

Active-fixation, steroid-eluting ventricular leads: the medium-term results in children

Aktif sabitlenen, steroid salgılayan ventriküler elektrodlar: Çocuklarda orta-dönem izlem sonuçları

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ABSTRACT

Objective: Low threshold characteristics and mechanical stability are important features of an ideal pacing lead, especially for children. We report our experience and medium-term results with a steroid-eluting, active-fixation ventricular lead in children.

Methods: Telectronics Accufix II DEC model 033-212 ventricular leads were implanted in 21 patients. Eighteen patients (11 male / 7 female; 10.6 ± 4.0 years), who were followed for a mean period of 6.47 ± 1.13 years were included in the study.

Results: Pacemaker mode was DDDR in three patients, and VVIR in the remaining 15 patients. Mean threshold value was 0.5 volts at implant, which increased to 0.7 volts in the first month ($p < 0.05$). It remained stable (0.62-0.78 V) until 5.5 years ($p > 0.05$), increased significantly at 5.5 years (0.99 ± 0.63 V at 5.5 years, $p < 0.05$) and remained significantly high after this time ($p < 0.05$). Pacing lead impedance did not differ significantly throughout the study ($p > 0.05$). Thirteen pulse generators reached end-of-life at ≥ 4 years. In all the patients whose generators were replaced (11 patients), the leads were kept in place.

Conclusion: Steroid-eluting active-fixation ventricular leads have long service lives and low chronic stimulation threshold values, allowing lower outputs. These features may have advantages in pacing therapy of children. (*Anadolu Kardiyol Derg 2005; 5: 278-82*)

Key words: Active-fixation lead, pacemaker, children

ÖZET

Amaç: Düşük uyarı eşiği ve mekanik stabilite ideal kalp pili elektrodunun özellikle çocuklarda önemli özelliklerindedir. Aktif sabitlenen ve steroid salgılayan ventriküler elektrodların çocuklarda kullanımı ile ilgili orta-dönem izlem sonuçlarımızı sunuyoruz.

Yöntemler: Telectronics Accufix II DEC, 033-212 model ventriküler elektrodlar 21 hastaya uygulandı. Ortalama 6.47 ± 1.13 yıl izlenen 18 hasta (11 erkek/7 kız; ortalama 10.6 ± 4.0 yaş) incelemeye alındı.

Bulgular: Üç hastada kalıcı kalp pili DDDR, diğerlerinde (15 hasta) VVIR modunda çalışıyordu. Uygulama sırasındaki ortalama uyarı eşiği 0.5 volt iken ilk ayın sonunda 0.7 volta yükseldi ($p > 0.05$). Eşik değeri 5.5 yıl 0.62-0.78V aralığında stabil seyrettikten sonra ortalama 0.99 ± 0.63 V yükseldi ve başlangıç değerlerine göre anlamlı olarak yüksek seyretti ($p < 0.05$). Elektrod direnci çalışma süresince anlamlı değişiklik göstermedi ($p > 0.05$). On üç hastada pil ömrü ≥ 4 yılda tükendi. Kalıcı kalp pili değiştirilen bütün hastalarda (11 hasta) elektrodlar yerinde bırakıldı.

Sonuç: Aktif sabitlenen ve steroid salgılayan ventriküler elektrodlar uzun ömürlüdür ve düşük uyarı eşiklerinin olmaması daha düşük voltaj çıkışı ile çalışmalarını sağlamaktadır. Bu özellikler çocukların kalp pili tedavisinde avantajlı olabilir. (*Anadolu Kardiyol Derg 2005; 5: 278-82*)

Anahtar kelimeler: Aktif sabitlenen elektrod, çocuk, kalıcı kalp pili

Introduction

The ideal pacemaker lead combines low threshold characteristics with mechanical stability (1). These features are especially important for children, since congenital cardiac malformations, postoperative changes in anatomy, and tissue characteristics may limit available sites for lead placement in them (2).

The stability of passive fixation leads remains to be a problem (1, 3, 4). On the other hand, some active-fixation leads, with

better mechanical stability and near zero dislodgment rates, have been reported to have problems with high chronic thresholds (1, 5). The use of steroid elusion with active fixation has been introduced as an important development (1, 6). The benefits of steroid elusion from actively fixed pacemaker leads with respect to threshold reduction have been documented well in adults (1, 7-17). However there are few studies on this subject in pediatric age group (2, 18-20), and none of these studies demonstrate medium or long-term results. We previously published the favorab-

le short-term (up to 24 months) results of steroid-eluting active fixation ventricular leads in children (21). In the present study, we report our medium-term results and experience with the same steroid-eluting, active-fixation, ventricular lead in a similar group of children.

Methods

Patients and Procedure

Accufix II DEC (model 033-212, Telectronics Pacing Systems, Englewood, Colorado) ventricular leads, which have active-fixation and steroid-eluting properties, were implanted in 21 patients since November 1994. This paper focuses on 18 of them (11 male/ 7 female; 10.6 ± 4.0 years), who were followed for a mean period of 6.47 ± 1.13 years. Telectronics Accufix II DEC model 033-212 lead was implanted and positioned in the right ventricular apex under ketamine anesthesia via percutaneous subclavian vein puncture. The pacemaker generator was placed in the subpectoral area. At the time of implantation, the stimulation threshold voltage at 0.5 ms pulse-width, pacing impedance, and R-wave amplitude were assessed, and the lead was implanted in the optimal place with the lowest threshold value.

Pulse Generators

Telectronics Meta III 1206 VVI or Meta 1254 DDDR pulse generators were used in all the patients. These pacing systems are rate responsive, which use minute ventilation as an index of metabolic demand. The programmable pulse amplitudes for Meta III 1206 VVI are 1.2, 2.5, 3.2, 3.7, 5.0, 6.2, or 7.5 Volts, and those for Meta 1254 DDDR are 2.5, 5, or 7 Volts.

Eleven pulse generators were replaced due to end-of-life or recommended replacement time indication on the telemetry during the follow-up period. Five generators were replaced with Pacesetter Regency SR+ 2400L, three of them were replaced with Pacesetter Affinity DR5530R, and the remaining three were replaced with CPI Discovery SR. Two of them are awaiting replacement.

Pacemaker Lead

Accufix II DEC is a ventricular, bipolar, active-fixation endocardial pacing lead with 55D polyurethane inner and outer insulation, an IS-1 connector, and a drug-eluting collar. The lead is a porous platinum and/or iridium electrode with a distal surface area of 6 mm². The distal tip diameter is 2.6 mm, and has an electrically inert active-fixation screw with a helix penetration of 1.7 mm. The screw is extended and retracted by rotating a fixation stylet. The silicone rubber drug-eluting collar, impregnated with approximately 0.7 mg of dexamethasone sodium phosphate, is situated adjacent to the distal electrode.

Follow-up

After the pacemaker implantation, the pacing parameters were tested on 5-7th day, and the patients were discharged. Follow-up evaluation was performed at first and third months after implantation, every 3 months in the first year and every 6 months thereafter. The evaluation included routine clinical examination, chest X-ray, and electrocardiogram. Chest X-ray was used routinely in the follow-up of patients to determine the lead length, position, and other problems like lead fractures, or lead perforation. The analysis of the pacing system was done using a Telectronics Programmer (model 5603 or 9602). Pacing thresholds were determined in volts at a pulse width of 0.5 ms. Threshold was considered to be the lowest voltage output at which there was

consistent capture. Threshold determinations were done with decreasing output settings. The resolution of the measurements were 0.2 Volts between 7.5-1 Volt, and 0.1 Volt for <1 Volt.

After the generators were replaced, Pacesetter APS Mode 3500 was used for Pacesetter pacemakers. The threshold resolution was 0.3 Volt (maximum 4.5 Volts). The CPI 2901 Programmer was used for the CPI pulse generators, the threshold resolution was 0.1 Volt (maximum 6.0 Volts).

We kept the pulse output amplitude at 5 Volts for the first three months disregarding the threshold measurements, after it was gradually decreased according to the measured threshold values. At the end of 9 months, the mean threshold was 0.60 ± 0.43 Volts. In eight patients the threshold value was <0.5 Volts, which enabled us to use the lowest output setting of the Telectronics pacemaker, which was 1.2 Volts. However the stimulation threshold changes during physical conditions like activity or rest, and temporary changes are also observed during minor illnesses like common colds (22). Therefore given the restricted programmability of output amplitudes, we preferred a wider safety margin, and assigned an output value more than twice the threshold level.

The sensitivity and the R-wave amplitude were noted. The lead impedance was measured at output settings of 5 V and 0.5 ms. It was not possible to determine R-wave amplitude in the follow-up visits because the majority of our patients were completely pacemaker dependent and had very slow ventricular escape rates.

A 24-hour ambulatory electrocardiographic monitoring and an exercise test were done every 12 months for all the patients. These tests were repeated when necessary (i.e. if the patients complained of symptoms like dizziness, or tiredness with little effort).

Statistical Analysis

Data are expressed as mean \pm SD. Median values were also provided for data with non-normal distribution. Paired t test was performed to analyze the change in time in the threshold values and the lead impedances.

Results

Eighteen patients with a mean follow-up period of 6.47 ± 1.13 years (median: 6.75 years; range: 4-7.5 years) constitute the study group. The clinical characteristics of the patients and the indications for pacing are shown in the Table 1.

The pacemaker mode was VVIR in all the patients, except in three of them who had DDDR pacemakers. The passive-fixation steroid-eluting atrial leads (Accufix II DEC 033-492 and ENCOR 330-854) were used with the active-fixation steroid-eluting ventricular leads in these patients. The VVIR pulse generators of two patients were replaced with DDDR generators after 4.5 and 5 years of follow-up, and the new generators were monitored for 3 and 1.5 years respectively after replacement. As the ventricular leads were kept in place, Pacesetter Tendril SDX 1488T-58 atrial leads were implanted.

Low acute threshold values (mean 0.5 ± 0.03 V) and good acute sensing characteristics (mean R wave: 9.7 ± 2.4 mV) were achieved at implantation of the electrode. The mean stimulation thresholds throughout the follow-up period are shown in Figure 1 and Table 2. Mean pacing threshold value raised slightly, but insignificantly until 5 years post-implantation ($p > 0.05$). After 5

years the threshold values were 0.99 ± 0.64 V or higher, and were significantly elevated compared to the implantation value ($p < 0.05$ for each value). During follow-up, energy saving was done by appropriate choice of pacing parameters especially the pacing output amplitude. Median output amplitude was kept at 5V until 3 months of implantation. In the vast majority of patients ventricular pacing was performed using 2.5V of pulse amplitude and 0.5 ms of pulse-width after 9 months while strictly maintaining at least a two-fold voltage threshold safety margin (Fig. 1). The mean pacing lead impedance was 591 ± 110 ohms (median: 570 ohms) at implantation. It remained within the range of 521-667 ohms, and did not differ significantly throughout the study ($p > 0.05$) (Fig. 1 and Table 2).

The mean follow-up period was 6.47 ± 1.13 years. Only one patient was followed for 4 years, all the other patients were followed for a minimum of 5 years. Half of the patients were followed for ≥ 7 years. Five patients suffered from dizziness between 3 months to 3 years of implantation, one patient complained of palpitation at 9th month, and another patient experienced tiredness with exertion 6.5 years post-implantation. The 24-hour am-

bulatory records, and exercise test results were normal in all of the patients. The pacemaker parameters were optimal and no program changes were made since these symptoms were not related to pacemaker dysfunction.

In one patient, due to growth in height, the loops of the lead within the pacemaker pocket were released after 4 years of implantation. A total of 13 pulse generators reached end of life within the follow-up period. Eleven of them were replaced within 4-6.5 years after implantation. The remaining two are awaiting replacement. The mean service life of these generators was 59 ± 7 months. When the new generators were implanted, the R-wave and threshold measurements of the leads were sufficient; therefore all the leads were kept in place. The service lives of the remaining five pulse generators were longer than the follow-up period (39%). The mean cell impedance was 1825 ± 950 ohms (median: 1375 ohms), the magnet rate was 89 ± 3 ppm (median: 90 ppm) at their last visit.

Discussion

A child who receives a pacemaker would expect several additional pacemaker implantations during his/her lifetime. Meanwhile lead revisions or explantations may be required for various reasons like sudden growth spurts, lead trauma, infection or dislodgement (2). Therefore better pacing electrodes, minimizing these circumstances are important in a young child necessitating a pacing therapy.

Many pediatric patients require pacing therapy after the surgical repair of a congenital heart defect. Half of our patients had pacemaker therapy because of surgical atrioventricular block. The surgical technique may cause extensive anatomical changes in the cardiac structure precluding a safe and stable

Table 1. Clinical characteristics of the paced patients

SEX	Male: 11 Female: 7
AGE	Mean: 10.6±4.0 years Median: 9.5 years Range: 5-18 years
FOLLOW-UP	Mean: 6.47±1.13 years Median: 6.75 years Range: 4.0-7.5 years
CARDIAC PATHOLOGY/ PM INDICATION	No Cardiac Pathology: 6 Congenital AV Block (mean HR<50/min) 4 AML and acquired complete AV block 1 Cardiac Pathology: 2 SND + subnormal AV conduction (HR<50/min) 1 Myocarditis + SND (pauses>3 sec) 1 L-TGA + complete AV Block 1 Surgical AV Block: 9
PM MODE:	VVIR: 15 DDDR: 3

AML: Acute myeloblastic leukemia, AV: atrioventricular, HR: heart rate, L-TGA: L-transposition of the great arteries, PM - pacemaker, SND: sinus node dysfunction

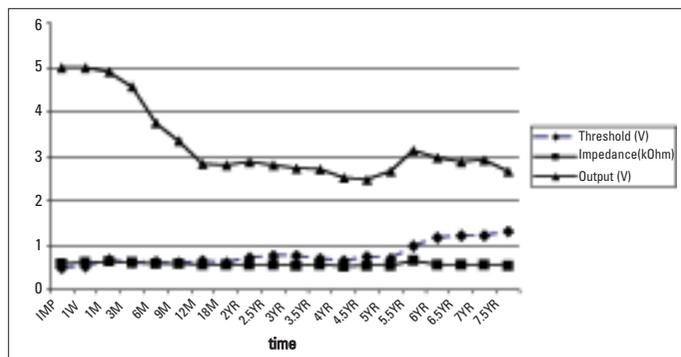


Figure 1. Change in mean threshold values, mean pulse output settings, and mean impedances of lead Accufix II DEC over time

IMP: implantation, M: month, W: week, YR: year,

*: $p < 0.05$ compared to the implantation value

Table 2. Mean stimulation voltage thresholds and impedances over time

Time	Threshold (Volts, Mean ± SD)	Impedance (Ohms, Mean ± SD)
Implantation Time	0.5 ± 0.11	591 ± 110
1 Week	0.52 ± 0.17	613 ± 115
1 Month	0.69 ± 0.44	627 ± 129
3 Months	0.62 ± 0.39	609 ± 106
6 Months	0.63 ± 0.41	595 ± 97
9 Months	0.62 ± 0.43	583 ± 86
12 Months	0.66 ± 0.48	568 ± 91
18 Months	0.62 ± 0.46	561 ± 88
2 Years	0.74 ± 0.64	563 ± 86
2.5 Years	0.77 ± 0.75	569 ± 82
3 Years	0.78 ± 0.71	549 ± 89
3.5 Years	0.71 ± 0.56	562 ± 78
4 Years	0.67 ± 0.58	521 ± 105
4.5 Years	0.75 ± 0.66	546 ± 106
5 Years	0.71 ± 0.62	545 ± 85
5.5 Years	0.99 ± 0.64*	667 ± 101
6 Years	1.18 ± 0.53*	569 ± 97
6.5 Years	1.22 ± 0.73*	558 ± 94
7 Years	1.23 ± 0.35*	569 ± 104
7.5 Years	1.32 ± 0.33*	537 ± 116

*: $p < 0.05$ compared to the implantation value

implantation of a pacemaker lead as in the case of a passive fixation lead. An actively fixed lead, however, may secure its place and reduce the likelihood of dislodgment. It also allows the implanter to avoid the areas of scar tissue and to select the best pacing site (2). Apart from these obvious benefits of actively fixed leads, the major disadvantage is that the long-term pacing thresholds tend to be higher than the passive fixation leads (14). This is probably due to an inflammation reaction surrounding the fixation mechanism. Addition of steroid elution to an active-fixation lead reduces this threshold rise by avoiding the local inflammatory reaction (1, 23, 24).

Active-fixation allowed us to implant the ventricular leads with good acute sensing and low pacing threshold values. During a mean follow-up of 6.47 ± 1.13 years, no lead failure or dislodgment was observed. Only one lead revision was made due to sudden growth spurt of the patient. Growth is an important factor in children undergoing implantation of transvenous pacemaker systems. While using short leads (36-45 cm) to reduce bulk at the pulse generator site (25), an additional lead-loop has to be left in the right atrium to allow for future growth. Gheissari et al (26) have computed that 80 mm right atrial lead-loop allows a mean 8-year of growth in infants and children without a need for reoperation to adjust the lead length. When inserting ventricular leads, we also leave an additional loop (approximately 5-6 cm) in the right atrium at the time of the lead insertion.

The mean pacing threshold values remained low with slight and statistically insignificant increments at the end of first month. Although the increase after 5.5 years was significant, we could confidently use lower output amplitudes throughout the follow-up period. In a study by Shepard et al, the highest mean thresholds were observed in the 6-12 years old age group. The time of maximum threshold occurred after one month in 59% of patients, independent of the lead type (22). Therefore question arises whether these threshold fluctuations are more typical in pediatric population. This is especially important for programming an adequate safety margin in children. Unfortunately there is no adult control group available, and this has to be further investigated.

The manufacturer sets the approximate longevity of the Telectronics Meta III pulse generators as 4.6 years. In our study only two pulse generators were replaced before this time. The mean service life of the generators during the follow-up was 59 ± 7 months. We observed that most of the pulse generators outlived their predicted lives. This is most probably due to the low threshold settings, which enable lower output voltages, and less battery drainage since patients with consistently higher threshold values had to experience earlier generator replacement than other patients. Lacking a control group with passive fixation leads is certainly a limitation of this study, however as stated in our previous study, Accufix II DEC has clear advantages over the passive-fixation electrodes including easier implantation, lower acute and chronic stimulation thresholds, less possibility of dislodgment (26). Furthermore most studies about adult patients and the characteristics of "low threshold leads", also conclude "low threshold leads" decrease the battery drain of the pacing system, hence increase the pacemaker longevity (1, 6, 10, 28-32).

The service life of the lead itself, apart from the pulse generator longevity is important in young patients. Among 18 patients the pulse generators of 13 patients reached end-of-life at the

end of 4 to 6.5 years of implantation. Eleven generators were replaced and the leads were kept in place. We observed that all these leads retained their optimal R wave and threshold values while working with the new generators.

Despite the currently accepted benefits of active-fixation electrodes, we used passive atrial electrodes in three patients with DDDR pacemakers. This was due to the previous experience mentioned in literature with the Accufix atrial active-fixation lead; concerning frequent retention wire fractures and spontaneous injury related to the J retention wires (34). However similar complications regarding the ventricular leads were not as frequent. Likewise we did not observe any lead related complications throughout our study. In 2004 Telectronics was not available for implantation, nevertheless we still believe long-term data about these leads are desirable. Pacemaker systems are apt to evolve technologically and by the time long-term data become available, extrapolating from the current practice will be moot. Therefore we ask clinicians to understand the limitations of the data presented and to recognize that the gradual and continuing advances in the pacemaker systems will still be guided by the "previous experience".

In conclusion, our data show that steroid-eluting active-fixation ventricular leads have low acute and chronic stimulation threshold values, allowing lower amplitude outputs, and thus suggesting an increase in longevity of the pacing system. These features offer clear advantages in the life-long pacing therapy of children, therefore active-fixation leads may be considered as the first choice of therapy in this group.

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