

HIFEM Technology Can Improve Quality of Life of Incontinent Patients

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Background:

Incontinence represents one of the most prevalent female intimate health issues negatively affecting a patients' quality of life (QoL). Currently, incontinence treatment requires a combination of pelvic floor muscles exercising which lacks proof of its therapeutic efficacy, intravaginal electrostimulation or drug treatment with side-effects. Patients are more and more concerned about the negative impact of UI on their life and seek for more efficacious solutions for addressing UI.

Aim:

The aim of this study was to investigate the effect of High-Intensity Focused Electromagnetic (HIFEM) technology on the pelvic floor muscles in incontinent patients.

Methods:

30 patients (N=30 women; mean age 53.05 years) with stress, urge and mixed type of incontinence were included in the pilot study using HIFEM technology by BTL EMSELLA device (BTL Industries Inc.). All patients attended 6 therapies scheduled 2x a week. Patients reported the number of used hygienic pads and completed a King's Health Questionnaire (KHQ) pre-treatment, post-treatment, during 3- and 6-month follow-ups. Additionally, patients reported their subjective feedback.

Results:

After 6 treatments, 95 % of treated patients improved their QoL according to the scores of the KHQ. These results were maintained during 3- and 6-month follow-ups. 67 % of the treated patients reduced or totally eliminated the use of hygienic pads in day-to-day life. 100 % of patients reported better awareness of the pelvic floor muscles.

Conclusion:

Results suggest that HIFEM technology by BTL EMSELLA device significantly improves the QoL of incontinent patients.

Keywords: urinary incontinence, hygienic pads, King's Health Questionnaire, Quality of Life, HIFEM technology, BTL EMSELLA

INTRODUCTION

Urinary incontinence (UI) is defined as an involuntary loss of urine, which objectively and subjectively represents a social, psychological and hygienic problem. It is estimated that 1 in every 4 women aged between 30 and 59 years has experienced a problem with urinary leakage. Estimation of worldwide UI prevalence is around 40 % of the female population. However, a vast majority of the patients is reluctant to discuss this intimate issue with their medical doctors. National Association for Incontinence (NAFC) reports that 4.5 out of 10 patients do not seek help. (1, 11)

Types of urinary incontinence

UI can be divided into 3 types according to its' etiology. Clinical symptoms of stress urinary incontinence (SUI) usually involve involuntary leakage of urine when events with increased intraabdominal pressure are performed (e.g. coughing, sneezing, laughing, lifting etc.). The cause of SUI is due to a loss of support of urethra and deconditioned pelvic floor musculature (PFM), which is usually a consequence of damage to the pelvic support structures. SUI is strongly associated with vaginal childbirth and menopausal hormonal changes (1). The second UI type is associated with a strong desire to void and pathological contractions of the bladder, so-called urge incontinence. Urge incontinence is a neuromuscular dysfunction commonly treated with pharmacotherapy. Urge incontinence is usually a symptom of an underlying problem (e.g. diabetes mellitus). The third UI type is mixed urinary incontinence (MUI) and involves a combination of the SUI and urge incontinence symptoms (1).

Treatment options for urinary incontinence

The choice of treatment for UI depends on its' type and severity. In the case of SUI, treatment options range from pelvic floor muscle exercising, intravaginal electrotherapy up to surgical intervention. Surgical intervention is recommended usually only in severe cases of SUI, whereas drug treatment of urge incontinence is common. A vast majority of patients uses hygienic pads and their quantity depends on the severity of UI and leakage episodes (13, 15)

HIFEM technology

High-intensity Focused Electromagnetic (HIFEM) technology triggers intense pelvic floor muscles contractions by targeting neuromuscular tissue and inducing electric currents. Electric currents depolarize neurons resulting in concentric contractions and lift up of all pelvic floor muscles. Key-effectiveness is based on focused electromagnetic energy, in-depth penetration, and stimulation of the entire pelvic floor area. HIFEM technology brings deep PFM stimulation and restoration of the neuromuscular control. HIFEM passes non-invasively through pelvic floor area. Therefore, it represents a non-invasive solution for incontinent patients, which remain fully clothed during the therapy (2-10, 12, 14-19).

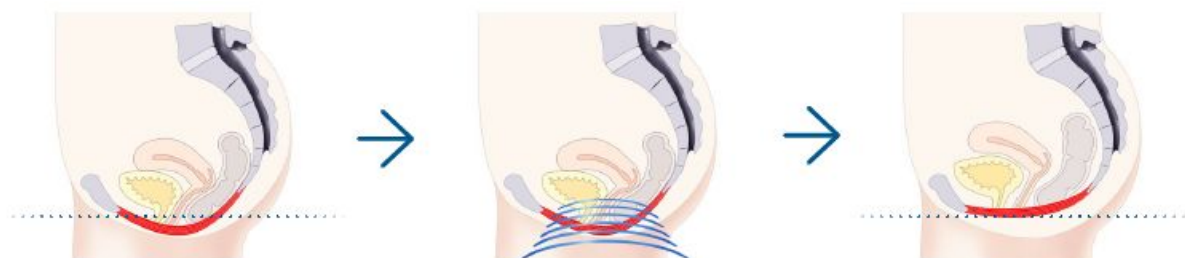


Figure 1: HIFEM technology (BTL EMSELLA device, BTL Industries Inc.)

MATERIALS AND METHODS

Aim

The aim of this pilot study was to evaluate the impact of HIFEM on QoL of incontinent patients. For such purpose 3 hypotheses were created:

- ***H0: Course of treatments with the HIFEM technology will not improve QoL of incontinent patients.***
- ***H1: Course of treatments with the HIFEM technology will improve QoL of incontinent patients.***
- ***H2: Course of treatments with the HIFEM technology will reduce the use of hygienic pads.***

Subjects

Subjects were enrolled in the pilot study after their voluntarily agreement and signed written informed consent. 30 patients (N=30 women) aged between 36 and 76 years (mean age 53.05 ± 11.74) with stress, urge and mixed incontinence were included in the pilot study. UI resulted out as a consequence of vaginal childbirth, hormonal changes (menopause) or through obesity. Device BTL EMSELLA with HIFEM technology (BTL EMSELLA, BTL Industries Inc.) was used in a course of treatments. Patients with pacemakers, metal implants, blood coagulation disorders, tumors, fever, menstruation and pregnant women were not included in this study.

Therapy protocol

All patients attended 6 therapies scheduled 2x a week. Therapy was performed by medical personnel, who positioned the patient into a comfortable sitting position, feet on the floor, hip, knee and ankle joints perpendicularly flexed. 30-minute duration for each treatment session; sinusoid pulse type, frequency range 20-30 Hz with trapezoid intensity modulation were used to achieve gradual motor unit recruitment. Relative intensity (in %) was gradually increased from patients' motor up to above the motor threshold.

DATA COLLECTION

Methodology

The impact of the course of treatments with the BTL EMSELLA on the QoL of incontinent patients was assessed through the King's Health Questionnaire (KHQ). The KHQ consists of 2 parts and detects the general health condition and impact of urinary leakage in patients' socio-emotional life and activities of daily living (ADL) (13). Additional questions to the KHQ were the number of used hygienic pads and subjective patient's feedback. Data was collected pre-treatment, post-treatment and to evaluate the long-term effect, 3- and 6-month follow-ups were completed.

Statistical evaluation

Data of 30 patients was collected and statistically evaluated. During the course of treatment no adverse events occurred and therapy was well-tolerated. KHQ scores were calculated and tested for statistical significance by the means of Student's t-test on the statistical significance level $p < 0.05$. Improvements were compared as follows: between pre-treatment and post-treatment data, between pre-treatment and 3- and 6-month follow-ups data. Patients' reports of the number of used hygienic pads were calculated as statistical frequency of occurrence between pre-treatment and post-treatment data, between pre-treatment and 3- and 6-month follow-ups data. Additionally, subjective feedback was collected from all patients. The frequency of answer occurrence was calculated.

RESULTS

The King's Health Questionnaire results

The KHQ has two parts – Part 1 reports about the general health perception; Part 2 reports about the incontinence impact on the patient's life. The scores are calculated separately. The research results proved/disproved following hypotheses and are discussed in the text below:

- *H0: Course of treatments with the HIFEM technology will not improve the QoL of incontinent patients.*

H0 hypothesis disproved. All patients (n=30) have improved their QoL after a course of treatment with the HIFEM technology, which was proved by H1.

- *H1: Course of treatments with the HIFEM technology will improve the QoL of incontinent patients.*

H1 hypothesis proved. After course of treatment with the HIFEM technology, 95 % of treated patients reported improvement in the QoL according to the scores of the KHQ. Before the therapy, the average score of the KHQ-Part 1 was 82.08 points. After course of treatment with the HIFEM technology, the average score of the KHQ-Part 1 was 51.67 points, which decreased to 45.42 points

during 3 months and to 48.33 points during 6 months, respectively. These improvements are demonstrated as 37%, 42% and 38% levels of improvement in general health perception ($p < 0.05$).

Before the therapy, the average score of the KHQ-Part 2 was 187.50 points. After a course of treatment with the HIFEM technology the average score of the KHQ-Part 1 was 103.75 points, which decreased to 81.11 points during 3 months and further to 74.44 points during 6 months, respectively. These improvements are demonstrated as 37%, 55% and 57% levels of improvement ($p < 0.05$).

Parameter	Q part 1	Q part 2
Score BEFORE (Mean±SD)	82.08±29.53	187.50±119.24
Score AFTER (Mean±SD)	51.67±33.62	103.75±83.07
Score, 3mFU, (Mean±SD)	45.42±26.83	81.11±64.94
Score, 6mFU, (Mean±SD)	48.33±23.66	74.44±58.03
Improvement BEFORE/AFTER	30.42±27.42	83.75±82.59
Improvement BEFORE/3mFU	36.67±31.67	106.39±85.84
Improvement BEFORE/6mFU	33.75±29.75	113.06±90.43
Level of improvement BEFORE/AFTER	37%	37%
Level of improvement BEFORE/3mFU	42%	55%
Level of improvement BEFORE/6mFU	38%	57%

Figure 3: Results of the KHQ score

SD = standard deviation; 3m FU = 3-month follow-up; 6m FU = 6-month follow-up

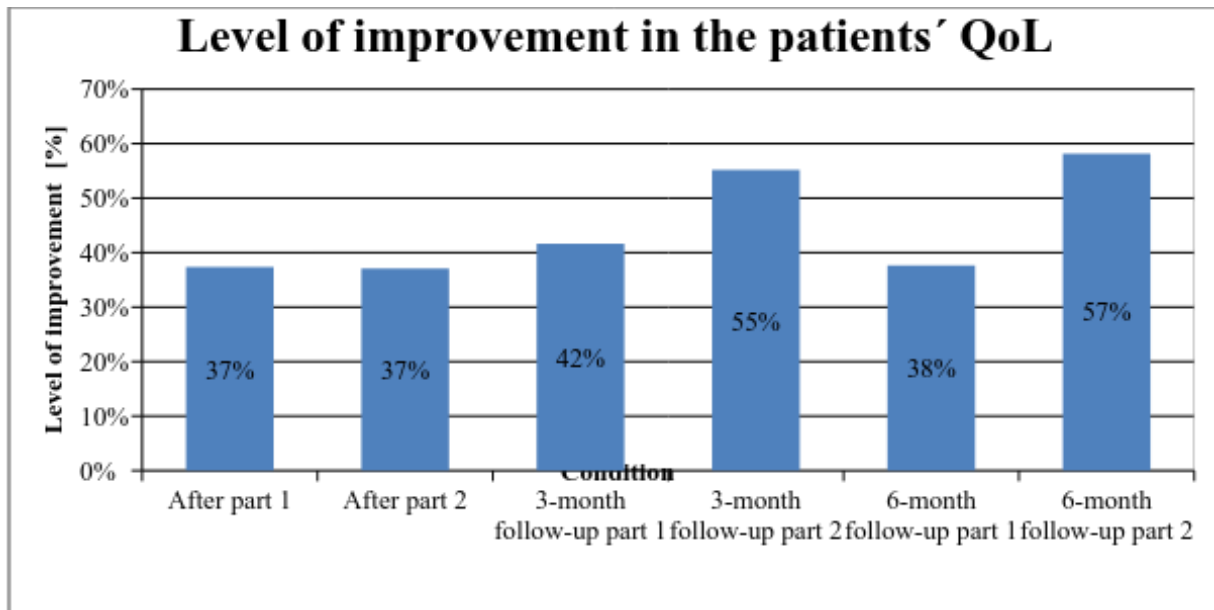


Figure 4: Level of improvement in the patients' QoL according to the KHQ scores

The results of use of hygienic pads

- *H2: Course of treatments with the HIFEM technology will reduce the number of used hygienic pads.*

H2 hypothesis proved. In this study, 12 patients wore hygienic pads during the day and night. Before the therapy, average number of used hygienic pads was 1.1 pad per day and night. After a course of treatment, 67 % (n=9) of treated patients totally eliminated or decreased the average number of used hygienic pads decreased to 0.45 pad per days and night. The results were maintained during the 3- and 6-month follow-ups.

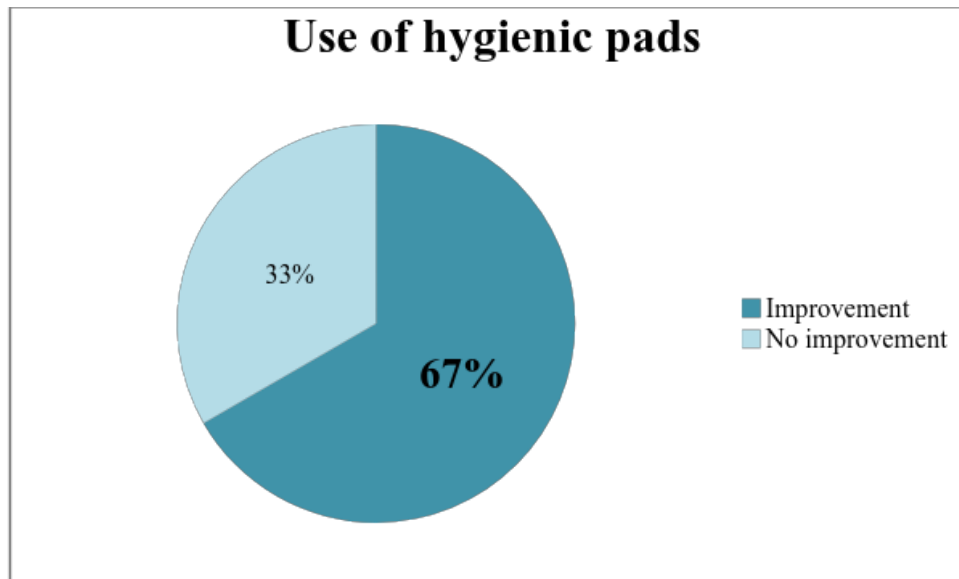


Figure 5: Use of hygienic pads

The patients' subjective evaluation of the therapy

Additionally, patients answered the question 'What is the major difference you noticed after the BTL EMSELLA therapies?'

40 % of patients reported that they are able to perform proper contraction of the PFM; 28 % of patients were able to contract PFM selectively; 20 % of patients reported better muscle firmness and 12 % of patients reported that the period between mictions is longer. Additionally, all patients (n=30; 100 %) reported better awareness of pelvic floor muscles.

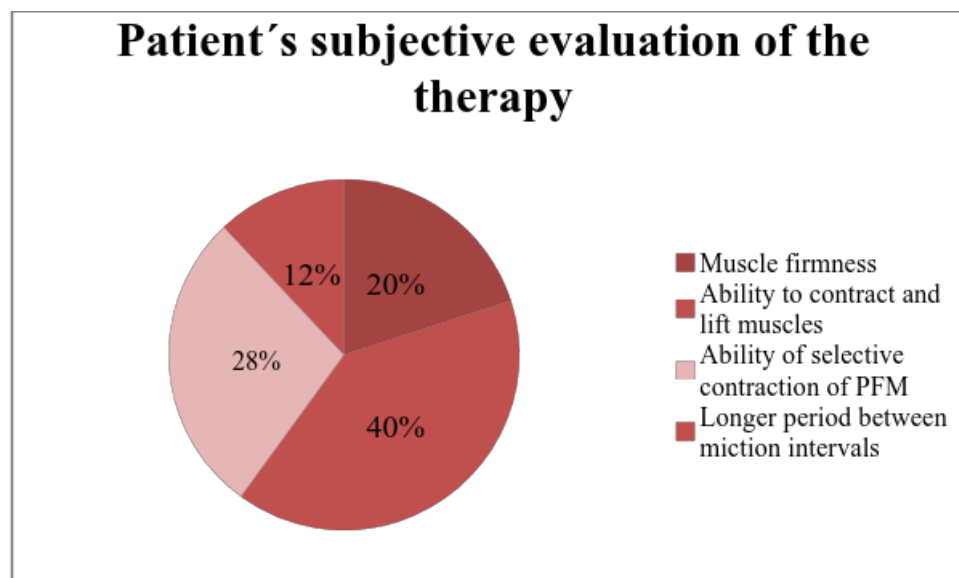


Figure 6: Patients subjective evaluation of the therapy

PFM = pelvic floor muscles

Discussion

To regain continence, regular pelvic floor muscles exercising is required. Normally, 300-500 contractions of the pelvic floor muscles should be performed to begin to develop a new motor pattern, whereas 3,000-5,000 contractions are required to erase and correct poor motor pattern. During 1 session using HIFEM technology, thousands PFM contractions are performed. This method is extremely important to PFM re-education as the patients are not able to perform this high-repetition rate pattern due to PFM weakness and an inability to consistently contract this muscle group. After 6 therapeutic sessions with HIFEM therapy, patients developed the new motor pattern needed to better control pelvic floor muscles and also regained muscle strength and continence control (3-9, 12-16).

Conclusion:

UI represents a significant psycho-socio-economical healthcare problem that has a major negative impact on today's modern lifestyles. The majority of patients are not satisfied with the current treatment methods offered, which include surgical intervention, drug therapy, pelvic floor muscles exercising (Kegel) or minimally invasive intravaginal procedures. This latest research, as well as, previous studies suggest that HIFEM technology leads to significant improvement in QoL of incontinent patients, maintains a patient's privacy all while avoiding more invasive approaches.

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