Case Report

Percutaneous Mechanical Assist for Severe Cardiogenic Shock Due to Acute Right Ventricular Failure

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Acute right ventricular failure can lead to severe cardiogenic shock and death. Recovery may be achieved with early supportive measures. In many patients, intravenous fluid and inotropic resuscitation is inadequate to improve cardiac output. In these cases, percutaneous mechanical assist may provide a non-surgical bridge to recovery. Herein, we describe a case series of patients with severe, refractory cardiogenic shock due to acute right ventricular failure who received a continuous flow percutaneous ventricular device primarily utilizing the right internal jugular vein for out flow cannula placement. © 2014 Wiley Periodicals, Inc.

Key words: heart failure; right ventricular function; shock; cardiogenic

INTRODUCTION

Cardiogenic shock due to severe, refractory right ventricular failure is associated with high mortality [1,2]. Common causes of this condition include acute right ventricular myocardial infarction and acute pulmonary embolism. Immediate treatment consists of reperfusion, intravenous fluid resuscitation, and intravenous inotropic support; however, despite these efforts, many patients will continue to have refractory shock and will eventually die. Percutaneous mechanical ventricular assist devices have been widely adopted in the United States to support patients with cardiogenic shock due to left ventricular failure. These devices include intermittent aortic balloon counter-pulsation and continuous flow mechanical support with and without adjunctive extracorporeal membrane oxygenation for cardiogenic shock due to acute left ventricular failure [3]. There is less experience using such devices for the treatment of cardiogenic shock due to acute right ventricular failure.

A modified use of the Tandem Heart (Cardiac Assist, Pittsburg, PA) continuous flow device has been described for the treatment of refractory right ventricular failure [4–9]. The typical configuration for left ventricular support is placement of the inflow cannula in the left atrium and the outflow cannula in an iliac artery. For right ventricular assist, the inflow cannula is placed in the right atrium and the outflow cannula in the pulmonary artery. In this configuration, the route of access is typically via the femoral veins. An alternative cannula configuration utilizing the right internal jugular vein for the outflow cannula and the right femoral vein for the inflow cannula has been previously reported [8,9]. Herein, we report a series of seven patients where TandemHeart percutaneous ventricular assist was employed for right ventricular support (pRVAD) in severe, refractory cardiogenic shock. In six of these, the right internal jugular vein was the access site chosen for placement of the outflow cannula.

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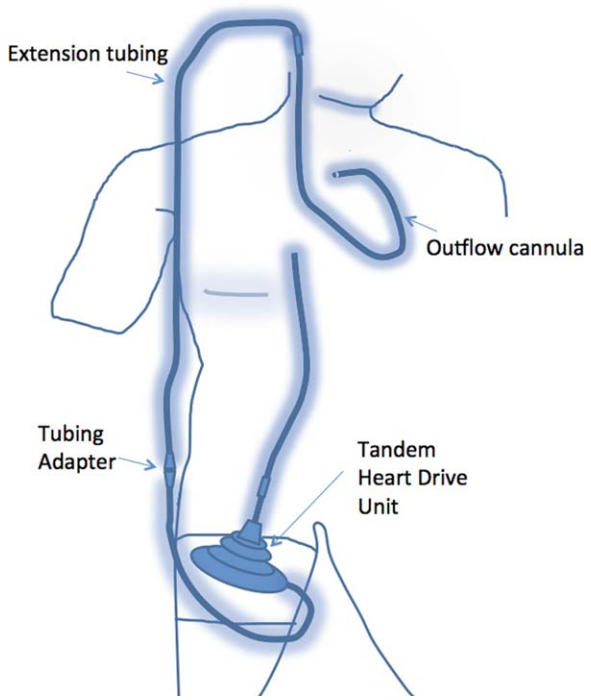

Fig. 1. Example of internal jugular vein—femoral vein pRVAD configuration. The inflow cannula is positioned in the right atrium via the right femoral vein and attached to the Tandem Heart Drive Unit. The outflow cannula is positioned in the pulmonary artery via the right internal jugular vein. The cannulae are connected to extension tubing placed using a tubing adapter. Patients of smaller stature may not require the extension tubing. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

CASE REPORT

All patients that required pRVAD support using the TandemHeart device were identified between January 2008 and July 2013. Patients considered eligible for pRVAD support at our institution require (i) evidence of sustained and refractory cardiogenic shock (systolic blood pressure < 90 mm Hg, severely reduced cardiac output or clinical evidence of systemic under-perfusion) despite at least two inotropic/vasopressor agents, (ii) suitable volume resuscitation with evidence of increased central venous pressure (CVP), (iii) at least moderate right ventricular dysfunction on echocardiography, and (iv) no significant hypoxemia. In the event of significant hypoxemia, extracorporeal membrane oxygenation was employed. Clinical history, echocardiographic, and hemodynamic data were utilized to determine whether right ventricular failure was a significant contributing factor to the patient's persistent shock. In all patients, extracorporeal membrane oxygenation was not felt to be necessary due to preserved oxygenation and predominant right ventricular failure contributing to cardiogenic shock, or previously placed surgical left ventricular assist device.

Medical records were reviewed and baseline demographics, hemodynamics, and clinical outcomes were recorded. All post-pRVAD hemodynamics were recorded within 48 hr after pRVAD placement. All percutaneous mechanical assist devices were placed in the Cardiac Catheterization Laboratory. The TandemHeart device consists of a centrifugal pump, drive lines, a console, and two cannulae. During device maintenance, heparin was administered intravenously to maintain an activated clotting time of $\sim$200 sec. If heparin-induced thrombocytopenia was suspected, argatroban was used to maintain an activated partial thromboplastin time (aPTT) of 2.5 times normal. All patients were sedated and intubated during pRVAD placement and for the duration of its use to prevent cannula migration from inadvertent patient movement. Patients were monitored in the cardiac intensive care unit by nurses trained in the use of the TandemHeart.

Two pRVAD cannulae configurations were used: (i) femoral vein–femoral vein and (ii) femoral vein–internal jugular vein for the inflow and outflow cannulae respectively (Figs. 1 and 2). For (i) femoral vein–femoral vein insertion, a 7 or 8 Fr introducer sheath was initially placed in each femoral vein. Under fluoroscopic guidance, a 7 Fr balloon tipped Swan Ganz catheter or 5 Fr Multi-purpose catheter was advanced into the pulmonary artery via the femoral vein. Following wire/catheter exchanges, a 0.035 cm $\times$ 260 cm Amplatz Extra Stiff wire was placed carefully in either the right or left pulmonary artery. A 21 Fr (62 cm) cannula (outflow) was advanced over the Amplatz wire and positioned in the pulmonary artery. Another 21 Fr cannula was exchanged for the opposite venous sheath and positioned in the right atrium. The pump was primed, the cannulae were de-aired, connected, and secured, and the pump was activated. For (ii) femoral vein–internal jugular vein insertion, two 21 Fr cannulae were utilized. A 7 Fr introducer sheath was placed in the right internal jugular vein and a femoral vein. Via the right internal jugular vein introducer, a 5 Fr Multipurpose catheter was used to advance a 0.035 cm $\times$ 260 cm Amplatz Extra Stiff wire into the pulmonary artery. Subsequently, the introducer sheath was removed and a 21 Fr cannula (outflow) was advanced over the wire into the main pulmonary artery. Via the femoral vein, another 21 Fr cannula (inflow) was advanced into the right atrium. Approximately, 2–3 feet of sterile extension tubing was cut and a connection adapter was used to connect to the outflow cannula and bridge the distance from the internal jugular and femoral vein. Notably, the use of extension tubing may not be required in patients of smaller stature, because the 21 cannulae provided with the

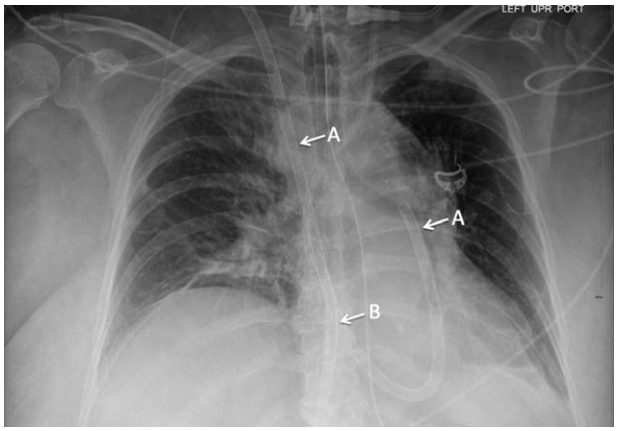

Fig. 2. Chest X-ray of a patient with internal jugular vein—femoral vein pRVAD configuration. A, outflow cannula; B, inflow cannula.

TandemHeart kit may be suitably long to directly connect with the connection adapter and pump. The pump was primed, the cannulae were de-aired, connected, and secured, and the pump was activated.

All cannulae were secured at the access points using a Horizontal Drain/Tube Attachment Device (Hollister Inc., Libertyville, IL). Between the Attachment Device and the skin entry site, a silk suture was used to further stabilize the cannula and prevent migration. The cannula sites were covered with an anti-microbial dressing and clear adhesive dressing.

RESULTS

Between January 2008 and July 2013, a total of seven patients with severe, refractory cardiogenic shock due to acute right ventricular heart failure, and adequate oxygenation underwent TandemHeart mechanical assist in a pRVAD configuration at our institution. None of these patients acutely required extracorporeal oxygenation. Mean age was 62 ± 9.8 years and four of the seven were men. Four patients (57%) had acute right ventricular myocardial infarction with delayed presentation; one (14%) patient had acute viral myocarditis with biventricular failure and refractory cardiogenic shock despite placement of a surgical left ventricular assist device; one patient (14%) with heparin-induced thrombocytopenia had simultaneous proximal right coronary artery in-stent thrombosis and sub-massive pulmonary embolism; and one (14%) patient had massive pulmonary embolism (Table I). All patients had refractory hypotension (systolic blood pressure < 90 mm Hg) and clinical signs of systemic mal-perfusion despite at least two intravenous inotropic/vasopressor agents, increased central venous fillings pressures, intra-aortic balloon pump in five patients, and surgical left ventricular assist device in one patient. The mean time from identification of right ventricular failure until pRVAD placement was 18.7 ± 15.7 hr. No patient had a history of prior cardiac disease, stroke, diabetes, or renal disease.

Device Insertion

The device was successfully placed in all seven patients without acute complication. Six of the seven patients had outflow cannulae placed via the right internal jugular vein plus femoral vein approach, whereas one patient had the standard femoral vein plus femoral vein configuration. None of the six patients with the outflow cannula placed via the right internal jugular vein required it to be repositioned, while one patient with bilateral femoral vein cannulae suffered repeated outflow cannula displacement into the enlarged right ventricle. In this case, the outflow cannula was repositioned under fluoroscopic guidance twice and it was subsequently removed 18 hr after initial placement (Table II). Following placement, the average revolutions per minute from the device was $6{,}500 \pm 850$, with a mean output of 3.4 ± 0.7 L/min.

Hemodynamic and Echocardiography Outcomes

Hemodynamic data pre- and post-pRVAD placement was available for all patients (Table III). Pre-pRVAD placement, the mean CVP was 21.7 ± 4.8 mm Hg and the mean cardiac index (CI) was 1.7 ± 0.3 L/min/m^2. Within 48 hr of pRVAD placement, the mean CVP decreased to a mean of 12 ± 3.3 mm Hg and the CI increased to a mean of 2.8 ± 0.4 L/min/m^2 across the entire cohort. There was no difference in the pulmonary artery systolic pressure before and after pRVAD placement. Echocardiographic data were available for all seven patients pre-RVAD placement and for six of seven post-pRVAD placement. Pre-pRVAD placement, six of seven patients had acute, severe RV systolic dysfunction by echocardiography, whereas it was moderately impaired in one of seven. Following pRVAD placement, RV systolic function normalized or was only mildly reduced in three patients and remained severely reduced in three patients. Three patients had severely reduced left ventricular ejection fraction at the time of pRVAD placement. The remaining four patients had normal left ventricular function.

Clinical Outcomes

Duration of mechanical pRVAD therapy was between 18 and 189 hr (mean 96 ± 57 hr). Three of seven patients

TABLE I. Patient Characteristics

Subject	Age (years)	Sex	Indication for pRVAD	Treatment Before pRVAD Placement					Time from RV failure until pRVAD (hr)
				No. inotropes[a]	No. vasopressor[b]	Inhaled nitric oxide	IABP	sLVAD	
1	67	F	RV infarct	3	0	No	Yes	No	5
2	61	M	RV infarct & Pulmonary embolism	3	1	No	Yes	No	24
3	50	M	RV infarct	3	1	No	No	No	43
4	54	F	Viral myocarditis	4	1	Yes	Yes	Yes	8
5	55	M	RV infarct	2	1	No	Yes	No	6
6	72	M	RV infarct	1	1	No	Yes	No	9
7	76	F	Pulmonary embolism	2	1	Yes	No	No	36

RV, right ventricle; IABP, intra-aortic balloon pump; sLVAD, surgical left ventricular assist device.
[a]Dopamine, dobutamine, epinephrine.
[b]Norepinephrine, vasopressin, phenylephrine.

TABLE II. pRVAD Cannula Position and Complications

Subject no.	Out flow cannula access	Cannula repositioned?	Duration of pRVAD (hours)	Units of PRBC	Stroke	Renal failure requiring dialysis	In-hospital death
1	Right IJV	No	46	4	Yes, embolic	No	No
2	Right IJV	No	78	6	Yes, hemorrhagic	Yes	No
3	Right IJV	No	189	8	No	Yes	Yes
4	Right IJV	No	135	37	Yes, hemorrhagic	Yes	Yes
5	Right IJV	No	96	8	No	Yes	No
6	Left FV	Yes	18	18	No	No	No
7	Right IJV	No	113	3	No	Yes	Yes

IJV, internal jugular vein; FV, femoral vein; PRBC, packed red blood cells.

TABLE III. Hemodynamic and Echocardiographic Data

Subject no.	Hemodynamic and echocardiographic data pre-pRVAD placement				Hemodynamic and echocardiographic data post-pRVAD placement		
	LVEF	CVP	CI	PA systolic	CVP	CI	PA systolic
1	65	29	NA	NA	18	NA	39 (e)
2	60	23	NA	38	12	4.75	40 (e)
3	50	18	1.83	51 (e)	10	1.7	50 (e)
4	10	18	2.14	35	10	2.36	NA
5	35	25	1.58	38	NA	3.14	33 (e)
6	20	17	1.45	NA	NA	2.64	NA
7	60	22	1.57	57 (e)	11	2.62	45 (e)

LVEF, left ventricular ejection fraction (%); CVP, central venous pressure (mm Hg); PA systolic, pulmonary artery systolic pressure (mm Hg); CI, cardiac index (L/min/m^2); NA, not available.
"e" denotes hemodynamic data obtained from echocardiography. All other hemodynamic data obtained from direct measurement using a pulmonary artery catheter.

died during their hospitalization. Two patients died from refractory multi-system organ failure, 4 days and 8 days following pRVAD placement. A third patient with a surgical LVAD died from a hemorrhagic stroke, 46 days following pRVAD removal. The four surviving patients were discharged home ($n = 2$) or temporary assisted living ($n = 2$). Five of seven patients had developed acute renal failure requiring temporary hemodialysis. No patients required surgical LVAD or RVAD placement after pRVAD deployment.

The ACT ranged from 161 to 400 sec, and aPTT ranged from 73 to 106. Significant bleeding requiring transfusions occurred around both the internal jugular and femoral vein cannulae in all patients. Two patients required a large volume of blood transfusion ($>$ 10 units of packed red blood cells). One patient requiring large volume of blood transfusion had a surgical LVAD placed prior to pRVAD placement. The second patient required repositioning of the pRVAD device resulting in a large volume of blood loss. Excluding

the patient who received the surgical LVAD, on average approximately 1 unit of packed red blood cells was transfused for every 4.5 ± 2.6 hr of device placement. Additionally, approximately 2.8 ± 3.3 units of platelets and 2.3 ± 2.1 units of fresh frozen plasma were transfused on average per patient. The five patients who did not have massive bleeding required significantly fewer units of packed red blood cells averaging 5.8 ± 2.3 units per patient, or one unit of packed red blood cells per 15.8 ± 37.0 hr of device placement.

DISCUSSION

This series suggests that the TandemHeart continuous flow percutaneous mechanical assist device can be used to treat extreme, refractory cardiogenic shock due to acute right ventricular failure, that right internal jugular vein access for the outflow cannula offers stable, long-term support and that severe bleeding despite attempting to target therapeutic range anticoagulation continues to be a major challenge in using this device for long intervals.

All commercially available percutaneous mechanical assist devices in the United States were designed and optimized to provide hemodynamic support for the failing left ventricle. The TandemHeart, Impella, CardioHelp left ventricular support systems are FDA approved for short-term left ventricular mechanical support. Clinical trials are underway testing modifications to these systems for right ventricular assist, but these devices are still considered investigational in the United States.

Previous reports have described off-label use of the TandemHeart as a pRVAD for hemodynamic support post-myocardial infarction [8–10], post-massive pulmonary embolism [11], treatment of severe pulmonary hypertension [12], during rejection after orthotopic heart transplant [8,13], following surgical LVAD placement [8,14], and post-pericardiotomy [4]. Our series was comprised of four patients in cardiogenic shock post-right ventricular infarction; one patient with acute viral myocarditis and biventricular failure with refractory cardiogenic shock despite placement of a surgical left ventricular assist device; one patient with heparin-induced thrombocytopenia with simultaneous proximal right coronary artery in-stent thrombosis and submassive pulmonary embolism; and one patient with isolated massive pulmonary embolism. Five out of seven patients had refractory shock despite inotropic agents and concomitant left ventricular assistance, whether with a surgically placed LVAD or intra-aortic balloon pump. In addition to right ventricular dysfunction, three of our seven patients also had severe left ventricular systolic dysfunction. pRVAD placement facilitated a marked improvement in hemodynamics and improved RV systolic function.

All except one pRVAD devices placed in our series were via a femoral plus internal jugular vein position for the inflow and outflow cannulae, respectively. None of the outflow cannulae positioned by this technique required repositioning suggesting this position combination may allow improved outflow cannula stability versus the femoral–femoral position. In addition, 21 Fr side-by-side femoral vein–femoral vein cannulae position may cause partial obstruction of the inferior vena cava which may potentially impair right ventricular filling or facilitate thrombosis. Cannula migration into the enlarged right ventricle could cause acute hemodynamic collapse, right ventricular arrhythmia, or perforation. In our experience, the right internal jugular vein approach for the outflow cannula with cannula fixation at the skin entry site provided for a consistent and secure device position in all patients.

In our experience, the TandemHeart pRVAD required a significant amount of blood product transfusion due to persistent bleeding around cannula sites, gasterointestinal bleed, and hemolysis. Large transfusion requirements were notable in two patients due to a need for cannula reposition or due to surgical LVAD related bleeding and hemolysis. In addition, many of these patients also develop systemic coagulopathies due to shock liver, disseminated intravascular coagulation, and drug induced thrombocytopenia which can be responsible for excess bleeding. Our maintenance target activated clotting time was 200 sec which is in the range recommended by the manufacturer for typical left ventricular assist.

There is limited data in the literature describing the use of pRVAD support for refractory right ventricular failure and cardiogenic shock. While we found that utilizing the internal jugular vein for outflow cannula position was most stable, larger prospective studies are needed to address this question further. Prospective studies are also needed to provide further guidance on patient selection for pRVAD placement and to address excess bleeding.

CONCLUSION

Continuous flow, percutaneous right ventricular assist device therapy is an option for patients with refractory cardiogenic shock due to right ventricular failure. The right femoral vein and right internal jugular vein for inflow–outflow cannula configuration offers stable cannulae position for prolonged pRVAD assist. Bleeding remains a challenging problem for this therapy.

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