

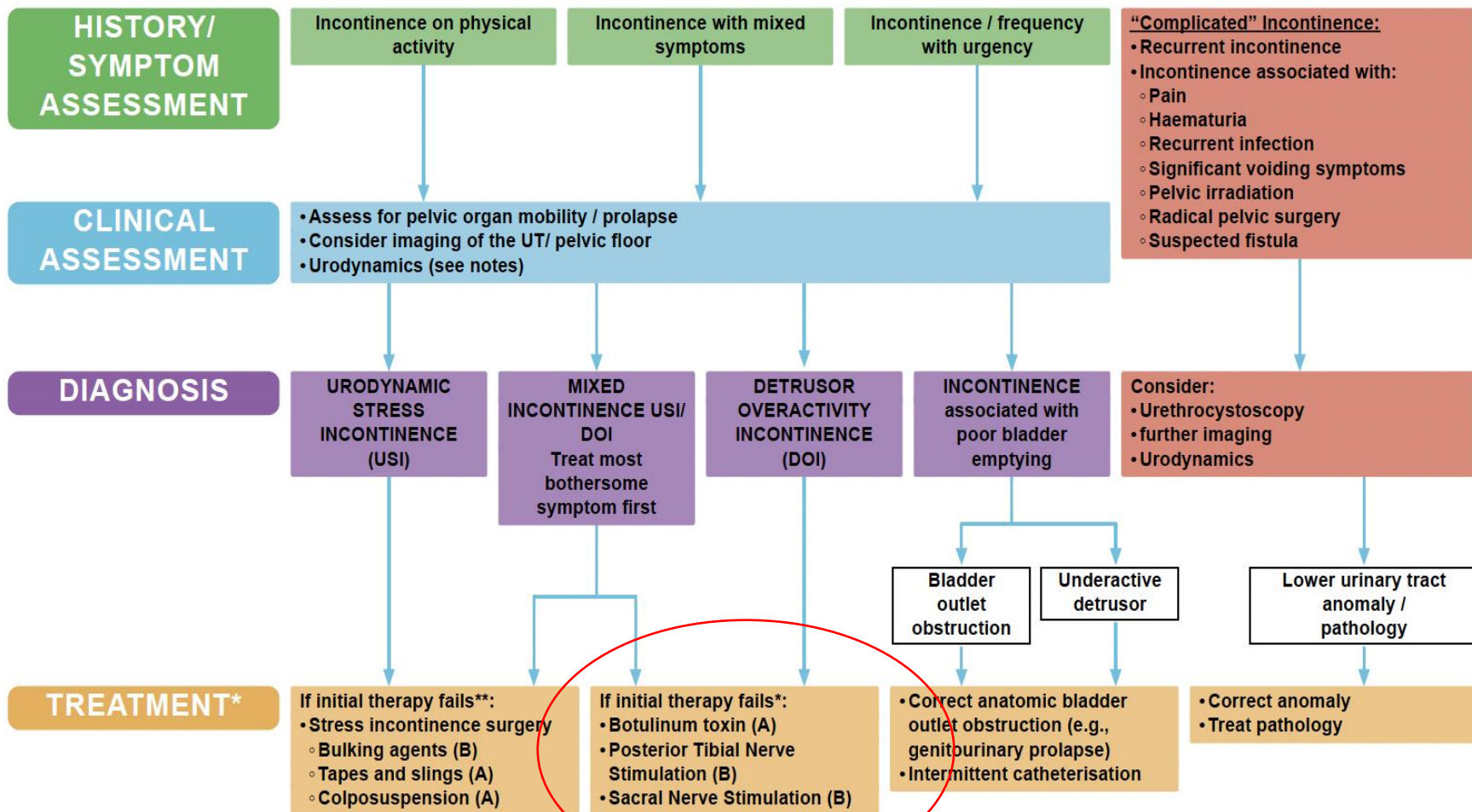


3ª Línea de tratamiento en Vejiga Hiperactiva Botox, PTNS vs NMRS

David Castro Diaz

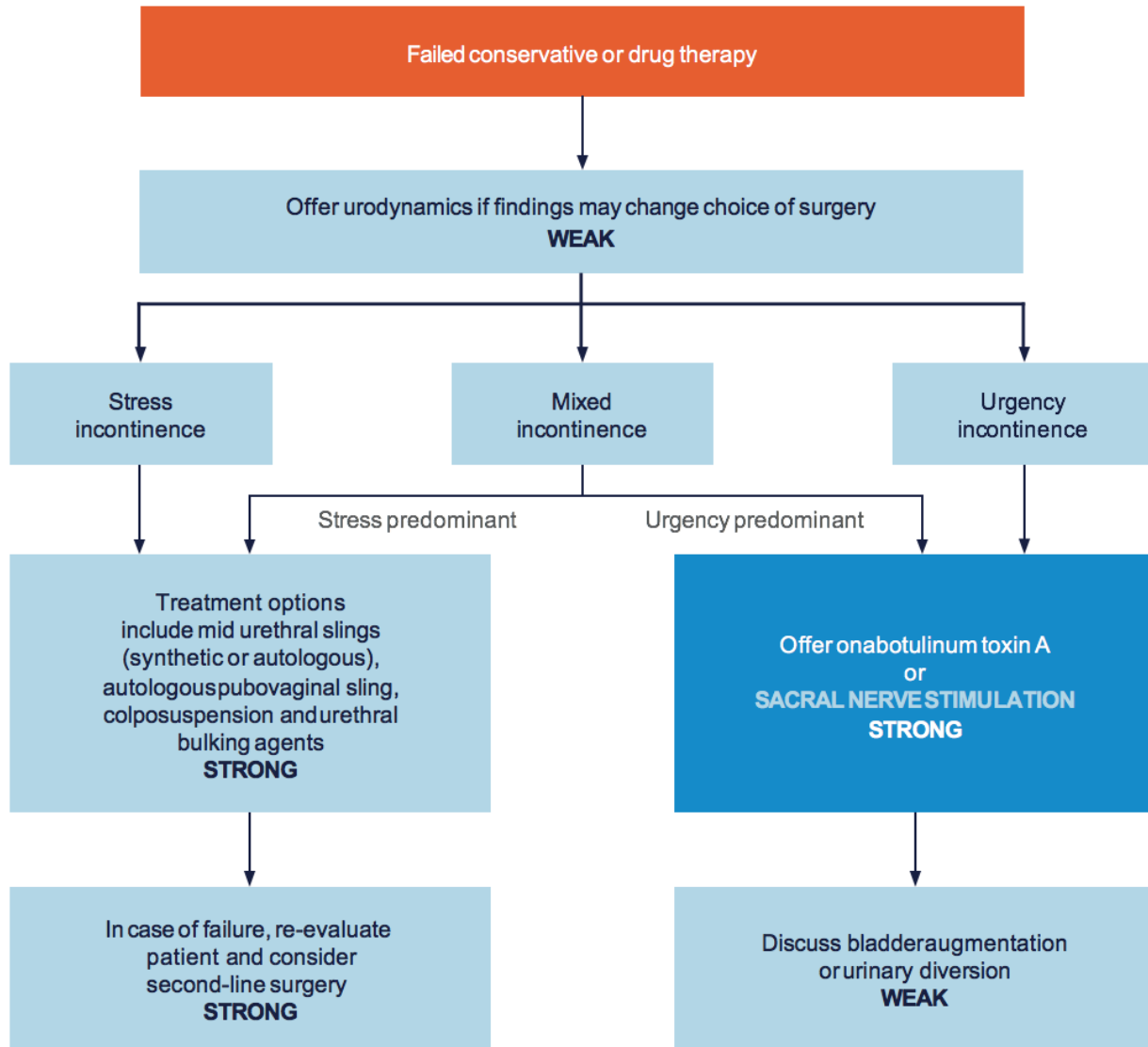
Hospital Universitario de Canarias. Santa Cruz de Tenerife. Spain

SPECIALISED MANAGEMENT OF URINARY INCONTINENCE IN WOMEN

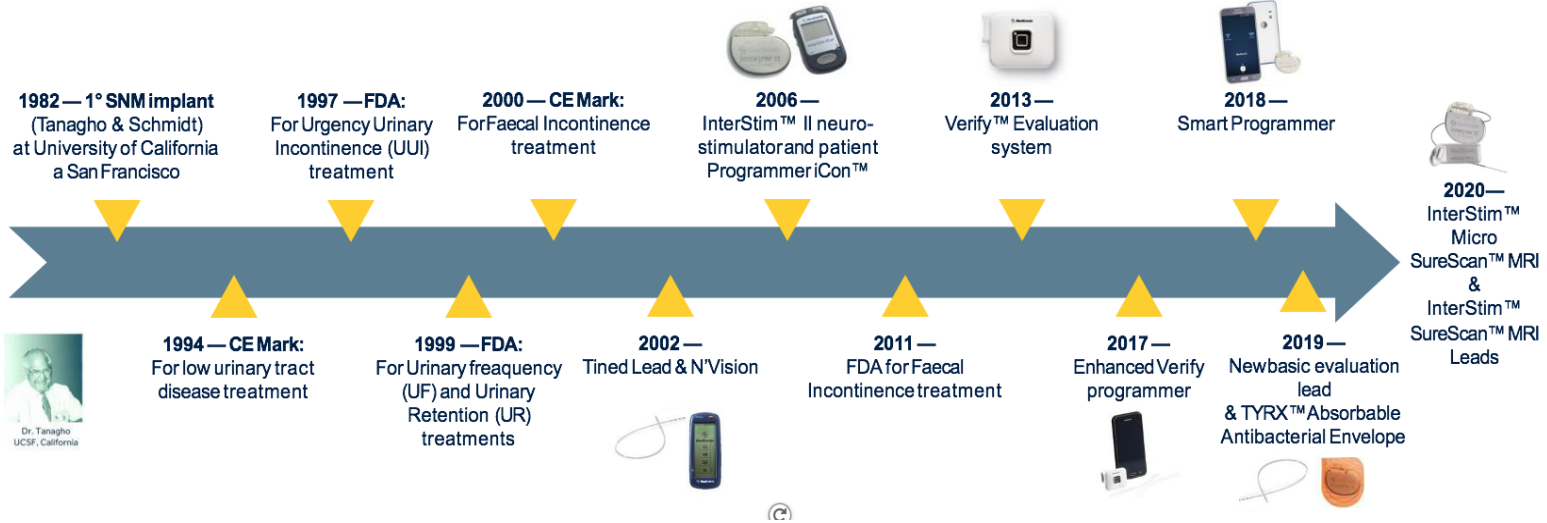


EAU Guidelines 2023

Recommendations	Strength rating
Offer prompted voiding to adults with overactive bladder (OAB) who are cognitively impaired.	Strong
Offer bladder training as a first-line therapy to adults with OAB/urge urinary incontinence (UUI).	Strong
Ensure that pelvic floor muscle training programmes are as intensive as possible.	Strong
Consider posterior tibial nerve stimulation as an option for symptomatic improvement of OAB/UUI.	Strong



Botox y Neuromodulación han pasado el test del tiempo



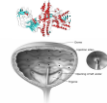
Indicaciones

Neuromodulación



VH Refractaria
Retención urinaria no obstructiva
Incontinencia Fecal

Toxina Botulínica



VH Refractaria
Hiperactividad neurógena del detrusor
Disinergia vesico-esfinteriana

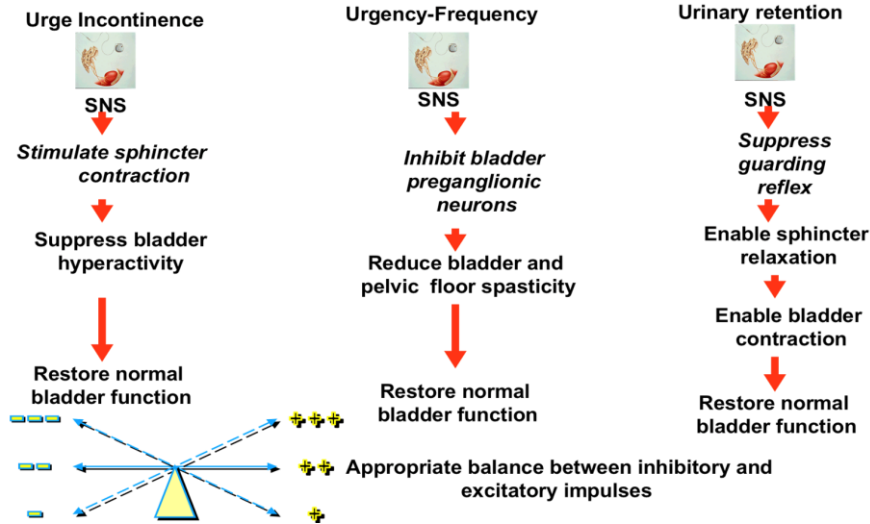
Indicaciones Emergentes

Disfunción miccional neurógena (lesión incompleta)
SDV/IC
Estreñimiento

SDV/IC
STUI / HPB

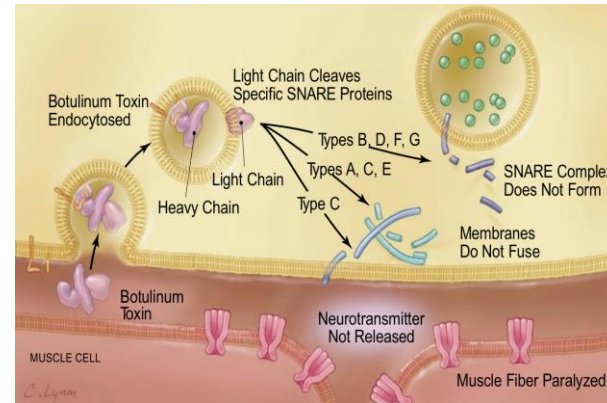
Mechanism of Action

Neuromodulation

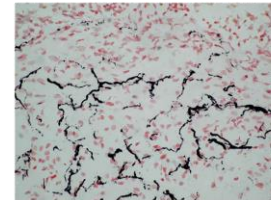


The mechanism seems to involve modulation of spinal cord reflexes and brain networks by peripheral sensory and possibly motor neurons

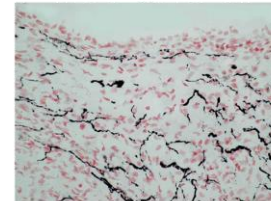
Botulinum toxin



Botulinum Toxin-A denervates the suburothelium



Pre-treatment

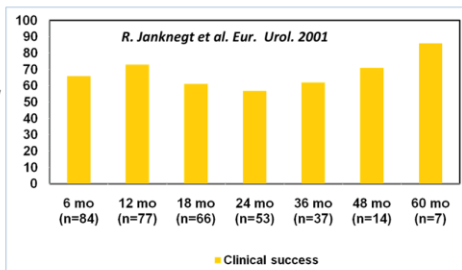


Post-treatment

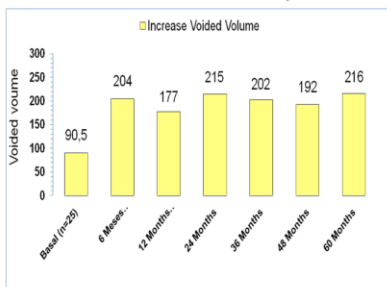
Alters the contractility of detrusor smooth muscle by reducing ACh release from motor nerves
 Reduces afferent nerve firing
 Reduces afferent nerve number/excitatory transmitters
 Reduction of sub-urothelial interstitial cell numbers
 Modulates release of urothelial-derived transmitters
 Modulates release of urothelial-derived transmitters
 Associated with the release of other bladder-active agents

Outcome of SNM & BTX injection

Urge Incontinence
% improvement on
Incontinence episodes / day

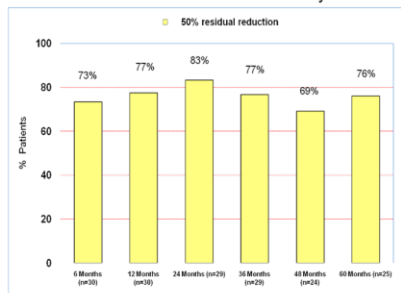


Urgency-Frequency
Maintained Clinical Efficacy



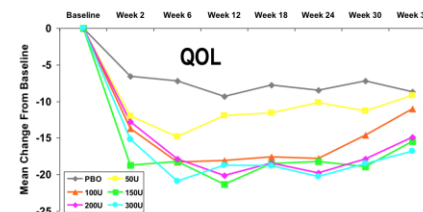
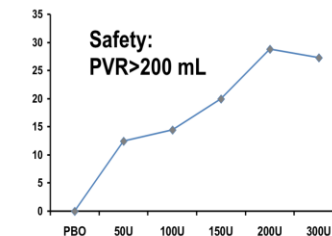
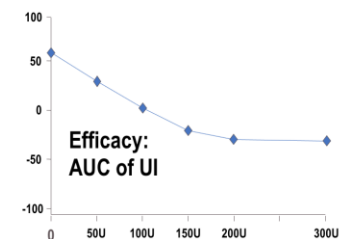
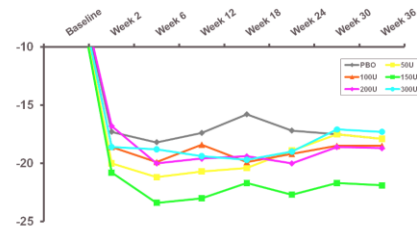
*van Voskuilen A et al. J Urol 2004;171(4suppl):328 (abs.1246)

Urinary Retention
Maintained Clinical Efficacy



*van Voskuilen A et al. J Urol 2004;171(4suppl):328 (abs.1246)

Pain at neurostimulator site	14.2%
New pain	10.8%
Suspected lead migration	9.1%
Infection	7.0%
Transient electric shock	5.6%
Pain at lead site	5.5%
Surgical revision	29.0%



Dmochowski, J Urol, 2010

Nitti et al¹

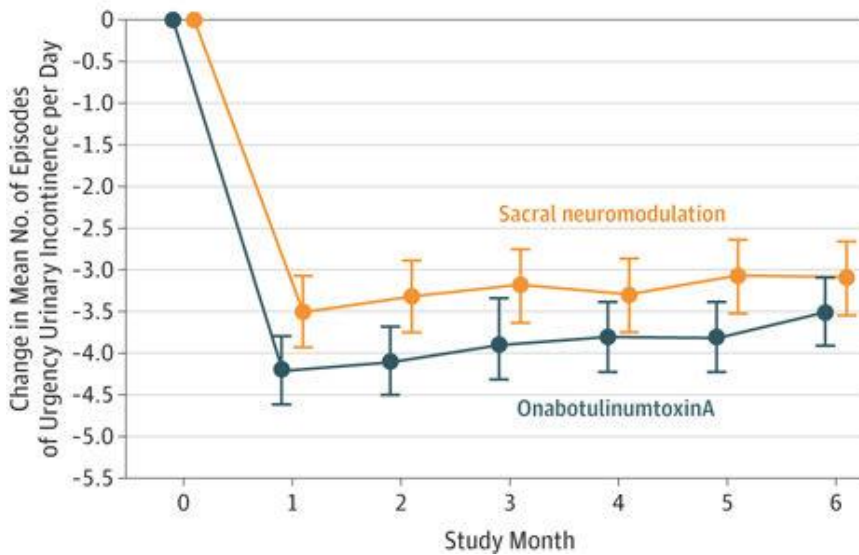
Chapple et al²

	OBTX 100U	Placebo	OBTX 100U	Placebo
Need for CIC	6.1%	0	6.9%	0.7%
UTI	24.5%	9.25%	24.1%	9.6%

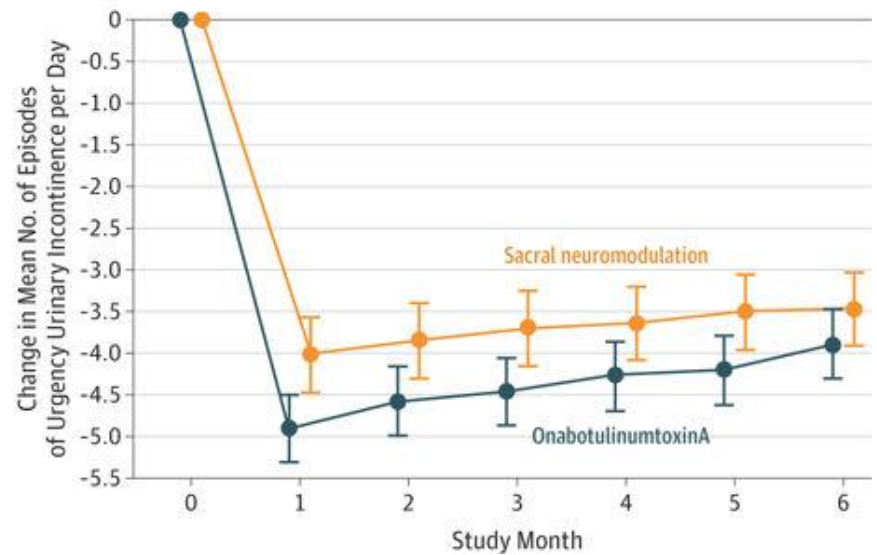
1. Nititi, VW et al. J Urol 2013; 189: 2186-93
2. Chapple C et al. Eur Urol 2013; 64: 249-56

OnabotulinumtoxinA vs Neuromodulación sacra en IUU refractaria. Ensayo clínico aleatorizado

A Intention-to-treat population



B Clinical responder population

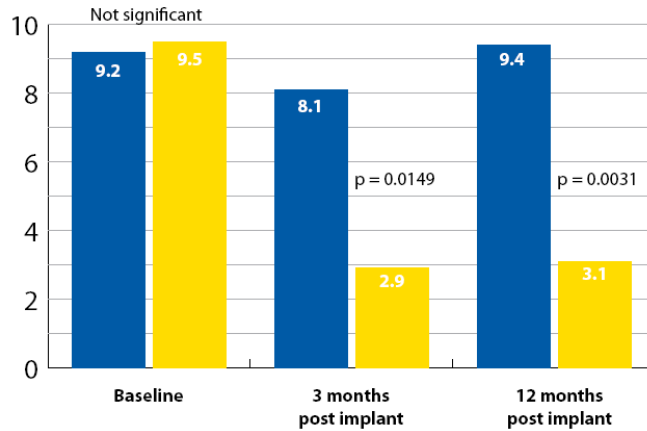


Sacral Nerve Stimulation is more Effective than Optimal Medical Therapy for Severe Fecal Incontinence: A Randomized, Controlled Study

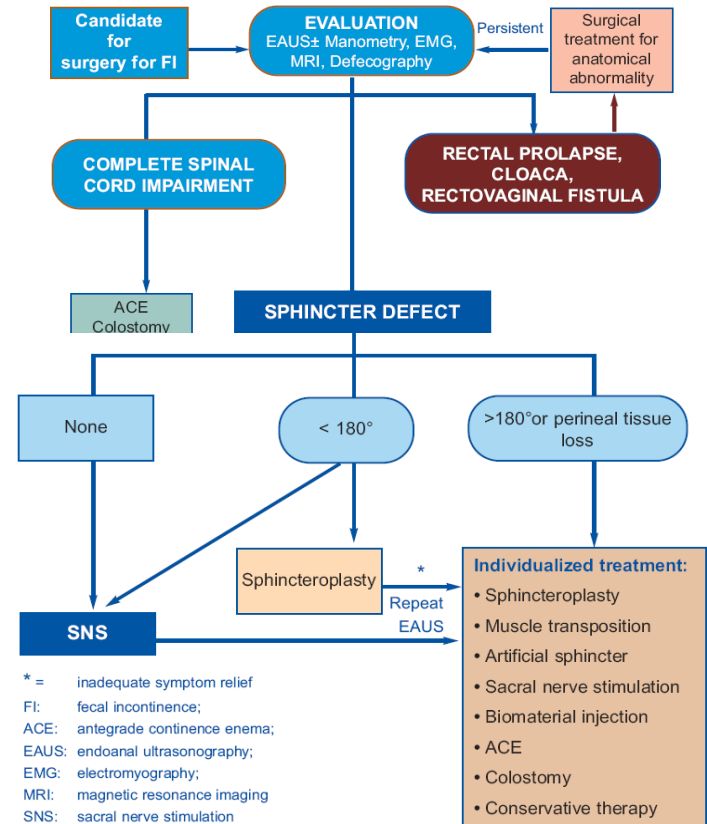
Joe J. Tjandra, M.D., F.R.A.C.S.^a • Miranda K. Y. Chan, M.B.B.S., F.R.A.C.S. • Chung Hung Yeh, M.D. • Carolyn Murray-Green

Number of Incontinence Episodes per Week

■ SNS group
■ Control group



Surgical Management of Faecal Incontinence



Neuromodulación vs Botox

Toxina Botulínica

- Aplicable por urólogo generalista
- No reprogramación
- No restricciones por RMN
- Fácil de aplicar
- Eficacia y seguridad a corto plazo

NRS

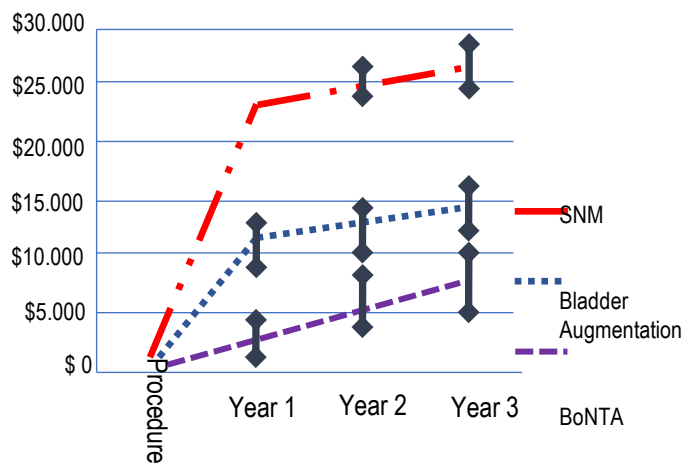
- Eficacia a largo plazo
- Seguridad a largo plazo
- Prueba temporal posible
- Puede tratar condiciones concomitantes
Incontinencia Fecal, estreñimiento, SDV
- Efectiva en UR
- Respuesta rápida
- Reversible
- Nivel de estimulación ajustable

Cost-Effectiveness of Sacral Neuromodulation Compared to Botulinum Neurotoxin A or Continued Medical Management in Refractory Overactive Bladder

Salvador Arlandis, MD^a, David Castro, MD^b, Carlos Errando, MD^c, Eldiberto Fernández, MD^d, Miguel Jiménez, MD^d, Paloma González^e, Carlos Crespo^{f,g}, Funke Staeuble^{h,*}, José Manuel Rodríguez^e, Max Brosa^f

- The initial cost of SNS is higher but the monthly cost during the follow-up is lower than the comparators.
- SNS may also have a higher mid-long-term effectiveness than BoNT at a reasonable cost, with ICERs below 30,000€ per QALY gained from the 4th year in forward.
- Probabilistic sensitivity analysis showed the robustness of the results in SNS vs OMT and, due to the lack of BoNT data, an important variability in the results of SNS vs BoNT.

Estimated cumulative cost curve (2007 USD) of Sacral Neuromodulation, Botulinum toxin A injection and Bladder augmentation for Refractory OAB



Adapted from Watanabe JH, Urology 2010

Treatment	Improvement	Costs/patient (cumulate, €)	QALY	ICER
Results year 1				
InterStim	79%	21,009	1.39	
Botox	74%	12,242	1.34	
OMT	0%	3,800	0.66	
Incremental: InterStim vs. Botulinum toxin year 1		8,766 €	0.04	203,120 €
Incremental: InterStim vs. OMT year 1		17,208 €	0.73	23,572 €
Results year 5				
InterStim	72%	26,899	4.03	
Botox	67%	22,947	3.81	
OMT	0%	18,697	2.91	
Incremental: InterStim vs. Botulinum toxin year 5		3,951 €	0.21	18,811 €
Incremental: InterStim vs. OMT year 5		8,202 €	1.12	7,336 €
Results year 10				
InterStim	60%	37,220	6.84	
Botox	54%	34,534	6.56	
OMT	3%	34,870	5.35	
Incremental: InterStim vs. Botulinum toxin year 10		2,680 €	0.29	9,286 €
Incremental: InterStim vs. OMT year 10		2,350 €	1.50	1,569 €

$$ICER = \frac{\text{CostoTFármacoNuevo} - \text{CostoFarmacoActual}}{\text{QALYTFármacoNuevo} - \text{QALYTFármacoActual}}$$

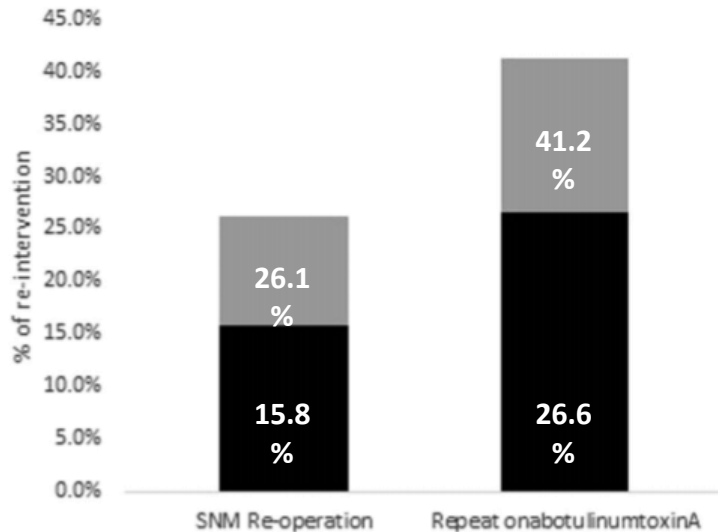
$$ICER = \frac{\text{Costo Incremental}}{\text{QALY ganadas}}$$

Real World Performance of Sacral Neuromodulation and OnabotulinumtoxinA for Overactive Bladder: Focus on Safety and Cost

Bilal Chughtai*,† J. Quentin Clemens, Dominique Thomas, Tianyi Sun, Hassan Ghomrawi and Art Sedrakyan

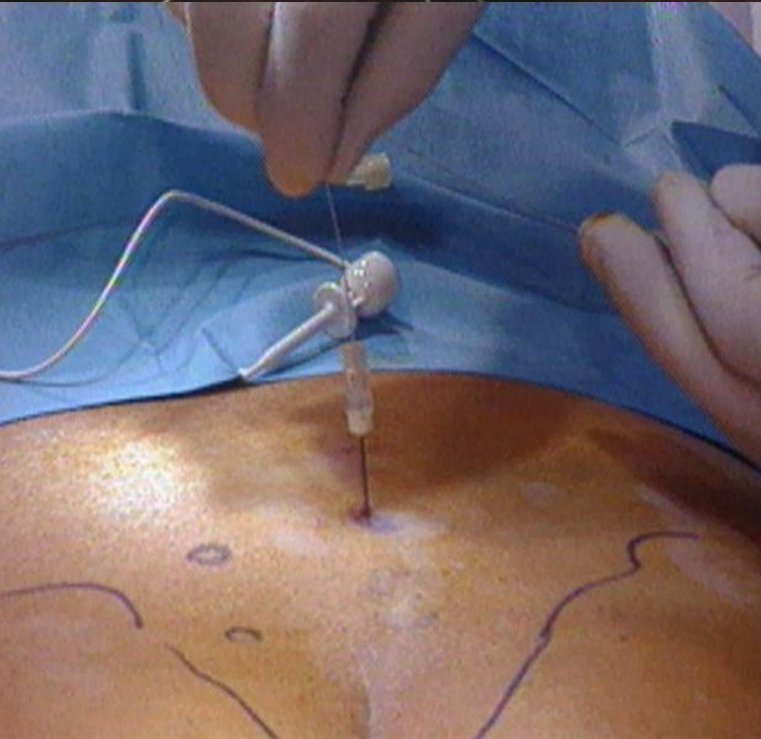
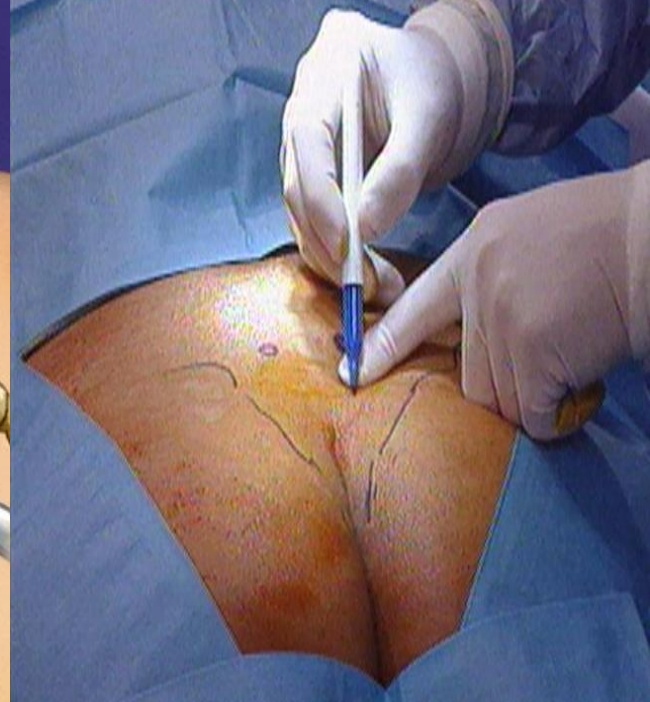
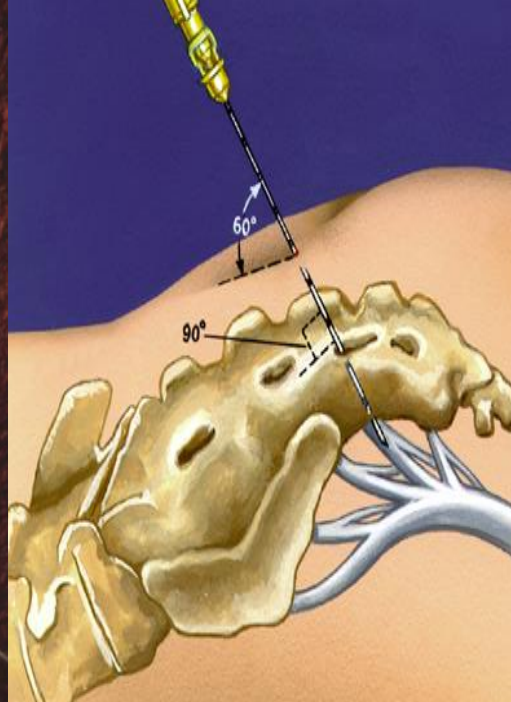
0022-5347/20/2031-0179/0
THE JOURNAL OF UROLOGY®

<https://doi.org/10.1097/JU.0000000000000462>
Vol. 203, 179-184, January 2020



Re-intervention rate within 1 (black bars) and 3 (gray bars) years in patients treated with SNM or onabotulinumtoxinA.

In this comparative analysis patients who received onabotulinumtoxinA therapy were at **higher risk for urinary tract infection, hematuria, urinary retention and an emergency room visit compared to those treated with sacral neuromodulation**. The overall cost of onabotulinumtoxinA was lower than the cost of the sacral neuromodulation device (cost at 1 year \$2,896 vs \$15,343 and at 3 years \$3,454 vs \$16,189, each $p < 0.01$).



Evolución de la técnica



La NRS está en continua evolución



Generador de impulsos más pequeño
Programador externo más pequeño
Control remoto del paciente inteligente
Dispositivo recargable
Compatibilidad con Resonancia Magnética Nuclear

Compatibilidad con RMN

- 50% de los pacientes con marcapasos necesitarán RMN a lo largo de su vida¹
- 23% retirada de NRS es debido a la necesidad de RMN²
- La incompatibilidad con RMN es una contraindicación para NRS³
- Es previsible que las nuevas tecnologías expandan las indicaciones de NRS

1.-Kalin R 2005, 2.-Guzman-Negron JM 2018, 3.-Goldman HB 2018,

NRS recargable

Tamaño

InterStim II IPG (no recargable) = 14 cm³ (7% dolor local)¹
Axonics (recargable) = 5,5 cm³ (2% dolor local)
InterStim Micro = 2,8 cc²

Longevidad

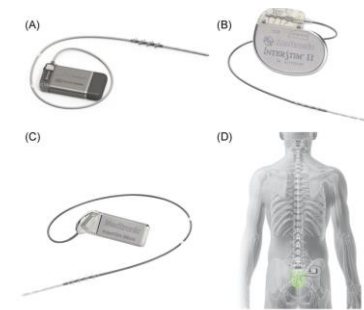
Duración de la batería de InterStim II = 5.-7 años
Duración estimada de recargable= 15 años³

Cumplimiento terapéutico

Destreza manual
Capacidad cognitiva
Conocimiento de la enfermedad

40% de la población adulta tiene problemas de sobrepeso⁴

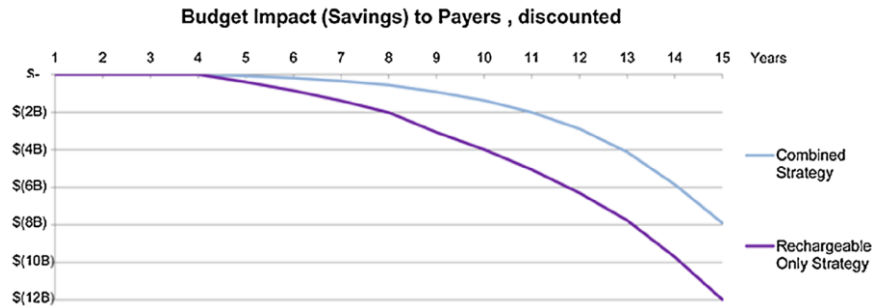
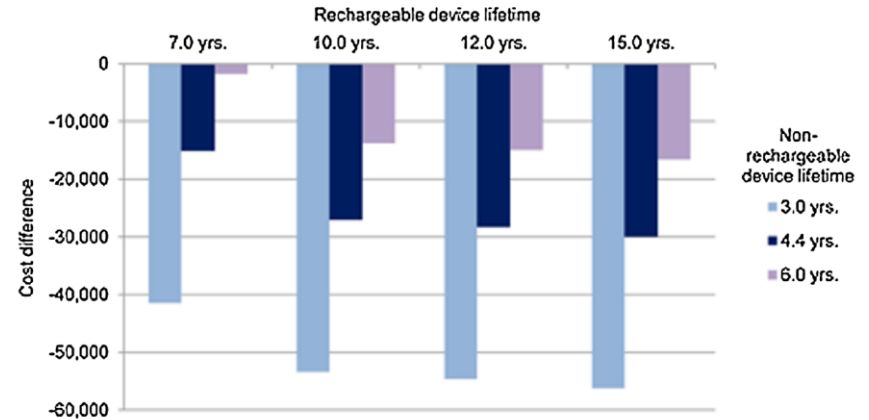
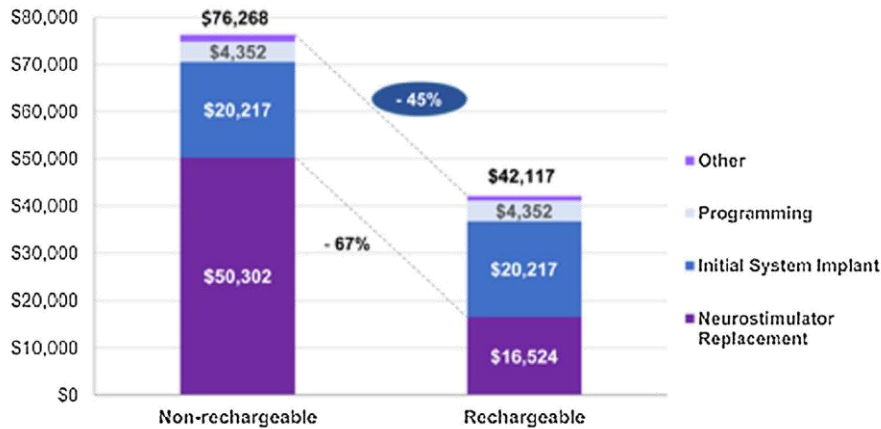
Riesgo más algo de “twiddler syndrome” (rotación del dispositivo) en pacientes obesos⁵





Cost Profiles and Budget Impact of Rechargeable Versus Non-Rechargeable Sacral Neuromodulation Devices in the Treatment of Overactive Bladder Syndrome

Karen L. Noblett,^{1*} Roger R. Dmochowski,^{2*} Sandip P. Vasavada,³ Abigail M. Garner,⁴ Shan Liu,^{4,5} and Jan B. Pietzsch⁴



One-year outcomes of the ARTISAN-SNM study with the Axonics System for the treatment of urinary urgency incontinence

Kevin Benson¹ | Rebecca McCrery² | Chris Taylor³ | Osvaldo Padron⁴ | Bertil Blok⁵ | Stefan de Wachter⁶ | Andrea Pezzella⁷ | Jennifer Gruenenfelder⁸ | Mahreen Pakzad⁹ | Marie-Aimee Perrouin-Verbe¹⁰ | Philip Van Kerrebroeck¹¹ | Jeffrey Mangel¹² | Kenneth Peters¹³ | Michael Kennelly¹⁴ | Andrew Shapiro¹⁵ | Una Lee¹⁶ | Craig Comiter¹⁷ | Margaret Mueller¹⁸ | Howard Goldman¹⁹ | Felicia Lane²⁰

129 treated patients

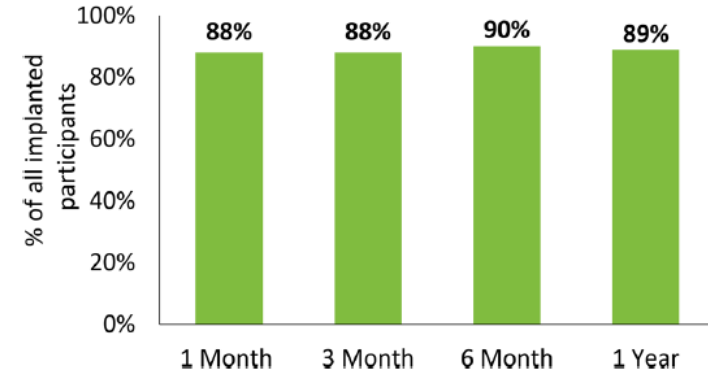


FIGURE 2 Therapy responder rates in all implanted participants at different follow-up visits post-implant. UUI therapy response is defined as $\geq 50\%$ reduction in UUI episodes at follow-up

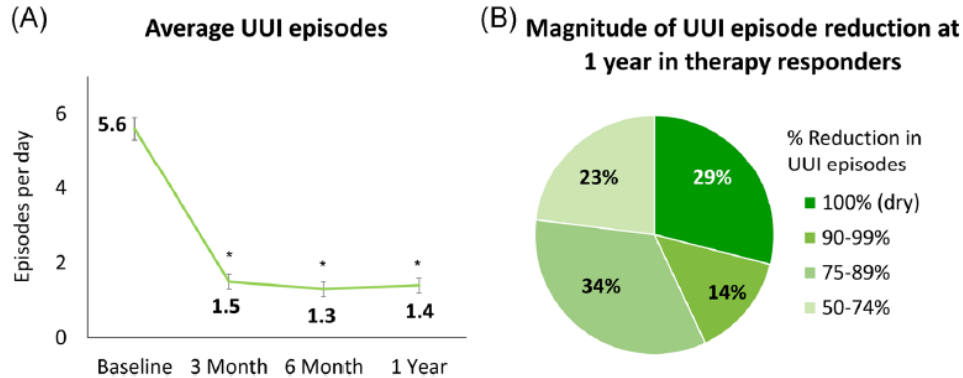



FIGURE 3 Symptom reduction in all implanted participants ($n = 129$) at 3 months, 6 months, and 1 year. A, Average number of UUI episodes in all implanted participants at baseline, 3 months, 6 months and 1 year. B, Magnitude of UUI episode reduction in therapy responders ($n = 115$) at 1-year follow-up. Error bars represent standard error. * $P < .0001$ compared to baseline. UUI, urinary urgency incontinence

92% satisfied with SNM therapy
92% would undergo therapy again
100% were able to charge the device
89% found device easy to charge
96% acceptable duration and charging frequency

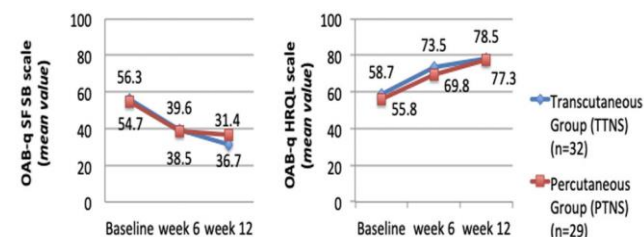
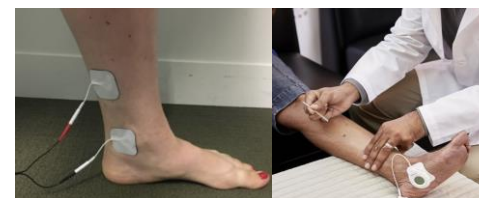
Criterios para la elección no recargable vs recargable

No recargable	Elección del paciente e impacto de factores externos	Recargable
Historia de no cumplimiento	Elección del paciente vs recomendación médica	Paciente motivado y habil
Cumplimiento reducido en 10-15 años	Factores socioeconómicos	Necesidad de alta energética de estimulación con duración estimada de batería ≤ 3 años
Paciente olvidadizo o falta de motivación	Soporte técnico si necesidad	Paciente delgado
Paciente con dificultades físicas	Acceso sencillo para recargar	Paciente con historia de dolor
Falta de conocimiento tecnológico	Coste si pérdida del recargador	Paciente con riesgo alto de infección
Incompatibilidad con estilo de vida		

Efficacy of transcutaneous stimulation of the posterior tibial nerve compared to percutaneous stimulation in idiopathic overactive bladder syndrome: Randomized control trial

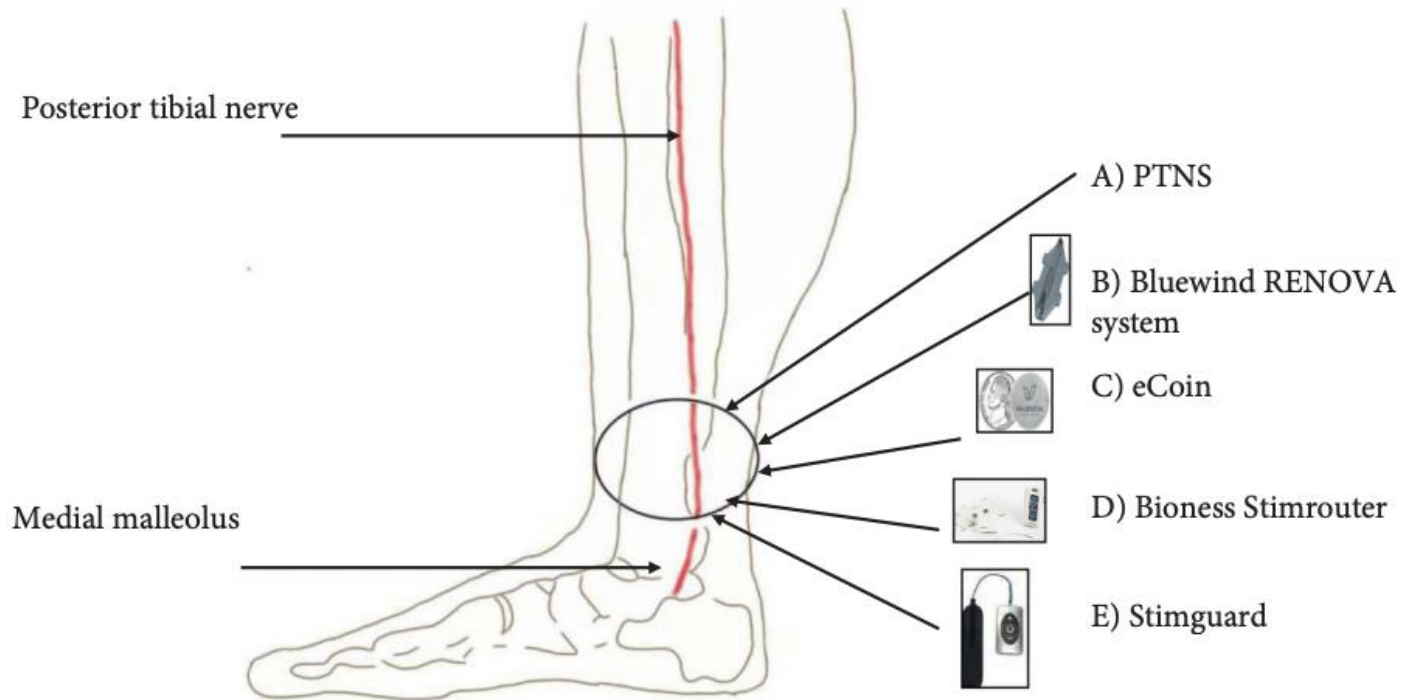
Inés Ramírez-García PT, BA, MSc, PhD^{1,2}  | Laia Blanco-Ratto PT, MSc¹ |
Stéphanie Kauffmann PT, MSc¹ | Andrea Carralero-Martínez PT, MSc¹ |
Emília Sánchez MD, MPH, PhD²

Quality-of-life questionnaires	TTNS group (<i>n</i> = 32)	PTNS group (<i>n</i> = 29)	Adjusted difference (95% CI)	<i>p</i>
Per-protocol analysis				
OAB-q-SF				
Symptoms scale	31.4 (20.0)	36.7 (22.6)	-5.3 (-16.2; 5.6)	.335
HRQL scale	78.5 (20.3)	77.3 (21.5)	1.2 (-9.5; 12.0)	.817
IQOL total score	71.9 (20.3)	68.8 (26.1)	3.1 (-8.8; 15.0)	.607
Intention-to-treat analysis (<i>n</i> = 34)				
OAB-q-SF				
Symptoms scale	32.1 (20.2)	39.7 (22.7)	-7.6 (-18.1; 2.7)	.148
HRQL scale	77.7 (20.9)	72.4 (24.1)	5.3 (-5.6; 16.2)	.337
IQOL total score	71.1 (20.4)	63.2 (28.3)	7.9 (-4.1; 19.8)	.192



Conclusion: A significant improvement of QoL was observed in both TTNS and PTNS groups. However, no patient-reported outcomes measures scores support a difference between the two groups. Therefore, these findings along with TTNS ease of application and less invasiveness may lead to an increased indication of this technique for OAB

Dispositivos implantables para Neuromodulación del Nervio Tibial Posterior



ClinicalTrials.gov ^{BETA}

Resources ▼ About ▼

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RECRUITING 📍

ClinicalTrials.gov Identifier: NCT05226286

Evaluation of Implantable Tibial Neuromodulation Pivotal Study (TITAN 2)

Information provided by MedtronicNeuro (Responsible Party)

Last Updated: November 11, 2022

Voiding Dysfunction

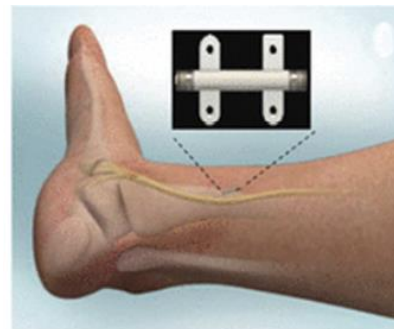
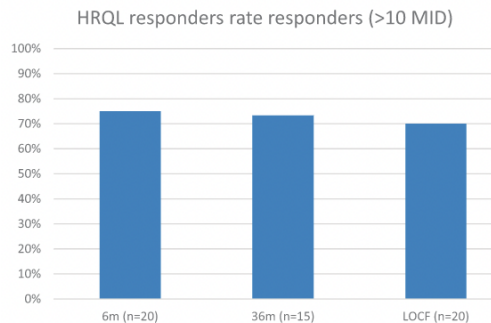
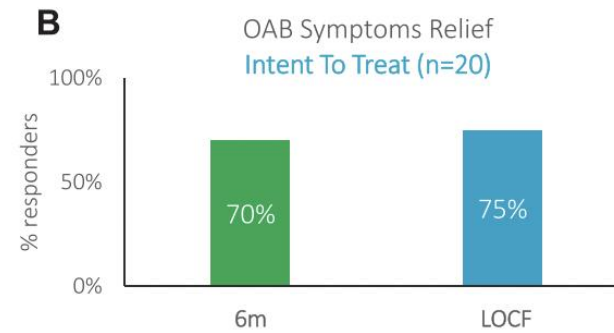
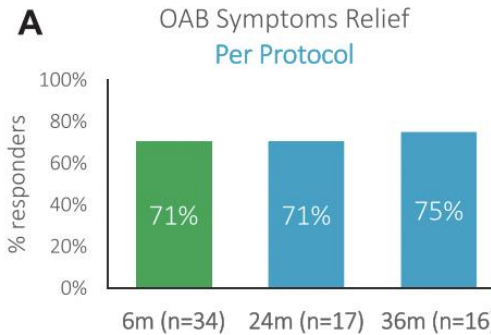
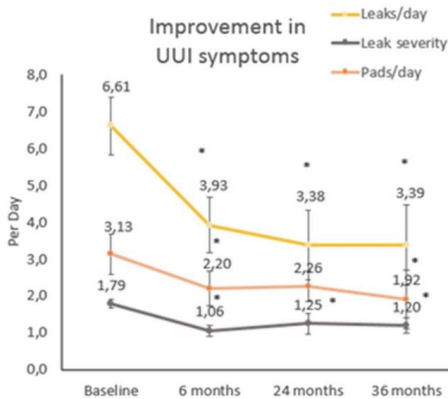
3-Year Followup of a New Implantable Tibial Nerve Stimulator for the Treatment of Overactive Bladder Syndrome



J Urol Sept 2020

Manon J. te Dorsthorst,* Giuseppe A. Digesu, Visha Tailor, Michelle Gore, Phillip E. van Kerrebroeck, Hendrikje M. K. van Breda, Sohier Elneil and John P. F. A. Heesakkers

From the Department of Urology, RadboudUMC, Nijmegen (MJTD, JPFAH), Department of Urology, Maastricht University Medical Center, Maastricht (PEVK), Department of Urology, UMC Utrecht, Utrecht (HMKvB), the Netherlands, Imperial College NHS Healthcare (GAD, VT, MG), Department of Uro-Neurology, National Hospital of Neurology and Neurosurgery (SE), London, United Kingdom



Conclusions: This 3-year followup study using the BlueWind RENOVA iStim system for the treatment of overactive bladder syndrome symptoms confirms the long-term good safety profile with no technical failures reported. Lasting treatment efficacy is mirrored by a sustained positive impact on patient quality of life.

Resumen

- LA NRS ha demostrado ser eficaz y segura para VH a corto, medio y largo plazo
- La NRS permite además tratar disfunciones intestinales
- La compatibilidad con RMN permitirá beneficiar a grupos específicos de pacientes
- Los dispositivos recargables ofrecen ventajas, beneficio clínico y reducción de costes
- La toxina botulínica es eficaz y segura a corto-medio plazo
- Los inconvenientes principales son la ITU y la retención urinaria
- La estimulación del n. tibial posterior ha demostrado ser segura y efectiva, pero requiere cronicidad del tratamiento