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Quality of life in women with refractory overactive bladder treated with percutaneous tibial nerve stimulation

Qualidade de vida de mulheres com bexiga hiperativa refratária tratadas com estimulação elétrica do nervo tibial posterior

Francine O. Fischer-Sgrott[1], Elisangela F. Manffra[2], Wilson F. S. Busato Junior[3]

Abstract

Objective: To investigate the effect of percutaneous tibial nerve stimulation (PTNS) in the quality of life (QoL) of women with overactive bladder (OAB). **Methods:** Uncontrolled clinical trial with 11 women that presented overactivity of the detrusor muscle in urodynamic tests. All of the subjects were previously treated with anticholinergic medication, without response. The treatment consisted of 12 PTNS sessions of 30 minutes each, two times a week. The electrical stimulator Dualpex 961® (Quark medical) was used. The instruments chosen to evaluate QoL were the King's Health Questionnaire (KHQ) and the "International Consultation on Incontinence Questionnaire – Short-Form" (ICIQ-SF). The questionnaires were applied before and after the treatment. **Results:** There was a significant improvement in the following domain scores of the KHQ: incontinence impact (74.55±27.75 versus 38.18±13.82; p=0.008), role limitations (66.45±25.89 versus 26.91±11.22; p=0.008), physical limitations (73.91±29.46 versus 30.91±12.79; p=0.008), social limitations (39.18±35.60 versus 17.45±12.26; p=0.028), personal relationships (25.64±29.16 versus 10.45±15.23; p=0.043), emotions (65.82±38.56 versus 26.00±20.45; p=0.005), sleep/energy (39.18±37.51 versus 16.45±18.17; p=0.012) and severity measures (62.00±17.70 versus 33.00±16.59; p= 0.003), except for general health perception (51.36±30.75 versus 37.73±25.63; p=0.068). In the ICIQ-SF scores it was also possible to observe a significant improvement (10.09±6.50 versus 3.73±3.00; p=0.008). **Conclusions:** The PTNS treatment improved the QoL of women with overactive bladder and refractory to anticholinergic medication. Therefore, PTNS can be considered a good alternative for OAB treatment as it is safe and inexpensive compared to other therapeutic approaches.

Key words: biomedical technology assessment; physical therapy; overactive urinary bladder; electrical stimulation; quality of life.

Resumo

Objetivo: Verificar o impacto do tratamento por estimulação elétrica do nervo tibial posterior (PTNS) na qualidade de vida (QV) de mulheres com bexiga hiperativa (BH). **Métodos:** Ensaio clínico não controlado com 11 mulheres com presença de contrações não inibidas do detrusor (CNI) no exame urodinâmico, todas anteriormente submetidas ao tratamento com anticolinérgicos, sem resposta. O tratamento fisioterápico constituiu-se de 12 sessões de 30 minutos da PTNS com o eletroestimulador Dualpex 961®, duas vezes na semana. Para avaliar a QV, foram utilizados os questionários *King's Health Questionnaire* (KHQ) e o "*Internacional Consultation on Incontinence Questionnaire – Short-Form*" (ICIQ-SF), e os seus escores pré e pós-tratamento foram comparados pelo teste de Wilcoxon para amostras pareadas, com nível de significância de 0,05. **Resultados:** Observou-se melhora significativa na QV em todos os domínios do KHQ, exceto na percepção geral da saúde (51,36±30,75 *versus* 37,73±25,63; p=0,068): impacto da incontinência (74,55±27,75 *versus* 38,18±13,82; p=0,008), limitações das atividades diárias (66,45±25,89 *versus* 26,91±11,22; p=0,008), limitações físicas (73,91±29,46 *versus* 30,91±12,79; p=0,008), limitações sociais (39,18±35,60 *versus* 17,45±12,26; p=0,028), relações pessoais (25,64±29,16 *versus* 10,45±15,23; p=0,043), emoções (65,82±38,56 *versus* 26,00±20,45; p=0,005), sono/disposição (39,18±37,51 *versus* 16,45±18,17; p=0,012) e nas medidas de gravidade (62,00±17,70 *versus* 33,00±16,59; p=0,003). Os escores do ICIQ-SF demonstraram também melhora na QV (10,09±6,50 *versus* 3,73±3,00; p=0,008). **Conclusões**: A terapia com PTNS foi capaz de melhorar a QV de mulheres com queixa de BH e refratárias ao tratamento medicamentoso. A PTNS mostra-se, portanto, uma boa alternativa terapêutica, além de ser segura e com baixo custo operacional.

Palavras-chave: avaliação da tecnologia biomédica; fisioterapia; bexiga urinária hiperativa; estimulação elétrica; qualidade de vida.

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[1] School of Physical Therapy, Universidade do Vale do Itajaí (UNIVALI), Itajaí (SC), Brazil
[2] Graduate Program in Health Technology, Pontifícia Universidade Católica do Paraná (PUCPR), Curitiba (PR), Brazil
[3] School of Medicine, UNIVALI
Correspondence to: Elisangela Ferretti Manffra, Curso de Engenharia Elétrica, Pontifícia Universidade Católica do Paraná, Rua Imaculada Conceição, 1155, CEP 80215-901, Curitiba (PR), Brazil, e-mail: elisangela.manffra@pucpr.br; elisangelaferretti@gmail.com

Introduction

The Standardization Committee of the International Continence Society (ICS) currently considers as urinary incontinence (UI) any involuntary loss of urine demonstrated objectively[1-3]. One of the clinical conditions associated with UI is overactive bladder (OAB)[4,5], which often involves multiple symptoms including urgency, urge incontinence, nocturia and pollakiuria[3,6,7].The latter is characterized by an increase in the daily frequency of urination, which under normal conditions does not exceed eight times, but can exceed 20 times in patients with OAB[8].

Although OAB is the second leading cause of UI in women[5,6,8], it is very challenging to establish its true incidence because of the difficulty in reaching a diagnosis, mainly due to the embarrassment of patients to talk about UI and the lack of in-depth clinical research[4-6]. The two main approaches to the treatment of OAB are drug treatment and physical therapy. The drug therapies are based on the use of anticholinergics and are only partially effective[3,8,9]. Published data demonstrate that the use of such medication has only 50% to 70% efficiency and is accompanied by adverse side effects such as dry mouth, constipation and blurred vision[8]. As a result of this, only 18% of patients continue the drug treatment after the first six months[3,8,9]. Behavioral therapy and physical therapy may be as effective as, or even more effective than, drug treatment[9]. Some physical therapy methods for treatment of UI employ electrical stimulation and consist of intermittent neuromodulation: intravesical, anal, vaginal, penile, perineal, transcutaneous suprapubic or in sacral region and in the posterior tibial nerve[9,10].

Percutaneous tibial nerve stimulation (PTNS) consists of transcutaneous electrical stimulation with the aid of needle electrodes in the posterior tibial nerve region[4,10-13]. Although it was proposed more than 20 years ago, the details of the action mechanism of PTNS are not fully known[14,15]. It has been suggested that this form of electrical stimulation inhibits bladder activity by the depolarization of sacral and lumbar somatic afferent fibers[14,15] that results from motor and sensory responses to stimuli in the posterior tibial nerve region. Centrally, this nerve enters the sacral spine in the same area where the nerve projections to the bladder are located. These are the most likely areas in which the therapeutic effect of neuromodulation of the bladder by PTNS acts, and this 30-minute stimulus already has a beneficial effect[16,17].

Authors who have studied the effects of PTNS consider it a good therapeutic option for the treatment of OAB because of its low cost and the lack of the side effects of drug therapy[4,10,11,14,15,18-24]. In comparison with other electrical stimulation techniques, it has the advantage of generating less discomfort and embarrassment to patients because it is not applied to the genital area[4,10,22-24]. Due to this fact, some studies have reported its indication in pediatric use[18,21].

Several authors have reported the application of PTNS in the treatment of urinary disorders[11,14,15,18,19,21]. Some cite the use of such electrical stimulation in children with neurogenic bladder, non-neurogenic urinary retention and uncoordinated voiding[18,21], and others relate their experience with adult men and women with neurogenic OAB by multiple sclerosis, Parkinson's disease, cord injury and idiopathic OAB[11,14,15,19]. However, a limitation of most of these studies is the study of mixed populations that include male and female patients[4,10,14,15,20-25] with neurogenic and idiopathic OAB[4,14,15,20,25], for example. In these studies, the authors use as methods of evaluation both urodynamic and quality of life (QoL) parameters[4]. This is because, currently, there is growing concern about the impact of UI on the lifestyle of patients[25]. In general, UI adversely affects the daily activities and the social and emotional relationships of people of all ages. Women with OAB, in particular, reported a lower QoL compared with other forms of UI[26,27].

The ICS recommends that measures of QoL evaluation using specific and validated questionnaires for the studied population be included in studies so that new evidence can be acquired in the global understanding of this pathology[1,2,25]. Thus, despite its subjective nature, the evaluation of QoL by structured questionnaires has gained importance in the evaluation of technologies of OAB treatment. This is due to the fact that other evaluation methods, such as the urodynamic test, the Pad test and the stress test, do not include the impact of this condition on the QoL and daily life of affected patients[2,25].

To be effective, these instruments must be simple and relevant to the disease. However, in the studies that used the PTNS to treat OAB, QoL was investigated by means of the SF-36[4-,10,11,14,15,18-25], which is not specific to UI. It is also recommended that the questionnaires be easy to understand and validated for the evaluated population because its interpretation is influenced by culture[25]. In Brazil, the King's Health Questionnaire (KHQ)[1] and the International Consultation on Incontinence Questionnaire - Short-Form (ICIQ- SF)[2] have been translated and validated. Given the need to evaluate PTNS as an alternative technology for the treatment of idiopathic OAB and given the negative effect of this pathology on the daily activities of the female population, the objective of the present work is to investigate the impact of treatment with PTNS on the QoL of women.

Methods

This study was conducted at the Department of Physical Therapy of the University of Vale do Itajaí (UNIVALI) and at

Santa Catarina Institute of Urology (INCAU), both in the city of Itajaí, SC, from March 2006 to August 2007. This research was approved by the Research Ethics Committee of UNIVALI, nº 442/2005.

Population and sample

Inclusion criteria for sample selection were clinical symptoms of OAB, without neurological deficits, with the presence of overactivity of the detrusor muscle in the urodynamic test. Exclusion criteria were age below 18 years, symptoms of irritative lower urinary tract due to OAB with neurological impairment, pregnancy or intended pregnancy during the study, urinary tract infection shown by urine culture within the past year, diagnosis of bladder cancer, bladder carcinoma in situ, bladder malignancy, diagnosed interstitial cystitis, urinary tract lithiasis, severe cardiopulmonary disease, cardiac pacemaker, gynecological or pelvic disorders, decompensated diabetes for more than six months, neurological disease, other forms of physical therapy treatment for urinary symptoms over the course of the study, bladder outlet obstruction demonstrated by pressure-flow study, use of anticholinergic drugs for OAB treatment, use of tricyclic antidepressants, alpha-blockers, adrenergics and antidepressants two weeks before the study or over the course of the study.

For the composition of the sample, 78 women diagnosed with OAB were contacted by telephone in June 2006. The contact details were obtained from the urologist who performed the urodynamic tests. Of these women, only two agreed to take part in this study. Between the months of February and March 2007, the research was advertised in a local health magazine and attracted four more participants. Five other participants were referred by the urologist who performed the urodynamic tests in 2007. Therefore, the study sample consisted of 11 women.

All participants had previous clinical tests with urologists and/or gynecologists that showed their clinical condition and the possibility of exclusion. Before taking part in the study, participants received information about the procedures and signed an informed consent form, according to resolution 196/96 of the National Health Council/MS of 10/10/96.

Materials and procedures

An initial interview was carried out with each participant to collect sociodemographic and clinical data and the gynecological and obstetric history. The KHQ and ICIQ-SF questionnaires were applied before and after the treatment protocol with PTNS. The KHQ is a questionnaire consisting of 30 questions divided into nine domains[1,26]: health perception, incontinence impact, role limitations, physical limitations, social limitations, personal relationships, emotions, sleep/energy and severity of urinary symptoms[1]. A score (range 0-100) is given in each domain separately, with no general score. The higher the score, the lower the QoL related to that domain[1].

In contrast, the ICIQ-SF is a simple, short questionnaire, with four questions that can be self-administrated[12]. It quickly evaluates the impact of urinary incontinence in QoL and quantifies urinary loss in both sexes. This questionnaire has an overall score ranging from 0 to 21 points. The higher the score is, the greater the impact of urinary loss on the QoL of the interviewee[2].

PTNS was applied during 12 sessions, twice a week. The choice of this frequency was based on several studies in which the beneficial effects of neuromodulation triggered by PTNS were observed after a median treatment of 12 sessions, once or twice weekly[4,10,11,14,15,18-25]. We chose to apply the sessions twice a week because this frequency is said to intensify the effects of PTNS in neuronal plasticity.

After PTNS application, the QoL questionnaires were reapplied by the same researcher who conducted the initial application and physical therapy intervention. Urodynamic tests were also carried out before and after PTNS by the same urologist at INCAU with the device Urosystem DS 5600 (Viotti Associados, Brazil). The test measured maximum cystometric capacity and the infused volume corresponding to the first urge to void and strong urge to void. The test also determined the presence or absence of uninhibited contractions of the detrusor.

For the purposes of PTNS, the patients remained in the lithotomy position, and the region of the medial malleolus was then palpated. An acupuncture needle was inserted five centimeters above that point, as shown in Figure 1. Before the insertion of the needle, the skin was disinfected with a 70% alcohol solution. The steel needle was sterile and disposable and measured 25x30 mm. A plastic cylinder, about 3 mm shorter than the needle was used to aid the insertion of the needle, which remained inserted approximately 3 to 4 cm posterior to the tibia after perforation of the skin and removal of the plastic cylinder. The needles were inserted in both legs at the same point, and with the same methodology[4,10,11,14,15,18-25].

A self-adhesive reference electrode was positioned close to the medial malleolus, near the heel, closing the circuit for the electrical stimulation, as shown in Figure 2. The electrical stimulation device was, then, connected to the needles and adhesive electrodes. The correct needle placement was confirmed by the flexion of the hallux or flexion of the second

or fifth metatarsal. For electrical stimulation, a rectangular, biphasic waveform current was used with amplitude of 0 to 10 mA, fixed pulse width of 200 μs, frequency of 10 Hz and no rest period, i.e. the stimulation was maintained throughout session[4,10,11,14,15,18-25]. The session lasted 30 minutes, and the current intensity was increased by the researcher until the pain threshold, reported by the participants, was reached[4,10,11,14,15,18-25].

The stimulation device used was Dualpex 961® (Quark Produtos Médicos) powered by a 9V battery to avoid interference from the electricity network. Before use in the study, the device was tested at the Laboratory of Rehabilitation Engineering of PUC/PR. With the aid of a digital oscilloscope and using a 1 kΩ resistor as load, the nominal values of the parameters of the waveform (rectangular form, pulse duration, frequency, amplitude range) were verified.

Statistical analysis

For comparison of initial and final scores of the domains of the QoL questionnaires, the non-parametric Wilcoxon test for paired samples was chosen, adopting 0.05 as the level of statistical significance.

Results

The Study group consisted of 11 women aged between 22 to 65 years, weighing between 50 and 68.8 kg, height between 1.56 and 1.64 m, and body mass index (BMI) between 18.83 and 25.78 kg/m. The mean time of urinary complaints was 7.7 years. All study participants had already had clinical intervention with the use of anticholinergic medication for at least three months without improvement in symptoms, thus the underlying pathology was refractory. The 11 volunteers completed the study, i.e. there was no sample loss.

Regarding the KHQ urinary symptom scale, there was a significant improvement, with a score decrease in eight of the nine KHQ domains, as shown in Table 1. In the ICIQ-SF score, there was also a statistically significant decrease from 10.09±6.50 before treatment to 3.73±3.00 after treatment, with p=0.008. As for the urodynamic test, there was no statistically significant difference in any of the investigated variables before and after treatment. However, it is worth noting that the maximum cystometric capacity before and after PTNS was obtained from only eight women. For the other three, the measurement was affected by the involuntary loss of urine during filling in one of the conditions (before or after). The uninhibited contractions of the detrusor were observed in eight of the 11 volunteers after treatment.

Discussion

Regarding the sample, we did not initially intend to evaluate the effects of PTNS on drug-refractory OAB. However, only women with these characteristics responded to numerous means used to compose the sample for this study. Therefore, it can be considered that patients with anticholinergic-refractory OAB have limited therapeutic options, and PTNS can be a valid alternative. The adherence of the participants throughout the study also shows that PTNS did not cause unwanted side effects, discomfort or embarrassment that would discourage them from completing the treatment.

With regard to the KHQ scores, it is noted that only one domain (general health perception) showed no statistically significant change after the application of PTNS. Concerning the KHQ domains that showed a reduction in scores after treatment with PTNS, it is worth noting the improvement

Figure 1. Needle insertion for PTNS application.

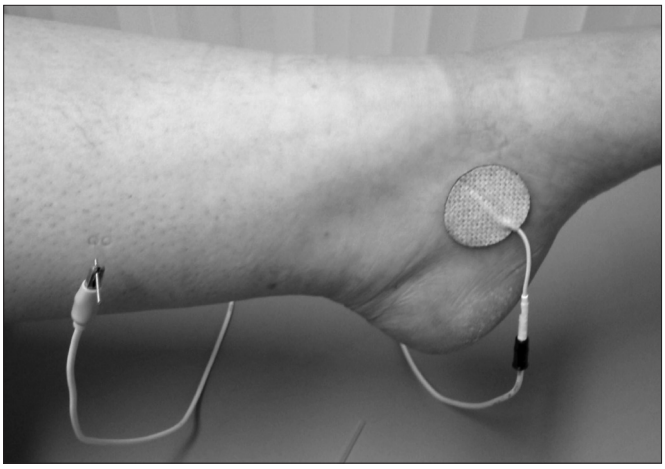

Figure 2. Needle and adhesive reference electrodes with cables from the electrical stimulator.

Table 1. Scores by domain before and after PTNS. treatment.

Domain	Before PTNS (Mean±SD)	After PTNS (Mean±SD)	P value
General Health Perception	51.36±30.75	37.73±25.63	0.068
Incontinence Impact	74.55±27.75	38.18±13.82	0.008
Role limitations	66.45±25.89	26.91±11.22	0.008
Physical limitations	73.91±29.46	30.91±12.79	0.008
Social limitations	39.18±35.60	17.45±12.26	0.028
Personal Relationships	25.64±29.16	10.45±15.23	0.043
Emotions	65.82±38.56	26.00±20.45	0.005
Sleep / Energy	39.18±37.51	16.45±18.17	0.012
Severity Measures	62.00±17.70	33.00±16.59	0.003

PTNS=percutaneous tibial nerve stimulation; KHQ=King´s health questionnaire.

in the domains: role limitations, social limitations, personal relationships and emotions. Thus, it can be said that these domains could measure objectively what the literature reports on incontinent patients: that they refrain from social activities like visiting friends, playing sports or going shopping and working as a result of urinary loss[28]. The literature also reports that people with UI fall into a vicious cycle of anxiety and grief over a possible loss of urine associated with feelings of embarrassment and the gradual worsening of urgency because of the anguish that often causes significant psychological discomfort and varying degrees of social isolation[29].

Despite its lower specificity, the ICIQ-SF showed an improvement in the perception of QoL after PTNS. The agreement of the results of this instrument with the KHQ suggests that it can be used as a measure of QoL in the evaluation of OAB treatments with the advantage of being more easily applied. As already mentioned, most studies that investigated the effects of PTNS in the QoL used the SF-36 questionnaire and I-QoL[4,10,11,14,15,18-25,30].The former is not specific to incontinence, and the latter is not validated in Portuguese. In any case, these authors reported a general improvement in QoL indexes after the application of PTNS.

However, one should consider each study in order to achieve a more appropriate comparison with the present results. The greater number of participants in the abovementioned studies and the composition of the population led the authors to diverse results. For example, in the work by van Balken et al.[30], the participants were classified as responders (who completed all 12 sessions of PTNS) and nonresponders (that dropped out of the treatment program). Analyzing the overall scores of the SF-36 questionnaire for the responsive group, the authors found no variations between the situations before and after PTNS, but noted an improvement in the score for the item "emotional well-being". This result can be compared with the present result for the KHQ questionnaire, in which there was no significant change in the "general health perception" domain, but improvements in more specific domains.

It can be argued that a limitation of this study is that it did not use the SF-36 questionnaire, therefore it cannot be compared directly with other works. However, the difference in the evaluated populations per se would already make this evaluation very difficult. Moreover, it is believed that the use of UI instruments to evaluate QoL in clinical research in Brazil allows a more accurately measurement of the results of therapeutic intervention. The absence of a control group or a placebo group can also be considered a limitation of this study. However, the fact that the population was not subjected to any other type of therapeutic intervention suggests that the positive effects on QoL resulted from the PTNS protocol.

Although the QoL questionnaires are considered valid scientific instruments for the evaluation of technology applied to health, they do not contribute to the understanding of the physiological mechanisms of action of PTNS. This would be possible from the results of the urodynamic tests. However, in this study, there were sample losses in obtaining urodynamic variables, which reduces the power of conclusion from these results. Moreover, one cannot say that the urodynamic test is free of bias. For example, the need to urinate in usual conditions may affect test results. Thus, we chose not to consider these results in the present study and not to discuss the physiological mechanisms involved in the action of the therapeutic protocol presented here.

Conclusions

The 12-session PTNS therapy program had a positive impact on the QoL of women with non-neurological, anticholinergic-refractory OAB. Participant adherence to the treatment

and the ease of application suggest that the application of PTNS is a viable option for the treatment of idiopathic OAB. It should be noted that these positive results were obtained from a relatively small sample, however they should encourage further studies on PTNS with a larger number of women and a control group.

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