Case series of high-risk percutaneous coronary intervention with rotational atherectomy under short-term mechanical circulatory support with TandemHeart in the setting of acute myocardial infarction

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Received 16 August 2019; first decision 12 September 2019; accepted 18 June 2020; online publish-ahead-of-print 3 August 2020

Background

TandemHeart is a percutaneous Ventricular Assist Device, most commonly used to provide mechanical circulatory support during high-risk percutaneous coronary intervention and postcardiotomy cardiac failure. However, TandemHeart has not been applied in patients with severe heart failure due to myocardial infarction during high-risk percutaneous coronary intervention with the need for rotational artherectomy (RA) before, so we present a first-in-man case series.

Case summary

Three patients with severe HF due to acute myocardial infarction revealed severely calcified lesions of the unprotected left main artery. We successfully used the TandemHeart as percutaneous Ventricular Assist Device during high-risk percutaneous coronary intervention with RA.

Discussion

We here report our experience and show that RA under TandemHeart mechanical circulatory support is feasible and safe in case of acute MI.

Keywords

Mechanical circulatory support • TandemHeart • Myocardial infarction • High-risk PCI • Heart failure • Rotational artherectomy • Case series

Learning points

• Mechanical circulatory support with TandemHeart is a potential option in acute MI with extremely calcified left main and complex artery disease.
• Mechanical circulatory support with TandemHeart can help experienced interventionists to deal with possible hemodynamic collapse during emergent high-risk percutaneous coronary intervention with rotational artherectomy.
Introduction

High-risk percutaneous coronary intervention (HR-PCI) plus rotational artherectomy (RA) with percutaneous Ventricular Assist Device (pVAD) represents a treatment option in patients with extensive calcified coronary artery disease and multiple comorbidities, who are evaluated as ineligible for coronary artery bypass grafting. There are different pVADs available, e.g. intra-aortic balloon pump (IABP), Impella (Abiomed Inc., Danvers, Massachusetts), TandemHeart (LivaNova PLC, London, UK), and extracorporeal membranous oxygenation.1 TandemHeart is designed as percutaneous extracorporeal left atrial-to-femoral artery continuous-flow centrifugal mechanical circulatory support (MCS). TandemHeart decompresses the left ventricle (LV) via trans-septal cannula.2 The main application of TandemHeart is MCS during HR-PCI, postcardiomyopathy cardiac failure and temporary bridge-to-bridge or heart transplantation.3

High-risk percutaneous coronary intervention is defined as intervention of left main (LM) artery with ejection fraction (EF) <35% or three-vessel disease with EF <30% or last patent coronary conduit.4 Depending on the estimated probability of haemodynamic collapse, a hybrid PCI approach with percutaneous haemodynamic support is reasonable to maintain perfusion. All-cause mortality for HR-PCI in non-shock patients is around 2.6%.5 Rotational artherectomy often becomes necessary for non-passable occlusions to modify severely calcified plaques with the aim of facilitating subsequent stent implantation and can be associated with slow-flow, hypotension and periprocedural myocardial infarction.6 However, to date, there is only limited data available on RA in the setting of HR-PCI with TandemHeart.7 To the best of our knowledge, this is the first use of TandemHeart for peri-interventional MCS in patients with acute myocardial infarction and need for emergent HR-PCI with RA in complex, unprotected LM disease.

Timeline

- Non-ST elevation myocardial infarction (NSTEMI) with severe HF
- Complex CAD
- Decision for high-risk percutaneous coronary intervention (HR-PCI)
- Implantation TandemHeart
- HR-PCI with rotational artherectomy
- Explantation TandemHeart

Case presentation

Patient information

Three patients suffered from acute non-ST elevation myocardial infarction (NSTEMI) complicated by severe heart failure (Table 1). Pre-procedural, hs-troponin levels were slightly elevated in all patients, but highest in patient 2. All patients revealed complex coronary artery disease and previous PCIs with multiple stent implantations. Coronary artery bypass grafting was considered as not feasible due to severe pre-existing medical comorbidities and previous cardiac surgical procedures. After weighting all options, interdisciplinary team opted for HR-PCI with RA and temporary MCS with TandemHeart.

Interventions

The timing of the procedure was 1–8 days after onset of acute coronary syndrome. LA was involved for all three procedures which increase the complexity of the procedure. TandemHeart was implanted at the beginning of the intervention with patient in supine position: right femoral vein (21 F trans-septal cannula) and right femoral artery (15 F arterial cannula) were cannulated in standard technique. After advancing the venous cannula to the inferior vena cava and into the right atrium, the venous cannula was guided over the wire via a trans-septal approach into the left atrium through a previously made trans-septal puncture (Figure 1A and B). If position of both cannulas were correct in the left atrium and femoral artery, the device was started (flow rates between 3 and 4 L/min). All three patients received full anticoagulation therapy with intravenous heparin bolus prior to pVAD implantation (activated clotting time of 250 s). Coronary angiography revealed severe three-vessel coronary artery disease with unprotected LM disease and heavily calcified lesions in all patients (SYNTAX >33). Patient 1 received RA of ramus intermedius (RI) and 2× drug-eluting stenting of LM, left anterior descending artery (LAD) and RI (Video 1A and B). In patient 2, initial PCI balloon recanalization attempt of occluded LAD was not successful due to distinctive calcified lesion (Video 2A). Therefore, the patient was treated on the following day by a successful RA of LM and left circumflex artery (LCX) (Figure 1C), which modified the LM plaque and allowed to perform stenting of LCX/LM/LAD (Figure 1D and Video 2B). Patient 3 was treated with RA and stenting of LCX/LAD/LM (Video 3A and B). Subsequently, TandemHeart was explanted after PCI. All patients remained haemodynamically stable throughout the procedure. Pericardial tamponade was excluded after intervention. No catecholamine support became necessary. Medical therapy in patient 3 was Aspirin 100 mg once a day and Ticagrelor 90 mg twice a day for 12 months after HR-PCI. In patient 1 with risk of LV thrombus relapse as well as patient 2 with atrial fibrillation, we suggested triple anticoagulation after HR-PCI (Phenprocoumon with Aspirin 100 mg and Clopidogrel 75 mg for 12 months). All patients received optimized heart failure therapy.

Outcome

We observed one minor vascular complication (5.5 × 1.2 cm haematoma over right femoral artery), which was treated conservatively. Post-procedural, only minimal hs-troponin elevation was observed in two patients, both were discharged between 6, respectively, 7 days after intervention. Patient 3 required 17 days of inpatient treatment following PCI due to a pre-existing acute biliary exudative pancreatitis. Patient 1 required subsequent PCI for an in-stent re-stenosis (peak hs-troponin level 5072 ng/mL) of RI and survived 9 months after PCI. Patients 2 and 3 survived >1 year after PCI.
Discussion

Data on temporary MCS during HR-PCI are limited and literature describes conflicting results without significant survival benefit but haemodynamic advantages.\(^1\) Comparing our patients to available data, they were older with higher STS and SYNTAX score. In addition, there was extensive coronary artery disease resulting in the need for RA.

The largest patient cohort was included in the Protect II trial, comparing Impella 2.5 with IABP. The study revealed a potential for MCS in Impella patients at 90 days for non-emergency cases. In RA, however, incidence of peri-procedural myocardial infarction was higher and the study was stopped prematurely.\(^8\) In case of more complex procedures, TandemHeart may be advantageous over Impella for the option of full-flow support enabling active MCS even in severely reduced LV function. In direct comparison with extracorporeal life support, TandemHeart can provide selective LV unloading and support with preserved lung perfusion. However, TandemHeart implantation with trans-septal puncture is technically more challenging, resulting in longer procedures but avoiding retrograde crossage of aortic valve. Incidence of bleeding in extracorporeal membrane oxygenation and TandemHeart is considered higher compared with other MCS devices. Nevertheless, we could not observe major vascular complications, tamponade or bleeding, indicating that risk is reasonable in experienced hands.

### Table 1  
Patients characteristics

| Table 1          | Patient 1                  | Patient 2                  | Patient 3                  |
|------------------|----------------------------|----------------------------|----------------------------|
| **Gender**       | Male                       | Male                       | Female                     |
| **Age (years)**  | 63                         | 79                         | 76                         |
| **Basic disease**| NSTEMI                     | NSTEMI (successful resuscitation) | NSTEMI                     |
| **Relevant Comorbidities** | Previous NSTEMI            | Previous NSTEMI            | Acute biliary exudative pancreatitis |
|                  | Lown IV                    | Atrial fibrillation        | Cholangitis                |
| **Previous interventions/operations** | CABG                   | PCI LAD                    | CABG                       |
|                  | LV aneurysmectomy and excision of LV thrombus | 2x MitraClip               | PCI                         |
|                  | PCI R. intermedius         | CRTD                       |                            |
|                  |                            | Hemicolecotomy and ileostomy |                            |
| **Cardiovascular risk factors** | Diabetes mellitus          | Diabetes mellitus          | Hypertension               |
|                  | Hypercholesterolemia       | Hypertension               | Hypercholesterolemia       |
|                  | Nicotine                   |                            |                            |
|                  | Positive family medical history |                        |                            |
| **Anatomy**      | Severe three-vessel CAD    | Severe three-vessel CAD    | Three-vessel CAD (high-grade stenosis LM/LCX) |
|                  | (high-grade stenosis LM/LCX, occlusion RCA) | (high-grade stenosis LAD/ LCX) |                            |
|                  | Open LIMA ad LAD, occlusion ACVB ad R. marginalis/R. intermedius | |                            |
| **HR-PCI**       | RA and PCI/2xDES LAD/LM/R. intermediate | Unsuccessful PCI LAD RA LCX and DES bifurcation (LCX/LAD) | RA and PCI/3xDES LCX/ LAD/ LM |
| **STS score**    | 8.4%                       | 84.3%                      | 13.4%                      |
| **NYHA**         | III                        | III                        | II                         |
| **LVEF (%)**     | 30%                        | 20%                        | 35%                        |
| **Survival**     | >12 months                 | >9 months                  | >12 months                 |

ACVB, artery coronary venous bypass; CAD, coronary artery disease; CKD, chronic kidney disease; CRTD, cardiac resynchronisation therapy device; DES, drug-eluting stent; HR-PCI, high-risk percutaneous coronary intervention; LAD, left anterior descending artery; LCX, left circumflex artery; LIMA, left internal mammary artery; LV, left ventricle; LVEF, left ventricular ejection fraction; LM, left main; NSTEMI, non-ST elevation myocardial infarction; NYHA, New York Heart Association; PAD, peripheral arterial disease; PCI, percutaneous coronary intervention; RA, rotational arterectomy; STS, Society of Thoracic Surgeons.
In respect of high probability of haemodynamic collapse on background of severely decreased LV function and planned LM or LM equivalent intervention, our patients were significantly high at risk for ventricular arrhythmias, acute MI, and low cardiac output syndrome. As short-term MCS cannot be considered as standard strategy in patients with severe heart failure and heavily calcified LM lesions, we suggest taking individual haemodynamic and procedural characteristics into account and increment a stepwise interventional approach to high-risk percutaneous coronary intervention.

This is a case series of a small number of patients. We demonstrate feasibility of MCS with TandemHeart during emergency HR-PCI with RA in selected patients and experienced centres. A larger, prospective study is needed for further evaluation of this approach.

In the case of acute myocardial infarction with extremely calcified LM and complex artery disease, full percutaneous approach of MCS with TandemHeart might be a valuable option in the hands of an expert and dedicated team. We propose to include TandemHeart in
the repertoire of experienced interventionalist in order to deal with possible haemodynamic collapse during emergent HR-PCI with RA.

Supplementary material

Supplementary material is available at European Heart Journal - Case Reports online.

Slide sets: A fully edited slide set detailing this case and suitable for local presentation is available online as Supplementary data.

Consent: The authors confirm that written consent for submission and publication of this case report including image(s) and associated text has been obtained from the patients in line with COPE guidance.

Conflict of interest: L.G., P.R., and R.B. have no conflicts of interest to declare. B.S. reports personal fees from Abbott, other from Berlin Heart, outside the submitted work. H.A.K. reports personal fees from Daiichi Sankyo, personal fees from AstraZeneca, personal fees from Roche Diagnostics, personal fees from Bayer Vital, outside the submitted work.

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