Te Whatu Ora
Health New Zealand

Leadless Cardiac Pacing

The Wireless Way Forward

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Background

- Implantation of permanent transvenous pacemakers improve quality of life and reduce mortality in at risk patients
- 1 in 8 transvenous patients may experience a complication in either the short term or long term
- Leadless cardiac pacemaker concept has been around since the 1970s and was developed to address limitations seen with transvenous systems
- Available to implant in NZ since 2019

Transvenous Pacing Complications

Implant Complications	Lead Complications	Pocket Complications
Arterial puncture	Dislodgement	Infection
Pneumothorax	Insulation/conductor breach	Erosion
Haemothorax	Connector issues	Pocket hematoma
Cardiac Tamponade	Venous thrombosis	Twiddler syndrome
	Tricuspid regurgitation	Aesthetic concerns of the patient

Leadless Pacemaker

- Does not require a transvenous lead
- Is implanted directly in the right ventricle via a catheter
- Does not require a device pocket
- Has no physical reminder of an implanted device

Selection Criteria

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

UK Expert Consensus Statement for the Optimal Use and Clinical Utility of Leadless Pacing Systems on Behalf of the British Heart Rhythm Society, 2022

Medtronic Micra vs Abbott Aveir

- 6.7mm x 25.9mm - mass 1.75g
- Nitinol Tines
- Steroid eluting tip
- 31 implanted at ACH since 2020

- 6.5mm x 38mm – mass 2.4g
- Fixed helix
- Steroid eluting tip
- 3 implanted at ACH this year (first in NZ)

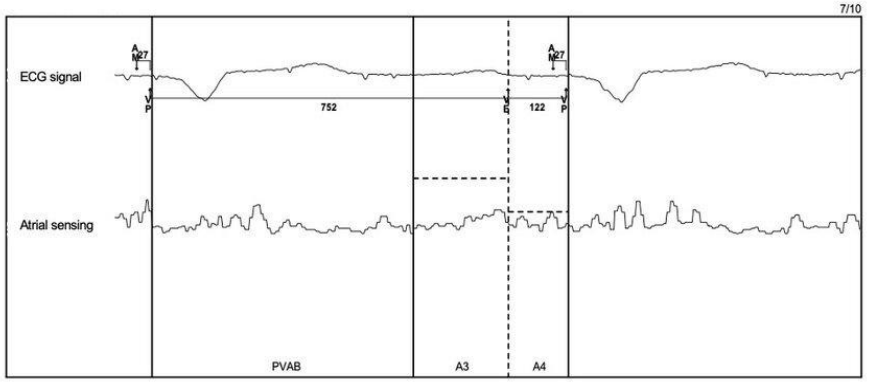
Medtronic Micra vs Abbott Aveir

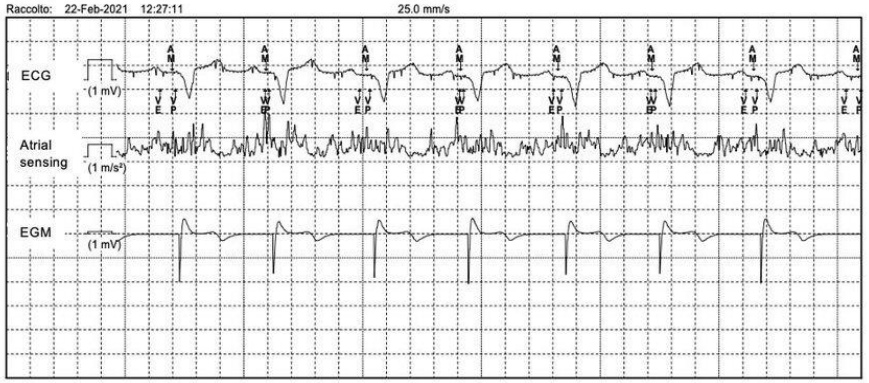
	Micra	Aveir
Single/dual chamber	VR and AV synchrony	VR and DR
Arrhythmia storage	No	No
Auto capture	Yes	No
Rate response	Accelerometer	Temperature sensed
Magnet response	No	No
Longevity	17 years	15 years
MRI	1.5T and 3T	1.5T and 3T
Telemetry	Inductive RF telemetry with header	Conducted communication with ECG
Remote monitoring	Yes	No
Delivery sheath size	27F	27F
Retrieval	No	Yes – long term

Micra AV

- Micra AV – same size as VR but different circuitry
- Detects mechanical atrial activity using 3-axis accelerometer
- AV synchrony up to ~110bpm
- 13 Micra AV patients implanted – 6 still programmed VDD
- Not suitable for SND as no atrial pacing

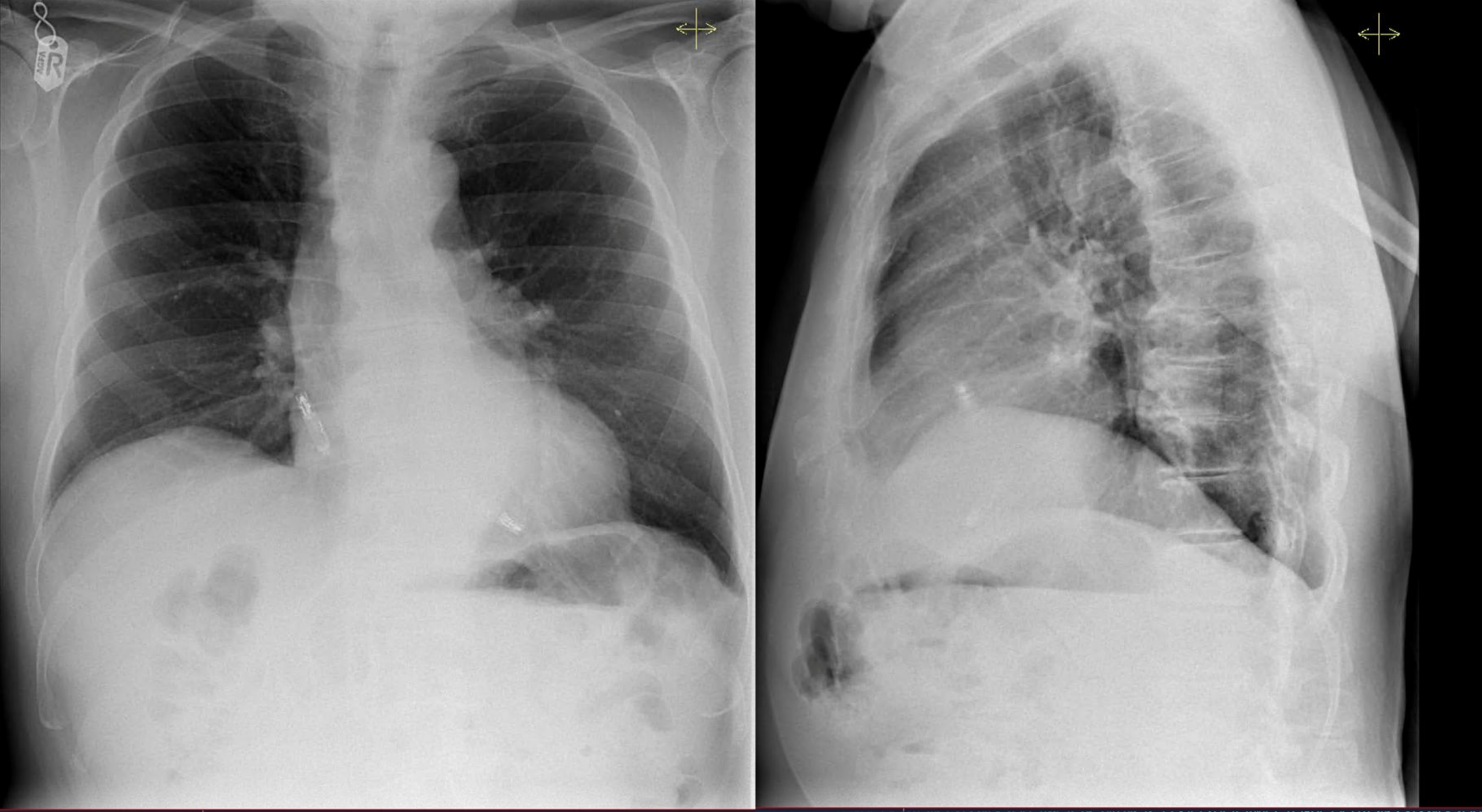
	Test values
Mode	VDD
Pacing rate	50 min-1
Atrial sensing vector	2+3
A3 Threshold	4.4 m/s²
A3 window end	750 ms
A4 threshold	1.7 m/s²





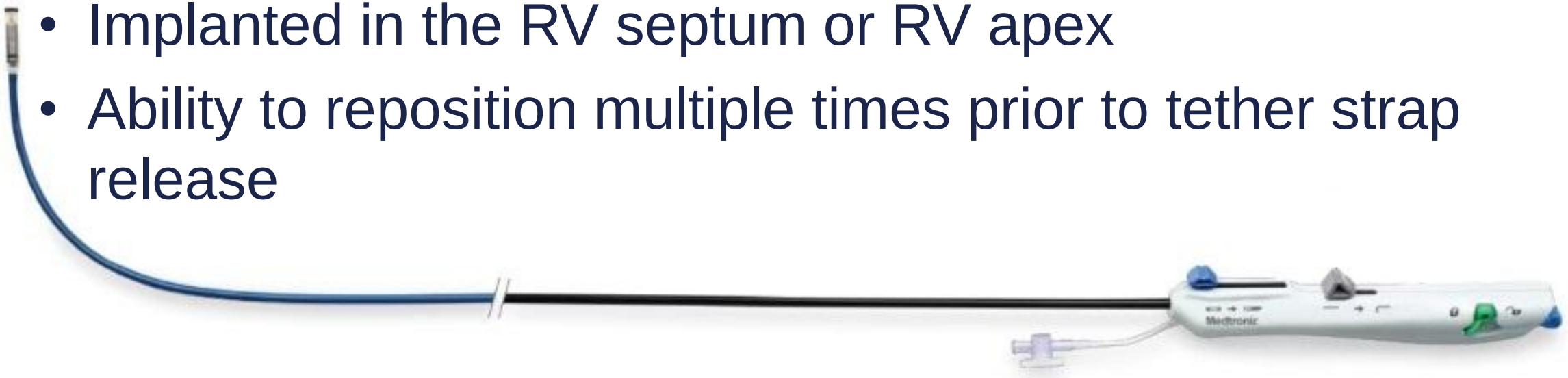
Dual Chamber Aveir

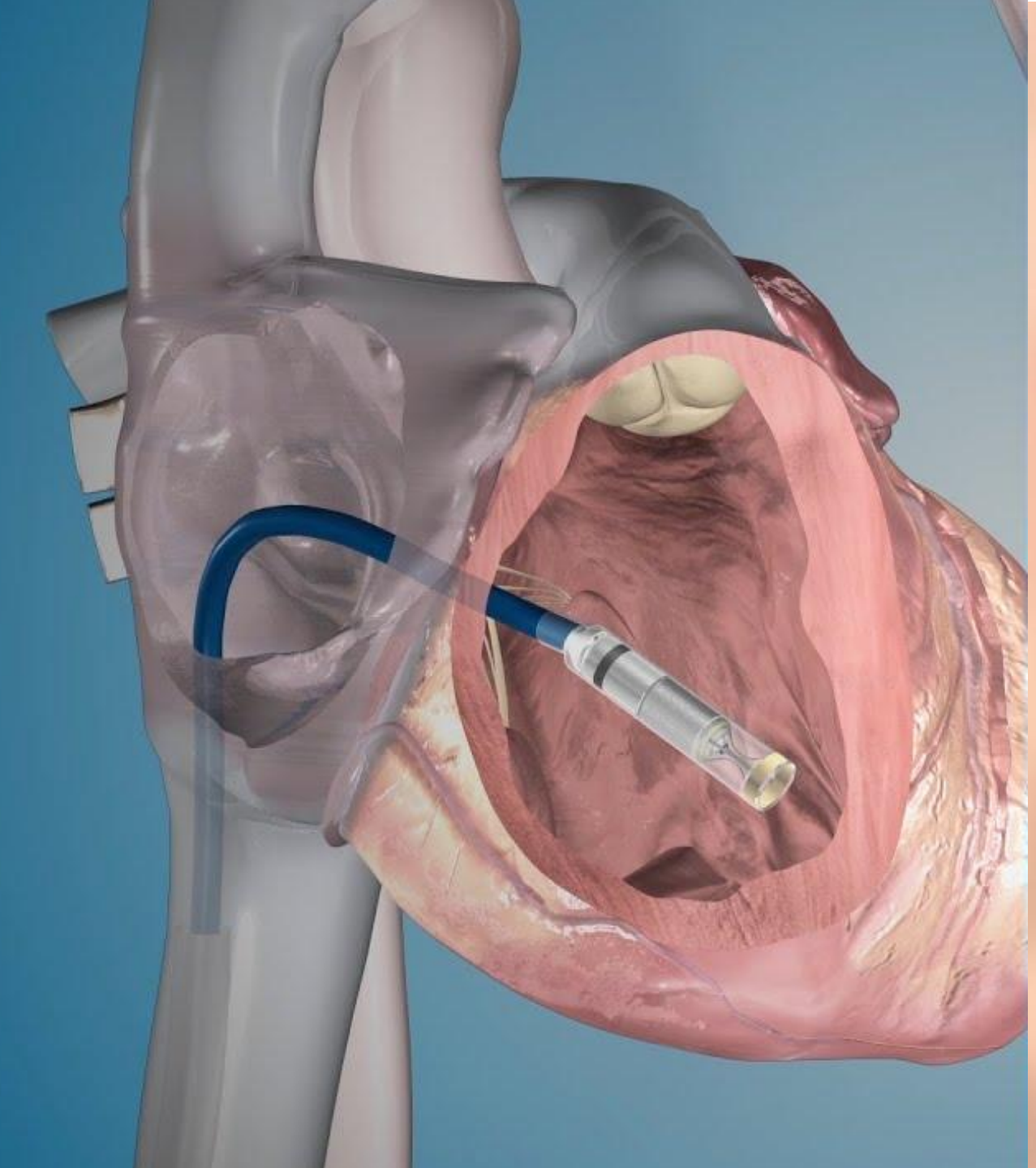
- Requires two Aveir implants, one in the atrium and one in the ventricle
- Atrial Aveir is slightly smaller
- Provides dual chamber pacing
- Conductive communication between the two pacemakers
- FDA approval July 2023, will be available to implant at ACH later this year

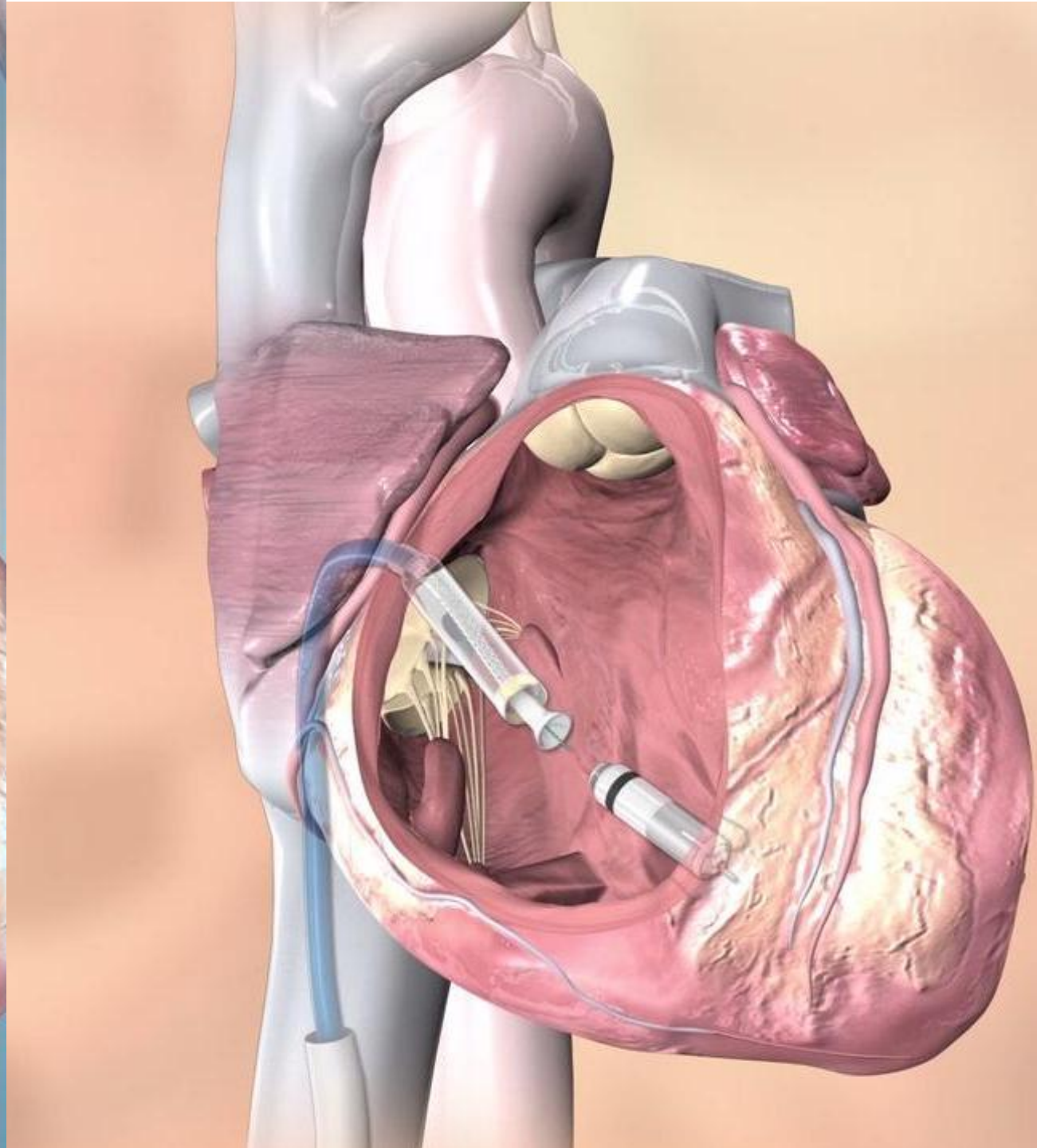


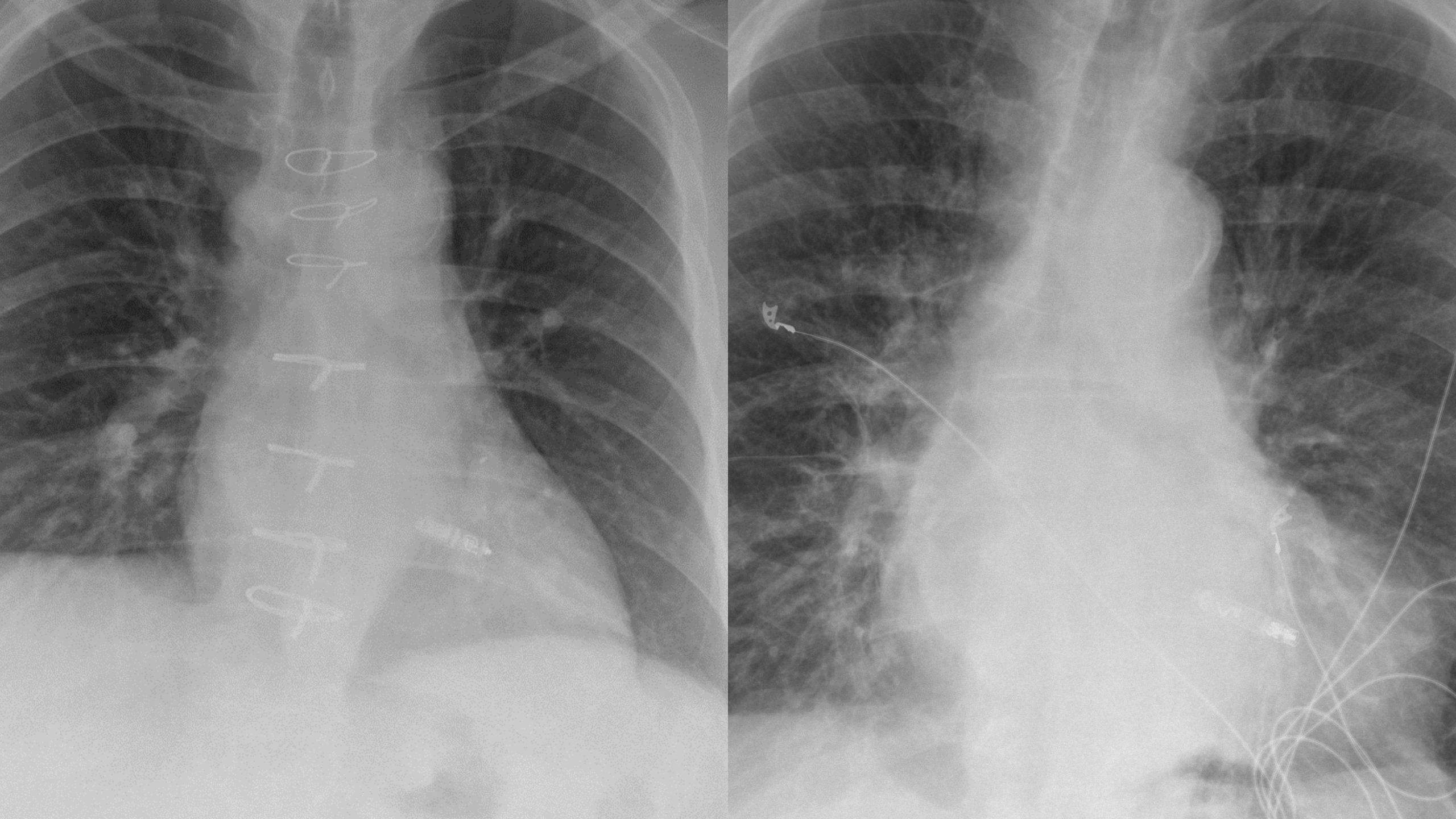
Implant Procedure

- Implanted via femoral vein
- 27F delivery sheath
- Steerable delivery catheter
- Implanted in the RV septum or RV apex
- Ability to reposition multiple times prior to tether strap release









Leadless II Trial

- Prospective, nonrandomised, multicenter clinical trial
- November 2020 and July 2021
- 210 patients across 43 centers in US, Canada and Europe
- Aveir LCP system in patients with standard VVI pacing indications
- Safety endpoint was freedom from serious adverse events 93.2%
- Efficacy endpoint pacing thresholds <2.0V @ 0.4ms,R wave >5.0mV at 1 year follow up. 95.1%
- Implantation success rate was 98%
- 82.4% did not require repositioning
- Most complications occurred in first 3 days post procedure (73% 11/15). 4 x tamponade, and 3 x premature deployment
- Four long term complications (2 x heart failure and 2 x pacing induced CM)

Reddy, V.Y. et al (2023) 1-Year Outcomes of a Leadless Ventricular Pacemaker: The LEADLESS II (Phase 2) Trial. J Am Coll Cardiol EP. 2023 Jul, 9, 1187-1189

Micra Transcatheter Pacemaker Study

- Prospective, nonrandomised, multicenter study
- 725 patients
- Micra LCP implanted in patients with indications for ventricular pacing
- Implantation success in 719 of 725 patients (99.2%)
- Safety endpoint was 96%
- Primary efficacy end point 98.3%
- 28 major complications in 25 patients of 725 patients (3.4%), 2 x embolism/thrombosis, 5 x groin puncture events, 11 x cardiac perforation/effusion, 2 x elevated pacing threshold, 8 x other

Reynolds, D. et al. (2016) A leadless Intracardiac Transcatheter Pacing System. N Engl J Med 2016; 374:533-541

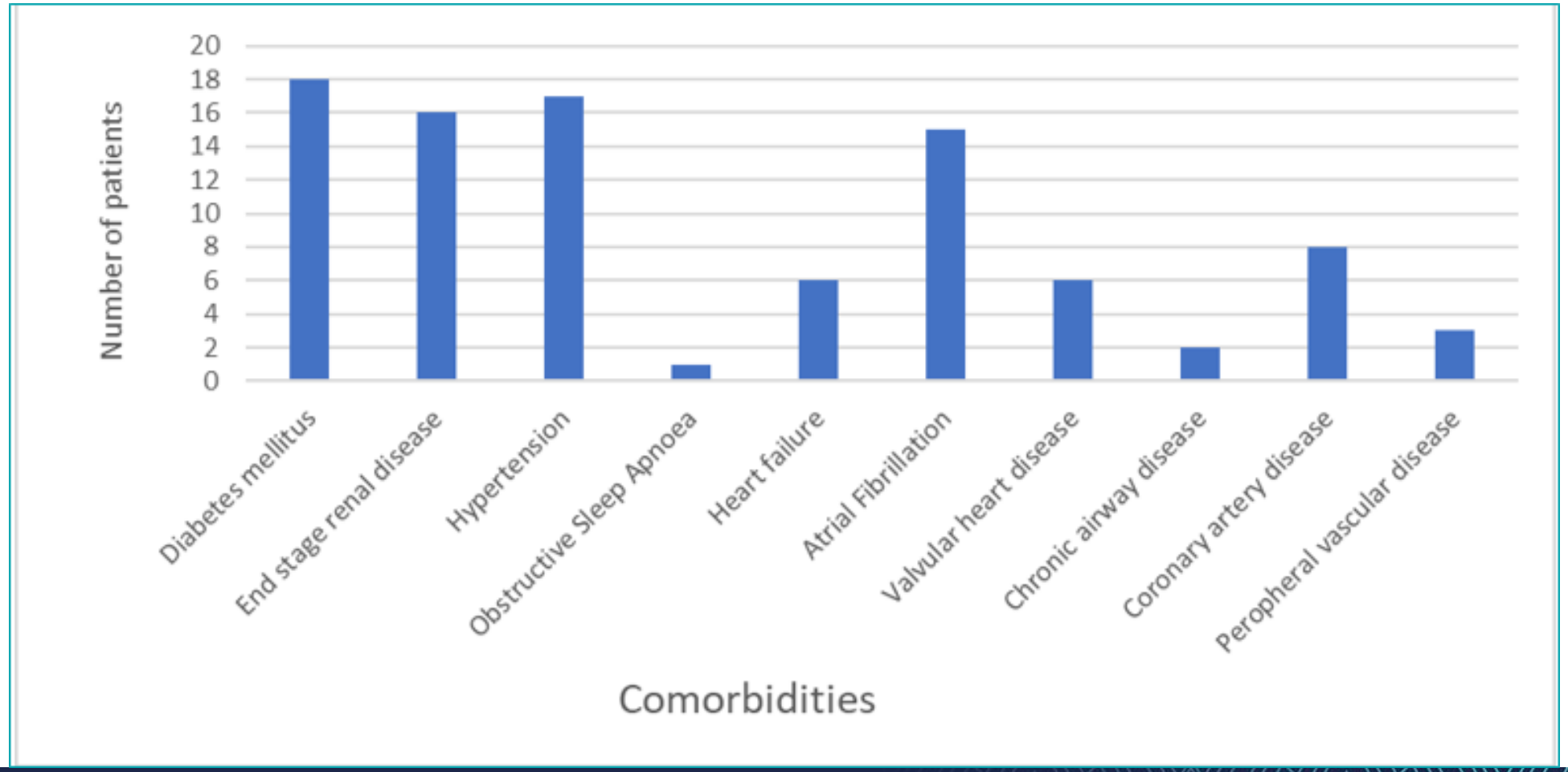
Auckland City Hospital Micra Data

- 31 implanted from 29/10/20 – 30/12/24
- 18 Micra VR and 13 Micra AV
- Standard transvenous pacing was not appropriate or possible
  – 12 patients had previous TV devices
- Followed in clinic in 6 monthly intervals

Demographics

LCP patients	N=31
Age, y	67 years (range 37-86)
Male, %	65
Pacing indication, n	
Complete heart block	18
Second degree heart block	3
Slow AF	3
Sinus node dysfunction	7

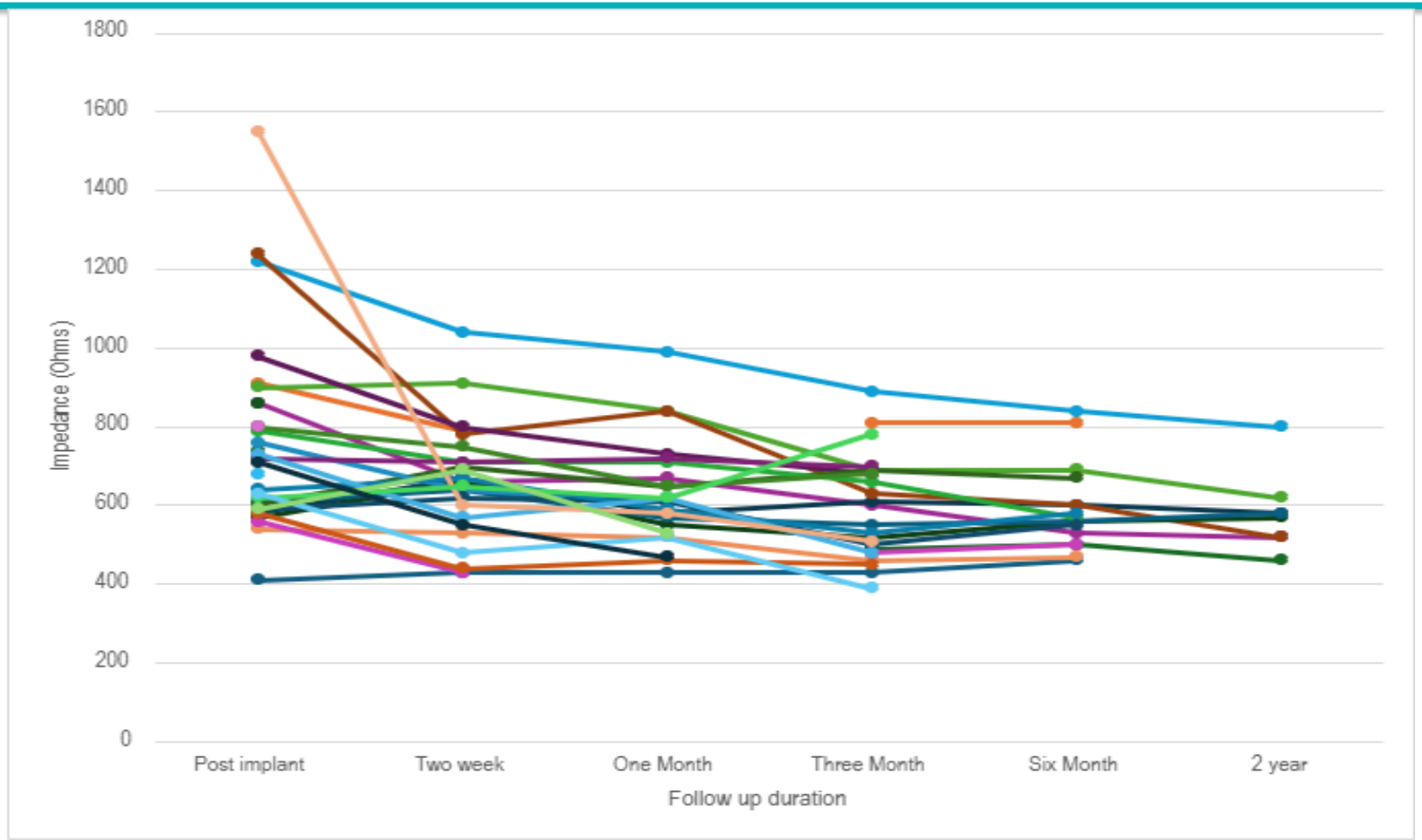
Comorbidities of Micra Patients



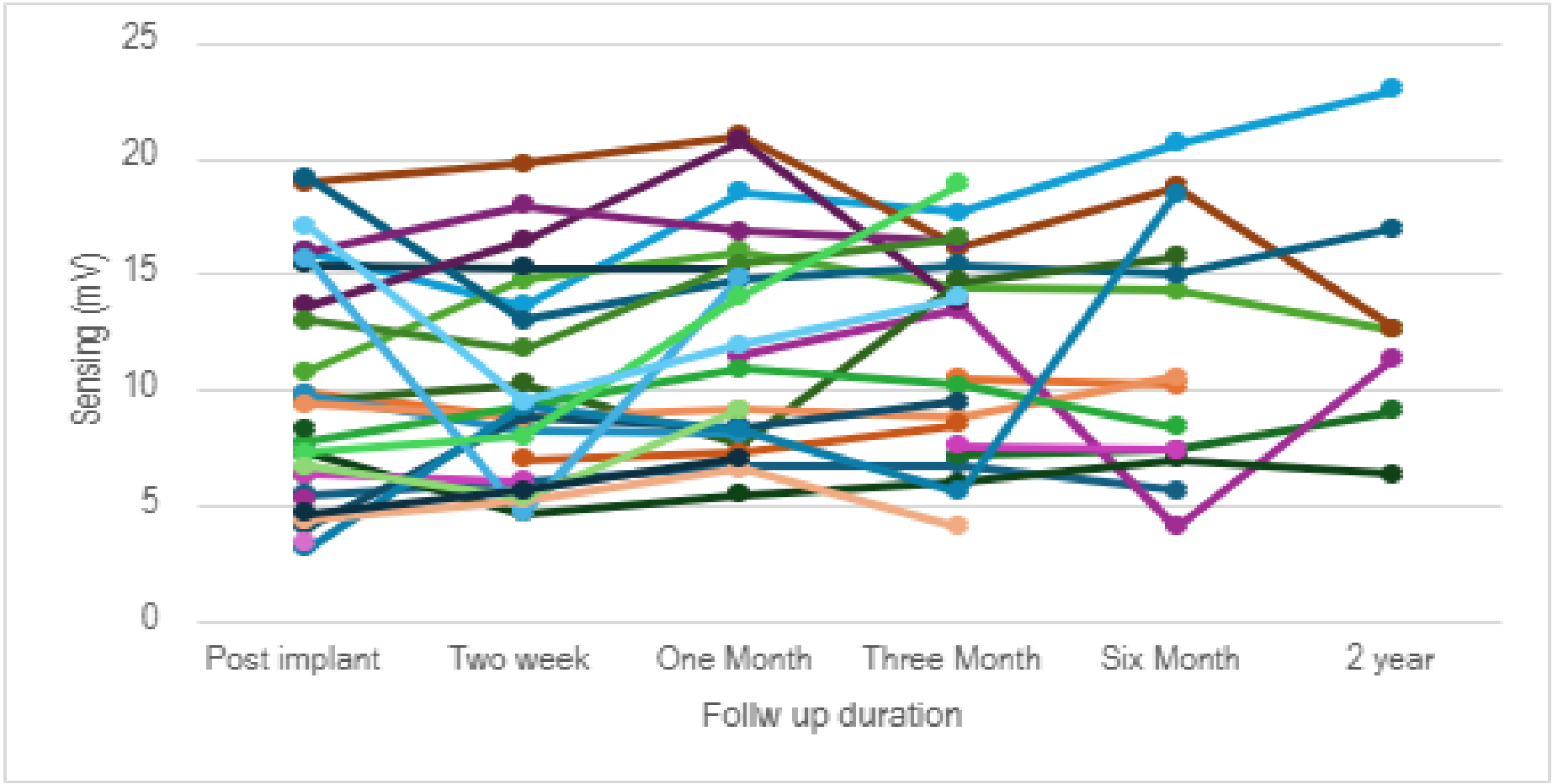
Procedural Information

Parameter	N=31
Procedure duration, min	56.6 +/- 30.7
Fluoroscopy time, min	6.5 +/- 5.1
Contrast volume, mls	36.7 +/- 28
General anaesthesia, n	8
Procedural complications, n	0
In Hospital procedural related complications, n	0

Pacing Performance
Electrode Impedance

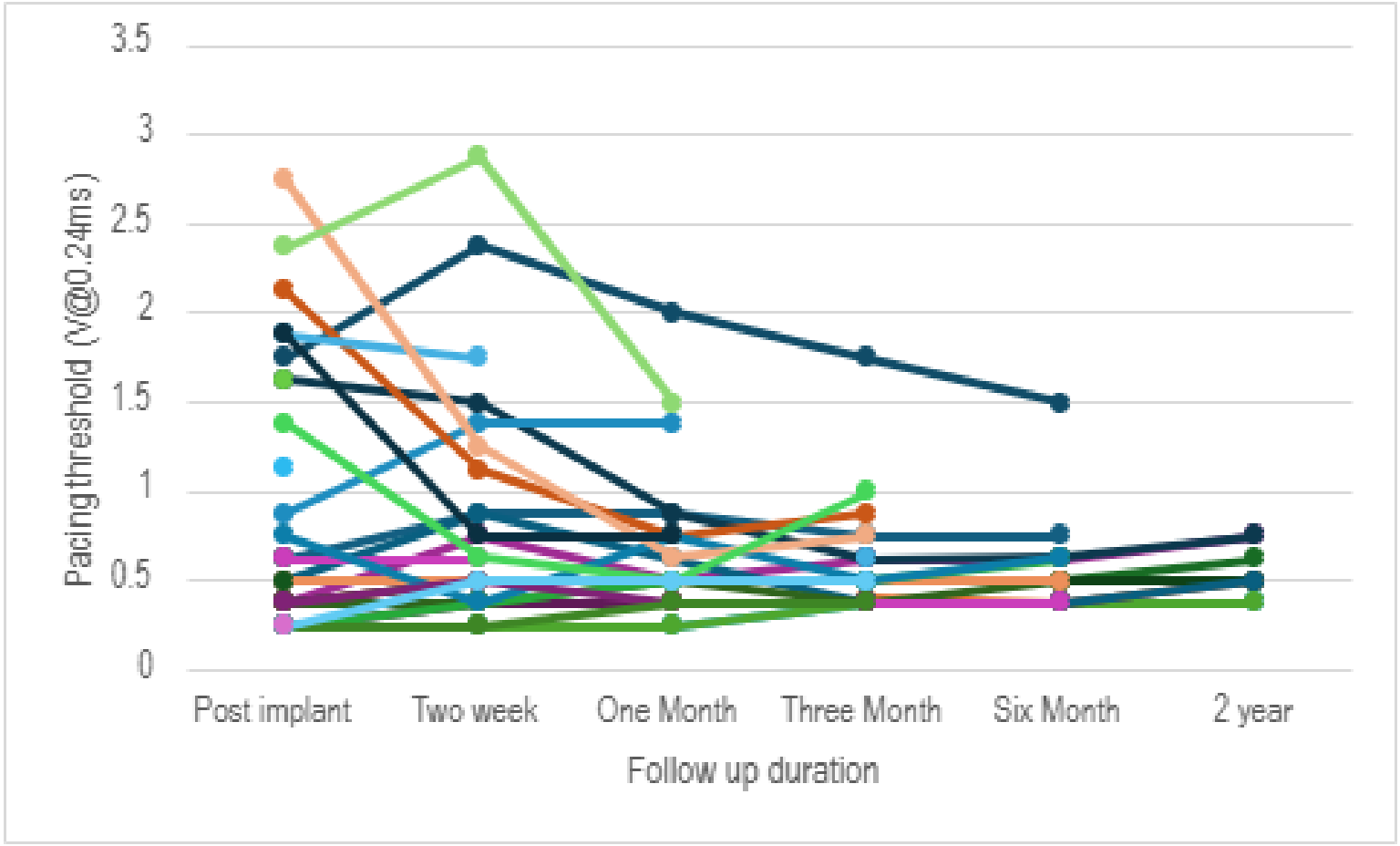


Pacing Performance
Sensing



Pacing Performance

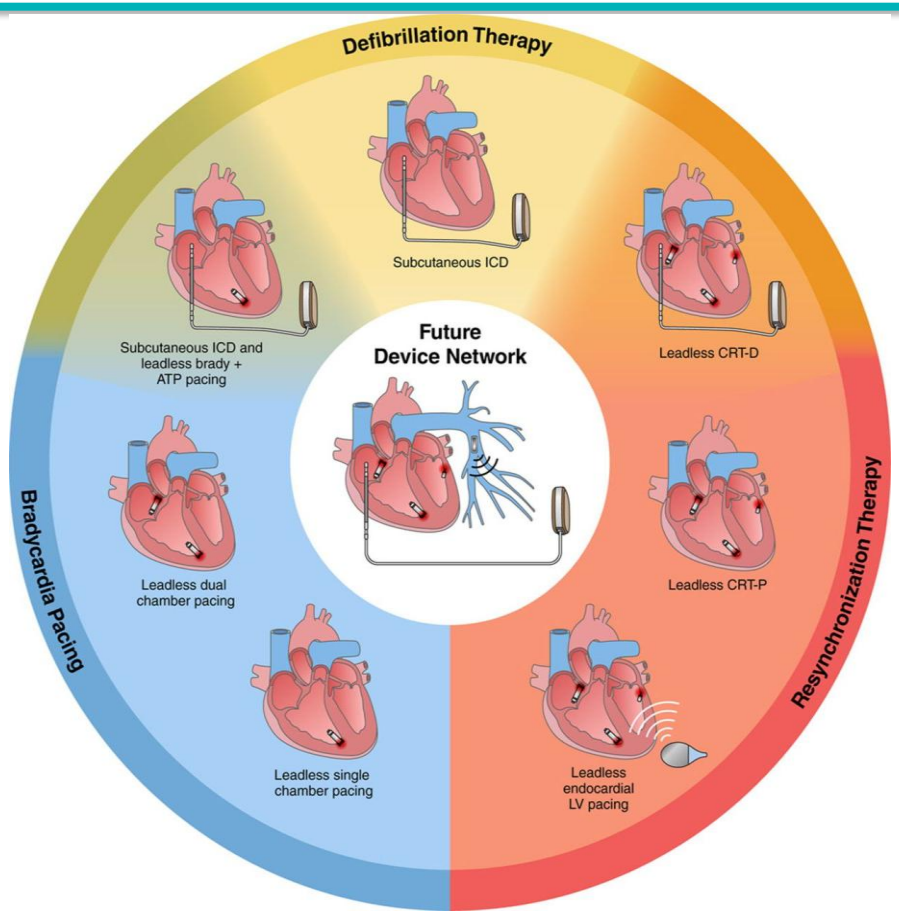
Pacing threshold



Summary

- Implanted in a select, comorbid population
- Provide basic pacing support
- Reduced complications
- Come with a list of limitations
- Transvenous pacing is still the gold standard

Wireless way forward?



Miller MA, Neuzil P, Dukkipati SR, Reddy VY. leadless cardiac pacemakers: back to the future. *J Am Coll Cardiol*. 2015;*66*:1179–1189. doi: 10.1016/j.jacc.2015.06.1081.