Ablation of frequent PVC in patients meeting criteria for primary prevention ICD implant: Safety of withholding the implant

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BACKGROUND Premature ventricular complex (PVC) ablation has been shown to improve left ventricular ejection fraction (LVEF) and New York Heart Association functional class in patients with left ventricular dysfunction. Both are considered key variables in predicting risk of sudden cardiac death.

OBJECTIVE The objective of this study was to assess whether ablation might remove the primary prevention (PP) implantable cardioverter-defibrillator (ICD) indication in patients with frequent PVC.

METHODS Sixty-six consecutive patients with PP-ICD indication and frequent PVC [33 (50%) men; mean age 53 ± 13 years; 11 (17%) with ischemic heart disease] underwent PVC ablation. The ICD was withheld and the indication was reevaluated at 6 and 12 months.

RESULTS LVEF progressively improved from 28% ± 4% at baseline to 42% ± 12% at 12 months ($P < .001$). New York Heart Association functional class improved from 2 patients with NYHA functional class I (3%) at baseline to 35 (53%) at 12 months ($P < .001$). The brain natriuretic peptide level decreased from 246 ± 187 to 176 ± 380 pg/mL ($P = .004$). The PP-ICD indication was removed in 42 patients (64%) during follow-up, from 38 (92%) of them at 6 months, showing an independent association with baseline PVC burden and successful sustained ablation. In patients with successful sustained ablation, a cutoff value of 13% PVC burden had a sensitivity of 100% and a specificity of 93% (area under the curve 99%) for removing ICD indication postablation. No sudden cardiac deaths or malignant ventricular arrhythmias were observed.

CONCLUSION In patients with frequent PVC and PP-ICD indication, ablation improves LVEF and, in most cases, allows removal of the indication. Withholding the ICD and reevaluating within 6 months of ablation seems to be a safe and appropriate strategy.

KEYWORDS Premature ventricular complex; Ablation; Implantable cardioverter-defibrillator; Primary prevention; Sudden cardiac death

ABBREVIATIONS **ASA** = acute successful ablation; **CRT** = cardiac resynchronization therapy; **ICD** = implantable cardioverter-defibrillator; **IHD** = ischemic heart disease; **LV** = left ventricle/ventricular; **LVEF** = left ventricular ejection fraction; **MI** = myocardial infarction; **NICM** = nonischemic cardiomyopathy; **NYHA** = New York Heart Association; **PP** = primary prevention; **PVC** = premature ventricular complex; **SCD** = sudden cardiac death; **SHD** = structural heart disease; **SOO** = site of origin; **SSA** = successful sustained ablation

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Introduction

Ablation of frequent premature ventricular complex (PVC) improves left ventricular ejection fraction (LVEF) in patients with left ventricular (LV) dysfunction.[1–7] Recently, it has been shown that this benefit occurs not only in patients with "PVC-induced" cardiomyopathy but also in those with "PVC-worsened" cardiomyopathy.[8,9] In contrast, primary prevention (PP) of sudden cardiac death (SCD) with an implantable cardioverter-defibrillator (ICD) improves survival in patients with heart failure and severely depressed LVEF due to either ischemic heart disease (IHD) or nonischemic cardiomyopathy (NICM).[10–12] As the decision to implant an ICD depends on the established cutoff value for

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LVEF, heart failure treatment must first be optimized with appropriate drugs (angiotensin-converting enzyme inhibitors and β-blockers) before LVEF is assessed. In fact, current guidelines[13] recommend withholding the implant in some circumstances, as, for instance, after surgical myocardial revascularization, with the assumption that LVEF could improve. However, there are no specific timing recommendations on the reevaluation of LVEF and the subsequent decision to proceed with the ICD after ablation of frequent PVC in patients meeting PP-ICD criteria.

The aim of the present study was to assess whether the indication for PP-ICD might be removed by PVC ablation as well as to evaluate the safety of withholding the implant.

Methods

This was a multicenter prospective study. The 3 participating centers included patients with frequent PVC who met at least one of the following criteria for PP-ICD implantation under current guidelines[13]: (1) LV dysfunction due to prior myocardial infarction (MI), ≥40 days post-MI with LVEF ≤30%, and New York Heart Association (NYHA) functional class I; (2) LVEF ≤35% due to prior MI, ≥40 days post-MI, and NYHA functional class II-III; or (3) NICM, LVEF ≤35%, and NYHA functional class II-III. Patients meeting at least one of the following criteria were excluded: survivors of SCD, previous spontaneous sustained ventricular arrhythmia or syncope, previous ICD, or diagnosis of arrhythmogenic right ventricular dysplasia.

Frequent PVC was defined as a burden of >4% at baseline 24-hour Holter monitoring, which is the lowest PVC burden associated with tachycardiomyopathy in the literature.[14] No patient was excluded because of the number of PVC morphologies or the presumed site of origin (SOO) according to the electrocardiographic (ECG) criteria. The entire population had received optimal medical therapy for heart failure at maximum tolerated dose for ≥3 months at the time of study inclusion.

The ICD was withheld and the implant indication was reevaluated at 6 and 12 months. In 1 center, an early reevaluation at 1 month was performed. The local ethics committee approved the study, and all participants signed the written informed consent form.

Baseline evaluation

A detailed medical history including drug therapies, a clinical evaluation, and a basal blood test including brain natriuretic peptide (BNP) levels were obtained for all participants. Before the ablation procedure, 12-lead surface ECG and 24-hour Holter monitoring were performed in all patients to evaluate the presence of multiple morphologies and to calculate PVC burden. Baseline echocardiography was performed within the 3 months before the procedure. Echocardiographic studies were blinded to ablation time and success. LVEF was calculated by using the Simpson formula, computing 3 consecutive averaged beats to minimize distortion generated by PVC. The echocardiographic evaluation did not include ectopic or postectopic cycles.

Ablation procedure

Before the ablation procedure, antiarrhythmic drugs except amiodarone were withdrawn for 5 half-lives. Ablation was guided by the CARTO navigation system (Biosense Webster Inc, Waterloo, Belgium) using a 3.5-mm irrigated-tip catheter (NaviStar, Biosense Webster Inc) for mapping and ablation. Acute successful ablation (ASA) was considered when targeted PVC was eliminated. Patients were monitored for 30 minutes after the procedure to ensure complete PVC abolition. As the entire population of the study had LV dysfunction, therapy with β-blockers was maintained, independent of ablation success.

Follow-up

Patients were followed up at the outpatient clinic at 6 and 12 months. Echocardiography was repeated, and the results were available for the scheduled outpatient visits, which included evaluation of functional class, 24-hour Holter monitoring, measurement of BNP level, and reevaluation of the ICD indication. One of the participating centers also conducted these evaluations at 1 month postablation. All patients completed the 1-year follow-up, irrespective of the initial findings at 6 months postablation. *Successful sustained ablation* (SSA) was defined as the persistent elimination of ≥80% of PVC after the ablation procedure, with no recurrences during follow-up.

Statistical analysis

Continuous variables are presented as mean ± SD. Categorical variables are presented as total number and percentages. To compare means of 2 variables, the Student *t* test was used (or Wilcoxon rank sum test when necessary). Proportions were compared using the χ^2 or Fisher exact test, as appropriate. The Friedman analysis of variance by ranks was used for repeated measures. Logistic regression analysis was used to study the effects of baseline characteristics in predicting the SSA procedure as well the probability of removal of the ICD indication during follow-up. A *P* value of <.10 was used to screen covariates for inclusion in the multivariate analysis. A backward stepwise selection algorithm was applied to select covariates for inclusion in the multivariate regression model. At each step, the least significant variable was discarded and odds ratio and 95% confidence interval were calculated. Receiver operating curve analysis was used to evaluate the optimal cutoff value for predicting the removal of the ICD indication during follow-up. To measure the association between the reduction in PVC burden and the change in LVEF, a Pearson correlation coefficient was computed. A *P* value of <.05 was considered statistically significant. Statistical analysis was performed using R software for Windows, version