Implantable Devices and Syncope

ICD, Pacemaker, CRT and ILR

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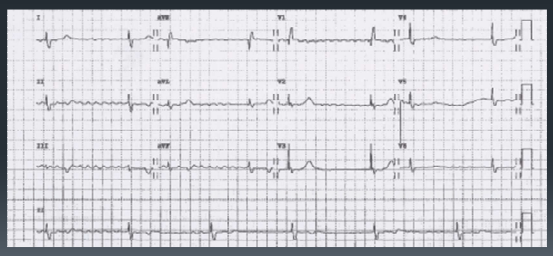
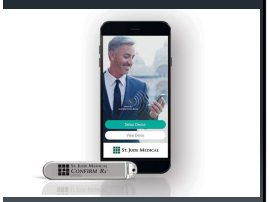
Indications for Pacing – Cardiac Syncope

Arrhythmic syncope is highly probable when the ECG shows:

- Persistent sinus bradycardia <40 b.p.m. or sinus pauses >3 s in awake state and in absence of physical training;
- Mobitz II second- and third-degree AV block;
- Alternating left and right BBB;
- VT or rapid paroxysmal SVT;
- Non-sustained episodes of polymorphic VT and long or short QT interval; or
- Pacemaker or ICD malfunction with cardiac pauses.



ILR – Detecting arrhythmic syncope



ILR Selection

- Exclude those with indication for PPM or ICD
- Include patients with high probability of recurrence

ILR is indicated in an early phase of evaluation in patients with recurrent syncope of uncertain origin, absence of high-risk criteria (listed in *Table 6*), and a high likelihood of recurrence within the battery life of the device.[175,174,181–184,200], *Supplementary Data Table 5*	I	A
ILR is indicated in patients with high-risk criteria (listed in *Table 6*) in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to a specific treatment, and who do not have conventional indications for primary prevention ICD or pacemaker indication.[174,180,187,188,195], *Supplementary Data Tables 5 and 6*	I	A
ILR should be considered in patients with suspected or certain reflex syncope presenting with frequent or severe syncopal episodes.[184–186]	IIa	B
ILR may be considered in patients in whom epilepsy was suspected but the treatment has proven ineffective.[137,189–191], *Supplementary Data Table 7*	IIb	B
ILR may be considered in patients with unexplained falls.[191–194], *Supplementary Data Table 8*	IIb	B

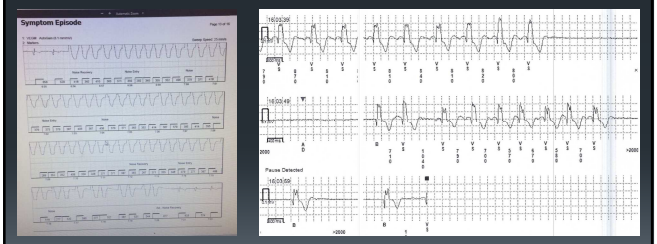
ILR Documentation

Diagnostic criteria		
Arrhythmic syncope is confirmed when a correlation between syncope and an arrhythmia (bradyarrhythmia or tachyarrhythmia) is detected.[172,184–186,188,200]	I	B
In the absence of syncope, arrhythmic syncope should be considered likely when periods of Mobitz II second- or third-degree AV block or a ventricular pause >3 s (with the possible exception of young trained persons, during sleep or rate-controlled atrial fibrillation), or rapid prolonged paroxysmal SVT or VT are detected.[185,188,197–199]	IIa	C

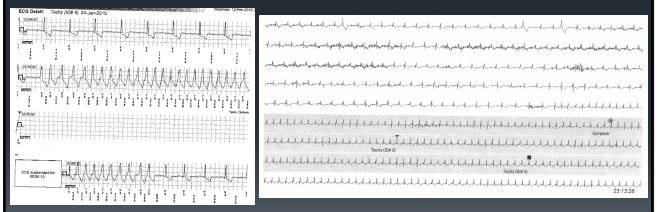
Additional advice and clinical perspectives

- Be aware that the pre-test selection of the patients influences the subsequent findings. Include patients with a high likelihood of arrhythmic events. The duration (and technology) of monitoring should be selected according to the risk and the predicted recurrence rate of syncope.[158–160,183]
- Exclude patients with a clear indication for ICD, pacemaker, or other treatments independent of a definite diagnosis of the cause of syncope.
- Include patients with a high probability of recurrence of syncope in a reasonable time. Owing to the unpredictability of syncope recurrence, be prepared to wait up to 4 years or more before obtaining such a correlation.[203]
- In the absence of a documented arrhythmia, presyncope cannot be considered a surrogate for syncope, whereas the documentation of a significant arrhythmia at the time of presyncope can be considered a diagnostic finding.[199]
- The absence of arrhythmia during syncope excludes arrhythmic syncope.

ILR Traces



ILR Cases



Areas of development

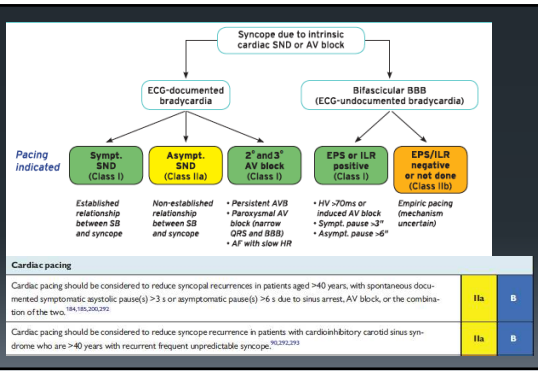
Areas of interest in which ILRs have been investigated:

Bundle branch block (BBB) in whom paroxysmal atrioventricular (AV) block is likely despite negative complete EPS: an arrhythmia was observed in 41% of these patients (being paroxysmal AV block in 70%) under ILR observation, based on pooled data from three studies

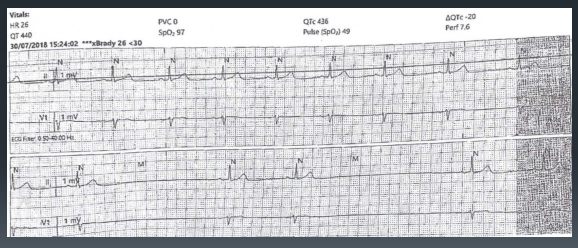
Epilepsy suspected but the treatment proven ineffective: in pooled data, an attack could have been documented by ILR in 62% of patients, with an arrhythmic cause being responsible in 26%

Unexplained falls: in pooled data, an attack could have been documented by ILR in 70% of patients, with an arrhythmic cause being responsible in 14%

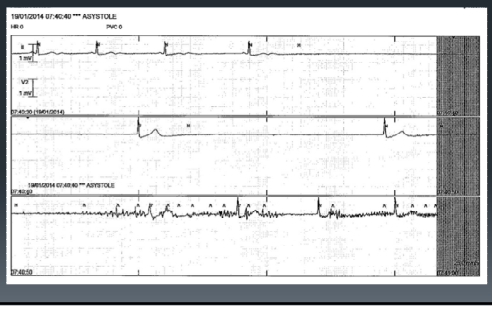
Patients with HCM, arrhythmogenic right ventricular cardiomyopathy (ARVC), or primary electrical diseases



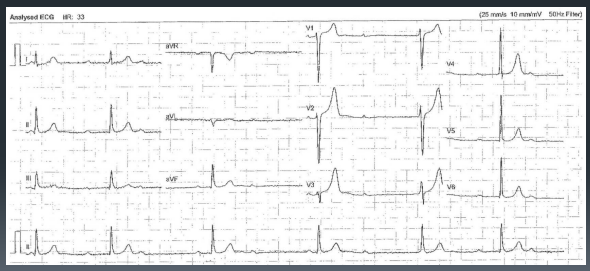
Sinus node disease



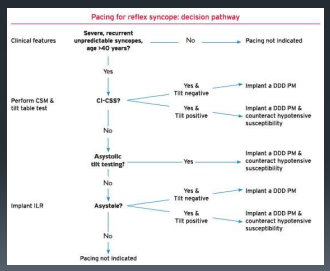
Sinus node disease



High grade AV block



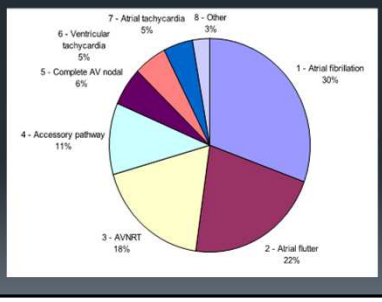
Pacing for Reflex Syncope



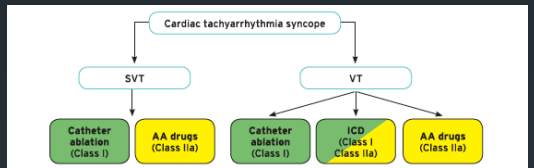
Cardiac Pacing

Cardiac pacing should be considered to reduce syncope recurrence in patients with cardioinhibitory carotid sinus syndrome who are >40 years with recurrent frequent unpredictable syncope.[90,292,293]	IIa	B
Cardiac pacing may be considered to reduce syncope recurrences in patients with tilt-induced asystolic response who are >40 years with recurrent frequent unpredictable syncope.[292,297,298,303]	IIb	B
Cardiac pacing may be considered to reduce syncope recurrences in patients with the clinical features of adenosine-sensitive syncope.[5,227,286]	IIb	B
Cardiac pacing is not indicated in the absence of a documented cardioinhibitory reflex.[299,300]	III	B

Cardiac tachyarrhythmia



Cardiac tachyarrhythmia



Tachycardia		
Catheter ablation is indicated in patients with syncope due to SVT or VT in order to prevent syncope recurrence.[46]	I	B
An ICD is indicated in patients with syncope due to VT and an ejection fraction ≤35%.[46]	I	A
An ICD is indicated in patients with syncope and previous myocardial infarction who have VT induced during EPS.[218]	I	C
An ICD should be considered in patients with an ejection fraction >35% with recurrent syncope due to VT when catheter ablation and pharmacological therapy have failed or could not be performed.[46]	IIa	C
Antiarrhythmic drug therapy, including rate-control drugs, should be considered in patients with syncope due to SVT or VT.	IIa	C

A history of pacing innovation

Pacing – what's new?

- Leadless devices
- His Bundle Pacing
- Subcutaneous ICD / S-ICD – new version
- Remote monitoring – blended biological sensors
- Infection control - Tyrx Mesh
- Longevity - Battery technology
- Extraction

Reliable but…

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)

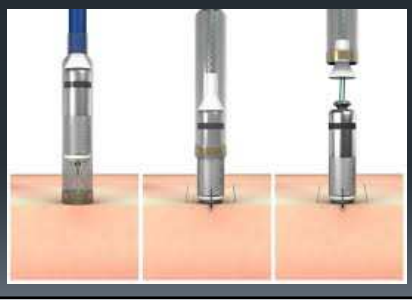
Kirkfeldt, R. E., J. B. Johansen, et al. (2014). "Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark." Eur Heart J 35(18): 1186-1194.

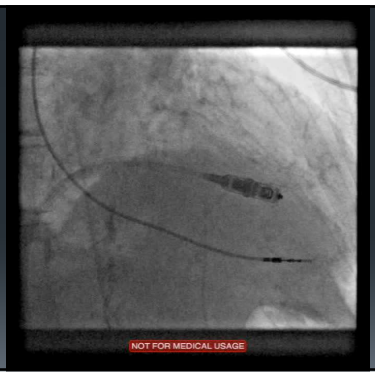
Why leadless pacing?

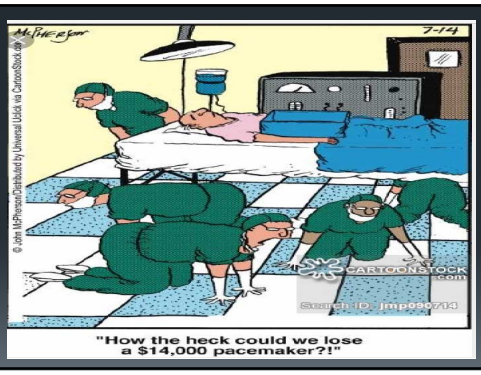
- 93% smaller than conventional pacemaker
- 99.2% implant success (0.1% dislodgments, 0.01% infection)
- No venous occlusion
- No risk of generator erosion
- 12 year longevity

- Only single chamber devices currently

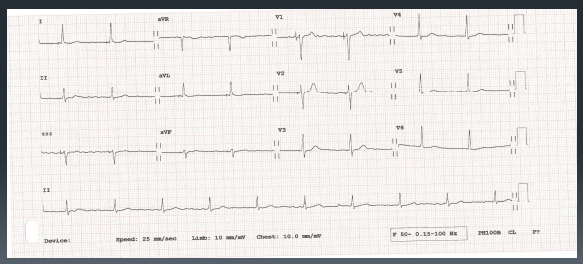
Micra Implant





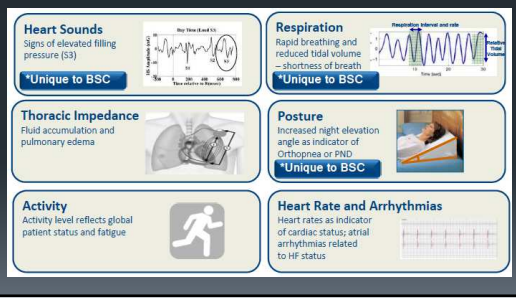


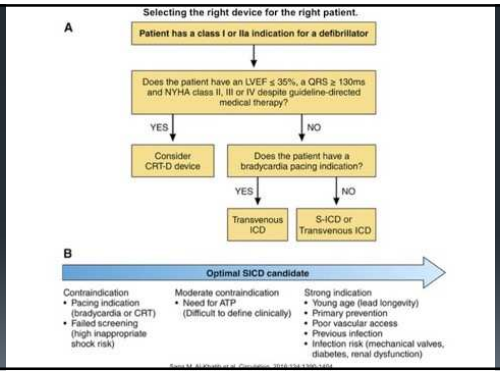
His Bundle Pacing



Remote monitoring

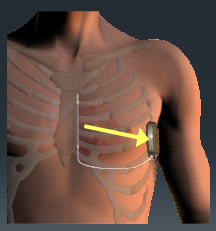
Remote Monitoring





S-ICD

S-ICD System Therapy

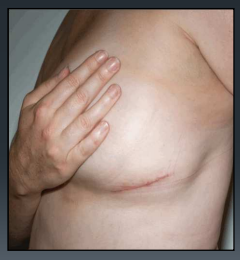


- Biphasic shock
- 80J (delivered)
  - Up to 5 shocks per episode
  - Charge time to 80J ≤ 10 sec
- Post-shock pacing only
- Full featured episode storage
- Battery longevity: 5 years*

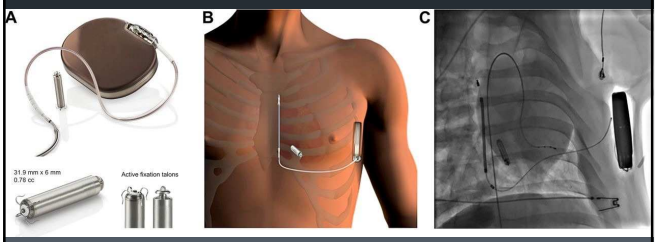
* Normal use, defined as 3 full-energy capacitor charges per year

Optimal Device Placement


One Month Post-Operative

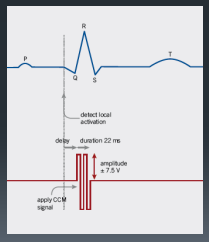



Third Generation

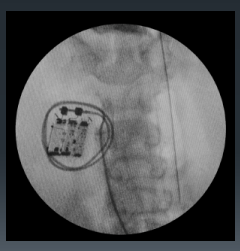


What next?

Impulse Dynamics – CCM Device



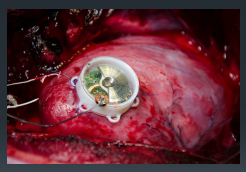
First batteryless solar-powered pacemaker

Vogel et al Heart Rhythm 2015

Leadless, batteryless pacemaker

- a Swiss approach to pacemaker longevity



Vogel et al Heart Rhythm 2016