

### **SESSIE 2: Electrophysiology & devices**

	Springerzaal	Voorzitters:					
	opgoaa.	dr. Pascal van Dessel, cardioloog MST					
		dr. Tom Verstraelen, AIOS Amsterdam UMC					
1	09.00 - 09.10	a Comparison of commonly Used QT Formulas in Healthy					
		Subjects					
		Lennaert Hoek (ICON plc, Early Development Services,					
		Groningen, University of Groningen, UMC Groningen)					
2	09.11 - 09.21	Smartphone Application-Based Heart Rhythm Management					
	GEANNULEERD	Around Cardioversion in Patients with Presumed Persistent					
		Atrial Fibrillation: Feasibility Substudy of TeleConvert-AF					
		Madelon D.E.A. Engels (Radboudumc, Nijmegen; MUMC+,					
		Maastricht)					
3	09.22 - 09.32	Re-Implantation Strategies in Cardiac Implantable Electronic					
		Devices					
		Leonard A. Dijkshoorn (Amsterdam UMC, Amsterdam)					
4	09.33 - 09.43	Regional Implementation of a Pharmacologic Cardioversion					
		Protocol: Insights in Patient Outcomes and Experience					
		Jeroen A.A. van de Pol (Netherlands Heart Network, Eindhoven)					
5	09.44 - 09.54	Predicting Structural Heart Disease in Cardiology Outpatients					
		Using Artificial Intelligence-based Electrocardiogram					
		Interpretation					
	00.55 40.05	Bauke K.O. Arends (Universitu Medical Centre Utrecht, Utrecht)					
6	09.55 - 10.05	PulseSelect™ Pulsed Field Ablation for Atrial Fibrillation:					
		Conscious Sedation or General Anesthesia?					
7	40.00 40.40	Marisa van der Graaf (St. Antonius ziekenhuis, Nieuwegein)					
/	10.06 - 10.16	Endocardial Findings in One- and Two-Staged Hybrid Atrial					
		Fibrillation Ablation: a Dual-Center Cohort Analysis					
8	10.17 - 10.27	Luca Aerts (Maastricht Medical University Center, Maastricht)  Development of an Al Algorithm for Automated Detection of					
0	10.17 - 10.27	Cardiovascular Procedure-Related Complications					
		Jippe C. Balt (St. Antoniusziekenhuis, Nieuwegein)					
		Sippe C. Dait (St. Antoniusziekennus, Meuwegein)					



Session 2: Electrophysiology & devices
Abstract 1

### a Comparison of commonly Used QT Formulas in Healthy Subjects

Presenting author: L. Hoek Department: EDS/cardiology

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#### Purpose:

The QT interval on an ECG is influenced by heart rate, requiring correction formulas for adjusted QT (QTc) values. The European Society of Cardiology recommends Bazett's formula, while the FDA recommends Fridericia's formula for drug development. Other commonly used formulas include Framingham and Hodges. This study compared the accuracy of these four frequently used formulas in correcting the QT interval for heart rate.

### Methods:

We retrospectively assessed ECGs from 22.063 medically assessed healthy individuals who participated in phase 1 trials between 1997 and 2023. Pearson correlation coefficient (r) between QTc and heart rate (HR) and the linear regression slope (b) were calculated for each formula and the influence of age, sex and body mass index.

#### **Results:**

The study analyzed 16,170 males and 5,893 females (mean age:  $34.9 \pm 15.3$  years) to assess QTc-heart rate (HR) correlations. The Fridericia formula showed the strongest reliability, with the lowest correlation (r = 0.018) and a nearly horizontal regression slope (b = 0.04). The Hodges (r = -0.182, b = 0.39) and Framingham (r = 0.200, b = 0.43) formulas followed. The Bazett formula performed worst (r = 0.483, b = 1.12). Fridericia remained the most accurate across subgroups except in low BMI groups and differed significantly from other formulas in both sexes (P < 0.05).

#### **Conclusion:**

The Fridericia formula is the most reliable method for correcting the QT interval for heart rate and we recommend its use in daily practice.

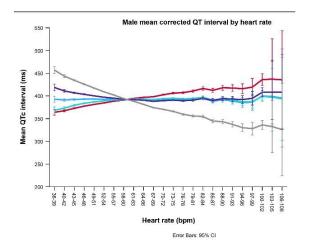
#### **Keywords:**

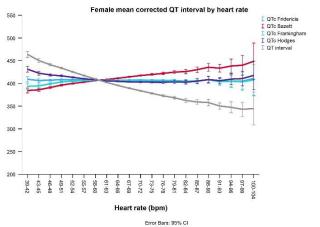
QT correction formulas, Fridericia formula, Bazett formula



### Figure:

Comparison of measured QT intervals and all mean HR-corrected QT intervals by heart rate (n = 22,063) and per 3 beats per min including 95% CI







Session 2: Electrophysiology & devices
Abstract 2

Smartphone Application-Based Heart Rhythm Management Around Cardioversion in Patients with Presumed Persistent Atrial Fibrillation: Feasibility Substudy of TeleConvert-AF

Presenting author: M.D.E.A. Engels

Department: Cardiology

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### Purpose:

A proportion of patients with presumed persistent AF, who are scheduled for electrical cardioversion (ECV), appear to have a paroxysmal AF pattern or convert spontaneously to sinus rhythm (SR) on the ECV waiting list. This results in unnecessary visits or interventions for patients, and costs and burden for the hospitals and health insurances. TeleConvert-AF is a prospective multicentre cohort study testing the effect of smartphone application-based heart rhythm monitoring around an elective ECV on cancelling unnecessary ECV appointments in case of paroxysmal AF patterns or spontaneous conversion of AF to SR in patients with presumed persistent AF scheduled for ECV.

This substudy of the TeleConvert-AF study assesses the feasibility of the smartphone application-based heart rhythm monitoring to detect paroxysmal AF patterns and spontaneous conversion of AF to SR in patients on the waiting list of an elective ECV.

#### Methods:

Patients aged ≥18 years with presumed persistent AF on the waiting list for an elective ECV were invited to participate. Reasons for exclusion were the presence of a cardiac device or the inability to use a smartphone application. Patients were instructed to perform three heart rate and rhythm recordings daily using a photoplethysmography (PPG)-based mobile app. Recordings were performed for a minimum of two weeks prior to ECV until four weeks follow-up. Recordings were evaluated by the investigators daily, and when changes in rhythm were observed patients were referred for electrocardiogram (ECG). ECV was cancelled in case of objective spontaneous conversion or paroxysmal AF. The primary endpoint is the occurrence of a paroxysmal AF pattern or self-terminating AF to SR. The secondary endpoint is recurrence of AF after ECV.

#### Results:

Up to now, 824 patients were screened and 233 patients agreed to participate in this study. Overall, adherence to the instruction to perform three heart rate and rhythm recordings daily has been optimal. According to the preliminary analysis of the first 120 patients (median age of 68 years [61.25-73.75], 70% male), paroxysmal AF patterns were observed in six patients (5.0%) and 13 patients (10.8%) showed a spontaneous conversion to SR on PPG recordings by the smartphone-application, which could be confirmed by a 12 lead resting ECG. Of 92 patients (76.7%), were ECV was acutely successful and were the patients left the hospital in SR, PPG recordings by the smartphone-application detected a recurrence of either persistent or paroxysmal AF within the 4-week follow-up period in 51 patients (55.4%), which could be confirmed by ECG.



#### **Conclusion:**

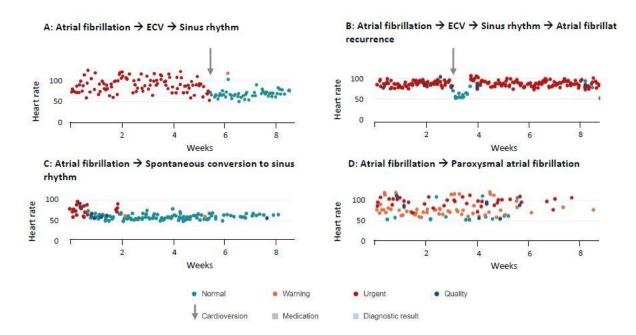
The TeleConvert-AF approach is feasible. PPG can accurately detect spontaneous conversion to SR and paroxysmal AF in patients waiting for an elective ECV. The effect of the TeleConvert-AF approach on ECV cancelation and the integration into AF treatment plans is currently investigated in the ongoing prospective TeleConvert-AF study.

#### **Keywords:**

Atrial Fibrillation, m-Health, Electrical cardioversion

#### Figure:

Figure 1: Representation of the four distinct patterns analysed in the Teleconvert-AF study. A) AF pre-ECV, with persistent SR after ECV; B) AF pre-ECV, with a short period of SR following ECV, followed by a recurrence of AF; C) AF at beginning of the monitoring period, with a spontaneous conversion to persistent SR; D) paroxysmal AF pattern. AF = atrial fibrillation; SR = sinus rhythm; ECV = electrical cardioversion





Session 2: Electrophysiology & devices
Abstract 3

Re-Implantation Strategies in Cardiac Implantable Electronic Devices

Presenting author: L.A. Dijkshoorn

Department: Cardiology

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#### Purpose:

This study aimed to evaluate clinical success, complications and re-implantation strategy of lead extractions.

#### Methods:

A retrospective cohort study was conducted at a single center, including patients who underwent lead extraction procedures between 2015 and 2023. Outcomes included clinical successful extraction, complications, re-implantation strategy and infection recurrence.

### Results:

Among 88 consecutive patients (median age 72yr, 84% male, 53% cardiomyopathy), a total of 40 implantable defibrillators (46%), 29 pacemaker (33%) and 19 cardiac resynchronization devices (33%) with a total of 203 leads were extracted. CIED infection was the main indication for extraction (84%). Median lead dwell time was 7 years (range 1.1–23 years). Clinical successful extraction was achieved in 78 (89%) of patients, and 4 (4.5%) experienced a major complication. Peri-procedural death was reported in 1 patient. CIED reimplantation was performed in 61%, of whom 60% transitioned to a non-transvenous device. Explanted devices were not reimplanted primarily due to a change in clinical indication. After a median follow-up of 3.8 years, 16 (18%) patients died, no infections reoccurred and none of those with non-transvenous device required transvenous implantation.

#### Conclusion:

In a cohort where lead extraction was mainly performed for CIED infections, lead extraction is effective with high success rates and low peri-procedural mortality. Moreover, reimplantation with a non-transvenous systems is effective and safe.

#### **Keywords:**

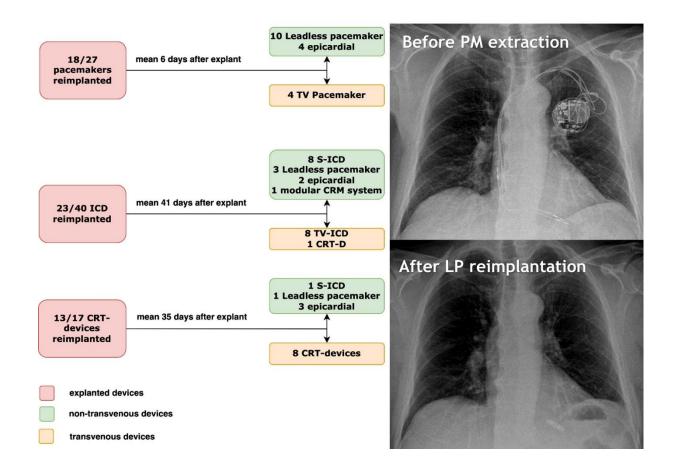
lead extraction, CIED infections, mortality



### Figure:

Figure 1: reimplantation strategies

TV: transvenous, ICD: implantable cardioverter defibrillator, S-ICD: subcutaneous implantable cardioverter defibrillator, CRM: cardiac rhythm management, CRT: cardiac resynchronization therapy, PM: pacemaker, LP: leadless pacemaker.





Session 2: Electrophysiology & devices
Abstract 4

### Regional Implementation of a Pharmacologic Cardioversion Protocol: Insights in Patient Outcomes and Experience

Presenting author: J.A.A. van de Pol

Department: Cardiology

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### Purpose:

A new protocol regarding preferred pharmacologic cardioversions (PCV) and, if unsuccesfull, 24-hour delayed electric cardioversion (ECV) was implemented across four hospitals in Southeast Netherlands, working together within the Netherlands Heart Network. This study evaluates the protocol's impact on both patient outcomes and care experience.

#### Methods:

The protocol was implemented in July 2022. After a brief run-in period, data were evaluated from September 2022 to May 2023. Data were extracted from electronic patient records to assess PCV success rates and subsequent use of ECV (same or following day). A patient experience questionnaire, as developed in collaboration between an atrial fibrillation care professional network and a regional patient advisory board, was distributed by emergency cardiac care nurses following acute PCV and/or ECV to compare PCV/ECV experiences.

#### Results:

PCV was successful in 271 out of 356 patients (76%). In the 85 non-successful PCV, ECV was performed the same or following day. Of 54 eligible patient questionnaires, 28 involved ECV, 12 PCV, and 14 both. No significant differences were observed between ECV and PCV regarding overall care (9.4 vs. 9.0 out of 10, p=0.22), or variables such as information provision (p=0.58), treatment explanation (p=0.58), shared decision-making (p=0.51), feeling safe (p=0.89), safe return home (p=0.14), or experience as impactful (p=0.33).

#### Conclusion:

PCV success rates aligned with expectations from literature. Patient experiences were comparable between ECV and PCV, despite initial expectations of reduced impact and less perceived safety with PCV. Future evaluation will focus on healthcare costs to provide a comprehensive assessment of patient value.

### **Keywords:**

Pharmacologic cardioversion, Patient experiences, Regional implementation



Session 2: Electrophysiology & devices
Abstract 5

## Predicting Structural Heart Disease in Cardiology Outpatients Using Artificial Intelligence-based Electrocardiogram Interpretation

Presenting author: B.K.O. Arends

Department: Cardiology

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### Purpose:

The growing prevalence of structural heart disease (SHD) has increased the burden on echocardiography laboratories, further strained by a sonographer shortage. To address this, efficient diagnostic strategies are essential. Electrocardiograms (ECGs) are cost-effective, accessible, and rapid tests that could assist in SHD detection. This study aimed to develop and validate an artificial intelligence-based algorithm to predict SHD using ECG data.

Methods:

We analyzed ECG-echocardiogram pairs from University Medical Center Utrecht and Catharina Hospital Eindhoven, dividing data into training, validation, and testing cohorts with no patient overlap. SHD was defined as a composite endpoint of any TTE with moderate-severe biventricular dysfunction/dilatation or moderate-severe valvular disease (aortic stenosis/regurgitation, mitral/tricuspid regurgitation). We constructed a testing cohort of newly referred outpatients from both centers. An ensemble model, combining a convolutional neural network and an extreme gradient boosting algorithm, was trained to predict the composite endpoint using only ECG data.

#### **Results:**

The model was trained on 80,579 ECGs from 51,902 patients and tested on 4,052 ECGs (median age: 64 [51–73] years, 50.9% male). The composite endpoint was present in 857 patients (22.5%). In the testing cohort, the model achieved an area under the receiver operating characteristic curve of 0.80 (95% confidence interval [CI]: 0.79–0.82), sensitivity of 0.94 (95% CI: 0.92–0.95), and specificity of 0.31 (95% CI: 0.29–0.32).

#### Conclusion:

We successfully developed an ensemble model that predicts absence of SHD using ECG data alone. With further validation, this algorithm could assist in risk stratification and streamline SHD diagnostics in outpatient settings.

#### **Keywords:**

structural heart disease, deep learning, electrocardiogram



### Figure:

Ensemble model performance in the outpatient test set. Abbreviations. AUPRC, area under the precision recall curve; AUROC, area under the receiving operator characteristic curve; AR, aortic regurgitation; AS, aortic stenosis; LVD, left ventricular dilatation; LVDD, left ventricular diastolic dysfunction; LVSD, left ventricular systolic dysfunction; MR, mitral regurgitation; NPV, negative predictive value; PPV, positive predictive value; RVD, right ventricular dilatation; RVSD, right ventricular systolic dysfunction; TR, tricuspid regurgitation.

	Prevalence	AUROC	AUPRC	Sensitivity	Specificity	PPV	NPV
Composite	0.22 (0.21-0.24)	0.80 (0.79-0.82)	0.62 (0.59-0.65)	0.94 (0.92-0.95)	0.31 (0.29-0.32)	0.28 (0.26-0.30)	0.94 (0.93-0.96)
LVSD	0.07 (0.07-0.08)	0.93 (0.92-0.95)	0.66 (0.61-0.71)	0.92 (0.89-0.95)	0.79 (0.78-0.80)	0.26 (0.24-0.29)	0.99 (0.99-1.00)
LVD	0.03 (0.03-0.04)	0.93 (0.91-0.95)	0.46 (0.37-0.55)	0.88 (0.82-0.93)	0.84 (0.83-0.85)	0.16 (0.13-0.19)	1.00 (0.99-1.00)
RVSD	0.02 (0.02-0.03)	0.89 (0.86-0.92)	0.20 (0.14-0.28)	0.94 (0.89-0.98)	0.58 (0.57-0.60)	0.05 (0.04-0.06)	1.00 (1.00-1.00)
RVD	0.02 (0.02-0.03)	0.82 (0.77-0.87)	0.18 (0.11-0.26)	0.78 (0.69-0.87)	0.69 (0.67-0.70)	0.05 (0.04-0.06)	0.99 (0.99-1.00)
LVDD	0.03 (0.03-0.04)	0.81 (0.77-0.84)	0.15 (0.12-0.21)	0.94 (0.90-0.98)	0.39 (0.38-0.41)	0.05 (0.04-0.06)	0.99 (0.99-1.00)
AS	0.04 (0.03-0.04)	0.80 (0.76-0.83)	0.18 (0.13-0.24)	0.87 (0.81-0.92)	0.54 (0.52-0.56)	0.07 (0.05-0.08)	0.99 (0.99-0.99)
AR	0.02 (0.02-0.03)	0.75 (0.70-0.79)	0.10 (0.06-0.16)	0.93 (0.87-0.97)	0.37 (0.36-0.39)	0.03 (0.03-0.04)	1.00 (0.99-1.00)
MR	0.06 (0.05-0.07)	0.84 (0.82-0.87)	0.31 (0.26-0.38)	0.93 (0.90-0.96)	0.45 (0.44-0.47)	0.10 (0.09-0.11)	0.99 (0.99-0.99)
TR	0.04 (0.04-0.05)	0.86 (0.84-0.89)	0.31 (0.25-0.38)	0.93 (0.90-0.97)	0.56 (0.54-0.57)	0.09 (0.08-0.10)	0.99 (0.99-1.00)



Session 2: Electrophysiology & devices
Abstract 6

## PulseSelect™ Pulsed Field Ablation for Atrial Fibrillation: Conscious Sedation or General Anesthesia?

Presenting author: M. van der Graaf

Department: Cardiology

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#### **Purpose:**

Pulmonary vein isolation (PVI) with pulsed field ablation (PFA) is typically performed under general anesthesia. However, PFA systems with an appropriate pulse profile may enable procedures under conscious sedation. In this study we assess the feasibility, efficacy and safety of performing PVI with the PulseSelect™ ablation system under conscious sedation, compared to general anesthesia in patients with atrial fibrillation (AF).

#### Methods:

Single center registry of AF patients undergoing an ablation with the PulseSelect™ (Medtronic, Minneapolis, USA) PFA system, between January 29th and December 31th, 2024 at the St. Antonius Hospital. Conscious sedation (CS) was used if no anesthesiology team was available to provide general anesthesia (GA). Endpoints included acute isolation of ablation targets, procedural characteristics and freedom from adverse events within 30 days. **Results:** 

The analysis included 174 patients (67.2% male, mean age 62.8±9.3 years), with 62.1% having paroxysmal AF. GA was used in 132 (75.9%) vs. CS in 42 patients (24.1%). There were no differences in baseline characteristics between the groups. Median skin-to-skin procedural time was comparable between groups: GA 39.0 min [IQR 34.0;46.0] vs. CS 42.0 min [IQR 37.5; 46.0], P= N.S and acute procedural efficacy was 100% in both groups. One patient in the GA group experienced a major bleeding complication. Intravenous lidocaine was administered in a subset of patients who experienced coughing during the procedure, with overall positive effects.

#### **Conclusion:**

Conscious sedation offers an efficient and safe alternative for PulseSelect™ PFA procedures, eliminating risks of general anesthesia and reducing personnel required for airway management.

#### **Keywords:**

Atrial fibrillation, Pulsed field ablation, Conscious sedation



### Figure:

Data is presented as counts (percentages) for categorical data, means ± standard deviations for normally distributed continuous data and median [interquartile range] non-normally distributed continuous data. Abbreviations: LVEF: Left Ventricular Ejection Fraction; LAVI: Left Atrial Volume index.

### TABLE 1

	Conscious sedation (n = 42)	General anesthesia (n = 132)	ρ-value		
Age, years	60.6 ± 9.6	63.4 ± 9.1	0.102		
Female sex	12 (28.6)	45 ( 34.1)	0.635		
LVEF >50%	34 (82.9)	99 ( 76.7)	0.536		
Enlargement left atrium (LAVI > 35ml/m <sup>2</sup> )	14 (40.0)	43 ( 35.5)	0.777		
CHA <sub>2</sub> DS <sub>2</sub> -VA score					
0	20 (47.6)	46 ( 35.1)			
1	10 (23.8)	36 ( 27.5)			
2+	12 (28.6)	49 ( 37.4)			
Total number of applications	32.0 [32.0, 33.0]	33.0 [32.0, 36.0]	0.001		
Procedure time (min)	42.0 [37.5, 46.0]	39.0 [34.0, 46.0]	0.108		
Fluoroscopy duration (min)	11.5 [10.0, 12.2]	12.0 [10.0, 15.0]	0.090		
Acute procedural success	42 (100.0)	132 (100.0)	1.000		



Session 2: Electrophysiology & devices
Abstract 7

## **Endocardial Findings in One- and Two-Staged Hybrid Atrial Fibrillation Ablation: a Dual-Center Cohort Analysis**

Presenting author: L. Aerts

Department: Cardiothoracic surgery

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#### Purpose:

Hybrid AF ablation combines thoracoscopic epicardial ablation with a transvenous endocardial approach. Electrophysiological findings during the endocardial part of hybrid ablation have not been reported in detail.

#### **Methods:**

This retrospective study included patients with symptomatic paroxysmal, persistent and longstanding-persistent AF who underwent 1-or-2-staged hybrid ablation. Here we discuss endocardial validation, touch up, and additional endocardial ablations. Secondly, findings during redo catheter ablation were described.

#### Results:

In the one-stage group there were more LSPAF patients (39.3% vs 10.3%, p=0.032), less prior catheter ablations (39.3% vs 79.3%, p=0.039) and a longer AF duration (117 vs 33 months, p=0.009), compared to two-staged patients. Endocardial validation confirmed entrance and exit block in the box lesion in 91.2% of one-stage and 86.2% of two-staged patients. Touch-up lesions and additional endocardial ablations during the hybrid procedure are described in table 1. Freedom from ATA at 12, 24, and 36 months was 71.4%, 66.3%, and 44.2% in the one-stage, and 82.8%, 59.1%, and 59.1% in the two-staged group. Complication rates were low.

Redo catheter ablations were performed in 5 one-stage patients with a mean interval of 15.4 months post-procedure, and in 1 two-staged patient after 8 months. During these redo ablations, isolation of pulmonary veins and box lesions was persistent. However, redo ablation did not result in freedom from ATA during follow up.

#### Conclusion:

The endocardial component of hybrid ablation confirms lesion completeness, with comparable outcomes between one- and two-staged approaches. Redo procedures after hybrid ablation did not result in freedom from ATA.

#### **Keywords:**

Hybrid AF ablation, Endocardial validation, Electrophysiological mapping



Figure:

Table 1. Procedural findings

Variable	Overall cohort	One Stage	Two Staged	p-value
	(n=57)	(n=28)	(n=29)	
SVC isolation (%)	55 (96.5%)	27 (96.4%)	28 (96.6%)	1.000
Additional epicardial lines				
Isthmus line (%)	2 (3.5%)	2 (7.1%)	0	0.237
LAA management (%)	56 (98.2%)	27 (96.4%)	29 (100%)	0.491
Touch -up				
Re-isolation roof line	2 (3.5%)		2 (6.9%)	
Re-isolation floor line	4 (7.0%)	1 (3.6%)	3 (10.3%)	
Re-isolation LPVs	1 (1.8%)	1 (3.6%)		
Re-isolation RPVs	1 (1.8%)	1 (3.6%)		
Additional endocardial lines				
CTI (%)	28 (93.0%)	28 (100%)	25 (86.2%)	0.112
Mitraal isthmus line (%)	11 (19.3%)	9 (32.1)	2 (6.9%)	0.021
Extra ablation LA (%)	3 (5.3%)	0	3 (10.3%)	0.237
Extra ablation RA (%)	3 (5.3%)	0	3 (10.3%)	0.237
RAA (%)	2 (3.5%)	0	2 (6.9%)	0.491
Intercaval line (%)	1 (1.8%)	1 (3.6%)	0	0.491
SVC (%)	2 (3.5%)	2 (7.1%)	0	0.237

CTI: cavotricuspid isthmus line, ECV: electrical cardioversion, LA: left atrium, LAA: left atrial appendage, LSPV: left superior pulmonary vein, SD: standard deviation, SR: sinus rhythm, SVC: superior vena cava, RA: right atrium, RAA: right atrial appendage, RPVs: right pulmonary veins.



Session 2: Electrophysiology & devices
Abstract 8

## Development of an Al Algorithm for Automated Detection of Cardiovascular Procedure-Related Complications

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#### Purpose:

In the present study, we describe the development of a fully automated, artificial intelligence (AI) driven complication registration, independent of health care worker input, after percutaneous coronary intervention (PCI), pulmonary vein isolation (PVI) and trans catheter aortic valve implantation (TAVI). This algorithm was designed to identify the most important complications (stroke, tamponade and vascular complications) in Epic, an electronic patient record system (EPRS) that is used worldwide.

#### **Methods:**

We created an AI model designed to identify complications in EPIC healthcare files following cardiac procedures at the St. Antonius Hospital in the Netherlands. After consent from the medical ethical committee, we collected anonymized data from EPIC healthcare files, conducting all analyses on a compute cluster situated within St. Antonius Hospital. The database consisted of 6564 cardiac procedures (PVI, PTCA and TAVI) performed at our hospital from 2017 to 2022. Diverse data sources were used, such as the registered diagnosis, procedure-logs, medication, laboratory measurements, clinical notes, and discharge letters. To ensure consistency, we adhered to data standardization using the OMOP Common Data Model and ZIB, a Dutch information standard mandatory for all hospitals. Standardization simplifies the integration of the AI model in current and future hospital settings.

Our model underwent training and testing using data from all patients undergoing PCI, PVI, or TAVI at our hospital from 2017 to 2022. The dataset was divided into a training and test set (n=2999) and a prospective validation set (n=3565). We developed models for specific complications—bleeding, tamponade, CVA, and phrenic paralysis—defined by the Dutch Heart Registration (NHR; see Table 1). For bleeding, the definition was expanded to include clinically relevant incidents, such as a bleeding that prolonged hospital stay, requiring surgical intervention or blood transfusion. The primary objective of the model was to achieve 100% sensitivity to avoid missing any complication, accepting a lower specificity and – consequently- false positives.

#### Approach

We employed a systematic ten-step approach, outlined in Figure 1. Steps 1-4 involved splitting the training dataset into groups with and without complications. Clinical presentations and patterns of each complication were discussed in workshops with healthcare professionals. These patterns were translated into data statements, forming the basis for a weak labeled dataset (see below for definition). Both structured data (medication,



lab measures, data from procedure-logs) and unstructured data (notes, discharge letters) were considered, flagging a patient if any statement was true within an admission. Manual reviews of selected files generated a strong dataset (see below), serving as the gold standard for fine-tuning and validating our models. A random sample of non-selected files did not yield additional complication cases.

In Step 5, Machine learning was employed to identify additional signals in the training set. Step 6 involved assessing whether the explained patterns aligned with the patient context, removing correlational signals from the model. For example the administration of fluoroscopic contrast was found as an additional signal by the model for CVA. It was removed because correlated with the making of a CT scan to diagnose a CVA. Step 7 integrated the three models into one, combining the identified criteria from Step 2 using structured and unstructured data, together with the additional signals found with machine learning. Different models

were applied for each complication, employing random forest (see below) and boosting classifiers (see below) for structured data and transformer embedding's for unstructured data. For fine-tuning we utilized the optuna framework (see below) for high sensitivity. Transparent and trustworthy results were ensured by incorporating explainable AI techniques, including small decision trees and exploration of synonyms for common associated words with each complication.

Step 8 tested the performance of the combined models on the validation dataset. In Step 9 and 10, manual checks were conducted on all files labeled as complications together with a random sample of files without a complication. We are reporting specificity, sensitivity, and precision for each model on both the training and validation datasets.

#### Results:

6564 patients who underwent PVI, PCI or TAVI procedures at our hospital between 2017 and 2022. The dataset was split into a training and test set (n=2999) and a prospective validation set (n=3565). Baseline characteristics are shown in table 1.

Sensitivity, specificity, positive predictive value and F-score for the automated detection of complications stroke, tamponade, bleeding and phrenic nerve palsy after PVI, PTCA and TAVI are shown in Table 2 and table 3. A sensitivity between 94.4% and 100% was achieved, while specificity ranged from 99.4% to 100%. This resulted in positive predictive values ranging from 47.5% to 81%, with F-scores varying between 0.64 and 0.87. Due to insufficient data, a meaningful AI-model for phrenic nerve palsy could not be created. This model used selected criteria only, containing structured data (such as medication, lab measures, procedures) and unstructured data (such as notes, discharge letters).

#### Conclusion:

We now have an AI driven tool that can automatically identify virtually all complications from the patient health care files, with very high sensitivity. This is achieved without the burden of prospective registration for the healthcare provider and without the intervention of data managers. This provides crucial input in the PDCA cycle, thereby aiding in patient safety and health care quality.

#### **Keywords:**

Artificial intelligence, complication registration,