Impacto económico dos neuromoduladores recarregáveis – Muda o paradigma?

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SNM - indications

• Urological
  • Refractory OAB – 75%
    • Wet -1997
    • Dry -1999
  • No obstructive urinary retention – NOUR -1999 – 25%

• Proctological
  • Fecal incontinence -2011
  • Chronic constipation - Europe
OAB treatment

• First-line treatment
  • **Behavioural therapies** - bladder training (BT) and pelvic floor muscle therapy (PFMT)
  • **Lifestyle changes** - fluid and caffeine intake, diet, weight loss, *management of bowel regularity, and optimization of other comorbidities*
  • **Patient education** - motivation and adherence to the previous strategies

• Second-line treatment
  • Pharmacological

• **Third-line treatment**
  • BTXA
  • SNM
SMN vs BTXA

• Which is the preferred/first, third line option remains open to debate

• Failed BTXA therapy
  • due to either lack of efficacy, urinary retention, or adverse reaction
  • patients may be candidates for SNM.
SNM - safety

• The most common adverse event
  • pain at the implant site
    in most studies varies between 3% and 42%

• Other adverse events reported
  • lead migration (1–21%)
  • bowel dysfunction (4–7%)
  • infection(4–10%).

SNM - efficacy

- Success rates have been reported between 64% and 88%.

Table 1: Results of SNM treatment in OAB patients [Hassouna et al. 2000; Hijaz et al. 2006; Sutherland et al. 2007; van Kerrebrokeck et al. 2007; van Voskuilen et al. 2006, 2007; Weil et al. 2000].

<table>
<thead>
<tr>
<th>Study</th>
<th>General improvement (%)</th>
<th>Void/day (%)</th>
<th>Volume/void (%)</th>
<th>Follow up (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hassouna et al. [2000]</td>
<td>88</td>
<td>−46</td>
<td>77</td>
<td>12</td>
</tr>
<tr>
<td>Hijaz et al. [2006]</td>
<td>75</td>
<td>NA</td>
<td>NA</td>
<td>16</td>
</tr>
<tr>
<td>Sutherland et al. [2007]</td>
<td>69</td>
<td>−35</td>
<td>NA</td>
<td>22</td>
</tr>
<tr>
<td>van Kerrebrokeck et al. [2007]</td>
<td>NA</td>
<td>−23</td>
<td>79</td>
<td>49</td>
</tr>
<tr>
<td>van Voskuilen et al. [2006]</td>
<td>80</td>
<td>−38</td>
<td>44</td>
<td>15</td>
</tr>
<tr>
<td>van Voskuilen et al. [2007]</td>
<td>64</td>
<td>NA</td>
<td>NA</td>
<td>64</td>
</tr>
<tr>
<td>Weil et al. [2000]</td>
<td>56 (100% continence)</td>
<td>NA</td>
<td>NA</td>
<td>12</td>
</tr>
</tbody>
</table>

SNM after BTXA

• To date, there has been little data on the efficacy of SNM after BTXA.
• Smits et al reported
  • 70% success rate for first-stage SNM (n=20).
  • 79% success at 1 year with the Permanent implantable pulse generator (IPG) (n=14)

SNM after BTXA

• Success rate of 70 % in BTXA-naïve patients (n=47)
  • 63.9 % for prior BTXA (n=36). P=0,5
  • 64.0 % for prior “ineffective” BTXA (n=25) P=0,6

• First-stage SNM success rate
  • 68 % (n=19) ≤ 2 BTXA treatments,
  • 58 % (n=17) ≥ 3 BTXA treatments (P=0.5).

SNM - cost-effectiveness related to BTXA

- SNM as the first therapeutic option for refractory idiopathic OAB-wet
  - is cost effective after 3 years
    - €21,259/QALY), (ICUR < 40.000 €/QALY)
  - and becomes dominant at 10 years
    - less costly—€333.22 saved
    - more effective—0.59 QALY gained

**SNM - cost-effectiveness**


<table>
<thead>
<tr>
<th>Year</th>
<th>Costs (€)</th>
<th>QALYs</th>
<th>ICUR (€/QALY)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Year 1</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNM strategy</td>
<td>12,423.36</td>
<td>0.85</td>
<td></td>
</tr>
<tr>
<td>BoNT/A strategy</td>
<td>6,500.17</td>
<td>0.79</td>
<td></td>
</tr>
<tr>
<td>SNM strategy versus BoNT/A strategy</td>
<td>5,923.19</td>
<td>0.05</td>
<td>109,333.34</td>
</tr>
<tr>
<td><strong>Year 2</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNM strategy</td>
<td>14,712.09</td>
<td>1.68</td>
<td></td>
</tr>
<tr>
<td>BoNT/A strategy</td>
<td>9,933.04</td>
<td>1.57</td>
<td></td>
</tr>
<tr>
<td>SNM strategy versus BoNT/A strategy</td>
<td>4,779.06</td>
<td>0.11</td>
<td>44,322.80</td>
</tr>
<tr>
<td><strong>Year 3</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNM strategy</td>
<td>16,901.10</td>
<td>2.49</td>
<td></td>
</tr>
<tr>
<td>BoNT/A strategy</td>
<td>13,249.41</td>
<td>2.32</td>
<td></td>
</tr>
<tr>
<td>SNM strategy versus BoNT/A strategy</td>
<td>3,651.69</td>
<td>0.17</td>
<td>21,258.72</td>
</tr>
<tr>
<td>Year 10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNM strategy</td>
<td>32,975.47</td>
<td>7.52</td>
<td></td>
</tr>
<tr>
<td>BoNT/A strategy</td>
<td>33,308.69</td>
<td>6.93</td>
<td></td>
</tr>
<tr>
<td>SNM strategy versus BoNT/A strategy</td>
<td>-333.22</td>
<td>0.59</td>
<td></td>
</tr>
</tbody>
</table>

SNM strategy, clinical pathway starting with sacral neuromodulation (SNM); BoNT/A, clinical pathway starting with Botulinum toxin A (BoNT/A) injections; QALY quality-adjusted life year, ICER incremental cost-effectiveness ratio.

**cost effective (ICUR < 40.000 €/QALY)**
SNM - cost-effectiveness

In Europe, the relative cost-effectiveness of SNM and BTXA has been investigated in Spain (1), Holland (2) and UK (3)


SNM - cost-effectiveness

as well as in the USA (4) and Canada (5)

- all of them suggesting that


SNM is cost-effective in the medium and long-term
Neuromoduladores recarregáveis – Muda o paradigma?
Cost Profiles and Budget Impact of Rechargeable Versus Non-Rechargeable Sacral Neuromodulation Devices in the Treatment of Overactive Bladder Syndrome

Noblett et al.

Neurourology and Urodynamics 2017 DOI 10.1002/nau
Non-rechargeable - Interstim II

- Current SNM device are not rechargeable, and require neurostimulator replacement every 3–6 years.
- Long term success rate proven to 5 years
- Acceptable cost-effectiveness profile
- Substantial upfront costs
- Replacement expenditures are the major cost contributor
An increased battery life is a desirable feature not only for patients, but also for healthcare payers.

Rechargeable neurostimulation systems are currently being developed and tested.
Cost profiles

• Analyze and compare the cost profiles of rechargeable versus non-rechargeable SNM devices
• Estimate the resulting long-term budget impact to payers
• Based on hypothetical scenarios

• Rechargeable strategy
  • reported lifetime of rechargeable spinal cord stimulation (SCS) systems (Eon MiniTM Rechargeable IPG; Nevro Senza SCS System)
• Non-rechargeable strategy
  • Reported lifetime of the established InterStim from the

InSite trial

Results of a Prospective, Randomized, Multicenter Study Evaluating Sacral Neuromodulation With InterStim Therapy Compared to Standard Medical Therapy at 6-Months in Subjects With Mild Symptoms of Overactive Bladder

Fig. 1. Fifteen-year undiscounted costs per patient, non-rechargeable versus rechargeable device, and percentage change in total cost and neurostimulator replacement cost.

*Neurourology and Urodynamics* DOI 10.1002/nau
Fig. 2. Cost difference between non-rechargeable and rechargeable SNM device strategy at 15 years for various scenarios of respective battery lifetimes. A negative number denotes a saving associated with the rechargeable SNM device strategy. All amounts discounted.
Fig. 3. Budget impact to Unites States payers for two adoption scenarios (gradual adoption of rechargeable devices vs. immediate full adoption scenario), considering new implants only. All amounts discounted.

*Neurourology and Urodynamics* DOI 10.1002/nau
Rechargeable devices

- Rechargeable SNM systems are not yet commercially available.
- Long-term performance is based on the best available evidence from comparable rechargeable systems used in the field of SCS.
- Rechargeable neurostimulator devices for sacral neuromodulation may deliver significant cost savings.
Rechargeable devices - Axonics

- The device was approved in 2016 for the treatment of OAB in Europe and Canada
- Consists of a small volume rechargeable neurostimulator (60% smaller than Interstim)
- Approved for head MRI like Interstim.
- The battery is rechargeable with a 15-year lifetime in the body
- There is no real-life data to support the efficacy up to 15 years
- Recharging, performed via a wireless charger, secured to the patient either by disposable carrier or a flexible belt, would be expected to take between 1 and 2 hours

• There is currently a prospective multicenter clinical study (RELAX-OAB trial) designed to confirm the performance of the Axonics SNM System.
Nuvectra

- Nu vectra Corporation submitted in 2/2017 to the FDA and CE Marking authorities for Virtis™ approval
- Is full body MRI compatible.
- Is dual channel, therefore can perform bilateral stimulation.
- Can last up to 10 years.
Pros and cons

• Rechargeable is not suitable for everyone
• InterStim can fit patients' lifestyles, providing FREEDOM to live without thinking about their therapy.
• At this time, there are no published data to the Axonics system.
Pros and cons

• **Coupling** with patient programmer or recharger might be more difficult with a smaller device.

• The **position**, changes in **depths** and the **orientation** of the device may vary with time.

• As a result, the **efficiency of the recharge** may decreased and more heat may be generated over time.

Pros and cons

• Numerical simulation to predict tissue temperatures in changes in depths and orientation
• The results show that temperatures do not rise to a level which can cause thermal injury.
• That level is generally considered to be 43°C.

Conclusions

• Today SNM is Interstim II
  • Safe
  • Long term success rate proven to 5 years, even in failed-BTXA
  • Cost-effective in the medium and long-term

• Rechargeable SNM
  • Not suitable for everyone
  • Probably in the next 2 years – Axonics, Interstim recarregável
  • May deliver significant cost savings
Obrigado!

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Apresentação disponível em: