The evaluation of the efficiency of treatment of stress urinary incontinence among females treated with the biofeedback method based on electromiographic triggered stimulation feedback (ETS biofeedback)

Maciej Kisiel, Henryk Konon
Ward of Urology at the Province Specialized Hospital in Biała Podlaska
Head of Urology Ward: Henryk Konon, MD

Key words: urinary incontinence, conservative treatment, biofeedback, intravaginal electromiographic stimulation

Summary

The objective:
The research attempts to evaluate the results of the conservative treatment of stress urinary incontinence by means of Electromiographic Triggered Stimulation (ETS).

Material and methods
In the period of 1st Feb. 2004 – 1st May 2004 fifty-two female patients of Urology and Gynecology Ward and the Urology Outpatient Unit aged 38 – 74, average age 61.5, were diagnosed for stress urinary incontinence. The patients agreed for conservative treatment by means of the ETS under the control of the EMG with the application of the Neuro Trac ETS apparatus made by Verity Medical Ltd.

All patients underwent a urodynamic test as well as the EMG of the muscles of the pelvic fundus before the therapy and after a 3 month therapy. Gynecological examination excluded significant deviations in relation to the anatomy of the urogenital system; in case of inflammation of the urogenital system, it was treated appropriately. During the therapy the patients noted down their observation. They were questioned by means of Gaudenz’s, BFLUTS and QOL questionnaires at the beginning and by the end of the therapy.

Results
All patients completed the therapy satisfactorily. The average values of VLPP (Valsalva Leak Point Pressure) and CLPP increased respectively by 23.2 and 43.6 cm H2O.

The number of case of urinary incontinence decreased by 1.75 /24 h on the average, and the number of pads decreased by 1.4 /24 h on the average.

In the EMG test the average muscular contraction AVR increased by 24.2 microvolts on the average, and the maximal contraction increased by 35.7 microvolts on the average.

The questionnaire on the standard of living presented the data of the improved life quality by 2.8 points on the average.

58% patients were regarded as healthy, 22% presented a significant improvement.

Conclusions
The Biofeedback method based on the ETS is an efficient method of treating stress urinary incontinence. The conditions that guarantee a successful treatment are: appropriate qualification and the consistency of exercising.
**Introduction**
Urinary incontinence is a social problem. It is estimated that approximately 50.7% of women at the menopause age suffer from this ailment. (1)
In 1997 American Urological Society reported that 25% of women at the age between 30, and 49 and 30% of women at the age of 45-64, had problems with urinary incontinence, especially, while making an effort. This ailment may concern even 11 million American women (2,3). Many authors claim that the conservative treatment of urinary incontinence should precede surgical treatment or should complement it.
In this research, an attempt is made to evaluate the efficiency of the biofeedback method based on the ETS under the control of the EMG in conservative treatment of urinary incontinence.

**The objective**
The objective of the research is to evaluate the efficiency of a 3 month therapy of stress urinary incontinence by means of the biofeedback method based on the ETS under the control of the EMG Neuro Trac ETS apparatus made by Verity Medical Ltd.

**Material and methods**
In the period of 1st Feb. 2004 – 1st May. 2004 at Urology Ward of Province Specialized Hospital 52 female patients aged 38-74, average age 61.5, diagnosed for stress urinary incontinence type I and II according to Blaivasa (4), in the degree I and II, were treated. All patients underwent urodynamic tests as well as the basic efficiency of the muscle of pelvic fundus was assessed by application of the EMG Neuro Trac ETS made by Verity Medical Ltd.
All patients conducted diaries as well as filled in Gaudenz’s, BFULTS and QOL questionnaires before and after the therapy. The patients were examined gynecologically to exclude significant deviations in the anatomy of the urogenital system. In case of inflammations, these were appropriately treated before the beginning of the therapy.
The open display was applied as an introductory technique of the therapy. An intravaginal electrode, Periform, and a self-adhesive contra lateral electrode onto the surface of a thigh were applied. On the screen the patient observed the changes of the EMG curve in the time of contraction and decontraction of the muscle of the pelvic fundus.
The technique of “Work/ Rest Assessment” being a function of the Neuro Track system was applied to evaluate introductory and periodical functions of the muscle of the pelvic fundus. The open display was applied as an introductory technique of the therapy. After the intravaginal and a contra lateral electrodes on the thigh surface were applied a patient performed a five time contraction and decontraction of the muscle of the pelvic fundus in the tempo dictated by the computer system (sound signals). The following parameters were assessed: the reaction time to the computer signal, the power of contraction, the stability of contraction (the scale of deviation from the average), the level of decontraction. The values were recorded graphically (a diagram), as well as the numerically, expressed respectively either in microvolts or seconds.
Next the ETS technique under the control of EMG was introduced. The position of the electrodes remained the same. The intensity of stimulation was set in such a way as it made a contraction last and at the same time it was accepted by a patient. One strong contraction performed on the signal defined the threshold. After that the stimulation was switched on. If a patient maintained the contraction above the threshold she received stimulation of previously defined parameters (frequency, width of the stimulus, time of contraction and decontraction, intensity). Overcoming a threshold made it possible to increase it by 20% next time, which at the same time encouraged a patient to pursue for a better performance. The results were all the time monitored by a patient on the screen.
The parameters of a muscle stimulation were individually selected: the frequency in the range of 10–40 Hz, the width of the stimulus 200–250 μs, time work/decontraction in the pattern of 4/4 s or 5/5 s, number of cycles 20–50.

The patients practiced for 12 weeks, 4 times a week.

The parameters which defined the improvement of the therapy were the following:
- Valsava Leak Point Pressure (VLPP) – the pressure of the point of urine leak at the Valsalva trial monitored during a urodynamic test.
- Cough Leak Point Pressure (CLPP) monitored during a urodynamic test
- Average value of the power of a muscle contraction measured in microvolts
- Maximal value of a muscle contraction
- Number of episode of urine incontinence during 24 hours
- Number of hygienic pads and other protective measure used up during 24 hours
- Life Quality Index QOL

Those patients were regarded as healthy ones who, in their questionnaires, reported 0–2 episodes of urine incontinence during a month after the therapy had been completed and the values of CLPP and VLPP in a control urodynamic test were respectively above 180 cm H2O and 110 cm H2O. The values of CLPP more than 160 H2O and VLPP more than 100 cm H2O as well as the decrease of urine incontinence, smaller number of used up pads and the increase of the average muscle contraction by 30% were regarded as a significant improvement.

Other results were found unsatisfactory.

**Results**

All patients completed the therapy satisfactorily. 58% of patients are regarded as healthy ones. 22% reveal significant improvement and have been qualified for further conservative treatment. 20% presented unsatisfactory results. They have been qualified for surgical treatment.

Number of episodes of urine incontinence during 24 hours was 2.3 before therapy, it has decreased to 0.6 after therapy which shows a falling tendency of 1.8 on the average.

Number of used up hygienic pads was 1.8/24 hours before treatment, it has decreased to 0.5 after it, the difference equals 1.3/24 hours. Thirty patients gave up using pads at all.

The CLPP value was on the average 136.5 cm H2O before the therapy, after it – 180 cm H2O. The increase of this parameter was 43.4 cm H2O on the average. Thirty three patients show the value of 180 cm H2O.

The VLPP value before the therapy was on the average 77.9 cm H2O, and after it was completed, the value grew to 101 cm H2O. The increase equals 23.8 cm H2O.

The average muscle contraction (avr) before the therapy was 27 microvolts, after it – 52 microvolts. The increase equals 25 microvolt on the average.

The maximal muscle contraction (peak) was at the beginning 59.7 microvolts, after the therapy it was 94.6 microvolts. The average increase is 35.7 microvolts.

The QOL index was approximately 4 points before the therapy, after it, it was 1.2, which show the difference of 2.8 points on the average.

For statistic calculation the test of average means for two trials was applies, a significant statistic difference between the results of parameters under the research before and after the therapy for the level of essence p <0.001 was indicated.
Diagram 1. The increase of the selected parameters after the therapy completion

Discussion
The basic theory concerning the treatment of urine incontinence was known as the integral theory of urine incontinence by Petros and Ulmsten (5). It assumes that the symptoms of the stress urinary incontinence as well as urgent urinary incontinence are related to the anatomic defect resulted from vagina relaxation and the structures surrounding it, included vaginal ligaments, muscles and the connective tissue of the pelvic fundus.

The biofeedback based on the ETS under the control of the EMG seems to be a method which has an impact upon the cause in the urinary incontinence.

Electromiographic stimulation is a well-known method, it is safe and well recognized. In 1976 Godec et.al. presented the technique and their results (6). The efficiency of the method in long lasting treatment reached the value of 90%. Furthermore, such a behavioral therapy may be connected with a pharmacological therapy. The efficiency of such an approach Burgio at.al. evaluated highly i.e. 84% in 2000 (7).

The Japanese authors assess its efficiency between 59% and 81% (8).

In Burns’ research three groups of patients were compared (non-treated, practising basic exercises, and practising exercises connected with the biofeedback). It was indicated that in the first group (non-treated) the symptoms worsened by 9%, in the second group the improvement reached the value of 54%, in the third group characteristic of a complex therapy the improvement concerned 64%, without a significant difference between the last two groups.

So far a standardized approach as to the length of therapy and the frequency of exercises has not been worked out. Many authors suggest a 8-12 week therapy both in urine incontinence and over-reactive bladder. Because the same authors proved that the over-reactive bladder may be treated in the same way and the symptoms disappear in 75% of cases (10).

The therapy has its advantage in very few counter indications. These are: pregnancy, vagina inflammations, bladder- urine reflux, cancer of the minor fundus.
The authors have not found any counter-indications of the EMG appliance. The producer does not recommend to apply the EMG in the time of menstruation, during the infection of urinary system and among patients who hardly control themselves. Theoretically, during an intravaginal stimulation there may develop irritation of the mucosa, but in our therapy none patients suffered from it.

**Conclusions**
The biofeedback based on the ETS is effective and cheap in treatment of urinary incontinence. The condition of a successful therapy lies in its long duration and consistency. The therapy may also complement a surgical treatment of urinary incontinence.

**Bibliography**