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CASE SERIES

Intracorporeal LVAD implantation in pediatric patients: A single-center 10 years' experience

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Abstract

Background: Mechanical cardiac support is currently an effective strategy to reduce morbidity and mortality in pediatric patients. However, solid evidence regarding the feasibility of intracorporeal devices in children still needs to be provided. We report our 10-year experience with intracorporeal left ventricular assist devices (LVAD) in children.

Materials and Methods: We included all patients undergoing intracorporeal, continuous-flow LVAD implantation between 2012 and 2022. Baseline and postoperative data were collected from the institutional database.

Results: Seven HeartWare and 4 HeartMate3 were implanted in 11 patients (median age 13.9 years, median body surface area – BSA – 1.42 m^2, IQR 1.06–1.68). The most frequent indication to LVAD implant was dilated cardiomyopathy (72.7%). All candidates underwent a thorough preoperative advanced imaging. Three-dimensional reconstructions and implant fit simulation were performed when BSA was <1.2 m^2, weight <30 kg, or internal transverse thoracic diameter <20 cm. There was no operative death. The most common postoperative complication was surgical re-exploration due to bleeding (27.3%). One patient died of severe neurological complications after about 3 months of hospitalization. No late deaths or unplanned re-hospitalizations occurred in the remaining 10, 6 of whom were discharged home. There were no major complications at the follow-up. All survivors underwent successful heart transplantation.

Conclusions: Intracorporeal LVAD implantation proved to be a potentially feasible and safe option in young teenagers and children whose BSA was >1.0 m^2. In borderline cases, the 3D reconstruction with implant fit simulation can effectively help to identify those patients who can safely undergo intrathoracic LVAD implantation.

KEYWORDS

children, end stage heart failure, Heartmate, HVAD, LVAD, pediatric, transplant

Irene Cao and Enrico G. Italiano share the first authorship.

1 | INTRODUCTION

Adults affected by end-stage heart failure (ESHF) are currently treated with a left ventricular assist device (LVAD), whose implantation is indicated when conventional maximal medical therapy cannot warrant survival until a heart transplant (HTx).[1] Although less prevalent, ESHF impacts a significant number of children, and their chances of survival hinge on the prospect of an HTx that may not occur, leading to unfavorable outcomes.[2] Adequate allograft is often exceptional in the pediatric population, and waiting a long time for a donor can lead to progressive clinical deterioration, potentially making any treatment ineffective if multi-organ dysfunction occurs.

Overall, experience with pediatric intracorporeal LVAD is limited but increasing over time. The Pediatric Interagency Registry for Mechanical Circulatory Support (PEDIMACS) currently includes more than 1000 patients implanted after 2012, with 41% of patients implanted with a 3rd-generation (namely, a continuous-flow) intracorporeal device.[3,4] Despite the large number of patients included in the registry, the use of such devices has been limited due to size constraints and pediatric guidelines for decision-making still need to be improved.

Among 3rd generation LVADs, the HeartWare (HVAD, Medtronic, Minneapolis, MN) has been the most commonly implanted device in pediatric patients[5,6] until it was retired from the market in June 2021.[7] The HeartMate3 (HM3, Abbott Inc., Chicago, Illinois, Il) is the only continuous-flow intracorporeal device available for long-term support. However, HM3 dimensions are slightly more significant than the HVAD pump, with some concern regarding the excessive encumbrance in children's thoracic cavities. Currently, a BSA $<1.2\,m^2$, a weight $<30\,kg$,[7] or an internal thoracic diameter $<20\,cm$ are considered parameters that increase the risk of HM3 pump unfitting. However, occasional reports have shown this may be false.[8]

In this context, patients with borderline thoracic dimension for intracorporeal LVAD implantation can benefit from thorough preoperative imaging, including computed tomography (CT)[9] and 3D reconstruction of the chest structures (heart, vessels, and thoracic cavity).

We report our comprehensive 10-year experience with 3rd-generation intracorporeal LVAD in children and adolescents, and we describe our preoperative multimodality imaging approach to evaluate the feasibility and safety of implants in borderline patients undergoing HM3 implantation.

2 | MATERIALS AND METHODS

2.1 | Study features

This retrospective, single-center study includes all patients <18 years of age requiring LVAD for ESHF from 2012 to 2022. The review of medical records was approved by our institutional Ethics Committee for clinical investigation (protocol n° 59004), and the patient's informed consent was waived. Patients were included in the study regardless of ESHF etiology, and LVAD was implanted as a bridge-to-candidacy, bridge-to-transplant, or destination therapy, as described elsewhere.[10] In the present study, patients undergoing paracorporeal device implants were excluded.

Whenever the indication to LVAD was decided, the feasibility of an intracorporeal LVAD implant was assessed according to BSA, weight, and intrathoracic transverse diameter. Preoperative data included demographics, etiology of ESHF, clinical characteristics, and imaging (2D echocardiography, cardiac catheterization, thoracic CT with contrast media). Outcomes included postoperative complications, early death (within 30 days from surgery), or late death (after 30 days or hospital discharge).

Follow-up data included the occurrence of either HTx or any adverse events (AEs): death, infective (e.g., exit-site infection, systemic infection), thrombotic/hemorrhagic, neurological, or need for a reintervention (surgical or not).

2.2 | Preoperative CT scan evaluation

All patients had a preoperative CT scan before the LVAD implant. However, starting in January 2022, a comprehensive 3D reconstruction of the heart and chest cavity was carried out for all cases with BSA $\leq 1.2\,m^2$, along with a virtual HM3 LVAD fit test was performed. This was promoted as a routine protocol after HVAD was discontinued in 2021, being HM3 larger than HVAD. Virtual fitting and surgical planning were performed using separate 3D models for the rib cage (Video S1 on supplemental material), the heart chambers, and the device considered for implantation. Also, simulations of different LVAD positions in the left chest were performed to optimize LVAD location. In some exceptional cases, airway and main vessel models were also generated and summed to allow for complete spatial reconstruction of the surgical site and outflow graft path planning. (Figure 1). Reconstructions were made using Mimics inPrint 3.0 software (Materialize NV, Leuven, Belgium).

For each BSA <1.2 m^2 case, a complete chest CT scan of the patient was imported, and the various structures, differentiated by density, contrast-enhancing, or spatial location, were segmented separately (Figure 2). The 3D models of the pumps were generated from CT scans of previously implanted patients, and their dimensions were confirmed to be accurate by comparing virtual measures with the physical dimensions as declared by the manufacturer's technical specifications. Finally, all models were combined, and the virtual fitting was carried out by freely moving and rotating the pump and its fixed metal outflow to the apex of the left ventricle while carefully controlling the inflow cannula depth within the ventricular wall and the clearance between the internal surface of the ribs and the device itself. (Figures 2 and 3).

CT scans were performed using a 320-slice CT scanner (Toshiba Aquilion ONE; Canon Medical Systems, Otawara, Japan). Gantry rotation time was 350 msec, slice thickness 0.5 mm, and recon increment 0.25 mm. Tube potential was generally low-dose (80 kV) for scanning most infants and children through the first decade of life. In comparison, 100 kV was used for overweight children or adolescents, especially if examining subtle details. Usually, a biphasic injection protocol (contrast followed by saline) was adopted, acquiring a single contrast scan (arterial phase) or a biphasic scan protocol (arterial and venous phase) by using automatic bolus tracking. Automatic exposure control (SURE exposure 3D, Toshiba Medical Systems) and iterative reconstruction (AIDR3D standard, Toshiba Medical Systems) were used. The quantity of contrast medium administered was 1.5 mL/kg (mean 60 mL) of lomeron delivered at 3 mL/s. Patients requiring detailed evaluation of structures prone to cardiac motion artifacts and those requiring functional assessment were scanned using ECG gating. Data were transferred to an external workstation (Vitrea2 FX version 6.3, Vital Images, Plymouth, MN, USA) providing multi-planar reformation (MPR), curved planar reformation (CPR), volume rendering technique (VRT), cine-view, and semiautomatic vessel analysis system to assess the vasculature.

We described continuous variables as median (interquartile range [IQR]), whereas discrete variables were

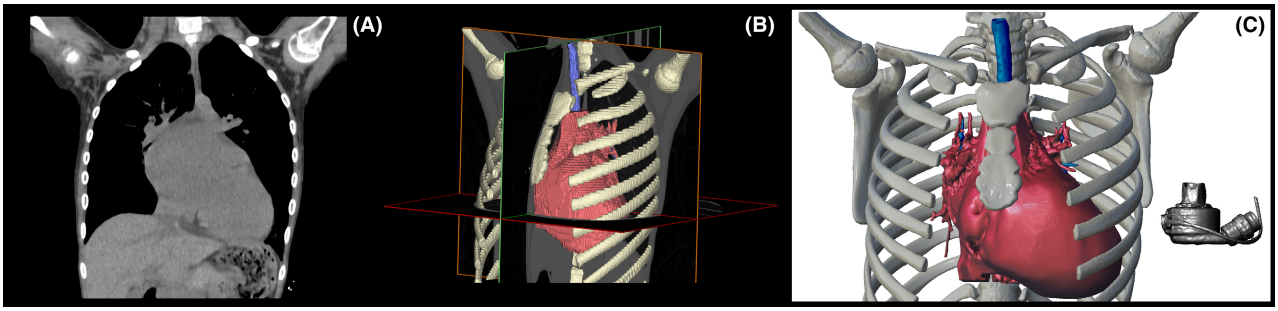

FIGURE 1 Virtual fitting workflow for patient 9. From a CT scan (panel A), a separate segmentation of all the different structures is carried out using suitable software (panel B) to reconstruct the 3-dimensional arrangement of the thorax. Finally, a VAD 3D model can be imported and moved freely in any position to find the optimal position (panel C). [Color figure can be viewed at wileyonlinelibrary.com]

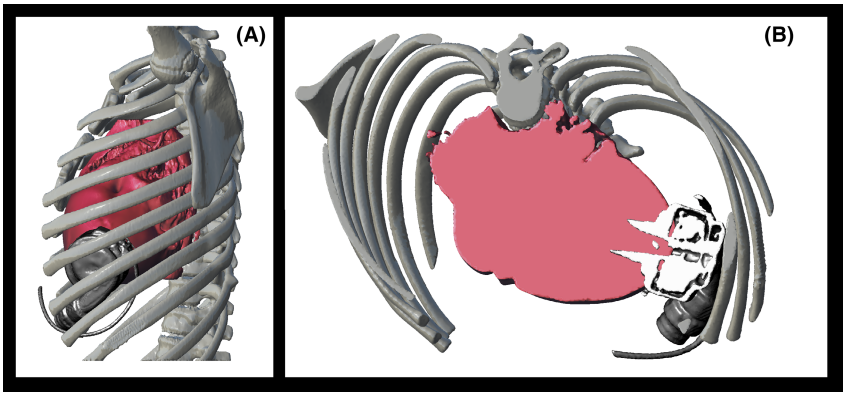

FIGURE 2 The final result of the virtual fitting of patient 9. The ribcage is confirmed as not interfering with the device (Panel A) and at the same time an oblique cut is created to test whether the pump is positioned appropriately within the heart mass (Panel B). This CT scan was acquired without a contrast medium, so a complete reconstruction of the heart chambers, such as in Figure 3, was not possible. [Color figure can be viewed at wileyonlinelibrary.com]

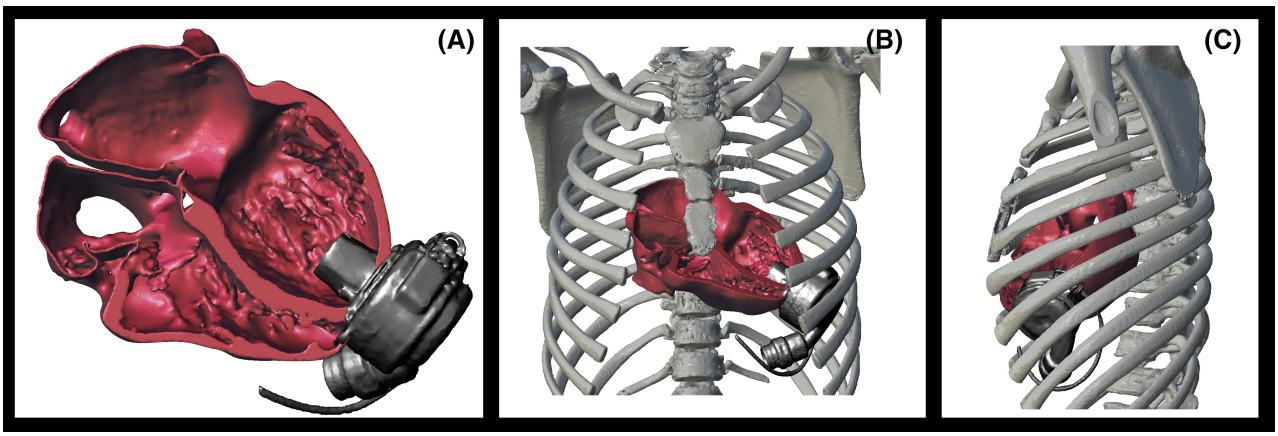

FIGURE 3 The final result of a virtual test of Patient 10. In this case, the extreme dilatation of both the left ventricle and left atrium required a more precise assay of the left ventricular wall thickness, the alignment of the apex and the mitral valve, and the spatial relationship with the ribcage. Thus, the heart was reconstructed fully, inside and outside, and the device was positioned in the correct position (slightly lateral to the apex and with the inflow cannula parallel to the interventricular septum, pointing at the mitral valve), as in panel A. Again the device-heart assembly was tested for interference with the thoracic wall (panel B and C). [Color figure can be viewed at wileyonlinelibrary.com]

described as numbers (with percentages). Baseline, intraoperative, and postoperative outcomes were collected.

3 | RESULTS

Thirty-one pediatric patients underwent LVAD implantation between 2012 and 2022. Among these patients, an intracorporeal LVAD was implanted in 11 (median age, 13.9 years; IQR 10.7–14.7, range 10.5–16, median BSA: 1.42 m^2, IQR 1.06–1.68). Preoperative characteristics are described in detail in Table 1. The etiology of ESHF was dilated cardiomyopathy in all but one (biventricular heart failure in a 12-year-old boy with corrected transposition of great arteries and pulmonary atresia after multiple surgical procedures in infancy).

The median preoperative left ventricular ejection fraction (LVEF) was 24% (IQR 15–26). The hemodynamic characteristics are reported in Table 1. All but one patient were on intravenous inotropic drug infusion (10/11 patients, 90.9%). The INTERMACS profile was 3 in 5 patients (45.5%), 2 in 2 patients (18.2%), and 1 in 3 patients (27.3%).

The last four more recent patients, planned for HM3 implant, underwent preoperative ECG gated CT scan and 3D reconstruction and virtual fitting (Figures 1–3).

The LVAD was implanted as bridge-to-transplant in seven cases (63.6%), as bridge-to-candidacy in 3 (27.3%), and as destination therapy (DT) in a 14-year-old patient with Duchenne's syndrome. All three patients implanted with a bridge-to-candidacy strategy had elevated pulmonary arteriolar resistances (12.67, 9.58, and 6.76 WU, respectively).

Three patients (27.3%) were on mechanical circulatory support before LVAD implant: 2 on femoral-femoral veno-arterial extracorporeal membrane oxygenation (VA-ECMO), one on paracorporeal LVAD configuration through apical cannulation (apical-femoral artery configuration), after an initial VA-ECMO. Four patients (36.4%) were on mechanical ventilation preoperatively.

Seven HeartWare (HVAD, Medtronic, Minneapolis, MN) (63.6%) were implanted between 2012 and 2020, while 4 HeartMate 3 (HM3, Abbott Inc., Chicago, Illinois, Il) (36.4%) were implanted in 2022 (Figure 4). The surgical LVAD implant was performed under median sternotomy in all but one 15.9-year-old boy (BSA 1.93 m^2) who underwent implantation through bithoracotomic access (as surgeon's choice). A right atrium-to-pulmonary artery temporary right ventricular mechanical support was necessary in 2 patients for 3 and 4 days, respectively. The median time of post-LVAD mechanical ventilation was 3 (IQR 1–3) days.

The most common postoperative complication was bleeding requiring surgical re-exploration (27.3%), with cardiac tamponade in one case only. Major infectious complications occurred in 2 patients (18.2%) successfully treated with antibiotics. The only in-hospital postoperative death occurred in a 12.4-year-old patient affected by complex congenital heart disease, who underwent multiple surgeries in infancy and had a cardiac arrest requiring resuscitation and emergent ECMO implantation before LVAD implantation. Despite a pre-LVAD neurological evaluation being unremarkable and recovery of cardiocirculatory stability after LVAD, he presented with cerebral anoxic damage leading to an irreversible comatose status, and care withdrawal was

TABLE 1 Baseline patient's characteristics. Numeric data are expressed as median and IQR (25–75).

Demographics	
Age, years	13.9 (10.7–14.7)
Gender (male), *n* (%)	9 (81.8)
Weight, kg	47.0 (28.0–65.0)
Height, cm	154.0 (140.0–163.0)
Body surface area, m^2	1.42 (1.06–1.68)
Heart failure etiology	
Dilated cardiomyopathy	10 (90.1)
Primitive idiopathic	4 (36.4)
Familiar restrictive	1 (9.1)
Carvajal's syndrome[a]	1 (9.1)
Iatrogenic (anthracycline)[a]	1 (9.1)
Duchenne's syndrome[a]	1 (9.1)
Post-myocarditis[a]	1 (9.1)
Non-compaction cardiomyopathy	1 (9.1)
Post-surgical correction of CHD in infancy	1 (9.1)
Preoperative organ function	
Renal function (creatinine), micromol/L	62.0 (46.0–77.0)
Liver function (total bilirubin), micromol/L	16.2 (12.7–31.3)
Liver function (direct bilirubin), micromol/L	9.3 (6.0–18.3)
Echocardiographic data	
Left ventricle ejection fraction, %	24.0 (15.0–26.0)
Left-ventricular end-diastolic diameter, mm	152.0 (130.0–198.0)
Right ventricular fractional area change, %	10.0 (7.5–14.8)
Tricuspid annular plane systolic excursion, mm	18.0 (13.0–20.0)
Emodynamic data (right heart catheterization)	
Pulmonary capillary wedge pressure, mm Hg	18.0 (17.0–21.0)
Cardiac index, L/min/m^2	2.0 (1.7–2.4)
Pulmonary arteriolar vascular resistance, WU	5.6 (2.4–10.4)
Implantation strategy	
BTT, *n* (%)	7 (63.6)
BTC, *n* (%)	3 (27.3)
DT, *n* (%)	1 (9.1)

Abbreviations: BTC, bridge-to-candidacy; BTT, bridge-to-transplant; DT, destination therapy, IQR, interquartile range.

[a] Percentage relative to the total number of dilated cardiomyopathy.

decided on postoperative day 119. All intra-operative details and postoperative complications are reported in detail in Table 2.

Among survivors, four patients (36.0%) were transplanted before being discharged home (median LVAD-to-HTx time 23.0 days, IQR 8.8–44.0). The remaining six patients were discharged home after a median hospital stay of 34.5 days (IQR 30.0–40.5). Anticoagulation therapy with fondaparinux was given to the three patients having the HM3, whereas warfarin with antiplatelet therapy (Clopidogrel in 2, acetylsalicylic acid in 1) was given to the others. The target INR ranged between 2.5 and 3.5.

After hospital discharge, there were no late deaths or complications. However, three had driveline exit-site infections successfully treated with intravenous antibiotics and local driveline exit-site management. All children underwent a successful HTX after 42, 110, 255, 290, 418, and 1387 days (median of 272 days, IQR 146–386) from LVAD implant. Figure 4 shows the onset of a single complication over time in Kaplan-Meyer curves of patients implanted with 3rd-generation LVADs.

Overall, all long-term survivors underwent a successful HTx, after a median wait of 110 (IQR 35–273) days. In particular, the two patients affected by pulmonary hypertension achieved normalization of pulmonary arteriolar resistances (passing from 12.7 to 2.7 WU and from 6.7 to 2.6 WU, respectively, in patients 5 and 8, Table 3), and both underwent a successful HTx without any right heart failure episodes. Also, the patient with Duchenne syndrome (LVAD implanted as DT) showed a stabilization of the neurological problem, with excellent clinical conditions, and after 1387 days of uncomplicated HVAD support, underwent a successful HTx. Table 3 summarizes the characteristics of patients implanted with HVAD and HM3, with similar outcomes in both groups.

4 | DISCUSSION

We report on the outcomes of a cohort of patients <18 years of age who underwent intracorporeal continuous-flow LVAD implantation, with a satisfactory 90.9% survival to HTx. Moreover, we report on the pre-implant CT evaluation and 3D virtual simulation of the adult-sized LVAD implantation to assess feasibility in children with BSA <1.2 m^2. In this experience, this preimplant virtual reconstruction was 100% effective and reliable, with no predictive errors causing a change of the operative planning (i.e., switch to an extracorporeal LVAD).

As described elsewhere,[11] in our cohort, dilate cardiomyopathies represented the most common indication of LVAD (81.8%). Such patients often present with slow but constant deterioration of the clinical conditions and frequent hospital admissions, which are known to have an increased risk of death, with an overall mortality rate ranging from 7 to 11%. Thanks to advanced technology

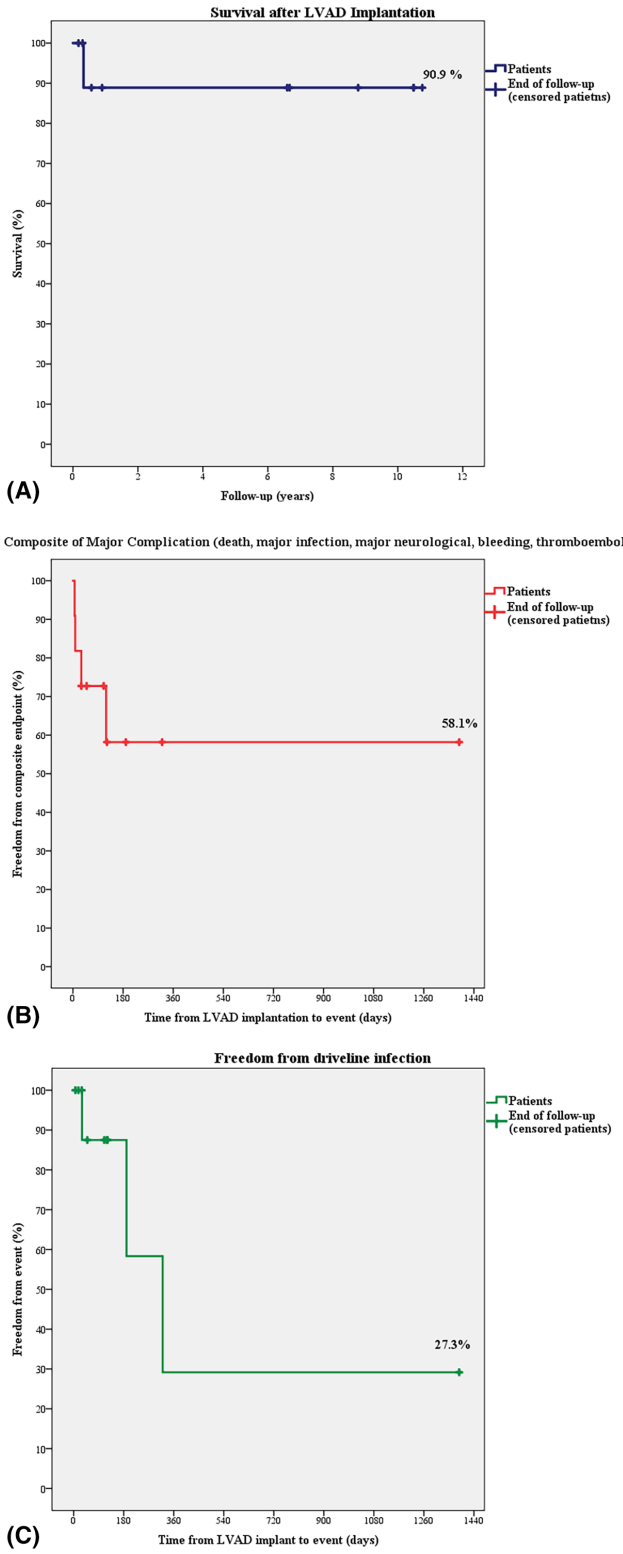

FIGURE 4 Kaplan-Meyer curves of patients implanted with 3rd-generation LVADs. (A) survival after LVAD implantation; (B) overall freedom from major complications during index hospitalization; (C) overall freedom from driveline infection. [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 2 Intraoperative details and postoperative outcomes.

Intraoperative	
Heartware HVAD implantation, *n* (%)	7 (63.6)
HM3, *n* (%)	4 (36.4)
Access: full median sternotomy, *n* (%)	10 (90.9)
Outcomes	
Post-surgery intubation time, median (IQR 25–75), days	3 (1–3)
In-hospital mortality, *n* (%)	1 (9.1)
30-day mortality, *n* (%)	0 (0.0)
Neurological complication, *n* (%)	3 (27.3)
Major neurological complication (post-anoxic coma)	1 (9.1)
Temporary RVAD, *n* (%)	2 (18.2)
Bleeding requiring surgery, *n* (%)	3 (27.3)
Infective complication, *n* (%)	5 (45.5)
Major (sepsis, pneumonia)	2 (18.2)
Minor (uncomplicated driveline exit-site infection at follow-up)	3 (27.3)

Abbreviations: HM3, HeartMate 3; HVAD, HeartWare VAD; IQR, interquartile range; RVAD, right ventricle assist device.

and improved perioperative care, LVAD outcomes have significantly improved and enabled sustained LVAD support up to a complete recovery of multi-organ function, increasing the chance for a successful HTx. In our series, the overall median time from LVAD implantation to a successful HTx was 110 (IQR 35–273) days, which compares well with what was reported by Spigel et al.[12] Also, long-term LVAD support as DT has been reported for chronic or incurable diseases in pediatric patients.[13] In our experience, one patient affected by Duchenne's syndrome and left ventricular dysfunction underwent an HVAD implant as DT. However, the ameliorated hemodynamic conditions and the favorable course of the genetic disease led to the decision to list the patient for HTx, who underwent successful HTX after more than 4 years of uncomplicated LVAD support, as already described by our group.[14]

Despite EXCOR pediatric VAD (Berlin Heart Inc., The Woodlands, TX) being most commonly implanted LVAD in children independently of the BSA, the technical evolution of VADs has led to more confidence in the intracorporeal continuous flow devices (i.e., the HVAD and the HM3) in pediatric patients. They have gradually become smaller and more flexible for small candidates. This pathway to completely intracorporeal continuous flow VADs has been driven by the experience with HVAD, a hydrodynamic centrifugal flow pump of 45 mL of volume that can

TABLE 3 The table resumes the main preoperative, intraoperative, postoperative and at follow-up details of the case series.

Pt#	Age (years)	Weight (kg)	BSA (m^2)	ESHF etiology	Baseline LVEF (%)	LVAD/	Strategy	Surgical access	Major complication	Time to HTx (d)	Outcome
1	10.5	26.5	1.06	Non-compaction DCM	10.0	HVAD	BTT	Median sternotomy	*None*	49	HTx
2	16	64.9	1.70	DCM in Carvajal Syndrome	15.0	HVAD	BTT	Median sternotomy	RVAD. Post-hospital discharge driveline infection	42	HTx
3	14.3	32.0	1.13	DCM Post-myocarditis	11.0	HVAD/	BTT	Median sternotomy	Bleeding requiring surgery	17	HTx
4	10.7	19.0	0.83	DCM	30.0	HVAD	BTT	Median sternotomy	Bleeding requiring surgery, infection (pneumonia)	29	HTx
5	14.6	47.0	1.42	DCM	31.0	HVAD	BTC	Median sternotomy	Post-hospital discharge driveline infection	255	HTx
6	14.7	73.0	1.68	DCM in Duchenne Syndrome	24.0	HVAD	DT	Median sternotomy	*None*	1385	HTx
7	12.4	58.8	1.64	CHD post-repair	25.0	HVAD	BTC	Median sternotomy	RVAD, Cerebral anoxic coma and death	119	Death
8	15.9	90.0	1.93	DCM	24.0	HM3	BTC	Bilateral-thoracotomy	Post-hospital discharge driveline infection	418	HTx
9	13.9	41	1.37	DCM post chemotherapy	26	HM3	BTT	Median sternotomy	*None*	110	HTx
10	11	25	1.01	DCM genetically mediated	18	HM3	BTT	Median sternotomy	Bleeding requiring surgery	6	HTx
11	10.7	60	1.66	DCM genetically mediated	18	HM3	BTT	Median sternotomy	*None*	290	HTx

Abbreviations: BSA, body surface area; BTC, bridge-to-candidacy; BTT, bridge-to-transplant; CHD, congenital heart disease; DCM, dilative cardiomyopathy; DT, destination therapy; ESHF, end-stage heart failure; HTx, Heart transplant; LVEF, left ventricle ejection fraction.

provide flows up to 10 L/min, which became the most frequently implanted LVAD in pediatric patients from 2012 to 2020.[9–13] However, since its withdrawal in 2021, the HM3 is the only available intracorporeal device approved for patients with BSA >1.5 m^2.[15] Safe implantation has been reported often for HVAD,[5,6,16] while fewer cases of successful use of HM3 in children with BSA <1.5 m^2 have been described. This concern is valid since, despite being of similar dimensions, HVAD and HM3 are not the same. In fact, the rotor and the electronic circuitry of the HM3 device, that are sitting outside the heart are slightly larger than HVAD,[17] potentially leading to spatial constraints on implantation in children with a small chest cavity. At the same time, the HM3 has a shorter inflow cannula that can facilitate implantation in smaller hearts, reducing the risk of mitral valve suction events.

In our experience, in borderline children with a BSA <1.2 m^2, the preoperative angio-CT scan of the chest was used to reconstruct the patient's heart and rib-cage anatomy in 3D models and simulation of the LVAD in place. This was useful to evaluate the safety and feasibility of intrathoracic LVAD since it was possible to assess the relationship between rib cage, heart, and LVAD and minimize the risk of complications related to LVAD/chest cavity mismatch (i.e., internal chest wall damage, causing postoperative pain or hemorrhage, or kinking of the outflow graft). In addition, in such cases in whom the risk of the LVAD pump rubbing on the internal chest wall was considered higher, we took the precaution of suturing a Gore DualMesh in the area where the LVAD was close to the rib cage. This sponge not only helped prevent potential complications during LVAD support but also facilitated the inevitable redo surgery and tissue dissection at HTx. Moreover, all 3D evaluations were conducted with the LVAD positioned in the left pleural space. As part of our surgical procedure, we systematically opened the inferior half portion of the pleura to accommodate the LVAD pump during surgery.

In our experience, the surgical plan (i.e., HM3 implant vs EXCOR) was never modified when the chest was open, since we did not experience significant mismatch in the prediction made using preoperative 3D reconstruction. Thus, virtual fitting programming facilitated precise anticipation of the anatomical conditions encountered in the operating room, enabling meticulous preoperative planning without modifying the surgical approach or the type of implanted device.

However, there are some issues and pitfalls with the virtual imaging methodology. First, the heart does not have a fixed shape, and while an ECG-gated CT scan can capture the cardiac muscle both in systole and diastole, the reconstruction itself is limited to a single moment in time. Thus, we decided to reconstruct the heart in diastole in all cases, being the ventricular muscular wall being the thinnest in this phase (it represents the moment in time with the maximal dilatation of the chamber, and as such, it is the worst-case scenario for virtual fitting). Second, after LVAD implantation, the previously overloaded-dilated ventricle (typical of these patients) results in an unloaded one (due to the proper ventricular venting). This volume change must be considered when planning the LVAD implant in small chest cavities. Suppose a virtual fitting is feasible with full (end diastole) ventricular dimensions. In that case, this will almost guarantee an actual fit in the operating room (namely, it has a high positive predictive value for device fitting).

On the contrary, if the LVAD interferes with other anatomical structures, virtual ventricular unloading and reshaping can be attempted with CAD software. This process cannot guarantee realistic results. However, it can help estimate how much additional clearance is needed to allow implantation. Last, the technique we have used for standard heart chamber segmentation is based on reconstructing the contrast medium-filled chambers and not on the muscular walls. As a solution, we expanded the surface mesh by a fixed amount (roughly similar to the ventricular diastolic thickness) to create a virtual epicardial surface as measured on the original CT scan. In later reconstruction, we resorted to reconstructing the myocardium directly, as this was more accurate, albeit more time-consuming (Figure 3).

Last, it is evident that an adult-sized LVAD will never be suitable for an infant with ESHF as long as new miniaturized devices are produced. Currently, the smallest patient undergoing a HM3 implant ever reported had a BSA = 0.78.[7] However, pushing the limits safely (by virtual fitting) can enhance the utilization of such effective LVAD in more children, who can recover well at home while on the waiting list, with a good quality of life compared to other extracorporeal devices.[10]

Overall, in our experience, the use of intracorporeal LVAD (HVAD in 7, HM3 in 4) was highly successful, with only one late death in a 12.4-year-old boy with complex congenital heart disease due to severe cerebral hypoxic damage. Unlike other children, this boy was admitted urgently from another hospital with a very severe low cardiac output syndrome requiring rescue V-A ECMO support. This has undoubtedly contributed to the poor outcome. As shown by Lamba et al.,[18] clinical outcomes after LVAD implantation are significantly worse when pre-LVAD ECMO support is necessary, and surgical timing is crucial for a successful and uncomplicated device implantation.[19] Also, the incidence of neurological injuries is reported to occur up to 25%[20] after LVAD implant, and the rate of stroke is reported to be as high as 8.7% per year. However, the incidence of neurological complications seems to decrease with the increasing utilization of HM3 during the last 3 years.[21] Similarly, a recent experience with HM3 in pediatric patients has reported encouraging results, with

no events reported among 34 patients after HM3 implant at a median follow-up of 78 days (range 2–646 days).[15]

Overall, in our series, the most frequent complication was postoperative hemorrhage (4 patients) in the immediate postoperative days, in which anticoagulation therapy was still being optimized, as described in current literature.[6] The second most frequent complication was the exit-site driveline infections in 3 patients (30%) that occurred late after discharge home, as reported elsewhere.[21] Since it is well known that prevention plays a very relevant role in this matter, patients, and families in our center, before discharge, usually undergo a training course to treat the wound effectively, and this helps to minimize the impact of this issue, which is probably not eradicable.

5 | LIMITATIONS

Our study presents limitations due to the small numerosity, especially of those with BSA <1.2 m^2. However, the pediatric experience with intracorporeal LVAD is still limited in all cardiac centers. For this reason, we believe that this series can be helpful in the medical community to enhance the safe utilization of intracorporeal LVAD in children with ESHF.

6 | CONCLUSION

Continuous flow LVAD implantation can be a safe and feasible option in pediatric patients with a BSA as low as 1 m^2, as long as a comprehensive preoperative assessment and virtual fitting simulation with a 3D reconstruction of the device and the patient's chest is performed. The current advances in technology can effectively help to extend its application even to small children, enhancing survival and quality of life while on the waiting list.

AUTHOR CONTRIBUTIONS

Irene Cao, Enrico Italiano: Conceptualization, methodology, formal analysis, investigation, writing—original draft; Francesco Bertelli: Methodology, formal analysis, investigation; Biagio Castaldi: imaging and methodology; Raffaella Motta, Valeria Pergola: Imaging and revision; Alvise Guariento, Fabio Scattolin: methodology and supervision; Giovanni Di Salvo and Vladimiro Vida: methodology and supervision; Massimo A. Padalino: Conceptualization, methodology, formal analysis, investigation, writing—original draft; revision, editing, supervision.

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CONFLICT OF INTEREST STATEMENT

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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