

Midterm Outcomes after Endovascular Therapy in Claudicant Patients

Intermittent claudication (IC) is the most common clinical manifestation in patients with peripheral vascular disease (PVD). Between 25-33% of PVD patients will present symptoms of IC; (1) however, major amputation rate in these patients will not be >3.3%. (2) The main purpose for the treatment of these patients is to improve quality of life and reduce complications. Traditionally, pharmacological therapy and supervised exercise have been the first-line treatment. Today, with the development of endovascular treatment, a new alternative arises, given the low morbidity and mortality rates and the positive short- and mid-term outcomes.

The purpose of this study was to analyze the technical success, complications, and clinical outcomes in a group of patients with symptoms of IC undergoing endovascular treatment. A descriptive, retrospective analysis was performed on 90 patients in whom 115 limbs were consecutively treated between September 2010 and January 2015.

Inclusion criteria for the analysis of these patients were vascular IC Rutherford grade I, II, and III. Of the 115 limbs treated, 19.2% were grade II, and 80.8% were grade III. Clinical follow-up was performed at 1, 3, 6, and 12 months, and annually through questioning and physical examination. Technical success was defined as residual stenosis <30% without flow-limiting dissection of the treated arterial segment.

Complications were divided into major -requiring open invasive treatments- or minor -requiring conservative or percutaneous treatments. The course of symptoms was divided into four groups. Asymptomatic group: patients had no symptoms of IC; symptomatic improvement group: patients with reduced Rutherford classification by one or more degrees; no improvement group: patients without clinical changes; and increased-symptom group: patients with IC increased by one degree in the classification.

The femoral, contralateral, or ipsilateral access was the elective approach. Retrograde approaches were used in 4 limbs (3.5%) due to failed recanalization. Primary nitinol self-expanding stent (nSES) followed by percutaneous transluminal angioplasty (PTA) was the technique of choice. Drug-eluting balloon angioplasty (DEB-PTA) was the treatment of choice for stenotic lesions, while occlusive lesions were approached with PTA with stent or DEB implantation, depending on the result. Table 1 shows the characteristics of the study population.

Among the 115 limbs considered for treatment, this was performed in the aortoiliac region in 45 (39%) and in the femoropopliteal region in 70 (61%). Infrapatellar vessel PTA was also performed in 9 limbs (7.8%) (Table 2). Technical success was reached in 114 (99.1%) of the 115 limbs treated. One hundred percent technical success was obtained in TASC A-B lesions,

Table 1. Risk Factors

Factor	n (%)
Kidney disease	14 (15.5)
DM	29 (23.22)
HTN	87 (96)
Dyslipidemia	72 (80)
Heart disease	24 (26.6)
Smoker	24 (26.6)
Ex-smoker	47 (52.22)

DM: Diabetes mellitus. HTN: Hypertension.

and 98.2% in TASC C-D lesions. In one of the limbs with femoropopliteal TASC D lesion, distal approach was not possible due to gross calcifications. Percutaneous transluminal angioplasty with nSES was used in 82 of the 115 limbs (71.3%); 23 (20%) were treated with DEB, and 10 (8.7%) with conventional PTA.

Complications occurred in 7 cases (6%): 4 (3.4%) were pseudoaneurysms treated with embolization with thrombin injection and 3 (2.6%) were hematomas, not requiring treatment.

Mean follow-up was 18 months (1-36 months) in 111 (96.5%) limbs. Among these, 104 (93.7%) were asymptomatic, 4 (3.6%) had symptomatic improvement, and 3 (2.7%) showed no clinical changes. During follow-up, 60.6% of the patients abandoned their smoking habit.

A total of 10 (8.7%) reoperations were performed in the 115 limbs treated. Four (40%) of these reoperations were in TASC A-B patients and 6 (60%) in TASC C-D patients. In turn, 8 (80%) of these reinterventions were on the femoropopliteal region, and 2 (20%) in the aortoiliac region, resulting in a reoperation rate of 4.4% for iliac lesions, and 11.42% for femoropopliteal lesions (p Fisher=0.311).

We can say that the natural history of patients with claudication is "benign"; however, at 5 years, between 10% and 20% of those without revascularization will progress to critical ischemia with an amputation rate of 2-5%. (2) Accordingly, treatment is based on management of risk factors, supervised exercise, and pharmacological treatment, a therapeutic approach that is effective only in 25-30% of cases. Cilostazol as drug therapy improves walking distance by 50%, but 15% of the patients stop treatment due to its adverse events. (3) Moreover, supervised exercise training in patients with severe limiting claudication does not increase significantly walking distance.

Shalger et al. reported a group of claudicant patients whose mean walking distance before treatment was 102 (66-155) meters, and increased to 154 (97-230) meters after exercise training. (4) In the work by Hobbs et al., the distance before supervised exercise

Table 2. Distribution of lesions by territory and technical success

TASC	Aortoiliac (n=45)	Femoropopliteal (n=70)	Technical success (Global 99.1%)
A	14 (31%)	19 (27.1%)	100%
B	11 (24%)	19 (27.1%)	
C	3 (6.7%)	8 (11.4%)	98.2%
D	17 (37.8%)	24 (34.4%)	

training was 111 (60-237) meters, and after exercise it increased to 124 (74-352) meters. (5)

In our series, 93.7% of the limbs treated at a mean follow-up of 18 months were asymptomatic, 3.6% presented improved symptoms, and 2.7% showed no clinical changes. It is important to point out that 81% of the patients in this series were Rutherford grade III. The therapeutic arsenal currently available has improved the technical success rate and patency of the treated lesions – a key point in claudicant patients –, since the relapse of symptoms is directly associated with restenosis or occlusion of the treated segment, as well as the development of new lesions. In our case-load, technical success was 99.1 %, regardless of classification and arterial territory of the limbs treated.

Conventional balloons, DEB, coated stents with and without eluting drugs, and atherectomy are among current endovascular alternatives. Regarding covered stents, McQuade et al. presented a randomized study comparing the patency of prosthetic bypass grafting versus Viabahn covered stent for the treatment of extensive femoropopliteal lesions, and found no statistically significant differences in primary patency at 4-year follow-up. (6) Recently, Tepe et al. carried out a multicenter randomized study to compare the outcomes of DEB angioplasty versus conventional balloon, reporting a primary patency of 82.2% and 52.4% at 12 months, respectively. (7)

In our experience, none of the 23 limbs treated with DEB required reoperation, and remained asymptomatic during the follow up period. Therefore, we could say that endovascular therapy for IC patients performed by experienced groups is safe and effective, with low morbidity and mortality rate. The indication of endovascular therapy in these patients should be agreed between doctor and patient based on the expectations and functionality of each person. Nonetheless, endovascular therapy should be considered as the treatment of choice in patients whose medical treatment is unsuccessful or insufficient for their expectations.

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Malpositioned Pacemaker Lead Mimicking Left Myocardial Injury

Pacemaker implantation is a common practice, with minimum prevalence of associated complications. However, inadvertent left-sided lead placement is one of them, which though rare, may have serious consequences as atrial thromboembolism.

We report the case of a 73-year-old hypertensive female patient, with no history of coronary heart disease, with ostium secundum atrial septal defect (ASD), severe pulmonary arterial hypertension (PAH) and right heart dilatation, and no other cardiovascular history. A DDD pacemaker had been implanted in another center due to extreme bradycardia in acute AF conversion, 30 days before consultation.

The patient presented with FC III precordial, burning pain of moderate intensity, spreading at rest, radiating to the back and the right arm, and relieved with opioid analgesics. Upon consultation, the patient was asymptomatic and normotensive, with no signs of congestive heart failure (CHF), jugular venous distention or Kussmaul's sign.

The electrocardiogram (ECG) showed ST-segment depression in V2 and V3 with negative T-waves (Figure 1A). No other ECG abnormalities were noted over previous ECGs (the patient had deviation of the axis and right bundle branch block associated with her history of ASD and PAH). Successive records showed ST segment resolution (Figure 1B). Elevated serum cardiac enzymes (CPK and cTnI) were observed in the appropriate time window.

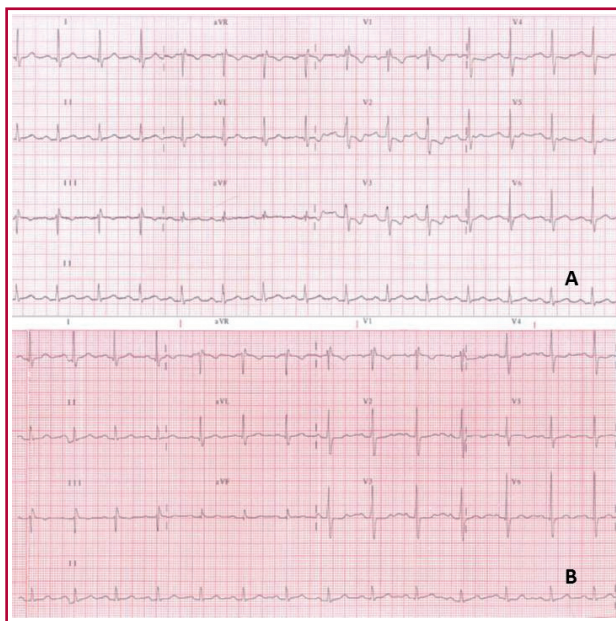


Fig. 1. Admission ECG. ST-segment changes in the anterior wall (A) with spontaneous resolution (B).

The patient was admitted to the intensive care unit with presumptive diagnosis of non-ST-segment elevation acute coronary syndrome. A coronary angiography ruled out coronary artery disease, and a left ventriculography revealed the position of the pacemaker lead, in direct contact with the inferoposterior left ventricular wall, where regional motility disorders were observed (Figure 2).

The echocardiography evidenced good biventricular function without regional motility disorders, and the passage of one of the pacemaker leads through the ASD and its position in relation to the left ventricular posterior wall was observed. The pacemaker lead was repositioned.

Left ventricular pacemaker lead implantation is a rare, underdiagnosed and little reported complication; for this reason, its incidence and prevalence are unknown. It is usually associated with cardiac structural abnormalities. Patients may remain asymptomatic or have up to 37% episodes associated with cerebral arterial thromboembolism. (1, 2)

Diagnosis is simple, but requires high suspicion. The image of right bundle branch block in the pacemaker capture and the position of the ventricular lead in the chest x-ray (front and lateral) suggest this condition, which should be confirmed by echocardiography. (3-5)

The therapeutic decision is not uniform in the publications; however, in all of them the approach has been lead removal and repositioning in patients with early diagnosis, (4, 6) or chronic anticoagulation in those where lead removal was not attempted or could not be performed. (1-3, 5)

In our case, the option was lead repositioning, giv-

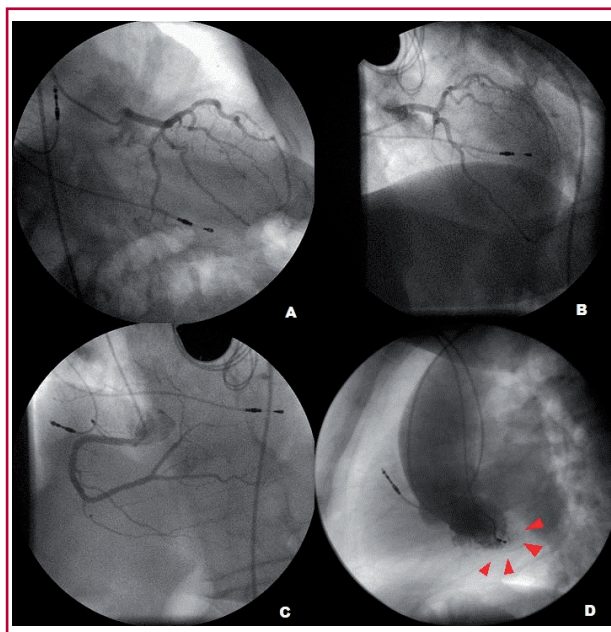


Fig. 2. Coronary angiography without evidence of significant lesions (A: Left coronary artery, right anterior oblique view. B: Left coronary artery, front cranial view. C: Right coronary artery, left anterior oblique view), and left ventriculography (D: Left view), showing lead position in the left ventricle and an akinetic segment where the lead is implanted (arrow heads).

en the close date of pacemaker implantation and the clinical correlation with the symptoms.

Left ventricular pacemaker lead implantation is an uncommon complication when positioning these devices, but it is not exempted of serious consequences. It is easily diagnosed but demands high suspicion. There is no consensus as to its management, but both anticoagulation and lead repositioning are accepted, depending on the patient.

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Efficacy of Cryoballoon Ablation. A Comparison Between First- and Second-Generation Balloon Catheters

Atrial fibrillation (AF) is the most common sustained arrhythmia encountered in clinical practice. Clinical trials based on epidemiology data predict that its prevalence will be 2-to-3-fold higher by 2050. (1)

Catheter ablation of paroxysmal or persistent AF is the treatment of choice in refractory and symptomatic patients, according to the current treatment guidelines. However, the procedure is not without complications, which are usually between 2% and 5%, as reported in the literature. (1)

While radiofrequency (RF) is the most widely used energy source, it encounters some limitations, and cryoablation has become an alternative treatment option by offering a safer lesion profile, among other advantages. (2-4) Since 2012, a second-generation balloon catheter has been used whose technological improvement consisted in the addition of 4 refrigerant injectors to the existing ones, and the location of a more distal injection coil within the balloon. (4-6)

However, these technical improvements have not been clinically evaluated in terms of efficacy. The purpose of this article is to compare the safety, efficacy, and success rate of this procedure between first-generation balloon (CB1) and second-generation balloon (CB2) catheters.

This is an observational, retrospective, single-center (Instituto Cardiovascular de Buenos Aires) study, including the first 35 consecutive ablations of paroxysmal AF performed with 28 mm Arctic Front® cryoballoon catheter (Medtronic, Inc.) (CB1), and 35 ablations performed with Arctic Front® Advance cryoballoon catheter (CB2), from November 2013 to December 2014 (Figure 1). It should be pointed out that selection criteria for any of the two catheters were not based on clinical criteria but on availability, since the CB2 catheter has been available in the Argentine market since August 2014.

A total of 70 patients were included in the study; 71.43% in the CB1 group and 73.33% in the CB2 group were men ($p=0.650$). Mean age was 54.2 ± 13.42 years in CB1 and 52.94 ± 12.25 in CB2 ($p=0.406$). All patients had history of documented recurrent paroxys-

Table 1. Technical characteristics of the procedure

	CB1	CB2	p
Number of applications per vein	2.27±0.59	1.11±0.32	0.01
Mean time to vein disconnection	82.08±15.67	47.02±9.45	0.0001
Mean temperature reached in each vein, °C	-38.18±4.76	-42.44±4	0.0003
Mean procedure time, min	83.83±18.34	61±12.88	0.0001
Fluoroscopy time, min	25.38±12.22	12.99±3.58	0.01
Mean fluoroscopy dose, mGy	243.43±142.43	131.73±90.03	0.002
Complications, %	0	2.85	0.307

mal AF (PAF) of 2-6 years evolution and refractory to antiarrhythmic treatment. Average CHA2DS2-VASC score was 1 (1-3) for both groups.

No significant differences were found in the left atrial (LA) area, [20.10 ± 3.63 cm² in the CB1 group and 19.94 ± 2.98 cm² in the CB2 group ($p=0.943$)], or in the ejection fraction [59.94 ± 4.17 in CB1 and 60.26 ± 2.85 in CB2 ($p=0.719$)].

Immediate success rate was 100% for both groups, and the number of applications per vein was 2.27 ± 0.59 in the CB1 group and 1.11 ± 0.32 ($p=0.01$) in CB2 group. Mean time to vein disconnection was 82.08 ± 15.67 seconds in the CB1 group and 47.02 ± 9.45 seconds ($p=0.0001$) in the CB2 group. Mean temperature in the CB1 group was -38.18 ± 4.76 °C, and -42.44 ± 4.05 °C ($p=0.0003$) in the CB2 group.

Procedure time was 83.83 ± 18.34 min in the CB1 group and 61 ± 12.88 min ($p=0.0001$) in the CB2 group; fluoroscopy duration was 25.38 ± 12.22 minutes for the CB1 group and 12.99 ± 3.58 min ($p=0.01$) for the CB2 group; fluoroscopy dose was 243.43 ± 142.43 MGy and 131.73 ± 90.03 mGy respectively ($p=0.002$).

As for the safety of the procedure, the CB1 group did not have phrenic nerve paralysis, while there was one case of phrenic paralysis in the CB2 group which reversed one month after ablation ($p = 0.307$).

Patients with over 6-month follow-up after the procedure were included in this study. Follow-up included all 70 patients; mean follow up was 11.95 ± 3.79 months and recurrence rate was 24.75% for the CB1 group, and 10.07 ± 3.67 months and 14.28 % for the CB2 group ($p=0.477$).

Radiofrequency ablation is currently the most widely used method for the effective treatment of AF; however, success rate and limitations to RF ablation have been properly described by our study team and in the literature.

Today, cryoablation is being used as an option to

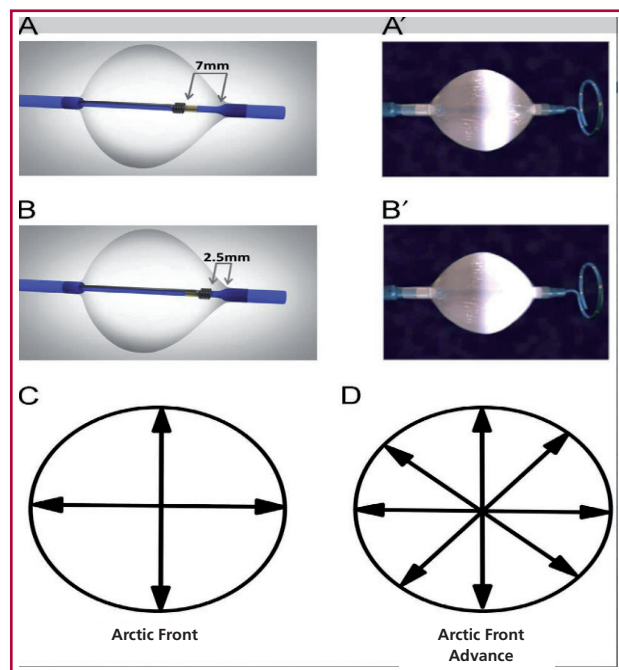


Fig. 1. A, C & A'. First-generation balloon with a more distal injection coil within the balloon and four refrigerant injectors, resulting in the cooling of the balloon at mid level.

B, D & B'. Second-generation balloon with a more distal injection coil within the balloon and eight refrigerant injectors, covering a wider freezing balloon surface area including its distal half.

RF ablation for pulmonary vein isolation. (2-4)

It is important to point out that, in our center, cryoablation was performed with different power catheters: the first 35 cases were treated with CB1 catheters, while CB2 catheters were used for the remaining 35 cases.

We understand that CB2 is more effective than CB1, because although vein isolation was achieved with both in 100% of cases, CB2 required fewer vein applications per patient, less time to reach the same goal, and achieved lower temperatures than CB1.

Cryoablation is associated with significantly shorter procedure times than those required by RF. In our initial experience, mean procedure times was 78.03 ± 19.84 min, (3) similar to those reported by other authors. (4-6) Results analyzed by subgroups showed a significant difference between both groups in favor of CB2 over CB1; the same occurred with time and fluoroscopy dose.

In our initial experience, AF-free rate was 80.73%, with a mean follow-up of 10.20 ± 3.83 months, (3) similar to that reported in the current literature. (4, 6) When results were analyzed by subgroups, a tendency in favor of CB2 (85.72%) over CB1 (75.25%) was observed, but the difference was not significant ($p=0.477$). These results could reach statistical significance with a larger number of patients.

We believe that cryoablation is a safe procedure; phrenic nerve paralysis is its most common complication, but it is usually transitory and reverses 24 hours after the procedure. Only a few persist after 12 months.

In this series, the rate of complications was 1% (1 patient), (3) due to phrenic paralysis that reverted within the first month, lower than the rate reported in the current literature. (4, 5) Phrenic paralysis occurred only in the CB2 group, and the difference was not significant ($p=0.307$).

The limitations of the study were its retrospective nature and the fact that it was single-center study, in which procedures were carried out by two different operators. Another aspect to be considered is that at first, when cryoballoon isolation of pulmonary veins began to be implemented, the only balloon available was the first generation one (the second generation balloon was implemented later), so that results could have been influenced by the learning curve. Lastly, we should mention that patient follow-up was higher for the CB1 group than for the CB2 group, a fact that might have influenced the AF-free rate.

In conclusion, cryoablation with CB2 proved to be as efficient as with CB1, but with shorter duration of the procedure and lower radioscopy dose. The safety profile is still favorable for CB1, with non-significant tendency.

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Transcatheter Ablation of Idiopathic Ventricular Fibrillation in a Patient with ICD and Arrhythmic Storm

We report the case of a 38-year-old male patient without coronary risk factors who was admitted in February 2012 at Hospital El Cruce after cardiac arrest secondary to ventricular fibrillation (VF). Anamnesis ruled out a family history of sudden death (SD) and other conditions; physical examination and ECG were normal, showing only signs of early repolarization in the inferior and lateral wall (slur). Cardiac magnetic resonance imaging (MRI) and coronary angiography (CAG) ruled out structural heart disease, and after 45-day recovery, a single-chamber cardioverter defibrillator was implanted (ICD). During the second year of follow-up, the patient underwent two shock therapies that corresponded to effective therapies of ventricular fibrillation episodes, according to the telemetry device interrogation.

In February 2015, the patient was readmitted at Hospital el Cruce due to arrhythmic storm. After shock therapies, the ECG showed signs of increased early ventricular repolarization (notch) in inferior and

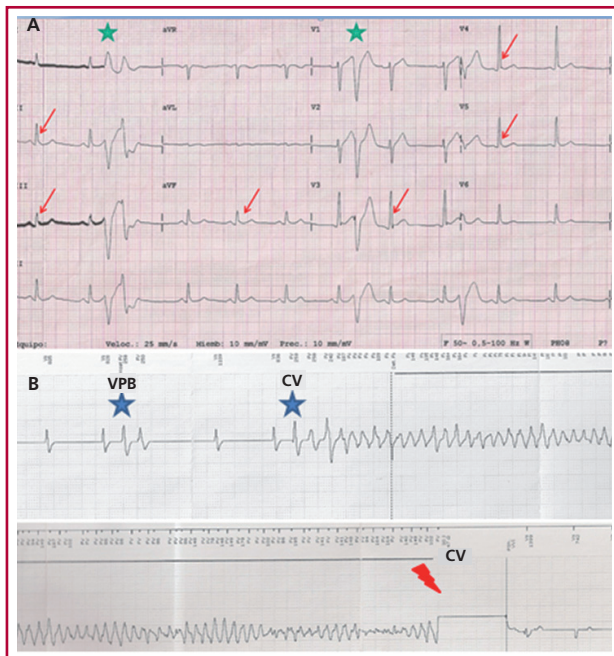


Fig. 1. A. 12-lead electrocardiogram showing ventricular premature beats (asterisks) with left bundle branch block, late R-wave transition in precordial leads, and R-on-T phenomenon. Early repolarization (slur and notch) are observed in the inferolateral wall (arrows). **B.** Implantable cardioverter defibrillator telemetry showing the episode of ventricular fibrillation gated by ventricular premature beats (VPB) that reverts with cardioversion (CV).

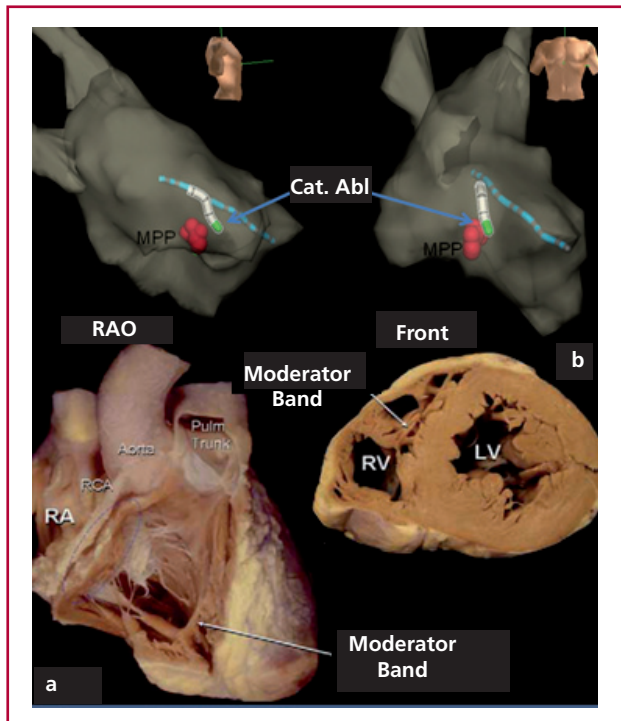


Fig. 2. a. Three-dimensional electroanatomical reconstruction of the right ventricle in right anterior oblique (RAO) and front views, showing the site of radiofrequency application (red spheres). **b.** Anatomical preparation showing the location of the moderator band in the right ventricle (RV).

anterolateral leads, and ventricular premature beats (VPB) with short coupling interval on the ascending limb of the T wave (Figure 1A). Device telemetry data showed VPB with very short coupling interval causing VF episodes that reversed with shock therapy (Figure 1B). A subsequent Holter monitoring study revealed a high-density of VPB with R-on-T phenomenon.

The patient underwent transcatheter ablation guided by three-dimensional electroanatomical mapping (Ensite system). Once the procedure was initiated under general anesthesia, total absence of VPB was found despite several methods of basal stimulation and high-dose isoproterenol infusion, and even after discontinuation of anesthetic drugs, representing a serious limitation to treatment. During continuous infusion of high esmolol doses (500 $\mu\text{g}/\text{kg}$ in 1 minute, followed by 100 $\mu\text{g}/\text{kg}/\text{min}$), return of VPB similar to those causing VF was achieved and localized on the moderator band in the right ventricle (Figures 2 a & b).

In this anatomic site, the endocavitary electrogram showed greater precocity, fascicular initial fast deflection, and perfect pace-mapping. The use of radiofrequency on that area accelerated the occurrence of ventricular rhythm similar to the morphology at VF onset, but was relieved after a few seconds due to permanent disappearance of VPB (Figure 3).

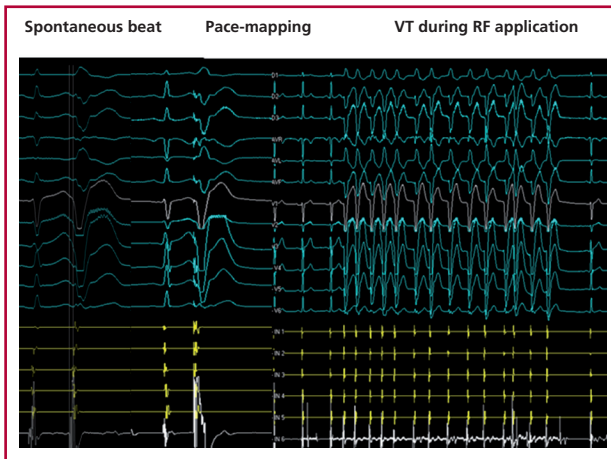


Fig. 3. Simultaneous surface and endocavitary electrocardiographic recordings showing, from left to right, clinical ventricular premature beats, pace-mapping at the site of application and time of radiofrequency application.

Since then, the patient did not repeat events, and absence of ventricular arrhythmia was confirmed both in stress test and Holter monitoring.

Sudden death accounts for 50% of cardiovascular deaths and 25% in adults, out of which 6-14% are individuals with no structural heart disease, many of them as debut. Most of those deaths are associated with known electrocardiographic patterns, such as long or short QT interval, Brugada syndrome, etc. However, in some cases the ECG signs are unclear, being identified as idiopathic ventricular fibrillation. (2)

For decades, early repolarization characterized by baseline J-point elevation on the 12-lead ECG has been considered as benign. However, its prevalence particularly in inferior and/or lateral leads has been associated with ventricular fibrillation vulnerability.

To avoid confusion with the early-repolarization pattern commonly found in young adults and trained athletes, whose J point and ST segment are elevated in V2-V4 precordial leads, the “inferolateral J-point elevation syndrome” associated with ventricular fibrillation is defined as J-point elevation manifested as a slow transition from the QRS segment to the ST segment (slur) or as a positive deflection inscribed at the end of the R wave (notch), with ST-segment elevation with upper concavity >1 mm in inferior leads (II, III, aVF) or lateral leads (DI, aVL, V5, V6), or in both. (2-5) This pattern is usually associated with sinus bradycardia and increased vagal tone, U wave, relatively short QT interval, vertical QRS axis, and attenuation

or disappearance with exercise.

Evidence has associated it with idiopathic VF, increasing 4 times the risk of cardiac death in young men. When it occurs in inferior and anterior leads associated with greater magnitude of J-point elevation (>2 mm) and horizontal/descending ST segment, it identifies an ECG profile with 10-fold higher risk of arrhythmic death, especially in young men. However, due to its high prevalence in the general population, detecting those criteria in a routine ECG in asymptomatic individuals with no family history of SD is not enough to account for a preventive therapy or a special follow-up.

Recently, the results of some few series of patients undergoing transcatheter ablation were published, whose origin was strongly associated with the moderator band of the right ventricle. (6)

Evidence suggests that radiofrequency ablation, although technically difficult, can be initially successful but nearly 50% of the patients require a second procedure. Initially successful ablation does not rule out cardioverter defibrillator implantation due to the high incidence of late relapses reported. (7)

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