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Original Research

Hemodynamic Monitoring of Pediatric Patients With Heart Failure and Pulmonary Hypertension Using CardioMEMS

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ABSTRACT

Background: The CardioMEMS is an implantable device for hemodynamic monitoring approved by the US Food and Drug Administration for adult patients with heart failure. It has been used in the adult population without structural heart disease and with congenital heart diseases, but we do not have data in the pediatric population.

Methods: We report the initial single-center experience of the CardioMEMS implantation in children. Feasibility of device implantation, procedural outcomes, and clinical utility in the pediatric population were evaluated.

Results: The CardioMEMS device was implanted without technical complications in 8 pediatric patients (mean age 7 years and mean weight 27.9 kg) with pulmonary hypertension (6/8, 75%) and heart failure (2/8, 25%). The device was delivered via femoral access in 7 (85%) patients and implanted in the left pulmonary artery in 7 (85%). The noninvasive recording of pulmonary pressures in patients with pulmonary hypertension allowed the monitoring of the evolution of mean pulmonary artery pressure, intensifying vasodilator treatment, and avoiding control cardiac catheterizations. In patients with heart failure, pulmonary hemodynamic monitoring guided the decongestive treatment prior to heart transplantation.

Conclusions: The implantation of CardioMEMS in the pediatric population is a feasible procedure that allows the noninvasive hemodynamic monitoring of patients with heart failure and pulmonary hypertension. Its implementation in selected patients aids in outpatient follow-up and therapeutic management of patients with complex cardiac conditions, avoiding invasive procedures that require hospitalization. Further large-scale studies in the pediatric population are recommended.

Introduction

Implantable devices for hemodynamic monitoring allow for ambulatory recording of pulmonary pressures with the aim of early detection of diastolic ventricular pressure elevation that precedes the clinical phase of heart failure decompensation.[1–5] CardioMEMS (Abbott) is a US Food and Drug Administration-approved implantable device for hemodynamic monitoring for adult patients with NYHA functional class III heart failure who have required at least 1 hospital admission in the year prior to implantation.[1,6] Studies conducted in adult populations without congenital heart disease have shown that heart failure treatment adjustments based on ambulatory pulmonary pressure recording reduced readmissions due to cardiac decompensation and improved the quality of life of heart failure patients.[2,5–10] The safety and accuracy of the CardioMEMS device have been confirmed in various studies of adult patients without structural heart disease[4–10] and in adult patients with congenital heart diseases,[11–13] but data in pediatric population are limited. Given the increasing survival of the pediatric population with heart failure and pulmonary hypertension,[14] ambulatory hemodynamic monitoring in children with the intrapulmonary CardioMEMS device may be a useful tool for disease control, to optimize treatment, to decrease cardiac decompensations, and to prevent hospital admissions that compromise survival and the quality of life of children and their families. Our objectives are to describe the feasibility and safety of percutaneous implantation of the CardioMEMS device in the pediatric population and to analyze the usefulness of noninvasive hemodynamic monitoring in detecting the progression of pulmonary hypertension and pediatric heart failure.

Methods

Patients under 18 years of age with at least moderate pulmonary arterial hypertension, on double or triple pulmonary vasodilator

Abbreviations: IPAH, idiopathic pulmonary arterial hypertension; mPAP, mean pulmonary artery pressure.

Keywords: CardioMEMS; children; heart failure; implantable hemodynamic device; pulmonary hypertension; remote monitoring.

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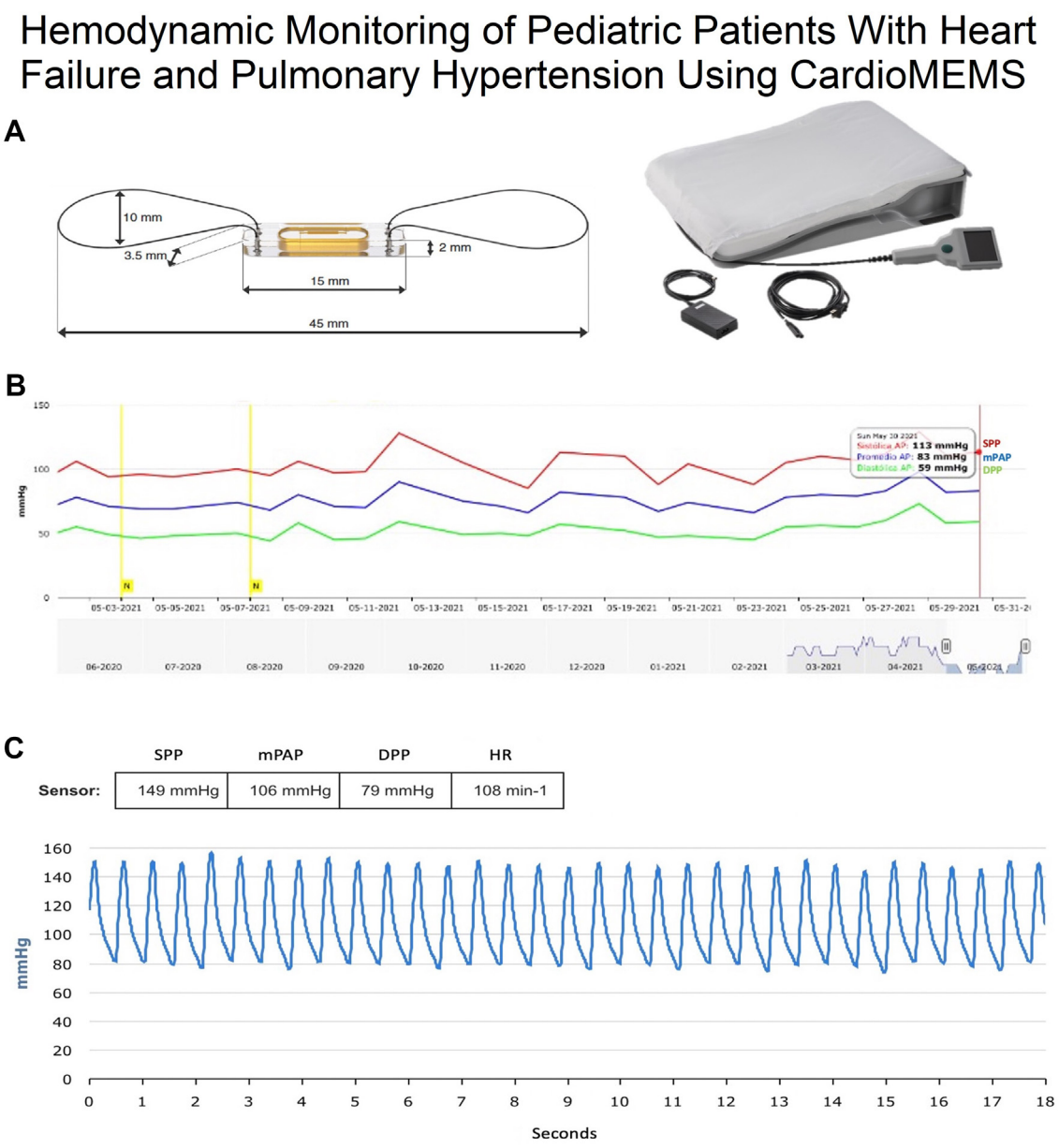

Central Illustration.
CardioMEMS in the pediatric population allows noninvasive hemodynamic monitoring of patients with heart failure and pulmonary hypertension. (**A**) The CardioMEMS sensor and patient home electronics unit (reprinted with permission from Abbott). (**B**) Patient 1, idiopathic pulmonary arterial hypertension: systolic pulmonary pressure (SPP) 113 mm Hg; mean pulmonary artery pressure (mPAP) 83 mm Hg; diastolic pulmonary pressure (DPP) 59 mm Hg. (**C**) Patient 1, idiopathic pulmonary arterial hypertension: SPP 149 mm Hg; mPAP 106 mm Hg; DPP 79 mm Hg. HR, heart rate.

therapy, and/or patients with heart failure with or without structural heart disease at high risk of cardiac decompensation were considered candidates for device implantation. All cases were discussed in a multidisciplinary session. No one case was indicated alone for the device implantation; all patients had a regular indication for hemodynamic evaluation. The study was conducted in compliance with the Declaration of Helsinki and was approved both by our institutional review board and by the Spanish Medicine and Healthcare Products Regulatory Agency. Parents were informed about the compassionate character of the indication and gave their informed consent in all cases. The following were established as exclusion criteria: unfavorable intrapulmonary anatomy for device implantation, active pulmonary or systemic infection, previous history of pulmonary thromboembolism, state of hypercoagulability and contraindication of anticoagulation or antiplatelet therapy during the first month postimplant. During the hemodynamic procedure, we routinely perform a pulmonary angiogram, at which time we analyze the morphology and dimensions of the pulmonary vasculature to decide if the intrapulmonary anatomy is favorable. Clinical and procedure data analyzed were sociodemographic variables, cardiac diagnosis, functional class and previous invasive procedures, technical issues, and complications. All patients had laboratory testing prior to implantation (complete blood count, metabolic panel, and coagulation testing). All patients received antiplatelet therapy during the first month after implantation, except for 2 patients with previous anticoagulant treatment and 1 patient who suffered a renal bleed related to a cystic kidney malformation. If there was no further indication for antiaggregation, aspirin was discontinued based on the lower thrombotic risk and higher bleeding risk in the pediatric population compared to the adult patients. Patients who were taking previous anticoagulation maintained it indefinitely. The

Table 1. Demographics, clinical data, and CardioMEMS device details.

Patient	Sex	Age, y	Weight, kg	Cardiac background	Therapy	Vascular access	CardioMEMS location
1	Female	11	30	IPAH	Triple vasodilators	Femoral	LPA
2	Male	4	18	Aortic stenosis	Berlin Heart Diuretics	Femoral	LPA
3	Male	4	12	CDH	Triple vasodilators	Femoral	RPA
4	Female	11	40	IPAH	Triple vasodilators	Femoral	LPA
5	Female	10	27	Eisenmenger	Triple vasodilators	Jugular	LPA
6	Female	10	30	Mitral atresia Fontan	Double vasodilators	Femoral	LPA
7	Male	2	11.5	BPD	Double vasodilators	Femoral	LPA
8	Female	14	55	Mitral stenosis	Diuretics	Femoral	LPA

BPD, bronchopulmonary dysplasia; CDH, congenital diaphragmatic hernia; IPAH, idiopathic pulmonary arterial hypertension; LPA, left pulmonary artery; RPA, right pulmonary artery.

CardioMEMS device (Central Illustration) is a radiopaque sensor 15 mm long × 3 mm wide × 2 mm thick that wirelessly transmits the pulmonary pressure recorded by the patient to a remote digital system. It contains 2 conducting plates that form a capacitor coupled to a coil and 2 nitinol loops at the ends to prevent migration. As the pressure changes, the distance in the capacitor changes, and the frequency of the circuit changes. This frequency change allows the pressure inside the pulmonary artery to be measured accurately. To record the pressure, an antenna is required, which is located on a pillow of the patient and emits a radiofrequency signal capable of picking up the resonant frequency of the sensor and sending the pressure information to a digital platform.

Prior to device implantation, all patients underwent a hemodynamic study followed by pulmonary angiography to determine the anatomy of the pulmonary vascular tree. Venous access is typically obtained via the right femoral or internal jugular vein. Clinical assessment and adherence to local protocols determine a patient's candidacy for implantation. This involves an echographic evaluation of the vein to ensure it has a minimum diameter of 3 mm in the axial section, followed by an angiographic verification of the vein's caliber through manual injection via the chosen introducer for standard catheterization. The entire procedure is conducted under fluoroscopic control using a biplane system (Artis Zee, Siemens) with a low-dose protocol at 7.5 images per second.

Hemodynamic catheterization adheres to conventional standards regarding catheters, guidewires, pressure measurements, and resistance calculations. If implantation is considered, a contrast injection is performed using a pump through an angiographic catheter positioned in the pulmonary trunk or left pulmonary branch (0.5 mL of isosmolar contrast per kilogram of body weight, diluted with isotonic saline solution in a 70% contrast to 30% saline ratio) and biplanar acquisition at 15 images per second. The pulmonary architecture is then examined to identify an ideal implantation site, requiring a length of at least 30 mm and initial and final diameters of 7 and 5 mm, respectively, with a bifurcation pattern showing branches larger than 3 mm in diameter. If this initial anatomical approach is insufficient, a rotational angiographic acquisition is performed with the same equipment, moving to the lateral plane for 5 seconds during injection into the trunk or main branch, with a 1-second delay from the injection, using 1 m: of volume (60% contrast, 40% saline). The generated image is assessed for quantification using MPR sequences with the same objectives as the previous conventional angiography, and the VRT volume is used in conjunction with the fluoroscopic image throughout the remainder of the procedure. Once the target site is selected, the angiographic catheter is exchanged over a conventional 0.035 guidewire, which serves as a support for successive dilations of the venous access point until the 12 F introducer advances without resistance. A multipurpose 5F catheter is then advanced over the guidewire, followed by a 0.35 hydrophilic guidewire to position the catheter in the selectedsegment. After removing the hydrophilic guidewire, a small manual contrast injection is performed to evaluate the distal anatomy before advancing a 0.018" guidewire Hi-Torque SteelcoreTM LT 300 cm (Abbott) through the catheter, ensuring the floppy segment does not distort or angle and that a non-floppy portion is present at the device implantation site.

With these considerations meticulously observed and the catheter removed, the catheter housing the CardioMEMS is advanced, paying attention to smooth and natural progression until reaching the destination and proceeding with its release. Following this, the catheter is removed, and the previous multipurpose catheter is reinserted to a position proximal to the device's release point. A manual contrast injection is then performed through the catheter via a Y-connector without removing the guidewire, and biplanar images are acquired to assess the occupied volume of the device, its loops, and any potential interference with the distal filling of that branch or collateral vessels. Calibration of the implanted sensor was performed with the detector located on the patient's back and direct measurement of pulmonary pressure with the catheter located in the same artery that houses the device, confirming the correct position of the CardioMEMS with pulmonary angiography. To reduce radiation doses in our pediatric population, we do not routinely perform chest x-rays to verify device position when remote transmissions are correct. Parents were instructed on how to use the CardioMEMS device to transmit readings once a day after placement and prior to hospital discharge. To verify that remote transmission was successful, the parents were contacted by the team for the first week after discharge. After the first week postimplantation, the parents were not contacted unless they reported a change in clinical status or the readings were repeatedly altered. Transmissions were reviewed by the team on a weekly basis.

Table 2. Characteristics of patients with pulmonary hypertension.

Patient	Sex	Age, y	Diagnosis	Initial mPAP, mm Hg	Follow-up	Outcome
1	Female	11	IPAH	70	2 y, 4 mo	Pulmonary transplant
2	Male	4	CDH	65	2 y, 5 mo	Clinical stability
3	Female	11	IPAH	50	1 mo, 12 d	Exitus (septic shock)
4	Female	10	Eisenmenger	50	2 y, 1 mo	Clinical stability
5	Male	2	BPD	65	1 y, 10 mo	Clinical stability
6	Female	14	Mitral stenosis	30	1 y, 2 mo	Clinical stability

BPD, bronchopulmonary dysplasia; CDH, congenital diaphragmatic hernia; IPAH, idiopathic pulmonary arterial hypertension; mPAP, mean pulmonary artery pressure.

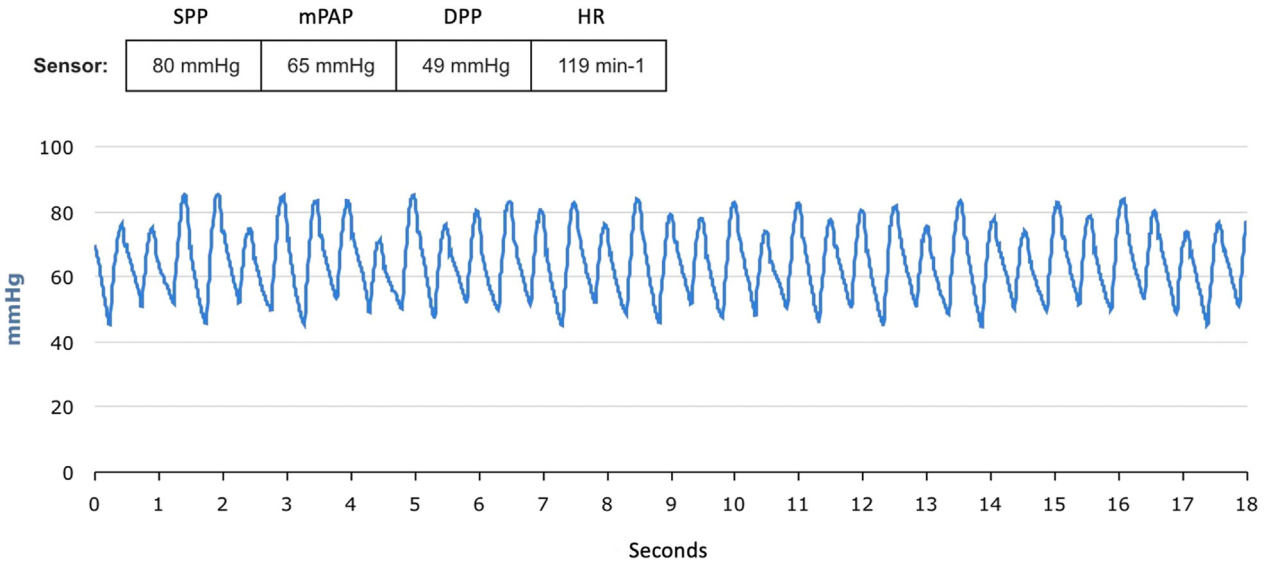

Figure 1.
Patient 7, bronchopulmonary dysplasia: systolic pulmonary pressure (SPP) 80 mm Hg; mean pulmonary artery pressure (mPAP) 65 mm Hg; diastolic pulmonary pressure (DPP) 49 mm Hg. HR, heart rate.

Results

The CardioMEMS device was implanted without technical complications in 8 pediatric patients (mean age 7 years and mean weight 27.9 kg) with pulmonary hypertension (6/8, 75%) and heart failure (2/8, 25%). Table 1 describes the general characteristics of the patients and details of the procedure. The device was placed in the left pulmonary artery in 7 patients and in the right pulmonary artery in 1 patient due to left pulmonary hypoplasia. The procedure performed in pediatric age requires some considerations compared to adulthood: (1) Children are considerably more ill compared to adults, and the manipulation of guides and catheters is more complex and delicate, as is the collection of oximetry samples and gases, as well as the tracings of pressures and the establishment of "0" must be much more demanding. (2) Special care is needed in vascular access, which should be echo-guided and treated in the same way as other complex interventional procedures. (3) The fact that patients are anesthetized means there is less interference from the movement of the thoracic cage, which favorably influences the decision of the anchoring site. (4) The length of the floppy end of the guidewire poses a challenge in pediatric patients. Avoiding distortions of the guidewire to minimize device movement during its removal makes it particularly complex to ensure sufficient length of the rigid portion at the point of release. (5) The smaller difference in the distance between the implantation point and the area where the interrogation is to be performed is advantageous and allows it to be carried out in locations that would not be viable in adults. (6) The size of the pulmonary branches in pediatric patients differs from the standard observed in adults and is related to the size and surface area of

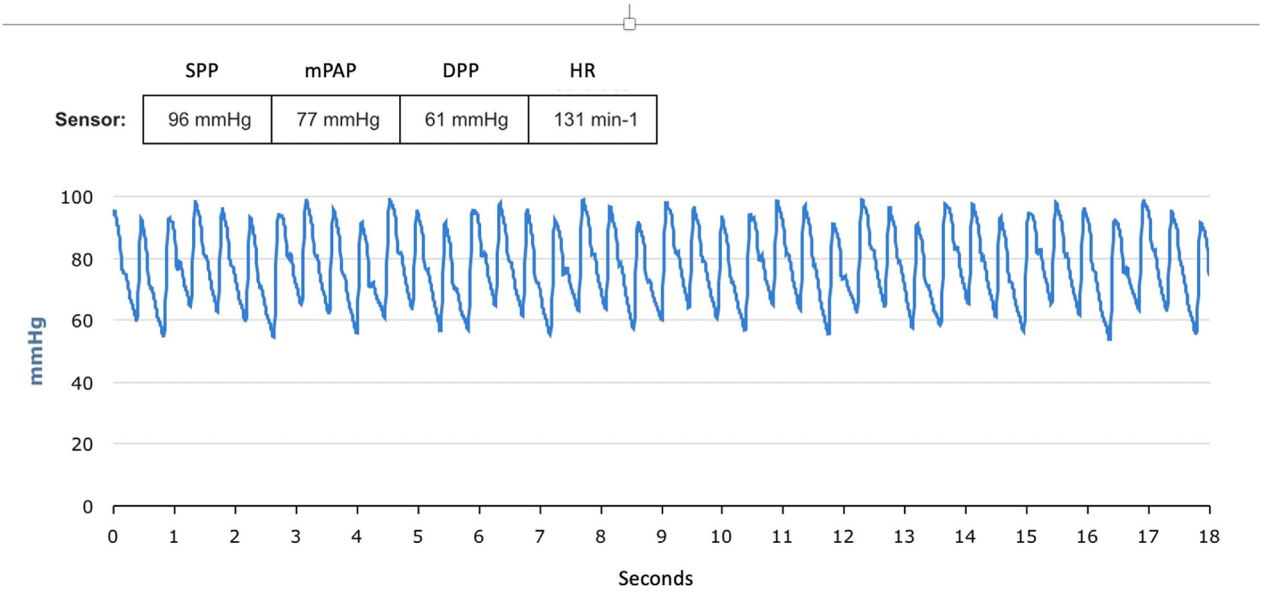

Figure 2.
Patient 3, congenital diaphragmatic hernia: systolic pulmonary pressure (SPP) 96 mm Hg; mean pulmonary artery pressure (mPAP) 77 mm Hg; diastolic pulmonary pressure (DPP) 61 mm Hg. HR, heart rate.

Table 3. Characteristics of patients with heart failure.

Patient	Sex	Age, y	Diagnosis	Initial mPAP, mm Hg	Follow-up	Outcome
1	Male	4	Aortic stenosis Berlin Heart	18	2 y, 6 mo	Heart transplant
2	Female	10	Failing Fontan	17	2 y	Heart transplant

mPAP, mean pulmonary artery pressure.

the pediatric patient. This necessitates a careful selection of the theoretical implantation site based on diameters, lengths, and bifurcation patterns. In these patients, subsequent catheterizations have been required due to their underlying conditions, during which control angiographic studies were conducted. These studies have not shown any interference in the flow within the hosting branch or at the bifurcations. Our implants were performed in procedures not indicated based on the need for implantation but on the need for the hemodynamic or interventional study required by the child; the pediatric cath lab is a biplane laboratory, and the average fluoroscopy time on plane A was 21.5 minutes (range, 11.02-39.53) and on plane B was 8.08 minutes (range, 3.2-25.45), and the DAP on plane A was 1367.36 mGy·cm^2 (range, 500.99-2149.92) and on plane B was 714.56 mGy·cm^2 (range, 162.89-2130.67).

The median follow-up was 24.1 months (range, 12.9-31.0 months). During the follow-up, there were no clinical pulmonary venous thromboembolic events. Implantation was ruled out in 2 more patients not included in the study, 1 with dilated cardiomyopathy due to the finding of a pulmonary arteriovenous fistula and another patient with idiopathic pulmonary arterial hypertension (IPAH) due to inadequate size of pulmonary branches. All patients carrying the device had undergone previous cardiac catheterizations due to their underlying condition and all were considered potential candidates for cardiac or pulmonary transplant. All patients, except 1, were followed for a minimum of 12 months postimplant and were evaluated clinically at 1 month postimplant and a minimum every 3 months.

Patients with pulmonary hypertension

Of the 6 patients with pulmonary hypertension, 2 of them were diagnosed with IPAH, 2 patients with congenital heart disease (large ventricular septal defect in Eisenmenger syndrome and mitral stenosis), 1 patient with repaired congenital diaphragmatic hernia, and 1 patient with bronchopulmonary dysplasia (Table 2). Prior to the device implantation, 4 patients were on triple vasodilator therapy (phosphodiesterase inhibitors, endothelin receptor antagonists, and subcutaneous prostanoids). The noninvasive monitoring of pulmonary pressures in patients on triple therapy allowed the tracking of the mean pulmonary artery pressure (mPAP), intensifying vasodilator treatment, and avoiding control cardiac catheterizations (Central Illustration). In 1 of the patients with IPAH, the progressive increase in mPAP above 90 mm Hg, despite maximal vasodilator therapy, coupled with functional deterioration and worsening echocardiographic findings, led to inclusion on the lung transplant waiting list (Central Illustration). In this patient with IPAH, we performed a magnetic resonance scan without any artifacts or subsequent effects on the function of the device. The second patient with IPAH on triple therapy suffered a renal bleed in the context of a cystic renal malformation, which worsened into fulminant sepsis and death. In the patient with bronchopulmonary dysplasia, the pulmonary vasodilator treatment with prostanoids was intensified after CardioMEMS implantation as the mPAP remained >60 mm Hg (Figure 1). The remaining 3 patients with pulmonary hypertension (congenital diaphragmatic hernia, Eisenmenger syndrome, and mitral stenosis) have remained clinically stable, with chronically elevated mPAP despite treatment (Figure 2).

Patients with heart failure

Of the 2 patients with heart failure and ventricular dysfunction, 1 was diagnosed with aortic valve stenosis and the other with complex congenital heart disease with multiple interventions in a single ventricle functional situation (Table 3). Prior to the intrapulmonary sensor implantation, the patient with aortic stenosis required a Berlin Heart type left ventricular assist device (LVAD) due to advanced heart failure refractory to medical treatment and was included on the

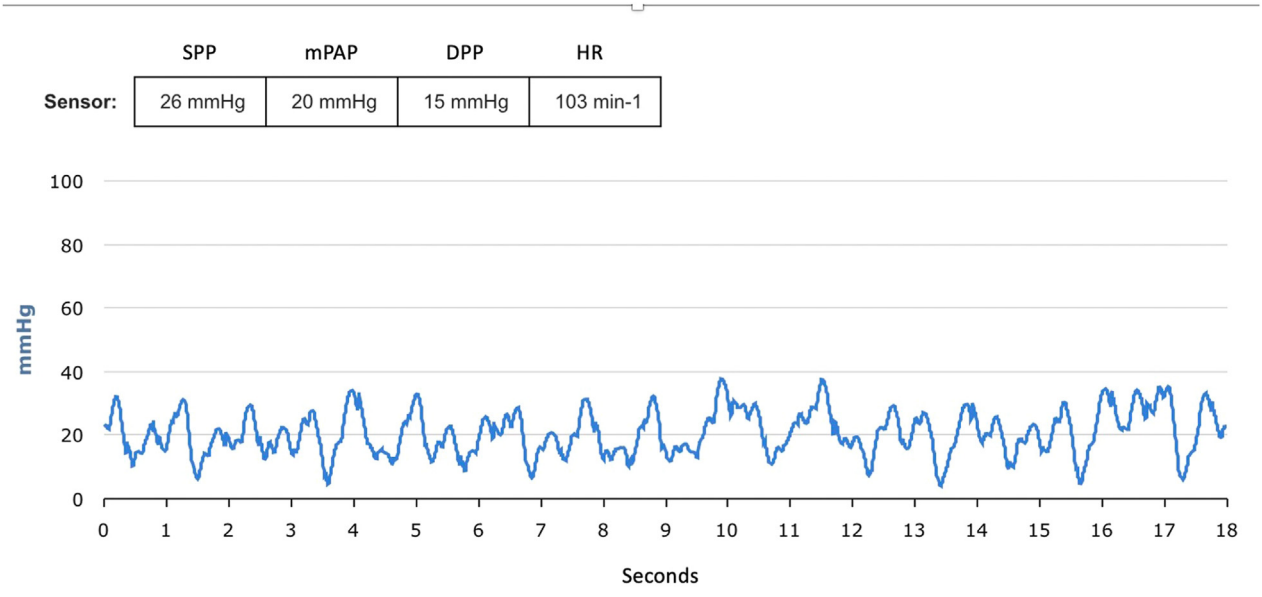

Figure 3.
Patient 2, aortic stenosis with Berlin Heart device awaiting heart transplant: systolic pulmonary pressure (SPP) 26 mm Hg; mean pulmonary artery pressure (mPAP) 20 mm Hg; diastolic pulmonary pressure (DPP) 15 mm Hg. HR, heart rate.

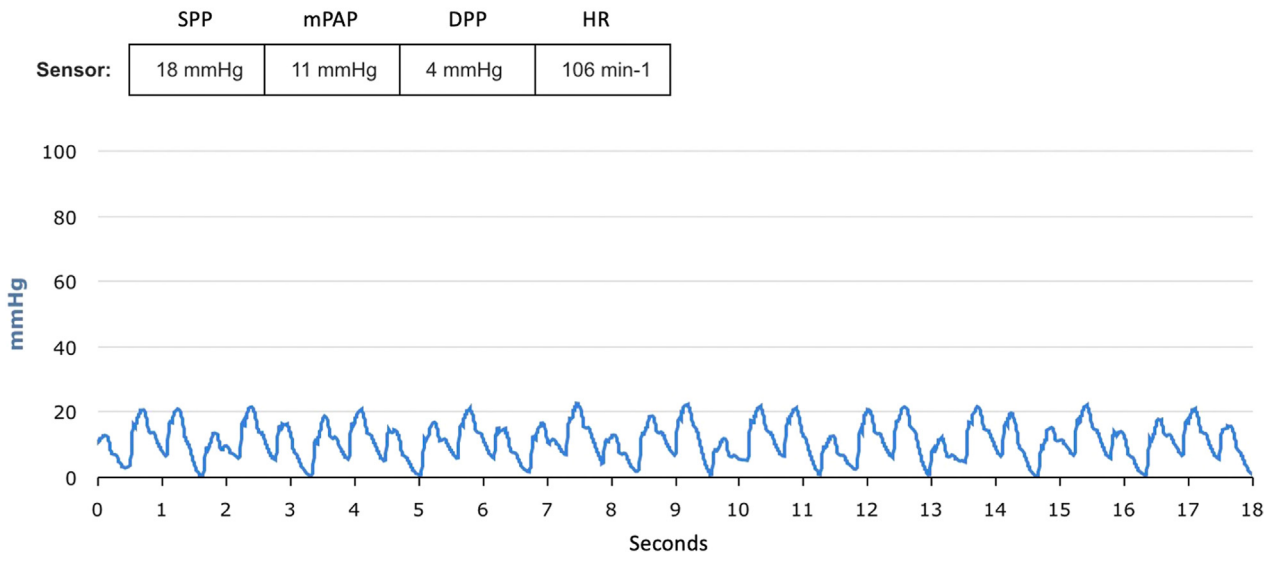

Figure 4.
Patient 2, aortic stenosis with Berlin Heart device after heart transplant: systolic pulmonary pressure (SPP) 18 mm Hg; mean pulmonary artery pressure (mPAP) 11 mm Hg; diastolic pulmonary pressure (DPP) 4 mm Hg. HR, heart rate.

heart transplant waiting list; monitoring pulmonary pressures in left ventricular assist allowed to guide anticongestive treatment while waiting for a transplant (Figure 3). After 1 year on the waiting list, the patient was successfully transplanted, and noninvasive control of pulmonary pressures has been maintained from the immediate posttransplant period to the present (Figure 4). The patient with a single ventricle had moderate ventricular dysfunction with functional class II to III; the CardioMEMS registered a constant mean pulmonary pressure of 18 mm Hg; hence, sildenafil and bosentan were added with good clinical tolerance and the mean pulmonary pressure being maintained between 15 to 18 mm Hg (Figure 5). She underwent a heart transplant 1 year after the CardioMEMS implant, but reliable pulmonary pressure values could not be achieved posttransplant. Despite several attempts to recalibrate the device, we were unable to obtain a reliable signal. Displacement of the device, a technical defect or a lost signal from an unclear mechanism could explain this scenario (Figures 6 and 7).

Discussion

We present the first experience in the use of the CardioMEMS device in the pediatric population with heart failure and pulmonary hypertension, with its implantation being feasible in our series in a patient under 3 years of age and weighing 11.5 kg. We gained vascular access via the right femoral vein in the majority of cases and the usual location of the device was the left pulmonary artery, without migration or thrombosis of the device. The right jugular access was used in a patient with congenital heart disease and interruption of the inferior vena cava. This access did not pose a limitation for the device implantation as described in the adult

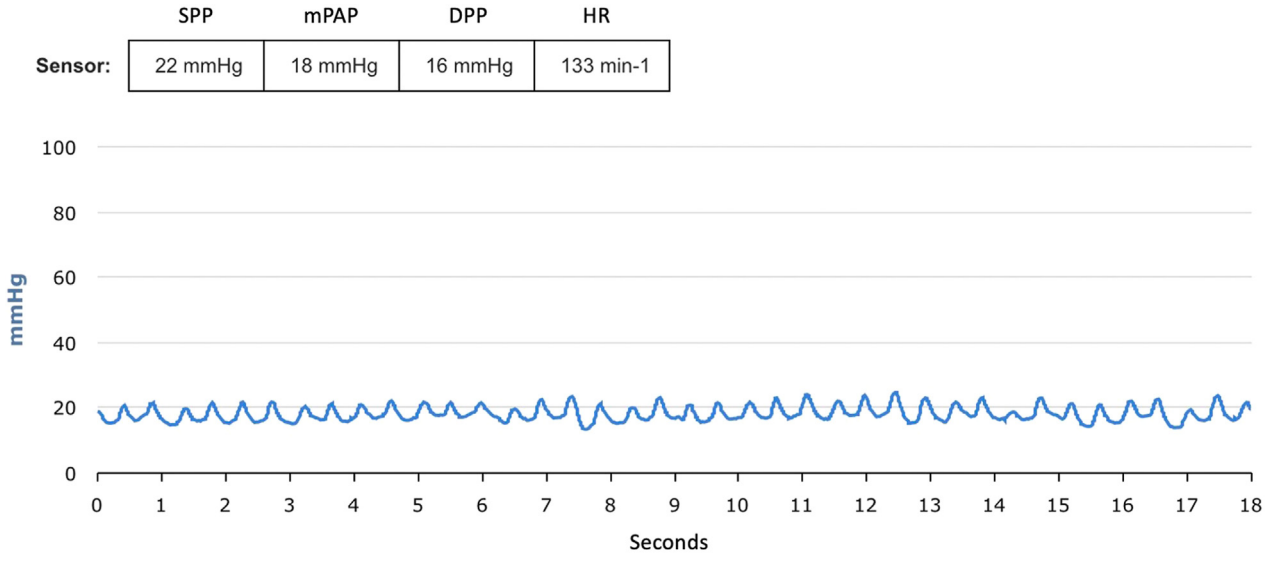

Figure 5.
Patient 6, Fontan awaiting heart transplant: systolic pulmonary pressure (SPP) 22 mm Hg; mean pulmonary artery pressure (mPAP) 18 mm Hg; diastolic pulmonary pressure (DPP) 16 mm Hg. HR, heart rate.

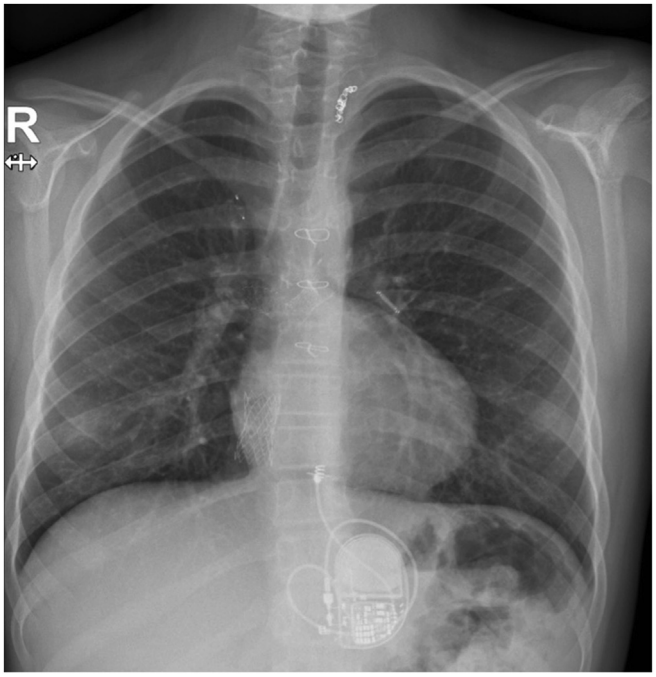

Figure 6.
Patient 6, Fontan awaiting heart transplant: CardioMEMS located in left pulmonary artery.

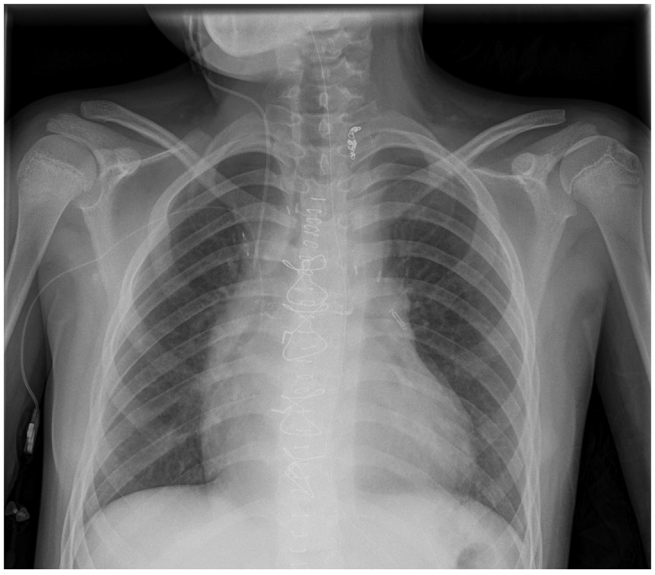

Figure 7.
Patient 6, Fontan after heart transplant: CardioMEMS located in a different position of the left pulmonary artery.

population as many centers have gained experience with the implant procedure.[15]

Following implantation, both acutely and in follow-up, valid serial records of pulmonary pressures (systolic, diastolic, and mean) and heart rate were obtained. In follow-up, we established a minimum review of pulmonary pressures 3 times a week and consequently, we maintained or intensified the vasodilator treatment depending on the serial records. Only in 1 patient with failed Fontan who underwent a heart transplant, the pressure recording quality decreased after the heart transplant, possibly due to the surgical intervention and manipulation and the change from passive to pulsatile pulmonary circulation. In the group of patients with pulmonary hypertension, the noninvasive monitoring of pulmonary pressures allowed an increase in vasodilator treatment without subjecting patients to a control catheterization. Although right heart catheterization continues to be the gold standard technique for measuring cardiopulmonary hemodynamics, it is an invasive procedure with risk of complications, and in children, it requires general anesthesia and orotracheal intubation. With CardioMEMS we avoid invasiveness in the pediatric population and home hemodynamic monitoring, unlike conventional hemodynamic evaluation at a single point. During the COVID-19 pandemic, the CardioMEMS sensor allowed us the possibility of remote pediatric care, decreasing hospital visits in periods of high pandemic peaks.

In the group of patients with heart failure, the serial information on pulmonary pressures facilitated the management of anticongestive medical treatment as has already been described in adult patients.[2–4] In the patient with Fontan, the device managed to monitor pulmonary pressures despite the absence of pulsatility, in the same way as the experience reported by Salavitabar et al[11] in adult patients with palliated congenital heart diseases. Recently Bhat et al[16] have reported the safety and utility of CardioMEMS device in eight pediatric Fontan patients without complications related to the implantation of the device. According to our experience, Bhat et al[16] highlight that this device may be safely utilized in pediatric population.

In the patient with aortic stenosis and severe ventricular dysfunction who had a Berlin Heart LVAD, CardioMEMS allowed us to adjust diuretic treatment until the time of heart transplant. This clinical scenario has also been described in adult patients with LVAD.[17–20] In the adult setting, a study investigated the feasibility of CardioMEMS monitoring before and after LVAD surgery, categorizing patients based on mPAP $\leq$25 mm Hg or >25 mm Hg. This study showed that combining CardioMEMS with LVAD therapy was safe and generated the hypothesis that patients with a mPAP >25 mm Hg were at higher risk of developing adverse outcomes such as acute kidney injury and right ventricular failure.[17–20]

In our pediatric patient with Berlin Heart LVAD, the implant of the CardioMEMS was feasible, safe, and useful in the long run to adjust the heart failure therapy.

Recently Brugts et al[21] have reported the European experience of hemodynamic monitoring of pulmonary pressure in adult patients with chronic heart failure (MONITOR-HF). In this randomized clinical trial, 348 patients were assigned to hemodynamic monitoring (CardioMEMS) or standard care, concluding that the remote monitoring substantially improved quality of life and reduced heart failure hospitalization in patients with moderate-to-severe heart failure treated according to contemporary guidelines. Multicenter studies in the pediatric population are needed to evaluate whether CardioMEMS holds additional value in the monitoring of children with advanced heart failure. To date, the limited data on this device in the pediatric population[16] has been satisfactory and its use in children may be safe without major complications. In the adult population approximately 2.8% of patients experience adverse events[22] such as lung injury/hemoptysis, access site bleeding, infection or device thrombosis. Cases of sensor failure requiring recalibration and/or device migration have also been reported. Therefore, we should be aware of these potential complications in the pediatric population.

Conclusion

The CardioMEMS device in the pediatric population is a feasible procedure that allows noninvasive hemodynamic monitoring of patients with heart failure and pulmonary hypertension. Its implementation in selected patients aids in outpatient follow-up and therapeutic management of patients with complex cardiac conditions, avoiding invasive procedures that require hospitalization. Multicenter studies are necessary to confirm safety and efficacy in the pediatric population with heart failure and pulmonary hypertension.

Declaration of competing interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethics statement and patient consent

This research adhered to the relevant ethical guidelines, and patient consent was obtained.

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