

Neonates and infants requiring life-long cardiac pacing: How reliable are epicardial leads through childhood?

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ABSTRACT

Background: In the literature, data is lacking on mid-term results of epicardial pacemaker implantation in neonates and infants. Our aim was to evaluate the mid-term results of epicardial pacemakers implanted in infants under 1 year of age.

Methods and results: We conducted a retrospective review of patients who underwent pacemaker implantation between 2000 and 2017. Pacemaker and lead parameters were reviewed at discharge, 2, 4 and more than 5 years after implantation. A total of 71 patients aged 4 ± 3 months and weighing 4 ± 2 kg were included in the study. Indications for pacemaker implantation were: acquired AV-block ($n = 44$), congenital AV block ($n = 22$), sick sinus syndrome ($n = 4$) and AV block type Mobitz II ($n = 1$). Median follow-up time was 5 years (range: 1 month–17 years). At 5 years of follow-up, atrial lead energy threshold for pacing decreased significantly ($0.72 \pm 0.71 \mu\text{J}$ to $0.45 \pm 0.35 \mu\text{J}$; $P < 0.001$) but was stable for ventricular leads ($0.57 \mu\text{J}$ [0.05; 39.47] to $0.64 \mu\text{J}$ [0.13; 9.45], $P = 0.97$). Atrial lead impedance increased significantly ($569 \pm 137 \Omega$ to $603 \pm 134 \Omega$, $P < 0.001$), whereas ventricular lead impedance decreased ($603 \pm 202 \Omega$ to $490 \pm 150 \Omega$, $P < 0.001$) after 5 years. Repeat operations were required for generator change ($n = 55$), lead exchange ($n = 17$) and infection ($n = 1$). At 2, 5 and 10 years, atrial lead survival was 96%, 91% and 76% and ventricular lead survival was 94%, 82% and 75%, respectively ($P = 0.45$).

Conclusion: Stable pacing thresholds after 5 years indicated that epicardial pacemakers are safe for infants under 1 year of age until at least school enrolment age. However, due to stimulation at higher heart rates in infancy, battery depletion is a frequent occurrence.

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1. Introduction

Epicardial PM implantation, with its need for an open access to the heart is, compared to endocardial pacing through the percutaneous approach, a rarely performed surgical procedure. In 2016, more than 75,000 endocardial PM systems were implanted in Germany, whereas

epicardial PMs are thought to account for less than 1% of this number [1]. Hence, only a few experienced institutions perform this challenging operation [2]. The main indications for permanent epicardial pacing in neonates and infants is bradycardia due to either a congenital complete heart block (CCHB), acquired complete heart block (ACHB) or sinus node dysfunction following open heart surgery [3]. The small size of the vessels, the significant risk of venous thrombosis and the implications of life-long pacing associated with the need for numerous exchanges of leads and PM generators, lead most surgeons to decide in favour of epicardial PM systems as the preferred option in this patient cohort [4]. Currently, data on very young patients who undergo PM implantation remain scarce. In this study we sought to investigate the mid-term results of permanent epicardial PM implantation in neonates and infants who required a PM system within the first year of life.

Abbreviations: ACHB, acquired complete heart block; CCHB, Congenital complete heart block; CHD, Congenital heart disease; CI, Confidence interval; IQR, Interquartile range; KM, Kaplan-Meier; MET, Minimum energy threshold; PM, Pacemaker.

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¹ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

2. Methods

2.1. Data collection

This study was approved by the Ethics Committee of the Technical University of Munich.

We reviewed the data of all patients undergoing a PM implantation between June 2000 and July 2017 at the German Heart Centre Munich. A complete search of the Centre's cardiac surgical and PM databases identified 209 patients receiving an epicardial PM implantation during their childhood. Since the study aimed to evaluate mid-term results, the study population was limited to patients who survived the first month after PM implantation. There were 4 deaths prior to 1 month following PM implantation who were therefore excluded: of these, none was actually attributable to the PM implantation but due to the underlying congenital cardiac malformation and related postoperative complications.

Inclusion criteria were as follows: (1) age < 1 year at time of implantation and (2) first PM implantation performed at our institution. End-points of the study were: (1) generator exchange, (2) lead exchange or (3) change to a transvenous system.

All patients without follow-up after January 2016 were considered as lost to follow-up. Thus 2 patients (who moved abroad) were lost to follow up.

After applying all inclusion and exclusion criteria, 71 patients remained for statistical analysis.

2.2. Patient population

The following demographic characteristics were collected for every patient: age and weight at the time of PM implantation, sex, indication for PM implantation, further diagnoses, surgical approach, implanted PM and lead types, and cardiac operations before PM implantation.

Indication for PM implantation was based on the American College of Cardiology/American Heart Association Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities [3]. The preferred surgical approach for each patient was discussed in a multidisciplinary team meeting, consisting of congenital cardiac surgeons, congenital electrophysiologists and congenital cardiologists.

Patients with CCHB or ACHB were compared for differences in demographic parameters.

2.3. Operative and technical data

Surgical access for PM implantation was via: (1) median or (2) partial inferior sternotomy; or (3) posterolateral thoracotomy. The surgical approach for each patient was chosen based on prior cardiac operations, cardiac anatomy and any planned concomitant operation at the time of PM implantation. Usually, bipolar steroid-eluting epicardial leads were fixated with two 5/0 polypropylene sutures. Screw-in leads were used in those patients in whom suture-fixation leads did not provide sufficient sensing and pacing thresholds. Atrial leads were attached to the lateral aspect of the right atrium. Ventricular leads were placed as close as possible to the apex of the right or left ventricle, depending on cardiac morphology. If sensing and pacing thresholds were satisfactory, the definitive position was then determined.

2.4. PM analysis and follow-up

In general, the PM generator and leads were analysed on the first day after surgery, before discharge from hospital and 1, 3 and 6 months after implantation. After that, PM analysis was conducted at follow-up every 6 months. Lead parameters measured during follow-up were: (1) sensed P- and R-wave amplitudes (in millivolts) if an underlying heart rhythm was present, (2) impedance of implanted leads (in

ohms), (3) minimal pacing threshold (in volts) and pulse width (in milliseconds) where consistent capture was still possible. To minimize the electrical energy output and to prolong the battery life, a longer pulse width was set before increasing the pacing voltage in some patients with rising pacing thresholds. In these cases, capture measurements during the next analysis were conducted with the newly set pulse width, reducing the pacing voltage until consistent capture was no longer achievable. Consequently, however, pure pacing voltages between patients with different pulse widths were no longer comparable. To get a reliable value for all patients, we calculated the MET according to the following formula [5].

$$\text{MET } (\mu\text{J}) = \frac{[\text{pacing voltage (V)}^2 \times \text{pulse width (ms)} \times 10^6]}{[\text{impedance } (\Omega) \times 10^3 \text{ ms/s}]}$$

Pacing and sensing thresholds, lead impedance and calculated MET were compared at the time at discharge from hospital, and after 2 years, 4 years and more than 5 years. Time at discharge from hospital was defined as the time from PM implantation to the last available analysis within the same hospital stay. This time span ranged from 1 to 54 days.

2.5. Outcome variables

The primary endpoint was the time to generator or lead exchange. Generator exchange was necessary either due to battery depletion, upgrade to dual-chamber pacing, cardiac resynchronization therapy, downgrade to single-chamber pacing or infection. Lead reintervention was necessary either because of lead dislocation, increase in pacing thresholds, phrenic nerve stimulation, lead fracture, loss of sensing or inappropriate sensing of myopotential signals of skeletal muscles.

2.6. Statistical analysis

Statistical analysis was performed using SPSS 23.0 software (IBM SPSS, IBM Corp., New York, USA). Frequencies are given as absolute numbers and percentages. Continuous data are given as medians with full range or IQR or as means with standard deviation. Comparisons for categorical variables (sex, pacing mode) were calculated with the two-tailed χ^2 -test. Comparisons for continuous variables (values for MET, impedance and sensing) were calculated with the *t*-test for independent samples. The KM method was used to estimate freedom from events. The time of PM generator or lead implantation was defined as time point zero. Differences between groups were calculated with the log-rank test (atrial vs. ventricular leads, pacing mode). Risk factors for PM or lead re-intervention were analysed with a linear univariate and multivariate Cox regression model. For all tests, a *P*-value ≤ 0.05 was considered as significant.

3. Results

3.1. Patient characteristics

Mean patient age and weight at PM implantation was 4 ± 3 months and 4 ± 2 kg, respectively. The smallest patient weighed 2.0 kg and the youngest patient was 2 days old. Median duration of follow-up was 5 years (range: 1 month–17 years). CHD was present in 60 patients (85%). Of the 11 patients with structural normal hearts, 9 had an isolated CCHB and 2 a sick sinus syndrome. Patient characteristics are summarized in Table 1.

Postoperative ACHB occurred after: arterial switch operation (*n* = 9), correction of partial or complete atrioventricular septal defect (*n* = 8), closure of a ventricular septal defect (VSD) (*n* = 7), resection of left ventricular outflow tract obstruction (*n* = 5), Tetralogy of Fallot repair (*n* = 3), total cavopulmonary connection (*n* = 2), partial cavopulmonary

connection (n = 3), mitral valve repair or replacement (n = 5), tricuspid valve repair (n = 1) and aortic valve replacement (n = 1).

Patients with ACHB (n = 44) had their PM implanted 2 months later than patients with CCHB (4 ± 3 months vs. 2 ± 3 months, respectively; n = 22, P = 0.027). There was no difference in all other demographic parameters between the two groups (weight: 4.6 ± 1.7 kg vs. 3.9 ± 1.7 kg, P = 0.10; duration of follow-up: 6.2 ± 5.2 years vs. 6.2 ± 5.1 years; P = 0.99).

3.2. Deaths

Eleven patients (15%) died during follow-up, at a median time of 4 months (IQR: 2 months–2 years) after PM implantation. All of these had congenital structural heart disease and 5 of them had a single ventricle physiology. The reasons for death were: chronic heart failure (n = 6), low cardiac output due to systemic inflammation response (n = 4) and one with an unknown reason for death. The median time those patients were paced was 4 months (IQR: 2 months–6 months). None of the deaths were attributable to the PM system.

3.3. PM modes at first implantation

Initially, single-chamber PM systems were implanted in 29 patients and dual-chamber PM systems in 42 patients. Patients with a single-chamber PM system were significantly younger (2 ± 2 months vs. 5 ± 3 months, P < 0.001) and had a lower weight than patients with a dual-chamber PM system (3.4 ± 1.2 kg vs. 5.2 ± 1.7 kg, P < 0.001). There was no statistical difference between the groups regarding duration of follow-up (6.0 ± 5.6 years vs. 6.3 ± 4.6 years, P = 0.80) and choice of surgical approach (median sternotomy: 38 vs. 22; partial inferior sternotomy: 4 vs. 6; posterolateral thoracotomy: 0 vs. 1; P = 0.18).

Table 1
Patient characteristics and surgical data for 71 patients with PM.

Variable	n (%)
Age	
< 30 d	19(27)
> 30 d	52(73)
Weight	
< 5 kg	47(66)
> 5 kg	24(34)
Sex	
Male	39(55)
FU	
< 5 years	34(48)
5–10 years	17(24)
> 10 years	20(28)
Indication for PM implantation	
Acquired complete heart block	44(62)
Congenital complete heart block	22(31)
Sick sinus syndrome	4(6)
AV-block type Mobitz II	1(1)
Surgical approach	
Median sternotomy	60(85)
Partial inferior sternotomy	10(14)
Posterolateral thoracotomy	1(1)
Diagnosis	
TGA	15(25)
CAVSD	12(20)
SV	11(19)
VSD	8(14)
TOF	4(7)
VSD + aortic arch hypoplasia	3(5)
Common arterial trunk	2(3)

PM = Pacemaker, TGA = Transposition of the great vessels, CAVSD = Complete atrioventricular septal defect, SV = Singular ventricle, VSD = Ventricular septal defect, TOF = Tetralogy of Fallot.

3.4. Pacemaker and lead data

Including all PM implantations, we implanted 35 single-chamber PM systems and 91 dual-chamber PM systems (72,2%). Different types of epicardial leads were used over the study period, they are depicted in Table 2.

Fig. 1 summarises atrial and ventricular lead impedances and MET over time. Impedance of atrial leads increased during the follow-up from 571 ± 131 Ω at discharge to 612 ± 133 Ω after more than 5 years (P < 0.001). At 2 years follow-up a slight, but not significant, decrease to 541 ± 108 Ω was noticed (P = 0.053). MET of atrial leads decreased significantly from 1.0 ± 0.9 μJ at discharge to 0.4 ± 0.3 μJ after more than 5 years (P < 0.001). Sensing of atrial leads stayed constant at 3.6 ± 1.6 mV at discharge and 3.2 ± 1.7 mV after more than 5 years (P = 0.13).

Impedance of ventricular leads showed a decrease from 603 ± 204 Ω to 490 ± 152 Ω (P = 0.009) from discharge to 5-years follow-up. MET of ventricular leads stayed constant (median MET from 0.56 μJ [IQR: 0.21–1.06 μJ] to 0.64 μJ [IQR 0.41–1.87 μJ], P = 0.970) and mean sensing values increased slightly from 8.8 ± 4.4 mV to 10.4 ± 3.5 mV after 5 years (P = 0.062).

Interestingly, out of 400 atrial and ventricular lead analyses, only seven analyses showed a pacing threshold ≥ 2 mV.

3.5. Pacemaker and lead reinterventions

A total of 63 device-related reoperations were performed in 33 patients (46%) after primary implantation. Eighteen patients underwent one reoperation, 6 patients needed a second, 5 a third, 2 a fourth and 2 a fifth reoperation.

During the 17 years of our study period we identified 55 PM generator exchanges. There were 9 (16%) early exchanges within 1 year of implantation and 46 (84%) after 1 year. In a cox risk factor analysis young age (P = 0.018) and implantation of a single-chamber PM system (P < 0.001) were identified as risk factors for an early PM system reintervention.

PM generator exchanges were necessary due to: battery depletion (n = 41), upgrades to dual-chamber systems (n = 9) or to cardiac resynchronization therapy (n = 3). One patient underwent PM system explantation due to PM pocket infection and there was 1 downgrade from a dual-chamber PM system to a single-chamber PM system. The median time to generator exchange was 4.0 years [IQR: 1.7–5.7 years].

Median time to generator exchange due to battery depletion was 5.5 years [range: 4.0–8.4 years] in single-chamber PM systems and 4.9 years [range: 0.3–8.4 years] in dual-chamber PM systems (P = 0.44).

Lead re-interventions were required in 11 ventricular and 6 atrial leads. Median time to atrial and ventricular lead re-intervention was 4.8 years [IQR: 0.1–9.1 years] and 4.7 years [IQR: 1.9–5.9 years], respectively. Lead survival at 2, 5 and 10 years was 96%, 91% and 76% and 94%, 82% and 75% for atrial and ventricular leads, respectively (P = 0.45). Combined lead survival, PM generator survival and event-free survival are shown in Fig. 2. There were no significant differences in lead and generator survival regarding the mode and the indication for PM implantation. Lead reintervention was performed due to lead fracture (n = 6), rising pacing thresholds (n = 2), sensing problems (n = 4), dislocation of the lead (n = 1), infection (n = 1) or during upgrade of PM system (n = 3).

3.6. Complications and infections

One case of infection attributable to the PM system was identified during the study period. This was a patient who was born with CCHB, cc-TGA, VSD and ASD, who was temporarily paced with transvenous leads, after a cardiac catheter examination, on the first day of life. At the age of 12 days, epicardial ventricular leads were implanted and a PM generator was placed into the abdominal sheath. After 1 month, a smear taken from the reddened surgical wound showed methicillin

Table 2
Implanted leads.

Manufacturer	Model	SE	Fixation	Atrial (n = 57)	Ventricular RV + LV (n = 85)	Total (n = 142)
Enpath Medical	MyoDex 1084T	+	Screw-in	0	4(5)	4(2)
Medtronic	Capsure EPI 4968/4965	+	Suture	56(98)	79(93)	135(95)
St. Jude Medical	MyoDex 1084 T-35	+	Screw-in	0	1(1)	1(1)
	Tendril SDX 1388T	+	Screw-in	1(2)	0	1(1)
Unknown	Unknown				1(1)	1(1)

SE = Steroid-eluting; data are presented as n (%).

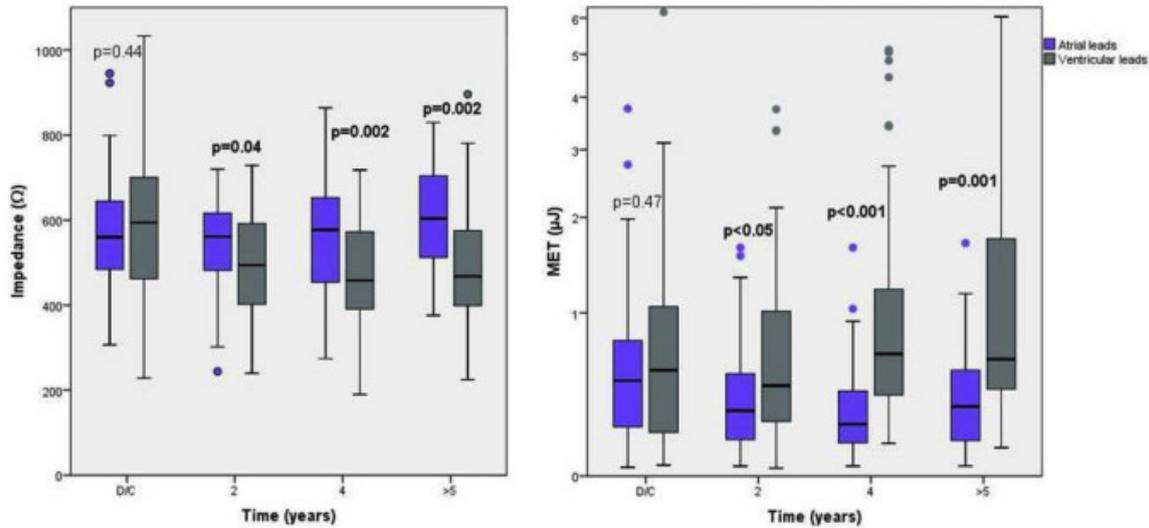


Fig. 1. Atrial and ventricular lead thresholds for impedance and MET are compared at four different time points. Y-scale in the left box is shown in Ω for impedance and on the right in μJ for MET. Comparisons were made with the two-tailed T-test.

resistant staphylococcus aureus infection. Treatment with antibiotics showed no improvement and consequently the whole PM system was explanted. The patient recovered over the next two months and was discharged from hospital in a stable condition with a heart rate of 50–60 beats per minute with no cardiac device. Two months later the patient received a new PM system without any complications.

One PM generator needed to be exchanged due to its failure to capture the high heart rate of the neonate. In this special situation a downgrade from a DDD-PM to a VVI-PM was performed.

4. Discussion

Implantation of PM systems in neonates and infants in the first year of life is challenging due to the small patient size and the ready availability of only adult-sized generators and leads. Furthermore, due to quick somatic growth of these young patients, implanted systems are rarely a life-long solution. Since there are no specialised paediatric PM systems available, surgeons and cardiologists must utilise the smallest adult-sized PM generators and leads provided.

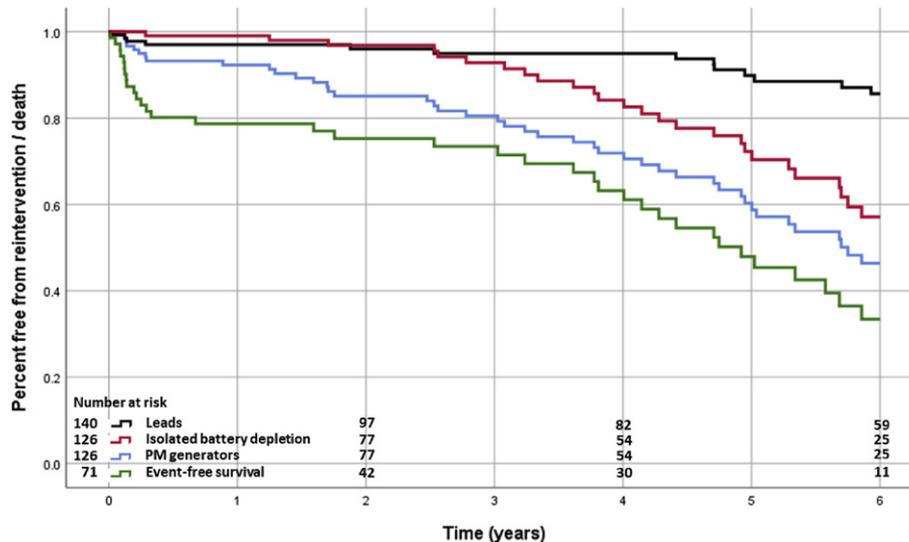


Fig. 2. Kaplan-Meier analysis for lead failure, PM system exchange because of battery depletion, PM system exchange in total and event-free survival.

In the present study we focussed on this very young patient group and demonstrated that epicardial PM systems in neonates and infants can function throughout childhood.

Compared to other major studies on epicardial pacing, our results show that epicardial pacing with bipolar steroid-eluting leads exhibits superior thresholds and a lower reoperation rate for lead exchange [6,7]. Cohen et al. documented a MET of 1.9 μJ ($n = 48$) for ventricular steroid-eluting leads for a patient population with a median age of 4.1 years after 2 years of follow-up [6]. This is higher than in our study with a mean MET of 1.1 μJ ($n = 61$) at 2 years. The 90% 5-year durability of leads shown in our study is also higher than the 83% shown in Cohen's study from 2001. CHD was present in 84% of their patients, a figure comparable to 85% in our study cohort. Their analysed PM implantations took place between 1983 and 2000 and they had a higher rate of implantations via lateral thoracotomy (29% compared to 1% in our study).

Lead malfunction in our study cohort after 5 and 10 years was 10% and 20%, respectively. These outcomes are lower than those found in the large study of Lau et al. which included 155 patients with CHD and PM implantation with a lead malfunction rate of 27% and 44% at 5 and 10 years, respectively [7]. The proportion of patients in that study with single ventricle physiology was very high at 49% (vs. 21% in our study) which may explain the differences.

We found that age at implantation and single-chamber PM are both associated with a higher incidence of early PM generator exchanges, but not with lead re-interventions. This is not surprising as we know that pacing high heart rates in neonates consumes more energy than pacing at a lower heart rate. Additionally, the Microny™ (St. Jude Medical) PM, used in most of the patients with single-chamber PM (68.6%) has a shorter battery life. We also found that in the first 4 months after VVI PM implantation, there were 4 (8% of all VVI PM) exchanges for upgrading to a dual-chamber pacing system; malfunction of the PM did not occur. In some patients with CHD, an upgrade to a dual-chamber pacing system is performed at the same time as a planned cardiac re-operation even prior to any malfunction of the single-chamber system.

Compared to other studies with similar patient characteristics, the postoperative complication rate was extremely low in our study with only one infection in 134 procedures [4,6,8,9]. No revisions for wound dehiscence, PM generator migration or any other complication related to the PM pocket preparation were necessary. Previous studies with fewer patients have described migrations of PM generators although this event occurred rarely [10,11]. Aellig et al. described 2 patients in their study including 22 neonates and infants with a median age of 35 days and a median weight of 3.2 kg in whom the PM had to be placed intraperitoneally in the abdominal cavity because of small patient size. An elective reoperation and repositioning of a new PM generator was necessary, since one patient's generator migrated further into the pelvic cavity and the risk of intestinal obstruction was high [10]. Even though our smallest patient weighed 2 kg, we were always able to implant the generator above the peritoneum. In their study of 48 patients under 1 year of age, Kwak et al. described 2 PM generator migrations, which penetrated from the rectus sheath or sub-costal area into the abdominal cavity [11]. These results prove that epicardial PM implantation is also feasible in small neonates when pacing is inevitable.

In searching for alternatives to epicardial pacing, different institutions have demonstrated the feasibility of implanting transvenous leads in neonates and infants but at the cost of a high rate of various complications, especially over the long-term [12,13]. Vos et al. showed that positioning of the PM generator in a pre-pectoral pocket as in adults was associated with a high incidence of skin necrosis and traction on the leads in 2 out of 7 patients [12]. PM generators, therefore, have to be placed in an abdominal or sub-pectoral pocket which implies a more invasive procedure [13]. Robledo et al. used these locations to fixate transvenous PM generators in 12 patients with a weight less than 10 kg and documented no wound dehiscence

at a mean follow-up of 32 months [13]. But even if positioning of the PM generator is feasible, long-term analysis shows that venous occlusion often limits the possibility of reoperation for lead exchange or any other diagnostic catheter examination. Konta et al. described in their long-term analysis of infants weighing less than 5 kg with transvenous PM implantation a subclavian vein occlusion rate of 69% [14]. Vos et al. found vascular occlusion followed by venous thrombosis on the PM lead in 2 of 7 patients (age and weight at PM implantation: 2 days, 5 kg and 413 days, 8.7 kg), 7 and 11 years after PM implantation, respectively [12]. Considering the life-long dependency on pacing in these patients with CHD, vascular access for future procedures needs to remain intact. Another limiting factor is that transvenous leads can induce tricuspid valve regurgitation and impair right ventricular function [15–17]. Even if the rate of this complication was described as rather low in Webster's study, which included 123 patients with a median age of 16 years, they found a significant increase in tricuspid valve regurgitation 27 months after endocardial lead implantation (from 1.54 to 1.69 on a 0 to 4 ordinal scale) [15]. In the long-term analysis conducted by Vos et al. all 7 patients with endocardial leads developed tricuspid valve insufficiency and 2 of them needed atrioventricular valve replacement [12].

4.1. Study limitations

This study, of neonates and infants who received a PM system within their first year of life, was one of the largest of its kind undertaken thus far, with 71 patients, 126 implanted PM generators and 142 implanted epicardial leads. However, the number of patients at long-term follow-up was still relatively small, with 37 patients remaining for analysis at 5 years.

5. Conclusion

Epicardial pacing in neonates and infants less than 1 year of age can be performed with excellent mid-term results, including low pacing thresholds, sufficient sensing and a moderate reoperation rate. Epicardial leads can be recommended, with excellent results, at least until the time of school enrolment, for this group of patients. If changing to endocardial leads will lead to less risk to the patient than keeping the epicardial leads, a transvenous approach can be considered.

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Declaration of competing interest

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijcard.2019.10.008>.

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