Séminaire
Winter Arrhythmia
School
Annual Cardiac Arrhythmia Meeting
Division of Cardiology, University of Toronto

CRT Optimization

The SonR Technology

François Philippon, MD, FRCPC, FHRS, FCCS

14th Annual
Collingwood, Ontario,
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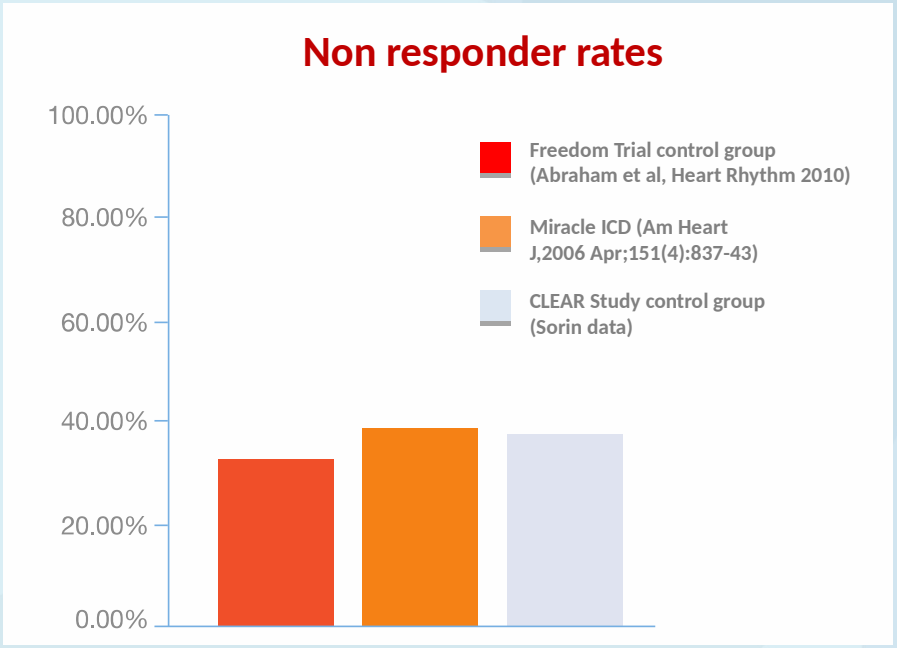
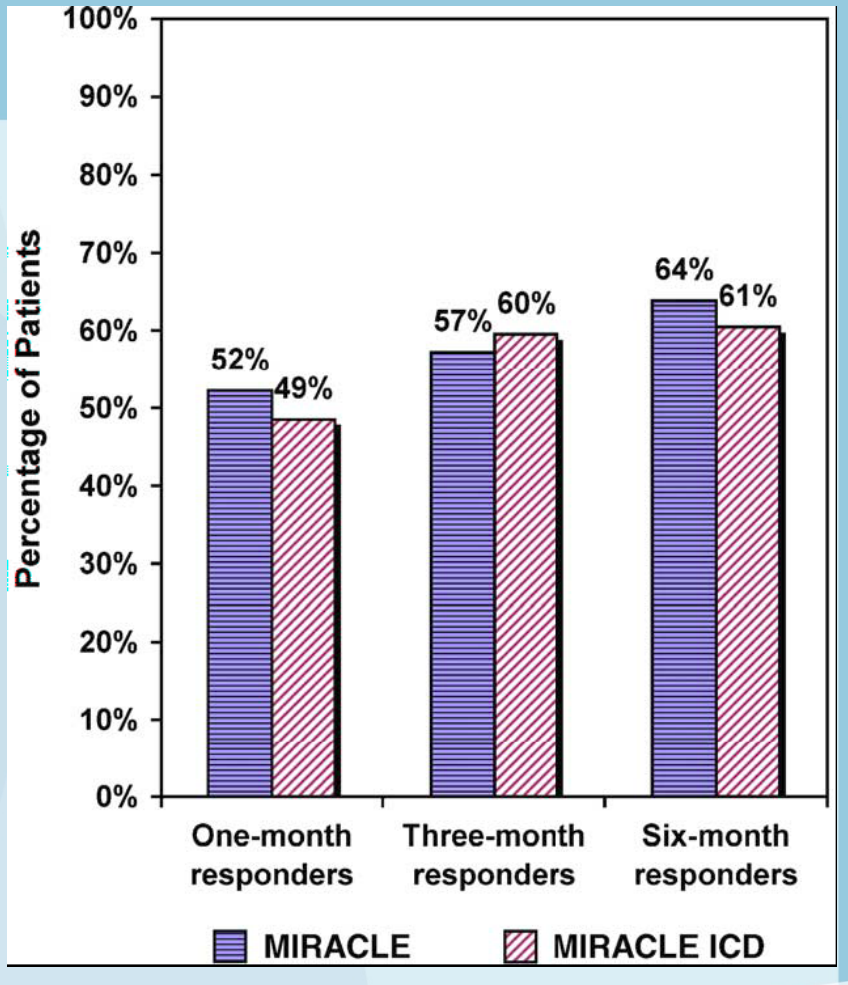
Disclosures

- Research grants
  - LivaNova (SonR-Echo study)
  - Medtronic
  - Boston Scientific
  - St-Jude Medical





(AHJ 2006)

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Objectives

- **Optimization**
  - **Before implantation**
    - Imaging
    - Electrical and mechanical delays
  - **At time of implant**
    - CS anatomy
    - Multipolar pacing
  - **After implant**
    - Non responders
    - Atrial fibrillation
    - Frequent PVCs
  - "Self optimization" using device algorithms
- **Importance of a "Heart Team" approach**

The Non Responders

- **Non modifiable factors:**
  - Advanced age
  - Male sex
  - Ischemic cause, scar tissue, CS anatomy
  - End-stage renal failure
  - Inadequate electrical delay, QRS < 150 ms
  - Absence of mechanical dyssynchrony
  - Severe mitral regurgitation

Pt Selection

- **Modifiable factors:**
  - Sub optimal medical therapy
  - Uncontrolled atrial fibrillation, frequent PVCs
  - LV lead location
  - Loss of BIV capture (inadequate programming)
  - Lack of device optimization

Pt FUP

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The Non Responders

- Better patient selection
- Better pre implantation evaluation
  - Scar burden
  - Mechanical reserve
  - CS anatomy
  - Use of imaging, MRI, 3D Echo, cardiac CT
- Better implantation technique
  - LV lead location
  - Acute assessment of response (Q-LV timing)
  - Implantation techniques
  - Multipolar Leads
  - Targeted LV lead implant
- Use of Device technologies

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Importance of a Concordant Lead Site

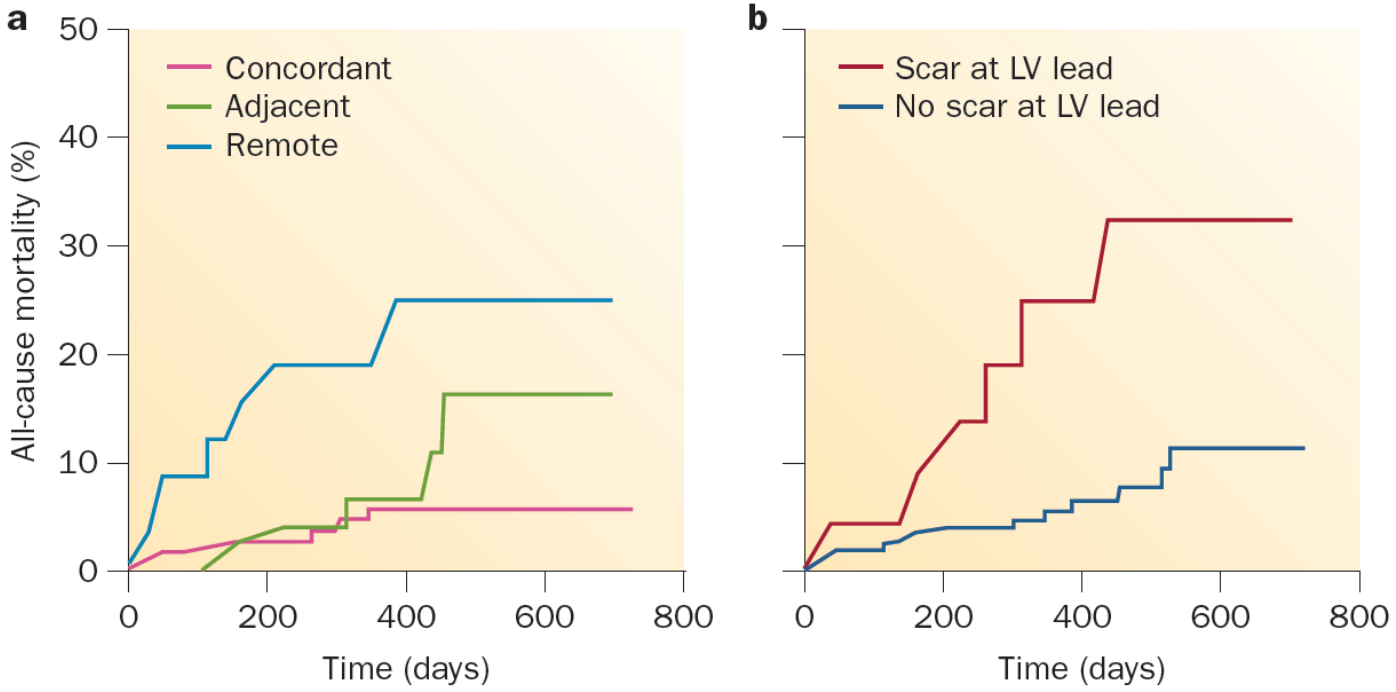


Figure 4 | Kaplan–Meier curves for all-cause mortality according to the site of LV pacing in the TARGET study.[78] **a** | A significant difference ($P = 0.002$) exists between patients with LV leads located concordant with, adjacent to (any of eight regions), or remote from the site of latest activation. **b** | Mortality also differed significantly ($P = 0.0034$) according to whether scarring was present at the site of the LV lead. Abbreviation: LV, left ventricular. Reprinted from *J. Am. Coll. Cardiol.* **59** (17), Khan, F. Z. *et al.* Targeted left ventricular lead placement to guide cardiac resynchronization therapy: the TARGET study: a randomized, controlled trial. 1509–1518 © Elsevier (2012).

Vernooy, K. *et al. Nat. Rev. Cardiol.* **11**, 481–493 (2014)

Role of Echocardiography

Table 1 Potential roles of echocardiography to improve patient response to CRT

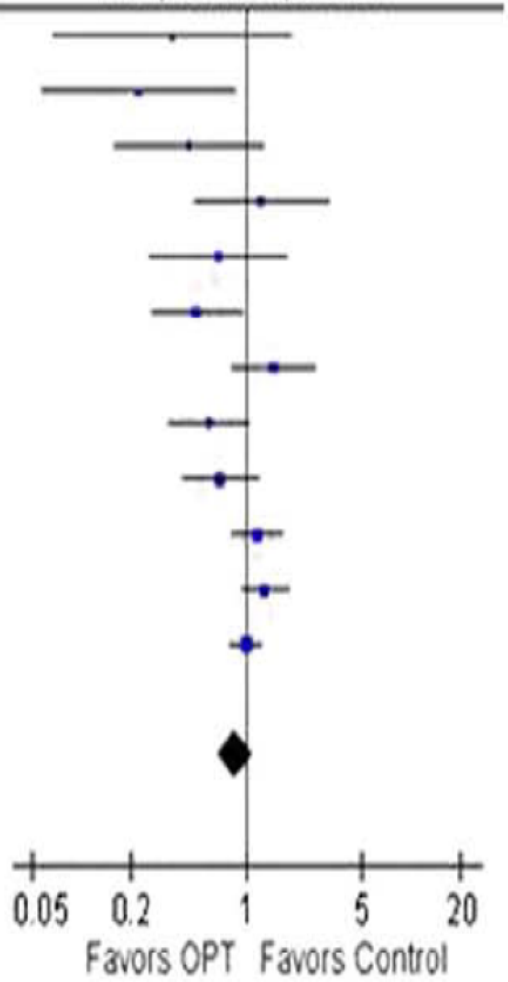
	Methods most widely supported	Evidence for clinical applications
Echocardiographic dyssynchrony at baseline	• Pre-ejection delay ≥ 140 ms • IVMD ≥ 40 ms • TDI opposing wall delay ≥ 80 ms • TDI Yu Index ≥ 32 ms • Radial strain delay ≥ 130 ms	• Prognostic value for all with routine CRT indications • Borderline QRS width (110-130 ms) as adjunct • Non-LBBB QRS morphology as adjunct • Narrow QRS width (< 130 ms): further studies on-going.
Echo guided lead positioning to site of latest activation	Speckle tracking radial strain site of latest activation	Patients with routine CRT indications
Echo guided lead positioning to avoid sites of regional scar	Avoid segments with < 10% radial strain amplitude	Patients with ischemic disease: emerging support, further studies on-going.
Atrioventricular and ventricular-ventricular optimization	• Mitral inflow velocity analysis • LV outflow tract time velocity integral	• Non-responders • Female patients with non-ischemic disease

CRT cardiac resynchronization therapy, *IVMD* interventricular mechanical delay, *TDI* tissue Doppler imaging, *LBBB* left bundle branch block, *LV* left ventricular

Meta-Analysis: AV and VV Optimization

Study	OPT Outcome	OPT Total	Control Outcome	Control Total	Weight	Odds Ratio M-H, Random, 95% CI
Morales 2006	3	26	4	15	1.9%	0.36 [0.07, 1.89]
Sawhney 2004	5	20	12	20	2.7%	0.22 [0.06, 0.86]
Response-HF	9	29	18	36	4.2%	0.45 [0.16, 1.25]
RHYTHM-II	25	78	8	29	4.8%	1.24 [0.48, 3.18]
Vidal 2007	10	51	13	49	4.8%	0.68 [0.26, 1.73]
Aldbrecht 2010	73	133	51	72	8.5%	0.50 [0.27, 0.92]
DECREASE-HF	70	104	59	101	9.2%	1.47 [0.83, 2.59]
Abraham 2012	30	122	41	116	9.3%	0.60 [0.34, 1.05]
CLEAR	47	123	54	115	10.1%	0.70 [0.42, 1.17]
In-Sync III	144	397	71	215	13.6%	1.15 [0.81, 1.64]
SMART-AV	170	655	69	325	14.3%	1.30 [0.95, 1.79]
FREEDOM	261	781	249	744	16.7%	1.00 [0.81, 1.23]
Total (95% CI)		2519		1837	100.0%	0.86 [0.68, 1.09]
Total events	847		649			

P = .21



Canadian Journal of Cardiology 29 (2013) 1346–1360

Society Guidelines

Canadian Cardiovascular Society Guidelines on the Use of Cardiac Resynchronization Therapy: Implementation

Ratika Parkash, MD, MSc,[a] François Philippon, MD,[b] Miriam Shanks, MD,[c] Bernard Thibault, MD,[d] Jafna Cox, MD,[a] Aaron Low, MD,[e] Vidal Essebag, MD, PhD,[f] Jamil Bashir, MD,[g] Gordon Moe, MD,[h] David H. Birnie, MD,[i] Éric Larose, MD,[b] Raymond Yee, MD,[j] Elizabeth Swiggum, MD,[k] Padma Kaul, PhD,[l] Damian Redfearn, MD,[m] Anthony S. Tang, MD,[k] and Derek V. Exner, MD, MPH[n]

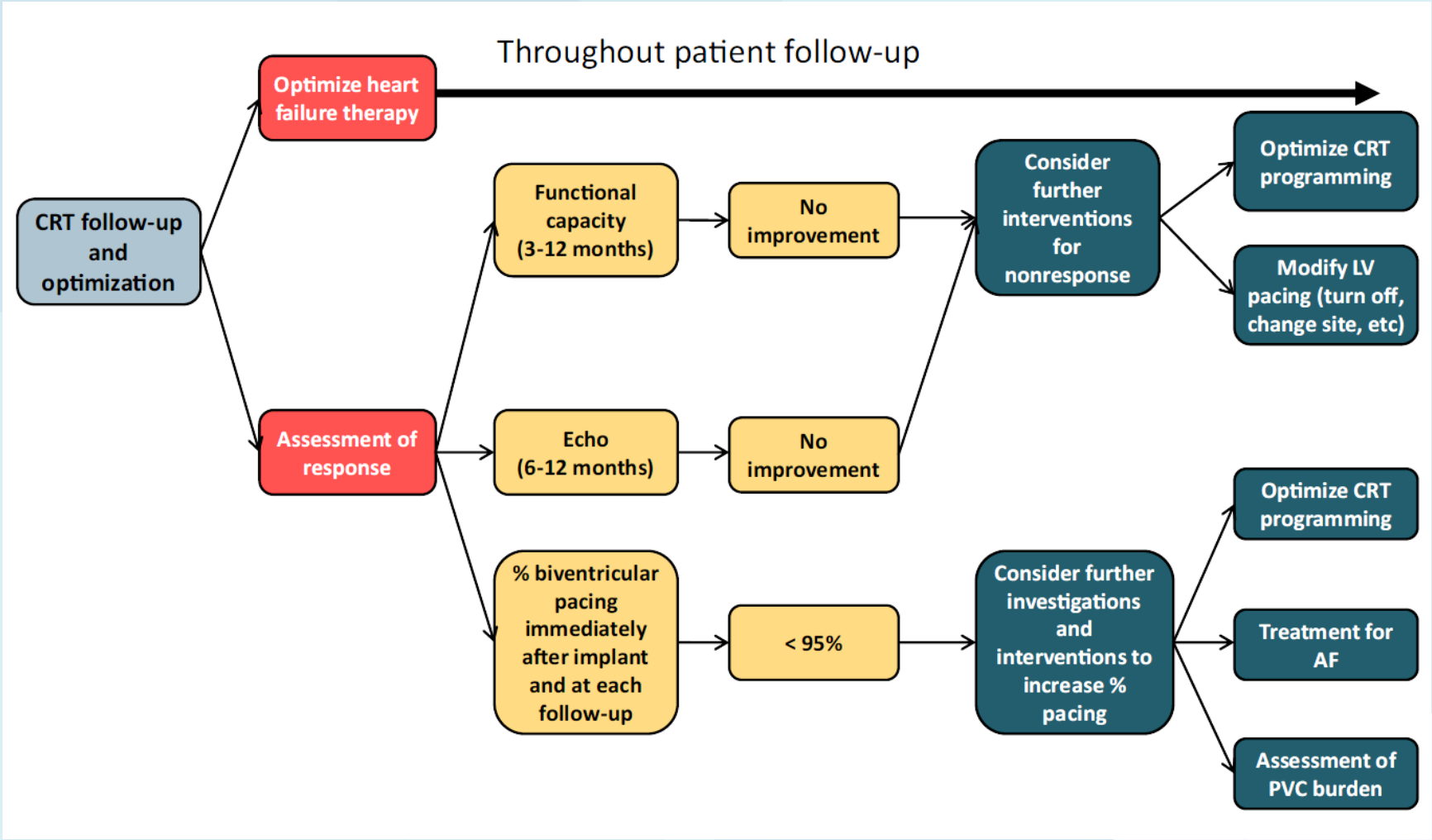
Optimization of Intracardiac Timing

Table 5. Select trials assessing optimization of intracardiac timing

Study	Comparison	Results
RHYTHM II[83]	Echo-optimized VV timing vs nominal VV settings	No difference in QOL, NYHA or 6MW
DECREASE-HF[85]	Simultaneous VV pacing vs EGM optimized VV timing	No difference in LV volumes or EF
FREEDOM[86]	Clinically optimized AV and VV timing vs serial EGM optimized AV and VV timing	No difference in clinical outcomes or functional measures
CLEAR[84]	Echo optimized AV and VV timing vs automatic adjustment of AV delays via contractility sensor	Improved clinical response with the contractility sensor
SMART AV[87]	Echo optimized AV and VV timing vs EGM optimized AV and VV timing vs fixed AV (120 ms) and VV (0 ms)	No difference in LV volumes, EF, or functional measures

Canadian Journal of Cardiology
Volume 29 2013

CRT Optimization



Canadian Journal of Cardiology
Volume 29 2013

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Contractility Sensor
The SonR™ Technology

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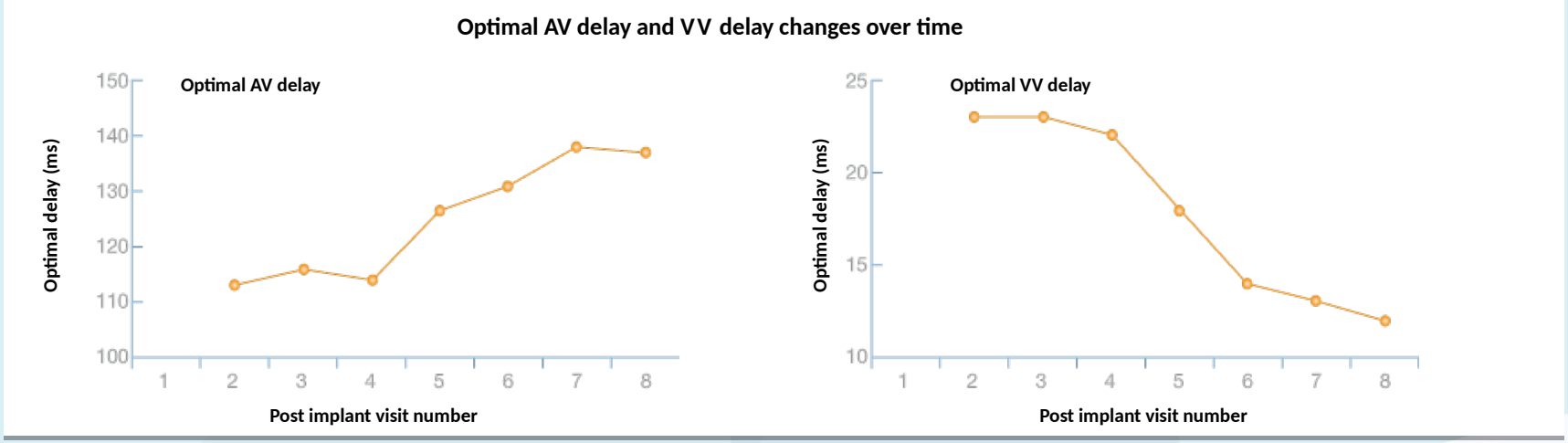
“Dynamic” Optimization

- Regular device optimization is important due to heart remodeling.
- Clinical data suggests that optimization performed at least every three months improves clinical outcomes

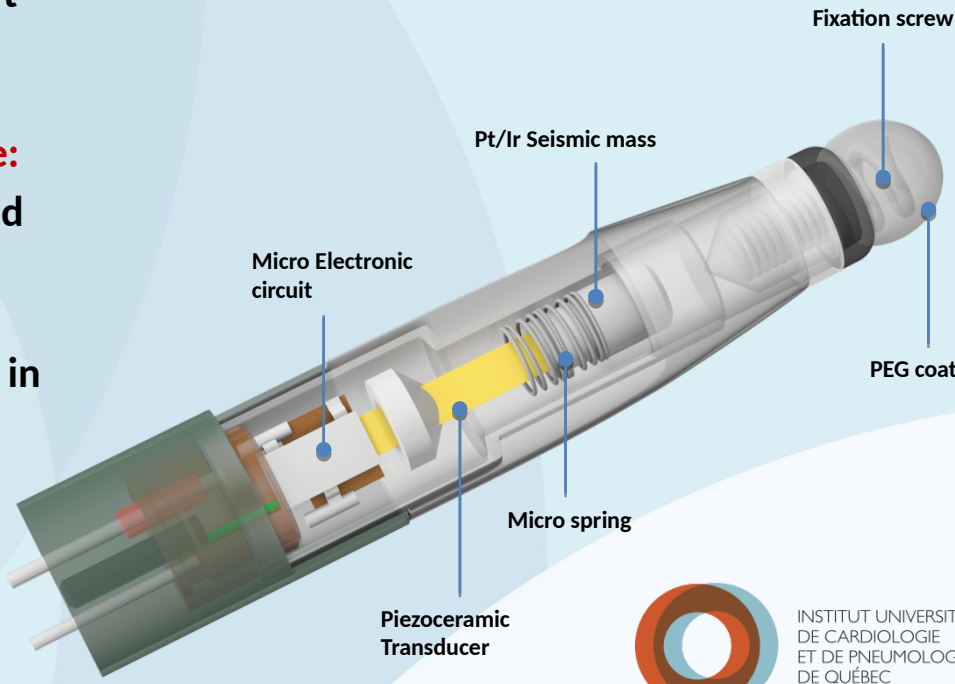


Pacing Clin Electrophysiol 2005;28(suppl 1):S24-26

Courtesy of LivaNova

What is the SonR™ Technology ?

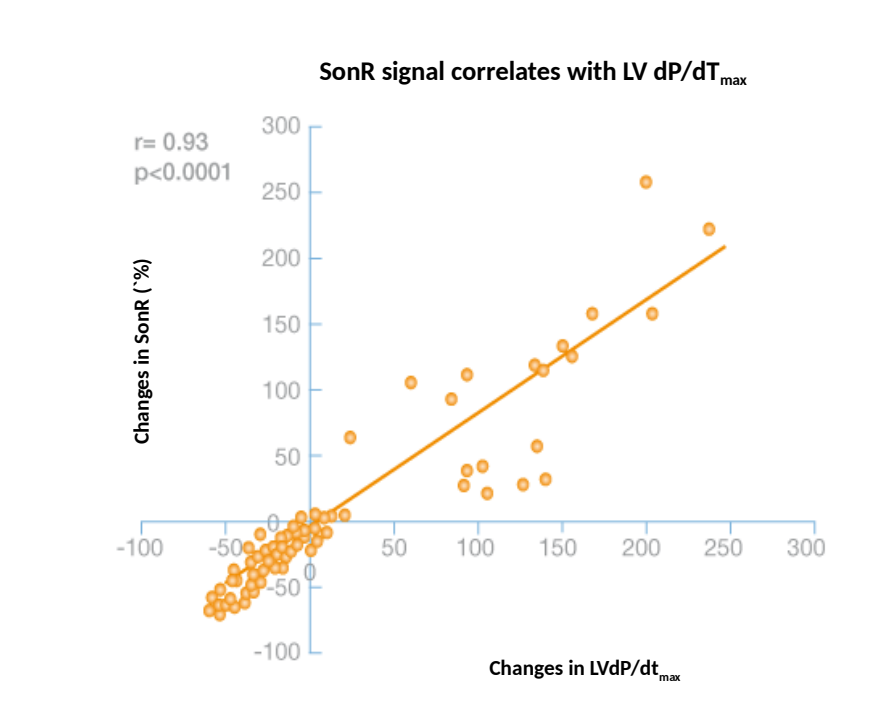
- **The technology is in the tip:**
  - SonR uses a unique hemodynamic sensor embedded in the tip of the SonRtip™ atrial sensing/pacing lead
  - The sensor detects cardiac muscle vibrations that reflect the first heart sound and correlate to left ventricular (LV) contractility
- **Measuring SonR amplitude is the same as measuring the first heart sound amplitude:**
  - Significant correlation between SonR and the first heart sound ($p<0.0001$)
  - Heart sound amplitude reflects changes in LV dP/dT max



Courtesy of LivaNova

Correlation with LV Contractility

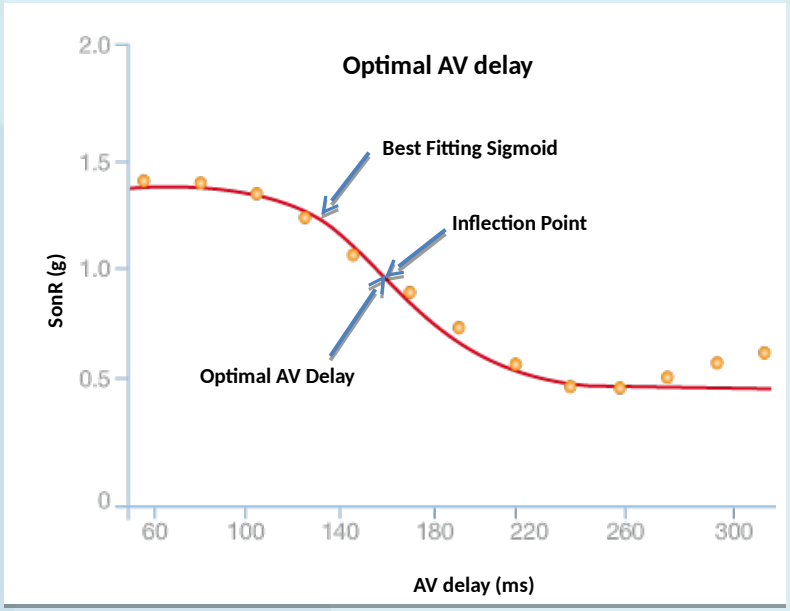
- SonR amplitude is an index of contractility and correlates with LV dP/dT max
  - SonR changes are highly related to contractility changes (r=0.93; <0.0001)
  - Correlation of SonR and LV dP/dT max has been verified during drug infusion, ischemic heart failure and pacing



Courtesy of LivaNova

AV Delay Optimization

- SonR signal varies like LV dP/dT max with VV delay changes
  - SonR measurements correspond to LVdP/dtmax and optimization is carried out on AV and VV delay combinations together, applying each value and measuring corresponding hemodynamics
  - Changes in contractility are immediately reflected by the SonR amplitude
    - The optimal value is the VV delay corresponding to the highest SonR amplitude across all AV delays tested
- SonR AV delay optimal value corresponds to echocardiography optimal value
  - Inflection point corresponds to the optimal AV delay



Heart Rhythm 2004;1(1S):377

Courtesy of LivaNova

Continuous Optimization
At Rest and Exercise

- **SonR provides weekly self-adjusting optimization of AV and VV delays**
  - For the optimal VV configuration, the optimal AV delay can be determined on a weekly basis
  - Every week, SonR tests 64 combinations for rest optimization
  - Every week, SonR tests 5 combinations for exercise optimization

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Europace 2008;**10**(7):801-8

Assessment of Myocardial Contractility by SonR Sensor in Patients Undergoing Cardiac Resynchronization Therapy

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GIUSEPPE RICCIARDI, M.D.,* PAOLO PIERAGNOLI, M.D.,* and LUIGI PADELETTI, M.D.*,‡

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Methods: *Thirty-one patients (19 men, 65 ± 7 years, LV ejection fraction [LVEF] 28% ± 5%, in sinus rhythm) were implanted with a CRT-defibrillator (CRT-D) device equipped with SonR sensor, which was programmed in VVI mode at 40 beats/min. Twenty-four hours after implantation, each patient underwent a noninvasive hemodynamic evaluation at rest and during isometric effort, including: (1) measurement of beat-to-beat endocavitary SonR signal; (2) echocardiographic assessment; and (3) continuous measurement of blood pressure with Nexfin method (BMEYE, Amsterdam, the Netherlands). The following contractility parameters were considered: (1) mean value of beat-to-beat SonR signal; (2) mean value of LV dP/dt by Nexfin system; and (3) fractional shortening (FS) by echocardiography.*

Results: *At the third minute of the isometric effort, mean value of SonR signal significantly increased from baseline ($P < 0.001$). Similarly, mean value of both LV dP/dt by Nexfin and FS significantly increased compared to the resting condition ($P < 0.001$; $P < 0.001$). While in 27 (88%) patients SonR signal increased at the third minute of the isometric effort, in four (12%) patients SonR signal decreased. In these patients, both LV dP/dt by Nexfin and FS consensually decreased.*

Conclusions: *In CRT patients, SonR sensor is able to detect changes in myocardial contractility in a consensual way like noninvasive methods such as Nexfin system and echocardiography. (PACE 2016; 39:268–274)*

Recording of Peak Endocardial Acceleration in the Atrium

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Conclusions: *The RA sonR signal was reliable and proportional to the RV signal on the short and long term, and reflected changes in activity. These observations suggest that the sonR sensor could be placed in the atrium for the hemodynamic monitoring of CRT system recipients. (PACE 2009; 32:S240–S246)*

EUROPEAN SOCIETY OF CARDIOLOGY®

Europace (2011) **13**, 402–408
doi:10.1093/europace/euq411

CLINICAL RESEARCH
Pacing and CRT

Endocardial acceleration (sonR) vs. ultrasound-derived time intervals in recipients of cardiac resynchronization therapy systems

Erwan Donal[1,2,3]*, Lionel Giorgis[2,3,4], Serge Cazeau[5], Christophe Leclercq[1,2,3], Lotfi Senhadji[2,3], Amel Amblard[4], Gael Jauvert[6], Marc Burban[7], Alfredo Hernández[2,3], and Philippe Mabo[1,2,3,8]

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Methods and results

We compared Doppler echocardiography to an automated system, based on the recording of sonR (formerly endocardial acceleration), in the detection of mitral and aortic valves closures and measurements of the duration of systole and diastole. We prospectively studied, under various conditions of cardiac stimulation, 75 recipients of CRT systems (69% men), whose mean age was 72 $\pm$ 9.2 years, left ventricular ejection fraction 35 $\pm$ 11%, baseline QRS duration 154 $\pm$ 29 ms, and New York Heart Association functional class 3.0 $\pm$ 0.7. We simultaneously recorded (i) sonR, detected by a non-invasive piezoelectric micro-accelerometer sensor clipped onto an electrode located in the parasternal region, (b) electrocardiogram, and (c) Doppler audio signals, using a multichannel data acquisition and analysis system. The correlation between timing of mitral and aortic valve closure by sonR vs. Doppler signals was examined by linear regression analysis. Correlation coefficients and the average absolute error were calculated. A concordance in the timing of the mitral ($r = 0.86$, error = 9.7 ms) and aortic ($r = 0.93$, error = 9.7 ms) valves closure was observed between the two methods in 94% of patients. Similarly, sonR and the Doppler-derived measurements of systolic ($r = 0.85$, error = 13.4 ms) and diastolic ($r = 0.99$, error = 12 ms) interval durations were concordant in 80% of patients.

Conclusion

A high concordance was found between sonR and the cardiac ultrasound in the timings of aortic and mitral valve closures and in the estimation of systolic and diastolic intervals durations. These observations suggest that sonR could be used to monitor cardiac function and adaptively optimize CRT systems.

Europace (2011) **13**, 402–408

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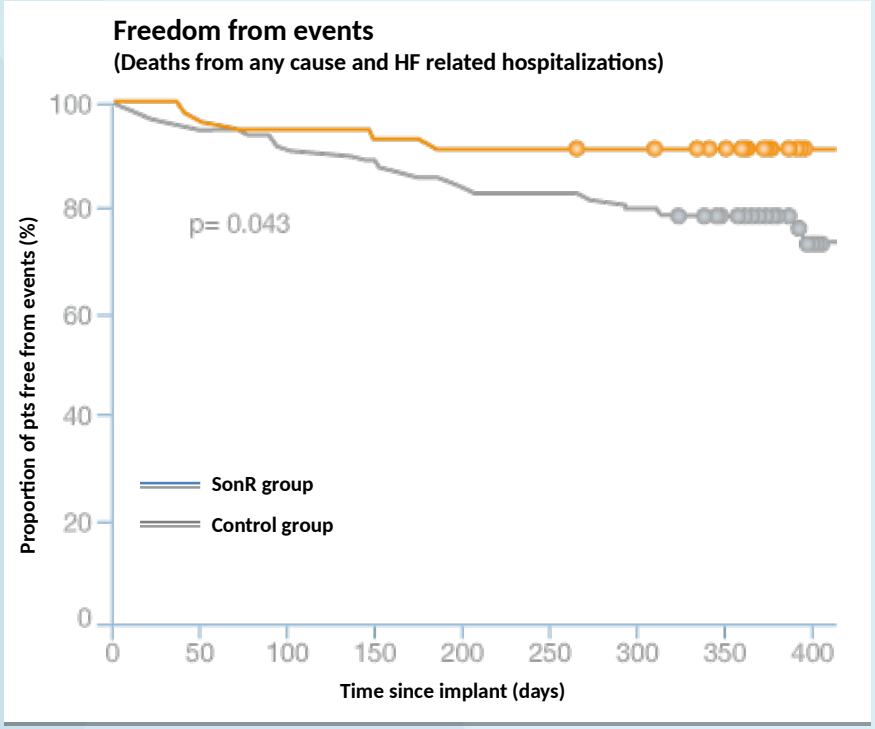
CLEAR Study

- Promising early results suggest SonR increases responder rates and reduces heart failure hospitalizations
  - In the CLEAR study, 78% of patients in the SonR arm compared with 62% in the standard medical practice arm improved, using the primary composite endpoints of death, heart failure (HF)-related hospitalizations, NYHA class and quality of life (QoL)
  - More patients in the SonR group than in the control group (91% vs. 75%; p<0.01) were free from events (death from any cause or hospitalization from HF)



HRS 2010;7(5S):AB27_4

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Association between frequent cardiac resynchronization therapy optimization and long-term clinical response: a *post hoc* analysis of the Clinical Evaluation on Advanced Resynchronization (CLEAR) pilot study

Peter Paul Delnoy[1]*, Philippe Ritter[2], Herbert Naegele[3], Serafino Orazi[4], Hanna Szwed[5], Igor Zupan[6], Kinga Goscinska-Bis[7], Frederic Anselme[8], Maria Martino[9], and Luigi Padeletti[10]

Conclusion These results further suggest that AVD and VVD frequent optimization (at implant, at 3 and 6 months) is associated with improved long-term clinical response in CRT-P patients.

Europace (2013) **15**, 1174–1181

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European Heart Journal (2016) **00**, 1–9
doi:10.1093/eurheartj/ehw526

CLINICAL RESEARCH
Heart failure/cardiomyopathy

Contractility sensor-guided optimization of cardiac resynchronization therapy: results from the RESPOND-CRT trial

Josep Brugada[1]*, Peter Paul Delnoy[2], Johannes Brachmann[3], Dwight Reynolds[4], Luigi Padeletti[5], Georg Noelker[6], Charan Kantipudi[7], José Manuel Rubin Lopez[8], Wolfgang Dichtl[9], Alberto Borri-Brunetto[10], Luc Verhees[11], Philippe Ritter[12], and Jagmeet P. Singh[13], for the RESPOND CRT Investigators†

Methods and results

RESPOND-CRT was a prospective, randomized, double-blinded, multicentre, non-inferiority trial. Patients were randomized (2:1, respectively) to receive weekly, automatic CRT optimization with SonR vs. an Echo-guided optimization of AV and VV timings. The primary efficacy endpoint was the rate of clinical responders (patients alive, without adjudicated HF-related events, with improvement in New York Heart Association class or quality of life), at 12 months. The study randomized 998 patients. Responder rates were 75.0% in the SonR arm and 70.4% in the Echo arm (mean difference, 4.6%; 95% CI, −1.4% to 10.6%; $P < 0.001$ for non-inferiority margin −10.0%) (Table 2). At an overall mean follow-up of 548 ± 190 days SonR was associated with a 35% risk reduction in HF hospitalization (hazard ratio, 0.65; 95% CI, 0.46–0.92; log-rank $P = 0.01$).

Conclusion

Automatic AV and VV optimization using the contractility sensor was safe and as effective as Echo-guided AV and VV optimization in increasing response to CRT.

European Heart Journal (2016) **00**, 1–9

Table I **Baseline characteristics**

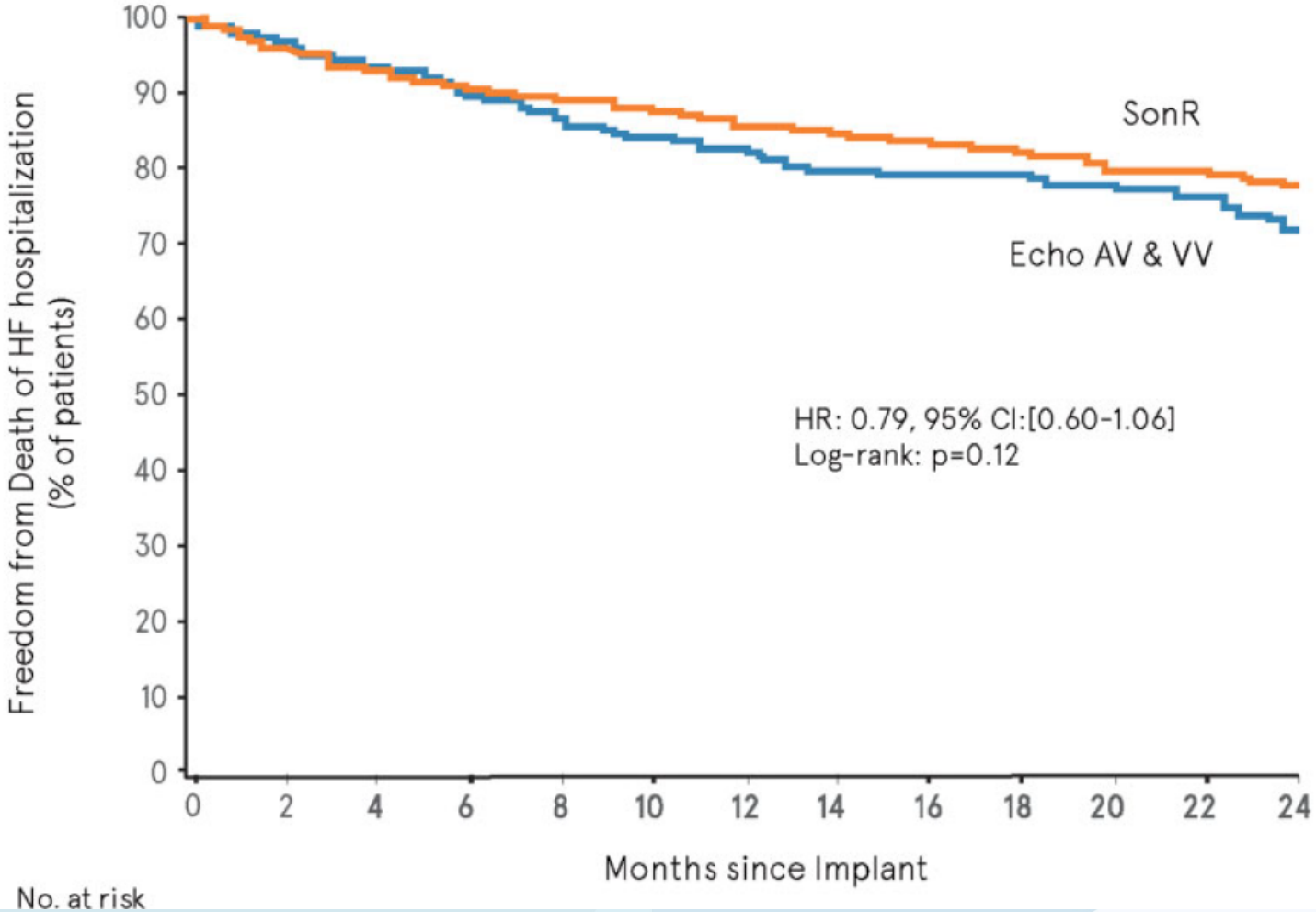
Baseline characteristics	SonR (*N*=670)	Echo (*N*=328)
Demographic		
Age, years	67.2±10.2	66.6±10.2
Men (%)	70.4 (472)	65.5 (215)
BMI, kg/m^2	28.5±5.6	27.9±5.0
NYHA class		
II	1.5 (10)	0.3 (1)
III	96.6 (647)	95.4 (313)
IV	1.9 (13)	4.3 (14)
Cardiac risk factors		
Atrial fibrillation	14.8 (99)	16.5 (54)
Diabetes	37.3 (250)	41.8 (137)
Current smoker	33.0 (221)	32.3 (106)
Systemic hypertension	62.1 (416)	61.6 (202)
Renal dysfunction	22.8 (153)	24.7 (81)
Chronic obstructive pulmonary disease	13.1 (88)	13.7 (45)
Cause of heart failure		
Ischaemic	45.5 (300)	42.5 (138)
LBBB	84.0 (563)	88.4 (290)
Non-LBBB	16.0 (107)	11.6 (38)
Heart rate, b.p.m.	70.7±13.4	70.9±13.6
PR interval, ms	188.1±44.9	188.3±42.7
Systolic blood pressure, mmHg	125.7±19.8	124.5±20.2
Diastolic blood pressure, mmHg	72.7±12.0	71.8±11.0
Echocardiographic finding		
Left ventricular ejection fraction		
≤25%	33.6 (225)	30.5 (100)
>25%	66.4 (445)	69.5 (228)
Left ventricular end-systolic volume, mL	162.0±72.5	159.8±75.0
Left ventricular end-diastolic volume, mL	226.2±88.0	225.6±94.3
Concomitant cardiac medications		
Beta-blocker	89.4 (599)	92.1 (302)
ACE inhibitor, substitutes, or ARB	89.9 (602)	88.7 (291)
Ivabradine	9.0 (60)	10.4 (34)
Diuretic	79.6 (533)	84.5 (277)
Spironolactone	57.9 (388)	56.7 (186)

European Heart Journal (2016) **00**, 1–9

Table 2 Clinical outcomes

Outcome	SonR (*N*=649)	Echo (*N*=318)	Mean % difference (95% CI)	*P*-value	
	% (*n*)			Non-inferiority	Superiority
Clinical responders[a]	75.0 (487)	70.4 (224)	4.6 (−1.4, 10.6)	<0.001	0.13
NYHA improved	65.6 (426)	61.9 (197)			
Stable NYHA, improved quality of life	9.4 (61)	8.5 (27)			
Clinical non-responders[b]	25.0 (162)	29.6 (94)			
Clinically stable	4.0 (26)	4.4 (14)			
Clinically worsened: secondary endpoint	21.0 (136)	25.2 (80)	4.2 (−1.5, 9.9)	<0.001	0.15
Death from any cause	5.5 (36)	6.0 (19)			
If no death, HF-related event	10.2 (66)	12.9 (41)			
Worsened NYHA class	0.9 (6)	0.3 (1)			
Worsened quality of life; stable NYHA stable	4.3 (28)	6.0 (19)			
Death or HF hospitalization	14.2 (92)	17.6 (56)	3.4 (−1.5, 8.4)	<0.001	0.18

European Heart Journal (2016) **00**, 1–9



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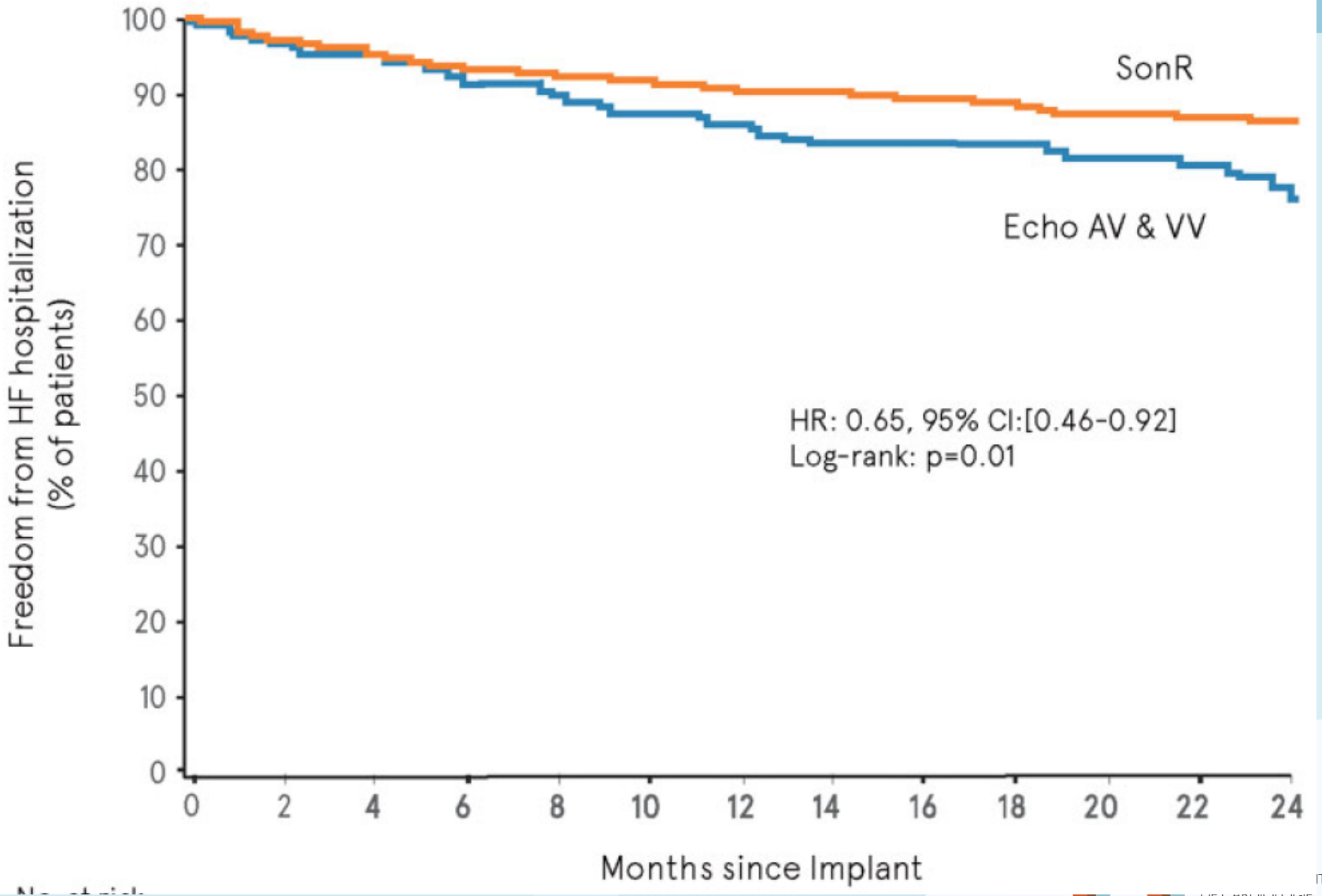
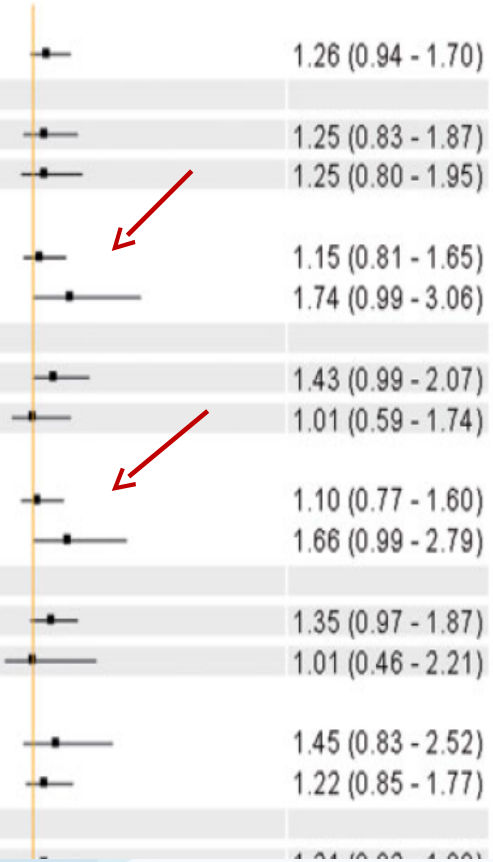
European Heart Journal (2016) **00**, 1–9



European Heart Journal (2016) **00**, 1–9

Variable	SonR (N=649) no. / total no.	Echo (N=318) (responder %)	P Value	Odds Ratio (95% CI)
Overall	487/649 (75.0)	224/318 (70.4)		1.26 (0.94 - 1.70)
Age			0.99	
< 68,5 Yr	228/314 (72.6)	115/169 (68.1)		1.25 (0.83 - 1.87)
>= 68,5 Yr	259/335 (77.3)	109/149 (73.2)		1.25 (0.80 - 1.95)
Gender			0.23	
Male	325/454 (71.6)	142/207 (68.6)		1.15 (0.81 - 1.65)
Female	162/195 (83.1)	82/111 (73.9)		1.74 (0.99 - 3.06)
BMI			0.30	
< 30 kg/m2	306/400 (76.5)	148/213 (69.5)		1.43 (0.99 - 2.07)
>= 30 kg/m2	156/216 (72.2)	67/93 (72.0)		1.01 (0.59 - 1.74)
LVEF			0.21	
> 25%	321/430 (74.7)	160/220 (72.7)		1.10 (0.77 - 1.60)
<= 25%	166/219 (75.8)	64/98 (65.3)		1.66 (0.99 - 2.79)
QRS Morphology			0.51	
LBBB	417/543 (76.8)	199/280 (71.1)		1.35 (0.97 - 1.87)
Non-LBBB	70/106 (66.0)	25/38 (65.8)		1.01 (0.46 - 2.21)
QRS Duration			0.62	
< 150ms	117/172 (68.0)	47/79 (59.5)		1.45 (0.83 - 2.52)
>= 150ms	360/462 (77.9)	173/233 (74.3)		1.22 (0.85 - 1.77)
PR Interval			0.89	



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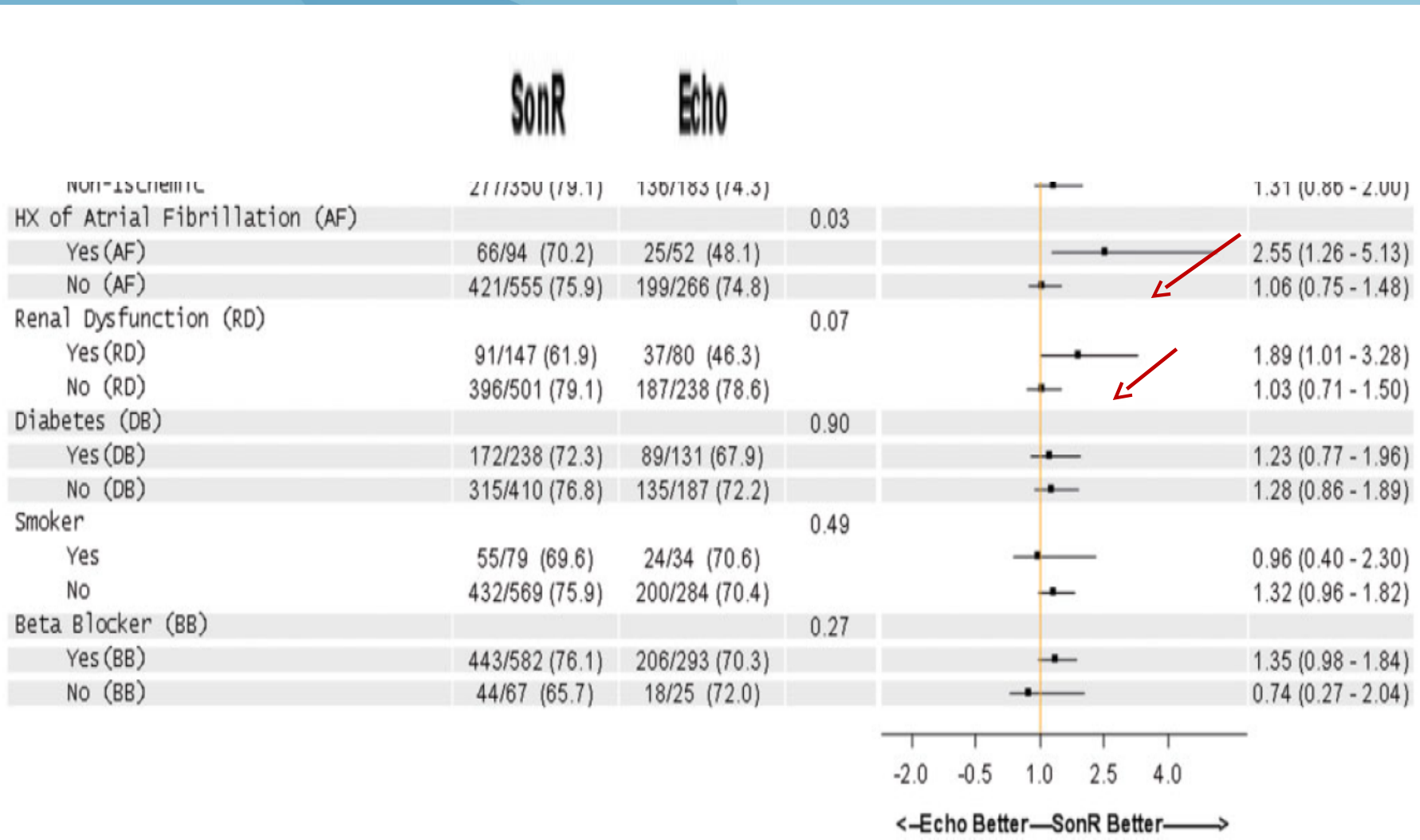

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European Heart Journal (2016) **00**, 1–9

Clinical Assessment of the SonR Algorithm in the PARADYM RF SonR CRT-D by Echocardiography (SonR-ECHO)

This study is ongoing, but not recruiting participants.

Sponsor:
LivaNova

Information provided by (Responsible Party):
LivaNova

ClinicalTrials.gov Identifier:
NCT01869062

First received: May 27, 2013
Last updated: November 19, 2015
Last verified: November 2015
History of Changes

Primary Outcome Measures:

- CRT-responders rate increase based on LVESV decrease at M6 / baseline [Time Frame: 6 months]

Secondary Outcome Measures:

- A-wave truncation assessment at M6 [Time Frame: 6 months]

Other Outcome Measures:

- Report LV remodeling from LVEDV decrease at M6 / baseline [Time Frame: 6 months]

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