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.

Guillermo Vaccarino [MTSAC], **Christian Gil, Pablo Desmeri, Diego Herrera Vega, Néstor Bustamante, Marcelo Guzmán**
Hospital Universitario Austral - Department of Cardiovascular Surgery. Pilar, Pcia. de Buenos Aires, Argentina

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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.

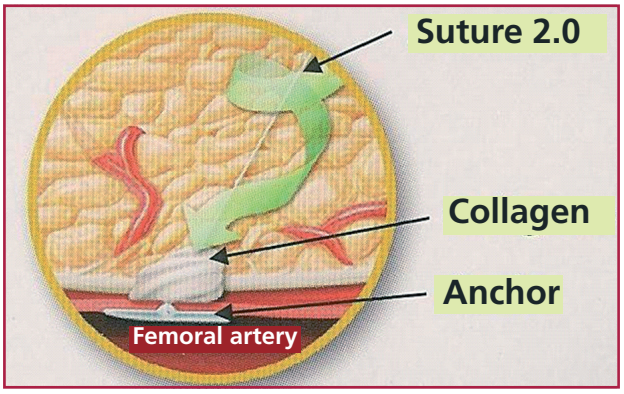

Fig. 1. Figure showing how the Angio-Seal™ device occludes the puncture site with the anchor and collagen plug.

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)

Sergio D. Zolorsa,
Sebastián A. Rizzone[1],
Daniel L. Di Nanno[1],
Álvaro E. P. Bordenave
[1] Cardiac Catheterization Laboratory at the Medical Campus of the Argentine Federal Police "Churruca-Visca"
e-mail: sebastianrizzone@yahoo.com.ar

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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.