ΕΞΑΝΤΛΗΣΗ ΑΠΙΝΙΔΩΤΗ ΣΕ ΑΣΘΕΝΗ ΜΕ ΚΑΡΔΙΑΚΗ ΑΝΕΠΑΡΚΕΙΑ/ΠΡΩΤΟΓΕΝΗ ΠΡΟΛΗΨΗ ΧΩΡΙΣ ΠΡΟΗΓΟΥΜΕΝΕΣ ΘΕΡΑΠΕΙΕΣ

ΑΝΤΙΚΑΤΑΣΤΑΣΗ;

ΓΕΩΡΓΙΟΣ ΣΤΑΥΡΟΠΟΥΛΟΣ
ΓΝΘ ΙΠΠΟΚΡΑΤΕΙΟ

IMPLANT/REPLACEMENT PREREQUISITES

- Risk of **arrhythmic death** following ICD implantation is **sufficiently high**
- Risk of **nonarrhythmic death sufficiently low**
- Reasonable overall **life expectancy**
- **Low risk of periprocedural complications** associated with ICD implant /replacement

EVIDENCE

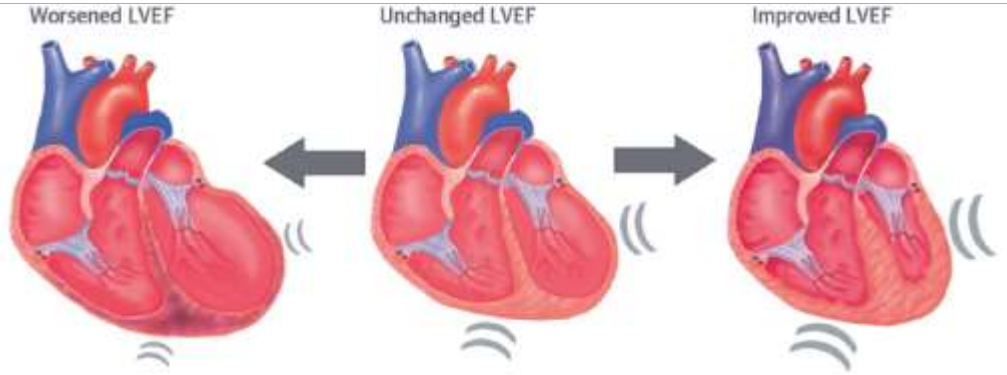
Evidence is considerably **less robust** related to

clinical reassessment to ensure that the patient continues to meet criteria at the time of device replacement

Compelled by ethical or legal considerations to replace the ICD regardless of whether the patient still meets implantation criteria

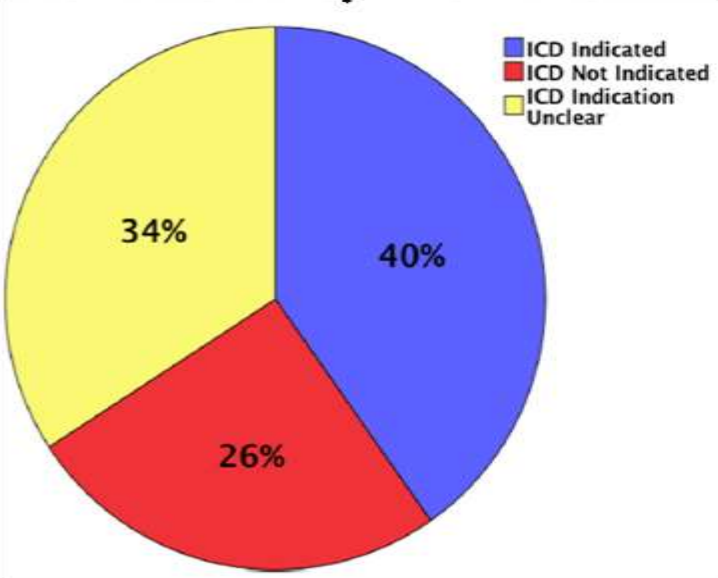
Implantable cardioverter defibrillator in patients with left ventricular dysfunction

Recommendations	Class[a]	Level[b]	Ref.[c]
ICD therapy is recommended to reduce SCD in patients with symptomatic HF (NYHA class II–III) and LVEF ≤35% after ≥3 months of optimal medical therapy who are expected to survive for at least 1 year with good functional status:			
– Ischaemic aetiology (at least 6 weeks after myocardial infarction).	I	A	63,64
– Non-ischaemic aetiology.	I	B	64,316, 317

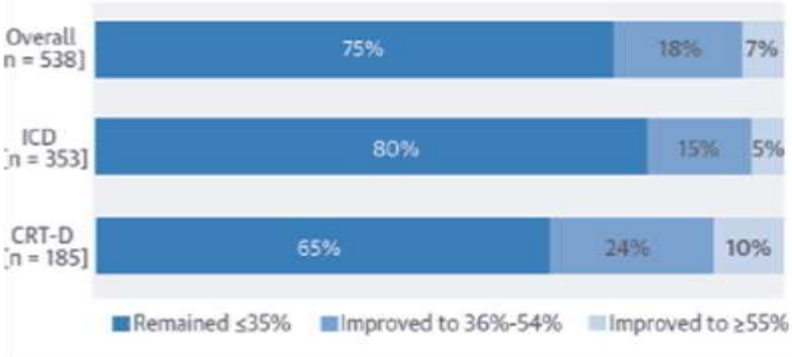


- how often guideline derived **indications** for primary prevention ICD therapy are **still present** on replacement?
- **how often** patients who no longer have an indication for primary prevention ICD at the time of generator replacement receive **ICD Therapies?**
- **Complications?**
- **Cost?**

ICD Indications at Elective Generator Replacement

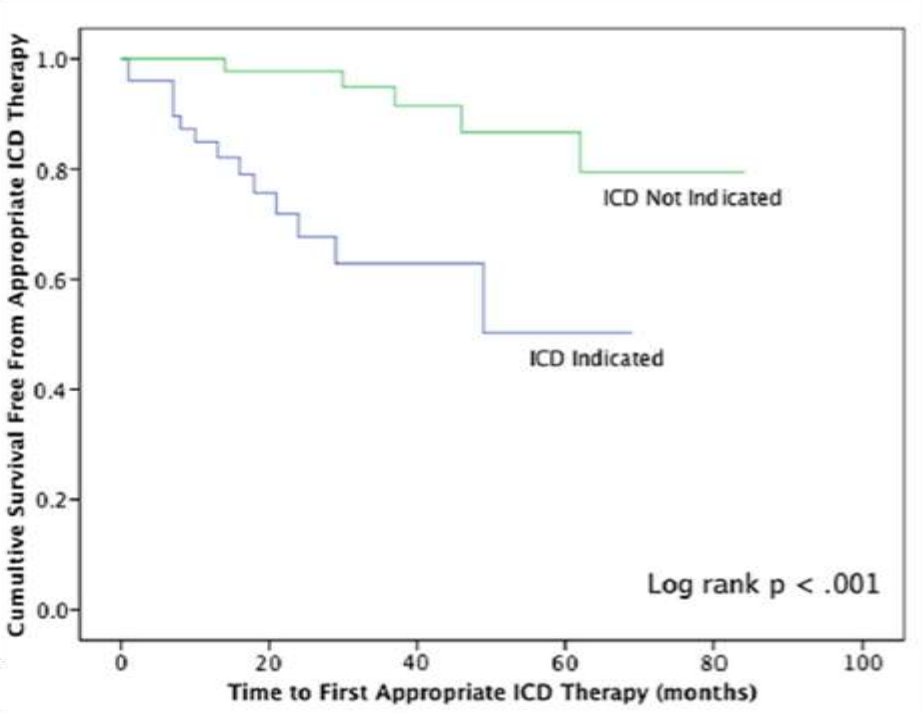


Kini et al.
June 10, 2014:2388–94
Appropriateness of ICD Generator Replacement



Zhang, Y. et al. J Am Coll Cardiol. 2015; 66(5):524-31.

Subsequent ICD Therapies After Elective Generator Replacement



Patients with no ICD indication at the time of generator replacement subsequently receive significantly fewer ICD therapies compared with patients with an ICD indication (2.8% vs. 10.7% per person-year, p < 0.001).

cost of ICD generator replacement $22,891 ICD generator explantation $1,907.55

NNT of 76 to prevent 1 appropriate ICD therapy
SCD-HeFT the NNT with ICD to prevent 1 death was 20,primary PCI vs Thr-lysis NNT 10.

PROSE ICD

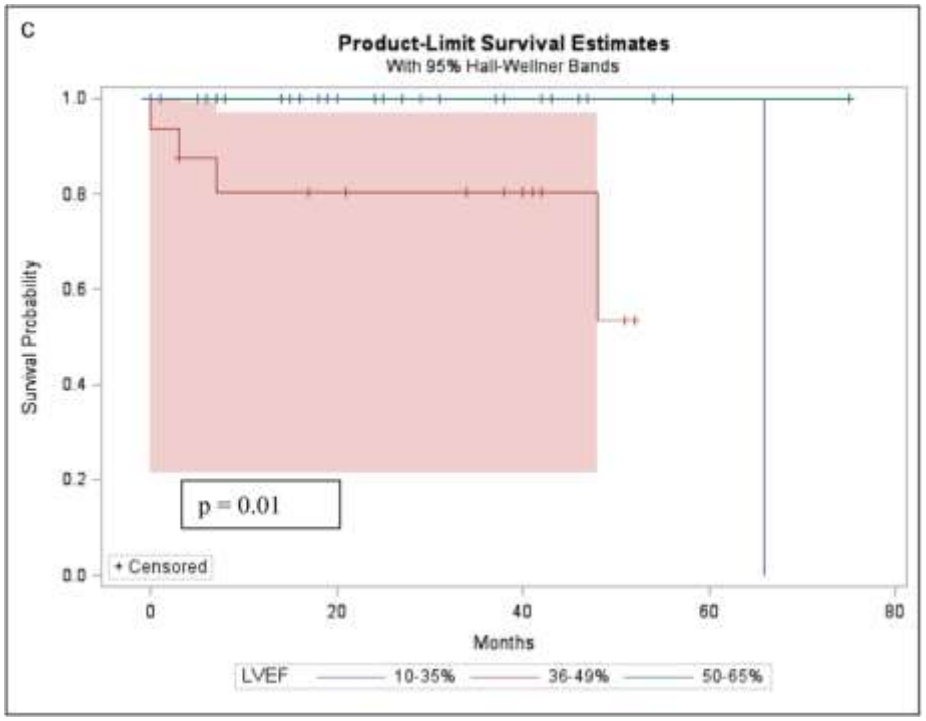
TABLE 3 Mortality and Appropriate Shock

	All-Cause Mortality				Appropriate Shock			
	Events/Total Number	Incidence Rate*	Model 1† HR (95% CI)	Model 2‡ HR (95% CI)	Events/Total Number	Incidence Rate*	Model 1† HR (95% CI)	Model 2‡ HR (95% CI)
Changes in LVEF§								
Worsened	20/70	20.0	1.48 (0.84–2.61)	1.54 (0.87–2.75)	1/48	2.3	0.41 (0.04–3.73)	0.51 (0.05–5.30)
Unchanged	59/253	11.7	Reference	Reference	20/219	6.9	Reference	Reference
Improved	17/215	3.8	0.31 (0.18–0.54)	0.33 (0.18–0.59)	6/197	2.2	0.33 (0.13–0.85)	0.29 (0.11–0.78)

Post-hoc analysis of the DEFINITE study, which randomized patients with non-ischemic cardiomyopathy to ICD vs. medical therapy, found that patients with an improvement in EF (> 5 % increase from baseline) had significantly lower levels of all-cause mortality and arrhythmic death compared to those who had a stable EF or those with further reduction in EF (mortality rate 3.2 %, 13 % and 33 %, respectively;

PROSE ICD

Normalization of Left Ventricular Ejection Fraction: *Very low risk patients*



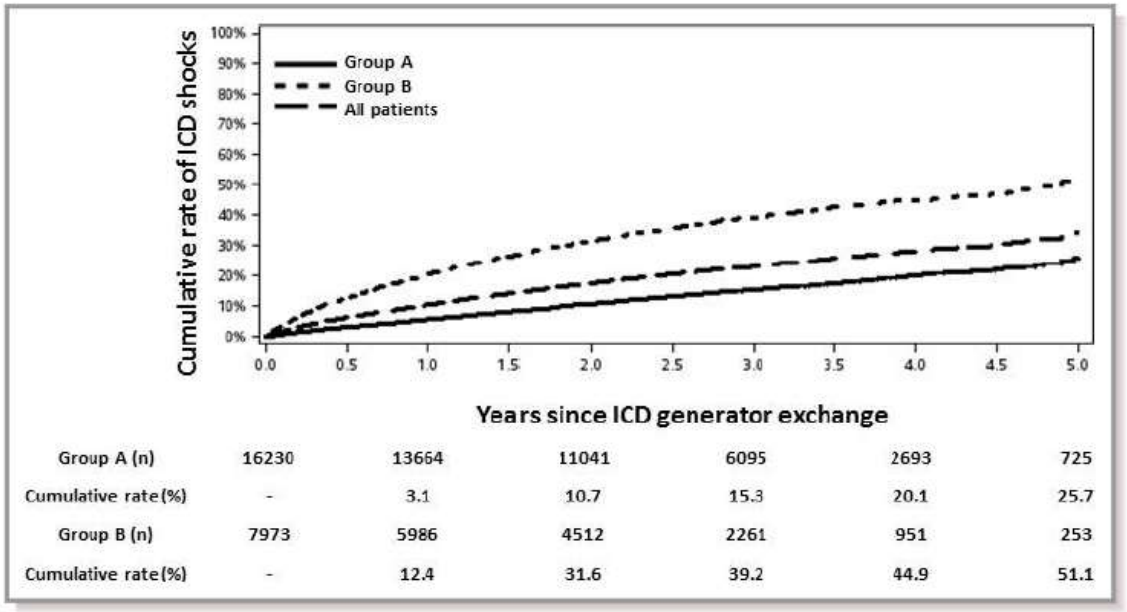
***None** of the individuals with normalized LVEF experienced appropriate antitachycardia therapy regardless of ICD or CRT-D.*

Journal of Cardiac Failure 2015

House et al

Incidence of Defibrillator Shocks After Elective Generator Exchange Following Uneventful First Battery Life

ALTITUDE STUDY



Group A (n)	16230	13664	11041	6095	2693	725
Cumulative rate (%)	-	3.1	10.7	15.3	20.1	25.7
Group B (n)	7973	5986	4512	2261	951	253
Cumulative rate (%)	-	12.4	31.6	39.2	44.9	51.1

The **occurrence of ICD shocks** prior to GE is an **important predictor** of shocks after GE; however, even among those without shocks during first battery life, the incidence of shocks at 5 years following GE is >25%. These data should **support informed decision making for patients and physicians** at the time of ICD generator end of service.

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Characteristics and Outcomes of Patients Receiving New and Replacement Implantable Cardioverter-Defibrillators: Results from the NCDR®

Daniel B. Kramer, MD[1,2,5], Kevin F. Kennedy, MS[3], Peter A. Noseworthy, MD[2,4], Alfred E. Buxton, MD[1,2], Mark E Josephson, MD[1,2], Sharon-Lise Normand, PhD[2,6], John A. Spertus, MD, MPH[3], Peter J. Zimetbaum, MD[1,2], Matthew R. Reynolds, MD, MSc[1,2], and Susan L. Mitchell, MD, MPH[1,2,5]

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PATENTS CHRACTERISTICS

<u>subjects who received replacement versus new ICDs :</u>

- older
- ↑Atrial fibrillation
- ↑congestive heart failure
- ↑noncardiac comorbidities (chronic lung disease, cerebrovascular disease, diabetes mellitus, lower GFR)

associated with **higher mortality after ICD replacement.**

- Shorter life expectancy

Inapropriate therapies

<u>NationalCardiovascularDataRegistry®</u>

COMPLICATIONS

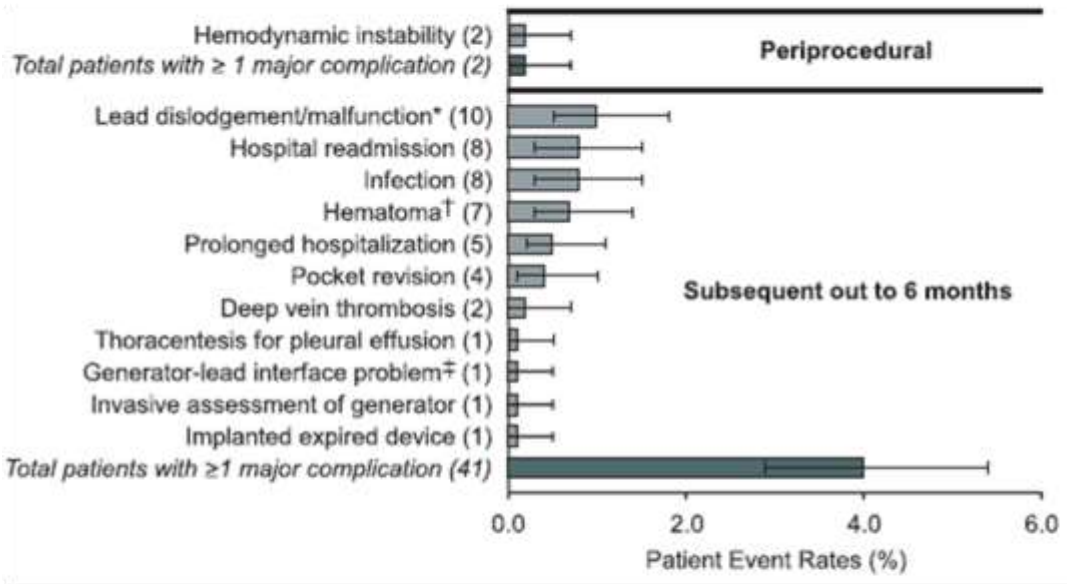

Table 4. Complications From 533 Elective Advisory Device Replacements

Severity and Complications	No. (%)*
Minor	
Incisional infection, medically managed	9 (1.7)
Significant site pain, medically managed	1 (0.2)
Heart failure requiring admission	1 (0.2)
Major psychological morbidity, medically managed	1 (0.2)
Major	
Pocket infection requiring extraction	10 (1.9)
Postextraction deaths	2 (0.4)
Hematoma requiring reoperation	12 (2.3)
System malfunction requiring reoperation	8 (1.5)
Significant site pain requiring reoperation	1 (0.2)

Poole et al Complications With Pacemaker and ICD Replacements

Circulation October 19, 2010

JAMA, April 26, 2006—Vol 295, No. 16

ICD generator replacement is not a benign procedure and carries a substantial risk of complications, which include death.

REPLACE DARE Mortality Risk Score

CALCULATOR | OVERVIEW

The REPLACE DARE (Death After Replacement Evaluation) mortality risk score *is a tool designed to further assist physicians in predicting expected 6-month all-cause mortality rates for patients prior to replacing an existing cardiac implantable electrical device (CIED). Its validity in patients undergoing the initial implant of a CIED has not been established.*

REPLACE DARE Mortality Risk Score Calculator

Admitted for Heart Failure in Previous 12 Months

Yes | ✔ No

NYHA Classification

Class I | Class II | Class III | Class IV

✔ None *(for subjects without a diagnosis for Heart Failure)*

Chronic Kidney Disease Stage

1 (Normal, or minimal disease with normal GFR of ≥ 90)

Class I or Class III Anti-arrhythmic Drug Use

Yes | ✔ No

History of Cerebrovascular Disease

Yes | ✔ No

Age

✔ < 63 | 63 - 72 | 73 - 79 | > 80

SCORE: 0.0

Reset

Mortality Risk Score	Observed Mortality in REPLACE (%)
0	1/108 (1.0)
1	6/484 (1.2)
2	12/446 (2.7)
3	16/291 (5.5)
4	11/128 (8.6)
5	10/72 (13.9)
6	5/34 (14.7)
7	5/9 (55.6)

Although this sub-analysis of the REPLACE registry was retrospective, the REPLACE data, including mortality, were collected prospectively. Data collection, though extensive, may have missed some confounding factors. The REPLACE DARE score was constructed using hazard ratios reflecting relative risk contributions of each variable which were combined into an additive mortality risk score equation. Internal validation was performed.

CONCLUSIONS

- Current guidelines for primary prevention ICD therapy are the same for patients undergoing initial implant as well as generator replacement
- far less evidence supporting the decision to replace an ICD than for primary implantation
  - Patients receiving replacement ICDs may be at **lower arrhythmic risk** and **higher procedural risk** than those undergoing initial ICD implant
- decision to replace a device should not be based on battery status alone
- Risk of future **inappropriate ICD sho**cks

CONCLUSIONS

Prospective, multicenter studies employing uniform ICD programming are needed to identify the risk factors associated with ICD shocks and SCD in these patients.

Until then, the decision of continuation vs. termination of ICD therapy will have to be individualized:

- Patient's EF
- NYHA class
- Etiology of cardiomyopathy (ischemic vs. non-ischemic)
- Comorbidities
- Patient's wishes.
- Non replacement=ICD deactivation should be carefully considered

replace

This is the first **prospective** multicenter report of comprehensive 6-month complication rates associated with pacemaker and ICD generator replacements

1031 cohort 1 patients

Appropriateness of Primary Prevention Implantable Cardioverter-Defibrillators at the Time of Generator Replacement

Are Indications Still Met?

Vinay Kini, MD,* Mohamad Khaled Soufi, MD,† Rajat Deo, MD, MTR,* Andrew E. Epstein, MD,*‡ Rupa Bala, MD,* Michael Riley, MD, PhD,* Peter W. Groeneveld, MD, MS,‡ Alaa Shalaby, MD,† Sanjay Dixit, MD*‡

Philadelphia and Pittsburgh, Pennsylvania

retrospective chart review
of **231** patients who underwent ICD replacement at the Philadelphia Veterans Affairs (VA) Medical Center and the VA Pittsburgh Healthcare System over a period of ***7* years** (March 2006 through March 2013)