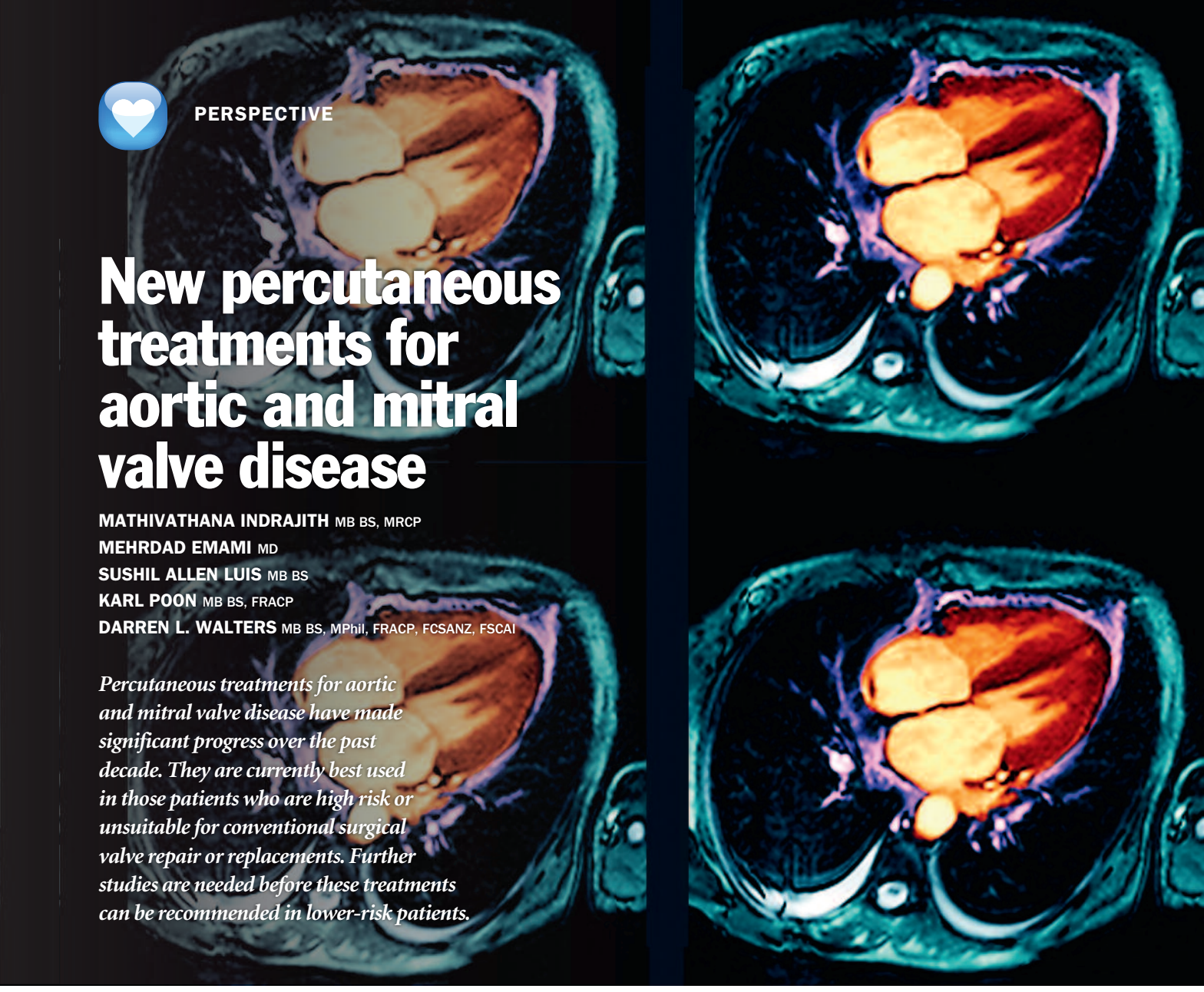

PERSPECTIVE

New percutaneous treatments for aortic and mitral valve disease

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Percutaneous treatments for aortic and mitral valve disease have made significant progress over the past decade. They are currently best used in those patients who are high risk or unsuitable for conventional surgical valve repair or replacements. Further studies are needed before these treatments can be recommended in lower-risk patients.

The past decade has seen significant developments in the percutaneous treatment of patients with aortic and mitral valve disease. Transcatheter aortic valve replacement (TAVR) and percutaneous mitral valve repair (PMVR) have progressed in a relatively short period of time from novel concepts to real therapeutic options for an increasing population of patients on a global scale.

Pivotal randomised controlled trials have been performed for both technologies.[1,2] These have shown them both to be noninferior to proven surgical techniques, and TAVR to have mortality benefits over conservative conventional treatment. TAVR and PMVR have a role in the treatment of older patients for whom surgery has been declined or for whom surgery poses an unacceptably high risk of serious complications, including death.[3-5]

Careful patient selection is an essential part of the successful application of these new percutaneous valve therapies. To this end, the concept of a heart care team approach has emerged as a vital strategy for the selection of patients who stand to gain

Key points

- **New treatments for valvular heart disease target older patients at high surgical risk.**
- **Transcatheter aortic valve replacement may be indicated for selected patients with symptomatic severe aortic valve stenosis.**
- **Percutaneous mitral valve repair may be considered for selected patients with symptomatic severe mitral regurgitation.**
- **Surgery continues to be the standard therapy for most patients with these conditions.**
- **Ongoing clinical trials will determine the role of these novel treatments in the future.**

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the most from these new and expensive technologies.[6-8] A heart care team assessment may typically include the treating cardiologist, an interventional cardiologist, an echocardiologist and a cardiothoracic surgeon. This has ushered in a new era of structural intervention in cardiology practice.

Questions frequently asked by GPs on TAVR and PMVR are answered on this page.

Aortic valvular disease

Aortic valve stenosis is the most common acquired heart valve disease in elderly patients, affecting 4.6% of people over the age of 75 years.[9] Symptomatic aortic valve stenosis is associated with an approximately 50% two-year mortality. This poor prognosis has prompted a focus on timely intervention in this group of patients.[10] Although surgical aortic valve replacement (sAVR) is associated with demonstrable survival benefits overall, it is not always practical in high-risk patients who have significant comorbidities, including older age, severe heart failure, previous cardiovascular disease, pulmonary disease, renal dysfunction and diabetes. Between 25 and 50% of patients with symptomatic severe aortic valve stenosis do not undergo sAVR because of their frailty and high surgical risk.[11-14] TAVR, where feasible, may play a significant role in the management of this patient group.

Balloon aortic valvuloplasty

Balloon aortic valvuloplasty is a technique that was largely abandoned in the 1990s because it provided only temporary relief of symptomatic aortic stenosis and was associated with a high rate of procedural complications.[15] In the current era, balloon aortic valvuloplasty nevertheless remains an important therapy as a bridge to TAVR or sAVR in selected patients, especially those with symptomatic heart failure or shock, or as a palliative option in those unsuitable for intervention. It is also useful in selecting patients who might benefit from TAVR.[15]

Balloon aortic valvuloplasty does not alter the patient's prognosis and restenosis is common following the procedure, occurring in up to 50% of patients at one-year follow up. However, balloon aortic valvuloplasty can be repeated as required for symptomatic relief, and complications are less frequent with the current generation of devices and techniques.[16]

Transcatheter aortic valve replacement

The first TAVR was performed by Alain Cribier in 2002 in a 57-year-old man with severe aortic valve stenosis, cardiogenic shock and multiple comorbidities, who had been declined for sAVR.[17] Today, there are two commonly available transcatheter valves used in clinical practice: the Edwards SAPIEN® valve, which has both US Food and Drug Administration (FDA) approval and European Regulatory Conformité Européne (CE) mark of approval (Figures 1a and b), and the CoreVALVE®

Frequently asked questions by GPs

What is my role after a percutaneous valve procedure?

- Review of femoral vascular access sites is required by the patient's treating GP at seven days post-procedure.
- Assess adequacy of wound healing and to clinically exclude pseudoaneurysm formation:
  - clinical signs of pseudoaneurysm formation include groin site tenderness, evidence of a pulsatile expansile mass on palpation and a new bruit on auscultation.
- Assess cardiac failure and fluid status with adjustment of diuretic therapy as required.
- Manage antiplatelet and anticoagulation therapy as suggested by the implanting cardiologist:
  - patients receiving the MitraClip®require a minimum of one month of dual antiplatelet therapy, with aspirin and clopidogrel, followed by a further five months of aspirin alone post-device implantation
  - patients with transcatheter aortic valve replacement implants require six months of dual antiplatelet therapy
  - patients taking warfarin in addition to antiplatelet therapy will require intensified monitoring and tailored treatment plan.

What post-procedural follow up will my patients receive?

- Ongoing follow up with their treating cardiologist following device implantation is required.
- Clinical and echocardiographic follow up are routinely performed at one, six, 12 and 24 months post-procedure.

What can I do to help minimise strokes and TIAs after the procedure?

- Appropriate use of antiplatelet agents in the early post-procedure phase is likely to reduce the incidence of cerebrovascular events.
- Patients with a past history of ischaemic cerebrovascular events should receive routine ongoing antiplatelet agents as recommended by the Australian Therapeutic Guidelines.
- Patients with atrial fibrillation should be assessed for their thromboembolic risk ($CHADS_2$ and CHA_2DS_2-VASc score) and consideration given to anticoagulation with warfarin where appropriate.
- Liaison with the treating cardiologist is important in order to determine the optimal duration of dual antiplatelet therapy when used in combination with warfarin.

Which patients are suitable for these new percutaneous treatments rather than standard surgical valve surgery?

- Patients who pose an unacceptably high risk of morbidity and mortality from conventional surgical procedures can be considered for these new percutaneous valve procedures.
- Patients eligible and suitable for open surgery should continue to undergo conventional valve surgery.

Figures 1a and b. Edwards SAPIEN® XT valve (currently pending Therapeutic Goods Administration approval) a (left). Side view. b (right). Top view. Images courtesy of Edwards Lifesciences.

Patient inclusion and exclusion criteria for transcatheter aortic valve replacement[6,7]

Inclusion criteria

- Severe symptomatic calcific degenerative aortic valve stenosis
- Adequate access vessel calibre (diameter >6 mm)
- Acceptable aortic valve annular diameter (20 to 29 mm)
- Unacceptably high risk of surgical morbidity and mortality, as defined by:
  - logistic EuroSCORE of more than 20% or a Society of Thoracic Surgeons mortality score more than 10%, and/or
  - other factors that may be associated with significant surgical morbidity and mortality, including:
    - age older than 80 years
    - cirrhosis of the liver (Child class A or B)
    - pulmonary insufficiency
    - previous cardiac surgery
    - porcelain aorta
    - pulmonary hypertension (>60 mmHg)
    - recurrent pulmonary embolus
    - right ventricular insufficiency
    - previous mediastinal radiotherapy
    - severe connective tissue disease resulting in a contraindication to surgery
    - cachexia

Exclusion criteria

- Active infection or sepsis
- Hypersensitivity or contraindication to antiplatelet therapy
- Bleeding diathesis or coagulopathies
- Life expectancy of less than 12 months
- Severe mitral regurgitation
- Subaortic stenosis
- Unrevascularised coronary artery disease (could consider prior percutaneous intervention)
- Femoral arterial diameter less than 6 mm or significant tortuosity (could consider subclavian or transapical approaches)
- Left ventricular thrombus (is an absolute contraindication)

valve, which has CE mark of approval. Additionally, several new percutaneous valves are in early clinical trials, including the Lotus™ Valve and Portico™ valve.[6,17] The indications for these technologies continue to be the subject of debate as evidence from clinical trials and registries continues to emerge.

Both the Edwards SAPIEN® and CoreVALVE® valves are implanted via a transarterial retrograde approach. Alternative techniques include subclavian arterial and transapical access for device implantation, with the transapical route requiring a mini-thoracotomy and left ventricular apical puncture.[6,8]

Currently TAVR is mainly considered when traditional surgical valve implantation is deemed unfeasible or if surgical risk is unacceptably high. However, it is still not approved in Australia by the Therapeutic Goods Administration. The technique is particularly suited to the frail elderly patient who may have multiple medical comorbidities.

Patient inclusion and exclusion criteria for TAVR are given in the box on this page.

The Placement of Aortic Transcatheter Valves (PARTNER) trial compared the Edwards SAPIEN® valve with standard medical therapy and sAVR in patients deemed to be at high surgical risk. One-year all-cause mortality was comparable to sAVR in the high-risk population, and superior to medical management.[12] Additionally, TAVR reduced the rate of rehospitalisation compared with medical therapy, conferring a 21.8% absolute risk reduction.

The most significant complication following TAVR is stroke, with reported rates of up to 10% in some series.[6] The risk of stroke following TAVR is higher when compared with both surgical and medical management, with the PARTNER trial reporting risks of 6% versus 3.1% for surgical management and 10% versus 4.5% for medical management.[3,12] Procedural stroke rates are probably attributable to embolisation of friable material from diseased and calcified aortic valves or aortic arches.

CoreVALVE® implantation is associated with an increased risk of requiring permanent pacemaker implantation (about 25%), which is thought to be attributable to the prosthesis length.[6] However, this risk is not increased with the use of the Edwards SAPIEN® valve.

Follow-up transthoracic echocardiography demonstrates mild regurgitation in 22.4% of patients and moderate paravalvular regurgitation in 34.4% of patients. Moderate regurgitation has been associated with increased mortality at two years following therapy.[4] Optimal sizing of the valve to the annulus may be an important factor in determining the degree of paravalvular leak. Further investigation is required in the future to improve the accuracy of left ventricular outflow tract assessment to ensure optimal device sizing and to minimise the frequency of paravalvular regurgitation.[18]

Case scenario

An 84-year-old man presented with shortness of breath on minimal exertion, including showering, and an exertional tolerance of just 40 metres. This was on a background of severe ischaemic cardiomyopathy (left ventricular ejection fraction of 31%) and previous coronary artery bypass grafting performed 15 years prior. His other significant medical history included a previous stroke with good functional recovery, paroxysmal atrial fibrillation, hypertension and dyslipidaemia. Echocardiography confirmed severe aortic stenosis and coronary angiography demonstrated occlusion of his venous graft to the left circumflex coronary artery.

The patient was evaluated by the cardiac surgeons with a view to aortic valve replacement and repeat of single vessel grafting to the left circumflex coronary territory. In light of technical difficulties related to a redo sternotomy, together with additional surgical risk posed by his comorbidities, he was deemed unsuitable for a conventional open surgical operation. His risk of surgical mortality was estimated at approximately 5%, with a combined risk of morbidity and mortality of 29%.

Further assessment regarding suitability for TAVR was performed. His unrevascularised left circumflex coronary territory was revascularised percutaneously with a stent to the left circumflex artery. He subsequently underwent transcatheter aortic valve replacement with a good procedural result.

At 12-month follow up he was independently conducting all his activities of daily living. His exertional tolerance had significantly improved and he could walk about 300 metres.

Although the role of TAVR in low- and intermediate-risk populations remains uncertain, TAVR has been demonstrated to reduce mortality and morbidity in patients with severe aortic valve stenosis who are ineligible for conventional sAVR.[12] It has also been shown to be noninferior to sAVR in high-risk populations.[12] In addition, further analysis of the PARTNER trial demonstrates significant improvement in quality of life measures at an acceptable cost efficacy when compared with other therapies in common use.[3] In suitable high-risk patients, consideration should be given to evaluation regarding the patients' suitability for entry into one of the ongoing TAVR trials and registries.

Another indication for the use of TAVR, in selected cases, is to treat bioprosthetic valve failure. These patients are frequently deemed a high surgical risk or not candidates for further surgical intervention. Although this is an off-label use of the device on compassionate grounds, there are a growing number of reports of the use of TAVR in this setting.[19,20]

The case scenario on this page describes an elderly man's assessment for aortic valve replacement.

Mitral valvular disease

Mitral valvular disease is the second most common valvular lesion after aortic valve stenosis.[9] There have been recent developments in percutaneous treatment of patients with mitral regurgitation. The MitraClip® system is now approved in Australia for the treatment of patients with functional and degenerative mitral regurgitation.

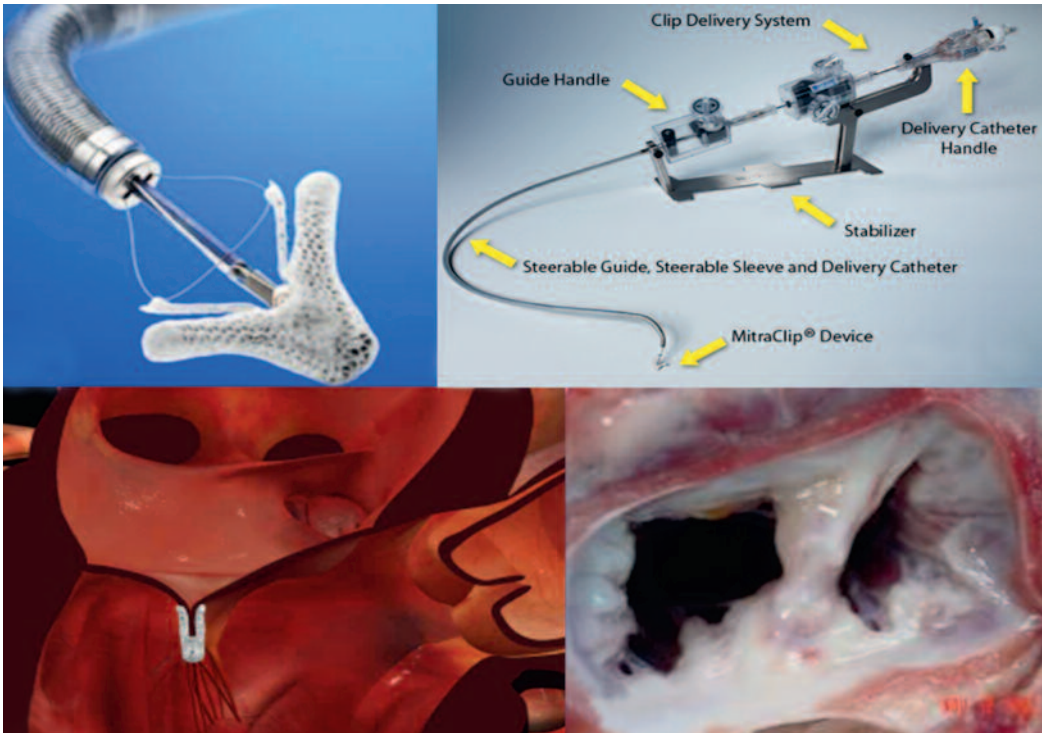
Mitral regurgitation

Dysfunction of any of the components of the mitral valvular–ventricular complex can lead to mitral regurgitation. Nonrheumatic mitral regurgitation can be mechanistically classified as degenerative or functional (Table 1).[21,22]

Traditional surgical treatment of patients with mitral regurgitation involves either mitral valve repair or replacement. Various attempts at percutaneous treatments for patients with mitral regurgitation have been made over the years, including with percutaneous annuloplasty rings; however, only the MitraClip® system has produced sufficiently satisfactory outcomes to be translated into clinical practice.

Table 1. Mechanisms of nonrheumatic mitral regurgitation

Classification	Mechanism	Examples
Functional	Ischaemic ventricle and/or papillary muscle dysfunction	Leaflet and subvalvular abnormalities Dilated left ventricle/annulus
Degenerative	Dilated cardiomyopathy Myocardial infarction	Mitral valve prolapse Flail mitral valve leaflet Mitral leaflet perforation Ruptured chordae/papillary muscle



Figures 2a to d. MitraClip® device. a (top left). Close up of MitraClip® device attached to delivery catheter. b (top right). MitraClip® delivery system. c (bottom left). Schematic diagram demonstrating MitraClip® device attached to the mitral valve leaflets. d (bottom right). Mitral valve six months post-deployment of MitraClip® device (in a porcine model) demonstrating a double orifice mitral valve with MitraClip® attached at the midpoint. Images courtesy of Abbott Vascular.

MitraClip®

The basis of the MitraClip® system stemmed from a surgical technique pioneered by Alfieri and colleagues in 1992, in which the leaflets were approximated with a stitch, creating a double orifice to reduce mitral regurgitation.[23] The excellent results initially attained were not easily replicated and the procedure fell out of favour in the surgical arena. However, the technique lent itself to percutaneous approaches and the first MitraClip® was implanted in 2003.[24] The MitraClip® is constructed from cobalt-chromium and covered with polyester. It has two arms that are about 8 mm long and 4 mm wide (Figures 2a to d). On the inner aspect of the arms are two corresponding 'grippers' that help secure the leaflets.

The MitraClip® procedure takes one to four hours, is performed under general anaesthesia and relies heavily on transoesophageal echocardiographic guidance. A steerable guide catheter is inserted in the right femoral vein, up to the right atrium then into the left atrium. Use of the steerable catheter requires a high level of technical skill from the operator, arguably more than that needed for TAVR given the challenging three-dimensional (3D) nature of a tiny clip in a mitral valve apparatus that moves in a complex manner. With more experience, it is now not uncommon for more than one clip to be required to satisfactorily reduce mitral regurgitation. Clip embolisation, dislodgement and thrombosis, as well as haemolysis, stroke and endocarditis, are pertinent risks and complications.

Insertion of the MitraClip® requires an experienced team of echocardiologists and interventional cardiologists who are required to define specific properties of the mitral valve apparatus using transoesophageal echocardiographic and 3D technology. A centrally located regurgitant jet is preferred. Length and depth of leaflet coaptation, leaflet thickness and calcification, mobility, specific types of leaflet involvement, ventricular function, as well as right ventricular function and pulmonary pressure, are all important factors.

The MitraClip® has been implanted in more than 5000 patients worldwide, and every case has been part of either a registry or a randomised controlled trial, thus providing a large volume of data supporting its use.[25-28]

The endovascular valve edge-to-edge repair study (EVEREST-II) was a prospective multicentre randomised controlled study designed to assess the safety and efficacy of the MitraClip® system for patients diagnosed with grade 3 (moderately severe) or grade 4 (severe) mitral regurgitation.[25] It also compared the system with conventional surgical repair or replacement, which was an ambitious comparison because patients were otherwise acceptable for open operations. The MitraClip® was compared with a well-established treatment option with decades of experienced use. The study enrolled 279 patients in a two to one randomisation between the MitraClip® (n=184) and surgery (n=95). The demographics were well matched between the two groups. The primary endpoint of the trial was a composite of freedom from death, mitral valve surgery or more than moderate (higher than grade 2) mitral regurgitation at one year. Two-year data have recently been presented at the American College of Cardiology scientific sessions (unpublished). The MitraClip® was found to be non-inferior to mitral valve surgery. MitraClip® use was associated with improved safety results, although much of this was due to increased transfusion rates in the surgical arm. At 24-month follow up, efficacy remained sustained with 78% of patients still not having undergone

mitral valve surgery. Despite similar symptomatic relief, however, patients in the MitraClip® group had significantly more residual mitral regurgitation and were more likely to require surgery for mitral valve dysfunction than those in the surgical arm.

Technical limitations prevent the use of the MitraClip® device, with just 20% of screened patients having mitral valve pathology deemed technically suitable for MitraClip® use. Additionally, the substantial residual mitral regurgitation in the MitraClip® group raises concerns, particularly regarding its impact on long-term outcomes.

Parallel to the EVEREST-II study, patients at high surgical risk not considered eligible for open surgery were enrolled into a high-risk registry. Compared with the EVEREST-II population, this cohort was older, had more significant comorbidities, was more likely to experience functional mitral regurgitation and had poorer left ventricular function. This high-risk patient group derived benefit from the MitraClip® therapy, with improvements in symptoms, reduced hospitalisations and favourable remodeling of the left ventricle.[5] In the real world European ACESSS registry, most of the 567 patient undergoing the MitraClip® procedure resembled this patient group.[29] This high-risk patient cohort probably represents those patients most likely to benefit from a percutaneous procedure rather than open surgery.[29] Young, lower risk patients who represent good surgical candidates are probably best served by open or minimally invasive surgical repair.

Conclusion

Several procedures are currently undergoing clinical trial for the percutaneous treatment of aortic and mitral valve disease. These treatments are currently used in patients who are high risk or unsuitable for conventional surgical valve repair or replacements. It is clear that these percutaneous valve treatments can offer significant clinical and quality of life benefits to selected individuals, especially older, high-risk or inoperable patients who would otherwise have few therapeutic options. Patient assessment and selection, via a multidisciplinary team approach including cardiologists and cardiothoracic surgeons, is essential for successful percutaneous valve treatment. Further studies with longer follow up will be needed before these percutaneous therapies can be recommended in lower-risk patients who would otherwise represent potential surgical candidates. **CT**

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