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Literature review

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Non-invasive neuromodulation in children with Neurogenic Bladder: an integrative review

Neuromodulação não invasiva em crianças com Bexiga Neurogênica: uma revisão integrativa

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RESUMO | INTRODUÇÃO: O tratamento da Bexiga Neurogênica (BN) pode ser feito através do manejo farmacológico e/ou não farmacológico. Dentro do tratamento não farmacológico temos a neuromodulação não invasiva (NMNI) realizada com aplicação de eletrodos transcutâneos que sugere uma modulação nos componentes excitatórios e inibitórios do controle da bexiga. **OBJETIVO:** Reunir evidencias que avaliem o efeito da NMNI na BN de crianças com disfunções neurológicas. **MÉTODOS:** Trata-se de um artigo de revisão integrativa que foi elaborada seguindo sete etapas. A busca foi feita nas bases de dados PubMed, Biblioteca Virtual de Saúde (BVS) e ScienceDirect. A escolha dos artigos foi realizada inicialmente por dois avaliadores independentes, obedecendo os critérios de elegibilidade: realizar tratamento para BN utilizando estimulação elétrica não invasiva com objetivo de neuromodulação da via urinária; população amostral composta por crianças com alteração miccional em decorrência de alguma disfunção neurológica e possuir os textos disponíveis na íntegra nas plataformas online de busca, no período de Agosto a Novembro de 2018. Foram incluídos artigos que utilizaram NMNI como tratamento da BN em crianças. **RESULTADOS:** Foram encontrados 440 artigos e apenas 5 atenderam aos critérios de inclusão. Ao todo, participaram dos estudos 141 crianças com acometimentos neurológicos. Os principais elementos utilizados nas avaliações foram diário miccional, o estudo urodinâmico, a coleta da história clínica e o exame físico. Os parâmetros de estimulação e posicionamento de eletrodos foram variados. **CONCLUSÃO:** A NMNI apresentou bons resultados no tratamento de crianças com BN e, foi observado também, efeitos positivos no intestino neurogênico, porém, são necessários mais estudos que sugiram protocolos bem delineados para a reprodução na prática clínica.

PALAVRAS-CHAVE: Bexiga urinaria neurogênica. Crianças. Estimulação elétrica nervosa transcutânea.

ABSTRACT | INTRODUCTION: The treatment of Neurogenic Bladder (NB) may be performed through pharmacological and/or non-pharmacological techniques. In relation to the non-pharmacological treatment, non-invasive neuromodulation (NINM) is widely used applying transcutaneous electrodes, which suggest a modulation on the excitatory components and bladder control inhibitors. **OBJECTIVE:** To gather evidence in order to assess the effect of NINM on the NB of children with neurological dysfunctions. **METHODS:** It is an integrative review article elaborated following seven steps. The research was done in the databases PubMed, Virtual Health Library (VHL) and ScienceDirect. Assortment of articles was initially made by two independent evaluators, obeying the eligibility criteria: perform NB treatment using noninvasive electrical stimulation aiming urinary tract neuromodulation; population sample composed by children with voiding alteration due to a neurological dysfunction and which have full texts available, from August to November 2018. Were included articles which used NINM as a treatment of NB in children. **RESULTS:** 440 articles were found, however only five met the inclusion criteria. Overall, 141 children with neurological afflictions were part of the study. The main evaluators elements were the voiding diary, the urodynamic study, collection of clinical history and physical exam. Parameters of stimulation and position of the electrodes varied between the studies. **CONCLUSION:** NINM showed agreable results in the treatment of children with NB, In addition, positive effects were observed in relation to the neurogenic intestine, despite the needing of further studies which suggest well-designed protocols for reproduction in clinical practice.

KEYWORDS: Urinary Bladder Neurogenic. Child. Transcutaneous electric nerve stimulation.

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Introduction

In average, there are 2.274 new cases of congenital neurological dysfunctions per year in Brazilian territory[1] which provokes motor and functional deficits withal masks other dysfunctions as urinary and intestinal ones. However, the treatment of paediatric patients in these conditions has been changed after an increase on life expectancy which enhances the interest on survival as well as on functional aims[2].

The nervous system incoordination on genitourinary functions is called Neurogenic Bladder (NB). In this condition there is failure during both storage and emptying phases of bladder as well as modification of the vesical sensibility, urine retention which can elevate the pressure on urinary tract and cause vesicoureteral reflux, provoke renal scars, deterioration of the superior urinary tract and lead to renal collapse on later phases, increasing significantly the treatment costs[3,4,5].

Dysfunction on voiding process harms the affected population quality of life once the inability to control their urinary flux negatively impacts the patients socialization, independency and also emotional aspects[6].

Once the diagnosis was made, the conservative treatment for NB can be performed by clean and intermittent catheterization associated to anticholinergic medication[7]. Another intervention strategy is the invasive neuromodulation performed by electrodes implanted on sacral foramen (S3) which shows important results improving the storage capacity of the bladder and urethral closure pressure, promoting a deceleration on urinary symptoms[8]. This benefit is caused by an inhibition or activation of the supraspinatus areas of the brain made by the caudal portion of the spinal cord. During the stimulation, as the process above occurs, there is a modulation on cortical and subcortical important components of the voiding, sense and alert of emptying as well as of the bladder storing feeling[9]. The same modulation may be performed noninvasively (NINM) per transcutaneous electrodes[10-18] suggesting a modulation on excitatory and inhibitory components of the bladder control[19].

The transcutaneous electrical stimulation shows to be a well-tolerated and powerful method to treat children who has hyperactive non-neurogenic bladder, which evidences improvements on vesical capacity, reduction on urine losses number and urinary tract infections[11,20,21].

Despite the benefits of NINM to the cases of NB as the decrease of the urinary incontinence index and improvement of the feeling of vesical storing, studies are made with not-well defined samples and varied protocols (electric current application parameters, stimulation and therapy period, among others factors)[10,14,16,18,22]. Given the absence of consensus in relation to the used parameters, is clear the need of new studies which aims to deepen the theme. Thus, the purpose of this study is to evaluate the effects of NINM on children who has NB due to neurological dysfunctions through an integrative revision.

Methods

This article is an integrative review prepared according to the PRISMA recommendations and including other types of studies besides controlled randomized clinical trials[23-26].

Theme identification and selection of search question

The theme selection was the outcome of the preparation and accomplishment of the "Journey - multiprofessional neurogenic bladder action" which is a partnership between the Santos Dumont Institute (Macaíba - RN, Brazil) and the Federal University of Rio Grande do Norte (UFRN). During the event, members of some northeast region of Brazil agreed in relation to the difficulty in establish treatment protocols using NINM among children with neurological dysfunctions.

Establishment of eligibility criteria

In order to establish eligibility criteria, studies which performed NINM to treat NB were used, regardless the application site, aiming the neuromodulation of the urinary tract; with sample population composed by children with voiding derangement due to some neurological dysfunction and which full text is available on online search platforms (PubMed, Biblioteca Virtual em Saúde and ScienceDirect). Were excluded review studies; which performed electrical stimulation aiming recruit muscle fibers; used invasive electrical stimulation; articles which

excluded children with neurological syndromes; did not describe its population sample; descriptive articles; did not has available full text; editorials or comment articles (Figure 1).

Study research on online platforms

The study research was performed through advanced search tool on online databases PubMed, Biblioteca Virtual de Saúde and ScienceDirect using the keyword group in relation to the bladder: Urinary bladder, Urinary incontinence, Neurogenic overactive bladder, Incontinence urgency, Overactive bladder, Urologic disorders congenital, Bladder dysfunction, Neurogenic bladder, Paediatrics neurogenic overactive, Urination disorders, Bladder bowel dysfunction, Lower urinary tract dysfunction, Neuropathic bladder; combined to the keywords group of stimulation: Transcutaneous electric nerve stimulation, Neuromodulation, Tibial nerve stimulation, Electroneurostimulation, Transcutaneous electrical nerve stimulation sacral, Electric stimulation therapy with the group Child, Pediatric e Children. The relation between the groups was established by the words OR and AND. The research was performed between the period of August to November/2018. In addition, a manual analysis was done aiming to find studies linked to previous articles in order to check if there are other references besides the used databases (Figure 2).

Study selection

The article triage was initially performed by two independent evaluators according to the eligibility criteria due to the study methodology. Afterwards, an examination revised all the studied in order to clear any disagreement.

Figure 1. Triage

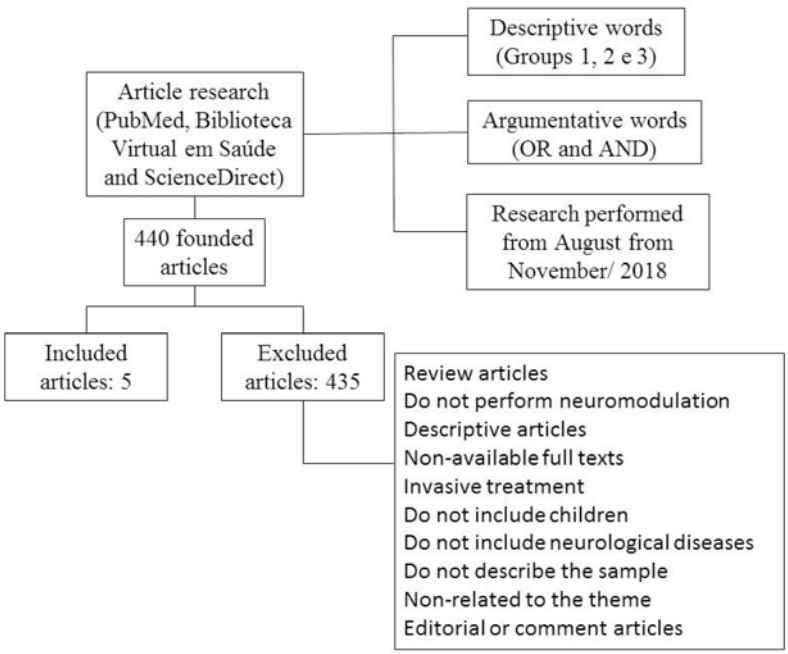
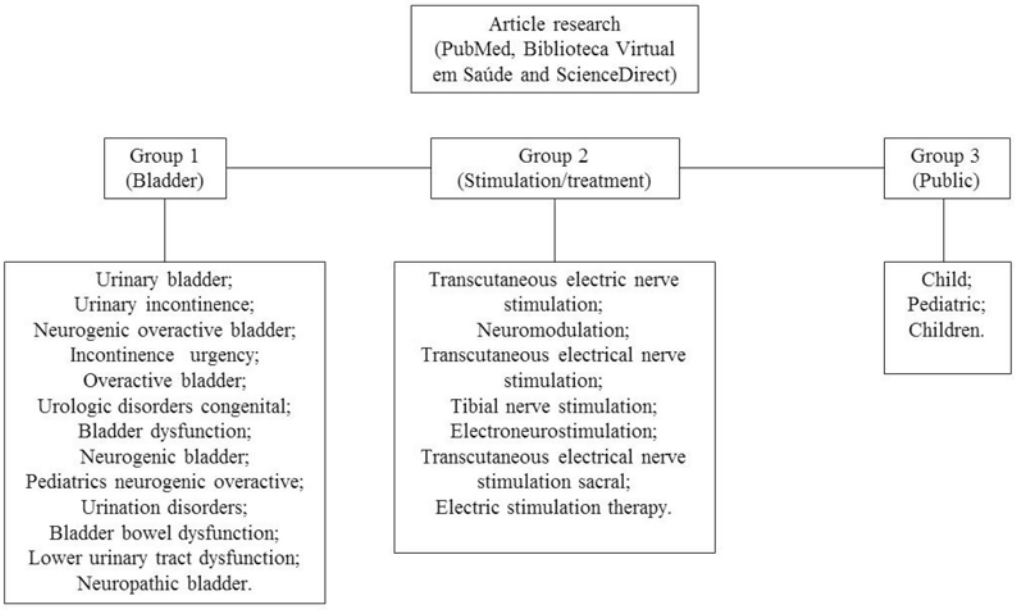


Figure 2. Research and selection



Categorization of the selected studies

Due to the methodological range among the selected articles, the score scale adapted by Taylor et al.[27] and Parry et al.[28] was used to qualify studied which have varied methodologies. The criteria evaluate aspects as structure and presentation of the study as well as basic principles to ensure the research validation. Each item which had no specified information or did not attend to the classification criteria received “escore zero”. In the individual evaluation, the maximal possible score is 30 points[27,28,29]. The qualification criteria as its respective scores can be found in Table 1. Scores were given by two evaluators and confronted after that. In case of disagreement, both evaluators would find a consensus.

Table 1. Qualification criteria and used scores

Qualification criteria	Score
Internal validation scale (type of study)	**0 to 5**
Randomized controlled trial	5
Coort	4
Case-control	3
Transversal study	2
Case report or serie of case	1
Not specified	0
Structured abstract*	**0 a 1**
Introduction with justification and basement*	**0 a 1**
Population recruitment method	**0 a 3**
Locals	3
Local residents (city/ suburb)	2
Services and clinic users	1
Not specified	0
Sample selection	**0 a 6**
Census	6
Simple random	5
Sistematic	4
Stratified	3
By conglomerates	2
Convenience	1
Not specified	0
Data collection instruments	**0 a 3**
Validated and padronized	3
Validated	2
Padronized	1
Not specified	0
Uninformed absence of answer tax*	**0 a 1**
Interviewers training*	**0 a 1**
Pre-defined answer measure methods*	**0 a 1**
Performed statistical analysis*	**0 a 1**
Study hypothesis and considered bias*	**0 a 1**
Studies interpreted according to evidences*	**0 a 1**
Result generalization scale	**0 a 5**
Anywhere	5
Same continent	4
Same country	3
Same geographic region	2
Specific population	1
Not specified	0
Maximum score	**30**

*Score equal to zero when the information was not specified or did not met the criteria.
Adapted from Taylor et al[27] and Perry et al[28].

Results

The advanced research among the databases PubMed, Biblioteca Virtual de Saúde and ScienceDirect resulted in 440 articles found. After further screening, only 5 articles were selected according to the eligibility criteria. In accordance to the score used to evaluate the methodological quality of the five studies, it has ranged from 9 to 20 points and the aspects which received lower scores were recruitment method, interviewed training and study hypothesis and bias (Table 2).

A total of 141 participated in the studies, 107 had dysraphism, 4 anorectal malformation, 1 spinal cord lipoma, 1 Arnold Chiari Malformation, sacrococcygeal teratoma, 1 Hirschsprung disease and 26 neurogenic bladder with no further cause described treated by some modality of non-invasive neuromodulation (Chart 1).

Table 2. Selected studies qualification according to the criteria and scores

Qualification criteria	Érico Correia Nepomuceno 2013	Lecompte JF 2015	Dragana Ćirović 2009	Abdol-Mohammad Kajbafzadeh 2009	Anthony H. Balcom 1997
Internal validation scale (type of study)	4	0	0	5	0
Structured abstract	1	1	1	1	1
Introduction with justification and basement	1	0	0	1	1
Population recruitment method	1	0	1	0	0
Sample selection	5	0	5	1	0
Data collection instruments	3	3	3	3	3
Uninformed absence of answer tax	1	1	0	1	1
Interviewers training	0	0	0	0	0
Pre-defined answer measure methods	1	1	1	1	1
Performed statistical analysis	1	1	1	1	1
Study hypothesis and considered bias	0	0	0	0	0
Studies interpreted according to evidences	1	1	0	1	1
Result generalization scale	1	1	1	1	1
MAXIMUM SCORE	**20**	**9**	**13**	**16**	**10**

Adapted from Parry[27] et al. e Taylor[28] et al.

The main evaluation methods used were the voiding diary, the urodynamic study, clinical history collection and physical exam. Only one study[14] has applied the incontinence diary described by Schurch et al. in 2000[30] (Chart 1).

The electrodes position vary according to the application mode of the technique, they were: malleolus region stimulating the posterior tibial nerve[14], on the parasacral region10, on the parasacral and abdominal regions[16,22] and sacral and pubic regions[18]. (Chart 1).

Stimulation parameters have ranged significantly. The frequency varied from 1Hz to 20Hz. The intensity varied from 1mA (below the motor threshold) to 100mA (maximum tolerated), the pulse width ranged from 200μs to 700μs. The application time was has shown to be widely diverse, for example 20 minutes, 1 hour or during the whole night, 3 times/week or every day, varying in a period from 1 to 9 months[10,14,16,18,22] (Chart 1).

Chart 1. Studies' overview

1st AUTHOR YEAR	SAMPLE	EVALUATION METHOD	ELECTRODES POSITION	STIMULATION PARAMETERS	APPLICATION TIME	RESULTS
Lecompte JF 2015	8 children (4 anorectal malformations, 1 spinal lipoma, 1 Arnold Chiari, 1 sacrococcygeal teratoma and 1 doença de Hirschsprung)	The UI dairy index (Schurch scale) and Jorge-Wexner score for FI	The positive one was positioned 3-4 centimeters above the medial malleolus and the negative one below the medial malleolus of the same member	Frequency of 10 Hz, pulse duration 200µs, with adjustable intensity below the motor threshold of the big finger generally between 10 and 25 mA	20 minutes every day performed by the patient in their houses during 9 months	After 2 months the IU index decreased among all the patients. In the 6th month, 83% of the patients did not refer any urine loss. NMNI do not provoke pain and is effective for faecal and urinary loss among children, even for congenital digestive diseases or neurological malformations
Érico Correia Nepomuceno 2013	26 children with NB. Divided into 2 groups: one performed oxybutynin and the other NINM.	Number of daily diapers used, urine losses between the catheterizations,vesical sensibility improvement perception and urodynamic study	Two electrodes on parasacral region (between S2 and S4)	Constant current, 10Hz frequency, 700µs pulse duration and amplitude to the level just below the motor threshold	3 applications per week of 20 minutes, for 10 weeks (total of 30 applications)	TENS PS improved the continence in 87,5%, while oxybutynin improved 66,67%. TENS PS and oxybutynin were effective to improve the vesical complacency and decrease the diapers number. The majority of the patients of TENS PS group showed better vesical storage sensibility.
Dragana Ćirović 2009	49 Children with dysraphism, 19 treat only with anticholinergic medication; 30 treated with anticholinergic medication associated to TENS and EC	Day wetting and bedwetting, urinary urgency and frequency; e urodynamic study	In relation to the TENS, paravertebrals electrodes near to S2-S4; for EC, suprapubic application on anterior abdominal wall	Non informed	Once a day during 1 hour for 1 month	Confronting both groups, the results of the combined group were better
Abdol-Mohammad Kajbafzadeh 2009	29 children. (19 received NINM while 10 received only a simulation)	Number of wet diapers, bedwetting, maximum detrusor pressure, post-voiding residue ,sphincter-detrusor lack of synergy, maximum vesical capacity and vesical complacency	2 electrodes positioned on pubic symphysis of both sides, and 2 others positioned near to the ischiatic tuberosity	Frequency of 1-20Hz, pulse duration of 250µs and repeat time of 6,6 seconds on treatment group. Increased range until reach a comfortable level of sensory consciousness with no visible muscle contractions. On younger children a intensity of 20 mA was applied.	18 cycles of NINM during 20 minutes, 3 times a week (total of 18 applications)	78% of the patients improved their continence immediately after the therapy and 60% kept their continence for the following 6 months (P <0,05). The urinary frequency and wetting were also recovered (P <0,05). The therapy shows to be effective on improving the voiding symptoms as incontinence and urodynamic parameter of children with NB. However prospective studies are necessaries including long term follow up
Anthony H. Balcom 1997	29 children	Previous history,physical exam, voiding proctography, renal US, urodynamic study, evoked somatosensory potential, physiotherapeutic evaluation and marching analysis by video.	One positioned obliquely along the ipsilateral gluteus, on the parasacral region and the other pair was positioned vertically, one electrode through the anterior abdominal wall and the other one through the paravertebral muscle on the same side	Pulse duration of 280µs, non informed frequency, intensity ranged from 1 to 100 mA, maximum current density of 0,46 pA./mm and maximum average power density on the electrodes of 25 FW./mm	Applied by the parents during bedding time during 6 nights per week for 9 months	This study shows benefic and safe effects in relation to the bladder capacity increasing and improving on conscience of vesical and rectal plenitud, which contributes to better functional continence. The parents reported good adherence and easiness on applying at home. This technique allows to decrease medication usage and surgical procedures

NB: Neurogenic Bladder; UI: Urinary Incontinence; FI: Fecal Incontinence; NINM: Non Invasive Neuromodulation; PS: Parasacral; EC: Exponencial Current;

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Discussion

The evaluation of the studies has shown a varied quality of evidence among the articles in addition to the fact that none of the articles reached the maximum score (Table 2). Studies which had lower scores presented scarcity of requirements in their structure, mainly recruitment method, evaluators training and study hypothesis and bias, which reveal a low quality amid the articles selected to this study. However, in order to the inexistence of cut-off point, classify articles as goods or not was impossible.

The studies samples were composed by children with neurological diseases as sacral and lumbar myelomeningocele, spinal cord lipoma, Arnold Chiari Malformation, sacrococcygeal teratoma and Hirschsprung disease even though two articles did not specify the dysfunction examined.

Despite the methodological diversity and selection or study design bias, it is possible to observe preliminary results of NINM to the bladder functions as increase on vesical capacity, complacency and sensibility improvement, recovery of bedwetting and incontinence as well as in relation to the vesical storage among children who suffer from neurological dysfunction.

Even though improve intestinal function was not includes as an objective of this study, some articles show recovery of faecal incontinence which suggests a positive effect of neuromodulation also in cases of neurogenic bowel.

According to the found studies, the used parameters varied widely. In relation to the frequency, it ranged from 1 to 20Hz, however was equal to 10Hz in 2 of the 5 articles[10,14]. The pulse duration ranged from 200 to 700μs. While the pulse range was lower than the motor threshold and patient comfort among all the studies. In addition to this, constant current was used in 4 of the 5 articles there was too use of exponential and interferential current. Only one article did not inform which current parameters used.

Aiming to reach the bladder nervous tract, the site of neuromodulation seems to introduce effects on voiding number, urodynamic patterns and bowel disorders, which makes it a dependent variable analyzed by this revision.

Posterior tibial nerve

The tibial nerve emerges from the L4-S3 spinal roots and is considered a sensory and motor nerve controlling the bladder and the pelvic floor. According to Jean-François Lecompte et al. (2014)[14] the neuromodulation was applied on tibial region aiming to treat faecal and urinary incontinence among children with neurological dysfunctions. A steady current was performed by two electrodes positioned one 3-4 centimetre above the medial malleolus and other below the medial malleolus of the same member with 10Hz of frequency and pulse duration equal to 200 μs, during 20 minutes every day for 9 months.

Following 6 months of stimulation, a significative improvement was observed on the fecal incontinence (p=0.02). Regarding the vesical function, urinary incontinence perception has decrease after 2 months in all the patients while after 6 months of treatment, 83% of patients did not reported any urinary leakage during day and night. This study used the scores of Jorge-Wexner[32] e Schurch[30] to evaluated both fecal and urinary incontinence respectively, in which there was a significant decrease after 6 months of stimulation.

Parasacral region

The S2, S3 and S4 sacral spinal segments innervate the pelvic muscles as the bladder by the pudendum and pelvic nerves. Therefore, Nepomuceno EC et al. in 2013[10] used two electrodes on the parasacral region between S2 and S4 symmetrical and in parallel to the centre line in order to stimulate the afferent tract of the bladder and sacral roots. There was a comparison between two groups, while one group used Oxybutynin as treatment, the other one performed only the parasacral neuromodulation using a steady current with frequency of 10Hz, pulse range of 700 μs and intensity equal to a level just below the motor threshold in 3 sessions per week of 20 minutes each during 10 weeks (total of 30 appointments).

It was observed a significant improvement among the neuromodulation group, which mean values were vesical complacency (p= 0,008) and significant decrease on the number of used diapers per day (p=0,016). The Oxybutynin group showed improvement on vesical complacency (p=0,030), loss pressure of the detrusor muscle (p=0,004), number of

diapers per day, maximum cystometric capacity and estimated vesical capacity with p<0,000. Each treated group has shown satisfactory results regarding any criteria analysed which allows a significant improvement on continence and complacence. Given these information, the author suggests that an association between both methods would promote better results and benefits to the patients

In 2013, Barroso et al. confronted the neuromodulation application on both parasacral and tibial regions and concluded that there were better results referring voiding dysfunctions on parasacral stimulation. The reason may be due to the direct stimulation of spinal reflexes which reaches supra-spinal centres more effectively[31].

Parasacral and abdominal region

Anthony H. et al. in 1997[16], used a circuit of 2 pairs of electrodes. One of the pairs was positioned obliquely along the ipsilateral gluteus, on the parasacral region and the other pair was positioned vertically, one electrode through the anterior abdominal wall and the other one through the paravertebral muscle on the same side. This last pair has also the function to stimulate the bowel function, due to the harmonious performance between the bladder and the bowel suggested by some authors.

In this study, the authors performed a steady current with pulse duration of 280 μs, the frequency was not detailed, during 6 nights per week while the patient slept, a period mean of stimulation of 10,5 hours per patient, during 9 months. It was found a significant increase on the maximum vesical capacity (p = 0,0021) and a subjective improvement on the vesical storage feeling because of the difficulty to determine this feeling even in undamaged patients. In addition, the decrease of fecal leakage was reported by the parents.

Dragana Ćirović et al. in 2009[22], compared two groups: the first one treated only by anticholinergic medication and the second one by combined therapy composed by medication and neuromodulation. The neuromodulation was performed for 1 month with 3 weeks pause, through two current types: steady current by electrodes located on parasacral region (S2-S4) and exponential current applied by electrodes on suprapubic region and anterior abdominal wall near to the bladder. The author regards that the exponential current was applied using parameters aiming to relax the detrusor muscle and modulate its hyperactivity despite the absence of description in relation to which parameters were used in each current.

Confronting the results after 12 months, better results were achieved by the combined therapy group: improvement of bedwetting (p<0,01), urgency (p<0,01), decrease on detrusor involuntary contractions (p<0,05) and sphincter-detrusor lack of synergy (p<0,05). The author also highlights the importance of regular monitoring of children even after significant achievements due to its tendency to relapsing.

Sacral and pubic region

Abdol-Mohammad Kajbafzadeh et al. in 200918 used 2 pairs of electrodes, one positioned on the pubic symphysis of both sides and the other under the ischiatic tuberosity, aiming a current crossing inside the bladder and pelvic floor muscles. Was performed a interferential current with a pulse duration of 250 μs and repeating time of 6,6 seconds, a frequency range of 1-20Hz, during 20 minutes, 3 appointments per week, totalizing 18 applications.

The experimental group was confronted to a sham group which received electrical current with no effect (SHAM) and it was observed that in the experimental group there was a significant recovery on the maximum detrusor pressure, post-voiding residue and sphincter-detrusor lack of synergy (p<0.05). Regarding to the relation between before and after treatment, the neuromodulation improved the mean of maximum detrusor pressure (p=0.01), vesical complacence (p=0.001), post-voiding residue (p<0.05), voiding frequency (p<0.05) and bedwetting (p=0.002).

Conclusion

There is preliminary evidence that suggest recovery on voiding symptoms as vesical complacence, bedwetting, urinary incontinence and vesical sensibility after NINM treatment. However, for now is not possible to determine its efficacy compared to other types of treatment due to the variability on applied protocols and on sample population as well as lack of methodological quality among the studies

Therefore, considering the showed discrepancies it is necessary to produce clinical trials with high population control and randomization in order to execute its neuromodulation parameters in the clinical practice covered by scientific evidences.

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Author contributions

Pereira TA contributed with the design of the work; search and selection of articles; analysis of results; writing of the article; approval end of the version to be published. Leal LCFL contributed to the search and selection of articles and analysis of results. Fonseca Filho GG contributed writing the article and reviewing the content. Bezerra NMB contributed to the analysis of the results; writing of the article; review of the content and referral of the scientific article. Lisboa LL contributed with the design of the work; organization and methodology of the article; content review; final approval of the version to be published.

Competing interests

No financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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