



Partial left ventriculectomy (the Batista procedure)

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www.nice.org.uk/guidance/ipg41

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of partial left ventriculectomy (PLV) does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake PLV should take the following action.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of <u>NICE's</u> information for the public is recommended.
 - Audit and review clinical outcomes of all patients having PLV. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE may review the procedure upon publication of further evidence.
- 1.3 This is a radical treatment for very ill patients that should only be considered in centres where alternative treatments for severe heart failure are available.

2 The procedure

2.1 Indications

2.1.1 Partial left ventriculectomy (PLV) is used to treat patients with irreversible (endstage) heart failure secondary to dilated disease, or Chagas' disease. It has also been used in some patients with ischaemic heart disease.

2.1.2 Surgical alternatives to PLV may include coronary artery bypass grafting (CABG), cardiac transplant and left ventricular assist devices (LVAD). Ventricular volume reduction procedures include mitral valve repair (mitralannuloplasty), endoventricular circular patch plasty and left ventricular aneurysmectomy. Medical therapy includes diuretics, vasodilator therapy, beta blockers and digoxin.

2.2 Outline of the procedure

- 2.2.1 Partial left ventriculectomy seeks to restore left ventricular function by reducing cardiac volume (and left ventricular wall tension) through the resection of the posterolateral wall of the left ventricle. It is often accompanied by valvuloplasty (or mitral annuloplasty) to prevent postoperative mitral regurgitation. Variations of the technique for PLV include lateral PLV, extended PLV and anterior PLV. The procedure is usually performed with the aid of cardiopulmonary bypass.
- In lateral PLV, an incision is made at the apex of the left ventricle and extended towards the base. A wedge-shaped portion of the left ventricle is resected, leaving the papillary muscles intact where possible. Extended PLV additionally excises the papillary muscles and the mitral valve. In anterior PLV, the area between the left anterior descending artery and the attachment of the left anterolateral papillary muscle is resected and closed as in lateral PLV.

2.3 Efficacy

2.3.1 Studies reported 30-day survival rates of between 50% and 99%. In one non-randomised study, there was no difference in survival rates between patients undergoing this procedure and patients undergoing heart transplant at 1 year. In a case series of 62 patients, survival was 80% and 60%, and event-free survival was 49% and 26%, at 1 and 3 years, respectively, after surgery. The survival rate at 1 year was achieved with the frequent use of ventricular assist devices and transplantation as salvage therapy. For more information, see the overview.

2.3.2 All the Specialist Advisors thought that efficacy, especially long-term efficacy, was uncertain. One Advisor commented that it is difficult to establish which patients would benefit from the procedure and that there is often no improvement in myocardial function.

2.4 Safety

- As noted in Section 2.3.1, 30-day mortality ranged from 1% to 50%. However, it is unclear from the studies whether these deaths were the result of the procedure or were attributable to the underlying condition. Reported complications included congestive heart failure, bleeding, arrhythmias, renal failure, respiratory failure and infection. For more information, see the <u>overview</u>.
- The Specialist Advisors were concerned about the high (30-day) mortality rate associated with this procedure. One Advisor listed late complications as arrhythmias, mitral regurgitation, and progressive dilation of the left ventricle. The same Advisor considered the main disadvantage of the procedure to be the need for resection of viable myocardium.

2.5 Other comments

- 2.5.1 The evidence for this procedure is difficult to interpret because of:
 - inconsistencies in patient selection
 - the variable nature of the surgery performed
 - inadequate information about duration and quality of life after the operation.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee described

in the overview.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.