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REVIEW OF THE USE OF INTRAVAGINAL HIFU THERAPY FOR THE TREATMENT OF VULVOVAGINAL ATROPHY, STRESS URINARY INCONTINENCE AND WIDE VAGINA SYNDROME

This review article reviews the published results of the clinical use of intravaginal non-invasive HIFU therapy for the treatment of urogenital atrophy, stress urinary incontinence, and wide vagina syndrome. Vaginal distension and genitourinary syndromes of menopause create physical, psychological, and functional problems for women and their partners. Existing invasive treatments can lead to certain complications, so safer and more effective minimally invasive medicine is desirable. Our goal was to evaluate the efficacy and safety of microfocus ultrasound therapy as a form of non-invasive HIFU therapy administered in the vaginal canal in female patients. This review uses the results of a number of recent studies from Argentina, Poland, Japan and other countries using medical devices: Feminine HIFU, manufactured by Sveltia, Argentina, and Ultra Vera, manufactured by Hironic, Republic of Korea.

The purpose of the study is to study the results of the clinical application of high-intensity focused ultrasound as a new treatment method in the field of gynecology.

High Intensity Focused Ultrasound (HIFU) is a new technology in gynecology that involves regenerative thermal effects on deeper layers of vaginal tissues that cannot be achieved with laser and radio frequency equipment. The results of studies with a total number of participants in more than 100 patients from several groups who underwent clinical examination support suggestions for a potential therapeutic effect as a preferred method of therapy or an addition to laser and other methods of treatment, supported by an evidence base.

The value of the study is to provide effective treatment of pathologies due to the formation of new collagen fibers that create a structural framework in the fascial plate of the vagina and adjacent fascia, and the muscles of the small pelvis due to a certain mode of HIFU exposure. The results are promising and motivate further research.

Key words: High Intensity Focused Ultrasound; microfocused ultrasound; HIFU; MFU; relaxed vagina syndrome, vulvovaginal atrophy; stress urinary incontinence; genital prolapse.

Introduction

Stimulation of tissue regeneration of the urogenital tract using devices based on the supply of thermal energy is used in gynecology for the treatment of vulvovaginal atrophy syndrome, relaxed vagina syndrome, genital prolapse and mild to moderate stress urinary incontinence.

The prevalence of urinary incontinence among women is 25-45%, increasing with age and exceeding 40% among women aged 70 years and older [1]. As an aging society further progresses in the future, the most effective and minimally invasive treatments possible are desirable.

Numerous histological and clinical data are presented in world practice [2-3], which prove the restoration of the tissues of the genitourinary tract after hardware thermal exposure. International associations of obstetricians and gynecologists repeatedly present such studies. Discussions about

which method of treatment is more effective, and safe will continue [4].

The proposed method is based on the use of HIFU, a non-invasive procedure using a controlled and regulated thermal effect of a high-intensity focused ultrasound wave. This study uses a particular type of HIFU technology – microfocused ultrasound (MFU), which is characterized by minimal exposure to cavitation energy, and also uses a much lower impact energy on tissues: 0.4 – 1.5 J / m², compared with the type of HIFU used for SMAS face and body tissue lifting in aesthetic cosmetology.

The thermal effect of HIFU (MFU) leads to the formation of thermal coagulation points in the submucosa and underlying structures of the vagina (actually – the fascial plate of the vagina, the muscles of the vagina, the fascia adjacent to the vagina and the muscles of the small pelvis). This happens due to the heating of the tissue to 60-70 degrees, which causes point coagulation of the protein, leads to heating of the

collagen and its instantaneous contraction. This effect promotes the formation of new collagen, stimulation of fibroblasts, which lasts up to 30 days, and leads to a general improvement in the density and elasticity of the own plate and superfascial muscle layer (Superficial Musculo Aponeurotic System – SMAS) of the vagina and small pelvis at a depth of 3 to 5 mm, normalization of blood circulation in zone of hypoxia.

Study selection

We decided to explore High Intensity Focused Ultrasound (HIFU) technology as an energetic method of exposure (in this case, thermal energy generated by ultrasonic waves) to provide adequate, controlled and adjustable thermal exposure at a known depth in areas where lasers cannot penetrate and where the impact of non-invasive RF is still being studied and analyzed [5]. To this end, and based on the knowledge gained from the use of HIFU in the field of facial aesthetics and supported by many publications over more than six years [6], studies have applied this technology in the field of treatment involving intravaginal regeneration to evaluate its impact on HUCM and instability. pelvic floor, including the consequences of SUI. Currently, focused ultrasound has found wide application in cosmetology. It has a large evidence base of safety and high efficiency in non-surgical lifting of soft tissues of the face and body [7].

Further research is still needed. The clinical data published until recently relate only to the functional restoration of the vaginal mucosa, when it is important to study changes in deeper tissues, the change of which is associated with the development of prolapses and urinary incontinence. Recovery of the vaginal mucosa is not enough to give long-term results in resolving pelvic floor dysfunction. There is a need for technology and related research to prove strengthening of the muscular-fascial layer (SMAS) of the vagina and perineum.

The prototype of this energy delivery mechanism has been used in oncology and the treatment of benign gynecological and urological pathology [8,9]. However, the technology was quickly transferred to aesthetic medicine, and the first device using HIFU for facelift appeared almost ten years ago, in 2009 (Ultherapy Machine, manufactured by Ulthera Inc., USA). Such equipment used thermal energy points to produce regenerative controlled microburns and SMAS lifting. As technology has advanced, we have seen the first devices for body lipolysis and contouring, and finally, vaginal devices have been developed to regenerate genital tissue at a depth that photonics technology cannot reach.

Based on the existing knowledge and results in aesthetic gynecology and cosmetology, devices for the treatment of wide vagina syndrome using HIFU technology in gynecology were created – the Ultra Vera device, manufactured by Hironic (Republic of Korea) and Feminine HIFU, manufactured by Sveltia, Argentina, described in the following research. The ceramic transducer with a concave emitting surface emits high-frequency ultrasonic pulses, and then promotes the generation of thermal energy by focusing the generated ultrasound, and through this operation, is used for thermal coagulation of the tissue. The method of non-invasive processing makes it possible to coagulate tissues in urology and gynecology.

Studies published in the International Journal of Obstetrics and Gynecology Research (IJOGR), Argentina, the Japanese Journal of Women's Pelvic Floor Medicine, Japan, and the Journal of Clinical Medicine, Poland show promising results that motivate further research. In these studies, microfocused ultrasound targets the vaginal submucosal tissue at known depths of 1.5 mm, 3.0 mm, and 4.5 mm deep, without damaging the outer surface of the vaginal mucosa, where lasers and radio frequencies have no effect. Given the wavelength, CO₂ and erbium lasers focus their energy on the mucosa and do not act on areas outside it [10]. Microfocused ultrasound achieves the desired effect mainly due to thermal energy [11].

Review and analysis of the results of the study

In a study on the treatment of urinary incontinence with transvaginal high-intensity focused ultrasound (HIFU) conducted by Shunsuke Suzuki and Naomi Moriguchi, Moriguchi Internal medicine Clinic (Japan), published in the Japanese Journal of Women's Pelvic Floor Medicine [1], included 46 patients (62.5 ± 13.9 years) who took part in transvaginal HIFU therapy procedures for three years: from February 2018 to January 2021.

58 patients came with complaints of urinary incontinence. Transvaginal HIFU procedure performed. The subjects were 46 patients in whom response could be assessed using the ICIQ-SF before and within 3 months after HIFU. Age 62.5 ± 13.9 years, 44 of them had natural childbirth.

Ultra Vera by Hironic was used as HIFU equipment. The cartridge was inserted into the vagina in the supine position without anesthesia and the entire circumference was irradiated circularly. The maximum output power was 10 (1.3 J) as standard, and decreased as needed with the onset of pain. Transvaginal cartridges M3.0 with a focus depth of

3.0 mm and D4.5 with a focus depth of 4.5 mm from the mucosal surface were used. The vaginal wall was divided into 3 parts in the longitudinal direction, while the area of the middle third was irradiated at M3.0, and the area of the anterior third was irradiated at M3.0 and D4.5. If the vaginal wall is short, such as after a total hysterectomy, only the anterior third was examined. In one case, it was not possible to install the attached 28mm cartridge, so we used the 23mm D4.5 cartridge, which was proposed and developed in cooperation with HIRONIC. The total exposure lasted 20–30 minutes. Irradiation was given only once and repeated if the patient wanted to do so because of the recurrence of symptoms at a later date. The ICIQ-SF short form of the International Meeting on Urinary Incontinence was used to evaluate the effectiveness.

The results of the study were very promising: many patients noticed a reduction in urinary incontinence symptoms relatively early after HIFU, and the ICIQ-SF score was significantly lower than before HIFU, even after 2 years.

The results of this study suggest that transvaginal HIFU may be a useful treatment option as a minimally invasive treatment for urinary incontinence in the elderly. It has recently been reported that the left and right bulbospongiosus muscles in women fuse anteriorly and laterally with the external anal sphincter, and the dorsal part of the vaginal wall is the external anal sphincter. Consistent with this, direct irradiation of the external anal sphincter on the dorsal side of the vagina with transvaginal HIFU could increase the contractile force of the external anal sphincter and, as a result, reduce fecal incontinence.

In another reviewed study of microfocused ultrasound therapy in patients with urogenital atrophy and vaginal weakness, conducted by P. Kolchevsky, M. Kozlovsky and A. Cymbalyuk-Ploska, Medical University in Szczecin, Al. Powstańców Wielkopolskich 72, 70-111 Szczecin, Poland (Poland), published in the *Journal of Clinical Medicine* [12], involved 20 women with VL (vaginal laxity) and VVA (vulvovaginal atrophy) aged 48 to 62 years (mean age 55.7 years).

Inclusion criteria included the following: patients with symptoms of GSM (menopausal genitourinary syndrome) and VL (vaginal flaccidity), perimenopause, menopause, and a negative cervical cytology for cancer. After history taking and physical examination, patients were selected and instructed about the procedure, and after providing information about the purpose of the study and informed consent, patients answered the following questionnaires: FSFI and VLQ. The condition of the vagina was examined using VHI – Vaginal Health Index (Vaginal Health Index).

The course of HIFU therapy consisted of two treatment sessions with an interval of 6 weeks on the Ultravera device manufactured by Hironic. Each treatment session included the vaginal application of two specially designed probes, respectively 1.5 mm and 3 mm, to accurately target two depths of the vaginal wall. Energy was adjusted based on patient feedback.

All 20 patients completed the study. All treatment sessions were carried out in accordance with the treatment protocol. No adverse events or side effects were observed. This study showed very good results.

For the VL (vaginal flaccidity) scoring criterion, post-hoc comparisons showed that significant differences were found between pre-study vaginal flaccidity and subsequent visits, but not between subsequent visits. The percentage improvement in VL between the first two weeks (before and 2 weeks after) ranged from 33.3% to 300%, with an average percentage change of 125%. A total of 8 women had a 100% change, one woman had a 150% change, one woman had a 200% change, and eight women had a 300% change.

Based on the FSFI score (Female Sexual Function Index, a widely accepted global assessment used in medical research on female sexuality, an overall FSFI score of 26 is recognized in the medical literature as an indicator of female sexual dysfunction (FSD). The change in FSFI during the study was 6-week follow-up showed a significant improvement in FSFI scores (from 25 (3.8) to 32 (2.25), and remained significantly better at 3 months of follow-up. Percentage change – before and after 6 months: in 75% of women, percentage change was at least 11.2% 25% of women had a percentage change of at least 25.6% Percentage change at 6 weeks versus 3 months: 25% of women had a percentage change of at least 7.1%.

The Vaginal Health Index (VHI) measures refer to vaginal moisture, vaginal fluid volume, vaginal elasticity, pH, and vaginal epithelial integrity. Overall, there was a significant improvement in VHI over time, with the largest and most significant change occurring between baseline and 21 days of follow-up. Percentage change before and after 21 days: 75% of women had a percentage change of at least 18.8%; In 25% of women, the percentage change was at least 100%. Percent change before and after 6 weeks: median 50%; in 75% of women, the percentage change was at least 41.4%; In 25% of women, the percentage change was at least 128%. Percentage change – before and after 3 months: in 75% of women, the percentage change was at least 37.3%; In 25% of women, the percentage change was at least 129%.

A study on the treatment of vaginal atrophy, vaginal hyperelasticity and stress urinary incontinence

with intravaginal HIFU therapy by H.A. Ekhas, M. Galich, G. Korin et al. Dr. Alberto Ernekian. Ezeiza. Buenos Aires, Argentina, published in the International Journal of Obstetrics and Gynecology Research (IJOGR) [13], was conducted with a total of 30 patients aged 50 to 67 years suffering from stress urinary incontinence (SUI), genital prolapse and gynecourinary menopause syndrome (GUSM) from November 10, 2017 to December 30, 2018. We used Feminine HIFU equipment manufactured by SVELTIA, Argentina – HIFU equipment with a vaginal applicator nozzle, with an operating frequency of 4 MHz and a depth of 3.0 and 4.5 mm, a rotation angle of 6°. The protocol used 1.5 Joules in each run during the first session and up to 2 Joules during the second treatment session depending on pain tolerance. Six months after completion of treatment and post-treatment biopsy, follow-up and follow-up with clinical follow-up was performed. Control included questioning and physical examination.

The results of the treatment were promising for further research and showed a significant improvement in the condition of the vagina after the use of HIFU therapy, according to the questionnaires ISIQ-SF, PISQ-12, FSFI, vaginal health index, biopsy studies, vaginal pH measurements.

The results of the study showed that 80-90% of patients have an adequate therapeutic response after only two outpatient sessions of painless intravaginal treatment, and follow-up observations confirm the maintenance of treatment benefits achieved within a year after the procedure.

The sexuality of all patients improved significantly. The assessment of the questionnaires (PISQ-12 and FSFI) is undeniable, and the patients of the group expressed an extraordinary degree of satisfaction with their visit to the doctor, the survey and feedback. The regeneration of the vaginal and vulvar mucosa using HIFU is visually evident and confirmed by the Vaginal Health Index, which is clearly and significantly improved from a statistical point of view. Photos of one of the cases from a sample of patients (before and after treatment), which are reflected in the article, speak for themselves. The regenerative effect is noticeable after two treatment sessions.

Questionnaires on urinary incontinence revealed a statistical improvement in symptoms. The pad test confirmed clinical data and analysis of the ICIQ-SF patient questionnaire. All patients diagnosed with mild SUI were cured, which was a very important finding given the predictive value implied by this concept, resulting in a benefit rate (recovery or improvement) of over 80%.

With regard to dystopia, the clinical examination revealed a clear improvement in prolapse, 50% of

patients progressed from Blaivas II to Blaivas I. This is due to the improved elasticity of the submucosal tissues that were treated. Follow-up six months after treatment allowed for a comprehensive follow-up of 27 patients who answered the call and made an appointment for a physical examination. 17 patients with SUI and all six patients with vaginal hyperelasticity were present at the follow-up visit.

This percentage given in this study makes it interesting to continue to explore the technology with more patients and evaluate the persistence of symptom correction over time.

Discussion

The purpose of this review of the study is to study the technology of regeneration in the mucosa, fascia and deeper muscle tissues. The results of the study are convincing regarding the positive effect of HIFU on patients with vulvovaginal atrophy, wide vagina syndrome, genital prolapse, and stress urinary incontinence.

Based on our knowledge of the physics of lighting and energy equipment, HIFU systems can produce regenerative thermal effects at great depths in a safe, known and programmable way.

The aim of researching this technology was to create a regenerative effect at target depths: not only in the mucous membrane, but also in the fascia, muscle tissue, where we find the supporting elements that determine the health of the pelvic floor and are affected by pregnancy, childbirth and hormonal deficiency.

No significant adverse events were found in these studies, which is consistent with studies published to date on HIFU face and body therapy [14]. The safety of the HIFU application technique was confirmed by the absence of negative dynamics in many indicators, namely: laboratory and instrumental studies, ultrasound of soft tissues, MRI diagnostics and histological studies. The technique, according to a histological examination at the site of the procedures, has shown its effectiveness and safety, since it starts the process of neocollagenesis in the deep layers of the dermis, while the upper layers of tissues, the dermis and skin appendages remain intact.

During the application of technology using focused ultrasound, there were no shortcomings in the work, as well as the expected possible adverse events. When using HIFU technology in gynecology, there were no wishes for improvement or the need to use additional procedures with other technologies. Within the framework of a verified treatment protocol, HIFU technology in gynecology is self-sufficient. The high safety of the use of Ultra Vera (Fig. 1) and

Feminine HIFU (Fig. 2) devices was noted during the procedure according to the treatment protocol: in case of incorrect connection or use errors, the device stopped working, preventing the possibility of

tissue burns. Ease of use, ease of control, ergonomic interface that allows the doctor not to be distracted from the treatment, which increases the level of safety of the procedure, were also noted.



Figure 1 – Medical device Ultra Vera, manufactured by Hironic, Korea (left) and used cartridges with different exposure depths (right)



Figure 2 – Feminine HIFU medical device manufactured by Sveltia, Argentina (left) and used cartridge with different exposure depths (right)

The proposed method for the treatment of stress and mixed urinary incontinence in women was performed in more than 100 women who took part in the study of different age groups and with GUMS. The results showed an improvement in the condition of all patients participating in the study.

Changes in the mucosal epithelium (stratification and increased glycogen content in superficial keratinocytes) fully explain the change in pH shown in the study and the improvement in the microbiota and vaginal condition [15]. This change is associated with many of the positive effects achieved in vulvovaginal atrophy, due to the pronounced thermal effect, which,

as we already know, causes an even stronger stimulus in the epithelium than local estrogens.

The sexual life and psychological state of all patients improved significantly. According to the assessment questionnaires (PISQ-12 [16] and FSFI [17]), the patients of the group expressed a high degree of satisfaction with their visit to the doctor, the survey and feedback. Many of the patients have regained full sexual satisfaction, which is another sign that many patients do not lose their libido. Restoration of mucosal tissues and restoration of vaginal lubrication, elasticity and compliance through neocollagenesis and angiogenesis, which

are characteristic of the thermal effect, in addition to anatomical restoration, increase patient confidence and self-esteem.

The regeneration of the vaginal and vulvar mucosa using HIFU microfocused ultrasound is visually evident and is confirmed by a significant improvement in the Vaginal Health Index.

The conclusions on the evaluation of photographs of some clinical cases from this sample (before and after treatment) are clear. The regenerative effect is noticeable after the first treatment session, and subsequent improvements within 2 months.

All participants demonstrated high adherence to treatment and its continuity, and most of them are

still under the supervision and control of therapy in its process.

It should be noted that studies on the use of HIFU therapy are also being conducted in the Republic of Kazakhstan. On the basis of the Tulip Medicine Center for Plastic Surgery, Astana, the Ultra Vera Device, registered in Kazakhstan, provided by Meditech LLC, is used. The results of the application of non-invasive HIFU technology with the participation of a group of 30 patients are additionally presented in the form of histological (Fig. 3), immunohistochemical (Fig. 4) and ultrasound studies (Fig. 5), which more clearly and significantly complements the data from Japan, Poland and Argentina by objective monitoring of treatment outcomes. Histological examination:

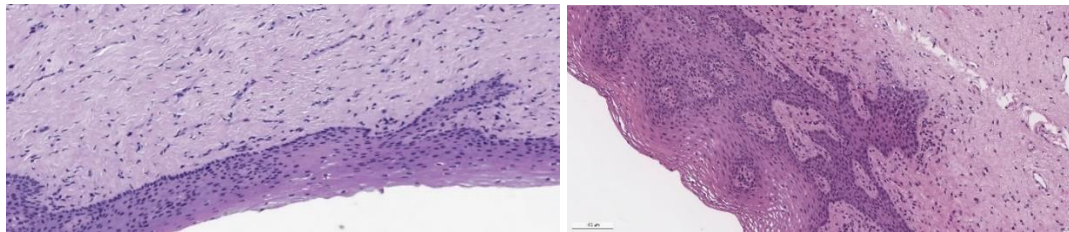


Figure 3 – Before the HIFU procedure (left) and 2 months after the procedure (right).

Immunohistochemical study:

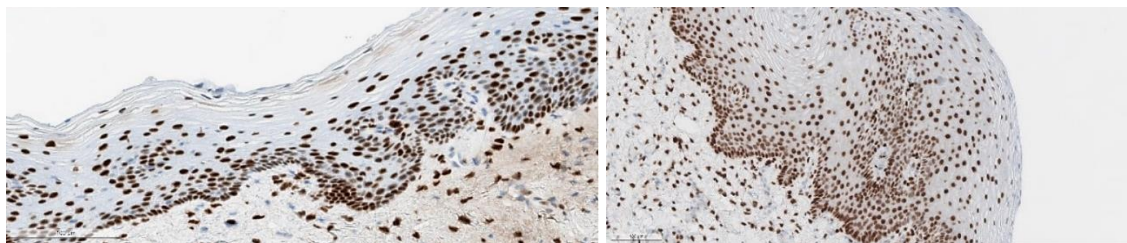


Figure 4 – Before the HIFU procedure (left) and 2 months after the procedure (right)

Ultrasound examination of the pelvic floor muscles:



Figure 5 – Example: The patient is 42 years old. Pelvic floor muscle changes: Before the HIFU procedure (left) and 1 month after the procedure (right)

The presented data on the results of questionnaires, clinical assessment of the vaginal mucosa and biopsy fully confirm the shown results of early studies.

The proven benefits of non-invasive HIFU technology in the field of aesthetic medicine and gynecology will continue to be complemented by more evidence of quality, efficacy and safety.

Conclusions

The presented studies showed promising results for the further dissemination and development of HIFU (and its particular type – MFU) technology in the field of aesthetic medicine, gynecology and urology.

HIFU microfocused ultrasound technology shows high clinical efficacy and safety in non-surgical,

minimally invasive correction of a number of gynecological diseases. HIFU therapy is effective for stimulating regenerative processes aimed at treating diseases such as stress urinary incontinence, genital prolapse, vulvovaginal atrophy, and wide vagina syndrome [18]. This technology has established itself as a breakthrough in hardware methods in the field of gynecology. HIFU microfocused ultrasound technology is self-sufficient and covers all technologies of warm exposure.

HIFU technology has proven to be a safe, effective and promising method for correcting urogynecological diseases, and has also demonstrated a high satisfaction of women with the aesthetic effect of the procedure. Research and observation of patients is ongoing, further randomized clinical trials are required.

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