Evaluation of Different Hysteresis Functions - A Study with the BIOTRONIK Actros DR

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Summary

Hysteresis functions in pacemakers favor the intrinsic rhythm by extending the basic interval. Preservation of the sinus rhythm prolongs the pacemaker lifetime and is assumed to provide hemodynamic benefits for the patient. This study evaluated various hysteresis functions offered by the Actros DR (BIOTRONIK, Germany) pacemaker: scan hysteresis, repetitive hysteresis, and the hysteresis extension in connection with the night program. The functions were tested on 31 pacemaker patients (16 male, 15 female) in 7 clinics. Basic rates were programmed to 15 to 25 bpm above the intrinsic rates, so the hysteresis functions could be observed without interference by the sinus rhythm. For the repetitive hysteresis test, 14 patients performed a mildly strenuous exercise of at least 3 min in duration to cover a period with a minimum of 180 consecutive atrial sensed beats. The programmed and observed number of beats (4.8±1.2) at the hysteresis rate were equal, indicating proper hysteresis functioning. Scan hysteresis can be started after a minimum of 180 consecutive atrial paced beats, a prerequisite that excluded several patients with frequent extrasystoles. In the remaining 23 patients, the scan function worked adequately. Correct rate shifts at the beginning and end of the night program were observed in all participating patients (n=30). Holter recordings from 15 patients confirmed the reliable functioning of all hysteresis options. While the clinical value of hysteresis pacing was not the subject of this study, hemodynamic improvements are to be expected in patients with significant periods of sinus rhythm, e.g., intermittent AV block or intermittent spontaneous rhythm, but it is less beneficial for patients who constantly depend on their artificial cardiac pacemaker.

Key Words

Scan hysteresis, repetitive hysteresis, night program, Holter, hemodynamics

Introduction

Hysteresis is defined by an escape interval longer than the automatic or basic interval of the pacemaker. In the pacemaker model used in this study (Actros DR, BIOTRONIK, Germany), the basic rate can be programmed between the extremes of 30 bpm and 180 bpm. Usually, the basic rate will vary between 50 and 80 bpm, depending on the hemodynamic and clinical state of the patient. To improve the hemodynamics of the patient as much as possible [1] and to decrease pacemaker utilization, lowering the basic rate from the standard 70 bpm to 50 bpm, has been suggested.

A fixed basic rate may not always be beneficial for the patient, especially not in patients with intermittent spontaneous rhythms. In some situations, a short-term adaptation of the basic rate may be needed or preferable, for example, in patients with frequent atrial or ventricular extrasystolic beats and subsequent post-extrasystolic pauses. If the hysteresis function has been turned off and a fixed basic rate is programmed, the pacemaker would start to pace at the basic rate in the episodes of a prolonged sinus pause. But new integrated circuits, and thus more sophisticated pacemaker technology, offer more options, such as scan hysteresis, repetitive hysteresis, and night program, which are extension of the basic principle of hysteresis. With these functions, the escape interval is not limited to a single beat, but may be extended to more beats (programmable up to a maximum of 10 in Actros DR).

Repetitive hysteresis (Figure 1) helps maintain the intrinsic rhythm and avoid unnecessary pacing and interference with the intrinsic rhythm, for instance, after periods of fast spontaneous rhythm followed by a steep and short decline of the heart rate or after a post-extrasystolic pause. The pacemaker continues to pace at the hysteresis rate for a programmable number of cycles instead of immediately starting to pace at the basic rate, giving an intrinsic rhythm time to recur. Repetitive hysteresis is only enabled when there has been a stable spontaneous rhythm for at least 180 cycles.

Scan hysteresis (Figure 2) promotes an intrinsic rhythm during phases of continuous stimulation. After 180 consecutive atrial paced events, the pacemaker reduces the pacing rate for a programmable number of beats to scan for a spontaneous rhythm, which may be just below the basic pacing rate. With the scan hysteresis function, the pacemaker stimulates at the programmed hysteresis rate for the programmed number of beats before returning to the basic rate if no intrinsic rhythm is detected.

Yet another form of adapting the basic rate is the night program, which mimics the decline of the heart rate during night. Normally, the average human heart rate at rest is at least 10 bpm lower at night than during the day. When the night program function is enabled, the pacemaker reduces the basic rate and the hysteresis rate gradually to the night values. The beginning and the end of nighttime can be programmed.

The proper functioning of these different types of hysteresis was evaluated in 31 patients with a DDD(R) pacemaker (Actros DR). Repetitive hysteresis was tested after exercising the patient at a very mild level. The objective of the night program mode was to decrease the basic and hysteresis rates at the beginning of the programmed time (± 5 min) and at the programmed rate, and to return these rates to the day settings at the end of the night.

Materials and Methods

Thirty-one patients (16 male, 15 female) were randomly selected from the pacemaker-carrier population and evaluated in seven clinics (see Appendix). Written informed consent was obtained from each patient. In all cases, at least one month had passed since pacemaker implantation. The average age of the patients was 69.5 ± 10.4 (range 32 to 85) years. Height and weight were 169.0 ± 8.9 (range 153 to 186) cm and 79.7 ± 16.8 (range 54 to 130) kg, respectively. Careful attention was paid to the chronotopic competence of the patients. Coronary artery disease was the most common diagnosis in 45.2% of the patients, followed

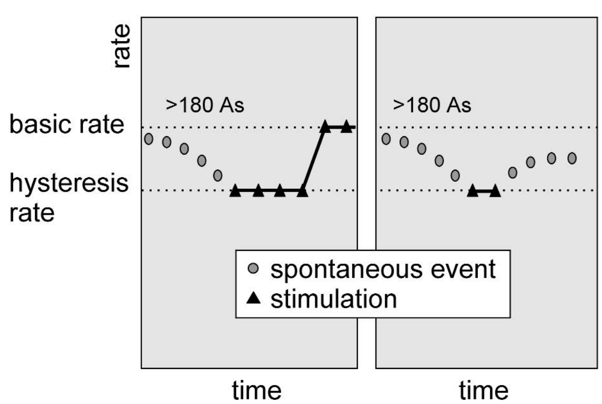

Figure 1. The principle of repetitive hysteresis. Following long periods of sensed events in the atrium (As) the escape interval is maintained for a programmable amount of beats to maintain sinus rhythm.

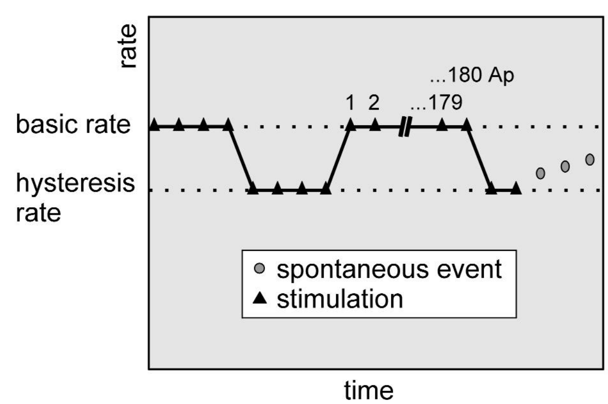

Figure 2. The principle of scan hysteresis. Following long periods of atrial paced events (AP) the pacemaker scans whether there is intrinsic rhythm just below the basic rate.

by diabetes with 16.1%. Therefore, cardiac medication was taken by a high percentage of the patients. Indications for pacemaker therapy were: total or intermittent AV block in 41.9%, sinus node disease in 45.2%, and brady/tachy syndrome in 19.4% of the patients. The medical history and medication are summarized in Table 1.

After pacemaker interrogation and a complete test of the pacemaker sensing and pacing functions, including impedance measurements, atrial and ventricular thresholds, and adequate sensing in the atrium and ventricle, surface ECGs were recorded for all patients. Special attention was paid to avoid undersensing at the atrium. To test the repetitive hysteresis function, the pacemaker was programmed as follows: DDD, basic rate 15 or 20 bpm above the intrinsic rate, a short AV delay to ensure ventricular capture, hysteresis "-5", and repetitive hysteresis "5." The atrial refractory period was programmed to 400 ms, and the other hysteresis functions to "off" to avoid any interference.

The patients participated in a mild bicycle exercise for at least 3 min to cover a period with a minimum of 180 consecutive atrial sensed beats, at which point the exercise was stopped. During recovery, the ECG was recorded continuously to demonstrate the repetitive hysteresis function. The test was repeated successful with 18 patients.

For the scan hysteresis test, the following program was used: DDD, basic rate 20 or 25 bpm above the intrinsic heart rate, hysteresis "-15," scan hysteresis "5," and the other hysteresis functions to "off." The ECG was recorded for a prolonged period of time and was stopped after demonstrating the adequate functioning of the scan hysteresis, i.e., a drop from the basic rate to the hysteresis rate for 5 beats if the intrinsic rate did not interfere during the hysteresis scan interval.

The night program was tested in the DDD mode. The basic rate was programmed at 15 to 20 bpm above the intrinsic heart rate. The beginning and end of the night program were defined. The rate decrease at the beginning of the night was set to 0.8 bpm/s, and the rate increase at the end of the night, to 1 bpm/s. The basic hysteresis function was set to "off." The ECG was recorded throughout the observation period.

In 10 patients, a 24-hour Holter ECG was recorded with the following pacemaker settings: DDDR, hysteresis "-10," repetitive hysteresis "5," scan hysteresis "5," night program "10 bpm." The beginning and end of night were set according to the patient's preference. Rate decrease and increase were programmed as described. The pacemaker counters were also cleared.

Results

Repetitive hysteresis

In 14 patients, all performed tests were successful. Fifteen patients could not tolerate the exercise test. Because a high basic rate and, thus, a relatively high

	Male	Female	Total
Other Medical Conditions			
Cardiomyopathy	0 (0.0%)	1 (6.7%)	1 (3.2%)
Chronic Obstructive Pulmonary Disease	2 (12.5%)	0 (0.0%)	2 (6.5%)
Congestive Heart Failure	1 (6.3%)	0 (0.0%)	1 (3.2%)
Coronary Artery Disease (CAD)	8 (50.0%)	6 (40.0%)	14 (45.2%)
Deabetes	2 (12.5%)	3 (20.0%)	5 (16.1%)
Peripheral Vascular Disease	1 (6.3%)	0 (0.0%)	1 (3.2%)
Other	1 (6.3%)	2 (13.3%)	3 (9.7%)
Current Cardiac Medications			
Antiarrhythmic (AA)	4 (25.0%)	6 (40.0%)	10 (32.3%)
Antihypertensive	3 (18.8%)	4 (26.7%)	7 (22.6%)
Beta Blocker	6 (37.5%)	1 (6.7%)	7 (22.6%)
Calcium Channel Blocker	1 (6.3%)	2 (13.3%)	3 (9.7%)
Cardiac Glycosides	3 (18.8%)	1 (6.7%)	4 (12.9%)
Diuretic	3 (18.8%)	3 (20.0%)	6 (19.4%)
Vasodilator	7 (43.8%)	3 (20.0%)	10 (32.3%)
Other	5 (31.3%)	4 (26.7%)	9 (29.0%)

Table 1. List of observed medical conditions and cardiac related drugs in the study population. CAD was most common and therefore patients receive AA (32.3%), ß-blockers (22.6%) and ACE inhibitors in most of the cases.

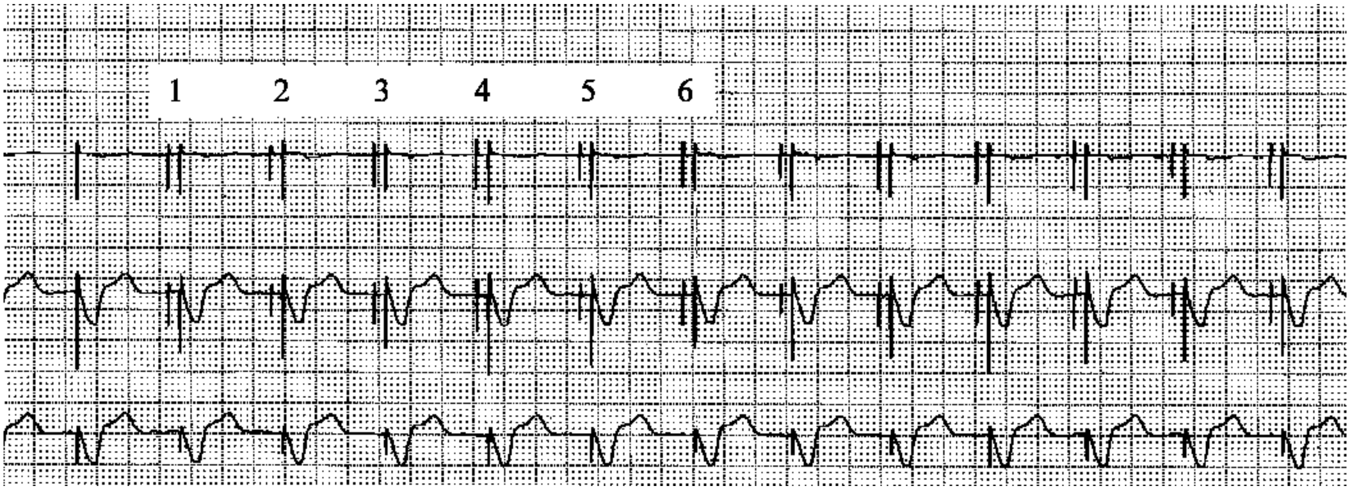

Figure 3. The ECG of an example of repetitive hysteresis. After exercise the intrinsic rate (first two beats) declines till the hysteresis rate (six pulses at 93 bpm) and finishes with six pulses (98 bmp).

hysteresis rate had been programmed, no intrinsic rhythm was observed during the tests. Programmed and observed rates were similar: 77.9±12.4 bpm (range 55 to 105 bpm). The programmed and observed number of beats at the hysteresis rate were equal: 4.8±1.2. An example is given in Figure 3. If the hysteresis rate had been programmed at a more usual or realistic rate, the intrinsic rhythm might have interfered during the scan. Intrinsic rates of 77.8±12.0 bpm (range 62 to 100 bpm) were recorded in 6 patients. With the usual hysteresis rates of 30 to 70 bpm, it would have been impossible to observe the number and rate of the repetitive hysteresis. However, the repetitive hysteresis functioned adequately at the chosen setting.

Scan hysteresis

Before the scan starts, 180 consecutive paced atrial events must occur. The exact number of paced events was 180 between the first and the second scan in the 23 patients evaluated. Patients with frequent extrasystolic beats, either of atrial or ventricular origins, could not be evaluated. During the first and second scan, a high basic rate was programmed (79.4±9.5 bpm; range 65 to 95 bpm), whereas the hysteresis rate was set to only "-15". Appropriate pacemaker function could be observed in all 23 patients fulfilling the criteria of 180 consecutive paced atrial beats. For an ECG-example of the scan hysteresis see Figure 4. During a third scan, a lower basic rate and hysteresis rate were programmed

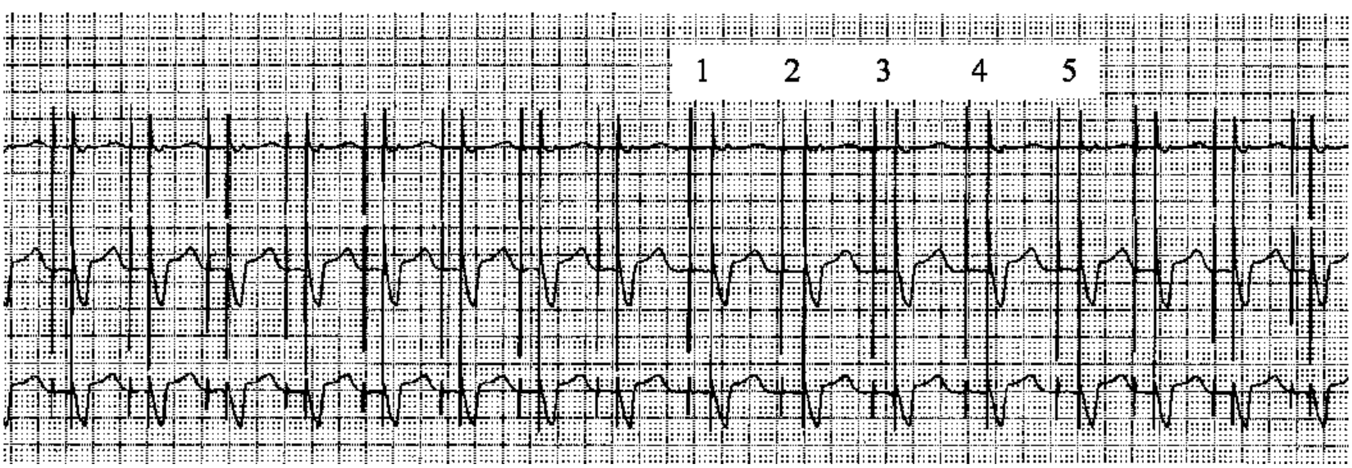

Figure 4. The ECG of a patient with continuous pacing, after 180 atrial paced events, the hysteresis function show a decrease of 20 bpm for five pulses, in search of intrinsic rhythm.

at 53.9±9 bpm, range 30 to 65 bpm. In 9 patients, this resulted in the appearance of the intrinsic rhythm during the hysteresis scan at a rate of 67.8±13.3 bpm (range 41 to 90 bpm). In the other 9 patients, the scan functioned accurately as programmed, without any interference from the intrinsic rhythm.

Night program

This test was performed in 30 patients. In 3 patients, the shift back from the night rate to the basic rate could not be observed due to a higher intrinsic rhythm. In the remaining 27 patients, the rate shifts caused by the night program were exactly as programmed: The night rate was 72.6±10.3 bpm (range 50 to 100 bpm). Differences in timing could occur within a range of ±5 min due to blocks of the internal time resolution of the pacemaker circuitry. The observed variation in time for Night Begin was -3.9±0.3 min (range -4 to -3 min), and for Night End 0.0±0.2 min (range -1 to 0 min). The pacemakers functioned well within their preset parameters.

Holter

A Holter recording in 15 patients showed appropriate functioning of the pacemaker with respect to all hysteresis functions.

Discussion

In the earlier days of pacemaker therapy, the clinical effects of hysteresis functions had been disputed due to detailed, negative reports by several authors [3-6] on the proarrhythmic effects of a low pacing rate. Even the induction of ventricular fibrillation was described [3]. However, first, we must consider that the hysteresis rate in earlier pacemaker models was not programmable, but fixed and preset by the manufacturer. In many cases, it was too low. Second, concerns referred to VVI pacemakers where retrograde ventriculo-atrial (VA) conduction could deteriorate the hemodynamic state of the patient, thus negating the beneficial hemodynamic effect of hysteresis [1]. Third, patients were not carefully selected. Some patients are more prone to ventricular arrhythmias. For these people, prolongation of the basic interval and introduction of a short-long coupling may introduce ventricular bigeminy, which is detrimental to the hemodynamics and affects the patient's health negatively. Langendorf et al. [7] described the influence of short-long coupling intervals on the appearance and continuation of ventricular extrasystole already in 1955. Thus, in certain patients a low and not reprogrammable hysteresis rate could be life threatening. Another problem with hysteresis can arise during ECG interpretation if the physician or technician is not aware that the hysteresis function is set to "on" and assumes a sensing malfunction instead [8].

On the other hand, hysteresis in different forms may promote spontaneous rhythm as much as possible. This has several advantages: It allows dominance of the intrinsic rhythm, and extends the service lifetime of the pulse generator in patients with sinus bradycardia and intermittent sinus arrests or intermittent AV block. It also prevents VA conduction, which occurs with VVI pacing but not with sinus rhythm [8]. Rosenqvist et al. [9] calculated a reduction of pacemaker utilization by 60% when decreasing the pacing rate from 70 to 50 bpm. This argument can probably not be so strongly extended to DDD(R) pacemakers. It must also be stressed that not every brand of DDD(R) pacemakers has a hysteresis function. Search hysteresis, basically another term for scan hysteresis, is reported to reduce VVI pacemaker utilization by 30% [9].

This study proved that the different forms of hysteresis functions available in the Actros DR pacemaker work reliably. Their clinical value has been further evaluated, but, according to the literature, hysteresis has been described to have a positive effect on hemodynamics [1, 8-10]. However, for safety reasons it is strongly advised to take the clinical and hemodynamic condition of the patient into account before programming any hysteresis functions. In constantly pacemaker-dependent patients, it does increase the risk of ventricular bigeminy without any potential benefits. Hemodynamic benefits are achieved in patients with intermittent AV block or intermittent spontaneous rhythm, especially if these patients were implanted with VVI pacemakers and show retrograde VA conduction.

Appendix

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