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Eunice Kennedy Shriver National Institute of Child Health and Human Development

Cost Effectiveness of Sacral Neuromodulation versus OnabotulinumtoxinA for Refractory Urgency Urinary Incontinence: Results of the ROSETTA Randomized Trial

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Background

- ROSETTA: Sacral Neuromodulation (SNM) and Botulinum Toxin 200 units (BTX) have similar efficacy through 2 years (Amundsen et al., 2018)
- Cost-effectiveness of SNM versus BTX has not been reported using within-trial data
- Relative cost per effectiveness and improvement in patient quality of life can help patients, clinicians, and payers make informed decisions about SNM and BTX therapy
  - Thresholds: UK guidelines £20,000 - £30,000 per QALY. US $50,000-$150,000 per QALY commonly used

ROSETTA Trial

- The Refractory Overactive Bladder: Sacral Neuromodulation versus Botulinum Toxin Assessment (ROSETTA) trial compared SNM to BTX 200u
  - ≥ 6 urge urinary incontinence episodes (UUIE) in a 3-day diary, refractory to medications and behavioral/physical therapy.
  - 386 women randomized to SNM vs BTX 200 units
  - SNM group: 82% underwent pulse generator implantation
  - BTX group : over 24 months, 72% requested a second injection and 47% requested a third injection.
- The cost effectiveness analysis includes the ROSETTA 24 month intent to treat population

Methods:

$$\frac{(Cost_A - Cost_B)}{(Effects_A - Effects_B)}$$

Costs

- Health care sector perspective
- Resource costing method:
  - Health care utilization data from ROSETTA
  - Medicare reimbursement rates or published prices
- Costs reported in 2017 U.S. dollars

Effects

- **Primary effectiveness outcome:**
  - **Quality-adjusted life-years (QALYs)** calculated from the Health Utilities Index Mark 3 (HUI-3)
- Condition- specific measures:
  - Change from baseline in mean **daily urinary urgency incontinence episodes (UUIE)**
  - Overactive bladder-specific quality of life: **OABq-SF**, **UDI-SF**
  - Patient satisfaction and symptom control: **OAB-SATq**, **PGSC**, **PGII**

Methods: Cost-Effectiveness Outcomes

$$\frac{(Cost_A - Cost_B)}{(Effects_A - Effects_B)}$$

- Primary: incremental cost-effectives ratio (ICER):

$$ICER = \frac{(\text{Cost SNM} - \text{Cost BTX})}{(\text{QALY SNM} - \text{QALY BTX})}$$

- Secondary: condition-specific:
  - Average cost per **decrease in UUIE per day**
  - Incremental cost per incremental improvement in UUI condition-specific HRQOL: **OABq-SF, UDI-SF, IIQ.**
  - Incremental cost per incremental improvement in satisfaction with treatment and symptom control: **OAB-SATq, PGSC, PGI-I.**
- Explore cost-effectiveness of SNM versus BTX over longer period: **modeled cost-effectiveness through 5 years.**

Baseline Characteristics and Clinical Outcomes

Characteristic	SNM	BTX
Age, years - mean (SD)	63.1 (11.8)	62.9 (11.5)
Race - no. (%) White Black Other	 149 (85.6) 16 (9.2) 9 (5.2)	 154 (81.1) 22 (11.6) 14 (7.4)
BMI, Kg/m^2 - mean (SD)	31.7 (7.5)	32.6 (8.7)
History of recurrent UTIs - no. (%)	25 (14.4)	24 (12.6)
UUIE / day - mean (SD)	5.19 (2.58)	5.39 (2.62)
Health Utility Index – Mark 3 - mean (SD)	0.74 (0.28)	0.71 (0.30)
OAB-q SF symptom bother - mean (SD)	76.1 (16.8)	74.6 (19.5)
OAB-q SF quality of life - mean (SD)	36.8 (21.6)	38.2 (23.0)
UDI - mean (SD)	59.2 (16.9)	60.9 (18.3)
IIQ - mean (SD)	52.5 (25.8)	52.7 (27.6)

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Estimated Effectiveness, 2-Year Trial Period

$$\frac{(Cost_A - Cost_B)}{(Effects_A - Effects_B)}$$

Effectiveness Component	SNM	BTX	Difference	P-value
QALYs per Person - mean (SD)	1.45 (0.04)	1.43 (0.04)	0.016 (0.05)	0.79
UUIE - mean (SD)	-3.25 (0.40)	-3.71 (0.38)	0.45 (0.51)	0.08
OABq SF - mean (SD) Symptom bother Quality of life	 -33.15 (29.34) 35.13 (28.15)	 -28.70 (28.56) 30.79 (27.79)	 -4.46 (3.32) 4.34 (3.21)	 0.18 0.18
PGI-I, 24 months - no. (%) Urinary leakage Bladder function	 78 (56.1) 76 (54.7)	 93 (59.6) 98 (62.8)		 0.54 0.16
UDI - mean (SD)	-17.8 (25.5)	-19.4 (23.5)	1.6 (2.8)	0.58
IIQ - mean (SD)	-25.6 (26.4)	-26.2 (26.4)	0.6 (3.1)	0.85

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Estimated Per-Person Costs, 2-Year Trial Period

$$\frac{(Cost_A - Cost_B)}{(Effects_A - Effects_B)}$$

Estimated Health Care Costs	SNM	BTX	Difference	P-value
Treatment - mean (SD) SNM BTX	 $34,754 (11,981) $170 (550)	 $3,949 (11,889) $2,738 (1,139)	 $30,805 (1,308) -$2,568 (94)	 <0.01 <0.01
Clinic Visits - mean (SD)	$321 (366)	$332 (405)	-$11 (39)	0.78
Adverse Events - mean (SD)	$99 (567)	$193 (269)	-$94 (48)	0.05
Other - mean (SD)	$330 (225)	$252 (143)	$78 (20)	0.09
Total Average Cost	**$35,674 (11,760)**	**$7,463 (11,778)**	**$28,211 (1,235)**	**<0.01**

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Estimated Per-Person Costs, 5-Year Analysis

$$\frac{(Cost_A - Cost_B)}{(Effects_A - Effects_B)}$$

Estimated Health Care Costs	SNM	BTX	Difference	P-value
Treatment - mean (SD) SNM BTX	 $34,919 (11,981) $396 (550)	 $3,963 (11,889) $6,486 (1,139)		
Clinic Visits - mean (SD)	$742 (366)	$824 (405)		
Adverse Events - mean (SD)	$153 (567)	$495 (269)		
Other - mean (SD)	$330 (225)	$252 (143)		
Total Average Cost	**$36,541**	**$12,019**	**$24,522**	**<0.01**

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Cost-Effectiveness of SNM versus BTX

$$ICER = \frac{(Cost_{SNM} - Cost_{BTX})}{(QALY_{SNM} - QALY_{BTX})}$$

Effectiveness/Cost Component	SNM	BTX	Difference or Increment	P-value
2 Years				
Total Estimated Cost per Person	$35,674 ($11,760)	$7,463 ($11,778)	$28,211 ($1,421)	<0.01
Average QALYs per Person	1.45 (0.04)	1.43 (0.04)	0.016 (0.05)	0.79
ICER			$1,812,215	
5 Years				
Total Estimated Cost per Person	$36,541 ($11,760)	$12,019 ($11,778)	$24,522 ($1,235)	<0.01
Average QALYs per Person	3.25 (0.10)	3.24 (0.10)	0.006 (0.14)	0.08
ICER			$4,177,543	

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Cost per reduction in UUIE based on bladder diary

Effectiveness/Cost Component	SNM	BTX	Difference or Increment
Cost per Reduction in 1 UUIE per Person, 2-years	$15.03	$2.75	$12.27
Cost per Reduction in 1 UUIE per Person, 5-years	$6.16	$1.77	$4.38

Other condition-specific measures also favored BTX at 2 and 5 years:

- Incremental cost per incremental improvement in UUI condition-specific HRQOL: **OABq-SF, UDI-SF and IIQ**
- Incremental cost per incremental improvement in satisfaction with treatment and symptom control: **OAB-SATq, PGSC, and PGI-I**

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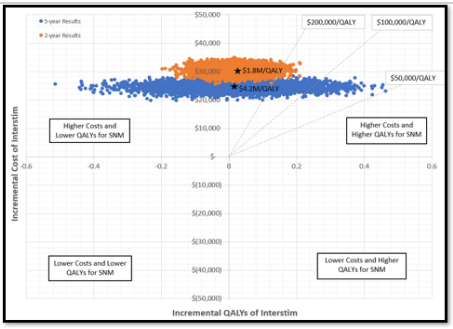
Cost effectiveness plane:
Uncertainty in mean cost and QALY differences and their joint distribution for SNM versus BTX: 2-year and 5-year plots



Cost-effectiveness of SNM versus BTX: Threshold analysis

- Incremental cost-effectives ratio (ICER):
  - **Reduction of SNM device and procedure cost by at least 68%:** Resulted in cost-effectiveness at $50,000/QALY.
  - **Increased frequency of BTX injections to 5.8 per year:** Resulted in cost-effectiveness at $50,000/QALY.

Conclusion

- **Effectiveness measures:** improved for both SNM and BTX; there were no differences between groups
- **Costs:** significantly higher for SNM versus BTX, at both 2 and 5 years
- **Cost-effectiveness:** analysis using both QALY and condition-specific measures favored BTX over SNM, at 2 and 5 years
- **Conclusion**:
  - SNM in its current form is not good value compared to BTX 200 units at 2 or 5 years
- Reduction of SNM cost or change in technology could improve cost effectiveness

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