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Clinical Study

Acute Effect of One Single Application of Intravaginal Electrostimulation on Urodynamic Parameters in Patients with the Overactive Bladder Syndrome

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Introduction. We performed this study to quantify the acute effect of one single application of intravaginal electrostimulation in patients with symptoms of the overactive bladder syndrome (OAB), using urodynamic parameters. *Materials and methods*. Prospectively forty female patients were consecutively selected by entry in two groups: urodynamics only and urodynamics combined with intravaginal electrostimulation. We applied intravaginal electrostimulation with a frequency of 8 Hz, pulse duration of 1000 microseconds and no pulse to rest. Urodynamic evaluations were performed according to ICS standards. *Results*. By comparing urodynamic measurements in both groups, it appeared that the first sensation of bladder filling, cystometric capacity, micturition volume, urethral pressure, and peak flow showed statistical significant improvement ($P < .05$) during intravaginal electrostimulation. *Conclusion*. In the present study, we were able to demonstrate an acute effect of one application of intravaginal electrostimulation on bladder function urodynamic parameters in patients with the overactive bladder syndrome. Whether our findings represent the clinical effect of intravaginal electrostimulation in patients with complaints of OAB symptoms needs to be clarified.

1. Introduction

In 2002, the International Continence Society defined the overactive bladder (OAB) as urgency with or without incontinence, with frequency and nocturia in the absence of local pathological or hormonal factors (a symptom-based definition) [1]. Detrusor overactivity (DO) incontinence is diagnosed during filling cystometry when DO is accompanied by involuntary urine loss. However, conventional filling cystometry is not able to register DO consistently. The reported sensitivity is 77.9% and the specificity is 38.7% [2]. Urge urinary incontinence (UI) with no detectable DO is mostly categorized as sensory UI. Currently, the term "overactive bladder" (OAB) is used when defining the symptom complex, disregarding the urodynamic features.

Patients with symptoms of the OAB-syndrome can be treated by medication (anticholinergics), biofeedback training, electrical stimulation, and pelvic floor muscle (PFM) exercises. During the past decades, electrical stimulation of the pelvic floor, bladder, sacral roots S2-S4, and pudendal nerves has been reported to be an effective treatment option [3]. There are different techniques of electrical stimulation like intra-anal or vaginal stimulation, tibial nerve stimulation [4], and sacral nerve stimulation [5]. Extra corporeal magnetic innervation (ExMI) therapy is a more recent technique [6, 7]. According to previous studies, electrostimulation of the external urethral sphincter inhibits and depresses unstable bladder contractions and decreases the frequency of micturition [8, 9]. The lack of controlled parameters has made it difficult to evaluate the true efficacy of intravaginal electrostimulation (ES). Moreover, the stimulation equipment as well as the treatment regimens are not standardized and it is difficult to draw conclusions about electrical parameters of frequency, pulse duration, pulse-to-rest ratio, length of treatment, power, and accurate success rates [10]. Almost three decades ago, Erlandson et al. made a first attempt to standardize the technique. Erlandson referred not only to electrode position but also to the choice of electrical parameters used for stimulation [11]. Most follow-up studies and review articles refer to this study of Fall and Lindstrom [12]. Based on previous studies, induction of bladder inhibition is most effective when using a frequency of 5–10 Hz.

We performed this study to quantify the acute effect of one single application of intravaginal ES in patients with symptoms of the overactive bladder syndrome using urodynamic parameters.

2. Materials and Methods

Forty consecutive female patients, visiting our out-patient clinic of urology and the pelvic floor center, diagnosed with urgency, frequency and/or urge incontinence were included in this study. Women with stress incontinence, mixed incontinence, neurogenic bladder, malignity, prolapse, ability to comply with instructions in Dutch, and bladder pain were excluded; notwithstanding that bladder pain could be an expression of detrusor overactivity. We did rule out clinical urinary tract infection; bacteriuria was not an exclusion criterion. All women were multiparous. Also they all had pelvic floor exercises (straining), bladder training, and urge suppression. All of them learned to contract the pelvic floor. Stress incontinence was excluded by history, urodynamics, bladder diary, and cystoscopy. At least two days before urodynamic investigations, anticholinergics (oxybutinine, tolterodine) had to be stopped, which should be enough considering the half-life of these drugs ($T_{1/2}$ elimination = 2-3, resp., 3-4 hours).

We obtained medical ethical approval of our medical ethical committee and the subjects provided informed consent.

Before urodynamic evaluation, all patients underwent comprehensive evaluation, including patient history, physical examination, urinary system ultrasound, and a voiding diary. All patients completed a diary in order to assess the micturition fluid intake, frequency, and severity of the loss of urine, micturition frequency over 24 hours and micturition volumes. A micturition frequency of over 8 times a day and more than once over night (in absence of cardiac failure) was considered as urge (ICS).

To investigate the effect of intravaginal electrostimulation we used the UD-2000 (Medical Measurement Systems, Enschede, the Netherlands). Urodynamics were performed with a four-fold microtip catheter (Gaeltec) with three-urethral and one-bladder pressure measuring electrodes. Rectal pressure was measured with a rectal balloon as a representative of the abdominal pressure. Activity of the pelvic floor during urodynamic investigation was monitored by 3-surface electrodes, 2 positioned on the perineum and 1 on the upper inner leg (reference electrode). In between both urodynamic investigations, the pelvic floor activity was measured with a vaginal probe (EMG, 2 rings, V. M. P. Bioparc).

Abdominal pressureis considered to be the pressure surrounding the bladder. In current practice it is estimated from rectal, vaginal, or, less commonly, extraperitoneal pressure or a bowel stoma. The simultaneous measurement of abdominal pressure is essential for the interpretation of the intravesical pressure trace. All investigations were performed in sitting position.

Urodynamics were performed according to ICS recommendations. The word "cystometry" is commonly used to describe the urodynamic investigation of the filling phase of the micturition cycle.

The filling phase starts when filling commences and ends when the patient and urodynamics decide that "permission to void" has been given. A medium-fill rate of 30 mL/min (ICS definition medium-fill rate is 10–100 mL/min) was used in order to prevent artificial detrusor overactivity. First sensation of filling (FSF) and maximum cystometric capacity were measured.

Cystometric capacityis the bladder volume at the end of the filling cystometrogram, when "permission to void" is usually given. The end point should be specified, for example, if filling is stopped when the patient has a normal desire to void. The cystometric capacity is the volume voided together with any residual urine (post-void residual).

Maximum cystometric capacity (MCC) in patients with normal sensation is the volume at which the patient feels that he/she can no longer delay micturition (has a strong desire to void). Before urodynamic investigation, patients had an explanation about FSF and MCC.

The voiding phase starts when "permission to void" is given, or when uncontrollable voiding begins, and ends when the patient considers that voiding has finished.

Flow rateis defined as the volume of fluid expelled via the urethra per unit time. It is expressed in mL/s.

Subjects were asked to void without straining. Ultrasound was used to measure the post-void residual volume.

In all patients, two urodynamic investigations were performed in succession.

Patients were submitted to urodynamics only (group I, $n = 20$) with two urodynamic fillings within one session or urodynamics plus one application of intravaginal electrostimulation (group II, $n = 20$) during the second filling within one session.

In group II, prior to the second urodynamic evaluation, electrostimulation was applied by a pelvic floor clinician using the Myomed 932 (Enraf Nonius, Delft, the Netherlands) with a vaginal probe (EMG, 2 rings, V. M. P. Bioparc). Ultrasound was used to measure the post-void residual volume. In both groups, patients underwent a physical examination by the pelvic floor physiotherapist [13] in between both urodynamic investigations.

A qualitative investigation of the pelvic floor function includes a qualitative physical examination of the pelvic floor function consisting of vaginal and anal visual inspection as well as digital palpation (including the pelvic organ prolapse quantification, POP-Q) [13]. Finally the pelvic floor function is assessed quantitatively by biofeedback registration.

Stimulation parameters were set at a frequency of 8 Hz, pulse duration of 1000 microseconds and no pulse to rest, during 20 minutes. Stimulation intensity was adjusted individually to a level just below a level giving unpleasant

Table 1

Parameters	Group 1 (n = 20); without stimulation First filling (± SEM)	Second filling (± SEM)	P-value	Group II (n = 20); with stimulation First filling (± SEM)	Second filling during intravaginal ES (± SEM)	P-value
First sensation of bladder filling (mL)	164,6 ± 31,6	170,5 ± 29	ns	164,5 ± 31,6	321,0 ± 38,7	0,001
Cystometric capacity (mL)	317,3 ± 40	340,3 ± 39	ns	337,3 ± 40,0	491,4 ± 34,1	0,0001
Micturation volume (mL)	190,3 ± 30	190,5 ± 32	ns	197,6 ± 42,6	252,1 ± 42,3	0,05
Average urethral pressure (cm H_2O)	154,1 ± 15,0	163,0 ± 12	ns	169,1 ± 16,5	160,2 ± 13,4	ns
Peak flow (mL/s)	11,0 ± 2,0	11,5 ± 1,9	ns	11,0 ± 2,0	15,7 ± 2,3	0,008
Post-void residual (mL/s)	61,0 ± 15,0	75,0 ± 21,0	ns	63,0 ± 14,7	59,2 ± 17,5	ns

sensations. Urodynamic procedures were repeated after the 20 minutes of intravaginal stimulation by an experienced clinician in our department.

At the end of the second bladder filling when the patient has a normal desire to void, electrostimulation was stopped and "permission to void" is usually given.

We documented maximal detrusor pressure at micturition (cm H_2O), first sensation of bladder filling (mL), cystometric capacity (mL), urethral pressure (cm H_2O) micturition volume (mL), peak flow (mL/s), and post-void residual (PVR). One investigation combining urodynamics and investigation of the pelvic floor function is a standard of care at our institute. Maximum urethral pressureis the maximum pressure of the measured profile.

The investigation was a diagnostic procedure and not a treatment. Urodynamics of both groups have been compared retrospectively. Printouts of the urodynamic evaluation with and without intravaginal electrostimulation were assessed by a urologist. The urologist was blinded to the treatment group.

Statistical analysis was performed using Wilcoxon and paired T-tests in SPSS 14.0. Significance was defined as $P < .05$.

3. Results

All except one patient had been treated before with pharmacotherapy 41, 3%, pelvic floor physiotherapy (all patients), urethral dilatation, and 56% of patients had at least one surgical intervention. We are a referral center and of a number of patients the exact number or the type of surgical interventions is lacking. Between groups there was no difference. 3% of patients in both groups were performing clean intermittent catheterization of the bladder.

All the women were multiparous. Also they had pelvic floor exercises (straining), bladder training, and urge suppression. They all learned to contract the pelvic floor.

The mean age of patients in group I was 37 years (range 31–65) standard deviation (SD) 21. Seven patients were diagnosed with urgency/frequency, ten patients with urgency/frequency and urge incontinence, and three patients with urge incontinence.

In this group, comparison of both urodynamic evaluations revealed no significant changes between urodynamic parameters.

The mean age of patients in group II was 45 years (range 22–67), SD 18. Ten patients were diagnosed with urgency/frequency, one patient with urge incontinence, and nine patients with urgency/frequency and urge incontinence.

There were no significant differences between patients in group I and group II that is between both fillings in group I and the first filling in group II (see Table 1). By comparing both urodynamic evaluations in group II, it appeared that the first sensation of bladder filling (FSF), cystometric capacity, micturition volume, and peak flow showed statistical significant improvement ($P \leq .05$) during ES. Other urodynamic parameters improved but not statistically significant (see Table 1). Observation during the urodynamic investigation showed that the introduction of the probe had no influence on urodynamic parameters in both groups.

Prior to intravaginal ES, we registered no involuntary detrusor contractions during bladder filling in this patient population (phasic detrusor overactivity). However, as an expression of detrusor overactivity, we observed a decreased maximum cystometric capacity at which patients could not longer delay micturition (terminal detrusor over activity).

Ultrasonography prior to urodynamic investigation indicated no relevant PVR in the studied patient population.

In this patient population the resting urethral pressure was high; this may be related to a high percentage of overactivity of the pelvic floor musculature in these patients (69% of patients $> 2\,\mu$V).

4. Discussion

We were able to demonstrate an acute effect of one application of intravaginal ES on bladder function in patients with the overactive bladder syndrome according to current criteria (ICS) using urodynamic parameters. Whether our findings represent the clinical effect of intravaginal electrostimulation in patients with complaints of OAB symptoms needs to be clarified. We believe that intravaginal electrostimulation facilitates the voiding process by lowering the urethral pressure (see Table 1).

In urge incontinence, two modes of action of electrostimulation have been described: stimulation of pudendal nerve afferents, which results in detrusor inhibition via central reflexes, and stimulation of efferents, which results in enhancement of pelvic floor and urethral sphincter musculature tone, inducing detrusor inhibition via the guarding reflex [12]. Hence, it is important to correlate the clinical results of this treatment with functional changes in the pelvic floor musculature. During electrostimulation, the urethral pressure is high because of the current, and after ES we noticed a better relaxation of the urethra which facilitates the voiding process. The quantitative investigation of the pelvic floor function consists of EMG registration of the behavior of the pelvic floor. Because of the absence of (inter)nationally accepted reference values, we defined, based on our experience for 18 years, a muscle tone at rest of 1-2 microvolt (μV) as normal and a resttone above 2 μV as an elevated restone [13].

In this population with symptoms of the OAB syndrome, we have found a very high concurrence of an overactivity of the rest tone of the pelvic floor. The urethral sphincter is an integral part of the pelvic floor, so we believe the urethral pressure is high, as a result of this phenomenon. We could not find any reference of this in the literature and this (consistent) phenomenon is the focus of a present study in our department.

Prior to intravaginal ES, we registered no involuntary detrusor contractions during bladder filling in this patient population.

However, as an expression of detrusor overactivity, we observed a decreased maximum cystometric capacity at which patients could no longer delay micturition. Ultrasonography of the bladder prior to urodynamic investigation indicated no relevant PVR in the studied patient population. The apparent post-void residual (PVR) is due to the fact that some patients were unable to void completely or even to void at all during urodynamics, because they were asked to refrain from straining or due to the urodynamic setting (inhibition as described in literature) [14].

Previous studies indicated that a prolonged trial of up to three months was needed to determine whether ES could be considered potentially successful for a given subject. Success can be obtained in approximately two-thirds of patients, but the therapy has the disadvantage of the necessity of maintenance therapy [15, 16]. The success rates are usually in the range from 55% to 80% and probably limited by the fact that no variables predictive of outcome have been identified. It is now generally accepted that electrostimulation works via the afferent rather than efferent nerves and effects at the level of the supraspinal nervous system [17]. Parallel to the gate control theory for pain, it may also be suggested that stimulation of large somatic fibers could modulate/inhibit the thinner afferent A-delta or C fibers, thus decreasing the perception of urgency [17, 18].

The effect of intravaginal ES on bladder, urethral, and pelvic floor function depends on several factors: the distance to and configuration of the electrodes with respect to the appropriate nerve fibers, the excitability of these fibers, the transfer characteristics of the central pathways (in case of bladder inhibition), and the properties of the peripheral effector organ. Voorham-van der Zalm et al. [19] stated that electrode placement has a profound influence on the threshold voltage: a small dislocation of the electrode carrier was often enough to cause a twofold or even threefold increase.

Pelvic floor physiotherapy is mostly based on experience and not evidence based. We indeed feel that in the absence of a gold standard all efforts should be made to give us tools to hold onto. In our experience, treatment with intravaginal ES was effective.

We are not aware of previous studies that focused on intravaginal electrostimulation and urodynamics.

Whether the acute effect of intravaginal electrostimulation we described in this study represents its therapeutical effect as a result of 8–12 sessions is not proven yet. However, the results underscore the rationale of intravaginal electrostimulation in patients with symptoms of the overactive bladder syndrome.

The limitation of our study is the lack of randomization of patients.

5. Conclusion

In the present study, we were able to demonstrate an acute effect of one application of intravaginal ES (8 Hz, pulse duration 1000 microseconds and no pulse to rest) on bladder function using urodynamic parameters in patients with symptoms of the OAB. Whether our findings represent the clinical effect of intravaginal ES in patients with complaints of OAB symptoms needs to be clarified.

References

[1] P. Abrams, L. Cardozo, M. Fall, et al., "The standardisation of terminology in lower urinary tract function: report from the standardisation sub-committee of the International Continence Society," *Urology*, vol. 61, no. 1, pp. 37–49, 2003.

[2] P. Abrams, J. G. Blaivas, S. L. Stanton, and J. T. Andersen, "The standardisation of terminology of lower urinary tract function. The International Continence Society Committee on Standardisation of Terminology," *Scandinavian Journal of Urology and Nephrology, Supplement*, vol. 114, pp. 5–19, 1988.

[3] T. Yamanishi, K. Yasuda, R. Sakakibara, T. Hattori, and S. Suda, "Randomized, double-blind study of electrical stimulation for urinary incontinence due to detrusor overactivity," *Urology*, vol. 55, no. 3, pp. 353–357, 2000.

[4] M. R. van Balken, V. Vandoninck, K. W. H. Gisolf, et al., "Posterior tibial nerve stimulation as neuromodulative treatment of lower urinary tract dysfunction," *The Journal of Urology*, vol. 166, no. 3, pp. 914–918, 2001.

[5] J. Groen, R. van Mastrigt, and J. L. H. R. Bosch, "Computerized assessment of detrusor instability in patients treated with sacral neuromodulation," *The Journal of Urology*, vol. 165, no. 1, pp. 169–173, 2001.

[6] P. J. Voorham-van der Zalm, R. C. M. Pelger, A. M. Stiggelbout, H. W. Elzevier, and G. A. B. Lycklama à Nijeholt, "Effects of magnetic stimulation in the treatment of pelvic floor dysfunction," *BJU International*, vol. 97, no. 5, pp. 1035–1038, 2006.

[7] T. Yamanishi, K. Yasuda, S. Suda, N. Ishikawa, R. Sakakibara, and T. Hattori, “Effect of functional continuous magnetic stimulation for urinary incontinence,” *The Journal of Urology*, vol. 163, no. 2, pp. 456–459, 2000.

[8] B. C. Eriksen and S. H. Eik-Nes, “Long-term electrostimulation of the pelvic floor: primary therapy in female stress incontinence?” *Urologia Internationalis*, vol. 44, no. 2, pp. 90–95, 1989.

[9] A. Shafik, “A study of the continence mechanism of the external urethral sphincter with identification of the voluntary urinary inhibition reflex,” *The Journal of Urology*, vol. 162, no. 6, pp. 1967–1971, 1999.

[10] J. J. Smith III, “Intravaginal stimulation randomized trial,” *The Journal of Urology*, vol. 155, no. 1, pp. 127–130, 1996.

[11] B. E. Erlandson, M. Fall, and C. A. Carlsson, “The effect of intravaginal electrical stimulation on the feline urethra and urinary bladder. Electrical parameters,” *Scandinavian Journal of Urology and Nephrology, Supplement*, no. 44, pp. 5–18, 1977.

[12] M. Fall and S. Lindstrom, “Electrical stimulation: a physiologic approach to the treatment of urinary incontinence,” *Urologic Clinics of North America*, vol. 18, no. 2, pp. 393–407, 1991.

[13] P. J. Voorham-van der Zalm, G. A. B. Lycklama à Nijeholt, H. W. Elzevier, H. Putter, and R. C. M. Pelger, ““Diagnostic investigation of the pelvic floor”: a helpful tool in the approach in patients with complaints of micturition, defecation, and/or sexual dysfunction,” *The Journal of Sexual Medicine*, vol. 5, no. 4, pp. 864–871, 2008.

[14] B. F. M. Blok, J. Groen, J. L. H. R. Bosch, D. J. Veltman, and A. A. Lammertsma, “Different brain effects during chronic and acute sacral neuromodulation in urge incontinent patients with implanted neurostimulators,” *BJU International*, vol. 98, no. 6, pp. 1238–1243, 2006.

[15] M. R. van Balken, “Percutaneous tibial nerve stimulation: the urgent PC® device,” *Expert Review of Medical Devices*, vol. 4, no. 5, pp. 693–698, 2007.

[16] J. Groen, J. L. H. Ruud Bosch, and R. van Mastrigt, “Sacral neuromodulation in women with idiopathic detrusor overactivity incontinence: decreased overactivity but unchanged bladder contraction strength and urethral resistance during voiding,” *The Journal of Urology*, vol. 175, no. 3, pp. 1005–1009, 2006.

[17] V. Vandoninck, M. R. van Balken, E. F. Agrò, et al., “Posterior tibial nerve stimulation in the treatment of urge incontinence,” *Neurourology and Urodynamics*, vol. 22, no. 1, pp. 17–23, 2003.

[18] I. K. Walsh, R. S. Johnstone, and P. F. Keane, “Transcutaneous sacral neurostimulation for irritative voiding dysfunction,” *European Urology*, vol. 35, no. 3, pp. 192–196, 1999.

[19] P. J. Voorham-van der Zalm, R. C. M. Pelger, I. C. van Heeswijk-Faase, et al., “Placement of probes in electrostimulation and biofeedback training in pelvic floor dysfunction,” *Acta Obstetricia et Gynecologica Scandinavica*, vol. 85, no. 7, pp. 850–855, 2006.