## Conservative Approach to HeartMate II Thrombosis

Thrombotic events in HeartMate II left ventricular assist devices (LVAD) are uncommon but extremely serious, often requiring device replacement; however, there are reports about their conservative treatment. We present a case of fibrinolytic therapy as an option to device replacement.

### CASE REPORT

We describe the case of a 56-year-old male patient with idiopathic dilated cardiomyopathy, who after several admissions due to decompensation under optimal treatment, outpatient inotropic therapy, and cardioverter-defibrillator implantation received a HeartMate II LVAD as bridge-to-transplantation.

As part of the routine management, after drainage removal, the patient was started on warfarin [with the therapeutic goal of an international normalized ratio (INR) ranging between 2.5 and 3.5] and aspirin 81 mg. After 5 days in ICU, the patient required prolonged use of inotropes due to right ventricular dysfunction, and was then transferred to the general ward. On postoperative day 7, the patient had upper gastrointestinal bleeding with melena (INR 3.7), so anticoagulants and aspirin were discontinued.

The following day, control LVAD parameters were altered, evidencing increased pump power value of 12, and rapid reduction of pulsatility index (Figures 1 A & Figure 2). Laboratory tests showed free hemoglobin and haptoglobin, and high LDH. In view of suspected thrombotic event, an echocardiography was performed, which showed a slightly increased LV diameter but no thrombotic obstruction in the inflow/outflow cannulae. Chest CT scan was negative for thrombus in the cannulae or device (Figure 1 B and C).

Given the evident failure of the LVAD and the presence of hemolysis, thrombosis of the device was diagnosed, requiring its replacement. Administration of low dose thrombolytic agents was considered as an option, considering the risk of hemorrhage in a patient with recent gastrointestinal bleeding.

The patient was transferred to the catheterization laboratory, where a catheter was carefully advanced into the outflow cannula and 1 mg of tissue plasminogen activator (tPA) was infused.

Parameters were immediately normalized, with work reduction and increased pulsatility index (Figure 1 D). Echocardiography performed 48 hours later showed reduction of LV size.

HeartMate II is the most widely used LVAD, with more than 10,000 implantations. Compared to earlier devices, HeartMate II is thrombus-resistant due to several unique features of its textured inner surface. (1)

Thrombotic event occurrence is low, with a rate of 0.01% to 6% and its diagnosis is a highly complex challenge. (2)

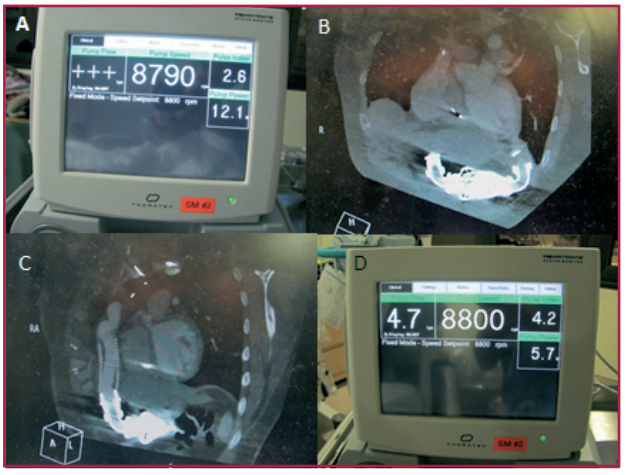


**Fig. 1. A** Abnormal increase in pump power and reduction of pulsatility index. **B** & **C.** CT scan of HeartMate II cannulas and device. **D.** Normalization of parameters following thrombolytic therapy.

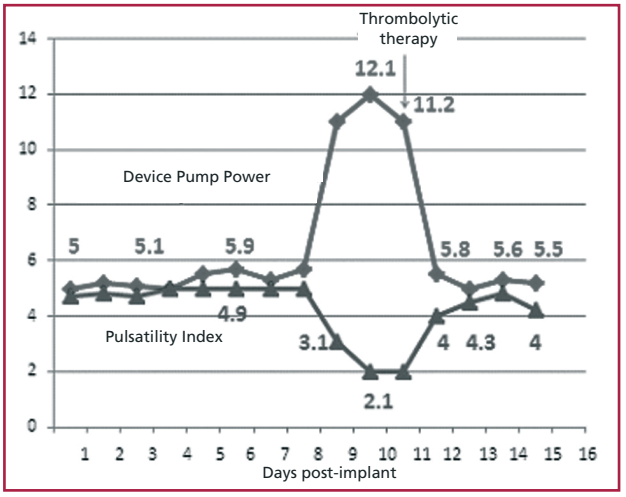


**Fig. 2.** Sequence of pulsatility index and pump power values.

CT scan is often unable to detect thrombosis, while echocardiography can assess thrombotic occlusion of the inflow cannula, presence of LV thrombus, absence of normal size variation response to LVAD speed changes (ramp test), or increased size of the left ventricular chamber as indirect expression of some type of LVAD occlusion, the last two observed in our patient.

Diagnosis is often presumptive and is based on lab tests and abnormal system parameter changes. Lab tests include suggestive hemolysis data such as increased LDH, free hemoglobin in plasma or haptoglobin. Among abnormal system parameter changes, increased LVAD work, showing some kind of obstruction, drop in the pulsatility index, evidencing reduced flow through the system and lack of response to speed

changes suggest thrombosis. (3)

Once the patient was diagnosed, the next problem was treatment definition. The prospect of a second major surgery to replace the LVAD in a relatively unstable patient with gastrointestinal bleeding was difficult and risky, while the use of systemic fibrinolytics was impracticable in the context of a recent gastrointestinal bleeding.

In a multidisciplinary meeting, it was agreed to use a "local" treatment in the inner part of the device, using low doses of thrombolytic agents, accepting both the risks of bleeding and of possible complications related to advancing a catheter into the LVAD. It was also agreed to prepare the patient for a possible emergency device replacement.

After the administration of local tPA (1 mg), device hemodynamic parameters were normalized, with resolution of echocardiography and laboratory abnormalities.

The references published about the "local" use of thrombolytic therapy in patients with LVAD are limited. Delgado et al. report the infusion of tPA at a rate of 1 mg/min through a catheter advanced into the left ventricle in Jarvik 2000 bearers, while Tshirkov et al. describe the use of tPA inside the inflow cannula of a Berlin Heart device; both procedures successful and with no bleeding complications. (4, 5)

Furthermore, Kieman et al. report a thrombus inside a HeartWare LVAD successfully managed with intraventricular tPA, also with no further complications. (6)

Our presentation is in line with those previously reported, and poses the administration of local low dose fibrinolytic therapy as a viable alternative to complex device replacement in selected patients.

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## Tibial Angioplasty with 2D Perfusion Imaging

Endovascular treatment for occlusive disease of the lower limbs has gained popularity in the treatment of patients with critical ischemia and lesions at the level of the tibial territory. (1, 2) New advances in technology, specific work material, more experience and new techniques, have turned tibial balloon angioplasty into a successful procedure in a selected group of patients. But the advent of this technique has entailed the need for angiosome-guided revascularization.

Angiosome is not a physiological but an anatomical concept, defined as the blood supply from a main, secondary or distributing artery to a specific tissue area. (3, 4)

Each angiosome includes skin, muscle, tendon, nerve and/or bone. Angiosome junction occurs in the deep muscles, providing anastomotic channels if the main artery and/or vein is blocked. (4)

The angiosome model for lower limb revascularization was incorporated since the first publication of Alexandrescu in 2008. (3, 5) This model accounts for blood supply to the skin and adjacent structures, allowing mapping of the three-dimensional vascular territories to plan incisions and flaps, and providing the basis for the interpretation of several physiological and pathological processes including delayed healing or flap necrosis. (4) It is used in various medical fields, including myocardial revascularization, selective visceral embolization, and flap, incision or amputation planning. Over the past decade, a small number of studies have analyzed the viability of angiosome-oriented revascularization strategy in critically ischemic legs with tissue lesions, showing higher benefits in treating wounds and in recovering ischemic limbs. (3, 6-8)

A second point is the possibility of verifying reperfusion of an ischemic territory/ulcer using 2D perfusion angiographic imaging. Specialized software is used not only to show but also to measure the contrast agent flowing in arteries or tissues. This technique shows the arrival rate or wash-out using a color scale. In this case, the perfusion image verified adequate angiographic and hemodynamic results, providing a direct source of perfusion to the lesion. The image is strictly correlated to the corresponding angiosome. The system consists of a Flat Panel Detector 20 (Philips Medical Systems, Netherlands) single-plane angiography in combination with a 3DRA workstation (Prototype, Philips Netherlands), responsible for per-

fusion reconstruction and density correlation versus time. We thus present our clinical experience on two-dimensional perfusion. This technology, based on measurement and comparison of contrast density versus time, allows the assessment of color differentiation at various arterial, parenchymal, and venous times in the same angiographic acquisition. Color differentiation is achieved with reconstruction algorithms by image pixel, parametrically assigning and codifying the angiography grayscale to a color scale for each pixel obtained. In this way, the software obtains qualitative data, by means of color differentiation of arterial vessels, as well as quantitative data. These data provide information about each area of interest targeted by the operator, allowing a comparison between pre- and post-treatment data. Time to peak (TTP), arrival time (AT), mean transit time (MTT) and wash-out (WO) are the most common times used, as each of them represents arterial time (AT + TTP), parenchymal time (TTP + MTT), and venous time (MTT + WO). Parametric color coding allows visual evaluation and quantification of blood circulation functionality under normal or pathological conditions; for example, MTT visualization of the contrast passage through the arterial circulation can recognize hypoperfused areas of circulation. These calculated rates can be combined with 3D reconstruction (volumetric) data, creating a dataset from which blood flow and volume of the perfused area are estimated.

The information is used as an angiographic perfusion study and may be an interesting tool to assess and differentiate complex blood restrictions in arteries or particular areas.

The case presented here corresponds to a patient with critical limb ischemia, with an ulcer in the anterior middle third of the left leg, with pain at rest and


**Fig. 1. A.** Wound on anterior left leg. **B.** Angiography showing occlusion of the anterior tibial artery. **C.** Perfusion image without perfusion even in collaterals of the anterior compartment of the leg.

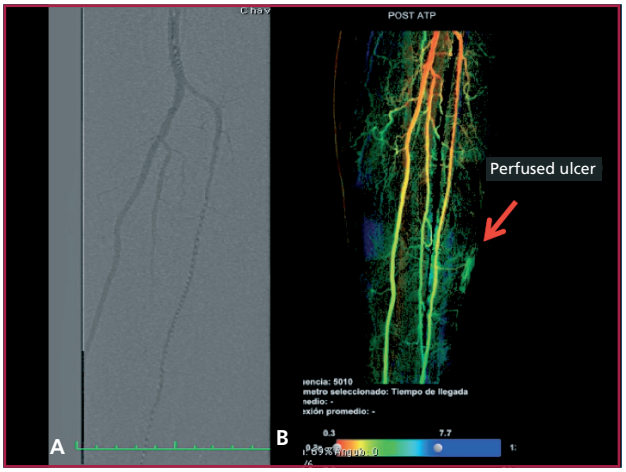


**Fig. 2.** Post-angioplasty result with complete recanalization of anterior tibial artery (**A**) and perfusion (**B**) of the anterior compartment (*arrow*). Marked perfusion territory in collateral of the anterior tibial artery with hyperperfusion of the lesion.

ankle-brachial index of 0.3. This is a diabetic patient with a 3-month history of trophic lesion of torpid evolution who underwent a selective 2D perfusion angiography of the limb.

Angiography showed complete occlusion of the anterior tibial artery at 5 cm from its origin, with recanalization into a distal tibial artery 3 cm above the frondiform ligament. A perfusion image revealed absence of direct or collateral circulation in the ulcerated area (Figure 1).

A tibial angioplasty with an Amphirion Deep 2/2.5 mm x 210 mm long tapered balloon (Medtronic-Invatec, Roncadelle, Italy) was performed, with correct angiographic outcome. The image also revealed not only the adequate patency of the tibial artery (TTP and TPM) but also the appearance of a collateral branch and a flush area matching the pretibial ulcer (Figure 2).

The patient was discharged the following day with an ankle-brachial index at rest of 0.86 and local wound treatment.

The success of the angiosome model to plan revascularizations intending to restore arterial flow suggests not only rechanneling arteries, but also consider those that directly supply the wound area, since the main flow to a certain area can be restored from arteries that do not belong to the original angiosome. However, in patients with chronic vascular inflammation and long-term diabetes, the compensatory capillary network is altered, indicating the need for a more specific, distal revascularization; thus, the probability of restoring an adequate blood supply to the affected territory will be greater. (3) The best healing outcomes for ischemic ulcers or limb salvage will depend on:

1. Direct angiosome revascularization;
2. Adequate wound treatment; and

3. Optimal clinical care, key to prognosis of patients with critical ischemia.

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## Uterine Leiomyomatosis Extending into the Cardiac Chambers: Two Different Cases

Intravenous leiomyomatosis is a rare condition typically occurring in the fifth or sixth decade of life in women with a benign uterine fibroid tumor, with invasion of the venous system. (1) Cases of intracardiac extension account for 10%. (2) Surgical treatment is recommended due to risk of embolism from right cardiac chambers, and tricuspid valve obstruction associated with sudden death. (3) Only a few cases have been reported in the literature, and most of them include signs of heart failure in the clinical presentation. (1)

### CASE REPORT 1

A 59-year-old patient without cardiovascular risk factors presented with edemas and ochre discoloration in the lower limbs (LL).

The echo-Doppler of the LL and abdominal ultrasound detected a uterine tumor and thrombosis in the inferior vena cava (IVC). Initially, gynecological surgery was not performed, and the patient was started on anticoagulation therapy with acenocoumarol. The patient progressed with edemas, abdominal distension, and progressive dyspnea, and a new abdominal ultrasound (US) revealed uterine tumor growth and IVC thrombosis. Our department of gynecology evaluated her and recommended surgical removal of the tumor. A total adnexo hysterectomy was performed, removing a 3-kg tumor. Pathological examination revealed uterine leiomyomatosis. The patient progressed with dyspnea and LL edema and transesophageal echocardiography confirmed a tumor in the right atrium, obstructing the right ventricular inflow tract. Thoracic and abdominal MRI angiography confirmed tumor expansion into the IVC and right cardiac chambers (Figure 1) and abdomen, and cardiac surgery was decided. Excision of the IVC and right atrial tumor was performed with a midsternal and abdominal right retroperitoneal approach (Figure 2). During the procedure, extracorporeal circulation time was 105 minutes, total circulatory arrest was 15 minutes, and hypothermia was 23 ºC. The patient is currently asymptomatic.

### CASE REPORT 2

This case corresponds to an asymptomatic 51-year-old patient who, in a routine cardiovascular examination, was diagnosed a tumor involving the lower retroperitoneal space with IVC and right cardiac chamber invasion. Initially, a midsternal approach was the option to remove the tumor and perform etiological diagnosis. Surgery was performed under extracorporeal circulation, hypothermia (20 °C) and circulatory arrest. The result of the excision was a hard tumor, which was affecting the right chamber lumen from the IVC, but without any evidence of myocardial infiltration. Postoperative course was satisfactory, and the patient was scheduled for a second stage IVC and retroperitoneal exploration. Pathological examination confirmed the diagnosis of leiomyoma.

The patient was away for 18 months since the first procedure, and returned totally asymptomatic for outpatient consultation. A new CT scan with contrast showed the same retroperitoneal images, with extensive intravenous invasion into the right iliac vein, IVC, and again complete filling of the right atrium, right ventricle, and pulmonary artery. Knowing the anatomopathological report, complete leiomyoma and intravenous proliferation resection was proposed in a one-stage operation.

Gynecological, peripheral vascular and cardiovascular teams were involved in the procedure. A total adnexo hysterectomy and resection of multiple uterine myomas extending into the perirectal area and iliac vessels (Figure 3) were performed. One of the myoma branches penetrated the distal part of the right iliac vein, and from there, blocked almost all the vena cava lumen towards the right cardiac chambers and pulmonary artery. The next step consisted of resternotomy, cannulation of the ascending aorta, superior vena cava and left femoral vein (not involved), and resection of intracardiac leiomyoma via right atriotomy using ex-

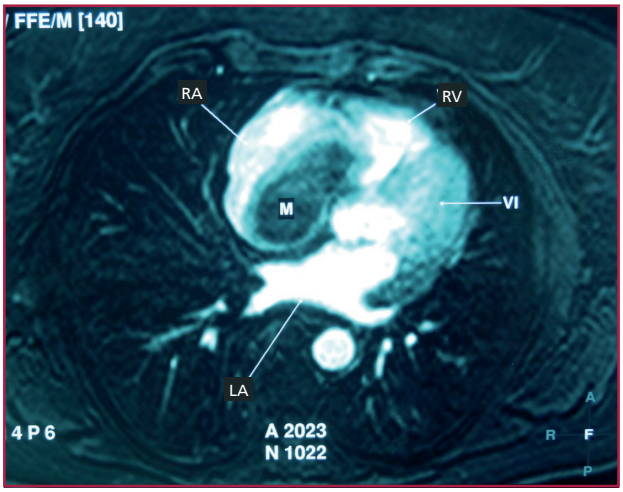


**Fig. 1.** MR angiography image. RA: Right atrium. RV: Right ventricle. LV: Left ventricle. LA: Left atrium. M: Myoma occupying the right atrium.

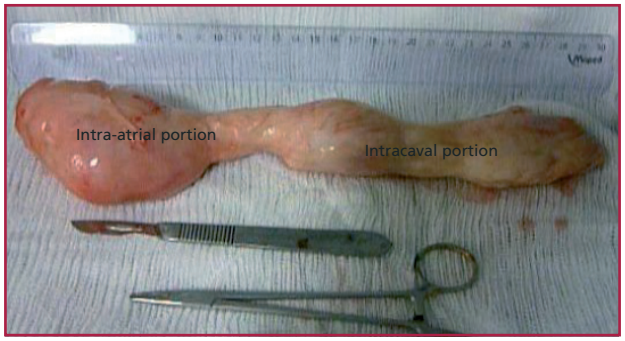


**Fig. 2.** Uterine fibroid 30 cm long, with intra-atrial portion of 10 cm and intracaval portion of 20 cm.

tracorporeal circulation without aortic clamping (Figure 4). Finally, IVC was explored and leiomyoma was totally resected from its proliferation site in the right iliac vein to the diaphragm. Thus, the leiomyoma was totally resected in a one-stage operation. Postoperative course was favorable and without complications. The patient was discharged 7 days after surgery.

Intravenous leiomyomatosis is a rare condition typically occurring in 50-60 year-old women with a benign uterine fibroid tumor, invading the venous system; cases of intracardiac extension account for approximately 10%. (1, 2) Surgical treatment is generally recommended due to the risk of embolism from right cardiac chambers or tricuspid valve obstruction. (1)

To date, few patients have been described, and fewer than 100 cases have been reported in the world. Most of them present symptoms of heart failure, as opposed to one of our patients, who was completely asymptomatic and without lower limb edemas. (1, 3)

Some elements from the medical record would help differentiate between a metastatic tumor and vena cava thrombosis: previous kidney surgery, bone fractures, previous pulmonary embolism, or deep vein thrombosis. (4) There are reports of intravenous myomatosis occurring several years after hysterectomy. (1) When patients exhibit diffuse symptoms, one of the diagnostic examinations to perform before hysterectomy due to uterine leiomyoma is abdominal Doppler US to detect extension into the inferior vena cava. (5)

According to the cases reported to date, sternotomy and adnexo hysterectomy for total resection of the pelvic tumor with intravenous invasion is the

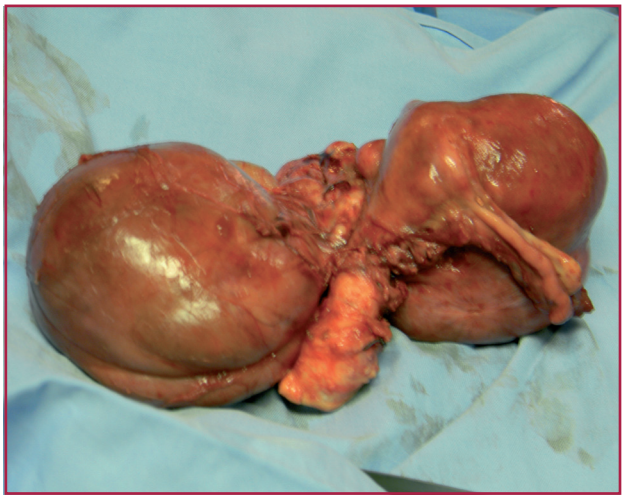

**Fig. 1.** Uterine tumor extending into the iliac vein and perirectal fat.

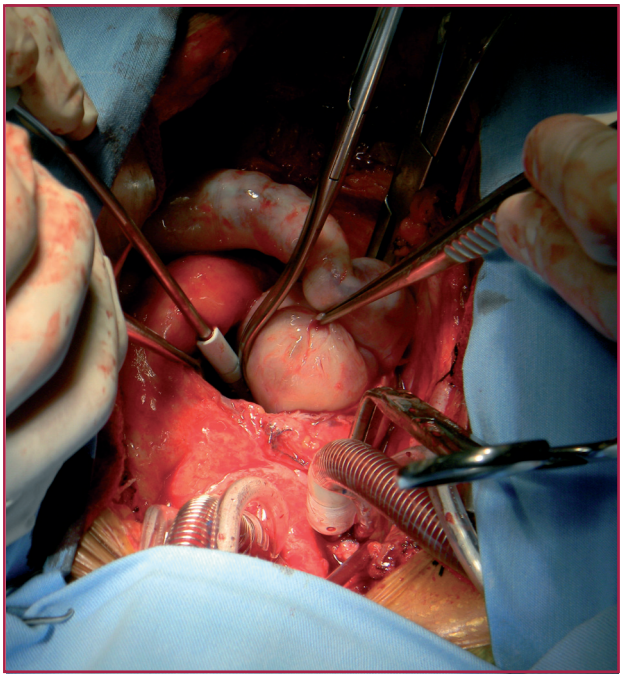

**Fig. 1.** Intraoperative image showing right atriotomy and intracardiac tumor resection.

treatment of choice. (6) Our second case demonstrated the recurrence of leiomyomatosis with continuous extension into the pulmonary artery after a little more than a year of incomplete treatment involving resection of the intracardiac portion only. While this is a histologically benign tumor, its growth is fast. Fortunately, our patients recovered without complications, and tumor resection was complete in both cases. To date, they are both in good clinical condition.

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## Usefulness of Angio-Seal™ as Mechanical Suture in Patients Undergoing Femoral Coronary Angioplasty

The diagnosis and endovascular treatment of atherosclerotic coronary disease is growing day by day, because it is a minimally invasive method requiring short hospital stay, which significantly reduces costs compared with myocardial revascularization surgery.

This technique is not free from complications. The most common one is the site of puncture, varying from 1% to 5% depending on the working groups, and reaching up to 15% in patients under multiple antiplatelet therapies, such as the combination of aspirin (AAS), clopidogrel, prasugrel, ticagrelor, bivalirudin, and IIb/IIIa inhibitors.

After performing femoral catheterization, different methods can be used to achieve hemostasis at the puncture site. The cheapest and most commonly used method is manual compression, and mechanical methods include Angio-Seal™, Femostop™, and Perclose™.

In our catheterization laboratory, we perform a wide range of endovascular diagnostic and therapeutic femoral procedures in coronary and extra-coronary territories, and the 6 or 8 French (Fr) Angio-Seal™ device is used in patients who are treated with two or more antiplatelet drugs.

The Angio-Seal™ device is a type of mechanical closure consisting of an anchor (2 mm wide x 10 mm long), a bovine collagen plug weighing about 18 mg, and a suture that connects the anchor to the outside. It is available in two sizes: 6 and 8 Fr. Figure 1 shows how the Angio-Seal™ device occludes the puncture site.

The purpose of our study was to assess the vascular complications following coronary angioplasty using Angio-Seal™ as mechanical closure in patients treated with two or more antiplatelet drugs and anticoagulation.

Vascular complications include hematoma at the puncture site (a palpable mass > 6 cm in diameter), pulsatile active bleeding in the area, pseudoaneurysm, absence of pulse and/or limb ischemia, and infection at the puncture site.

An echo-Doppler to confirm pseudoaneurysm and a soft-tissue ultrasound to document the size of the hematoma were performed.

The study was carried out at the cardiac catheterization laboratory of the Medical Campus of the Argentine Federal Police. It was an observational, retrospective study including 1,854 patients with urgent or elective coronary angioplasty, between January 2001 and January 2014.

All patients signed the informed consent form, were over 18 years of age, and only underwent coronary angioplasty.

All patients received ASA, beta blockers, and clopidogrel. Clopidogrel had two therapeutic schedules: one with a loading dose of 300 or 600 mg for urgent angioplasty, or 75 mg/day a week before the procedure for patients with elective angioplasty. After that, the scheme was 75 mg/day during hospitalization, with duration at the discretion of the treating physician.

Use of abciximab, tirofiban, eptifibatide or bivalirudin, as well as low-molecular-weight heparin, depended on the medical condition required for the intervention and the risk categorization of the intervention according to the history and comorbidities of each patient, as described in the literature. In 1,800 patients 6 Fr introducers were used, and in the remaining 54 patients 7 and 8 Fr introducers.

Once the procedure was over and the Angio-Seal™ was aseptically implanted in the catheterization laboratory, a superficial bandage was applied and the patient was transferred to the Coronary Intensive Care Unit.

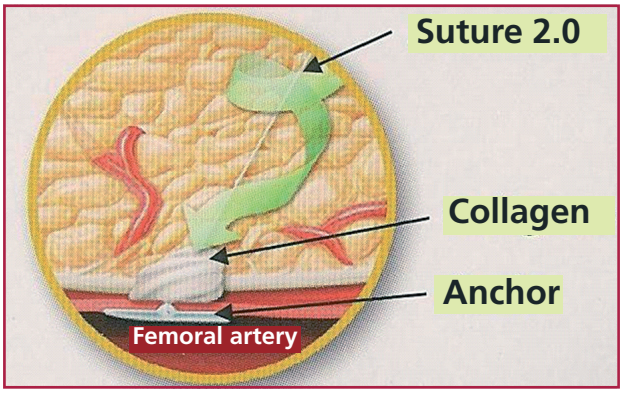


**Fig. 1.** Figure showing how the Angio-Seal™ device occludes the puncture site with the anchor and collagen plug.

Implantation of the device involved three physicians.

Patients remained in this unit 24-48 hours following the procedure for the possible vascular complications described above, and then they were transferred to the general ward, where they began ambulation at their discretion until hospital discharge.

All patients received ASA, and 93% received clopidogrel and one of the following drugs: 38% were treated with IIb/IIIa inhibitors (out of which 57.93% received abciximab, 33.56% tirofiban, and 8.51% eptifibatide), 19% bivalirudin, and 43% sodium heparin (70 IU/kg).

Regarding the complications described above, correct hemostasis using the device was not achieved in 3 patients, so manual compression during 15 minutes was successfully performed, and a compressive bandage was applied for 8 hours following the procedure. Infection at the puncture site was observed in one patient, which was successfully treated with antibiotics. In another patient, the bioabsorbable anchor was improperly positioned and the patient presented with limb ischemia 3 hours after the procedure. Doppler examination revealed that the anchor had migrated to the anterior tibial artery, and surgery at the Department of Vascular Surgery was performed to remove the anchor without complications. Table 1 shows the percentages of such data.

Reassessment of 17 patients was necessary within the first 48 hours following the procedure, and access was decided 2 cm above the first puncture, without any complications.

It was necessary to use 7 and 8 Fr introducers, and to implant a 6 Fr Angio-Seal™ in 54 patients; hemostasis was achieved with no complications during the procedure or hospital stay.

Several studies have assessed vascular complications in patients undergoing endovascular repair in which different methods of endovascular closure were used. For example, Oweida et al (1) in the 1980s, observed in a population of 4,868 patients, 1% vascular complications and Popma et al (2) reported 5.9% in 1,418 patients. More recently, in the 1990s, Walman et al (3) evidenced 6.1% vascular complications in 5,042 procedures.

A meta-analysis including 12,000 patients assessed manual compression versus mechanical methods, and found a significant reduction in the rate of complications with the use of closure devices (2.4% vs. 4.9% ($p < 0.001$). (4)

Our study included 1,854 patients who underwent angioplasty and received at least two or more antiplatelet drugs and anticoagulation; it is therefore a representative sample of the safety of Angio-Seal™ as a mechanical closure approach. Its limitations include absence of a control group, the fact that it is a retrospective study carried out in a single center –although three operators were involved in the implantation of the device–, and that a single method of mechanical closure was used.

We can conclude that Angio-Seal™ is a safe and effective method of mechanical closure in urgent or elective angioplasty procedures, in patients aggressively treated with anticoagulants and antiplatelet drugs. In our experience, we could prove that the rate of complications was very low.

**Table 1.** Complications

| Complication | n Total = 1,854 % (n) |
|---|---|
| Inability to achieve hemostasis | 0.16 (3) |
| Infection at the puncture site | 0.05 (1) |
| Bioabsorbable suture anchor migration | 0.05 (1) |

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## Applicability of the New American Heart Association Guidelines for Cardiovascular Risk Assessment, and its Implication on Statin Administration in an Argentine Population

Cardiovascular diseases (CVD) are the leading cause of early disability and death worldwide. According to the World Health Organization (WHO), a total of 17 million deaths occurred in the world during 2011 due to cardiovascular diseases. (1) In Argentina, 52% of deaths are due to cancer or cardiovascular diseases. (2) The magnitude of these figures reflects the impact of CVD on the population. Therefore, the epidemiological surveillance strategies proposed by national and international health organizations are focused on identifying cardiovascular risk factors (CRF). To assess the extent of the interaction among the various CRF, scientific societies have used the Global Cardiovascular Risk (GCR), a mathematical method that estimates the likelihood of a cardiovascular event in a given period of time. In the Cardiovascular Risk Guideline (CRG), the National Ministry of Health has proposed the use of the WHO score for Region B of the Americas (AMRB). (3) In turn, two important American organizations –the American College of Cardiology and the American Heart Association (ACC/AHA)– have published in November 2013 the latest guideline with a new score on CRF management,. This guideline recommends establishing whether the patient belongs to any of the four high-risk groups before initiation of statin therapy. (4)

Shortly after its release, this guideline has been widely criticized by different associations and cardiovascular health care professionals, and some studies argue that it overestimates CRF and increasingly recommends statin therapy in the population. (5, 6)

In this context, the purpose was to assess CRF in a population-based cohort of Argentina using the WHO charts (AMRB) and the new ACC/AHA chart, analyzing the potential implications of the new recommendations in the indication of statin therapy in the local setting.

An observational, retrospective study was designed for that purpose, initially consisting of 870 men and women, aged between 17 and 65 years, who underwent the required tests to obtain the Work Health Card from the Department of Preventive Medicine at the Hospital Municipal Dr. Leónidas Lucero, in the city of Bahía Blanca, province of Buenos Aires, Argentina, between 2009 and 2011. Subjects whose required data for the study were not recorded and those aged < 40 years were excluded, the final sample consisting of 183 individuals.

Age, sex, and smoking habits were the data recorded from all subjects. Weight and height were measured, body mass index (BMI) was calculated, and blood pressure (BP) was monitored. Biochemical parameters measured were glucose, triglycerides, total cholesterol (TC), high-density (HDL-C) and low-density (LDL-C) lipoprotein cholesterol.

**Table 1**. Risk according to different scores

| Risk | WHO n (%) | ACC/AHA n (%) |
|---|---|---|
| Low | 158 (86.3) | 135 (73.8) |
| Moderate or high | 25 (13.7) | 48 (26.3) |

WHO: World Health Organization ACC/AHA ACC/AHA: American College of Cardiology/American Heart Association

**Table 2**. Classification of cardiovascular risk categories: moderate, high and low, according to WHO and ACC/AHA functions

| | ACC/AHA Score < 7.5 % n (%) | ACC/AHA Score≥ < 7.5 % n (%) |
|---|---|---|
| WHO Score < 10% | 128 (69.9%) | 30 (16.4%) |
| WHO Score > 10% | 7 (3.8%) | 18 (6.0%) |

WHO: World Health Organization
ACC/AHA: American College of Cardiology/American Heart Association

The scores chosen to calculate cardiovascular risk were the WHO score (AMRB) and the ACC/AHA score.

The variables included in each scale are the following:

- WHO score (AMRB): age, sex, TC, systolic blood pressure (SBP), (presence or absence of) diabetes, and smoking. (3)
- ACC/AHA score: age, sex, race, TC, HDL-C, (pres ence or absence of) diabetes, (treated or untreated) SBP, and smoking. (4)

Individuals with a CVR ≥ 10% for the WHO score, (3) and ≥ 7.5% for ACC/AHA score were classified as mild or high risk patients. (4)

Regarding medication, patients > 40 years with CVR between 20% and 30% and TC of 190 mg/dL, and those with CVR > 30% irrespective of TC value were candidates for statins according to the WHO recommendation; (3) and patients with CVR ≥ 7.5%, those with LDL-C ≥ 190 mg/dL, diabetic patients with LDL-C between 70 and 189 mg/dL, and those with established atherosclerotic CVD were candidates for statins according to the ACC/AHA guideline. (4)

The characteristics of the subjects studied and CVR levels were described using measures of central tendency and dispersion for quantitative variables and percentages for categorical variables. Mean values were compared with Student's t test for quantitative variables and the chi-square test for qualitative variables. The alpha level of statistical significance $p < 0.05$ was used in all cases.

Data were analyzed using the Statistical Package for the Social Sciences for Windows version 17.0 software.

Of the total study population (62% men and 38% women), mean age was 51 ± 8 years, and mean value of laboratory and anthropometric parameters were: glucose (mg/dL) 101 ± 29, BMI (kg/m2) 29 ± 6, TC (mg/dL) 204 ± 36, HDL-C (mg/dL) 52 ± 15, and SBP (mm Hg) 125 ± 19. Thirty percent of the population smoked.

Table 1 shows that ACC/AHA included a greater number of subjects within the high-risk group (p=0.000). The greatest number of subjects belonged to the low-risk group in both tables.

Table 2 shows that both scores categorized 69.9% of the study population within the low-risk group. Conversely, the number of subjects in the high-risk group according to ACC/AHA and with low risk for WHO was significantly greater (p = 0.000) than the subjects in the high-risk group according to WHO with low risk for ACC/AHA.

Regarding statin therapy, 15 individuals (8.2% of the study population) would be treated according to the WHO guideline, whereas 50 subjects would receive statins following ACC/AHA recommendation (27.3% of the study population) (p=0.000).

Mean age was significantly higher in the ACC/AHA group than in the WHO group (p=0.035). The age group with increased indications for statins was between 50 and 60 years for both scores.

Based on these results, we can conclude that the ACC/AHA score categorizes a greater number of subjects with moderate-high risk than the WHO score. Furthermore, the ACC/AHA score significantly increases the recommendation for statin therapy in the study population when compared with a table validated for local application as is the case of the WHO chart.

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