Transvenous cardiac pacing in children: problems and complications during follow-up

Çocuklarda transvenöz pacemaker tedavisi deneyimlerimiz: İzlemde problem ve komplikasyonlar

Alpay Çeliker, Osman Başpınar, Tevfik Karagöz

From the Department of Pediatric Cardiology, Faculty of Medicine, Hacettepe University, Ankara, Turkey

ABSTRACT

Objective: Transvenous permanent cardiac pacing (TPCP) has become a frequently used therapeutic modality in children. The purpose of this study was to evaluate the outcome of pediatric TPCP regarding problems and complications.

Methods: Records of 155 patients (mean age 9.2±4.7 years) who underwent implantation of TPCP between 1993 and 2003 were reviewed retrospectively. Indications for pacing included atrioventricular block in 76% and sinus node dysfunction in 22% patients. In 92 patients, bradyarrhythmia was secondary to cardiac surgery. Percutaneous subclavian puncture was used for lead implantation in 96% of patients. Pacemakers were placed to the right side of the chest in 84% and in the subpectoral area in 68%. Pacing modes were VVIR in 72%, VDD in 13%, AAIR in 8%, and DDD in 7% of patients at the initial implantation time. Of all electrodes, 95% had steroid elution and 53% had an active fixation mechanism. Mean follow-up period was 37±28 (1-120) months.

Results: Forty-five (29%) patients had 21 minor and 45 major complications. Forty-four of 76 revisions were due to lead problems and battery extraction. Most of the lead problems were dislodgment and stretching (n=14). Kaplan Meier analysis of lead survival did not show any difference between lead types. During the follow-up, there were three sudden unexpected deaths.

Conclusions: In children, TPCP can be used safely and effectively. Although, complications are possible and sometimes lead or generator revision may be necessary, long-term outcome is favorable. *(Anadolu Kardiyol Derg 2007; 7: 292-7)*

Key words: Endocardial pacing, childhood, complications

ÖZET

Amaç: Kalıcı transvenöz pacemaker tedavisi çocuklarda da sıklıkla kullanılan bir tedavi yöntemi olmaktadır. Bu çalışmanın amacı pil tedavisinin çocuklarda uzun dönem problem ve komplikasyonlarını belirlemektir.

Yöntemler: Bin dokuz yüz doksan üç-iki bin üç yıllarında pacemaker yerleştirilen 155 hastanın (ortalama yaş 9.2±4.7 yıl) kayıtları geriye yönelik olarak incelendi. Pil gereksinimi %76 atriyoventriküler blok, %22 hastada sinüs nod disfonksiyonuydu. Bradiaritmi 92 hastada kalp cerrahisine ikincil gelişmişti. Elektrotlar %96 oranında perkütan subklaviyan girişim ile yerleştirildi. Pacemaker %84 göğsün sağ tarafına, %68 subpektoral bölgeye yerleştirildi. Pil modları %72 VVI, %13 VDD, %8 AAI ve %7 DDD şeklindeydi. Elektrotlar %95 steroid içeren, %53 aktif sabitleme mekanizmalıydı. İzlem zamanı ort 37±28 (1-120) ay olarak belirlendi.

Bulgular: Hastaların 45'inde (%29), 21 minör ve 45 majör komplikasyon oldu. Revizyonların %58'i elektrot problemi ve pil çıkarılması nedeni ileydi. Elektrot problemlerin çoğunluğu yer değiştirme ve gerilme (14 kez) şeklinde oldu. Kaplan Meier yaşam analizi ile elektrot tipleri arasında istatistiksel anlamlı bir fark gösterilemedi. İzlem sırasında beklenmeyen üç ani ölüm oldu.

Sonuç: Komplikasyonlar olabilmesine ve bazen elektrot ve pil revizyonu gerekebilmesine rağmen çocuklarda pil implantasyonu güvenli ve etkili bir şekilde yapılabilir. *(Anadolu Kardiyol Derg 2007; 7: 292-7)*

Anahtar kelimeler: Endokardiyal pil yerleştirilmesi, çocukluk çağı, komplikasyonlar

Introduction

Permanent transvenous cardiac pacing in children is being used increasingly. Long-term pacing therapy has become more reliable with developments in lead and generator technology and implantation techniques (1, 2). There are several reports describing the utility and usefulness of epicardial pacemaker system. Although epicardial pacing is useful to spare the venous system, there are various pitfalls of epicardial pacing (3, 4). After the infancy period, it is advised to implant endocardial pacemakers (5). Endocardial pacing systems have many advantages, including lower capture thresholds and fewer lead problems. There are few reports of medium-term results of endocardial pacing in children (6, 8).

Address for Correspondence: Osman Başpınar, MD, Gaziantep Üniversitesi Tıp Fakültesi, Pediatrik Kardiyoloji Bilim Dalı 27310 Gaziantep, Turkey
Phone: +90 342 360 60 60 Fax: +90 342 360 39 28 E-mail: osmanbaspinar@hotmail.com

In this study, we retrospectively evaluated the long-term results of transvenous pacemaker treatment in children underwent pacemaker implantation, and data regarding the indications, methods, complications and revisions in children in our center.

Methods

Patient characteristics: From January 1993 to December 2003, 155 patients received permanent transvenous pacing systems in the department of Pediatric Cardiology of Hacettepe Medical School. There were 62 males (40%), 93 females (60%) with a mean age 9.2±4.7 (9 months to 22 years) years, and body weight 29±15 (6.4-80) kg. Their records were reviewed retrospectively. The patients were monitored with 1587 outpatient visits (3.4 per patient/year) during follow-up.

Evaluation included routine clinical examination, electrocardiogram, chest X-ray, echocardiogram, and a full analysis of the pacing system measurements. The voltage stimulation threshold at 0.5-ms pulse width, pacing impedance, and R or P wave amplitude were assessed at time of implantation, 2nd day, 4th week, 3rd month, 6th month, and every six months thereafter. The 24-hour ambulatory electrocardiographic monitoring and, if the patient was suitable, treadmill exercise testing was performed every year.

Pacing indications: Indications for pacemaker implantation included advanced second- or third degree surgical/acquired (n=84, 54%), congenital (n=38, 25%) atrioventricular block (AVB), sinus node dysfunction (SND) (n=29, 19%) and other reasons such as long QT syndrome and hypertrophic cardiomyopathy (n=4, 3%) (Table 1). Of all, 67 (43%) patients had had implanted epicardial lead system previously. Ventricular septal defect closure (n=21), total correction for tetralogy of Fallot (n=18), and subaortic resection (n=13) were the most frequent cardiac operations leading to postoperative AVB. Mean time to implantation time for postoperative AVB was 19 days following surgery. Of the 77 patients with surgical AVB, five patients had also sinus node dysfunction in addition to late onset AVB. Eight (21%) of the patients with congenital AVB had structural congenital heart disease. The most common lesion was congenitally corrected transposition of the great arteries. Among the patients with acquired AVB (n=7), cardiomyopathy and/or myocarditis were present in four.

When the patients with surgical AVB (n=77) were excluded, 40 (51%) of the remaining 78 patients had symptoms related to bradycardia, such as seizures, syncope, presyncope, dizzy spells (n=19, 24%), and exercise intolerance (n=21, 27%). Although the remaining 38 patients with severe bradycardia were asymptomatic, 15 (19%) of them had a pause >3 seconds while awake or >5 seconds while sleeping, 10 (13%) of them had complex ventricular arrhythmias, and five (6%) of them had left ventricular dysfunction associated with severe bradycardia.

Twenty-four of 34 patients with SND had a congenital heart defect or previous cardiac surgery. All of them were symptomatic and eight of 34 (24%) were defined as having brady-tachy syndrome. Five of 34 SND patients also had concomitant atrioventricular conduction disturbance, as mentioned above. Pacemaker implantation was performed in this subgroup at mean of 410 days following surgery.

Twenty-five of 155 patients (16%) were pacemaker dependent, with an intrinsic heart rate less than 30 bpm. Twenty-one of them (84%) had postoperative brady-dysrhythmia.

Implantation procedure: The same cardiologist performed the implantation procedure in the catheterization laboratory under general anesthesia. Endocardial leads were implanted by the percutaneous subclavian technique in 96% of cases. The pacemaker pocket was placed beneath the pectoral

Table 1. Pacing indications and symptoms related required pacemaker therapy

	Pacing indications	**n (%)**
Surgical or acquired AV block		84 (54)
	VSD closure operation	21
	TOF operation	18
	Subaortic resection operation	13
	Cardiomyopathy and/or myocarditis	7
	Other cardiac operations	25
Congenital reasons		67 (43)
	Atrioventricular block	38
	Sinus node dysfunction	29
Other	Long QT syndrome and hypertrophic cardiomyopathy	4 (3)
	Pacing symptoms	**n (%)**
Postoperative status		77 (50)
Bradycardia related seizures, syncope, presyncope		19 (12)
Bradycardia related exercise intolerance		21 (13.5)
Asymptomatic bradycardia		38 (24.5)

AV- atrioventricular, TOF- tetralogy of Fallot, VSD - ventricular septal defect

muscle in 92 patients (59%) and subcutaneous in 49 patients (32%) through the subclavicular incision, and under the pectoral muscle in 14 patients (9%) through the axillary incision at the initial implantation. Pacemakers were placed to the right side in 84% and left side in 16% of patients, respectively. Patients were discharged from the hospital between the second to fifth days after implantation.

Battery type: Pacing modes were VVIR in 112 (72%), VDD in 20 (13%), AAIR in 12 (8%), and dual chamber devices (DDD) in 11 (7%) patients at the initial implantation. Mean age was 7.8±4.5 (0.75-21) years in VVIR, 12.2±5.8 (1.1-22) years in AAIR, 13.1±2.6 (7-16) years in DDD, and 10.2±3.9 (1.3-17) years in VDD pacing group. Initial pacemaker mode was based on cardiac status, age, and weight of the patient.

Electrode characteristics: In 155 patients, 166 leads were used at the initial implantation. Additionally, 25 leads were required due to revisions or upgrading from single to dual chamber pacing during the follow-up. Active fixation leads with steroid eluting (n=102, 53%), passive fixation leads with steroid eluting (n=80, 42%) were used in the majority of the patients. There were no differences regarding age (9.3±4.8 vs 8.8±4.9 years, p=0.46) and weight (29.4±16 vs 27.6±14.6 kg, p=0.45) between patients with these two types of electrodes. Seven patients with congenitally corrected transposition of the great arteries had implanted screw-in leads placed into the anatomic left ventricle.

Statistical analysis: Exploratory data analysis was performed using descriptive measures. All ages reported are

Table 2. Pacing and sensing measurements in groups with different types of leads

Parameters	Time	Passive fixation group	Active fixation group	p**
Ventricular capture threshold, V	Implantation	0.6±0.7	0.6±0.2	0.825
	3rd month	1.0±0.6	1.06±0.6	0.927
	End of follow-up	2.4±10.2	1.2±0.7	0.379
	*F	0.468	1.523	
	*p	0.497	0.223	
Ventricular lead impedance, Ohm	Implantation	607±132	589±110	0.395
	3rd month	619±164	631±149	0.675
	End of follow-up	634±207	606±166	0.424
	*F	1.135	2.539	
	*p	0.290	0.117	
R wave, mV	Implantation	8.5±3.5	10.4±5.7	0.061
	3rd month	9.1±4.5	11.2±6.8	0.186
	End of follow-up	9.8±7.1	10.5±7.0	0.664
	*F	1.008	0.367	
	*p	0.329	0.558	
Atrial capture threshold, V	Implantation	1.0±0.8	0.9±0.4	0.780
	3rd month	1.2±0.6	1.2±0.4	0.966
	End of follow-up	0.8±0.3	1.0±0.5	0.341
	*F	0.315	0.703	
	*p	0.631	0.415	
Atrial lead impedance, Ohm	Implantation	590±139	533±138	0.440
	3rd month	643±50	540±133	0.039
	End of follow-up	775±106	553±142	0.158
	*F	0.719	0.015	
	*p	0.486	0.904	
P wave, mV	Implantation	3.9±2.0	2.9±1.1	0.090
	3rd month	1.2±0.7	3.1±1.5	0.001
	End of follow-up	1.3±1.3	3.0±1.7	0.014
	*F	0.422	0.916	
	*p	0.544	0.361	

*F test and p values for one way ANOVA analysis comparison of lead characteristics through 3 measurements within groups, **p - values for Student`s unpaired t test for comparison between groups data

mV- millivolts, V- volts

mean ages at implantation. Data are expressed as mean±SD. One-way analysis of variance (ANOVA) with Bonferroni corrected post hoc t test was used to compare the threshold, impedance and R/P wave values within active and passive lead groups. The comparison of lead characteristics between active and passive lead groups were done using Student`s unpaired t test. A p value of <0.05 was considered significant. Survival analysis was assessed by using Kaplan Meier analysis with significance based on the log-rank test. Survival time was calculated from the date of implantation to the date of lead related events or unknown death of the patient. The analyses were performed using the Statistical Package for the Social Sciences 11.0 (SPSS, Inc., Chicago, IL, USA) for Windows computer program.

Results

Electrical measurements (Table 2): The changes in electrical characteristics during the 3 follow-up measurements within groups were not significant (p>0.05). There were no significant differences regarding ventricular thresholds, ventricular lead impedance, intrinsic R wave amplitudes, atrial thresholds between ventricular active and passive electrode groups at the implantation, third month and the end of the follow-up period. There were significant differences between groups in atrial impedance (3rd month - p=0.03) and P wave amplitude (p=0.001 for 3rd month and p=0.04 for the end of follow-up) during follow-up period.

Complications: Forty-five patients (29%) developed 66 complications, 16 of them were detected in first 15 days after implantation and the others occurred thereafter. Twenty-one of them were minor and 45 (68%) were major. Major complications are noted in Figure 1. Beyond the implant time, the most frequent minor complications were muscle and phrenic nerve stimulation, and major complications were lead stretching and dislodgment (Fig. 1). No patient developed syncope or presyncope. Seven of the eight of dislodgements were seen in patients with passive fixation leads.

Lead survival: Follow-up was available for 133 patients. The mean follow-up period was 37±28 (range 1 to 120) months.

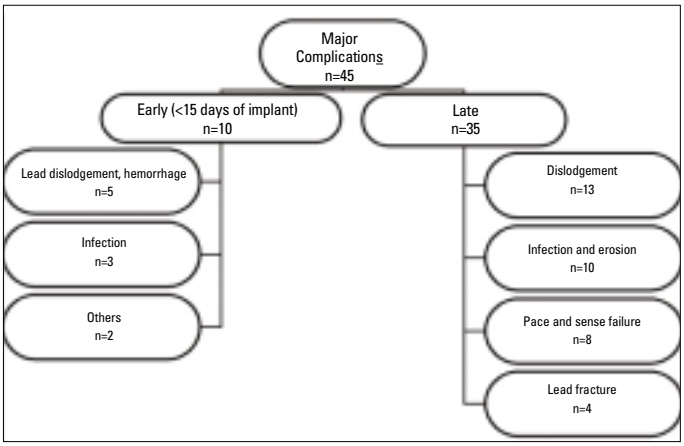

Figure 1. Major complications of pacemaker implantation

Lead related events were encountered 13 times; loss of pacing and sensing in five, fracture in four, unknown death in three, damage to screw mechanism in one patient. Lead survival was 33±27 months in active fixation group and 41±28 months in passive fixation group. Kaplan Meier survival analysis did not show any difference in their distributions with log rank test (p=0.78).

Lead or battery revisions: During follow-up, 76 patients required revision. Forty-three (57%) of them were related to the pacemaker, with the most common reason being battery end-of-life (n=32, 42%). Lead revision was required 33 times, with the most common reason being lead dislodgment and stretching (n=14, 19%) (Fig. 2).

Deaths: There were eight deaths. Five of them were related to the underlying cardiac diseases. First one was thromboembolic event at the gravity in one who had mitral valve replacement; second -dysfunctional prosthetic aortic valve with severe congestive heart failure and chronic atrial fibrillation; third had atrial fibrillation with rapid ventricular conduction; fourth - severe congestive heart failure with dilated cardiomyopathy; and last one died due to the postoperative infectious complications. There were three sudden unexpected deaths, including two patients who had open cardiac surgery. None of them was pacemaker-dependent. The cause of death was unknown, but battery malfunction and/or exit block could not be excluded as possible etiologies. Their follow-up periods were 43, 23 and 3 months and their pacing mode was VVIR.

Discussion

In the present study, we report our long-term experience with endocardial cardiac pacing in 155 children up to a 9-year follow-up. The indications for permanent pacing in children are well established (5, 8, 9). Pacing in the pediatric patient is more difficult because of the size of the patient (5, 7). Transvenous pacing in children has become widespread since the early 1980s. In our unit, we prefer epicardial system at the infancy

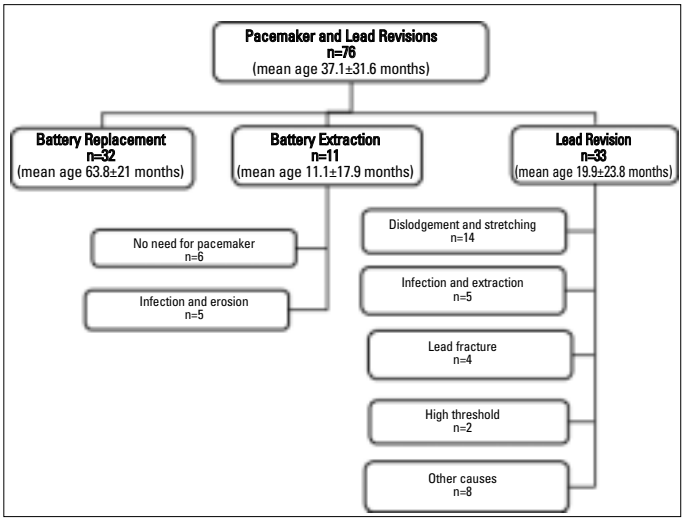

Figure 2. Pacemaker and lead revisions

period. The improved reliability and long life of cardiac pulse generators justify pacing in symptomatic patients and those with potentially life-threatening conditions. A pediatric patient can anticipate receiving 10 to 15 pacemaker implantations during his lifetime (8). In our study, the most common indication for pacing was bradyarrhythmias following cardiac surgery.

Placing one lead in children is technically easier than two leads and theoretically has a lower risk for venous obstruction (10). The incidence of venous obstruction following implantation of transvenous pacing leads in children was found to have a large spectrum from 2-5% to 18% (10, 11). However, most of pediatric patients with stenosis or occlusions of the venous system have venous collateral formation. No clinical signs of occlusion were observed in our patients except one. This patient was managed by oral antiplatelet treatment to prevent arm swelling.

Rate adaptive pacing may further improve functional status by increasing exercise capacity and this pacing mode produced equivalent exercise improvement when compared to the DDD mode (8, 12). Use of relatively reliable sensors mimicking daily activity has improved the rate adaptation mechanism of these pacemakers. Although, we have used rate responsive systems in most of our patients, the main difficulty for these pacing systems was the adjustment of appropriate rate response factor. Pacemaker syndrome may develop in some children with single chamber ventricular pacing. Pacing system upgrading may be necessary in these children to solve this problem during follow-up (13).

Active fixation leads are much easier to stabilize and more easily provide acceptable pacing and sensing indices when underlying anatomy is altered. Scar tissue formation due to cardiac surgery and anatomic variations due to congenital heart disease may limit available sites for implantation of passive fixation leads. Children are more active then adults and lead displacement may be more frequent (14-17). Although dislodgement may occur with active and passive fixation leads, current data show that active fixation reduces the incidence of lead dislodgement. Passive leads with auto capture function had been used more than active ones at the beginning of this study. We have shown that two leads did not differ significantly in ventricular sensing or pacing properties, however, the study was retrospective, not controlled and the recipients and site of implantation were not homogeneous in the groups. Pacing and sensing thresholds generally were good with minimally observed acute to chronic threshold changes. In addition, septal pacing can improve myocardial dysfunction secondary to right ventricular apical pacing, which is possible with active fixation electrodes (18).

Pacing leads are the most important part of the transvenous pacing system, since any problem related with this component may necessitate a serious intervention. The most common causes for lead revision include high threshold, lead migration, lead fracture, insulating defects, subcutaneous tissue infection, recovery of iatrogenic AVB, lead migration, lead trapped in a valve, too many leads, pain, and venous thrombosis (15-17, 19). In this study, pacemaker and lead-related complications were relatively frequent; 29% of patients experienced a complication related to their pacemaker system. The most common complications were lead dislodgement and infection of pacing system. The use of an active fixation mechanism may prevent lead dislodgement (15-17). We did not see any case of lead migration in the last five years owing to use of these electrodes routinely. Lead and pacing system infection may necessitate intervention, since they cannot be managed by medical treatment with antibiotics or local drainage alone (19). Lead fracture at the thoracic entry was another important complication, and a new electrode insertion had been required (20). Lead revisions and removal could be performed successfully in most cases without major complications. However, the large size of laser sheaths may preclude the use of this system in small children (20).

Patient growth may produce lead stretching and tricuspid valve interference. In our study group, we performed revisions to treat this problem without serious complication. Nevertheless, in most cases, the complications were not dangerous and could be managed appropriately.

Our results indicate that endocardial pacing is feasible in children. Although lead-related complications were relatively frequent, they could be managed without significant morbidity and mortality. Lead extraction tools designed for children may be useful for the treatment of lead problems. Smaller pulse generators and steroid-eluting active fixation leads are few of the technological advances that have made pacing in children easier, safer, and more durable. Continued experience may result in further improvements in endocardial pacing in children.

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