

Table

Characteristics of Patients

Age, y	48.4 ± 8.8
Weight, kg	75.4 ± 17.8
Height, cm	170.1 ± 8.2
Primary prevention	9 (75)
Clinical disease	
Ischemic heart disease	5 (41.7)
Dilated (nonischemic) cardiomyopathy	1 (8.3)
Channelopathies	1 (8.3)
Idiopathic VF	1 (8.3)
Hypertrophic cardiomyopathy	2 (16.7)
Other	2 (16.7)
LVEF, %	45.7 ± 16.7
Sensing vector	
Primary	6 (50)
Secondary	6 (50)
Alternate	0 (0)
Conditional zone rate, bpm	190.8 ± 11.6
Shock zone rate, bpm	248.3 ± 3.9

LVEF, left ventricular ejection fraction; VF, ventricular fibrillation. Data are expressed as no. (%) or mean ± standard deviation.

difference may reflect not only the relative simplicity of the 2-incision method, but also the accumulated overall experience with the procedure. In all 12 patients, the device was programmed with 2 antitachycardia zones: 1 conditional discrimination zone and 1 shock zone. Patients were discharged the day after the procedure. After a mean follow-up of 6.25 months (range, 1–13 months), there have been no major or minor complications, no cases of lead displacement, and no need for reoperation. During follow-up, there have been no recorded events due to appropriate or inappropriate sensing and no inappropriate or appropriate shocks; these results are identical to those obtained in the patients who underwent implantation using the 3-incision method. Notably, the devices fitted in 6 of the patients who underwent the 2-incision procedure were programmed with the secondary sensing vector (between the distal electrode and the pulse generator), with no effect on the results; this sensing vector involves the distal sensing electrode, potentially the

more vulnerable to problems due to lead dislocation in the 2-incision technique.

The results of our series show that the S-ICD can be appropriately positioned using the 2-incision technique, permitting cardiac signal detection without oversensing or undersensing, providing appropriate defibrillation, and ensuring system stability during follow-up. These results support the adoption of this technique as a first-line approach in S-ICD implantation.

CONFLICTS OF INTEREST

M.A. Arias is a proctor for the S-ICD system and Associate Editor of *Revista Española de Cardiología*.

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Available online 27 February 2016

REFERENCES

- Burke MC, Gold MR, Knight BP, Barr CS, Theuns DA, Boersma LV, et al. Safety and efficacy of the totally subcutaneous implantable defibrillator: 2-year results from a pooled analysis of the IDE Study and EFFORTLESS Registry. *J Am Coll Cardiol*. 2015;65:1605–15.
- Arias MA, Pachón M, Akerström F, Puchol A, Giacomani-Hernández S, Rodríguez-Padial L. Implante de desfibrilador subcutáneo S-ICD™: experiencia inicial en un centro español. *Rev Esp Cardiol*. 2015;68:629–30.
- Akerström F, Arias MA, Pachón M, Puchol A, Jiménez-López J. Subcutaneous implantable defibrillator: State-of-the art 2013. *World J Cardiol*. 2013;5:347–54.
- Knops RE, Brouwer TF, Barr CS, Theuns DA, Boersma L, Weiss R, et al. The learning curve associated with the introduction of the subcutaneous implantable defibrillator. *Europace*. 2015. <http://dx.doi.org/10.1093/europace/euv299>.
- Knops RE, Olde Nordkamp LR, de Groot JR, Wilde AA. Two-incision technique for implantation of the subcutaneous implantable cardioverter-defibrillator. *Heart Rhythm*. 2013;10:1240–3.

<http://dx.doi.org/10.1016/j.rec.2015.12.008>

Usefulness of MitraClip for the Treatment of Mitral Regurgitation Secondary to Failed Surgical Annuloplasty



Utilidad de MitraClip® como tratamiento de la insuficiencia mitral secundaria a anuloplastia quirúrgica fallida

To the Editor,

Valve surgery is the treatment of choice for mitral regurgitation (MR) when the latter is accompanied by ventricular dysfunction or its symptoms. In such cases, valve repair is usually preferred to valve replacement, since the prognosis is generally more favorable. However, despite the implementation of modern valve repair techniques, the rate of MR recurrence can come close to 30%¹ and, in the case of ischemic MR, can reach nearly 50% at 2 years. This leads to a significant number of repeat valve interventions,² which may involve a high degree of risk, especially in elderly patients or those with numerous comorbidities.

The MitraClip device (Abbott Laboratories, Abbott Park, Illinois, United States) has been shown to be a safe and effective therapy that improves the symptoms of patients who are unable to undergo surgery.³ The experience gained in recent years has allowed the indications for this treatment to be extended to other groups of patients with MR. The treatment of patients with a prior failed annuloplasty has been reported previously,⁴ but the information concerning this scenario is still limited. The objective of this study was to present the experience in the treatment of failed annuloplasties with MitraClip in Spain. Between October 2010 and October 2015, 300 MitraClip implantations were performed in the Iberian Peninsula; they include a subseries of 8 procedures (2.6%) performed in 6 patients, which were carried out in annuloplasty rings.

The characteristics of the population, the procedure, and follow-up are shown in the [Table](#). The median time between annuloplasty and MitraClip implantation was 5 years, and the most common cause was recurrence in patients treated surgically for functional MR. In most cases, a central regurgitant jet was

Table

Patient Characteristics at Baseline, According to Echocardiography, and During the Procedure and Follow-up

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Age, y	53	81	59	77	82	67
Sex	Male	Male	Male	Male	Female	Male
NYHA functional class	III	II	III	IV	III	II
Logistic EuroSCORE, %	11	10.6	22.2	26	21.2	17.5
Time since MVS, y	5	9.3	4	2	5	8
Type of ring	Physio 28	Duran 29	IMR 28	Physio 34	Physio 28	IMR 26
<i>Preprocedural</i>						
Rhythm	AF	SR	SR	AF	AF	SR
LVEF	20	70	44	50	55	30
Etiology of MR	FMR	DMR	FMR	DMR	FMR	FMR
Leaflet restriction (posterior/anterior)	Posterior	Posterior	Posterior	Posterior	Posterior	Posterior
MR grade	4+	4+	4+	4+	3+	4+
Jet location	Central	Central	Lateral	Central	Central	Medial
PASP	110	56	65	75	42	45
MV area	4.8	4.2	4.1	4	3.5	2.7
MV gradient	2	3	3.8	3.7	3.2	1
<i>Procedure</i>						
Success	Yes	Yes	Yes	Yes	Yes	Yes
No. of clips	1	1	1	1	1	1
<i>Postprocedural</i>						
MR grade	3+	1+	1+	1+	0	2+
MV gradient	3	4	7.4	6	3.2	2.4
MV area	3	3.1	4	3.7	2.3	1.6
Procedure-related complications	No	No	No	No	No	No
Complications	No	No	No	No	Jugular hematoma	No
Hospital stay, d	1	13	4	3	25	3
<i>Follow-up</i>						
Duration, d	450	354	150	120	180	30
MitraClip REDO	Yes	No	No	Yes	No	No
MR grade	2+	2+	2+	1+	0	2+
LVEF	19	70	44	60	55	30
PASP	48	47	50	65	33	37
NYHA functional class	II	II	I	II	II	I

AF, atrial fibrillation; DMR, degenerative mitral regurgitation; FMR, functional mitral regurgitation; LVEF, left ventricular ejection fraction; MR, mitral regurgitation; MV, mitral valve; MVS, mitral valve surgery; NYHA, New York Heart Association; PASP, pulmonary artery systolic pressure; SR, sinus rhythm.

encountered, although, in 2 patients, the jet was proximal to the commissures. The procedure was successful in all the patients, resulting in a significant reduction of MR (Figures A-E), although when monitored prior to discharge, patient no. 1 was found to have grade 3+ MR (the acute result according to transesophageal echocardiography performed at the end of the procedure was grade 2+ MR, thus indicating a successful intervention). There were no major complications and the median hospital stay was 3.5 days. Recurrence of MR was detected during follow-up in 2 patients. In both, the procedure could be repeated to place a new clip, which resulted in trivial MR, without drastic reductions in valve area or excessive increases in the gradient. Patient no. 1 remained in good clinical condition until 9 months after the procedure. At that time, he was in a higher functional class and imaging studies revealed MR progression due to an increase in the width of the jet medial to the implanted clip (in connection with the severe restriction of the posterior leaflet). The options were studied and the decision was made to implant a new device in the central jet, which resulted in a sustained reduction of MR to grade 2+ and, again, an improvement in the functional class. After the initial success, follow-up of patient no. 4 revealed MR recurrence lateral to the implanted clip, which was treated with

another device 6 months later. At the time of writing, after a median follow-up of 165 days, all the patients were alive, were in New York Heart Association class \leq II, and had MR \leq 2+ with gradients similar to those observed after the initial procedure. Only patient no. 3 had a noteworthy increase in the gradient, with no clinical impact, in connection with the annulus area according to planimetric measurement (2.4 cm²); this measurement was 4 cm² at the level of the mitral orifice. Moreover, a reduction of the pulmonary pressure from 60.5 mmHg to 47.5 mmHg was observed.

In this series, the largest reported in literature, we describe our experience in the treatment of MR following annuloplasty. The data show that the procedure is safe and that a satisfactory outcome is usually achieved with a single clip. However, in the case of recurrence, our results demonstrate that a second clip can be implanted without significantly affecting the mitral valve area or the resulting gradient. This finding is of great importance as it is the first time that it has been reported in the literature, and because the possibility of inducing mitral stenosis is a cause for concern when the MitraClip is used in this scenario (due to the reduction of the area caused by the ring). The main determinants for the use of the device are the presence of leaflets of adequate length, a clear

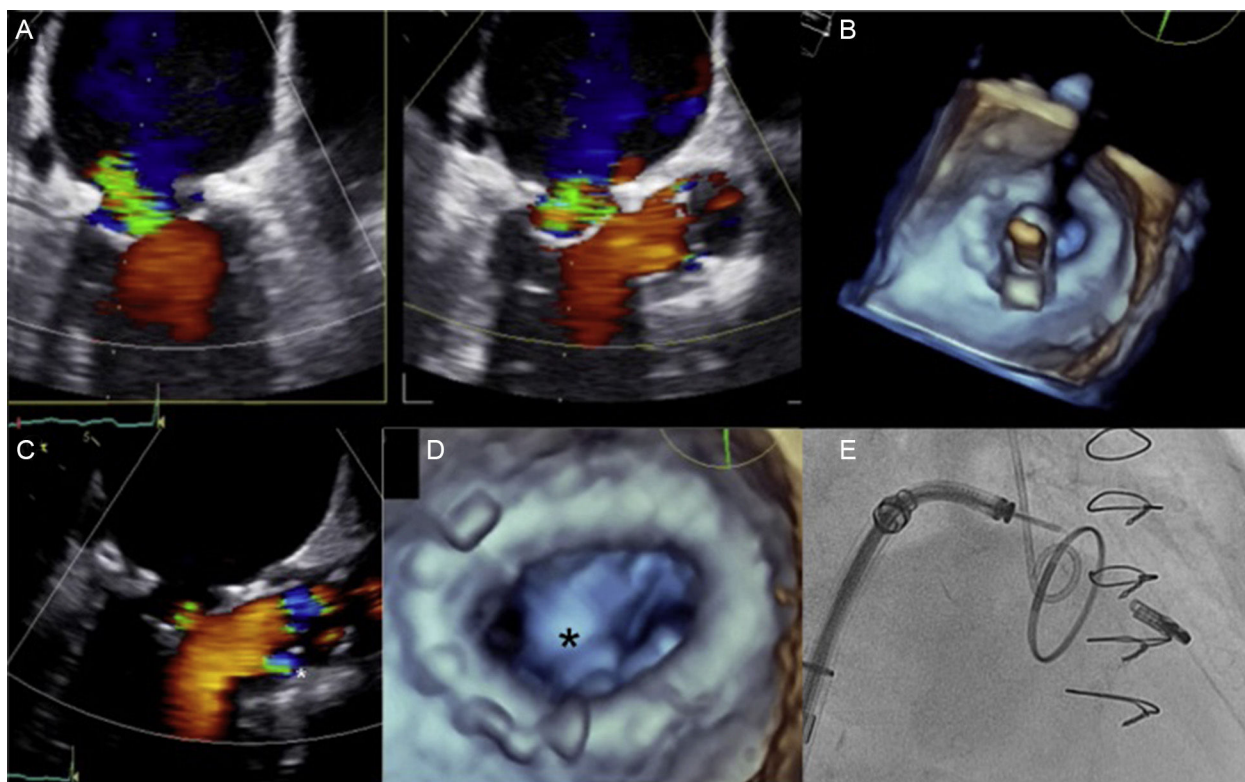


Figure. A: Severe mitral regurgitation following annuloplasty; B: Real-time 3-dimensional transesophageal echocardiogram showing perpendicularity of the clip with respect to leaflets and ring; C: Achievement of mild mitral regurgitation following clip implantation; D: 3-dimensional transesophageal echocardiogram showing a double orifice with the clip in between (asterisk); E: Fluoroscopic image showing the position of the implanted clip in relation to the annuloplasty ring.

view of these leaflets (sometimes shadowed by the effect of the ring itself) and, given that a marked restriction of the posterior valve is usually encountered, the freedom to maneuver the device to ensure access to the site where MR is most severe. In this respect, wide experience with the use of the MitraClip is essential.

The possibility of drawing conclusions from our study is limited in terms of the predictors of recurrence; however, in both of our cases of MR recurrence, the marked restriction of the posterior leaflet played a relevant role. In patients with extreme restriction of this leaflet (immobile posterior leaflet), perhaps other therapeutic alternatives should be considered.

In short, the MitraClip is a safe and effective option for the treatment of MR following surgical annuloplasty.

CONFLICTS OF INTEREST

R. Estévez-Loureiro, D. Arzamendi, F. Carrasco-Chinchilla, and X. Freixa are proctors for MitraClip and have received conference fees from Abbot Vascular. J. Suárez de Lezo has also received conference fees from Abbot Vascular.

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Available online 27 February 2016

REFERENCES

- McClure RS, Athanasopoulos LV, McGurk S, Davidson MJ, Couper GS, Cohn LH. One thousand minimally invasive mitral valve operations: early outcomes, late outcomes, and echocardiographic follow-up. *J Thorac Cardiovasc Surg.* 2013;145:1199-206.
- Kron IL, Hung J, Overbey JR, Bouchard D, Gelijns AC, Moskowitz AJ, et al. Predicting recurrent mitral regurgitation after mitral valve repair for severe ischemic mitral regurgitation. *J Thorac Cardiovasc Surg.* 2015;149:752-61.e1.
- Carrasco-Chinchilla F, Arzamendi D, Romero M, Gimeno de Carlos F, Alonso-Briales JH, Li CH, et al. Experiencia inicial del tratamiento percutáneo de la regurgitación mitral con dispositivo MitraClip® en España. *Rev Esp Cardiol.* 2014;67:1007-112.
- Lim DS, Kunjummen BJ, Smalling R. Mitral valve repair with the MitraClip device after prior surgical mitral annuloplasty. *Catheter Cardiovasc Interv.* 2010;76:455-9.

<http://dx.doi.org/10.1016/j.rec.2015.12.011>