Two years outcomes of the treatment of overactive bladder with the miniaturized, rechargeable Axonics System

INTRODUCTION
Sacral neuromodulation (SNM) is a guideline-recommended treatment for overactive bladder (OAB) patients after conservative treatments have failed. Historically, the only commercially available SNM System was a non-rechargeable system with a lifespan of 3-6 years\(^a\). This device requires multiple replacement surgeries resulting in increased surgical risks and healthcare costs, which could be reduced by use of a longer lived, rechargeable system\(^b\). The Axonics\(^\text{®}\) System is a miniaturized, rechargeable SNM system approved to last for 15 years by regulatory bodies in Europe, Canada and Australia. RELAX-OAB is a post-market clinical study in Europe designed to test the safety and efficacy of the Axonics System. 2-year follow-up results are presented here.

METHODS

Objective
Post-market study to confirm the safety and efficacy of the Axonics System as a treatment of OAB symptoms.

Study Design
Prospective, multi-center, single-arm study with each subject serving as their own control. Subjects were implanted with the Axonics System in a single, non-staged procedure without an external trial. In order to be comparable with clinical literature, the 1st month of therapy was considered a trial period.

Subjects/ Centers
• 61 subjects with urgency frequency (UF) or urinary incontinence (UI) or both were implanted across 7 centers.
• 46 subjects were available for follow-up at the 6-month visit, 43 subjects at the 1-year visit and 40 subjects at the 2-year visit.

Clinical Assessments
• 3-day voiding diary
• Quality of life questionnaires (ICIQ-OABql, SF-12, EQ-5D, ICIQ-UI Short Form)
• Patient satisfaction with treatment
• Adverse events

RESULTS

DEMOGRAPHICS

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<tr>
<th>GENDER</th>
<th>Female</th>
<th>Male</th>
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<td>% of subjects</td>
<td>25%</td>
<td>75%</td>
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BASELINE SYMPTOMS

<table>
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<th>Test Responders</th>
<th>All Subjects</th>
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<td>72%</td>
<td>71%</td>
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2-YEAR CLINICAL OUTCOMES

90% of Test Responders continued to respond to therapy responders at 2 years

72% of Test Responders were UF responders at 2 years

88% of Test Responders were UI responders at 2 years

CONCLUSIONS
• The Axonics System provides long-term, safe and effective treatment as evidenced by 2-year outcomes.
• Patients receive significant improvements in quality of life and are satisfied with rechargeable SNM therapy.
• Patients find the frequency and duration of recharging to be acceptable.
• A rechargeable system may provide significant cost-savings while reducing patient and physician burden and risk associated with repeat surgeries.

References

PATIENT SATISFACTION

• 93% of Test Responders were “Satisfied” with r-SNM therapy for their OAB treatment

• 90% of Test Responders would “Likely” recommend r-SNM to a friend

• 86% of Test Responders rated the frequency and duration of recharging as “Acceptable”

SAFETY
• Cumulative follow-up of 1,048 months is available among all study subjects.
• No unanticipated adverse events or serious device related adverse events were reported.
• 7 subjects explanted – 1 due to procedure-related infection, 4 due to lack of efficacy, 1 due to need for MRI, 1 due to high impedances

The system is now approved in Europe for Full Body MRIs under specific conditions.

References

Disclosures: The RELAX-OAB study was funded by Axonics Modulation Technologies, Inc., developer of a rechargeable SNM system. Several of the investigators receive compensation for providing consulting services to Axonics.