International Journal of Trend in Scientific Research and Development (IJTSRD)
Special Issue on Innovative Development of Modern Research
Available Online: www.ijtsrd.com e-ISSN: 2456 – 6470

Role of HIFU Therapy in Treatment of Benign Prostate Hyperplasia (Sonablate®-500 Equipment)

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ABSTRACT

The health and quality of life of elderly men is directly dependent on non-neoplastic diseases, among which benign prostatic hyperplasia (BPH) is of particular importance. Currently, various methods of minimally invasive surgical treatment of BPH are flourishing. Among the methods that can rightfully be considered the gold standards of surgical treatment of BPH (transurethral resection of the prostate, laser enucleation of the prostate), a special place is occupied by borderline techniques that work at the junction of conservative and surgical treatment of BPH. Such techniques include HIFU (High Intensity Focused Ultrasound) or transrectal ablation with high-intensity focused ultrasound, which allows directed ultrasound to destroy deep tissue without damaging nearby healthy areas. In the focusing area, the intensity of ultrasound reaches a very significant level, which is sufficient for a local increase in the tissue temperature in the focusing area up to 70-100 ° C. This leads to tissue necrosis of prostatic hyperplasia, and then, after rejection of the necrotic ablated areas, to improvement. Lower urinary tract symptoms associated with BPH.

KEYWORDS: *prostatic hyperplasia, ultrasound ablation, transrectal, minimally invasive*

Relevance:

The increase in the life expectancy of the population has led to the fact that the proportion of elderly and elderly people has increased, in connection with which the structure and level of morbidity have changed. The health and quality of life of men over 50, according to the modern gerontological concept, is directly dependent on non-oncological diseases: benign prostatic hyperplasia, stress, cardiovascular diseases, erectile dysfunction. Given the increasing trend towards an increase in life expectancy and an aging population, the problem of BPH treatment seems to be very urgent [1, 2].

BPH is a disease characterized by overgrowth of prostate tissue that surrounds the urethra, resulting in obstruction of the urinary tract. In the structure of urological pathology in the United States, the following are sequentially distributed in frequency: diseases of the prostate gland, urinary incontinence, erectile dysfunction, and urolithiasis. Every year from 7 to 8 million patients seek medical help, concerned about difficulty urinating due to the presence of prostatic hyperplasia [2, 3]. In Germany, about 40% of urological beds are occupied by patients with this disease. Numerous studies of domestic and foreign urologists have shown that although the most vulnerable to prostate adenoma disease is the age from 60 to 70 years, however, over the past 20-30 years there has been a significant rejuvenation of patients with prostate diseases. According to autopsy data, BPH is detected in more than 90% of men over 80 years old. [3]. The mechanism of urination disorders in patients with BPH is multifaceted and complex; its causes are bladder outlet obstruction (mechanical and dynamic components) and impaired detrusor function. It is the urinary disorders, represented by the symptoms of the lower urinary tract (LUTS), that are the main reason for the decline in the quality of life in patients with BPH. Any method of treating prostate adenoma is aimed primarily at eliminating or reducing the intensity of LUTS [4].

Currently, the assessment of the results of BPH treatment consists of two parameters: life expectancy and its quality. It is the patient's quality of life that is of particular economic and social importance. In recent years, the success of urologists in the treatment of BPH is quite significant, since they have mastered endoscopic and laparoscopic methods, and robotic-assisted technologies are being actively introduced [1, 2]. The choice of the method of treatment in patients with symptomatic BPH depends on many factors: medical, economic and social, in this connection, the treatment of BPH remains one of the urgent problems of modern urology. Many of the existing modern methods of surgical treatment of this pathology, despite their effectiveness, carry the risk of intraoperative, early and late postoperative complications. [3, 4].

Until now, the generally accepted "gold standard" of surgical treatment of BPH due to its safety and effectiveness, including long-term results, is transurethral resection of the prostate (TURP). But this procedure is not devoid of such intraoperative complications as bleeding, hyponatremia, and less often TUR syndrome. Despite this, TURP has been the procedure of choice in the surgical treatment of vesical obstruction (IVO) due to BPH for more than 50 years. However, the significant number of complications after TURP necessitates the search for new alternative methods of treatment. In recent years, the procedures of transrectal laser enucleation of prostatic hyperplasia, which include holmium and thulium laser enucleations, have become very important. Today, many authors refer these techniques to the new "gold" standard of surgical treatment for BPH. However, these procedures are not without complications and are often accompanied by ejaculation disorders, which significantly reduce the quality of life of patients with BPH, especially in sexually active patients. All of the above required further search and development of new minimally invasive technologies in the treatment of BPH. Over the past decades, many new experimental treatments have been developed, such as thermal tissue destruction, balloon dilatation, prostatic stents, transrectal microwave hyperthermia, aqua ablation [5, 6].

The history of the method

Transrectal therapy with high-intensity focused ultrasound ((HIFU), English - High Intensity Focused Ultrasound (HIFU)) is one of the methods of treatment of prostate adenoma, based on thermal effect on tissue. HIFU is focused ultrasonic waves emitted by a transducer that cause tissue damage through mechanical, thermal and cavitation effects. HIFU transmits ultrasonic energy, followed by thermal destruction of tissues at specific distant points from the ultrasound probe without significant temperature rise or tissue damage in the path of the ultrasound beam. Recently, the use of HIFU has expanded both in urological practice and in surgery and oncology [7, 8, 9].

The first work on the study of the biological effects of high-intensity ultrasound was carried out by Wood and Loomis [10] in 1926-1927. in Tuxedo Park, New Jersey. They observed the effect of ultrasonic waves on unicellular microorganisms, tissues, small fish and animals. In 1942 Lynn J.G., Zwemer R.L., Chick A. J., Miller A.G. the first work was published describing the possibility of local heating of tissues when focusing ultrasonic waves to one point. In their article, scientists describe a generator used in their work to focus ultrasonic waves, demonstrate the results of such an effect in experiments on paraffin blocks and beef liver [11].

Although HIFU research began as early as the 1940s at Indiana University, the study of the potential of HIFU developed significantly in the 1950s. As a method for the treatment of oncological diseases, HIFU was first proposed by A.K. Burov in 1956 [12, 13]. Due to the lack of visual control, the proven effectiveness of focused ultrasound in the destruction of tumor tissues at that time did not find clinical use.

In the 1970s. L. D. Rosenberg and M.G. Sirotyuk [14] developed non-invasive methods for measuring the acoustic field in tissues, a method for monitoring temperature measurement and increasing cavitation in tissues using special receivers, which made it possible to understand the mechanism of the destructive effect of ultrasound [15].

In the early 1990s, there was an early study of the role of HIFU in the treatment of BPH. A ground-breaking study was the work in experimental animals (dogs) on the safety and efficacy of HIFU by Sanghvi et al. In 1992-93. at the Indiana University School of Medicine Bihrle et al. with the help of HIFU, the first group of patients with BPH was treated [6]. At the same time, the question arose about the possibility of using HIFU in the treatment of prostate cancer. And, the first application for the treatment of prostate cancer in humans was started in 1994 (Michael Marberger and Stephan Madersbacher) at the University of Vienna in Austria using the Sonablate-200 equipment [16]. The goal was to see if the energy delivered was sufficient to destroy the desired tissue. Research has shown that the treatment can be done safely. Since then, several research papers have been published on the use of HIFU, including a 5-year observation by Blana A. et al. [17] and a multicenter study in Europe by Thuroff S. et al. [18]

In 1995, another study from Indiana University showed that the entire prostate could be treated without damaging the prostate capsule or rectal wall. In 1999, in Japan, Dr. Toyaki Uchida treated patients with Sonablate-200. The device received approval for use in Europe with the CE mark in 2001 and 2004, and the treatment became available in hospitals and treatment centers in Mexico, Costa Rica, South Africa and the Caribbean. Health Canada approved Sonablate®-500 in June 2005 and the first Sonablate®-500 HIFU surgeries were performed in Toronto in March 2006 [19].

Today, all over the world, ultrasound ablation is used for the radical or palliative treatment of patients with tumor neoplasms of various localization: liver, pancreas, kidneys, prostate, breast, bone tissue, soft tissue sarcomas [20-24]. Significant experience has been accumulated abroad in carrying out such procedures, however, due to the relative youth of the method, there is still no need to talk about long-term results (except for data on ultrasonic ablation of prostate cancer).

HIFU therapy for the radical treatment of patients with malignant neoplasms is most often used in the treatment of localized forms of prostate cancer, as evidenced by the data of large randomized trials. Blana et al. [25], published the results of HIFU therapy in 146 patients with a mean follow-up period of 22.5 months.

In Russia, the method of HIFU-therapy of oncological diseases began to gain popularity only at the beginning of the XXI century [26]. In the clinic of urology named after R.M. Fronshteyn 1-MGMU them. THEM. Sechenov, high-intensity focused ultrasound ablation of the prostate with the "Ablaterm" apparatus of the "EDAP" company has been used since 2003. Over the past period, 95 treatment sessions have been performed. All patients underwent a conventional examination, including magnetic resonance imaging of the prostate with contrast [27].

In 2012, doctors and scientists from the Samara Regional Clinical Oncological Dispensary demonstrated the possibilities of high-intensity focused ultrasound ablation in patients with hormone-resistant localized and locally advanced prostate cancer. The study involved 341 patients. The mean follow-up time after ultrasound ablation was 36 (3-52) months, with significant clinical efficacy 3-year relapse-free survival in 95.5%. Two years later, the same scientists presented an estimate of the overall and 5-year relapse-free survival in 86.2% of patients with prostate cancer [28].

The emergence and development of such visual control methods as ultrasound and MRI made it possible to evaluate the effectiveness of the procedure performed online, and to control the zone of exposure to focused ultrasound. Since then, the biological effects of the action of high-intensity focused ultrasound on biological systems have been studied more deeply, and considerable experience has been accumulated in its application in medical practice [9, 29, 30].

Thus, this method of treatment was developed as a minimally invasive method of treatment, comparable in its effectiveness with the surgical method of treatment and various types of radiation therapy, but with fewer complications. Currently, the effectiveness of HIFU therapy is widely discussed in the medical community. Today in the world there is a highly developed material and technical base for the implementation of the method. Every year more and more medical institutions are equipped with equipment for HIFU-therapy under the control of MRI or ultrasound. A significant number of publications by doctors and scientists from different countries of the world on this topic testifies to the effectiveness of using the method and the prospects for conducting large-scale multicenter studies in this direction in Uzbekistan as well.

HIFU has many unique features and qualities, some of which are described here:

1. When used with an appropriate peak focal intensity in situ, HIFU can increase the tissue temperature in the focal zone to 80-100 ° C for a very short exposure time (1-10 s) while maintaining the intermediate tissue temperature at a physiologically safe level;
2. HIFU does not come into contact with the treated tissues and organs;
3. HIFU forms sharply limited and predictable lesions. The size and shape of each lesion depends on the width of the ultrasound beam, the intensity and duration of exposure [31, 32].
4. When the individual lesions are combined in a matrix format, a large contiguous lesion of the desired size and shape can be created [33].
5. As the tissue temperature rises rapidly, the need for blood transfusion is minimized during HIFU treatment [34, 35].
6. The energy of ultrasound does not ionize and can be used repeatedly.
7. The HIFU procedure can be performed on an outpatient basis

Thanks to the receipt of the US-made Sonablate®-500 device, for the first time in Central Asia in 2014, the Intramed clinic in the city of Samarkand began to use HIFU-therapy for BPH. The Sonablate®-500 System has been specially designed for the treatment of the prostate. Its sophisticated software allows, due to technologically advanced electronics, to provide accurate and safe treatment of patients with BPH.

Clinical application of HIFU for BPH using the Sonablate® 500 device

The device was developed after extensive animal safety research, analytical computer simulations and laboratory research. The Sonablate® 500 system is a medical device that uses high-intensity focused ultrasound (HIFU) energy to induce thermal coagulation tissue necrosis in a selected area at a specified distance from the focused transceiver element (s). A unique feature of the Sonablate® 500 system is the use of technology using the only TRUST ultrasound transceiver (transrectal ultrasound scanning and therapy) capable of performing both imaging and treatment. This dual-function piezoelectric ultrasonic transceiver is located in the transrectal probe and provides an accurate positioning of the focus of treatment, as well as visualization of the treatment process in real time; images are updated after each treatment cycle [36]. The Sonablate®-500 system includes a console, digital thermal printer, flat screen monitor, and two transrectal probes with two transceivers with different focal lengths, an articulated probe handle and a cooler module. There are other probes with different focal length combinations that are not included with the standard Sonablate®-500 system.

Fig. 1. Equipment for ultrasonic ablation of hyperplasia tissue

Prostate Sonablate®-500

The procedure was performed under spinal anesthesia after placing the patient on his back in a lithotomy position with raised and bent legs on a conventional operating table. A Foley catheter 16-18 Ch. Was inserted into the bladder. The bladder is then filled with distilled water. A high-frequency transducer, placed in a balloon filled with degassed liquid (Fig. 2) at room temperature or cooled, is inserted into the rectum, which provides visual control of the prostate against the background of the catheter and selection of the ablation zone. Cooling of the rectal wall is carried out using a special device - the Sonachill ™ cooler (Fig. 3).

Fig. 2 Ultrasonic transducer for HIFU therapy, filled with degassed liquid.

Fig. 3 Sonachill ™ cooler for cooling the rectal wall during HIFU therapy.

The Sonachill ™ Cooler is a special device designed to circulate degassed water through a probe and to cool the rectal wall and HIFU transceiver. The Sonachill ™ chiller is connected to the back of the Sonablate® 500 system with a detachable cable. This connection provides power to the Sonachill ™ chiller and temperature feedback to the system. The three main components of the Sonachill ™ device are:

- active cooling unit (liquid-air cooler);
- hose pump;
- water tank.

The built-in Sonachill ™ degasser is capable of permanently degassing the water in the water circuit, making it unnecessary to use degassed water when first filling the system. The Sonachill ™ is connected to the probe with connecting tubing. The Sonachill ™ also has another critical function: removing any air bubbles from the closed system before starting the procedure. The water tank has a connector on the side wall that is connected to the syringe. This is done in order to change the level of the canister, increasing and decreasing the pressure in the canister by, respectively, pumping water or removing it.

Before treating a patient after the console and software are ready. Preparation procedures include:

- preparation of the probe;
- input of patient data;
- location of the patient;
- introduction of the probe;
- imaging of the prostate before planning treatment.

Critical factors for successful treatment are proper rectal / bowel cleansing and proper tube insertion into the patient's body. Before therapy, the patient should be subjected to at least one cleansing enema.

The patient should be positioned in a modified lithotomy position, the patient's abdomen should be fixed with a compression tape. A rectal examination is done to check for any remaining stool. In the presence of feces, the rectum should be rinsed with water until it is clean.

Probe insertion

1. 1.Using a 60 ml syringe, fill it with ultrasonic gel (remove all air bubbles) and inject 10-30 cc. cm into the patient's rectum.
2. Using the 60 ml syringe from step 1, gently apply 10-30 ml of ultrasonic gel to the probe tip. Eliminate any air bubbles that may have gotten into the gel.
3. It is necessary to loosen and adjust the position of the probe so that the transceiver window is at the front and the reference mark is at zero angular level. After securing the cuff of the probe manipulator, the probe must be secured in this position.
4. Next, it is necessary to loosen the central handle of the probe manipulator and carefully insert the probe tip into the patient's rectum.
5. When the probe is positioned accurately and satisfactory preliminary visualization is achieved, the bracket of the multifunctional probe is rigidly fixed to prevent the focus of the ablation zone from shifting, after which, under visual ultrasound guidance in real time, the prostate is conditionally divided into 3 treatment zones from apex to base. prostate and 2 zones from one edge to the other (Fig. 4).

Fig 4 Stages of bracket fixation and introduction of a multifunctional rectal probe (sensor)

The multifunctional Sonablate®-500 transducer operating at a frequency of 3-8 MHz is used to demarcate the prostate capsule. The high-energy ultrasound beam combined with simultaneous target imaging ensures accurate and efficient tissue ablation. The multifunctional dual focus probe provides imaging of the gland margin and precise targeting in one compact device. This allows two emitters to be combined: the first provides imaging, identification of the target tissue, and treatment of the anterior prostate, and the second the posterior. The smart probe device allows the doctor to select between emitters by pressing one button without moving the probe. The system has 2 sensors: a low energy sensor (3-4 MHz) for imaging and a high energy sensor for treatment. The prostate is seen in the sagittal and frontal sections, the target area of the therapeutic effect is indicated. Both systems sequentially perform an intervention in which the treatment zone is first heated, and then cooled, during which the computer-controlled systems move to the next treatment zone, which is distant from the first zone. During the cooling phase, diagnostic imaging is performed, which allows real-time monitoring of changes in target tissues within the affected area, as well as monitoring of sound changes in the nearby area of the rectal wall.

Checking the effectiveness of treatment

Tissue Changing Monitoring (TCM) allows you to visually monitor the process of prostate treatment. If certain tissues have not been heated enough to destroy them, then the imaging will be done with TCM color coding. This allows this part to be processed in real time to confirm that the entire prostate has been treated. TCM calculates the changes that are taking place and displays them on the screen. The radio frequency signal is sent to the treatment site before the HIFU procedure, then another signal is sent after the HIFU to the same site. TCM detects tissue changes based on real-time comparison of radio frequency (RF) ultrasound echoes at each treatment site.

A special neurovascular bundle detector allows identifying blood vessels and nerves, as well as instantly integrating them into the image on the screen (Fig. 5). This makes it possible to automatically adjust the therapeutic plan for the procedure, which avoids damage to the neurovascular bundles - which is especially important for maintaining erectile function.

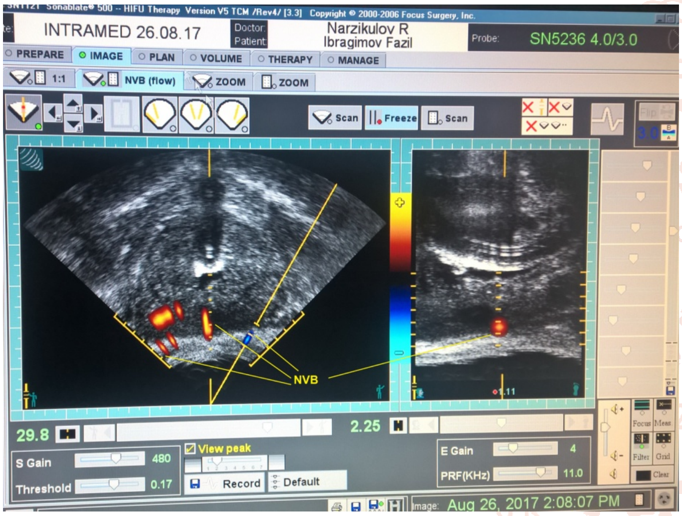

Fig 5 Function of the neurovascular bundle detector.

Wide viewing angle treatment

A wide viewing angle of 900 allows visual coverage of the entire gland, and this allows most procedures to be carried out without moving the probe. This feature significantly reduces the time spent on treatment.

As shown in fig. 5, for the treatment of the entire prostate gland as a whole is divided into several zones. The first zone is always located along the anterior part of the prostate with subsequent treatment zones towards the rectal wall (posterior part), thereby ensuring that all parts of the prostate are treated. A 4.0 cm probe must be used to treat the front (top row). To treat the central part of the prostate (central row), a 3.0 cm transceiver must be used, if the rectal wall is at least 1.0 cm from the transceiver, then a 4.0 cm probe is used. the posterior side of the prostate is made using a 3.0 cm transceiver.

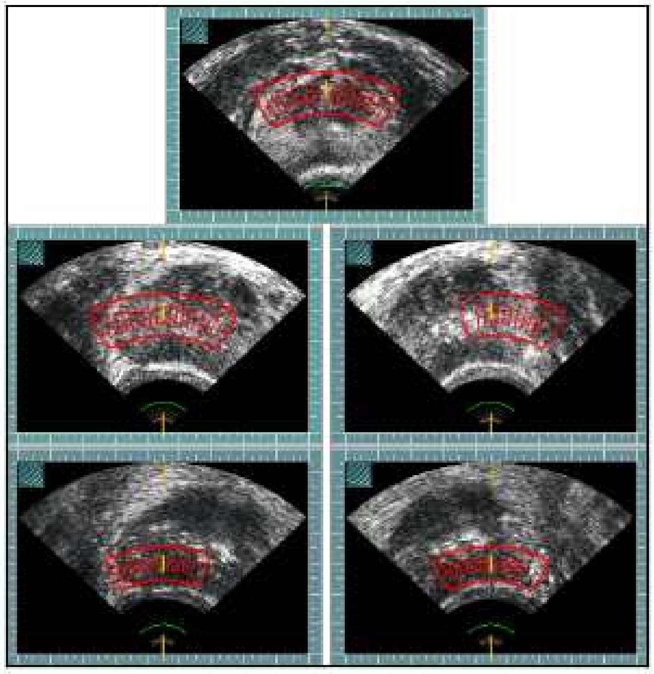

Fig 6 Marking of zones of the prostate

The safety function built into the Sonablate®-500 device allows you to prevent errors and even interrupt the procedure if any of the parameters go beyond the safe limits. The rectal wall is cooled to 16-200 C to prevent tissue damage. During the entire procedure, the position of the sensor relative to the rectal wall is constantly monitored. Measurement of visual visibility and continuous comparison with reference images (Reflectivity Index Measurment - RIM). The Sonablate®-500 software allows the surgeon to adjust the degree of exposure in each of the conditional zones that were formed during the marking before performing the ablation. The HIFU signal precisely and precisely affects the prostate tissue in different zones and allows you to accurately determine the treatment area in relation to the borders of the prostate or the external sphincter of the urinary bladder. After the completion of the operation, the bladder was drained with a Foley catheter 16-18 Ch.

Conclusion

HIFU therapy in the treatment of BPH is one of the modern developing minimally invasive methods. Currently, there is insufficient data on the long-term results of HIFU use in patients with BPH. However, with the correct selection of patients and appropriate indications, the prostate volume is up to 90 cubic meters. cm, no middle lobe, no complications of BPH, it is possible to achieve significant clinical improvement. All this allows us to conclude that the HIFU method has the right to exist as one of the minimally invasive methods of treating prostate adenoma, however, additional research is required in this direction.

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