Relevance of ICD longevity in clinical practice

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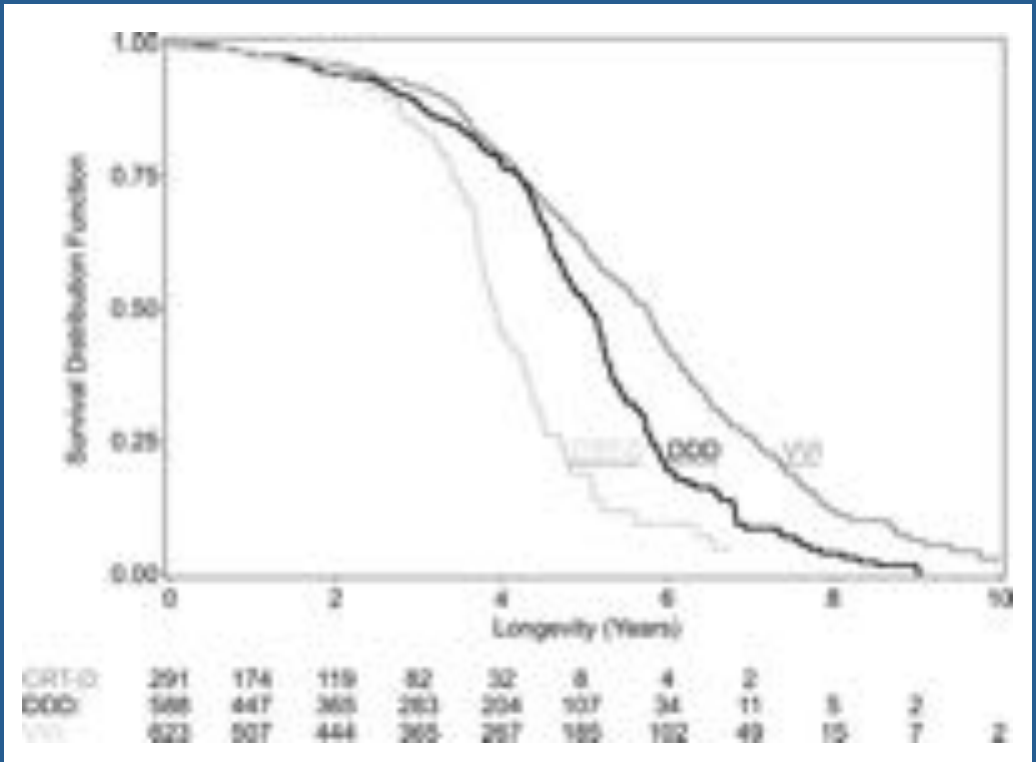
NO CONFLICT OF INTEREST TO DECLARE

How long do ICDs last in clinical practice?

ICD LONGEVITY

- **980 unselected pts** with ICD or CRT-D (total devices: 1502)
  June 1988 – June 2009
- Mean age at implant: 61 ± 14 years



Mean longevity, excluding premature replacements for non-battery reasons:

- 7 years for VVIs,
- 5.7 years for DDDs,
- 4.4 years for CRT-Ds.

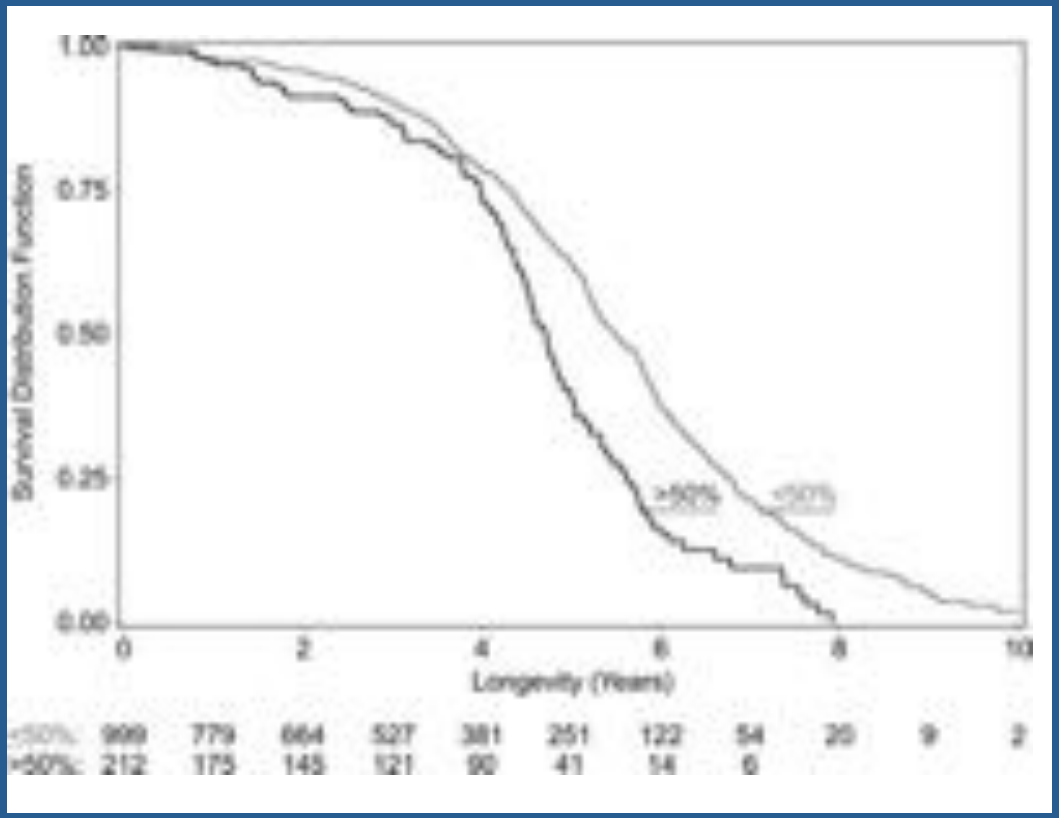
Analysis of single and dual chamber ICDs showed only little improvements in clinical longevity for the newer devices.

The longevity of their ICDs is crucial for pts

FRITZ W. HORLBECK et al - Real-World Data on the Lifespan of ICDs Depending on Manufacturers and the Amount of Ventricular Pacing
J Cardiovasc Electrophysiol 2012;23(12):1336-42.

How long do ICDs last in clinical practice?

ICD LONGEVITY PREDICTORS



The mean longevity of single and dual chamber ICDs was 5.5 years for ICDs with a "low" (VP≤50%) and 4.7 years (SE 0.14) for those with a "high" (VP > *50%)* cumulative percentage.

Age, male sex, AF, CAD, dilated cardiomyopathy, and the indication for ICD implantation (primary or secondary prevention) failed to show any significance in the context of ICD lifespans.

%V pacing, type of device and device manufacturer were significant independent predictors of ICD lifespan

FRITZ W. HORLBECK et al - Real-World Data on the Lifespan of ICDs Depending on Manufacturers and the Amount of Ventricular Pacing
J Cardiovasc Electrophysiol 2012;23(12):1336-42.

How long do ICDs last in clinical practice?

CRT-D LONGEVITY

- **1726 consecutive CRT-D** implanted in 9 Italian centers
- Period: January 2008 – March 2010
- 708 earlier-generation devices (released before 2007) & 1018 recent-generation families (released since 2007)

- 5 years after a successful CRT-D implantation procedure, 46% of devices were replaced on account of battery depletion, and LV lead output and unipolar pacing configuration turned out to be independent determinants of early depletion.

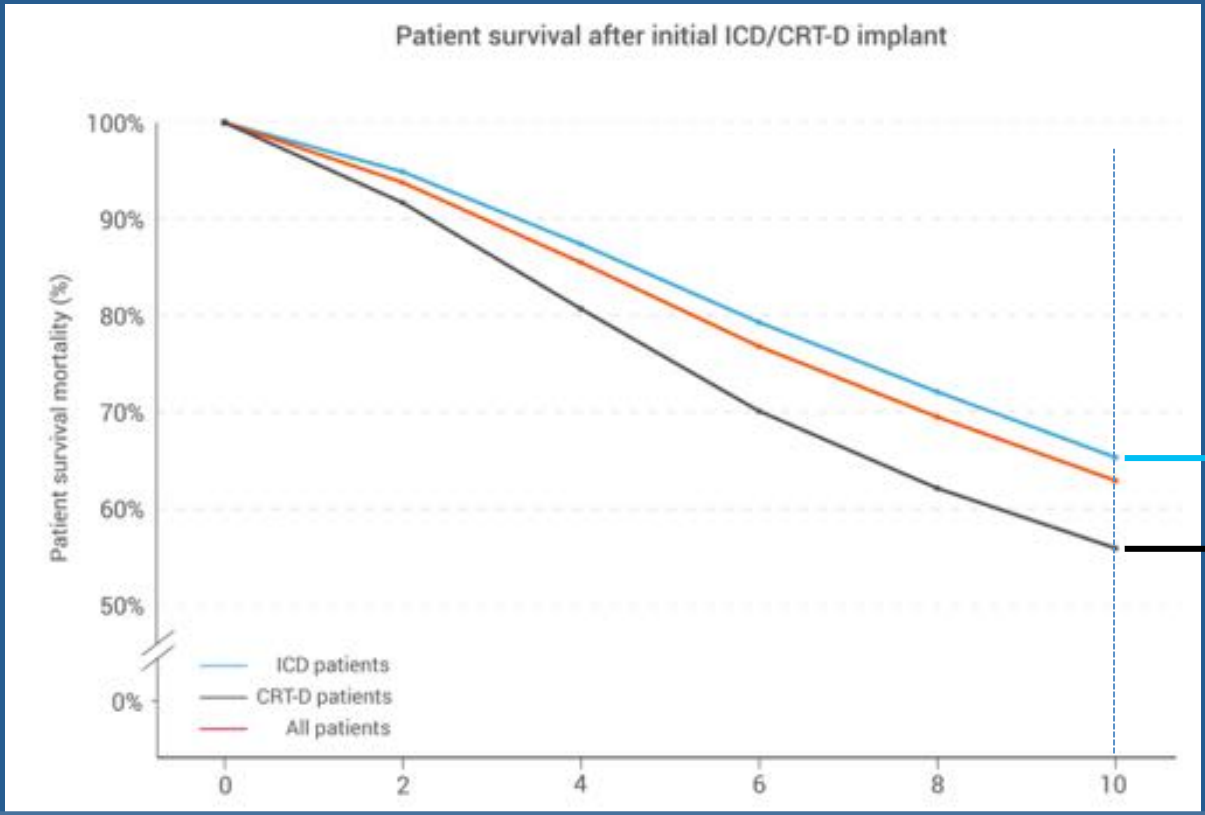
- Recent-generation CRT-D (mostly released onto the market after 2007) displayed significantly greater longevity than those of early generations.

CRT-D device longevity at 5 yrs: 54%

Landolina M et al - Longevity of ICDs for CRT in current clinical practice: an analysis according to influencing factors, devicegeneration, and manufacturer. ***Europace 2015;17:1251–8***

How many patients do need a replacement?

MORTALITY IN CLINICAL PRACTICE



- **329.455 unselected patients** with an initial implant of an ICD or CRT-D device between January 1998 and November 2013
- Mean age at implant 64 ± 13 years

> 65% of ICD pts are still alive after 10 yrs

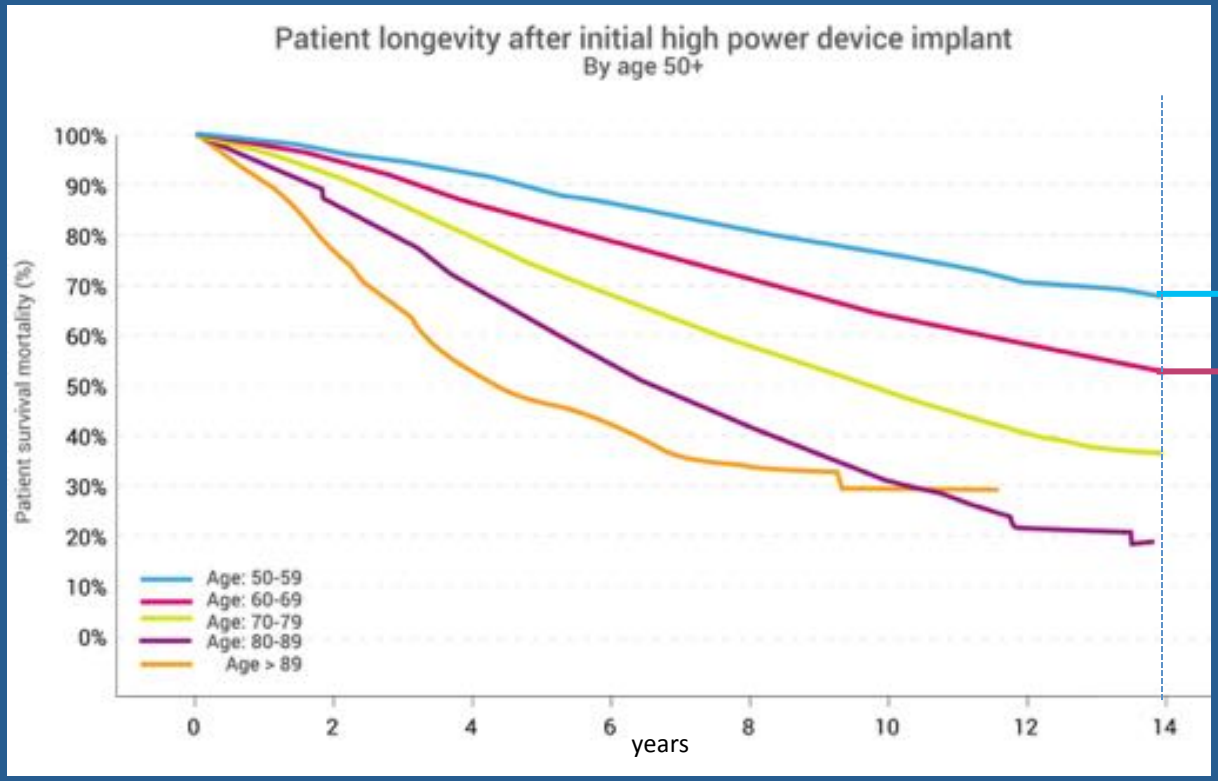
> 55% of CRT pts are still alive after 10 yrs

It is reasonable to assume that most of pts will require a device replacement during their life

Sims J.J. et al. Long-term survival following ICD and CRT-D implant in a large unselected population.
HER- EUROPACE 2015, P289 Medtronic Carelink® database

How many patients do need a replacement?

MORTALITY IN CLINICAL PRACTICE



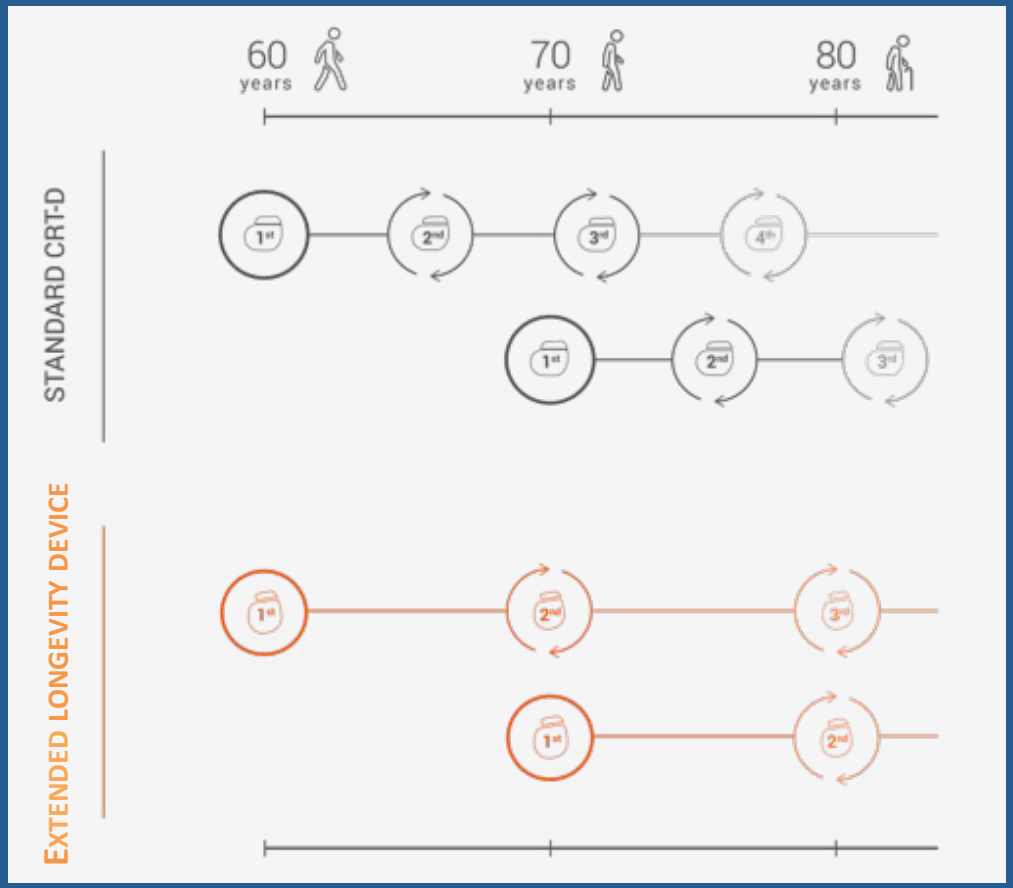
> 65% of pts receiving first implant 50-59 years old are **still alive after 14 yrs**

> 50% of pts receiving first implant 60-69 years old are **still alive after 14 yrs**

Many patients could require more than one replacement ...

Sims J.J. et al. Long-term survival following ICD and CRT-D implant in a large unselected population.
HER- EUROPACE 2015, P289 Medtronic Carelink® database

What if … devices could last more?



164 patients with 301 ICD implants

The longevity needed to avoid one replacement was defined as longevity of that ICD + the longevity of the subsequent ICD

One of the goals of an increase in ICD longevity is to avoid replacements.

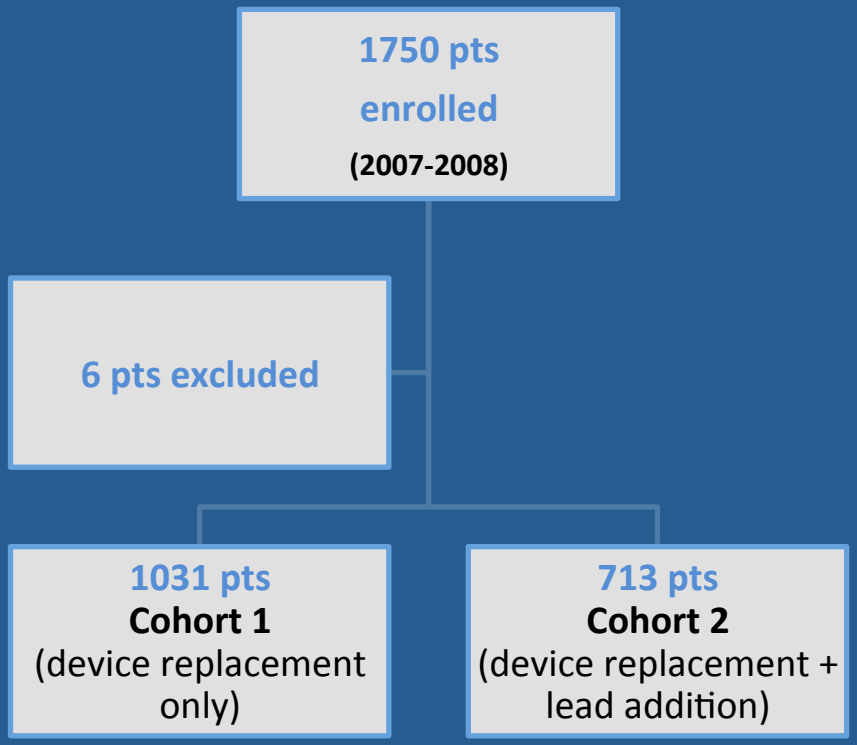
If all ICDs had lasted 5, 7, or 9 years, then 26%, 58%, and 84% of pts, respectively, would not have needed an ICD replacement

Prolongation of battery life over 9 yrs is important to reduce patient risks and decrease costs.

Ramachandra I. Impact of ICD battery Longevity on Need for Device Replacements-Insight from Veterans Affairs Database. **PACE 2010**;33:314-9

Do replacements associate with complications?

RESULTS FROM THE REPLACE REGISTRY



REPLACE Registry

- prospective, multicenter study
- 72 centers (private & academic)
- **1750 pts implanted** with ICD or PM

Population:

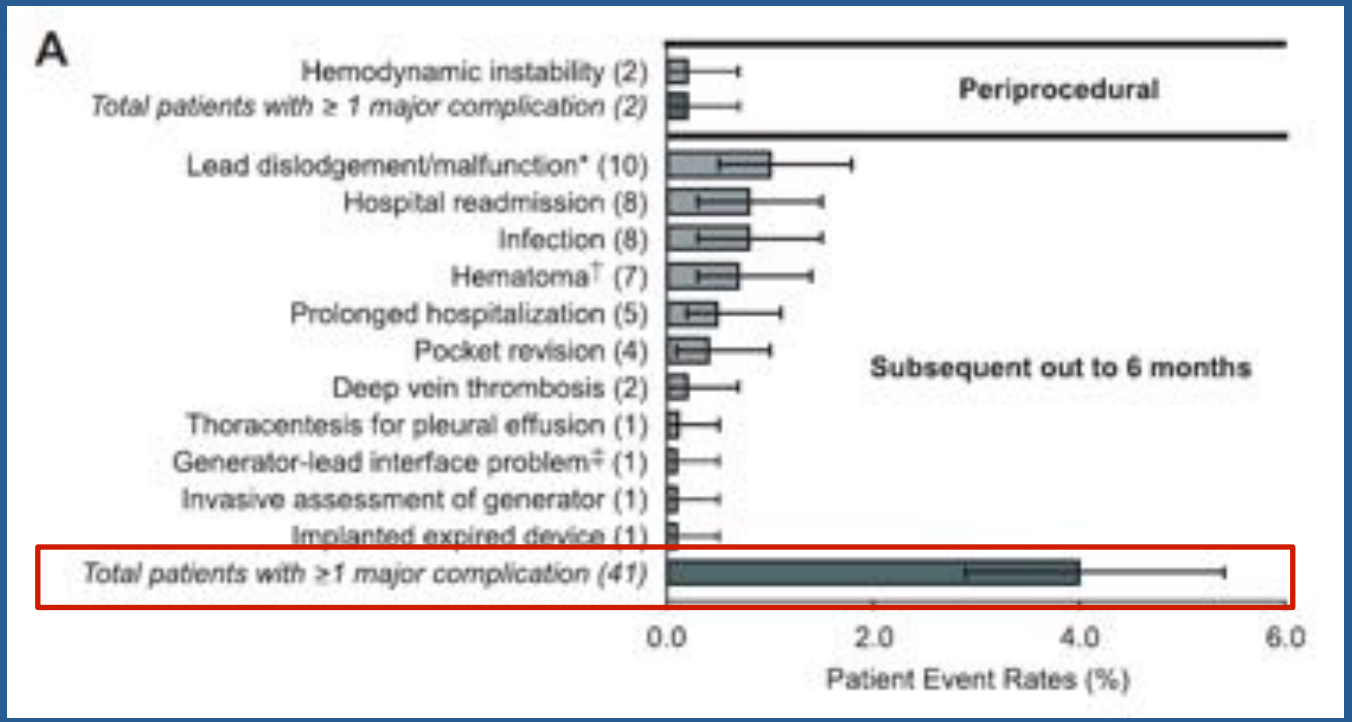
	Cohort 1 (n=1031)	**Cohort 2** (n=713)
Age (mean ± SD)	70.6 (± 14.1)	69.5 (±12.9)
PM – single ch.	90 (8.7%)	71 (10.0%)
PM – dual ch.	425 (41.2%)	258 (36.2%)
ICD – single ch.	101 (9.8%)	137 (19.2%)
ICD – dual ch.	226 (21.9%)	183 (25.7%)
CRT-P	14 (1.4%)	15 (2.1%)
CRT-D	175 (17.0%)	49 (6.9%)

Aim: collecting and evaluating (major and minor) complication data on pts for 6 months after replacement of a PM or ICD generator

Poole J et al. Complication Rates Associated With PM or ICD Generator Replacements and Upgrade Procedures Results From the REPLACE Registry - ***Circulation 2010;122:1553-61***

Do replacements associate with complications?

MAJOR COMPLICATIONS (Cohort 1 device replacement only)



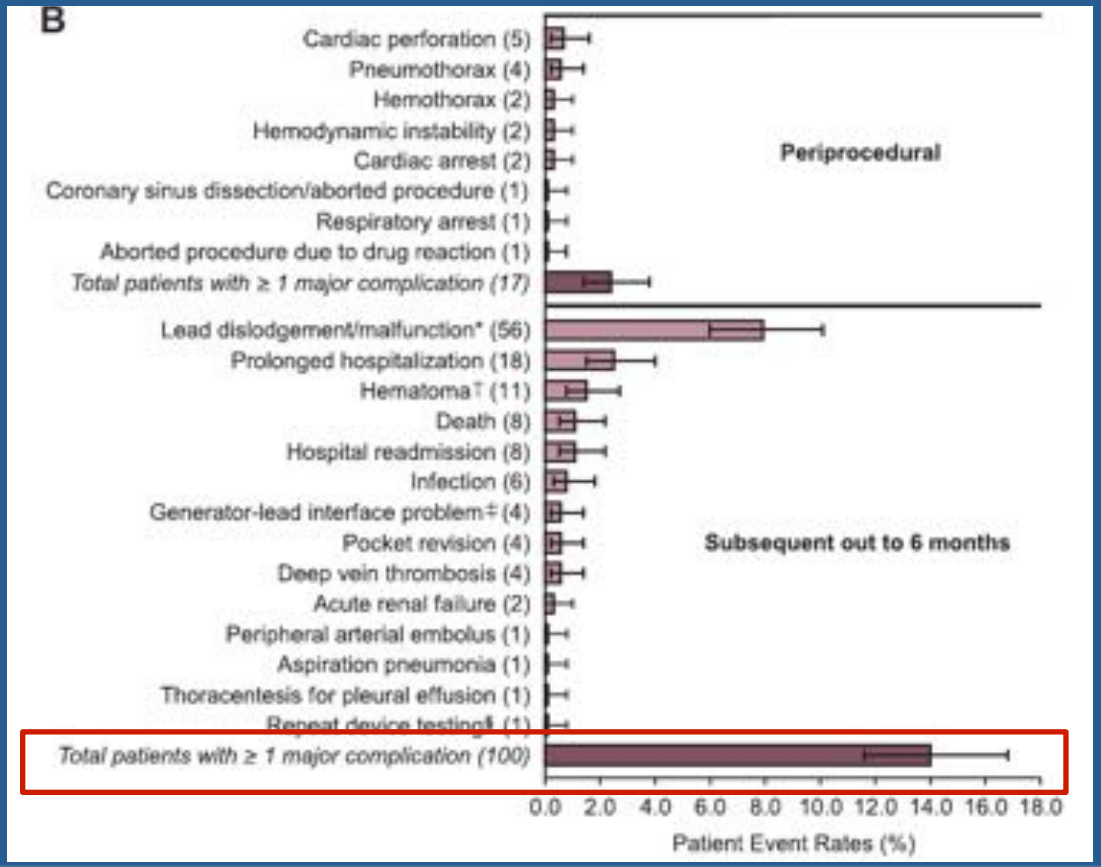
"The major complication rate was 4.0% with a periprocedural event rate of 0.2% and a subsequent event rate out to 6 months of 4.0%"

The most common complication was the need for re-operation resulting from lead dislodgement or lead malfunction in 10 pts (1.0%)

Poole J et al. Complication Rates Associated With PM or ICD Generator Replacements and Upgrade Procedures Results From the REPLACE Registry - ***Circulation 2010;122:1553-61***

Do replacements associate with complications?

MAJOR COMPLICATIONS (Cohort 2 device replacement + additional lead)



N = 109 pts had 1 or more major complication

N = 54 pts had 1 or more minor complication.

The major complication rate was 15.3% :

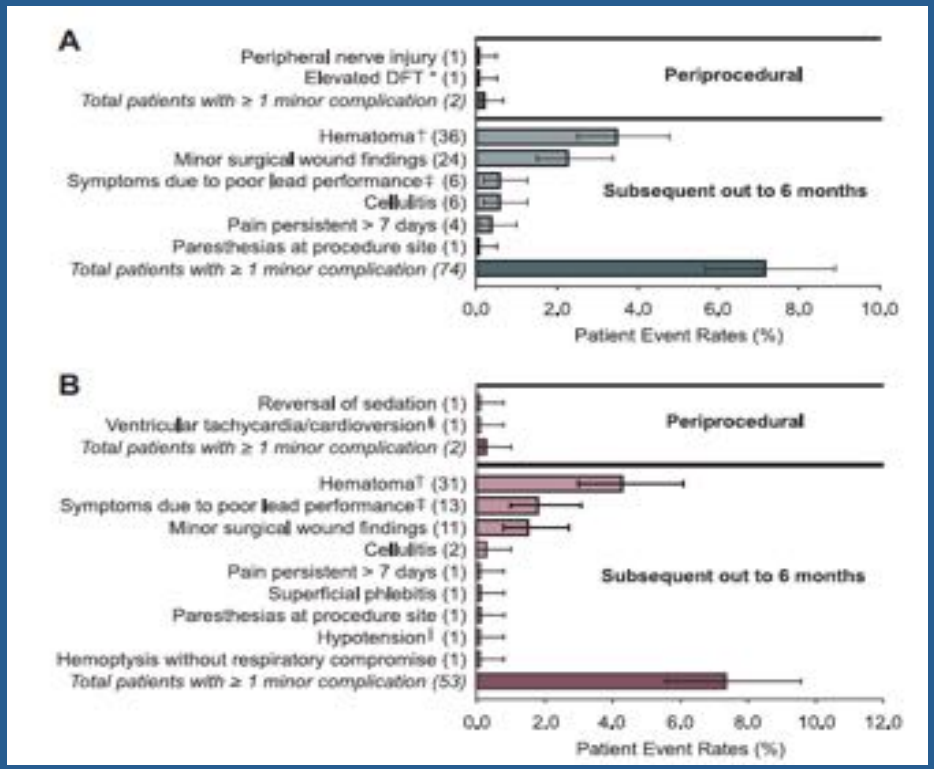
- periproc. event rate 2.4%
- subsequent event rate 14.0%

In both cohorts, a higher complication rate was seen with more complex devices (from PM to ICD to CRT). These observations may reflect differences in severity of underlying cardiac disease

Poole J et al. Complication Rates Associated With PM or ICD Generator Replacements and Upgrade Procedures Results From the REPLACE Registry - ***Circulation 2010;122:1553-61***

Do replacements associate with complications?

MINOR COMPLICATIONS



"Minor complications were common, occurring in 7.4% of cohort 1 patients and 7.6% of cohort 2 patients. Although these events could be interpreted as inconsequential, they frequently prompt additional phone calls and clinic visits and may increase the use of healthcare resources to allay concerns"

CONCLUSIONS:

Recommendations for lifelong device therapy should include consideration of the risks associated with generator replacements and lead additions, especially in situations in which the benefit may be less certain. **These data emphasize the need for future efforts directed at extending battery longevity and minimizing lead-related complications.**

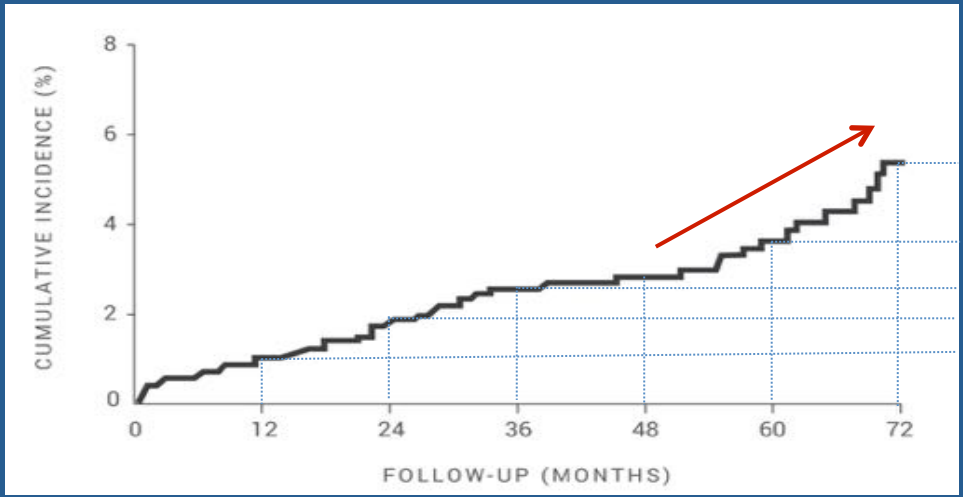
Poole J et al. Complication Rates Associated With PM or ICD Generator Replacements and Upgrade Procedures Results From the REPLACE Registry - ***Circulation 2010;122:1553-61***

Do replacements associate with RISKS?

RISK OF INFECTION

- **2476 patients** implanted with ICD/CRT-D in Leiden University (NL); Jan 2000 – Sept 2009
- Mean age at implant 62 ± 13 years

Incidence of cardiac device infection after initial implantation



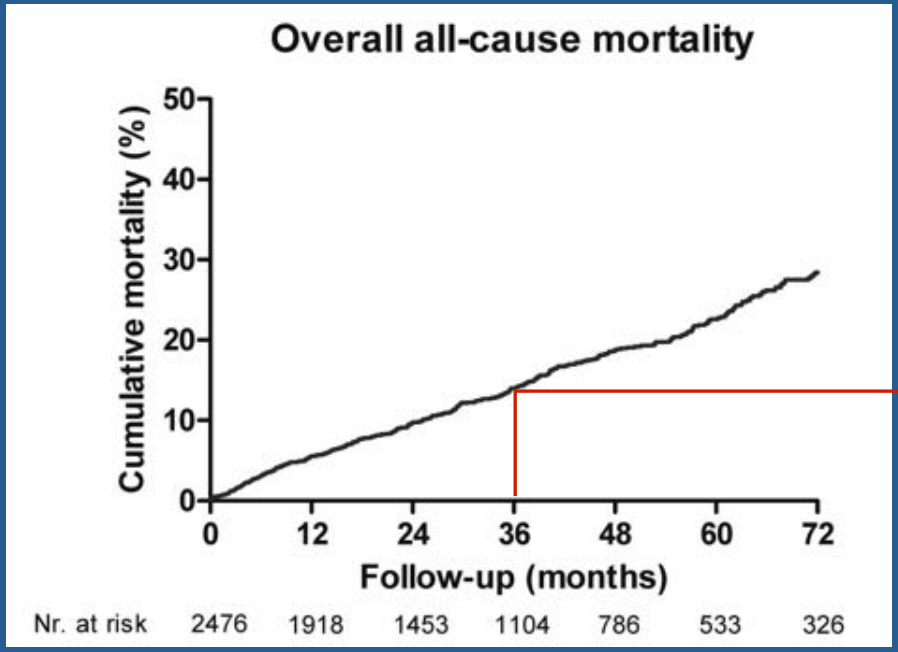
- Median FU 30 months
- 64 pts (2.6%) underwent device and lead extraction for **cardiac device infection** (CDI)
- The cumulative incidenxe of CDI was:
  - 1.1% at 1-year
  - 2.6% at 3-years
- At 4.5-years the cumulative incidence increased exponentially

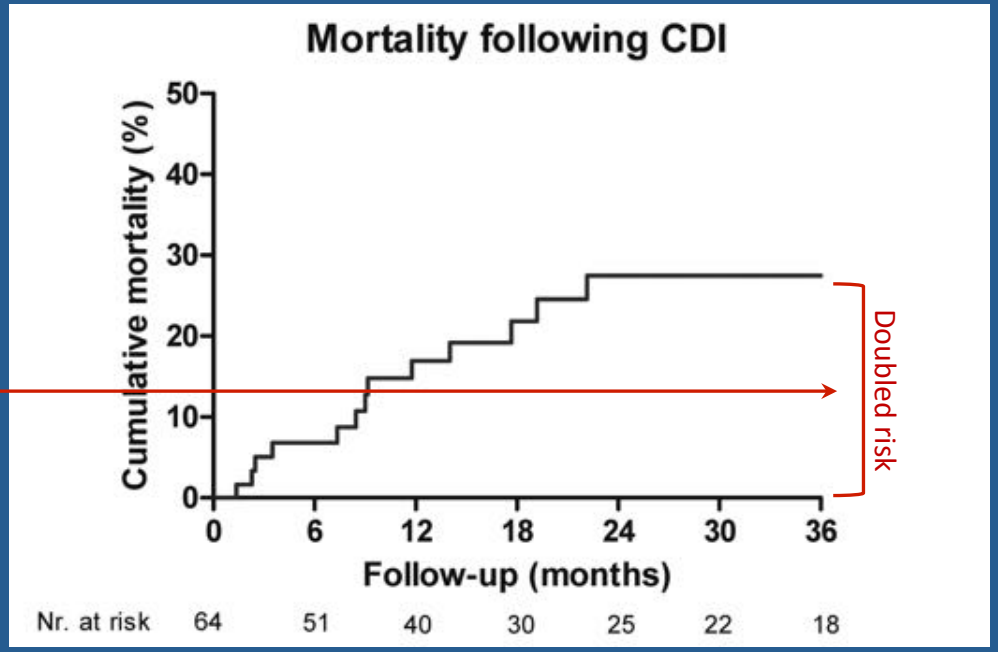
All but one (92%) patient, in whom CDI occurred >4.5 years after the initial device implantation, had undergone a generator exchange before the occurrence of CDI.

De Bie M.K. et al. Cardiac device infections are associated with a significant mortality risk. ***Heart Rhythm 2011;9:494-8***

Do replacements associate with RISKS?

RISK OF INFECTION





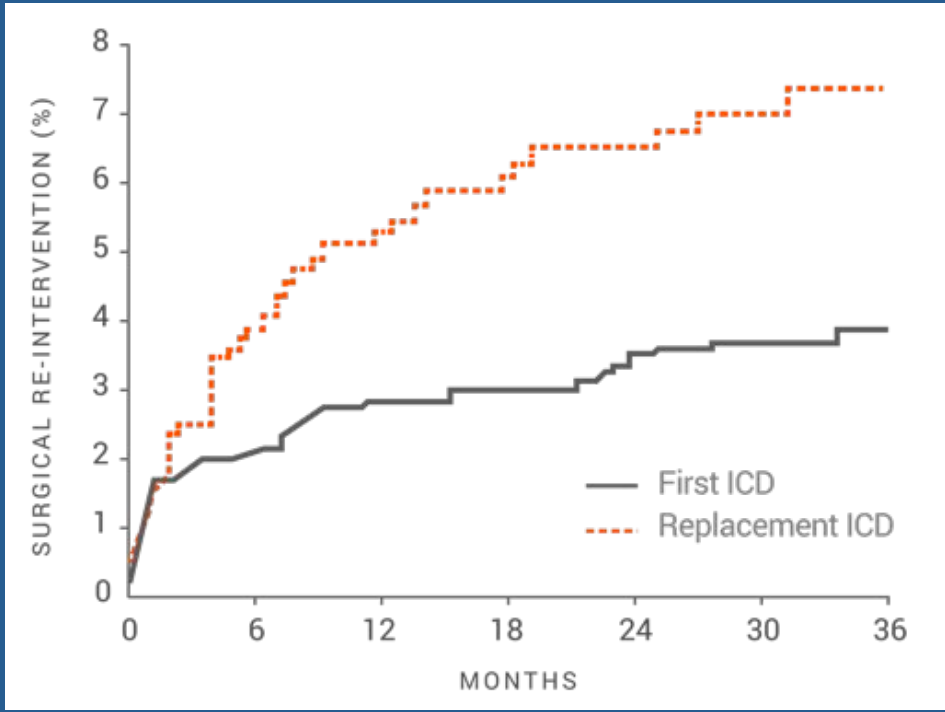
For pts presenting with Cardiac Device Infections (CDI), the risk of death was 1.9 times higher than that for pts without CDI (5.6% vs 16.9% at 1Y; 14.0% vs 27.5% at 3Y)

De Bie M.K. et al. Cardiac device infections are associated with a significant mortality risk. ***Heart Rhythm 2011;9:494-8***

Do replacements associate with RISKS?

RISK OF REINTERVENTION

First surgical re-intervention after replacement ICD versus primo-implant



- **2415 patients** receiving an ICD in Leiden University – The Netherlands
- 1992-2008

Aim: to evaluate the differences in event rates between the first implanted ICDs and replacement ICDs

- The 3-year cumulative incidence of a first surgical re-intervention was 3.9% for first implanted ICDs and 7.5% for replacement ICDs.
- Replacement ICDs demonstrated a doubled occurrence of pocket-related surgical reinterventions when compared to first implanted ICDs

Conclusions: Every effort should be addressed to improve ICD longevity, hence decreasing the need for device replacement.

Borleffs CJW, Thijssen J et al. Recurrent ICD Replacement Is Associated with Increasing Risk of Pocket-Related Complications – ***PACE 2013;33:1013-9***

Do replacements associate with complications?

NEW TRIAL

Detect Long-term Complications After ICD Replacement (DECODE): Rationale and Study Design of a Multicenter Italian Registry

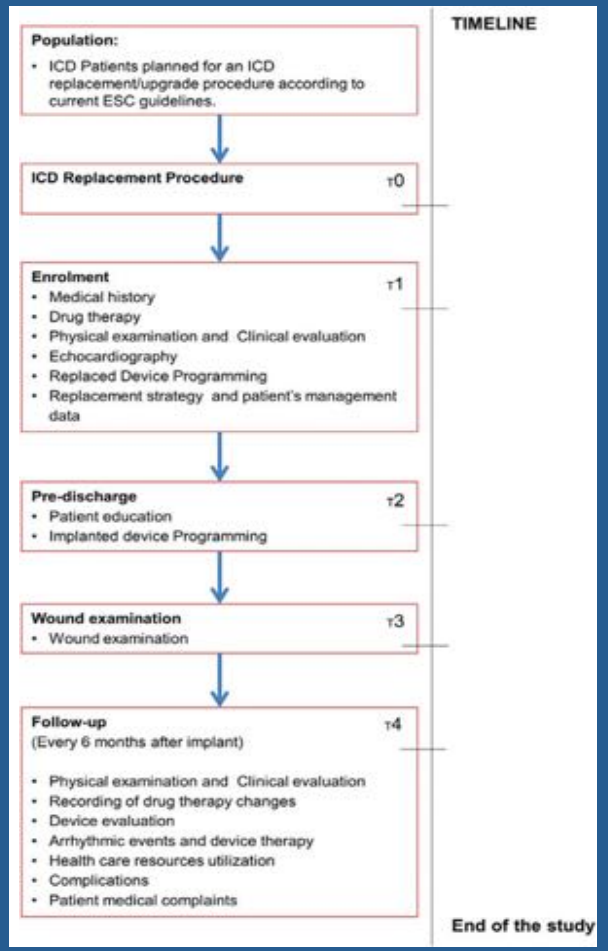
N = 800 patients
with previously implanted CRT-D or single-chamber/dual-chamber ICD device
&
Standard indications for ICD generator replacement

PRIMARY ENDPOINT:

1. Rate of complications associated with ICD replacement/upgrade (12 month FUP)

SECONDARY ENDPOINTS:

1. Predictors of overall complications
2. Very long-term complications (up to 60 months FUP)
3. Evaluation of preventive strategies for the prophylaxis of ICD replacement–related infections (before & after surgical procedure)
4. Long-term costs of ICD/upgrade procedure
5. Evaluation of clinical response for upgrade to CRT-D



Clin. Cardiol - Diemberger I & al. *(In Press)*

Do replacements impact on COSTs?

Model of long-term costs for extending device longevity over a 15-year time window.

The Longevity Model was applied to four different, typical, patient populations:

Population A:
Pts with SCD risk
&
preserved LV systolic function

Population B:
Pts with SCD risk
&
impaired LV function due to isch. or non-isch. cardiomyopathy

Population C:
Pts with impaired LV function
&
mild HF (NYHA II)
&
wide QRS

Population D:
Pts with impaired LV function
&
moderate HF (NYHA III)
&
wide QRS

ICD therapy (single chamber)

CRT-D therapy

Boriani G et al. Impact of extending device longevity on the long-term costs of ICD therapy: a modelling study with a 15-year time horizon
Europace 2013;15:1453–62

Do replacements impact on COSTs?

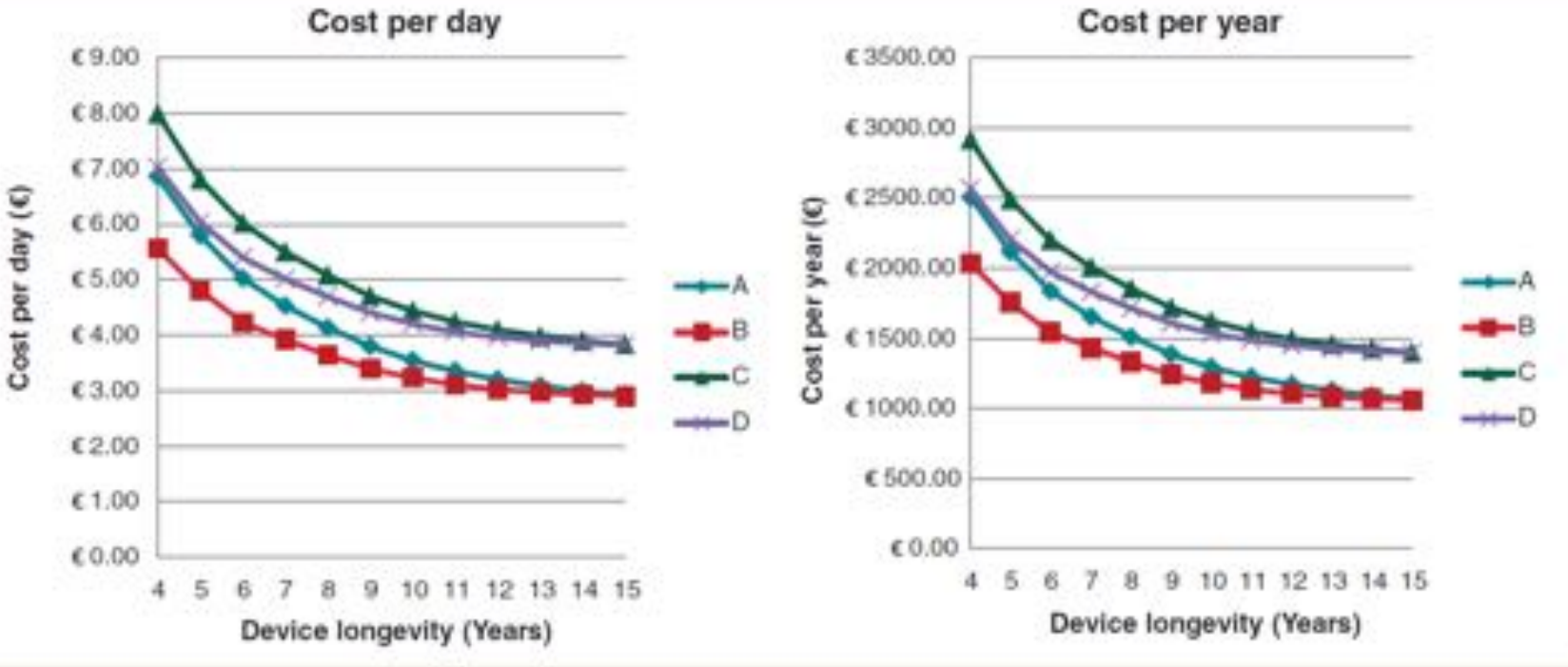


Figure 3 Cost per day (left panel) and cost per year (right panel) of ICD and CRT-D therapy according to the different patient populations.

Conclusions: Extending device longevity has an important effect on the long-term cost of device therapy, both for ICD and CRT-D. This has important implications for device choice.

Boriani G et al. Impact of extending device longevity on the long-term costs of ICD therapy: a modelling study with a 15-year time horizon
Europace 2013;15:1453–62

Conclusions - 1/2

- Nowadays implantable cardiac devices longevity doesn't fit with pts' life expectancy. Many pts require a device replacement for battery depletion

- Long-lasting ICD longevity could improve clinical outcome by reducing the nbr. of replacements, contributing to:
  - reducing the rate of infections
  - reducing the rate of re-interventions
  - reducing costs of the overall therapy

Conclusions - 2/2

- A consistent extension of device longevity should be a must for manufacturers, to improve clinical practice and pts' overall treatment

- This goal could be achieved by using:
  - Highly performing batteries with extended lifespan
  - Electronics improvement to reduce intrinsic consumptions
  - "Reforming-free" capacitors to eliminate waste of energy
  - Algorithms to optimize pacing and shocks management