3ª línea de tratamiento en Vejiga Hiperactiva PTNS

Isabel Montes Posada
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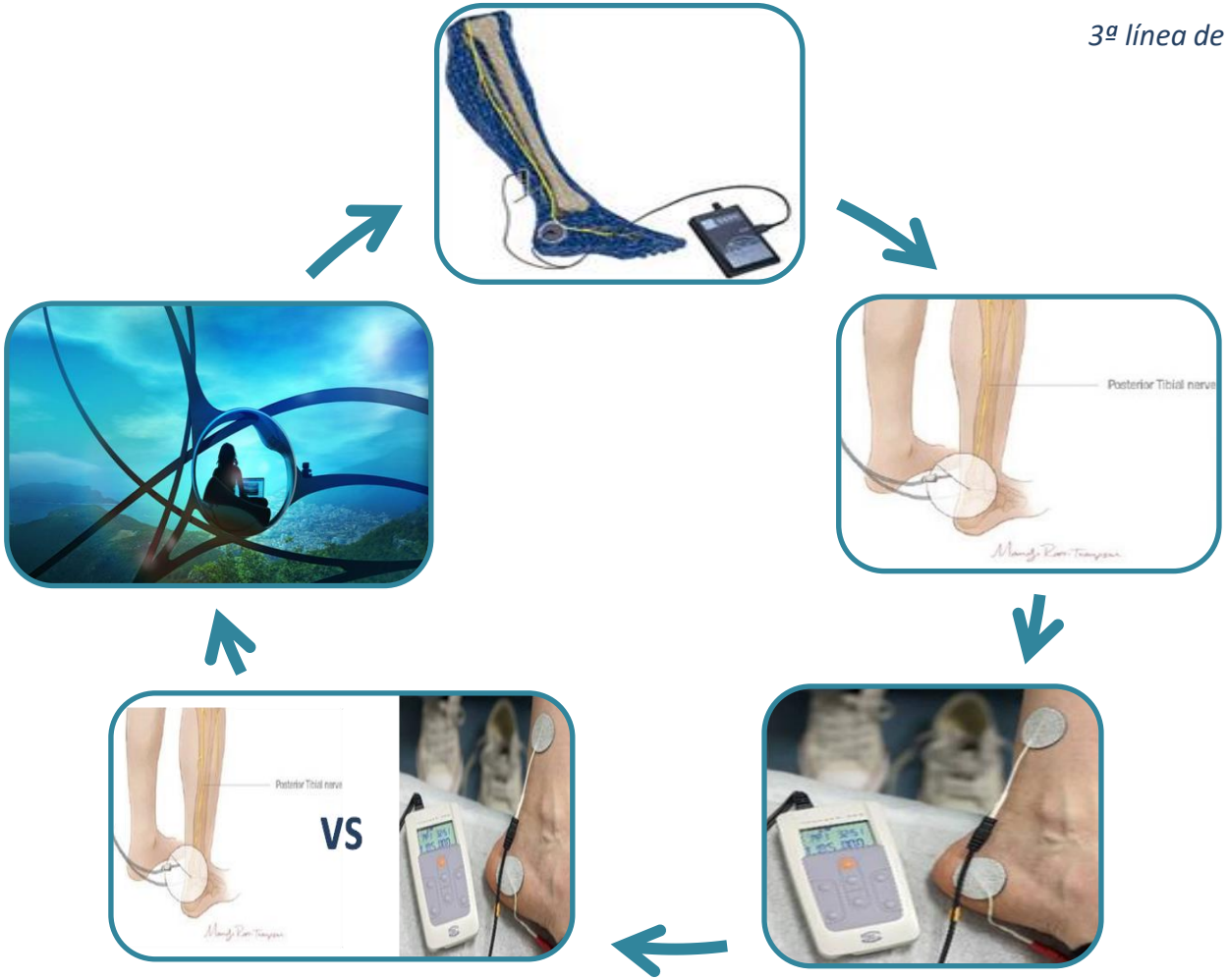

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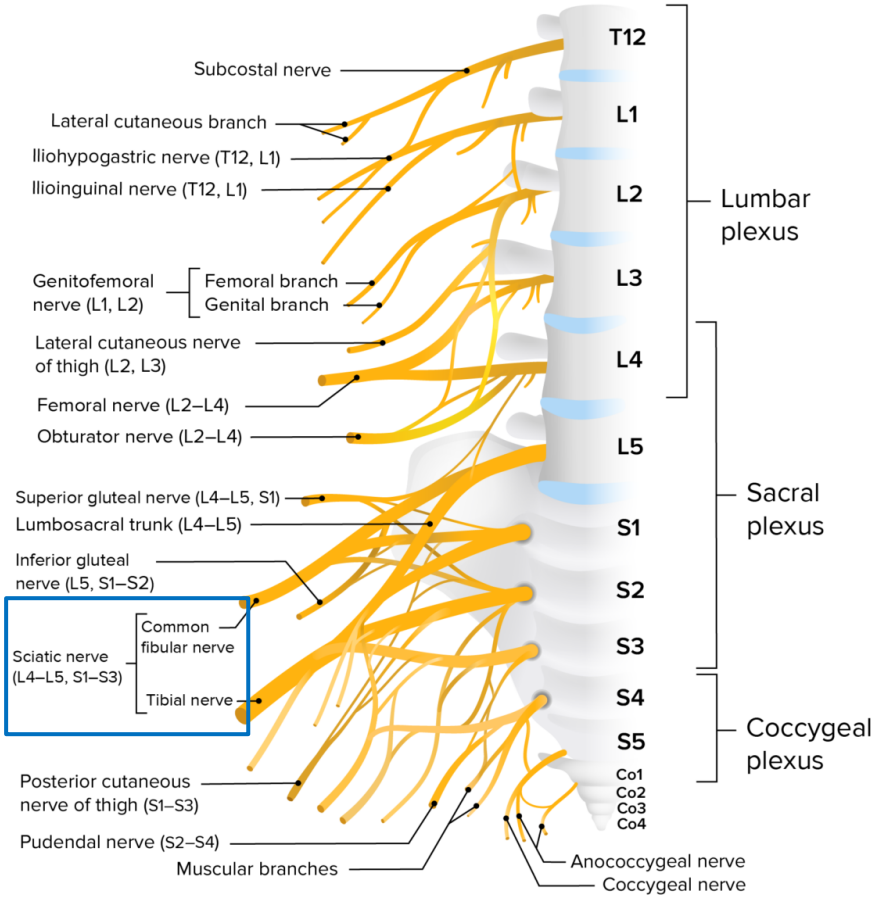

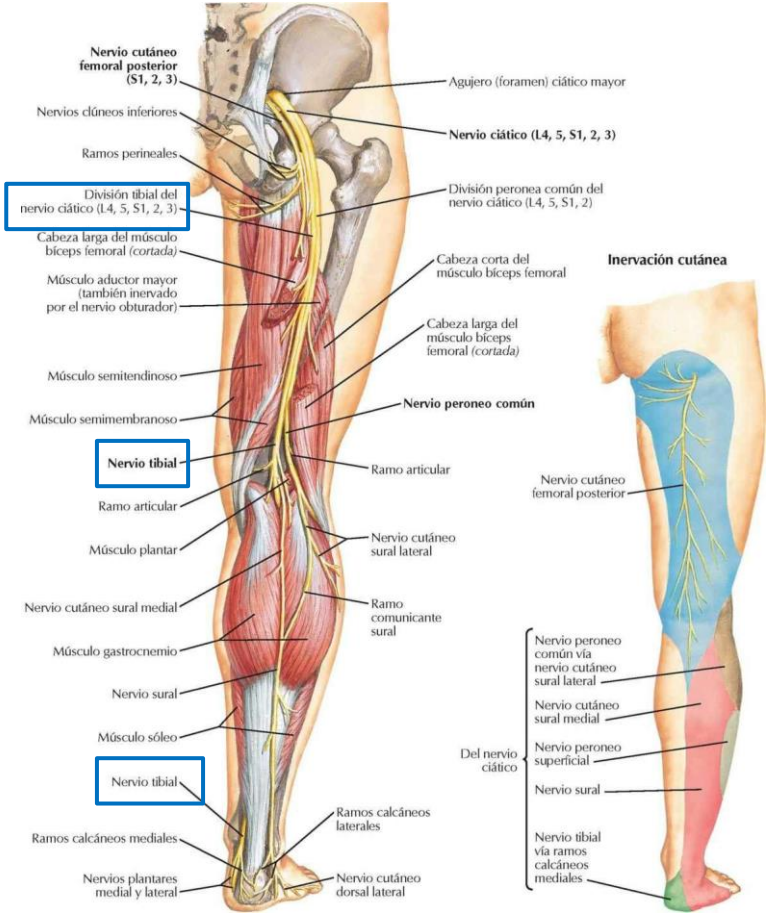

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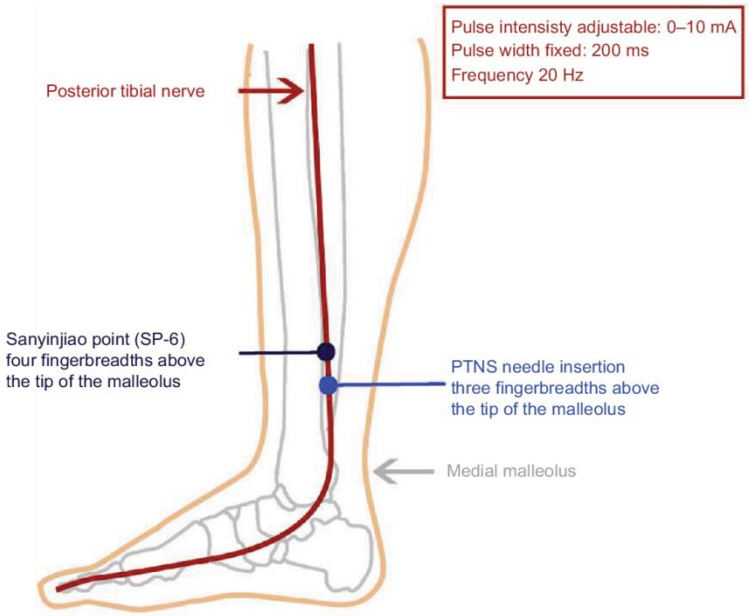
- Tratamiento mínimamente invasivo.
- Aguja 34G.
- A 5 cm en sentido cefálico desde el maléolo medial y posterior al borde de la tibia.
- 20 Hz (frec), ancho de pulso 200 µs, estimulación a 0,5-9 mA (int).
- 12 sesiones, 1v/sem, 30 min.



Sonmez, Rafet, Necmettin Yildiz, and Hakan Alkan. "Efficacy of percutaneous and transcutaneous tibial nerve stimulation in women with idiopathic overactive bladder: A prospective randomised controlled trial." *Annals of physical and rehabilitation medicine* 65.1 (2022): 101486.

Estimulación de las aferencias del nervio tibial

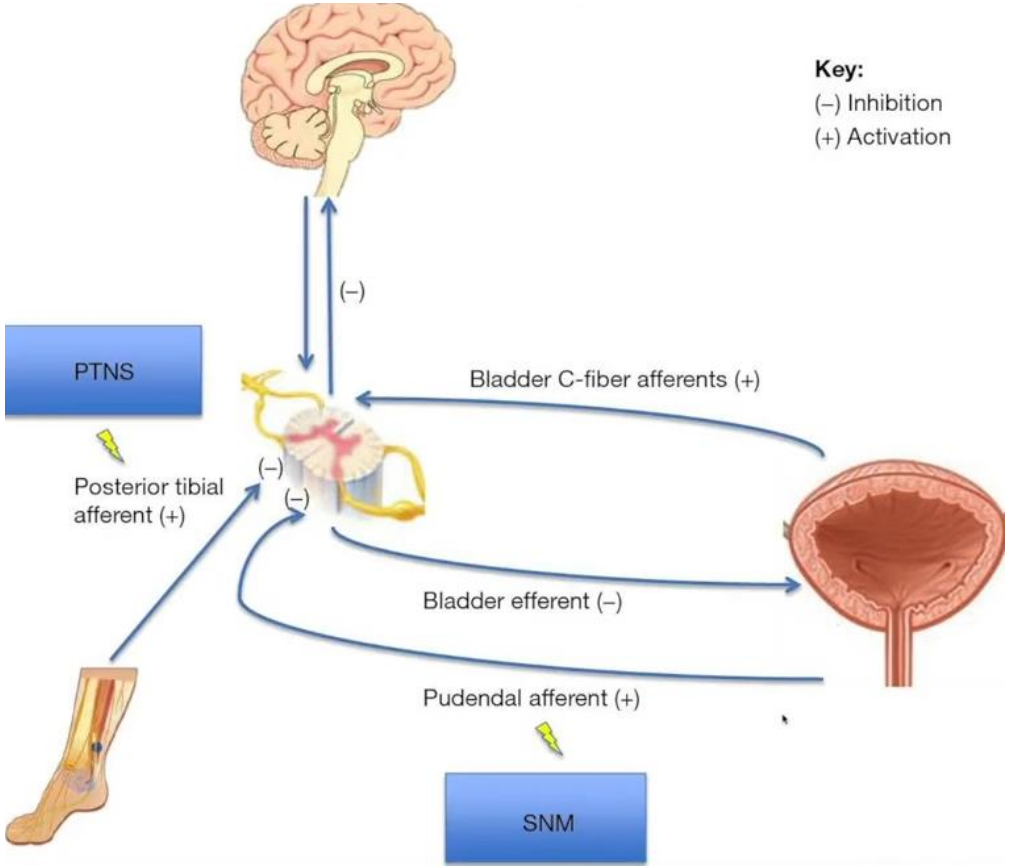
Plexo Parasimpático de la vejiga

Estimula el plexo sacro (S2-S4)

Centro Sacro de la Micción

Inhibición de las neuronas motoras parasimpáticas

Relajación del detrusor



- **McGuire**, EENT ↓hiperactividad del detrusor (1983)
- **Stoller** introdujo por primera vez la PTNS como neuromodulación del TUI en 1999, **SANS** (**Stoller afferent nerve stimulation**).
- Aprobada por la **FDA** para su uso en VH en **2006**.

Mcguire, Edward J., et al. "Treatment of motor and sensory detrusor instability by electrical stimulation." *The Journal of urology* 129.1 (1983): 78-79.
Gaziev, Gabriele, et al. "Percutaneous tibial nerve stimulation (PTNS) efficacy in the treatment of lower urinary tract dysfunctions: a systematic review." *BMC urology* 13 (2013): 1-11.

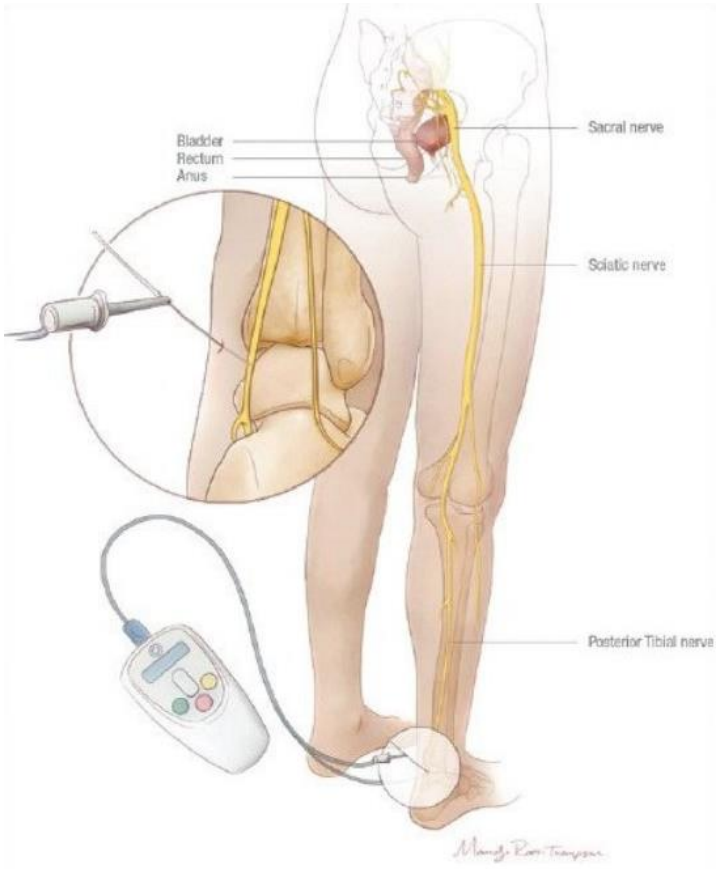
A peripheric neuromodulation technique for curing detrusor overactivity: Stoller afferent neurostimulation

2005

Abstract

Objective. To perform Stoller afferent neurostimulation (SANS) with and without a low-dose anticholinergic (oxybutynin hydrochloride) in patients with detrusor overactivity and compare the results obtained with the two therapeutic approaches. *Material and methods.* A total of 43 patients with symptoms of detrusor overactivity (frequency, urgency, urge incontinence) underwent urodynamic studies (UDS). Those in whom UDS revealed phasic detrusor overactivity were evaluated using a quality of life questionnaire and voiding diaries. Patients were randomized into two groups: Group 1 received SANS alone; Group 2 received SANS combined with a low-dose anticholinergic (5 mg of oral oxybutynin hydrochloride). Both groups were re-evaluated following 8 weeks of therapy. *Results.* There were 21 patients in Group 1 and 22 in Group 2. The treatment response rate was 61.6% and 83.2% in Groups 1 and 2, respectively. In both groups, the best symptomatic improvements were obtained in patients with urge incontinence. The percentage decreases in the mean number of symptoms of frequency and urgency were 36.7% and 46.1%, respectively in Group 1 and 44.2% and 61.1%, respectively in Group 2. However, there were no statistically significant differences in the effects on frequency and urgency between the two groups. The anticholinergic drug was well tolerated by all patients in Group 2. One patient reported local tenderness, and a small hematoma developed in another following SANS therapy. *Conclusion.* SANS is an easy and inexpensive therapeutic method with low morbidity in patients with an overactive bladder. Combination with a low-dose anticholinergic increases the success rate without causing any significant side-effects.

Karademir, Kenan, et al. "A peripheric neuromodulation technique for curing detrusor overactivity: Stoller afferent neurostimulation." *Scandinavian journal of urology and nephrology* 39.3 (2005): 230-233.



Percutaneous tibial nerve stimulation: the Urgent PC® device

Michael R van Balken

Lower urinary tract disorders, with its main representative the overactive bladder, are an increasing problem that impact patients' quality of life tremendously. Neuromodulative treatment may fill the gap between conservative measures and invasive surgery. Percutaneous tibial nerve stimulation (Urgent PC®) is a neuromodulation technique that is minimally invasive and easy to perform. Stimulation is carried out in 12 weekly sessions of 30 min each, through a percutaneously placed needle cephalad to the medial malleolus. Success can be obtained in approximately two-thirds of patients, but the therapy has the disadvantage of the necessity of maintenance therapy. The development of a small implantable device may be the future next step in the evolution of the technique.

Expert Rev. Med. Devices 4(5), 693–698 (2007)

2007

https://p1.aprimocdn.net/laborie/58b5233a-24f3-4413-9ed3-aea60090bbfe/MKT-00605A%20_UPC-Intl-Brochure-A4_Original%20file.pdf

Shireman, Jordan, et al. "Treating overactive bladder with percutaneous tibial nerve stimulation." *Journal of the American Academy of PAs* 34.12 (2021): 27-30.

Urgent PC Versus a Generic Posterior Tibial Neurostimulator for Overactive Bladder: A Retrospective Noninferiority Study

2022

Objective: The aim of the study was to determine whether a generic posterior tibial neurostimulator was noninferior to Urgent PC in the treatment of nonneurogenic OAB, urgency urinary incontinence, and mixed urinary incontinence. Secondary outcomes include rates of starting and completing 3 months of maintenance therapy, treatment success after 3 months, and adverse events.

Methods: We performed a retrospective cohort analysis of women whose nonneurogenic OAB, urgency urinary incontinence, or mixed urinary incontinence was treated with either Urgent PC or a generic posterior tibial neurostimulator. Previous research shows a 55% treatment success rate for posterior tibial nerve stimulation (PTNS). To demonstrate noninferiority with a limit of 14% and 80% power, our analysis required 157 patients per group.

Results: We included 267 Urgent PC and 234 generic patients and excluded 51 patients from analysis. A per-protocol analysis demonstrated treatment success in 55.3% (121 of 219) of the Urgent PC and 48.6% (85 of 175) of the generic cohort (P = 0.187). An intention-to-treat analysis showed treatment success in 45.3% (121 of 267) of the Urgent PC and 36.3% (85 of 234) of the generic cohort (P = 0.690). There were no significant differences in rates of starting (82.2% vs 78.2%, P = 0.409) or completing (79.9% vs 70.9%, P = 0.129) 3 months of maintenance therapy, treatment success after 3 months (78.5% vs 73.8%, P = 0.485), and adverse events (0.37% vs 0.85%, P = 1.000) in the Urgent PC versus generic group, respectively.

Handler, Stephanie Jillian et al. “Urgent PC Versus a Generic Posterior Tibial Neurostimulator for Overactive Bladder: A Retrospective Noninferiority Study.” *Female pelvic medicine & reconstructive surgery* vol. 28,3 (2022): 136-141.

Urgent PC Versus a Generic Posterior Tibial Neurostimulator for Overactive Bladder: A Retrospective Noninferiority Study

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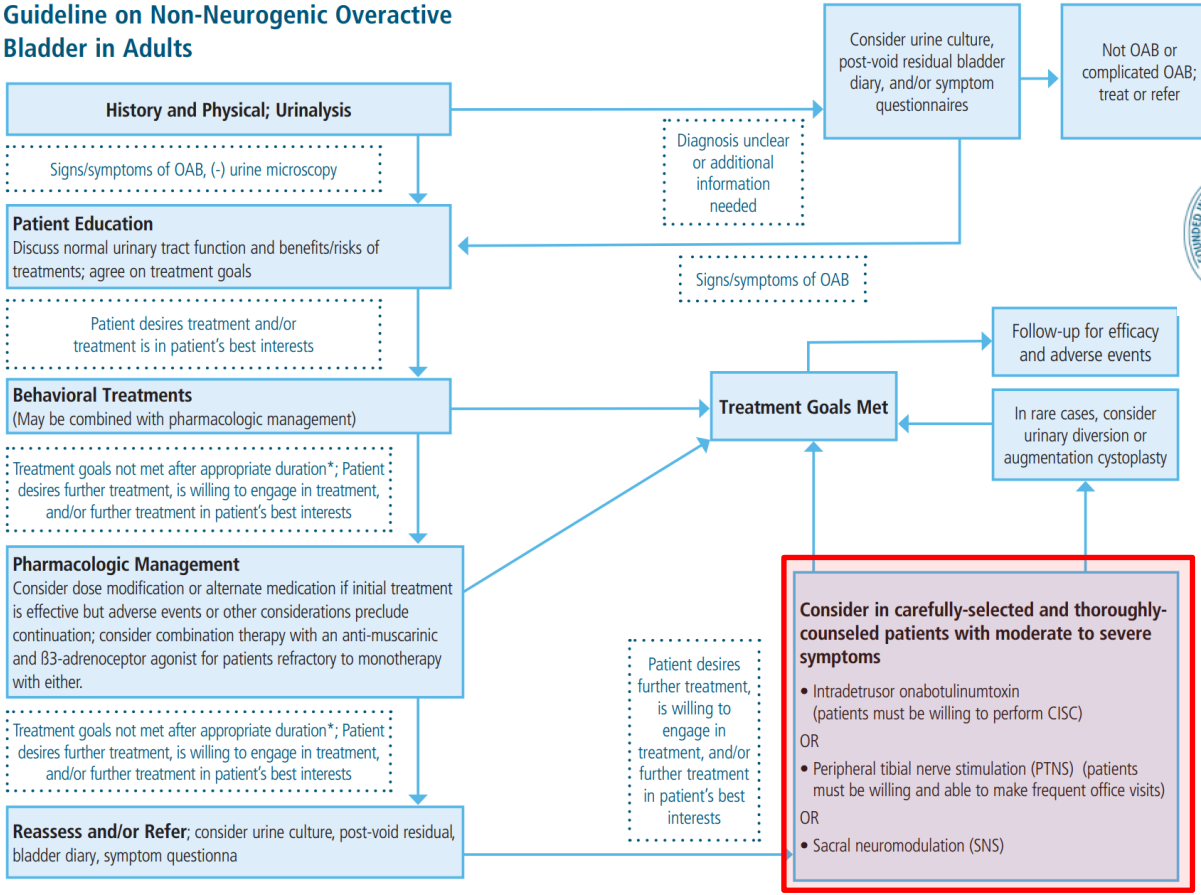
Conclusions: In this cohort of women undergoing PTNS for nonneurogenic OAB, urgency urinary incontinence, or mixed urinary incontinence, the generic neurostimulator demonstrated noninferior rates of treatment success compared with Urgent PC.

versus generic group, respectively.

Handler, Stephanie Jillian et al. "Urgent PC Versus a Generic Posterior Tibial Neurostimulator for Overactive Bladder: A Retrospective Noninferiority Study." *Female pelvic medicine & reconstructive surgery* vol. 28,3 (2022): 136-141.

Diagnosis & Treatment Algorithm: AUA/SUFU Guideline on Non-Neurogenic Overactive Bladder in Adults



American Urological Association

The complete OAB Guideline is available at AUAnet.org/Guidelines.

This clinical framework does not require that every patient go through each line of treatment in order as there are many factors to consider when identifying the best treatment for a particular patient.

*Appropriate duration is 8 to 12 weeks for behavioral therapies and 4 to 8 weeks for pharmacologic therapies

https://www.auanet.org/guidelines-and-quality/guidelines/non-oncology-guidelines

American Urological Association

Third-line Treatments: PTNS and Neuromodulation

18. Clinicians may offer intradetrusor onabotulinumtoxinA (100U) as third-line treatment in the carefully-selected and thoroughly-counseled patient who has been refractory to first- and second-line OAB treatments. The patient must be able and willing to return for frequent post-void residual evaluation and able and willing to perform self-catheterization if necessary. *Standard (Evidence Strength Grade B)*
19. Clinicians may offer peripheral tibial nerve stimulation (PTNS) as third-line treatment in a carefully selected patient population. *Recommendation (Evidence Strength Grade C)*
20. Clinicians may offer sacral neuromodulation (SNS) as third-line treatment in a carefully selected patient population characterized by severe refractory OAB symptoms or patients who are not candidates for second-line therapy and are willing to undergo a surgical procedure. *Recommendation (Evidence Strength Grade C)*
21. Practitioners and patients should persist with new treatments for an adequate trial in order to determine whether the therapy is efficacious and tolerable. Combination therapeutic approaches should be assembled methodically, with the addition of new therapies occurring only when the relative efficacy of the preceding therapy is known. Therapies that do not demonstrate efficacy after an adequate trial should be ceased. *Expert Opinion*

Guideline Statement 19.

Clinicians may offer peripheral tibial nerve stimulation (PTNS) as third-line treatment in a carefully selected patient population. *Recommendation (Evidence Strength Grade C)*

https://www.auanet.org/guidelines-and-quality/guidelines/non-oncology-guidelines

PTNS

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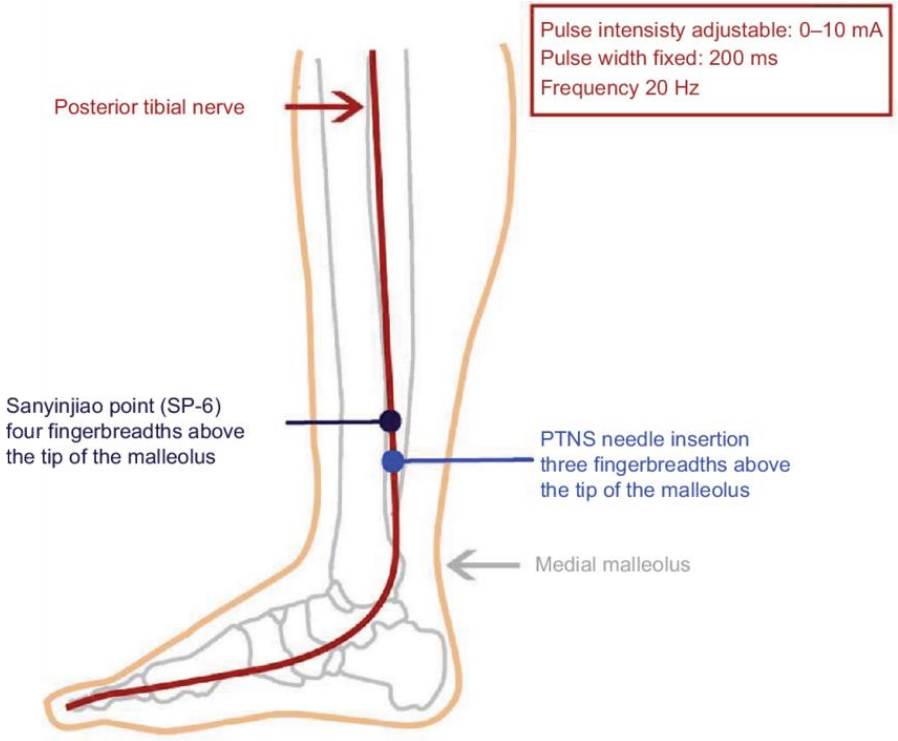
- La PTNS:
  - Programa de tratamiento: 30 min/sem, 12 sesiones.
  - Personal capacitado.
  - Entorno clínico o de atención secundaria.
  - Compromiso significativo de tiempo y viajes por parte de los pacientes.
- El procedimiento requiere tiempo.



- Técnica:
  - **Percutánea** con una aguja fina (34-G), insertada justo encima de la cara medial del tobillo (**P-PTNS**).
  - **Transcutánea** a través de electrodos de superficie que no penetran la piel (**T-PTNS**).
- No se ha determinado el programa de tratamiento óptimo, pudiendo ser diarios y semanales.

Peyronnet, B., et al. Benefits and Harms of Conservative, Pharmacological, and Surgical Management Options for Women with Bladder Outlet Obstruction: A Systematic Review from the European Association of Urology Non-neurogenic Female LUTS Guidelines Panel. Eur Urol Focus, 2022. 8: 1340.

Subjective and objective responses to PTNS and predictors for success: a retrospective cohort study of percutaneous tibial nerve stimulation for overactive bladder

2019

Introduction and hypothesis We investigated the objective improvements in overactive bladder (OAB) symptoms in patients undergoing percutaneous tibial nerve stimulation (PTNS) and predictive factors of patient satisfaction.

Methods In this single-center retrospective cohort study at a tertiary urogynecology center, we identified all female patients who underwent PTNS therapy from 1 October 2007 – 1 January 2016 and followed them from their initial visit through medication therapy and PTNS treatments. Patients who tried at least one medication prior to starting PTNS therapy and completed at least one PTNS visit were included. Baseline demographic data, urinary data, and details of medication and PTNS therapy sessions were collected from records through chart review. Paired or two-sample *t*-tests were used to compare changes over time or groups. Bivariate and multivariable logistic regression were performed.

Results Two hundred thirteen patients underwent PTNS therapy and 183 patients met the criteria. Overall patients were able to decrease voiding frequency by 1 h, decrease nocturia episodes by 0.8, and decrease urge incontinence episodes with PTNS therapy by ten episodes per week ($p = 0.02$). Patients who continued OAB medications did not have additional improvements compared with patients who did not continue OAB medications during PTNS. Overall, 25.4% (43/169) patients reported ≥ 75% improvement during PTNS therapy, and 61.5% (104/169) reported ≥ 50% improvement. When evaluating predictive factors of ≥ 50% overall improvement, the number of PTNS sessions increased odds of subjective success (OR = 1.8, $p = 0.004$). Other factors were not significant predictors of subjective PTNS success.

Conclusions PTNS can provide both objective and subjective improvements for patients who do not respond to OAB medication therapy.

Iyer, Shilpa, et al. "Subjective and objective responses to PTNS and predictors for success: a retrospective cohort study of percutaneous tibial nerve stimulation for overactive bladder." *International Urogynecology Journal* 30 (2019): 1253-1259.

ORIGINAL ARTICLE

CrossMark

2019

Subjective and objective responses to PTNS and predictors for success: a retrospective cohort study of percutaneous tibial nerve stimulation for overactive bladder

- Tasa de **respuesta** más alta y fue superior al grupo simulado con mejoría en la **FMD, FMN, Urg e IUU.**
- **Efecto terapéutico** continuo en un estudio retrospectivo con un seguimiento de 9 años.

Iyer, Shilpa, et al. "Subjective and objective responses to PTNS and predictors for success: a retrospective cohort study of percutaneous tibial nerve stimulation for overactive bladder." *International Urogynecology Journal* 30 (2019): 1253-1259.

Percutaneous tibial nerve stimulation for overactive bladder syndrome: a systematic review and meta-analysis

2020

Menghua Wang[1] · Zhongyu Jian[1,2] · Yucheng Ma[1] · Xi Jin[1] · Hong Li[1] · Kunjie Wang[1]

Abstract

Introduction and hypothesis This systematic review and meta-analysis aimed to evaluate the efficacy and safety of percutaneous tibial nerve stimulation (PTNS) for the treatment of overactive bladder (OAB) syndrome.

Methods PubMed, Embase, Web of Science and Cochrane Library were searched systematically to identify all the relevant studies. Void frequency per day, nocturia frequency per day, urgency episodes per day, incontinence episodes per day, urodynamic values, success rate and side effects, etc., were extracted from the included studies and analyzed.

Results Twenty-eight studies with 2461 patients in total were included. Results showed that there was a significant clinical effect on the voiding frequency per day (MD = −2.48; 95% CI −3.19, −1.76; $P < 0.001$), nocturia frequency per day (MD = −1.57; 95% CI −2.16, −0.99; $P < 0.001$), urgency episodes per day (MD = −2.20; 95% CI −3.77, −0.62; $P = 0.006$), incontinence episodes per day (MD = −1.37; 95% CI −1.71, −1.02; $P < 0.001$), maximum cystometric capacity (MD = 63.76; 95% CI 31.90, 95.61; $P < 0.001$) and compliance (MD = 7.62; 95% CI 0.61, 14.63; $P = 0.033$). The pooled success rate was 0.68 (95% CI 0.59, 0.78). The major complication was the pain at the puncture site, but the incidence was low.

Conclusions PTNS is effective and safe in treating OAB symptoms.

Keywords Meta-analysis · Overactive bladder · Percutaneous tibial nerve stimulation · PTNS

Wang, Menghua, et al. "Percutaneous tibial nerve stimulation for overactive bladder syndrome: a systematic review and meta-analysis." *International Urogynecology Journal* 31 (2020): 2457-2471.

Percutaneous tibial nerve stimulation for overactive bladder syndrome: a systematic review and meta-analysis

2020

- **Revisión sistemática y un metanálisis** PTNS en VH:
  - Mayoría de los estudios incluidos con poblaciones con una edad media >50 años.
  - Tasa de respuesta del 68%.
- **Efectos adversos:**
  - Pocos y menores, incluido dolor en el lugar de la aguja, hematomas y sangrado.

Wang, Menghua, et al. "Percutaneous tibial nerve stimulation for overactive bladder syndrome: a systematic review and meta-analysis." *International Urogynecology Journal* 31 (2020): 2457-2471.

2020

- Estudios a largo plazo muestran que la **adherencia** es **deficiente**.
  - Retrospectivo en más de 400 pacientes tratados con PTNS para la VH.
  - Solo el **57% continúa** después del tratamiento inicial de 12 semanas.
  - El **40%** de ellos **suspendió** la terapia de **mantenimiento** debido a razones logísticas y esfuerzo físico.

Te Dorsthorst, Manon J., John PFA Heesakkers, and Michael R. van Balken. "Long-term real-life adherence of percutaneous tibial nerve stimulation in over 400 patients." *Neurourology and Urodynamics* 39.2 (2020): 702-706.

Comparative Study > J Urol. 2013 Jan;189(1):210-6. doi: 10.1016/j.juro.2012.08.085.

Epub 2012 Nov 20.

Cost of neuromodulation therapies for overactive bladder: percutaneous tibial nerve stimulation versus sacral nerve stimulation

- El uso de la estimulación periférica percutánea es eficiente a pesar de su moderado coste. (1)

1.Martinson, Melissa, Scott MacDiarmid, and Edward Black. "Cost of neuromodulation therapies for overactive bladder: percutaneous tibial nerve stimulation versus sacral nerve stimulation." *The Journal of urology* 189.1 (2013): 210-216.

T-PTNS

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2018

REVIEW ARTICLE

WILEY Neurourology Urodynamics ICS SUFU

The effectiveness of transcutaneous tibial nerve stimulation (TTNS) for adults with overactive bladder syndrome: A systematic review

Aims: To evaluate effectiveness of transcutaneous tibial nerve stimulation (TTNS) for treating adults with overactive bladder (OAB) of idiopathic or neurogenic origin, using a systematic review of the literature.

Methods: Systematic searches of four databases were undertaken between 1980 and 2017. Included studies investigated effects of TTNS on OAB. Study selection, data extraction, quality appraisal was performed by two independent reviewers. Narrative analysis was undertaken where meta-analysis was not possible due to study heterogeneity. Meta-analysis of RCTs was performed using a fixed effects model.

Results: Ten RCTs and three prospective cohort studies involving 629 participants were reviewed. Meta-analysis of two trials comparing TTNS with sham showed mean reduction in total ICIQ Urinary Incontinence Short Form (ICIQ-UI SF) associated with TTNS of −3.79 (95% CI −5.82, −1.76; $P = 0.0003$, $I^2 = 25\%$). Narrative review showed TTNS and antimuscarinic treatment were equally effective (four trials), TTNS provided greater benefit for OAB symptoms than behavioral interventions (two trials), tibial nerve, and sacral foramen stimulation were equally effective but combined stimulation was most effective (one trial). Significant improvements in OAB symptoms were reported by 48-93% participants and UI cure rates of 25-45%. No adverse events were reported.

Conclusions: Limited evidence is provided that TTNS is an effective, safe intervention for idiopathic OAB in adults and may be of benefit in those with neurogenic OAB. Further studies are essential to confirm these results as well as to determine efficacy and associated costs for specific patient groups, most effective stimulation dosage, duration of effect, and stimulation regimes for longer-term maintenance.

Booth, Joanne, et al. "The effectiveness of transcutaneous tibial nerve stimulation (TTNS) for adults with overactive bladder syndrome: a systematic review." *Neurourology and urodynamics* 37.2 (2018): 528-541.

REVIEW ARTICLE

WILEY Neurourology Urodynamics ICS SUFU

2018

The effectiveness of transcutaneous tibial nerve stimulation (TTNS) for adults with overactive bladder syndrome: A systematic review

- Dada su seguridad, bajo costo, facilidad de aplicación y potencial para **respaldar la autoadministración**, existe un claro impulso para que se realicen más investigaciones para establecer evidencia definitiva sobre el papel de la **TTNS** como terapia de **segunda línea**, después de que se hayan implementado cambios en el estilo de vida, comportamentales y como **alternativa directa al tratamiento farmacológico en adultos con VH.**

Booth, Joanne, et al. "The effectiveness of transcutaneous tibial nerve stimulation (TTNS) for adults with overactive bladder syndrome: a systematic review." *Neurourology and urodynamics* 37.2 (2018): 528-541.

P-PTNS vs T-PTNS

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2019

- Un **ECA de no inferioridad** que comparó **T-PTNS** con **P-PTNS** informó mejoras significativas en la **frecuencia diurna**, la **urgencia** y los episodios de **IUU** sin diferencias significativas entre los brazos de tratamiento después de 12 semanas de tratamiento.

Ramírez-García, Inés, et al. "Efficacy of transcutaneous stimulation of the posterior tibial nerve compared to percutaneous stimulation in idiopathic overactive bladder syndrome: randomized control trial." *Neurourology and urodynamics* 38.1 (2019): 261-268.

Treatment for overactive bladder

A meta-analysis of transcutaneous tibial nerve stimulation versus percutaneous tibial nerve stimulation

2021

Abstract

Background: We aim to compare the safety and effectiveness of transcutaneous tibial nerve stimulation (TTNS) versus percutaneous tibial nerve stimulation (PTNS) in treating overactive bladder.

Methods: A systematical search on PubMed, Embase, clinicalTrial.gov, and Cochrane Library Central Register of Controlled Trials from January 1, 1999 to November 1, 2020 was performed. The primary outcomes were the changes in a 3-day voiding diary. Quality of life scores were also evaluated. Review Manager 5.3 (Cochrane Collaboration, Oxford, UK) was applied to conduct all statistical analyses.

Results: A total of 4 trials (2 randomized controlled trials, 1 retrospective study, and 1 before-after study) with 142 patients were eventually enrolled. Compared with PTNS, TTNS had a similar performance in the voiding frequency in 24 hours (mean difference [MD] = −0.65, 95% confidence interval [CI]: −1.35 to 0.05, $P = .07$), the number of urgency episodes in 24 hours (MD = 0.13, 95% CI: −0.36 to 0.62, $P = .60$), the number of incontinence episodes in 24 hours (MD = 0.01, 95% CI: −0.13 to 0.14, $P = .93$), as well as in the nocturia frequency (MD = −0.14, 95% CI: −0.52 to 0.24, $P = .47$). Moreover, comparable results were observed regarding HRQL scores ($P = .23$) and incontinence quality of life scores ($P = .10$) in both groups. The total complication rate in the current study was 2.1% (3/142). No adverse events were identified in the TTNS group.

Conclusion: Current data supported that TTNS is as effective as PTNS for the treatment of overactive bladder, moreover, with no reported adverse events. However, the evidence is low-grade and well-designed prospective studies with a large sample size are warranted to verify our findings.

Abbreviations: AEs = adverse events, I-QoL = incontinence quality of life questionnaire, OAB = overactive bladder, PTNS = percutaneous tibial nerve stimulation, TTNS = transcutaneous tibial nerve stimulation.

Keywords: overactive bladder, percutaneous tibial nerve stimulation, transcutaneous tibial nerve stimulation

Yang, Ding-Yuan, Liu-Ni Zhao, and Ming-Xing Qiu. "Treatment for overactive bladder: A meta-analysis of transcutaneous tibial nerve stimulation versus percutaneous tibial nerve stimulation." *Medicine* 100.20 (2021)

Treatment for overactive bladder

A meta-analysis of transcutaneous tibial nerve stimulation versus percutaneous tibial nerve stimulation

2021

Characteristics of included studies.

Study (year)	Design	Duration (year)	Group	N (women/men)	Age (years)	Treatment protocol	Stimulation parameters	Follow-up
Ramírez-García (2019)	RCT	2015–2016	TTNS	21/13	62.4 ± 16	30 min/wk	20 Hz and 200 cycles	12 wk
			PTNS	25/9	56.8 ± 16	30 min/wk	20 Hz and 200 cycles	12 wk
Martin-Garcia (2019)	RCT	2015–2016	TTNS	12/0	54 ± 12	≥30 min × 3/wk	20 Hz and 200 cycles	6 mo
			PTNS	12/0	58 ± 10	30 min/4 wk	20 Hz and 200 cycles	6 mo
Alfonso Barrera (2013)	R	2011–2012	TTNS	21/0	–	30 min/wk	20 Hz and 200 cycles	12 wk
			PTNS	13/0	–	30 min/wk	20 Hz and 200 cycles	12 wk
Maurelli (2012)	Before and after	–	TTNS	13/3	–	30 min/wk	20 Hz and 200 cycles	19.7 mo
			PTNS	13/3	–	30 min/wk	20 Hz and 200 cycles	–

PTNS = percutaneous tibial nerve stimulation, R = retrospective, RCT = randomized controlled trial, TTNS = transcutaneous tibial nerve stimulation.

Yang, Ding-Yuan, Liu-Ni Zhao, and Ming-Xing Qiu. "Treatment for overactive bladder: A meta-analysis of transcutaneous tibial nerve stimulation versus percutaneous tibial nerve stimulation." *Medicine* 100.20 (2021)

2021

Treatment for overactive bladder

A meta-analysis of transcutaneous tibial nerve stimulation versus percutaneous tibial nerve stimulation

The treatment protocol of nerve stimulation in each study.

Study (year)	Group	Treatment protocol	Stimulation parameters	Electrode size	Location of electrode	Stimulator	Current range
Ramírez-García (2019)	TTNS	30 min/wk, for 12 wk	Biphasic square waves, 20 Hz and 200 cycles	32 mm	5 cm above the medial malleolus	TENS URO stim2	0.5–20 mA
	PTNS	30 min/wk, for 12 wk	Biphasic square waves, 20 Hz and 200 cycles	40 mm × 0.20 mm acupuncture needles (34 gauge)	Percutaneous insertion of a needle 5 cm above the medial malleolus	TENS URO stim2	0.5–20 mA
Martin-Garcia (2019)	TTNS	≥30 min × 3/ wk, for 6 mo	20 Hz and 200 cycles	30 mm	Three finger-breaths cranial to the medial malleolus	NeuroTrac Pelvitone	0–20 mA
	PTNS	30 min/4 wk, for 6 mo	20 Hz and 200 cycles	40 mm × 0.20 mm acupuncture needles (34 gauge)	Three finger-breaths cranial to the medial malleolus	AS SUPER 4 digital	0–20 mA
Alfonso Barrera (2013)	TTNS	30 min/wk, for 12 wk	20 Hz and 200 cycles	–	3 to 4 cm above the medial malleolus	Stimulator NeuroTrac	0–10 mA
	PTNS	30 min/wk, for 12 wk	20 Hz and 200 cycles	34-gauge needle	Percutaneous insertion of a needle 3–4 cm above the medial malleolus	Stimulator Urgent	0–10 mA
Maurelli (2012)	TTNS	30 min/wk, for average 19.7 mo	20 Hz and 200 cycles	–	5 cm above the medial malleolus	LogiSTIM	0–10 mA
	PTNS	30 min/wk	20 Hz and 200 cycles	40 mm × 0.20 mm acupuncture needles (34 gauge)	Percutaneous insertion of a needle 5 cm above the medial malleolus	LogiSTIM	0–10 mA

Yang, Ding-Yuan, Liu-Ni Zhao, and Ming-Xing Qiu. "Treatment for overactive bladder: A meta-analysis of transcutaneous tibial nerve stimulation versus percutaneous tibial nerve stimulation." *Medicine* 100.20 (2021)

3ª línea de tratamiento en VH PTNS

2021

Treatment for overactive bladder

A meta-analysis of transcutaneous tibial nerve stimulation versus percutaneous tibial nerve stimulation

Abstract

Background: We aim to compare the safety and effectiveness of transcutaneous tibial nerve stimulation (TTNS) versus percutaneous tibial nerve stimulation (PTNS) in treating overactive bladder.

Methods: A systematical search on PubMed, Embase, clinicalTrial.gov, and Cochrane Library Central Register of Controlled Trials from January 1, 1999 to November 1, 2020 was performed. The primary outcomes were the changes in a 3-day voiding diary. Quality of life scores were also evaluated. Review Manager 5.3 (Cochrane Collaboration, Oxford, UK) was applied to conduct all statistical analyses.

Results: A total of 4 trials (2 randomized controlled trials, 1 retrospective study, and 1 before-after study) with 142 patients were eventually enrolled. Compared with PTNS, TTNS had a similar performance in the voiding frequency in 24 hours (mean difference [MD] = −0.65, 95% confidence interval [CI]: −1.35 to 0.05, $P = .07$), the number of urgency episodes in 24 hours (MD = 0.13, 95% CI: −0.36 to 0.62, $P = .60$), the number of incontinence episodes in 24 hours (MD = 0.01, 95% CI: −0.13 to 0.14, $P = .93$), as well as in the nocturia frequency (MD = −0.14, 95% CI: −0.52 to 0.24, $P = .47$). Moreover, comparable results were observed regarding HRQL scores ($P = .23$) and incontinence quality of life scores ($P = .10$) in both groups. The total complication rate in the current study was 2.1% (3/142). No adverse events were identified in the TTNS group.

reported adverse events. However, the evidence is low-grade and well-designed prospective studies with a large sample size are warranted to verify our findings.

Abbreviations: AEs = adverse events, I-QoL = incontinence quality of life questionnaire, OAB = overactive bladder, PTNS = percutaneous tibial nerve stimulation, TTNS = transcutaneous tibial nerve stimulation.

Keywords: overactive bladder, percutaneous tibial nerve stimulation, transcutaneous tibial nerve stimulation

Yang, Ding-Yuan, Liu-Ni Zhao, and Ming-Xing Qiu. "Treatment for overactive bladder: A meta-analysis of transcutaneous tibial nerve stimulation versus percutaneous tibial nerve stimulation." *Medicine* 100.20 (2021)

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2021

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Conclusion: Current data supported that TTNS is as effective as PTNS for the treatment of overactive bladder, moreover, with no reported adverse events. However, the evidence is low-grade and well-designed prospective studies with a large sample size are warranted to verify our findings.

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- Aunque la **percutánea** ha demostrado ser eficaz y aceptable, la alternativa con estimulación **transcutánea** puede ser más **cómoda y factible**.
- **PTNS y TTNS** tuvieron efectos clínicos **similares**.
- El tratamiento no invasivo para **TTNS** **reemplaza** las agujas finas con electrodos de superficie.

•Yang, Ding-Yuan, Liu-Ni Zhao, and Ming-Xing Qiu. "Treatment for overactive bladder: A meta-analysis of transcutaneous tibial nerve stimulation versus percutaneous tibial nerve stimulation." *Medicine* 100.20 (2021)
•Sonmez, Rafet, Necmettin Yildiz, and Hakan Alkan. "Efficacy of percutaneous and transcutaneous tibial nerve stimulation in women with idiopathic overactive bladder: A prospective randomised controlled trial." *Annals of physical and rehabilitation medicine* 65.1 (2022): 101486.
•Ramírez-García, Inés, et al. "Efficacy of transcutaneous stimulation of the posterior tibial nerve compared to percutaneous stimulation in idiopathic overactive bladder syndrome: randomized control trial." *Neurourology and urodynamics* 38.1 (2019): 261-268.
•Zonić-Imamović, Maida, et al. "Effects of Transcutaneous and Percutaneous Tibial Nerve Stimulation in Bosnian Female Patients with an Idiopathic Overactive Urinary Bladder." *Acta Medica Academica* 50.2 (2021).

- No hubo una diferencia estadísticamente significativa entre **PTNS** y **TTNS** en la mejora de la **frecuencia de micción diurna**.
- La **PTNS** fue mejor que la TTNS para **mejorar** la **nocturia**, posiblemente porque la aguja fina permite que la estimulación eléctrica actúe directamente sobre el nervio y el efecto es más preciso.
- **PTNS** tiene más **reacciones adversas** que TTNS.

•Sonmez, Rafet, Necmettin Yildiz, and Hakan Alkan. "Efficacy of percutaneous and transcutaneous tibial nerve stimulation in women with idiopathic overactive bladder: A prospective randomised controlled trial." *Annals of physical and rehabilitation medicine* 65.1 (2022): 101486.
•Martin-Garcia, Miguel, and Jennifer Crampton. "A single-blind, randomized controlled trial to evaluate the effectiveness of transcutaneous tibial nerve stimulation (TTNS) in Overactive Bladder symptoms in women responders to percutaneous tibial nerve stimulation (PTNS)." *Physiotherapy* vol. 105,4 (2019): 469-475. doi:10.1016/j.physio.2018.12.002

- El análisis combinado de tres ensayos **no mostró diferencias** entre la estimulación **intravaginal** y la estimulación transcutánea del nervio tibial posterior (**T-PTNS**) en términos de **frecuencia urinaria, nocturia y calidad de vida**.

Zomkowski, K., et al. The effectiveness of different electrical nerve stimulation protocols for treating adults with non-neurogenic overactive bladder: a systematic review and meta-analysis. Int Urogynecol J, 2022. 33: 1045.

- Estos dos métodos de estimulación del nervio tibial tuvieron una **eficacia clínica similar.**
- **Diferencias**: la **T-PTNS** tuvo un **tiempo de preparación más corto**, **menos** nivel de **incomodidad** y una **mayor satisfacción** del paciente que la **P-PTNS**.

Sonmez, Rafet, Necmettin Yildiz, and Hakan Alkan. "Efficacy of percutaneous and transcutaneous tibial nerve stimulation in women with idiopathic overactive bladder: A prospective randomised controlled trial." *Annals of physical and rehabilitation medicine* 65.1 (2022): 101486.

2022

Review Article

Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines

- La PTNS se puede utilizar de forma **segura** antes del tratamiento invasivo en la **VH resistente** y fue más **efectiva** si se usaba **tres veces por semana** que realizarla una vez por semana en pacientes con VH refractaria.

Al-Danakh, Abdullah et al. "Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines." *Parkinson's disease* vol. 2022 2700227. 16 Mar. 2022.

PTNS implantado

Isabel Montes Posada
Medicina Física y Rehabilitación HUGCDr Negrín

2020

- Se están investigando varios estimuladores **implantables** del nervio tibial para obtener la aprobación de la FDA para la VH.
- Pueden eliminar los problemas logísticos de la terapia de mantenimiento con PTNS y una terapia más eficaz con **estimulación continua o semicontinua.**

Vollstedt, Annah, and Jason Gilleran. "Update on implantable PTNS devices." *Current urology reports* 21 (2020): 1-5.

Review of New Implantable Tibial Nerve Stimulators in Comparison to Established Third Line Treatment Modalities for Nonneurogenic Overactive Bladder

2020

Introduction: New technologies are currently evolving in the treatment of overactive bladder syndrome, giving physicians and patients additional options when conservative care fails to resolve symptoms. The purpose of this review is to compare the prospective clinical data of the new small implantable devices stimulating the tibial nerve to recent prospective clinical studies of sacral nerve stimulation, percutaneous tibial nerve stimulation and botulinum toxin injection, which are currently the most established third line treatment modalities in overactive bladder syndrome.

Methods: A literature search on PubMed®/MEDLINE® was performed for new technologies in neuromodulation to improve overactive bladder syndrome. Additionally, a search was performed for all currently established third line treatment options for comparison of treatment results. The reported prospective clinical data were statistically compared using Fisher's exact test.

Results: Two new small implantable devices that stimulate the tibial nerve have been reported over the recent years, BlueWind RENOVA™ and eCoin™. These new implantable devices that stimulate the tibial nerve show very comparable 3-month and 6-month clinical success rates regarding reduction of urinary incontinence episodes when compared to well-established treatment options such as sacral nerve stimulation, percutaneous tibial nerve stimulation and botulinum toxin injections.

Tipton, William A et al. “Review of New Implantable Tibial Nerve Stimulators in Comparison to Established Third Line Treatment Modalities for Nonneurogenic Overactive Bladder.” *Urology practice* vol. 7,6 (2020): 530-537.

Review of New Implantable Tibial Nerve Stimulators in Comparison to Established Third Line Treatment Modalities for Nonneurogenic Overactive Bladder

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Conclusions: The 2 new small implantable devices stimulating the tibial nerve, BlueWind RENOVA and eCoin, show promising clinical results. Both devices are currently undergoing U.S. Food and Drug Administration approval and 1-year followup data should soon be available. Still more clinical data with larger patient cohorts and multicenter studies are necessary to verify the therapeutic efficacy of these new small implantable devices. If confirmed these new small implantable neuromodulation devices may become well-established in the treatment of patients with overactive bladder syndrome.

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Tipton, William A et al. “Review of New Implantable Tibial Nerve Stimulators in Comparison to Established Third Line Treatment Modalities for Nonneurogenic Overactive Bladder.” *Urology practice* vol. 7,6 (2020): 530-537.

Isabel Montes Posada
Medicina Física y Rehabilitación HUGCDr Negrín

	GEKO™ [14]	Stimrouter [18, 19]	eCoin® [21]	Bluewind RENOVA® [15, 16]	Stimguard® [22-24]
Size	15 cm	15 cm	2.3 cm	2.5 cm	12 cm
Duration of stimulation	Daily or weekly	Up to 12 hours / day	30 min / 2-15 days,	30 minutes tid	8 hours / day
Pulse width (µsec)	70-560	7-500		50-800	50-500
Pulse amplitude (mA)	27	1-200	0.5-15	0-9	0-15
Pulse rate (Hz)	1			0-40	2-1500
External component	TENS – External pulse generator with adhesive surface electrodes.	Adhesive external pulse transmitter. Patient programmer.	No external component.	Wearable unit with leg band.	External device in a sleeve at the ankle.
Energy transfer	Trans-cutaneous	Electrical field through surface electrodes.	Battery powered.	Magnetic resonance 6.78 MHz ISM band Closed-loop	Magnetic resonance 915 MHz ISM band Open-loop

	GEKO™ [14]	Stimrouter [18, 19]	eCoin® [21]	Bluewind RENOVA® [15, 16]	Stimguard® [22-24]
Advantage	1. No surgery.	1. 8 Treatment programs. 2. Computerized feedback on use. 3. No implanted battery.	1. Operates automatically. 2. Leadless.	1. Tailored settings. 2. No migration. 3. Computerized feedback on use. 4. Leadless. 5. No implanted battery.	1. Treatment overnight. 2. Tailored settings. 3. No implanted battery.
Disadvantage	1. Fixed amplitude and frequency. 2. High impedance. 3. No computerized feedback.	1. Loss of energy due to use of surface gel pads. 2. Long lead requiring tunneling.	1. Non-rechargeable battery. 2. Fixed stimulation parameters 3. Requires replacement surgeries. 4. No computerized feedback on use	1. Open-procedure	1. No anchoring system. 2. Long lead requiring tunneling.

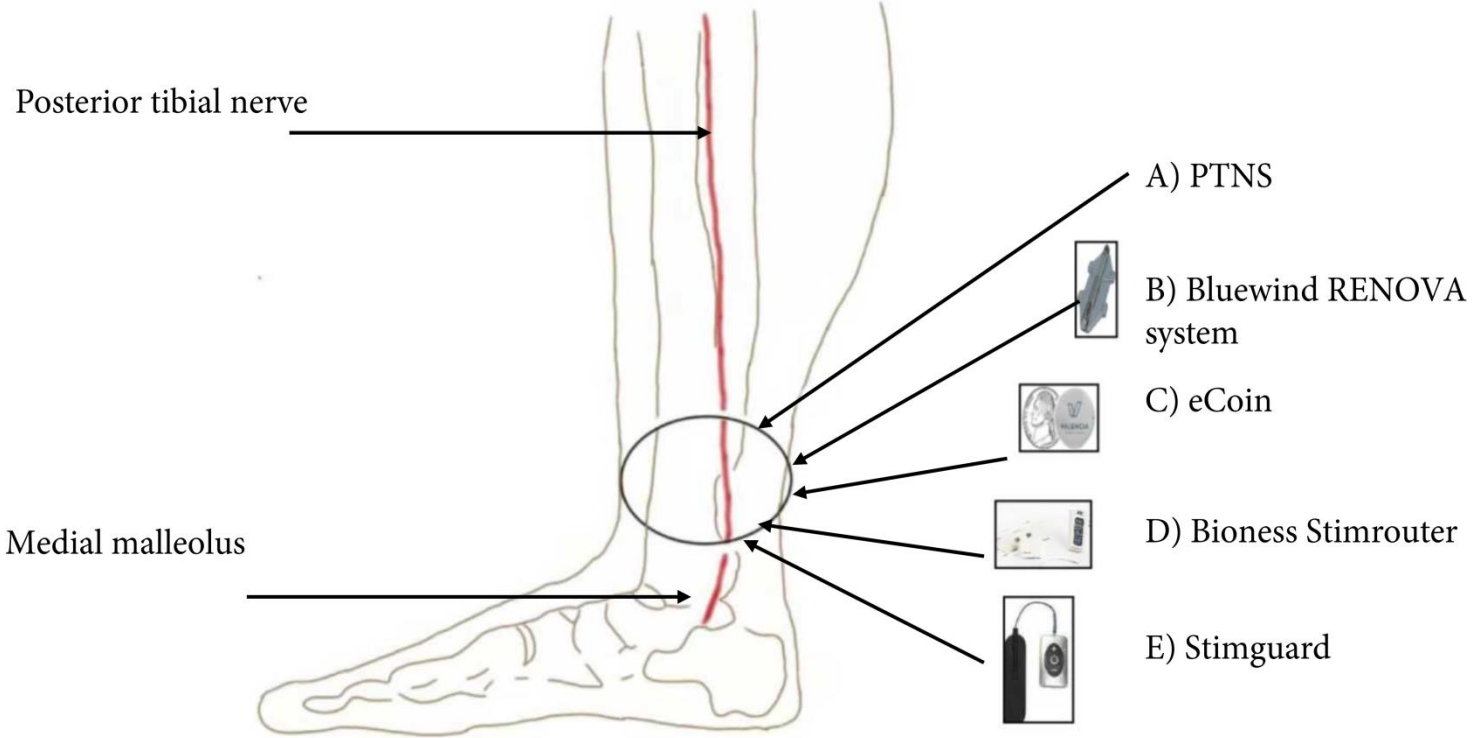
2020

Te Dorsthorst, Manon, Michael van Balken, and John Heesakkers. "Tibial nerve stimulation in the treatment of overactive bladder syndrome: technical features of latest applications." *Current Opinion in Urology* 30.4 (2020): 513-518.

Review Article

2022

Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines



Al-Danakh, Abdullah et al. "Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines." *Parkinson's disease* vol. 2022 2700227. 16 Mar. 2022.

2022

Review Article

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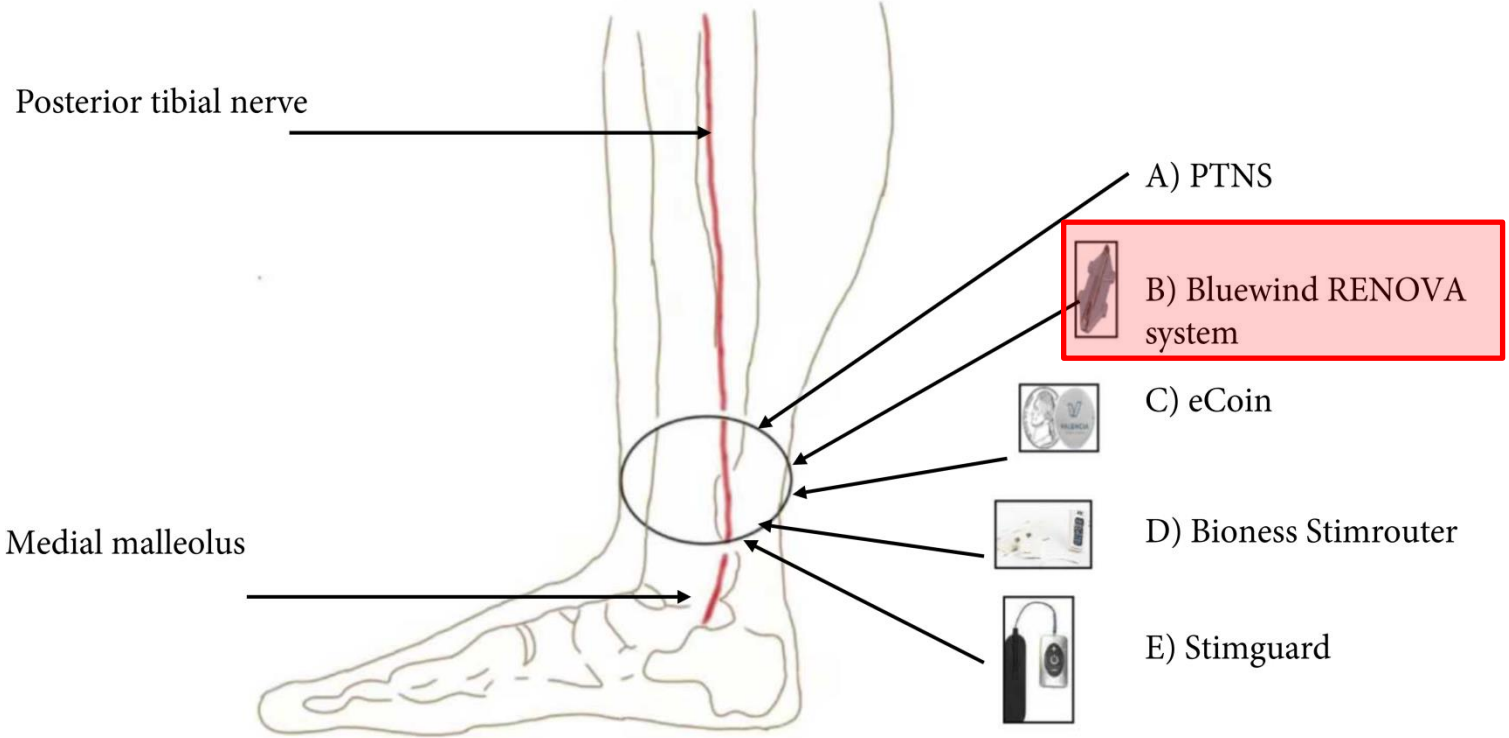

Al-Danakh, Abdullah et al. "Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines." *Parkinson's disease* vol. 2022 2700227. 16 Mar. 2022.

Proven efficacy, proven results

In the OASIS pivotal study, Revi demonstrated significant reductions in UUI episodes after 6 months of treatment in the ITT population (P<.0001). In the Completers analysis* (N=139) at 12 months, Revi demonstrated:[1]

82% patients had **≥ 50% reduction** in UUI episodes.

67% of patients had **≥ 75% reduction** in UUI episodes.

50% of patients were **dry** on 3 consecutive days.

Revi Implant has a battery-free design, allowing it to be miniature in size at only 3 cm in length and 3 mm in diameter. This tibial implant delivers reliable and long-lasting performance in a compact form factor.

https://bluewindmedical.com/providers/revi-for-uui/

Isabel Montes Posada
Medicina Física y Rehabilitación HUGCDr Negrín

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

Purpose: We evaluated the 3-year safety and efficacy of the BlueWind Medical RENOVA™ iStim system for the treatment of overactive bladder syndrome.

Materials and methods: All patients who previously underwent implantation with the RENOVA system were offered continued participation. The primary long-term study end point was to evaluate the safety profile based on incidence of serious adverse events (system and/or procedure related), which was measured by the impact and frequency of serious adverse events. The secondary end points included clinical improvement compared to baseline and quality of life improvement compared to baseline at 36 months, which was measured by 3-day voiding diary and quality of life questionnaires at certain time points.

Results: Of the 34 patients with overactive bladder syndrome who previously underwent implantation with the RENOVA system 20 consented to continuation in this 3-year followup study. Mean patient age was 56.1 years and 80% (16) of the study cohort was female. The overall treatment success rate was 75% at 36 months in the per protocol (16) and the intent to treat (20) analyses. In total, 73% of the patients reported improvement in health related quality of life scores above the minimal important difference of 10 points.

2020

Dorsthorst, Manon J Te et al. "3-Year Followup of a New Implantable Tibial Nerve Stimulator for the Treatment of Overactive Bladder Syndrome." *The Journal of urology* vol. 204,3 (2020): 545-550.

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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.

2020

Dorsthorst, Manon J Te et al. "3-Year Followup of a New Implantable Tibial Nerve Stimulator for the Treatment of Overactive Bladder Syndrome." *The Journal of urology* vol. 204,3 (2020): 545-550.

Abstract

Purpose: The aim of this study was to demonstrate features predictive of treatment response for patient-tailored overactive bladder (OAB) intervention with an implantable tibial neurostimulator using patient and technical prediction factors.

Materials and Methods: This study was designed as a follow-up study based on parameter settings and patients' preferences during the pilot and extended study of the implantable tibial nerve stimulator (RENOVA™ iStim system). For this study, we compared all treatment parameters (stimulation amplitude, frequency, and pulse width) and usage data (duration of treatment) during the different follow-up visits.

Results: We obtained usage data from a total of 32 patients who were implanted with the system between February and September 2015. Age, sex, body mass index (BMI) and previous experience with percutaneous tibial nerve stimulation (PTNS) treatment were considered as possible prediction factors for treatment success. However, only BMI was considered a statistically significant prediction factor ($p = 0.042$). A statistically significant increase in mean treatment level was seen in the responder group during the 3 month follow-up visit (mean: 6.7 mA, *SD* 0.416) as compared with the initial system activation visit (mean: 5.8 mA, *SD* 0.400) ($p = 0.049$). No other visits demonstrated statistically significant changes in both groups (responders and non-responders) during the defined timepoints.

Conclusion: This data underscores the need to use patient-tailored OAB treatment. BMI was found to be a negative predictive factor for treatment success. However, it was not possible to develop a specific responder model. A model predicting response to treatment could be useful for implementing shared decision making.

Patient-tailored healthcare and tibial nerve neuromodulation in the treatment of patients with overactive bladder symptoms

5 | CONCLUSION

It was not possible to develop a specific responder model for OAB treatment using an implantable tibial neurostimulation system. A responder model could be useful for implementing shared decision making with the patient. Although similar to other neuromodulation reports, BMI was found to be a negative prediction factor for this treatment modality, no other predictive factors could be obtained. The need for patient-tailored healthcare is critical and might improve the long-term treatment outcome and compliance for each patient. Possibly new multicenter studies with a larger number of patients will shed light on a better predictive model in the treatment of OAB using an implantable tibial neurostimulation device.

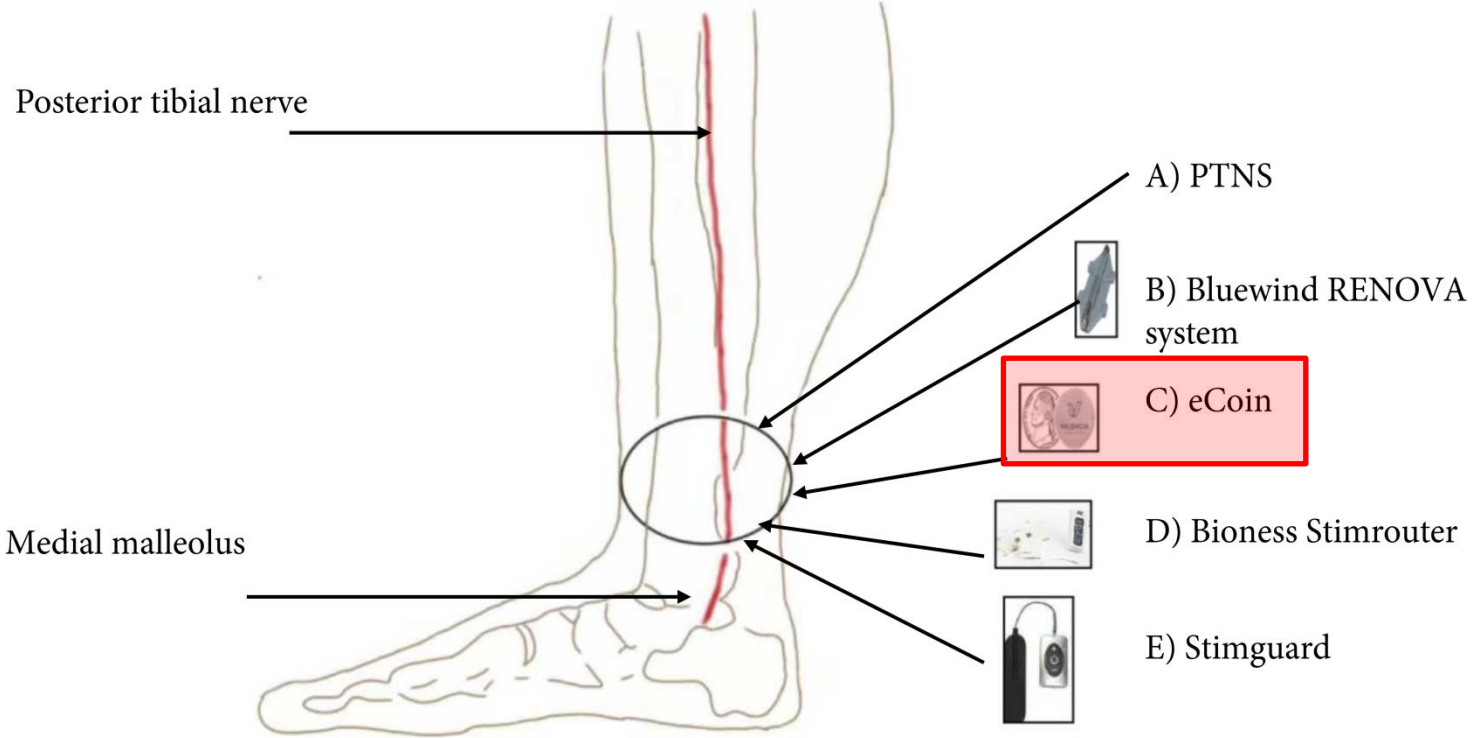
2022

Te Dorsthorst, Manon, et al. "Patient-tailored healthcare and tibial nerve neuromodulation in the treatment of patients with overactive bladder symptoms." *Neurourology and Urodynamics* 41.2 (2022): 679-684.

2022

Review Article

Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines



Al-Danakh, Abdullah et al. "Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines." *Parkinson's disease* vol. 2022 2700227. 16 Mar. 2022.

- El dispositivo **automático**:
  - 30 minutos/2d durante 12 semanas.
  - Posteriormente: 1/15d.
  - El paciente no tiene acción para iniciar una sesión de tratamiento.
  - Controlador externo para cambiar la amplitud de 0,5 a 15 mA.
- Otros parámetros son fijos: pulso ancho de 0,2 milisegundos y frecuencia de pulso de 20 milisegundos.

2019

MacDiarmid, Scott, et al. "Feasibility of a fully implanted, nickel sized and shaped tibial nerve stimulator for the treatment of overactive bladder syndrome with urgency urinary incontinence." *The Journal of Urology* 201.5 (2019): 967-972.

Clinical Trial > Urology. 2021 Nov;157:71-78. doi: 10.1016/j.urology.2021.04.039.

Epub 2021 May 26.

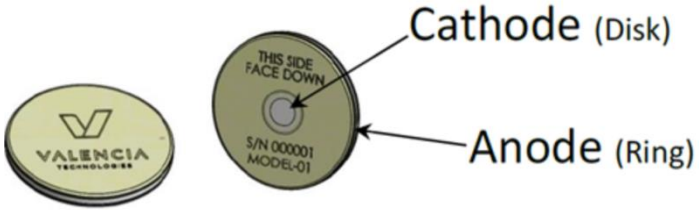
Twelve-month Durability of a Fully-implanted, Nickel-sized and Shaped Tibial Nerve Stimulator for the Treatment of Overactive Bladder Syndrome with Urgency Urinary Incontinence: A Single-Arm, Prospective Study

2021

Gilling, Peter et al. "Twelve-month Durability of a Fully-implanted, Nickel-sized and Shaped Tibial Nerve Stimulator for the Treatment of Overactive Bladder Syndrome with Urgency Urinary Incontinence: A Single-Arm, Prospective Study." *Urology* vol. 157 (2021): 71-78.

Neuroestimulador periférico eCoin – P200036

Nombre del producto: Neuroestimulador periférico eCoin®
Solicitante: Valencia Technologies Corporation
Dirección: 28464 Westinghouse Place Valencia, CA 91355
Fecha de aprobación: 1 de marzo de 2022



Device Name	Category	Date
eCoin Peripheral Neurostimulator - P200036	Bladder Control	03/01/2022

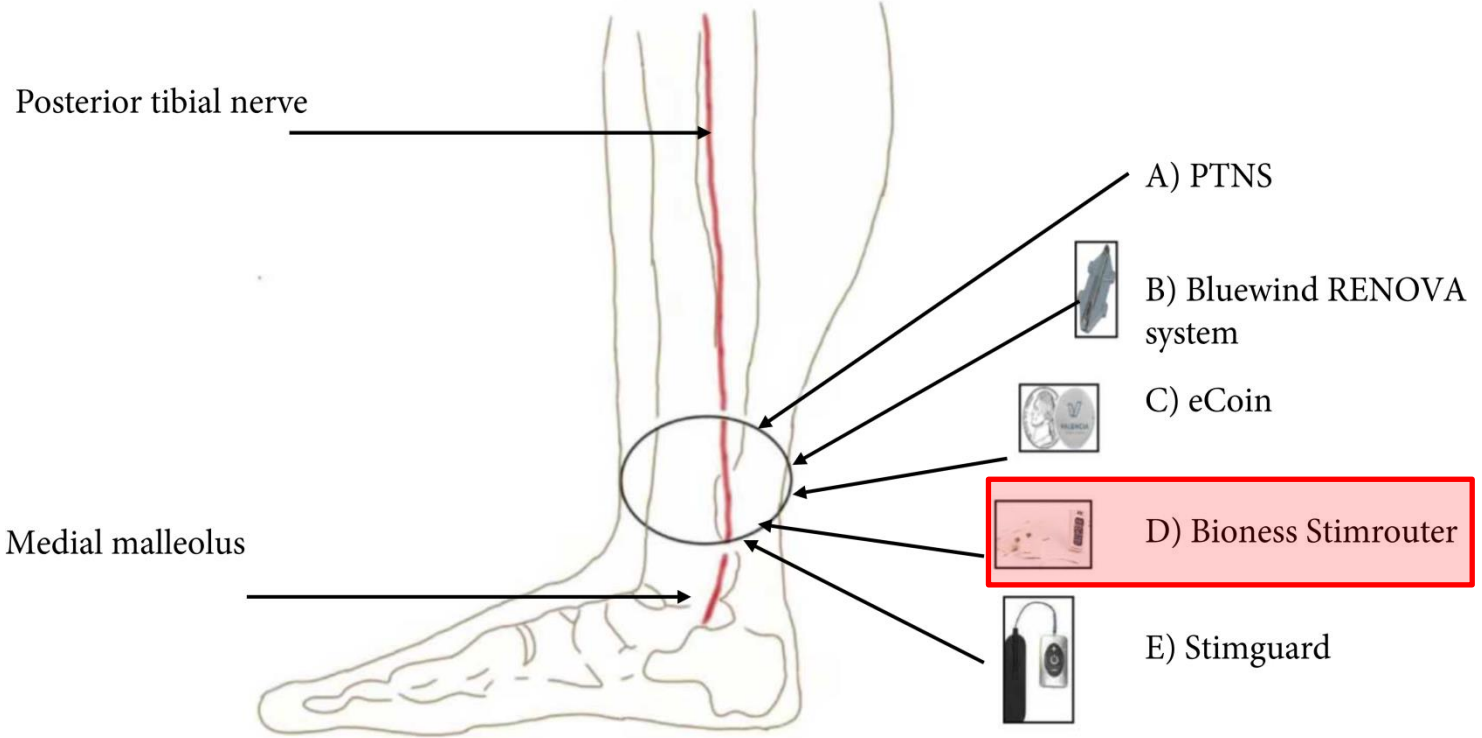
Número de solicitud	Solicitante	Nombre del dispositivo	Especialidad Médica	Fecha de aprobación de la PMA	Nombre del estudio	Estado del estudio
P200036	Corporación Tecnológica Valenciana	Neuroestimulador Periférico eCoin	Gastroenterología/ Urología	01/03/2022	Seguimiento continuo del estudio clínico G170301	En curso
					Estudio posterior a la aprobación de eCoin - RECETA	En curso

https://www.fda.gov/medical-devices/recently-approved-devices/ecoin-peripheral-neurostimulator-p200036#
https://www.fda.gov/medical-devices/recently-approved-devices/2022-device-approvals

Review Article

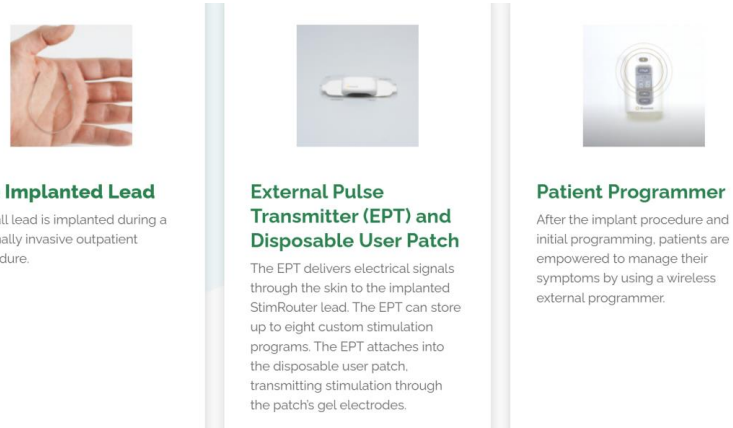
2022

Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines



Al-Danakh, Abdullah et al. "Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines." *Parkinson's disease* vol. 2022 2700227. 16 Mar. 2022.

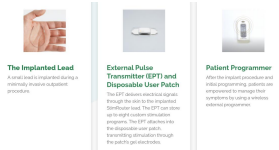
- Bioness StimRouter es un cable transcutáneo hecho a medida alimentado por un generador de impulsos externo (EPG). Un receptor, electrodos y un sistema de anclaje están incluidos en el plomo implantado.



2017

Guzman-Negron, Juan M., and Howard B. Goldman. "New devices and technologies for the management of overactive bladder." *Current Urology Reports* 18 (2017): 1-6.

Overactive Bladder Treatment Using StimRouter Neuromodulation System: A Prospective Randomized Trial



Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	180 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Triple (Participant, Care Provider, Investigator)
Masking Description:	The implanting investigator, the study subjects, and the individuals who assess the outcome measures for each subject will be blinded to the subjects' randomization groups. Each study site's programmers will be unblinded to the randomization assignment and will receive each subject's randomization assignment. The programmers will then set the stimulation parameters and train the subjects on device use.
Primary Purpose:	Treatment
Official Title:	Prospective, Multi-Center, Randomized, Double-Blinded Trial of Percutaneous Tibial Nerve Stimulation With the Bioness StimRouter Neuromodulation System Versus Sham in the Treatment of Overactive Bladder (OAB)
Actual Study Start Date :	February 10, 2017
Estimated Primary Completion Date :	July 30, 2021
Estimated Study Completion Date :	July 30, 2021

ClinicalTrials.gov Identifier: NCT02873312

Recruitment Status : Unknown
Verified July 2020 by Bioness Inc.
Recruitment status was: Recruiting
First Posted : August 19, 2016
Last Update Posted : January 29, 2021

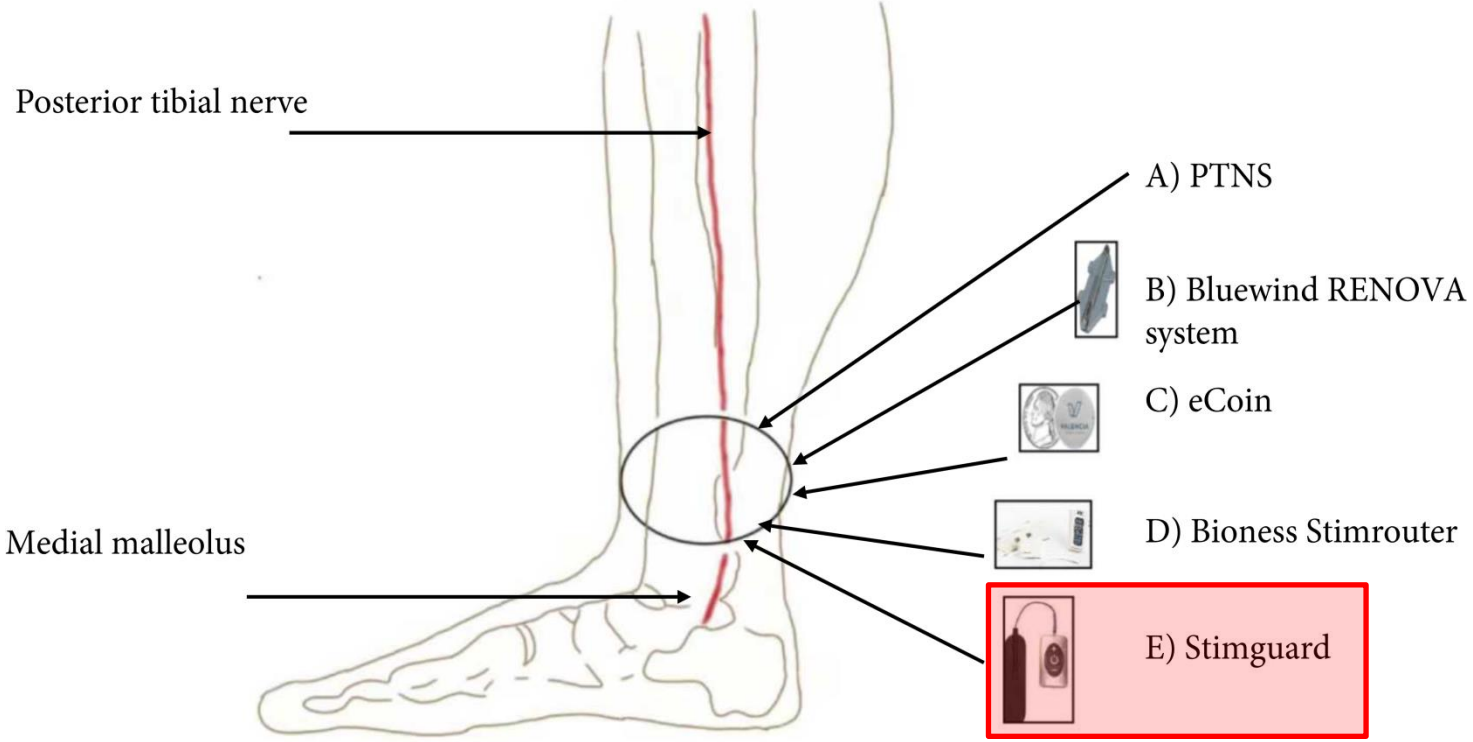
NIH U.S. National Library of Medicine
ClinicalTrials.gov

https://classic.clinicaltrials.gov/ct2/show/NCT02873312

2022

Review Article

Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines



Al-Danakh, Abdullah et al. "Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines." *Parkinson's disease* vol. 2022 2700227. 16 Mar. 2022.

E) Stimguard

StimGuard Announces Corporate Name Change to Micron Medical and Appointment of CEO as part of Expansive Executive Management TeamMicron Medical Expects U.S. Commercial Launch of Protect PNS for Treatment of Overactive Bladder in Q3 2020

Published: Apr 03, 2020

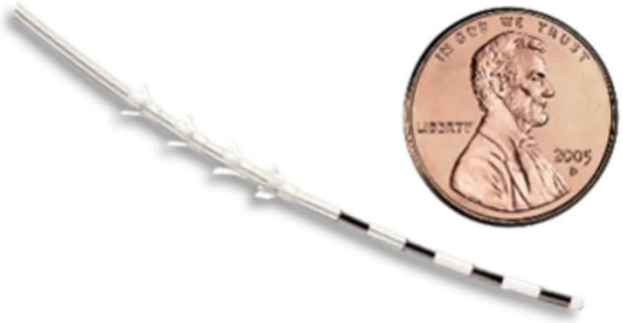
CAUTION-Investigational Device. Limited by Federal or U.S. law to investigational use

Uro Medical Corporation Acquires Micron Medical and Initiates the FDA IDE Approved "Guardian" RCT of the Protect PNS Injectable Tibial Stimulator for Treatment of Overactive Bladder

Published: Jul 06, 2021

Isabel Montes Posada
Medicina Física y Rehabilitación HUGCDr Negrín

uromedical



PROTECT STUDY FOR OVERACTIVE BLADDER (OAB)

Actively Recruiting Patients

Protect PNS is being studied for the treatment of urgency urinary incontinence. OAB is characterized by symptoms including urgency, frequency, nocturia and often associated with a leakage of urine.

GUARDIAN STUDY FOR OVERACTIVE BLADDER (OAB)

Now Actively Recruiting

Protect PNS is being studied for the treatment of urgency urinary incontinence associated with OAB for patients who have failed pharmaceutical treatment. OAB is characterized by symptoms including urgency, frequency, nocturia and often with a leakage of urine.

https://uromedical.com/

Patients – Getting you back to doing the things you love

- At home, non-invasive therapy for urge urinary incontinence and urinary urgency without the need for surgery, implants, or drugs.
- Quick and convenient – 30 minutes as little as once per week – when you want to
- Personalized treatment calibrated to your EMG signal

https://avation.com/vivally-system/

RECRUITING

A Sham-Controlled Study to Evaluate the Safety and Efficacy of a Smart, Self-Adjusting, Surgery-Free, Wearable Bladder Neuromodulation System for Overactive Bladder (REDUCEOAB)

ClinicalTrials.gov ID NCT05381116

Sponsor Avation Medical, Inc.

Information provided by Avation Medical, Inc. (Responsible Party)

Last Update Posted 2022-05-19

STUDY START (ACTUAL)
2022-04-14

PRIMARY COMPLETION (ESTIMATED)
2025-01

STUDY COMPLETION (ESTIMATED)
2025-03

ENROLLMENT (ESTIMATED)
150

STUDY TYPE
Interventional

Study Overview

Brief Summary:
This is a prospective, multi-center, sham-controlled study comparing the safety and effectiveness of the self-adjusting, surgery-free, wearable Active System to a Sham System on adult Subjects diagnosed with OAB.

OFFICIAL TITLE

A Prospective, Sham-Controlled, Safety and Efficacy Study of a Smart, Self-Adjusting, Surgery-Free, Wearable **Bladder** Modulation and Digital Health System With Objective Confirmation of Nerve Activation for Use in Home by Subjects With **Overactive Bladder Syndrome**

CONDITIONS

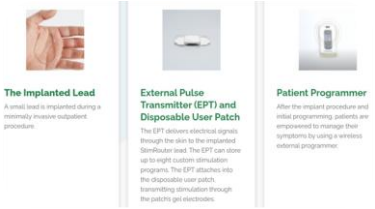
Overactive Bladder | Urinary Urge Incontinence | Urge Incontinence

INTERVENTION / TREATMENT

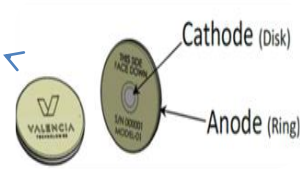
Device: Avation System

Device: Sham Avation System

https://clinicaltrials.gov/study/NCT05381116?cond=Overactive%20Bladder%20Syndrome&intr=neuromodulation&rank=8


The Implanted Lead
A small lead is implanted during a minimally invasive outpatient procedure.
External Pulse Transmitter (EPT) and Disposable User Patch
The EPT delivers electrical signals through the skin to the implanted StimRouter lead. The EPT can store up to eight custom stimulation programs. The EPT attaches into the disposable user patch, transmitting stimulation through the patch's gel electrodes.
Patient Programmer
After the implant procedure and initial programming, patients are empowered to manage their symptoms by using a wireless external programmer.


BlueWind Medical RENOVA™ iStim Neurostimulation Device for OAB
Stimulator implanted near Tibial nerve
Patient wearable powers stimulator
Clinician Programmer
Daily at-home treatment session


Cathode (Disk)
Anode (Ring)
VALENCIA

Posterior tibial nerve stimulation for overactive bladder—techniques and efficacy

2020

- La **evidencia** muestra que los resultados de PTNS mejoran los **síntomas** de la VH a **corto y largo plazo**.
- Los **efectos secundarios** de este tratamiento son **más tolerables** que los observados con **antimuscarínicos** como sequedad de boca y estreñimiento.
- Procedimiento de implante de **un solo paso menos invasivo** en comparación con la terapia de neuromodulación sacra.

Bhide, Alka A., et al. "Posterior tibial nerve stimulation for overactive bladder—techniques and efficacy." *International urogynecology journal* 31 (2020): 865-870.

Review Article

Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines

2022

- La **SNM** se consideraba el tratamiento de tercera línea para pacientes con VH, pero ha logrado menores avances.
  - **Deficiencias**: Tamaño del dispositivo SNM, coste, exposición a la radiación para implantar su cable cerca de un nervio sacro, y dos cirugías .
  - **Complicaciones** a corto y largo plazo: alrededor del 30-40% requieren retirada y reemplazo.
- **PTNS** aprobado para el tratamiento de pacientes con VH muestra un alto **progreso tecnológico, rentabilidad y sostenibilidad** con **menos eventos adversos** que **SNM**.

Al-Danakh, Abdullah et al. "Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines." *Parkinson's disease* vol. 2022 2700227. 16 Mar. 2022.

Review Article

Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines

2022

- Las nuevas tecnologías **implantables** demuestran resultados prometedores en términos de **eficacia, tolerancia** del paciente y **reducir la carga** sobre los médicos y el sistema sanitario.
- Este resultado se basa en ensayos a corto plazo; se requiere **investigación adicional** para demostrar **eficacia y seguridad a largo plazo y a gran escala**.

Al-Danakh, Abdullah et al. "Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines." *Parkinson's disease* vol. 2022 2700227. 16 Mar. 2022.

Review Article

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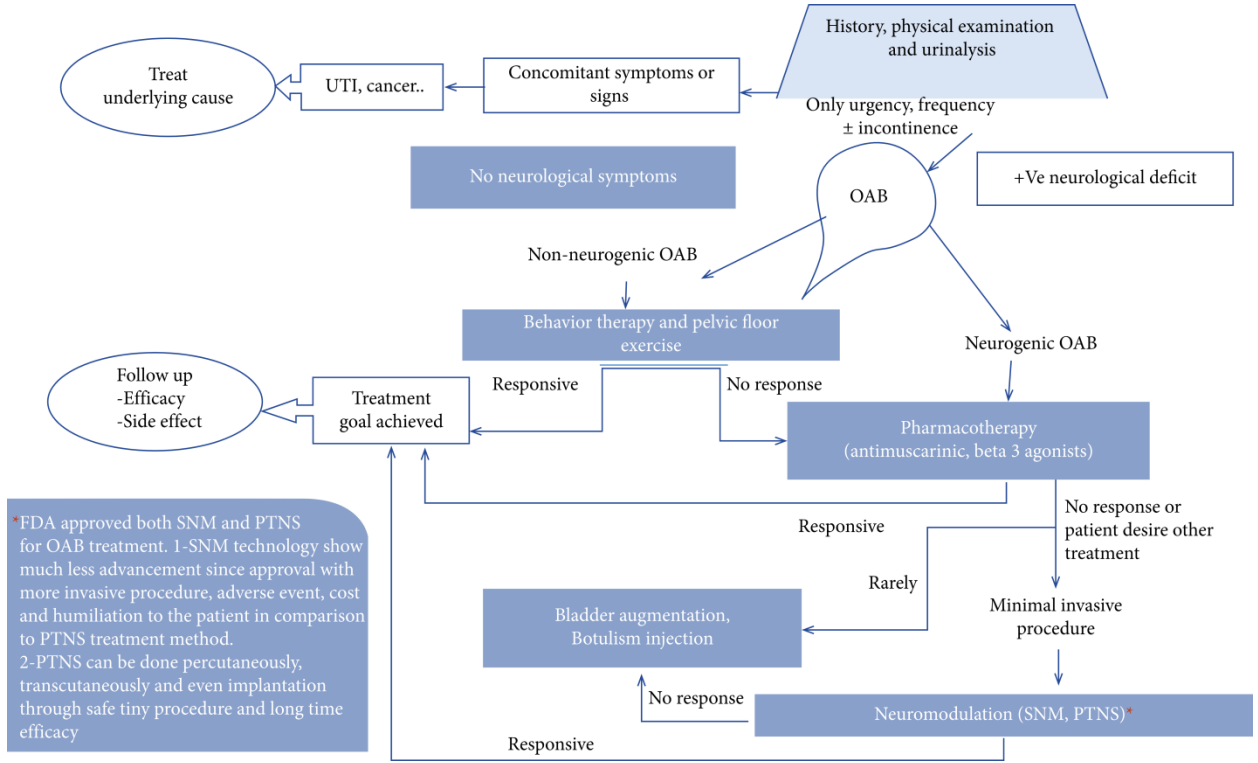

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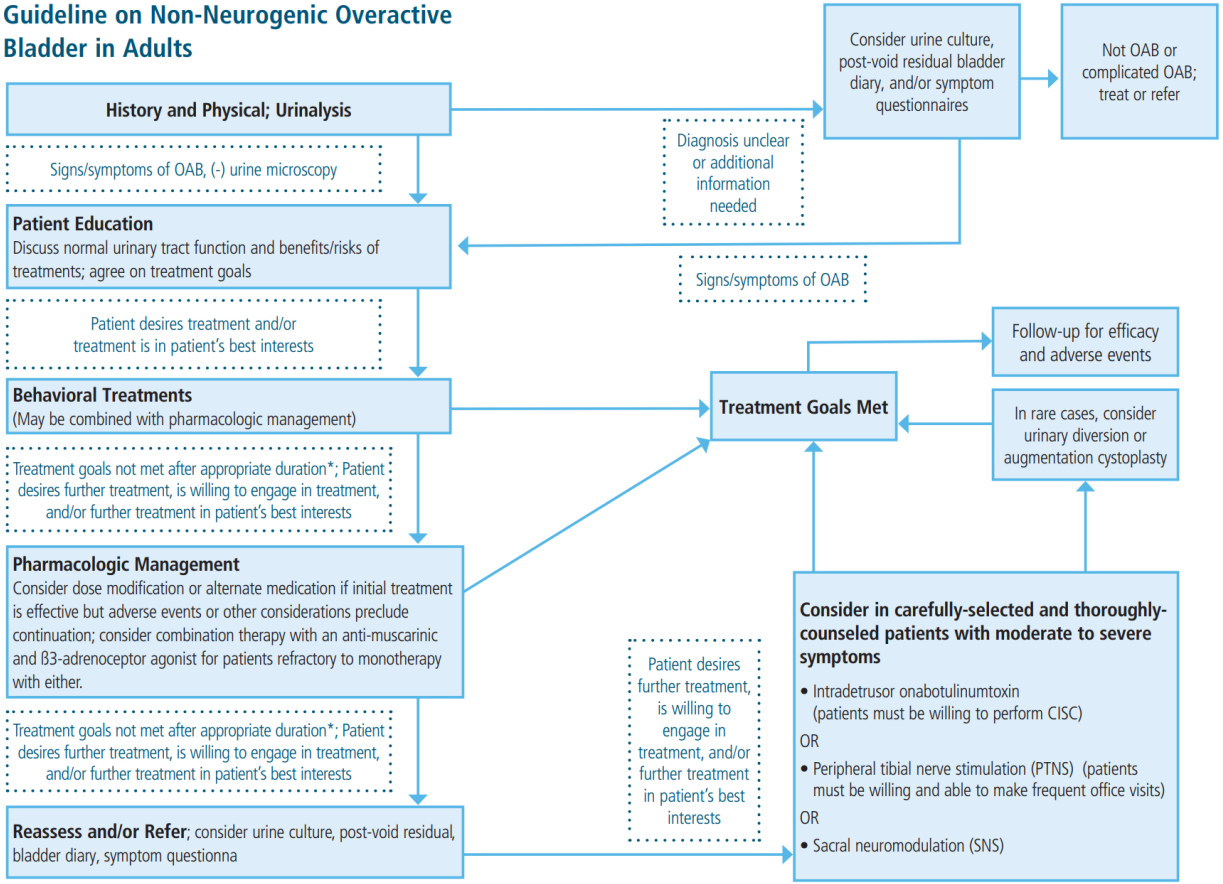
Diagnosis & Treatment Algorithm: AUA/SUFU Guideline on Non-Neurogenic Overactive Bladder in Adults



The complete OAB Guideline is available at AUAnet.org/Guidelines.

This clinical framework does not require that every patient go through each line of treatment in order as there are many factors to consider when identifying the best treatment for a particular patient.

*Appropriate duration is 8 to 12 weeks for behavioral therapies and 4 to 8 weeks for pharmacologic therapies

American Urological Association

https://www.auanet.org/guidelines-and-quality/guidelines/non-oncology-guidelines

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American Urological Association

AMENDMENT SUMMARY

Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline

Amendment Panel
Deborah J. Lightner, MD (Chair); Alexander Gomelsky, MD; Sandip P. Vasavada, MD

Purpose: The purpose of this guideline is to provide a clinical framework for the diagnosis and treatment of non-neurogenic overactive bladder (OAB).

Summary of Guideline Changes

American Urological Association

Section 6: Treatment, clarifying importance of patient factors in selecting optimal treatment

This clinical framework does not require that every patient go through each line of treatment in order. There are many factors to consider when identifying the best treatment for a particular patient, including information regarding allergies, sensitivity to various adverse drug events, patient ability and motivation to comply and availability of and access to specific treatments. It should be duly noted that, as mentioned above, every patient does not need to proceed through each line of therapy before considering the next. In other words, the lines of therapy, while representing a successive increase in risk or invasiveness, are not intended to represent a strict algorithm. This is specifically relevant with regard to PTNS, as it is the opinion of the Panel that, given the minimally invasive and reversible nature of this therapy, juxtaposed with the potential side effects and cost of medications, PTNS can be considered in drug-naïve patients who opt to forego pharmacotherapy.

https://www.auanet.org/guidelines-and-quality/guidelines/non-oncology-guidelines

Mínimamente invasivo y reversible

Efectos secundarios y coste de los medicamentos

American Urological Association

Pacientes que no han recibido tratamiento previo y que optan por renunciar a la farmacoterapia

https://www.auanet.org/guidelines-and-quality/guidelines/non-oncology-guidelines

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EAU Guidelines on Management of Non-Neurogenic Female Lower Urinary Tract Symptoms

Summary of evidence	LE
Prompted voiding, either alone or as part of a behavioural modification programme, improves continence in elderly, care-dependent, people in the short-term.	1b
Bladder training is effective for improvement of UUI in women, but efficacy appears to be lower than that of pharmacotherapy.	1b
Pelvic floor muscle training may improve symptoms of frequency of OAB in women.	1b
Electrical stimulation may improve symptoms of OAB in some women, but the type and mode of delivery of ES remains variable and poorly standardised.	1a
Posterior tibial nerve stimulation is more effective than antimuscarinics in reducing UUI episodes but with no difference in improving other OAB symptoms.	1a
A maintenance programme of P-PTNS has been shown to be effective for up to 3 years.	2a
Transcutaneous-PTNS appears to be effective in reducing OAB symptom compared to sham treatment.	1a
Transcutaneous -PTNS is not inferior to percutaneous -PTNS with regard to improvement in urinary urgency, frequency, and QoL scores.	1a

EAU Guidelines. Edn. presented at the EAU Annual Congress Milan March 2023. ISBN 978-94-92671-19-6.

EAU Guidelines on
Management of Non-Neurogenic Female Lower Urinary Tract Symptoms

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

EAU Guidelines. Edn. presented at the EAU Annual Congress Milan March 2023. ISBN 978-94-92671-19-6.

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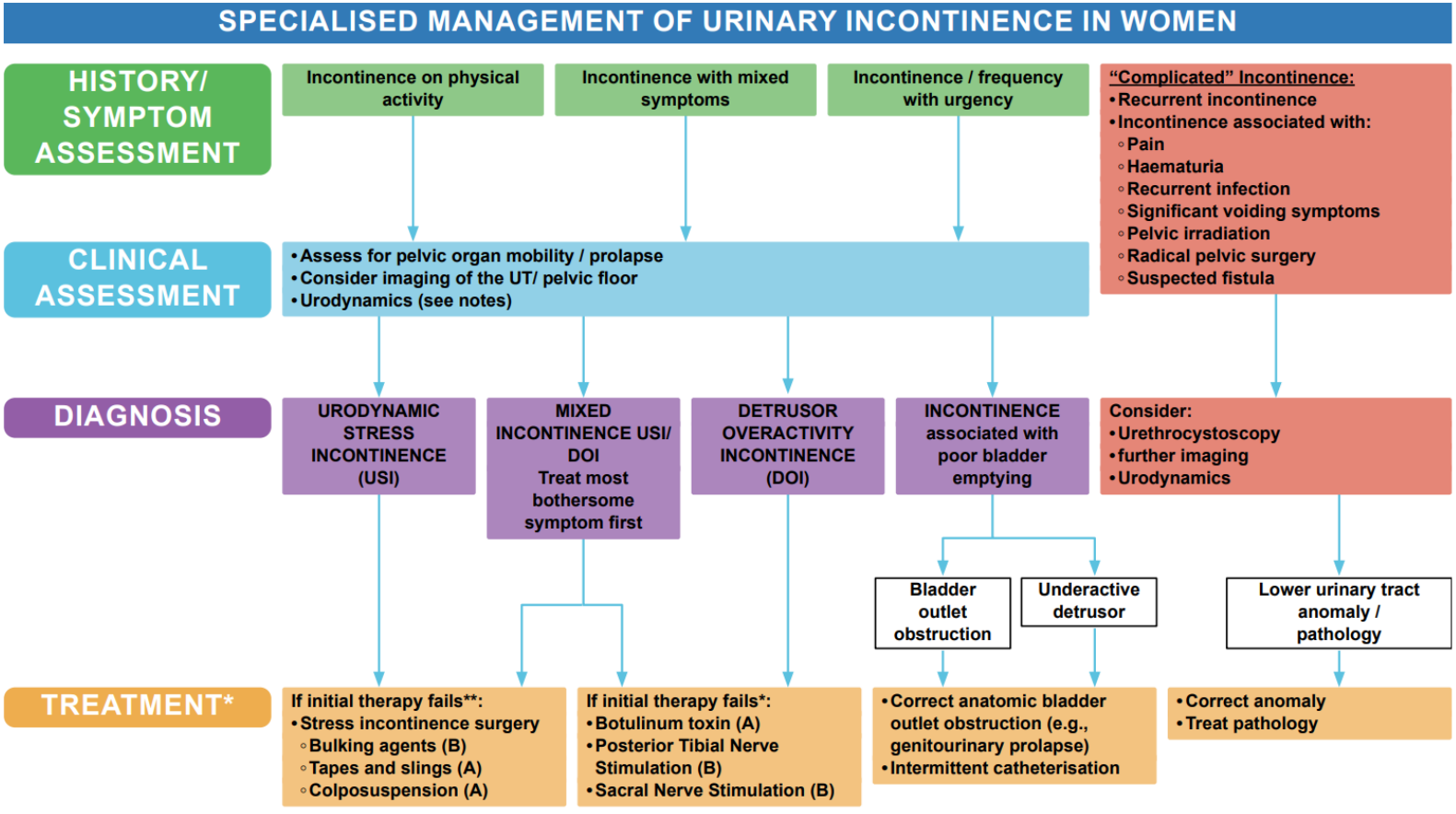
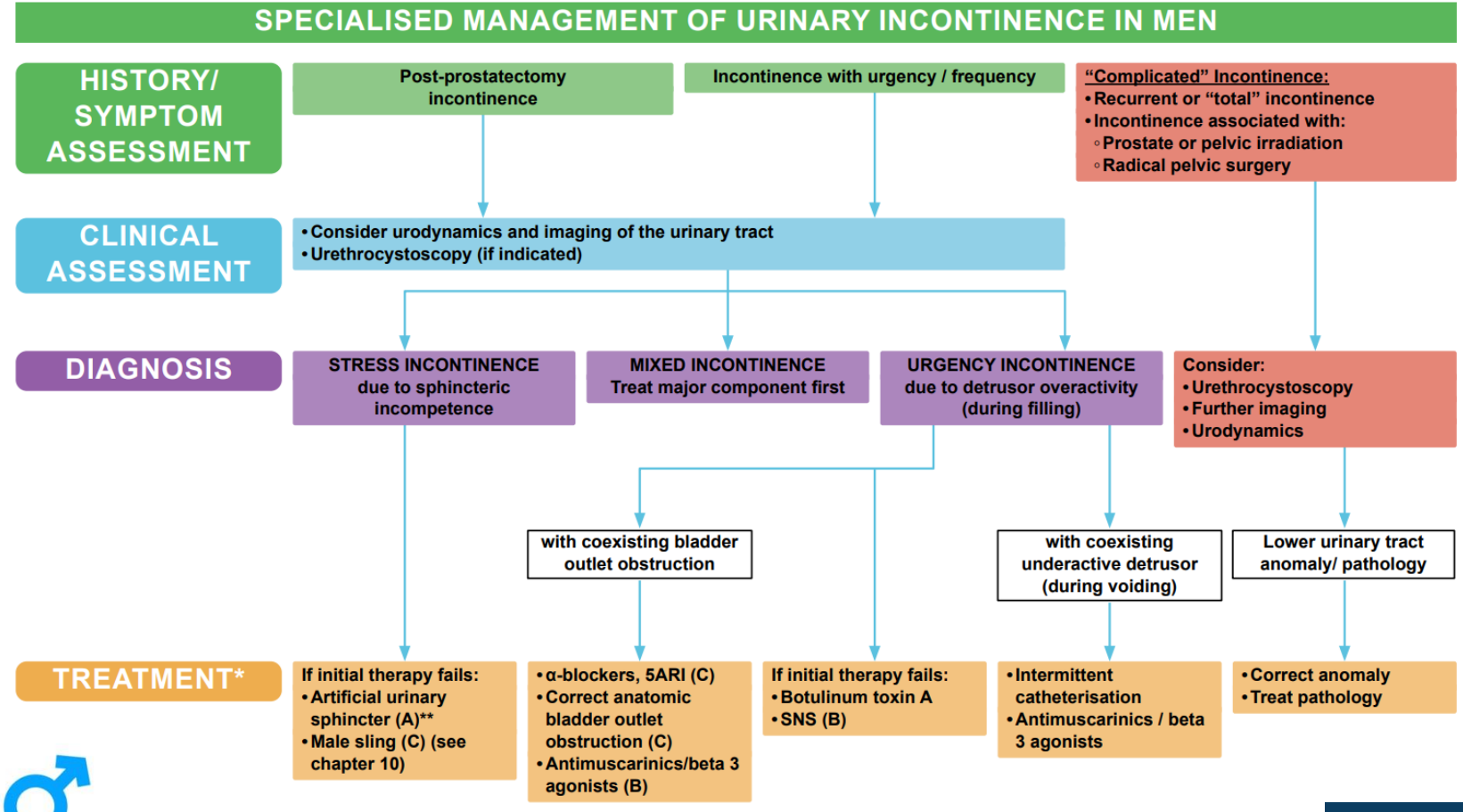
EAU Guidelines on Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS), incl. Benign Prostatic Obstruction (BPO)

Summary of evidence	LE
Prompted voiding, either alone or as part of a behavioural modification programme, improves continence in elderly, care-dependent people.	1b
The combination of bladder training (BT) with antimuscarinic drugs does not result in greater improvement of UI but may improve frequency and nocturia.	1b
There is conflicting evidence on whether the addition of BT, electrostimulation or biofeedback increases the effectiveness of PFMT alone.	1b
Pre-operative PFMT does not confer additional benefit to men undergoing radical prostatectomy.	1b
Electrical stimulation may add benefit to PFMT up to six months.	2
Electrical stimulation may improve UI compared to sham up to six months.	2
There is limited evidence for the effectiveness of PTNS in male population.	2
There is no evidence that PTNS cures UUI in male population.	2

EAU Guidelines. Edn. presented at the EAU Annual Congress Milan March 2023. ISBN 978-94-92671-19-6.


SPECIALISED MANAGEMENT OF URINARY INCONTINENCE IN WOMEN
HISTORY/ SYMPTOM ASSESSMENT
Incontinence on physical activity
Incontinence with mixed symptoms
Incontinence / frequency with urgency
"Complicated" Incontinence:
•Recurrent incontinence
•Incontinence associated with:
◦Pain
◦Haematuria
◦Recurrent infection
◦Significant voiding symptoms
◦Pelvic irradiation
◦Radical pelvic surgery
◦Suspected fistula
CLINICAL ASSESSMENT
•Assess for pelvic organ mobility / prolapse
•Consider imaging of the UT/ pelvic floor
•Urodynamics (see notes)
DIAGNOSIS
URODYNAMIC STRESS INCONTINENCE (USI)
MIXED INCONTINENCE USI/ DOI
Treat most bothersome symptom first
DETRUSOR OVERACTIVITY INCONTINENCE (DOI)
INCONTINENCE associated with poor bladder emptying
Consider:
•Urethrocystoscopy
•further imaging
•Urodynamics
Bladder outlet obstruction
Underactive detrusor
Lower urinary tract anomaly / pathology
TREATMENT*
If initial therapy fails**:
•Stress incontinence surgery
◦Bulking agents (B)
◦Tapes and slings (A)
◦Colposuspension (A)
If initial therapy fails*:
•Botulinum toxin (A)
•Posterior Tibial Nerve Stimulation (B)
•Sacral Nerve Stimulation (B)
•Correct anatomic bladder outlet obstruction (e.g., genitourinary prolapse)
•Intermittent catheterisation
•Correct anomaly
•Treat pathology


SPECIALISED MANAGEMENT OF URINARY INCONTINENCE IN MEN
HISTORY/ SYMPTOM ASSESSMENT
Post-prostatectomy incontinence
Incontinence with urgency / frequency
"Complicated" Incontinence:
•Recurrent or "total" incontinence
•Incontinence associated with:
◦Prostate or pelvic irradiation
◦Radical pelvic surgery
CLINICAL ASSESSMENT
•Consider urodynamics and imaging of the urinary tract
•Urethrocystoscopy (if indicated)
DIAGNOSIS
STRESS INCONTINENCE due to sphincteric incompetence
MIXED INCONTINENCE Treat major component first
URGENCY INCONTINENCE due to detrusor overactivity (during filling)
Consider:
•Urethrocystoscopy
•Further imaging
•Urodynamics
with coexisting bladder outlet obstruction
with coexisting underactive detrusor (during voiding)
Lower urinary tract anomaly/ pathology
TREATMENT*
If initial therapy fails:
•Artificial urinary sphincter (A)**
•Male sling (C) (see chapter 10)
•α-blockers, 5ARI (C)
•Correct anatomic bladder outlet obstruction (C)
•Antimuscarinics/beta 3 agonists (B)
If initial therapy fails:
•Botulinum toxin A
•SNS (B)
•Intermittent catheterisation
•Antimuscarinics / beta 3 agonists
•Correct anomaly
•Treat pathology

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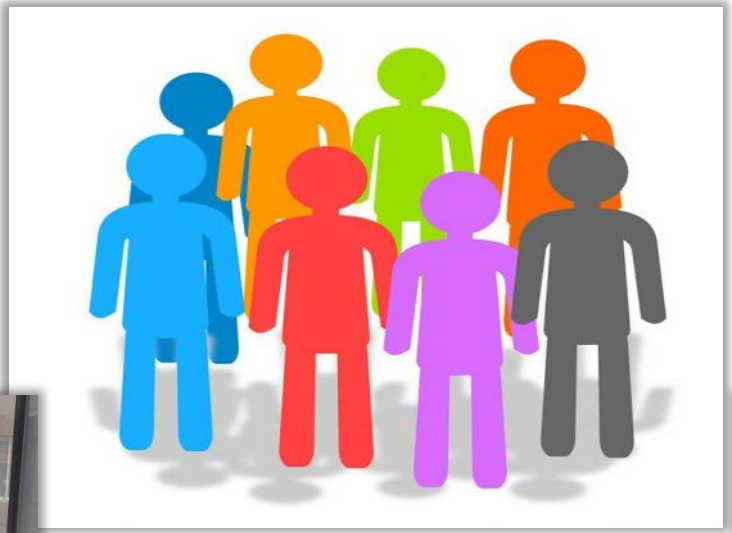
Servicio Canario de la Salud
HOSPITAL UNIVERSITARIO DE GRAN CANARIA DOCTOR NEGRÍN

Servicio Canario de la Salud
Complejo Hospitalario Universitario Insular - Materno Infantil



Gobierno de Canarias

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Medicina Física y Rehabilitación HUGCDr Negrín

Review Article

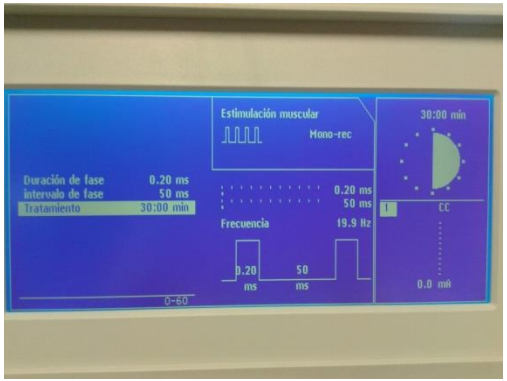
Physical and Rehabilitation Therapy for Overactive Bladder in Women: A Systematic Review and Meta-Analysis

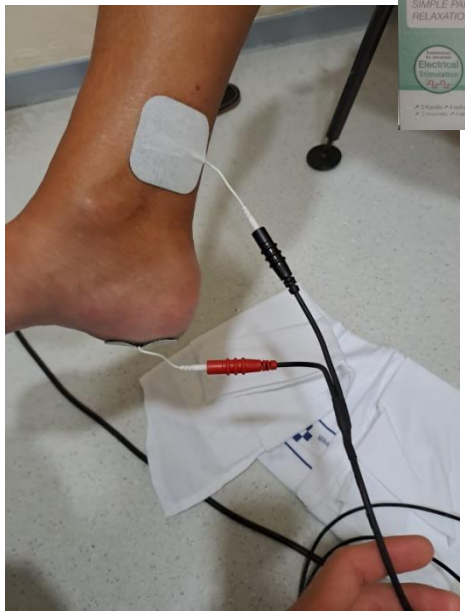
2023

- Diferentes **terapias físicas y de rehabilitación** pueden mejorar los síntomas de la VH.
- Cada institución debe elegir las terapias físicas y de rehabilitación de acuerdo con su propia **configuración** y base de **personal**.
- PTNS, BT + ES y BT + BF + ES pueden considerarse terapias prioritarias cuando la **situación** lo permite.

Bai, Jingwen, et al. "Physical and Rehabilitation Therapy for Overactive Bladder in Women: A Systematic Review and Meta-Analysis." *International Journal of Clinical Practice* 2023 (2023).

3ª línea de tratamiento en VH PTNS





Servicio Canario de la Salud
HOSPITAL UNIVERSITARIO DE GRAN CANARIA DOCTOR NEGRÍN

Gobierno de Canarias

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REVIEW ARTICLE

WILEY

2018

The effectiveness of transcutaneous tibial nerve stimulation (TTNS) for adults with overactive bladder syndrome: A systematic review

- Dada su seguridad, bajo costo, facilidad de aplicación y potencial para **respaldar la autoadministración**, existe un claro impulso para que se realicen más investigaciones para establecer evidencia definitiva sobre el papel de la **TTNS** como terapia de **segunda línea**, después de que se hayan implementado cambios en el estilo de vida, comportamentales y como **alternativa directa al tratamiento farmacológico en adultos con VH.**

Booth, Joanne, et al. "The effectiveness of transcutaneous tibial nerve stimulation (TTNS) for adults with overactive bladder syndrome: a systematic review." *Neurourology and urodynamics* 37.2 (2018): 528-541.

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Posterior tibial nerve stimulation for overactive bladder—techniques and efficacy

2020

- La **evidencia** muestra que los resultados de PTNS mejoran los **síntomas** de la VH a **corto y largo plazo**.
- Los **efectos secundarios** de este tratamiento son más tolerables que los observados con antimuscarínicos como sequedad de boca y estreñimiento.

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Treatment for overactive bladder

A meta-analysis of transcutaneous tibial nerve stimulation versus percutaneous tibial nerve stimulation

2021

Abstract

Background: We aim to compare the safety and effectiveness of transcutaneous tibial nerve stimulation (TTNS) versus percutaneous tibial nerve stimulation (PTNS) in treating overactive bladder.

Methods: A systematical search on PubMed, Embase, clinicalTrial.gov, and Cochrane Library Central Register of Controlled Trials from January 1, 1999 to November 1, 2020 was performed. The primary outcomes were the changes in a 3-day voiding diary. Quality of life scores were also evaluated. Review Manager 5.3 (Cochrane Collaboration, Oxford, UK) was applied to conduct all statistical analyses.

Results: A total of 4 trials (2 randomized controlled trials, 1 retrospective study, and 1 before-after study) with 142 patients were eventually enrolled. Compared with PTNS, TTNS had a similar performance in the voiding frequency in 24 hours (mean difference [MD] = −0.65, 95% confidence interval [CI]: −1.35 to 0.05, $P = .07$), the number of urgency episodes in 24 hours (MD = 0.13, 95% CI: −0.36 to 0.62, $P = .60$), the number of incontinence episodes in 24 hours (MD = 0.01, 95% CI: −0.13 to 0.14, $P = .93$), as well as in the nocturia frequency (MD = −0.14, 95% CI: −0.52 to 0.24, $P = .47$). Moreover, comparable results were observed regarding HRQL

Conclusion: Current data supported that TTNS is as effective as PTNS for the treatment of overactive bladder, moreover, with no reported adverse events. However, the evidence is low-grade and well-designed prospective studies with a large sample size are warranted to verify our findings.

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Abbreviations: AEs = adverse events, I-QoL = incontinence quality of life questionnaire, OAB = overactive bladder, PTNS = percutaneous tibial nerve stimulation, TTNS = transcutaneous tibial nerve stimulation.

Keywords: overactive bladder, percutaneous tibial nerve stimulation, transcutaneous tibial nerve stimulation

Yang, Ding-Yuan, Liu-Ni Zhao, and Ming-Xing Qiu. "Treatment for overactive bladder: A meta-analysis of transcutaneous tibial nerve stimulation versus percutaneous tibial nerve stimulation." *Medicine* 100.20 (2021)

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2022

- Estos dos métodos de estimulación del nervio tibial tuvieron una **eficacia clínica similar.**
- **Diferencias**: la **T-PTNS** tuvo un **tiempo de preparación más corto**, **menos** nivel de **incomodidad** y una **mayor satisfacción** del paciente que la **P-PTNS**.

Sonmez, Rafet, Necmettin Yildiz, and Hakan Alkan. "Efficacy of percutaneous and transcutaneous tibial nerve stimulation in women with idiopathic overactive bladder: A prospective randomised controlled trial." *Annals of physical and rehabilitation medicine* 65.1 (2022): 101486.

2020

Los tres tratamientos de tercera línea son efectivos

Discutir cuidadosamente los pros/contras de cada tratamiento con el paciente

Determinar la estrategia adecuada en función de cada situación individual

Lo, Chi-Wen, et al. "Comparing the efficacy of onabotulinumtoxinA, sacral neuromodulation, and peripheral tibial nerve stimulation as third line treatment for the management of overactive bladder symptoms in adults: Systematic review and network meta-analysis." *Toxins* 12.2 (2020): 128.

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PTNS vs SNM vs BonTA

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2020

Comparing the Efficacy of OnabotulinumtoxinA, Sacral Neuromodulation, and Peripheral Tibial Nerve Stimulation as Third Line Treatment for the Management of Overactive Bladder Symptoms in Adults: Systematic Review and Network Meta-Analysis

- Primera revisión que combina toda la **evidencia actualizada** y compara la **eficacia** de cualquier dosis de **OnabotulinumtoxinA**, **neuromodulación sacra** y **PTNS** para el tratamiento del síndrome de VH en adultos.

Lo, Chi-Wen, et al. "Comparing the efficacy of onabotulinumtoxinA, sacral neuromodulation, and peripheral tibial nerve stimulation as third line treatment for the management of overactive bladder symptoms in adults: Systematic review and network meta-analysis." *Toxins* 12.2 (2020): 128.

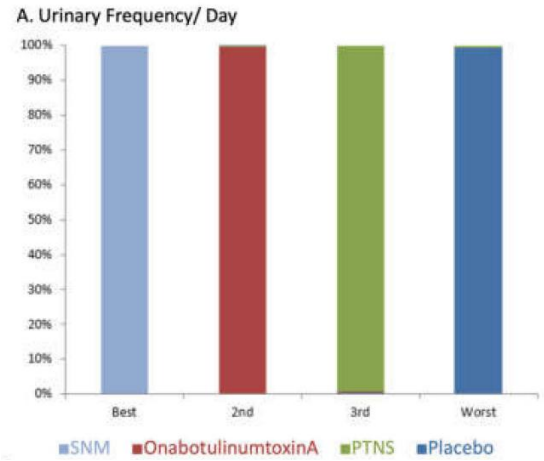
- En comparación con el placebo, los tres tratamientos fueron más eficaces para los parámetros de resultado seleccionados.
- La **onabotulinumtoxinA** provocó un mayor número de **complicaciones**, incluidas infecciones del tracto urinario y retención de orina.
- En comparación con la onabotulinumtoxinA y la PTNS, la **SNM** produjo la **mayor reducción** de los episodios de **IU y FMD**. Falta comparación de eficacia a largo plazo.
- Se justifican más **estudios sobre la eficacia a largo plazo** de las tres opciones de tratamiento, con cuestionarios y parámetros estandarizados.

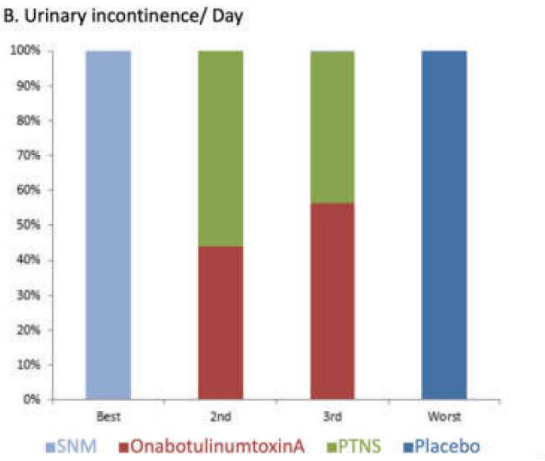
Lo, Chi-Wen, et al. "Comparing the efficacy of onabotulinumtoxinA, sacral neuromodulation, and peripheral tibial nerve stimulation as third line treatment for the management of overactive bladder symptoms in adults: Systematic review and network meta-analysis." *Toxins* 12.2 (2020): 128.

Table 2. Pairwise meta-analyses result for different endpoints.

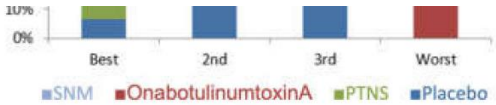
Endpoint	Comparison	*N*	I^2 (%)	*p* Value	Standard Mean Difference (95% CI)
Urinary frequency/ day	OnabotulinumtoxinA vs. Placebo	4	92	< 0.001	−0.65 (-0.24–−1.06)
	PTNS vs. OnabotulinumtoxinA	1			−1.02 (−1.55–−0.48)
	PTNS vs. Placebo	3	37.1	0.204	−0.37 (-0.03–−0.70)
	SNM vs. Placebo	1			−1.12 (-0.53–−1.71)
Urge urine incontinence	OnabotulinumtoxinA vs. Placebo	2	70.7	0.065	−0.37 (−0.05—0.79)
Urgency Episode	OnabotulinumtoxinA vs. Placebo	4	97.6	<0.001	−0.84 (-0.08—1.60)
Maximal	PTNS vs. Placebo	1			1.35 (0.79–1.92)
	SNM vs. Placebo	1			0.91 (0.33–1.48)
I-QoL	OnabotulinumtoxinA vs. Placebo	2	99.1	<0.001	0.98 (−0.89–2.86)
	PTNS vs. Placebo	1			0.86 (0.13–1.59)
Incontinence	OnabotulinumtoxinA vs. Placebo	3	97.8	<0.001	-0.84 (-1.62—0.06)
	PTNS vs. OnabotulinumtoxinA	1			0.54 (0.02–1.06)
	PTNS vs. Placebo	1			-1.49 (-2.28—0.70)
	SNM vs. Placebo	2	74.6	0.047	-2.10 (-3.07—1.12)
≥50% Improvement	Placebo vs. OnabotulinumtoxinA	2	0.0	0.410	0.53 (0.40–0.70)
	PTNS vs. OnabotulinumtoxinA	2	0.0	0.371	0.50 (0.32–0.76)
	Placebo vs. PTNS	3	52.5	0.122	0.21 (0.07–0.61)
	SNM vs. Placebo	1			1.27 (0.87–1.87)
Urinary tract infection	OnabotulinumtoxinA vs. Placebo	8	0	0.486	2.55 (1.89–3.43)
	PTNS vs. OnabotulinumtoxinA	1			0.20 (0.01–4.34)
	SNM vs. OnabotulinumtoxinA	1			0.33 (0.19–0.56)
Clean intermittent catherization	OnabotulinumtoxinA vs. Placebo	9	0	0.786	5.95 (3.08–11.46)
	PTNS vs. OnabotulinumtoxinA	1			0.20 (0.01–4.34)
	SNM vs. OnabotulinumtoxinA	1			0.01 (0.00–0.23)

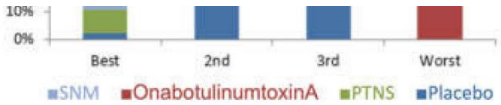
Lo, Chi-Wen, et al. "Comparing the efficacy of onabotulinumtoxinA, sacral neuromodulation, and peripheral tibial nerve stimulation as third line treatment for the management of overactive bladder symptoms in adults: Systematic review and network meta-analysis." *Toxins* 12.2 (2020): 128.



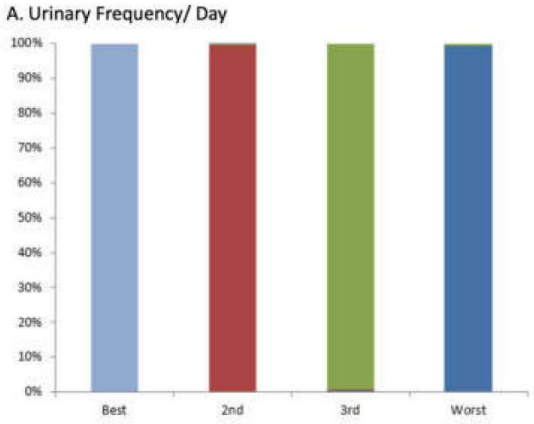


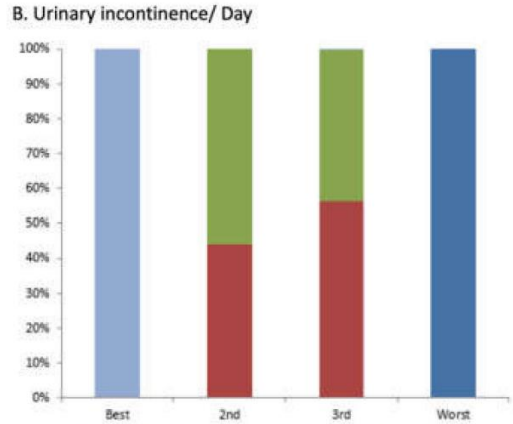
- **Reducción de la frecuencia urinaria**: 1º SNM, 2º OnabotulinumtoxinA 3º PTNS ocupó el tercer lugar y 4º placebo.



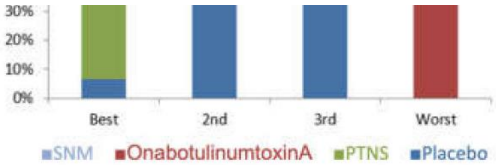


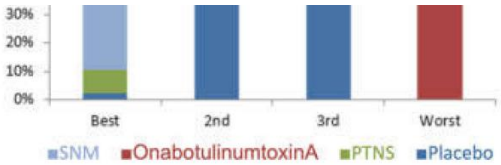
Lo, Chi-Wen, et al. "Comparing the efficacy of onabotulinumtoxinA, sacral neuromodulation, and peripheral tibial nerve stimulation as third line treatment for the management of overactive bladder symptoms in adults: Systematic review and network meta-analysis." *Toxins* 12.2 (2020): 128.





- **Reducción de los episodios de incontinencia**: 1º SNM, 2º PTNS ocupó el segundo lugar, 3º OnabotulinumtoxinA y el 4º placebo.





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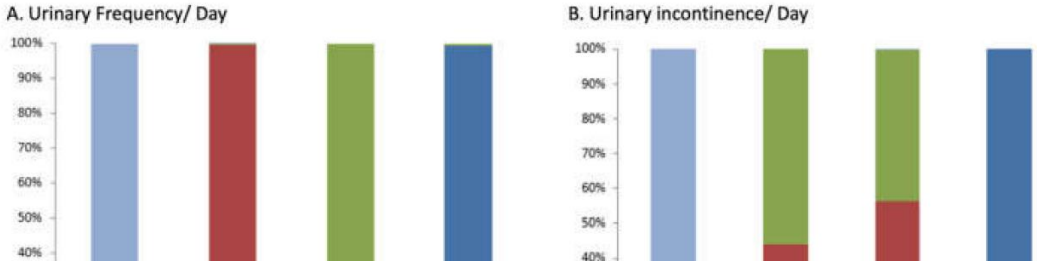
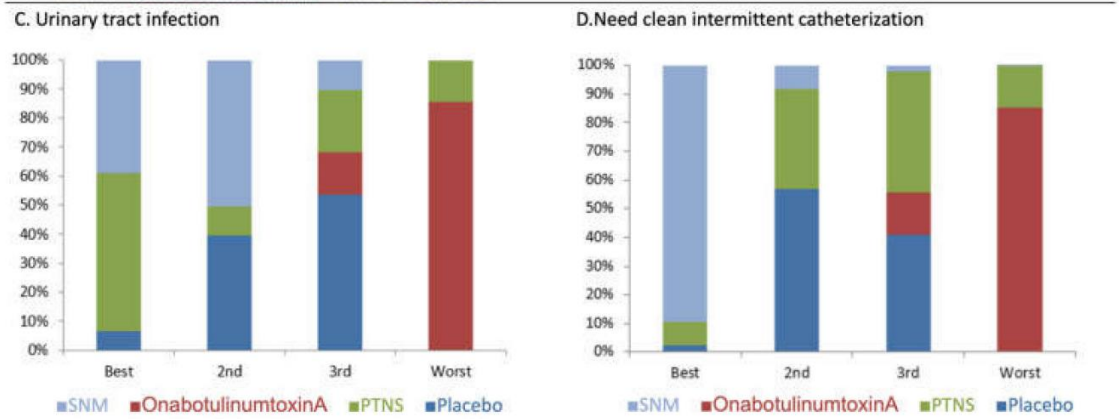


- **Infecciones urinarias**: 1º PTNS, 2º SNM 3º placebo y la onabotulinumtoxinA ocupó el peor lugar.



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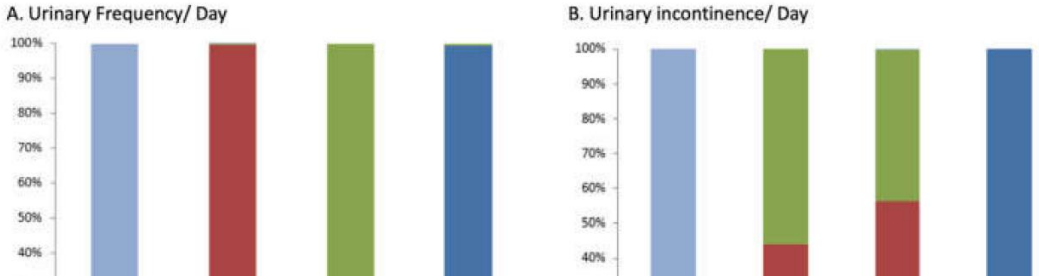
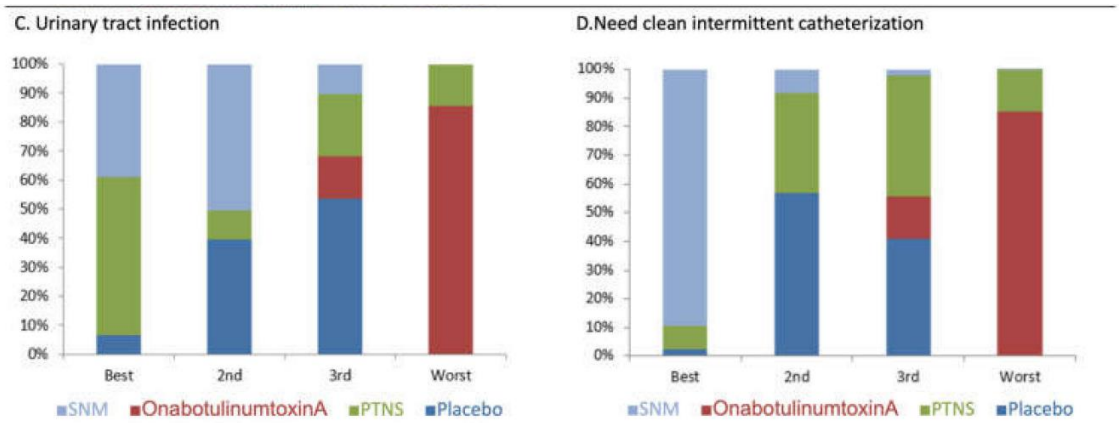


- **Retención urinaria**: 1º OnabotulinumtoxinA, 2º PTNS, 3º placebo y 4º SNM.



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2020

- La **SNM**: mayor **reducción** en los episodios **IU y FMD**.
- La **onabotulinumtoxinA**: mayor riesgo de **retención** de orina e ITUs.
- La **SNM**: tratamiento **más caro** vs onabotulinumtoxina A y PTNS a **corto plazo**.
- La rentabilidad de **SNM** fue comparable a la de onabotulinumtoxinA **a medio y largo plazo**.

Lo, Chi-Wen, et al. "Comparing the efficacy of onabotulinumtoxinA, sacral neuromodulation, and peripheral tibial nerve stimulation as third line treatment for the management of overactive bladder symptoms in adults: Systematic review and network meta-analysis." *Toxins* 12.2 (2020): 128.

Efectos adversos

- **OnabotulinumtoxinA**:
  - Hematuria, bacteriuria, infecciones urinarias, retención de orina y aumento de orina residual posmiccional.
  - Tasa significativamente mayor de CIC e ITU.
  - La tasa más alta de CIC no fue consistente entre los ensayos incluidos y la revisión de la literatura, por lo que esta conclusión podría ser controvertida.
- **SNM**:
  - Dolor en los sitios del estimulador y del cable. Migración del cable, infección y la necesidad de revisión quirúrgica.

Lo, Chi-Wen, et al. "Comparing the efficacy of onabotulinumtoxinA, sacral neuromodulation, and peripheral tibial nerve stimulation as third line treatment for the management of overactive bladder symptoms in adults: Systematic review and network meta-analysis." *Toxins* 12.2 (2020): 128.

- Las tres modalidades fueron eficaces en el tratamiento del síndrome de VH en adultos y todas fueron mejores que un placebo en los síntomas específicos informados como resultado del estudio.
- Esta revisión muestra que a las 12 semanas de seguimiento:
  - La **SNM**: mayor reducción en los episodios de incontinencia urinaria y en la frecuencia urinaria/día.
  - La **onabotulinumtoxinA**: mayor incidencia de complicaciones, incluidas infección del tracto urinario y retención urinaria.

Lo, Chi-Wen, et al. "Comparing the efficacy of onabotulinumtoxinA, sacral neuromodulation, and peripheral tibial nerve stimulation as third line treatment for the management of overactive bladder symptoms in adults: Systematic review and network meta-analysis." *Toxins* 12.2 (2020): 128.

Review Article

Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines

2022

- La **SNM** se consideraba el tratamiento de tercera línea para pacientes con VH, pero ha logrado menores avances.
  - **Deficiencias**: Tamaño del dispositivo SNM, coste, exposición a la radiación para implantar su cable cerca de un nervio sacro, y dos cirugías .
  - **Complicaciones** a corto y largo plazo: alrededor del 30-40% requieren retirada y reemplazo.
- **PTNS** aprobado para el tratamiento de pacientes con VH muestra un alto progreso tecnológico, rentabilidad y sostenibilidad con menos eventos adversos que SNM.

Al-Danakh, Abdullah et al. "Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines." *Parkinson's disease* vol. 2022 2700227. 16 Mar. 2022.

Neurourology Urodynamics · SUFU · WILEY

Third-line therapy for overactive bladder in the elderly: Nuances and considerations

2022

Abstract

Introduction: Overactive bladder (OAB) disproportionally affects older adults in both incidence and severity. OAB pharmacotherapy is often problematic in the elderly due to polypharmacy, adverse side effect profiles and contra-indications in the setting of multiple comorbidities, and concerns regarding the risk of incident dementia with anticholinergic use. The burden of OAB in older patients coupled with concerns surrounding pharmacotherapy options should motivate optimization of nonpharmacologic therapies in this popula-tion. At the same time, several aspects of aging may impact treatment efficacy and decision-making. This narrative review critically summarizes current evidence regarding third-line OAB therapy use in the elderly and discusses nuances and treatment considerations specific to the population.

Methods: We performed an extensive, nonsystematic evidence assessment of available literature via PubMed on onabotulinumtoxinA (BTX-A), sacral neuromodulation, and percutaneous tibial nerve stimulation (PTNS) for OAB, with a focus on study in elderly and frail populations.

Conclusion: Advanced age and frailty should not preclude third-line therapy for refractory OAB, as available data support their efficacy and safety in these populations. Ultimately, treatment choices should be individualized and involve shared decision-making.

Zillioux, Jacqueline, Emily A. Slopnick, and Sandip P. Vasavada. "Third-line therapy for overactive bladder in the elderly: Nuances and considerations." *Neurourology and Urodynamics* 41.8 (2022): 1967-1974.

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Third-line therapy for overactive bladder in the elderly: Nuances and considerations

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Results: While limited, available studies show all three third-line therapies are efficacious in older populations and there is no data to support one option over another. BTX-A likely has a higher risk of urinary tract infection and retention in older compared to younger populations, especially in the frail elderly. PTNS incurs the lowest risk, although adherence is poor, largely due to logistical burdens.

Conclusion: Advanced age and frailty should not preclude third-line therapy for refractory OAB, as available data support their efficacy and safety in these populations. Ultimately, treatment choices should be individualized and involve shared decision-making.

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