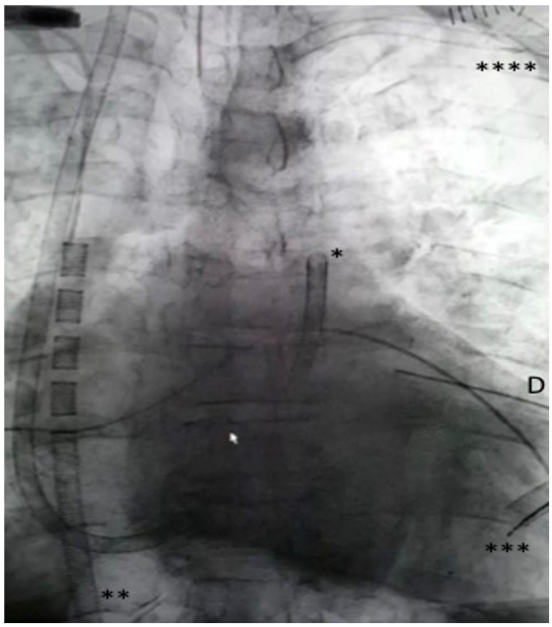

Figure 2. Chest radiograph following biventricular assist device implantation. Right ventricular assist device return (*) and drainage (**) cannulas. Left ventricular assist device drainage (***) and return (****) cannulas.

showed right ventricular systolic dysfunction. In view of this situation, it was decided to implant a BiVAD.

Left axillary artery cannulation was performed via end-to-side anastomosis of a 10-mm Dacron graft into which a Medtronic EOPA arterial cannula (18-Fr) was inserted. A 34-Fr Levitronix CentriMag LVAD return cannula (Abbott) was implanted via left anterior minithoracotomy. This was followed by percutaneous placement of a right ventricular assist device (RVAD) in the pulmonary vein and insertion of a drainage cannula in the right femoral vein; a 17-Fr return cannula (Bio-Medicus, Medtronic) was directed through the right jugular vein to the main pulmonary artery, before the bifurcation, following the procedure recently described by Uribarri et al.[4] This approach, consisting of percutaneous placement of the RVAD and minimally invasive implantation of the LVAD, reduced the degree of surgical aggression required to achieve circulatory support (figure 1 and figure 2). Amines were withdrawn after 24 hours of BiVAD support and the patient was extubated at 96 hours and placed on a waiting list for an urgent heart transplant. The heart transplant was performed 7 days later, and in the absence of significant postsurgical complications, the patient was discharged home at 21 days.

BiVAD implantation by minimally invasive surgery offers an alternative to conventional median sternotomy. It is associated with a lower incidence of bleeding and infectious complications, and in the case of heart transplant patients, reduces the risk of perioperative complications, largely by eliminating the need for 2 median sternotomies.

Percutaneous RVAD placement allows for the addition of an oxygenator to the VAD circuit to provide circulatory and respiratory support to patients who experience respiratory deterioration. In such cases, anticoagulation is necessary. In addition, if the patient shows good respiratory and right ventricular recovery, the RVAD can be removed at the bedside, eliminating the need for surgical decannulation.

In conclusion, minimally invasive surgery for BiVAD implantation carries a lower risk of complications than median sternotomy and could provide an alternative for critically ill patients who are potential candidates for heart transplant.

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First national registry of evolocumab in clinical practice in cardiology units in Spain. The RETOSS-CARDIO study

Primer registro nacional de evolocumab en la práctica clínica en unidades de cardiología en España. Estudio RETOSS-CARDIO

To the Editor,

Reducing low-density lipoprotein cholesterol (LDLc) with lipid-lowering therapy decreases cardiovascular events in both primary and secondary prevention; hence, the sharper the decrease, the lower the cardiovascular risk and the earlier the decrease occurs.[1]

Despite receiving statin therapy alone or in combination with ezetimibe, only 25% to 30% of patients in Spain with ischemic heart disease achieve the recommended LDLc targets.[2]

Proprotein convertase subtilisin/kexin type 9 inhibitors are highly effective in lowering LDLc levels and the risk of cardiovascular complications. In the FOURIER[3] study, patients with established atherosclerotic cardiovascular disease showed significant reductions in cardiovascular events when evolocumab was added to the standard lipid-lowering therapy. However, as there may be substantial differences between clinical trials and "real life", it is essential to know how these drugs perform in clinical

Table 1
Patients' baseline characteristics

Variable	Total (n = 186)
Biodemographic characteristics	
Age, y	60.3 ± 9.8
Sex, male	134 (72.0)
Family hypercholesterolemia	66 (35.5)
Primary prevention (family hypercholesterolemia)	11 (5.9)
Secondary prevention	175 (94.1)
Baseline LDLc, mg/dL	144.0 ± 49.0
Physical examination	
Body mass index	28.5 ± 4.3
Heart rate, bpm	66.1 ± 10.3
Systolic blood pressure, mmHg	131.6 ± 17.5
Diastolic blood pressure, mmHg	76.6 ± 11.3
Cardiovascular risk factors	
Hypertension	109 (58.6)
Diabetes mellitus	49 (26.4)
Smoker	
Never	59 (31.7)
Ex-smoker	111 (59.7)
Active	16 (8.6)
Family history of cardiovascular disease (men < 55 years and women < 60 years)	91 (48.9)
Vascular disease	
Myocardial infarct	122 (65.6)
Heart failure	19 (10.2)
Peripheral arterial disease	16 (8.6)
Chronic kidney disease	16 (8.6)
Stroke	9 (4.8)
Lipid-lowering therapy at the start of evolocumab	
Statins	
Some type of statin	100 (53.8)
High intensity (LDLc reduction ≥50%)	83 (44.6)
Moderate intensity (LDLc reduction 30%-50%)	15 (8.1)
Low intensity (LDLc reduction < 30%)	2 (1.1)
None	86 (46.2)
Ezetimibe	95 (51.1)
*Statin intolerance**	93 (50.0)

HDLc, high-density lipoprotein cholesterol; LDLc, low-density lipoprotein cholesterol.
* Complete intolerance: cannot tolerate statins at any dose; partial intolerance: cannot tolerate statins at high doses.
Values are expressed as No. (%) or mean ± standard deviation.

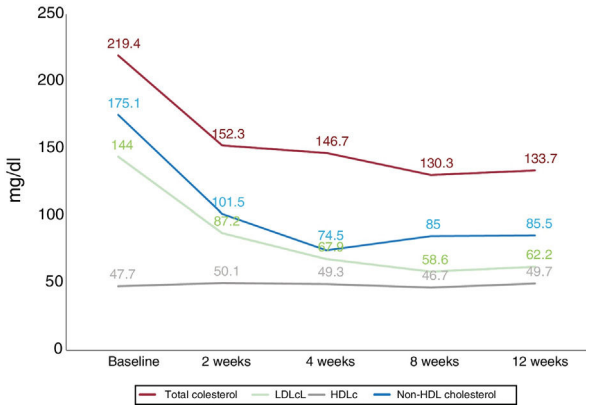

Figure 1. Changes in concentrations of total cholesterol, LDLc, HDLc, and non-HDL cholesterol during evolocumab therapy. HDLc, high-density lipoprotein cholesterol; LDLc, low-density lipoprotein cholesterol.

practice. Unfortunately, there are very few studies analyzing the role of evolocumab in real-life settings[4,5] and those that exist include only a small number of patients.

The RETOSS-CARDIO study (RETrospective Observational Study of Evolocumab Use in Spanish Cardiology Units), endorsed by the Spanish Research Agency of the Spanish Society of Cardiology, was designed to analyze the effect evolocumab on the lipid profile and its safety in the real world of patients treated in hospital cardiology units in Spain. This retrospective, multicenter, observational study analyzed the medical records of patients starting evolocumab in the usual clinical practice of Spanish hospital cardiology units between February 2016 and May 2017 (first years after publication of the therapeutic positioning report). The study was approved by the Ethics Committee of University Hospital La Paz in Madrid. Data were collected retrospectively from the 12 weeks before the start of treatment until 12 weeks after treatment initiation.

In total, 186 patients were included: mean age was 60.3 ± 9.8 years, 35.5% had a family history of hypercholesterolemia, 94.1% had experienced a previous cardiovascular event, and baseline LDLc was 144.0 ± 49.0 mg/dL. At baseline, 53.8% were taking statins (high intensity in 44.6%, moderate intensity in 8.1%, and low intensity in 1.1%) and 51.1% were taking ezetimibe. Among the total, 50% had total or partial statin intolerance (table 1).

In all cases, patients were prescribed an initial evolocumab dose of 140 mg, mainly every 2 weeks (97.3%). The treatment was interrupted in only 6 patients (3.2%): in 5 cases at the patient's request (with no mention of adverse effects) and in 1 case due to myalgia (0.5%), although causality was not conclusively demonstrated. Treatment adherence was adequate in most patients (92.3%).

Evolocumab therapy was associated with significant reductions in total cholesterol, LDLc, and triglycerides. Levels of high-density lipoprotein cholesterol did not significantly change during follow-up (figure 1). At 12 weeks, 82.5% of patients had LDLc < 100 mg/dL, 64.9%, < 70 mg/dL, and 49.1%, < 50 mg/dL.

This study analyzed a relatively large population of patients who received evolocumab for the first time in Spanish cardiology units in accordance with clinical practice and the therapeutic positioning report. The main results show that evolocumab led to marked LDLc reductions with virtually no adverse effects, and that LDLc targets were achieved in a high percentage of patients. One recent study performed in the Unites States in patients with atherosclerotic cardiovascular disease found that only 15% of patients in clinical practice met the inclusion/exclusion criteria of the FOURIER[6] study, indicating that real-life studies such as ours are needed to complete the information from clinical trials.

We found that evolocumab administration was associated with significant LDLc reductions starting from day 2 of treatment. These decreases were maintained and even increased over the following weeks of treatment to reach almost 60% at 12 weeks, which led to high percentages of LDLc control during follow-up. These findings concur with those observed in the FOURIER study.[3]

Adherence to therapy was very high (>92%), and the regimen was interrupted in only 1 patient (0.5%) due to adverse effects. Tolerance to evolocumab was very good in both the clinical trials and clinical practice studies, with very low interruption rates.[3–5]

In conclusion, the RETOSS-CARDIO study is the first national registry of patients treated with evolocumab in hospital cardiology units in Spain. Evolocumab therapy was associated with LDLc reductions close to 60% at 12 weeks, with good

adherence and very low discontinuation rates due to adverse events. These data, obtained in dyslipidemia patients in Spanish cardiology units, are consistent with those reported in the FOURIER study.

FUNDING

This study was sponsored by Amgen España, which had no influence on its development, and was validated by the Research Agency of the Spanish Society of Cardiology.

CONFLICTS OF INTEREST

C. Roldan works in the Amgen Medical Department. The remaining authors have received fees from Amgen for consulting/presentations.

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