36. LEFT VENTRICULAR RECONSTRUCTIVE SURGERY

Surgical procedures for treatment of patients with Ischemic Cardiomyopathy and Advanced Heart Failure (AHF) may be classified in procedures for "ventricular replacement" and procedures for "ventricular reconstruction or restoration".

Replacement procedures used for surgical treatment of AHF include heart transplantation, ventricular assist devices as "destination therapy", and total artificial heart. Heart transplantation is the preferred surgical treatment, in terms of survival and life quality. Nevertheless, in addition to the clinical indications for "ventricular replacement", the limited number of donors, the existence of comorbidities, or advanced age entail that only a limited number of patients with heart failure may benefit from this therapy.

Ventricular replacement procedures does not imply cure since, regardless of improvement in survival and heart failure symptoms, many dimensions of the life quality of patients transplanted or with ventricular support devices are deficient.

Ventricular reconstruction procedures must not be understood as a failure or bridge therapy to replacement treatments, but as representing a reasonable option.

Among the ventricular reconstruction procedures performed either in isolation or preferably combined are: coronary revascularization, mitral reconstruction or replacement, ventricular morphology reconstruction techniques (endoventricular circular patch plasty or Dor procedure, septal anterior exclusion…), ventricular assist devices as "bridge-to-recovery" and even in combination with other of the previous procedures, ventricular resynchronization electronic devices.

For this type of treatment, diagnostic imaging techniques, primarily cardiac magnetic resonance (CMR) and probably in the future molecular imaging, have achieve a leading role in the diagnosis, selection, technical planning and follow-up of these patients so that an adequate and complete preoperative assessment of the patient includes measurement of left ventricle volume (systolic and diastolic), global and regional systolic function, existence, extension and viability of the asynergy area as well as the remote myocardium, and, lastly, dilatation of the mitral ring and the distance between papillary muscles, factors contributing to the functional mitral regurgitation. A systematic CMR, performed by

experienced staff, provides in less than an hour all the required information for surgical indication and technique selection. Currently, this information must be completed with a preoperative coronarography and with the systematic use of intraoperative transesophageal echocardiography.

From the surgical perspective, the approach to these patients must be understood as a triad: acting on the coronary arteries (if there is pathology) through an extensive revascularization; repairing the mitral valve if there is at least a moderate (≥ degree 2) chronic regurgitation; and performing a ventricular volume reduction (if the left ventricular end-systolic volume index is >70 ml/m^2).

This surgical technique documented at the result level by the prospective multicentre study RESTORE 3, is currently being analyzed through a prospective random study (STICH TRIAL). Given the current scientific evidence, the European Society of Cardiology in the 2008 recommendations for treatment of AHF considers "left ventricular reconstruction" in patients who previously suffered acute myocardial infarction (AMI), as an IIb recommendation ("may be taken into consideration") with evidence level C.

Given the preoperative characteristics, and the possible intra and post operative complications of these patients, it seems logic that this therapeutic procedure is performed in centres with a ventricular care and heart transplantation programme allowing easy conversion to these therapeutic modalities. The critical importance of preoperative selection and preoperative treatment of the candidates to the procedure requires expert assessment of cardiologists, radiologists, anaesthetists, intensivists, and heart surgeons.

A. Rationale for the proposal

► Epidemiological data on the disease (incidence and prevalence).	Mortality on the heart transplantation waiting list is 10%; to this figure must be added the number corresponding to patients who are removed from the waiting list due to severe failures (around 9%). Therefore, mortality of patients with advanced heart failure waiting for a heart is estimated to be 19%. In developed countries, heart failure **incidence** in patients >40 years old is 1%. In our country, **annual incidence rate** of heart failure is 2 cases out of every 1,000 people. **Prevalence** of heart failure (HF) fluctuates between 2-3%. This prevalence is increasing due to the aging of the population and to the decreasing of mortality in acute heart events. 50% of the patients with HF die within 4 years. Different studies have

	found that after an AMI, showing a "left ventricular end-systolic volume index" higher than 45 ml/m^2 is a predictor of progression to heart failure and if it is over 60 ml/m^2 it is associated to a higher cardiac mortality (up to 30% during the first year).
► Data on the use of left ventricular reconstructive surgery.	In Spain, there is no reliable information in terms of the number of patients who undergo this type of treatment. The number of transplanted patients after 23 years of activity in our country is 5,482 (from 1984 until 2007); out of these, 4,919 are patients > 16 years old, 216 < 16 years old and 172 are retransplantations. In 2007, the total number of transplantations was 241, whereas the number of ventricular assistance has not exceeded 50. In 2007, mortality while in the waiting list has been 10% and the receptors average waiting time for transplantation in the last year has been 103 days. According to the Spanish Society of Cardiovascular Surgery, each year, an average of 40 ventricular assistance devices is implanted in Spain. According to the Spanish Society of Thoracic and Cardiovascular Surgery, since 1993 an average of 28 ventricular assistances is placed per year in Spain. In 2007, in the whole country 40 ventricular assistances were placed (15 ECMO) per year and there was a hospital mortality rate of 65%.

B. Guidelines to be followed by Centres, Services and Units in order to be designated as Reference Centres, Services and Units performing left ventricular reconstructive surgery

► Experience of the Reference Centres, Services and Units:	

- Activity: • Number of left ventricular reconstructive surgery procedures that should be performed in a year to ensure an adequate care.	- A minimum of 10 left ventricular reconstructive procedures in a year
• Number of procedures similar to those specific to the designation requested that should be performed in a year to ensure an adequate care.	- The cardiovascular service must perform 450 heart surgeries per year. - The cardiovascular service must have: ◆ An active programme of mitral valve reconstruction and perform at least 20 procedures per year. ◆ An active program of coronary surgery performing at least 150 procedures/year. ◆ An active programme for advance heart failure diagnosis and treatment.
- Other data: research on the subject, postgraduate teaching, continuing training, publications, etc.	- Accredited postgraduate teaching: unit participation in the internship and residency programme in cardiology and cardiovascular surgery of the Centre. - Participation in research projects and publications in the field[a]. - Continuing training programme standardized and authorized by the centre's board of directors, including nursing staff, intensive care staff, and perfusionists. - Clinical multidisciplinary sessions at least once a month, in order to make decisions and coordinate treatments.
► Specific resources of the Reference Centres, Services and Units:	
- Human resources required for adequate performing of left ventricular reconstructive surgery.	- Cardiology and cardiovascular surgery continuous care, including perfusion team for extracorporeal circulation, and the ability to perform transesophageal and/or transthoracic echocardiography. - 2 cardiovascular surgeons. - 1 cardiologist. - Perfusionists.

	- Nursing and surgical staff. - If there is not a heart transplantation programme in the centre, intensivists and nursing staff for patient transportation to a centre with such a programme.
- Basic education of the team members [b].	- Cardiovascular surgeons with 5 years experience in left ventricular reconstruction. - Cardiologist with experience in intraoperative transesophageal echocardiography. - Perfusionists with experience in patients undergoing left ventricular reconstructive surgery. - Nursing and surgical staff, with experience in patients undergoing left ventricular reconstructive surgery.
- Specific equipment required for adequate performing of left ventricular reconstructive surgery.	- Transthoracic and transesophageal ultrasound scanner to be used pre, intra, and post operative. - Ventricular assist devices.
► Resources from other units and services besides those belonging to the Reference Centres, Services and Units required for adequate performing of left ventricular reconstructive surgery [b].	-Unit for the diagnosis and treatment of advanced heart failure. - Electrophysiology and arrhythmias unit with experience in complex ablations, implants, and control of automatic implantable defibrillators and resynchronization devices. - Anaesthesia services/unit with experience in patients undergoing left ventricular reconstructive surgery. - Intensive care and/or resuscitation services/unit with experience in patients undergoing left ventricular reconstructive surgery. - Diagnostic imaging services/unit, with MR and at least a radiologist and cardiologist with experience in functional studies of the heart with cardiac magnetic resonance for pre and post operative assessment. - Rehabilitation services/unit with experience in patients who have undergone left ventricular reconstructive surgery. - Haematology and Hemotherapy unit/services. - Nephrology services/unit.

	- Active heart transplantation programme and authorized according to the Royal Decree 2070/1999, December 30th, establishing the general basis for clinical harvesting and use of human organs and the territorial coordination in donation and transplantation of organs and tissues, allowing for response and continuity to the needs arising from the treatment of patients with complex congenital heart disease (complications or poor progress).
► Procedure and clinical results indicators of the Reference Centres, Services and Units [c]:	**The indicators will be agreed with the Units that will be designated.**
► Existence of an adequate IT system (Type of data that the IT system must include to allow identification of the activity and evaluation of the quality of the services provided)	- Filling up the complete MBDS of hospital discharge. - If there is an active heart transplantation programme in the centre, participation in the Spanish Registry for Heart Transplantation from the National Transplant Organization is required. - Participation in the Registry for Ventricular Assistance of the Spanish Society of Cardiovascular Surgery is advisable. - The unit must have a *registry of patients who have undergone left ventricular reconstructive surgery* which at least must include: - Medical record number. - Date of birth. - Sex. - Patient's habitual region of residence. - Admission date and discharge date. - Type of admission (Emergency, planned, other). - Type of discharge (Home, hospital transfer, voluntary, death, transfer to a healthcare centre, other.) - Service in charge of patient's discharge. - Cause for admission: Decompensated heart failure, angina, arrhythmias, mixed.

	- Number of previous hospital admission due to the same cause. - Main diagnosis (ICD-9-CM). Preoperative baseline functional levels. - Other diagnosis (ICD-9-CM). - Diagnostic procedures provided to the patient (ICD-9-CM): Type of procedure and date when it was provided. ◆ Basic preoperative echocardiographic data: Ejection fraction; MI existence, quantification and mechanisms; pulmonary artery systolic pressure; segmental contractility anomalies. ◆ Basic preoperative hemodynamic study data: Coronary disease and extension; pulmonary pressure; in case of ventriculography, ventricular morphological classification. ◆ Basic preoperative cardiac magnetic resonance data: Ejection fraction; left ventricular end-systolic and end-diastolic volume; beat volume; akinetic or dyskinetic anterior wall. - Therapeutic procedures provided to the patient (ICD-9-CM): Type of procedure and date when it was provided. ◆ Euroscore rate. ◆ Type of surgical procedure (ICD-9-CM): ventricular reconstruction technique, mitral surgery associated and procedure, coronary surgery associated. - Complications (ICD-9-CM): Hospital mortality, need for circulatory assistance and method, emergency heart transplant, other complications. - Patient monitoring: Survival, hospital readmissions due to the same cause, need for heart transplantation, echocardiographic and cardiac magnetic resonance data. - The unit must have the required data which should be sent to the Spanish National Health Service Reference Centres, Services and Units Appointment Commission Secretariat for reference unit monitoring.

[a] *Criteria to be assessed by the Appointment Commission.*
[b] *Experience will be accredited by certification from the hospital manager.*
[c] *Clinical results standards, agreed to by the experts group, will be assessed, initially by the Appointment Commission, while in the qualification process, as more information from the Reference Centres, Services and Units is being obtained. Once qualified by the Appointment Commission, the Quality Agency will authorize its compliance, as for the rest of guidelines.*

Bibliography:

1. Cuenca J. Tratamiento quirúrgico de la insuficiencia cardíaca. Restauración ventricular y cirugía de la válvula mitral. Rev Esp Cardiol Supl 2006; 6(F):71F-81F.
2. Lloyd SG, Buckberg GD, and the Restore Group. Use of cardiac magnetic resonance imaging in surgical ventricular reconstructive. Eur J Cardiothorac Surg 2006; 29S:S216-S224.
3. Athanasuelas CL, Buckberg GD, Stanley AWH, Siler W, Dor V, Di Donato M, et al. Surgical ventricular reconstructive in the treatment of congestive heart failure due to post-infarction ventricular dilation. J Am Coll Cardiol 2004; 44:1439-1445.
4. Torsten Doenst. To STICH or not to STICH: We know the answer, but do we understand the question? J Thorac Cardiovasc Surg 2005; 129: 246-9.
5. Dickstein K and ESC Committee for Practice Guidelines. ESC Guidelines for the diagnostic and treatment of acute and chronic heart failure 2008. European Heart Journal (2008) 29; 2388-2442.
6. Gaudron P, Eilles C, Kugler I, Ertl G. Progresive left ventricular dysfunction and remodelling after myocardial infarction: potential mechanism and early predictors. Circulation 1993;87:755-63.
7. Cuenca J, Herrera JM, Rodriguez-Delgadillo MA, Campos V, Valle JV, Rodríguez F, et al. Tratamiento de los aneurismas ventriculares mediante Plastia Circular Endoventricular. Rev Esp Cardiol 1999;52(S4):85.