BRIEF REPORT

Implant of Cardiac Resynchronization Therapy Device in Patients with High Percentage of Right Ventricular Pacing and Refractory Heart Failure

Implante de resincronizador cardíaco en pacientes con alto porcentaje de estimulación en el ventrículo derecho e insuficiencia cardíaca refractaria

GASTÓN ALBINA, SANTIAGO RIVERA, IGNACIO MONDRAGÓN, NICOLÁS VECCHIO, ALBERTO GINIGER, FERNANDO SCAZZUSO

ABSTRACT

Background: Implant of a cardiac resynchronization therapy device in patients with pacemaker or implantable cardioverter defibrillator who develop heart failure with left ventricular dysfunction is controversial.
Objective: The aim of this study was to evaluate the outcome of these patients after upgrading to cardiac resynchronization therapy.
Methods: Patients undergoing therapy upgrade between 2011 and 2015 were evaluated.
Results: A total of 21 patients were included with mean age of 70.7±10.8 years. Mean QRS duration was 180.9±23.2 ms and left ventricular ejection fraction was 26.8 ± 7.7%. The frequency of right ventricular pacing was 90.5±19.3%. Ten patients were in functional class II and 11 in FC III. The implant was successful in 18 patients (85.7%).
Left ventricular ejection fraction was 33.9±10.4% one year after upgrading (p=0.028). Among the total number of patients, 13 improved their functional class in at least one category and only 4 were rehospitalized due to heart failure (p=0.048). The rate of complications was 14.28%.
Conclusions: Therapy upgrade improved symptoms and reduced hospitalizations due to heart failure.

Key words: Cardiac resynchronization therapy - Upgrade - Cardiac failure - Pacemaker - Implantable cardioverter defibrillator

RESUMEN

Introducción: El implante de un resincronizador cardíaco en pacientes que presentan marcapasos o cardiodesfibrilador y que desarrollan insuficiencia cardíaca (IC) con disfunción sistólica es controvertido.
Objetivo: Evaluar la evolución de estos pacientes (upgrade).
Material y métodos: Se analizaron los pacientes a quienes se les realizó upgrade durante el período 2011 a 2015.
Resultados: Se incluyeron 21 pacientes, cuya edad promedio era de 70,7 ± 10,8 años. La duración del QRS fue de 180,9 ± 23,2 ms y la FEVI de 26,8 ± 7,7%. En cuanto a la estimulación del ventrículo derecho el resultado fue de 90,5 ± 19,3%. Diez pacientes fueron clasificados en clase funcional (CF) II y 11, en CF III. Se lograron implantes exitosos en 18 pacientes (85,7%).
La FEVI al año de realizado el upgrade fue de 33,9 ± 10,4% (p = 0,028). Del total de pacientes, trece mejoraron al menos en una clase funcional, y solo cuatro volvieron a ser internados por IC (p = 0,048).El porcentaje de complicaciones fue del 14,28%.
Conclusiones: La terapia de upgrade permitió mejorar los síntomas y reducir internaciones por insuficiencia cardíaca.

Palabras clave: Resincronización cardíaca - Insuficiencia cardíaca - Marcapasos - Desfibrilador implantable

Abbreviations

LBBB	Left bundle-branch block	**HF**	Heart failure
ICD	Implantable cardioverter defibrillator	**PM**	Pacemaker
FC	Functional class	**CRT**	Cardiac resynchronization therapy

INTRODUCTION

Cardiac resynchronization therapy (CRT) is an accepted treatment for heart failure (HF) patients who remain with symptoms despite optimal medical treatment. This therapy proved to be beneficial in terms of HF hospitalizations and mortality in the subgroup of patients with QRS duration ≥130 ms, particularly in those with complete left bundle branch block (LBBB). Though with less evidence, the European guidelines also recommend implantation of a CRT device in pa-

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Address for reprints: Gastón Albina. Blanco Encalada 1543 (C1428DCO). e-mail: gastonalbina@gmail.com

Instituto Cardiovascular de Buenos Aires (ICBA)

tients with conventional pacemaker (PM) or implantable cardioverter defibrillator (ICD) presenting high percentage of ventricular pacing and who develop HF with low left ventricular ejection fraction (LVEF) and no other evident cause. (1) The risk of complications is higher in implant upgrades because the venous accesses are more complex, and the rate of infections is higher. In addition, the risk increases with lead removal or with the number of leads implanted.

The aim of the present study was to evaluate the outcome of patients undergoing CRT upgrade and the short and long term complications of the procedure.

METHODS

The information of all the patients who underwent upgrading from PM or ICD to CRT with or without automatic defibrillation was retrospectively analyzed in a single center between 2001 and 2015.

The technique of implantation, its result and the long-term outcome were analyzed. The procedure required the use of only two sheaths to cannulate the coronary sinus, a 0.14'' guide wire and a bipolar or quadripolar coronary sinus lead depending on the patient's medical coverage. In no case were subselection catheters or advanced CRT implantation techniques available.

Statistical analysis

Discrete variables were expressed as percentages and continuous variables as mean and standard deviation or median and interquartile range, according to their distribution. The chi square test was used to compare discrete variables and continuous variables were analyzed using Student's t test or the Mann-Whitney test depending on sample distribution. A linear univariate analysis was performed to identify predictors associated with LVEF improvement. A p value <0.05 was considered statistically significant.

Ethical considerations

The study was evaluated and approved by the institutional Ethics Committee.

RESULTS

A total of 21 patients who underwent upgrading to CRT between 2011 and 2015 were included in the study. Twenty patients were men and the device implanted included an ICD in 20 cases. Mean age was 70.7±10.8 years. The devices previously implanted were 12 DDD pacemakers, 3 VDD pacemakers, 1 dual-chamber ICD and 4 single-chamber ICD. Five patients had chronic atrial fibrillation, and 21 patients had mitral regurgitation which was mild in 13, moderate in 6 and severe in 2 cases. Mean QRS duration was 180.9±23.2 ms and the percentage of right ventricular (RV) apical pacing was 90.5±19.3%. Fifteen patients had ischemic-necrotic cardiac disease, 4 idiopathic dilated cardiomyopathy and 2 Chagas' dilated cardiomyopathy. Mean LVEF was 26.8±7.7 %. Ten patients were in functional class II and 11 in FC III. Ten patients had a history of at least one previous hospitalization due to HF and the average number of hospitalizations during the previous year was 1±1.3.

The procedure was successful in 18 patients (85.7%). In 14 patients, it was performed via the left subclavian artery and the catheters implanted through the right subclavian artery were abandoned. The implant was performed at the same site of the previous device and in one case the catheter was introduced via a contralateral access and was tunneled toward the other site (Figure 1). The procedure was unsuccessful in 3 patients because it was impossible to cannulate an adequate coronary sinus vein.

Left ventricular ejection fraction increased to 33.9±10.4% after one year (p=0.028). Functional class improved in 13 patients, 6 passed to FC I, 13 to FC II and 2 to FC III (p=0.0018). Only 4 patients were rehospitalized due to HF (p=0.048) so the number of hospitalizations was reduced to 0.3±0.8 (p=0.09). Finally, QRS duration decreased from 180.9±23.2 ms to 152.6±31.7 ms (p=0.003) (Table 1). The percentage of RV apical pacing and QRS duration were the only variables associated with a significant increase above 5% in LVEF (Table 2).

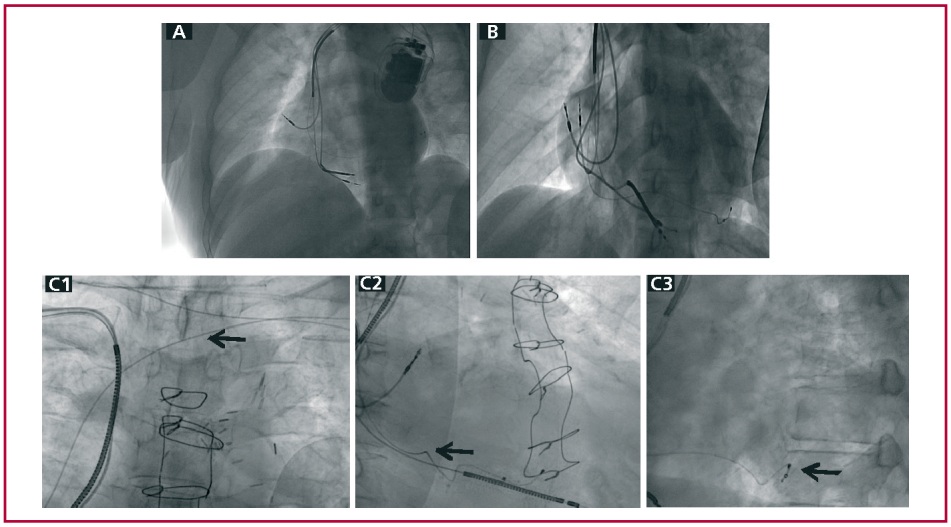

Fig. 1. A. Upgrade from a DDD PM implanted via the left subclavian artery to CRT-D through the same access. B. Upgrade from a DDD PM to CRT-D via a contralateral access. C. Upgrade from a CDI to CRT-D via a contralateral access with left-to-right tunneling due to chronic thrombosis of the ipsilateral vein. The arrow shows the coronary sinus catheter.
DDD PM: Dual chamber pacemaker. CRT-D: Cardiac resynchronization therapy defibrillator

Table 1. Results

Parameters	Before the upgrade	After the upgrade	p
NYHA I / II / III	0 / 10 / 11	06 / 13 / 02	0.0018
QRS	180.9 ± 23.2	152.6 ± 31.7	0.003
LVEF	26.81 ± 7.7	33.9 ± 10.4	0.028
Hospitalization due to HF	1 ± 1.3	0.33 ± 0.8	0.09

NYHA: New York Heart Association. LVEF: Left ventricular ejection fraction.

Table 2. Univariate analysis of the variables related with left ventricular ejection fraction improvement (5% increase in absolute value)

Variable	p
Creatinine	0.765
Pacing (%)	0.005
QRS duration (ms)	0.014
LVEF (%)	0.102
Cardiomyopathy	0.075
NYHA	0.565
Age	0.190

LVEF: Left ventricular ejection fraction. NYHA: New York Heart Association.

Six patients died during follow-up: 3 of HF, 1 due to acute myocardial infarction, 1 due to electrical storm and 1 of colon cancer.

Of the 3 unsuccessful implants, one patient presented pocket infection and two died due to HF. During follow-up, the coronary sinus catheter presented failure to capture in 2 patients.

DISCUSSION

In this study, we demonstrated that the implant of a biventricular pacing system in patients with RV apical pacing and ventricular dysfunction is feasible in our setting and has a low rate of complications, even in the absence of all the tools available. Several studies demonstrated the benefits of CRT in terms of morbidity and reverse remodeling in patients with HF and RV apical pacing. (2, 3) Despite the benefits observed in these multiple small studies, upgrading to CRT is not a common therapy, probably because of procedural complexity, which would have greater risks than that associated with de novo implants. However, many studies demonstrated that the rate of success and the complications associated with the procedure are similar. (4) In the RAFT Upgrade Substudy, the rate of success of ICD upgrade to CRT was 90%, with low rate of complications. (5) Nevertheless, the information available is scarce. In a recent study, the risk of cardiac device-related infective endocarditis in patients undergoing CRT was 4 times greater. (6) However, the European CRT Survey compared 692 upgrades versus 1,675 de novo implants and reported no significant differences in complications and mortality between upgrades and de novo procedures. (7) In this way, and despite the lack of large randomized trials, there is sufficient evidence and consensus to perform therapy upgrade in patients with high proportion of RV apical pacing who develop HF and worsen their LVEF during follow-up. The 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure are cautious and classify upgrading as a class IIb recommendation with a level of evidence B. The ongoing Budapest CRT Upgrade Study, which includes patients from Europe and Israel, will evaluate the impact of CRT in reverse remodeling and clinical outcome of patients with permanent or intermittent right ventricular pacing. (9)

In our study, we have observed a high mortality rate in these patients. However, a percentage of them could benefit from improved symptoms and reduced hospitalizations.

Limitations

Our study has some limitations. It is an observational, retrospective, non-randomized study, with a small sample size, and the results reflect the experience of a single center.

CONCLUSION

Cardiac resynchronization therapy upgrade is a procedure that can be successful and with low rate of complications in patients with high percentage of right ventricular pacing and left ventricular dysfunction that develop HF refractory to drug treatment. Further research is necessary with large randomized trials to evaluate the high-scale impact of this procedure in terms of morbidity and mortality.

Conflicts of interest

None declared. (See authors' conflicts of interest forms on the website/Supplementary material).

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