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Initial experience with the coronary sinus reducer for the treatment of refractory angina in Spain

Resultados iniciales del dispositivo reductor de seno coronario para el tratamiento de la angina refractaria en España

To the Editor,

The term refractory angina (RA) refers to a clinical picture of chronic angina-like chest pain, lasting for ≥ 3 months and is associated with reversible ischemia that persists despite optimal medical treatment and current percutaneous and surgical revascularization.[1] Coronary sinus reducers (CSR) have proven to be effective in reducing symptoms in patients with RA,[2] although experience with these devices and available evidence remain scarce.[3,4] The aim of the present study was to describe the safety and efficacy of CRSs during an initial experience in Spain.

We conducted an observational retrospective multicenter registry of consecutive patients with RA and CSR implants in Spain. The protocol was approved by a central reference ethics committee, which waived informed consent because the data were guaranteed to be anonymous. The primary efficacy endpoint was change in functional class according to the Canadian Cardiac Society classification (FC-CCS) and the safety endpoint was procedure-related complications.

The CSRs were implanted in 48 patients with RA who could not undergo surgical or percutaneous revascularization. Implantation was considered suboptimal in 1 patient because, during follow-up, we observed device shift toward the pulmonary artery, which was asymptomatic (angiographic finding). Table 1 shows the baseline characteristics of the patients, all of whom had documented ischemia in the left coronary territory. One patient died before completing the 6-month follow-up due to causes unrelated to the intervention, and so no follow-up data are available for this patient. At 6 months postimplantation, FC-CCS class improved in 40 patients (85%), and by ≥ 2 classes ($P<.001$) in 22 (47%) patients (figure 1). The baseline data of the patients show that the severity of angina was higher than that described in previous studies: 90% of our patients were in FC-CCS 3 or 4 before implantation and the patients were taking a mean of 3.8 ± 1.3 antianginal drugs at baseline.

The greater severity of angina in our patients could explain the responses observed, which were significantly superior to those found in the COSIRA study[2] and the RESOURCE and REDUCER-I registries.[3,4] Figure 1B shows the change in FC-CCS at 6 months postimplantation.

Regarding complications, there was bruising at the puncture site in 2 patients (4.2%), although they did not require transfusion or specific treatment. In 1 patient (2.1%), there was minor coronary sinus dissection, which was documented on angiography and

Table 1
Baseline characteristics of the 48 patients undergoing coronary sinus reducer implantation

Clinical characteristics	
Age, y	69 ± 10
Women	13 (27.1)
Hypertension	43 (89.6)
Diabetes mellitus	25 (52.1)
Dyslipidemia	45 (93.8)
Smoking	5 (10.4)
Glomerular filtration rate < 60 mL/min/m^2	17 (35.4)
Kidney failure on hemodialysis	2 (4.2)
Previous myocardial infarction	29 (60.4)
Previous PCI	41 (85.4)
Previous coronary intervention	26 (54.2)
Previous stroke or TIA	5 (10.5)
Left ventricular ejection fraction	53.6 ± 9.9
Drug treatment	
Number of drugs	3.8 ± 1.3
Treatment with beta-blockers	42 (87.5)
Treatment with nondihydropyridine calcium channel blockers	9 (18.8)
Treatment with dihydropyridine calcium channel blockers	34 (70.8)
Treatment with nitrates	43 (89.6)
Treatment with ranolazine	23 (47.9)
Treatment with trimetazidine	8 (16.7)
Treatment with ivabradine	13 (27.1)
Treatment with alopurinol	7 (14.6)
Treatment with antidepressants	18 (37.5)
Angiographic characteristics	
Number of vessels with significant stenosis, nonrevascularized	1.6 ± 1.0
Chronic total occlusion, nonrevascularized	35 (72.9)
Significant disease in common arterial trunk, nonrevascularized	0
Significant disease in left anterior descending artery, nonrevascularized	28 (58.3)
Significant disease in circumflex artery, nonrevascularized	29 (60.4)
Significant disease in intermediate branch, nonrevascularized	6 (12.5)
Significant disease in right coronary artery, nonrevascularized	26 (54.2)
Significant disease in venous graft, nonrevascularized	11 (22.9)
Significant disease en arterial graft, nonrevascularized	8 (16.7)
Coronary arteries without significant stenosis (microvascular angina disease), nonrevascularized	5 (10.4)

TIA, transient ischemic attack; PCI, percutaneous coronary intervention.
Data are expressed as No. (%) or mean ± standard deviation.

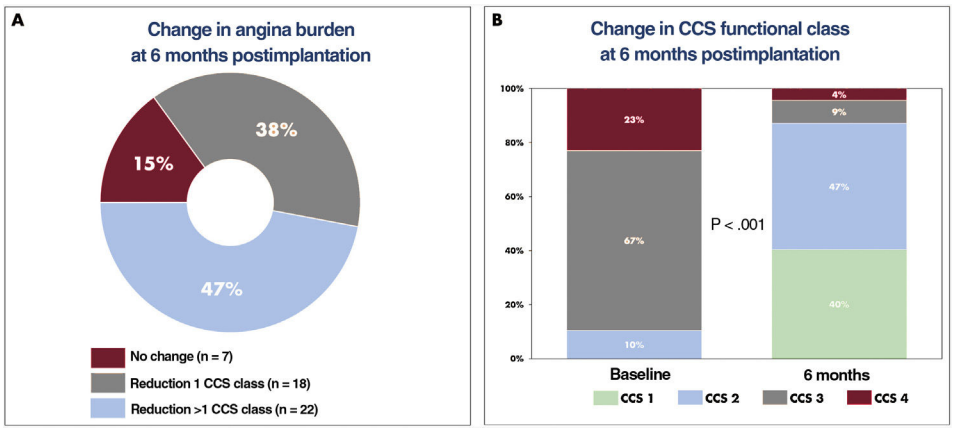

Figure 1. Change in angina burden (A) and angina functional class (B) at 6 months postintervention. No 6-month follow-up data for 1 patient. CCS, Canadian Cardiology Society.

managed without specific treatment. There were no other major implant- or device-related complications during intervention. Regarding incidents, there was device shift in 2 patients during implantation. The devices were recovered without complications through femoral venous access and a second device was successfully implanted in both patients.[5]

In summary, our initial experience with CSRs in Spain for the treatment of patients with RA has been favorable. Most of the patients experienced symptom improvement without any serious intervention- or device-related complications being reported.

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AUTHORS' CONTRIBUTIONS

Study design: O. Rodríguez-Leor and S. Jiménez Valero; manuscript drafting: O. Rodríguez-Leor and S. Jiménez Valero; data collection: all authors; manuscript revision: all authors; statistical analysis: O. Rodríguez-Leor; database review: all authors.

CONFLICTS OF INTEREST

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APPENDIX. SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version, at https://doi.org/10.1016/j.rec.2022.10.012

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Impact of the revised hemodynamic definition of pulmonary hypertension

Impacto de la nueva definición hemodinámica de la hipertensión pulmonar

To the Editor,

The European Society of Cardiology (ESC) and the European Respiratory Society (ERS) have recently published new guidelines for the diagnosis and treatment of pulmonary hypertension (PH),[1] replacing the 2015 ESC/ERS Guidelines[2] and updating the hemodynamic definition proposed by PH experts at the 6th World Symposium of Pulmonary Hypertension held in Nice in 2018.[3]

For hemodynamic diagnosis, the pulmonary vascular resistance (PVR) cutoff level has been lowered from 3 to 2 WU, thus redefining pulmonary arterial hypertension (PAH) as mean pulmonary arterial pressure (mPAP) > 20 mmHg with pulmonary arterial wedge pressure (PAWP) < 15 mmHg and PVR above 2 WU. Group 2 postcapillary PH is redefined as mPAP > 20 mmHg, PAWP > 15 mmHg, and PVR < 2 WU, and combined precapillary and postcapillary PH is redefined as mPAP > 20 mmHg, PAWP > 15 mmHg, and PVR > 2 WU. The new hemodynamic definition is based on population studies confirming the normal range for mPAP and PVR.

The impact of changes to the hemodynamic criteria of the earlier consensus guidelines has been specifically studied in patients with systemic sclerosis (SSc).[4,5]

The aim of our study was to determine the impact of the new grading criteria on patients who underwent right heart catheterization (RHC) at our hospital between September 1, 2019 and July 31, 2022 and who had an indication for a PH study due to unexplained dyspnea or for PAH screening in the case of SSc.

Table 1
Hemodynamic parameters of right heart catheterization with PVR between 2 and 3 WU

Disease	mPAP, mmHg	PAWP, mmHg	PVR, WU
CTED	28	12	2.7
CTED	24	14	2.8
CTED	21	6	2.1
SSc	29	14	2.8
SSc	26	13	2.9
SSc	21	7	2.4
SSc	34	14	2.6
SSc	22	11	2.1

CTED, chronic thromboembolic disease; mPAP, mean pulmonary arterial pressure; PAWP, pulmonary arterial wedge pressure; PVR, pulmonary vascular resistances; SSc, systemic sclerosis; WU, Wood units.

A total of 74 RHCs were performed as per the protocol in our hospital, and all patients gave written informed consent. According to the previous guidelines, 40 (54%) patients did not meet the criteria for PH whereas 8 (10.8%) were classified as group 1, 22 (29.7%) as group 2, and 4 (5.4%) as group 4; all of these patients retained the PH diagnosis on application of the new criteria.

The new definition impacted 18 (24.3%) patients with mPAP > 20 mmHg and PVR between 2 and 3 WU. Among these patients, 10 with postcapillary PH were reclassified as combined precapillary and postcapillary PH, 3 patients with chronic thromboembolic disease were reclassified as having chronic thromboembolic PH (group 4), and 5 patients with SSc met the criteria for PAH (group 1) (figure 1).

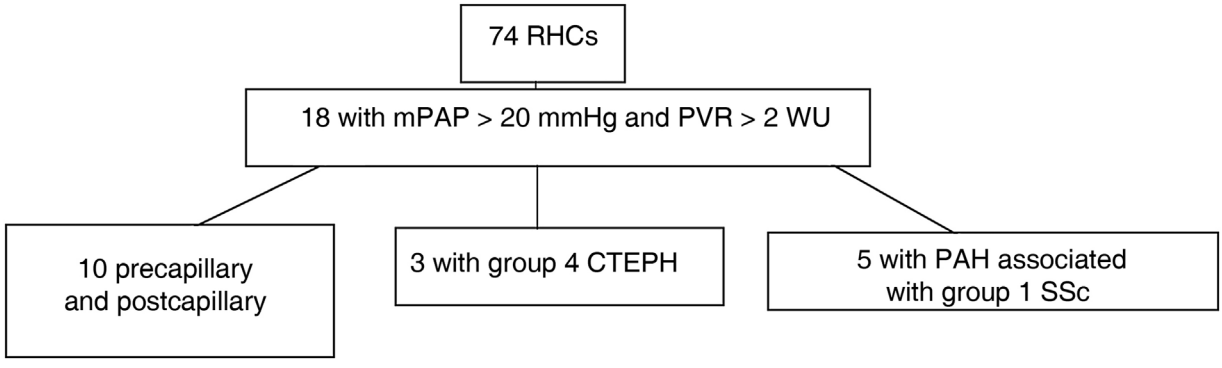

Figure 1. Hemodynamic reclassification of RHCs. CTEPH, chronic thromboembolic pulmonary hypertension; mPAP, mean pulmonary arterial pressure; PAH, pulmonary arterial hypertension; PVR, pulmonary vascular resistance; RHC, right heart catheterization; SSc, systemic sclerosis; WU, Wood units.