Clinical Commissioning Policy Proposition:

Percutaneous mitral valve leaflet repair for primary degenerative mitral regurgitation

Reference: NHS England 1714

Prepared by NHS England Specialised Services Clinical Reference Group for Cardiac Services

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Contents

1 Executive Summary

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Plain Language Summary

About: Percutaneous mitral valve edge-to-edge leaflet repair for primary degenerative mitral regurgitation

The heart contains four valves which ensure the proper flow of blood through the heart. The mitral valve is on the left side of the heart and ensures the forward flow of blood from the upper chamber of the heart (left atrium) into the lower chamber (left ventricle). The left ventricle is the main pumping chamber of the heart. The valve has two leaflets (or flaps of tissue) that open and close to ensure blood travels in one direction into the left ventricle. Sometimes the valve does not close properly resulting in blood leaking back (regurgitating) into the left upper chamber (left atrium). If the volume of blood leaking backwards is large, the heart has to work harder to effectively pump blood through the body. Symptoms caused by the heart having to work harder are shortness of breath and fatigue and over time this will lead to fluid retention due to heart failure. This impacts on quality of life and makes daily activities harder.

The cause of mitral regurgitation is broadly divided into degenerative (or 'primary mitral regurgitation' where the valve itself is structurally abnormal) and functional (or 'secondary mitral regurgitation' where the valve is structurally normal, but another

condition affects the structure and/or function of the heart so that the valve cannot close properly). This proposition focusses on patients with primary degenerative mitral regurgitation (DMR).

About current treatments

The current standard of care is mitral valve repair or replacement surgery. Some patients however will not be able to undergo surgery because of the risk caused by other health conditions. These patients end up being treated with medication to try and control symptoms, but medical therapy cannot alter the underlying valve disease process.

About the new treatment

Mitral valve repair can now be undertaken without the need for open heart surgery. A less invasive procedure to repair the valve leaflets involves inserting a large flexible tube or catheter into a large vein in the groin which leads to the right side of the heart. This tube is passed to the left upper chamber of the heart (left atrium) and the valve leaflet repair device is advanced through this tube. The device is then advanced down to the mitral valve and positioned at the areas that are leaking. The device such as a clip brings the leaking portions of the two leaflets of the valve together so that the blood leaking back from lower chamber (left ventricle) into the upper chamber (left atrium) of the heart is reduced. The device replicates an accepted surgical repair technique called an “edge-to-edge leaflet repair” to improve the valve function and in selected patients this procedure can reduce the symptoms due to severe mitral regurgitation and can improve quality of life.

What we have decided

NHS England has carefully reviewed the evidence to treat primary, degenerative mitral regurgitation with percutaneous mitral valve edge-to-edge leaflet repair. We have concluded that there is enough evidence to consider making the treatment available.

Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to routinely commission percutaneous mitral valve edge-to-edge leaflet repair for mitral regurgitation. This document also describes the proposed criteria for commissioning, proposed governance arrangements and proposed funding mechanisms.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

A final decision as to whether percutaneous mitral valve edge-to-edge leaflet repair for mitral regurgitation will be routinely commissioned will made by NHS England following a recommendation from the Clinical Priorities Advisory Group.

2 Proposed Intervention and Clinical Indication

Primary or degenerative mitral regurgitation (DMR) describes pathology causing structural abnormality of the valve. Whilst there may be an indication for mitral valve surgery in the presence of symptomatic, severe DMR, a significant proportion of patients do not undergo surgery due to advanced age, frailty and co-morbidities. These patients have an increased risk of complications, prolonged intensive care unit stay and mortality which may make surgical option high risk or inappropriate. Progressive worsening mitral regurgitation however risks decline into a heart failure syndrome whereby the left ventricle struggles to maintain its function. The percutaneous mitral valve edge-to-edge leaflet repair system offers an alternative approach to treating patients with DMR who may be inoperable or at high surgical risk but would benefit from intervention.

Percutaneous mitral valve edge-to-edge leaflet repair is a minimally invasive procedure for the treatment of mitral regurgitation (MR, leaking of the mitral valve). It is performed in the cardiac catheterisation laboratory/hybrid theatre under general anaesthesia with trans-oesophageal echocardiography (ultrasound imaging by placing a specialised probe in the oesophagus) and X-ray guidance. The percutaneous leaflet repair system is based on a surgical technique described

as the "Alfieri stitch" but instead of a stitch, a device (for example a clip) is attached to the mitral valve leaflets to reduce retrograde blood flow through the valve. Vascular access is via the femoral vein which leads to the right atrium and trans-septal puncture is performed to access the left atrium and place a guide catheter. The device is delivered via this guide catheter within a delivery system. The device can be manoeuvred in the left atrium to approach the mitral valve. For example, in the case of the MitraClip device specifically, the arms of the clip open, the MitraClip is passed below the valve and then pulled back to grasp and bring together the segments of the two valve leaflets responsible for the leak. The reduction in MR is assessed and if necessary, the further adjustments in position may be made to improve the MR reduction. The device which is firmly attached to the valve leaflets is then detached from the delivery system which is withdrawn. Additional clips may be inserted to improve the MR reduction.

3 Definitions

Atrium: The heart is divided into four chambers that are connected by heart valves. The upper two chambers are called atria. The atria are separated into the left atrium and the right atrium by an interatrial septum.

Commissioning through Evaluation (CtE): An NHS England programme whereby a limited number of patients undergo treatments that are not routinely funded by the NHS but have been shown to have potential significant benefit. Treatment is offered within a limited timeframe and clinical and patient experience data are collected within this formal evaluation programme to inform NHS England funding decisions.

Computerised Tomography (CT): imaging scan which uses computer-processed combinations of many X-ray measurements taken from different angles to produce cross-sectional images from within a specific area.

Echocardiogram: scan of the heart which uses a probe that sends out sound waves which are reflected back by the muscle and tissues in your heart to give information about the structures of the heart

Mitral valve: The valve that ensures blood flows from the upper left chamber of the heart (left atrium) to the lower left chamber of the heart (left ventricle).

Mitral valve regurgitation: the leakage of blood backward through the mitral valve into the left atrium.

MitraClip: this is an example of a percutaneous mitral valve edge-to-edge leaflet repair technique. The device is used to treat mitral valve regurgitation for individuals who are unable to undergo open heart surgery. It is placed via a large catheter introduced from the groin and involves bringing together the two portions of the mitral valve leaflets causing leakage of blood.

Percutaneous: through the skin

Quality of Life (QoL): the individual's perception of their well-being with respect to daily life

Transoesophageal echocardiography (TOE): A transoesophageal echocardiogram is an alternative way to perform an echocardiogram. A specialised probe containing an ultrasound transducer at its tip is passed into the patient's oesophagus.

Trans-septal puncture: a technique to access the left atrium from the right atrium by crossing the inter-atrial septum which separates the upper two chambers of the heart

4 Aims and Objectives

This policy proposition considered: The clinical criteria under which NHS England will routinely commission percutaneous mitral valve edge-to-edge leaflet repair.

The objectives were to:

- Determine the clinical effectiveness and safety of percutaneous mitral valve edge-to-edge leaflet repair for primary degenerative mitral valve regurgitation
- Determine the patient eligibility criteria for percutaneous mitral valve edge-to-edge leaflet repair, ensuring the best clinical and cost-effective use and taking account of patient risk stratification.

- Ensure robust monitoring and follow up arrangements to enable audit of effectiveness of treatment and safety including adverse events and procedure/device related complications.

5 Epidemiology and Needs Assessment

Accurate epidemiological data for valvular heart disease (VHD) are limited, particularly for mitral regurgitation due to its different aetiologies.

- The most common cause of mitral regurgitation in the elderly population is degeneration. The gradual rise in life expectancy has been accompanied by a progressively increasing frequency of degenerative valve disease
- The preferred procedure in medically fit patients regardless of age is surgical mitral valve repair. However only 50% of patients with severe, symptomatic mitral valve regurgitation may be eligible for this
- The indication for is hence proposed for the very high risk or surgically inoperable population
- In contrast to percutaneous mitral valve edge-to-edge leaflet repair, medically treated patients are much more likely to suffer twice to three times as high annualised rates of death and readmissions for heart failure in the medium term (Everest II HR study, 2012; Swanns et al, 2014; Velasquez et al, 2015)
- The characteristics of this surgically inoperable group reflect, in general, the over 80 years of age population. Conventionally, very high or "prohibitive" surgical risk is defined by an estimated surgical 30-day mortality of ≥8% using the STS replacement calculator or ≥6%. Such scores have limited accuracy in identifying very high risk patients (see proposed criteria for commissioning)

Population estimate of need

A population-based study by Nkomo et al in 2006 on over 28,000 adults reported prevalence of valvular heart disease (VHD) in the USA increasing to 13.3% in those over 75 years of age. This study reported only moderate to severe VHD. The most common valve condition was mitral regurgitation with a prevalence in the over 75 years of age group of approximately 8%. The dominant aetiology of MR in the VHD Euro Heart Survey on Valvular Heart Disease in 2001 was degenerative and it

represents 65% of the MR population. Degenerative MR comprises a spectrum of pathologies, and mitral valve prolapse which is the main pathology treated with percutaneous mitral valve leaflet repair is seen in 50% of cases of degenerative MR. However, only half of the patients with severe symptomatic mitral regurgitation in the VHD Euro Heart Survey were offered surgery.

A population-based study in the UK using echocardiographic screening in primary care (OxVALVE) showed a higher prevalence of moderate or severe left sided valve disease increasing to 18.7% in the over 75 years old. This study projected that the number of patients with heart valve disease will double by 2046, due to an increasingly elderly population.

In a population of 53 million (England), 7.8% are aged over 75 years of age, giving a target population of 4 million.

Of this group, approximately 8% have moderate-severe degenerative mitral regurgitation which equals a population of 320,000.

50% or 160,000 of these will have significant mitral prolapse. Of these, 25%, i.e. 40,000 patients will have anatomy suitable for invasive mitral valve intervention such as percutaneous mitral valve edge-to-edge leaflet repair. This patient population will encompass a broad group of clinical scenarios including absence of symptoms, both acute and elective presentations and co-morbidities. Whilst patients who are inoperable or of high surgical risk should be considered for percutaneous mitral valve edge-to-edge leaflet repair, there will be some patients for whom any intervention will be futile. It is probable that only 10% of this population, i.e. 4000 patients might be considered for percutaneous mitral valve edge-to-edge leaflet repair. It is estimated that approximately 10% of patients eligible for edge-to-edge leaflet repair would be referred. It may therefore be expected that approximately 400 patients might presently be considered for percutaneous mitral valve edge-to-edge leaflet repair in England on an annual basis. This may be expected to increase annually with improved referral networks and clinical awareness.

6 Evidence Base

NHS England has concluded that there is sufficient evidence to support a proposal for the routine commissioning of this treatment for the indication.

Summary of Results

Fifteen studies (reported in 37 publications) met the predefined inclusion criteria for clinical effectiveness and the safety profile of MitraClip, as well as healthcare resource use. Twelve of these were single-armed observational studies by (primary study cited only) (Tay et al., 2016, Sorajja et al., 2017b, Rudolph et al., 2013, Reichenspurner et al., 2013, Rahhab et al., 2017, Nickenig et al., 2016a, Lim et al., 2014, Geis et al., 2015, Estevez-Loureiro et al., 2013a, Braun et al., 2014, Baldus et al., 2012, Whitlow et al., 2012). Three comparative studies were identified (Whitlow et al., 2012, Velazquez et al., 2015, Swaans et al., 2014). No randomised controlled studies were identified that met the inclusion criteria.

Two further studies informed the economic analysis (Vemulapalli et al., 2017, Mealing et al., 2013).

Clinical effectiveness of MitraClip in DMR patients

The principal outcomes in scope that pertained to clinical effectiveness were reduction in MR grade, improvements in NYHA class, and mortality rate.

There was unequivocal evidence (classed as Grade A) that the MitraClip procedure improved echocardiographic outcomes compared with baseline, as measured by reduction in MR grade. Eight studies reported a large statistically and clinically significant reduction in MR grade, and this improvement appeared to persist for at least 12 months. This was mirrored by parallel improvements in symptoms as measured by NYHA class, (n=10 studies) with one study additionally reporting a significant improvement in physical and mental health-related quality of life (HR-QoL).

Longer-term mortality was an important outcome that was reported in seven studies (mortality or survival rates at 1 year or more). At one year, mortality ranged from 16.3% to 24.7%. Comparative mortality that was measured in three studies, each using retrospective controls, reported a significantly higher death rate in

patients receiving conventional medical management (CMM) compared with MitraClip (in a mixed aetiology case mix of patients). However, there were methodological limitations with these studies. The relatively high mortality rate in these DMR patients highlights the high levels of comorbidity in this patient group.

Procedural safety of MitraClip in DMR patients

The procedural and/or technical success rate of MitraClip was reported in all the single-armed observational studies. Direct comparisons between studies are made difficult due to use of different definitions and terminology for "success"; however overall the success rate appears to be around 93% in patients with DMR at high risk of surgery. Although the peri-procedural mortality rate was low, 30-day mortality rate was reported as higher (6.3% in the study rated as being of the highest methodologically quality). These rates were considerably lower than would be predicted using surgical prediction rules such as EuroSCORE or STS (Society of Thoracic surgeons).

Total procedural adverse event rates were reported as being around 15% in three studies, although meaningful synthesis of data was not possible due to different definitions and low event rates in this restricted DMR population.

Healthcare resource use associated with MitraClip in DMR patients

Data on healthcare resource use were poorly reported by the studies. One study reported that treatment with MitraClip was associated with a significant decrease in hospital admissions for heart failure. Most patients were discharged directly back to a home setting after a length of hospital stay of 2 to 3 days.

Economic evidence

One cost utility analysis was identified which employed clinical inputs from a mixed aetiology population considered to be at high risk of surgery and a retrospective control group receiving medical management (EVEREST II HRS study). The study was from the perspective of the NHS, and UK relevant costs and utilities were used. It reported that MitraClip was likely to be cost effective at a time horizon of 5 or 10 years with an incremental cost-effectiveness ratio (ICER) of £22,200 and £14,800 per quality-adjusted life-year (QALY) at 5 and 10 years respectively.

Results of this study should be treated with caution because of the extrapolated time horizon used, and the relatively low quality (and low numbers of patients enrolled) of the study informing clinical effectiveness.

Evidence from a "before and after" US study found MitraClip was cost-saving due to reductions in admission for heart failure. However, this study had poor generalisability and did not include device or procedure cost, which are substantial.

Factors that may aid patient selection

There was limited evidence that lower age, higher left ventricular ejection fraction, absence of severe tricuspid regurgitation, and the absence of significant renal or lung disease were associated with better prognosis following treatment with MitraClip in patients with DMR.

Limitations of review

This review focussed on patients with DMR who were at high risk from surgery, which was poorly reported in the literature base, with most reported populations being comprised of patients with FMR or of mixed aetiologies. Partly because of this, the quality of evidence was poor, and mainly limited to single-armed studies. Although it was possible to extract disaggregated data on DMR patients, comparative analysis (with CMM or surgery) was generally not possible. In the future, good, high-quality experimental studies, preferably in the form of RCTs, are necessary to determine the clinical and economic effectiveness of MitraClip in this population compared with other treatment modalities.

Commissioning through Evaluation

In order to evaluate the MitraClip procedure, NHS England set up a multi-centre observational registry using the process of Commissioning through Evaluation (CtE). The registry was designed to include patients who had moderate or severe MR of degenerative or functional aetiology, and for whom conventional surgery was deemed to be an excessively high-risk intervention. The registry recorded a range of clinical outcomes with a maximum follow up of 2 years. The aims of the CtE registry were to provide data on the safety, efficacy and costs of MitraClip in a

real-world setting, and specifically to answer 11 pragmatic questions concerning these issues. As the registry was single-armed, a parallel literature search was undertaken in order to present the registry findings in the context of published studies in comparable populations, and to assess whether procedural outcomes were consistent with previously reported studies. Information gained from the registry will be used to inform future commissioning.

The MitraClip registry enrolled 272 patients, of whom 199 were eligible for CtE data analyses. The 199 patients included in the CtE analyses had functional (60%) or degenerative (40%) MR with a mean age of 76.2 years. Most patients were men (69%) and most patients (66%) had moderate or severe left ventricular impairment. The majority of patients were recruited electively (84.4%), with 13.6% admitted urgently and 2.0% undergoing the procedure as an emergency. Nearly all patients had moderate or severe MR (grade 3+ or 4+), which was symptomatic in 92% of cases (New York Heart Association [NYHA] class 3 or 4). The mean EuroSCORE II (per cent risk of dying from cardiac surgery) was 6.4 (range 0.67 to 42.46).

The procedural success rate was 85.9% (95% confidence interval 80.3 to 90.4%), with 8.2% of procedures being associated with an in-hospital major complication including ten deaths (5.1%) and four additional interventions (2.0%) in the DMR subgroup. In patients successfully treated, there was an immediate and significant improvement in MR, with a reduction from 100% MR grade ≥3+ to 7% MR grade ≥3+. These peri-procedural outcomes were consistent with observational studies identified in the literature with similar populations and emphasise the early clinical benefits but also the high mortality associated with this sick cohort.

In the medium term, the MR benefits of MitraClip were largely sustained, with 76% of patients having mild or absent MR (grade ≤2+) at 1 year. This was reflected in significantly improved patient symptoms, with 82% having mild or no symptoms of dyspnoea (NYHA class ≤2), and significant improvements in quality of life (QoL), as measured by EQ-5D. The mortality rate at 1 year was 11.6%. Again, these findings were consistent with those published in observational studies. The CtE registry was unable to provide robust information on the likely demand for MitraClip, its impact on hospital readmission, or long-term outcomes. However,

limited data from published studies suggest cardiac readmissions are relatively high (over 20%) in the first year and that MitraClip may lose efficacy (in terms of MR reduction) at longer follow up times (4 years and above). Planned data linkage of CtE registry data to Hospital Episode Statistics (HES) should provide more insight into outcomes for the cohort.

There was no significant difference in mortality rate, MR grade, NYHA class, and adverse events in patients with degenerative or functional MR aetiologies. Patients receiving MitraClip as an urgent or emergency case had a greater risk of death, with 68.2 dying per 100 person years (PY) compared with 22.1 per 100 PY in the elective cohort ($p = 0.0105$). This increased risk of death was driven by in-hospital mortality. When only post-discharge mortality was considered, there was no significant difference.

A limitation of the CtE registry, common to all device registries, was that it did not report a control arm of optimal medical management without MitraClip. As the EAC was also unable to identify a study with an appropriate and robust control, it is currently unknown how registry patients would have fared without treatment, particularly in terms of mortality.

In conclusion, the CtE registry has reported data that show MitraClip is associated with an immediate reduction in MR. This effect is sustained in the medium term (1 year) and is associated with significant improvements in symptoms and QoL, with 17 of 20 patients surviving for at least 2 years. The longer-term complications and benefits of MitraClip are unknown because of a lack of long-term studies with suitable comparators. It is hoped that on-going RCTs will inform these gaps in the evidence.

Any clinical benefits of MitraClip should be considered in the context of an estimated cost for all procedures of £32,560 (range £28,800 to £34,100). Although conclusions cannot be made about the cost effectiveness or cost saving potential of the procedure, work to address the latter is planned for later in 2018, assuming the EAC can access linked data from Hospital Episode Statistics.

Conclusion:

The results of the CtE echo those of the evidence review. There is consistency of evidence of high rates of technical success and clinical benefit (when MitraClip is undertaken electively) with symptomatic and QOL improvement and reduction of severity of MR grade from moderate/severe to mild/absent. However in 20%, clinical benefit reduces by one year. In addition there can be a significant and progressive death and major complication rate), which is higher in urgent/emergency cases.

In those patients who are fit enough and can have surgery, surgery has superior longer-term outcomes than MitraClip. In patients who are assessed very high risk for mitral valve surgery, MitraClip has better short-term outcomes than conservative medical management.

Selection of patients is key to identify those with a good future prognosis i.e. patients with fewer co-morbidities, lower frailty and good prospective life-expectancy who are most likely to benefit longer term and with reduced potential for death, complications and re-admissions on follow-up.

7 Proposed Criteria for Commissioning

Percutaneous mitral valve edge-to-edge leaflet repair will be commissioned for patients with symptomatic, severe (defined as grade 3+ and 4+) primary degenerative mitral regurgitation. Patients must be assessed by the Heart Team as inoperable or very high risk for conventional mitral valve surgery and in whom reduction of mitral regurgitation would be expected to provide sustained symptom and quality of life benefits. Patients should be considered as having a high likelihood of procedural and medium term successful outcomes with respect to effective and durable reduction in mitral regurgitation. Individual improvement in symptoms, quality-of-life, and functional status as well as survival must be considered

Patients will be classified as having a very high or inoperable surgical risk using the Society of Thoracic Surgeons calculator or logistic EuroSCORE surgical risk scores, assessment of frailty, significant organ dysfunction and co-morbidities.

Additional factors that may preclude surgery include severe mitral annular calcification, the presence of a hostile chest (e.g., prior mediastinal radiation or chest malformation), patent left internal mammary artery bypass graft crossing the midline and prior tracheostomy.

Eligibility Criteria

Inclusion

1. Patients with symptomatic (NYHA 2-4a), severe mitral regurgitation (grade ≥3+) due to primary abnormality of the mitral valve apparatus (degenerative MR)
2. Patients determined as inoperable or very high risk for mitral valve surgery by a mitral valve specialist surgeon as part of the Heart Team assessment
3. Patients deemed anatomically suitable for percutaneous mitral valve edge-to-edge leaflet repair
4. Healthy life expectancy at least > 12 months with quality of life benefits to be gained from reduction in mitral regurgitation

Exclusion

1. Patients who cannot tolerate procedural anti-coagulation
2. Active endocarditis
3. Rheumatic mitral valve disease
4. Evidence of inferior vena cava or femoral venous thrombus
5. Echocardiographic evidence of intracardiac mass, thrombus
6. NYHA functional class IVb or ACC/AHA stage D chronic heart failure
7. Severe adverse cardiac factors: severe LV impairment <20% or LVEDD >60mm, severe TR and moderate-severe RV impairment, severe pulmonary hypertension

8. Hypertrophic cardiomyopathy, restrictive cardiomyopathy, constrictive pericarditis or other structural heart disease causing heart failure

9. Life expectancy < 12 months due to non-cardiac condition

10. Severe frailty – Rockwood CSHA-CFS >6

11. Oxygen dependent lung disease

12. Severe chronic kidney or liver disease

13. Significant bleeding diathesis

14. Malnourished with low serum albumin and unintentional weight loss

15. Significant anaemia (in the absence of a clearly reversible cause)

16. Dementia (if Heart Team with geriatric assessment suggests unlikely benefit)

Anatomical criteria

The following criteria should be considered as unsuitable for treatment with percutaneous mitral valve leaflet repair:

- Perforations or clefts
- Haemodynamically significant mitral stenosis
- Significant calcification in the leaflet grasping area

Heart Team assessment

Joint decision-making by the multidisciplinary Heart Team should govern patient selection. The core members of the Heart Team should include a cardiac surgeon with mitral valve expertise, expert imaging cardiologist with structural intervention echocardiography skills, trans-catheter heart valve/structural heart interventionist, cardiac anaesthetist and allied health professionals such as specialist nurses. Access to elderly care input and comprehensive geriatric assessment should be available to support decision making and patient selection by the Heart Team.

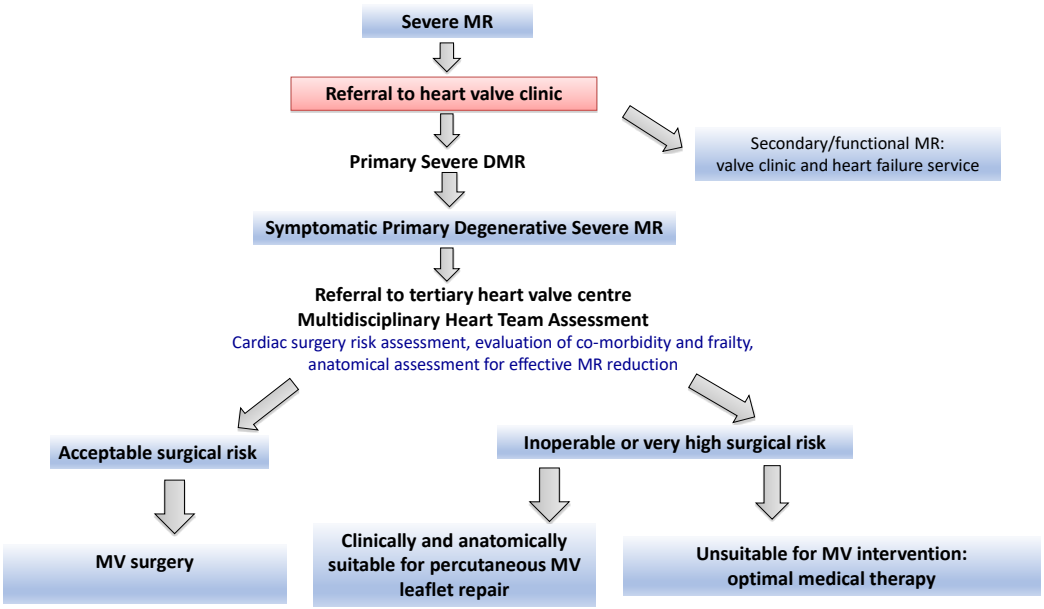
Shared decision-making

Decision making in inoperable and very high risk patients is complex and shared decision-making principles which are patient centred should be applied. The process should be based on discussing "what matters to you", ensure clear explanation of the risks of the procedure and discuss the option of optimal medical therapy as an alternative to percutaneous mitral valve leaflet repair if the patient is considered eligible for intervention.

8 Proposed Patient Pathway

Patients with symptomatic, severe primary DMR should be referred via secondary cardiology services. A clear referral pathway between these services and the specialist valve intervention team should be established. A referral network that ensures equitable and efficient access to assessment and therapy for patients across all secondary care facilities should exist. The patient pathway should ensure patients are assessed by the Heart Team which must include a mitral valve specialist surgeon to determine inoperability or very high surgical risk.

The figure below is an illustrative example of the steps in a patient pathway for primary degenerative mitral regurgitation and intervention with percutaneous mitral valve edge-to-edge leaflet repair.



9 Proposed Governance Arrangements

Treatment will be commissioned from a limited number of specialised mitral valve centres that meet criteria for trans-catheter heart valve interventions as per service specification.

It is expected that sites will produce patient information leaflets (clinical indications, clinical benefits, complications, need for follow up, current evidence base and its limitations) about percutaneous mitral valve leaflet repair.

A National Registry will be set up to record procedural and follow up outcomes with percutaneous mitral valve edge-to-edge leaflet repair. Agreed endpoint definitions for standardised reporting of clinical and safety outcomes will need to be used for to ensure comparability of outcome data. Submission of data to this database will be mandatory for all procedures undertaken by designated centres.

The use of the percutaneous mitral valve edge-to-edge leaflet repair system with any device will be subject to the NHS England prior approval system.

A suspected problem ('adverse incident') with the medical device should be reported using the Yellow Card Scheme as soon as possible at the following link: https://www.gov.uk/report-problem-medicine-medical-device

10 Proposed Mechanism for Funding

The device is excluded from the national tariff and will be funded by pass through payments made against invoices raised by provider Trusts or through the high cost tariff excluded devices (HCTED) programme.

The procedure is included in tariff and will be funded through the routine contract procedures. A specific code exists for percutaneous mitral valve leaflet repair (K35.8).

11 Proposed Audit Requirements

Centres should undertake an annual audit of their percutaneous mitral valve edge-to-edge leaflet repair programme, reporting efficacy, safety and survival outcomes within the clinical governance structure of their hospital and network. They should

benchmark themselves against existing and developing regional, national and international data. The establishment of a national registry will facilitate collection of consistent data across centres.

Audits should cover all points in the patient pathway including referral, patient selection, procedure indications, method of anaesthesia, intra-procedural imaging, procedural outcome, duration of hospital stay, number of devices per patient, peri-procedural, discharge and follow-up complications including survival and readmissions. Complications (including time of occurrence) to be monitored would include strokes/TIAs/myocardial infarction/bleeding/vascular complication/acute kidney injury/device embolization/pericardial effusion +/- cardiac tamponade +/- pericardiocentesis/in-hospital and 30-day mortality, re-intervention for device complications and further mitral valve intervention including surgery. Valve (dys)function, heart failure hospitalisations and quality of life endpoints are also expected to be reported. Minimum requirements for follow up in the centre in which the procedure was carried out are at 6-8 weeks and12 months.

12 Documents That Have Informed This Policy Proposition

This document updates and replaces Clinical Commissioning Policy Statement: Percutaneous mitral valve leaflet repair for mitral regurgitation April 2013 (Reference: NHSCB/A09/PS/b).

13 Date of Review

This document will lapse upon publication by NHS England of a clinical commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned. This policy will be formally reviewed when additional data become available.

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