Therapeutic and Preventive Benefits of Stimulation with Floating Electrodes

F.A. LUCCHESE
Hospital São Francisco, Porto Alegre, Brazil

for the BRASILEAD study group.

Summary

*Dual chamber stimulation with a single lead combines the advantages of single lead VDD pacing and conventional DDD therapy. The total volume and number of leads is minimized, yielding a simplified and less complication-prone implant procedure. Current results of the BRASILEAD clinical project for a validation of the OLBI (**O**verlapping **B**iphasic **I**mpulse) principle for single lead dual chamber pacing confirm the feasibility of this method. Further approaches for antibradycardia and low energy antitachycardia therapy using floating electrodes and the OLBI stimulation are discussed in this work.*

Keywords

OLBI, single lead dual chamber pacing, atrial stimulation, floating electrodes, BRASILEAD

Introduction

In order to reduce thrombogenicity and the risk of complications, as well as burdening of the circulatory system, the total volume and number of used leads in single lead DDD systems is to be minimized. Also the implantation procedure itself has to be simplified. Several approaches[1,2] to provide reliable single lead dual chamber pacing yielded high capture thresholds or complex electrode geometry. The novel OLBI (OverLapping Biphasic Impulse) pacing mode for safe and effective atrial stimulation via floating ring electrodes was developed and evaluated in several experimental and acute clinical investigations[3,4] (figure 1). Two identical pulses with inverse polarity are emitted by the respective ring electrodes on the ventricular lead, yielding an efficient electrical field distribution in the atrial myocardium. The BRASILEAD project aims to evaluate and confirm previous observations[5-9] on OLBI midterm threshold stability and atrial capturing performance in a controlled group of patients.

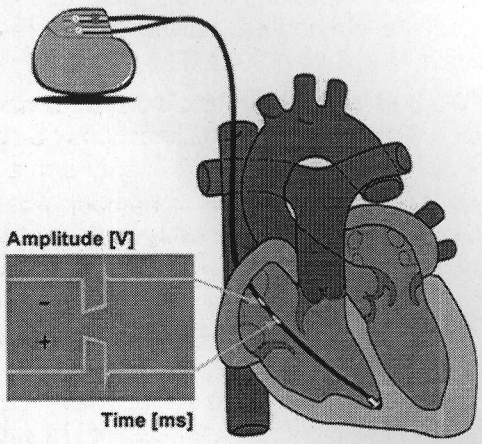

***Figure 1**: Single lead dual chamber pacing via floating atrial rings using Overlapping Biphasic Impulses.*

Materials and Methods

Actual experimental and clinical results[3-9] have proven the OLBI pacing form to be an effective and reliable method for atrial pacing with floating electrodes. For further clinical validation of this concept at 15 clinical centers 94 patients (47m, 47f) with a mean age of 63±14 years (26-84) were included in the BRASILEAD project. Single lead electrodes (BIOTRONIK SL60/11

(28%), 13 (65%), 15 (7%)) with 10 mm atrial ring spacing were utilized (figure 2). After intraoperative measurements for the assessment of the optimal lead position, pacemakers with atrial OLBI pacing capability (EIKOS SLD, BIOTRONIK) were implanted in patients with symptomatic AV-block II or III. Atrial capture thresholds and p-waves were measured during implant, on discharge day and 6 weeks after. Pacing mid-term stability at various body positions and breathing maneuvers was determined.

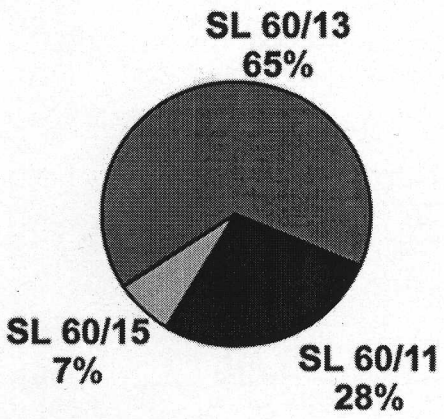

Figure 2. Distribution of utilized electrodes in 94 patients of BRASILEAD.

Results

In 68% of the cases atrial capture thresholds below 2.5 V were measured. Threshold values lower than 3.5 V were obtained in 88% of patients. Mean threshold was 2.4±0.8V at discharge follow up. Obtained p-wave values for discharge and 6 week follow up were 1.6±1.2mV and 1.4±0.9mV respectively.

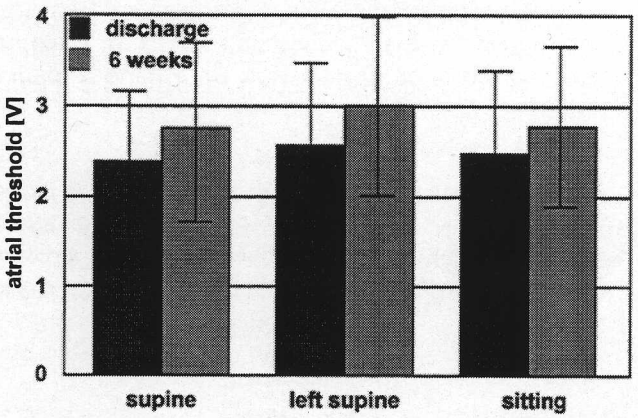

Figure 3: Atrial capture thresholds obtained with OLBI stimulation at supine left supine and sitting position during discharge and 6 week follow up.

With respect to the effect of position changes the atrial capture threshold in supine, left supine and sitting positions obtained during discharge and 6 week follow up is summarized in figure 3.

During discharge the threshold was 2.4±0.8V, 2.6±0.9V and 2.5±0.9V for supine, left supine and sitting position respectively. The measurements during 6 week follow up showed no significant changes. Consequently the effect of changes in posture are neglectable with OLBI stimulation since there are no significant variations in the atrial threshold.

The effect of breathing maneuvers on the stability of the threshold was observed in the BRASILEAD project. The results are presented in figure 4. Mean atrial thresholds in the range of 2.7V were obtained during normal breathing and Valsalva maneuver, both at discharge and 6 week follow up.

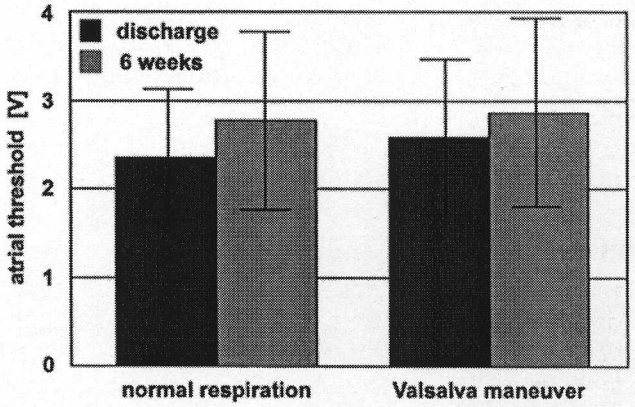

Figure 4: Atrial capture thresholds obtained with OLBI stimulation during normal respiration and Valsalva maneuver at discharge and 6 week follow up.

Also the course of atrial threshold from discharge to 6 week follow up with OLBI stimulation is to be observed in figures 3 and 4. A stable atrial capture threshold in the range of 2.7V allowing reliable pacing with floating electrodes is to be observed during the entire follow up period. As there is no grow-in behavior of the ring electrodes to be taken into consideration the stable course of the atrial threshold was previously expected.

Regarding the preferred region as position for the atrial ring electrodes the low atrium was selected in 51% percent of 94 patients involved in the BRASILEAD project. The mid right atrium was preferred in 32% and the high right atrium in 17% of cases. Figure 5 shows the rates of successful stimulation with respect to secondary stimulation and capture losses for

the selected atrial regions. Although the mid right atrium shows a high success rate (96%) in discharge follow up, the mid term performance of the low right atrium with 81% is higher compared to mid and high atrium.

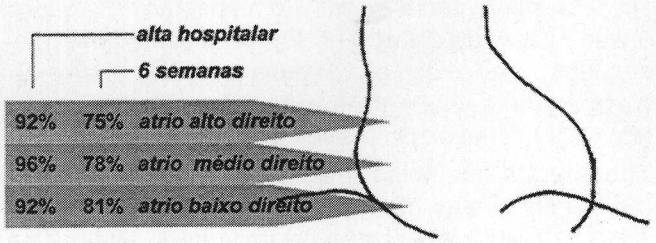

Figure 5: *Comparison of success rates concerning safe and effective capturing with regard to the selected atrial regions for the floating ring electrodes.*

In figure 6 the corresponding atrial thresholds for the selected atrial regions are presented. Here again the low right part is superior to the other regions of the atrium.

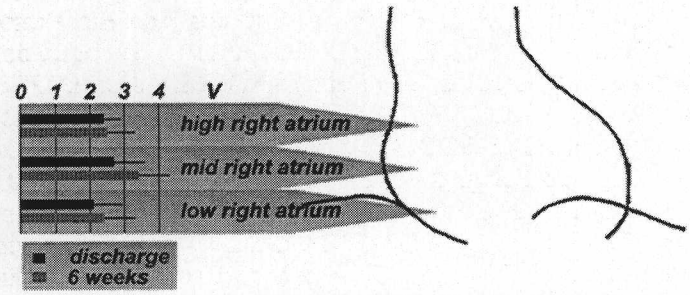

Figure 6: *Atrial capture thresholds for high, mid and low right atrium using OLBI pacing.*

Hence at different clinical centers comparable atrial thresholds in the range of 2.7V have been observed. These similarly low and consequent threshold values obtained at several clinics using independent implantation techniques, prove the OLBI stimulation to be a reliable configuration for pacing with floating electrodes.

Implant Procedure

One important criteria before the implantation is to select a proper ECG derivation in order to have a good atrial signal.

Figure 7 demonstrates and summarizes the following major 3 steps of the implantation procedure:

Depending on the size of right atrium and ventricle and the position of the tricuspid valve the lead is selected so that the atrial rings will remain in a floating position in the right atrium (LRA to be preferred). Here basically the rules for single lead VDD stimulation apply.

1. The tip of the lead is placed in the apex of the right ventricle, allowing the rings to remain in a stable atrial position parallel to the wall.

2. For the final positioning of the atrial rings the following criteria play a major role:

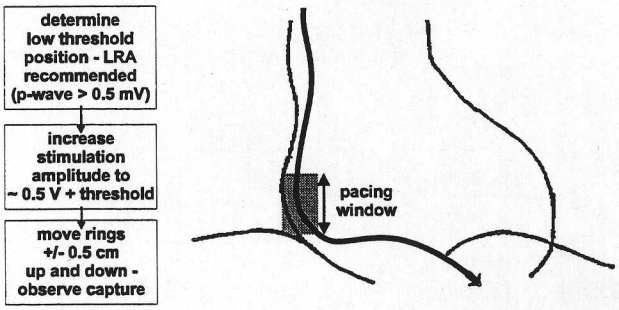

Figure 7: *Flowchart of implant procedure and graphical representation of the „pacing window".*

- start in the LRA
- try to obtain a p-wave of at least 0.5mV
- measure capture threshold (2.5±0.5V are acceptable)
- in case of diaphragmatic stimulation move to another region and repeat the steps in above
- after determining the location with the mentioned criteria increase the stimulation threshold for 0.5V and move the lead slightly up and down, while observing the capture behavior. Determine a „pacing window"

The final position is the location allowing these movements without permanent loss of capture. For example, a loss in capture while moving down will indicate, that the rings have to be moved to a slightly higher position.

Discussion

The OLBI configuration proves itself to be a suitable method for effective and reliable stimulation of the

atrium with floating ring electrodes. The obtained clinical results of several investigations and the BRASILEAD project show that safe atrial pacing is possible with low atrial thresholds while maintaining the reliable sensing properties of VDD single lead systems. The atrial capture thresholds, especially in the low right atrium, remain stable and within a high safety margin since effects like high acute thresholds due to fibrosis or ischemia are eliminated. Furthermore, as a result of pacing via floating electrodes, the stimulation becomes independent from the point of fixation. So a „dynamic" stimulation is obtained.

The stimulation occurs via an electrical far-field. The intention is to yield a high number of myocardial cells to be depolarized simultaneously. So prevention of atrial tachycardia and/or fibrillation by keeping as many as possible cells refractory at the same time and herewith avoiding re-entry mechanisms is one of the further expected benefits.

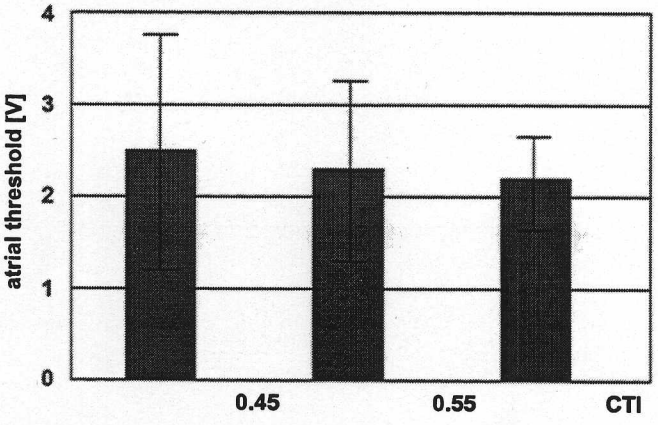

Figure 8: *Atrial threshold histogram for varying cardiac thorax index (CTI) in supine position during discharge.*

Also the stimulation of large masses of myocardium is supposed to allow the therapy of cardiac diseases like Chagas. The cardiac thorax index (CTI) gives information about the heart size with respect to the thorax. Normally this number is 0.5 . Observing the thresholds for small and big numbers of the CTI shows that there are no significant changes (figure 8). This leads to the conclusions that the stimulation with floating electrodes may be an effective way for the therapy of patients with dilated hearts like in the case of Chagas disease, which is a major problem especially in South America.

A further application is the idea of antitachycardia pacing using the OLBI configuration for instable atria. As the number of cells captured simultaneously is expected to be higher due to electrical far-field stimulation the possibility to terminate atrial tachycardias is supposed to be higher.

Conclusions

With the OLBI principle the stimulation of a large number of cardiac cells becomes possible, providing reliable and physiological pacing with floating ring electrodes. Based on an optimized electrical field configuration obtained by the OLBI configuration new possibilities in antibradycardia and low energy antitachycardiac therapy independent from any fixation of the electrode to the myocardium become feasible.

Acknowledgments

We thank the participants of the BRASILEAD study:

LUCCHESE F.A., HALPERIN C., Hospital São Francisco, Porto Alegre; MENEZES A.S., Hospital Santa Helena, Goiânia; LIMA A.M.C., Hospital Santa Casa de Goiânia, Goiânia, BRAILE D.M., Hospital de Base de São José do Rio Preto, São José do Rio Preto; MEIRA E.B.S., PIMENTA J., Hospital do Servidor Público Estodual, São Paulo; ANDRADE J.C., LOPES M.G., Escola Paulista de Medicina, São Paulo; PACHON MATEOS J.C., Instituto Dante Pazzanese de Cardiologia, São Paulo; SOBRINHO J.J., OLIVIERA M., Hospital Pedro Ernesto, Rio de Janeiro, GOLDANI J., Hospital São Lucas - PUCRS, Porto Alegre; MOTA N.J.M., Hospital Santa Isabel, Blumenau; BROFMAN P.R.S., Hospital Cajuru, Curitiba; PEREIRA R.E., GRECO N., Hospital Santa Isabel / Hospital São Rafael, Salvador, COSTA R., MARTINELLI FILHO M., INCOR / Hospital das Clínicas / FMUSP, São Paulo; BERNARDES R.C., Hospital Madre Tereza, Belo Horizonte; GALVÃO FILHO S.S. Beneficência Portuguesa de São Paulo, São Paulo in Brazil.

For the technical support we thank TASKIRAN M. and STRÖBEL J.P.. from the Department of Biomedical Engineering, Friedrich-Alexander University, Erlangen-Nuremberg, Germany.

References

[1] BONGIORNI MG, Bedendi N, and multicenter study group, Atrial stimulation by means of floating electrodes: a multicenter experience. PACE 1992; 15: 1977.

[2] WAINWRIGHT R, Crick J, Sowton E, Clinical Evaluation of a single pass implantable electrode for all modes of pacing. The "Crown of Thorns" lead, PACE 1983; 6:210

[3] HARTUNG WM, Hidden-Lucet F, Mc Teague K et al., Overlapping biphasic stimulation: a novel pacing mode with low capture thresholds. Circulation 1994; 90: Pt. 4, Suppl. I, I-69.

[4] HARTUNG WM, Mc Teague K, Götte A et al., Atrial pacing via floating ring electrodes - first results in humans using overlapping biphasic stimulation. 68th Scientific Sessions of the American Heart Association, Anaheim, USA, Nov. 1995.

[5] LUCCHESE F, Halperin C., Ströbel JP et al.: Single Lead DDD Pacing with Overlapping Biphasic Atrial Stimulation - First Clinical Results. PACE 1996; 19: 601

[6] REY JL, El Ghelbazouri F, Hermida JS et al.: Biphasic Atrial Pacing Using the Floating Electrodes of a VDD Single Lead Pacing System. Eur. J.C.P.E. Supplement 1996; Vol. 6 Nr.1: 35-42

[7] HARTUNG WM, Ströbel JP, Taskiran M. et al.: „Overlapping Biphasic Impulse" - Stimulation Using a Single Lead Implantable Pacemaker System - First Results. PACE 1996; 19: 601

[8] TSE HF, Lau CP, Leung KC et al.: Preliminary Clinical Results with the Single Lead DDD System. Eur.J.C.P.E., 1996; Vol. 6, Suppl. 5: 240

[9] GASCÓN D, Pérez-Vico F, Espina P et al.: „Single Lead DDD Pacing" Eur.J.C.P.E., 1996; Vol. 6, Suppl. 5: 239