
HIFEM PROCEDURE ENHANCES QUALITY OF LIFE OF ELDERLY MEN WITH POST-PROSTATECTOMY INCONTINENCE

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ABSTRACT

Background: Post-prostatectomy incontinence (PPI) is a common and bothersome side effect of the surgery which may be persistent. Aim of this pilot study is to document the change in quality of life (QoL) of subjects with PPI treated by High-Intensity Focused Electromagnetic (HIFEM) procedure.

Materials and methods: Ten male subjects (72.90±3.90 years) with history of prostatectomy accompanied by persistent PPI were recruited. They received six 28-minute HIFEM treatments spaced two treatments per week. Change in subject's QoL was monitored by using standardized King's Health Questionnaire (KHQ) at the baseline, after the last therapy, at 1 month, and 3 months. The usage of absorbent pads was assessed by 24-hour Pad Usage questionnaire. Data was statistically analyzed and tested for normality ($\alpha=5\%$).

Results: All patients showed improvement of QoL after HIFEM treatments. KHQ score decreased significantly in both parts of questionnaire (30.8 points in Part I, $P=0.002$; 107.5 points in Part II, $P=0.001$) revealing that subjects improved most in the domains: incontinence impact (23.3 points; $P=0.01$), social limitations (21.1 points; $P=0.01$), emotions (18.9 points; $P<0.001$), role limitations (18.3 points; $P=0.03$), and sleep/energy (13.3 points; $P=0.04$). All of the differences in domain scores exceeded the minimally clinically important difference of 5 points. The 1-month and 3-month data showed further improvement in subject's QoL. All ten subjects were using absorbent pads at the baseline. Post-treatment, they reported average reduction of 1.0 absorbent pad per day. Also, two subjects were pad free after the last therapy. HIFEM procedure was safe and no adverse event was found.

Conclusion: The first use of HIFEM procedure for the treatment of PPI in men showed that HIFEM can significantly improve QoL immediately after the last treatment and this improvement may be sustained. In future research, it is necessary to identify longevity of achieved outcomes.

INTRODUCTION

Surgical removal of prostate referred as radical prostatectomy is one of the most common therapeutic options for patients with localized prostate cancer¹⁻³. Despite the latest advancements in surgical techniques and therapeutic approaches, still post-prostatectomy incontinence (PPI) is a commonly reported side effect of the operation with prevalence reaching up to 60%². Although patients may recover from PPI in one year post surgery, as much as 65% of them continue to experience incontinence symptoms beyond 12 months^{4,5}.

During surgery the prostatic segment of urethra is being removed with occasional intraoperative damage to intrinsic and striated urethral sphincters along with impairment of detrusor contractility, triggering the PPI^{1,6,7}. Urodynamic examination revealed that vast majority of incontinent men after prostatectomy tend to describe symptoms consistent with stress urinary incontinence (SUI)⁸. There are also several risk factors which increase the subjects predisposition to develop PPI, including pre-existing abnormalities of bladder function, high body mass index, and advancing age^{2,9}.

PPI is a clinically significant and distressing condition. It has a high impact on quality of patient's life (QoL)³, negatively affects mental health and subsequently leads to social isolation¹⁰. Nevertheless, due to the similar etiology of PPI and SUI, the non-surgical strengthening of pelvic floor muscles (PFM) may be effectively used to recover subject's continence and self-esteem.

Continence in men depends on the contribution of urethral constriction by striated muscles which maintains its activation during urine storage and prevents urine leakage when intra-abdominal pressure is suddenly raised during physical activities⁶. To enhance muscular control of urinary incontinence (UI), patients are recommended to perform pelvic floor muscle training (PFMT) by teaching an accurate voluntary PFM contractions timed against increases in intra-abdominal pressure². However, the conventional PFMT faces the difficulty to selectively engage the PFM and patients may not be able to sustain the intensity of contractions.

We hypothesized that High-Intensity Focused Electromagnetic (HIFEM) procedure may be a promising alternative for a non-invasive PPI treatment. It utilizes time-varying magnetic fields of great intensities which selectively targets neuromuscular tissue to induce supramaximal PFM contractions. In contrast to voluntary contractions, the supramaximal contractions are of higher tension and they can be easily sustained, therefore the muscles are encouraged to improve its strength and function. The efficacy of HIFEM procedure for UI treatment and QoL changes in women has been established by the recent research¹¹⁻¹⁴, nonetheless its effectiveness in men is not clear yet.

The aim of this pilot study is to document changes in quality of life following HIFEM procedure in male population suffering from persistent PPI.

MATERIALS AND METHODS

Ten elderly men with average age of 72.90 ± 3.90 years were recruited. All of them had a history of radical prostatectomy (2014-2017) accompanied with continuous PPI symptoms. At the time of enrollment, they were examined for medical history and eligibility with inclusion/exclusion criteria listed in the manual of investigated device. The study was carried out with respect to generally accepted ethical standards stated in Declaration of Helsinki and all subjects signed informed consent prior to the treatments.

In the course of three weeks the subjects were required to undergo six 28-minute HIFEM procedures (2 sessions per week). Treatments were performed over the pelvic area by utilizing EMSELLA device (BTL Industries Inc., Boston, MA; see Figure 1), capable of inducing supramaximal PFM contractions. EMSELLA uses flat spiral coil to generate HIFEM fields which may be modulated according to the patient's tolerability on the scale from 0-100% (2.5 Tesla). As the proper positioning is necessary to maximize therapy

outcomes, subject's posture was supervised by the therapist and verified by using device's positioning system to achieve optimal PFM contractions.



Figure 1: Subject device. The spiral coil is embedded in the center of the therapeutic chair and connected to the main unit which supplies the whole system with power and allows operator to adjust therapy settings.

The evaluation of change in subject's QoL was assessed by the standardized King's Health questionnaire (KHQ, Part I and Part II) and 24-hour Pad Usage questionnaire at baseline and after completion of the treatments. The 1-month and 3-month follow-up visits have been scheduled as optional. Subjects were monitored throughout the whole study for occurrence of any adverse events.

Obtained results were compared to baseline and statistically analyzed by two-tailed paired t-test with level of significance set as 5%. Normality of data was verified by the Shapiro-Wilks test for normality.

RESULTS

All subjects successfully finished the treatments while three subjects completed also the 1-month and 3-month non-mandatory visits. The KHQ showed significant improvement in QoL of all treated patients. The total baseline KHQ score was significantly reduced from 426.9 ± 117.5 to 288.6 ± 133.4 points. The improvement was seen in both parts of questionnaire. Score of Part 1 (general health perception and incontinence impact) decreased on average from 114.2 ± 24.2 to 83.3 ± 26.4 points (-27.0%; $P=0.002$) post treatment, whereas Part II (role limitations, physical limitations, personal relationships, emotions and sleep/energy, severity measures) showed even more pronounced improvement from 312.8 ± 98.1 to 205.3 ± 93.9 points (-34.4% $P=0.001$).

The change in score divided according the particular KHQ domains is shown in Figure 2. Detailed analysis revealed that subjects improved most in sleep/energy domain (-13.3 points, 53.3%; P=0.04), emotions (-18.9 points, 42.5%; P<0.001) and social limitations domain (-21.1 points, 42.2%; P=0.01) which indicated a significant shift in subject's QoL. The greatest absolute improvement in score was observed in the incontinence impact domain, as subjects reported reduction of 23.3 points (-30.4%; P=0.01). Also, the role limitations domain, which refers to limitations of daily

8, who also showed continuous improvement of QoL at 1 month which persisted at 3 months. Nonetheless, subject No. 6 was not able to sustain treatment-induced changes at 3 months and reported slight elevation of score in both parts of KHQ, since he returned to his post-treatment values.

24-hour Pad Usage questionnaire revealed that all of the subjects were using absorbent pads at baseline with an average use of 2.5 pads per day. In addition, four subjects reported they wore pads at night due to the nocturia. After

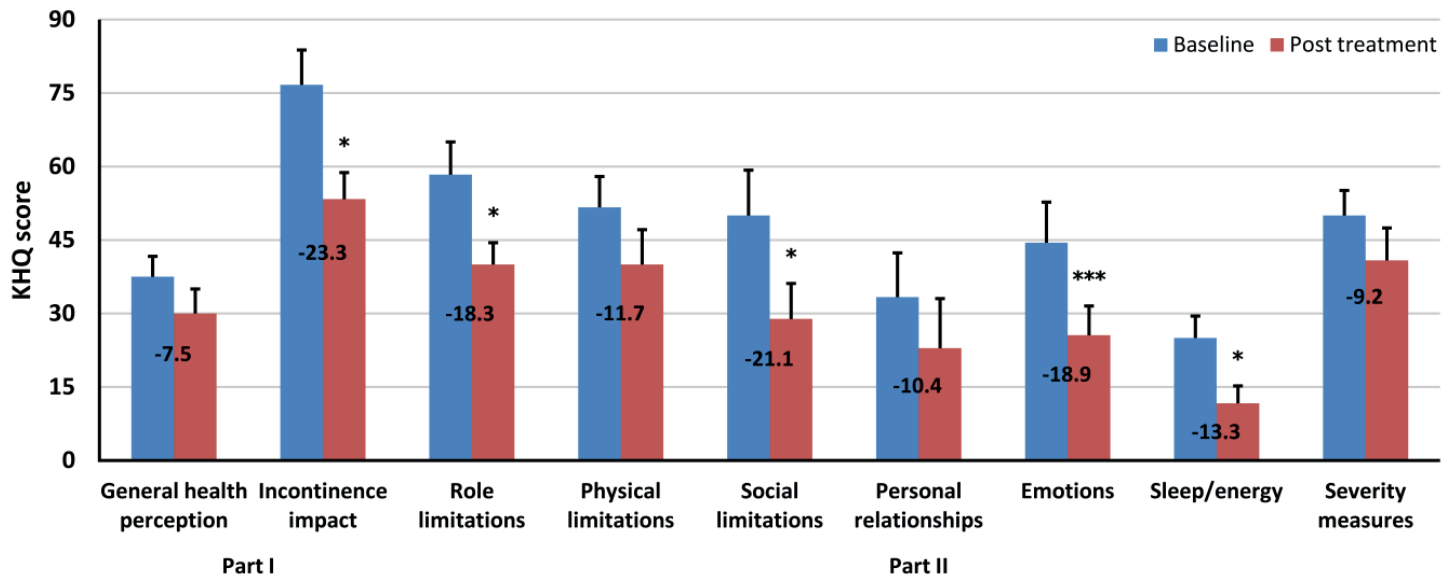


Figure 2: Difference in mean KHQ score achieved in particular KHQ domains (mean ± standard error). Maximum score of each domain is 100 points. Lower scores indicate patient wellbeing and higher scores mean that the QoL is severely affected by the PPI. The statistical significance of difference in score is highlighted by the asterisk (*P<0.05; ***P<0.001).

activities, showed substantial improvement of 18.3 points (31.4%; P=0.03). In general, all of the differences in domain scores exceeded the minimal clinically important difference (MCID) of 5 points, suggested by Kelleher et al¹⁵.

Further improvement was seen at 1 month in those subjects (N=3) who referred to their follow-up visits (see Table 1). Documented results suggest that effect of HIFEM procedure may improve in time as the examined patients showed a decrease in Part I and Part II scores at 1 month. Subject No. 5 even reached zero score in Part I of the KHQ, meaning that incontinence did not affect his life and he also rated his health condition as “very good”. Results of subject No. 5 persisted up to 3 months followed with noticeable improvement in Part II of the questionnaire, leading to overall score of 16.7 points (reported in physical limitations domain). Similar tendency was observed in subject No.

the treatments the whole patient group reduced pad usage on average by 1.0 pad (1.5 pads per day on average). Furthermore, two subjects reported to be pad free and two out of four subjects achieved complete reduction of pads used during the sleep.

DISCUSSION

Post-prostatectomy incontinence considerably compromises men's quality of life. As health-related QoL is a multidimensional construct, it involves all aspects of human wellbeing including health status in general, physical activities, psychological state and social interactions¹⁶. Therefore, many individuals are seeking for an effective treatment options, hoping that they no longer have to worry about the inability to control their bladder during their day-to-day activities. This study documented that HIFEM procedure may be effectively used for treatment of PPI.

The present results showed clinically significant decrease in all KHQ domains which also corresponds with reduced usage of absorbent pads. The procedure was safe and no adverse event was documented.

Previous studies have described that impact of PPI can be reduced by PFM strengthening by the means of pelvic floor muscle exercises or electromagnetic stimulation^{2,5}. Majority of the papers studied the evolution of UI and QoL in the 12-month post-treatment period or evaluated effects

This study documented significant improvement in QoL after only six HIFEM treatments. Presumably, adding additional two to four treatments according to the severity of subject's symptoms may result into more noticeable improvement. At baseline subjects achieved highest KHQ score in the incontinence impact domain, followed by the role limitations, physical limitations, social limitations, emotions and severity measures domains, which in general corresponds to severe post-operative UI¹⁹. The greater is the urinary loss, the greater impact it has on these domains of QoL.

ID	Part I score (range 0-200)				Part II score (range 0-700)			
	Baseline	Post treatment	1 month	3 months	Baseline	Post treatment	1 month	3 months
5	83.3	33.3	0.0	0.0	244.4	83.3	41.7	16.7
6	116.7	116.7	58.3	91.7	233.3	194.4	186.1	222.2
8	91.7	83.3	58.3	58.3	275.0	202.8	113.9	113.9

Table 1: KHQ score (Part I and Part II) of subjects at 1 month and 3 months.

of pre-operative PFMT on male continence as the PPI is iatrogenic, therefore predictable and perhaps preventable¹⁷. Although it was found that patients with stronger PFM need less time to be continent after the surgery, and at the same time they report higher QoL levels, the evidence is still limited due to the lack of randomized controlled trials^{2,18,19}. Also the exercise protocols may possibly fail to properly target the muscles that control continence in men or do not target the aspect of function that needs to be trained⁶.

The PPI is associated with impaired functioning of striated urethral sphincter, pubovisceralis, bulbocavernosus, and levator ani muscles which cannot fully compensate the prostate removal, thus control urethral pressure and prevent descent from excessive abdominal pressure^{20,21}. Therefore, it is hypothesized that optimal treatment strategy should aim to target these particular muscles. HIFEM procedure utilizes non-invasive and painless electromagnetic stimulation of pelvic floor. It selectively activates motor neurons²² that innervate striated muscles. The high repetition rate of stimulation forces muscles to perform intense supramaximal contractions which lead to enhanced strength, endurance²³, and re-education. Due to the great penetration, depth, and zero attenuation of magnetic field in biological tissues²⁴; the HIFEM procedure is able to effectively stimulate the muscles involved in the male continence mechanism, treat incontinence and consequently improve QoL.

As the severity of incontinence symptoms decreased after the treatments, patients showed uniform improvement in all KHQ domains accompanied with a reduced number of pads used. The examination showed that elderly subjects with persistent PPI appreciated that they were less limited in their social life (being able to visit relatives without being afraid of urine leakage) or when performing daily/physical activities and they also slept better. Emotions domain showed that patients did not feel depressed due to the PPI after the treatments and in general, they reported a more pro-active life style.

We see the strength of our study in detailed analysis of KHQ which is complex, highly reliable, and validated questionnaire that covers important aspects of patient's QoL. On the other hand there are several limitations in this pilot research. The sample size of ten subjects is relatively small and enables only basic statistical analysis. Furthermore, this study lacks solid follow-up data, since only three subjects referred to their 1-month and 3-month follow-ups. In future studies it would be mandatory to observe prolonged effect of HIFEM procedure on QoL similarly to Yamanishi et al¹⁹, as the individual results of subjects 5,6, and 8 suggest that outcomes may considerably improve over time. This coincides with the findings of Frontera et al²⁵, who observed significant and continuous muscle changes in an elderly man in a 12-week period (approximately 3 months) after the strength training

program. Results may be also influenced due to the specific patient group consisting of elderly men (average age of almost 73 years), where muscle response is mediated through a combination of hypertrophy and neural adaptation²⁶, and strength gains (although substantial), may be less than in young individuals. Moreover, the male urinary incontinence is being often associated with erectile dysfunction²⁷. Since sexual function is also an integral part of QoL, later studies should consider assessing its changes as well.

CONCLUSION

This pilot study documented the first use of HIFEM procedure for the treatment of persistent post-prostatectomy incontinence

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