Acute Heart Failure Exacerbation in the Setting of Electrical Storm: Total Artificial Heart vs. Ventricle Assist Device

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Introduction
Total artificial heart (TAH) is a novel device with over a thousand implantations worldwide, being a suitable option for patients as a bridge to transplantation (BTT). The following case was the second implantation of a TAH at our institution.

Case report
We report the case of a 64-year-old Caucasian male with past medical history of idiopathic dilated cardiomyopathy, reduced left ventricular ejection fraction (LVEF of 16%) reported during his last acute decompensation in 2012, sinus bradycardia with biventricular implantable cardioverter defibrillator (ICD) placement for secondary prevention of sudden cardiac death, in 2015, and atrial fibrillation. The patient was brought to the emergency department complaining of severe dyspnea and palpitations, preceded by multiple electrical shocking episodes (46 episodes). At admission, his electrocardiogram (ECG) showed a ventricular tachycardia (VT). He was monitored on telemetry, which evidenced a monomorphic VT with a mean heart rate of 188 beats per minute (bpm). The electrophysiology team was consulted; the device was interrogated and confirmed the above-mentioned number of shocks. Initial treatment with Lidocaine 2 mcg/kg/hr and Amiodarone 150 mg IV bolus achieved rate control. Initial laboratory testing showed hemoglobin of 16.2, WBC 12.1, platelets 186, Na 139, K 4.8, Cl 104, Cr 1.8 (GFR 38), BUN 36, glucose 169, AST 39, ALT 42, ALP 140, Ca 9.4, albumin 4.4, INR 4.2, digoxin 2.2.

The patient was transferred to the Coronary Care Unit (CCU), where physical examination revealed normal temperature, blood pressure of 94/65 mmHg, and heart rate of 91 bpm. His cardiovascular and lung exam was unremarkable. Chest X-ray showed small bilateral pleural effusions. Transthoracic Echocardiography showed markedly enlarged LV with severely decreased function (EF of 10-15%), severely generalized left ventricular hypokinesis, severely decreased right ventricular systolic function, right ventricular systolic pressure (RVSP) of 41 mmHg, right-to-left shunt at atrial level. At that point, no inotropic support was necessary.

The initial diagnosis was refractory VT (VT storm at presentation) in the setting of secondary acute systolic heart failure. Serial ECG strips were obtained, as shown in Figure 1. Unfortunately, his systolic blood pressure substantially decreased down to 60 mmHg, so he was placed on invasive monitoring, with a cardiac index of 1.81 L/min/m², estimated right atrial pressure (RAP) of 16 mmHg and mean pulmonary arterial pressure of 36 mmHg. At that point, cardiogenic shock required hemodynamic support therapies.

Electrophysiology staff attempted VT ablation, which showed possible endocardial and epicardial substrate. Consequently, EP performed epicardial VT ablation, with subsequent endocardial VT ablation, after an additional endocardial arrhythmic source was found during the procedure. Unfortunately, ablation was unsuccessful in controlling heart rhythm and his LVEF kept declining, this time to a LVEF of 5%.

Keywords
Dilated Cardiomyopathy; Heart Failure; Defibrillators, Implantable; Cardiac Resynchronization Therapy; Arrhythmias Cardiac.
The heart failure team considered temporary extracorporeal membrane oxygenation (ECMO) for short-term stabilization. Long-term hemodynamic support devices were discussed in detail in order to determine the best option (LVAD vs. TAH). If the patient had adequate right ventricular function and a controlled arrhythmia, left ventricular assist device (LVAD) would have been a suitable option. However, both these issues were a problem in this case; therefore, LVAD was not a suitable option. Biventricular assist device (BiVAD)
was also considered, but the arrhythmogenic ventricle was always a great concern. For that reason, a novel alternative therapy was pursued: the implantation of a total artificial heart (SynCardia) as a BTT. This was successfully done and the patient is now stable and on a waiting list for heart transplantation.

Discussion

Advanced heart failure with reduced ejection fraction remains a clinical dilemma in the medical world. Despite optimal medical therapy, cardiac resynchronization and ICD, there is a large population of patients that fail to compensate for the disease and demand heart transplantation. Due to low availability of heart transplantation, ventricular assist device (VAD) provides the mechanical circulatory support needed by these patients, as a bridge to transplant. In relation to our patient, decisions concerning the different types of VADs were made taking into account that right ventricular dysfunction and uncontrolled arrhythmias are a major limiting factor for LVAD use, making TAH a better option to maintain circulatory support in such case. A TAH was the most suitable option; LVAD limitations in this patient were right ventricular dysfunction and incessant ventricular refractory arrhythmias.2,3

Table 1 - FDA indications for Total Artificial Heart (Syncardia) inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Inclusion criteria:</th>
<th>Exclusion criteria:</th>
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<tr>
<td>Eligible for transplantation</td>
<td>Use of any vascular assist device</td>
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<tr>
<td>New York Heart Association (NYHA) class IV</td>
<td>Pulmonary vascular resistance ≥ 8 Wood units (640 dyne.sec.cm⁻⁵)</td>
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<td>Body surface area 1.7–2.5 m², or T10 ≥ 10 cm (distance on computed tomographic scan from the anterior vertebral body to the sternum inner table at the level of the 10th thoracic vertebra)</td>
<td>Dialysis in previous 7 days</td>
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<td>Hemodynamic insufficiency demonstrated by A or B:</td>
<td>Serum Creatinine level ≥ 5 mg/dL</td>
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<tr>
<td>A. Cardiac index ≤ 2 L/min/m² and one of the following:</td>
<td>Cirrhosis and/or total bilirubin level ≥ 5 mg/dL</td>
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<tr>
<td>- Systolic arterial pressure ≤ 90 mmHg</td>
<td></td>
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<tr>
<td>- Central venous pressure ≥ 18 mmHg</td>
<td>Cytotoxic antibody ≥ 10%</td>
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<tr>
<td>B. Two of the following:</td>
<td></td>
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<tr>
<td>- Dopamine ≥ 10 μg/kg/min</td>
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<tr>
<td>- Dobutamine ≥ 10 μg/kg/min</td>
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<tr>
<td>- Epinephrine ≥ 2 μg/kg/min</td>
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<tr>
<td>- Isoproterenol ≥ 2 μg/kg/min</td>
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<tr>
<td>- Milrinone ≥ 0.5 μg/kg/min</td>
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<tr>
<td>Other drugs at toxic levels. Intra-aortic balloon pump, cardiopulmonary bypass.</td>
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Mechanical support therapies are alternative therapies for BTT patients who do not have an available heart donor. Nowadays, the industry provides several novel heart failure devices. Most of them are intended to provide additional flow support, either continuous or pulsatile, for achieving temporary flow support. However, novel therapies, such as the TAH, have aimed to provide a long-term support even in the outpatient setting, with the great advantage of supplying the patient with fully autonomous ventricular function, making it a quite suitable option if no transplant is immediately available and for those patients with refractory, life-threatening malignant ventricular arrhythmias. Interestingly, the patient described in our case report did not fit the guidelines, which made him a candidate for hemodynamic support with assist devices, but the main issue was to choose the most beneficial therapy.

The TAH, commonly known by the brand name “SynCardia”, is a device option for patients with end-stage heart failure, particularly those with biventricular heart failure with no response to other assisted therapies. The FDA approved the device in 2004 as a BTT for biventricular failure. Table 1 shows all FDA-approved indications. Therefore, its use has been slowly increasing due to the lack of implantation experience and clear guidelines supporting the indications, in addition to the absence of worldwide consensus and
high costs for the patient, which are not usually covered by insurance companies.\(^7\) The total artificial heart is a pneumatic, biventricular, orthotopic, pulsatile device that displaces 400 ml per cycle\(^7\) (see Figure 1). Blood flow follows the normal physiology of the human heart, with flow rates of up to 9.5 L/min (barely turbulent). The device generated a Starling-like response by matching cardiac output with venous return and balancing blood flow between both ventricles.\(^8\)

One of the main challenges facing the widespread use of TAH was the lack of clear indications. As far as we know, there are no clinical trials on course aiming to evaluate indications and outcomes of this device. The indications for TAH implantation are a matter of controversy. However, the FDA established inclusion and exclusion criteria, as shown in Table 1. Another important limiting factor is the short experience with TAH that makes this device a complex option for acute ill patients. Most surgeons would need proctor’s help prior to implantation. Also the experience curve would have a slow-linear slope, making this device an option exclusively for highly specialized cardiovascular centers.\(^9\)

**Conclusion**

Total artificial heart is a novel device that achieved more than expected benefits, particularly for BTT patients with right ventricle dysfunction and recalcitrant ventricular arrhythmias in need of mechanical support. However, no multicenter clinical trials have been conducted to assess its efficacy or safety in comparison with other assist devices. Short-experience still represents a hindrance for the device to be deployed. The lack of clear indications supported by international guidelines makes the use of these devices a skeptical decision that should only be made by experts.

**Author contributions**

Conception and design of the research: Rico JS, Prasad M. Acquisition of data: Rico JS, Prasad M. Analysis and interpretation of the data: Rico JS, Prasad M. Statistical analysis: Rico JS, Prasad M. Writing of the manuscript: Rico JS, Arango-Isaza D, Saldarriaga C. Critical revision of the manuscript for intellectual content: Rico JS, Arango-Isaza D, Prasad M, Saldarriaga C. Supervision / as the major investigator: Rico JS.

**Potential Conflict of Interest**

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**Study Association**

This study is not associated with any thesis or dissertation work.

**References**


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