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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии

საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

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GMN: Georgian Medical News is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

GMN: Медицинские новости Грузии - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНИТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

GMN: Georgian Medical News – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНИТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

WEBSITE

www.geomednews.com

К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman** (**Кириллица**), для текста на грузинском языке следует использовать **AcadNusx.** Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи**. Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - http://www.spinesurgery.ru/files/publish.pdf и http://www.nlm.nih.gov/bsd/uniform_requirements.html
В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректура авторам не высылается, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

При нарушении указанных правил статьи не рассматриваются.

REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or compu-ter-printed on a single side of standard typing paper, with the left margin of **3** centimeters width, and **1.5** spacing between the lines, typeface - **Times New Roman** (**Cyrillic**), print size - **12** (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.icmje.org/urm_full.pdf
In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

Articles that Fail to Meet the Aforementioned Requirements are not Assigned to be Reviewed.

ავტორთა საყურადღებოდ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე,დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx.** შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შეღებვის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფჩხილებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

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CLINICAL CHARACTERISTICS, IMAGING EFFICACY, AND SAFETY OF MRI-GUIDED FOCUSED ULTRASOUND ABLATION (FUS-MRI) IN THE TREATMENT OF UTERINE FIBROIDS: A SINGLE-CENTER EXPERIENCE

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Abstract.

Introduction: Uterine fibroids remain one of the most common benign tumors of the female reproductive system and a significant cause of menorrhagia, pain, symptoms of pelvic organ compression, and a reduced quality of life. Due to the limitations of surgical methods, organ-preserving and minimally invasive technologies are attracting increasing interest, including MRI-guided focused ultrasound ablation (FUS-MRI).

Objective: To evaluate the immediate imaging efficacy, early morphological response, and safety of FUS-MRI in the treatment of uterine fibroids based on the non-perfused volume ratio (NPVR) and 3-month changes in fibroid volume.

Materials and Methods: A prospective, single-center study was conducted involving 120 female patients with symptomatic uterine fibroids who underwent FUS-MRI ablation between December 20, 2019, and October 7, 2024. We analyzed clinical characteristics, morphological and MRI parameters of the target lesion, technical characteristics of the procedure, immediate post-procedural effects, and safety indicators. Efficacy was assessed based on contrast-enhanced MRI data immediately after the procedure, with determination of NPVR (%), as well as by changes in the volume of the target lesion at 3 months. Safety was assessed based on data from the registry and medical records.

Results: The mean age of the patients was 47.3 ± 6.1 years. The most common complaints were bladder pressure (49.2%), dysmenorrhea (24.2%), and menorrhagia (20.8%). The median NPVR was 80% (IQR 48–90), and the mean was 68.2 ± 29.2%. An NPVR threshold of ≥60% was reached in 71.7% of patients, ≥70% in 61.7%, ≥80% in 54.2%, ≥90% in 38.3%. Median NPVR values were numerically higher in hypointense and isointense nodules than in hyperintense nodules; however, the overall between-group comparison did not reach statistical significance (Kruskal–Wallis test, $p = 0.532$). After 3 months, the median reduction in the volume of the index nodule was 2.32% (IQR 1.29–3.69), with a mean of 2.96 ± 2.80%. No serious complications requiring invasive intervention, emergency hospitalization, or referral for surgical treatment were reported.

Conclusion: In a single-center setting, FUS-MRI demonstrated high immediate post-procedural imaging efficacy and a favorable safety profile. T2-weighted MRI characteristics of the lesion showed a numerical association with NPVR in the present cohort, although the between-group differences were not statistically significant and should be interpreted cautiously.

Key words. Uterine fibroids, FUS-MRI, MRgFUS, HIFU, non-perfused volume, NPVR, magnetic resonance imaging, organ-preserving treatment, safety, efficacy.

Introduction.

Uterine fibroids remain one of the most common benign tumors of the female reproductive system and a significant cause of abnormal uterine bleeding, pain, symptoms of pelvic organ compression, reduced quality of life, and impaired reproductive function. According to current data, the disease imposes a substantial clinical, social, and economic burden, and the global prevalence of uterine fibroids has remained high in recent years, necessitating further refinement of organ-preserving and minimally invasive treatment approaches [1,2].

Traditional surgical approaches, including myomectomy and hysterectomy, remain an important part of the treatment of symptomatic uterine fibroids; however, they are associated with invasiveness, anesthetic burden, postoperative recovery, and the risk of organ loss or scar formation. Consequently, organ-preserving and minimally invasive technologies are gaining increasing importance in modern clinical practice; the choice of these approaches must take into account clinical symptoms, the size and location of the fibroids, the patient's reproductive plans, and the balance between the expected efficacy and safety of the procedure [3,4].

MRI-guided focused ultrasound ablation (MR-HIFU, MRgFUS) is considered a non-invasive, organ-preserving alternative for carefully selected patients with symptomatic uterine fibroids. The method combines high-intensity focused ultrasound with MRI navigation and MRI thermometry, allowing for controlled thermal ablation of the tumor tissue without a surgical incision. According to recent reviews, MR-HIFU demonstrates a favorable safety profile and clinically significant efficacy in some patients; however, treatment outcomes depend on the anatomical characteristics of the tumor, its MR signal, size, availability of an acoustic window, and the parameters of the procedure itself [1,3,4].

Despite the accumulation of international experience, the analysis of real-world treatment outcomes within the context of a specific center—including an assessment of the immediate therapeutic effect and the procedure's safety profile—remains important for clinical practice. Such data allow us to clarify the clinical applicability of the method, compare local results with the global literature, and identify factors that

potentially influence the completeness of ablation and the early morphological response.

Purpose of the study.

To evaluate the immediate imaging efficacy, early morphological response, and safety of FUS-MRI treatment for uterine fibroids based on immediate NPVR and changes in fibroid volume over a 3-month follow-up period.

Materials and Methods.

This study was conducted as a prospective, single-center study based on the treatment of patients who underwent MRI-guided focused ultrasound ablation for symptomatic uterine fibroids. The study reflects the results of FUS-MRI application in clinical practice at the Multidisciplinary Center of Oncology and Surgery in Ust-Kamenogorsk.

The results of treatment for patients who underwent FUS-MRI ablation of uterine fibroids between December 20, 2019, and October 7, 2024, were analyzed. The analysis included 120 patients with a complete set of clinical, procedural, and instrumental data sufficient to evaluate the main parameters under study. The study took into account the clinical characteristics of the patients, the morphological features of the target myomatous node, baseline instrumental parameters, technical characteristics of the procedure, indicators of immediate post-procedural effects, and parameters for retrospective safety assessment.

The study was approved by the Local Ethics Committee (Protocol Number: No [4]; Date: 10.02.2023). Informed consent for participation in the study and data processing was obtained from all patients.

Inclusion and exclusion criteria:

The inclusion criteria were: voluntary informed consent to participate in the study; the presence of symptomatic uterine fibroids (menorrhagia, pain syndrome, infertility, pelvic organ dysfunction); and the presence of a target fibroid considered technically suitable for FUS-MRI based on preprocedural MRI evaluation.

In the final cohort, treated index fibroids corresponded to FIGO types 0–5, reflecting real-world patient selection based primarily on technical feasibility, MRI accessibility, and the presence of a safe acoustic window.

The criteria for excluding a patient from the study were the presence of endometrial hyperplasia, pregnancy, the development of severe complications from surgical treatment, the detection of malignant or atypical changes during histological examination of uterine fibroids and/or the endometrium, as well as refusal to continue participating in the study at any stage.

The study analyzed the following parameters: patients' clinical and anamnestic characteristics; primary complaints at the time of treatment; number of myomatous nodules; morphological characteristics of the index nodule, including its MRI signal intensity type on T2-weighted images;

the location of the node according to the FIGO classification; linear and volumetric characteristics of the myoma and uterus; anatomical parameters affecting the technical feasibility of the procedure, including the thickness of subcutaneous fat, the distance from the ultrasound focus to the center of the node, and the distance from the center of the node to the sacrum; technical parameters of FUS-MRI, including the total number of sonication sessions, the number of test and therapeutic sonication sessions, the power of the treatment, energy characteristics, and the volume of the treatment area (ROT); immediate post-procedural efficacy indicators; data from a retrospective safety assessment.

The T2 signal intensity of the index node was classified as hyperintense, isointense, or hypointense, and the location of the node was assessed according to the FIGO system. Volumetric parameters included baseline fibroid volume, uterine volume, region of treatment (ROT) volume, non-perfused volume (NPV) after contrast enhancement with Gadovist, and the percentage of the coagulation ablation zone. Additionally, data on the follow-up assessment of the nodule volume at 3 months and the calculated percentage reduction were presented.

FUS-MRI was performed according to a standard protocol using MR navigation and MR guidance during the procedure. During the procedure, the total number of sonication pulses, the number of verification pulses (Verify), the number of treatment pulses (Treat), the Measured Power value, and the energy parameters of the treatment—including the average, minimum, and maximum sonication energy—were recorded. Additionally, the volume of the treatment area (ROT) was recorded as one of the technical parameters of the procedure. This ensured a standardized description of the volume and intensity of the ultrasound exposure.

The efficacy of FUS-MRI was assessed at two levels: based on the immediate post-procedural instrumental effect and on the early volume dynamics of the target lesion during follow-up. The primary immediate instrumental criterion was non-perfused volume (NPV), determined based on contrast-enhanced MRI data after the procedure. Additionally, the percentage of the coagulation ablation zone (NPVR (%)) was assessed, reflecting the proportion of devitalized tissue within the treated nodule.

For follow-up, the volume of the index lesion at 3 months and the percentage of its reduction relative to baseline were recorded in the database. This parameter was considered an early morphological response to treatment.

The safety of FUS-MRI was assessed based on the registry and medical records. The primary focus was on the tolerability of the procedure and the identification of serious adverse events, particularly complications requiring invasive intervention, emergency hospitalization, or referral for surgical treatment. Additionally, the occurrence of clinically significant post-procedural complications was taken into account. This approach allowed for the characterization of the method's safety profile.

Statistical analysis:

Data analysis was performed using descriptive and inferential statistical methods. Quantitative variables were presented as mean ± standard deviation (M ± SD) for approximately normal distributions and as median [interquartile range] for skewed distributions. Categorical variables were presented as absolute values and percentages, n (%). Differences in NPVR among the T2-weighted MRI signal-intensity groups (hypointense, isointense, and hyperintense) were assessed using the Kruskal–Wallis test. This nonparametric test was chosen because NPVR was analyzed as a non-normally distributed variable and the hyperintense subgroup was small. A two-sided p value <0.05 was considered statistically significant.

Results.

The study included 120 female patients who underwent FUS-MRI ablation of symptomatic uterine fibroids between December 20, 2019, and October 7, 2024. The mean age of the patients was 47.3 ± 6.1 years, with a median of 46.0 years and an interquartile range of 43.0–49.5; the age range varied from 38 to 67 years. The sample was dominated by patients of late reproductive and perimenopausal age, which corresponds to the typical age profile of women seeking organ-preserving treatment for uterine fibroids.

Most common clinical complaints:

To analyze clinical symptoms, the primary complaint—which served as the main reason for seeking treatment—was recorded. The primary clinical symptoms in the study sample were heterogeneous; however, most frequently, patients reported complaints related to pelvic organ compression and menstrual dysfunction. The most common reason for seeking care was pressure on the bladder, reported by 59 patients (49.2%). Dysmenorrhea was noted in 29 patients (24.2%), menorrhagia in 25 (20.8%), while pelvic pain as the primary complaint was observed less frequently—in 7 patients (5.8%). The data obtained show that compression symptoms and menstrual disorders predominated in the clinical presentation of indications for FUS-MRI in this cohort.

Number of uterine fibroids:

According to instrumental assessment, the number of myomatous nodules in a single patient ranged from solitary

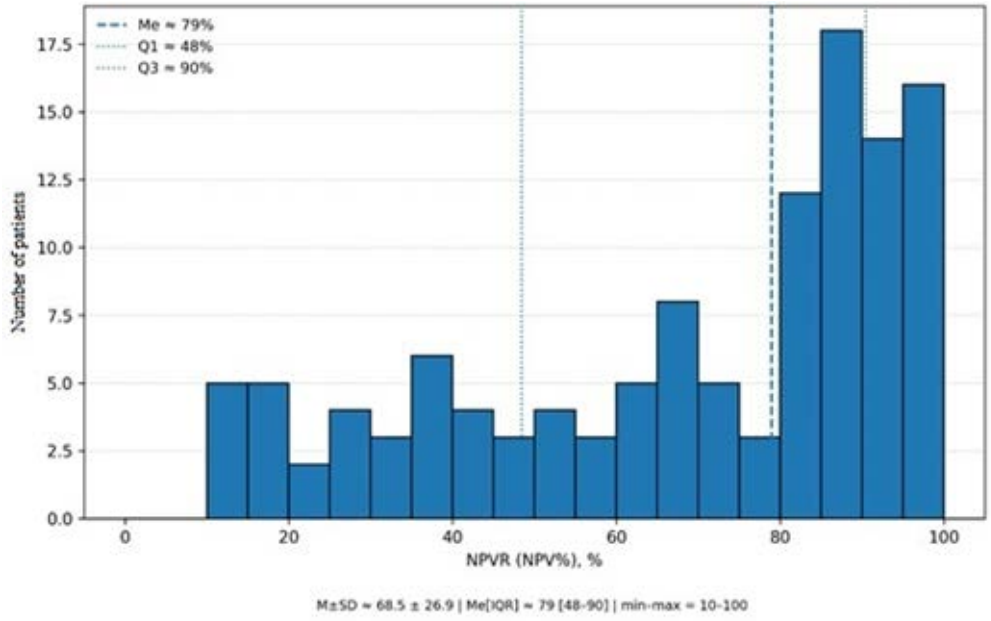

Figure 1. *Distribution of NPVR (%) based on contrast-enhanced MRI performed immediately after FUS-MRI.*

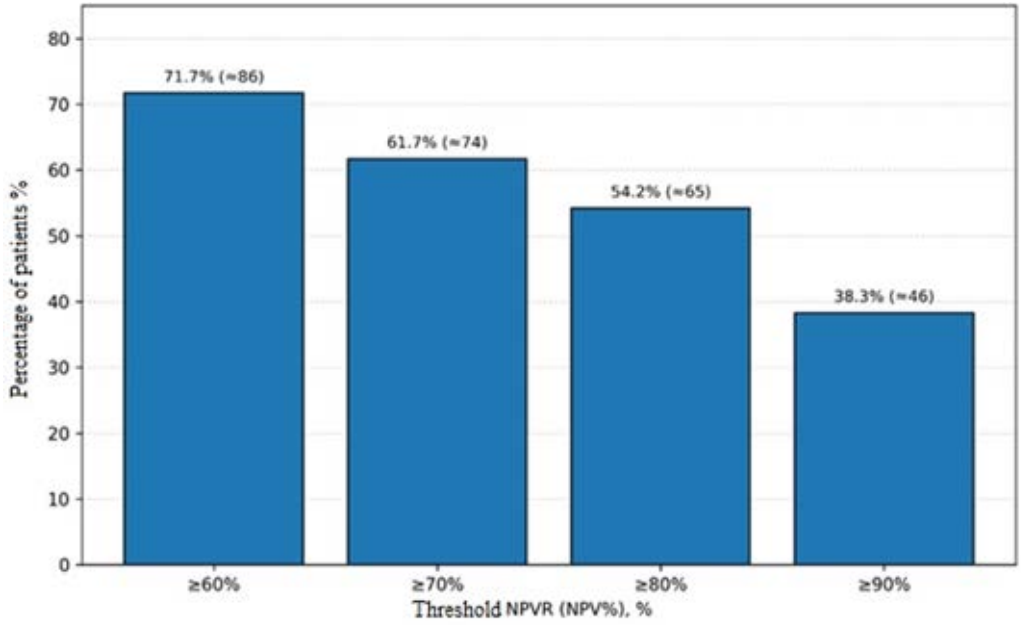

Figure 2. *Cumulative achievement of clinically significant thresholds for the percentage of the coagulation ablation area in the study cohort.*

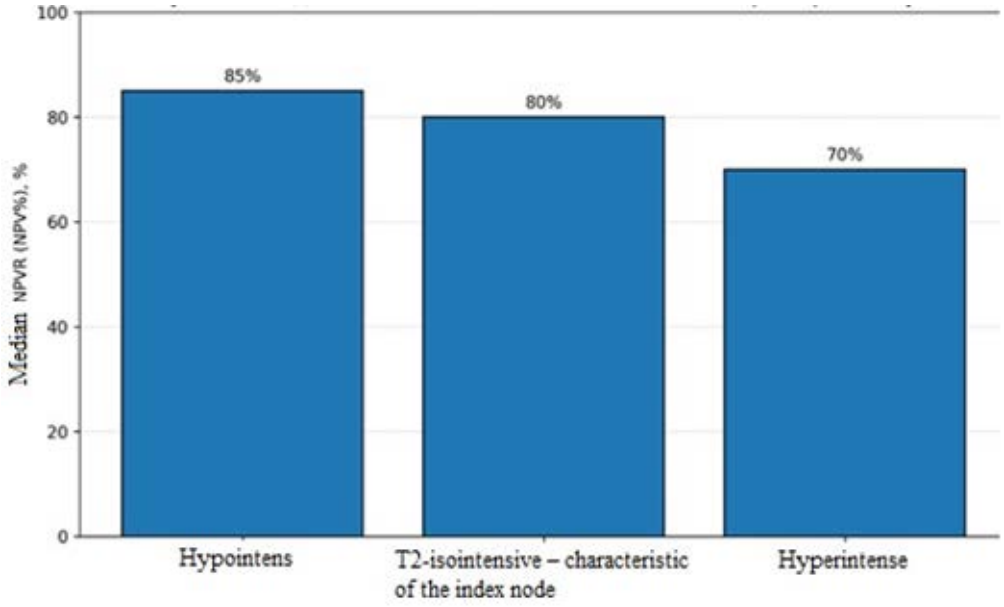

Figure 3. *Median percentage of the coagulation ablation zone as a function of the T2 characteristics of the index node.*

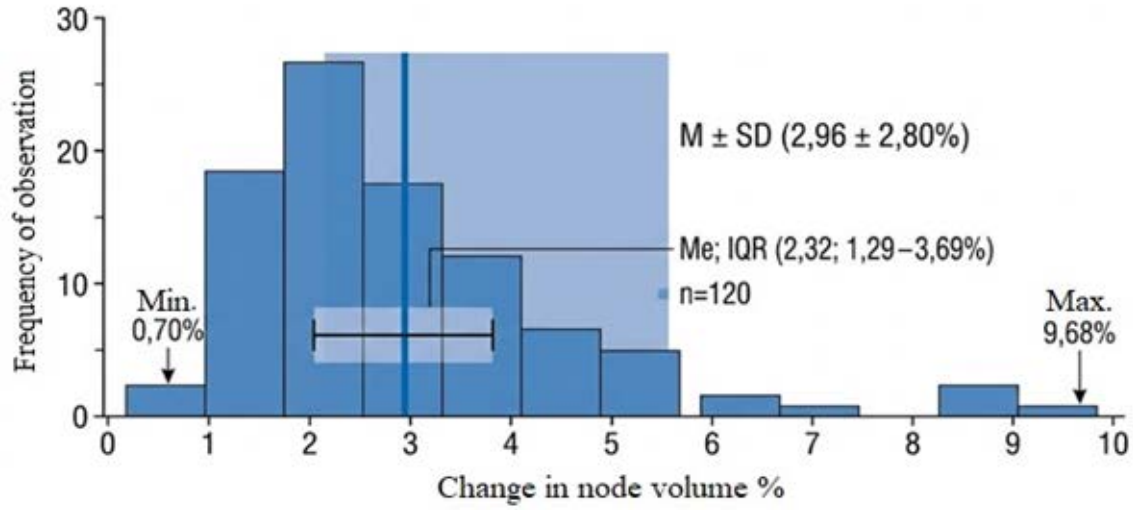

Figure 4. *Distribution of the percentage change in the volume of the index node after 3 months of observation (n=120).*

to multiple forms. The median number of nodules was 1 (IQR 1–2), while the mean was higher at 1.91 ± 2.15. The maximum number of nodules reached 11. Overall, the data indicate a predominance of patients with single or few myomatous nodules, while maintaining clinically significant heterogeneity within the cohort.

Morphological characteristics of the index node:

To standardize the assessment of the therapeutic effect, the primary myomatous node—selected as the target for treatment and subsequent MRI follow-up—was included in the analysis. The morphological characterization of the index node was based on two key parameters: the topographic-anatomical type according to the FIGO classification and signal intensity on T2-weighted images.

FIGO type 2 was the most common among the index nodes, with 62 cases (51.7%), indicating a predominance of nodes with a predominantly intramural location and limited extension into the uterine cavity. FIGO type 1 was the second most common, with 35 cases (29.2%). FIGO 0, 3, and 4 nodes were significantly less common—6 cases each (5.0% each), while FIGO 5 was recorded in 5 cases (4.2%).

Based on T2-weighted imaging, the distribution was nearly equal between hypointense and isointense nodules: 55 cases (45.8%) and 54 cases (45.0%), respectively. Hyperintense lesions were significantly less common, occurring in 11 cases (9.2%). This distribution was taken into account when interpreting the direct results of FUS-MRI.

Initial instrument parameters of the index node and anatomical constraints:

During the pre-procedural evaluation phase, the dimensional characteristics of the target lesion and anatomical parameters that could potentially affect the feasibility and safety of FUS-MRI were analyzed. Key indicators included the maximum diameter of the node, the initial volume of the myoma, the thickness of the subcutaneous fat layer, the distance from the

Table 1. *Demographic characteristics of the sample and the patients' ages.*

Indicator	Meaning
Activation period	20.12.2019 – 07.10.2024
Number of female patients, n	120
Age, years (M ± SD)	47,3 ± 6,1
Age, years (Me; IQR)	46,0; 43,0–49,5
Age, years (min–max)	38–67

Table 2. *Clinical complaints among female patients.*

Complaints	n	%
Pressure on the bladder	59	49,2
Dysmenorrhea	29	24,2
Menorrhagia	25	20,8
Pelvic pain	7	5,8
Total	120	100,0

Table 3. *Number of myomatous nodules per patient.*

Indicator	Meaning
Number of nodes (Me; IQR)	1; 1–2
Number of nodes (M ± SD)	1,91 ± 2,15
Number of nodes (max)	11

Table 4. *Morphological characteristics of the index node (A,B).*

A. Distribution according to the FIGO classification.

FIGO type	n	%
FIGO 0	6	5,0
FIGO 1	35	29,2
FIGO 2	62	51,7
FIGO 3	6	5,0
FIGO 4	6	5,0
FIGO 5	5	4,2
Total	120	100,0

A. T2 characteristic of the index node.

Signal type on T2-VI	n	%
Hypointense	55	45,8
Isointense	54	45,0
Hyperintense	11	9,2
Total	120	100,0

acoustic focus of the ultrasound to the center of the node, and the distance from the center of the node to the sacrum.

Baseline instrumental parameters were characterized by marked interindividual variability. The greatest heterogeneity was observed for the volume of the myoma: with a median of 84.0 cm³, the mean was 194.1 ± 269.1 cm³, and the range of variation was from 4.4 to 1189.0 cm³. The median maximum diameter of the index node was 58.5 mm (IQR 43.0–74.0), and the mean value was 64.3 ± 28.0 mm.

From an anatomical and technical perspective, the median thickness of the subcutaneous adipose tissue was 29.1 mm, the median distance from the ultrasound focus to the center of the myomatous nodule was 80.2 mm, and the median distance from the center of the nodule to the sacrum was 35.8 mm. These parameters characterize the depth of the target lesion and the features of the acoustic window, which largely determine the feasibility and technical performance of the MRgFUS procedure.

The acoustic window is defined as a safe and energy-efficient path for the ultrasonic beam to travel from the transducer to the target nodule without the interposition of critically important anatomical structures. Its quality depends on several interrelated factors. First and foremost, the size of the uterine fibroid is of significant importance: large nodules require a larger ablation volume, a greater number of sonication cycles, and more precise step-by-step coverage of the entire target, whereas with a large lesion volume, the likelihood of uneven heating, prolonged procedure time, and incomplete thermal ablation of peripheral regions increases. Equally important is the location of the tumor within the uterine structure: intramural and anterior wall fibroids are generally more accessible to treatment, whereas posterior wall, cervical, low-lying, subserosal, or fibroids located near bony structures may limit the effectiveness of focusing due to proximity to the sacrum, intestinal loops, or insufficient safety margin.

A key limiting factor is the position of the small intestine in the ultrasound beam's field of view. The interposition of intestinal loops, especially those containing gas, makes ultrasound examination unsafe and unpredictable, since gas sharply disrupts the propagation of ultrasound energy, causing its scattering and reflection, and also increases the risk of off-target heating of adjacent tissues. This is precisely why the presence of the intestine in the beam path often requires preliminary preparation of the patient, repositioning of the body, filling of the bladder or rectum, as well as the use of techniques to displace the uterus and intestinal loops to create an adequate acoustic window.

The anatomical position of the uterus itself is also of fundamental importance. In anteversion/anteflexion, the uterus is generally positioned more favorably for anterior ultrasound access, whereas in retroversion/retroflexion, the angle of beam entry changes, the depth of the target increases, and intestinal interposition occurs more frequently, which can significantly complicate the achievement of stable and safe focusing. In addition, the configuration of the pelvic cavity, the height of the uterine fundus, the degree of its rotation, as well as the relationship of the uterus to the anterior abdominal wall and pelvic bony landmarks all play a role.

The thickness of the subcutaneous fat layer is an additional parameter that affects the acoustic window, since an increase in soft tissue thickness along the beam path is accompanied by attenuation of ultrasonic energy, a reduction in the intensity of the effect at the focal point, and a potential increase in the risk of overheating the tissues of the anterior abdominal wall. In turn, the distance from the focus to the center of the lesion reflects the depth of the therapeutic target: as this distance increases, so do the requirements for sonication energy parameters and the precision of temperature monitoring. The distance from the nodule to the sacrum is also clinically significant, since with a posterior location of the lesion and insufficient clearance from bony structures, the risk of unwanted heating of the sacrum and surrounding tissues increases. Thus, the size of the myoma, its topography, the position of the uterus, its relationship to the intestines, and the depth of the target location form the individual characteristics of the acoustic window and, collectively, determine the technical feasibility, safety, and potential efficacy of MRgFUS therapy.

Table 5. *Initial instrument parameters for the index node and anatomical constraints.*

Parameter	Me (IQR)	M ± SD	Min–Max
Maximum diameter of the mass (D), mm	58,5 (43,0–74,0)	64,3 ± 28,0	22,0–117,0
Volume of the fibroid, cm³	84,0 (49,0–169,5)	194,1 ± 269,1	4,4–1189,0
Thickness of subcutaneous fat, mm	29,1 (22,9–39,2)	31,3 ± 10,8	10,6–50,5
Distance from the ultrasound focus to the center of the mass, mm	80,2 (60,6–90,3)	74,6 ± 20,2	40,1–114,3
Distance from the center of the mass to the sacrum, mm	35,8 (10,9–53,7)	33,6 ± 22,5	2,2–70,2

Table 6. *Groups by initial size of the index node.*

Group	Volume criterion	n	%
Group 1	< 50 cm³	38	31,7
Group 2	50–80 cm³	29	24,2
Group 3	> 80 cm³	53	44,2
Total	—	120	100,0

Table 7. *Technical parameters of FUS-MRI therapy.*

Parameter	Me (IQR; range)	M ± SD
Total number of sonication sessions, n	49 (34–74; 28–152)	57,1 ± 30,6
Verification sessions (Verify), n	1 (1–2; 1–6)	1,76 ± 1,30
Treatment sessions (Treat), n	48 (32–71; 25–151)	54,0 ± 26,1
Measured Power, W	145 (130–150; 69–177)	142,0 ± 23,4
Sonication energy (average), J	3189 (2755–3634; 1696–4101)	3122,8 ± 602,5
Sonication energy (maximum), J	5261 (4779–5703; 2433–7329)	5199,1 ± 974,2
Volume of the treatment area (ROT), cm³	84,0 (53,1–186,0; 4,2–650,0)	140,7 ± 133,9

Table 8. *Immediate post-procedural instrumental effect based on MRI data.*

Indicator	Me (IQR; range)	M ± SD
NPVR (%) based on post-procedural MRI data, %	80 (48–90; 10–100)	68,2 ± 29,2

Table 9. *Achievement of clinically significant NPVR thresholds (%).*

Threshold	Percentage of patients, %
≥60%	71,7
≥70%	61,7
≥80%	54,2
≥90%	38,3

Table 10. *NPVR (%) according to T2-weighted MRI signal intensity of the index lesion.*

T2-weighted MRI signal intensity of the index lesion	n	NPVR, % (Me [IQR])	Min–Max
Hypointense	55	85 [48–95]	10–100
Isointense	54	80 [40–90]	10–100
Hyperintense	11	70 [60–85]	10–100

** Overall comparison: Kruskal–Wallis test, p = 0.532.*
NPVR was compared across three independent groups using the Kruskal–Wallis test because the variable was analyzed as non-normally distributed and the hyperintense subgroup was small (n = 11).

Table 11. *Changes in the volume of the index lesion 3 months after FUS-MRI.*

Measure	Meaning, %
Change in node volume, M ± SD	2,96 ± 2,80
Change in node volume, Me (IQR)	2,32 (1,29–3,69)
Range	0,70–9,68

Table 12. *Key safety indicators for FUS-MRI in the study cohort.*

Indicator	Meaning
Serious complications requiring invasive intervention, n (%)	0 (0,0)
Referral for surgical treatment due to complications, n (%)	0 (0,0)
Overall tolerability of the procedure	Satisfactory

Stratification of the index node by initial volume:

For further clinical interpretation, the index nodes were stratified into three groups according to baseline volume: <50 cm^3, 50–80 cm^3, and >80 cm^3.

The study sample was dominated by tumors larger than 80 cm^3, reflecting the inclusion of a significant proportion of patients with clinically significant tumors. Smaller-volume nodules were less common. This sample composition is important for the subsequent interpretation of treatment technical parameters and the immediate post-procedural effect, since nodule size potentially influences both the ablation volume and the need for a greater number of therapeutic sonication cycles.

According to Table 6, the largest proportion of cases was in the group with a target lesion volume >80 cm^3 (44.2%), while the groups with volumes <50 cm^3 and 50–80 cm^3 accounted for 31.7% and 24.2%, respectively. This indicates that FUS-MRI was used not only for small but also for relatively large myomatous nodes, which increases the practical significance of the subsequent analysis of efficacy depending on the initial volume.

Technical parameters of the treatment:

The technical parameters of FUS-MRI were characterized by the expected variability resulting from differences in the size, depth, and morphological features of the target lesion. The median total number of sonication sessions was 49, of which 48 were therapeutic sonication sessions. The median measured power was 145 W, the median average ablation energy was 3,189 J, and the median maximum energy was 5,261 J. The volume of the treatment area (ROT) varied widely, reflecting the individualized nature of the ablation protocol and the dependence of the treatment volume on the clinical and anatomical characteristics of the node.

Immediate post-procedural instrumental effect:

The immediate procedural efficacy of FUS-MRI was assessed based on contrast-enhanced MRI performed immediately after the procedure. The primary endpoint in this analysis was the percentage of the NPVR coagulation ablation zone (%) as determined by post-procedural MRI. The median value was 80% (IQR 48–90), indicating a significant volume of devitalized tissue in most patients.

As shown in Table 8, the median NPVR (%) was 80% (IQR 48–90), with a mean of 68.2 ± 29.2%. The upper limit of the distribution reached 100%, reflecting the possibility of achieving nearly complete devitalization of the node in some patients under favorable anatomical and morphological conditions.

Achievement of clinically significant NPVR thresholds (%):

For clinical interpretation of the immediate result, the proportion of patients who achieved predefined NPVR thresholds (%) was additionally assessed. This approach allows the treatment efficacy to be presented in a practical format that is convenient for clinical interpretation and comparison with data from published studies, where similar thresholds are often used as benchmarks for the technical success of ablation.

As shown in Table 9, more than 70% of patients achieved a threshold of ≥60%, and more than half achieved a threshold of ≥80%, indicating a high rate of achieving a clinically significant immediate post-procedural effect. The gradual decrease in the proportion of patients as the thresholds become stricter, up to ≥90%, reflects the expected clinical and anatomical difficulty of achieving nearly complete coagulation-induced devitalization of the node.

Distribution of the ablation index according to the T2 characteristics of the lesion:

Median NPVR values differed numerically across T2-weighted MRI signal-intensity groups, being highest in hypointense fibroids, intermediate in isointense fibroids, and lowest in hyperintense fibroids. Specifically, median NPVR values were 85% [48–95] in the hypointense group, 80% [40–90] in the isointense group, and 70% [60–85] in the hyperintense group. However, the overall between-group comparison did not reach statistical significance (Kruskal–Wallis test, $p = 0.532$). Therefore, these findings should be interpreted as exploratory rather than confirmatory.

As shown in Table 10, median NPVR values were numerically lower in hyperintense fibroids than in hypointense and isointense fibroids; however, these differences were not statistically significant. Accordingly, the observed pattern should be interpreted with caution and may be considered hypothesis-generating rather than definitive.

3-month trend in the volume of the index node:

To assess the early morphological response following FUS-MRI, the volume of the index lesion was analyzed after 3 months of follow-up. According to follow-up MRI data, a trend toward a decrease in the volume of the treated lesion was observed in the study cohort, which is consistent with the expected early stage of post-ablation remodeling. At the 3-month mark, the morphological response has not yet reached its maximum extent, as the processes of tissue resorption and structural remodeling continue into later time points.

According to descriptive statistics, the median reduction in the volume of the index node at 3 months was 2.32% (IQR 1.29–3.69), and the mean was 2.96 ± 2.80%. The range of the indicator varied from −0.70% to 9.68%, indicating heterogeneity in the early morphological response within the study cohort. In most cases, a positive trend was observed, whereas isolated minimal negative values may reflect variability in MRI measurements, features of post-irradiation edema, or incomplete devitalization of the nodal tissue.

Thus, the observed 3-month reduction in fibroid volume should be interpreted as an early imaging marker of post-ablation remodeling rather than as a definitive estimate of long-term therapeutic benefit. A longer follow-up period is required to determine the full extent of fibroid shrinkage and its relationship to symptom relief.

Safety:

According to our data, no serious complications requiring invasive intervention, referral for surgical treatment, or emergency hospitalization were reported in the study cohort. Overall, the procedure was well tolerated. Thus, FUS-MRI analysis demonstrated a favorable safety profile in the setting of routine clinical practice at a single center.

Thus, in the study cohort, FUS-MRI demonstrated a high immediate post-procedural instrumental effect, a high rate of

achieving clinically significant thresholds in the coagulation ablation zone, and a favorable safety profile. Although median NPVR values were numerically lower in T2-hyperintense fibroids, the overall between-group comparison was not statistically significant; therefore, this observation should be interpreted as exploratory.

Discussion.

In this study, FUS-MRI demonstrated a high immediate post-procedural therapeutic effect and a favorable safety profile in a single-center routine practice setting. The median percentage of the coagulation ablation area was 80%, with 71.7% of patients reaching the ≥60% threshold and 54.2% reaching the ≥80% threshold. These data allow the results to be considered clinically significant and generally consistent with the concept of MR-HIFU as a technically effective non-invasive treatment method in carefully selected patients with symptomatic uterine fibroids. Current reviews indicate that MR-HIFU ranks among organ-preserving technologies alongside uterine artery embolization and radiofrequency methods, and the achieved effect largely depends on the size of the tumor, its location, the acoustic window, and the MR characteristics of the tissue.

These findings are noteworthy in the context of expanding the range of organ-preserving treatments for symptomatic uterine fibroids. While myomectomy and hysterectomy remain important options, minimally invasive and non-invasive technologies are becoming increasingly significant, as they reduce the invasiveness of treatment and preserve the uterus. A major 2025 review noted that MR-HIFU is one of the current alternatives for patients with suitable clinical and anatomical characteristics; however, the method's efficacy cannot be considered outside the context of proper patient selection. A similar rationale is reflected in the 2025 JOGC clinical guidelines, where energy-based uterus-sparing methods are considered part of the modern therapeutic spectrum for symptomatic uterine fibroids [3,4].

Our safety data are also consistent with the published literature. No serious complications requiring invasive intervention, emergency hospitalization, or referral for surgical treatment were reported in the study cohort. This is consistent with the findings of the systematic review by Kociuba et al., in which MRgFUS is characterized as a generally safe technology with a relatively low incidence of major adverse events, as well as the 2024 review by Ali et al., according to which HIFU for uterine fibroids is characterized in most cases by mild and transient side effects, with severe complications being rare. Thus, data from our center confirm the favorable safety profile of MRgFUS in real-world clinical practice [5-8].

We would like to specifically highlight the relationship between the immediate effect and the MRI type of the nodule. In our cohort, median NPVR values were numerically higher in hypointense and isointense nodules and lower in hyperintense nodules. However, the overall between-group comparison did not reach statistical significance (Kruskal–Wallis test, $p = 0.532$). Therefore, this pattern should be interpreted cautiously as an exploratory observation rather than as definitive evidence of a T2-dependent difference in ablation efficacy. At the same time, recent studies suggest that the T2 characteristics of a myoma may reflect features of its internal structure and perfusion and may therefore be associated with the efficacy of thermal ablation. In the study by Jiang et al., hyperintense nodules were considered a more challenging category for HIFU treatment, while the study by Zhou et al. emphasized the significance of preoperative prediction of NPVR based on T2-MRI features [5,6].

In practice, the numerical pattern observed in this cohort may still be of clinical interest; however, given the lack of statistical significance and the small size of the hyperintense subgroup, it should not be overinterpreted. Rather, it may be regarded as a hypothesis-generating finding that warrants validation in larger cohorts with balanced subgroup sizes. This is consistent with the modern approach to individualized treatment planning, which takes into account the size, location, and tissue characteristics of the nodule, as well as the patient's reproductive plans [3-6].

When comparing our results with the literature, it should be noted that direct quantitative comparisons between studies are limited by differences in study design, inclusion criteria, type of HIFU navigation, ablation protocols, the composition of the included nodes, and methods for calculating endpoints. Nevertheless, the overall trend of the data is consistent: HIFU is considered an effective and relatively safe uterus-sparing technology, and in meta-analyses, compared with surgical approaches, it has been associated with faster recovery and a lower incidence of major complications, with comparable rates of symptom control in a subset of patients [3,9].

At the same time, the clinical significance of the method in a broader sense is determined not only by the percentage of the coagulation ablation zone achieved (NPVR (%)), but also by the subsequent reduction in symptoms, changes in tumor size, quality of life, frequency of repeat procedures, and reproductive outcomes. According to the current literature, it is precisely the long-term effects that are significant for the patient that remain one of the most important areas for further research in the field of HIFU technologies for uterine fibroids [3]. Accordingly, the 3-month volume change reported in the present study should not be interpreted as a surrogate for final clinical benefit, particularly with respect to compression symptoms, menstrual symptoms, and quality-of-life improvement.

This study has several limitations. First, it was conducted at a single center, which may limit the generalizability of the findings. Second, the assessment of treatment outcomes was focused primarily on immediate post-procedural imaging parameters and early 3-month morphological changes. Therefore, the present dataset does not permit a direct assessment of clinical efficacy in terms of symptom relief or quality-of-life improvement. Third, the follow-up period for fibroid volume assessment was limited to 3 months, which reflects only the early phase of post-ablation tissue resorption and remodeling rather than the final therapeutic effect. Finally, the comparison of NPVR across T2-weighted MRI signal-intensity groups should be interpreted in light of the unequal group sizes, particularly the small number of hyperintense fibroids. These limitations should be taken into account when interpreting the results and comparing them with published studies.

Conclusion.

In a single-center setting, FUS-MRI demonstrated high immediate instrumental efficacy and a favorable safety profile.

Most patients achieved substantial immediate post-procedural devitalization of the target lesion, and no serious complications requiring surgical intervention were observed. Although median NPVR values were numerically lower in hyperintense nodules than in hypointense and isointense nodules, the between-group differences were not statistically significant in the present cohort and should therefore be interpreted as exploratory. Overall, the findings confirm the technical feasibility, favorable short-term imaging profile, and safety of FUS-MRI. Further studies with larger cohorts and longer follow-up are needed to clarify the role of MRI-based predictors and to assess clinical efficacy in terms of symptom relief and quality-of-life improvement.

Author Contributions.

Conceptualization – M.M.M., A.A.A., Y.N.; methodology - M.M.M., A.A.A., Y.N.; software – M.M.M., A.A.A., A.M.A.; validation – M.M.M., A.A.A., O.S.M.; formal analysis – M.M.M., A.A.A., R.S.K.; investigation - M.M.M., A.A.A., O.S.M.; data curation - M.M.M., A.A.A., O.S.M.; writing-original draft preparation - M.M.M., A.A.A.; writing-review and editing - M.M.M., A.A.A.; visualization - M.M.M., A.A.A.; supervision - A.A.A.; project administration - A.A.A.; funding acquisition - M.M.M., A.A.A.

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None of the authors have any conflicts of interest to disclosure.

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