Ventricular Capture Control and the Increase of Pacemaker Lifetime

A.S. MENEZES JR.
Heart Stimulation Department, Hospital Santa Helena, Goiânia, Goiás, Brazil

C.F.M. QUEIROZ, F.P CARZOLA, J.C. DOURADO, W.L. CARVALHO
Federal University of Goiás, Brazil

Summary

One of the great obstacles to extending pacemaker serviceable lifetime is the need to always pace with a margin of safety above the measured pacing threshold. The Logos DDD pacemaker adjusts the pacing parameters via a negative feedback loop, based on an algorithm that performs auto-tests at scheduled time intervals, determining the efficacy of ventricular stimulation. This allows the margin of safety to be decreased. The presented study tested the stability and effectiveness of the capture control algorithm to demonstrate that this algorithm allows stimulation within the ventricular pacing threshold range, without compromising the safety of the system. As a consequence, the serviceable lifetime of the device should increase. From January to August 1997, 14 patients with a mean age of 60.6 ± 9.77 years were implanted with Logos DDD pacemakers within a mean time of 159.4 ± 46 days. All patients had Chagas' disease; 9 were male and 4 female. Sinus bradycardia was evident in the ECGs of 6 patients, second-degree AV block in 3 patients, and total AV block in 5. The ventricular pacing threshold was measured, and the pacemaker was programmed to this threshold. The stability of the pacing threshold was evaluated by means of 24-h Holter recording. The lifetime of the battery when pacing with the capture threshold was compared to the nominal lifetime values of a Logos pacemaker programmed to standard parameters: pacing amplitude 3.6 V, electrode impedance 500 W, pulse width 0.5 ms, heart rate 60 bpm, and 100 % DDD stimulation, resulting in a current drain which determines the lifetime of 78 months. For a mean R-wave amplitude of 10.18 ± 6.87 mV and a mean ventricular capture threshold of 1.31 ± 0.22 V, the variance test did not show significant differences between the number of observed captures and the number of effective captures ($p > 0.05$). But a significant difference was found ($p = 0.001$) between the average nominal lifetime (113.2 ± 6.42 months) of pacemakers programmed with the capture thresholds and the estimated lifetime (78 months) of pacemakers programmed with standard thresholds of 3.6 V. Since the ventricular pulse width used with ventricular capture threshold was stable and the negative feedback control maintained the safety of the system, it is concluded that the lifetime of the battery can be increased.

Key Words

Dual chamber pacemaker, Logos DDD, capture control, fractal electrode

Introduction

The transmembrane action potential (TAP) of the myocytes reflects the current intensity and duration through the cellular membrane. The ion flow through the membrane is responsible for the speed of the excitation wave and for the cellular contractility. Thus, the morphology of the heart action potential can indicate electrophysiologic characteristics of the heart. However, registration of TAPs requires the implantation of a microelectrode in a single myocardial cell, limiting its use to in vitro preparations. On the other hand, the monophasic action potential (MAP) and the ventricular evoked response (VER) reflect the TAP course and permit its extracellular measurement in a beating heart, in vivo. MAPs reflect the depolarization and repolarization course of the myocytes [1].

A high resolution is necessary for MAP recordings. The sensitivity of the measuring system depends on the lead architecture and especially the properties of the

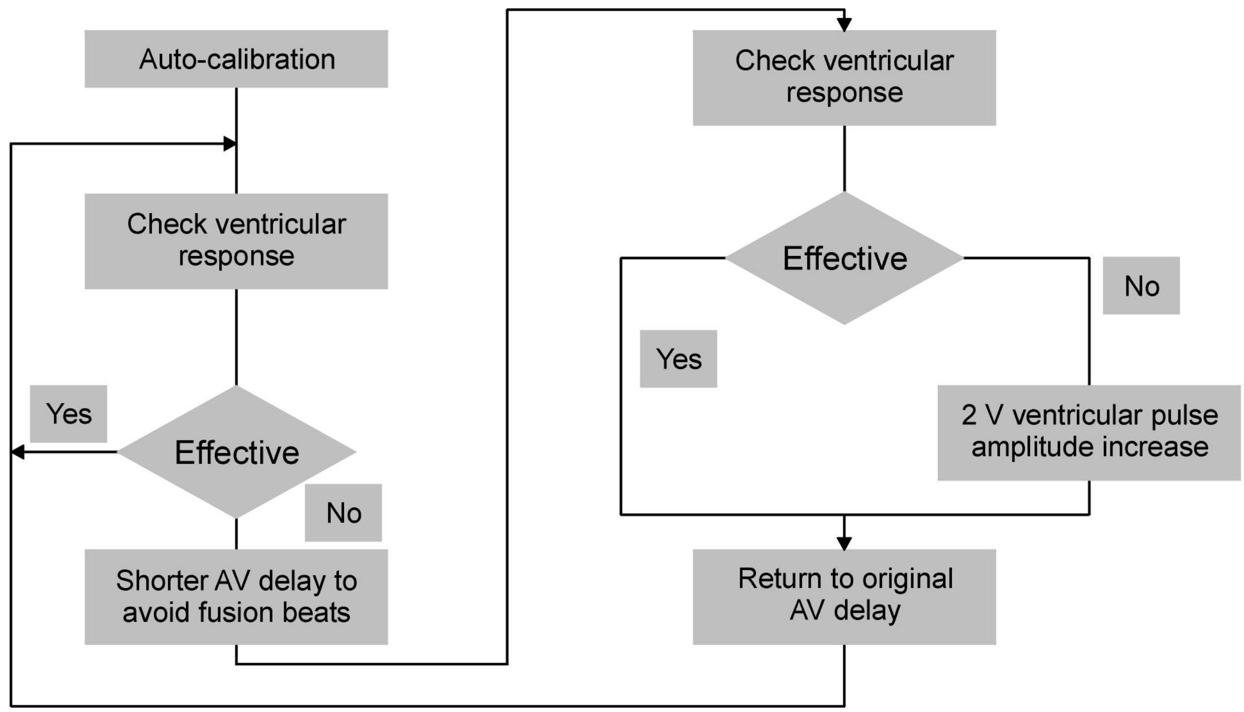

Figure 1. Capture control algorithm for discriminating fusion beats from ineffective stimuli.

interface between the heart and the detection electrode. The need for a large Helmholtz capacitance and a small tip is met with fractal structured leads that have self-repeating, ever smaller surface structures on the tip-reaching an electrochemically active area approximately three magnitudes of order larger than the geometric surface [2].

In vitro tests have proven that fractal structured leads offer excellent stability regarding their physical and chemical behavior and lower fibrotic tissue formation during the first weeks after implantation. The stimulation properties with fractal surfaces remain stable for more than five years. A comparison of the MAP signals obtained with silver-silver chloride (Ag/AgCl) and fractal surface leads placed in the same endocardial location showed an almost perfect correlation ($r > 0.98$) [2].

The Logos capture control function looks for a ventricular response after each pacing pulse. This evoked response can be effective (resulting in a satisfactory ventricular answer) or ineffective (resulting in extrasystoles, capture loss, or an intrinsic event). If no effective answer is detected, the pacemaker increases the pulse amplitude, according to a specific algorithm that manages this function (figure 1), in order to re-establish effective ventricular capture. After a certain programmed period of time (every 8.5 min, 2 h, 12 h, or 24 h), the pacemaker performs an auto-test: The ventricular pulse amplitude is decreased. If no effective answer is detected, the pacemaker switches to a shorter AV delay to exclude the possibility of fusion beats and then increases the pacing amplitude in 2-V increments until capture is detected (figure 2) [3].

In contrast, in pacemakers without a capture control function, a ventricular pulse amplitude with a high margin of safety to the chronic pacing threshold must be programmed to secure patient safety [4-6]. Therefore, a pacemaker with a capture control function should theoretically save energy and possibly increase device lifetime.

This study intends to demonstrate that the Logos DDD capture control algorithm allows ventricular stimulation with pulse amplitude values similar to the chronic pacing thresholds without compromising the function and safety of the system, thus increasing pacemaker lifetime.

Materials and Methods

The study was carried out in three stages: a) investigation of the auto-test for capture control; b) evaluation of the safety and reliability of capture control over 24 h; c) analysis of the increased lifetime of the battery. Between January and August 1997, the tests were performed in a clinical study on 14 patients (P) (mean age: 60.6 ± 9.77 years) implanted with Logos DDD pacemakers (BIOTRONIK, Germany). The mean implant time was 159.4 ± 46 days. Nine patients were male, 5 female, and all suffered from Chagas' disease. The ECGs showed sinus bradycardia in 6 patients, second-degree AV block in 6, and total AV block in 5. Fractal surface Y60BP leads (BIOTRONIK, Germany) were implanted in the ventricle, following the usual technique. No immediate and late postoperative complications were observed.

In the first stage at discharge, we measured the sensitivity, capture, and impedance in the atrium and the ventricle. According to the specific algorithm, we calibrated with a ventricular pulse amplitude of 2.5 V and a pacing rate of 20 ppm above the patient's intrinsic rate, evaluating in the VVI and DDD modes. The calibration test was performed with the capture control turned on, the auto-test set to every 8.5 min, and a 2-V increase of the ventricular pulse amplitude with an ineffective evoked potential (if ineffective, the programmed ventricular pulse amplitude was below threshold).

In the second stage (60 days after implantation), all pacemakers were programmed with ventricular pacing

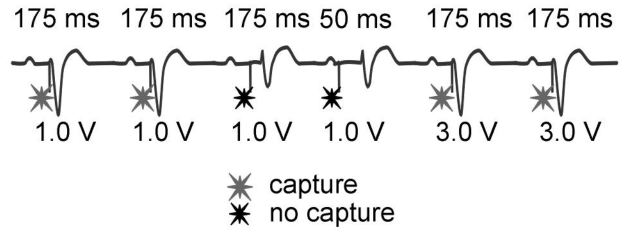

Figure 2. ECG illustrating loss of capture at 1.0 V and following the reaction of the capture control algorithm to increase the output voltage to a safe value.

amplitudes of 0.5 V. We activated capture control with the auto-test, re-initializing every 8.5 min, and performed 24-h Holter recording with beat-to-beat analysis and evaluation of capture control (figure 4). We obtained the number of expected captures as a function of time (Ce); the number of observed captures from the Holter analysis (Co); and the number of efficient captures (Cf). We established three indexes: i1 = Co/Ce; i2 = Cf/Ce; and i3 = Cf/Co. For statistical analysis, we applied the χ^2 -test with a significance level of 0.975.

In the third stage (120 days after implantation), we programmed a ventricular pulse amplitude (voltage) that was equal to the determined ventricular pacing threshold. We evaluated the stability of ventricular capture through beat-to-beat analysis of 24-h Holter recordings. We compared the theoretical lifetime of the battery with the nominal lifetime of the Logos pacemaker, programmed with conventional thresholds of 3.6 V, fixed impedance values of 500 Ω, pulse width of

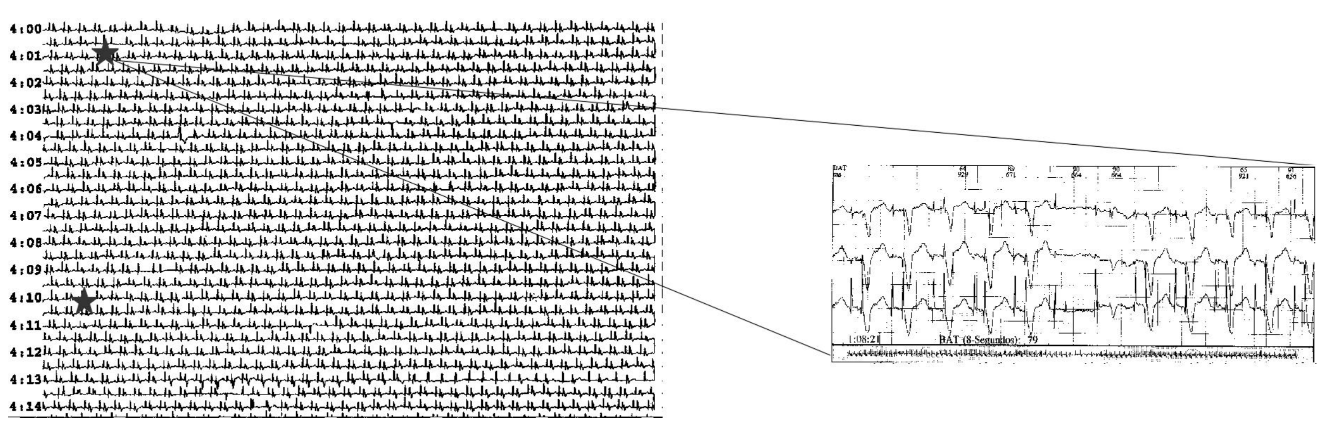

Figure 3. Holter recording of pacemaker patient paced in DDD mode with capture control. The capture-test was performed every 8.5 min. Efficient captures, Cf, were counted in 24 h holter and compared with the data recorded by the pacemaker.

Patient	Ce	Co	Cf
1	150	127	157
2	165	143	138
3	163	155	130
4	161	153	146
5	150	141	138
6	164	143	139
7	164	138	136
8	128	84	74
9	157	136	133
10	158	126	128
Mean	157 + 11	136 + 21	132 + 22

Table 1. Number of expected (Ce), observed (Co), and effective (Cf) captures during the test of capture control. Data were obtained by Holter recording of capture control pacemaker patients.

Patient	Ventricular Threshold (V)	Theorical longevity* (months)
1	1.8	105
2	1.1	119
3	1.6	107
4	1.1	119
5	1.5	109
6	1.2	114
7	1.9	103
8	1.2	117
9	1.1	119
10	1.3	114
Mean	1.36 ± 0.30	113 ± 6.30

* considering ventricular pulse amplitude programmed at the same value of ventricular threshold

Table 2. Ventricular threshold and theoretical serviceable lifetimes for each patient included in stage 3 of the study.

0.5 ms, pacing rate of 60 ppm, and 100 % DDD stimulation. The following formulas were used:

Lifetime [years] = Qc / (8760 (h/year) x (Ic + Il))

where Qc = battery load, Ic = current drain of the circuit at demand, and Il = current drain of the lead.

Il [μA] = (Vo x 2 x t / (Zp x CL)) x 10^{-6}

where Vo = output voltage of the generator (pulse width), t = pulse bandwidth (0.5 ms), Zp = impedance (500 Ω), CL = cycle length (1000 ms), all values apply for 100 % DDD stimulation. The used statistical test was a student's t-test with a significance level of 0.001.

Results

In the first stage, the mean P wave was 2.97 ± 1.99 mV; the atrial threshold, 0.4 ± 0.08 V; and impedance, 499 ± 82.25 W. The R wave was 10.4 ± 4.52 mV; the ventricular threshold, 0.44 ± 0.68 V; and the impedance, 527 ± 120.18 W. Calibration was not possible in the VVI or DDD mode in two patients who had VER amplitudes smaller than 2.5 mV and in one patient with an older ventricular lead (without a fractal surface). Automatic calibration was performed in 11 patients in VVI followed by DDD. In these patients, the auto-test in the first 8.5 min showed capture control with satisfactory response, in all cases.

In the second stage, in which 10 patients were included up to now, the mean R wave observed was 10.18 ± 6.87 mV, and the mean ventricular threshold was 1.31 ± 0.22 V. Analysis of these data and of their variance did not show a significant difference ($p > 0.05$) between the number of observed capture (Co) derived from 24 h Holter and number of effective capture (Cf) recorded in pacemaker (table 1).

In the third stage the mean ventricular pacing threshold was 1.37 ± 0.30 V. The correlation of difference between the average theoretical serviceable lifetime (113.2 ± 6.42 months) for patients programmed with values approximating chronic pacing thresholds and the estimated serviceable lifetime (78 months) for thresholds of 3.6 V was determined to be significant ($p = 0.001$) (table 2). Analyzing the Holter, no loss of ventricular capture was observed.

Discussion

Present pacemakers use lithium-iodine polyvinyl pyridine batteries, which have replaced the mercury-zinc batteries. Lithium-iodine batteries are energy sources that possess high energy density, allowing small dimensions and great durability. In the end-of-service phase of pacemakers, pulse width varies, increasing in most devices, and the pacing rate decreases. With this battery type, the generators generally decrease the rate gradually. Manufacturers advise that the generators be replaced when the rate is reduced by 10 to 20 % of the regular operating values as indicated by magnet rate. Although the fall in pacing rate and/or increase in pulse width are early signs of battery depletion and an indication for generator replacement. Recent studies have demonstrated that an average period of 19 months can pass until generator replacement becomes necessary. Less pressure is consequently placed upon scheduling the replacement surgery.

In pacemaker development, considerations of safety weighed against durability have limited implementation of new technologies. Battery lifetime was incrementally extended with new software providing hysteresis functions and also with the antitachycardia function, intracardial Holter monitoring, and greater varieties of programmability. The development of fractal technology also contributed to increased lifetime with lower threshold, higher sensitivity and long-term electrode stability. It was demonstrated that the sensitivity properties and the stimulation capabilities of leads with a fractal surface remained stable for more than five years.

In the first stage, auto-calibration was not accomplished in two patients with average VER amplitudes below 2.5 mV. These incidents illustrate the evident need for a sufficient intracardial signal which defines effective and ineffective responses. One of these patients had an older lead implanted (only the generator had been replaced); the inferior performance of this lead reaffirms the importance of fractal technology in obtaining appropriate intracardial signals.

The Logos DDD pacemaker takes now the advantage not only from outstanding sensitivity and stability which fractal technology has to offer. Its capture control algorithm facilitated an incrementally larger battery lifetime; these results were apparent in the last stage of our research. The difference among the average serviceable lifetime (113.2 ± 0.42 m) for devices programmed to the stimulation thresholds and the expected serviceable lifetimes (78 months) with 3.6 V thresholds was significant ($p = 0.001$). In the Logos DDD pacemaker, only the minimum amount of energy required for delivering an effective pulse was used. In other pacemakers without capture control function, higher energy pulses, exceeding the stimulation threshold, are delivered for safety purposes. In addition stage 2 of the study proofed with 24 h Holter that the capture control algorithm provides safe ventricular stimulation. When the programmed output voltage was below the threshold then the Logos increased output automatically to a safe value. Thus, increased lifetime was not compromised with lower safety for the patient. The savings in energy can be translated, therefore, into the benefits resulting from the greater periods of time until pacemaker generator replacement is needed. Either increasing the number of installed software programs or decreasing the generator size is possible without changing the battery composition.

Conclusion

The stability of the ventricular capture (with a value equal to that of the pacing threshold) and the safety offered by capture control allow energy-saving programming, making an increase in battery lifetime and consequently in serviceable generator lifetimes foreseeable.

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