

## SIMULTANEOUS PULMONARY VEIN MAPPING AND ABLATION WITH THE LASER BALLOON AND THE ACHIEVE™ PV CATHETER IS FEASIBLE, SAFE AND REDUCES NEED FOR REMAPPING

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**Introduction:** PV isolation (PVI) is the mainstay of catheter-based treatment of AF. Studies have shown PVI with visually guided laser balloon (VGLB) is as effective as RF and cryoballoon, but with longer mean procedure, ablation and fluoro times. This may be related to the VGLB not providing PV electrogram recordings. We propose a novel method of simultaneous PV mapping during VGLB PVI using the Achieve™ PV catheter (Fig.1).

**Methods:** 20 consecutive patients were treated with VGLB with single transeptal, followed by exchange for a circular PV catheter (GP1/n = 10) or double transeptal and simultaneous recording with the Achieve™ (GP2/n = 10). Contiguous, overlapping lesions were placed around the PV ostia. If isolation did not occur after one complete encirclement, subsequent lesion placement was guided by the mapping catheter. Data are presented as mean ± SEM.

**Results:** Groups were matched in GP1/GP2 (63 ± 3 vs. 56 ± 3yrs, PAF 80% vs. 70%). There were no significant differences in procedure time (122 ± 6 vs. 132 ± 5mins), fluoro time (23.8 ± 2 vs. 27.9 ± 2mins), laser time (89 ± 8.7 vs. 81.3 ± 6mins), LPV lesions (30 ± 2.2 vs. 26 ± 2.5) or RPV lesions (26.8 ± 2.2 vs. 25.8 ± 2.5) for PVI. 4/40 treated PVs required remapping/ablation in GP1 compared to 1/40 in GP2. Procedural outcome was good (mean EHRA score 2.2 to 1.3, FU 110 ± 10days) with 1 femoral vascular complication.

**Conclusions:** These data demonstrate that simultaneous PV mapping with an Achieve™ catheter with VGLB is safe, effective with no increase in procedure/fluoro time or complications. Procedure times were shorter than previous studies. A larger study may show a reduction in the need for remapping and the number of lesions required for PV isolation.

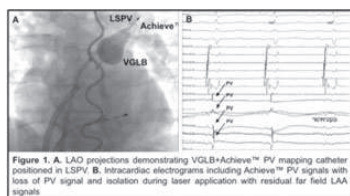


Figure 1. A. LAO projections demonstrating VGLB+Achieve™ PV mapping catheter positioned in LSPV. B. Intracardiac electrograms including Achieve™ PV signals with loss of PV signal and isolation during laser application with residual far field LAA signals.

**Conflict of interest:** none

## SAFER IS ASSOCIATED WITH A RISK REDUCTION OF FIRST-ONSET AF IN PATIENTS WITH ATRIO-VENTRICULAR BLOCKS: RESULTS FROM THE ANSWER STUDY

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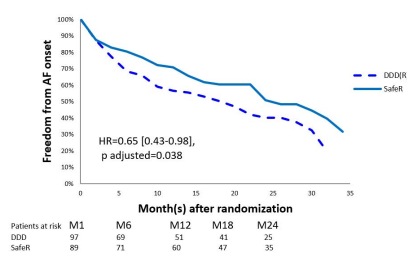
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Atrial fibrillation (AF) is a frequent incident comorbidity in the pacemaker patient population and has been associated with higher risk of heart failure, stroke and death. The Safer pacing mode is designed to manage first-, second- and third-degree atrio-ventricular blocks (AVB); and its effectiveness has been demonstrated in the randomized, multicenter ANSWER trial on both patients implanted for sinus node disease or AVB. We sought to investigate specifically for AVB patients the possible benefit associated with Safer for first onset of AF.

**Methods:** The first onset of AF was ascertained from the pacemaker memory. Predictors of AF were identified using a Cox proportional-hazards model in patients implanted for AVB (n = 186, 70.3 ± 12.2 years, 65.1% males), without any history of atrial arrhythmias either prior to enrollment or during the 1st month after randomization. Results were adjusted on age, gender, coronary disease, cardiomyopathy, valvular disease, LVEF, HF history, diabetes.

**Results:** Over 3 years, 96 (51.3%) patients experienced first-onset AF. Of this group, 42 (47.2%) were programmed in Safer and 54 (55.7%) in DDD mode. Safer was associated with a 35% risk reduction in the first onset of AF (adjusted HR = 0.65, 95% CI: [0.43-0.98], p = 0.038), as compared to DDD (Figure). No other parameter studied was predictive of AF incidence.

**Conclusion:** The Safer mode is associated with a significantly reduced risk of first-onset AF as compared with DDD in AVB patients.



**Conflict of interest:** Consultant or speaker bureau for Bayer, BMS/Pfizer, Boehringer, Boston Scientific, Medtronic, Sorin

## VENTRICULAR PACING FROM THE SUBSTERNAL SPACE IN HUMANS

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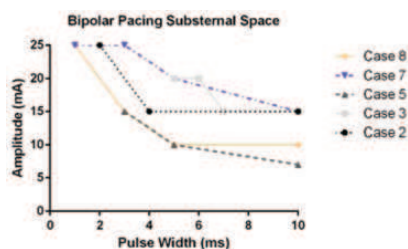
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**Introduction:** Transvenous lead failure remains an important drawback of transvenous implantable cardioverter-defibrillators (ICD). The subcutaneous ICD overcomes this issue, but lacks pacing capabilities. The objective of this study was to assess feasibility of ventricular pacing and thresholds from within the substernal space to examine a new extravascular ICD configuration with pacing capabilities.

**Methods:** Patients with midline sternotomy for coronary arterial bypass grafting (CABG) or aortic valve replacement (AVR) were enrolled. After the sternum was opened, a duodecapolar diagnostic pacing catheter was positioned in the substernal space anterior to the pericardium, and a cutaneous patch in the left midaxillary line, after which the chest was closed. Different pacing configurations were assessed: bipolar between the catheter electrodes (inter electrode spacing 2mm, 30mm, or 60mm) and unipolar between the catheter electrodes and the patch. A downwards stepwise pacing protocol was used to identify the best configuration, starting at 25mA with a pulse width (PW) of 10ms.

**Results:** Eight patients, (6 males), with mean age 69 ± 9 years, of whom 7 underwent AVR and one CABG, were included. In five out of eight patients ventricular capture was achieved in ≥1 configuration. The mean bipolar pacing thresholds at PW 10ms, 5ms, 3ms, 1ms were 12.4 ± 3.7mA (5 pts), 13.3 ± 5.8mA (3 pts), 18.3 ± 5.7mA (3 pts) and 25 ± 0mA (2 pts) respectively. The 60mm electrode spacing was the most successful bipolar configuration. Unipolar pacing was attempted in 4 pts and successful in 3 pts with mean thresholds of 10 ± 0mA at 10ms (3 pts), 15 ± 0mA at 5ms (3 pts), 16.7 ± 2.9mA at 3ms (3 pts) and 20 ± 7.1mA at 1ms (2 pts). The optimal unipolar vector was from the catheter electrodes over the right ventricle to the patch.

**Conclusion:** We demonstrate the feasibility of ventricular pacing from the substernal space in patients with midline sternotomy. Studies in patients with a closed sternum are needed to determine pacing thresholds more accurately.



**Conflict of interest:** Research grant Medtronic

## CONVENTIONAL VVI PACING IN DENMARK. A BENCHMARK FOR LEADLESS PACING

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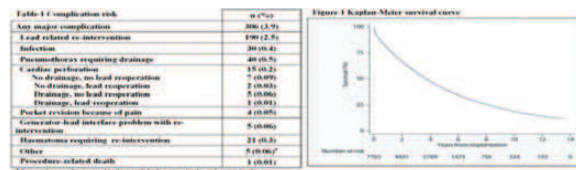
**Purpose:** After introduction of leadless pacing systems, detailed data on conventional single lead ventricular pacemaker (VVI-PM) implantations including procedure-related data, data on complications, and mortality have become important for benchmarking. We aim to provide such data in a large cohort of consecutive patients undergoing VVI-PM implantation.

**Methods:** A nationwide cohort study was performed based on detailed data on consecutive patients who underwent VVI-PM implantation in Denmark from 1997 to 2008. Baseline data, data on complications within the first 3 months after implantation, and mortality came from the Danish Pacemaker and ICD Register. Time to death was calculated using Kaplan-Meier survival statistics.

**Results:** A total of 7765 patients (corresponding to 27% of all PM implantations during the study period) were included in the study: men, n = 4301 (55%); median age: 82 years (25 and 75 percentiles: 75 – 87); indication: atrio-ventricular block (n = 2100, 27%), sick sinus syndrome (n = 1107, 14%), atrial fibrillation with bradycardia (n = 4371, 56%), other (n = 187, 2%); procedure priority: elective (n = 6974, 90%), emergency (n = 389, 5%), unknown (n = 402, 5%); median procedure duration: 39 minutes (25 and 75 percentiles: 28 – 55); median fluoroscopy time: 3.7 minutes (25 and 75 percentiles: 2.1 – 6.5). Median follow up time was 2.9 years (25 and 75 percentiles: 1.3 – 5.1).

A total of 306 patients (3.9%) experienced at least one complication within the first 3 months and lead related complications were the most common cause of early re-intervention (Table 1). Cardiac perforation was uncommon and most often conservatively treated. During the study period, 5083 patients died with a median time to death of 1.9 years (25 and 75 percentiles: 0.7 – 3.9). Five-year all-cause mortality was 60%, Figure 1.

**Conclusions:** In a large real-life cohort of consecutive VVI-PM patients, median age is high, main indication for PM implantation is atrial fibrillation with bradycardia, and most procedures are elective. The risk of complications is relatively low, with only very few patients experiencing cardiac perforation or procedure-related death. Mortality is high within the first years after implantations. This should be taken into consideration when selecting patients for leadless pacing.



**Conflict of interest:** none