Chapter 8

Acute effect of one single application of intravaginal electrostimulation on urodynamic parameters in patients with the overactive bladder syndrome

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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). Patients with symptoms of the OAB-syndrome can be treated by medication (anticholinergics), biofeedback training, electrical stimulation and pelvic floor muscle exercises (PFM). During the past decades, electrical stimulation of the pelvic floor, bladder, sacral roots and pudendal nerves, has been reported to be an effective treatment option (2). There are different techniques of electrical stimulation, like intra-anal or vaginal stimulation, Tibial Nerve Stimulation (3) and Sacral Nerve Stimulation (4). Extra corporeal magnetic innervation therapy (ExMI) is a more recent technique (5; 6). According to previous studies, electrostimulation of the external urethral sphincter inhibits and depresses unstable bladder contractions and decreases the frequency of micturition (7; 8). The lack of controlled parameters has made it difficult to evaluate the true efficacy of intravaginal electro stimulation (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 (9). Almost three decades ago, Erlandson and Fall 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 (10). The precise mode of action of electrostimulation is unclear, but it is believed “to restore the balance within the central nervous system” (11).

Based on previous studies, induction of bladder inhibition is most effective when using a frequency of 5-10 Hz. (12).

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.
Material and methods

Forty consecutive female patients diagnosed with urgency/frequency and/or urge incontinence, without stress incontinence and/or combined incontinence were included in a prospective study. Before urodynamic evaluation all patients underwent comprehensive evaluation, including patient history, physical examination, urinary system ultrasound and a voiding diary.

To investigate effect of intra vaginal electrostimulation, we used the UD-2000 (Medical Measurement Systems, Enschede, the Netherlands). Urodynamics were performed with a four fold micro tip 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. Urodynamics were performed according to ICS recommendations. A fill rate of 30 ml/min was used. First sensation of Filling (FSF) and maximum cystometric capacity was measured. Subjects were the asked to void without straining. Voided volume and maximal urethral pressure were measured. In all patients two urodynamic investigations were performed in succession.

Patients were submitted to urodynamics only (group I, n=20) or urodynamics plus one application of intravaginal electrostimulation (group II, n=20). Patients were consecutively submitted to urodynamics or urodynamics plus electrostimulation based on the availability of the pelvic floor physiotherapist during the study period. If the pelvic floor physiotherapist was present both investigations were performed simultaneously as described, if not present, only urodynamics were performed during a separate outpatient appointment.

In group II, prior to the second urodynamic evaluation, electrostimulation was applied by a pelvic floor physiotherapist using the Myomed 932® (Enraf Nonius, Delft, the Netherlands) with a vaginal probe (EMG, 2 rings, V.M.P.Bioparc®*). The probe was inserted up to the thinnest part, at the level of the introitus. Stimulation parameters were set at a frequency of 8 Hz, pulse duration of 1000 μsec and no pulse to rest, during 20 minutes. Stimulation intensity was adjusted individually to a level just below a level giving unpleasant 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.

Printouts of the urodynamic evaluation with and without intravaginal electrostimulation were assessed by an urologist. The urologist was blinded to the treatment group.

We documented maximal detrusor pressure at micturition (cm H2O), first sensation of bladder filling (ml), cystometric capacity (ml), urethral pressure (cm H2O) micturition volume (ml) and peak flow (ml/sec). Rectal pressure was measured with a rectal balloon as a representative of the abdominal pressure (table). Both policies are standard of care at our institute. The investigation was a diagnostic procedure and not a treatment. Urodynamics of both groups have been compared retrospectively.

Statistical analysis was performed using Wilcoxon and paired T-tests in SPSS 12.1. Significance was defined as p < 0.05.

**Results**

All except one patient had been treated before, with pharmacotherapy 41, 3 %, pelvic floor physiotherapy (all patients), urethral dilatation, and surgery (56 %), and including colposuspensus, urethral dilatation or even self-catheterization (3%).

The mean age of patients in group I was 37 years (range 31-65). Seven patients were diagnosed with urgency/frequency, ten patients with urgency/frequency and urge incontinence and three patients with urge incontinence. Observation during the urodynamic investigation indicated that the introduction of the probe had no influence on urodynamic parameters in both groups.

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). Ten patients were diagnosed with urgency/frequency, one patient with urge incontinence and nine patients with urgency/frequency and urge incontinence.

Comparison of the initial urodynamic investigations of both groups revealed no differences. 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 ≤ 0.05) during ES. Other urodynamic parameters improved but not statistically significant (Table).
Table: Comparison of urodynamic parameters of two urodynamic evaluations; group I, without ES and group II, with intravaginal ES during the second filling.

However, ultrasonography prior to urodynamic investigation indicated no relevant PVR in the studied patient population. There were no significant differences between patients in group I and group II.

**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 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 (Table). 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.
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)(13). With respect to the stimulation parameters for intravaginal electrostimulation, as yet there is no consensus regarding optimal stimulation parameters for intravaginal electrostimulation in patients with overactive bladder. As far as we know, studies systematically evaluating the optimal settings of electrostimulation are lacking. Settings used in literature are mainly empirical.

The mechanisms responsible for the beneficial effect of intravaginal electrostimulation in the treatment of bladder dysfunction remain unclear. One hypothesis is, that detrusor over activity is known to be associated with female stress urinary incontinence as a result of pelvic floor relaxation. This may suggest that afferent nerve activity from pelvic floor and urethra is involved in detrusor inhibition during bladder filling (14).

Percutaneous Tibial Nerve stimulation (PTNS has) a clear carry-over effect: 30 minutes of stimulation induces a lasting beneficial effect. Cat experiments in which a 5-minute stimulation of afferent nerves resulted in more than 1 hour of bladder inhibition; confirm the existence of this carry-over effect. Previous studies indicated 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). Groen et al stated that SNS has been applied in various conditions refractory to conservative approaches (16). The success rates are usually in the range of 55 % to 80 % and probably limited by the fact that no variables predictive of outcome have been identified. It is now generally accepted that SNS works via stimulation of 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 (16; 18).

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

The most accepted mode of action of intravaginal ES is related to its effect on the afferent nerves, innervating organs as the bladder, urethra, vagina, rectum and pelvic floor musculature (19). 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 et al. (20) 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.

Literature is scarce on the topic of the optimal stimulation parameters. The generally accepted parameters are a frequency of 5-10 Hz and pulse duration of 400-1000 μ sec. In pelvic floor practice the pulse duration variates from 20 - 1000 μ sec, representing the limitations of equipment. In our institution we have experienced over the last 15 years that the combination of a frequency of 8 Hz, pulse duration of 1000 μsec and no pulse to rest proved to be optimal in relieving patient’s symptoms. We are not aware of previous studies 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.

Conclusions.

In the present study we were able to demonstrate an acute effect of one application of intravaginal ES (8 Hz, pulse duration 1000 μseconds 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.
Reference List


