Impella CP-Assisted High-risk Coronary Percutaneous Intervention: First Experience in Spain

Asistencia ventricular percutánea Impella CP en la angioplastia de alto riesgo: experiencia inicial en España

To the Editor,

The use of percutaneous ventricular assist devices (PVAD) during high-risk coronary percutaneous intervention is controversial. The European guidelines for myocardial revascularization[1] provide no recommendations on their application in clinical practice. A consensus document has recently been published on the hemodynamic support validated by the evidence available to date.[2]

The Impella CP has been approved as a short-term ventricular assist device. It is capable of providing assistance of up to 4 L/min, maintaining an integrally percutaneous insertion, and is easier to use than other PVAD. It has been successfully used as a bridge to cardiac transplant.[3]

We present the cases of 5 patients, who were consecutively admitted to hospital between January and December 2015 with multivessel or unprotected left main coronary artery disease, and different degrees of ventricular dysfunction. The patients were referred for percutaneous coronary intervention (PCI), and their angioplasties were done with the support of the Impella CP system. Surgery had been considered contraindicated in high-risk patients, because of the impossibility of complete revascularization and/or patient choice. The indication for Impella CP was carried out using a clinical database and the operator's discretion.

In all patients, the Impella CP was implanted electively prior to PCI. The insertion was done using femoral access, and the position was maintained under fluoroscopic guidance (Figure). Based on the experience in our center, we employed the Prostar XL percutaneous closure system.

The patients' baseline characteristics are shown in the Table. The mean age was 74.4 ± 5.3 years, and the patients were admitted for non–ST-segment elevation acute coronary syndrome. Patient No. 1 was hospitalized in Killip class II, but rose to Killip class IV because of damage to the right ventricle, and patient No. 5 was hospitalized in Killip class II. None of the remaining patients had heart failure. The mean left ventricular ejection fraction was 35.4% ± 6.8%.

The Table also shows the coronary anatomy of the patients, the revascularization performed, and the complications. The mean number of vessels involved was 2.60 ± 0.55, and angioplasty was performed in a mean of 2.00 ± 0.7 vessel. The Impella CP provided a continuous flow of 3.0 to 3.5 L/min and hemodynamic stability was maintained throughout PCI. There was no in-hospital mortality. In patient No. 4, who had femoral calcification, there was a tear in the arterial wall and, when the suture was closed with the Prostar XL system, the patient required emergency vascular surgery, which produced mild anemia.

Our case series is the first that describes patients undergoing high-risk PCI with the support of the Impella CP. Until the development of the new PVAD, the intra-aortic balloon pump was the only available percutaneous assist device. The randomized PROTECT II trial[4] evaluated the prognostic effect of the Impella 2.5 system compared with the intra-aortic balloon pump as support for high-risk angioplasty. There were no significant differences in the primary endpoint of major adverse cardiovascular events at 30 days but, at 90 days, there was a strong trend toward their reduction. Patel et al.[5] identified 18 094 PCI procedures performed with hemodynamic support in the database of the Nationwide Inpatient Sample. In all, the intra-aortic balloon pump was the most frequently used system, reported in 90.3% of the procedures vs 6% with PVAD and 1% with both. An analysis involving propensity score matching reported that the use of PVAD was associated with reduced mortality (odds ratio = 0.55; 95% confidence interval, 0.36-0.83; $P = .004$).

Because of the absence of recommendations in clinical practice guidelines, the limited evidence available, and the extra cost of using PVAD, patient selection is essential. The above-mentioned consensus document[2] endorses the use of PVAD as support in angioplasty for patients with left main coronary artery disease involving 3 vessels or with a last patent vessel. The latter is fundamental when a complex procedure is foreseen or the patient has severe ventricular dysfunction.

Our experience with Impella CP is favorable. It is simple to insert and the programming facilitates its use, whereas the hemodynamic support it provides allows the performance of high-risk angioplasties with the utmost safety.

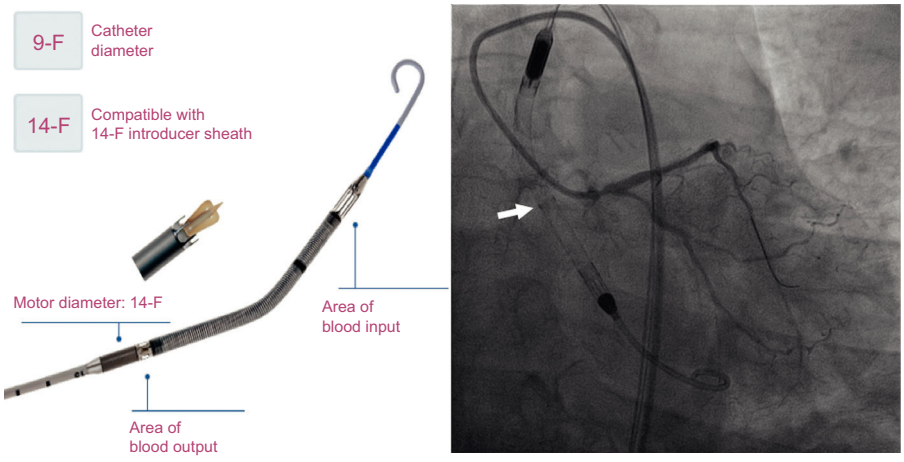

Figure. Impella CP (slide, left). Angiographic image of the Impella CP inserted into patient No. 4 (right). The radiopaque marker of the assist device (arrow) should be aligned with the image of the aortic valve.

Table
Patients' Baseline Characteristics, Coronary Anatomy, Characteristics of Percutaneous Intervention and Complications

	Patient No. 1	Patient No. 2	Patient No. 3	Patient No. 4	Patient No. 5
Age, y	67	76	80	71	78
Sex	Male	Female	Male	Male	Male
History of ischemic heart disease	Previous AMI	Stable coronary artery disease	—	Previous surgical coronary artery revascularization for ischemic dilated cardiomyopathy	—
Previous heart failure	No	No	No	Yes	No
Hypertension	Yes	Yes	Yes	No	Yes
Diabetes mellitus	Yes	No	Yes	No	Yes
Peripheral arterial disease	No	Yes	No	No	No
Intracardiac devices	—	TAVI, dual-chamber pacemaker	—	ICD	
Reason for hospital admission	NSTEMI	Unstable angina	NSTEMI	Unstable angina	NSTEMI
Killip class admission	IV (RV dysfunction)	I	I	I	II
LVEF (%)	45	30	40	32	30
Coronary arterial disease	LMCA to proximal RCA	LMCA, proximal LAD to proximal RCA	LMCA, proximal RCA to proximal LAD	Proximal and mid LAD, chronically occluded proximal Cx, chronically occluded mid RCA Bypass radiological images: left mammary artery to an ostial LAD occlusion, saphenous to 1st obtuse marginal patent branch	Mid LAD, proximal Cx to chronically occluded proximal RCA
Syntax score	16	22	27	-	45
Percutaneous coronary intervention	LMCA to proximal RCA	LMCA-LAD	Proximal RCA LMCA-LAD	LAD	Mid LAD, distal LAD, proximal Cx to obtuse marginal branch
Number of lesions to be treated	2	1	4	1	4
Number of stents implanted	0 (drug-eluting angioplasty balloon over stent-in-stent restenosis)	1	4	2	5
Length of the lesion to be treated, mm	40	14	65	34	95
Preparation of lesion / other devices	—	—	• Rotablator • Cutting balloon	–	Finecross Microcatheter
Duration of the procedure, min	150	150	174	120	120
Was the intervention finished in the catheterization laboratory?	Yes	Yes	Yes	Yes	Yes
Periprocedural AMI	No	No	Yes	No	Yes
Other complications	—	—	—	• Tear in femoral artery • Transient hypotension	—

AMI, acute myocardial infarction; Cx, circumflex artery; ICD, implantable cardioverter-defibrillator; LAD, left anterior descending; LMCA, left main coronary artery; LVEF, left ventricular ejection fraction; NSTEMI, non–ST-segment elevation myocardial infarction; RCA, right coronary artery; RV, right ventricle; TAVI, transcatheter aortic valve implantation.

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Performance of a New Software Tool for Automatic Quantification of Left Ventricular Trabeculations

Rendimiento de un nuevo software *para la cuantificación automática de trabeculaciones en el ventrículo izquierdo*

To the Editor,

We aimed to evaluate the performance of the first published software tool[1] for the automatic quantification of left ventricular noncompaction (LVNC) based on automatic delineation of the epicardial and endocardial borders of the left ventricular (LV) and trabecular recesses.

Twenty-one LVNC patients meeting Petersen's criteria[2] were compared with 14 control individuals (relatives not meeting LVNC criteria who were free from family mutations). Eleven (52.3%) of the affected patients had systolic dysfunction (8 of those with LV dilatation), 1 had dilatation without systolic impairment, and 1 had LV hypertrophy (20-mm maximum wall thickness). Ten individuals had isolated hypertrabeculation meeting LVNC criteria (Table).

Cardiac magnetic resonance cine images (repetition interval of 2.8 ms, echo time of 1.4 ms, flip of 60°, matrix of 190 x 200, echo train length of 23, cutting thickness of 8 mm, with 30 phases) were reviewed by 2 experienced investigators independently. Fourteen (5.8%) of 242 slices were of insufficient quality. Short axis slices, from the apex to the mitral annulus in end-diastole were analyzed with dedicated software. A standard protocol was used for measurements of LV volumes and wall thickness.

Delineation of the endocardial border, endocardial compacted layer, and pericardial border was performed automatically.[1] The trabecular zones are detected inside and around the LV cavity. The software produces measurements of area, volume, and estimates of mass of compacted and noncompacted LV myocardium per slice, and total LV. All measurements are presented as absolute values and are indexed by body surface area. The proportion of trabeculated mass from total LV mass was also calculated. Delineation of the borders was subjectively scored by 2 skilled cardiologists.

The LVNC patients and control groups showed significant differences in the trabeculated layer mass in most apical and mid slices (slices 2-6) both for absolute and indexed values (Figure). Although the percentage of trabeculation was higher in all slices, it was significant only for apical slices 2 and 3 and basal slice 8. There was no difference in the compacted layer between groups.

When slices were grouped into apical, mid and basal and all 3 segments showed significantly higher values for absolute trabeculated layer, indexed trabeculated layer and percentage of trabeculation in the LVNC group. As with individual slices, there were no differences in the mass of the compacted layer by segments between groups.

The trabeculated layer and percentage of trabeculation was significantly higher in LVNC patients than in the control group (86.6 ± 27.4 g vs 56.1 ± 24.4 g; P = .002 and 32.3 ± 4.6% vs 25.0 ± 7.7%; P = .001, respectively).

On multivariate analysis, the indexed trabeculated layer was the variable independently associated with the diagnosis of LVNC (hazard ratio, 1.11; 95% confidence interval, 1.03-1.19; P = .009).

Receiver operating characteristics curve analysis of the 2 variables that differentiated LVNC patients and controls was performed to identify cutoff values. These were 0.82 (95% confidence interval, 0.67–0.96; P = .002) for the indexed trabeculated layer and 0.78 (95% confidence interval, 0.61-0.95; P = .006) for the percentage of trabeculation. A cutoff value of 40.0 g/m^2 of the indexed trabeculated layer had a sensitivity of 81.0% and a specificity of 78.6%. Similarly, a cutoff value of 27.4% of the percentage of trabeculation had a sensitivity of 90.5% and a specificity of 71.4%.

All (88.6%) but 4 individuals from the total of 35 individuals were appropriately classified. Seventeen (81.0%) of the 21 LVNC patients had values above the 2 cutoffs, and 2 (9.5%) reached only 1 of them.

The performance of the automatic software was evaluated first by the engineers and then by cardiac magnetic resonance expert cardiologists, with very good visual agreement in 96% of the slices. Trabeculation was particularly prominent in apical slices with a

Table
Baseline Characteristics and Summary of Results

	Controls	LVNC patients	*P*
N	14 (40.0%)	21 (60.0%)	
Male/female	7/7	12/9	.7
Age	32.4 ± 13.6	41.5 ± 12.2	.05
BSA, m²	1.69 ± 0.18	1.73 ± 0.19	.05
iLVED, mL/m²	81.6 ± 16.9	97.3 ± 15.1	.01
iLVES, mL/m²	37.2 ± 12.1	53.0 ± 14.7	.005
LVEF, %	55.0 ± 8.2	46.1 ± 9.9	.02
Trabeculated layer, g	56.1 ± 24.4	86.6 ± 27.4	.002
iTrabeculated layer, g/m²	32.7 ± 12.1	50.0 ± 15.7	.001
Compacted layer, g	169.6 ± 48.7	183.3 ± 60.8	.5
iCompacted layer, g/m²	100.2 ± 26.3	106.0 ± 36.2	.6
Trabeculation, %	25.0 ± 7.7	32.3 ± 4.6	.001
iTrabeculated layer, g/m²			
Apical	4.1 ± 2.2	7.2 ± 3.1	<.00001
Mid	6.1 ± 2.0	8.6 ± 2.5	<.00001
Basal	4.6 ± 3.0	6.4 ± 3.4	.03
iCompacted layer, g/m²			
Apical	10.2 ± 3.4	10.9 ± 4.1	.3
Mid	15.6 ± 3.2	17.3 ± 5.2	.1
Basal	18.2 ± 2.6	19.2 ± 5.5	.3
Trabeculation, %			
Apical	28.7 ± 11.6	39.2 ± 10.0	<.00001
Mid	28.2 ± 8.9	33.4 ± 6.4	.008
Basal	19.0 ± 11.5	24.4 ± 9.7	.04

BSA, body surface area; i, BSA indexed; iLVED: indexed left ventricular end-diastolic volume; iLVES, indexed left ventricular end systolic volume; LVEF, left ventricular ejection fraction; LVNC, left ventricular noncompaction.