Comparison of right ventricular septal pacing and right ventricular apical pacing in patients receiving cardiac resynchronization therapy defibrillators

The SEPTAL CRT study

(NCT: 00833352)

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ESC congress,
Barcelona, September 1st , 2014

The SEPTAL CRT study was supported by grants from Boston Scientific

Disclosure Information

Christophe Leclercq, MD, PhD

•Research Grants:
Boston Scientific, Medtronic, Sorin Group, St. Jude Medical,

•Consulting / Advisory board:
Boston Scientific, Biotronik, Medtronic, St. Jude Medical, Sorin Group

•Lectures:
Boston Scientific, Biotronik, Medtronic, St. Jude Medical, Sorin Group, GE, Boehringer, Bayer, BMS

Primary and Main Secondary Endpoints

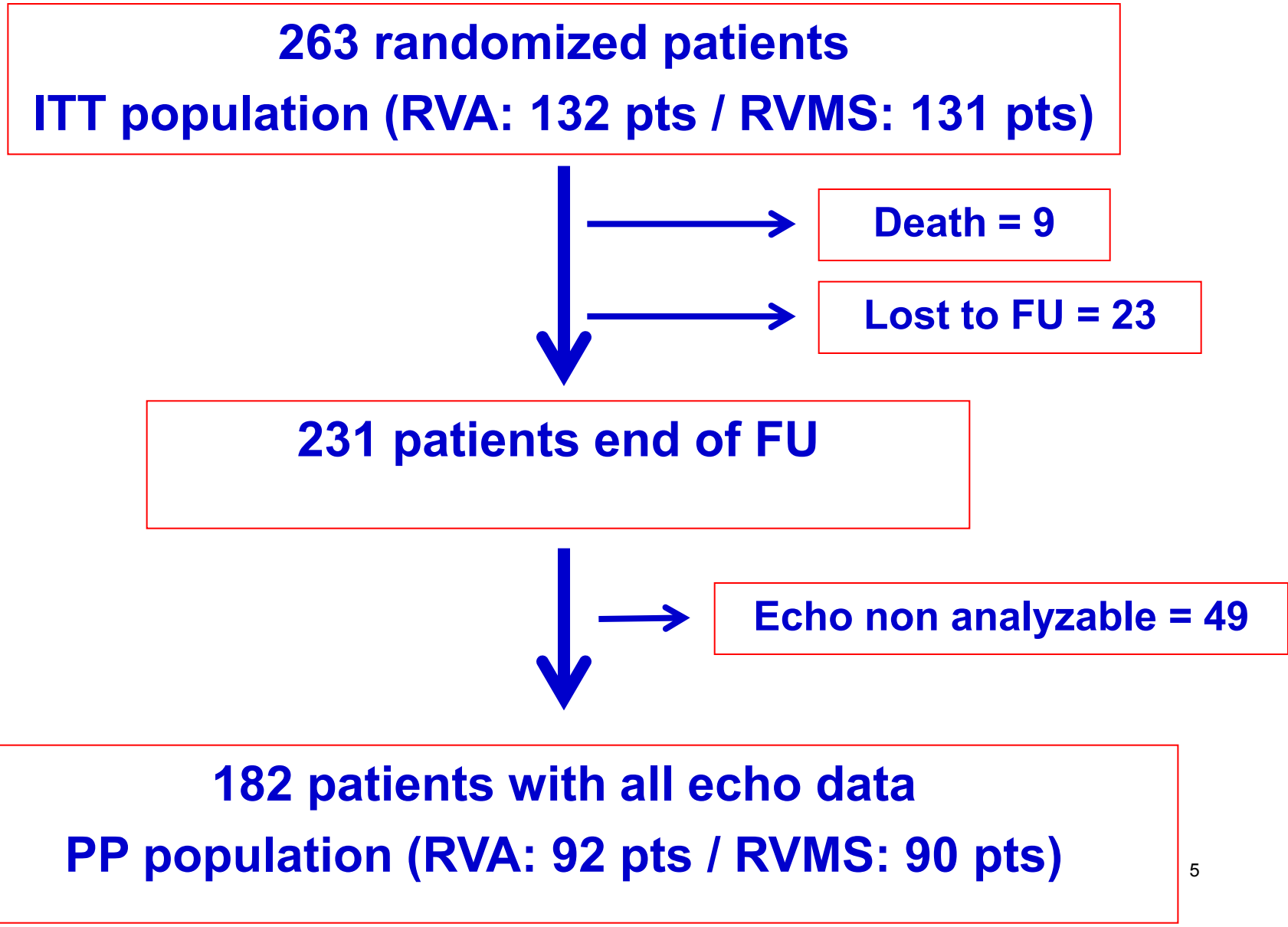
Non inferiority hypothesis

- **Primary endpoint:**
  - **Changes in the LVESV between baseline and 6 months**
- **Secondary endpoints:**
  - **the percentage of "echo-responders" defined by a reduction in the LVESV ≥ 15% at 6 months**
  - **the implant success rate of the RV lead**
  - **the proportion of patients experiencing ≥1 MAE,**
    - **including deaths from all causes,**
    - **serious cardiac AE**
    - **procedure-related or device-related MAE**

Study Design

- **Prospective, multicenter, European, single-blind, randomized controlled trial:**
  - **1:1 randomization**
  - **Apical vs. mid-septal RV location**
  - **In office visits after implant at 1, 6 and 12 months**
- **Designed to detect the non-inferiority in the primary endpoint with:**
  - **a 90% power**
  - **At the 2.5% unilateral significance level**
  - **Per protocol (PP) population analysis by use of the lower limit of the confidence interval of the difference in the reduction of LVESV between treatments with a cut-off value of - 20 mL**
  - **Sample size requirement of 240 patients**
- **25 Centers: 19 in France (173 patients), 9 in Spain (90 patients)**

Study flowchart



Baseline Characteristics – PP Population

	Apex (92)	Septum (90)	Total (182)
Men (%)	73.9	71.1	72.5
Age, (y)	64.1 ± 9.7	62.5 ± 9.8	63.3 ± 9.8
NYHA class II (%)	5.4	10.1	7.7
NYHA class III (%)	90.2	85.4	87.8
NYHA class IV ambulatory (%)	4.3	4.5	4.4
Ischemic cardiomyopathy (%)	27.2	25.6	26.4
LVEF (%)	30 ± 8.	30 ± 8.	30 ± 8
Baseline medication :			
Diuretics (%)	83.7	86.7	85.2
ACE inhibitor or ARB (%)	93.5	95.6	94.5
Aldosterone antagonist (%)	38.0	40.0	39.0
Beta-blocker (%)	90.2	91.1	90.7
Primary prevention (%)	98.9	97.8	98.4
QRS duration, ms	159.9 ± 19.8	157.7 ± 22.6	158.8 ± 21.2

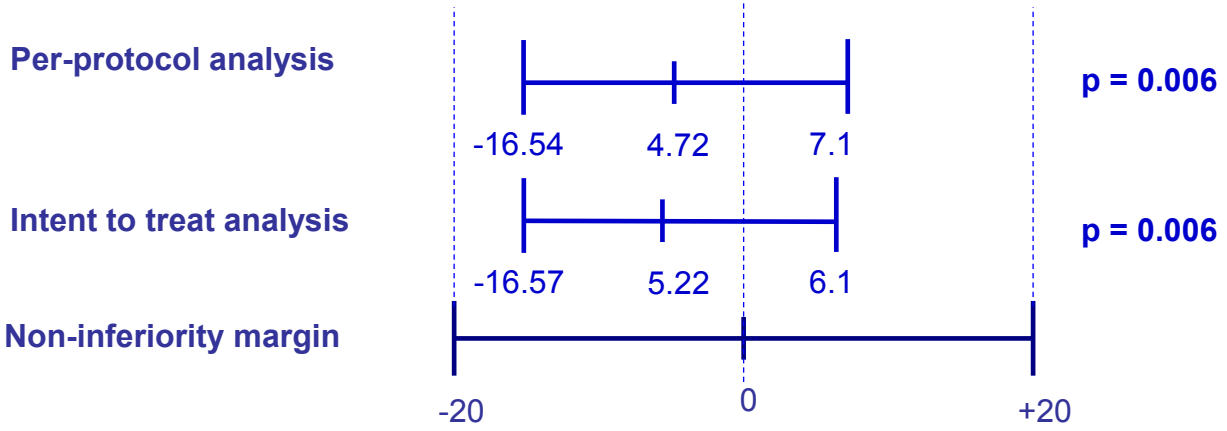
No difference between ITT and PP population for all parameters

Results : Primary Endpoint

	Septal (n=90)	Apical (n=92)
LVESV baseline (mL)	157.8 ± 83	153.5 ± 72
LVESV 6 months (mL)	132.5 ± 86	124.2 ± 67
Difference (mL)	-25.3 ± 39	-29.3 ± 44

PP analysis :

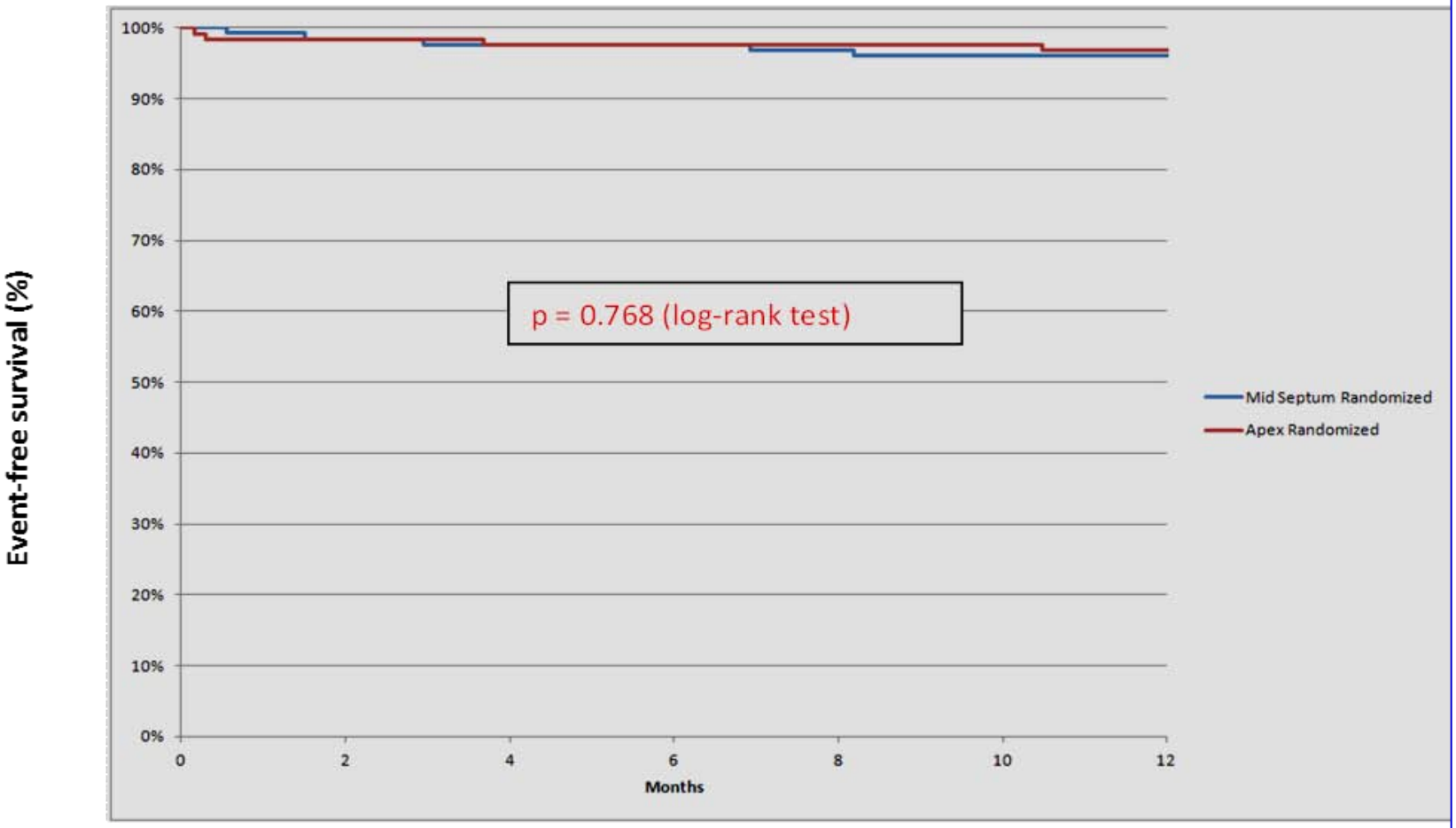
mean difference in LVESV reduction - 4.7 mL with lower limit of the unilateral 97.5% confidence interval at - 16.54 mL (p= 0.006)



Main Secondary Endpoints

- **No ≠ in the percentage of "echo-responders, i.e. reduction in LVESV > 15% at 6 months, 50% in both groups, p = 0.99**
- **No ≠ in the implant success rate:**
  - **90.0% in the Septum randomized group**
  - **86.8% in the Apex randomized group**
  - **"Low" implant success rate ➔ mostly due to the lack of defibrillation testing (n = 27)**
  - **2 patients crossed over due to failure of fulfilling the RV implantation criteria in each group**

1-year mortality



Number at risk	0	3	6	12 months
RV apex	132	120	119	70
RV Mid-Septum	131	123	122	56

Conclusions

- **First multicenter randomized prospective trial comparing RV apical and RV septal pacing in CRT-D recipients**
- **Septal CRT demonstrates the non-inferiority of RV septal pacing when compared to conventional RV apical pacing in CRT patients**
  - ✓ **No ≠ in LVESV reduction between baseline and 6 months**
  - ✓ **Similar percentage of "echo-responders" (50%)**
  - ✓ **No difference in implant success rate**
- **No statistical ≠ for the safety and efficacy endpoints:**
  - ✓ **Total mortality: 3.0% vs.3.8% (p=0.749)**
  - ✓ **MAE : 34.8% vs. 39.7% (p=0.446)**