

***The Day the Heart Stood Still
Gadgets, Gizmos and the New World of
Syncope***



***Blair P. Grubb MD
Professor of Medicine and Pediatrics
Health Science Campus
University of Toledo***

SYNCOPE

- The transient loss of consciousness and postural tone with spontaneous recovery
- Derived from the Greek word *ΣΥΝΧΟΠΑ*, meaning “to cut short”



CDC Estimates

Syncopal accounts for 300,000
ER visits/year and 75,000-
100,000 hospital
admissions/year.



Even if the cause is benign,
recurrent syncope places
a huge psychologic
burden on both patients
and their families.



It's not the fall that
hurt's, it's that sudden
stop at the end...



-Will Rogers



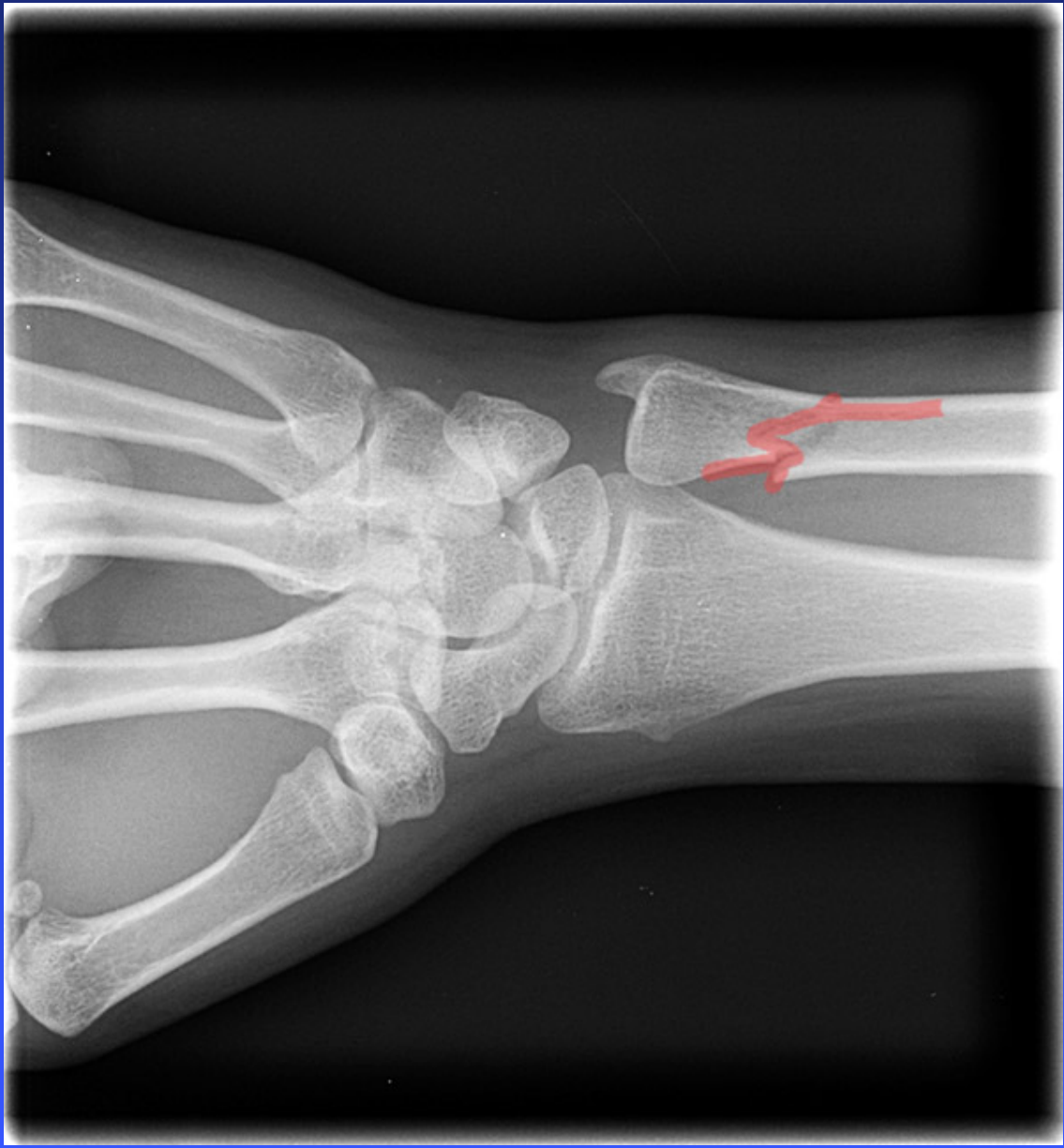




16 yr old with
recurrent NCS
had syncope at school
and fell down 2 flights
of concrete stairs

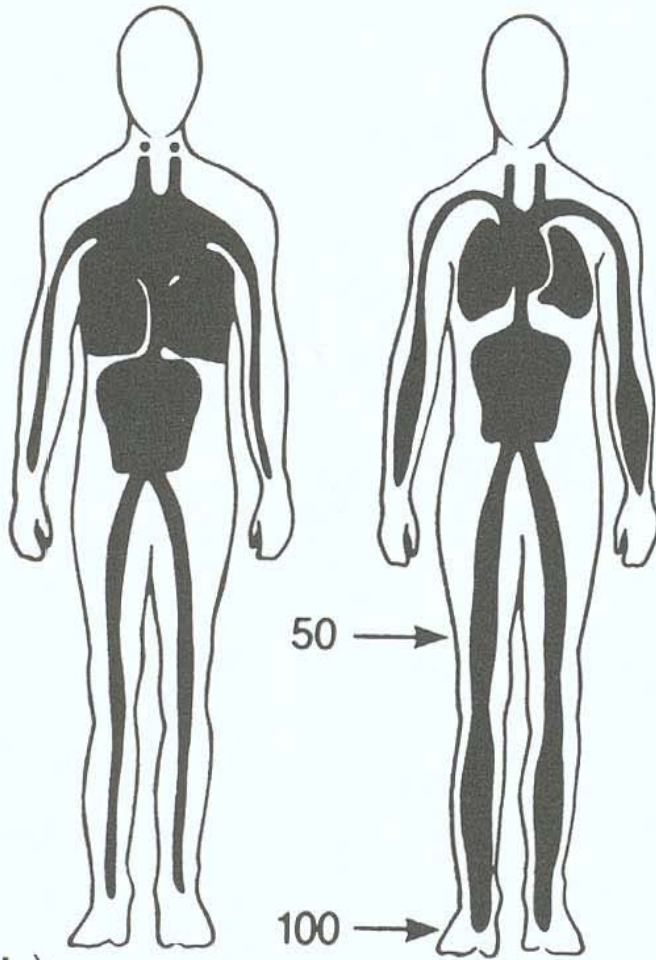


23 yr old college student with recurrent NCS who passed out in class and hit the edge of a desk



Supine

Standing



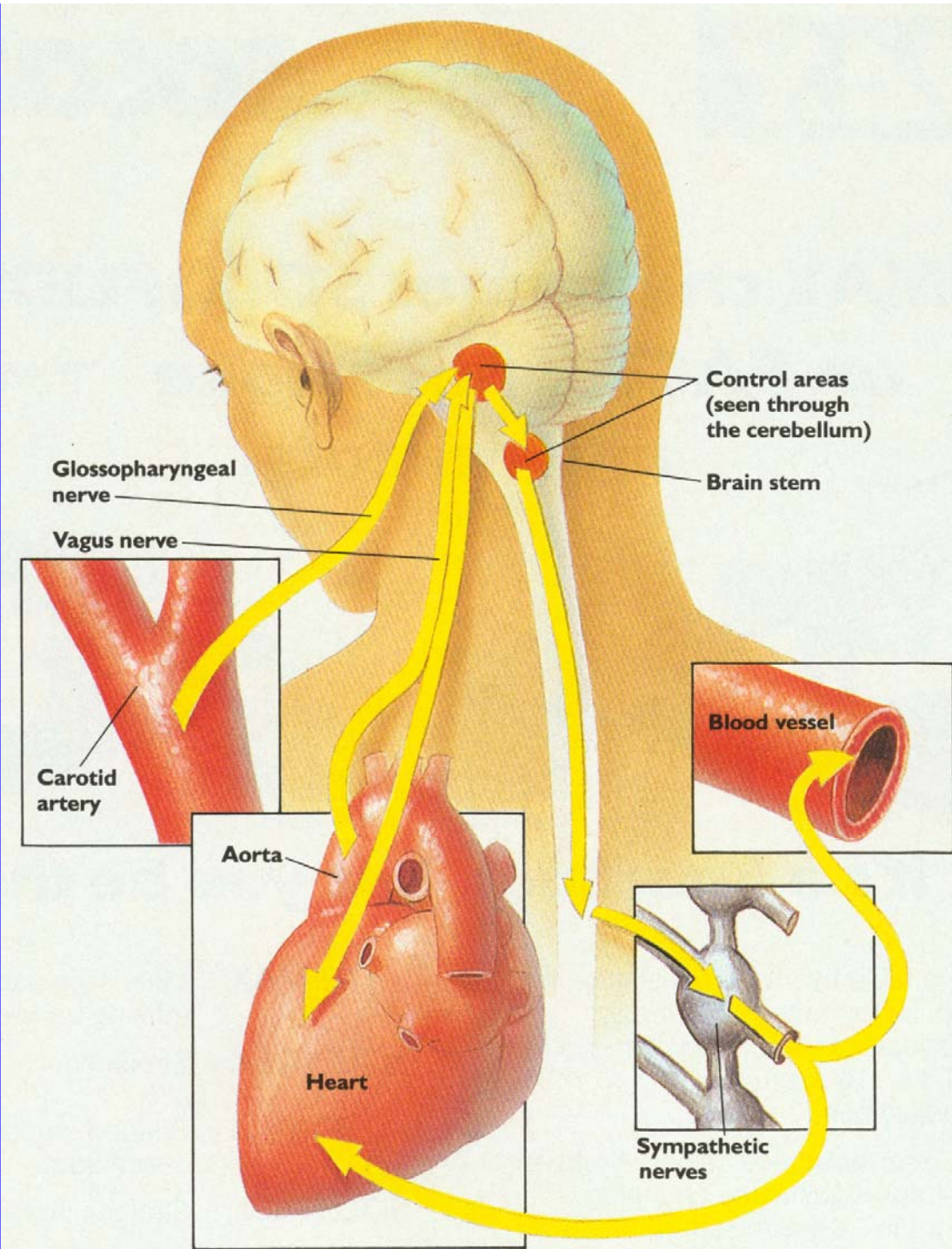
Central
venous
pressure

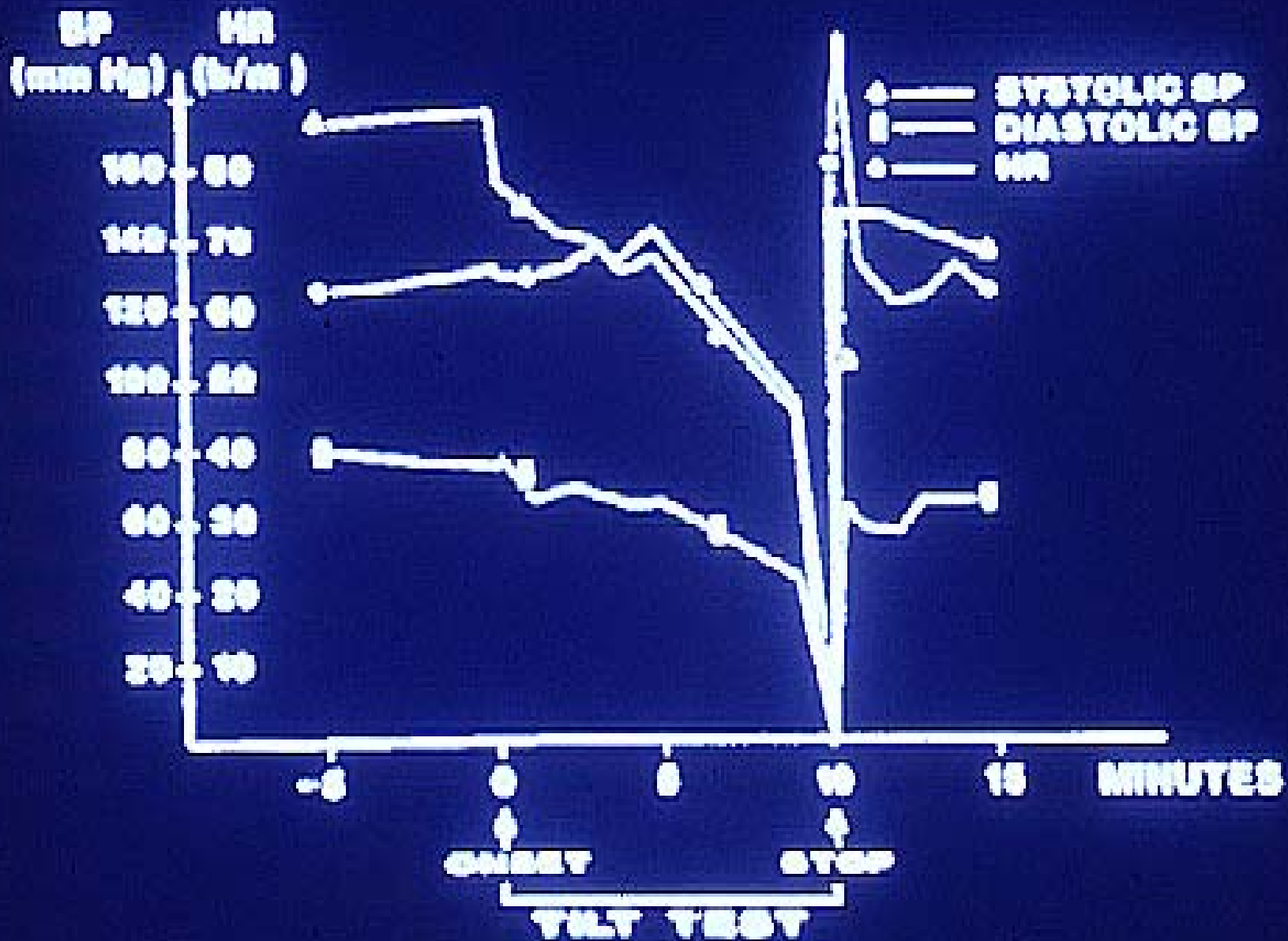
5 mmHg

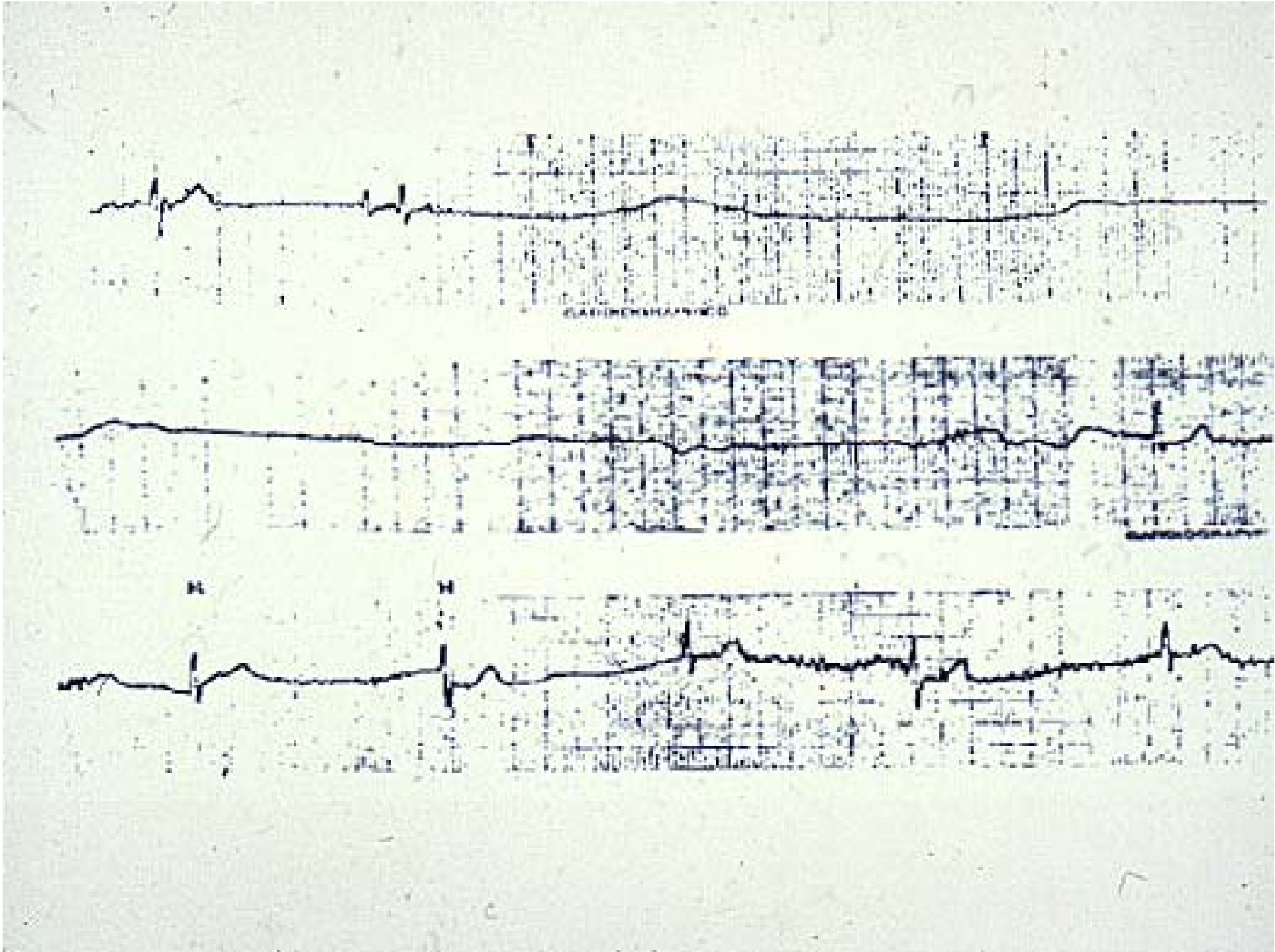
0 mmHg

- ↓ CBV
- ↓ Arterial pulse pressure
- Mechanoreceptor unloading
- ↑ Sympathetic outflow
- ↓ Vagal tone
- Veno-arteriolar reflexes
- Activation of renin angiotensin system









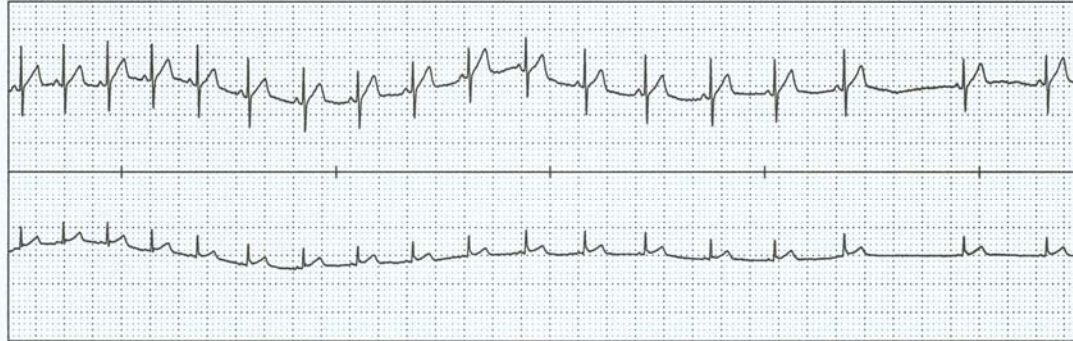


UNIVERSITY MEDICAL CENTER

THE UNIVERSITY OF TOLEDO

Time: 15:01:15

12.5 mm/sec 5 mm/mV



Time: 15:01:30

12.5 mm/sec 5 mm/mV



Time: 15:01:45

12.5 mm/sec 5 mm/mV



The North American Vasovagal Pacemaker Study (VPS). A randomized trial of permanent cardiac pacing for the prevention of vasovagal syncope.

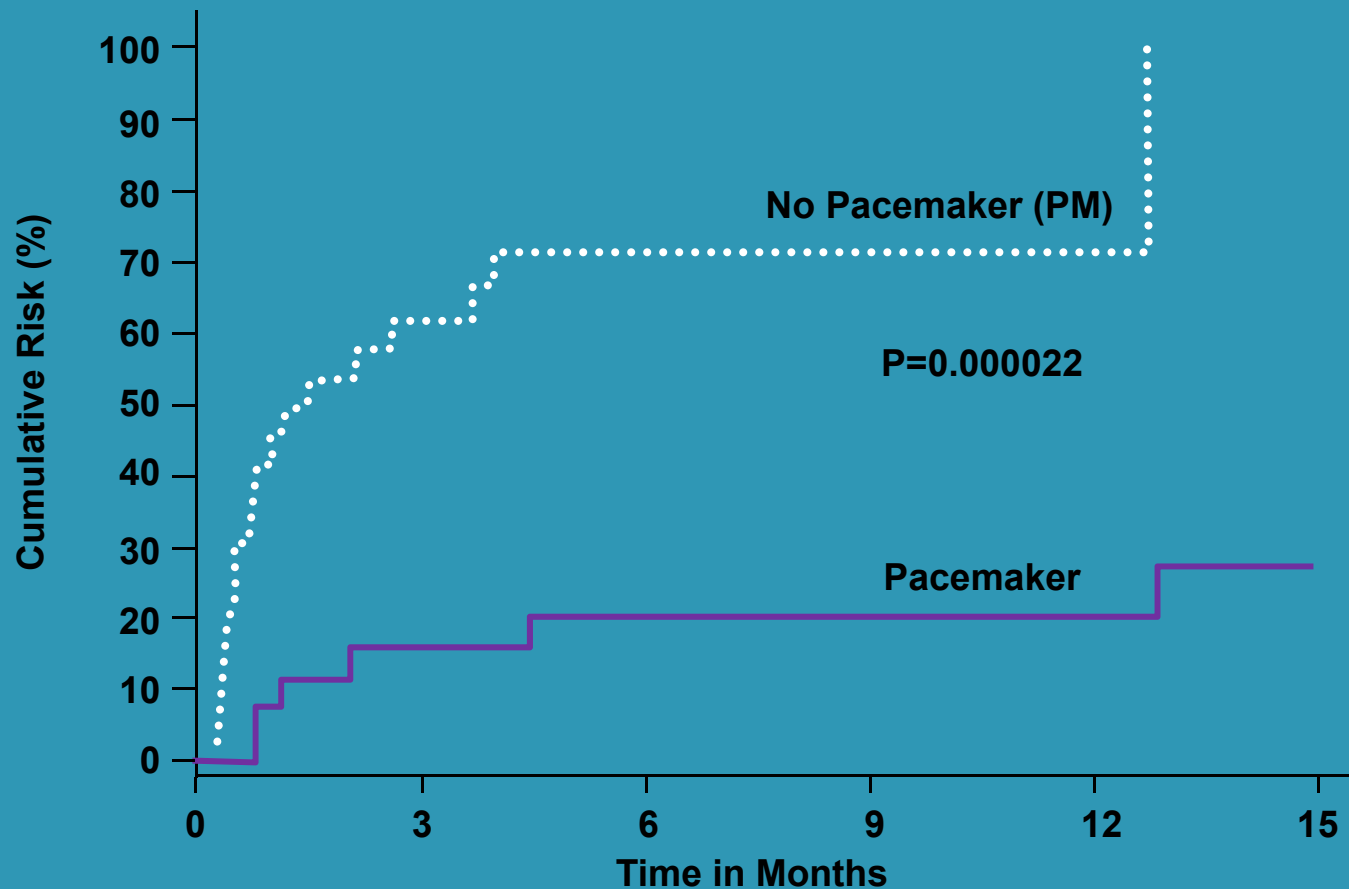
Connolly SJ, Sheldon R, Roberts RS, Gent M.

- **Primary outcome : Time to recurrence of syncope**
- **284 pts enrolled. Pilot of 60 pts.**
- **Trial prematurely terminated**
- **CONCLUSIONS: Dual-chamber pacing with rate-drop response reduces the likelihood of syncope in patients with recurrent vasovagal syncope.**

J Am Coll Cardiol. 1999 Jan;33(1):16-20

VPS I

(North American Vasovagal Pacemaker Study)



Results:

- 6 (22%) with PM had recurrence vs. 19 (70%) without PM
- 84% RRR (2p=0.000022)

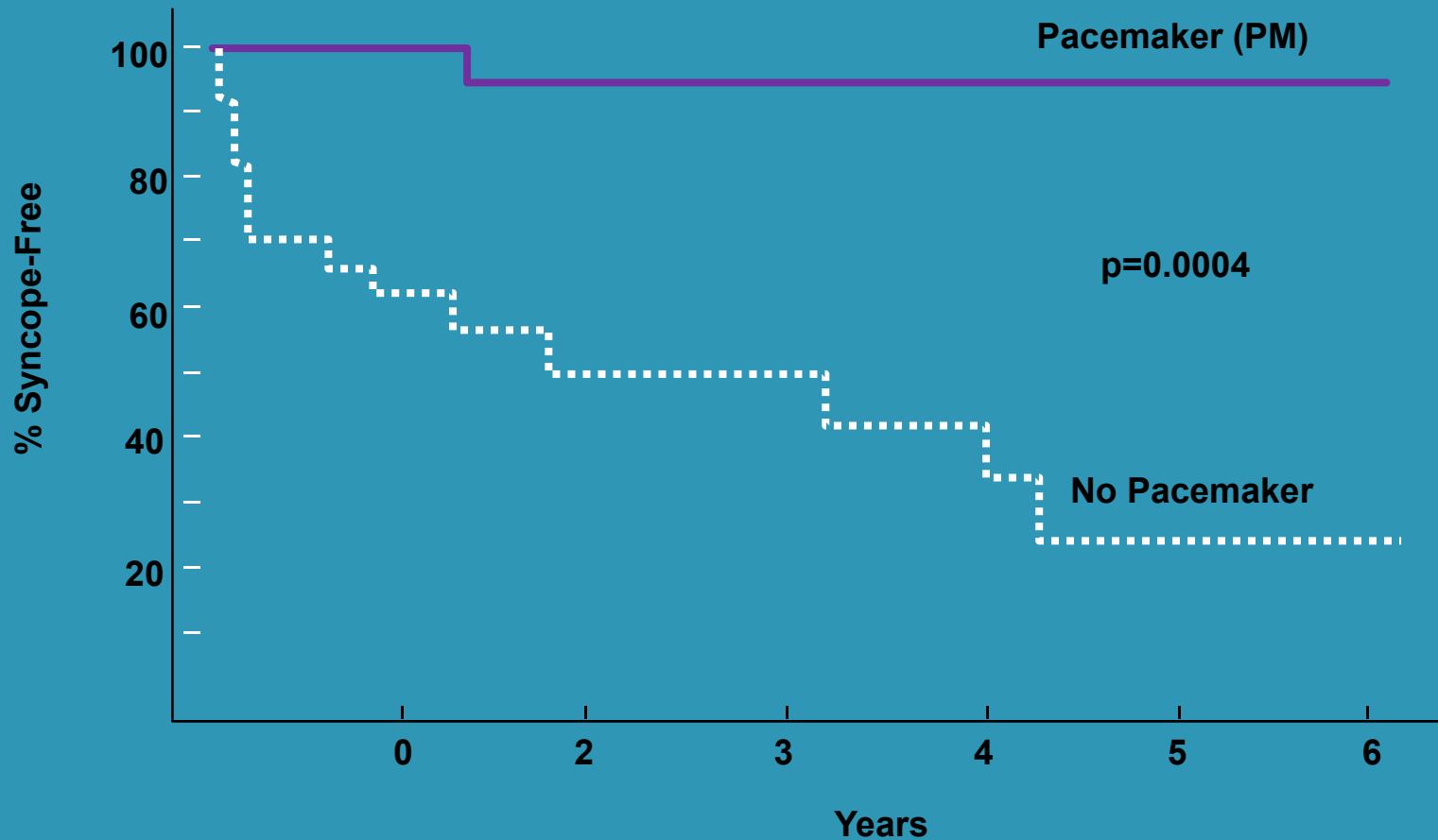
Connolly SJ. *J Am Coll Cardiol.* 1999;33:16-20.

VASIS

(VAsovagal Syncope International Study)

- Objective: To evaluate pacemaker therapy for severe cardioinhibitory tilt-positive neurally mediated syncope
- Randomized, prospective, multi-center
- N=42 patients
 - ◆ 19: DDI pacemaker (80 bpm) with rate hysteresis (45 bpm)
 - ◆ 23: No pacemaker
- Inclusion: Positive cardioinhibitory response
- Primary outcome: First recurrence of syncope

VASIS (VAsovagal Syncope International Study)



Results:

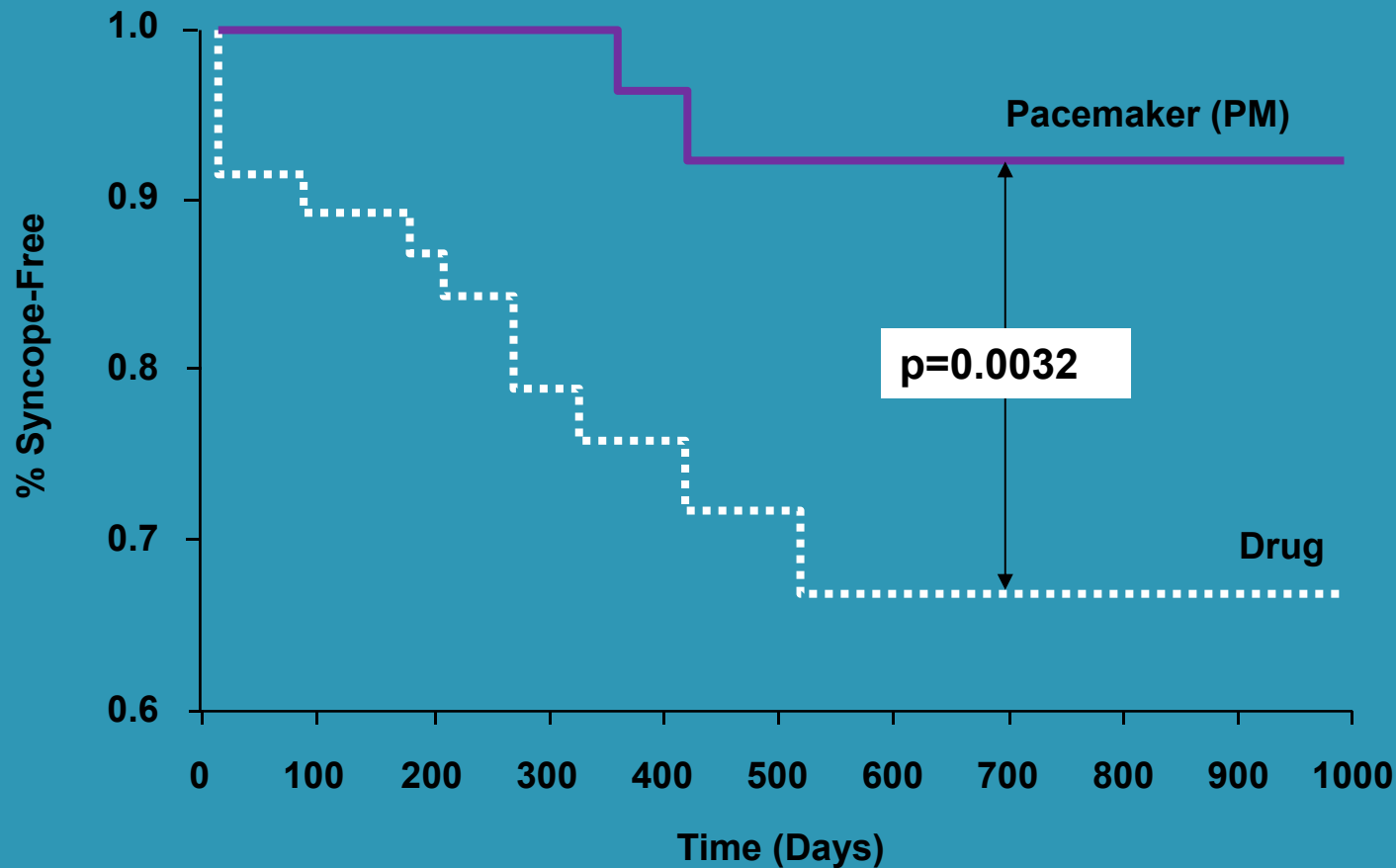
- 1 (5%) with PM had recurrence vs. 14 (61%) without PM

SYDIT

(Syncope Diagnosis and Treatment)

- Objective: To compare the effects of cardiac pacing with pharmacological therapy in patients with recurrent vasovagal syncope
- Randomized, prospective, multi-center
- N=93 patients
 - ◆46: DDD pacemaker with rate drop response
 - ◆47: Atenolol 100 mg/d
- Inclusion: Positive HUT with relative bradycardia
- Primary outcome: First recurrence of syncope

SYDIT (SYncope DIagnosis and Treatment)



Results:

- 2 (4%) with PM had syncope recurrence vs. 12 (26%) without PM

Ammirati F. Circulation. 2001;104:52-57.

Pacing for NCS



*VPS II Trial : Comparison of pacing on vs off
No significant reduction in time to first
syncope recurrence JAMA 2003;289:2224*

*SYNPACE : No difference between pacing on
and off , except for the group with asystole
during tilt had an increase in time to syncope
recurrence compared to those with bradycardia
(91 vs. 11 days) PACE 2003;9:1016*



Norman Holter developed the first ambulatory ECG system in 1947. The original device weighted 85 pounds. By 1964 he had gotten the size down to 2.8 lbs.





Current Holter device.
Still bulky and inconvenient
To use. Most insurers will
Only pay for one day of
Monitoring.





Event recorders are somewhat better but still impractical for many people. Many require the pt. To activate the device after an episode.



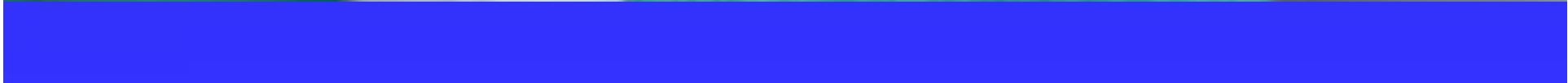
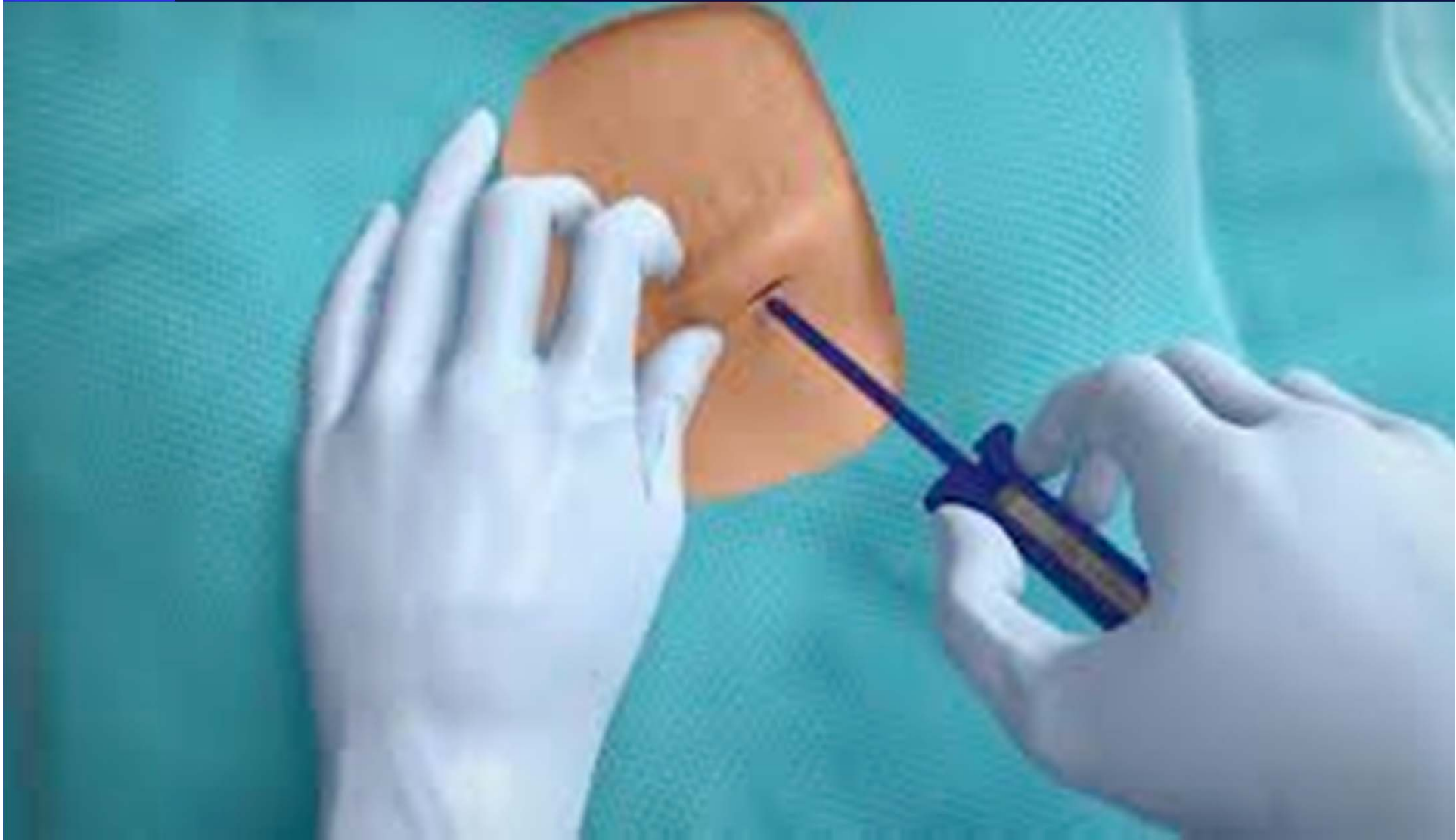






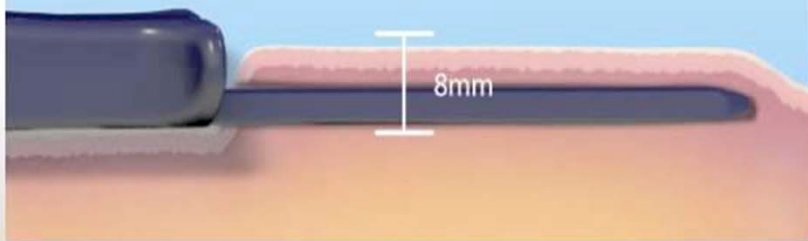






3 *Pinch skin and insert supplied insertion tool*

If necessary, pinch the skin adjacent to incision and then insert the tool probe completely to create a tunnel 8 mm under the skin

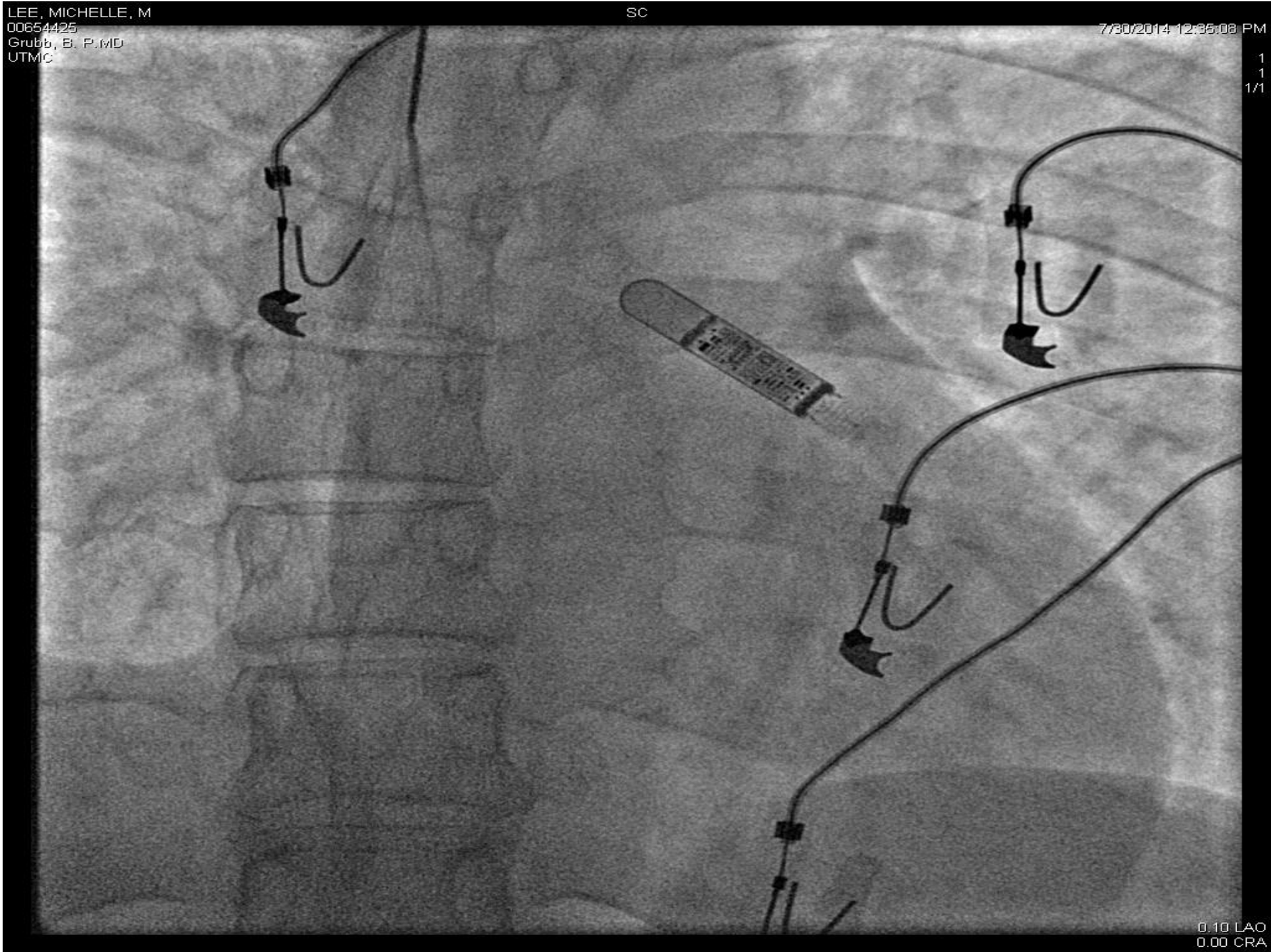


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Grubb, B. P. MD
UTMIC

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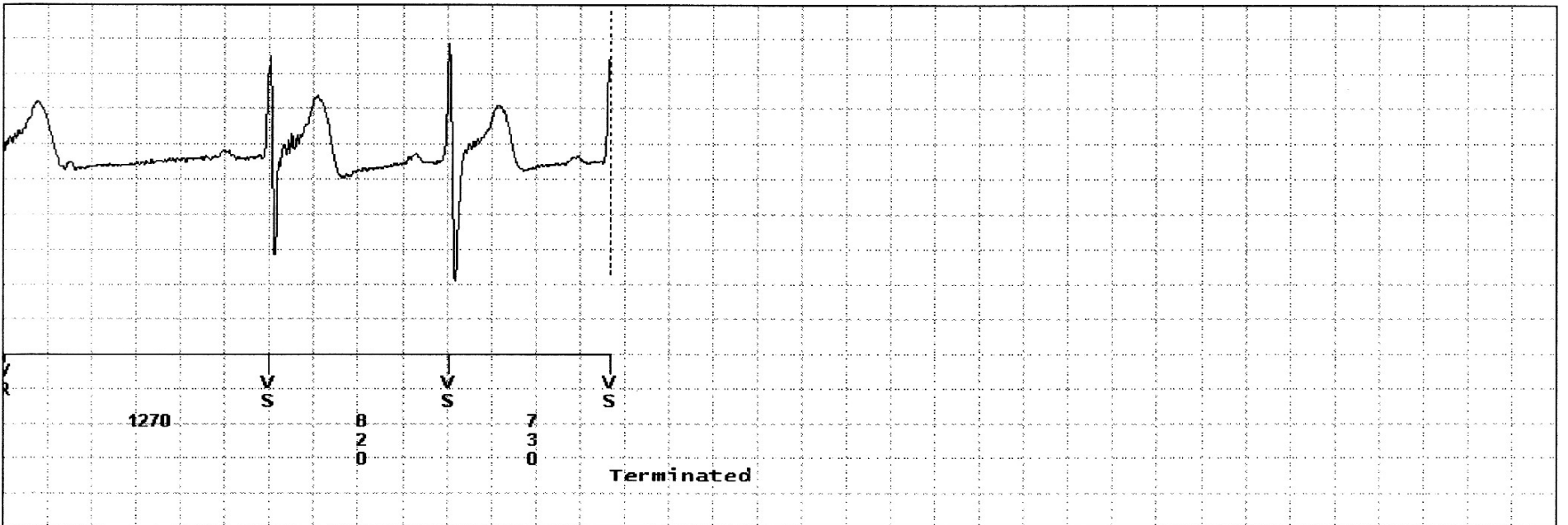
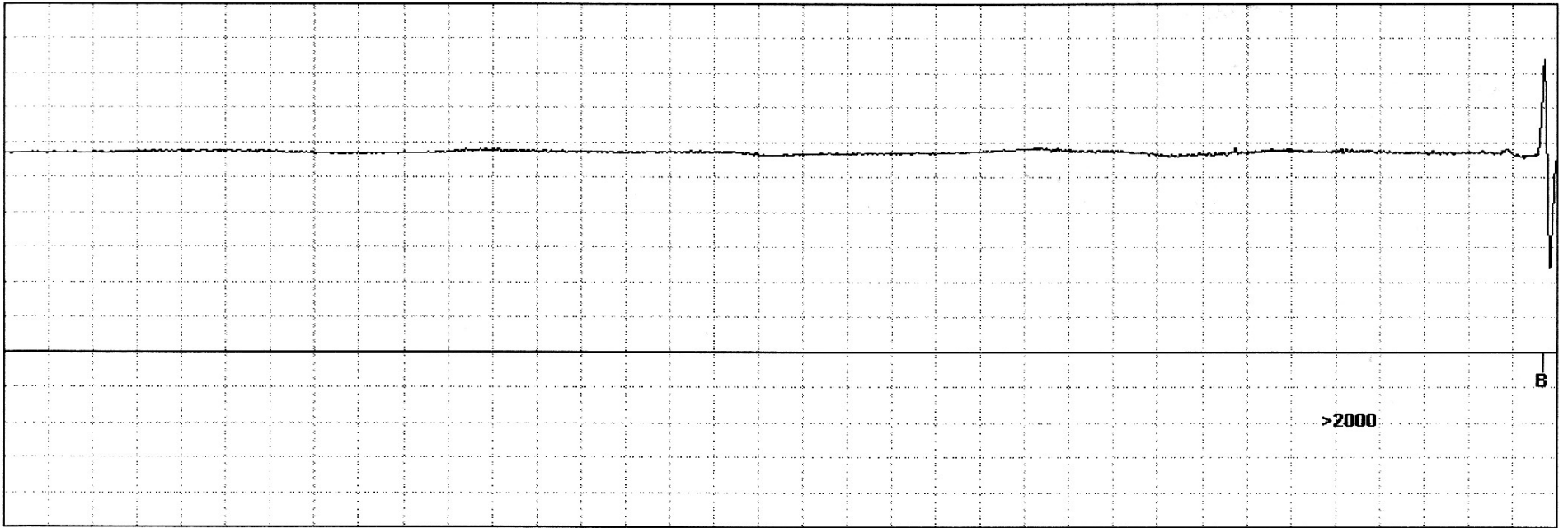
7/30/2014 12:35:03 PM

1
1
1/1



0.10 LAO
0.00 CRA

A 10 year old young man from Florida referred for evaluation of recurrent convulsive episodes that have occurred since age 1. Pt will suddenly turn very pale, fall to the floor and have convulsive activity lasting from 30 second to 1 minute. Often has urinary incontinence, mildly confused afterward, severely fatigued afterward. Bad episodes occur 5 to 7 times a year, milder ones about once a month. ECG, Echo, Holter, EEG, MRI of brain all WNL. A event moniter failed to capture episode. Neurologist said episodes were “psychogenic”. An ILR was inserted at UTMC. One month later mother called to say he had a “mild” episode while sitting during which he bruised his forehead and chipped a tooth.

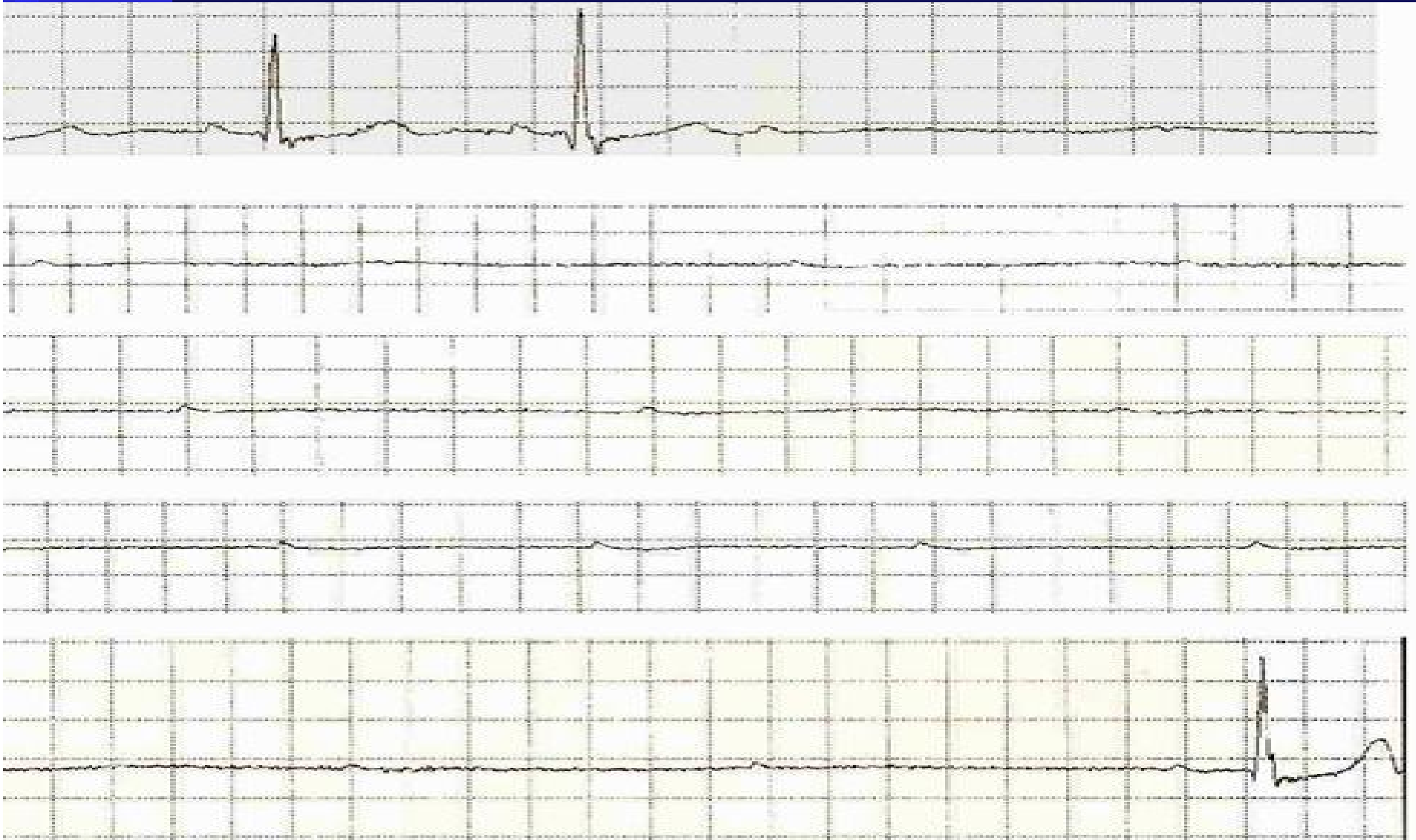


55 yr old woman with a history of
Bipolar disorder with recurrent convulsive
episodes lasting 5 minutes or more with
Prolonged LOC and urinary incontinence.
ECG, Echo, EEG, Cardiac Cath, Holter monitor
And external event recorder all unremarkable.
Patient told she is “crazy” and that her episodes are
“Psychogenic”. Is seen at UTMC Syncope clinic
And undergoes ILR placement. Two months later
Has 3 separate convulsive events...

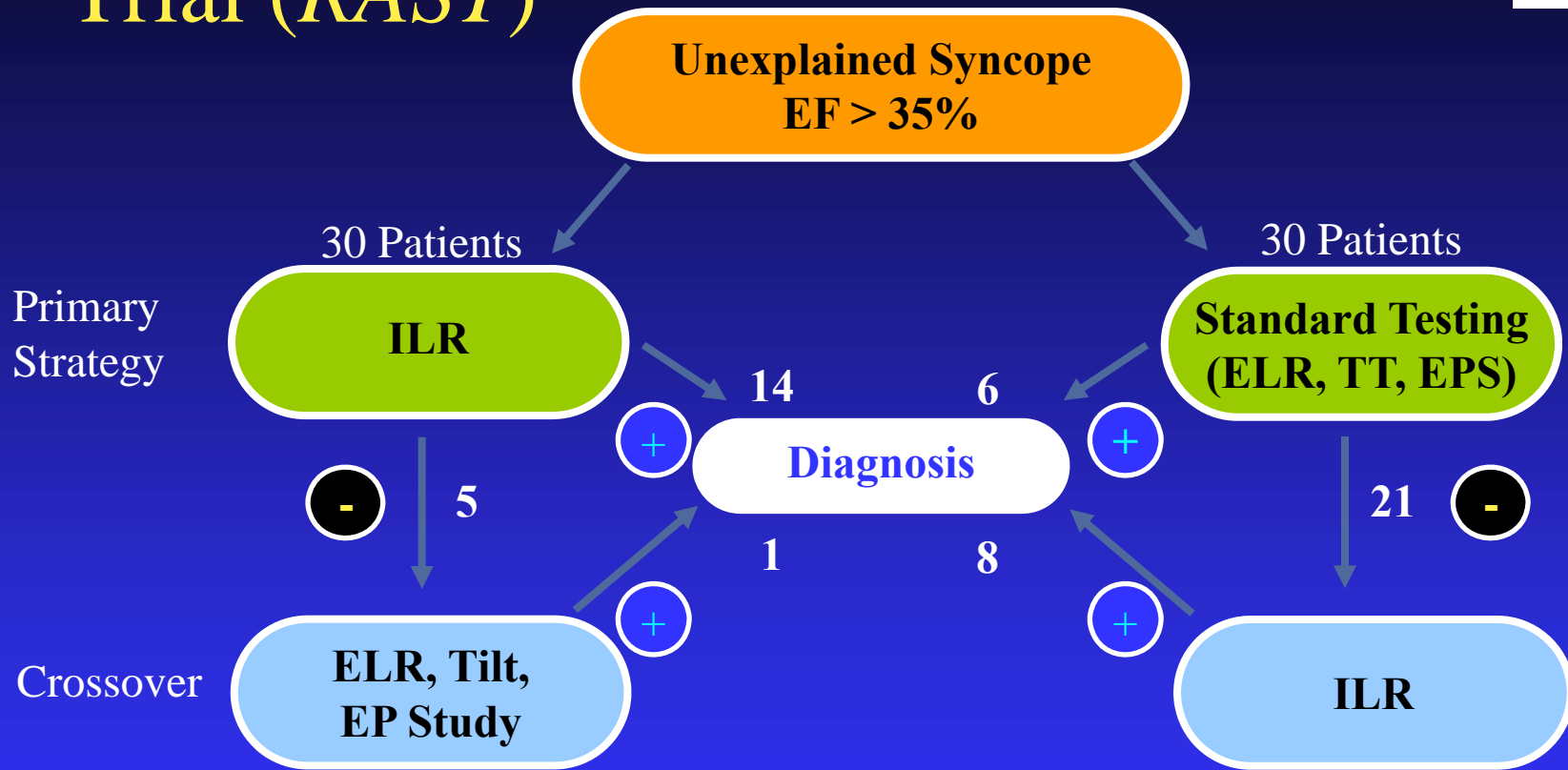




One episode occurred due to 44 seconds of Asystole, the others were 22 and 20 seconds



Randomized Assessment Of Syncope Trial (RAST)



- Combining primary strategy with crossover, the diagnostic yield is 43% for ILR only vs. 20% for conventional only
- Cost/diagnosis of ILR is 26% less than conventional testing

Seizures and Syncope: Manchester Study

Inclusion

74 patients:

- Diagnosed with epilepsy, 2 or more episodes, and normal or nondiagnostic EEGs

Testing

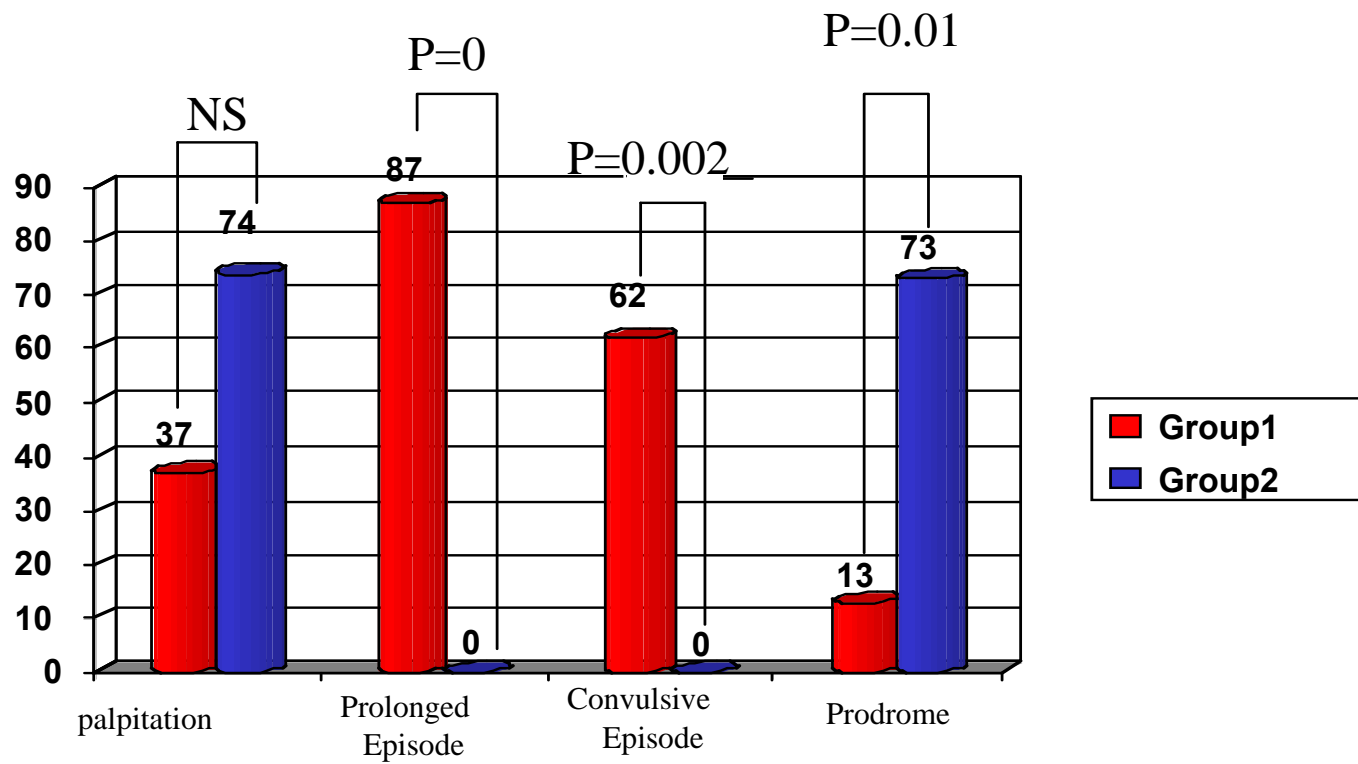
- Tilt Table with Video EEG monitoring
- Carotid sinus massage
- ILR implants (10)

Results

40% had cardiovascular causes of their episodes



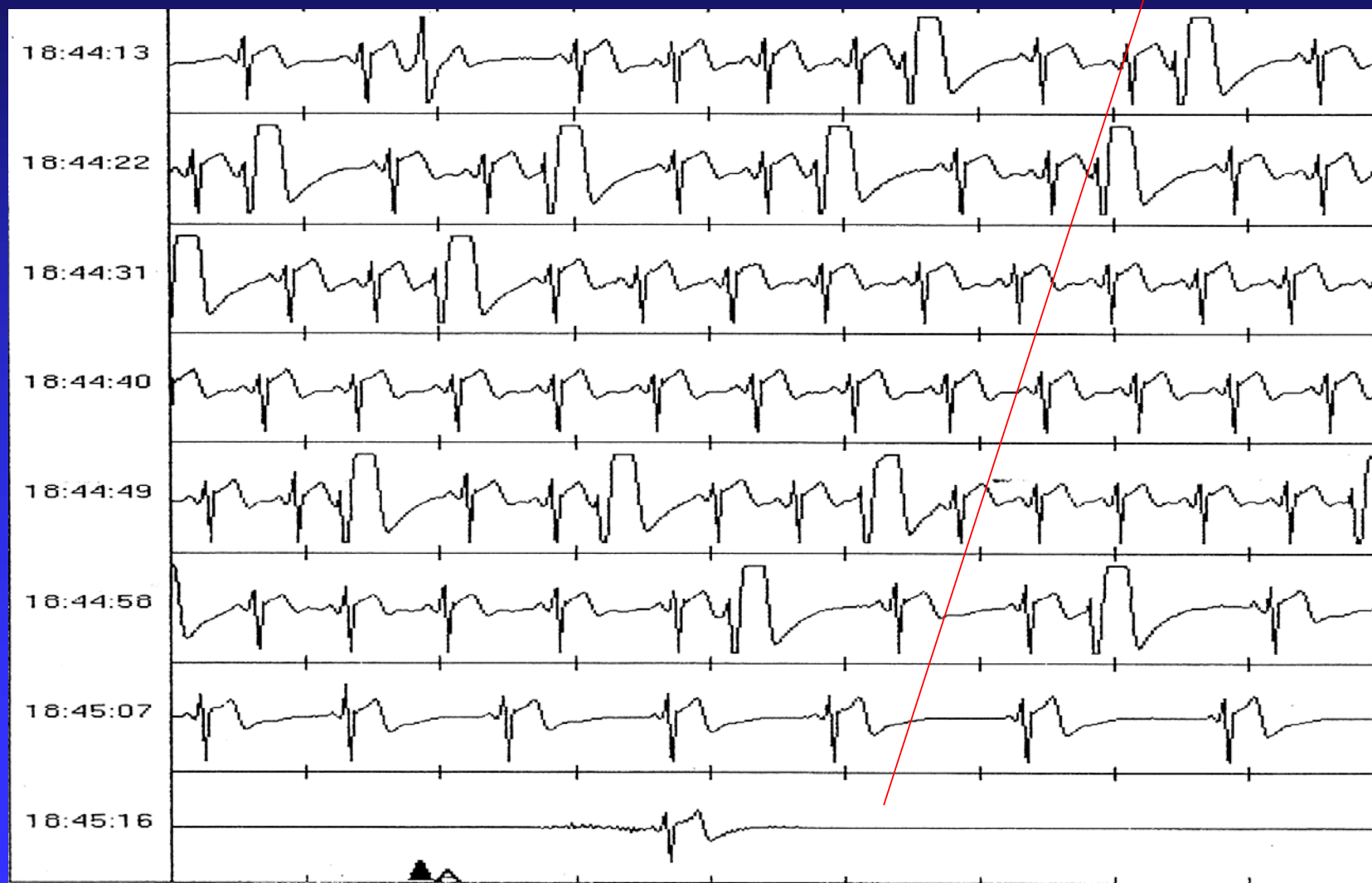
Clinical Predictors of an Asystolic Response during ILR Recording

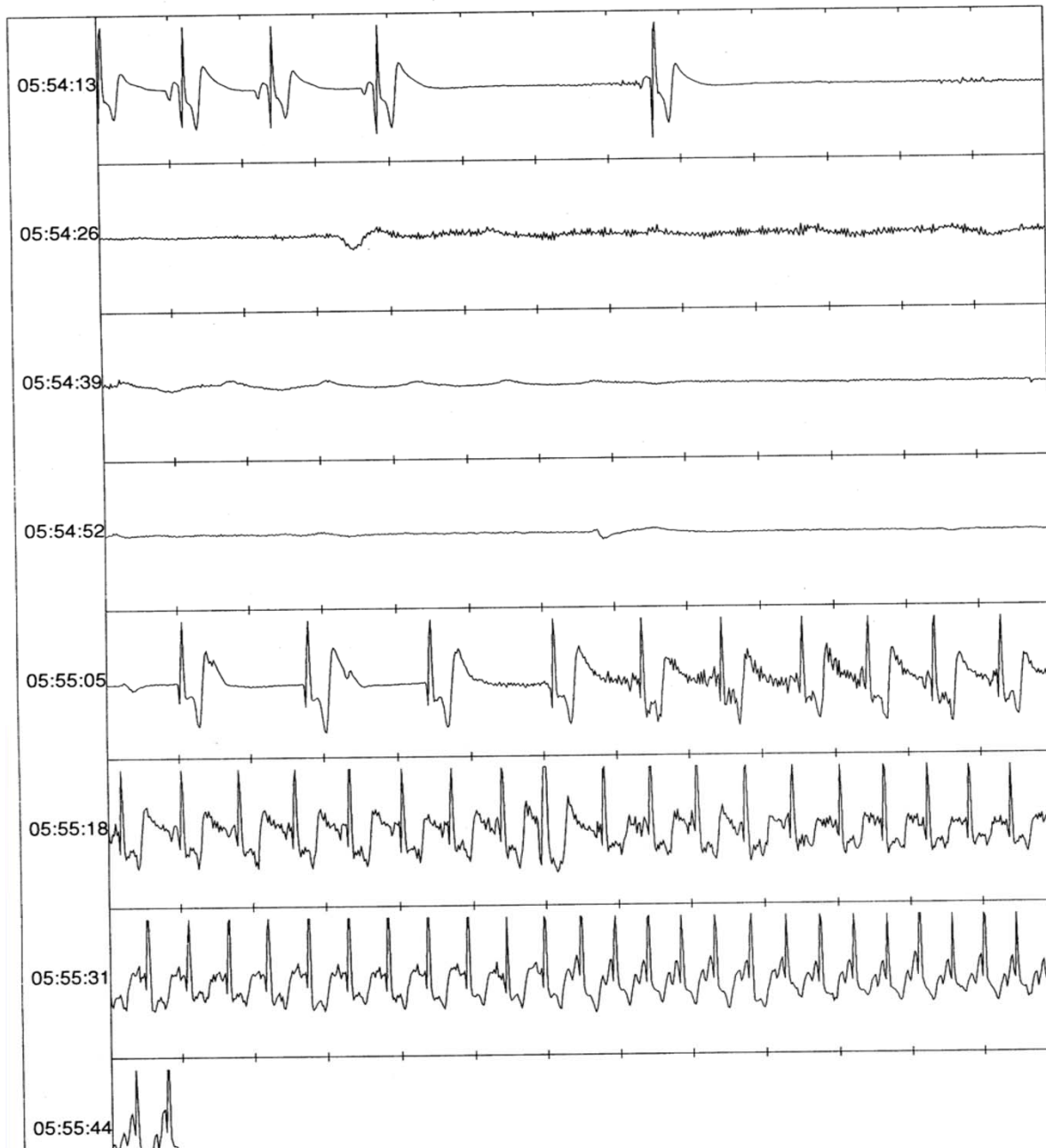


16 yr old girl with recurrent syncope, complete evaluation WNL . Diagnosed with a conversion disorder



“Psychogenic asystole”

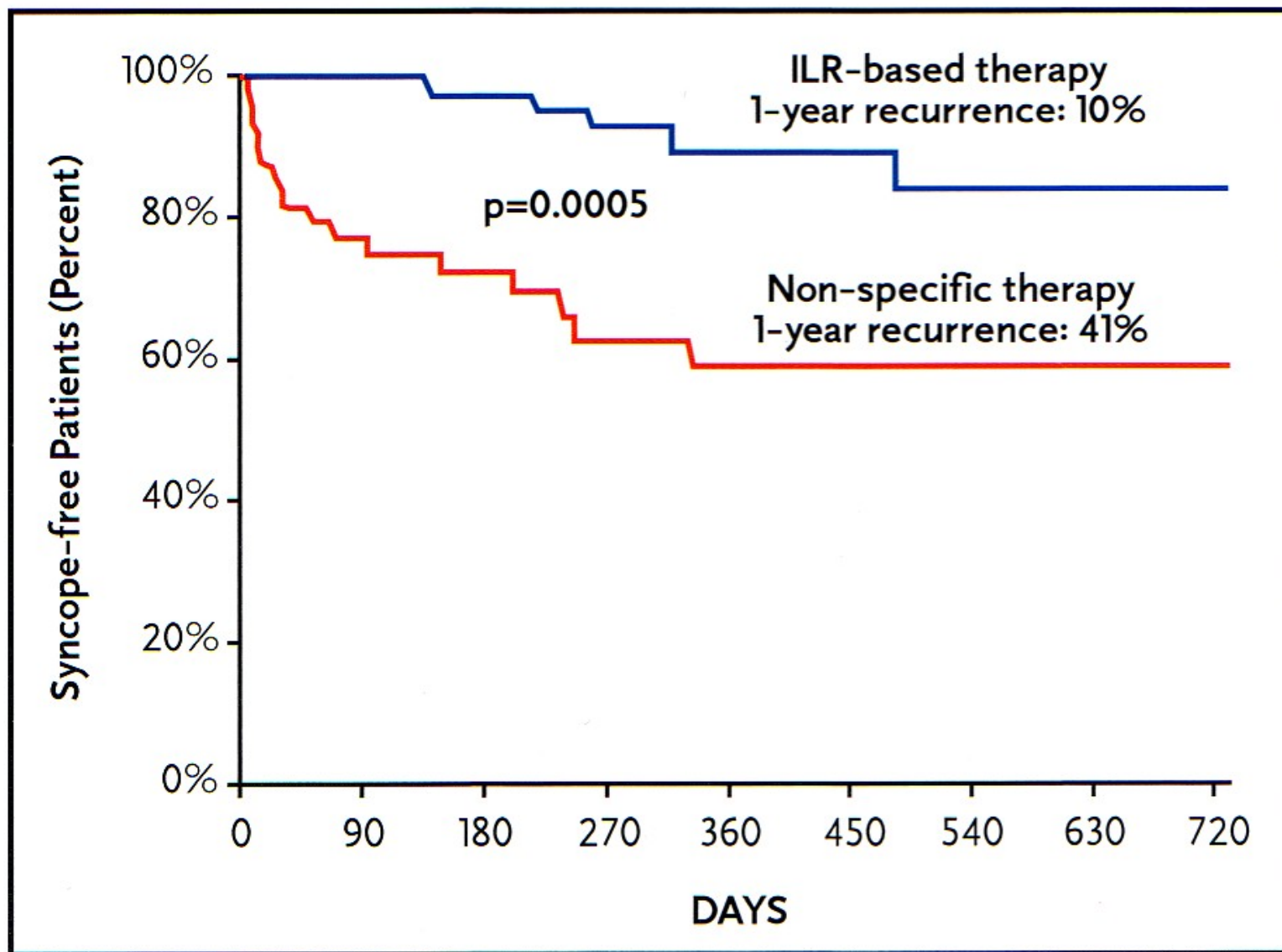




56 yr old man
With recurrent
syncope
And periods of
Disorientation,
And slurred
speech
EPS and HUTT
Were normal

ISSUE II Trial

Syncopal-free Patients Over Time

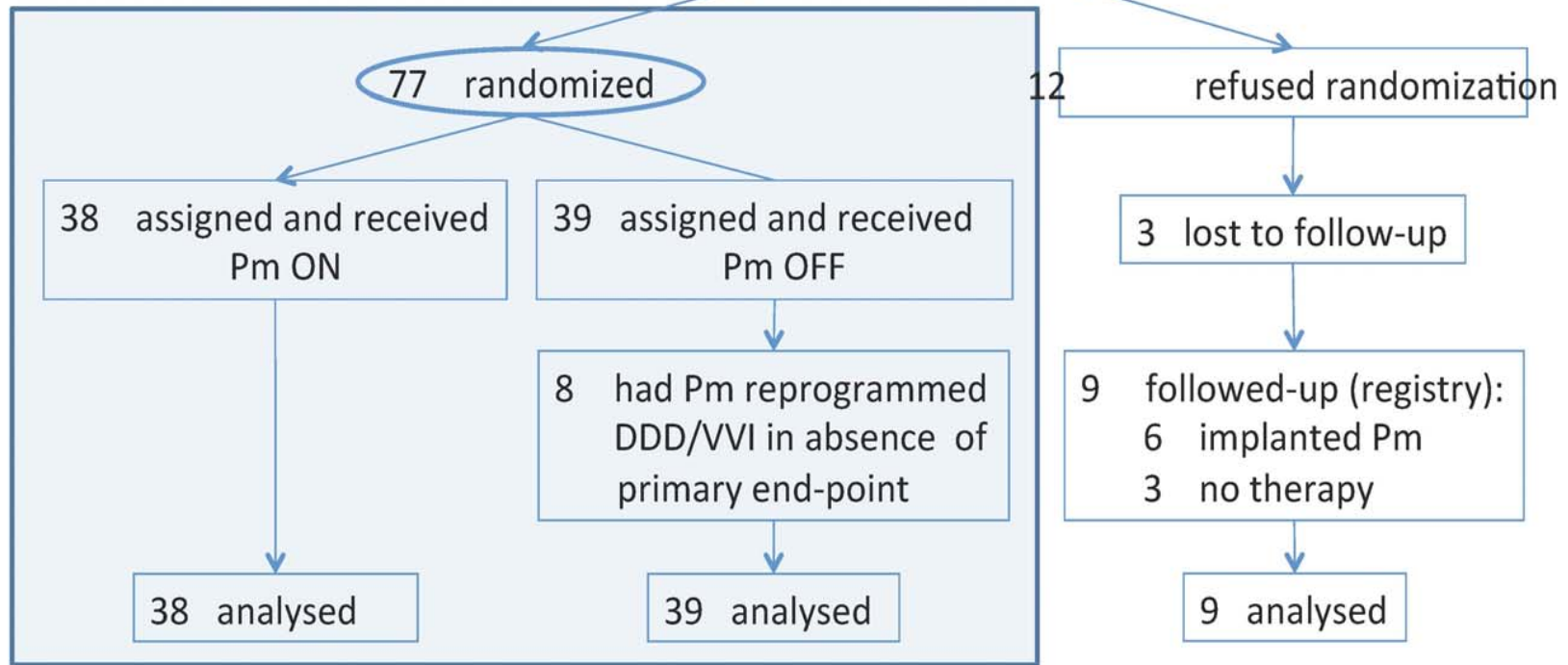


Screening phase

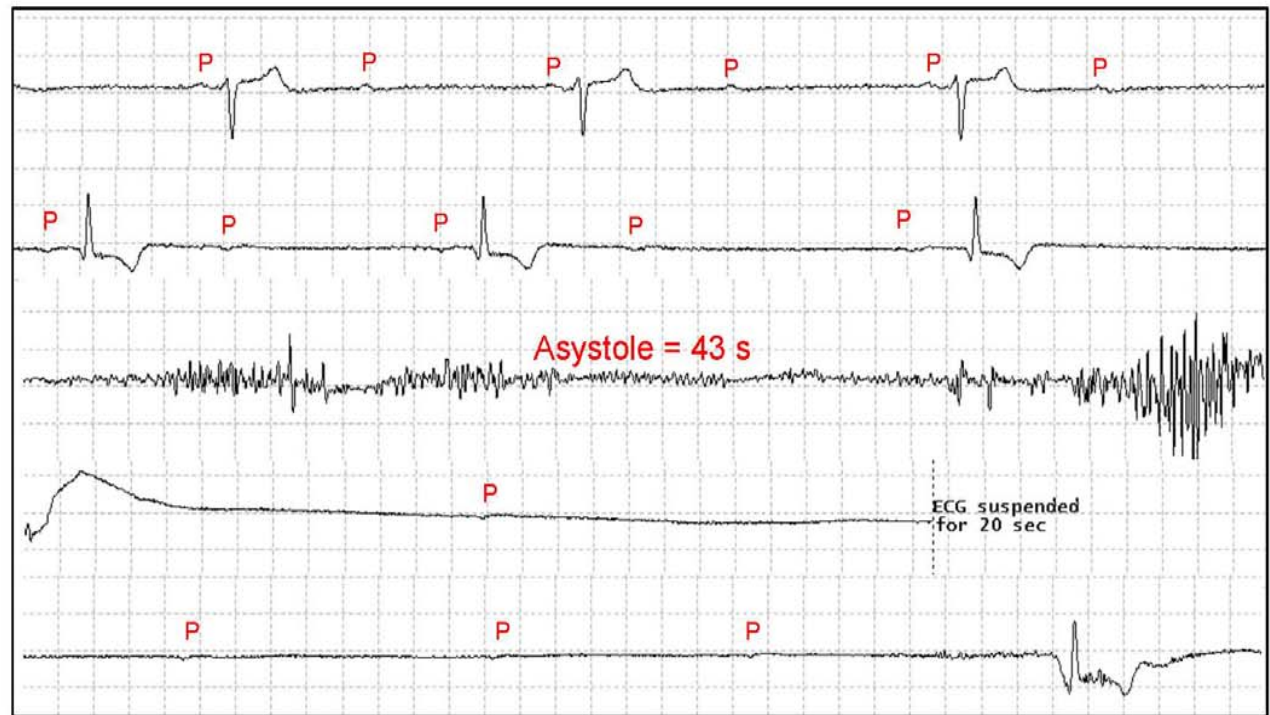
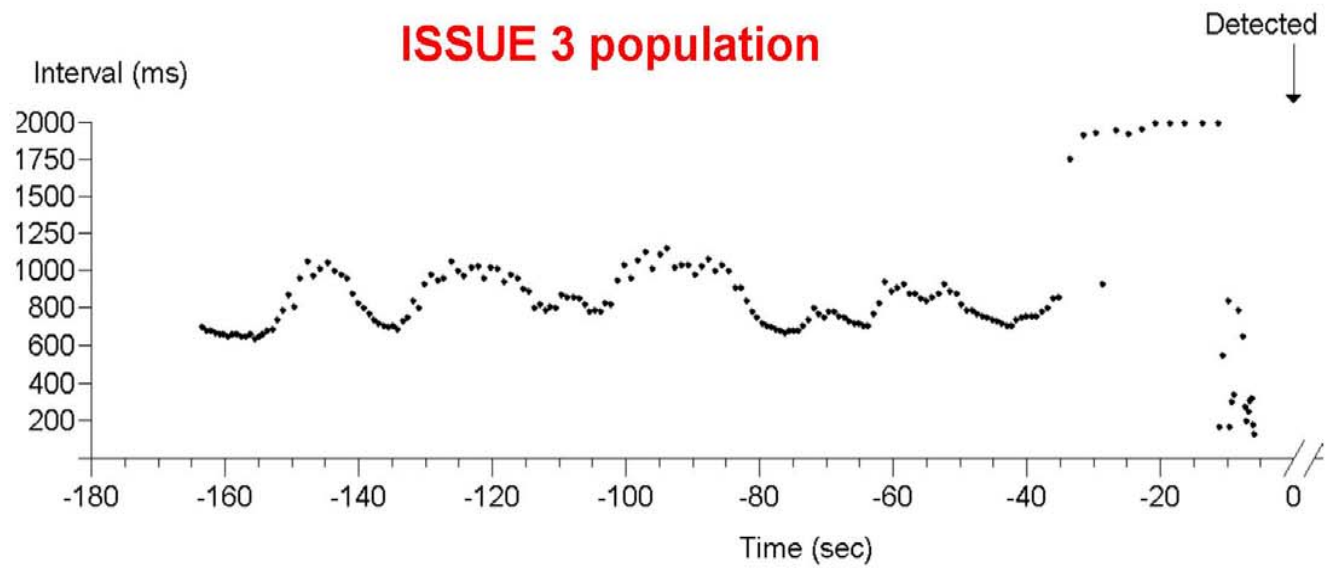
511 met inclusion criteria and received an ILR

Study phase

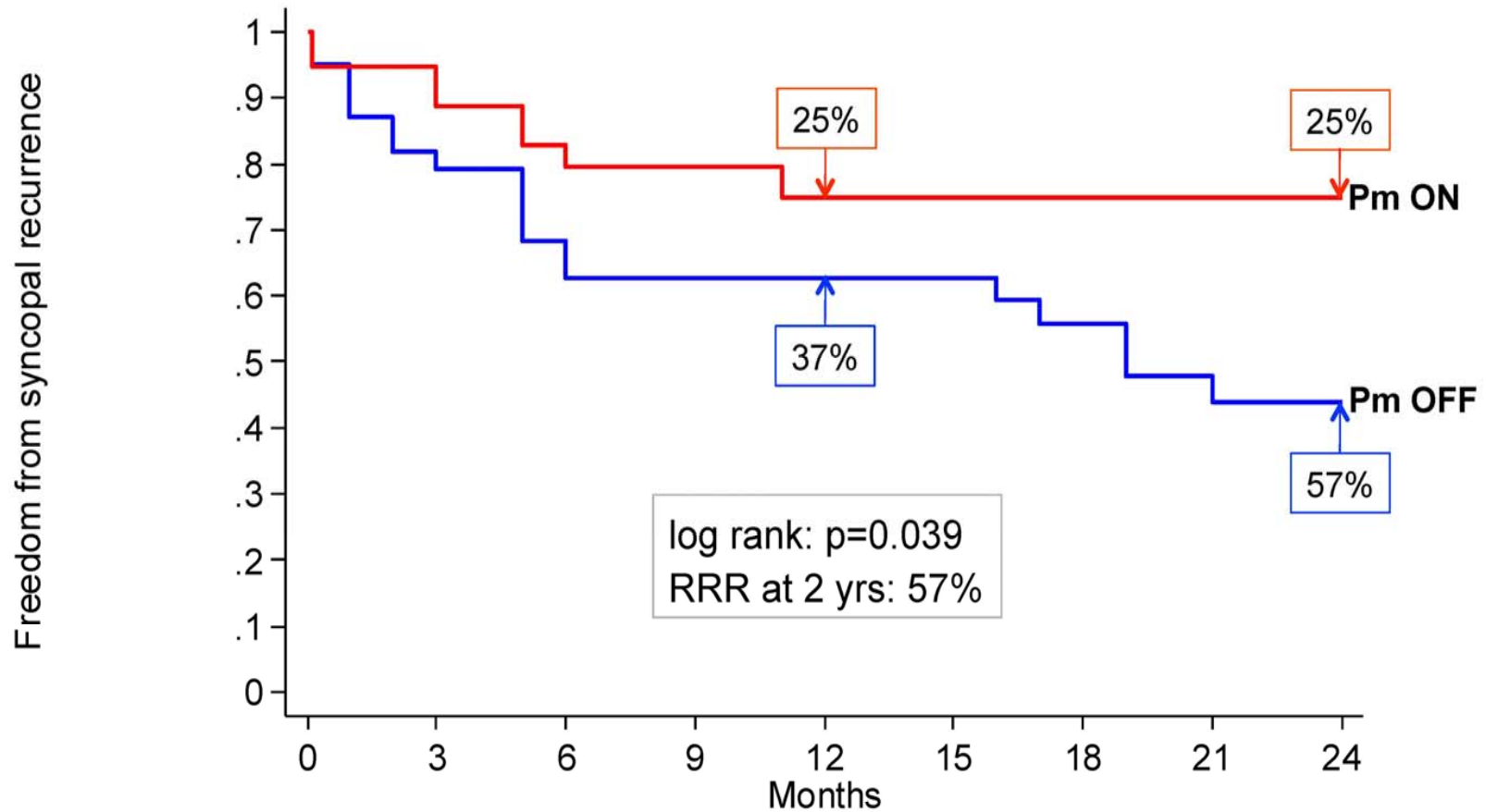
89 had ECG documentation of:
- syncopal recurrence with asystole of 12 ± 10 s (#72)
or
- non-syncopal asystole of 10 ± 6 s (#17)



ISSUE 3 population



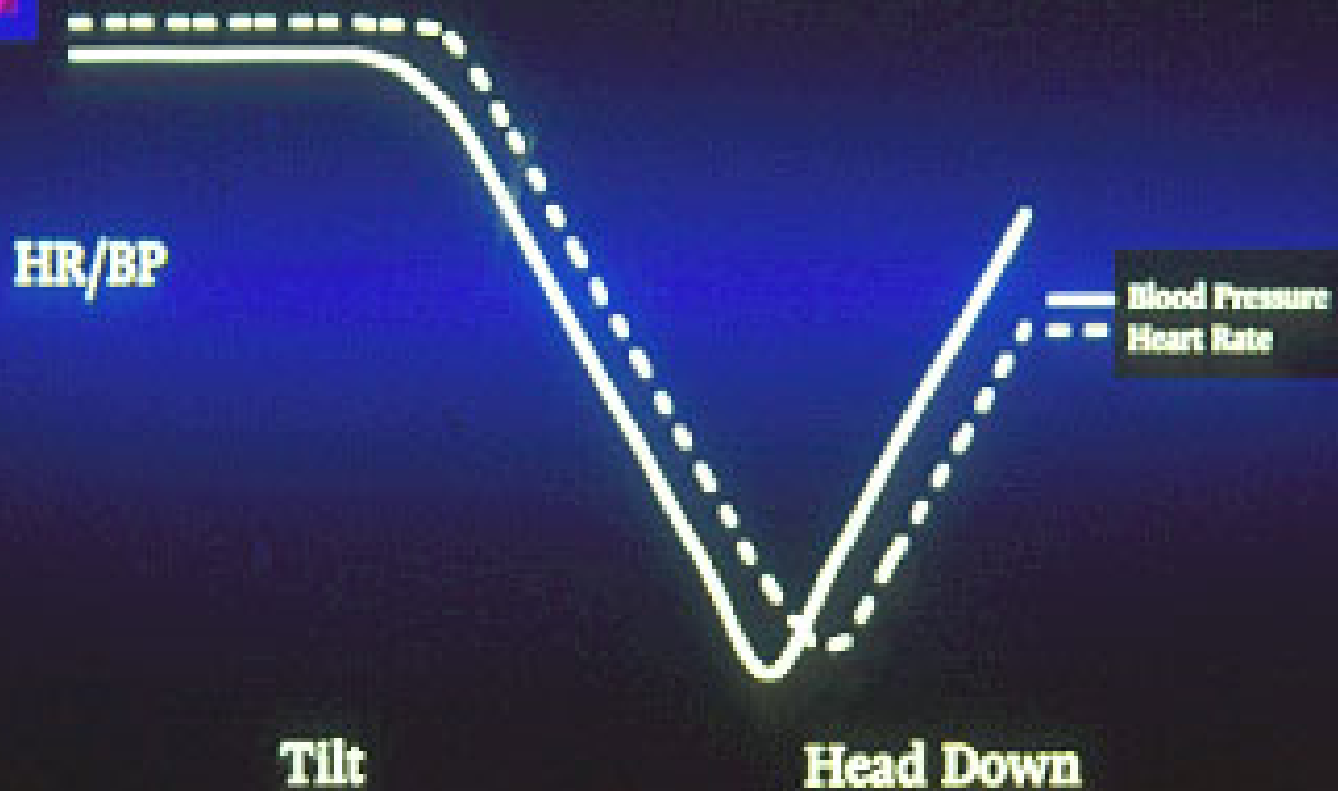
First syncope recurrence (intention-to-treat)



Number at risk

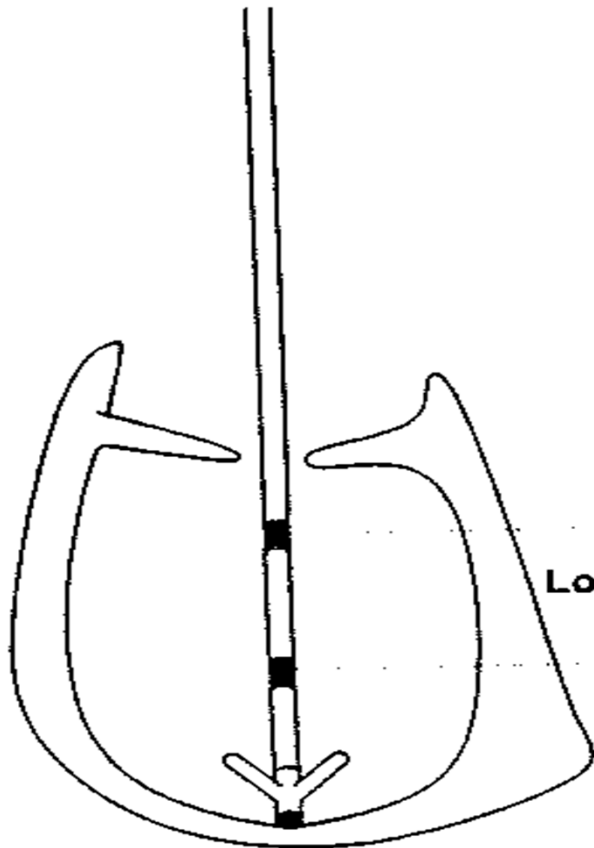
Pm OFF	39	31	25	21	21	18	15	12	8
Pm ON	38	32	27	22	16	14	13	13	11

Classic Neurocardiogenic (Vasovagal) Response



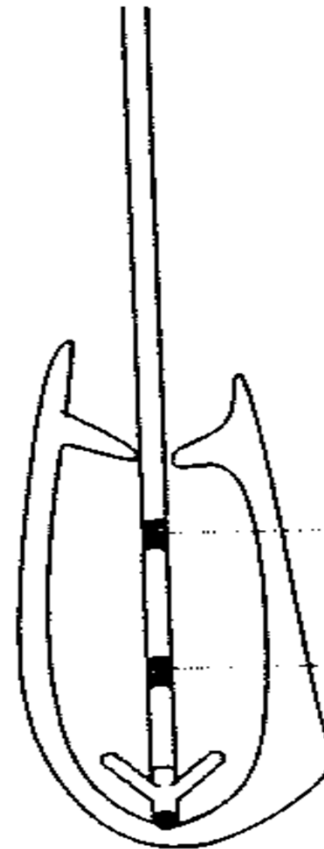


The Precept Model 4400 tripolar lead measured relative right ventricular volume via a current passed between the distal electrode in the right ventricle and pacemaker can. Impedance is directly proportional to the volume of blood in the ventricle



Large volume

Low impedance

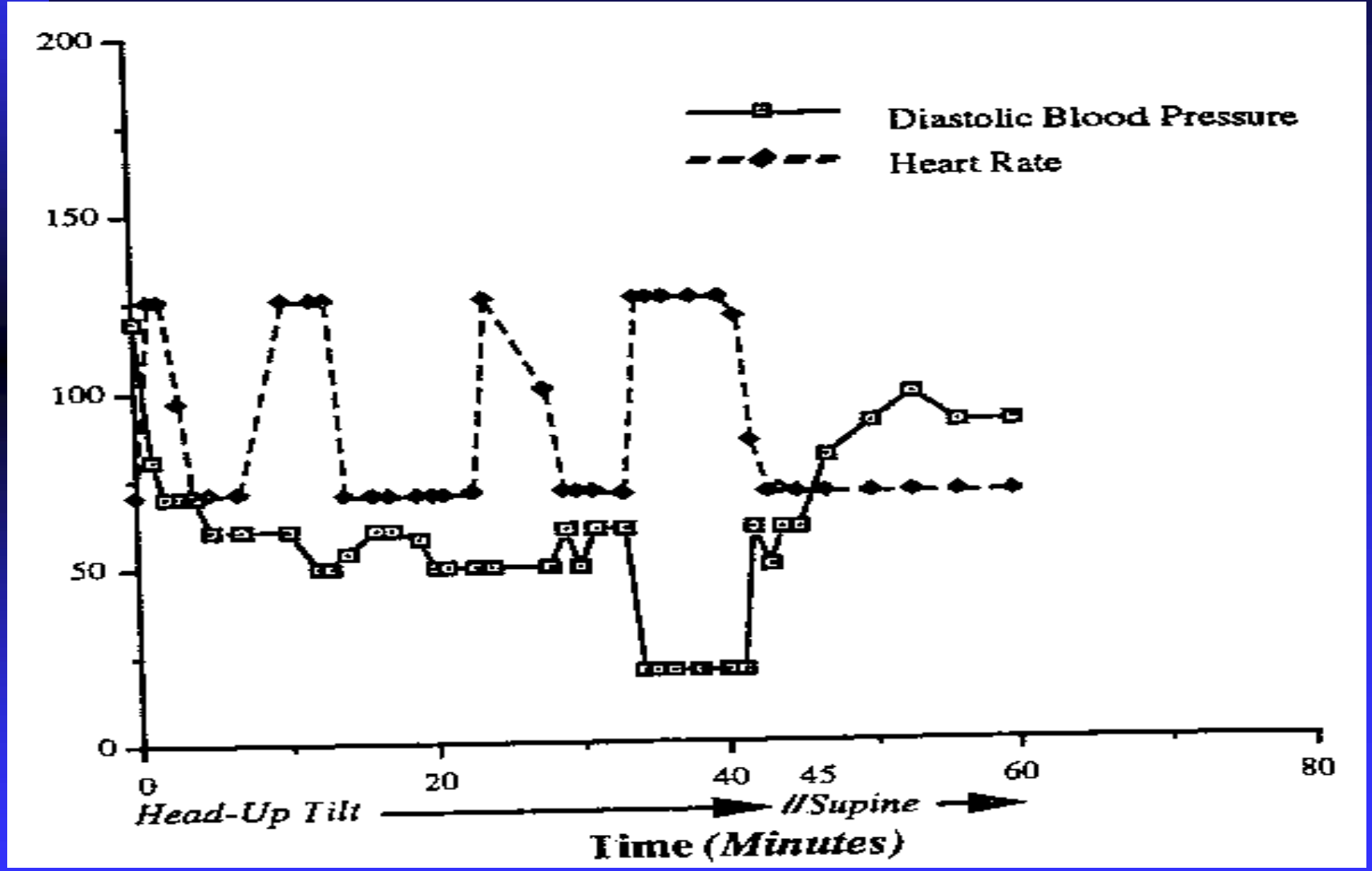


Small volume

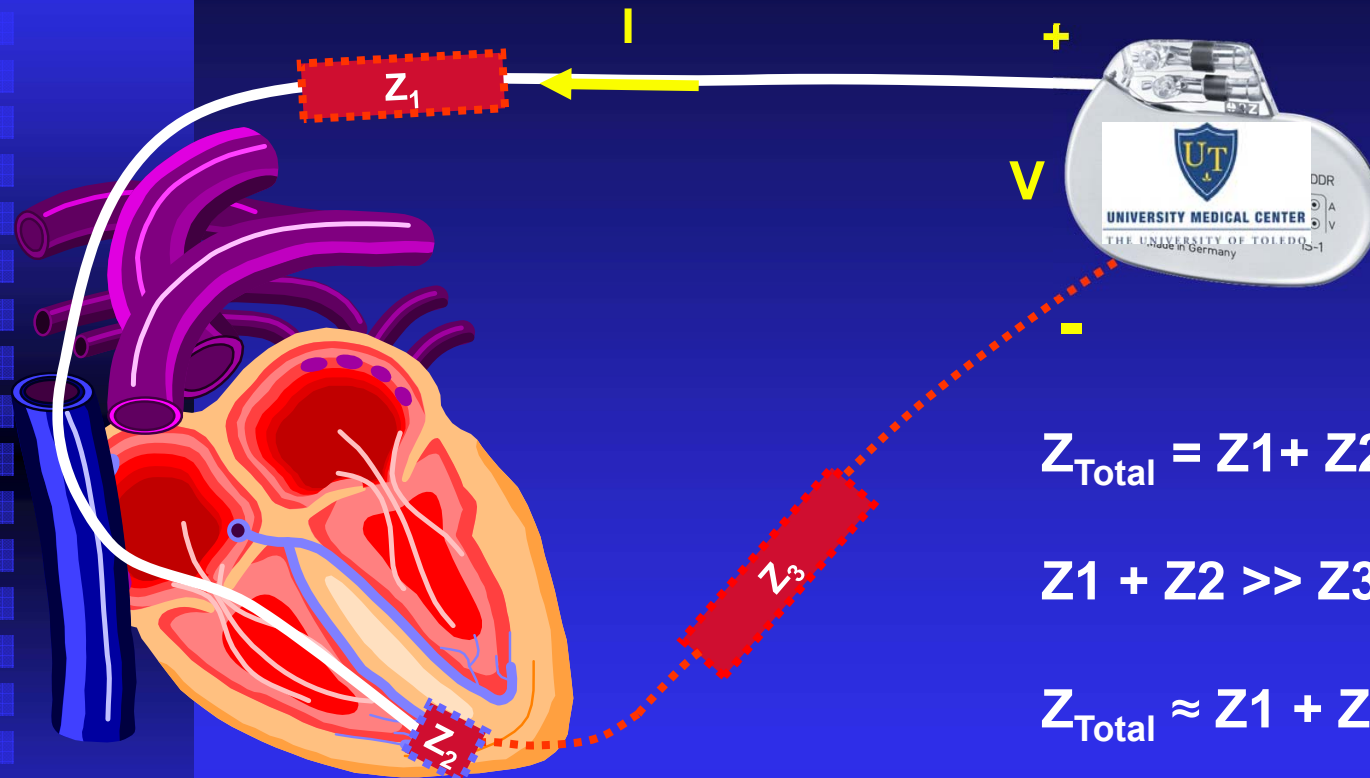
High impedance



Diastolic blood pressure and heart rate response to head-up tilt during rate adaptive pacing controlled by preejection interval



CLS Measures Impedance as an Ohm-meter



$$Z_{\text{Total}} = Z_1 + Z_2 + Z_3$$

$$Z_1 + Z_2 \gg Z_3$$

$$Z_{\text{Total}} \approx Z_1 + Z_2$$

During systole, Z₁ (lead) is constant,

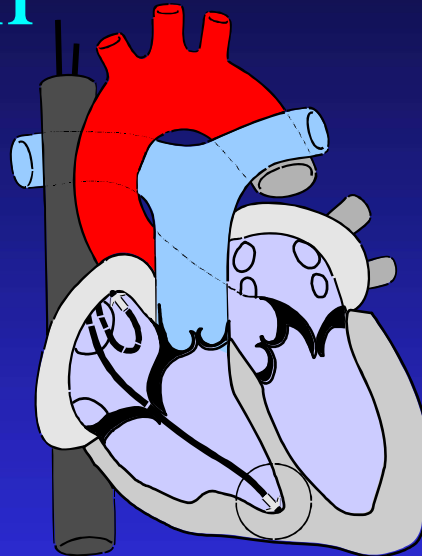
$$\Delta Z_{\text{Total}} = \Delta Z_2$$

Impedance changes during the contraction

End-Diastole

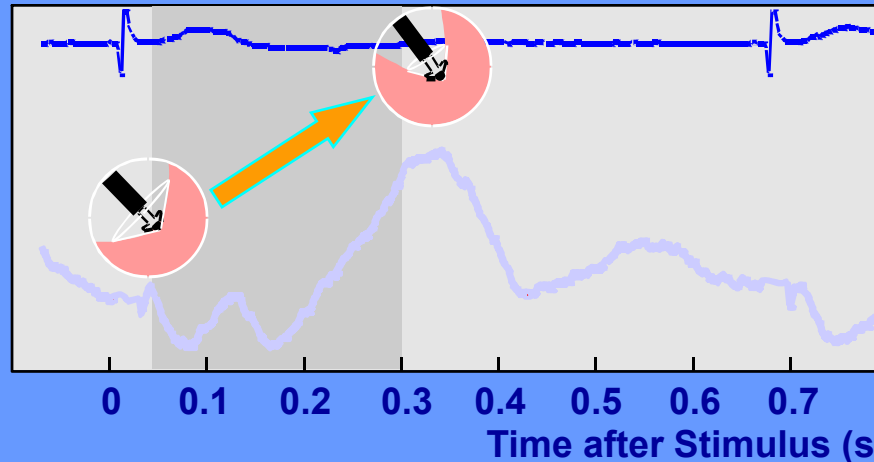


End-Systole



Smaller Fraction
of Myocardium
=
Low Impedance

Intracardiac impedance



Larger Fraction
of Myocardium
=
High Impedance

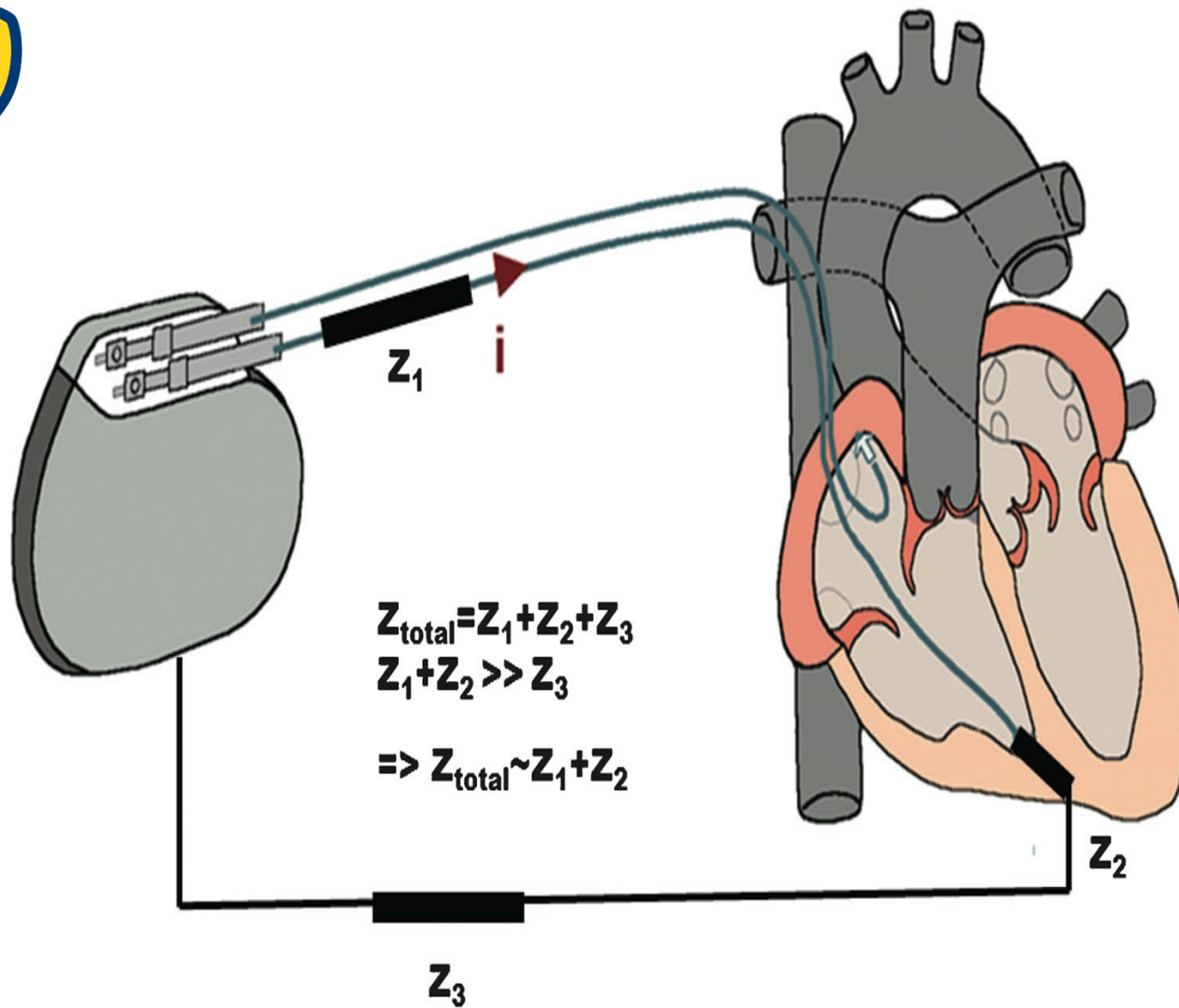
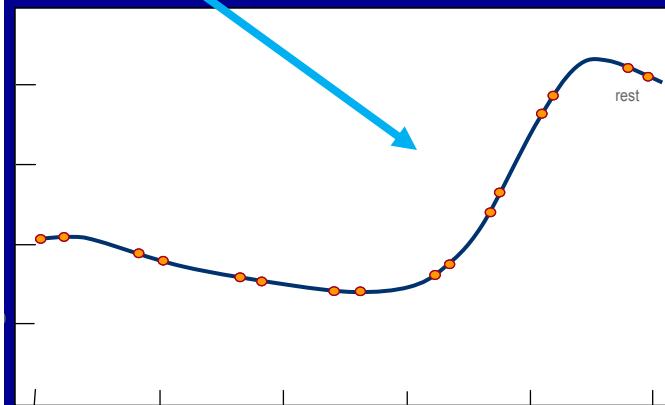


Figure 1: Illustration demonstrating the impedance at the lead tip myocardial interface (Z_2) assessed by the closed loop (CLS) system.

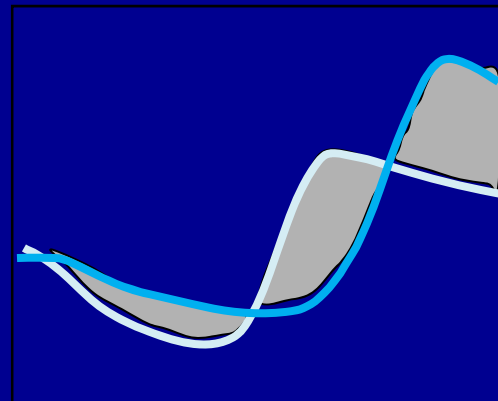


How does CLS work?

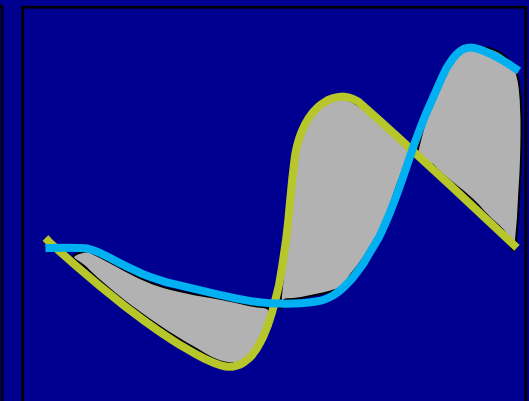
- CLS monitors localized RV impedance
 - Impedance is a direct assessment of myocardial wall motion
- Changes in myocardial wall motion (contractility) are directly correlated to changes in autonomic tone to form rate variations, dictated by the brain
- CLS is able to provide a paced heart rate on a beat-to-beat basis driven by the central nervous system



16 impedance measurements create reference waveform with patient at rest



Waveform changes compared to baseline and heart rate adjusted according to the measured differential





Baseline characteristics

Age	41±11
Females	30(85%)
Mean Follow-up (Months)	12±3
Total Number of Devices	44
Total number of Patients	35
Number of Patients receiving Cylos	32
Number of Patients receiving OLS	12
Number of Patients in Cylos group with prior OLS implants	9

Effect of closed loop pacing on syncope burden

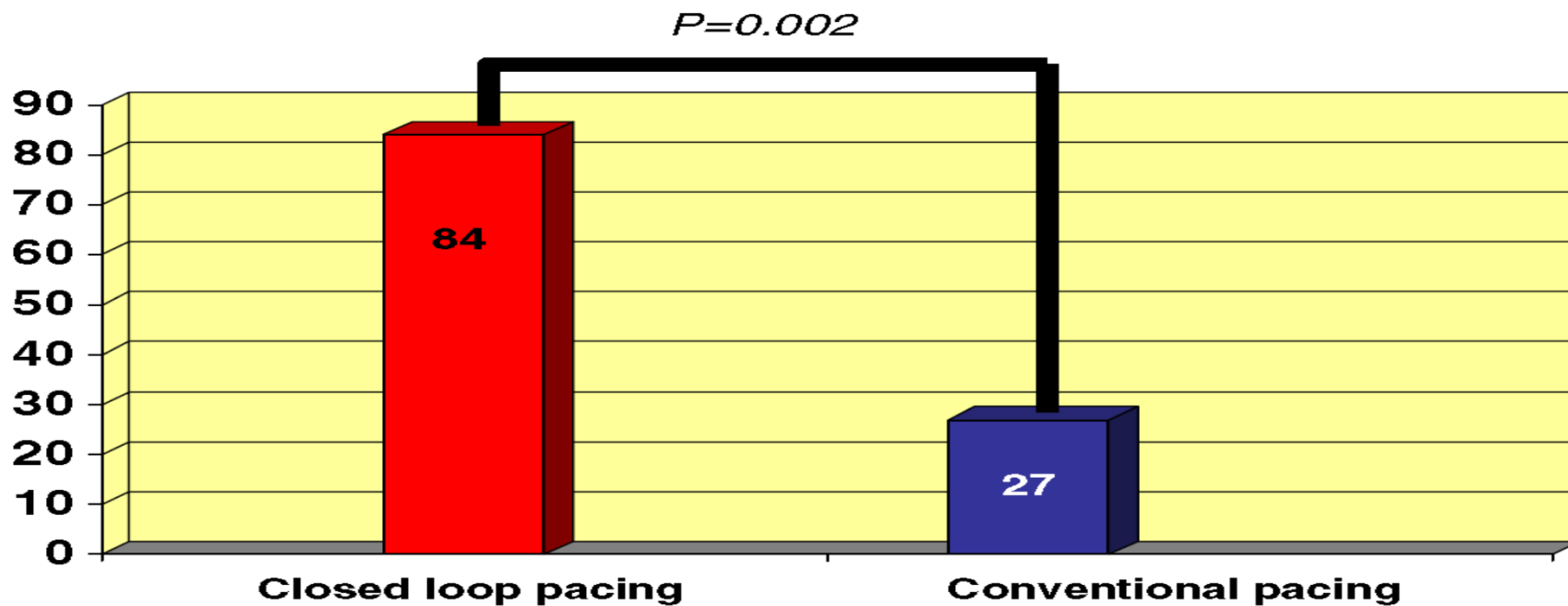
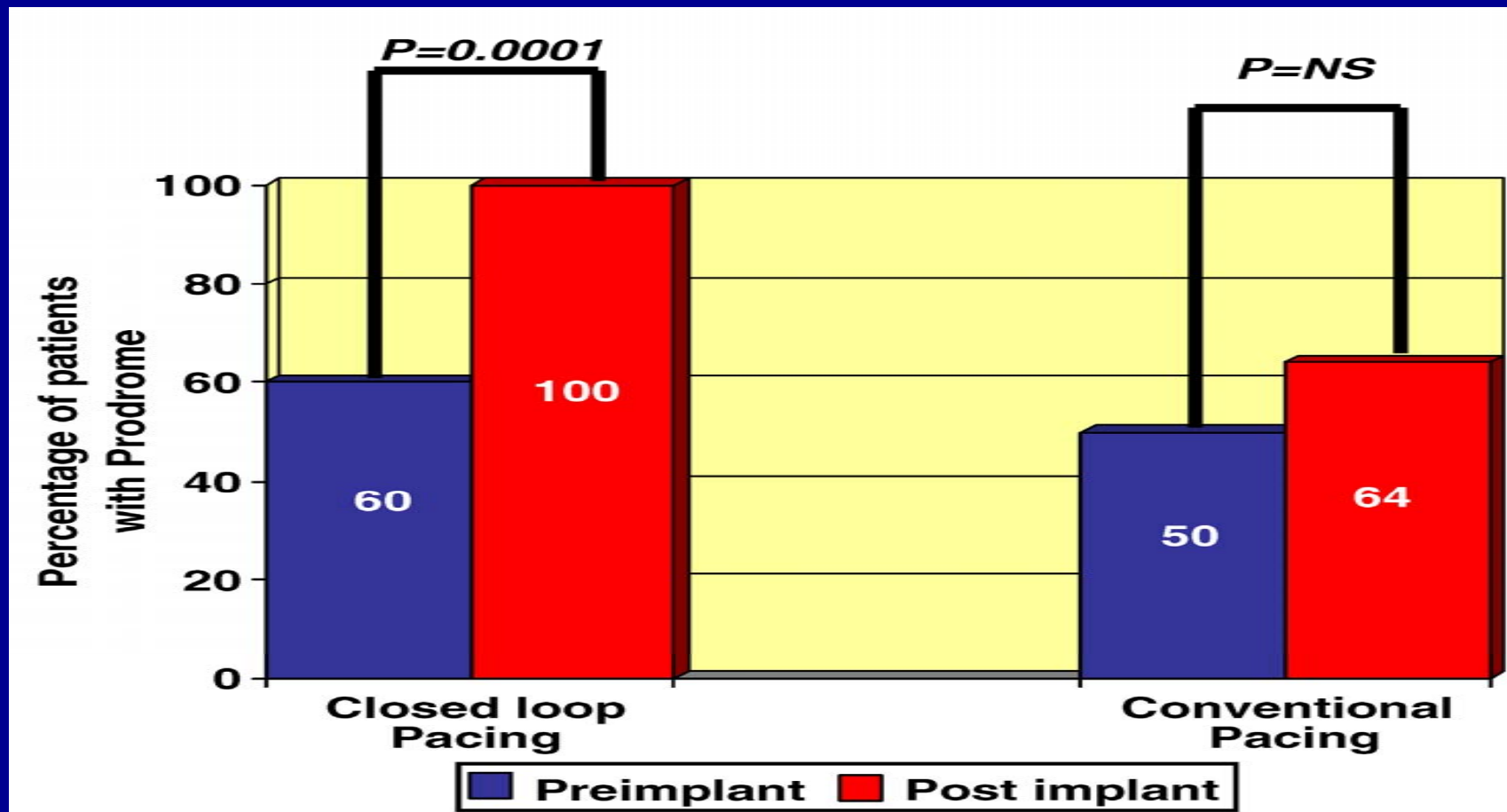


Fig. 2 Pacemaker success and reduction in syncope burden (>50%) in close loop vs conventional pacing

Khalil Kanjwal, Blair Grubb et al. Preliminary observations on the use of closed-loop cardiac pacing in patients with refractory neurocardiogenic syncope. J Interv Card Electrophysiol. 2009 Nov 25.



Effect of closed loop pacing on prodrome or warning signs.



Khalil Kanjwal , Blair Grubb et al . Preliminary observations on the use of closed-loop cardiac pacing in patients with refractory neurocardiogenic syncope. J Interv Card Electrophysiol. 2009 Nov 25.



Recurrence rates in closed loop versus conventional pacing

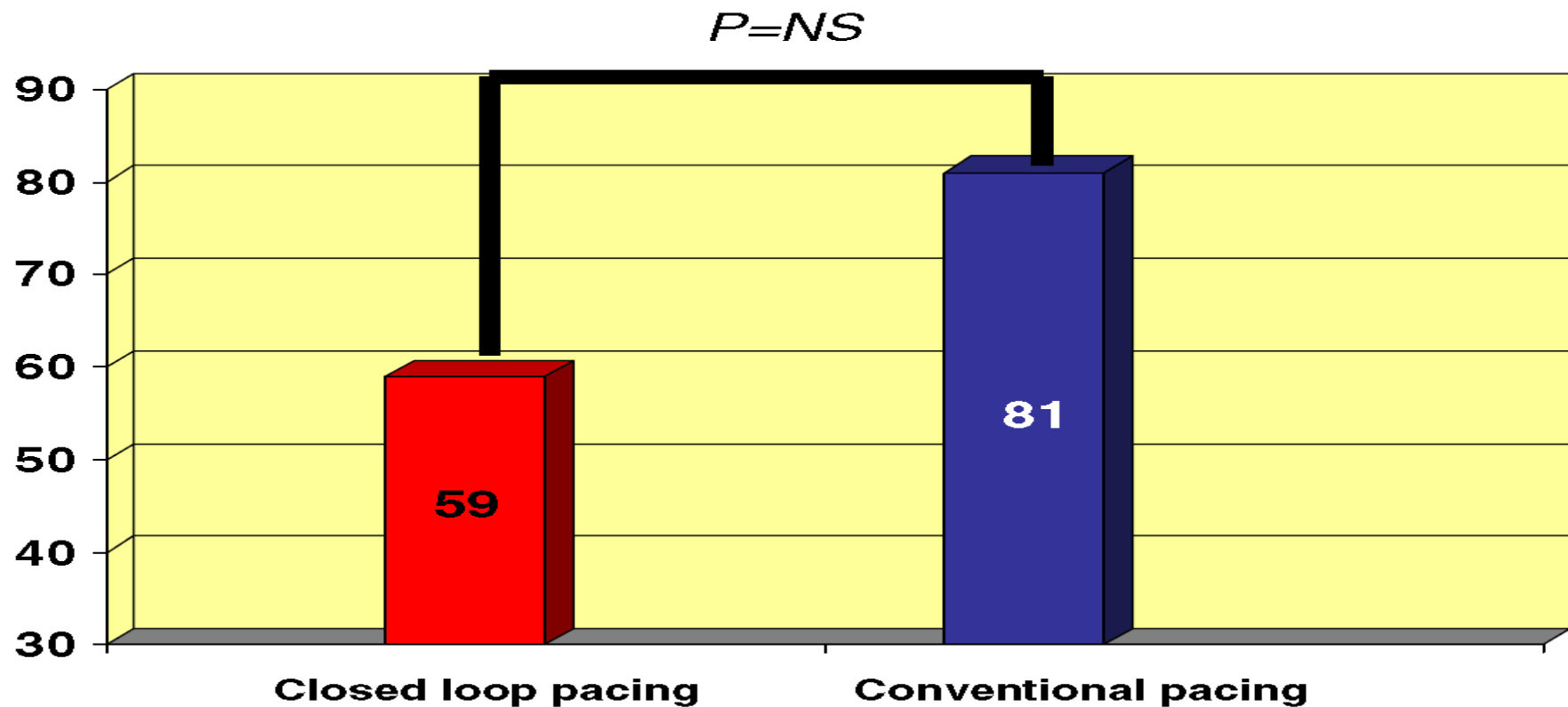


Fig. 1 Recurrence rates in close loop versus conventional pacing

Khalil Kanjwal , Blair Grubb et al . Preliminary observations on the use of closed-loop cardiac pacing in patients with refractory neurocardiogenic syncope. J Interv Card Electrophysiol. 2009 Nov 25.



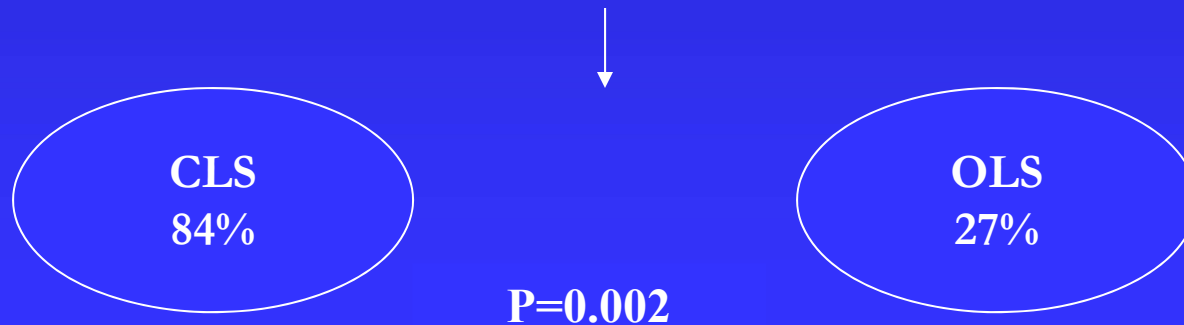
Pacemaker Success



The pacemaker implantation was termed successful if

- there was no recurrence of syncope,
- if the syncope burden decreased by $\geq 50\%$,
- if only presyncope occurred and
- if the syncope occurred but with significant warning symptoms following pacemaker implantation.

Pacemaker Success





Preliminary observations on the use of closed-loop cardiac pacing in patients with refractory neurocardiogenic syncope

Khalil Kanjwal · Beverly Karabin · Yousuf Kanjwal · Blair P. Grubb

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Abstract

Background In many patients with recurrent neurocardiogenic syncope (NCS), a significant fall in blood pressure precedes any appreciable decline in heart rate. Closed-loop pacing (CLS) employs a sensing system that measures myocardial contractility, thereby providing a potential way to detect the onset of NCS at a much earlier point in time than that provided by standard pacing systems.

Methods Patients were included in the study if they suffered from recurrent NCS and met all of the following criteria: (1) They had suffered at least two syncopal episodes in the preceding 6 months. (2) Patients were refractory to (or intolerant of) all conventional, non-pharmacological, or pharmacological treatments. (3) They had evidence of asystole (>10 s) or severe bradycardia (heart rate <30 bpm) on implantable loop recorder or during head-up tilt test (HUTT).

Results Thirty five patients meeting the above criterion received 44 devices. Twelve patients received a standard unit (with rate drop or rate hysteresis response) and 32 patients received a CLS unit (Cynos, Biotronik). The pacemaker implantation was termed successful if there was no recurrence of syncope, if the syncope burden

decreased by $\geq 50\%$, if only presyncope occurred, or if the syncope occurred but with significant warning symptoms. Thirty-five patients, 29 females and six males, age 41 ± 11 , with refractory NCS underwent pacemaker implantation. Mean follow-up was 9 ± 3 months. Out of 32 patients who received CLS, nine had a conventional pacemaker implanted in the past. Recurrence (59% vs 83%), reduction in syncope burden and pacemaker success (84% vs 25%, $P=0.002$), and occurrence prodrome/warning signs (40% vs 16%) were much better in the closed-loop group.

Conclusion These preliminary observations suggest that dual-chamber CLS pacing may be promising therapy for refractory NCS. Further randomized trials will be needed to better determine the role of this therapy in refractory NCS.

Keywords Closed-loop pacing · Neurocardiogenic · Syncope · Pacemaker

1 Introduction

Permanent cardiac pacing has been a controversial therapy for the prevention of recurrent episodes of neurocardiogenic syncope (NCS) [1]. While early-published reports suggested that permanent pacing was useful in preventing NCS [2–8], subsequent trials did not support the concept [9, 10]. However, the investigations employed pacemakers that were only capable of sensing heart rate. In many patients with recurrent NCS, a significant fall in blood pressure precedes any appreciable decline in heart rate [1]. These

K. Kanjwal · B. Karabin · Y. Kanjwal · B. P. Grubb
Electrophysiology Section, Division of Cardiology,
Department of Medicine,
The University of Toledo Medical Center,
Toledo, OH, USA



Closed-loop cardiac pacing vs. conventional dual-chamber pacing with specialized sensing and pacing algorithms for syncope prevention in patients with refractory vasovagal syncope: results of a long-term follow-up

Pietro Palmisano*, Maria Zaccaria, Giovanni Luzzi, Frida Nacci, Matteo Anaclerio, and Stefano Favale

Department of Emergency and Organ Transplantation, Cardiology Unit, University of Bari, Pietro Palmisano, Piazza Giulio Cesare 11, 70124 Bari, Italy

Received 18 September 2011; accepted after revision 16 December 2011

Aims

Closed-loop stimulation (CLS) pacing has shown greater efficacy in preventing the recurrence of vasovagal syncope (VVS) in patients with a cardioinhibitory response to head-up tilt test (HUTT) compared with conventional pacing. Moreover, there is no conclusive evidence to support the superiority of CLS over the conventional algorithms for syncope prevention. This study retrospectively evaluated the effectiveness of CLS pacing compared with dual-chamber pacing with conventional specialized sensing and pacing algorithms for syncope prevention in the prevention of syncope recurrence in patients with refractory VVS and a cardioinhibitory response to HUTT during a long-term follow-up.

Methods and results

Forty-one patients (44% male, 53 ± 16 years) with recurrent, refractory VVS (26% with trauma) and a cardioinhibitory response to HUTT who had undergone pacemaker implantation were included in the analysis. Twenty-five patients received a dual-chamber CLS pacemaker (CLS group) and 16 patients received a dual-chamber pacemaker with conventional algorithms for syncope prevention (conventional pacing group): 9 patients with Medtronic rate drop response algorithm and 7 patients with Guidant-Boston Scientific sudden brady response algorithm. During the follow-up (mean 4.4 ± 3.0 years, interquartile range 2.2–7.4 years) one patient (4%) in the CLS group and six (38%) in the conventional pacing group had syncope recurrences ($P = 0.016$). The Kaplan–Meier actuarial estimate of first recurrence of syncope after 8 years was 4% in the CLS group and 40% in the conventional pacing group ($P = 0.010$).

Conclusions

The results of this retrospective analysis show that, in order to prevent a recurrence of VVS in patients with a cardioinhibitory response to HUTT, dual-chamber CLS pacing was more effective than dual-chamber pacing with conventional algorithms for syncope prevention in preventing bradycardia-related syncope.

Keywords

Vasovagal syncope • Cardioinhibitory • Pacemaker • Closed-loop stimulation • Rate drop response • Head-up tilt test

Introduction

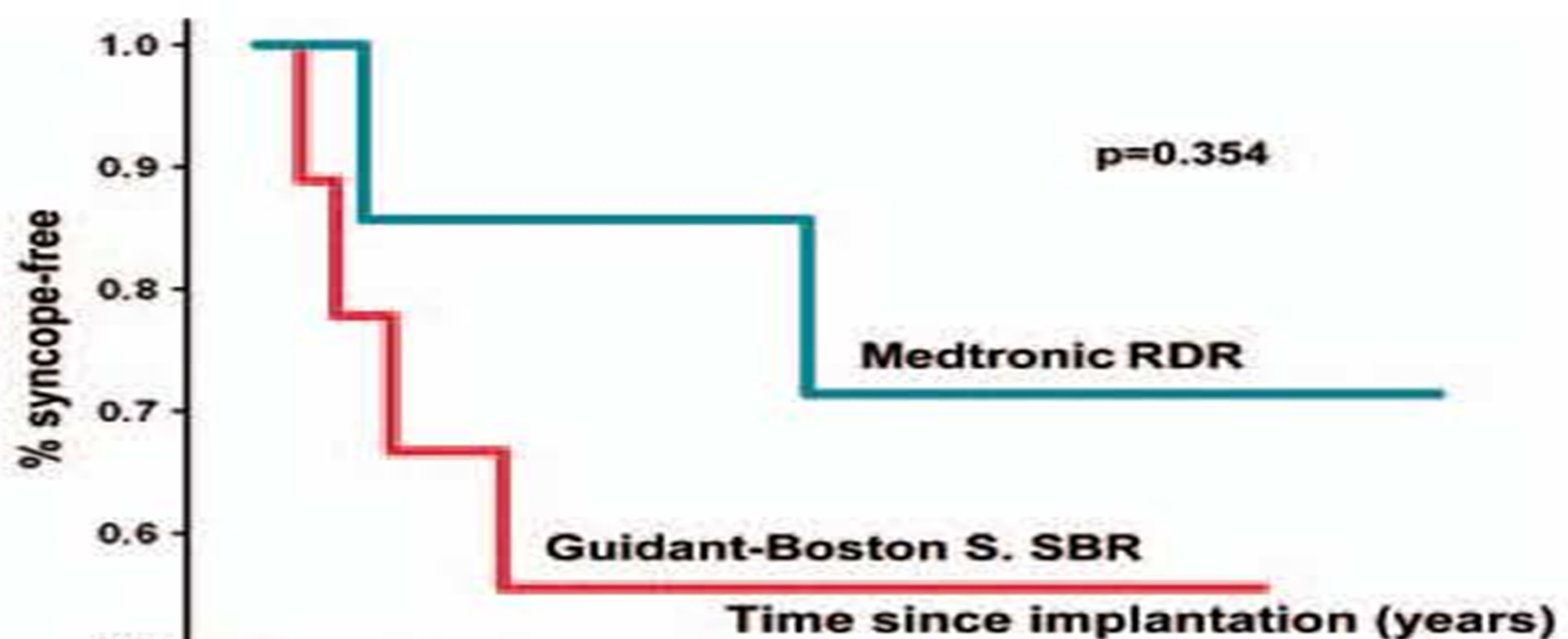
Vasovagal syncope (VVS) is a common disorder of the autonomic cardiovascular regulation.^{1,2} Significant bradycardia or prolonged asystole and concomitant hypotension in patients with recurrent,

severe, cardioinhibitory VVS can result in serious physical injuries and psychological impairment, including substantial limitations to their social and working life.^{3–7}

Some initial, uncontrolled, follow-up studies^{8–11} as well as subsequent, randomized, controlled trials^{12–14} have suggested that,

*Corresponding author. Tel: +390805592765/+390805575720; fax: +390805478796. Email: dr.palmisano@libero.it

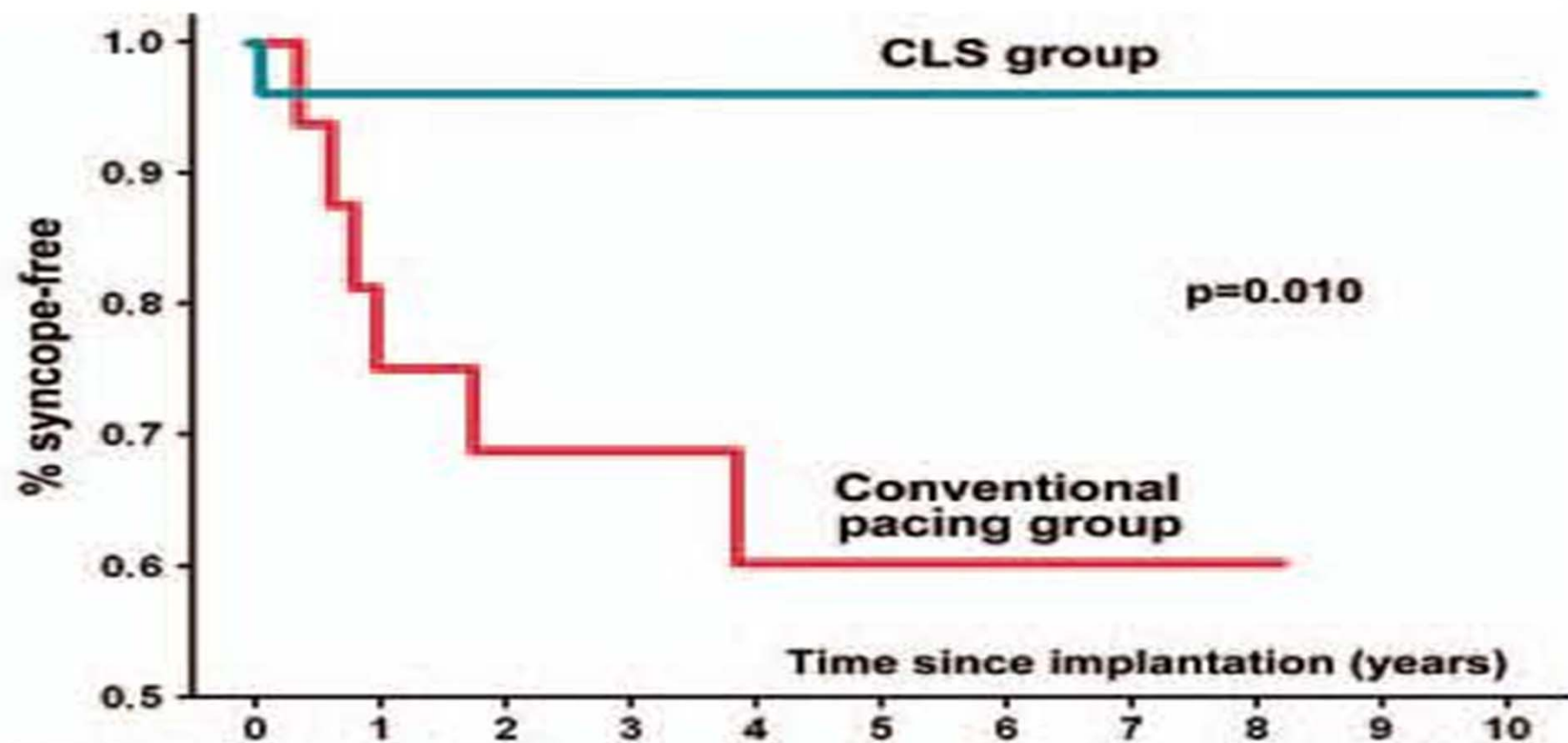
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N. of pts with RDR algorithm	7	6	6	6	5	5	5	5	3	0
N. of pts with SBR algorithm	9	7	3	3	2	2	2	2	0	0

RDR: Rate Drop Response; SBR: Sudden Brady Response.

Figure 2 Kaplan–Meier estimates of probability of remaining free of syncopal recurrences in seven patients who received a pacemaker with Medtronic rate drop response algorithm (blue line) and nine who received a pacemaker with Guidant-Boston Scientific sudden brady response algorithm (red line).



CLS: Closed Loop Stimulation.

Figure 1 Kaplan–Meier estimates of probability of remaining free of syncopal recurrences in 25 patients in closed-loop stimulation group (blue line) and 16 patients in control group (red line).

Long-term follow-up of DDDR closed-loop cardiac pacing for the prevention of recurrent vasovagal syncope

Miriam Bortnik, Eraldo Occhetta, Gabriele Dell'Era, Gioel G. Secco, Anna Degiovanni, Laura Plebani and Paolo Marino

Aims Vasovagal syncope (VVS) is a common disorder characterized by a drop in blood pressure accompanied with bradycardia; although it is generally considered a benign condition, some patients may be highly symptomatic despite general counselling and/or pharmacological therapy. Closed-loop stimulation (CLS), responding to myocardial contraction dynamics, demonstrated effectiveness in short-term prevention of recurrent VVS. The aim of this study was to evaluate CLS pacing in a long-term follow-up.

Methods The study involved 35 patients (mean age 59 ± 15 years) with 3 years' follow-up (mean 61 ± 35 months). We compared syncopal events and presyncope before and after CLS implantation. Mean number of syncopes for patients was six (range 1–24; 212 syncopal spells registered) before pacemaker implantation.

Results At follow-up, 29 of 35 patients (83%) were asymptomatic; one patient experienced recurrent loss of consciousness but reported an improvement in the quality of life (one syncope or presyncope per month after CLS, vs.

one syncope per week and daily presyncope before CLS). Five patients experienced syncopal recurrences after CLS (range: 1–7, with a total of 15 episodes); in all the cases, the number of post-CLS syncopes was significantly lower.

Conclusion Our study seems to confirm previous results of short-term trials: DDDR-CLS pacing is an extremely useful tool in the prevention of recurring VVS, even in long-term follow-up.

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Keywords: cardiac pacing, closed-loop stimulation, neurocardiogenic, vasovagal syncope

Division of Cardiology, University of Eastern Piedmont, Maggiore della Carità Hospital, Novara, Italy

Correspondence to Dr Miriam Bortnik, Divisione Clinicizzata di Cardiologia, Azienda Ospedaliera Universitaria Maggiore della Carità, Corso Mazzini 18, 28100 Novara, Italy
 Tel: +39 321 3733294; fax: +39 321 3733407; e-mail: miriam.bortnik@libero.it

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Introduction

Vasovagal syncope (VVS) is the most common cause of fainting, accounting for more than 50% of all admissions at the emergency room.^{1,2} It is now accepted that the main cause of VVS is an acute impairment of the complex neuroautonomic and cardiovascular interactions that maintain cerebral perfusion. The Bezold–Jarisch reflex, inappropriately activated by the stimulation of the mechanoreceptors located inside the left ventricle should be primarily responsible for this phenomenon.³ Each patient complaining of VVS presents a combined mechanism of vasodepression and cardioinhibition causing the event, with cardioinhibitory response (with or without complete asystole) usually following an abrupt increase in myocardial contractility.

The closed-loop stimulation (CLS) algorithm implemented in Biotronik (GmbH & Co., Germany) pacemakers offers a valid therapy for rate-variable stimulation of the heart based on the closed-loop principle with a negative feedback. The pacemaker assesses the variations of intracardiac impedance on a beat-to-beat basis during the systolic phase of the cardiac cycle at the apex of the right ventricle (Fig. 1). The detection of an increase in contractility during the prodromic phase of

VVS triggers cardiac pacing, thus preventing the subsequent hypotension, bradycardia and syncope.⁴

The role of CLS in preventing VVS has been established by Occhetta *et al.*^{5,6} in the INVASY (INotropy controlled pacing in VAsovagal SYncope) studies, and more recently by Kanjwal *et al.*⁷

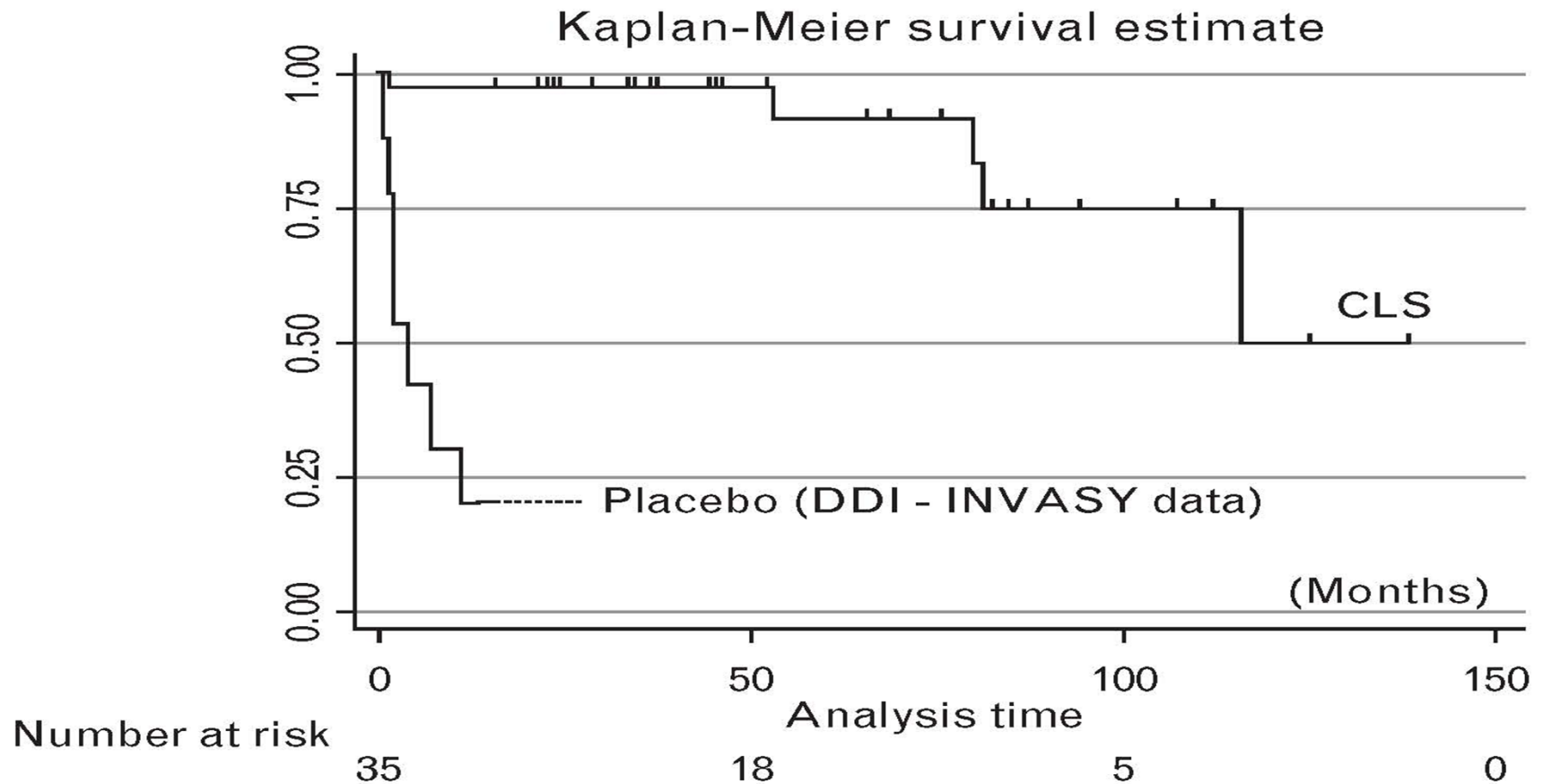
The main limit of both the pre-INVASY registry⁵ and the INVASY trial⁶ was the relatively short-term follow-up, which, given the natural VVS history with possibly long asymptomatic periods, could reduce the impact of the findings.

Thus, the aim of our study was to evaluate the long-term effectiveness of CLS pacing in a population of patients with recurrent VVS.

Population and methods

From October 1998 to February 2009, 51 patients (30 males) received a CLS pacemaker for recurrent VVS at our institution. Patients were chosen for CLS pacing because of clinical history and instrumental documentation of VVS/presyncope with impairment of quality of life.

Fig. 3



Kaplan–Meier analysis, freedom from vasovagal syncope is shown. Closed-loop stimulation (CLS) pacing shows a great benefit over conventional pacing ('placebo' data from the INVASY study), providing a very long syncope-free time span.



UT CLS Pacing for NCS

- 175 patients with refractory NCS*
- 115 women, 17 men*
- Mean number of episodes in 6 months prior to implant 5+/- 3*
- 54 had suffered severe trauma due to syncope including*
 - Skull fracture: 6*
 - Concussions: 21*
 - Jaw fracture: 9*
 - Fracture of arm or leg : 12*
 - Cerebral hemorrhage :6*



UT CLS Pacing for NCS

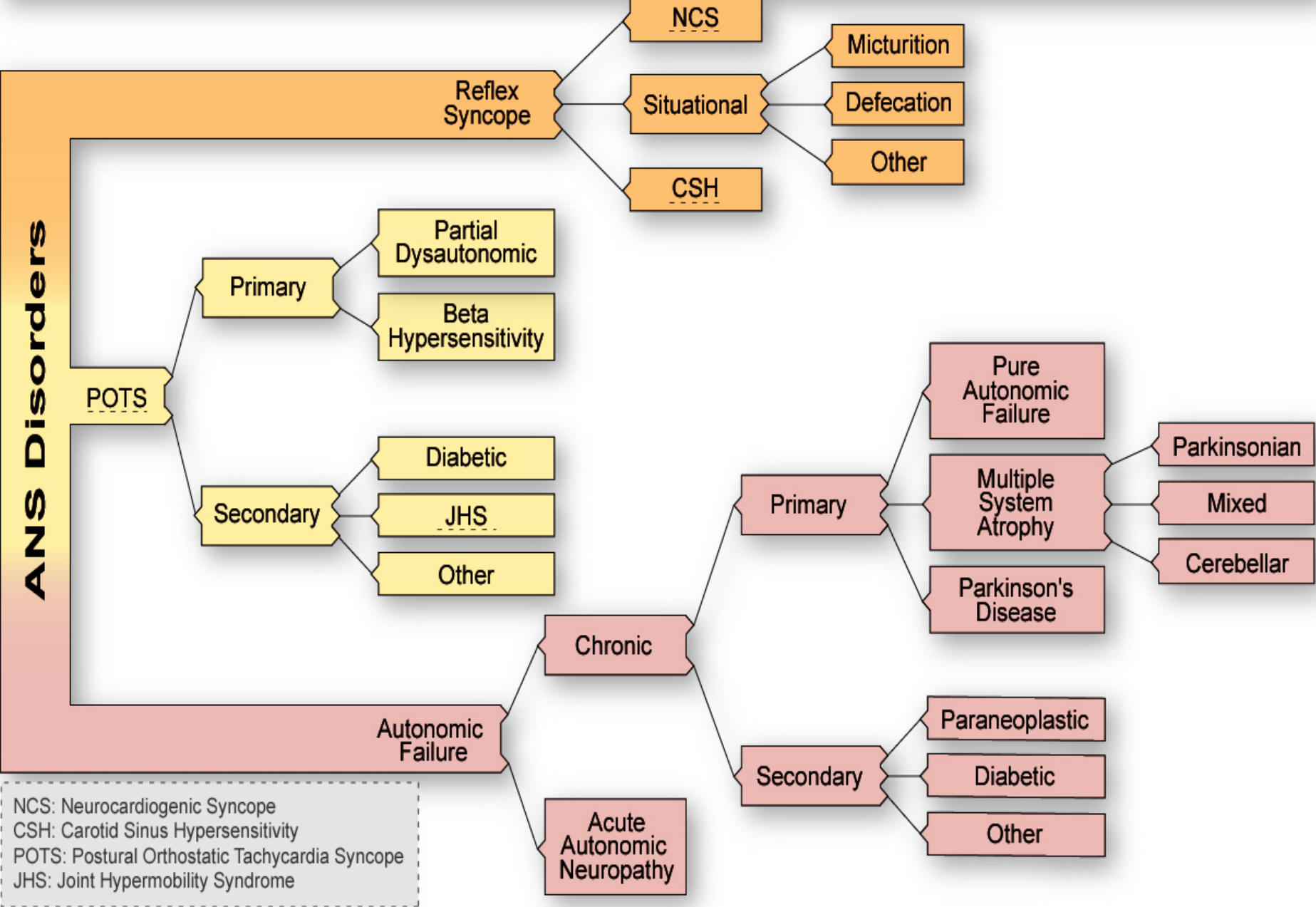
Mean follow up: 18+/- 4 months

Total Responders: 144 (82%)

Responder Characteristics:

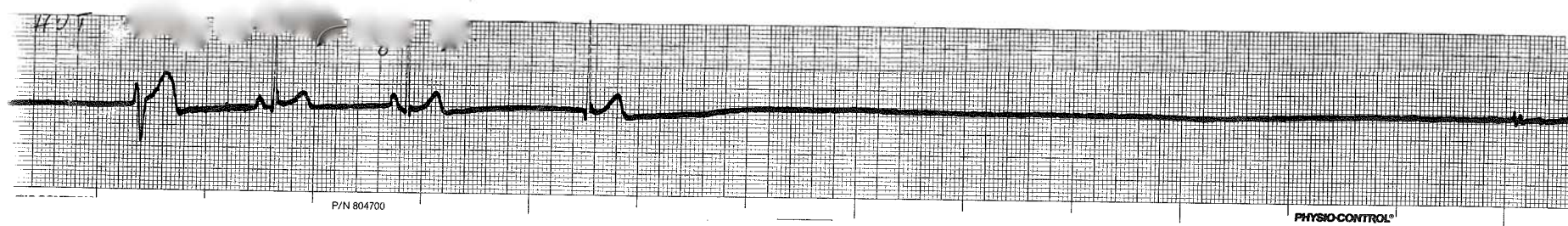
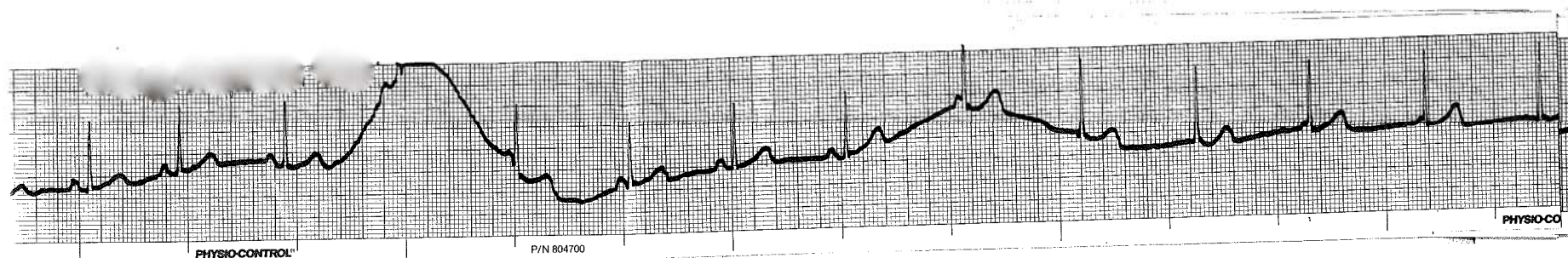
- 1) Prolonged asystole or CHB on ILR*
- 2) Convulsive Activity*
- 3) History of Injury*
- 4) Prolonged LOC (>5 minutes)*
- 5) Lack of prodrome*

Figure 1. Disorders of the Autonomic Nervous System Associated with Orthostatic Intolerance

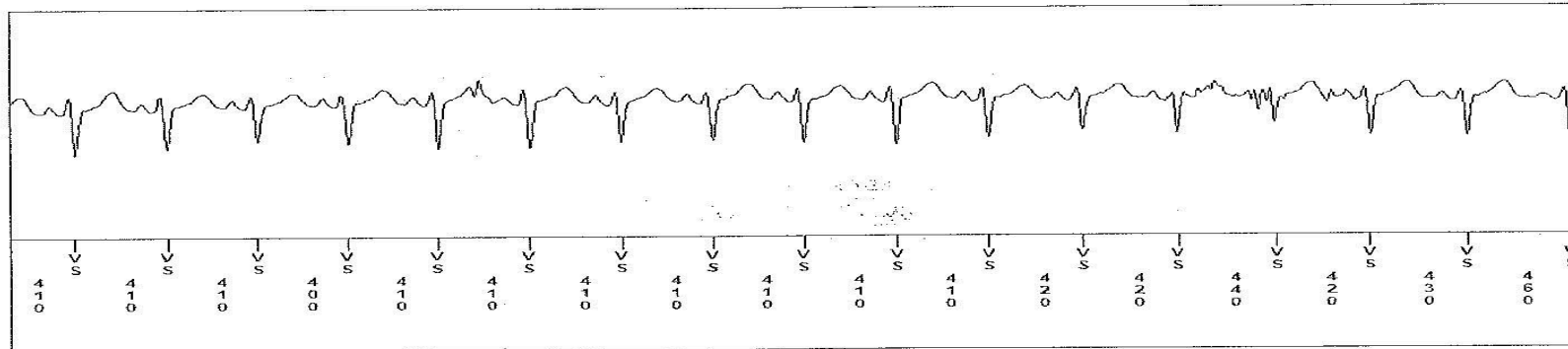
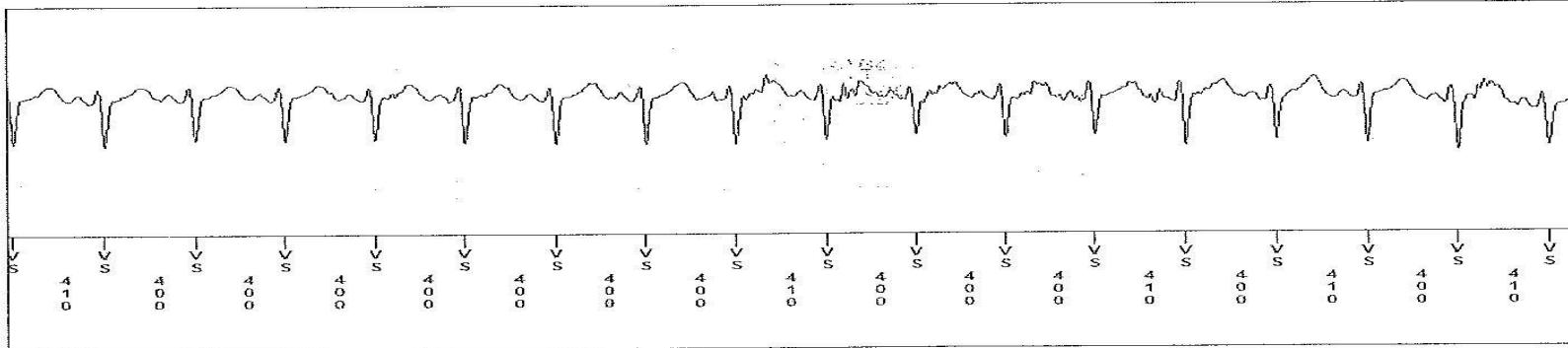
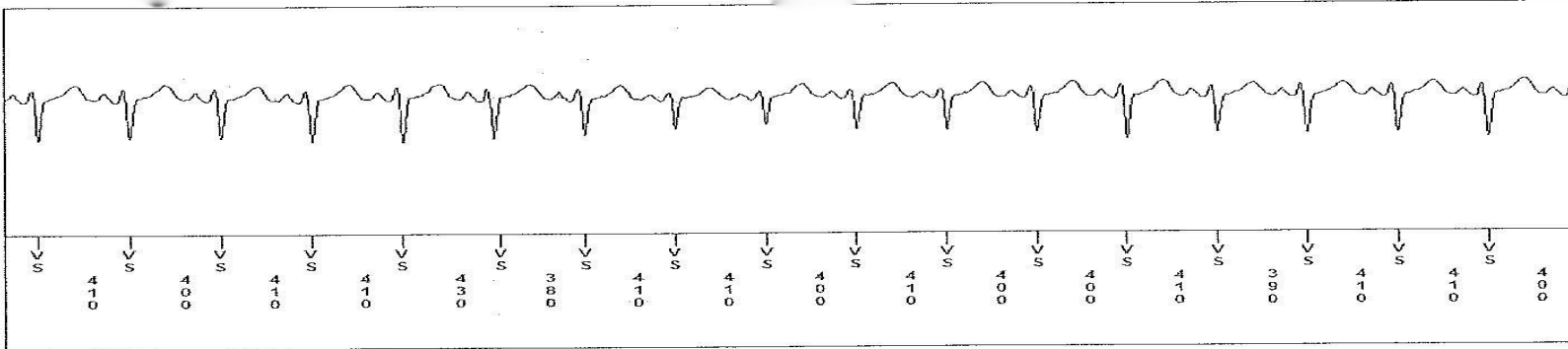




Could some POTS patients with recurrent severe syncope have asystole?



Episode of asystole seen in POTS pt during Tilt Table Test



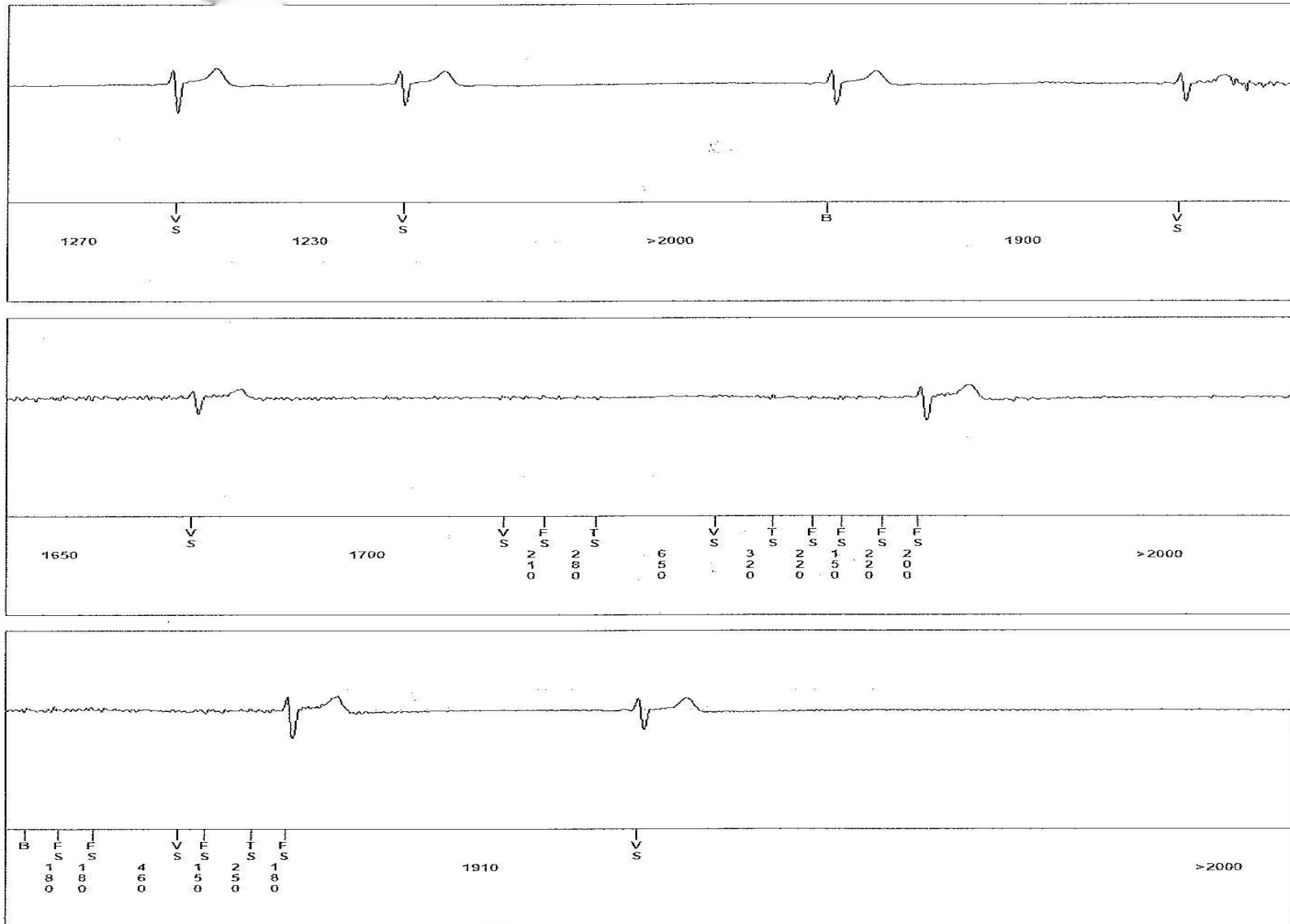
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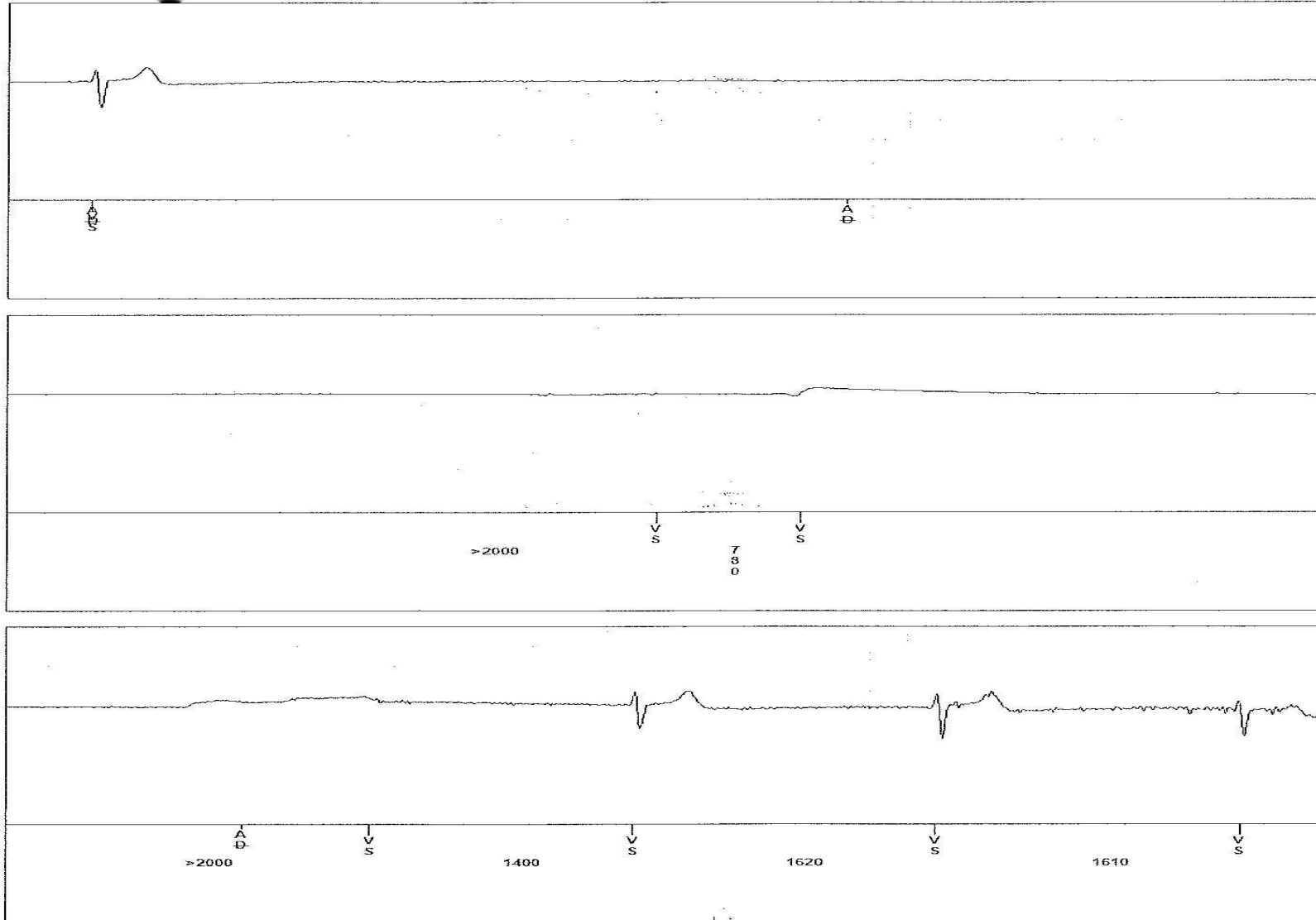


SYMPTOM Episode #3070

Date of Interrogation: 15-May-2014 09:13:15

Episode #3070 Chart speed: 25.0 mm/sec







Preliminary analysis:

Approximately 20 - 25 % of POTS

Pts with recurrent syncope with;

1. no prodrome

2. prolonged LOC > 5 minutes

3. Convulsive activity

***May have significant bradycardia
during their syncopal events that
can respond to pacing***

Reflex
Syncope

Pure
Autonomic
Failure

Multiple
System
Atrophy

Postural
Orthostatic
Tachycardia
Syndrome

Many patients suffering from severe NCS
Are often young and concerned about the
Cosmetic appearance of the ILR or pacemaker
(or ICD) scar

At the same time device infection rates in the US
Are rising.

*There had to be a way of reducing infections
And reducing scar formation...*



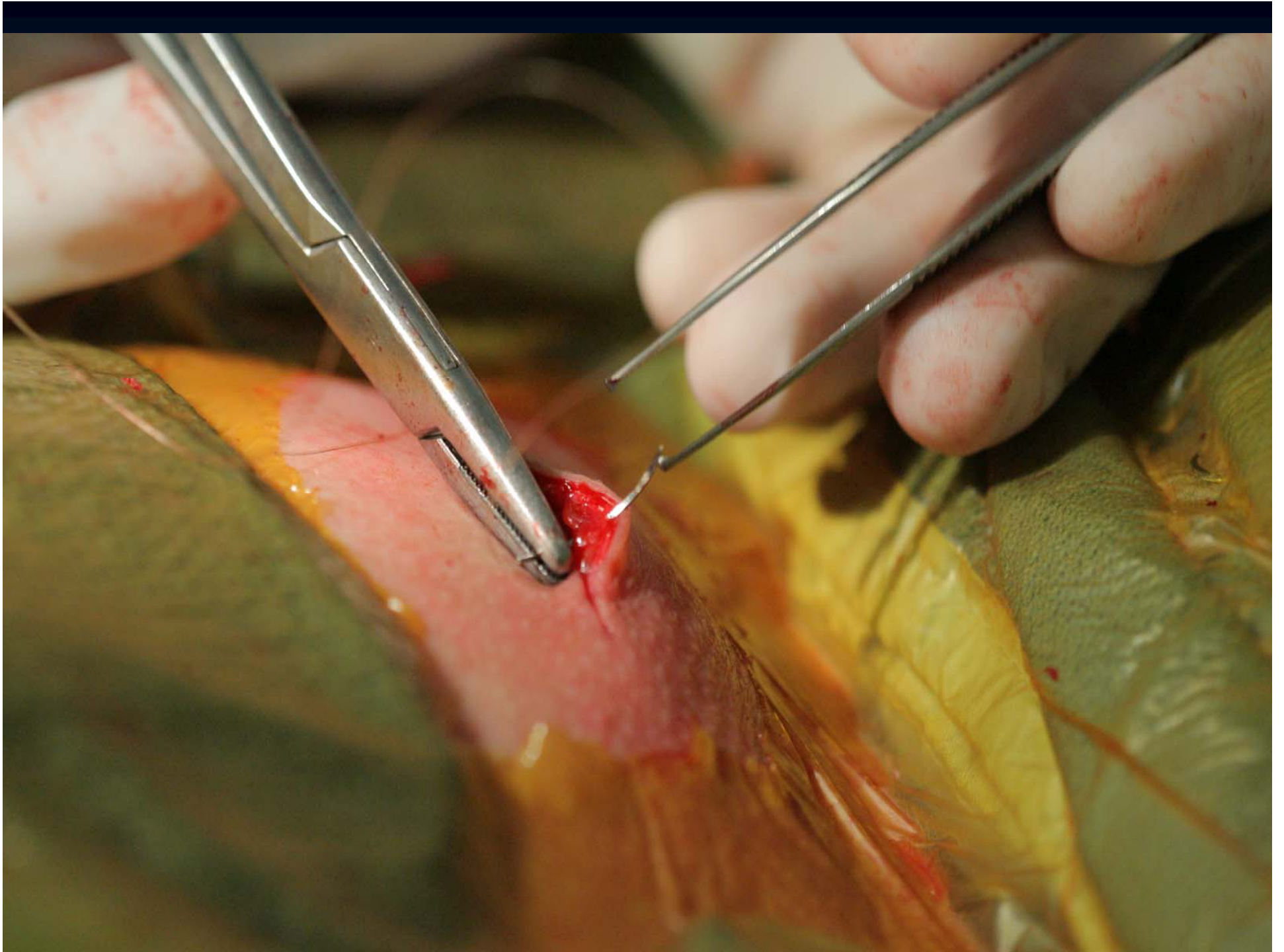
Methods and Results:

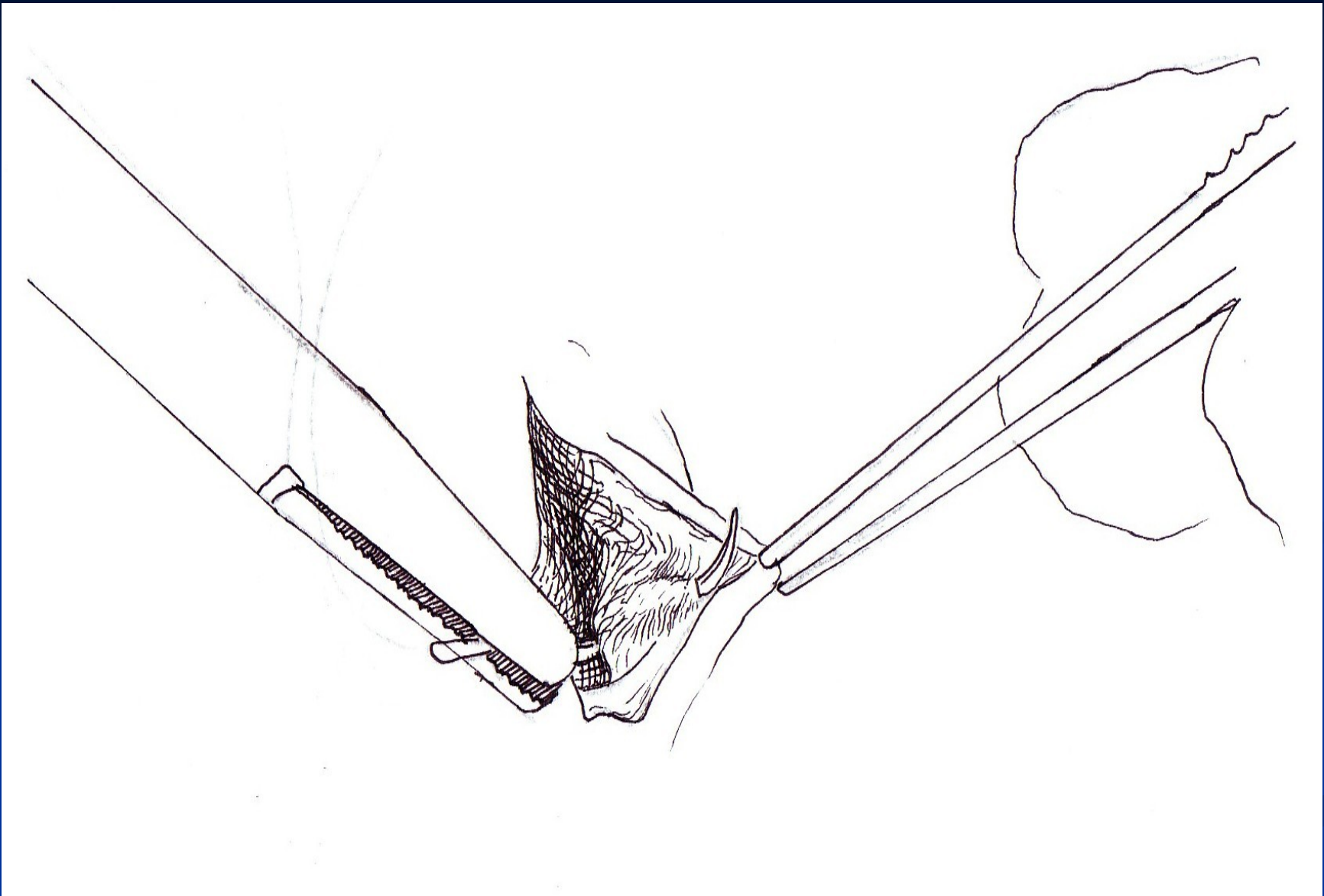
- **Study was approved by IRB**
- **Patients were recruited from amongst those individuals undergoing routine cardiac device implantation (either new or replacement) at our institution.**
- **A total of 124 patients were included in the study.**

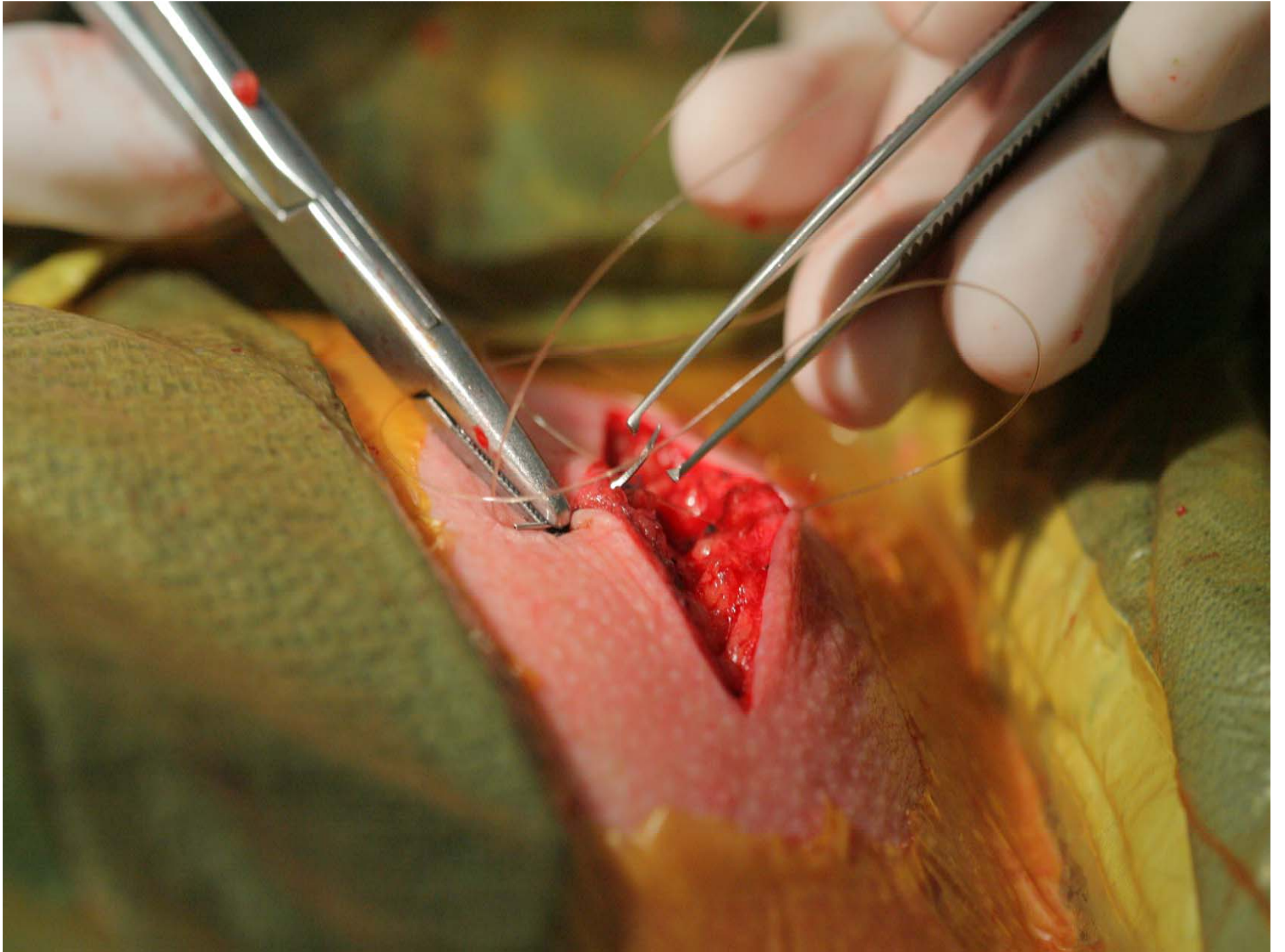
Would closure Technique

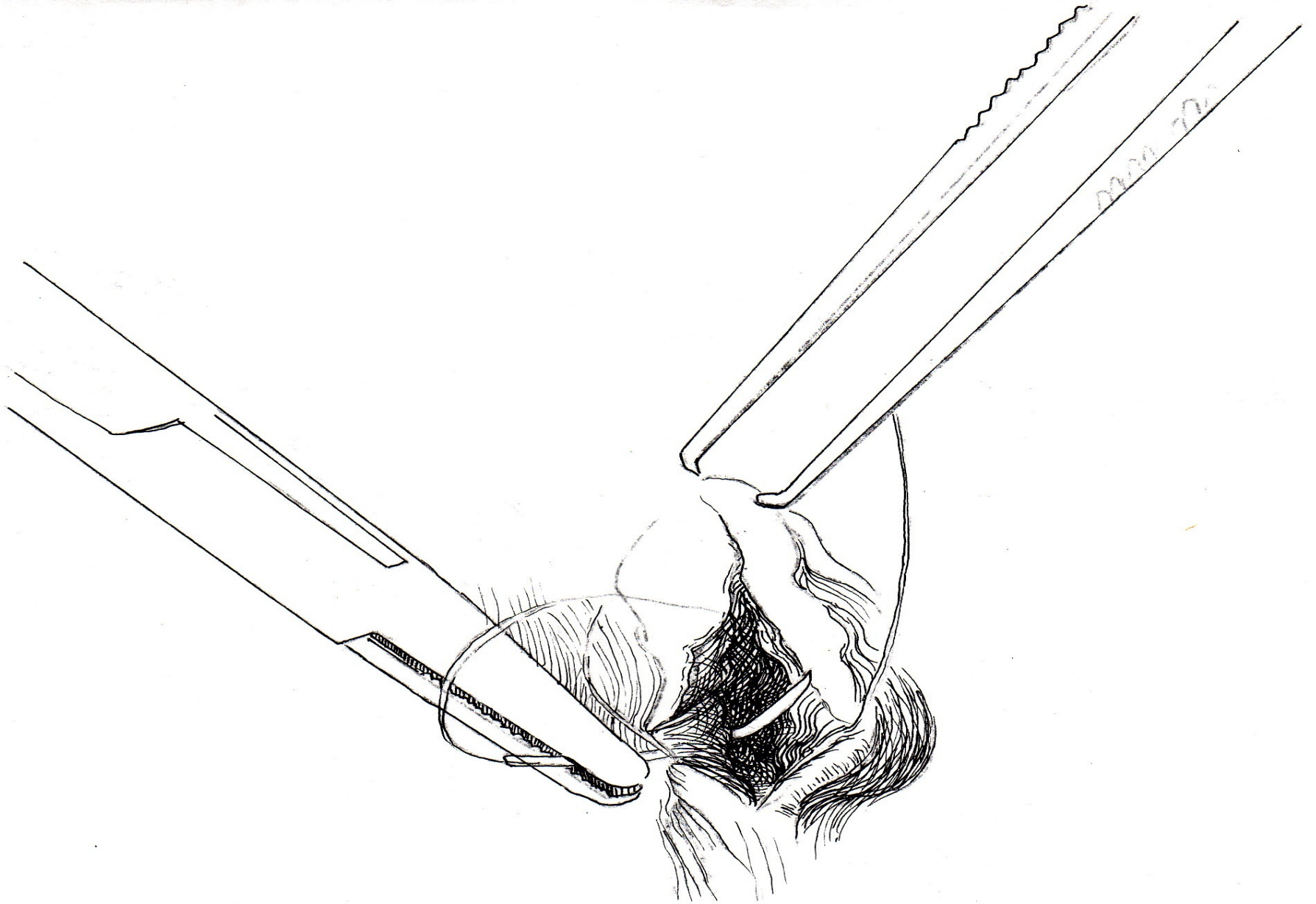
- **Introduction: Infection is a well-recognized complication that can occur following the implantation of cardiac devices such as pacemakers and implantable defibrillators (ICDs).**
- **Reported infection rates following new device implantation are reported to be around 1 % while infection rates following device generator replacements are higher with a reported average of up to 4-5% per year(1-4).**
- **We report here our experience using a modified plastic surgical technique for cardiac device wound closure designed to both reduce infections and enhance cosmetic outcomes.**





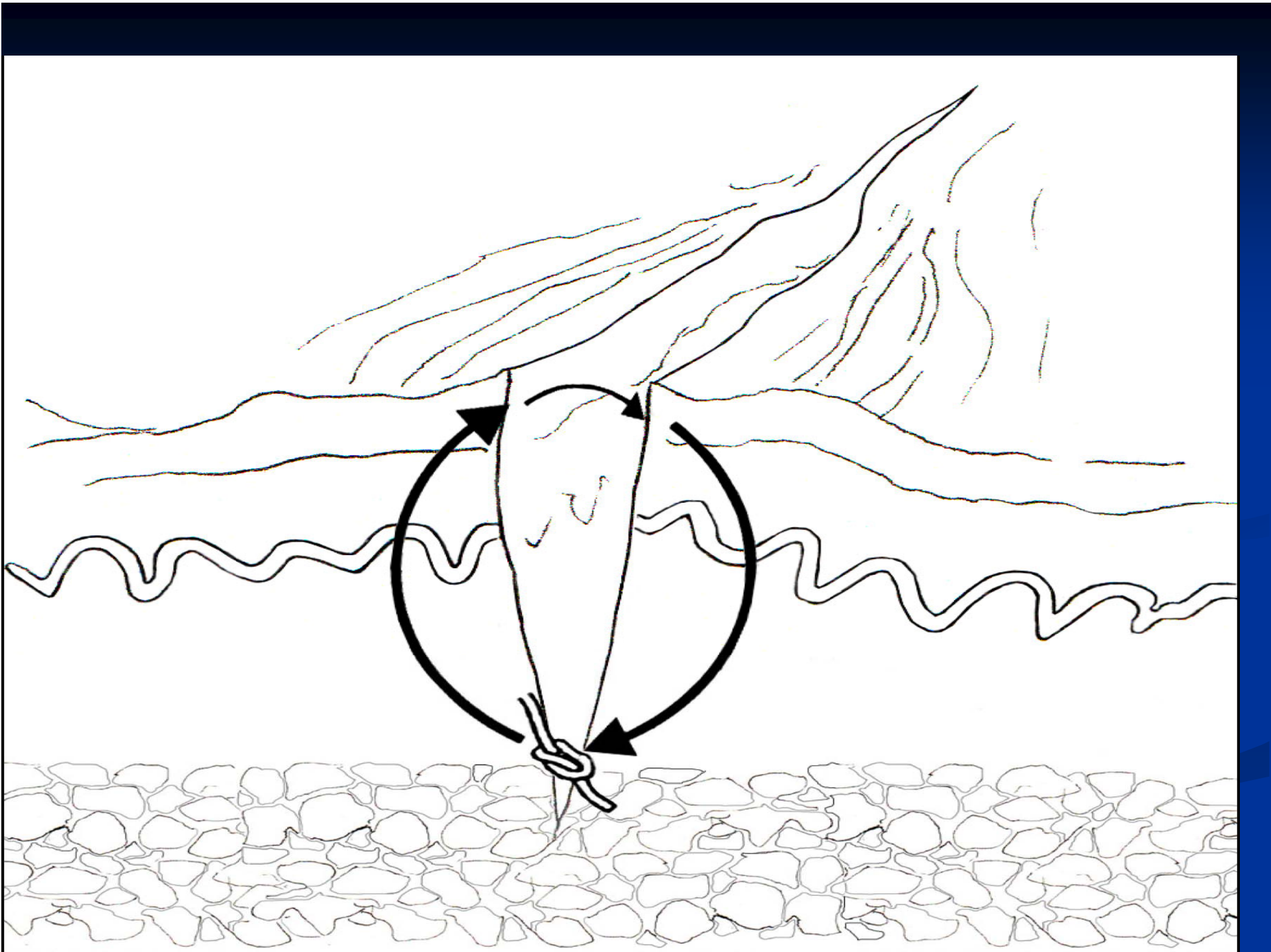






















Appearance of pacemaker scar one month after insertion



Long Term Wound Closure Data



- Data collected
 - Age
 - Sex
 - BMI
 - Preoperative antibiotics
 - Comorbidities
 - Diabetes
 - Obesity
 - Hypertension
 - Coronary artery disease
 - Current or past history of smoking
 - Corticosteroid use
 - Infections
 - Wound dehiscence
 - Time between implantation and most recent follow up

Results in wound closure

- 313 total patients
 - 118 Males
 - 195 Females
 - Mean age: 54 ± 25 years
 - 169 Loop Recorders
 - 105 Pacemakers
 - 24 Cardioverter-defibrillators
 - 13 Biventricular Cardioverter-defibrillators
- Follow up ranged between 1 month and 69 months
- 1 case of wound dehiscence of ILR (due to heavy radiation to chest for breast CA)
- 1 case of allergic reaction to the metal of the device in ILR
- 1 case of infection
 - Infection rate of 0.32%

Primary Infections between 7/1/09 and 7/21/14

Standard closure: 383

23 infections (14 ICDs, 9 pacemakers)

12 within first month

11 within 90 days (CMS criteria)

6 % infection rate

Modified closure: 313

1 infection

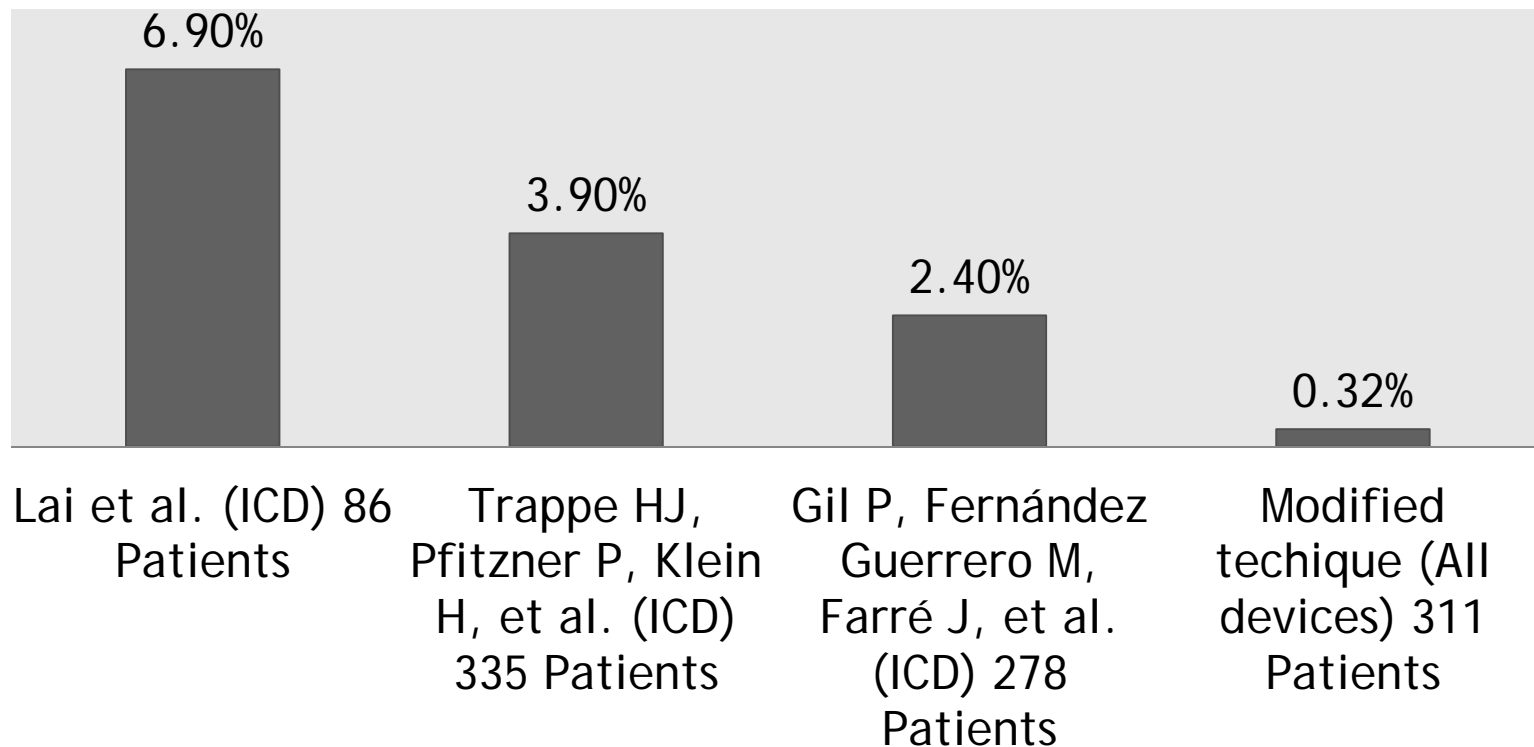
0.3% infection rate



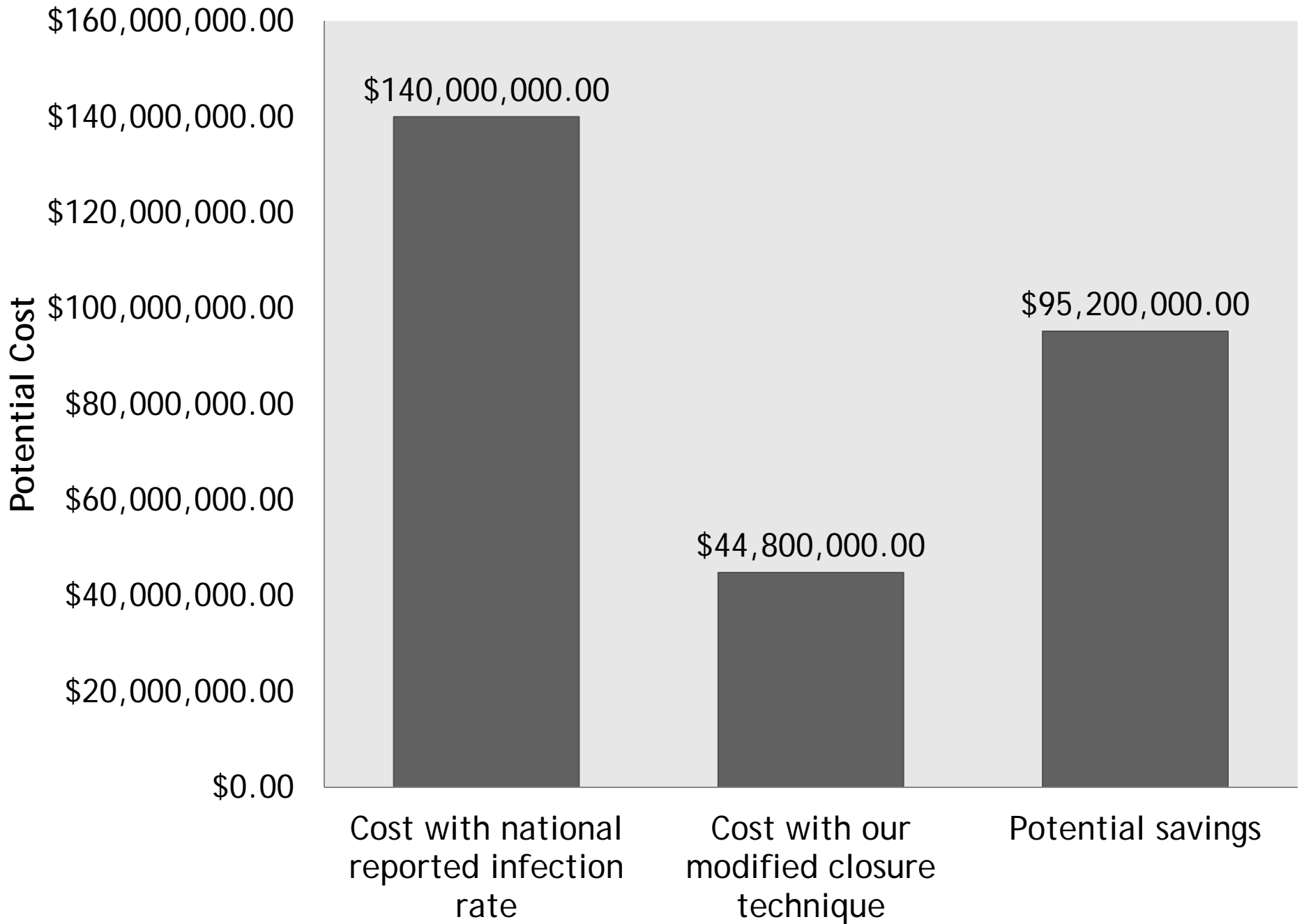


Discussion

Infection Rates



Potential Saving Using the Modified Closure Technique



“He who saves a single life, it is as if
he had saved an entire world...”



Pirke Avot
The Talmud
200 C.E.



“May I never forget that the patient is a fellow creature in pain. May I never consider him only a vessel of disease”



Maimonides:
The Physicians' Oath
12th Century C.E.

For Barbara Straus MD

1950 - 2015

*Physician, Mother, Dancer, Wife
Community leader, Educator, Adventurer*



May her memory be for a blessing...

"If I have accomplished anything in life it is all because of you"

*"I would like to be known as an intelligent woman,
a courageous woman, a loving woman, a woman
who teaches by being..."*

Maya Angelou



Barbara Lynn Straus
"A Life well Lived"