

There was no significant change in LVMI. At the end of the study, the geometric pattern showed significant improvement (Figure).

- Functional changes: LV systolic function was normal in all patients and did not change. Regarding LV diastolic function, 28% of patients had normal filling, almost 69% had an impaired relaxation pattern, and 3% had pseudonormal filling. At the end of the study, E wave velocity had increased, E/A ratio had decreased, and deceleration time had shortened. At the end of follow-up, LV diastolic function had significantly improved, with 69% of patients showing normal filling.

A high percentage of our patients showed some type of ventricular remodelling, the most common type being eccentric hypertrophy, which concurs with reports by other authors.⁶ Unlike other studies, the improved geometric pattern in our patients was fundamentally due to a marked reduction in RWT, with no significant changes in LVMI. This improvement in ventricular geometry was accompanied by normalization of diastolic function in more than half of the patients.

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Left Atrial Appendage Occlusion With the New Amulet™ Device: Feasibility, Safety and Short-term Efficacy



Cierre percutáneo de la orejuela izquierda con el nuevo dispositivo Amulet™: factibilidad, seguridad y eficacia a corto plazo

To the Editor,

Percutaneous occlusion of the left atrial appendage (LAA) is an alternative to oral anticoagulation therapy for the prevention of ischemic stroke in patients with nonvalvular atrial fibrillation.¹

Currently, the 2 devices most frequently used for percutaneous LAA occlusion are the Watchman™ system (Boston Scientific) and the Amplatzer™ Cardiac Plug (St. Jude Medical). A recently designed second generation of the Amplatzer™ Cardiac Plug, the Amulet™ device (St. Jude Medical), introduces modifications to facilitate device implantation and reduce complications.²

The Amulet™ device obtained the European Economic Area CE mark in January 2013, and in February 2013 the device received a restricted launch in selected centers, producing good results.^{2,3} However, difficulties were encountered with the release of a new internal delivery cable, forcing the company to halt distribution in July of the same year. After modification of the cable, the Amulet™ device was relaunched in a restricted setting in October 2014, and to our knowledge, there has been no published report to date on its safety and short-term efficacy.

The study included all consecutive patients undergoing percutaneous LAA with the Amulet™ device at 2 centers between October and December 2014. Procedures were performed as described,³ and clinical and echocardiographic follow-up was scheduled for 2 to 3 months after the procedure.

A total of 20 patients were included; population and procedure characteristics are shown in the Table.

Table

Study Population and Procedure Characteristics

Patients, no.	20
Age, years	77 ± 7
Men	14 (70)
Indication for LAA occlusion (contraindication for OAC), %	
Gastrointestinal bleeding	70
Other	30
CHA ₂ DS ₂ -VASc score	4.9 ± 1.3
HAS-BLED score	4.9 ± 1.16
Rhythm during implantation	
Sinus rhythm	6 (30)
AF	14 (70)
LAA morphology	
Cactus	2 (10)
Chicken wing	6 (30)
Windsock	7 (35)
Cauliflower	5 (25)
Number of LAA lobes	
1	11 (55)
2	9 (45)
Maximum LAA diameter by angiography, mm	19.7 ± 5
Maximum LAA diameter by TEE, mm	19.9 ± 5.5
Device size, mm	24.1 ± 5.3
Successful implants	20 (100)
Periprocedural complications	0 (0)

AF, atrial fibrillation; HAS-BLED, hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile international normalized ratio, elderly (> 65 years), drugs/alcohol concomitantly; LAA, left atrial appendage; OAC, oral anticoagulation therapy; TEE, transesophageal echocardiogram. Values are expressed as no. (%) or mean ± standard deviation.

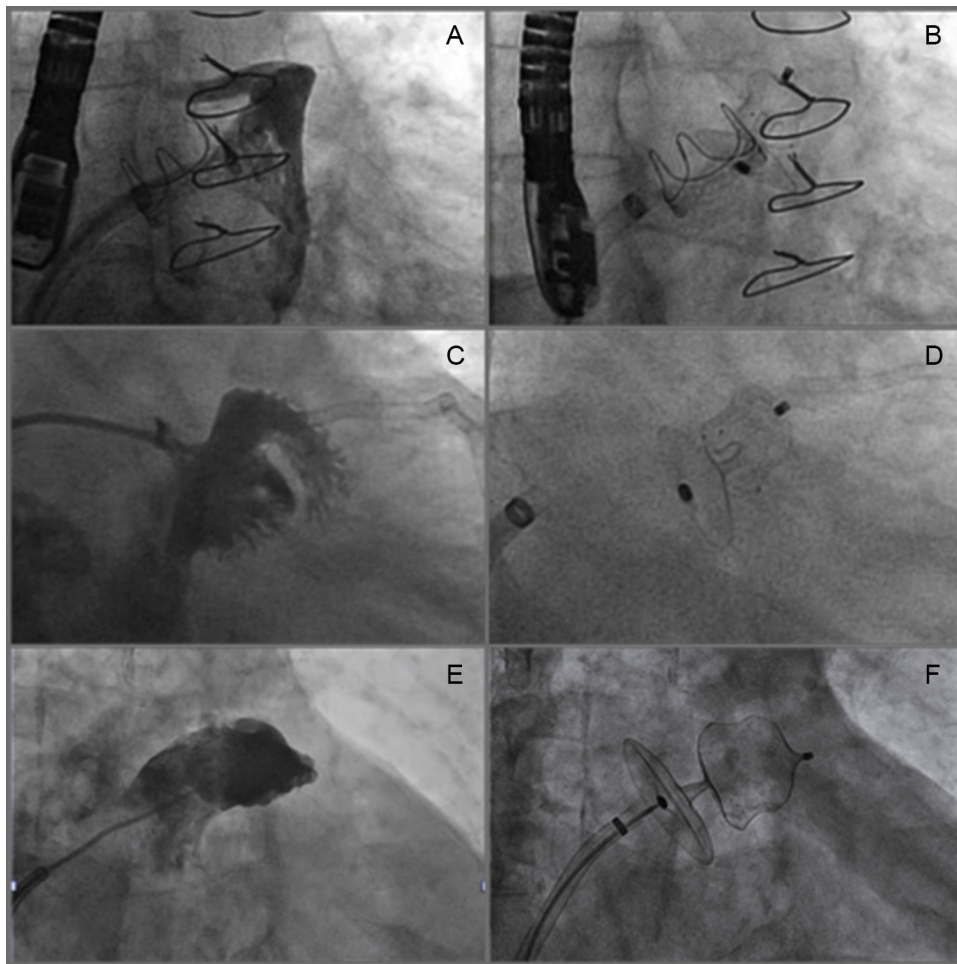


Figure. Examples of LAA occlusion with the Amulet device. A and B: Small LAA (maximum diameter 12 mm) with "chicken wing" morphology; a 16-mm Amulet device was implanted, producing good results. C and D: Early bifurcating LAA with a long and very narrow lobe (maximum diameter 11 mm) and no well-defined landing zone; a 16-mm Amulet device was implanted, producing good results. E and F: Large LAA (landing zone 30 mm) with "windsock" morphology; a 34 mm Amulet device was implanted, producing good results. LAA, left atrial appendage.

Implantation was successful in 100% of the patients, despite the complicated morphology of some appendages (Figure). There were no periprocedural cases of device embolization, pericardial effusion, stroke, acute myocardial infarction, or death.

All patients underwent clinical follow-up examination after a median postprocedure interval of 60 days (interquartile range, 48-80 days). One patient had a transient ischemic attack without sequels, likely related to the patient's decision to prematurely terminate antiplatelet therapy, and another patient was diagnosed a few weeks after the procedure with pericarditis, which resolved with corticoid therapy.

Echocardiographic follow-up was completed in 100% of the patients. Complete sealing of the LAA was observed in all patients, with no peridevice leaks, thrombosis, or pericardial effusion.

The present study thus demonstrates that percutaneous LAA occlusion with the new Amulet™ device is feasible, safe, and shows efficacy in short-term follow-up.

The Amulet™ device is distinguished from the Amplatzer™ Cardiac Plug by several key modifications: the new device is fully preloaded within the delivery system, the disc diameters are larger, the connecting waist between the lobe and disc is longer, the lobe is longer and is available in wider diameters (up to 34 mm), there are more stabilizing wires, the device features a new delivery cable with a distal cone, and the distal and proximal end-screws do not protrude after release.²

In our study, the Amulet™ device successfully occluded the LAA in all patients, despite the challenging anatomies encountered (10% of appendages had a maximum diameter ≥ 30 mm and 30% had a "chicken-wing" morphology). Because of the larger lobe, increased number of stabilizing wires, and longer waist between lobe and disc, the lobe can be positioned deeper in the LAA while keeping the proximal disc outside of the LAA ostium, thus favoring complete closure even of complex LAA structures such as the "chicken-wing" morphology.³

The success achieved here with the Amulet™ device is greater than that reported for the Watchman™ system and the Amplatzer™ Cardiac Plug,^{1,4} and is similar to that reported by other investigators.^{2,3} We observed no periprocedural complications. These findings can be explained by our accumulated expertise in percutaneous LAA occlusion and the new modifications introduced in the Amulet™ device. Follow-up transesophageal echocardiography detected no complications (device embolization, thrombosis, or pericardial effusion).

The major limitations of this study are its observational design and the small number of patients. When interpreting the excellent results, it is important to consider that the procedures were performed in centers with experience in LAA occlusion. Given the small number of patients and the short-term follow-up, it is not possible to establish a direct link between the nondetection of thrombi or complications by transesophageal echocardiography

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

Ignacio Cruz-González is proctor and consultant for St. Jude Medical and Boston Scientific. Dabit Arzamendi is proctor and consultant for St. Jude Medical.

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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 TCMR007/06 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.