
HK Heart Foundation, Dr. CO Pun and Dr. Mary BL Kwong Scholarship Symposium

# The Journey of Pacing Development where are we now

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# First endocardial pacemaker in 1958

# Evolution of pacemaker

- Dual chamber pacing
- Rate response features
  - Accelerometer, mini-ventilation, temperature sensor, Intracardiac impedance
- Auto-capture features
- MRI compatibility
- Algorithm to minimize ventricular pacing
- Remote monitoring capabilities
- **Leadless pacing technology**
- **Conduction system pacing**

# Leadless pacemakers

- Medtronic Micra VR, Micra AV
- Abbott Aveir VR

# Advantage of a leadless pacemaker system

| **Advantage** | **Disadvantage** |
|---|---|
| No risk of pocket related hematoma or infection | Difficulty in implantation of 2nd or 3rd device in chamber<br>- Retrievability in Abbott Aveir system |
| Ideal for patients with limited venous access | At present can only provide RV pacing<br>- May NOT be ideal for sick sinus patients<br>- Atrial LP is being investigated |
| Smaller wound (1cm in groin vs 3-5cm in pectoral region) | |
| Comparable longevity to transvenous pacing (in general 8-12 years) | |

# Micra Post Approval Registry

**Table 2** Major Complications Through 30 Days Post Implant

| Adverse Event | No. (Patients, %) |
|---|---|
| Total Major Complications | 13 (12, 1.51) |
| Deep Vein Thrombosis | 1 (1, 0.13) |
| Events at Groin Puncture Site | 6 (6, 0.75) |
| Arteriovenous fistula | 1 (1, 0.13) |
| Hematoma | 2 (2, 0.25) |
| Incision site hemorrhage | 1 (1, 0.13) |
| Persistent lymphatic fistula | 1 (1, 0.13) |
| Vascular pseudoaneurysm | 1 (1, 0.13) |
| Cardiac Effusion/Perforation | 1 (1, 0.13) |
| Pacing Issues | 2 (2, 0.25) |
| Device dislodgement | 1 (1, 0.13) |
| Device pacing issue | 1 (1, 0.13) |
| Other | 3 (3, 0.38) |
| Chest pain | 1 (1, 0.13) |
| Pulmonary edema | 1 (1, 0.13) |
| Sepsis | 1 (1, 0.13) |

**Table 3** Components of Major Complications for Post-Approval and Investigational Studies

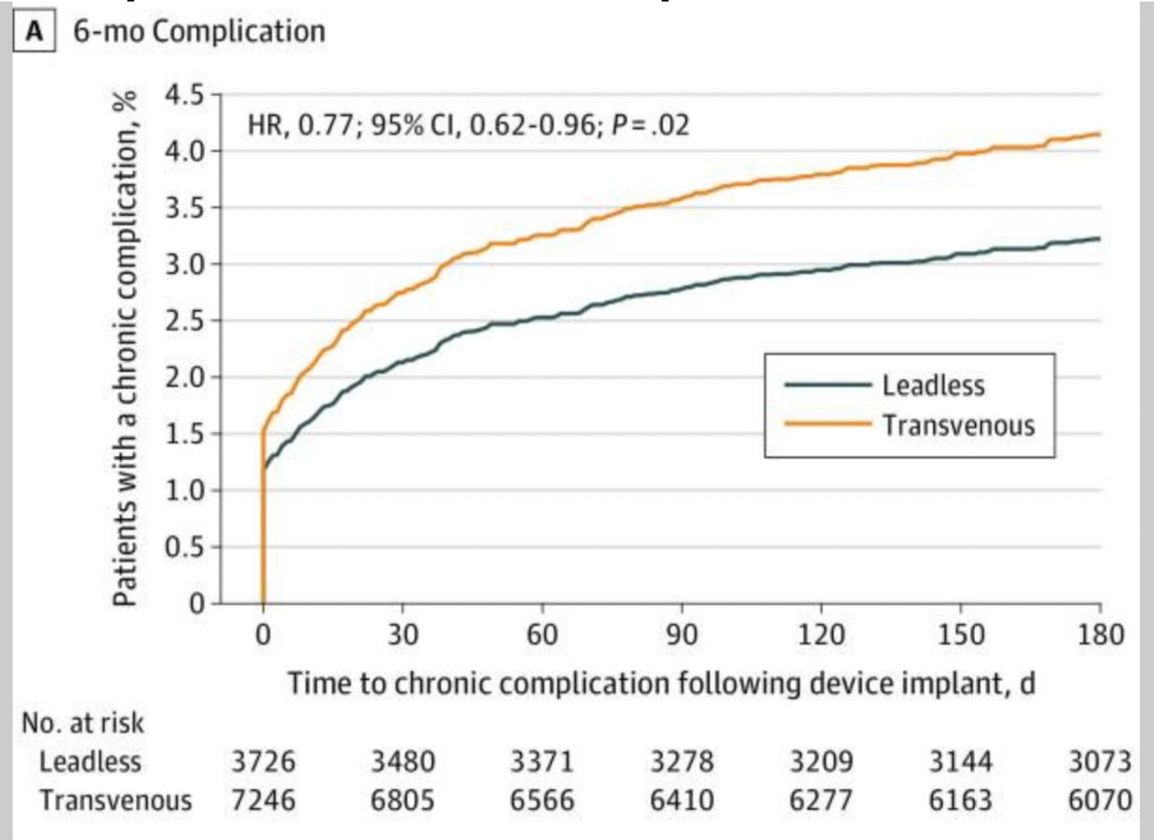
| | 30-Day Event Rate | | |
|---|---|---|---|
| Major Complication Criterion | Post-Approval (n = 795) No. (Patients, %) | Investigational (n = 726) No. (Patients, %) | Odds Ratio (Post-Approval vs Investigational) (95% CI) |
| Total Major Complications | 13 (12, 1.51%) | 24 (21, 2.89%) | 0.58 (0.27, 1.25)* |
| Death | 1 (1, 0.13%) | 1 (1, 0.14%) | 0.91 (0.06–14.66) |
| Hospitalization | 4 (4, 0.50%) | 9 (8, 1.10%) | 0.45 (0.14–1.51) |
| Prolonged hospitalization | 9 (8, 1.01%) | 16 (14, 1.93%) | 0.52 (0.22–1.24) |
| System revision | 2 (2, 0.25%) | 3 (3, 0.41%) | 0.61 (0.10–3.65) |
| Loss of device function | 0 (0, 0%) | 2 (2, 0.28%) | NE |

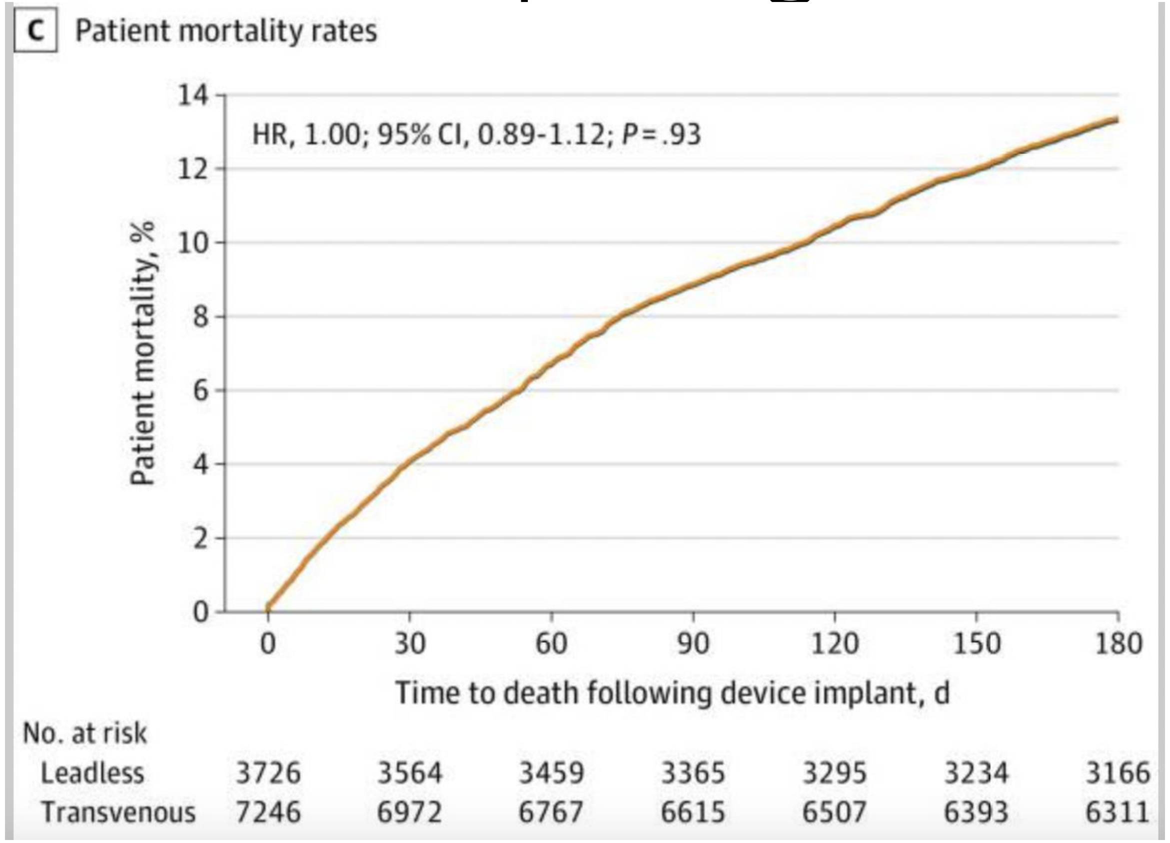
CI = confidence interval; NE = not estimable.

*Adjusted analyses for baseline characteristics (P = 0.16). Unadjusted results were similar (0.52, 95% CI: 0.25-1.05).

Roberts PR, Clementy N, Al Samadi F, et al. A leadless pacemaker in the realworld setting: the Micra transcatheter pacing system post-approval registry. Heart Rhythm 2017;14: 1375e9.

# Leadless pacemaker have a favorable safety profile compared with transvenous pacing




Contemporaneous comparison of outcomes among patients implanted with a leadless vs transvenous single-chamber ventricular pacemaker. JAMA Cardiol 2021;6(10):1187e95.

# Comparable efficacy and safety outcome between HK cohort and IDE and PAR cohort

| | IDE | PAR | CUHK | P value[a] | P value[b] |
|---|---|---|---|---|---|
| Successful implant | 719/725 (99.2%) | 1801/1817 (99.1%) | 145/147 (98.6%) | 0.63 | 0.64 |
| Reaching efficacy outcome | 292/297 (98.3%) low and stable threshold at 6 months | 349/360 (97%) low and stable threshold at 1 year | 140/147 (95.2%) (Successful implant with low and stable threshold at implant and all first year visits) | N/A | N/A |
| | | | 129/130 (99.2%) (low and stable threshold at 3 month visit) | N/A | N/A |
| Reaching safety outcome | 696/725 (96.0%) | 1776/1817 (97.7%) at 12 months | 143/147 (97.3%) | 0.64 | 0.58 |
| Pericardial effusion | 13/725 (1.79%) | 14/1817 (0.77%) | 3/147 (2.0%) | 0.74 | 0.13 |
| PE requiring intervention | 9 (1.24%) | 10 (0.55%) | 2 (1.36%) | >0.99 | 0.23 |
| Pericardiocentesis | 7 (0.97%) | 8 (0.44%) | 2 (1.36%) | | |
| Surgical repair | 2 (0.28%) | 2 (0.11%) | 0 (0%) | | |
| PE settled with observation | 4 (0.55%) | 4 (0.22%) | 1 (0.68%) | | |
| Possible death related to procedure | 1/725 (0.14%) | 5/1817 (0.28%) | 1/147 (0.68%) | 0.31 | 0.37 |

PE = pericardial effusion, low and stable threshold means a threshold of $\leq$2 V/0.24 msec and increase of $\leq$1.5 V/0.24 msec from implantation.
IDE=Investigational Device Exemption; PAR=post-approval registry.
[a] P value of comparisons between IDE and CUHK cohort.
[b] P value of comparisons between PAR and CUHK cohort.

Mark Tsz Kin TAM, Anna Kin Yin CHAN, Alex Chi Kin Au, Lily CHEUNG, Gary Chin Pang Chan, Joseph Yat Sun Chan, Effect of low body mass index in outcome of Micra leadless pacemaker implantation *Journal of the Hong Kong College of Cardiology* 2022;29(2):43-52 https://doi.org/10.55503/2790-6744.1213

# Caution to implant in low BMI patients

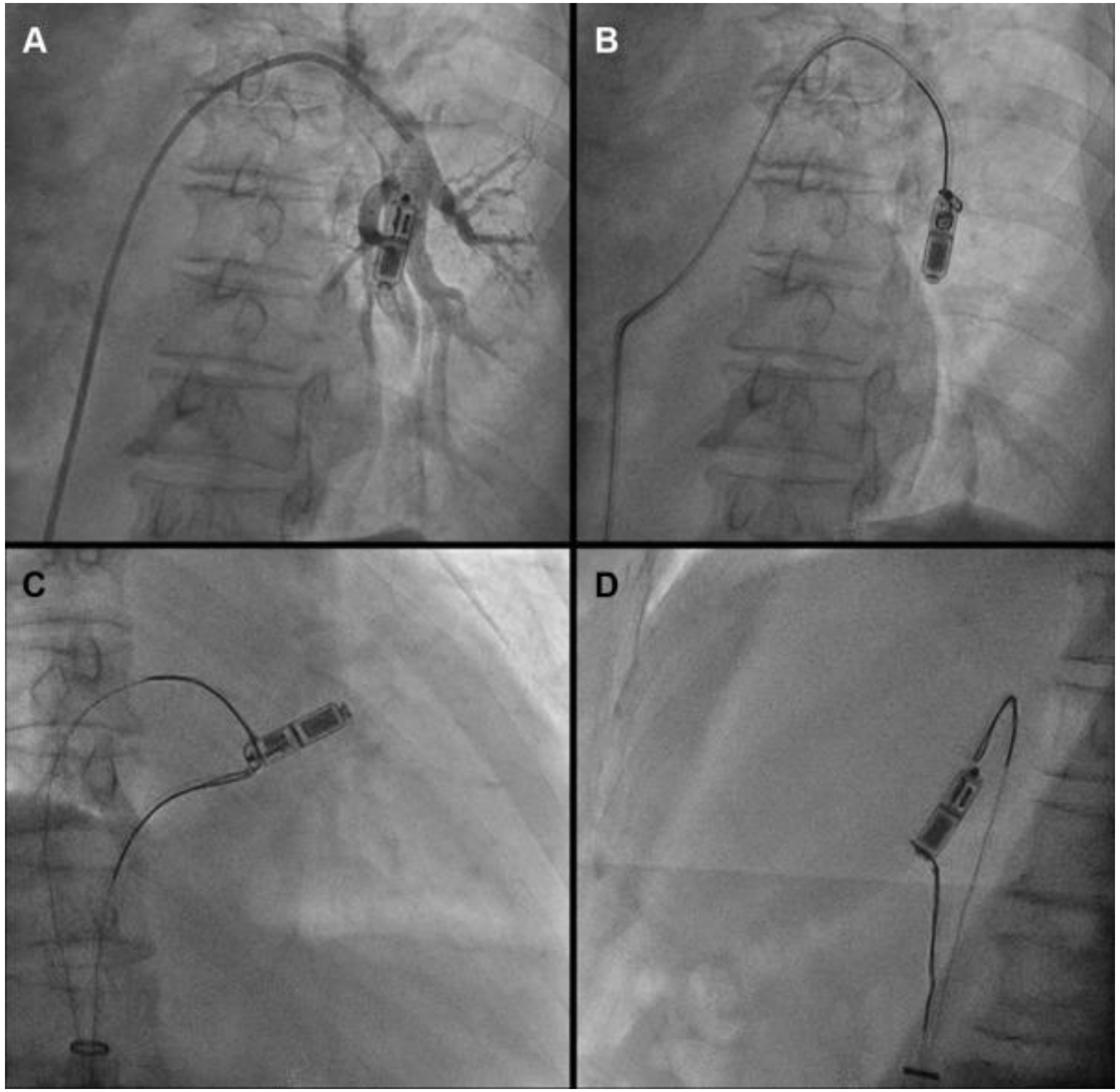
*Table 5. Secondary analysis of BMI affecting on implant position, need for device recapture and procedure time.*

| | High BMI group (n = 71) | Low BMI group (n = 71) | P value |
|---|---|---|---|
| Age (year) | 80.79 ± 9.38 | 80.29 ± 8.19 | 0.731 |
| Male sex | 41 (58%) | 30 (42%) | 0.065 |
| Creatinine clearance (ml/min/1.73m$^2$) | 55.99 ± 21.63 | 59.63 ± 23.11 | 0.334 |
| BMI (kg/m$^2$) | 26.53 ± 2.64 | 20.93 ± 2.11 | <0.001 |
| BSA (m$^2$) | 1.69 ± 0.16 | 1.51 ± 0.15 | <0.001 |
| Implant position at mid or high septum | 12 (17%) | 35 (51%) | <0.001 |
| Deployment attempts | 1.27 ± 0.97 | 1.86 ± 1.97 | 0.026 |
| Need for recapture | 12 (17%) | 22 (31%) | 0.049 |
| Procedure time (in minutes) | 37.7 ± 15.4 | 46.0 ± 20.5 | 0.007 |
| Poor composite outcome | 1 (1.4%) | 10 (14%) | 0.009 |
| Poor efficacy outcome | 1 (1.4%) | 6 (8.5%) | 0.116 |
| Poor safety outcome | 0 | 4 (5.6%) | 0.120 |

BMI = Body mass index, BSA = body surface area.

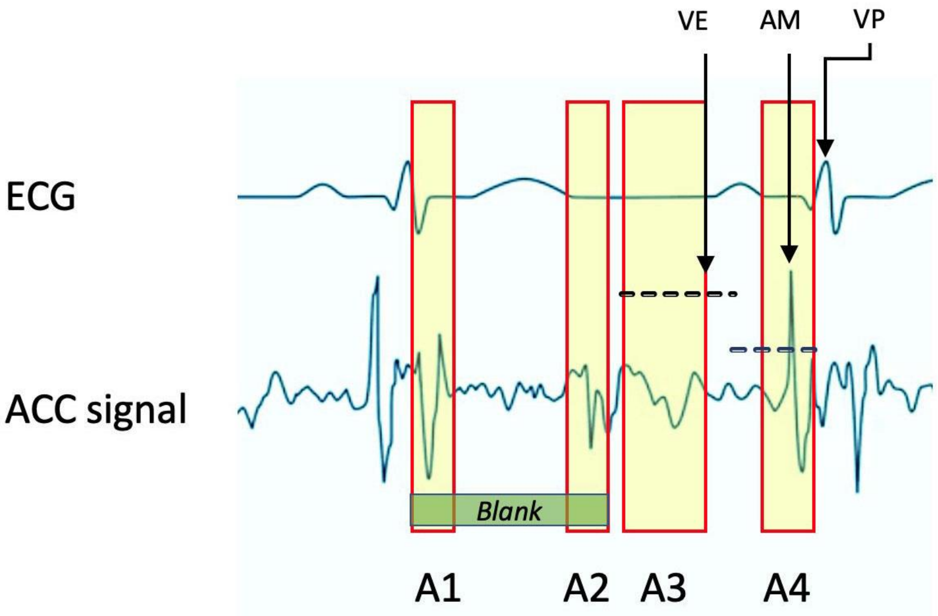
Mark Tsz Kin TAM, Anna Kin Yin CHAN, Alex Chi Kin Au, Lily CHEUNG, Gary Chin Pang Chan, Joseph Yat Sun Cha
Effect of low body mass index in outcome of Micra leadless pacemaker implantation *Journal of the Hong Kong College of Cardiology* 2022;29(2):43-52 https://doi.org/10.55503/2790-6744.1213

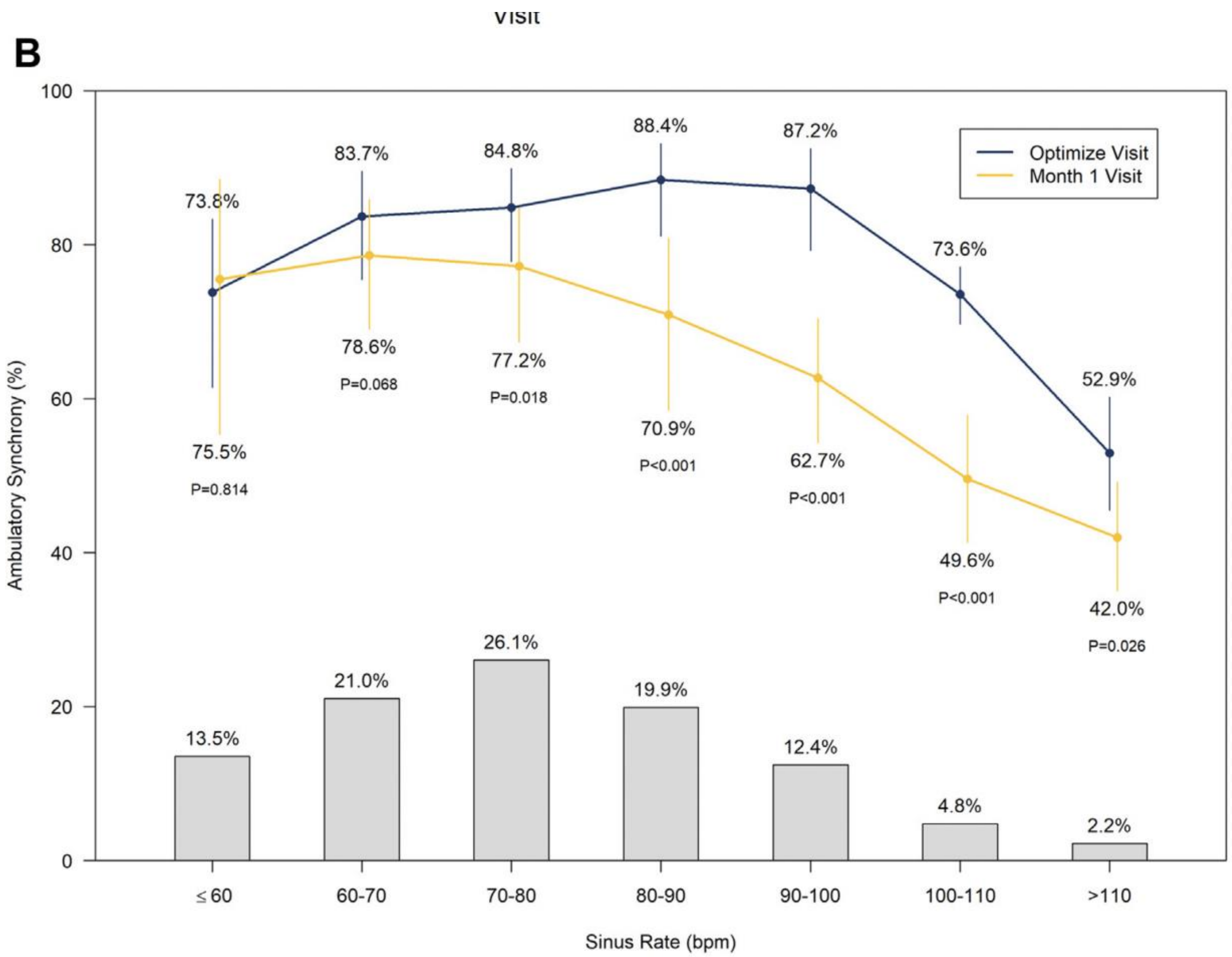
# Device complication can still occur




Tam, Tsz Kin, et al. "Leadless pacemaker tether failure during recapture attempt leading to device embolization." *HeartRhythm Case Reports* 5.5 (2019): 247-250.

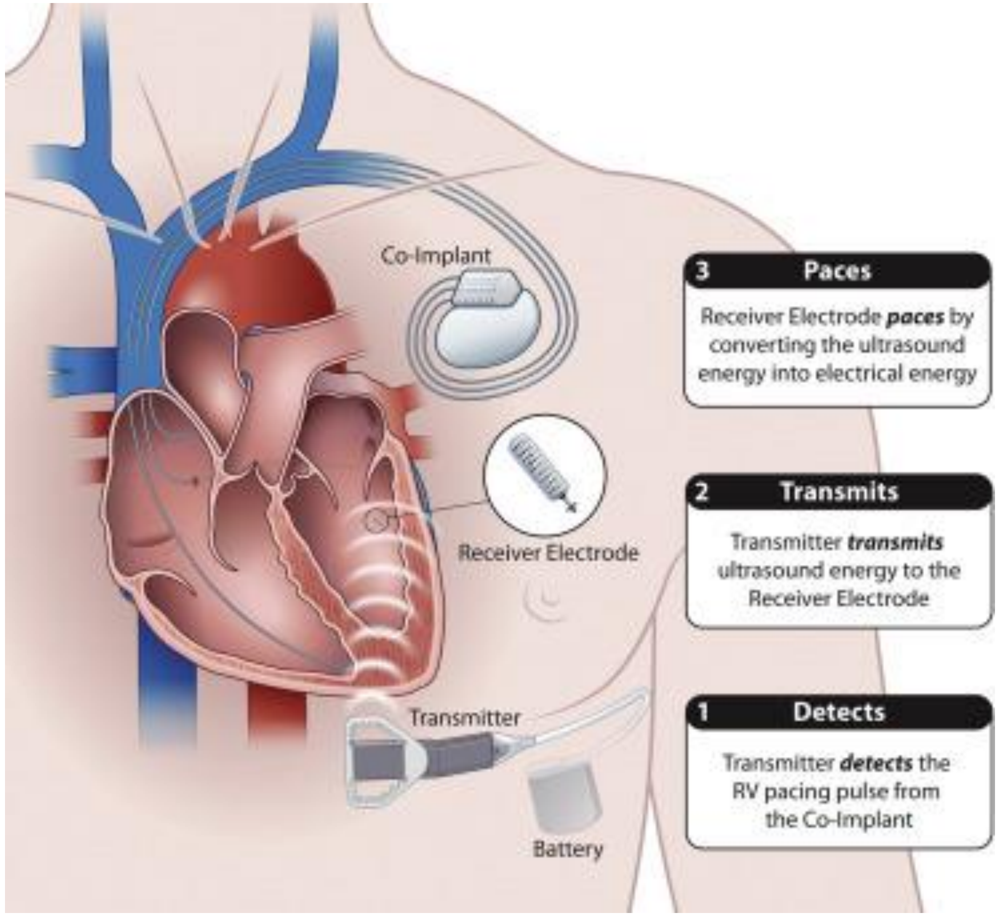
# AV synchrony in Micra AV for heart block

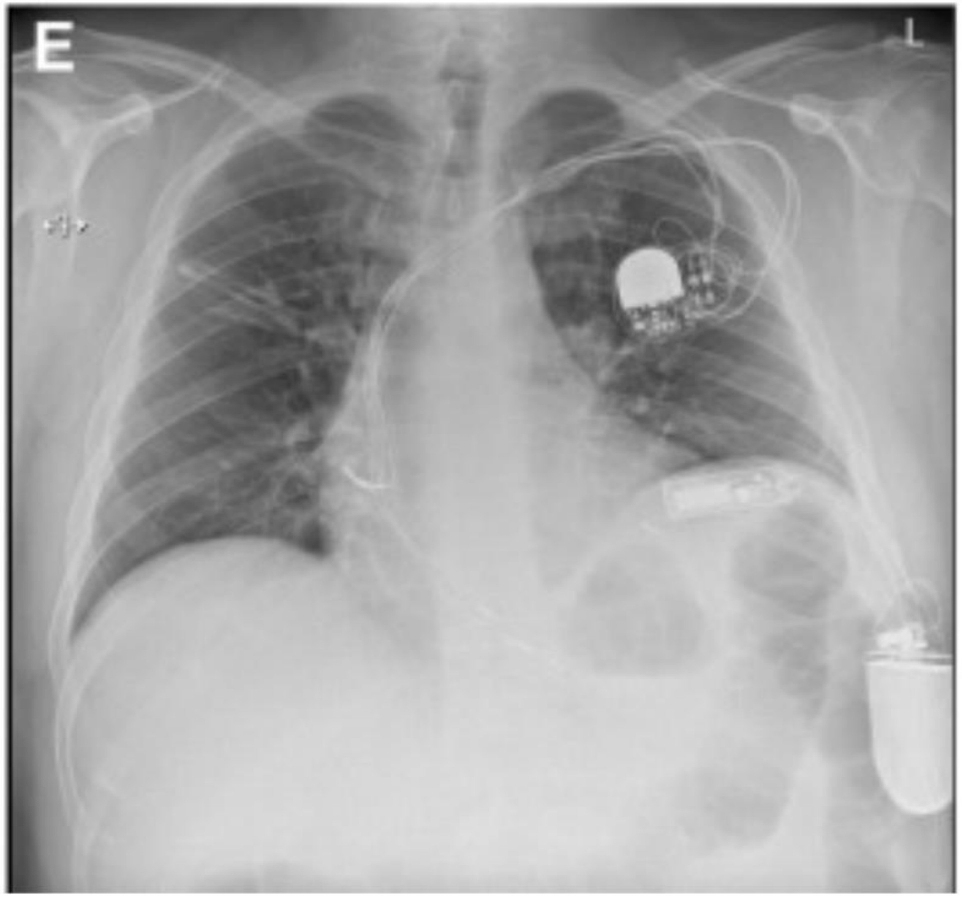



Chinitz, L. A., El-Chami, M. F., Sagi, V., Garcia, H., Hackett, F. K., Leal, M., ... & **Chan, J. Y. S.** (2023). Ambulatory atrioventricular synchronous pacing over time using a leadless ventricular pacemaker: Primary results from the AccelAV study. *Heart Rhythm*, *20*(1), 46-54.

# LV leadless pacemaker for CRT



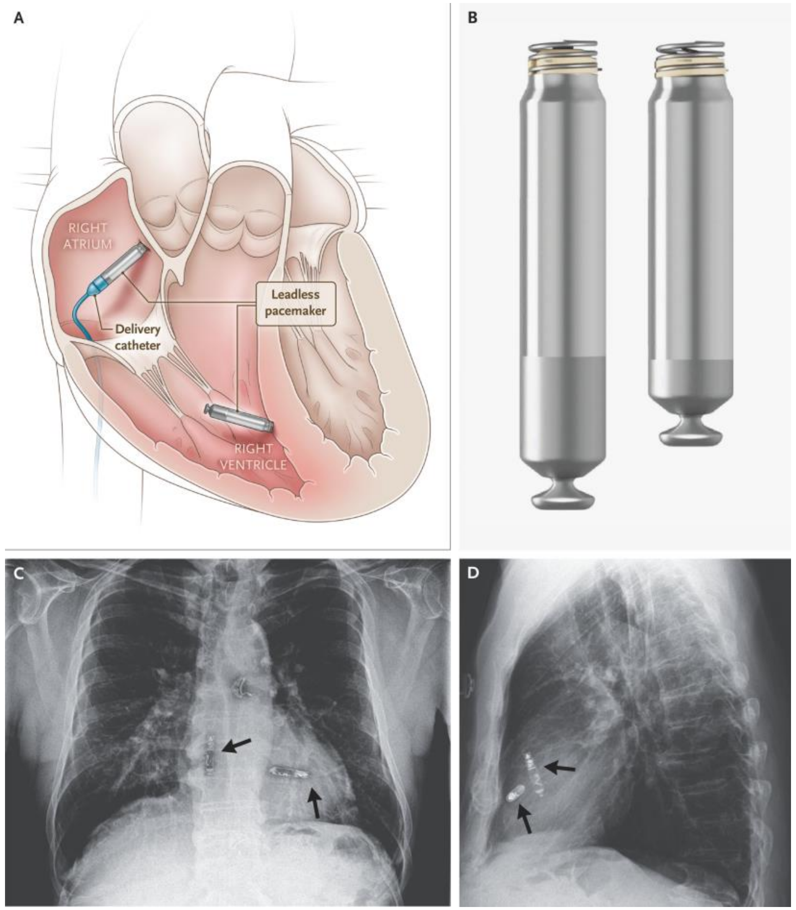



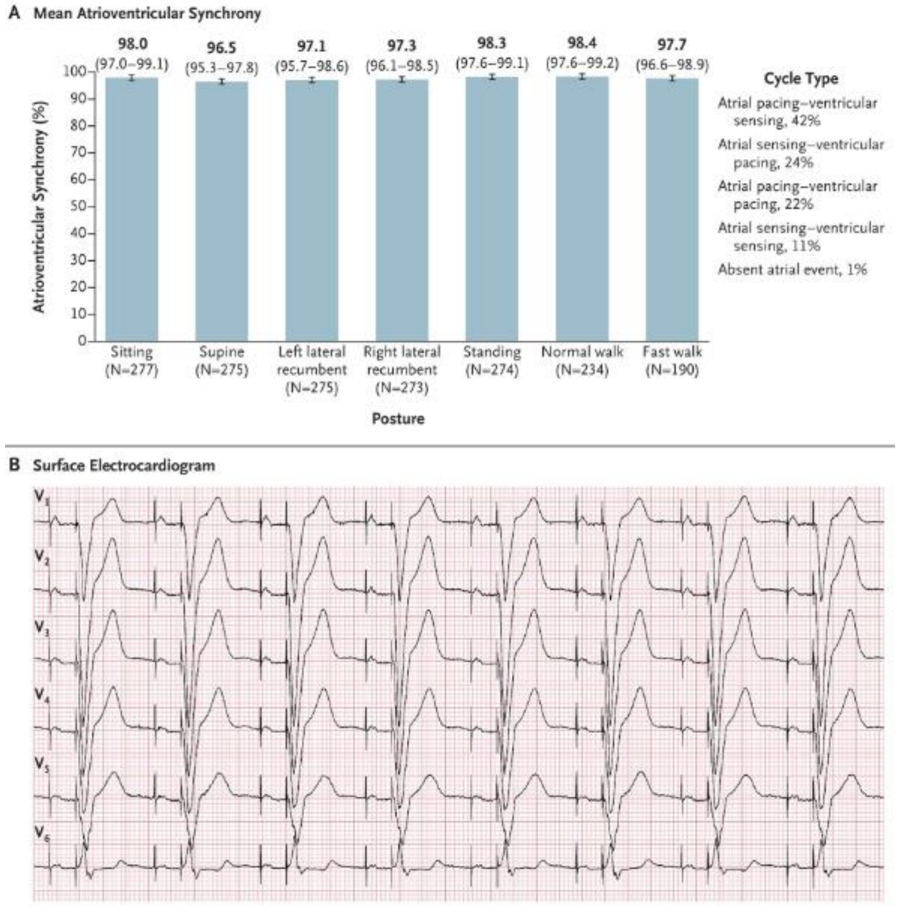

Sieniewicz, Benjamin J., et al. "Real-world experience of leadless left ventricular endocardial cardiac resynchronization therapy: a multicenter international registry of the WiSE-CRT pacing system." *Heart Rhythm* 17.8 (2020): 1291-1297.

ORIGINAL ARTICLE

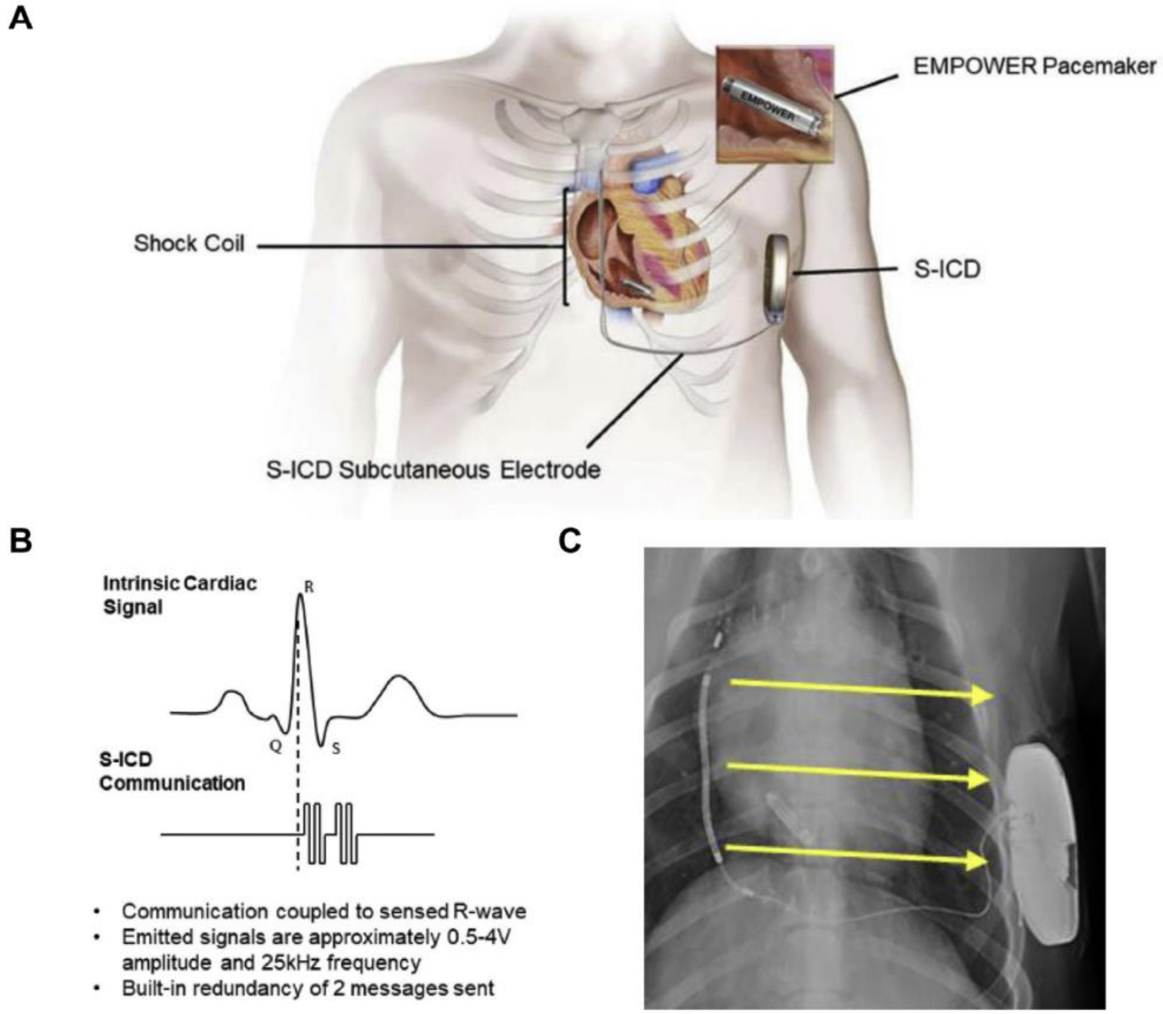
# A Dual-Chamber Leadless Pacemaker

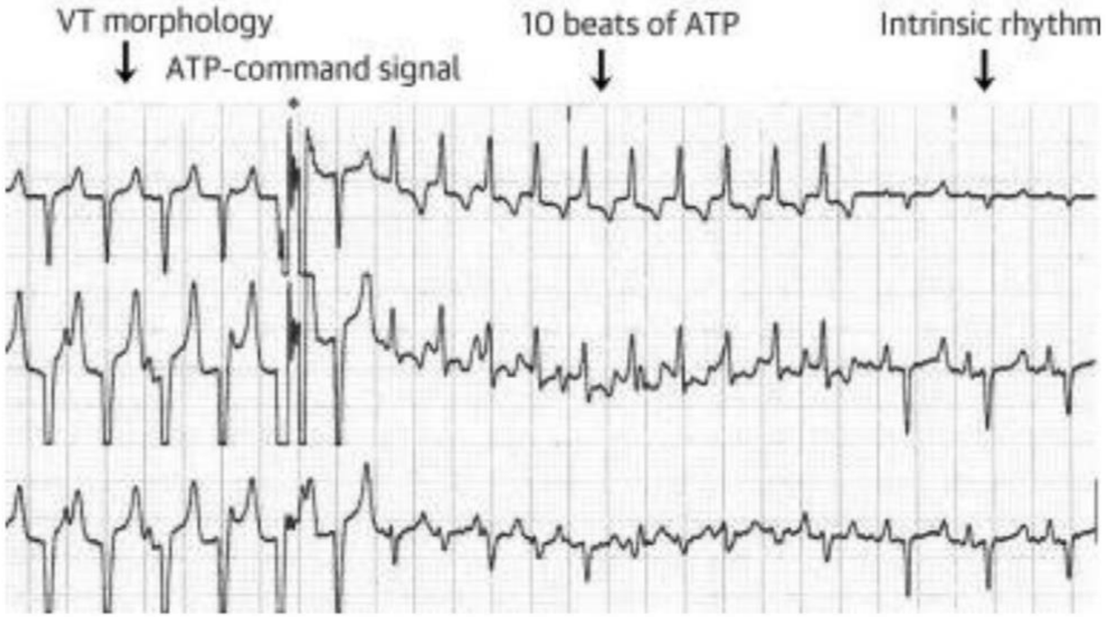
Reinoud E. Knops, M.D., Ph.D., Vivek Y. Reddy, M.D., James E. Ip, M.D., Rahul Doshi, M.D., Derek V. Exner, M.D., M.P.H., Pascal Defaye, M.D., Robert Canby, M.D., Maria Grazia Bongiorni, M.D., Morio Shoda, M.D., Gerhard Hindricks, M.D., Petr Neužil, M.D., Mayer Rashtian, M.D., et al., for the Aveir DR i2i Study Investigators*



# Possible future? Leadless pacemaker communicating with SICD in preclinical studies



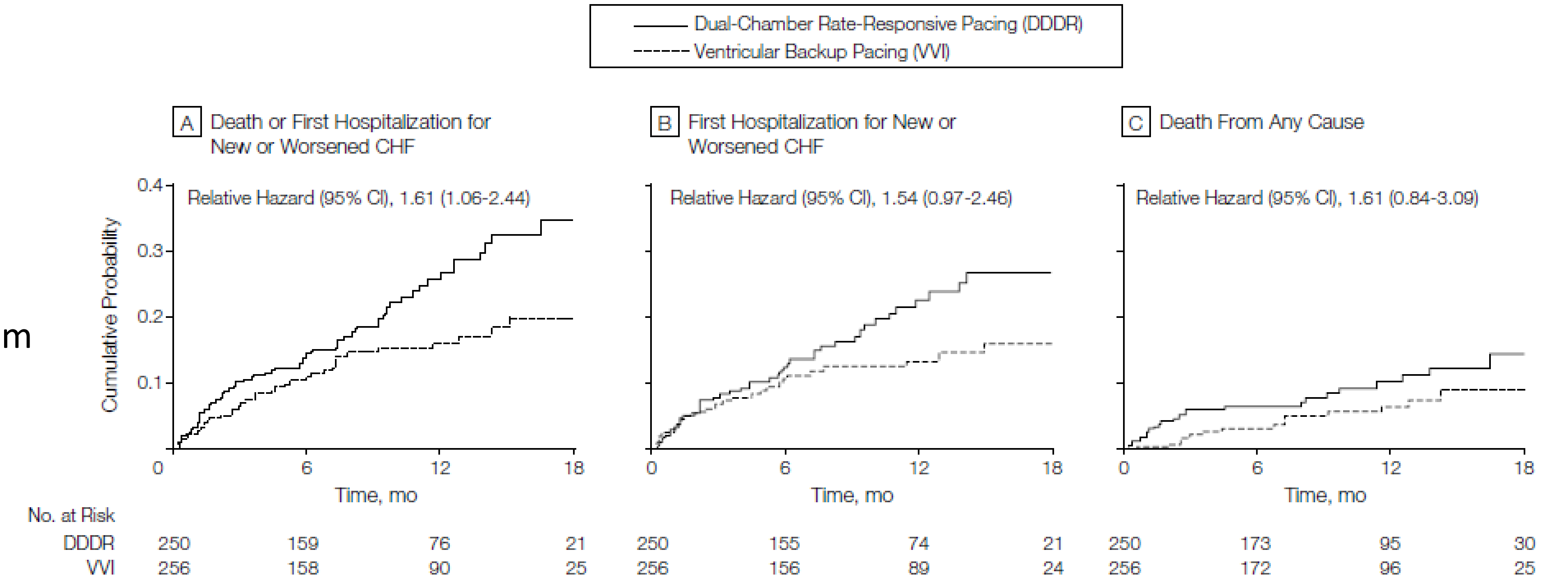




Breeman, Karel TN, et al. "Long-term performance of a novel communicating antitachycardia pacing–enabled leadless pacemaker and subcutaneous implantable cardioverter-defibrillator system: A comprehensive preclinical study." *Heart Rhythm* 19.5 (2022): 837-846.

# Conduction system pacing

# DAVID trial: RV pacing increases risk of death or HF hospitalization

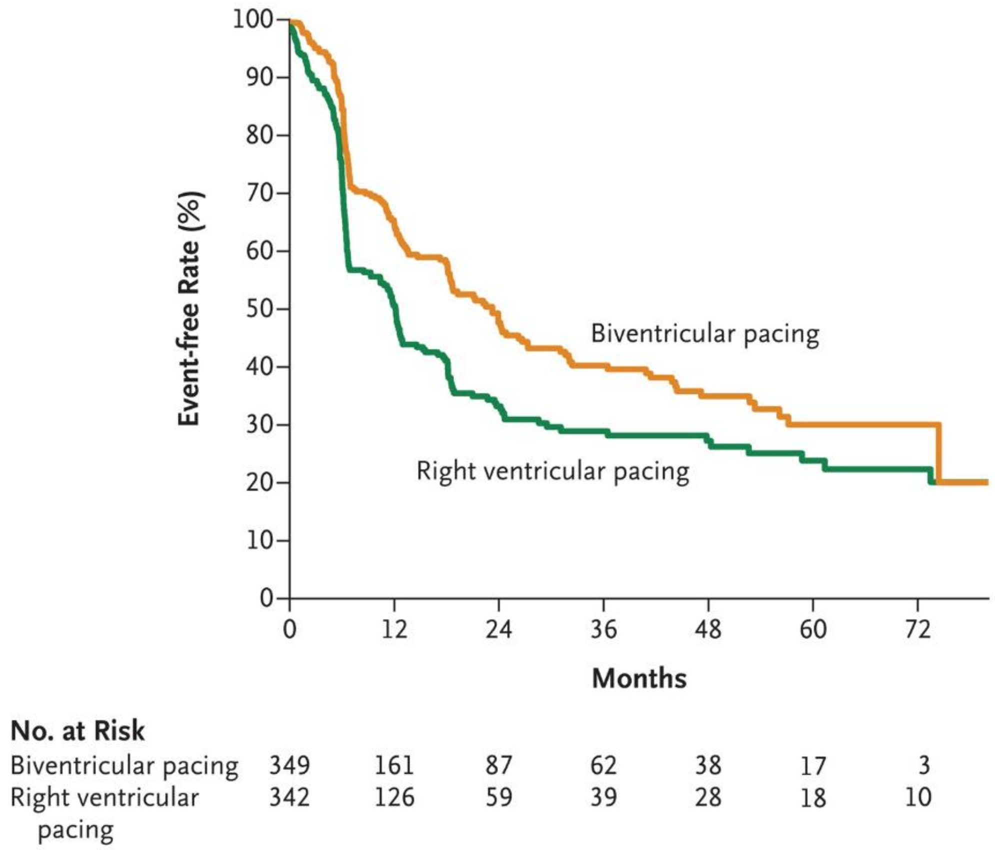
Patient with LVEF <=40% with ICD indication randomized into VVI 40bpm or DDDR 70bpm




For all plots, time zero is the day of randomization. CI indicates confidence interval. A, Survival to death or first hospitalization for congestive heart failure (CHF). Unadjusted *P*=.02; adjusted for sequential monitoring, *P*=.03. B, Survival to first hospitalization for CHF. Patients are censored at death. Log-rank *P*=.07. C, Survival to death from any cause. Log-rank *P*=.15.

Wilkoff, Bruce L., et al. "Dual-chamber pacing or ventricular backup pacing in patients with an implantable defibrillator: the Dual Chamber and VVI Implantable Defibrillator (DAVID) Trial." *Jama* 288.24 (2002): 3115-3123.

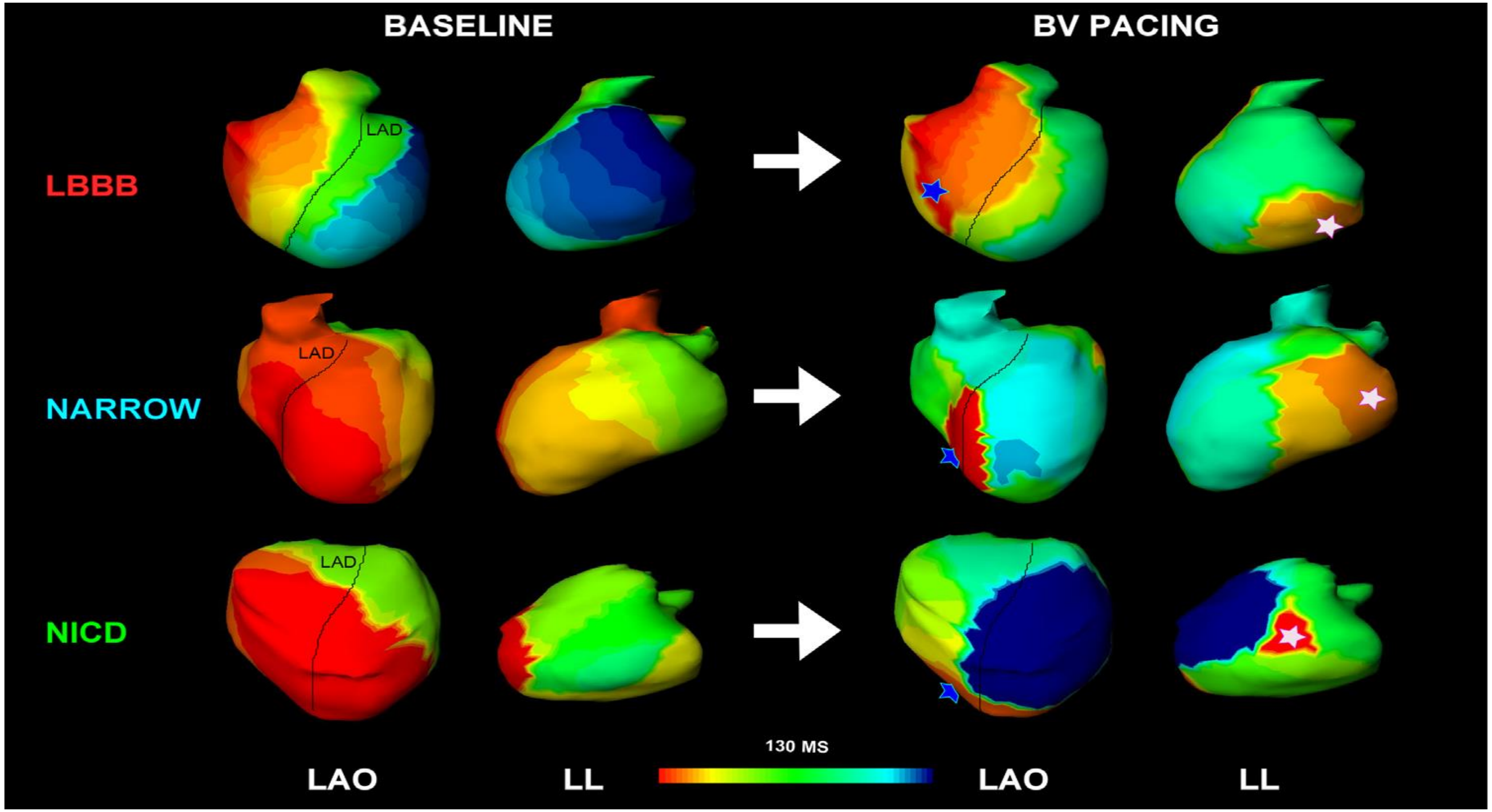
# Block HF trial: BiVp is superior to RVp in patients with LVEF <=50%




HR 0.74 (95% CI: 0.60 to 0.90)

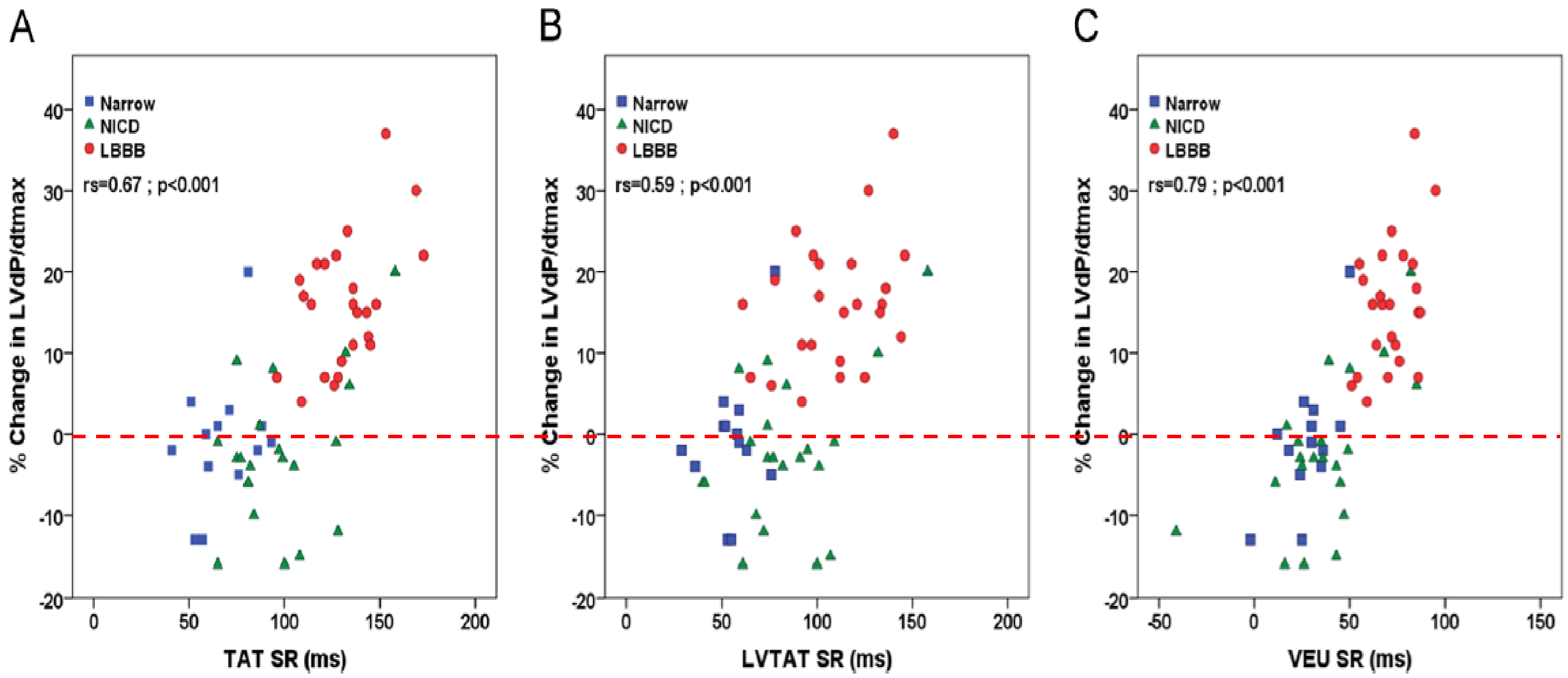
Curtis, Anne B., et al. "Biventricular pacing for atrioventricular block and systolic dysfunction." *New England Journal of Medicine* 368.17 (2013): 1585-1593.

# BiV induced Dyssynchrony



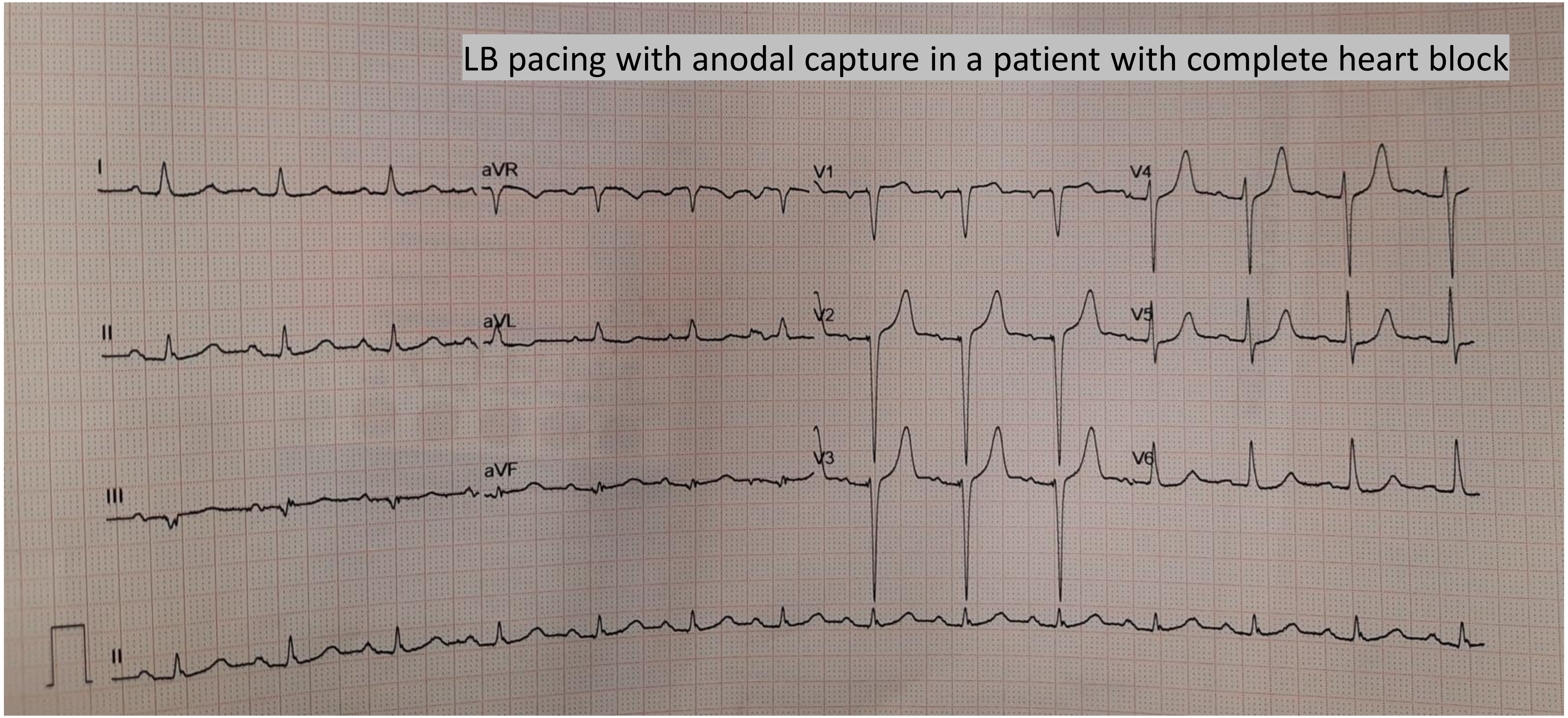

Ploux S et al Heart Rhythm 2015

# BiV induced Dyssynchrony




Ploux S et al Heart Rhythm 2015

# The beauty of conduction system pacing



# Variety of conduction system pacing

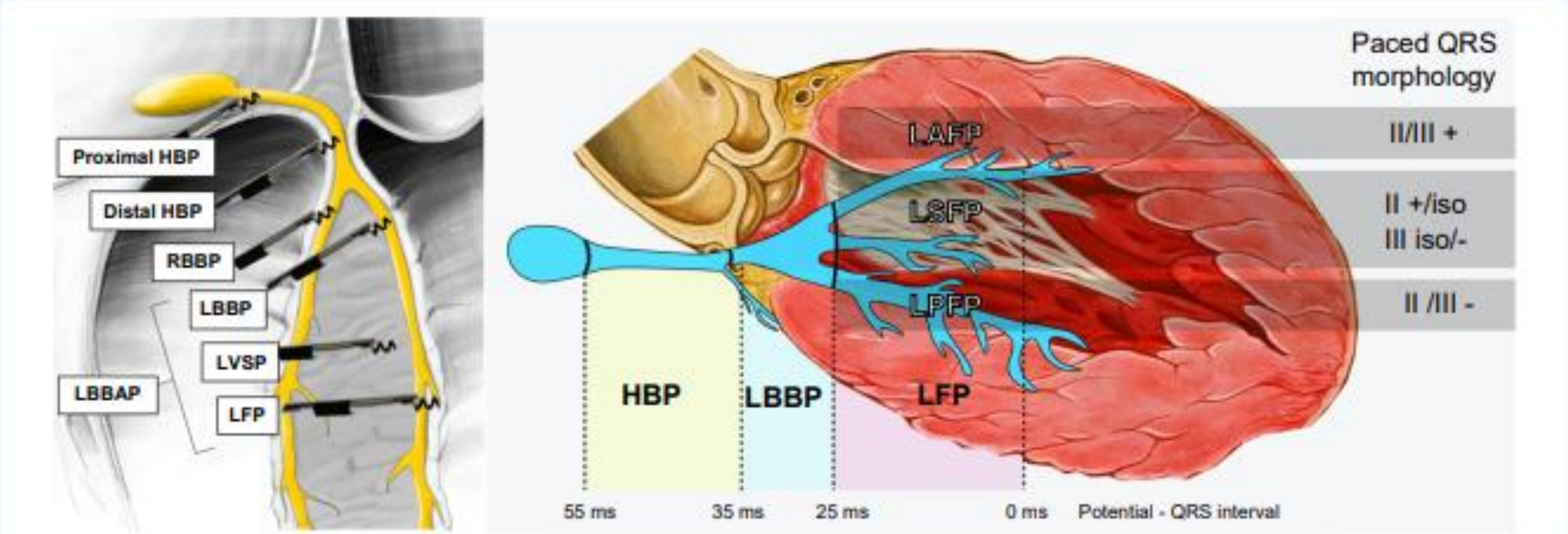
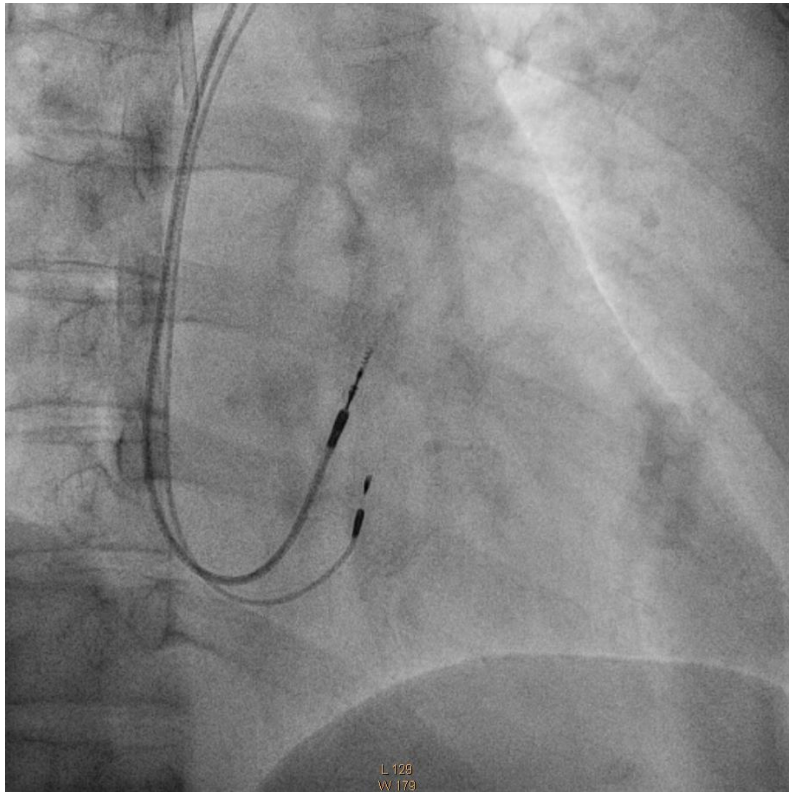


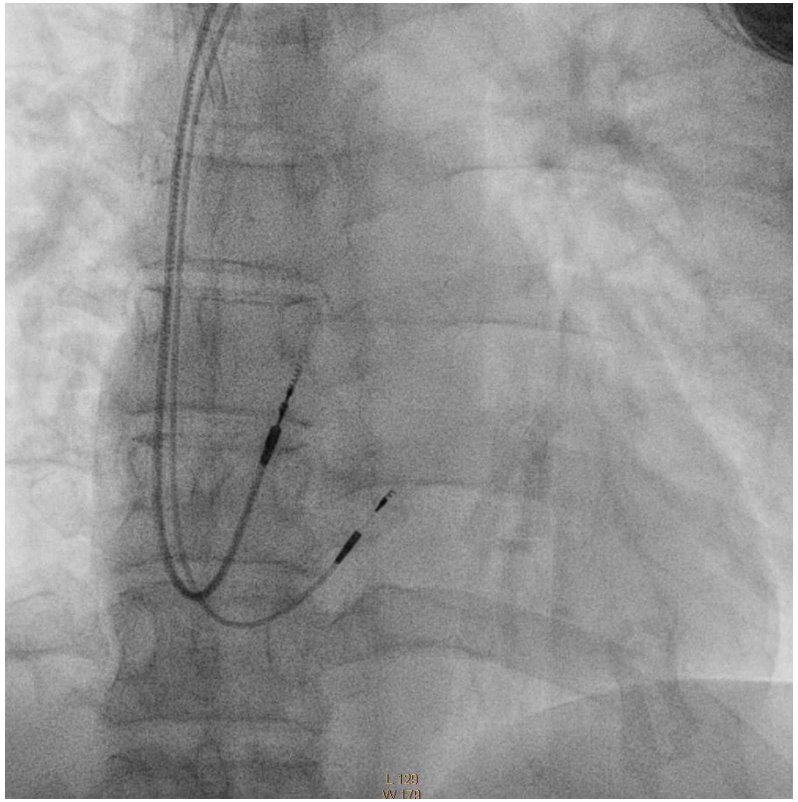

**Figure 1** Categories of conduction system pacing. Anatomical position of the pacing lead, potential to QRS interval (if visualized), and paced QRS morphology in leads II and III are used to determine the level of CSP. RBBP and LVSP are not shown on the right panel. HBP = His bundle pacing; iso = isoelectric; LAFP = left anterior fascicle pacing; LBBAP = left bundle branch area pacing; LBBP = left bundle branch pacing; LFP = left fascicular pacing; LPFP = left posterior fascicle pacing; LSFP = left septal fascicle pacing; LVSP = left ventricular septal pacing; RBBP = right bundle branch pacing. Modified with permission from Filip Plesinger and from Jastrzebski *et al.*[7]

# His Bundle Pacing

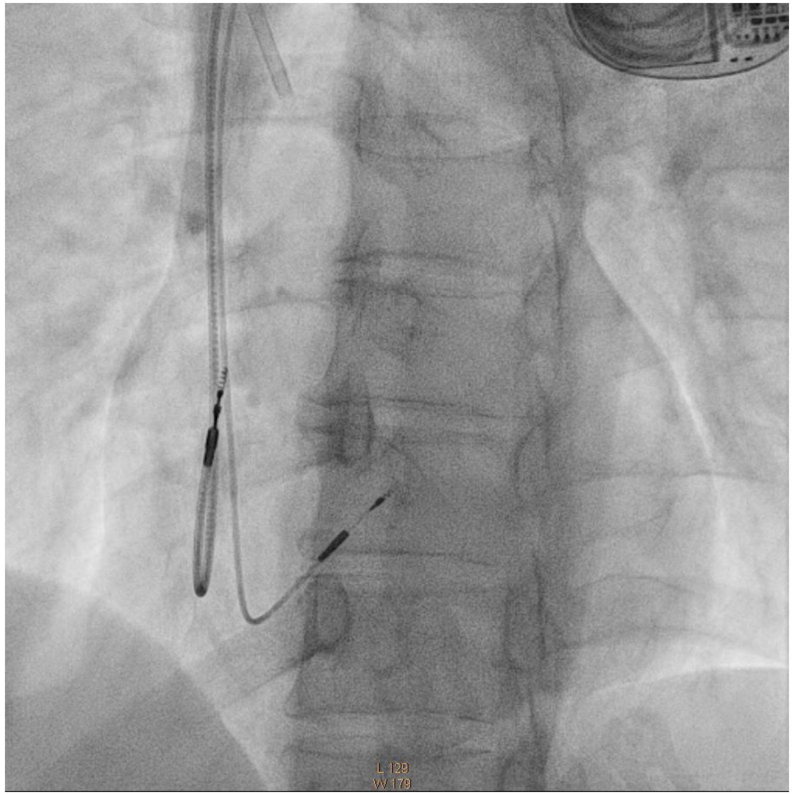
RAO




AP

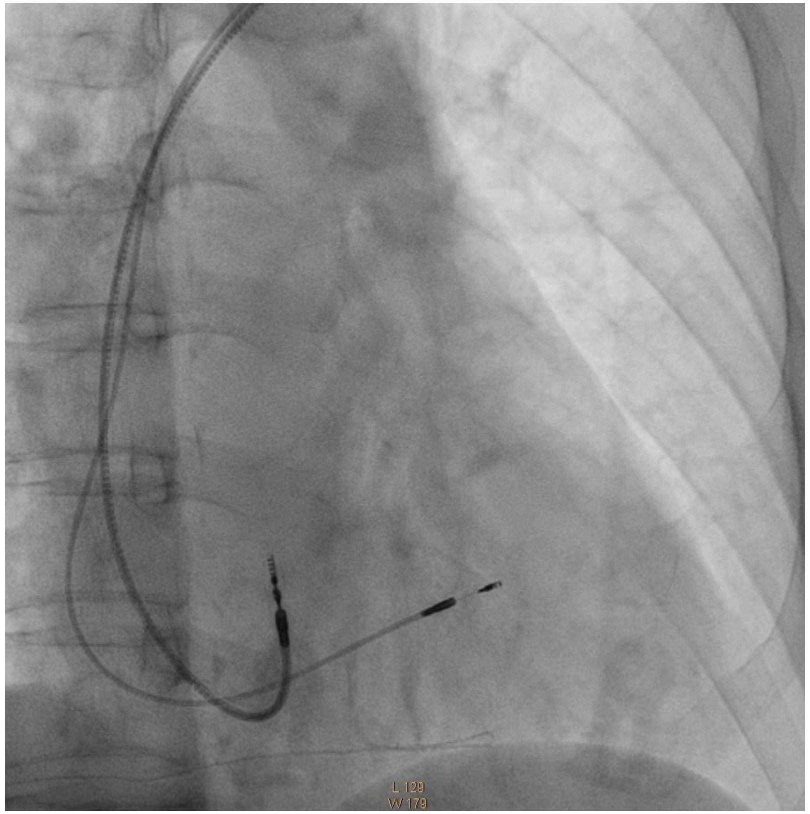



LAO



# LB pacing

RAO

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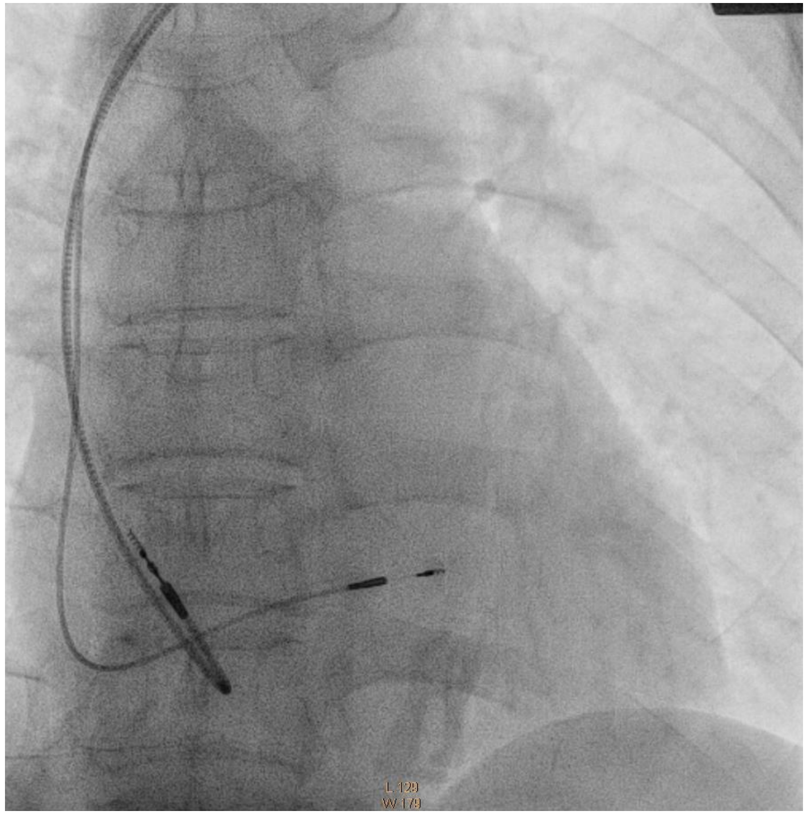
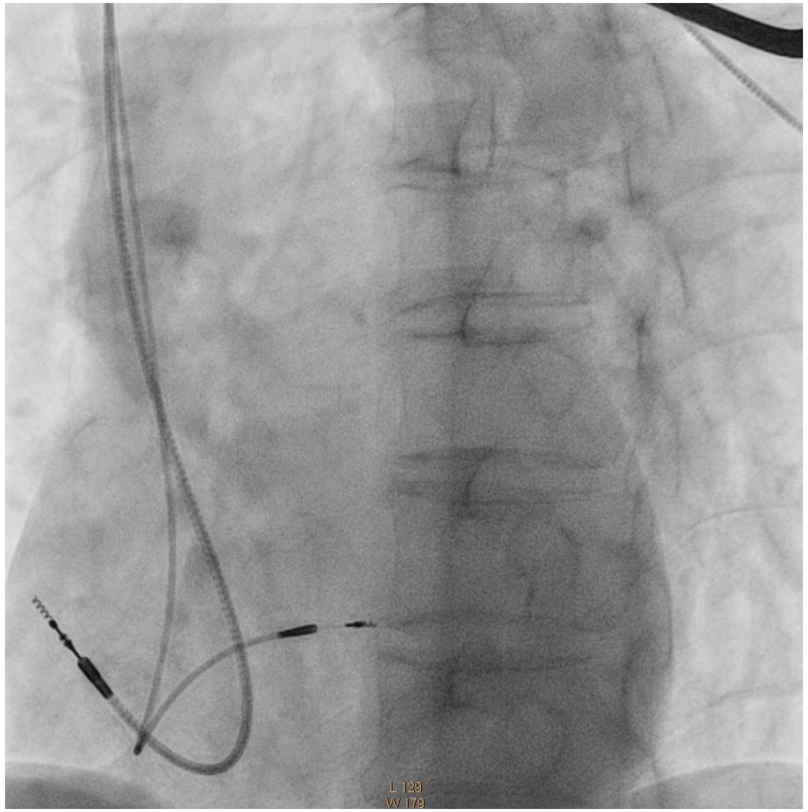
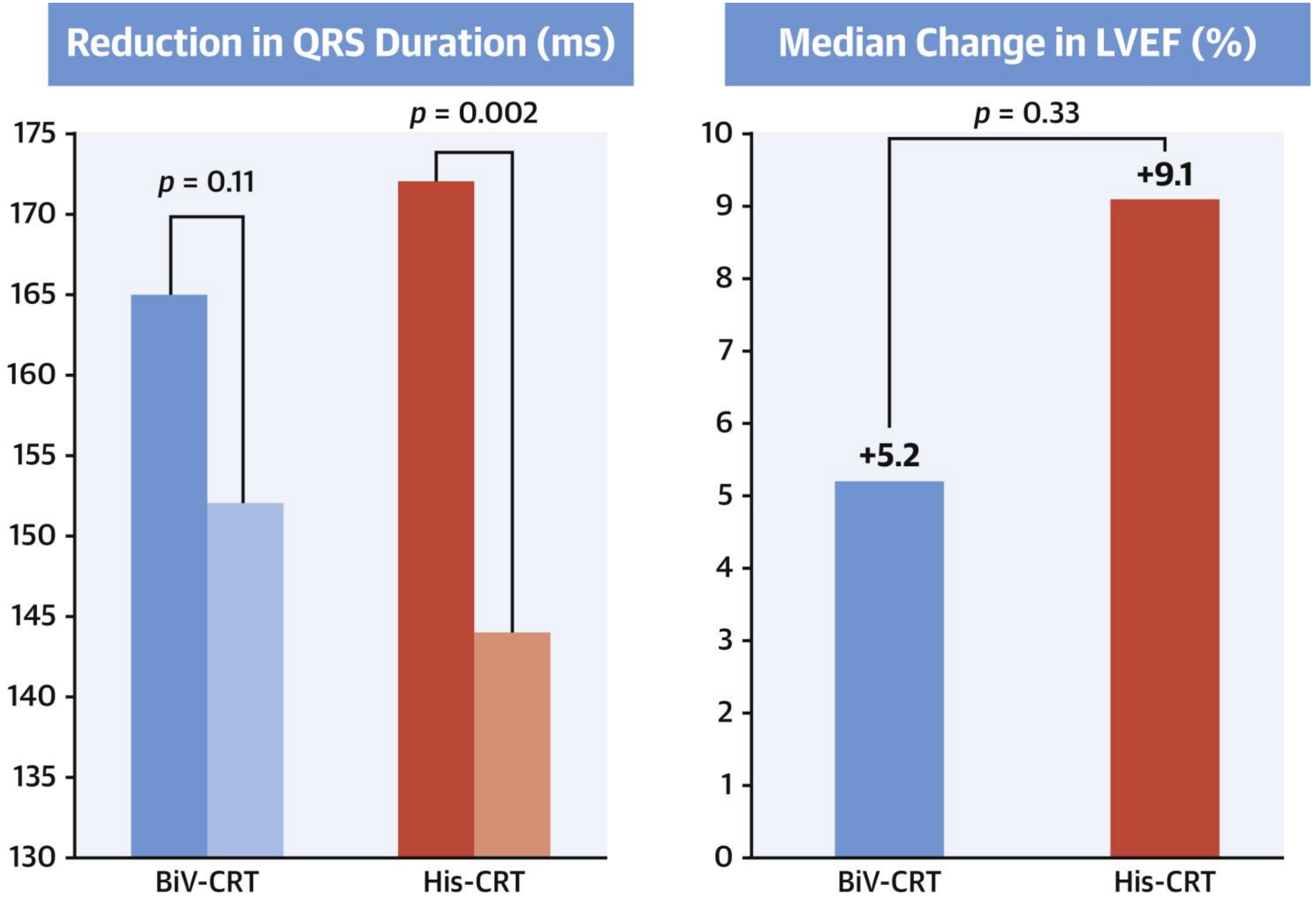



LAO



# HIS Sync trial: failed to demonstrate superiority of HBP over BiVCRT in patients with CRT indications




Upadhyay, Gaurav A., et al. "His corrective pacing or biventricular pacing for cardiac resynchronization in heart failure." *Journal of the American College of Cardiology* 74.1 (2019): 157-159.

| Recommendations | Class[a] | Level[b] |
| --- | --- | --- |
| In patients treated with HBP, device programming tailored to specific requirements of HBP is recommended.[430,431] | 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.[318,424,440,443] | IIa | B |
| In patients treated with HBP, implantation of an RV lead used as 'backup' for pacing should be considered in specific situations (e.g. pacemaker dependency, high-grade AVB, infranodal block, high pacing threshold, planned AVJ ablation) or for sensing in the case of issues with detection (e.g. risk of ventricular undersensing or oversensing of atrial/His potentials).[423,426,444] | 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 the intrinsic QRS is narrow.[197,199,200,318] | IIb | C |

| | | |
| --- | --- | --- |
| HBP may be considered as an alternative to RV pacing in patients with AVB and LVEF >40%, who are anticipated to have >20% ventricular pacing.[42,433] | IIb | C |

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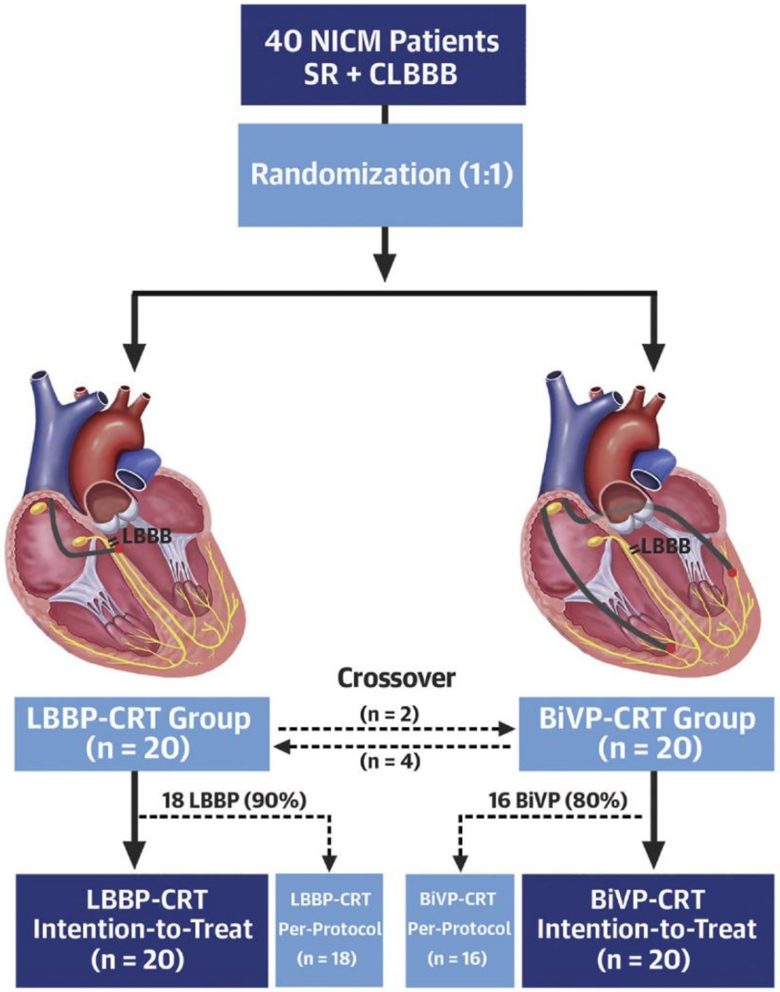
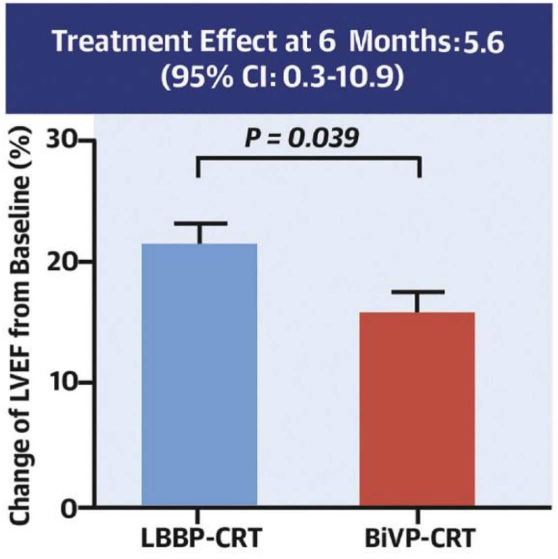
- ESC guideline on pacing 2021

**CENTRAL ILLUSTRATION: Left Bundle Branch Pacing vs Biventricular Pacing for cardiac Resynchronization Therapy**




Wang Y, et al. J Am Coll Cardiol. 2022;80(13):1205-1216.

# His bundle pacing vs Left Bundle Pacing

- Theoretically HBP is the most physiological
- Downside of HBP
  - More technical demanding
  - lead dislodegement
  - high acute threshold
  - Chronic increase in lead threshold
  - block below the HIS bundle
- Downside of LBP
  - Not as “physiological”, particularly with distal LB pacing
  - Perforation of septum into LV cavity
  - Difficulty in ascertaining left bundle capture

# Conclusion

- Pacing has gone a long way since Dr Ake Senning implanted the first pacemaker in 1958
- Leadless pacemaker has a favourable complication rates over conventional pacemaker. AV synchrony is attainable (but not perfect) with specific leadless pacemaker model.
- Dual chamber leadless pacemaker has shown to be reliable in achieving AV synchrony. It is however not yet commercially available.
- Conduction system pacing (HBP and LBP) is an appealing alternative pacing strategy. This is particularly relevant for patients with heart failure and heart block.
- An RCT has demonstrated superiority of LBP over BiVP in patients with LBBB and heart failure

# Thank you

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