

# ICD Therapie – welcher für wen?

Aktuelles aus der ICD Therapie

**PD Dr. med. Eimo Martens**

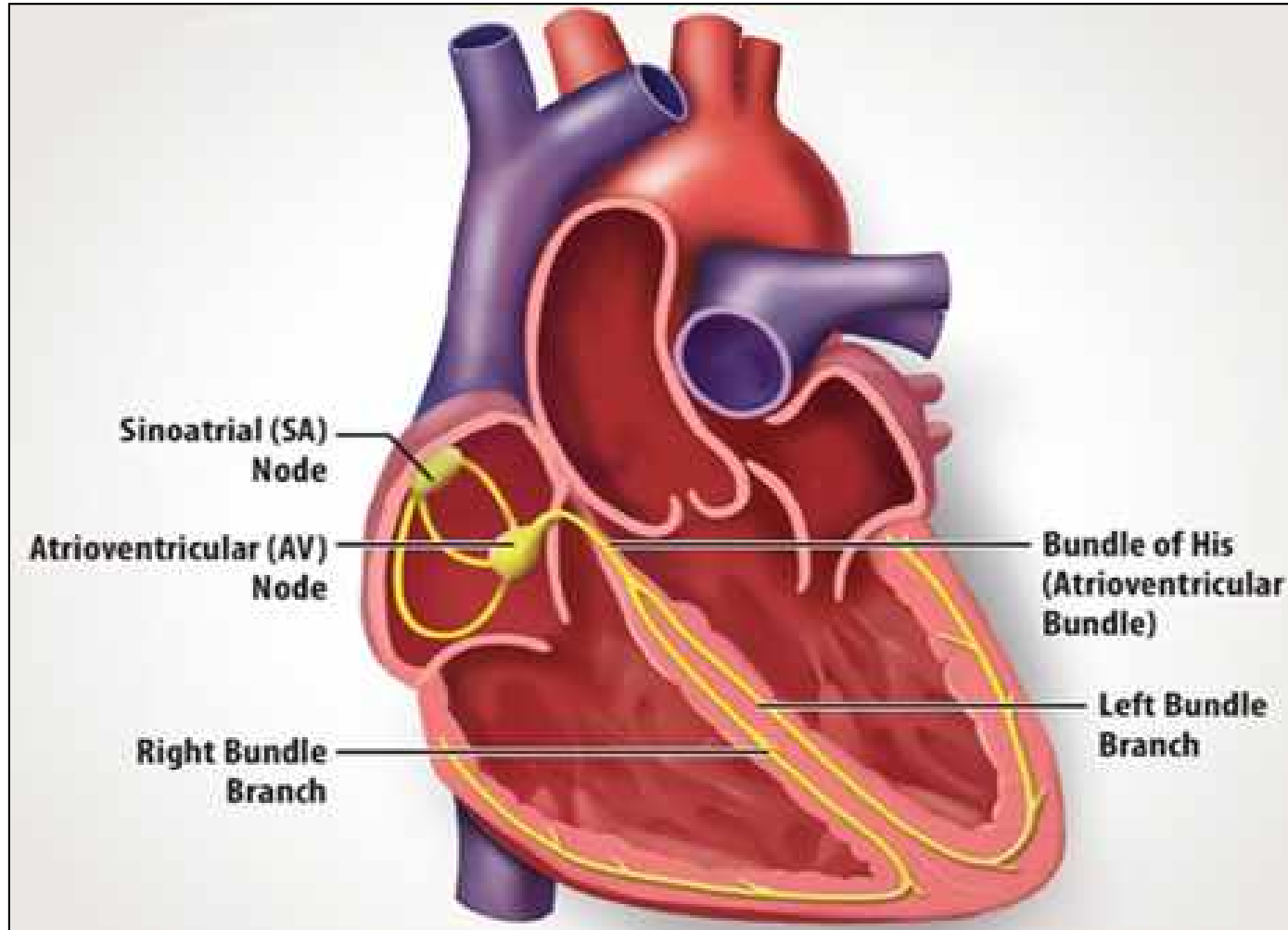
**Head of Device Therapy & Telemedicine Centre**

**EHRA certified Cardiac Device Specialist  
DGK Certification on Rhythmology & Heart Failure  
Clinical Department for Cardiology**

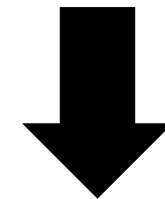
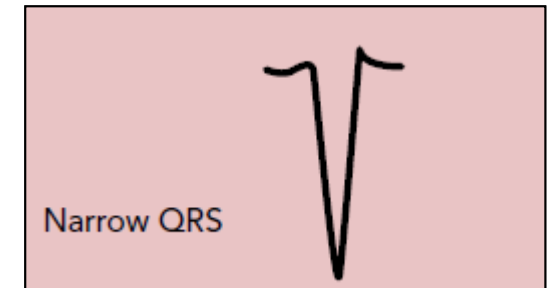
# Agenda

- **HIS- bzw. Conduction Pacing**
- **Leadless Pacing**
- **Subkutaner ICD**
- **Remote-Monitoring**

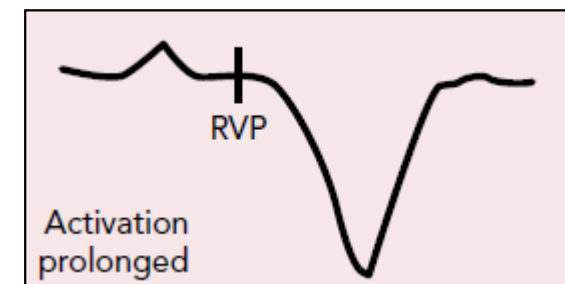
# Normal conduction and typical pacemaker stimulation



Normal conduction



RV-Pacing



# Background RV Stimulation

- **RV pacing causes and inter- and intraventricular dyssynchrony.**
- **Clinical and preclinical studies have demonstrated that high levels of pacing in the RV worsen global cardiac function and promote the development of heart failure**
- **MOST\* trial and DAVID\*\* trial: RVP is a predictor for heart failure hospitalization**



**The search for alternative stimulation sites and algorithms has been developing slowly for years (first studies 2002)**

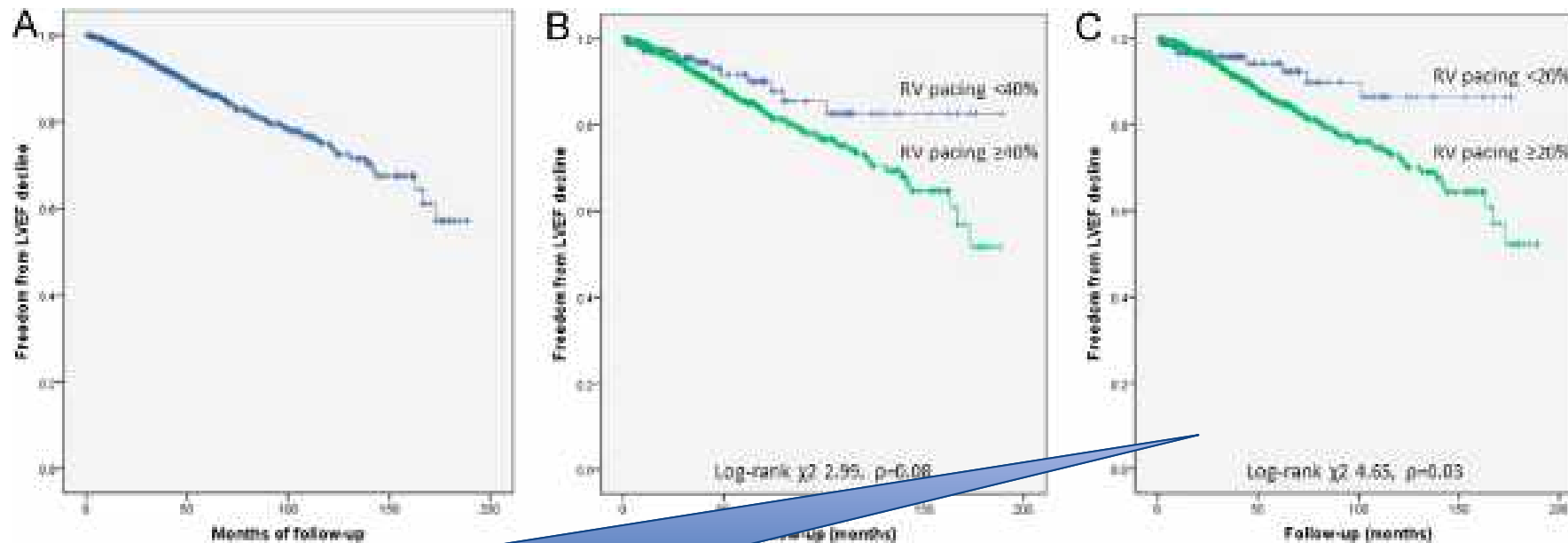
**The Deleterious Consequences of Right Ventricular Apical Pacing: Time to Seek Alternate Site Pacing**

ANTONIS S. MANOLIS

# Epidemiology Pacing-induced cardiomyopathy

*Incidence and predictors of right ventricular pacing-induced cardiomyopathy in patients with complete atrioventricular block and preserved left ventricular systolic function*

Erich L. Kiehl, MD, Tarek Makki, MD, Rahul Kumar, MD, Divya Gumber, MD, Deborah H. Kwon, MD, John W. Rickard, MD, FHRS, Mohamed Kanj, MD, FHRS, Oussama M. Wazni, MD, FHRS, Walid I. Saliba, MD, FHRS, Niraj Varma, MD, FHRS, Bruce L. Wilkoff, MD, FHRS, Daniel J. Cantillon, MD, FHRS

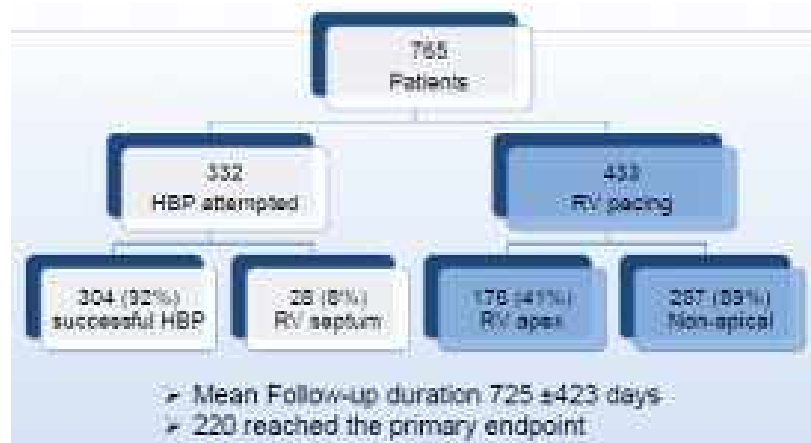


Of the 823 study patients (EF mean  $58 \pm 4\%$ ),  
101 (12.3%) developed PICM over the mean follow-up of  $4.3 \pm 3.9$  years.

PICM is not uncommon in patients receiving PPM with CHB with preserved LVEF

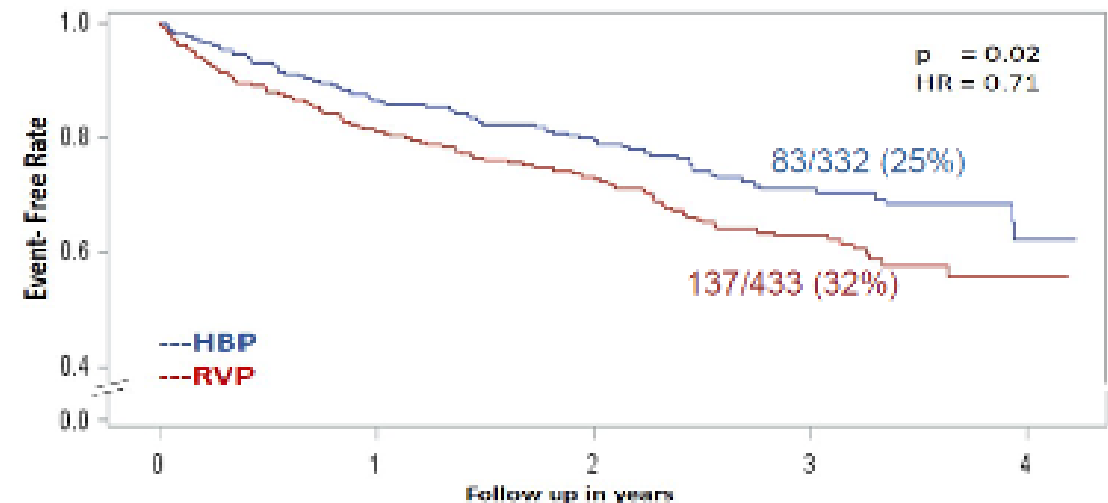
It is strongly associated with RV pacing burden >20%

# Clinical Outcome of HIS Bundle Pacing Compared to RV Pacing

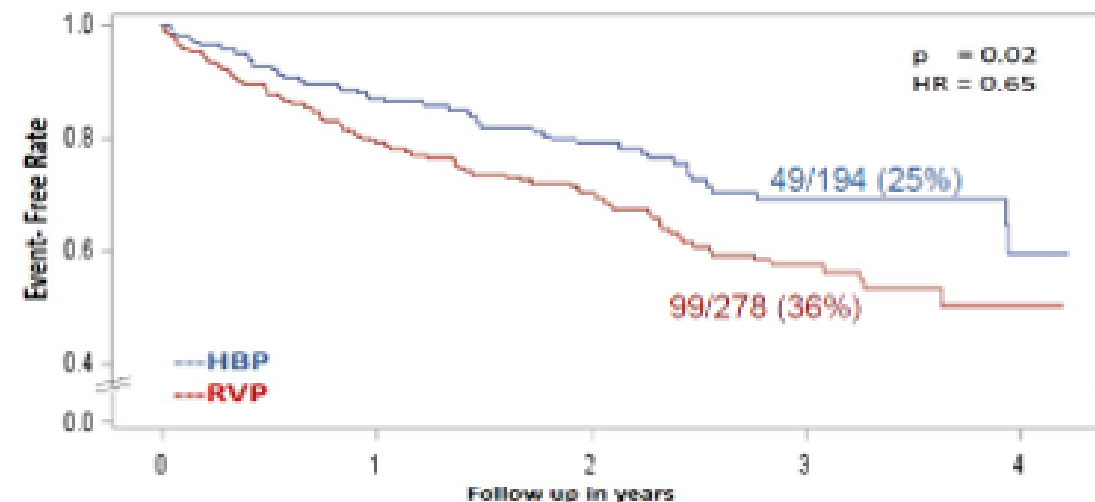


The composite end point of all cause mortality, first episode of HFH or upgrade to biventricular pacing.

Primary endpoints for all patients:



Patients with VP>20%:



# Outcome?

- ECS Recommendation **Aug 2021**
- **not in all patients successful** stimulation at the HIS is possible (success rate ~81%)
  - **technical difficulties** to reach the HIS
  - **deeper block**, no activation of the ventricle
  - **Intermittent complete AV-Block**
- in ~15% of HBP patients, a rise in stimulation **thresholds** occurred month after the procedure, leading to revision
  - **deeper AV block?**

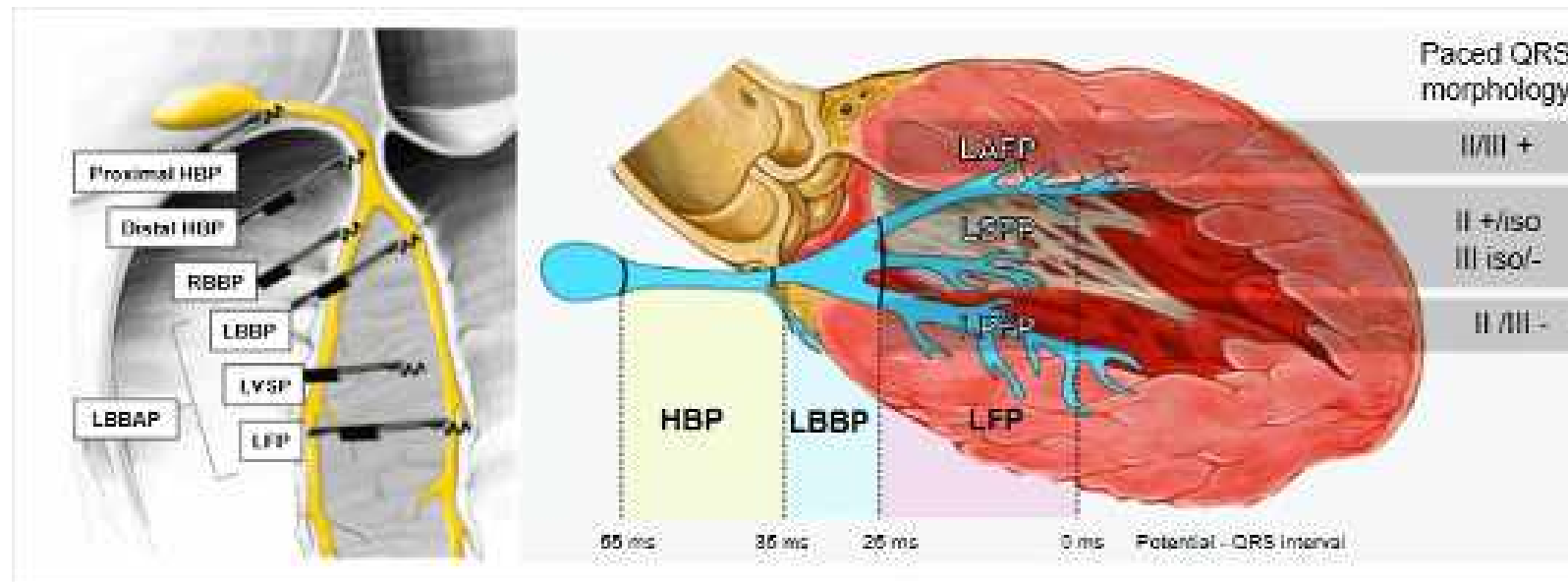
Alternate site pacing		
<i>His bundle pacing</i>		
In patients treated with HBP, device programming tailored to specific requirements of His bundle pacing is recommended.	I	C
In CRT candidates in whom coronary sinus lead implantation is unsuccessful, HBP should be considered as a treatment option along with other techniques such as surgical epicardial lead.	IIa	B
In patients treated with HBP, implantation of a right ventricular lead used as "backup" for pacing should be considered in specific situations (e.g. pacemaker-dependency, high-grade AVB, infra-nodal block, high pacing threshold, planned AVJ ablation), or for sensing in case of issues with detection (e.g. risk of ventricular undersensing or oversensing of atrial/His potentials).	IIa	C
HBP with a ventricular backup lead may be considered in patients in whom a "pace-and-ablate" strategy for rapidly conducted supraventricular arrhythmia is indicated, particularly when intrinsic QRS is narrow.	IIb	C
HBP may be considered as an alternative to right ventricular pacing in patients with AVB and LVEF >40%, who are anticipated to have >20% ventricular pacing.	IIb	C

# Solution: Conduction-System-Pacing

- EHRA implantation statement **Feb 2023**
- Various locations along the conducting system
- Aim: narrow QRS under pacing / Time-to-R-Wave-Peak.

**EHRA clinical consensus statement on conduction system pacing implantation: endorsed by the Asia Pacific Heart Rhythm Society (APHRS), Canadian Heart Rhythm Society (CHRS), and Latin American Heart Rhythm Society (LAHRS)**

Haran Burri<sup>1,4</sup>, Marek Jastrzebski<sup>1</sup>, Óscar Cano<sup>3,4</sup>, Karol Čurila<sup>5</sup>, Jan de Pooter<sup>6</sup>, Weijian Huang<sup>7</sup>, Carsten Israel<sup>8</sup>, Jacqueline Jozá<sup>9</sup>, Jorge Romero<sup>10</sup>, Kevin Vernooij<sup>11</sup>, Pugazhendhi Vijayarajan<sup>12</sup>, Zachary Whinnest<sup>13</sup>, and Francesco Zanon<sup>14</sup>



# Cardiac physiologic pacing (CPP)

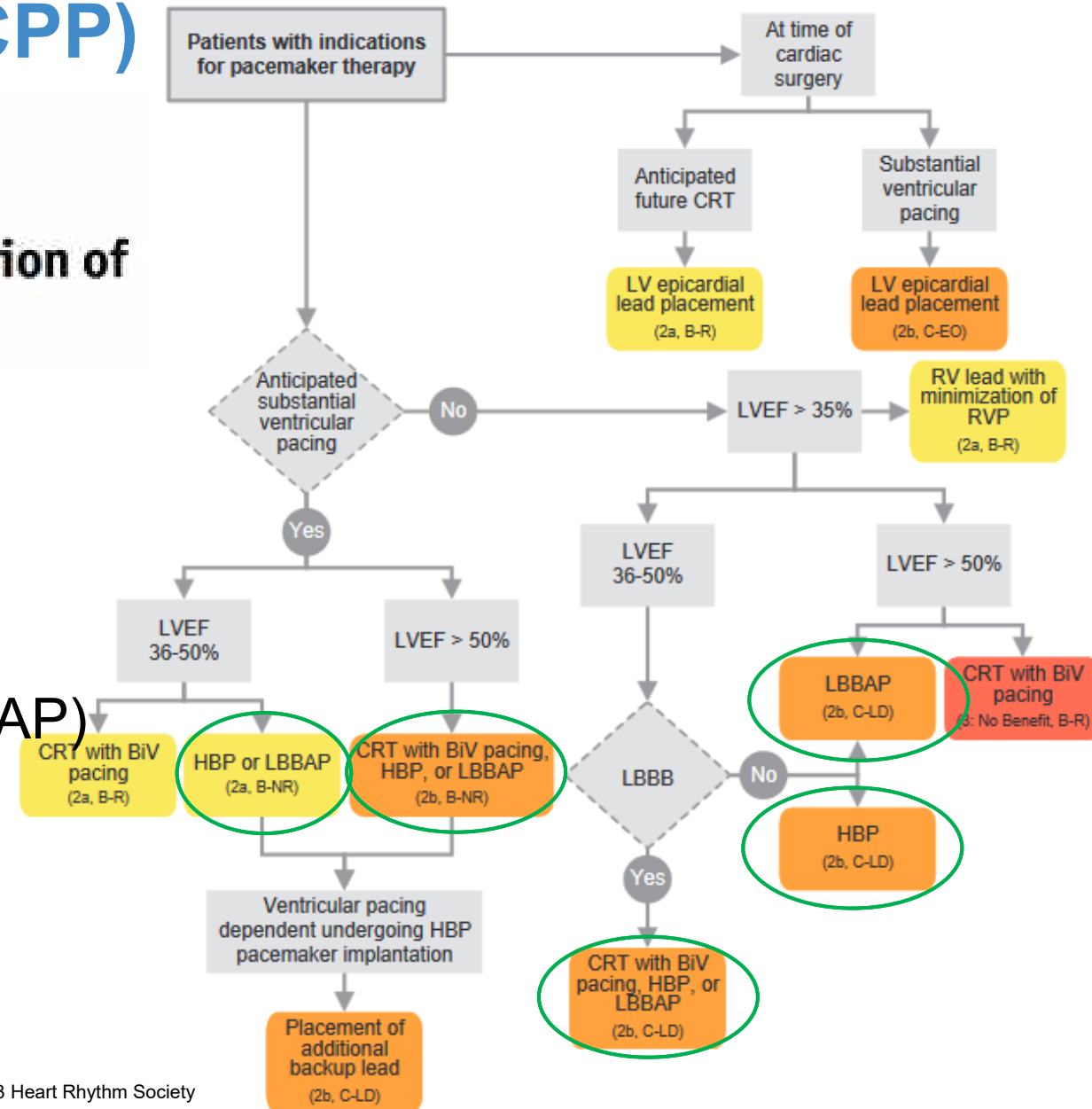
NEWS FROM THE HEART RHYTHM SOCIETY

2023 HRS/APHRS/LAHRs guideline on cardiac physiologic pacing for the avoidance and mitigation of heart failure 📅 Oct 2023

## Cardiac physiologic pacing (CPP)

- Cardiac-Resynchronization (BiV)
- His-Bundle-Pacing
- Conduction-System-Pacing resp. Left-Bundle-Branch-Area Pacing (LBBAP)

CPP in the consideration for each patient individually



# Initial Experience Left-Bundle-Branch-Area Pacing

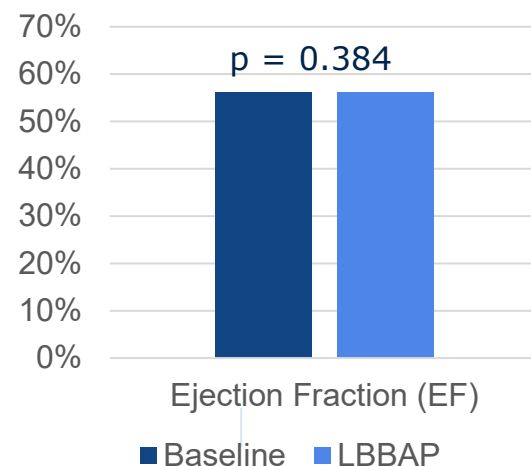
- Prospective multicenter registry (8 centers)
- Most operators = certified electrophysiologist with large (>5 years) experience in implanting CIED
- N = 353 consecutive patients undergoing LBBAP for bradycardia or HF indications
- Mean number of implants per center = 25
- Stylet driven leads 6F
- Follow-up (FU) scheduled at 1, 6 and 12 months; mean FU = 9±5 months

In this large multicenter study, LBBAP with SDL is associated with

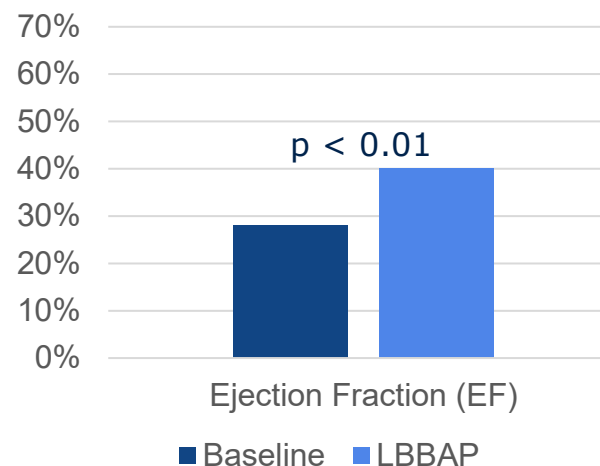
- **high implant success,**
- **stable pacing characteristics,**
- **and low complication rates.**

The observations of this study suggest that **LBBAP can be performed safely** with a variety of standard pacing leads, which might contribute to a wider implementation of LBBAP as a new pacing modality.

Development of EF:  
Patients with normal EF



Development of EF:  
Patients with reduced EF



0 patients developed de novo heart failure

0 patients experienced worsening heart failure

# Left Bundle Branch Area Pacing - LBBAP

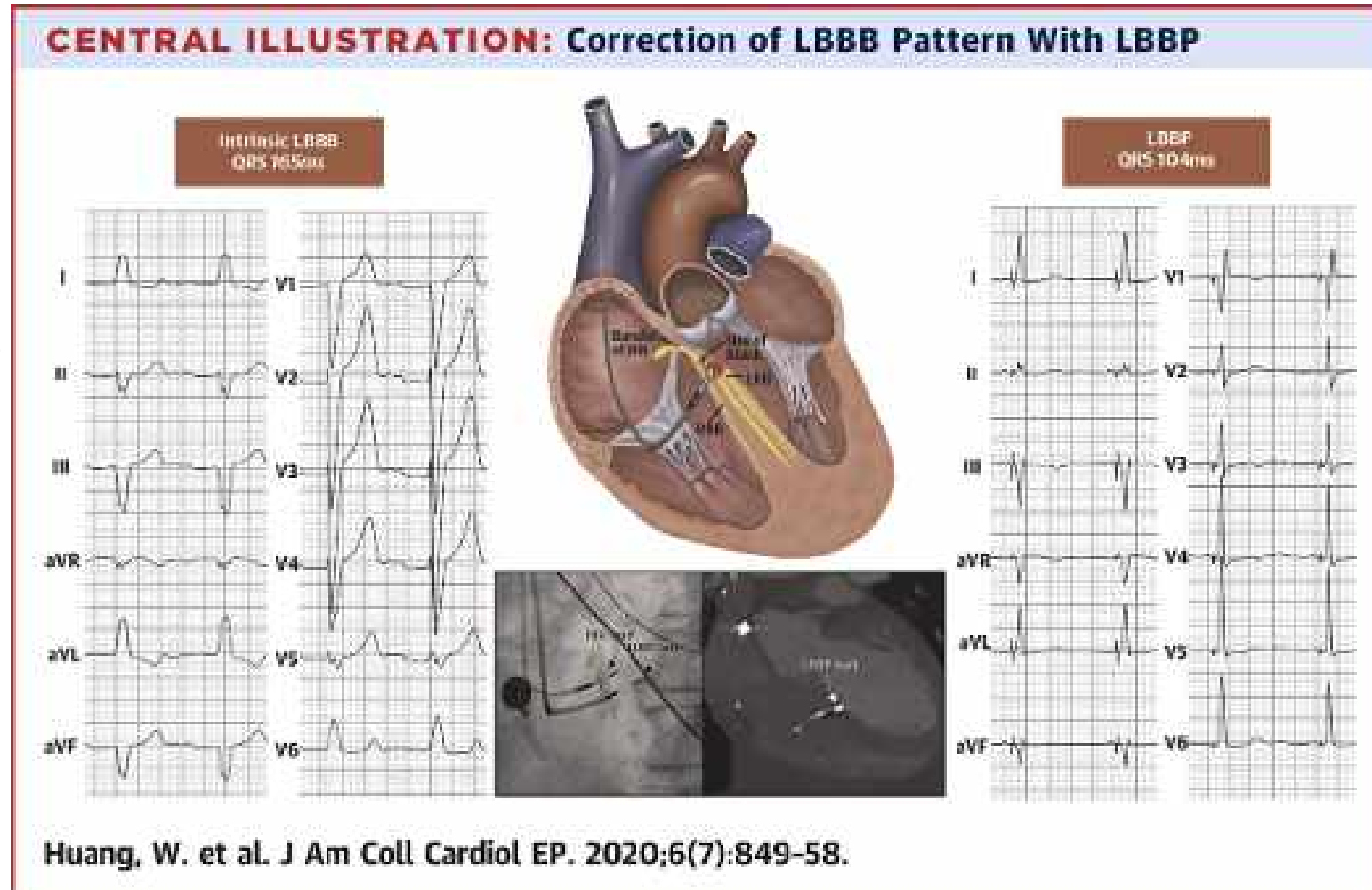
- Systematic review and **meta-analysis** of twenty-five trials with **4250** patients.
  - LBBAP has lower risk of **Heart Failure Hospitalizations** compared to RVP.
  - LBBAP shows better results in all-cause **mortality** than RVP.
  - **QRSd was shorter in the LBBAP** group at follow-up
  - **AF occurrence** rates are lower with LBBAP.
  - LBBAP had **similar pacing thresholds** ( $p = 0.860$ ) and **higher R wave amplitudes** ( $p = 0.009$ ) than RVP.
- ➔ **LBBAP has better clinical outcomes, preserves ventricular electrical and mechanical synchrony and has excellent pacing parameters, with no difference in complications compared to RVP.**



# Left Bundle Branch Area Pacing for CRT

## Multicenter Study prospective in 6 centers (2017/2018)

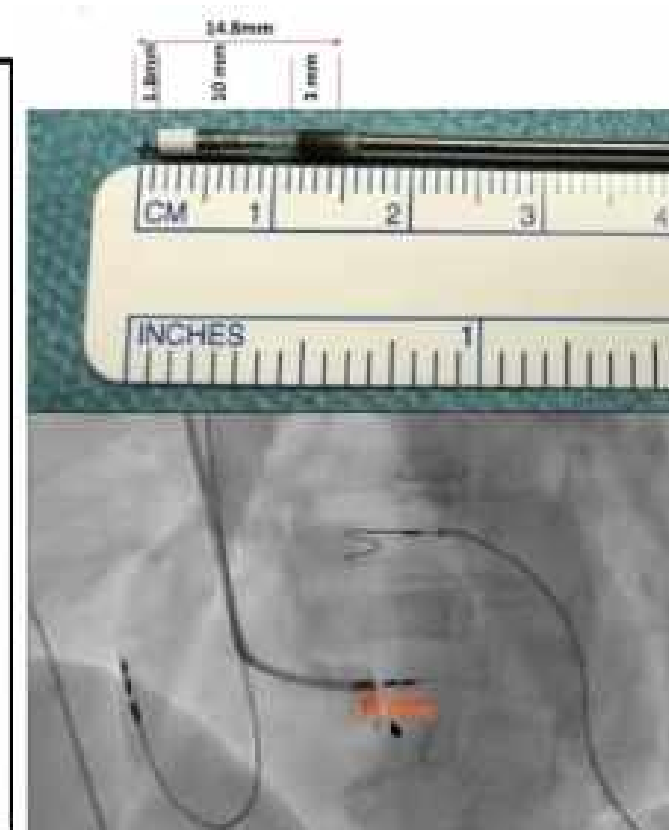
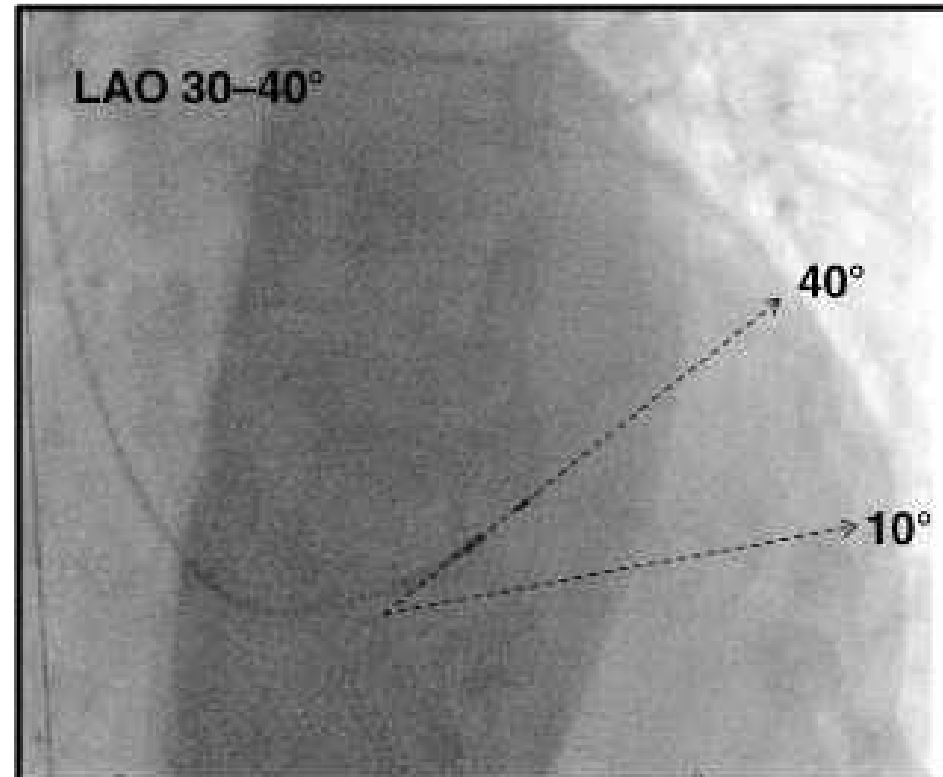
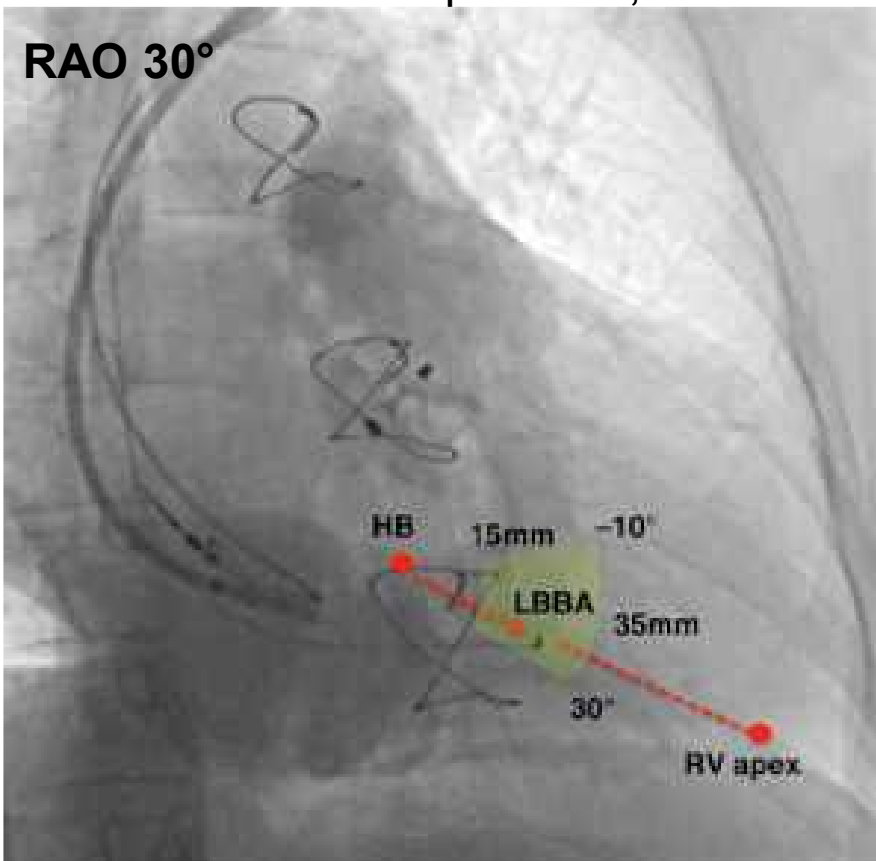
- 63 Patients with CRT-Indication
- 97% Successful LBBP Implantation
- QRS duration narrowed from  $169 \pm 16$  to  $118 \pm 12$  ms ( $p < 0.001$ )
- Pacing threshold and R-wave amplitude remained stable at 1-year follow-up
- LVEF increased significantly ( $33 \pm 8\%$  vs.  $55 \pm 10\%$ ;  $p < 0.001$ )



# Left Bundle Branch Area Pacing for CRT – how to do it?

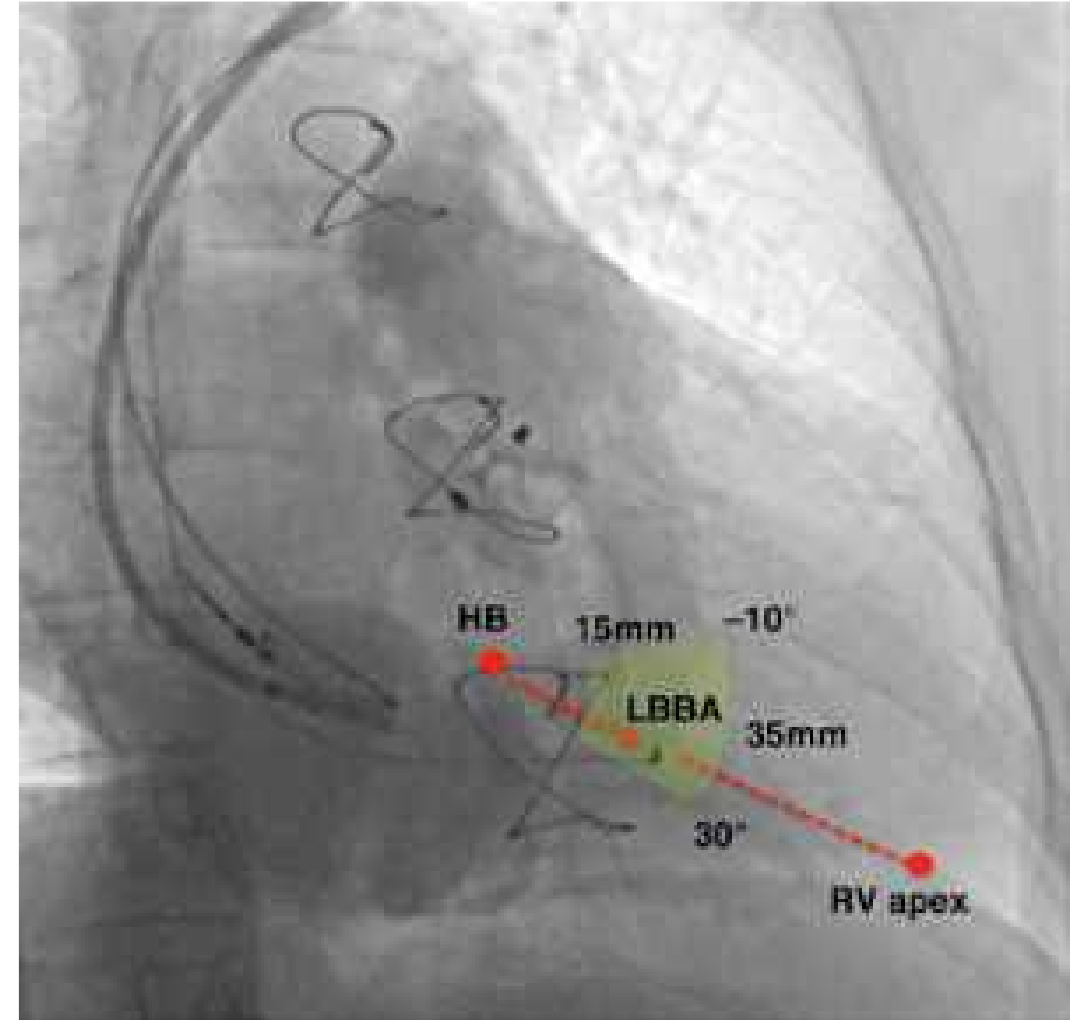
## Orientation via:

- X-ray + if necessary contrast agent (depth)
- 12 channel ECG (!)
- Stimulation impedance,



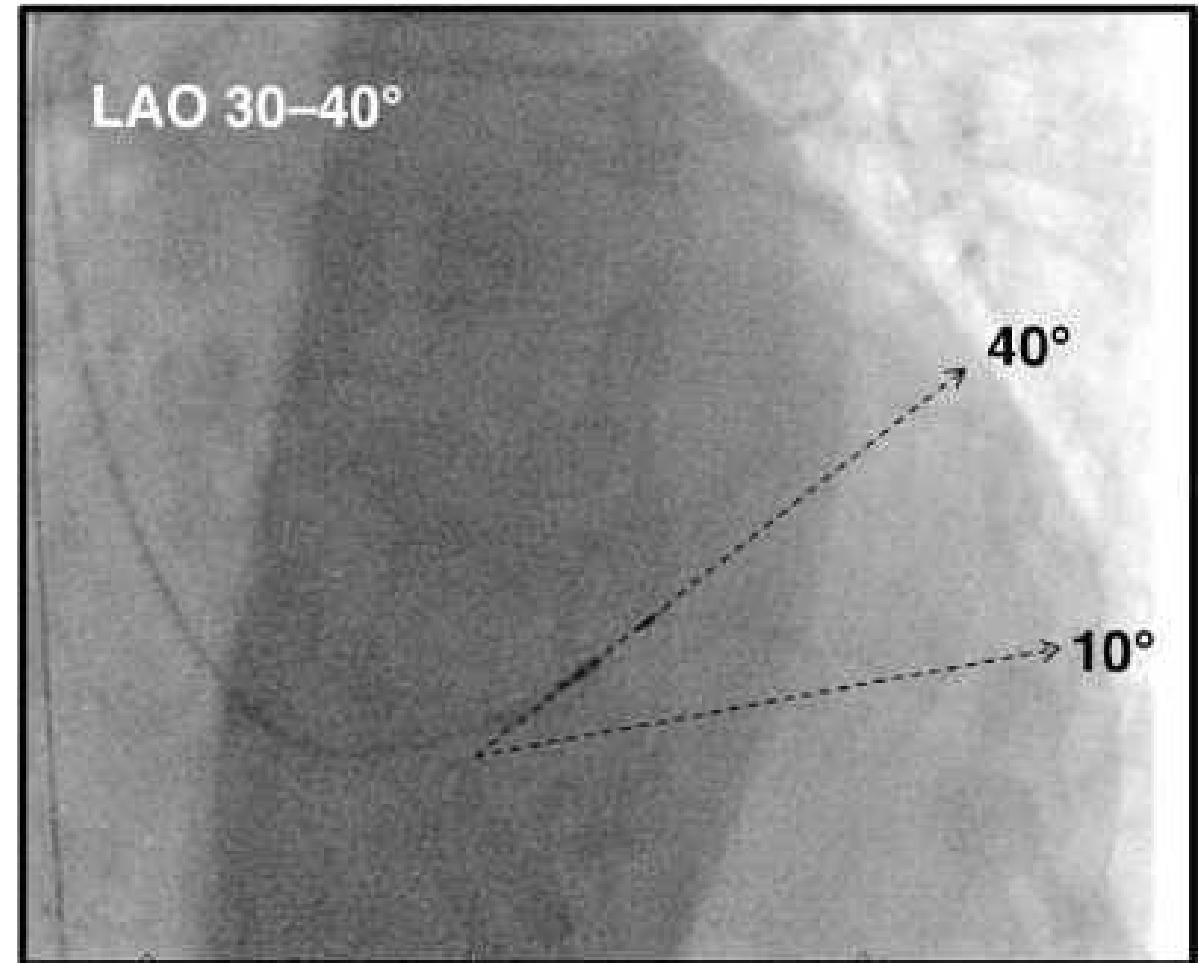
# Positioning the catheter

- Localisation of the His bundle or the tricuspid annulus apex in the RAO 20-30° fluoroscopy  
Save reference image
- Advance the guiding catheter 15-20 mm from the His bundle towards the apex in the right ventricle. The electrode remains in the guide catheter. Turn the catheter anti-clockwise to position it against the septum.
- Advance the electrode by a few millimetres. A potential for injury indicates good wall contact.



# Positioning the catheter

- LAO view from 30-40°. The guiding catheter should orientate the electrode at an angle of 10-40° above the horizontal plane to be perpendicular to the septum.
- An injection of contrast medium via the guiding catheter can optionally be performed to delineate the septum.

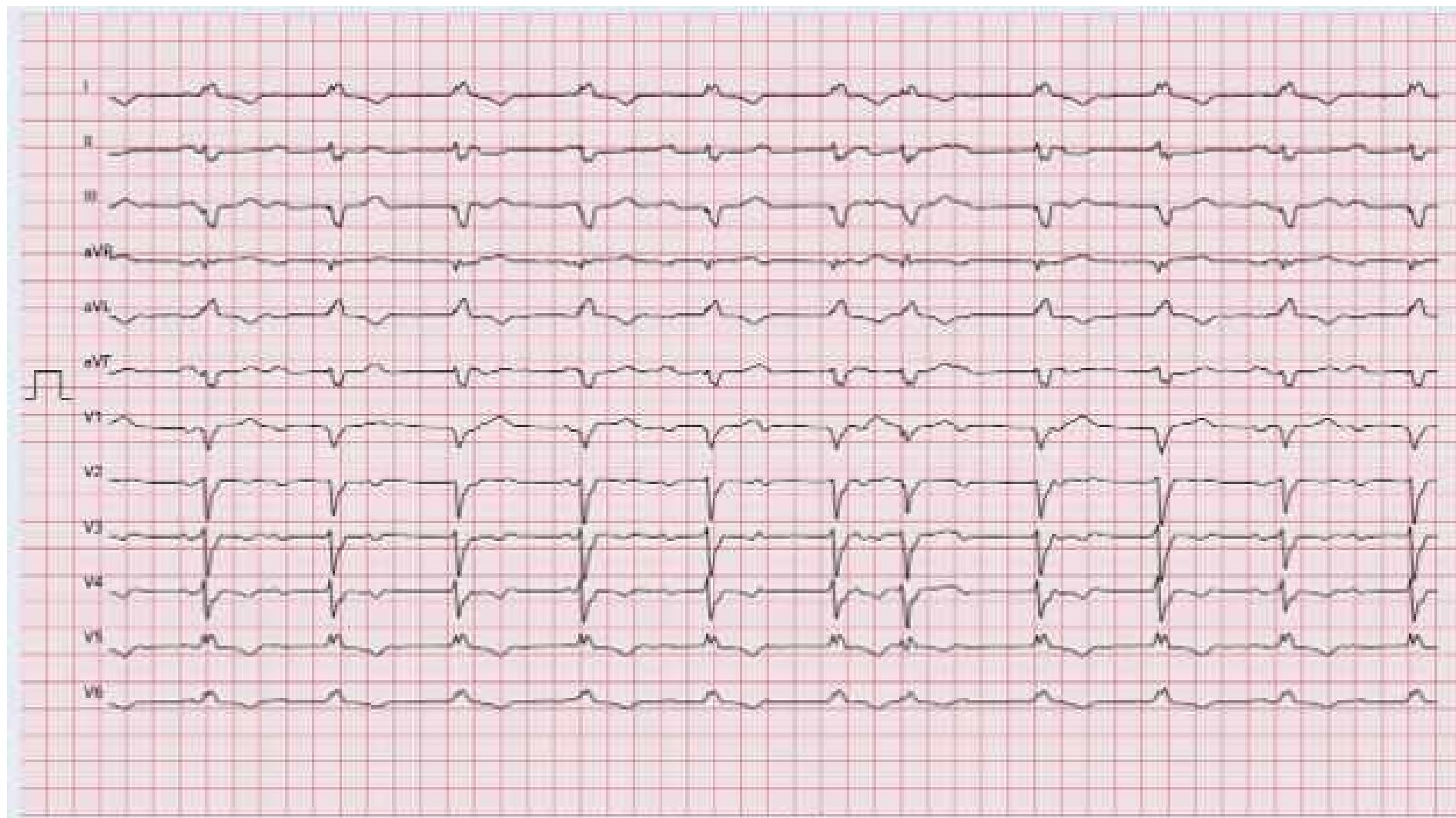


# Conduction-System-Pacing – special case

Patient 47a with AV-Block III° with Corrected Transposition of the Great Arteries

NYHA III

EF 37%



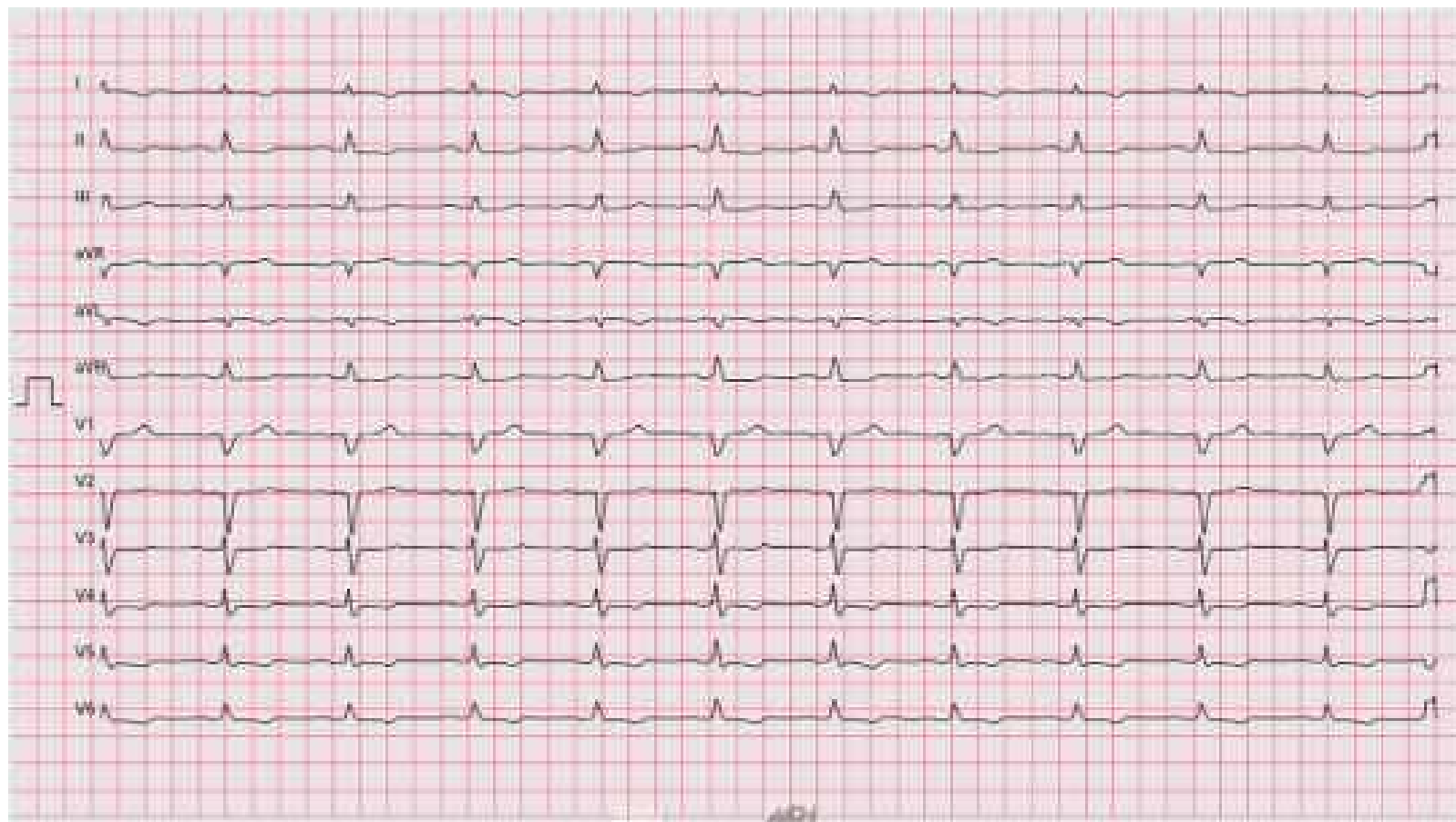
# Conduction-System-Pacing – special case

Patient with AV block III° at cTGA - 1 year later

NYHA I

EF 47%

QRS 110ms



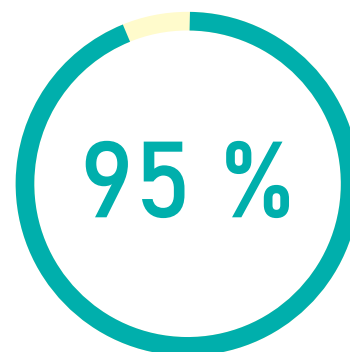
# Conduction System Pacing – Implant Success

With modern catheters and style-driven leads, successful execution of LBBAP procedures is possible!

- European prospective multicenter registry study (n = 353, 8 centers).
- Consecutive enrollment of patients undergoing LBBAP procedure for bradycardia or heart failure.
- Mean follow-up duration = 9±5 months

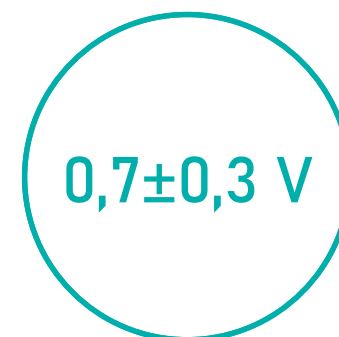


High success  
rate



Implantation  
success

Stable  
stimulation  
thresholds



At 0.4 ms,  
at 12-month  
follow-up.

Low  
complication rates



LBBAP electrode  
revision rate during  
follow-up

Catheters are now available from almost all manufacturers in various designs – **including ICD/CRT-Therapy**

# Conclusions

- Moderne transvenöse Device-Therapie optimiert die Stimulation so physiologisch wie möglich!
- Auch ICD-Systeme bei Stimationsnotwendigkeit mit LBBP-Option



J. ELECTROCARDIOLOGY, 3 (3-4) 325-331 (1970)

Special Article

## Totally Self-Contained Intracardiac Pacemaker\*

J. WILLIAM SPIGELER, M.D., AND S. RABON, PH.D., PAUL KRZYZ, M.D.,  
E. W. MORA, M.D., R. F. BOHLEN, P.E., AND CHARLES LAWITT, P.E.

**SUMMARY**

Recent developments in miniature long-life power sources and electronics, such as nuclear batteries and integrated circuits make feasible a new generation of pacemakers, the intracardiac pacemaker (IC), i.e., a completely

circuits have been improved substantially. In addition, the development of the endocardial catheter electrode has broadened the choice of operative procedures to include a larger portion of the patient population. Two major problems that still exist with conventional pacemakers are perforation or dislocation of

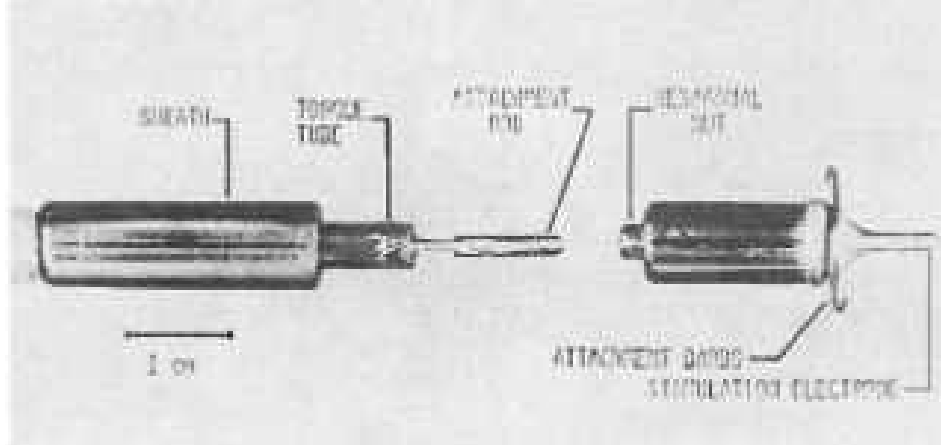


Fig. 4. Intracardiac pacemaker with catheter for transcatheter insertion.

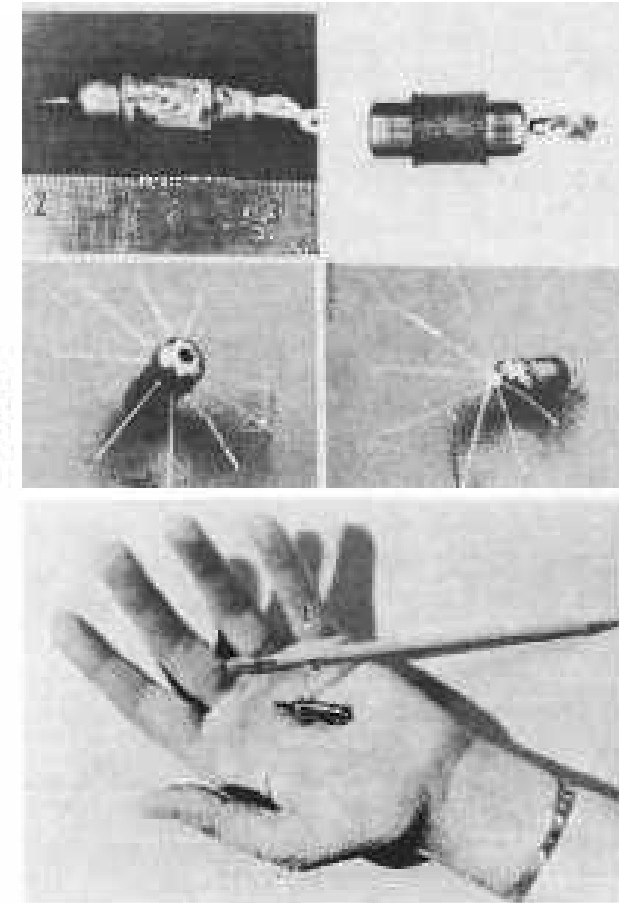
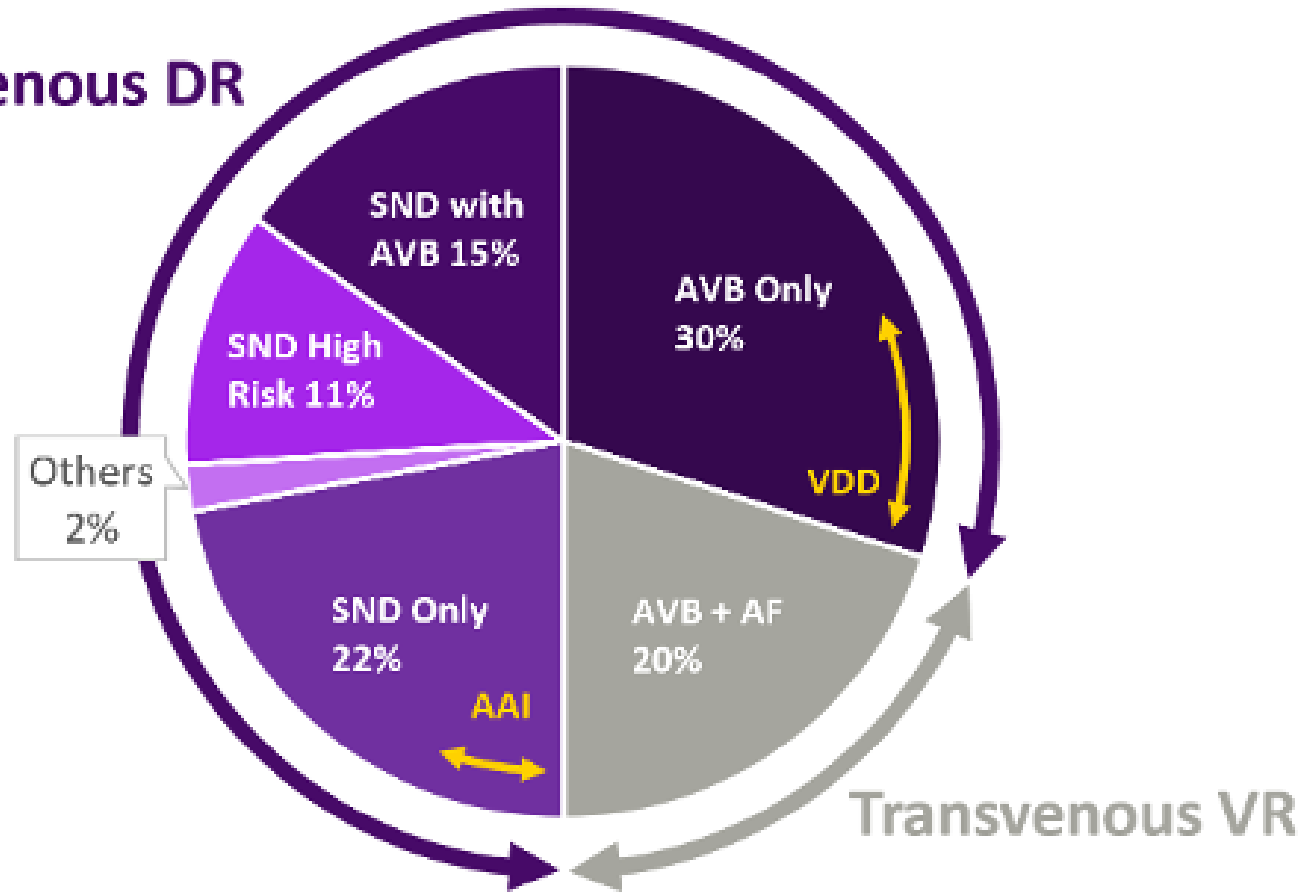


Fig. 8. Nuclear-powered intracardiac pacemaker.

# TV Patient Indication Pie Chart

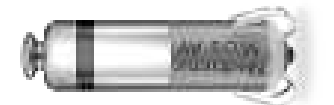
## Transvenous DR



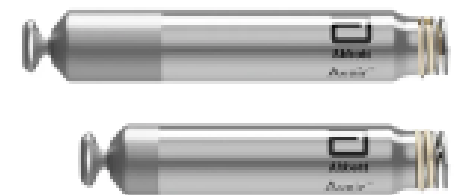
### Leadless VR



### Leadless VDD



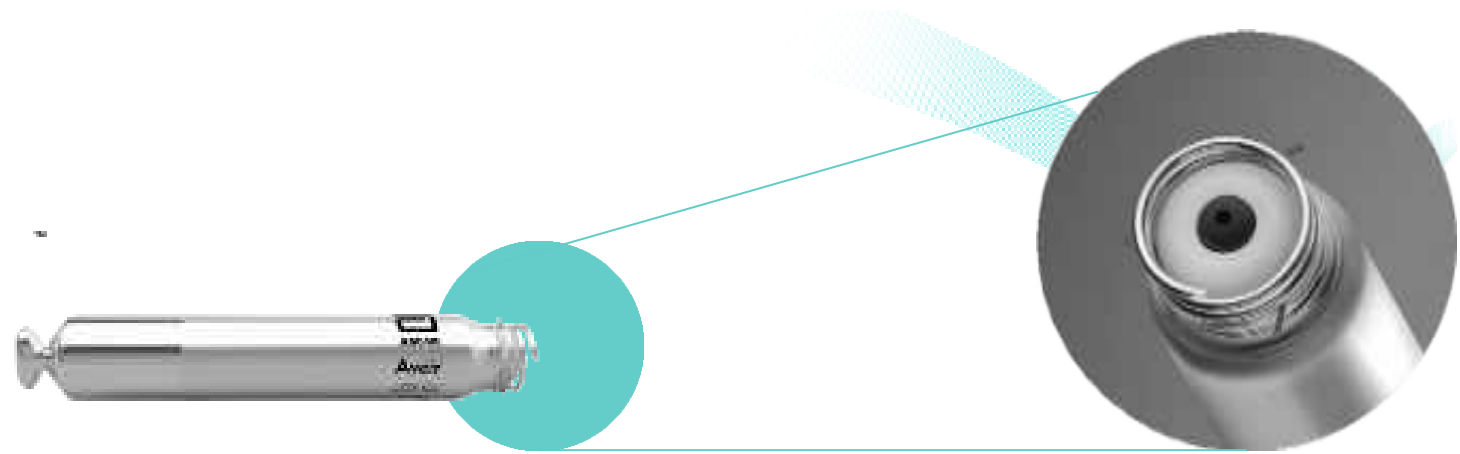
### Leadless DR / AAI



„all“ indications available leadless!

- Burri H, Jastrzebski M, Cano O, et al. EHRA clinical consensus statement on conduction system pacing implantation: endorsed by the Asia Pacific Heart Rhythm Society (APHRS), Canadian Heart Rhythm Society (CHRS), and Latin American Heart Rhythm Society (LAHRS). *Europace* 2023; **25**(4): 1208-36.
- Nielsen JC, Thomsen PE, Hojberg S, et al. A comparison of single-lead atrial pacing with dual-chamber pacing in sick sinus syndrome. *Eur Heart J* 2011; **32**(6): 686-96.
- Kristensen L, Nielsen JC, Mortensen PT, Pedersen OL, Pedersen AK, Andersen HR. Incidence of atrial fibrillation and thromboembolism in a randomised trial of atrial versus dual chamber pacing in 177 patients with sick sinus syndrome. *Heart* 2004; **90**(6): 661-6.

# Extraction – a new option!



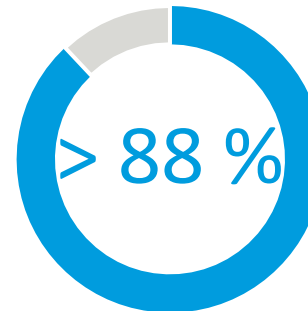
## EXTRACTION MECHANISM WITH THREE-LOOP SNARE FOR REDOCKING



Electrical mapping  
before fixation  
(98% success rate)

## ACTIVE FIXING SCREW

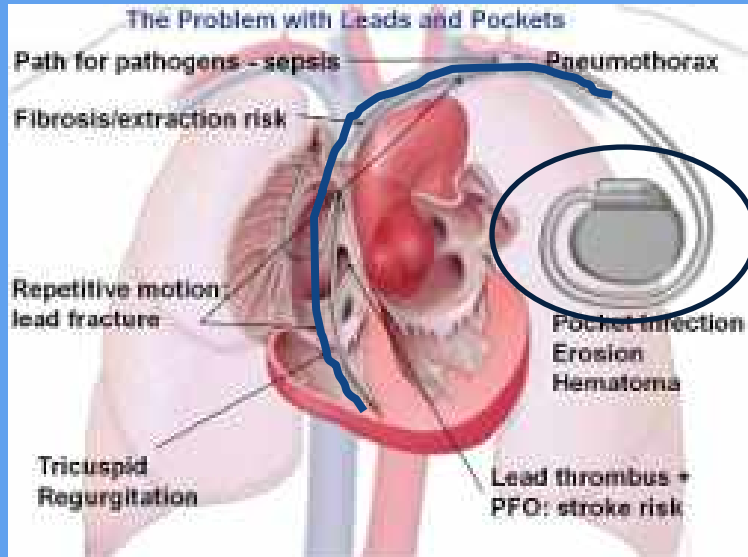
The active fixation screw of the Leadless Pacemaker uses a screw-in mechanism that allows both implantation and extraction of the HSM after a longer period of time.<sup>4</sup>



Range 0 to 9 years  
(mean value  $3.1 \pm 1.8$   
years)n = 241

## OVERALL SUCCESS RATE WITH REGARD TO EXTRACTION

of devices with screw fixation of over 88 % with up to 9 years of extraction experience. The AVEIR VR LeadlessPacemaker is designed for extraction after a longer period of time. Limited data is available for the AVEIR VR Leadless Pacemaker.<sup>3</sup>



## Eliminated Pocket-related Complications<sup>1</sup>

- Infection
- Hematoma
- Erosion

## Eliminated Lead-related Complications<sup>1</sup>

- Fractures
- Insulation breaches
- Venous thrombosis and obstruction
- Tricuspid regurgitation

## Redefined Patient Experience

- No chest scar
- No bump
- No visible or physical reminder of a pacemaker under the skin
- Fewer post-implant activity restrictions

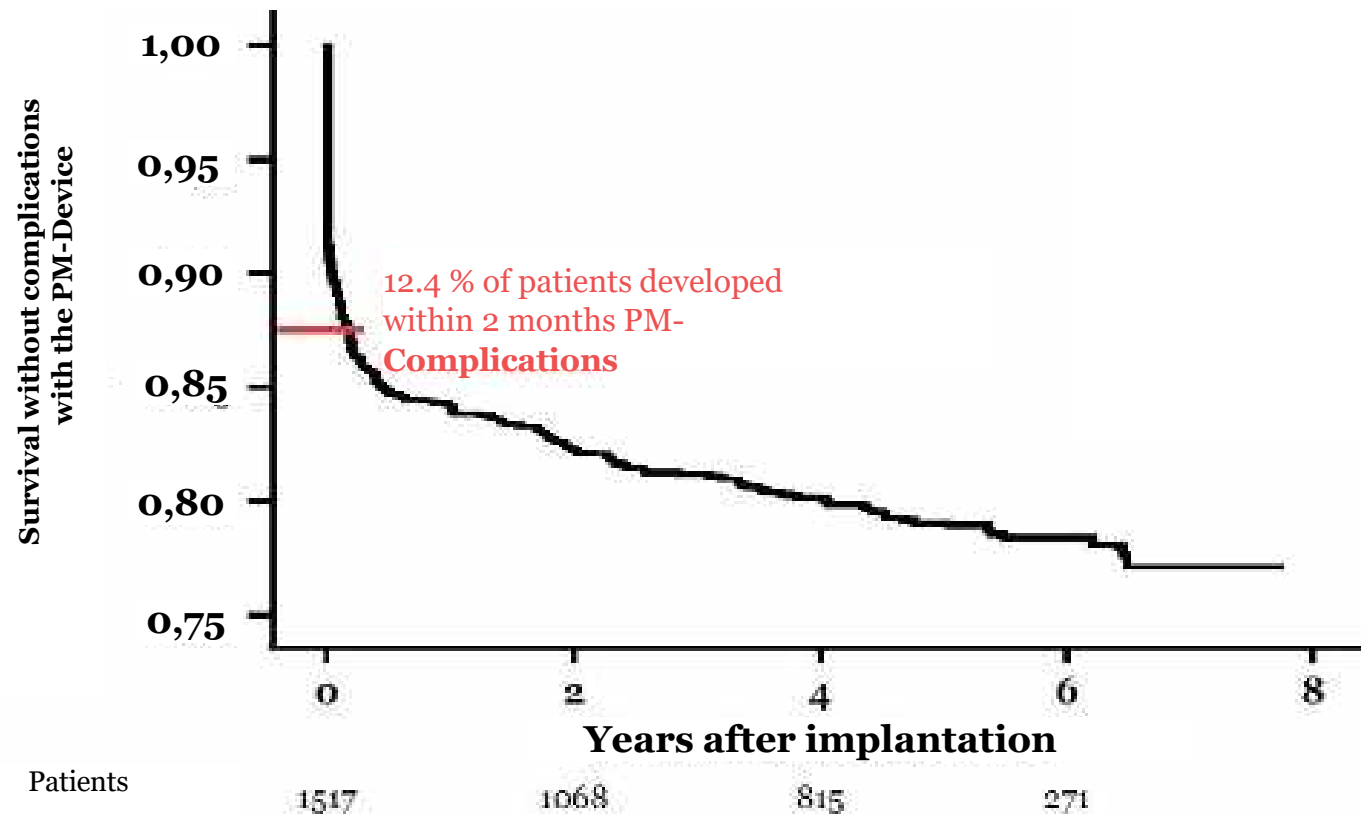
**~1 in 8 patients treated with a traditional pacing system experience a complication attributed to the pocket or leads.<sup>1</sup>**

**Lead- and pocket-related complications can be costly to the hospital and patient.<sup>2</sup>**

<sup>1</sup>Udo EO, Zuithoff NP, van Hemel NM et al. Incidence and predictors of short- and long-term complications in pacemaker therapy the FOLLOWPACE study. *Heart Rhythm*. May 2012;9(5):728-735.

<sup>2</sup>Cantillon DJ, Exner DV, Badie N, et al. Complications and Health Care Costs Associated With Transvenous Cardiac Pacemakers in a Nationwide Assessment. *JACC Clin Electrophysiol*. November 2017;3(11):1296-1305.

# Complications in transvenous Pacemaker Patients



Results of the  
FOLLOWPACE-  
STUDY<sup>1</sup>

**1517** Patients with an  
average follow-up time  
of **5,8 years**

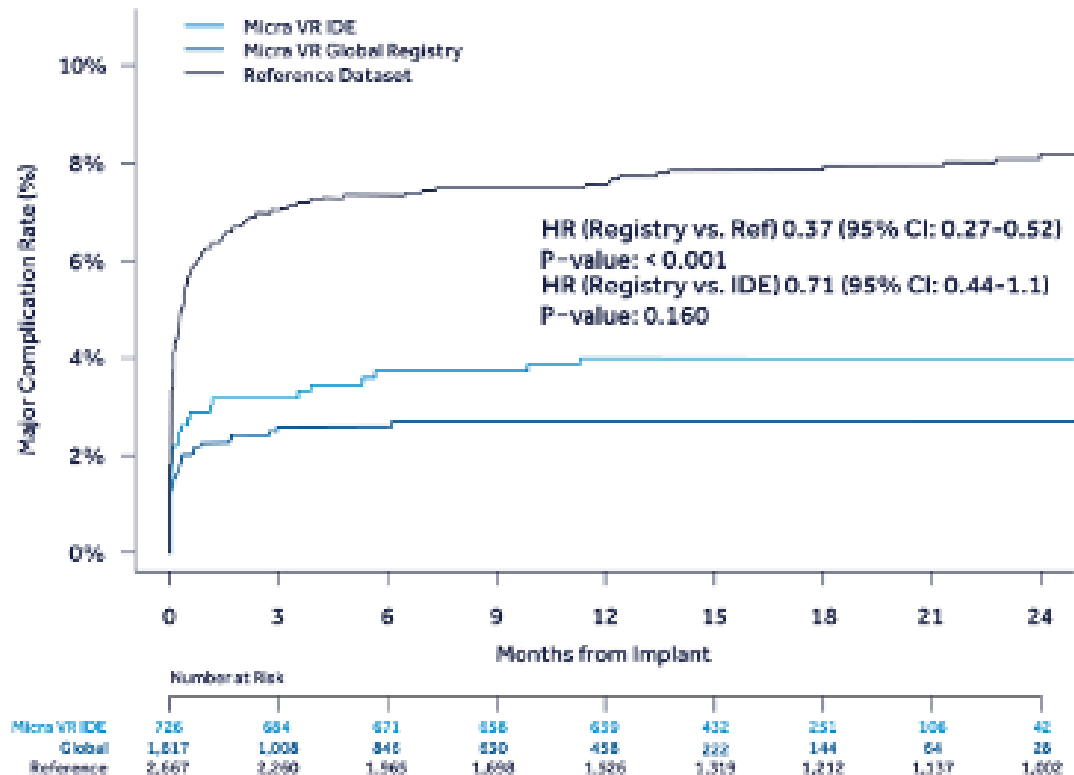
## COMPLICATIONS

acute: 10–15 %

chronic: 9–10 %

<sup>1</sup> Udo EO, Zuithoff NP, van Hemel NM et al. Incidence and predictors of short- and long-term complications in pacemaker therapy the FOLLOWPACE study. *Heart Rhythm*. May 2012;9(5):728-735.

## 4,000+ PATIENTS STUDIED



**63%**

Fewer major complications than traditional pacemakers (n = 1,817).<sup>3</sup>

### Updated performance of the Micra VR transcatheter pacemaker in the real-world setting<sup>3</sup>

#### Objective

To report updated performance of the Micra VR transcatheter pacemaker from a worldwide PAR and compare it with the IDE study and a transvenous historical control.\*

#### Analysis Design

System- or procedure-related complications through 12 months were compared for 1,801 successfully implanted leadless VR registry patients versus 726 Micra VR IDE patients and 2,667 patients with transvenous pacemakers.

#### Results

Performance of leadless VR in real-world clinical practice remains consistent with previously reported data.

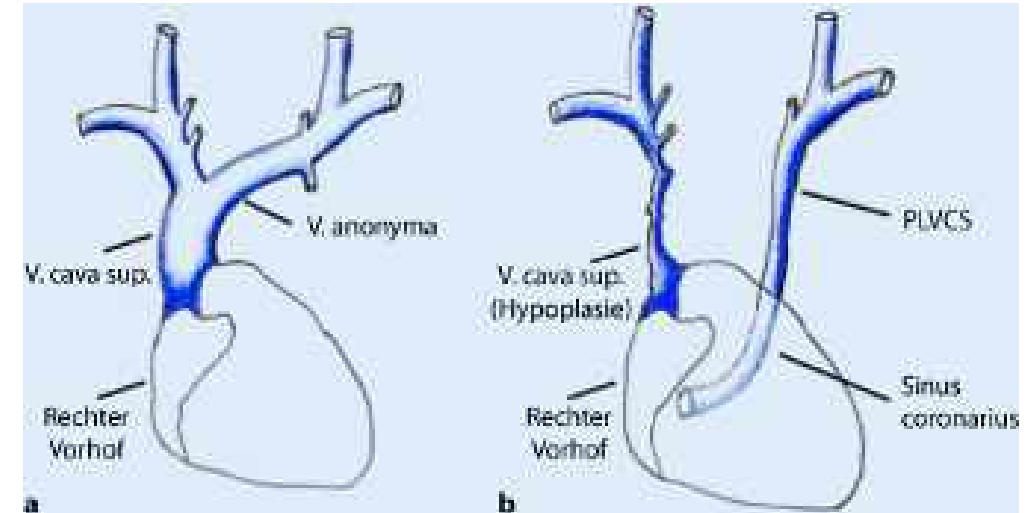
**AVEIR PREMIER LEADLESS  
Registry started!**

\*Historical cohort comprised of 2,667 patients from six trials of commercially available technology (HR: 0.44 vs. IDE, 95% CI: 0.31-0.61). Propensity matching to a subset of the historical control confirmed a reduction in major complications.

## Punction right



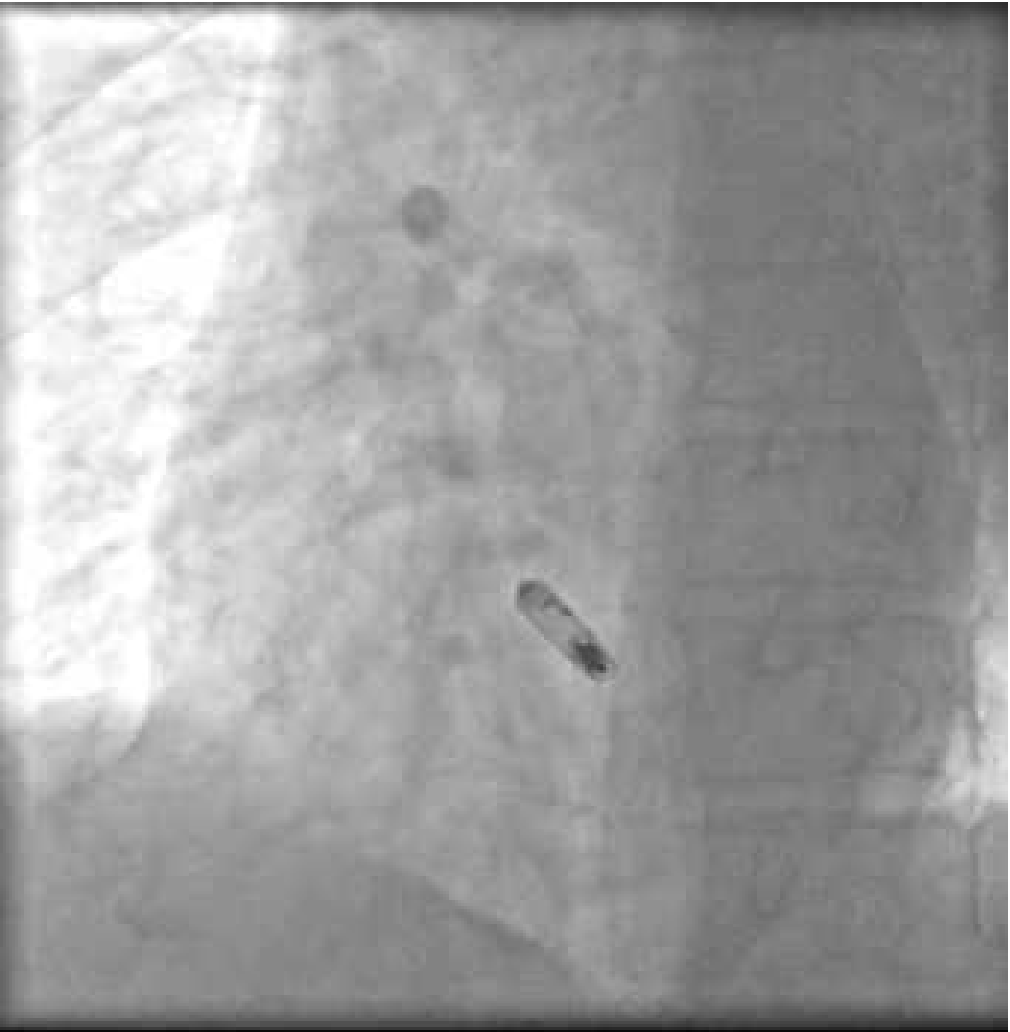
## Persistent left superior vena cava



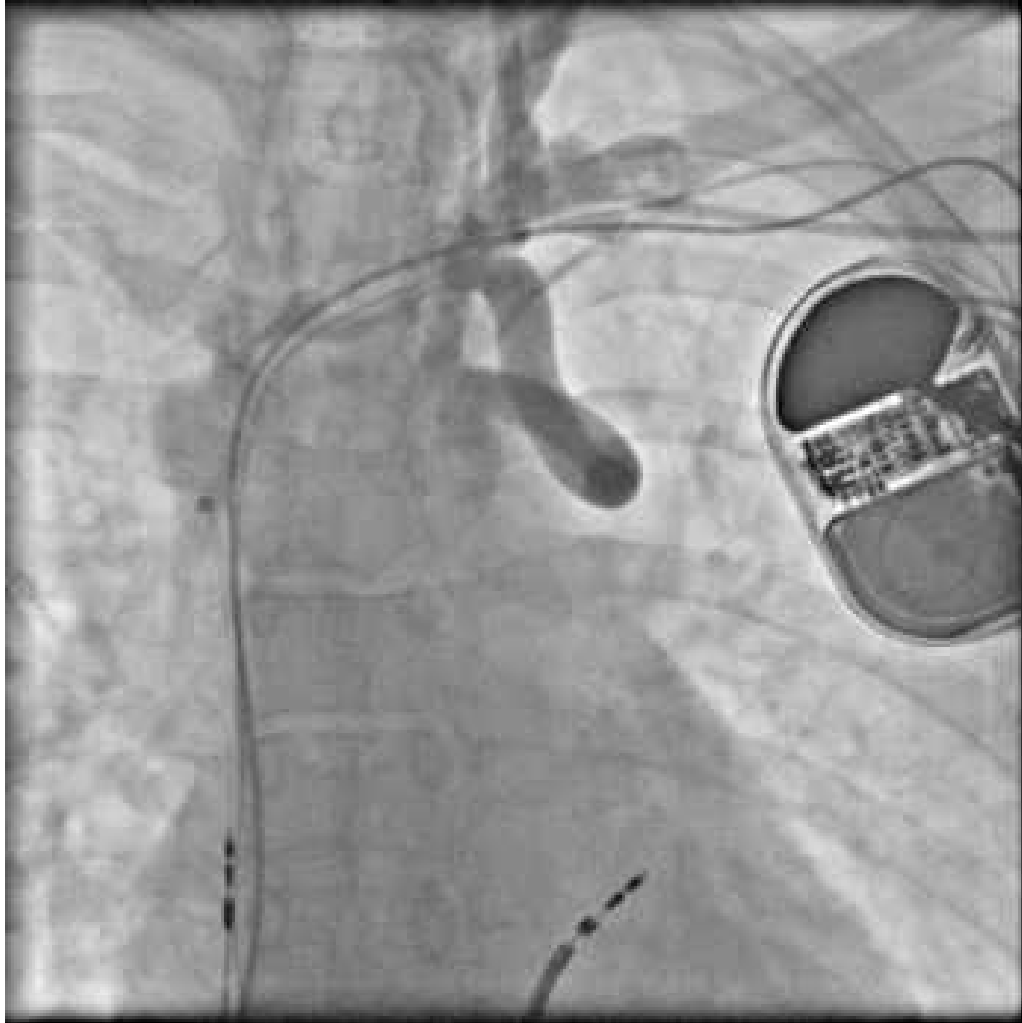
- Incidence 0.5-2%.
- In 82-90% of cases, the right superior vena cava is also present but may be smaller
- Less commonly, the left superior vena cava may also drain into the left atrium
- Very less common: Both subclavian veins drain into the CS

# limited venous access – aFib Patient

## Punction right



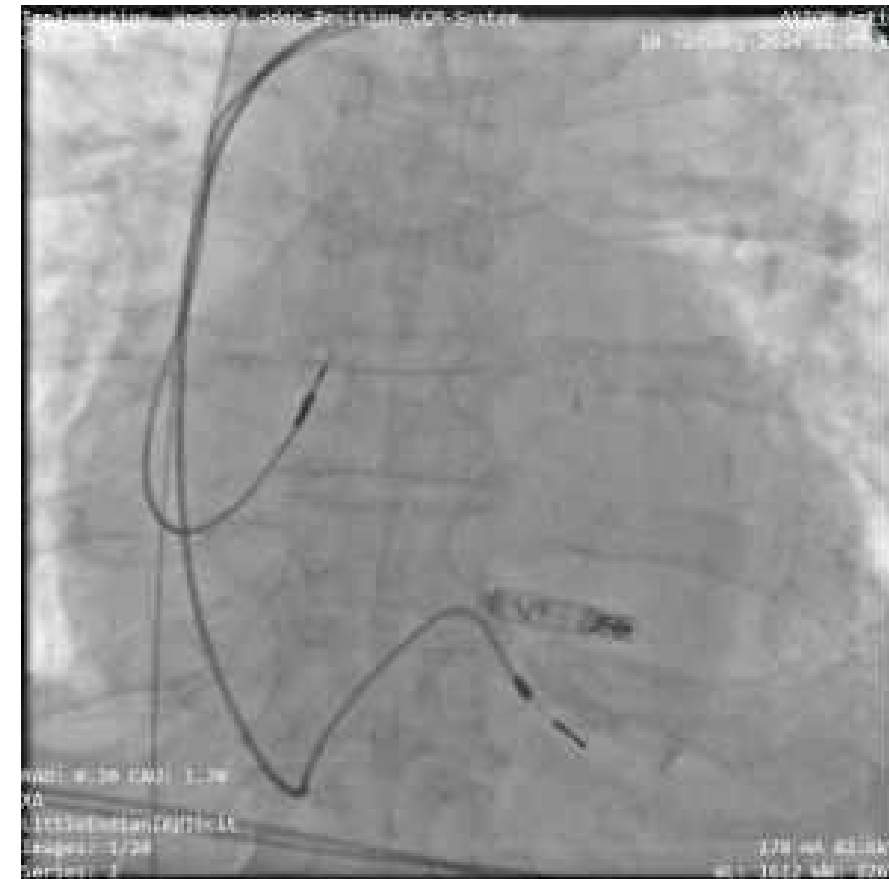
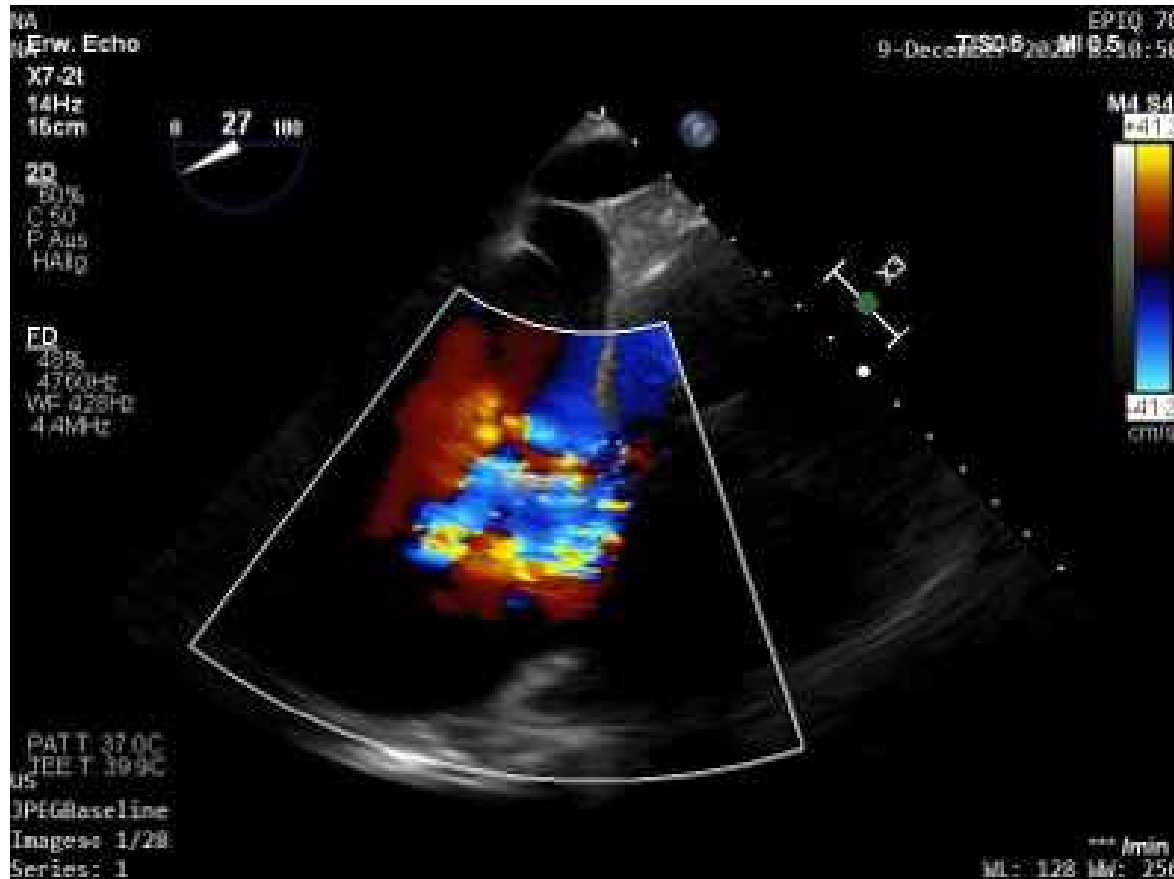
# Device-related stenosis or thrombosis of the upper veins



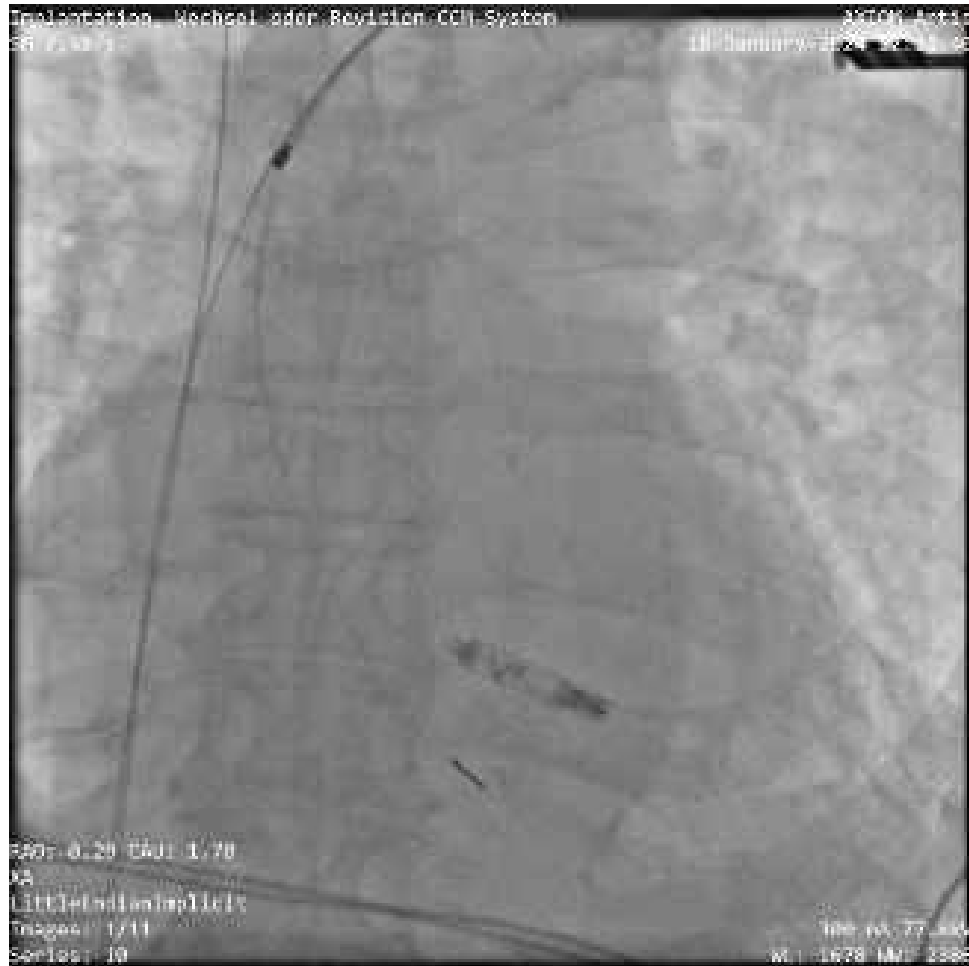


- **Underrepresented clinical picture**
  - High number of unreported cases
- Unspecific symptoms
  - Migraine
  - Feeling of congestion (arm or head)
  - Noisy ears
  - arm weakness
- Treatment still not very standardized
- Anticoagulation mostly unsuccessful

# Severe tricuspid valve insufficiency



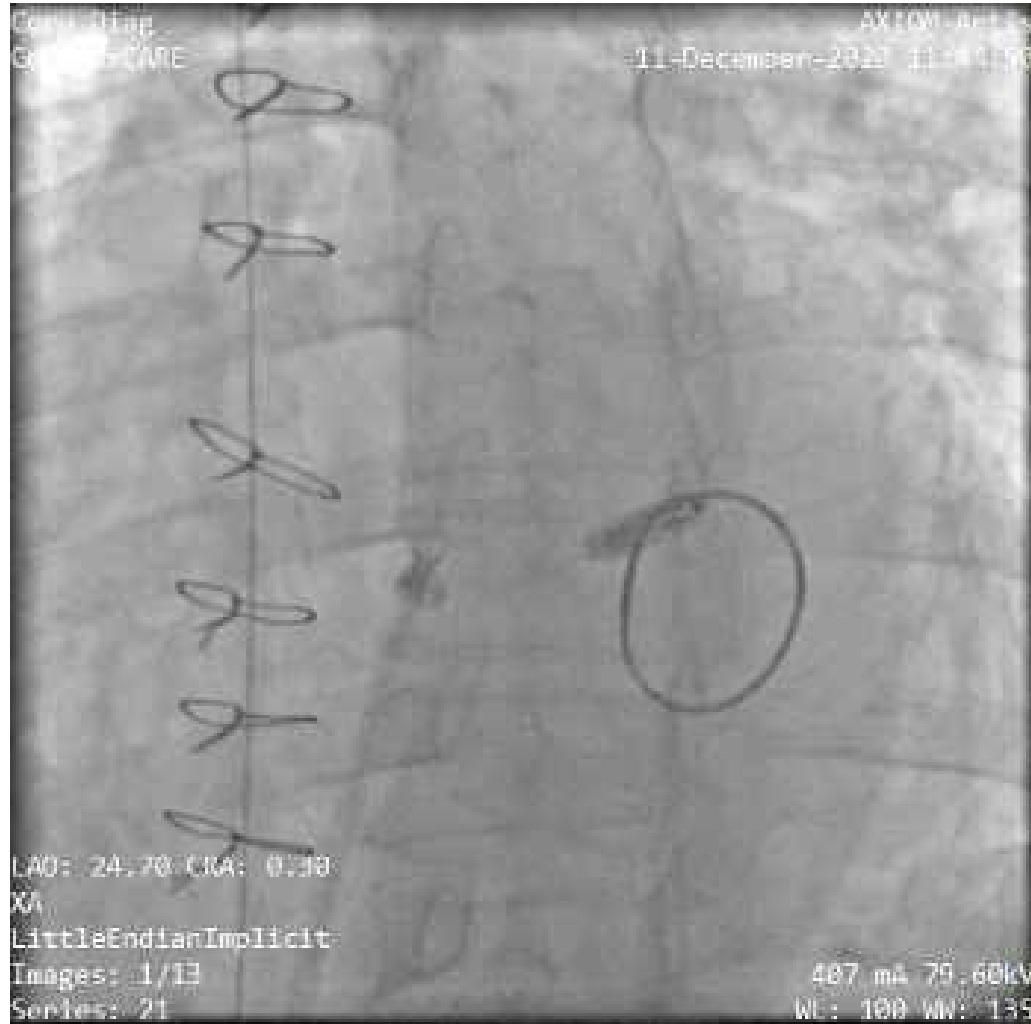
# Severe tricuspid valve insufficiency



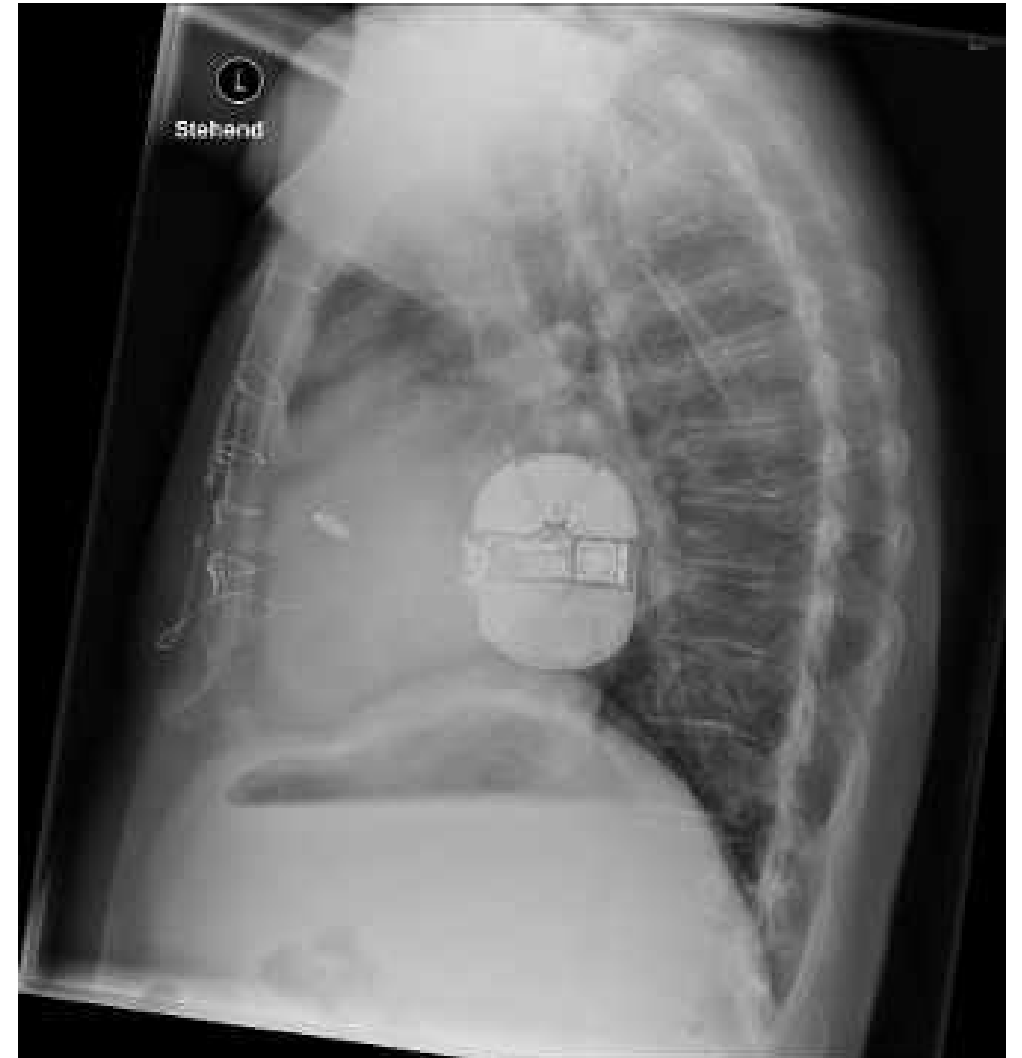
# Severe tricuspid valve insufficiency – Case II



# Severe tricuspid valve insufficiency – Case II



# Severe tricuspid valve insufficiency – Case II



## EHRA Position Paper 2022

### ESC Pacing Guidelines 2021

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>
Leadless pacemakers should be considered as an alternative to transvenous pacemakers when no upper extremity venous access exists or when risk of device pocket infection is particularly high, such as previous infection and patients on haemodialysis. <sup>45,47–50,450</sup>	IIa	B
Leadless pacemakers may be considered as an alternative to standard single-lead ventricular pacing, taking into consideration life expectancy and using shared decision-making. <sup>45,47–50</sup>	IIb	C

© ESC 2021

➔ Update needed?

Table 2. LCPM position statements based on the underlying arrhythmia and clinical circumstances based on expert opinion

Pacing indication clinical conditions	Transvenous VVI or VVI with need of backup pacing and low anticipated ventricular pacing burden	Best current available history syncope and low anticipated ventricular pacing burden <sup>a</sup>	DR with complete AVB with a sinus node for a high tracking rate	Permanent AF on a CVD where ventricular response is well tolerated and no need for increased ventricular pacing rate	DR and AVN with increased anticipated ventricular pacing burden <sup>b</sup>	DR with increased anticipated ventricular pacing burden <sup>b</sup>
Minimally symptomatic atrial fibrillation, if one or long-term heart disease	♥	♥	♥	♥	♥	♥
History of frequent or QRS-tachycardia, if possible avoid catheter ablation, history of recurrent electrical fast (e.g. supraventricular tachycardia)	♥	♥	♥	♥	♥	♥
Triglyceride elevation risk (e.g. low cholesterol or more)	♥	♥	♥	♥	♥	♥
Recurrent atrial tachycardia	♥	♥	♥	♥	♥	♥
Heart failure and moderate to severe (NYctal volume >400 ml) raising ICD therapy	♥	♥	♥	♥	♥	♥
Age < 60 years including young patients < 30 years of age	♥	♥	♥	♥	♥	♥
Profound sinus node dysfunction	♥	♥	♥	♥	♥	♥

<sup>a</sup> No atrial fibrillation, AF, atrial tachycardia, AVB, AVN, or sinus node dysfunction; <sup>b</sup> Atrial AF, atrial tachycardia, AVB, atrial fibrillation, AVN, or sinus node dysfunction.

## Main Recommendations

- **Education for implanters and referrers regarding the benefits and safety** of leadless pacing systems should be improved.
- **Awareness and training** on the use of leadless devices should be improved **for non-leadless implanters**.
- A **registry should be developed** to track the complications and risks associated with the use of leadless devices.
- **Leadless devices should be more widely used** so that implanters can better understand and mitigate the risks involved with the device.
- The **choice to use a leadless pacemaker** should be **clinically driven** to ensure the **best outcome** for the patient.

## Delphi process in UK Device-Centers

72 implanters identified

- \_ 40% response rate
- \_ 23 of 36 statements
- \_ ≥90% agreement

## Main Recommendations

- Leadless pacemakers should be considered in certain patient populations (Table 2).

**Table 2: Recommended Patient Criteria for Considering Leadless Pacemaker Implantation**

• High risk of infection
• End-stage renal disease
• Previous device infection
• Anatomical constraints complicating/precluding transvenous pacing
• Immunocompromised
• Biological medicines (including immunosuppressants and steroids)
• Undergoing radiotherapy
• Congenital heart disease
• Under 40 years of age
• Have, or at high probability of needing, indwelling vascular catheters

## Delphi process in UK Device-Centers

72 implanters identified

- \_ 40% response rate
- \_ 23 of 36 statements
- \_ ≥90% agreement

# Data for AAI Pacing?

Permanent single-chamber atrial pacing: an obsolete or viable alternative to dual-chamber pacing in selected patients with sinus node disease?

Prof. Michaela P. März, MD, PhD, Jochen Böhm, MD

**Monitoring of the AV conduction is relevant over the entire lifetime of the patient!**

**No impact on mortality - is presentation with symptoms sufficient?**

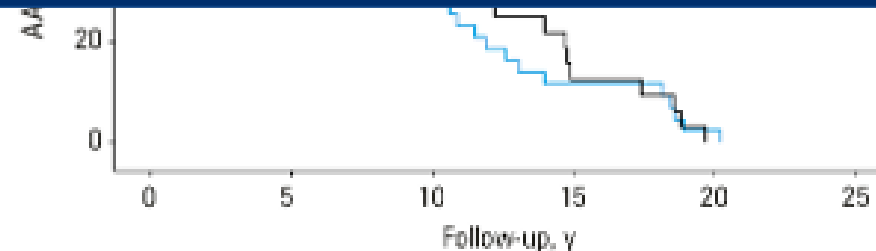
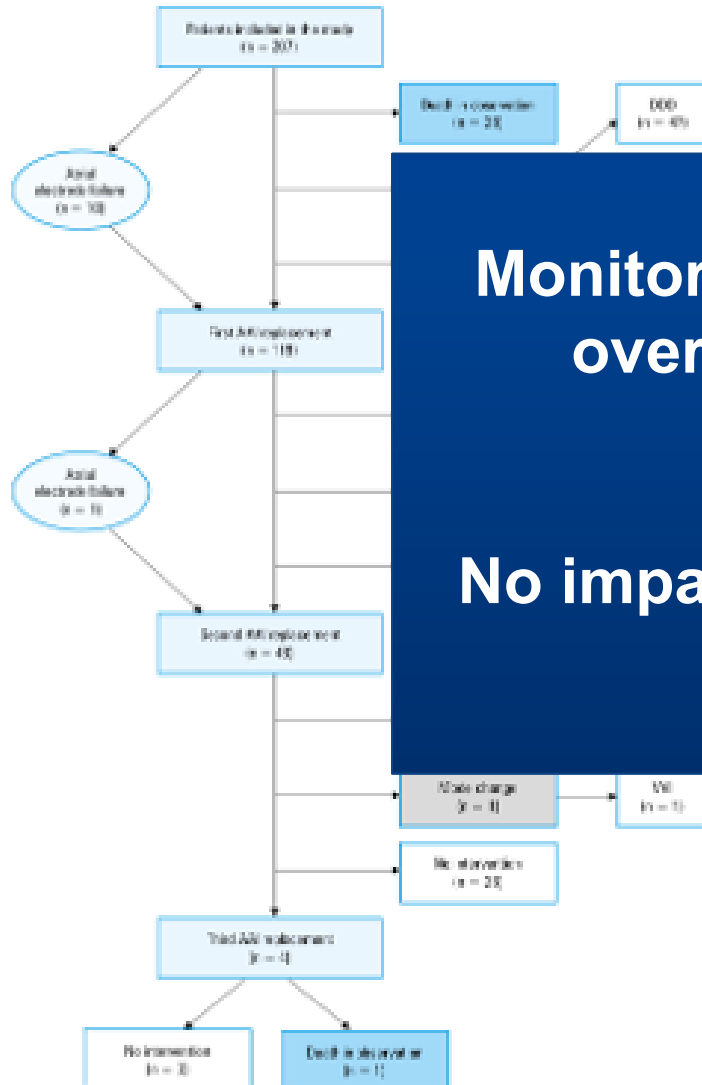
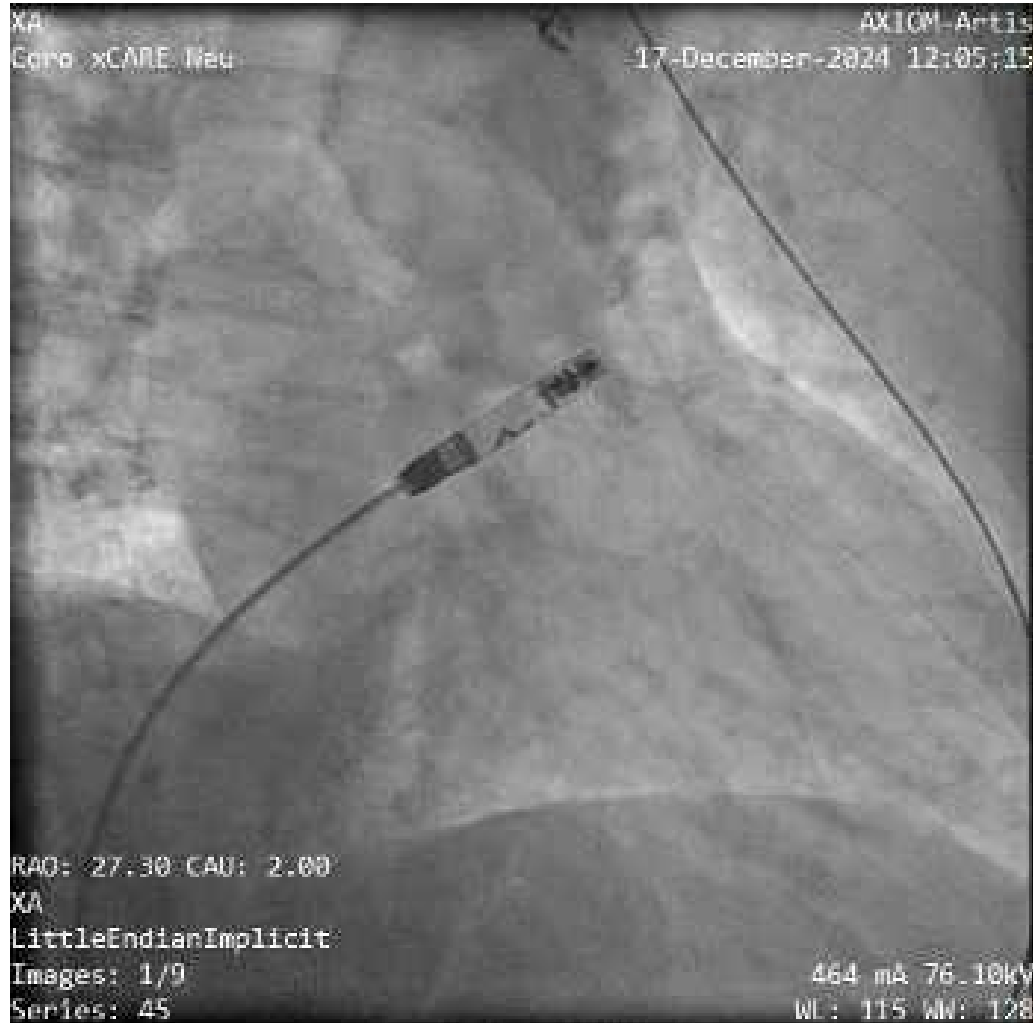


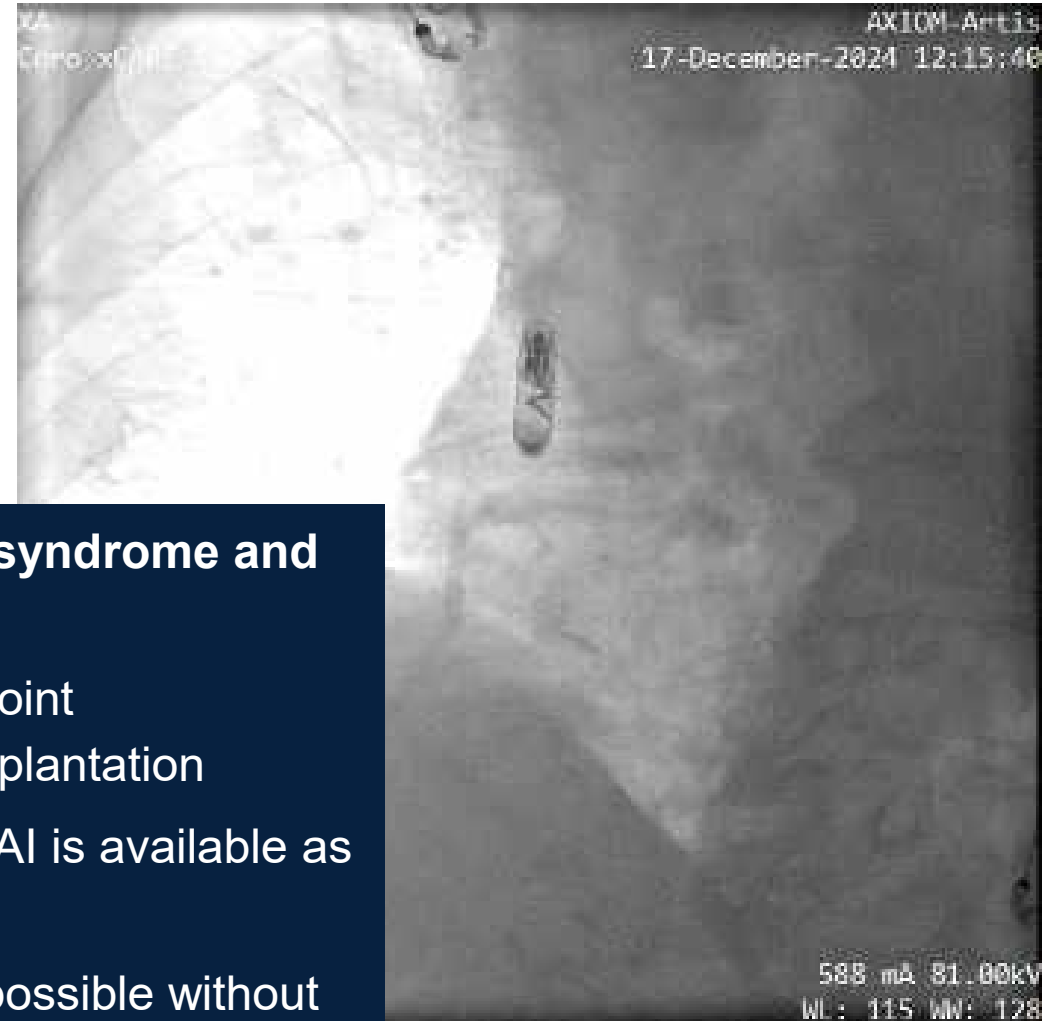
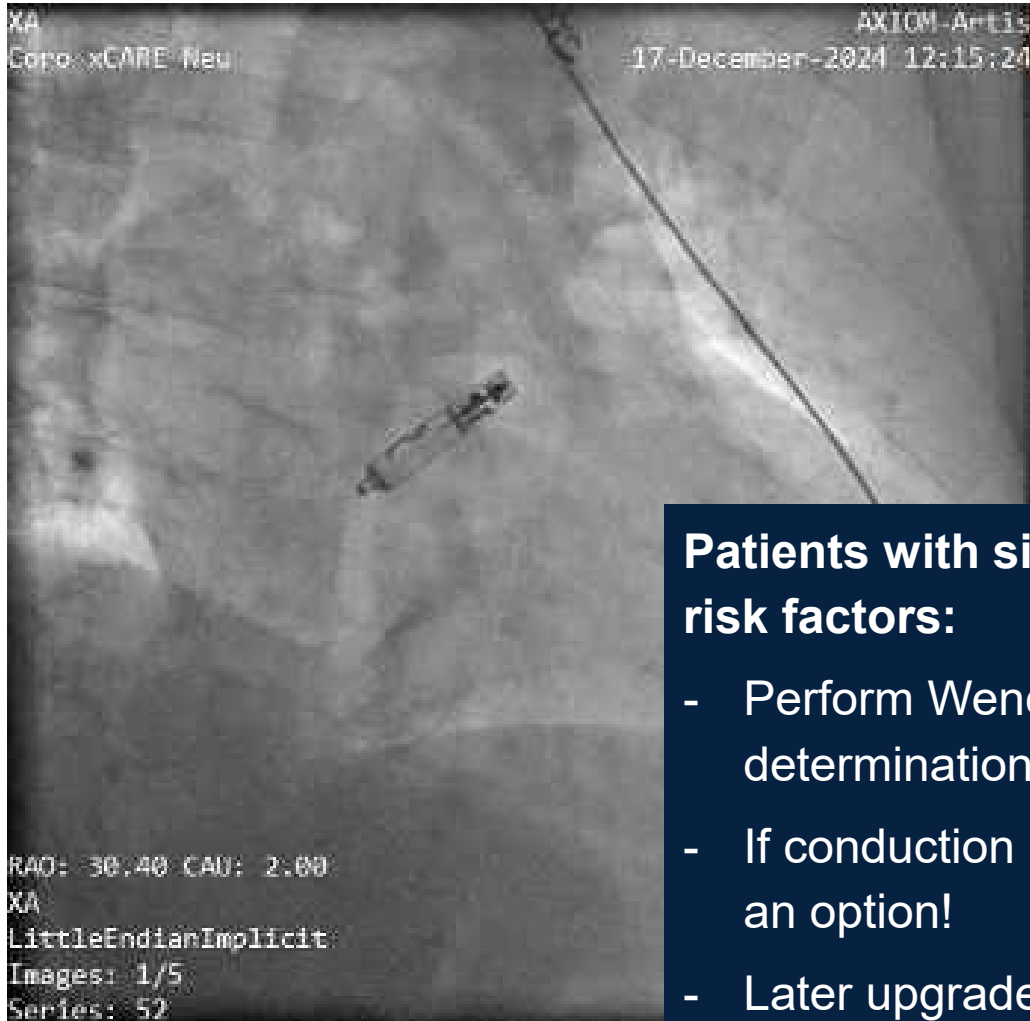
Figure 2. Cumulative maintenance of AAI pacing mode in the Kaplan-Meier analysis; log rank (Mantel-Cox)  $P = 0.55$

Abbreviations: AVB, atrioventricular block; others, see [Table 1](#)

# AAI stimulation revived?



# AAI stimulation revived?



## Patients with sick sinus syndrome and risk factors:

- Perform Wenckebach point determination during implantation
- If conduction is good, AAI is available as an option!
- Later upgrade to DDD possible without any problems

# DDD leadless – a new option!

Alle Pacing-  
Optionen jetzt auch  
leadless einsetzbar!



Two dedicated  
pacemakers



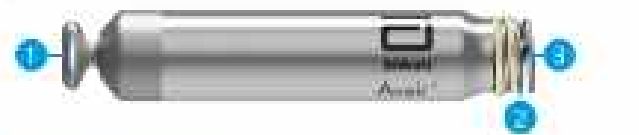
Upgradeable



Implantation in  
two chambers



AV synchronisation  
(95% synchronicity)



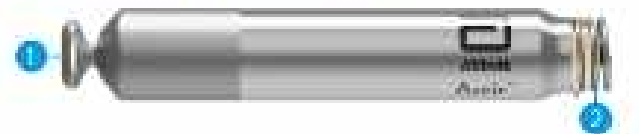
AVEIR® AR Atrial LP

- 1. Driving button
- 2. Outer fixation helix
- 3. Inner helix tip electrode

Length: 32.2 mm Diameter: 6.5 mm

The atrial device has an additional sense helix that is used as a sense helix for pacing and sensing, while also designed to provide stable anchoring and stability in the atrium.<sup>1</sup>

## THE VENTRICULAR DEVICE

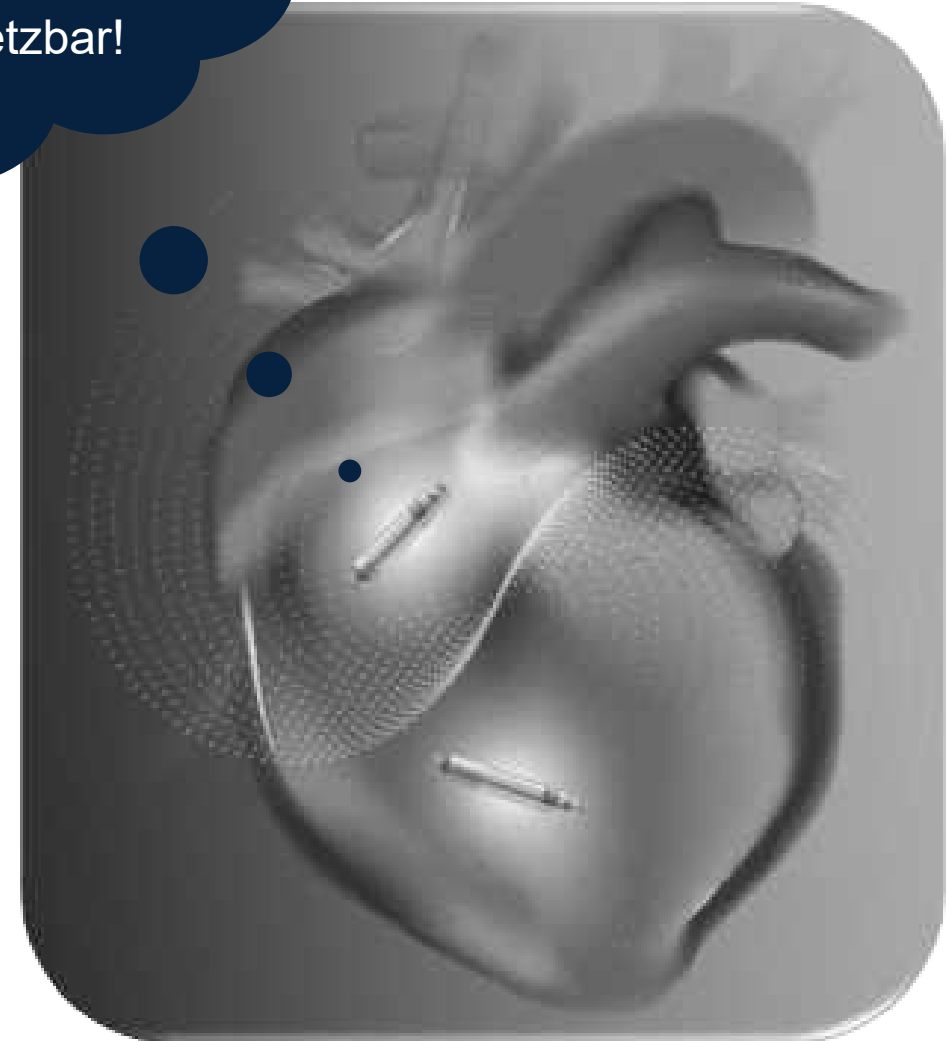


AVEIR® VR Ventricular LP

- 1. Driving button
- 2. Fixation helix and distal sense tip electrode (see picture)

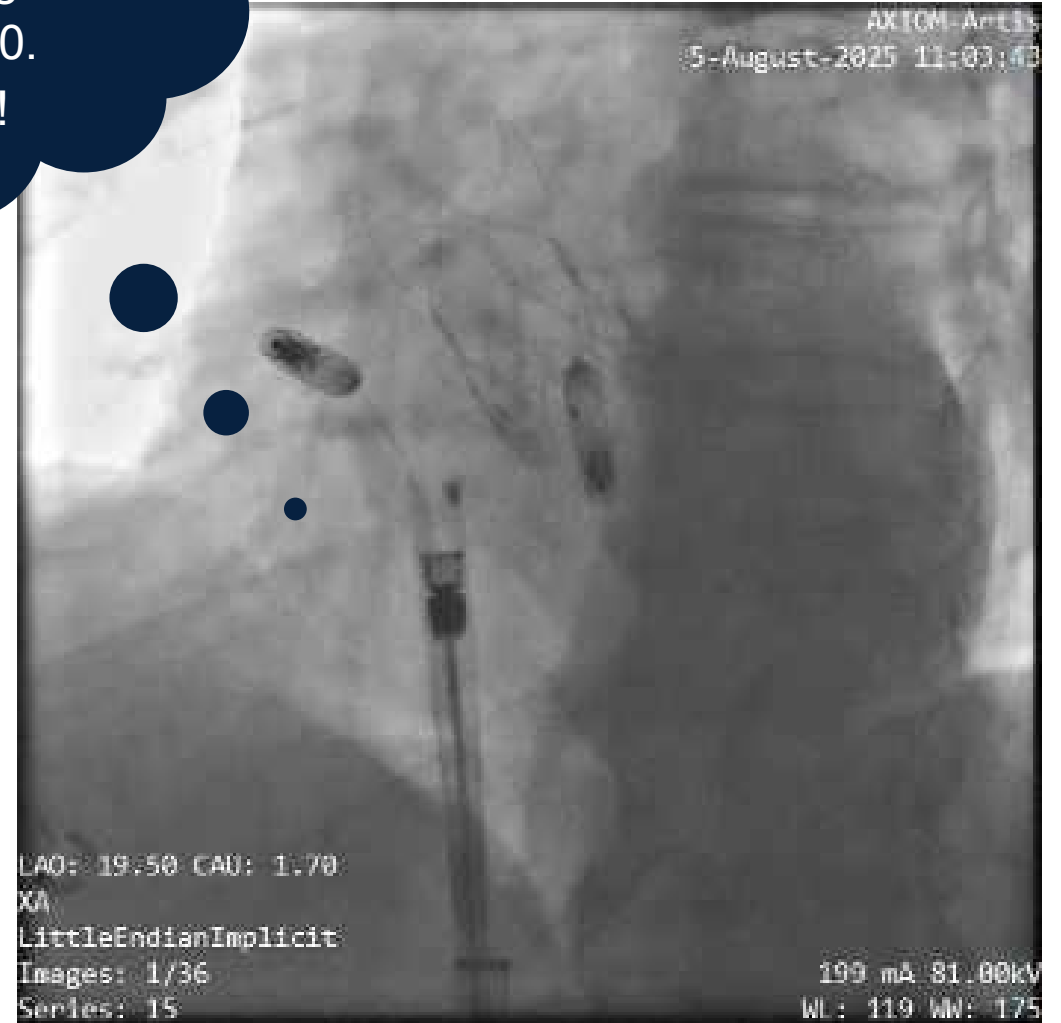
Length: 31.3 mm

Diameter: 6.5 mm



# DDD leadless possible

NUB  
Beantragung bis  
zum 31.10.  
möglich!

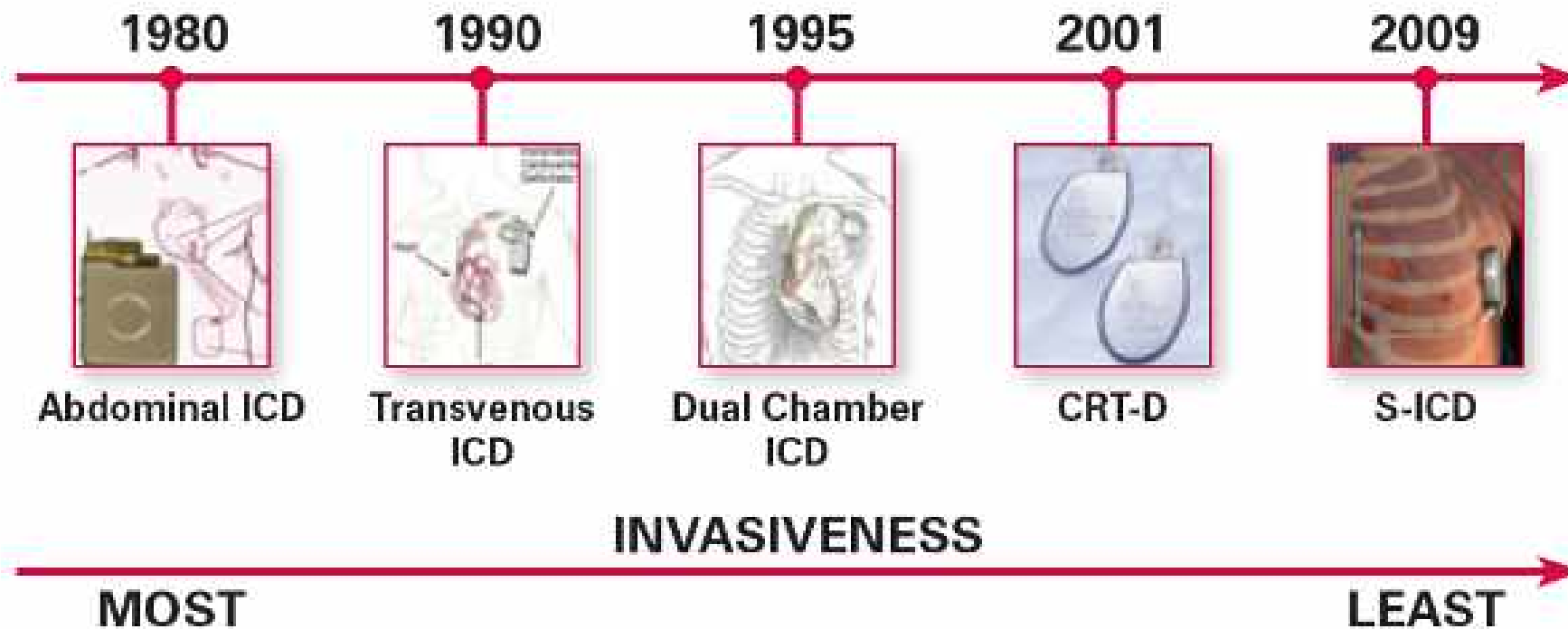


# Device Selection – TUM Checklist

- ✓ **Patients with severe kidney disease / dialysis**
- ✓ **Previous infections / high infection risk (e.g. diabetes, Immune insufficiency, i.v. catheters)**
- ✓ **Thrombosis/occlusion of the subclavian vein or lack of venous access**
- ✓ **Post-lead extraction**
- ✓ **Tricuspid valve insufficiency / right heart failure**
  
- ✓ **Carcinoma patients / Radiotherapy necessary / chemo-therapy necessary**
- ✓ **Existing defective leads**
- ✓ **Patients with a high risk of pneumothorax (e.g. older, BMI <25 or COPD patients)**
- ✓ **Patients with a high CHADS-VASC-SCORE and continued anticoagulation (high risk of pocket haematomas)**
- ✓ **Psychiatric patients / dementia patients**
- ✓ **Special requirements in congenital heart disease or for young patients (e.g. climbing)**

**Prevention of transvenous Leads is a goal in modern Device-Therapy**

# Subcutaner ICD



# Alternative Systeme – subcutaner ICD

Das System wird komplett subkutan implantiert,  
es werden keine intrakardialen Sonden benötigt

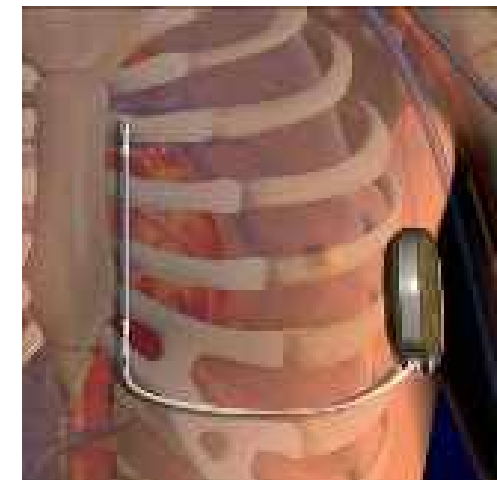
Das System kann Schocks bis zu 80 Joule abgeben

Post-Schock-Stimulation für 30 Sekunden möglich  
darüber hinaus keine Schrittmacherfunktion

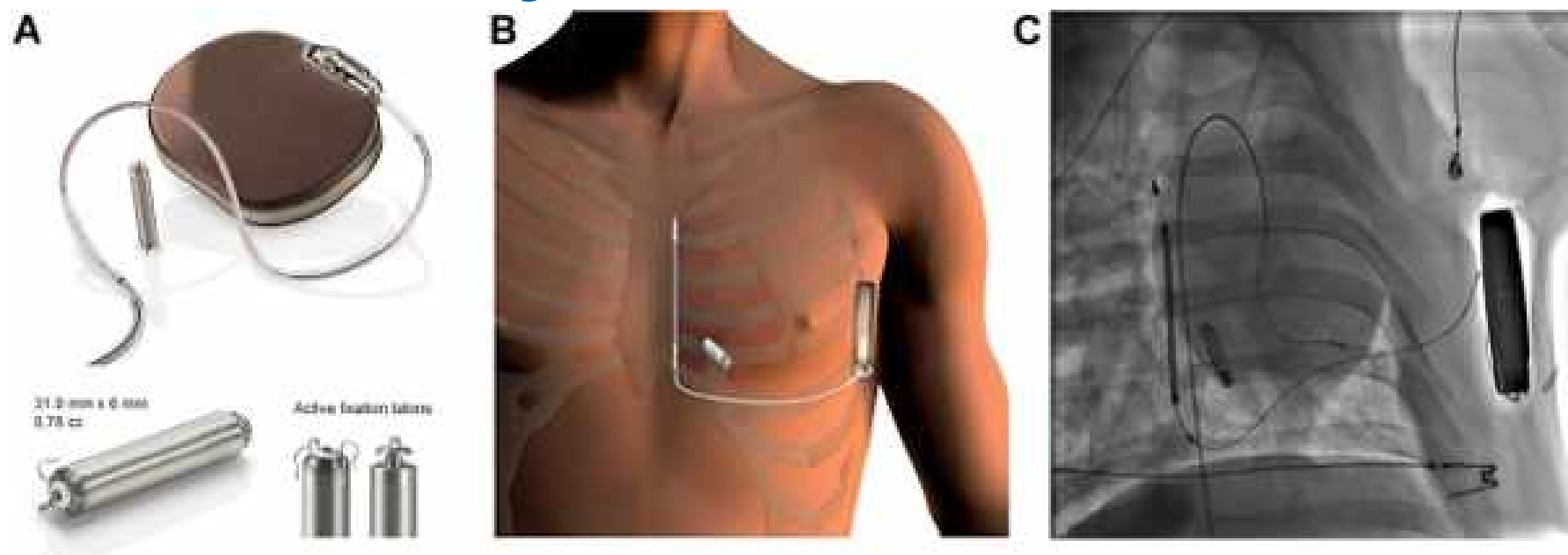
Anti-tachycardia-pacing (ATP) ist nicht möglich

Spezielles Screening erforderlich

MRT fähig, Telemedizin fähig, AF Monitoring



# Alternative Systeme – subcutaner ICD



sICD inkl. Leadless Pacer – aktuell noch in der Zulassung – voraussichtlich 2029 in Europa verfügbar

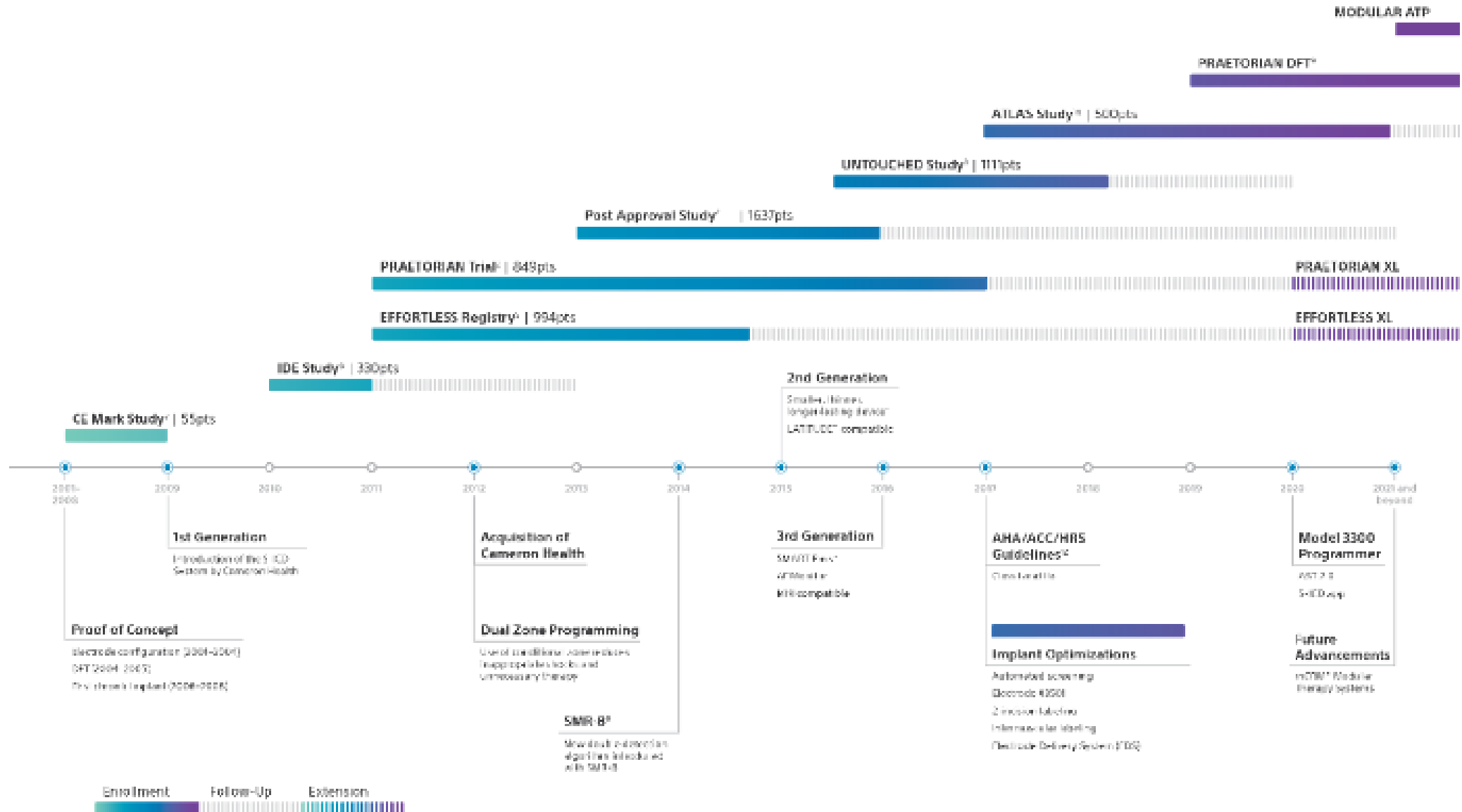
Zusätzlich zum sICD wird ein kabelloser Schrittmacher transvenös in den rechten Ventrikel implantiert

Schrittmacher-Stimulation möglich - ATP möglich

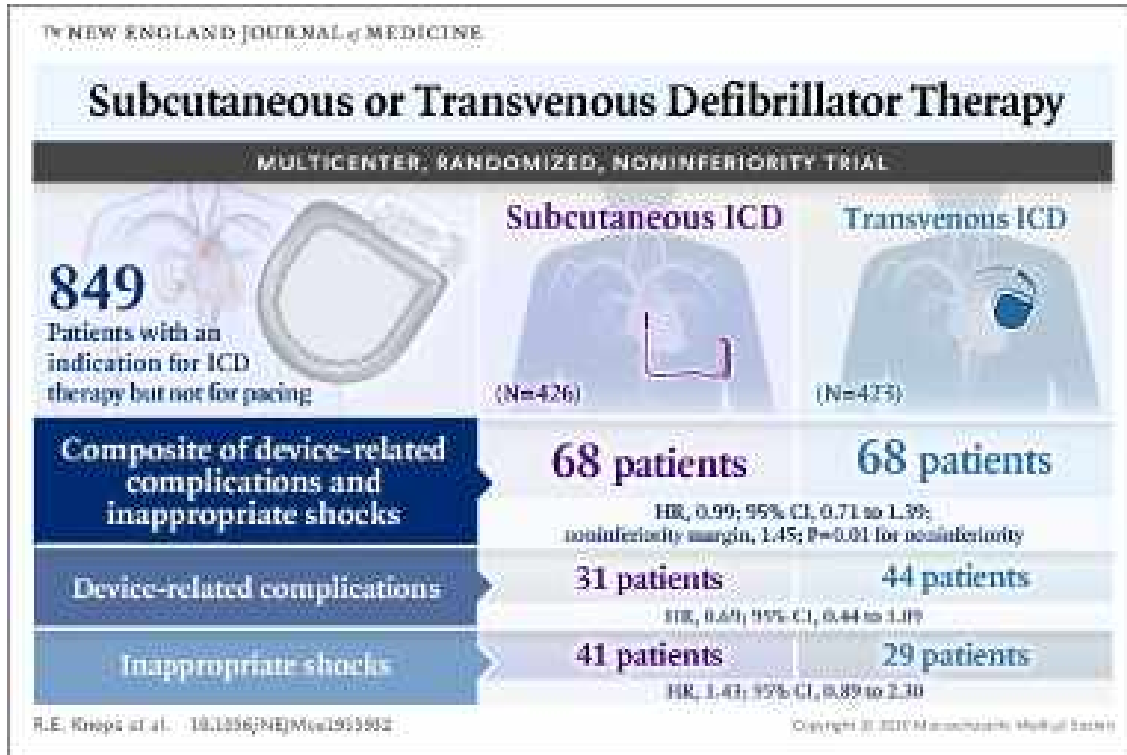
Laufzeit ~15 Jahre – danach weiterer leadless Pacer nötig

Auch mit anderen  
Leadless-Systemen  
möglich!

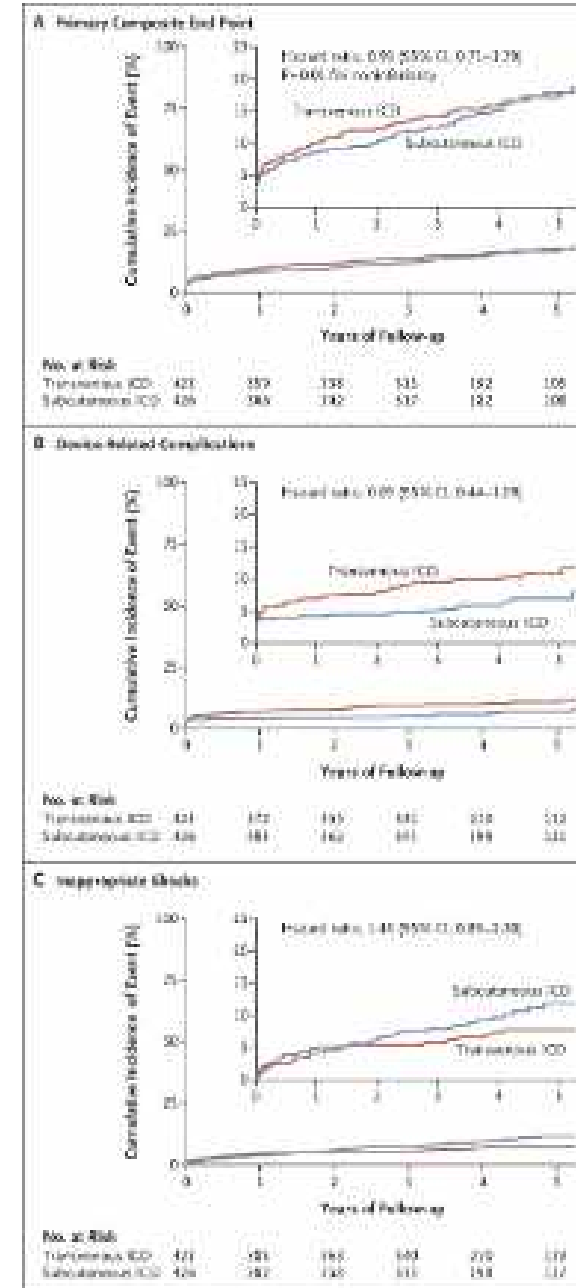
# Alternative Systeme – subcutaner ICD



# PRETORIAN Trial 2020



➔ NICHT – Unterlegenheit gegenüber TV-ICD



6.6%



1.4%



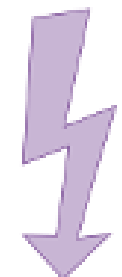
TV-ICD

S-ICD

LEAD-RELATED COMPLICATIONS\*

p = 0.001

VERY LOW 1-YEAR  
INAPPROPRIATE SHOCK RATES\*



4.8%

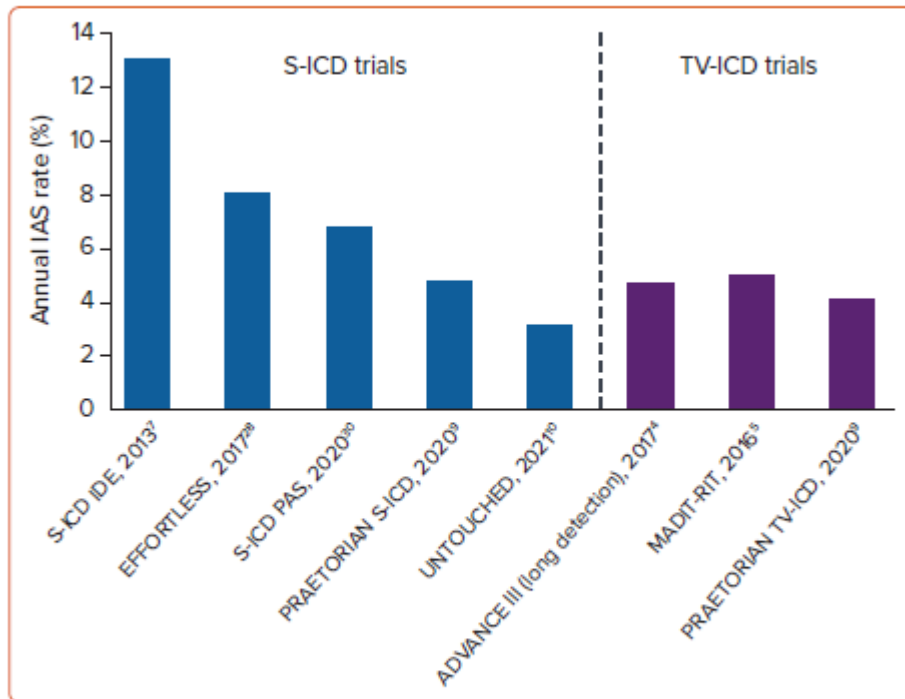
S-ICD

4.1%

TV-ICD

# sICD 2026

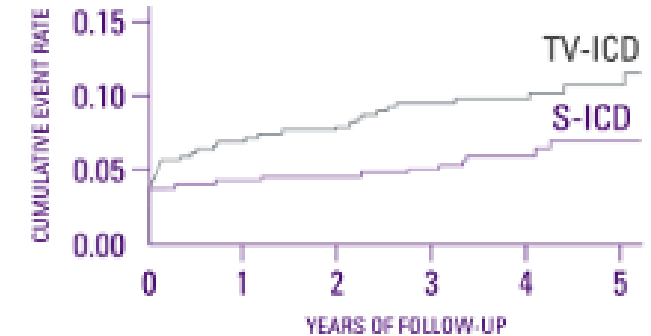
Figure 1: Rates of Inappropriate Shocks in Major Trials



Comparison of the annual rate of IAS amongst the major S-ICD and TV-ICD trials demonstrates improvement over time. IAS rates in the latest S-ICD trials are comparable to those in TV-ICD trials. IAS = inappropriate shock; S-ICD = subcutaneous ICD; TV-ICD = transvenous ICD.



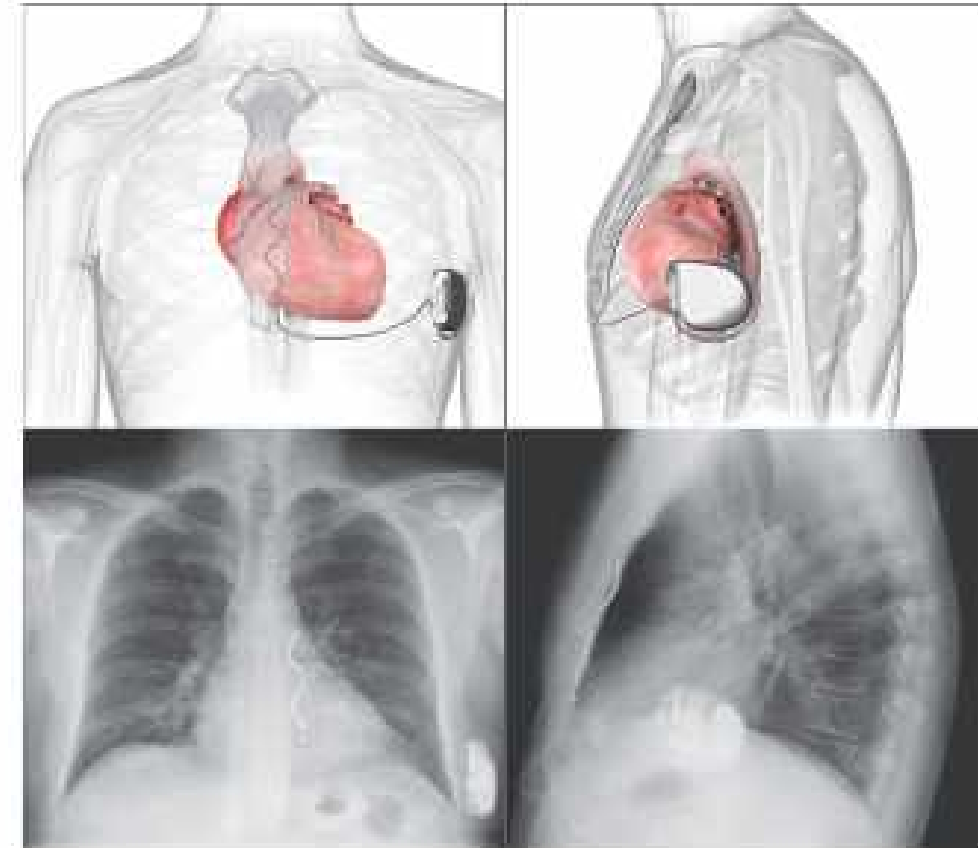
TREND IN LOWER COMPLICATIONS AT 4 YEARS<sup>1</sup>



- Besonders für junge Patienten geeignet
- Patienten mit hohem Infektrisiko profitieren besonders
- Fehltherapien mit aktueller Gerätegeneration vergleichbar mit TV-ICD
- Langfristig weniger Komplikationen
- Technische Weiterentwicklungen im Bereich Monitoring



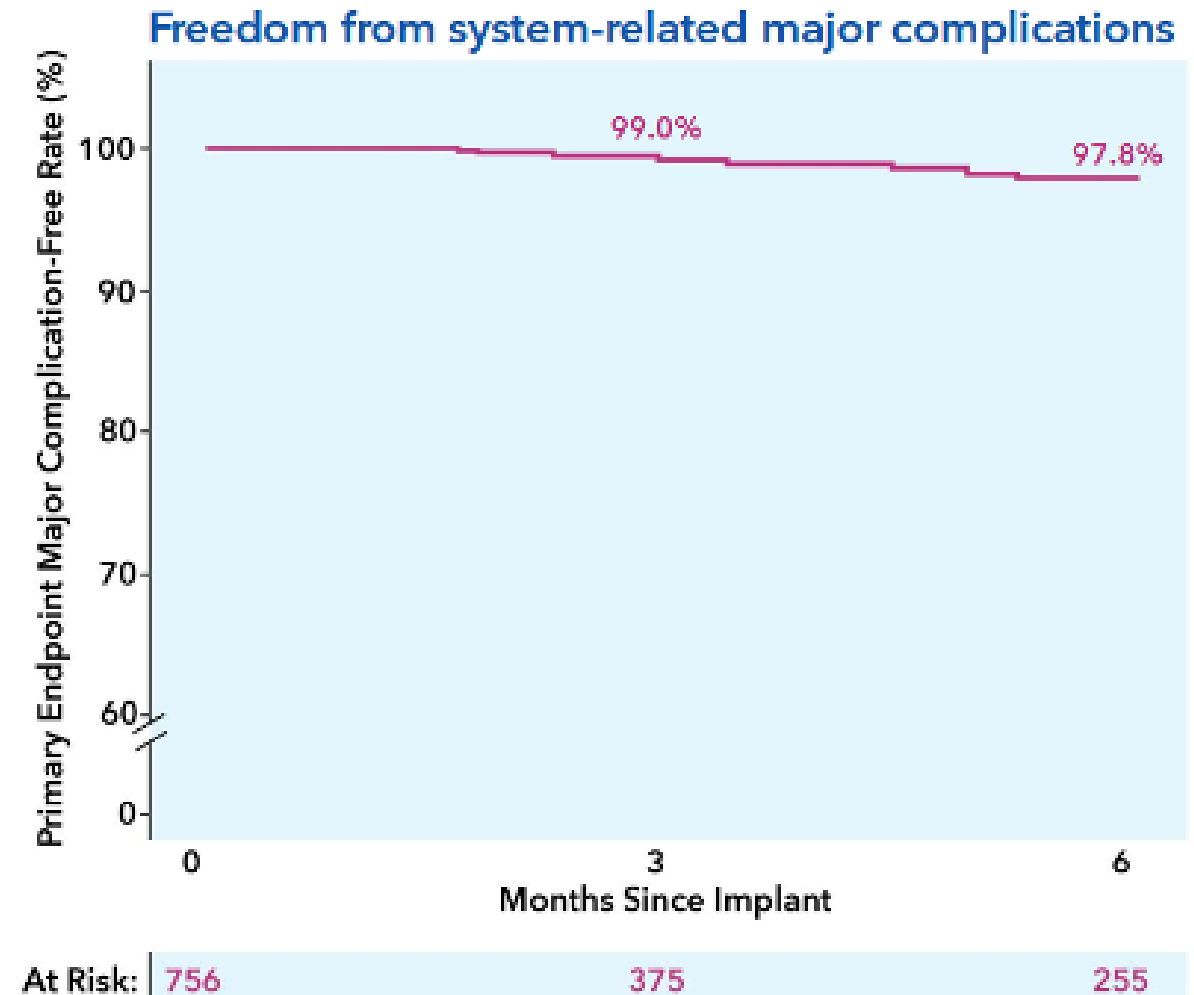
Anterior and lateral views of implanted EV-ICD<sup>2</sup>



- The extravascular implantable cardioverter-defibrillator (EV-ICD) provides ATP and low energy defibrillation therapy while avoiding the vasculature
- EV-ICD demonstrated a low complication rate and high therapy success rate in pre-market studies<sup>1</sup>
- The post-market Aurora EV-ICD is equipped with a novel algorithm (Smart Sense) aimed at reducing inappropriate shock due to P-wave oversensing
- However, the chronic real-world safety and performance of Aurora EV-ICD is not known
- **Objective: assess the real-world safety & performance of the Aurora EV-ICD system through 6 months**

# Primary endpoint

- Primary endpoint<sup>†</sup> will be assessed at 5 years
- 97.8% freedom from chronic system-related major complications at 6 months (**Figure**)
  - In line with Pivotal (98.0% at 6 months)
- 8 system-related major complications in 8 patients:
  - Inappropriate shock delivery<sup>†</sup> (N=5)
  - Lead dislodgement (N=2)
  - Implant site pain (N=1)



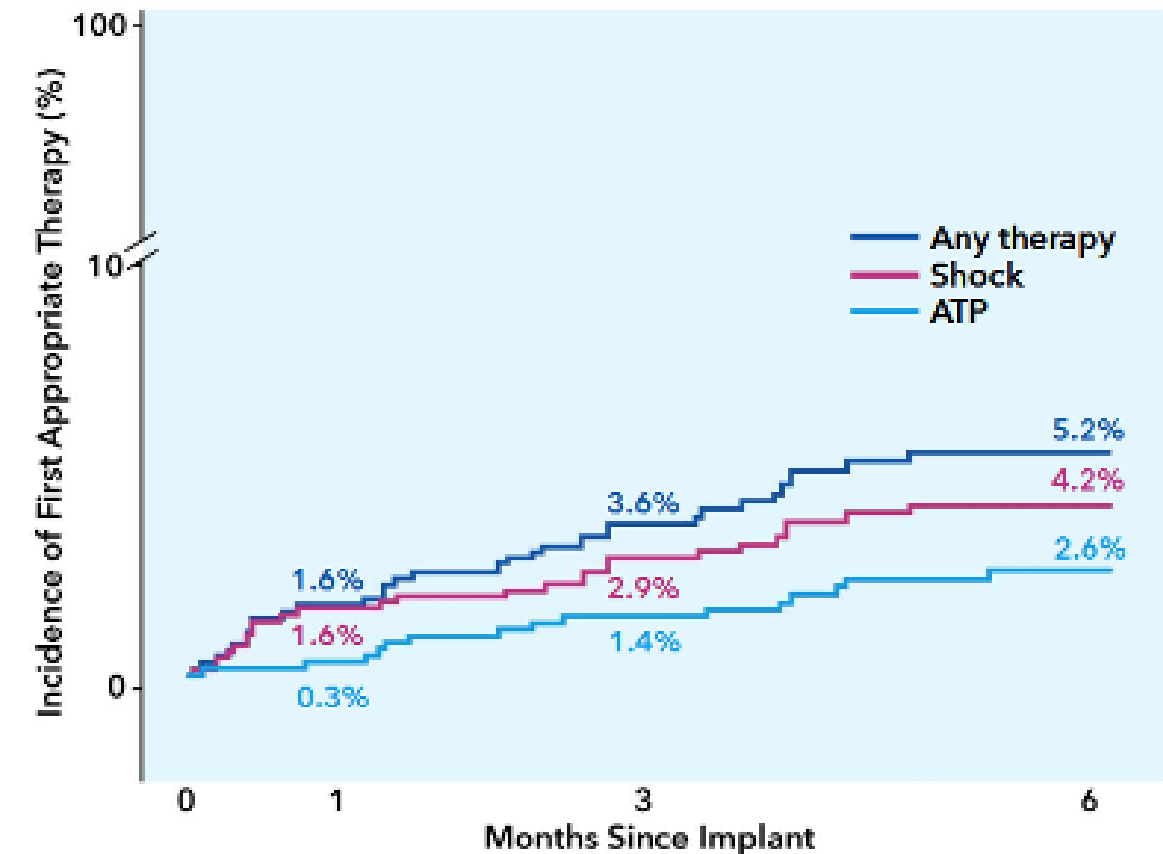
# Appropriate therapy

- 5.2% rate of first appropriate therapy at 6 months (Figure)
- 195 total appropriately treated episodes in 44 patients through mean of 7.9 months follow-up:

195 total appropriately treated episodes		
Shock only 67.2%	ATP only 22.6%	Both 10.3%

- 100% (47/47) shock success for discrete spontaneous VT/VF episodes
- 95.7% (45/47) first shock success (one episode required 2 shocks; one episode required 3)

Rate of first appropriate therapy



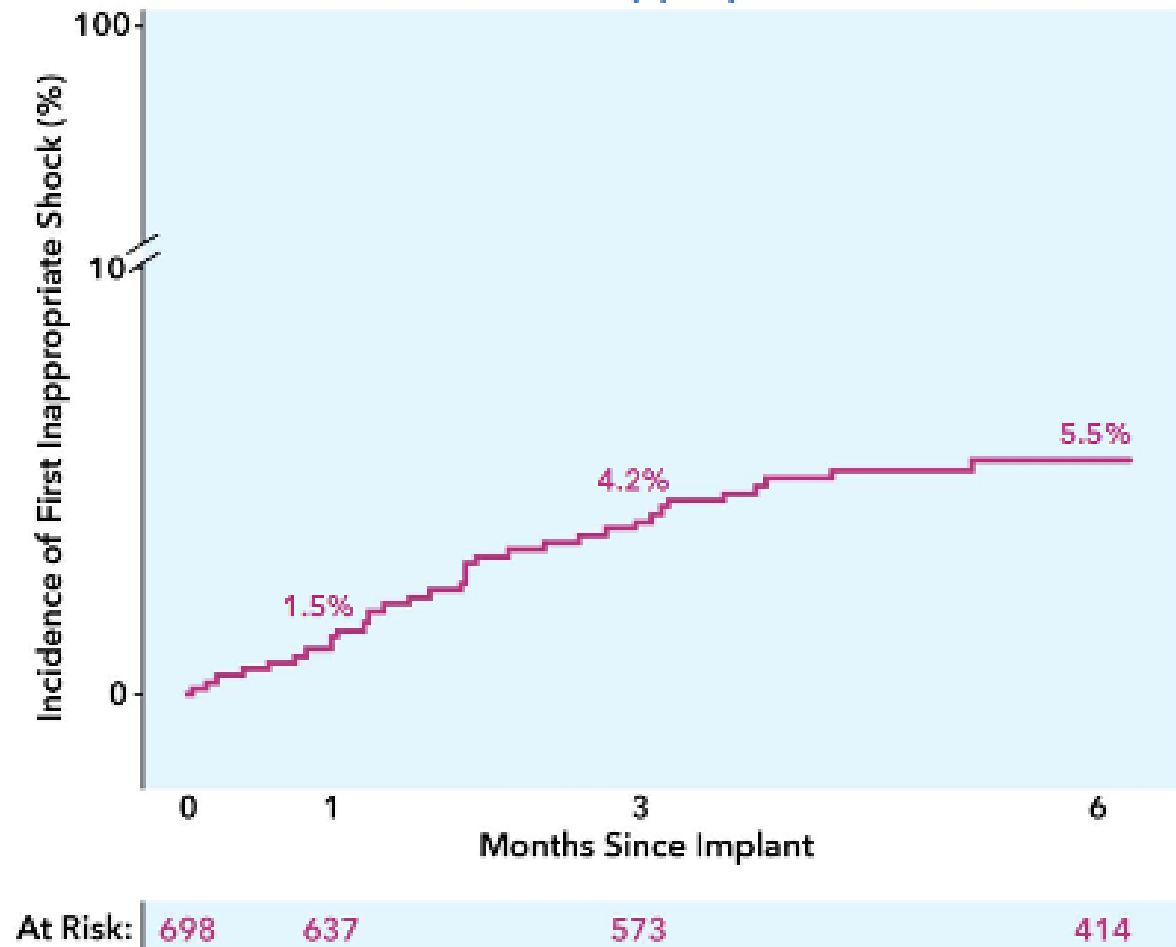
At Risk:	0	1	3	6
Any therapy	698	635	575	412
Shock	698	644	588	425
ATP	698	635	575	412

# evICD

## Inappropriate shock

- 5.5% rate of first inappropriate shock at 6 months (Figure)
- 66 total inappropriate shocks in 43 patients through a mean of 7.9 months follow-up
- 32.1% lower rate than what was observed in Pivotal (8.1% rate at 6 months<sup>1</sup>)

Rate of first inappropriate shock



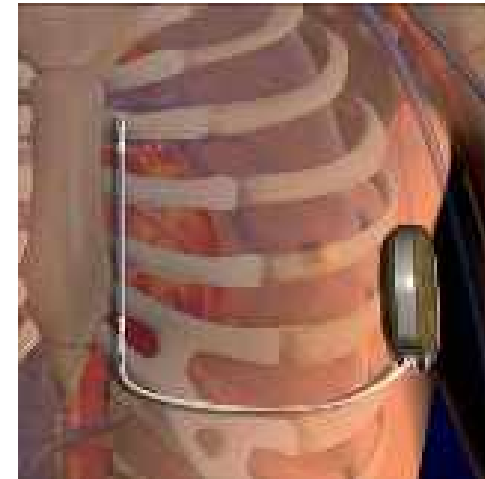
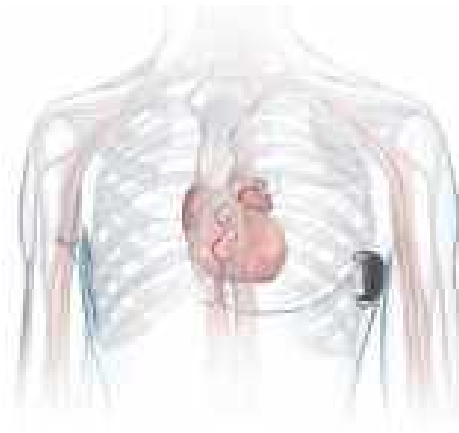
# Conclusions

**Preliminary evidence from a large real-world cohort with more than a third secondary prevention patients, the Aurora EV-ICD has demonstrated:**

- **A high implantation success rate & low rate of chronic complications through 6 months**
  - 99.2% achieved tunneling and lead placement success
  - 96.2% completed the procedure with a device
  - 97.8% freedom from system-related major complications at 6 months
  - Low rate of major infection (1.4%), none resulting in mediastinitis, sepsis, or endocarditis
- **Effective appropriate therapy**
  - 5.2% rate of first appropriate therapy at 6 months
  - 100% shock success for discrete spontaneous episodes
  - 66.9% GEE-adjusted ATP success rate (60.3% raw success rate) avoiding 44 shocks in 17 patients
- **Reduced inappropriate shock rate compared to Pivotal<sup>1</sup>**
  - 5.5% inappropriate shock rate at 6 months versus 8.1% in Pivotal (32% reduction)
  - 34.8% reduction in proportion of inappropriate shocks caused by PWOS compared to Pivotal

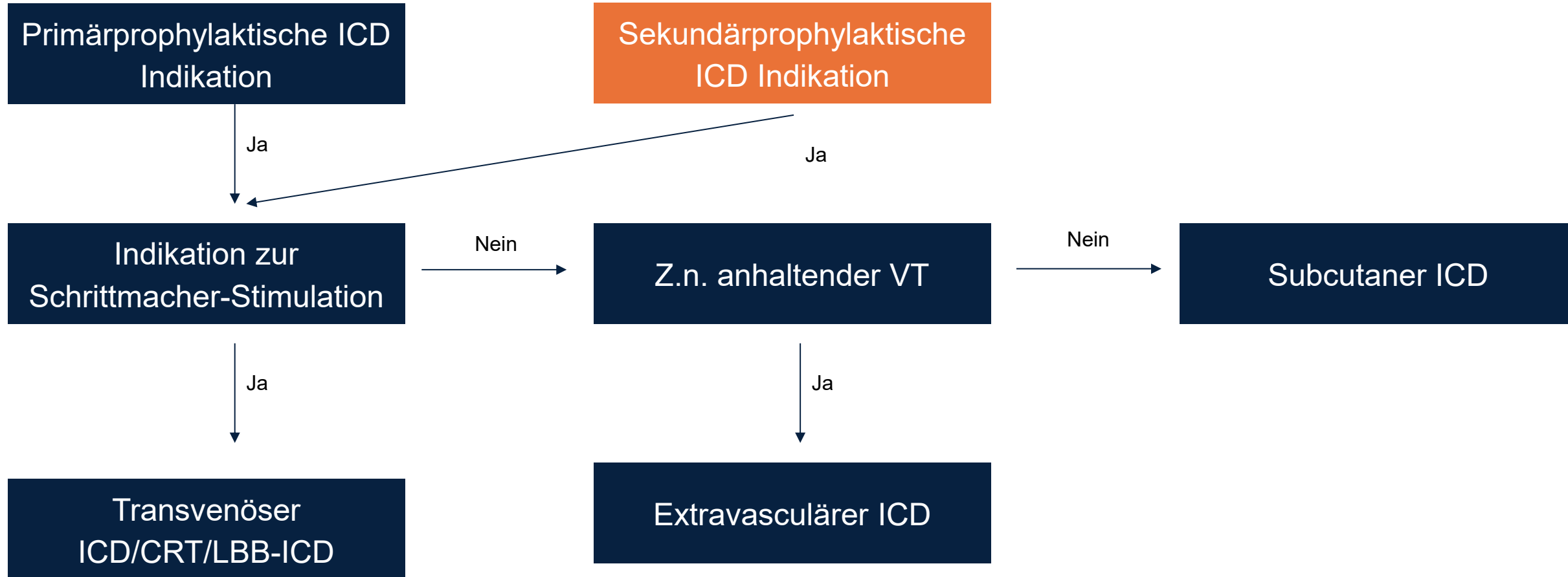
# ICD Therapy - Ziele

- Ziel ist, so lange wie möglich Sonden im Herzen zu vermeiden!
- Wenn Schrittmacher-Simulation notwendig, dann so physiologisch wie möglich!
- Alle Geräte-Klassen haben Limitationen – Individuelle Auswahl nötig!








# ICD Decision Tree

Ziel ist, so lange wie möglich Sonden im Herzen zu vermeiden!



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## Initial Experience with Intercostal Insertion of an Extravascular ICD Lead Compatible with Existing Pulse Generators

Martin C. Burke,  Reinoud E. Knops,  Vivek Reddy, Johan Aasbo,  Michael Husby,  Alan Marcovecchio, Mark O'Connor,  Rick Sanghera, Don Scheck, Shari Peplinkhuizen, Adrian Ebner

doi: <https://doi.org/10.1101/2023.02.21.23286264>

Now published in *Circulation: Arrhythmia and Electrophysiology* doi: [10.1161/CIRCEP.123.011922](https://doi.org/10.1161/CIRCEP.123.011922)

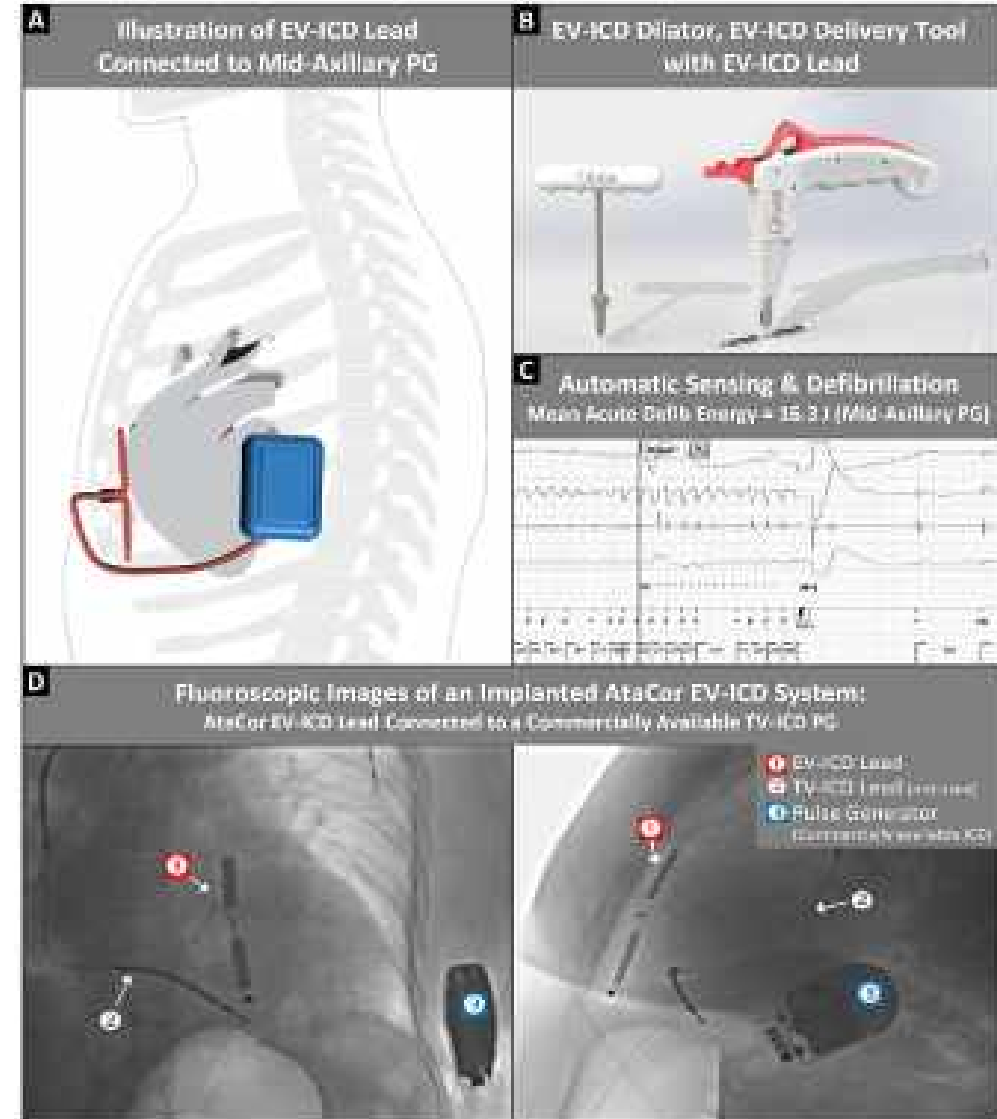
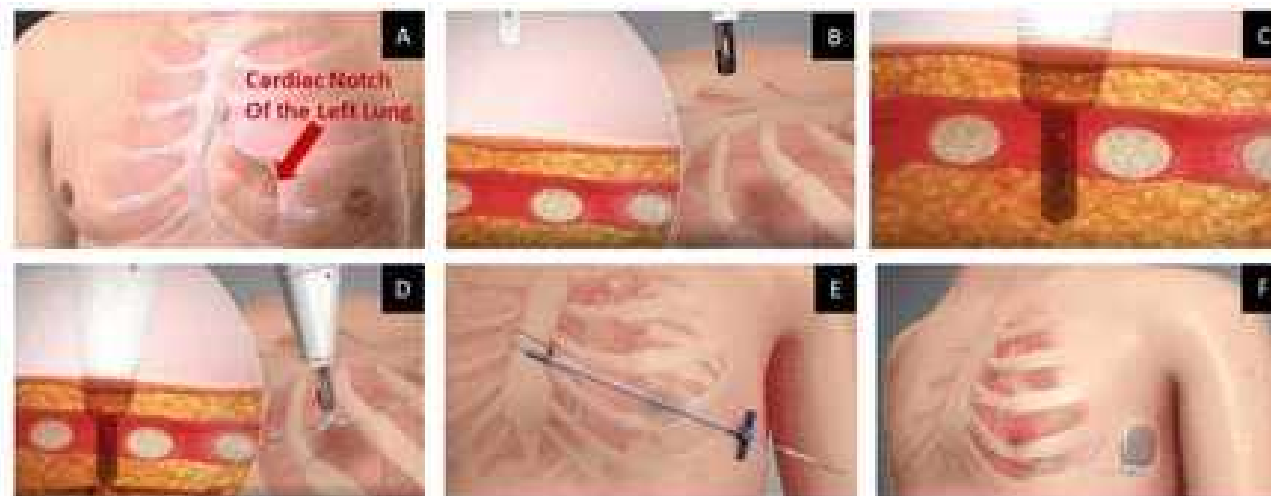
Abstract

Full Text

Info/History

Metrics

📄 Preview PDF



# Conclusions

- **sICD gleichwertig zum TV ICD bei guter Indikationsstellung**
- **Komplikationsrate mit neuer Generation geringer als TV ICD**
- **Transvenöse leads so lange wie möglich vermeiden.**
- **Individuelle Entscheidung für jeden Patienten anhand des Individuellen Risikos und der körperlichen Aktivitäten.**

Thank you very much!

