

# Single A-V Lead Pacing

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## SUMMARY

*In this review the single AV lead is revisited in its two actual aspects.*

*The first and more known concerns the capability to "detect" the atrial EGM through floating electrodes free to move in the right atrial blood pool. The characteristics of the atrial signal, processed by the pulse generator sensing amplifier, are at the base of its capability to "detects and discriminates" the cardiac signal from any other kind of interferences. On this selective sensing peculiarity it may be possible develop some specific algorithms for the identification and the characterization of different cardiac arrhythmias. This is an ambitious target but very profitable and with immediate clinical application.*

*To achieve the complete performances of a single A-V lead P-synchronous pacing systems, five stiff rules must be satisfied: a) reliable atrial EGM detection, b) availability of dedicated device systems, c) accurate patient selection, d) optimal implant procedures, e) careful pulse generator programming.*

*Many papers were written and many speculations were made about the possibility to constantly pace the atrium with non contact electrodes, because the idea to realize a DDD pacing using a single A-V lead was very suggestive. This system will simplify implant procedures, allowing the introduction of only one lead in an unique venous approach, will reduce vascular burdening and the correlated clinical complications, and will leave space for many other possible application.*

*Some solutions, the modern technology gives us, are represented not only by the electrode surface modification (the increase of the electrode electrochemical surface improves both pacing and sensing performances) and by modified structure and shaping of the lead (the use of shaped curves in the lead body can promote the electrode contact with the atrial wall, allowing a more constant and reliable pacing), but also by the availability of new pulse morphology and emission methodologies. This, pacing occurring with a lesser dispersion of energy, should avoid the parasitic phrenic nerve stimulation.*

*The rational and optimal exploitation of the mentioned solutions could favor the realization of the "All-In-One Device" we longed for since several years.*

## KEY WORDS

atrial synchronous pacing, single lead dual chamber pacing, single A-V lead, all-in-one device.

## Introduction

The atrial synchronous pacing using a dedicated pulse generator and a single A-V lead, born in the 70s to replace the VVI mode and to assure a reliable atrio-ventricular synchronization in patients with high degree AV block and normal sino-atrial function, is now a widely accepted reality.

The original lead was presented in Montreal in 1979<sup>[1-3]</sup>, it had an unipolar floating atrial electrode at a distance of 13/16 cm apart from the ventricular tip in order to float in the high or medium-high right atrial chamber. The designs of the several atrial bipolar configurations of single A-V leads, developed since the 80s<sup>[4-20]</sup>, embodies all the deductions,

implementations and clinical experiences made over the years. Included in 1991 in the "Guidelines for Pacemaker Implant", published by AHA and ACC<sup>[20]</sup>, this pacing modality is now widely used in the clinical pacing therapy. The attempt to minimize its relevance with inconsistent and precarious argumentations, which did not and will not survive in the time at the experience evidence, and to distort its philosophy claiming properties and functions it does not have<sup>[22-25]</sup>, it is an unacceptable misleading conceptual mistake. It is also wrong and clinically unacceptable, for several technical and methodological implications, to set it against the DDD/DDDR mode. By its characteristics, its collocation in an equidistant position between the two main pacing methodologies will

better respect the matter of facts <sup>[26-30]</sup>. Nowadays many devices, each one with its own characteristics, are available from different manufactures.

Past and recent literature reports hundreds of clinical experiences with several Single A-V lead VDD systems. Those in the following list are the most popular in the clinical practice.

A: CPI ULTRA II 910, no longer available, using the original unipolar configuration with a single atrial ring electrode.

B: MEDICO PHYMOS (many models), which uses a tripolar lead with a wide (30 mm) longitudinal dipole and atrial ring electrodes.

C: CCS MAESTRO SAVVI 305 and 333, whose first experiences were made in USA and Europe, which uses a tripolar lead with a short (two half-ring 7 mm spaced and diagonally opposed) atrial dipole (DAB).

D: LEM Biomedica Twinal 30 and 30S, which uses the same lead of the CCS System but with an dipole size of 5 mm.

E: Intermedics UNITY 294, which uses a lead like CCS SAVVI's one.

F: Vitatron SAPHIR (many models) and Medtronic THERA (many models), which uses a quadripolar lead with a short (8.5 mm) longitudinal dipole and atrial ring electrodes.

G: Biotronik DROMOS SL, which uses a tripolar lead with a short (10 mm) longitudinal dipole and atrial ring electrodes.

H: Pacesetter ADD VENT, which uses a quadripolar lead with a mid (12 mm) longitudinal dipole and atrial ring electrodes.

I: Sorin Biomedica SWING VDR1, which uses a tripolar lead with a mid (13 mm) longitudinal dipole and atrial ring electrodes.

Up front of a correct design of the sensing amplifier, the reliability and performance of the system depend by lead configuration and structure, which have to maintain the atrial dipole as close as possible to the high or medium-high atrial wall <sup>[27]</sup>. A too big in size and stiff lead is prone to stay too far from the atrial wall, and to substantially change dipole /sinus node relative position during the cardiac cycle and body postural changes, while a lead excessively "soft" presents serious difficulties in positioning and is prone to arrange the dipole along the direction of the gravitational momentary axle. Now the optimal characteristics of a single A-V lead are: 7 to 8 Fr.

diameter, about 10 mm of atrial dipole spacing with a geometric electrode surface of 6-15 mm<sup>2</sup>, dipole located at 13-16 cm apart from the ventricular tip. In our experience, conductors with coaxial structure and light polyurethane insulation seem to be the best technical compromised to achieve a long term stable and reliable single A-V lead. In many conditions, like during physical exercise, postural variations, deep breathing, arm and shoulder movements, coughing, etc., this configuration is able to detect atrial EGM s with proper amplitude and dV/dt. It is not significantly affected by EMI and neither by ventricular far fields and it maintain an unaltered trigger capability. However, during physical exercise the major volume of blood flowing in the atrium increase the distance between atrial wall and electrode inducing a discontinuous attenuation of the detected signal ("biological filtering"), whose consequences can be, in few cases, the loss of sensing. Since there is no contact with the atrial wall, the floating electrode does not provoke the usual fibrotic reaction which usually occurs with traditional electrodes, so the detected signal is not influenced. Chronic measurements, made during pulse generator replacement, do not show significative variations of P-wave amplitude and morphology even after several years from implant. The loss of sensing loss should not be confused with signal attenuation. The lower values of P-wave amplitude, when compared with the same directly measured at lead connectors during implant, detected through the pulse generator telemetry are less critical than the attenuation induced by the field variations and the input filter characteristics <sup>[31-38]</sup>.

Several extensive and multicenter clinical experiences were conducted all around the world with different single lead systems. The reports published during last few years and those presented in many recent international meetings confirm that floating electrodes, when located near the medium-high atrial wall, can detect atrial EGMs with good characteristics and able to maintain the system performance over the time <sup>[39-43]</sup>.

The optimization of the perception capability of the single A-V lead VDD system, given by improvements in the lead structure and in the pulse generator input amplifier, became as sophisticated as we can consider it as "unique". Future implementations of new functions may give to the system not only more flexibility and safety, but also will allow to reach other important targets of immediate clinical applications. A typical example can be the suppression of improper stimulation or defibrillation through elaboration, based on the floating EGMs detection, of more sophisticated algorithms to identify and discriminate different types of arrhythmias.

To achieve the optimal performance of the actual single A-V lead systems, few simple rules must be respected <sup>[27]</sup>.

1. RELIABLE ATRIAL EGMS DETECTION.
2. AVAILABILITY OF DEDICATED DEVICE SYSTEM
3. ACCURATE PATIENT SELECTION
4. OPTIMAL IMPLANT PROCEDURES
5. CAREFUL PACEMAKER PROGRAMMING

### 1. RELIABLE ATRIAL EGMS DETECTION.

Many conditions affect the characteristics of the atrial EGMS detected by an electrode free to float in the atrial blood pool. Since the floating condition itself introduces morphology and amplitude variation of the signal during exercise, heavy breathing, coughing, change in posture, arm and shoulder movements. Also the anatomical structure of the atrial chamber (crista terminalis, auricular appendix, etc.), the aging of its fibers and the electrode position and configuration, can influence the wavefront propagation and the morphology of the sensed signal <sup>[27]</sup>. When distance increases, the peak amplitude of the field signal developed by the depolarization wavefront decreases as well as the spread between the positive and negative peaks increase, and the frequency decrease. This is a consequence of the reduction of intensity of isopotential field lines ("biological filtering"). Thus, the ideal dipole spacing should be equivalent to the spatial peak to peak distance (3-5 mm) of the depolarization wavefront. The best tuning is reached by a short atrial dipole, whose inter-electrode distance is in accordance with the signal wavelength. On the contrary in widely spaced dipole the lower effect of the differential subtraction reduces the perception / discrimination capability. One cm dipole gives sharper and higher in amplitude atrial signals than a widely dipole and even a better A/V ratio in different atrial positions, with a preference for the medium to high position. In this position, the dipole allows the differential subtraction process and gives a best signal with a higher frequency content <sup>[44-46]</sup>, while the major distance from the ventricular myocardium gives to a best rejection of the ventricular far field. In the lowest zone, that correspond to the atrial floor, values are critical, and the short dipole detects signals similar to those seen in a 3 cm dipole. In this zone both dipole electrodes are at the greatest distance from the atrial wall since the lead transit through the tricuspid valve.

Also the electrodes geometric surface may affect the atrial signal. Large electrode area acts as an averager of isopotential lines and gives a resultant signal that is lower than the peak amplitude of the extracellular potential. Small electrode will show a high source impedance that may create problems of cross-talking or phase imbalance in detected signal. To avoid this last phenomenon the electrode impedance should be 10-100 times lower than the input impedance of the sensing amplifier. The optimal geometric surface of each electrode will be in the order of 6-15 mm<sup>2</sup>.

### 2. AVAILABILITY OF DEDICATED DEVICE SYSTEMS.

Single AV lead VDD pacing does not simply require a specific and well conceived atrio-ventricular lead but also a pulse generator properly designed, in which the most important electronic component is the atrial amplifier. The characteristic of the differential atrial amplifier must also include an input filter bandwidth ranging from 15 to 140 Hz, with a center frequency settled between 50 to 70 Hz, and the capability to detect signal amplitude as small as 0.1 mV. The pulse generator should also be widely programmable and should have built-in algorithms and protection mechanisms against premature ventricular contractions and retrograde ventriculo-atrial conduction, in order to avoid sustained PMTs. Telemetry characteristics are very important. The availability of an automatic atrial sensing threshold measurement and the transmission of a reliable intra-atrial EGM allows to maintain over time a safe sensitivity setting and also allows the analysis and solution of many oversensing problems, which are incomprehensible through the sole analysis of the surface EKGs.

The more recent models further provide new fundamental features, as: the backup VVIR rate-responsive mode, the automatic temporary reversion from VDD /VDR to VDI/VDIR or VVI/VVR modes, the rate modulated AV delay and PVARP and the overnight rate adjustment. The availability of a backup VVIR mode, replacing the VDD mode when the sinus function fails, assures a ventricular rate modulation proportional to metabolic needs, but its algorithm must be programmed so that the sensor-induced rate will never "walk-over" the sinus-tracked rhythm during exercise and/or emotional stress. The conversion function, which automatically reverts VDD to VDI/VDIR or VVI/VVR mode when supraventricular paroxysmal tachyarrhythmias suddenly occur, represents an effective protection mechanism against tracking in ventricle the atrial fast rate. Finally the overnight rate adjustment, lowering the basic-rate at

night time, enables to continue the P-synchronous even when nocturnal bradycardias occur.

### 3. ACCURATE PATIENT SELECTION.

The ideal candidates for this pacing mode are patients with high degree AV block and normal sinoatrial function. Patients with mild sinus node dysfunction or with blunting of atrial responsiveness only at high levels of activity can also benefit from this pacing mode. Atrial size and functions, including the mechanical one, must be carefully evaluated, using 2D Echo Doppler, Holter monitoring and exercise test when available, because it give us further important elements to identify patients with a potential arrhythmologic risk, and relevant informations about sinus rhythm variations during daily life. Chronotropic function should be assessed with respect to the patient age. Presently, normal sinus node function is defined as a minimum sinus rate of 60 bpm when patient is resting or a sinus rate of 85 bpm minimum when patient is performing a submaximal exercise. There are evidences that P-synchronous pacing is much more physiological than VVIR one during workloads corresponding to those currently performed by the majority of elderly patients during daily life. So that, it seems correct to maintain a VDD pacing mode in these patients and in those in which a mild sinus node dysfunction does not preclude a substantial increase in sinus rate according to physiological requirements. It is reasonable to consider that they represent the 20% of the entire population that first time undergo to a pacemaker implantation.

Absolute contraindications to this mode of pacing include: chronic atrial flutter and fibrillation and extreme and persistent sinus bradycardia. Episodic supraventricular tachycardias and atrial flutter and fibrillation are not a contra-indication if the pacemaker is equipped to switch automatically from VDD to VDI/VDIR or VVI/VVR mode, and viceversa when the normal sinus rhythm is restored. This function have to be regulated by advanced algorithm based on the whole and beat-to-beat analysis of the sinus rhythm. Intermittent sinus bradycardia does not contraindicate single AV lead VDD pacing if the lower rate of the pacemaker can be programmed below the minimum patient sinus rate found during Holter monitoring. If the lower rate is higher than the patient minimum sinus rate, an unsynchronized ventricular pacing can be induced, which may cause a retrograde VA conduction and trigger a pacemaker mediated tachycardia (PMT). Retrograde VA conduction by itself is not a contra-indication to this pacing mode, if the pacemaker has an adequate programmability range and built-in protection against retrograde P-

wave sensing and PMTs <sup>[44]</sup>. Further, a prolonged sinus bradycardia occurring night-time during sleep is acceptable if an automatic programmable overnight rate is available.

### 4. OPTIMAL IMPLANT PROCEDURES.

We can discriminate few phases:

A: Before the implant, a previous chest fluoroscopy or 2D Echocardiography allows to select a lead with the right A-V inter-electrode distance, even if the 13 cm seems to be correct in the majority of cases.

B: After the fixation of the ventricular tip in the selected position, the lead should be maneuvered in order to place the dipole as close as possible to the mid-high atrial wall.

C: During implant procedure patient should be requested to perform particular movements to simulate the normal daily activity, as: deep breathing, coughing, postural changes, arm and shoulder movements in order to verify that the induced variations on the atrial EGM don't became critical.

D: The minimum amplitude of the atrial EGM, measured during all conditions, must not be lower than 0.5 mV. The minimum acceptable value must be suitable with the sensing programmable range of the pacemaker with a signal minimum amplitude / programmed sensitivity 4:1 ratio.

E: Before termination of the surgical procedures, to verify the stability of the atrial dipole, the amplitude of the atrial signal must be tested again through the automatic sensing threshold analysis of the implanted device. A good quality atrial EGM is extremely important to obtain a reliable synchronization during all daily activities.

### 5. CAREFUL PACEMAKER PROGRAMMING.

Programming a single A-V lead VDD or a conventional VDD/DDD system is similar.

1. The atrial sensitivity must be programmed at a value at least 3 to 4 time higher than the minimum amplitude of the signal detected during implant maneuvers or through the atrial sensitivity threshold test.
2. The A-V delay, fixed or rate modulated, must be programmed within a range and adaptation algorithm which, using an exercise test, give a most effective hemodynamic result. If an ergometric test is not

possible, we can consider as optimal the value that optimize the transmitralic flux at rest.

3. The PVARP should be extended enough to ignore any possible retrograde P-wave, or a even rare oversensing of the tail of the T-wave. If specific algorithms to prevent or terminate PMTs, as: input filter with programmable bandwidth, automatic mode switching, algorithms which break the re-entry loop of the PMT, are not available, the PVARP extension will limit the sinus tracking rate during exercise.

4. The backup VVIR function, if present, must be programmed to respond to exercise with an algorithm giving a pacing rate slightly lower than the corresponding sinus rate, using the same algorithm of the automatic switch. In this way, the sensor-induced pacing rate will never walk-over the sinus-tracked paced rhythm during exercise and then will not vanish the intimate philosophy of the system.

It is easy to finish this first part of the discussion confirming that this pacing system is become a current and extensive clinical approach today. Performance and reliability of the system absolutely depends on the combination of a high quality devices design and technology, joined to the optimal knowledge of the indications and limits of the system and of the "strategies" for its full use. Its present primary indications for implant are those presented by patients with complete, advanced and paroxysmal AV block with:

- 1) Normal sinoatrial function (the ideal indication).
- 2) Mild sinus node dysfunction with an acceptable increase in sinus rate according to physiologic needs during daily life activities, indicatively elderly patients with a low chronotropic function (minimum rate 80-85 bpm at submaximal exercise).
- 3) Paroxysmal atrial flutter or fibrillation, only if the pulse generator can be temporary and automatically reverted in VDI/VDIR or VVI/VVR mode.
- 4) Dilated or obstructive cardiomyopathy with or without mild sinus node dysfunction, where atrial electrodes properly distanced from the ventricular tip can be used.
- 5) Drug refractory intermittent atrial flutter/fibrillation in which a complete AV block was induced by His bundle ablation.
- 6) Symptomatic first degree AV block with hemodynamic impairment, with or without structural cardiac lesions.

However the impossibility to constantly pace the atrium when necessary was the major limit of this pacing mode. Many proposals to solve this problem were presented and tested, because the idea to

achieve the DDD pacing using a single A-V lead was very suggestive, but no one was able to overcome the preliminary clinical evaluation.

Today we are looking to some interesting solutions, whose rational use could help the realization of the "unique device" we longed for since long time<sup>[47-48]</sup>. For this reason, in this favorable era of new ideas and technology development, we think correct to briefly revisit the basic steps of this evolution.

The first attempts concerning the possibility to realize a transvenous atrio-ventricular pacing using a temporary investigational multipolar lead, forced to contact the inner atrial wall, were reported since the early '70s<sup>[49-51]</sup>. In these first attempts it was observed that the atrial pacing was joined to a constant and painful phrenic nerve stimulation due to the high voltage of the stimulus. Some years later other investigators<sup>[52]</sup> reported the same results using two P-Synchronous permanent implants performed using a custom single A-V lead connected to a standard pulse generator. It was reported that the endothelization, occurred at the contact site between the electrode and the inner atrial wall, could be the possible cause of the failure of atrial sensing at the chronic stage of the implants. At the end of the '70s a special quadripolar lead was suggested. This lead must be inserted in the coronary sinus, with the proximal dipole appropriately spaced from the distal one, so as to gain a permanent atrio-ventricular pacing when connected to a custom designed pulse generator<sup>[53]</sup>. In fact, the possibility to permanently pace the atrium through the coronary sinus<sup>[54,55]</sup> was well-known. From the coronary sinus could also be paced the left ventricle with better hemodynamic results than those achieved by the right ventricular pacing<sup>[56,57]</sup>. Between the end of '70s and the beginning of '80s there were a lot of interesting proposals. In one experimental study<sup>[58]</sup>, the so-called single atrio-ventricular lead was in concrete an assembly of two leads closely joined, that, in the atrial site, appeared divided into two parts (in the atrial unipolar electrode configuration), or in three parts (in the atrial bipolar electrode configuration). After positioning of the ventricular electrode, the removal of the guidewire allowed a basket-like expansion of the atrial portion of the lead, forcing the contact between electrode and atrial inner wall. Also the lead called "crown of thorns"<sup>[59]</sup>, even if very interesting for its configuration made by three atrial electrodes protruding from the lead main body, was not successful because the complexity to fix the "thorns" (the atrial electrodes) to the atrium.

At Europacing 1981<sup>[60]</sup> was presented a single A-V lead with a preshaped lobe form at atrial level, which was taking form when the guidewire was removed, allowing a good and stable contact of the electrodes to the atrial inner wall, but no new experiences in this field were done subsequently.

In order to make easier the simultaneous positioning of both atrial and ventricular electrodes and minimize complications, in 1982 we improved the original single A-V lead adding a ventricular active fixation and bending the lead at the single atrial electrode level, at 13 cm from the ventricular tip<sup>[61]</sup>. The ventricular active fixation allowed a better anchoring of the lead and improved its handling at atrial electrode positioning. The pre-formed bending, taking form at the extraction of the guidewire, was conceived to make more stable the atrial electrode in respect of the atrial wall and, if possible, to allow atrial stimulation. This new lead was tested in three patients, between 1982 and 1983, connecting the lead to a standard VDD Medtronic mod. Enertrax 7100 pacemaker. Atrial pacing threshold was three to four time higher than the same usually found by using traditional atrial leads<sup>[6]</sup>. Current waste was so high because the low impedance shown by the system and induced constant phrenic nerve stimulation, making then unacceptable this approach to atrial pacing.

In our long experience<sup>[10,61]</sup> with single A-V lead VDD pacing, many times we had the opportunity to verify the real feasibility of this performance, as published at the beginning of '90s<sup>[62]</sup>. A total of 21 CHB patients (pts), all with normal sinus function, were involved. All were implanted with dual chamber DDD pacing systems in which, for several reasons, only the VDD mode was programmed. The DDD mode was activated only during routinely follow-ups<sup>[63]</sup>. The atrial unipolar leads shown no atrial pacing at all in 7 patients, when an intermittent pacing was achieved in 6 patients, with atrial pacing threshold ranging from 4 to 7.5 V, depending by patient postural positions. The preshaped leads showed the same behavior of the unshaped leads and, even at 10 V of pulse amplitude, a reliable and constant pacing was not achieved. In unipolar leads pacing was possible only in those cases in which a contact between electrode and atrial wall was evidenced by chest X-ray. Atrial bipolar leads gave an intermittent atrial pacing only when dipole was very close to atrial wall and the pacing threshold ranged from 3.5 to 7.5 V. Dipole with 30 mm length shown an higher percentage of captures, at threshold over 5.5 V, only if the proximal atrial electrode was very closed or in contact to the inner wall at the exit of the superior vena cava. Usually, the parasitic stimulation of the phrenic nerve was induced by voltage lower than those allowing atrial capture.

Aim of all mentioned attempts was to induce the atrial depolarization applying a pulse on a floating electrode, using the same pulse shape and polarity as in the contact electrodes, which will generate an electric field extended enough to include the atrial myocardium. At this time, none of the systems using this pulse approach, unipolar or bipolar, preshaped or not, can assure a 100% reliable DDD stimulation without painful side effects. In a recent report of long term follow-up<sup>[63]</sup>, floating atrial stimulation was unable to reach the 50% of success.

We think useful to underline these points:

1. A depolarization wavefront into a neuromuscular fiber can be generated using two approaches:

a) directly, by a direct injection of an electric current that will generate a massive cell depolarization (this is the case of the conventional pacing through contact electrodes). In this case the electric field correlated to the current waste is limited in quantity and spatial effect.

b) indirectly, by an electromagnetic field supplied through two spaced electrodes not in contact with the active tissue. In this case the field intensity must be strength enough and horthogonal to the longitudinal axis of the muscular fibers to introduce an electric current sufficiently high to generate a self maintaining depolarization front.

2. Since the phrenic nerve is traveling in a mediastinic position, close to external right side of the atrial wall, it can be rarely affected by the direct pacing approach, but, on the contrary, it can be easily involved in the mechanism of the indirect approach.

It may be of some interest to make some considerations about the physical behavior of the electromagnetic field generated during the indirect approach to atrial pacing.

A. If the field is of unipolar type, i.e. it is generated between the unipolar floating atrial electrode and the pulse generator case, its spatial shape is oriented in the plane including both the electrode and the case; this plane usually do not include the phrenic nerve. Because the distance between the two electrodes is high the field strength is low. Then to reach a value of field strength sufficient to induce the depolarization in the atrial myocardium the pulse voltage must be increased at values that may generate a field spread sufficiently strong to invest the phrenic nerve and induce its parasitic activation.

B. If the field is of bipolar type, i.e. it is generated between one floating atrial electrode (active) and the second floating atrial electrode (indifferent), its spatial

shape is approximately spherical and it may include the phrenic nerve. Because the distance between the two electrodes is short the field strength is high and uniformly dispersed in the space around the dipole. To reach a field strength value sufficient to induce the depolarization in the atrial tissue the pulse voltage can be lower than the unipolar but the phrenic nerve may be easily affected by the spatial distribution of the field.

Then, to perform a DDD stimulation with single A-V lead it was useful re-analyze the cardiac stimulation history, intervening in some of its main concepts. We had to put attention to: a) pulse morphology and emission, to optimize its yield when a floating electrode array in the atrium blood pool is used; b) lead structure and configuration to improve and make it reliable for atrial stimulation.

### **PULSE MORPHOLOGY AND EMISSION.**

In our knowledge on this argument there are no reports in literature, except the following.

Animal experiments, followed by a clinical approach<sup>[65-67]</sup>, showed the possibility to pace the atrium and reduce the phrenic stimulation risk, changing the pulse morphology and its emission on floating dipole. With this new technique, called OLBI (OverLapping Biphasic Impulse), two single unipolar pulses, with same amplitude and duration but with opposite polarity, are simultaneously and separately sent by the dipole electrodes to the pacemaker case, the positive pulse is sent by the distal and the negative by the proximal electrode. This way, in the atrial myocardium facing the dipole a high field strength is induced, which is sufficient to generate depolarization with pulse amplitudes of only 1-2 V. In the outer side of the atrial wall the interaction of opposite isopotential lines minimizes the field strength decreasing the possibility to stimulate the phrenic nerve. In practice an high energy density is concentrated in the electric field that includes a portion of the atrial myocardium in the dipole-pacemaker case plane. This approach, which uses conventional ring electrodes<sup>[68]</sup>, shows a constant atrial capture in more than 80% of patients, with few side effects<sup>[69]</sup>.

### **LEAD STRUCTURE AND CONFIGURATION.**

All described pacing pulse morphologies want the dipole to stay as close as possible to the atrial wall. Since the field strength is inversely proportional to the square of the distance between active tissue and

electrode, if the dipole is far away from the atrial wall is more probable to have a loss of capture or sensing.

A first structural modification was the surface treatment of the electrode surface (Fractal coating) in order to dramatically increase their electrochemical surface<sup>[68]</sup>. This treatment induces a substantial decrease of the polarization impedance, during the emission of the pulse, and of the amplitude of the after-potential. This result in a better sensing and pacing capability. Also with these efforts, 100% atrial stimulation was not possible and phrenic stimulation was still a clinical problem<sup>[70]</sup>.

It is obvious that a "straight" single lead will never be able to assure a constant and reliable atrial stimulation since its dipole will be free to float in the atrial blood pool.

So it was necessary to follow the "old" way of preshaping the lead in its atrial portion<sup>[60-61]</sup>, to keep the dipole close, or in stable contact, with the atrial wall but far from the phrenic nerve.

In the recent literature we found a new polyurethane lead called "DAC" (Dual Atrial Contact), which have several preshaped curves<sup>[71]</sup>. The first curves are located at the level of the superior vena cava, just before its exit in the right atrium. This shape is like an S to obtain a support point which trust the remaining atrial portion of the lead, lobe shaped, to maintain the electrodes in contact with the atrial wall. Electrodes are positioned at the apex of the lobe, they are made by two platinum-iridium half-ring, spaced of 7mm, both oriented in order to face the atrial wall. This solution does not present critical changes in the electrode structure, and allows a stable positioning of the dipole in anterior atrial wall, far from the phrenic nerve.

Tried only in experimental way, the sensing capability was optimal in all electrode combination, while the pacing capability showed lower threshold values when an unipolar pulse was induced simultaneously on both dipole electrodes, this pacing approach is called "Unipolar Proximal + Distal Parallel Cathode". This particular lead preshaping and the use of polyurethane insulation for each coaxial conductor assures a certain strain to the lead and bring at least one of the electrode in contact with the atrial wall. If there is no constant contact between electrode and atrial wall the preshaped lobe of the lead assures, at least, that the dipole stay very close to the excitable myocardium, in this way threshold variations can be maintained in an acceptable range.

Today it is impossible, and it will not be prudent, to forecast future developments, like those said before. But if we recall at our mind all the basic past steps of

the history of the original single A-V lead improvement, and if we consider that the disbelief, that produced a substantial slow-down in its development, has, in effect, favored the born of a complete new pacing system which can be the launching-pad to greater horizons, we must be positive. Compared to our usual expectations, in cardiac pacing the time required to realize the most ambitious projects seems even too long. However we should not consider an hazard the hypothesis that, if the early clinical evaluations in the new methods of pulse emission will give a positive result, moreover if they are associated with new pre-shaped lead configurations, in the forthcoming future the DDD stimulation with a single AV lead will cease to be a simple utopia to become a reality.

At the beginning of the third millennium this reality will illuminate the way for the realization of the "All-In-One Device", that, since long time, we are awaiting for all applications.

As faster and more incisive will be the interaction between different technologies as soon we will see realized our hopes.

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