


Temporary right ventricular circulatory support following right ventricular infarction: results of a groin-free approach

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Abstract

Aims Acute right heart failure (RHF) is a severe complication of right ventricular infarction. The management of acute RHF poses a number of challenges, such as providing haemodynamic support. Temporary circulatory support (TCS) may be required upon failing medical therapy. The ProtekDuo® dual lumen cannula provides a minimally invasive option for (TCS) through a groin-free internal jugular vein approach. We present the largest patient series to date using the ProtekDuo® cannula as temporary right ventricular assist device (t-RVAD) in RHF after acute myocardial infarction (MI).

Methods and results From July 2016 to November 2019, 10 patients underwent t-RVAD implantation for RHF following acute MI. Transthoracic and transoesophageal echocardiography were performed in all patients to assess cardiac function, with a particular focus on RV function. Cumulative 30-day survival was 60%. Mean TAPSE was 6.4 ± 3.1 mm, mean fractional area change was $12.1 \pm 4.2\%$, and mean right ventricular end diastolic area was 19.8 ± 2.7 cm². Mean implantation time was 32.8 ± 8.3 min. Mean interval after first cardiac intervention was 4.6 ± 5.8 days. Mean t-RVAD time was 10.0 ± 7.4 days with a significant reduction in central venous pressure 19.3 ± 2.7 vs. 8.2 ± 2.6 mmHg, $P < 0.001$ and a significant increase in central venous saturation 52.8 ± 15.6 vs. $80.0 \pm 6.0\%$, $P < 0.001$. Mean intensive care unit stay was 18.6 ± 12.2 days. Four patients were weaned from TCS. Two patients were bridged to a long-term paracorporeal RVAD. There were no t-RVAD associated complications. Causes of death ($n = 4$) were multiorgan failure, electromechanical dissociation, and haemorrhagic stroke. Mean follow-up time was 96.0 ± 107.6 days. No independent predictors of mortality were identified in univariate analysis.

Conclusions We show that groin-free, percutaneous implantation of the ProtekDuo® cannula is a feasible and safe tool for TCS in acute RHF post-MI. This approach provides the advantages of percutaneous implantation including complete mobilization and non-surgical bedside explantation, as well as the option for adding an oxygenator to the t-RVAD circuit.

Keywords Temporary circulatory support; Myocardial infarction; Assist device; Percutaneous implantation

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Introduction

With coronary artery disease still a leading cause of death worldwide, acute right heart failure (RHF) is an established complication of acute myocardial infarction (MI). First described as a clinical syndrome in the 1970s, there remain

differing definitions of right ventricle (RV) dysfunction, right ventricular failure, and RHF. Right ventricular dysfunction can be defined by the presence of acute systolic RV dysfunction in echocardiography, increase of natriuretic peptides without LV failure, or by specific RV strain patterns in ECG control.¹ Right ventricular failure can be described as RV

dysfunction with low cardiac output or cardiogenic shock, resulting in organ malperfusion and subsequent multiorgan failure. Defined as a clinical syndrome, RHF is due to an alteration of RV structure or function of the right-sided circulatory system.¹

The culprit vessel in RV infarction is usually the right coronary artery or a marginal branch in a left-dominant coronary system. In general, the RV has a higher tolerance for acute ischaemia, because of its reduced oxygen demand, higher coronary flow reserve, double coronary artery supply, and a more homogeneous transmural perfusion across one cardiac cycle.² However, the incidence of in-hospital mortality is higher in patients with inferior wall MI.³ This may be related to the incidence of refractory cardiogenic shock in these patients due to reduced left ventricular preload with entailing low cardiac output leading to systemic hypoperfusion ('right to left failure').^{4,5}

Following discharge from hospital, patients with RV infarction actually have a better long-term prognosis compared with those suffering from LV infarction.⁶ This is thought to be due to partial recovery of RV function over time or that persistent RV dysfunction is better tolerated in the long term.

Echocardiography remains an essential diagnostic tool in the evaluation of right heart function. Rudski *et al.* presented a guideline document for the optimal echocardiographic study of the RV, with reference values for larger study population or pooled values from different studies in order to facilitate assessment of the right heart.⁷ With regard to prediction and early recognition of RHF, risk scoring and predictive models for RHF have all been developed in the setting of left ventricular assist device implantation and are not sensitive to functional RV changes after MI.⁸

For the cohort of patients who require temporary circulatory support (TCS) for RHF following acute MI, management depends on the timing and severity of the RHF. Patients in acute cardiogenic shock need prompt management.⁹ While inotropic support remains the first-line treatment, TCS in the setting of acute heart failure has evolved, and different devices are available. Extracorporeal membrane oxygenation (ECMO) can be used to stabilize patients in cardiogenic shock or to bridge patients to other modes of mechanical circulatory support (MCS).¹⁰ TCS such as miniaturized axial pump devices or veno-arterial ECMO are still the main therapeutic tools in the treatment of acute cardiogenic shock after MI.⁷ However, the resulting systemic blood flow will be non-pulsatile. A study from Itoh *et al.* demonstrated that pulsatile blood flow in an ECMO setting produces significantly higher haemodynamic energy with improvement of systemic microcirculation when compared with non-pulsatile ECMO perfusion in acute cardiac failure.¹¹

The ProtekDuo® dual lumen cannula (LivaNova PLC, London, UK) provides a true minimally invasive option for RV TCS, whether with the TandemHeart™ pump (LivaNova PLC, London, UK) or any other extracorporeal centrifugal

pump (e.g. CentriMag™ assist device, Abbott Laboratories, Chicago, USA).⁷ However, the major advantage of the ProtekDuo® cannula is the possibility to provide minimally invasive groin-free full RV support with no need for direct cannulation of the right atrium and the pulmonary artery (PA), obtaining the ability to add gas exchange if need be (*Figure 1*). Sternotomy is not necessary at all when only temporary support is anticipated, and implantation trauma is very limited. Furthermore, through the internal jugular approach, implantation and explantation can be performed on awake patients with no need for cardiopulmonary bypass (CPB) and no limitation on mobilization once TCS is established.^{12,13} Additionally, the physiological pulsatile blood flow caused by regular ejection of the left ventricle is preserved. To the best of our knowledge, in this study, we present the largest detailed results with the groin-free right heart TCS using the ProtekDuo® cannula in a subgroup of acute MI with subsequent RHF as temporary right ventricular assist device (t-RVAD).

Methods

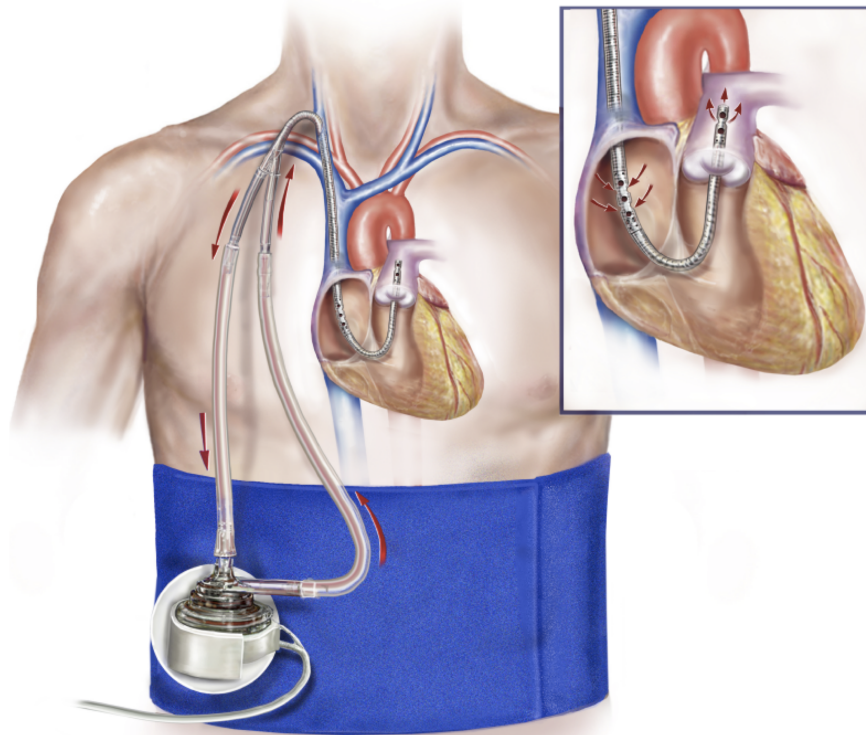
Patients

From July 2016 to November 2019, we implanted 10 temporary right ventricular assist devices (t-RVAD) in patients with RHF after acute MI. In a retrospective single-centre study, we evaluated this selective patient cohort for a perioperative and postoperative outcome analysis. This study complies with the Declaration of Helsinki and was approved by the ethical committee of the University of Heidelberg, S-568/2019.

Right ventricular assist device implantation

Our implantation technique of the ProtekDuo® cannula, with a TandemHeart™ or Centrimag™ centrifugal pump, has been described before.⁷ Using fluoroscopic and transesophageal echocardiography control, a balloon-catheter was placed over a guide-wire into the PA via the right jugular vein using Seldinger technique. With the removal of the balloon-catheter, the dual lumen ProtekDuo® cannula was inserted into the main PA. Depending on the procedural setting, t-RVAD support was initiated with either weaning from CPB by gradually decreasing CPB flow or solely by increasing t-RVAD flow to a maximum of 7,500 rpm and 3.8 L/min, respectively. Anticoagulation was monitored through activated partial thromboplastin time, with a target value of 60–80 s and measured activated clotting time of 180–220 s commencing from the beginning of the implantation. Transthoracic and transoesophageal echocardiography were performed in all patients to assess cardiac function, with a particular focus on RV function.

FIGURE 1 Illustration of the ProtekDou® dual lumen cannula (reproduced with kind permission of LivaNova PLC London, UK).



Right ventricular assist device weaning protocol

To evaluate RV function, a patient's inotropic requirement, inhalative nitric oxide (iNO) concentrations, RV function in transthoracic echocardiography, and clinical status were evaluated daily on the intensive care unit (ICU). After weaning from iNO support, extubation was targeted as early as possible. According to functional status and RV recovery, t-RVAD support was gradually decreased by 500–1,000 rpm until a minimal of 3,500 rpm. Echocardiography and central venous saturation analysis were monitored routinely. Inotropic support with dobutamine or milrinone/levosimendan was calculated according to haemodynamic analysis.

Statistics

All statistical analyses were performed using the IBM SPSS Statistics version 25 software (SPSS, Chicago, IL, USA). Normally distributed continuous variables were reported as mean \pm standard deviation and were compared by a two-tailed *t*-test. Categorical variables were reported as frequencies and percentages and were analysed by χ^2 test. Survival was calculated using the Kaplan–Meier method. The threshold for significance was set at $P < 0.05$.

Results

Patient data

During the study period 10 patients (nine male, 90.0%) received a t-RVAD for acute RHF after MI. Eight of the 10 patients were at least in NYHA class III at the time of admission (3.3 ± 0.8). Cardiopulmonary resuscitation had been necessary in four patients prior to the t-RVAD implantation. T-RVAD support was indicated in cases of heart failure with preserved LV ejection fraction for right ventricular failure. Clinically, patients had progressive cardiogenic shock (as defined by common shock characteristics, e.g. haemodynamic instability, increase in inotropic and vasopressor support, and worsening of end-organ function) without LV dysfunction.

Four patients needed RV support for acute NSTEMI (40.0%), two patients suffered from acute STEMI with post-infarction ventricular septum defect (20.0%), and another two patients (20.0%) showed complications related to percutaneous coronary intervention with acute RCA dissection (10.0%) and RCA occlusion (10.0%). One patient (10.0%) needed a RV support after minimally invasive mitral valve reconstruction with subsequent RCA embolism and

acute RHF. Another patient in this cohort underwent thoracotomy for haemothorax following coronary artery bypass grafting and biologic aortic valve replacement with subsequent NSTEMI and additional need of off-pump RCA bypass surgery during t-RVAD implantation. A summary of the patient collective is presented in *Table 1*.

In four patients, additional MCS was necessary in addition to t-RVAD implantation. One initially received a central veno-arterial ECMO, which was downgraded to a less invasive t-RVAD with oxygenator during t-RVAD implantation. Two patients needed IABP-counter pulsation support after primary cardiac surgery to improve coronary flow. Another patient needed IABP implantation during t-RVAD implantation for further improvement of coronary flow; IABP support was weaned 3 days later. Further baseline data are presented in *Table 2*.

Intraoperative data

Intraoperative echocardiography showed a mean tricuspid annular plane systolic excursion at the time of t-RVAD implantation of 6.4 ± 3.1 mm. The fractional area change was measured at a mean of $12.1 \pm 4.2\%$ and the mean right ventricular end diastolic area was 19.8 ± 2.7 cm². LV ejection fraction was $52.3 \pm 13.1\%$ at the time of t-RVAD implantation. Mean LV outflow tract velocity time integral was 14.0 ± 2.5 cm with a calculated mean cardiac output of 4.0 ± 1.1 L/min. Echocardiography data are listed in *Table 3A*.

Mean implantation time was 32.8 ± 8.3 min. And mean interval after first cardiac intervention was 4.6 ± 5.8 days, with five patients in whom the ProtekDuo® cannula was implanted secondary to the initial cardiac intervention, surgical, or interventional. More intraoperative patient data are depicted in *Table 3B*.

Table 1 Patient collective

Cardiac diagnosis	Concomitant cardiac surgery	Time to t-RVAD implantation
Patient 1 STEMI with acute RCA dissection	PCI of the RCA, CABG with ECMO implantation	3
Patient 2 NSTEMI	CABG + IABP	0
Patient 3 STEMI with post-myocardial infarction VSD	PCI of the RCA, VSD repair, and CABG	4
Patient 4 NSTEMI with severe aortic stenosis	CABG and aortic valve replacement	0
Patient 5 STEMI with acute RCA occlusion after PCI	CABG	0
Patient 6 Severe mitral valve regurgitation with intraoperative STEMI	Mitral valve reconstruction with CABG	0
Patient 7 STEMI with post-myocardial infarction VSD	VSD repair	15
Patient 8 NSTEMI with acute RCA dissection	PCI of the RCA	0
Patient 9 Severe aortic stenosis with postoperative NSTEMI	Aortic valve replacement with CABG	1
Patient 10 NSTEMI	PCI of the RCA	1

CABG, coronary artery bypass graft; NSTEMI, non-ST-elevation myocardial infarction; PCI, percutaneous coronary intervention; RCA, right coronary artery; STEMI, ST-elevation myocardial infarction, VSD, ventricular septal defect.

Table 2 Baseline data

Male	9 (90.0)
Height (cm)	175.0 \pm 6.3
Weight (kg)	82.4 \pm 13.1
Diabetes mellitus	3 (30.0)
Hyperlipidaemia	4 (40.0)
Arterial hypertension	8 (80.0)
Smoking	3 (30.0)
Peripheral artery disease	2 (20.0)
Carotid artery stenosis	2 (20.0)
Renal impairment ^a	5 (50.0)
NYHA	3.3 \pm 0.8
Angina pectoris	6 (60.0)
Instable angina pectoris	5 (50.0)
Dyspnoea	4 (40.0)
Hepatomegaly	0
Peripheral oedema	0
Acute myocardial infarction	8 (80.0)
Syncope	0
Pulmonary embolism	0
Acute heart failure	8 (80.0)
Previous reanimation	5 (50.0)
Creatinine (mg/dL)	1.9 \pm 1.3
Bilirubin mg/dL)	0.7 \pm 12.8
AST	599.2 \pm 816.9
ALT	316.2 \pm 503.1
CK (U/L)	7175.0 \pm 9902.6
CK-MB (U/L)	367.3 \pm 330.2

ALT, alanine transaminase; AST, aspartate transaminase; CK, creatinine kinase; CK-MB, creatinine kinase-MB; INR, international normalized ratio; NYHA, New York Heart Association functional classification.

^aCreatinine >1.3 mg/dL + urea >45 mg/dL.

Postoperative data

A detailed description of postoperative data is listed in *Table 4*. Mean t-RVAD support duration was 10.0 ± 7.4 days. Mean ICU stay was 15.8 ± 11.6 days. Mean ventilation time was 251.0 ± 165.0 h with mean iNO ventilation time of 142.8 ± 126.0 h in nine patients.

Table 3A Presents Intraoperative echocardiography values

Name	Mean value \pm standard deviation
TAPSE	6.4 \pm 3.2 mm
FAC	12.1 \pm 4.3%
RV/LV ratio	0.8 \pm 0.1
RVEDD	44.6 \pm 5.6 mm
RV ED area	19.8 \pm 2.7 cm ²
LVEF	52.3 \pm 13.1%
LVOT VTI	14.1 \pm 2.5 cm
cardiac output	4.0 \pm 1.2 L/min

FAC, fractional area change; LVEF, left ventricular ejection fraction; LVOT VTI, Left ventricular outflow tract velocity time integral; RVEDD area, right ventricular end-diastolic area; RVEDD, right ventricular end-diastolic diameter; TAPSE, tricuspid annular plane systolic excursion.

Central venous pressure was significantly lower after t-RVAD implantation: 19.3 \pm 2.7 vs. 8.2 \pm 2.6 mmHg, $P < 0.001$. There was a significant increase in central venous saturation directly postoperatively under t-RVAD support: 52.8 \pm 15.6 vs. 80.0 \pm 6.0%, $P < 0.001$. An amelioration in end-organ function was measured by a decrease in creatinine, bilirubin, aspartate (AST), and alanine transaminases (ALT); however, the difference did not reach statistical significance. Preoperative and postoperative mean creatinine values were 1.9 \pm 1.3 vs. 1.1 \pm 0.3 mg/dL, $P = 0.086$; mean total bilirubin 2.8 \pm 3.8 vs. 0.6 \pm 0.3 mg/dL, $P = 0.111$; mean AST 599.2 \pm 816.9 vs. 36.8 \pm 16.6 U/L, $P = 0.073$; and mean ALT 316.2 \pm 503.1 vs. 68.6 \pm 58.2 U/L, $P = 0.303$.

All patients received adrenalin, dobutamine, and noradrenalin postoperatively while on t-RVAD support. There were no signs of infections at the cannulation sites. Six patients were given i.v. milrinone, and four were supported with levosimendan on t-RVAD. Four patients received an additional oxygenator to the t-RVAD circuit, of whom one patient could be successfully weaned under continuous t-RVAD support. In one case, oxygenation support reached 0.45 FiO₂ at the time of t-RVAD explantation, while two patients died during t-RVAD support due to multiorgan failure. Ventilation parameters were titrated according to arterial blood gas and end-tidal carbon dioxide values. All surviving patients (60%) were successfully mobilized during ICU stay while on t-RVAD support. A t-RVAD weaning protocol is presented in Table 5.

Table 3B Presents Intraoperative data

Mean t-RVAD implantation time (min)	32.8 \pm 8.3
Interval after first cardiac intervention (days)	4.0 \pm 5.8
Intubation before t-RVAD	3 (30.0)
IABP before t-RVAD	1 (10.0)
va-ECMO before t-RVAD	2 (20.0)

IABP, intra-aortic balloon pump, va-ECMO, veno-arterial extracorporeal membrane oxygenation; t-RVAD, temporary right ventricular assist device.

Table 4 Postoperative data

iNO (h)	142.8 \pm 126.0
ECMO	0
Noradrenalin	10 (100.0)
Dopamine	1 (10.0)
Dobutamine	10 (100.0)
Adrenalin	9 (90.0)
Milrinone	6 (60.0)
Sildenafil	5 (50.0)
Arrhythmia	8 (80.0)
Renal insufficiency	5 (50.0)
Dialysis	8 (80.0)
Intubation time (h)	251.0 \pm 165.0
Reintubation	1 (10.0)
Tracheotomy	3 (30.0)
ICU stay (days)	15.8 \pm 11.6
Creatinine at discharge	1.1 \pm 0.3
Bilirubin at discharge	0.6 \pm 0.3
AST at discharge	36.8 \pm 16.7
ALT at discharge	68.6 \pm 58.2

ALT, alanine transaminase; AST, aspartate transaminase; ECMO, extracorporeal membrane oxygenation; ICU, intensive care unit; iNO, inhalative nitric oxide.

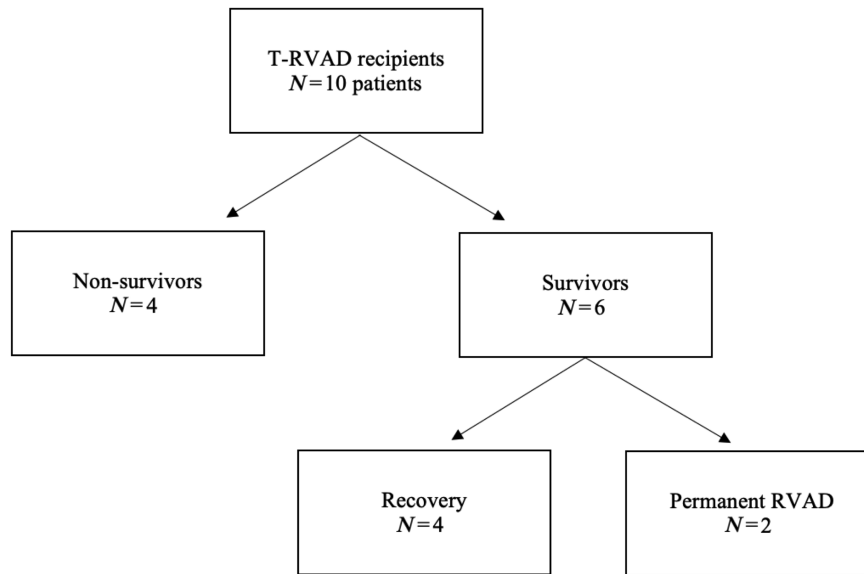
Complications and adverse events

Eight patients (80.0%) needed haemodialysis for acute kidney failure and to facilitate fluid balance. Four patients (40.0%) had postoperative bleeding, with re-thoracotomy for haematoma evacuation required in two patients. Notably, bleeding was not associated with the ProtekDuo[®] cannula or cannulation site. We did not experience any t-RVAD-associated complications, in particular no pump thrombosis (and therefore no need for pump lysis), no vessel injury, and no increased bleeding propensity.

One patient suffered from LV dysfunction after t-RVAD implantation and received an IABP-counter pulsation support bedside on the ICU to treat LV failure. One patient (10%) suffered from postoperative haemorrhagic stroke while on t-RVAD support. One patient (10%) required subtotal colectomy, ileum resection, and cholecystectomy as a result of low output syndrome following ventricular septum defect repair with coronary artery bypass grafting and secondary t-RVAD. Chest infections occurred in four patients (40%) and of these two fulfilled postoperative sepsis criteria including bacteraemia.

Survival and follow-up

In total, four patients (40%) died during the first week after t-RVAD implantation on the ICU. In one patient, the cause of death was electromechanical dissociation despite immediate cardiopulmonary resuscitation 4 hours after t-RVAD explantation. Another patient died following haemorrhagic cerebellum stroke on postoperative day five. Two patients suffered from multiorgan failure due to biventricular failure

FIGURE 2 Flowchart of patient outcomes after temporary right ventricular assist device (t-RVAD) implantation.

with low output syndrome despite MCS with t-RVAD and IABP.

Four patients (40.0%) were successfully weaned from t-RVAD. Two patients (20.0%) received an upgrade to a permanent paracorporeal RVAD (Excor® Adult single chamber RVAD, Berlin Heart GmbH, Berlin, Germany) and were subsequently listed for heart transplantation (*Figure 2*). Both patients treated with a long-term RVAD as bridge-to-transplantation concept underwent another coronary angiography under t-RVAD support to rule out further coronary treatment options, before the decision was taken to implant a permanent paracorporeal Excor® Adult single chamber RVAD. Regular transthoracic and transesophageal echocardiography examinations showed highly reduced RV function under maximum RV drainage through the t-RVAD in these cases. Both patients were listed for heart transplantation without any VAD-related complications and received regular outpatient care. One patient underwent successful heart transplantation after 444 days of permanent RVAD Excor® support. All six surviving patients showed improved functional status from NYHA class III to NYHA class I during follow-up after hospital discharge.

As to variables such as time to t-RVAD implantation, pre-operative values of creatinine, bilirubin, AST, and ALT, as well as CK and CK-MB values before t-RVAD implantation, there were no independent predictors of mortality in univariate analysis. Cumulative 30-day survival was 60%, with no death during short-term and long-term follow-up and 1-year survival of equal to 60%. Mean follow-up time was 404.7 ± 422.9 days with cumulative follow-up time 3697 days.

Discussion

The optimal management of acute right ventricular failure after MI remains a topic of ongoing discussion in current literature.¹⁴ As RHF after acute MI is often temporary in contrast to LV dysfunction in acute MI, only selected patients require TCS. Treatment options for acute RHF include (i) optimization of preload, (ii) inotropic agents, (iii) revascularization, (iv) maintenance of atrioventricular synchrony, and (v) advanced TCS. Percutaneous TCS devices serve as temporary solution, allowing for recovery-time of RV function or as

Table 5 Selected criteria for weaning protocol of t-RVAD

Continuous reduction of t-RVAD support gradually by 500–1000 rpm/days (0.25–0.5 L/min) until minimal support of 3500 rpm/min	
Reduction of inotropic support	
Sustaining reduction of central venous pressure (mmHg)	<15 mmHg
Augmentation central venous saturation (%)	>65%
Amelioration of end-organ function	<ul style="list-style-type: none"> • Normalization of liver enzymes • Amelioration of renal function
In case of additional oxygenator	FiO ₂ ≤45% or Horovitz index of >300

bridge to other permanent therapeutic options.⁴ By introducing our t-RVAD approach, the threshold for TCS implantation can be reduced. The risk profile of early circulatory support through t-RVAD with the ProtekDuo[®] cannula is favourable compared with the risks of extensive surgical complications with standard veno-arterial ECMO support. This favourable risk profile includes avoiding thrombosis as a result of blood stasis in the pulmonary vasculature, sometimes observed in VA-ECMO. Our approach also allows for preserving the physiological pulsatile blood flow caused by ejection of the left ventricle.

Here, we describe the initial results of groin-free t-RVAD for acute MI in a cohort of 10 patients. In a communication from Ravichandran *et al.*, they report only on two patients who received sole t-RVAD for predominant unspecified RV failure.¹² With the implantation of the ProtekDuo[®] cannula using only fluoroscopic and transesophageal echocardiographic control with Seldinger technique via the right jugular vein, this therapeutic application is just as feasible to be performed in a catheter laboratory without mandatorily needing surgery, CPB, or sternotomy. In our cohort, mean implantation time was 30 min. The percutaneous t-RVAD support using the ProtekDuo[®] cannula has evolved to become the standardized approach within our institution. In cases of semi-elective implantation or scheduled downgrade from ECMO, an interdisciplinary approach to decision making included the heart team and intensivists. In cases of emergency or intraoperative indication for t-RVAD support, implantation was performed immediately with subsequent heart team discussion after surgery.

In these 10 patients, time to t-RVAD implantation after first cardiac event could not be identified as an independent risk factor for mortality. However, different studies could demonstrate that optimal timing of TCS therapy can improve patient outcomes and reduce morbidity and mortality.¹⁵ Cheung *et al.* showed in their retrospective study that TCS with the Impella Recover RD[®] (Abiomed, Danvers, USA) could lead to a recovery rate of 70% in patients with acute RHF after RV infarct with successful device explantation. This partic-

ular TCS system was a micro-axial pump for temporary RV support up to 10 days which was surgically implanted through a sternotomy, with direct anastomosis of the inflow cannula to the right atrium and outflow cannula to the PA.¹⁶ However, the Impella RD[®] is no longer available for clinical use.

Within our cohort, 40% of the patients were successfully weaned completely from the RVAD and overall survival after t-RVAD implantation was 60%. In this study, we were able to demonstrate that at the time of discharge, all six surviving patients showed functional status of NYHA class I compared to NYHA class III or IV at the time of admission. Given our experience with the ProtekDuo[®] cannula utilized with an extracorporeal centrifugal pump as t-RVAD, we propose cut-off values and selection criteria for evaluation of t-RVAD implantation in this specific patient cohort. In *Table 6*, echocardiographic and clinical evaluation parameter of RV function and end-organ function are listed with corresponding proposals. Because mortality in acute RHF remains high, further studies are needed to help defining which patients will profit from a groin-free t-RVAD in the setting of acute MI with or without timely percutaneous coronary intervention or cardiac surgery.

In summary, this approach shows the feasibility of a non-surgical device implantation in a catheter laboratory. The utilization of the ProtekDuo[®] cannula with an extracorporeal centrifugal pump combines a number of key advantages, including minimally invasive implantation avoiding any (re-)sternotomy and the early mobilization of the patients which is of huge benefit in postoperative surgical recovery.^{17,18} Early mobilization on the surgical ICU is an important factor for patient recovery.¹⁸

Early intervention with patient-specific treatment is critical for this complex patient cohort. For TCS, one should focus on less invasive implantation and explantation techniques. The technique presented here avoids the disadvantages associated with a VA-ECMO support, such as peripheral cannulation, retrograde perfusion, and the risk of limb ischaemia and continuous systemic blood flow.^{19–21} MCS through

Table 6 Proposed cut-off values and selection criteria for evaluation of t-RVAD implantation

Echocardiography:	
TAPSE (mm)	<10mm
Fractional area change	<25
RV end-diastolic diameter (mm)	>44mm
RV/LV end-diastolic ratio	<0.75
Clinical parameter:	
RV deterioration under rising inotropic support	
Central venous pressure (mmHg)	>15mmHg
Central venous saturation (%)	< 55%
End-organ failure defined by	<ul style="list-style-type: none"> • Rise of transaminases, alkaline phosphatase, bilirubin, albumin, serum creatinine, sodium, potassium • Reduction of GFR • New onset of oliguria • New ascites

GFR= glomerular filtration rate; LV= left ventricle; RV= right ventricle, TAPSE= tricuspid annular plane systolic excursion

VA-ECMO also entails the risk of systemic inflammatory response syndrome due to complement systems becoming activated as a result of blood exposure to the vast extracorporeal circuit, which ultimately ends in a systemic inflammatory response and end-organ damage.²² By introducing smaller TCS systems and avoiding oxygenation whenever feasible, inflammation-related adverse events can be reduced. With 60% survival in our cohort, we were able to demonstrate the benefits of early t-RVAD implantation in a non-surgical setting after acute MI, during short-term and long-term follow-up.

A major advantage of the implantation of the ProtekDuo® cannula in a t-RVAD setting is optimization of treatment to the specific clinical scenario. In the setting of isolated RHF without pulmonary involvement, blood pumping alone is sufficient. However, if RHF is accompanied by oxygenation failure, an additional oxygenator can be easily added to the circuit. Comparing our t-RVAD approach to the Impella RP® system (Abiomed, Danvers, USA), one sees two different pump mechanisms and different cannulation sites. The Impella RP® is a percutaneous, single vascular-access micro-axial pump designed for RV support, mandatorily inserted through the femoral vein resulting in the inevitable immobilization of the patient. A study from Anderson *et al.*, reports four cases in which the Impella RP® treatment regime was escalated to a surgical RVAD (CentriMag™) because need for oxygenator became present.²³ We recently published our results of two cases with an interventional/minimally invasive LV support through Impella® 5.0 or 5.5 and RV support through the ProtekDuo® cannula. This approach provides full biventricular support and LV unloading, with reducing surgical trauma and inflammatory response and allows for a subsequent weaning from left-side or right-side support.²⁴

The minimally invasive implantation technique, the possibility to easily add and remove an oxygenator to the circuit alongside the benefits of the groin-free approach, favours the ProtekDuo® cannula as t-RVAD in cases of complicated MI.

Here, we demonstrate that the ProtekDuo® cannula for TCS of the RV is an effective tool in the acute and emergency setting. The fast, uncomplicated, and efficient RV unloading without major surgery and trauma offers means for fast recovery in the setting of RHF after acute MI. These promising early results will require more experience to further validate this approach. Limitations of this study include the small heterogenous patient cohort and its retrospective nature.

Conclusions

In summary, we report the first case series results for patients with acute MI and subsequent RHF managed via the minimally invasive approach of the ProtekDuo® cannula as t-RVAD. Temporary mechanical RV support through a groin-free percutaneous implantation of a ProtekDuo® cannula in the setting of acute MI is a feasible and safe tool in RHF. Our technique significantly reduces the threshold for t-RVAD implantation by providing all advantages of a percutaneous implantation including complete mobilization and non-surgical bedside explantation, as well as the option for adding an oxygenator to the t-RVAD circuit. Through fluoroscopic and transesophageal echocardiography control, the implantation in Seldinger technique via the right jugular vein is feasible in a catheter laboratory, too, without mandatory sternotomy and surgery. Furthermore, the ProtekDuo® t-RVAD performs as a bridge-to-decision support before long-term RVAD may become necessary, if weaning from t-RVAD fails. Further studies are needed to generate more data for evaluation.

Conflict of interest

None declared.

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