TRANSCATHETER MITRAL VALVE REPAIR WITH A CLIP

Summary sheet of the guidance produced by the Institut national d’excellence en santé et en services sociaux

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**Project team members**

**Principal authors**
François Désy, Ph. D., M. Sc. ETS  
Maria Vutcovici Nicolae, M. Sc.  
Laurie Lambert, Ph. D.

**Internal collaborator**
Lucy Boothroyd, Ph. D.

**Scientific coordinator**
Laurie Lambert, Ph. D.

**Director**
Michèle de Guise, M.D., FRCPc, M. M.

**Knowledge transfer**
Claude Boutin, M. Ps., professional scientist  
Jocelyne Guillot, B.A., graphic designer  
Renée Latulippe, M.A., coordinator
CONTEXT

Patients with mitral regurgitation can suffer from shortness of breath, fatigue, palpitations and swelling in the legs. When severe, mitral regurgitation profoundly affects the patient’s functional capacity and quality of life. It then requires frequent hospitalizations and can lead to a mortality rate of up to 50% of patients at 5 years.

**MITRAL REGURGITATION**

Is present in about:

- 10% of people aged 75 years or older;
- 40% of patients with heart failure.

In Québec, three facilities specialized in the treatment of advanced heart failure have begun offering an alternative to conventional cardiac surgery for the treatment of mitral regurgitation. This treatment uses a transcatheter device with a clip (e.g., MitraClip®), which carries less risk for certain carefully-selected patients. The facilities already using this device are the McGill University Health Centre (MUHC), the Montreal Heart Institute (ICM) and the Québec Heart and Lung Institute (IUCPQ).

Despite the growing expertise of multidisciplinary teams, the scientific community has not yet succeeded in precisely determining the characteristics of patients most likely to benefit from this technology. Also, uncertainty persists concerning the value of this treatment in the real-world setting.

**INESSS’S MANDATE**

Unlike in the case of medications, the introduction of medical devices does not follow a formal, standardized evaluation process in order to determine coverage by public funds. The implantation of such devices is often carried out on the basis of decentralized decisions made at the individual institutions themselves. This is the context in which the Ministry of Health and Social Services (MSSS) asked INESSS to assess the relevance of using a transcatheter device with a clip to treat mitral regurgitation in Québec.

To fulfill this mandate, INESSS first carried out a review of the scientific literature in accordance with a pre-specified protocol that was validated by INESSS’s Comité d’excellence clinique en services de santé. Subsequently, data collected during meetings with a committee of clinical experts, health professionals from the implanting facilities, an advisory committee, representatives of the device’s manufacturer and the Comité d’excellence clinique en services de santé were put in the Québec context.

During this mandate, INESSS more specifically evaluated the treatment of chronic mitral regurgitation using the MitraClip® device.
IN THE WORLD AT LARGE

Seven of 13 regulatory organizations and health technology assessment agencies identified in the literature have released recommendations that do not support using a transcatheter device with a clip. The insufficient level of the evidence with respect to safety, efficacy and benefits of the procedure was the main motive for refusing to implement or reimburse such a treatment. Six other organizations, including the Food and Drug Administration (FDA), Health Canada and the Ontario Health Technology Advisory Committee (OHTAC) have released conditional acceptances of the technology, while underlining the weak quality of the evidence.

SUMMARY OF RECOMMENDATIONS

INESSS recommends in particular that the use of a transcatheter device with a clip:
• be limited to a small number of facilities designated by the Ministry;
• can be offered only to patients suffering from primary or secondary mitral regurgitation who present with specific, well-defined characteristics.

In addition, the following conditions should be met by the designated centres offering this technology. These centres should:
• have all the necessary medical and surgical expertise for managing advanced heart failure;
• 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;
• select patients through the involvement of a multidisciplinary Heart Team that consists of an expert in interventional cardiology, a cardiac surgeon, an echocardiologist and a cardiologist who is an expert in managing advanced heart failure;
• implement an informed decision-making process to support patients in their therapeutic choice, in line with their care goals and life plan.

Finally, a standardized method should be ensured to identify patients treated by a transcatheter device with a clip in medico-administrative databases, in order to facilitate the monitoring of longer-term clinical outcomes.

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PRINCIPAL FINDINGS BY INESSS:
• The use of a transcatheter device with a clip appears to be safe, since short-term mortality and adverse event rates are generally low;
• The level of evidence concerning the efficacy of the device is still weak for the treatment of primary and secondary mitral regurgitation.
Head office
2535, boulevard Laurier, 5th Floor Québec
(Québec) G1V 4M3
418 643-1339

Montréal office
2021, avenue Union, Suite 10.083 Montréal
(Québec) H3A 2S9
514 873-2563

inesss@inesss.qc.ca
inessss.qc.ca