SALA SCANSANO

**S3. SIMPOSIO CONGIUNTO SNO/SIN - ANMCO**

(Associazione Nazionale Medici Cardiologi Ospedalieri)

Moderatori: Maria Grazia Bongiorni (Pisa), Giuseppe Martini (Siena), Pasquale Notarstefano (Arezzo)

14.00 – 14.15
**Prevenzione dell'ictus cardioembolico nel paziente con FA**
Francesco De Sensi (Grosseto)
14.15 – 14.20
Discussant: Raffaele Guida (Arezzo)

14.20 – 14.35
**Indicazioni all'utilizzo del loop recorder**
Luca Segreti (Pisa)
14.35 – 14.40
Discussant: Gennaro Miracapillo (Grosseto)

14.40 – 14.55
**Prevenzione secondaria dell'ictus cerebrale**
Patrizia Nencini (Firenze)
14.55 – 15.00
Discussant: Giovanni Linoli (Arezzo)

Luca Segreti
UO Cardiologia 2 – Aritmologia
Direttore MG Bongiorni
Azienda Ospedaliero Universitaria Pisana

# Indicazioni all'utilizzo del loop recorder

Europace (2009) **11**, 671–687
doi:10.1093/europace/eup097

EHRA POSITION PAPER

## Indications for the use of diagnostic implantable and external ECG loop recorders

## Linee guida AIAC all'impianto di pacemaker, dispositivi per la resincronizzazione cardiaca, defibrillatori automatici e *loop recorder*

update 2011

**Shen W-K, et al.**
**2017 ACC/AHA/HRS Syncope Guideline**

## 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope

European Heart Journal (2016) **37**, 2893–2962
doi:10.1093/eurheartj/ehw210

ESC GUIDELINES

## 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS

Europace (2009) **11**, 671–687
doi:10.1093/europace/eup097

EHRA POSITION PAPER

# Indications for the use of diagnostic implantable and external ECG loop recorders

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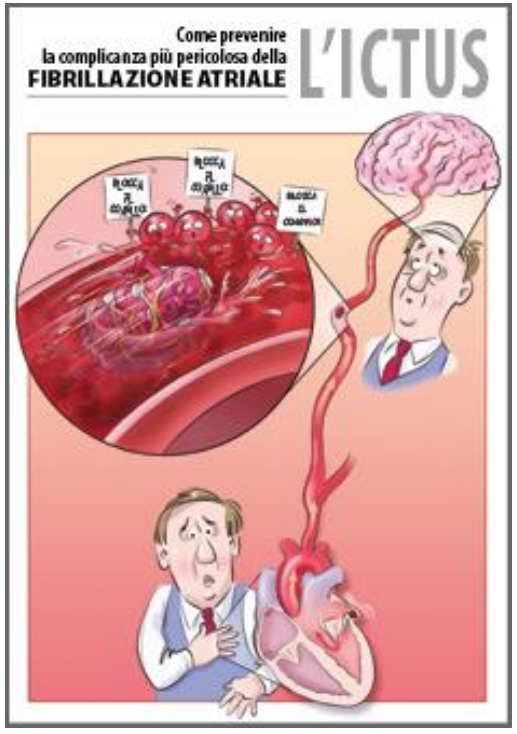
Brignole M et al, Europace 2009

# Indicazioni all'utilizzo del loop recorder

- Stabilire presenza di correlazione tra sintomi e ritmo cardiaco → sincope.

- Ricercare alterazioni del ritmo in assenza di sintomi –> fibrillazione atriale.



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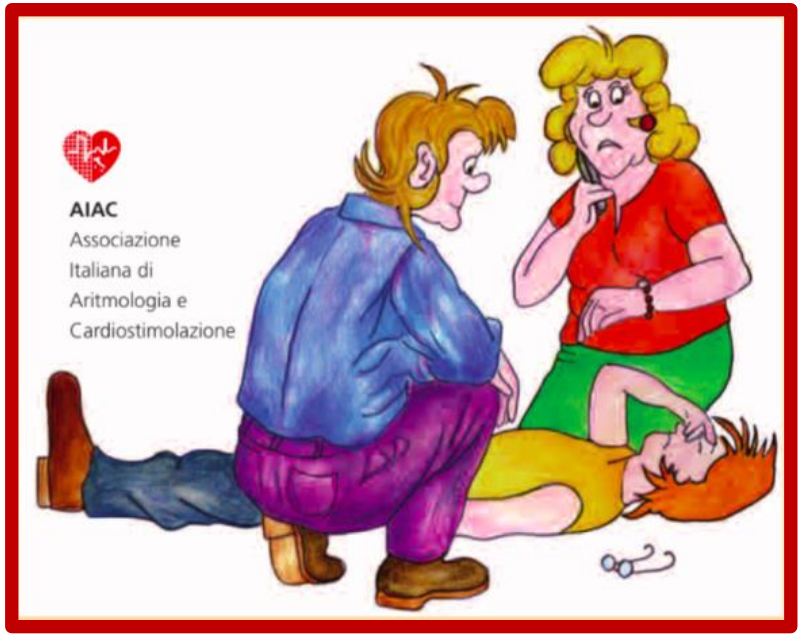
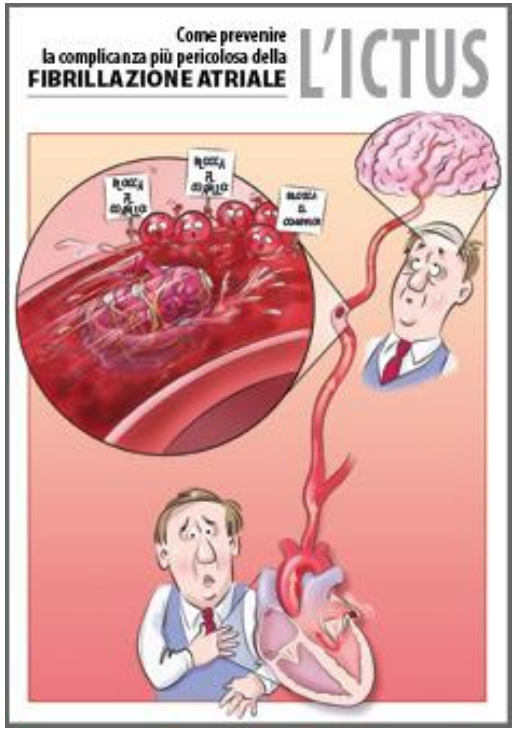


# LOOP RECORDER NELLA DIAGNOSI DI SINCOPI INSPIEGATE

**SINCOPE:** Perdita di coscienza per ridotto flusso sanguigno cerebrale

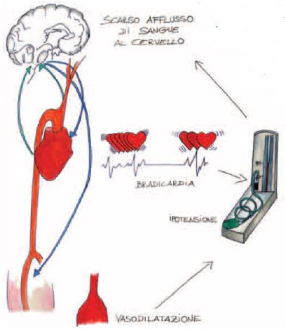
- **INCIDENZA**:

  da 1.3 a 2.7 casi per 1000 persone l'anno; E' più elevata nei più anziani (81 per 1000/anno nei >80 anni)

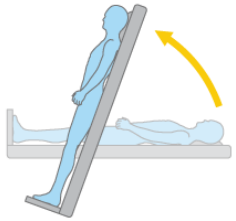
  Fino al 40% della popolazione ha almeno una sincope nella sua vita[1,2].

- **CAUSE**:

Sincope Neuromediata,

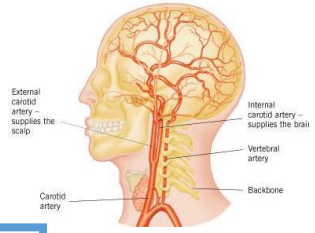



Ortostatica,



Cardiaca,

Cerebrovascolare,




Inspiegata (37%[3])

La **sincope Cardiaca:**

✓ è comune,

✓ **2x** **Rischio di morte**

✓ > **10** **% di mortalità a 6 mesi**[3]

- **DIAGNOSI:**

✓ La diagnosi è importante per trovare la cura e evitare le recidive (>35% sono sincopi traumatiche)[4]

1 Savage DD, et al. The Framingham Study. *Stroke*. 1985;16(4):626-629.
2 Chen L et al. The Framingham Heart Study. Am J Cardiol. 2000;85(10):1189-1193.
3 Soteriades ES, et al. N Engl J Med. 2002;347(12):878-885
4 Edvardsson et al. the PICTURE registry. Europace. 2011;13(2):262-269.

# The benefit of a remotely monitored implantable loop recorder as a first line investigation in unexplained syncope: the EaSyAS II trial


**Aims** This prospective randomized controlled study evaluated the first-line use of a novel remotely monitored implantable loop recorder (ILR) in the initial investigation of unexplained syncope, and compared this to conventional therapy and a dedicated Syncope Clinic (SC).

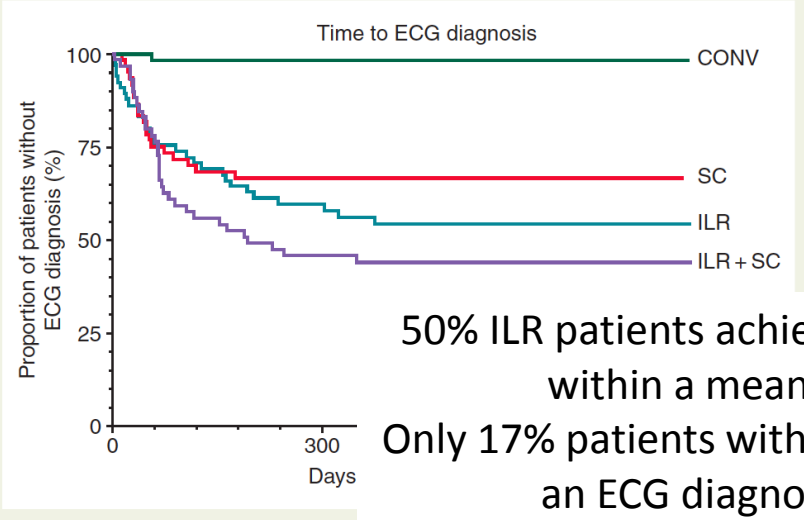
**Methods and results** A total of 246 patients (mean age 70.3 years) were randomly allocated to conventional management, SC alone, ILR alone, or SC + ILR. Median follow-up was 20 months (IQR 15–25 months). Time to electrocardiogram (ECG) diagnosis was significantly shorter with ILR alone vs. conventional [hazard ratio (HR) 35.5, $P = 0.0004$] and with SC vs. conventional (HR 25.6, $P = 0.002$). Seventy-four per cent of first syncopal events documented in the SC groups occurred during provocative tilt testing. Twenty-two per cent of patients who received an ILR were found to have a bradycardia indication for permanent pacing, compared with 3% of patients who did not. Overall, more investigative tests were undertaken in the conventional group than in any other. Only patients who received an ILR had a significant increase in time to second syncope ($P = 0.02$), suggesting successful diagnosis and management of treatable causes of syncope.

**Conclusions** Implantable loop recorder monitoring achieved a more rapid diagnosis in unexplained syncope than usual care. Conventional management of syncope failed to achieve an ECG diagnosis despite a large number of investigative tests. Syncope Clinic and provocative tilt testing delivered a rapid ECG diagnosis, but did not prevent recurrent syncope. Implantable loop recorders offered rapid diagnosis, increased the likelihood of syncope being reported, demonstrated a high rate of intermittent bradycardia requiring pacing, and reduced recurrent syncope.



**Keywords** Syncope • Implantable loop recorder

Sulke N, et al. Europace (2016) 18, 912–918




50% ILR patients achieved an ECG diagnosis within a mean of 95.2 days.
Only 17% patients without ILRs who achieved an ECG diagnosis (P , 0.001).

**Figure 2** Time to ECG diagnosis in all the four groups.

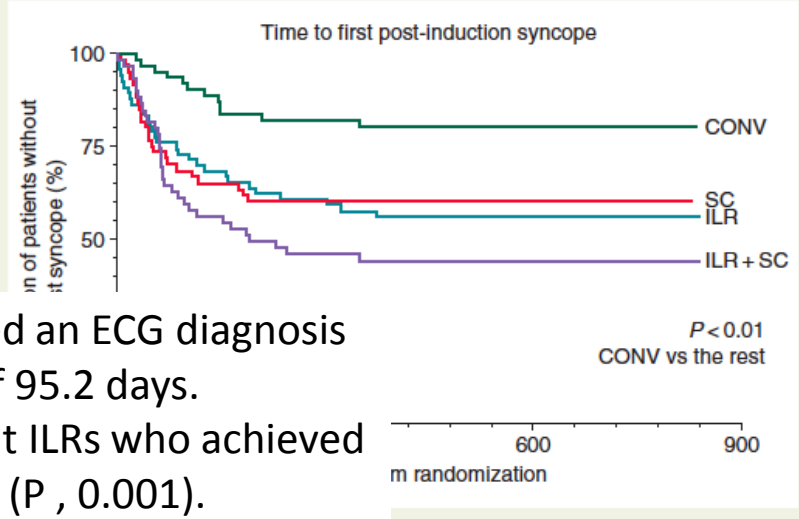
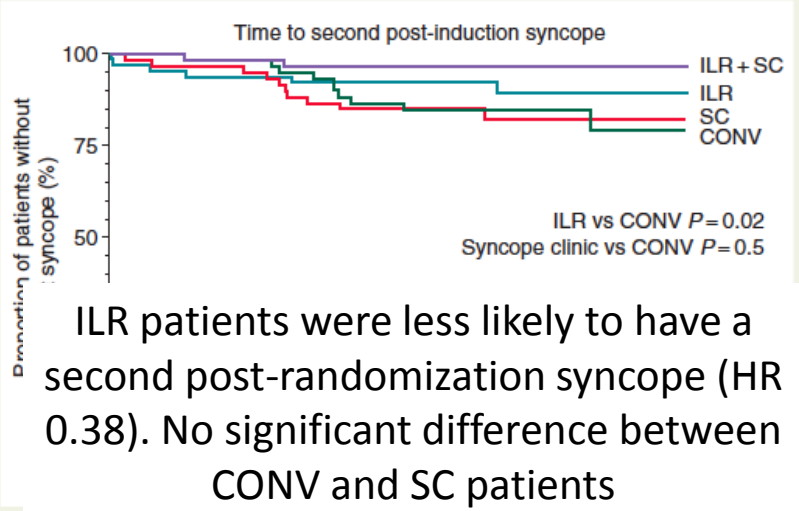



**Figure 3** Time to first post-randomization syncope.




ILR patients were less likely to have a second post-randomization syncope (HR 0.38). No significant difference between CONV and SC patients

**Figure 4** Time to second post-randomization syncope.

**Table 3 Electrocardiogram-directed therapy**

| | Conventional management | SC | ILR | ILR + SC | *P*-Value for difference |
|---|---|---|---|---|---|
| *n* | 61 | 60 | 66 | 59 | – |
| Invasive interventions | | | | | |
| Permanent pacemaker (PPM) insertion | 1 | 3 | 13 | 15 | <0.001 |
| [PPM for symptomatic bradycardia <40 b.p.m.] | [0] | [0] | [5] | [6] | |
| [PPM for intermittent atrioventricular block] | [1] | [3] | [8] | [9] | |
| Electrophysiology study + ablation | 0 | 0 | 2 | 2 | NS |
| Total invasive interventions (%) | 1 (1.6%) | 3 (5.0%) | 15 (22.7%) | 17 (28.8%) | <0.001 |
| Non-invasive interventions | | | | | |
| Specialist referral | 0 | 0 | 1 | 1 | NS |
| Medication adjustment | 10 | 5 | 4 | 1 | 0.03 |
| Lifestyle modification and counter-measures | 5 | 17 | 6 | 15 | 0.002 |
| Total non-invasive interventions (%) | 15 (24.6%) | 22 (36.7%) | 11 (16.7%) | 17 (28.8%) | NS |
| Total interventions (%) | 16 (26.2%) | 25 (41.7%) | 26 (39.3%) | 34 (57.6%) | 0.006 |

Sulke N, et al.
Europace 2016

# Sincope inspiegata

*Class I.* ILR is indicated:

- In an early phase of evaluation of patients with recurrent syncope of uncertain origin who have:
  - –absence of high-risk criteria that require immediate hospitalization or intensive evaluation, i.e. those listed in the *Table 5*; and
  - –a likely recurrence within battery longevity of the device *(Level of evidence A)*
- In high-risk patients in whom a comprehensive evaluation (that listed in *Table 5*) did not demonstrate a cause of syncope or lead to specific treatment *(Level of evidence B)*

*Class II A.* ILR may be indicated:

- To assess the contribution of bradycardia before embarking on cardiac pacing in patients with suspected or certain neurally mediated syncope presenting with frequent or traumatic syncopal episodes *(Level of evidence B)*

*Class II B.* ILR may be indicated:

- In patients with T-LOC of uncertain syncopal origin in order to definitely exclude an arrhythmic mechanism *(Level of evidence C)*

**Table 6 Short-term high-risk criteria that require immediate hospitalization or early intensive evaluation as appropriate (according ESC guidelines on syncope[2])**

- *Situations in which there is a clear indication for ICD or pacemaker treatment* independently of a definite diagnosis of the cause of syncope according to recent ICD/CRT guidelines
- *Severe structural cardiovascular or coronary artery disease* (heart failure or low ejection fraction or previous myocardial infarction)
- *Clinical or ECG features suggesting an arrhythmic syncope:*
  - –Syncope during exertion or supine
  - –Palpitations at the time of syncope
  - –Family history of sudden death
  - –Non-sustained ventricular tachycardia
  - –Bundle branch block (QRS duration ≥0.12 s)
  - –Inadequate sinus bradycardia (<50 bpm) or sinoatrial block in the absence of negatively chronotropic medications except physically-trained person
  - –Pre-excited QRS complexes
  - –Prolonged or short QT interval
  - –Right bundle branch block pattern with ST-elevation in leads V1–V3 (Brugada syndrome)
  - –Negative T waves in right precordial leads, epsilon waves, and ventricular late potentials suggestive of arrhythmogenic right ventricular dysplasia
- *Important comorbidities* (severe anaemia, electrolytic disturbance, etc)

Brignole M et al, Europace 2009

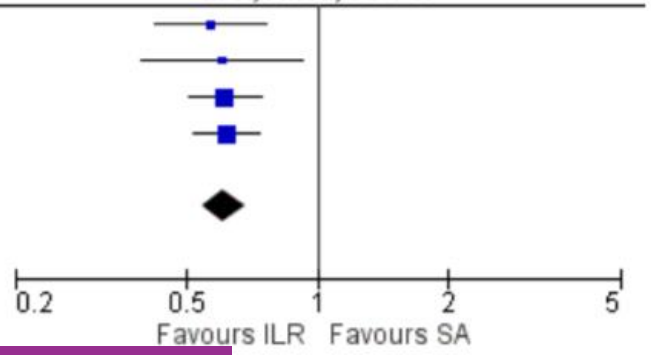
# Diagnosi di sincope non certa, ma solo sospettata

- Pazienti con epilessia, ma con trattamento inefficace
- Pazienti anziani che presentano cadute non accidentali inspiegabili
- Pazienti con gravi malattie depressive ed episodi inspiegabili di sincope

**Figure 5. Forest plot of comparison: 1 ILR vs SA, outcome: 1.2 Diagnosis.**

| Study or Subgroup | ILR Events | ILR Total | Standard assessment (SA) Events | SA Total | Weight | Risk Ratio (Non-event) M-H, Fixed, 95% CI |
|---|---|---|---|---|---|---|
| Podoleanu 2014 | 18 | 39 | 2 | 39 | 14.6% | 0.57 [0.42, 0.77] |
| Krahn 2001 | 14 | 27 | 6 | 30 | 9.0% | 0.60 [0.39, 0.93] |
| Sulke 2015 | 62 | 125 | 21 | 121 | 40.1% | 0.61 [0.50, 0.74] |
| Farwell 2006 | 43 | 101 | 7 | 97 | 36.3% | 0.62 [0.52, 0.74] |
| **Total (95% CI)** | | **292** | | **287** | **100.0%** | **0.61 [0.54, 0.68]** |
| Total events | 137 | | 36 | | | |

Heterogeneity: Chi² = 0.24, df = 3 (P = 0.97); I² = 0%
Test for overall effect: Z = 8.46 (P < 0.00001)




**Implantable loop recorder versus conventional diagnostic workup for unexplained recurrent syncope (Review)**

*Solbiati M, et al. Cochrane Database of Systematic Reviews* 2016

Ancora non ben spiegati nella popolazione epilettica:

- Le sincopi frequenti
- L'alta frequenza di morte improvvisa

## Prolonged implantable electrocardiographic monitoring indicates a high rate of misdiagnosis of epilepsy—REVISE study

Sanjiv Petkar, et al. Europace 2012

**Methods and results**

We included patients previously diagnosed with epilepsy, but considered to have a definite or likely misdiagnosis of epilepsy after specialist neurological review. All received an ILR (Reveal Plus®/Reveal DX®, Medtronic Inc.), and tilt-table testing. One hundred and three patients were included, mean age of 46 ± 17 years, with 58 of 103 (56%) female patients. A diagnosis of epilepsy was previously made by a neurologist in 69%, but definite tonic-clonic seizures were only noted in the history in 4%. In 22 patients (21%), the ILR recorded profound bradyarrhythmia or asystole with convulsive features, and they were offered pacemaker implantation. After pacing and withdrawal of antiepileptic drugs, 60% of these patients were asymptomatic. Only 14% of patients had a positive tilt-table test. In these, there was no correlation with the ECG findings of a spontaneous blackout during ILR recording.

E' importante diagnosticare l'origine cardiaca di una sincope convulsiva per:

- Evitare un trattamento anticonvulsivante non indicato
- Valutare la presenza di aritmia ipocinetica nei pz con persistente sincope nonostante terapia

# Use of event recorders and loop recorders in clinical practice: results of the European Heart Rhythm Association Survey

Elena Sciaraffia[1]*, Jian Chen[2,3], Meleze Hocini[4], Torben Bierregaard Larsen[5], Tatjana Potpara[6], and Carina Blomström-Lundqvist[1]

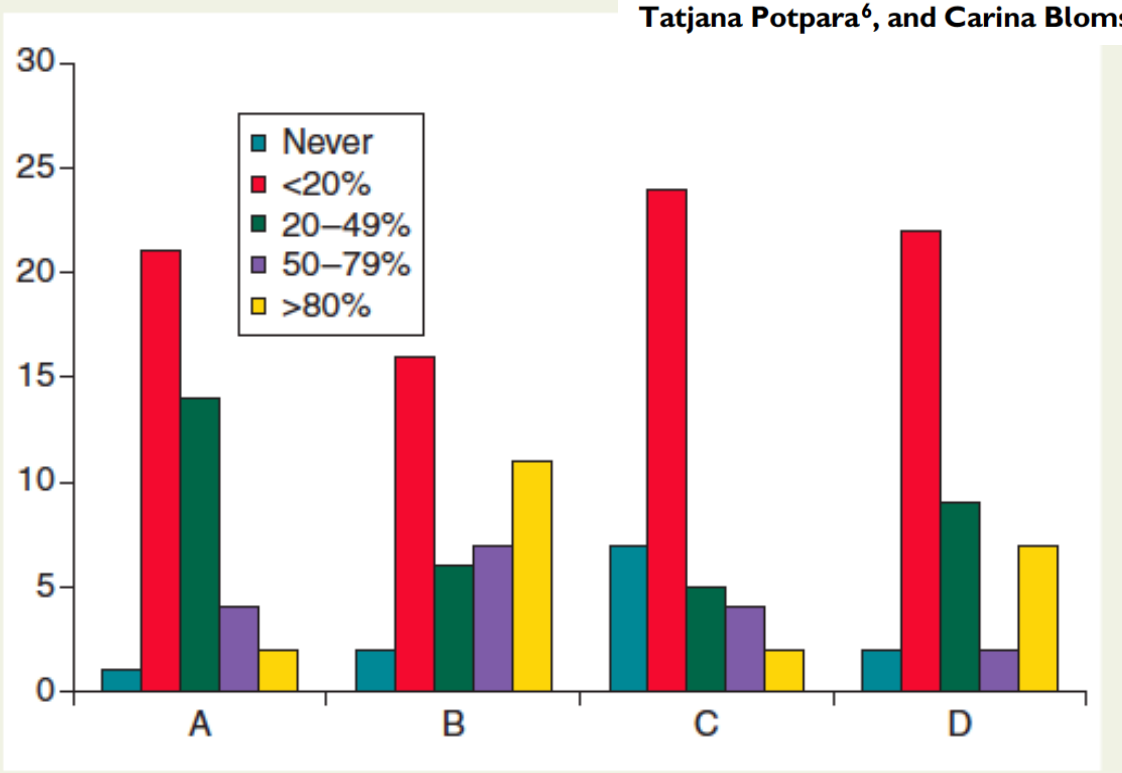



**Figure 1** Use of ILR in syncope. A, recurrent syncope with no structural heart disease; B, recurrent syncope in high-risk patients; C, bradycardia in neurally mediated syncope; D, possible arrhythmia in recurrent transient loss of consciousness.

The most interesting finding of this survey is the discrepancy between clinical practice and the current guidelines on the use of ILRs in patients with unexplained syncope.

With the exception of high-risk patients with recurrent syncope and a negative screening, whereby 43% of the centres would resort to ILR implantation in >50% of the cases, in all other instances the use of ILRs was limited to <20% of the cases in most of the centres.

EXPENSIVE
INVASIVE

In conclusion, the results of this survey show a poor adherence to the guidelines regarding the use of ILRs in unexplained syncope and better results in the use of ECG monitoring systems in patients with palpitations and AF. A possible explanation of these findings

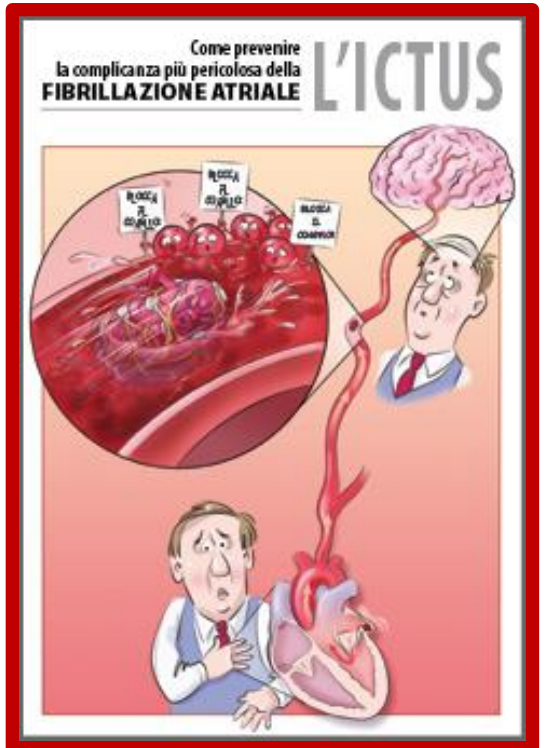
EUROPEAN SOCIETY OF CARDIOLOGY®

Europace (2014) **16**, 1384–1386
doi:10.1093/europace/euu222

# Indicazioni all'utilizzo del loop recorder

- Stabilire presenza di correlazione tra sintomi e ritmo cardiaco → sincope.

- Ricercare alterazioni del ritmo in assenza di sintomi –> fibrillazione atriale.



## 3.1 Incidence and prevalence of atrial fibrillation

In 2010, the estimated numbers of men and women with AF worldwide were 20.9 million and 12.6 million, respectively, with higher incidence and prevalence rates in developed countries.[1,2] One in four middle-aged adults in Europe and the US will develop AF.[3–5] By 2030, 14–17 million AF patients are anticipated in the European Union, with 120 000–215 000 newly diagnosed patients per year.[2,6,7] Estimates suggest an AF prevalence of approximately 3% in adults aged 20 years or older,[8,9] with greater prevalence in older persons[1] and in patients with conditions such as hypertension, heart failure, coronary artery disease (CAD), valvular heart disease, obesity, diabetes mellitus, or chronic kidney disease (CKD).[7,10–15] The increase in AF prevalence can be attributed both to better detection of silent AF[16–18], alongside increasing age and conditions predisposing to AF.[19]

**Table 3 Cardiovascular morbidity and mortality associated with atrial fibrillation**

| Event | Association with AF |
|---|---|
| Death | Increased mortality, especially cardiovascular mortality due to sudden death, heart failure or stroke. 2 fold in women and 1.5 in men |
| Stroke | 20–30% of all strokes are due to AF. A growing number of patients with stroke are diagnosed with 'silent', paroxysmal AF. |
| Hospitalizations | 10–40% of AF patients are hospitalized every year. |
| Quality of life | Quality of life is impaired in AF patients independent of other cardiovascular conditions. |
| Left ventricular dysfunction and heart failure | Left ventricular dysfunction is found in 20–30% of all AF patients. AF causes or aggravates LV dysfunction in many AF patients, while others have completely preserved LV function despite long-standing AF. |
| Cognitive decline and vascular dementia | Cognitive decline and vascular dementia can develop even in anticoagulated AF patients. Brain white matter lesions are more common in AF patients than in patients without AF. |

AF = atrial fibrillation; LV = left ventricular.

Oral anticoagulation (OAC) with vitamin K antagonists (VKAs) or non- VKA oral anticoagulants (NOACs) markedly reduces stroke and mortality in AF patients.

1. Hart RG, et al. Ann Intern Med 2007
2. Ruff CT, et al. Lancet 2014

Other interventions such as rhythm control and rate control improve AF-related symptoms and may preserve cardiac function, but have not demonstrated a reduction in long-term morbidity or mortality.

3. Kirchhof P, et al. Am Heart J 2013
4. Al-Khatib SM, et al. Ann Intern Med 2014

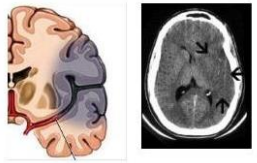
# ICM PER LA DIAGNOSI DI AF nell'ICTUS criptogenico

IL PROBLEMA **ICTUS:** Deficit focale delle funzioni cerebrali

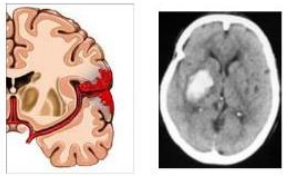
- **INCIDENZA**:
  - ✓ nel mondo 15 milioni di persone hanno un ictus ogni anno[1];
  - ✓ 5.7 milioni ogni anno muoiono e 5 milioni hanno disabilità permanenti[1].
  - ✓ In Europa si contano 2 milioni di eventi nuovi o recidivanti ogni anno[2],di cui circa 120 000 in ITALIA

- **CAUSE[1]:**

**Ischemico (80%)**



**Emorragico (15%)**



**Emorragia Sub Aracnoidea (5%)**

✓ **30** % **CRIPTOGENICO[3]**

✓ L'**FA** ne è un importante predittore e ne **aumenta il rischio di 5 volte**[4-6]

**5x**

✓ **Con FA ha probabilità doppia di essere fatale** rispetto ad uno non associato ad FA[7]

**2x**

1 World Heart Federation. http://www.world-heart-federation.org/cardiovascular-health/stroke/

*2 Truelsen T et al. Eur J Neurol. 2006; 13(6):581-98*

3 Guercini Fet al. *J Thromb Haemost*. 2008;6(4):549-554..

4 Wolf PA, et al.The Framingham study. *Neurology.* 1978;28(10):973-977.

5 Wolf PA, et al. the Framingham Study. *Stroke*. 1991;22(8):983-988.

6 Wang TJ, et. Al The Framingham Heart Study. *JAMA*. 2003;290(8):1049-1056

7 Lin HJ et al. *Stroke.* 1996; 27:1760-1764.

# Detection of atrial fibrillation in stroke survivors

- AF detection is not uncommon in unselected stroke patients (6.2%), but is more likely in patients with cryptogenic stroke implanted with loop recorders or who have had ECG monitor for several weeks.

- Sequential stratified ECG monitoring detected AF:
  - in 24% (95% CI 17–31) of stroke survivors,
  - and in 11.5% (95% CI 8.9%–14.3%) in another meta-analysis
- with large variations depending on the timing, duration, and method of monitoring.

- Cryptogenic stroke is defined as
  - a stroke in which the cause could not be identified after extensive investigations.
  - Embolic stroke of undetermined source.

CONTEMPORARY REVIEW

# Cryptogenic stroke: Is silent atrial fibrillation the culprit?

Taya V. Glotzer, MD, FACC, FHRS,* Paul D. Ziegler, MS†

Heart Rhythm 2015;12:234–241

**Table 2** AF detected by insertable cardiac monitors in patients with cryptogenic stroke

| Study (year) | No. of patients | AF definition | Monitoring duration | AF detection yield | Notes |
|---|---|---|---|---|---|
| Cotter et al[25] (2013) | 51 | 2 minutes | Mean 229 (116) days | 25.5% | Median time from ICM implant to first new AF episode: 48 days (range 0–154 days)<br>Median duration of first new AF episode: 6 minutes (range 1– 4320 minutes) |
| Ritter et al[26] (2013) | 60 | 2 minutes | 1 year | 16.7% | Mean time from ICM implant to first new AF episode: 64 days (1-556). 7-day Holter detected AF in only 1.7% |
| Etgen et al[27] (2013) | 22 | 6 minutes | 1 year | 27.3% | Mean time from stroke to first new AF episode: 5 months |
| Rojo-Martinez et al[28] (2013 ) | 101 | 2 minutes | 281 ± 212 days | 33.7% | |
| SURPRISE[29] (2014) | 85 | 2 minutes | 569 ± 310 days | 16.1 % | Mean time from stroke to first new AF episode 109 ± 48 days |
| CRYSTAL AF[11] (2014) | 221 | >30 seconds* | Minimum 6 months | 8.9% at 6 months<br>12.4% at 12 months<br>30.0% at 36 months | |

Data suggest that silent AF is identified in approximately 30% of cryptogenic stroke patients and has important therapeutic implications.

Oral anticoagulation likely should be prescribed when silent AF is detected

# Cryptogenic Stroke and Underlying AF - CRYSTAL AF

Randomized 441 pts to assess whether monitoring with an insertable cardiac monitor (ICM) is more effective for detecting atrial fibrillation in patients with cryptogenic stroke

Primary Endpoint: Detection of AF at 6 months

## PATIENT INCLUSION CRITERIA

- ≥ 40 years of age
- Cryptogenic stroke (or clinical TIA) with infarct seen on MRI or CT within the previous 90 days and no mechanism identified after:
  - 12-lead ECG
  - 24-hour ECG monitoring (e.g., Holter)
  - Transesophageal echocardiography
  - CTA or MRA of head and neck to rule out arterial source
  - Screening for hypercoagulable states in patients < 55 years old

AF definition > 30 sec.

## END POINTS

**Primary**

- Time to first detection of AF at 6 months of follow-up

**Secondary**

- Time to first detection of AF at 12 months of follow-up
- Recurrent stroke or TIA
- Actions taken after patient diagnosed with AF

Division of Cardiovascular Diseases - University Hospital of Pisa (Italy)

Sanna T, et al. Cryptogenic Stroke and Underlying Atrial Fibrillation (CRYSTAL AF). *N Engl J Med.* 2014; 370(26):2478-2486

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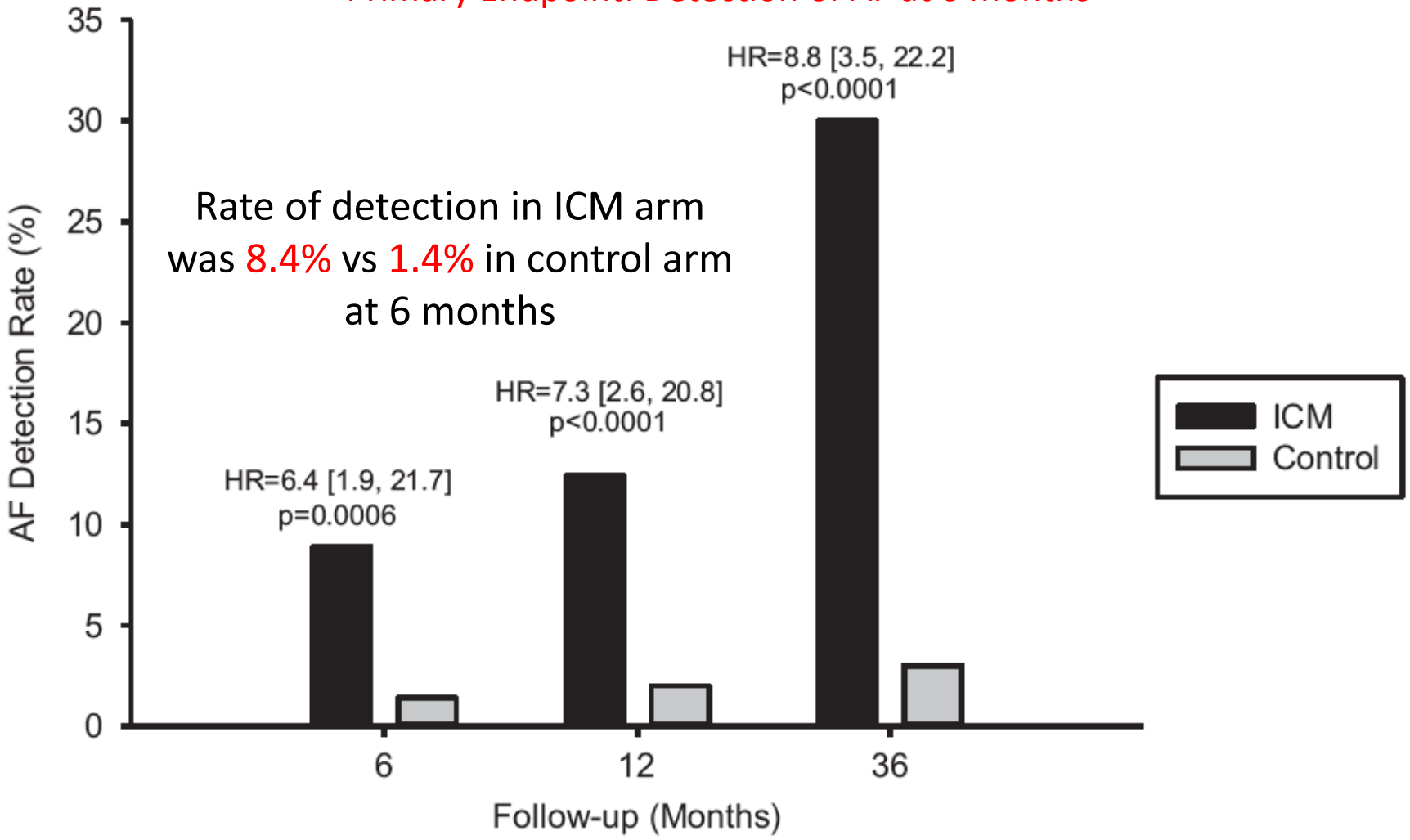
Randomized 441 pts to assess whether monitoring with an insertable cardiac monitor (ICM) is more effective for detecting atrial fibrillation in patients with cryptogenic stroke

Primary Endpoint: Detection of AF at 6 months




Sanna T, et al. Cryptogenic Stroke and Underlying Atrial Fibrillation (CRYSTAL AF). *N Engl J Med.* 2014; 370(26):2478-2486

**Table 2:** Studies of loop recorder monitoring in patients with ischemic stroke or TIA

Perez-Rondon J et al. JAFIB 20

| Study [ref] | No. of patients | Study design | Mean age (y) | Study population | Interval from CV event | Definition of PAF | Detection Method | Duration of monitoring | Diagnostic Yield |
|---|---|---|---|---|---|---|---|---|---|
| Barthélemy JC et al [9 bis 19] | 60 | Prospective cohort | 64.0 ± 16.3 | Any TIA or stroke (including 28 with CS or CTIA) | Mean 10 ± 2 d | 30 s | aELR | 4 d (70±31 h) | 20% whole cohort, 14.3% CS/CTIA |
| Jabaudon et al [9 bis 20] | 88 | Prospective cohort | 72 (56-91) in the AF group and 66 (37-93) in the non-AF group | Any TIA or stroke (patients with remote PAF were not excluded) | Mean 55 d | NA | aELR | 7 d | 5,5% |
| Elijovich et al [ 9 bis 21] | 20 | Retrospective cohort | 68 ± 14 | CS or CTIA | NA | 30 s | aELR | ≤ 30 d | 20% |
| Flint et al [9 bis 22] | 239 | Prospective cohort | 64.6 ± 13.8 | CS | Mean 29 d (17 – 50 ) | 5 s | aELR | ≤ 30 d (24.5 ± 9 d) | 12.1% |
| Higgins et al [9 bis 23] | 100 | Randomizaed trial | 65.8 ± 12.3 | Any TIA or stroke without known AF | ≤ 7 d | Non-sustained: 6 VC Sustained: 20 s | aELR | 7 d | Any: 44% Sustained: 18% |
| EMBRACE [9 bis 17] | 572 | Randomized trial | 72.5 ± 8.5 | >55 y CS or CTIA | Mean 75.1 ± 38.6 d | 30 s | aELR | 30 d | 16.1% |
| Dion F et al [15] | 24 | Prospective cohort | 49±13.6 | <75 y CS | Mean 3 ±1.1 m | Any duration | ILR | 14.5 m | 4% |
| Mercé J et al (13) | 14 | Prospective cohort | 65.4 ± 10.9 | CS | < 1 m | 2 min | alLR | 29 ± 5.9 m | 36% |
| Cotter PE et al [16] | 51 | Prospective cohort | Median 52 (17 – 73) | CS | NA | 2 min | alLR | 116 d | 25.5% |
| Etgen T el al (17) | 22 | Prospective cohort | 65.8 (45.3-86.4) in the AF group and 60.0 (54.4–65.6) in the non AF group | CS | NA | ≥ 6 min | aLR | 12 m | 27.3 % |
| SURPRISE study (18) | 85 | Prospective cohort | 66.9 in the AF and 54.0 in the non -AF group | CS | Mean 107 ± 117 d | 2 min | alLR | Mean 569 ± 310 d | 20.7% |
| CRYSTAL AF (12) | 441 | Randomized trial | 61.5 ± 11.3 | > 40 y CS | Mean 48 d aprox. | 2 min | alLR | 36 m | 30% |

6 m

8.4%

# Temporal Proximity of Silent AF Episodes to Thromboembolic Event

| Year | Trial | Number of patients with TE Event | Definition of AF episode | Any AF Detected Prior to TE Event | AF Detected only After TE event | No AF in 30 Days Prior to TE Event | Any AF in 30 days Prior to TE Event |
|---|---|---|---|---|---|---|---|
| 2011 | TRENDS | 40 | 5 mins | 20/40 50% | 6/40 15% | 29/40 73% | 11/40 27% |
| 2014 | ASSERT | 51 | 6 mins | 18/51 35% | 8/51 16% | 43/51 84% | 4/51 8% |
| 2014 | IMPACT | 69 | 36 of 48 atrial beats ≥200 bpm | 20/69 29% | 9/69 13% | 65/69 94% | 4/69 6% |

Interestingly, the majority of patients (75%) did not show a temporal association with the detected atrial episode and their adverse event, with a mean bag period of 46.7+-71.9 days before the TE complication

European Heart Journal (2016) 37, 2893–2962
doi:10.1093/eurheartj/ehw210



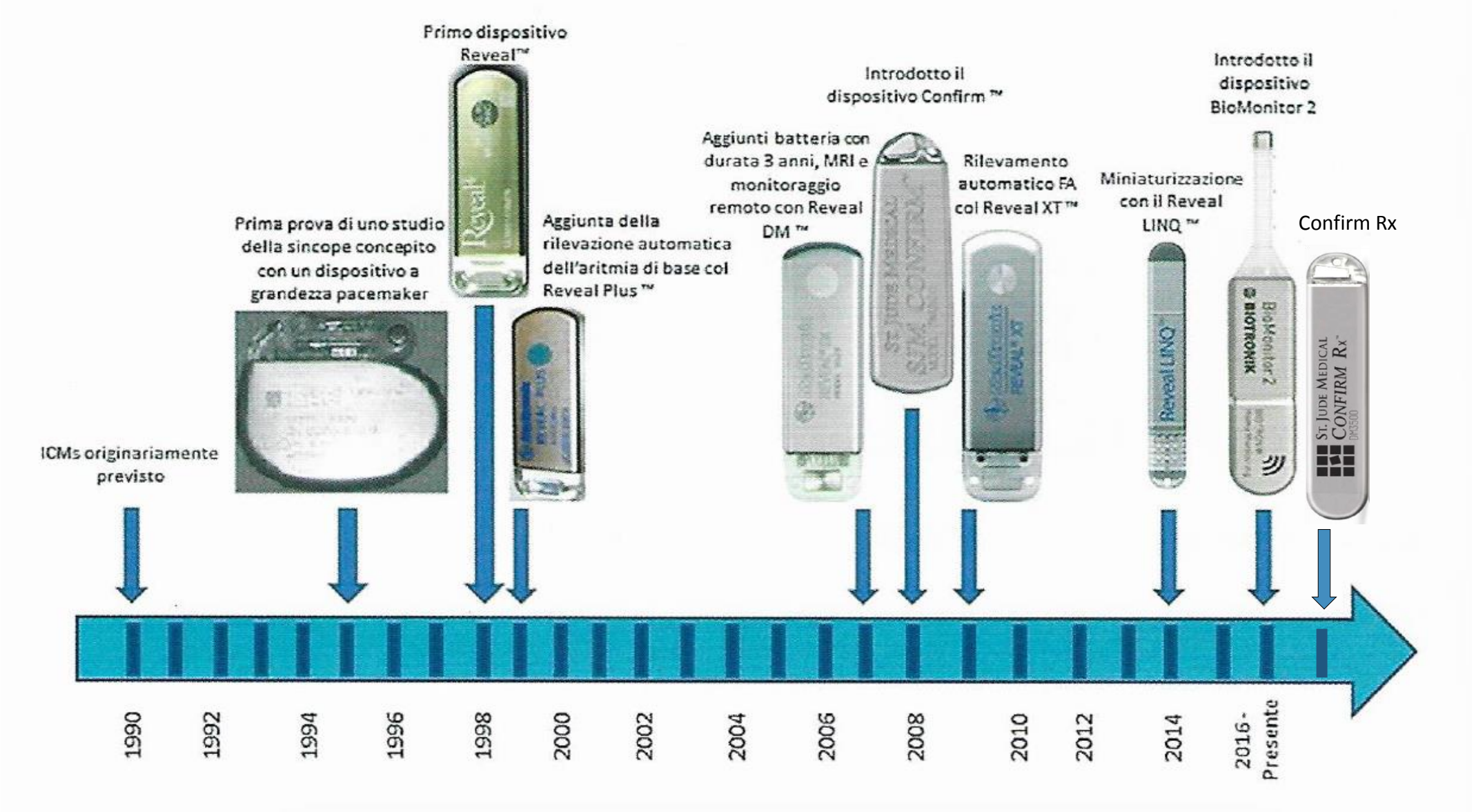
# 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS

- Several studies have also found AF in patients in whom another competing cause for stroke has been identified clinically (e.g. hypertension or carotid artery stenosis).
- Hence, prolonged ECG monitoring seems reasonable in all survivors of an ischaemic stroke without an established diagnosis of AF.

**Recommendations for screening for atrial fibrillation**

| Recommendations | Class[a] | Level[b] | Ref[c] |
|---|---|---|---|
| Opportunistic screening for AF is recommended by pulse taking or ECG rhythm strip in patients >65 years of age. | I | B | 130, 134, 155 |
| In patients with TIA or ischaemic stroke, screening for AF is recommended by short-term ECG recording followed by continuous ECG monitoring for at least 72 hours. | I | B | 27, 127 |
| It is recommended to interrogate pacemakers and ICDs on a regular basis for atrial high rate episodes (AHRE). Patients with AHRE should undergo further ECG monitoring to document AF before initiating AF therapy. | I | B | 141, 156 |
| In stroke patients, additional ECG monitoring by long-term non-invasive ECG monitors or implanted loop recorders should be considered to document silent atrial fibrillation. | IIa | B | 18, 128 |
| Systematic ECG screening may be considered to detect AF in patients aged >75 years, or those at high stroke risk. | IIb | B | 130, 135, 157 |

# Evoluzione del loop recorder



# Left Axillary Implantation of Loop Recorder

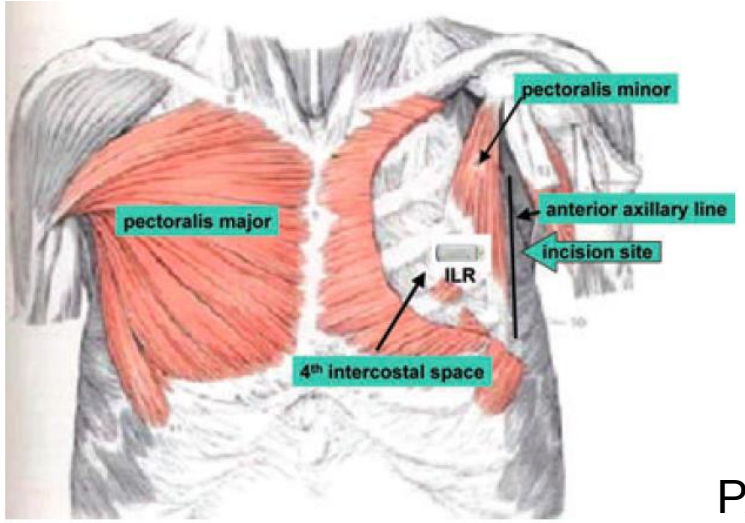
GENNARO MIRACAPILLO, M.D.,* ALESSANDRO COSTOLI, M.D.,*
LUIGI ADDONISIO, M.D.,* LUCIA GEMIGNANI, D.N.S.,* ENRICO MANFREDINI, E.T.,†
GIORGIO CORBUCCI, PH.D.,‡ SILVA SEVERI, M.D.,* and S. SERGE BAROLD, M.D.§

***Background:*** *We compared the clinical course of 10 patients who received an implantable loop recorder (ILR) at a traditional site with 11 patients whose ILRs were implanted via a subpectoral site via a left axillary approach without complications.*

***Methods and Results:*** *R-wave amplitude was determined at implantation and during follow-up. Each patient was followed after 7 days to optimize device setting and then at 1 and 3 months. The R-wave amplitude obtained with the new technique was significantly higher and more stable than that obtained with the standard procedure. Our preliminary experience suggests that axillary access for ILR implantation is feasible, safe, well tolerated, and reliable in terms of sensing function and device performance. Moreover, it is superior aesthetically to the standard approach and carries the potential of minimizing permanent scarring after ILR extraction. (PACE 2010; 33:999–1002)*

## Conclusions

ILR implantation through the axillary region is feasible, safe, well tolerated, and reliable. This technique is superior to the standard technique from the aesthetic point of view and should be offered to the relatively young patients.



PACE 2010; 33:999–1002

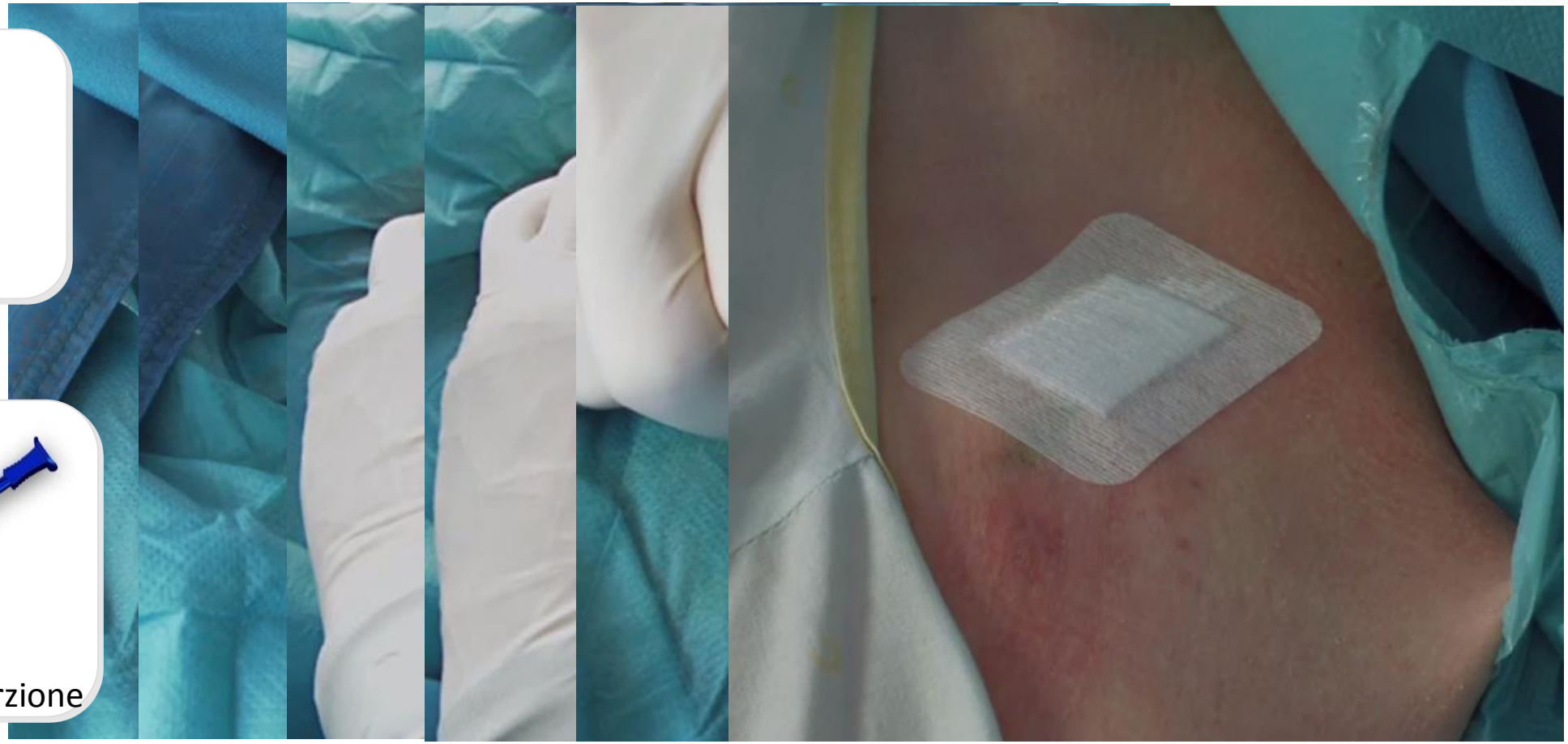
**Figure 1.** *Left pectoralis major muscle was removed and the final position of the delivery is shown, anterior to the left pectoralis minor muscle, at the fourth intercostal space.*

# Benefici della miniaturizzazione

LINQ Device

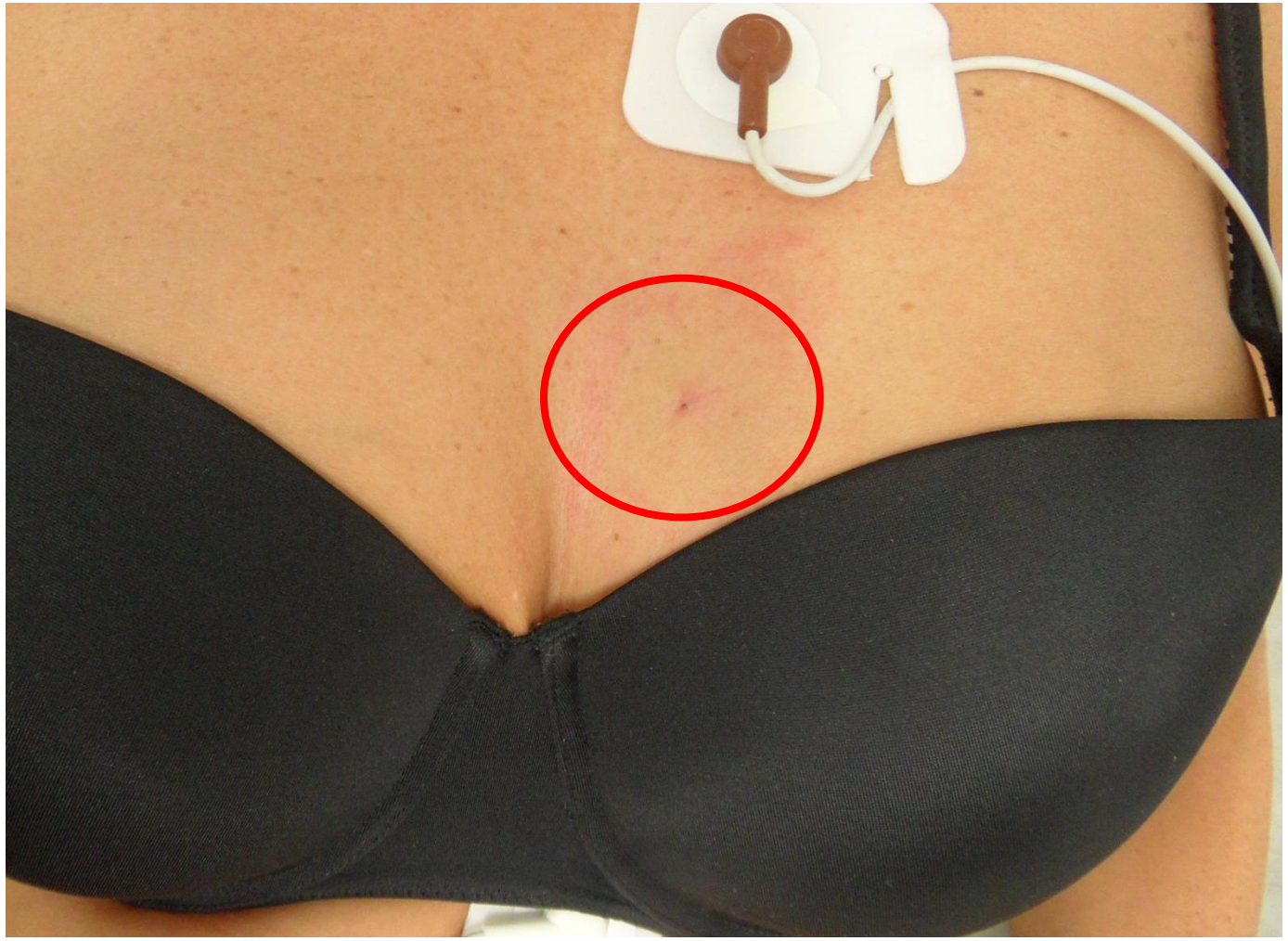
+

Tool di Incisione  Tool di inserzione

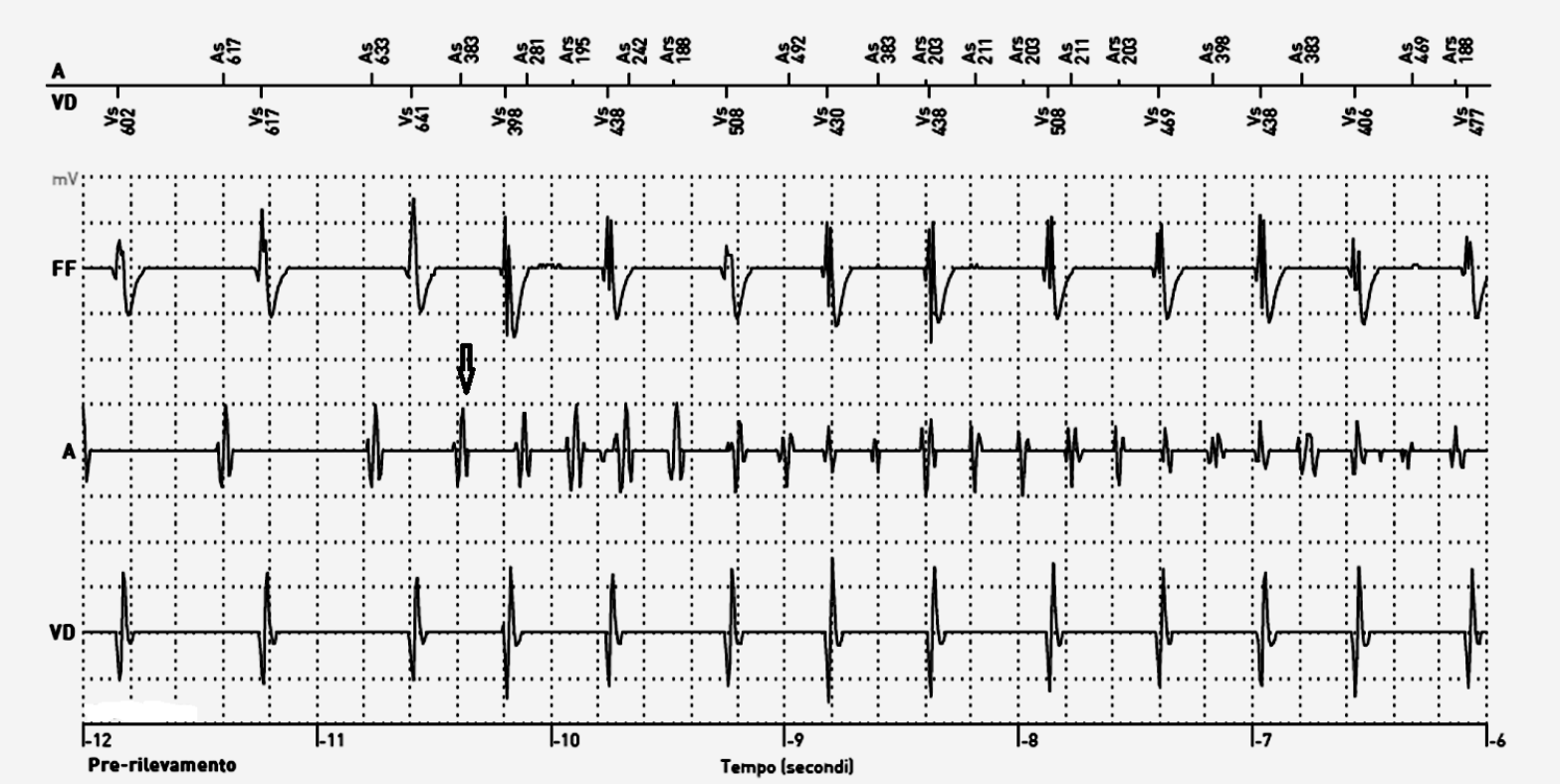


# Maggiore accettazione da parte del paziente e confort

**87% PIU' PICCOLO**



# Migliore AF detection




| STUDY | DEVICE | Sensitivity % | Specificity % | PPV % | NPV % |
|---|---|---|---|---|---|
| XPECT Study[1] | Reveal XT | 96.1 | 85.4 | 79.3 | 97.4 |
| LINQ Usability Study[2] | Reveal LINQ | 97.4 | 97.0 | 92.5 | 99 |

**Il 97% delle volte il Reveal LINQ identificherà correttamente AF.**
**Quando il Reveal LINQ non trova AF, il 99% delle volte questa non è effettivamente presente.**

1. Hindricks G et al. Circ Arrhythm Electrophysiol 2010
2. Sanders P, et al. Heart Rhythm. 2016

| Caratteristica | BioMonitor 2-AF | Reveal XT | Reveal LINQ | Confirm AF |
|---|---|---|---|---|
| Variante per la sincope | BioMonitor 2 -S | Reveal DX | NO | Confirm 2100 |
| Dimensioni (lu-la-sp) | 88 x 15 x 6 | 62 x 19 x 8 | 44,8 x 7,2 x 4 | 56,3 x 18,5 x 8 |
| Volume (cc) | 5 | 9 | 1,2 | 6,5 |
| Peso (g) | 10 | 15 | 2,5 | 12 |
| Durata Batteria | 4 anni | 3 anni | 3 anni | 3 anni |
| Rilevazione QRS | 88 mm | 40 mm | 38 mm | 39 mm |
| Tempo tot Registrazioni | > 60 min | < 60 min | 60 min | < 60 min |
| Tempo per registrazione | 55 x 40 s episodi<br>4 x 7.5 min episodi attivati dal paziente | 27 min episodi<br>22.5 min episodi attivati dal paziente | 27 min episodi<br>30 min episodi attivati dal paziente<br>2 min episodi lunghi AF | 147 episodi |
| Gestione di memoria | SMART | First in, First out | First in, First out (per tipo di episodio) | First in, First out |
| n. trasmissioni/die HM | 6 | NO | 1 | NO |
| Compatibilità RMN | SI, 3 T | SI, 3 T | SI, 3 T | SI, 1.5 T |

I loop recorder sono dispositivi dotati di memoria retrospettiva: sono in grado cioè di registrare e cancellare continuamente la traccia elettrocardiografica.

# Conclusions

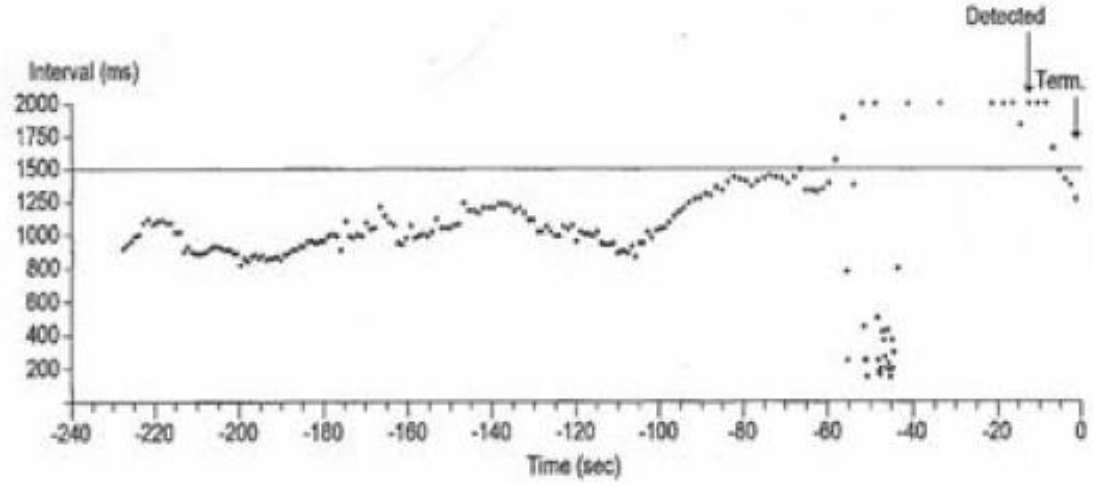
- ILR technology has advanced
  - Devices are smaller, easy to implant
  - Detection algorithms have improved
  - Remote monitoring allows fast recognition of asymptomatic arrhythmias
- Use in evaluation of syncope is well established but still underused
- Role in detecting arrhythmias in situations where early recognition could lead to change in treatment and outcome
- Valuable tool in diagnosis of asymptomatic Afib in stroke patients

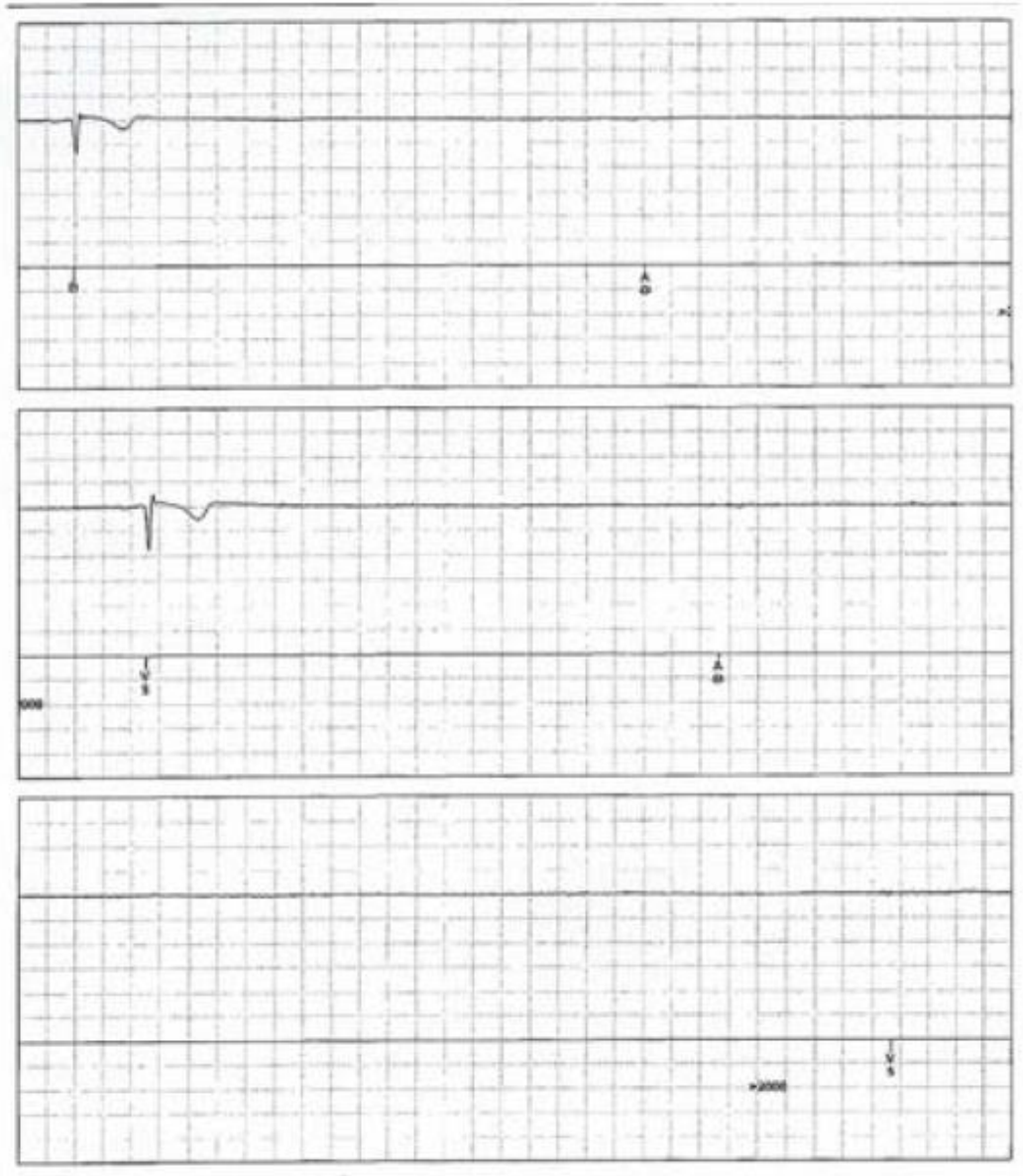
# SINCOPE inspiegata che non richieda ospedalizzazione

Sincope neuromediata, da seduto

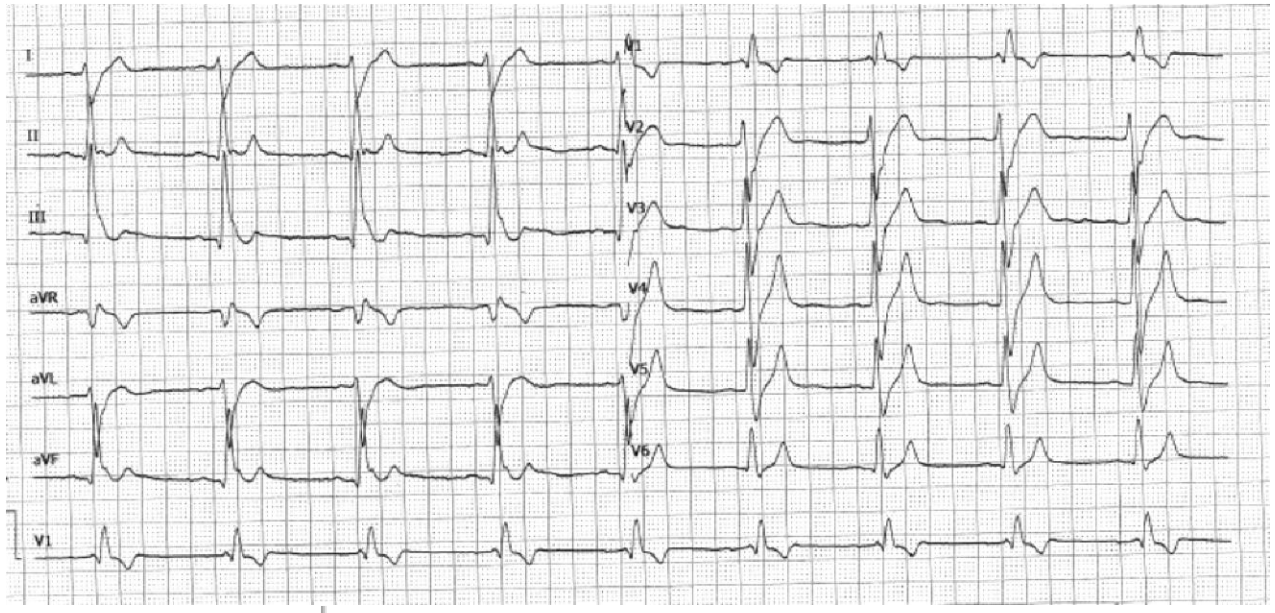
| ID# | Type | Date | Time hh:mm | Duration hh:mm:ss | Max V. Rate | Median V. Rate |
|---|---|---|---|---|---|---|
| 4 | Brady | 09-Feb-2014 | 23:26 | :13 | Min <30 bpm | <30 bpm (>2000 ms) |

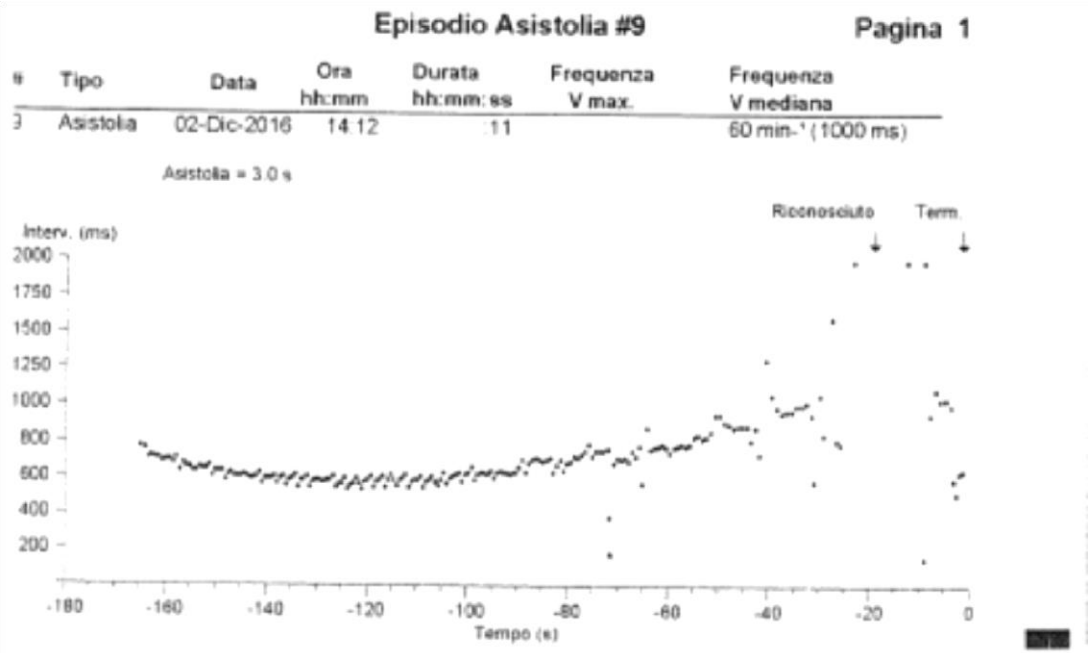
Brady = 1500 ms

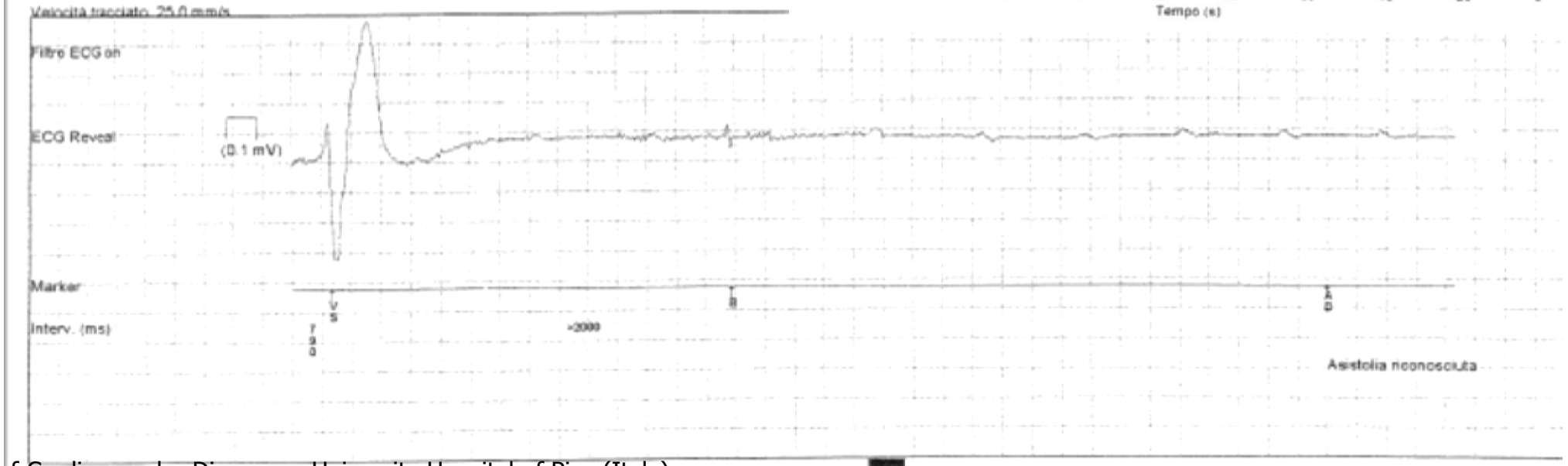


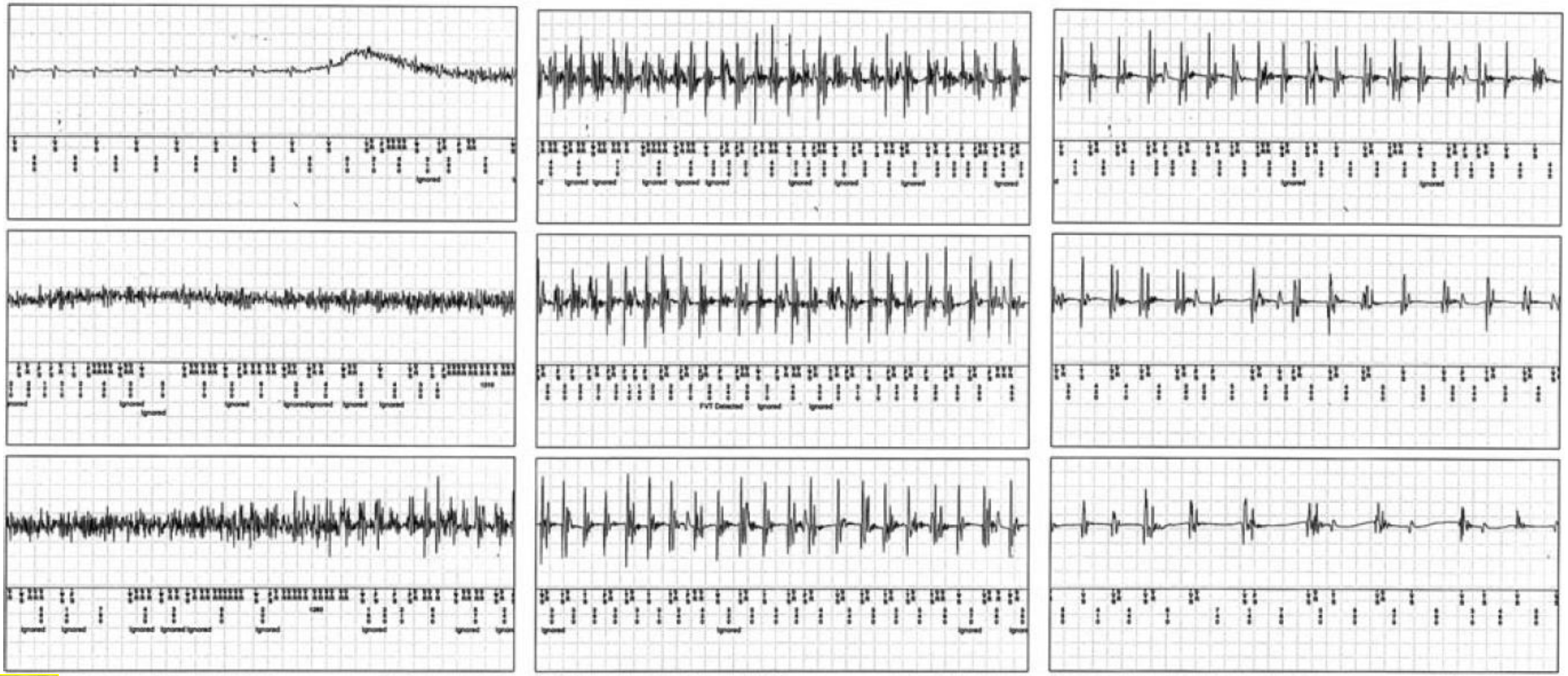
# SINCOPE inspiegata che non richieda ospedalizzazione



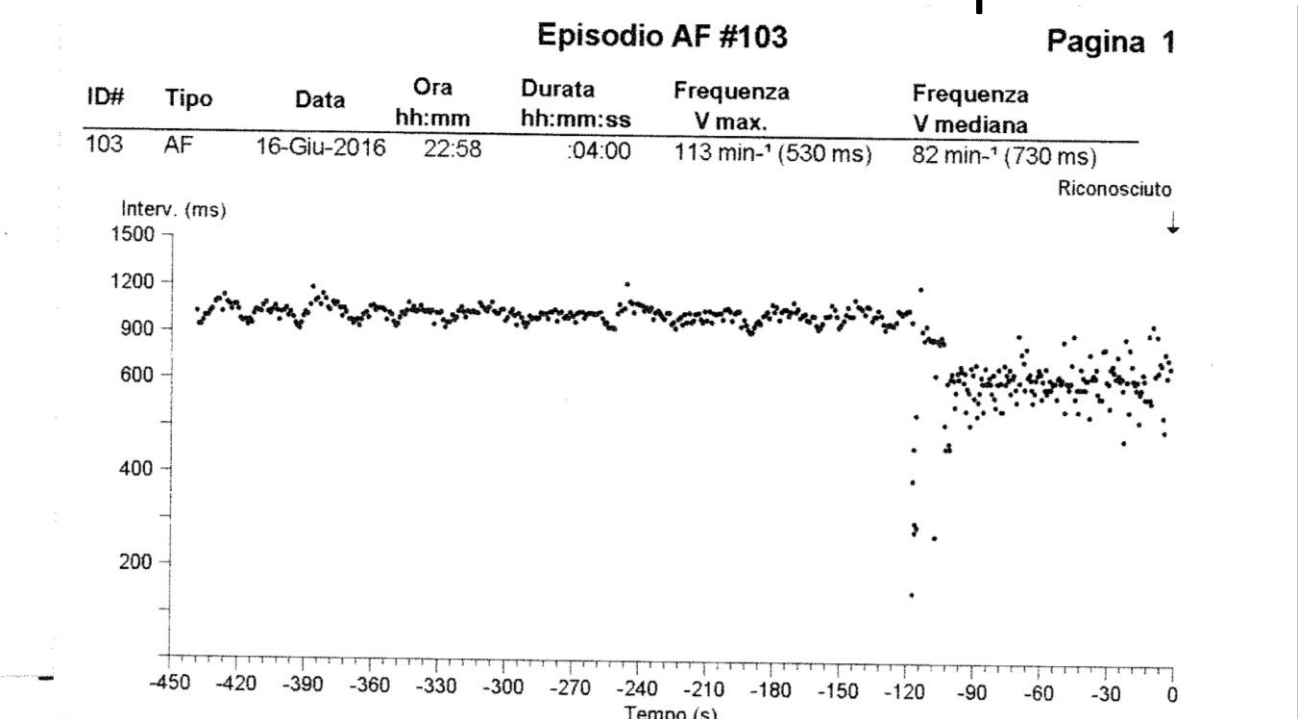



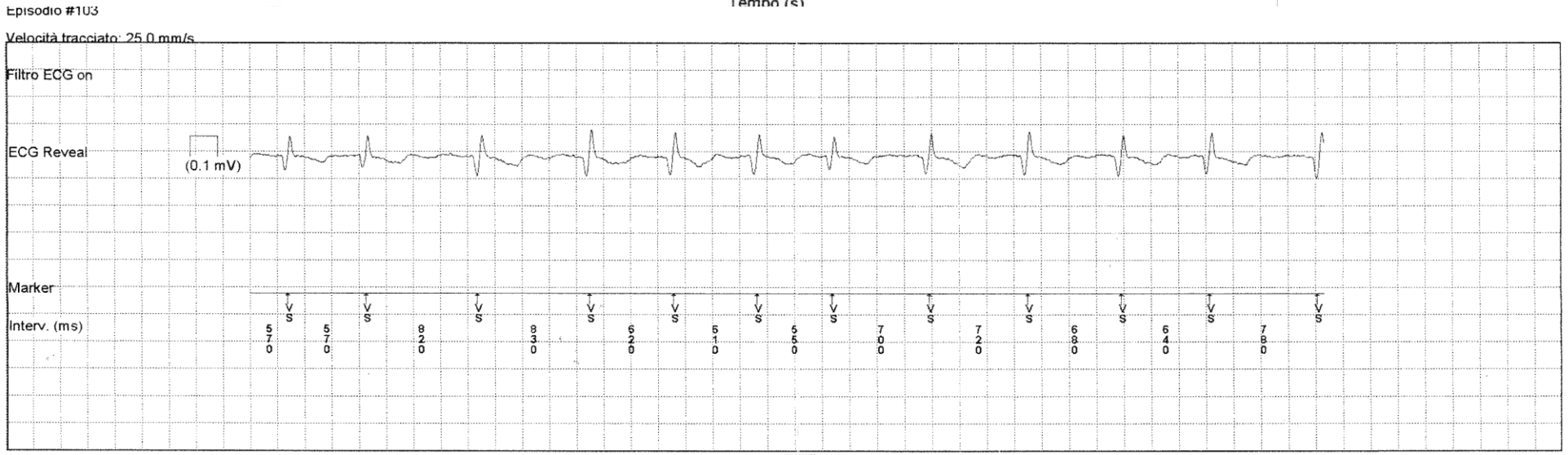



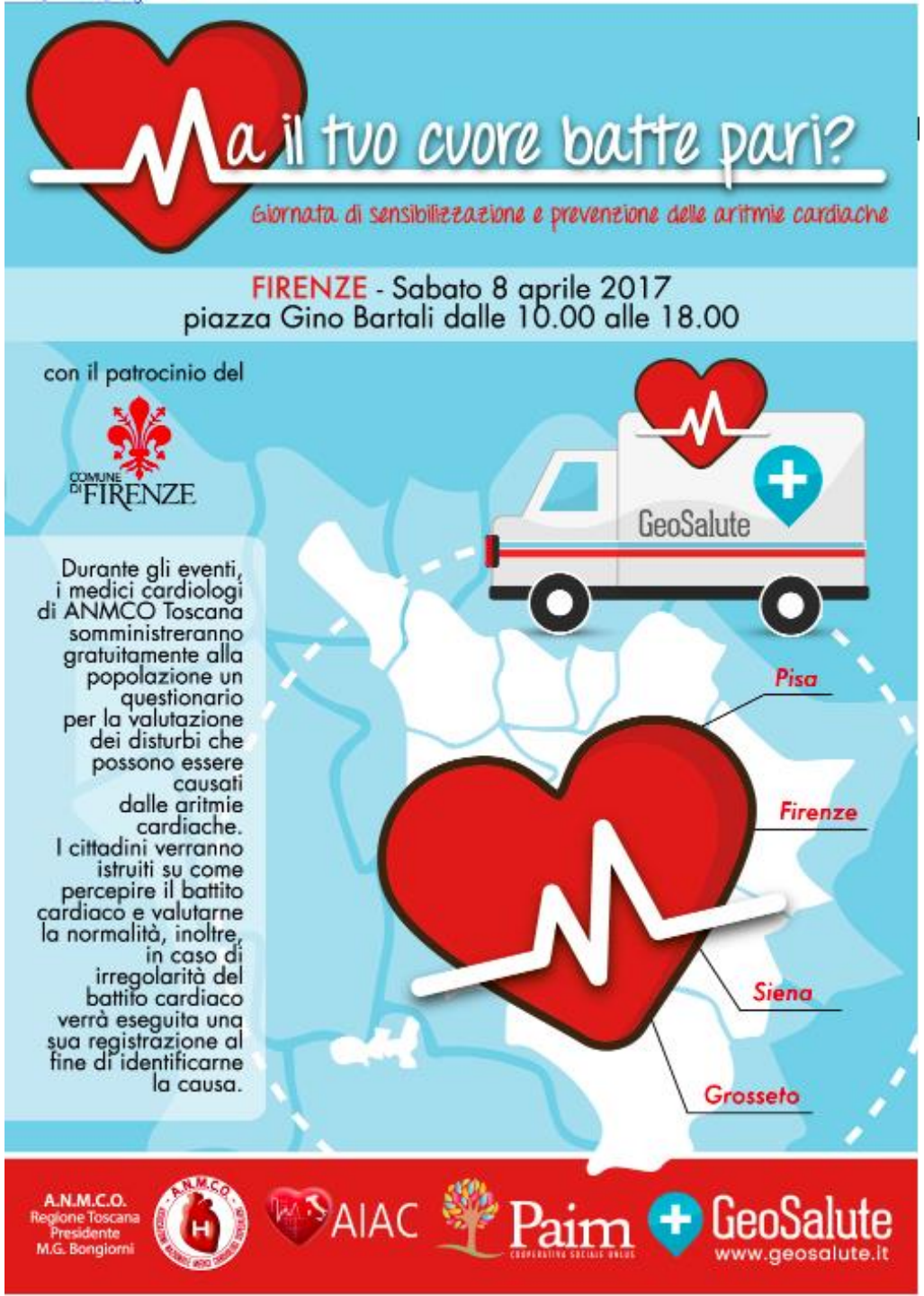
# EPILESSIA con sincope nonostante terapia anticonvulsivante



# Ricerca della FIBRILLAZIONE ATRIALE post Ictus Ischemico






## Recommendations for screening for atrial fibrillation

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ECG Check