

Indications for CRT
Israel
Data from the Israeli ICD Registry

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- Guidelines
- Israeli Guidelines
- Data from the Israeli ICD registry

Previous Recommendations

- Practice in Israel as to CRT implantation relied on the 2008 ACC/HRS recommendations and on the Israeli 2003 guidelines for CRT and the 2007 guidelines for ICD implantation
- We chose to follow the ESC 2010 recommendations in general, except for a few modifications based on new data from the MADIT CRT and RAFT studies

CRT in patients with heart failure in NYHA FC III-IV

- Most previous CRT studies included patients with
 - NYHA FC III-IV
 - LVEF<35%
 - LV dilatation (LVESD<55mm)
 - NSR
 - Wide QRS
 - Ambulatory class IV pts with no IV inotropes or mechanical support

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Cardiac-Resynchronization Therapy for Mild-to-Moderate Heart Failure

Anthony S.L. Tang, M.D., George A. Wells, Ph.D., Mario Talajic, M.D.,
Malcolm O. Arnold, M.D., Robert Sheldon, M.D., Stuart Connolly, M.D.,
Stefan H. Hohnloser, M.D., Graham Nichol, M.D., David H. Birnie, M.D.,
John L. Sapp, M.D., Raymond Yee, M.D., Jeffrey S. Healey, M.D.,
and Jean L. Rouleau, M.D., for the Resynchronization–Defibrillation
for Ambulatory Heart Failure Trial (RAFT) Investigators

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Cardiac-Resynchronization Therapy for the Prevention of Heart-Failure Events

Arthur J. Moss, M.D., W. Jackson Hall, Ph.D., David S. Cannom, M.D., Helmut Klein, M.D., Mary W. Brown, M.S.,
James P. Daubert, M.D., N.A. Mark Estes III, M.D., Elyse Foster, M.D., Henry Greenberg, M.D.,
Steven L. Higgins, M.D., Marc A. Pfeffer, M.D., Ph.D., Scott D. Solomon, M.D., David Wilber, M.D.,
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European Heart Journal (2010) 31, 2677–2687
doi:10.1093/eurheartj/ehq337

ESC GUIDELINES

2010 Focused Update of ESC Guidelines on device therapy in heart failure

An update of the 2008 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure and the 2007 ESC guidelines for cardiac and resynchronization therapy

Recommendation in patients with heart failure in New York Heart Association function class III/IV

Recommendation	Patient population	Class ^a	Level ^b	Ref. ^c
CRT-P/CRT-D is recommended to reduce morbidity and mortality ^d	NYHA function class III/IV LVEF ≤35%, QRS ≥120 ms, SR Optimal medical therapy Class IV patients should be ambulatory ^e	I	A	5–19

- In pts with an indication for ICD and with a life expectancy of 1 year – CRTD should be preferred over CRTP
- LV dilatation is no longer required to meet these criteria

Recommendation in patients with heart failure in New York Heart Association function class II

Recommendation	Patient population	Class ^a	Level ^b	Ref. ^c
CRT preferentially by CRT-D is recommended to reduce morbidity or to prevent disease progression ^d	NYHA function class II LVEF \leq 35%, QRS \geq 150 ms, SR Optimal medical therapy	I	A	9, 20–22

ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012

The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC

Recommendations for the use of CRT where the evidence is strong—patients in sinus rhythm with NYHA functional class III and ambulatory class IV heart failure and a persistently reduced ejection fraction, despite optimal pharmacological therapy

Recommendations	Class ^a	Level ^b	Ref ^c
<p>LBBB QRS morphology</p> <p>CRT-P/CRT-D is recommended in patients in sinus rhythm with a QRS duration of ≥ 120 ms, LBBB QRS morphology, and an EF $\leq 35\%$, who are expected to survive with good functional status for >1 year, to reduce the risk of HF hospitalization and the risk of premature death.</p>	I	A	156, 157
<p>Non-LBBB QRS morphology</p> <p>CRT-P/CRT-D should be considered in patients in sinus rhythm with a QRS duration of ≥ 150 ms, irrespective of QRS morphology, and an EF $\leq 35\%$, who are expected to survive with good functional status for >1 year, to reduce the risk of HF hospitalization and the risk of premature death.</p>	IIa	A	156, 157

Recommendations for the use of CRT where the evidence is strong—patients in sinus rhythm with NYHA functional class II heart failure and a persistently reduced ejection fraction, despite optimal pharmacological therapy

Recommendations	Class ^a	Level ^b	Ref ^c
<p>LBBB QRS morphology</p> <p>CRT, preferably CRT-D is recommended in patients in sinus rhythm with a QRS duration of ≥ 130 ms, LBBB QRS morphology, and an EF $\leq 30\%$, who are expected to survive for >1 year with good functional status, to reduce the risk of HF hospitalization and the risk of premature death.</p>	I	A	154, 155
<p>Non-LBBB QRS morphology</p> <p>CRT, preferably CRT-D should be considered in patients in sinus rhythm with a QRS duration of ≥ 150 ms, irrespective of QRS morphology, and an EF $\leq 30\%$, who are expected to survive for >1 year with good functional status, to reduce the risk of HF hospitalization and the risk of premature death.</p>	IIa	A	154, 155

**2012 ACCF/AHA/HRS Focused Update of the 2008
Guidelines for Device-Based Therapy of Cardiac
Rhythm Abnormalities**

**A Report of the American College of Cardiology Foundation/American
Heart Association Task Force on Practice Guidelines**

Class I

1. CRT is indicated for patients who have LVEF less than or equal to 35%, sinus rhythm, LBBB with a QRS duration greater than or equal to 150 ms, and NYHA class II, III, or ambulatory IV symptoms on GDMT. (Level of Evidence: A for NYHA class III/IV¹⁶⁻¹⁹; Level of Evidence: B for NYHA class II^{20,21})

Modified recommendation (specifying CRT in patients with LBBB of ≥ 150 ms; expanded to include those with NYHA class II symptoms).

Class IIa

1. CRT can be useful for patients who have LVEF less than or equal to 35%, sinus rhythm, LBBB with a QRS duration 120 to 149 ms, and NYHA class II, III, or ambulatory IV symptoms on GDMT.^{16-18,20-22} (Level of Evidence: B)
2. CRT can be useful for patients who have LVEF less than or equal to 35%, sinus rhythm, a non-LBBB pattern with a QRS duration greater than or equal to 150 ms, and NYHA class III/ambulatory class IV symptoms on GDMT.^{16-18,21} (Level of Evidence: A)
3. CRT can be useful in patients with atrial fibrillation and LVEF less than or equal to 35% on GDMT if a) the patient requires ventricular pacing or otherwise meets CRT criteria and b) AV nodal ablation or pharmacologic rate control will allow near 100% ventricular pacing with CRT.^{23-26,26a,48} (Level of Evidence: B)
4. CRT can be useful for patients on GDMT who have LVEF less than or equal to 35% and are undergoing new or replacement device placement with anticipated requirement for significant (>40%) ventricular pacing.^{25,27-29} (Level of Evidence: C)

New recommendation

New recommendation

Modified recommendation (wording changed to indicate benefit based on ejection fraction rather than NYHA class; level of evidence changed from C to B).

Modified recommendation (wording changed to indicate benefit based on ejection fraction and need for pacing rather than NYHA class); class changed from IIb to IIa).

עדכון התוויות להשתלת CRT

מסמך עדכון ואימוץ ההמלצות האירופאיות של

האיגוד הקרדיולוגי בישראל
ISRAEL HEART SOCIETY

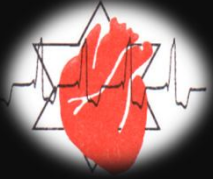


מטעם החוג לקיצוב ואלקטרופיזיולוגיה והחוג לאי ספיקת לב

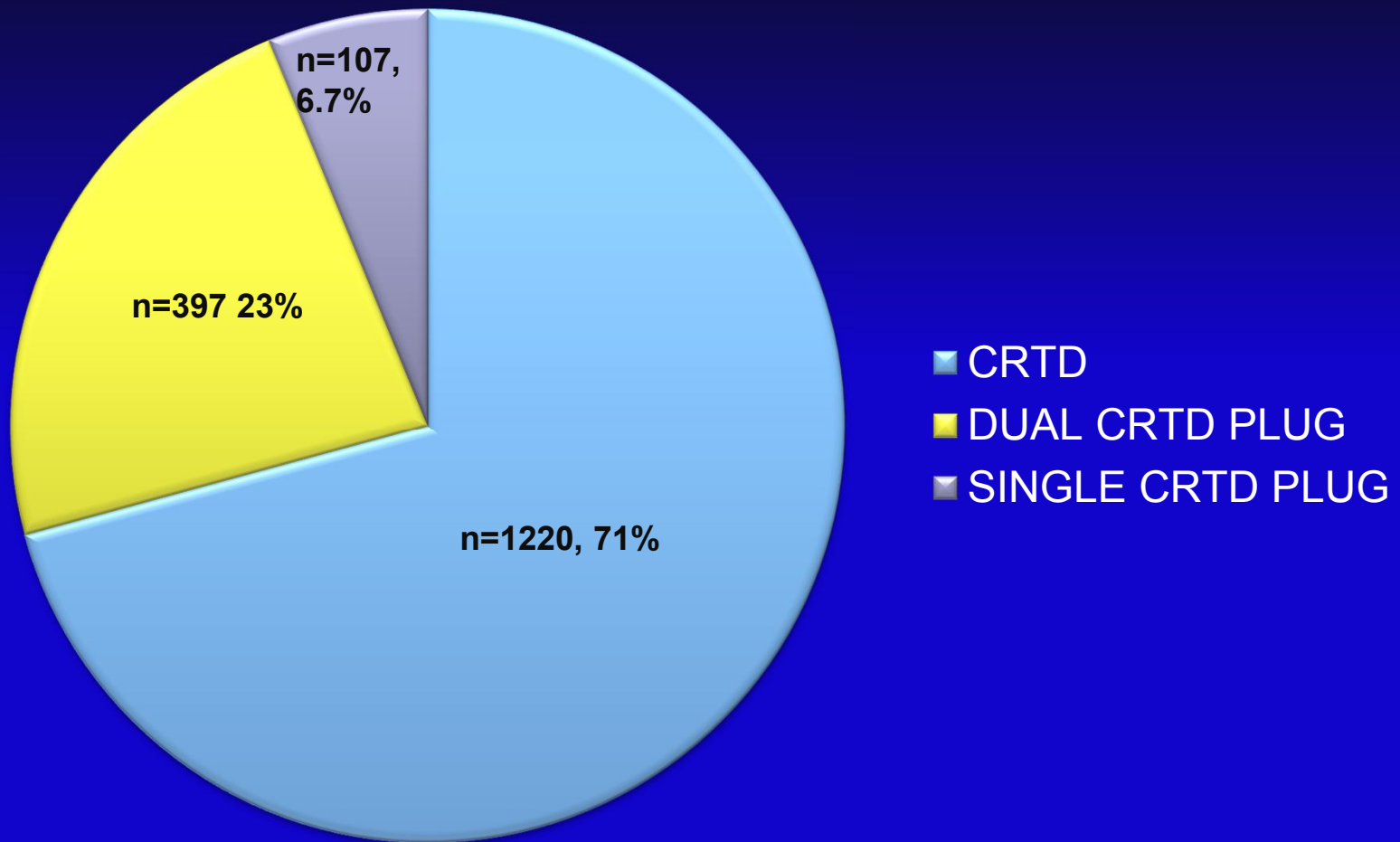
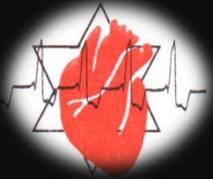
יוני 2011

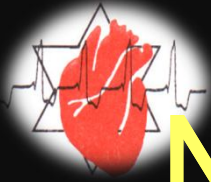
המלצה עדכנית: השתלת קד"ח עם או בלי דפיברילטור לצורך הפחתת תחלואה ותמותה: בחולים עם א"ס לב ומקטע פליטה קטן מ 35%, QRS רחב מ 120 מ"ש, בקצב סינוס ודרגה תפקודית III או IV אמבולטוריים.

1. קיצוב דו חדרי מסנכרן (CRT), בעדיפות באמצעות CRTD (בהתאם להתוויות ICD) מומלץ על מנת להפחית תחלואה ולמנוע התקדמות המחלה, בחולים שמתקיימים בהם התנאים הבאים: אי ספיקת לב דרגה II, LVEF < 30%, רוחב מקטע QRS גדול מ 150 מ"ש, הנמצאים בקצב סינוס ואשר מקבלים טיפול תרופתי אופטימלי. דרגת ההמלצה IA.
2. אנו ממליצים על CRT – ובעדיפות ל CRTD בחולים עם תבנית LBBB גם אם ה QRS צר מ 150 מ"ש. ורחב מ 120 מ"ש (דרגת המלצה LOE IIA = A).



- There were 3116 ICD implants from July 2010- to October 2012
- Of them CRTD devices 1724 (55%)

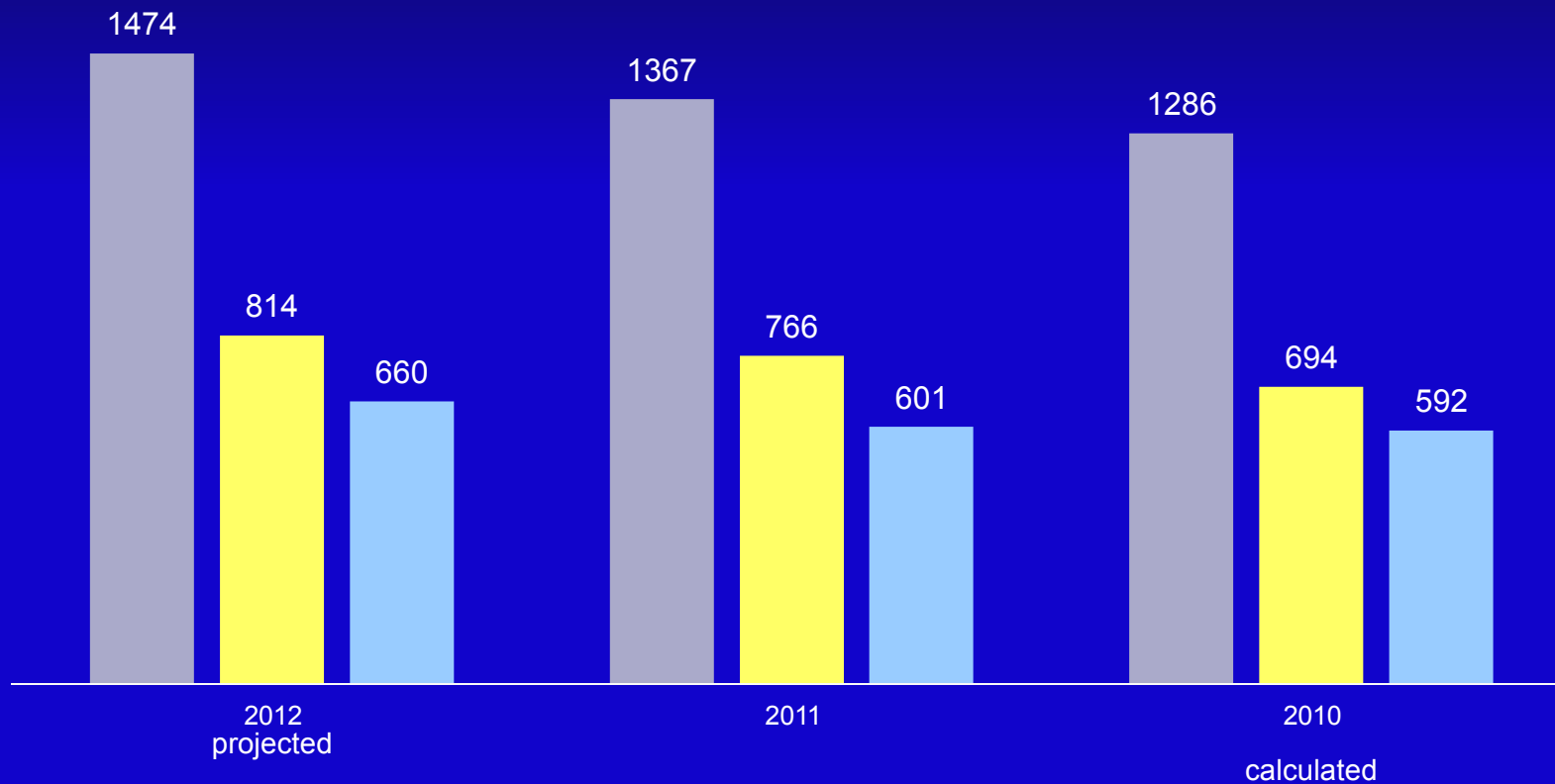


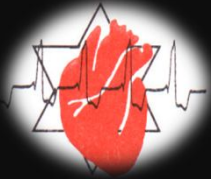


New ICD and CRTD implants 2010-2012

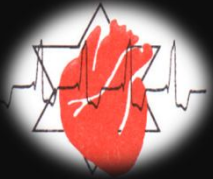
New Implants

■ ICD ■ CRTD ■ TOTAL

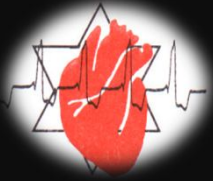




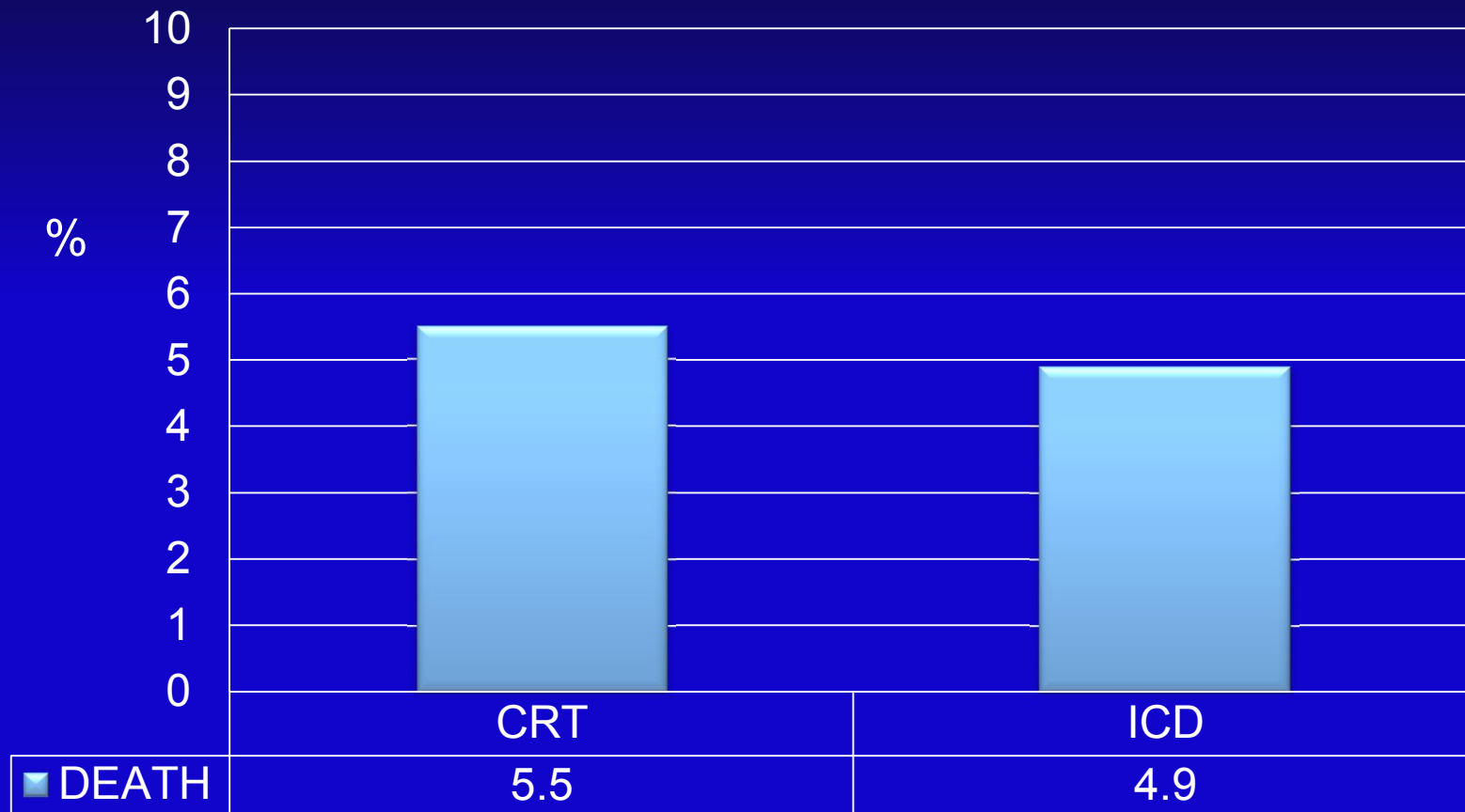
	ICD	CRTD
*Age (mean±SD)	62±15	67±11
*Prim Prevention	62%	84%
*Secondary Prevention	38%	16%
*CHF	60%	94%
*NYHA II	63%	34%
*NYHA III-IV	19%	61%
*LVEF<30%	37%	69%
*QRS (ms)MEDIAN	100	133

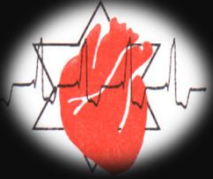


	ICD	CRTD
LBBB	39%	79%
RBBB	47%	12%
IVCD	9%	5%
Paced	5%	4%
Non Ischemic CMP	17%	25%
AF	17%	25%

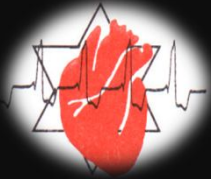


1-year DEATH





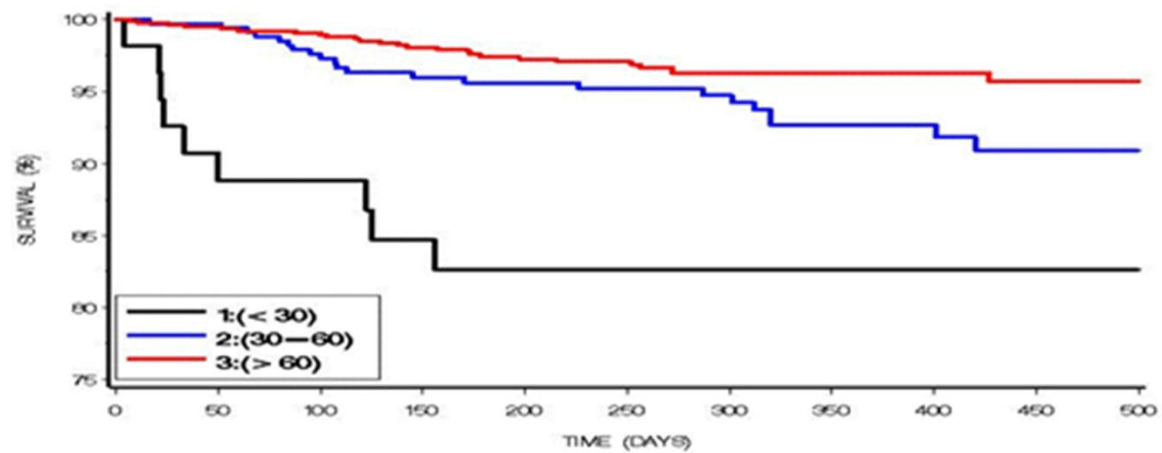
Sub Analyses



GFR

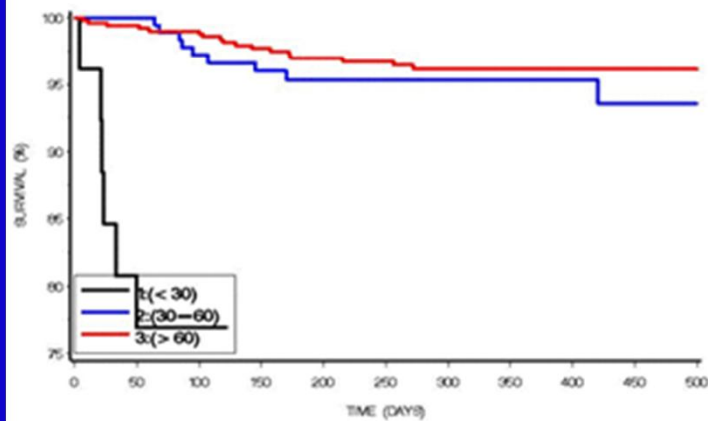
LETHAL OUTCOME BY GFR GROUPS

P(log_rank) < 0.001



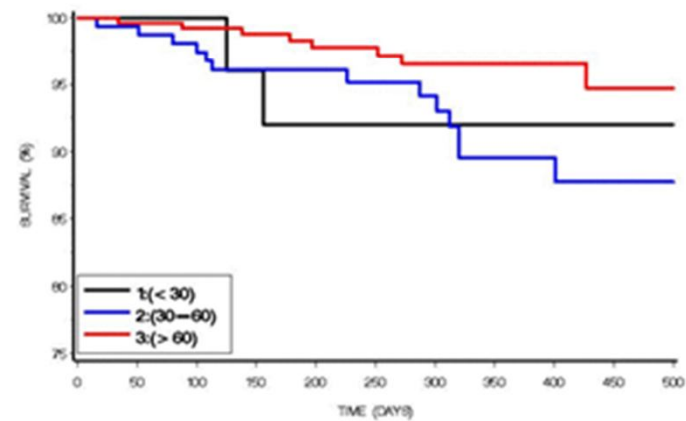
LETHAL OUTCOME BY GFR GROUPS IN ICD PATIENTS

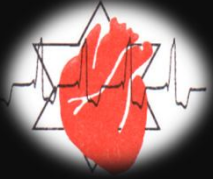
P(log_rank) < 0.0001



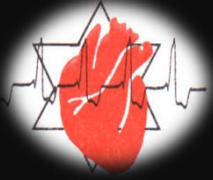
LETHAL OUTCOME BY GFR GROUPS IN CRTD PATIENTS

P(log_rank) = 0.055



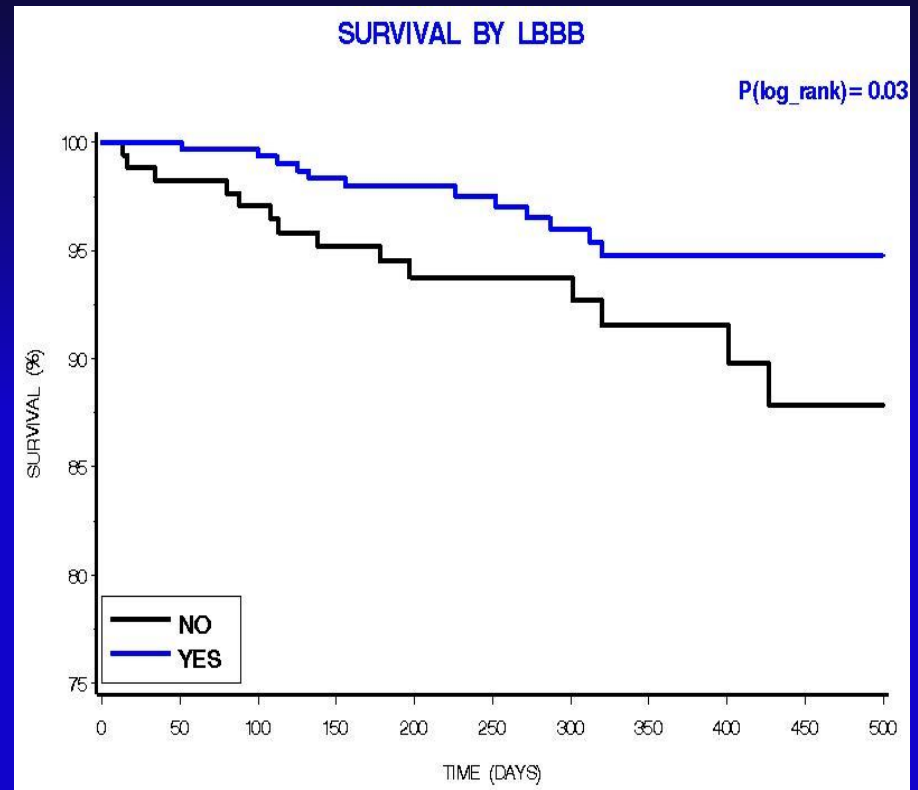


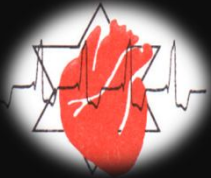
- There were 3116 ICD implants from July 2010- to October 2012
- Of them CRTD devices 1724 (55%)



LBBB CRT pts.

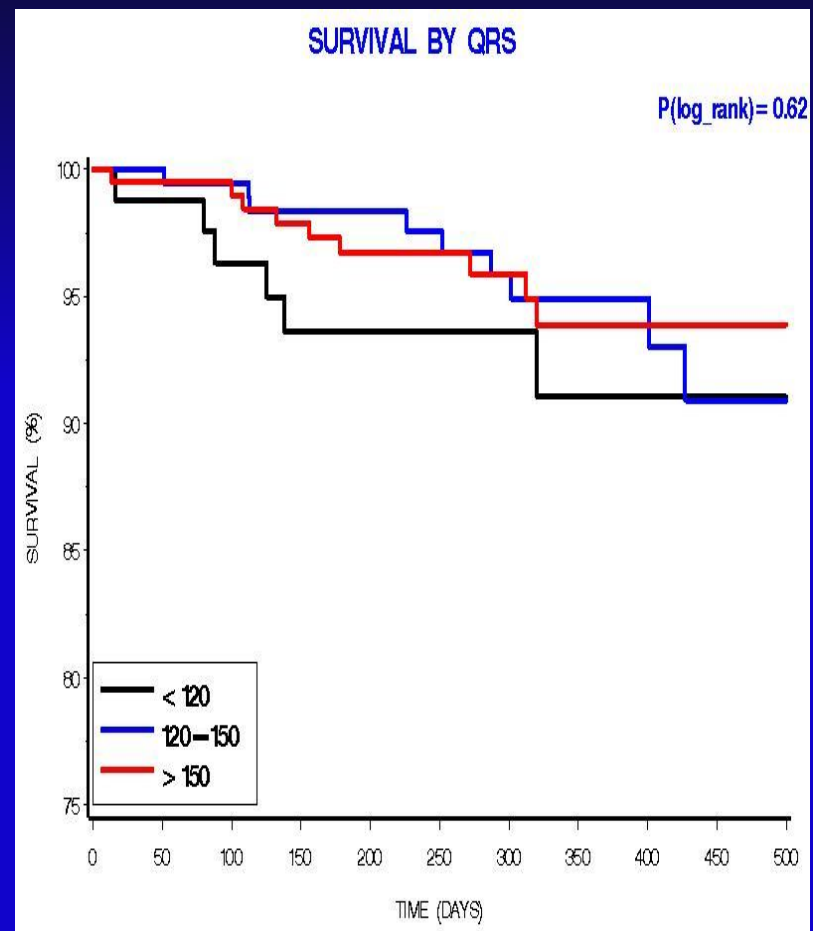
	LBBB	NON LBBB
Mortality	3.6%	8.7%





QRS Width

	<120	120-150	>150
	7.3%	5.3%	4.4%





CRT implant trend in ISRAEL

Country Population	2007	2008	2009	2010	2011
Ehra WhiteBook	7.112.359	7.112.359	7.233.269	7.353.985	7.473.052

CRT-P	2007	2008	2009	2010	2011
Ehra WhiteBook	79	123	154	105	100
Israeli ICD National Registry					
Data used in the model					
CRT-D	2007	2008	2009	2010	2011
Ehra WhiteBook	489	699	838	720	627
Israeli ICD National Registry				694 + replacements	766 + replacements
Data used in the model					



Estimate of CRT penetration in ISRAEL



Population (year 2011):
7.473.052 (EHRA WhiteBook 2012)

HF prevalence range:
~ 75.000 ÷ 150.000

CRT-indication prevalence range:
~ 7.500 ÷ 15.000

Pts with a CRT implanted*:
~ 4.965

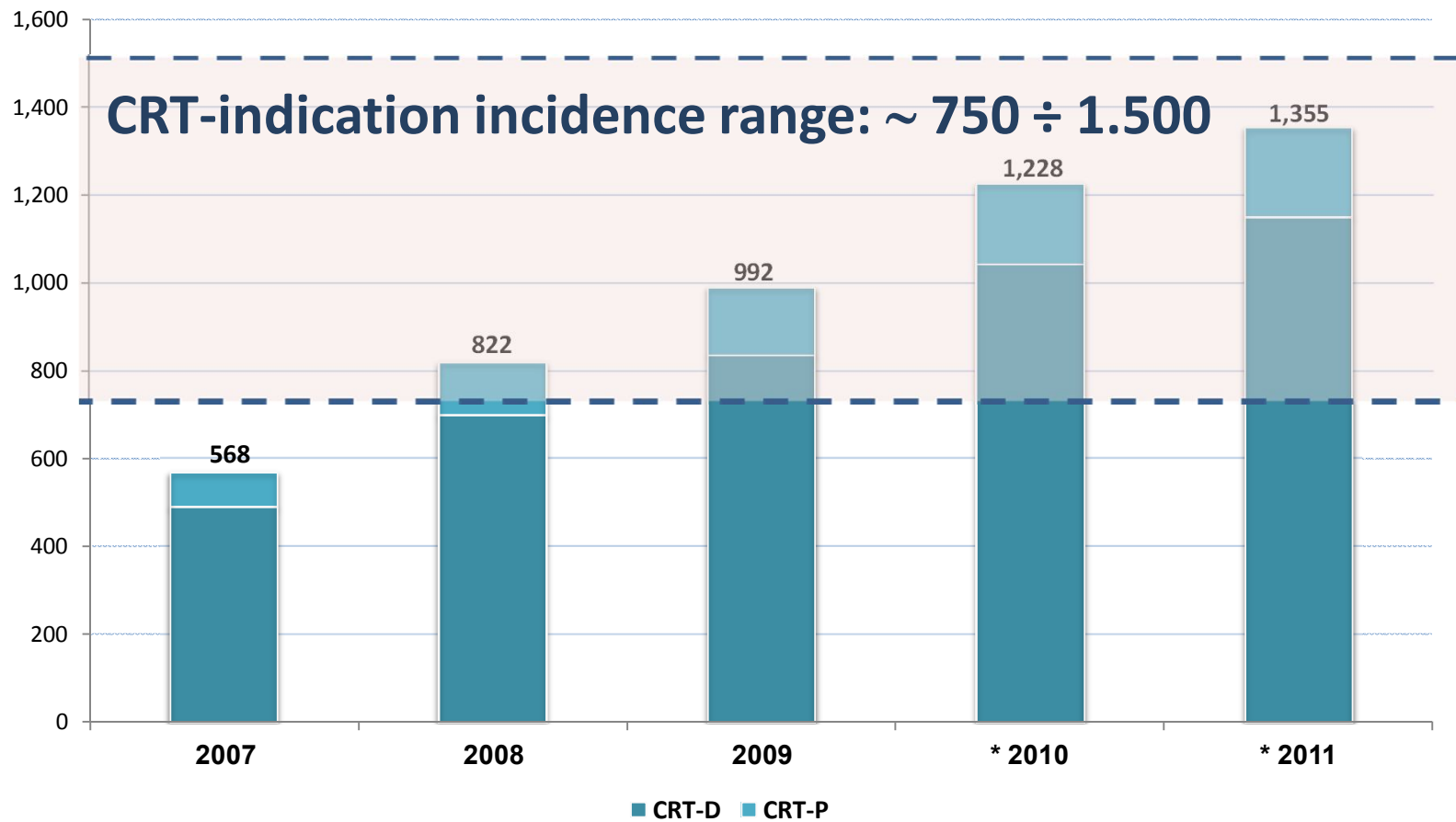
Estimated CRT Penetration Prevalence range: ~ 33 ÷ 66 %

** Estimated as 5-year cumulative CRTP+CRTD implants (from 2007 to 2011) from EHRA White Book and from Israeli ICD Registry*



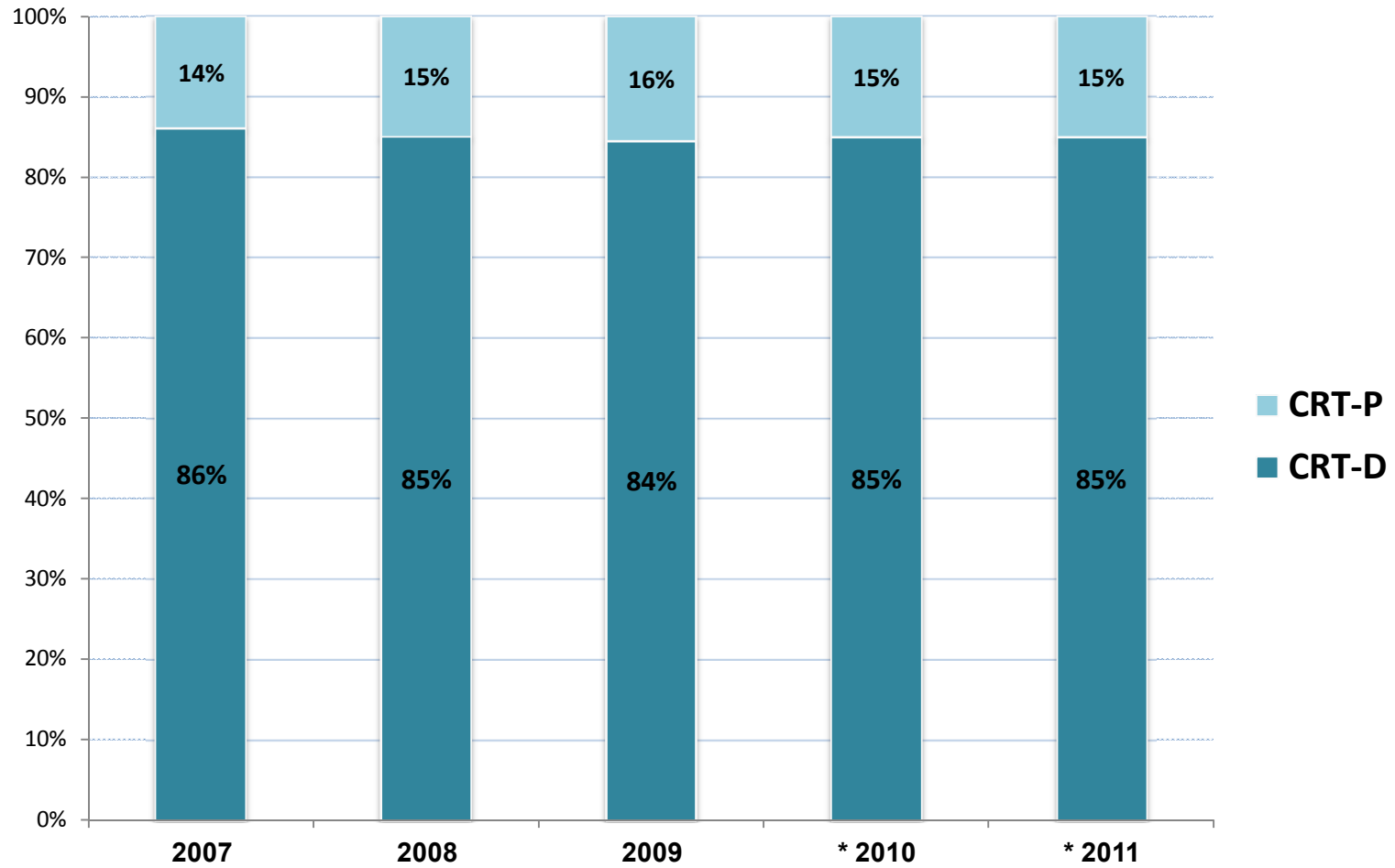
CRT implant trend and indication incidence range in ISRAEL

CRT implant rate trend in ISRAEL





CRT-P / CRT-D Mix trend in ISRAEL



* Approx.



CRT implanting centers in ISRAEL

6. Cardiac resynchronization therapy devices

CRT units implanted and number of implanting centres		
	2010	2011
Total CRT units implanted	825	527
Thereof, CRT pacemaker	105	100
Thereof, CRT ICD	720*	627**

* including CRT-D with plug; ** full CRT with LV lead

Specialty performing implants	
Other: Cardiac electrophysiologists	100%



Obstacles to guidelines implementation in ISRAEL

Obstacles to guideline implementation	Ranking of importance*					
	1	2	3	4	5	
Lack of centres	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2
Lack of reimbursement, limited financial resources	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2
Lack of referral	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3
Lack of trained personnel	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7
Low awareness of guidelines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6
Lack of operators	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7

1 = no obstacle

5 = great obstacle

* (1 = top; 7 = lowest)



Main factors affecting for CRT implementation

- Lack of sufficient Infrastructure (LABS)
- Lack of Proper Reimbursement for Public Hospitals
- Lack of enough trained implanting physicians
- Lack of awareness by general cardiologists and Primary Care physicians
- Knowledge of Guidelines- up to date

Thank You

- Israeli ICD Registry
- Boston Scientific
- Israeli Society for Prevention of Heart Attacks

Moti Haim, MD