

and the design of the new device. Nonetheless, to our knowledge, this is the first study published on LAA occlusion with the Amulet™ device since the modification of the cable and is one of the most extensive studies with the device so far.

CONFLICTS OF INTEREST

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Idiopathic Dilated Cardiomyopathy Treated With Intracoronary Infusion of Autologous Bone Marrow Cells: Long-term Follow-up



Miocardiópatia dilatada idiopàtica tratada con infusió intracoronària de cèl·lules autòlogues de medulla òsea: seguiment a largo plazo

To the Editor,

Various studies have shown improved left ventricular ejection fraction (LVEF) in ischemic heart disease following infusion of autologous mononuclear bone marrow cells.^{1,2} There is little information on the long-term results of this approach in nonischemic dilated cardiomyopathy.³⁻⁵ Our objective was to analyze the long-term results, as well as the clinical angiographic, echocardiographic, and biological factors associated with good outcomes.

The present study involved a mean follow-up of 53 ± 14 months in 27 patients with dilated cardiomyopathy in optimal clinical treatment and with symptomatic heart failure who underwent intracoronary infusion of autologous mononuclear bone marrow cells between 2008 and 2010. All patients were participants in the TCMR0007/06 trial. Baseline characteristics have been described in a publication from our group.⁶

The baseline clinical, echocardiographic, hemodynamic (Table), and biological data⁶ were analyzed to evaluate their influence on late response.

Data are expressed as mean \pm standard deviation and as percentages; $P < .05$ was considered statistically significant.

Fifteen patients (56%) showed no major events (group I) and 12 (44%) did (group II). Patients were considered responders if their LVEF had improved more than 5% at the 6-month angiographic evaluation; 21 patients were responders (14 from group I) and 6 were nonresponders (5 from group II).⁶ The events in group II were as follows: 3 deaths (due to heart failure), 2 at 21 months and 1 at 69 months (a cardiac resynchronization device was implanted in this patient at 18 months after the infusion); 3 patients were admitted at least once due to heart failure (29 ± 11 months); and 6 patients required cardiac resynchronization

therapy (25 ± 7 months). After various admissions for heart failure, 1 of the patients with a cardiac resynchronization device received a heart transplant (41 months). All group I patients were in functional class I-II, whereas most of those in group II were in functional class II-III (1.6 ± 0.6 in group I vs 2.3 ± 0.9 in group II; $P < .05$). The last natriuretic peptide value was 156 ± 450 pg/mL (69 ± 58 pg/mL in group I vs 280 ± 750 pg/mL in group II; $P < .05$). The mean of the last LVEF by transthoracic echocardiography was $35\% \pm 13\%$ ($42\% \pm 11\%$ in group I vs $26\% \pm 5\%$ in group II; $P < .05$), with a global LVEF gain (follow-up LVEF minus baseline LVEF) of $7.4\% \pm 11\%$ ($11.6\% \pm 12.1\%$ in group I vs $2.5\% \pm 7.4\%$ in group II; $P < .05$). There were no differences in cell biological parameters or adverse events directly associated with the treatment.

Differences were found in age (48 ± 11 years in group I vs 58 ± 11 years in group II; $P < .05$); baseline echocardiogram, with lower mean baseline systolic volume (112 ± 52 mL in group I vs 165 ± 56 mL in group II; $P < .05$) and higher LVEF ($30\% \pm 5\%$ in group I vs $23\% \pm 9\%$ in group II; $P < .05$) and baseline angiogram, with higher LVEF and post-premature ventricular contraction LVEF ($31\% \pm 9\%$ vs $24\% \pm 7\%$; $P < .05$; and $46\% \pm 13\%$ vs $35\% \pm 11\%$; $P < .05$) and lower diastolic volume (143 ± 49 mL/m² in group I vs 183 ± 76 mL/m² in group II; $P < .05$). Group I had a better baseline New York Heart Association functional class (2.1 ± 0.4 vs 3.0 ± 0.7 ; $P < .05$).

At 5 years follow-up, 43% of patients were free of major events. At 6 months, 52% of responders were event-free; at 5 years, only 17% of the nonresponders were event-free. Benefits appeared to be maintained over time, with a 69% 5-year survival rate (Figure). In previous series of nonischemic dilated cardiomyopathy patients treated with conventional therapy, the 5-year survival varied between 55% and 65%. In our series, more than half of the patients with idiopathic dilated cardiomyopathy treated with infusion of autologous mononuclear bone marrow cells showed a favorable clinical course 5 years later and were in functional class I-II and free of major events. A better late clinical course was shown by younger patients, in better clinical condition, with smaller ventricular diameters and better baseline LVEF. Infusion of these cells can be considered a promising and safe therapy because there were no adverse events related to the therapy in our series. However, the results of our study should be carefully interpreted due to the lack of a control group.

Table
Baseline Clinical and Echocardiographic Parameters

	Group I (n = 15)	Group II (n = 12)	P
Age, mean \pm SD, y	49 \pm 12	58 \pm 11	<.05
Men, %	73	75	NS
NYHA	2.2 \pm 0.4	2.7 \pm 0.7	<.05
BNP, pg/mL	341 \pm 415	481 \pm 424	NS
Cholesterol, mg%	167 \pm 47	183 \pm 28	NS
LDL-C, mg%	99 \pm 30	115 \pm 19	NS
HDL-C, mg%	37 \pm 10	36 \pm 13	NS
Triglycerides, mg%	145 \pm 107	168 \pm 108	NS
Hypertension, %	53	58	NS
Hyperlipidemia, %	60	75	NS
Smoking, %	73	58	NS
Diabetes mellitus, %	27	50	NS
LVEF, %	30 \pm 5	23 \pm 9	<.05
LV end-diastolic volume, mL	164 \pm 78	214 \pm 64	NS
LV end-systolic volume, mL	112 \pm 52	165 \pm 56	<.05
Degree of mitral regurgitation	0.53 \pm 0.7	0.50 \pm 0.5	NS
LVEF in sinus rhythm, %	31 \pm 9	24 \pm 7	<.05
LVEF in sinus rhythm post-PVC, %	46 \pm 13	35 \pm 11	<.05
Sinus end-diastolic volume, mL/m ²	143 \pm 49	183 \pm 76	<.05
Post-PVC end-diastolic volume, mL/m ²	163 \pm 48	194 \pm 74	NS
End-systolic sinus volume, mL/m ²	99 \pm 41	142 \pm 64	NS
Post-PVC end-systolic volume, mL/m ²	90 \pm 40	127 \pm 60	NS
Systolic pressure of the pulmonary artery, mmHg	34 \pm 18	37 \pm 13	NS

BNP, brain natriuretic peptide; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; LV, left ventricle; LVEF, LV ejection fraction; NS, no significant; NYHA, New York Heart Association functional class; post-PVC, post-premature ventricular contraction.

All echocardiographic parameters were determined using the Simpson method.

Group I: patients without follow-up events. Group II: patients with follow-up events.

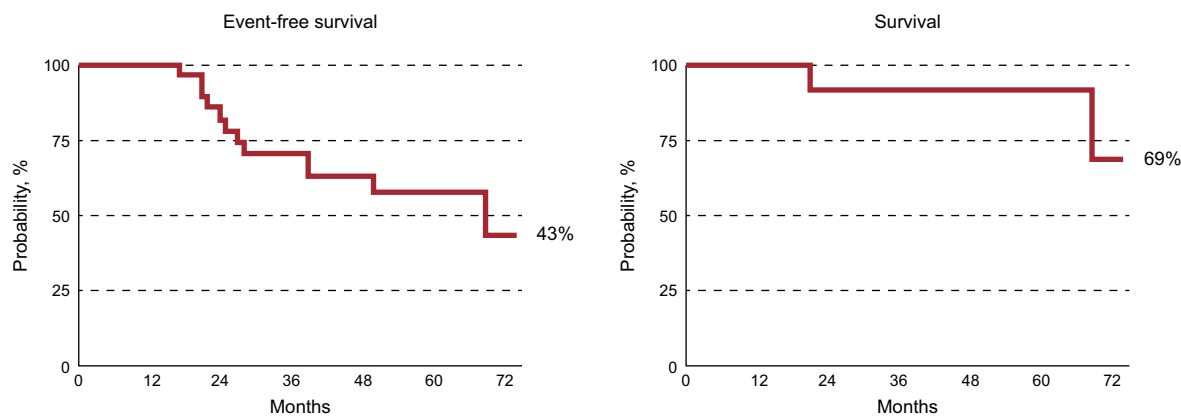


Figure. Probability of event-free survival, 5-year survival, and changes in left ventricular ejection fraction at 5 years.

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Long-term Results of Repeat Percutaneous Mitral Valvuloplasty: Is it Still a Viable Option?



Resultados a largo plazo de la revalvuloplastia mitral percutánea: ¿es todavía una opción real?

To the Editor,

In 1984, the percutaneous mitral valvuloplasty (PMV) technique of the Japanese surgeon Inoue was published, revolutionizing mitral stenosis treatment and, due to better results, supplanting the surgical technique.¹ In the Euro Heart Survey of 2001, mitral stenosis was seen in 9.5% of 5001 patients.² Of 112 patients who underwent a stenosis intervention, 34% received a percutaneous treatment.² This intervention showed excellent results in subsequent studies with follow-up durations of up to 20 years.³ However, some valve restenosis patients later require valve replacement surgery; nonetheless, some patients could still be candidates for a repeat PMV. Because repeat PMV data are

scarce in the literature³ and nonexistent in Spain, our objective was to determine the characteristics and clinical course of patients who underwent a repeat PMV in an extensive PMV series.

A total of 1138 consecutive PMV were retrospectively reviewed. These procedures were performed between 1988 and 2004 using the Inoue technique (with a single balloon containing 3 regions, initially in the form of an hourglass, the waist of the balloon is the least compliant part and opens the commissures). Clinical data were collected from the medical records and follow-up in the clinic or by telephone. Of the PMV, 35 repeat PMV were identified between 1989 and 2012. Of these, 5 were in men, and the mean patient age was 57.3 years (Table). Ten patients received a suboptimal PMV that required a second catheterization before 60 days. Overall, the median time to repeat PMV was 4.7 years (7.1 years if suboptimal PMV were excluded). The median follow-up was 10.8 years (Figure). One patient required urgent surgery after the repeat PMV due to procedure-related complications. During follow-up, 17 patients died (median survival, 8.1 years), 7 of cardiac causes (including 1 cardiac arrest and 2 related to

Table

General Characteristics of Patients in the Entire Cohort and Divided According to the Intervention Type (Elective or Due to a Previous Failed/Suboptimal Valvuloplasty). The Events Registered During Follow-up Are Detailed According to the Above Groups

	Total	Elective	Previous suboptimal valvuloplasty ^a
Patients	35	25	10
Age at 1 st valvuloplasty, years	52.4 ± 13.5	54.5 ± 13.7	47.9 ± 12.2
Age at repeat, years	57.3 ± 13.8	61.3 ± 12.7	47.9 ± 12.2
Women	30 (85.7)	22 (88.0)	8 (80.0)
Previous stroke	2 (5.7)	2 (8.0)	0
Chronic atrial fibrillation	17 (48.5)	14 (56.0)	3 (30.0)
Previous surgical commissurotomy	4 (11.4)	4 (16.0)	0
Wilkins score	7.86 ± 1.8	8.00 ± 2.0	7.5 ± 1.0
LVEF, %	64.5 ± 7.1	64.5 ± 7.9	63.4 ± 3.9
Mitral gradient before repeat	12.0 (6.0-15.0)	11.5 (6.0-10.0)	12.0 (4.5-19.0)
Mitral gradient after repeat	5.4 (3.9-7.5)	5.78 (3.9-8.0)	5.0 (2.7-7.2)
Events during follow-up			
Follow-up, years	10.8 [6.6-13.8]	10.2 [6.1-13.0]	16.9 [9.74-23.4]
Urgent surgery (< 24 h)	1 (2.8)	0	1 (10.0)
Mitral valve surgery	17 (48.5)	12 (48.0)	5 (50.0)
Time to mitral surgery, years ^b	8.4 [2.0-13.1]	6.9 [1.52-12.1]	13.05 [4.31-23.4]
Follow-up/preoperative de novo AF	4 (2.8)/17 (48.5)	3 (12.0)/14 (56.0)	1 (10.0)/3 (30.0)
Stroke during follow-up	5 (14.2)	4 (16.0)	1 (10.0)
Endocarditis	1 (2.8)	1 (4.0)	0
Readmission due to stable angina	1 (2.8)	0	1 (10.0)
Acute coronary syndrome	2 (5.7)	2 (8.0)	0
Cardiogenic shock	2 (5.7)	2 (8.0)	0
NYHA > I	15 (42.8)	12 (48.0)	5 (50.0)
MACE	26 (74.2)	20 (90.9)	6 (60.0)
Death	17 (48.5)	14 (56.0)	3 (30.0)

AF, atrial fibrillation; LVEF, left ventricular ejection fraction; MACE, major adverse cardiac events (composite variable of death from any cause, mitral valve surgery, stroke, or mitral valve endocarditis); NYHA, New York Heart Association functional class.

The data are expressed as No. (%), mean ± standard deviation, or median [interquartile range].

^a Less than 2 months following the first procedure.

^b Considering the time from the first cardiac surgery or until the end of follow-up in those not requiring surgery, previously censored (n=18; about 51% of patients).