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MAGNETIC RESONANCE-GUIDED FOCUSED ULTRASOUND ABLATION IN THE MANAGEMENT OF SYMPTOMATIC ADENOMYOSIS: ASSESSMENT OF CLINICAL EFFICACY, SAFETY, AND IMPACT ON FERTILITY. A CASE SERIES

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Abstract

Introduction Adenomyosis is a common cause of chronic pelvic pain and impaired fertility in women. Traditional radical treatments, such as hysterectomy, are unacceptable for patients who wish to preserve reproductive function. The implementation of organ-sparing, non-invasive methods, such as Magnetic Resonance-guided Focused Ultrasound (MRgFUS), is highly relevant, especially given the limited experience in regional medical centers in Kazakhstan.

Materials and Methods A prospective case series study was conducted, including 69 patients with symptomatic adenomyosis treated with MRgFUS (ExAblate 2100 system) from 2022 to 2024. Inclusion criteria were strictly limited to ensure safety and technical applicability. Primary outcomes were assessed by the dynamics of pain syndrome by Visual Analogue Scale (VAS) and menstrual bleeding by Pictorial Blood Loss Assessment Chart (PBAC). Secondary outcomes included objective efficacy (Non-Perfused Volume, NPV via MRI at 3 and 6 months), safety, and pregnancy rate.

Results All 69 patients successfully tolerated the procedure. A significant clinical response was achieved in the majority: 85% reported reduced pain (VAS: 7.2 to 3.0), and 76% reported reduced menorrhagia. Objective efficacy was confirmed by NPV formation averaging 74% by 6 months. No late complications were registered. Three pregnancies were reported within 12 months post-procedure, two of which resulted in successful live births, indicating the preservation of reproductive function.

Conclusion MRgFUS is a highly effective, non-invasive, and safe organ-sparing treatment for symptomatic adenomyosis. The results align with international data, confirming its suitability, particularly for women interested in preserving fertility. This initial clinical experience in Kazakhstan demonstrates the need for further integration of MRgFUS into national clinical practice.

Keywords: Adenomyosis, MRgFUS, Focused Ultrasound, Non-Invasive Treatment, Dysmenorrhea, Fertility, Non-perfused Volume.

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Резюме

**МАГНИТНО-РЕЗОНАНСНАЯ ТОМОГРАФИЯ-КОНТРОЛИРУЕМАЯ
ФОКУСИРОВАННАЯ УЛЬТРАЗВУКОВАЯ АБЛАЦИЯ (МРФУЗ)
В ЛЕЧЕНИИ СИМПТОМАТИЧЕСКОГО АДЕНОМИОЗА: ОЦЕНКА
КЛИНИЧЕСКОЙ ЭФФЕКТИВНОСТИ, БЕЗОПАСНОСТИ И ВЛИЯНИЯ
НА ФЕРТИЛЬНОСТЬ. СЕРИЯ СЛУЧАЕВ.**

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Актуальность Аденомиоз является распространенной причиной хронической тазовой боли и нарушения фертильности у женщин. Традиционные радикальные методы лечения, такие как гистерэктомия, неприемлемы для пациенток, желающих сохранить репродуктивную функцию. Внедрение органосохраняющих, неинвазивных методов, таких как МРФУЗ, является крайне актуальным, особенно в контексте ограниченного опыта в региональных медицинских центрах Казахстана.

Методы Проведено проспективное исследование серии случаев, включающее 69 пациентки с симптоматическим аденомиозом, пролеченных методом МРФУЗ (система ExAblate 2100) с 2022 по 2024 год. Критерии включения были строго ограничены для обеспечения безопасности и технической применимости. Первичные исходы оценивались по динамике болевого синдрома по Визуально-аналоговой шкале (ВАШ) и менструальных кровотечений по Иллюстрированной таблице оценки кровопотери (ИТОК). Вторичные исходы включали объективную эффективность (Объем неперфузии, (НПО) по МРТ через 3 и 6 месяцев), безопасность и частоту наступления беременности.

Результаты Все 69 пациентки успешно перенесли процедуру. Значительный клинический ответ был достигнут у большинства: 85% сообщили о снижении болевого синдрома (ВАШ: 7.2 до 3.0), 76% – об уменьшении меноррагии. Объективная эффективность подтверждена формированием НПО в среднем 74% к 6 месяцам. Не зарегистрировано поздних осложнений. Отмечено наступление трех беременностей в течение 12 месяцев после процедуры, две из которых завершились успешными родами, что свидетельствует о сохранности репродуктивной функции.

Выводы МРФУЗ является высокоэффективным, неинвазивным и безопасным органосохраняющим методом лечения симптоматического аденомиоза. Результаты согласуются с международными данными, подтверждая его целесообразность, особенно для женщин, заинтересованных в сохранении фертильности. Данный первый клинический опыт в Казахстане демонстрирует необходимость дальнейшего внедрения МРФУЗ в национальную клиническую практику.

Ключевые слова: Аденомиоз, МРФУЗ, фокусированный ультразвук, неинвазивное лечение, дисменорея, фертильность, объем неперфузии

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Түйіндеме

СИМПТОМАТИКАЛЫҚ АДЕНОМИОЗДЫ ЕМДЕУДЕГІ МАГНИТТИ-РЕЗОНАНСТЫҚ ТОМОГРАФИЯМЕН БАСҚАРЫЛАТЫН ФОКУСТАЛҒАН УЛЬТРАДЫБЫСТЫҚ АБЛАЦИЯ (МРФУД): КЛИНИКАЛЫҚ ТИІМДІЛІГІН, ҚАУІПСІЗДІГІН ЖӘНЕ ФЕРТИЛЬДІККЕ ӘСЕРІН БАҒАЛАУ. КЕЙСТЕР СЕРИЯСЫ

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Өзектілігі Аденомиоз әйелдерде созылмалы жамбас қуысындағы ағзалардың ауырсынуы мен фертильдіктің бұзылуының жиі себебі болып табылады. Гистерэктомия сияқты дәстүрлі радикалды емдеу әдістері репродуктивті функцияны сақтағысы келетін пациенттер үшін қолайсыз. МРФУД сияқты ағзаны сақтайтын, инвазивті емес әдістерді енгізу, әсіресе Қазақстанның аймақтық медициналық орталықтарында тәжірибе шектеулі болғандықтан, өте өзекті.

Әдістері 2022-2024 жылдар аралығында МРФУД әдісімен емделген (ExAblate 2100 жүйесі) симптоматикалық аденомиозы бар 69 пациентті қамтитын проспективті кейстер сериясы зерттеуі жүргізілді. Қауіпсіздік пен техникалық қолданылуын қамтамасыз ету үшін қосу критерийлері қатаң шектелді. Негізгі нәтижелер ауырсыну синдромының Көрнекі аналогтық шкаласымен (КАШ) және етеккір қан кетуінің қан жоғалтуды бағалаудың суретті кестесі (ҚЖБСКҚ) динамикасы бойынша бағаланды. Қосымша нәтижелер объективті тиімділікті (3 және 6 айдан кейінгі МРТ бойынша перфузияланбаған көлем, ПК), қауіпсіздікті және жүктілік жиілігін қамтыды.

Нәтижелер Барлық 69 пациент процедураны сәтті өткізді. Көпшілігінде айтарлықтай клиникалық жауап алынды: 85%-ы ауырсыну синдромының төмендеуін (КАШ: 7.2-ден 3.0-ке дейін), 76%-ы меноррагияның азайғанын хабарлады. Объективті тиімділік 6 айға қарай орташа есеппен 74% ПК қалыптасуымен расталды. Кеш асқынулар тіркелген жоқ. Процедурадан кейінгі 12 ай ішінде үш жүктілік тіркелді, оның екеуі сәтті босанумен аяқталды, бұл репродуктивті функцияның сақталғанын көрсетеді.

Қорытынды МРФУЗ симптоматикалық аденомиозды емдеудің жоғары тиімді, инвазивті емес және ағзаны сақтайтын қауіпсіз әдісі болып табылады. Нәтижелер халықаралық деректермен сәйкес келеді, бұл оның мақсаттылығын, әсіресе фертильдікті сақтауға мүдделі әйелдер үшін, растайды. Қазақстандағы осы алғашқы клиникалық тәжірибе МРФУЗ-ті ұлттық клиникалық практикаға одан әрі енгізу қажеттілігін көрсетеді.

Түйіндеме сөздер Аденомиоз, МРФУЗ, фокусталған ультрадыбыс, инвазивті емес емдеу, дисменорея, фертильдік, перфузияланбаған көлем.

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Introduction

Adenomyosis is a prevalent form of internal endometriosis characterized by the invasion of endometrial tissue into the thickness of the myometrium. This condition significantly impairs the quality of life for women of reproductive age, standing as a leading cause of chronic pelvic pain, abnormal uterine bleeding (hypermenorrhea), and impaired reproductive function [10; 13].

The management of patients with symptomatic adenomyosis requires a differentiated approach. When conservative therapy (hormonal agents) proves ineffective, the question of surgical intervention often arises. However, traditional radical procedures, such as hysterectomy, result in the loss of the organ, which is unacceptable for patients who wish to preserve fertility. Consequently, modern gynecology is actively focusing on the development of organ-sparing and minimally invasive treatment modalities that can provide effective symptom relief with minimal risk while preserving reproductive potential.

In recent years, interest has grown significantly in Magnetic Resonance-guided Focused Ultrasound Ablation (MRgFUS) as a promising, non-invasive alternative. The MRgFUS technology is based on the remote delivery of high-intensity focused ultrasound energy. Under precise MRI guidance, the ultrasound beam is focused on the pathological lesion within the myometrium. The resulting local heating causes thermal necrosis (ablation) of the pathological tissue, while surrounding healthy structures remain intact [15]. Thus, MRgFUS adheres to the principles of organ-sparing and non-invasive treatment, making it particularly valuable for patients planning future pregnancies.

According to current literature, MRgFUS is an effective and safe method for treating adenomyosis, demonstrating encouraging outcomes, particularly in terms of fertility preservation. A number of studies and meta-analyses suggest that the rates of pregnancy and live birth following MRgFUS are comparable to those following other conservative methods [3; 4; 6–9; 12]. Nevertheless, the evidence base is still limited by a lack of large prospective studies, and some authors note a potentially higher frequency of re-interventions compared to surgical options [3; 7; 14].

Despite the global experience, data regarding the efficacy, safety, and impact on reproductive function of MRgFUS in domestic clinical practice, and specifically in regional medical centers of Kazakhstan, are scarce.

This paper presents an analysis of the first clinical experience with the application of MRgFUS in the management of symptomatic adenomyosis, conducted at the "Multidisciplinary Center of Oncology and Surgery" in Ust-Kamenogorsk city — the sole center in Kazakhstan utilizing this technology.

Objective: To evaluate the immediate and medium-term clinical efficacy, safety, and impact on reproductive function of Magnetic Resonance-guided Focused Ultrasound Ablation in the management of patients with symptomatic adenomyosis.

Materials and Methods

This study included 69 patients diagnosed with symptomatic adenomyosis. The research constitutes a prospective case series analysis and reflects the early

clinical experience with MRgFUS application at the "Multidisciplinary Center of Oncology and Surgery" in Ust-Kamenogorsk city during the period from 2022 to 2024. The cohort comprised all patients who met the strict inclusion criteria and underwent the procedure within the specified time frame.

The diagnosis of adenomyosis was verified based on comprehensive clinical and instrumental data, including patient history, transvaginal ultrasound (TVUS), and Magnetic Resonance Imaging (MRI) of the pelvis with contrast enhancement.

Inclusion criteria were: age between 25 and 48 years, preserved menstrual cycle, presence of symptoms (dysmenorrhea, hypermenorrhea, pelvic pressure sensation), and refusal of radical surgical treatment (hysterectomy). Exclusion criteria included: suspicion of malignancy, presence of an intrauterine device (IUD), severe adhesive disease, presence of a submucosal component of adenomyosis, or inadequate acoustic access.

The high specificity of the selection criteria, particularly technical limitations, resulted in a relatively small sample size, which is characteristic of studies involving the implementation of new high-technology methods.

The MRgFUS Procedure

Ablation procedures were performed using the ExAblate 2100 system (InSightec) in conjunction with a GE 3.0T Magnetic Resonance Imaging scanner. Standard planning protocols for the target zone were utilized, involving step-by-step MR-visualization and real-time temperature monitoring. All interventions were conducted on an outpatient basis, without the use of general or local anesthesia. The average duration of the MRgFUS session was 180 minutes.

Treatment efficacy was assessed based on pre-defined primary and secondary outcomes:

Primary Outcome

Clinical response, defined as the elimination or significant reduction of the primary adenomyosis symptoms. This assessment included:

1. Dynamics of pain syndrome using the Visual Analog Scale (VAS).
2. Dynamics of menstrual bleeding, assessed via The Pictorial Blood Loss Assessment Chart (PBAC), which possesses high sensitivity in detecting abnormal uterine bleeding [5].

Secondary Outcomes

1. Objective (Radiological) Efficacy: Reduction in the volume of the pathological focus according to MRI data, specifically the evaluation of the Non-Perfused Volume (NPV). Control MRI scans were performed at 3 and 6 months post-procedure.
2. Safety: Recording of complications during the procedure and in the early/delayed postoperative periods.
3. Impact on Reproductive Function: Frequency of pregnancy and delivery outcomes during the follow-up period.
4. Overall Tolerability: Assessment of the subjective reduction in complaints and return to normal physical activity.

The study was approved by the Local Ethics Committee (Protocol Number: № [Insert Protocol Number]; Date: [Insert

Date)). Informed consent for participation in the study and data processing was obtained from all patients.

Statistical Analysis

Continuous variables are presented as the mean $\pm$ standard deviation (SD) for normally distributed data or as the median with interquartile range (IQR) for non-normal distributions. Categorical variables are presented as frequencies (percentages). The Student's t-test was used to compare groups for normally distributed continuous variables, and the Mann-Whitney U test was used for non-normal continuous or ordinal data. Fisher's exact test was applied to compare categorical variables.

A two-sided p-value ≤ 0.05 was considered statistically significant. All analyses were performed using IBM SPSS Statistics, Version 26 (Armonk, NY, USA) software.

Results

The study included 69 patients with symptomatic adenomyosis. The mean age of the patients was 43.14 ± 3.82 years (range 38–47 years), which corresponds to the peak incidence of the disease (Table 1).

Analysis of the main clinical symptoms before treatment showed that for all patients the primary reason for seeking treatment was the sensation of pelvic pressure. Menstrual cycle disorders included menorrhagia in 19 women, while dysmenorrhea (menstruation-related pain) was noted in 14 patients. Non-menstruation-related pelvic pain was reported by 3 women. The mean number of myomatous nodes per patient was 2.03 (range 1–11). The mean total volume of fibroids in this group was 203.15 cm^3 .

Table 1:

Baseline Demographic and Clinical Characteristics of Patients (n=69)

Variables	Values
Age, years	43,14 (38-47)
Symptoms	
Pressure on the bladder, n	33
Menorrhagia, n	19
Dysmenorrhea, n	14
Pelvic pain, n	3
Number, Location, and Volume of Fibroids	
Total number of fibroids per patient, n	2,03 (1-11)
Submucosal (FIGO Classification), n	3
Intramural < 50% (FIGO Classification), n	20
Intramural > 50% интрамуральная (FIGO Classification), n	34
Interstitial-submucosal node (FIGO Classification), n	3
Intramural fibroid (FIGO Classification), n	4
Subserosal-intramural node (FIGO Classification), n	4
<50 cm ³ , n	24
≥50 и ≤80 cm ³ , n	20
>80 cm ³ , n	25
Fibroid Volume, cm ³	203,15

Primary Outcome

All 69 patients successfully tolerated the MRgFUS procedure. During the first 3 months of follow-up, 58 out of 69 patients (85%) reported a significant reduction in pain severity: the mean VAS score decreased from 7.2 ± 1.1 to

3.0 ± 1.4 . A reduction in the duration and intensity of menstrual bleeding was observed in 52 patients (76%). The sensation of pelvic pressure completely resolved in 44 women (64%).

Table 2:

Primary Outcome.

Symptom	Before	After	p-value
Pain Syndrome (VAS score reduction)	$7,2 \pm 1,1$	$3,0 \pm 1,4$	$p < 0.001$
Duration and Intensity of Menstrual Bleeding (PBAC score reduction)	$9,2 \pm 1,3$	$7,1 \pm 1,0$	$p < 0.05$
Complaint, n	69	21	$p < 0.05$

Secondary Outcomes

Control MRI with contrast enhancement performed at 3 months post-procedure registered the formation of a non-perfused volume (NPV) averaging 67% of the initial lesion volume. This further increased to 74% in 40 patients (58%) at 6 months, correlating with a continued improvement in the clinical picture **Figure 1**.

In no case was a repeat procedure or transition to an alternative treatment method required, and none of the patients reported complaints indicative of late complications. Three patients reported achieving pregnancy within 12 months after the procedure (all following focal adenomyosis treatment), two of which resulted in uncomplicated live births.

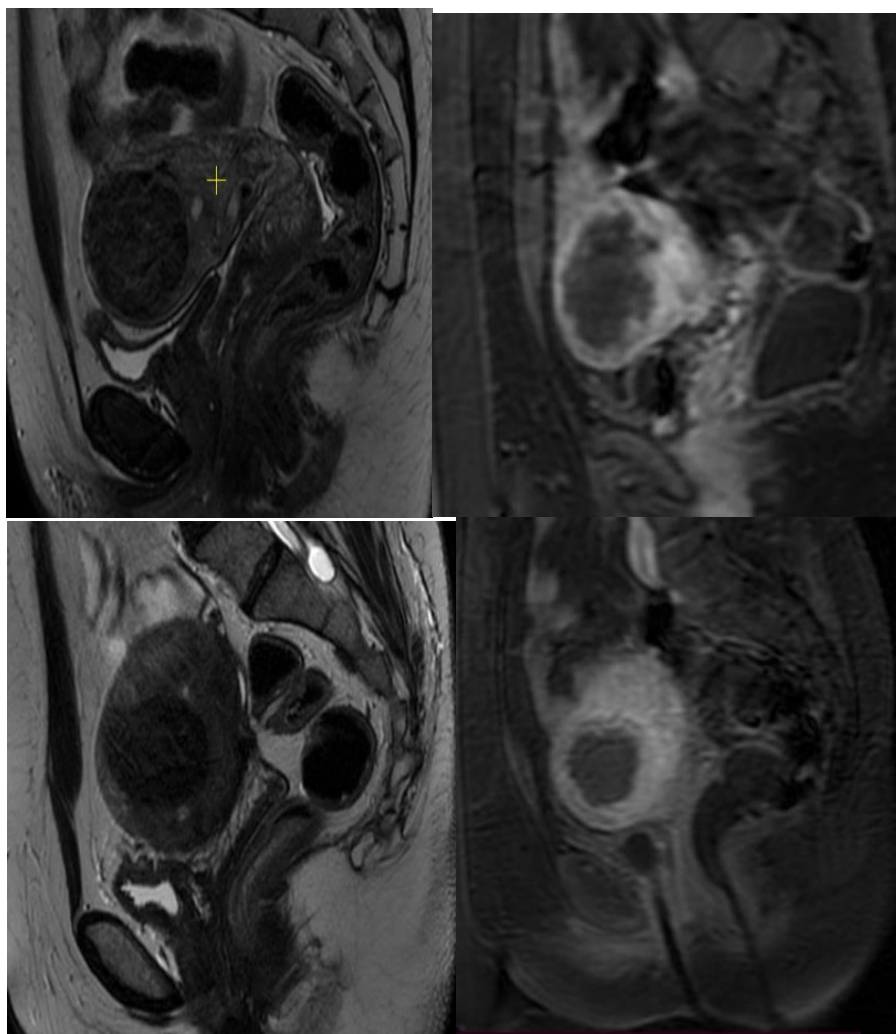


Figure 1: Fibroid Volume before (left) and after (right) MRgFUS procedure.

Discussion

The obtained results convincingly affirm the high clinical efficacy of the MRgFUS method in managing symptomatic adenomyosis. A significant majority of patients (85%) reported a marked reduction in pain syndrome, and 76% noted a decrease in the volume of menstrual bleeding. The mean VAS score decreased by more than 50%, which is consistent with previously published international data. For instance, in a study by Chin W. et al. (2016), clinical improvement was observed in 80–85% of patients during the first half-year [15].

The clinical success directly correlates with objective radiological indicators. Control MRI scans recorded the formation of a significant Non-Perfused Volume (NPV), reaching 74% by 6 months of follow-up. This indicator falls within the range noted in the works of Duc N.M. and Huy H.Q. (2018), confirming thermal destruction of the adenomyotic tissue as the key pathogenetic mechanism for symptom regression [11]. The observed increase in the non-perfused zone by 6 months suggests an ongoing process of necrosis and tissue remodeling, which correlates with further clinical improvement.

MRgFUS offers several unique advantages compared to surgical and endovascular methods: it is a non-invasive procedure, requiring no incisions or general anesthesia. We noted the absence of complications in our cohort, and all

procedures were performed on an outpatient basis, ensuring rapid rehabilitation and preserved working capacity for the patients. The method allows for the preservation of the myometrial and endometrial architecture, which is critically important for women of reproductive age.

Thus, our data confirm the high safety profile and excellent tolerability of MRgFUS, while common but non-treatment-requiring side effects (such as pelvic pain or nausea, described in [1; 2; 11; 15]) were minimal and did not lead to procedure cancellation or hospitalization.

One of the most valuable outcomes of our study is the evaluation of reproductive results. The fact that three pregnancies occurred in patients treated with MRgFUS, with two successful live births within 12 months, holds great clinical significance. These findings attest to the preservation of reproductive function after MRgFUS and support the feasibility of considering this method as a promising alternative to hysterectomy, as well as myomectomy or uterine artery embolization (UAE), in women planning pregnancy. Unlike UAE, MRgFUS is associated with a potentially lower risk of miscarriage and abnormal placentation [3; 7; 8; 12; 14].

Study Limitations and Unique Experience

The main limitations of this study are its non-randomized nature (case series) and the relatively small

sample size (n=69). However, it should be emphasized that this sample reflects the entire cohort of patients treated at our center over a three-year period. The small number of observations is due to the high specificity of indications for MRgFUS and the necessity of adhering to strict technical requirements, which confirms the study's focus on safety and the initial experience of introducing the technology.

A crucial aspect is that this study represents the first and unique clinical experience of MRgFUS application in the treatment of adenomyosis in Kazakhstan, as the procedure is exclusively available at the KGP on PHV VKO "Multidisciplinary Center of Oncology and Surgery" in Ust-Kamenogorsk. This underscores the relevance of further dissemination of the technology, which requires careful patient selection and the development of national clinical protocols.

Conclusion

MRgFUS is a highly effective, non-invasive, and organ-sparing method for treating adenomyosis, demonstrating a sustained reduction in clinical symptoms, improved quality of life, and a positive impact on reproductive function. The results obtained in the Kazakhstan clinical practice are consistent with international data and confirm the safety of the technology, its applicability in outpatient settings, and its promise for women interested in preserving fertility. Given the urgency of the problem and the availability of the method in only one center in the country, it is necessary to expand access to MRgFUS and further integrate it into national clinical guidelines.

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