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High-intensity focused ultrasound: opportunities and prospects in the treatment of uterine fibroid and deep infiltrative endometriosis

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This literature review is devoted to the use of focused ultrasound in gynecological practice as an alternative to the traditional surgical treatment of uterine fibroids and deep infiltrating endometriosis. According to available data, the effectiveness of the treatment of uterine fibroids with focused ultrasound varies widely, ranging from 16.4% to 93.0%. Due to the lack of prospective studies, it is not possible to draw reliable conclusions about the effect of ablation of uterine fibroid with focused ultrasound on fertility. However, unplanned pregnancies after such treatment occurred up to 19.5%, and in 66.3% of cases, pregnancies ended with the childbirth. Research results demonstrate that in 87% of cases, treatment of retrocervical infiltrative endometriosis using focused ultrasound is feasible. Further data accumulation is required to determine the range of patients with uterine fibroids and deep infiltrating endometriosis, to whom the treating technique could be most effective and safe.

Keywords: uterine fibroids; magnetic resonance-guided focused ultrasound surgery; deep infiltrating endometriosis; transrectal high-intensity focused ultrasound; pregnancy; delivery; caesarean section.

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Возможности и перспективы в лечении лейомиомы матки и инфильтративного эндометриоза — высокоэнергетическая фокусированная ультразвуковая абляция

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Обзор литературы посвящен применению фокусированного ультразвука в гинекологической практике в качестве альтернативы традиционному хирургическому лечению лейомиомы матки и инфильтративных форм эндометриоза. Эффективность лечения лейомиомы матки фокусированным ультразвуком широко варьирует и составляет от 16,4 до 93,0 %. В связи с отсутствием проспективных исследований не представляется возможным сделать достоверные выводы о влиянии абляции узлов лейомиомы фокусированным ультразвуком на фертильность. Тем не менее частота незапланированных беременностей после такого лечения составляет до 19,5 %, и в 66,3 % случаев беременность завершается рождением ребенка. Лечение ретроцервикального инфильтративного эндометриоза при помощи фокусированного ультразвука осуществимо в 87 % случаев. Необходимо дальнейшее накопление данных, чтобы четко очертить круг пациенток с лейомиомой матки и инфильтративным эндометриозом, в лечении которых данная методика может быть наиболее эффективна и безопасна.

Ключевые слова: лейомиома матки; фокусированная ультразвуковая абляция под МРТ-контролем; инфильтративный эндометриоз; трансректальная высокоинтенсивная фокусированная ультразвуковая абляция; беременность; роды; кесарево сечение.

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In 1880, brothers Paul-Jacques Curie (1856–1941) and Pierre Curie (1859–1906) discovered the piezoelectric effect occurring in a quartz crystal following mechanical action. A year later, Jonas Ferdinand Gabriel Lippmann (1845–1921) applied his theorem of the reversibility of physical phenomena and postulated the existence of the inverse piezoelectric effect, which was confirmed experimentally by the Curie brothers. Based on these experiments, Paul Langevin (1872–1946) subsequently developed a technique for manufacturing devices emitting ultrasonic waves of various frequencies; since then, ultrasound has been widely used in medicine for diagnosis and treatment.

One of these techniques involves pathological and remote targeting of focused ultrasound (FUS) waves on tissues to destroy them. This technique was first used in an experiment involving biological tissues and animals and was published in 1942 [1]. The technique mediates its effect on tissues via three damaging mechanisms. The first is thermal ablation. In this step, high-energy ultrasound passes through tissues without damaging them. However, focusing the ultrasonic wave through the emitter lens in a limited area of 1.0 cm^3, called "spot," instantly increases the temperature to 90°C, resulting in coagulation necrosis. In this case, the integumentary tissues and those surrounding the focus are not damaged. Another mechanism involves acoustic cavitation, which leads to tissue necrosis as a result of mechanical action. The third mechanism involves damage to the vessels of a pathological formation (e.g., tumor) [2–4]. The pathological focus becomes avascular, which results in termination of growth, reduction in size, decrease in functional activity and, subsequently, decrease in clinical manifestations. Within 2 weeks of ultrasound ablation, the pathological formation gradually wrinkles and is replaced with fibrous tissue [5, 6].

Uterine leiomyoma is the most common benign tumor of the female genitourinary system, with an incidence of 20%–40% among women of reproductive age. The causal factors include disturbances in the metabolic conversion of estrogens, changes in the ratio of their fractions, and increased concentrations of progesterone A and B receptors. As a result of hyperplasia and hypertrophy of smooth muscle cells, the myometrium mass can significantly increase [7–12]. Uterine leiomyoma often adversely affects reproductive plans in women. Notably, the number of women being operated for uterine leiomyoma is steadily increasing ranges from 41% to 74% across various gynecological hospitals. However, the search for the optimal treatment for uterine leiomyoma is still ongoing [9, 13, 14].

FUS ablation under the control of magnetic resonance imaging (FUSMRI) is a promising and organ-sparing, non-invasive method for treating uterine leiomyoma that can compete successfully with myomectomy and uterine artery embolization. FUSMRI ablation was approved for the treatment of uterine leiomyoma by the US Food and Drug Administration (FDA) in 2004 and was registered for use in the Russian Federation in 2009 (FS2009/372) [15, 16].

The equipment used for FUSMRI ablation of uterine leiomyoma nodes involves a magnetic resonance imaging scanner, a device for generating and focusing ultrasonic waves, and a software that connects these two devices. Based on the analysis of a series of T2-weighted images obtained in three orthogonal projections, a treatment procedure is planned.

After visualizing the leiomyoma node, spots are "placed" in it and sonicated (by exposure of a FUS wave on the tissue). The duration of sonication for each spot ranges from 7–8 s to 20 s. This technique allows real-time registration of the temperature at the spot and helps control any change in the organ position relative to the acoustic window [17, 18]. In some cases, to position the leiomyoma node at the optimal focal length (8–10 cm) relative to the ultrasound source, displace the small bowel loops from the path of ultrasound waves, and eliminate the effect on the sacral and sciatic nerves, the bladder and rectum are filled with isotonic sodium chloride solution [4].

According to the literature, the effectiveness of FUSMRI for treating uterine leiomyoma is 85%–90%, considering the technical limitations [16]. The widespread use of this technique is limited by the following technical factors: leiomyoma nodes located along the anterior wall and in the area of the uterine fundus; sizes up to 10.0 cm, leiomyoma nodes of 2–6 types according to FIGO classification; and the possibility of FUS affecting only typical "dark" myomatous nodes, which does not exceed 3–4 [7, 16, 19, 20]. The limitation associated with using FUSMRI for treating nodes located along the posterior uterine wall is the risk of damage to the sacral and sciatic nerves during surgery. Nerve damage occurs owing to heating of the sacrum and the subsequent transfer of heat to these nerves. Owing to this, a distance of at least 40 mm between the insonation focus and the sacrum is considered safe [19, 21–23]. In addition, the application of the technique depends on the distance between the transducer and the leiomyoma node. If this distance increases by more than 8 cm, the nodes become inaccessible for the effect of FUS [22, 23].

Thus, the nodes located along the anterior wall can be treated using FUSMRI. However, recent evidence has demonstrated that this limitation can be overcome. In their study, Nazarenko et al. (2016) assessed 28 patients with uterine leiomyoma, in whom the sacrum was <35 mm from the middle of the node. They could perform FUSMRI ablation with constant monitoring of the sacrum temperature and energy levels. In addition, when the sacrum was heated, it was cooled with ice, and in case of pain, the energy levels were reduced and the slices were changed more often [24].

Although various organ-sparing methods are available for the treatment of uterine leiomyoma, none of them eliminate the disease cause and, therefore, do not protect against disease recurrence, the frequency of which varies widely [25, 26]. Table 1 shows the literature data on the recurrence frequency of clinical manifestations of uterine leiomyoma after FUSMRI, for which additional treatment was performed (repeated FUS, myomectomy, hysterectomy, and uterine artery embolization).

The available data on the use of FUSMRI ablation for uterine leiomyoma can be effectively used in patients of reproductive age with large "symptomatic" uterine leiomyomas who are scheduled for laparoscopic myomectomy and have contraindications to other types of drugs [31].

Several authors believe that FUSMRI of uterine leiomyoma cannot be the treatment choice in patients planning pregnancy and cannot replace surgical organ-sparing treatment. They associate this treatment with aseptic inflammation and necrosis in the nodal area, which can affect negatively endometrium receptivity, leading to its inadequate response to hormonal stimulation and reducing implantation potential [32]. In addition, accidental exposure to the ovarian tissue, when nodes are located close to the uterus, can permanently decrease ovarian reserve. It is believed that the use of these techniques in young patients is not reasonable owing to the high incidence of leiomyoma recurrence [33, 34]. Therefore, according to FDA recommendations, FUSMRI of uterine leiomyoma is not indicated for women planning pregnancy [15]. Such restrictions are not specified in the Russian clinical guidelines [16, 35].

Currently, very few studies have analyzed the long-term effects of FUSMRI of uterine leiomyoma on the reproductive function. There are single reports of isolated cases or series of cases involving the monitoring of pregnancy course and its completion after FUSMRI. Table 2 presents literature data on the frequency of pregnancy after FUSMRI ablation of uterine leiomyomas.

Notably, there are no prospective studies evaluating the effect of FUSMRI on fertility. Patients, whose data are presented in Table 2, did not plan the pregnancy. In this regard, it is not possible to draw reliable conclusions regarding the effect of FUSMRI on fertility.

Table 3 presents data on pregnancy outcomes after the use of FUSMRI.

Table 3 shows that 66.3% of 323 pregnancies that occurred following FUSMRI of uterine leiomyoma ended in the birth of a child. The series of cases presented, considering the small number of patients included, does not suggest that FUSMRI increases the frequency of spontaneous abortions, premature births, and deliveries by caesarean section, as well as suggests the absence of such influence.

Thus, currently, for women whose fertility problems are presumably associated with uterine leiomyoma, FUSMRI is

Table 1. Literature data on the relapse frequency of uterine leiomyoma after MRI-guided focused ultrasound ablation, which necessitated additional treatment

Authors, year	*n*	Follow-up period, months	Number of relapses, *n* (%)
Dobrotwir A. et al., 2012 [27]	100	12	7 (7)
Yoon S.W. et al., 2013 [28]	60	12	6 (10)
Trumm C.G. et al., 2013 [29]	115	12	8 (7)
Politova A.K. et al., 2015 [5]	72	36	27 (38)
Nazarenko G.I. et al., 2016 [24]	109	32	23 (21)
Malysheva Ya.R. et al., 2019 [30]	195	12	163 (83.6)

Table 2. Literature data on the incidence of pregnancy after MRI-guided focused ultrasound ablation of uterine leiomyoma

Authors, year	Number of patients after FUSMRI	Follow-up period, months	Number of women who become pregnant (%)	Total number of pregnancies (%)	Spontaneous pregnancies (%)
Funaki K. et al., 2009 [36]	80	24	4/80 (5)	4/80 (5)	4/4 (100)
Juan Qin et al., 2012 [37]	435	36	24/435 (5.5)	24/435 (5.5)	24/24 (100)
Nazarenko G.I. et al., 2013 [38]	19	6,5	1 (5.3)	1 (5.3)	1/1 (100)
Kamp J.E. et al., 2012 [39]	54	12	8/54 (14.8)	8/54 (14.8)	8/54 (14.8)
Bing-song Z. et al., 2016 [40]	169	84	9/169 (5.3)	10/169 (5.9)	10/10 (100)
Li J.S. et al., 2017 [41]	189	60	131/189 (69.3)	131/189 (69.3)	125/131 (95.4)
Zou M. et al., 2017 [42]	406	59	78/406 (19.2)	80/406 (19.7)	76/80 (95)
Total	1352	6.5–84	255/1352 (18.8)	258/1352 (19.1)	247/258 (97.5)

Note. FUSMRI — MRI-guided focused ultrasound ablation

Table 3. Literature data on pregnancy outcomes after MRI-guided focused ultrasound ablation of uterine leiomyoma

Authors, year	Number of pregnancies/ completed	Abortion		Preterm delivery, *n* (%)	Mode of delivery	
		induced, *n* (%)	spontaneous, *n* (%)		VD, *n* (%)	Caesarean section, *n* (%)
Gavrilova-Jordan L.P. et al., 2007 [43]	1/1	0	0	0	1/1 (100)	0
Hanstede M.M. et al., 2007 [44]	1/1	0	0	0	1/1 (100)	0
Morita Y. et al., 2007 [45]	1/1	0	0	0	1/1 (100)	0
Funaki K. et al., 2009 [36]	4/4	0	2/4 (50)	2/4 (50)	2 cases (no data on the mode of delivery)	
Zaher S. et al., 2010 [46]	1/1	0	0	0	1/1 (100)	0
Rabinovici J. et al., 2010 [47]	54/43	7/54 (13)	14/54 (26)	1/54 (1,9)	14/22 (64)	8/22 (36)
Yoon S.W. et al., 2010 [48]	1/1	0	0	0	1/1 (100)	0
Nazarenko G.I. et al., 2011 [49]	1/1	0	0	0	0	1/1 (100)
Bouwsma E.V. et al., 2011 [50]	1/1	0	0	0	1/1 (100)	0
Zaher S. et al., 2011 [51]	1/1	0	0	0	0	1/1 (100)
Qin J. et al., 2012 [37]	24/24	15/24 (62.5)	2/24 (8.3)	0	0	7/7 (100)
Nazarenko G.I. et al., 2013 [38]	1/1	0	1 (100)	0	0	0
Kamp J.E. et al., 2012 [39]	8/7	0	0	0	4/7 (57.2)	3/7 (43)
Bing-song Z. et al., 2016 [40]	10/10	7/10 (70)	0	0	0	3/10 (30)
Li J.S. et al., 2017 [41]	133/114	4/133 (3.0)	17/133 (12.8)	2/133 (1.5)	26/93 (28)	67/93 (72)
Zou M. et al., 2017 [42]	80/74	0	3/80 (3.75)	3/71 (4.2)	15/71 (21.1)	56/71 (78.8)
Shchedrina I.D. et al., 2018 [52]	1/1	0	0	0	0	1/1 (100)
Total	323/286	33/323 (10.2)	39/323 (12.1)	8/323 (2.5)	212 (+2 uknown) (66.3)	
					65/212 (30.7)	147/212 (69.3)

Note. VD — vaginal delivery.

indicated either if they strongly refuse to undergo surgery or if they have an unacceptably high risk of surgery. Further accumulation of data will enable either to radically revise this idea or to finally reinforce in it.

Recently, another application of FUS in gynecology has been for the treatment of infiltrative forms of endometriosis.

Under unresponsive drug therapy, the only treatment method for a long time was surgical intervention with the excision of the endometrioid infiltrate or even removal of the affected organ, despite the significant risk of adverse events. The efficiency of FUS in the treatment of adenomyosis is less studied than in the treatment of uterine leiomyoma. Thus, this method is still considered experimental for treating adenomyosis. As a result, the 2020 national clinical guidelines for "Endometriosis" do not mention the use of FUS ablation as a method for the treatment of infiltrative forms of endometriosis; however, the guidelines mention yoga and acupuncture for pain [53]. Nevertheless, the results of international studies on the application of the FUS technique seem to be very promising. Data have revealed that the use of FUS ablation is effective enough to alleviate, at least partially, the symptoms of adenomyosis, including menorrhagia and dysmenorrhea [54]. Therefore, this technique can be considered as an alternative to hysterectomy in cases of ineffective drug therapy and when a woman desires to preserve the uterus. However, further research is required to conclude that this technique does not adversely affect fertility.

In 2020 Philip et al. described the results of a phase I, uncontrolled, prospective clinical study of the Focal One® transrectal FUS (TRFUS) device for the treatment of deep infiltrative endometriosis involving the rectosigmoid intestine [55]. The study was conducted from September 2015 to October 2019 at the Croix-Rousse University Hospital in Lyon, which is a specialized center for the treatment of endometriosis. Just as B. Newwirth introduced a urological resectoscope in 1976 to remove submucous myomatous nodes, the TRFUS technique originated in urology. Focal One® is a TRFUS device used for the treatment of prostate cancer. The study aimed to assess the possibility of using this technique in the treatment of deep infiltrative endometriosis with damaged rectosigmoid intestine, as well as to determine its clinical efficacy and safety.

The study included 23 female patients with deep infiltrative endometriosis after ineffective conservative hormonal therapy. All patients aged >25 years, and none of them planned pregnancy within the next 6 months. In these patients, transvaginal sonography and magnetic

resonance imaging confirmed the presence of endometrioid infiltration of the uterus posterior wall, extending to the rectosigmoid intestine. Patients with endometriosis of the ovaries, bladder and ureters, and other parts of the intestine were excluded. Technically, it was possible to expose infiltrates to FUS in 20 of the 23 women (feasibility factor: 87.0%), so that the lesion was treated completely in 13 women and partially in 7. There was a significant decrease in the severity of dysmenorrhea, dyspareunia, diarrhea, constipation, dyschesia, false urge to defecate, pelvic pain, and asthenia compared with that determined during the preoperative examination. The authors report the absence of serious complications both during the procedure and after the procedure. Thus, TRFUS may become a non-invasive alternative technique for surgical intervention in the presence of deep infiltrative endometriosis spreading to the rectosigmoid intestine, if further studies confirm its clinical efficacy and safety.

CONCLUSIONS

The use of FUS in gynecology is of great clinical importance for treating uterine leiomyoma and infiltrative forms of endometriosis. Owing to its non-invasiveness, FUS is associated with almost no risk of intra- and postoperative complications, such as bleeding and infections, as well as complications associated with the provision of anesthetic support. This technique can be used on an outpatient basis. Moreover, owing to these advantages, the use of FUS may become especially widespread during the new coronavirus pandemic.

Currently, it is essential to further accumulate clinical experience regarding the use of FUS in gynecological practice. It is necessary to clearly outline patients with uterine leiomyoma and infiltrative endometriosis for whom this treatment may be the most effective and to determine patients for whom it is not indicated. Issues of influence on fertility as well as course and outcomes of pregnancy also remain open and require detailed study.

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