Author's response to reviews

Title: A case report on the clinical benefit of Cardiac Resynchronization Therapy optimization using a device-based hemodynamic sensor in a patient with dilated cardiomyopathy

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The comments of the 2 reviewers are:

1. The Introduction doesn’t explain the relevance of the case to the medical literature
2. Specifications on the improvement of clinical outcome such as dispnea, edemas, body weight and urinary output. The etiology of dilated cardiomyopathy needs to be added.

The authors thank reviewers for their comments.

Comment #1: The Introduction doesn’t explain the relevance of the case to the medical literature
The Introduction was revised to reposition the case report in the context of studies published on the device. The Introduction section is now the following:

“Introduction
Cardiac resynchronization therapy (CRT) has been proven to be an established therapy for patients with heart failure (HF) symptoms, left ventricular systolic dysfunction, and a wide QRS, on top of optimal medical therapy. However, the magnitude of clinical and hemodynamic benefit of CRT among recipients varies and non-responders can account for up to 30% of treated patients. The non-response can be partly caused by inappropriate settings of atrioventricular (AV) and interventricular (VV) delays leading to persistent AV, VV and intraventricular dyssynchrony. Several methods have been developed to optimize AV and VV delays, including device based algorithms allowing automatic optimization of delays. Encapsulated in the SonRTip™ atrial lead (Sorin CRM SAS, Clamart, France), the hemodynamic SonR sensor automatically optimizes AV and VV delays weekly in HF patients in sinus rhythm, at rest and exercise.

The SonR sensor was clinically evaluated in the CLEAR multicenter, single-blind, randomized (1:1) pilot study (n=199) using the SonR system integrated to a CRT device with pacemaker. The primary effectiveness was the response rate based on a hierarchical Clinical Composite Score (CCS) including (a) death, (b) HF-related hospitalization, (c) New-York Heart Association (NYHA) and (d) quality of life using the EQ-5D questionnaire. Responders’ rate were 76% in the SonR arm vs. 62% in the control arm (p=0.03) at 1 year; this result was driven by improvement of symptoms. A post-hoc analysis of the study showed that systematic optimization (n=66, three times during one year, whatever the method used SonR or echo) was associated with more responders using the CCS, fewer deaths or HF hospitalizations and less symptoms vs. non-systematic optimization (n=133, 48% of patients...
never optimized, 29% optimized once, 23% optimized twice), suggesting that favorable outcomes were associated with optimization frequency, not with the optimization method used\(^3\). This repeated optimization strategy was found cost-effective vs. the non-systematic optimization arm in most European countries, in a cost-effectiveness analysis published recently\(^2\). Finally, Dr. Duncker at al. published a prospective, multicenter, non-randomized study design to assess the safety and electrical performances of the atrial SonRtip lead in 99 patients implanted with CRT device with defibrillator (CRT-D)\(^4\).

We describe a case report of a non-responder patient implanted with this atrial lead, who became a responder to CRT, after the sensor activation.”

Comment #2: Specifications on the improvement of clinical outcome such as dyspnea, edemas, body weight and urinary output. The etiology of dilated cardiomyopathy needs to be added. The etiology of the cardiomyopathy and symptoms of the patient were added in the case report presentation:

At the beginning of the section:
“A 78-year old men presented with dilated ischemic cardiomyopathy, left bundle branch block, left ventricular ejection fraction (LVEF) of 35%, NYHA class III/IV, diabetes, paroxysmal atrial fibrillation (AF), dyspnea when undergoing mild exercise and lower limbs’ edema.”

At the end of the section:
“Symptoms (dyspnea and lower limbs edema) had disappeared at the 7-month post-implant visit.”

Additionally, the Conclusion section and References were slightly revised.