Role of ventricular autocapture function in increasing longevity of DDDR pacemakers: a prospective study

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Aims Autocapture is an algorithm for automatic adaptation of ventricular output to capture threshold. The aim of this prospective study was to estimate the effects of ventricular Autocapture algorithm on DDD–DDDR pacemaker longevity.

Methods and results Eighty-three patients implanted with a DDD–DDDR pacemaker (Affinity or Entity; St Jude Medical, USA) were enrolled and the Autocapture function was activated pre-discharge. Ventricular pulse duration was randomly programmed at 0.3 or 0.4 ms, with a cross-over at 8–12 weeks and again at 13–14 months. Diagnostic data were retrieved from device memory and by calculating battery current drain from long-term threshold recordings; device longevity was estimated at the following settings: Autocapture with a pulse duration of 0.3 and 0.4 ms, respectively, standard output (3.5 V, 0.4 ms) and conventional low output programming (2.5 V, 0.4 ms). According to a series of assumptions, Autocapture was associated with a 55–60% increase in estimated device longevity compared with standard output programming and a 6–7% increase in longevity compared with low output programming. No significant differences were found between Autocapture programmed with a pulse duration of 0.3 or 0.4 ms. In projections to a 10-year follow-up, use of the Autocapture function resulted in a 42% reduction in pacing-related estimated costs compared with standard output programming at 3.5 V, 0.4 ms.

Conclusion Pacing with constant adaptation of ventricular output in dual-chamber devices has the potential to increase generator longevity and to reduce sizeably pacing-related costs compared with standard programming.

Introduction

The longevity of an implantable cardiac pacemaker is determined by the capacity of the battery, its chemistry, and current drain.1–3 To improve pulse generator longevity, pacing systems with low output stimulation, capable of monitoring ventricular capture and automatically adjusting the output to correct for transient loss of capture have been designed.4–10 Maintenance of effective ventricular cardiac stimulation is an obvious requirement to guarantee patient safety, despite the variability in stimulation threshold and the possibility of transient increases in stimulation threshold due to metabolic and pharmacological factors.11 Autocapture is a system for continuous and automatic adaptation of ventricular output to capture threshold. Its increased generator longevity in VVI–VVIR devices compared with standard programming at conventional low-energy settings has been demonstrated.12

The aims of the prospective study were to (i) calculate the battery current drain in a population implanted with a series of DDD–DDDR pacemakers capable of automatic sampling of ventricular stimulation threshold and of automatic adjustment of ventricular output known as Autocapture, (ii) evaluate the effect of ventricular Autocapture function on longevity of a dual-chamber device, and (iii) calculate the potential impact of this feature on long-term pacing-related costs.

KEYWORDS
Autocapture; Cardiac pacing; Cost-effectiveness; Stimulation threshold

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Methods

Patient population

Patients with conventional indications for dual-chamber cardiac pacing with advanced atrioventricular block (stable or pacemaker), in whom constant stimulation of at least 75% of the total beats was expected after pacemaker implant, were considered for the study. Written informed consent was obtained from all the patients.

Material and study design

The study was designed to calculate the battery current drain and device longevity by evaluating ventricular pacing output during long-term follow-up of a group of patients who had received a dual-chamber pacemaker with Autocapture function (Affinity DR 5330 and DC 5230 or Entity DR 5326 and DC 5226, St Jude Medical, USA) with a battery capacity of 0.95 Ah. As previously reported in detail, Autocapture is a programmable option for automatic adaptation of ventricular device output to stimulation threshold, in order to guarantee continuous ventricular capture. All patients had received low polarization, low threshold bipolar ventricular leads (Membrane E and EX, St Jude Medical). At implantation, conventional measurements of lead impedance, pacing threshold, sensing amplitude, and slew rate were performed. Ventricular evoked response was measured in order to allow proper functioning of the Autocapture algorithm.

In accordance with the study protocol, patients, pre-discharge, underwent (i) active programming of Autocapture and (ii) randomized allocation to a ventricular pulse duration of 0.3 or 0.4 ms. A cross-over for ventricular pulse duration was scheduled at 8- and 12-week follow-up visits. Analysis of data obtained from the ventricular threshold vs. time recordings, retrieved at 8- and 12-week, 13- and 14-month follow-up visits using a sampling frequency of 140 Hz (with a total sampling time of 32 days), was performed to calculate battery current drain and to estimate device longevity under multiple output settings: (i) Autocapture at 0.3 ms pulse duration in the ventricle and 2.5 V, 0.4 ms in the atrium; (ii) Autocapture at 0.4 ms pulse duration in the ventricle and 2.5 V, 0.4 ms in the atrium; (iii) standard programming at 3.5 V, 0.4 ms in the atrium and the ventricle; (iv) conventional low output programming at 2.5 V, 0.4 ms in the atrium and the ventricle. The Autocapture setting provides a ventricular output equal to the capture threshold at 2.5 V, 0.4 ms in the atrium and the ventricle; (iv) conventional low output programming at 2.5 V, 0.4 ms in the atrium and the ventricle. The Autocapture setting provides a ventricular output equal to the capture threshold increased by 0.25 V. The estimated pacing-related costs of the device provided with Autocapture function were compared with those estimated by the device at conventional low output settings, using a series of assumptions already reported.

Data analysis

A series of factors known to affect current drain and pacemaker longevity were considered. As documented, pacemaker longevity is inversely proportional to current consumption and is directly proportional to battery capacity, such that the larger the battery and/or the lower the current drain, the greater the longevity expected from the device, according to the formula $L = 114^C/IL^1$, where $L$, device longevity (years); $C$, battery capacity (Ah); $I$, battery current (μA). The total amount of current is calculated as the sum of the house-keeping current (i.e. the current for internal device functions correspondent to 11.2 μA) and the current for sensing and backup pulses. Calculations have been carried out considering a basic rate of up to 60 bpm, assuming 100% pacing either at atrial or ventricular level. Data on ventricular pacing threshold and on output pulse amplitude were retrieved from diagnostics stored in the memory of the device, allowing the availability of detailed data on the pacing threshold in two 4-week periods (i.e. between the 8th and 12th week, and between the 13th and 14th month after device implant). For each patient follow-up, the corresponding pacing threshold graph was evaluated using a 6 h sampling rate providing the rough data from which the current drain calculations were performed. When Autocapture was active, calculation of longevity included a rate of 0.8% of backup ventricular pulses (stimulation at 4.5 V and at the programmed pulse duration) over the entire time period considered, according to the data obtained from the manufacturer.

Projections of the costs of the DDD/DDDR pacing system at different settings, with or without activation of the Autocapture function, were based on partial modification of the assumptions published by Sutton and Bourgeois. In detail, the following costs in arbitrary currency units were considered: 166 currency units for the dual-chamber device, 26 units for the two leads, 148 units both for implant and replacement procedure, and 8 units for each follow-up visit. Two follow-up visits per year were considered when the Autocapture was active (one for the first year) and one follow-up visit per year when it was active (two for the first year and after the fourth year).

Statistical analysis

All data related to current drain and generator longevity were analysed comparing mean values by repeated measures analysis of variance (SPSS Advanced Statistics, SPSS Inc., Chicago, IL, USA) with a $P$-value less than 0.05 to define statistical significance. For cost comparison, the limited number of discrete observations related to the investigated period (10 years) makes a time series analysis not feasible. The comparison has, therefore, been performed as analysis of variance with the 'repeated measures' design.

Results

Eighty-three patients (60 men, 23 women) were enrolled in the study and all reached the 12-week follow-up. Thirty-two patients completed the follow-up at 14 months after implant. The mean age was 74 ± 10 years (range 42–94). During the study period, no clinical complications were observed.

At 12-week and at 14-month follow-up visits, ventricular pacing impedance was 702 ± 143 Ω (range 435–1289 Ω) and 711 ± 150 Ω (range 430–1289 Ω), respectively; atrial pacing impedance was 604 ± 131 Ω (range 397–1073 Ω) and 652 ± 120 Ω (range 402–929 Ω), respectively. Evoked response amplitude was 13.3 ± 6.1 mV (range 3.0–29.9 mV) and 12.7 ± 5.5 mV (range 2.8–26.4 mV), respectively. Amplitude of polarization signal was 0.65 ± 0.52 mV (range 0.20–2.74 mV) and 0.63 ± 0.57 mV (range 0.20–3.33 mV), respectively. The mean output voltage (Autocapture +0.25 V) at 0.3 ms pulse duration during 4–12 weeks and 12–14 months was 1.25 ± 0.32 V (range 0.75–2.09 V) and 1.25 ± 0.40 V (range 0.80–2.73 V), respectively, whereas at 0.4 ms pulse duration, it was 0.99 ± 0.22 V (range 0.69–1.43 V) and 1.01 ± 0.41 V (range 0.63–2.38 V), respectively. At 12-week follow-up, the actual percentage of ventricular pacing was >75% in 90% of the patients and >90% in 57% of the patients. These figures were comparable at the 14-month follow-up.

Using recorded data (29 392 samples), current drain and generator longevity (time to recommended replacement time) were calculated for the different settings defined and for the two separate monitoring periods. Programming Autocapture function in Affinity or Entity pacemakers with a pulse duration of 0.4 ms resulted, according to data collected in the first study period (up to 12 weeks after implant), in a 60% increase in estimated longevity compared with standard output programming and in a 7% increase in...
estimated longevity compared with low output programming. According to data collected 12–14 months after implant, Autocapture resulted in a 55% increase in estimated longevity compared with standard output programming and in a 6% increase in estimated longevity compared with low output programming (Figs 1 and 2). No difference emerged considering the use of Autocapture associated with a programmed pulse duration of 0.3 or 0.4 ms.

The cumulative costs of a pacing device and leads including implantation, follow-up visits, and replacement over the long-term, based on previously described assumptions and computed in units of cost for the projected longevity, are shown in Fig. 3. In a projection at 10 years, activation of Autocapture function appeared to be associated with a 42% reduction in pacing-related costs compared with a standard setting of 3.5 V, 0.4 ms output.

Analysis of threshold data revealed that stimulation thresholds >2.5 and 1.5 V occurred in 4 (5%) and 20 patients (24%), respectively; this analysis did not take into consideration the first month after implant and considered only threshold trends indicating an evident threshold increase.

Discussion

The prolongation of pulse generator longevity is an important goal to be achieved in order to reduce the costs of cardiac pacing.2 Considering that pacing threshold may vary significantly as a result of several factors,11 programming the pacemaker at a low output in order to increase the service life is limited by the necessity to maintain a safety margin with a 2:1 ratio14 and may be time consuming. Pacing at low output has been used only in a small proportion of patients in clinical practice before the availability of systems with automatic capture verification and adaptation of output to threshold.15

This study demonstrates the important implications of the Autocapture function which promotes the extension of projected pulse generator longevity, while maintaining an adequate safety margin in case of fluctuations in stimulation threshold. The automatic ventricular output regulation guaranteed by the Autocapture function has provided effective stimulation in those patients (5–24 % of the population) in whom conventional low output programming would have caused an inadequate safety margin for ventricular capture, with the potential for adverse events. The reliable safety profile of the same Autocapture system that we used, on a beat-by-beat basis, has been recently confirmed in an observational study on 83 patients, implanted with either VVIR or DDDR pacing systems.16 In that study, Autocapture allowed safe ventricular pacing even in a subgroup of five patients with large variations (>1 V) in ventricular capture threshold that would have required a larger safety margin than commonly applied using standard devices without the Autocapture feature.

The present study shows how the use of Autocapture is associated with significant advantages in device expected longevity in comparison with different output settings. The Autocapture function in a dual-chamber pacemaker (Affinity DR or Entity DR, in this study), permits a service life of about 11 years, 4 years longer than that expected with standard programming of the same pacemaker and about 8–9 months longer than that expected using conventional low output programming.

At present, such a service life seems particularly useful and appropriate in light of epidemiological studies indicating that patient longevity has improved substantially and is expected to extend further in coming years.17,18 Sutton and Bourgeois13 calculated a 61–71% survival rate at 10 years in patients with AV block or SSS implanted with a DDD pacemaker. Recently, a longitudinal study of unselected patients followed for 30 years in a pacemaker clinic showed an overall survival of 44.8 and 21.4% at 10 and 20 years, respectively, with a net improvement in prognosis in the last decade.18

The availability of pacemakers with a long projected service life seems to be concordant with the need to

**Figure 1** Projections of device longevity for different programming based on threshold data measured at 8–12 weeks of follow-up.

**Figure 2** Projections of device longevity for different programming based on threshold data measured at 13–14 months of follow-up.
contain the costs of long-term cardiac pacing. Our projections of costs savings determined by the Autocapture feature in comparison with different settings show a reduction of up to 42% is achievable at 10 years of follow-up. In this study, randomized programming to a pulse duration of 0.3 or 0.4 ms allowed a comparison to demonstrate that there is no significant difference in projected longevity using these two programmed values. Therefore, in clinical practice, the choice of pulse duration to be programmed in combination with Autocapture may be left to physician preference, although a lower duration theoretically would imply an advantage in expected longevity, although of limited, if not negligible, extent.

The positive effects demonstrated by this study in terms of longevity of the device and of relative costs should be even more considerable when the Autocapture function is evaluated in devices with low internal energy consumption circuitry and in devices with automatic regulation of output also in the atrial channel.

Study limitations
The present study has some limitations. The longevity of the devices was not directly measured; it was estimated on the basis of projections and calculations derived from data on ventricular pacing threshold and on output pulse amplitude. All the projections and calculations were applied to devices from the same manufacturer. Therefore, these results cannot be extrapolated to other DDD-DDDR devices currently used in clinical practice. Moreover, device management matters, such as long-term troubleshooting, and infections or lead complications were not taken into account.

Conclusions
Projections of device longevity based on threshold data prospectively monitored during the follow-up of patients implanted with a DDD-DDDR device indicate that a device algorithm for automatic adaptation of ventricular output may increase significantly the service life in comparison with the same pacemaker with standard or conventional low output programming. These estimates also indicate that using the Autocapture algorithm a significant reduction in projected costs of pacing may be expected. Confirmation of long-term projections will require prospective evaluations in larger number of patients over longer follow-up periods. According to our data, programming of pulse duration at 0.3 or at 0.4 ms in combination with Autocapture did not result in relevant differences with regard to estimated longevity or costs.

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Appendix

References


