



Lahey Hospital
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Leadless pacing with fixation by hook mechanism

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October 16 - 18
14th EDITION **2015**



MY CONFLICTS OF INTEREST ARE

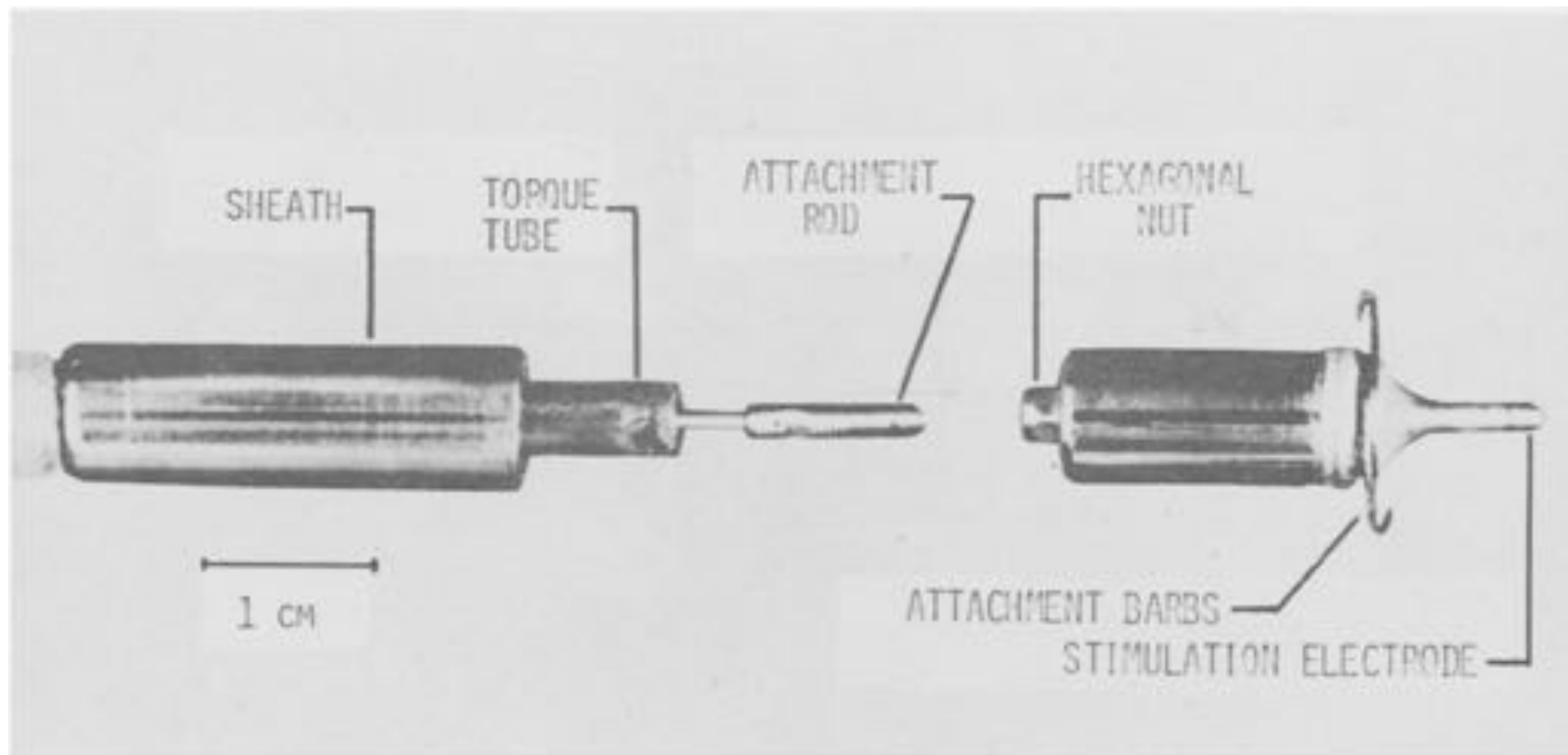
Consultant: Medtronic

Consultant: St. Jude Medical

Special Article

Totally Self-Contained Intracardiac Pacemaker*

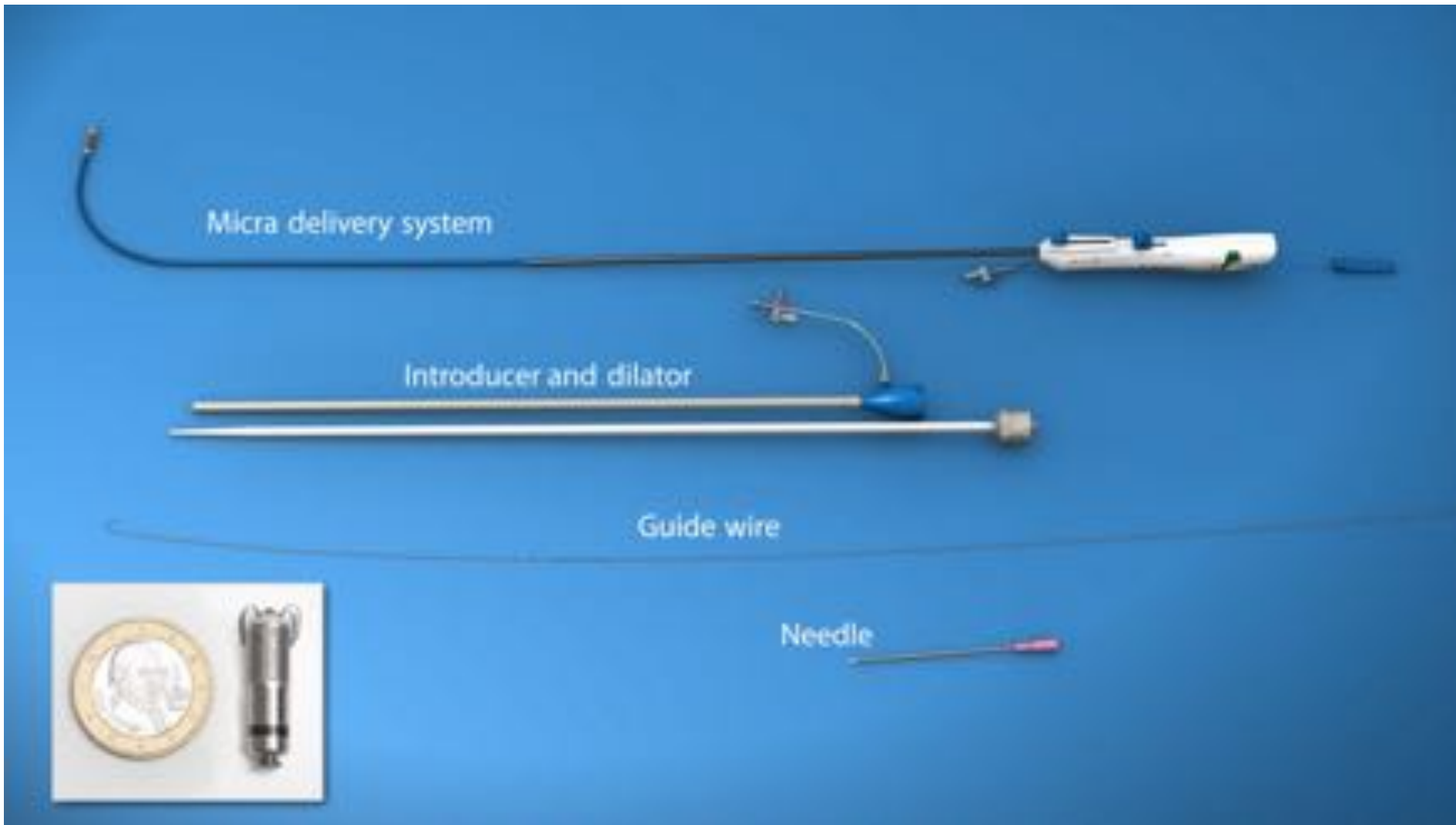
J. WILLIAM SPICKLER, PH.D., NED S. RASOR, PH.D.†, PAUL KEZDI, M.D.
S. N. MISRA, M.D., K. E. ROBINS, P.E., AND CHARLES LeBOEUF, P.E.





Micra Device Features

| | |
|---------------------|---|
| Size | 7mm x 26mm, 2 grams |
| Fixation | nitinol tines |
| Rate Response | accelerometer-based |
| Capture management | yes (threshold +0.5V with hourly confirmation) |
| Communication | standard programmer (Medtronic 2090) |
| MRI compatibility | yes |
| Battery | lithium silver vanadium oxide/carbon monofluoride |
| Projected Longevity | 12 years |



Micra delivery system

Introducer and dilator

Guide wire

Needle

Protective Sleeve Being Withdrawn - Tines Extending

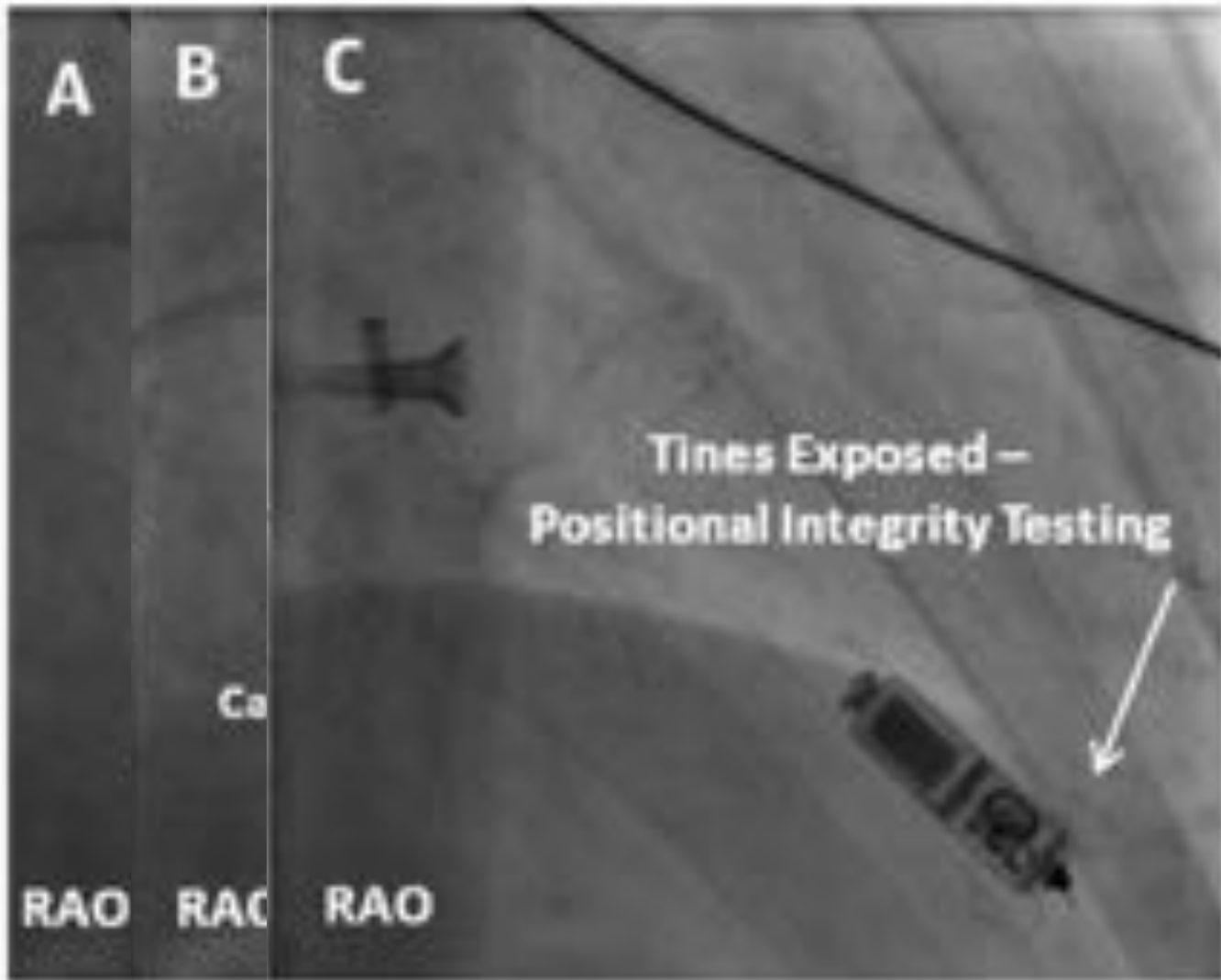


Tines Completely Retroflexed - Micro Still In Sheath



Sleeve Withdrawn - Micro Remains Tethered at Delivery Tool Interface





The rationale and design of the Micra Transcatheter Pacing Study: safety and efficacy of a novel miniaturized pacemaker

**Philippe Ritter^{1,2*}, Gabor Z. Duray³, Shu Zhang⁴, Calambur Narasimhan⁵,
Kyoko Soejima⁶, Razali Omar⁷, Verla Laager⁸, Kurt Stromberg⁸, Eric Williams⁸, and
Dwight Reynolds⁹ for the Micra Transcatheter Pacing Study Group**

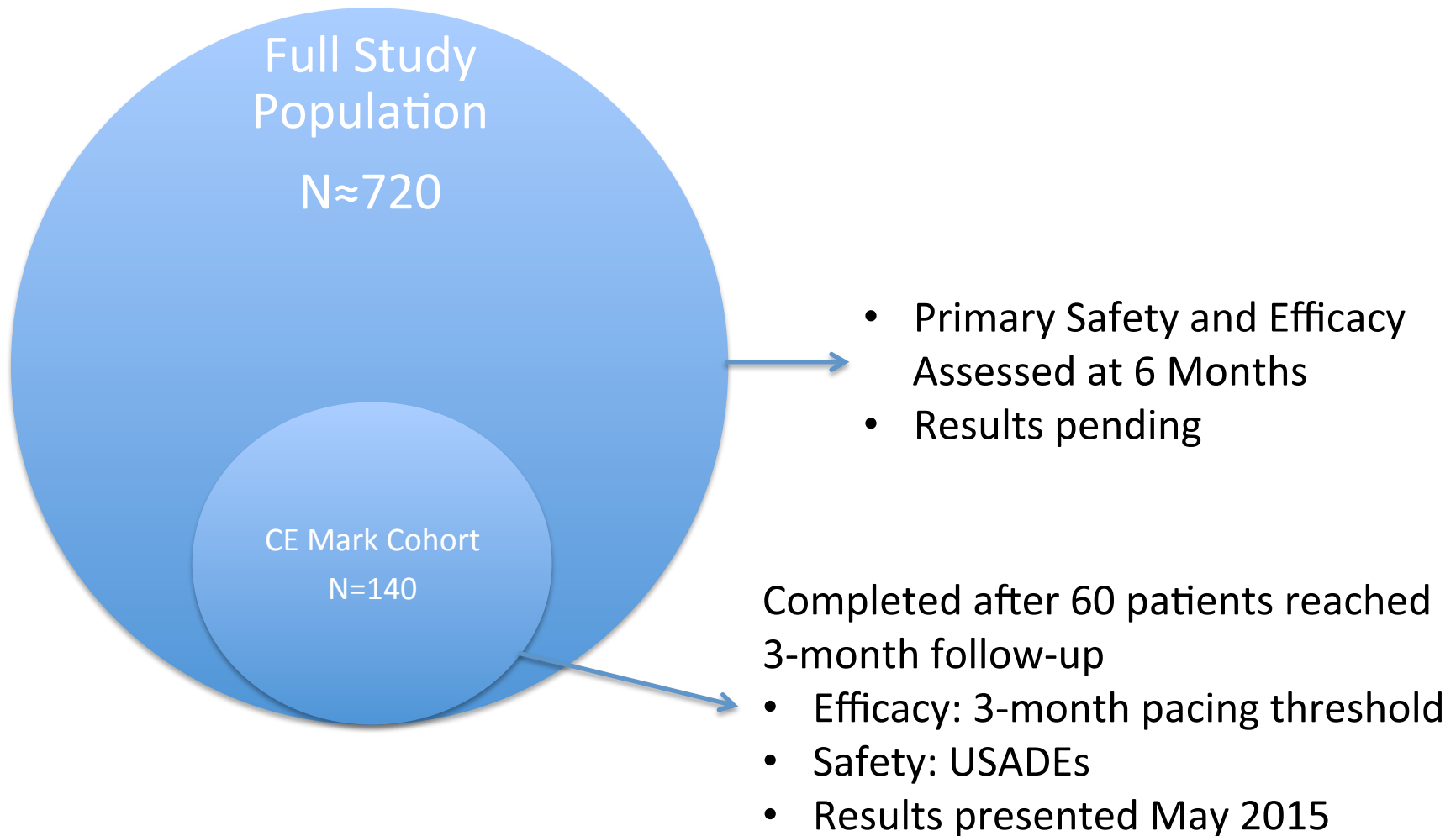
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Received 11 October 2014; accepted after revision 17 January 2015; online publish-ahead-of-print 8 April 2015

Micra Transcatheter Pacing Study (TPS)

- International non-randomized study designed to meet regulatory requirements for both EU and USA
- Patients with guideline Class I or II indications for single chamber ventricular pacing included
- Pacemaker dependence (escape rhythm ≤ 30 bpm) excluded for first 25 patients
- Primary safety and safety goals based on performance criteria derived from recent Medtronic transvenous pacemaker studies

Micra TPS Overview





Early performance of a miniaturized leadless cardiac pacemaker: the Micra Transcatheter Pacing Study

Philippe Ritter^{1*}, Gabor Z. Duray², Clemens Steinwender³, Kyoko Soejima⁴, Razali Omar⁵, Lluís Mont⁶, Lucas VA Boersma⁷, Reinoud E. Knops⁸, Larry Chinitz⁹, Shu Zhang¹⁰, Calambur Narasimhan¹¹, John Hummel¹², Michael Lloyd¹³, Timothy Alexander Simmers¹⁴, Andrew Voigt¹⁵, Verla Laager¹⁶, Kurt Stromberg¹⁶, Matthew D. Bonner¹⁶, Todd J. Sheldon¹⁶, and Dwight Reynolds¹⁷, Micra Transcatheter Pacing Study Group

Patient Characteristics

| Micra TPS: CE Mark Population | N=140 |
|--|-------------|
| Age, yrs | 77.0 ± 10.2 |
| Male | 85 (60.7%) |
| Pacing Indication: | |
| AV block with atrial arrhythmia | 72 (51.4%) |
| Sinus node dysfunction | 40 (28.6%) |
| 2 nd -3 rd degree AV block ± SND | 21 (15.0%) |
| Syncope | 55 (39.3%) |
| Heart failure | 13 (9.3%) |

| | |
|---|---------------|
| Implant attempted ($n = 140$) | |
| Received TPS | ($n = 140$) |
| Did not receive TPS | ($n = 0$) |

Position attempts:

1 = 59%

2 = 22%

>2 = 19%

↓

| | |
|---------------------------|-------------|
| Follow-up | |
| Death | ($n = 1$) |
| Lost to follow-up | ($n = 0$) |
| Discontinued intervention | ($n = 0$) |

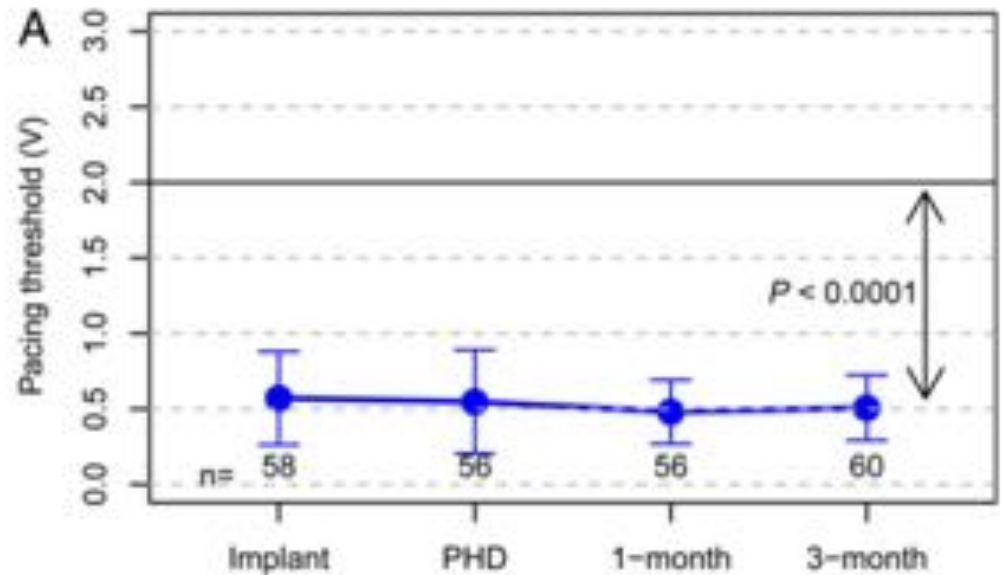
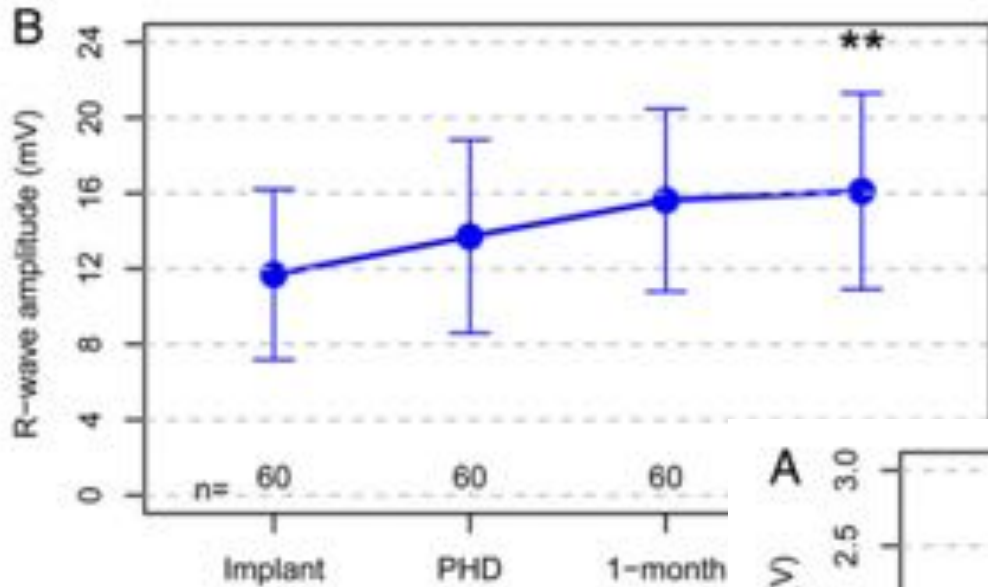
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| | |
|--|---------------|
| Analysed for early performance objectives | |
| Safety | ($n = 140$) |
| Three-month efficacy | ($n = 60$) |

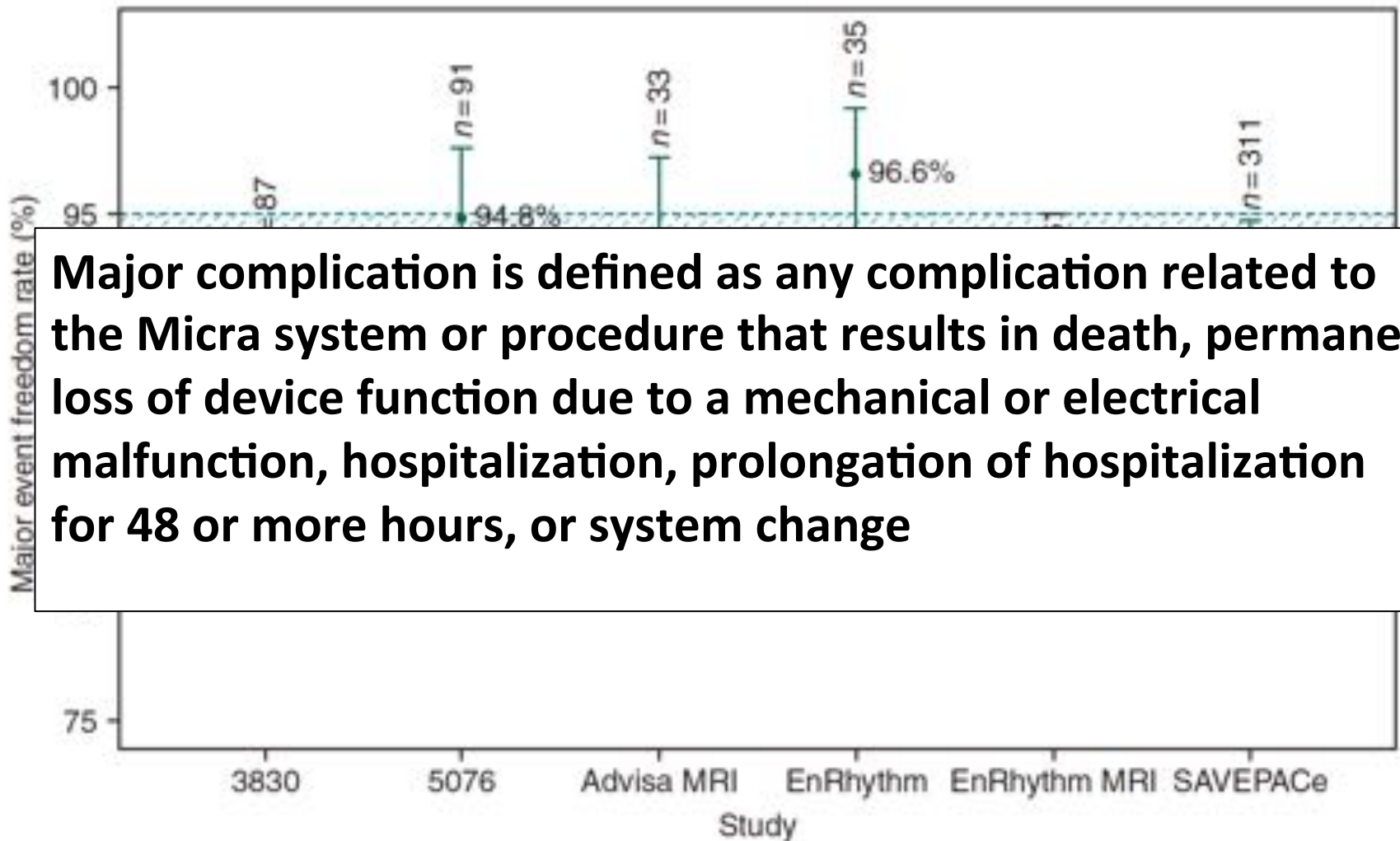
Safety Results

- No USADEs (CE mark end point)
- 30 adverse events in 26/140 (18.6%) patients
- 4 cases transient AV block, 3 managed with temporary pacing wires
- 11 access site complications, mostly minor bleeding
- Two serious adverse events
 - 1 psuedoaneurysm managed with thrombin injection
 - 1 significant pericardial effusion with drain inserted (90 year old female, 18 repositioning of device)

Pacing Efficacy (n=60)



6-Month Safety End Point: Freedom From Major Complications

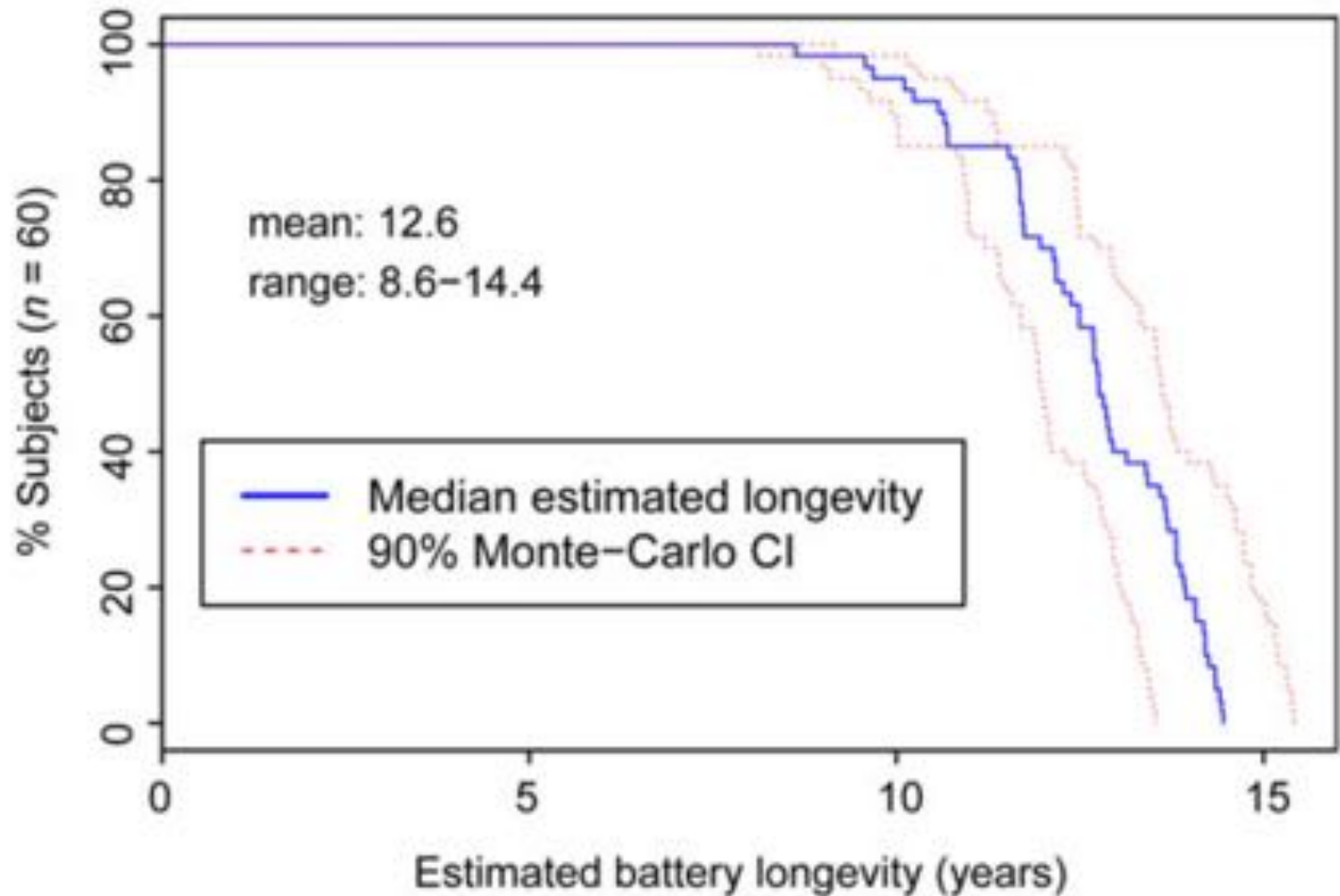


Major complication is defined as any complication related to the Micra system or procedure that results in death, permanent loss of device function due to a mechanical or electrical malfunction, hospitalization, prolongation of hospitalization for 48 or more hours, or system change

6-Month Effectiveness

- pacing capture threshold of ≤ 2 V at 0.24 ms without increasing by more than 1.5 V from implant
- The primary efficacy objective will be met if the percentage of subjects meeting this endpoint is significantly $>80\%$ (i.e. lower boundary of the two-sided confidence interval must be $>80\%$)

Projected Longevity



Conclusions

- The Micra “leadless” pacing system is entering world-wide commercialization
 - CE Mark granted April 2015
 - US registration study to be presented Nov. 2015
- Early results show high procedural success, low rate of serious complications, excellent pacing efficacy
- This and other systems will offer an alternative to traditional transvenous single-chamber pacing



The Future?

