## **SESSIE 1: ELECTROPHYSIOLOGY**

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# **Quality of Life After Shocks or Complications is Similar Between Subcutaneous and Transvenous Defibrillator Therapy**

Presenting author: J.A. de Veld

Department: Heart Center, Department of Clinical and Experimental Cardiology, Amsterdam

Cardiovascular Sciences, Amsterdam UMC, location AMC.

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#### Purpose:

The PRAETORIAN trial showed that the subcutaneous implantable cardioverter defibrillator (S-ICD) is noninferior to the transvenous ICD (TV-ICD) with respect to device-related complications and inappropriate shocks in a conventional ICD population. Nevertheless, the type of complications and underlying mechanism for inappropriate shocks differ between devices. Earlier studies have reported a decrease in quality of life (QoL) in ICD patients with shocks or complications. It is unknown if there is a difference in QoL between the devices in general, and whether shocks and complications are associated with the same burden in both arms. This prespecified analysis of the PRAETORIAN trial compares the impact of the S-ICD and TV-ICD on QoL and investigates if shocks and complications cause a device-specific

reduction in QoL.

#### Methods:

In the PRAETORIAN trial, 849 patients were randomized to S-ICD (n=426) or TV-ICD (n=423) therapy. QoL was prospectively measured at baseline, discharge and 12 and 30 months after ICD implant, by measuring cardiac-specific physical functioning with the Duke Activity Status Index (DASI) and psychological and physical well-being with the 36-Item Short Form Health Survey (SF-36, divided in 8 subscales). Patients who completed the questionnaires at baseline were included in this analysis. At each time point the mean change in score from baseline was calculated. Patients with and without a shock or device related complication requiring intervention before their 12 month QoL were compared. Regression models and Wilcoxon rank sum tests were used to compare groups.

#### Results:

A total of 823/849 patients completed the questionnaires at baseline. Questionnaires were also completed by the majority of these patients at discharge (92%), 12 months (85%) and 30 months (69%). There was no difference in QoL between the arms at any time point (figure). At 12 months, patients with a shock or complication showed a significantly lower QoL on the DASI (p=0.005) and SF-36 subscales bodily pain (p=0.04), vitality (p=0.006) and role specific functioning – emotional (p=0.03). This was not significantly different between the arms.

#### **Conclusion:**

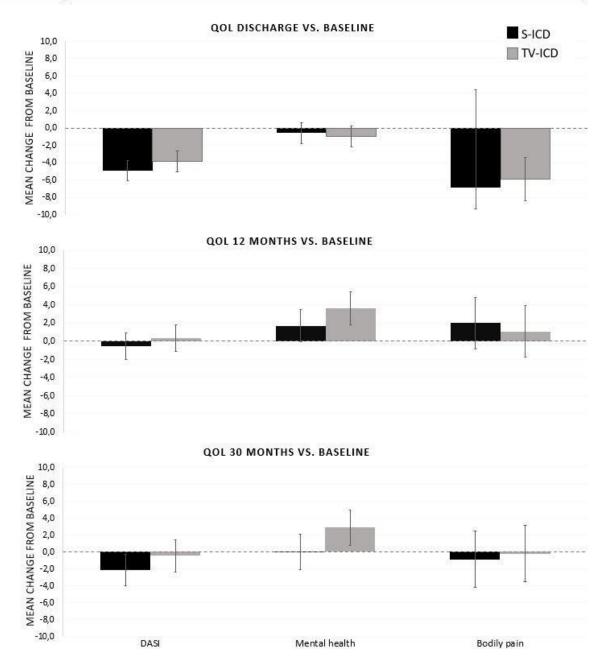
There were no differences in QoL between S-ICD and TV-ICD treatment in the first 30 months after implant. Patients with ICD shocks or complications requiring intervention showed a reduction in QoL at 12 months, but this did not differ between arms. These results confirm that the S-ICD is an acceptable alternative for the TV-ICD.

#### **Keywords:**

Quality of life, Subcutaneous ICD, Transvenous ICD

Figure:

Mean change in DASI and most relevant SF-36 subscales. Presented as mean with 95% CIs.



# Post-Implantation CMR Imaging to Study Biventricular Pacing Effects on the Left and Right Ventricle in Left Bundle Branch Block Patients

Presenting author: L.H.G.A. Hopman

Department: Cardiology

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#### Purpose:

Recently introduced cardiovascular magnetic resonance (CMR) conditional cardiac resynchronization therapy defibrillator (CRT-D) devices allow biventricular (BIV) pacing during CMR. This study assesses the feasibility of CMR to study acute effects of BIV-stimulation on left ventricular (LV) and right ventricular (RV) volumes and function in patients implanted with a CMR conditional CRT-D.

#### Methods:

Ten CRT-D patients were included in this prospective pilot study. Patients underwent CMR imaging (1.5T) prior to device implantation (baseline), and six weeks after device implantation (including CRT-on and CRT-off). LV end systolic volume (ESV), end diastolic volume (EDV), ejection fraction (EF), and strain measures of LV dyssynchrony and dyscoordination were assessed on cine images. Additionally, RV parameters (ESV, EDV, and RVEF) were assessed.

#### Results:

After six weeks of CRT, reverse LV remodeling was observed with reduction in ESV (253.8 $\pm$ 41.3ml vs. 194.9 $\pm$ 37.1ml, p<0.001) and EDV (336.9 $\pm$ 52.8ml vs. 268.1 $\pm$ 42.3ml, p<0.001) during intrinsic rhythm (CRT-off) while adverse RV remodeling was observed (ESV: 88.9 $\pm$ 21.1ml vs. 119.0 $\pm$ 26.4ml, p<0.001, EDV: 175.1 $\pm$ 22.8ml vs. 200.8 $\pm$ 34.2, p<0.01). During CRT-on, LVEF acutely improved from 27.4 $\pm$ 5.9% to 32.2 $\pm$ 8.7% (p<0.01) and strain assessment showed abolishment of left bundle branch block contraction pattern. RVEF did not improve at CRT-on as compared to baseline (48.6 $\pm$ 6.6% vs. 49.6 $\pm$ 8.1%, p=0.75).

#### **Conclusion:**

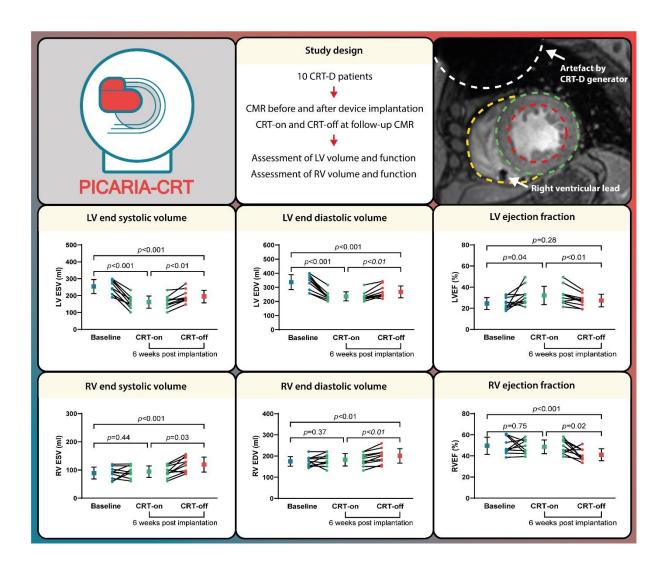
Post-CRT implantation CMR assessing acute pump function is feasible and provides important insights in the effects of BIV-pacing on cardiac function and contraction patterns. LV hemodynamics improved during BIV-pacing, but RV hemodynamics did not benefit from CRT.

### **Keywords:**

CRT, Remodeling, Pacing

#### Figure:

Figure: PICARIA-CRT study design and results of LV and RV hemodynamics assessed by CMR at baseline and during follow-up in CRT-D patients.



## Predicted Need for Atrial and Ventricular Pacing per Indication Group in Patients with Dual-chamber Pacemakers

Presenting author: K.T.N. Breeman

Department: Cardiology

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#### Purpose:

Bradyarrhythmias are adequately treated with pacemakers. Currently, different pacing modes (single- and dual-chamber, cardiac resynchronization therapy and physiologic pacing) and device types (leadless/transvenous) are available. Expected pacing need is important for determining optimal pacing mode and device type. We aimed to evaluate atrial (AP) and ventricular pacing (VP) percentages over time for the most common pacing indications.

## Methods:

We included patients ≥18 years with a DDD(R) pacemaker implantation and ≥1 year follow-up at a tertiary center between January 2008 and January 2020. Baseline characteristics and AP and VP at yearly follow-up visits up to 6 years after implantation were retrieved from the medical records.

#### Results:

381 patients were included, primary pacing indications were incomplete AV block (AVB) in 85 (22%), complete AVB in 156 (41%) and sinus node dysfunction (SND) in 140 (37%). Mean age at implantation was respectively 71 $\pm$ 14, 69 $\pm$ 17, 68 $\pm$ 14 years (p=0.23). Median follow-up was 42 months (25-68 months). Overall, AP was highest in SND with median 37% (7-75%), versus 7% (1-26%) in incomplete AVB and 3% (1-16%) in complete AVB (p<0.001); VP was highest in complete AVB with median 98% (43-100%), versus 44% (7-94%) in incomplete AVB and 3% (1-14%) in SND (p<0.001). VP increased significantly over time in patients with incomplete AVB and SND (both p=0.001).

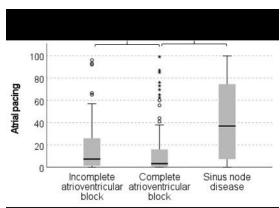
#### Conclusion:

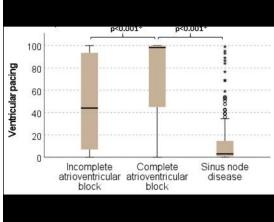
These results confirm the pathophysiology of different pacing indications, causing clear differences in pacing need and expected battery longevity. These results may help guide optimal pacing mode and suitability for leadless or physiologic pacing.

#### **Keywords:**

atrioventricular block, sinus node dysfunction, pacing percentage

**Figure:**Overall atrial pacing (AP) and ventricular pacing (VP) percentages, comparison between indication groups.





# Assessing Feasibility and Safety of a Large Cardiac Device Program in the Curação Medical Center

Presenting author: M.Y. Ruiz Department: Cardiology/devices

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#### Purpose:

The hospital of Curaçao has a large cardiac device program without surgical backup and uses the European guidelines. However, comorbidities in this multi-ethnic population are higher compared to the Dutch population (e.g. increased incidence of hypertension, diabetes mellitus II, stroke, heart failure and dialysis). For this reason we investigated the feasibility and safety of the device program in this specific population.

#### **Methods:**

This was a single-center, retrospective study from January 1st 2020 to September 13th 2022. Patients who underwent a primary device implantation, upgrade, or generator or lead change within the Curaçao Medical Center were included. Several parameters were assessed within 24 hours, 30 days and one year post-procedure.

#### Results:

The study population consisted of 243 patients (63.1% male, median age 72.5, 62.8% hypertension, 40% DMII) including 143 single- and dual-chamber devices, 36 primary and 13 upgraded biventricular devices, and 52 generator or lead changes. Two (0.8%) procedures were unsuccessful due to unfavorable anatomy. There were no in-hospital mortalities, 1 (0.4%) OHCA within 30 days and 3 (1.2%) cardiovascular deaths within one year. There were 4 (1.6%) lead dislocations within 30 days, of which 2 occurred within the first 24 hours. All dislocations required a revision. One (0.4%) patient developed a pneumothorax, however no cardiac tamponades, hemothorax, pocket hematomas that required intervention and infections were recorded.

#### Conclusion:

This real-time data showed a high survival rate with a low complication rate in this specific study population. These findings indicate a feasible and safe device program.

#### **Keywords:**

Cardiac Implantable Electronic Devices, Ethnicity, Safety

# First Draft of a Novel PLN p.Arg14del Heart Failure Risk Model to Potentially Aid Patient Selection for Future Gene Therapy

Presenting author: M.Y.C. van der Heide

Department: Cardiologie

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#### Purpose:

Gene therapy is a rapidly developing treatment option that will alleviate heart disease by directly targeting pathophysiological mechanisms underlying hereditary heart disease. As it stands today, patient selection is focused on the early-stage, young patients with severe and lethal cardiomyopathies for whom other treatment options are lacking. Many severely affected PLN p.Arg14del carriers precisely fit in this characterization, but risk stratification is needed to select patients as this genetic cardiomyopathy is characterized by incomplete penetrance.

The purpose of this study is therefor to develop a prediction model for heart failure in PLN p.Arg14del carriers to help future patient selection for gene therapy.

#### Methods:

Data were collected of 500 PLN p.Arg14del mutation carriers, aged 39.7 ± 16 years, 42.8% male, with no history or presentation of left ventricular ejection fraction (LVEF) <30%, heart failure hospitalization, left ventricular assist device (LVAD), heart transplantation (HTX) or heart failure (HF) death. We performed a lasso regression to select covariates and used these to develop a cox regression model.

#### Results:

During a median follow-up of 6 years (Interquartile range 2.9-9.2) after first MRI, 43 (8.6%) carriers experienced a composite endpoint of HF, consisted of a LVEF <30%, hospitalization, LVAD, HTX or HF death. Cox regression was performed with lasso penalty for selection of covariates. Cross validation was used to select the lasso penalty. Based on the number of events in a 10:1 ratio and appearance after cross validation we included AF (hazard ratio (HR) 2.31 [95% CI, 1.57-3.04]; p=0.064), NYHA class ≥2 at presentation (HR 2.74 [95% CI, 1.83-3.65], p=0.037), low-voltage ECG (HR 1.70 [95% CI, 0.99-2.41], p=0.15) and late gadolinium enhancement on MRI (HR 2.18 [95% CI, 1.40-2.97], p=0.064) in the final multivariable Cox regression model. The 5-year risk for heart failure was calculated for each carrier, after which the cohort was divided into two risk groups. Carriers in the high risk group had one or more risk factors and experienced most events and carriers in the low risk group experienced the least events. This resulted in an optimism-corrected C-statistic of 0.76 (95% CI, 0.67-0.85). It should be noted, however, that the number needed to treat at 5 year is still 20 and only after 9 years its declines towards 6 in the high risk group.

#### Conclusion:

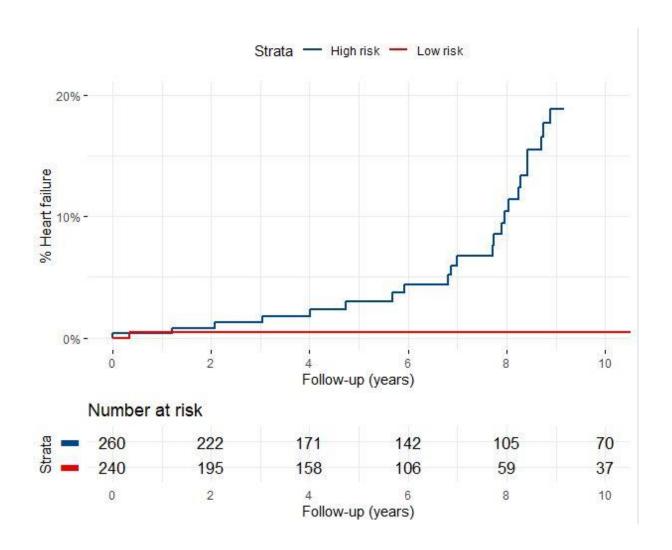
This is the first outline of a novel PLN p.Arg14del risk prediction model for heart failure to potentially aid patient selection for gene therapy in the future when validated.

### **Keywords:**

Heart failure, Prediction model, Gene therapy

### Figure:

Figure 1. Kaplan-Meier plot, incidence of first heart failure event stratified by risk group



# Stereotactic Arrhythmia Radioablation for Ventricular Tachycardia: Results from the Dutch STARNL-1 Trial

Presenting author: W.F. Hoeksema Department: Department of Cardiology

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#### Purpose:

Stereotactic arrhythmia radioablation (STAR) has recently been proposed as a new treatment technique in patients with ventricular tachycardia (VT) recurrences refractory to current treatment options, although prospective studies evaluating its efficacy and safety remain limited. We aimed to evaluate the efficacy and safety of STAR for VT in a prospective trial.

#### Methods:

The STARNL-1 was a prospective pre-post intervention study with 12 months follow-up. Six patients with VT recurrences despite optimal anti-arrhythmic medication, after one or more unsuccessful catheter ablation(s), were considered therapy-refractory. Patients were treated with a single fraction of 25 Gy to the pro-arrhythmic region. The efficacy endpoint was a reduction in VT episodes comparing the 12 months after treatment with the 12 months before treatment, and safety endpoints were a reduction in left ventricular ejection fraction (LVEF) and pulmonary function and an evaluation of adverse events. Additionally, ICD safety was evaluated during ICD readouts.

#### Results:

All patients were male and all suffered from ischaemic cardiomyopathy. Four patients (67%) completed 12-month follow-up, two patients died during follow-up of non-treatment related causes. Figure 1 shows the number of VT episodes before and after treatment. Median reduction in VT episodes was 87%. No reduction in LVEF or pulmonary function was observed and there were no treatment related serious adverse events. There were no relevant alterations to ICD parameters during follow-up.

#### Conclusion:

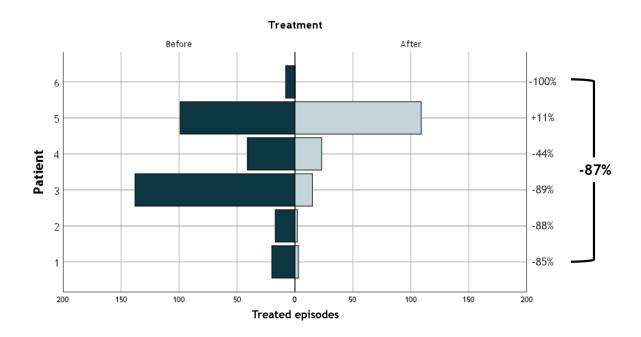
STAR for VT has a high efficacy and favourable safety profile in the first 12 months after treatment in patients with therapy-refractory VT.

#### **Keywords:**

Stereotactic Arrythmia Radiotherapy, Cardiac radioablation, Ventricular tachycardia

Figure:

The VT episodes in the 12 months before and 12 months after treatment (with a 6-week blanking period after treatment).



# Impact of Obesity on Quality of Life and Clinical Outcome in Patient with Atrial Fibrillation undergoing Primo Pulmonary Vein Isolation

Presenting author: N. van Pouderoijen

Department: Cardiology

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### Purpose:

Obesity is a major risk factor for the incidence and progression of atrial fibrillation (AF), negatively impacting AF ablation outcomes. Weight loss in obese patients prior to AF ablation may improve quality of life (QoL) and AF ablation success rates. This study assessed the impact of overweight and obesity on patient-reported outcomes (QoL scores) and clinical outcomes (AF recurrence) in patients undergoing index AF ablation procedure.

#### Methods:

This single-center cohort study retrospectively included 238 patients undergoing primo radiofrequency (RF) pulmonary vein isolation (PVI) who completed 1 year follow-up, including the Toronto AF Severity Scale (AFSS) questionnaire at baseline, 4-, and 12 months post-PVI for assessment of QoL (AF severity, AF burden, and global well-being). At baseline, patients were categorized by body mass index (BMI): normal (<25 kg/m2); overweight (≥25 - <30 kg/m2); and obese (≥30 kg/m2). AF recurrence was evaluated by either 24-h Holter monitoring, AliveCor KardiaMobile devices, or conventional electrocardiograms (ECG). **Results:** 

Patients were divided based on BMI: 37.8% normal; 44.1% overweight; and 18.1% obese. Obese patients were more likely to be women (men 46.5%,p<0.01), and have diabetes mellitus (25.6%,p<0.01).

AF recurrence rates detected during 12 months follow-up were similar among the three BMI groups: normal 27.8%, overweight 33.3%, and obese 30.2% (p=0.70). After AF ablation, all QoL scores in each BMI group improved, with no between-group differences. Subgroup analysis showed significantly improved QoL scores in patients without AF recurrence independent of BMI category, however in patients with AF recurrence no significant improvement of AF severity and global well-being was found (Fig 1). Despite AF recurrence, self-reported AF burden significantly improved in the normal and overweight categories, but not in obese patients.

#### Conclusion:

A high BMI was not a major determinant of AF recurrence rates after a primo PVI. QoL after PVI was found to be determined by AF recurrence rather than BMI. This study suggests that obese patients might benefit from PVI to a similar extent compared to non-obese patients, though self-reported AF burden might differ between groups.

#### **Keywords:**

Atrial fibrillation ablation, Obesity, Quality of life

Figure:

Differences in quality of life scores between patients with and without AF recurrence during follow-up within every BMI category.

