

JUST HOW USEFUL ARE IMPLANTABLE LOOP RECORDERS?

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ILR is diagnostic implantable ECG- device.



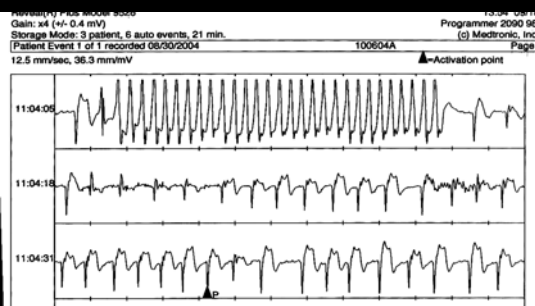
Loop recorders have many names :

- Implantable Loop Recorder ILR, (ILR will be used during this presentation)
- Insertable Cardiac Monitor, ICM
- Insertable Heart Monitor, IHM
- Insertable Loop Recorder, ILR
- Implantable ECG Loop Recorder, ILR

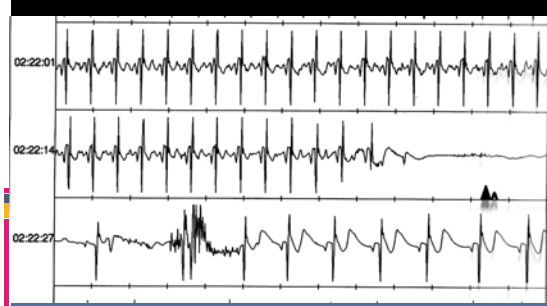
Main indications for ILRs

- Unexplained syncope attacks
- Unexplained palpitation attacks.
- Follow-up after ablation therapy.
- Neurology with T-lock (A-fib?).
- Epilepsy?

Patient- activated during palpitations



Auto-activation of Reveal



Evaluation of Guidelines in SYNCOPE Study
(EGSYS total 980 patients) useful by ESC guidelines

- ECG 95 % red=useful
- Blood test 77 % white=lessuseful
- Chest X- ray 27 %
- Holter 22 %
- CT/MRI scan 20 %
- Echocardiogram 18 %
- Carotid massage 13 %
- EEG 13 %
- Tilt test 7 %
- EP study 2 %
- Coronaryangiography 1 %
- Exercise test 1 %

M Brignole et al
Europace 2003

Conclusions of the EGSYS study

- In the 28 Italian EGSYS- hospitals there were a great difference and management of syncope.
- Therefore the study group was unable to describe any standard for the management of syncope.

Conventional Holter ECG:

8 studies, 2612 patients:

- 19 % patients had symptoms with Holter
 - Only 4% had arrhythmia with symptoms
 - 79% were without symptoms
 - 14% had arrhythmia despite absence of symptoms
 - Conclusions:
 - Low Yield
 - Poor symptom – arrhythmia concordance!
- ACC/AHA Task Force, JACC 1999; 912-948

EHRA ILR – indications 2008 (upgraded from ESC 2004).

ILRs have a Class I indication in an early phase for unexplained syncope patients.

(Class I: Evidence and general agreement that a given diagnostic procedure is beneficial, useful and effective.)

The third generation of ILR's features

- Longevity : 3 years
- Auto- activation and/or patient activation
- Event markers make ECG analysis easier
- Safe for MR environment
- Can use Medtronic Care Link network for remote management.
- User-friendly

Technical information of Reveal Memory functions:

- ECG-memory time for events: 49,5 minutes.
- Patients activated events: 22,5 min.
- Autoactivation: 27 minutes.
- Arrhythmia episodes: 30 events.

How useful are the ILS?

- Two retrospective studies of the outcome of ILRs at our hospital in Lund, Sweden were executed.
- When we started 1998 the only ILR was Reveal from Medtronic.

The Reveal studies at Lund.

1. The "Reveal PLUS" study:

During 1998- 2007: 142 devices

Reveal : 20

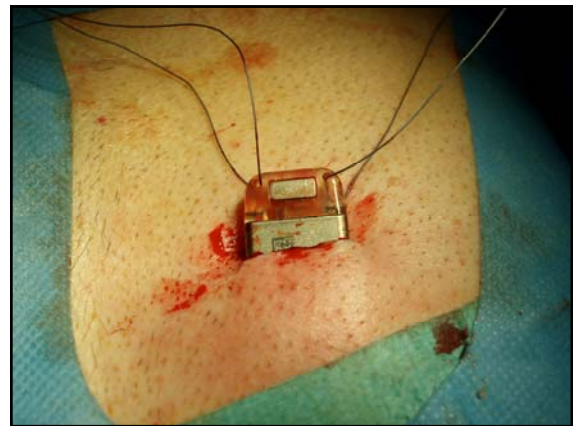
Reveal Plus: 122

2. The "Reveal DX- XT" study:

During 2007 – April 2009: 97 devices

Reveal DX : 90

Reveal XT : 7



Patients and follow-up since Jan 1998

- n: 142 pts
- Age: 7- 89 years (m: 58,9 years)
- Lost during follow- up: 5 pts
- Arrhythmia deaths documented by Reveal: 2 patients (VT-VF)

Symptoms and indications before Reveal implantation

- Syncope (one or several): 139/142 (97%) pts
- Palpitations, other symptoms : 14/142 (9%) pts

Arrhythmias detected by Reveal

Arrhythmias: 51/104 (49 %) pts:

- SSS : 17
- AV- block: 1
- SSS+AV-block: 5
- PSVT: 8
- A. fib : 13
- VT-VF : 7

Time until diagnosis by Reveal (104 pts)

- Shortest: 4 days
- Longest: 18 months
- Pts > 20 months excluded
- Mean time until diagnosis: 8,7 months
- Lost data: 5 pts.(other hospitals)

Case report 1.

- 9 year old boy
- Several syncope and seizures attacks all his life.
- At the age of 3 years diagnosed with epilepsy and drug treatment started.
- No improvements on medication.
- After 6 years (!) a Reveal was implanted.

Case report 1 cont'd.

- One week after Reveal implantation he had a new syncope attack.
- Reveal disclosed AV-block III with a heart stand still during 26 seconds.
- Next day he received a pacemaker DDDR and since then he has been free from syncope.

Other findings during Reveal recordings

- In patients with syncope, **without** any arrhythmias, syncope "disappeared" in 33/104 (32%) cases after Reveal implantation!
- Syncope **continues** in 13/104 (12,5%) pts. without any rhythm disorder via ILR. This is also important information.

Syncope study nr 2 ILR devices-implantation 2008 in Lund

- Total: 51 devices
 - Reveal DX: 44
 - Reveal XT: 4
 - Others: 3

Symptoms and Indications, 51 pts.

- Undiagnosed (one or several) syncope: 91 %
- Vertigo, dizziness: 19 %
- Palpitations, suspected atrial fibrillation: 15 %

ILR diagnosis: 32/51 patients during 2008.

Diagnosis in 63%!

- SSS: 15 pts
- AV- block III: 6 pts
- Parox atrial fib: 2
- PSVT: 1
- VT: 8

Implantation arrhythmias during implantation of Reveal 2008

3 patients had syncope during the Reveal implantation. Asystole was documented in all cases up to 30 seconds.

Reveal was not implanted but a pacemaker instead.

Vasovagal syncope? (Pacemaker or not?)

Reveal and CareLink



New ILR- indications from EHRA 2008

- **Class I** : ILR is indicated:
 - In an early phase of patients with recurrent syncope of uncertain origin...
- **Class II A** : ILR may be indicated:
 - To assess bradycardia before a planned pacemaker operation with suspected neurally mediated syncope with trauma.....
- **Class II B** : ILR may be indicated:
 - T-LOC of uncertain syncopal origin to exclude arrhythmia...