

## VDD Pacing With a Conventional Straight Single AV Lead and Back-up DDD OLBI Stimulation - Results of the Italian Extensive Clinical Trial

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### Summary

*In 40 Italian implant centers, single-lead VDD / DDD-OLBI pacing systems (Dromos SL M7 and Eikos SLD, both Biotronik) were implanted in 250 patients, all with symptomatic AV block and without sinus node dysfunction. The purpose of the study was to evaluate the feasibility of pacing the right atrium through floating electrodes using the overlapping biphasic (OLBI) stimulation approach. Atrial OLBI pacing thresholds, atrial sensing, and the occurrence of side effects were assessed during follow-up. Stable atrial capture (> 98 %) was achieved in 80.6 % of the patients at 1 year, with negligible fluctuations during follow-up. Minimum P-wave sensing ranged from 0.83 mV to 0.78 mV at discharge and 1 year, respectively, without significant variations during follow-up. The mean OLBI pacing threshold ranged from 2.6 V at discharge to 2.8 V at 1 year. The only side effect evidenced during follow-up was phrenic nerve stimulation, which occurred in 15.2 % of the patients. 24-hour ECG Holter monitoring, performed during patients' daily life activities, confirmed the data gathered during ambulatory tests. Data discrimination evidences that atrial sensing and the OLBI pacing threshold were slightly affected by the electrode position, implant site and patient posture, while phrenic nerve stimulation only showed a strong dependence on the body mass index of the patients (no phrenic nerve stimulation for body mass index > 25 and > 23 for male and female patients, respectively). OLBI atrial stimulation through floating atrial electrodes is feasible in about 80 % of the patients at reasonable atrial pacing thresholds and without side effects. The results of this clinical trial demonstrate that this approach may deliver reliable back-up atrial pacing in selected patients implanted with a single-lead VDD pacing system, who may develop sporadic chronotropic incompetence.*

### Key Words

OLBI pacing, atrial pacing threshold, phrenic nerve stimulation, body mass index, dipole position

### Introduction

Several reports have been published on the clinical results with acute and chronic DDD pacing using straight single AV leads, originally designed for VDD pacing [1-20]. These efforts aimed to depolarize the atrium by the electric field generated in the neighborhood of the floating dipole electrodes. Via electrolytic conduction, current flow in the muscle fibers provokes cellular depolarization [21]. Various electrode configurations have been used to create the field, including unipolar bipolar and the novel overlapping biphasic (OLBI) stimulation modes [22-27].

Clinical experience with straight single AV lead unipolar atrial electrodes began in the 1990s and has involved more than a thousand patients (pts). A report on more than 500 pts demonstrated that the atrium can be stimulated without side effects and with acceptable pacing thresholds in less than 40 % of the pts originally implanted with such single-lead systems at one year or more after the implantation [8-9]. This long-term experience did show the feasibility to stimulate the atrium through floating electrodes, but the long-term results indicate that the unipolar approach is not reli-

Atrial Pacing Threshold						
Follow-up	1 day	disch.	1 month	3 months	6 months	12 months
APT (± SD)[V]	2.52 (0.93)	2.58 (1.00)	2.90 (0.96)	2.77 (1.02)	2.84 (1.00)	2.78 (1.05)
Number of patients	402	402	402	402	402	385

Table 1. Mean values and SD of APTs at 0.5 ms pulse width in the supine position during follow-up.

able enough even for simple back-up DDD pacing in patients with mild and sporadic chronotropic incompetence.

Parasitic phrenic nerve stimulation (PNS) is a major obstacle to successful atrial pacing with single AV leads. Phrenic nerve stimulation occurs when the electrical field outside the atrial wall, where the phrenic nerve passes, is strong enough to stimulate it. OLBI stimulation of the atrium produces an intense field in the proximity of the dipole and within the atrial wall, but the field strength decreases significantly outside the heart, due to the cancellation of oppositely directed fields. The resulting field is oriented within a stratum that contains the dipole and the case of the pulse generator. The spread of the field is thus limited, and the possibility to induce PNS is reduced [13].

The results of an Italian multicenter study of DDD - OLBI stimulation, involving 40 implant centers, are summarized in the presented study.

**Materials and Methods**

A population of 402 pts, 241 male and 161 female, age 74.3 ± 9.3 years (range: 40 to 103 years), all with

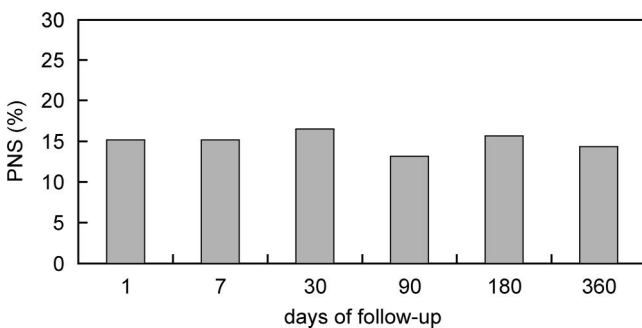


Figure 1. Percentage of pts showing PNS during atrial OLBI pacing (at 0.5 ms pulse width and < 4.8 V pulse amplitude), detected in the supine position.

Constancy of Pacing (> 95 % of atrial stimuli result in capture)					
postural position	disch.	1 month	3 months	6 months	12 months
Supine	81.6	86.3	82.8	82.6	82.9
Sitting	79.8	82.7	82.4	81.9	82.0
Standing	80.7	83.5	80.4	80.4	81.1
Left decubitus	76.2	79.8	74.8	73.9	73.6
Right decubitus	74.9	76.4	75.9	72.7	74.7

Table 2. Body posture vs. stability of atrial pacing.

symptomatic AV block and without evidence of sinus node dysfunction, were implanted with 107 Dromos SL-M7 pacemakers and 295 Eikos SLD pacemakers (both Biotronik), allowing supervised and unsupervised atrial OLBI pacing, respectively. The maximum programmable amplitude of these pulse generators in the OLBI mode was 4.8 V. Each device was connected to a single AV lead, model SL 60 (Biotronik), with 1.0 cm atrial dipole spacing, passive ventricular fixation, and fractal iridium coating on all electrodes. An AV distance of 13 cm was used in 94 % of the patients, and of 15 cm, in the remaining 6 %.

Lead implantation followed the standard procedure for single-lead VDD systems. The atrial lead position was selected solely on the basis of the P-wave amplitude and stability characteristics. The atrial OLBI pacing threshold was not measured during implantation. Atrial pacing thresholds (APT) and occurrence of PNS were assessed at day 1, at discharge, and at 1, 3, 6 and 12 months after the implantation. Follow-up data were

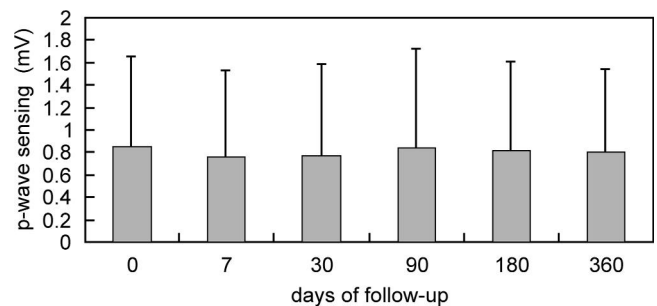


Figure 2. Mean and SD of the minimal P-wave amplitude, measured in the supine position during follow-up.

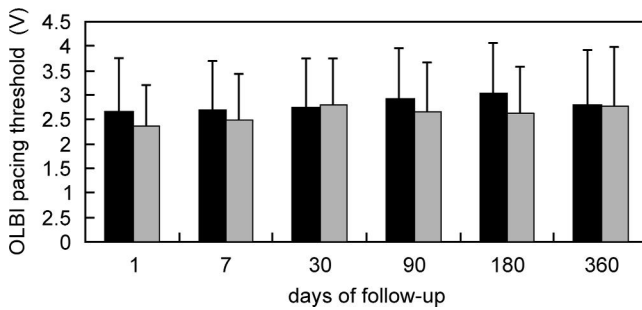


Figure 3. Male vs. female gender: mean value of OLBI APTs at 0.5 ms, measured in the supine position during follow-up.

analyzed on the basis of gender, body mass index (BMI), orientation of the stimulation vector (i.e., whether the pacemaker was implanted on the left or right side of the chest), and the position of the dipole in the atrium. Data were collected with the patient in various postures (supine, sitting, standing, right and left decubitus), and a 24-hour dynamic ECG recording (Holter) was performed at the third and twelfth month follow-up in 235 pts.

## Results

The mean values and standard deviations (SD) of the APT at 0.5 ms pulse width were measured in the supine position and are shown in Table 1. The differences in the mean values were not significant using one-way variance analysis. In only one patient, atrial capture could not be achieved (APT > 4.8 V) at 1 day and at discharge, but at 1 month, stable atrial capture was achieved at an APT of 3.5 V.

The percentages of pts with PNS in the supine position, at pulse amplitudes below the maximum programmable value (4.8 V), are depicted with respect to time in Figure 1.

The measured minimum P-wave amplitudes (mean  $\pm$  SD) were:  $0.85 \pm 0.82$  mV at 1 day,  $0.76 \pm 0.78$  mV at discharge,  $0.77 \pm 0.80$  mV at 1 month,  $0.84 \pm 0.82$  mV at 3 months,  $0.82 \pm 0.77$  mV at 6 months, and  $0.80 \pm 0.75$  mV at 12 months (see Figure 2). The differences were not significant. No P-wave undersensing was ever detected during the entire follow-up period.

The stability of atrial capture was also investigated in terms of postural changes. The results, expressed as percentage of pts showing more than 95 % of captured atrial events, are presented in Table 2.

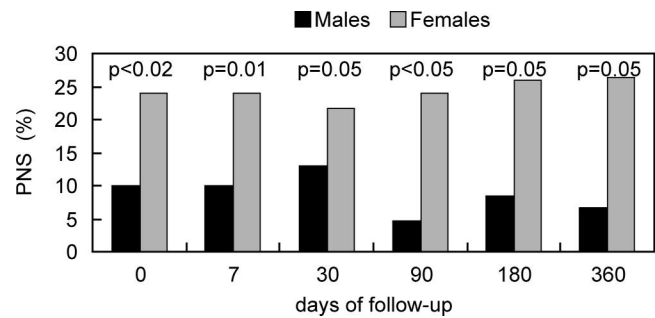


Figure 4. Male vs. female gender: PNS occurrence (at OLBI 0.5 ms pulse width and < 4.8 V pacing amplitude), detected in the supine position during follow-up.

The stability of the data during the entire follow-up shows that there was still no vascular and endocardial endothelization evident around the lead after one year from implant. The dipole was quite free to float within the atrial chamber, changing its spatial position. Respiration and gravity affected capture, especially during supine decubitus.

For 235 pts, all implanted with Eikos SLD pacemakers, a 24-hour Holter monitoring was performed at the third and twelfth month follow-up. Prior to the Holter recording, each pulse generator was permanently programmed in the DDD mode at rates 15 % to 20 % higher than the patient's sinus rate at rest (range: 80 to 94 bpm). The OLBI pulse amplitude was increased by 50 % above the detected pacing threshold. Then the patient was allowed to return home to attend normal daily activities. At the end of the Holter recording, each pulse generator was reprogrammed to the previous VDD pacing mode. The overall performance was good with steady atrial pacing at rest and during moderate exercise in 87.2 % (205 / 235) of the participants. Regular inhibition by spontaneous atrial activity was observed when the patient's spontaneous atrial rate rose above the programmed rate. In the remaining 12.8 % of pts, the rate of atrial capture ranged from 47 % to 86 %. In 8 of these pts, loss of capture was associated with standing or sitting posture (56 % to 86 % atrial capture rate), while the capture rate was good during the night (> 90 %). In 16 pts, atrial capture was very good (90 % to 100 %) during the day and exercise, but poor (47 % to 75 %) during the night. However, none of the 235 pts reported any symptoms either of PNS or in relation to changes in pacing mode. Pacing results in male and female pts were compared. The mean values of the APTs are shown in Figure 3.

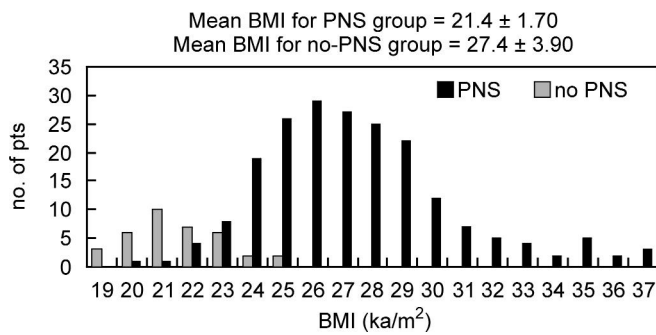


Figure 5. PNS vs. BMI distribution, regardless of the subject's gender.

Statistical differences between values were not significant. The APTs showed substantial stability in both groups.

Substantial differences between the two gender groups were observed in PNS occurrence, as illustrated in Figure 4.

As there are no evident anatomic or physiologic reasons to justify the difference in occurrence of PNS in men and women, the PNS distribution was tested for correlation with the body mass index (BMI), expressed as weight / height<sup>2</sup> (kg / m<sup>2</sup>). The results, as shown in Figure 5, indicate a clear inverse correlation between PNS and BMI.

By deduction, one assumes that the position of the pulse generator, whether it is on the left or right side of the chest, would strongly influence the direction of the electric field vector and the anatomic area affected by it. When the pulse generator is implanted in the right pectoral area, the field is expected to influence the tissues of the right free wall of the atrium more strongly. When the pulse generator is located in the left pectoral area, the field should exert more influence on the atrial septum. This hypothesis was also tested.

Atrial Pacing Threshold - Left vs. Right Implants						
Follow-up	1 day	1 week	1 month	3 months	6 months	12 months
Left Impl. (± SD) [V]	2.3 (0.9)	2.4 (1.0)	2.6 (1.0)	2.6 (0.9)	2.7 (1.0)	2.6 (1.0)
Right Impl. (± SD) [V]	2.8 (1.0)	2.9 (1.0)	2.9 (0.9)	3.0 (1.0)	2.9 (1.0)	2.9 (1.0)

Table 3. Left vs. right pectoral implants. - Mean values of the APTs at 0.5 ms pulse width in the supine position.

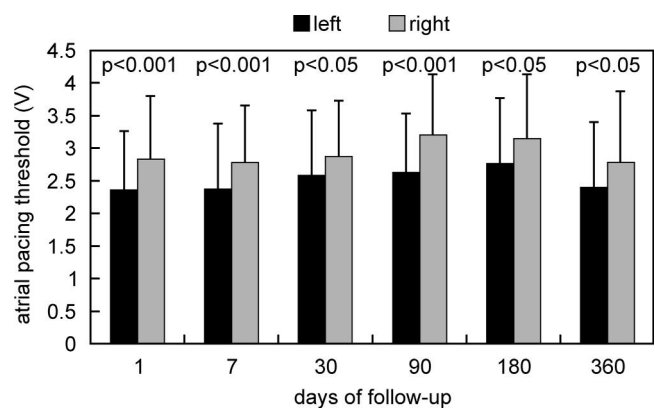


Figure 6. Left vs. right pectoral implants. Mean value of OLBI APTs at 0.5 ms pulse width, measured in the supine position during follow-up.

In this patient group, 212 and 190 pacemakers were implanted in the left and right pectoral position, respectively. The mean values of the APTs at 0.5 ms pulse width are shown for left and right implants in Table 3.

The differences were statistically significant at all the follow-ups, as shown in Figure 6. The APT values were constantly lower for implants on the left side. Differences were also observed between right- and left-sided implants with respect to the occurrence of PNS. The percentage of pts experiencing PNS sensitivity (in the supine position and at pulse amplitudes < 4.8 V) was higher for left-sided implants, as shown in Figure 7. This may be interpreted as evidence that the

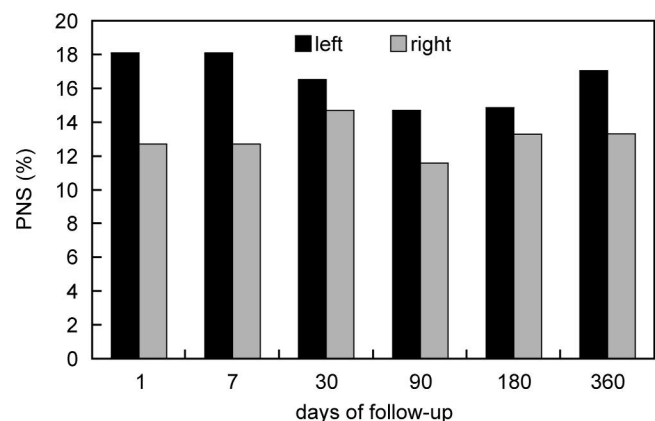


Figure 7. Left- vs. right-sided implants: OLBI PNS at 0.5 ms pulse width, detected in the supine position during follow-up.

Position	Atrial Dipole Position			
	SVC	High	Mid	Low
<b>1 day (%)</b> (n = 402)	11 (2.7)	170 (42.3)	178 (44.3)	43 (10.7)
<b>3 months (%)</b> (n = 402)	10 (2.5)	211 (52.5)	152 (37.8)	29 (7.2)
<b>12 months (%)</b> (n = 385)	9 (2.3)	201 (52.2)	149 (38.7)	26 (6.7)

Table 4. Position of the atrial dipole on day 1 and at 3 and 12 months, assessed by fluoroscopy.

dipole of a lead implanted through the right access takes a position in the atrium farther away from both the atrial wall and the phrenic nerve than when the lead is inserted through left access.

Atrial sensing was steady in both groups, and there was no statistically significant difference between the two access paths.

Finally, the position of the dipole inside the atrium was considered. The position of the floating dipole within the atrium was assessed by fluoroscopy on day 1 and at 3 and 12 months. The findings are presented in Table 4 and, based on the percentages, show that a substantial number of dipoles originally positioned in the mid and lower portion of the atrium moved upward as they became progressively more stable. In contrast, no substantial change was observed with the dipoles positioned in or at the exit of the superior vena cava (SVC). Figure 8 shows the mean values for the APTs, measured at various dipole positions at day 1 and at the 3-month follow-up. The differences between the groups are not significant. Acutely, lower thresholds were measured at the exit of the SVC, but chronically, the

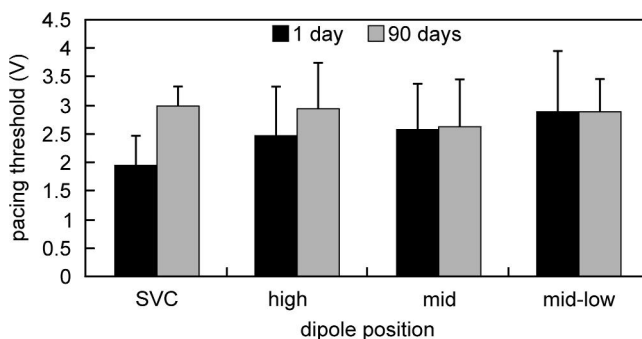


Figure 8. OLBI atrial pacing trend at 1 day and 3 months at various dipole positions in the atrium.

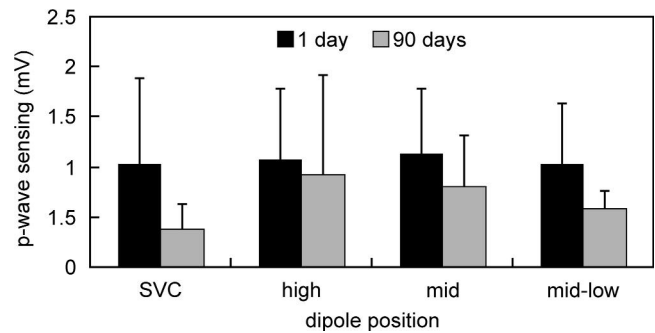


Figure 9. Minimum P-wave amplitude trends at day 1 and 3 months at various dipole positions in the atrial chamber.

mid atrium seems to show lower and more stable thresholds.

Figure 9 shows the mean amplitudes of the smallest P waves at the same positions as before. At day 1, the amplitudes were similar in all positions, but at 3 months, the values were largest in the high and mid atrium, even though those two positions showed the largest variations as judged by their large SD. It is assumed that the dipole at these positions has more freedom to move away from the atrial endocardium.

Finally, Figure 10 shows the percentages of pts with PNS observed with various dipole positions. Both on day 1 and at 3 months, most of the dipoles associated with PNS were in the high and mid portions of the atrium. The small number of dipoles positioned inside or at the exit of the SVC and in the low atrium at day 1 and at 3 months is insufficient for any conclusion.

On the basis of the last three figures, we may conclude that the mid atrium represents the best compromise for APTs, P-wave sensing, and low incidence of PNS for single AV lead atrial pacing with OLBI.

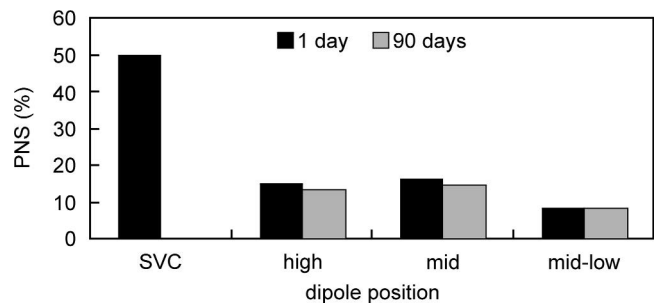


Figure 10. PNS trends at day 1 and 3 months at various dipole positions in the atrium.

It is very important to note that thoracic muscle stimulation never occurred in any patient during the entire follow-up period.

In 61 pts, 43 male and 18 female, who developed a mild or sporadic chronotropic incompetence during the first 3 months after the implantation, the Eikos SLD pacing system was permanently programmed to DDD pacing. All pts showed constant atrial capture higher than 98 % and no evidence of PNS during the first 3 months of follow-up, i.e., before the permanent reprogramming. The basic rate of the device was programmed 5 % to 10 % higher than the patient's sinus rate at rest, and the OLBI pulse amplitude, to 1.5 times the APT.

When the presented report was written, the mean follow-up time for these pts was  $14.6 \pm 5.2$  months (range: 8 to 28). Monthly performance of a 24-hour ECG Holter monitoring showed full "on demand" DDD pacing in all pts. Losses of atrial capture were sporadic and limited to few (2 - 3) consecutive beats only, essentially during night. No reprogramming of OLBI pulse amplitudes was necessary in any patient. All pts also reported a good quality of life without any symptoms related to PNS or losses of atrial capture.

## Discussion

This extensive trial has provided encouraging results. Based on the gathered data, OLBI pacing allows reliable DDD pacing, at acceptable pacing pulse amplitudes and without side effects, in more than 80 % of the pts during daily activities and exercise. Losses of atrial capture occurred more frequently when the patient was in the supine or lateral decubitus position and during night.

The phrenic nerve is more readily excited in pts whose BMI is low ( $< 28$  for males and  $< 22$  for females). This seems to be the sole anatomic factor that explains the differences observed between the gender groups. Leads implanted via left access were associated with lower APTs, both acutely and chronically, and with a slightly higher incidence of PNS than those implanted via right access.

No correlation was found between the minimum amplitude of the sensed P wave and the OLBI threshold. Long-term stability of both pacing and sensing seems to be superior with the dipole positioned in the mid atrium.

Before concluding this article, the authors would like to

include an additional remark, based on clinical evidence, to dispel the still existing belief that single AV lead VDD pacing systems may show a high incidence of post-implant atrial complications, such as atrial fibrillation and permanent loss of P-wave sensing [31-45]. During the last decade, 646 pts, 383 male and 263 female, with a mean age of  $72.3 \pm 9.6$  years, had pacemakers implanted for symptomatic II and III degree AV block with no evidence of sinus dysfunction in three of the centers participating the OLBI trial. Single-lead VDD and dual-lead DDD systems were used in 525 pts and in 125 pts, respectively. A retrospective study was performed in order to evaluate the incidence of atrial fibrillation and loss of atrial sensing in this large population of homogeneous pts.

The incidence of paroxysmal and chronic atrial fibrillation and the loss of atrial sensing were assessed by means of clinical evaluation, standard ECG, 24-hour ECG Holter monitoring, and device-internal diagnostic functions for the detection of atrial arrhythmias.

In the pts implanted with single-lead VDD pacing systems (follow-up period  $3.2 \pm 1.8$  years), an overall incidence of paroxysmal and chronic atrial fibrillation of 1.33 % (a ratio of 0.42 % atrial fibrillation / year) and 3.24 % (a ratio of 1.01 % atrial fibrillation / year), was observed, respectively.

In the group of dual-lead DDD paced pts (follow-up period  $3.4 \pm 2.1$  years), an identical incidence for both paroxysmal and chronic atrial fibrillation of 6.4 % (a ratio of 1.88 % atrial fibrillation / year) was observed. Atrial sensing loss requiring a permanent device programming to VVI mode occurred in 1.52 % and 1.6 % of pts for single-lead VDD and dual-lead DDD systems, respectively.

Thus, the long-term follow-up shows that single-lead VDD pacing has a significantly lower occurrence of paroxysmal and chronic atrial fibrillation than dual-lead DDD pacing, while permanent atrial sensing loss occurs at practically the same rate in the two systems.

## Conclusion

In conclusion, the Italian extensive evaluation of the single AV lead DDD / OLBI system has demonstrated its reliability for back-up atrial pacing. An additional investigation has demonstrated that the occurrence of chronic atrial complications is lower, as in the case of atrial fibrillation, or equivalent, as in the case of permanent loss of P-wave sensing, in single AV lead sys-

tems than in conventional dual-lead DDD systems. Therefore, the Eikos SLD pacing system should be considered as the primary choice of pacing for patients with complete or advanced AV block associated or not associated with mild or sporadic chronotropic incompetence. Moreover, this system may be considered as the starting base toward "primary DDD non-contact pacing", a concept that seems no longer to be merely a dream but a clear objective.

### Acknowledgment

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