



COLEGIO ARGENTINO DE CIRUJANOS CARDIOVASCULARES

INSTITUTIONALS AND PROFESSIONALS RECOMMENDATIONS AND REGULATIONS FOR TRANSCATHETER AORTIC VALVE REPLACEMENT TAVR PROGRAM

In recent years, the technological progress has led to incorporate the use of percutaneous heart valve as an alternative to conventional valve replacement techniques (TAVR-Transcatheter Aortic Valve Replacement). The commissioning and maintenance of a TAVR program demands compliance with certain requirements aiming at optimize the results and offer better quality care for patients. While this is of relevance to all aspect of medical practice, it is of particular importance because of the higher cost of medical benefits due to the impact on the finance health care.

In our country, we have regulations to categorize or prioritize health institutions or trained professionals, qualifying them to practice complex procedures. In general, the following guide includes issues such as the experience and skills of the professional, health institution data on procedure volumen and complementary services in order to ensure not only a proper performance but also the management of possible complications.

Being aware that our local reality is far from the medical practice in institutions in Europe or EE. UU., the Argentinian College of Cardiovascular Surgeons by means of the commission of Cardiac Surgery has implemented recommendations and basic regulations in order to standardize these percutaneous procedures.

This document intends:

1. To emphasize the access to an appropriate treatment to all patients with heart valve disease, including all forms of therapy either conventional surgery, endovascular technique, transcatheter, or palliative care; and also include centers of reference in order to facilitate the best medical treatment.
2. To emphasize that patients and family being well informed regarding all treatment options according to their clinical circumstances, generic risks, potential benefits, goals of care and recovery participating meaningfully in their healthcare decisions.

This document does NOT recommend that those centers which do not meet all requirements should close their TAVR Programs. On the contrary, the Argentinian College of Cardiovascular Surgeons by means of the commission of Cardiac Surgery recommends that centers, professionals and even regular

or prepaid health insurance systems or public health agencies review their quarterly reports and evaluate if they are within National or International benchmarks required for an acceptable quality of care.

Recent guidelines continue to emphasize on a team-based approach (HEART TEAM) for patient management. An appropriate diagnostic and imaging, optimal medical therapy (particularly of comorbidities), application and outcome for both TAVR and SAVR, procedural and perioperative care, and long-term follow-up should be performed by a multidisciplinary team with an extensive knowledge of valvular heart disease (VHD) comprising cardiologists and cardiac surgeons based on the fact that no one individual, group, or specialty possesses all the necessary skills for optimal patient outcomes.

PATIENTS REQUIREMENTS

Risks and benefits for any form of therapy whether they are a candidate for TAVR or SAVR should be informed and carefully discussed with patient. Both patients and their relatives should be included in the Heart Team. A TEAM - BASED APPROACH is a key requirement for TAVR program.

In Argentina Republic, the laws 26.529 and 26.742 about Patients' Rights and their relationship with physicians and health institutions establishes that any patient considered for TAVR must be informed about its medical condition, available therapies, professionals recommendations, risks and benefits, side effects (bleedings, infections, heart dysfunction, vascular or neurological disorders) and alternative therapies (medical and/or surgical).

HEART TEAM REQUIREMENTS

1. Considering high-risk patients to be treated, technical complexity of the procedure and cost, the HEART TEAM should be a joint effort with cardiologists, cardiovascular surgeons and interventional cardiologists as well as include physicians and medical personnel from many specialties, each with their own skillset, working together to provide the best possible patient-centered care^{1,3}. TAVR programs should ONLY be established if this multidisciplinary partnership is present. This is based on the underlying principle that NO ONE INDIVIDUAL, GROUP, OR SPECIALITY POSSESSES ALL THE NECESSARY SKILLS FOR OPTIMAL PATIENTS OUTCOMES^{1,2}.

This Multidisciplinary Team (MDT) should also include: echocardiographic and radiographic image specialist, cardiovascular anesthesiologist,

nurse practitioner/physician assistant for pre- and peri procedure care.

1. All TAVR procedure should be planned, performed and followed up by an interventional cardiologist and cardiovascular surgeon. This will not only ensure the appropriate medical therapy and procedure performed but also the treatment of immediate and mediate complications.

2. Cardiovascular Surgeons as well as Cardiovascular Surgery Department should be certified by the Argentinean College of Cardiovascular Surgeons in order to provide assistance to members, as well as to monitor the quality of TAVR Program.

HEART TEAM RECOMMENDATIONS

The HEART TEAM should include:

1. One Cardiovascular surgeon with knowledge and experience in TAVR certified by a medical college or equivalent. Because of the complexity of TAVR, the procedure should only be performed by a surgeon who has participated in at least 20 TAVR or simulator under the supervision of an experienced team.

2. One interventional cardiologist with knowledge and experience in TAVR certified by a medical college or equivalent.

3. It should also include other physicians and medical personnel from many specialties such as Echocardiographic and radiographic image specialist, Cardiovascular anesthesiologist, Nurse practitioner/physician assistant for pre- and peri procedure care, TAVR administrative coordinator/program navigator, Hospital administration representative.

FACILITIES AND INSTITUTIONAL RESOURCES

Centers for Medicare or hospitals should be approved for TAVR programs if they have an appropriate infrastructure including:

a. One Cardiovascular Surgery Department experienced in endovascular procedures as well as an active Cardiac Surgery Program. We recommend to be certified by the Argentinian College of Cardiovascular Surgeons.

b. A cardiac catheterization laboratory, hybrid catheterization laboratory, or hybrid operating room (OR)/catheterization lab equipped with a fixed radiographic imaging system and flat-panel fluoroscopy, offering catheterization laboratory-quality imaging and hemodynamic capability.

c. Post procedure recovery and intensive care facility with personnel experienced in managing cardiovascular patients.

d. Noninvasive imaging (Echocardiography, echo-doppler, multidetector CT or cardiac magnetic resonance MR).

e. Essential consultative resources: renal medicine with dialysis capabilities, vascular surgery support, neurology stroke team, electrophysiology capabilities for implantation of permanent pacemakers, etc.

f. Medical centers should not only offer the appropriate infrastructure and support but also follow a regulatory system through the establishment of certification criteria to ensure that ONLY INTERVENTIONAL CARDIOLOGIST OR CARDIOVASCULAR SURGEON CERTIFIED BY AN ACCREDITED MEDICAL COLLEGE OR MEDICAL ASSOCIATION provide these services.

g. A financial structure that shares physician reimbursement for these procedures is a recommended incentive for collaboration between cardiac surgeons and cardiologists. This important principle will ensure that cardiac surgeons and cardiologists participate jointly in performing procedures and that each patient receives optimal patient-centered treatment.

We recommend that Health Public Authority and healthcare providers promote the participation in a national data registry or local registries aim:

a. To identify and analyze the patients, professionals and services providers included in the HEART TEAM.

b. To ensure compliance with HEART TEAM requirements.

c. To ensure a Long-term outcome report for at least one year. Long-term follow-up for these patients is imperative which is an incumbent responsibility of the HEART TEAM and the hospital administration.

d. Identify data such as:

- Risk-adjusted operative mortality
- Neurologic events, including (stroke or TIAs)
- Major vascular complications
- Procedural failure
- Device failure
- Renal failure
- TAVR structural valve failure
- Quality of life at 1- year follow up.

It is important to emphasis on the need for Health care systems to monitor the TAVR Program in order to improve patient outcomes and evaluate quality benchmarks, cost, cost- effectiveness, and durability.

REFERENCES

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