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Évaluation de l'efficacité de la neuromodulation sacrée dans le traitement de l'hyperactivité vésicale neurogène

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Liste des abréviations

SNM : Sacral Nerve Modulation

nOAB : Neurogenic Overactive Bladder

CL : Cerebral Lesion

MS : Multiple Sclerosis

Park : Parkinsonian syndrome

CP : Cerebral Palsy

SCI : Spinal Cord Injury

ICS : International Continence Society

VD : Voiding Dysfunction

PGI-I : Patient's Global Impression of Improvement

IPG : Implantable Pulse Generator

CISC : Clean Intermittent Self-Catheterization

MSA : Multiple System Atrophy

HAV : Hyperactivité Vésicale

SEP : Sclérose En Plaques

MP : Maladie de Parkinson

PC : Paralysie Cérébrale

LM : Lésion Médullaire

LC : Lésion Cérébrale

NMS : Neuromodulation Sacrée

AVC : Accident Vasculaire Cérébral

HAD : Hyperactivité Détrusorienne

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Resume

Objective

To assess the efficacy of sacral nerve modulation (SNM) in the treatment of neurogenic overactive bladder (nOAB).

Materials and Methods

This retrospective multicenter study was conducted across four French university hospital centers (Lille, Rennes, Nantes, Bordeaux). Eligible participants included patients with nOAB associated with an underlying neurological condition, who underwent a SNM test phase between 2007 and 2023. The primary outcome measure was clinical efficacy, determined by the definitive implantation of the device, corresponding to an improvement of at least 50% in one of the 3-day bladder diary parameters during the test phase. Secondary outcome measures included, among others, the maintenance of efficacy within 3 years following definitive implantation.

Results

Among the 136 included patients, 36 had a cerebral lesion (CL), 33 had multiple sclerosis (MS), 27 had a parkinsonian syndrome (Park), 13 had cerebral palsy (CP), and 9 had an incomplete spinal cord injury (SCI). Clinical efficacy was achieved in 74% of patients overall, and specifically in 88%, 77%, 72%, 70%, and 33% of patients with a diagnosis of MS, CP, CL, Park, and incomplete SCI, respectively. Efficacy was maintained at 3 years in 67%, 58%, 50%, and 44% of cases for patients diagnosed with CP, MS, Park, and CL, respectively. None of the 4 patients with incomplete SCI reported sustained efficacy at 3 years.

Conclusion

In patients with nOAB, SNM appears to exhibit clinical efficacy comparable to that observed in the non-neurological population, albeit with a medium-term loss of efficacy.

Keywords

Sacral neuromodulation; neurological condition; neurogenic overactive bladder; multiple sclerosis; Parkinson's disease; cerebral lesion; stroke; spinal cord injury; cerebral palsy.

Introduction

The International Continence Society (ICS) defines neurogenic overactive bladder (nOAB) as urgency, with or without urgency urinary incontinence, usually with increased daytime frequency and nocturia in the setting of a clinically relevant neurologic disorder with at least partially preserved sensation (1).

A significant proportion, up to 100% (2), of patients suffering from neurological pathologies such as multiple sclerosis (MS), Parkinson's disease, cerebral palsy, spinal cord injury (SCI) or brain injury present symptoms of overactive bladder, which can sometimes be at the forefront of complaints and reduce quality of life (3), especially as these patients are already coping with the comorbidities of their neurological disease. Restoring normal bladder function appears to be one of the main priorities in these patients.

Current management of nOAB consists in behavioral therapies, lifestyle modifications, pharmacological treatments as anticholinergics and β3-adrenergic receptor agonists, tibial nerve stimulation, intra-vesical injections of botulinum toxin A and sacral nerve modulation (SNM). With more than 300,000 procedures (4) per year worldwide, SNM is a well-established third-line treatment for refractory lower urinary tract dysfunction (5).

In 1988, Tanagho et al. based their pioneering clinical research of sacral nerve stimulation on neurological subjects (6), but available studies on SNM in this subpopulation are limited. In 2021, Van Ophoen et al. in a meta-analysis reported a SNM success rate of 66.2% in patients with nOAB (4) but based on studies with small sample sizes and heterogeneous populations.

New SNM devices with conditional safety for full-body magnetic resonance imaging (MRI) were recently introduced (7) and will offer wider access to a patient group that has often been considered a contraindication due to the need for regular MRI investigations, such as MS.

The aim of our study was to assess the efficacy of SNM in patients with nOAB secondary to an underlying neurological disease.

Methods

Study design and data collection

This study was designed as a retrospective multicenter study and was conducted in four French academic hospital centers: Lille, Nantes, Bordeaux and Rennes. The study protocol was declared to the French Advisory Committee on Information Processing in Material Research in the Field of Health (Commission Nationale Informatique et Liberté – CNIL) under the reference DEC21-241. All patients who underwent a two-staged SNM between January 2007 and September 2023 for the management of nOAB, with or without associated voiding dysfunction (VD), secondary to an underlying neurological disease were included. Patients with isolated VD were not included in the study. Epidemiological data, 3-day bladder diary parameters and urodynamic parameters, when available, were collected from the patient's paper or computerized medical record.

Sacral nerve modulation

The SNM devices implanted in the four centers were the InsterStim™, InsterStim II™ and InterStim Micro™ systems (Medtronic, Minneapolis, MN, USA). These systems consist in a neurostimulator combined with a quadripolar lead. The device was implanted following a two-staged procedure. During the first procedure, the unilateral lead was implanted under general anesthesia at the level of the S3 sacral nerve root (more rarely S4, depending on intraoperative motor responses) under fluoroscopic guidance. The lead was then connected to a temporary external generator and the procedure was followed by a test phase lasting between 1 and 4 weeks, at the end of which a 3-day bladder diary and a Patient’s Global Impression of Improvement (PGI-I) score were submitted. In case of efficacy, corresponding to an improvement of at least 50% in one of the 3-day bladder diary parameters, the implantable pulse generator (IPG) was implanted under local anesthesia during a second surgical procedure. In case of failure, the lead was explanted during this second procedure.

Outcomes of interest

The primary endpoint was the clinical efficacy of SNM, defined by the improvement of at least 50% in one of the 3-day bladder diary parameters at the end of the test phase, corresponding in practice to an IPG implantation. Secondary endpoints included self-assessment of efficacy using the PGI-I score, evolution of the 3-day bladder diary parameters before and at the end of the test phase (number of daytime micturitions and/or Clean self-intermittent catheterization (CISC), number of nocturnal micturitions and/or CISC, presence of daytime and nocturnal urgency episodes, and presence of urinary incontinence episodes). In patients that finally underwent an IPG implantation, the mid-term maintenance of the efficacy was also assessed - at 3 months, then annually - up to 3 years. Maintenance of efficacy was defined by a PGI-I score ≦ 3 (“a little better”, “much better” or “very much better”) and the absence of any new nOAB treatment. Primary and secondary endpoints were presented for the overall population, as well as for the 5 following subpopulations: MS, parkinsonian syndrome, brain injury, cerebral palsy and incomplete SCI.

Statistical analysis

Categorical variables are expressed as numbers (percentage). Continuous variables are expressed as median [range]. Normality of distribution is assessed using histograms and the Shapiro-Wilk test. Comparison of parameters before and after the SNM test phase was assessed using Chi-square test (or Fisher’s exact test in case of expected value < 5) for categorical variables and Student’s t test (or Mann–Whitney U test in case of non-Gaussian distribution) for continuous variables. Statistical testing was conducted at the two-tailed α-level of 0.05. Data were analyzed using pvalue (Medistica., pvalue.io, a graphic user interface to the R statistical analysis software for scientific medical publications., 2019-22. Available on: https://www.pvalue.io)

Results

Patient's characteristics

A total of 136 patients, including 88 female patients (65%), were included in the study. The median age was 61.5 [44.4; 71.7]. Concerning the underlying neurological disease, 36 had a brain injury, 33 a MS, 27 a parkinsonian syndrome, 13 a cerebral palsy, 9 an incomplete SCI, 13 a peripheral neurological lesion (including deep pelvic endometriosis patients), 3 an incomplete cauda equina syndrome and 2 a spina bifida. The average follow-up time was 27.3 (± 23.0) months. To note, 18 patients presented with threatening detrusor overactivity - defined by a maximum detrusor pressure ≧ 40 cmH_2O – before lead implantation. Of these patients, 2 underwent a multichannel urodynamic study during the test phase. Patients' characteristics at baseline are detailed in Tables IA to IF.

Clinical efficacy

Clinical efficacy, corresponding to the IPG implantation in the event of a least 50% improvement in one of the 3-day bladder diary parameters, was achieved in 101 patients (74%), including 29 patients with MS (88%), 26 patients with brain injury (72%), 19 patients with parkinsonian syndrome (70%), 10 patients with cerebral palsy (77%) and 3 patients with incomplete SCI (33%).

Patient's Global Impression of Improvement (PGI-I) score

In the overall population, 84 patients (68.6%) reported a PGI-I score ≦ 2 ("much better" or "very much better"). This percentage was reported to be 81.8%, 69.4% 55.5%, 54.0% and 44.4% in patients with MS, parkinsonian syndrome, brain injury, cerebral palsy and incomplete SCI, respectively. The PGI-I score is detailed in Figure 1.

3-day bladder diary parameters

In the overall population, the median number of daily micturitions and/or CISC decrease from 10.0 [8.00; 12.0] prior to the test phase to 7.00 [6.00; 10.0] at the end of the test phase ($p < 0.001$). Similarly, the median number of nocturnal micturitions and/or CISC decreased from 2.00 [0; 4.00] to 1.00 [0; 2.00] ($p < 0.001$). The prevalence of urinary incontinence decreased from 84% to 44% ($p < 0.001$), while the prevalence of diurnal urgency decreased from 97% to 60% ($p < 0.001$) and the prevalence of nocturnal urgency decreased from 45% to 15% ($p < 0.001$). Changes in the 3-day bladder diary parameters before and at the end of the SNM test phase are detailed in Tables IIA to IIF.

Mid-term maintenance of efficacy

In the context MS, a maintenance of efficacy was observed in 58.3% of cases 3 years after IPG implantation. This percentage was up to 66.7% among patients with parkinsonian syndrome and cerebral palsy, while patients with brain injury reported a maintenance of efficacy in 44.4% of cases. Conversely, none of the 3 patients with incomplete SCI who underwent IPG implantation reported a maintenance of efficacy at 3 years. The maintenance of efficacy for each underlying neurological disease considered is detailed in Figures 2A to 2E.

Discussion

The aim of our study was to assess the clinical efficacy of SNM to treat nOAB. Our findings align with those observed in the non-neurological population (8), with an IPG implantation rate of 74%. Notably, a high success rate of the test phase was observed in four of the five subpopulations considered: 88% in MS patients, 77% in patients with cerebral palsy, 72% in patients with brain injury and 70% in patients with parkinsonian syndrome. In contrast, the implantation rate was significantly lower in incomplete SCI patients (33%). It is also important to note that we have observed a weakening trend in the efficacy of SNM over the medium term, in all 5 sub-populations concerned.

Addressing the test phase, our results mirror those reported by Kessler et al. (2010), demonstrating a success rate of 68% among a cohort of 256 neurologic patients (9). Since then, six studies have reinforced these findings, complemented by a meta-analysis conducted by Von Ophoven et al. in 2021 (4).

With 33 MS patients included, the present study is the largest conducted in this specific population. Until now, Minardi et al. (2011) included 25 MS patients, yielding a success rate of 60.0% (10). Subsequent to this, three additional studies including fewer MS patients, reported success rates ranging from 53.3% to 94.0% (11–13). Our study suggests that although SNM efficacy may decrease in the medium term, more than half of the patients will still be improved three years after IPG implantation. Given the high success rate of the test phase, the use of SNM therefore seems particularly attractive in MS patients, especially since the use of 1.5T and 3T MRI-compatible body devices (Axonics, Irvine, CA and Medtronic, Minneapolis, MN), paving the way for more implantations (7).

Few studies have focused on the use of SNM in cerebral palsy and brain injury. Regarding cerebral palsy, Marinkovic et al. (2013) found a 66% implantation rate in a series of 3 patients with voiding dysfunction (14); and Lippmann et al. (2013) published a case report of successful SNM implantation in a 12-year-old patient complaining of nOAB (15). In our study, we reported a success rate of 77% on 13 patients. Regarding brain injury, Von Ophoven et al. reported 8 patients with a history of stroke with a success rate of 50% (4). In our study, we included 36 patients with SNM implanted in the context of an underlying brain injury, including 16 with a history of stroke, twice the number of previously published cases. Our results give new insight into SNM as an nOAB treatment in patients with cerebral palsy and brain injury, with interesting results, which should be confirmed by future research.

Concerning parkinsonian syndrome, Martin et al. (2022) reported a success rate of 82% in a study of 34 patients with idiopathic Parkinson's disease (16). Millet et al. (2021) showed a lower success rate of 31.8% in 22 patients, including 77% with idiopathic Parkinson's and 23% with Multiple System Atrophy (MSA) (17). While our patient group is heterogeneous, it is important to highlight that of the 27 patients with parkinsonian syndrome, 23 exhibited idiopathic Parkinson's disease. This subset, inherently more responsive to SNM compared to other parkinsonian syndromes, likely accounts for our comparatively high success rate, closely approximating the results of Martin et al.

Taken together, these results suggest that neurological pathologies involving the brain could be considered as potential good responders to SNM, at least for the treatment of nOAB. This is in any case what the results obtained in incomplete SCI patients suggest. Indeed, even if Lombardi et al. (2009), reported a 100% implantation rate in a cohort of 24 incomplete SCI patients (18), it is important to remind that the scientific literature is particularly heterogeneous regarding this topic. In our study, and even though the number of patients with incomplete SCI remained modest, this specific population seemed to be the least able to respond to SNM, with

a relatively low success rate during the test phase of 36% and a loss of efficacy in all implanted patients in the first 3 years.

Our study's strengths are underscored by its multicenter nature, enrolling patients from four French academic hospitals, and its notable patient count, particularly within the MS, brain injury, and cerebral palsy subpopulations – each of which boasts the largest series reported thus far. Notably, the efficacy criterion was uniformly assessed across all enrolled patients, mandating a minimum 50% improvement in one of the three-day bladder diary parameters. This standardized approach presents an advantage compared to existing studies where the definition of efficacy remains ambiguous.

However, our study is not devoid of limitations, many stemming from its retrospective design. Notably, a substantial proportion of patients were lost to follow-up, hampering extended assessment. The 3-year lost to follow-up rate was reported to be 14.3% for MS patients, 25% for cerebral palsy patients, 40% for those with parkinsonian syndrome, 43.8% for brain injury patients and 50% for incomplete SCI patients. Moreover, several patients were recently included, between 2021 and 2023, particularly in the MS subpopulation, curtailing the scope of follow-up.

It is worth highlighting the significant challenge posed by the prevention of uro-nephrological complications when managing neurogenic lower urinary tract dysfunction. However, it is important to recognize that the data presented in the present study focused primarily on clinical efficacy, with urodynamic information rarely available, particularly during the test phase. Thus, even if 91.2% of patients had had a urodynamic multichannel study before lead implantation, it was only carried out in 9.5% of cases during the test phase. Among the subset of 18 patients exhibiting threatening detrusor overactivity before the procedure, only 2 patients underwent a multichannel urodynamic study during or after the test phase. While SNM demonstrates clinical

efficacy, it should be noted that it does not inherently mitigate uro-nephrological risks.

There are legitimate concerns about maintaining efficacy year after year, with efficacy at 3 years varying from 0% to 66.7% depending on the neurological disease considered. This makes it difficult to distinguish between a real loss of efficacy over time, or a progression of the underlying neurological disease, particularly in the case of progressive neurological diseases such as MS. Published studies differ on the role of disease progression in maintaining the efficacy of SNM. Chaabane et al. (2011) reports a predominant role for disease progression (19), while Peters et al. (2013) suggests that disease progression is not a related to the loss of efficacy (20).

Conclusion

In conclusion, our study provides valuable insights into the clinical efficacy of SNM as a treatment of nOAB across diverse neurological conditions. While SNM demonstrates promising results in improving urinary symptoms, particularly in patients with MS, cerebral palsy, parkinsonian syndrome and brain injury, the challenges of uro-nephrological complications highlight the need for comprehensive assessment and ongoing research in positioning SNM in the treatment of nOAB.

Introduction (Français)

L'International Continence Society (ICS) définit l'hyperactivité vésicale (HAV) neurogène comme une incontinence urinaire impérieuse, avec ou sans urgence, généralement accompagnée d'une augmentation de la fréquence des mictions diurnes et nocturnes dans le cadre d'un trouble neurologique cliniquement pertinent avec une sensibilité mictionnelle au moins partiellement préservée (1).

Une proportion significative, jusqu'à 100% de patients (2) souffrant de pathologies neurologiques telles que la sclérose en plaques (SEP), la maladie de Parkinson (MP), la paralysie cérébrale (PC), les lésions de la moelle épinière (LM) ou les lésions cérébrales (LC) présentent des symptômes d'hyperactivité vésicale, qui peuvent parfois être au premier plan des plaintes et réduire la qualité de vie (3), d'autant plus que ces patients doivent déjà faire face aux comorbidités de leur maladie neurologique. Le rétablissement d'une fonction vésicale normale semble être l'une des principales priorités chez ces patients.

La prise en charge actuelle de l’HAV neurogène consiste en des thérapies comportementales, des modifications du mode de vie, des traitements pharmacologiques tels que les anticholinergiques et les agonistes des récepteurs β3-adrénergiques, la stimulation du nerf tibial, les injections intra-vésicales de toxine botulique A et la neuromodulation sacrée (NMS). Avec plus de 300 000 procédures par an dans le monde (4), la NMS est un traitement de troisième intention bien établi pour le traitement des troubles réfractaires du bas appareil urinaire (5).

En 1988, Tanagho et al. ont basé leur recherche clinique pionnière sur la NMS sur des sujets neurologiques (6), mais les études disponibles sur la NMS dans cette sous-population sont limitées. En 2021, Van Ophoen et al. ont rapporté dans une méta-analyse un taux de succès de de 66,2 % chez les patients souffrant d’HAV neurogène (4), mais ils se sont basés sur des études avec des échantillons de petite taille et des populations hétérogènes.

De nouveaux dispositifs de NMS compatibles avec l'imagerie par résonance magnétique (IRM) du corps entier ont été récemment introduits (7), et offriront un accès plus large à un groupe de patients qui a souvent été considéré comme contre-indiqué à la NMS en raison de la nécessité d'examens IRM réguliers, tels que la SEP.

Le but de notre étude était d'évaluer l'efficacité de la NMS chez les patients souffrant d'HAV secondaire à une maladie neurologique sous-jacente.

Discussion (Français)

Le but de notre étude était d'évaluer l'efficacité clinique de la NMS dans le traitement de l'HAV neurogène. Nos résultats sont conformes à ceux observés dans la population non neurologique (8), avec un taux d'implantation définitive du dispositif de 74 %. Un taux élevé de succès de la phase de test a notamment été observé dans quatre des cinq sous-populations considérées : 88% chez les patients atteints de SEP, 77% chez les patients atteints de paralysie cérébrale, 72% chez les patients souffrant de lésions cérébrales et 70% chez les patients atteints de syndrome parkinsonien. En revanche, le taux d'implantation était significativement plus faible chez les patients atteints de lésions médullaires incomplètes (33%). Il est également important de noter que nous avons observé une tendance à la diminution l'efficacité de la NMS à moyen terme, dans les 5 sous-populations concernées.

En ce qui concerne la phase de test, nos résultats reflètent ceux rapportés par Kessler et al. (2010), montrant un taux de réussite de 68 % dans une cohorte de 256 patients neurologiques (9), Depuis, six études sont venues renforcer ces résultats, complétés par une méta-analyse réalisée par Von Ophoven et al. en 2021 (4).

Avec 33 patients atteints de SEP, notre étude est la plus importante menée au sein de cette population. Jusqu'à présent, Minardi et al. (2011) ont inclus 25 patients atteints de SEP, avec un taux de réussite de 60,0 % (10). Par la suite, trois autres études incluant moins de patients ont rapporté des taux de réussite allant de 53,3 % à 94,0 % (11 – 13). Notre étude suggère que, bien que l'efficacité de la NMS puisse diminuer à moyen terme, plus de la moitié des patients seront encore améliorés trois ans après l'implantation du dispositif. Compte tenu du taux de réussite élevé de la phase test, l'utilisation de la NMS semble donc particulièrement intéressante chez les patients atteints de SEP, surtout depuis l'utilisation de dispositifs compatibles avec l'IRM 1,5T et 3T (Axonics, Irvine, CA et Medtronic, Minneapolis, MN), ce qui

ouvre la voie à un plus grand nombre d'implantations (7).

Peu d'études se sont intéressées à l'utilisation de la NMS dans les cas de paralysie cérébrale et de lésions cérébrales. En ce qui concerne la paralysie cérébrale, Marinkovic et al. (2013) ont constaté un taux d'implantation de 66 % dans une série de 3 patients présentant un trouble de vidange vésicale (14); et Lippmann et al. (2013) ont publié une étude de cas d'implantation réussie chez une patiente de 12 ans présentant une HAV neurogène (15). Dans notre étude, nous avons rapporté un taux de réussite de 77% sur 13 patients. En ce qui concerne les lésions cérébrales, Von Ophoven et al. ont rapporté le cas de 8 patients avec antécédent d'accident vasculaire cérébral (AVC) avec un taux de réussite de 50 %(4). Dans notre étude, nous avons inclus 36 patients avec une NMS implantée dans le cadre d'une lésion cérébrale sous-jacente, dont 16 avec antécédent d'AVC, soit deux fois plus que le nombre de cas précédemment publiés. Nos résultats donnent un nouvel aperçu de la NMS en tant que traitement de l'hyperactivité vésicale chez les patients atteints de paralysie cérébrale et de lésions cérébrales, avec des résultats intéressants qui doivent être confirmés par de futures recherches.

En ce qui concerne le syndrome parkinsonien, Martin et al. (2022) ont rapporté un taux de réussite de 82 % dans une étude portant sur 34 patients atteints de la maladie de Parkinson idiopathique (16). Millet et al. (2021) ont montré un taux de réussite plus faible de 31,8 % chez 22 patients, dont 77 % souffraient de maladie de Parkinson idiopathique et 23 % de l'atrophie multisystématisée (AMS) (17). Bien que notre groupe de patients soit hétérogène, il est important de souligner que sur les 27 patients atteints de syndrome parkinsonien, 23 présentaient une maladie de Parkinson idiopathique. Cette sous population, intrinsèquement plus sensible à la NMS que les autres syndromes parkinsoniens, explique probablement notre taux de réussite comparativement élevé, qui se rapproche des résultats de Martin et al.

L'ensemble de ces résultats suggère que les pathologies neurologiques impliquant le cerveau pourraient être considérées comme de bons répondeurs potentiels à la NMS, au moins pour le traitement de l'hyperactivité vésicale. C'est en tout cas ce que suggèrent les résultats obtenus chez les patients atteints de lésions médullaires incomplètes. En effet, même si Lombardi et al. (2009), ont rapporté un taux d'implantation de 100% dans une cohorte de 24 patients atteints de lésions médullaires incomplètes (18), il est important de rappeler que la littérature scientifique est particulièrement hétérogène à ce sujet. Dans notre étude, et même si le nombre de patients atteints de lésions médullaires incomplètes reste modeste, cette population spécifique semble être la moins apte à répondre à la NMS, avec un taux de succès relativement faible durant la phase de test de 36% et une perte d'efficacité chez tous les patients implantés au cours des 3 premières années.

Les points forts de notre étude sont sous tendus par sa nature multicentrique, avec le recrutement de patients dans quatre hôpitaux universitaires français, et son nombre important de patients, en particulier dans les sous-populations de SEP, lésions cérébrales et paralyse cérébrale - chacune d'entre elles étant la plus grande série rapportée jusqu'à présent. De plus, le critère d'efficacité a été évalué de manière uniforme pour tous les patients inclus, correspondant à une amélioration d'au moins 50 % de l'un des paramètres du calendrier mictionnel sur trois jours. Cette approche standardisée présente un avantage par rapport aux études existantes où la définition de l'efficacité reste ambiguë.

Cependant, notre étude n'est pas dépourvue de limites, dont beaucoup découlent de sa conception rétrospective. Une proportion importante de patients notamment a été perdue de vue, ce qui empêche une évaluation à plus long terme. Le taux de patients perdus de vue à trois ans était de 14,3 % pour les patients atteints de SEP de 25 % pour les patients atteints de paralysie cérébrale, de 40 % pour ceux atteints du syndrome parkinsonien, de 43,8 % pour les patients souffrant de lésions cérébrales et de 50 % pour les patients souffrant d'une lésion

médullaire incomplète. En outre, plusieurs patients ont été inclus récemment, entre 2021 et 2023, en particulier en cas de sclérose en plaques, ce qui réduit la portée du suivi.

Il convient de souligner le défi important que représente la prévention des complications uro-néphrologiques lors de la prise en charge d'un dysfonctionnement neurogène du bas appareil urinaire. Cependant, il est important de souligner que les données présentées dans la présente étude se concentrent principalement sur l'efficacité clinique, les informations urodynamiques étant rarement disponibles, en particulier pendant la phase test. Ainsi, même si 91,2 % des patients ont bénéficié d'un bilan urodynamique avant l'implantation du dispositif, celui-ci n'a été réalisé que dans 9,5 % des cas pendant la phase test. Parmi le sous-ensemble de 18 patients présentant une hyperactivité détrusorienne (HAD) menaçante avant l'intervention, seuls 2 patients ont fait l'objet d’un bilan urodynamique pendant ou après la phase test. Bien que la NMS démontre son efficacité clinique, il convient de noter qu'elle ne réduit pas intrinsèquement les risques uro-néphrologiques.

Il est légitime de s'interroger sur le maintien de l'efficacité année après année, l'efficacité à 3 ans variant de 0 % à 66,7 % selon la maladie neurologique considérée. Il est difficile de faire la distinction entre une réelle perte d'efficacité au fil du temps ou une progression de la maladie neurologique sous-jacente, en particulier dans le cas de maladies neurologiques progressives telles que la SEP. Les études publiées divergent sur le rôle de la progression de la maladie dans le maintien de l'efficacité de la NMS. Chaabane et al. (2011) rapportent un rôle prédominant de la progression de la maladie (19), tandis que Peters et al. (2013) suggèrent que la perte d’efficacité n’est pas liée à la progression de la maladie (20).

Conclusion (Français)

En conclusion, notre étude fournit des informations précieuses sur l'efficacité clinique de la NMS en tant que traitement de l’HAV neurogène sous tendue par différentes maladies neurologiques. Alors que la NMS montre des résultats prometteurs dans l'amélioration des symptômes urinaires, en particulier chez les patients atteints de SEP, de paralysie cérébrale, de syndrome parkinsonien et de lésions cérébrales, les défis posés par les complications uro-néphrologiques soulignent la nécessité d'une évaluation complète et d'une recherche continue pour positionner la NMS dans le traitement de l’HAV neurogène.

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Annexes

Table IA: Patients' characteristics at baseline - Overall population

Epidemiological		
Age (years), *median [IQR]*	61.5	[44.4; 71.6]
BMI (kg/m^2), *median [IQR]*	25	[22.4; 29.7]
Gender		
Men	48	35%
Women	88	65%
Clinical		
Type of disorder		
Pure OAB	82	60%
OAB with associated VD	55	40%
Duration of symptoms (months), *median [IQR]*	96	[42.0; 180]
Voiding mode		
Spontaneous voiding	108	79%
CISC	18	12%
Spontaneous voiding and CISC	9	6.6%
Third-person catheterization	1	0.73%
Urinary incontinence	**115**	**84%**
Urge incontinence	96	70%
Stress incontinence	6	4.4%
Mixed incontinence	13	9.5%
SNM-related factors		
Duration of test phase, *median [IQR]*	14.0	[14.0; 15.0]
Urodynamic parameters (N=124/136)		
Q_{max} (ml/s), *median [IQR]*	13.9	[8.53; 19.7]
PVR (ml), *median [IQR]*	20	[0; 95.0]
B1 (mL), *median [IQR]*	150	[100; 218]
Maximal cystometric capacity, *median [IQR]*	272	[174; 352]
Detrusor overactivity	90	73%
Volume of first UDC (mL), *median [IQR]*	110	[74.8; 213]
$Pdet_{max}$ (cmH20), *median [IQR]*	34	[17.2; 49.0]

Values are presented as frequency, percentage unless otherwise indicated.

BMI: Body mass index; **OAB**: Overactive bladder; **VD**: Voiding dysfunction; **CISC**: clean intermittent self-catheterization; **SNM**: Sacral nerve modulation; **PVR**: Post-void residual; **UDC**: uninhibited detrusor contraction

Table IB: Patients' characteristics at baseline – Multiple sclerosis

Epidemiological		
Age (years), *median [IQR]*	57.5	[45.6; 62.9]
BMI (kg/m^2), *median [IQR]*	25	[23.1; 28.1]
Gender		
Men	6	18%
Women	27	82%
Clinical		
Type of disorder		
Pure OAB	12	36%
OAB with associated VD	21	64%
Duration of symptoms (months), *median [IQR]*	126	[111; 231]
Voiding mode		
Spontaneous voiding	22	67%
CISC	7	21%
Spontaneous voiding and CISC	3	9.1%
Third-person catheterization	1	3%
Urinary incontinence	**27**	**82%**
Urge incontinence	23	70%
Stress incontinence	3	9.1%
Mixed incontinence	1	3%
Neurological history		
EDSS, *median [IQR]*	4.00	[2.50; 5.50]
Type of MS		
RRMS	21	64%
SPMS	6	18%
PPMS	6	18%
SNM-related factors		
Duration of test phase, *median [IQR]*	14.0	[13.0; 16.0]
Urodynamic parameters (N=31/33)		
Q_{max} (ml/s), *median [IQR]*	14.5	[9.28; 17.0]
PVR (ml), *median [IQR]*	80.0	[20.5; 150]
B1 (mL), *median [IQR]*	148	[111; 296]
Maximal cystometric capacity, *median [IQR]*	276	[200; 362]
Detrusor overactivity	20	65%
Volume of first UDC (mL), *median [IQR]*	125	[85.0; 200]
$Pdet_{max}$ (cmH20), *median [IQR]*	22.0	[15.0; 43.0]

Values are presented as frequency, percentage unless otherwise indicated.

BMI: Body mass index; **OAB**: Overactive bladder; **VD**: Voiding dysfunction; **CISC**: clean intermittent self-catheterization; **SNM**: Sacral nerve modulation; **PVR**: Post-void residual; **UDC**: uninhibited detrusor contraction; **EDSS**: Expanded disability status scale; **RRMS**: Relapsing-remitting multiple sclerosis; **SPMS**: Secondary progressive multiple sclerosis; **PPMS**: Primary Progressive multiple sclerosis

Table IC - Patients' characteristics at baseline – Parkinsonian syndrome

Epidemiological		
Age (years), *median [IQR]*	72.1	[66.3; 76.4]
BMI (kg/m^2), *median [IQR]*	24.3	[22.7; 29.4]
Gender		
Men	14	52%
Women	13	48%
Clinical		
Type of disorder		
Pure OAB	21	78%
OAB with associated VD	6	22%
Duration of symptoms (months), *median [IQR]*	60.0	[54.0; 72.0]
Voiding mode		
Spontaneous voiding	25	96%
CISC	0	0%
Spontaneous voiding and CISC	1	3.8%
Third-person catheterization	0	0%
Urinary incontinence	**25**	**93%**
Urge incontinence	15	58%
Stress incontinence	1	3.8%
Mixed incontinence	1	3.8%
Neurological history		
Type of parkinsonian syndrome		
IP	23	85%
MSA	2	7.4%
DLBD	1	3.7%
CD	1	3.7%
SNM-related factors		
Duration of test phase, *median [IQR]*	14.0	[13.0; 15.0]
Urodynamic parameters (N=24/27)		
Q_{max} (ml/s), *median [IQR]*	10.0	[5.00; 20.0]
PVR (ml), *median [IQR]*	0	[0; 20.0]
B1 (mL), *median [IQR]*	125	[77.0; 170]
Maximal cystometric capacity, *median [IQR]*	238	[147; 356]
Detrusor overactivity	18	75%
Volume of first UDC (mL), *median [IQR]*	110	[70.0; 215]
$Pdet_{max}$ (cmH20), *median [IQR]*	30.0	[20.0; 61.0]

Values are presented as frequency, percentage unless otherwise indicated.

BMI: Body mass index; **OAB**: Overactive bladder; **VD**: Voiding dysfunction**; CISC**: clean intermittent self-catheterization; **SNM**: Sacral nerve modulation; **PVR**: Post-void residual; **UDC**: uninhibited detrusor contraction; **IP**: Idiopathic Parkinson's ; **MSA**: Multiple system atrophy; **DLBD**: Diffuse Lewy body disease; **CD**: Corticobasal degeneration

Table ID - Patients' characteristics at baseline – Brain injury

Epidemiological		
Age (years), *median [IQR]*	63.2	[50.1; 73.3]
BMI (kg/m^2), *median [IQR]*	26.2	[22.3; 29.8]
Gender		
Men	13	37%
Women	22	63%
Clinical		
Type of disorder		
Pure OAB	27	75%
OAB with associated VD	9	25%
Duration of symptoms (months), *median [IQR]*	120	[42.0; 273]
Voiding mode		
Spontaneous voiding	30	83%
CISC	2	5.6%
Spontaneous voiding and CISC	2	5.6%
Third-person catheterization	0	0%
Urinary incontinence	**30**	**83%**
Urge incontinence	27	75%
Stress incontinence	0	0%
Mixed incontinence	3	8.3%
Neurological history		
Etiology		
Traumatic	4	11%
Inflammatory	2	5.6%
Infectious	4	11%
Tumoral	1	2.8%
Vascular	16	44%
Other	9	25%
Cognitive disorders	10	29%
Phasic disorders	7	20%
Motor disorders	17	49%
Cerebellar syndrome	2	5.7%
SNM-related factors		
Duration of test phase, *median [IQR]*	14.0	[14.0; 16.0]
Urodynamic parameters (N=32/36)		
Q_{max} (ml/s), *median [IQR]*	18.0	[8.40; 26.0]
PVR (ml), *median [IQR]*	7.50	[0; 100]
B1 (mL), *median [IQR]*	131	[116; 166]
Maximal cystometric capacity, *median [IQR]*	275	[200; 325]
Detrusor overactivity	24	75%
Volume of first UDC (mL), *median [IQR]*	113	[60.2; 205]
$Pdet_{max}$ (cmH20), *median [IQR]*	34.5	[17.0; 49.5]

Values are presented as frequency, percentage unless otherwise indicated.

BMI: Body mass index; **OAB**: Overactive bladder; **VD**: Voiding dysfunction**; CISC**: clean intermittent self-catheterization; **SNM**: Sacral nerve modulation; **PVR**: Post-void residual; **UDC**: uninhibited detrusor contraction

Table IE: Patients' characteristics at baseline – Incomplete SCI

Epidemiological		
Age (years), *median [IQR]*	52.5	[40.1; 63.7]
BMI (kg/m²), *median [IQR]*	26.8	[23.3; 31.6]
Gender		
Men	3	33%
Women	6	67%
Clinical		
Type of disorder		
Pure OAB	5	56%
OAB with associated VD	4	44%
Duration of symptoms (months), *median [IQR]*	108	[84.0; 192]
Voiding mode		
Spontaneous voiding	7	78%
CISC	1	11%
Spontaneous voiding and CISC	1	11%
Third-person catheterization	0	0%
Urinary incontinence	**7**	**78%**
Urge incontinence	7	78%
Stress incontinence	0	0%
Mixed incontinence	0	0%
Neurological history		
Etiology		
Traumatic	4	44%
Inflammatory	1	11%
Infectious	0	0%
Tumoral	1	11%
Vascular	0	0%
Other	1	11%
Unknown	2	22%
Lesion level		
Cervical	1	11%
Thoracic	3	33%
Lumbar	3	33%
Unknown	2	22%
SNM-related factors		
Duration of test phase, *median [IQR]*	14.0	[13.0; 15.0]
Urodynamic parameters (N=9/9)		
Q_{max} (ml/s), *median [IQR]*	8.00	[4.00; 17.0]
PVR (ml), *median [IQR]*	70.0	[55.0; 125]
B1 (mL), *median [IQR]*	153	[116; 167]
Maximal cystometric capacity, *median [IQR]*	200	[130; 313]
Detrusor overactivity	6	67%
Volume of first UDC (mL), *median [IQR]*	130	[80.0; 200]
$Pdet_{max}$ (cmH20), *median [IQR]*	25.0	[15.0; 30.0]

Values are presented as frequency, percentage unless otherwise indicated.

BMI: Body mass index; **OAB**: Overactive bladder; **VD**: Voiding dysfunction**; CISC**: clean intermittent self-catheterization; **SNM**: Sacral nerve modulation; **PVR**: Post-void residual; **UDC**: uninhibited detrusor contraction;

Table IF: Patients' characteristics at baseline – Cerebral palsy

Epidemiological		
Age (years), *median [IQR]*	35.2	[24.1; 41.5]
BMI (kg/m^2), *median [IQR]*	24.1	[22.4; 28.7]
Gender		
Men	7	54%
Women	6	46%
Clinical		
Type of disorder		
Pure OAB	7	54%
OAB with associated VD	6	46%
Voiding mode		
Spontaneous voiding	8	62%
CISC	3	23%
Spontaneous voiding and CISC	1	7.7%
Third-person catheterization	1	7.7%
Urinary incontinence	**11**	**85%**
Urge incontinence	10	77%
Stress incontinence	0	0%
Mixed incontinence	1	7.7%
SNM-related factors		
Duration of test phase, *median [IQR]*	14.0	[14.0; 26.0]
Urodynamic parameters (N=11/13)		
Q_{max} (ml/s), *median [IQR]*	12.8	[8.88; 15.5]
PVR (ml), *median [IQR]*	25.0	[0; 55.0]
B1 (mL), *median [IQR]*	110	[75.0; 115]
Maximal cystometric capacity, *median [IQR]*	332	[305; 358]
Detrusor overactivity	10	91%
Volume of first UDC (mL), *median [IQR]*	90.0	[58.0; 201]
$Pdet_{max}$ (cmH20), *median [IQR]*	45.0	[40.5; 47.0]

Values are presented as frequency, percentage unless otherwise indicated.

BMI: Body mass index; **OAB**: Overactive bladder; **VD**: Voiding dysfunction**; CISC**: clean intermittent self-catheterization; **SNM**: Sacral nerve modulation; **PVR**: Post-void residual; **UDC**: uninhibited detrusor contraction;

Figure 1 - Distribution of PGI-I score at the end of SNM test phase

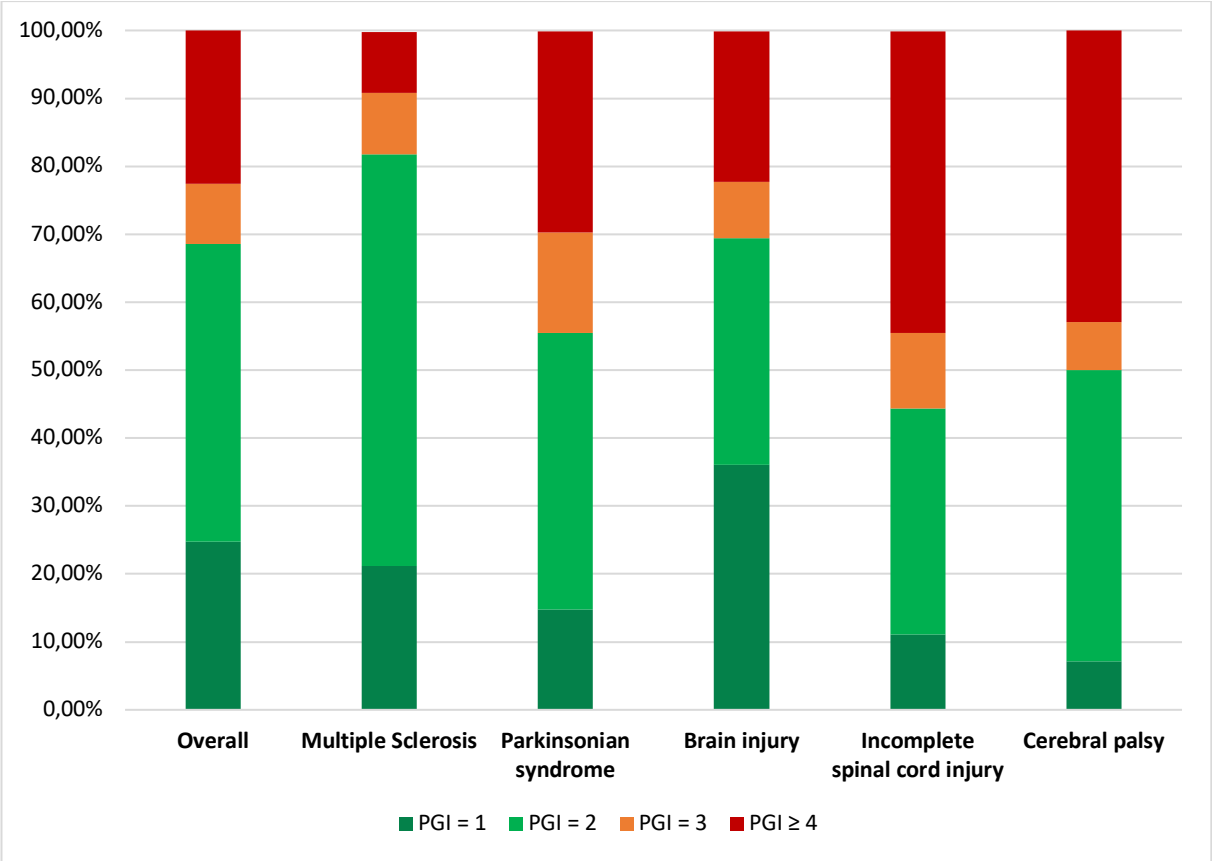


Table IIA: 3-day bladder diary parameters before and at the end of SNM test phase - Overall population

	Before test phase n = 136	At the end of test phase n = 136	Δ mean	p value
Number of micturitions and/or CISC per day, *median [IQR]*	10.0 [8.00; 12.0]	7.00 [6.00; 10.0]	-2.38	**<0.001**
Number of micuritions and/or CISC per night, *median [IQR]*	2.00 [0; 4.00]	1.00 [0; 2.00]	-1.28	**<0.001**
Urinary incontinence, *n (%)*	115 (84%)	60 (44%)	-	**<0.001**
Daytime urgency, *n (%)*	132 (97%)	71 (60%)	-	**<0.001**
Nocturnal urgency, *n (%)*	51 (45%)	16 (15%)	-	**<0.001**

SD: standard deviation, **CISC**: clean self-intermittent catheterization

Table IIB: 3-day bladder diary parameters before and at the end of SNM test phase - Multiple sclerosis

	Before test phase n = 33	At the end of test phase n = 33	Δ mean	p value
Number of micturitions and/or CISC per day, *median [IQR]*	9.00 [7.00; 12.0]	7.00 [6.00; 8.00]	-2.18	**<0.001**
Number of micuritions and/or CISC per night, *median [IQR]*	2.50 [1.00; 3.75]	1.00 [0; 2.00]	-1.43	**<0.01**
Urinary incontinence, *n (%)*	27 (82%)	6 (18%)	-	**<0.001**
Daytime urgency, *n (%)*	32 (97%)	14 (54%)	-	**<0.01**
Nocturnal urgency, *n (%)*	12 (43%)	2 (8.3%)	-	0.077

SD: standard deviation, **CISC**: clean self-intermittent catheterization

Table IIC: 3-day bladder diary parameters before and at the end of SNM test phase - Parkinsonian syndrome

	Before test phase n = 27	At the end of test phase n = 26	Δ mean	p value
Number of micturitions and/or CISC per day, *median [IQR]*	10.0 [9.00; 14.0]	9.00 [6.50; 12.0]	-2.09	**<0.01**
Number of micuritions and/or CISC per night, *median [IQR]*	2.50 [0.750; 5.00]	1.00 [0; 2.00]	-1.14	**0.013**
Urinary incontinence, *n (%)*	25 (93%)	17 (65%)	-	**0.023**
Daytime urgency, *n (%)*	26 (96%)	20 (80%)	-	0.13
Nocturnal urgency, *n (%)*	11 (46%)	6 (27%)	-	0.48

SD: standard deviation, **CISC**: clean self-intermittent catheterization

Table IID: 3-day bladder diary parameters before and at the end of SNM test phase - Brain injury

	Before test phase n = 36	At the end of test phase n = 36	Δ mean	p value
Number of micturitions and/or CISC per day, *median [IQR]*	10.0 [8.00; 12.0]	8.00 [6.00; 10.0]	-2.82	**0.01**
Number of micuritions and/or CISC per night, *median [IQR]*	2.00 [0; 3.00]	0 [0; 1.00]	-1.19	**<0.01**
Urinary incontinence, *n (%)*	30 (83%)	15 (42%)	-	**<0.001**
Daytime urgency, *n (%)*	35 (97%)	21 (62%)	-	**<0.01**
Nocturnal urgency, *n (%)*	17 (52%)	2 (6.7%)	-	**<0.01**

SD: standard deviation, **CISC**: clean self-intermittent catheterization

Table IIE: 3-day bladder diary parameters before and at the end of SNM test phase – Incomplete SCI

	Before test phase n = 9	At the end of test phase n = 9	Δ mean	p value
Number of micturitions and/or CISC per day, *median [IQR]*	10.0 [8.50; 11.5]	7.50 [5.50; 9.50]	-2.33	0.17
Number of micuritions and/or CISC per night, *median [IQR]*	4.00 [1.50; 6.00]	1.50 [0.250; 2.75]	-2.36	0.37
Urinary incontinence, *n (%)*	7 (78%)	6 (67%)	-	1
Daytime urgency, *n (%)*	8 (89%)	5 (56%)	-	**0.039**
Nocturnal urgency, *n (%)*	3 (33%)	1 (11%)	-	0.23

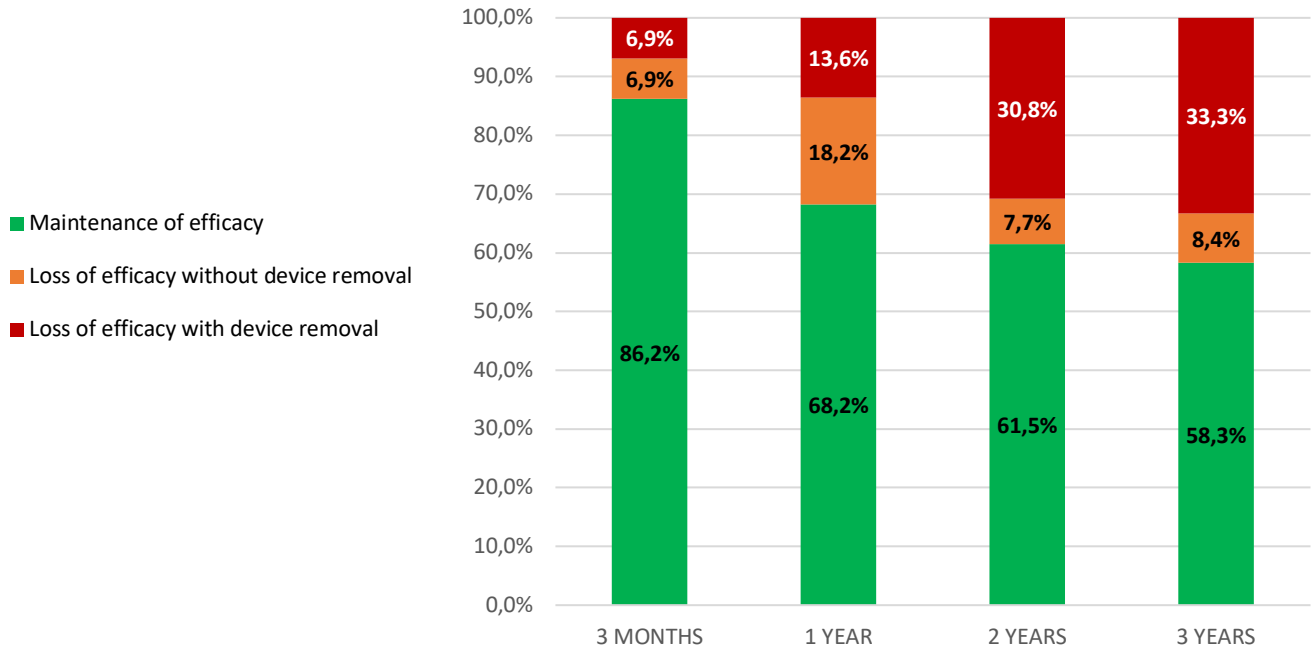
SCI: spinal cord injury, **SD**: standard deviation, **CISC**: clean self-intermittent catheterization

Table IIF: 3-day bladder diary parameters before and at the end of SNM test phase - Cerebral palsy

	Before test phase n = 13	At the end of test phase n = 13	Δ mean	p value
Number of micturitions and/or CISC per day, *median [IQR]*	9.00 [7.00; 10.0]	10.0 [6.00; 11.0]	-0.333	0.71
Number of micuritions and/or CISC per night, *median [IQR]*	0 [0; 0]	0.50 [0; 1.00]	0.375	0.46
Urinary incontinence, *n (%)*	11 (79%)	8 (57%)	-	0.25
Daytime urgency, *n (%)*	11 (85%)	5 (50%)	-	0.25
Nocturnal urgency, *n (%)*	2 (22%)	4 (50%)	-	0.5

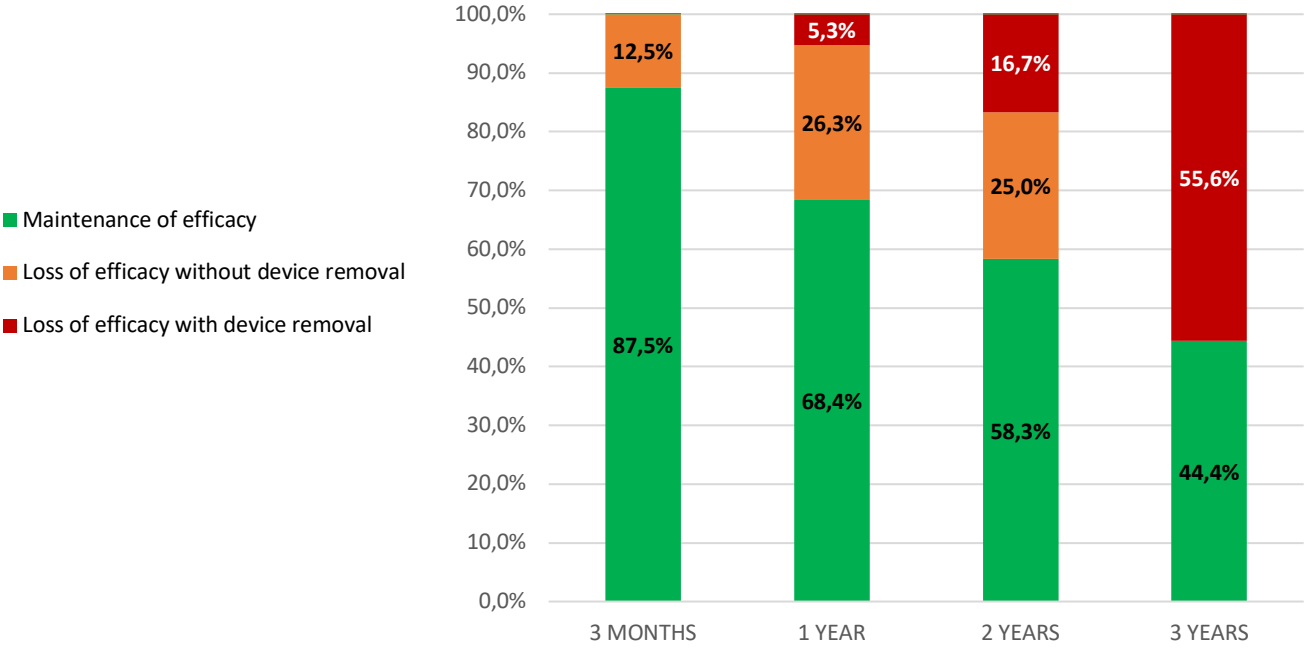
SD: standard deviation, **CISC**: clean self-intermittent catheterization

Figure 2A: Maintenance of efficacy at 3 years – Multiple sclerosis



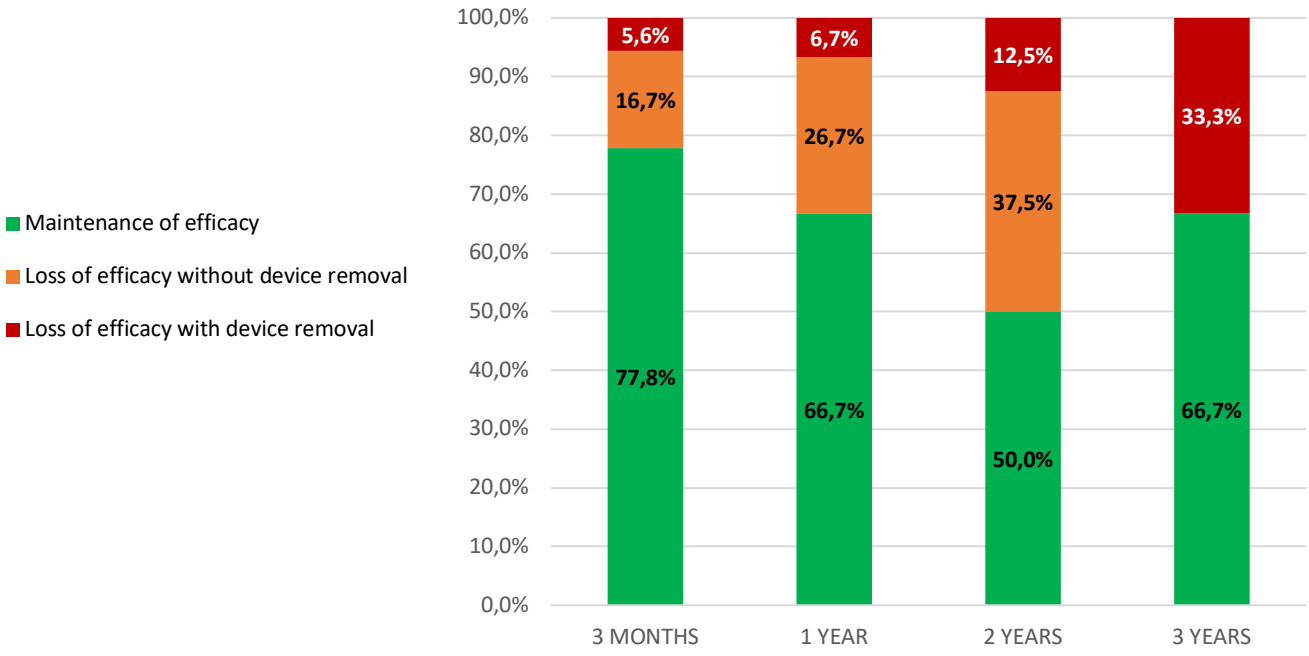
Patients followed-up n (%)	29 (100%)	22 (91.7%)	13 (86.7%)	12 (85.7%)
Patients lost to follow-up n (%)	0 (0%)	2 (8.3%)	2 (13.3%)	2 (14.3%)

Figure 2B: Maintenance of efficacy at 3 years – Brain injury



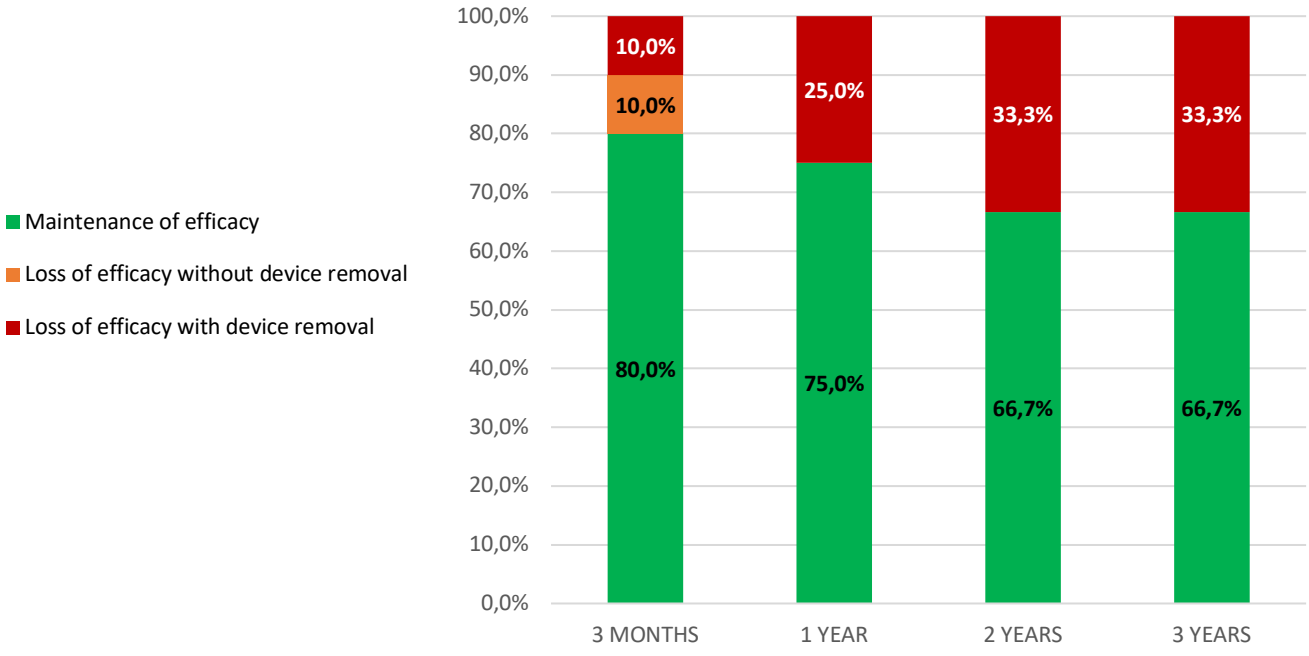
Patients followed-up n (%)	24 (92.3%)	19 (86.4%)	12 (66.7%)	9 (56.3%)
Patients lost to follow-up n (%)	2 (7.7%)	3 (13.6%)	6 (33.3%)	7 (43.8%)

Figure 2C: Maintenance of efficacy at 3 years – Parkinsonian syndrome



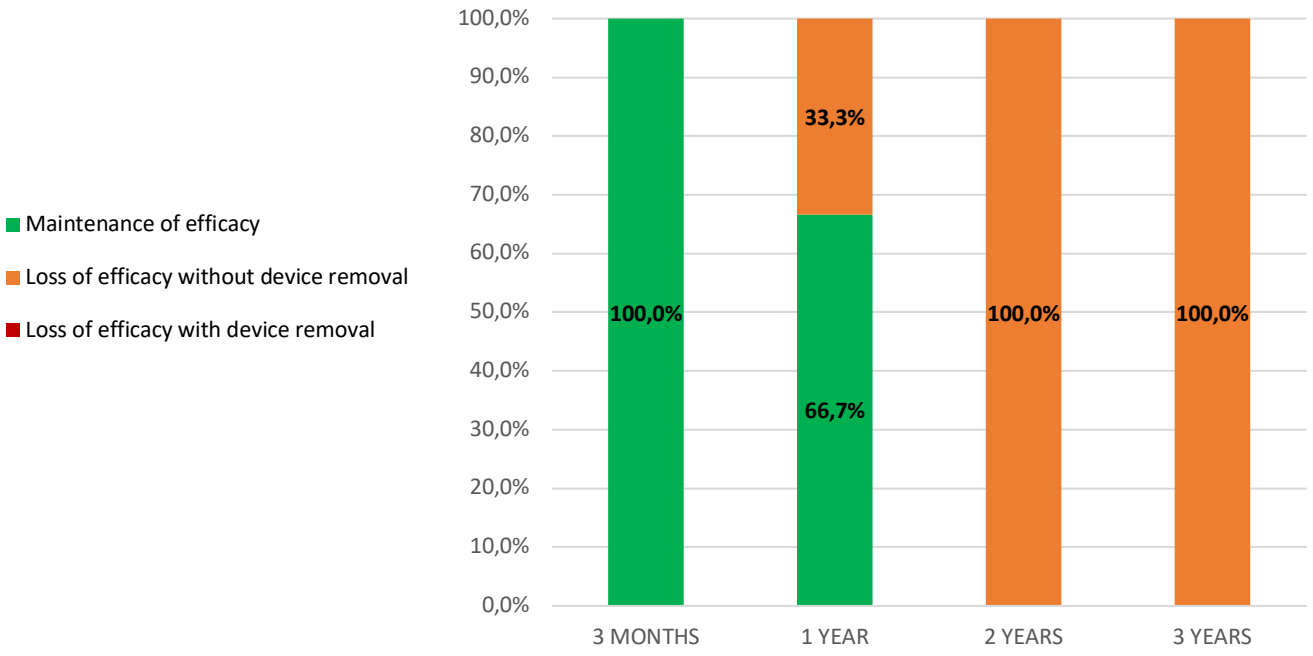
Patients followed-up n (%)	18 (94.7%)	15 (88.2%)	8 (72.7%)	6 (60%)
Patients lost to follow-up n (%)	1 (5.3%)	2 (11.8%)	3 (27.3%)	4 (40%)

Figure 2D: Maintenance of efficacy at 3 years - Cerebral palsy



Patients followed-up n (%)	10 (100%)	8 (88.9%)	6 (75%)	6 (75%)
Patients lost to follow-up n (%)	0 (0%)	1 (11.1%)	2 (25%)	2 (25%)

Figure 2E: Maintenance of efficacy at 3 years – Incomplete SCI



Patients followed-up n (%)	3 (100%)	3 (100%)	1 (50%)	1 (50%)
Patients lost to follow-up n (%)	0 (0%)	0 (0%)	1 (50%)	1 (50%)

AUTEUR : Nom : CAROLUS **Prénom : Benjamin**

Date de soutenance : 13 septembre 2023

Titre de la thèse : Évaluation de l'efficacité de la neuromodulation sacrée dans le traitement de l'hyperactivité vésicale neurogène

Thèse - Médecine - Lille 2023

Cadre de classement : Urologie – Neurologie

DES : Urologie

Mots-clés : Neuromodulation sacrée ; maladie neurologique ; hyperactivité vésicale ; sclérose en plaques ; maladie de Parkinson ; lésion cérébrale ; AVC ; lésion médullaire ; IMC

Résumé :

Objectif : Évaluer l'efficacité de la neuromodulation sacrée (NMS) dans le traitement de l'hyperactivité vésicale (HAV) neurogène.

Matériels et méthodes : Il s'agit d'une étude rétrospective multicentrique menée dans quatre centres hospitalo-universitaires français (Lille, Rennes, Nantes, Bordeaux). Tous les patients présentant une HAV évoluant dans un contexte de maladie neurologique sous-jacente et ayant bénéficié entre 2007 et 2023 d'une phase de test de NMS étaient éligibles. Le critère de jugement principal était l'efficacité clinique, déterminée par l'implantation définitive du dispositif, correspondant à l'amélioration d'au moins 50% d'au moins un des paramètres du calendrier mictionnel au cours de la phase de test. Les critères de jugements secondaires comprenaient, entre autres, le maintien de l'efficacité dans les 3 ans suivant l'implantation définitive.

Résultats : Sur les 136 patients inclus, 36 présentaient une lésion cérébrale (LC), 33 une sclérose en plaques (SEP), 27 un syndrome parkinsonien (Park), 13 une paralysie cérébrale (PC) et 9 une lésion médullaire incomplète (LMI). L'efficacité clinique était atteinte chez 74% des patients, et plus spécifiquement chez 88%, 77%, 72%, 70% et 33% des patients ayant respectivement un diagnostic de SEP, PC, LC, Park et LMI. L'efficacité était maintenue à 3 ans dans respectivement 67%, 58%, 50% et 44% des cas chez les patients ayant un diagnostic de PC, SEP, Park et LC. Aucun des 4 patients ayant une LMI ne rapportait de maintien de l'efficacité à 3 ans.

Conclusion : Chez les patients présentant une HAV dans un contexte de maladie neurologique sous-jacente, la NMS semble présenter une efficacité clinique comparable à celle retrouvée dans la population non neurologique, avec cependant une perte de l'efficacité à moyen terme.

<u>Composition du Jury</u> :

Président : Pr A. VILLERS

Assesseurs : Pr P. VERMERSCH, Pr M-A. PERROUIN-VERBE, Dr A. BLANCHARD-DAUPHIN

Directeur de thèse : Dr X. BIARDEAU