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THE SONR HEMODYNAMIC SENSOR GUIDED RESYNCHRONIZATION THERAPY IS ASSOCIATED WITH REDUCTION IN HEART FAILURE HOSPITALIZATION: RESULTS FROM THE RESPOND-CRT TRIAL

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Main Text

Purpose of study: The aim of the RESPOND-CRT study is to assess the safety and effectiveness of the SonR CRT system in heart failure (HF) patients eligible for cardiac resynchronization therapy (CRT). SonR is a CRT-D system with a unique atrial lead, SonRtip, featuring an embedded sensor that continuously measures cardiac contractility. The system automatically adjusts AV and VV timings according to the individual needs of each patient. The purpose of the study is to assess the benefit of this dynamic and personalized optimization on clinical outcome.

Methods: RESPOND-CRT is a prospective, double-blinded, multi-center, non-inferiority (NI) trial. After implant, patients were randomized (2:1) to receive repetitive, automatic optimization of AV and VV delays with SonR versus Echo-guided optimization performed once at discharge. The primary effectiveness end point was the rate of clinical responders up to 12 months. Responders were defined as being alive, without adjudicated HF-related events and with an improvement in NYHA class or quality of life. The co-primary safety end points were >91% freedom from acute complications related to the SonRtip lead (0-3 months) and >94% freedom (3-12-months). Death or HF hospitalization was a key secondary end point. Long-term follow-up data (up to 24 months) regarding the HF hospitalizations component alone were also analyzed.

Results: The study enrolled 1,039 patients from 125 sites in 12 countries across Europe, USA and Australia. A total of 998 patients were randomized to either the SonR arm (n=670) or the Echo arm (n=328). The primary end point of the study was met with 75.0% of clinical responders in the SonR group versus 70.4% within the Echo group (P<0.001, NI). Notably, the co-primary safety end points of the study were also met. Death or HF hospitalization occurred in 14.2% of patients in the SonR arm versus 17.6% in the Echo-guided optimization arm (P<0.001, NI). During the extended follow up period of 24 months, the SonR group was associated with a 35% risk reduction in HF hospitalization compared with Echo group (HR=0.65, 95%CI:[0.46-0.92], p=0.014). In addition, the percentage of patients with 0, 1 or ≥2 HF hospitalizations significantly differed between the two arms (p=0.025, Table).

Conclusion: The SonR-based CRT optimization was found to be as safe and effective as Echo-guided optimization in increasing response to CRT at 12 months. SonR provided additional benefits through reduced HF hospitalization during the extended follow up period.

Rate of the HF hospitalization component

Number of patients (%)	SonR (n=670)	Echo (n=328)
Not hospitalized	591 (88.2%)	270 (82.3%)
Hospitalized once	47 (7.0%)	39 (11.9%)
Hospitalized twice or more	32 (4.8%)	19 (5.8%)