

Scientific letter

Treatment of spontaneous coronary artery dissection with fenestration: clinical and angiographic follow-up**Tratamiento de la disección coronaria espontánea con fenestración: evolución clínica y angiográfica****To the Editor,**

Although uncommon, spontaneous coronary artery dissection (SCAD) is increasingly recognized as a cause of acute coronary syndrome (ACS), particularly in women. It has a different pathophysiology to atherothrombotic ACS, with a favorable outcome after the acute phase and a natural tendency to spontaneous repair of the arterial wall.¹ An expectant conservative approach, reserving intervention for patients who are clinically unstable, has been shown to be safe and have good outcomes.² Data from the *Registro Nacional de Disección Coronaria Espontánea* (National Registry of Spontaneous Coronary Dissection) show that 80% of patients received conservative management, with good outcomes.³ In addition, intervention in SCAD (initial or after a failed conservative approach) is complex, with results that are not always satisfactory and a high rate of complications.⁴ We present the outcomes and clinical, angiographic and optical coherence

tomography (OCT) follow-up of 3 patients with SCAD who required revascularization, treated with coronary fenestration. The patients gave informed consent for their data collection and subsequent reporting (NCT-03607981).

The first case was a 41-year-old woman who was admitted with unstable angina pectoris with ST elevation in the anterior leads. Coronary angiography showed occlusion of the left anterior descending artery (LAD) (figure 1A; video 1 of the supplementary data) that, on OCT, corresponded to an intramural hematoma (figure 2A). Given the persistent symptoms and lack of flow, multiple dilatations were performed with a cutting balloon (AngioSculpt 2.5 × 15 mm, Spectranetics, USA), with angiographic and clinical improvement (figure 1B; video 2 of the supplementary data; OCT findings in figure 2B). At follow-up, the clinical progress was satisfactory and without incident. Follow-up coronary angiography was scheduled for 6 months, which showed images consistent with persistence of the intimal tear in the segment treated with fenestration (figure 1C; video 3 of the supplementary data); this was confirmed by OCT, showing a double lumen and diffuse intimal thickening (figure 2C,D).

The second case was a 46-year-old woman who was admitted with non-ST-elevation ACS. Coronary angiography was performed when the patient was stable at 48 hours. A type 1 SCAD was seen in

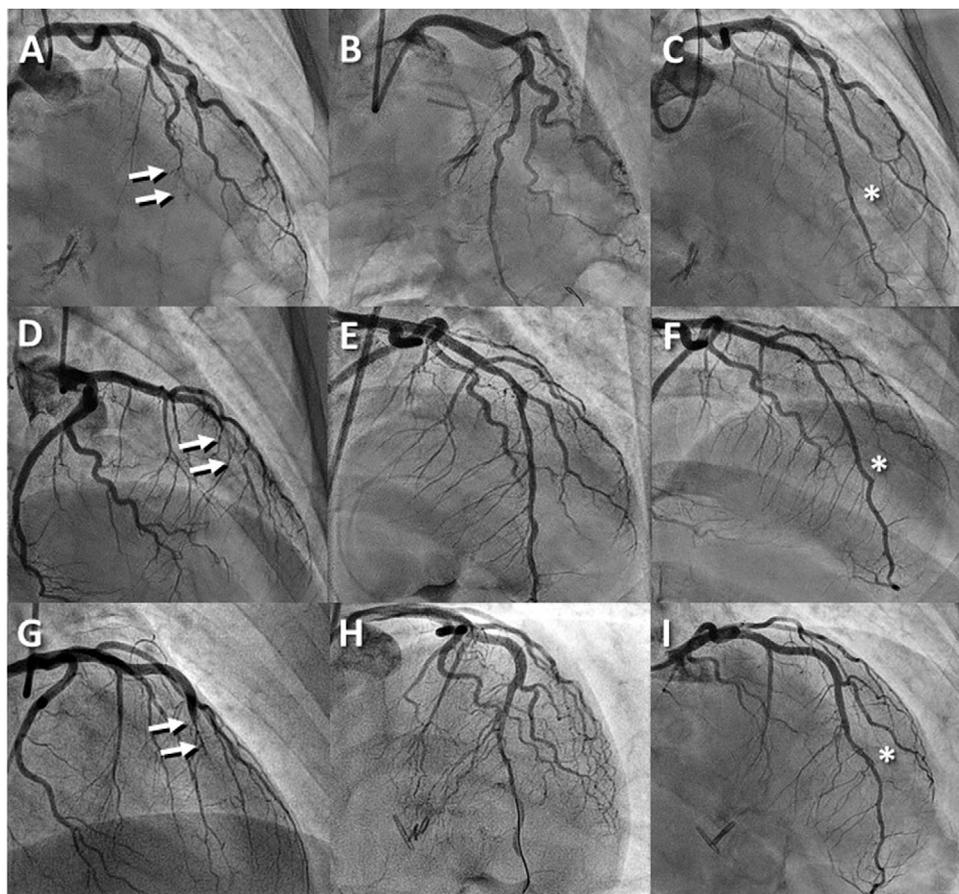


Figure 1. Coronary angiogram in the acute setting (before and after fenestration) and at follow-up at 6 months. The arrows indicate occlusion of the left anterior descending artery. The asterisks indicate images compatible with residual dissection.

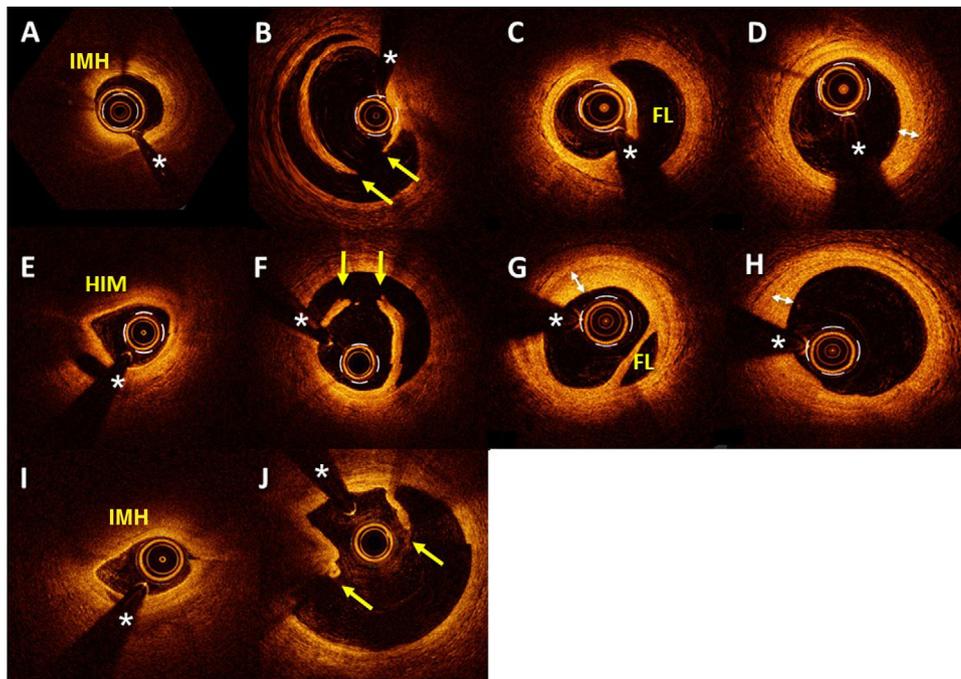


Figure 2. Optical coherence tomography scan in the acute setting (before and after fenestration) and at follow-up at 6 months. The yellow arrows show the intimal tears. The white double-headed arrows indicate the thickened intima. The asterisks show guidewire artefact. FL, false lumen; IMH, intramural hematoma.

the mid LAD, with TIMI (Thrombolysis in Myocardial Infarction) 3 distal flow, and we decided to manage conservatively. A few hours after discharge the patient developed further chest pain accompanied by ST-segment elevation in the anterior leads. Urgent coronary angiography showed deterioration in coronary flow (TIMI 1) (figure 1D). OCT confirmed an intramural hematoma (figure 2E) which was treated with dilatation using a cutting balloon (AngioSculpt 2.5 × 8 mm). Flow then recovered to TIMI 3 (figure 1E) and the pain disappeared. OCT showed multiple fenestrations (figure 2F). Repeat coronary angiography at the 6-month follow-up showed a localized intracoronary filling defect indicative of a residual intimal tear in the fenestrated segment (figure 1F), with good flow. OCT confirmed persistence of the localized dissection and intimal thickening in this area (figure 2G,H).

The third case was a 43-year-old woman who was admitted with ACS with ST elevation in V₁ to V₃. Urgent coronary angiography revealed an occlusion of the LAD (figure 1G) and OCT confirmed an intramural hematoma (figure 2I). Multiple dilatations were performed with a cutting balloon (AngioSculpt 2 × 20 mm), until there was restoration of TIMI 3 flow (figure 1H) and signs of successful fenestration on OCT (figure 2J). Coronary angiography at 6 months showed the persistence of images consistent with residual intimal tear, with good flow in the previously treated area (figure 1I). As the angiographic image was diagnostic of residual dissection, and the vessel was relatively small, we decided not to perform OCT.

There is increasing evidence that coronary intramural hematoma is the initial pathophysiological event in SCAD.⁵ The increase in intramural pressure would cause compression of the lumen and myocardial ischemia. Tearing of the intimal layer would therefore provide a natural “escape” for the hematoma, with formation of the typical double lumen image, release of intramural pressure and improvement in coronary flow. In patients with SCAD who require intervention, it is common to find intramural hematoma without the double lumen.^{3,4} Fenestration with a cutting balloon has been shown to be an effective therapeutic alternative to achieve transformation of the parietal hematoma in cases of SCAD with

a double lumen, improving coronary flow and achieving clinical stabilization. This strategy means stent implantation can be avoided.

This article is the first to report a series of consecutive patients with invasive treatment of SCAD using coronary fenestration with systematic follow-up. The initial results and mid-term clinical outcomes have been excellent. However, at follow-up, we observed the persistence of localized residual dissection and diffuse intimal thickening in the treated segment. These findings indicate that the vascular repair was not complete (*restitutio ad integrum*), as is usual in patients managed conservatively. Further studies will be needed to determine the clinical implications of these new findings and whether the postfenestration vascular repair phenomenon is incomplete or simply takes much more time.

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AUTHORS' CONTRIBUTIONS

All the authors contributed substantially to the conception and design, data collection or analysis and interpretation, wrote or critically reviewed the article for intellectual content, gave approval of the final version of the article for publication, and agree to accept responsibility for all aspects of the article and to investigate and resolve any questions related to the accuracy or trueness of any part of this work.

CONFLICTS OF INTEREST

None of the authors have any conflicts of interest in relation to this article.

APPENDIX. SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at <https://doi.org/10.1016/j.recesp.2021.07.010>

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Design and interim results of a registry of left atrial appendage occlusion with the Watchman device in patients on hemodialysis: EPIC06-WATCH-HD



Diseño y resultados intermedios del registro de cierre de orejuela izquierda con el dispositivo Watchman en pacientes en hemodiálisis, EPIC06-WATCH-HD

To the Editor,

Atrial fibrillation (AF) is common in patients with end-stage chronic kidney disease (ESCKD), with a prevalence of 7% to 24%.¹ AF leads to a 6-fold increase in the risk of stroke in hemodialysis patients¹ and a 5-fold increase in the hazard of bleeding.² Several reports have found that warfarin is associated with an increased risk of bleeding and no prevention or even a higher risk of stroke in this population.³ Few publications have evaluated the effects of direct oral anticoagulants (DOACs) in patients with ESCKD⁴ and there have been no studies of their clinical benefit in this scenario. The recently reported (and prematurely stopped) Renal-AF trial (NCT02942407) found no significant differences between apixaban and warfarin in terms of stroke and bleeding rates.

In this scenario, percutaneous left atrial appendage occlusion (LAAO) appears to be an appealing alternative therapy.⁵ The LAAO with Watchman Device in Patients with Non-valvular Atrial Fibrillation and End-stage Chronic Kidney Disease on Hemodialysis (EPIC06-WATCH-HD) study (NCT03446794) is a prospective, multicenter, observational study to investigate the reduction on stroke and bleeding events after LAAO with Watchman 2.5 or Watchman FLX (Boston Scientific, USA) during a clinical follow up of 24 months.

We adopted an adaptive approach to determine the sample size for this study. The incidence of stroke and major bleeding events in this population were approximately 5% and 9% per year, respectively.^{1,2} Using simulation, we initially hypothesized that 95 patients would be necessary to demonstrate a 50% reduction in these rates with a power of 80% ($\alpha = 0.05$), considering a 15% of potential missing participants per year. An interim analysis was planned when 50 patients were recruited.

Inclusion and exclusion criteria are summarized in table 1. The primary efficacy objective is a composite endpoint including embolic (transient ischemic attack, stroke, systemic embolism) and major bleeding (Bleeding Academic Research Consortium > 2) events at 2 years. The secondary safety endpoints are: peripro-

Table 1
Eligibility criteria

Inclusion criteria
Age > 18 y.
End-stage chronic kidney disease (glomerular filtration rate < 15 mL/min) on hemodialysis.
History of AF (paroxysmal, persistent, permanent).
CHA ₂ DS ₂ -VASc score ≥ 2 or active oral anticoagulation due to AF.
HAS-BLED score ≥ 3 or a history of major bleeding (Bleeding Academic Research Consortium > 2).
Patient provision of written informed consent.
Exclusion criteria
Life expectancy < 2 y.
Indication for oral anticoagulation other than from AF.
Severe pericardial effusion.
Previous percutaneous closure of atrial septal defect.
Intracardiac thrombus.
Severe hepatic dysfunction with spontaneous INR > 1.5.

AF, atrial fibrillation; INR, international normalized ratio.

cedural major adverse events (mortality, stroke, systemic embolism, pericardial tamponade, pericardial effusion requiring intervention), and device-related adverse events at 2 years (thrombosis, significant residual leak > 5 mm, embolization).

The study was approved by local ethics committees and all patients signed an informed consent form before inclusion. Enrollment in this multicenter registry started in 2017 and 51 patients have already been included at 12 sites in Spain. Baseline characteristics are detailed in table 2. LAAO was successfully performed in all patients except 1 (detection of thrombus into the LAA) with 2 transient complications: 1 case of anaphylactic shock (potentially related to contrast) and 1 LAA perforation successfully treated with LAAO (no pericardial drainage was needed). All the patients were discharged free from the safety endpoint; only 8 patients remained on oral anticoagulation at discharge.

During follow-up, device-related thrombosis was found in 2 patients by transesophageal echocardiography. Both patients were treated with enoxaparin, with subsequent disappearance of thrombus. Only 1 patient showed a significant peridevice leak > 5 mm. During a median follow up of 246 [interquartile range,