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Review

Durable mechanical circulatory support in paediatric heart failure: The experience at Great Ormond Street Hospital

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ABSTRACT

Durable ventricular assist devices (VAD), despite being a standard therapy for adults in end-stage heart failure, are not so extended among the paediatric population for some reasons. These may include the complex underlying congenital heart disease in some cases, but also due to the lack of small medical devices available. In most of the cases, left ventricular assist devices are implanted as a bridge to transplant therapy, with a high success rate.

Great Ormond Street Hospital in London, being one of the two centres in the UK implanting VAD in children, has a wide experience in VAD management in infants, children and adolescents. So far, 98 Berlin Heart devices and 18 HeartWare have been implanted, with a successful bridging to transplant (80.6% and 72.2%, respectively). This is a consequence of a large and well-trained multidisciplinary team, involved in the whole process: from the indication to the subsequent follow-up of the patients in their local facilities. However, the incidence of adverse events is still high, with 30.61% of neurological vascular complications for Berlin Heart and 22.22% for HeartWare. Hence, it is essential to give the patient and family sufficient information regarding possible risks and benefits of long-term mechanical circulation support, and referring these patients to a centre with an expert and trained multidisciplinary team to get the best results.

Soporte circulatorio mecánico de larga duración en insuficiencia cardíaca pediátrica: la experiencia en el Great Ormond Street Hospital

Palabras clave:
Asistencia circulatoria
Insuficiencia cardíaca
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RESUMEN

El uso de asistencias de larga duración (VAD) en adultos es una práctica estandarizada que, por el contrario, no se encuentra muy extendida en la población pedátrica: tanto por la complejidad de las cardiopatías, como por el tamaño disponible de los dispositivos. En la mayoría de los casos estas se implantan como puente a trasplante, con un alta tasa de éxito.

El Great Ormond Street Hospital, en Londres, siendo uno de los 2 centros en el Reino Unido que implantan este tipo de dispositivos, dispone de una gran experiencia en el manejo de asistencias en niños y adolescentes. Hasta el momento actual se han implantado 98 dispositivos Berlin Heart® y 18 HeartWare®, con un alta tasa de puente a trasplante (80,6 y 72,22%, respectivamente). Esto es a consecuencia de un gran y experto equipo multidisciplinar, implicado desde el momento de la indicación hasta el seguimiento del paciente en su centro local. Aún así, la tasa de complicaciones asociadas sigue siendo alta: 30,61% de accidentes cerebrovasculares (isquémicos o hemorrágicos) para Berlin Heart® y 22,22% para HeartWare®. Por ello, es fundamental educar tanto a los pacientes como a las familias en los posibles riesgos y beneficios del soporte mecánico circulatorio a largo plazo, y tener disponible un equipo multidisciplinar con la adecuada formación y experiencia para conseguir los mejores resultados.

Abbreviations: GOSH, Great Ormond Street Hospital; MRI, Magnetic Resonance Imaging; A & E, Accident and Emergency; APTT, Activated Partial Thromboplastin Time; ATIII, Antithrombin III; SD, standard deviation; ccTGA, congenitally corrected transposition of great arteries; DORV, double outlet right ventricle; PS, pulmonary stenosis; BSA, body surface area; HOCM, hypertrophic obstructive cardiomyopathy; ALCAPA, Anomalous Left Coronary Artery from Pulmonary Artery; TCPC, total cavo-pulmonary circulation; iNO, inhaled nitric oxide.

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Background

The use of mechanical circulatory support devices (MCSD) has experienced a dramatic rise during the past decades, due to the increasing number of patients developing end-stage heart failure.

In terms of therapy duration, we can distinguish two types of ventricular assist devices (VAD): temporary or short-term, commonly indicated in acute heart failure patients, and durable or long-term devices, usually implanted as a bridging therapy for transplant (BTT) or as a destination therapy.

Temporary mechanical circulatory support, such as the Extracorporeal Membrane Oxigenator (ECMO), has been widely used in both adult and paediatric population; but when it comes to long-term VAD (ltVAD), its use on infants, young children and even adolescents, despite the international and multicentric registries, still has some lack of evidence.

Whereas ltVAD is a well established therapy in adults,[1–3] the experience in children (specially young infants) is still scarce.

On the one hand, paediatric cardiac population includes a large range of physiological and anatomical variations; consequently, it is more difficult to determine the right timing and candidacy for ltVAD implantation. On the other hand, patient size can be an issue since most devices have been initially developed for adult population.

Nevertheless, and according to the last data obtained from studies, such as PediMACS, VAD as BTT has proved to reduce up to 50% the mortality while on the waiting list,[4] with post-transplant results comparable to those patients not requiring MCSD.[5]

The Great Ormond Street Hospital for Children, in London, is one of the only two centres in the UK implanting ltVAD in paediatric patients, with a great experience over the past 15 years.

Long-term VAD patients management at Great Ormond Street Hospital

The multidisciplinary VAD team at the Great Ormond Street Hospital comprises a large number of highly-trained and experienced professionals, including nurses, intensivists, cardiologists and cardiothoracic surgeons.

Ethical considerations

All the patients' information included in this paper has been collected after obtaining a signed consent form for data submission. Being a descriptive study, without involving any clinical trial, human nor animal experiment, approval from the Hospital Ethical Board was waived.

Who's who in the GOSH VAD team?

Cardiac surgeon

Involved in the decision making process for patient eligibility, type of VAD and timing. Device implant operator. Also involved in the postoperative management: resolution of possible complications (bleeding, surgical re-exploration, device mechanical dysfunction), wound and incision review.

Cardiology transplant team

Perform an initial assessment for the paediatric patient on heart failure. This team coordinates the patient admission, the diagnostic tests prior to implantation (echocardiogram, MRI, complete cardiac diagnosis), and discuss with the rest of the team the possible candidacy for long-term support in a multidisciplinary team meeting. After the implantation, they run a very close follow-up in the Cardiac Intensive Care Unit (CICU), in the Cardiology ward and, when possible, in the outpatient clinic after the discharge.

VAD nurse specialist

Specialist nurses trained in VAD management. They are also involved in the implant decision, and lead the process to inform the patients and their families about the overall strategy, the risks and benefits, as well as the possible changes to be done in their lifestyle once they are on VAD support. They do not only inform the family but also all the potential people involved in the post-implant management: local doctors and carers, local A & E team, school staff, etc. In order to do this, they are provided with educational resources for explaining the device functioning, the further plan after implant and all the possible long-term complications that might arise. Once the device has been implanted, they perform a close monitoring of the VAD.

Cardiac paediatric intensivist

Medical team specially involved in cardiothoracic acute patients. Hence, they manage patients before VAD implant (in case they are in acute heart failure situation), and immediately after surgery. They are also involved in the decision making process, and also have a special role in managing the anticoagulation and antiplatelet therapy for the first days (or weeks) after the implant.

Perfusionist

They participate in the implant procedure, but also in the acute postoperative course. They are involved in the identification and resolution of possible mechanical complications or device malfunctioning (device thrombosis, dysfunction, cannulae issues. etc.)

Cardiac Intensive Care Unit ECMO-VAD nurses

Specialist nurses who have received a specific training in ECMO-VAD. Usually they manage patients right after device implant (1 nurse per patient), along with the intensivist care specialist nurses.

Patient eligibility and pre-implant assessment

This part is mainly conducted by the Transplant Team. Every potential candidate for mid or long-term mechanical circulatory support is assessed by several multidisciplinary specialists, and some patient baseline characteristics are evaluated: (1) age and size, (2) Estimated duration of VAD support, (3) further strategy (BTT, bridge to recovery, destination therapy), (4) underlying cardiac condition, (5) other comorbidities and conditions that might be affected by the VAD implantation.

For patients presenting with acute heart failure, being invasively ventilated and on inotropes, the strategy usually involves short-term MCS (ECMO or Levitronix) and subsequent long-term VAD implantation if needed once they are more stable.

Once the decision to be a possible candidate for VAD has been made, patients (in case they are competent enough) and relatives are extensively informed about the whole process, making a special emphasis on the potential benefits and risks. VAD specialist nurses lead this part of the process, by meeting the family and carefully explaining the implications VAD will have in their lives and the pathway to transplant.

After the implant: postoperative immediate care

The postoperative acute care implies different management strategies depending on the type of support and the patient status: ventilation, right heart failure, potential bleeding and reexploration, etc.

One of the main aspects to be taken care of is anticoagulation: unfractionated Heparin is commenced 24 h post implantation, for

an antiXa between 0.3 and 0.5. Prior to drain removal, Dipyridamole and Aspirin are commenced for platelet suppression. Daily routine checks include antiXa level, APTT, ATIII, fibrinogen, platelet count and full blood count. Platelet aggregation test is also assessed as per Haematology. Is not an uncommon complication to develop thrombus in the BH circuit (10 ml chambers have the higher risk), and first thing is to check the anticoagulation status, giving unfractionated Heparin if doses are low; in some cases chamber will need to be replaced.

An early mobility is aimed by performing primary chest closure in theatre, early drain removal and extubation, enteral feeding and physiotherapy for a prompt recovery.

After discharge: long-term plan education

The VAD cardiac nurse specialist offers support to patients and families even after discharge. Prior to going home, they involve parents in postoperative care, training them to deal with the new device. They also visit local facilities to teach local medical carers about complication management and resolution. Once patients have been discharged, they perform periodic visits to check the patients status on their way to transplant.

Results

Paracorporeal pulsatile devices: Berlin Heart EXCOR (Berlin Heart GmbH, Berlin, Germany)

This is a pneumatically driven paracorporeal support system providing either right, left or biventricular assistance. The wide range of cannulae and chamber sizes (10, 15, 25, 30, 50, 60 and 80 ml) makes it suitable for neonatal, paediatric, adolescent and adult population

The first Berlin Heart (BH) EXCOR implanted at GOSH was in 2004.

So far, 98 patients have been supported on BH VAD. The mean age at the moment of the implant was 5.13 years (SD 4.71). The median weight was 12.8 kg (95% reference range 5.6–60 kg).

The primary diagnosis was mainly dilated cardiomyopathy (DCM) (67.34%); 4 patients (4.08%) were diagnosed with a congenital heart disease (CHD), including: Ebstein's anomaly, ccTGA, DORV + PS and congenital aortic stenosis + regurgitation.

34.65% of the patients were on ECMO support prior to BH implant.

67 patients (68.36%) had only LVAD support, whereas one of them had to be upgraded to BiVAD 4 days after the implant due to right heart failure.

Mean days on support was 94.50 (SD 147.63), being 75% of the patients supported on BH for more than 19 days. 79 patients (80.6%) of the patients were successfully bridged to transplant, while 12 (12.24%) died while being supported, 6 (6.12%) BH were explanted prior to transplantation and 1 is still on Berlin Heart waiting for transplant.

The most feared adverse event related to this device, the neurological complications, occurred in 38 patients, 30 of them (30.61%) were vascular related: 20 of them had a ischaemic stroke, 9 had intracranial bleeding and 2 had both ischaemic and haemorrhagic complications. Other complications related to the BH support were: surgical re-exploration due to mediastinal bleeding ($n = 20$; 20.4%), gastro-intestinal severe bleeding ($n = 7$; 7.14%), cannulae issues ($n = 4$; 4.08%) and device-related sepsis ($n = 1$; 1.02%).

Intracorporeal continuous-flow devices: HeartWare Ventricular Assist Device (HVAD) (HeartWare, Medtronic Inc., Minneapolis, MN)

HVAD, on the contrary, is an intrapericardial continuous-flow device. Although it has been reported to cause less neurological adverse events, this device was initially created for adult population; therefore, only large sizes are available. For this reason, it is only implanted in adolescents and large children with a BSA greater than 1 m^2.

The first implant in our institution was in 2014. 18 patients have been implanted a HVAD at GOSH since then.

Mean age at implantation was 12.8 years (SD 2.22), being the youngest 7 years old, and the eldest 15. The mean weight was 44.94 kg (SD 14.36), and the mean BSA was 1.39 m^2 (SD 0.28).

The diagnosis, as in the BH group, was most commonly DCM (72.22%), the rest of the patients being diagnosed with pulmonary hypertension (1), HOCM (1), ALCAPA (1) and mixed ethiology cardiomyopathy (2).

8 patients (44.44%) were on ECMO support prior to implantation (mean duration of previous ECMO support: 11 days). 2 patients had two runs of ECMO before implantation.

Most patients (17 of 18) required only LVAD support, while the other one had a BiVAD support consisting on HVAD plus Centrimag and subsequent Berlin Heart for the right ventricle.

After implantation, patients were invasively ventilated for a median length of 7 days.

The mean length of support on HVAD was 248.07 (SD 345.88), and the median was 156 (95% reference range 4–1331).

The registered complications were: driveline infection ($n = 5$; 27.78%), neurological adverse events ($n = 4$, 2 ischaemic and 2 haemorrhagic strokes; 22.22%), surgical re-exploration due to bleeding or tamponade ($n = 2$; 11.11%), device thrombosis ($n = 2$; 11.11%), HVAD failure due to massive pulmonary regurgitation and right heart failure, requiring BiVAD support ($n = 1$; 5.55%). 3 patients (16.67%) required device change due to malfunctioning or thrombosis.

Currently, 13 patients (72.22%) have already been transplanted: 7 of them before being discharged home, and the other 6 after discharge (1 was transferred to Harefield adult department and was transplanted there). 1 patient died within the in-hospital postoperative course. The other 4 are still waiting for heart transplant: 2 are currently at home, 1 has been transferred to an adult department at Harefield, and 1 is still an inpatient.

Discussion

Despite the increasing number of centres performing VAD implants in children, MCS in paediatric population still offers many challenges to be solved.

The Pediatric Interagency Registry for Mechanical Circulatory Support (PediMACS), provides periodic reports, offering a multicentre perspective on the paediatric ventricular assist device outlook.

The results seem promising so far: paediatric survival on long-term VAD is 81% at 6 months.[6] Being bridge to transplant the primary indication for durable VAD in children in the vast majority of cases (more than 85%), the success rate of bridging the patient to transplant on support is 86%.[5] The last report, published in 2018, states that 50% of patients underwent heart transplant within the first 6 months after the device implant. Furthermore, results of patients being bridged to transplant on VAD are comparable to those undergoing transplant without requiring support.[7] Death rate among patients on VAD who are listed and waiting for transplant has been recently reported to be 16% in the current era,[8] while the peak hazard for death is 2 weeks after VAD implantation.[5]

This mortality risk while being on VAD support is directly related to the underlying cardiac diagnosis: patients with congenital heart disease present worse outcomes. Although most patients in end-stage heart failure receiving durable MCS are diagnosed with cardiomyopathy (in our experience, DCM is the most common indication for VAD), the CHD group still remains an outstanding challenge for implantation surgical strategy as well as for postoperative management.[8,9] It is extremely important to assess correctly the anatomy and physiology of the patient prior to the implant, paying special attention to previous cardiac procedures and palliations. Hence, single ventricle physiology poses a particularly difficult situation. Weinstein et al. reported their experience with Berlin Heart EXCOR in patients with functionally single ventricle,[10] obtaining very poor outcomes in babies after palliation stage I, and getting better results after Glenn and TCPC stage palliations. However, special considerations need to be taken when implanting any support device in these patients, as they may require to take down the TCPC circulation and separate the systemic venous return from the pulmonary circulation.[11] Other cardiac diagnosis may require further interventions prior to the assist device implant: severe aortic regurgitation, for example, is a formal contraindication for LVAD, therefore it needs to be addressed before the implantation. In our series, the only patient presenting with aortic valve disease (both regurgitation and stenosis), underwent an aortic valve replacement; but other solutions, as aortic exclusion, have been proposed.[12]

In addition to having a potentially more complex anatomy and physiology in paediatric population compared to adults, patient size can also be an issue. Most assist devices have been developed for adult population, which makes impossible its use in small infants. Currently, only paracorporeal pulsatile devices such as Berlin Heart EXCOR, which offers a range of cannulae and pump sizes, are widely used in small children. In fact, the median weight of patients receiving BH support at GOSH is 12.8 kg, being the lowest 3.9 kg. The disposition of this device (paracorporeal, with cannulae connecting the patient to an external pump), makes it possible to exchange BH support to ECMO or Levitronix when needed, until the patient gets proper stabilization.

In fact, ECMO support prior to BH implant is a common practice: 34.65% of our patients went on ECMO before going to BH. Almond et al. reported in 2013[9] that early mortality after BH implantation was directly related to lower body weight, higher bilirubin and BiVAD support, whereas late mortality was related to both liver and kidney dysfunction; therefore, end-organ failure at the moment of the implant is associated to a poor prognosis. Consequently, two strategies should be adopted at this point: a correct timing for implant before end-organ dysfunction occurs, and ECMO support for organ recovery before going into durable VAD support. High volume and experienced centres are more likely to get better outcomes, mostly due to a better timing and candidacy decision.

Furthermore, BH offers the possibility of BiVAD support, in case of associated right heart failure. In our case, 32.65% of patients on BH required biventricular support. Right ventricle failure after LVAD implant, such as HeartWare, can be a major problem, and it has been reported to happen in 7–30% of the patients having initially only left heart support.[13,14] The perioperative management should then include the initiation of iNO prior to weaning off bypass during the LVAD implant, and continuation in the immediate postoperative course.[15]

Still, the main burden of BH support is the high rate of associated complications: specially neurological insult and significant bleeding. Cassidy et al. published in 2013 the experience with BH in 2 UK high volume centres: GOSH and Newcastle.[16] Even though survival results were excellent (84% of patients in BH made it to transplant or recovery and explant), 25.4% of patients had a stroke while receiving BH support. This percentage can even be higher in some series (up to 30%), while in ours, the rate of neurological damage is 30.61%. This needs a deep consideration, as one of three patients receiving a BH device might experience any kind of neurological adverse event.

The risk for developing any neurological or haemorrhagic complication while on support, has been reported to be higher in pulsatile than in continuous flow devices. Even Dipchand et al. recently published that survival at 2 years after implant is lower for pulsatile devices.[8] Not to mention other intracorporeal devices advantages: patients are able to be discharged home while waiting for transplant (Fraser et al. have recently reported a discharge home rate of 85% since 2004[17]), and, although rarely, they can be used as destination therapy in adolescents with fatal prognosis systemic disease, such as Duchenne's myopathy[18] (despite this last indication is not currently commissioned in the UK). As a consequence of this, the overall trend is to increase the number of implants of CF devices in detriment of pulsatile flow ones.[19]

Although it has been used for many years in children,[20] the main issue related to the use of HVAD is the size: its intended use is for adult population, therefore, it can be only used in adolescents or large children with a BSA greater than 1 m^2. In fact, according to the last PediMACS report,[21] including 432 devices implanted in 364 patients, the median age for paracorporeal devices was 1.7 years old, while this was 15 years old for continuous flow devices. Miera et al.,[14] though, reported a multicentre study of HVAD in children with a median BSA of 0.8 m^2, with a survival rate of 92.3%, similar to older patients. Nevertheless, being an intracorporeal device, it makes very challenging to implant it in small infants.

Having this in mind, the National Heart, Lung and Blood Institute (NHLBI), launched the PumpKIN (Pumps for Kids, Infants and Neonates) program and subsequently developed the Infant Jarvik 2015 device,[22] with promising perspectives in the future of VAD in children.

However, it is crucial to involve patients and their families in the whole process of the decision making and post-implant device management. Gilmore et al. reported in 2011 the experience of parents and children who had been bridged to transplant with VAD.[23] The overall feeling was that, although parents reassured they had made the right decision by accepting the treatment, there was an inadequate information at the time of giving consent, specially when considering it's a psychologically stressful situation. Children are frequently left out of the equation, not involving them in the explanations about the long-term plan and how VAD will possibly change their lives. That's why a solid VAD unit requires a large and multidisciplinary team, who can help families and patients deal with this big change, and inform about the benefits and possible complications that may appear along the way to transplant.

Conclusion

Long-term VAD has been increasing on use and popularity for end-stage heart failure in paediatric population for the past years. Its success lies on the high percentage of these patients being safely bridged to transplant and the high survival after this. However, there are many challenges that still need to be solved. Outcomes are directly related to the patient's baseline condition, like underlying congenital cardiac disease, end-organ failure, or weight at the time of the implant. However, they are also related to the device-related adverse events that might occur while being on support. Paracorporeal pulsatile-flow devices, such as Berlin Heart, which are the most commonly used for infants due to the small-sized cannulae and pump availability, still present a vascular neurological complication rate up to 30%. Therefore, is essential to give the patients and their relatives the adequate amount of information, and get all

these potential candidates referred to a high experienced centre, with a well-trained multidisciplinary team, in order to get the best results

Conflict of interests

None.

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