HISPANIC-LATIN AMERICAN CONSENSUS

2009 CONSENSUS ON THE ENDOVASCULAR TREATMENT OF ABDOMINAL AORTIC ANEURYSM

CARTAGENA CONSENSUS

INTRODUCTION

Aortic pathologies are possibly the most complex disease faced in Vascular Surgery. In turn, aortic dilation is a condition that requires ceaseless research and development efforts to try to avoid thousands of annual deaths associated with its complications. The endovascular treatment (EVT) of abdominal aortic aneurysm (AAA) has evolved in a few years, significantly reducing morbidity and mortality rates, when compared to open surgery (OS).

On suggestion of the Colegio Argentino de Cirujanos Cardiovasculares y Endovasculares (CACCVE – Argentine College of Cardiovascular and Endovascular Surgeons), we appointed a Writing Committee to draft a document entitled "2009 Consensus on the Endovascular Treatment of Abdominal Aortic Aneurysm" to be used as a reference in the election of the best therapy for this condition. Once it was drafted, it was reviewed by the Argentine Peer-Review Committee, and then submitted to the approval of the Executive Committee (EC) of the CACCVE and of the Sociedad Argentina de Angiología (Argentine Angiology Society).

Given that several of the members of the CACCVE were certain that the situation is quite similar in Hispanic-Latin American countries, the EC gave the Writing Committee the assignment to contact the main Endovascular Surgeons in Spain and Latin America so that the "2009 Consensus on the Endovascular Treatment of Abdominal Aortic Aneurysm" was improved by an Hispanic-Latin American Peer-Review Committee.

After being transformed and enriched with the contributions of all participants, the document was submitted to the President of CELA (Cirujanos Cardiovasculares de Latino América - Cardiovascular Surgeons of Latin America), Dr. Marcelo Cerezo, to be presented at the next Conference in Cartagena, and to be approved as "2009 Hispanic-Latin American Consensus on the Endovascular Treatment of Abdominal Aortic Aneurysm" and to be published in all our countries, in Spanish, Portuguese and English, with the purpose of sharing our views within the scientific community.

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DEFINITION

The term aneurysm comes from the Greek term aneurysma that means "broadening". Hence, according to current description criteria, an aneurysm is defined as the localized and permanent dilation of an artery, whose diameter exceeds the usual diameter of the artery by 50% (1). Because the diameter of arteries varies with age, gender, body structure and other factors, in the case of the abdominal aorta there is a generalized consensus to define that there is aneurysm when the artery's diameter is above 30 mm.

The first description of Abdominal Aortic Aneurysm (AAA) was made by Vesalius in the 16th century (2). Since that century, the efforts to treat the condition were permanent until 1888, when Rudolph Matas (3) described the technique of the obliterative endaneurysmorrhaphy, which was the true start of the development of the treatment of this condition. Another significant develo-

pment occurred in 1951 when, in Paris, Charles Dubost successfully removed an AAA for the first time, and made the aortic reconstruction with homologous graft. In 1990, in Buenos Aires, Juan Carlos Parodi was the first to treat an AAA with an aortic stent, thus transforming cardiovascular surgery (4).

AAAs account for 70% of all true aortic aneurysms, occur below renal arteries, and are greatly prone to rupture in direct relationship to their size and shape. This turns them into a serious public health concern. Most of them affect the infrarenal aorta, only 5% involve the suprarenal aorta and 25% of cases involve the iliac arteries (5). Hereditary factors and genetics are involved in the origins of this condition, but it is specially linked to arteriosclerosis and to degenerative diseases of the aorta. Five percent of AAAs occur in men and 1% in women of +65 years of age; the risk increases to 10% among patients with peripheral vascular disease, to 25% if there is another aneurysm in the body and to 53% if there is associated popliteal aneurysm (6-9).

INDICATION FOR TREATMENT

The danger of this condition resides in its complications specially rupture which is fatal in 80-90% of all cases. Of these cases, 50% of patients die on their way to hospital, 25% of them die at the hospital before surgery, and 42% of surviving patients die during surgery (6). Rupture is linked to the diameter of the AAA —the greater the diameter, the higher the rupture rate.

Repair with elective open surgery (OS) is recommended by the 1998 UK Small Aneurysm Trial (7) when the aneurysm is over 5.5 cm in diameter, which is confirmed by the ADAM Trial (8). In turn, in the UK Trial, 60% of patients followed-up with Color Duplex Ultrasound for an average of 4.6 years had undergone surgery due to complications or growth of the AAA, while out of the 120 patients who entered the second phase of the study alive, it was reported that in 2002 (9), 50% had been operated on similar causes. The final report, published in 2007, established that after an average follow-up of 12 years, 65.5% of the 1,090 patients had died, 85.2% had undergone surgery and only 1% of them had survived without surgery. During follow-up, 75% of the control group population had required surgery (10).

In turn, in the ADAM Trial, with an average follow-up period of 4.6 years, 61% of the patients randomized to receive follow-up underwent surgery due to increased AAA diameter or complications. Among patients whose aneurysms reached 4 to 4.4 cm in diameter, 27% were operated; 53% were operated with aneurysms 4.5 to 4.9 cm in diameter, and 81% with aneurysms 5 to 5.5 cm in diameter.

It should be noted that the ADAM Trial has no significant female population, unlike the UK Trial, which included this population. Mortality due to rupture is 5% among men and 14% among women. Based on this, the study concluded that the aortic diameter from which the female population should be operated cannot be determined (9). For this reason, the guidelines for the treatment of AAAs issued by the American Association for Vascular Surgery and the Society for Vascular Surgery recommend treating female AAAs of between 4.5 and 5 cm in diameter (11).

We have reviewed all the studies that use diameter as criterion to recommend OS instead of EVT. Another multi-center 5-year retrospective study (12) concluded that patients whose aneurysms have smaller diameters (< 5cm) are better candidates for EVT, with a 5-year survival without AAA-related death of 99%; of 97% in aneurysms 5 to 6 cm in diameter, while patients whose aneurysms are >6 cm in diameter have a shorter long-term survival and a higher rate of AAA-related complications.

In our countries, due to the lack of patient awareness and/or the continuous transfer of patients who —due to non-medical reasons are transferred from one health care center to the other— follow-up is more difficult.

Based on the foregoing, this consensus recommends the treatment of male aneurysms greater than 5 cm in diameter and female aneurysms greater than 4.5 cm in diameter —as well as those presenting with signs and symptoms (pain and embolization) or a growth of 0.5 cm or more within 6 months.

INDICATIONS FOR EVT

Conventional elective surgery of the abdominal aorta per se is considered "high risk surgery" (13-14), on the ground that it is associated with a mortality risk of 4-5% (15), which risk increases to 8% in community centers (16-18). These findings are significantly increased by advanced age (> 70 years) and by the concomitant conditions that we specify below:

- Heart disease: (13,14)
  - High risk predictors:
    - Acute or recent myocardial infarction with evidence of ischemic risk as determined by symptoms and/or non-invasive tests.
    - Unstable angina (FC III or IV)
    - Unstable heart failure.
    - Significant arrhythmias:
      - High-degree AV block.
      - Symptomatic ventricular arrhythmias.
      - Supraventricular arrhythmias with uncontrolled ventricular rhythm.
    - Severe vascular disease.
  - Mid risk predictors:
    - Moderate angina (FC I or II)
    - Prior pathological Q-wave myocardial infarction.
    - History of heart failure.
- Chronic obstructive pulmonary disease (COPD with FEV1 < 35% of reference value, PaO2 < 60 mm Hg or PaCO2 > 45 mm Hg).
- Chronic renal failure: creatinine above 2 mg% or in dialysis.
- Horseshoe kidney.
- Liver failure.
- Coagulation disorders.
- Organ transplant.
- Hostile abdomen: patients with prior abdominal surgeries, eventrations, colostomies, ileostomies, etc., and/or irradiated abdomen.
- Neoplastic patients with mean life expectancy under 2 years.

Hospital mortality associated with EVT is lower than that associated with OS. In 2004, out of a total of 7,172 patients registered on an American administrative database compiled in 2001, Lee et al. (19) found a mortality rate of 1.3% with EVT and of 3.8% with OS [p<0.001]. Likewise, in randomized and controlled studies, such as EVAR-1, these figures were respectively 1.7% (EVT) vs. 4.8% (OS) [p=0.007] (20) and in the DREAM study, 1.2% (EVT) vs. 4.6% (OS) [p=0.1] (21).

In the EUROSTAR Registry, among 4,888 patients treated with endovascular treatment, mortality reached 2.6% (22). Medicare data show that among 45,660 patients, mortality was lower with EVT — 1.2 % vs. 4.8% with OS (23).

RECOMMENDATIONS FOR EVT OF AAAs

We have adopted the GRADE System (Grades of Recommendation, Assessment, Development and Evaluation Working Group) (24), on the ground that it is the conjunction of an evidence system based on references and on the recommendations of the physicians that are part of the consensus. The quality assigned to evidence determines the reliability to estimate whether an effect is correct or not. The recommendation determines that the adherence to the effect may be beneficial or prejudicial. This distinction between quality of the evidence and recommendation enables those using the consensus (physicians, patients and public health authorities) to evaluate not only the evidence but also patients' judgments and preferences, which the expert committee took into consideration when making the consensus.

For that reason, although the evidence may be of low quality, experts may make a strong recommendation based on their judgments and preferences, so that even when evaluating low quality evidence, they trust in that the advantages of the procedure will compensate undesirable outcomes, or conversely. For example, in atrial fibrillation anticoagulation treatment is recommended even though it is proved that hemorrhagic effects are certain complications; it is considered that the treatment outweighs the circumstances of the complications (24, 25). In this recommendation system, strong recommendations are classified as GRADE 1 and weak recommendations are classified as GRADE 2.

Based on its quality, evidence is classified as "high quality" (long and well-conducted studies, as well as randomized trials), "moderate quality" (less rigorous studies, little consistently randomized trials or observational studies), and of "very low quality" (observational studies, case series or systematic clinical observations).

AAAs IN HIGH-RISK PATIENTS

Strong recommendation and moderate quality evidence

Strong recommendation and moderate quality evidence

In this high-risk group, there is evidence and/or general consensus that the procedure is useful and effective in patients at high risk for OS, since, in the short term, it reduces morbidity and mortality and has the same survival rate as the group of untreated patients between 12 and 24 months. In order to increase survival, the treatment of concomitant diseases must be strengthened.

These are patients with AAAs more than 5 cm in diameter (men) or 4.5 cm in diameter (women) or with rapid growth ? 0.5 cm in 6 months, or symptomatic and/or inflammatory cases, whose anatomy is favorable for stent graft and at high surgical risk. The benefits of EVT in these patients were already described by the American College of Cardiology and the American Heart Association in their 2005 guidelines for the management of peripheral arterial diseases, where it is classified as Class IIa recommendation (the weight of evidence and opinion favors its use or efficacy) (26). The 2001 recommendations of the Ministry of Health of the Republic of Argentina also classify it in the same way (27).

According to the risks previously defined, almost 25% of the patients would have high risk for OS (20-28). In EVAR-2 (29), a randomized study comparing the outcomes of EVT and the medical treatment of patients at high risk for OS, no differences between both groups were found. Greenhalgh, the main author of the EVAR studies, stated that EVT may benefit patients at high surgical risk with a longer survival, if their co-morbidities are improved (30).

Thus, in a retrospective study conducted at 5 American sites (28), with a two and a half-year follow-up of patients treated with EVT and OS, it was concluded that there are benefits in terms of 30-day mortality (2.9% with EVT and 5.1% with OS), but that the 4-year survival was of 56% and 66%, respectively. In this study, the 30-day mortality rate was 2.9%, while in EVAR-2, mortality reached 9%. Likewise, mortality in the OS group is low among high-risk patients, and it is usually above 8% (16-18, 31).

In another recent study conducted among 45,660 Medicare patients. Schermerhorn et al. also found a decreased mortality with EVT when compared to OS (1.2% vs. 4.8%) [p<0.001], which a larger difference among elderly patients (2.1% among patients 67-69 years old vs. 8.5% for patients above 85 years old) [p<0.001]. Survival was also similar in both groups as of 3 years post-surgery (23).

AAAs IN LOW-RISK PATIENTS

Strong recommendation and high quality evidence

This group is formed by patients that may be treated with OS or with EVT. In these cases, physicians' preferences favor EVT, supported by the patients' option, based on their own information, the overt lower invasiveness and/or the popularity of the endovascular method. These are patients with AAAs more than 5 cm in diameter (men) or 4.5 cm in diameter (women) or with rapid growth ? 0.5 cm in 6 months or symptomatic patients, whose anatomy is favorable for stent graft and at normal or mild to moderately-increased surgical risk (15).

There are two multi-center, prospective and randomized studies comparing OS with EVT among patients at normal risk. They are EVAR-1 (20-32) and DREAM (21-33), with 4-year and 2-year outcomes, respectively.

In the EVAR-1 study, 30-day mortality decreased from 4.7% in OS to 1.7% in EVT [p<0.001]. At 4 years, aneurysm-related mortality was half of that found among patients that had undergone surgery, while overall mortality not related with the aneurysm was similar in the group treated with OS and with EVT (26% vs. 29%). Furthermore, re-interventions are more frequent in patients treated with EVT than in patients treated with OS (20% vs. 6%) (20).

While DREAM and EVAR-1 have a similar design, the former has a lower number of patients (351 cases). In both studies, 30-day mortality dropped in patients treated with EVT as compared to those treated with OS, although global survival at 2 years was similar (89.7% in the EVT group and 89.6% in the OS group). Deaths related with AAA were more frequent among patients treated with OS (5.7% vs. 2.1%), but there were more re-interventions in the group treated with EVT (21).

The evidence is based on the following facts:

- Lower perioperative morbidity and mortality, with a shorter hospital stay and quicker return to usual activities.
- The decreased aneurysm-related mortality observed with the endovascular treatment persists over time.
- The initial decreased mortality with EVT tends to be lost 12 to 24 months after the procedure.
- A greater number of re-interventions in patients treated with EVT, although most of them are minor and are generally endovascular, which is similar to re-hospitalizations and re-laparotomies in patients treated with OS.

- Many younger patients request the endovascular treatment because they do not wish to lose their sexual function.
- Among elderly patients, the differences in the morbidity and mortality rates with EVT and with OS are more clearly noted.

RUPTURED AAAs (rAAAs) OR COMPLICATED AAAs

Strong recommendation and moderate quality evidence

In this case, it is difficult or impossible to conduct randomized trials, on ethical grounds. For decades, the mortality associated with open surgery remained between 35% and 80% (34-38), while —according to the main series— the mortality rate of EVT is 5% to 38% (39, 40) with an overall drop of 38% as compared to OS (41).

A recent publication (42) of an American national registry with 28,123 admissions due to rAAAs showed a clear decrease in mortality in recent years. The use of EVAR increased significantly, from 6% of emergency repairs in 2001 to 11% in 2004 [p<.01]. Mortality decreased from 43% to 29% [p<.01] with EVT, but remained stable for OS (from 40% to 43%). A comparison of both groups in 2004 showed that EVT-associated mortality was lower (31% vs. 42%), that hospital stay was shorter (6 days vs. 9 days) and that home discharge was also higher (59% vs. 37%) with similar cost ($71,428 vs. $74,520 [p=.59] (42).

We believe that patients with rAAAs are at the highest risk of aneurysm-related death. Therefore, depending on the anatomy of the AAA, we recommend EVT as a first-line treatment for patients with ruptured or complicated AAAs.

Anatomic Indications for EVT in AAA:

- Proximal necks =< 32 mm in diameter, and at least 10 mm long.
- Aorta angulation at the proximal neck level less than 60 degrees.
- Iliac arteries diameters must have at least 7 mm to enable the entrance of devices.
- If there are iliac stenoses, physicians must consider dilation, stent implant, stent graft, intraluminal stent or the performance of a retroperitoneal prosthetic duct.
- Iliac aneurysm is not a contraindication for EVT.
- It is recommended to preserve at least one patent internal iliac artery to avoid intestinal ischemia.
- Likewise, it is recommended to take consideration of industry specifications for the use of each stent.

RESOURCES NECESSARY TO PERFORM EVT

The natural environment to perform EVT of AAAs is the operational room (OR), where complications may be handled or the procedure may be transformed into OS. The OR must be equipped with adequate radiology equipment. In some cases, the hemodynamics room may be used, if it is prepared as an OR, in sterile conditions, with OR equipment and the adequate training of the staff that will take part of the procedure. In other words, it must have the adequate characteristics to turn an endovascular intervention into an OS, if necessary (43).

I) Recursos materiales

A) Procedure Room:

- Size: at least 30 square meters of surface area, with a minimum height of 2.60 meters.
- Lead shielding as per the Public Health Radiophysics regulations of each country.
- Centralized gas facilities (oxygen, compressed air and aspiration)
- Ground connection of all the equipment.
- Lead-shielded aprons, thyroid protectors, lead-shielded goggles and x-ray exposure dosimeters for all the staff exposed to radiation.
- Surgical table apt for chest and abdomen surgical and radiological procedures, together with instrumental tables to place the endovascular material
- Contrast agent injection pump.
- Complete anesthesia machine and table, to perform spinal and/or total anesthetization.
- Multi-parameter monitoring equipment (ECG, oxymeter, capnograph, temperature and 2 channels to monitor invasive AT).
- Cardio-defibrillator.
- Thermal mattress.
- Equipment to monitor coagulation time (ACTest) activated.

B) Radiological Equipment:

- High-definition image enhancer.
- Two high-definition monitors.
- Real-time digital subtraction.
- Roadmapping.
- Digital filing system.

C) Material Conditioning Room:

- Minimum surface area: 6 square meters.
- It must have two separated sectors: 1) wet (dirty), and 2) dry (clean).
- Non-porous, easy-to-clean countertop.
- Compressed air.
- Furniture adequate to storage the materials.

D) Institutional Resources:

- Cardiovascular recovery room (CVR).
- Nephrologist support.
- Laboratory and Hemotherapy support.

E) Materials Used in EVT (44):

- Stents and extensions.
- 16 G arterial puncture needles.
- 5, 6, 7, 8, 10 and 12F introducers with hemostatic valves.
- Guidewires:
  - Two 0.035" Teflon guidewires, 180 and 260 cm long.
  - Two 0.035" hydrophilic guidewires, 180 and 260 cm long, angled tip.

- One 0.035" Benson or Magic Torque guidewire to navigate tortuous arteries, 180 cm long.
- One 0.035" super stiff Amplatz guidewire, 260 cm long.
- One 0.035" Lunderquist guidewire, 260 cm long.
- Torque device for 0.035" guidewires.

• Catheters:
- One pigtail centimeter-ruled catheter, 90 cm long.
- One straight catheter, 90 cm long.
- One multi-purpose catheter, 100 cm long.
- One right coronary catheter, 100 cm long.
- One Simmons catheter, 100 cm long.
- One Cobra catheter, 65 cm long.
- One breast catheter, 100 cm long.
- One vertebral catheter, 100 cm long.
- One lace catheter (Goose-Neck)
- One 8F multi-purpose guide catheter, 100 cm long with Y coupling.

• Balloon catheters:
- Two elastometric (low pressure) aortic balloons.
- One ultra-thin angioplasty balloon catheter, 8 x 4 x 120 cm
- One ultra-thin angioplasty balloon catheter, 10 x 4 x 120 cm
- One ultra-thin angioplasty balloon catheter, 12 x 4 x 120 cm

• Other materials:
- Surgical instruments box to perform conventional AAA open surgery.
- Dacron bifurcated vascular stents, 0 porosity, in different sizes.
- Straight vascular stents (PTFE/Dacron) in different sizes.
- Embolization coils and/or plugs in different diameters.
- Non-ionic contrast agent.
- Manometer injection syringes.
- Radiopaque ruler (centimeters).
- 18, 20, 22 and 24F Coons dilator set for iliac arteries.
- Extra-large expandable balloon stent.

I) Human Resources

The professionals performing this type of procedures must follow the recommendations for thoracic aneurysm EVT, since they are applicable to the EVT of AAAs. They must be educated and trained in the following fields (45).

A)Patient Selection:

To select patients, the professional must be familiar with current diagnostic techniques (Multislice Computed Tomography, 3D reconstructions thereof and Angio-MRI).

In some cases, conventional computed tomography (CT scan) with 3 to 5 mm-slices together with conventional angiography with centimeter-ruled pigtail may be used to plan the EVT of an AAA with low anatomic complexity.

Conventional angiography or Angio-MRI must always be made in cases of concomitant intermittent claudication that supports a suspected iliac-femoral-popliteal occlusive pathology.

B) Training Level:

An adequate training level is deemed to be reached after participating in at least 50 aortic endovascular procedures, or in 25 when acting as main surgeon. In order to perform these procedures, the intervening surgeon must be certified by the specialization authority of each country (e.g., Colegio Argentino de Cirujanos Cardiovasculares y Endovasculares in Argentina).

As with the implementation and development of any surgical technique, training is one of the main elements to delimit the so-called "learning curve". It is desirable that failed interventions and complications due to lack of experience be reduced to the minimum. For this reason, training at expert centers, including those dedicated to basic intervention procedures, together with the adequate selection of patients are key to obtain good outcomes. It is not acceptable to start endovascular experience with abdominal stents. This intervention may require a combination of endovascular skills that are not applicable if the intervening professional has not prior experience with them.

An issue that receives worldwide debate is the quantity of prior procedures necessary to be "accredited" as Endovascular Surgeon. Table 1 specifies the minimums required by the different Scientific Societies in the United States (46).

TABLE 1	Society of Cardiov and Intervent Radiology	Society for Cardiac Angiogr and Interventions	American College of Cardiology	American Heart Association	Society Vascular Surgery 1998
Angiographies	200	100 (50)	100	100	100 (50)
Surgeries	25	50 (25)	50 (25)	50 (25)	50 (25)

( ) specifies the number of surgeries required as main surgeon.

This Table may serve as a guideline to set the experience necessary to perform an abdominal stent graft, presuming that this technique may be deemed as a having mid- to high level of difficulty in endovascular surgery.

C) Training in Peripheral Intervention Procedures:

It is very important to be competent in the different endovascular techniques, in order to perform the procedure, diagnose and treat complications. The following should be considered:

- Catheter selection and selective catheterization techniques.
- Femoral and brachial (Seldinger) puncture techniques.
- Balloon angioplasty and stenting techniques especially in the renal and iliac areas.
- Use of recovery laces.
- Selective embolization techniques.
- Intra-arterial fibrinolysis.
- Competence in the use and protection required by radiological techniques.

D) Knowledge of Abdominal Aortic Disorders:

The surgeon must be familiar with the diagnosis and treatment of the most usual clinical complications (renal failure, contrast agent side-effects, myocardial ischemia, ateroembolism, etc.)

E) Ability to Solve Complications of Endovascular Treatment with Open Surgery:

It is crucial that the surgeon is capable of treating complications inherent in the procedure (surgical conversion, trombectomy, by-pass graft techniques, femoral and brachial dissection, etc.).

ENDOVASCULAR PROSTHESIS (STENT)

- Each stent has different structures and placement methods, so that the professionals may hardly have previous experience with all of them.
- Some systems are bifurcated, some have one, two or three pieces, others have hooks to set them in place, others have transrenal free stents (free flow) and yet others do not have any of these elements. Some stents require a minimum 18 mm diameter at the distal aorta, or a monoiliac system must be used. Some stents may be used in cases of iliac dilations (20-22 mm ?) and other may not be used in these cases, and must be anchored to the external iliac artery.
- The materials with which they are built also differ: their bodies may be of stainless steel, nitinol or cobalt-chromium. Some are coated with Dacron and others with PTFE.
- The intervening team must be knowledgeable of the characteristics of the usually implanted stents, but also of the main characteristics of the rest of the stents, in order to use the one that best fits the patient's condition.
- The surgeon in charge must order and claim the stent that he/she needs for each patient, based on his/her experience and on patient's needs.
- The surgeon must not assume the responsibility to use a stent with which he/she is not familiar, or that he/she believes may harm the patient, in the short or the long term, and must communicate such anomalies to the Associations or Colleges working in each country.

RESPONSIBILITIES

- The people in charge of the procedure performed to a patient presenting with complications or without complications that are treated endoluminally are the Head of the team and the surgeon (if other than the Head of the team).
- If the procedure is complicated or requires concomitant surgical treatment (conversion to open surgery, femoral-popliteal by-pass graft, iliac duct, etc.) the person in charge of the procedure is the intervening surgeon, irrespective of the responsibilities of the Head of the team (if the surgeon is not the Head of the team).

COMMON SENSE

Some times, based on the signs and symptoms and risks of the patient, the urgency of the procedure or other medical factors, the surgeon may make decisions that are not described in this consensus, but that are necessary to save the patient's life.

FOLLOW-UP

- Once operated, the patient must be followed-up for life.
- The patient must assume this responsibility, which must be included in the informed consent.
- Follow-up must be made 30 days after the procedure, and at 6 and 12 months during the first year, and once a year thereafter.

- Check-ups must include the following:
  - o Plain abdominal x-ray (frontal, lateral and oblique views) to observe any structural alterations of the metal structure of the stent.
  - o Computed Tomography with contrast agent, aimed at detecting leaks (endoleaks), migrations or other causes requiring treatment, as well as at evaluating the increase or decrease of the aneurysm sac.
  - o In patients with contraindication for Computed Tomography and in services qualified for the performance of Color Duplex Ultrasound, this method may be used as routine technique and Computed Tomography may be reserved for cases in which the Color Duplex Ultrasound detects the presence of complications (47-48).
- Healthcare plans and/or medical insurance companies must guarantee patients that they will be able to consult with their surgeon, even if their coverage changes.

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