

Table D15: Harms reported in the studies assessing effectiveness of CRT-D

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
Strimel, 2011 ⁷⁸	CRT-D	Cardiac perforation/ tamponade	42	34 months (mean)	1	1	NR	NR
	Dual ICD	Cardiac perforation/ tamponade	37	34 months (mean)	0	0	NR	NR
	CRT-D	Pocket hematoma	42	34 months (mean)	2	2	NR	NR
	Dual ICD	Pocket hematoma	37	34 months (mean)	2	2	NR	NR
	CRT-D	Device Infection	42	34 months (mean)	0	1	NR	NR
	Dual ICD	Device Infection	37	34 months (mean)	1	0	NR	NR
	CRT-D	Lead dislodgement	42	34 months (mean)	1	1	NR	NR
	Dual ICD	Lead dislodgement	37	34 months (mean)	1	1	NR	NR
	CRT-D	Pneumothorax	42	34 months (mean)	0	0	NR	NR
	Dual ICD	Pneumothorax	37	34 months (mean)	0	0	NR	NR
Gasparini, 2009 ⁵³	Protect	Ventricular arrhythmias	164	NR	NR	311(NR)	NR	NR
	Control	Ventricular arrhythmias	160	NR	NR	310(NR)	NR	NR
Ouellet, 2012 ¹⁶ MADIT CRT Sub Study	ICD	Ventricular arrhythmias	731	NR	161(22)	NR	NR	NR
	CRT-D	Ventricular arrhythmias	1089	NR	166(15.2)	NR	NR	NR
Boven, 2013 ⁴⁹	Total study population	Inappropriate ICD shocks (CRT-D only)	543	NR	33(6.1)	NR	NR	NR
Theuns, 2005 ⁸¹	Overall	Ventricular	86	NR	36(42)	724(NR)	NR	NR

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
		arrhythmias						
	Primary prophylaxis	Ventricular arrhythmias	38	NR	7(18.4)	NR	NR	NR
	Secondary prophylaxis	Ventricular arrhythmias	48	NR	29(60.4)	NR	NR	NR
Landolina,2011 ⁶²	Overall	Device Infection	3253	NR	30(0.92)	NR	NR	NR
Knight,2004 ⁵⁹	Overall	Device Infection	443	NR	5(1.1)	NR	NR	NR
Auricchio,2014 ⁴⁵	All patients	Pneumothorax	521	13 months	NR	(0.8)	NR	NR
	All patients	Pocket hematoma	521	13 months	NR	(2.8)	NR	NR
	All patients	Device Infection	521	13 months	NR	(1.8)	NR	NR
	All patients	Lead dislodgement	521	13 months	NR	(9.8)	NR	NR
Bossard,2014 ⁴⁸	All patients	Device Infection	49	NR	NR	2(NR)	NR	NR
	All patients	Lead dislodgement	49	NR	NR	4(NR)	NR	NR
	All patients	Ventricular arrhythmias	49	NR	14(28.6)	NR	NR	NR
	All patients	Inappropriate ICD shocks (CRT-D only)	49	NR	7(14.3)	NR	NR	NR
Duray,2008 ⁵²	Overall	Pneumothorax	79	6 months	1(1.3)	NR	NR	NR
	Overall	Pocket hematoma	79	6 months	1(1.3)	NR	NR	NR
	Overall	Device Infection	79	6 months	0(0)	NR	NR	NR
	Overall	Cardiac perforation/ tamponade	79	6 months	0(0)	NR	NR	NR

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
	Overall	Death (within a week)	79	6 months	0(0)	NR	NR	NR
Gilis,2014 ²⁴ RAFT Sub Study	ICD	Procedure related complications -not specified	904	NR	147(16.4)	159(NR)	NR	NR
	ICD-CRT	Procedure related complications -not specified	894	NR	126(13.9)	246(NR)	NR	NR
	ICD	Length of hospital stay 14896Days	904	NR	NR	NR	NR	NR
	ICD-CRT	Length of hospital stay 12783Days	894	NR	NR	NR	NR	NR
	ICD	Pocket hematoma	904	NR	NR	3(NR)	NR	NR
	ICD-CRT	Pocket hematoma	894	NR	NR	8(NR)	NR	NR
	ICD	Device Infection	904	NR	NR	20(NR)	NR	NR
	ICD-CRT	Device Infection	894	NR	NR	25(NR)	NR	NR
	ICD	Inappropriate ICD shocks (CRT-D only)	904	NR	NR	30(NR)	NR	NR
	ICD-CRT	Inappropriate ICD shocks (CRT-D only)	894	NR	NR	20(NR)	NR	NR
	ICD	Cardiac perforation/ tamponade	904	NR	NR	1(NR)	NR	NR
	ICD-CRT	Cardiac	894	NR	NR	1(NR)	NR	NR

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
		perforation/ tamponade						
Nian-Sang,2010 ⁶⁷	Overall(CRT-D)	Ventricular arrhythmias	54	3 days	4(7.4)	NR	NR	NR
Moss,2009 ⁹	ICD	Pneumothorax	NR	30 days	NR(0.8)	NR	NR	NR
	CRT-D	Pneumothorax	NR	30 days	NR(1.7)	NR	NR	NR
	ICD	Pocket hematoma	NR	30 days	NR(2.5)	NR	NR	NR
	CRT-D	Pocket hematoma	NR	30 days	NR(3.3)	NR	NR	NR
	ICD	Device Infection	NR	30 days	NR(0.7)	NR	NR	NR
	CRT-D	Device Infection	NR	30 days	NR(1.1)	NR	NR	NR
Higgins,2003 ⁴⁰ VENTAK CHF/CONTAK CD	CRT	Ventricular arrhythmias	117	6 months	36(30.8)	NR	NR	NR
	No CRT	Ventricular arrhythmias	110	6 months	39(35.5)	NR	NR	NR
Abraham,2004 ³⁴ MIRACLE ICD II	Control	Ventricular arrhythmias	101	6 months	26(26)	NR	NR	NR
	CRT	Ventricular arrhythmias	85	6 months	19(22)	NR	NR	NR
	Overall	Cardiac perforation/ tamponade	210	From time of procedure to hospital discharge	3(1.4)	NR	NR	NR
	Overall	Lead dislodgement	210	From time of procedure to hospital discharge	5(2.4)	NR	NR	NR
	Overall	Cardiac perforation/ tamponade	191	6 months	1(0.5)	NR	NR	NR

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
	Overall	Lead dislodgement	191	6 months	11(5.8)	NR	NR	NR
Kuhlkamp, 2002 ⁶¹	Overall	Pneumothorax	81	Median: 185 days	2(NR)	2(NR)	NR	NR
	Overall	Lead dislodgement	81	Median: 185 days	1(NR)	1(NR)	NR	NR
	Overall	Lead dislodgement	81	Median: 185 days	2(NR)	2(NR)	NR	NR
	Overall	Lead dislodgement	81	Median: 185 days	4(NR)	4(NR)	NR	NR
	Overall	Lead dislodgement	81	Median: 185 days	1(NR)	1(NR)	NR	NR
	Overall	Device Infection	81	Median: 185 days	2(NR)	2(NR)	NR	NR
Pinter,2009 ⁴²	CRT ON	Ventricular arrhythmias	36	6 months	7(19.4)	NR	NR	NR
	CRT OFF	Ventricular arrhythmias	36	6 months	6(16.7)	NR	NR	NR
Boven,2013 ⁵⁰	Functional Nonresponders	Inappropriate ICD shocks (CRT-D only)	100	NR	3(7.1)	NR	NR	NR
	Functional Responders	Inappropriate ICD shocks (CRT-D only)	42	NR	9(9)	NR	NR	NR
Gopalumurugan,2014 ⁵⁴	CRT-D	Procedure related complications -not specified	117	NA	41(35)	NR(NR)	NR	HR: NR 95%CI: NR p: 0.74
	ICD	Procedure related complications -not specified	63	NA	24(38.1)	NR(NR)	NR	NR
Jamerson,2014 ¹⁵	Males-ICD	Procedure related complications -not specified	NR	<=30 days	14(2.5)	NR(NR)	NR	NR

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
	Males-CRTD	Ventricular arrhythmias	NR	</=30 days	23(2.9)	NR(NR)	NR	HR: NR 95%CI: NR p: <0.001
	Females ICD	Ventricular arrhythmias	NR	</=30 days	5(2.9)	NR(NR)	NR	HR: NR 95%CI: NR p: 0.018
	Females CRTD	Ventricular arrhythmias	NR	</=30 days	23(7.7)	NR(NR)	NR	NR
	Males-ICD	Ventricular arrhythmias	NR	</=30 days	3(0.5)	NR(NR)	NR	NR
	Males-CRTD	Cardiac perforation/ tamponade	NR	</=30 days	3(0.3)	NR(NR)	NR	NR
	Females ICD	Cardiac perforation/ tamponade	NR	</=30 days	0(0)	NR(NR)	NR	NR
	Females CRTD	Cardiac perforation/ tamponade	NR	</=30 days	1(0.3)	NR(NR)	NR	NR
	Males-ICD	Cardiac perforation/ tamponade	NR	</=30 days	2(0.3)	NR(NR)	NR	NR
	Males-CRTD	Device Infection	NR	</=30 days	5(0.6)	NR(NR)	NR	NR
	Females ICD	Device Infection	NR	</=30 days	0(0)	NR(NR)	NR	HR: NR 95%CI: NR p: 0.05
	Females CRTD	Device Infection	NR	</=30 days	2(0.7)	NR(NR)	NR	NR
	Males-ICD	Device Infection	NR	</=30 days	3(0.5)	NR(NR)	NR	NR
	Males-CRTD	Ventricular arrhythmias	NR	</=30 days	5(0.6)	NR(NR)	NR	NR
	Females ICD	Device Infection	NR	</=30 days	2(1.1)	NR(NR)	NR	NR

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
	Females CRTD	Device Infection	NR	<=30 days	7(2.5)	NR(NR)	NR	NR
Haugaa,2014 ⁵⁶	Overall	Device Infection	266	24 months	39(15)	NR(NR)	NR	NR
Masoudi,2014 ⁶⁵	ICD	Device Infection	NR	12 months	24(0.7)	NR(NR)	NR	HR: NR 95%CI: NR p: 0.012
	CRTD	Lead dislodgement	NR	12 months	45(1.3)	NR(NR)	NR	NR
	ICD	Ventricular arrythmias	NR	36 months	32(1)	NR(NR)	NR	NR
	CRTD	Pneumothorax	NR	36 months	62(1.9)	NR(NR)	NR	HR: 1.9 95%CI: 1.07- 3.37 p: 0.004
Vado,2014 ⁸²	Overall	Pneumothorax	45	>9 months	3(6.7)	NR(NR)	NR	NR
Ruwald,2014 ¹⁸	Overall	Pneumothorax	752	>12 months	109(14.5)	NR(NR)	NR	NR
Wollmann,2014 ⁸⁵	All Patients	Device Infection	246	1 Month	2(6)	NR(NR)	NR	NR
	DR-ICD	Device Infection	114	1 Month	1(8)	NR(NR)	NR	NR
	CRT-D	Device Infection	132	1 Month	1(5)	NR(NR)	NR	NR
	All Patients	Cardiac perforation/ tamponade	246	1 Month	2(6)	NR(NR)	NR	NR
	DR-ICD	Cardiac perforation/ tamponade	114	1 Month	2(15)	NR(NR)	NR	NR
	CRT-D	Cardiac perforation/ tamponade	132	1 Month	0(0)	NR(NR)	NR	NR
	All Patients	Lead	246	1 Month	1(3)	NR(NR)	NR	NR

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
		dislodgement						
	DR-ICD	Lead dislodgement	114	1 Month	0(0)	NR(NR)	NR	NR
	CRT-D	Lead dislodgement	132	1 Month	1(5)	NR(NR)	NR	NR
	All Patients	Ventricular arrhythmias	246	1 Month	7(21)	NR(NR)	NR	NR
	DR-ICD	Ventricular arrhythmias	114	1 Month	2(15)	NR(NR)	NR	NR
	CRT-D	Ventricular arrhythmias	132	1 Month	5(25)	NR(NR)	NR	NR
	All Patients	Inappropriate ICD shocks (CRT-D only)	246	1 Month	NR(NR)	196(NR)	NR	NR
	DR-ICD		114	1 Month	NR(NR)	94(NR)	NR	NR
	CRT-D		132	1 Month	NR(NR)	102(NR)	NR	NR
Ricci,2014 ⁶⁹	Overall		1404	NR	102(7.3)	272(NR)	NR	NR

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