# State of the Art
# Leadless Pacing

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# Incidence and predictors of short- and long-term complications in pacemaker therapy: The FOLLOWPACE study

Erik O. Udo, MD,*† Nicolaas P.A. Zuithoff,† Norbert M. van Hemel, MD, PhD,*
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Heart Rhythm 2012;9:728–735

**Table 3** Complications within 2 months and during long-term follow-up occurring in 1517 patients with a first pacemaker

| | Within 2 months | | During follow-up | |
|---|---|---|---|---|
| | n | % | n | % |
| Traumatic complications—total | 42 | 2.77 | 1 | 0.07 |
| Perforation of cardiac structure | 6 | 0.40 | 1 | 0.07 |
| Pneumo(hemo)thorax | 34 | 2.24 | 0 | 0 |
| Pericardial effusion | 2 | 0.13 | 0 | 0 |
| Lead related complications—total | 84 | 5.54 | 84 | 5.54 |
| Lead fracture* | 2 | 0.13 | 6 | 0.40 |
| Lead dislocation or disconnection* | 50 | 3.30 | 24 | 1.58 |
| Insulation problem* | 4 | 0.26 | 11 | 0.73 |
| Infection (ie, lead endocarditis)* | 0 | 0 | 3 | 0.20 |
| Stimulation threshold problem | 12 | 0.79 | 26 | 1.71 |
| Diaphragm or pocket stimulation | 11 | 0.73 | 10 | 0.66 |
| Diaphragm or pocket stimulation* | 0 | 0 | 1 | 0.07 |
| Other† | 5 | 0.33 | 3 | 0.20 |
| Pocket complications—total | 72 | 4.75 | 49 | 3.23 |
| Hematoma | 44 | 2.90 | 1 | 0.07 |
| Difficult to control bleeding* | 4 | 0.26 | 2 | 0.13 |
| Infection | 10 | 0.66 | 4 | 0.26 |
| Infection* | 4 | 0.26 | 8 | 0.53 |
| Discomfort due to pocket or pacemaker | 1 | 0.07 | 17 | 1.12 |
| Discomfort due to pocket or pacemaker* | 2 | 0.13 | 9 | 0.59 |
| Skin erosion | 7 | 0.46 | 8 | 0.53 |
| Pulse generator problem—total | 5 | 0.33 | 23 | 1.52 |
| Problem with connection screw | 5 | 0.33 | 0 | 0 |
| Manufacturer recall | 0 | 0 | 5 | 0.33 |
| Manufacturer recall* | 0 | 0 | 6 | 0.40 |
| Reset to default settings | 0 | 0 | 4 | 0.26 |
| Device cannot be programmed | 0 | 0 | 2 | 0.13 |
| Pacemaker tachycardia | 0 | 0 | 2 | 0.13 |
| Malfunction of software algorithm | 0 | 0 | 4 | 0.26 |
| Total number of complications in need of reoperation | 64 | 4.22 | 61 | 4.02 |
| Number of patients experiencing a complication | 188 | 12.4 | 140 | 9.20 |

*Complication is managed with reoperation. Numbers do not add up, because patients can experience multiple complications.

European Heart Journal (2014) **35**, 1186–1194
doi:10.1093/eurheartj/eht511

**CLINICAL RESEARCH**
*Arrhythmia/electrophysiology*

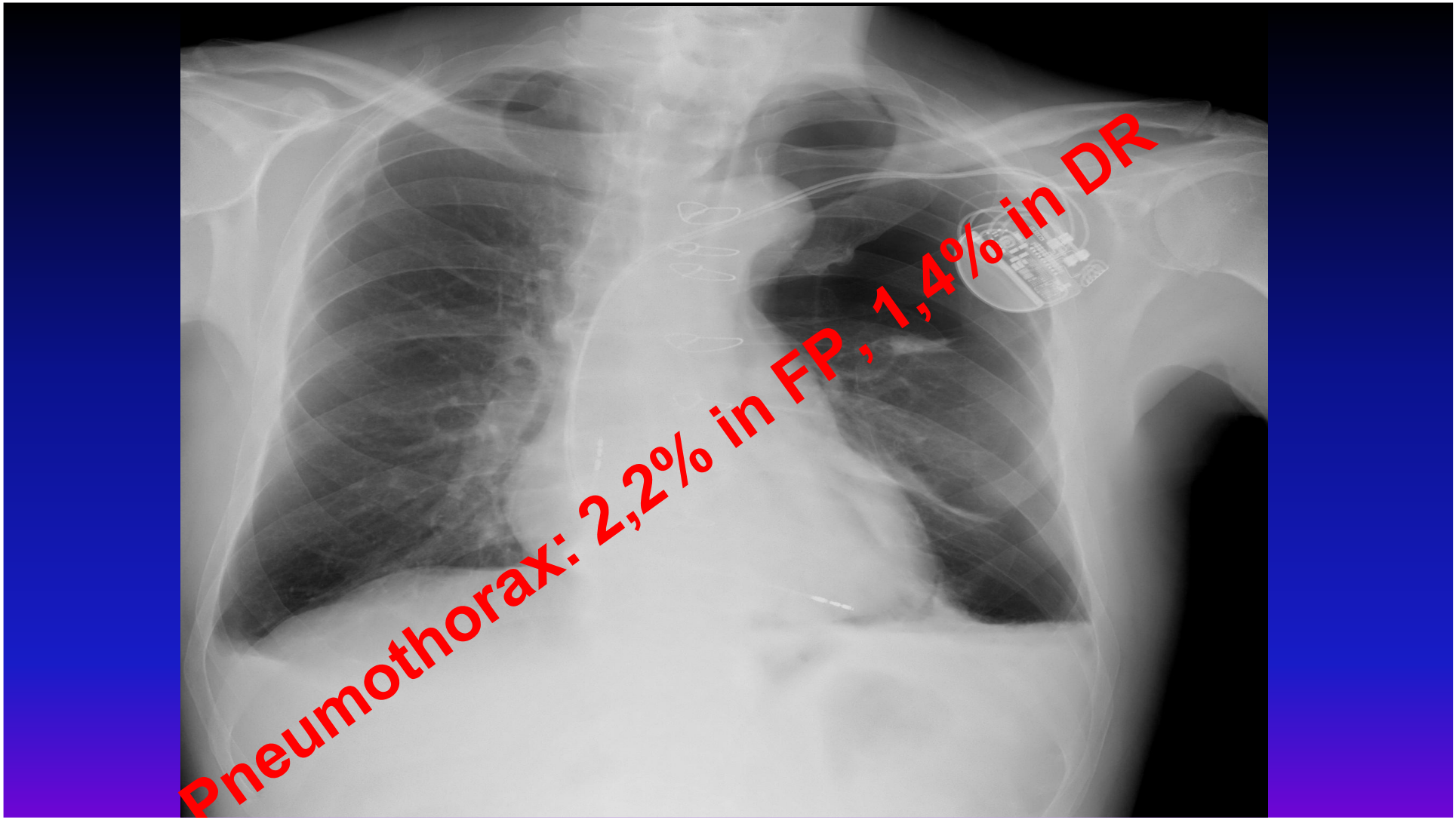
# Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark

**Rikke Esberg Kirkfeldt[1,2]*, Jens Brock Johansen[2,3], Ellen Aagaard Nohr[4], Ole Dan Jørgensen[2,5], and Jens Cosedis Nielsen[1]**

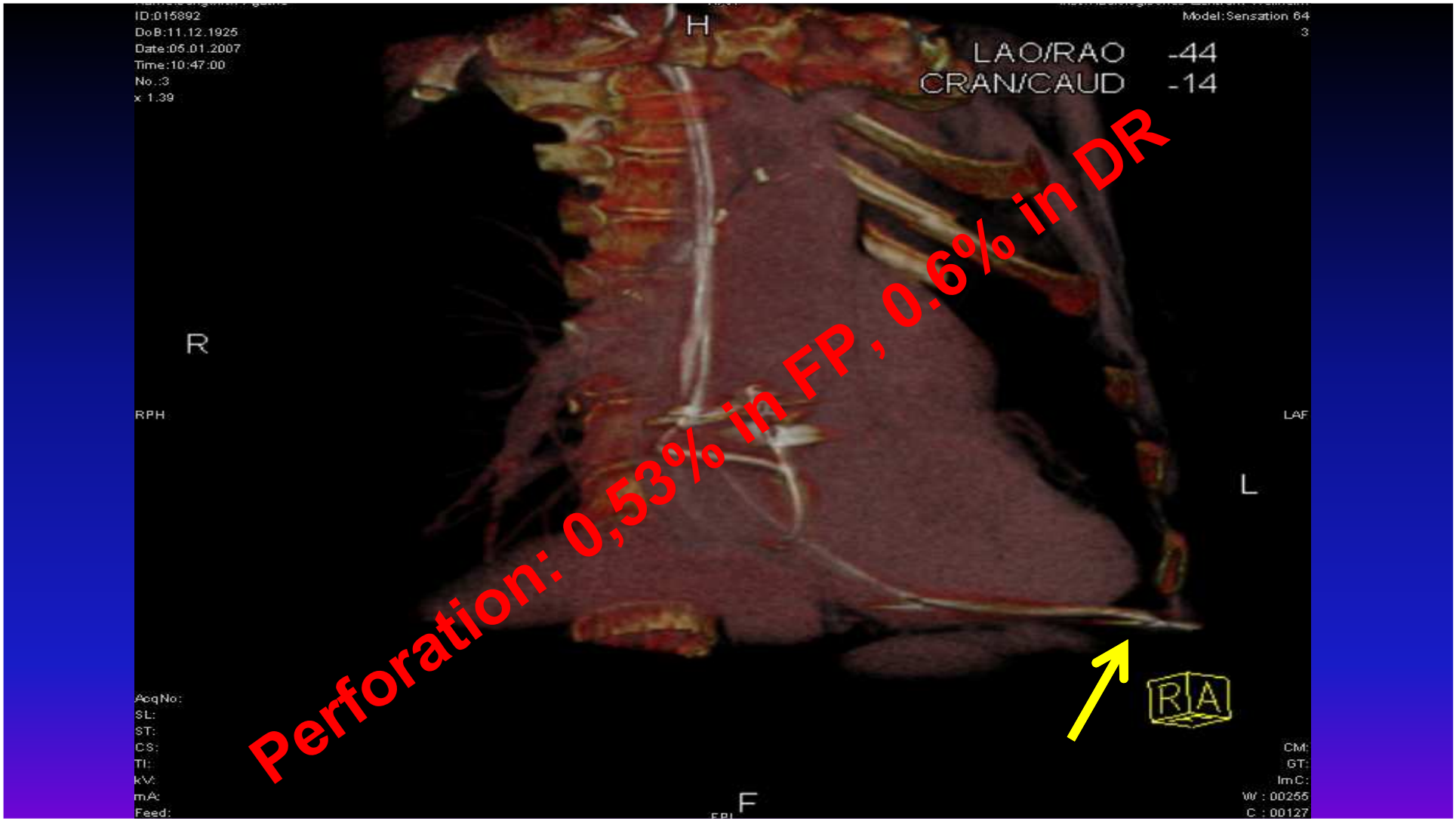
**Table 2** Cumulative incidence of complications at six months[a]

| | All ($n$ = 5918) | New implant ($n$ = 4355) | Generator replacement ($n$ = 1136) | Upgrade/ lead revision ($n$ = 427) |
|---|---|---|---|---|
| Any complication | 562 (9.5; 8.7–10.2) | 432 (9.9; 9.0–10.8) | 67 (5.9; 4.5–7.3) | 63 (14.8; 11.4–18.1) |
| Any major complication | 329 (5.6; 5.0–6.1) | 253 (5.8; 5.1–6.5) | 40 (3.5; 2.4–4.6) | 36 (8.4; 5.8–11.1) |
| Any minor complication | 250 (4.2; 3.7–4.7) | 189 (4.3; 3.7–4.9) | 30 (2.6; 1.7–3.6) | 31 (7.3; 4.8–9.7) |
| Major complications | | | | |
| Lead related re-intervention | 143 (2.4; 2.0–2.8) | 120 (2.8; 2.3–3.2) | 10 (0.9; 0.3–1.4) | 13 (3.0; 1.4–4.7) |
| Infection | 49 (0.8; 0.6–1.1) | 24 (0.6; 0.3–0.8) | 17 (1.5; 0.8–2.2) | 8 (1.9; 0.6–3.2) |
| Local infection | 22 (0.4; 0.2–0.5) | 10 (0.2; 0.1–0.4) | 8 (0.7; 0.2–1.1) | 4 (1.0; 0.0–1.9) |
| Systemic infection/endocarditis | 27 (0.5; 0.3–0.6) | 14 (0.3; 0.2–0.5) | 9 (0.8; 0.3–1.3) | 4 (0.9; 0.0–1.9) |
| Pneumothorax requiring drainage | 51 (0.9; 0.6–1.1) | 45 (1.0; 0.7–1.3) | 0 | 6 (1.4; 0.3–2.5) |
| Cardiac perforation | 38 (0.6; 0.4–0.8) | 35 (0.8; 0.5–1.1) | 0 | 3 (0.7; 0.0–1.5) |
| No intervention | 21 (0.4; 0.2–0.5) | 18 (0.4; 0.2–0.6) | 0 | 3 (0.7; 0.0–1.5) |
| Intervention[b] | 17 (0.3; 0.2–0.4) | 17 (0.4; 0.2–0.6) | 0 | 0 |
| Pocket revision because of pain | 25 (0.4; 0.3–0.6) | 10 (0.2; 0.1–0.4) | 9 (0.8; 0.3–1.3) | 6 (1.4; 0.3–2.5) |
| Generator-lead interface problem with re-intervention | 7 (0.1; 0.0–0.2) | 3 (0.1; 0.0–0.1) | 4 (0.4; 0.0–0.7) | 0 |
| Haematoma requiring re-intervention | 10 (0.2; 0.1–0.3) | 9 (0.2; 0.1–0.3) | 1 (0.1; 0.0–0.3) | 0 |
| Other[c] | 16 (0.3; 0.1–0.4) | 16 (0.4; 0.2–0.5) | 0 | 0 |
| Minor complications | | | | |
| Haematoma[d] | 138 (2.3; 1.9–2.7) | 104 (2.4; 1.9–2.8) | 20 (1.8; 1.0–2.5) | 14 (3.3; 1.6–5.0) |
| Wound infection treated with antibiotics | 69 (1.2; 0.9–1.4) | 47 (1.1; 0.8–1.4) | 12 (1.0; 0.5–1.7) | 10 (2.3; 0.9–3.8) |
| Pneumothorax conservatively treated | 39 (0.7; 0.5–0.9) | 32 (0.7; 0.5–1.0) | 0 | 7 (1.6; 0.4–2.8) |
| Lead dislodgement without re-intervention | 10 (0.2; 0.1–0.3) | 9 (0.2; 0.1–0.3) | 0 | 1 (0.2; 0.0–0.7) |

[a]Reported as absolute frequencies and percentages with 95% CIs in parenthesis.
[b]Lead revision, pericardiocentesis, or both.
[c]Deep venous thrombosis ($n$ = 8), Twiddler's syndrome ($n$ = 3), wound revision ($n$ = 3), stroke ($n$ = 1), myocardial infarction ($n$ = 1)
[d]Resulting in prolonged hospital stay, hospital re-admission, or additional out-patient visit.


Pneumothorax: 2,2% in FP , 1,4% in DR


Hematoma: 2,5% in FP, 3,2% in DR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Model:Sensation 64
3
LAO/RAO -44
CRAN/CAUD -14
R
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L
Perforation: 0,53% in FP , 0.6% in DR
RA
AcqNo:
SL:
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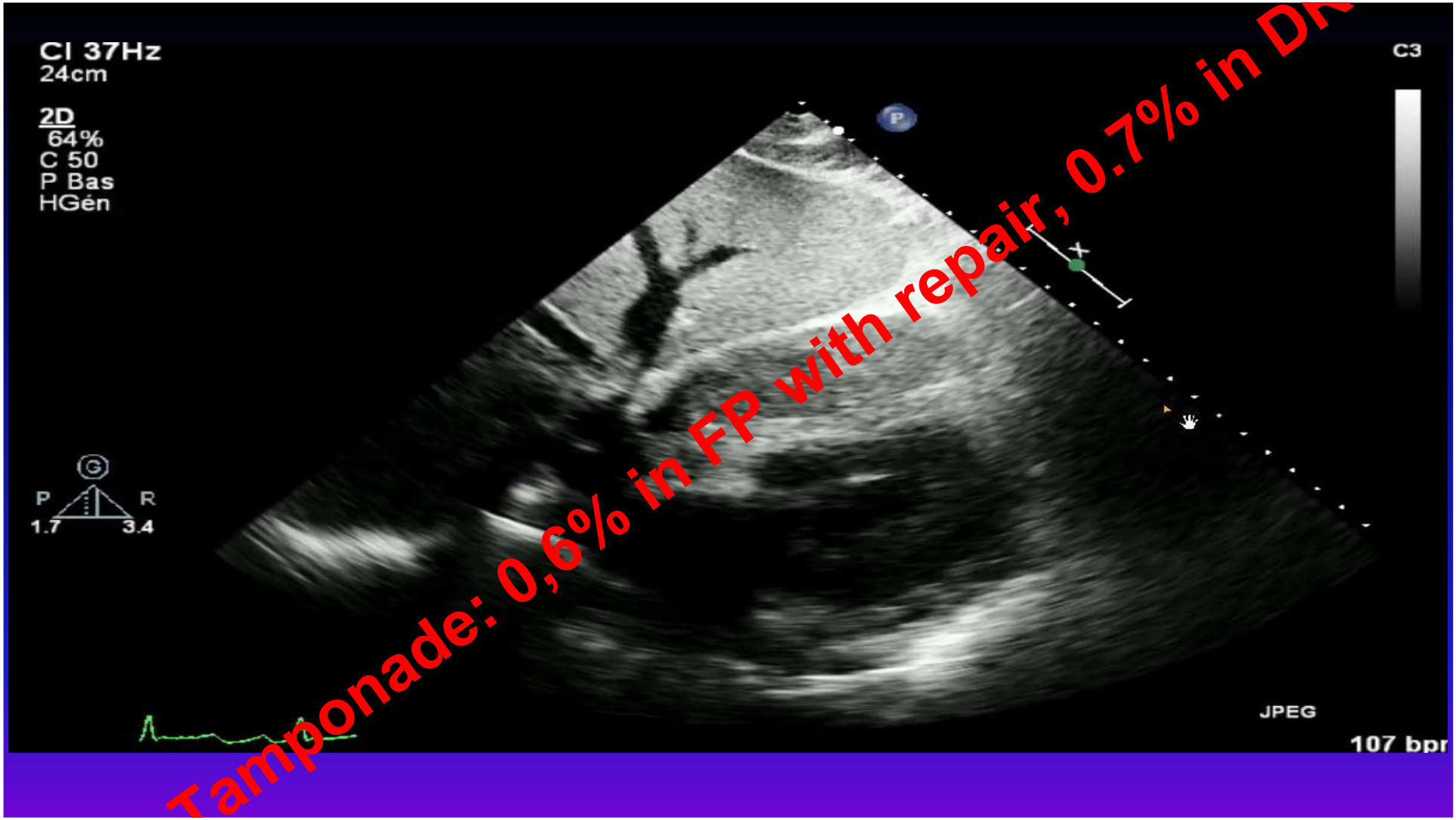
ImC:
W : 00255
C : 00127


CI 37Hz
24cm
2D
64%
C 50
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R
1.7
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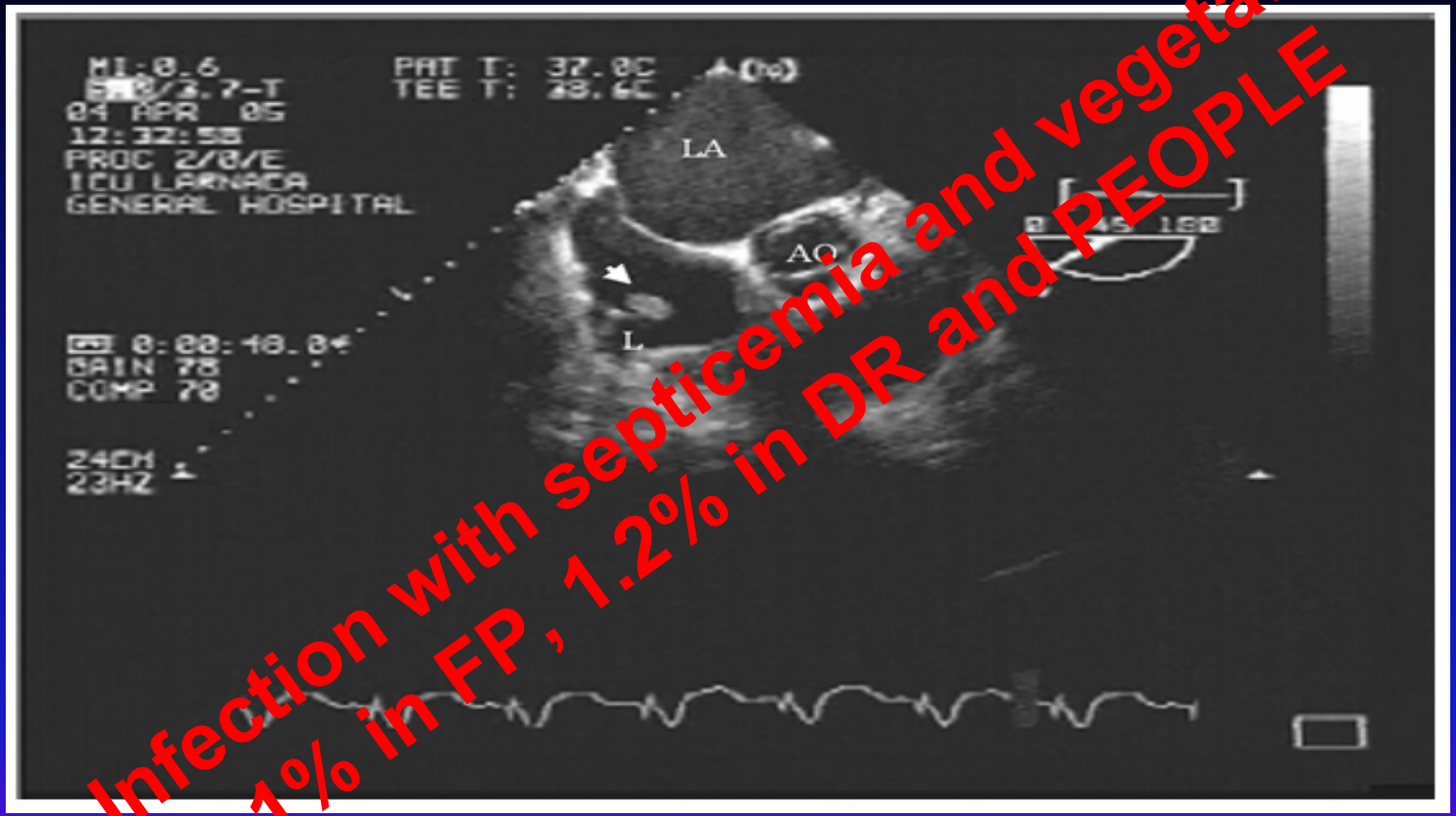
107 bpr
Tamponade: 0,6% in FP with repair, 0.7% in DK


Pocket Erosion


MI:0.6
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PROC 2/0/E
ICU LARNACA
GENERAL HOSPITAL
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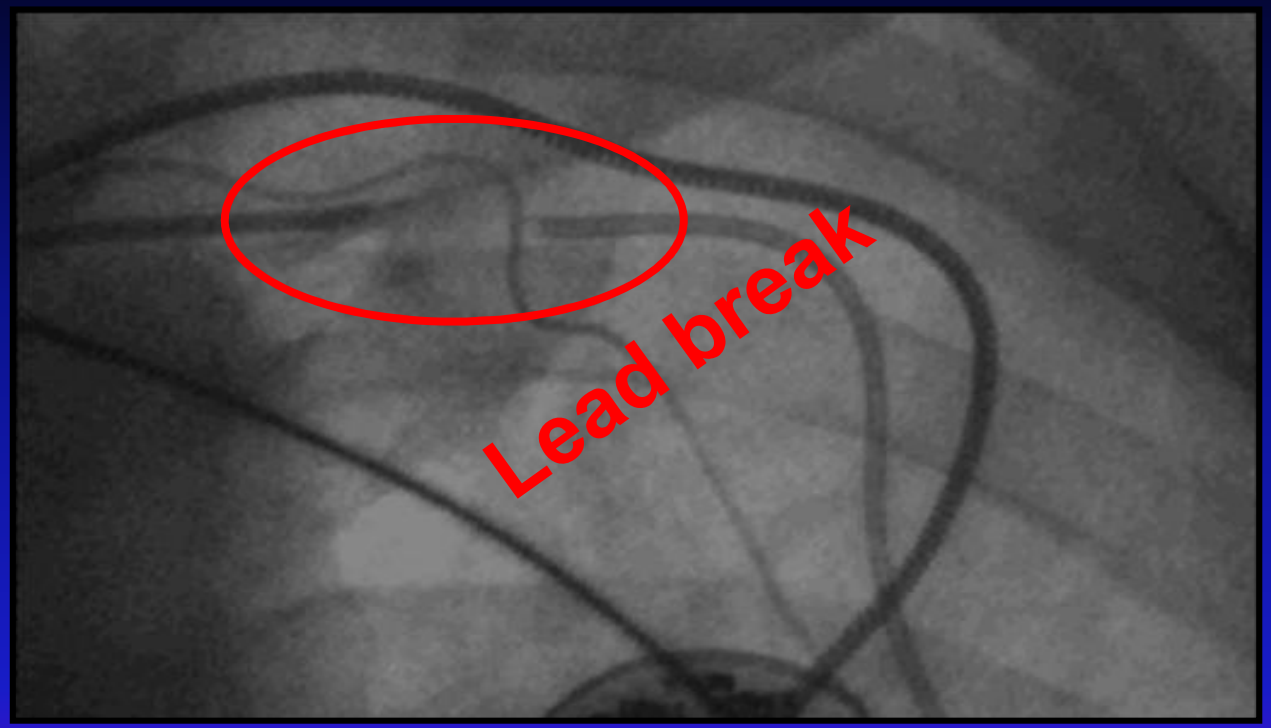
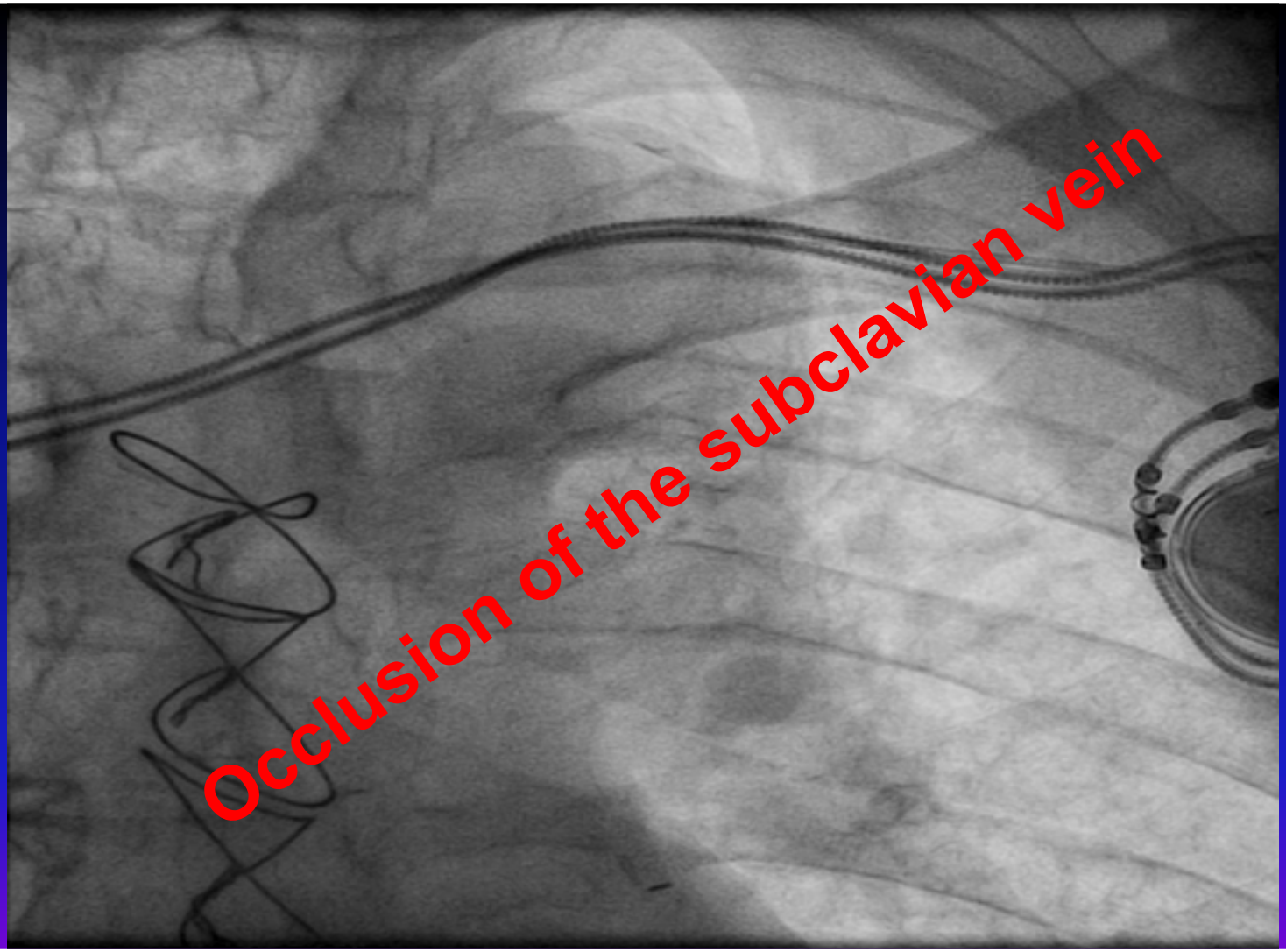
Infection with septicemia and vegetation
1% in FP , 1.2% in DR and PEOPLE


Lead break


Insulation erosion


Occlusion of the subclavian vein

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

Special Article

# Totally Self-Contained Intracardiac Pacemaker*

J. WILLIAM SPICKLER, PH.D., NED S. RASOR, PH.D.†, PAUL KEZDI, M.D.
S. N. MISRA, M.D., K. E. ROBINS, P.E., AND CHARLES LeBOEUF, 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 self-contained pacemaker implanted inside

circuits have been improved substantia
addition, the development of the endo
catheter electrode has broadened the
of operative procedures to include a
portion of the patient population. Two
problems that still exist with conver
pacemakers are perforation or dislocat
the transvenous electrode and the short
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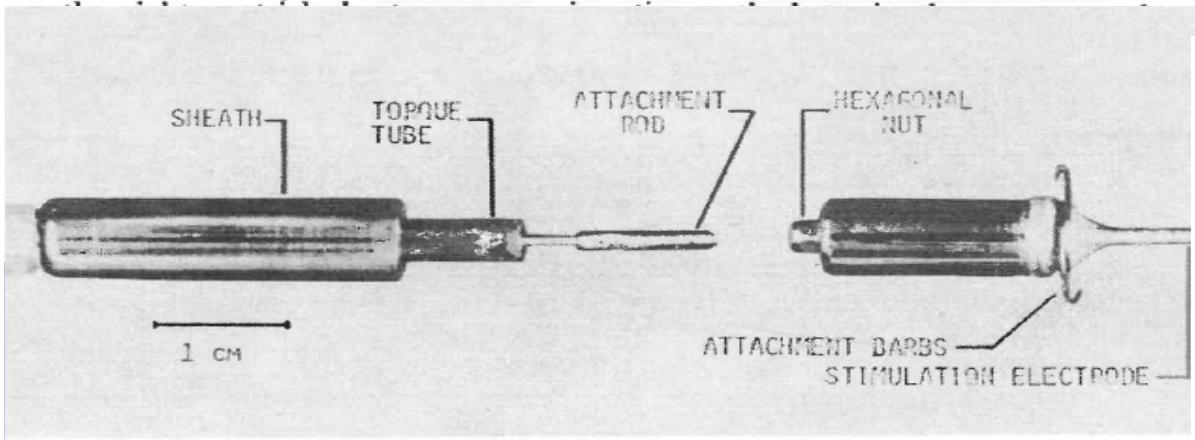
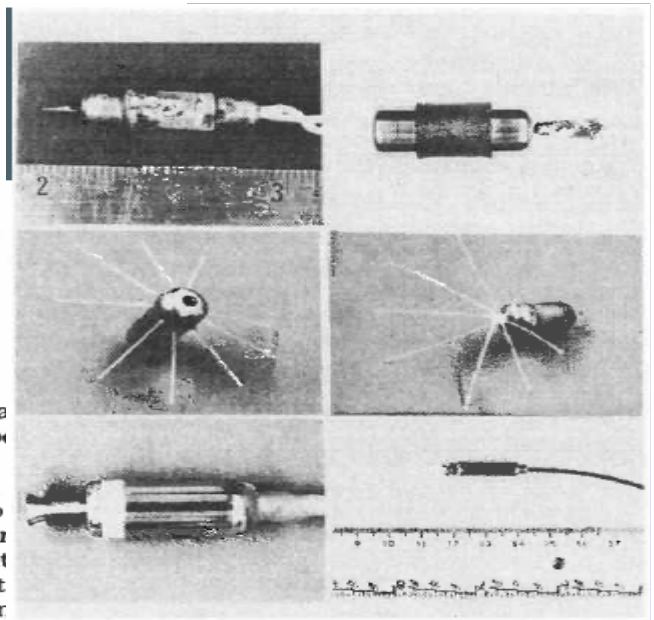



Fig. 4. Intracardiac pacemaker with catheter for transvenous insertion.



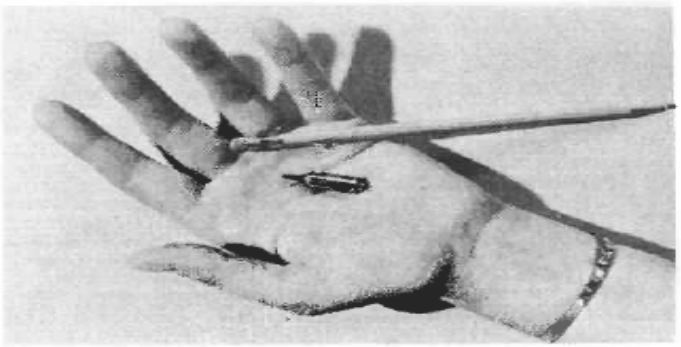
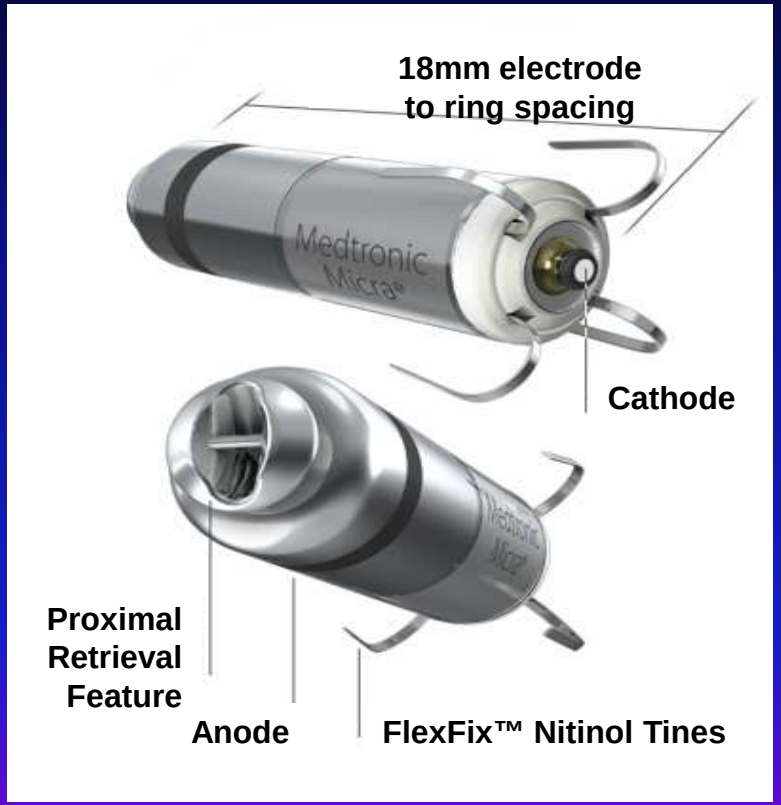


Fig. 8. Nuclear-powered intracardiac pacemaker.

# Two systems available, two study results

# Micra Capabilities

- VVIR stimulation
- MRI compatible (1.5 T or 3 T)
- Accelerometer-based rate response
- Capture Management™
- CareLink™ Remote Monitoring capability
- Device-Off Mode



# Implant Procedural Overview

# Long-Term Performance of a Transcatheter Pacing System:

## 12-month results from the Micra Global Clinical Trial

Philippe Ritter, MD; Gabor Z. Duray, MD, PhD, FESC; Sachin Yalagudri, MD; Razali Omar, MD; Jose M. Tolosana, MD; Shu Zhang, MD; Kyoko Soejima, MD; Clemens Steinwender, MD, FESC; Mikhael F. El-Chami, MD; Dwight Reynolds, MD; Micra Transcatheter Pacing Study Group

# Methods for Long-Term Analysis

Patients:

- 726 implant attempts
  - 99.2% success rate (n=719)
- Followed for average duration of 16.4 ± 4.9 months

Analyses:

- Pre-specified Long-term Safety Objective: Freedom from major complications at 12 months
- Comparison to transvenous control cohort
- Micra Electrical Performance characterized

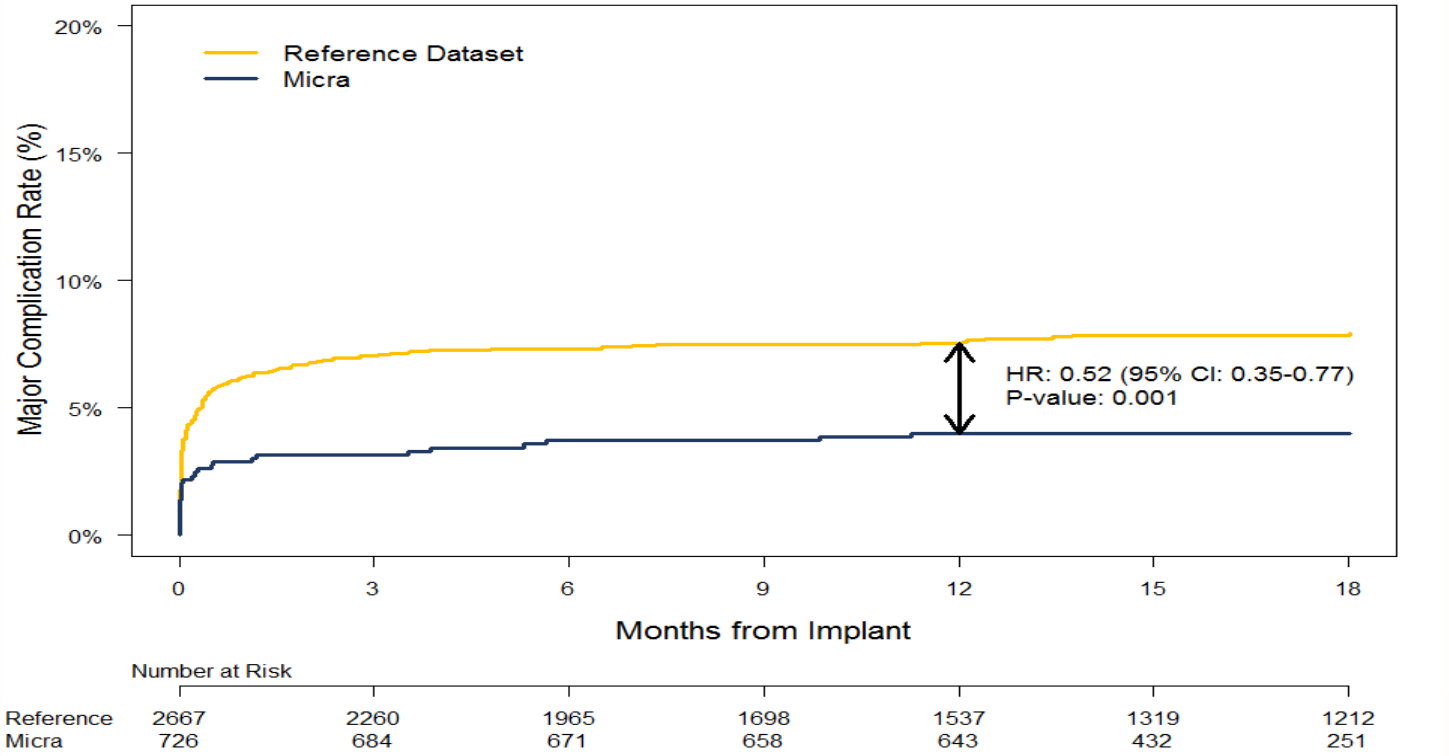
# Results: Micra Long-Term Safety (12 months, n=726)

- Long-term safety objective met
  - Major complication rate 4.0%
- Major complications:
  - 24 events (75%) through 30 days
  - 6 events (19%) >30 days - 6 months
  - 2 events (6%) > 6 months
- No dislodgements (0%)
- No infections (0%)

# Micra Major Complications (n=726)

| | Within 30 days | 30 days – 6 Mos | > 6 Mos | Events (Patients, %) |
|---|---|---|---|---|
| Total | 24 | 6 | 2 | 32 (29, 4.0%) |
| Cardiac Perforation/Effusion | 10 | 1 | 0 | 11 (11, 1.5%) |
| AV Fistula/Pseudoaneurysm | 5 | 0 | 0 | 5 (5, 0.7%) |
| Cardiac Failure | 0 | 4 | 2 | 6 (6, 0.8%) |
| Elevated Thresholds | 2 | 0 | 0 | 2 (2, 0.3%) |
| Pacemaker Syndrome | 1 | 1 | 0 | 2 (2, 0.3%) |
| Acute MI | 1 | 0 | 0 | 1 (1, 0.1%) |
| Deep Vein Thrombosis | 1 | 0 | 0 | 1 (1, 0.1%) |
| Metabolic Acidosis | 1 | 0 | 0 | 1 (1, 0.1%) |
| Presyncope | 1 | 0 | 0 | 1 (1, 0.1%) |
| Pulmonary Embolism | 1 | 0 | 0 | 1 (1, 0.1%) |
| Syncope | 1 | 0 | 0 | 1 (1, 0.1%) |

# 48% Fewer Major Complications with Micra vs Transvenous Pacemakers




To adjust for differences in patient populations, propensity matching to a subset of the historical control confirmed a reduction in major complications with Micra (HR: 0.46; 95% CI: 0.30-0.72; p<0.001).

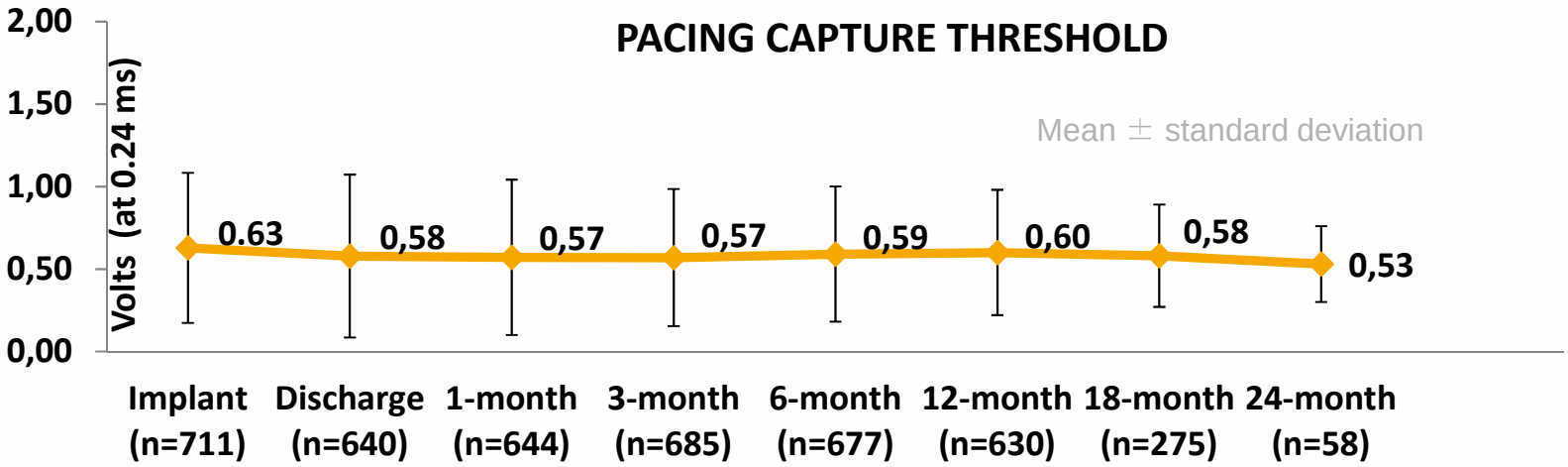
# Healthcare Utilization

47% Fewer Hospitalizations and 82% Fewer System Revisions with Micra versus Transvenous Pacemakers

| 12-Month Kaplan-Meier Estimates | Micra (n=726) | Historical Control (n=2667) | Relative Risk Reduction |
|---|---|---|---|
| **Total Major Complications** | **4.0%** | **7.6%** | **48%, P=0.001** |
| **Death** | **0.1%** | **0%** | NS |
| **Hospitalization** | **2.3%** | **4.1%** | **47%, P=0.017** |
| **Prolonged Hospitalization** | **2.2%** | **2.4%** | NS |
| **System Revision** | **0.7%** | **3.8%** | **82%, P<0.001** |
| **Loss of device function** | **0.3%** | **0%** | NS |

Not mutually exclusive as a single event may meet more than one major complication criteria.
NS = Not significant

# Low and Stable Pacing Thresholds




## Battery Longevity Estimate:

- Based on use conditions at 12-months, median battery longevity estimate is 12.1 years*

*Use conditions included: median pacing 53.5%, median pacing threshold 0.50V, median impedance 543Ω; 89% of patients with >10 year projected longevity; 99% of patients with >5 year longevity.

# Conclusions

- The Micra transcatheter ventricular pacemaker was successfully implanted (99.2%) in clinically diverse patients around the world, while meeting the prespecified long-term safety endpoint.
- Major complications occurred in 4% of patients, 48% less than the transvenous pacemaker control group.
- Importantly, this resulted in 47% fewer hospitalizations and 82% fewer system revisions, led by the elimination of pneumothoraces and absence of Micra dislodgements.
- Pacing thresholds remained low and stable through 12 months.

# Who Are the Optimal Patients for a Leadless Pacemaker?

Europace (2013) **15**, 1070–1118
doi:10.1093/europace/eut206

ESC GUIDELINES

## 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

**The Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA).**

**Authors/Task Force Members: Michele Brignole (Chairperson) (Italy)*, Angelo Auricchio (Switzerland), Gonzalo Baron-Esquivias (Spain), Pierre Bordachar (France), Giuseppe Boriani (Italy), Ole-A Breithardt (Germany), John Cleland (UK), Jean-Claude Deharo (France), Victoria Delgado (Netherlands), Perry M. Elliott (UK), Bulent Gorenek (Turkey), Carsten W. Israel (Germany), Christophe Leclercq (France), Cecilia Linde (Sweden), Lluís Mont (Spain), Luigi Padeletti (Italy), Richard Sutton (UK), Panos E. Vardas (Greece)**

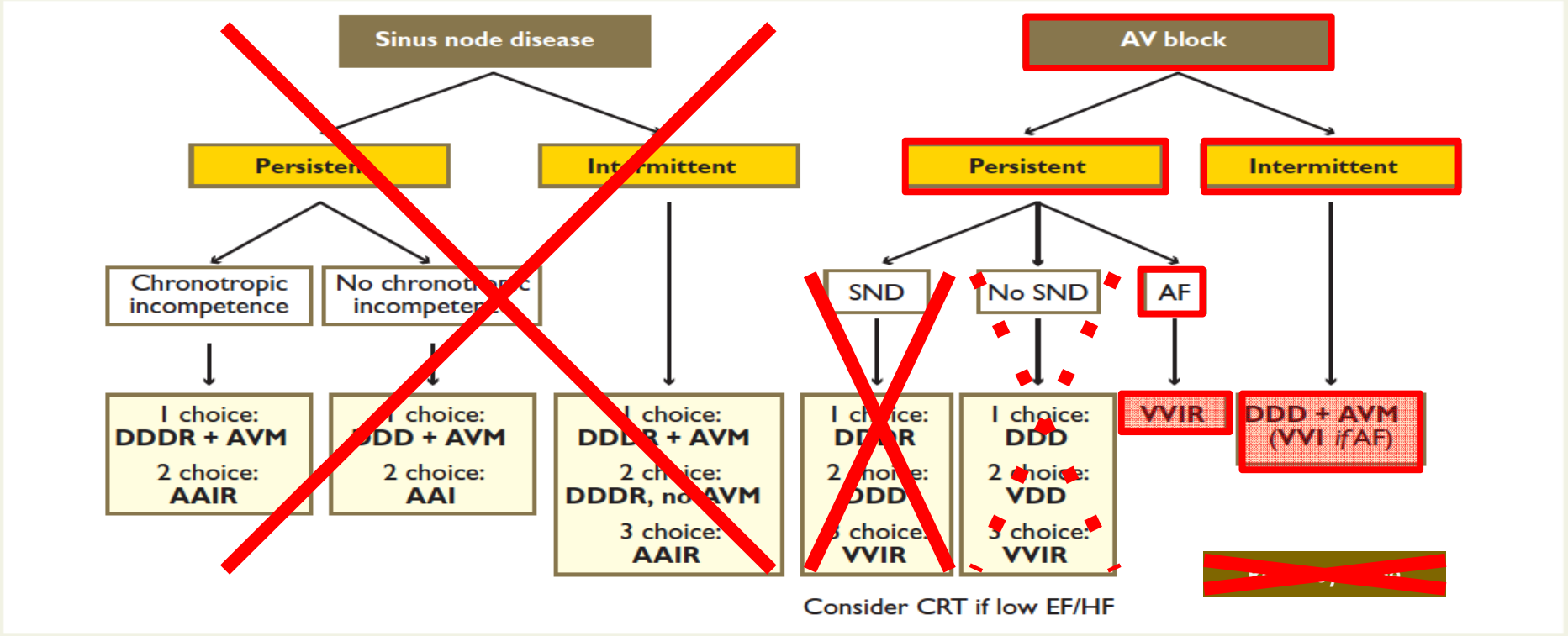



**Figure 3** Optimal pacing mode in sinus node disease and AV block. AF = atrial fibrillation; AV = atrioventricular; AVM = AV delay management, i.e. to prevent unnecessary right ventricular pacing by means of manual optimization of AV interval or programming of AV hysteresis; SND = sinus node disease.

# Case 1

- **75y male**
- **Ischemic HD, 52% EF**
- **1 syncope, and dizziness episodes**
- **Chronic AF, 110 ms QRS**
- **Mean diurnal V rate = 42 bpm after drugs interruption, 5 s pause at night, CS massage: 18 s pause with syncope**

- **Leadless pacemaker implanted**
  - Good parameters
  - Asymptomatic at follow-up

- ***The ideal indication***

# Case 2

- **92y female**
- **44 kgs, frailty**
- **Previous breast cancer with radiation exposure**
- **Previous steroïd drug treatment**
- **2 Adams Stokes syncopes**
- **Chronic AF, mean V rate = 34 bpm**
- **Attempt to implant a leadless PM**
  - Perforation
  - Surgical repair with difficulty
  - Epicardial VVI implant
  - Alive after 6 months without symptoms nor sequelae

- ***A contra-indication!***

# Case 3

- **79y female**
- **Persistent AF, failure of AF ablation procedures**
- **Fast V rate with drop in EF (40%) each time AF resumes**
- **Decision: AVJ ablation with VVIR PM**
- **Breast cancer on right side, contralateral occlusion of sub-clavian vein after a car accident**

- **Difficult implantation**
  - 4 repositioning with poor electricals
  - Finally average parameters
  - Hopefully AVJ ablation not performed the same day, because…
  - … pacing threshold rises up: 2.25 at D1, 3.25 after 2 weeks, 3.63 after 6 weeks...

- ***We keep the principle of 2 weeks between PM and ablation***

# Case 4

- **56y male**
- **AoV replacement**
- **Syncope with facial trauma**
- **Tri-fascicular block with abnormal EP study**
- **Presumption of paroxysmal AVB**
- **Pacing rate assumed to be infrequent**

- **Easy implant procedure:**
  - Excellent parameters
  - Remained asymptomatic at 2-year follow-up

- ***An acceptable indication***

# Case 5

- **50y male**
- **Racing driver**
- **Dizziness, and 2 syncopes within the last 6 months**
- **Sinus rhythm, complete heart block**
- **Rejects the conventional device (safety harness)**
- **Heard about LCP**

- **Implantation easy but:**
  - Major difficulties to set rate-responsiveness correctly
  - Racing licence lost…

- ***Respect of AV synchrony is mandatory in frequent/permanent AVB***

# Case 6

- **79y male**
- **Implanted with a DDD device for 23 years for AVB**
- **Battery change 5 months before, PM dependent**
- **PM can extrusion, no fever, low white cells count, low CRP, no bacteriemia, Staph Epidermidis in PM pocket**
- **Conclusion: local infection**

- **Explantation completed with immediate LCP implantation**
  - Leads cultures came back positive (same Staph) !!!
  - 6-week antibiotic therapy
  - No sign of infection after 9 months

- ***Probably not a correct practice!***

# Case 7

- **22y female**
- **Congenital heart block**
- **Became symptomatic with fatigue, dyspnea and 2 syncopes**
- **110 bpm sinus rhythm, no retrograde conduction**

- **Staff decision to implant Micra**
  - Easy procedure
  - Excellent parameters
  - Excellent status after 18 months

- ***Can be discussed***

# Conclusion

- **Main indications for LCP:**
  - Chronic AF with slow V rate or after AVJ ablation
  - Paroxysmal AVB with presumed infrequent pacing
  - No access from SVC network
- **Acceptable indication, in specific conditions:**
  - Complete AVB without retrograde conduction
- **Contra-indications:**
  - Presence of IVC clip or tricuspid prosthesis
  - Frail elderly female with comorbidities: dilated RV, previous steroïds, radiation exposure, renal failure
  - Neuro-cardiogenic causes of syncope
  - AVB with retrograde conduction
- **Some issues:**
  - Age / after death / risky infective conditions