

Complications and Risk Assessment of 25 Years in Pediatric Pacing

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Background. Children who require cardiac pacemaker implantation have presented a small patient subpopulation since the breakthrough of this technology in the 1950s and 1960s. Their small bodies result in a technical challenge for the operating surgeon and put the patient at risk for a series of specific complications. Our study aims to analyze complications and to identify risk factors of endocardial and epicardial pacemaker systems in children.

Methods. All pacemaker-related operations in pediatric patients up to the age of 18 years from 1985 through 2010 were retrospectively evaluated. Demographic data including age, height, and weight were recorded. Idiopathic and postoperative dysrhythmias were analyzed separately.

Results. A total of 149 pacemaker operations were performed in 73 patients. Thirty-two patients did not have a previous cardiac operation. Indications for revision included box exchange, lead-related problems,

pacemaker pocket complications, impaired left ventricular function, and pectoral muscle stimulation. Increased pacing thresholds occurred in 17.2% of the patients with epicardial leads compared with 2.9% in the endocardial group. Aside from threshold-related revision, lead problems are more common in the endocardial group (30.4% vs 17.2%). Venous thrombosis occurred in 13.7% of the patients (only endocardial), preferentially (25%) in the weight group less than 15 kg and in idiopathic patients (15.6% vs 10.5% with prior cardiac surgery).

Conclusions. Cardiac pacing is particularly challenging in the pediatric patient population facing a large number of reoperations during their lifetime. The lack of clear superiority of either epicardial or endocardial pacing systems requires an individual concept.

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In 1957 Dr Clarence Walton Lillehei (University of Minnesota) placed the first pediatric pacemaker. At the end of a surgical procedure for structural heart disease, he used epicardial pacing leads and attached them to the cardiac surface [1, 2]. Two years later Dr Seymour Furman was able to use a transvenous technique to place the pacemaker leads endocardially [3, 4].

Children represent less than 1% of all pacemaker patients and can have pacemaker systems placed with either method. The endocardial method is preferred in older children and adults. However, in children smaller than 10 to 15 kg many centers have advocated the use of epicardial pacemaker systems. Specific concerns with the endocardial approach in this population include venous occlusion, growth-related lead problems, the need for future lead extractions or replacements, and skin erosions at the pectoral generator site. Smaller generators and the use of various techniques such as looping the pacemaker lead in the right atrium to allow for future growth have

lessened, but not eradicated, some of these concerns. Venous occlusion, in particular, remains a major concern in children smaller than 15 kg. For this reason, epicardial systems have been preferred in these children. On the other hand, there has been a global trend in using endocardial pacemaker systems in younger and smaller patients including those weighing less than 10 to 15 kg [5–10].

This retrospective study seeks to analyze complications of pediatric pacemaker systems and to identify relevant risk factors. In addition, we add our experience using endocardial pacemaker systems in small children weighing less than 15 kg to the small body of the current literature. In order to gain greater knowledge about the incidence of pacemaker-related complications in pediatric patients, we compare the existing literature to our findings.

Material and Methods

Patients

We analyzed all pacemaker implantations performed on patients between birth and the age of 18 years at the University Hospital of Düsseldorf between 1985 and 2010. All children with endocardial and epicardial pacemaker

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systems were included. Operative reports and patient charts were analyzed. Demographic information such as age, gender, height, and weight as well as medical and surgical history was obtained. Data reviewed included type of pacemaker system (epicardial versus endocardial), operative time, generator and lead information, and pacemaker mode. A retrospective analysis of perioperative complications and indications for pacemaker revision was conducted.

Materials

Pacemaker lead models were documented. Specific features including polarity, insulation material, and lead-tip configuration are illustrated in [Table 1](#).

Operative Technique

EPICARDIAL PACEMAKER SYSTEMS. Various methods of epicardial pacemaker placement are available. Implantation of epicardial pacemaker systems can be done by left thoracotomy, sternotomy, or a subxiphoid approach. The generator can be placed in various locations. In our study, pacemaker pocket placement for epicardial systems was either under the rectus abdominis sheath or subpectoral. Other techniques that have been described include subxiphoid and subcostal placement [11].

ENDOCARDIAL PACEMAKER SYSTEMS. Placement of our endocardial pacemaker systems were performed through an incision in the clavicular-pectoral groove. Venous access was established by cannulation of the cephalic vein. If the diameter of the cephalic vein was not sufficient, we used the sheath dilatation technique as previously described by Ong and colleagues [12]. In order to allow for the

child's growth, the pacemaker electrode was looped in the right atrium under fluoroscopy.

Groups

Our study included children with postoperative and non-postoperative symptomatic bradycardias, most commonly complete atrioventricular blocks (grade III). The non-postoperative group was subdivided into congenital and non-postoperatively acquired conduction abnormalities. Data were analyzed separately for patients with epicardial versus endocardial pacemaker systems.

There were 19 out of 73 patients who had previous pacemaker operations at other institutions. For the analysis of the total number of revisions these patients were included. The remaining 54 patients, whose first pacemaker operations were done in the study period of 1985 and 2010, were analyzed separately because not all the demographic data were available prior to 1985.

Statistical Methods

All applicable data were written into a spreadsheet. Descriptive statistical analysis was done using Microsoft Excel 2010 and SPSS for Windows, version 18.0.

Results

Patients

During the study period of 1985 to 2010, a total of 73 patients underwent 149 pacemaker operations. Nineteen patients had at least 1 previous pacemaker operation at other facilities. Twenty-seven patients were female (37%) and 46 patients were male (63%). The average clinical follow-up period was 7.9 years. The average age during the initial pacemaker implantation was 6.7 years; for

Table 1. List of Pacemaker Leads

Manufacturer	No.	Model	Lead-Tip	Polarity	Steroid-Eluting	Insulation
Medtronic	4033	CapSure-Z	Passive	Unipolar	Yes	Polyurethane
Medtronic	4023	CapSure-SP	Passive	Unipolar	Yes	Polyurethane
Medtronic	4003	CapSure	Passive	Unipolar	Yes	Polyurethane
Medtronic	4011	TargetTip	Passive	Unipolar	No	Polyurethane
Medtronic	2151	SP	Passive	Unipolar		
Medtronic	4081	TargetTip	Passive	Unipolar	No	Polyurethane
Medtronic	5076	CapSureFix-Novus	Active	Bipolar	Yes	Silicone
Medtronic	4067	CapSureFix	Active	Unipolar	Yes	Polyurethane
Medtronic	4057	Screw-In	Active	Unipolar	No	Polyurethane
Medtronic	4057M	Screw-In	Active	Unipolar	No	Polyurethane
Medtronic	6957	Spectraflex	Active	Unipolar	No	Polyurethane
Medtronic	4068	CapSureFix	Active	Bipolar	Yes	Polyurethane
Medtronic	4951	Spectraflex	Epicardial	Unipolar	No	Polyurethane
Medtronic	4968	CapSure-EPI	Epicardial	Bipolar	Yes	Silicone
Medtronic	4965	CapSure-EPI	Epicardial	Unipolar	Yes	Silicone
Boston-Scientific	NA	Endotak-Reliance-SG-Single-Coil	Active	Bipolar	Yes	Silicone
Boston-Scientific	NA	Acuity-Steerable	J-shaped	Bipolar	Yes	Silicone + ETFE
Boston-Scientific	NA	Acuity-Spiral	Helical-shaped	Unipolar	Yes	Polyurethane

ETFE = ethylene tetrafluoroethylene.

epicardial systems it was 2.2 years, and for endocardial systems it was 8.3 years. The average weight was 26.5 kg and the average height was 116.8 cm. Demographics at the time of initial pacemaker implantation data are shown in [Table 2](#).

Mortality

The overall mortality in our study period was 11% (8 deaths). None of the deaths happened in the immediate postoperative period after pacemaker implantation, nor were they identifiably related to the pacemaker system. The deaths occurred between 1989 and 2005, with initial pacemaker placements between 1987 and 1997. We compared the mortality of patients who had symptomatic bradycardia after cardiac surgeries for structural malformations and the mortality in the non-postoperative group. Results are shown in [Table 3](#).

Two of 3 non-postoperative patients had hereditary cardiomyopathies. One of these 2 patients died of an anterolateral myocardial infarction that resulted in left ventricular failure. The other died of cardiac failure awaiting heart transplantation. Detailed data about the cause of death in the third patient are retrospectively not available, but were noted to be due to cardiac failure.

Of 5 mortalities in postoperative patients, 3 were due to cardiac arrests outside of the hospital setting. One patient died at an outside institution due to cardiac failure after a prolonged intensive care unit stay. Further details were not available to us. The fifth patient died awaiting cardiac transplantation. The underlying congenital abnormalities in these patients were hypertrophic obstructive cardiomyopathy, double-outlet right ventricle, transposition of the great vessels, and 2 cases of ventricular septal defects, respectively.

All deaths occurred in patients with endocardial pacemaker systems. One of the patients in the non-postoperative group previously had an epicardial pacemaker but had been switched to an endocardial system 3 months prior to his death. The average shortening fraction was 16.7% (range, 7% to 30%).

Pacemaker Revisions

The average time between revisions was 5 years. Intervals were analyzed separately for epicardial systems versus endocardial systems and are shown in [Figure 1](#). There was no significant difference between the 2 groups.

There were a total of 54 primary pacemaker operations and 95 revisions. We compared the indications for

Table 2. Age, Weight, and Height at Initial Pacemaker Placement: Demographic Data of Included Children

Group	Epicardial	Endocardial	Total
Age (years) ^a	2	7.6	6.4
Weight (kg) ^a	10.6	26.5	23
Height (cm) ^a	78.8	117.5	109.3

^a Height and weight were not available for every patient. We subtracted these patients for the average age calculation, which explains the difference to the age value given in the text.

Table 3. Mortality of Patients in the Non-Postoperative Versus Postoperative Group

Group	Patients (n)	Deaths (n)	Mortality (%)
Non-postoperative	32	3	9.4
Postoperative	41	5	12.2
Total	73	8	11

revision in endocardial pacemaker systems with epicardial pacemaker systems ([Fig 2](#)). Three patients had combined pacemaker systems (endocardial and epicardial) and were excluded from the analysis in [Figure 2](#). In 2 cases the indication was inadequately documented and 2 patients had failed attempts. A successful attempt was subsequently done within 1 to 3 days on the contralateral side; the indication for these revisions was only counted once. This results in 88 applicable revisions that are analyzed in [Figure 2](#). There were a total of 10 combined indications such as “generator failure and lead dislocation,” which is why there are 98 indications for 88 revisions. [Figure 2](#) shows an illustration of the indications for revision of endocardial versus epicardial systems.

Venous Occlusion

There were 11 patients that developed a thrombosis of the subclavian vein with or without progression into the superior vena cava. This included 3 patients with epicardial systems. All 3 patients had postoperative atrioventricular blocks. The structural malformations of these 3 patients were transposition of the great vessels, ventricular septal defect, and atrioventricular septal defect. They had no known coagulopathy and adequate ventricular function with an average shortening fraction of 34.2%, as well as mild tricuspid valve regurgitation. The other 8 patients had endocardial pacemakers. Dys-synchrony was noted in 1 patient with an endocardial pacemaker.

Nine out of the 11 patients had no symptoms or relevant findings on physical exam. Two patients developed

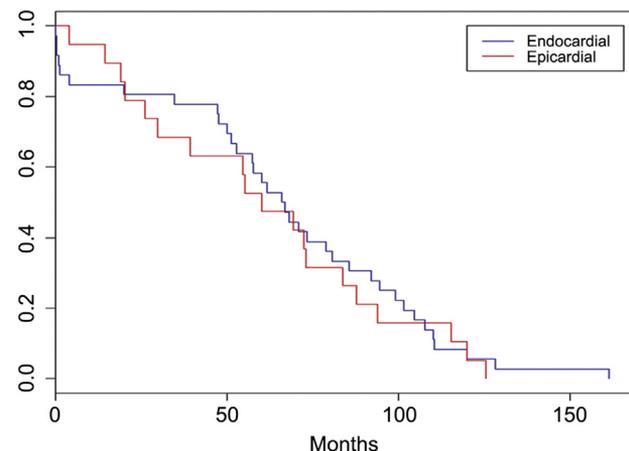
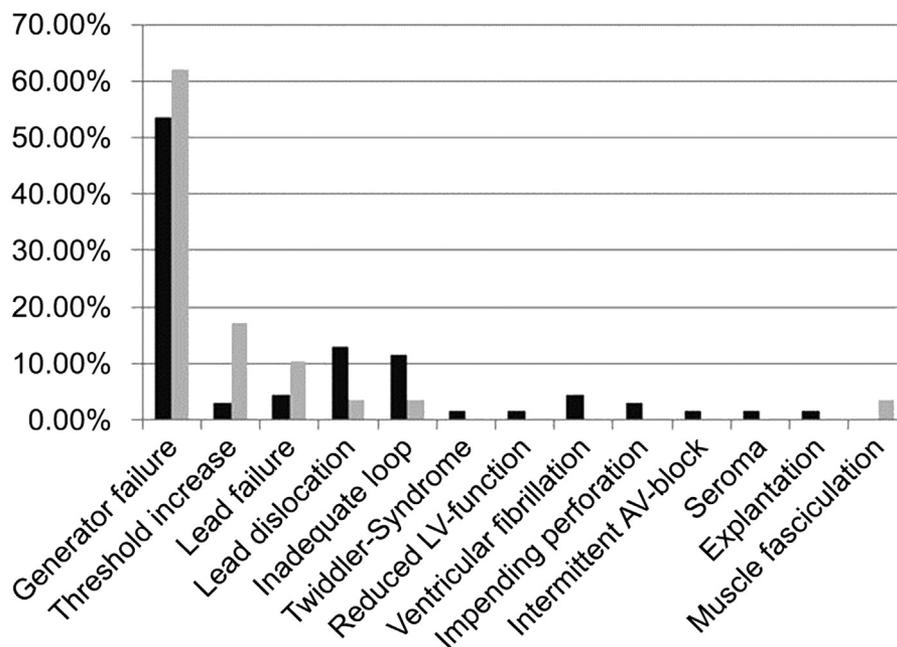


Fig 1. Kaplan-Meier graph of months to first revision.

Fig 2. Indications for revision of endocardial (black bar) versus epicardial (gray bar) systems. (AV = atrioventricular; LV = left ventricular.)



complications. One of them developed a symptomatic thrombosis with upper extremity swelling. The patient was subsequently anticoagulated, which was further complicated by bleeding into an ovarian cyst requiring blood transfusions and transfer to an intensive care unit. The other patient required lead extraction due to inadequate length of the pacemaker electrode secondary to excessively fast growth (the patient was in the 97th percentile for growth). Due to stenosis and adherence of the pacemaker electrode to the subclavian vein the patient required extraction of the lead under cardiopulmonary bypass. Table 4 shows patient, lead, and pacemaker system characteristics of the patients that developed a thrombosis.

In order to investigate risk factors for thrombosis in patients with endocardial systems, we analyzed this group separately. Table 5 shows patient and lead

characteristics for children with endocardial systems who developed thrombosis versus no thrombosis. Table 6 shows the relative risk (RR) and odds ratio (OR) of potential patient-, lead-, or pacemaker-related risk factors. An increased risk of thrombosis was noticed for an age under 1 year (RR = 1.5, OR = 1.6), weight less than 15 kg (RR = 2.9, OR = 3.6), female sex (RR 3.3, OR = 4), presence of cardiomyopathy (RR = 2.2, OR = 2.5), and use of single-chamber as opposed to dual-chamber-systems (RR = 5.3, OR = 6.6).

Comment

General Considerations

Advantages and disadvantages of epicardial and endocardial pacemaker systems in children have been discussed since the 1980s [13]. Generally, the endocardial

Table 4. Patient, Lead, and Pacemaker System Characteristics of Patients Who Developed Thrombosis

Cause of Dysrhythmia	Pacemaker System and Mode	Shortening Fraction (%)	Tricuspid Regurgitation	Age at Initial Implantation	Age at Diagnosis (years)
Postoperative	Epicardial VVIR	40.6	Mild	0.4	4.9
Postoperative	Epicardial VVIR	31	Mild	6.9	11.9
Postoperative	Epicardial VVIR	31	Mild	1.7	2.9
Postoperative	Endocardial AAI	35.8	NA	12.8	26.1
Postoperative	Endocardial VVIR	31	Moderate	0.7	6.8
Myocarditis	Endocardial VVIR	30	Mild	3.5	13.5
Myocarditis	Endocardial VVIR	31.8	Mild	11.7	25.1
Congenital	Endocardial DDD	26	Mild	16.3	20.6
Congenital	Endocardial VVIR	41	Mild	0.3	5.5
Congenital	Endocardial VVIR	38	Mild	0.02	4.0
Congenital	Endocardial VVIR	37.9	Mild	2.0	22.9

A = atrium; I = inhibited; NA = not applicable; R = rate modulation; V = ventricle.

Table 5. Patients With Thrombosis Versus Patients Without Thrombosis (Endocardial Pacemaker Systems)

Characteristic	Thrombosis		No Thrombosis		Total	
	n	%	n	%	n	%
Age (years, mean)	6.7	NA	8.6	NA	8.3	NA
Weight (kg, mean)	28.2	NA	26.1	NA	26.4	NA
Height (cm, mean)	112	NA	118	NA	117	NA
Female	5	22.7%	17	77.3%	22	100.0%
Male	2	6.9%	27	93.1%	29	100.0%

NA = not applicable.

method has emerged to be the preferred option due to its less invasive nature and safety. However, for infants and small children this approach remains controversial. In addition, pediatric patients with congenital heart disease may have an anatomy that excludes the possibility of a transvenous access; for example, in the Fontan circulation. As an alternative, transhepatic catheterization and pacemaker placement has been reported in these patients [14]. Nevertheless, even though this method is technically possible, it has not been proven to have any superior benefit for the patient.

Worldwide, centers have decided upon the preference of either system based on individual patient characteristics and local expertise. In centers that prefer the epicardial technique for small children, the cutoff for age and weight varies and there is no consensus as to what size is considered to be too small for endocardial pacemaker systems. The weight cutoff, which has been used to study pacemaker complications in infants and small children, ranges anywhere from 10 to 20 kg [5]. Superiority of either the endocardial or epicardial approach in these patients has not been demonstrated in any large prospective study. Ethical considerations, small patient numbers, and

variables in patient characteristics make it hard to foresee if such a study will ever be conducted in the future. Results of retrospective studies remain controversial and are subject to small patient numbers and potential bias. We will discuss the concepts and the approach that is proposed by various authors and compare their findings with the results of our study.

In our study we have attempted to compare the long-term outcome, the number of required pacemaker revisions, the longevity of systems, and the rate of surgical complications between pediatric patients with epicardial pacemaker systems and endocardial pacemaker systems. In addition we compared our findings included with the current literature.

Epicardial Pacemaker Systems

Despite an increasing number of centers using the endocardial technique even in infants and children that weigh less than 10 to 15 kg, most authors still consider epicardial pacemaker systems as the preferred choice [5]. With epicardial pacemaker systems there is the possibility of a steep rise in pacemaker thresholds and earlier lead fractures as well as other causes of lead failure [9, 15-19]. However, excellent long-term performance is also well known. Improvements have been achieved due to the advent of steroid eluting pacemaker lead tips. Particularly, the bipolar version of the Medtronic (Minneapolis, MN) CapSureEpi leads, which use steroid eluting 'button' electrodes that are sewn onto the surface of the epicardium, tend to have more stable chronic thresholds that compete well with endocardial leads [20]. However, particularly this model has shown to be more prone to fracture [5].

In our retrospective review epicardial pacemaker systems had a lead failure rate of 10.3% (compared with 4.3% in the endocardial group). A pacemaker threshold increase was the indication for revision in 17.2% of cases (as opposed to 2.9% in the endocardial group). It was the second most common reason for revision in this group after revisions for generator exchanges. Our pacemaker pockets were either placed under the rectus abdominis sheath or subpectoral. Lichtenstein and colleagues [11] hypothesized that a retro-costal approach would reduce the rate of lead failure due to fracture, but their results did not show superiority of the sub-costal position.

Table 6. Relative Risk and Odds Ratio of Potential Risk Factors for Thrombosis Formation

Risk Factor	Thrombosis (%)	Relative Risk	Odds Ratio
Age less than 1 year	18.2	1.5	1.6
Age greater than 1 year	12.5		
Weight less than 15 kg	25.0	2.9	3.6
Weight greater than 15 kg	8.6		
Female	22.7	3.3	4.0
Male	6.9		
Malformation	6.9	0.3	0.3
No malformation	22.7		
Cardiomyopathy	25.0	2.2	2.5
No cardiomyopathy	11.6		
Postoperative	10.5	0.7	0.6
Non-postoperative	15.6		
Single-chamber system	22.2	5.3	6.6
Dual-chamber system	4.2		
Unipolar electrode	14.6	1.5	1.5
Bipolar electrode	10.0		

Endocardial Pacemaker Systems

Endocardial leads have been reported to be more reliable [5]. Venous occlusion, on the other hand, has been reported as one of the major concerns in patients with endocardial systems, particularly in infants and small children.

Our rate of venous occlusion in children with endocardial pacemaker systems was 13.7%, which is in the range of previously reported occlusion rates. In one of the largest retrospective studies by Welisch and colleagues [21], the observed venous occlusion was 4.8% [21]. On the other hand, Bar-Cohen and colleagues [22] reported a partial occlusion rate of 12% and a complete occlusion rate of 13%. The authors' conclusion was that age, size, and lead factors do not predict the risk of venous occlusion. Even though their study design was superior compared with ours in particularly addressing venous occlusion by contrast venogram, our results are difficult to compare because their study did not include patients younger than 3 years of age. That being said, we did find an increased relative risk in patients weighing less than 15 kg (RR = 2.9) and in patients less than 1 year (RR = 1.5). Like Bar-Cohen and colleagues, we did not find lead factors that predict the risk of venous obstruction.

Interesting findings of undetermined significance in our study were an increased relative risk of developing venous occlusion in females and in patients with single-chamber pacemaker systems as opposed to dual-chamber pacemaker systems. The latter might suggest that hemodynamic factors are more important than the number of intravascular leads as risk factors of venous occlusion. By that rationale it would be interesting to see more research that compares atrial and ventricular single-chamber systems. In our study the power was too low. Among single-chamber patients who did not develop venous occlusion, 3 were paced atrially and 28 ventricularly. The ratio is nearly identical to patients with venous occlusion (1:9).

As shown in our study, venous occlusion is usually asymptomatic. However, a major clinical concern is that in patients who require lifelong pacing, lead extraction and replacement can become an exceedingly difficult challenge [23]. In some cases lead extraction requires open surgery [24]. In our study, 1 out of 8 patients with thrombosis at the site of the indwelling lead required lead extraction with cardiopulmonary bypass.

Even though epicardial pacemaker systems are associated with more lead fractures and other causes of dysfunction, endocardial pacemaker systems can also be complicated by lead problems. Typically, as shown in our study, these are more commonly lead dislocations rather than lead failure due to fractures. Another problem can be inadequate length of the lead as the child grows. Even a redundant loop of ventricular lead made within the right atrium may not be enough to overcome lead stretch from many years of growth [5]. Welisch and colleagues [21] reported that the overall rate of lead problems in a group of 181 patients was 18%. Counting lead failure, lead dislocation, and inadequate redundant loop, our study had a higher rate of lead problems than previously reported.

Limitations

The main limitation of our study was its retrospective design. In addition, despite being one of the largest retrospective studies about this topic to date, the power is limited due to a small patient number when compared to research about clinical problems with higher incidences. It was impossible to use a matched case-control design to avoid possible confounders when calculating relative risks and odds ratios.

Conclusions

Cardiac pacing is particularly challenging in the pediatric patient population. Children may depend on a pacemaker for the rest of their life. For infants and children weighing less than 15 kg superiority of either epicardial or endocardial pacing systems has not been established. Each system has a number of advantages and disadvantages. Even though we have gained knowledge about the typical complications of each system, the clinical significance and long-term consequences remain incompletely understood. Hence, an evidence-based practice is currently difficult.

The accurate choice of a pacemaker system heavily depends on a variety of patient-specific factors including anatomy and advantages for each system when considering specific patient factors. In order to gain a better understanding of the long-term outcome of pediatric pacemaker patients, we encourage a greater use of data collection systems such as the Midwest Pediatric Pacemaker Registry [25].

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