Editorial

The cardiologist's way to do the Alfieri stitch: transcatheter mitral valve edge-to-edge repair revisited

Tienush Rassaf

Department of Cardiology and Vascular Medicine, West German Heart and Vascular Center, University Hospital Essen, Essen, Germany

Correspondence to: Tienush Rassaf, MD. Department of Cardiology and Vascular Medicine, West German Heart and Vascular Center, University Hospital Essen, Essen, Germany. Email: Tienush.Rassaf@uk-essen.de.

Provenance: This is an invited Editorial commissioned by the Section Editor Hai-Long Dai (Department of Cardiology, Yan'an Affiliated Hospital of Kunming Medical University, Yunnan, China).

Comment on: Praz F, Spargias K, Chrissoheris M, *et al.* Compassionate use of the PASCAL transcatheter mitral valve repair system for patients with severe mitral regurgitation: a multicentre, prospective, observational, first-in-man study. Lancet 2017;390:773-80.

Submitted Oct 08, 2017. Accepted for publication Oct 21, 2017.

doi: 10.21037/jtd.2017.10.134

View this article at: http://dx.doi.org/10.21037/jtd.2017.10.134

More than 10% of people 75 years and older suffer from severe symptomatic mitral regurgitation (1). This number even increases with increasing age. Whereas mitral valve repair and replacement is the gold standard in younger patients with normal left ventricular function, surgical risk dramatically increases with increasing age and impairment of left ventricular function. Fifty percent and more patients with severe symptomatic mitral valve regurgitation are denied surgery (2) due to high perioperative mortality, unsatisfactory longterm survival, and questionable benefit on quality of life (3), especially in older patients. The 2017 European guidelines on valvular heart disease recommend to consider a percutaneous edge-to-edge procedure in patients with severe secondary mitral valve regurgitation and left ventricular function >30%, who remain symptomatic in spite of optimal medical management and cardiac resynchronisation therapie (CRT) (if indicated), when valve morphology is suitable (4).

Edge-to-edge repair of the mitral valve has emerged from a surgical concept (5,6) to a percutaneous transfemoral transcatheter mitral valve repair system. The so-called MitraClip system is the most common used approach for the interventional treatment of mitral regurgitation. In the EVEREST II trial (7) transcatheter mitral valve repair has been compared to surgical mitral valve reconstruction or replacement. After 5 years, there were no differences in mortality but a higher rate of reinterventions in the MitraClip group due to more frequent cases of mitral regurgitation (8). The MitraClip system has been investigated in multiple national and international registries (ACCESS-EU, GRASP, MARS, MitraSwiss, STS/ACC TVT, SENTINEL, TRAMI) (9-15). In most cases, patients undergoing the MitraClip-repair suffer from symptomatic functional mitral regurgitation with left ventricular dysfunction. Only less frequently patients with degenerative mitral valve regurgitation and high surgical risk have been included. Several smaller studies have been performed in order to improve the technical approach and to understand the pathophysiology behind the beneficial effects of the mitral valve repair (16-19). The procedure has been proved to be save and most patients show improvement of functional capacity with reduction in, e.g., NYHA classification and increases in 6-MWT.

The MitraClip-system, however, has limitations and there have only been made minimal modifications on the system to improve for the apparent restraints. Several patients show anatomical hurdles and are therefore not suitable for the repair using the MitraClip approach. Difficulties in handling and implanting make it difficult to apply this system in patients with complex anatomy. The so-called EVEREST-criteria (7) define patients who are ideal candidates for this interventional approach. Extension to patients with more complex anatomy is common, but does often not lead to the expected results (20). This is associated with a worse outcome.

Praz *et al.* present results of the novel PASCAL

transcatheter mitral valve repair system, which has been investigated in a multicenter, prospective, observational, first-in-man study (21). Twenty-three patients suffering from symptomatic, severe functional, degenerative or combined functional and degenerative mitral regurgitation were included. All patients were discussed in the heart team and patients were denied surgery due to high risk. Most patients furthermore showed anatomical obstacles, which made an interventional approach using the MitraClip system impossible.

Implantation of the device was successful in all patients. Procedural mitral regurgitation was 0 and 1 in 17 and 22 patients showed mitral regurgitation of grade 2+ or less. In 6 patients a second device has been implanted. Two patients suffered from procedural complications, 3 patients died during the 30-day follow-up. The authors present a functional improvement, comparable to that seen in other studies of patients who underwent transcatheter mitral valve repair.

What makes the PASCAL transcatheter mitral valve repair system so special and do we really need a system, which—at least on the first sight—looks like a refined MitraClip system?

Both systems require transseptal puncture under transesophageal echocardiography guidance. The PASCAL system consists of a steerable guide sheath (22 French), a steerable catheter, and an implant catheter with the implant pre-attached at the distal end. The guide sheath and the catheter can be controlled using rotational knobs on the handles. The implant consists of a 10-mm spacer, which acts as a filler in the regurgitation orifice (21), and that is attached to two paddles with about 25 mm width in grasping position and clasps of 10 mm lengths. This spacer in combination with the—compared to the MitraClip—wider and longer paddles, and the ability to independently grasp the anterior and posterior leaflet, might allow to treat patients with functional and different types of degenerative mitral regurgitation. And this seems to be one of the major advantages of this system. Patients with more complex anatomy might be eligible for treatment using this approach.

Many questions arise; how does the ideal patient look like? Do we have to define PASCAL-criteria analogous to EVEREST-criteria in order to define the right patient and anatomy? What about durability and what role may this approach play in context of other transcatheter mitral valve repair systems like, e.g., direct and indirect annuloplasty technologies, chordal technologies, and/or ventriculoplasty systems?

The emerging of the plethora of novel transcatheter technologies is more than exciting. Cardiologists gain more and more tools to treat patients who can not undergo surgery due to high risk. Further studies are on their way and necessary in order to teach us how to use which approach for which patient, when to go forward, and when to rather be cautious.

Acknowledgements

None.

Footnote

Conflicts of Interest: The author has no conflicts of interest to declare.

References

1. Nkomo VT, Gardin JM, Skelton TN, et al. Burden of valvular heart diseases: a population-based study. Lancet 2006;368:1005-11.
2. Goel SS, Bajaj N, Aggarwal B, et al. Prevalence and outcomes of unoperated patients with severe symptomatic mitral regurgitation and heart failure: comprehensive analysis to determine the potential role of MitraClip for this unmet need. J Am Coll Cardiol 2014;63:185-6.
3. Andalib A, Mamane S, Schiller I, et al. A systematic review and meta-analysis of surgical outcomes following mitral valve surgery in octogenarians: implications for transcatheter mitral valve interventions. EuroIntervention 2014;9:1225-34.
4. Baumgartner H, Falk V, Bax JJ, et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease: The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). Eur Heart J 2017;38:2739-91.
5. Maisano F, Torracca L, Oppizzi M, et al. The edge-to-edge technique: a simplified method to correct mitral insufficiency. Eur J Cardiothorac Surg 1998;13:240-5; discussion 245-6.
6. Alfieri O, Denti P. Alfieri stitch and its impact on mitral clip. Eur J Cardiothorac Surg 2011;39:807-8.
7. Feldman T, Foster E, Glower DD, et al. Percutaneous repair or surgery for mitral regurgitation. N Engl J Med 2011;364:1395-406.

8. Feldman T, Kar S, Elmariah S, et al. Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation: 5-Year Results of EVEREST II. J Am Coll Cardiol 2015;66:2844-54.
9. Maisano F, Franzen O, Baldus S, et al. Percutaneous mitral valve interventions in the real world: early and 1-year results from the ACCESS-EU, a prospective, multicenter, nonrandomized post-approval study of the MitraClip therapy in Europe. J Am Coll Cardiol 2013;62:1052-61.
10. Grasso C, Capodanno D, Scandura S, et al. One- and twelve-month safety and efficacy outcomes of patients undergoing edge-to-edge percutaneous mitral valve repair (from the GRASP Registry). Am J Cardiol 2013;111:1482-7.
11. Nickenig G, Estevez-Loureiro R, Franzen O, et al. Percutaneous mitral valve edge-to-edge repair: in-hospital results and 1-year follow-up of 628 patients of the 2011-2012 Pilot European Sentinel Registry. J Am Coll Cardiol 2014;64:875-84.
12. Puls M, Lubos E, Boekstegers P, et al. One-year outcomes and predictors of mortality after MitraClip therapy in contemporary clinical practice: results from the German transcatheter mitral valve interventions registry. Eur Heart J 2016;37:703-12.
13. Sorajja P, Mack M, Vemulapalli S, et al. Initial Experience With Commercial Transcatheter Mitral Valve Repair in the United States. J Am Coll Cardiol 2016;67:1129-40.
14. Yeo KK, Yap J, Yamen E, et al. Percutaneous mitral valve repair with the MitraClip: early results from the MitraClip Asia-Pacific Registry (MARS). EuroIntervention 2014;10:620-5.
15. Surder D, Pedrazzini G, Gaemperli O, et al. Predictors for efficacy of percutaneous mitral valve repair using the MitraClip system: the results of the MitraSwiss registry. Heart 2013;99:1034-40.
16. Gajjar M, Yadlapati A, Van Assche LM, et al. Real-Time Continuous Left Atrial Pressure Monitoring During Mitral Valve Repair Using the MitraClip NT System: A Feasibility Study. JACC Cardiovasc Interv 2017;10:1466-7.
17. Utsunomiya H, Itabashi Y, Kobayashi S, et al. Effect of Percutaneous Edge-to-Edge Repair on Mitral Valve Area and Its Association With Pulmonary Hypertension and Outcomes. Am J Cardiol 2017;120:662-9.
18. Rammos C, Zeus T, Balzer J, et al. Percutaneous Mitral Valve Repair in Mitral Regurgitation Reduces Cell-Free Hemoglobin and Improves Endothelial Function. PLoS One 2016;11:e0151203.
19. Rassaf T, Balzer J, Zeus T, et al. Safety and efficacy of deep sedation as compared to general anaesthesia in percutaneous mitral valve repair using the MitraClip system. Catheter Cardiovasc Interv 2014;84:E38-42.
20. Lesevic H, Karl M, Braun D, et al. Long-Term Outcomes After MitraClip Implantation According to the Presence or Absence of EVEREST Inclusion Criteria. Am J Cardiol 2017;119:1255-61.
21. Praz F, Spargias K, Chrissoheris M, et al. Compassionate use of the PASCAL transcatheter mitral valve repair system for patients with severe mitral regurgitation: a multicentre, prospective, observational, first-in-man study. Lancet 2017;390:773-80.

Cite this article as: Rassaf T. The cardiologist's way to do the Alfieri stitch: transcatheter mitral valve edge-to-edge repair revisited. J Thorac Dis 2017;9(12):4832-4834. doi: 10.21037/jtd.2017.10.134

