

Rhythm or rate control strategy in CRT recipients with long-standing persistent atrial fibrillation - preliminary results of the PilotCRAFT study

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Background: The presence of atrial fibrillation (AF) in cardiac resynchronization therapy (CRT) recipients is common and AF is a marker of poorer CRT response. The negative influence of AF on CRT efficacy is mediated mainly by the drop of the effectively captured biventricular paced beats percentage (BiVp%) which should exceed 95-98% to warrant good CRT response. Sinus rhythm (SR) restoration may improve CRT efficacy which in turn may protect AF recurrence. However, there is lack of randomized studies comparing rhythm and rate control strategies in these patients.

Purpose: The purpose of the Pilot-CRAFT study (NCT01850277) was to compare the efficacy of rhythm vs rate control strategy in CRT patients with long-standing persistent or permanent atrial fibrillation.

Methods: The study included patients with CRT and permanent or persistent AF lasting for ≥ 6 months, resulting in BiVp% $< 95\%$, who were randomly assigned to rhythm or rate control strategy. The rhythm control strategy comprised of external electrical cardioversion (EEC). The rate control strategy included pharmacotherapy and atrioventricular node ablation (AVNA) as needed. Both of the study arms received amiodarone. The follow-up lasted 12 months. The primary endpoint was the 12-month BiVp%. The patients underwent ECHO, cardiopulmonary test, quality of life (QoL) and clinical outcomes assessment.

Results: The study included 43 CRT patients (97,7% males) aged 68,4 (SD: $\pm 8,3$) years with mean BiVp% 82,4% $\pm 9,7\%$ at baseline. The mean duration of AF paroxysm was 25 ± 19 months. The mean baseline left ventricular ejection fraction (LVEF), left atrium area and maximal oxygen uptake (VO2max) were: 30 $\pm 8\%$, 33 ± 7 cm², 14 ± 5 mL/(kg*min), respectively. The EEC was performed in 19 out of 22 patients assigned to the rhythm control arm. The immediate success rate of EEC was 58%. 42% of the rhythm control arm patients remained in SR after 12 months. In the rate control group 1 person underwent AVNA and in 1 patient spontaneous SR resumption was observed. After 12 months there was significant BiVp% increase in both the rhythm and the rate control arms (98,1 $\pm 2,3$ vs 96,3 $\pm 3,9\%$, respectively). The BiVp% differences between the groups were not significant ($P = 0,093$). However, in the per protocol analysis, the rhythm control group had greater LVEF after 12 months as opposed to the rate control arm (36,8% vs 29,9% respectively, $P = 0,039$). The LVEF raised significantly in the rhythm control group (Δ LVEF 5,0 (95%CI: 1,54; 8,46)). No significant differences between the groups in the VO2max, QoL, clinical and safety end-points were noticed.

Conclusions: Structured follow-up of CRT patients with long-standing persistent or permanent AF leads to significant BiVp% increase exceeding 95%. The rate control strategy did not improve CRT effectiveness, irrespective of high BiVp%. However limited in the efficacy, the rhythm control strategy may improve CRT outcome in these patients, resulting in LVEF increase.