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Mechanical Circulatory Support for Right Ventricular Failure

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Objectives The aim of this study was to explore the clinical utility of a commercially available centrifugal flow pump as a centrifugal flow-right ventricular support device (CF-RVSD) in patients with right ventricular failure (RVF).

Background RVF is associated with high in-hospital mortality. Limited data regarding efficacy of the CF-RVSD for RVF exist.

Methods We retrospectively reviewed data from 46 patients receiving a CF-RVSD for RVF from a registry comprising data from 8 tertiary-care hospitals in the United States. CF-RVSD use was recorded in the setting of acute myocardial infarction; myocarditis; chronic left heart failure; after valve surgery, orthotopic heart transplantation, left ventricular assist device surgery, coronary bypass grafting. Devices were implanted via the percutaneous ($n = 22$) or surgical ($n = 24$) route.

Results No intraprocedural mortality was observed. Mean time from admission to CF-RVSD implantation was 5.7 ± 8.5 days, with a mean of $6{,}769 \pm 789$ rotations/min, providing 4.2 ± 1.3 l/min of flow. Mean duration of support was 5.4 ± 5.1 days. Mean arterial pressure (65 ± 12 mm Hg vs. 73 ± 14 mm Hg; $p < 0.05$), right atrial pressure (21 ± 8 mm Hg vs. 16 ± 7 mm Hg; $p = 0.05$), pulmonary artery systolic pressure (43 ± 15 mm Hg vs. 33 ± 15 mm Hg; $p = 0.01$), and cardiac index (1.7 ± 0.7 vs. 2.2 ± 0.6; $p = 0.01$) were improved within 48 h of CF-RVSD implantation. Total in-hospital mortality was 57% and was lowest in the setting of left ventricular assist device implantation, chronic left heart failure, and acute myocardial infarction. Increased age, biventricular failure, and Thrombolysis In Myocardial Infarction–defined major bleeding were associated with increased in-hospital mortality.

Conclusions Use of the CF-RVSD for RVF is clinically feasible and associated with improved hemodynamic status. Observations from the registry of patients who have received this device may support the development of prospective studies that will examine the role of percutaneous circulatory support for RVF. (J Am Coll Cardiol HF 2013;1:127–34)

Right ventricular failure (RVF) is a major cause of global morbidity and mortality. Irrespective of the injurious mechanism, a decline in RV function is associated with increased morbidity and mortality (1–4). Several studies have reported poorer clinical outcomes in patients with RV failure in the setting of left-sided heart failure (5), acute myocardial infarction (AMI) (6), pulmonary hypertension (7,8), after cardiac surgery (9), or acute pulmonary embolus (10). Contemporary algorithms for the management of RVF focus on reversing the underlying cause, maintaining adequate preload, reducing RV afterload, and enhancing RV contractility. In cases of RVF refractory to medical therapy, options include atrial septostomy, surgical RV assist device (AD) implantation, venoarterial extracorporeal membrane oxygenation, and heart transplantation (11).

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Abbreviations and Acronyms

AD = assist device
AMI = acute myocardial infarction
CABG = coronary artery bypass grafting
CF-RVSD = centrifugal flow-right ventricular support device
IABP = intra-aortic balloon pump
LV = left ventricle
MAP = mean arterial pressure
PA = pulmonary artery
PAPi = pulmonary artery pulsatility index
PCOP = pulmonary capillary occlusion pressure
RA = right atrium
RPM = rotations per minute
RV = right ventricle
RVF = right ventricular failure
RVSW = right ventricular stroke work
SD = support device
T-CO = total cardiac output

In 2006, the first successful percutaneous implantation of a commercially available centrifugal flow pump* as a TandemHeart-right ventricular support device (CF-RVSD) was reported (12). Since then, CF-RVSDs have been implanted for RVF in the settings of AMI (13), after left ventricular (LV) AD surgery (14), severe pulmonary hypertension (15), and cardiac rejection after orthotopic heart transplantation (16). Unlike conventional therapy for RVF with the intra-aortic balloon pump (IABP), the CF-RVSD provides flow from the right atrium (RA) to the main pulmonary artery (PA), thereby bypassing a poorly functioning RV (12,17). Limited data on the clinical utility of the CF-RVSD exist (18). The aim of this study was to explore the hemodynamic effects and clinical outcomes associated with use of the CF-RVSD for RVF in clinical practice.

Methods

In this retrospective study, we reviewed the records of 46 patients with RVF who received a CF-RVSD by the percutaneous or surgical route between 2007 and 2011 at 8 tertiary-care institutions. These patients represent all patients who had received the CF-RVSD for RVF at each institution at the time of data acquisition. Patients in whom the CF-RVSD was used as an extracorporeal membrane oxygenation circuit were excluded. All patients received standard clinical care for RVF during their index hospitalization. The indications for device implantation were determined from available medical records at each center. The institutional review board at each participating institution approved the study protocol.

Demographic information, hemodynamic and echocardiographic data, laboratory parameters, and outcomes data were recorded by investigators at each institution. Device-specific information, including implantation approach, rotations per minute (RPM), and direct measures of flow obtained by a flow probe attached to the outflow cannula, was analyzed in all patients. Flow parameters were dictated on an individual basis by each operator because no algorithm for CF-RVSD use exists. To explore the hemodynamic effects of the CF-RVSD, PA catheter indices obtained 24 h after device implantation were compared with baseline measurements. In 38 of 46 patients, both pre- and post-procedural hemodynamic data were available for analysis. Cardiac filling pressures; cardiac output (Fick method); and hemodynamic measures of RV function, including the ratio of RA pressure to pulmonary capillary wedge pressure (PCWP) (19), pulmonary artery pulsatility index (PAPi) (calculated as PA pulse pressure/RA pressure) (20), and right ventricular stroke work (RVSW) (calculated as: stroke volume [SV] × [mean PA pressure − PCWP] × 0.0136), were analyzed. Qualitative echocardiographic grading scores of RV systolic function, chamber dilatation, and tricuspid regurgitation in all study patients within 24 h before CF-RVSD implantation were analyzed. Quantitative echocardiographic indices were not available in the majority of patients studied. Clinical outcomes, including in-hospital mortality; time to device activation; and *device-associated complications,* defined as complications related to the CF-RVSD occurring during or within 24 h of device implantation or removal, were reported by each institution.

Description of CF-RVSD implantation. Percutaneous implantation of the CF-RVSD via bifemoral and right internal jugular approaches has been previously described (12,17). Surgical implantation can be accomplished by direct cannulation of the RA and PA or by peripheral cannulation of the femoral vein and direct cannulation of the PA (21). Percutaneous cannulation was performed with 21-F cannulas in all cases. Surgical cannula sizes varied between 15- to 24-F as per the operator's discretion. All patients received continuous anticoagulation with unfractionated heparin to a goal activated clotting time >250 s or partial thromboplastin time >50 s after CF-RVSD implantation.

Statistical analysis. Data are expressed as mean ± SD for continuous variables. Differences between groups and conditions were compared by t test for continuous variables and by the Fisher exact test for categorical variables. Specifically, comparisons were made between percutaneous and surgical CF-RVSD groups; between baseline (pre–CF-RVSD) and post–CF-RVSD conditions in the total group; and between survivors versus nonsurvivors. All statistical analyses were performed using SigmaStat version 3.1 and SPSS version 16.0.1 (both, Systat Software, Inc., Chicago, Illinois). A p value <0.05 denoted a significant difference.

Results

Demographics and implant characteristics. In total, 46 patients who received the CF-RVSD via percutaneous (n = 22) or surgical (n = 24) implantation route were studied (Fig. 1). The baseline characteristics of the total study population are provided in Table 1. Qualitative echocardiographic indices of RV function demonstrated moderate to severe RV systolic dysfunction in all patients. Concurrent *LV systolic dysfunction,* defined as an LVEF <50%, was observed in 29 (63%) of all patients. No significant differences in baseline characteristics or

*Trademark: TandemHeart (CardiacAssist, Inc., Pittsburgh, Pennsylvania).

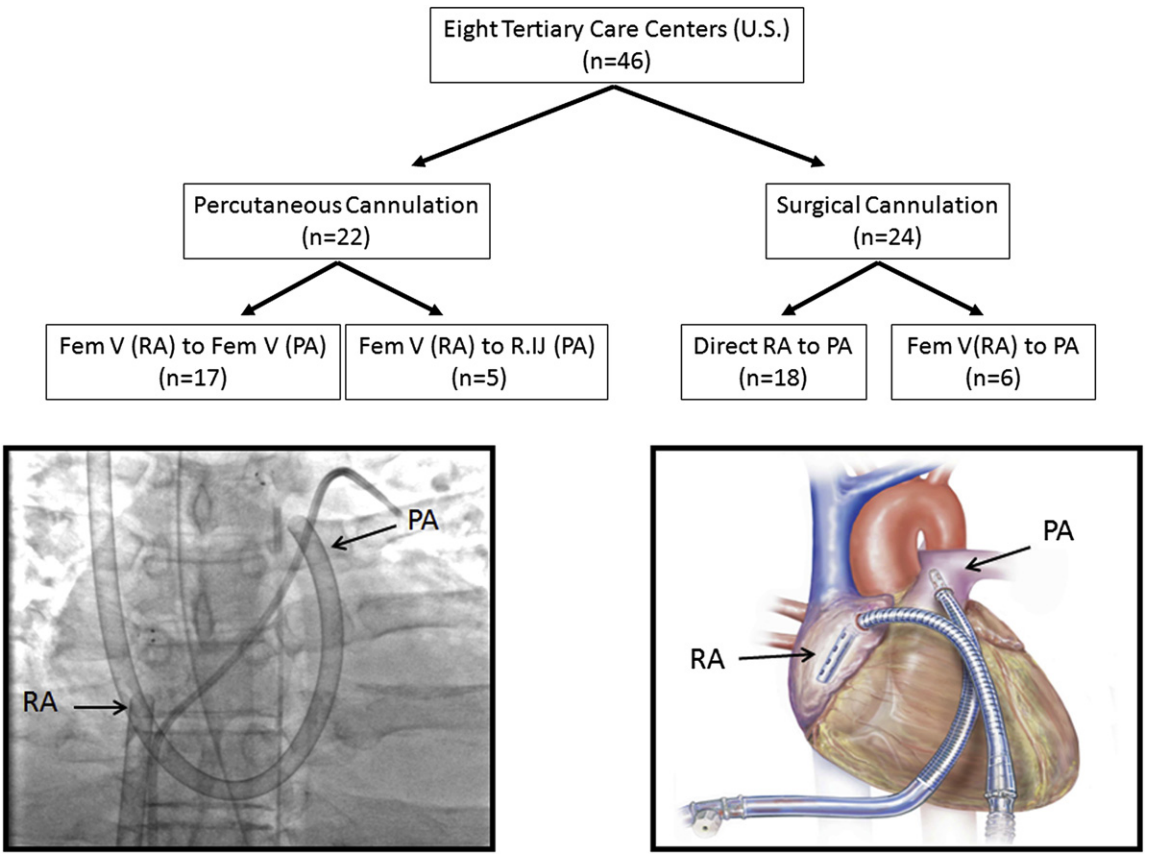

Figure 1 **Distribution of Patients in the Study**

(A) Patient distribution in the study by mode of vascular access for cannulation. Representative images of **(B)** percutaneous cannulation via the femoral vein (Fem V) to right internal jugular (R.IJ) and **(C)** surgical right atrial (RA) to pulmonary artery (PA) cannulation.

echocardiographic measures of RV function were observed between the percutaneous and surgical cohorts. Higher use of mechanical ventilation before CF-RVSD implantation was recorded in the surgical cohort (100% vs. 64%; $p < 0.01$). Time from admission to device implantation was significantly shorter in the percutaneous versus the surgical group (3 ± 3.6 days vs. 8.7 ± 9.5 days; $p = 0.01$).

RVF occurred acutely in the setting of post–valve surgery in 32% (n = 15), AMI in 26% (n = 12), after orthotopic heart transplantation in 11% (n = 5), after LVAD surgery in 11% (n = 5), after CABG in 7% (n = 3), and in the settings of chronic heart failure in 7% (n = 3) and myocarditis in 7% (n = 3). Of the 15 patients with RVF after valve surgery, 12 (80%) had received aortic valve replacements and 3 (20%), mitral valve replacements. In 3 patients (7%) with chronic left heart failure, RVF occurred in the setting of persistent ventricular tachycardia, severe sepsis, and acutely decompensated heart failure. None of the patients had a documented history of chronic RVF. Modes of implantation among these various indications are shown in Table 2. In addition to the 5 patients who received a CF-RVSD after surgical LVAD placement, 6 required placement of a concurrent LVSD due to biventricular failure at the time of CF-RVSD deployment. Of these 6, 3 patients had myocarditis; 1 patient had a chronic, dilated, nonischemic cardiomyopathy; 1 patient had RVF that developed after aortic valve surgery; and 1 patient with a history of AMI required emergent surgical revascularization and placement of a concurrent left heart SD. All patients with a history of AMI presented with acute right coronary artery occlusion. Eleven underwent successful percutaneous coronary revascularization at the time of presentation.

Hemodynamic variables and clinical outcomes After CF-RVSD implantation. Hemodynamic variables before and after CF-RVSD implantation are presented in Table 3. Despite inotropic and/or vasopressor support in all patients, the mean cardiac index was 1.7 ± 0.7 l/min/m^2, and mean pulmonary capillary occlusion pressure (PCOP) was elevated, at 24 ± 10 mm Hg, within 24 h before CF-RVSD implantation. Inhaled nitric oxide was used in 61% (n = 28) of patients before CF-RVSD deployment. Within 48 h after CF-RVSD implantation, mean arterial pressure (MAP), cardiac index, and PA oxygen saturation were increased significantly, whereas RA pressure and PA

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Table 1 Baseline Clinical Characteristics of the Study Population

Characteristic	Percutaneous (n = 22)	Surgical (n = 24)	p Value
Age, yrs	59 ± 15	54 ± 22	0.30
Male	13 (59)	14 (58)	0.95
Caucasian	19 (86)	16 (67)	0.12
History of myocardial infarction	9 (41)	6 (25)	0.26
Out-of-hospital cardiac arrest	3 (14)	1 (4)	0.27
Intra-aortic balloon pump	13 (59)	11 (46)	0.38
Mechanical ventilation	14 (64)	24 (100)	<0.01
LV ejection fraction, %	40.5 ± 20.1	31.8 ± 17.8	0.13
Duration of CF-RVSD support, days	4.8 ± 6.1	6.5 ± 6.2	0.61
Echocardiographic indices of RV function*			
RV systolic grade	3.05 ± 0.89	3.47 ± 0.70	0.11
RV dilation grade	2.80 ± 1.01	2.84 ± 1.07	0.90
Tricuspid regurgitation severity	2.55 ± 0.94	2.26 ± 1.10	0.39

Values are mean ± SD or n (%). *Scale: 1 = normal; 2 = mild; 3 = moderate; and 4 = severe.
LV = left ventricular; RV = right ventricular; CF-RVSD = commercially available right ventricular support device.

systolic pressure decreased significantly in the total study population. No significant changes in mean PCOP, RVSW, or mean PA pressure were noted after device activation. No significant changes in parameters of hepatic congestion were observed. The number of vasoactive/inotropic agents used was not significantly decreased within 48 h after CF-RVSD activation. IABP use was reported in 52% (n = 24) of patients. Among all patients, laboratory parameters showed increased sodium and decreased hemoglobin and platelet values after device implantation.

Overall in-hospital mortality was 57% among CF-RVSD recipients and was due to multiorgan failure in all cases. The mean durations of CF-RVSD support were 4.8 ± 6.1 days and 6.5 ± 6.2 days in the percutaneous and surgical groups, respectively (Table 1). In-hospital mortality was similar between the percutaneous and surgical groups (50% vs. 62%; p = 0.4). In-hospital mortality was highest among recipients who presented with acute myocarditis (100%), after valve surgery (87%), and after CABG (67%) and lowest among patients with RVF after orthotopic heart transplantation (40%), AMI (33%), chronic left heart failure (33%), and after LVAD implantation (20%).

Table 2 Distribution of Percutaneous and Surgical Routes of RV Support Device Implantation, Stratified by Clinical Indication

Indication	Percutaneous	Surgical
Chronic heart failure	2	1
Myocarditis	0	3
Post-valve surgery	6	9
Post-orthotopic heart transplant	1	4
Post-left ventricular assist device	1	4
Post-coronary artery bypass grafting	1	2
Acute myocardial infarction	11	1

Values are n.
AMI = acute myocardial infarction; CABG = coronary artery bypass grafting; LVAD = left ventricular assist device; RV = right ventricular.

Increased age (61 ± 18 years vs. 51 ± 17 years; p < 0.05), a higher prevalence of biventricular failure (85% vs. 35%; p < 0.05), and a higher prevalence of Thrombolysis In Myocardial Infarction (TIMI) (22)-defined major bleeding (58% vs. 25%; p < 0.05) were observed in nonsurvivors compared with survivors (Table 4). No significant differences in the other baseline hemodynamic or laboratory parameters between the survivors and the nonsurvivors were observed (Table 5). The difference in IABP use between survivors and nonsurvivors was nonsignificant (55% vs. 50%; p = 0.7). Within 24 h after CF-RVSD implantation, survivors exhibited improved MAP and reduced RA pressure (both, p < 0.05 vs. baseline), whereas nonsurvivors did not. Survivors demonstrated a numerically greater but statistically nonsignificant increase from baseline in cardiac index after device implantation, whereas nonsurvivors did not (p = 0.06 and p = 0.1, respectively, vs. baseline).

Device function. Device flow was significantly greater in the surgical recipients (p < 0.01), whereas the difference in mean RPM settings between the percutaneous and surgical groups was not significant (Table 6). In the percutaneous group, no significant differences in RPMs or device flow were observed between bifemoral and right internal jugular cannulation. With surgical cannulation, significantly lower RPM settings were observed (p < 0.01), together with numerically but not significantly greater device flow, with direct RA-to-PA versus femoral vein-to-PA cannulation. Both the percutaneous and surgical groups demonstrated increased MAP and PA oxygen saturation after device deployment (all p < 0.05 vs. baseline) (Table 7).

To explore the degree of hemodynamic support provided by the CF-RVSD, total cardiac output (T-CO), measured using the Fick method after device implantation, was compared with CF-RVSD flow, measured by a probe attached to the outflow cannula of the device. The ratio of flow/T-CO represented the percent of total blood flow augmented by the CF-RVSD. Overall percent augmentation was 77 ± 18%. Compared with the percutaneous group,

Table 3 Hemodynamic Effects of CF-RVSD in All Patients (N = 46)

Variable	Baseline	Post-CF-RVSD	p Value
Hemodynamic			
MAP, mm Hg	65 ± 12	73 ± 14	0.01
Heart rate, beats/min	87 ± 22	88 ± 19	0.77
RA pressure, mm Hg	21 ± 8	16 ± 7	0.01
Mean PA pressure, mm Hg	31 ± 11	29 ± 11	0.33
PCOP, mm Hg	24 ± 10	24 ± 10	0.71
Cardiac index, l/min/m^2	1.7 ± 0.7	2.2 ± 0.6	0.01
Systemic vascular resistance, dyne/s/cm^2	1,259 ± 699	986 ± 439	0.16
Pulmonary vascular resistance, dyne/s/cm^2	227 ± 204	158 ± 212	0.35
PA oxygen saturation, %	52 ± 15	64 ± 13	<0.01
RVSW, g·m/beat	4.1 ± 4.6	4.5 ± 4.3	0.75
RA:PCOP ratio	0.9 ± 0.4	0.8 ± 0.5	0.74
RA pressure >16, %	80	40	<0.01
PAPi	0.9 ± 0.8	0.9 ± 0.5	0.95
Laboratory			
Sodium, mEq/l	138 ± 6	141 ± 5	0.04
Blood urea nitrogen, mg/dl	29 ± 19	28 ± 17	0.75
Creatinine, mg/dl	1.7 ± 1.2	1.7 ± 0.8	0.89
ALT, IU/l	1,423 ± 421	1,053 ± 425	0.65
AST, IU/l	2,368 ± 664	1,872 ± 750	0.71
Total bilirubin, mg/dl	5.2 ± 3	3.5 ± 3	0.53
Hemoglobin, g/dl	11 ± 2	9.6 ± 2	0.02
Platelets, × 10^3 cells/μl	193 ± 134	114 ± 83	<0.01

Values are mean ± SD.
ALT = alanine aminotransferase; AST = aspartate aminotransferase; MAP = mean arterial pressure; PA = pulmonary artery; PAPi = PA pulsatility index; PCOP = pulmonary capillary occlusion pressure; RA = right artery; RVSW = right ventricular stroke work; other abbreviations as in Table 1.

the surgical group had significantly higher augmentation (72 ± 20% vs. 88 ± 12%; p = 0.01). No significant differences in T-CO, flow, or percent augmentation were observed between survivors and nonsurvivors. No significant changes in laboratory values were observed within 24 h of device implantation.

Device-associated complications. The most commonly reported device-associated complication, TIMI-defined major bleeding, was observed in 44% (n = 20) of the total study group. The difference in TIMI-defined major bleeding between the percutaneous and surgical groups was not significant (n = 9 [41%] vs. n = 11 [46%]; p = 0.75). In the percutaneous group, 1 patient experienced a retroperitoneal bleed and deep vein thrombosis. No cardiac perforation was reported in any patients in the percutaneous group. Two patients in the surgical group experienced injury to the main PA during implantation, and 2 cases of deep vein thrombosis were reported.

Table 4 Clinical Characteristics of Survivors and Nonsurvivors

Variable	Survivors (n = 20)	Nonsurvivors (n = 26)
Age, yrs	51 ± 17*	61 ± 18
Male	13 (65)	14 (54)
Caucasian	15 (75)	20 (77)
History of myocardial infarction	5 (25)	10 (38)
Out-of-hospital cardiac arrest	2 (10)	2 (8)
Intra-aortic balloon pump	11 (55)	13 (50)
Mechanical ventilation	16 (80)	21 (81)
LV ejection fraction, %	39 ± 22	34 ± 17
Duration of CF-RVSD support, days	6 ± 5	5 ± 7
RV systolic grade†	3.2 ± 0.7	3.3 ± 0.9

Values are mean ± SD or n (%). *p < 0.05 vs. nonsurvivors. †Scale: 1 = normal; 2 = mild; 3 = moderate; and 4 = severe.
Abbreviations as in Table 1.

Discussion

This registry of patients who have received the CF-RVSD is the largest, multicenter, retrospective analysis of a centrifugal RVSD that can be deployed via either the percutaneous and surgical route for RVF. The central finding of this report is that implantation of the CF-RVSD is clinically feasible and is associated with acutely reduced right heart filling pressure and improved cardiac index across a broad variety of clinical presentations. In this study, all CF-RVSD recipients presented with evidence of RVF as measured by qualitative echocardiography and invasive hemodynamic status; however, more than one-half of patients had concurrent LV dysfunction, as evidenced by a low LVEF or elevated left heart filling pressures. Overall in-hospital mortality remained high in this critically ill population and was lowest among CF-RVSD recipients presenting with RVF in the setting of LVAD implantation, chronic heart failure, and AMI. Device flow rates ranged from 2.7 to 4.2 l/min after percutaneous implantation and from 3.1 to 7.4 l/min after surgical implantation. Higher flow rates after surgical

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Table 5 Hemodynamic and Laboratory Values in Survivors and Nonsurvivors

Variable	Survivors (n = 20)		Nonsurvivors (n = 26)	
	Baseline	Post–CF-RVSD	Baseline	Post–CF-RVSD
Hemodynamic				
MAP, mm Hg	64 ± 10*	80 ± 12†	66 ± 13	69 ± 14
Heart rate, beats/min	86 ± 21	86 ± 17	87 ± 23	90 ± 20
RA pressure, mm Hg	21 ± 8*	14 ± 7*	21 ± 8	18 ± 7
Mean PA pressure, mm Hg	31 ± 8	25 ± 9	31 ± 12	31 ± 11
PCOP, mm Hg	21 ± 8	20 ± 9	27 ± 10	26 ± 10
Cardiac index, l/min/m^2	1.7 ± 0.8	2.3 ± 0.6	1.7 ± 0.7	2.2 ± 0.7
Systemic vascular resistance, dyne/s/cm^2	1,279 ± 549	1,207 ± 396	1,241 ± 827	845 ± 421
Pulmonary vascular resistance, dyne/s/cm^2	236 ± 200	243 ± 305	218 ± 217	265 ± 213
PA oxygen saturation, %	55 ± 13	62 ± 12	49 ± 16	64 ± 14‡
RVSW, g·m/beat	5.5 ± 3.5	5.4 ± 4.0	5.1 ± 3.0	4.6 ± 3.7
RA/PCOP ratio	1.0 ± 0.4‡	1.0 ± 0.7	0.8 ± 0.3	0.7 ± 0.3
RA pressure >16, %	80	40	80	50
PAPi	1.1 ± 1.1	1.4 ± 2.2	0.8 ± 0.5	0.6 ± 0.3
Vasopressor/inotropes	3.0 ± 1.1	3.0 ± 1.3	2.8 ± 1.4	3.4 ± 1.6
Laboratory				
Sodium, mEq/l	138 ± 7	138 ± 4†	138 ± 6	142 ± 5‡
Blood urea nitrogen, mg/dl	38 ± 29	32 ± 20	23 ± 12	25 ± 14
Creatinine, mg/dl	2.2 ± 1.7	1.8 ± 0.8	1.3 ± 0.6	1.7 ± 0.9
ALT, IU/l	683 ± 209	330 ± 181	315 ± 206	613 ± 1356
AST, IU/l	1,162 ± 348	517 ± 283	440 ± 260	1,110 ± 2,413
Total bilirubin, mg/dl	4.4 ± 3.7	4.5 ± 3.2	2.4 ± 2.8	2.7 ± 2.6
Hemoglobin, g/dl	11.2 ± 2.9	9.6 ± 1.9	10.3 ± 1.8	10 ± 1.6
Platelets, × 10^3 cells/μl	199 ± 119*	124 ± 92	189 ± 146	107 ± 78‡
Arterial pH	7.3 ± 0.1*	7.4 ± 0.1	7.3 ± 0.1	7.4 ± 0.2
Lactate, mEq/l	6 ± 5	4.2 ± 7.0	11 ± 8	46 ± 37

Values are mean ± SD. *p < 0.05 vs. non-survivor baseline; †p < 0.05 vs. survivor post–CF-RVSD; ‡p < 0.05 vs. non-survivor post–CF-RVSD.
Abbreviations as in Table 3.

implantation were likely due to the use of larger and shorter cannula sizes compared with those used in the percutaneous approach. The most common device-associated complication was bleeding. Taken together, our data suggest that the CF-RVSD is a feasible treatment option that should be considered for patients with RVF refractory to medical therapy.

Our findings have several important clinical implications. We identified that the CF-RVSD is being used in a wide variety of clinical settings. The findings suggest that both surgical and percutaneous deployment strategies are clinically feasible with minimal complications. Because the CF-RVSD provides centrifugal flow from the RA to main PA, penetration into the heart is required to bypass a poorly functioning right ventricle. Although antegrade or retrograde cannula migration is possible, none of the institutions reported migration as a device-associated complication. No reports of clinically significant pulmonic or tricuspid valve insufficiency, pump thrombosis, or need for pump exchange were received. TIMI-defined major bleeding was the most common complication associated with the CF-RVSD and was likely secondary to the need for continuous anticoagulation and deployment of large-bore device cannulas. Mechanical complications associated with the CF-RVSD were rare and included isolated cases of injury to the main PA during surgical deployment only and an isolated case of retroperitoneal bleed associated with peripheral venous cannulation. The development of deep vein thrombosis was reported in 3 cases despite required anticoagulation during device support and may have been due to venous obstruction resulting from device cannulation and coagulopathy in the setting of severe multiorgan dysfunction.

In this experience from clinical practice, we also identified that evaluation of RVF does not always involve quantitative measures of RV function and further may not include

Table 6 Device Function, Stratified by Cannulation Approach

Cannulation/Approach (Inflow to Outflow)	RPM	Device Flow (l/min)
Percutaneous		
Overall (n = 22)	6,481 ± 905	3.4 ± 0.5*
FV to RIJ (n = 5)	6,560 ± 887	3.4 ± 0.8
FV to FV (n = 17)	6,456 ± 938	3.5 ± 0.5
Surgical		
Overall (n = 24)	6,538 ± 818	4.9 ± 1.4
RA to PA (n = 17)	6,350 ± 827	5.2 ± 1.5
FV to PA (n = 7)	7,100 ± 494	4.0 ± 0.6†

Values are mean ± SD. *p < 0.01 vs. surgical. †p < 0.05 vs. RA to PA.
FV = femoral vein; RIJ = right internal jugular; RPM = rotations/min; other abbreviations as in Table 3.

Table 7 Hemodynamic Effects of Percutaneous Versus Surgical Cannulation

	Percutaneous (n = 22)		Surgical (n = 24)	
Hemodynamic Variable	Baseline	Post–CF-RVSD	Baseline	Post–CF-RVSD
MAP, mm Hg	62 ± 10*	72 ± 15	68 ± 12*	77 ± 12
Heart rate, beats/min	83 ± 24	86 ± 18	91 ± 20	91 ± 19
RA pressure, mm Hg	25 ± 6*†	18 ± 6*	17 ± 8	15 ± 7
Mean PA pressure, mm Hg	29 ± 9	30 ± 11	32 ± 12	27 ± 10
PCOP, mm Hg	24 ± 8	24 ± 10	24 ± 11	23 ± 9
Cardiac index, l/min/m	1.8 ± 0.9	2.2 ± 0.7	1.7 ± 0.6*	2.3 ± 0.6*
Systemic vascular resistance, dyne/s/cm^2	1,111 ± 500	946 ± 466	1,433 ± 873	1,067 ± 407
Pulmonary vascular resistance, dyne/s/cm^2	190 ± 166	178 ± 251	265 ± 238	198 ± 150
PA oxygen saturation, %	46 ± 16*	60 ± 12*	56 ± 12*	68 ± 9*
RVSW, g·m/beat	4.7 ± 3.7	4.6 ± 5.0	4.5 ± 4.0	4.4 ± 3.3
RA/PCOP ratio	1.0 ± 0.3*	0.9 ± 0.4	0.7 ± 0.4	0.8 ± 0.6
RA pressure >16, %	100*†	60*	52	32
PA pulsatility index	0.7 ± 0.4*	0.8 ± 0.8	1.2 ± 1.0	1.9 ± 1.1
Vasopressor/inotropes	3.9 ± 1.3	3.5 ± 1.5	2.8 ± 1.2	2.9 ± 1.4

Values are mean ± SD. *$p < 0.05$ vs. post–CF-RVSD; †$p < 0.05$ vs. surgical baseline; ‡$p < 0.05$ vs. surgical post-CF-RVSD.
Abbreviations as in Table 3.

comprehensive evaluation and management of concurrent LV dysfunction. The lack of available quantitative echocardiographic data (23), such as tricuspid annular plane systolic excursion, RV S′, or estimated dP/dt, highlights the need for better algorithms to assess candidacy for mechanical RV support in both the operating room and the catheterization laboratory. Furthermore, we identified that a significant number of recipients had concurrent LV dysfunction. The use of the CF-RVSD did not significantly alter left heart filling pressures despite an increased mean cardiac index, suggesting that targeting RVF alone may be insufficient to improve systemic perfusion and allow for adequate treatment of pulmonary congestion. Consistent with this observation, percent augmentation did not correlate with improved clinical outcomes, suggesting that optimal flow generation and right heart support alone may be insufficient to provide full cardiac support in these patients. Although more than one-half of patients received an IABP before CF-RVSD use and all patients received inotropic or vasopressor support, 11 of 46 patients in this study had concurrent LVAD deployment. Importantly, the difference in IABP use between survivors and nonsurvivors was not significant. The importance of LV failure in this population of CF-RVSD recipients is further highlighted by a significantly greater prevalence of biventricular failure in the nonsurvivors. These data suggest that the identification and management of LV failure is required when considering mechanical support for RVF. Finally, we identified that in-hospital mortality varied widely among different indications for mechanical RV support. Overall in-hospital mortality was 57% in this study. Mortality was highest among patients with acute myocarditis causing biventricular failure (100%) and after valve surgery (87%)—findings comparable to in-hospital mortality rates of 86% reported for biventricular failure (24) and 46% to 100% reported for postcardiotomy RV failure (25). Patients with predominant RVF, as in the case of acute RCA occlusion or after LVAD implantation, had a significantly lower in-hospital mortality rate with use of the CF-RVSD than did patients more likely to have ongoing, concurrent LV pathology. Indeed, we noted significantly lower mortality in patients with RVF due to AMI compared with data from the SHOCK (Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock) trial (33% vs. 53%) (6). Overall, mortality remained high despite hemodynamic benefit after CF-RVSD deployment. Several possible explanations for this observation include: 1) delayed time to device utilization (18); 2) potential need for a biventricular support strategy versus RV support alone; 3) variability among the types of RVF; and 4) degree of salvageable RVF.

A small number of patients were studied, with a wide variety of clinical indications, which reflects the challenge of studying RVF and highlights the need for reporting clinical experience with this type of mechanical support strategy. Therefore, subgroup analyses are limited with regard to statistical power. There was a lack of large comparison groups of patients with RVF managed with medical treatment only, surgical RVADs, or extracorporeal membrane oxygenation. A prospective study that includes a clear definition of *refractory RV failure,* guidelines for device use, and appropriate control groups is required.

As experience with percutaneously delivered, RV-dedicated circulatory support devices grows, their role in the armamentarium of mechanical therapies for RVF will depend less on the technical ability to place the device and more on improved algorithms for patient selection, monitoring, and weaning protocols. The registry of data from patients who have received the CF-RVSD (THRIVE [TandemHeart in Right Ventricular Failure] registry) provides insight into the evaluation, management, and use of mechanical support for RVF. Findings from this registry may inform the development of future prospective

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clinical studies to evaluate the role of mechanical support for RVF.

Conclusions

Use of the CF-RVSD for RVF is clinically feasible and associated with improved hemodynamic status. Observations from the THRIVE registry may support the development of prospective studies that will examine the role of percutaneous circulatory support for RVF.

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