Mechanical Support for Patients With Congenitally Corrected Transposition of the Great Arteries and End-Stage Ventricular Dysfunction

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Despite great advances in caring for patients with congenitally corrected transposition of the great arteries (ccTGA), a high proportion of these patients go on to develop heart failure and death in early adulthood. Adults with congenital heart disease (ACHD) only comprise a small number of patients receiving ventricular assist devices (VAD), but ccTGA accounted for 36% of ACHD patients in the INTERMACS database. Review of the literature describing ccTGA patients receiving VAD therapy shows promising results. With newer devices and the assistance of advanced imaging, mechanical circulatory support is becoming a desirable option for this population of patients and has the potential to provide significant long-term support, relieving them of heart failure symptoms and delaying and perhaps in the future avoiding, the need for cardiac transplantation.

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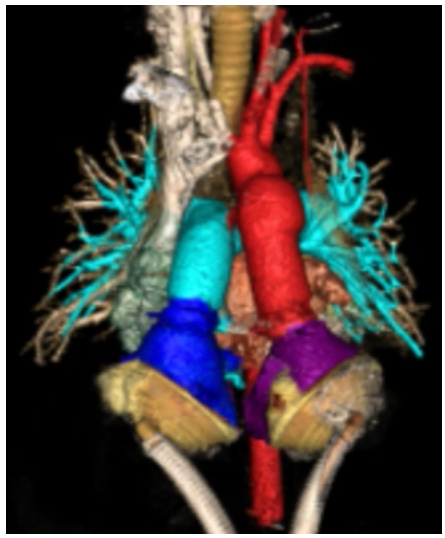
Keywords: ccTGA, mechanical circulatory support, ventricular assist device, total artificial heart, heart failure, adult congenital heart disease



CT reconstruction of total artificial heart placement in a patient with ccTGA.

Central Message

Mechanical circulatory support is an important adjunct to the care of heart failure patients with ccTGA moving forward and has already shown excellent outcomes in this particular ACHD population.

The natural history of congenitally corrected transposition of the great arteries (ccTGA) results in severe heart failure in over 30% of patients by their early 30s and over half the patients beyond age 40 [1]. The "classic repair" is a physiologic repair aimed at correcting shunting and other defects while maintaining the right ventricle as the systemic ventricle. Unfortunately, this approach has been associated with development of severe right heart failure in over 30% of patients with 30% mortality at 13-year follow-up [2]. This led to the development of the "anatomical repair" following the innovation of the arterial switch operation for dextrotransposition of the great arteries. The anatomical repair for ccTGA consisted of the arterial switch or Rastelli in combination with an atrial switch operation, either Mustard or Senning. This new approach still resulted in 31% of patients developing significant heart failure (NYHA Class II or greater) of suffering late death at 20-year follow-up [3]. Therefore, it is clear that a significant proportion of our ccTGA patients will present to our programs eventually with

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medically resistant heart failure. It is likely that most of them will already be adults by the time they come to us.

THE TECHNOLOGY

There are a multitude of devices currently available which can provide durable mechanical circulatory support to both pediatric and adult patients; however, there is very limited information regarding their outcomes and use in adults with congenital heart disease (ACHD). Of the 16,182 adult patients in the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database, only 126 (0.8%) have congenital heart disease (CHD) [4]. But according to the PediMacs database, congenital programs treat a very different population with 21% (77) of patients having a diagnosis of CHD, of which 48 (62%) are single ventricle lesions [5]. There are only a few dozen articles covering the use of ventricular assist device (VAD) use in adults with congenital heart disease from 2008 to 2017 [6–13]. These consist mainly of case reports or small series of less than 10 patients. Furthermore, the variety of diagnoses and devices represented in these reports greatly impeded any substantial conclusions to be drawn about VAD support in this population. These reports culminated in 36 ACHD patients with VADs, representing 8 different diagnoses with a 75% survival. Surprisingly, ccTGA accounted for 13 (36%) of these patients. This represented the extent of our knowledge of VADs in ACHD until the first INTERMACS analysis of their ACHD population [4].

From the first report, we learned that the 125 ACHD patients were significantly younger (42 years old vs 56 years old), with more biventricular assist device (BiVAD) support (11% vs 5%) and total artificial heart (TAH) support (10% vs 2%) than non-ACHD patients. They were also found to have more right ventricular dysfunction (47% vs 32%). However, they had the same proportion of INTERMACS 1 profile patients (18% vs 17%), which was surprising considering the hesitation often noted in the field to mechanically support these patients (ie, difficult anatomy, multiple resternotomies). Of the ACHD patients, 63 (50%) had a systemic morphologic left ventricle, 45 (36%) had a systemic morphologic right ventricle, and 17 (14%) had a single ventricle. ACHD patients were experiencing very good outcomes with 73% having a positive outcome at 1 year after mechanical circulatory support implantation considering this included single ventricle patients. However, it was worse than the 80% in non-ACHD. But when left ventricular assist devices (LVADs) were considered alone, survival was the same. Thus for LVADs, ACHD patients had similar outcomes to non-ACHD patients suggesting that LVADs are underutilized in ACHD patients with end-stage heart failure. Looking past just survival, a subsequent analysis of the INTERMCS data identified a propensity matched VAD/TAH cohort in a 4:1 fashion from the non-ACHD patients [14]. This study found that ACHD patients, despite having longer lengths of stay after implantation, had similar rates of adverse events and readmission with similar functional status and quality of life outcomes. This further supported the notion that more VADs should be used in ACHD patients.

THE TIME

Now is the time to increase VAD use because they are no longer being used by congenital programs just as a means to reach transplantation. They are being placed to help patients with medically resistant heart failure get out of the hospital to improve their quality of life and overall health. For this reason, we want to attempt to move away from an era of saying "bridge-to-transplant" or "destination therapy" as being a transplant candidate is no longer a prerequisite for consideration for

Table 1 Reports of Mechanical Support in Patients With Congenitally Corrected Transposition of the Great Arteries Since 2002

Year	Age, Gender	Type of VAD	Outcome
Stewart et al (2002) [15]	30 y M	TCI HeartMate	Txed after 8 mo
Gregoric et al (2005) [16]	53 y F	HeartMate	Txed after 6 mo
Sugiura et al (2006) [17]	13 y M	Toyobo LVAD	Explant on POD 43. Bacteremia
Joyce, et al (2010) [18]	35 y M	Debakey VAD	Txed
Morales et al (2012) [13]	17 y M	SynCardia TAH	Txed after 5 mo
Jacobs et al (2012) [19]	49 y M	LA-Right SCA VAD (CircuLite)	Alive on device at 10 mo
Huang et al (2012) [20]	66 y M	HVAD	Alive on device at 24 mo
Huebler et al (2012) [21]	59 y M	HVAD	Alive on device 140 d
Mohite et al (2012) [22]	53 y M	HeartMate II	Txed
Inoue et al (2013) [23]	26 y M	Nipro-LVAD	Died after 4.7 y
Morgan et al (2013) [24]	66 y M	HeartMate II	Alive on device at 9 mo
Rajagopalan et al (2013) [25]	38 y M	HeartMate II	Txed
Hanke et al (2015) [26]	58 y F	HVAD	Alive on device at 3 mo
Tanoue et al (2015) [27]	60 y M	Jarvik 2000	Alive on device at 1 y
Si et al (2016) [28]	13 y M	TAH 70/70cc	Txed after 8 d
Soofi et al (2016) [29]	62 y M	HVAD	Txed after 1 y
Fujita et al (2017) [30]	57 y M	EVAHEART	Txed after 2 y
Toyama et al (2018) [31]	28 y F	AB5000 VAD, Jarvik 2000	Alive on device 2 mo
Fukushima* 2018	32 y M	HeartMate II	Alive on device

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a device. The patient's future treatment should not dictate whether or not they should be eligible for device therapy but just that the device will prolong life and its quality. The authors feel that in the future, many of our ccTGA patients will be chronically supported with VADs in the near-future.

A review of the literature revealed 19 single patient case reports of VADs being placed in pediatric and adult ccTGA patients beginning in 2002 (Table 1). Since that time, the number of VADs in ccTGA has been increasing with 10 implantations occurring from 2013 to 2018. When considering these reports as one, the mean age was 41 years (13–66 years) with 3 (16%) being pediatric patients and 12 different devices being used. Positive outcomes were reported in 90% of the patients with 7 (43%) having undergone transplantation and 8 (47%) still alive on the device. A negative outcome was reported in 2 (10%) with 1 dying with the device and another dying after explantation. Obviously, this is not the entire experience rather only what has been reported, which is certainly biased toward positive outcomes. Nonetheless, it does give one a sense of what is being done with these patients regarding VAD support and demonstrates the ingenious ways these devices have been placed.

Through direct communication, we know that in the TAH experience, 11 (16%) of the CHD patients had a diagnosis of ccTGA with 1 being female and 1 being a pediatric patient. Positive outcomes were reported in 64% of ccTGA patient at 6 months' follow-up after implantation. Two of the 11 were alive on the device as of this publication and another 4 have been successfully transplanted.

A PRACTICAL APPROACH

It is critical to have a full, detailed history and anatomical understanding of patients with ccTGA before starting to contemplate mechanical circulatory support. Important considerations include what their original operation was, that is, classic or double switch. This includes knowing anything else that was repaired at that time as well as what residual lesions may be present. An understanding of whether the patient will likely be on chronic VAD support or bridged-to-transplant should not determine eligibility for VAD support but can be helpful in

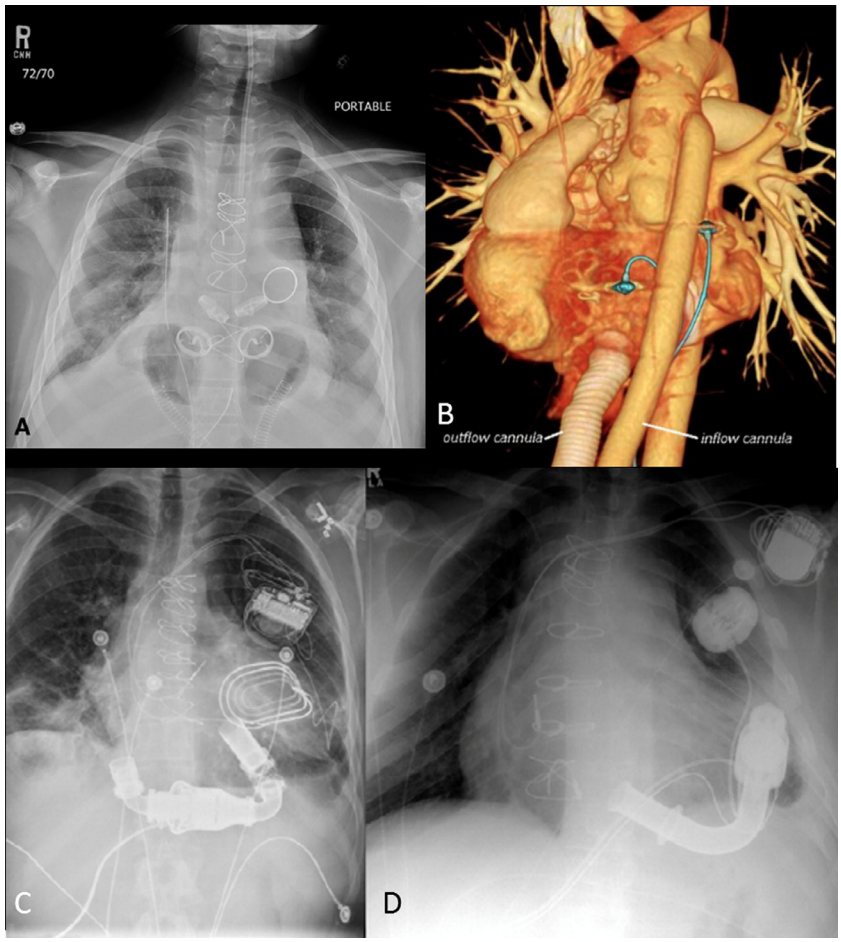

Figure 1 (A) Total Artificial Heart (SynCardia, Tuscon, AZ) placed in a 13-year-old male [28]. (B) Paracorporeal pulsatile Nipro-LVAD (Nipro, Osaka, Japan) placed in 26-year-old male [23]. (C) Demonstration of a DeBakey VAD (MicroMed, Technology, Houston, TX) placed normally (C) and with altered configuration through the right ventricle in a 35-year-old male (D) [18]. Reprinted with permission [18,19,23,28].

selecting the most appropriate device for each patient. In the case of a patient requiring a multiple reoperation with need for residual lesions to be repaired, a higher threshold for implantation may be reasonable as well as consideration of a TAH. Common residual lesions in these patients which need addressing include shunts, through either ventricular or atrial septal defects, the need for a conduit change, or valvular insufficiency (ie, aortic valve).

Anatomical considerations will also alter the approach and device placement such as which ventricle is the systemic ventricle or the cardiac position within the thoracic cavity. A systemic ventricle that is morphologically the left ventricle will be very anterior. Should the patient have dextro- or mesocardia, determining the most appropriate outflow course of the VAD may factor into the position of a right ventricle to pulmonary artery conduit. All of these factors make placing these devices challenging which has required a plethora of unique, patient-tailored strategies over time (Figs. 1–3).

APPLICATION OF TECHNOLOGY

It has become obvious that as we explore the lower limits of implanting these devices in our smaller ACHD patients and those with unusual anatomy that using advanced radiological software is essential. We believe using body surface area (BSA) and weight to determine fit is antiquated. At our hospital, our first use of virtual reality was a two-person job (cardiology imaging specialist and cardiothoracic surgeon) whereby the physicians worked together within a computer program to manipulate the 3D rendering of the thoracic cavity using a mouse and keyboard to develop optimal device fit (Fig. 4).

This technology has now advanced to a one-person virtual suite where the surgeon has all devices available at a motion of his finger and can manipulate the anatomy and device in space with his hands (Fig. 5). This allows for more facile testing of device placement and optimal visualization of all the surrounding anatomy as the surgeon can quickly move his head and hands around the virtual image.

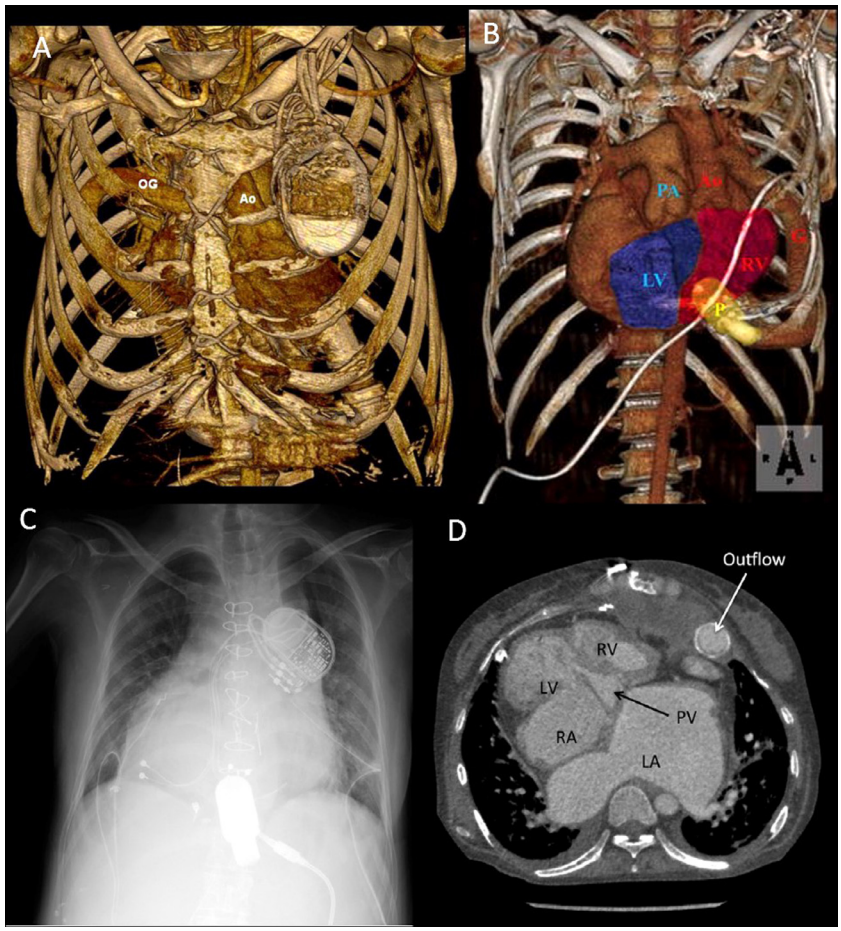

Figure 2 (A) HeartMate II (Thoratec, Chicago, IL) placed in a 53-year-old male with outflow graft (OG) passing posterior to sternum before anastomosing the aorta (Ao) [22]. (B) Jarvik 2000 (Jarvik Heart, Inc., NYC, NY) placed in a 60-year-old male with a systemic morphologically right ventricle (RV) [27]. (C and D) Chest X-ray and CT scan showing placement of a Jarvik 2000 in a 28-year-old female with unrepaired congenitally corrected transposition of the great arteries. LV, pulmonary morphologic left ventricle; P, pump body; PA, main pulmonary artery; PV, pulmonary valve [31]. Reprinted with permission [22,27,31].

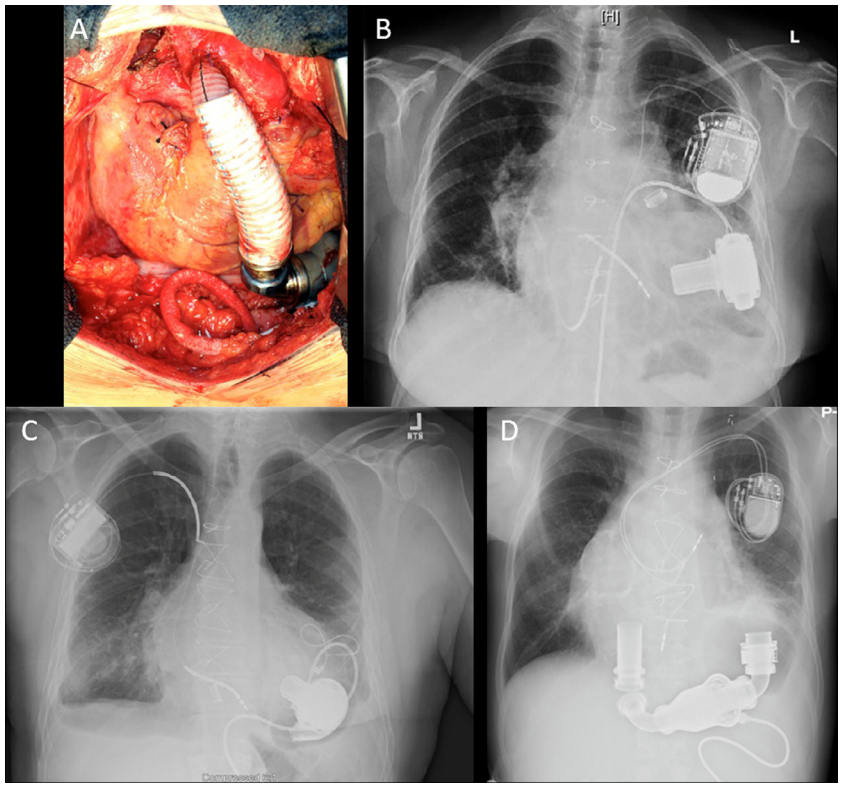

Figure 3 (A) HeartMate II placed in a 66-year-old male [24]. (B and C) HVAD (HeartWare, Inc, Framingham, MA) placement in a 58-year-old female (B) [26], a 66-year-old male (unrepaired) (C) [20]. HeartMate II in a 32-year-old man (status post double switch operation) (D). Reprinted with permission [20,24,26].

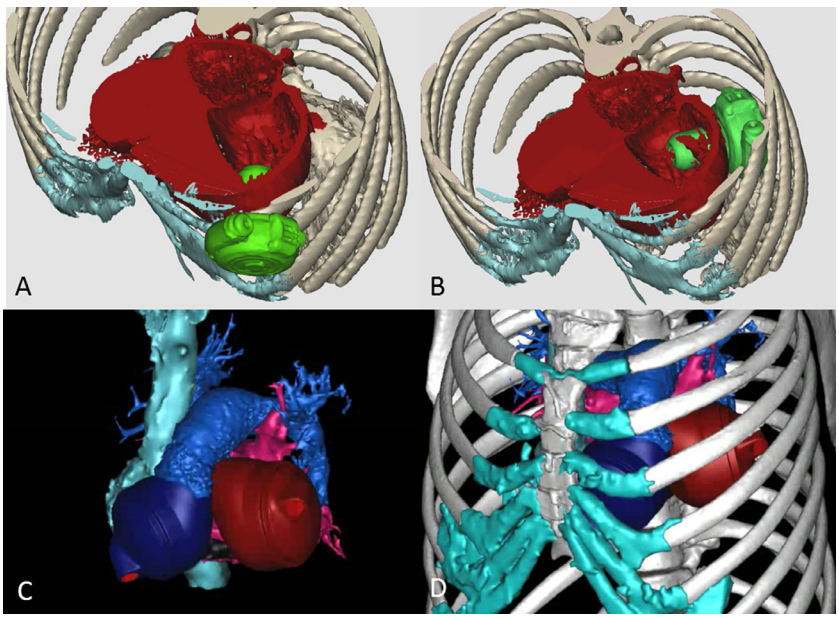

Figure 4 Implantation of HVAD in 11-year-old thought to be too small for device showing traditional placement (A) and modified placement using virtual reality which suited the patient (B). Implantation of total artificial heart in 11-year-old Fontan demonstrating good fit in virtual reality (C and D).

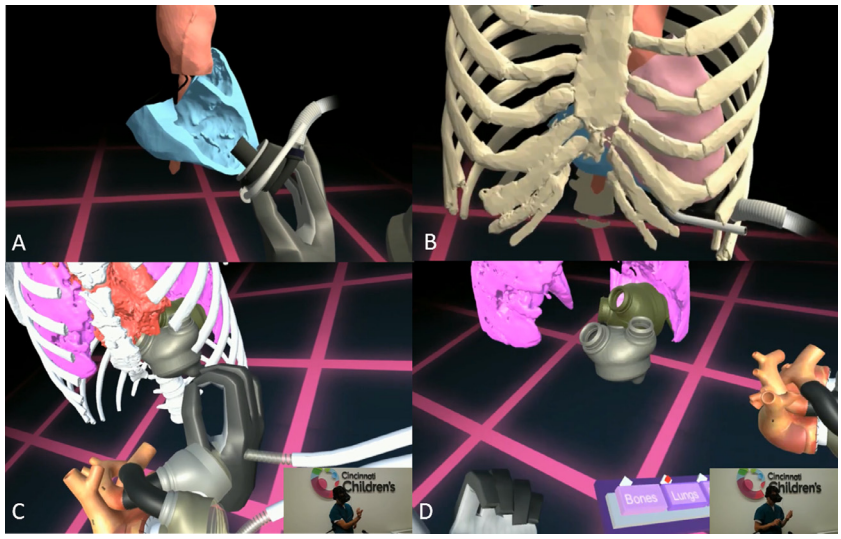

Figure 5 Implantation of HVAD in a single ventricle heart in virtual reality suite (A and B). Implantation of total artificial heart in virtual reality suite (C and D).

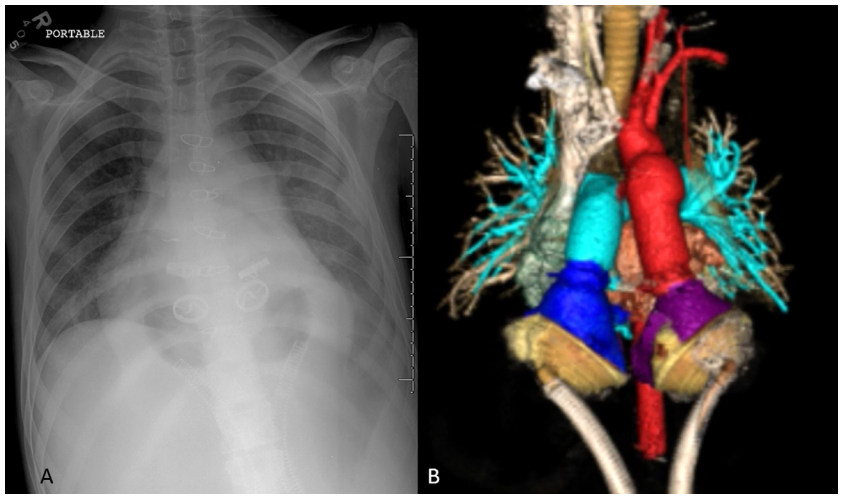

Figure 6 Postoperative chest X-ray (A) and CT reconstruction of TAH placement (B). CT, computed tomography; TAH, total artificial heart.

Case 1

The first TAH at a pediatric hospital was implanted in a 17-year-old boy with ccTGA and dextrocardia who was in heart failure with an implantable cardioverter defibrillator after a classic repair [13]. He had also developed severe aortic insufficiency with a very stenotic right ventricle to pulmonary artery conduit and had been awaiting heart transplant for 1 month. We had elected to avoid an LVAD since the patient was clinically stable and this would be a fifth time sternotomy and require right ventricle to pulmonary artery conduit replacement, aortic valve repair, and closure of a residual shunt prior to VAD placement. However, over a 24-hour period, his clinical status rapidly deteriorated leading to pulmonary, renal, and hepatic insufficiency. We therefore urgently decided to place a TAH to bridge him to transplantation (Fig. 6). He was successfully discharged home on postoperative day 28 and underwent successful transplantation 5 months later.

Case 2

A 32-year-old male presented with heart failure after a double switch operation (Senning plus Rastelli operation) for ccTGA. He previously had 4 operations including a Blalock-Taussig shunt, a pulmonary valvotomy, the double switch operation, and decortication of his right ventricular outflow tract, plus a pacemaker placement before the age of 15. He had multiple in-hospital treatments for congestive heart failure in recent years leading to the decision to implant a HeartMate II. His anatomy was complicated by the previous LeCompte maneuver which made placement of the outflow tract challenging (Fig. 7).

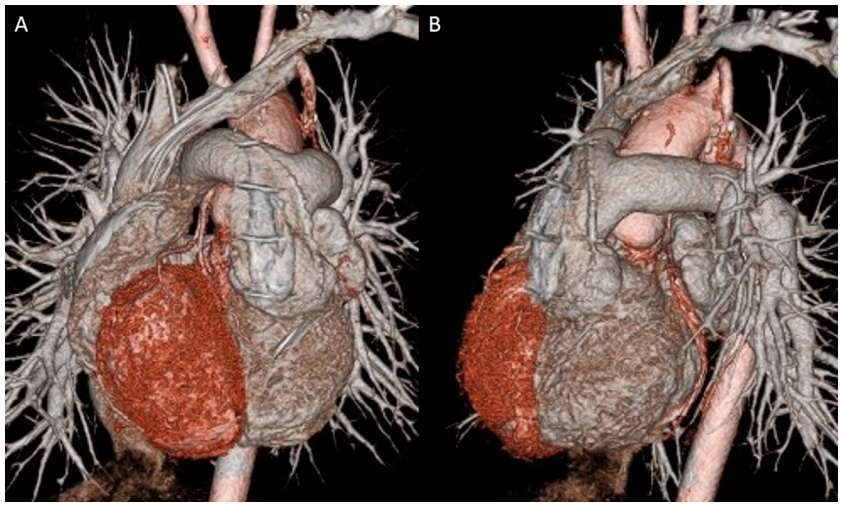

Figure 7 CT rendering of ccTGA after LeCompte maneuver during double switch operation. ccTGA, congenitally corrected transposition of the great arteries; CT, computed tomography.

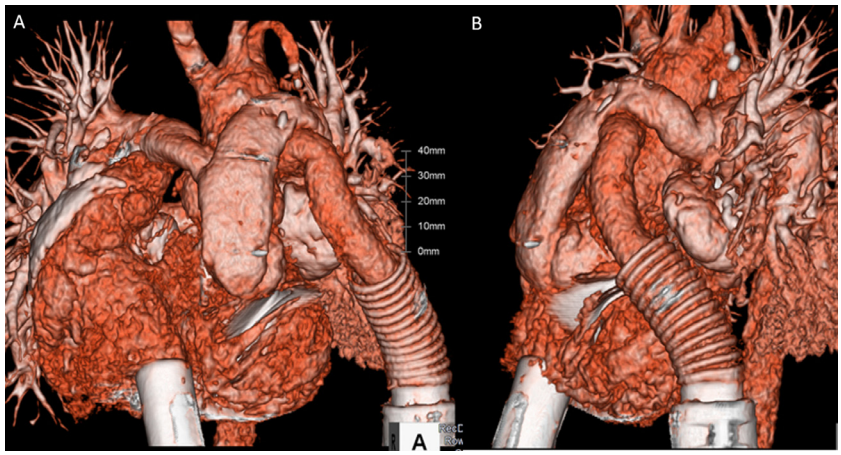

Figure 8 CT rendering following surgical repair and HeartMate II implantation. CT, computed tomography.

A 3D replica was printed to enhance understanding of the anatomy and plan the operation. In order to fit the device, aortobicaval cannulation was initiated followed by removal of allograft right ventricular outflow tract and repair of the residual ventricular septal defect. The inflow was sutured to the left ventricular apex while the outflow wrapped around to the left side of the ascending aorta. Subsequently, the right ventricular outflow tract was repair by new allograft material. A postoperative computed tomography scan showed excellent device placement with unobstructed outflow (Fig. 8).

The patient was successfully discharged home and stable for 6 months after the device implantation and is awaiting cardiac transplantation.

SUMMARY

We know that there is an increasing adult population with CHD and heart failure with the largest portion of them being ccTGA. There currently exist devices to support the majority of these patients successfully. In just the past year, data have, for the first time, emerged that supports increasing the use of VADs for these patients and at earlier stages in their disease process. However, these patients must be approached with a well thought out device strategy with regards to type of device, position, and timing of implantation. Lastly, the use of virtual surgery will not only determine if a device can fit, but how best it will fit within these patients with complex CHD. Interestingly, it is our own success in caring for patients, both surgically and medically, with ccTGA which has created this growing cohort of adults with heart failure. This presents our specialty yet another challenge which we must manage with increased clinical awareness, improving technology, and a responsibility to care for this cohort of patients we have created.

AUTHORS' CONTRIBUTIONS

Drs Riggs, Rizwan, and Morales conceptualized and designed the study, reviewed the literature, and revised the manuscript.

Dr Riggs carried out the draft of the initial manuscript.

Drs Fukushima and Fujita provided the second case report with images and reviewed the manuscript for important intellectual content.

Work is from Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA and the National Cerebral and Cardiovascular Center, Osaka, Japan.

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