NICE guidance

Cardiac contractility modulation device implantation for heart failure

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg655

1 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. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Further research should ideally be in the form of 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 people 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, rate of hospitalisation and quality of life.

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

3.4 Patient commentary was sought but none was received.

Committee comments

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

3.6 The committee noted that the efficacy may be better in people with less

severe heart failure, and this underpinned their recommendation for more research to identify the group of patients most likely to benefit from this procedure.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation