



עילפון-

דגש על שימוש ב - ILR



ד"ר אריה מיליטיאנו
היחידה לאלקטרופיזיולוגיה,
מרכז רפואי "כרמל" ומחוז חיפה וג"מ
שירותי בריאות כללית

Insertable Loop Recorders (ILR)

Reveal®

Medtronic Inc., Minneapolis, MN

- manual/auto trigger
- remote download
- home monitor



Confirm®

St Jude Medical, St Paul, MN

- manual/auto trigger
- remote download
- home monitor

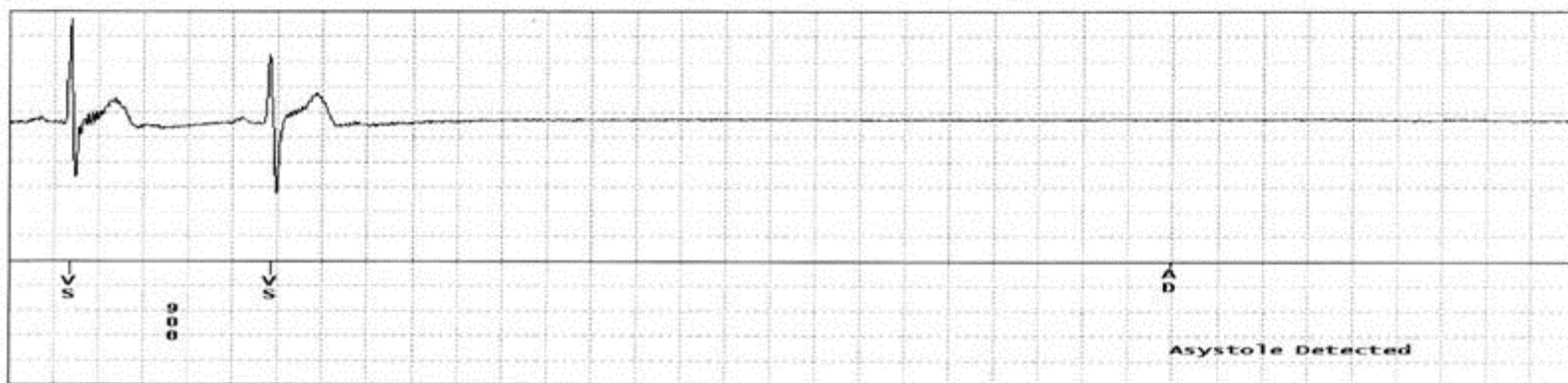
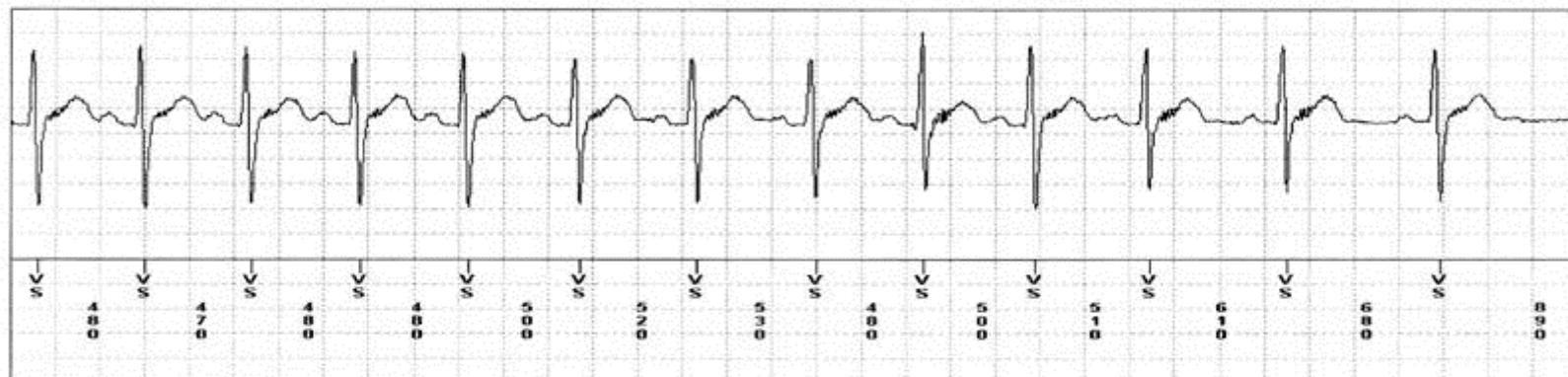


Sleuth AT™

Transoma Medical, St. Paul, MN

- manual/auto trigger
- remote download
- wireless home monitor





תרשים זרימה לאיבחון T-LOC

Transient loss of consciousness

Initial evaluation

History, physical examination, supine & upright BP, standard ECG ± C.S.M

Syncope

Non-syncopal

Certain diagnosis

Uncertain diagnosis

Risk stratification*

Confirm with specific test or specialist's consultancy

Treatment

High risk**

ILR

Early evaluation & treatment

Low risk recurrent episodes

ILR

Delayed treatment guided by ECG documentation

Cardiac or reflex-mediated test as appropriate

Low risk Single/rare episodes

No further evaluation

ILR?

Treatment

Re-appraisal

International Study on Syncope of Uncertain Etiology - ISSUE 1 ; 2 ;3

Issue 1-

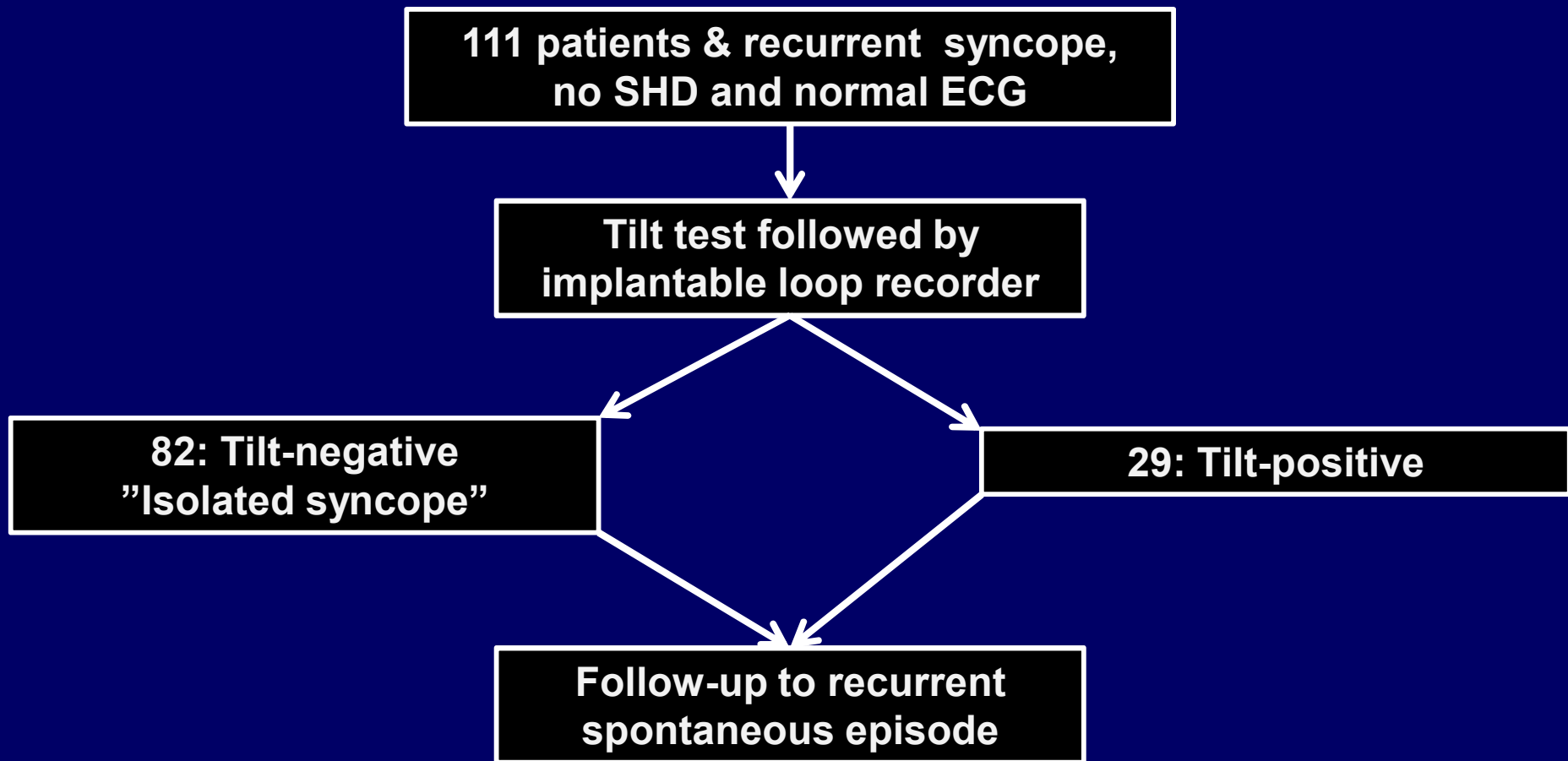
- **Recurrent Syncope and Tilt-Positive**
- **Recurrent Syncope and Tilt-Negative Syncope, Isolated Syncope**
- **Recurrent Syncope in Patients With BBB and Negative EPS**
- **Recurrent Syncope in Patients With SHD and Negative EPS**

Moya A, et al. Circulation 2001;104:1261-67

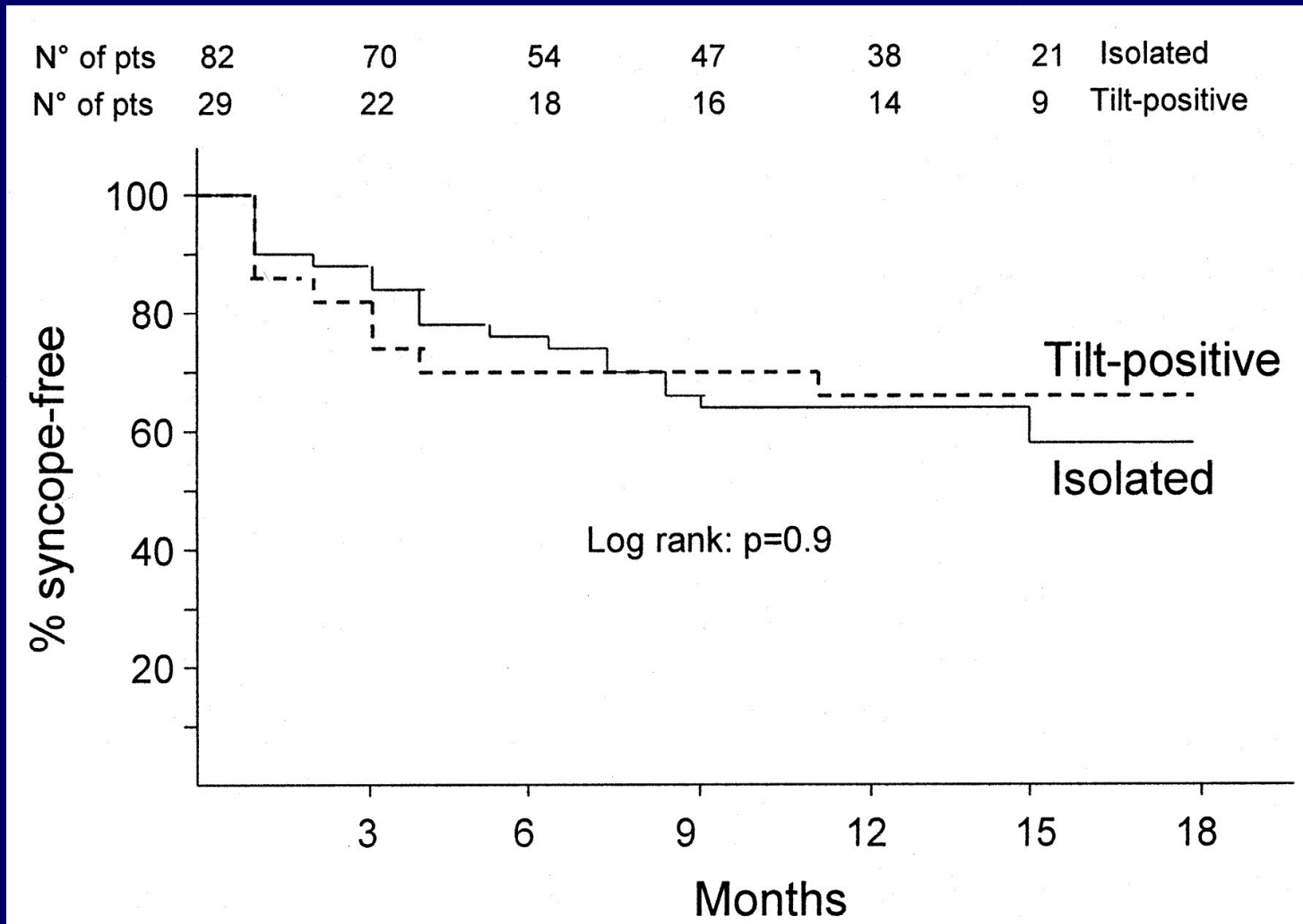
Brignole M et al. Circulation 2001; 104: 2045-50

Menozi C et al. Circulation 2002; 105: 2741-45

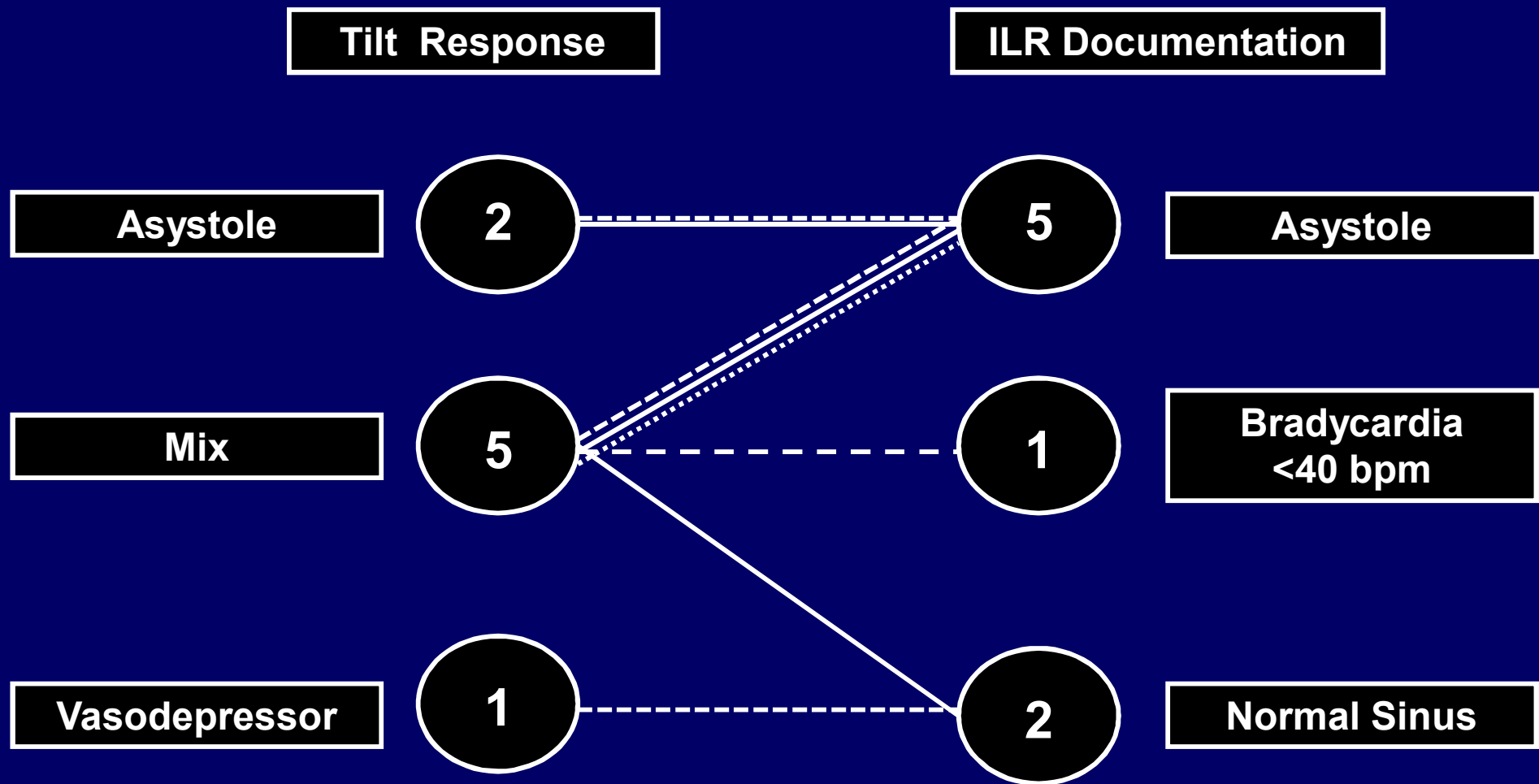
International Study on Syncope of Uncertain Etiology - ISSUE Study design



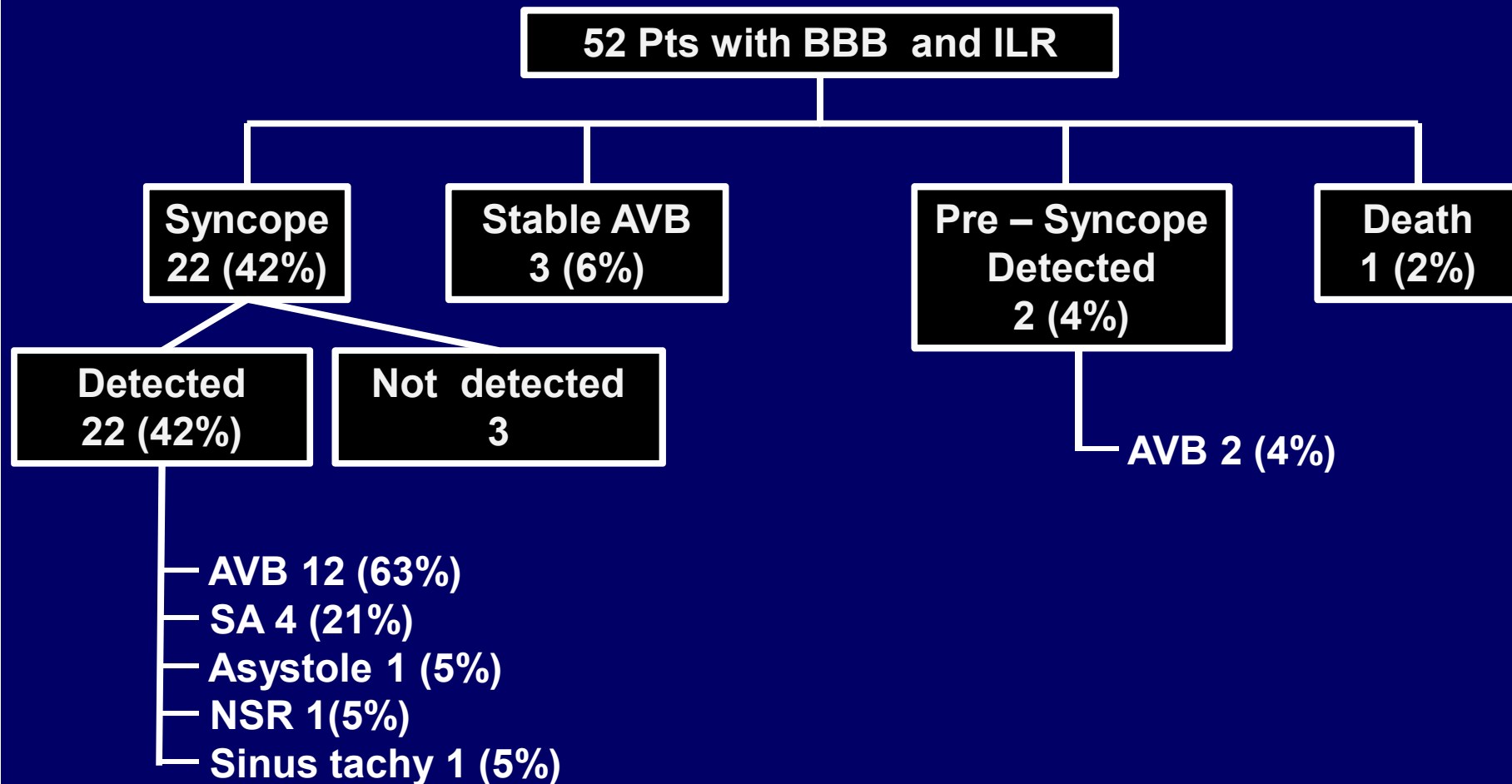
Kaplan-Meier estimates of the probability of remaining free of syncopal recurrences in the isolated syncope group and in the tilt-positive group



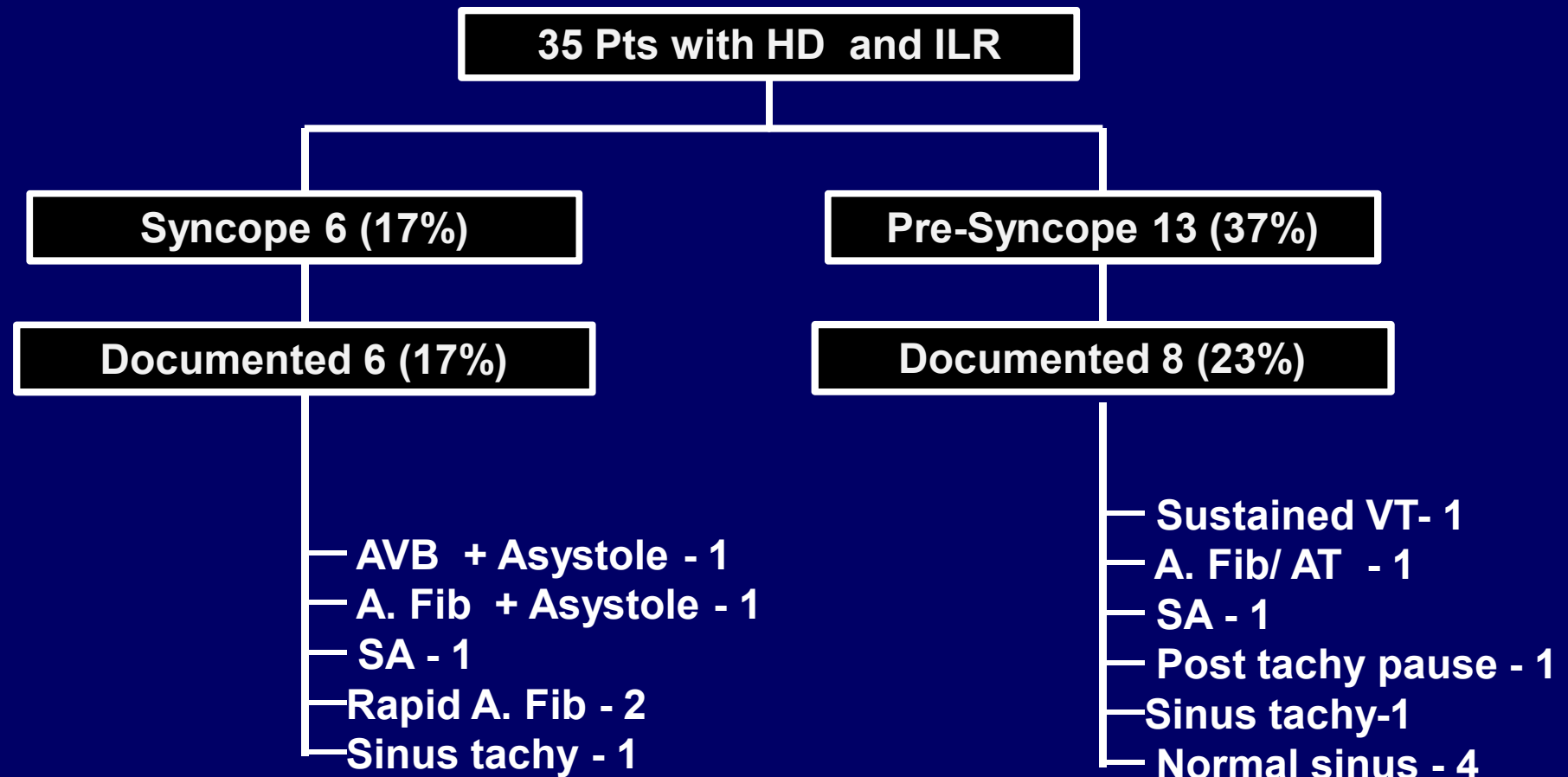
Correlation between tilt-induced responses and spontaneous documented syncope



Mechanism of Syncope in Patients With BBB and Negative EPS – ISSUE 1



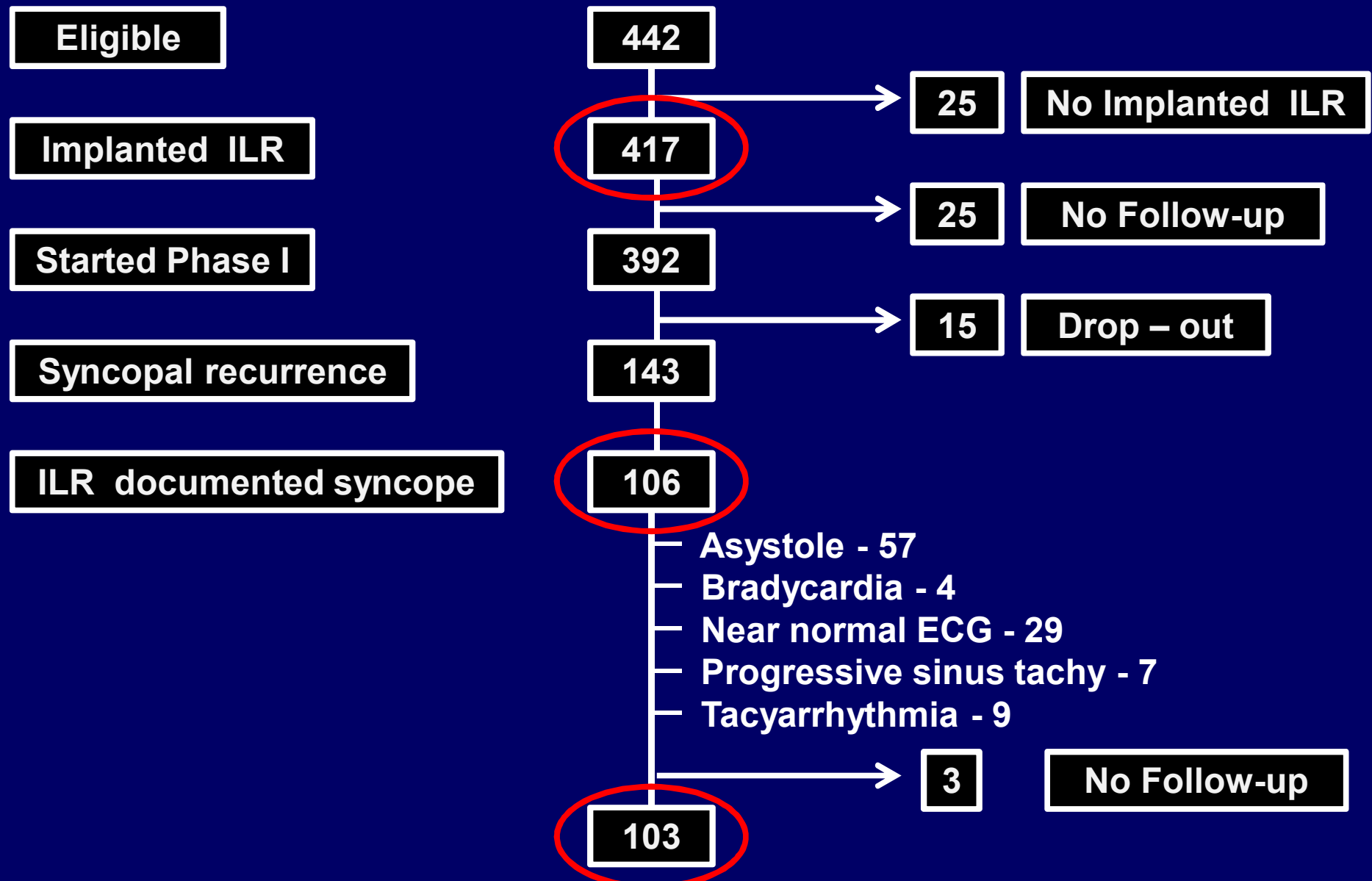
Mechanism of Syncope in Patients With Heart Disease and Negative EPS – ISSUE 1



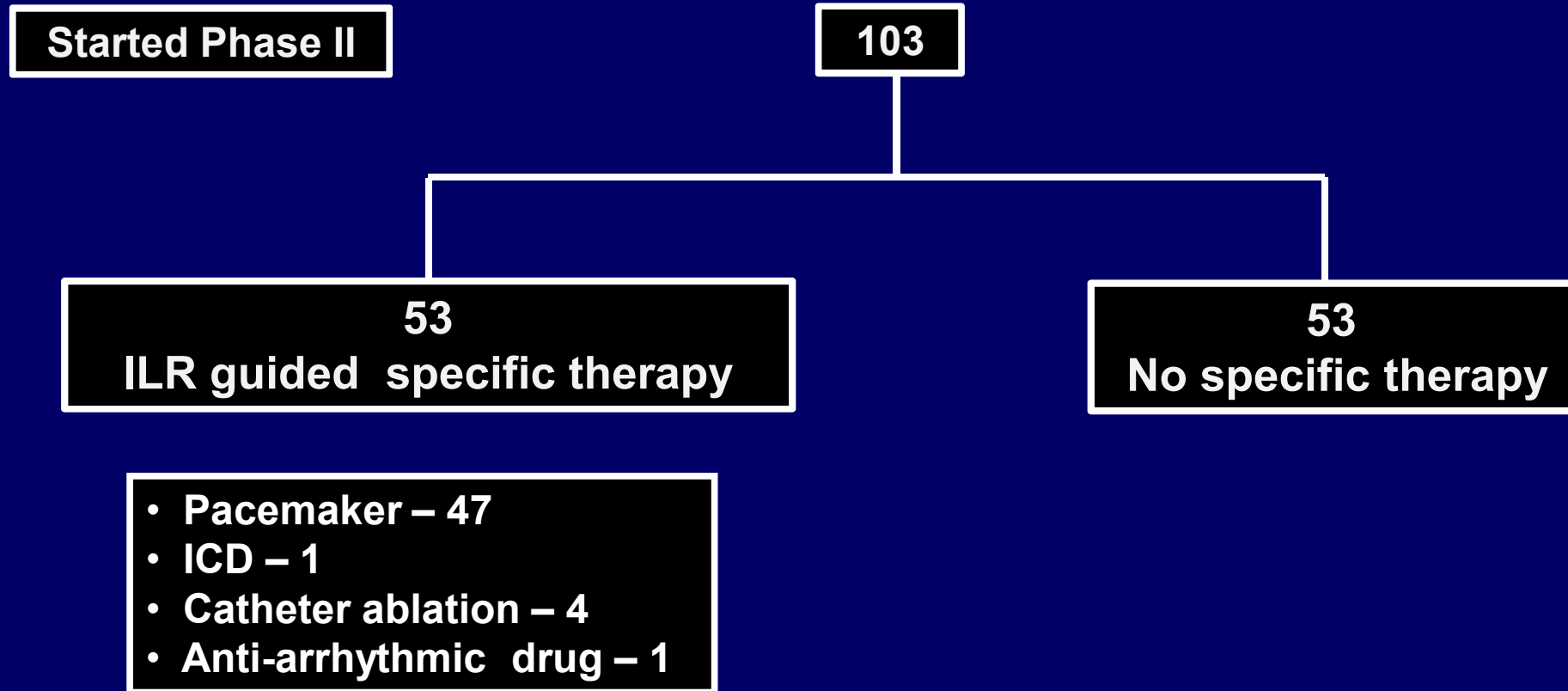
**Early application of an implantable loop recorder
allows effective specific therapy in patients
with recurrent suspected neurally mediated syncope
– ISSUE 2**

Brignole M, *et al.* Eur Heart J 2006;27:1085-92

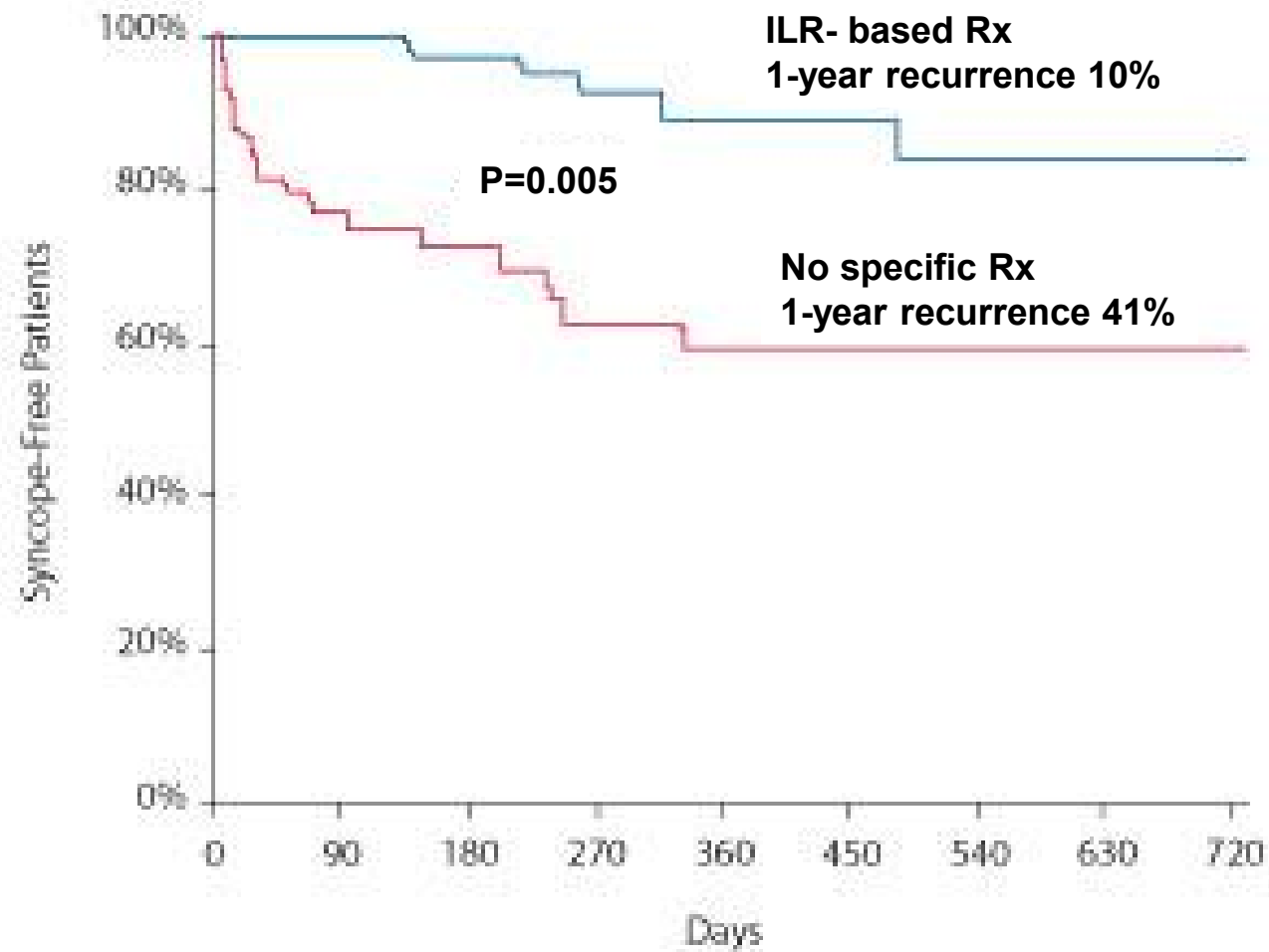
ISSUE 2



ISSUE 2



Syncope – Free Patients Over Time ISSUE 2



**Pacemaker therapy for patients with
neurally-mediated syncope and documented asystole**

A randomized controlled double-blind trial

- ISSUE 3

Screening phase

511 met inclusion criteria
and received an ILR

Study phase

89 Had ECG documentation of :
- syncopal recurrence with asystole of 12 ± 10 s (#72)
or
- non-syncopal asystole of 10 ± 6 s (#17)

77 randomized

38 assigned and received
Pm ON

39 assigned and received
Pm OFF

38 analysed

8 had Pm reprogrammed
DDD/VVI in absence of
primary end-point

39 analysed

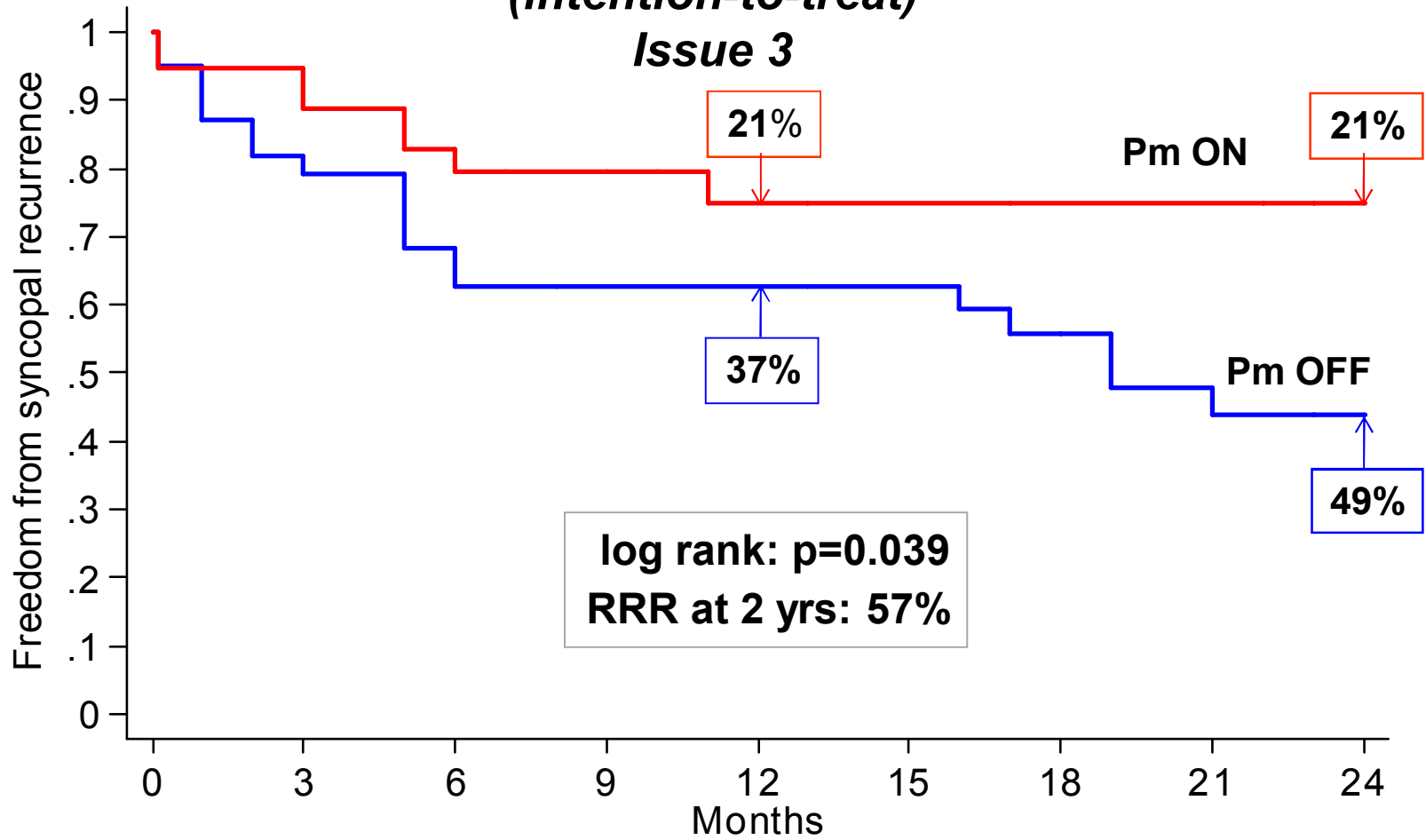
12 refused randomization

3 lost to follow-up

9 followed-up (registry):
6 implanted Pm
3 no therapy

9 analysed

**First syncope recurrence
(intention-to-treat)
Issue 3**



Number at risk

Pm OFF	39	31	25	21	21	18	15	12	8
Pm ON	38	32	27	22	16	14	13	13	11

Screening phase

511 met inclusion criteria and received an ILR

NND = 6

Study phase

89 (17%) Had ECG documentation of :
- syncopal recurrence with asystole of 12 ± 10 s (#72)
or
- non-syncopal asystole of 10 ± 6 s (#17)

9 ILR > 1 Syncope saving

77 randomized

38 assigned and received Pm ON

39 assigned and received Pm OFF

Syncope recurrence @ 24 Mo

8 (21%)

19 (49%)

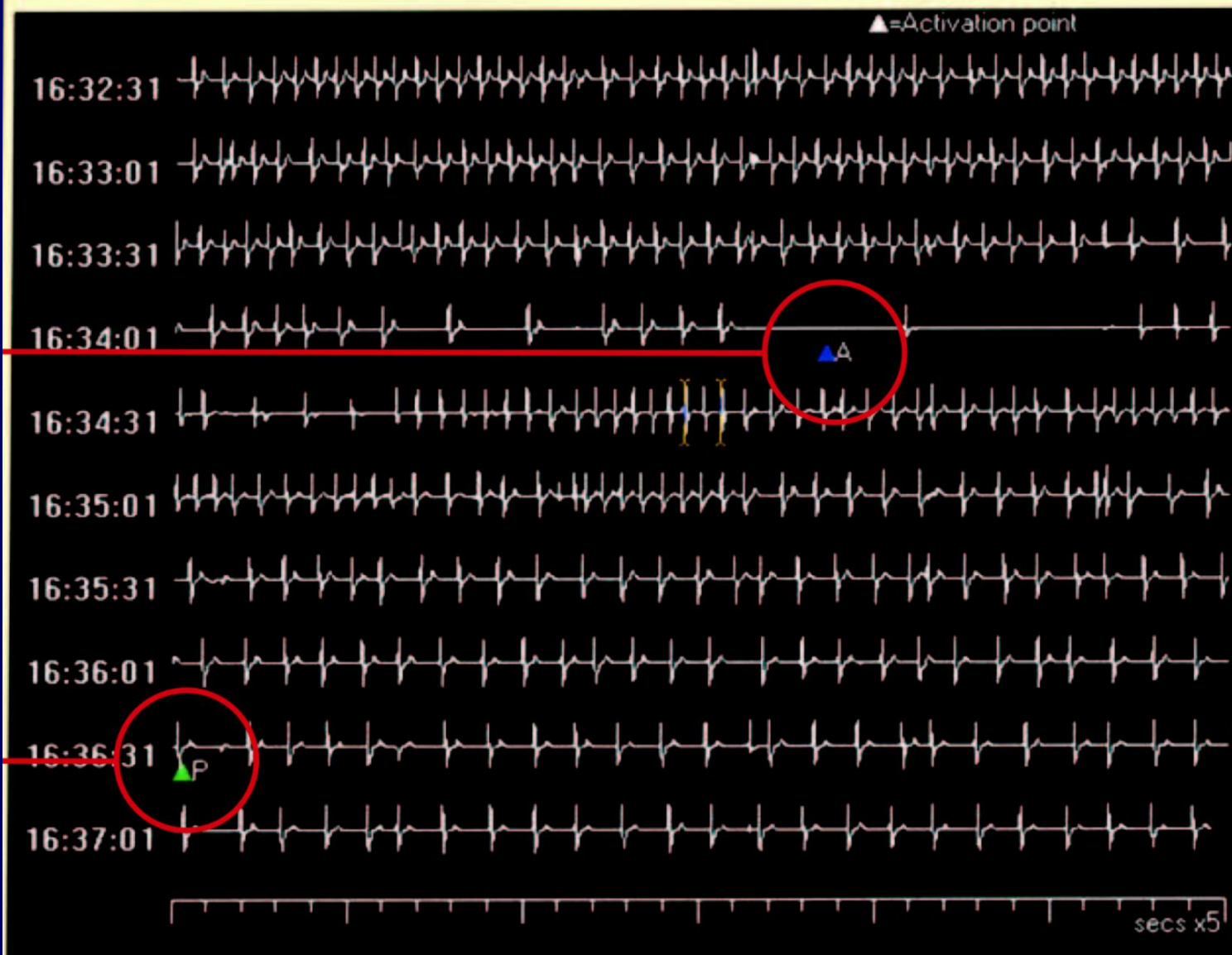
NNT = 3

Classification of ECG recordings obtained with ILR, with their probable-related mechanism

	Classification	Suggested mechanism
Type 1, asystole: R–R pause ≥ 3 s	Type 1 A. Sinus arrest: progressive sinus bradycardia or initial sinus tachycardia followed by progressive sinus bradycardia until sinus arrest.	Probably reflex
	Type 1B, Sinus bradycardia plus AV block: -progressive sinus bradycardia followed by AV block (and ventricular pause/s) with concomitant decrease in sinus rate -or sudden onset AV block (and ventricular pause/s) with concomitant decrease in sinus rate	Probably reflex
	Type 1C, AV block: sudden onset AV block (and ventricular pause/s) with concomitant increase in sinus rate	Probably intrinsic
Type 2, bradycardia: decrease in HR >30% or <40 bpm for >10 s		Probably reflex
Type 3, no or slight rhythm variations: variations in HR <30% and heart rate >40 b.p.m.		Uncertain
Type 4, tachycardia: increase in heart rate >30% of >120 b.p.m.	Type 4 A. Progressive sinus tachycardia	Uncertain
	Type 4 B. Atrial fibrillation	Cardiac arrhythmia
	Type 4 C. SVT (except sinus)	Cardiac arrhythmia
	Type 4 D. VT	Cardiac arrhythmia

011100A

16:32 01/11/2005 Patient Activated Event 1 of 1



Calipers

1000 msec
 bpm

Left Right
← → ← →

Both
← Home →

Print...

Zoom Out

020999A

15:21 02/09/1999 Patient Activated Event 1 of 1



Calipers

1000

msec

bpm

Left

Right



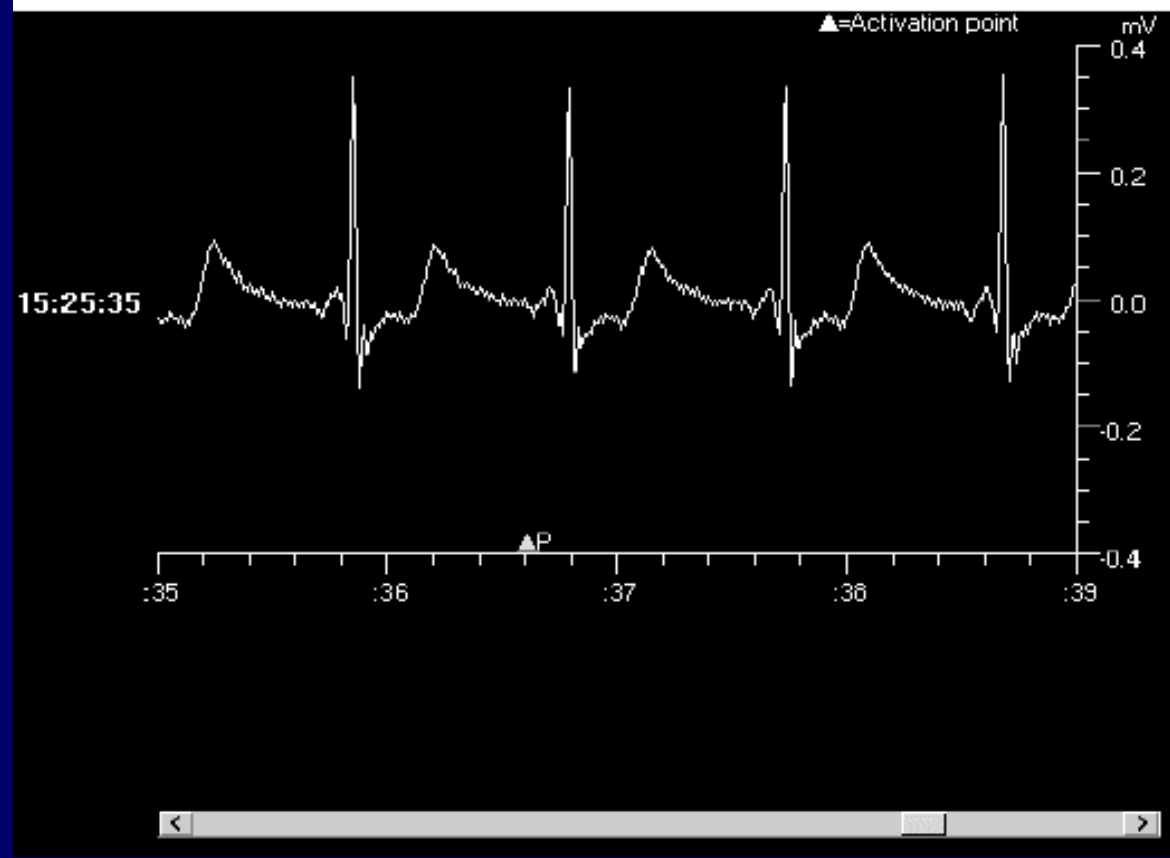
Both



Print...

Zoom Out

020999A 15:21 02/09/1999 Patient Activated Event 1 of 1



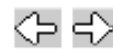
Calipers

1000 msec

bpm

Left

Right



Both



Home



Print...

Zoom Out

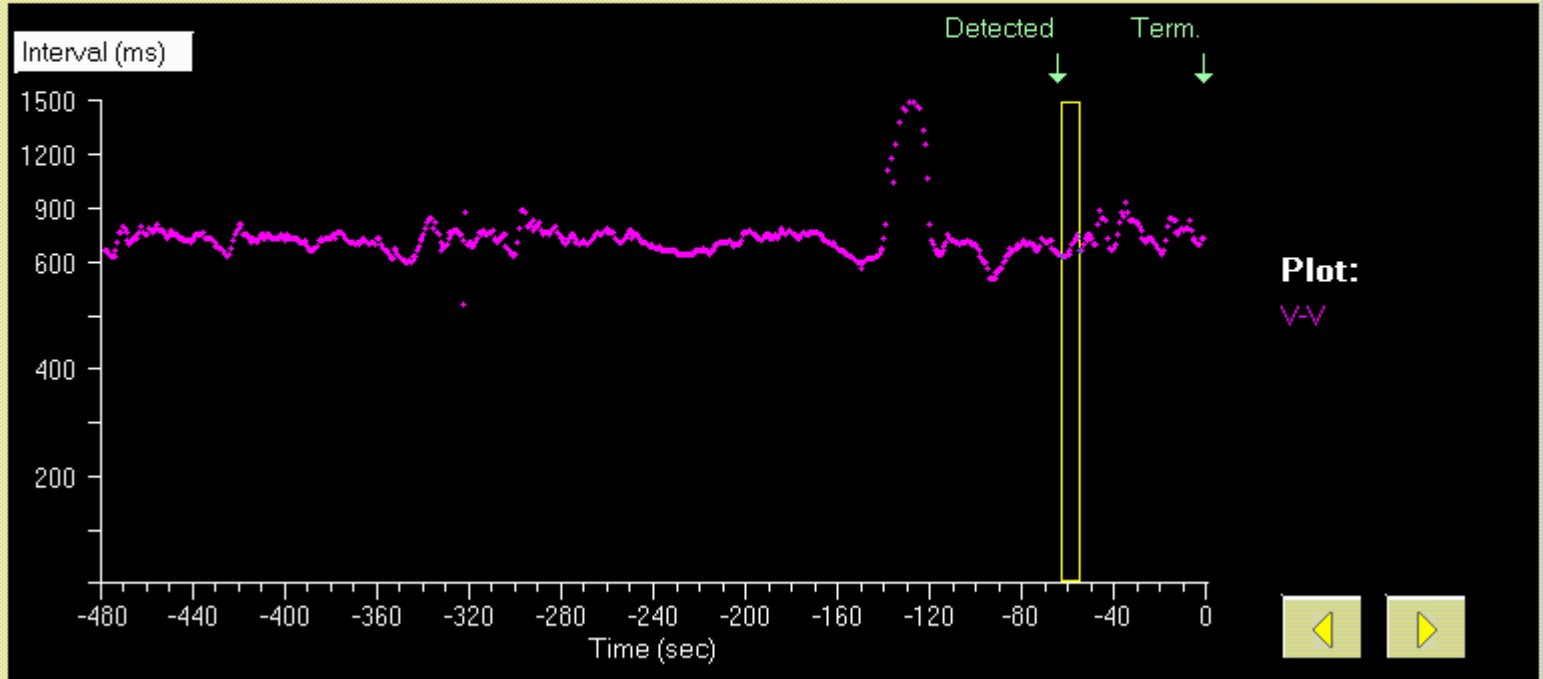
Arrhythmia Episodes

#	Type	Date	Time	Duration	Max V.	Median V.	Detail
14	SYMPTOM	28-Jun-2009	18:16				ECG

#14: Plot ECG Text

Previous

Next



Print...

Close

Arrhythmia Episodes

#	Type	Date	Time	Duration	Max V.	Median V.	Detail
14	SYMPTOM	28-Jun-2009	18:16				ECG

#14: Plot ECG Text

Previous

Next



ECG Reveal



Markers



Interval (ms)

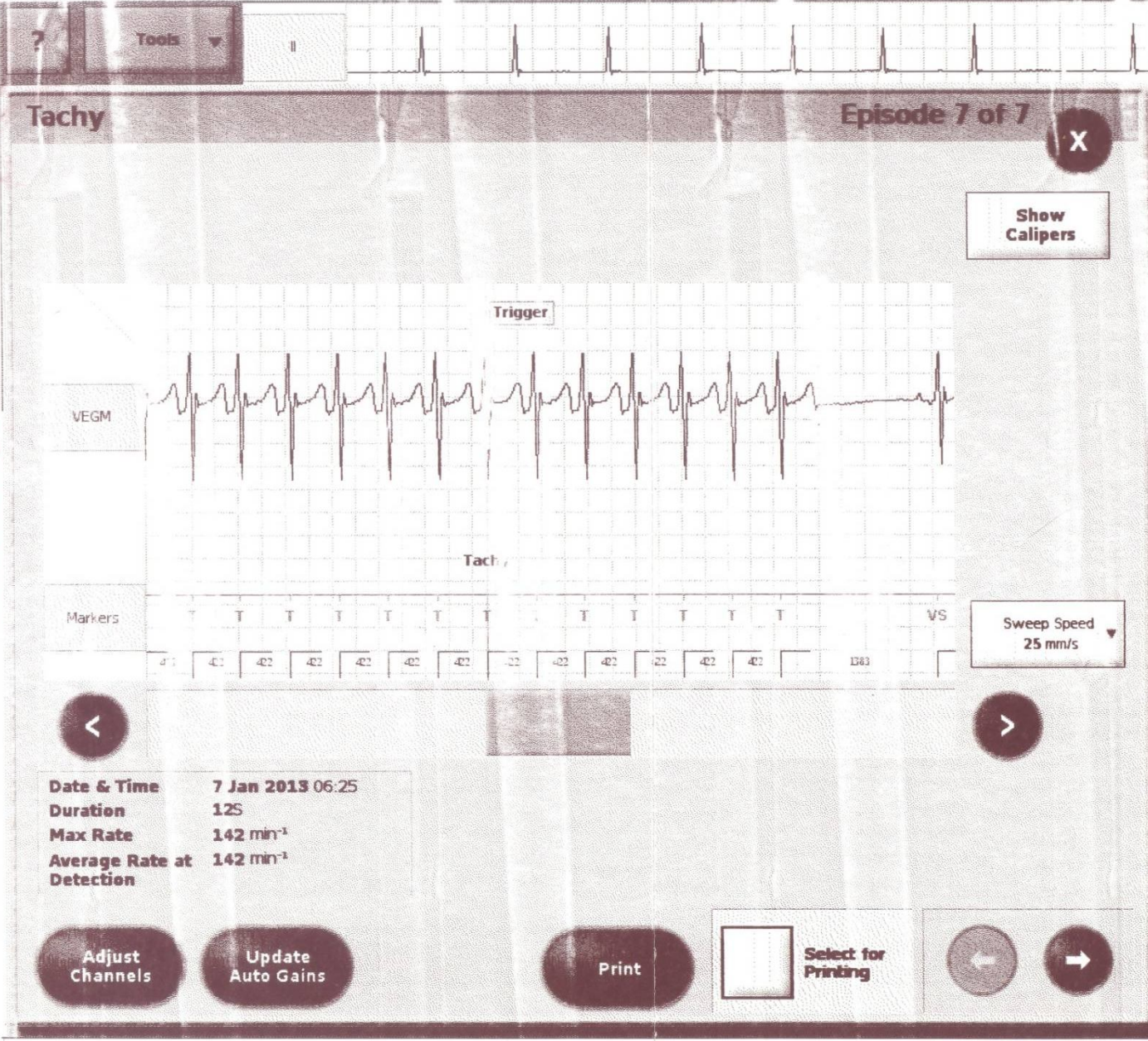
0000 0000 0000 0000 1110 1180 1050 1260

Print...

Close

7 Jan 2013 06:17

Screen Image



Ready

FastPath™ Summary

Episodes

Diagnostics

Tests

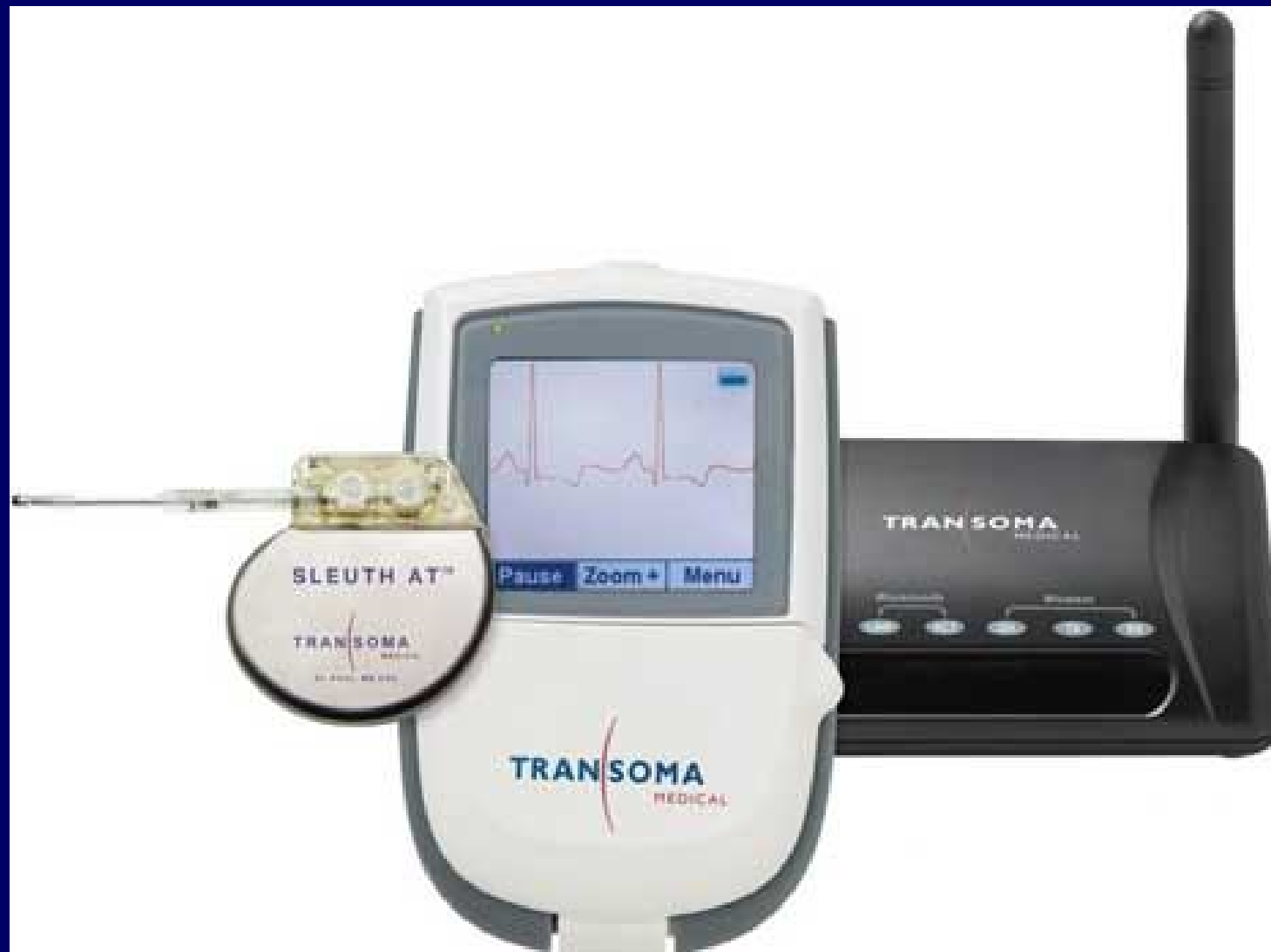
Parameters

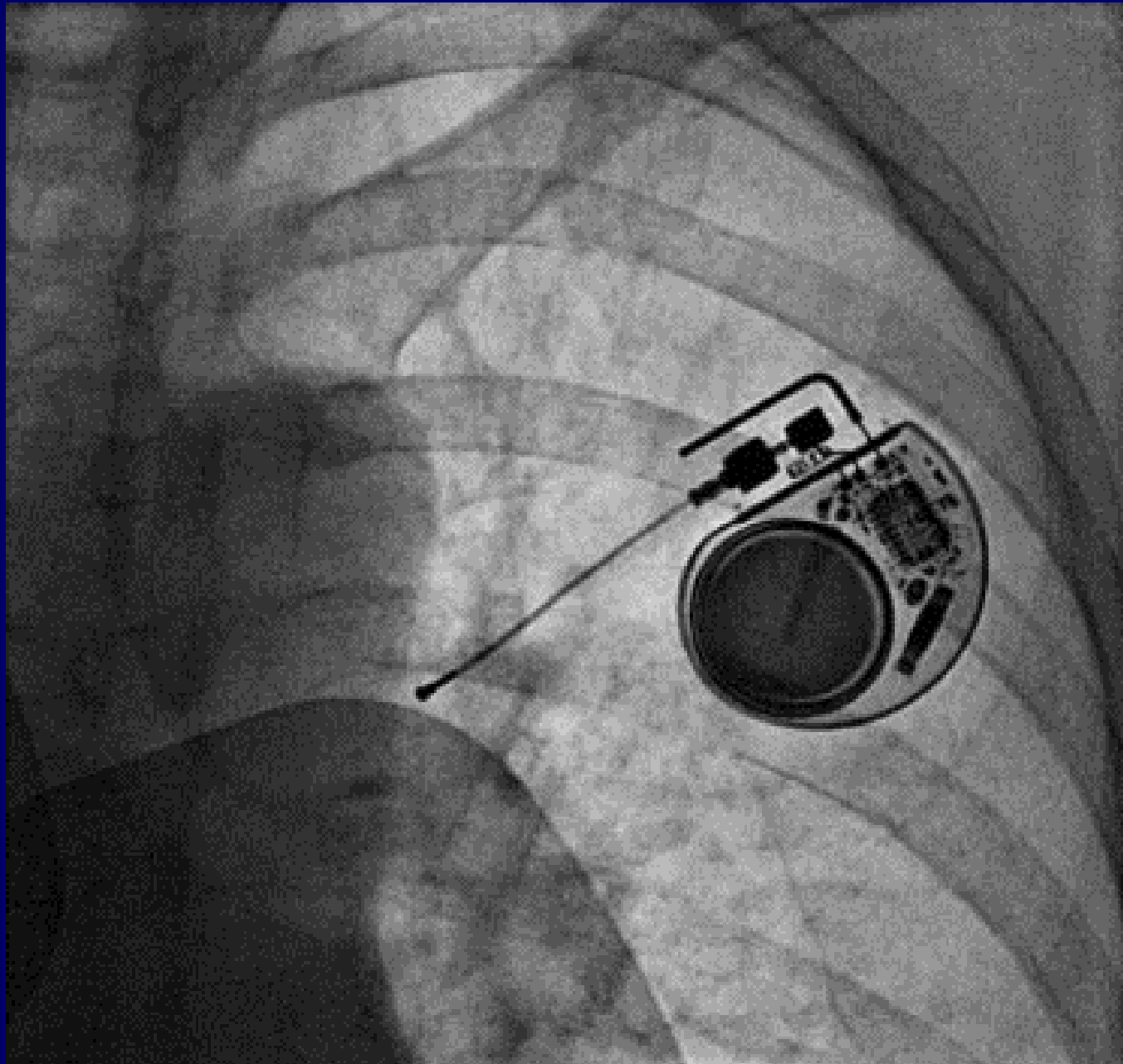
Wrap-up™ Overview

Screen Image page 1 of 1

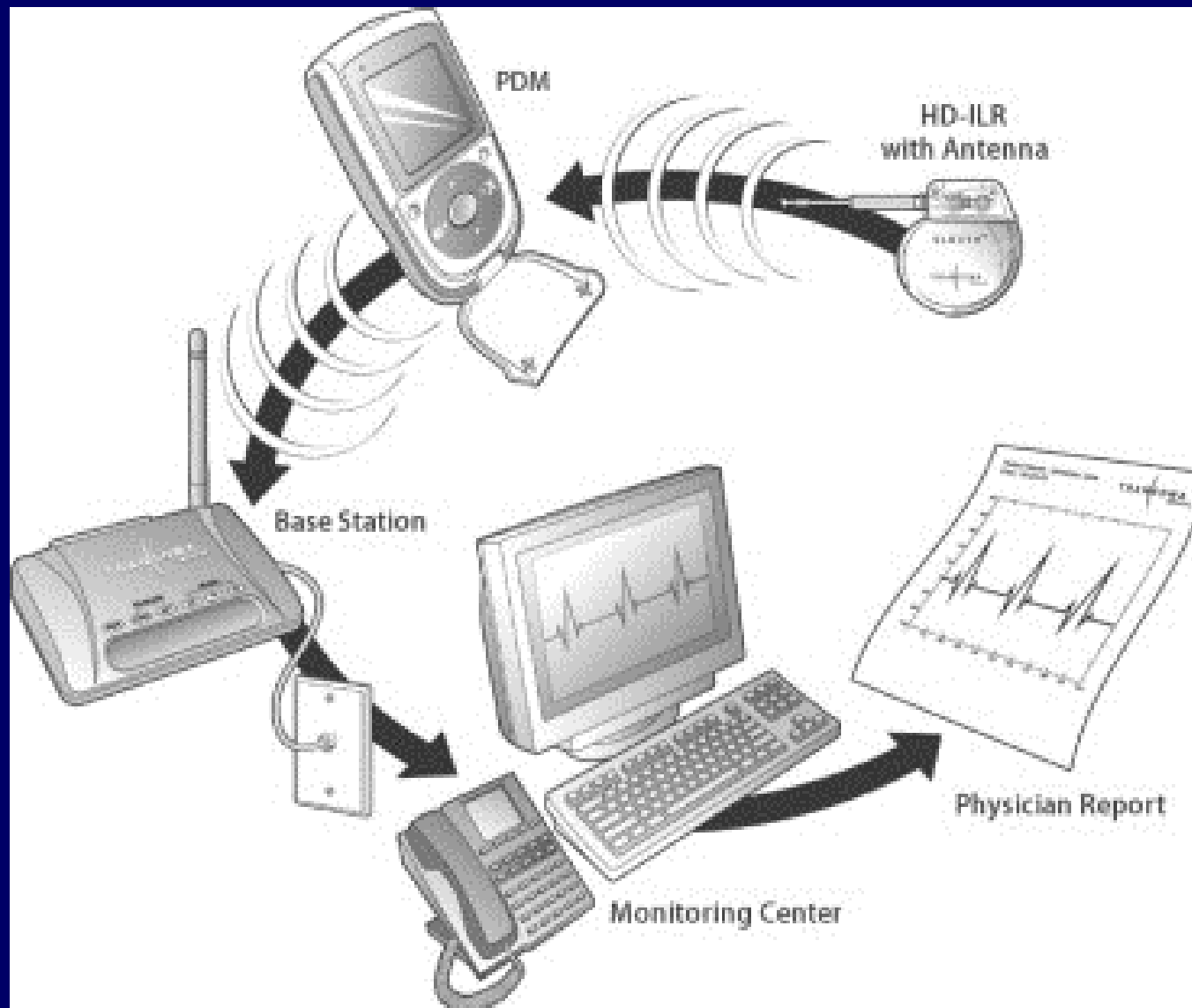
ST. JUDE MEDICAL

**Immediate use of a remotely monitored ILR in
diagnosing unexplained syncope:
The Second Eastbourne Syncope Assessment Study
-EaSyAS II**





Schematic overview of the Sleuth ILR system



EaSyAS II

Acute presentation to Accident and
Emergency Unit/Medical Admissions Unit
CCU/other Wards/Out Patient clinics

- Age > 16
- ≥ 2 un-diagnosed syncopal episodes in last 24 months
- No high grade AV block on ECG
- No other pathology requiring admission
- Normal FBC, U&Es, Glucose; No significant postural drop
- No Significant Cognitive impairment

Randomization

Sleuth ILR

No Sleuth ILR

Discharge
review if event
Tel 3 Mo

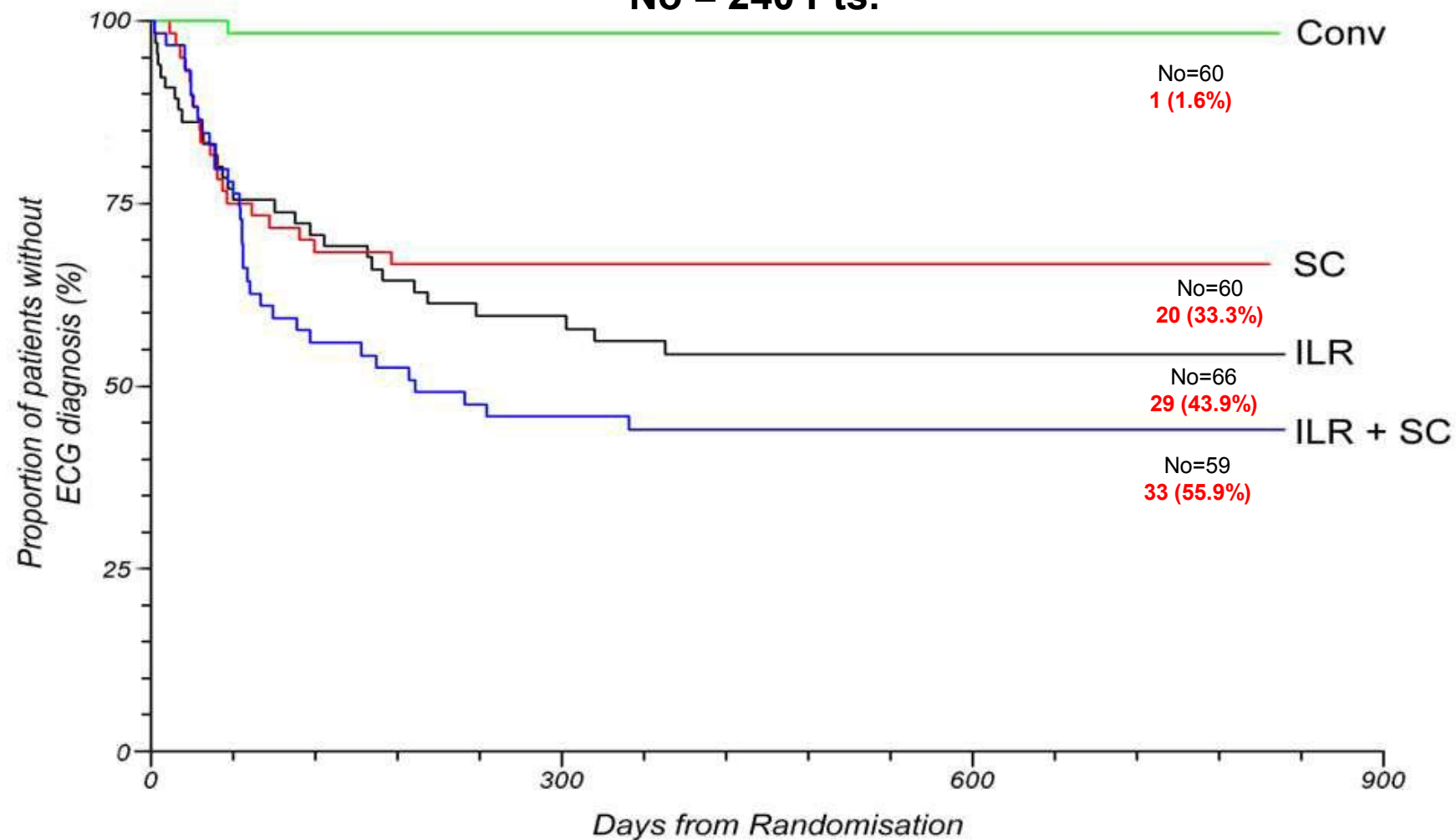
Syncope clinic
review in 2 W
Then as directed
Tel 3 Mo

Standard
investigation and
management
Tel 3 Mo

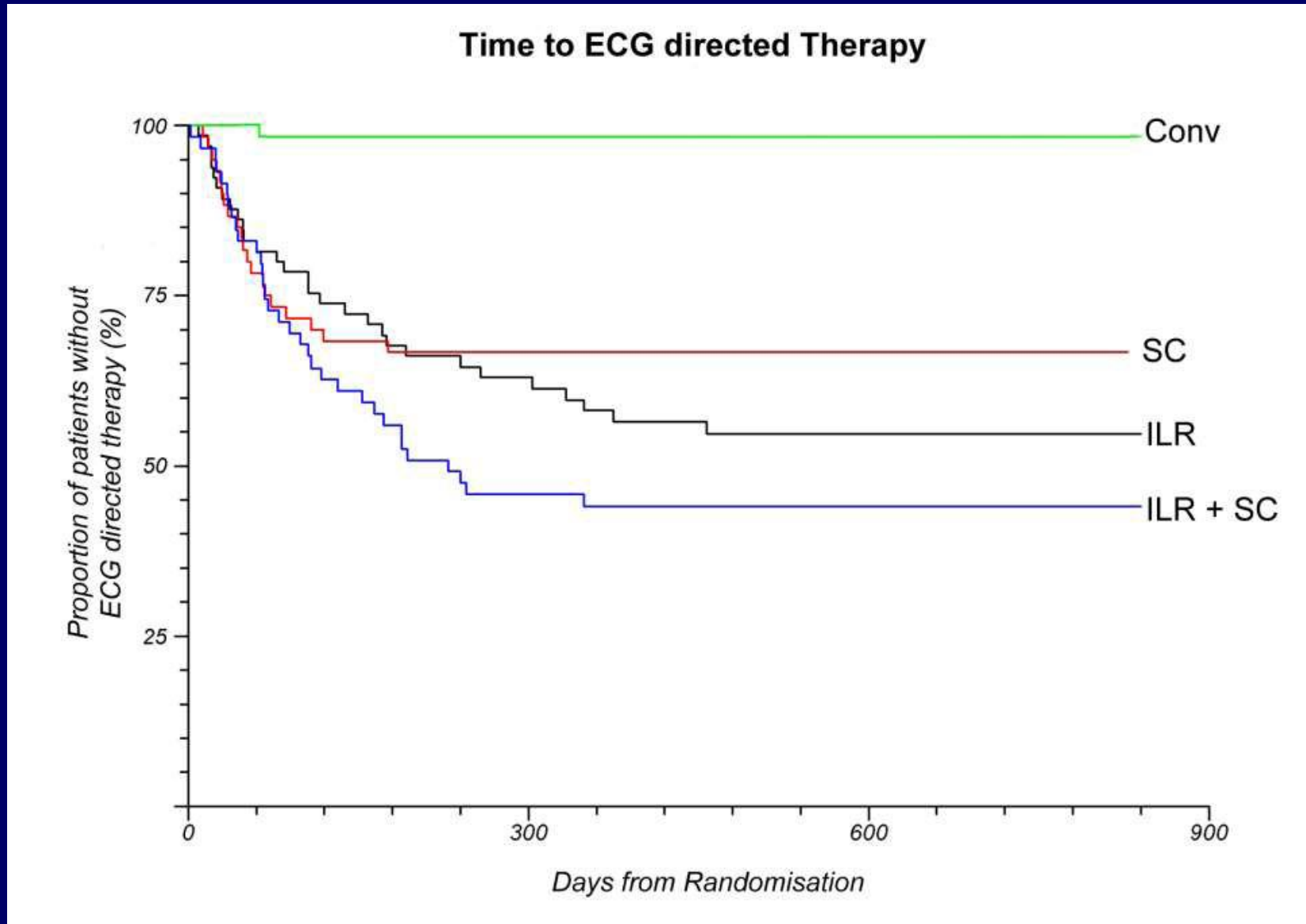
EaSyAS II

Time to ECG Diagnosis

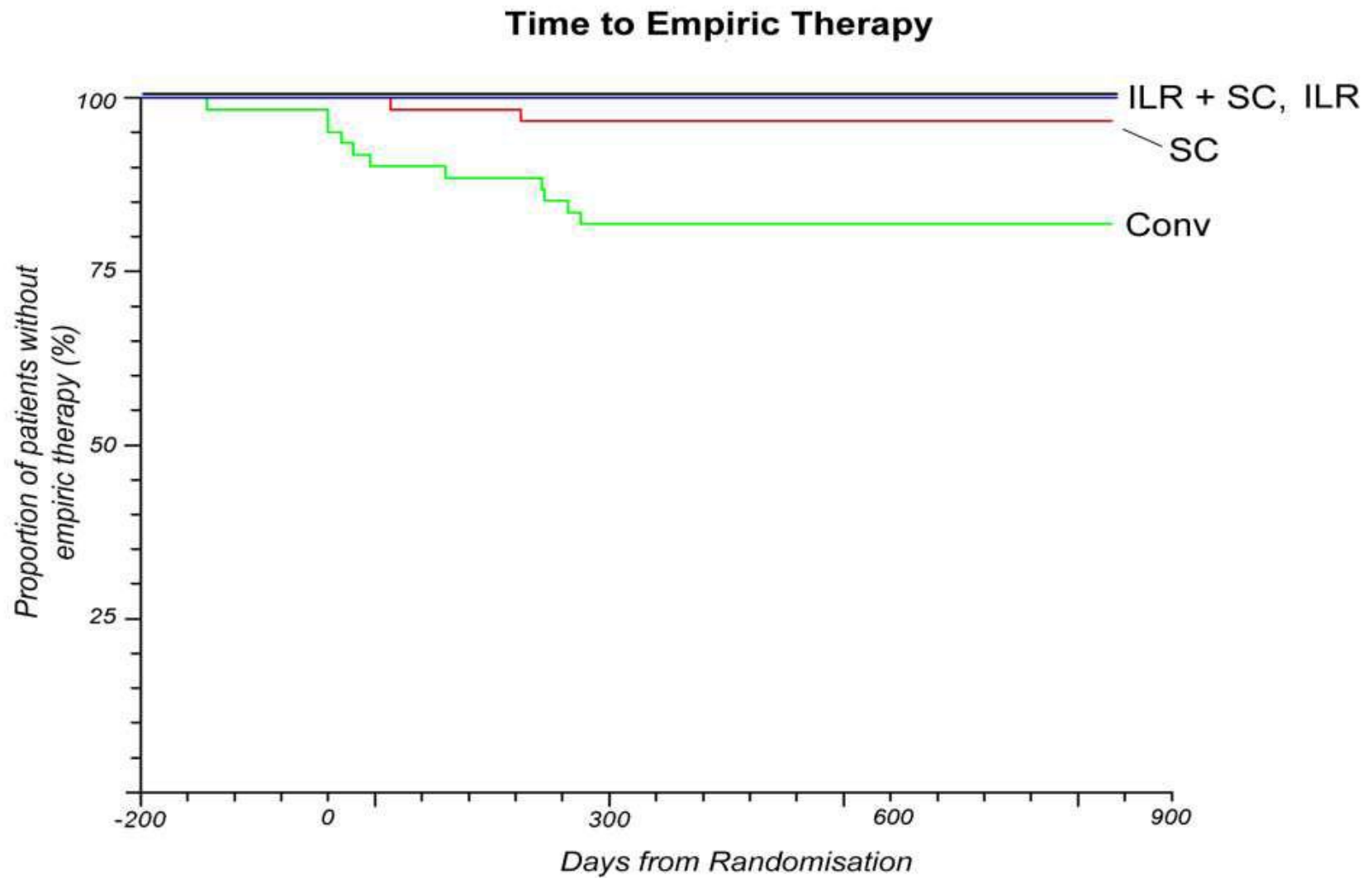
No = 240 Pts.



EaSyAS II

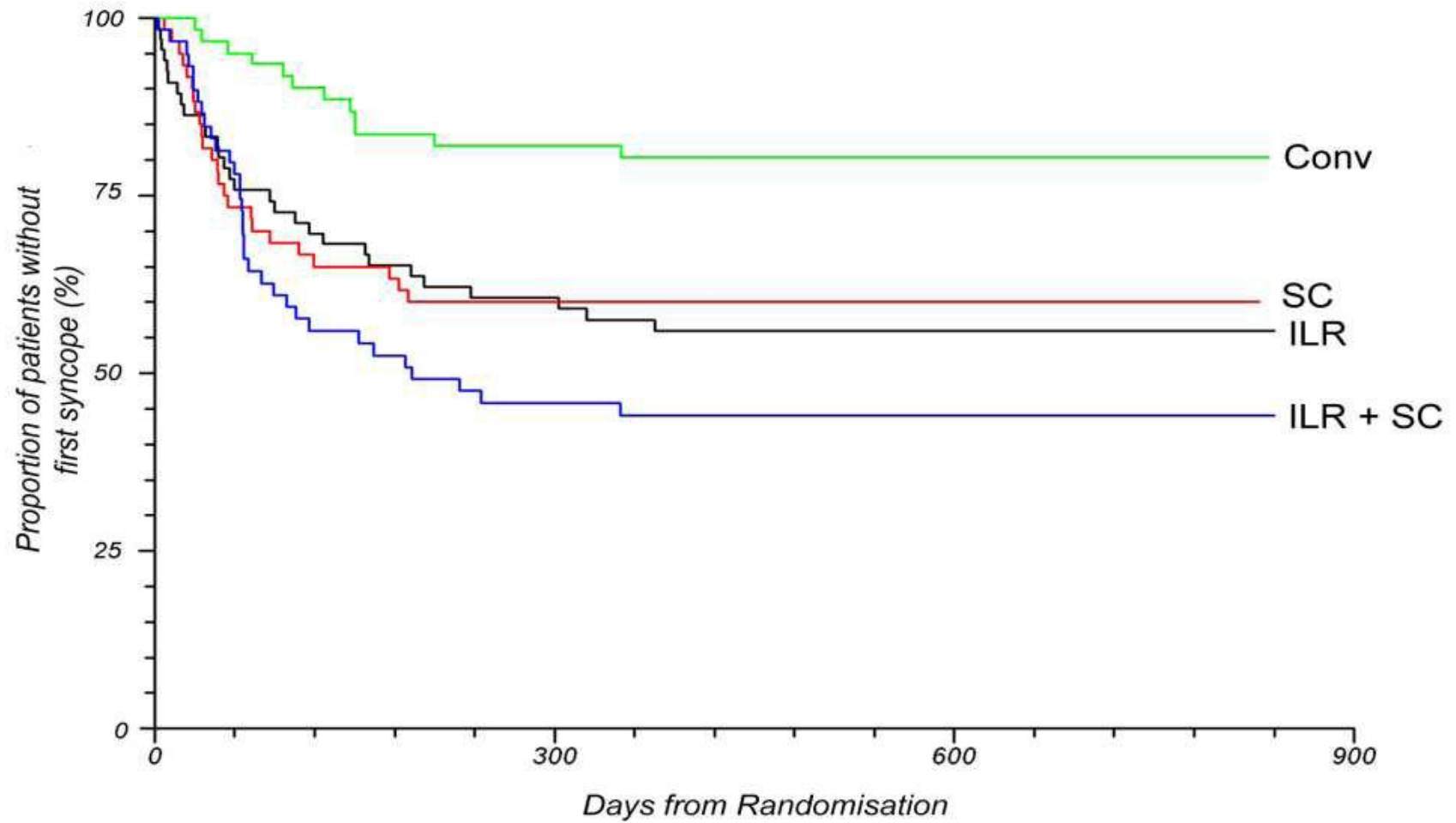


EaSyAS II



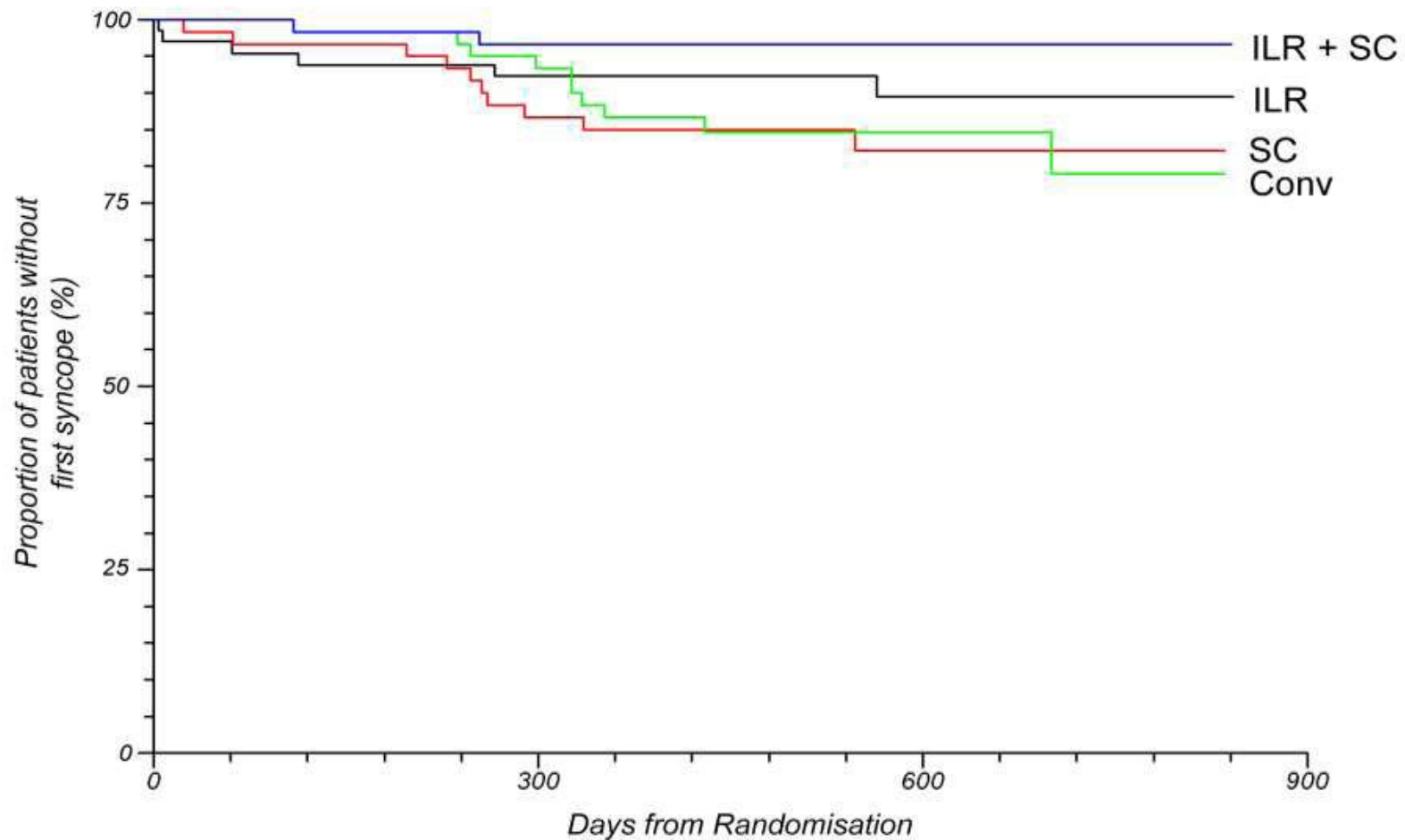
EaSyAS II

Time to first post-induction syncope



EaSyAS II

Time to second post-induction syncope



חישובי עלות תועלת

Investigations per randomized group at study census

Investigation	Conventional N=61	Syncope Clinic N=60	ILR N=66	ILR + Syncope Clinic N=59
Echo	37	13	19	3
Tilt test	1	55	2	53
ILR	1	0	-	-
MIBI scan	1	1	2	0
CT head	3	1	9	1
ETT	9	4	1	0
Coronary angio	1	0	2	0
EEG	2	0	1	0
24 hour holter	27	1	6	1
ELR	25	2	0	0
MRI head	7	0	1	0
Carotid dopplers	3	0	2	0
EMG	0	0	1	0
24 hour BP	0	0	2	0
Stress echo	3	0	0	0
Sleep studies	1	0	0	0
CT angio	1	0	0	0
Total	122	77	48	58

Results from the PICTURE registry: History of diagnostic tests performed before ILR implant

Total recruitment	(100%) 570
Standard ECG	(98%) 556
Echocardiography	(86%) 490
Basic laboratory tests	(86%) 488
Ambulatory ECG monitoring	(67%) 382
In-hospital ECG monitoring	(55%) 311
Exercise testing	(52%) 297
Orthostatic blood pressure measurements	(48%) 275
MRI / CT scan	(47%) 267
Neurological or psychiatric evaluation	(47%) 270
EEG	(39%) 222
Carotid sinus massage	(36%) 205
Tilt test	(35%) 201
Electrophysiology testing	(25%) 144
Coronary angiography	(23%) 133
External loop recording	(12%) 67
ATP test	(3%) 15
Other tests	(9%) 52
No tests performed	(0%) 1

Tilt testing is more cost-effective than implantable loop recorder monitoring as a means of directing pacing therapy in people with recurrent episodes of suspected vasovagal syncope that affect their quality of life or present a high risk of injury



Davis S. *et al* Heart .2012 Dec 18

Deputy Director of the NICE Decision Support Unit



הפרקטיקה הנהוגה מרכז רפואי "כרמל" המרפאות להפרעות בקצב ועלפון מחוז חיפה וגליל מערבי



תרשים זרימה לאיבחון T-LOC

Transient loss of consciousness

Initial evaluation

History, physical examination, supine & upright BP, standard ECG ± C.S.M

Uncertain diagnosis

High risk

Low risk
recurrent episodes

Epilepsy ?

ILR?

Early evaluation
& treatment

No clue
(Drop attacks)

Sus.
Reflex-Mediated

Sus. Brady-Tachy

EPS

Tilt Test

Negative

Positive

Treatment

Positive

Negative

Treatment

No correlation &
presenting symptoms

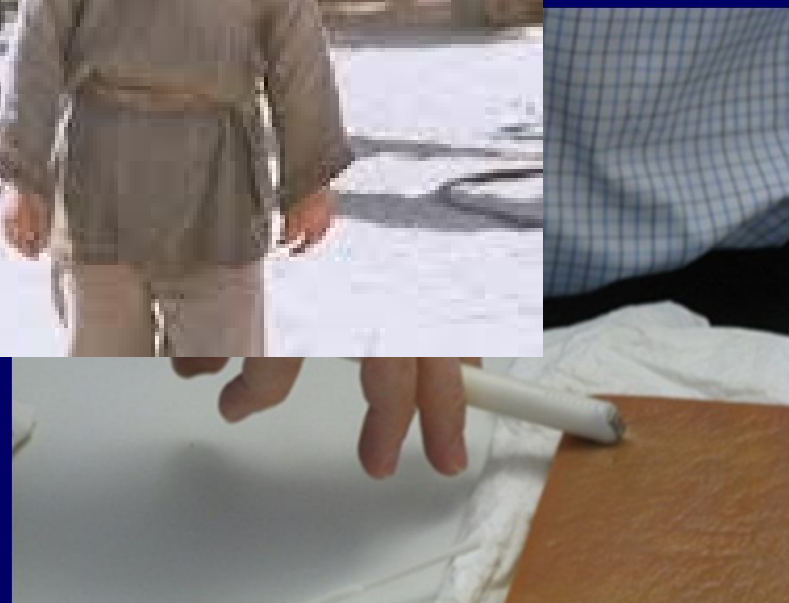
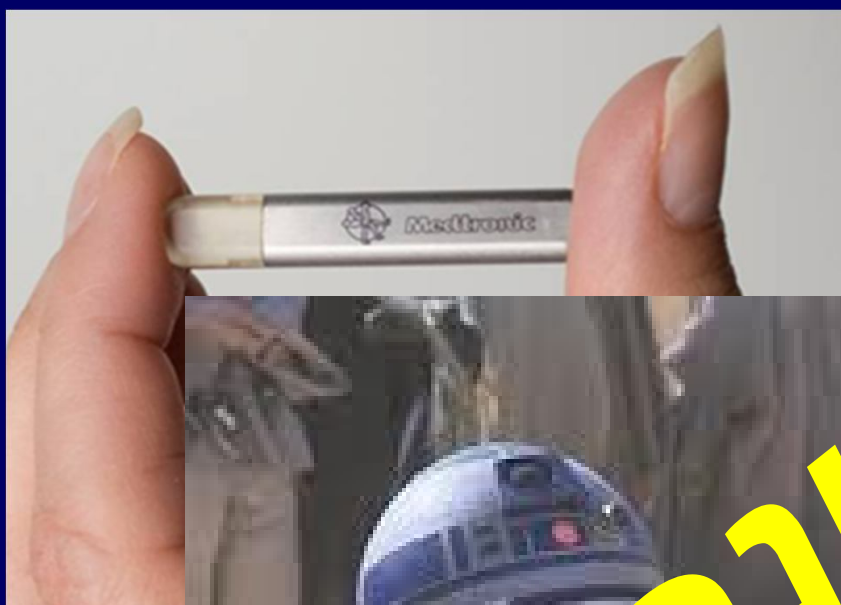
ILR

ILR

ILR

ILR

ILR



תרשים זרימה לאיבחון T-LOC

Transient loss of consciousness

Initial evaluation

History, physical examination, supine & upright BP, standard ECG ± C.S.M

Uncertain diagnosis

Low risk
recurrent episodes

“Injectable” Loop Recorder
לכוונוולם ????



תודה

רבה

© Bahai World Center

