NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Cardiac contractility modulation device implantation for heart failure

Heart failure means your heart is not able to pump blood around your body well enough. In this procedure, a device is placed under the skin of the chest and connected to the heart by 2 or 3 leads. It delivers electrical pulses that make the heart contract more strongly. The aim is to improve a person's ability to exercise and quality of life.

The National Institute for Health and Care Excellence (NICE) is looking at cardiac contractility modulation device implantation for heart failure. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide.

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our

interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 21 March 2019

Target date for publication of guidance: June 2019

1 Draft recommendations

1.1 The evidence on cardiac contractility modulation device implantation for heart failure raises no major safety concerns. However, the evidence on efficacy is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.

1.2 Further research should ideally be in the form of blinded randomised controlled trials. These should report details of patient selection, duration and timing of stimulation, and duration of effect of stimulation. Outcomes should include ejection fraction, oxygen consumption, New York Heart Association classification and patient-reported outcomes, including quality of life.

2 The condition, current treatments and procedure

The condition

2.1 Heart failure is a complex clinical syndrome of symptoms and signs that happen when the heart is not working well enough, leading to reduced blood flow to body tissues. It can lead to oedema in the lungs (causing breathlessness) and swelling of the legs. Other symptoms include reduced ability to exercise, fatigue and malaise. Heart failure can be caused by structural or functional abnormalities of the heart.

Current treatments

2.2 NICE's guideline describes the diagnosis and management of chronic heart failure in adults. Treatments for heart failure include drugs to improve heart function, cardiac rehabilitation, cardiac resynchronisation therapy and cardiac transplantation. Cardiac contractility modulation device implantation may be an option for patients with advanced heart failure that hasn't responded to conventional therapy.

The procedure

2.3 Cardiac contractility modulation device implantation for heart failure is usually done under local anaesthesia. A device similar to a pacemaker is implanted in the right or left pectoral region and is connected to 2 standard pacemaker leads that are threaded through veins into the right ventricle. The electrodes in the right ventricle are placed on the ventricular septum at least 2 cm apart. These sense ventricular activity and deliver cardiac contractility modulation signals. An optional additional lead may be used to sense atrial activity (usually placed in the right atrial appendage). In

contrast to a pacemaker or a defibrillator, the system is designed to modulate the strength of contraction of the heart muscle rather than the rhythm. Pulses are delivered at regular intervals throughout the day.

2.4 The device is recharged using a home-based charger system, typically on a weekly basis. Charging sessions last about 40 to 60 minutes.

2.5 The aim is to improve the heart's contractility, therefore improving a person's ability to exercise and quality of life.

3 Committee considerations

The evidence

3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 8 sources, which was discussed by the committee. The evidence included 1 systematic review, 3 randomised controlled trials (2 of which were also included in the review), 1 non-randomised comparative study (included in the review) and 3 case series, and is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The committee considered the key efficacy outcomes to be: improved ejection fraction, oxygen consumption during and following stimulation, New York Heart Association classification and quality of life.

3.3 The committee considered the key safety outcomes to be: pneumothorax, infection, bleeding, arrhythmias and lead displacement.

Committee comments

3.4 The committee noted that there was a large placebo effect reported in some of the studies.

3.5 The efficacy appeared to be less in people with severe heart failure.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee
February 2019

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