

Output Adjustment with the DDD Pacemaker with Automatic Capture-Control Algorithm

D. GUILLEMAN¹, H. BUSSILLET², P. SCANU¹, D. RAGUIN³, J. C. AISENFARB⁴, P. BIENVENU⁵, J. F. MEUNIER⁶, N. CANOT⁶

¹Centre Hospitalier de Caen, ²Hôpital cardiologique de Lyon, ³Clinique Victor Pauchet d'Amiens, ⁴Centre Hospitalier de Dunkerque, ⁵Centre Hospitalier de Laval, ⁶Biotronik France

Summary

A capture control algorithm, using the ventricular evoked response, was applied in 24 patients for output adjustment. The long term stability of the algorithm was investigated and the effectiveness of calibration and output adjustment were measured. 24 patients had been involved in the study and a follow-up was performed after 6 weeks, 3 month and 6 month. The algorithm increasing the ventricular amplitude automatically when detecting an ineffective stimulus, was applied with the pacemaker Logos (Biotronik). The potency of the algorithm has been shown by effective ventricular capture control and output adjustment, which has been observed in all patients. After 6 month, up to 94% of the programmed ventricular output was alright. In conclusion, by using an automatic capture control algorithm, a method for programming ventricular pacing near the pacing threshold with stable ventricular capture is available. Therefore, safe pacing and energy-saving programming, increasing battery life is possible.

Key Words

Capture control, ventricular evoked response

Introduction

The goal of this study is to clinically evaluate the long term stability of a ventricular capture control algorithm of a dual chamber pacemaker based on beat-to-beat analysis of ventricular evoked response (VER). The ventricular amplitude is automatically increased when an ineffective stimulus is detected.

Capture Control Algorithm

Calibration: During the adjustment procedure the pacemaker Logos (Biotronik) records and averages the evoked responses of several effective pacing impulses. The device stores this reference curve, taking the safety margin into account, and uses it for assessing effectiveness of impulses.

Capture Control function: The pacemaker monitors the effectiveness of every ventricular impulse with the help of the reference curve. If no response is detected and in order to exclude the possibility of a fusion beat or pseudo fusion beat, the AV interval is reduced to 50 ms. If the stimulus is effective, the AV delay is increased to the original timing. In case of no capture,

the amplitude is increased by 2V. After a selected interval has elapsed, the amplitude is reduced to the programmed value to determine whether a smaller amplitude will suffice.

Logos is a lightweight dual chamber pacemaker with a wide range of functions for diagnosis and therapy of bradycardia. Additionally, it is equipped with a special safety feature: Capture control, the automatic output control function, monitors every emitted ventricular pacing impulse. The feature monitors VER to determine whether the stimulus was actually effective. If no response to the stimulus is detected, the pacemaker automatically reacts by increasing the stimulation amplitude to achieve effective stimulation (Figure 1). This further increases the safety of the stimulation system compared to a conventional system without capture control.

Caution: Using capture control requires the use of a low-polarization lead in the ventricle. Any fractal lead may be used. These leads are identified by the specification «surface structure: fractal».

SAFETY WITH CAPTURE CONTROL ALGORITHM

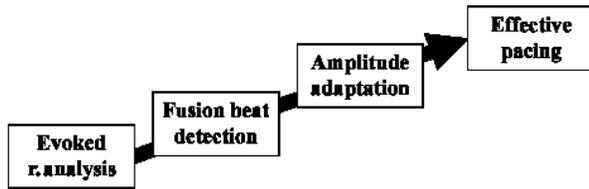


Figure 1. Capture-control algorithm.

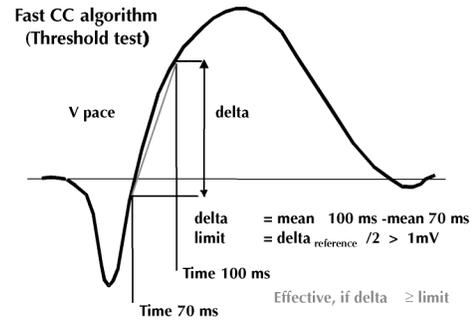


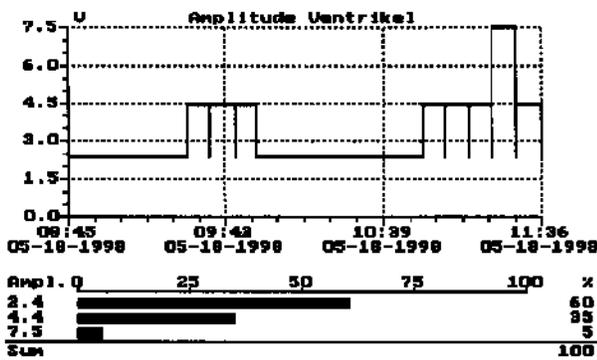
Figure 2. Evoked-response analysis.

Capture control

The capture-control function automatically monitors the effectiveness of the ventricular safety pacing. Capture control is designed as an additional safety feature to protect against unforeseen or transient elevated thresholds. The capture-control function monitors the effectiveness of every ventricular pulse the pacemaker emits. The system monitors the ventricular evoked response (VER) to determine whether the stimulus is detected, the pacemaker automatically reacts by increasing the stimulation amplitude to achieve effective stimulation (Figure 2).

To determine the stimulus effectiveness, the VER is evaluated in an automatically optimized time frame in the range from 70 to 100 ms following a ventricular pulse. Within this time range, stable depolarization signals resulting from the excitation of the myocardium can be detected and clearly distinguished from ineffective impulses that fail to capture.

The response of the capture-control function is recorded in the pacemaker's amplitude trend and is then available for assessment during follow-up. This function records the times at which the last amplitude changes (up to 128) occurred. The data can be displayed graphically and printed as numeric values (data, time) (Figure 3).



Amplitude Protocol Ventricles
(Time Resolution: 0.5 min)

No.	Date [M-D-Y]	Start [h:min]	Duration [h:min]	Amplitude [V]
1	05-18-1998	08:45	00:43	2.40 V
2	05-18-1998	09:28	00:26	4.40 V
3	05-18-1998	09:53	01:00	2.40 V
4	05-18-1998	10:53	00:26	4.40 V
5	05-18-1998	11:18	00:09	7.50 V
6	05-18-1998	11:27	00:09	4.40 V
7	05-18-1998	11:36	<00:09	2.40 V

Figure 3. Amplitude trend monitor.

Fusion beats

If fusion beats or pseudo fusion beats occur, the capture-control function may define these as 'non effective'. However, increasing the amplitude is not indicated. Logos has a special algorithm that prevents an incorrect reaction in this case:

To exclude the possibility of wrong decision caused by a fusion beat or pseudo fusion beat, the AV interval is reduced to 50 ms (DDD Mode) or extended by 100 ms (VVI mode) after a non-capture event. If effective stimulation is detected after the change in interval length, the previous « non capture » event will be interpreted as a fusion pseudo fusion beat, and the stimulation amplitude will not be increased. If the opposite is the case the stimulation amplitude will be increased as described above (Figure 4 and 5).

Capture control acts as an additional safety feature to protect against unforeseen or transient elevated thresholds. The initial programmed amplitude should be programmed with the standard pacemaker safety margin (e.g. 100%) above the measured threshold. Capture

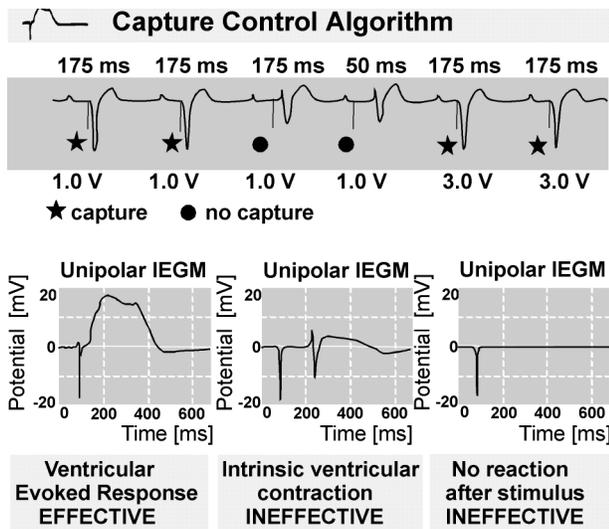


Figure 4. Capture control reacting to loss of capture.

control can be enabled or disabled; the programmable parameters are "On" or "Off". The programmable time frame (test every X hours) specifies the interval, at which the unit checks whether an increased amplitude is still indicated by reducing the amplitude to the programmed value.

Material and Methods

Between November 1997 and April 1999 24 patients (9 female, 15 male), mean age 74 ± 9.4 years have been implanted with a dual chamber pacemaker (Logos, Biotronik). The ventricular leads were: 8 Polyrox (PX 60 BP), 9 Synox (SX 60 BP), 1 Medtronic Capsure Z 5034, 1 ELA Stelid BT 46D, 1 APC, 1 Osypka, 1 Stela UT 46 and 2 Pacesetter 1450 T. The capture-control algorithm was tested temporarily at 6

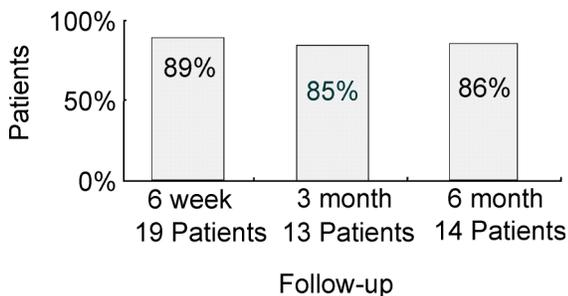


Figure 6. Effectiveness calibration and output adjustment.

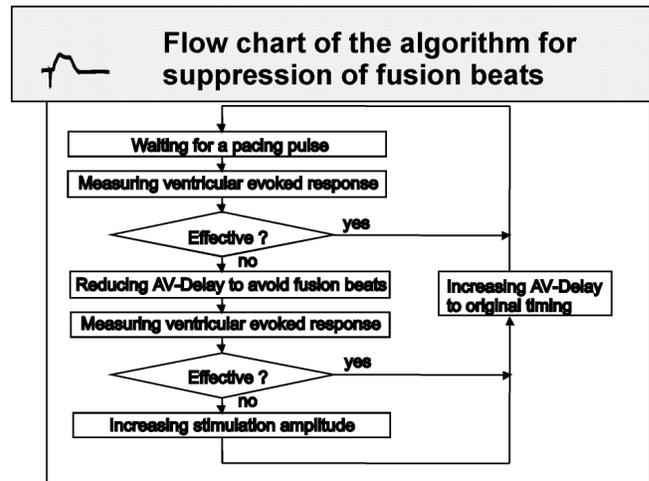


Figure 5. Algorithm flowchart.

week, 3 month and 6 month follow-up. For 10 patients, the algorithm was programmed permanently at the 6 week follow-up and then monitored.

Results

Effective ventricular capture control and output adjustments have been observed for all the patients. In four patients, however, we did have problems with initializing the algorithm (Figure 6). Failure was caused by one lead dislocation, a temporary ventricular threshold increase and unstable signal morphology in a patient after CABG operation and an Osypka lead. For permanent programming, automatic setting of the ventricular amplitude was easily performed via a monitor. Up to 94 % of the programmed ventricular output had not to be modified. Loss of capture, maybe caused by a too

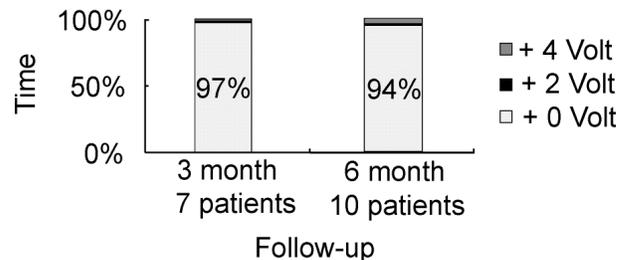


Figure 7. Ventricular amplitude variations at long term.

rigorous analysis of the VER, or a hyperpolarisation phenomenon, have its origins in the automatic adaptation of the output amplitude (Figure 7).

Conclusion

The stability of the ventricular capture with a value equal to that of the pacing threshold and the safety offered by capture control allows energy-saving programming, and increases battery life.

Reference

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