Integrative optimization in CRT recipients

Kamil Sedláček, MD
Dptm. of Cardiology
Electrophysiology
Institute of Clinical and Experimental Medicine (IKEM)
Praha, Czech republic

20 years of cardiac resynchronization therapy in the Czech Republic

An international symposium to commemorate
the 20th anniversary of the first CRT implants in the Czech Republic

June 12, 2019

Periods in CRT therapy - outline

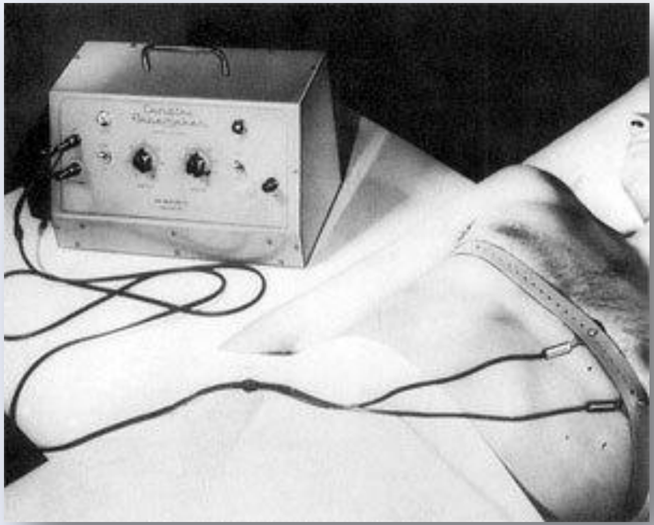
before 1990	physiological a technological concepts
1990 – 2000	development of CRT technique
2000 – 2010	establishment of successful EB therapy
2010 – 2019	optimization era (integration of knowledge)
2019 –	4th revolution in device therapy

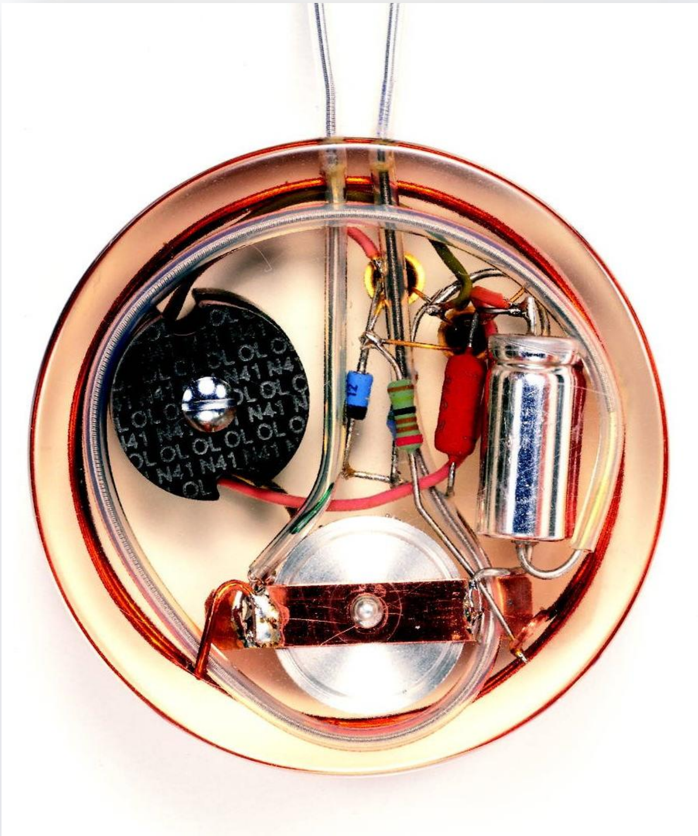
Before 1990

Physiological and technological concepts

Birth of device cardiology

1952 transcutaneous pacing (Paul M. Zoll, Boston)
1956 endocardial temporary pacing (S. Furman, US)
1958 implantable PM





Drs. Rune Elmqvist Ake Senning

Zoll PM: Resuscitation of heart in ventricular standstill by external electrical stimulation. NEJM 247:768, 1952
Furman S, Robinson G: Use of an intracardiac pacemaker in the correction of total heart block. Surg Forum 9:245, 1958

First PM in former Czechoslovakia

DARTMOUTH MEDICINE

A Magazine for Alumni and Friends of Dartmouth Medical School and Dartmouth-Hitchcock Medical Center Winter 2005

Contents Discoveries Vital Signs Essays Letters Features Campaign Profiles Art of Medicine

The Dufek File

PDF Version Printer-Friendly Version

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The story of the first pacemaker implantation performed behind the Iron Curtain is as suspenseful as any John le Carré novel. But this saga's literary twists and technological turns—from the pen of the DMS graduate who performed the operation—have to do not with espionage, but with surgery. And humanity.

By Timothy Takaro, M.D.

The Cold War—when Communism was a constant specter and few Americans were allowed behind the Iron Curtain—now seems long ago and far away. I was recently reminded of the divisions and fears of that era when I came across a file of correspondence more than 40 years old. The cache of letters, cables, and news clippings stirred up memories of an unusual experience I had back then—and of the fact that human connections can be forged even across seemingly impenetrable barriers.

It was the spring of 1962. Just over a year earlier, Russian leader Nikita Khrushchev had disrupted a session of the United Nations by banging his shoe on a desk. The Berlin Wall had been up for eight months, sealing off East Berliners from all contact with the West. The Cuban Missile Crisis was nearing its denouement.

Yet amidst the tensions, there were glimmers of the detente to come. I was about to leave to spend several months in the Soviet Union under the auspices of the newly signed U.S.-U.S.S.R. Scientific and Cultural Exchange Agreement. I had gotten approval to take a leave from my post as associate chief of staff at the VA Hospital in Oteen, N.C., and had acquired a working knowledge of Russian. My

THIS IMAGE: GLEN ALLISON; ALL HISTORICAL IMAGES: COURTESY OF THE AUTHOR

Jan Dufek, MD
IKEM, 6. July 1962

Dartmouth Medicine Winter 2005

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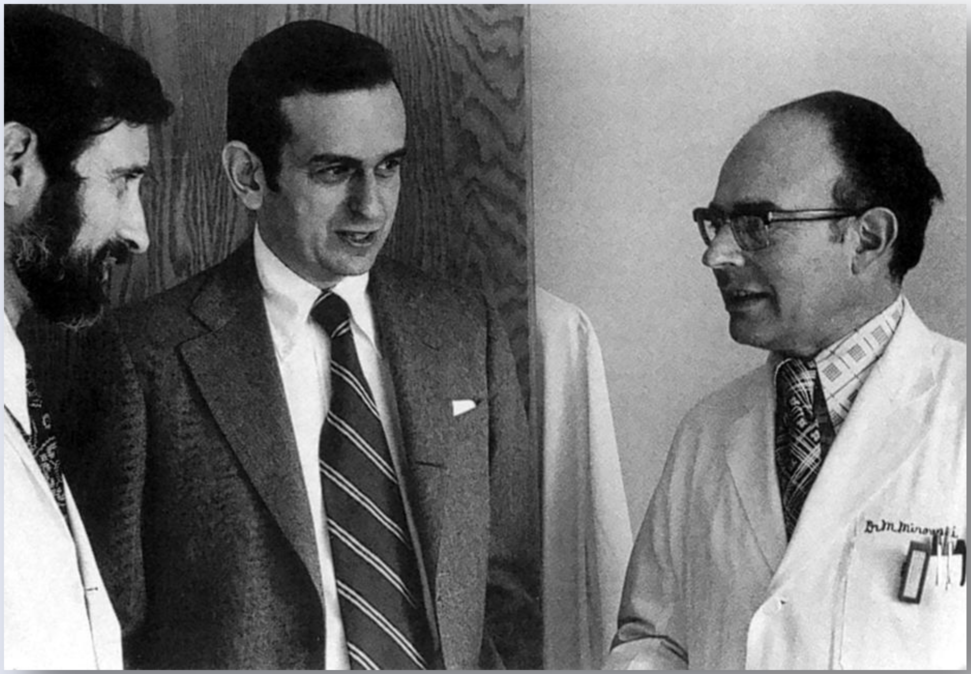
ICD



1970-72: drs. Mower, Moss, Mirowski

ICD – first implants in Europe

1982 France -October 14

1984 Germany – January 17

Switzerland - March 6

Netherlands - April 4

Belgium – April 11

U.K. – April 27

Spain – June 16

Norway - August 7

Sweden – September 19

Italy – September 27

Czech Republic – Oct 31 – dr. Bytešník, dr. Náprstek

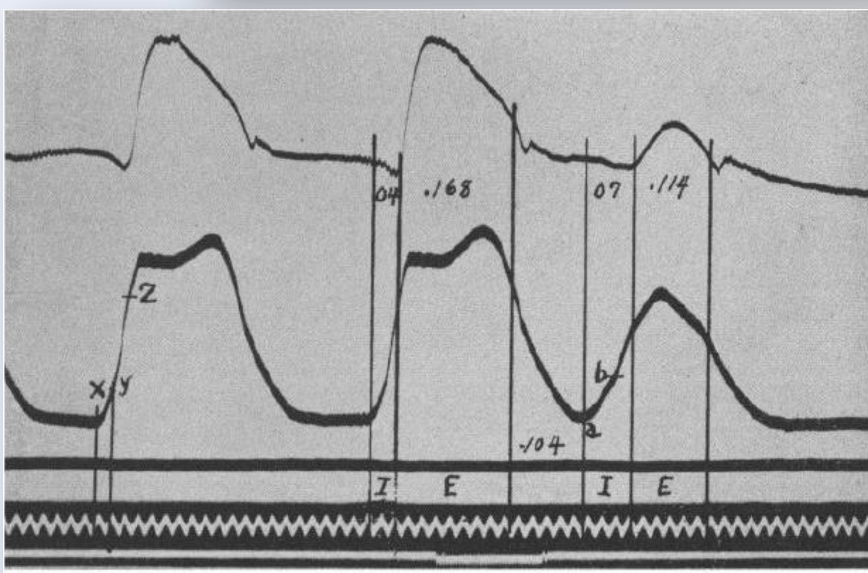
THE MUSCULAR REACTIONS OF THE MAMMALIAN VENTRICLES TO ARTIFICIAL SURFACE STIMULI

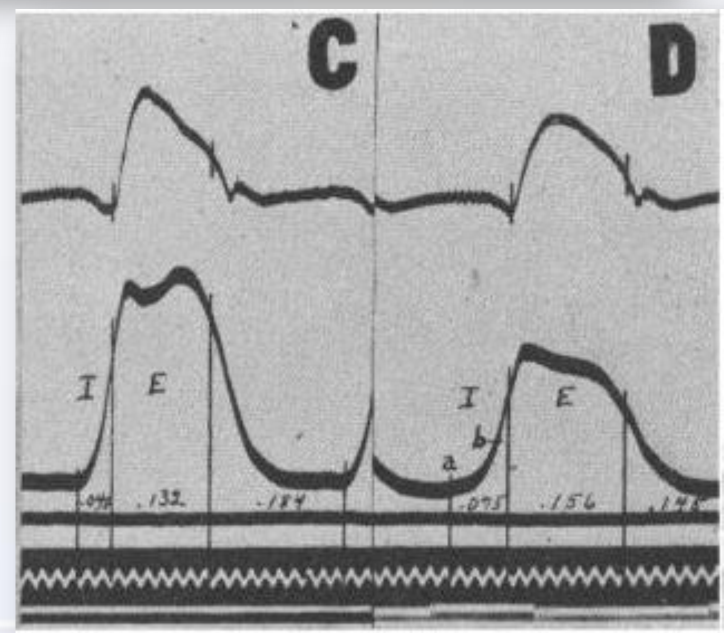
CARL J. WIGGERS

From the Physiological Laboratory, Western Reserve University, School of Medicine, Cleveland, Ohio

Received for publication April 20, 1925

The muscular reactions of the mammalian ventricles to localized artificial stimuli have not been studied with the degree of precision that the subject merits. This is due partly to the fact that, until recently, we





Wiggers, C. (1925). "The muscular reactions of the mammalian ventricles to artificial surface stimuli."American Journal of Physiology**73**(2): 346-378.

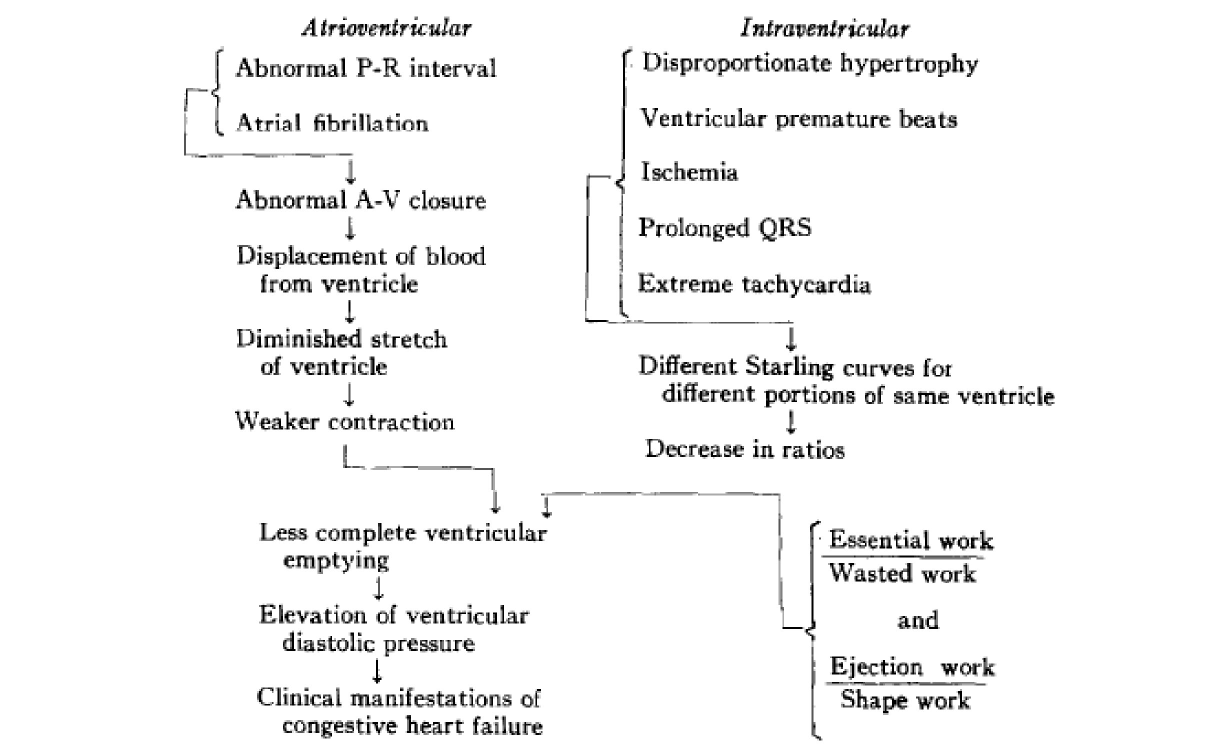
Review

Some unanswered questions concerning enlargement and failure of the heart

Grady Reddick Memorial Lecture

*Tinsley R. Harrison, M.D.**
Birmingham, Ala.

Table II. Some probable mechanisms of cardiac asynergy

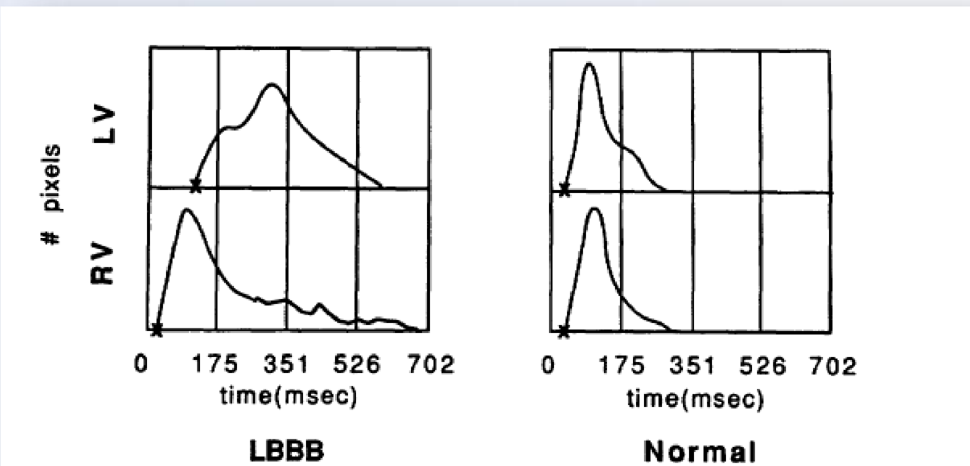


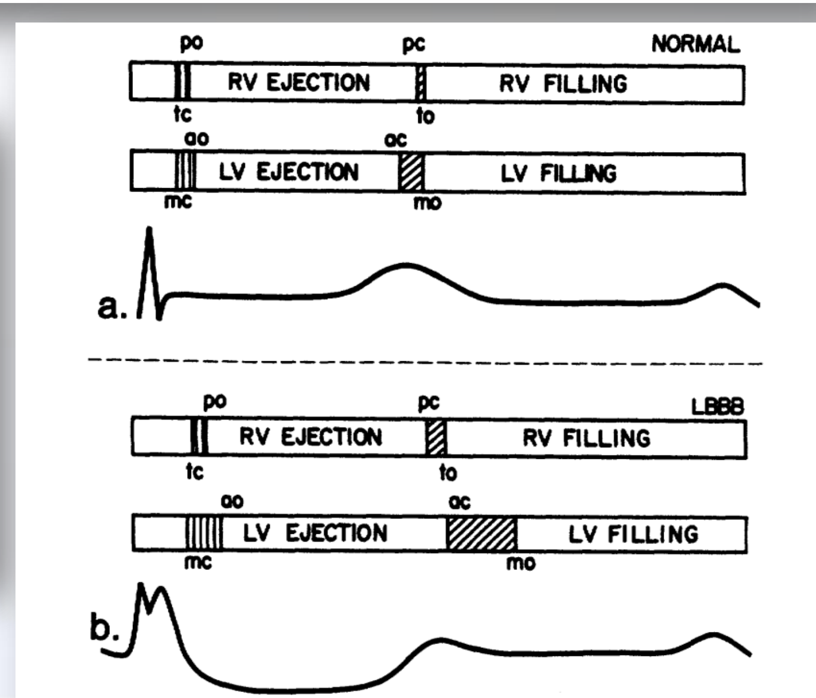
Harrison TR Am H. J 1965

Functional Abnormalities in Isolated Left Bundle Branch Block

The Effect of Interventricular Asynchrony

Cindy L. Grines, MD, Thomas M. Bashore, MD, Harisios Boudoulas, MD,
Shari Olson, BS, Phillip Shafer, MD, and Charles F. Wooley, MD





Grines, C. L., et al. (1989). Functional abnormalities in isolated left bundle branch block. The effect of interventricular asynchrony. Circulation**79**(4): 845-853.

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An Even More Physiological Pacing: Changing the Sequence of Ventricular Activation

E. de Teresa, J. L. Chamorro, L. A. Pulpón, Carmen Ruiz, Isabel R. Bailón, J. Alzueta, M. de Artaza

Summary: Physiological pacing includes preservation of A-V sequential stimulation and adaptation of heart rate to body requirements. However the sequence of ventricular activation (VA) is also important. In four patients with aortic valvular disease, LBBB and HV $\geqslant$ 70 msec a Medtronic Versatrax DDD pacemaker was implanted at the time of aortic valve surgery. The ventricular electrode was placed in the free wall of the LV. With differents pulse generator A-V intervals (PG-AV), we obtained: A) LBBB morphology when PG-AV was > A-V conducted interval (C-AV); B) "RBBB" morphology when PG-AV < C-AV, and C) intermediate ("fusion") morphology when PG-AV $\simeq$ C-AV. A mean delay of 70 $\pm$ 5 msec between beginning of the spontaneous activation of RV and arrival of stimulation to ventricular electrode in LV favoured these fusion beats. The sequence of mechanical ventricular emptying was non-invasively assessed by radioisotopic (Tc-99 m Pyp labelled red blood cells) study of the "wave of emptying" and of phase histograms, using the Fourier's analysis. The most "normal" pattern was found in C. LV ejection fraction (radioisotopic cineangiogram) was 0.59 $\pm$ 0.035 in C versus 0.51 $\pm$ 0.047 in B ($p < 0.001$) and 0.47 $\pm$ 0.045 in A ($p < 0.001$). We conclude than an appropriate placement of ventricular electrode besides a correct programation of A-V delay in DDD pacemakers allows for a more synergistic ventricular activation in patients with LBBB, improving their ventricular performance.

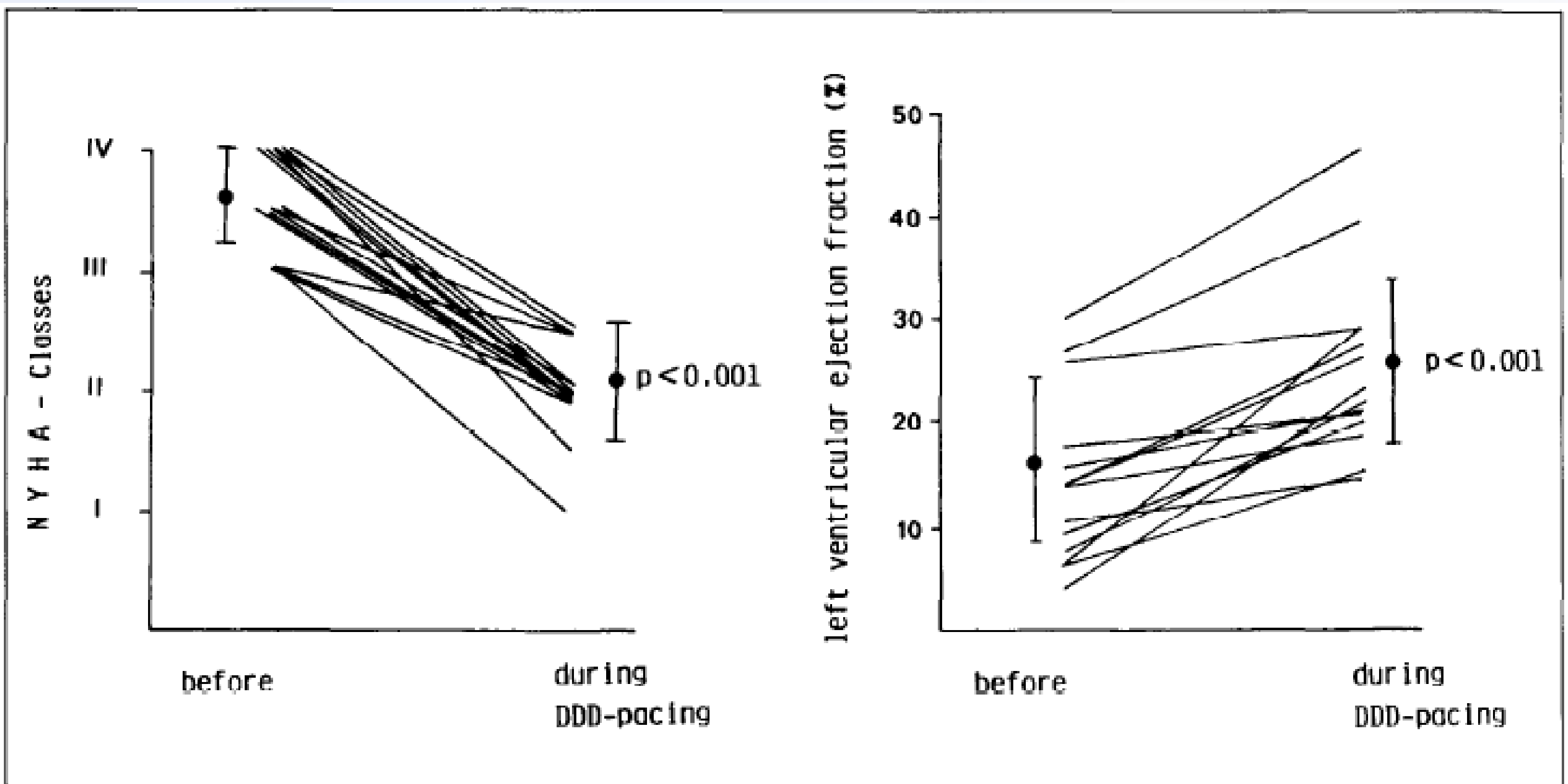
de Teresa E, Chamorro J, Pulpon L, et al. An even more physiological pacing: changing the sequence of ventricular activation. In: Steinbach K, Laskovics A, editors. Proceedings of the 7th World Symposium on Cardiac Pacing. Darmstadt, Germany: Steinkopff-Verlag, 1983: 395–401.

1990-2000

Development of CRT technique

Usefulness of Physiologic Dual-Chamber Pacing in Drug-Resistant Idiopathic Dilated Cardiomyopathy

Margarete Hochleitner, MD, Helmut Hörtnagl, MD, Choi-Keung Ng, MD, Heide Hörtnagl, MD, Franz Gschnitzer, MD, and Wolfgang Zechmann, MD



Hochleitner M et al. Am J Cardiol. 1990

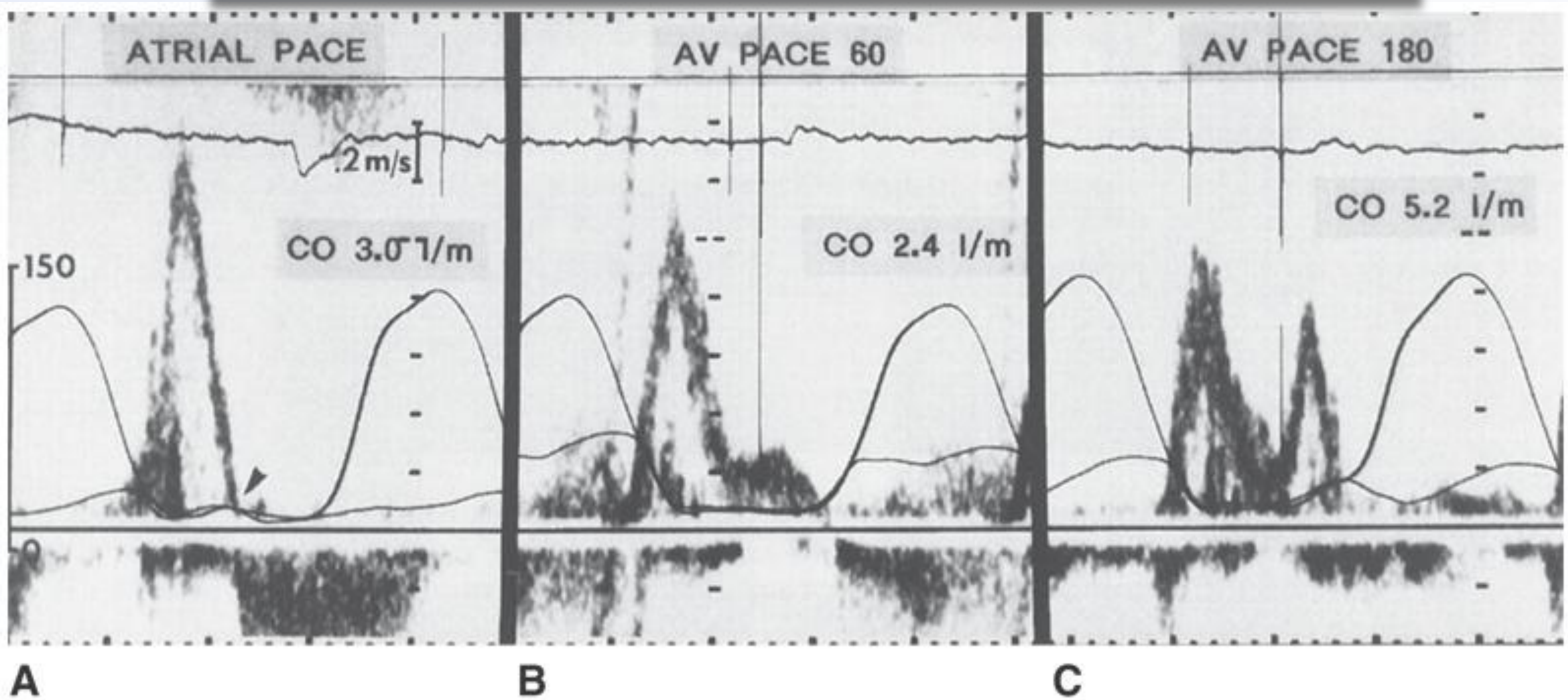
JACC Vol. 25, No. 2
February 1995:281–8

CLINICAL STUDIES HEART FAILURE

Mechanism of Hemodynamic Improvement by Dual-Chamber Pacing for Severe Left Ventricular Dysfunction: An Acute Doppler and Catheterization Hemodynamic Study

RICK A. NISHIMURA, MD, FACC, DAVID L. HAYES, MD, FACC,
DAVID R. HOLMES, JR., MD, FACC, A. JAMIL TAJIK, MD, FACC

Rochester, Minnesota



(From Nishimura RA, Hayes DL, Holmes DR: Mechanism of hemodynamic improvement by dual chamber pacing for severe left ventricular dysfunction: An acute Doppler and catheterization hemodynamic study. J Am Coll Cardiol 25:281, 1995.)

Nishimura RA. JACC 1995

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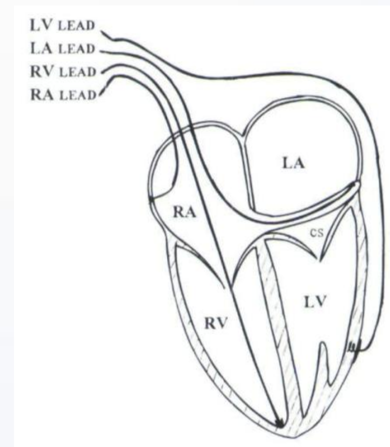
Four Chamber Pacing in Dilated Cardiomyopathy

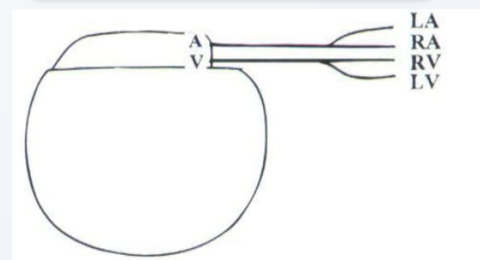
S. CAZEAU, P. RITTER, S. BAKDACH, A. LAZARUS, M. LIMOUSIN,*
L. HENAO, O. MUNDLER,** J.C. DAUBERT,† and J. MUGICA

Table I.

Acute Study	Spontaneous	Standard VDD			4-Chamber Pacing		
QRS							
Duration (msec)	200		200			160	
Axis (°)	0		−10			−20	
Morphology	LBBB		LBBB			LBBB	
Hemodynamics							
AV delay (msec)		95	140	190	95	140	190
PCWP (mmHg)	36	30	28	30	28	25	26
Cardiac Output (L/min)	3.90	4.45	5.17	4.10	5.69	5.08	4.95

AV = atrioventricular; LBBB = left bundle branch block; PCWP = pulmonary capillary wedge pressure.





„We doubt that this technique will have an impact on long-term survival, but it could be of major importance to improve the patient's well-being and control heart failure..“.

2000-2010

Establishment of successful EB therapy

EBM - CRT

Trial (ref)	No.	Design	NYHA	LVEF	QRS	Primary endpoints	Secondary endpoints	Main Findings
MUSTIC-SR[52]	58	Single-blinded, crossover, randomized CRT vs. OMT, 6 months	III	<35%	≥150	6MWD	NYHA class, QoL, peak VO_2,LV volumes, MR hospitalizations, mortality	CRT-P improved 6MWD, NYHA class, QoL, peak VO_2, reduced LV volumes and MR and reduced hospitalizations
PATH-CHF[51]	41	Single-blinded, crossover, randomized RV vs. LV vs. BiV, 12 months	III–IV	NA	≥150	Peak VO_2, 6MWD	NYHA class, QoL hospitalizations	CRT-P improved NYHA class, QoL and 6MWD and reduced hospitalizations
MIRACLE[49]	453	Double-blinded, randomized CRT vs. OMT, 6 months	III–IV	≤35%	≥130	NYHA class, 6MWD , QoL	Peak VO_2 LVEDD, LVEF, MR clinical composite response	CRT-P improved NYHA class, QoL and 6MWD and reduced LVEDD, MR and increased LVEF
MIRACLE-ICD[54]	369	Double-blinded, randomized CRT-D vs. ICD, 6 months	III–IV	≤35%	≥130	NYHA class, 6MWD , QoL	Peak VO_2 LVEDD, LVEF, MR clinical composite response	CRT-D improved NYHA class, QoL, peak VO_2
CONTAK-CD[53]	490	Double-blinded randomized CRT-D vs. ICD, 6 months	II–III–IV	≤35%	≥120	NYHA class, 6MWD , QoL	LV volume, LVEF composite of mortality, VT/VF, hospitalizations	CRT-D improved 6MWD, NYHA class, QoL, reduced LV volume and increased LVEF
MIRACLE-ICD II[60]	186	Double-blinded, randomized CRT-D vs. ICD, 6 months	II	≤35%	≥130	Peak VO_2	VE/VCO_2, NYHA, QoL, 6MWD, LV volumes and EF, composite clinical endpoint	CRT-D improved NYHA, VE/CO_2 and reduced LV volumes and improved LVEF
COMPANION[55]	1520	Double-blinded randomized OMT vs. CRT-P / or vs. CRT-D, 15 months	III–IV	≤35%	≥120	All-cause mortality or hospitalization	All-cause mortality, cardiac mortality	CRT-P and CRT-D reduced all-cause mortality or hospitalization
CARE-HF[56]	813	Double-blinded randomized OMT vs. CRT-P 29.4 months	III–IV	≤35%	≥120	All-cause mortality or hospitalization	All-cause mortality, NYHA class, QoL	CRT-P reduced all-cause mortality and hospitalization and improved NYHA class and QoL
REVERSE[61]	610	Double-blinded, randomized CRT-ON vs. CRT-OFF, 12 months	I–II	≤40%	≥120	% worsened by clinical composite endpoint	LVESV index, heart failure hospitalizations and all-cause mortality	CRT-P/CRT-D did not change the primary endpoint and did not reduce all-cause mortality but reduced LVESV index and heart failure hospitalizations.
MADIT-CRT[50]	1820	Single-blinded, randomized CRT-D vs. ICD, 12 months	I–II	≤30%	≥130	All-cause mortality or heart failure hospitalizations	All-cause mortality and LVESV	CRT-D reduced the endpoint heart failure hospitalizations or all-cause mortality and LVESV. CRT-D did not reduced all-cause mortality
RAFT[62]	1798	Double-blinded, randomized CRT-D vs. ICD 40 months	II–III	≤30%	≥120	All-cause mortality or heart failure hospitalizations	All-cause mortality and cardiovascular death	CRT-D reduced the endpoint all-cause mortality or heart failure hospitalizations. In NYHA III, CRT-D only reduced significantly all-cause mortality

Brignole M et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy
Eur Heart J. 2013;34:2281-329.

EBM - CRT

Trial (ref)	No.	Design	NYHA	LVEF	QRS	Primary endpoints	Secondary endpoints	Main Findings
MUSTIC-SR[52]	58	Single-blinded, crossover, randomized CRT vs. OMT, 6 months	III	<35%	≥150	6MWD	NYHA class, QoL, peak VO_2,LV volumes, MR hospitalizations, mortality	CRT-P improved 6MWD, NYHA class, QoL, peak VO_2, reduced LV volumes and MR and reduced hospitalizations
PATH-CHF[51]	41	Single-blinded, crossover,	III–IV	NA	≥150	Peak VO_2, 6MWD	NYHA class, QoL hospitalizations	CRT-P improved NYHA class, QoL and 6MWD and reduced
COMPANION[55]	1520	Double-blinded randomized OMT vs. CRT-P / or vs. CRT-D, 15 months	III–IV	≤35%	≥120	All-cause mortality or hospitalization	All-cause mortality, cardiac mortality	CRT-P and CRT-D reduced all-cause mortality or hospitalization
CARE-HF[56]	813	Double-blinded randomized OMT vs. CRT-P 29.4 months	III–IV	≤35%	≥120	All-cause mortality or hospitalization	All-cause mortality, NYHA class, QoL	CRT-P reduced all-cause mortality and hospitalization and improved NYHA class and QoL
REVERSE[61]	610	Double-blinded, randomized CRT-ON vs. CRT-OFF, 12 months	I–II	≤40%	≥120	% worsened by clinical composite endpoint	LVESV index, heart failure hospitalizations and all-cause mortality	CRT-P/CRT-D did not change the primary endpoint and did not reduce all-cause mortality but reduced LVESV index and heart failure hospitalizations.
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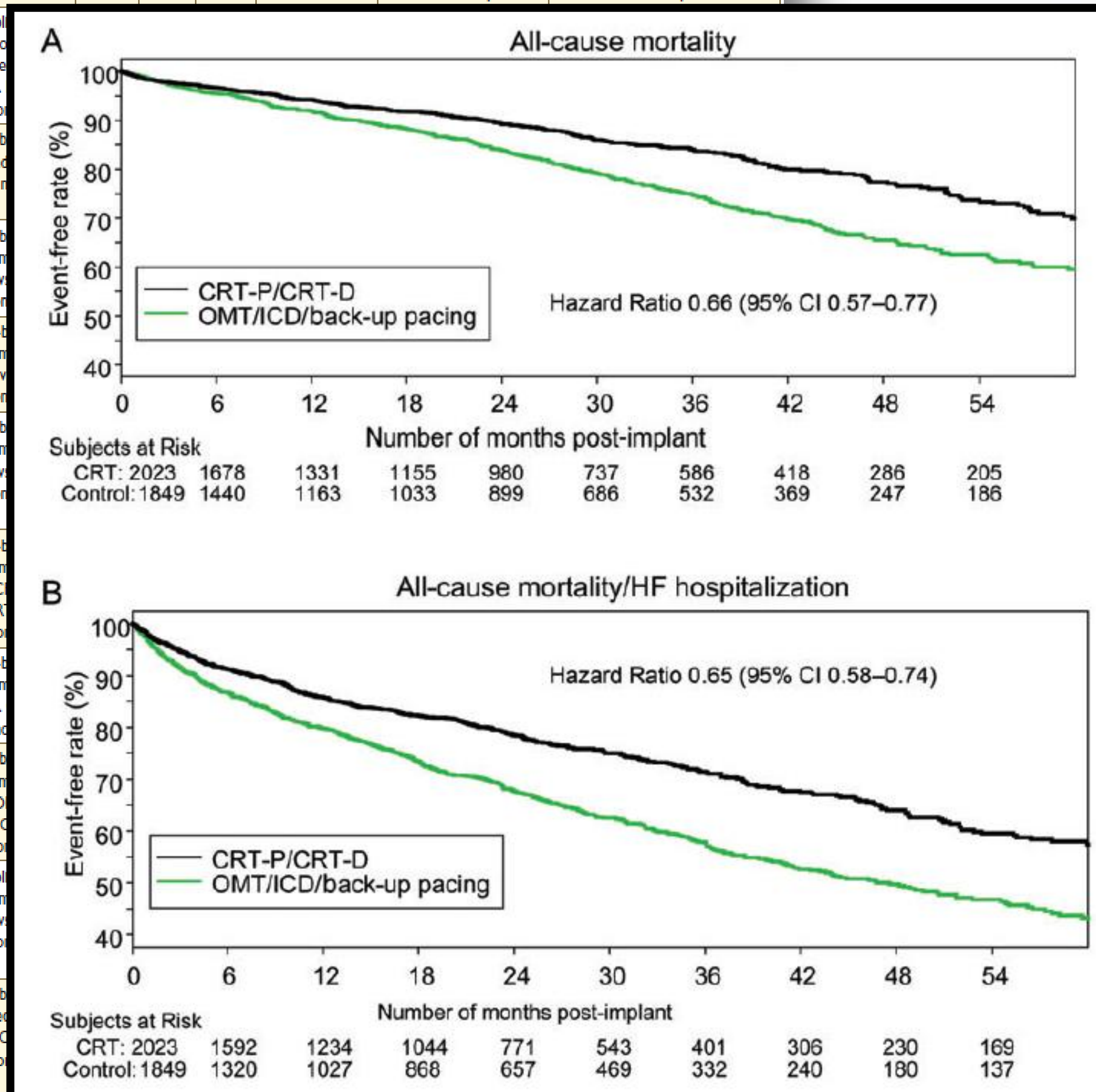
RAFT[62]	1798	Double-blinded, randomized CRT-D vs. ICD 40 months	II–III	≤30%	≥120	All-cause mortality or heart failure hospitalizations	All-cause mortality and cardiovascular death	CRT-D reduced the endpoint all-cause mortality or heart failure hospitalizations. In NYHA III, CRT-D only reduced significantly all-cause mortality

40 months hospitalizations NYHA III, CRT-D only reduced significantly all-cause mortality

Brignole M et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy
Eur Heart J. 2013;34:2281-329.

EBM - CRT

Trial (ref)	No.	Design	NYHA	LVEF	QRS	Primary endpoints	Secondary endpoints	Main Findings
MUSTIC-SR[52]	58	Single-blinded, crossover, randomized CRT vs. OMT, 6 months	III	<35%	≥150	6MWD	NYHA class, QoL, peak VO_2, LV volumes, MR hospitalizations, mortality	CRT-P improved 6MWD, NYHA class, QoL, peak VO_2, reduced LV volumes and MR and reduced hospitalizations
PATH-CHF[51]	41	Single-bl crosso randomize LV vs. 12 mo						
MIRACLE[49]	453	Double-b randomized OMT, 6 n						
MIRACLE-ICD[4]	369	Double-b random CRT-D v 6 mon						
CONTAK-CD[53]	490	Double-b random CRT-D v 6 mon						
MIRACLE-ICD II[60]	186	Double-b random CRT-D v 6 mon						
COMPANION[55]	1520	Double-b random OMT vs. C vs. CR 15 mo						
CARE-HF[56]	813	Double-b random OMT vs. 29.4 mo						
REVERSE[61]	610	Double-b random CRT-O CRT- 12 mo						
MADIT-CRT[50]	1820	Single-bl random CRT-D v 12 mo						
RAFT[62]	1798	Double-b randomize vs. IC 40 mo						



Eur Heart J. 2013 Dec;34(46):3547-56

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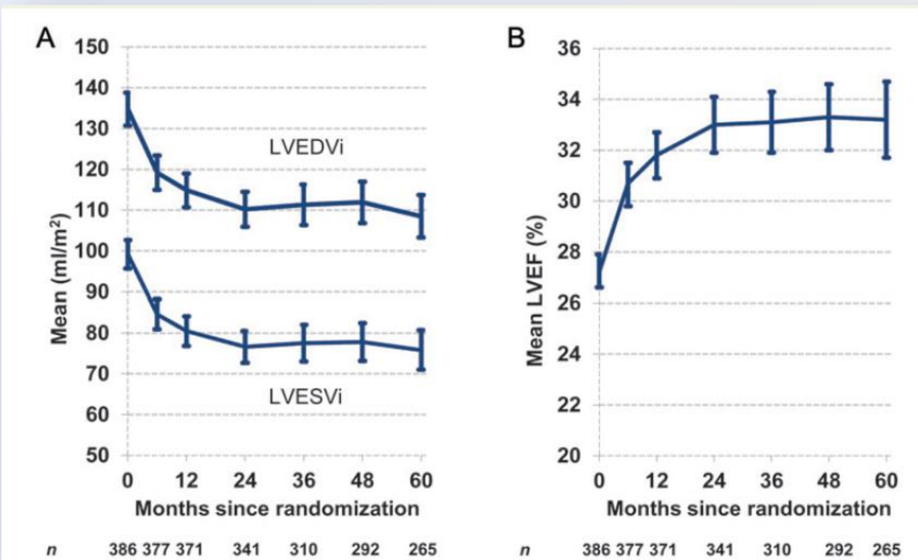
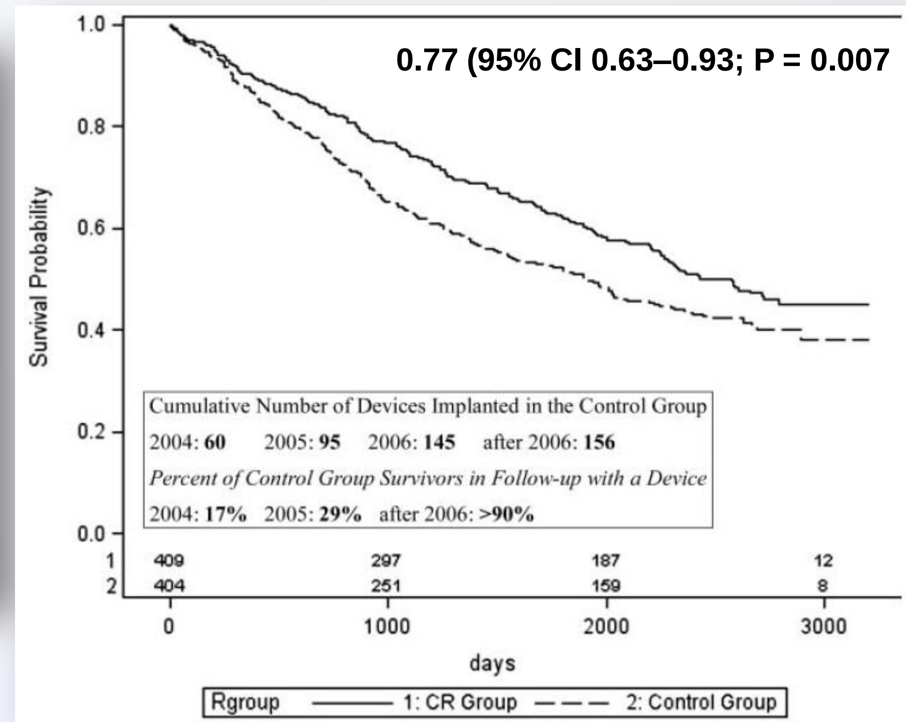
Long-term CRT effect

REVERSE (5 yrs)



CARE-HF (9 yrs - mortality)



Linde C et al. Long-term impact of cardiac resynchronization therapy in mild heart failure:
5-year results from the REVERSE study. *European heart journal. 2013;34:2592-9.*

Cleland JG et al. Long-term mortality in the CARE-HF trial. *European journal of heart failure. 2012;14:628-34.*

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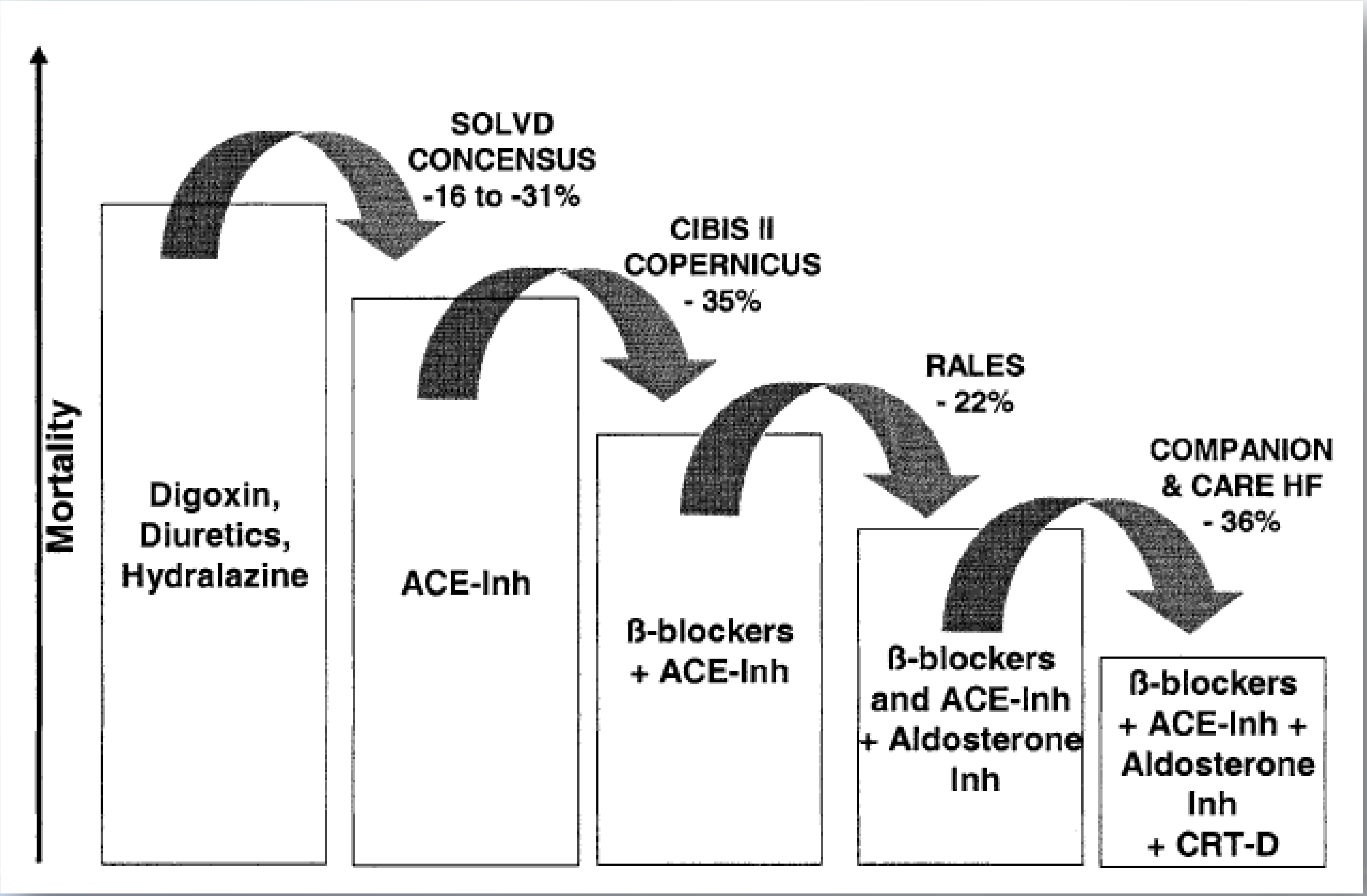
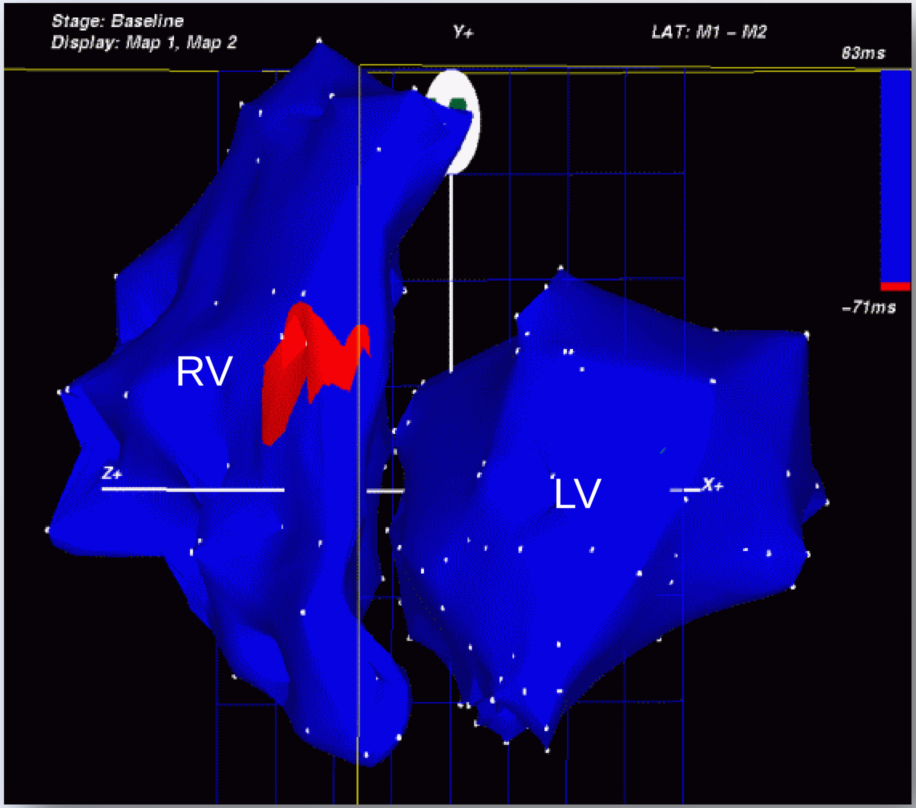
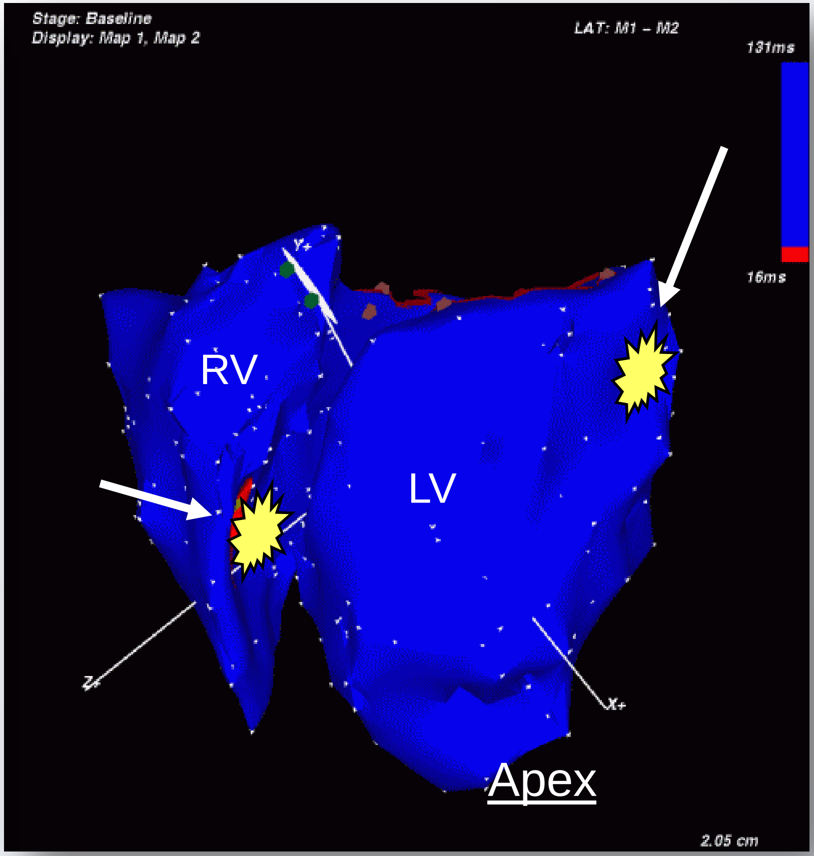
EB HF therapy



Principle of CRT



Electric activation in LBBB



Biventricular pacing

Peichl P, Kautzner J, 2006

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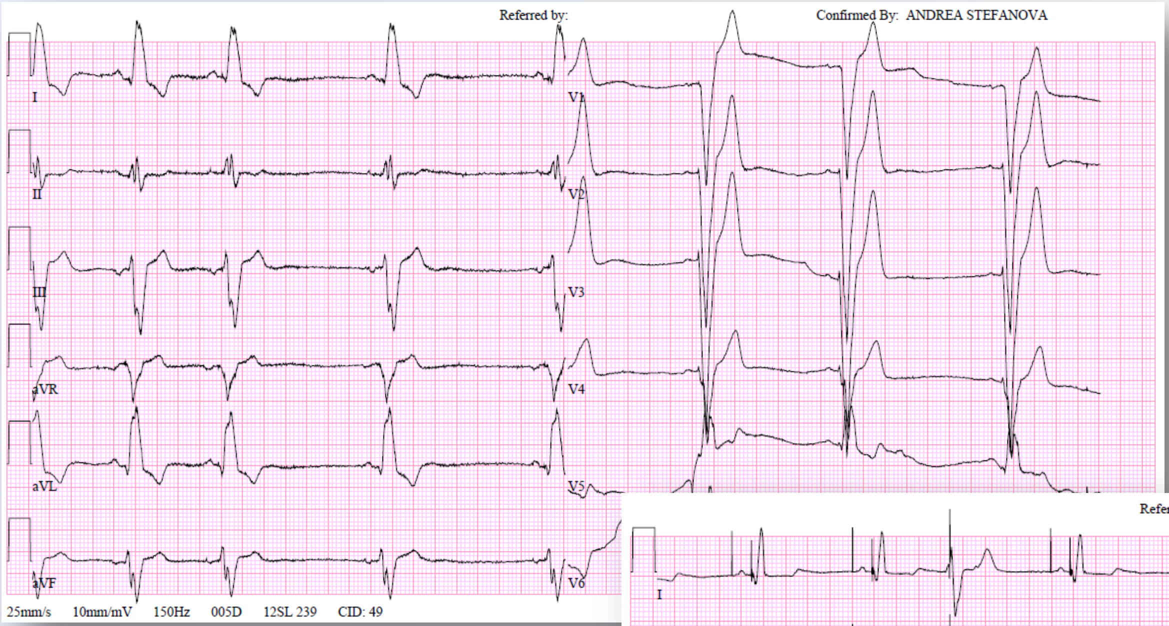
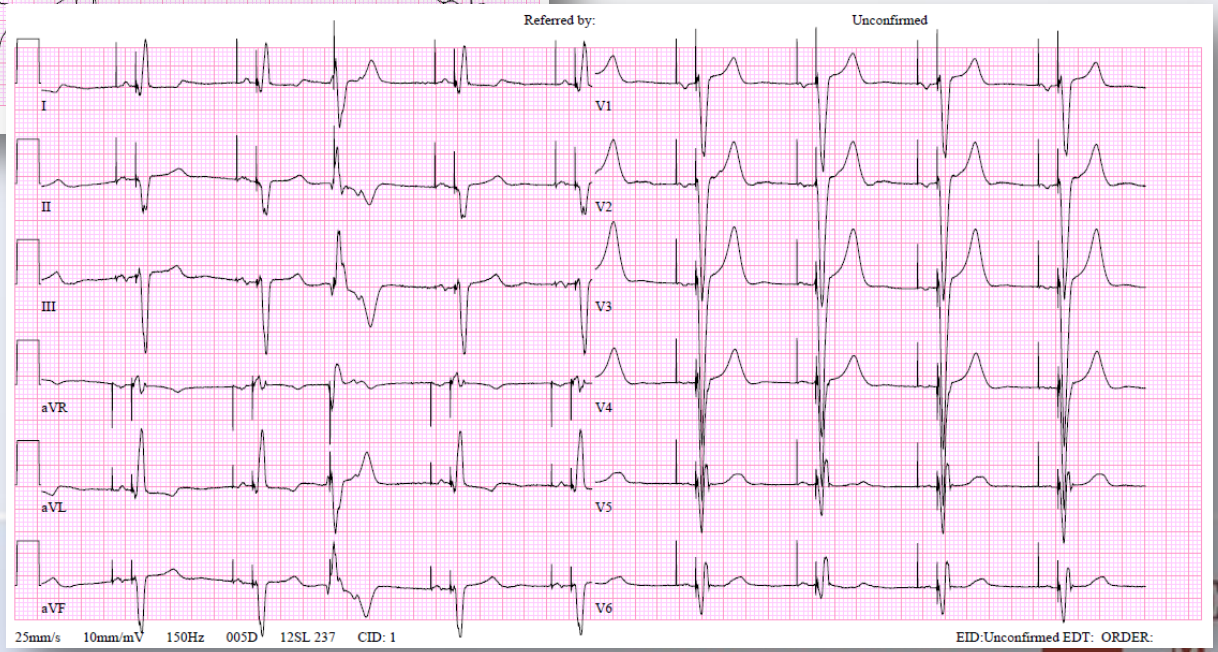
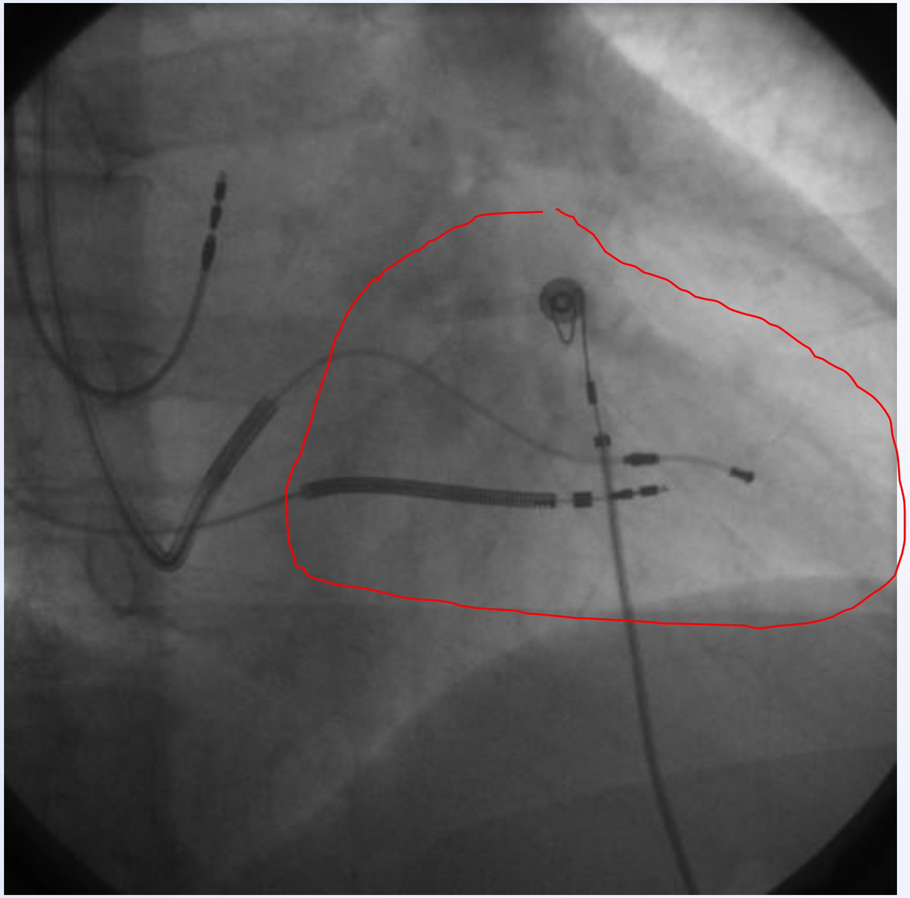
CRT is an electric therapy



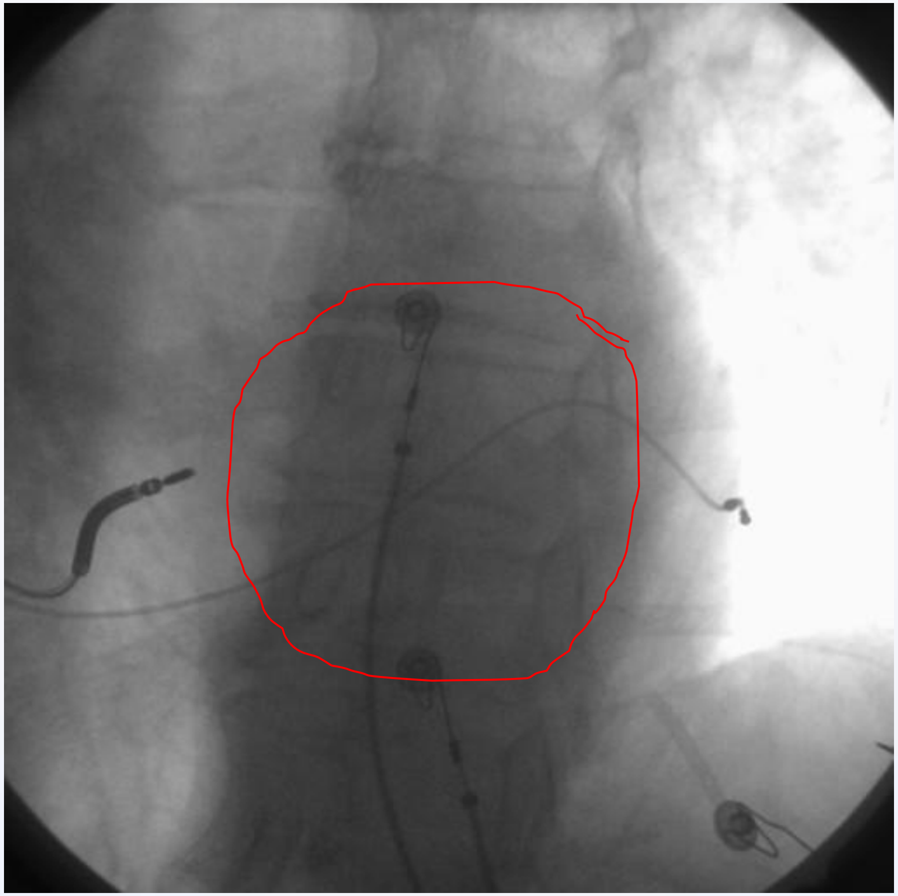


Lead system

RAO



LAO



CRT guidelines

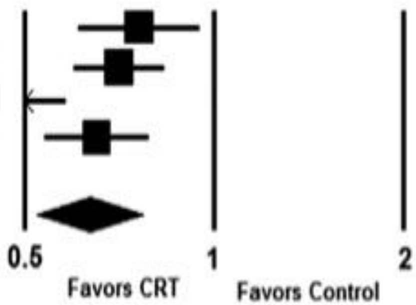
Recommendations	Class[a]	Level[b]
CRT is recommended for symptomatic patients with HF in sinus rhythm with a QRS duration ≥150 msec and LBBB QRS morphology and with LVEF ≤35% despite OMT in order to improve symptoms and reduce morbidity and mortality.	I	A
CRT should be considered for symptomatic patients with HF in sinus rhythm with a QRS duration ≥150 msec and non-LBBB QRS morphology and with LVEF ≤35% despite OMT in order to improve symptoms and reduce morbidity and mortality.	IIa	B
CRT is recommended for symptomatic patients with HF in sinus rhythm with a QRS duration of 130–149 msec and LBBB QRS morphology and with LVEF ≤35% despite OMT in order to improve symptoms and reduce morbidity and mortality.	I	B
CRT may be considered for symptomatic patients with HF in sinus rhythm with a QRS duration of 130–149 msec and non-LBBB QRS morphology and with LVEF ≤35% despite OMT in order to improve symptoms and reduce morbidity and mortality.	IIb	B
CRT rather than RV pacing is recommended for patients with HFrEF regardless of NYHA class who have an indication for ventricular pacing and high degree AV block in order to reduce morbidity. This includes patients with AF (see Section 10.1).	I	A
CRT should be considered for patients with LVEF ≤35% in NYHA Class III–IV[d] despite OMT in order to improve symptoms and reduce morbidity and mortality, if they are in AF and have a QRS duration ≥130 msec provided a strategy to ensure bi-ventricular capture is in place or the patient is expected to return to sinus rhythm.	IIa	B
Patients with HFrEF who have received a conventional pacemaker or an ICD and subsequently develop worsening HF despite OMT and who have a high proportion of RV pacing may be considered for upgrade to CRT. This does not apply to patients with stable HF.	IIb	B
CRT is contra-indicated in patients with a QRS duration < 130 msec.	III	A

2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure European Heart Journal (2016) 37, 2129–2200

Subanalyses in patients with non-LBBB

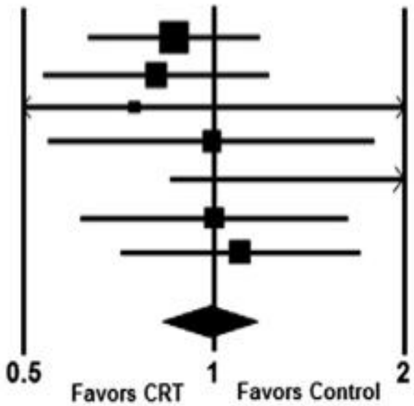
LBBB

Study name	Risk Ratio	Lower Limit	Upper limit	Z-Value	p-Value
COMPANION[10] - LBBB	0.76	0.61	0.95	-2.43	0.016
CARE-HF[11,32] - LBBB	0.70	0.60	0.83	-4.21	<0.0001
MADIT-CRT[12,13,15] - LBBB	0.45	0.35	0.58	-6.20	<0.00001
RAFT[14] - LBBB	0.65	0.54	0.79	-4.44	0.00001
Meta Analysis	**0.64**	**0.52**	**0.77**	**-4.55**	**0.00001**



Non-LBBB

Study name	Risk Ratio	Lower Limit	Upper Limit	Z-Value	p-Value
COMPANION[10] - Non-LBBB	0.86	0.63	1.17	-0.96	0.34
CARE-HF[11,32] - RBBB	0.81	0.54	1.22	-0.99	0.32
CARE-HF[11,32] - IVCD	0.75	0.24	2.33	-0.50	0.62
MADIT-CRT[12,13,15] - RBBB	0.99	0.55	1.79	-0.03	0.97
MADIT-CRT[12,13,15] - IVCD	1.44	0.88	2.36	1.45	0.15
RAFT[14] - RBBB	1.00	0.62	1.62	0.00	1.00
RAFT[14] – IVCD	1.10	0.71	1.69	0.43	0.67
Meta Analysis	**0.97**	**0.82**	**1.15**	**-0.32**	**0.75**



Sipahi I, et al. *Am Heart J* 2012;163:260-267.e3.)

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CRT Trials: Effect of QRS Duration

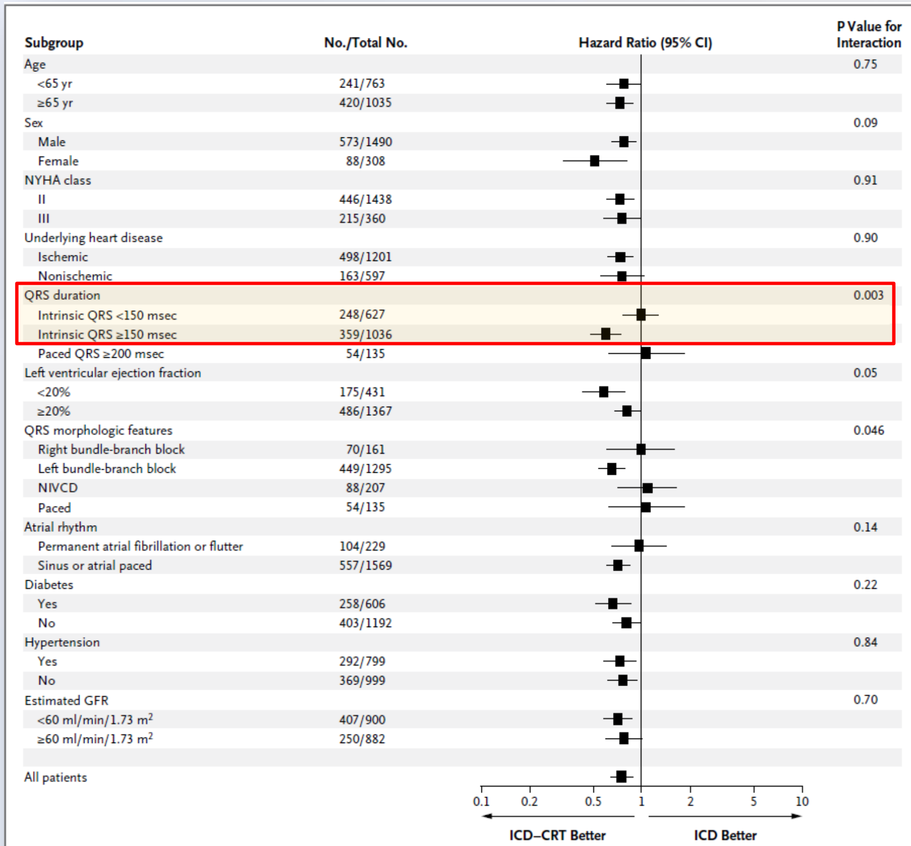
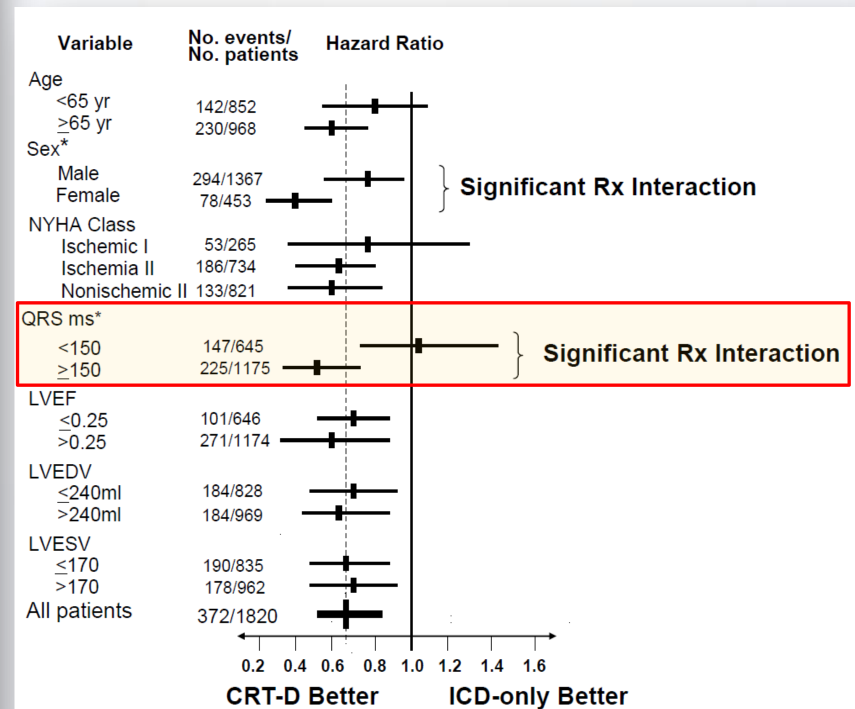


Figure 3. **Subgroup Analyses of Death or Hospitalization for Heart Failure (Composite Primary Outcome).**
Hazard ratios and 95% confidence intervals are shown for the primary outcome in each prespecified subgroup. GFR denotes glomerular filtration rate, NIVCD nonspecific intraventricular conduction delay, and NYHA New York Heart Association.

Tang et al. RAFT Trial. NEJM 2010



Moss et al. MADIT-CRT Trial. NEJM 2009

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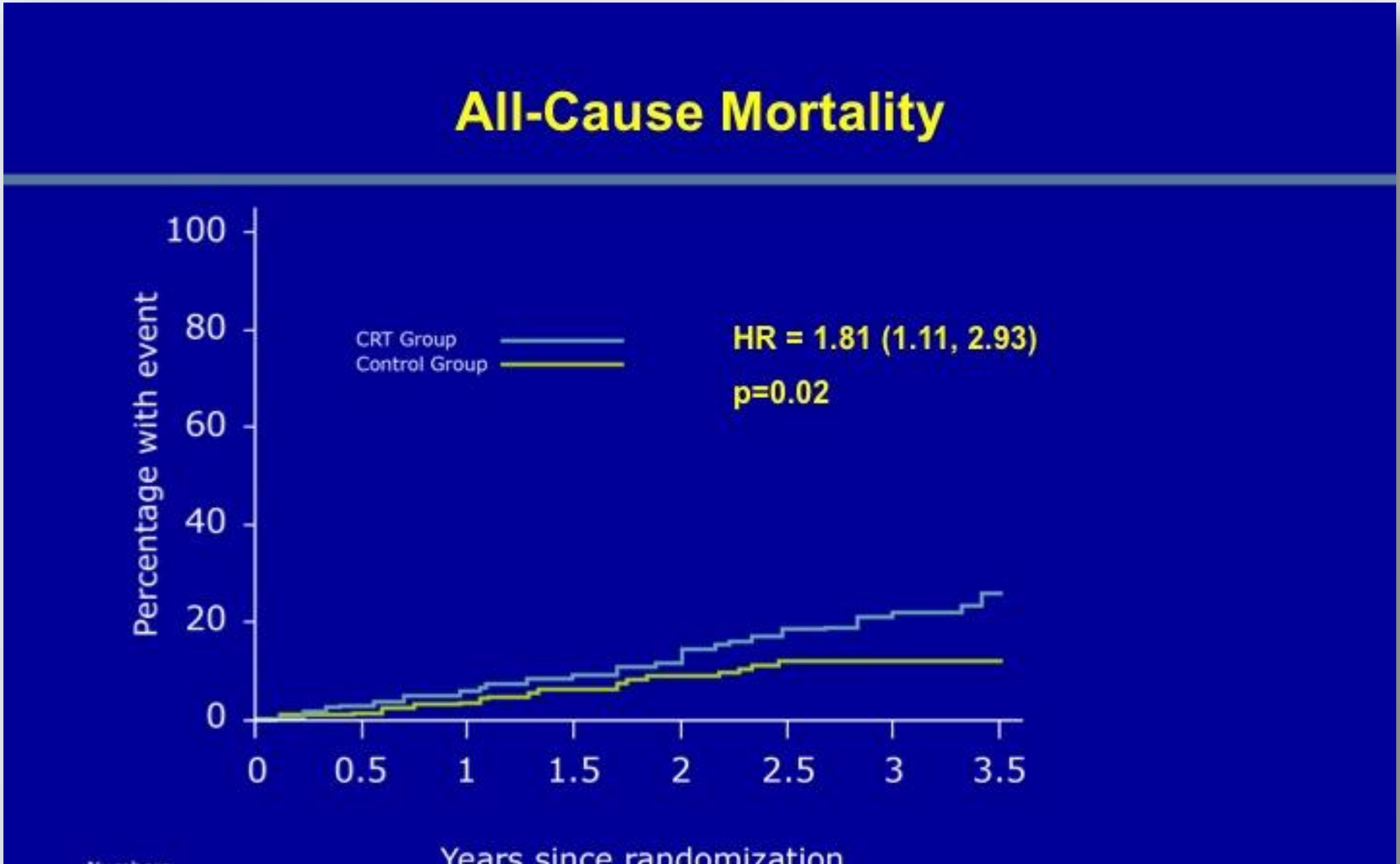
Echo-CRT



Numbers at risk								
CRT Group	404	334	267	199	132	84	56	25
Control Group	405	335	269	195	141	87	62	27

4 deaths in the control group and 1 death in CRT group were after (L)VAD/ Transplant and were excluded from analysis.

2010-2019

Optimization era - integration of knowledge

Components of CRT benefit (integrative approach)

Preimplant – patient selection

- LBBB (true LBBB) and QRS width
- Absence of scar/fibrosis/dilatation – TTE, CMR
- Absence of end-stage renal disease
- Absence of significant MR

Intraimplant

- LV lead position (all lead configuration)
- Correct programming
- Minimization of complications (infections)

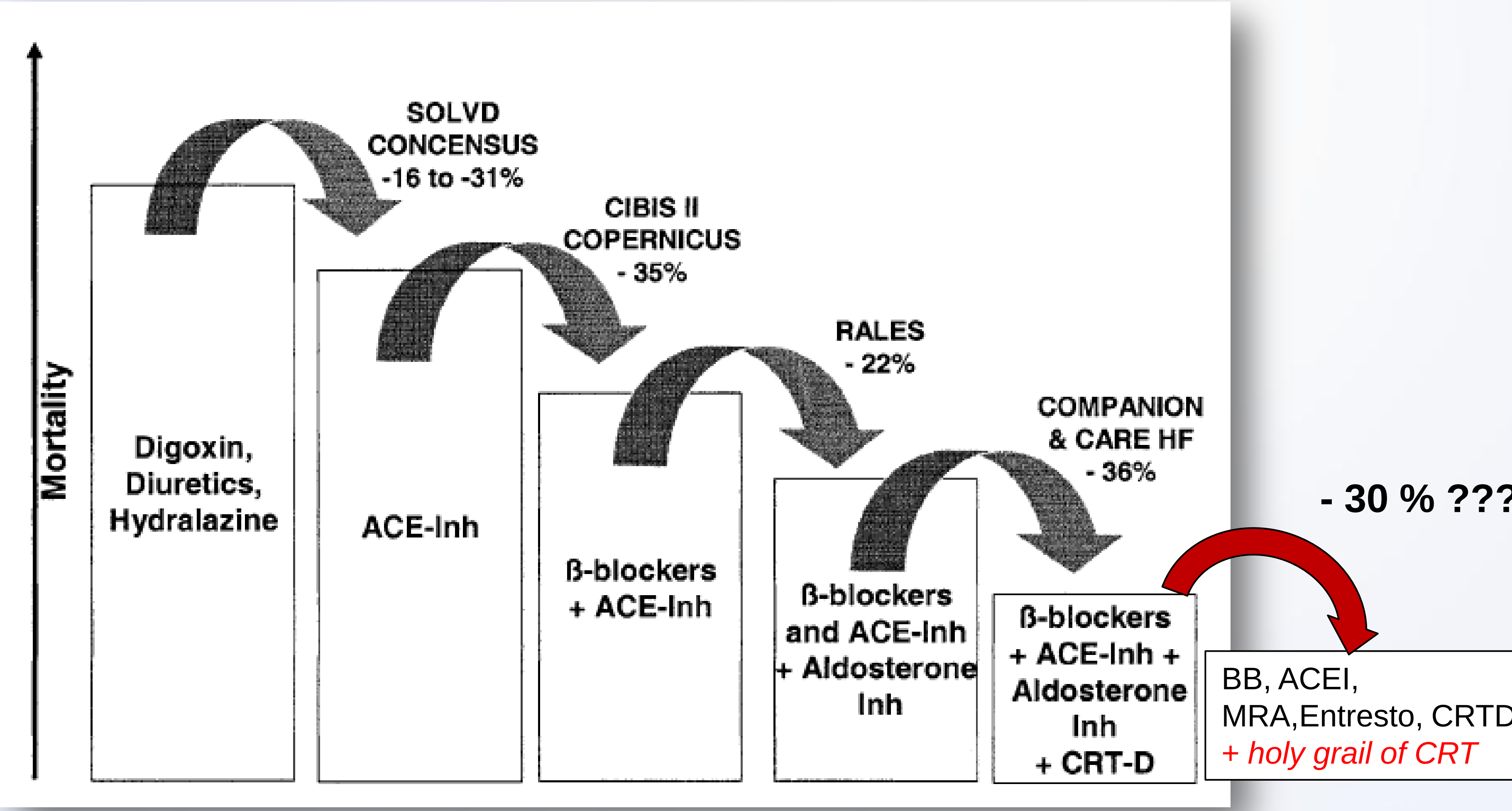
Postimplant

- Pharmacotherapy optimization
- AVN ablation in pts. with AFIB
- Reprogramming
- Remote monitoring
- Device-based optimization
- Management of complications

2019-….

4th revolution in device cardiology

EBM in HF



BB, ACEI,
MRA,Entresto, CRTD
+ holy grail of CRT

Hot topics in CRT

Multisite pacing

LV endocardial pacing

Combined strategies for HF and MR

- CRT
- Surgery
- Mitra-clip
- Intra-CS therapies

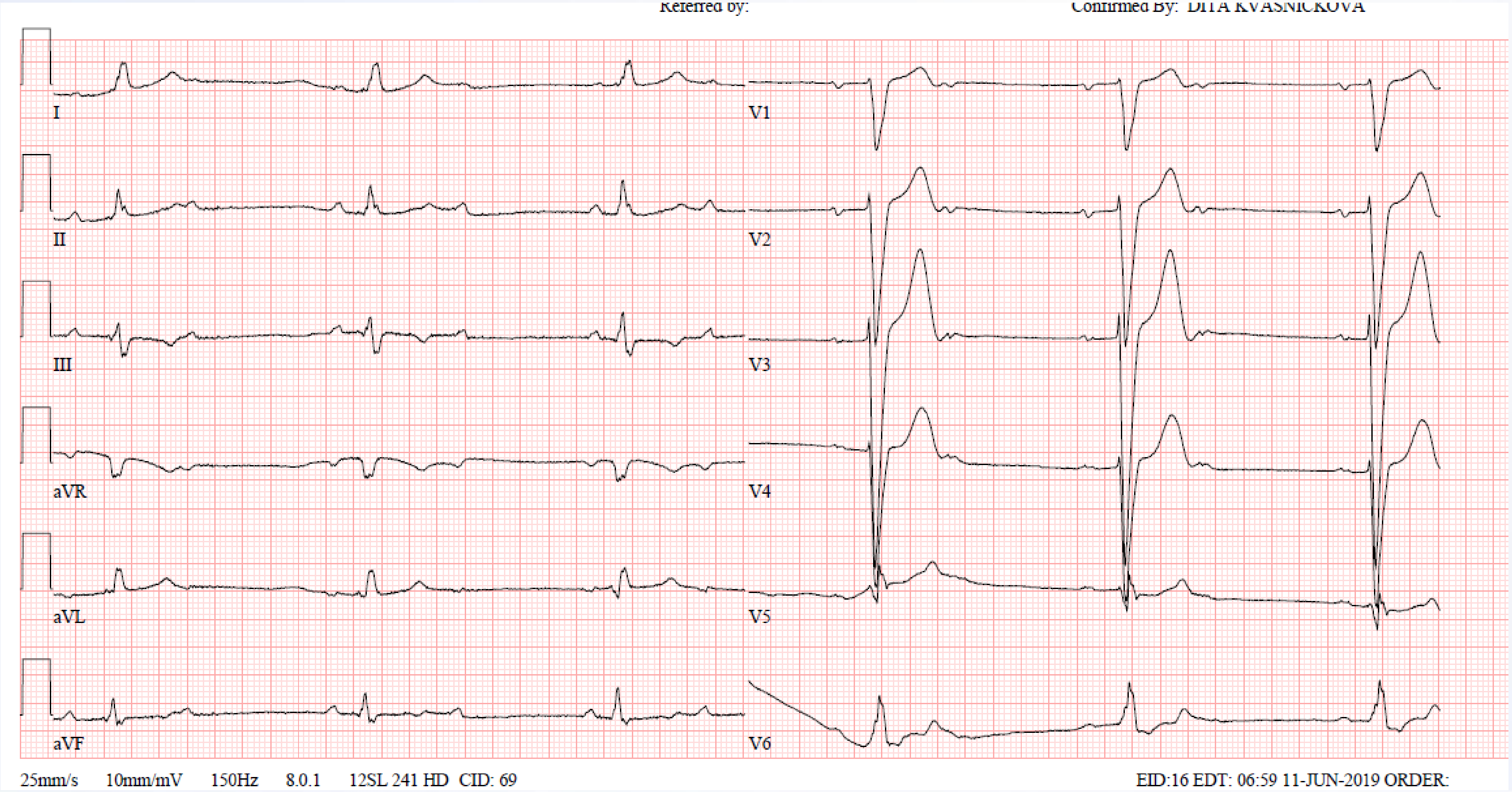
Direct conduction system pacing

Case presentation

- 36-year old man, previously healthy
- Nov 2018 admitted for AVB 3° - discharged after AV conduction normalized (ABx therapy for suspected Lyme borreliosis, neg. serology)
- June 2019 – admitted for AVB 3° recurrence
- Normal TTE, normal CMR, neg. Serology
- No significant family history

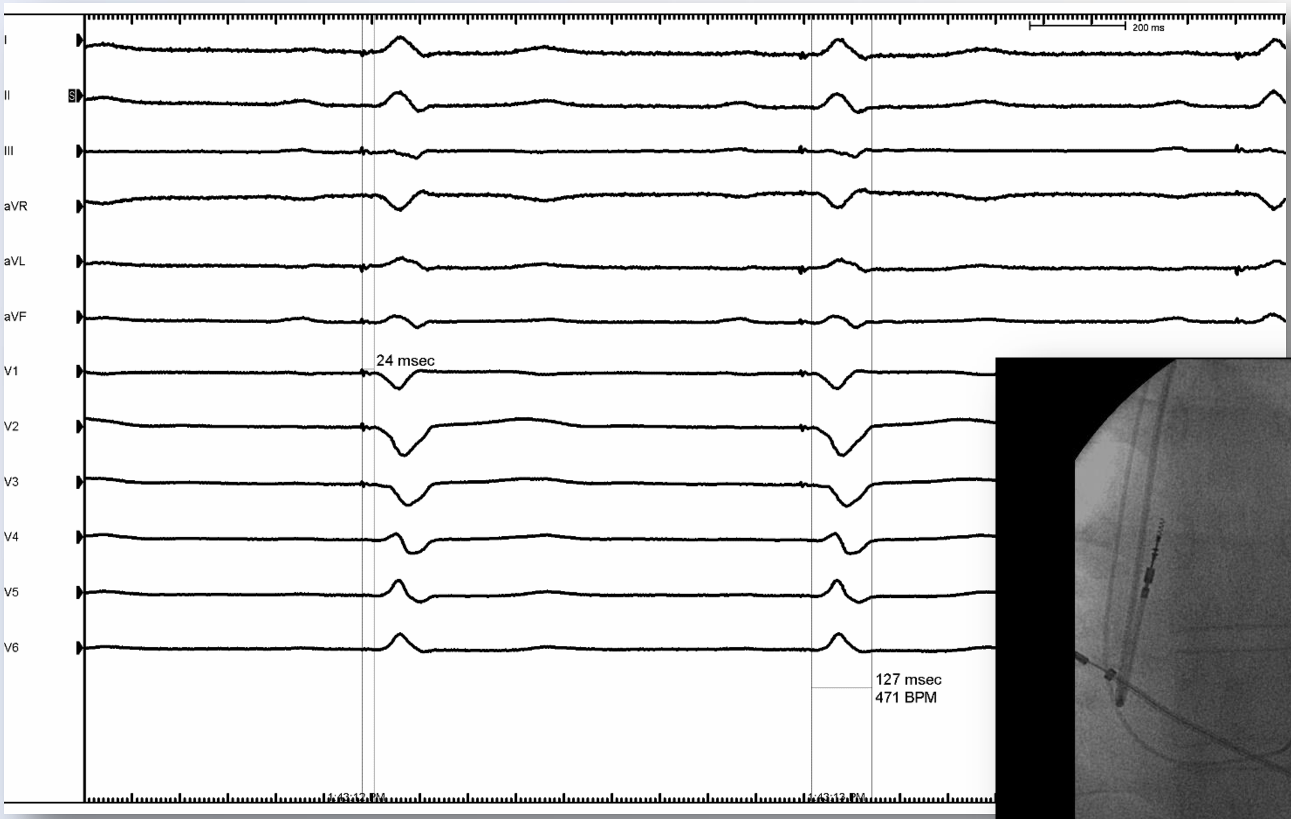
Direct conduction system pacing

Presenting ECG

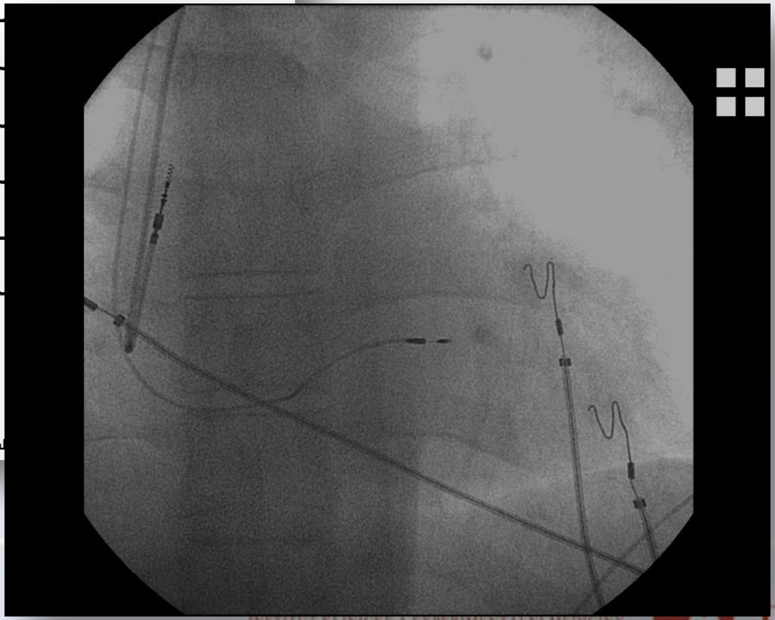


Direct conduction system pacing

Selective transseptal LBB pacing

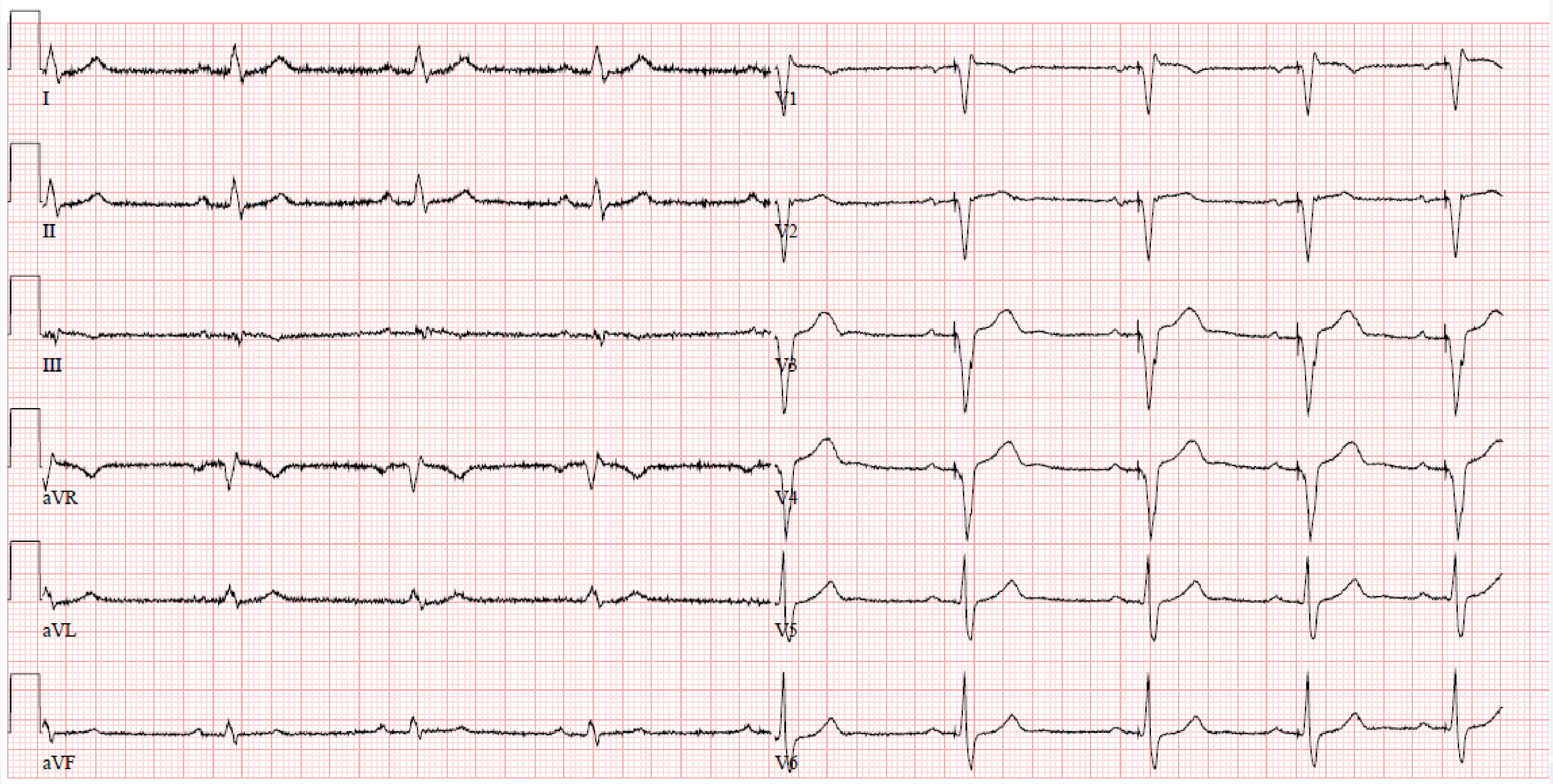


- Threshold 0,5V/0,4ms
- QRS 127 ms
- LB-V 24 ms
- Fluoro time 6 min
- Procedure 93 min
- Techs:
  - C315His
  - Select Secure lead



Direct conduction system pacing

Nonselective LBB pacing



Conclusions

CRT has evolved from sound physiological reasoning

Not too many therapies have comparable evidence

Technology has changed and currently meets implanters´ needs

Response to CRT is a continuum between super-response and harm

Comprehensive optimization of CRT delivery and follow-up may maximize benefit

Conduction system pacing is the most important disruptive tech/concept