

**Table D18: Harms reported in the studies assessing harms of CRT P vs. 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
Killu,20113 <sup>58</sup>	Overall	Pneumothorax	722	30 DAYS	10(1.4)	NR	NR	NR
	≤80	Pneumothorax	632	30 DAYS	8(1.3)	NR	NR	NR
	≥80	Pneumothorax	90	30 DAYS	2(2.2)	NR	NR	NR
	Overall	Pocket hematoma	722	30 DAYS	4(0.6)	NR	NR	NR
	≤80	Pocket hematoma	632	30 DAYS	3(0.5)	NR	NR	NR
	≥80	Pocket hematoma	90	30 DAYS	1(1.1)	NR	NR	NR
	Overall	Device Infection	722	30 DAYS	2(0.3)	NR	NR	NR
	≤80	Device Infection	632	30 DAYS	0.3(2)	NR	NR	NR
	≥80	Device Infection	90	30 DAYS	0(0)	NR	NR	NR
	Overall	Cardiac perforation/ tamponade	722	30 DAYS	1(0.1)	NR	NR	NR
	≤80	Cardiac perforation/ tamponade	632	30 DAYS	1(0.2)	NR	NR	NR
	≥80	Cardiac perforation/ tamponade	90	30 DAYS	0(0)	NR	NR	NR
Schuchert,2013 <sup>37</sup>	CRT-P	Device Infection	174	12 months	2(1.3)	NR	NR	NR
MASCOT Sub Study	CRT-D	Device Infection	228	12 months	3(1.2)	NR	NR	NR
Takaya,2013 <sup>80</sup>	Overall	Death (within a week)	40	6 months	0(0)	0(0)	NR	NR
Azizi,2006 <sup>46</sup>	Overall	Cardiac	285	Mean 1.7	NR	1(0.3)	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		years (SD 1.3)				
	Overall	Pneumothorax	285	Mean 1.7 years (SD 1.3)	NR	2(0.6)	NR	NR
	Overall	Death (within a week)	285	Mean 1.7 years (SD 1.3)	NR	0(0)	NR	NR
	Overall	Device Infection	285	Mean 1.7 years (SD 1.3)	NR	2(0.6)	NR	NR
Swindle,2010 <sup>79</sup>	CRT-D (19-79yrs, Co-Morbidity score 0)	Length of hospital stay 2Days	NR	NR	NR	NR	NR	NR
	CRT-D (80-85yrs, Co-Morbidity score 0)	Length of hospital stay 2Days	NR	NR	NR	NR	NR	NR
	CRT-D (>85yrs, Co-Morbidity score 0)	Length of hospital stay 3Days	NR	NR	NR	NR	NR	NR
	CRT-D (19-79yrs, Co-Morbidity score 1-2)	Length of hospital stay 3Days	NR	NR	NR	NR	NR	NR
	CRT-D (80-85yrs, Co-Morbidity score 1-2)	Length of hospital stay 3Days	NR	NR	NR	NR	NR	NR
	CRT-D (>85yrs, Co-Morbidity score 1-2)	Length of hospital stay 5Days	NR	NR	NR	NR	NR	NR
	CRT-D (19-79yrs, Co-Morbidity score >/=3)	Length of hospital stay 6Days	NR	NR	NR	NR	NR	NR
	CRT-D (80-85yrs, Co-Morbidity score >/=3)	Length of hospital stay 8Days	NR	NR	NR	NR	NR	NR
	CRT-D (>85yrs, Co-Morbidity score >/=3)	Length of hospital stay 8Days	NR	NR	NR	NR	NR	NR

<b>Author,Year Trial</b>	<b>Arm(name)</b>	<b>Harms Units</b>	<b>N for analysis</b>	<b>Timepoint(s)</b>	<b>n (%) patients with outcomes</b>	<b>n (%) events with outcomes</b>	<b>Within Arm Comparisons</b>	<b>Between Arm Comparisons</b>
	Co-Morbidity score >/=3)	hospital stay 10Days						
	CRT-D (19-79yrs, 0 complication)	Length of hospital stay 2Days	NR	NR	NR	NR	NR	NR
	CRT-D (80-85yrs, 0 complication)	Length of hospital stay 3Days	NR	NR	NR	NR	NR	NR
	CRT-D (>85yrs, 0 complication)	Length of hospital stay 3Days	NR	NR	NR	NR	NR	NR
	CRT-D (19-79yrs, >/= complication)	Length of hospital stay 9Days	NR	NR	NR	NR	NR	NR
	CRT-D (80-85yrs, >/= complication)	Length of hospital stay 8Days	NR	NR	NR	NR	NR	NR
	CRT-D (>85yrs, >/= complication)	Length of hospital stay 8Days	NR	NR	NR	NR	NR	NR
	ICD (19-79yrs, Co-Morbidity score 0)	Length of hospital stay 2Days	NR	NR	NR	NR	NR	NR
	ICD (80-85yrs, Co-Morbidity score 0)	Length of hospital stay 3Days	NR	NR	NR	NR	NR	NR
	ICD (>85yrs, Co-Morbidity score 0)	Length of hospital stay 4Days	NR	NR	NR	NR	NR	NR
	ICD (19-79yrs, Co-Morbidity score 1-2)	Length of hospital stay 3Days	NR	NR	NR	NR	NR	NR
	ICD (80-85yrs, Co-Morbidity score 1-2)	Length of hospital stay 4Days	NR	NR	NR	NR	NR	NR
	ICD (>85yrs, Co-	Length of	NR	NR	NR	NR	NR	NR

<b>Author,Year Trial</b>	<b>Arm(name)</b>	<b>Harms Units</b>	<b>N for analysis</b>	<b>Timepoint(s)</b>	<b>n (%) patients with outcomes</b>	<b>n (%) events with outcomes</b>	<b>Within Arm Comparisons</b>	<b>Between Arm Comparisons</b>
	Morbidity score 1-2)	hospital stay 6Days						
	ICD (19-79yrs, Co-Morbidity score >/=3)	Length of hospital stay 6Days	NR	NR	NR	NR	NR	NR
	ICD (80-85yrs, Co-Morbidity score >/=3)	Length of hospital stay 8Days	NR	NR	NR	NR	NR	NR
	ICD (>85yrs, Co- Morbidity score >/=3)	Length of hospital stay 10Days	NR	NR	NR	NR	NR	NR
	ICD (19-79yrs, 0 complication)	Length of hospital stay 3Days	NR	NR	NR	NR	NR	NR
	ICD (80-85yrs, 0 complication)	Length of hospital stay 4Days	NR	NR	NR	NR	NR	NR
	ICD (>85yrs, 0 complication)	Length of hospital stay 6Days	NR	NR	NR	NR	NR	NR
	ICD (19-79yrs,>/= complication)	Length of hospital stay 9Days	NR	NR	NR	NR	NR	NR
	ICD (80-85yrs, >/= complication)	Length of hospital stay 9Days	NR	NR	NR	NR	NR	NR
	ICD (>85yrs, >/= complication)	Length of hospital stay 11Days	NR	NR	NR	NR	NR	NR
	CRT-P (19-79yrs, Co-Morbidity score 0)	Length of hospital stay 2Days	NR	NR	NR	NR	NR	NR
	CRT-P (80-85yrs, Co-Morbidity score 0)	Length of hospital stay 2Days	NR	NR	NR	NR	NR	NR
	CRT-P (>85yrs,	Length of	NR	NR	NR	NR	NR	NR

<b>Author,Year Trial</b>	<b>Arm(name)</b>	<b>Harms Units</b>	<b>N for analysis</b>	<b>Timepoint(s)</b>	<b>n (%) patients with outcomes</b>	<b>n (%) events with outcomes</b>	<b>Within Arm Comparisons</b>	<b>Between Arm Comparisons</b>
	Co-Morbidity score 0)	hospital stay 3Days						
	CRT-P (19-79yrs, Co-Morbidity score 1-2)	Length of hospital stay 3Days	NR	NR	NR	NR	NR	NR
	CRT-P (80-85yrs, Co-Morbidity score 1-2)	Length of hospital stay 4Days	NR	NR	NR	NR	NR	NR
	CRT-P (>85yrs, Co-Morbidity score 1-2)	Length of hospital stay 7Days	NR	NR	NR	NR	NR	NR
	CRT-P (19-79yrs, Co-Morbidity score >/=3)	Length of hospital stay 7Days	NR	NR	NR	NR	NR	NR
	CRT-P (80-85yrs, Co-Morbidity score >/=3)	Length of hospital stay 8Days	NR	NR	NR	NR	NR	NR
	CRT-P (>85yrs, Co-Morbidity score >/=3)	Length of hospital stay 8Days	NR	NR	NR	NR	NR	NR
	CRT-P (19-79yrs, 0 complication)	Length of hospital stay 3Days	NR	NR	NR	NR	NR	NR
	CRT-P (80-85yrs, 0 complication)	Length of hospital stay 3Days	NR	NR	NR	NR	NR	NR
	CRT-P (>85yrs, 0 complication)	Length of hospital stay 5Days	NR	NR	NR	NR	NR	NR
	CRT-P (19-79yrs,>/= complication)	Length of hospital stay 9Days	NR	NR	NR	NR	NR	NR
	CRT-P (80-85yrs, >/= complication)	Length of hospital stay 8Days	NR	NR	NR	NR	NR	NR
	CRT-P (>85yrs,	Length of	NR	NR	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
	>= complication)	hospital stay 13Days						
Verbrugge,2013 <sup>83</sup>	CRT-D	Inappropriate ICD shocks (CRT-D only)	74	NR	3(4.1)	NR	NR	NR
Verbrugge,2013 <sup>84</sup>	<70 years	Pneumothorax	76	NR	0(0)	NR	NR	NR
	70-79years	Pneumothorax	95	NR	1(1)	NR	NR	NR
	>=80 years	Pneumothorax	49	NR	0(0)	NR	NR	NR
	<70 years	Cardiac perforation/ tamponade	76	NR	0(0)	NR	NR	NR
	70-79years	Cardiac perforation/ tamponade	95	NR	1(1)	NR	NR	NR
	>=80 years	Cardiac perforation/ tamponade	49	NR	0(0)	NR	NR	NR
	<70 years	Lead dislodgement	76	NR	2(3)	NR	NR	NR
	70-79years	Lead dislodgement	95	NR	1(1)	NR	NR	NR
	>=80 years	Lead dislodgement	49	NR	1(2)	NR	NR	NR
Romeyer- Bouchard,2010 <sup>71</sup>	Overall	Pneumothorax	303	NR	1(0.3)	NR	NR	NR
	Overall	Pocket hematoma	303	NR	29(9.5)	NR	NR	NR
	Overall	Device Infection	303	NR	13(4.3)	NR	NR	NR
	Overall	Lead dislodgement	303	NR	21(6.9)	NR	NR	NR
Bristow,2004 <sup>29</sup>	Optimal	Cardiac	308	NR	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
COMPANION	Pharmacological Therapy	Perforation/ Tamponade						
	CRT-P	Cardiac Perforation/ Tamponade	617	NR	(0.5)	NR	NR	NR
	CRT-D	Cardiac Perforation/ Tamponade	595	NR	(0.3)	NR	NR	NR
Carson,2005 <sup>31</sup> COMPANION Sub Study	Optimal Pharmacological Therapy	Death within a week	308	NR	77 (25.0)	NR	NR	NR
	CRT-P	Death within a week	617	NR	131 (21.2)	NR	NR	NR
	CRT-D	Death within a week	595	NR	105 (17.6)	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