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Can the temporary use of right ventricular assist devices bridge patients with acute right ventricular failure after cardiac surgery to recovery?

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Abstract

A best evidence topic in cardiac surgery was written according to a structured protocol. The question addressed was: Can the temporary use of right ventricular assist devices (RVADs) bridge patients to recovery who suffer acute right ventricular failure after cardiac surgery? More than 183 papers were found using the reported search, of which 13 represented the best evidence to answer the clinical question. The authors, journal, date and country of publication, patient group studied, study type, relevant outcomes and results of these papers are tabulated. Indications for surgical intervention included coronary artery bypass surgery, valve replacement, post-heart transplant and left ventricular assist device insertion. Significant reductions in central venous pressure ($P = 0.005$) and mean pulmonary artery pressures ($P < 0.01$) were reported during and after RVAD support. Furthermore, increases in right ventricular cardiac output ($P < 0.05$), right ventricular ejection fraction ($P < 0.05$), right ventricular stroke work ($P < 0.05$) and pulmonary artery oxygen saturations ($P < 0.05$) were also seen. Assessment by one study showed that on Day 7 after RVAD removal, the right ventricular ejection fraction had increased by up to 40%. Dynamic echocardiography studies performed before, during and after RVAD placement demonstrated that after RVAD implantation, right ventricular end-diastolic dimensions ($P < 0.05$) and right atrial dimensions decreased ($P < 0.05$) and right ventricular ejection fraction ($P < 0.05$) increased. Although several studies successfully weaned patients from an RVAD, there were several complications, including bleeding requiring surgical intervention. However, this may be reduced by using percutaneous implantation (bleeding incidence: 4 of 9 patients) rather than by a surgically implanted RVAD (bleeding incidence: 5 of 5 patients). However, mortality is higher in percutaneous RVAD patients rather than in surgical RVAD (80–44%) patients. Causes of death cited for patients on an RVAD included multiorgan failure, sepsis, thromboembolic events, reoccurring right heart failure and failure to wean due to persistent right ventricular failure. We conclude that RVADs have been successfully used to bridge patients to recovery after cardiac surgery; however, RVADs carry numerous risks and a high mortality rate.

Keywords: Review • Ventricular dysfunction, right • Heart assist devices

INTRODUCTION

A best evidence topic was constructed according to a structured protocol. This is fully described in the *ICVTS* [1]

THREE-PART QUESTION

In [patients with acute right ventricular failure after cardiac surgery] can [temporary use of Right Ventricular Assist Devices] help to [bridge patients to recovery]?

CLINICAL SCENARIO

A patient is admitted for insertion of a left ventricular assist device (LVAD) while awaiting heart transplantation, and you are aware that this procedure carries a risk of acute right ventricular failure (RVF). You wonder if this complication should occur whether a right ventricular assist device (RVAD) could be used to bridge him to recovery?

SEARCH STRATEGY

An English language literature review was performed on Medline from 1948 to May 2012, using the OVID interface: ['Ventricular Dysfunction, Right'] AND ['Heart-Assist Devices'].

SEARCH OUTCOME

The search returned 183 papers, of which 13 were identified as answering our question. These are presented in Table 1.

Table 1: Best evidence papers

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key words	Comments
Jett *et al.* (1987), J Thorac Cardiovasc Surg, USA [2] Animal case–control study (level V)	16 lambs with surgically induced RVF (PA banding and later right ventriculotomy) were supported with either a pulmonary artery balloon counterpulsation (PABCP) (n = 6), ABIOMED RVAD (n = 6) or no support (n = 4)	**Support time (h)** PABCP RVAD No support	 7 ± 2 (range 1–15) 5 ± 2 (range 1–10) (all studies electively terminated) Survival <40 min	Data show that RVAD and PABCP both are able to provide circulatory support in right ventricular failure
		RV peak systolic pressure (mmHg) (on vs off) PABCP RVAD	 41 ± 3 vs 56 ± 5 (P < 0.0001) (23 ± 4% decrease) 43 ± 6 vs 44 ± 8 NS	
		RV systolic pressure time index (mmHg s/min) (on vs off) PABCP RVAD	 710 ± 65 vs 1140 ± 79 (P < 0.0001) (34 ± 7% decrease) 969 ± 211 vs 1514 ± 232 (P < 0.01) (45 ± 14% decrease)	
		Right atrial pressure (mmHg) PABCP (on vs off) RVAD (on vs off) RVAD vs PABCP	 11 ± 1 vs 14 ± 1 (P < 0.0001) 12 ± 2 vs 19 ± 2 (P < 0.01) −39 ± 6 vs −17 ± 3% (P < 0.01)	
		RV end-diastolic pressure (mmHg) (On vs off support) PABCP RVAD	 11 ± 1 vs 15 ± 1 (P < 0.0001) 12 ± 1 vs 19 ± 3 (P < 0.01)	
		Pulmonary artery peak systolic pressure (mmHg) PABCP (on vs off) RVAD (on vs off) RVAD vs PABCP	 40 ± 1 vs 31 ± 2 (P < 0.0001) (34 ± 7% increase) 52 ± 5 vs 27 ± 3 (P < 0.01) (114 ± 26% increase) 114 ± 26 vs 34 ± 7% (P < 0.01)	
		Aortic systolic pressure (mmHg) PABCP (on vs off) RVAD (on vs off) RVAD vs PABCP	 99 ± 6 vs 78 ± 7 (P < 0.0004)(35 ± 9% increase) 85 ± 9 vs 53 ± 9 (P < 0.01) (85 ± 13% increase) 85 ± 13 vs 35 ± 9% (P < 0.01)	
		Aortic diastolic pressure (mmHg) (on vs off) PABCP RVAD	 59 ± 5 vs 50 ± 5 (P < 0.01) (27 ± 12% increase) 40 ± 5 vs 29 ± 4 (P < 0.01) (46 ± 17% increase)	

Continued

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key words	Comments
		Systemic blood flow (l/min)		
		PABCP (on vs off)	1.45 ± 0.13–2.03 ± 0.13 ($P < 0.0001$) (54 ± 11% increase)	
		RVAD (on vs off)	0.72 ± 0.15–2.23 ± 0.23 ($P < 0.01$) (153 ± 39% increase)	
		RVAD vs PABCP	0.72 ± 0.15 vs 1.45 ± 0.16 ($P < 0.01$)	
		Left atrial pressure (mmHg)		
		PABCP (on vs off)	13 ± 1 vs 12 ± 1 (NS)	
		RVAD (on vs off)	11 ± 1 vs 7 ± 1 ($P < 0.01$) (63 ± 15% increase)	
		RVAD vs PABCP	63 ± 15 vs 12 ± 5% ($P < 0.05$)	
		RVSWI (gm m/kg/beat)		
		PABCP (on vs off)	0.081 ± 0.011–0.121 ± 0.017 ($P < 0.01$) (66 ± 26% increase)	
		RVAD (on vs off)	0.042 ± 0.019–0.075 ± 0.26 ($P < 0.01$) (215 ± 87% increase)	
		RVAD vs PABCP	215 ± 87 vs 66 ± 26% ($P < 0.05$)	
Yano *et al.* (1996), Ann Thorac Surg, Japan [3]	12 dogs were implanted with a pRVAD following insertion of an LVAD. Biventricular failure was induced in all animals by normothermic global cardiac ischaemia and electrically induced VF	**Haemodynamic effects with PRVAS off vs on after induced ischaemia**		The study concluded that pRVADs can be used to support animals in RVF, and hence thoracotomy may not be required to support RVF with an RVAD
Animal study (level V)		Cardiac output (l/min)	0.75 ± 0.36 vs 1.16 ± 0.25 ($P = 0.0003$)	
		Cardiac index (ml min^{-1} kg^{-1})	53.3 ± 31.8 vs 77.8 ± 31.7 ($P = 0.0001$)	
		Mean aortic pressure (mmHg)	43.5 ± 12.3 vs 57.5 ± 11.2 ($P = 0.0001$)	
		Mean pulmonary artery pressure (mmHg)	11.1 ± 6.3 vs 14.8 ± 5.5 ($P = 0.024$)	
		Right ventricular systolic pressure (mmHg)	17.9 ± 10.2 vs 14.4 ± 10.2 ($P = 0.0038$)	
		Right ventricular end-diastolic pressure (mmHg)	8.2 ± 4.5 vs 5.9 ± 4.5 ($P = 0.0035$)	
		Right atrial pressure (mmHg)	7.4 ± 2.5 vs 5.1 ± 2.5 ($P = 0.0009$)	
		Left atrial pressure (mmHg)	–1.2 ± 6.9 vs 0.7 ± 5.5 ($P = 0.0169$)	
		RVSWI (ml mmHg kg^{-1})	4.2 ± 6.1 vs 1.0 ± 1.8 ($P = 0.0495$)	
		Pulmonary vascular resistance index (mmHg min kg l^{-1})	549.9 ± 536.0 vs 260.7 ± 153.6 ($P = 0.0431$)	
		Heart rate (bpm)	119.5 ± 38.1 vs 108.3 ± 38.7 (NS)	

Continued

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key words	Comments
	6 goats were implanted with a pRVAD, and the goats were allowed to wake up with the device implanted	Support time in days (range)	2–8	
		Cause of sacrifice	Pump standstill secondary to thrombi (*n* = 2), kinking of cannula (*n* = 1) and post-experiment (*n* = 2). Plus a death due to intrathoracic haemorrhage (*n* = 1)	
		Pathological changes after pRVAD implantation	No destruction of pulmonary or tricuspid valves or inner surface of the heart. Lungs demonstrated no pulmonary oedema or intra-alveolar haemorrhage	
		Plasma-free haemoglobin concentration (mg/dl)	6.8 ± 1.9 pre-pRVAD use, and increased over follow-up, although declined immediately post-pump change	
Shum-Tim *et al.* (1997), Ann Thorac Surg, USA [4] Animal case–control study (level V)	RVF was surgically induced in 3-week-old lambs either without support (control, *n* = 5) or with supported for 6 h with the MEDOS HIA-VAD (*n* = 5)	**Mean survival (min)** Control RVAD **Mean systemic arterial pressure (mmHg) after RVF induced RVF. RVAD on vs off** 10 min 2 h 4 h 6 h **Mean right atrial pressure (mmHg) after RVF induced. RVAD on vs off** 10 min 2 h 4 h 6 h **Mean pulmonary artery pressure (mmHg) after RVF induced. RVAD on vs off** 10 min 2 h	 71.4 ± 9.4 after the surgical RVF induction 58.2 ± 28.2 after removal of support 75.0 ± 13.7 vs 38.8 ± 10.4 (*P* < 0.05) 75.2 ± 12.5 vs 34.6 ± 9.6 (*P* < 0.05) 73.2 ± 11.6 vs 32.8 ± 4.9 (*P* < 0.05) 68.0 ± 13.0 vs 33.4 ± 6.7 (*P* < 0.05) 6.0 ± 3.0 vs 16.8 ± 2.3 (*P* < 0.05) 5.6 ± 2.3 vs 12.6 ± 0.05 (*P* < 0.05) 6.6 ± 2.6 vs 14.0 ± 1.0 (*P* < 0.05) 8.2 ± 2.3 vs 15.0 ± 2.3 (*P* < 0.05) 20.6 ± 2.3 vs 23.2 ± 3.8 (*P* > 0.05) 25.8 ± 5.6 vs 15.2 ± 2.2 (*P* < 0.05)	The group studied the MEDOS device in RVF. The MEDOS has a stroke volume of 9 ml, which would make the device possible to use in neonates. The study demonstrated that RVADs could support lambs with RVF

Continued

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key words	Comments
		4 h	25.4 ± 4.3 vs 13.8 ± 2.8 ($P < 0.05$)	
		6 h	24.8 ± 6.5 vs 15.6 ± 3.1 ($P < 0.05$)	
		Mean left atrial pressure (mmHg) after RVF induced. RVAD on vs off		
		10 min	5.0 ± 1.6 vs 1.4 ± 0.5 ($P < 0.05$)	
		2 h	5.6 ± 2.1 vs 2.4 ± 1.5 ($P < 0.05$)	
		4 h	4.6 ± 2.1 vs 2.2 ± 1.3 ($P < 0.05$)	
		6 h	6.4 ± 2.1 vs 2.6 ± 0.9 ($P < 0.05$)	
		CO (l/min) after RVF induced. RVAD		
		10 min (on vs off)	1.0 ± 0.3 vs 0.6 ± 0.1 ($P < 0.05$)	
		2 h on	0.9 ± 0.1	
		4 h on	1.0 ± 0.2	
		6 h on	1.0 ± 0.2	
		Pulmonary vascular resistance (mmHg min/l) after RVF induced		
		10 min (on vs off)	16.5 ± 2. vs 40.8 ± 10.9 ($P < 0.05$)	
		2 h on	22.8 ± 6.9	
		4 h on	22.0 ± 8.5	
		6 h on	18.6 ± 8.2	
		Heart rate (bpm) after RVF induced. RVAD (on vs off)		
		10 min	168.4 ± 32.2 vs 147.0 ± 14.6 ($P > 0.05$)	
		2 h	171.2 ± 25.2 vs 177.2 ± 31.6 ($P > 0.05$)	
		4 h on	183.0 ± 31.2 vs 175.2 ± 31.7 ($P > 0.05$)	
		6 h on	190.4 ± 7.0 vs 166.2 ± 50.9 ($P > 0.05$)	
Sugiki *et al.* (2009), Asian Cardiovasc Thorac Ann, Singapore [5] Retrospective cohort study (level IIb)	7 patients (5 males; 2 females; mean age 54 + 7) supported with Impella Recover RD *Indications:* post-orthotopic heart transplant ($n = 4$), post-redo mitral valve replacement ($n = 2$) and post-LVAD insertion ($n = 1$)	**CVP (mmHg)**		With 2 of 7 patients with pump dysfunction, the paper suggests a need for improved reliability of RVADs. The 1 patient who was successfully bridged to transplant had not been exclusively maintained on an RVAD but had been switched to hybrid support with Thoratec p-VAD prior to transplantation
		Pre-implant	15.3 ± 1.4	
		Post-implant	9.3 ± 1.2 ($P = 0.005$)	
		Support time (days)	Mean: 4.9 ± 4.5 Range: 1–13	
		Weaned	3 of 7 weaned (at 3–13 day postop) 1 of 7 bridged to transplant with hybrid device inserted Day 8 postop	
		Survival	1 of 7 (14%) survived to transplant and discharge 3 died on the device. *Cause:* MOF 3 weaned patients died. *Cause:* recurrent RVF ($n = 1$) and pulmonary infection ($n = 2$)	

Continued

BEST EVIDENCE TOPIC

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key words	Comments
		Complications	Re-exploration for bleeding (*n* = 2); renal dysfunction and dialysis (*n* = 6); pump dysfunction (*n* = 2)	
		Laboratory values		
		Haematocrit, creatinine, serum glutamic-oxaloacetic transaminase, serum glutamate pyruvate transaminase, bilirubin and lactate	No significant difference between pre- and post-implantation values	
		Delay between aortic cross-clamp removal and RV support initiation (h)	8.3 ± 6.6 (range 1–48)	
Chen *et al*. (1996), Ann Thorac Surg, USA [6] Retrospective cohort study (level IIb)	11 patients (10 males; 1 female; mean age 52.1 ± 13.0 years) supported with either ABIOMED 5000 BVS (*n* = 5) or BioMedicus centrifugal (*n* = 6) for >1 h *Indications:* Right ventricular failure after heart transplant (*n* = 8), LVAD insertion (*n* = 1) and 1 patient who received an RVAD for right ventricular failure after an LVAD and then 5 months later after transplantation (counted as 2 patients due to insertion at two events)	Support time (h)	Mean: 133.6 ± 33.6 Range: 107–190	Small study. A study used low threshold for haemofiltration
		Mean pulmonary artery diastolic pressure in survivor (mmHg)		
		Pre-implantation On RVAD (survivors) After RVAD	27.2 ± 4.3 23.7 ± 6.3 13.2 ± 3.9 (*P* < 0.01)	
		CVP (mmHg)		
		Pre-implant On RVAD (survivors) On RVAD (non-survivors) After RVAD	22.2 ± 4.4 11.7 ± 5.6 (*P* < 0.01) 18.2 ± 7.3 5.4 ± 2.3 (*P* < 0.01)	
		Cardiac output		
		Pre-implant Post-implant	3.8 ± 1.1 7.0 ± 4.0	
		Weaned	6 of 11 weaned 5 of 11 died on RVAD	
		Mortality	*Causes of death*: sepsis (*n* = 2), biventricular failure (*n* = 2) and coagulopathy (*n* = 1)	
		Urine output	Improved throughout support in survivors, but not non-survivors	
		Complications	3 of 6 survivors and 1 of 5 non-survivors required haemofiltration or haemodialysis	
Bhama *et al*. (2009), J Heart Lung Transplant, USA [7] Retrospective cohort study (level IIb)	29 patients (mean age 57 ± 14) supported with the CentriMag RVAD system *Indications:* PCCS (*n* = 7), cardiac transplant (*n* = 10), LVAD implant (*n* = 12) *Primary diagnosis:* Ischaemic cardiomyopathy (PCCS *n* = 5, 71%; transplant *n* = 6, 60%; LVAD *n* = 4, 33%) Non-ischaemic	Support time (days)	8 ± 8	Early implant felt to be key by authors. More than 50% of patients survived until discharge
		Weaned	66%: 3 of 7 PCCS, 7 of 10 transplants, 7 of 12 LVADs (3 of 12 failure of weaning patients placed on PCAD)	
		Early death (<30 days or before discharge)	14 of 29 (48%) 9 of 14 (31%) died with the RVAD in situ *Causes:* sepsis, LVF, stroke and care withdrawn	

Continued

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key words	Comments
	cardiomyopathy (PCCS *n* = 0; transplant *n* = 3, 30%; LVAD *n* = 6, 50%) Other (PCCS *n* = 2, 29%; transplant *n* = 1, 10%; LVAD *n* = 2, 17%) Comorbidities: diabetes (PCCS *n* = 5, 71%; transplant *n* = 1, 10%; LVAD *n* = 3, 25%), hypertension (PCCS *n* = 4, 57%; transplant *n* = 4, 40%; LVAD *n* = 3, 25%)	Late death (post-discharge) Complications	2 of 15 *Causes:* stroke and withdrawal of care Major infection (*n* = 13), arrhythmias (*n* = 13), reoperation for bleeding (*n* = 10), stroke/ encephalopathy (*n* = 3) and air embolism (*n* = 1)	
Moazami *et al.* (2004), J Heart Lung Transplant, USA [8] Retrospective cohort study (level IIb)	30 patients (13 males, 17 females; mean age 58 ± 15 years) supported with an RVAD for isolated RVF *Indications:* post-CABG ± valve (*n* = 12), valvular surgery (*n* = 5), ascending aortic dissection (*n* = 6), heart transplant (*n* = 3) and pulmonary thromboendarterectomy (*n* = 4) Comorbidities: renal failure (23%), myocardial infarction (43%), history of smoking (57%), NYHA Grade IV (40%)	Support time (days) Weaned Time to wean (days) Death Survival to discharge Post-RVAD right ventricular function **Post-RVAD haemodynamics** Pulmonary arterial pressure Cardiac output CVP	Mean: 5 ± 4, range: 2–8 13 of 30 successfully weaned Median: 3, range: 1–36 20 of 30 died 17 unable to be weaned *Causes of death:* RV/ failure to wean (*n* = 12), sepsis (*n* = 3), cerebrovascular accident (*n* = 2) and respiratory failure (*n* = 1) 3 died post-weaning from the RVAD *Causes:* sepsis (*n* = 1), stroke (*n* = 1) and respiratory failure (*n* = 1) 10 of 30 Normal (*n* = 2) Improved but global hypokinesis (*n* = 11) 25.1 ± 6.5 mmHg 4.8 ± 2.0 l 16.5 ± 3.7 mmHg	40% died of RVF, but for those weaned RV function was compatible with life. The study limited by the lack of pre-RVAD haemodynamics
Morgan *et al.* (2004), Ann Thorac Surg, USA [9] Retrospective case–control study (level IIb)	17 patients (14 males; 3 females; mean age 50.4 ± 12.4) supported with the HeartMate device *Indications:* patients requiring an RVAD in addition to an LVAD to bridge to transplant in heart failure secondary to coronary artery disease (*n* = 6), idiopathic cardiomyopathy (*n* = 9) or other (*n* = 2)	Support time (days) **LVAD implantation score** Early RVAD vs late RVAD Pre-LVAD haemodynamics CVP (mmHg) Mean pulmonary artery pressure (mmHg) Lower right ventricular stroke work (mmHg)	Median: 4.0 Mean: 5.4 ± 3.9 Range: 0.2–15.0 6.9 ± 1.4 vs 5.0 ± 1.5 (*P* = 0.001) RVAD vs non-RVAD patients 26.25 ± -20.19 vs 20.75 ± 17.05 (*P* = 0.044) 14.50 ± 10.28 vs 29.75 ± 13.85 (*P* = 0.032) 10.34 ± 3.45 vs 15.88 ± 22.93 (*P* = 0.045)	This study aimed to isolate risk factors predicting the need for RVAD placement after LVAD *Conclusion:* early detection and insertion is key. Allow adequate time on RVAD for haemodynamics to recover Needs bigger study

Continued

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key words	Comments
		Weaned off RVAD before operation	9 of 11	
		Early (< 24 h) vs delayed (>24 h) RVAD insertions	6 of 7 (85.7) vs 3 of 4 (75.0%)	
		Mortality on RVAD	6 of 17 (35.3%) *Causes of death:* MOF (*n* = 3), stroke (*n* = 1), respiratory failure (*n* = 1) and arrhythmias (*n* = 1)	
		Successfully bridged to transplant RVAD vs non-RVAD	11 of 17 (64.7%) vs 163 of 226 (72.1%) (*P* = 0.046)	
		Early (< 24 h) vs delayed (>24 h) RVAD insertions	7 of 10 (70%) vs 4 of 7 (57.1%) (*P* < 0.001)	
		Post-transplant actuarial survival (1, 5 and 10 years) 1 year 5 years 10 years	**RVAD vs non-RVAD** 71.4 vs 90.5% 71.4 vs 80.4% 71.4 vs 78.5% (*P* = 0.366)	
		RVAD as a predictor of post-transplant mortality	OR 0.646 (95% CI 0.328-0.972) (*P* = 0.864)	
Shuhaiber *et al.* (2007), J Heart Lung Transplant, UK [10] Retrospective cohort study (level IIb)	27 patients supported (mean age 47.9, range 19–72 years; 19 males) with Levitronic CentriMag VAD (uni- or biventricularly) *Indications:* end-stage heart failure but not candidate for transplant (*n* = 9), RVF post-LVAD placement (*n* = 5), post-cardiotomy (*n* = 7) and acute donor graft failure (*n* = 6) BiVAD (*n* = 14); LVAD (*n* = 7); RVAD (*n* = 6) *Aetiology of end-stage heart failure:* idiopathic cardiomyopathy (*n* = 1), dilated cardiomyopathy (*n* = 3), ischaemic cardiomyopathy (*n* = 3), valve-related cardiomyopathy (*n* = 1) and chronic allograft cardiomyopathy (*n* = 1) *Post-cardiotomy procedures included:* CABG (*n* = 4), CABG and aortic valve replacement (*n* = 1), CABG and left ventricular aneurysmectomy (*n* = 1), septum primum defect repair and mitral valve replacement (*n* = 1)	Support time (days), mean (range)	BiVAD: 11 (1–51) LVAD: 13.7 (1–30) RVAD: 26.6	This study merged the RVAD, LVAD and BiVAD results, and therefore, it is difficult to assess the exact impact on the RVAD support only in this study
		Average bilirubin (survivors vs non-survivors)	24.1 vs 42 IU (*P* = 0.045)	
		Weaned from device	5 of 27 1 of 4 required re-transplant	
		Bridged to transplant	3 of 27 1 of 3 was a repeat transplant after acute donor failure	
		Complications	Re-operation for bleeding (*n* = 8), clinical cerebral thromboembolism (*n* = 3), sepsis (*n* = 1) and aortic thrombus formation (*n* = 1) Clot formation in the tubing (*n* = 1). No mechanical failure	
		Mortality	19 of 27 100% mortality in the RVAD group *Causes:* MOF, stroke, sepsis, ischaemic bowel and aortic thorombus 11 underwent autopsy: 6 thromboembolic events (including 3 cerebrovascular infarcts)	

Continued

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key words	Comments
		Survival to discharge	8 of 27 1 of 8 of survivors has an cerebral infarct	
Haneya *et al.* (2012), Eur J Cardiothorac Surg, UK [11] Retrospective cohort study (level IIb)	8 patients (6 males, 2 females; mean age 52, range 41–58) supported with pRVAD *Indication:* postoperative acute RVF following LVAD implantation	Support time (days) **Pulmonary artery pressure (mmHg)** Pre-RVAD vs on RVAD Pre-explantation off RVAD **CVP (mmHg)** Pre-RVAD vs On RVAD Pre-explantation Post-RVAD **Cardiac output (l min^{-1})** Pre-RVAD vs On RVAD Pre-explantation Post-RVAD **Echo: RVEF (%)** Pre-RVAD vs On RVAD Pre-explantation Post-RVAD Echo: RVEDD (mm) Echo: right atrial dimensions (mm) Weaned Hospital discharge Complications	Mean: 14, range: 12–14 42 ± 11 32 ± 12 ($P < 0.05$) 24 ± 13 ($P < 0.05$) 26 ± 13 ($P < 0.05$) 29 ± 8 17 ± 8 ($P < 0.05$) 11 ± 9 ($P < 0.05$) 11 ± 9 ($P < 0.05$) 3.9 ± 0.8 4.3 ± 0.9 ($P < 0.05$) 5.1 ± 1.1 ($P < 0.05$) 5.4 ± 1.1 ($P < 0.05$) 24 ± 12 31 ± 15 ($P < 0.05$) 43 ± 1 ($P < 0.05$) 41 ± 8 ($P < 0.05$) 39 ± 9–29 ± 9 mm ($P < 0.05$) 54 ± 13–39 ± 10 mm ($P < 0.05$) 6 of 8 with no signs of RVF afterwards 5 discharged, 2 in-hospital death: 1 MOF and 1 intracerebral bleeding 1 post-discharge death from MOF None observed	Side effects included bleeding and infection No mechanical failure
Kapur *et al.* (2011), J Heart Lung Transplant, USA [12] Retrospective cohort study (level IIb)	9 patients (mean age 55 ± 17) supported with a Tandem Heart pRVAD *Indications:* medically refractory RVF due to acute IWMI ($n = 6$), post-cardiotomy syndrome ($n = 2$) and severe sepsis ($n = 1$) Compared with 5 patients (mean age 65.4 ± 5) with an sRVAD secondary to RVF in a peri-operative setting Comorbidities: *in pRVAD:* peripheral vascular disease ($n = 3$, 33.3%), hypercholesterolaemia ($n = 4$, 44.4%), hypertension ($n = 3$, 33.3%), diabetes mellitus ($n = 1$,	**Time from presentation to implantation of pRVAD (h)** IWMI Non-IWMI Survivors Non-survivors **Mean arterial pressure (mmHg) in pRVAD** Pre-implant Post-implant	 28.5 ± 27 59 ± 73 ($P < 0.05$) 18 ± 6 114 ± 84 ($P < 0.05$) 57 ± 7 74 ± 19 ($P < 0.05$)	No significant haemodynamic changes seen in patients implanted with sRVAD Survivors noted to have a significantly higher mean arterial pressure and pulmonary artery oxygen saturation and reduced right atrial pressure and RVSW within 24 h compared with non-survivors *Limitations:* small number of patients in the study, no large comparison group available

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BEST EVIDENCE TOPIC

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key words	Comments
	11.1%), history of MI (*n* = 3, 33.3%) and history of systolic heart failure (*n* = 1, 11.1%)	**Cardiac index (l/min/m²) in pRVAD** Pre-implant Post-implant	 1.50 ± 0.37 2.25 ± 0.54 (*P* < 0.05)	
	Comorbidities: *in sRVAD:* peripheral vascular disease (*n* = 1, 25%), hypercholesterolaemia (*n* = 4, 80%), hypertension (*n* = 5, 100%), diabetes mellitus (*n* = 4, 80%), history of MI (*n* = 4, 80%) and history of systolic heart failure (*n* = 4, 80%)	**Pulmonary artery oxygen saturation (%) in pRVAD** Pre-implant Post-implant **RVSW (g m/beat) in pRVAD** Pre-implant Post-implant **Right atrial pressure (mmHg) in pRVAD** Pre-implant Post-implant	 40 ± 14 58 ± 4 (*P* < 0.05) 3.41 ± 3.88 9.66 ± 6.83 (*P* < 0.05) 22 ± 3 15 ± 6 (*P* < 0.05)	
		Laboratory values (sodium, BUN, creatinine, ALT, AST, bilirubin, haemoglobin, platelets, pH and lactate) in pRVAD	NS	
		Pre-implant medical support	pRVAD vs sRVAD	
		Inotropes Vasopressors	1.4 ± 0.05 vs 1.8 ± 0.05 1.8 ± 0.08 vs 3.0 ± 0.7 (*P* = 0.02) No difference seen in survivors vs non-survivors	
		Support time (days)	3.1 ± 1.8	
		Discharged	5 of 6 (83%) patients with acute IWMI survived till discharge	
		Mortality pRVAD sRVAD	 4 (44%) patients died secondary to persistent MOF All post-cardiotomy (*n* = 2) and severe sepsis (*n* = 1) patients died 4 (80%) patients died in hospital	
		Major bleeding after device implantation (thrombolysis in MI criteria) pRVAD sRVAD	 4 of 9 patients 5 of 5	
Loforte *et al.* (2010), Interact CardioVasc Thorac Surg, Italy [13] Retrospective cohort study (level IIb)	6 patients (5 males; 1 female; age range 31–64) received simultaneous temporary CentriMag RVAD along with the HeartMate II LVAD due to patients being at high risk for RVF *Indications for LVAD:* bridge to transplant (*n* = 5) and permanent support (*n* = 1)	RVAD support time (average) Discharge Right ventricular ejection fraction 7 days after RVAD removal CVP 7 days after RVAD removal	17.5 (13–20) days 6 of 6 patients survived to discharge with uneventful hospital stays 38–40% 10–15 mmHg	Nitric oxide and catecholamine support given postoperatively for additive support

Continued

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key words	Comments
	Indications for temporary RVAD: unable to wean from cardiopulmonary bypass (*n* = 2), primary option for patients with poor preoperative right ventricular function (*n* = 4) *Aetiology of dilative cardiomyopathy:* idiopathic (*n* = 2) and ischaemic (*n* = 4)	Complications	No reopening for bleeding	
Reiss *et al.* (2000), J Cardiovasc Surg, [14] Retrospective cohort (level IIb)	9 patients (mean age 52, 7 males and 2 females) were implanted with a Biomedicus centrifugal pump *Indications:* RVF after cardiac transplant either due to primary graft failure (*n* = 7) or chronic graft vasculopathy (*n* = 2) Comorbidities: Two patients had had pervious cardiac surgery (aortocoronary bypass ± aortic valve replacement)	Support time (h) Weaned from device Re-transplanted (without weaning) Discharged home Mortality Bleeding	4–348 6 of 9 patients: median support time 112.5 h 2 of 9 3 of 9 6 of 9; MOF and septicaemia (*n* = 5); died on device (*n* = 1) 4 of 9	Ischaemic time for transplantation was between 165–245 min. The study showed that patients could be bridged to re-transplant or weaned with the use of RVAD post-transplantation

ALT: alanine transaminase; AVR: aortic valve replacement; AST: aspartate transaminase; bpm: beats per minute; BiVAD: biventricular assist device; BUN: blood urea nitrogen; CO: cardiac output; CVP: central venous pressure; CABG: coronary artery bypass grafting; Echo: echocardiograph; IWMI: inferior wall MI; LVAD: left ventricular assist device; LVF: left ventricular failure; MOF: multiple organ failure; MI: myocardial infarction; NS: non-significant; pRVAD: percutaneous right ventricular assist system; PCCS: post-cardiotomy cardiogenic shock; PABCP: pulmonary artery balloon counterpulsation; RV: right ventricle; RVAD: right ventricular assist device; sRVAD: surgically implanted right ventricular assist device; RVEF: right ventricular ejection fraction; RVEDD: right ventricular end-diastolic dimensions; RVF: right ventricular failure; RVSW: right ventricular stroke work; RVSWI: right ventricular stroke work index; VAD: ventricular assist device; VF: ventricular fibrillation.

RESULTS

Jett *et al.* [2] conducted a feasibility study in which RVF was surgically induced in 16 lambs that were either unsupported (*n* = 4) or supported with an RVAD (*n* = 6) or with a pulmonary artery balloon counterpulsation (PABCP) (*n* = 6). Unsupported lambs died within 40 min. Haemodynamic improvement was seen in both RVAD and PABCP lambs.

Yano *et al.* [3] conducted a further feasibility study when they implanted 12 dogs with a percutaneous RVAD (pRVAD) following LVAD insertion and then surgically induced biventricular failure. RVAD animals showed haemodynamic improvement. The group conducted a further study of pRVAD implantation. They implanted pRVAD in six goats for up to 8 days, of which two survived to the end of the experiment. One animal required pump replacement due to thrombi formation.

Shum-Tim *et al.* [4] surgically induced RVF in lambs, five supported with an RVAD and five unsupported. Animals with an RVAD survived the experiment duration, whereas unsupported animals died in 71.4 ± 9.4 min. The RVAD animals showed haemodynamic improvement.

Sugiki *et al.* [5] reviewed patients requiring support with an Impella Recover RD RVAD following cardiac transplant (*n* = 4), redo mitral valve replacement (*n* = 2) or LVAD insertion (*n* = 1). Central venous pressure (CVP) decreased post-implantation ($P = 0.005$). Complications of RVAD insertion included renal dysfunction (*n* = 6), bleeding (*n* = 2) and pump dysfunction (*n* = 2). Three patients were weaned, but subsequently died from recurrent RVF (*n* = 1) or pulmonary infection (*n* = 2). One patient survived to successful transplantation, following hybrid support initiation.

Chen *et al.* [6] assessed 11 patients with RVF following heart transplant (*n* = 9) or LVAD insertion (*n* = 2) who were implanted with an RVAD. Four patients required renal support following RVAD implantation. Six patients were weaned and discharged. In these patients, a decrease in CVP ($P < 0.01$) and a decrease in pulmonary artery diastolic pressure were observed, and an increase in cardiac output (CO).

Bhama *et al.* [7] reviewed 29 patients implanted with an RVAD, following cardiotomy (*n* = 7), cardiac transplant (*n* = 10) and LVAD implant (*n* = 12). Implantation of RVAD was complicated by major

infection ($n = 13$), arrhythmias ($n = 13$), bleeding ($n = 10$), stroke/encephalopathy ($n = 3$) and air embolism ($n = 1$). Fifteen patients were weaned and discharged, although 2 subsequently died. Fourteen patients died before 30 days, including 9 deaths prior to weaning from the RVAD. Causes of death included sepsis, left ventricular failure, stroke and withdrawal of care.

Moazami *et al.*'s [8] study contains RVF following CABG ± valve ($n = 12$), valvular surgery ($n = 5$), ascending aortic dissection repair ($n = 6$), heart transplantation ($n = 3$) and pulmonary thromboendarterectomy ($n = 4$). Thirteen of the 30 patients were weaned from the RVAD, 10 surviving to discharge. Following weaning, RV function was sufficient to sustain systemic perfusion. The cause of death was RVF in 40%.

Morgan *et al.* [9] analysed 17 patients requiring an RVAD in addition to an LVAD to bridge to transplant. Eleven patients were successfully transplanted, 9 of whom were weaned preoperatively. The 10-year survival rate was 71.4% in those bridged to transplant.

Shuhaiber *et al.* [10] assessed 27 patients requiring a Levitronix CentriMag Ventricular Assist Device (uni- or bilaterally) for end-stage heart failure who were not candidates for transplantation ($n = 9$); RVF occurred post-LVAD placement ($n = 5$), post-cardiotomy ($n = 7$) and acute donor graft failure ($n = 6$). Complications included bleeding ($n = 8$), cerebral thromboembolism ($n = 3$) and sepsis ($n = 1$). All the 5 patients who received an RVAD after LVAD implant died. One patient who received RVAD support after acute donor graft failure was successfully bridged to re-transplant.

Haneya *et al.* [11] reviewed 8 patients with acute RVF following LVAD placement requiring an RVAD. Seventy-five percent were successfully weaned. Significant increases in CO and RV ejection fraction were observed and a decrease in pulmonary artery pressure, CVP and right heart dimensions following use of the RVAD.

Kapur *et al.* [12] studied 9 patients supported with a pRVAD and 5 supported with a surgically implanted RVAD (sRVAD) for medically refractory RVF due to acute inferior wall MI ($n = 6$), post-cardiotomy syndrome ($n = 2$) and severe sepsis ($n = 1$). The pRVADs produced a significant increase in mean arterial pressure, cardiac index, pulmonary artery oxygen saturation and right ventricular stroke work index, as well as a significant decrease in right atrial pressure ($P < 0.05$). Mortality was 44% in pRVAD patients compared with 80% in the sRVAD group. Bleeding complicated in 4 of the 9 pRVAD and all sRVAD recoveries.

Loforte *et al.* [13] supported 6 patients with an RVAD, alongside LVAD support, following failure to wean from cardiopulmonary bypass ($n = 2$), or on an elective basis for patients with poor pre-cardiac surgery right ventricular function ($n = 4$). All the patients survived to discharge with no complications. Seven days after removal of the RVAD, right ejection fraction was between 38 and 40% and CVP was 10–15 mmHg.

Reiss *et al.* [14] reviewed 9 patients implanted with an RVAD following RVF post-cardiac transplantation. Two patients were re-transplanted for persistent RVF, but subsequently died. Six patients were successfully weaned. Bleeding and multiorgan failure complicated patient recoveries.

CLINICAL BOTTOM LINE

RVADs have successfully assisted in bridging to transplant or recovery in patients with RVF following cardiotomy or cardiac transplant with evidence of improved haemodynamic stability. However, the small numbers of patients and varying indications for an RVAD seen in the studies combined with the high mortality and morbidity rates associated with RVADs suggests that there is no clear evidence of the benefit for using an RVAD for any one patient group. We conclude that RVADs need to be carefully considered on an individual patient basis.

Conflict of interest: none declared.

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