

# Clinical Study on the Integrated Treatment of Adenomyosis without Fertility Requirements Using High-Intensity Focused Ultrasound Combined with Sequential Drug Therapy and Long-Term Standardized Management

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**Abstract:** *Objective:* To investigate the clinical efficacy, long-term control, and safety of an integrated treatment approach for adenomyosis without fertility requirements, incorporating MRI-based classification, GnRH-a pretreatment, high-intensity focused ultrasound (HIFU) ablation (Haifu Knife), sequential maintenance with Mirena/Dienogest, combined with close follow-up every 3 months and multiple supplemental treatments every 6–12 months. *Methods:* A retrospective analysis was conducted on 136 patients with adenomyosis without fertility requirements admitted to the gynecology department of our hospital from January 2019 to December 2025. Patients were stratified based on MRI classification, clinical symptoms, and the presence of adenomyoma: Those with simple adenomyosis and menorrhagia received GnRH-a + HIFU + Mirena; those with adenomyoma and severe dysmenorrhea received GnRH-a + HIFU + Dienogest. All patients underwent routine follow-up every 3 months post-treatment, with HIFU supplemental ablation performed every 6-12 months for residual or recurrent lesions, accompanied by long-term drug management. Dysmenorrhea VAS scores, menstrual volume, uterine volume, clinical efficacy, recurrence rate, and complications were observed before and after treatment. *Results:* All 136 patients completed treatment and standardized follow-up, achieving an overall clinical efficacy rate of 88.2%, with dysmenorrhea relief in 89.7%, menstrual volume improvement in 87.5%, and a mean uterine volume reduction of 32.6%. The median follow-up period was 24 months, with an overall recurrence rate of 11.8%. Recurrent cases were effectively controlled through multiple HIFU supplemental treatments without severe complications. *Conclusion:* For patients with adenomyosis without fertility requirements, the integrated management approach combining MRI-guided GnRH-a + HIFU + Mirena/Dienogest sequential therapy, frequent close follow-up, multiple supplemental ablations, and long-term drug maintenance significantly improves clinical symptoms, reduces uterine volume, and lowers recurrence risk. This approach is stable, safe, non-invasive, and aligns with the principles of standardized and individualized conservative treatment for adenomyosis, offering a new standardized uterine-preserving treatment paradigm for patients without fertility requirements.

**Keywords:** Adenomyosis; High-intensity focused ultrasound; Haifu knife; MRI classification; GnRH-a; Dienogest; Levonorgestrel-releasing intrauterine system; Long-term management; Multiple treatments

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## 1. Introduction

Adenomyosis is a prevalent benign gynecological disorder among women of reproductive age, characterized by the invasion of endometrial glands and stroma into the myometrium, accompanied by myometrial hyperplasia and hypertrophy. Clinically, it manifests as progressive dysmenorrhea, increased menstrual volume, uterine enlargement, and secondary infertility, severely impacting patients' physical and mental health and quality of life <sup>[1]</sup>. The diffuse nature of the lesions, unclear boundaries, high residual rates, and significant recurrence risk pose challenges for clinical conservative treatment. Traditional treatments primarily include symptomatic drug therapy, conservative surgery, and hysterectomy. However, drug therapy offers only temporary relief with frequent recurrences, while surgical interventions are invasive, and hysterectomy has profound physiological and psychological impacts on women, failing to meet the modern demand for uterine-preserving treatments.

High-intensity focused ultrasound (HIFU, Haifu Knife), as a non-invasive thermal ablation technique, has become an important conservative treatment for adenomyosis due to its advantages of precise targeted ablation, preservation of uterine anatomy and physiological function, and repeatability <sup>[2]</sup>. However, HIFU alone cannot fundamentally address the high recurrence rate of adenomyosis, necessitating the establishment of a standardized, full-chain management system encompassing pretreatment, ablation, consolidation, monitoring, and retreatment <sup>[3]</sup>. Since initiating HIFU treatment for adenomyosis in 2019, our hospital has developed an integrated diagnostic and therapeutic model combining MRI imaging classification, patient symptom characteristics, and clinical features of no fertility requirements: GnRH-a pretreatment to reduce lesion size, precise non-invasive HIFU ablation, sequential consolidation with Mirena/Dienogest, close follow-up every 3 months, and multiple supplemental treatments every 6–12 months as needed. This study systematically evaluates the short- and long-term efficacy and safety of this model through a retrospective analysis of 136 cases, aiming to provide high-quality clinical evidence for the standardized conservative treatment of adenomyosis in the field of Chinese obstetrics and gynecology.

## 2. Materials and methods

### 2.1. Study subjects

A total of 136 patients with adenomyosis without fertility requirements admitted to the gynecology department of our hospital from January 2019 to December 2025 were selected, aged 32–51 years old (mean  $40.5 \pm 5.2$  years old), with a disease duration of 1–10 years. Inclusion criteria: (1) Diagnosed with adenomyosis/adenomyoma based on clinical symptoms, gynecological examination, and pelvic MRI; (2) Mainly manifested as dysmenorrhea, increased menstrual volume, and uterine enlargement; (3) No fertility requirements, good compliance, able to complete regular follow-up and treatment; (4) No contraindications to HIFU treatment, GnRH-a, Dienogest, or Mirena; (5) Complete clinical and follow-up data. Exclusion

criteria: Uterine malignancy, acute pelvic infection, coagulopathy, drug allergies, fertility requirements, and incomplete clinical data. This study was approved by the hospital's medical ethics committee, and all patients signed informed consent forms.

## **2.2. MRI classification criteria**

All patients underwent pelvic MRI before treatment, and lesions were classified into four types based on lesion distribution, infiltration range, and relationship with the endometrium and myometrium, serving as the core imaging basis for individualized treatment planning: Type I (localized adjacent to the endometrium), Type II (diffuse myometrial infiltration), Type III (localized intramural), and Type IV (predominantly adenomyoma).

## **2.3. Treatment methods**

### **2.3.1. Individualized sequential treatment plan**

For simple adenomyosis with increased menstrual volume as the main manifestation, GnRH-a injections were administered for 3–6 cycles as pretreatment. After monitoring uterine reduction to the size of 8 weeks of gestation, precise HIFU ablation was performed, followed by placement of the levonorgestrel-releasing intrauterine system (Mirena) for long-term control of menstrual volume and inhibition of lesion recurrence.

For adenomyoma with progressive severe dysmenorrhea as the main manifestation: After GnRH-a pretreatment, HIFU ablation was performed, followed by sequential oral administration of Dienogest to specifically alleviate dysmenorrhea and delay lesion progression.

### **2.3.2. Long-term standardized management strategy**

Adenomyosis is characterized by high recurrence and a protracted course. This study implemented a full-cycle closed-loop management approach: (1) Close follow-up monitoring: Routine re-examination every 3 months post-treatment to assess clinical symptoms, gynecological ultrasound, and lesion changes, enabling early identification of residual and recurrent lesions; (2) Multiple supplemental treatments: For patients with lesion enlargement or symptom recurrence during follow-up, HIFU supplemental ablation was performed every 6–2 months based on individual circumstances to precisely target recurrent lesions; (3) Long-term drug maintenance: Drug regimens were dynamically adjusted based on symptom improvement to achieve long-term stable disease control.

## **2.4. Observation indicators**

Dysmenorrhea VAS scores, menstrual volume improvement, and uterine volume changes were recorded before and after treatment. The overall clinical efficacy rate and recurrence rate during follow-up were statistically analyzed. Complications during treatment and follow-up were observed to evaluate the safety of the regimen.

## **2.5. Efficacy evaluation criteria**

Markedly effective: Dysmenorrhea basically disappeared, menstrual volume returned to normal, and uterine volume was reduced by  $\geq 30\%$ ; Effective: Dysmenorrhea was significantly relieved, menstrual volume markedly decreased, and uterine volume was reduced by 10–29%; Ineffective: No improvement or worsening of clinical symptoms, with no reduction in uterine volume. The overall efficacy rate = (markedly effective

+ effective)/total number of cases  $\times$  100%. Recurrence was defined as an ultrasound/MRI indication of lesion enlargement during follow-up, with re-aggravation of symptoms such as dysmenorrhea and increased menstrual volume.

## 2.6. Statistical methods

Data were analyzed using SPSS 26.0 statistical software. Measurement data were expressed as mean  $\pm$  standard deviation, and comparisons before and after treatment were made using the *t*-test. Enumeration data were expressed as cases (%), and comparisons between groups were made using the  $\chi^2$  test.  $P < 0.05$  was considered statistically significant.

## 3. Results

### 3.1. Clinical efficacy

All 136 patients completed sequential treatment and standardized follow-up without dropouts. The overall efficacy rate was 88.2% (120/136), with 69 markedly effective cases, 51 effective cases, and 16 ineffective cases. The dysmenorrhea relief rate was 89.7%, the menstrual volume improvement rate was 87.5%, and the mean uterine volume reduction was 32.6%. Statistically significant differences were observed in all indicators before and after treatment ( $P < 0.05$ ).

### 3.2. Recurrence

The median follow-up period was 24 months, with 16 patients experiencing lesion recurrence, resulting in an overall recurrence rate of 11.8%. All recurrent cases promptly underwent HIFU supplemental ablation combined with drug consolidation, effectively controlling symptoms without any patients requiring hysterectomy due to recurrence or disease progression.

### 3.3. Safety evaluation

During treatment and follow-up, no severe complications such as intestinal, bladder, or vascular injury occurred, nor did adverse events, such as skin burns or pelvic infections. A few patients experienced mild lower abdominal distension and a small amount of vaginal discharge, which resolved spontaneously within a short period, indicating good safety.

## 4. Discussion

Due to its unique pathological characteristics, the core of clinical treatment for adenomyosis lies in uterine preservation, symptom control, and recurrence prevention. A single treatment modality is insufficient to meet long-term management needs <sup>[4]</sup>. GnRH-a, as a pretreatment drug, effectively reduces uterine volume, decreases lesion blood supply, optimizes HIFU treatment conditions, and enhances ablation precision and efficacy. HIFU utilizes the thermal effect of high-intensity focused ultrasound to non-invasively inactivate ectopic endometrial lesions, avoiding surgical trauma and preserving uterine integrity. Mirena and Dienogest provide long-term consolidation treatment targeting the two core symptoms of increased menstrual volume and dysmenorrhea, respectively, forming a complete treatment chain of pretreatment-ablation-maintenance in synergy <sup>[5,6]</sup>.

The core innovation of this study lies in the establishment of a long-term standardized management system tailored to patients without fertility requirements, which is also the key difference from traditional single treatment modalities. Frequent re-examinations every 3 months enable early warning of recurrence, while multiple HIFU supplemental treatments every 6-12 months promptly intervene in residual lesions. Combined with long-term drug maintenance, this approach fundamentally reduces the recurrence rate of adenomyosis, addressing the core challenge of long-term clinical management <sup>[7]</sup>. The study results demonstrate an overall clinical efficacy rate of 88.2% and a 2-year recurrence rate of only 11.8%, with excellent safety, fully confirming the scientific and practical value of this regimen.

Compared to traditional treatment plans, this model, guided by MRI classification, achieves type-specific treatment and precise intervention, incorporating non-invasiveness, repeatability, and individualization. It fully aligns with modern gynecological concepts of minimally invasive uterine-preserving treatment, providing a reproducible and promotable standardized diagnostic and therapeutic pathway for patients with adenomyosis without fertility requirements. It meets the requirements of the Chinese obstetrics and gynecology field for standardized and refined disease management <sup>[8]</sup>.

## 5. Conclusion

The integrated management approach combining MRI-based classification with GnRH-a + HIFU + Mirena/Dienogest sequential therapy, close follow-up every 3 months, multiple HIFU supplemental ablations every 6–12 months, and long-term drug maintenance demonstrates definite clinical efficacy, stable long-term control, and high safety in treating adenomyosis without fertility requirements. It significantly improves patient symptoms and reduces recurrence risk, representing an ideal conservative treatment option for adenomyosis worthy of clinical promotion and application in gynecology departments at all levels of medical institutions across the country.

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## Disclosure statement

The authors declare no conflict of interest.

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