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Title Page

Percutaneous haemodynamic and renal support in patients presenting with decompensated heart failure:

A multi-centre efficacy study using the Reitan Catheter Pump (RCP)

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All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation

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Conflict of interest statement:

SK is employed by Cardiobridge for clinical support.

ÖR is the inventor of the RCP and clinical consultant to Cardiobridge.

All other authors have no conflicts of interest to declare.

Key words

Decompensated heart failure, congestion, cardiac support, renal dysfunction

Structured Abstract

Background Worsening heart failure complicated by congestion, hypotension, and renal dysfunction is difficult to manage, increasingly common and predicts a poor outcome. Novel therapies are required to facilitate diuresis and implementation of disease-modifying interventions in preparation for hospital discharge. Accordingly, we investigated the haemodynamic and renal effects of the Reitan Catheter Pump (RCP) percutaneous support device in patients admitted with decompensated heart failure (DHF).

Methods This was a prospective observational study of 20 patients admitted with DHF, ejection fraction <30%, and Cardiac index (CI) < 2.1 L/min/m² in need of inotropic / mechanical support.

Results Patients underwent RCP support for a mean of 18.3 (+/- 6.3) hours. The RCP increased CI from 1.84 L/min/m² (+/- 0.27), to 2.41 L/min/m² (+/- 0.45, p=0.04), increased urine output (71 ml / hr (+/- 65) to 227 ml / hr (+/- 179) (p=0.006) with a concomitant reduction in serum creatinine (188 µmol/L (+/- 87) to 161 µmol /L (+/- 78) (p=0.0007). There were no clinically significant haemolysis, vascular injury, or thrombo-embolic complications.

Conclusions For patients admitted with DHF, the RCP improves cardiac index, diuresis and renal function without causing important complications.

Introduction

Despite advances in the management of patients with chronic heart failure the outcome of patients admitted with decompensated heart failure (DHF) remains poor (1). The main reason for admissions is congestion and not low cardiac output (2). Persistent congestion combined with hypotension and renal dysfunction has a particularly bad prognosis (3-5). Furthermore, the presence of renal dysfunction results in the under-use of guideline-recommended therapies (6). A treatment that enhanced diuresis and improved renal function could have an important role in managing such patients.

Improving haemodynamics pharmacologically with either inotropic or vasodilator agents has been met with limited success in managing DHF(7); as has ultrafiltration (8). Percutaneous mechanical support devices might be useful, if safe, convenient and cost-effective but there are few data on their effects on diuresis and congestion in patients with DHF (9,10). Accordingly, we investigated the haemodynamic and renal effects of a novel temporary percutaneous device (Reitan Catheter Pump, CardioBridge, Hechingen, Germany) in patients admitted with DHF.

Methods

Twenty patients with advanced chronic heart failure presenting with acute decompensation requiring inotropic or mechanical circulatory support were recruited in four European tertiary cardiac centres. Patients had a left ventricular ejection fraction (EF) of < 30% as documented by transthoracic echocardiography and a cardiac index (CI) of < 2.1 L/min/m² as measured by pulmonary artery thermo-dilution catheter. Patients with primary right ventricular failure, pulmonary hypertension with pulmonary

capillary wedge pressure (PCWP) <15 mm Hg, severe peripheral arterial disease were excluded. The maximum planned duration for haemodynamic support was 24 hours.

The study was approved by the regulatory authorities and ethical committees within each recruiting country and all patients provided written informed consent at the time of the index procedure.

Device Description

The RCP is a temporary percutaneous circulatory support system consisting of a catheter-mounted distal pump-head with a foldable propeller and surrounding cage, an interface unit, and an external drive unit with user console. The collapsed pump-head is delivered via a 14 French sheath placed in the femoral artery and is advanced retrogradely to the proximal descending aorta just distal to the left subclavian artery. Once in situ, the propeller arms are extended and rotated (Figure 1), creating a pressure gradient within the aorta. When tested in an animal model, the device demonstrated reduction in afterload, significant unloading effect on the left ventricle and increased perfusion pressure for the lower part of the body (11). A first in man study proved feasibility and safety in a cohort of patients with reduced ejection fraction undergoing elective high-risk percutaneous coronary intervention, and also suggested improved renal function when measured post procedure (12).

Study Procedure

Prior to RCP insertion, all subjects underwent radial arterial cannulation and urinary catheterisation. A Swan-Ganz pulmonary artery catheter was introduced for haemodynamic measurements.

An aortogram was acquired using a 6F graduated pigtail catheter to confirm descending thoracic aortic size of ≥ 22 mm. Via a 14F femoral introducer sheath (14F Check-Flow Performer®, Cook Inc., USA) the RCP was then inserted under fluoroscopy into the descending aorta 5-10 cm below the left subclavian artery. The pump head was deployed and then set to rotate at 8000-11000 revolutions per minute to achieve a radial-femoral mean arterial pressure gradient of 10mmHg, as has previously been described (12). Patients were anti-coagulated using intravenous unfractionated heparin for the duration of support with a target activated clotting times (ACT) of between 180 - 230 seconds.

Haemodynamic measurements and blood samples were taken at 0, 4, 8, 12, 16, 20, and 24 hours after commencing RCP support. Hemodynamic measurements included cardiac output / cardiac index (CO/CI), central venous pressure (CVP), pulmonary capillary wedge pressure (PCWP), and mean pulmonary artery pressure (PAPm).

At the end of the treatment period, the RCP and the 14F femoral artery sheath were removed. Femoral access site was closed as per local protocol; closure techniques included: manual or mechanical external compression, percutaneous closure device and planned direct surgical closure.

Endpoints And Follow Up

The primary end points were changes of cardiac index (CI) and serum creatinine and eGFR for the duration of device support. Secondary end points included: changes in CVP, PCWP, PAPm, urine output, device related adverse events, and 30-day mortality. All patients were followed up for major events including death, myocardial infarction (MI), cerebro-vascular accident (CVA), re-hospitalization for heart failure, renal replacement, and cardiac transplantation for 30 days.

Statistical Analysis

Categorical data are presented as numbers and percentages, while continuous data are presented as mean +/- standard deviation (SD). Differences between means have been tested using a using a paired t-test and the p-values have been obtained using a Monte Carlo approach with 1000000 permutations. A bootstrap method with 9999 re-samplings has been used to obtain 95% confidence limits for mean differences. This approach avoids strong distributional assumptions, such as the normality of data, in the statistical inferences. A p-value of < 0.05 was considered statistically significant. All statistical analyses have been carried out using the computer program R (R CRAN 2016).

Results

Baseline patient characteristics are shown in Table 1. Mean age was 66 years (SD 9 years) and 90% were male. All patients had advanced LV dysfunction, and 85% were in NYHA class IV. Most patients had significantly impaired renal function with a mean eGFR of 37.9 ml/min/1.73m².

Of the 20 patients recruited, 18 patients underwent RCP implantation. One patient had an inadequately sized aorta at attempted RCP placement. Another patient had tortuous and calcified peripheral vessels such that delivery of the device to the descending aorta was not possible. Of the 18 patients that had an RCP implanted, the mean running time was 18.3 hours (SD 6.3 hours).

Inotropic support and diuretic therapy

Of the 18 patients treated with the RCP, 9 were on inotropes prior to commencing RCP support (at baseline). 2 of these patients had their dose marginally increased during treatment, 2 had

their dose marginally reduced, 1 patient had inotropes stopped and another had a low dose of inotrope commenced. All patients going into the trial were on diuretics. Those with modest diuresis continued to receive diuretics, those with large diuresis had their diuretics reduced. There was no net increase in either inotropic support or diuretic therapy during the study period.

Access closure techniques

Femoral access site was closed as per local protocol; closure techniques included – planned direct surgical closure (12 patients), manual pressure (4), FEMOSTOP™ (2) (St Jude Medical Inc, MN, USA), and percutaneous closure device (2) (Perclose / Prostar XL, Abbott Laboratories, Illinois, USA).

Haemodynamic Indices

Cardiac index (CI)

The CI increased from 1.84 L/min/m² (SD 0.27) at baseline to 2.22 L/min/m² (SD 0.45 p<0.005) at 12 hours, and to 2.41 L/min/m² (SD 0.45 p=0.04) at 24 hours.

Central venous pressure (CVP)

The mean central venous pressure at baseline was 20.5 mmHg (SD 6.1), and fell to 16.43 mmHg at 12 hours (p=0.045), and 14.6 mmHg (SD 5.5, p=NS) at 24 hours.

Pulmonary capillary wedge pressure (PCWP)

The PCWP did not reduce significantly during the study period, baseline of 25 mmHg, to 20.50 mmHg at 12 hours (p=0.06) and 20.25 mmHg at 24 hours (p=0.625).

Pulmonary artery mean pressure (PAPm)

There was a significant reduction in PAPm from 37.3 (SD 9.4) mmHg to 34.0 (SD 9.1) at 12 hours (p=0.038) but not significantly reduced at 24 hours 31.5 (SD 7.7) mmHg (p=0.11).

Renal Function And Diuresis

Serum creatinine was significantly reduced from a baseline mean of 188.4 $\mu\text{mol/L}$ (SD 87.1) to 160.9 $\mu\text{mol/L}$ (SD 79.6) at 24 hours (p=0.0007). This was associated with significantly improved eGFR from a baseline mean of 37.9 ml/min/1.73m² (SD 17) to 45.7 ml/min/1.73m² (SD 19.5 p=0.002) at 24 hours (see Figure 2).

Urine output at baseline was a mean of 71.2 ml / hr (SD 65), and increased to 226.8 ml / hr (SD 179.3) at 12 hours (p=0.006). The mean urine output at 24 hours was 146.1 ml / hr (SD 101.5) (p=0.156).

Safety Endpoints

Bleeding

Bleeding complications were classified according to the BARC criteria (13).

There was a single case of minor femoral blood loss from the sheath site, (BARC 2) controlled with a pressure dressing. There was one major bleeding event (BARC 3a) in a patient who was on concomitant dual anti-platelet therapy. The subject suffered significant gastro-intestinal bleeding after 13 hours of RCP treatment, requiring blood transfusion and emergent gastroscopy. The patient recovered in an uneventful manner and was discharged home.

Thrombo-embolic events

There were no clinical thrombo-embolic events during the treatment or follow up period.

Haemolysis

Haemolysis was assessed by measuring plasma free haemoglobin (PFHb mg/dl), and results are shown in Figure 3.

There were no instances of myocardial infarction, cerebrovascular accident, transient ischaemic attack, or significant vascular injury / ischaemia.

30-day mortality

There were 4 deaths within 30 days (20%). One patient died during the treatment period, 5 hours after implantation of the RCP. The patient had an ejection fraction of 20%, and had been declining haemodynamically for some hours prior to the RCP implantation. The cause of death was advanced heart failure and was not device related. Three further patients died within the 30-day period. All had completed an uneventful 24-hour RCP treatment period. Causes of death included: multi-organ failure and sepsis (day 23 post RCP treatment), retro-peritoneal bleeding complicating the use of another mechanical support device (day 3), and multi-organ failure (day 15).

Clinical Progress Post RCP Treatment

Two patients had previously been declined for heart transplantation on the basis of significant renal dysfunction prior to the study. During RCP treatment both demonstrated improvements in serum creatinine (from 220 $\mu\text{mol /L}$ to 150 $\mu\text{mol /L}$ and 138 $\mu\text{mol /L}$ to 94 $\mu\text{mol /L}$ respectively). Both patients were subsequently

reassessed and on the basis of renal function reversibility were accepted for heart transplantation, which occurred in both patients within 12 months of the RCP treatment. Post-transplant their renal function stabilized at the level observed following RCP treatment (145 $\mu\text{mol/L}$ and 90 $\mu\text{mol/L}$ respectively).

Discussion

This study evaluated the efficacy of a novel percutaneous mechanical circulatory support device - the Reitan Catheter Pump - in patients with advanced chronic heart failure presenting with decompensation and congestion, requiring haemodynamic support. The study showed that RCP use led to:

1. A significant increase in the cardiac index for the duration of the device implantation.
2. An improvement in renal function as demonstrated by a decrease in serum creatinine and an increase in eGFR, sustained even after removing the device.
3. A marked increase in diuresis with urine output tripling at 12 hours.
4. No clinically significant haemolysis, or vascular complications.

DHF continues to carry high mortality and morbidity, with no significant progress in recent years. Congestion is the most frequent problem and plays a major role in the observed multi-organ impairment. Renal dysfunction commonly co-exists and is associated with an adverse prognosis.

RCP percutaneous support system creates a pressure gradient in the descending aorta, reducing pressure proximal to the propeller leading to afterload reduction and increases pressure distal to the propeller leading to increased perfusion pressure for the lower part of the body including renal arteries.

Haemodynamic Effects

This study demonstrated that the RCP percutaneous support system significantly improved cardiac index by 0.57 L/min/m² (31% improvement from baseline). The improvement in cardiac index is likely to be the result of afterload reduction, with offloading of the left ventricle causing a favourable displacement of the Starling curve to the left and upwards. This increase is similar to the one described by the use of other percutaneous circulatory support devices in the acute setting (14,15), and significantly greater than those of the IABP (16). However, we have to note that that level of support is not always enough to maintain adequate perfusion as exhibited by the case of deteriorating haemodynamics and subsequent death.

Renal Effects

This study is the first to show a significant improvement in renal function within the DHF cohort. The aetiology of the renal function decline in DHF patients is multifactorial. The cardio-renal syndrome (CRS) is used to identify disorders of the heart and kidneys whereby acute or chronic dysfunction in one organ may induce acute or chronic dysfunction in the other (17). Patients with DHF may develop CRS in response to renal congestion and hypo-perfusion, inflammation and neuro-hormonal activation, chronic renal parenchymal disease, renal artery disease and the effects of treatments for heart failure (18). Whilst diuresis is an essential component of medical therapy, this often is performed at the expense of renal function or is withheld due to concerns of further renal deterioration.

Recent clinical trials have focused on pharmacotherapy and ultrafiltration, which over the last decade have provided disappointing results. No interventions have been demonstrated to positively affect renal function either acutely or long term (8,19-22).

RCP percutaneous support system significantly reduced serum creatinine and increased eGFR at 24 hours of device therapy. This improvement in renal function was accompanied by marked increase in diuresis. Urine output tripled at 12 hours, and was maintained at twice baseline levels after 24 hours, without an increase in diuretics or inotropic use. This beneficial effect of RCP use could potentially be explained by increased kidney perfusion pressure but also by renal decongestion. There was indeed a drop in the filling pressure of the right ventricle as expressed by CVP, which is probably related to the decongestion driven by increased urine production. The marked diuresis with parallel renal function improvement achieved by the device could be of important clinical use if confirmed in larger studies. The RCP could be used as an adjunct, alternative or ultimate solution in the attempt to reduce congestion in patients with DHF +/- renal impairment. A randomised controlled trial should test this hypothesis.

Renal function improvement appeared to last beyond the treatment period with the potential to facilitate the introduction or up-titration of prognostic medications and diuretics. Furthermore to the benefits in the acute setting during the index hospital admission, the renal function improvement affected long-term prognosis; two patients were accepted and underwent successful heart transplantation having been previously turned down due to renal insufficiency. Based on these results, it would be interesting to speculate whether RCP treatment could be used to test renal reversibility in patients with significant renal dysfunction who might otherwise not be considered for heart transplantation. It is also plausible that specific patient groups could benefit from renal optimisation prior to interventions including coronary artery bypass grafting, and

percutaneous coronary intervention. Of course, these speculations need to be tested in properly designed studies.

Safety

In this study, RCP showed a favourable safety profile. There were two bleeding events in our cohort; one mild femoral access related (BARC 2), and one gastro-intestinal (BARC 3a) requiring blood products. This number of bleeding complications is expected and acceptable taking into consideration that the reported bleeding complications by the use of percutaneous support devices in the acute setting varies from 4 to 42 % (14,23,24). Importantly, there were no vascular complications or limb ischaemia. The presence of a rotary pump in the circulation inevitably leads to mechanical erythrocyte shear stress, but reassuringly biochemical markers of haemolysis only showed a small transient elevation and confirmed no clinically relevant haemolysis.

There were no myocardial infarction, cerebrovascular accident or transient ischaemic attack up to 30 days follow up. The 30 day mortality was 20%, which reflects the advanced state and comorbidities of our cohort.

Access is a key issue with regard to technical feasibility of mechanical support device delivery. In 2 patients the RCP could not be implanted due to patient related vascular limitations. Reassuringly however, no significant vascular complications were observed. Since completion of this study a 10F RCP device has been developed, down-sizing delivery profile from 14F. Subsequent to regulatory processes, the 10F device may further enhance its vascular safety profile, and delivery in more complex vascular anatomy.

Limitations

The present study has a number of limitations. First of all, it is a prospective single arm observational study and as such there is no control group. The patient cohort is small and only a percentage of them had haemodynamic measurements at 24 hours, making statistical analysis less robust. It is unknown, for example, whether large numerical differences like the one in CVP would have been statistically significant if a larger number of patients had full data set in 24 hours. However, the statistically significant and clinically relevant changes in renal function and diuresis are at least hypothesis generating, providing justification for a larger randomised study assessing the effect of RCP in treating congestion and improving renal function in patients with advanced heart failure.

The duration of RCP therapy was limited by protocol to a maximum of 24 hours. It is uncertain whether a more prolonged period of support may have been advantageous or would exhibit a similar safety profile, that said asking conscious hospitalised patients with heart failure to remain recumbent for >24 hours is challenging.

While the RCP is designed as a temporary cardiac and renal support device, there are other devices in early development aiming to improve renal blood flow and aid decongestion in the longer term. These include the Procyrion Aortix device (Texas, USA) (25) and the Second Heart Assist device (California, USA). While they share an implantation position within the descending aorta, there are differences in impeller design and therefore operational speeds, and the degree of cardiac and renal support. In turn this has effects on stability, safety, and haemolysis. Both have different implantation techniques and stabilisation mechanisms within the aorta. We await first

in man data to understand the safety and efficacy of these potentially longer duration support therapies.

Conclusions

The Reitan Catheter Pump percutaneous support system when inserted into patients with advanced decompensated heart failure and renal dysfunction resulted in a significant increase in cardiac index, and a concomitant profound diuresis associated with improvement in renal function which persisted out to 48 hours. This was achieved without clinically significant haemolysis, bleeding or vascular complications.

A randomised controlled trial is now warranted for both safety and efficacy across a larger decompensated heart failure patient cohort.

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Figure titles and legends

Figure 1

A) The RCP head being deployed.

The propeller is surrounded by longitudinal flexible polymer filaments forming a cage protecting the aortic wall from the rotating propeller blades. The RCP is seen collapsed, partially and fully deployed.

B) Fluoroscopic image of the deployed pump head in vivo.

The polymer filaments are not visible.

C) Diagram demonstrating the correct positioning of the RCP

RCP positioned within the descending aorta (Ao) 5 to 10 cm distal to the origin of the left subclavian artery (LSCA).

Figure 2

Graph showing serum creatinine at baseline and at 24 hours post RCP implantation (p=0.0007).

Figure 3

Graph showing plasma free Haemoglobin (PFH mg/dl) at baseline and at 12, and 24 hours after RCP implantation. Baseline PFHb was 4.1 mg/dl (+/- 4.2 mg/dl) and rose to 13.0 mg/dl (+/- 9.5 mg/dl * p=0.016) at 12 hours, before returning to baseline values at 24 hours (8.5 mg/dl +/- 9 p=0.125)