Biffi M et al., American Congress of Cardiology 2026

CRT-NEXT

CRT-DX is Non-inferior to Conventional CRT-D Systems

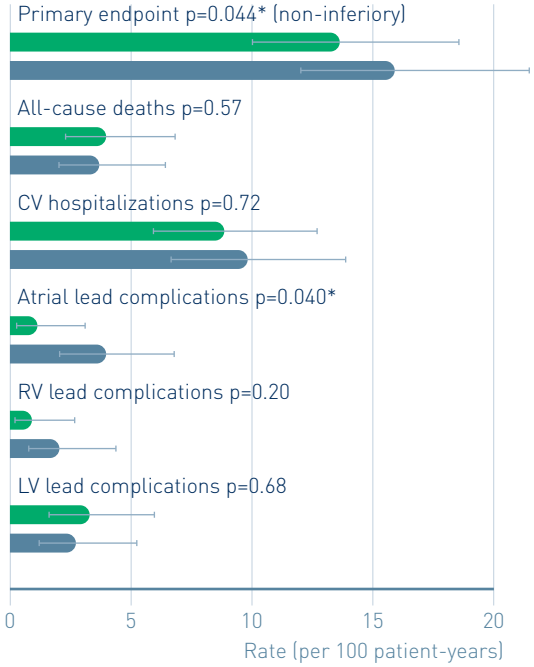
Study Design

- Large, prospective, multicenter, randomized, controlled, interventional study (NCT03587064)
- BIOTRONIK 2-lead CRT-DX systems vs. any conventional 3-lead CRT-D systems
- 636 patients (323 CRT-DX; 313 CRT-D) from 23 Italian centers
- Indication for CRT-D implantation according to ESC guidelines on cardiac pacing and CRT, and no sinus node dysfunction under optimized medical therapy
- 12 months follow-up duration, extended until last patient exited study
- Primary endpoint: Clinical composite of all-cause mortality, CV hospitalization, and lead-related complications at 12 months
- Main secondary endpoints: Individual components of the combined primary endpoint, reverse remodeling, LVEF, LVEDV index, LVESV index, six minutes walking distance, implant procedure and fluoroscopy times

Main Result

2-lead CRT-DX was non-inferior to conventional 3-lead CRT-D

The primary composite endpoint of all-cause mortality, CV hospitalization, and lead-related complications occurred in 13.1% of CRT-DX and 15.6% of CRT-D patients[1]. Individual components showed no significant differences, except for a three-fold reduction of atrial lead-related complications related to right atrial functionality observed in the CRT-DX arm (1.3% CRT-DX vs. 4.2% CRT-D; p=0.040).



CRT-DX non-inferior to CRT-D, with 3x less atrial lead-related complications

Figure1: Bar Plot of the event rates per 100 patient-years for the composite primary endpoint and its individual components in the intention-to-treat cohort
*statistically significant

Clinical Relevance

CRT-DX pilot studies have shown that atrial pacing is not necessary in CRT-D patients without sinus node dysfunction. CRT-DX might reduce atrial lead–related events and procedure time without impairing clinical outcomes, indicating that CRT-DX is sufficient for the vast majority of appropriately selected CRT-D recipients.

1 Hazard ratio of 0.82 (95% CI, 0.54–1.25; p=0.044)

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Patient Selection Was Straightforward With Easy to Apply Selection Criteria

Patients were eligible if they had

- Standard indication for CRT-D implantation according to contemporary guidelines on cardiac pacing and CRT
- No sinus node dysfunction under optimized medical therapy
- Either a resting sinus rate ≥45 beats/min at baseline (on beta-blocker therapy at optimal dose) or a maximum heart rate ≥85 beats/min during a 6-minute walk test when the baseline sinus rate was <45 beats/min
- No indication for atrial pacing
- NYHA Class I–III
- No permanent atrial fibrillation; replacement or upgrade of a previously implanted pacing system
- No dialysis; no breastfeeding or pregnancy
- Sinus rhythm at implantation
- ≥18 years of age

CRT-DX Procedures Were 14% Shorter Than Conventional CRT-D Implantations

Procedures were significantly shorter in the CRT-DX group than in the CRT-D group (92 vs. 107 min), with a trend toward reduced fluoroscopy time that did not reach statistical significance (18 vs. 21 min).

	CRT-DX (N = 323)	**CRT-D** (N = 313)	P-Value
Procedural time, minutes	92 ± 42	107 ± 45	0.028
Fluoroscopy time, minutes	18 ± 14	21 ± 15	0.072

Tab. 1: Procedural data

CRT Response Rate and Functional Capacity at 12 Months Were Comparable

CRT response rates at 12 months were similarly high in the CRT-DX and CRT-D arms (77% vs. 76%), as were LVEF, LVEDV index, and LVESV index. The distance covered during the 6minute walk test (6MWT) was 400m in CRT-DX and 398m in CRT-D, and maximal heart rate during the test was 90 and 90 beats/min, respectively, with no between-group differences.

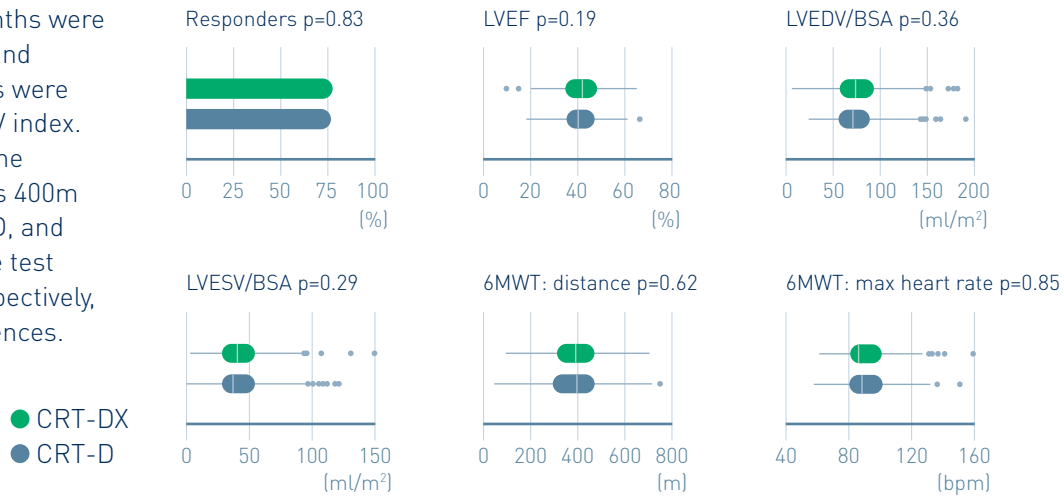

Fig. 2: Box plots of echocardiographic and 6MWT data in the intention-to-treat cohort after 12 months

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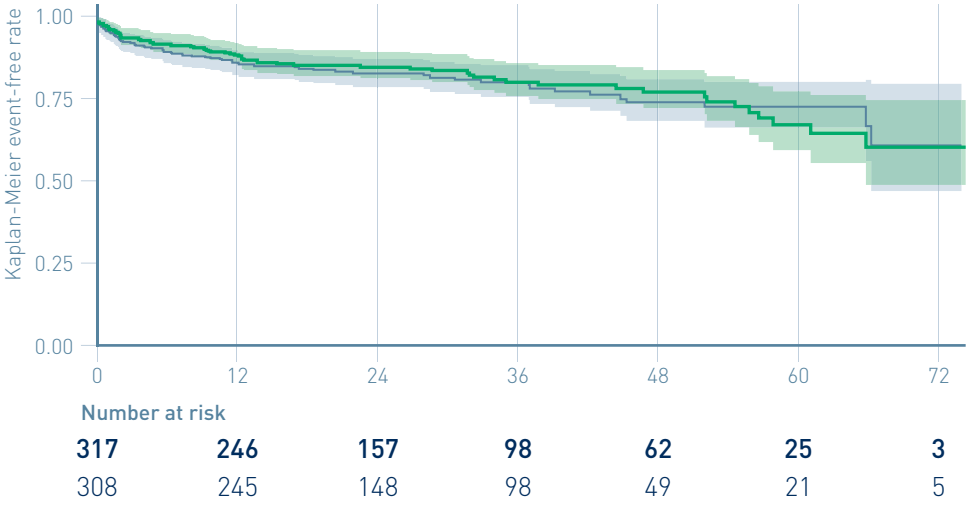
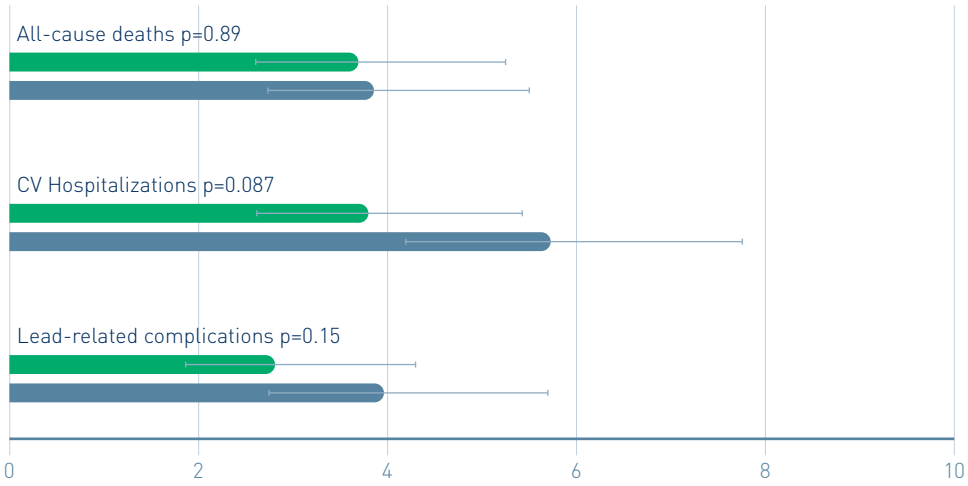
Comparable Clinical Endpoints at Long-term Follow-up

After a median follow-up of 2.4 years, the primary endpoint occurred in 19.9% of the patients in the CRT-DX group and 21.4% of the patients in the CRT-D group, yielding a hazard ratio of 0.87 (95% confidence interval, 0.61–1.24; p=0.45). The event rates per 100 patient-years for the individual components of the primary endpoint did not differ significantly between two study arms: all-cause death 3.7 (CRT-DX) versus 3.9 (CRT-D); cardiovascular hospitalizations 3.8 (CRT-DX) versus 5.7 (CRT-D), lead-related surgical interventions 2.8 (CRT-DX) versus 4.0 (CRT-D)



No difference in time to primary endpoint in the long term

Fig. 3: Kaplan–Meier estimates of primary endpoint free survival during extended Follow-up



No difference in primary endpoint components in the long term

Fig. 4: Bar plot of the event rates per 100 patient-years for the primary endpoint components after a median of 2.4 years follow-up

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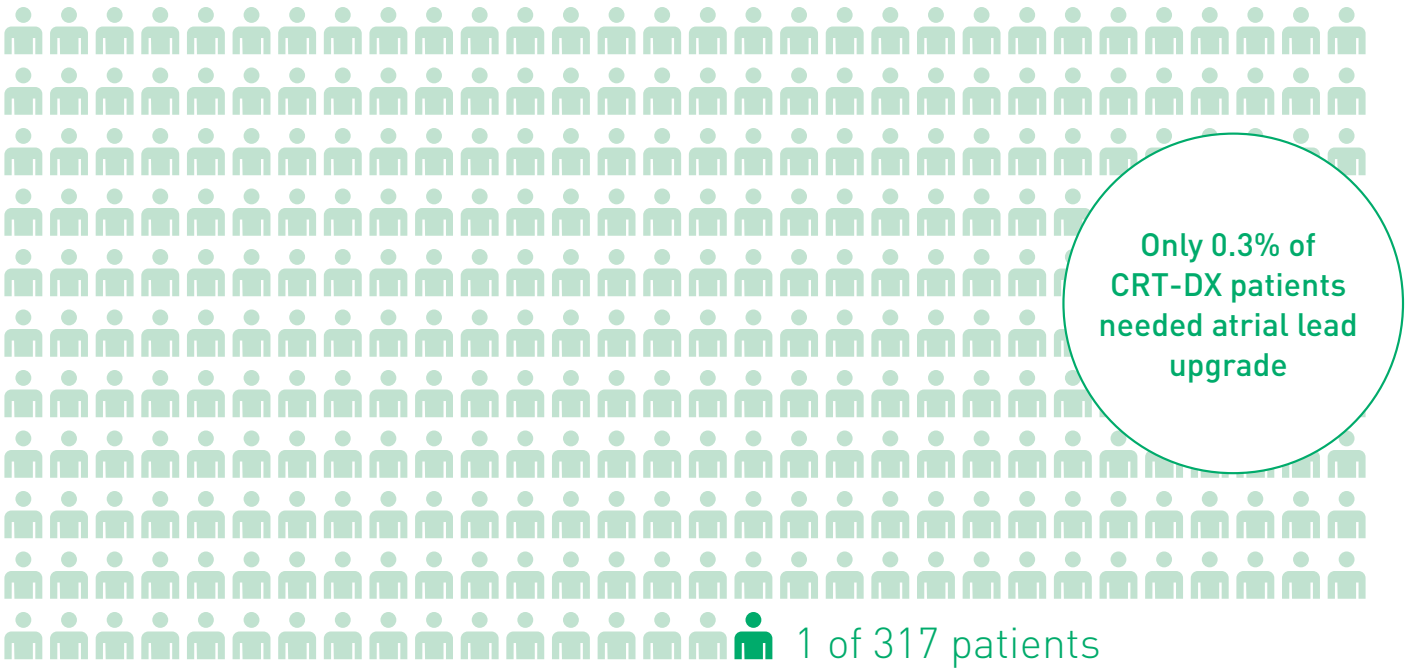
Atrial Sensing and CRT Pacing Was Stable during Extended Follow-Up

	CRT-DX[a]	CRT-D[a]	P-Value[b]
CRT (%)	94 ± 16	92 ± 23	0.34
Atrial sensing (mV)	4.9 ± 3.3	4.1 ± 2.8	0.006

Tab. 2: CRT percentage, and atrial sensing during median follow-up (2.4 years; IQR, 1.3–3.8). Atrial sensing amplitude at 12 months was 5.0 ± 3.9 and 3.8 ±1.9 mV for CRT-DX and CRT-D, respectively. CRT percentages at 12 months were 94 ± 16% (CRT-DX) and 94 ±19% (CRT-D).
a Data reported as average ± standard deviation
b Wilcoxon rank sum test with continuity correction

Extremely Rare Need of Atrial Lead Upgrade in CRT-DX Patients in the Long Term

During the entire follow up, only one CRT-DX patient (0.3%) required implantation of a standard atrial lead because of newly developed need for atrial pacing after 4.5 years. Based on a median follow-up duration of 2.4 years, this translates to an atrial upgrade rate of 0.1 per 100 patient-years.



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