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Research Article

HIFEM Procedure Enhances the Quality of Life in Elderly Men with Post-Prostatectomy Incontinence: A Pilot Study

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ABSTRACT

Objective: Post-Prostatectomy Incontinence (PPI) is a common and bothersome side effect of the surgery, which may be persistent. This pilot study aims to document the change in the Quality of Life (QoL) of subjects with PPI treated by the HIFEM procedure.

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

Results: Each of the patients (n=10) showed improvement in QoL after HIFEM treatments. KHQ score decreased significantly in both parts of the questionnaire by 27.0% and 34.4% respectively (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 (-30.4%; 23.3 points; P=0.01), social limitations (-42.2%; 21.1 points; P=0.01), emotions (-42.5%; 18.9 points; P<0.001), role limitations (-31.4%; 18.3 points; P=0.03), and sleep/energy (-53.3%; 13.3 points; P=0.04). All of the differences in domain scores exceeded the minimal clinical significance difference of 5 points. All ten subjects were using absorbent pads at the baseline. Post-treatment, patients reported reduction in pad usage of 1.0 absorbent pad per day on average. Additionally, two subjects were completely pad-free after the last therapy. The HIFEM procedure was concluded to be safe without any adverse event occurrence.

Conclusion: This pilot study investigating the therapeutic effects of the HIFEM procedure in a male population has shown a significant improvement in all domains of QoL as per KHQ immediately following the last treatment. Available data points towards a promising solution for PPI, giving the affected men their lives back.

Keywords: Post-prostatectomy; Incontinence; Non-invasive; Electromagnetic muscle stimulation; Pelvic Floor Muscles; HIFEM; Quality of Life (QoL)

INTRODUCTION

Radical Prostatectomy (RP) is one of the most common therapeutic options for patients with localized prostate cancer [1-3]. Despite the latest advancements in surgical techniques, high survivability rates and good outcome prospects, as much as 65% of the RP patients continue to experience incontinence symptoms up to 5 years' post-treatment [4,5]. During the surgery, the prostatic segment of the urethra is removed with occasional intraoperative damage to the intrinsic and striated urethral sphincters, along with impairment of detrusor contractility, causing PPI [1,6,7]. Additionally, risk factors associated with developing PPI include pre-existing abnormalities of bladder function, high body mass index, and advancing age [2,8].

PPI is a life-altering and distressing condition. Urodynamic examination reveals that most post-prostatectomy incontinent men tend to describe symptoms consistent with Stress Urinary Incontinence (SUI) [9]. Incontinence dramatically impacts the quality of patients' lives (QoL) [3], negatively affecting mental health, social life and intimacy, eventually leading to social isolation [10]. However, due to the etiological similarities of PPI and SUI, non-surgical strengthening of Pelvic Floor Muscles (PFM) may be a viable treatment in recovering continence and giving these men their lives back.

Continence in men is maintained via urethral constriction by striated muscles [11]. Likewise, these muscles' strength facilitates urine storage and prevents urine leakage, especially when intra-

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abdominal pressure is suddenly raised, such as during physical activity [6]. In order to enhance muscular control of Urinary Incontinence (UI), patients are recommended to perform Pelvic Floor Muscle Training (PFMT) [2]. However, the conventional PFMT may fail to engage the PFM selectively, and the patients may not be able to sustain the intensity of contractions [12].

HIFEM procedure utilizes time-varying magnetic fields that selectively target neuromuscular tissue, causing supramaximal PFM contractions. In contrast to the voluntary contractions, the HIFEM-induced supramaximal contractions are of higher intensity and sustained tension. The efficacy of the HIFEM procedure for UI treatment and QoL changes in women has been well documented [13,14]. As the HIFEM treatment targets the pelvic floor muscles, it is postulated that an analogous mechanism of action targets the same muscles in male populations due to anatomical similarities.

This pilot study aims to document the changes in quality of life following the HIFEM procedure in the male population suffering from persistent post-prostatectomy incontinence.

MATERIALS AND METHODS

The study was initiated in January 2019 with the enrollment of ten elderly men with an average age of 72.90 ± 3.90, a history of radical prostatectomy (2014-2017), continuous PPI symptoms and active pad usage. A review of participants' medical history, along with an evaluation of inclusion and exclusion criteria, was conducted during enrollment. The study was carried out respecting ethical standards stated in the Declaration of Helsinki, and all subjects signed informed consent before the treatments. The study was concluded in December 2019.

The subjects underwent six 28-minute HIFEM procedures delivered twice weekly for three consecutive weeks. Treatments were performed over the pelvic area using the EMSELLA device (BTL Industries Inc., Boston, MA; see Figure 1), which uses HIFEM technology to induce supramaximal PFM contractions.

EMSELLA uses a flat spiral coil to generate a magnetic field (2.5 Tesla) to target pelvic muscles. The intensity of this field can be adjusted according to the patient's feedback from 0%-100%. The patient should sit in the center of the chair applicator (Figure 1) during the procedure with their spine straight. The chair's height can be adjusted to ensure the patient's feet are on the ground. As proper positioning is necessary to maximize therapy outcomes, the subject's posture was supervised by the therapist and verified by using the device's positioning system to achieve optimal PFM contractions.

The evaluation of change in the 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 last treatment. KHQ Part I assesses general health perception and incontinence impact. KHQ Part II investigates role-, physical- and social limitations, personal relationships, emotional state, sleep/energy levels and severity measures. The questionnaire assesses quality of life with a 5-point Likert scale for the General Health perceptions, a 4-Point Likert scale with an addition of "Non-Applicable" option for the personal relationships domain, and a 4-Point Likert scale for the seven other domains. Each domain is scored separately according to the KHQ procedure. It is important to note that the lower the score the better QoL. The obtained results were compared to the baseline and statistically analyzed by a two-tailed paired t-test with the level of significance set as 5%. The Shapiro-Wilks test for normality verified the normality of data.

Figure 1: HIFEM 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 the operator to adjust therapy settings.

RESULTS

All subjects successfully finished the treatments. The KHQ showed significant improvement in the QoL of all treated patients. The total baseline KHQ score was significantly reduced from 426.9 ± 117.5 to 288.6 ± 133.4 points following the last therapy, indicating a significant improvement in both questionnaire domains. The score of Part I decreased on average from 114.2 ± 24.2 to 83.3 ± 26.4 points (-27.0%; P=0.002), whereas Part II showed significant improvement from 312.8 ± 98.1 to 205.3 ± 93.9 points (-34.4% P = 0.001) post-treatment.

The change in score divided according to the particular KHQ domains is shown in (Figure 2). Detailed analysis revealed that subjects improved the most in the 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 indicates a significant shift in subject's QoL. The most notable improvement in score was observed in the incontinence impact domain, as subjects reported a reduction of 23.3 points (-30.4%; P =0.01). Additionally, the role limitations domain, which refers to limitations of daily activities, showed a substantial improvement of 18.3 points (31.4%; P=0.03).

The 24-hour Pad Usage questionnaire revealed that all subjects were using absorbent pads at baseline with an average of 2.5 pads per day. Four subjects reported they wore pads at night due to the nocturia. After the treatments the whole patient group reduced pad usage on average by 40%. Furthermore, two subjects reported being completely pad-free and two out of four subjects that wore pads at night due to nocturia reported that they did not need to wear pads during night after the treatments.

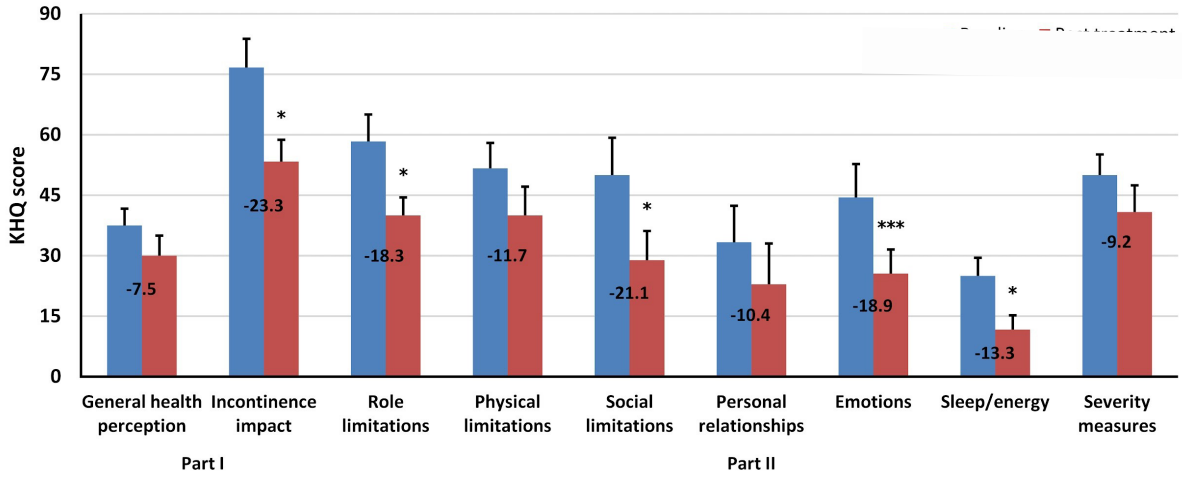

Figure 2: Difference in mean King's Health Questionnaire (KHQ) score achieved in particular domains (mean ± standard error). The maximum score of each domain is 100 points. Lower scores correlate with patient well-being; higher scores indicate that PPI severely affects the patients' quality of life. Note: The asterisk highlights the statistical significance of the score difference (*P<0.05; ***P<0.001) (■) Baseline; (■) Post treatment.

DISCUSSION

Post-prostatectomy incontinence considerably compromises men's quality of life. As health-related QoL is a multidimensional construct, it encompasses all aspects of well-being, including general health, physical activity, psychological welfare, and social life [15]. Therefore, many individuals seek effective treatment options, hoping to alleviate the anxiety of the inability to control their bladder during their day-to-day activities. The present study documents that the HIFEM procedure may be effectively used to treat PPI. The results show clinically significant decreases in all KHQ domains corresponding to the reduction of absorbent pads used. No adverse effects were reported, indicating the procedure's safety.

The PPI is associated with impaired functioning of the striated urethral sphincter, pubovisceralis, bulbocavernosus, and levator ani muscles, which cannot fully compensate for prostate removal, compromising urethral control from excessive abdominal pressure [16,17]. Therefore, the hypothesis is that the optimal treatment strategy should target the aforementioned muscles. HIFEM procedure utilizes non-invasive and painless electromagnetic stimulation of the pelvic floor. It selectively activates motor neurons that innervate striated muscles [18]. The high repetition rate of stimulation forces muscles to perform intense supramaximal contractions, which leads to enhanced strength, endurance, and re-education [19]. Due to the great penetration depth, and zero attenuation of the magnetic field in biological tissues, the HIFEM procedure can effectively stimulate the muscles involved in the male continence mechanism, treat incontinence, and consequently improve QoL [20].

Studies focusing on the onset of UI and QoL in the 12-month post-treatment period, and the evaluation of pre-operative PFMT on male continence, conclude that PPI is iatrogenic; therefore, predictable and perhaps preventable [21]. It has been demonstrated that the impact of PPI can be reduced by pelvic floor muscle strengthening via PFM exercises or electromagnetic stimulation [2,5]. It was found that patients with stronger PFM need less time on average to be continent after the surgery and concurrently report higher QoL levels [2,22,23]. However, the exercise protocols may fail to target the muscles that control continence in men accurately, or in the very least, do not target the aspect of function that needs to be trained [6]. A comparative study concluded that HIFEM technology surpasses electrostimulation treatments, offering greater improvements [14].

This study documented significant improvement in QoL after six HIFEM treatments. Additional two to four treatments, according to the severity of the subjects' symptoms, may yield all the more significant results. At the baseline, the subjects achieved the highest KHQ score in the incontinence impact domain, followed by role limitations, physical limitations, social limitations, emotions and severity measures domains, which generally correspond to severe post-operative UI [21]. The greater the urinary loss, the greater impact it has on these domains of QoL. As the severity of incontinence symptoms decreased after the treatments, patients showed uniform improvement in all KHQ domains, accompanied by a reduced number of pads used. The examination showed that elderly subjects with persistent PPI appreciated improvements in their social lives (being able to visit relatives without urine leakage anxiety), performing daily/physical activities and gaining invaluable quality sleep. Emotion domain showed that patients no longer suffer PPI related depression and in general report a more proactive lifestyle. In general, all of the differences in domain scores exceeded the Minimal Clinically Important Difference (MCID) of 5 points, as suggested by Kelleher et al [24].

KHQ is a complex, highly reliable, and validated questionnaire that covers important aspects of a patient's QoL. It allows for a deep insight into the lives of the PPI affected. However, the sample size of ten subjects is relatively small and enables only basic statistical analysis, posing a limitation in the study. Furthermore, the lack of mandatory follow-up resulted in data collection at post-treatment only. It would be of great interest to track the long-lasting effects of HIFEM procedure on QoL similarly to Yamanishi et al [23]. This coincides with the findings of Frontera et al [25], who observed significant and continuous muscle changes in elderly men over a 12-week period (approximately 3 months) after the strength training program. Additionally, the patient demographic, particularly the

age, may have played a role in the results obtained. Muscle response is mediated through a combination of hypertrophy and neural adaptation [26], and the strength gains (although substantial), may be less in younger individuals. Moreover, the male urinary incontinence is often associated with erectile dysfunction [27]. Sexual function being an integral part of QoL, merits consideration in prospective studies.

CONCLUSION

The pilot study documents the effects of the HIFEM procedure across a population of 10 elderly men in treating persistent post-prostatectomy incontinence. The results demonstrate that HIFEM is not only a viable but an excellent option in the fight against PPI. The participants have displayed a significant improvement in all affected aspects of their lives, including significant pad reduction usage, and a considerable 30.4% (P=0.01) reduction in the Incontinence Domain of KHQ. Further investigation is needed to verify the longevity of achieved changes and thus establish HIFEM as a convenient, non-invasive, first-line modality for the treatment of male incontinence.

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