



CJC Open 1 (2019) 19-27

Original Article

Prophylactic Right Ventricular Assist Device for High-Risk Patients Undergoing Valve Corrective Surgery

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ABSTRACT

Background: Right ventricular failure (RVF) after cardiac surgery is associated with poor outcomes. Treatment commonly consists of afterload reduction, contractility optimization, and systemic vasopressors. The aim of this study was to propose a novel strategy of prophylactic right ventricular assist device (RVAD) insertion during valve corrective surgery for patients at high risk for RVF.

Methods: Between 2014 and 2017, 10 consecutive patients at high risk for RVF (severe baseline right ventricular dysfunction or systemic pulmonary artery pressures) underwent valve reconstructive surgery with prophylactic RVAD insertion. We reviewed patient characteristics and outcomes.

Results: All 10 patients had successful RVAD insertion, support and wean, and survival to hospital discharge. Generally, the right ventricle showed echocardiographic evidence of worsening function perioperatively but recovery of function at the time of follow-up. Patients required minimal inotropic support, and no patients required extracorporeal membrane oxygenation. Major complications included prolonged

RÉSUMÉ

Introduction : L'insuffisance ventriculaire droite (IVD) après l'intervention chirurgicale au cœur est associée à une évolution médiocre. Le traitement consiste généralement dans la réduction de la postcharge, l'optimisation de la contractilité et les vasopresseurs systémiques. L'objectif de la présente étude était de proposer une nouvelle stratégie d'implantation d'un dispositif d'assistance ventriculaire droite (DAVD) à visée prophylactique durant l'intervention de correction valvulaire chez les patients exposés à un risque élevé d'IVD.

Méthodes : Entre 2014 et 2017, 10 patients consécutifs exposés à un risque élevé d'IVD (dysfonction initiale grave du ventricule droit ou pressions artérielles pulmonaires systémiques) ont subi une intervention de reconstruction valvulaire accompagnée de l'implantation d'un DAVD à visée prophylactique. Nous avons passé en revue les caractéristiques et l'évolution des patients.

Résultats : Les 10 patients ont eu l'implantation d'un DAVD, l'assistance et le sevrage, et la survie jusqu'à la sortie de l'hôpital. Généralement, le ventricule droit montrait des signes échocardiographiques de

Right ventricular failure (RVF) after cardiac surgery is a predictor of poor outcomes, and patients with compromised baseline right ventricular (RV) function or severe pulmonary hypertension are at particularly increased risk of RVF.¹⁻³ The usual strategies of pulmonary vasodilators, contractility optimization, and vasopressors are not always enough to prevent RVF. Mechanical support, in the form of a right ventricular assist device (RVAD), can help bridge RV recovery and transition to an improved hemodynamic state.^{4,5} Early RVAD insertion has been associated with better outcomes in patients requiring left ventricular assist

device (LVAD) support with marginal RV function, because once RV failure ensues, rescue measures are generally unsuccessful.⁴⁻⁸ Predictors for RVF after cardiac surgery include preoperative ventilation or hemodialysis, high international normalized ratio (INR), low RV systolic work index, high central venous pressure, preoperative RV dysfunction, and severe pulmonary hypertension.^{3,9,10}

We sought to investigate the outcomes of high-risk patients undergoing valvular surgery who were at significant risk for postoperative RVF and were chosen to have a prophylactic RVAD inserted during the primary operation.

Received for publication October 5, 2018. Accepted October 9, 2018.

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See page 26 for disclosure information.

https://doi.org/10.1016/j.cjco.2018.10.001

Ethics Statement: The study was approved by the Western University Research Ethics Board, which waived the need for individual patient consent.

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mechanical ventilation (n = 4), metabolic encephalopathy (n = 1), and sternal wound infection (n = 2). At a mean follow-up of 445.1 \pm 230.9 days, 7 of 8 patients had clinically New York Heart Association functional class 1 (n = 7), and 1 patient had New York Heart Association functional class 2 (n = 1). There were 2 late mortalities.

Conclusion: Prophylactic RVAD insertion may be useful in supporting patients at high risk for RVF perioperatively when undergoing high-risk valve corrective surgery. Further investigation is warranted.

Material and Methods

Between January 2015 and December 2017, 10 high-risk patients with valvular heart disease underwent prophylactic RVAD insertion during the primary operation. All 10 patients were selected to undergo prophylactic RVAD insertion preoperatively based on (1) near or supra-systemic systemic pulmonary artery pressures or (2) severe RV dysfunction as determined by preoperative echocardiography. None of the patients had the decision for RVAD insertion made intraoperatively or as a rescue measure after failure to successfully wean from cardiopulmonary bypass. The final decision to insert RVAD was made by a multidisciplinary team, including a cardiac surgeon, heart failure cardiologist, and cardiac anaesthesiologist, after reviewing the clinical, echocardiographic, and hemodynamic information. There were other patients assessed during the same time period in whom prophylactic RVAD was deemed unnecessary because of adequate RV reserve. No patients considered to be eligible for a prophylactic RVAD underwent surgery with conventional therapies alone. All operations were performed by a single surgeon. The patients were retrospectively reviewed and enrolled in this study.

Preoperative characteristics, including baseline patient demographics (Table 1), operative outcomes, postoperative course, and survival information, were collected. All patients had preoperative echocardiography (transthoracic \pm transesophageal) to specifically assess RV function and pulmonary pressure, as well as cardiac catheterization, to assess concomitant coronary disease and hemodynamics (Table 2). RV function was assessed both qualitatively, based on visual assessment, and quantitatively (tricuspid annular plane systolic excursion and RV tissue Doppler-derived S wave). A right heart catheterization was performed when possible to better characterize the patient's physiology.

RVAD insertion

All 10 patients received temporary RV support with the CentriMag centrifugal pump (Thoratec Corporation, Pleasanton, CA), a magnetically levitated centrifugal pump (Fig. 1 and Video 1 , view video online). RVAD cannulation was performed after completing the valve reconstructive surgery and removal of the aortic crossclamp. RVAD outflow cannulation was achieved with a 20F Medtronic (Minneapolis, détérioration de la fonction en phase périopératoire, mais un rétablissement de la fonction au moment du suivi. Les patients ont eu besoin d'un traitement inotrope minimal, mais aucun patient n'a eu besoin d'une oxygénation par membrane extracorporelle. Les principales complications étaient les suivantes : la ventilation mécanique prolongée (n = 4), l'encéphalopathie métabolique (n = 1) et l'infection de plaie sternale (n = 2). Au suivi moyen de 445,1 \pm 230,9 jours, 7 des 8 patients étaient cliniquement dans la catégorie 1 selon la clase fonctionnelle de la New York Heart Association (n = 7), et 1 patient était dans la catégorie 2 selon la clase fonctionnelle de la New York Heart Association (n = 1). Le taux de mortalité tardive était de 2. **Conclusion :** L'implantation d'un DVAD à visée prophylactique peut être utile chez les patients exposés à un risque élevé d'IVD en phase périopératoire lorsqu'ils subissent une intervention de correction valvulaire à risque élevé. D'autres études sont justifiées.

MN) EOPA cannula inserted into the main pulmonary artery, externalized under the bottom of the sternotomy wound. The RVAD inflow cannula consisted of a 28F straight venous cannula placed through the right atrial purse string after weaning from cardiopulmonary bypass and venous decannulation. CentriMag flows were then titrated by hemodynamic and transesophageal echocardiography guidance to ensure good right ventricle decompression and adequate left ventricle filling.

Postoperative management and RVAD removal

After optimal RVAD flows were achieved, the chest was fully closed and patients were brought to the intensive care unit (ICU). Patients received enteric-coated aspirin 81 mg daily and dalteparin 5000 U subcutaneously daily. They were not fully anticoagulated. While on RVAD, patients were treated similarly to any other patient after cardiac surgery,

Table 1. Preoperative d	lemographics
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	$ Mean \pm SD \text{ or No. (\%)} \\ N = 10 $
Age, y	66.3 ± 14.5
Female	6 (60)
Diabetes	0
COPD	1 (10)
Atrial fibrillation	4 (40)
Preoperative dialysis	1 (10)
Preoperative mechanical ventilation	0
Preoperative vasopressors	0
Preoperative mechanical support	0
Acute myocardial infarction	1 (10)
Previous cardiac surgery	0
Coronary artery disease	1 (10)
CCS class	0.4 ± 1.3
NYHA class	3.4 ± 0.7
Left ventricular grade III or IV	0 (0)
euroSCORE II	8.19 ± 4.97
Elective	3 (30)
Urgent	6 (60)
Emergent	1 (10)
Rheumatic heart disease	4 (40)

CCS, Canadian Cardiology Society; COPD, chronic obstructive pulmonary disease; euroSCORE, European System for Cardiac Operative Risk Evaluation; NYHA, New York Heart Association; SD, standard deviation.

Table	2. Preope	Iable 2. Preoperative echocardiography and hemodynamics	graphy and		iynariics													
		RV function	RV size						Aorta	PA								
Patient	LVEF	(decreased)	(dilated)	RVSP	RVSP TAPSE RVDd	RVDd	RV S'	Ū	pressure	pressure	PCWP	CVP	RVSWI	TR	MR	MS	AS	AR
_	60.7	60.7 Moderate-severe Moderate	Moderate	87	1.6	5.1	10.1	1.6	134/54	101/51	34	14	23.1	Moderate	Moderate-severe	Mild	None	Trace
2	69.8	Mild-moderate	Moderate	75	1.9	5.3	9.4	n/a	100/62	82/39	37	31	4.93	Moderate	Severe	None	None	Mild-Moderate
e S	52.3		Normal	١	1.4	4.6	16.0	2.31	110/60	29/14	13	13	7.8	Mild	Trace	None	None	Trace
4	> 70*	Severe*	Mild*	١	١	١	ı	3	$133/71^{\dagger}$	$28/10^{\dagger}$	10^{\dagger}	8	8.4^{+}	Trace*	Severe*	None*	None*	Trace*
Ś	> 70	Normal	Moderate	120	١	2.8	ı	2.9	100/60	140/55	36	Ś	43.8	Moderate	Mild	Severe	None	Mild
9	38.2	Moderate-severe	Normal	51	1.9	3.4	13.0	4.35	119/53	54/23	25	6	17	Mild-moderate	Moderate-severe	None	None	Mild-moderate
7	60.2	Normal	Normal	110	1	3.9	8.0	١	158/77	95/40	30	16	23.3	Moderate- severe	Mild	Severe	None	Mild
8	76.4	Mild	Mild	78.7	1.7	4.7	١	1.83	110/70	101/30	14	6	21	Mild	Trace	None	Severe	Trace
6	47.9	Moderate-severe	Mild	91	2.4	4.8	١	2.35	124/84	59/32	18	18	38.2	Mild-moderate	Moderate-severe	None	None	None
10	67.3		Mild	62.1	0.78	4.4	ı	ŀ	113/58	ı	١	١	ı	Moderate	Severe	None	None	Trace
AR	, aortic regu	AR, aortic regurgitation; AS, aortic stenosis; CI, cardiac index; CVP, central venous pressure; LVEF, ejection fraction; MR, mitral regurgitation; MS, mitral stenosis; n/a, not available; PA, pulmonary artery; PCW	ic stenosis; C	DI, cardiae	c index; C	VP, centra	al venous	s pressui	re: LVEF.	siection fra	ction: MF	L mitral	reouroitat	ion: MS. mitral ster	nosis: n/a. not availa	ble: PA.	nulmonar	v artery: PCWP.

pulmonary capillary wedge pressure; RV, right ventricular; RVDd, RV basal diastolic diameter; RVS', right ventricular s wave; RVSP, right ventricular systolic pressure; RVSVI, right ventricular systolic work index; TAPSE, tricuspid annular plane systolic excursion; TR, tricuspid regurgitation.

* Transesophageal echocardiography was reported, which was performed closer to operation as the patient's condition was worsening. [†] Hemodynamic measurements

are from 4 years before operation.

with weaning of inotropes, vasopressors, and ventilator support, including routine early extubation and mobilization.

An algorithmic approach to optimization of RV function for weaning and decannulation of RVAD support consisted of the following: (1) optimization of RV preload and volume status, including aggressive continuous intravenous diuresis when required, and inducing tachycardia pharmacologically or with pacing to avoid RV distention; (2) augmentation of RV contractility with milrinone and/or dobutamine; (3) management of RV afterload, including avoidance of hypoxia and acidosis, minimizing positive end-expiratory pressure on mechanical ventilation and early extubation when possible, and a low threshold for initiating inhaled pulmonary vasodilators; and (4) maintenance of adequate myocardial perfusion pressure, preferring higher vasopressin doses over norepinephrine to more selectively spare pulmonary vasoconstriction.

Once RV function was thus optimized, after a 24- to 48hour period to allow perioperative myocardial stunning to improve or resolve, assessment for weaning RVAD support consisted of daily morning transient reduction of RVAD support while monitoring invasive hemodynamics. In general, decreased dependence on inotropic drugs, hemodynamics, and overall clinical status were all used to guide weaning decisions, supported by serial transthoracic echocardiography and point-of-care ultrasound. Echocardiography was often used during weaning with valvular regurgitation, septal geometry and ventricular contractility being assessed during reductions in pump flow rates. When favourable, RVAD support was gradually weaned by 1 L/min per 12- to 24-hour period. The decision to explant was determined through consensus by the cardiac intensivist, cardiologist, and cardiac surgeon. Final wean and discontinuation of the RVAD took place in the operating room under direct vision and transesophageal echocardiography guidance, with subsequent decannulation and definitive chest closure.

Data collection and statistical analysis

The study was approved by the Western University Research Ethics Board, which waived the need for individual patient consent. All data were retrospectively collected from patients' medical records. Categorical variables are presented as proportions, and continuous variables are summarized as means \pm standard deviations. Survival was calculated using the Kaplan-Meier method. Data were stored and analyzed using Microsoft Excel (Microsoft Corp, Redmond, WA).

Results

Baseline characteristics

Ten consecutive patients underwent prophylactic RVAD insertion during primary operation for high-risk valve disease. Baseline characteristics are shown in Table 1, and preoperative echocardiography and hemodynamics are shown in Table 2.

The primary diagnosis, European System for Cardiac Operative Risk Evaluation II, and surgery performed for each individual patient are shown in Table 3. In summary, of 10 patients, 8 underwent mitral valve repair or replacement, 8 underwent tricuspid valve repair, and 2 underwent aortic valve replacements. No patients received concomitant coronary

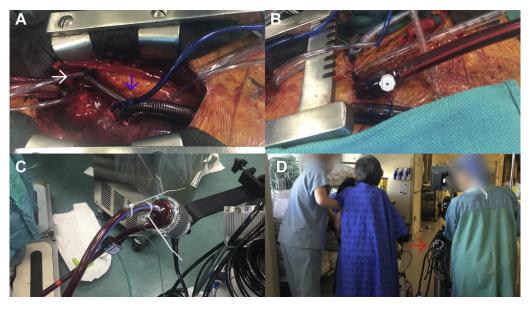


Figure 1. Perioperative photographs showing (A) pulmonary artery cannulation (white arrow), right atrium cannulation (blue arrow), (B) cannula externalization, (C) Thoratec CentriMag (Thoratec Corporation, Pleasanton, CA), and (D) patient mobilization with right ventricular assist device (RVAD) (red arrow).

artery bypass surgery, LVAD insertion, or extracorporeal membrane oxygenation. Patients received an initial mean RVAD flow rate of 2.8 \pm 1.0 L/min and received RVAD support for a mean of 3.6 \pm 1.2 days. In general, the RVAD support was weaned by 1 L/min per day. Patients had a median ICU stay of 8 \pm 3.8 days and hospital stay of 19.5 \pm 11 days. Further operative and postoperative details are shown in Table 4.

Postoperative cardiac support and hemodynamics

Most patients required minimal inotropic support within the first few postoperative days, which is shown in Figure 2. Eight of 10 patients required similar or less inotropic support after RVAD explant, and all patients were weaned off inotropes by postoperative day 8. Additionally, only 1 patient required nitric oxide, 2 patients required intra-aortic balloon pump (IABP), and no patients required concomitant or late LVAD or extracorporeal membrane oxygenation support. Six of 10 patients were extubated and ambulated with the RVAD in situ, before removal of the RVAD. Figure 3 shows the

Table 3.	Primary	diagnosis	and	operation	performed
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patients' RV function and size over time by echocardiography. Video 2 (view video online) is a complete demonstration of a clinical case highlighting the perioperative hemodynamic changes and RVAD support in a high-risk patient.

Complications and mortality

Infections. Three patients had their postoperative stay complicated by infection (1 patient each experienced sepsis, superficial sternal infection, deep sternal infection), with 1 patient requiring readmission for deep sternal infection washout and debridement.

Respiratory. Four patients had respiratory failure requiring mechanical ventilation for > 40 hours (volume overload, difficult to wean from ventilator, pulmonary hypertension requiring nitric oxide, and chronic obstructive pulmonary disease exacerbation); however, only 1 patient required temporary tracheostomy to facilitate successful wean from ventilator.

Patient	Primary diagnosis	euroSCORE II	Prophylactic RVAD	Surgery performed
1	Rheumatic mitral valve	3.56	Yes	MVR, TV repair
2	Rheumatic mitral valve	6.08	Yes	MVR, TV repair
3	Post-MI VSD	19.34	Yes	VSD repair, TV repair
4	Mitral valve prolapse and flail	6.27	Yes	MV repair, PFO closure
5	Rheumatic mitral valve	2.3	Yes	MVR, TV repair
6	Chemotherapy/radiation-induced cardiomyopathy	7.21	Yes	AVR, MVR, TV repair
7	Rheumatic mitral valve	9.55	Yes	MVR, TV repair
8	Severe aortic stenosis	8.12	Yes	AVR
9	Mitral valve prolapse and flail	6.14	Yes	MV repair, TV repair, ASD repair, PDA ligation
10	Mitral valve prolapse and flail	13.37	Yes	MV repair, TV repair

ASD, atrial septal defect; AVR, aortic valve replacement; euroSCORE, European System for Cardiac Operative Risk Evaluation; MI, myocardial infarction; MV, mitral valve; MVR, mitral valve replacement; PDA, patent ductus arteriosus; PFO, patent foramen ovale; RVAD, right ventricular assist device; TV, tricuspid valve; VSD, ventricular septal defect.

Table 4. Operative and postoperative details

	Mean \pm SD or	
	No. (%)	Median (IQR)
Mitral valve replacement	5 (50)	
Mitral valve repair	3 (30)	
Tricuspid valve repair	8 (80)	
Aortic valve replacement	2 (20)	
Ventricular septal defect repair	1 (10)	
Patent foramen ovale closure	1 (10)	
Atrial septal defect repair	1 (10)	
Patent ductus arteriosus ligation	1 (10)	
Prophylactic RVAD insertion	10 (100)	
Left ventricular assist device	0	
ECMO	0	
Coronary bypass surgery	0	
Bypass time	147.5 ± 40.5	
Crossclamp time	95.5 ± 33.5	
Days on RVAD	3.6 ± 1.1	
Ventilation time (h after operation 1)	46.4 ± 41.5	
Extubated and mobilized with RVAD	6 (60)	
Ventilation time (h after operation 2)	62.3 ± 118.1	
Ventilation time (h total)	108.7 ± 151.1	
ICU length of stay, d (median)		8 (3.7)
Hospital length of stay, d (median)		19.5 (11)

ECMO, extracorporeal membrane oxygenation; ICU, intensive care unit; IQR, interquartile range; RVAD, right ventricular assist device; SD, standard deviation.

Cardiovascular and renal. Two patients required IABP in the early postoperative period for blood pressure support despite vasopressors. In terms of arrhythmias, 1 patient had ventricular tachycardia arrest (thought to be caused by left ventricular scar with ejection fraction < 20%) with return of spontaneous circulation after 1 minute of cardiopulmonary resuscitation, and 1 patient developed complete heart block requiring insertion of permanent pacemaker. None of the patients experienced renal failure requiring hemodialysis.

Neurologic. One patient had an episode of decreased level of consciousness requiring readmission to the ICU and initiation of antiepileptics. Further neurological workup revealed metabolic encephalopathy possibly related to higher tranexamic acid dosing (the patient fully recovered). A second patient developed ICU delirium treated with antipsychotic medications. Symptoms resolved, and medications were discontinued by patient discharge. Table 5 shows the complete complication rates.

Mortality and follow-up

There were no 30-day or in-hospital mortalities. Two patients died during the follow-up study period. One patient died at day 76 post-RVAD explantation. Unfortunately, she had iatrogenic subtherapeutic INRs leading to early valve thrombosis and subsequent malignant arrhythmia. This patient declined repeat surgery and decided to pursue palliative care. The second patient died at day 36 post-RVAD explantation secondary to a chronic obstructive pulmonary disease exacerbation and hypercarbic respiratory failure. Figure 4 shows the complete survival data. At a mean follow-up of 445.1 \pm 230.9 days, 7 of 8 patients had New York Heart Association functional class 1 (n = 7) and 1 patient had New York Heart Association functional class 2 (n = 1).

Discussion

RVF after cardiac surgery is uncommon but is associated with significant morbidity and mortality. Although RV afterload reduction, high coronary perfusion pressures, and contractility optimization remain the hallmark therapy for most patients, RV mechanical circulatory support represents an important option in patients with poor RV baseline function or systemic pulmonary hypertension. It has been shown that given enough time, the right ventricle can recover. Because of complex mechanisms involved in RV remodelling and hemodynamic changes after high-risk valve surgery, it is difficult to predict the degree of RV recovery and who will be at risk for failure.¹⁰

Others have studied outcomes after RVAD insertion postcardiotomy and have shown varying degrees of success. Sugiki et al.¹¹ presented 7 Impella Recover RD (Abiomed, Danvers, MA) cases, 2 inserted during reoperative mitral valve repair operations, resulting in 1 patient surviving to discharge (received transplant). Moazami et al.¹² presented 30 patients, 5 after valve surgery and 12 after coronary artery bypass grafting and valve surgery, who had various RVADs; 13 patients could be successfully weaned, and 10 patients survived to discharge. A number of other studies show similar results with significantly high mortality trying to rescue patients with right heart failure with mechanical circulatory devices.

One signal that has emerged from the literature is that early insertion of RVAD appears to be associated with better outcomes. Bhama et al.⁶ presented 7 patients with postcardiotomy cardiogenic shock from right heart failure and had RVADs inserted. The authors suggested that early implantation was important because 3 patients were able to be weaned and survived. Likewise, Morgan et al.¹³ directly studied this question and investigated RVADs inserted post-LVAD as a bridge to cardiac transplantation. Seven of 10 patients who had RVAD insertion early postsurgery (<24 hours) survived to transplant, whereas only 4 of 7 patients in the delayed group (>24 hours) survived to transplant.

It has been described in the LVAD literature, in which RV failure is more common, to strategically predict which patients are high risk and "prophylactically" inserting an RVAD planned as part of the primary operation. Some of the characteristics thought to be predictive are preoperative ventilation or hemodialysis, high INR, low RV systolic work index, high central venous pressure, preoperative RV dysfunction, and severe pulmonary hypertension.^{3,9,10} Loforte et al.⁴ presented 6 patients undergoing LVAD insertion: Four of 6 patients electively had an RVAD inserted and 2 of 6 patients had an RVAD inserted during the primary operation after RV failure during weaning from cardiopulmonary bypass. All patients survived to discharge without additional complications. In addition, Fitzpatrick et al.⁷ investigated 99 patients with a biventricular assist device and found that when comparing planned RVAD (n = 71) with delayed RVAD (n = 28) insertion, there was superior survival to discharge (51% vs 29%, P < 0.05) and a trend toward improved bridging to transplant.

We demonstrated in a small cohort that a novel strategy of preplanning and prophylactically inserting an RVAD during valve corrective surgery in high-risk patients is feasible and may reduce perioperative morbidity, with an associated sustained improvement in pulmonary pressures. As a reference, these patients represented only 10 of a total of 410 valve

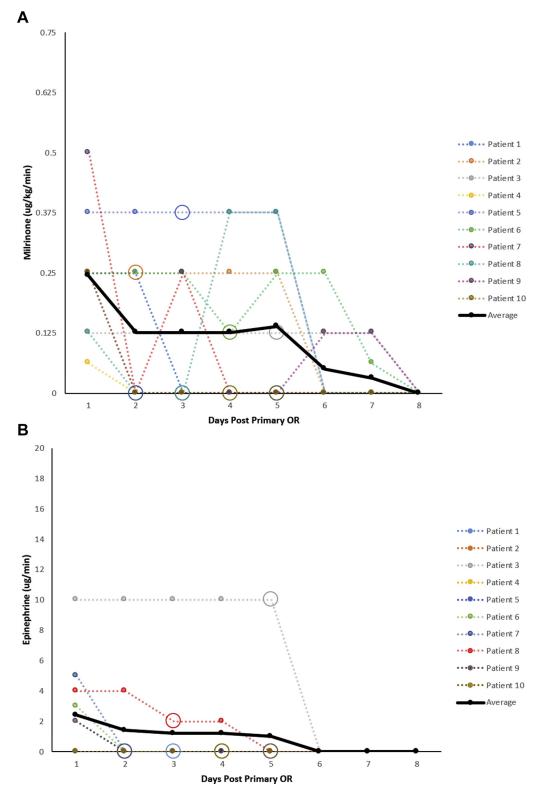


Figure 2. Number of days after primary operation for each patient and dose of (A) milrinone and (B) epinephrine. Larger and unfilled circular markers represent day of RVAD explantation. OR, operation.

operations performed by the same surgeon during the study period. In our previous experience, these high-risk patients were often able to be weaned from cardiopulmonary bypass initially, but experienced delayed RV failure in the ICU within the first 48 hours, requiring high-dose inotropic and vasopressor rescue, IABP insertion, and emergency extracorporeal membrane oxygenation support. Mortality rates were often high, and those who survived often experienced a

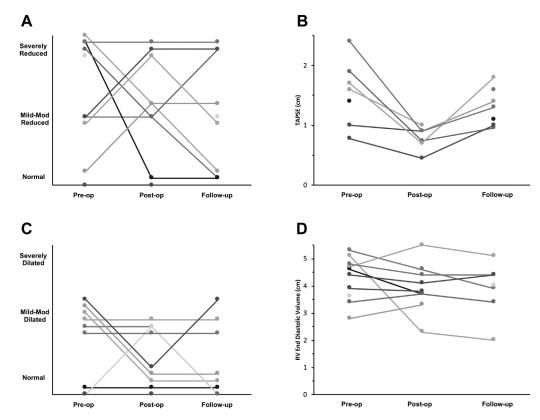


Figure 3. (A) Right ventricular (RV) systolic function, (B) tricuspid annular plane systolic excursion, (C) RV size, and (D) RV end-diastolic diameter graded by echocardiography preoperatively, postoperatively, and at last follow-up. RV, right ventricle; TAPSE, tricuspid annular plane systolic excursion.

myriad of complications related to RV failure and low cardiac output syndrome, including renal failure, ischemic bowel, delirium, and multisystem organ failure, which resulted in prolonged hospital lengths of stay and mandatory hospital repatriation for prolonged rehabilitation.

We chose to use the Thoratec CentriMag Acute Circulatory System from Abbott (Abbott Laboratories, Abbott Park, IL), a magnetically levitated blood pump, because of its ease of insertion, low levels of hemolysis, and anecdotal tolerance for

Table 5.	Postoperative	complications
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Complication	No. (%)
In-hospital/30-d mortality	0
New atrial fibrillation	1 (10)
Postoperative IABP	2 (20)
Reintervention	0
Deep sternal infection	1 (10)
Superficial wound infection	1 (10)
Sternal dehiscence	0
Arrest/arrhythmia	2 (20)
Renal failure with dialysis	0
Septicemia	1 (10)
Postoperative MI	0
Respiratory failure	4 (40)
Tracheostomy	1 (10)
Neurologic complication	1 (10)
Reoperation for bleed	0
Gastrointestinal bleed	0
Delirium	1 (10)

IABP, intra-aortic balloon pump, MI, myocardial infarction.

low or no systemic anticoagulation. The RVAD support likely significantly reduced the need for postoperative inotropes or IABP, despite often having worsening RV function and size noted on echocardiography. This was particularly important in the patients who underwent concomitant tricuspid repair (n = 8), which incrementally increased RV afterload to further compromise perioperative RV function. All patients were successfully weaned from the RVAD and survived hospitalization.

Complications were limited but were notable for infection in 3 patients, 2 with sternal wound infection and 1 with sepsis. Given the need to reopen the chest to remove the RVAD, this was a potential consequence. Despite this, there was no significant bleeding complications, including need for reoperation for bleeding or excessive blood losses requiring massive transfusions. Other important complications include 4 patients who required prolonged mechanical ventilation and 1 patient requiring temporary tracheostomy. These were not surprising given the patients' comorbidities and the requirement of reintubation and 2 operations within a few days of each other. Finally, we were pleased with the early 100% survival despite the elevated risks of this patient cohort; however, there were 2 late deaths due to (1) iatrogenic subtherapeutic INR leading to early valve thrombosis and malignant arrhythmia, and (2) chronic obstructive pulmonary disease exacerbation and hypercarbic respiratory failure.

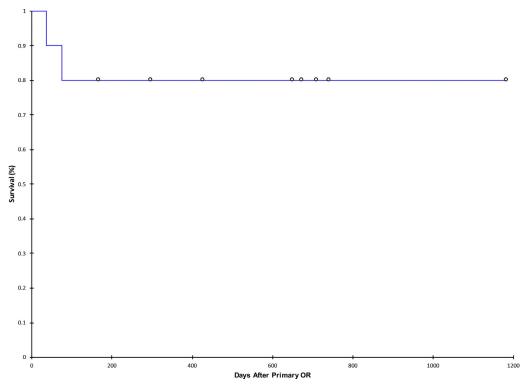


Figure 4. Early and late survivals of patients. OR, operation.

Study limitations

There are many important limitations to our study. Two of the most important are based on the design: It was retrospective and there was no comparator group. Because of the design of prophylactic RVAD before RV failure and without a comparator group of similar high-risk patients undergoing similar surgeries, we cannot comment on how these patients would have done clinically without an RVAD. In lieu of a comparator, this study depends on the body of research, which to date shows poor outcomes with medical management in these high-risk patients. In this context, the results from this study should be interpreted as hypothesis generating alone and could serve as the foundation for the development of a prospective, randomized trial. We believe a relatively simple intervention such as a prophylactic RVAD is justified for a very select high-risk population and may seem attractive for a future research protocol. Another limitation is that selection was not based on a validated scoring system, because one does not yet exist. The patients in this study had a commonality of RV dysfunction or severe pulmonary hypertension, but the decision was finally made on the basis of not 1 factor, but with a multidisciplinary team examining the patient as a whole. Last, the generalizability of this study's findings will likely be limited to established multidisciplinary teams comfortable with managing mechanically assisted patients. Some centres may be unfamiliar with early mobilization of patients with ventricular assist devices, which would limit the external validity of this study.

Future research may focus on better identifying the patients at highest risk for right heart failure after high-risk valvular surgery and carefully designing a randomized clinical trial investigating the salutary effects of prophylactic RVAD insertion on perioperative RV function.

Conclusions

We set out to examine a group of highly selected patients treated with prophylactic RVADs who were at high risk for right heart failure after high-risk valvular surgery. We observed good patient outcomes but acknowledge that these data should be viewed as hypothesis generating alone and are limited by the small sample size and a retrospective, observational design. Further prospective study is necessary to delineate exactly who would benefit from this therapy.

Disclosures

The authors have no conflicts of interest to disclose.

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Supplementary Material

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