Methods for testing automatic mode switching in patients implanted with DDD(R) pacemakers

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The assessment of automatic mode switching (AMS) algorithms is impossible *in vivo*, due to a low chance of seeing the patient at the onset of a spontaneous episode of atrial fibrillation (AF). As the induction of AF to test AMS has clinical concerns, three alternative and non-invasive techniques may be proposed for this purpose: myopotentials, chest wall stimulation, and an external supraventricular arrhythmia simulator. The first method is simple and does not require additional equipment, even though in some patients adequate signals cannot be generated with a soft effort such as handgrip or hand compression. The main advantage of the chest wall stimulation method is the possibility that it be performed in every implanting center, since it is based on the use of standard devices for cardiac stimulation. The method based on the external supraventricular arrhythmia simulator allows the most detailed of the ECG traces, but it needs a dedicated electronic device.

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Introduction

Physiological pacing reduces the incidence of atrial fibrillation (AF) with respect to VVI pacing[1], but a conventional DDD mode will track the atrial arrhythmia at high and irregular ventricular rates during the episodes of AF. Special considerations are required in the choice of pacing modalities in patients with paroxysmal AF (PAF) and the automatic mode switching (AMS) function has been designed to pace the ventricle independently of the atrium when PAF occurs, providing protection against rapid ventricular pacing rates during the arrhythmia. Fast AMS seems preferable especially in symptomatic patients experiencing frequent PAF episodes and in those treated with atrioventricular node ablation and pacing[2,3]. Mode switching algorithms are classified according to AF detection criteria (Table I) and by the type of fallback response[4,5].

However, the efficacy of these algorithms is critically dependent on the detection of endocardial AF waves to satisfy the high rate criteria. The rate of the endocardial AF signals in a DDD pacemaker may be affected by the rate of AF itself or by the effective rate detected by the device. The rate of AF may be slowed down by antiarrhythmic medications, or when AF is converted to atrial flutter (AFL) such that some of the AFL waves may fall regularly into atrial blanking periods and fail to satisfy the AMS criteria. The assessment of all the proposed AMS algorithms is almost impossible *in vivo*, due to an extremely low chance of seeing the patient at the onset of a spontaneous AF episode. Difficulties in verifying proper functioning of AMS pose special problems, especially when failure or abnormalities of this function are suspected, that require careful and time-consuming reprogramming of the pacemaker parameters[6,7].

As the induction of AF in order to test the performance of the AMS function has clinical and logistic concerns, three alternative and non-invasive techniques may be proposed for this purpose: myopotentials[8], chest wall stimulation[9], and an external supraventricular arrhythmia simulator[10].

Handgrip test

The technique based on myopotentials generated by hand compression or handgrip exercise is quite easy, practical and fast. In this setting myopotentials may be detected by the atrial channel and, therefore, mimic an atrial tachycardia (AT), provided that a unipolar sensing and a high

Table I. Classification of different methods of atrial tachycardia detection in current automatic mode switching algorithms.

Criterion	Examples	Indications for mode switching	Manufacturers
Rate cut-off	Pulsar/Vigor/Meridian/Discovery	Incremental/decremental counter	Guidant
	Inos/Logos	Ratio of short/total cycles e.g. 4/7 consecutive cycles	Biotronik
	Kappa 400/700	Ratio of short/total cycles e.g. 4/7 consecutive cycles	Medtronic
	Marathon DR	Consecutive short cycles	Intermedics
	Meta DDDR (model 1254/1256)	Incremental/decremental counter	Telectronics
Running average rate	Thera DR	"Matched atrial interval" computed from prevailing atrial rate	Medtronic
	Trilogy DR+ Affinity	"Filtered atrial interval"	St. Jude Medical Pacesetter
Sensor-based	Clarity/Diamond	Single beat outside a "physiological rate band" (15 or 30 b/min)	Vitatron BV
Physiological rate	Marathon DR	Smar tracking rate range (accelerometer sensor)	Intermedics
	Meta DR (model 1250)	Sensor controlled PVARP	Telectronics
	Living 1/Living 1 Plus	Sensor indicated rate to define tachycardia detection	Sorin Biomedica
Complex	Marathon DR	Smar tracking and rate cut-off	Intermedics
	AT 500	Rate cut-off and PR relationship	Medtronic

PVARP = post-ventricular atrial refractory period.

atrial sensitivity are programmed[8]. With a unipolar atrial sensitivity of 0.5 mV during the handgrip test, there is a high probability to force myopotential sensing in the atrial channel, simulating an AT. To avoid interference with the ventricular channel, the relative sensing must be programmed bipolar or unipolar at a relatively low sensitivity (> 4 mV).

The study published by Mascia et al.[8] evaluated 18 patients (13 males, 5 females, mean age 75 ± 6 years) implanted with bipolar leads and a dual chamber pacemaker (VITA DDD(R), Vitatron) equipped with beat-to-beat switch-mode referred to the programmed upper rate limit (136 ± 10 b/min). The enrolled patients were implanted for sinus node disease or atrioventricular block. All underwent a handgrip test and both surface ECG and telemetered pacemaker markers were recorded in real time to monitor the signals detected by the device and the resulting rhythm. All maneuvers were performed at least 1 month after implantation to guarantee a stable fixation of the lead.

Before starting the evaluation, a ventricular far-field test was performed to avoid the detection of this artifact in the atrium, and to adjust the atrial blanking and mask it when present. During the test, lasting at least 10 cardiac cycles, 12 out of 18 patients (66%) had atrial inhibition lasting > 5 s. Figure 1 shows the typical tracing relative to a patient implanted for sinus node disease without atrioventricular block: in this case the pace-

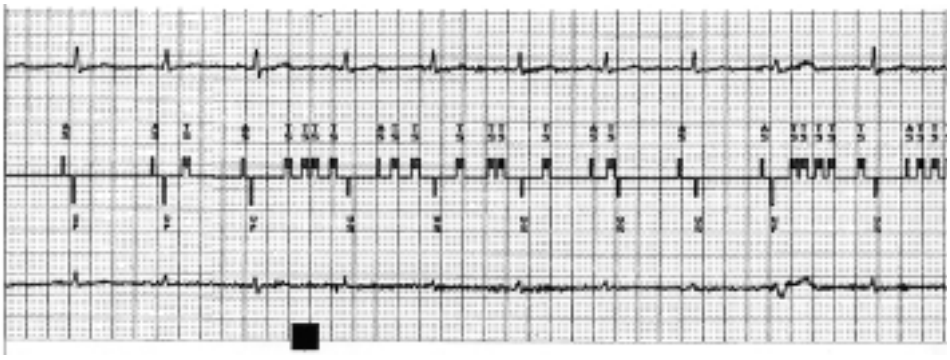

Figure 1. *The myopotentials are detected in the atrial channel and classified as atrial arrhythmia by the pacemaker (Vita DDD, Vitatron); the immediate switching from the DDD to the DDI mode enables the detection of the spontaneous ventricular rhythm without tracking the signals sensed in the atrial channel.*

maker switches to DDI(R) mode during the myopotential interference, just as during atrial tachyarrhythmias, without tracking the sensed atrial signals.

This method is simple and does not require additional equipment, thus enabling fast evaluation of the AMS of the implanted device. Of course, it is mandatory to monitor the marker channel to assess the sensing of the generated artifacts. On the other hand, if a more precise test is needed, myopotentials cannot guarantee a continuous and stable generation of electrical signals, and in some patients adequate signals cannot be generated with a soft effort such as handgrip or hand compression.

Chest wall stimulation

Leung et al.[9] studied 33 patients (16 males, 17 females) with a mean age of 69 ± 11 years. Ten of these patients had third degree atrioventricular block, 3 patients had symptomatic Mobitz type II atrioventricular block, and the remaining 20 patients had sinus node disease. All were implanted with a DDDR pacemaker (Marathon, Intermedics). To assess the effectiveness of the AMS, an external stimulator was connected to two skin electrodes placed on the chest of the patient: in the area between the case and the atrial electrode. The atrial sensitivity was programmed unipolar and the ventricular sensitivity bipolar to exclude detection of the artifacts by the ventricular channel and to favor the detection by the atrial channel. This setting allows the detection of the artifacts only by the atrial channel, forcing the pacemakers to classify these signals as atrial tachyarrhythmias. The external stimulator is a standard temporary stimulator allowing the adjustment of the output amplitude and rate. The duration of the delivered pulses is quite short (1 ms) and so they are partially filtered by the sensing circuits of the implanted devices, but increasing the output amplitude compensates the attenuation of the filters always allowing the possibility of inhibiting the atrial channel. The pacing rate of the external stimulator may be adjusted to be above the atrial tachyarrhythmia detection rate of the device (Fig. 2). Of course, the delivered external pulses are clearly superimposed on the ECG traces and the starting point of the simulated arrhythmia and its duration are arbitrary and operator-dependent. The main advantage of this method is the possibility that it be performed in every implanting center, since it is based on the use of standard devices for cardiac stimulation.

Supraventricular arrhythmia simulator

The technique proposed by Padeletti et al.[10] was tested in 35 patients implanted with DDDR pacemakers (Diamond II in 23, Clarity DR in 12; Vitatron). These devices were chosen for their largely documented performance of AMS[2,11], thus representing an ideal basis for the evaluation of a new method. The supraventricular arrhythmia simulator is an external battery powered device able to deliver on the patient's skin a train of pulses with an amplitude of 200 mV, and a duration of 20 ms to get over the sensing filters of the pacemakers. The rate of the delivered pulses is selectable among 300 b/min to simulate AF, 250 b/min to simulate AFL, and 160 b/min to simulate AT. The pulses are delivered to the chest of the patient through two skin electrodes in the region between the pacemaker and the apex of the heart (Fig. 3). The same placement of the surface electrodes is fine also for chest wall stimulation. All patients (26 males, 9 females, mean age 73.45 ± 6.02 years) able to perform a stress test were considered eligible for the study. Each patient underwent two tests: one at rest and the other during exercise. Baseline telemetric interrogation of the pacemaker was first done and, before starting any test, the atrial channel sensitivity was programmed unipolar at 0.5 mV, while the ventricular channel sensitivity was programmed bipolar at a value > 2 mV. The pacemaker

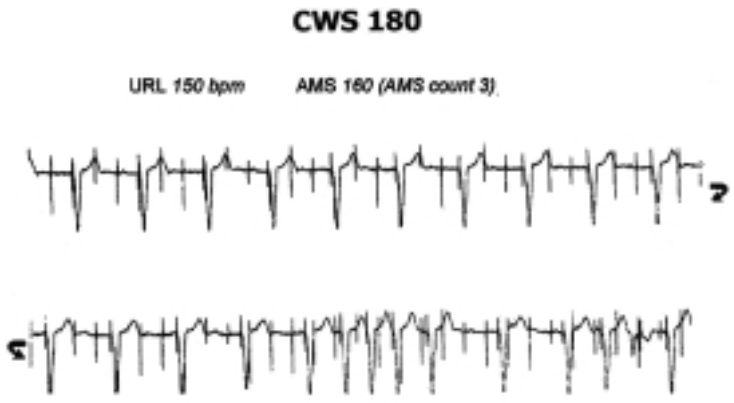

Figure 2. *Chest wall stimulation (CWS) at 180 b/min with the atrial arrhythmia detection rate set at 160 b/min (Marathon, Intermedics). AMS = automatic mode switching.*

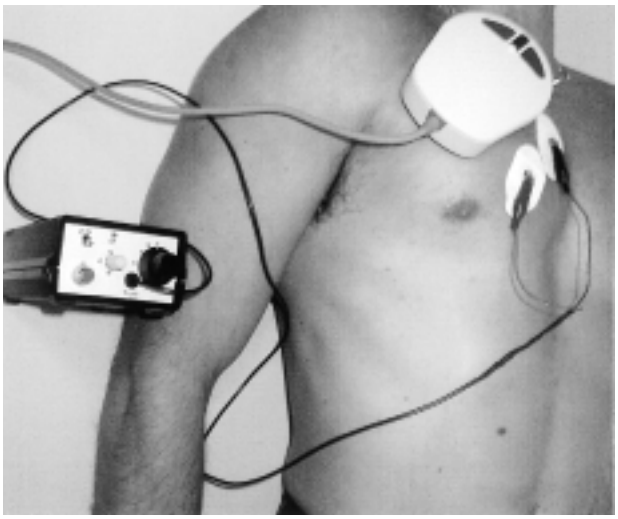

Figure 3. *A supraventricular arrhythmia simulator and relative skin electrodes placed on the chest of the patient to deliver the simulation pulses.*

was programmed in the DDDR mode, with a lower rate and an upper rate set at 60 and 140 b/min respectively, and the AMS function was then turned on. With the patient lying down three trains of pulses simulating AF, AFL and AT were delivered, each lasting 15 s. The second test was performed during exercise (50 W for 6 min) on a bicycle, and consisted of two simulations: the first, in which AF was simulated after 3 min of exercise; and the second, in which AFL was simulated after 5 min of exercise. During each test, the surface ECG was recorded and symptoms annotated. The following parameters were evaluated: the reaction time of the AMS algorithm at the onset and at the offset of the simulated arrhythmia, the stability during the 15 s of each pulse train, and the presence of any symptoms.

The pulses delivered by the supraventricular arrhythmia simulator were correctly sensed by the pacemaker's atrial channel with an amplitude ranging from 1 to 3 mV in both the supine and upright positions. Despite the use of different pacemaker leads, the performance of the system was not altered. As indicated by the on-line marker channel, all pulses, except those falling in the blanking period, were detected by the pacemaker. No symptoms related to pacemaker mode switching were reported, and no adverse events due to the supraventricular arrhythmia simulator interacting with the pacemaker occurred. Figure 4 shows the typical trace of a simulated AFL. The analysis of the ECG tracings during any simulated arrhythmias always allowed a detailed evaluation of the AMS performance. The pulses delivered by the supraventricular arrhythmia simulator did not alter the quality of ECG tracings, thus rendering the analysis easy and reliable. This method allows a detailed analysis beat by beat of the ECG traces and a detailed evaluation of the AMS performance, but it needs a dedicated electronic device.

Discussion

From a clinical point of view, AF is usually recognized by the onset of symptoms such as palpitations and anxiety which are common in PAF or dyspnea and chest discomfort which are often noted in persistent AF.

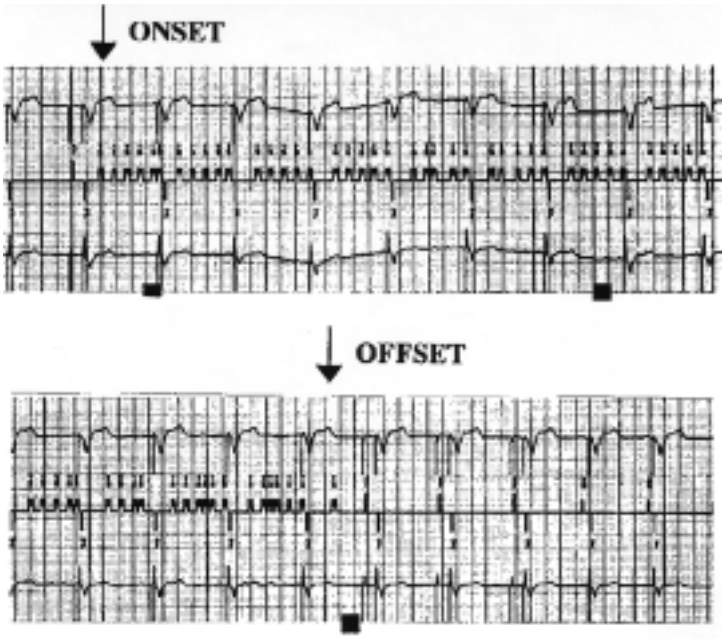

Figure 4. *Onset and recovery of simulated atrial flutter. The pacemaker (Clarity DR, Vitatron) maintains a stable ventricular rate and some atrial spontaneous sensing is superimposed on the artificial signals.*

However, in at least one third of patients, AF is associated with no obvious symptoms and no noticeable degradation of the quality of life: this is the silent or asymptomatic form of AF[12]. Those patients without a history of atrial tachyarrhythmias prior to implant, but in whom such a conduction disorder was diagnosed at least once post-implant, have presented with atrial arrhythmias by the third year. The problem of silent AF is underestimated, and the number of patients with asymptomatic atrial arrhythmias revealed by implanted devices will progressively increase[13].

Mode switching pacemakers provide adequate protection against rapid sustained tracking of atrial tachyarrhythmias and also the benefit of atrioventricular synchrony. These devices are indicated in all patients with the brady-tachy syndrome, but it could be argued that all patients should receive a device with AMS capability because one cannot predict which patients will eventually develop AF, or already have episodes of silent AF.

Many algorithms have been used by different manufacturers, and they do not behave similarly. Optimal care of the pacemaker patient requires a thorough knowledge of his or her arrhythmia history, atrial electrogram amplitude (in sinus rhythm and atrial tachyarrhythmia), basic timing cycles for the initiation of AMS, and the characteristics of the various available AMS algorithms.

Having stated the importance of this feature in all patients with dual-chamber stimulators, some methods to test AMS in implanted pacemakers should be available and validated as far as safety and effectiveness are concerned. The aim of our review is to specifically point out that some techniques are available to test this function in every patient. Starting from hand compression to generate myopotential signals, to chest wall stimulation and the supraventricular arrhythmia simulator, every physician can choose between a simple but less accurate method or a more complex but more accurate one, depending on the specific clinical requirements. The possibility of testing this function allows for the additional advantage of investigating the performance of the implanted device in case of AT, AFL or AF, allowing the best setting of the parameters involved in the AMS performance. The use of myopotential signals to test AMS represents a first-line approach, which is both safe and simple. If inhibition of the atrial channel is only sporadic, the use of other methods such as chest wall stimulation or a supraventricular arrhythmia simulator is mandatory: these methods require more time and some external devices, but they guarantee a reliable result.

Conclusions

Three methods may be proposed to test AMS in pacemakers already implanted in patients: myopotential signals, chest wall stimulation, and the supraventricular arrhythmia simulator. All of them have been validated in implanted patients. They have been shown to be safe, reliable, and easy to perform and will be a useful additional opportunity for most pacemaker centers.

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