

Initial experience with dual-sensor rate-responsive pacemakers in children

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The efficacy of a new single-chamber, rate-responsive pacemaker that utilizes information from two sensors, activity and stimulus to T wave, was evaluated in 15 children during a mean follow-up period of 10.3 ± 3.3 months (range 5–16 months). There were 10 males and five females, with a mean age of 5.9 ± 3.8 years (range 9 months–16 years). The indication for pacing was high grade atrioventricular block in 10 (eight postoperative, two congenital), and sinus node dysfunction in five patients.

In endocardial implants the mean T wave amplitude was 2.48 ± 0.7 mV, and mean T wave sensing $91 \pm 6.3\%$, whereas in epicardial implants T wave amplitude and sensing were inadequate. Each patient underwent 24-h Holter monitoring and 10 performed a graded treadmill test in three sensor-blending modes (Stimulus-T=Activity, Stimulus-T>Activity, Stimulus-T<Activity), using the chronotropic assessment exercise protocol. Sensor cross-checking was analysed by continuous tapping over the pacemaker. Holter monitoring demonstrated that pacing

rate variations were closely related to daily activity. At the initial phases of exercise testing, the mean percentage of increase in pacing rate was significantly lower in Stimulus-T>Activity mode, when compared to Stimulus-T=Activity ($P<0.01$); however, the initial disparity among the three modes disappeared halfway through the exercise and similar heart rate changes were observed thereafter. Continuous tapping over the pacemaker in Stimulus-T=Activity mode caused an initial increase in pacing rate, and inappropriate responses were quickly corrected by sensor cross-checking.

Rate modulation with a single-chamber, dual-sensor pacemaker is adequate and safe in children, and may offer significant advantages over single-sensor devices in endocardial implants.

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Key Words: Dual sensor pacing, sensor blending, rate adaptive, children.

Introduction

The advantages of rate responsive ventricular (VVIR) pacing over fixed rate ventricular pacing (VVI) are well established^[1,2]. Several different sensors, including central venous temperature, oxygen saturation, pH value, stimulus to T wave, body activity, respiratory rate, right ventricular dP/dt, minute ventilation, stroke volume, evoked potentials and atrial rate have been used for rate modulated pacing^[3–12]. However, each sensor has its advantages and disadvantages and no single pacing device can adapt its pacing rate appropriately to all changing circumstances.

Recent developments in pacing provided the opportunity to combine information from two sensors into a rate-adaptive algorithm, which may offer advantages over individual sensors. Thus, a new single-

chamber rate-responsive pacemaker (Topaz, Vitatron Medical, The Netherlands) became available that utilizes information from two sensors, activity and stimulus to T wave^[13].

There are several reports about the efficacy of this new device in adults, but there is limited information about its use in children^[14–16]. The aim of this study is to evaluate the efficacy and reliability of this dual-sensor pacing system in children.

Methods

Patients

The Topaz models 500 or 515 were implanted in 15 children. There were 10 males and five females whose mean age was 5.9 ± 3.8 years (range 9 months–14 years) at the time of implantation. Indications for permanent cardiac pacing were high grade atrioventricular block in 10 patients (eight postoperative, two congenital), and sinus node dysfunction in five patients.

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Table 1 Initial and final data of the patients

	Initial		Final	
Programmed values				
Sensor blending	QT=ACT		QT=ACT(n:6), QT<ACT(n:9)	
Activity threshold	medium		med(n:10), med-low(n:3), med-high(n:1), high(n:1)	
Minimal rate (ppm)	64.3 ± 9.2	(M:60)	64.3 ± 9.2	(M:60)
Maximal rate (ppm)	146.6 ± 11	(M:150)	146.6 ± 11	(M:150)
Slope	auto		auto	
Sensitivity (mV)	2.1 ± 0.3	(M:2)	2.1 ± 0.3	(M:2)
Pulse duration (ms)	0.41 ± 0.03	(M:0.4)	0.41 ± 0.03	(M:0.04)
Refractory period (ms)	328.5 ± 7.1	(M:330)	328.5 ± 7.1	(M:330)
Pulse amplitude (V)	4.78 ± 0.69	(M:5.3)	3.9 ± 0.62	(M:5.3)
Measured data				
Amplitude threshold (volt)	<1.3		<1.3	
Pulse duration threshold (ms)	<0.1		<0.1	
Lead impedance (ohm)	437 ± 101	(M:400)	437 ± 101	(M:400)
Paced ventricular rate (%)	85.5 ± 20	(M:95)	86 ± 20	(M:95)
T wave amplitude (mV)*	2.48 ± 0.7	(M:2.8)	2.77 ± 0.7	(M:2.8)
T wave sensing (%)*	91 ± 6.3	(M:94)	73.4 ± 3.2	(M:94)

ACT=activity; M=median; med=medium, n=number of patients, QT=stimulus to T wave; * =in endocardial implants.

Seven patients underwent an initial implant and eight had depleted generators replaced. In five patients the epicardial implants were inserted by a cardiovascular surgeon, and in 10 insertion was via percutaneous transvenous endocardial implantation by puncture of the subclavian vein and took place in the cardiac catheterization laboratory. The generators were positioned in the subpectoral area in the latter group. The electrodes were unipolar and bipolar in epicardial and endocardial implants, respectively.

Pacing device

The implanted device (Topaz, Vitatron) is the first available single-chamber, dual-sensor rate-responsive pacemaker⁽¹³⁾. It utilizes information derived from the stimulus to the T wave, and from an activity-sensing piezoelectric crystal to determine pacing rate. The contribution of each sensor (sensor blending) is programmable for each patient and if there is disagreement between the two sensors with regard to the optimum pacing rate, 'sensor cross checking' is designed to correct any inappropriately high pacing rate.

Assessment and follow-up protocol

The patients were discharged from hospital between the 5th and 7th days after implantation and follow-up controls were performed at the 4th week, 3rd month, 6th month, and every 6 months thereafter for a full analysis of the pacing systems. Evaluation included routine clinical examination, electrocardiogram, chest X-ray, and the assessment of pacemaker threshold and sensor function.

Patients able to perform an exercise test (i.e. children older than 6 years) underwent symptom-limited graded treadmill testing. Chronotropic assessment exercise protocol (CAEP) was performed in three sensor blending modes (Stimulus-T=Activity, Stimulus-T>Activity, Stimulus-T<Activity) in each patient, with the activity threshold programmed to medium.

Each patient underwent 24-h ambulatory monitoring (Holter) to evaluate the quality of response of the pacemaker to usual daily activities. Sensor cross-checking was analysed by tapping over the pacemaker generator.

Statistical analysis

Data are expressed as mean ± SD. Differences in heart rate increase during exercise testing among three sensor-blending modes were examined by Kruskal-Wallis one-way ANOVA (analysis of variance). When there was a significant difference among three groups, the Mann-Whitney U test was performed to compare two groups. A value of $P<0.05$ was considered significant.

Results

At the time of implantation, the pacing threshold was <1.3 volts (V) in all but one of the patients with an epicardial electrode, whose pulse amplitude threshold was 2.7 V. The mean pulse width was 0.41 ms (median=0.40), the mean ventricular impedance was 437 ± 100 Ω (median=400 Ω), and the mean refractory period was 328.5 ± 7.18 (median=330) ms (Table 1). The programmed mean lower rate and mean upper rate were 64.3 ± 9.2 (median=60) and 146.6 ± 11 (median=150),

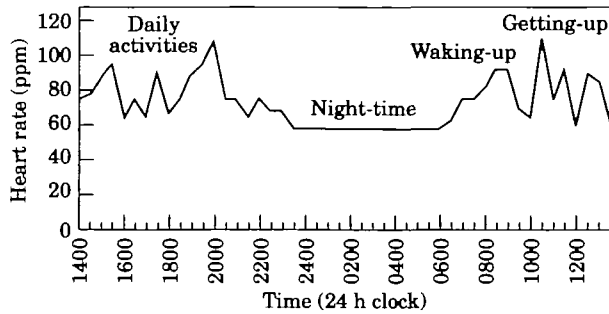


Figure 1 An example of a 24-h Holter monitoring report demonstrating a close relationship between pacing rate and daily activity.

respectively. Most of the patients had completely paced cardiac rhythm and the mean paced ventricular rate was $85.5 \pm 20\%$ (median = 95%). The initial activity threshold was programmed to medium, and sensor blending to Stimulus-T=Activity mode.

The mean T wave amplitude in endocardial implants was 2.48 ± 0.7 mV (range 1.3–3.1 mV), but it was undetectable in epicardial implants. T wave sensing was $91 \pm 6.3\%$ (range 44–99%) in the former group, but inadequate in the latter group. During follow-up, a slight decrease in mean T wave sensing was observed (to $73.4 \pm 32.2\%$; median 85%), due to a significant decrease in T wave sensing in one of the patients. The other parameters remained stable throughout the follow-up period.

Results of 24-h Holter monitoring demonstrated that the increases in pacing rate were closely related to daily activity (Fig. 1), but none of the patients reached the programmed maximal heart rate level during daily activity. Minimal, maximal and the mean heart rates are illustrated in Table 2.

Exercise testing

Exercise testing was performed in 10 patients with three different sensor blending modes (Stimulus-T=Activity, Stimulus-T>Activity, Stimulus-T<Activity). The mean duration of exercise was similar in the three modes. Furthermore, the mean value of the maximal pacing rate and the mean percentage of total pacing rate change at the end of the exercise test were not significantly different. However, the mean percentage of increase in pacing rates at the initial phases of the treadmill test was significantly different in three sensor blending modes (Table 3). In the Stimulus-T>Activity mode there was a slower initial increase in pacing rate at the beginning of the exercise test, whereas in Stimulus-T=Activity mode a faster increase in pacing rate was achieved ($P < 0.01$). Heart rate response to exercise was not statistically significant in Stimulus-T=Activity and Stimulus-T<Activity modes. The initial disparity among the three modes disappeared halfway through the exercise and similar heart rate changes were observed thereafter (Fig. 2).

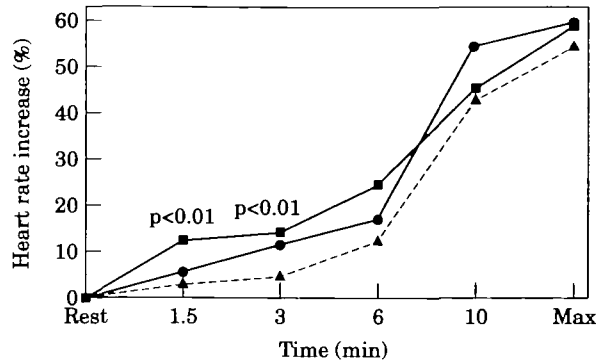


Figure 2 Diagram representing the mean percentage of increase in pacing rate during chronotropic assessment exercise protocol in 10 patients, comparing different sensor blendings. Rate response was significantly lower at the onset of exercise in Stimulus-T>Activity mode, but the disparity disappeared halfway through the exercise. ■ = Stimulus-T=Activity; ▲ = Stimulus-T>Activity; ● = Stimulus-T<Activity.

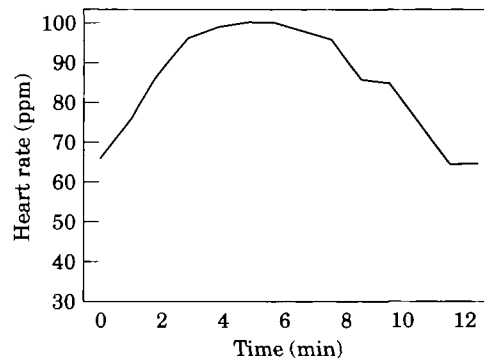


Figure 3 Changes in pacing rate induced by continuous gentle tapping over the pacemaker. Initial increase in pacing rate due to activity sensing was corrected by cross-checking from the Stimulus-T sensor.

Table 2 Results of 24-h Holter monitoring

	Mean	Median	Range
Mean heart rate (ppm)	77.3 ± 8.8	76.5	67–96
Minimal rate (ppm)	64.2 ± 11.7	62.5	50–92
Maximal rate (ppm)	122.8 ± 11.7	122	103–140

Sensor cross-checking

Continuous gentle tapping on the pacemaker in the Stimulus-T=Activity mode in endocardial implants caused an initial increase in pacing rate from 66 ± 5 ppm to a peak of 98 ± 13 ppm. The maximum acceleration of 14.8% was achieved 2.4 min after the beginning of tapping, and afterwards the pacing rate decreased to the initial level at the 12th min of tapping (Fig. 3).

Table 3 Mean heart rate and percent of heart rate increase during exercise

	QT=ACT (A)	QT>ACT (B)	QT<ACT (C)
Rest	70.9 ± 10	74.3 ± 12	71.5 ± 11
1-5th min (HR)	79.5 ± 14	76.4 ± 11	75.3 ± 12
(% increase)	(12.1 ± 7.8)*	(2.9 ± 4.6)*	(5.3 ± 7.8)
3rd min (HR)	87.6 ± 15.3	77.1 ± 10	79.7 ± 14
(% increase)	(13.9 ± 8.2)*	(4.3 ± 6)*	(11.4 ± 10)
6th min (HR)	87.6 ± 15	82.9 ± 11	83.5 ± 18
(% increase)	(24 ± 19)	(12.1 ± 8)	(16.7 ± 16)
10th min (HR)	103 ± 24	111 ± 22	106 ± 24
(% increase)	(45.1 ± 28)	(42.6 ± 35)	(54.5 ± 34)
Maximum exercise (HR)	115.2 ± 37	117.8 ± 30	125 ± 32
(% increase)	(58.9 ± 41)	(54.5 ± 37)	(59.5 ± 32)

* = $P(A-B) < 0.01$; HR = heart rate (ppm); (%increase) = percent of heart rate increase. For other abbreviations see Table 1.

Follow-up

Mean follow-up was 10.3 ± 3.3 months (range: 5–16 months). During follow-up, dislodgment of the leads due to trauma was seen in two patients. There were no other early or late pacemaker-related complications. A variation of initial programming was performed according to exercise test results and consequently the final sensor blending mode was adjusted to Stimulus-T<Activity in nine patients, and to Stimulus-T=Activity in six patients. Activity threshold was programmed to medium in 10 patients, medium-low in three patients, medium-high and high each in one patient (Table 1).

Discussion

Rate-adaptive pacemakers have been shown to improve exercise capacity and quality of life when compared to fixed rate ventricular pacing^{17–20}. Several different sensors have been utilized in pacemaker algorithms to provide a 'rate response'. Among possible sensors, body movements (activity) and stimulus to T wave (QT) interval had been widely used. However, neither these nor the other currently available sensors for rate-responsive pacing can be said to be ideal, and each sensor has its own advantages and disadvantages. The 'non-physiological' activity sensors react quickly to body motion and as a result have a rapid response at the onset of exercise. However, the pacing rate is not proportional to metabolic demand and they do not respond well to mental stress or isometric exercise where there are few body movements. On the other hand, physiological sensors, such as stimulus to T wave, temperature, pH, respiratory rate or oxygen saturation, may vary their pacing rate in accordance with physiological demand, though their rate of adaptation at the beginning of exercise is often poor^{21–23}.

Recent developments in pacing have provided the opportunity to combine the information from different sensors into a rate-adaptive algorithm²⁴. Topaz is a new single-chamber rate-responsive pacemaker that

utilizes information from two sensors, activity and stimulus to T wave, and can programme the contribution of each sensor to the overall rate response.

In our study, to find the optimal sensor-blending mode, exercise testing was performed using three different sensor blendings (Stimulus-T=Activity, Stimulus-T>Activity, Stimulus-T<Activity), in each patient. The initial rate response in Stimulus-T>Activity mode was too slow, whereas rate responses in Stimulus-T=Activity and Stimulus-T<Activity were appropriate during exercise testing. Although rate variations might be expected, in this study no significant differences in rate response in Stimulus-T=Activity and Stimulus-T<Activity modes were detected. With the contribution of both sensors we prevented non-physiological responses that were too fast or too slow, but achieved an appropriate heart rate increase at the onset of exercise testing. However, we evaluated only the chronotropic response to exercise but not workload. Therefore, further studies are needed in children to determine the optimum sensor blending mode that causes rate response proportional to the level of workload.

It is well known that programmed exercise protocols may not simulate daily activity exactly, since daily life includes bursts of activity, mental stress and intellectual effort in addition to graded physical stress^{25,26}. Hence 24-h Holter monitoring may be more demonstrative of the daily use of the sensor function. When we examined the results of 24-h Holter monitoring in our patients, we found that the changes in pacing rate were closely related to daily activity.

Sensor cross-checking is an important feature of this device. We tested it by continuous tapping on the generator, with the pacemaker programmed to Stimulus-T=Activity mode. This procedure produced an initial increase in pacing rate because of activity sensing, but within a few minutes the inappropriate response was corrected by cross-checking from the Stimulus-T sensors.

Our study demonstrated that T wave sensing was satisfactory both at implantation and during follow-up in endocardial implants. However, due to inadequate T

wave sensing, dual-sensor pacemakers may not offer significant advantages over single-sensor devices in epicardial implants. Therefore, in epicardial implants, an activity-only device may be more suitable in order to save the extra expenditure of the dual-sensor system. However, if dual-sensor devices are preferred, sensor blending should be programmed to either activity-only or to Stimulus-T<Activity in these patients.

In conclusion, single-chamber, dual-sensor ventricular rate-responsive pacing appears to be efficacious and safe in children. The system is very easy to use and the default setting of the activity threshold to medium, and the sensor blending to Stimulus-T<Activity or Stimulus-T=Activity were appropriate for most of the patients. We think that combining and cross-checking data from the two rate-response sensors utilized the advantages of each system, while eliminating the disadvantages of each separate system.

References

- [1] Hedman A, Norlander R. QT sensing rate responsive pacing compared to fixed rate ventricular inhibited pacing: A controlled clinical study. *PACE* 1989; 12: 374–85.
- [2] Cabrera ME, Hanisch DG, Cohen MH *et al.* Cardiopulmonary responses to exercises in children with activity sensing rate responsive ventricular pacemakers. *PACE* 1993; 16: 1386–93.
- [3] Griffin JC, Jutzy KR, Claude JP *et al.* Central body temperature as a guide to optimal heart rate. *PACE* 1983; 6: 498–502.
- [4] Wirtzfeld A, Heinz R, Liess HD. An active optical sensor for monitoring mixed venous oxygen saturation for an implantable rate responsive pacing system. *PACE* 1983; 6: 494–7.
- [5] Cammilli L, Alcidì L, Papeschi G *et al.* Preliminary experience with pH-triggered pacemaker. *PACE* 1978; 1: 448–57.
- [6] Richards AF, Donaldson RM, Thalen HJ. The use of QT interval to determine pacing rate: early clinical experience. *PACE* 1983; 6: 346–54.
- [7] Anderson K. A rate variable pacemaker which automatically adjust for physical activity. *PACE* 1983; 6: 350–5.
- [8] Rossi P, Plicchi G, Canducci G *et al.* Respiratory rate as a determinant of optimal pacing rate. *PACE* 1983; 6: 502–7.
- [9] Heynen H, Sharma A, Sutton R *et al.* Clinical experience with VVIR pacing based on right ventricular dP/dt. *Eur J Cardiac Pacing Electrophysiol* 1991; 1: 138–46.
- [10] McKey RG, Spears JR, Aroestry JM *et al.* Instantaneous measurement of left and right ventricular stroke volume and pressure-volume relationships with an impedance catheter. *Circulation* 1984; 69: 703–7.
- [11] Singer I, Olash J, Brennan AF *et al.* Initial clinical experience with a rate responsive pacemaker. *PACE* 1989; 12: 1458–62.
- [12] Aubert AE, Goldreyer BN, Wiman NE *et al.* Filter characteristics of the atrial sensing circuit of a rate responsive pacemaker. To see or not to see. *PACE* 1989; 12: 525–30.
- [13] Connelly DT, the Topaz Study Group. Initial experience with a new single chamber, dual sensor rate responsive pacemaker. *PACE* 1993; 16: 1833–41.
- [14] Van Krieken FM, Perrins JP, Sigmund M. Clinical results of automatic slope adaptation in a dual sensor VVIR pacemaker. *PACE* 1992; 15: 1815–20.
- [15] Cowell R, Morris-Thurgood J, Paul V, Ilsley C, Camm AJ. Are we being driven to two sensors?: Clinical benefits of sensor cross-checking. *PACE* 1993; 16: 1441–4.
- [16] Provenier F, Van Acker R, Backers J, Van Wassenhove E, De Meyer V, Jordaens L. Clinical observations with a dual sensor rate adaptive single chamber pacemaker. *PACE* 1992; 15: 1821–5.
- [17] Miller JF, Young ML, Atkins DL *et al.* Rate responsive pacing in pediatric patients. *Am J Cardiol* 1989; 64: 1052–3.
- [18] Ragonese P, Guccione P, Drago F, Turchetta A, Calzolari A, Formigari R. Efficacy and safety of ventricular rate responsive pacing in children with complete atrioventricular block. *PACE* 1994; 17: 603–10.
- [19] Lau C-P, Rushby J, Leigh-Jones M *et al.* Symptomatology and quality of life in patients with rate responsive pacemakers: A double-blind, randomized, crossover study. *Clin Cardiol* 1989; 12: 505–12.
- [20] Mehta D, Lau C-P, Toff WD *et al.* Randomized crossover trial of rate responsive Activitrix and conventional fixed rate ventricular pacing. *Br Heart J* 1987; 58: 613–16.
- [21] Landman MAJ, Senden PJ, Van Rooijen H, Van Hemel NM. Initial clinic experience with rate adaptive cardiac pacing using two sensors simultaneously. *PACE* 1990; 13: 1615–22.
- [22] Bellamy CM, Roberts DH, Hughes S, Charles RG. Comparative evaluation of rate modulation in new generation evoked QT and activity sensing pacemakers. *PACE* 1992; 15: 993–9.
- [23] Sowton E. Exercise testing in the indication and evaluation of pacemaker treatment. *Eur Heart J* 1987; 8: 155–8.
- [24] Alt E, Theres H, Heinz M *et al.* A new rate modulated pacemaker system optimized by combination of two sensors. *PACE* 1988; 11: 1119–29.
- [25] Sulke AN, Pipilis A, Henderson RA, Bucknall CA, Sowton E. Comparison of the normal sinus node with seven types of rate responsive pacemaker during everyday activity. *Br Heart J* 1990; 64: 25–31.
- [26] Oto A, Tokgözoğlu SL, Özin B *et al.* The use of rate response function during daily life in patients with rate adaptive pacemakers with two different sensors. *Eur J Cardiac Pacing Electrophysiol* 1993; 3: 59–62.