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Transcatheter mitral valve repair and replacement; current therapies and general evaluation of new approaches

Katater aracılığıyla mitral kapak onarımı ve değiştirilmesi; güncel tedaviler ve yeni yaklaşımların genel değerlendirmesi

Yakup Alsancak, Ahmet Seyfeddin Gürbüz, Mehmet Akif Düzenli

Necmettin Erbakan University, Faculty of
Medicine, Division of Cardiology, Konya,
TURKEY

Abstract

There have been a revolution in catheter based therapies for structural valvular heart diseases in last decade and many incredible improvements in the percutaneous treatment of mitral and aortic valve diseases. The use of transcatheter mitral valve repair has gained widespread acceptance in worldwide. More than 50.000 patients have been treated with percutaneous edge-to-edge repair system or annuloplasty systems. Although the most experience has been obtained with MitraClip®, using of percutaneous direct and indirect annuloplasty devices have been on the forefront in recent years. In addition, the percutaneous mitral valve replacement, like the transcatheter aortic valve replacement (TAVI), will also be mentioned more in the near future.

Keywords: Mitral valve, MitraClip, Mitral regurgitation, Percutaneous

Öz

Son on yılda yapısal kalp kapakçık hastalıklarının kateter bazlı tedavilerinde bir evrim meydana gelmiş, mitral ve aort kapak hastalıklarının perkütan tedavisinde inanılmaz birçok gelişme olmuştur. Transkateter mitral kapak onarımı, dünya çapında yaygın kabul görmüştür. 50000'den fazla hasta perkütan uc-uca tamir sistemi veya perkütan anuloplasti sistemleri ile tedavi edilmiştir. En fazla deneyim MitraClip® ile elde edilmiş olsa da, perkütan direkt ya da indirekt anuloplasti cihazlarının kullanımı son yıllarda ön plana çıkmıştır. Ek olarak, transkateter aort kapak replasmanı (TAVI) gibi perkütan mitral kapak replasmanı da yakın gelecekte daha çok gündeme gelecektir.

Anahtar kelimeler: Mitral kapak, MitraClip, Mitral yetersizlik, Perkütan

Introduction

Percutaneous heart valves repairs or replacements are among the most popular topics in interventional cardiology within the last decade. Particularly, the fact that percutaneous aortic valve replacement (TAVI) has been widely used in daily life plays an important role in the investigation of percutaneous treatment of other heart valves. At this point, TAVI is recommended in patients who are not suitable for surgical aortic valve implantation as assessed by the Heart Team with class I and level evidence B indication according to recently published Guidelines for the management of valvular heart disease by European Society of Cardiology [1]. Although mitral valve regurgitation is the most prevalent valvular heart disease, transcatheter mitral valve therapies have progresses more slowly due to the complex anatomy of mitral valve [2].

Corresponding author / Sorumlu yazar:

Yakup Alsancak

Address / Adres: Necmettin Erbakan Üniversitesi
Tıp Fakültesi, Kardiyoloji Kliniği, Konya /
Türkiye

E-mail: dryakupalsancak@gmail.com

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In patients with severe degenerative or primary mitral valve regurgitation and secondary mitral regurgitation who undergo coronary artery bypass graft surgery with greater than 30% left ventricular ejection fraction, surgically mitral valve repair is the generally accepted “gold standard” treatment of choice [1]. However, as known, overall one of the two patients with severe MR cannot be operated on due to accompanying comorbid conditions and too high risk nature for open heart surgery [3]. Various catheter based mitral valve repair methods have been applied and developed for these patients who have extremely high mortality and cannot be operated.

Percutaneous mitral valve repair systems for mitral regurgitation

Percutaneous edge-to-edge repair system: MitraClip

MitraClip system (Abbott Vascular, Santa Clara, CA) has the most experience method in percutaneous mitral valve repair in worldwide and recommended as the only percutaneous treatment method in current guidelines [1]. This technique is aimed to decrease mitral regurgitation with create a double orifice by attaching the mitral valve leaflets to each other (edge-to-edge leaflet repair) and the clip is implanted percutaneously via a transseptal approach under general anesthesia or deep sedation and transesophageal ultrasound and fluoroscopy guidance. The efficacy and safety of the MitraClip method has been demonstrated with several studies [4,5]. As a general outcomes of these studies that; the MitraClip is less effective at reducing mitral regurgitation than a surgical approach, but it was found to be associated with a favorable safety profile, similar mortality rates as well as similar improvements in functional status, quality of life, and left ventricular size during follow up. The results of these studies led to its CE (Conformite Europeenne) marked approval in 2008 for use in patients with symptoms due to primary and secondary mitral regurgitation who are at high risk for surgery and FDA approval in 2013 only for primary mitral regurgitation. Currently, the guidelines of European Society of Cardiology recommend this method with a class II b indication for primary and secondary mitral valve regurgitation, the guidelines of American Heart Association provide a class II b indication for primary mitral valve regurgitation in symptomatic patients who are at prohibitive risk for mitral valve surgery [1,6].

Transcatheter direct or indirect mitral annuloplasty systems

Recurrent mitral regurgitation after the MitraClip therapy may be observed. This situation can explain with continued mitral annular dilatation. In addition to the percutaneous edge-to-edge mitral leaflet repair, the annulus of mitral apparatus is the other target for catheter based treatment of choice. Although several methods have been investigated in the last two decade, we have no FDA approved direct or in-direct annuloplasty device, and only three devices have received Conformite Europeenne (CE) mark for percutaneous mitral valve annuloplasty. The only currently CE approved device in the category of indirect annuloplasty is the Carillon Mitral Contour

System (Cardiac Dimensions, Kirkland, WA), which has been used in over 500 patients. In this method, the device is placement via the jugular vein to the coronary sinus. After the deployment of device, manual traction is performed on the delivery system to compress the periannular tissue neighborhood of posterior annulus. Several limitations of this device have been reported, including reports of potential nitinol wire fracture with or without clinical events and especially compression of circumflex coronary artery [7]. This technique peri-procedural success is lower than MitraClip according to published studies.

The Cardioband device (ValtechCardio, OrYehuda, Israel) is one of the direct annuloplasty percutaneous techniques mimicking to surgical annuloplasty. The device is implanted percutaneously via transseptal approach under general anesthesia with transesophageal echocardiography and fluoroscopy guidance. The safety and feasibility of the procedure was shown with a few studies with low participants [8]. Interestingly, periprocedural device success was very high and the recurrence of mitral regurgitation was lower than other percutaneous mitral valve repair system during follow up. That may be considered that the rate of using this method in daily practice will increase further.

The Mitralign device (Mitralign, Tewksbury, MA) is the another direct annuloplasty method via the trans-femoral arterial approach with CE marked. Specifically, the P1 and P3 scallops regions of the posterior mitral annulus are targeted in order to decrease the anterior-posterior dimension. The mitral valve is punctured from the ventricular surface of the posterior annulus to pass the atrial side allowing for the delivery of pairs of pledgeted sutures. These pledgets are then cinched and locked to reduce the annular diameter. Peri-procedural device success was lower than other techniques and further studies are needed to understand the Mitralign effectiveness [9].

Transcatheter mitral valve replacement

Transcatheter mitral valve replacement is a new promising therapeutic option especially in patients who have high surgical risk for mitral valve surgery. The development of percutaneous mitral valve replacement system has been more complex compared to percutaneous aortic valve replacement systems due to asymmetric morphology of mitral annulus, the proximity of the mitral valve to the left ventricular outflow tract and the heterogeneity of pathologies of patients with mitral valve regurgitation [10,11].

Several types of transcatheter mitral valves are being developed and the effectiveness and safety of these systems have been tested with first clinical studies or case based interventions. These implantations were performed with different approach such as transapical, transatrial or transfemoral or transseptal. Significant hemodynamic compression of left ventricular outflow tract (LVOT), device embolization, significant paravalvular leak, valve thrombosis and perforation are known as the main complications of procedure [12]. The Fortis valve (Edwards Lifesciences, Irvine, CA), The Tendyne Bioprosthetic Mitral Valve System (Tendyne Holdings, Roseville, MN), the CardiAQ-Edwards transcatheter mitral valve system (Edwards Lifesciences, Irvine, CA), the Tiara system (Neovasc Inc.,

Richmond, British Columbia, Canada) and the Intrepid Twelve system (Medtronic, Minneapolis, MN) are using for transcatheter mitral valve replacement and the devices are under clinical evaluation [13]. This treatment modality is at an early phase for clinical using, and progress will be significantly slower than the development of transcatheter aortic valve replacement due to the complexity of the mitral valve anatomy and different pathological types.

Conclusion

The mortality rate in patients with severe mitral regurgitation reaches 50% at 5 years of follow-up, and many of the surviving patients had one or more re-hospitalization for decompensated heart failure within the 5 years after the first diagnosis [3,14]. Although it is known that gold standard treatment for degenerative mitral regurgitation is surgery, it is unclear which therapeutic approach is superior for functional mitral regurgitation. So, we need more data to accept that percutaneous treatments modalities are more effective than medical treatment. Herein, the ongoing studies (The ongoing Cardiovascular Outcomes Assessment of the MitraClip® Percutaneous Therapy for Heart failure Patients with Functional Mitral Regurgitation (COAPT), the Randomized Study of the MitraClip Device in Heart Failure Patients with Clinically Significant Functional Mitral Regurgitation (RESHAPE) and CARILLON Mitral Contour System® for Reducing Functional Mitral Regurgitation (REDUCE FMR)) will reveal whether percutaneous edge-to-edge repair or indirect annuloplasty are superior to medical treatment. And also, large scale studies with long term follow up will be a guide for clinical use of direct percutaneous annuloplasty devices.

Finally, we need more clinical experiences to appreciate consistent safety and efficacy of percutaneous mitral valve replacement system for severe mitral regurgitation or severe calcific mitral stenosis. There are no mitral devices yet established itself decently or approved for use in daily practice anywhere in the world.

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