



MitraClip[®] mitral valve repair in patients with moderate-to-severe or severe mitral regurgitation who are not eligible for surgery

What is mitral regurgitation?

Mitral regurgitation is when blood flows the wrong way through the heart during a heartbeat. This happens because the mitral valve, which sits between two chambers of the heart, has become deformed or damaged through heart disease.

There are two types of mitral regurgitation. Functional mitral regurgitation is when the heart muscles have been damaged, causing the mitral valve to be pulled out of shape. Degenerative mitral regurgitation occurs when the parts of the mitral valve are damaged. In both types of mitral regurgitation the valve doesn't close properly, allowing blood to flow the wrong way.

What is MitraClip[®] mitral valve repair?

MitraClip[®] mitral valve repair is a minimally invasive procedure for repairing the mitral valve to resolve/reduce mitral regurgitation. The MitraClip[®] device is inserted through a large blood vessel in the groin and passed up into the heart. A clip is inserted to hold segments of the mitral valve together (like a clothes peg) creating two smaller openings for blood to flow through.

Why is this important?

Left untreated, mitral regurgitation can lead to heart failure, an irregular heartbeat or death. Severe symptoms may prevent patients for performing everyday tasks and simple activities, such as climbing a set of stairs. Current treatments for severe mitral regurgitation include surgical repair or replacement of the mitral valve. However some patients are not eligible for this surgery. The MitraClip[®] System offers a minimally invasive way to repair the mitral valve while avoiding the risks associated with open heart surgery.

What we did

We assessed whether MitraClip[®] mitral valve repair is safe and effective for treating mitral regurgitation in patients who are not eligible for surgery. We also looked at whether MitraClip[®] was good value for money in this patient group.

What we found

There are two recent trials comparing MitraClip® plus medication with medication alone in patients with functional mitral regurgitation. One trial was in the USA and one in France. The American trial found that MitraClip® reduced the risk of being hospitalised due to heart failure by an estimated 47%, and the risk of dying due to heart disease by 57%, within 2 years of having the procedure. Quality of life and the distance a patient could walk in 6 minutes both improved significantly within 1 year of MitraClip® implantation in this trial. The French trial found no significant improvements for patients treated with MitraClip® plus medication compared with patients treated with medication alone. The most common complications in these trials were device implantation failure (4.2%) and the need for unplanned mitral valve surgery or MitraClip® implantation (3.2%).

Evidence from observational studies (where patients are not allocated to specific treatments) seem to support the findings of the American trial where MitraClip® was beneficial.

A pragmatic register of patients in England, most of whom had functional mitral regurgitation, reported that 5% of patients who had the MitraClip® procedure died in hospital, 8.2% had a major complication, and 11.6% died within 1 year of having the procedure.

Patients from the English register mentioned above and patients who responded to a separate survey in England described positive experiences, including improved symptoms and quality of life following MitraClip®.

Four observational studies evaluated MitraClip® in patients with degenerative mitral regurgitation. In these studies there were reductions in the severity of mitral regurgitation, improvements in patient quality of life, and reductions in hospitalisations due to heart failure. However, an estimated 24% of patients in two of these studies died within 1 year of the MitraClip® procedure. The most common complications in these studies related to bleeding and partial detachment of the clip used in the MitraClip® procedure.

The MitraClip® System costs approximately £16,500 plus VAT. In NHS England it was estimated that the MitraClip® procedure (including preoperative and postoperative care) would cost around £32,560 per patient. We didn't find any new published evidence from the UK on whether MitraClip® is good value for money. Three studies from other countries suggest that MitraClip® might be good value for money but it is uncertain if these results would apply in Scotland.

Hospitals that performed more MitraClip® procedures per year were associated with better patient outcomes, including fewer deaths and complications.

What SHTG considered when developing advice for NHSScotland

- The group discussed reasons why the two trials on MitraClip® in patients with functional mitral regurgitation came to different conclusions. Proposed explanations related to

differing normal care in the USA and France, how experienced the staff doing the procedure were, and the different lengths of time patients were followed after the procedure.

- The committee felt it was important that advice to NHSScotland covered both functional and degenerative mitral regurgitation.
- The lack of effective alternative treatments for degenerative mitral regurgitation should be considered when formulating advice. It was acknowledged that the evidence on using MitraClip® in patients with degenerative mitral regurgitation was of lower quality than evidence for patients with functional mitral regurgitation.
- Current and future estimates of the number of patients in Scotland who may be eligible for MitraClip® were discussed briefly.

What is our advice to NHSScotland?

Minimally invasive valve repair using the MitraClip® device should be considered for patients with severe or moderate-to-severe mitral regurgitation who are not eligible for surgery. Treatment decisions should be made by a team of healthcare professionals with different expertise and who have experience of performing this procedure. This team should take into account individual patients' level of risk, other existing conditions, preferences and quality of life.

Annual MitraClip® procedure volume per centre should be maximised to support optimal patient outcomes and ensure clinical experience with this complex procedure is achieved and retained.

Future work

More research is needed to clarify whether MitraClip® is effective for reducing both types of mitral regurgitation compared with medication. Studies that assess the value for money of MitraClip® from a UK perspective are also desirable.

This plain language summary has been produced based on SHTG Advice 05-19
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