Mitral Transcatheter Edge-to-edge Repair: British Cardiovascular Intervention Society Position Statement

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Abstract

Transcatheter mitral leaflet repair is a non-surgical technique used to treat severe mitral regurgitation. The technique has matured significantly since its commercial introduction, and with device iteration and increasing operator experience, it is now an important treatment option for patients at higher risk for conventional mitral valve surgery. Randomised clinical trials have established the safety and efficacy of the technique in the treatment of primary and secondary mitral regurgitation, and its use was approved by the National Institute for Health and Care Excellence in 2019. This position statement summarises the clinical evidence and indications for the procedure and provides expert consensus on best practice in terms of patient selection, the procedure and post-procedure care. Standards are also described with respect to team composition, minimum case volume and collection of procedural and outcome data.

Keywords

Percutaneous mitral leaflet repair, mitral regurgitation, British Cardiovascular Intervention Society guidance

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Transcatheter edge-to-edge repair (TEER) of the mitral valve is a percutaneous catheter-based procedure used to treat patients with severe mitral regurgitation (MR). It is an adaptation of a surgical technique, the Alfieri stitch, where a suture is used to bring the free margins of the mitral valve leaflets together at the site of the regurgitant jet (leaflet approximation) to create a double orifice. The technique can be used to treat both primary (degenerative) and secondary (functional) MR. The procedure was first carried out in 2003 using the Evalve system, later the MitraClip (Abbott Vascular), which received a CE mark in 2008, followed by Food and Drug Administration approval in 2013 for primary MR, and in 2019 for secondary MR. A second device, the PASCAL system (Edwards Lifesciences), became available in 2019.

Mitral TEER was expanding in the UK when commissioning was withdrawn in 2013 to be replaced by the commissioning through evaluation process. This ran from 2013 to 2017 and included only three UK centres and produced no data of value. The National Institute for Health and Care Excellence used international data to approve percutaneous leaflet repair in 2019 for patients at high surgical risk.[1] The procedure was commissioned for primary MR later the same year, and the number of UK centres offering treatment has increased to 23.[2] Despite this increase in availability, the number of mitral TEER procedures was 5 per million population in 2021, compared to 77 per million in Germany and 44 per million in Switzerland.[3] There has also been considerable geographical variation in uptake, with a fivefold difference between procedural volume per million in London compared with the north of England.

Evidence

A single randomised trial compared TEER to conventional surgical repair.[4] Seventy per cent of the patients included in the study had primary MR.

Freedom from death, reintervention or severe MR was more common in the surgical group (73% versus 55%), but safety strongly favoured the percutaneous procedure. More contemporary data from the US Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry show that approximately 34,000 procedures were undertaken from 2014 to 2020, predominantly to treat primary MR (71%). Procedural success was 98%, with a reduction in MR to less than or equal to moderate in 91%. In-hospital mortality was 2.2%.[5] Increased experience, refinements in technique and device iteration have led to improved procedural outcomes.[6]

Treatment of patients with secondary MR with TEER has now been examined in four randomised trials.[7–10] The COAPT study included patients who fulfilled strict anatomical criteria and were on maximal guideline-directed medical therapy. It demonstrated a mortality reduction at 2 years with TEER using the MitraClip device (29% versus 46%). By contrast, the MITRA-FR study, a 'standard clinical practice' trial, showed no benefit. The difference in outcome between the two studies was driven principally by patient selection, with COAPT including patients with more severe MR, less severe ventricular dilatation and for whom guideline-directed medical therapy had been optimised before the intervention. More recently, RESHAPE-HF2 reported similar outcomes to COAPT in 505 patients with a 37% rate of death or heart failure hospitalisation in the TEER group compared to 59% with medical therapy.[9] In the smaller MATTERHORN study, TEER was non-inferior to surgical mitral valve repair/replacement in a lower-risk cohort.[10]

Indications

Mitral TEER should be considered for:

- patients with severe symptomatic primary MR who are anatomically suitable for TEER and are not considered to be good candidates for mitral valve surgery; and
- patients with severe symptomatic secondary MR despite optimal medical therapy who are not considered to be good candidates for mitral valve surgery.

Elective, urgent and emergency TEER should all be considered. Most cases will be elective, but treatment of acute decompensated primary mitral valve regurgitation should increasingly be offered as an alternative to high-risk surgery.

Pre-procedure

Patients are usually referred for mitral TEER by a cardiologist or cardiac surgeon. Patients will have had a baseline transthoracic echocardiogram but may not have had a transoesophageal echocardiogram (TOE) at the time of referral. The operator should ideally see the patient in person and satisfy themselves that they are a good candidate for the procedure, with a good chance of meaningful clinical improvement. Factors that may influence a decision not to proceed include a relative lack of symptoms, severely impaired left ventricular function, adverse mitral valve anatomy, patient ambivalence, physical frailty, poor mobility and cognitive impairment.

A pre-procedure TOE may be requested, although increasingly a good quality transthoracic echocardiogram will suffice.

If there are doubts about the relative merits of surgery versus TEER, the case should be discussed with a multidisciplinary team (MDT) that should include a minimum of a relevant cardiac surgeon, cardiac anaesthetist, imaging and interventional cardiologists. If the decision to undertake TEER is uncontentious, discussion at an MDT may not be necessary.

Imaging Requirements

TEER is very dependent on high-quality interventional echocardiography to guide the procedure. Each service should have a minimum of one, but ideally two or more, appropriately trained imaging specialists (physiologist or cardiologist) who can direct the procedure. Assessment should include:

- qualitative and quantitative assessment of MR severity;
- aetiology of MR;
- leaflet pathology (e.g. size, extent and location of affected scallop[s], length of flail segment and size of flail gap);
- leaflet length and quality, presence of leaflet tip or subvalvular calcification;
- coaptation plane; and
- mitral valve gradient and area.

Procedure

The procedure is carried out under general anaesthesia with TOE guidance. If the patient is anticoagulated, this may be continued throughout or briefly paused according to operator preference. Vascular access (usually right femoral vein) should be obtained using ultrasound guidance and, once obtained, full-dose IV heparin should be given prior to the transseptal puncture. Prophylactic IV antibiotics should be given.

The procedure can be done by two consultants, a consultant and a fellow, or one consultant alone. The optimal septal puncture position is usually mid-septal and posterior to achieve a height above the mitral valve annulus of greater than 4 cm. Once successfully crossed, the transseptal sheath is advanced into the left atrium (LA) and exchanged for an extra support guidewire. The device sheath is then positioned in the LA to facilitate delivery of the device (implant) and delivery system after appropriate de-airing. The delivery system and implant are steered towards the mitral valve under echocardiographic guidance. The strategy for treatment of the MR will depend on the pathology (degenerative or functional) and location (central A2/P2 or non-central) of the regurgitant jet. Device choice (MitraClip or PASCAL) will depend on operator preference.

Clip location, orientation, grasp quality, degree of reduction in MR, and presence of any stenosis are all assessed in real time by TOE, before a decision is made to release the device. A second and rarely a third device can be required to optimise MR reduction. Reduction in mean LA pressure has high specificity (particularly in patients with primary MR) but modest sensitivity for overall MR reduction. Patients with severe tricuspid regurgitation may rarely shunt right to left post-procedure requiring closure of the small atrial septal defect. Suture-based closure of the femoral vein access is usual. Reversal of heparin is not advised.

Mitral TEER is a remarkably low-risk procedure, despite the highly comorbid patient population. Device-related complications include single leaflet detachment (1.5–5%), device embolisation (0.1–0.7%), and leaflet injury (2%). Procedure-related complications include access site bleeding (1–4%), gastric or oesophageal injury from TOE (1–2%), cardiac tamponade (0.5%), and MI or stroke due to air embolism (1–3%).

Post-procedure

Following the procedure, the patient should be monitored intermittently for 2 hours before gentle mobilisation. Vascular access site and

procedure-related complications (such as cardiac tamponade or oesophageal bleeding) should be apparent early post-procedure. Patients can be discharged the next day or the same day. Repeat echocardiography should be done prior to discharge or at early follow-up. Patients should be commenced on a single anti-platelet agent for 6 months post-procedure unless they are anticoagulated.

In-person follow-up with transthoracic echocardiography is recommended at 6–12 weeks, although remote review is also reasonable in selected cases where the geographical area is large and face-to-face review is challenging.

Standards

TEER should be carried out in surgical cardiac centres to concentrate expertise and volume. All surgical centres should provide TEER as part of a complete MR service alongside surgical repair and replacement. There should ideally be a minimum of two consultant operators and two imaging operators who can provide the service alongside the associated specialised lab staff. Each centre should have a minimum of one but ideally two or more structural heart specialist nurses who can help coordinate the service, provide a patient point of contact, and contribute to patient follow-up. Centres need to be commissioned by NHS England (or the relevant regional commissioning authority) to undertake the procedure.

Implanting centres should have a comprehensive referral network with referring cardiologists to be able to discuss patient selection. An MDT should include outreach centres that refer in for TEER procedures, virtually or in person. Each centre should perform at least 25 cases per year, rising to 50 after 3 years. An operator who is undertaking more than 50 cases per year can be a trainer to consultant colleagues or fellows.

Operators should be able to manage complications relating to cardiac tamponade, device embolisation and vascular access. Operators should attend device training sessions before starting a programme. On-site proctoring for a minimum of 10 cases is necessary prior to going it alone. Training will usually occur at post-Certificate of Completion of Training or consultant level.

Procedural and outcome data should be entered into the Transcatheter Mitral and Tricuspid Valve Registry held at the National Institute for Cardiovascular Outcomes Research, which holds data on all percutaneous mitral and tricuspid procedures.

Conclusion

TEER is a safe and effective treatment for patients with severe symptomatic MR. The availability of TEER is currently limited to 23 sites but should be expanded to all cardiac surgical centres in the UK as part of a comprehensive MR service. ❑

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