

**Which patient should get
advantage from the longest
lasting ICD and which one from
the smallest ICD?**

Gaetano Senatore

**DIVISION OF CARDIOLOGY
HOSPITAL OF CIRIE' & IVREA
ITALY**

DIVISION OF CARDIOLOGY CIRIE' & IVREA ITALY

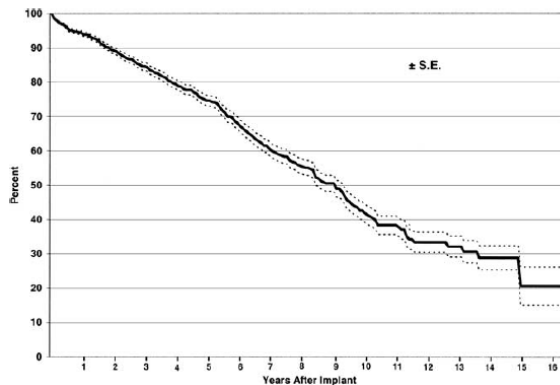


A.S.L. 6 Ospedale di Cirié

Longevity is important for **ALL**

Patients

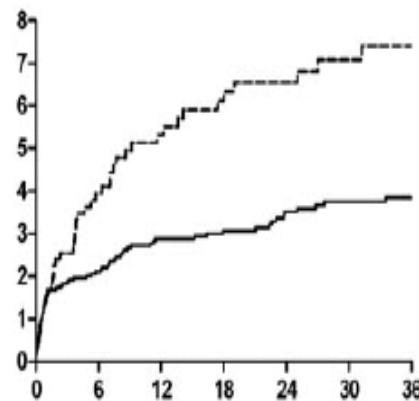
Patients live longer than their devices



Hauser, JACC 2005

Physicians

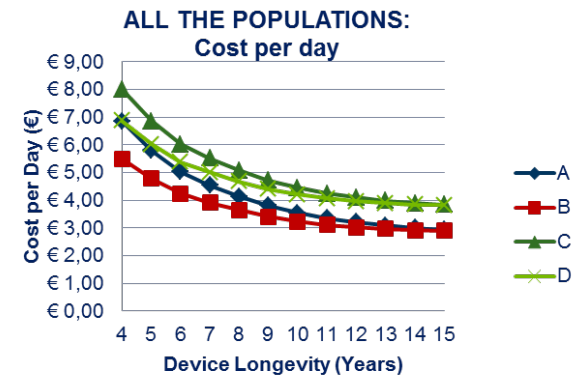
Doubled risk for surgical reintervention related to the pocket



Borleffs, PACE 2010

Hospital

The longevity of the device has a direct effect on operating costs

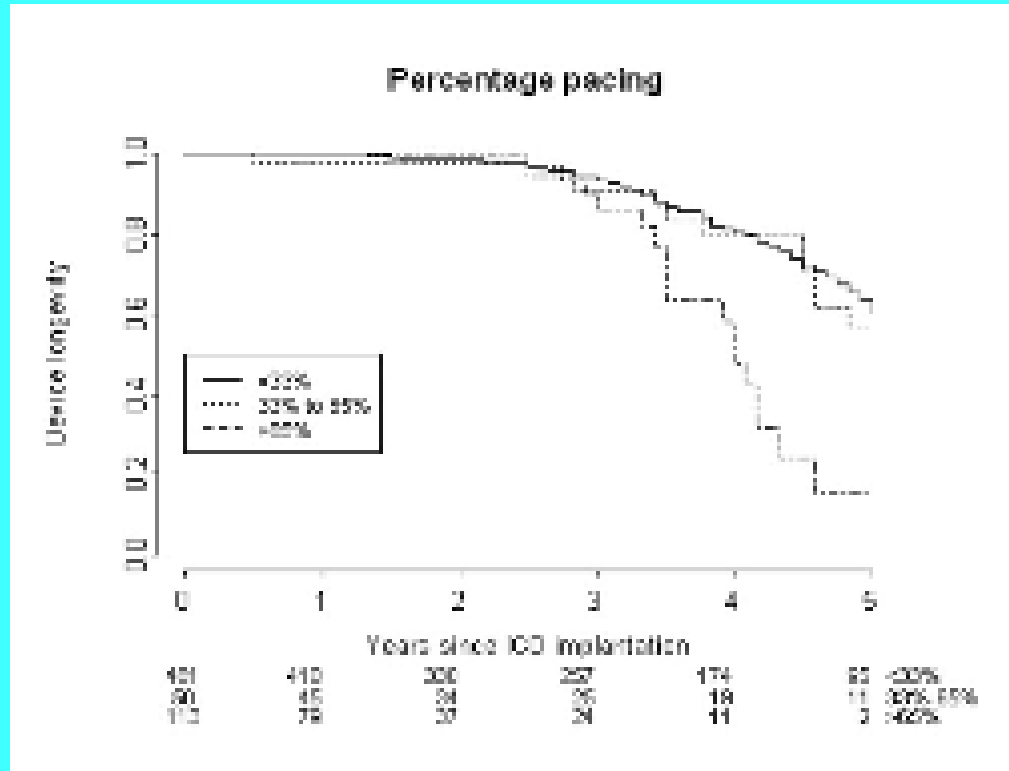


Boriani, Europace 2013

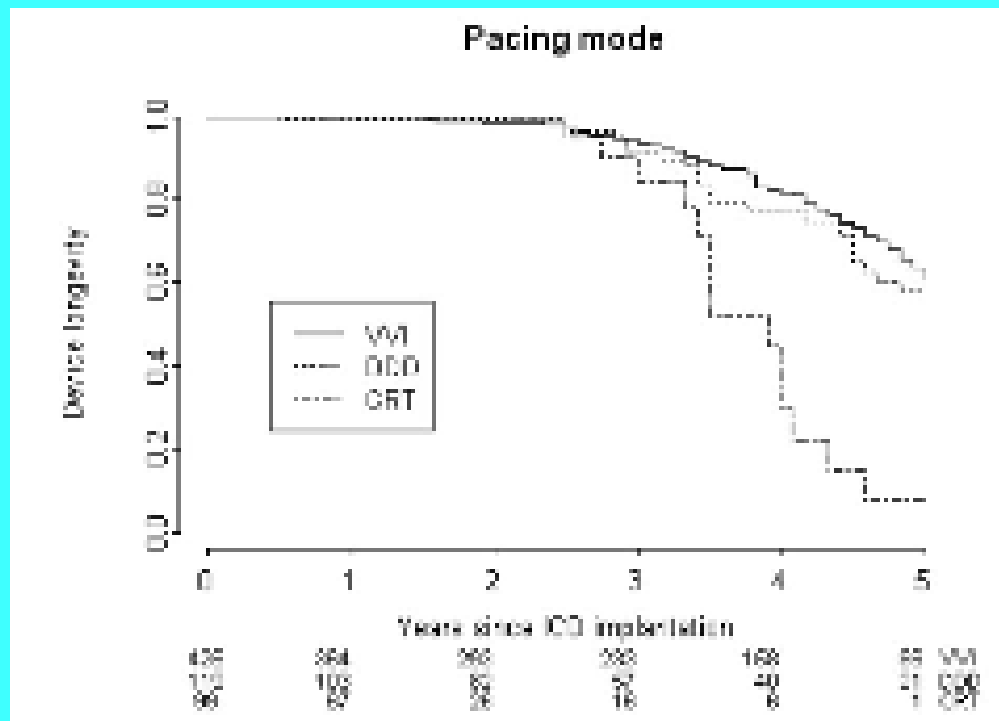
Replacement Procedures

- Battery related
- Non-battery related
 - device upgrade
 - device infection
 - device advisory or recall
 - system malfunction
 - heart transplantation

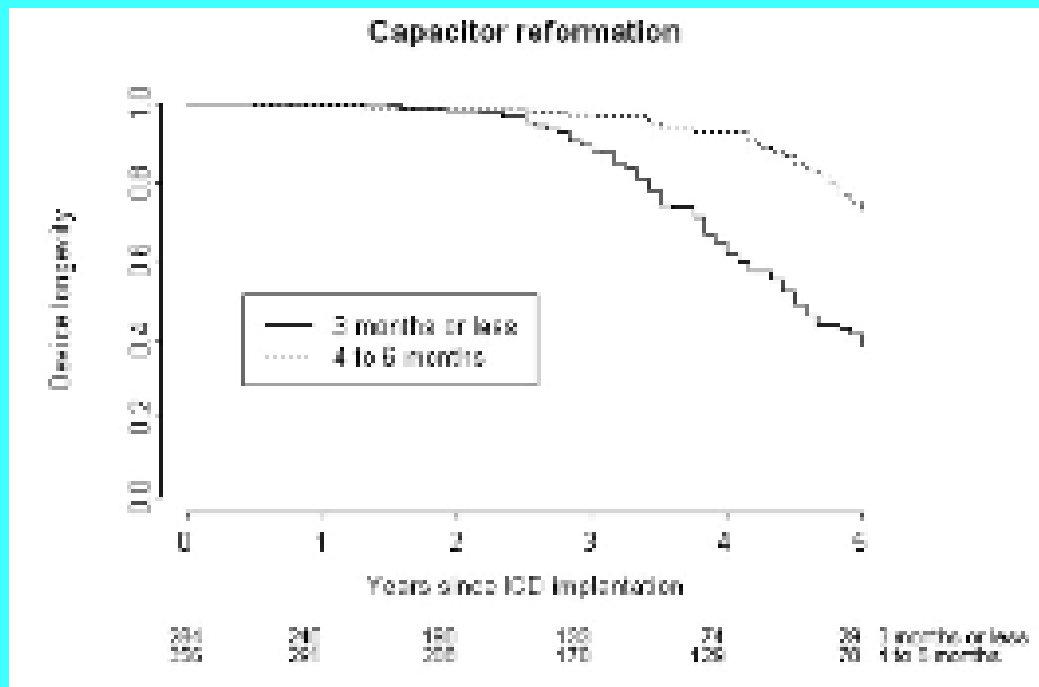
- device type (single, dual, or cardiac resynchronization)
- manufacturer
- generation
- pacing rate, mode, percentage, output
- shocks



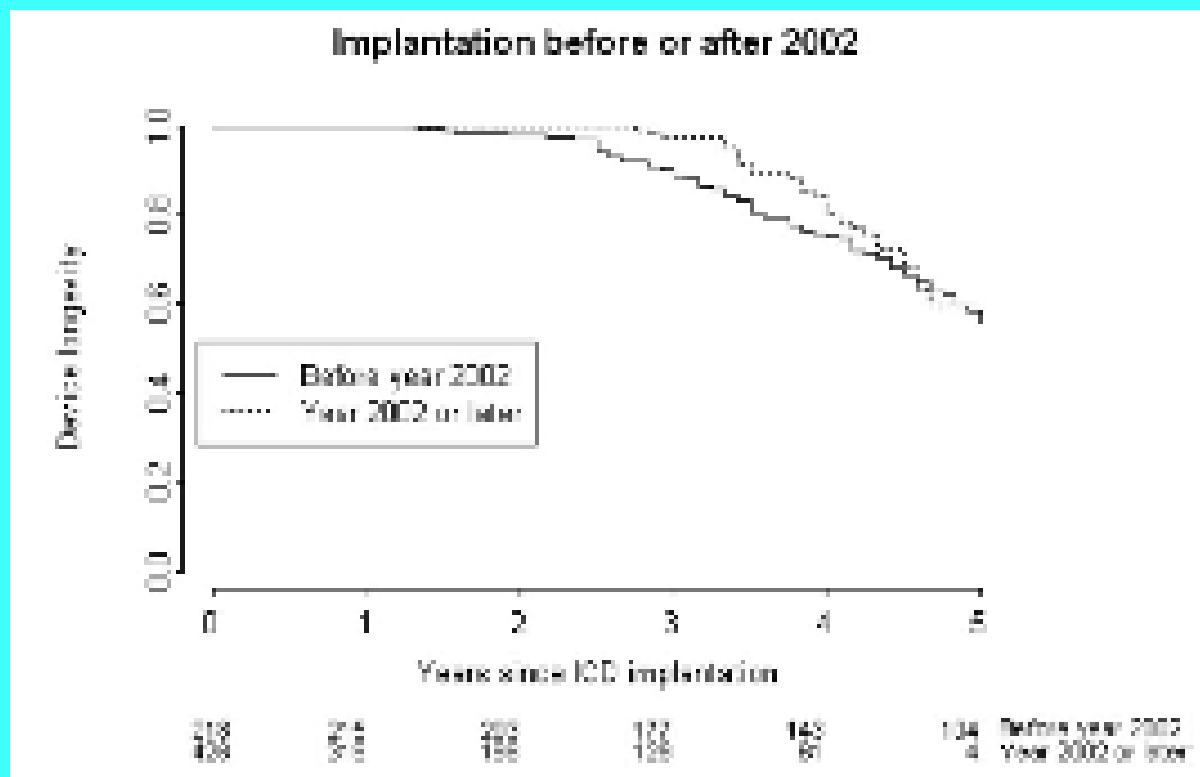
Schaer BA et al, Heart Rhythm 2009



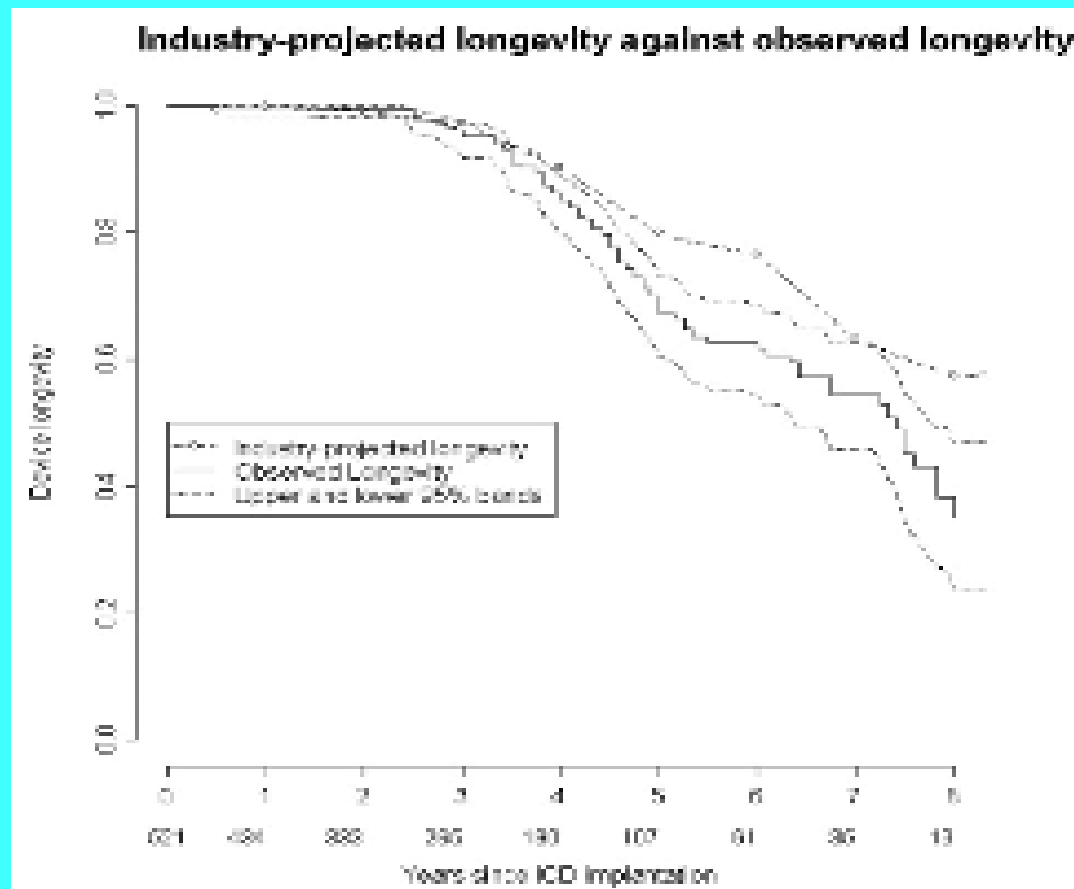
Schaer BA et al, Heart Rhythm 2009



Schaer BA et al, Heart Rhythm 2009



Schaer BA et al, Heart Rhythm 2009



Schaer BA et al, Heart Rhythm 2009

Longevity is important for the **patients**

73% of the patients are worried about the longevity of their device



Today patients live longer than their device

70% of ICD patients **requires at least 1 replacement**
because of battery life

40% requires a **second replacement** because of battery life

70% of patients is **still alive 10 years after ICD and CRT-D**
implantation

40% of ICD patients is **less than 65 years old**

1. High Voltage Patient Survey, January 2011. **Double-blind** online **survey** administered by 3rd party vendor; conducted among **189 high voltage device patients**.
2. Saxon L et al; Circulation 2010; 122:2359-2367. Long-term Outcome after ICD and CRT Implantation and Influence of Remote Device Follow-up. The LATITUDE Survival Study
3. Hauser. The growing mismatch between patient longevity and the service life of implantable cardioverter-defibrillators. JACC 2005; 45; 2022-5.
4. Swedish ICD and Pacemaker Register: Annual Statistical Report 2011. <https://www.pacemakerregister.se/icdpmr/>

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Longevity is important for the physicians

Increased risk of infection

- The infection rate in new implants is < 1% vs **2,6-7%** after the replacement procedure
- 80 % of infections could be prevented if the device would last nine years
- Longer lasting ICDs reduce the incidence of the replacements

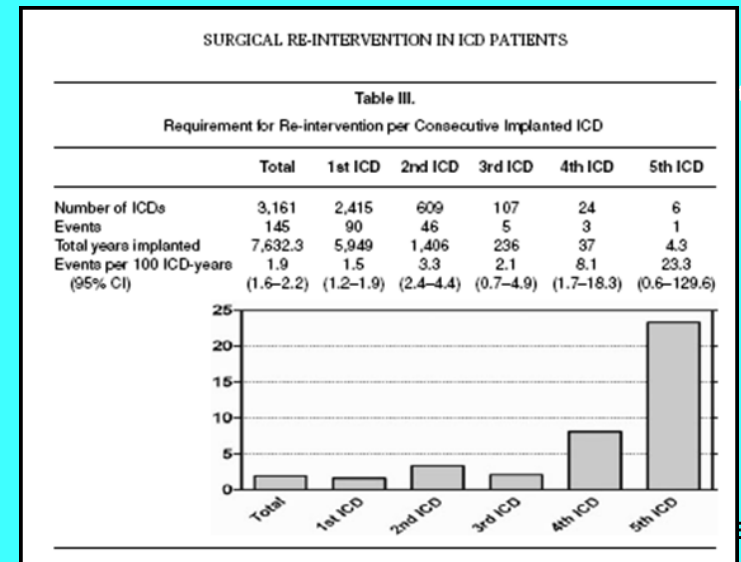


Pocket infection/erosion

Doubled risk for pocket related surgical re-intervention

3.161 ICD, 38 months follow-up

- Risk of infection increased by 2.5 times
- Risk of other complications increased by 1.7 times



ti,

3,9%

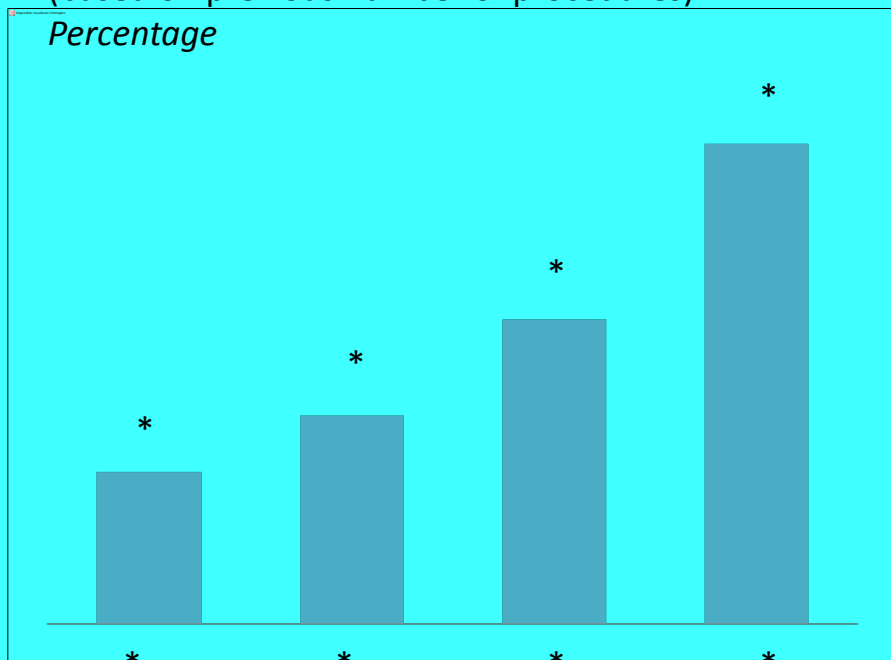
2010

Longevity is important for the **physicians**

Infection rate

(based on previous number of procedures)

Percentage



Number of procedures

Complication rate

(DR pacemaker)

% patients with complications

Major complication rate: 2.6%

+

Minor complication rate: 5.9%

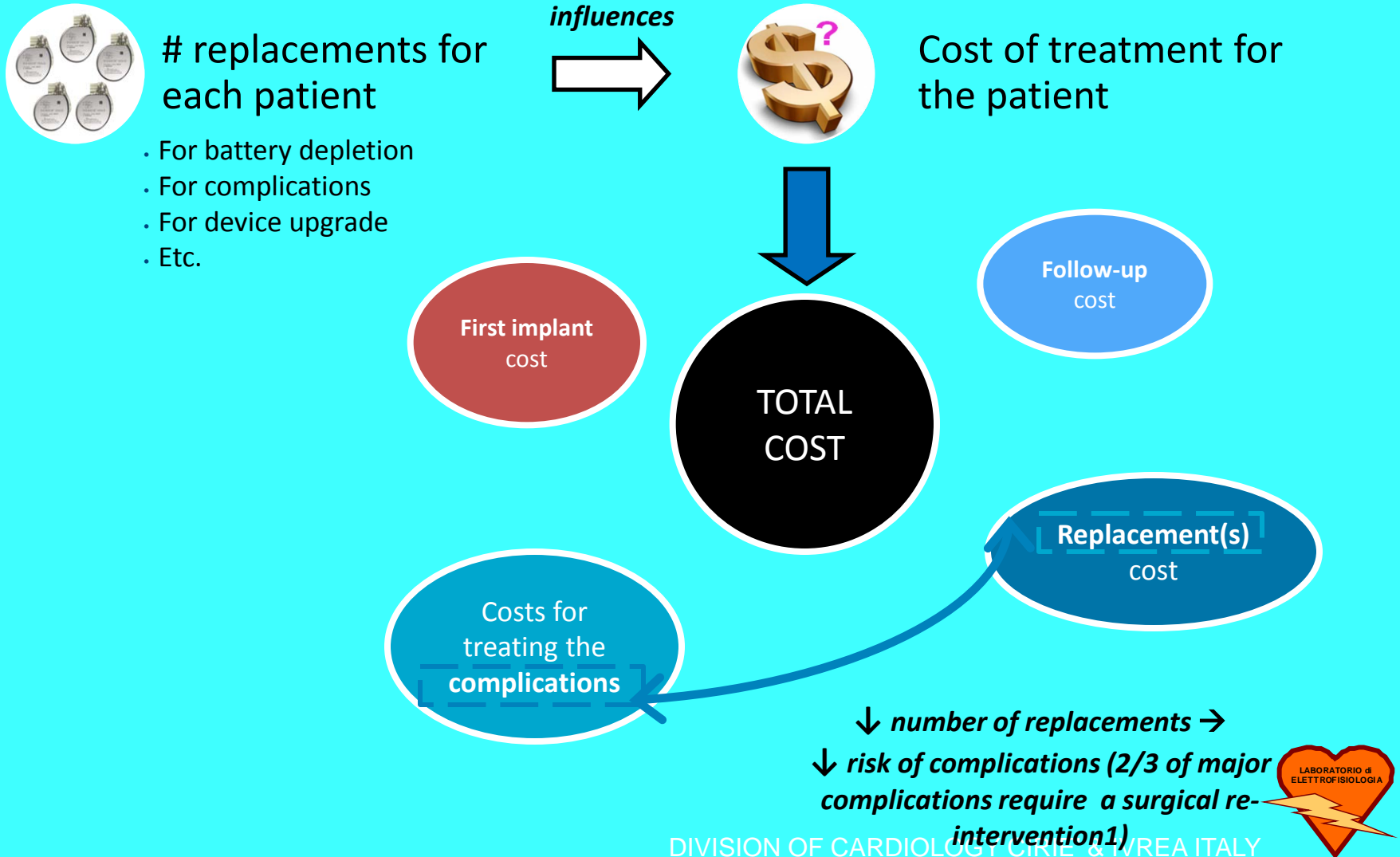
8,5% total
complication rate

1. Infection after pacemaker implantation: JB Johansen et al., European Heart Journal, January 20, 2011, N=46,299.
2. Gleva, MJ., Heart Rhythm Society, 2009 Scientific Sessions, May 13-16, Boston, MA. <http://www.theheart.org/article/971381.do> , N=425, Complication Rates Associated with Pacemaker or Implantable Cardioverter-Defibrillator Generator Replacements and Upgrade Procedures. Poole, JE, Gleva, MJ, et al. Circulation, 10/4/10.

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Longevity is important for the hospitals



Longevity is important for the **hospitals**

An hospital that would reduce costs without reducing the activity or the quality of care may benefit from a **greater longevity** of the implantable devices.

Longevity **reduces the daily and yearly cost of treatment** maintaining at the same time the other factors unchanged

For example, if you take into account:

- A period of 15 years of care beginning with the first implant
- The total costs of the therapy (*device, procedure, follow-up, complications costs*)

and an extension of the **device longevity by 3 or 4 years** compared to the duration of the devices currently in use, the **calculated total saving is around 30%!***

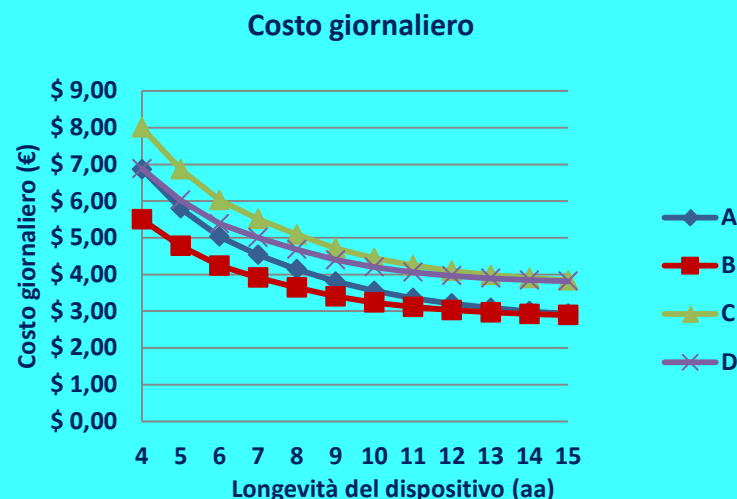
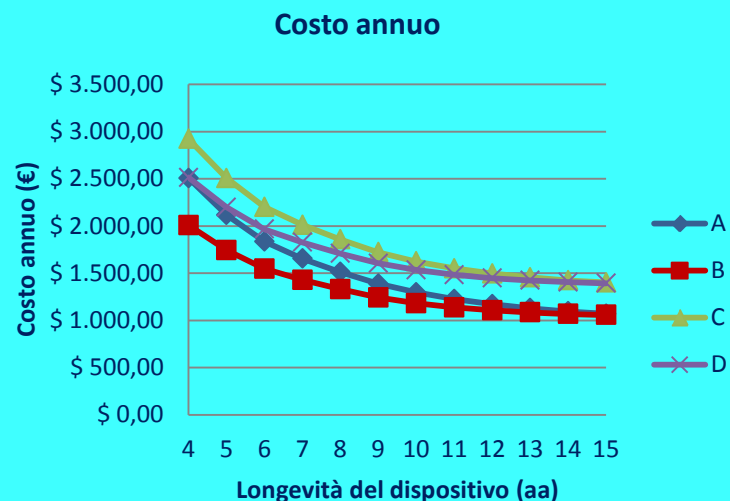
	<i>Device longevity extension (ys)</i>	<i>Average daily savings</i>	<i>Average total savings</i>	<i>Total savings %</i>
ICD	5→9 (4 ys)	1,70 €	9.300 €	31%
CRT-D	4→7 (3 ys)	2,24 €	12.300 €	30%

* Boriani G et al. Impact of extending device longevity on the long-term costs of implantable cardioverter-defibrillator therapy: a modelling study with a 15-year time horizon. Europace 2013



Longevity is important for the hospitals

The daily and annual costs of treatment for an ICD patient **always reduce with the increase of the device longevity**, but in different ways depending on the considered population*:



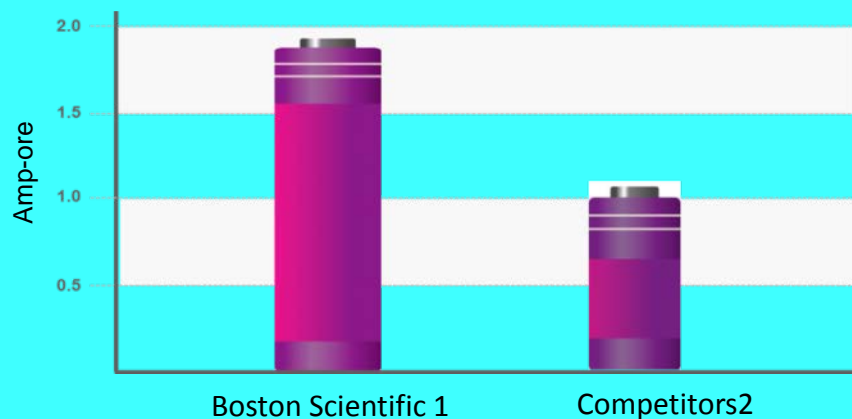
Analysed populations are:

- A:** patients with preserved EF and first ICD implant
- B:** patients with depressed EF and ICD implant
- C:** HF patients in NYHA class II and CRT-D implant
- D:** HF patients in NYHA class III and CRT-D implant

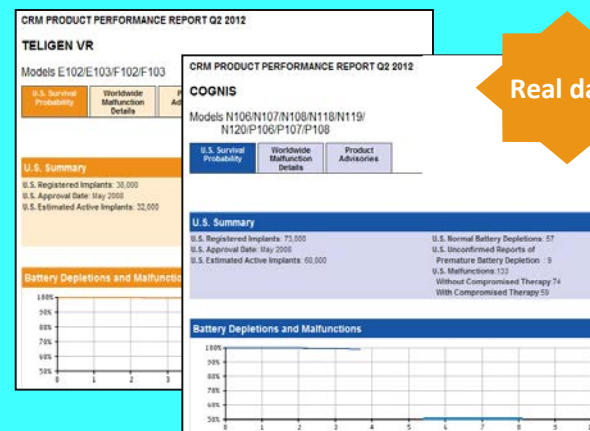
* Boriani G et al. Impact of extending device longevity on the long-term costs of implantable cardioverter-defibrillator therapy: a modelling study with a 15-year time horizon. Europace 2013.



Doubled battery capacity compared to similar devices

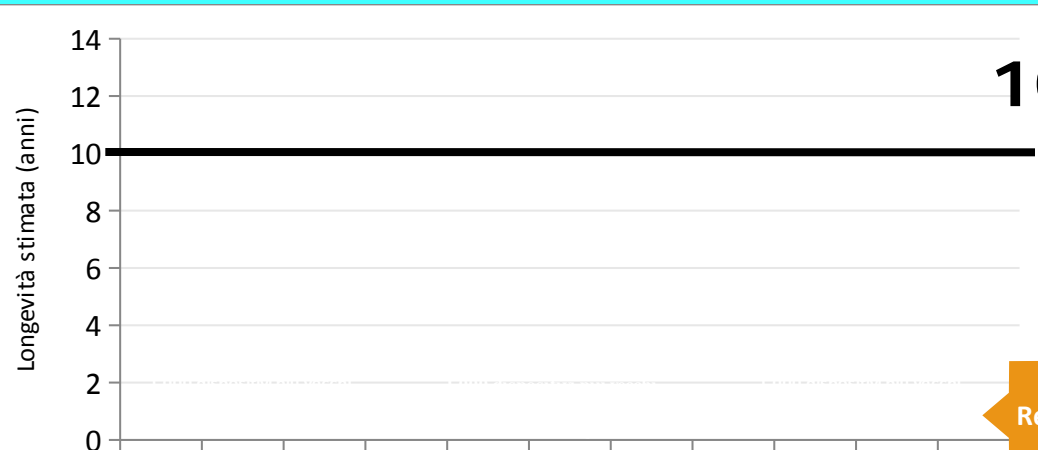


0,1% battery depletion at ~4 years from PPR



Real data

Longevity projections on over 90.000 dispositivi followed with Latitude



10 years

Real data

- 1 - BSC ICD e CRT-D, dati in archivio presso Boston Scientific.
- 2 - Protecta™ ICD VR D364VRG 2010 p295 & VIVA™ XT CRT-D DTBA2D4 2012 pagina 28
- 3 - Boston Scientific CRM Q2 2012 Product Performance Report cut off del dati 13 aprile, 2012
4. Longevità prevista Latitude: non intesa a sostituire le stime di longevità indicate nella certificazione
 - Analisi dei dati globali del sistema di gestione del paziente LATITUDE: da 3.000 pazienti del 19 agosto 2011. Dati in archivio.
 - Sintomi, situazioni, circostanze e risultati possono variare da individuo a individuo. Queste informazioni non devono essere utilizzate per la diagnosi o il trattamento medico né devono sostituire la consulenza medica professionale.
 - La programmazione del dispositivo è stata determinata dai medici. Pertanto, la media globale rappresenta un valore medio basato sulla programmazione reale.
 - I dati riflettono le longevità previste sulla base delle impostazioni dei parametri, piuttosto che sulle prestazioni osservate.
 - Queste informazioni sono una serie di dati definiti e in futuro potrebbero cambiare.
 - La bassa variabilità può essere il risultato dei dispositivi ancora relativamente nuovi. Poiché i dispositivi continuano a invecchiare, le differenze del paziente nella stimolazione e altri fattori possono causare una maggiore variabilità nel tempo approssimativo prima della data dell'espanto.
 - Si presume che i dati LATITUDE siano rappresentativi della popolazione di pazienti generali.
 - La distribuzione è non normale; pertanto la deviazione standard va interpretata con attenzione. Potrebbe non essere necessariamente vero che il ~95% dei dati rientra nelle 2 deviazioni standard della media, il ~99,7% nelle tre, ecc.

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Are there any exceptions to the longevity?

MINI is designed for a **20% reduction in pocket size** when compared to other devices

tiny can



Physician benefits

- ✓ Easier to fit for replacements
- ✓ Smaller incision for initial implant
- ✓ Lower risk of pocket-related complication
- ✓ Lower skin pressure
- ✓ More options to offer patients

The world's smallest and thinnest ICD

Designed to benefit patients

MINI's small footprint and thin profile is designed for patient comfort and aesthetic.

tiny can

Patients comfort



"I have some ache when I lay on my left side. I'd rather have my device be smaller."

Small and thin patients



"Seatbelts bother me so much, it makes me more aware of it."

Aesthetic reasons



"I'd like my device to be really thin. I just don't want to notice it."



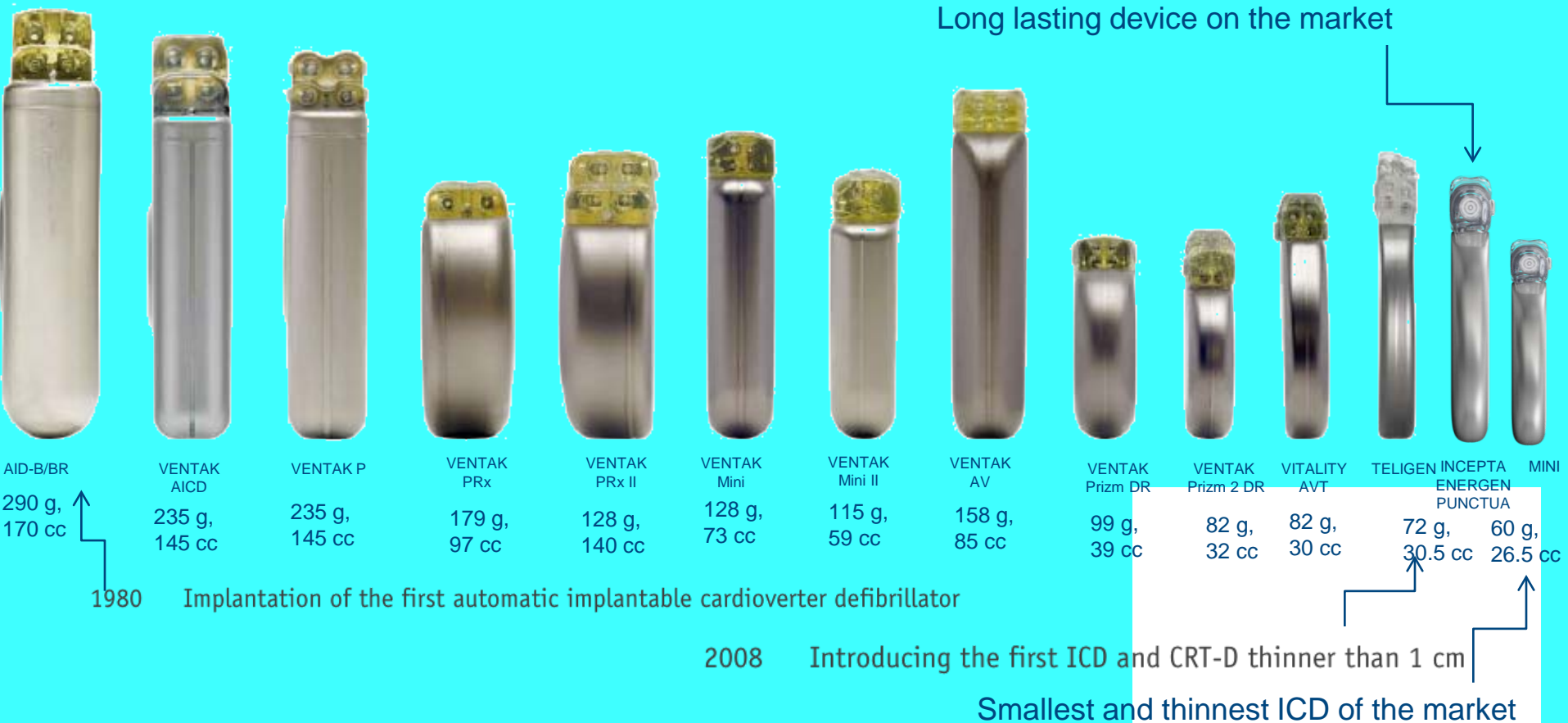
MINI Patient Preference Study, January 2014. Double-blind focus group and questionnaire administered by 3rd party vendor; conducted among 30 device patients. Indicate whether or not the availability of each of the ICDs listed below would influence your willingness to express a preference for one ICD over another to your physician (based on size, shape and thinness alone). Devices tested include the MINI VR ICD, Fortify™ VR ICD, Ellipse™ VR ICD, Protecta™ VR ICD, and Evera™ VR ICD

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Leader in the ICD innovation

From the world's first ICD...

...to the world's smallest and thinnest ICD (less than 1 cm!).



Boston Scientific continues to invest in industry leading technology innovation

HUGE BREAKTHROUGH

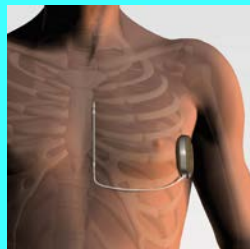
1st
ICD



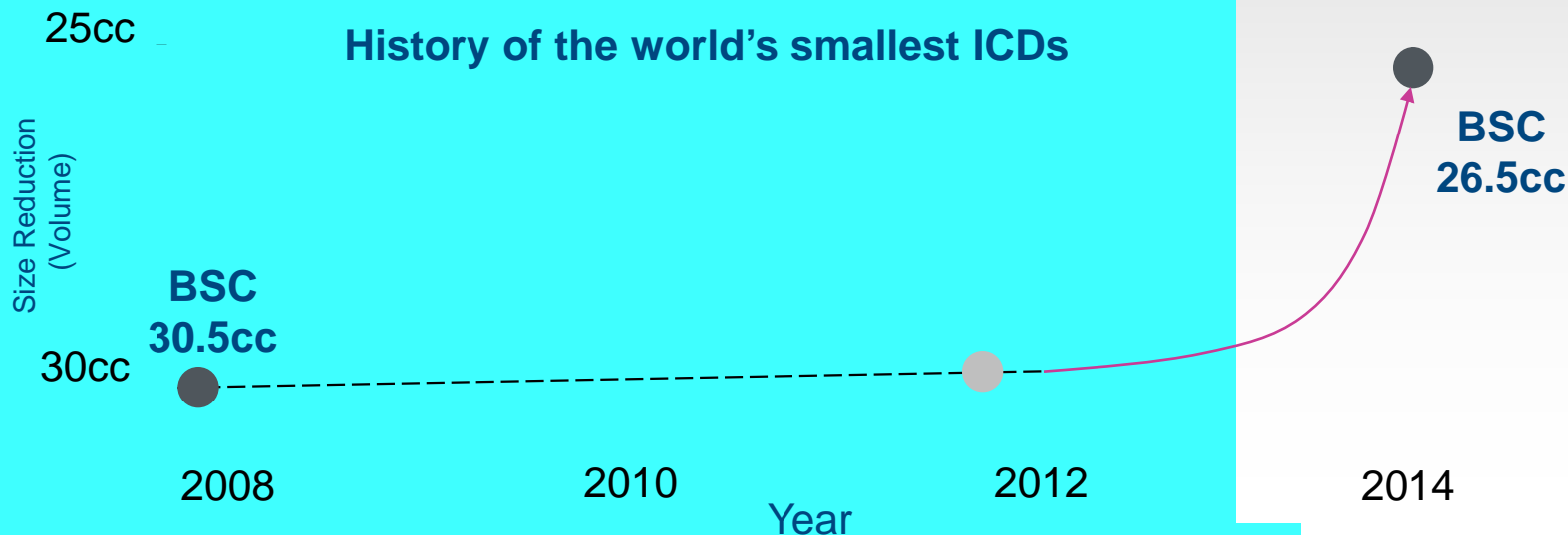
1st
Triple Chamber
CRT-D



1st
Subcutaneous
ICD



1st 26.5cc ICD



1 St. Jude Medical™ High-Voltage Devices User's Manual 2013 page 16

1) Patient Case

- **Patient description:**

- 14 year-old girl
- Tall and with very thin body, looking more like 11 year-old girl

- **Device indications:**

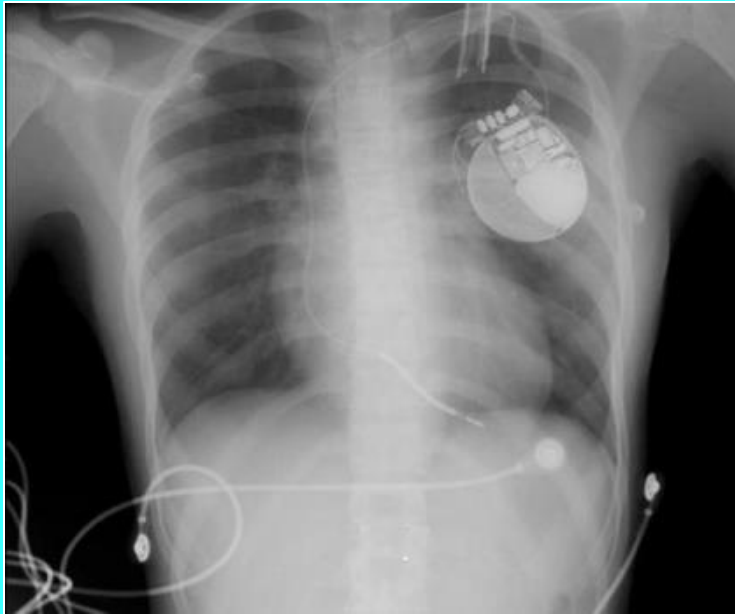
- Dyspnea during physical exertion due to fast TV, also with syncope
- Waiting heart transplant
- 2 little sisters dead in the past
- Under optimal pharmacological therapy

Patient case outcome

- **Implanted device:** Boston Scientific MINI ICD

Physicians comments:

"Pediatric patients request a particular approach, starting from a dedicated arrhythmias ambulatory in which they can meet physicians ready to manage both arrhythmias and psicological consequences during childhood and adolescence"



2) Patient Case

- **Patient description:**

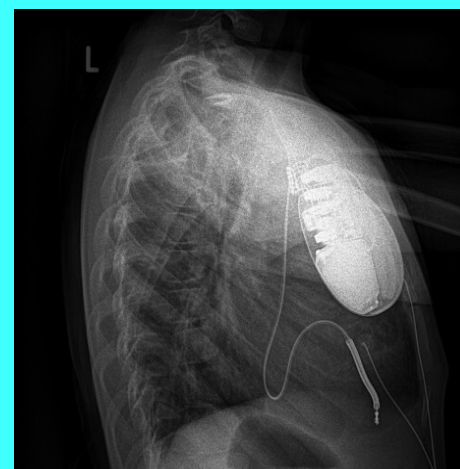
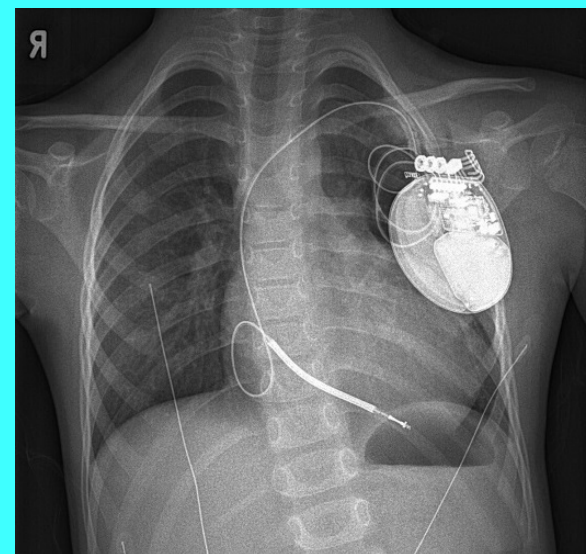
- 8 year-old boy
- Small and thin - 132 cm, 17kg
- EF = 30%
- No LBBB

- **Device indications:**

- Dilated Cardiomyopathy after Myocarditis

Patient case outcome

- **Implanted device:** Boston Scientific MINI ICD



CONCLUSIONS

- Although there has been a focus to reduce device size, it may occur at the expense of battery longevity
- Manufactures should reconsider the availability of longer lived batteries
- Survey revealed that the majority of pts would prefer a larger device with longer longevity over a smaller device that is less noticeable but requires more frequent surgery

