A first step beyond traditional boundaries: destination therapy with the SynCardia total artificial heart

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Abstract

The SynCardia total artificial heart is currently used as a bridge to transplantation therapy in cases of irreversible, acute or chronic, biventricular heart failure. We describe the implementation of this technology in the context of destination therapy in a patient with an end-stage heart failure on grounds of primary amyloidosis.

Keywords: Artificial heart • Cardiac failure • Amyloidosis

INTRODUCTION

The SynCardia total artificial heart (TAH) is a pneumatically driven pulsatile system used for orthotopic replacement of the native ventricles in cases of irreversible biventricular heart failure resulting either from chronic, ischaemic or non-ischaemic dilated cardiomyopathy [1] or from fulminant acute myocardial infarction [2]. Emerging indications include restrictive and infiltrative cardiomyopathies, cardiac neoplasms, transplant failure and left ventricular assist device (LVAD) failure [3]. Besides bridge to transplant (BTT), the US Food and Drug Administration (FDA) recently approved a Humanitarian Use Device (HUD) designation for the 70-cc SynCardia TAH to be used for destination therapy (DT) in patients not eligible for transplantation [3], thus paving the way for a later approval under the Humanitarian Device Exemption (HDE) pathway.

CASE PRESENTATION

A 74-year old male Caucasian patient was admitted for further evaluation of a failing infiltrative cardiomyopathy on grounds of primary amyloidosis. Despite optimal medical therapy and inotropes, the patient continued to decline (NYHA IV and INTERMACS 2). Since he was not eligible for transplantation and right ventricular function was still normal, we implanted an LVAD system (HeartMate II; Thoratec Corp., CA, USA) as DT. However, amyloidosis-induced myocardial hypertrophy resulted in intermittent occlusion of the inflow cannula and progressive decline of right ventricular function. The patient was finally switched on postoperative day 4 to a SynCardia TAH. Late tamponade resulted in acute renal failure demanding temporary renal replacement therapy. In the further course, renal function recovered fully. Postoperative course was prolonged, owing largely to the need for intensive physiotherapy-supervised mobilization and exercise. The patient was switched to the Freedom Driver, trained in INR self-management and discharged home on Day 113. As of this writing, 325 days post-implant, TAH therapy is still ongoing. Since implantation, the patient had to be readmitted twice due to anaemia resulting from ineffective erythropoiesis, initially requiring transfusion and finally long-term therapy with recombinant human erythropoietin. Degree of haemolysis is low (lactate dehydrogenase 663 U/l; range 526–785 U/l). There have been no minor or major neurological events. Compared with baseline, quality of life, measured by the Minnesota living with Heart Failure Questionnaire, improved (45 vs 93). The patient is now able to perform everyday activities (NYHA I–II).

DISCUSSION

The results of the post market approval (PMA)-(4) and the post-PMA trial [1] established the BTT indication for the SynCardia TAH. However, we should not overlook the limitations of this technology: mechanical parts that are prone to wear and tear, the need for a permanent external driver and dependency on external energy supply. Fully implantable devices are still in an early stage of development and far from being applicable in the clinical setting. In the meantime, advancements in pharmacological management as well as interventional treatment have led to even more cases of end-stage heart failure, thus increasing the demand for cardiac transplantation, while unfortunately, the number of instances of organ donation is in steady decline. Despite short duration of support, this case demonstrates that therapy with a SynCardia TAH has the potential to expand beyond BTT towards DT for patients.
ineligible for transplantation. Besides the well-known effect of end-organ recovery [4], quality of life obviously improves. However, in this early stage, it is crucial to carefully select the appropriate patient. Due to unique features, namely diastolic dysfunction of the left and, as a result of ventricular interdependence, diastolic dysfunction of the right ventricle, myocardial hypertrophy and relatively poor transplantation results [5], infiltrative cardiomyopathies obviously predispose end-stage heart failure patients to TAH therapy and could therefore, beginning with highly selected cases, be helpful in establishing DT with a SynCardia TAH.

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