ICD and CRT – Benefit and Guideline -focused on primary prevention of SCD

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COI Disclosure

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ICD

Defibrillator Implantation in Patients with Nonischemic Systolic Heart Failure

Ix : Non-ischemic DCM (LV EF ≤ 35 %)
FU : 67.6 Mo
Primary endpoint : death from any cause
Secondary endpoint : SCD, CV death, Cardiac arrest

Characteristic	ICD Group (N=556)	Control Group (N=560)
Median age (IQR) — yr	64 (56–72)	63 (56–70)
Median left ventricular ejection fraction (IQR) — %	25 (20–30)	25 (20–30)
Median estimated GFR (IQR) — ml/min/1.73 m^2	74 (58–91)	73 (58–92)
Medications — no. (%)		
ACE inhibitor or ARB	533 (96)	544 (97)
Beta-blocker	509 (92)	517 (92)
Mineralocorticoid-receptor antagonist	326 (59)	320 (57)
Amiodarone	34 (6)	32 (6)
CRT — no. (%)	322 (58)	323 (58)
Preexisting pacemaker or CRT pacemaker — no. (%)	56 (10)	46 (8)

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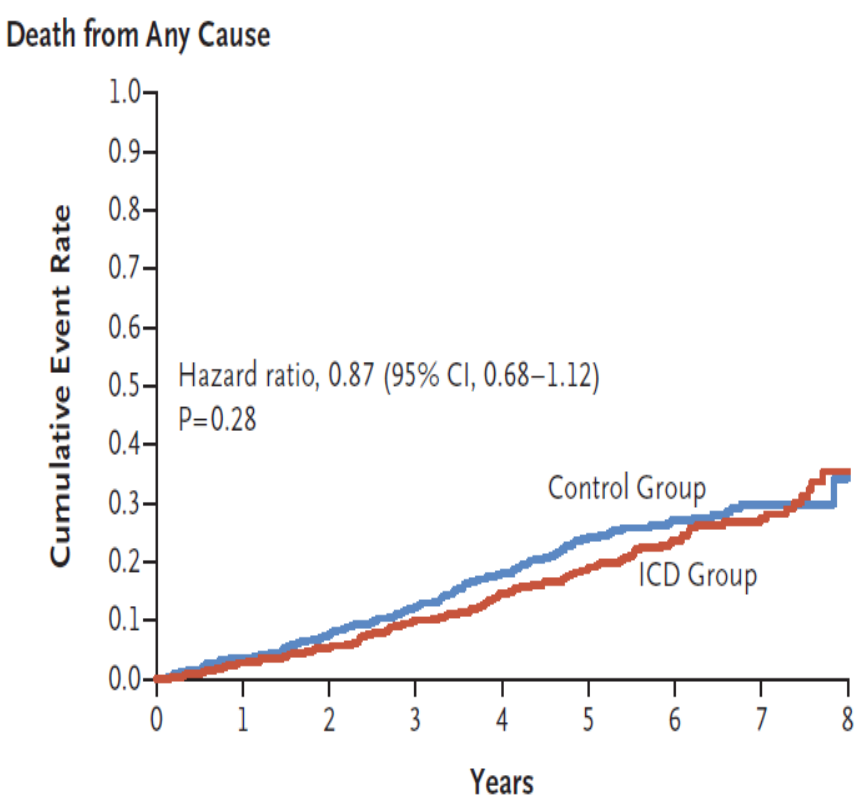
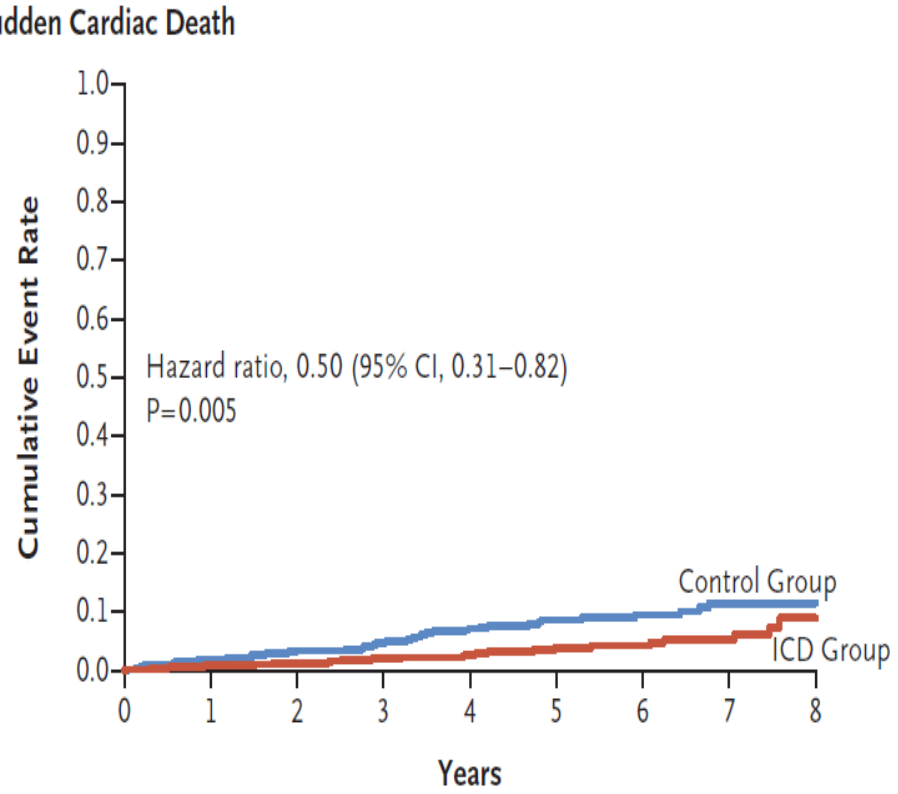
Defibrillator Implantation in Patients with Nonischemic Systolic Heart Failure





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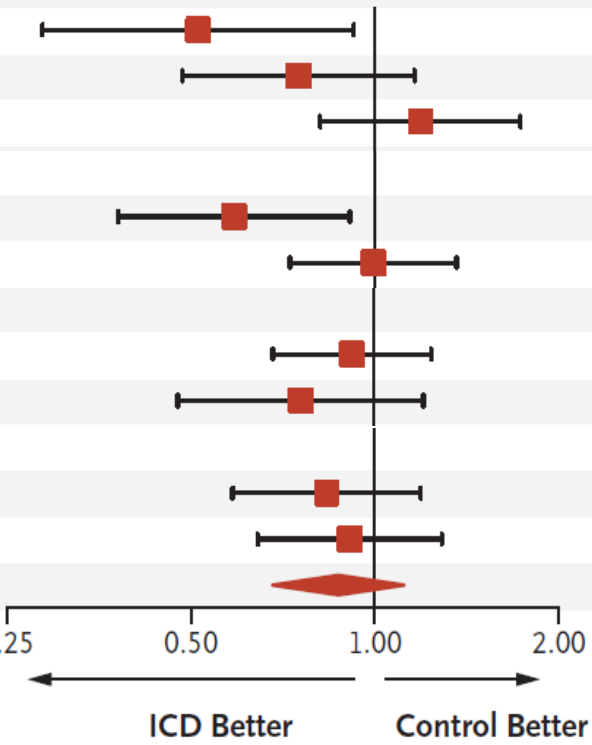
Defibrillator Implantation in Patients with Nonischemic Systolic Heart Failure

Rate of death from any cause

Subgroup	ICD Group	Control Group	Hazard Ratio (95% CI)	P Value
	no. of events/total no.			
Age				
<59 yr	17/167	34/181	0.51 (0.29–0.92)	0.02
≥59 to <68 yr	36/173	50/202	0.75 (0.48–1.16)	0.19
≥68 yr	67/216	47/177	1.19 (0.81–1.73)	0.38
NT-proBNP				
<1177 pg/ml	32/266	74/268	0.59 (0.38–0.91)	0.02
≥1177 pg/ml	57/292	88/290	0.99 (0.73–1.36)	0.96
Permanent atrial fibrillation				
No	83/421	91/447	0.92 (0.68–1.24)	0.58
Yes	37/135	40/113	0.76 (0.48–1.20)	0.24
CRT				
No	58/234	65/237	0.83 (0.58–1.19)	0.31
Yes	62/322	66/323	0.91 (0.64–1.29)	0.59
Overall			0.87 (0.68–1.12)	0.28



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Mortality Effect of ICD in Primary Prevention of Nonischemic Cardiomyopathy: A Meta-Analysis of Randomized Controlled Trials

Publication	Country	Study Name	Study Size	Age Range (Years)	Mean/Median Duration of Follow-Up Period (Months)
Bansch[11]	Germany	The Cardiomyopathy Trial	104	41–63	22.8
Bardy[6]	USA	SCD-HeFT Trial	2521	51.2–69.2	45.5
Bristow[7]	USA	COMPANION Trial	1520	66–68	12.0
Kadish[12]	USA	DEFINITE Trial	458	20.3–83.9	29
Kober[13]	Denmark	DANISH Trial	1,116	56–72	67.6
Strickberger[14]	USA	AMIOVIRT Trial	103	58–72	24

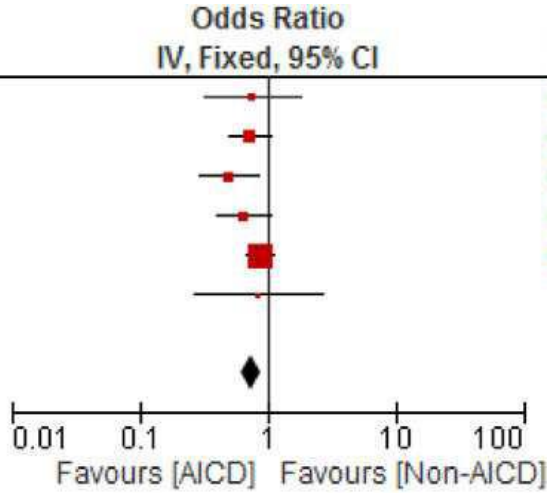
Study/Year	N	Study Cohorts (n)	Duration of Heart Failure	Mortality (n)	Age (Year)	Male (%)	DM (%)	HTN (%)	LV EF (%)	CRT (%)
Bansch[11]	104	ICD (n = 50)	3 m	13(26%)	52	43	–	–	24	–
		Control (n = 54)	2.5 m	17(31%)	52	40			25	
Bardy H[6]	2,521	Amio (n = 845)	–	240 (28%)	60.4	76	29	56	25	–
		Placebo (n = 847)	–	244 (29%)	59.7	77	32	56	25	
		ICD (n = 829)	–	182 (22%)	60.1	77	31	55	24	
Bristow[7]	1,520	OMT (n = 308)	3.6 yr	77(25%)	68	69	45	–	22	
		Pacer (n = 617)	3.7 yr	131(21%)	67	67	39		20	67
		Pacer-D (n = 595)	3.5 yr	105(18%)	66	67	41		22	66
Kadish[12]	458	Standard (n = 229)	3.27 yr	40(17%)	58.1	69.9	23.1	–	21.8	–
		ICD (n = 229)	2.39 yr	28(12%)	58.4	72.5	22.7		20.9	
Kober[13]	1,116	ICD (n = 556)	20 m	120(22%)	64	27	18	33	25	58
		Control (n = 560)	18 m	131(23%)	63	28	20	30	25	58
Strickberger[14]	103	Amio (n = 52)	3.5 yr	7(13%)	60	74	36	67	23	–
		ICD (n = 51)	2.9 yr	6(12%)	58	67	31	58	22	

JCE 2017; in press

Mortality Effect of ICD in Primary Prevention of Nonischemic Cardiomyopathy: A Meta-Analysis of Randomized Controlled Trials

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Fixed, 95% CI
Bansch 2002	-0.2683	0.4357	4.2%	0.76 [0.33, 1.80]
Bardy 2005	-0.3127	0.1941	21.2%	0.73 [0.50, 1.07]
Bristow 2004	-0.6931	0.2779	10.3%	0.50 [0.29, 0.86]
Kadish 2004	-0.429	0.2486	12.9%	0.65 [0.40, 1.06]
Kober 2016	-0.1362	0.1273	49.2%	0.87 [0.68, 1.12]
Strickberger 2003	-0.1542	0.595	2.3%	0.86 [0.27, 2.75]
Total (95% CI)			**100.0%**	**0.76 [0.64, 0.91]**

Heterogeneity: Chi² = 3.92, df = 5 (P = 0.56); I² = 0%
Test for overall effect: Z = 3.08 (P = 0.002)



Study/Year	N	Study Cohorts (n)	Duration of Heart Failure	Mortality (n)	Atrial Fib. (%)	BB (%)	ACE-I (%)	ALD-RB (%)
The cardiomyopathy	104	ICD (n = 50)	3 m	13(26%)	20.4	4	94	NA
		Control (n = 54)	2.5 m	17(31%)	11	3.7	98.1	NA
					28	–	12	
SCD-HeFT	521	Amio (n = 845)	–	240 (28%)	16	69	87	14
		Placebo (n = 847)	–	244 (29%)	14	69	85	16
		ICD (n = 829)	–	182 (22%)	17	69	83	14
COMPANION	520	OMT (n = 308)	3.6 yr	77(25%)	–	66	69	55
		Pacer (n = 617)	3.7 yr	131(21%)		68	70	53
		Pacer-D (n = 595)	3.5 yr	105(18%)		68	69	55
DEFINITE	458	Standard (n = 229)	3.27 yr	40(17%)	26.2	84.3	87.3	NA
		ICD (n = 229)	2.39 yr	28(12%)	22.7	85.6	83.8	NA
DANISH	116	ICD (n = 556)	20 m	120(22%)	24	92	96	59
		Control (n = 560)	18 m	131(23%)	20	92	97	57
AMIOVIRT	103	Amio (n = 52)	3.5 yr	7(13%)	–	50	81	19
		ICD (n = 51)	2.9 yr	6(12%)		53	90	20

JCE 2017; in press

Ix for ICD in pts with LV dysfunction

Recommendations	Class[a]	Level[b]
ICD therapy is recommended to reduce SCD in patients with symptomatic HF (NYHA class II–III) and LVEF ≤35% after ≥3 months of optimal medical therapy who are expected to survive for at least 1 year with good functional status:		
– Ischaemic aetiology (at least 6 weeks after myocardial infarction).	I	A
– Non-ischaemic aetiology.	I	B

Optimal medical Tx : ACEi, beta-blocker, mineralocorticoid Rc antagonist

ESC 2015, EHJ 2015;36:2793

Ix for ICD in pts with LV dysfunction –Korean insurance

(1) 심근경색 발생 후 40일 경과한 허혈성 심부전으로 적절한 약물치료에도 불구하고 아래에 해당하며 1년 이상 생존이 예상되는 경우

(가) 심구혈률(EF) ≤ 30%

(나) 심구혈률(EF) 31~35%로 NYHA class Ⅱ, Ⅲ의 증상을 보이는 경우

(다) 심구혈률(EF) ≤ 40% 환자로 비지속성 심실빈맥이 있으며 임상전기생리학적검사에서 혈역동학적으로 의미있는 심실세동이나 지속성 심실빈맥이 유발되는 경우

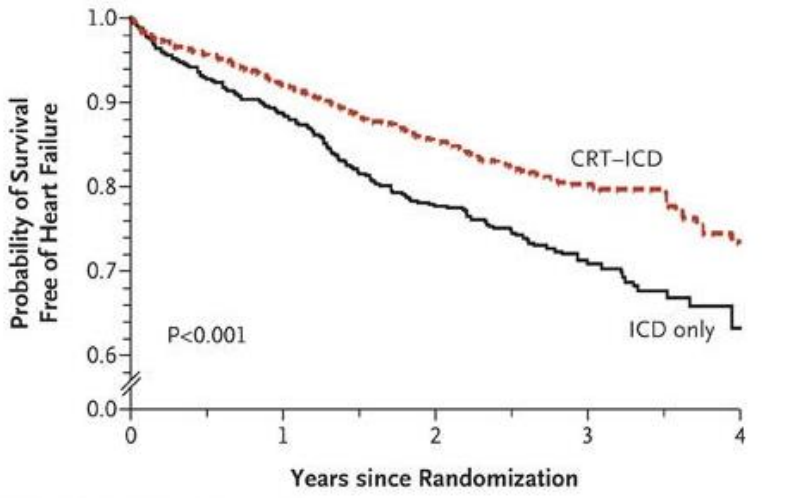
(2) 비허혈성 심부전으로 3개월 이상의 적절한 약물치료에도 불구하고 NYHA class Ⅱ, Ⅲ의 증상을 보이는 심구혈률(EF) ≤ 35%인 환자에서 1년 이상 생존이 예상되는 경우

CRT

CRT reduce the all-cause mortality

MADIT-CRT (2009)

Pt : ICD+CRT 1089 Pts, ICD 731 Pts
FU 4.5 yrs
Ix : EF < 30%, QRS > 130 ms

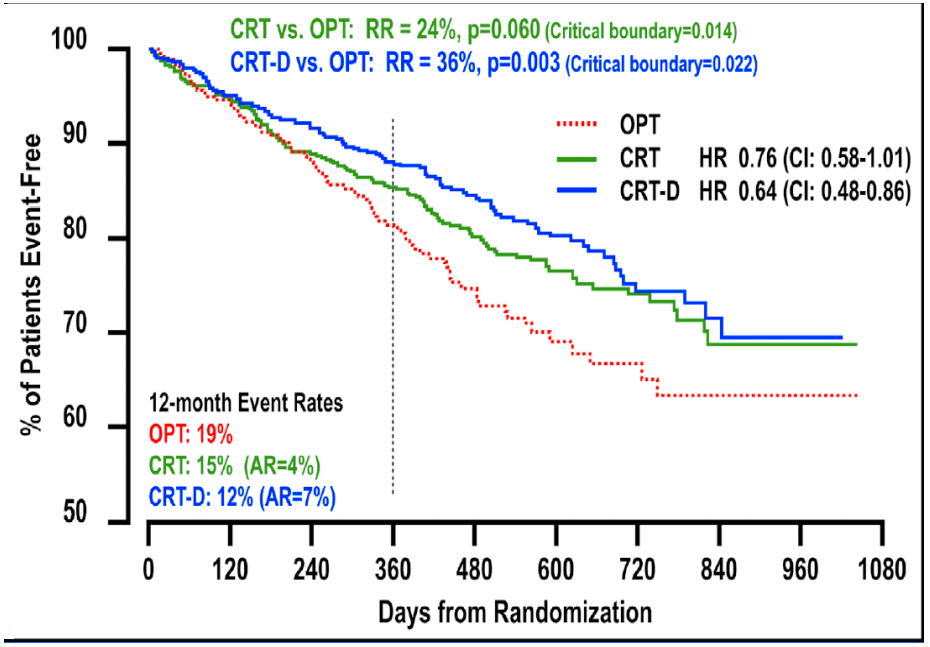


No. at Risk (Probability of Survival)

ICD only	731	621 (0.89)	379 (0.78)	173 (0.71)	43 (0.63)
CRT–ICD	1089	985 (0.92)	651 (0.86)	279 (0.80)	58 (0.73)

COMPANION (2004)

Pt : medical 308 Pts, ICD+CRT 595 Pts,
CRT 617 Pts
FU 12 mo
Ix : EF < 35%, QRS > 120 ms



Ix for CRT in Pts with sinus rhythm with LBBB (NYHA III/IV)

Recommendations	Class[a]	Level[b]
CRT is recommended to reduce all-cause mortality in patients with an LVEF ≤35% and LBBB despite at least 3 months of optimal pharmacological therapy who are expected to survive at least 1 year with good functional status:		
– With a QRS duration >150 ms	I	A
– With a QRS duration of 120–150 ms	I	B

ESC 2015, EHJ 2015;36:2793

Ix for CRT in Pts with sinus rhythm without LBBB (NYHA III/IV)

Recommendations	Class[a]	Level[b]
CRT should or may be considered to reduce all-cause mortality in patients with an LVEF ≤35% without LBBB despite at least 3 months of optimal pharmacological therapy who are expected to survive at least 1 year with good functional status:		
– With a QRS duration >150 ms	IIa	B
– With a QRS duration of 120–150 ms	IIb	B

ESC 2015, EHJ 2015;36:2793

Ix for CRT in Pts with sinus rhythm with LBBB (NYHA II)

Recommendations	Class[b]	Level[c]
CRT-D is recommended to reduce all-cause mortality in patients with a QRS duration ≥130 ms, with an LVEF ≤30% and with LBBB despite at least 3 months of optimal pharmacological therapy who are expected to survive at least 1 year with good functional status.	I	A
CRT-D may be considered to prevent hospitalization for HF in patients with a QRS duration ≥150 ms, irrespective of QRS morphology, and an LVEF ≤35% despite at least 3 months of optimal pharmacological therapy who are expected to survive at least 1 year with good functional status.	IIb	A

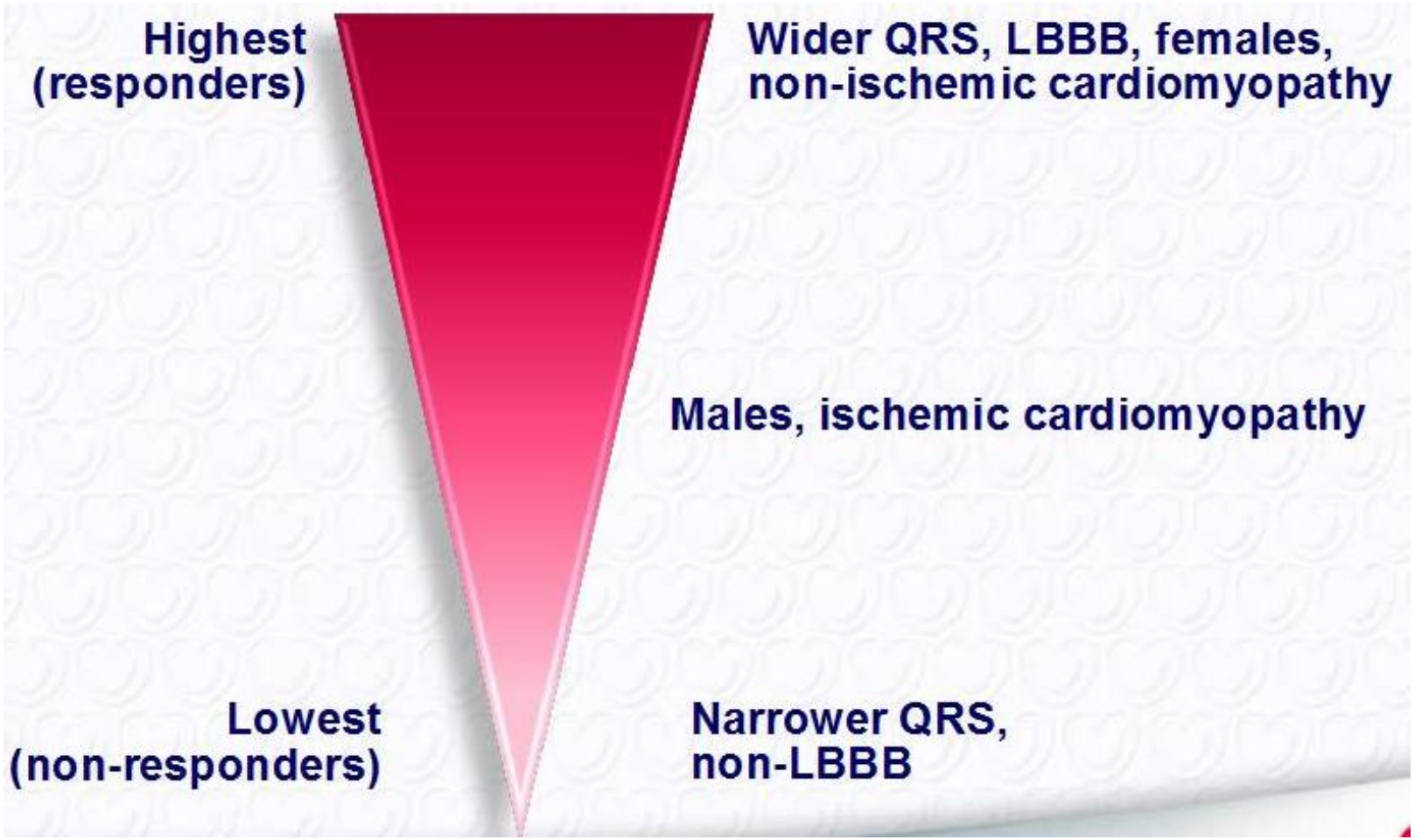
ESC 2015, EHJ 2015;36:2793

Ix for CRT in Pts with permanent AF (NYHA III/IV)

Recommendations	Class[a]	Level[b]
CRT should be considered to reduce all-cause mortality in patients with chronic HF, QRS ≥120 ms and LVEF ≤35% who remain in NYHA functional class III/ambulatory class IV despite at least 3 months of optimal pharmacological therapy who are expected to survive at least 1 year with good functional status, provided that biventricular pacing as close as possible to 100% can be achieved.	IIa	B
AV junction ablation should be considered in case of incomplete biventricular pacing.	IIa	B

ESC 2015, EHJ 2015;36:2793

Magnitude of benefit from CRT in sinus rhythm



ESC 2013, EHJ 2013;34:2281

Ix for CRT in pts with LV dysfunction – Korean insurance

가. CRT-P(CRT-Pacemaker)

3개월 이상의 적절한 약물치료에도 불구하고 증상이 지속되는 아래의 심부전 환자

(1) 동율동(Sinus Rhythm)의 경우

(가) QRS duration ≥ 120ms인 LBBB로 EF ≤ 35%,

NYHA class Ⅱ, Ⅲ, ambulatory class Ⅳ

(나) QRS duration ≥ 150ms인 NON-LBBB로 EF ≤ 35%,

NYHA class Ⅲ, ambulatory class Ⅳ

(2) 영구형 심방세동(Permanent atrial fibrillation)의 경우

(가) QRS duration ≥ 120ms, EF ≤ 35%, NYHA class Ⅲ, ambulatory class Ⅳ

(나) EF ≤ 35%에서 심박수 조절을 위해 방실결절차단술(AV junction ablation)

Ix for CRT in pts with LV dysfunction – Korean insurance

가. CRT-P(CRT-Pacemaker)

(3) 기존 Pacemaker나 ICD의 기능 향상이 필요한 경우

- LVEF ≤ 35%, NYHA class Ⅲ, ambulatory class IV 에서 심조율의 비율이 40% 이상인 경우

(4) Pacemaker의 적응증에 해당하는 경우 – AV Block

- LVEF ≤ 35%인 환자에서 심조율의 비율이 40% 이상 (3개월 이상의 적절한 약물치료가 없는 경우에도 인정 가능함.)

나. CRT-D(CRT-Defibrillator)

CRT-P와 ICD 기준에 모두 적합

가(1)에 해당, NYHA class Ⅱ인 경우에는 QRS duration ≥ 130ms인 LBBB이고 EF ≤ 30%인 경우.

Thank you for your attention

CRT-P vs CRT-D

Factors favouring CRT-D	Factors favouring CRT-P
Life expectancy >1 year	Advanced heart failure
Stable heart failure, NYHA II	Severe renal insufficiency or dialysis
Ischemic heart disease (low and intermediate MADIT risk score)	Other major co-morbidities
Lack of comorbidities	Frailty
	Cachexia

ESC 2013, EHJ 2013;34:2281