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# INTRAOPERATIVE PREDICTORS OF SACRAL NEUROMODULATION IMPLANTATION & TREATMENT RESPONSE - RESULTS FROM ROSETTA

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# Sacral Neuromodulation & ROSETTA

- Sacral neuromodulation (SNM) for overactive bladder (OAB)
  - Over 80% of patients had successful Stage 1 test stimulation[1]
  - Therapeutic success is 64% - 81% at 1-2 years after implant[1]

- ROSETTA[2]
  - Sacral neuromodulation vs 200 units onabotulinum toxin
  - Prospective, randomized, controlled, open-label comparison
  - Women with overactive bladder who failed 2+ medications

1. Noblett K, et al. Neurourol Urodyn. 2018; 37(5): 1667-71. | 2. Amundsen C, et al. JAMA. 2016; 316(13): 1366-74.

# What Predicts SNM Success?

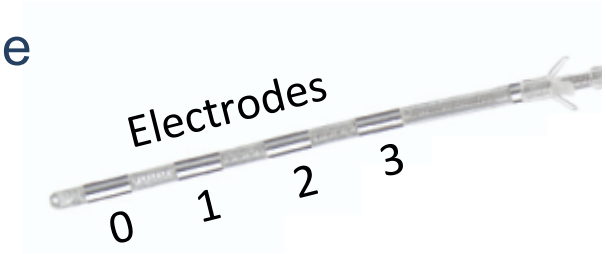
- Intraoperative predictors
  - Testing sensory response is not associated with outcomes[1]
  - Motor response *may* be associated with success & durability[2,3]

- Hypothesis: Stage 1 success and long-term reduction in daily urgency incontinence are associated with more definitive intraoperative responses at lower amplitudes.

1. Peters, et al. Neurourol Urodyn. 2011; 30: 1489-92. | 2. Pizarro-Berdichevsky, et al. J Urol. 2018; 199: 1032-6.
3. Cohen, et al. J Urol. 2006; 175: 2178-81.

# Primary ROSETTA Data & Testing Details

- Demographics, baseline & follow-up OAB symptoms, surgeries
- Collected intraoperatively for each electrode
  - Stimulation amplitude (threshold)
  - Subjective strength of motor response
  - Subjective strength of sensory response



# Intraoperative Parameter Collection

**First Stage Lead Placement (Surgical Team to Complete): INTRAOPERATIVE DATA**

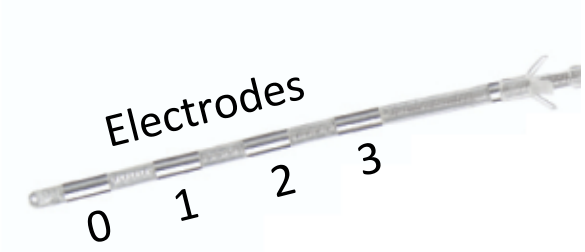
**Intraoperative Motor Response and Stimuli Used to Test:** (Enter stimuli data and check all that apply)

| Electrode | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Amplitude | | | | |
| Rate | | | | |
| Pulse Width | | | | |
| Pelvic Response or Bellows: | 0. ☐ Absent | 0. ☐ Absent | 0. ☐ Absent | 0. ☐ Absent |
| | 1. ☐ Small, less than normal; trace | 1. ☐ Small, less than normal; trace | 1. ☐ Small, less than normal; trace | 1. ☐ Small, less than normal; trace |
| | 2. ☐ Lower half of normal range | 2. ☐ Lower half of normal range | 2. ☐ Lower half of normal range | 2. ☐ Lower half of normal range |
| | 3. ☐ Upper half of normal range | 3. ☐ Upper half of normal range | 3. ☐ Upper half of normal range | 3. ☐ Upper half of normal range |
| | 4. ☐ Enhanced, more than normal | 4. ☐ Enhanced, more than normal | 4. ☐ Enhanced, more than normal | 4. ☐ Enhanced, more than normal |

| Electrode | 0 |
|---|---|
| Amplitude | |
| Rate | |
| Pulse Width | |
| "Do you feel any sensation in your **vulvar or vaginal region**? If so, is it..." | 0. ☐ None |
| | 1. ☐ Mild |
| | 2. ☐ Moderate |
| | 3. ☐ Severe |
| | 4. ☐ Unable to Answer |

# Data Analysis

- Electrode counts and patterns
  - Total count of responsive electrodes
  - Differences between specific electrodes
- Amplitudes
  - Minimum responsive amplitude (threshold)
  - Mean amplitude across electrodes
- Amplitude-Response Score
  - Definitive response at low amplitude (Maximum 90)
  - No response at high amplitude (Minimum 0)



# Study Sample

| Characteristic | Total N=161 | Stage 1 Success N=139 (86%) | Stage 1 Failure N=22 (14%) | p-value |
|---|---|---|---|---|
| Age (years)[1] | | | | 0.9376 |
| Mean (SD) | 62.7 (11.8) | 62.7 (11.8) | 62.9 (11.7) | |
| Median (min-max) | 64.0 (24 - 88) | 64.2 (24 - 88) | 61.7 (43 - 83) | |
| Race[2], N (%) | | | | 0.1763 |
| White | 138 (86%) | 117 (84%) | 21 (95%) | |
| Black/African American | 16 (10%) | 16 (12%) | 0 (0%) | |
| American Indian/Alaskan Native | 1 (1%) | 1 (1%) | 0 (0%) | |
| Asian | 1 (1%) | 1 (1%) | 0 (0%) | |
| More than one race | 1 (1%) | 0 (0%) | 1 (5%) | |
| Other | 3 (2%) | 3 (2%) | 0 (0%) | |
| Unknown | 1 (1%) | 1 (1%) | 0 (0%) | |
| BMI[1] | | | | 0.2760 |
| Mean (SD) | 32.1 (7.6) | 32.4 (7.8) | 30.5 (6.4) | |
| Median (min-max) | 31.0 (19 - 55) | 31.0 (19 - 55) | 30.0 (22 - 50) | |
| % Improvement in UUIE/day[3] | | | | <.0001 |
| Mean (SD) | 75.2 (27.2) | 83.7 (15.3) | 21.1 (23.8) | |
| Median (min-max) | 82.4 (-30 - 100) | 86.7 (50 - 100) | 28.1 (-30 - 47) | |
| Second Stage Surgery[2], N (%) | | | | <.0001 |
| Yes | 145 (90%) | 139 (100%) | 6 (27%) | |

- No significant differences in comorbidities or baseline symptoms

# Stage 1 success vs failures

- 141/161 (88%) had motor response on 2+ electrodes at < 5V
- No differences with motor or sensory response by electrode
- Average amplitudes & minimum amplitudes did not differ
- Counts & patterns of responsive electrodes did not differ

# Stage 1 Amplitude-Response Score

- Best bellows score on Electrode 3
  - Associated with Stage 1 failure
  - 11/22 (50%) vs 36/138 (26%), p = 0.0409
- No other scores associated with Stage 1 outcomes

# Predictive Modeling for Stage 1 Outcome

- Stepwise logistic regression & LASSO models for Stage 1
  - Best bellows score on Electrode 3 → strongest predictor of failure
  - Odds Ratio (95% Confidence Interval): 0.35 (0.14 – 0.88), p=0.0262
- Daily urgency urinary incontinence improvement during Stage 1
  - Best bellows score on Electrode 3 → less symptom improvement
  - Binary Outcome: 79.0% $\pm$ 25.0% vs 66.4% $\pm$ 30.7%, p=0.008

# Association with ROSETTA Outcomes

- No predictors of daily urgency urinary incontinence at 6 months
- Daily urgency urinary incontinence at 24 months
  - Negatively associated with intraop. Electrode 3 sensory response
  - With vs without: -2.5 $\pm$ 2.2 vs -5.0 $\pm$ 3.2, p=0.005

# Limitations & Strengths

- Limitations
  - Use of the analog test stimulation device (Model 3625)
  - Relatively small sample size (i.e. Stage 1 Failure Group)

- Strengths
  - Prospective, randomized, multi-center → generalizable
  - Thorough and comprehensive data collection

# Conclusions

- Higher magnitudes of intraoperative responses did not predict Stage 1 success or long-term reduction of urgency incontinence
- Modeling did identify a negative association between intraoperative response on electrode 3 and successful outcomes
- Further prospective research on predictors of sacral neuromodulation outcomes is warranted

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