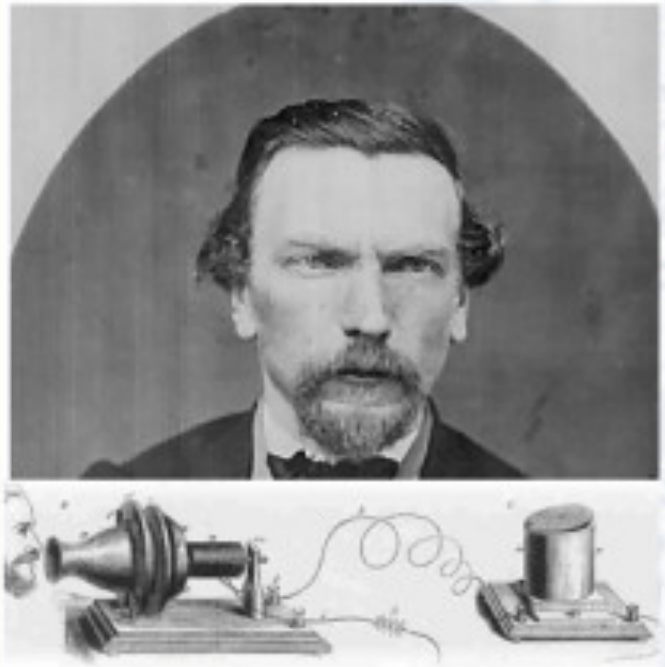
Conoscere e Curare il Cuore 2015

RIVOLUZIONE IN ARITMOLOGIA: IL PACEMAKER SENZA FILI ED IL DEFIBRILLATORE SOTTOCUTANEO

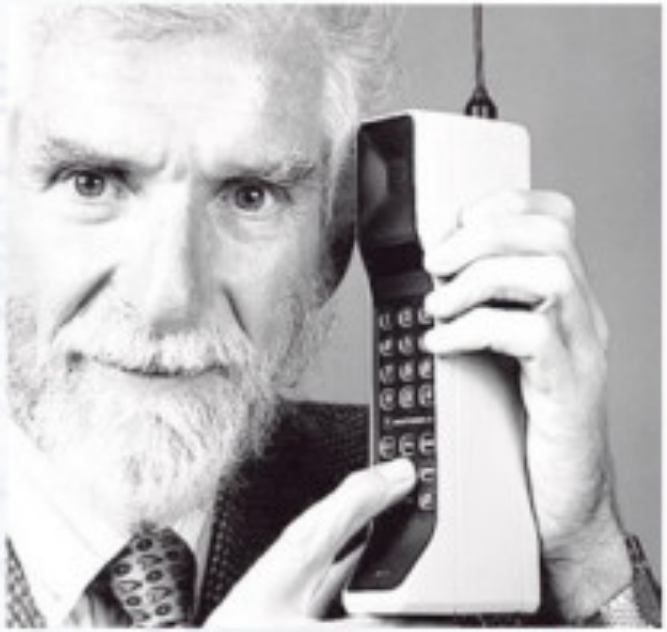
Carlo Pappone

Policlinico San Donato, Milan University

Wireless Revolution



In 1865 Innocenzo Manzetti invented the first wired telephone



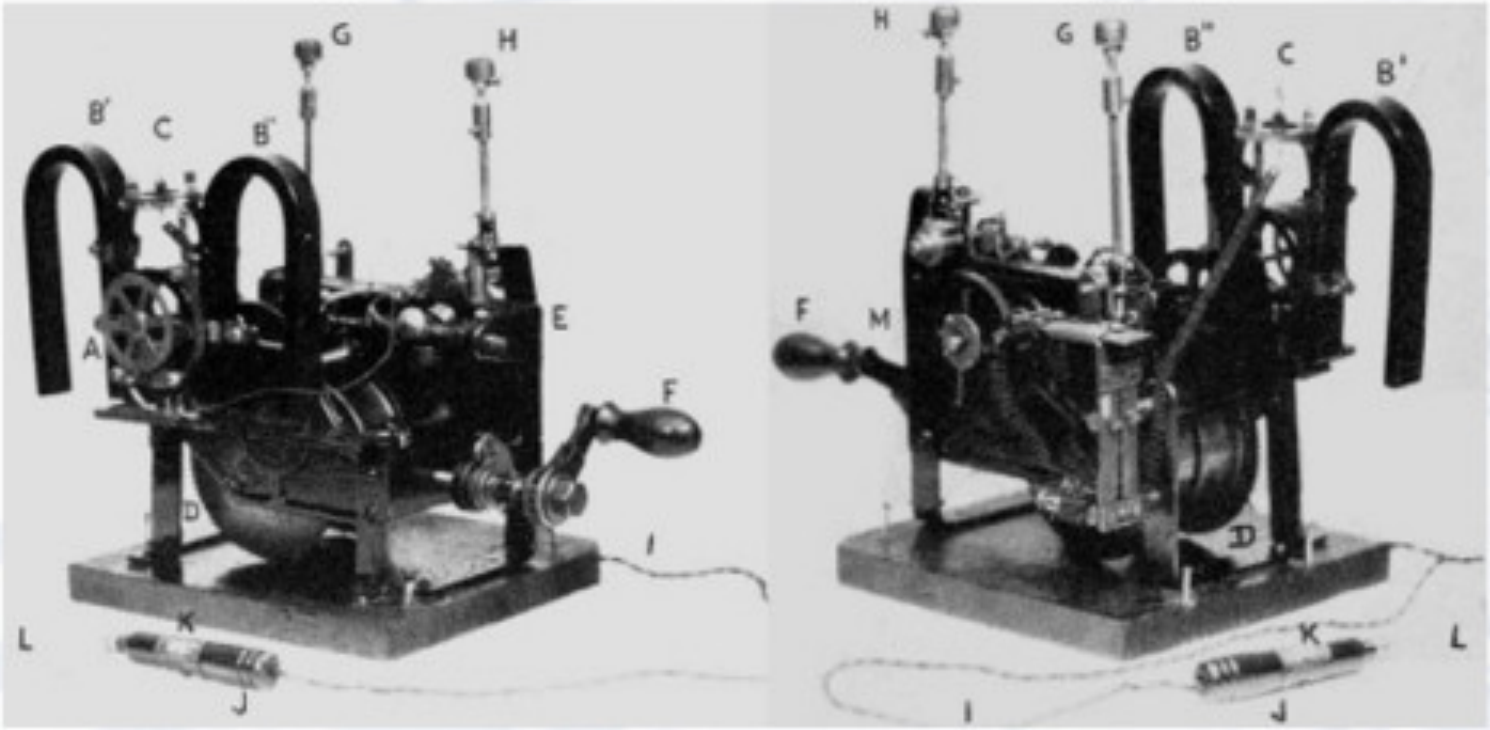
108 years later Martin Cooper made the first call with a mobile phone

Smallest is better ?

1983 - Motorola DynaTAC 8000X
Lenght: 25 cm
Weight: 790 gr

2003 – Samsung Watch phone
Lenght: 5 cm
Weight: 60 gr

First attempts…



In 1932, American physiologist **Albert Hyman**, working independently, described an electro-mechanical instrument of his own, powered by a spring-wound hand-cranked motor. Hyman himself referred to his invention as an "**artificial pacemaker**", the term continuing in use to this day…..

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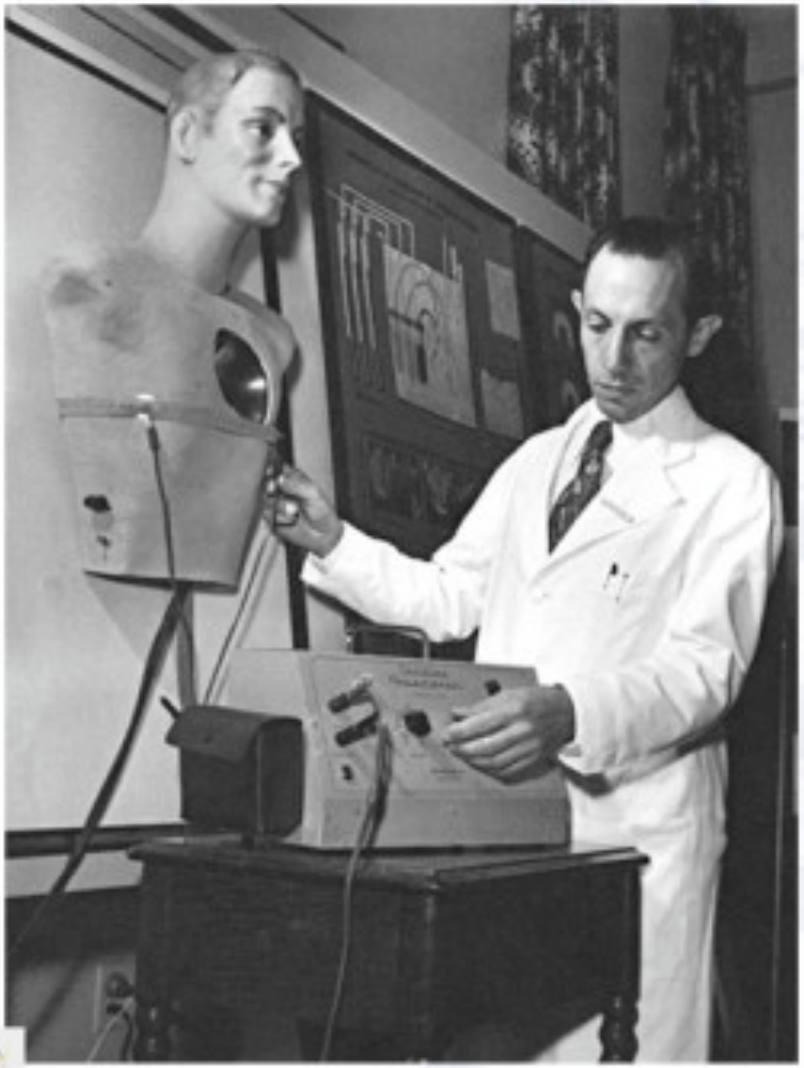

In 1950 an external pacemaker was designed and built by the Canadian electrical engineer **John Hopps** based upon observations by cardio-thoracic surgeon **Wilfred Gordon Bigelow** at Toronto General Hospital. A substantial external device using vacuum tube technology to provide transcutaneous pacing, it was somewhat crude and painful to the patient in use and, being powered from an AC wall socket, carried a potential hazard of electrocution of the patient by inducing ventricular fibrillation.

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In 1958 Colombian doctor **Alberto Vejarano Laverde** and Colombian electrical engineer **Jorge Reynolds Pombo** constructed an external pacemaker, similar to those of Hopps and Zoll, weighing 45 kg and powered by a 12 volt car lead acid battery, but connected to electrodes attached to the heart. This apparatus was successfully used to sustain a 70-year-old priest, Gerardo Florez.

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In 1958, engineer **Earl Bakken** of Minneapolis, Minnesota, produced the first wearable external pacemaker. This transistorized pacemaker, housed in a small plastic box, had controls to permit adjustment of pacing heart rate and output voltage and was connected to electrode leads which passed through the skin of the patient to terminate in electrodes attached to the surface of the myocardium of the heart.

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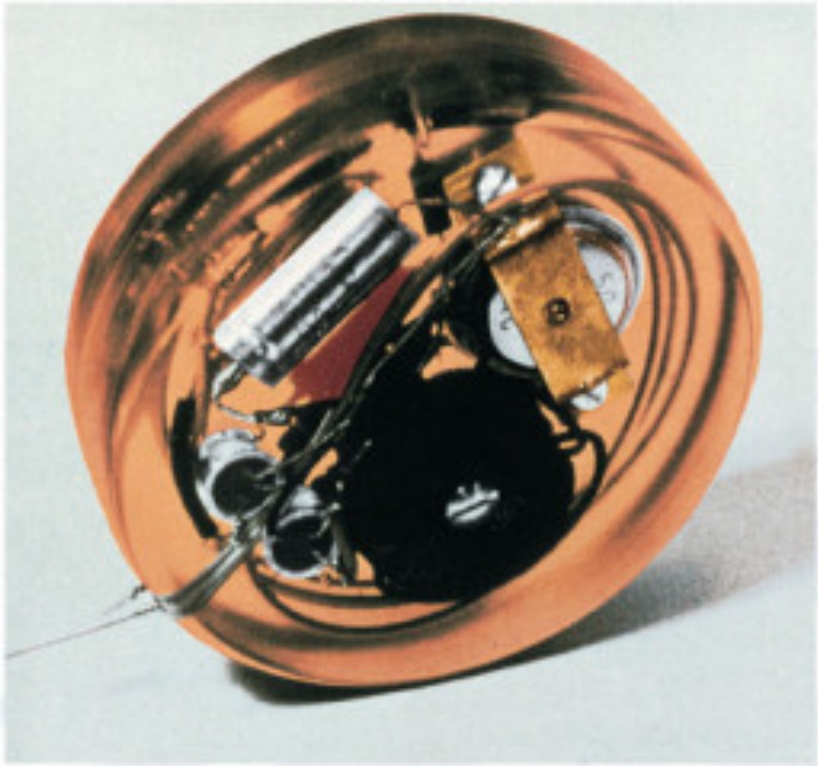
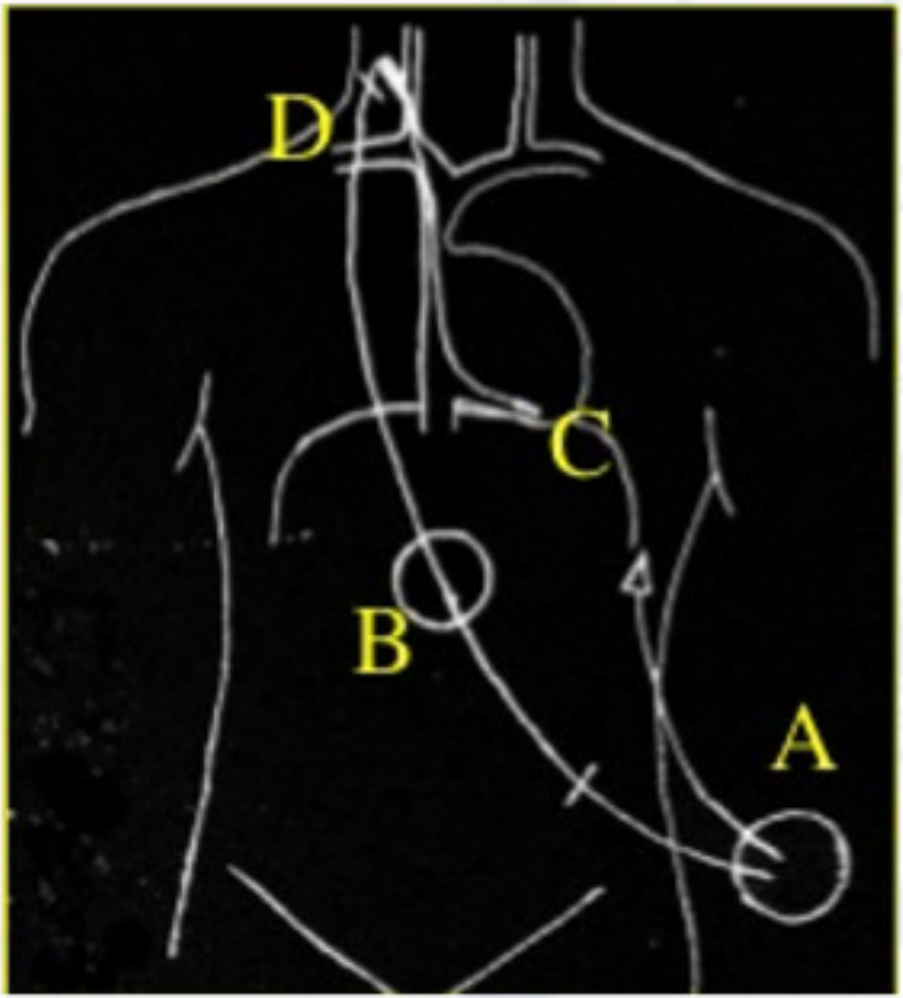


In 1958 The first clinical implantation into a human of a fully implantable pacemaker was at the **Karolinska Institute** in Solna, Sweden, using a pacemaker designed by **Rune Elmqvist**, connected to electrodes attached to the myocardium of the heart by thoracotomy. The device failed after three hours. A second device was then implanted which lasted for two days. The world's first implantable pacemaker patient, **Arne Larsson**, went on to receive 26 different pacemakers during his lifetime. He died in 2001, at the age of 86, outliving the inventor as well as the surgeon



In 1962–63 The first use of transvenous pacing in conjunction with an implanted pacemaker was **by Parsonnet** in the USA, **Lagergren** in Sweden and **Jean-Jaques Welti** in France . The transvenous, or pervenous, procedure involved incision of a vein into which was inserted the catheter electrode lead under fluoroscopic guidance, until it was lodged within the trabeculae of the right ventricle. This method was to become the method of choice by the mid-1960s.

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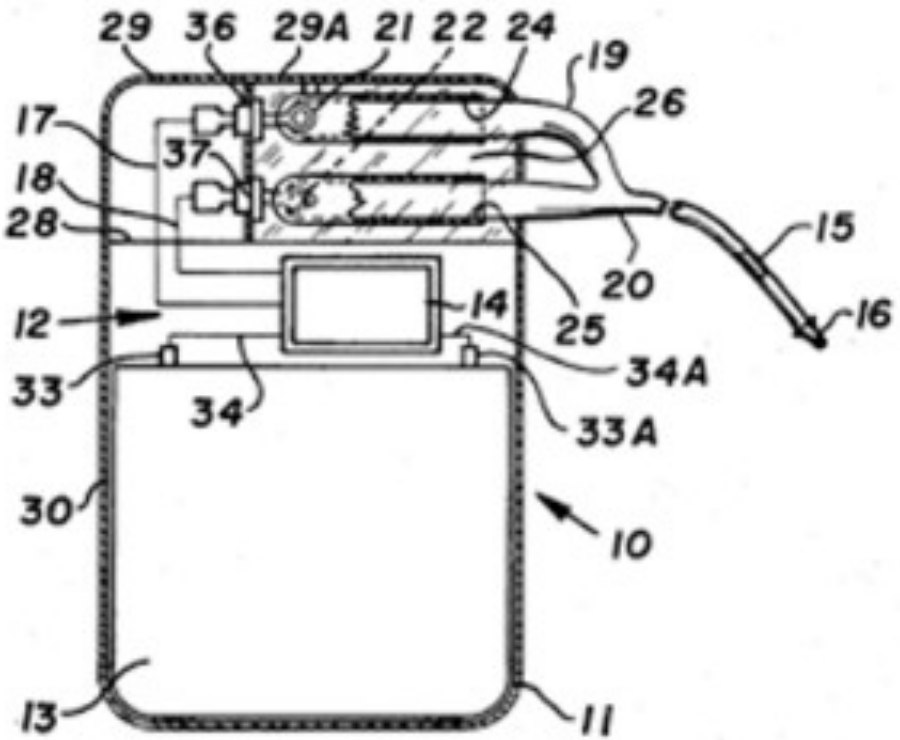

In July 9 of 1974, **Manuel A. Villafaña** and **Anthony Adducci** founders of **Cardiac Pacemakers, Inc. (Guidant)** in St. Paul Minneosta, manufactured the worlds first pacemaker with a lithium anode and a lithium-iodide electrolyte solid-state battery

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ST. JUDE MEDICAL

In 1995 SJM present Microny II SR+ Diagnostics
The Microny II SR+ pacemaker is among the world's smallest, single-chamber rate-responsive pulse generator.

Weight: 14 gr
Size: 6 cc

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The history of Leadless Pacemaker : An old Story

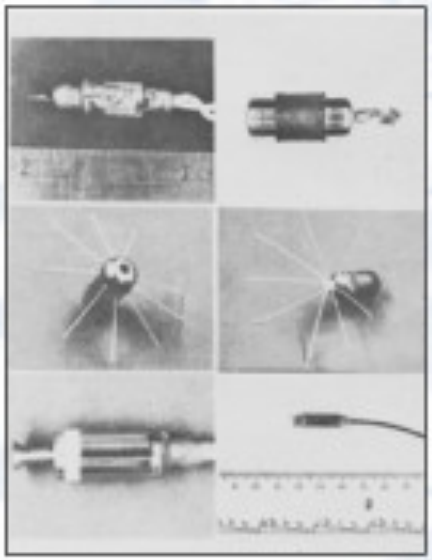
The first totally self-contained leadless pacemaker system was proposed by **Spickler in 1970** using a device powered by mercury-zinc and nuclear power that was successfully tested in animals.

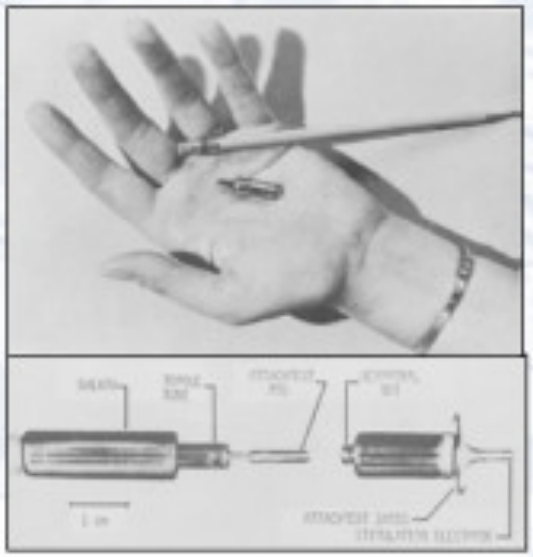
J. ELECTROCARDIOLOGY, 3 (3-4) 325-331, 1970

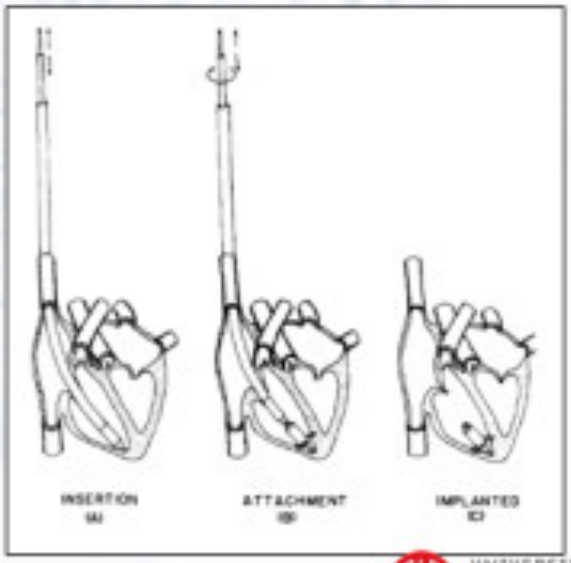
Special Article

Totally Self-Contained Intracardiac Pacemaker*

J. WILLIAM SPICKLER, PH.D., NED S. RASOR, PH.D.†, PAUL KEIDD, M.D.
S. N. MISRA, M.D., K. E. ROBBINS, P.E., AND CHARLES LaBOEUF, P.E.







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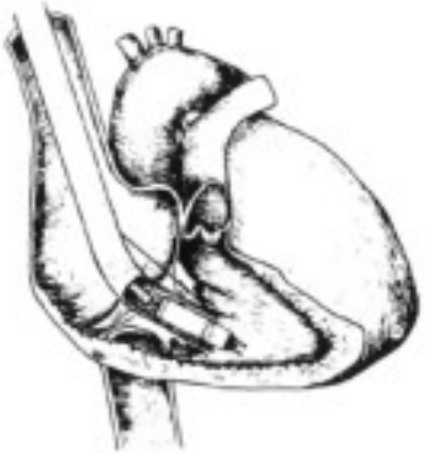
The history of Leadless Pacemaker : in **1991** leadless PM was tested in animals



© by EBM

EUR J CPE 1991;1:27–30

A Miniature Pacemaker Introduced Intravenously and Implanted Endocardially. Preliminary Findings from an Experimental Study

P.E. VARDAS, C. POLITOPOULOS, E. MANIOS, F. PARTHENAKIS, and C. TSAGARAKIS

In 1991, Vardas et al created a cylindrical VOO pacing device specifically for an animal study. The device measured 5.8mm in diameter and 23 mm in length, and it consisted of three batteries and a CMOS timer. The authors stated that "if [a miniature pacing device] can be made programmable without an unreasonable increase in size, if the battery can be made sufficiently long lasting or externally rechargeable, if technology can rise to meet these challenges, then such a miniature device might one day take its place among regularly used pacemakers and, eventually, even supercede them."

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In 2013 Nanostim™ was ready....

The VVIR Nanostim™ Pacemaker is introduced inside the right ventricle trough the femoral vein

UNIVERSITY & RESEARCH HOSPITALS

In 2013 Nanostim™ was ready....

The VVIR Nanostim™ Pacemaker is introduced inside the right ventricle trough the femoral vein

- **High capacity battery** (more than 10 years with standard pacing threshold) thanks to **low impedence** of stimulation (absence of lead) and low energy consumption of **communication system**

UNIVERSITY & RESEARCH HOSPITALS

In 2013 Nanostim™ was ready....

The VVIR Nanostim™ Pacemaker is introduced inside the right ventricle trough the femoral vein

- **High capacity battery** (more than 10 years with standard pacing threshold) thanks to **low impedence** of stimulation (absence of lead) and low energy consumption of **communication system**

- It has the same **steroid eluting system** of standard catheter

UNIVERSITY & RESEARCH HOSPITALS

In 2013 Nanostim™ was ready....

The VVIR Nanostim™ Pacemaker is introduced inside the right ventricle trough the femoral vein

- **High capacity battery** (more than 10 years with standard pacing threshold) thanks to **low impedence** of stimulation (absence of lead) and low energy consumption of **communication system**
- It has the same **steroid eluting system** of standard catheter
- It' designed to prevent displacement with a **double fixation system**

UNIVERSITY & RESEARCH HOSPITALS

In 2013 Nanostim™ was ready....

The VVIR Nanostim™ Pacemaker is introduced inside the right ventricle trough the femoral vein

- **High capacity battery** (more than 10 years with standard pacing threshold) thanks to **low impedence** of stimulation (absence of lead) and low energy consumption of **communication system**
- It has the same **steroid eluting system** of standard catheter
- It' designed to prevent displacement with a **double fixation system**
- **Dedicated rescue system**

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Nanostim™: Delivery System

- Catheter delivery system
- Soft and flexible catheter with complete steerable tip

Shaft with main 4 functions:

- Catheter bending
- Securing/releasing LCT
- LCP rotation
- Releasing modality with

- 18 F femoral vein sheat

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Arrhythmia/Electrophysiology

Permanent Leadless Cardiac Pacing
Results of the LEADLESS Trial

Vivek Y. Reddy, MD; Reinoud E. Knops, MD; Johannes Sperzel, MD; Marc A. Miller, MD; Jan Petru, MD; Jaroslav Simon, MD; Lucie Sediva, MD; Joris R. de Groot, MD, PhD; Fleur V.Y. Tjong, MD; Peter Jacobson, BS; Alan Ostrosff, MS; Srinivas R. Dukkipati, MD; Jacob S. Koruth, MD; Arthur A.M. Wilde, MD, PhD; Josef Kautzner, MD, PhD; Petr Neuzil, MD, PhD

- Goals: Feasibility and safety of LCP
- Perspective, not-randomized, multicenter study
- 33 patients enrolled

Median age 77 y.o. (53-91 anni); 67% male
67% with chronic AF and advanced AV block
18% Synus rhythm and reduced life expectancy
15% with infrequent pauses and unexplained syncope

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LEADLESS study

- **LCP was successfully implanted in32/33 patients (97%)**
  - 1 minor femoral hematoma
  - 1 cardiac perforation → cardiac surgery → during degency patient dead for major stroke
- **Procedural Time:**
  - Skin to skin : 28 minutes *(range 11 – 74 min)*

- **Hospitalization time**: 1 day *(Range 1 – 4)*
- **Intraprocedure LCP replacement** : 0.5/paziente *(Range 0 – 3)*

Riposizionamento dell'LCP	N° pazienti	% pazienti
0	**23**	**70%**
1	4	12%
2	4	12%
3	2	6%

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LEADLESS Study: Performance 12 months after implantation

	Implant	Pre-discharge	2-weeks	6-months	12-months
Threshold (V)	0.80 ± 0.20	0.41 ± 0.31	0.48 ± 0.30	0.40 ± 0.26	0.43 ± 0.30
R wave sensing (mV)	8.26 ± 3.14	9.67 ± 2.74	10.37 ± 2.52	10.64 ± 2.64	10.32 ± 2.23
Impedence (Ohms)	773 ± 243	719 ± 196	657 ± 175	625 ± 205	627 ± 209
Battery voltage (V)	3.17 ± 0.03	3.26 ± 0.04	3.26 ± 0.03	3.23 ± 0.06	3.29 ± 0.02

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LEADLESS **OBSERVATIONAL** STUDY (Europe)

Leadless PMCF	
Design	▪ Single arm, perspective, not randomized study ▪ Target of 1.000 patients in 100 European centre
Primary Endpoint	▪ Primary endpoint is to evaluate 90 days complications free rate Identified as an Serious Adverse Device Effect (SADE).
Secondary Endpoint	▪ Evaluate 6 month incidence of SADE
Supplementary Endpoints	▪ Pacing and sensing performance ▪ Implant success rate ▪ Procedure time ▪ Time to discharge

ONGOING……. But……

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WARNING!

The European study in may 2014 was stopped after reports of **six perforations**, including **two** that resulted in **death** (among 200 patients were enrolled). Patient enrollment up until that point was in the "mid-100s," according to Mark Carlson, MD, vice president of global clinical affairs and chief medical officer for device maker St. Jude Medical, headquartered in St. Paul, Minn.

*"**St. Jude's analysis** determined that the adverse events **were due in part to inappropriate patient selection and in part to operator inexperience**, according to Antalffy's note," Sarvestani continues. She further says that Antalffy wrote, "The company determined that five of the six perforations 'would not have occurred if the European registry aligned with the US pivotal [trial] inclusion/exclusion criteria.'*

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European observational study: Severe Adverse Events, preliminary data

Tabella 1: Riassunto dettagliato degli eventi avversi seri correlati al dispositivo (SADEs) a partire dal 5 Gennaio 2015

Eventi Avversi Seri correlati al Dispositivo	Nanostim™ EU Post Market – Pre Pausa (23 Dicembre 2013 – 17 Aprile 2014) N = 147 pazienti	Nanostim™ EU Post Market- Post Pausa (2 Giugno 2014 – 5 Gennaio 2015) N = 93 pazienti	Nanostim™ IDE (4 Febbraio 2014 – 5 Gennaio 2015) N = 322 pazienti	Nanostim™ EU Post Market (Post Pausa) + IDE N = 415 pazienti
Versamento Pericardico o perforazione (totale)	4,1% (6)	2,2% (2)	1,6% (5)	1,7% (7)
- Osservazioni[3]	0% (0)	1,1% (1)	0,3% (1)	0,5% (2)
- Complicazioni[4]	4,1% (6)	1,1% (1)	1,2% (4)	1,2% (5)
Sposizionamento	1,4% (2)	0,0% (0)	1,9% (6)	1,4% (6)
Cattura Intermittente o Mancata Cattura o Soglia Elevata	0,0% (0)	1,1% (1)	1,2% (4)	1,2% (5)
Rilascio accidentale del dispositivo durante l'impianto con conseguente recupero e impianto di pacemaker convenzionale	0,7% (1)	0,0% (0)	0,0% (0)	0,0% (0)
Sanguinamento del Sito di Accesso o Ematoma	0,7% (1)	0,0% (0)	1,2% (4)[1]	1,0% (4)
Embolia Polmonare	0,0% (0)	0,0% (0)	0,3% (1)[2]	0,2% (1)
Infezione	0,0% (0)	0,0% (0)	0,0% (0)	0,0% (0)

[1] Due di questi eventi erano osservazioni.
[2] Questo evento era una osservazione.
[3] Le osservazioni sono definite come SADE che non richiedono interventi invasivi.
[4] Le complicazioni sono definite come SADE che richiedono interventi invasivi (comprende anche l'abbandono della procedura e l'impianto di un pacemaker convenzionale).

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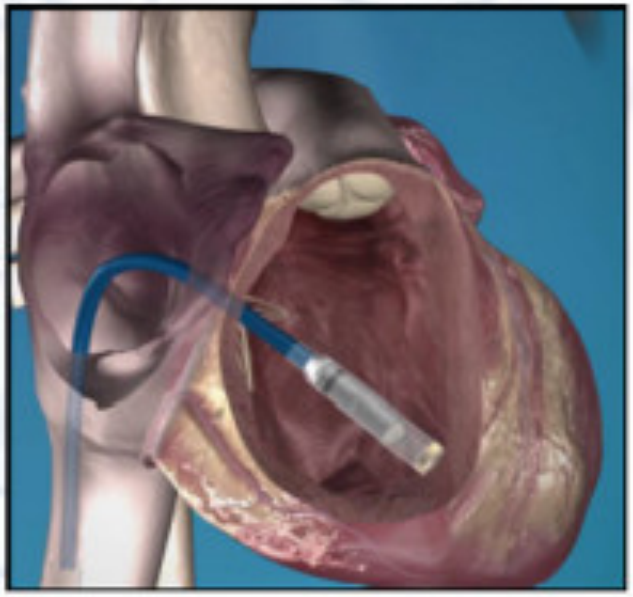
Micra tm Transcatheter Pacing System (TPS) By Medtronic

- 25.9mm, < 1cc miniaturized PM
- 10 years longevity
- Percutaneous access to RV apex via femoral vein
- Active fixation via 4 self-expanding tines



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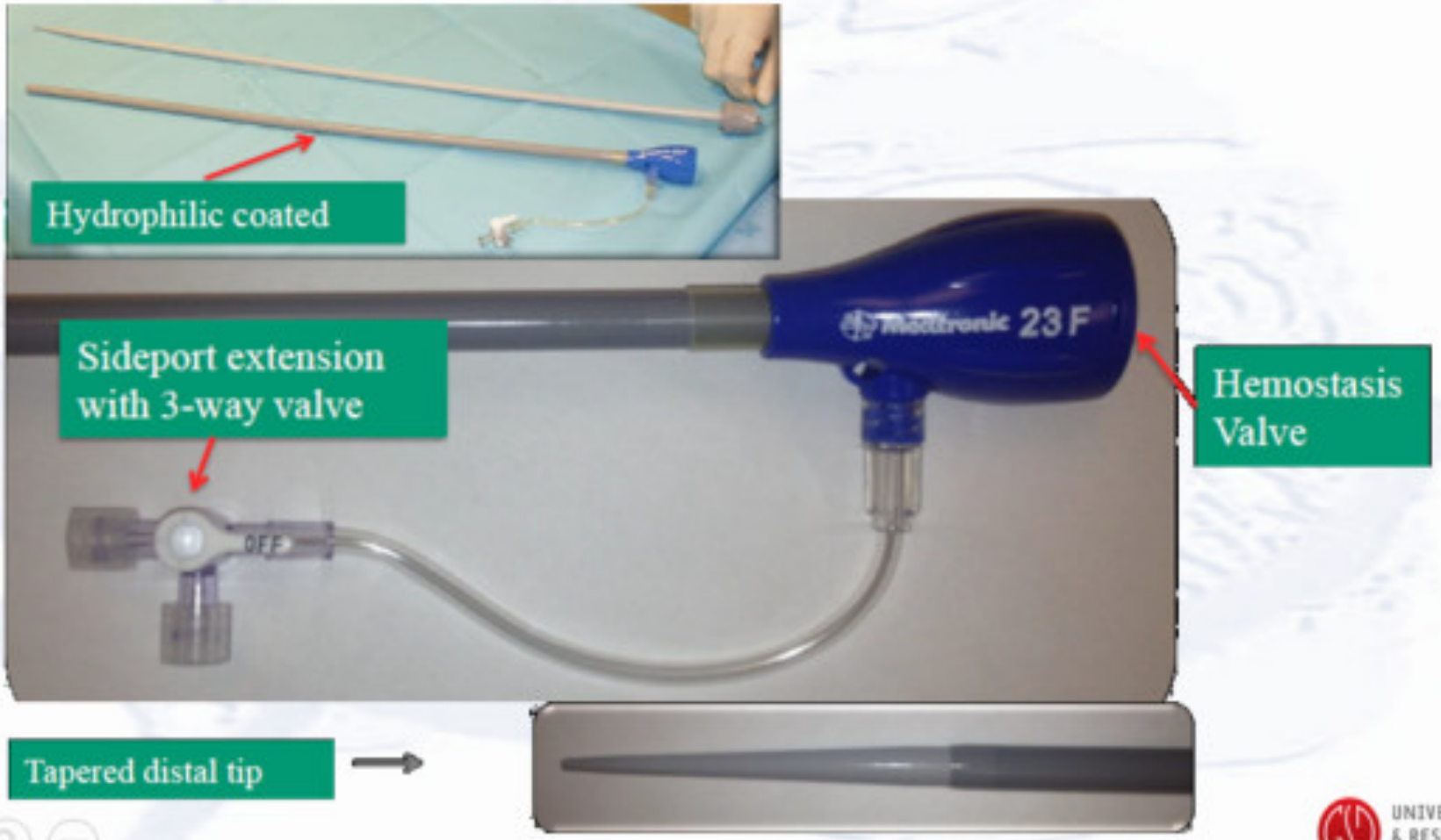
Micra Delivery System



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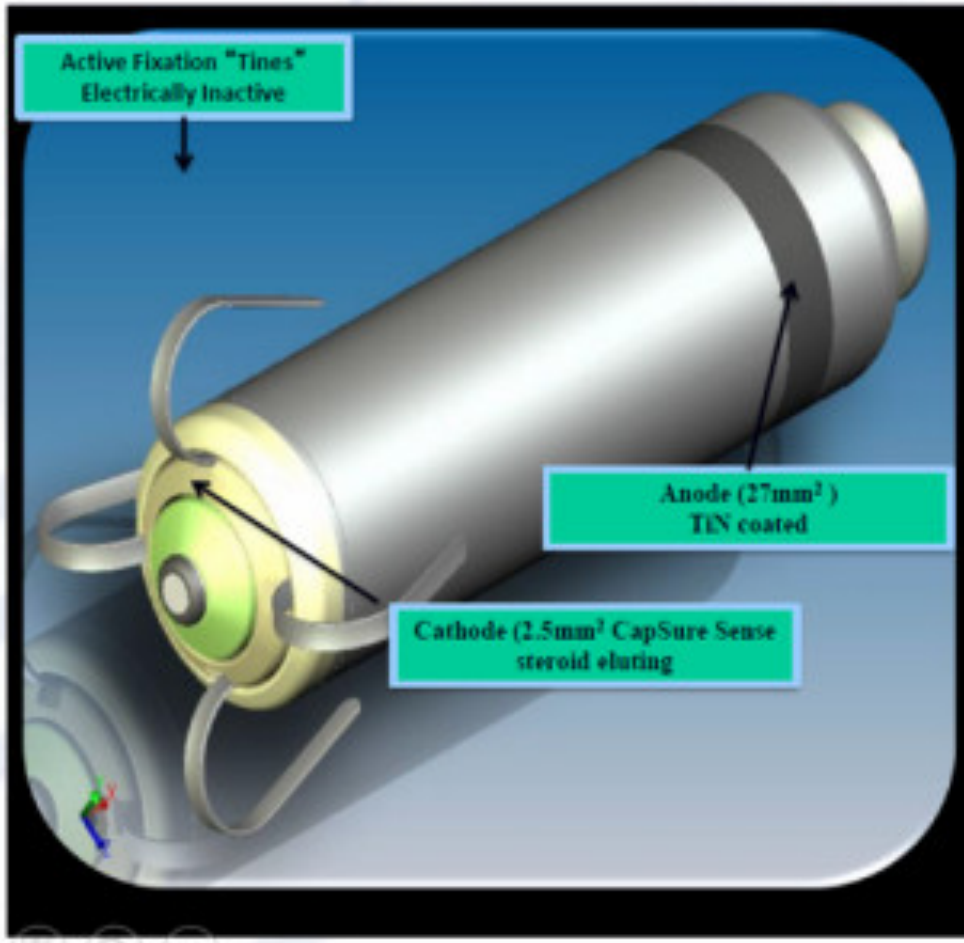
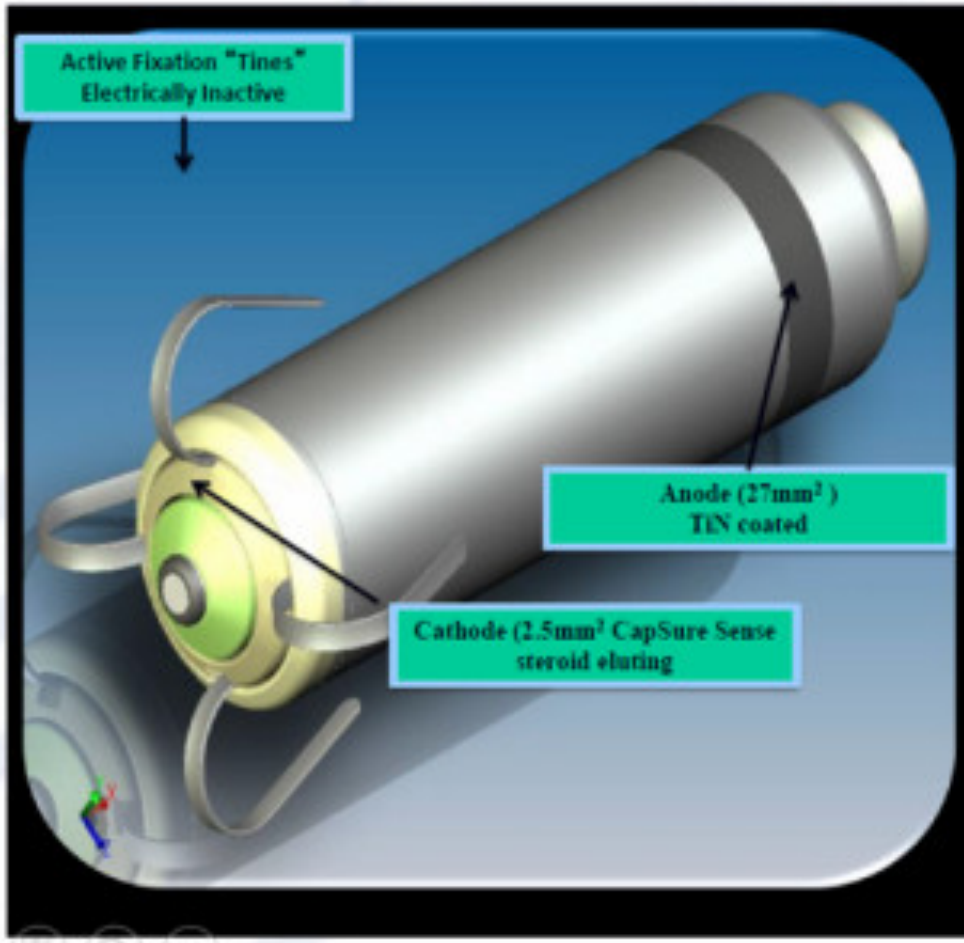
Micra Device



- Pacing Mode: VVIR
- Volume: 0.75cc
- Mass: 2g
- Length: 24mm
- Width: 20Fr
- Bipolar sensing (17mm spacing)

- Programmable
- Capture Management
- Rate Response
- Essential Diagnostics: battery status, pacing threshold, pacing impedance, % paced, longevity estimator
- Standard communication with 2090 programmer
- Device will be deactivated at EOL

Micra Device



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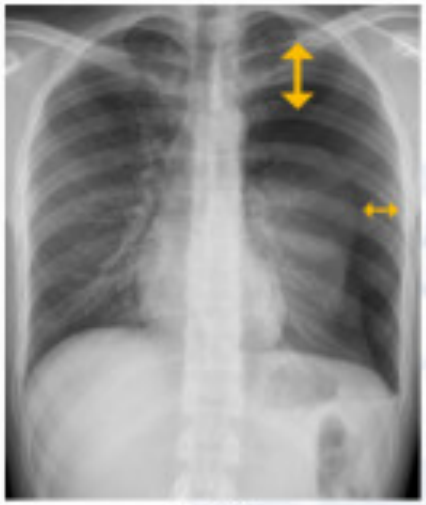
From st. Jude Medical

Complications related to conventional PM implantation

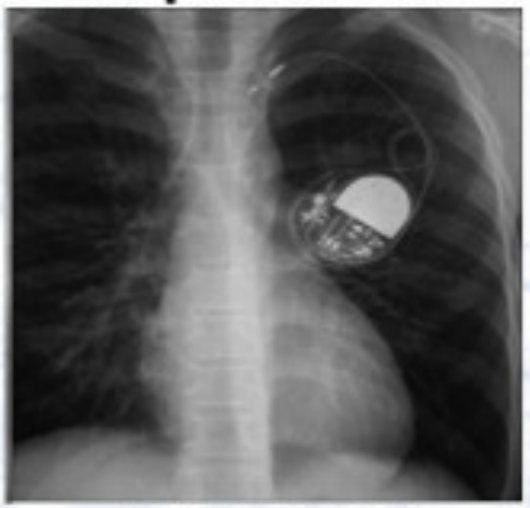
Complications	Incidence
Catheter displacement	2.2% - 3.7%
Pneumothorax	1.6% - 2.6%
Perforations	< 1%
Venous thrombosis	1%-3%
Pacing/sensing failure	2%-4% (5 y. FUP)
Pocket Hematoma	<0.5%
Pocket Erosion (device replacement)	0.8-0.9%[2]
Infections	< 1% for VVI 1% - 2% for DDD

Conventional PM Complications



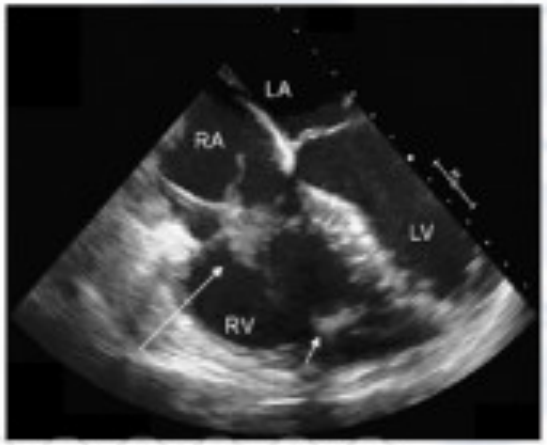
PNX

Lead perforation

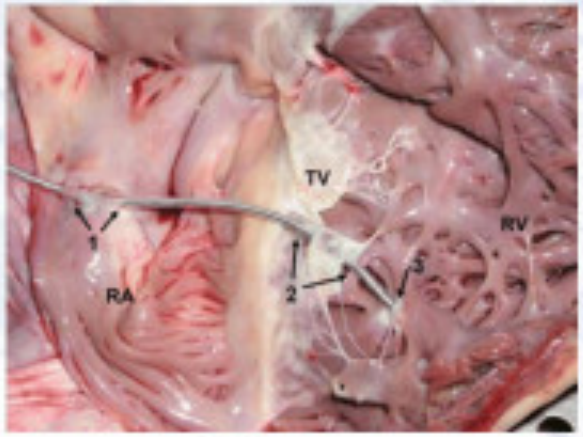


Lead dislodgement

Pocket infections



Endocarditis



TV damage

Haematoma

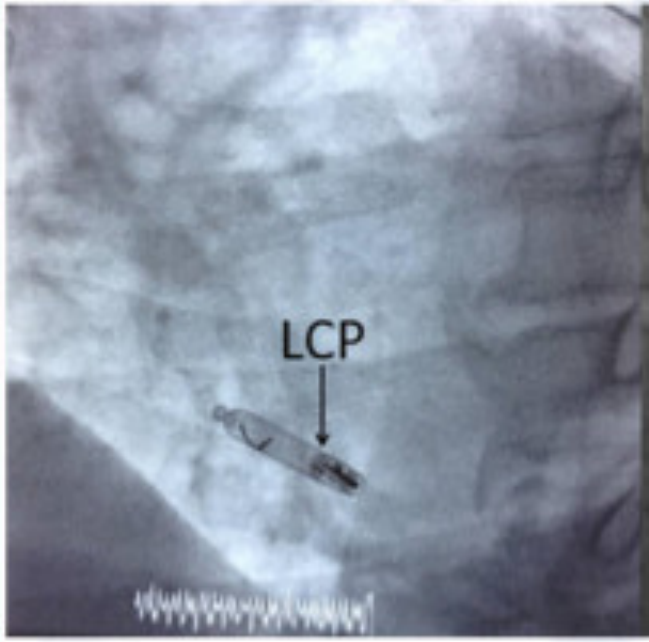
LCP Vs traditional PM

From st. Jude Medical

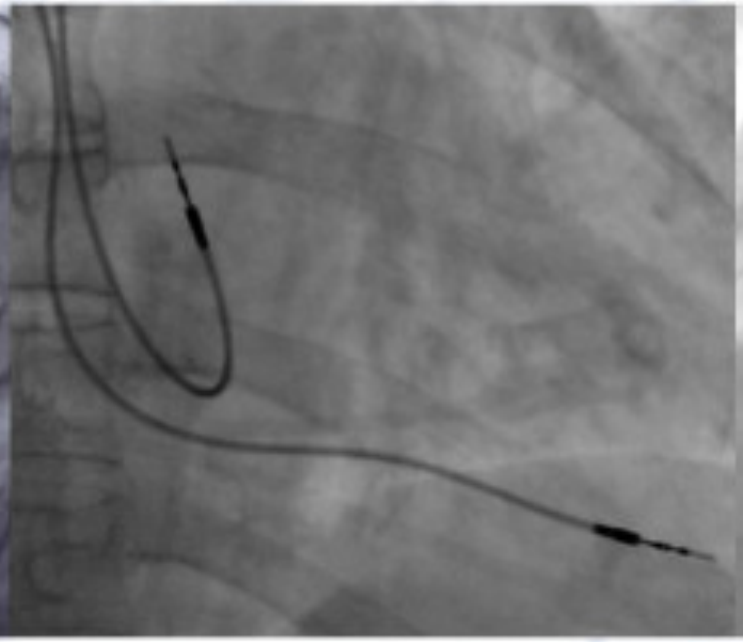
Characteristics	Conventional Pacemaker	Leadless PM
Implant Procedure	Surgical pocket + catheter (7F)	Percutaneous femoral access (18F)
Procedure Time	30 – 40 minutes	15 – 20 minutes
X-Ray exposure	For the physicians: Next to x-ray source	For the physicians: Faraway from x-ray source
Connection	Case-Catheter connection	None
Device inside Vascular System	yes: catheter	No (leadless)
Device crossing tricuspid valve	Yes: catheter	No (leadless)
Longevity (2.5V, 500 Ω, 60 bpm)	100% pacing – 11.2 years 75% pacing – 11.8 years 50% pacing – 12.5 years 25% pacing – 13.3 years	100% pacing – 9.8 years 75% pacing – 11.7 years 50% pacing – 14.5 years 25% pacing – 18.9 years
Battery Replacement	Surgical	Femoral access: removal + reimplant (possibility to implante a new one next to old one)
Compatibilità MRI	Conditional – artefatti di imaging	MRI certification ongoing

Look at the difference:

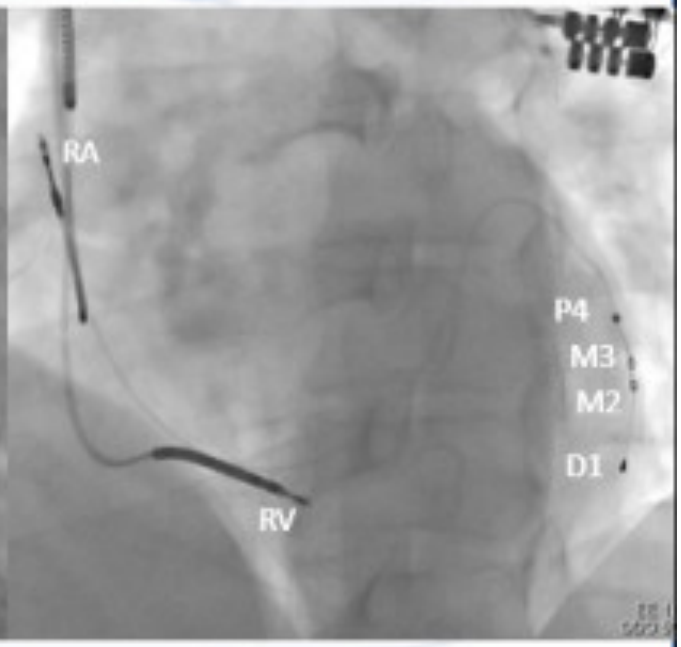
Leadless pacemaker



DDD conventional pacemaker



Conventional CRT-D



So why we prefer Iphone 6……

Remind that LCP.....

It is only a single chamber...

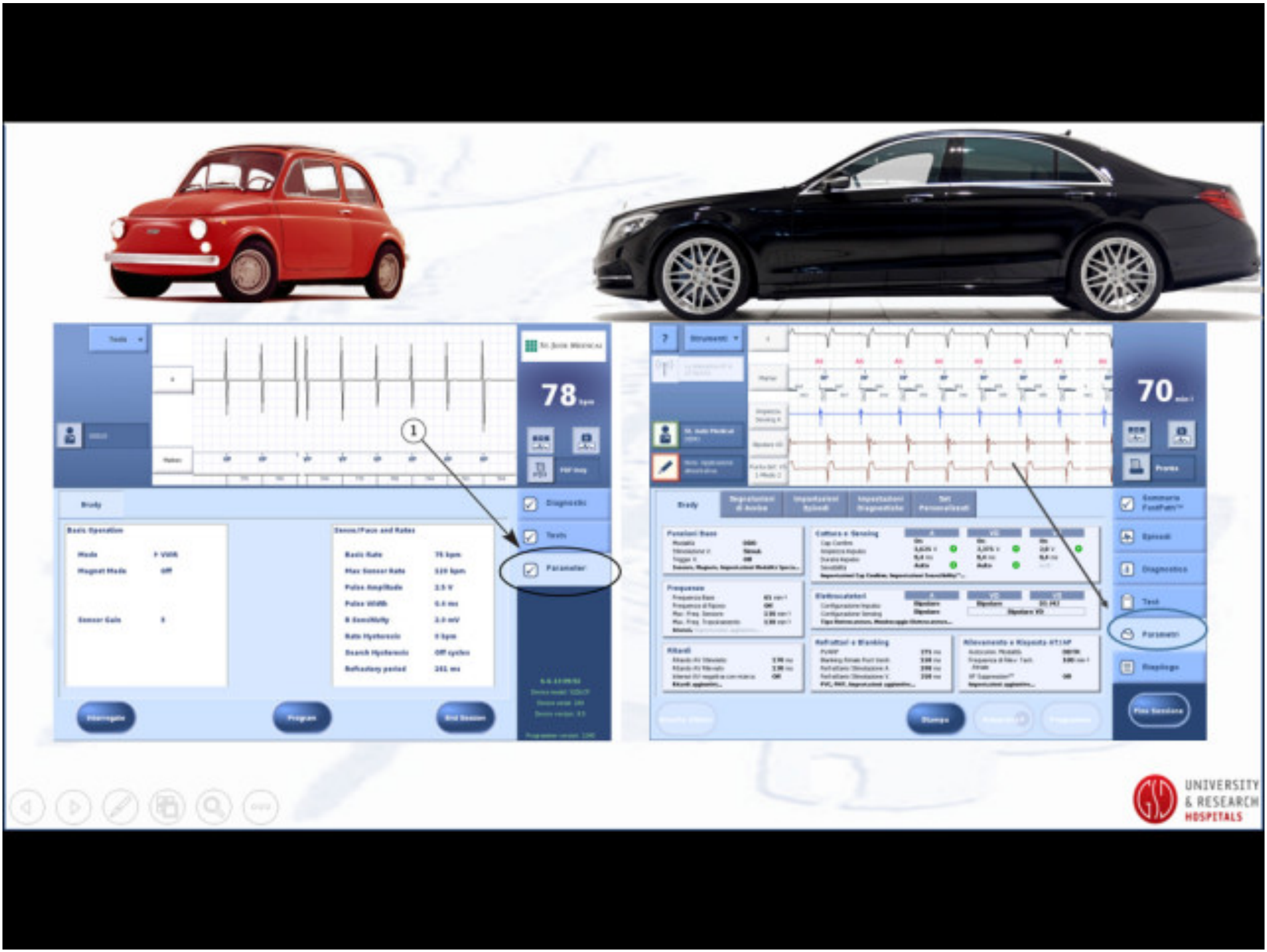
Tabella 31. Distribuzione degli impianti in base al tipo di generatore. Dati mancanti: primi impianti 23, sostituzioni 19.

	Primi impianti (n=9138)		Sostituzioni (n=4709)		Combinati (n=13 847)	
Monocamerale	2688	29.4%	598	12.7%	3286	23.7%
Bicamerale	3440	37.6%	1121	23.8%	4561	32.9%
Biventricolare	3010	32.9%	2990	63.5%	6000	43.3%

Remind that LCP……

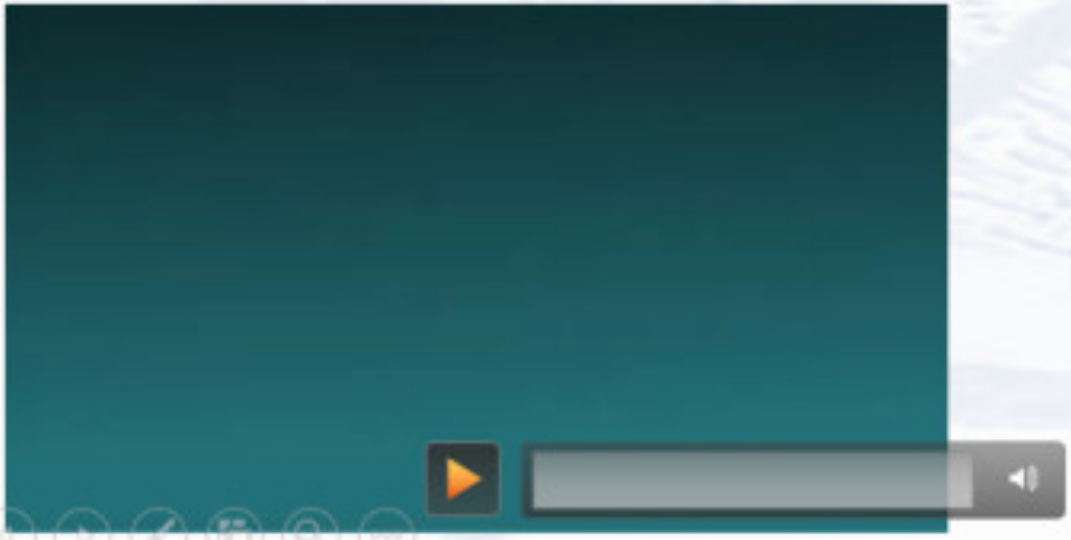
Remind that LCP……

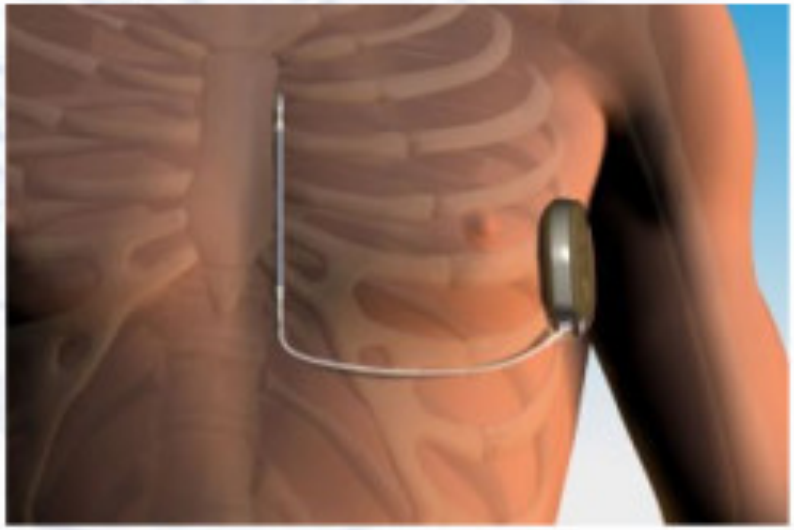
- It has only a thermal sensor
- It cannot record arrhythmic episodes
- It has not home monitoring
- It has not autocapture or autosensing
- It has not antitachicardia pacing
- It has not advanced pacing SW


78
1
Brady
Diagnostics
Tests
Parameter
Basic Operation
Mode
Magnet Mode
Sensor Gain
Sensor/Pace and Rates
Basic Rate
Max Sensor Rate
Pulse Amplitude
Pulse Width
R Sensitivity
Rate Hysteresis
Search Hysteresis
Refractory period
Interrogate
Program
End Session
70
Brady
Stampa
Parameter
Display
Fine Sessione
UNIVERSITY
& RESEARCH
HOSPITALS

And what about totally subcutaneous ICD ?

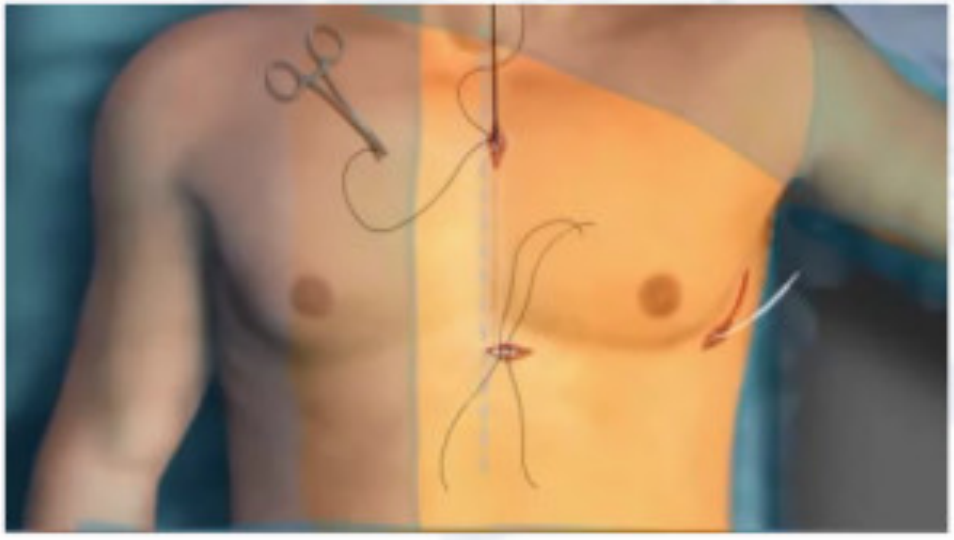
Cameron Health

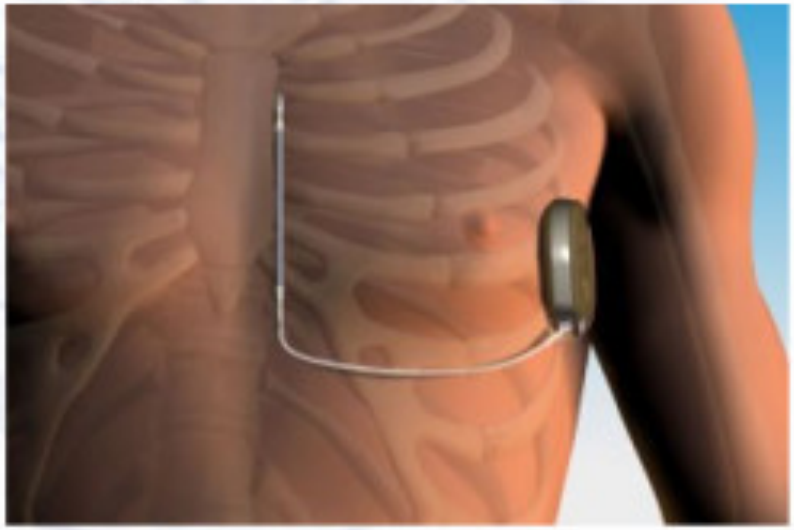




And what about totally subcutaneous ICD ?

Cameron Health





SUBCUTANEOUS ICD vs TV- ICD

ADVANTAGE

- *Extravascular*

EQUIVALENT

- *Pocket infection*
- *Generator complications*
- *Inappropriate shock*

DISADVANTAGE

- *No pacing capabilities*
- *No advanced diagnostic*
- *Time to Defibrillation*

European Heart Journal (2014) 35, 1657–1665
doi:10.1093/eurheartj/ehu112

CLINICAL RESEARCH
Arrhythmia/electrophysiology

Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry

Pier D. Lambiase[1]*, Craig Barr[2], Dominic A.M.J. Theuns[3], Reinoud Knops[4], Petr Neuzil[5], Jens Brock Johansen[6], Margaret Hood[7], Susanne Pedersen[8,9], Stefan Kääb[10], Francis Murgatroyd[11], Helen L. Reeve[12], Nathan Carter[12], and Lucas Boersma[13], on behalf of the EFFORTLESS Investigators

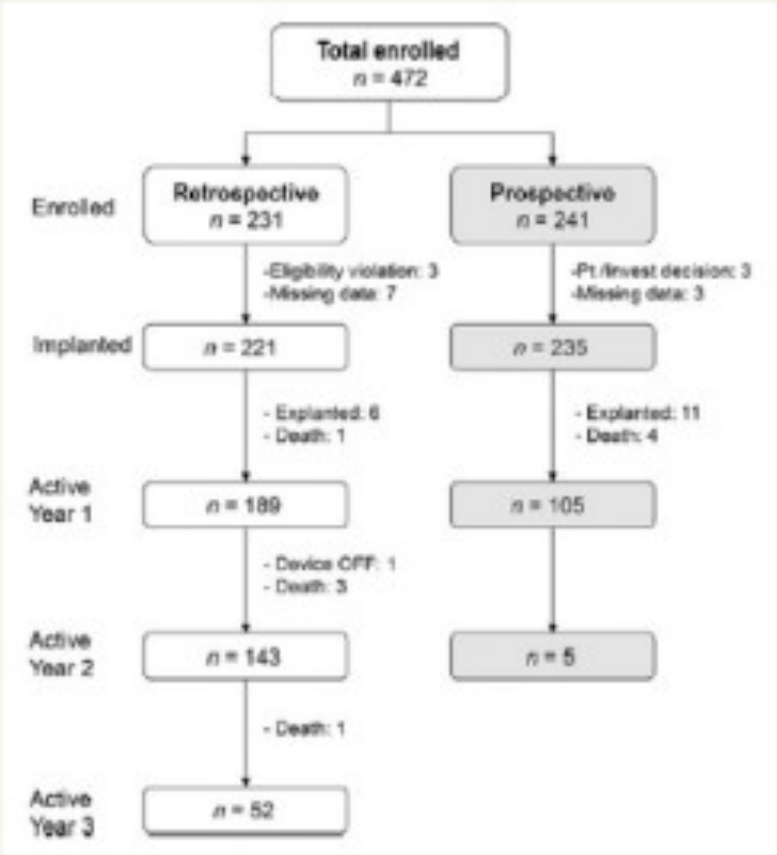
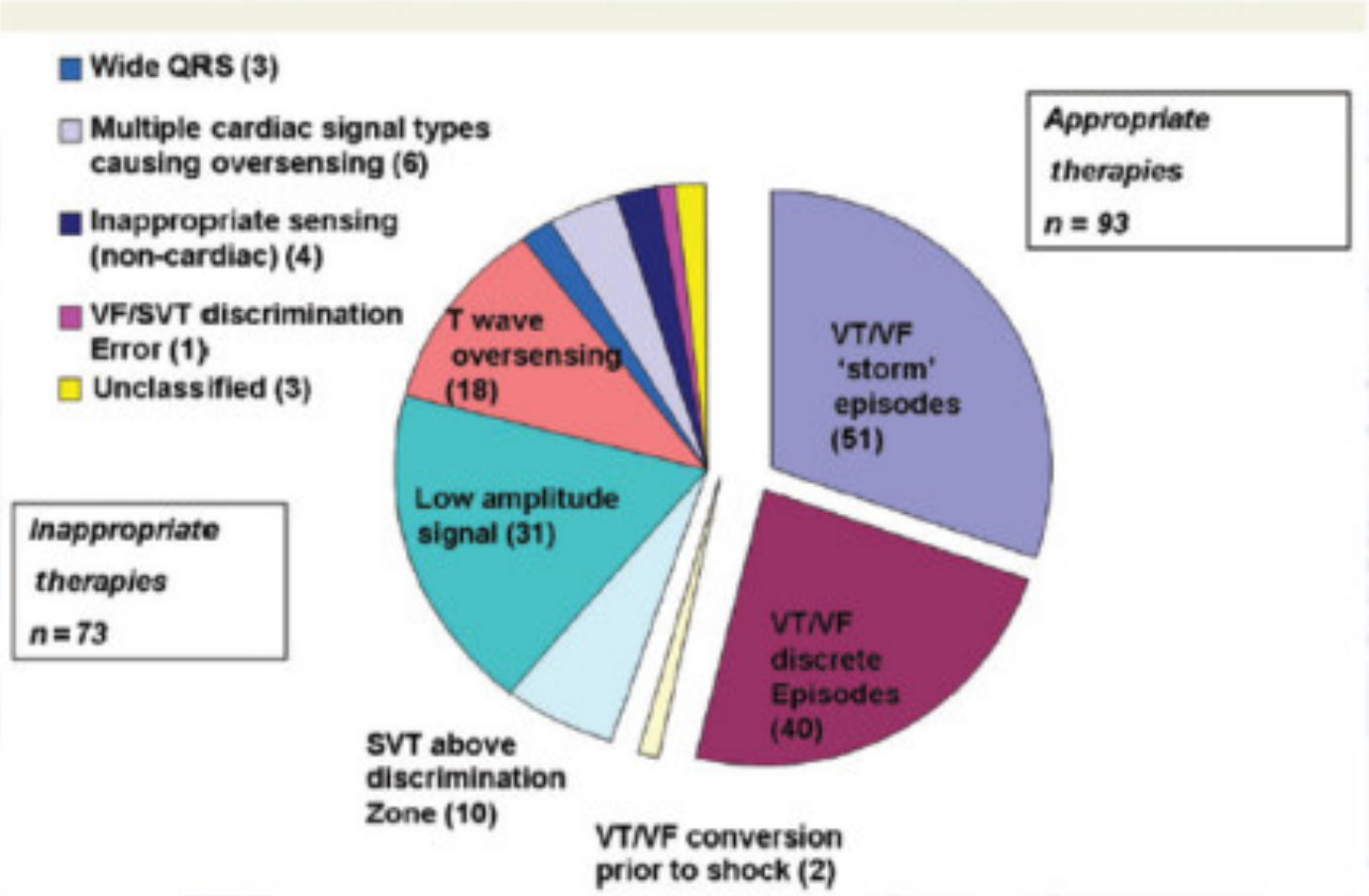


Figure 2 Patient flow chart for EFFORTLESS Subcutaneous Implantable Defibrillator Registry.

Table 2 Spontaneous episodes recorded and classified by the subcutaneous implantable defibrillator system

S-ICD system performance	Number of episodes	Number of patients (% of 456)
Therapy delivered	169	59 (13)
Appropriate therapy	93	33 (7.2)
VT/VF discrete episodes	51	29
VT/VF 'storm' episodes	40	4
VT/VF conversion prior to shock	2	2
Inappropriate therapy[a]	73	32 (7.0)
SVT above discrimination zone	10	6
Inappropriate sensing (cardiac)[b]	58	24
Inappropriate sensing (non-cardiac)	4	4
VF/SVT discrimination error	1	1
Rhythm unclassified[c]	3	1
Therapy withheld[d]	145	61 (13)
Episode unclassified[e]	3	3
Total	317	85 (19)

EFFORTLESS STUDY: Appropriate and inappropriate therapies distribution



EFFORTLESS STUDY: Procedure-related complications

Complication	Number of events	Patients *n* (%)
Erosion or extrusion of implanted electrode or pulse generator	4	4 (0.9)
Haematoma	1	1 (0.2)
Failure to convert spontaneous VF episode	1	1 (0.2)
Inability to communicate with device	1	1 (0.2)
Inappropriate shock: oversensing	2	2 (0.4)
Incision/superficial infection	2	2 (0.4)
Near syncope/dizziness/shortness of breath/confusion	1	1 (0.2)
Pleural effusion	1	1 (0.2)
Pneumothorax	1	1 (0.2)
Premature battery depletion	1	1 (0.2)
Shock delivered for non-VT/VF	1	1 (0.2)
System infection	12	11 (2.4)
Suboptimal electrode position/electrode movement	5	5 (1.1)
Suboptimal pulse generator position	1	1 (0.2)
Suture discomfort	1	1 (0.2)
Total complications (% of 456)	35	29 (6.4)

STATE-OF-THE-ART PAPER

Implantation-Related Complications of Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy Devices

A Systematic Review of Randomized Clinical Trials

Johannes B. van Rees, MD, Mihály K. de Bie, MD, Joep Thijssen, MD,
C. Jan Willem Borleffs, MD, PhD, Martin J. Schalij, MD, PhD, Lieselot van Erven, MD, PhD
Leiden, the Netherlands

Table 3 Pneumothorax Related to Implantation of Nonthoracotomy Devices

Trial	Year	Patients Undergoing Implantation, n	Events, n (%)
Nonthoracotomy ICD systems			
AVID	1997	539	6 (1.1)
DEFINITE	2004	227	2 (0.9)
MADIT-CRT (ICD arm)	2009	731	6 (0.8)
Total		1,497	14 (0.9)
Nonthoracotomy CRT systems			
MIRACLE	2002	568	1 (0.2)
MIRACLE ICD	2003	421	3 (0.7)
CARE-HF	2005	404	2 (0.5)
RethinQ	2007	176	2 (1.1)
REVERSE	2008	642	4 (0.6)
MADIT-CRT (CRT arm)	2009	1,089	18 (1.7)
Total		3,300	30 (0.9)

Data not reported in the CAT, MADIT II, DINAMIT, SCD-HeFT, IRIS, CIDS, and COMPANION studies. Abbreviations as in Table 1.

Table 5 Implant Site Hematoma or Bleeding

Trial	Year	Successful Implants, n	All Events, n (%)	Duration, months
Thoracotomy and nonthoracotomy ICD systems				
MADIT*	1996	94	1 (1.1)	27
CABG Patch†	1997	434	22 (4.9)	0.5†
CASH‡	2000	94	6 (6.1)	57 ± 34
Total		622	29 (4.7)	
Nonthoracotomy ICD systems				
AVID‡	1997	539	8 (1.5)	27 ± 13
CAT‡	2002	50	2 (4.0)	25
MADIT-CRT (ICD arm)‡	2009	712	18 (2.5)	29
Total		1,301	28 (2.2)	
Nonthoracotomy CRT systems				
RethinQ‡	2007	172	2 (1.2)	6
REVERSE‡	2008	621	5 (0.8)	12
MADIT-CRT (CRT arm)‡	2009	1,007	36 (3.3)	29
Total		1,800	43 (2.4)	

Data not reported in the MADIT-II, DINAMIT, DEFINITE, SCD-HeFT, IRIS, CIDS, MIRACLE, COMPANION, MIRACLE ICD, and CARE-HF studies. *No time frame indicated. †Complications occurred within 30 days following implantation. ‡Complications occurred during follow-up.
Abbreviations as in Table 1.

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Implantation-Related Complications of Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy Devices

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REVERSE	2008	642	4 (0.6)
MADIT-CRT (CRT arm)	2009	1,089	18 (1.7)
Total		3,300	30 (0.9)

Data not reported in the CAT, MADIT II, DINAMIT, SCD-HeFT, IRIS, CIDS, and COMPANION studies. Abbreviations as in Table 1.

Table 6 Lead Dislodgement During Follow-Up in Nonthoracotomy Requiring Implanted Devices

Trial	Year	Successful Implants, n	All Events, n (%)	Duration, months
Nonthoracotomy ICD systems				
AVID*	1997	593	8 (1.5)	27 ± 13
CAT†	2002	50	2 (4.0)	0.5†
DEFINITE*	2004	227	6 (2.6)‡	29 ± 14
Total		870	16 (1.8)	
Nonthoracotomy CRT systems				
MIRACLE*	2002	526	31 (5.9)	6
MIRACLE ICD§	2003	379	11 (2.9)	6
CARE-HF†	2005	390	11 (2.8)	0.5†
RethinQ‖	2007	172	13 (7.6)¶	6
REVERSE‖	2008	621	66 (10.6)	12
MADIT-CRT (CRT arm)†	2009	1,007	44 (4.4)#	0.5†
Total		3,095	176 (5.7)	

Data not reported in the MADIT, CABG-Patch, MADIT II, DINAMIT, SCD-HeFT, MADIT-CRT (ICD-treated arm), IRIS, and COMPANION studies. *Complications occurred during follow-up. †Complications occurred within 30 days following implantation. ‡Also included lead fracture. §Complications occurred during hospitalization. ‖No time frame indicated. ¶Five cases (2.9%) involved the left lead. #Included left ventricular lead only.
Abbreviations as in Table 1.

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Leiden, the Netherlands

Table 4 Complications Related to Coronary Sinus in Recipients of a Nonthoracotomy CRT Device With or Without Defibrillator

Trial	Year	Patients Undergoing Implantation	Coronary Vein Dissection, Perforation or Tamponade	Coronary Vein Dissection	Coronary Vein Perforation	Coronary Vein Tamponade*
MIRACLE†	2002	568	35 (6.2)	23 (4.0)	12 (2.0)	NR
MIRACLE ICD‡	2003	421	19 (4.5)	15 (3.6)	4 (1.0)	NR
COMPANION†	2004	1,212	22 (1.8)	5 (0.4)	12 (1.0)	5 (0.4)
CARE-HF†	2005	404	6 (1.5)	5 (1.2)	NR	2 (0.5)
RethinQ§	2007	176	1 (0.6)	1 (0.6)	NR	NR
REVERSE†	2008	642	3 (0.5)	3 (0.5)	NR	NR
MADIT-CRT (CRT arm)†	2009	1,089	5 (0.5)	5 (0.5)	NR	NR
Total		4,512	91 (2.0)	57 (1.3)	28 (1.3)	7 (0.4)

Values are n or n (%). *Also included pericardial effusion. †Complications occurred during the procedure. ‡Complications occurred during hospitalization. §No time frame indicated.
Abbreviations as in Table 1.

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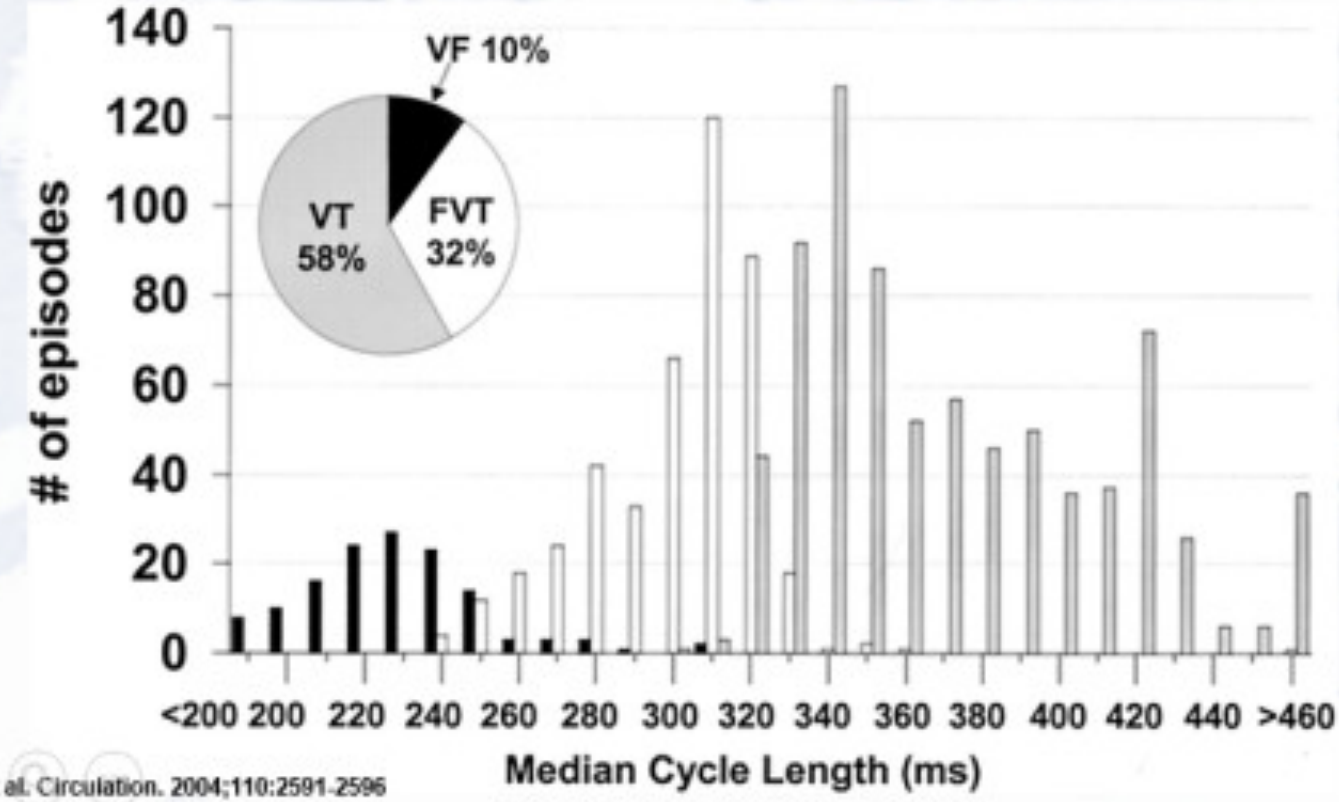
COMPANION†	2004	1,212	22 (1.8)	5 (0.4)	12 (1.0)	5 (0.4)
CARE-HF†	2005	404	6 (1.5)	5 (1.2)	NR	2 (0.5)
RethinQ§	2007	176	1 (0.6)	1 (0.6)	NR	NR
REVERSE†	2008	642	3 (0.5)	3 (0.5)	NR	NR
MADIT-CRT (CRT arm)†	2009	1,089	5 (0.5)	5 (0.5)	NR	NR
Total		4,512	91 (2.0)	57 (1.3)	28 (1.3)	7 (0.4)

Values are n or n (%). *Also included pericardial effusion. †Complications occurred during the procedure. ‡Complications occurred during hospitalization. §No time frame indicated.
Abbreviations as in Table 1.

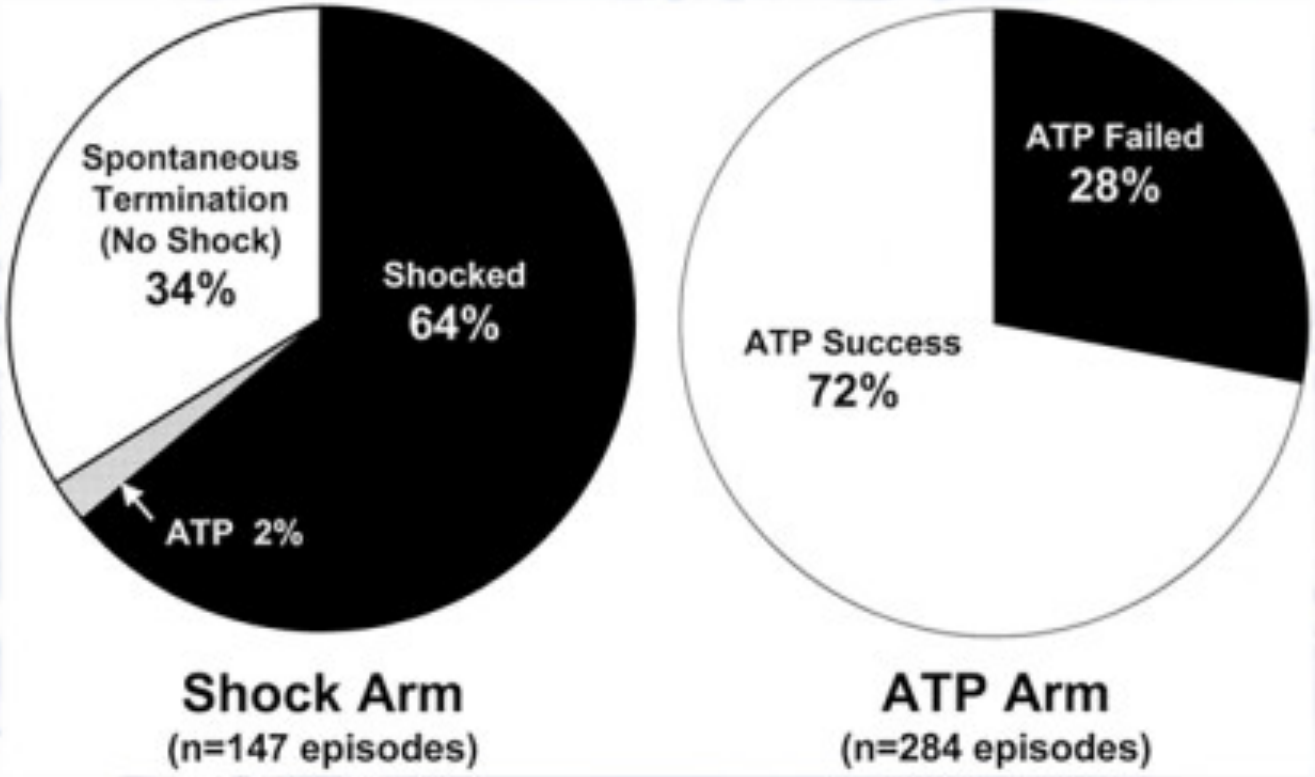
The lesson of PainFREE Rx II Trial :

Distribution of ventricular arrhythmias by detection zone and median CL. In conventional ICD programming, all episodes <320 ms (VF and FVT in pie chart) would be detected as VF and shocked without ever attempting ATP. Note that FVT episodes represent 76% of these rhythms.



Mark S. Wathen et al. Circulation. 2004;110:2591-2596

Terminating therapy for FVT episodes in each arm.



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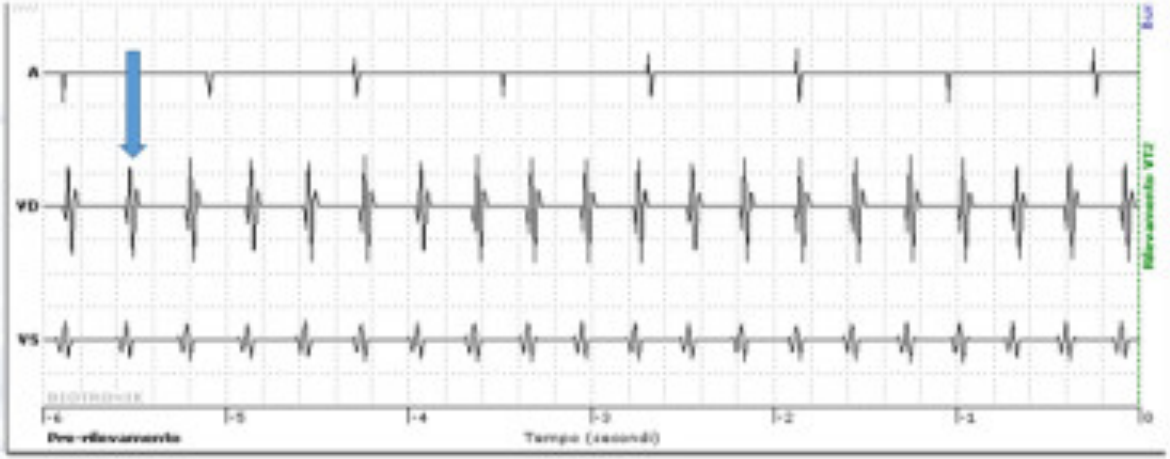

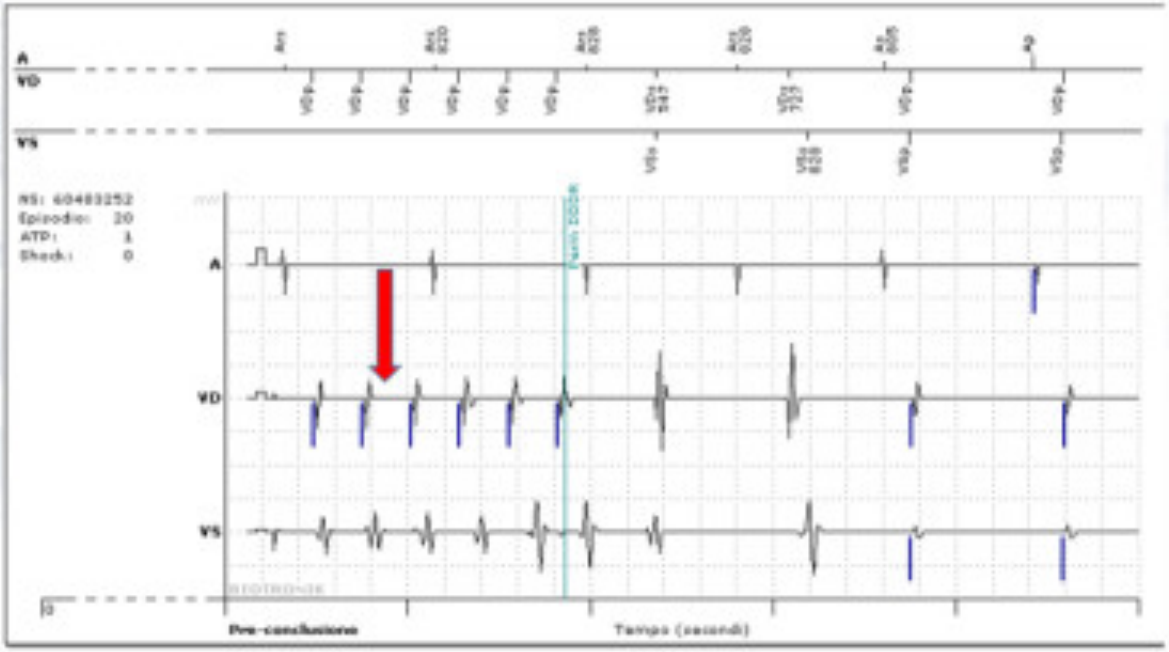

E.g.: FVT treated with ATP (EGM from Biotronik home monitoring)

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FVT interrupted by high voltage Shock by a Subcutaneous ICD

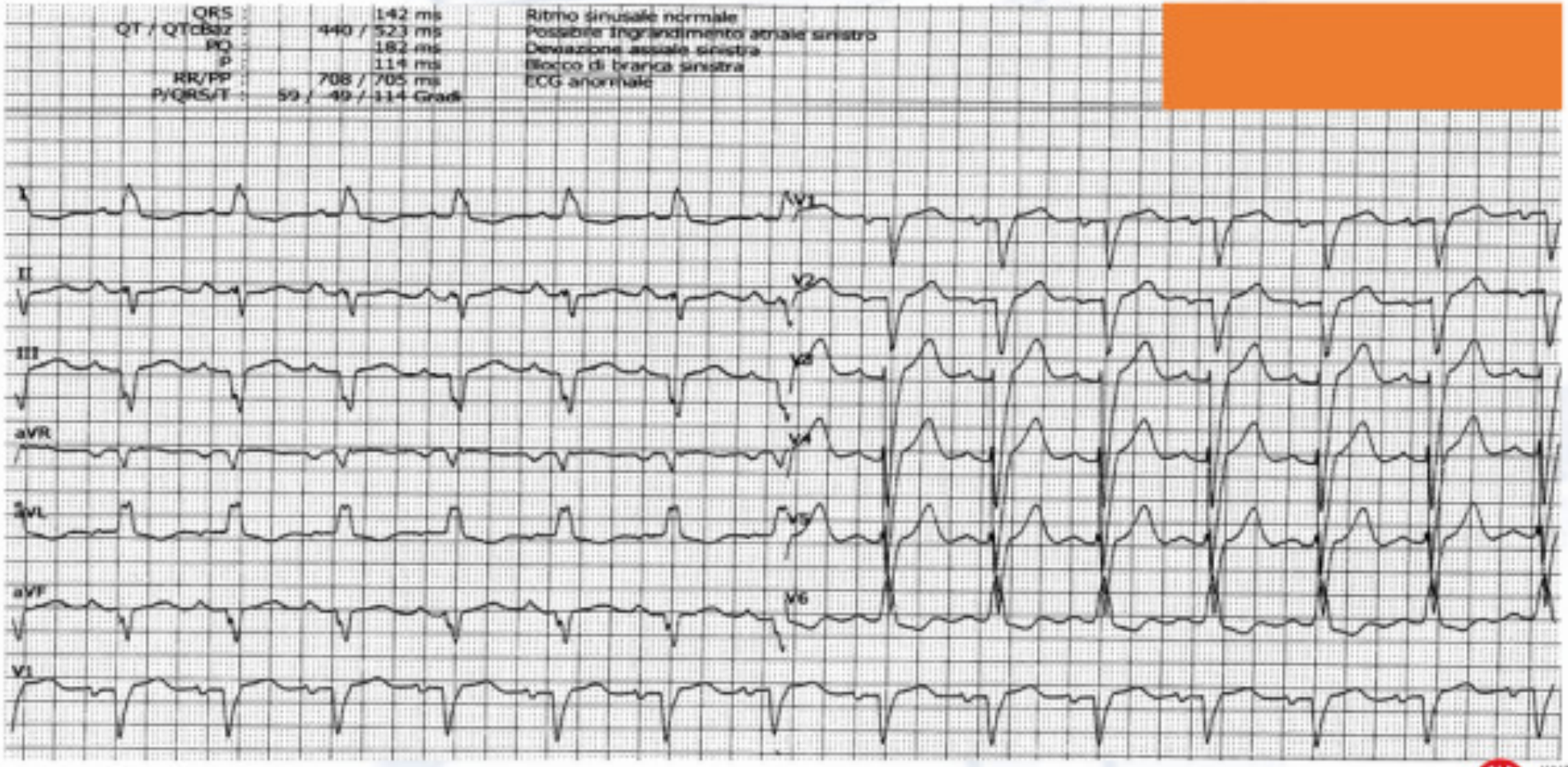
FVT interrupted by high voltage Shock by a Subcutaneous ICD

And don't forget that the most of patients that require an ICD.....

- **CRT resynchronization therapy is increasing**
- **Underlying pathologies often involves also conduction system**
- **The most of patients are under pharmacological therapy potentially affecting Conduction system (B-blockers, Ca-antagonist, AAD…)**

Require also Pacing.....

LEFT BUNDLE BRANCH BLOCK



Post-Myocarditis LBBB

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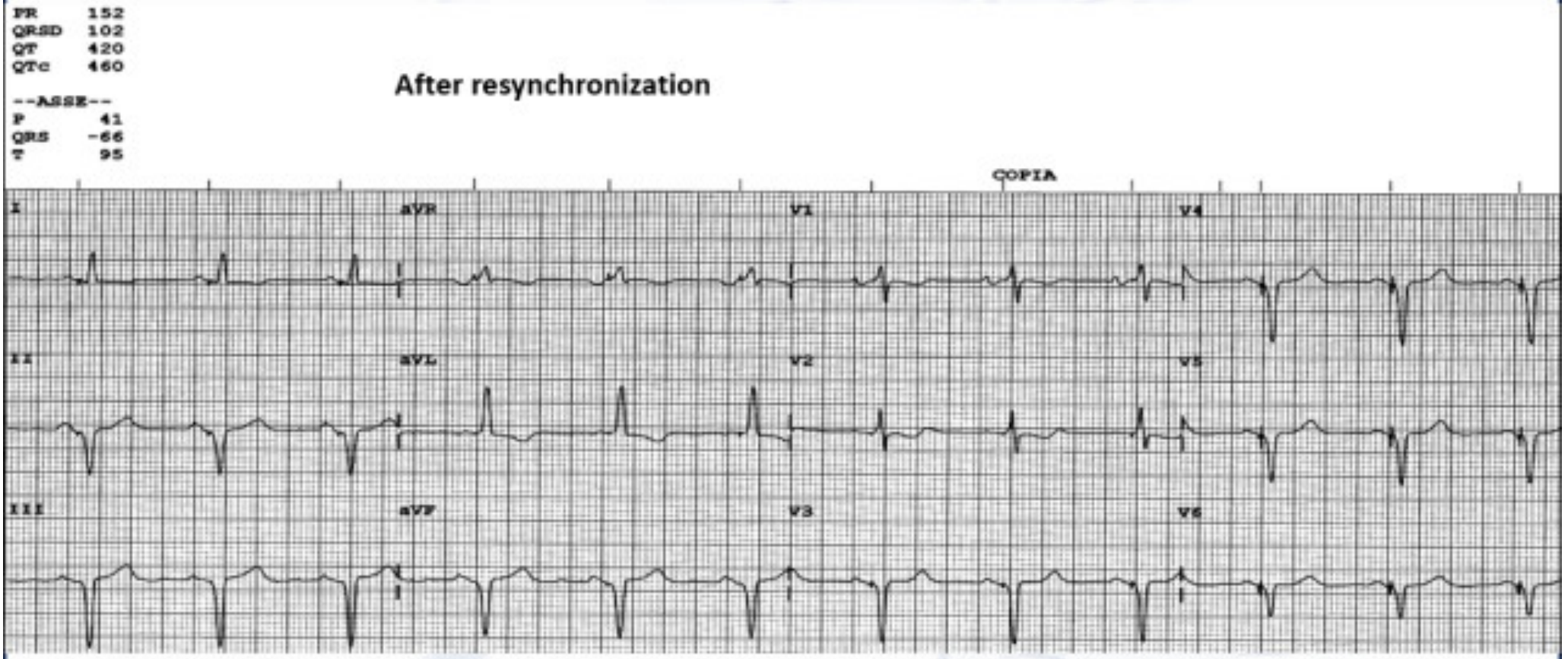
LEFT BUNDLE BRANCH BLOCK



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LEFT BUNDLE BRANCH BLOCK

Unify Quadra MP™ CRT-D

FR 152
QRSD 102
QT 420
QTc 460

--AXES--
P 41
QRS -66
T 95

After resynchronization

COPIA

I aVR V1 V4

II aVL V2 V5

III aVF V3 V6

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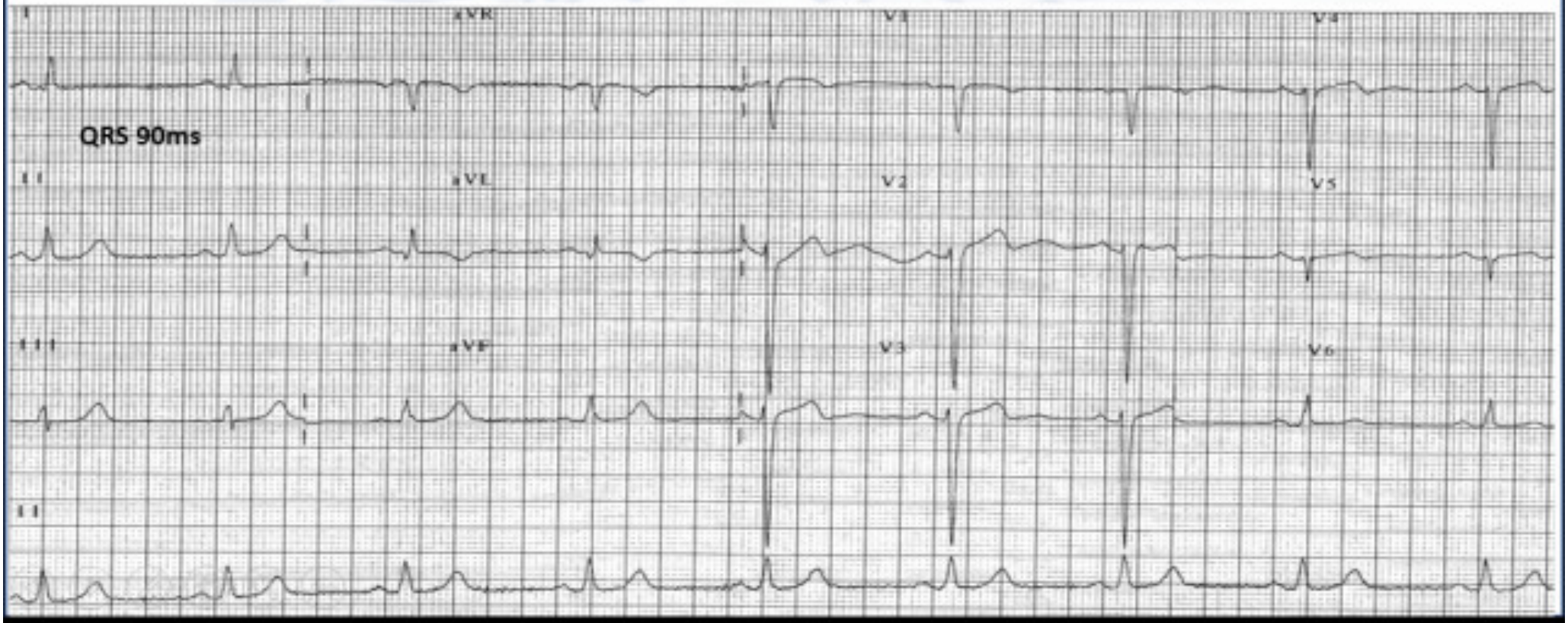
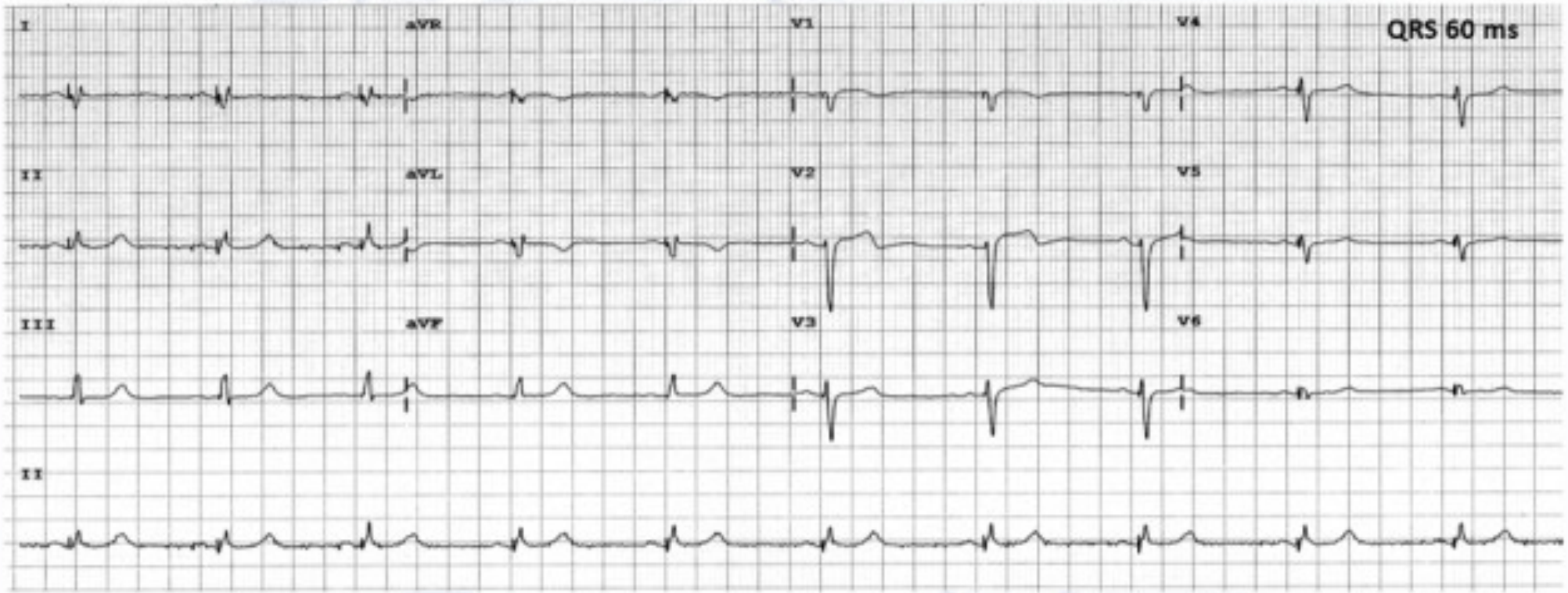
IS IT POSSIBLE TO MAKE FAST CONDUCTION EVEN FASTER?



IS IT POSSIBLE TO MAKE FAST CONDUCTION EVEN FASTER?

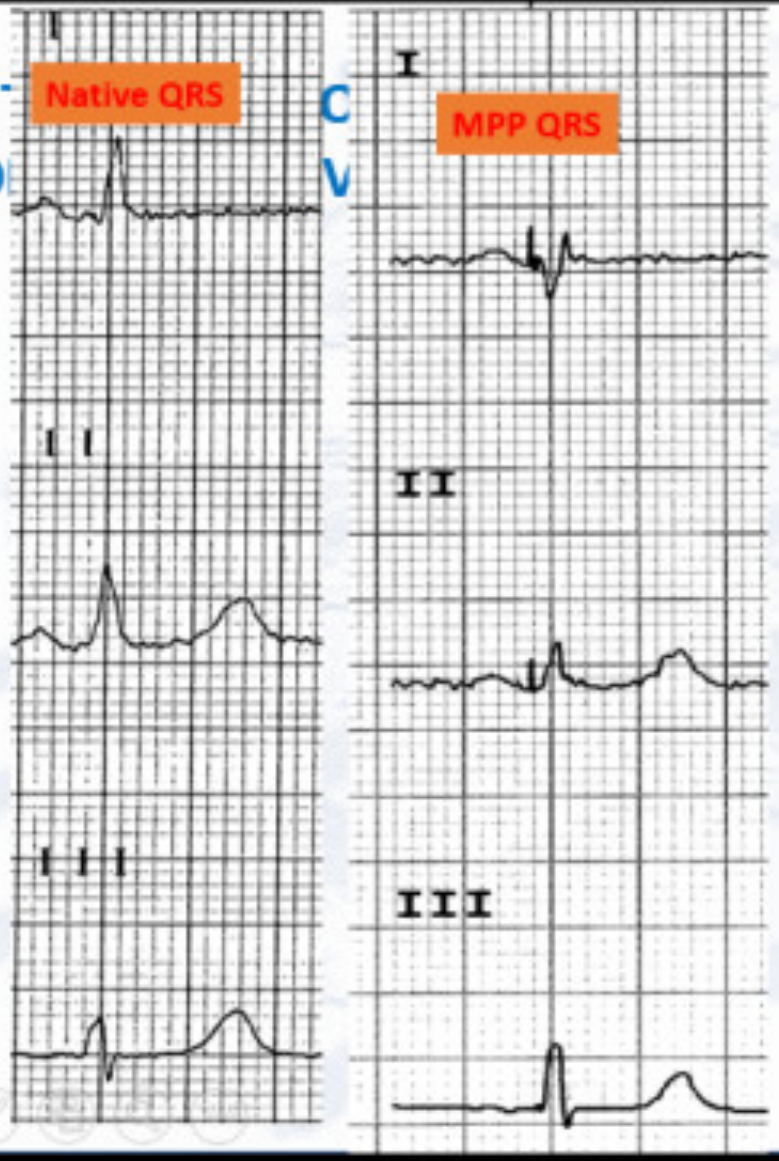


IS I

CO

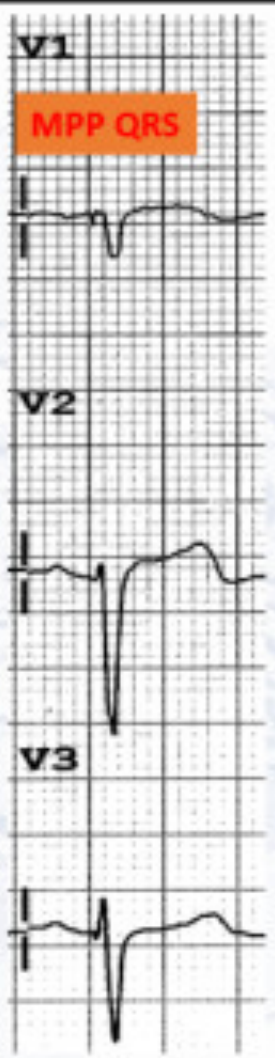
IS I

CO


Native QRS
I
II
III

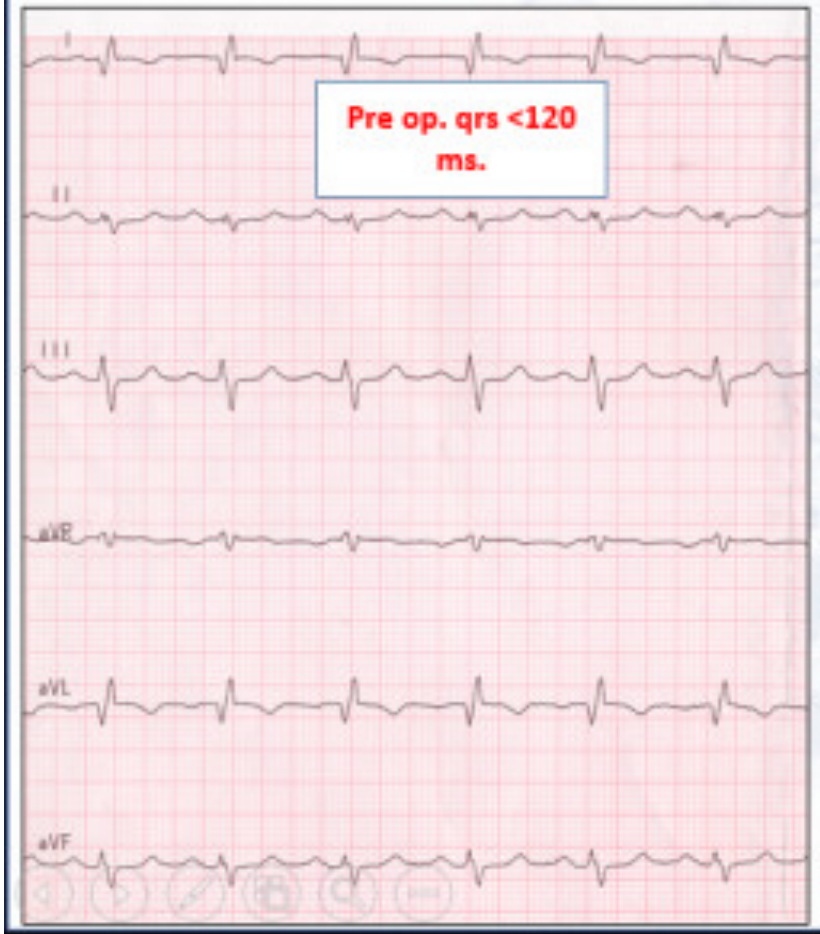
MPP QRS
I
II
III


Native QRS
V1
V2
V3

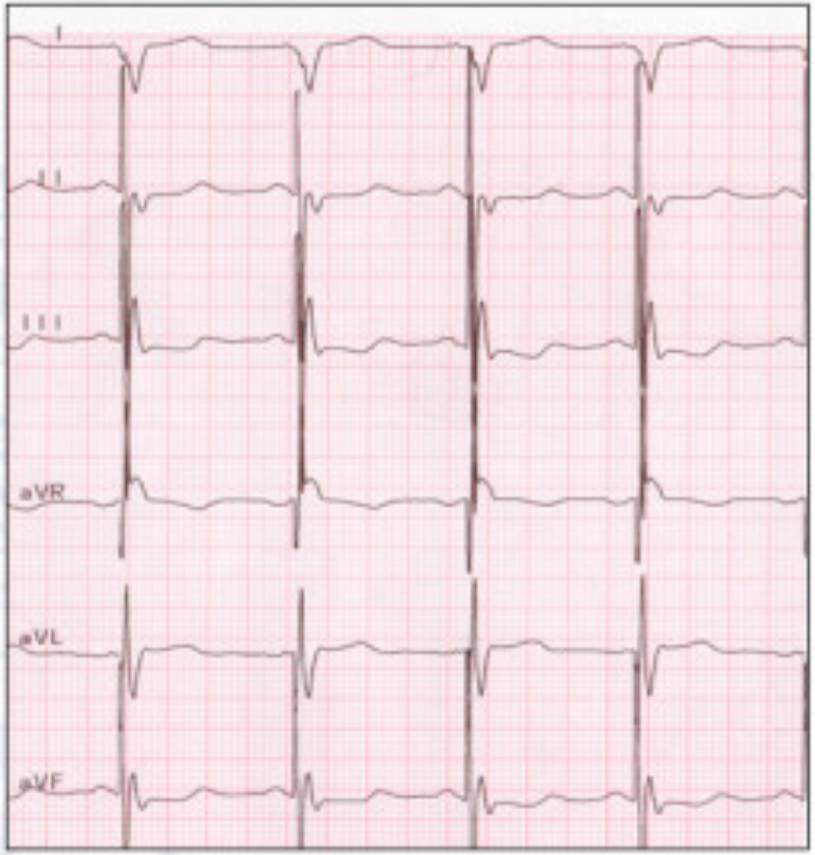

MPP QRS
V1
V2
V3

NARROW QRS

HOW TO PERFORM IT?

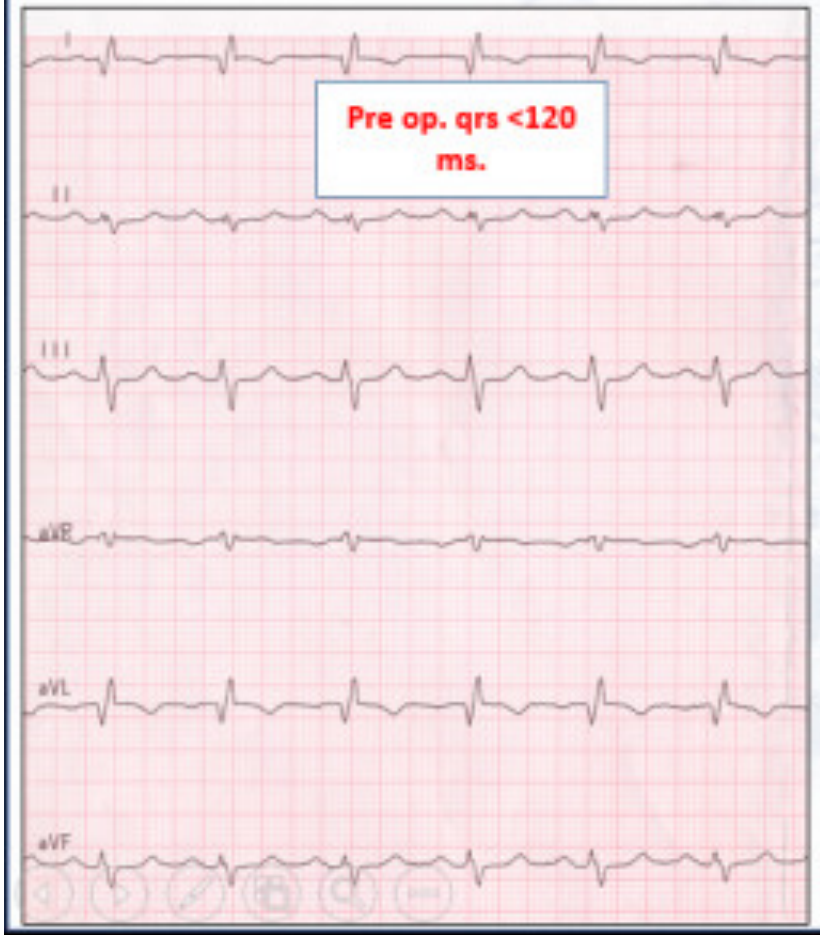


Conventional CRT worsen QRS duration in narrow QRS patients

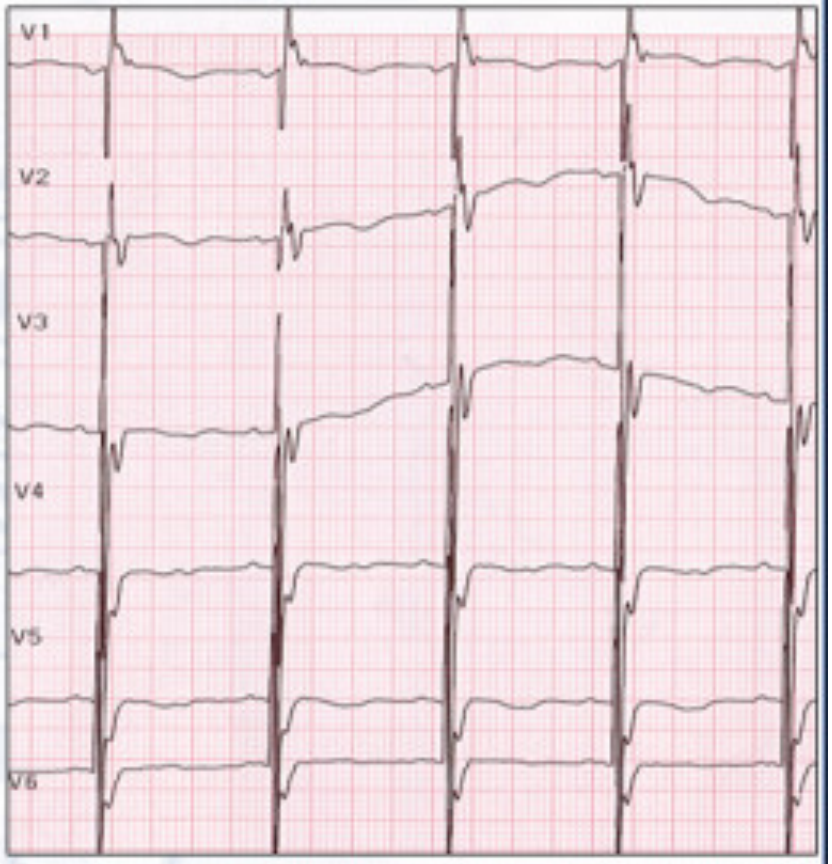


NARROW QRS

HOW TO PERFORM IT?

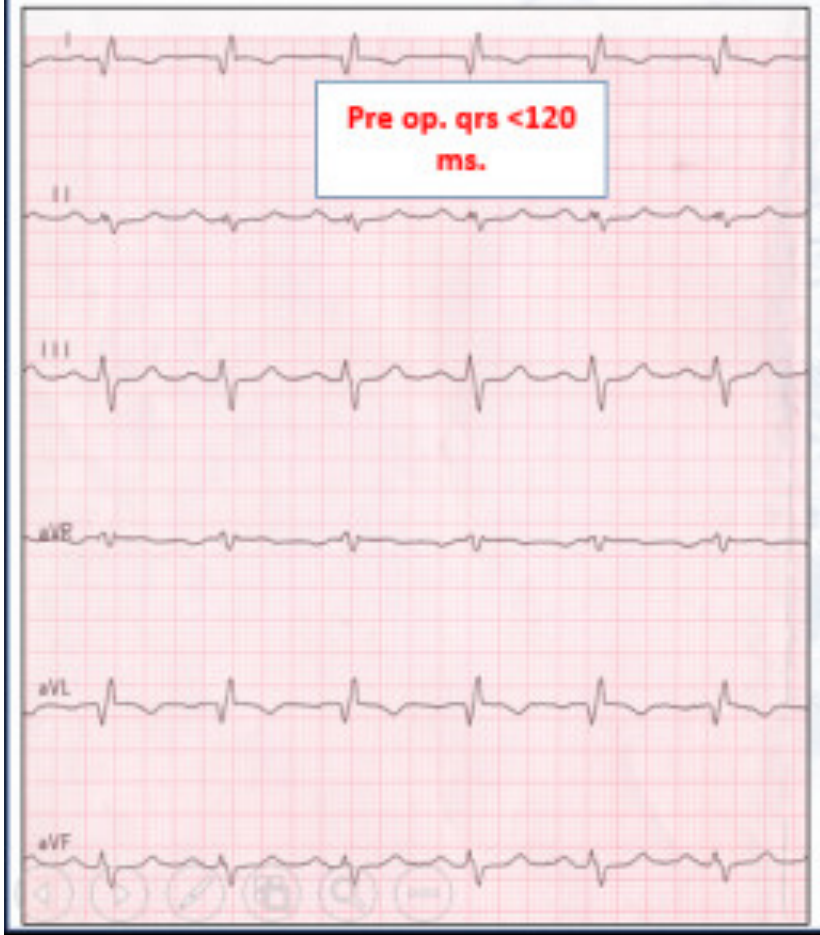


Multisite pacing with 2 leads warrants a better result further shortening narrow QRS also



NARROW QRS

HOW TO PERFORM IT?



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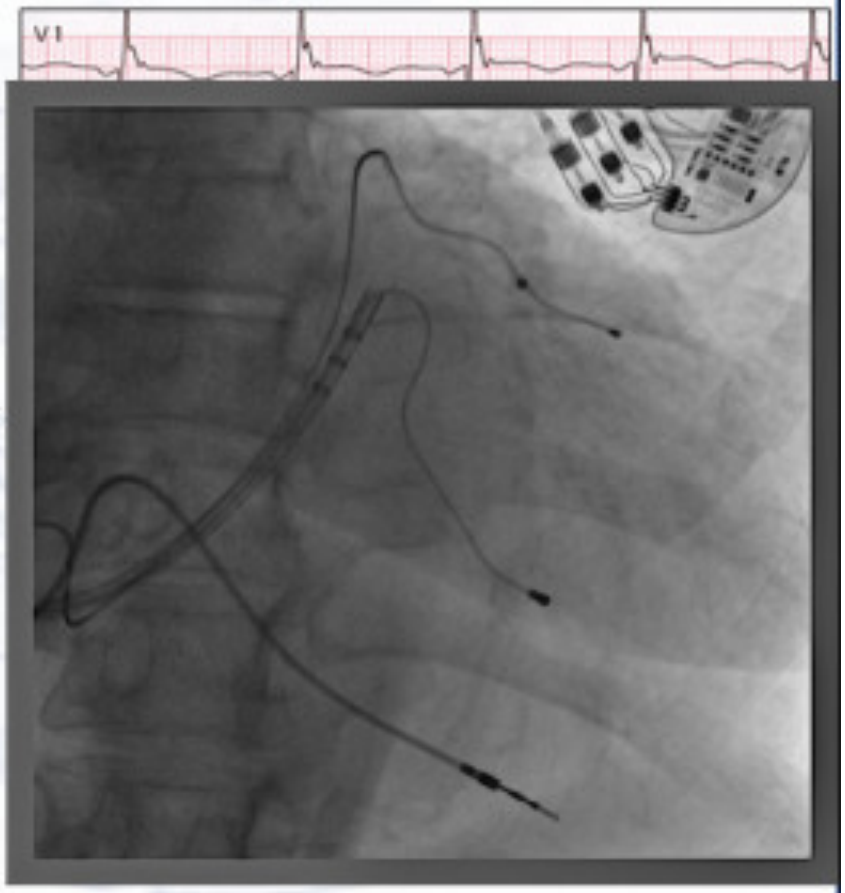
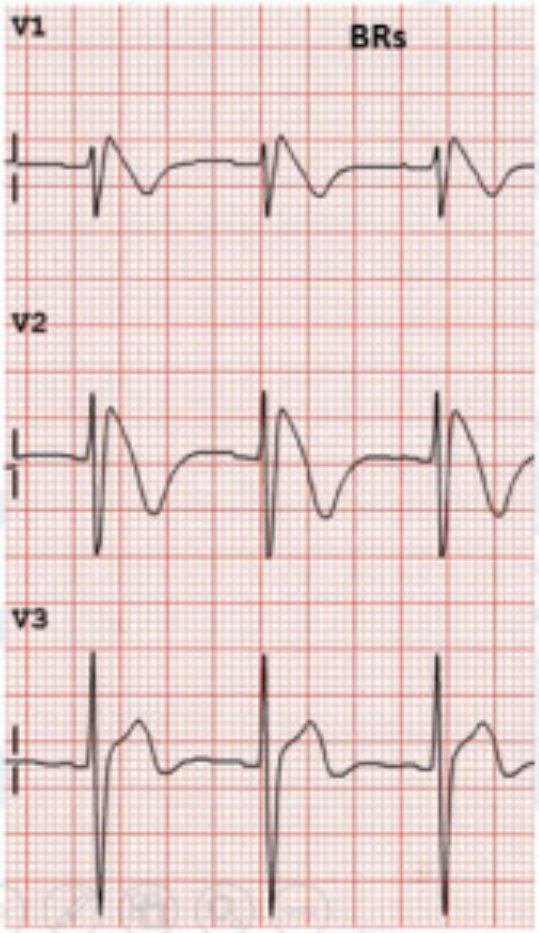
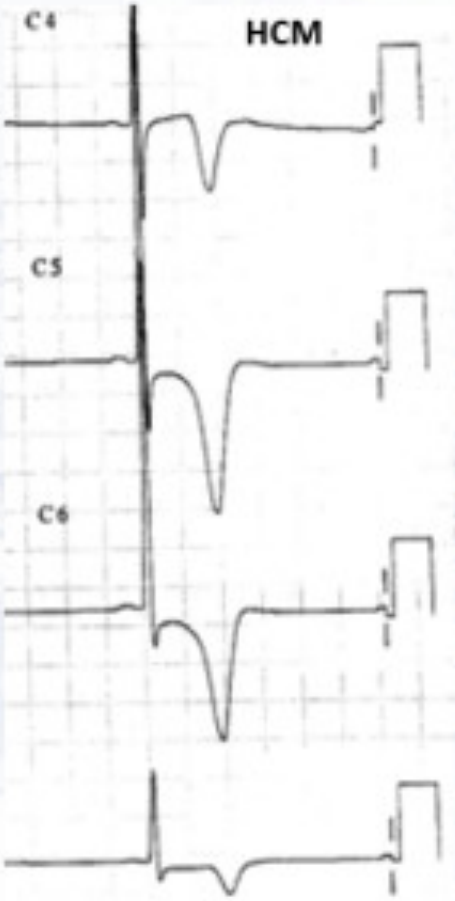
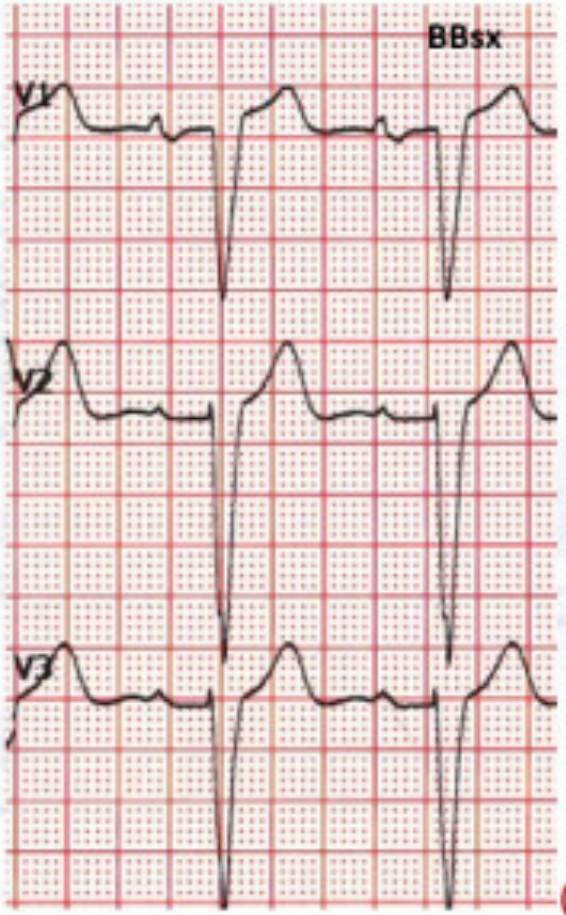


Limits of S-ICD:

T- Wave oversensing and Morphology missinterpretation







So when prefer a S-ICD…..

When you cannot reach your target!!!!!

So when prefer a S-ICD…..

- Venous thrombosis
- Complex cardiomiopathies
- Trouble in gaining a venous access
- Recurrent endocarditis

When you cannot reach your target!!!!!