

Treatment of mitral regurgitation by a percutaneous device with clip (TMVRc)

English summary

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Direction des services de santé et de l'évaluation
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This is the English summary of the guidance entitled Traitement de l'insuffisance mitrale par un dispositif percutané avec clip (TMVRc) published in March 2019.

The complete version of this guidance (in French) is available on the website of INESSS in the Publications section.

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SUMMARY

Introduction

Mitral regurgitation (MR) occurs when the mitral valve allows a clinically significant volume of blood to flow back from the ventricle to the left atrium during systole. Primary MR results from an abnormality in one or more of the valve's components, while secondary MR occurs in patients with dilated cardiomyopathy whose valve is structurally normal but distorted as a result of left ventricular dilation.

Mitral regurgitation can compromise the patient's vital prognosis. For primary MR, repair or replacement surgery may be the treatment of choice. If the surgical risk is excessive, a transcatheter mitral valve repair with a clip (TMVRc), or MitraClip[®], may be considered.

For secondary MR, until recently, there was insufficient evidence to confirm that an intervention to reduce mitral regurgitation could prolong survival. However, a recent randomized clinical trial (RCT) casts doubt on this point of view.

Context

In Québec, three facilities have set up TMVRc programs, and procedural volumes are increasing. The Ministère de la Santé et des Services sociaux asked the Institut national d'excellence en santé et en services sociaux (INESSS) to assess the relevance of using transcatheter mitral valve repair with a clip (TMVRc) for the treatment of MR.

Methods

A literature review was carried out, and the data collected were put in context following meetings and discussion with a committee of clinical experts, health professionals from the implanting facilities, an advisory committee, representatives of the device's manufacturer, and INESSS's Clinical Excellence in Health Services Committee.

Findings

- Severe MR is a potentially serious condition that can profoundly affect the patient's functional capacity and quality of life, requires frequent hospitalization and can lead to death.
- A significant proportion of patients with severe symptomatic MR are at a therapeutic impasse.
- TMVRc appears to be safe, as short-term mortality and adverse event rates are generally low.
- The level of evidence regarding the efficacy of the device is still low for the treatment of both primary and secondary MR. The results of the two recently published RCTs are equivocal. However, over the next few years, analyses with longer follow-up durations and other RCTs focused on MR treatment will be published.

- Currently, the only indication approved by Health Canada is for primary MR. However, the population presently treated in Québec consists mainly of patients with secondary MR.
- The learned societies and jurisdictions that have made decisions about how TMVRc should be introduced agree in recommending that programs be set up at centres of excellence, which have all the necessary medical and surgical expertise for managing patients with complex cardiac valve disorders and advanced heart failure.
- Several organizations that have evaluated TMVRc required an assessment in a real-world setting as a condition for use or coverage.
- The learning curve and maintenance of competence are based on a minimum number of procedures that need to be performed. However, two of the three programs in Québec are having difficulty meeting the manufacturer's recommended minimum threshold volume of two procedures per month, despite the fact that current practice in Québec addresses both indications, i.e., patients with primary or secondary MR.
- Since a large number of devices for percutaneous mitral valve treatment are currently being developed, it is plausible that many of them will come to market and add to the diversity of the available options in the near future.

Recommendations

Given the significant uncertainty regarding the value of TMVRc in the real world setting, INESSS recommends that:

- The use of TMVRc be limited to a small number of facilities designated by the MSSS:
 - that have all the necessary medical and surgical expertise for managing advanced heart failure;
 - that are able to offer all the treatment options for managing advanced heart failure and that have the necessary technical resources;
 - that have a high-volume program for the treatment of cardiac valve diseases;
 - that are most likely to achieve the volume of TMVRc (two per month) required for developing and maintaining competence, in well-selected patients.
- TMVRc be available to patients with primary MR:
 - who have symptoms attributable to chronic, severe mitral regurgitation, despite optimal medical treatment according to the current guidelines and;
 - in whom surgical replacement or repair of the mitral valve is contraindicated or considered overly risky and;
 - who have favourable anatomical conditions and;
 - who are likely to see their quality of life improve and whose existing comorbidities would not interfere with the benefit that correcting the mitral regurgitation is expected to provide.
- TMVRc be available to patients with secondary MR:

- who have persistent symptoms, despite optimal medical treatment (as defined in the protocol for the COAPT trial (*Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation*)[Stone *et al.*, 2018]and;
- who meet the selection criteria for the COAPT trial, particularly with regard to the regurgitant orifice area ($> 30 \text{ mm}^2$) and left ventricular dilation (end-diastolic dimension $\leq 70 \text{ mm}$)[Stone *et al.*, 2018].
- The following conditions should be met by facilities offering TMVRc:
 - Patients should be selected by a multidisciplinary heart team that includes an expert in interventional cardiology, a cardiac surgeon, an echocardiologist and a cardiologist who is an expert in managing advanced heart failure;
 - An informed decision-making process should be implemented to support patients in their therapeutic choice, in line with their care goals and life plan;
- The facilities that will be designated for a TMVRc program should participate in an evaluative process by which they will be required to compile data in a provincial registry that will be used to assess the value of this technology in the real-world care setting.

The data to be compiled should include at least the following measures:

- The level of regurgitation severity (pre- and post-procedure);
- Quality of life (pre- and at 1 year post-procedure);
- Functional capacity (pre- and at 1 year post-procedure);
- Hospital readmissions at 1 and 2 years;
- Vital status at 1 and 2 years.
- The MSSS should ensure a standardized method to identify patients who have undergone TMVRc in medico-administrative databases in order to facilitate the monitoring of longer-term clinical outcomes.

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