



Mechanical circulatory support for acute right ventricular failure in the setting of pulmonary embolism

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Background: Right ventricular (RV) failure due to pulmonary embolism (PE) increases morbidity and mortality and contributes to prolonged hospital length of stay and higher costs of care. RV mechanical circulatory support (MCS) including Impella RP devices have been increasingly used in hemodynamically compromised PE patients who are refractory to intravascular volume expansion and inotropic therapy. However, effectiveness and safety of Impella RP, in hemodynamically unstable PE patients is unknown.

Methods: We included consecutive patients who presented to Detroit Medical Center between November 3, 2015 and October 2, 2017 with acute PE and had evidence of hemodynamic compromise indicating Impella RP.

Results: Total of five cases were identified. All patients met the shock definition due to massive or submassive PE and therefore received Impella RP on admission. Cardiac index was improved from mean of 1.69/min/m² (0.88-2.15 L/min/m²), to 2.5 L/min/m² (range 1.88-3.4), after 24 h of treatment. Similarly, mean heart rate reduced to 92 beats per minute (79-105), and mean systolic blood pressure increased to 140 mmHg (115-179). No significant changes were found in renal function, hemoglobin and platelets level during device use. One patient experienced hemoglobin drop from 13.7 to 7.3 g/dL but did not require blood transfusion. All patients survived to discharge.

Conclusion: In patients with PE and RV shock, Impella RP device resulted in immediate hemodynamic benefit with reversal of shock and favorable survival to discharge.

KEYWORDS

cardiogenic shock, Impella RP, mechanical circulatory support, pulmonary embolism, right ventricle failure

1 | INTRODUCTION

Pulmonary embolism (PE) continues to be challenging both in diagnosis and management and accounts for more than 275 000 hospital admissions per year in the United States with associated mortality which is 15% within the first 3 months of presentation.¹⁻⁴ In patients

presenting with hemodynamically stable PE, treatment with systemic anticoagulation leads to case-fatality rates of approximately 2%.⁵⁻⁷ However, approximately 5% of patients with acute PE who develop hemodynamic instability, mortality can be as high as 20-50%.⁸

Evidence of RV failure measured by strain from transthoracic echocardiography, or CT-scan, enhance prediction of clinical deterioration

after PE.⁸⁻¹⁰ Nevertheless, normotensive patients with RV dysfunction represented 30-40% of patients presenting with PE, of those, 10% develop PE-related shock after admission.⁹ This indicates that substantial latent hemodynamic impairment among patients with PE.

Multiple studies focused on strategies to risk-stratify patients with acute PE and guide use of potentially effective adjunctive therapies such as thrombolytics. Similarly, RV mechanical circulatory support (MCS) devices have been increasingly used in hemodynamically compromised patients who are refractory to intravascular volume expansion and inotropic therapy.¹¹

The safety and efficacy of Impella RP (Abiomed, Danvers, MA) in patients with RVF has been studied in RECOVER RIGHT study, a prospective, open label, non-randomized multicenter trial, and showed both safety and efficacy in patients with RVF after left ventricular assist device (LVAD) and acute myocardial infarction.¹² However, effectiveness and safety of Impella RP, in hemodynamically unstable PE patients is unknown.

2 | METHOD AND MATERIALS

2.1 | Study population

We included consecutive patients who presented to Detroit Medical Center between November 3, 2015 and October 2, 2017 with acute PE and had evidence of hemodynamic compromise indicating Impella RP. Patient received Impella RP if the diagnosis of massive or submassive PE was confirmed. Based on the currently available guidelines, massive PE is defined as acute PE with sustained hypotension (systolic blood pressure <90 mm Hg for at least 15 min despite optimal medical treatment of intra vascular volume expansion with repeated normal saline 0.9% boluses, or refractory hypotension despite inotropic therapy, not due to a cause other than PE (ie, arrhythmia, hypovolemia, sepsis, or LV dysfunction), pulselessness, or persistent profound bradycardia (heart rate <40 bpm with signs or symptoms of shock).^{10,13} While submassive PE is defined as acute PE without systemic hypotension (systolic blood pressure >90 mm Hg) but with either RV dysfunction or myocardial necrosis.¹⁴ All patients were monitored with repeated echocardiography exams to assess RV size and function, continuous hemodynamic monitoring with a pulmonary artery catheter and invasive blood pressure monitoring.

2.2 | Data acquisition

Demographics, baseline clinical characteristics, pre-implantation clinical course, and post-implantation outcomes were obtained from the medical record. Risk stratification using Pulmonary Embolism Severity Index (PESI) and simplified PESI (sPESI) scores were done for all patients prior to Impella RP in order to support the clinical indication for MCS (Table 1).^{15,16}

The pulmonary artery pulsatility index (PAPi) is a novel index to detect RV failure in myocardial infarction (MI) involving the RV. PAPi value <0.9 showed good correlation with mortality or the need for RV mechanical circulatory support for refractory RV failure.¹⁵ PAPi < 2

predicts right side heart failure after left ventricular assist device (LVAD) implantation.^{11,16} The value of PAPi in the prediction of mortality or the requirement of RV mechanical circulatory support in PE patients has not been validated. PAPi score has been calculated for all five patients.

2.3 | Mechanical circulatory support

The Impella Right Peripheral (RP) was used in all cases. Impella RP is a temporary right ventricular assist device (RVAD) that provides mechanical circulatory support to the right ventricle. Impella RP is a 3-dimensional catheter-based microaxial pump designed specifically for temporary RV support. In 2012, Abiomed's Impella RP was approved by the FDA for temporary mechanical circulatory support for cardiogenic shock due to RV failure in the setting of LV assist device (LVAD), myocardial infarction, heart transplant, or open-heart surgery.¹⁷

The device consists of 22 Fr pump head containing the electric motor, axial blood pump, and outflow cannula, mounted on an 11Fr catheter. It is placed percutaneously through the femoral vein and advanced in an antegrade fashion across the pulmonic valve into the pulmonary artery under fluoroscopic guidance. The inflow portion of the catheter resides in the inferior vena cava, and a flexible nitinol cannula traverses the right atrium, tricuspid valve, and pulmonic valve. The outflow portion of the catheter resides in the main pulmonary artery. The device can supply perfusion of up to 4.4 L/min for an anticipated duration of up to 14 days. The pump is inserted through a right heart catheterization procedure via the femoral vein, and requires a 23 Fr sheath introducer. After advancing the right heart catheter into the level of the pulmonary artery, a guide wire is advanced to the level of the left pulmonary artery. The Impella RP device is advanced over the guide wire to its position. The guide wire is removed and the device then secured and activated. Anticoagulation is always recommended while Impella RP is used to prevent clotting. Heparin is already in the Impella purge solution and supplemental intravenous heparin was administered to maintain activated clotting time (ACT) between 200 and 250 s. Impella RP weaning was facilitated through the use of several parameters evaluating the hemodynamic stability which include; improved systolic BP without inotropic support, improved cardiac index, and improved urine output to >0.5 mL/kg/min. Once hemodynamic stability is achieved, gradual power and output was decreased. Once the patients remained hemodynamically stable for several hours with minimal mechanical circulatory support, the patients were deemed ready for device removal. Once the device was removed, surgical closing sutures, mattress suture or figure of eight suture techniques with manual compression was used to achieve hemostasis.

2.4 | Catheter-directed ultrasound-accelerated thrombolysis

The EKOS EkoSonic® Endovascular system (EkoSonic Endovascular System, EKOS Corporation; Bothell; WA) delivers low-intensity

TABLE 1 Pulmonary embolism severity index parameters and risk stratification

Parameters	PESI	Simplified PESI		
Age	Age in years	1 point (if age >80 years)		
Male sex	+10 points	—		
Cancer	+30 points	1 point		
CHF	+10 points	1 point		
Chronic pulmonary disease	+10 points	1 point		
Pulse rate ≥ 110 b.p.m		1 point		
SBP <100 mmHg	+30 points	1 point		
Respiratory rate >30 per min	+20 points	—		
Temperature <36°C	+20 points	—		
Altered mental status	+60 points	—		
Arterial oxyhemoglobin saturation <90%	+20 points	1 point		
Risk stratification^a				
	Points	30-day mortality		
PESI	Class I	≤ 65	Very low	0-1.6%
	Class II	66-85	Low	1.7-3.5%
	Class III	86-105	Moderate	3.2-7.1%
	Class IV	106-125	High	4.0-11.4%
	Class V	>125	Very high	10.0-24.5%
Simplified PESI	0		1.0%	
	≥ 1		10.9%	

PESI, Pulmonary Embolism Severity Index; CHF, congestive heart failure; SBP, systolic blood pressure; b.p.m, beats per minute; PESI, pulmonary embolism severity index. Green highlighted fields indicated simplified PESI parameters and risk stratification. Green highlighted field represent sPESI.

^aBased on the sum of points.

ultrasound for the purpose of facilitated thrombolysis using low-dose fibrinolytic therapy.¹⁸ The ultrasound disaggregates fibrin strands, increases permeability of the clot, and disperses the fibrinolytic drug into clot through acoustic microstreaming effects. The EkoSonic Endovascular System includes an Intelligent Drug Delivery Catheter (IDDC), MicroSonic Device (MSD) containing a series of miniature ultrasound transducers positioned along the treatment zone, and a Control Unit. The IDDC is a 5.2Fr multi-lumen sideport infusion catheter, with infusion lengths ranging from 6 to 50 cm, which accommodates the coaxial 0.035" MSD to deliver uniform radial ultrasound energy (2.2 MHz) to the entire infusion zone with simultaneous rt-PA infusion. The Control Unit continuously monitors treatment zone temperature measured by the IDDC's thermocouples and automatically adjusts delivered ultrasound power to optimize thrombolysis. The EkoSonic System has been approved by the US FDA for the infusion of solutions into the pulmonary arteries in April 2008.

3 | RESULTS

Five patients with PE complicated with hemodynamic instability and cardiogenic shock were treated with Impella RP due to acute RV failure. Preoperative patient characteristics are reported in Table 2. One patient presented with cardiogenic shock on admission whereas the other four presented with submassive PE which was complicated with shock after admission. Three out of the five patients had saddle emboli. Two patients experienced massive PE that extend from the main pulmonary artery into five branches as seen on CT angiography and pulmonary angiogram (Figures 1 and 2). All patients were screened for deep vein thrombosis (DVT) before device insertion. One patient was diagnosed with DVT in the right femoral and popliteal veins below the level of the common femoral vein and thus did not preclude from device insertion through the right femoral vein. One patient was diagnosed with DVT in the left femoral and popliteal veins. Three patients had now DVT. All patients were treated with IV heparin for

TABLE 2 General characteristics of patients presenting with massive or submassive PE and shock

	Age	BSA	VTE history	Cancer history	AC	CAD	ICD	HTN	DM	HCL	Cr	Hgb	Plt
Patient 1	72	2.21	PE in 2012	No	No	No	No	YES	No	No	1	14.8	157
Patient 2	28	2.21	No	No	No	No	No	No	No	No	1.32	14.2	215
Patient 3	52	2.23	No	No	No	No	No	No	No	No	1.09	8.1	220
Patient 4	58	2.05	DVT in 2016	No	No	No	No	No	No	No	1.25	13.5	100
Patient 5	44	3.56	PE in 2012	No	No	No	No	No	No	No	0.88	14.3	154

PE, pulmonary embolism; BSA, body mass index; VTE, venous thromboembolism; AC, anticoagulation; CAD, coronary artery disease; ICD, Implantable Cardioverter Defibrillator; HTN, hypertension; DM, diabetes mellitus; HCL, hypercholesterolemia; Cr, creatinine; Hgb, hemoglobin; Plt, platelet.

anticoagulation with bolus dose of 5000 units and maintenance dose adjusted to patient weight with routine monitoring of ACT to target of 200-250 s.

Echocardiogram was performed for all five patients prior to Impella RP insertion. Using 4-chamber view, fractional area change, and tricuspid annular plane systolic excursion (TAPSE). Based on these measurements, all five patients had remarkable RV dilation with moderate to severe dysfunction prior to Impella RP insertion. The LV ejection fraction was preserved in all five patients and (>50%) (Table 3).

Risk stratification using PESI and sPESI scores indicated high risk of 30-day mortality in all patients (mean PESI 101 and mean sPESI 7.3) (Table 4). Using the right heart catheterization numbers before Impella RP insertion, mean PAPI was 1.6, despite marked RV dilation and function abnormalities on echocardiography (Table 4). Mean pulmonary artery pressure was 43 mmHg as measured during initial right heart catheterization (range of 33-57 mmHg) (Table 5).

The mean time for Impella RP support was 3.2 days (range of 1-6 days). Prior to device insertion systolic blood pressure ranged from 85 to 127 mmHg. For patients with systolic blood pressure >90 mmHg, the systolic blood pressure dropped by 40 mmHg or more from baseline which met the shock definition. Also, the mean heart rate was 114 beats per minutes (ranging from 94 to 145 beat per minute) on presentation indicating the hemodynamic instability of these patients. Invasive hemodynamic assessment and all patients had right heart catheterization before Impella RP device was inserted (Table 5).

Cardiac index (CI) was low indicating cardiogenic shock on presentation with mean CI of 1.69 L/min/m² (range 0.88-2.15 L/min/m²) (Table 5). Based on echocardiogram that was done on admission as well, all patients had preserved LV function with ejection fraction >50% which ruled out LV dysfunction as mechanism for cardiac shock.

Patients received treatment with catheter-directed ultrasound-accelerated thrombolysis (CDUAT) using the EKOS EkoSonic® Endovascular system. The use of CDUAT was based on the operator discretion. Two patients received two systems based on the operator assessment of the pulmonary angiogram that showed heavy clot burden (Table 4). Length of thrombolysis therapy varied between 6 and 12 h. Alteplase 5 mg was administered as bolus treatment during device deployment, followed by infusion at a rate of 2 mg/h for 4 h then 1 mg/h for the remaining time.

With Impella RP treatment, all patients showed significant clinical and hemodynamic improvement. Mean heart rate reduced to 92 beats per minute (79-105), and mean systolic blood pressure increased to 140 mmHg (115-179). Similarly, cardiac index increased from 1.69 L/min/m² (0.88-2.15) to 2.50 L/min/m² (1.95-3.40) immediately after initiation of Impella RP. Echocardiogram at 3 days following Impella RP showed improvement in RV function, TAPSE, and FAC (Table 3).

The length of mechanical circulatory support use was 1 day for two patients 3, 5, and 6 days for the other patients. There is no standardized protocol for device weaning and explantation. Device

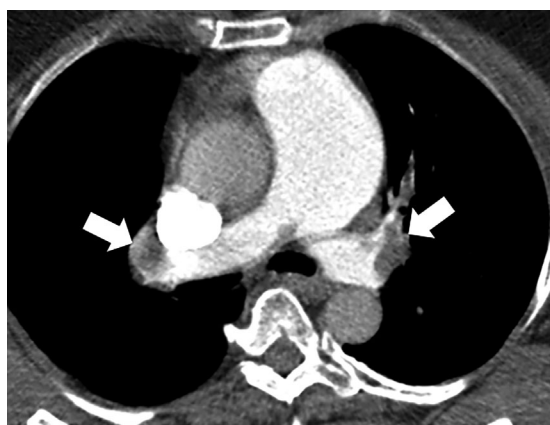
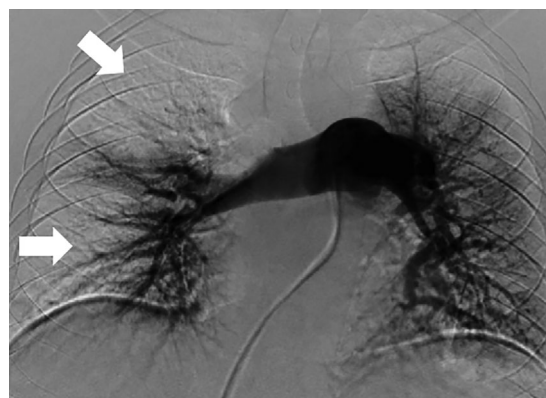
**FIGURE 1** CT angiography showing massive pulmonary embolism involving the right and left main pulmonary arteries (arrows).**FIGURE 2** Pulmonary angiography shows pulmonary embolism with bilateral oligemia more prominent on the right side (arrow).

TABLE 3 RV assessment by echo at index day and follow up

	DAY 0			Before discontinuation of MCS		
	RV			RV		
	A4C	FAC	TAPSE	A4C	FAC	TAPSE
Patient 1	60	22	15	56	45	20
Patient 2	50	17	13	48	27	17
Patient 3	56	9	16	60	23	17
Patient 4	53	11	12	46	23	13
Patient 5	NA	NA	NA	NA	NA	NA

Follow up shows improvement in RV size and function based in apical 4-chamber view, fractional area change and tricuspid annular plane systolic excursion. Left ventricular ejection fraction was preserved in all patients (> 50%).

RV, right ventricle; MCS, mechanical circulatory support; A4C, apical 4-chamber view; FAC, fractional area change; TAPSE, Tricuspid annular plane systolic excursion; NA, not available.

explantation was done when the patients were off inotropic support, free of sepsis and with stable hemodynamics with minimal support. Echocardiogram findings that suggested RV recovery was another parameter that we used to wean MCS.

Overall, all patients showed stable hemodynamics that continued after Impella RP MCS removal. All patients also, were successfully discharged from index admission and had 100% 1 month follow-up survival.

3.1 | Safety endpoint

No change in renal function, hemoglobin, or platelet level was noted at the end of Impella RP MCS support. One patient, treated with Impella RP for 6 days, had a fall in hemoglobin levels from 13.7 g/dL to a nadir

of 7.30 g/dL. No patients received packed red blood cell transfusion during Impella RP treatment and all patients were successfully discharged from the hospital. One patient required treatment with milirone 0.75 mcg/kg/min for 48 h and sildenafil 20 mg TID for residual severe pulmonary hypertension that was continued to discharge. One patient developed enterococcus faecalis bacteremia and septic shock required short term inotropic support with norepinephrine.

4 | DISCUSSION

This study demonstrates the rapid reversal of right ventricular failure among patients with massive and submassive PE who were treated with Impella RP. The device appeared to be associated with a favorable side effect profile. This case series provides the first demonstration of the feasibility and clinical effects of a mechanical circulatory support to rapidly improve RV dysfunction in patients with acute PE.

Beside systemic thrombolysis therapy for patients presenting with massive PE with shock, catheter-directed therapy is regarded as safer alternative due to reported lower rates of major bleeding and hemorrhagic complications.^{10,19} This method is now indicated for massive and submassive PE patients to reduce immediate and long-term complications.²⁰ In order to further decrease the dose of thrombolytics and decrease bleeding complications, catheter-directed ultrasound-accelerated thrombolysis (CDUAT) has emerged which decreased the dose of thrombolytics and also increased clot penetration.^{18,21} Although these technologies showed decreased clot burden for patients with acute PE and shock, they lack mechanical support for failing RV. Furthermore, no study has been done to show improvement in invasive hemodynamics using CDUAT.

The current guideline recommends fluids boluses as the first step for acute RV failure with emphasis to avoid excessive volume overload

TABLE 4 Vital signs and risk stratification before and after MCS with Impella RP.

	Impella (days)	Peak Trop	Peak NT-proBNP	EkoSonic	PESI	sPESI	PAPi	HR		BP		
								Before	After	Admission	Before	After
								Patient 1	3	0.023	758	1
Patient 2	1	0.092	5069	2	58	8.9	1.66	106	92	155/112	99/69	173/97
Patient 3	6	0.434	8245	1	103	8.9	0.56	103	94	96/80	86/71	125/85
Patient 4	5	6.166	NA	2	129	8.9	1.15	124	79	93/60	87/56	150/71
Patient 5	1	0.06	1821	1	134	8.9	0.81	92	101	129/107	138/97	129/103

Risk stratification using PESI sPESI showed moderate to severe m30-days mortality (please refer to table 1 for PESI and sPESI score details). PAPi score was low in 2 out of 5 patients despite severe RV dilatation and dysfunction on echocardiogram (PAPi score < 1 indicates RV).

MCS, mechanical circulatory support; Trop, troponin (ng/L); NT-proBNP, N-terminal pro-brain natriuretic peptide (pg/mL); EkoSonic, Catheter-directed ultrasound-accelerated thrombolysis; PESI, Pulmonary Embolism Severity Index; sPESI, simplified PESI; PAPi, pulmonary artery pulsatility index; HR, heart rate; BP, blood pressure.

TABLE 5 Right heart hemodynamics before and after treatment with MCS

	RA		RV		PA		CI	
	Before	After	Before	After	Before	After	Before	After
Patient 1	19/20/16	22/21/26	53/9/18	71/15/23	72/23/39	62/34/44	2	Na
Patient 2	20/24/21	Na	76/16/27	Na	77/42/57	Na	1.75	Na
Patient 3	19/24/23	Na	42/11/26	Na	41/28/33	Na	2.15	Na
Patient 4	29/30/32	19/19/18	41/15/18	Na	58/21/39	57/31/40	0.88	3.7
Patient 5	24/23/21	NA	58/21/26	NA	57/36/45	NA	1.65	NA

Pressure values are described as systolic/diastolic/mean pressures. MCS, mechanical circulatory support; RA, right atrium pressure (mmHg); RV, right ventricle pressure (mmHg); PA, pulmonary pressure (mmHg); CI, cardiac index (l/min/m²); NA, not available.

which may result in extreme RV dilatation and a precipitous decline in RV performance.²² Second-line management includes inotropic support to increase RV cardiac output by increasing RV contractility and heart rate.²³ Patients refractory to those treatments, RV support with MCS has been suggested as a “bridging” intervention for faster recovery.²⁴ RV acute MCS now represents an important step in the management of RV failure and provides an opportunity to rapidly stabilize patients with cardiogenic shock involving the RV. Several iterations of surgical RVAD has been developed but continue to require large-bore cannulas, anticoagulation and sternotomy or thoracotomy. These limitations led to the development of percutaneous MCS devices, including Impella RP that allows for early intervention in RV failure without the need for surgery.^{12,25} However, the effectiveness of this device for use in acute RV failure has not been demonstrated in patients with acute submassive or massive PE accompanied with RV-mediated cardiogenic shock.

Our findings support the utility of MCS using Impella RP in patients presenting with massive PE accompanied with RV-mediated cardiogenic shock (Figure 3). All patients in our series received guideline based treatment with anticoagulation, volume expansion, inotropic support and catheter-mediated thrombolysis. Also, all patients

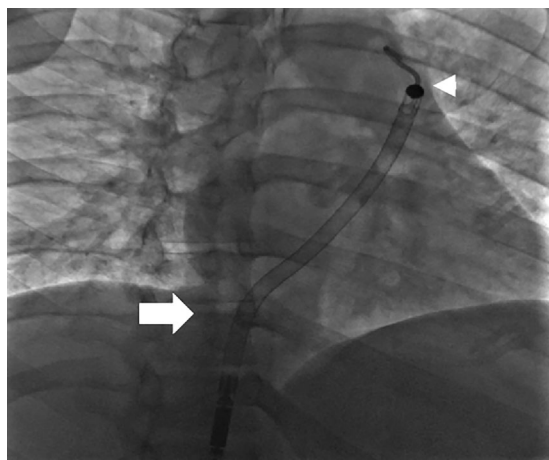


FIGURE 3 Impella RP positioned across the pulmonic valve. The inlet is at the inferior vena cava (IVC) and right atrium junction (arrow) and outlet is into the main pulmonary artery (arrow head).

received CDUAT using EkoSonic Endovascular System. Despite following guideline-directed management, patients continued to be in shock as indicated with invasive hemodynamics as well as echocardiogram findings that suggested severe RV dilatation and dysfunction. All patients

Despite low number of cases, the results of the present study are comparable to the previous studies, demonstrating successful device explantation and survival to discharge in all cases.²⁵ Importantly, we have also shown that all patients exhibit normal RV function after device explantation. This is better to what other studies have shown of partial (15%) improvement in RV failure after device explantation. This suggests that RV functional recovery may continue over the first year after device explantation. Based on these findings, we recommend using continuous pulmonary arterial pressure monitoring routinely for patient with RV failure treated with MCS devices, preferably dual lumen Swan-Ganz catheter. This approach will provide continuous right atrial and pulmonary pressures which will provide further guidance for hemodynamic support using MCS.

We have described the clinical outcomes of patients with acute RV failure due to acute PE supported with the Impella RP. Our findings suggest that implantation of these devices is clinically feasible, associated with acute hemodynamic improvement, and facilitate successful bridge-to-recovery in most patients.

4.1 | Limitations

Although the current case series showed favorable outcome, these results should be interpreted with caution given the retrospective data collection, small sample size that may not be very representative of the patient population. Although not all patient had invasive hemodynamic assessment at the end of the case, our echocardiogram assessment showed evidence of RV recovery which could be used as surrogate marker for improved cardiac output. Also, the decision to use Impella RP was solely based on operator discretion with lack of standardized protocol which could inherently affect the results of the study. This may undermine the external validity of the current findings and therefore definitive recommendations cannot be made. Therefore, larger studies with control group is needed to confirm the favorable results.

5 | CONCLUSION

In patients with PE and RV shock, Impella RP device resulted in immediate hemodynamic benefit with reversal of shock and favorable survival to discharge. These findings support its probable benefit in this gravely ill patient population.

DISCLOSURE

None.

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