

Guidelines to be followed by centres, services and units in order to be designated as Reference Centres, Services and Units of the National Health System, as agreed by the Interterritorial Board

34. COMPLEX MITRAL VALVE RECONSTRUCTIVE SURGERY

Mitral valve reconstructive surgery is a heart surgery technique which objective is to re-establish adequate mitral functioning maintaining the mitral valve and subvalvular apparatus, as an alternative to mitral valve replacement. Nowadays, mitral valve reconstruction has become the surgical procedure chosen for mitral regurgitation since it has proven to have higher survival, better life quality and less need for anticoagulation than mitral valve replacement¹⁻⁵. A recent study by the Spanish Ministry of Health and Social Policy has shown the less cost and higher effectiveness of the reconstruction versus the replacement in our environment⁶.

Mitral regurgitation has a variable prognosis depending on the aetiology^{6,8}, which is diverse and includes degenerative pathologies, endocarditis, rheumatic heart disease, ischemic heart disease and cardiomyopathies. Each aetiology causes mitral regurgitation through a specific physiopathological mechanism and each mechanism involves a specific reconstruction technique. Therefore, for a correct mitral reconstruction, a comprehensive and multidisciplinary study must be performed by clinical cardiologists, echocardiographers and heart surgeons in order to assess the aetiology, mechanism and reconstruction possibilities of the mitral regurgitation.

Most of the Spanish heart surgery services have a good command of reconstruction techniques for mitral regurgitation of ischemic origin or posterior leaflet prolapse. However, when there is involvement of the anterior leaflet, of both leaflets, diffuse involvement of the posterior or anterior leaflet as in Barlow's disease, or in cases of rheumatic valvulopathy, mitral reconstruction requires more experience and it is performed in centres with the adequate training and volume. These procedures are the ones designated as **complex mitral valve reconstruction surgery**.

Creation of these national reference units or services would be mainly directed to perform complex techniques for reconstruction of mitral regurgitation: Anterior leaflet prolapsed with or without chordal rupture, prolapsed of both mitral leaflets with or without chordal rupture, commissural prolapses, Barlow's disease, annular or leaflet calcification, rheumatic aetiology following endocarditis.

A. Rationale for the proposal

<p>► Epidemiological data on mitral regurgitation (incidence and prevalence).</p>	<p>- Mitral regurgitation incidence: >10% of people over 55 years old. - Mitral regurgitation prevalence: 1.7% (1.5-1.91%) in the general population, reaching 9.3% (8.1-10.9%) in people over 75 years old²⁰.</p>
<p>► Data on the use of complex mitral valve reconstructive surgery.</p>	<p>Mitral reconstruction is very variable depending on the aetiology, mechanism and experience of the centre where is performed: Thus, the Mayo Clinic repairs 80% of the mitral regurgitation; the 2005 USA STS reports 54%; in the 2003 European Survey on Valvular Heart Disease, 46.5%; and in the 2005 registry of the Spanish Society of Thoracic and Cardiovascular Surgery, an average of 20% with a very important variability; the centres that more mitral regurgitation reconstructions perform approach 60%.</p> <p>In case of predominant mitral regurgitation, percentage of valve preservation in the United States reference centres in general is over 80% and only over 60% when the anterior mitral leaflet is involved, although it is also variable according to the centre's experience. In Spain, the average preservation of the mitral valvular apparatus does not exceed 30% and if it affects the anterior leaflet is fewer than 10%. Nevertheless, in some centres with experience it reaches 80%¹⁵⁻¹⁷.</p>

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

<p>► Experience of the Reference Centres, Services and Units:</p> <p>- Activity:</p> <ul style="list-style-type: none"> • Number of procedures that should be 	<p>- 45 mitral valve reconstructions per year. Out of these, at least 20 complex</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------

<p>performed in a year to ensure an adequate care.</p> <ul style="list-style-type: none"> • Number of procedures similar to those specific to the designation requested that should be performed in a year to ensure an adequate care. <p>- Other data: research on the subject, postgraduate teaching, continuing training, publications, etc.</p>	<p>reconstructions. Complex mitral surgery refers to surgery dealing with: anterior leaflet prolapsed with or without chordal rupture, prolapsed of both mitral leaflets with or without chordal rupture, commissural prolapses, Barlow's disease, annular or leaflet calcification, mitral regurgitation of rheumatic aetiology or following endocarditis.</p> <ul style="list-style-type: none"> - The cardiovascular surgery services must performed 450 heart surgical procedures per year. - Accredited postgraduate teaching: unit participation in the internship and residency programme 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. - Clinical multidisciplinary sessions, at least once a month, in order to make decisions and coordinate treatments.
<p>► Specific resources of the Reference Centres, Services and Units:</p> <ul style="list-style-type: none"> - Human resources required for the adequate performing of complex mitral valve reconstructive surgery. <p>- Basic education of the team members^b.</p>	<ul style="list-style-type: none"> - 24 hours continuous care of cardiovascular surgery. - 2 cardiovascular surgeons. - 1 cardiologist. - 1 perfusionist. - Nursing and surgical staff. <p>- Cardiac surgeons with 5 years or more of experience in mitral valve reconstructive surgery.</p>

<p>- Specific equipment required for the adequate performing of complex mitral valve reconstructive surgery.</p> <p>► Resources from other units and services besides those belonging to the Reference Centres, Services and Units required for the adequate performing of complex mitral valve reconstructive surgery^b.</p>	<ul style="list-style-type: none"> - Cardiologist with specific training and experience in mitral reconstruction assessment using echocardiography and performing intraoperative transesophageal echocardiography (TEE). - Perfusionist with experience in patients undergoing cardiovascular surgery. - Nursing and surgical staff with experience in patients undergoing cardiovascular surgery. - Intraoperative transesophageal echocardiography (TEE), 3D TEE advisable. - Complete equipment for extracorporeal circulation (at least 3 roller pumps, one centrifugal, heat exchangers, gas exchangers, extracorporeal circuits with oxygenators and filters). - Videothoracoscopic equipment for cases of minimally invasive surgery. - Anaesthesia services/unit with experience in patients undergoing cardiovascular surgery. - Intensive care and/or resuscitation services/unit with experience in patients undergoing cardiovascular surgery.
<p>► Procedure and clinical results indicators of the Reference Centres, Services and Units^c:</p>	<p>The indicators will be agreed with the Units that will be designated.</p>
<p>► 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)</p>	<ul style="list-style-type: none"> - Filling up the complete MBDS of hospital discharge. - The unit must have a <i>registry of patients who underwent complex mitral valve reconstructive surgery</i> which at least must include: <ul style="list-style-type: none"> - Medical record number. - Date of birth. - Sex. - Patient's habitual region of residence.

	<ul style="list-style-type: none"> - 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. - Main diagnosis (ICD-9-CM). <ul style="list-style-type: none"> ◆ Pre-existing heart disease. ◆ Type of anatomical mitral injury. - Other diagnosis (ICD-9-CM). - Diagnostic procedures provided to the patient (ICD-9-CM): <ul style="list-style-type: none"> ◆ Type of procedure and date when it was provided. - Therapeutic procedures provided to the patient (ICD-9-CM): <ul style="list-style-type: none"> ◆ Type of procedure and date when it was provided. ◆ Surgical data in relation to the extracorporeal, type of mitral reconstruction technique used, and intraoperative TEE results. ◆ Post operative data. - Complications (ICD-9-CM). <ul style="list-style-type: none"> ◆ Surgeries resulting in valve replacement procedures. ◆ Other. - Patient monitoring: <ul style="list-style-type: none"> ◆ Echocardiogram at discharge. ◆ Mitral regurgitation state at discharge (degree according to ultrasound). ◆ Discharge status. ◆ New surgeries, interventionist catheterization, doctor's visits, etc. <p>- 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.</p>
--	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

^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. F. Bursi, M. Enriquez-Sarano V.T. Nkomo, et al. Heart failure and death after myocardial infarction in the community: the emerging role of mitral regurgitation, *Circulation* 111 (2005), pp. 295–301.
2. F. Grigioni, M. Enriquez-Sarano, K.J. Zehr, K.R. Bailey and A.J. Tajik. Ischemic mitral regurgitation: long-term outcome and prognostic implications with quantitative Doppler assessment, *Circulation* 103 (2001), pp. 1759–1764.
3. J. Zamorano, M. Quezada et al. Prognostic significance of functional mitral regurgitation after a first non-ST-segment elevation acute coronary syndrome Perez d, I, *Eur Heart J* 27 (2006), pp. 2655–2660.
4. D. Aronson, N. Goldsher, R. Zukermann et al. Ischemic mitral regurgitation and risk of heart failure after myocardial infarction. *Arch Intern Med* 166 (2006), pp. 2362–2368.
5. G.A. Lamas, G.F. Mitchell, G.C. Flaker et al. Clinical significance of mitral regurgitation after acute myocardial infarction: Survival and Ventricular Enlargement Investigators. *Circulation* 96 (1997), pp. 827–833.
6. Evaluación económica del tratamiento de la insuficiencia de la válvula mitral. Reparación frente a sustitución protésica. Informe, estudios e investigación 2008. AETSA (Andalusian Agency for Health Technology Assessment) 2006/31. Ministerio de Sanidad y Consumo (Ministry of Health and Social Policy).
7. B. Barzilai, V.G. Davis, P.H. Stone, A.S. Jaffe. Prognostic significance of mitral regurgitation in acute myocardial infarction: The MILIS Study Group, *Am J Cardiol* 65 (1990), pp. 1169–1175.
8. E.A. Grossi, J.D. Goldberg, A. LaPietra et al. Ischemic mitral valve reconstruction and replacement: comparison of long-term survival and complications, *J Thorac Cardiovasc Surg* 122 (2001), pp. 1107–1124.
9. K.G. Lehmann, C.K. Francis, H.T. Dodge. Mitral regurgitation in early myocardial infarction. Incidence, clinical detection, and prognostic implications: TIMI Study Group, *Ann Intern Med* 117 (1992), pp. 10–17.
10. G.G. Pellizzon, C.L. Grines, D.A. Cox et al. Importance of mitral regurgitation inpatients undergoing percutaneous coronary intervention for acute myocardial infarction: the Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications (CADILLAC) trial, *J Am Coll Cardiol* 43 (2004), pp. 1368–1374.

11. P. Buja, G. Tarantini, B.F. Del et al. Moderate-to-severe ischemic mitral regurgitation and multivessel coronary artery disease: Impact of different treatment on survival and rehospitalization, *Int J Cardiol* 111 (2006), pp. 26–33.
12. B.H. Trichon, D.D. Glower, L.K. Shaw et al. Survival after coronary revascularization, with and without mitral valve surgery, in patients with ischemic mitral regurgitation, *Circulation* 108 (Suppl 1) (2003), pp. II103–II110.
13. D.H. Kang, M.J. Kim, S.J. Kang et al., Mitral valve repair versus revascularization alone in the treatment of ischemic mitral regurgitation, *Circulation* 114 (1 suppl) (2006), pp. I499–I503.
14. M.D. Diodato, M.R. Moon, M.K. Pasque et al. Repair of ischemic mitral regurgitation does not increase mortality or improve long-term survival in patients undergoing coronary artery revascularization: a propensity analysis, *Ann Thorac Surg* 78 (2004), pp. 794–799.
15. A.R. Akar, G. Doukas, A. Szafrank et al., Mitral valve repair and revascularization for ischemic mitral regurgitation: predictors of operative mortality and survival, *J Heart Valve Dis* 11 (2002), pp. 793–800.
16. K.M. Harris, T.M. Sundt III, D. Aeppli, R. Sharma, B. Barzilai. Can late survival of patients with moderate ischemic mitral regurgitation be impacted by intervention on the valve? *Ann Thorac Surg* 74 (2002), pp. 1468–1475.
17. A.M. Gillinov, P.N. Wierup, E.H. Blackstone et al. Is repair preferable to replacement for ischemic mitral regurgitation?. *J Thorac Cardiovasc Surg* 122 (2001), pp. 1125–1141.
18. A.M. Gillinov, D.M. Cosgrove III. Current status of mitral valve repair. *Am Heart Hosp J* 1 (2003), pp. 47–54.
19. V.H. Thourani, W.S. Weintraub, R.A. Guyton et al. Outcomes and long-term survival for patients undergoing mitral valve repair versus replacement: effect of age and concomitant coronary artery bypass grafting. *Circulation* 108 (2003), pp. 298–304.