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Transcatheter Mitral Valve Repair: Is there a Future?

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Mitral regurgitation (MR) is a common disease in developed countries, affecting an estimated 9.3% of the population aged ≥ 75 years.¹ Although surgical valve repair or replacement is currently the “gold standard” treatment for severe symptomatic MR, almost one-half of the patients are denied surgery.² These are usually older patients with moderate left ventricular dysfunction and several non-cardiac co-morbidities. The aim of transcatheter mitral valve repair is to provide a treatment that is at least as effective as conventional valve surgery, and is associated with less morbidity and mortality.³ Currently an important number of devices are under evaluation, and can be categorized according to the treatment strategy.⁴⁻²²

1) Edge-to-edge techniques

Creation of a double orifice mitral valve (Alfieri procedure) using:

- A clip device – **MitraClip** (Evalve, Inc., Menlo Park, California), EVEREST I + II trials.⁴⁻⁶
- A stitch device – **MOBIUS** (Edwards Lifesciences Corp., Irvine, California), no longer in clinical trial.^{7,8}

2) Direct annuloplasty techniques

Remodeling of the annulus of the mitral valve by:

- Suture-based techniques – **Percutaneous Suture Annuloplasty** (Mitralign, Inc., Tewksbury, Massachusetts) – **AccuCinch** (Guided Delivery Systems, Santa Clara, California).^{9,10}
- Application of radiofrequency energy – **QuantumCor Endovascular Device** (Quantum-Cor, San Clemente, California)¹¹

3) Indirect annuloplasty techniques

Remodeling of the mitral valvular complex by:

- Trans-ventricular devices – **iCoapsys** (Myocor, Maple Grove, Minnesota)^{12,13} (no longer in clinical trial)
- Trans-atrial devices – **Percutaneous Septal Sinus Shortening (PS3) system** (Ample Medical, Foster City, California)^{14,15}

4) Coronary sinus annuloplasty techniques

Remodeling of the annulus of the mitral valve by devices implanted in the coronary sinus:

- **Percutaneous Mitral Annuloplasty (PTMA) device** (Viacor Inc., Wilmington, Massachusetts), PTOLEMY 1 + 2 trials.¹⁶⁻¹⁹
- **CARILLON** Mitral Contour System (Cardiac Dimensions Inc., Kirkland, Wash-

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ington), AMADEUS + TITAN trials.^{20,21}

- **MONARC System** (Edwards Lifesciences Corp., Irvine, California), EVOLUTION 1 trial.²²

5) Transcatheter Mitral Valve Implantation – hybrid techniques

- **Endovalve** (Endovalve Inc., Princeton, NJ) (minimally invasive surgery)
- **Lutter Mitral Valve** (trans-apical)²³
- **CardiaQ** (CardiaQ Valve Technologies, Inc., Winchester, MA) (trans-femoral)
- **MiCardia** (Micardia Inc., Irvine, CA) (Dynaplasty shape memory technology – DYANA Study)

Currently, the device with the most clinical experience is the MitraClip, which is also CE approved.⁴⁻⁶ The implantation technique is quite demanding since a trans-septal puncture is needed. The results of the EVEREST II trial are expected in the second quarter of 2010. Coronary sinus annuloplasty techniques have emerged, mainly because they are technically simpler.¹⁶⁻²² However, the response rate is only around 60% and the treatment is applicable to a minority of patients, due to anatomic considerations (e.g. proximity of the coronary sinus with the mitral annulus and the circumflex coronary artery).

The complexity of the mitral valve apparatus and the multifactorial pathophysiology of MR have led to a slower than anticipated progress for transcatheter mitral valve therapies. However, in the era of less invasive interventions, and given the increasing clinical demand in an ageing population, it is a matter of time when transcatheter mitral valve repair will expand and become a routine procedure.

REFERENCES

1. Iung B, Baron G, Butchart EG, et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. *Eur Heart J* 2003; 24:1231–1243.
2. Mirabel M, Iung B, Baron G, et al. What are the characteristics of patients with severe, symptomatic, mitral regurgitation who are denied surgery? *Eur Heart J* 2007; 28:1358–1365.
3. Piazza N, Asgar A, Ibrahim R, Bonan R. Transcatheter mitral and pulmonary valve therapy. *J Am Coll Cardiol* 2009; 53:1837–1851.
4. St Goar FG, Fann JI, Komtebedde J, et al. Endovascular edge-to-edge mitral valve repair: short-term results in a porcine model. *Circulation* 2003; 108:1990–1993.
5. Fann JI, St Goar FG, Komtebedde J, et al. Beating heart catheter based edge-to-edge mitral valve procedure in a porcine model: efficacy and healing response. *Circulation* 2004; 110:988–993.
6. Condado JA, Acquatella H, Rodriguez L, et al. Percutaneous edge-to-edge mitral valve repair: 2-year follow-up in the first human case. *Catheter Cardiovasc Interv* 2006; 67:323–325.
7. Naqvi TZ, Zarbatany D, Molloy MD, et al. Intracardiac echocardiography for percutaneous mitral valve repair in a swine model. *J Am Soc Echocardiogr* 2006; 19:147–153.
8. Naqvi TZ, Buchbinder M, Zarbatany D, et al. Beating-heart percutaneous mitral valve repair using a transcatheter endovascular suturing device in an animal model. *Catheter Cardiovasc Interv* 2007; 69:525–531.
9. Tibayan FA RF, Liang D, Daughters GT, et al. Paneth suture annuloplasty abolishes acute ischemic mitral regurgitation but preserves annular and leaflet dynamics. *Circulation* 2003; 108:II128–133.
10. Aybek T, Risteski P, Miskovic A, et al. Seven years' experience with suture annuloplasty for mitral valve repair. *J Thorac Cardiovasc Surg* 2006; 131:99–106.
11. Heuser RR, Witzel T, Dickens D, Takeda PA. Percutaneous treatment for mitral regurgitation: the QuantumCor system. *J Interv Cardiol* 2008; 21:178–182.
12. Mishra YK, Mittal S, Jaguri P, Trehan N. Coapsys mitral annuloplasty for chronic functional ischemic mitral regurgitation: 1-year results. *Ann Thorac Surg* 2006; 81:42–46.
13. Pedersen WR BP, Feldman T. The iCoapsys repair system for percutaneous treatment of functional mitral insufficiency. *Eurointervention* 2006; 1:A44–48.
14. Rogers JH, Macoviak JA, Rahdert DA, et al. Percutaneous septal sinus shortening: a novel procedure for the treatment of functional mitral regurgitation. *Circulation* 2006; 113:2329–2334.
15. Palacios IF, Condado JA, Brandi S, et al. Safety and feasibility of acute percutaneous septal sinus shortening: first-in-human experience. *Catheter Cardiovasc Interv* 2007; 69:513–518.
16. Liddicoat JR, Mac Neill BD, Gillinov AM, et al. Percutaneous mitral valve repair: a feasibility study in an ovine model of acute ischemic mitral regurgitation. *Catheter Cardiovasc Interv* 2003; 60:410–416.
17. Daimon M, Shiota T, Gillinov AM, et al. Percutaneous mitral valve repair for chronic ischemic mitral regurgitation: a real-time three-dimensional echocardiographic study in an ovine model. *Circulation* 2005; 111:2183–2189.
18. Dubreuil O, Basmadjian A, Ducharme A, et al. Percutaneous mitral valve annuloplasty for ischemic mitral regurgitation: first in man experience with a temporary implant. *Catheter Cardiovasc Interv* 2007; 69:1053–1061.
19. Sack S, Kahlert P, Bilodeau L, et al. Percutaneous transvenous mitral annuloplasty: initial human experience with a novel coronary sinus implant device. *Circ Cardiovasc Interv* 2009; 2:277–284.
20. Schofer J, Siminiak T, Haude M, et al. Percutaneous mitral annuloplasty for functional mitral regurgitation: results of the CARILLON Mitral Annuloplasty Device European Union Study. *Circulation* 2009; 120:326–333.
21. Siminiak T, Hoppe UC, Schofer J, et al. Effectiveness and safety of percutaneous coronary sinus-based mitral valve repair in patients with dilated cardiomyopathy (from the AMADEUS trial). *Am J Cardiol* 2009; 104:565–570.
22. Harnek J. Percutaneous mitral valve repair - coronary sinus annuloplasty. EuroPCR May 2008; Barcelona, Spain.
23. Lutter G, Quaden R, Osaki S, et al. Off-pump transapical mitral valve replacement. *Eur J Cardiothorac Surg* 2009; 36:124–128.