Peroneal Nerve Neuromodulation for Overactive Bladder: A Pilot Study Assessing Efficacy and Safety in Patients with Multiple Sclerosis

Sara Freixo[1], Patrícia Pereira[1], João Esteves Sousa[1], Cátia Barbosa Martins[1], Manuela Mira Coelho[1]

Abstract

Introduction: Overactive bladder (OAB) symptoms are highly prevalent among patients with multiple sclerosis (MS), significantly impairing quality of life. Peroneal nerve neuromodulation (PNM) has emerged as a potential alternative to posterior tibial nerve stimulation for managing refractory OAB symptoms, although no studies to date have directly evaluated its effects in MS patients.

We aimed to assess the clinical and urodynamic effects of transcutaneous peroneal nerve neuromodulation in patients with MS and neurogenic OAB.

Methods: This prospective single-center open-label pilot study included 18 patients with MS and OAB symptoms refractory or intolerant to first-line treatments. Participants received weekly transcutaneous PNM for 12 weeks. Outcomes included changes in urgency episodes (OAB-SF), symptom severity and impact in quality of life (ICIQ-OAB), and urodynamic parameters. Data were analyzed using paired statistical tests ($p < 0.05$).

Results: Statistically significant improvements were observed in urgency-related items of the OAB-SF and ICIQ-OAB questionnaires, reflecting reduced symptom burden and increased bladder control. Urodynamic data revealed a significant increase in maximum cystometric capacity ($p = 0.041$), with a trend toward improved urgency volume ($p = 0.053$). One mild adverse event (local skin burn) was reported and resolved spontaneously. No other adverse effects occurred.

Conclusion: Peroneal nerve neuromodulation appears to be a safe and potentially effective intervention for improving urgency and bladder storage capacity in MS patients with OAB. These findings support further investigation in larger, controlled studies with longer follow-up and functional neuroimaging to better understand therapeutic mechanisms and long-term outcomes.

Keywords: Multiple Sclerosis/complications; Patient Reported Outcome Measures; Peroneal Nerve; Transcutaneous Electric Nerve Stimulation; Urinary Bladder, Overactive/etiology; Urinary Bladder, Overactive/therapy

1 – Physical Medicine and Rehabilitation Service, Hospital de Braga, Braga, Portugal

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Introduction

Overactive bladder (OAB) is characterized by urinary urgency, usually accompanied by increased frequency and nocturia, with or without urgency urinary incontinence, in the absence of urinary tract infection or other obvious pathology. Symptoms of OAB are present in a significant proportion of MS patients, with prevalence rates ranging between 50% and 97%.[1-3] Frequency and urgency are the most frequent symptoms, manifested in 31%–86% of patients and lower urinary tract symptoms (LUTS) are one of the complications that most concern patients with multiple sclerosis, alongside fatigue and muscle weakness.[3,4] These symptoms not only interfere with the physiological function of the bladder but also substantially impact patients quality of life, adversely affecting daily activities, social relationships, and psychological well-being.[5,6] Consequently, bladder dysfunction in MS is associated with increasing morbidity and potentially affects disease progression, an increased risk of complications, such as urinary tract infections and social isolation, highlighting the need for therapeutic interventions that can improve both symptoms and quality of life in these patients.[7,8]

Treatment options include behavioral measures, pharmacotherapy, and, in refractory cases, detrusor botulinum toxin injections and neuromodulation approaches. Posterior tibial nerve stimulation (PTNS) is well-established for OAB in different populations.[9-13]

More recently, emerging evidence suggests that peroneal nerve neuromodulation (PNM) might also be effective, possibly involving distinct cerebral areas.[14,15] This nerve contains motor and sensory fibers that influence pelvic floor and bladder function through central and peripheral mechanisms. Studies by Krhut and colleagues demonstrated that transcutaneous stimulation of peroneal afferents recruits distinct supraspinal networks compared with tibial stimulation on functional imaging, providing a mechanistic rationale to test targeted PNM in MS-related OAB.[15,16] Based on the available literature, this is among the first prospective pilot study to evaluate targeted peroneal nerve neuromodulation specifically in MS-related OAB. The objective of this study is to evaluate the clinical and urodynamic impact of peroneal nerve neuromodulation in patients with OAB and MS, using symptom and quality-of-life questionnaires, as well as urodynamic studies.

Methods

Study Design: Prospective single-center open-label pilot study included 18 patients with multiple sclerosis (MS) and neurogenic OAB. All participants underwent peroneal nerve neuromodulation once per week for 12 consecutive weeks, and clinical as well as urodynamic evaluations were performed before and after the intervention. The study was conducted between October 2024 and January 2025 at the Department of Physical and Rehabilitation Medicine of Braga Hospital.

Inclusion Criteria: Age over 18 years; a confirmed diagnosis of MS; the presence of OAB symptoms (urgency, increased frequency, nocturia, and/or urgency incontinence) that were refractory or intolerant to first-line treatments; a urodynamic study within the last two years with no therapeutic modifications since then; and the ability to provide signed informed consent.

Exclusion Criteria: Diagnosis of urinary tract infection during the study period, MS relapse, pregnancy, cognitive impairment, implanted pacemaker or neurostimulator, cutaneous lesions at the electrode application site, any therapeutic changes targeting OAB or MS during the study period, tibial neuromodulation within the previous 6 months, detrusor botulinum toxin injection within the previous year, pelvic floor rehabilitation during the study, intermittent catheter use or significant post-void residual.

Screening eligibility, enrollment and patients included in analysis are summarized in Fig. 1.

Intervention: The PNM technique involved placing the active electrode approximately 2–3 cm distal to the fibular head, in the area where the peroneal nerve is most susceptible to transcutaneous stimulation, and positioning the ground electrode about 5 cm below.[17] Circular electrodes of 2.5 cm in diameter were used. Stimulation was delivered with biphasic symmetrical current at 20 Hz and a pulse width of 200 microseconds, with intensity adjusted until a visible contraction (dorsiflexion/eversion of the ankle) was achieved and tolerated by the patient. PNM was delivered using Soleo Galva electrostimulator (Zimmer Medizin Systeme, Germany). At each session, stimulation intensity was titrated to the minimum level that produced a visible ankle dorsiflexion/eversion and was well tolerated, for each participant, the required intensity remained broadly similar across sessions. Adverse events were systematically queried at every visit.

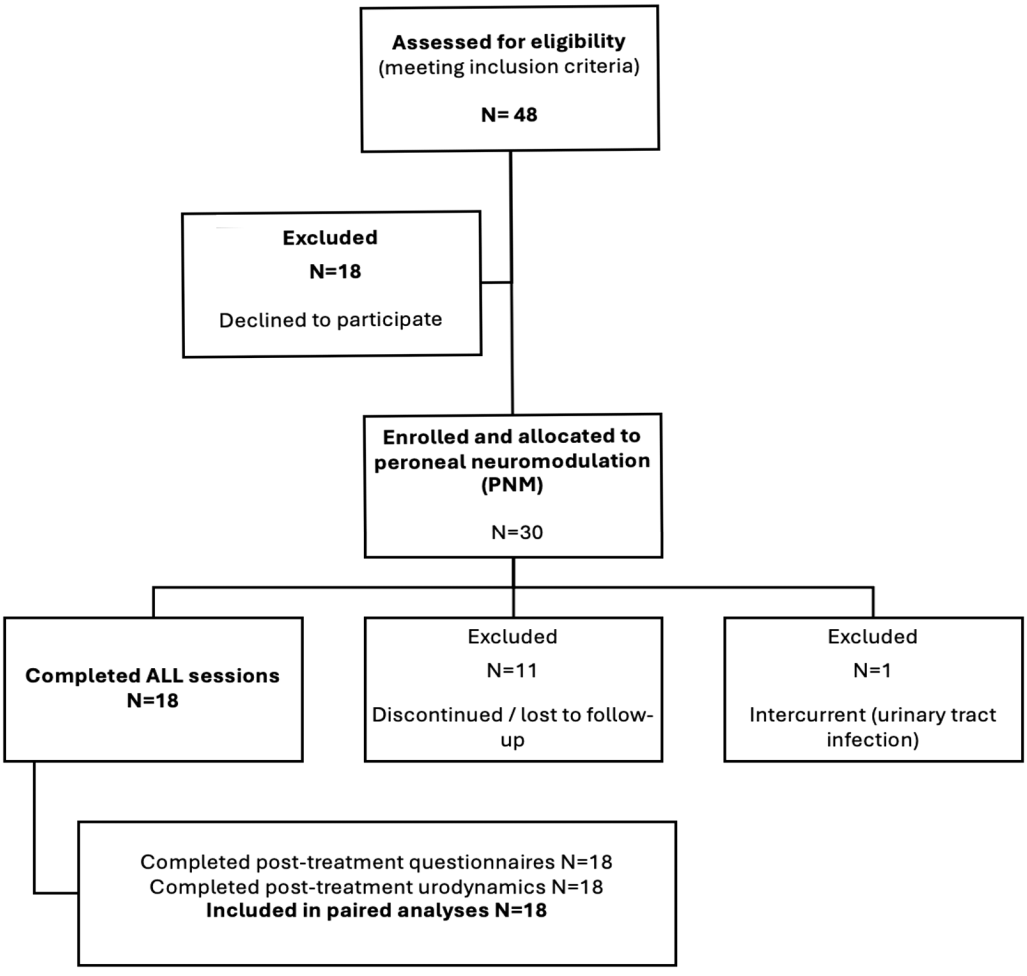

Figure1 – Patient recruitment flowchart

Primary Outcome: Change in the number of urgency episodes, based on the ICIQ-OAB questionnaire, comparing baseline and 12 weeks after treatment

Secondary Outcomes: Comparison between baseline and 12 weeks of treatment on ICIQ-OAB questionnaire scores and urodynamic parameters, and on the incidence of adverse events.

Data Collection and Monitoring: Outcome measures included the results of International Consultation on Incontinence Questionnaire Overactive Bladder (ICIQ-OAB), validated for Brazilian Portuguese[18] (Appendix 1) —in addition to urodynamic parameters such as presence of detrusor overactivity (DO), bladder volume at the onset of detrusor overactivity (DOVol), sphincter dyssynergia (SD), obstructive flow (OF), maximum cystometric capacity (MCC), volume at first desire to void (V1stD), volume at urge (Vurg), bladder compliance (BC), and maximum free flow rate (Qmax) and post-void residual volume (PVR) measured on uroflowmetry. The Portuguese version of the ICIQ-OAB scale is freely available for use. The authors are identified in the translation article, which is accessible at URL: https://doi.org/10.1590/S0100-72032010000600004. The applied scale can be accessed at:https://escalasdefuncionalidade.com/iciq-oab and is detailed in Appendix 1. Appendix 2 also presents the English translation of the same scale for reference purposes only; it was not used in the study.

Statistical Analysis: conducted using software such as JASP, applying paired Wilcoxon or paired Student's t-tests according to data normality, and adopting a significance level of 5% ($p < 0.05$). Continuous variables were summarized as mean ± SD and categorical variables as n (%).

This was an open-label study, the staff who collected questionnaires and performed urodynamics were not blinded. To mitigate assessment bias, all records were pseudonymized and filed under unique study codes, patient names were not available to assessors. Urodynamic studies were acquired and reported using a prespecified protocol, and post-treatment tracings were interpreted without side-by-side access to the corresponding baseline tracings. Data linkage to pre/post time points was performed only at the analysis stage.

This study was conceived as an exploratory feasibility study with a pre-specified target of n = 18, determined by the expected recruitment capacity and the methodological need to estimate variance and preliminary effect sizes to inform a subsequent, adequately powered trial. Accordingly, the present analyses are hypothesis-generating and the study was not powered for definitive efficacy conclusions.

The study protocol was reviewed and approved by the Hospital Ethics Committee and the Data Protection Department. All procedures were conducted in accordance with ethical standards, including the principles outlined in the Declaration of Helsinki. Written informed consent was obtained from all participants before enrollment, ensuring that their rights and well-being were fully protected.

The authors declare no relevant conflicts of interest.

Results

Study Population and Baseline Characteristics:

A descriptive analysis of the study population is detailed in Table 1. A total of 18 patients with MS were included, predominantly with relapsing-remitting MS (RRMS), except for one participant with a secondary progressive form (EMSP). Among these 18 participants, 14 (78%) were women and four (22%) were men. Ages ranged from 20 to 74 years, and the majority (83%) presented with urgency urinary incontinence (IUU), and a smaller subset (17%) reported mixed incontinence (IUM) and voiding symptoms. All participants were under disease-modifying therapies for MS, including natalizumab, ocrelizumab, teriflunomide, rituximab and glatiramer acetate. A portion of the sample was also receiving pharmacological treatment targeting lower urinary tract symptoms, such as alpha-blockers (alfuzosin, tamsulosin), antimuscarinics (solifenacin, trospium chloride, oxybutynin), beta-adrenergic agonists (mirabegron) and GABA-ergic agonist (baclofen). No patients were receiving onabotulinumtoxina (BTX-A) detrusor injections, tibial or sacral neuromodulation at baseline.

Table1 – Study Population and Baseline Characteristics. Mean age was 44 years (range: 20–74 years):

		Nº (%)
Gender	Male Female)	4 (22% 14 (78%)
MS subtype	RRMS SPMS	17 (94%) 1 (6%)
Bladder symptom	Urgency incontinence Mixed incontinence Difficulty emptying	15 (83%) 2 (11%) 1 (6%)
Bladder medication	Alfuzosin Tamsulosin Solifenacin Trospium chloride Oxybutynin Mirabegron Baclofen	7 (39%) 4 (22%) 4 (22%) 1 (6%) 0 (0%) 4 (22%) 4 (22%)
MS medication	Natalizumab Ocrelizumab Teriflunomide Rituximab Glatiramer acetate	5 (28%) 4 (22%) 6 (33%) 1 (6%) 2 (11%)

RRMS - relapsing-remitting multiple sclerosis; SPMS - secondary progressive; MS - multiple sclerosis

Table 2 – ICIQ-OAB Questionnaire Analysis

(Values represent mean scores at baseline (ICIQ-OAB_i) and after the intervention (ICIQ-OAB_f). Statistical comparisons performed using the Wilcoxon signed-rank test or Student's t-test as appropriate)

Quest	ICIQ-OAB_i mean(SD)	ICIQ-OAB_f mean(SD)	Test	Statistic	z	Df	*p*
1	2.06 (1.09)	1.78 (0.94)	Student	0.846	-	16	0.410
1a	5.17 (3.26)	3.00 (2.59)	Wilcoxon	111.500	2.925	-	0.003
2	2.72 (1.32)	2.44 (1.42))	Wilcoxon	28.000	1.400	-	0.152
2a	3.94 (3.59)	2.89 (3.14)	Wilcoxon	60.000	1.647	-	0.103
3	3.00 (0.97)	2.44 (0.86)	Wilcoxon	50.500	2.344	-	0.015
3a	5.44 (3.13)	3.89 (2.68)	Student	2.544	-	17	0.021
4	2.50 (0.99)	1.78 (0.73)	Wilcoxon	73.000	2.667	-	0.006
4a	5.56 (3.60)	3.61 (3.53)	Student	3.201	-	17	0.005

ICIQ-OAB_f - Final International Consultation on Incontinence Questionnaire Overactive Bladder); ICIQ-OAB_i - Initial International Consultation on Incontinence Questionnaire Overactive Bladder)

Questions: 1. How often do you pass urine during the day; 2. During the night, how many times do you have to get up to urinate, on average?; 3. Do you have to rush to the toilet to urinate?; 4. Does urine leak before you can get to the toilet?. The sub-item evaluates the degree of bother using a 0 to 10 scale.

ICIQ-OAB Questionnaire:

This questionnaire contains four main questions (1–4) focusing on daytime frequency, nocturia, urgency, and urgency incontinence, each followed by a sub-question (1a–4a) that assesses the degree of bother. The results of the statistical analysis of the ICIQ-OAB questionnaire responses are detailed in Table 2. Statistically significant improvements emerged in question 1a ($p = 0.003$), which evaluates the level of bother related to daytime frequency; question 3 ($p = 0.015$), which addresses the need to rush to the bathroom; question 3a ($p = 0.021$), the associated bother; question 4 ($p = 0.006$), concerning urinary leakage before reaching the bathroom; and question 4a ($p = 0.005$), the bother associated with that leakage. There were no significant differences in question 1, question 2, or question 2a ($p = 0.05$), questions related to urinary frequency and nocturia. These results show an improvement in urgency symptoms and accidental leakage, and the associated bother, as well as certain aspects of daytime frequency.

Urodynamic Data:

A comparison of urodynamic parameters before and after the intervention revealed a significant increase in MCC ($p = 0.041$), from 260 to 313 mL, corresponding to an average improvement of 35 mL of storage and indicates a clinically meaningful gain in storage function. VUrg showed a concordant near-significant increase, from 224 to 272 mL, corresponding to an improvement of 48 mL, suggesting a trend toward improved sensory thresholds that warrants confirmation in a larger powered study. No significant changes were observed in DO, V1stD, BC, PVR, SD or Qmax ($p > 0.05$). The results obtained for the urodynamic study parameters before and after the intervention are detailed in Table 3. In summary, these findings demonstrate enhanced storage capacity, in line with the clinical improvements reported in the questionnaires.

Adverse Events:

Adverse events related to peroneal nerve stimulation were systematically monitored throughout the study. We specifically assessed for skin irritation, pain or discomfort at the electrode site, muscle spasms, and any neurological or systemic symptoms. Among the 18 patients included, only one experienced a mild skin burn at the site of electrode placement. This resolved spontaneously within 48 hours without requiring medical intervention. No other adverse events were reported.

Discussion

Management of OAB in patients with neurological disease, such as MS, typically follows a stepwise pathway. First-line conservative measures include behavioral therapy, bladder training/timed voiding, and pelvic-floor muscle training. In MS cohorts, these strategies are recommended early but often provide only partial control, prompting escalation to pharmacotherapy.[19] Second--line treatment includes antimuscarinics, which can reduce urgency and incontinence, although their use and adherence are frequently limited by adverse effects. An alternative is the β3--adrenergic agonists, which are generally better tolerated; combination therapy may enhance efficacy at the cost of additive side-effects. Third-line interventions include onabotulinumtoxinA detrusor injections, sacral neuromodulation (SNM), and peripheral

Table 3 – Urodynamic Studies Analysis

Urodynamic parameter	Pre-intervention Mean (SD) / N(%)	Post-intervention Mean (SD) / N(%)	Test	Statistic	z	df	p
DO	16 (89%)	12 (67%)	Wilcoxon	17.500	1.468	-	0.129
DOVol (mL)	191.88 (56.12)	162.73 (74.17)	Wilcoxon	32.500	1.185	-	0.260
V1stD (mL)	161.11 (70.62)	143.89 (80.89)	Wilcoxon	84.500	0.853	-	0.407
Vurg (mL)	224.44 (59.63)	272.22 (103.67)	Student	-2.077	-	17	0.053
MCC (mL)	260.0 (88.85)	313.33 (107.54)	Student	-2.218	-	17	0.041
BC (mL/cmH2O)	78.12 (28.19)	85.88 (24.69)	Wilcoxon	14.500	-0.948	-	0.370
PVR (mL)	43.33 (67.39)	24.71 (47.71)	Wilcoxon	12.000	1.214	-	0.281
SD	11 (61%)	9 (75%)	Wilcoxon	22.500	0.630	-	0.530
Qmax (mL/s)	15.65 (8.78)	15.83 (8.47)	Student	-0.182	-	16	0.858

DO - detrusor overactivity; DO_Vol - bladder volume at the onset of detrusor overactivity; V1stD -volume at first desire to void; Vurg - volume at urge; MCC - maximum cystometric capacity; BC - bladder compliance; PVR - post-void residual; SD - sphincter dyssynergia; Qmax - maximum flow rate

neuromodulation such as tibial nerve stimulation. Among third--line options, onabotulinumtoxinA consistently improves OAB symptoms but carries a meaningful risk of transient urinary retention requiring clean intermittent catheterization. SNM provides durable symptom control for many patients but is invasive, with device and revision-related complications that must be weighed against benefit. Posterior tibial nerve stimulation offers a non-invasive alternative with short-term response rates commonly around 50%–80% across mixed OAB populations, minimal adverse effects, and a need for maintenance sessions to sustain benefit.[19,20]

Against this backdrop, PNM, as used in the present study, retains the non-invasive advantages of PTNS, while emerging neuroimaging data indicate partly distinct supraspinal engagement.[15] In this pilot cohort, PNM was associated with significant improvements across several OAB questionnaire items, as well as an increase in MCC on urodynamic testing. These findings support the hypothesis that peroneal nerve stimulation may serve as a viable third-line option for lower urinary tract symptoms (LUTS) in people with MS, mirroring the benefits previously reported for posterior tibial nerve stimulation in OAB.[9,11,12,21]

Recent work published by Khurt *et al* showed that transcutaneous electrical stimulation of the peroneal nerve can reduce OAB symptoms and modulate brain circuits differently from tibial nerve stimulation.[15,16] These studies provide evidence that peroneal PNM activates brain structures previously implicated in the neural control of bladder filling and in mechanisms involved in coping with urgency. Our current research aligns with that line of investigation, suggesting that peroneal neuromodulation is well--tolerated and may produce promising clinical results. The observed increase in MCC is clinically meaningful and suggests storage-phase facilitation under peroneal neuromodulation. Several mechanisms may account for this finding: PNM could enhance descending inhibitory control, modulate afferent signaling from the bladder-outlet complex, or promote detrusor adaptation during the filling phase. From a mechanistic standpoint, PNM likely delivers somatic afferent input that gates pelvic afferent traffic at the spinal level and augments descending inhibitory control over the pontine–periaqueductal gray micturition network. Functional magnetic resonance imaging (MRI) studies with peroneal stimulation have shown distinct modulation of the insula, anterior cingulate, premotor and supplementary motor, and prefrontal regions, consistent with an upregulation of cortical inhibitory circuits that favor bladder storage.[15,16] In parallel, altered afferent signaling from the bladder-outlet complex may raise sensory thresholds (first desire and urgency), allowing filling to progress further before the emergence of urgency. The near-significant increase in urgency volume in our cohort ($p = 0.053$) supports this interpretation and implies that a larger sample or extended follow-up might confirm additional changes. PNM may rebalance storage reflexes, via spinal gating and supraspinal inhibitory influences, which could underlie the clinically meaningful capacity gain observed.

This study has inherent limitations: the small pilot sample and single-center design limit generalizability. An active control group (e.g., PTNS or pharmacotherapy) was not included, which prevents direct comparison of efficacy. The absence of a sham control precludes quantifying placebo contribution. The short/ /medium-term follow-up (12 weeks) does not allow conclusions about the long-term durability of the effect. Patient-reported measures such as ICIQ-OAB are subject to expectation bias.

Outcome assessors were not blinded, which may introduce assessment bias despite standardized protocols. Additionally, there are no standardized parameters for peroneal nerve neuromodulation, which limits reproducibility and comparison across studies.

Conclusion

Peroneal nerve neuromodulation shows promising efficacy in improving several OAB symptom domains, as measured by standardized questionnaires, and in increasing MCC in patients with MS and overactive bladder. These results, in line with previous studies investigating peroneal neuromodulation, support the feasibility of exploring this technique as an alternative to other FDA (Food and Drugs Administration) approved neuromodulation methods (podendal, tibial or sacral), being a nerve with greater accessibility to electrical stimulation and possibly associated with the activation of brain structures likely involved in the neural control of bladder storage and urinary urgency.

Larger controlled studies are needed on this population to evaluate the efficacy of peroneal neuromodulation relative to other modalities (eg, PTNS) and associate the functional outcomes with brain structures activation, using brain functional MRI. Longer follow-up studies are needed to assess the long-term persistence of therapeutic benefits.

Ethical Disclosures

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Confidentiality of Data: The authors declare that they have followed the protocols of their work center on the publication of patient data.

Protection of Human and Animal Subjects: The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and those of the Code of Ethics of the World Medical Association (Declaration of Helsinki as revised in 2024).

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Contributorship Statement:

SF: Concept, design, acquisition, analysis and interpretation of data and manuscript drafting.

PP, JES and CBM: Acquisiton, analysis and interpretation of data.

MMC: Concept and design, manuscript drafting and critical review.

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Corresponding Author:
Sara Freixo
Rua Professor Doutor João Carvalho, 34 - 4700-289 Braga
Email: sara_freixo@hotmail.com
ORCID: https://orcid.org/0000-0003-4490-344X

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Appendix 1. International Consultation on Incontinence Questionnaire Overactive Bladder ICIQ-OAB - Portuguese version

Questionário de Bexiga Hiperativa da Associação Internacional de Incontinênica
ICIQ-OAB (validado para português do Brasil)

Agradecemos a sua participação ao responder a estas perguntas para sabermos como tem sido o seu incomodo durante as últimas 4 semanas.

1.Quantas vezes você urina durante o dia?
( ) 1 a 6 vezes
( ) 7 a 8 vezes
( ) 9 a 10 vezes
( ) 11 a 12vezes
( ) 13 vezes ou mais

1a.O quanto isso incomoda você?
Circule um número de 0 (não incomoda) a 10 (incomoda muito).
0 1 2 3 4 5 6 7 8 9 10

2.Durante a noite, quantas vezes, em média, você têm que se levantar para urinar?
( ) nenhuma vez
( ) 1 vez
( ) 2 vezes
( ) 3 vezes
( ) 4 vezes ou mais

2a.O quanto isso incomoda você?
Circule um número de 0 (não incomoda) a 10 (incomoda muito).
0 1 2 3 4 5 6 7 8 9 10

3.Você precisa se apressar para chegar ao banheiro para urinar?
( ) nunca
( ) poucas vezes
( ) às vezes
( ) na maioria das vezes
( ) sempre

3a.O quanto isso incomoda você?
Circule um número de 0 (não incomoda) a 10 (incomoda muito).
0 1 2 3 4 5 6 7 8 9 10

4.Você perde urina antes de chegar ao banheiro?
( ) nunca
( ) poucas vezes
( ) às vezes
( ) na maioria das vezes
( ) sempre

4a.O quanto isso incomoda você?
Circule um número de 0 (não incomoda) a 10 (incomoda muito).
0 1 2 3 4 5 6 7 8 9 10

Appendix 2. International Consultation on Incontinence Questionnaire Overactive Bladder ICIQ-OAB - English version

"International Consultation on Incontinence Questionnaire Overactive Bladder"
(ICIQ-OAB)

Many people experience urinary symptoms some of the time. We are trying to find out how many people experience urinary symptoms, and how much they bother them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

1. How often do you pass urine during the day?
( ) 1 a 6 times
( ) 7 a 8 times
( ) 9 a 10 times
( ) 11 a 12 times
( ) 13 or more times

1a. How much does this bother you?
Please ring a number between 0 (not at all) and 10 (a great deal)
0 1 2 3 4 5 6 7 8 9 10

2. During the night, how many times do you have to get up to urinate, on average?
( ) none
( ) one
( ) two
( ) three
( ) four or more

2a. How much does this bother you?
Please ring a number between 0 (not at all) and 10 (a great deal)
0 1 2 3 4 5 6 7 8 9 10

3. Do you have to rush to the toilet to urinate?
( ) never
( ) occasionally
( ) sometimes
( ) most of the time
( ) all of the time

3a. How much does this bother you?
Please ring a number between 0 (not at all) and 10 (a great deal)
0 1 2 3 4 5 6 7 8 9 10

4. Does urine leak before you can get to the toilet?
( ) nunca
( ) poucas vezes
( ) às vezes
( ) na maioria das vezes
( ) sempre

4a. How much does this bother you?
Please ring a number between 0 (not at all) and 10 (a great deal)
0 1 2 3 4 5 6 7 8 9 10