Stratos LA – The First "Real" Triple-Chamber Pacemaker for AV Synchronous Biatrial Therapy

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Summary

The new Stratos LA cardiac pacemaker for biatrial, atrioventricular (AV) synchronous pacing has been available since October 2002. This device offers a number of new and unique features, such as separate programming of both atrial channels, three atrial fibrillation preventive algorithms, a new timing concept, and extensive diagnostic functions. This paper summarizes the technical features and describes the first implantation of this pacemaker in Germany within the framework of a pacemaker replacement.

Key Words

Biatrial pacing, atrial fibrillation (AF), AF-preventive algorithms, interatrial conduction

Introduction

Normal sinus rhythm is characterized by a regular and coordinated activation and contraction sequence of the atria and ventricles, based on the intrinsic pacemaker activity of specialized myocytes in the sinus node. In contrast, atrial fibrillation (AF) is characterized by rapid and irregular activation of the atria, independent of sinus node activity due to ectopic activity and/or reentry circuits [1]. Atrial fibrillation is a cardiac rhythm disorder that mainly affects the older population and is responsible for enormous costs to the public health system [2]. Though not directly life-threatening, AF strongly influences patients' quality of live and enhances the risk of thromboembolism and stroke, and therefore increases mortality [3] compared with the general population. Because AF is an extremely heterogeneous disease with several possible causes for its initiation, strong efforts have been made in the past to find suitable therapeutic approaches. However, there has not been much success in preventing AF, which should motivate us to intensify our research efforts in this field.

One therapeutic approach is electrotherapy using cardiac pacemakers. Modern innovative devices are equipped with special preventive algorithms (e.g., overdrive pacing) that have been shown during clinical trials to be effective in reducing the number and time of AF episodes in many patients [4-6]. However, in the past mainly dual-chamber pacemakers, pacing the right atrium and right ventricle, were used for this purpose. Nowadays, it is becoming increasingly evident that the left atrium is the most important location of AF initiation [7]. Beyond this, interatrial conduction disturbances leading to a delayed left-atrial contraction are known to be an important substrate for the initiation and perpetuation of AF [8]. Pacing both atria simultaneously compensates for these interatrial conduction delays and has been shown to be beneficial in reducing paroxysmal AF in selected patients [9-11]. Biatrial pacing has also been shown to be effective in preventing AF after open-heart surgery [12-14], a common side-effect leading to increased morbidity and hospitalization time.

In the past, biatrial pacing was achieved by splitting the atrial channel into two parts using a Y-bifurcated connector, one for the right-atrial lead, the other for left-atrial pacing via a lead implanted into the coronary sinus [15]. However, the splitting of one channel does not allow separate left-atrial pacing and sensing and also does not allow independent programming of the pacing and sensing parameters for both atrial channels.

Then pacemakers with two channels for biatrial pacing (AAD mode) were developed (e.g., Logos DS, Biotronik). This pacemaker allowed the separate programming of both atrial channels. However, the pacemaker statistics and diagnostic tools were limited, and AV synchronous pacing was not possible due to the two-channel concept.

The new pacemaker Stratos LA (Biotronik, Germany, see Figure 1) is the first pacemaker on the market worldwide that offers real three-channel features (biatrial, AV synchronous pacing) together with three different AF-preventive algorithms, new timing characteristics, and sophisticated statistics for all three channels. This paper roughly portrays the options that this new device offers and describes the experience of the first implantation in Germany.

Material and Methods

Triple-chamber Pacemaker

The triple-chamber Stratos LA pacemaker (generic code DDDRA) allows you to combine biatrial (or bifocal) pacing and three AF-preventive algorithms with new timing features and sophisticated statistics for all three channels (seen Table 1 for a list of key features). The biatrial resynchronization concept of this pacemaker requires a clear description in analogy to the common triple-digit generic code. The first digit represents the pacing properties, BiA for pacing in both atria. The second digit stands for the sensing properties, BiA for sensing in both atria, RA for sensing only in the right atrium. And finally the third digit stands for the triggering, BiA-T for triggering in both channels, RA-T for triggering only from the right atrium. To have full access to the pacemaker functionalities, the pacemaker is programmed to DDD(R) mode with biatrial synchronization BiA BiA BiA-T because left atrial statistics are only activated in that mode. In this mode intrinsic events of both atria are taken into account for the control of pacing. This setting enables the triggering on left-atrial extrasystoles, which probably represent the most important triggers for the initiation of AF.

Figure 1. Stratos LA (Biotronik, Germany).

Biatrial pacing and sensing

- Separate programmable pulse parameters for right and left atrium (pacing amplitudes, pulse width, polarities)
- Separate true unipolar/bipolar sensing in right and left atrium
- Separate right- and left-atrial IEGM

Biatrial timing features

- Separate interatrial delays after pace and sense (0 – 30 ms)
- Selective synchronization of only right AES or right and left AES
- Selective synchronization of early or/and late AES

Separate right- and left-atrial statistics, diagnostic functions

- Event counter, event episodes, histograms
- Up to 10.5 min of IEGM for all three channels plus marker annotations automatically stored (after mode switch, AF detection, VT detection with onset and/or resolution of tachycardic episode). This enables detailed analysis of arrhythmia initiation.

AF-preventive algorithms

- Dynamic overdrive pacing (DDD+)
  - Pacing slightly above the intrinsic rate
  - After every atrial sensed event, the pacing rate is increased by a programmable number of cycles
  - Then a stepwise decrease will be carried out
- Post AES pacing (PAESP)
  - Avoidance of pro-arrhythmic short-long sequences
  - After detection of an AES, the basic interval is shortened
  - Subsequent prolongation of the PAESP interval until the basic interval is reached
- Rate fading (post-exercise response)
  - Avoidance of sudden rate drops in the atrium and ventricle (e.g., after exercise, during onset of mode switch, 2:1 block)
  - Constant transition from high intrinsic rates to sensor or basic rate in case of sudden bradycardia
  - In case of sudden rate drop, pacing with backup rate (intrinsic rate –10 bpm)
  - Backup rate follows intrinsic rhythm with a programmable delay

Table 1. Key features of the Stratos LA (Biotronik, Germany). IEGM = intracardiac electrogram; AES = atrial extrasystole; VT = ventricular tachycardia.

Figure 2. Corox LA (Biotronik, Germany).

When BiA BiA BiA-T is combined with DDD (AAI) mode, biatrial cross-triggering will occur. This means that a single (non-refractory) right- or left-atrial sense triggers a pace in the opposite atrium. In combination with DDT/A (AAT) mode, BiA BiA BiA-T leads to biatrial double-triggering. This means that a single (non-refractory) right- or left-atrial sense leads to pacing sof both atria. For example, a sensed left-atrial extrasystole would lead to an immediate pace in both atria. In the BiA RA RA-T mode both atria are paced. However, due to the inability of left-atrial sensing, only right-atrial events are taken into account for atrial resynchronization; i.e., left atrial extrasystoles do not evoke any response of the device. Finally, atrial resynchronization can be deactivated by programming RA RA 0. In that mode the pacemaker works as a normal dual-chamber, AV synchronous device.

Lead for Pacing the Left Atrium

The Corox LA lead (Biotronik, Figure 2) was specially developed for implantation into the coronary sinus and pacing the left atrium from this location. The electrically inactive distal portion serves to anchor the lead in a side vessel of the coronary sinus. The placement is facilitated by a "positioning soft tip" (PST). The PST is a 7-mm long elongation made of silicone rubber that provides easy access to the coronary sinus vessels. The tip of the PST has a metal part that serves as X-ray contrast. Bipolar pacing of the left atrium is accomplished via two ring electrodes floating in the coronary sinus. The lead body is a coaxial coil structure insulated with silicone, with well-proven reliability. All electrode poles of the Corox LA are coated with fractal iridium for optimal electrical performance. A silicone thread at the electrically inactive distal portion of the lead provides atraumatic fixation. Fixation is accomplished by turning the thread into a suitable side branch of the coronary sinus. This method is advantageous especially in view of a potential repositioning or extraction of the lead since it can be loosened again by simply turning it.

Case Report

The following describes the first implantation in Germany. In 1998, a 74-year old man who suffered from paroxysmal AF received a Logos DS pacemaker for biatrial pacing therapy (AAD mode, interatrial delay 0 ms). Before his first pacemaker implantation, he had suffered from AF episodes occurring on average once a week, especially after exercise, he had a prolonged P wave as evidence of interatrial conduction disturbances, and was treated with β-blocker, digitalis, and sotalol. Since implantation of the Logos DS pacemaker the patient was free of any symptoms related to atrial fibrillation and consequently was free of antiarrhythmic medication. Now it was necessary to exchange the device due to end of battery life. It was decided that this patient was elligible to receive a Stratos LA for biatrial, AV synchronous pacing therapy.

Within the scope of this pacemaker exchange, a Stratos LA was implanted on October 24th, 2002. During implantation, the P wave duration was measured and still exhibited a prolonged shape (duration 140 ms) which indicated a delayed interatrial conduction. The atrial leads had already been implanted in 1998 together with the Logos DS; the right-atrial lead (Y53/SBP, Biotronik) at the lateral wall, and the lead for left-atrial pacing (Corox LA) in the distal coronary sinus (the electrode rings) with the distal fixation in the lateral vein. During the current Stratos LA implantation, an Arox 60-BP lead (Biotronik) was placed within the right ventricle. The implantation lasted 55 min with X-ray monitoring for 16 min. The measurement of pacing and sensing characteristics (all leads bipolar configuration) provided the following values (Table 2).

	Pacing threshold at 0.5 ms (V)	Impedance at 4 V/0.5 ms (Ω)	Sensing threshold (mV)
Right-atrial lead	0.3 V	460	4.5
Left-atrial lead	5.1 V	420	2.7
Right-ventricular lead	0.2 V	800	13.3

Table 2. Pacing and sensing characteristics of the implanted leads.

No problems occurred during pacemaker implantation. Before the patient was discharged, the pacemaker mode was set to DDD and BiA BiA BiA-T with an interatrial delay of 5 ms (after pace and after sense). The AF-preventive algorithms "dynamic overdrive pacing (DDD+)" and "rate fading" were deactivated, "post AES pacing" was activated. The AV delay was set to 300 ms and the basic rate to 60 ppm.
During the next follow-up (6 weeks after implantation), the sophisticated diagnostic tools of this new device will be used to look for potential non-symptomatic AF episodes. However, the clinical history of this patient has already shown a clear benefit of biatrial pacing.

Conclusion

The innovative and unique features of the Stratos LA together with the special coronary sinus lead Corox LA allow the attainment of new promising concepts for powerful AF therapies. In general, a trigger (e.g., left-atrial extrasystole) for initiation and a substrate for perpetuation are necessary to induce sustained AF (Figure 3). Stratos LA is the first device that tries to treat AF based on affecting both, i.e., possible triggers (by AF-preventive algorithms, synchronization of AES) and a substrate that is known to be responsible for perpetuating this arrhythmia (compensation of interatrial conduction block by biatrial pacing). These features enable new promising therapies for AF prevention.
The first implantation of a Stratos LA in Germany was successful. However, to date we cannot estimate the therapeutic success of this device for biatrial resynchronization therapy. We have to wait for the first follow-ups to get a sense of the AF-preventive potential of this new pacing device.
Nevertheless, the therapeutic efficacy of this new technique still has to be proven in large multicenter clinical trials. Soon the MISSION study (Multisite Stimulation and Overdrive Pacing for the Prevention of Atrial Arrhythmias) will start and will investigate the effect of biatrial resynchronization with and without activation of AF-preventive algorithms using Stratos LA pacemakers. Only patients with a known history of paroxysmal AF and interatrial conduction disturbances (P wave duration ≥ 120 ms) will be included in this trial. The MISSION study has the potential to show the success or failure of biatrial pacing therapy in specially selected patients. Since Stratos LA is the first "real" triple-chamber pacemaker that is able to activate different AF-preventive algorithms, it will be exciting to look for a potential synergistic effect of atrial synchronization and preventive algorithms. In combination, these unique features will hopefully lead to a more successful therapy for AF prevention by treating the arrhythmia from different directions.

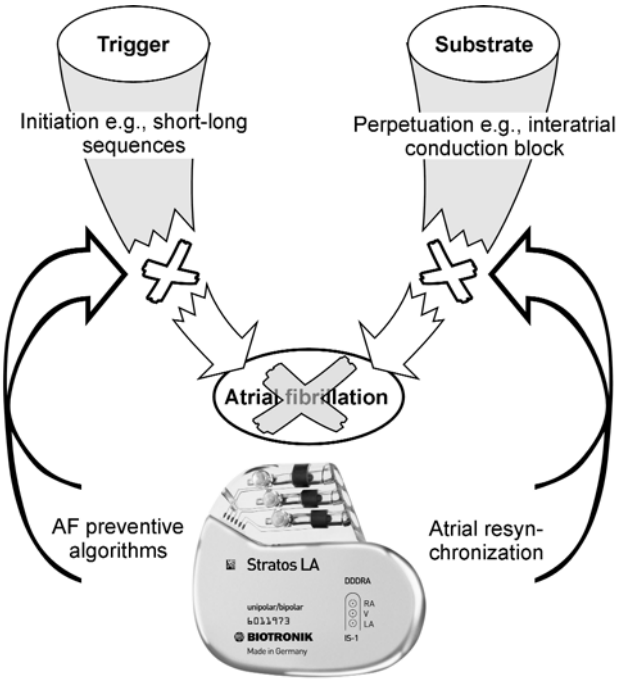

Figure 3. Scheme of atrial fibrillation (AF) preventive effects.

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