BIO|REDUCE: Safety and Performance Aspects of CRT-DX Systems in Patients With Sinus Rhythm

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Study Design

- Prospective, single-arm, non-controlled, multicenter observational study (BIO|REDUCE; NCT03839121)
- 110 CRT-DX patients from 21 centers in 4 European countries
- Indication for CRT-D implantation according to the ESC Guidelines and no need for atrial pacing
- BIOTRONIK two-lead CRT-DX systems using Plexa ProMRI S DX ICD leads
- 12 month follow-up duration
- Primary endpoint: RA lead implantation within 12 months

Main Result

The BIO|REDUCE study showed that the two-lead CRT-DX concept is a feasible alternative for chronotropically competent CRT-D patients. The study revealed a very high atrial lead implantation–free rate of 98.2%. This translates to only 1.8% of cases requiring an upgrade to atrial pacing within one year. This rate would have been even lower if the patient selection criteria had been applied more stringently in the study.

High right atrial lead implantation-free rate at 12 months

Clinical Relevance

- Reducing the complexity of implantable therapeutic devices may ease application, reduce complications, and mitigate costs.
- A comparison of CRT systems with single and dual- chamber ICDs suggests that the rate of complications may be related to the number of leads.
- Omitting the atrial lead in patients with sinus rhythm and maintained chronotropic competence may be a way to simplify the CRT-D system and reduce complication rates.

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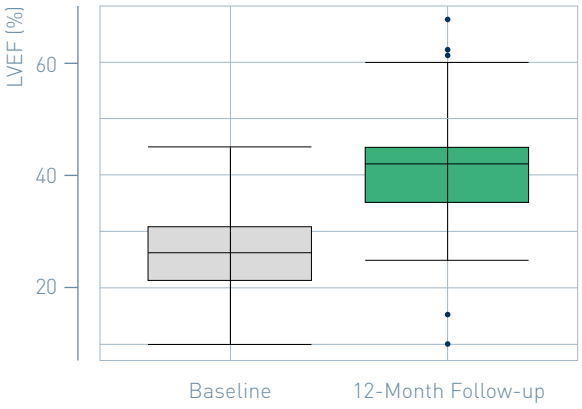
The selection of patients suited for CRT-DX therapy is straightforward ...

- Indication for CRT-D implantation according to ESC Guidelines
- Heart rate at rest >40 bpm
- Heart rate during exercise >100 bpm
- No sinus dysfunction
- No 2nd or 3rd degree AV block
- PVC burden ⩽5%

... and leads to effective cardiac resynchronization ...

Fig 1: LVEF at baseline and study end at 12-month follow-up

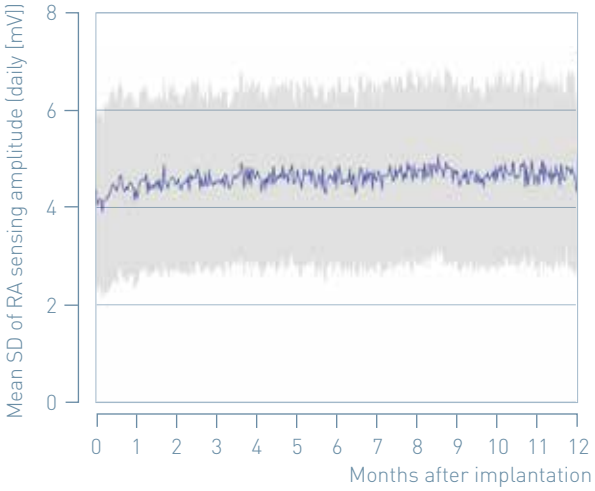


LVEF
+ 14.7%
±11.0%

LVEF improvement was found to be higher than that reported in larger, comparable studies*

... based on good and stable atrial sensing.

Fig. 2: Daily mean RA sensing amplitude over one year of follow-up



Long-term atrial sensing amplitude ⩾4.7 mV

99.8% atrial sensing-triggered ventricular pacing (AsVp)

Source: Kolb C et al. Biventricular Cardiac Resynchronization Therapy with Atrial Sensing but no Atrial Lead: A Prospective Registry to Patient Selection, Complications, and Therapy Response. J Clin Med 2025, 14, 5009. doi.org/10.3390/jcm14145009.
* Cleland JG et al. N Engl J Med. 2005 Apr 14;352(15):1539-49; Linde C et al. J Am Coll Cardiol. 2008 Dec 2;52(23):1834-1843; Moss AJ et al. N Engl J Med. 2009 Oct 1;361(14):1329-38.

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