algorithms can decrease inappropriate shocks in the primary prevention patient population by 82%.

**Key takeaway:**
SmartShock potentially eliminates 82% of inappropriate shocks at 5 years post-implant.
CareLink® ATP Analysis Antitachycardia Pacing Treats More Episodes but Reduces All-Cause Shocks in 200,000 ICD Recipients

Summary
Antitachycardia pacing (ATP) reduces shocks for ventricular tachycardia (VT). We sought to determine if ATP reduces all-cause shocks in a heterogeneous ICD population. Episodes consisted of monomorphic and polymorphic VT, all forms of supraventricular tachycardia, and T Wave oversensing. Analysis included devices with and without ATP during charging capabilities. Even with ATP programmed ON, some VT episodes will go directly to shock therapy. In spite of these factors, ATP still significantly reduces the overall number of shocked events.

Authors

Source
HRS Conference 2010.

Study Type
CareLink ATP retrospective analysis.

Design
We analyzed episodes from patients with single, dual, and CRT ICDs in a large de-identified database. All episodes with rates between 188–250 bpm were analyzed. Episodes faster than 250 bpm were excluded since ATP is unlikely to be beneficial.

Objectives
To determine if ATP reduces all-cause shocks in a heterogeneous ICD population.

Key Results
- Of 205,433 patients, there were 173,738 episodes between 188 AND 250 bpm that met detection duration
- ATP resulted in a 35% relative reduction in shocked episodes
- ATP ON patients had a total of 50,756/143,028 shocked episodes (36%) compared to the ATP OFF group with 16,785/30,710 (55%, p < 0.0001)
- Thirteen percent of ATP ON episodes went directly to shock without ATP delivery due to variations in cycle length or programmed ATP limit
- Since some episodes terminated spontaneously during charging or failed to meet redetection criteria, 45% of ATP OFF episodes avoided a shock

Conclusion
In a large cohort of ICD patients with mixed implant indications, ATP treats 35% more episodes than a ‘shock only’ approach. Even with ATP programmed ON, some VT episodes will go directly to shock therapy. In spite of these factors, ATP still significantly reduces the overall number of shocked events.

Clinical Implications
ATP should be utilized as much as possible in order to reduce shocks.

Key takeaway:
One out of three shocks is avoided due to ATP.

(AtP success versus cycle length)

ATP reduces total shocked episodes

<table>
<thead>
<tr>
<th>Episodes</th>
<th>ATP OFF</th>
<th>ATP ON</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shock only (%)</td>
<td>16,785 (55)</td>
<td>18,570 (13)</td>
</tr>
<tr>
<td>ATP only (%)</td>
<td>0</td>
<td>78,356 (55)</td>
</tr>
<tr>
<td>ATP and shock (%)</td>
<td>0</td>
<td>32,186 (23)</td>
</tr>
<tr>
<td>Aborted</td>
<td>13,925 (45)</td>
<td>13,916 (10)</td>
</tr>
</tbody>
</table>

(PainFREE Rx II) Prospective Randomized Multicenter Trial of Empirical Antitachycardia Pacing Versus Shocks for Spontaneous Rapid Ventricular Tachycardia in Patients with Implantable Cardioverter-Defibrillators

Summary
This prospective, randomized, multicenter trial compares the safety and utility of empirical ATP with shocks for FVT in a broad ICD population. Compared with shocks, empirical ATP for FVT is highly effective, is equally safe, and improves quality of life. ATP may be the preferred FVT therapy in most ICD patients.

Authors
Wathen MS, Degroot PJ, Sweeney MO, et al, for the PainFREE Investigators.

Source

Study Type
Prospective, randomized, multicenter trial.

Design
634 ICD patients were randomized to two arms – standardized empirical ATP (n = 313) or shock (n = 321) – for initial therapy of spontaneous FVT. ICDs were programmed to detect FVT when 18 of 24 intervals were 188–250 bpm and 0 of the last 8 intervals were > 250 bpm. Initial FVT therapy was ATP or shock. Syncope and arrhythmic symptoms were collected through patient diaries and interviews.

Objectives
The primary objective tested whether duration for FVT episodes initially treated with ATP was ≥ 6 seconds longer than those treated by shock. Secondary objectives included self-reported QoL, ATP efficacy and acceleration, and syncope.

Key Results
- FVT is common (76% of all devices detected FVTs)
- ATP successfully terminated three out of four FVTs
- ATP added no additional risk from syncope or acceleration

Conclusions
Compared with shocks, empirical ATP for FVT is highly effective, is equally safe, and improves quality of life. ATP may be the preferred FVT therapy in most ICD patients.

Clinical Implications
Program ATP as first therapy for FVTs (188-250 bpm).

Key takeaway:
ATP successfully eliminates three out of four shocks, thus improving quality of life.
Summary
ICD lead failures typically present as inappropriate shock therapy. Identifying lead failures before their clinical presentation may prevent patient discomfort, improve device longevity, and avoid device-induced pro-arrhythmia. Oversensing combined with abnormal impedance trends may be used to identify ICD lead failures.

Authors

Source

Study Type
Testing of an algorithm by tracking lead impedance measurements.

Design
The impedance measure tracked lead impedances every day and each week. Abnormal impedance was defined as a decrease in impedances or an outlier value compared with baseline. Lead failures were identified when both oversensing measures were met, or abnormal impedance and one oversensing measure occurred. The stored data from 696 patients with an ICD were analyzed to determine the sensitivity and specificity of the algorithm to detect lead failures.

Objectives
The goal of this analysis was to test an algorithm that identifies implantable cardioverter defibrillator (ICD) lead problems before clinical failure and/or inappropriate therapy.

Key Results
• Twenty-nine patients demonstrated clinical lead failures
• The two oversensing measures used in the algorithm predicted 72% (21 of 29) of the lead failures
• Fulfilling at least two of the three impedance and oversensing measures, the sensitivity of our algorithm was 83% (24 of 29) with 100% (667 of 667) specificity

Conclusions
Oversensing combined with abnormal impedance trends may be used to identify ICD lead failures with high sensitivity and very high specificity.

Clinical Implications
Lead Integrity Alert accurately and automatically provides at least 3 days' advanced warning in three out of four patients with lead fracture.

Key takeaway:
Lead Integrity Alert works while maintaining sensitivity and specificity.

Lead Integrity Alert Abstract (HRS) – Downloadable Software Reduces Inappropriate Shocks Caused by ICD Lead Fractures: Results from a Prospective Study

Summary
Fractures of pace-sense conductors in ICD leads may cause oversensing and inappropriate shocks. Alerts based on high impedance provide limited warning. A Lead Integrity Alert approved for download into previously implanted ICDs, is triggered either by high impedance or rapid oversensing. It responds by initiating a delay in VF detection and frequent audible and/or Internet-based patient alerts. The Lead Integrity Alert download reduced inappropriate shocks in patients with Fidelis lead fractures. Prompt response to alerts by patients and physicians may reduce inappropriate shocks further.

Authors
Swerdlow CD, Gunderson B, Ousdigian K, Sachanandani H, Ellenbogen K.

Source
HRS Conference 2010.

Study Type
Prospective study.

Design
Patients were included if they had Sprint Fidelis® pace-sense fractures (confirmed by analysis of explanted, returned leads) and stored device data was available for analysis. The primary end point was the fraction of patients with ≥ 1 inappropriate shock.

Objectives
To determine if the Lead Integrity Alert could reduce inappropriate shocks compared to a concurrent cohort of patients monitored by impedance only (control group).

Key Results
• The Lead Integrity Alert download reduced inappropriate shocks in patients with Fidelis lead fractures
• Prompt response to alerts by patients and physicians may reduce further inappropriate shocks

Conclusions
The Lead Integrity Alert Group had a 50% reduction in the fraction of patients who had ≥ 5 shocks. There was a 47% reduction in the fraction of patients with ≥ 1 shock. Of the Lead Integrity Alert patients who were shocked, 27% had 3 days of warning.

Clinical Implications
Lead Integrity Alert accurately and automatically provides at least 3 days' advanced warning in three out of four patients with lead fracture.

Key takeaway:
Lead Integrity Alert can decrease inappropriate shocks.
Modification to Lead Integrity Alert Improves Performance

**Summary**
ICD Lead Fractures may result in inappropriate shocks. While advanced warning of Lead Fractures may reduce their clinical consequences (e.g., shocks, loss of pacing), false alarms may increase medical burden and/or unnecessary procedures. We compared Lead Integrity Alert, a firmware download to detect Lead Fractures, to a modified Lead Integrity Alert that requires further evidence of Lead Fractures. The modified Lead Integrity Alert and Lead Integrity Alert provide similar advance warning for a high percentage of patients with ICD-lead fractures, but modified Lead Integrity Alert had higher positive predictive value and fewer false positives than Lead Integrity Alert.

**Authors**
Patel AS, Gunderson BD, Ousdigian KT, Abeyratne AI, Swerdlow CD, Ellenbogen KA.

**Source**
HRS 2010.

**Study Type**
Prospective study.

**Design**
To compare the two algorithms, the same set of 15,970 Fidelis patients from the Medtronic CareLink Network Database was retrospectively analyzed to estimate false positives per patient-year and positive predictive value.

**Objectives**
We compared the Lead Integrity Alert, a firmware download to detect LFs, to a modified Lead Integrity Alert that requires further evidence of LF.

**Key Results**
- The modified Lead Integrity Alert significantly reduced FPs to 1 in 1,285 patient-years
- The modified Lead Integrity Alert had no significant difference in the 3-day advance warning compared to Lead Integrity Alert in the returned product analysis patients

**Conclusions**
The modified Lead Integrity Alert and Lead Integrity Alert provide similar advance warning for a high percentage of patients with ICD lead fractures, but modified Lead Integrity Alert had higher PPV and fewer false positives than Lead Integrity Alert.

**Clinical Implications**
Lead Integrity Alert accurately and automatically provides at least 3 days' advanced warning in three out of four patients with lead fracture.

**Key takeaway:**
Modification to Lead Integrity Alert can provide at least 3 days' advance warning.

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Downloadable Algorithm to Reduce Inappropriate Shocks Caused by Fractures of Implantable Cardioverter-Defibrillator Leads

**Summary**
The primary method for monitoring implantable cardioverter defibrillator lead integrity is periodic measurement of impedance. Sprint Fidelis leads are prone to pace-sense lead fractures, which commonly present as inappropriate shocks caused by oversensing. A lead-integrity algorithm developed for download into existing implantable cardioverter defibrillators increases short-term warning of inappropriate shocks in patients with lead fractures and reduces the likelihood of inappropriate shocks. It is the first downloadable RAMware to enhance the performance of nominally functioning implantable cardioverter defibrillators and the first implantable cardioverter defibrillator monitoring feature that triggers real-time changes in ventricular fibrillation detection parameters to reduce inappropriate shocks.

**Authors**
Swerdlow CD, Gunderson BD, Ousdigian KT, et al.

**Source**

**Study Type**
Analysis of a new algorithm.

**Design**
The algorithm was tested on 15,970 patients by downloading it into current devices.

**Objectives**
To test an algorithm to enhance early identification of lead fractures and to reduce inappropriate shocks.

**Key Results**
- The lead-integrity algorithm provided at least a 3-day warning of inappropriate shocks in 76% of patients versus 55% for optimal impedance monitoring
- Its positive predictive value was 72% for lead fractures and 81% for lead fractures or header-connector problems requiring surgical intervention
- The false-positive rate was 1 per 372 patient-years of monitoring

**Conclusions**
A lead-integrity algorithm developed for download into existing implantable cardioverter defibrillators increases short-term warning of inappropriate shocks in patients with lead fractures and reduces the likelihood of inappropriate shocks. It is the first downloadable RAMware to enhance the performance of nominally functioning implantable cardioverter defibrillators and the first implantable cardioverter defibrillator monitoring feature that triggers real-time changes in ventricular fibrillation detection parameters to reduce inappropriate shocks.

**Clinical Implications**
Lead Integrity Alert accurately and automatically provides at least 3 days' advanced warning in three out of four patients with lead fracture.

**Key takeaway:**
Enhanced Lead Integrity Alert provides at least 3 days' advanced warning for 76% of patients with ICD lead fractures.

<table>
<thead>
<tr>
<th>Measure</th>
<th>LIA</th>
<th>mLIA</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPV</td>
<td>73.2%</td>
<td>85.7%</td>
<td>0.005</td>
</tr>
<tr>
<td>FP</td>
<td>15</td>
<td>6</td>
<td>0.004</td>
</tr>
<tr>
<td>FP/patient-year</td>
<td>0.0019</td>
<td>0.0008</td>
<td>NA</td>
</tr>
<tr>
<td>3-day warning (from RPA)</td>
<td>76%</td>
<td>75%</td>
<td>0.85</td>
</tr>
</tbody>
</table>
A Simplified Biventricular Defibrillator with Fixed Long Detection Intervals Reduces Implantable Cardioverter Defibrillator (ICD) Interventions and Heart Failure Hospitalizations in Patients with Nonischemic Cardiomyopathy Implanted for Primary Prevention: The RELEVANT [Role of long dEtection window programming in patients with LEft Ventricular dysfunction, Non-ischemic eTiology in primary prevention treated with a biventricular ICD] Study

**Summary**

This study investigated the efficacy and safety of a cardiac resynchronization therapy with defibrillator (CRT-D) device with simplified ventricular tachycardia management in patients with nonischemic heart failure (HF) and primary prevention implantable cardioverter defibrillator (ICD) indication. Efficacy was assessed by computing appropriate and inappropriate detections and therapies during follow-up; safety compared hospitalizations and syncopal events between groups. A simplified CRT-D device with fixed long detection reduced overall ICD therapy burden and HF hospitalizations without entailing any additional adverse events in primary prevention nonischemic HF patients.

**Authors**


**Source**


**Study Type**

Prospective, controlled, parallel, multicenter, nonrandomized study.

**Design**

324 primary prevention nonischemic HF patients implanted with CRT-D devices from 2004 to 2007. Protect group, 164 patients implanted with a Medtronic InSync® III Protect device and Control group, 160 patients utilizing other Medtronic CRT-D devices.

**Objectives**

To investigate the efficacy and safety of cardiac resynchronization therapy with a defibrillator (CRT-D) device with simplified ventricular tachycardia management in patients with nonischemic heart failure (HF) and primary prevention implantable cardioverter defibrillator (ICD) indication.

**Key Results**

- Efficacy was assessed by computing appropriate and inappropriate detections and therapies during follow-up; safety compared hospitalizations and syncopal events between groups.
- Ninety percent of both ventricular and supraventricular tachyarrhythmias terminated within the 13-29 beat detection interval with the Protect algorithm.
- The Protect group showed a significantly better event-free survival to first delivered therapy for total. In the Protect group, a significantly reduced HF hospitalization rate was observed without any increase of syncope or death.

### Table

<table>
<thead>
<tr>
<th>Protect</th>
<th>Control</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shocked in ICD</td>
<td>10 (3)</td>
<td>5 (3)</td>
</tr>
<tr>
<td>Shocked in CRT-D</td>
<td>22 (10)</td>
<td>17 (7)</td>
</tr>
<tr>
<td>Appropriate therapy for total</td>
<td>36 (12)</td>
<td>289 (36)</td>
</tr>
<tr>
<td>Inappropriate therapy for total</td>
<td>20 (8)</td>
<td>242 (24)</td>
</tr>
</tbody>
</table>

**Conclusions**

A simplified CRT-D device with fixed long detection interval can benefit HF patients by reducing overall ICD therapy burden and HF hospitalizations.

**Clinical Implications**

Whenever possible, a longer fixed-detection interval can benefit HF patients by reducing overall ICD therapy burden and HF hospitalizations.

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(PREPARE Trial) Strategic Programming of Detection and Therapy Parameters in Implantable Cardioverter-Defibrillators Reduces Shocks in Primary Prevention Patients: Results from the PREPARE (Primary Prevention Parameters Evaluation) Study

**Summary**

Strategically chosen ICD VT/VF detection and therapy parameters have been shown in previous studies to reduce the number of shocked episodes. In the PREPARE (Primary Prevention Parameters Evaluation) study, these prior strategies were combined with additional strategies specific to primary prevention patients. Strategically chosen VT/VF detection and therapy parameters can safely reduce shocks and other morbidities associated with ICD therapy in patients receiving an ICD for primary prevention indications.

**Authors**

Wilkoff BL, Williamson BD, Stern RS, et al, for the PREPARE Study Investigators.

**Source**


**Study Type**

The PREPARE study was a prospective, nonrandomized, cohort-controlled study.

**Design**

PREPARE analyzed 700 patients with primary prevention indications for an ICD from 38 centers and followed them for 1 year.

**Objectives**

Our purpose was to demonstrate that strategically chosen ICD VT or VF detection and therapy parameters can reduce the combined incidence of device-delivered shocks, arrhythmic syncope, and untreated sustained symptomatic VT/VF.

**Key Results**

- A 63% reduction in unnecessary shocks for PREPARE patients
- PREPARE patients were less likely to receive a shock in the first year
- Less than 4% of PREPARE patients received an inappropriate shock
- Overall safety was excellent, as measured by arrhythmic syncope and mortality

**Conclusions**

Strategically chosen VT/VF detection and therapy parameters can safely reduce shocks and other morbidities associated with ICD therapy in patients receiving an ICD for primary prevention indications.

**Clinical Implications**

Consider PREPARE programming for primary prevention patients:
- NID 30/40
- Fast detection rate at 182 bpm (330 ms)
- ATP for fast VTs

**Key takeaway:**
Sixty-three percent reduction of shocks in primary prevention patients with an extended NID, short charge time, fast detection rate, and ATP for fast VTs.

---

**Table**

<table>
<thead>
<tr>
<th>Episodes</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>100</td>
</tr>
<tr>
<td>200</td>
</tr>
<tr>
<td>300</td>
</tr>
<tr>
<td>400</td>
</tr>
<tr>
<td>500</td>
</tr>
<tr>
<td>600</td>
</tr>
</tbody>
</table>

**Diagram**

![Diagram showing distribution of episodes]
Programming Strategies Associated with Shock Reduction in 88,804 Implantable Defibrillator Patients

Summary

Controlled clinical studies have found that programming can reduce ICD shocks. We sought to determine the impact of programming strategies on ICD shocks in a large cohort of patients. Strategic programming of faster VT/VF detection thresholds, longer detection durations, SVT discriminators, and ATP for FVT reduced shocks. Clinical actions to reduce morbidity from shocks should include ensuring adequate rate control for patients with AF as well as programming to increase the VT/VF detection rate and duration thresholds.

Authors
Wilkoff BL, Johnson JW, Ousdigian, KT, Gillberg JM, Fischer A.

Source
HRS 2010, Late-Breaking Clinical Trial.

Study Type
CoHORT analysis from a de-identified CareLink database.

Design
88,804 patients in > 2,500 institutions were followed for 2.5 years. The primary end point was the number of spontaneous all-cause shocked episodes per 100 patient-years.

Objectives
To determine the impact of programming strategies on ICD shocks in a large cohort of patients.

Key Results
- After adjusting for all variables, results showed that the following were associated with more shocks:
  1. A slower VT/VF rate detection threshold
  2. VF NID 12/16; younger age (< 70 years)
  3. AF
  4. Patients with replacement devices

- The following were associated with fewer shocks:
  1. VF NID 24/32 or 30/40
  2. SVT discriminators ON
  3. ATP ON
  4. Females
  5. Patients with CRT-D devices

Conclusions
Strategic programming of faster VT/VF detection thresholds, longer detection durations, SVT discriminators, and ATP for FVT reduced shocks. Clinical actions to reduce morbidity from shocks should include ensuring adequate rate control for patients with AF, as well as programming to increase the VT/VF detection rate and duration thresholds.

Clinical Implications
To reduce shocks, it is important to ensure adequate rate control for AF with RVR, as well as programming to increase the VT/VF detection rate and duration thresholds.

Key takeaway:
Faster VT/VF detection zones using ATP and SVT discriminators and programming of longer detection intervals decrease shocks.


Summary

Despite published data demonstrating the benefits of shock reduction programming, adherence to recommended programming parameters remains low. We sought to determine whether patients participating in the Shock-Less (SL) study are programmed differently from non-study patients followed in Shock-Less enrolling centers. The data suggests that merely participating in a trial aimed at examining ICD programming habits affects device programming. The programming differences occurred without any feedback to investigators in this study. The extent to which targeted feedback will further influence device programming is the goal of this trial.

Authors
Fischer A, Li S, Pickett RA, Ravinovich R, Silver MT, Sterns L.

Source
HRS 2010.

Study Type
Subgroup analysis of patients participating in the Shock-Less study.

Design
Save-to-disk data was obtained from 560 patients enrolled in SL between April and December 1, 2009. De-identified CareLink transmitted programming data from March to April 2009 was retrieved for 483 patients from centers actively enrolling in SL as a contemporary comparison group.

Objectives
To determine whether patients participating in the Shock-Less study are programmed differently from non-study patients followed in SL enrolling centers.

Key Results
- When brought to their attention, physicians will program shock reduction strategies in patients, even without targeted feedback.

Conclusions
This data suggests that merely participating in a trial aimed at examining ICD programming habits affects device programming. The programming differences occurred without any feedback to investigators in this study. The extent to which targeted feedback will further influence device programming is the goal of this trial.

Clinical Implications
Shock reduction programming is under-utilized and needs further adoption.

Key takeaway:
Less than 20% of centers are programming according to PREPARE programming.

<table>
<thead>
<tr>
<th>Programmable Parameter</th>
<th>Choice</th>
<th>Control Patients</th>
<th>Study Patients</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VF NID (number of intervals to detect)</td>
<td>12 of 16</td>
<td>18 of 24</td>
<td>24 of 32</td>
<td>30 of 40</td>
</tr>
<tr>
<td>ATP During Charging™</td>
<td>ATP Before Charging™*</td>
<td>59 (12.2%)</td>
<td>413 (85.5%)</td>
<td>11 (2.2%)</td>
</tr>
<tr>
<td>ATP During Charging minimal interval</td>
<td>200 ms</td>
<td>210 ms</td>
<td>230 ms</td>
<td>240 ms</td>
</tr>
</tbody>
</table>
(WAVE Study) Improving SVT Discrimination in Single-Chamber ICDs: A New Electrogram Morphology-Based Algorithm

**Summary**
Widespread adoption of ICD therapy has focused efforts on improving the quality of life for patients by reducing inappropriate shock therapies. To this end, distinguishing supraventricular tachycardia from ventricular tachycardia remains a major challenge for ICDs. More sophisticated discrimination algorithms based on ventricular electrogram morphology have been made practicable by the increased computational ability of modern ICDs. Results from this prospective study of the Wavelet electrogram morphology discrimination algorithm operating as the sole discriminator in the ON mode demonstrate that inappropriate therapy for supraventricular tachycardia in a single-chamber ICD can be dramatically reduced compared to rate detection alone.

**Objectives**
- Evaluation of the Wavelet algorithm, using morphology discrimination, to discriminate SVTs from true VTs in a single-chamber ICD.

**Key Results**
- Substantially reduced inappropriate therapy (78.2%).
- Maintained 99.2% sensitivity based on 100% spontaneous arrhythmias.

**Conclusions**
Results from this prospective study of the Wavelet electrogram morphology discrimination algorithm operating as the sole discriminator in the ON mode demonstrate that inappropriate therapy for supraventricular tachycardia in a single-chamber ICD can be dramatically reduced compared to rate detection alone.

**Clinical Implications**
Wavelet should be utilized in single-chamber ICDs to discriminate SVTs from VTs, thereby decreasing inappropriate shocks.

**Key takeaway:**
Wavelet can discriminate SVTs using a morphology algorithm while maintaining sensitivity and improving specificity.

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Head-to-Head Comparison of Three Morphology Discrimination Algorithms in Implantable Cardioverter-Defibrillators: Arrhythmia Discrimination of Atrial and Ventricular Arrhythmias

**Summary**
Despite published data demonstrating the benefits of shock-reduction programming, inappropriate therapy for atrial tachyarrhythmias by contemporary ICDs remains an important clinical challenge. Morphology discrimination was developed to improve arrhythmia discrimination without compromising device safety. A direct comparison of different single-chamber morphology discrimination algorithms has not been previously described. Arrhythmia discrimination based solely on electrogram morphology has the potential to reject atrial tachyarrhythmias; however, the specificity of different morphology discrimination algorithms ranges from 53% to 87%. Several factors affect specificity of arrhythmia discrimination, including detected ventricular rate, algorithm implementation, and electrogram source used for morphology discrimination.

**Objectives**
- To make a direct comparison of different single-chamber morphology discrimination algorithms.

**Key Results**
- Sensitivity was 85% for MD, and 100% for both Rhythm ID and Wavelet.
- Specificity for atrial tachyarrhythmias was significantly different for Wavelet (87%) compared to Rhythm ID (56%) and MD (53%).
- The majority of classification errors occurred during episodes of atrial fibrillation.
- Misclassification of atrial tachyarrhythmias was observed more frequently at ventricular rates > 190 bpm.

**Conclusions**
Arrhythmia discrimination based solely on electrogram morphology has the potential to reject atrial tachyarrhythmias; however, the specificity of different morphology discrimination algorithms ranges from 53% to 87%. Several factors affect specificity of arrhythmia discrimination, including detected ventricular rate, algorithm implementation, and electrogram source used for morphology discrimination.

**Clinical Implications**
All morphology algorithms do not perform equally. Wavelet has significantly higher specificity while maintaining 100% sensitivity.

**Key takeaway:**
Specificity of Wavelet compared to Rhythm ID and MD morphology discriminators was significantly higher (87% versus 56% and 53%, respectively).
Automatic Identification of T Wave Oversensing (TWOS) by Patterns of Alternating Amplitude and Frequency Content in Implantable Cardioverter-Defibrillator Electrograms

Summary
T Wave oversensing may cause inappropriate shocks in ICD patients. Programming options to prevent T Wave oversensing are limited and may compromise sensing of ventricular fibrillation (VF) or tachycardia (VT). This abstract presents a novel automatic T Wave oversensing rejection algorithm that does not require ICD reprogramming. This novel T Wave oversensing rejection algorithm reduced inappropriate detection of VT/VF in spontaneous T Wave oversensing episodes by 97.5% while maintaining 100% sensitivity for detecting true VT/VF.

Authors
Cao J, Shrivastiv M, Koehler JL, Swerdlow C, Gillberg J.

Source

Study Type
Algorithm development and testing were performed with an ICD model using stored electrograms of spontaneous T Wave oversensing and VT/VF from ICD patients.

Design
95 TWOS episodes with small R Waves and 92 with large R Waves were analyzed; 1,103 true VT/VFs were also analyzed.

Objectives
To present a novel automatic T Wave oversensing rejection algorithm that does not require ICD reprogramming.

Key Results
- Of 95 T Wave oversensing episodes with small R Waves (< 3 mV) and 92 with large R Waves (≥ 3 mV), 97.5% were appropriately rejected
- The primary reason for algorithm failure was small R Waves with large amplitude and high-frequency T Waves
- There was no missed or delayed VT/VF detection in 1,103 true VT/VFs

Conclusions
A novel T Wave oversensing rejection algorithm reduced inappropriate detection of VT/VF in spontaneous T Wave oversensing episodes by 97.5% while maintaining 100% sensitivity for detecting true VT/VF.

Clinical Implications
A novel T Wave oversensing algorithm can benefit patients who have T Wave oversensing without reprogramming the device.

Key takeaway:
A novel T Wave oversensing algorithm reduced inappropriate detection of VT/VF by 97.5%.

Withholding ICD Shocks for Detected Lead Fracture

Summary
ICD sensing noise from lead fractures causes inappropriate shocks. This study evaluated a new algorithm to discriminate ICD lead fracture noise from VT/VF by analysis of far-field electrograms (EGM). This new lead sensing noise algorithm can safely withhold 83.7% of inappropriate ICD detection due to lead fracture. A 45-second timeout prevents indefinite withholding of therapy in VT/VF but does not significantly reduce the benefit of the new algorithm.

Authors
Zhand X, Volosin KJ, Kumar A, Gunderson B, Gillberg J.

Source

Study Type
This study evaluated a new algorithm by analysis of far-field EGMs.

Design
The algorithm was tested using far-field EGMs recorded in ICDs. There were 60 patients (149 lead sensing noise episodes) with lead fracture and 505 VT/VF episodes from 180 patients. Testing was performed with VF detection interval at 320 ms and VF NID at 18/24.

Objectives
To develop an algorithm that can analyze ICD EGMs in real time in order to:
- Withhold shocks when lead fracture is recognized
- Alert physicians/patients to take clinical action

Key Results
- The algorithm detected 505 VT/VF episodes without delay but caused additional delay in detecting 2 episodes of polymorphic VT/VF with low-amplitude EGMs
- The algorithm withheld inappropriate shocks for 83.7% of lead sensing noise with the timeout feature disabled

Conclusions
This new lead sensing algorithm can safely withhold 83.7% of inappropriate ICD detection due to lead fracture. A 45-second timeout does not significantly reduce the benefit of the new algorithm.

Clinical Implications
This new algorithm can be utilized in ICD patients to prevent inappropriate shocks due to lead fracture and noise.

Key takeaway:
New algorithm can withhold 83.7% of inappropriate detection for lead sensing noise.
Summary
Programming of VT or VF detection and therapy for ICDs is complex, requires many choices by highly-trained physicians, and directly influences the frequency of shocks and patient morbidity. Standardized EMPIRIC ICD programming for VT/VF settings is at least as effective as patient-specific, physician-tailored programming, as measured by many clinical outcomes. Simplified and pre-specified ICD programming is possible without an increase in shock related morbidity.

Authors

Source

Study Type
Randomized study.

Design
A total of 900 ICD patients were randomly assigned to standardized (EMPIRIC, n = 445) or physician-tailored (TAILORED, n = 455) VT/VF programming and followed for 1 year.

Objectives
The purpose was to determine whether a strategically chosen standardized set of programmable settings is at least as effective as physician-tailored choices, as measured by the shock-related morbidity of implantable cardioverter defibrillator (ICD) therapy.

Key Results
• The primary end point was met: the adjusted percentages of both VT/VF and supraventricular tachycardia or other non-VT/VF event episodes that resulted in a shock were non-inferior and lower in the EMPIRIC arm compared to the TAILORED arm
• The time to first all-cause shock was non-inferior in the EMPIRIC arm
• The EMPIRIC trial had a significant reduction of patients with five or more shocks for all-cause and true VT/VF
• There were no significant differences in total mortality, syncope, emergency room visits, or unscheduled outpatient visits
• Unscheduled hospitalizations occurred significantly less often in the EMPIRIC arm

Conclusions
Standardized EMPIRIC ICD programming for VT/VF settings is at least as effective as patient-specific, physician-tailored programming, as measured by many clinical outcomes. Simplified and pre-specified ICD programming is possible without an increase in shock-related morbidity.

Clinical Implications
Three programming strategies resulted from EMPIRIC that are part of our recommended best practices today. These include:
• Rejecting SVTs at more rapid rates than had been done before
• Applying multiple sequences of ATP to more rapid rates than had been done before
• Changing the nominal VT cutoff from 400 ms to 360 ms

Key takeaway:
Standardized ICD programming is as safe and effective in reducing shocks for VT/VF detection and therapy as physician-tailored programming.
Summary
We hypothesized that shocks for any cause result in more healthcare utilization (HCU) than ATP-terminated ventricular tachyarrhythmia (VTA) episodes in MVP, a randomized trial of 1,030 typical ICD patients. VTA detection and therapies were standardized. Shocks for any cause result in greater HCU's versus ATP-treated VTA episodes. Further investigation is needed to determine if reducing shocks reduces HCU's.

Authors
Sweeney MO, Ellenbogen KA, Tang ASL, et al.

Source
HRS 2010 abstract.

Study Type
Retrospective analysis of an MVP randomized trial.

Design
Investigated 1,030 typical ICD patients with standardized detection and therapy.

Objective
Characterize the prevalence of acute HCU's following non-induced shocks for any cause, and ATP-terminated ventricular tachyarrhythmias.

Key Results
• Only 24 percent of patients who receive ATP to terminate a potentially life-threatening arrhythmia visited the hospital, clinic or emergency room at least once within three days of receiving therapy, versus nearly 60 percent of patients who were treated with shock therapy.
• Specifically, 56% of appropriately shocked patients and 61% of inappropriately shocked patients sought medical attention within 3 days of a shock.

Conclusions
Shocks for any cause result in greater HCU's versus ATP-treated VTA episodes. Further investigation is needed to determine if reducing shocks reduces HCU's.

Clinical Implications
Shocks can result in an increase in healthcare utilization. If inappropriate shocks can be decreased, physicians and clinics can become more efficient.

Key takeaway:
Shocks for any cause are associated with increased healthcare utilization.

Examining the Psychosocial Impact of Implantable Cardioverter Defibrillators: A Literature Review

Summary
Even though there are many numbers of patients implanted with cardioverter defibrillators, the psychosocial impact of having one is not well understood. The purposes of this paper are (1) to review the available literature documenting the psychosocial impact of the ICD on patients, (2) to hypothesize possible mechanisms for this psychosocial impact, and (3) to suggest clinical risk profiles and indications for psychological consultation.

Authors
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Source

Study Type
Review paper of different existing studies that focused on the post-psychosocial assessment of ICD patients. Both electronic and library searches were performed to examine the psychosocial impact of ICDs.

Design
Only those studies that investigated the psychosocial outcomes, either prospectively or cross-sectionally, were used for review. No literature review or secondary sources were utilized.

Objectives
Available literature was reviewed to attempt to document the psychosocial impact of ICDs on patients, to try to discover possible mechanisms of this impact, and to discover any clinical risks or reasons for psychosocial consultations.

Key Results
• Despite the fact that ICD patient QoL and acceptance of the device are generally quite good, approximately 13-38% of patients experience diagnosable levels of anxiety.
• ICD-specific fears and symptoms of anxiety are the most common psychological symptoms.
• Young ICD patients and those receiving high discharge rates may experience the most adjustment issues.

Conclusions
Generally, acceptance of the ICD and QoL are quite good. The most common psychological symptom is anxiety; ICD fears are common among all patients and appear to be the most pervasive psychosocial adjustment challenge. Symptoms of depression are also common among ICD patients. There are certain characteristics of ICD patients that can help to identify those at risk for the development of psychosocial issues.

Clinical Implications
Because anxiety can be high in many patients, shock reduction should be an adopted strategy in order to minimize any fear of shocks as much as possible.

Key takeaway:
Thirteen to thirty-eight percent of ICD patients experience diagnosable levels of anxiety.
Quality of Life in the Canadian Implantable Defibrillator Study (CIDS)

Summary
Quality of life (QoL) was compared between patients randomized to ICD therapy and those receiving amiodarone treatment. The secondary end point was QoL in patients who received shocks. QoL did not improve in the subgroup of patients in the ICD-treated group who received five or more shocks from their device.

Authors

Source

Study Type
Review paper of an existing study.

Design
Assessments of 317 patients were done in-hospital and with mailed questionnaires at 2, 6, and 12 months follow-up. The QoL tests focused on the mental and physical status, as well as emotional issues and lifestyle.

Objectives
Compare QoL outcomes between patients receiving ICD therapy and those on amiodarone.

Key Results
- The analysis revealed a significant effect on total mental health, psychological distress, and psychological well-being sub-scales, and on energy, physical mobility, emotional reactions, sleep disturbance, and lifestyle impairment.
- Emotional and physical health scores were shown to improve significantly in the ICD group and were either unchanged (emotional health) or deteriorated (energy and physical mobility) in the amiodarone-treated group by means of post-hoc comparisons.
- QoL did not improve in the subgroup of patients in the ICD-treated group who received > 5 shocks from their device.

Conclusions
The QoL of patients is better with ICD therapy than amiodarone treatment. However, patients who have received numerous shocks from their device do not recognize these benefits. Interventions that reduce the frequency of shocks appear to be necessary in order to assist patients in effectively coping with this issue and to optimize the benefit of their ICD therapy.

Clinical Implications
Reducing the frequency of shocks appear to improve patients quality of life and optimize the benefits of ICD therapy.

Key takeaway:
Numerous shocks are associated with a reduction in ICD patients’ perceived quality of life.

Quality of Life with Defibrillator Therapy or Amiodarone in Heart Failure

Summary
Implantable cardioverter defibrillator (ICD) therapy significantly prolongs life in patients at increased risk for sudden death from depressed left ventricular function. However, whether this increased longevity is accompanied by deterioration in the QoL is unclear. Psychological well-being in the entire ICD group, as compared with medical therapy alone, was significantly improved at 3 months and 12 months but not at 30 months. In a large primary prevention population with moderately symptomatic heart failure, single-lead ICD therapy was not associated with any detectable adverse QoL effects during 30 months of follow-up.

Authors
Mark DB, Anstrom KJ, Sun JL, et al, for the Sudden Cardiac Death in Heart Failure Trial Investigators.

Source

Study Type
Randomized, prospective trial.

Design
We compared ICD therapy or amiodarone with state-of-the-art medical therapy alone in 2,521 patients who had stable heart failure with depressed left ventricular function. QoL was prospectively measured.

Objectives
To determine whether quality-of-life deteriorates among ICD patients.

Key Results
- Psychological well-being in the ICD group, as compared with medical therapy alone, was significantly improved at 3 months and at 12 months but not at 30 months.
- No clinically or statistically significant differences in physical functioning among the study groups were observed.
- Additional QoL measures were improved in the ICD group at 3 months, 12 months, or both, but there was no significant difference at 30 months.
- ICD shocks in the month preceding a scheduled assessment were associated with a decreased QoL in multiple domains.
- The use of amiodarone had no significant effects on the primary QoL outcomes.

Conclusions
In a large primary prevention population with moderately symptomatic heart failure, single-lead ICD therapy was not associated with any detectable adverse QoL effects during 30 months of follow-up. As compared with patients in the ICD group who did not receive a shock, the QoL of patients in the month after a shock was characterized by a significant decrease in perceived general health, physical and emotional functioning, social functioning, and self-rated health.

Clinical Implications
When patients receive shocks from their ICD, their QoL is affected. Shock reduction is important in maintaining the best QoL possible for ICD patients.

Key takeaway:
ICD therapy is not associated with any detectable adverse QoL effects during 30 months of follow-up.