NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of Partial Left Ventriculectomy

Introduction

This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by specialist advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Procedure name

Partial Left Ventriculectomy
The Batista Procedure

Specialty society

Society of Cardiothoracic Surgeons of Great Britain and Ireland

Executive Summary

Left partial ventriculectomy (PLV) seeks to treat dilated cardiomyopathy by reducing cardiac volume and hence heart wall pressure through the resection of a portion of the left ventricle. Patients receiving it are generally suitable for cardiac transplant but unable to receive it, often for social or economic reasons. PLV is an emerging procedure and the vast majority of evidence is case series, although there has been one retrospective comparative study of PLV and transplantation. Hospital mortality was reported for up to 30% of patients and overall mortality was around 40% of patients. Thirty day survival ranged from 50% to 99%, and no significant difference was found between PLV and transplant. One-year survival ranged from 46% to 80% and three-year survival was reported in one study as 60%. Event-free survival was reported as 80% at 30 days, 49% at 1 year and 26% at three years. Use of a left ventricular assist device or relisting for cardiac surgery was reported in one study at between 5% and 15% of patients at 30 days and in 43% at 1 year and 58% at 3 years. Left ventricular function (as measured by echocardiography) and functional status were found to improve significantly post-operatively. Event-free survival was found to be statistically significantly worse for patients aged over 65 and for those with the poorest functional status preoperatively. Surgeon experience with the procedure was also significantly associated with patient outcome, with event-free survival being poorer for the first four patients in series compared with the subsequent 5, 10, 20 or 30 patients. Event-free survival was not found to be statistically

significantly affected by gender, body mass, underlying pathology, mitral regurgitation, preoperative symptoms, preoperative left ventricular function, preoperative indication for transplant or whether the patient was a child or adult.

Indication(s)

Partial left ventriculectomy is indicated for patients with irreversible (end-stage) heart failure secondary to acute myocarditis.[1] Dilated cardiomyopathy, valvular disease, hypertrophic cardiomyopathy and Chagas disease have all been treated with this procedure.[2] Although more generally indicated in patients with non-ischaemic cardiomyopathy, it has also been shown to be effective in some patients with ischaemic cardiomyopathy.[3] Dilated or congestive cardiomyopathy occurs when the left ventricle becomes dilated and loses function as a result of global hypokinesia (reduced muscle function from high stress on the heart wall muscles). Hypertrophic cardiomyopathy results from the thickening of the heart wall muscles and in its obstructive form leads to reduced blood flow. Symptoms of heart failure include oedema, shortness of breath, dizziness, fainting, fatigue and angina pectoris. Arrhythmias and thrombus or embolus may result from the reduced function of the left ventricle and if left untreated may lead to sudden heart attack and death.

*Potential patient population:*In the US more than 2000 heart transplants were performed during 1998 and 1999. In 1997 more than 500,000 bypass operations, 89,000 valve replacements and 92,000 other open-heart surgical procedures were performed.[4] In the UK 171 heart transplants were performed in 2001 with a further 113 patients on the waiting list, waiting on average 164 days for adults and 73 days for children.[5] According to the British Heart Foundation more than 120,000 people in the UK died in 2000 from coronary heart disease related causes.[6] The prevalence of ischaemic heart disease in the UK (1994 -1998) was between 24 and 41% for males and 14 and 24% for females. In 1999/2000 over 50,000 people were hospitalised for coronary artery bypass surgery or angioplasty.[7]

Summary of procedure

Partial left ventriculectomy (PLV) 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.[8,9] In *lateral PLV*, either on a beating heart, or via cardiopulmonary bypass, an incision is made at the apex of the left ventricle and extended towards the base[10] and a wedge shaped portion of the left ventricle is resected,[8] leaving the papillary muscles intact where possible. The incision is closed with single layer of suture followed by a second haemostatic suture and air carefully removed from the left ventricle.[10] PLV is often accompanied by valvuloplasty (or mitral annuloplasty) to prevent postoperative mitral regurgitation.[2,3,8,10] *Extended PLV* additionally excises the papillary muscles and the mitral valve where there is organic disorders, or if the distance between the papillary muscles is insufficient to allow adequate reduction in ventricular dimensions.[2] 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 per lateral PLV (i.e. sutured in two layers).

Surgical alternatives to PLV include coronary artery bypass grafting (CABG), cardiac transplant, intraaortic balloon pumping and left ventricular assist devices (LVAD). Conceptually similar ventricular volume reduction procedures include mitral valve repair (mitral annuloplasty), endoventricular circular patch plasty and left ventricular aneurysmectomy.[1,2] Medical therapy includes vasodilator therapy, digitalis, and dobutamine infusion.

Literature review

A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index using Boolean search terms was conducted, from the inception of the databases until October 2002. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, National Research Register, SIGLE, Grey Literature Reports, relevant online journals and the Internet were also searched in October 2002. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data on partial left ventriculectomy in the form of randomised controlled trials (RCT), other controlled or comparative studies, case series and case reports. Initial searches identified 153 references to partial left ventriculectomy. Review articles, background articles and animal studies were excluded. One non-randomised comparative study was identified, and 99 articles reporting case series or case reports. These were subsequently excluded if the sample size was smaller than 20 or if there was limited information regarding safety and efficacy of partial left ventriculectomy (for example studies of histopathology or DNA retroviral analysis). This left 29 case series for potential inclusion. The four case series studies tabulated were selected based on sample size and completeness of reporting. There is one international registry study[11] which has been included because it focuses on indications for surgery, although some of the patients included in the registry may have been reported on by individual authors from the participating institutions. Excluded studies are listed in the annex.

List of studies tabulated

Non-randomised comparative studies - 1
Case series – 4 (8 papers)

Summary of key efficacy and safety findings

See following tables;

Abbreviations

CAD	coronary artery disease
CABG	coronary artery bypass grafting
CVA	cardiovascular accident
ECC	cardiopulmonary bypass time
HF	heart failure
ICU	intensive care unit
LV	left ventricular
LVAD	left ventricular assist device
LVEDD	left-ventricular end-diastolic diameter
LVEDVI	left ventricular end-diastolic volume index
LVEF	left ventricular ejection fraction
LVESD	left ventricular end-systolic diametre
LVESVI	left ventricular end-systolic volume index
MR	mitral regurgitation
MOF	multiple organ failure
MV	mitral valve
NYHA	New York Heart Association
PLV	partial left ventriculectomy
OHT	orthotopic heart transplantation
RV	right ventricular

Study	Key efficacy findings	Key safety findings	Validity and generalisability
Non-randomised comparative study			
Etoch *et al.* 1999[12] **USA** (patients at Jewish Hospital, Lewisville, Kentucky) Retrospective comparative study of PLV vs transplantation October 1996-April 1998 (retrospective heart transplant data from January 1995-April 1998) N=45 PLV – 16 OHT – 29 (17 patients received transplant – see comments) *Mean follow-up:* 11.1 months PLV, 16.4 months OHT *Selection criteria:* idiopathic dilated cardiomyopathy, LVEDD > 7cm, NYHA class IV despite maximal medical therapy, severely impaired exercise oxygen Not excluded if: RV dysfunction, elevated transpulmonary gradient, presence of incidental coronary disease, need for inotropic agents, or intra-aortic balloon pump	Operative survival – PLV 94%; OHT 94% (p=0.97) Kaplan-Meier 12-month survival from time of surgery – PLV 86%; OHT 93% (p=0.9) Kaplan-Meier 12-month survival from time of listing – 86% PLV; 75% OHT (p=0.76) (due to 21% waiting list mortality rate for OHT) Kaplan-Meier 12-month freedom from death or relisting for transplant – PLV 65%; OHT 86% (p=0.63) Freedom from need for relisting for transplant – PLV 73%; OHT 93% (p=0.003) Relisting for transplant – 4 PLV (2 LVAD placements in meantime); 1 OHT	• post-op mortality – 2 PLV (sepsis – 1, heart failure –1); 1 transplant	*Potential for bias:* • groups not randomised and patients suitable for either OHT or PLV given both options, patients not suitable for OHT given option of PLV or medical therapy • retrospective data subject to historical biases *Outcome measures:* *Other comments*: • of 29 patients listed for OHT, 17 received a heart transplant, 6 patients on transplant waiting list died before surgery (21% waiting list mortality rate) and 6 patients remained on list for transplant

Study	Key efficacy findings	Key safety findings	Validity and generalisability
Case Series Studies			
Fujimura *et al.* 2001[3]; Kawaguchi *et al.* 2001[13], 1998[2] JAPAN & BRAZIL (patients at Hospital Angelina Caron, Curitiba, Brazil) August 1994 – March 1997 N=461 Lateral PLV 295 Extended PLV 101 Anterior PLV 65 *Follow-up:* 13.6[12.4] months (range 8-38) *Selection criteria:* Patients with cardiomyopathy, coronary artery disease (anterior PLV indicated), valvular disease, Chagas disease	Operative • ECC time (mins) – 64[50] • arrest time (mins) – 38[24] • % arrest - 194[42.1] • ICU stay (days) – 5.3[4.6] • hospital stay (days) – 10.2 [5.5] Echocardiographic results: – preop to postop (n=101 FU=5.0[2.6] days postop) • LVEDD – 57.6mm to 45.1mm (anterior PLV); 50.1mm to 46.0mm (extended PLV); 61.2mm to 60.6mm (lateral PLV) • LVESD – 68.8mm to 60.8 (anterior PLV); 72.7mm to 61.1mm (extended PLV); 72.9 to 66.3mm (lateral PLV) • % ventricular fractional shortening – 18.7% to 27.5% (anterior PLV); 17.1% to 23.8% (extended PLV); 16.1% to 23.6% (lateral PLV) • MR – 0.9 to 0.4 (anterior PLV); 1.0 to 0.2 (extended PLV); 1.0 to 0.4 (lateral PLV) Survival: - early postoperative • 30 days – 75% anterior PLV, 72% lateral PLV, 50% extended PLV • 60 days – 75% anterior PLV, 70% lateral PLV, 45% extended PLV • Survival time – 13.6[12.4] months (range 8 to 38)	• Hospital deaths – 138 (30%) (cardiac failure – 27; renal failure – 23; arrhythmia – 13; noncardiac causes – 7; miscellaneous – 5; undetermined – 52) • Died after discharge – 44 (9.5%) (arrhythmia – 10; renal failure – 7; cardiac failure – 5; undetermined – 10) • Overall mortality – 182 (39.5%) In extended PLV 30% (17/57) deaths occurred within 24 hours postoperatively compared with 14% (15/106) of lateral PLV patients ($p<0.05$)	*Potential for bias:* • histopathological analysis performed by pathologist blinded to clinical information • no information regarding whether patient selection was consecutive *Outcome measures:* MR – mitral regurgitation 0 – none 1- mild (validity of this rating scale unknown) % ventricular fractional shortening = LVEDD-LVESD/LVEDD x 100 *Other comments*: • associated procedures included mitral valvuloplasty in 75% of patients with nonischaemic disease; patients undergoing anterior PLV more likely to have CABG and less likely to have valvular procedures; lateral PLV: extended PLV performed about 3:1 in all pathological subgroups • a sub-group analysis of patients with non-ischaemic (n=168) and ischemic cardiomyopathy (n=94) (Fujimura *et al.* 2001[3]) and excluding patients with valvular disease, Chagas disease, and CAD found that the majority (75%) underwent later PLV but ischemic patients required CABG more frequently (79% vs 0.6% $p<0.0001$) and therefore operation time was longer, (74 vs 47 mins, $p<0.0001$) and arrest was required by more patients (43% vs 19%, $p<0.0001$). However, ICU stay was shorter (4.4 vs 5.9 days, $p=0.05$) with hospital stay similar, resulting in similar hospital survival rates (69% vs 71%) and functional capacity. Concluded that PLV may be indicated for ischemic as well an non-ischemic cardiomyopathy.

[ ] = standard deviation

Study	Key efficacy findings	Key safety findings	Validity and generalisability
Franco-Cereceda *et al.* 2001[8]; Starling & McCarthy, 1999[9]; McCarthy *et al.* 1997[14] **USA** (patients at Cleveland Clinic, Cleveland, Ohio) May 1996 – December 1998 N=62 *Mean follow-up:* 24[12] (max 3.5 years) *Selection criteria:* • LVEDD > 7.0cm • dilated cardiomyopathy without extensive scar tissue • no medical contraindications • NY Heart Association functional class III/IV • heart failure > 6months • optimised on medical therapy for heart failure prior to surgery	<u>Echocardiographic results</u>: – immediate preoperative to immediate postoperative • LVEDD 8.4[1.1]cm to 5.92[0.8]cm (p<0.01) • LVEDVI 133[48.6]mL to 64.1[26]mL (p<0.0001) • LVEF 16[7.6] to 31.5[10.9] (p<0.0001) <u>Survival:</u> • survival 30 days – 99% • survival 1 year – 80% • survival 3 years – 60% • event-free survival 30 days – 80% • event-free survival 1 year - 49% • event-free survival 3 years – 26% <u>LVAD rescue therapy</u>: 11 (18% CL 13 – 24%) (2 died of multiorgan failure, 8 transplant, 1 LV recovery) • freedom from LVAD at 30 days – 85% • freedom from LVAD at 1 year – 83% • freedom from LVAD at 3 years – 82% <u>Return to class IV HF</u>: – 32 • Freedom from class IV HF 30 days – 81% • Freedom from class IV HF 1 year – 57% • Freedom from class IV HF 3 years – 42%	• hospital deaths – 2 (3.2%, 95%CI: 1.0% -7.5%) • risk of death - 6%/month in early phase (up to 4 months); 1.2/month (by 12 months) • mortality causes: o HF/arrhythmias – 11 o sudden death – 4 o multiorgan failure – 4 (1 after transplantation) o stroke – 1 o witnessed cardiac arrest – 1 o acute rejection – 1 • 3+ mitral regurgitation – 1 • implantable cardioverter/defibrillators – 28 (7 present preoperatively) • arrhythmias treated with defibrillators – 10/28 Increased systolic pulmonary artery pressure, decreased maximum exercise oxygen consumption, increased left atrial pressure were associated with failure and/or death Degree of preoperative mitral regurgitation did not correlate with clinical outcome	*Potential for bias:* • FU complete for clinical outcomes • no information regarding whether patient selection was consecutive *Outcome measures:* NYHA functional class – validated measure of functional status *Other comments*: • patients were selected from around 3000 referrals (for transplantation) – authors state that patients were most often turned down for medical reasons, because the patient was too well, or because they had refused PLV after informed consent procedure • survival rates incorporate aggressive treatment of subsequent heart failure (with LVAD and transplantation) therefore higher than event-free survival • postoperative adjustment of medical treatments may have contributed to outcomes from surgery • defibrillators (to treat postoperative arrhythmias) only implanted routinely in later patients.

[ ] = standard deviation

Study	Key efficacy findings	Key safety findings	Validity and generalisability
Batista *et al.*1997[10] **BRAZIL & USA** (patients at the Hospital Angelina Caron, Brazil, and Buffalo General Hospital, New York) From July 1995 N=120 Hospital Angelina Caron – 50 Buffalo General Hospital – 70 PLV alone – 40 PLV + valve – 51 PLV + CABG – 10 PLV + autotransplantation – 7 PLV + other – 12 *Follow-up:* up to 22 months for Buffalo General Hospital patients *Selection criteria:*(for Buffalo General Hospital patients) elderly patients with viral and idiopathic dilated cardiomyopathy with or without valvular disease Excluded – cardiac transplant patients (for Hospital Angelina Caron patients) all patients with dilated cardiomyopathy	Postoperatively: NYHA functional class I – 57% NYHA functional class II – 33% NYHA functional class III/IV – 10% <u>Survival:</u> • 2 year survival rate – 55% (only reported in abstract not text of paper) • life table analysis o over 22 months (June 1995-April 1997) (n=23) cumulative probability of mortality – 33% o over 13 months (from May 1996 – April 1997) (n=18) – 66% o over 10 months in last 10 patients in series – 89.5%	• 30-day mortality/morbidity rates in two institutions combined: o operative mortality – 22% o congestive HF – 18% o bleeding – 7% o arrhythmias – 5% o renal failure – 4% o respiratory failure – 4% o infection – 4% o others – 5 %	*Potential for bias:* • combined patients groups from the two institutions differ significantly in indications for surgery (i.e. eligibility for transplantation) • no information regarding whether patient selection was consecutive *Outcome measures:* NYHA functional class – validated measure of functional status *Other comments*: most of the mortality and complications occurred during initial experience with PLV due to poor case selection, learning curve, emergency operations on patients who should have received LVADs and inadequate resection of LV muscle to preserve MV

Study	Key efficacy findings	Key safety findings	Validity and generalisability

Kawaguchi *et al.* 2001[11]
INTERNATIONAL REGISTRY STUDY
 	
1996 – 1999 onwards
 	
N=287
48 institutions
11 countries
Asia – 134 patients
Europe – 119 patients
US – 34 patients
 	
Follow-up: 3+ years (0 – 3.3yrs)
 	
Selection criteria: excluded patients undergoing Dor procedure or LV aneurysmectomy (81 cases); patients with CAD
	Factors effecting event-free survival:
	• male/female – female lower (p=0.14)
	• smaller body surface area <1.6m^2 – reduced survival (p=012)
	• younger/older than 60 – no difference (p=0.587)
	• younger/older than 65 – no difference (p=0.069)
	• paediatric/adult – 1yr survival 45.5% vs 54.1%
	• underlying cardiac pathology – no significant difference
	• moderate-severe mitral regurgitation/no or mild regurgitation at 1 year – 47.5% vs 61.3% (p=0.152)
	• preop symptoms <3yrs/preop symptoms>9yrs – 1yr survival 60.4% vs 42.6% (p=0.14)
	• preop NYHA class ≤ IV/class IV – 1yr survival 65% vs 45% 2yr 59% vs 39% (log-rank p=0.002, Wilcoxon p=0.0008
	• no significant difference in event-free survival by preoperative end-diastolic dimensions or mass
	• absence/presence transplant indication preop – 1 year survival 47% vs 55% (p=0.59) (actuarial patient survival p=0.191)
	• extended PLV/lateral PLV – not significant difference
	• first four cases PLV/subsequent cases – poorer for initial cases than fifth case onwards (p=0.011) tenth case onwards (p=0.008) twentieth case onwards (p=0.001) thirtieth case (p=0.03)
		• died during initial admission – 85 (30%)
		• died after discharge – 38 (13%)
		• overall mortality – 123 (43%)
		• LVAD required or listing for transplantation after 3 to 35 months – 14
		  ○ received transplantation – 11 (6 survived, 3 died, 2 lost to FU)
		  ○ died on list – 2
		  ○ still waiting LVAD – 1
		
		Causes of death or failure: events (px)
		LV failure: Hosp 36 (3), Late 16 (11), Total 52 (14)
		sepsis: 12, 1, 13
		MOF: 9, 3, 12
		arrhythmia: 7, 4, 11
		sudden death: 5, 5, 10
		hepatic failure: 2, 2, 4
		CVA: 4, 0, 4
		RV failure: 3, 0, 3
		pneumonia: 1, 1, 2
		others: 6, 6, 12
		
		TOTAL: 85 (3), 8 (11), 123 (14)
		
		(Number in brackets is number of patients)
			Potential for bias:
			• submission of data to the register voluntary
			• size of experience and study period varied from region to region
			• Asian data submission appeared to be more complete than data submitted from Europe and the USA
			
			Outcome measures:
			NYHA functional class – validated measure of functional status
			
			Other comments:
			no Brazilian centres were included in the registry – instead the Kawaguchi series (see tabulated studies 2,3&13 were excluded and compared with registry data "to avoid mass effect and to contrast local factors" (p.20)

Specialist advisor's opinion / advisors' opinions
Specialist advice was sought from Society of Cardiothoracic Surgeons of Great Britain and Ireland.

The Specialist Advisors considered partial left ventriculectomy to be a novel procedure likely to be performed in only a few specialised centres in the UK. It was recommended that considerable caution should be exercised regarding the adoption of this technique. It was also recommended that this procedure should only be carried out in hospitals with facilities for pre and postoperative evaluation by MRI scans and cardiopulmonary exercise tests. One Specialist Advisor commented that, while the surgery is effective for patients with end-stage left ventricular failure, there is a high 30 day mortality rate, and late complications include arrhythmia, scar stretching, mitral regurgitation, progressive dilation of the left ventricle and the need for cardiac transplant. The principle drawback of the procedure is the need for resection of viable myocardium, and uncertainties exist regarding the medium to long-term outcomes of the procedure.

Issues for consideration by IPAC
Partial left ventriculectomy has been most enthusiastically embraced in Brazil and Japan. In neither country is heart transplant surgery readily available, in Brazil for socio-economic reasons and in Japan because of laws governing organ donation. So there has been a strong motivation in these countries to find an alternative to transplantation. However, in countries like the US and UK where there is relatively easy access to heart transplant surgery, partial left ventriculectomy is likely to remain a minority procedure.

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Annex – Excluded Studies

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