

Table D14: Outcomes reported in the trials assessing effectiveness of CRT-D (Hospitalization for heart failure and All-cause mortality)

Author,Year Trial	Arm(name)	Harms Units	N for analysis	Timepoint(s)	n (%) patients with outcomes	n (%) events with outcomes	Within Arm Comparisons	Between Arm Comparisons
Hospitalization for heart failure								
Tang,2010 ²² RAFT	ICD	Hospitalization for heart failure	904	NR	236(26.1)	NR	NR	HR: 0.68 95% CI: 0.56- 0.83
	ICD-CRT	Hospitalization for heart failure	894	NR	174(19.5)	NR	NR	NA
Healey-2012- ²⁵	ICD	Hospitalization for heart failure	115	12 months	NR(27.8)	NR	NR	HR: 0.58 95% CI: 0.38- 1.01
	CRT-ICD	Hospitalization for heart failure	114	12 months	NR(19.3)	NR	NR	NA
Diab, 2011, ³⁸	Arm 1	Hospitalization for heart failure	27	6 months	27()	2()	NR	NR
	Arm 2a	Hospitalization for heart failure	21	6 months	21()	1()	NR	NR
	Arm 2b	Hospitalization for heart failure	19 (unclear)	6 months	19 (unclear)()	2()	NR	NR
Birnle,2013 ²³ RAFT Sub Study	ICD-CRT (LBBB)	Hospitalization for heart failure	594	NR	104(17.5)	NR	NR	HR: 0.603 95% CI: 0.469- 0.774
	ICD-CRT (Non- LBBB)	Hospitalization for heart failure	143	NR	39(27.3)	NR	NR	HR: 1.085 95% CI: 0.702- 1.680
	ICD-CRT (RBBB)	Hospitalization for heart failure	60	NR	15(25)	NR	NR	HR: 1.142 95% CI: 0.580- 2.249
	ICD-CRT (NIVCD)	Hospitalization for heart failure	83	NR	24(28.9)	NR	NR	HR: 1.021 95% CI: 0.574- 1.815

Author,Year Trial	Arm(name)	Harms Units	N for analysis	Timepoint(s)	n (%) patients with outcomes	n (%) events with outcomes	Within Arm Comparisons	Between Arm Comparisons
	ICD(LBBB)	Hospitalization for heart failure	581	NR	151(26)	NR	NR	NR
	ICD(Non-LBBB)	Hospitalization for heart failure	165	NR	42(25.5)	NR	NR	NR
	ICD(RBBB)	Hospitalization for heart failure	81	NR	19(23.5)	NR	NR	NR
	ICD(NIVCD)	Hospitalization for heart failure	84	NR	23(27.4)	NR	NR	NR
Moss,2009 ⁹	ICD	Hospitalization for heart failure	731	NR	167(22.8)	NR	NR	HR: 0.59 95% CI: 0.47- 0.74
	CRT-D	Hospitalization for heart failure	1089	NR	151(13.9)	NR	NR	NA
Arshad,2011 ¹⁰	Women	Hospitalization for heart failure	453	6 months	73(NR)	NR	NR	HR: 0.3 95% CI: 0.18-0.5
	Men	Hospitalization for heart failure	1365	6 months	249(NR)	NR	NR	HR: 0.65 95% CI: 0.5- 0.84
	Women, Ischemic heart disease	Hospitalization for heart failure	125	6 months	23(NR)	NR	NR	HR: 0.31 95% CI: 0.12- 0.76
	men, Ischemic heart disease	Hospitalization for heart failure	874	6 months	180(NR)	NR	NR	HR: 0.58 95% CI: 0.43- 0.79
	Women, Non Ischemic heart disease	Hospitalization for heart failure	328	6 months	50(NR)	NR	NR	HR: 0.31 95% CI: 0.17- 0.56
	men, Non Ischemic heart	Hospitalization for heart	493	6 months	69(NR)	NR	NR	HR: 0.88 95% CI: 0.54-

Author,Year Trial	Arm(name)	Harms Units	N for analysis	Timepoint(s)	n (%) patients with outcomes	n (%) events with outcomes	Within Arm Comparisons	Between Arm Comparisons
	disease	failure						1.45
	Women, QRS <150ms	Hospitalization for heart failure	148	6 months	23(NR)	NR	NR	HR: 0.26 95% CI: 0.1- 0.65
	Men, QRS <150ms	Hospitalization for heart failure	497	6 months	107(NR)	NR	NR	HR: 1.08 95% CI: 0.71- 1.6
	Women, QRS >=150ms	Hospitalization for heart failure	305	6 months	50(NR)	NR	NR	HR: 0.31 95% CI: 0.17- 0.58
	Men, QRS >=150ms	Hospitalization for heart failure	870	6 months	142(NR)	NR	NR	HR: 0.45 95% CI: 0.32- 0.64
	Women, Non LBBB	Hospitalization for heart failure	59	6 months	10(NR)	NR	NR	HR: 1.95 95% CI: 0.4- 9.53
	Men, Non LBBB	Hospitalization for heart failure	478	6 months	96(NR)	NR	NR	HR: 1.04 95% CI: 0.67- 1.61
	Women, LBBB	Hospitalization for heart failure	394	6 months	63(NR)	NR	NR	HR: 0.22 95% CI: 0.12- 0.4
	Men, LBBB	Hospitalization for heart failure	887	6 months	153(NR)	NR	NR	HR: 0.47 95% CI: 0.34- 0.66
Barsheshet, 2011 ¹¹	All Ischemia	Hospitalization for heart failure	1046	6 months	NR	NR	NR	HR: 0.58 95% CI: 0.45- 0.77
	Ischemia NYHA II	Hospitalization for heart failure	781	6 months	NR	NR	NR	HR: 0.57 95% CI: 0.41- 0.77
	Non Ischemia	Hospitalization for heart failure	774	6 months	NR	NR	NR	HR: 0.5 95% CI: 0.35-0.75
Zareba, 2011 ²¹	LBBB	Hospitalization	1281	6 months	NR	NR	NR	HR: 0.41

Author,Year Trial	Arm(name)	Harms Units	N for analysis	Timepoint(s)	n (%) patients with outcomes	n (%) events with outcomes	Within Arm Comparisons	Between Arm Comparisons
MADIT CRT Sub Study		for heart failure						95% CI: 0.31-0.54
	Non LBBB	Hospitalization for heart failure	536	6 months	NR	NR	NR	HR: 1.23 95% CI: 0.76-1.68
	RBBB	Hospitalization for heart failure	228	6 months	NR	NR	NR	HR: 0.88 95% CI: 0.46-1.67
	IVCD	Hospitalization for heart failure	308	6 months	NR	NR	NR	HR: 1.31 95% CI: 0.78-2.18
Higgins,2003 ⁴⁰ VENTAK CHF/CONTAK CD	CRT	Hospitalization for heart failure	245	6 months	32(13.1)	NR	NR	NR
	No CRT	Hospitalization for heart failure	245	6 months	39(16)	NR	NR	NR
All-cause mortality								
Tang,2010 ²² RAFT	ICD	All-cause mortality	904	NR	236(26.1)	NR	NR	HR: 0.75 95% CI: 0.62-0.91
	ICD-CRT	All-cause mortality	894	NR	186(20.8)	NR	NR	NA
Higgins,2003 ⁴⁰ VENTAK CHF/CONTAK CD	CRT	All-cause mortality	245	6 months	11(4.5)	NR	NR	NR
	No CRT	All-cause mortality	245	6 months	16(6.5)	NR	NR	NR
Moss,2009 ⁹	ICD	All-cause mortality	731	NR	53(7.3)	NR	NR	HR: 1 95% CI: 0.69-1.44
	CRT-D	All-cause mortality	1089	NR	74(6.8)	NR	NR	NA
Healey,2012 ²⁵	ICD	All-cause	115	12 months	NR(30.4)	NR	NR	HR: 1.04

Author,Year Trial	Arm(name)	Harms Units	N for analysis	Timepoint(s)	n (%) patients with outcomes	n (%) events with outcomes	Within Arm Comparisons	Between Arm Comparisons
RAFT Sub Study		mortality						95% CI: 0.66-1.62
	CRT-ICD	All-cause mortality	114	12 months	NR(36.8)	NR	NR	NA
Solomom,2010 ¹⁹ MADIT CRT Sub Study	ICD	All-cause mortality	623	12 months	98(16.8)	NR	NR	NR
	CRT-D	All-cause mortality	749	12 months	55(7.8)	NR	NR	NR
Tompkins, 2013, ²⁰	ICD	All-cause mortality	81	12 months	see Figure 3b(2)	see Figure 3b(2)	NR	NR
	CRT-D LAFB	All-cause mortality	75	12 months	see Figure 3b(4)	see Figure 3b(4)	NR	NR
	CRT-D non-LAFB	All-cause mortality	49	12 months	see Figure 3b(2)	see Figure 3b(2)	NR	NR
	ICD	All-cause mortality	68	24 months	see Figure 3b(6)	see Figure 3b(6)	NR	NR
	CRT-D LAFB	All-cause mortality	66	24 months	see Figure 3b(8)	see Figure 3b(8)	NR	NR
	CRT-D non-LAFB	All-cause mortality	43	24 months	see Figure 3b(2)	see Figure 3b(2)	NR	NR
Diab, 2011 ³⁸	Arm 1	All-cause mortality		6 months	0()	()	NR	NR
	Arm 2	All-cause mortality		6 months	0()	()	NR	NR
	Arm 3	All-cause mortality		6 months	1()	()	NR	NR
Birnie,2013 ²³ RAFT Sub Study	ICD-CRT (LBBB)	All-cause mortality	594	NR	105(17.7)	NR	NR	HR: 0.664 95% CI: 0.516-0.853
	ICD-CRT (Non-LBBB)	All-cause mortality	143	NR	29(20.3)	NR	NR	HR: 0.705 95% CI: 0.444-1.121
	ICD-CRT (RBBB)	All-cause mortality	60	NR	10(16.7)	NR	NR	HR: 0.544 95% CI: 0.264-

Author,Year Trial	Arm(name)	Harms Units	N for analysis	Timepoint(s)	n (%) patients with outcomes	n (%) events with outcomes	Within Arm Comparisons	Between Arm Comparisons
								1.121
	ICD-CRT (NIVCD)	All-cause mortality	83	NR	19(22.9)	NR	NR	HR: 0.93 95% CI: 0.491- 1.761
	ICD(LBBB)	All-cause mortality	581	NR	145(25)	NR	NR	NR
	ICD(Non-LBBB)	All-cause mortality	165	NR	47(28.5)	NR	NR	NR
	ICD(RBBB)	All-cause mortality	81	NR	28(34.6)	NR	NR	NR
	ICD(NIVCD)	All-cause mortality	84	NR	19(22.6)	NR	NR	NR
Barsheshet,2011 ¹¹	All Ischemia	All-cause mortality	1046	6 months	NR	NR	NR	HR: 0.99 95% CI: 0.65- 1.52
	Ischemia NYHA II	All-cause mortality	781	6 months	NR	NR	NR	HR: 0.96 95% CI: 0.59- 1.55
	Non Ischemia	All-cause mortality	774	6 months	NR	NR	NR	HR: 0.87 95% CI: 0.45- 1.67
Arshad,2011 ¹⁰ MADIT CRT Sub Study	Women	All-cause mortality	453	6 months	20(NR)	NR	NR	HR: 0.28 95% CI: 0.1- 0.79
	Men	All-cause mortality	1365	6 months	107(NR)	NR	NR	HR: 1.05 95% CI: 0.7- 1.57
	Women, Ischemic heart disease	All-cause mortality	125	6 months	5(NR)	NR	NR	HR: 0.17 95% CI: 0.02- 1.66
	men, Ischemic heart disease	All-cause mortality	874	6 months	83(NR)	NR	NR	HR: 0.99 95% CI: 0.62- 1.57
	Women, Non Ischemic heart	All-cause mortality	328	6 months	15(NR)	NR	NR	HR: 0.33 95% CI: 0.1-

Author,Year Trial	Arm(name)	Harms Units	N for analysis	Timepoint(s)	n (%) patients with outcomes	n (%) events with outcomes	Within Arm Comparisons	Between Arm Comparisons
	disease							1.1
	men, Non Ischemic heart disease	All-cause mortality	493	6 months	24(NR)	NR	NR	HR: 1.34 95% CI: 0.55- 3.31
	Women, QRS <150ms	All-cause mortality	148	6 months	8(NR)	NR	NR	HR: 0.4 95% CI: 0.09- 1.8
	Men,QRS <150ms	All-cause mortality	497	6 months	42(NR)	NR	NR	HR: 1.2 95% CI: 0.62- 2.34
	Women, QRS >=150ms	All-cause mortality	305	6 months	12(NR)	NR	NR	HR: 0.18 95% CI: 0.04- 0.89
	Men,QRS >=150ms	All-cause mortality	870	6 months	65(NR)	NR	NR	HR: 1.03 95% CI: 0.61- 1.75
	Women,Non LBBB	All-cause mortality	59	6 months	0(NR)	NR	NR	NR
	Men,Non LBBB	All-cause mortality	478	6 months	0(NR)	NR	NR	NR
	Women,LBBB	All-cause mortality	394	6 months	17(NR)	NR	NR	HR: 0.22 95% CI: 0.07- 0.7
	Men,LBBB	All-cause mortality	887	6 months	68(NR)	NR	NR	HR: 0.84 95% CI: 0.67- 1.61
Zareba,2011 ²¹ MADIT CRT Sub Study	LBBB	All-cause mortality	1281	6 months	NR	NR	NR	HR: 0.75 95% CI: 0.49- 1.16
	Non LBBB	All-cause mortality	536	6 months	NR	NR	NR	HR: 1.79 95% CI: 0.9- 3.57
	RBBB	All-cause mortality	228	6 months	NR	NR	NR	HR: 1.53 95% CI: 0.54- 4.37

Author,Year Trial	Arm(name)	Harms Units	N for analysis	Timepoint(s)	n (%) patients with outcomes	n (%) events with outcomes	Within Arm Comparisons	Between Arm Comparisons
	IVCD	All-cause mortality	308	6 months	NR	NR	NR	HR: 2 95% CI: 0.8-5.02
Abraham,2004 ³⁴ MIRACLE ICD II	Control	All-cause mortality	101	6 months	2(NR)	NR	NR	NR
	CRT	All-cause mortality	85	6 months	2(NR)	NR	NR	NR
Young,2003 ²⁶ MIRACLE ICD	Control	All-cause mortality	182	6 months	15(NR)	NR	NR	NR
	CRT	All-cause mortality	187	6 months	14(NR)	NR	NR	NR
Lozano,2000 ⁴¹	BV Pacing	All-cause mortality	109	3 months	5(4.6)	NR	NR	NR
	No Pacing	All-cause mortality	113	3 months	10(8.8)	NR	NR	NR
Goldenberg, 2014 ¹³	CRTD(LBBB)	All-cause mortality	NR	NR	NR	NR	NR	HR: 0.59 95% CI: 0.43- 0.80 P<0.001
	ICD(LBBB)	All-cause mortality	NR	NR	NR	NR	NR	NA
	CRTD(Non- LBBB)	All-cause mortality	NR	NR	NR	NR	NR	HR: 1.57 95% CI: 1.03- 2.39 P: 0.04
	ICD(Non-LBBB)	All-cause mortality	NR	NR	NR	NR	NR	NA

CRT-P=Cardiac Resynchronization Therapy Paced, CRT-D=Cardiac Resynchronization Therapy with Defibrillator, ICD=Implantable Cardioverter Defibrillator, N=Number, HR=Hazard Ratio, CI=Confidence Interval, OR=Odds Ratio, RD=Risk Difference, P=P value, NA=Not Applicable, LBBB=Left Bundle Branch Block, LVEF=Left Ventricular Ejection Fraction, CABG=Coronary Artery Bypass Graft, CRT=Cardiac Resynchronization Therapy, Biv=Bi-Ventricular, RV=Right Ventricular, IHD=Ischemic Heart Disease, NR=Not Reported, SD=Standard Deviation, NA=Not Applicable