Clinical Investigation

Comparison of Percutaneous and Surgical Right Ventricular Assist Device Support After Durable Left Ventricular Assist Device Insertion

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ABSTRACT

Background: Early right ventricular (RV) failure after left ventricular assist device (LVAD) implantation increases morbidity and mortality. Percutaneous right ventricular assist device (pRVAD) support is an alternative to more invasive surgical RVAD (sRVAD).

Methods and Results: We retrospectively reviewed patients receiving isolated pRVAD or sRVAD after durable LVAD at our center in the years 2007−2018. Hemodynamic parameters before and after implantation and survival outcomes were compared among groups. Nineteen patients received pRVAD and 21 sRVAD. Hemodynamic parameters improved immediately with the use of pRVAD; central venous pressure decreased (from 15.9 ± 2.4 to 12.3 ± 3.2 mm Hg; $P<.001$) and cardiac index increased (from 2.4 ± 0.5 to 3.5 ± 0.8 $L{\cdot}min^{-1}{\cdot}m^{-2}$; $P<.001$). These were sustained after device removal and were similar to those with the use of sRVAD. Patients with pRVAD required fewer blood transfusions and mechanically ventilated days than those with sRVAD. Among survivors, intensive care unit and hospital days were fewer with the use of pRVAD: 21 (16−27) versus 34 (27−46) ICU days ($P=.01$); 43.5 (30−66) versus 91 (62−111) hospital days ($P=.03$). There was no significant difference in 30-day mortality with the use of pRVAD compared with sRVAD (21.1% vs 42.9%; $P=.14$), but there was a trend toward a higher rate of discharge free from hemodialysis (73.7% vs 47.6%; $P=.09$).

Conclusions: Novel pRVAD systems for RV failure provide hemodynamic benefits similar to sRVAD, are associated with less morbidity, and should be considered as an alternative to sRVAD. (*J Cardiac Fail 2019;25:105−113*)

Key Words: Right ventricular failure, right ventricular assist device, percutaneous, left ventricular assist device, heart failure.

Early right ventricular (RV) failure affects up to 30%−40% of patients undergoing left ventricular assist device (LVAD) insertion, and is associated with increased morbidity and mortality in this population.[1−5] Multiple tools for identifying patients at risk of RV failure have been proposed, with varying degrees of accuracy.[2−4,6] Although some patients are supported sufficiently with the use of medical therapy, others require RV mechanical support, traditionally with the use of surgically implanted devices.

Because early RV dysfunction often improves sufficiently over a short period of time, many patients may not require prolonged RV mechanical support.[7] Typically, recovery occurs within days to weeks, making temporary

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mechanical support with less invasive modalities an attractive alternative to surgically placed devices in this population as a bridge to recovery.

As an alternative to surgical right ventricular assist devices (sRVADs), recent advances in percutaneous technology have brought multiple devices into practice that allow rapid deployment of RV mechanical support percutaneously.[7–11] These devices include the Impella RP (Abiomed, Danvers, Massachusetts), a micro-axial-flow intracorporeal device, and the Protek Duo (Tandemlife, Pittsburgh, Pennsylvania) dual-lumen cannula, which can be used with a centrifugal-flow extracorporeal pump.

Currently, data regarding the efficacy of support with such percutaneous devices are limited. In the present study, we sought to characterize the hemodynamic effects and outcomes observed with the use of percutaneous RVADs (pRVADs) and compare them with those associated with the use of sRVADs.

Methods

Patient Population

We retrospectively reviewed all patients who underwent isolated pRVAD or sRVAD implantation at Columbia University after durable LVAD insertion from March 2007 to April 2018. We included adult patients who received an Impella RP or Protek Duo pRVAD with either a Tandemheart (Tandemlife, Pittsburgh, Pennsylvania) or Centrimag (Thoratec, Pleasanton, California) pump and those who had placement of an sRVAD (Centrimag) for refractory RV failure after LVAD implantation. RV failure was defined according to our institutional definition as a cardiac index (CI) < 2.2 L·min^{-1}·m^{-2} with a mean arterial pressure (MAP) <70 mm Hg or the need for >2 high-dose vasoactive medications to maintain these parameters despite an elevated central venous pressure (CVP). Patients who had an RVAD placed for other indications (eg, acute myocardial infarction or postcardiotomy shock), or those who had any RVAD implanted concomitantly with the LVAD were excluded from the analysis. Two patients who received both pRVAD and sRVAD were excluded from the analysis (1 received sRVAD first, 1 received pRVAD first). This study was approved by the Columbia University Institutional Review Board.

Variables and Outcomes of Interest

All clinical data were collected through a review of electronic medical records. Demographic and clinical information were collected, including comorbidities and laboratory values. Hemodynamic data, including LVAD flows, were collected before RVAD insertion, 12 and 24 hours after device insertion, and 24 hours after device removal. Cardiac output (CO) and CI were calculated with the use of the Fick method. Other hemodynamic values were calculated to evaluate baseline ventricular function, including cardiac power output, cardiac power index, pulmonary artery pulsatility index (PAPI), and RV stroke work index (RVSWI).

The primary outcomes of interest were survival at 30 days and survival to hospital discharge. Secondary outcomes collected included intensive care unit (ICU) and hospital lengths of stay, which were calculated both for all patients and for patients who survived to hospital discharge. Clinical outcome measures during device support were collected, including days on mechanical ventilation, hours of inhaled nitric oxide therapy, transfusions of packed red blood cells, and need for renal replacement therapy with continuous venovenous hemofiltration or intermittent hemodialysis. For patients who underwent orthotopic heart transplantation during the index admission, length of stay outcomes were censored at the time of transplantation.

Statistical Analysis

For continuous variables, normality was tested with the use of the Shapiro-Wilk test, and data are presented as mean ± SD or median with interquartile range (IQR) as appropriate. Categoric variables are presented as count and percentage. Student *t* test and Wilcoxon rank sum test were used where appropriate to compare continuous variables across groups, and the Fisher exact and chi-square tests were used where appropriate to compare categoric variables across groups. Significance was defined as $P < .05$.

Results

We identified 19 patients who received pRVADs and 21 patients who received sRVADs for RV failure after LVAD implantation. During this time period, 30 patients underwent surgical RVAD insertion at the same time as durable LVAD implantation. Patients received sRVADs throughout the study period, whereas pRVADs were used only since 2015. The types of RVAD insertion by implantation year are displayed in Fig. 1. Patients had a mean age of 58.6 ± 11.8 years, and the majority were men. Clinical and demographic characteristics of this population, including significant comorbidities are presented in Table 1. There was no significant difference in demographic parameters, comorbidities, or common laboratory values before device implantation between patients receiving percutaneous or surgical devices.

Before LVAD implantation, the mean right atrial/pulmonary capillary wedge ratio (RA/PCW) was 0.43 ± 0.19, the mean RVSWI was 7.1 ± 4.3 g·m^{-2}·beat^{-1}, and the mean PAPI was 4.0 ± 4.6. Six (15%) patients had an RA/PCW >0.63 and 11 (27.5%) had a PAPI <1.85. Three patients (7.5%) were at high risk of RV failure according to the RV Failure Risk Score,[4] and no patients (0%) were at high risk according to the EUROMACS RV Failure Risk Score.[2]

Hemodynamics measured after durable LVAD implantation at the time of RVAD implantation were similar between the 2 groups and reflect a population with significant hemodynamic compromise (Table 2). Before RVAD implantation, patients in the combined cohort had a mean

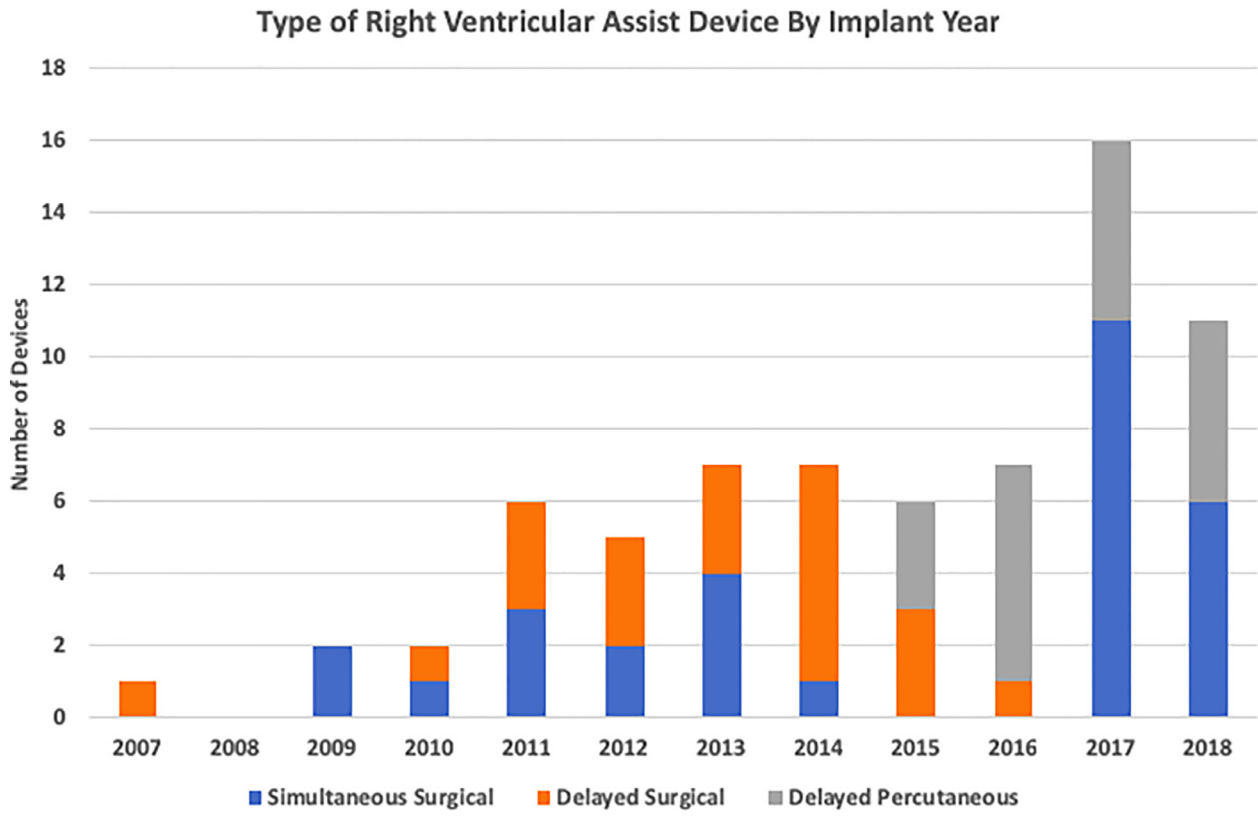

Fig. 1. Type of right ventricular assist device by implantation year.

CVP of 15.9 ± 2.8 mm Hg with diastolic pulmonary artery pressure of 22.3 ± 5.1 mm Hg, mean pulmonary arterial pressure of 28.3 ± 6.9 mm Hg, and pulmonary vascular resistance of 2.3 ± 1.4 Wood units. MAP was 73.8 ± 11.8 mm Hg while on an average of 3.7 ± 1.0 vasopressors and inotropes, with average systemic vascular resistance (SVR) of 1006 ± 506 dyne·sec/cm^5. Mean CO and CI before RVAD implantation were 5.0 ± 2.0 L/min and 2.4 ± 0.8 L·min^{-1}·m^{-2}, respectively, with cardiac power index of 0.4 ± 0.2 W/m^2. The average PAPI was 1.2 ± 0.6 and RVSWI 3.4 ± 2.2 g·m^{-2}·beat^{-1}, which was consistent with severe RV dysfunction.

Of the 19 patients receiving pRVAD, 4 (21.1%) received Impella RP and 15 (78.9%) received Protek Duo cannulation (Table 1; Fig. 2). In 12 cases, the Protek Duo was used with the Tandemheart pump, and in the remaining 3 cases with a Centrimag pump. All 21 patients supported with sRVAD had Centrimag RVADs. Eighteen (85.7%) had right atrial to pulmonary arterial (PA) cannulation, and 3 (14.3%) had RV to PA cannulation. Patients underwent RVAD implantation a median of 1 day (IQR 1−4.5) after LVAD implantation; the median time to sRVAD implantation was 3 days (IQR 1−7) and to pRVAD 1 day (IQR 1−3; $P = .15$). RVAD flow was significantly higher with the use of sRVADs compared with pRVADs (5.2 ± 0.9 vs 4.0 ± 0.4 L/min; $P < .001$); LVAD flow while on RVAD support was higher in the surgical compared with the percutaneous group (5.8 ± 1.7 vs 4.8 ± 0.8 L/min; $P = .02$).

Table 3 summarizes hemodynamic changes seen with device support and after device removal with the use of pRVADs and sRVADs. Hemodynamic parameters, including CVP, MAP, and CI, improved immediately with the use of pRVADs (Fig. 3). These changes were accompanied by a substantial reduction in vasopressor doses (Fig. 4). The hemodynamic changes with the use of sRVADs and pRVADs were similar (Fig. 4). There was a similar sustained decrease in CVP seen with the use of both devices, with similar values at baseline (16.2 ± 3.3 vs 15.6 ± 2.4 mm Hg; $P = .56$), 24 hours after device insertion (11.2 ± 2.8 vs 12.3 ± 3.2 mm Hg; $P = .29$), and after device removal (11.2 ± 4.2 vs 10.8 ± 2.9 mm Hg; $P = .88$). CO and CI were similar at most time points on RVAD support. CI was higher 24 hours after device insertion with the use of sRVAD compared with pRVAD (4.6 ± 1.3 vs 3.5 ± 0.8 L·min^{-1}·m^{-2}; $P = .01$); however, this difference was not sustained after device removal (3.5 ± 0.6 vs 3.3 ± 0.6 L·min^{-1}·m^{-2}; $P = .45$).

Figure 4 illustrates changes in vasopressor and inotrope requirements with both devices, as well as change in urine output. There was a significant decrease in norepinephrine and vasopressin dosages with both pRVAD and sRVAD support; among patients supported with the use of pRVAD, norepinephrine dose decreased from 13.2 ± 7.0 to 6.3 ± 5.0 μg/min 24 hours after device insertion ($P = .004$) and to 3.7 ± 4.4 μg/min at 48 hours ($P < .001$). Vasopressin dose decreased from 4.6 ± 1.5 to 3.2 ± 2.1 U/h at 24 hours

Table 1. Demographics and Baseline Characteristics of Patients Receiving Percutaneous (pRVAD) and Surgical (sRVAD) Right Ventricular Assist Devices, n (%) or Mean ± SD

Variable	All (n = 40)	pRVAD (n = 19)	sRVAD (n = 21)
Demographics			
Age (y)	58.6 ± 11.8	61.7 ± 12.5	55.7 ± 10.6
Sex (male)	34 (85.0%)	17 (89.5%)	17 (80.1%)
BMI (kg/m^2)	29.0 ± 6.2	29.1 ± 6.1	28.9 ± 6.3
Comorbidities			
CAD	19 (47.5%)	10 (52.6%)	9 (42.8%)
HTN	21 (52.5%)	10 (52.6%)	11 (52.4%)
DM	13 (30.3%)	6 (31.5%)	7 (33.3%)
CVA	3 (7.5%)	1 (5.3%)	2 (9.5%)
COPD	4 (10.0%)	3 (15.8%)	1 (4.8%)
Smoker	17 (42.5%)	9 (47.4%)	8 (38.1%)
Laboratory values			
Creatinine (mg/dL)	1.6 ± 0.6	1.6 ± 0.6	1.6 ± 0.6
Lactate (mmol/L)	2.8 ± 1.8	2.3 ± 1.4	3.5 ± 2.2
Hemoglobin (g/dL)	9.3 ± 1.3	9.1 ± 1.5	9.4 ± 1.2
Total bilirubin (mg/dL)	2.0 ± 1.3	1.9 ± 1.1	2.2 ± 1.5
AST (U/L)	140 ± 271	118 ± 197	160 ± 330
ALT (U/L)	92 ± 205	55 ± 107	126 ± 266
Device			
Impella RP	4 (13.3%)	4 (21.1%)	N/A
Protek Duo	15 (37.5%)	15 (78.9%)	N/A
Centrimag	21 (52.5%)	N/A	21 (100%)
Heartmate II	19 (47.5%)	5 (26.3%)	14 (66.7%)
Heartware	6 (15.0%)	1 (5.3%)	5 (23.8%)
Heartmate 3	14 (35.0%)	13 (68.4%)	1 (4.8%)
Other	1 (2.5%)	0	1 (4.8%)
Device parameters			
Days after LVAD inplantation	1 (1−4.5)	1 (1−3)	3 (1−7)
RVAD flow (L/h)	4.6 ± 0.9	4.0 ± 0.4	5.2 ± 0.9
LVAD flow (L/h)	5.2 ± 1.3	4.8 ± 0.8	5.8 ± 1.7

BMI, body mass index; CAD, coronary artery disease; HTN, hypertension; DM, diabetes mellitus; CVA, cerebrovascular accident; COPD, chronic obstructive pulmonary disease; AST, aspartate aminotransferase; ALT, alanine transaminase; LVAD, left ventricular assist device.

Table 2. Hemodynamic Parameters at Time of Device Insertion for Patients Receiving Percutaneous (pRVAD) and Surgical (sRVAD) Right Ventricular Assist Devices

Hemodynamic Parameter (units, n)	All	pRVAD (n = 19)	sRVAD (n = 21)
CVP (mm Hg, 34)	15.9 ± 2.8	15.6 ± 2.4	16.2 ± 3.3
PA, systolic (mm Hg, 29)	40.3 ± 11.3	41.5 ± 12.3	38.0 ± 9.4
PA, diastolic (mm Hg, 29))	22.3 ± 5.1	21.7 ± 4.6	23.4 ± 5.9
PA, mean (mm Hg, 29)	28.1 ± 6.6	27.9 ± 6.7	28.4 ± 6.5
MAP (mm Hg, 37)	73.8 ± 11.8	72.2 ± 10.7	75.4 ± 13.0
SVR (dyne·s/cm^5, 35)	1006 ± 506	1032 ± 463	978 ± 561
PVR (Wood units, 23)	2.3 ± 1.4	2.5 ± 1.6	1.9 ± 0.7
CO (L/min, 29)	5.0 ± 2.0	4.8 ± 1.4	5.4 ± 2.7
CI (L·min^{-1}·m^{-2}, 29)	2.4 ± 0.8	2.3 ± 0.5	2.6 ± 1.1
CPO (W, 29)	0.9 ± 0.4	0.8 ± 0.1	1.0 ± 0.5
CPI (W/m^2, 29)	0.4 ± 0.2	0.4 ± 0.1	0.5 ± 0.2
PAPI (25)	1.2 ± 0.6	1.4 ± 0.6	1.0 ± 0.5
RVSWI (g·m^{-2}·beat^{-1}, 22)	3.4 ± 2.2	3.8 ± 2.2	2.8 ± 2.1

All measurements reported were collected after implantation of a durable left ventricular assist device and before implantation of the RVAD. CVP, central venous pressure; PA, pulmonary artery; MAP, mean arterial pressure; SVR, systemic vascular resistance; PVR, pulmonary vascular resistance; CO, cardiac output; CI, cardiac index; CPO, cardiac power output; CPI, cardiac power index; PAPI, pulmonary artery pulsatility index; RVSWI, right ventricular stroke work index.

($P = .04$) and 2.0 ± 1.8 U/h at 48 hours ($P < .001$). There was no significant change in inotropes at 48 hours with the use of either device, although there was a nonsignificant decrease in epinephrine doses with the use of pRVAD and in epinephrine and dobutamine doses with the use of sRVAD.

Indicators of end-organ function were similar with pRVAD and sRVAD support, with similar serum lactate levels, creatinine, and urine output between the 2 groups (Table 3). Serum lactate was reduced 24 hours after pRVAD insertion, although this difference was not statistically significant (2.28 ± 1.4 vs 1.60 ± 1.53 mg/dL; $P = .13$). There was no significant change in renal function with pRVAD support as measured by serum creatinine (1.63 ± 0.6 vs 1.78 ± 1.0 mg/dL; $P = .56$), although there

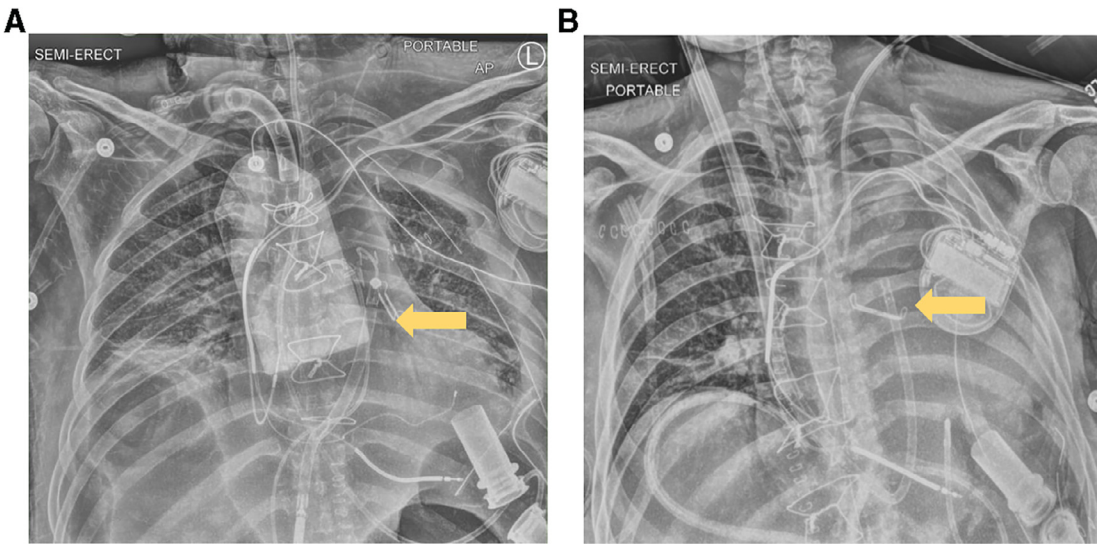

Fig. 2. Chest radiographs illustrating placement of (A) Impella RP, with femoral cannulation, and (B) Protek Duo, with internal jugular cannulation.

Table 3. Hemodynamic Parameters of Patients Receiving Percutaneous (pRVAD) and Surgical (sRVAD) Right Ventricular Assist Devices: Before Device Implantation, 12 and 24 Hours After Implantation, and 24 Hours After Device Removal

Parameter (Units, n)	pRVAD (n = 19)	*P* Value	sRVAD (n = 21)	*P* Value	pRVAD vs sRVAD: *P* Value
Central venous pressure (mm Hg, 34)					
Before	15.6 ± 2.3		16.2 ± 3.3		.56
12 h	13.3 ± 2.8	.008	10.6 ± 3.4	<.001	.01
24 h	12.3 ± 3.2	<.001	11.2 ± 2.8	<.001	.29
After	10.9 ± 3.0	<.001	11.2 ± 4.2	.008	.88
Mean arterial pressure (mm Hg, 37)					
Before	72.2 ± 10.6		75.4 ± 12.9		.42
12 h	81.4 ± 7.2	.004	82.4 ± 9.6	.08	.773
24 h	77.7 ± 6.9	.08	82.6 ± 12.0	.10	.15
After	83.7 ± 9.6	.003	78.3 ± 10.3	.56	.20
Systemic vascular resistance (dyne·s/cm^5, 35)					
Before	1032 ± 463		978 ± 561		.75
12 h	878 ± 397	.29	775 ± 403	.28	.49
24 h	832 ± 336	.15	671 ± 237	.08	.15
After	920 ± 217	.45	959 ± 196	.93	.70
Cardiac output (L/min, 29)					
Before	4.7 ± 1.4		5.4 ± 2.7		.40
12 h	6.9 ± 1.9	.001	7.3 ± 3.6	.19	.70
24 h	7.1 ± 1.5	<.001	8.1 ± 3.7	.07	.31
After	6.5 ± 1.5	.006	6.7 ± 0.8	.32	.84
Cardiac index (L·min^{-1}·m^{-2}, 29)					
Before	2.3 ± 0.5		2.6 ± 1.0		.30
12 h	3.4 ± 0.9	<.001	3.9 ± 1.1	.02	.27
24 h	3.5 ± 0.8	<.001	4.6 ± 1.3	<.001	.01
After	3.3 ± 0.6	<.001	3.5 ± 0.6	.11	.45
Lactate (mg/dL 33)					
Before	2.28 ± 1.4		3.46 ± 2.2		.07
12 h	1.83 ± 1.5	.34	3.69 ± 4.8	.87	.12
24 h	1.60 ± 1.3	.13	2.59 ± 3.6	.45	.28
Vasopressors and inotropes (n, 36)					
Before	3.8 ± 1.1		3.5 ± 0.7		.03
12 h	3.2 ± 0.9	.14	2.8 ± 0.9	.02	.07
24 h	2.7 ± 0.9	.03	2.4 ± 0.9	<.001	.03
Creatinine (mg/dL, 40)					
Before	1.63 ± 0.6		1.57 ± 0.6		.77
24 h	1.80 ± 0.8	.41	1.53 ± 0.6	.80	.19
48 h	1.78 ± 1.0	.57	1.46 ± 0.6	.56	.23
Urine output (mL/24 h, 39)					
Before	1700 ± 1145		2175 ± 2196		.40
24 h	2660 ± 1783	.05	2647 ± 2009	.48	.98
48 h	3081 ± 3017	.07	2637 ± 1745	.47	.57

All measurements reported before RVAD placement were collected after implantation of a durable left ventricular assist device.

was a trend toward an increase in urine output (1700 ± 1145 vs 3081 ± 3017 mL/24 h; $P = .07$) at 48 hours (Fig. 4C).

Patients who received pRVADs had a median time with the device of 9 days (IQR 7−13) and those receiving sRVADs had the device for a median of 18 days (IQR 11−28); when controlling for patients undergoing transplantation or dying with the RVAD, these were not significantly different ($P = .57$). Patients supported with pRVADs required significantly less time mechanically ventilated than those supported with pRVADs (8.5 [IQR 2−19] vs 21 [IQR 10−32 days; $P = .03$). There was no difference in use of inhaled nitric oxide (54 [IQR 30−161] vs 54.5 [IQR 2.5−121.5] days; $P = .75$), or need for temporary renal replacement therapy (33.3% vs 42.8%; $P = .52$). Patients undergoing pRVAD support required significantly fewer transfusions of packed red blood cells than those with sRVADs (3 [IQR 0−6] vs 6.5 [IQR 5−16); $P < .001$). Three patients (14.3%) receiving sRVADs ultimately had the device explanted at the time of orthotopic heart transplantation; 1 patient (5.3%) with a pRVAD was bridged to transplantation while on RVAD device support.

Peak lactate dehydrogenase (LDH) levels while on RVAD support were 1006 ± 660 U/L and 1207 ± 1242 U/L in the percutaneous and surgical cohorts, respectively ($P = .53$). No device was removed owing to hemolysis. For 1 patient (8.3%) with a Protek Duo pRVAD, a Tandemheart pump was changed to a Centrimag pump owing to pump malfunction (low device line pressure) and for 1 patient (33.3%), the Impella RP device fractured on removal from the body, although all components of the device were removed percutaneously without incident. In addition, 1 patient (33.3%) with an Impella RP pRVAD and 1 (6.7%) with a Protek Duo required return to the cardiac catheterization laboratory for repositioning of the pRVAD. Eight patients (38.1%) supported by sRVAD required

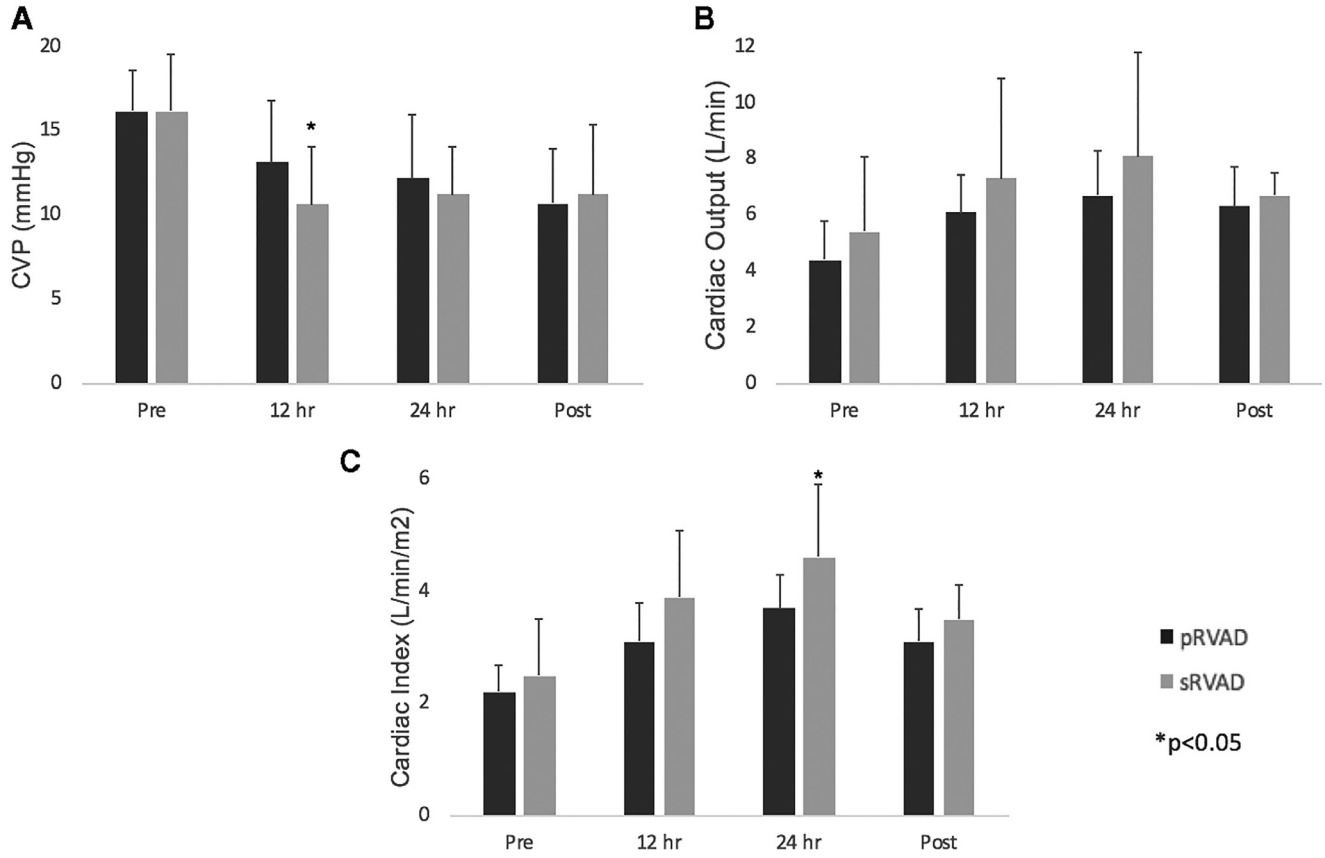

Fig. 3. Changes in hemodynamic parameters with percutaneous (pRVAD) and surgical (sRVAD) right ventricular assist device support. CVP, central venous pressure.

return to the operating room for mediastinal exploration in the setting of bleeding while on sRVAD support.

Patients receiving pRVADs required a median of 21 (10−27) ICU days following implantation, compared with 27 days (IQR 15−44; $P = .14$) for those receiving sRVADs. Among those surviving to hospital discharge, ICU length of stay was 21 days (IQR 16−27) for patients receiving pRVADs and 34 days (IQR 27−46) for those receiving sRVADs ($P = .01$). Post-RVAD hospital length of stay was 34.5 days (IQR 21−59) in the group receiving pRVADs and 60 days (IQR 21−95) in the group receiving sRVADs ($P = .35$). Among survivors, hospital length of stay was significantly shorter for patients receiving pRVADs (43.5 [IQR 30−66] vs 91 [IQR 62−111] days; $P = .03$).

Mortality with the use of pRVADs was lower compared with sRVADs, although the difference was not statistically significant. Three patients (15.8%) with pRVADs died within 30 days of device implantation, compared with 7 patients (33.3%) with sRVADs ($P = .29$). Fifteen patients (78.9%) with pRVADs and 11 (52.4%) with sRVADs survived to discharge (risk difference 0.22 [95% confidence interval [CI] −0.06 to 0.50] and odds ratio 2.81 [95% CI 0.69−11.42]; $P = .14$). There was a trend toward a higher rate of discharge free from dialysis among those treated with the use of pRVADs (73.7% vs 47.6%; $P = .09$; Table 4). One- and 2-year survivals were, respectively, 52.4% and 38.1% for those treated with the use of sRVADs and 78.9% and 70.2% for those with the use of pRVADs ($P = .08$).

Discussion

Our data provide a comparison between sRVADs and 2 more recent percutaneous options for RVAD support after durable LVAD implantation. Our principal findings are as follows: (1) both sRVAD and pRVAD support systems provided immediate improvement in hemodynamic profiles for patients; (2) although sRVAD provided higher overall flow than pRVAD, the hemodynamic improvements were similar between these 2 types of device; and (3) pRVAD use was associated with less morbidity than sRVAD use. Our goal was not to compare the 2 percutaneous devices studied here, but rather to compare the percutaneous approach with the more traditional surgical intervention.

In our cohort of patients with severe RV failure after LVAD implantation, both pRVAD and sRVAD support provided immediate improvement in hemodynamic parameters. Despite pRVAD support resulting in lower flow compared with sRVAD support, hemodynamics were similar with the use of the 2 devices. Specifically, we observed a significant reduction in CVP and improvement in cardiac output as well as an improvement in MAP with rapid

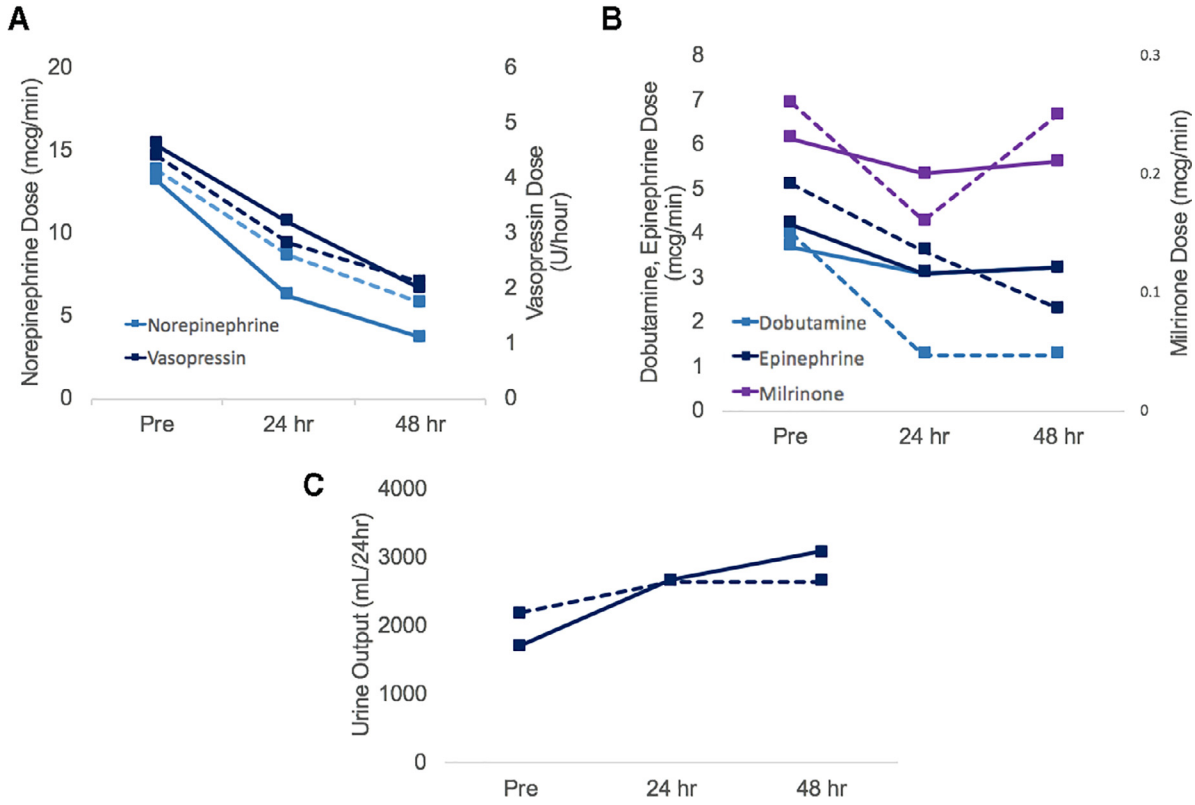

Fig. 4. Changes in (A) vasopressor and (B) inotrope doses over time with percutaneous (pRVAD; *solid lines*) and surgical (sRVAD; *dotted lines*) right ventricular assist device support.

decrease in vasopressor dose requirement seen within hours of pRVAD placement. Not surprisingly, this was coupled with a doubling of the daily urine output, though this was not statistically significant ($P = .07$).

Importantly, in the majority of patients, the RV was able to recover from the various insults experienced in the post-operative period so that the device could be removed. Although the mean SVR was within normal limits for the study cohort, it is important to understand that this was while patients were receiving multiple vasopressors at high doses. This underscores the fact that the typical hemodynamic profile of RV failure after LVAD implantation is one of a vasoplegic patient with a relatively low CI (despite LVAD support and multiple inotropes). Although the RV will typically be able to eventually wean from support, when faced with vasodilatory physiology it is unable to provide that increase in CO that would compensate for the reduction in SVR. In combination, these 2 hemodynamic derangements can be very hard to overcome with vasoactive medications alone. For this reason, easily deployed circulatory support devices designed to support the RV and spare the patient's end-organs from the effects of high-dose vasoconstrictors have the potential to significantly improve the recovery from LVAD implantation for those who transiently manifest this pathophysiology.

Table 4. Outcomes With Percutaneous (pRVAD) and Surgical (sRVAD) Right Ventricular Assist Devices, n (%) or Median (Interquartile Range)

Outcome	pRVAD (n = 19)	sRVAD (n = 21)	*P* Value
Days on ventilator	8 (2–19)	21 (10–32)	.03
Inhaled nitric (h)	54 (30–161)	54.5 (22.5–121.5)	.75
CVVH/HD	6 (33.3%)	9 (42.8%)	.52
PRBC transfusions	3 (0–6)	6.5 (5–16)	<.001
OHT	1 (5.3%)	3 (14.3%)	.28
Days in ICU (all)	21 (10–27)	27 (15–44)	.14
Days in ICU (survivors)	21 (16–27)	34 (27–46)	.01
Days in hospital (all)	34.5 (21–59)	60 (21–95)	.35
Days in hospital (survivors)	43.5 (30–66)	91 (62–111)	.03
Death at 30 days	3 (15.8%)	7 (33.3%)	.29
In-hospital death	4 (21.1%)	9 (42.9%)	.14
Discharge free from HD	14 (73.7%)	10 (47.6%)	.09

CVVH, continuous venovenous hemofiltration; HD, hemodialysis; PRBC, packed red blood cells; OHT, orthotopic heart transplantation; ICU, intensive care unit.

Several authors have previously described the use of percutaneous or minimally invasive RVADs. Kapur et al reported the first study using percutaneous mechanical RV support with the use of the Tandemheart device in 9 patients, though the majority had suffered an inferior myocardial infarction, as opposed to our cohort of RV failure following LVAD implantation.[9] Haneya et al described the use of a minimally invasive surgical RVAD in 8 patients with RV failure after LVAD implantation and found improvements in hemodynamic parameters similar to those seen in our cohort.[8] Those authors described the insertion

of the outflow cannula through a Dacron graft anastomosed to the PA, meaning that the RVAD deployment was more invasive but that removal could be performed with minimal intervention when patients were weaned from RVAD support. Anderson et al published the largest study examining the use of percutaneous RV support in a prospective single-arm trial with the use of the Impella RP.[7] That study included 30 patients with RV failure, 18 of whom required RV support after LVAD implantation. Those authors also demonstrated improvements in hemodynamics similar in magnitude to those in our cohort. That study did not have a comparator group but instead compared outcomes with a benchmark established for a contemporary sRVAD. Most recently, Ravichandran et al described the use of the Protek Duo catheter to provide pRVAD support after LVAD implantation.[11] However, our data represent the largest comparison of hemodynamic changes and outcomes between the 2 device support strategies.

In our cohort of early RV failure patients, support with the use of pRVADs was associated with less morbidity compared with sRVAD support. Specifically, those supported with the use of pRVADs had a shorter period of mechanical ventilation and less requirement for blood transfusion. There was a trend toward improved discharge free from dialysis among the pRVAD group. In addition, hospital and ICU length of stay after RVAD insertion among survivors was shorter with the percutaneous devices. This decreased morbidity is likely related to multiple factors. First, the pRVAD approach is less invasive, allowing for more rapid recovery from both the implantation and the removal procedure. Second, though not significant, the median time to pRVAD implantation after LVAD was one-third that to sRVAD placement. In addition, serum creatinine, transaminases, and lactate were numerically lower at baseline (though not statistically significant) in patients receiving pRVADs. Though the difference in time to RVAD implantation was not significantly different, these findings raise the possibility that the ability to rapidly deploy the pRVAD in the cardiac catheterization laboratory may lower the threshold for initiating RV support and, in turn, result in overall improved outcomes.

Planned RVAD support for patients at high risk of RV failure likely remains the optimal strategy when implanting a durable LVAD.[12] Similarly, even when RVAD implantation is unplanned, patients with overt RV failure manifesting in the operating room are likely better supported by concomitant RVAD implantation as opposed to delayed implantation if the patient's condition does not improve.[13] However, the fact that most of the patients in our cohort were not deemed to be at high risk for RV failure underscores the limitations of the currently available risk models and highlights the need for a rapidly deployed RV support device. Therefore, for RV failure manifesting unexpectedly after LVAD implantation, our data suggest that percutaneous support may be a viable alternative to a surgical support device in many cases.

Study Limitations

It is important to note that this is a single-center retrospective study, which introduces several important limitations. Because patients were not randomized to sRVAD or pRVAD, there may have been selection bias in their use; furthermore, because both pRVAD systems used are relatively novel, the 2 cohorts are not entirely contemporary and device use changed over time. It is possible that the risk of RV failure varied with growing experience managing LVAD patients, and this may have contributed to differences between the cohorts of patients receiving the different types of RVAD. Importantly, though, we did not note differences in demographic or baseline hemodynamic characteristics between those receiving sRVADs and pRVADs. Although we limited our analysis to patients who received continuous-flow LVADs, the risk of RV failure may vary with different pump technologies. In addition, because hemodynamic data were collected retrospectively, full hemodynamic profiles were not available for all patients. The relatively small number of patients in our study limited our ability to detect differences in outcomes between the devices studied, although to our knowledge this is the largest comparison of these 2 device strategies. Finally, to better understand the differences between these 2 devices, we limited our analysis to patients with RV failure after LVAD implantation, thus limiting our ability to extrapolate these conclusions to other etiologies of RV failure.

Conclusion

Novel percutaneous RVAD support systems allow for rapid deployment of RV mechanical support after durable LVAD implantation. These systems provide almost immediate improvement in hemodynamics and are associated with less morbidity than their surgical counterparts, and should be considered as viable alternatives to sRVAD placement for this patient population.

Disclosures

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