

# Steroid-eluting epicardial pacing in children

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## Abstract

**Background:** *Permanent cardiac pacing is a known method of the treatment for children with bradycardia. Epicardial pacing is required in small children and in children with some congenital heart defects. Steroid-eluting leads (SEL) have been introduced to reduce implant site fibrosis and to retain permanent low-pacing threshold values. Our aim was to evaluate the pacing characteristic and follow-up of children with epicardial steroid-eluting pacing.*

**Material and methods:** *We implanted steroid-eluting epicardial pacing systems in 53 children (age at implantation: 2 days – 17.5 years, mean 4.6 years), of whom 37 (70%) had congenital heart disease and 22 of these had already had cardiac surgery. These children formed group I. Group II was the control group and consisted of 29 children (age at implantation: 10 days – 13 years, mean 6.5 years) with non-steroid epicardial pacing systems; 15 patients (51%) had diagnosed congenital heart disease, and 9 of these had had cardiac surgery. The pacing threshold (PT) was obtained during implantation, before discharge, 1–3 and 6 months following implantation and then every 6 months.*

**Results:** *In group I the mean PT during the implantation procedure was 1.6 V/0.4 ms and decreased significantly before discharge. In group II the PT during the implantation procedure was low and increased before discharge. In group I the PT of the atrial leads was low and stable during the follow-up period, while the PT of the ventricular leads slowly increased and four years following implantation was similar to that of group II.*

**Conclusions:** *In children with permanent epicardial pacing the ventricular PT was significantly lower when steroid-eluting leads had been used than when these had not been used, but during the follow-up period the PT slowly increased, while the pacing threshold of atrial steroid-eluting leads remained stable. (Folia Cardiol. 2006; 13: 312–318)*

**permanent cardiac pacing, children, epicardial steroid-eluting electrodes**

## Introduction

The first pacemaker implantation in a child took place in 1962. Since then this has been a recognised treatment in children with bradyarrhythmia. The technological development of both pacemakers and leads has contributed to a higher proportion of children receiving implants and to higher accessibility of the method even for the youngest children.

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At first epicardial stimulation was used in children, because the available endocardial leads were too clumsy. It was later discovered that this method of cardiac pacing had numerous complications. Implantation of an epicardial pacemaker system is a more invasive procedure than implantation of an endocardial one. It is performed by a surgeon or cardiologist under general anaesthesia. When access has been gained to the heart the leads are stitched on, the heart, which sometimes causes post-pericardiotomy syndrome and increases the risk of further complications, such as unintended pleura piercing. An increase in the pacing threshold (PT) is often observed, resulting from tissue fibrosis and scarring around the lead. As a result, programming of a higher impulse amplitude and/or width is needed, which leads to shortening of the pacemaker's life. Sometimes the PT is so high that it makes heart stimulation impossible (exit block). A replacement of the implanted pacemaker system is then needed. Positive experience from endocardial pacing in adults and ongoing progress in the method has made usage of this method in very young children increasingly popular. However, there are still patients with indications for epicardial pacing (EP), including low body weight, intracardial septal defects (risk of thrombosis), venal defects or obstructions and operated complex congenital heart defects (CHD) making implantation of the endocardial leads impossible (for example hearts after Fontan operation).

Epicardial steroid-eluting leads, introduced in the mid-1980s, have contributed to a lowering of the PT through a decrease in inflammation in the area where the lead touches the heart [1–13].

The aim of the study was to monitor the pacing parameters in children with EP with steroid-eluting leads (SEL).

### **Material and methods**

Between May 1989 and June 2004 we monitored 82 patients of the Department of Cardiology of The Children's Memorial Health Institute (CMHI) with epicardial pacing systems. Group I included 53 children (27 female, 26 male) with EP with SEL (available from 1996). Group II (the control group) was made up of 29 children (17 female, 12 male) with non-SEL EP. The possibility of a comparison of the monitored stimulation parameters across the groups was an additional criterion for selection to the control group. Of all our patients without SEL EP we chose those whose impulse width was similar to that of our SEL EP patients. All the children

were thoroughly examined, underwent ECG, chest X-ray, echo and Holter ECG. Heart catheterisation was also performed where needed.

The implantation of the EP was performed by a cardiologist with the patients under general anaesthesia. The leads were stitched to the heart, while the pacemaker was usually placed under the left rib arch. In a few cases the epicardial leads were stitched during cardiosurgical correction of congenital heart disease. The children were observed during the postoperative period and any complications were examined. The PT was measured during the implantation using an ERA 300 Biotronic programmer. The PT was then measured before discharge from the hospital, 1–2 months after implantation and every 6 months thereafter with the use of a programmer relevant to the pacemaker (Medtronic or St. Jude Medical). The pacing parameters were analysed retrospectively and prospectively. The patients were monitored until they reached maturity or the EP system was replaced.

For statistical purposes Student's *t* tests were run using Microsoft Excel.

### **Results**

#### **Group I**

Group I was made up of 53 children. The age of the patients during implantation of the EP with SEL ranged from 2 days to 17.5 years (average: 4.6 yrs). The indications for pacemaker implantation are presented in Table 1.

For 44 patients EP with SEL was the first system implanted. Nine children had previously had a pacemaker: three had had an endocardial pacemaker and six had had an epicardial one without SEL. One patient had the EP with SEL implanted for the third time.

In 33 cases single-lead epicardial stimulation was applied (28 VVIR and 5 VVI), 20 patients had double-lead systems implanted (12 DDD, 7 DDDR, 1 DDI). In total 73 SEL were implanted in 53 children, including 53 ventricular and 20 atrial leads. All leads were manufactured by Medtronic (10366, 4965 and 4968). The PT of ventricular leads during implantation ranged from 0.5 to 5 V with an average of 1.6 V and an impulse width of 0.4 ms. In 8 cases PT amplitude was higher than 2 V for a few minutes after implantation (6 patients had had congenital heart disease correction while two had myocarditis) but decreased spontaneously after a short time. The PT of atrial leads during implantation ranged from 0.4 to 3 V with an average of 1.6 V, impulse width 0.4 ms.

**Table 1.** Indications for implantation of an epicardial pacemaker system and CHD in group I

Indications for implantation of EP	Congenital heart defect	
Postoperative CHB — 18	AVSD — 3	
	AVSD, TAPVD — 1	
	VSD — 3	
	VSD, ASD — 1	
	VSD, ASD, PDA — 2	
	CTGA, VSD — 2	
	TGA — 1	
	TGA, VSD, ASD, PS — 1	
	DILV, ASD, PDA — 1	
	DILV, TGA, CoA, PDA — 1	
	ToF, PVA — 1	
	SAS — 1	
	Postoperative, paroxysmal CHB — 2	AVSD — 1
DORV, PS — 1		
Postoperative sinus node dysfunction — 2	TGA, DORV, PS, AVSD — 1	
	TGA, AT, PS, ASD, PDA — 1	
Congenital CHB — 20	No CHD — 10	
	SV, SA — 1	
	ASD — 2	
	ASD, PDA — 1	
	VSD — 1	
	CTGA — 2	
	SV — 2	
	CTGA, VSD — 1	
	Paroxysmal CHB — 2	VSD, ASD — 1
		ASD — 1
Congenital sinus node dysfunction — 2	DILV, PS — 1	
	ASD — 1	
Postinflammatory CHB — 5	No CHD — 5	
	ASD, PDA, PS — 1	
Postinflammatory sinus node dysfunction — 2	No CHD — 1	

EP — epicardial pacemaker; CHB — complete heart block; CHD — congenital heart defect; ASD — atrial septal defect; VSD — ventricular septal defect; AVSD — atrioventricular septal defect; ToF — tetralogy of Fallot; TGA — transposition of great vessels; CTGA — corrected transposition of great vessels; DILV — double inlet left ventricle; DORV — double outlet right ventricle; SV — single ventricle; SA — single atrium; PS — pulmonary valve stenosis; SAS — supraaortic valve stenosis; PDA — persistent ductus arteriosus; TAPVD — total anomalous pulmonary vein drainage; PVA — pulmonary valve atresia; CoA — coarctation of aorta

In 24 patients (45.3%) no complications were witnessed during the operation or the early postoperative period. One patient had a short episode of ventricular tachycardia while the leads were being stitched. In 7 cases non-effective stimulation was observed over some minutes following implantation as a result of a high PT (up to 5 V); subsequent

measurements showed a rapid decrease in PT. A total of 14 patients (26.4%) suffered an exudation in the pericardium during the first few days after EP implantation and of these ten required drainage of the pericardium. In two cases spontaneous supraventricular tachycardia occurred shortly after implantation, which required anti-arrhythmic drug treatment (both patients had had episodes of this supraventricular tachycardia before the operation). In two neonates the pacemakers dislocated into the pleura: in one of these patients the pacemaker was repositioned under the rib arch. In one child with a postoperative complete heart block (CHB) after correction of a ventricular septal defect (VSD) and atrial septal defect (ASD) a rapid increase in PT was observed. This child had to have the pacemaker replaced with an endocardial one.

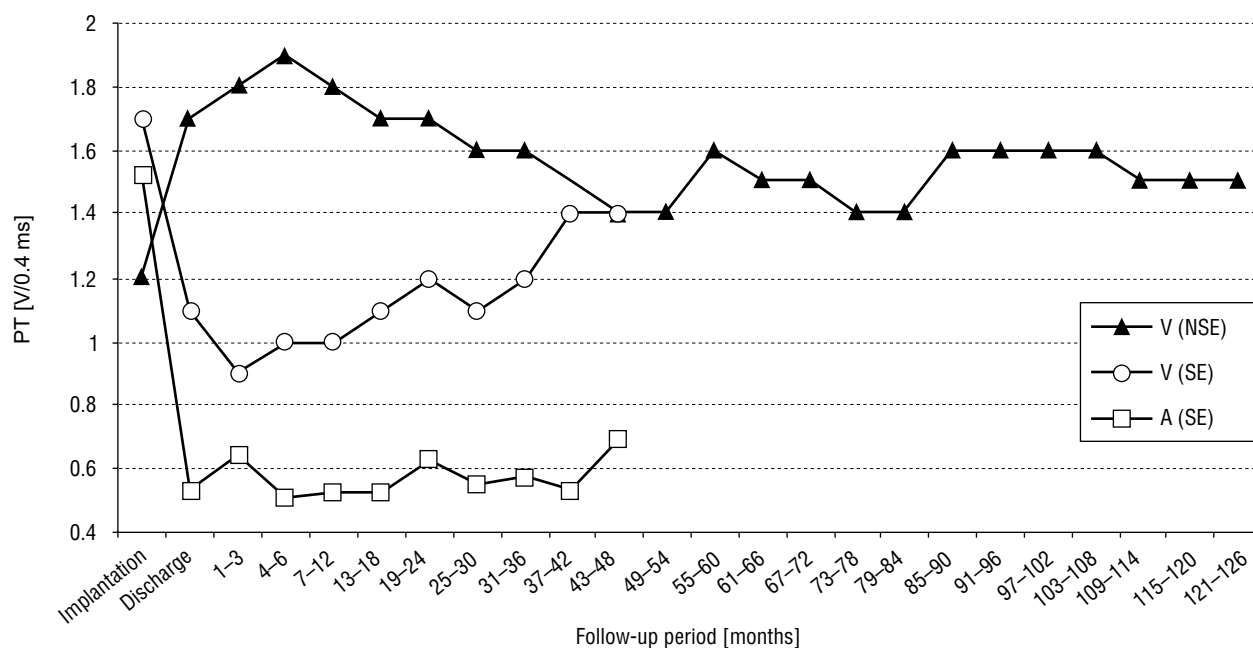
Despite correct pacing two neonates with CHB and complex congenital heart disease died soon after the pacemaker implantation. One of the patients had a Blalock-Taussig shunt. The second had had aortic valvuloplasty. In both cases increasing symptoms of heart and internal organ failure were observed.

The measurement of PT at discharge from the hospital (on average on the 7<sup>th</sup> day after the operation) showed a significant decrease in the PT of the ventricular leads, ranging from 0.4 to 4.5 V, with an average of 1.1 V (impulse width 0.4 ms). The PT of the atrial leads dropped by 0.2–1 V, with an average of 0.53 V (impulse width 0.4 ms). The differences between PT during implantation and PT at discharge were statistically significant ( $p < 0.01$ ).

The observation period of patients with EP with SEL ranged from one week (early postoperative deaths) to 7.3 years, with an average of 2.5 years. Three patients died within 4 months of leaving the hospital. These had complex CHD and increasing symptoms of heart failure despite correct cardiac pacing.

The average PT amplitude values (at an impulse width of 0.4 ms) subsequently measured in our patients are presented in Figure 1. The PT of the atrial leads was stable in the observation period, while the PT of the ventricular leads gradually increased from the second year after implantation.

During the observation period 6 patients required replacement of the EP with SEL. In one case the reason for the replacement was a gradual increase in the PT of the ventricular lead; in this case only the atrial lead was left. In 5 patients defects were discovered in one or both leads between 21 and 70 months following implantation. In two of these cases the pacemaker was reprogrammed on VVIR, while in two other children the EP system



**Figure 1.** Changes in the pacing threshold (PT) of atrial (A) and ventricular (V) steroid-eluting (SE) leads and ventricular non-steroid leads (NSE) during the follow-up period.

was replaced with an endocardial one and one patient had another EP system with SEL implanted. In two patients pacemakers were replaced because of battery depletion: after one year in one child with fibroelastosis and long QT syndrome who had a high PT and in another after 5 years.

At present 43 children from Group I are monitored by the Department of Cardiology of CMHI. A total of 39 patients (73.6%) still have their first EP systems with SEL, three patients had reached adult age and one child is under the supervision of the Cardiological Outpatient Clinic in Zabrze. One patient has had a heart transplantation and does not require cardiac pacing. The physical development and condition of our patients and of those who are now adults is good.

## Group II

Group II included 29 children (17 female and 12 male). The patient's age at implantation of the EP system without SEL ranged from 10 days to 13 years, with an average of 6.5 yrs). The pacemaker implantation indications are presented in Table 2.

For 24 patients EP without SEL was the first implanted system. Five children had previously had a pacemaker: four had had an endocardial pacemaker and one had had an epicardial one without SEL. In these 5 children the reason for implanting a new pacemaker system was lead damage.

**Table 2.** Indications for implantation of epicardial pacemaker system and CHD in group II

Indications for implanting EP	Congenital heart defect
Postoperative CHB — 7	AVSD — 2 VSD — 2 ASD, PS — 1 ToF — 1 TGA, VSD — 1
Postoperative, paroxysmal CHB — 1	VSD — 1
Postoperative sinus node dysfunction — 1	TGA after SO — 1
Congenital CHB — 18 (with LQTS — 2)	No CHD — 13 CTGA — 2 SV, TGA — 1 SV, ASD, PS — 1 ASD — 1
Congenital sinus node dysfunction — 1	ASD — 1
LQTS — 1	No CHD — 1

EP — epicardial pacemaker; CHB — complete heart block; CHD — congenital heart defect; ASD — atrial septal defect; VSD — ventricular septal defect; AVSD — atrioventricular septal defect; ToF — tetralogy of Fallot; TGA — transposition of great vessels; CTGA — corrected transposition of great vessels; SV — single ventricle; PS — pulmonary valve stenosis; LQTS — long QT syndrome; SO — Senning operation

In all cases single-lead epicardial stimulation was applied (21 VVI and 8 VVIR). The leads implanted were manufactured by Biotronic (in 22 patients), CPI (6 patients) and Siemens (1 child). PT during implantation ranged from 0.3 to 2.4 V, with an average of 1.2 V (impulse width 0.4 ms).

In 12 patients (41%) no complications were observed during the operation or the early postoperative period. A total of 9 patients (31%) suffered from an exudation in the pericardium and of these two required pericardium drainage. Delayed healing of the surgical wound was observed in two children and one child had intermittent fever. Other complications (pleural effusion, brain ischaemia and inflammation of the sternum) were due to cardio-surgical correction of CHD.

The measurement of the PT at discharge from the hospital (on average on the 7<sup>th</sup> day after the operation) showed a significant increase in PT, ranging from 0.8 to 2.8 V, with an average of 1.7 V (impulse width 0.4 ms). The differences between PT during implantation and PT at discharge were statistically significant ( $p < 0.01$ ).

The observation period of patients in group II ranged from two months (lead damage) to 15 years, with an average of 7.7 years. Two patients have died: one, a female with complex CHD (single ventricle and subvalvular pulmonary stenosis with CHB), two months after the EP system implantation and the second, a girl who had fibroelastosis and LQTS, three months after implantation. Both cases showed increasing symptoms of heart failure, although their cardiac pacing was correct.

The average PT amplitude values (impulse width 0.4 ms) subsequently measured are presented in Figure 1. During the follow-up period the PT increased gradually in the first 6 months after implantation and then stabilised.

During the observation period 6 patients required EP system replacement. The procedures were performed between two months (because of lead damage) and 11 years (change for an endocardial pacing system) after implantation (at a mean 3.8 years). In 4 children the EP system was replaced by an endocardial one. Two patients had another EP system implanted but with SEL. Three patients required a new pacemaker system because of lead damage; in one child the pacing system was replaced during cardio-surgical correction of CHD. A total of 6 children required pacemaker replacement because of battery depletion (3.5 to 7 years after implantation, at a mean of 5.5 years).

At present 11 children from Group II are still our patients, 15 patients have reached adult age.

Eighteen patients have their first EP system. One patient has gone abroad and so far we have received no information about her. The physical development and condition of our patients, as well as of those who have reached adulthood, is good.

The amplitudes (the impulse duration remaining constant at 0.4 ms) of the PT measured in the two groups were compared. Patients with EP and SEL had a lower PT amplitude during pacing system implantation and the two subsequent years than patients who did not receive SEL. The differences were statistically significant ( $p < 0.04$ ). During the third and fourth year after pacemaker implantation this difference gradually decreased and after four years PT was much the same in children with and without SEL.

## Discussion

In the first years of heart pacing epicardial leads were commonly used in children. It soon became apparent that numerous problems arise when using EP. In 20–30% of patients an increase in TP is observed, which requires programming of a higher amplitude and/or higher impulse width. This leads to faster battery depletion and pacemaker replacement. Lack of correct pacing (exit block) requires replacement of the implanted pacing system. Because of these problems endocardial pacing systems were increasingly used even in the youngest children. However, EP is needed by patients with low body weight, intracardial septal defects, venal anomalies or obstruction or complex congenital heart defects, making implantation of the endocardial lead impossible. The introduction of SEL has contributed to a wider usage of EP. It has turned out that pacing parameters with the use of SEL are significantly better for a longer period of time than when non-steroid EP is used and are comparable to endocardial pacing parameters [13–15].

In Group I the PT during implantation was higher than described by other authors, although it dropped quickly and significantly after an average of 7 days, which was comparable to cases described in other papers. Usage of different pacing programmers may explain the difference in PT values referred to above. In our patients the PT of the atrial leads did not change significantly during the follow-up period, while ventricular lead PT started to rise gradually after two years of observation. Similar differences in lead parameters were observed by Johns and others within one year of implantation. However, other authors have written that the ventricular and atrial PT was stable and low for years, although there were also cases of increasing PT and

exit block in children with SEL [14–16]. This later problem also affected two of our patients.

In this paper we have compared the clinical course of EP in two groups, similar in indications of pacemaker implantation and heart diseases. In both groups the method's complications and their frequency are in line with the findings reported in other medical papers [14–20]. In the early postoperative period patients can suffer from exudation in the pericardium. This was observed in 23 (28%) of our patients. The most common cause of pacemaker system change in our patients, and in the cases described by other authors, is lead damage. A case of dislocation of the pacemaker to the chest, as occurred in two of our youngest patients, has also been described [21].

Children with SEL had a low PT in the first years after their operation, which is in line with numerous reports in the literature [13, 22–25]. After an average period of 4 years the pacing parameters of the ventricular leads were similar in the two groups, those with and those without steroid-eluting leads. Despite the rise in PT found in Group I, 4 years of low PT is a significant advantage for our patients. In addition, using pacemakers with an autocapture function in the youngest patients prolongs the battery life and delays its replacement.

The high quality of steroid-eluting leads and their parameters have encouraged their widespread usage in children. The implantation of an EP system with SEL as the first one in the youngest patients, even when the use of endocardial pacing is possible, is considered a preferable way of proceeding in many hospitals. This should have a positive impact on children's developing blood vessels. Stitching of the lead in a place avoiding the right ventricle apex is equally important.

Children with permanent cardiac pacing need this treatment throughout their lives. Maximising the duration of correct pacing should be the main goal. This can be achieved by the use of top quality leads and pacemakers, allowing the child to lead a normal active life. The pacemakers with long-life batteries and the autocapture function should be used more often. Post-implantation systematic monitoring of a patient is also important [1, 4, 9–12, 26–29].

### Conclusions

1. The pacing thresholds of children with epicardial pacing and steroid-eluting leads are significantly lower than those of patients with non-steroid-eluting leads.

2. The pacing threshold of ventricular steroid-eluting leads increases throughout the several years of follow-up, while the pacing threshold of atrial steroid-eluting leads remains stable.

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