# Does Changing the Pacing Configuration Affect Phrenic Stimulation?

## - A substudy of the DETECT PS Trial -

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**On behalf of the Detect PS Investigators**

# Quantification of Phrenic Stimulation Threshold Changes with Posture

## - A substudy of the DETECT PS Trial -

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**On behalf of the Detect PS Investigators**

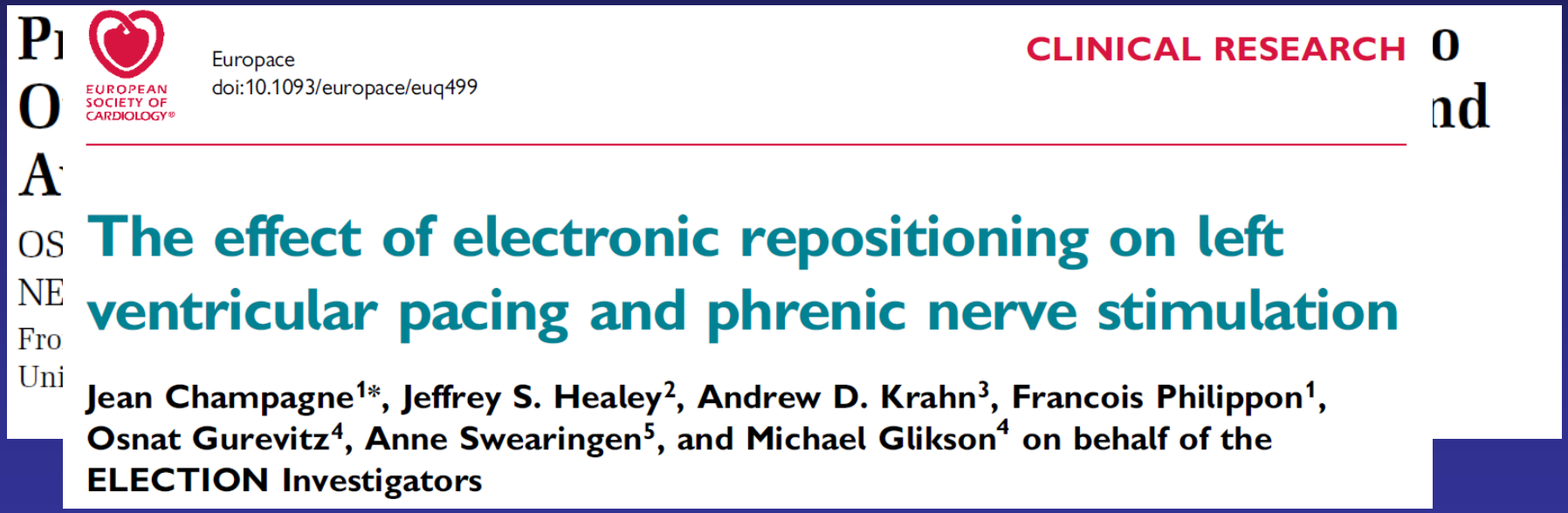
# Conflicts of Interest

**Detect PS study was funded and organized by Boston Scientific**

- **Michael Glikson, MD**
  - **Speaker bureau and educational activity, Boston Scientific and Medtronic. Research grant support from Medtronic and Biotronik**
- **Vladmir Khalameizer, MD**
  - **n/a**
- **Dominique Babuty, MD**
  - **Honoraires from Boston Scientific, Saint Jude, Sorin, Medtronic.**
- **Sunipa Saha**
  - **Boston Scientific employee**
- **Holly Rockweiler**
  - **Boston Scientific employee**
- **Mauro Biffi, MD**
  - **Modest speaker bureau and educational activity from Biotronik, Boston Scientific, and Medtronic**
- **Bela Merkely, MD**
  - **Consultant fees/honoraria from Boston Scientific**
- **Oliver Przibille, MD**
  - **Speaker/Honoraria: Medtronic; Consultant/Advisory Board: Biotronik, Boston Scientific**

# Phrenic Nerve Stimulation (PS)

- Found in 20-30 % of patients implanted with CRT may lead to surgical revision or LV lead abandonment in up to 5-10% of cases



Europace
doi:10.1093/europace/euq499

CLINICAL RESEARCH

## The effect of electronic repositioning on left ventricular pacing and phrenic nerve stimulation

Jean Champagne[1]*, Jeffrey S. Healey[2], Andrew D. Krahn[3], Francois Philippon[1], Osnat Gurevitz[4], Anne Swearingen[5], and Michael Glikson[4] on behalf of the ELECTION Investigators

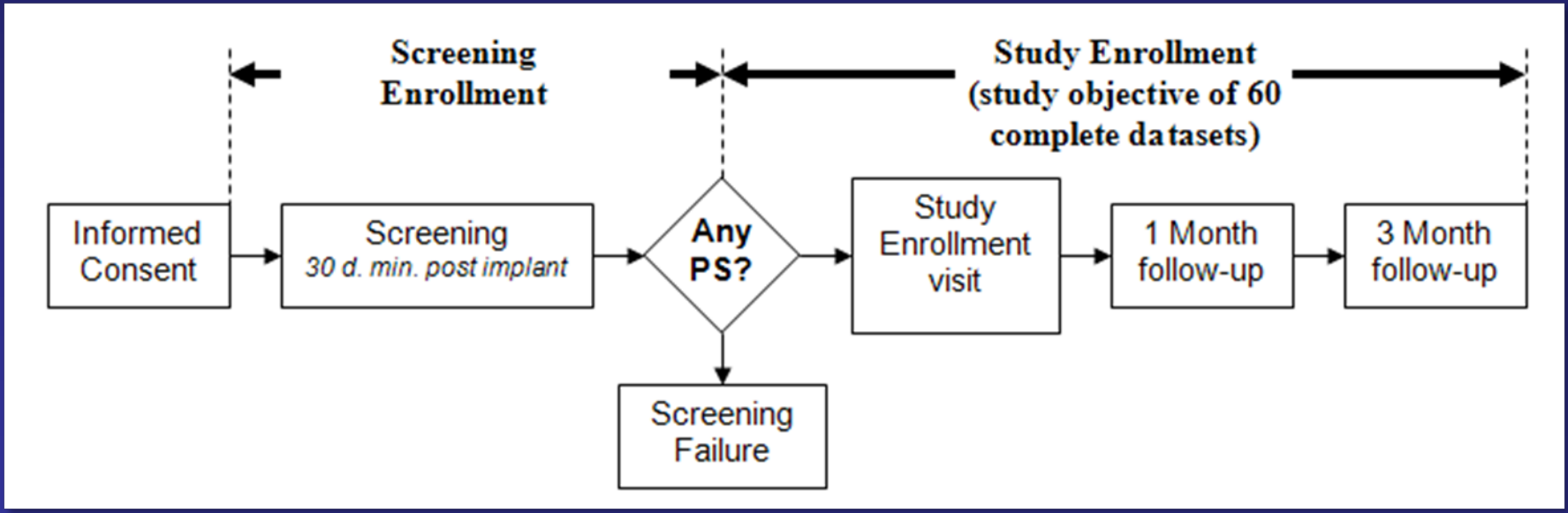
# Detection of Phrenic Nerve Stimulation using Accelerometer and Electrogram Signals (DetectPS) Clinical Study

- 17 centers , 7 countries, 3 Israeli centers
- Main Objective: collect sensor data during PS in order to design an automatic PS detection algorithm

- Secondary Objectives:
  - Evaluate the relationship between different LV pacing configurations and PS
  - Evaluate the influence of a change in body posture on PS
  - Characterize the impact of changing pulse widths on PS
  - Evaluate the changes over time in PS thresholds and prevalence
  - Evaluate the relationship between pt characteristics and PS

# Methods

Data were recorded from 60 patients with Cognis ® CRTD during induced episodes of PS using manual and automatic algorithms for testing LV capture and PS thresholds



# Patient & Device Demographics

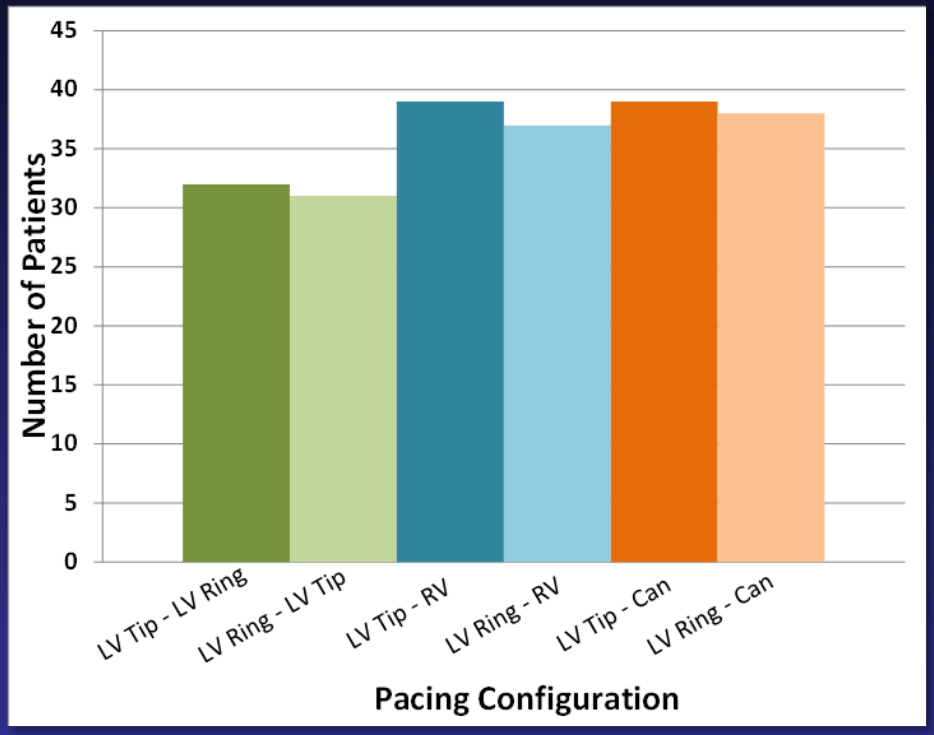
| | All Patients | All Enrolled Patients | Patients without PS at Screening |
|---|---|---|---|
| Number of Patients | 164 | 60* | 104 |
| LVEF (%) | 28.8 ± 7.2 | 30.4 ± 7.3 | 27.8 ± 7.1 |
| NYHA (I/II/III/IV/Unknown) | 22/100/37/0/5 | 11/34/12/0/3 | 11/66/25/0/2 |
| BMI | 27.4 ± 4.3 | 27.4 ± 4.1 | 27.4 ± 4.5 |
| Pocket Location (L Pectoral/R Pectoral/L Submusc/Unknown) | 153/6/1/4 | 56/2/0/2 | 97/4/1/2 |
| Number of Acute Device at Screen/Enroll (≤ 60 days) | 32 | 18 | 14 |
| Number of Acute LV Leads at Enrollment (≤ 60 days) | 23 | 13 | 10 |
| LV Lead Position (Left Lateral/Posterior/Other) | 97/26/41 | 36/9/15 | 61/17/26 |
| LV Lead Manufacturers (BSC/MDT/STJ/Unknown) | 125/25/12/1 | 43/12/4/0 | 82/13/8/1 |

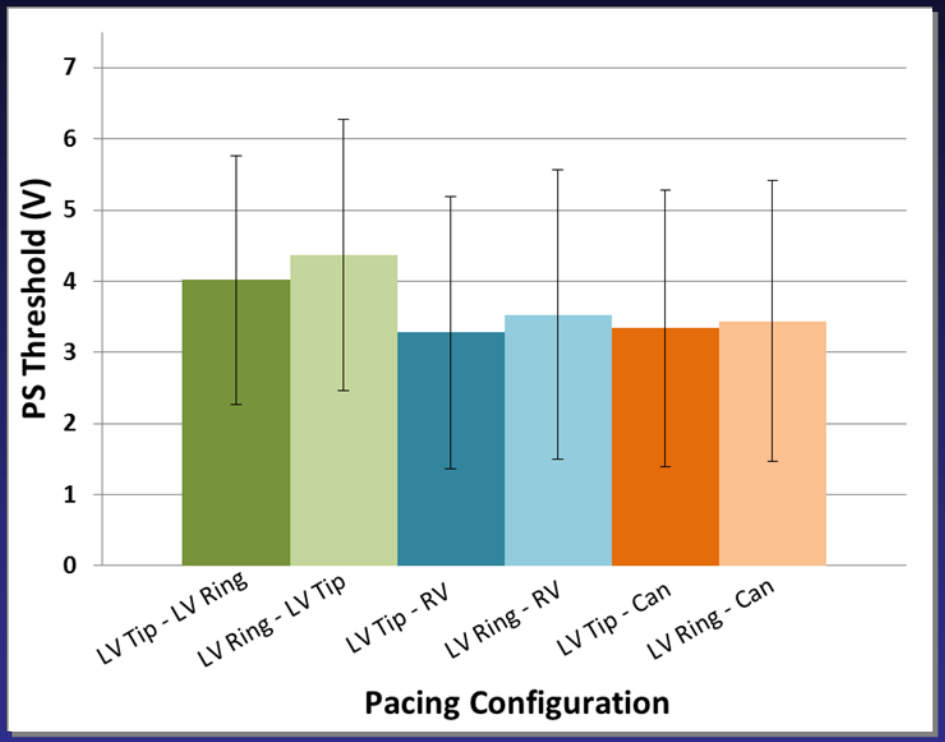
* 53 complete data sets were obtained from 15 sites

# Pacing Configuration Testing

- Programmer-driven, automatic, step-up LV pacing voltage tests [0.8V to 7.5V] were conducted at a pulse width of 0.4ms in up to 6 pacing vectors:
  - 2 bipolar
  - 2 extended bipolar (LV-RV)
  - 2 unipolar (LV-Can)
- Patient-reported PS thresholds were recorded for each test
- Cathodes tested: LV Tip and LV Ring
- Anodes tested: LV Ring/Tip, RV, or Can

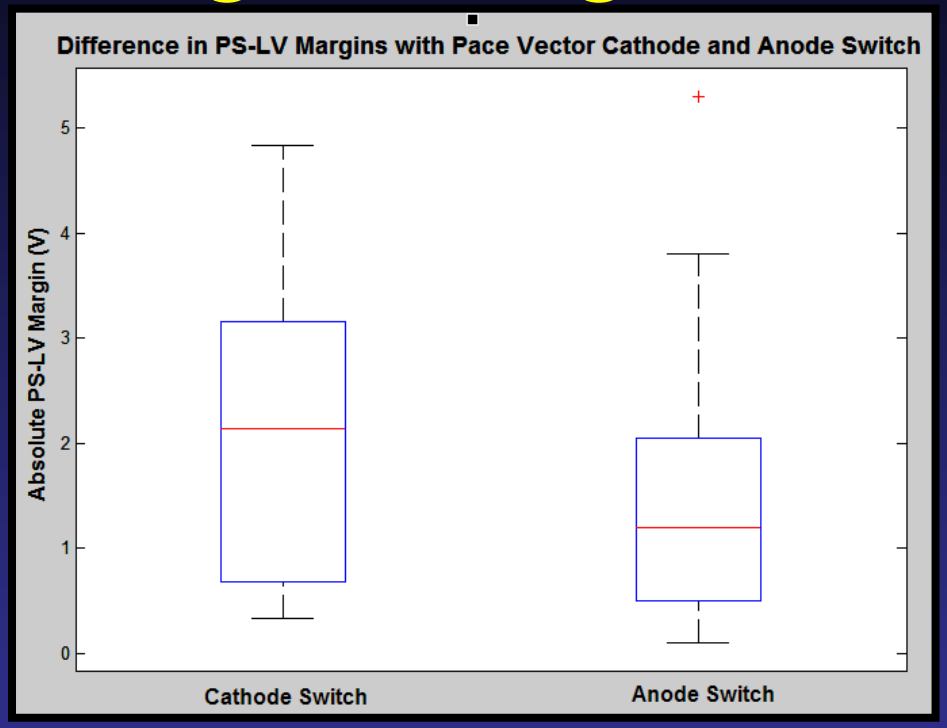
# PS in various Pacing Configurations ( n = 53 , 1 month test, PW = 0.4 msec)




- Presence of PS and PS thresholds are similar across different pacing configurations
- >25% of patients exhibited PS in all 6 configurations

# PS & Pacing Configurations




| | Average ΔPS-LV threshold margin | % Pts who lost PS at 7.5V with switch | % Remaining pts who gained a PS-LV margin ≥2.0V |
|---|---|---|---|
| Switching cathode | 2.1±1.4V | 38% | 55% |
| Keeping cathode constant, switching anode | 1.4±1.1V | 25%, 32% | 23%, 22% |

# Conclusion

- The likelihood of observing PS is similar across different pacing configurations (bipolar, extended bipolar, and unipolar)
- Some patients exhibit PS in all 6 pacing configurations
  - Testing the PS threshold or PS-LV margin in all six configurations will be necessary to program the LV output
- Changing the pacing cathode has a larger impact on the PS-LV threshold margin than changing the pacing anode
  - Changing the cathode results in higher likelihood of avoiding PS at 7.5V (40%)
  - However, PS may be avoided in up to 1/3 of patients by changing the anode

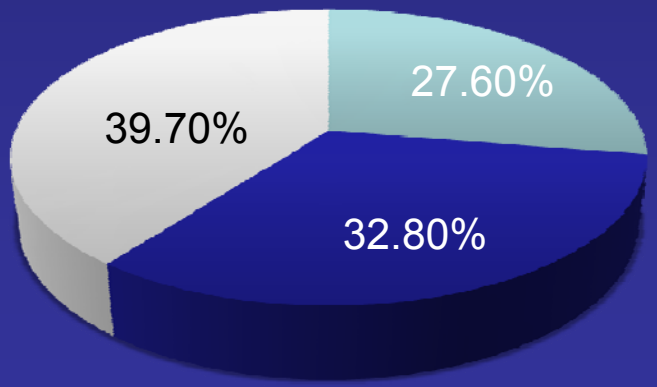
# Posture Testing

- PS threshold testing at Enrollment Visit was extended to include posture variation:
  - Sitting
  - Supine
  - Left Lateral Recumbent
- Step-up pacing test conducted in the pacing configuration-pulse width combination with the lowest PS voltage threshold

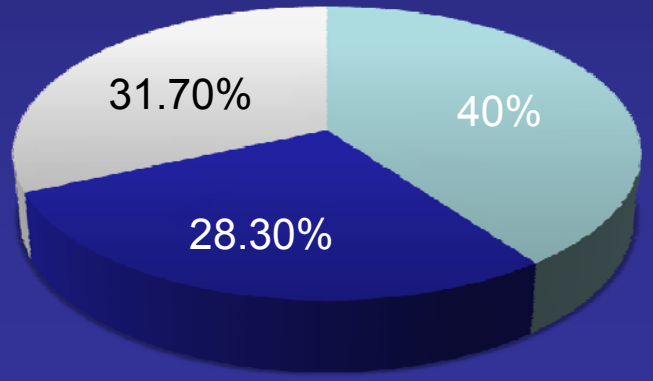
# Results

- PS presence and thresholds differed across postures for all patients
- Posture with the highest or lowest PS threshold also varied
  - Average PS threshold for each posture:
    - Left-Lateral Recum. = 2.78 V, Sitting = 3.02 V, Supine = 2.70 V

Posture with the Highest PS Threshold

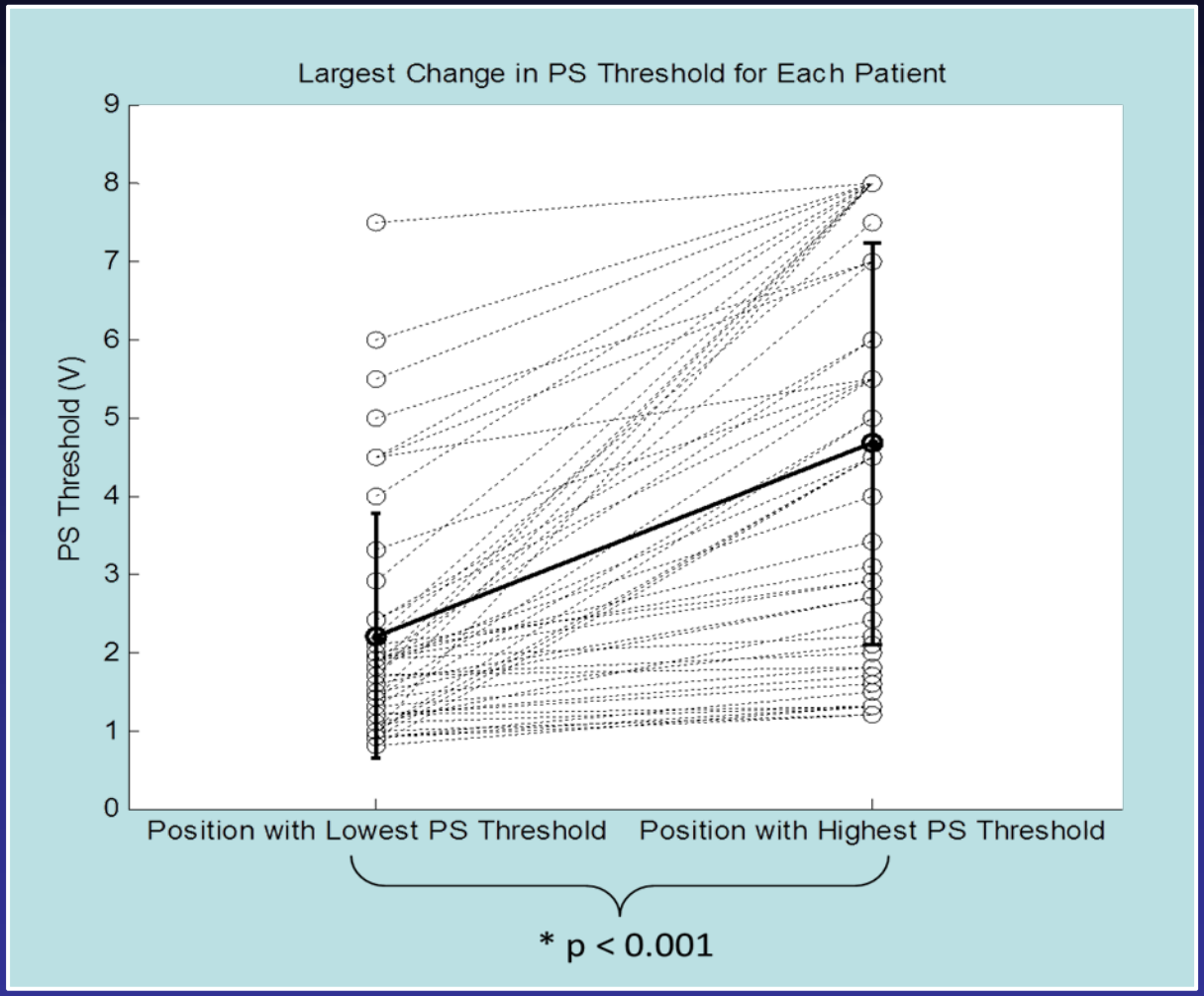



Posture with the Lowest PS Threshold



# Results

- The largest single change between postures ranged from 0.1-7V
- Mean change across postures = 2.5V+/-2V




Error bars = standard deviation

# Results

- Most patients demonstrated PS in all 3 postures
- Patients with PS in all 3 postures had lower PS thresholds on average

| Percent of Patients with PS | | Average PS Threshold Across Postures (V) |
|---|---|---|
| 1 Posture | 9% | 4.2 +/- 2.4 |
| 2 Postures | 15% | 4.5 +/- 2.4 |
| 3 Postures | 75% | 2.6 +/- 1.7 |

# Conclusion

- PS thresholds can significantly change with posture
- Of the 3 tested postures (sitting, supine, left lateral recumbent), no single posture consistently has the lowest PS threshold
- In a patient with PS it is recommended to test all postures for PS thresholds when adjusting outputs

# List of Centers and PI's

| Country | Site code | Site Name | City | PI Name | Screened patients | Enrolled patients | Withdrawn patients |
|---|---|---|---|---|---|---|---|
| Austria | AUGR | Medizinische Universität | Graz | Dr Rotman | 24 | 9 | 0 |
| France | FRTO | CHU – Hôpital Trousseau | Tours | Pr Babuty | 15 | 6 | 0 |
| Germany | GEHL | University Hospital | Halle | Dr Heinroth | 8 | 4 | 1 |
| | GEBO | HDZ NRW | Bad Oeynhausen | Dr Gutleben | 8 | 2 | 0 |
| | GEBH | DHZ Berlin | Berlin | Dr Götze | 8 | 4 | 1 |
| | GEBU | Herzzentrum | Bernau | Dr Butter | 3 | 2 | 0 |
| | GEFR | CCB Frankfurt | Frankfurt | Dr Przibille | 12 | 0 | 0 |
| | GEMO | Otto von Guericke Univ. Hospital | Magdeburg | Pr Braun-Dullaeus | 4 | 0 | 0 |
| Hungary | HUBU | Semmelweis University Hospital | Budapest | Pr Merkely | 6 | 3 | 0 |
| Israël | **ISTE** | **Sheba Medical Center** | **Tel Hashomer** | **Pr Glickson*** | 6 | 1 | 0 |
| | ISAS | Barzilaï Medical Center | Ashkelon | Dr Khalameizer | 8 | 3 | 1 |
| | ISTA | Ichilov Medical Center | Tel Aviv | Pr Zeltser | 9 | 5 | 1 |
| Italy | ITRR | Ospedale Civile Rovigo** | Rovigo | Dr Zanon | NA | NA | NA |
| | IT56 | Policlinico Tor Vergata | Roma | Pr Romeo | 7 | 0 | 0 |
| | ITBO | Ospedale San Orsola - Malpighi | Bologna | Pr Boriani | 28 | 18 | 2 |
| | ITO5 | Presidio Ospedaliero Policlinico Casilino | Roma | Dr Calò | 18 | 3 | 0 |
| Poland | PLKM | All Medicus** | Katowice | Dr Gibinski | NA | NA | NA |

Thank you.

Questions?