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ARTICLE

Advancements in Drug Treatment for Adenomyosis

Yang Guo[1] Xiao Yanbing[2]

1.Graduate School of Zunyi Medical University, Zunyi City, Guizhou Province 564300
2.Gynecology, Zunyi Maternal and Child Health Hospital, Zunyi City, Guizhou Province 564300

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ABSTRACT

Adenomyosis is a common gynecological disease causing secondary dysmenorrhea, menstrual irregularities, and infertility. Traditionally, the treatment of adenomyosis has been primarily surgical; however, with the deepening understanding of the disease and the contemporary demand for fertility preservation, non-surgical treatments are gaining more attention. Pharmacotherapy, a key non-surgical approach, encompasses diverse strategies such as hormonal agents, anti-hormonal drugs (e.g., gonadal axis suppressants/blockers), non-steroidal anti-inflammatory drugs (NSAIDs), and traditional Chinese medicine (TCM). It plays a crucial role in managing adenomyosis, enhancing patients' quality of life, and preserving fertility.

In recent years, traditional Chinese medicine (TCM) and the integration of TCM with Western medicine have demonstrated unique advantages in adenomyosis management. Traditional Chinese medicine considers the main cause of adenomyosis to be "blood stagnation in the uterus," leading to poor circulation of qi and blood, which causes symptoms such as dysmenorrhea and menstrual abnormalities. The treatment principle is to invigorate blood circulation and resolve stasis, warming the meridians to improve qi and blood circulation, combined with lifestyle adjustments and other comprehensive interventions. The team has long been committed to clinical research on the grading treatment of adenomyosis, proposing the concept and approach of the "Danhuang San Plan," which integrates traditional and Western medicine based on the principles of Western medicine's gonadal axis suppression/blocking treatment and traditional Chinese medicine's invigorating blood circulation and resolving stasis, achieving good results and providing references for preserving the uterus and fertility in adenomyosis treatment. This article reviews the current status of drug treatment for adenomyosis and the team's related concepts and research results, aiming to provide references for non-surgical treatment of adenomyosis and support the practical need for fertility preservation in adenomyosis.

**Corresponding Author:*
Yang Guo, female, born on November 1, 1990, Miao nationality, from Fenghuang County, Hunan Province, holds a bachelor's degree and is a chief physician specializing in gynecology and obstetrics.

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Adenomyosis (AM) is a common gynecological disease found in women of reproductive age[1]. It exhibits hormone-dependent proliferation and invasive growth similar to malignant tumors, with its pathogenesis related to hormonal drives, genetic susceptibility, immune imbalance, and changes in the local microenvironment. Imaging or pathology presents benign characteristics, but long-term clinical management is required to avoid functional impairment or disease progression, hence it is often referred to as "benign cancer." There is currently no unified conclusion regarding the pathogenesis of AM, with various theories having theoretical limitations and academic controversies. Among many theories, the "in situ endometrium determination theory" and "3A model" proposed by Academician Lang Jinghe have gained widespread recognition[2]. Traditionally, the treatment of AM has been primarily surgical, especially for patients with larger uterine volumes or those who have failed conservative treatment[3-5]. However, surgical treatment has long recovery times and risks of loss of fertility[6], which does not align with the current context of declining birth rates, the national open fertility policy, and the strong advocacy for fertility preservation in academia[7]. Therefore, exploring non-surgical treatment methods for AM is of significant practical importance.

Non-surgical treatment methods for adenomyosis mainly include various drug therapies and physical therapies. Drug treatments include progestins/anti-hormonal drugs, intrauterine drug delivery systems, traditional Chinese medicine, and non-steroidal anti-inflammatory drugs[8-9]. Physical therapy, represented by High-Intensity Focused Ultrasound (HIFU), is a non-invasive treatment option[10-11]. However, HIFU treatment has limitations such as high equipment costs, dependence on acoustic pathways, selection of lesion types (better effects on anterior wall and focal types), combination schemes, and long-term recurrence, which restrict its clinical application[12-13].

Adenomyosis is a mass lesion formed by the endometrium located ectopically in the uterine myometrium under the influence of estrogen, leading to repeated bleeding and fibrosis[14]. Theoretically, methods that suppress the gonadal axis and atrophy the ectopic endometrium can treat this disease, which is the basic principle of various gonadal axis blocking/suppressing drugs and progestin treatments. Throughout the history of drug treatment for AM, various progestins or anti-hormonal drugs have been the mainstay, such as Danazol, Nemezine, and Dienogest; gonadal axis suppressants like Mifepristone and GnRHa[15-20]. These drugs primarily achieve therapeutic goals by atrophying the ectopic endometrium or suppressing the gonadal axis system, preventing the formation of new lesions. On this basis, the diseased tissue is absorbed by the body, and the pathogenic lesions/uterine volume are reduced to a certain extent. However, this reduction is very limited and does not favor the restoration of uterine morphology and fertility.

With the rise of fertility preservation concepts, traditional Chinese medicine and the combination of traditional and Western medicine have shown unique characteristics and advantages in the clinical treatment of AM[21-23]. The team explored the use of compound traditional Chinese medicine to treat ICR mouse models of adenomyosis over a decade ago, achieving good results[24]. Based on this, the team adopted the concept of combining traditional and Western medicine and proposed a methodology for grading treatment of AM, achieving satisfactory treatment outcomes[25]. This article aims to review the current status of drug treatment for AM and the team's related research results, providing references for non-surgical treatment and fertility preservation in AM.

一、Hormonal Treatment Drugs

1.Danazo　A synthetic progestin that acts like an androgen. Its main mechanism of action is to inhibit the synthesis of estrogen, thereby reducing the occurrence of endometriosis. However, this drug has notable side effects, such as weight gain, acne, and other androgen-related side effects, and has been largely eliminated[26-29].

2.Nemezine　A progestin derivative of 19-nortestosterone, previously used to treat endometriosis and AM. Studies have shown its poor efficacy and significant side effects[30-31], such as irreversible male characteristics with long-term continuous use, leading to poor patient compliance, and it has now been largely eliminated.

3.Dienogest　A synthetic progestin that primarily inhibits the proliferation of endometrial cells by activating progesterone receptors in the endometrium and reducing the biological activity of estrogen, thereby alleviating symptoms of AM, such as pain and irregular menstruation[32-34]. Some patients may experience irregular vaginal bleeding during use, affecting compliance. In addition, Dienogest does not significantly reduce lesions (uterine volume), which is not conducive to eliminating lesions and restoring uterine volume and morphology, thus hindering the recovery of uterine fertility.

4.Mirena　A levonorgestrel-releasing intrauterine device widely used in the treatment of AM. It can control menstrual bleeding and alleviate pain to a certain extent through continuous release of progestin[35]. However,

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Mirena's effectiveness drops as the size of the uterus or lesion increases, exhibiting a "lesion threshold" phenomenon[36-37]. Studies have shown that using Mirena alone for AM treatment is ineffective when the maximum myometrial thickness or maximum diameter of the adenomyoma (MD) > 35 mm, indicating that the effective "lesion threshold" for Mirena treatment of AM is MD ≤ 35 mm, with a recommendation for use at MD < 30 mm[38-40]. The "lesion threshold" is an academic viewpoint proposed by the team in the "Mirena Three Plan" for grading treatment of AM, which predates similar findings by foreign scholars by two years[40-41]. The academic viewpoint of the "lesion threshold" provides a reference for the clinical application of Mirena in treating AM, avoiding its excessive use.

The "Mirena Three Plan" based on grading treatment provides a complete methodology for "uterus-preserving" treatment of AM, but Mirena is an intrauterine device, and standard major uterine wall resection and reconstruction (MURU) has contraceptive effects[42]. More importantly, Mirena can only control symptoms, prevent disease progression, or recurrence within a limited degree of lesions (MD ≤ 35 mm), with no significant effect on reversing signs/lesions, which is not conducive to restoring uterine morphology and regaining fertility. This is a limitation of Mirena and the Mirena Three Plan in the context of fertility preservation.

二、Gonadal Axis Suppressants

1.Gonadotropin-Releasing Hormone Agonists (GnRHa) GnRHa is an analogue of Gonadotropin-Releasing Hormone (GnRH). GnRHa competitively inhibits pituitary GnRH receptors, blocking the pulsatile action of endogenous GnRH, achieving "chemical ovarian ablation" and reducing estrogen effects, thereby inhibiting repeated bleeding and fibrosis of ectopic lesions and preventing the formation of new lesions[17,43]. Due to its powerful "chemical ablation" effect, it can achieve a state similar to "artificial menopause," thus showing significant treatment effects during medication[44-45]. However, GnRHa drugs also have corresponding issues, such as high costs, low estrogen effects, and osteoporosis, making long-term use impractical[46-47]. Additionally, while these drugs can reduce lesions (uterine volume) through tissue absorption based on gonadal axis suppression, they cannot eliminate lesions or restore the uterus to normal size, which is not conducive to restoring uterine morphology and fertility. Therefore, they are often used as a phased treatment or in combination therapy[44].

2.Mifepristone Mifepristone is a progesterone receptor antagonist commonly used for medical abortion. With the expansion of clinical applications and in-depth research, it has been found that this drug participates in regulating the function of the hypothalamic-pituitary-ovarian axis (HPO axis). Mifepristone can act on the hypothalamus to inhibit the secretion of Gonadotropin-Releasing Hormone (LHRH), thereby affecting the secretion of Follicle-Stimulating Hormone (FSH) and Luteinizing Hormone (LH). At the same time, it can directly act on the pituitary to inhibit the release of FSH and LH, suppressing ovarian function and reducing the secretion of estrogen and progesterone, thereby inhibiting the growth of fibroids and adenomyosis[48-49]. Multiple studies have confirmed that Mifepristone has good efficacy in treating AM, especially suitable for patients wishing to preserve fertility[50-52]]. Other studies have shown that Mifepristone effectively alleviates the inflammatory response and related symptoms of AM by inhibiting the secretion of inflammatory cytokines, limiting mast cell activation, and reducing nerve fiber density[51]. Clinical studies have shown that Mifepristone can significantly relieve symptoms in adenomyosis patients, such as dysmenorrhea and heavy menstrual bleeding, while also reducing uterine volume[52]. However, compared to GnRHa drugs, Mifepristone's suppressive effect on the gonadal axis is milder. Although it can downregulate the secretion of FSH, LH, and estrogen, it does not reach the level of "chemical ovarian ablation" seen with GnRHa drugs, thus its therapeutic effect is also lower[53].

三、Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

NSAIDs are the first choice for pain management in AM patients, reducing the synthesis of prostaglandins by inhibiting the activity of cyclooxygenase (COX-1 and COX-2), thereby decreasing the inflammatory response in the uterine myometrium[17]. In the pathogenesis of AM, local inflammatory responses are prominent, with prostaglandins (especially PGE2) playing a key role in pain and abnormal uterine contractions. NSAIDs alleviate inflammation, reduce pain, abnormal smooth muscle contractions, and abnormal uterine bleeding by inhibiting cyclooxygenase (COX) and blocking the conversion pathway of arachidonic acid to prostaglandins, thus reducing PGE2 synthesis[4,54]. However, NSAIDs do not reduce ectopic lesions and have gastrointestinal discomfort and damage as side effects with long-term use, making them not a routine or commonly used drug for treating AM.

四、Traditional Chinese Medicine Treatment

Traditional Chinese medicine has shown certain

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effects in the treatment of AM due to its unique treatment concepts. Traditional Chinese medicine categorizes AM under "dysmenorrhea" and "heavy menstrual bleeding," attributing it to pathogenesis categories such as "qi stagnation and blood stasis" and "spleen deficiency and blood stasis." The treatment principle is to invigorate blood circulation and resolve stasis to improve qi and blood circulation. Research by Cai Xiaohui et al. showed that the serum containing Guizhi Fuling Pill with additional ingredients could reduce the wet weight and uterine coefficient in AM rats[55]. Luo Xuejuan et al. used Xuefu Zhuyu Decoction to treat AM, demonstrating that this formula achieves clinical efficacy through its regulatory effect on the hormonal endocrine system[56]. Research by Li Kunyin's team confirmed that modified Shaoyao Gancao Decoction can inhibit the proliferation of human adenomyosis cells, reduce cell migration, effectively regulate endometrial thickness and uterine volume, adjust serum hormone levels, alleviate dysmenorrhea symptoms, and improve disease outcomes[57-59]. Traditional Chinese medicine has unique characteristics in treating AM, alleviating dysmenorrhea, reducing menstrual flow, and shrinking lesions through methods such as invigorating blood circulation and resolving stasis. However, pure traditional Chinese medicine treatment has limitations such as slow onset and long treatment duration, making it difficult to effectively shrink or eliminate ectopic lesions, leading to symptom recurrence.

五、Combination of Traditional and Western Medicine Treatment

The combination of traditional and Western medicine in treating AM reflects the complementary advantages and synergistic effects of both approaches. Western medicine can quickly suppress the gonadal axis, reduce estrogen production, or atrophy ectopic endometrium, preventing the formation of new lesions; while traditional Chinese medicine's effects of "invigorating blood circulation and resolving stasis" can eliminate existing lesions (old lesions) and reduce the side effects of Western medicine, enhancing treatment compliance. Clinical research by Wei Xinjun et al. showed that compared to using Dienogest alone, the combination of Xuandan Sanjie Decoction and Dienogest effectively improved clinical symptoms in patients with qi stagnation and blood stasis type AM, especially in reducing abnormal uterine bleeding caused by Dienogest[23]. Jia Haijin used Shaofu Zhuyu Decoction combined with Leuprolide to treat AM postoperative patients, achieving higher overall efficacy and reducing dysmenorrhea scores, disease indicators, and adverse reaction rates compared to using Leuprolide alone[60]. Wang Liyuan et al. showed that the combination of Sanjie Zhen Tong Capsule and Dienogest in treating AM could exert synergistic effects through multi-target mechanisms, significantly improving hormonal balance, uterine morphological indicators, optimizing menstrual cycle characteristics, and ensuring medication safety[61]. Research by Qiao Xiaoli et al. demonstrated that the combined application of Guizhi Fuling Wan and Ethinyl Estradiol/Progesterone Tablets could enhance clinical efficacy in AM through multi-target synergistic mechanisms, significantly alleviating dysmenorrhea symptoms, reducing uterine volume, improving coagulation function, and downregulating serum-related factor levels[62]. Research by Li Juan et al. showed that Mifepristone combined with Xuefu Zhuyu Decoction has a definite therapeutic effect on AM, outperforming the single Mifepristone regimen[63]. The combination of traditional and Western medicine leverages their respective advantages, forming complementary and synergistic effects, providing new ideas and methods for the comprehensive treatment of AM.

The team has long been dedicated to research on AM treatment, validating the therapeutic effects of compound traditional Chinese medicine based on Danshen and Huangqi in ICR mouse models of adenomyosis over a decade ago[24]. This compound traditional Chinese medicine is the same as the "Danhuang Quyu Capsule/Tablets" (referred to as Danhuang) formula (20 medicinal materials), with the main functions being: invigorating blood circulation and relieving pain, softening and resolving masses, suggesting that Danhuang may have a therapeutic effect on AM (this indication is not listed in the Danhuang instructions). In subsequent exploratory and non-systematic clinical observations using Danhuang to treat moderate to severe patients, the team found that using Danhuang alone for treatment took a long time and had poor efficacy. Therefore, the team combined the rich theoretical and practical experience accumulated from the previous "Mirena Three Plan" grading treatment of AM and the principles of pharmacoeconomics maximizing cost-effectiveness and efficacy, adopting a combination of traditional and Western medicine and grading treatment approach, gradually forming a methodology based on "Danhuang," used alone or in combination with Mifepristone or Leuprolide/Triptorelin to treat mild, moderate, and severe AM, achieving satisfactory treatment outcomes through prospective and systematic clinical research[25]. The "Danhuang Three Plan" consists of: 1. Danhuang Plan: using Danhuang alone, suitable for mild AM; 2. Danmi Plan: Danhuang + Mifepristone, suitable

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for moderate AM; 3. Danrui Plan: Danhuang + Leuprolide (Leuprolide/Triptorelin), suitable for severe AM[64].

Clinical research results of the "Danhuang Three Plan" indicate that the grading treatment of mild, moderate, and severe AM is very significant. Considering efficacy alone, the "Danrui Plan" shows the fastest effect and best efficacy, making it worthy of priority consideration for patients with severe AM who need to rapidly reduce uterine lesions to meet fertility needs. However, under the premise of ensuring efficacy, the three principles of pharmacoeconomics must be considered in clinical practice. The "grading and adjustment" treatment model of the Danhuang Three Plan not only reduces treatment costs but also minimizes potential toxic side effects of drugs, reflecting the maximization of cost-effectiveness and efficacy, and is the reason and charm of "grading" treatment. The "Danhuang Three Plan" provides a systematic, complete, and non-invasive treatment concept and methodology for AM, representing another innovation and breakthrough by the team following the "Mirena Three Plan" grading treatment of AM.

六、Conclusion and Outloo

AM is prevalent among women of reproductive age, with an incidence rate of 5% to 70% in the female population[65-66]. In the context of fertility preservation, treatments for AM that protect fertility should receive widespread attention. Among the existing methods for preserving fertility, the combination of traditional and Western medicine has shown unique advantages. Its core advantage lies in the synergistic effects of traditional and Western medicines, as seen in the "Danhuang Three Plan," where Western medicine (Mifepristone, GnRHa) suppresses/block the gonadal axis and prevents the formation of new lesions; while Danhuang's "invigorating blood circulation and resolving stasis" eliminates already formed lesions, thus having a significant effect on reversing signs (shrinking lesions) and restoring uterine morphology and volume, which undoubtedly has clear practical significance in the context of fertility preservation. The concept of blending traditional and Western medicine should become the foundation for drug treatment of AM to achieve non-invasive and rapid elimination of lesions.

Furthermore, AM is a disease primarily characterized by changes in the uterine myometrium, with varying degrees of lesions, akin to cancer staging treatment, which should be treated differently based on "staging" or "grading" with different treatment plans. The team's treatment model for AM combining traditional and Western medicine, grading, and adjustment is conducive to non-invasive, precise, and standardized disease treatment, also aligning with the three principles of health economics and clinical medication habits. The idea of "grading" treatment should become the cornerstone of AM treatment.

Although the combination treatment concept represented by the "Danhuang Three Plan" has shown satisfactory therapeutic effects in preserving fertility in AM, there are also corresponding issues, such as the lack of AM indications in the Danhuang guidelines, which hinders clinical application under strict insurance controls; gastrointestinal reactions caused by oral Danhuang may obstruct treatment continuity and affect efficacy; AM is a chronic disease requiring long-term management, all of which are clinical challenges. Therefore, increasing the new indications for existing traditional Chinese medicines (such as Danhuang) or developing new formulations (such as injections); conducting in-depth research on new traditional Chinese medicines that can effectively shrink ectopic lesions and establishing long-term chronic disease management systems should be the direction for non-invasive and fertility-preserving treatment of AM.

With reason and belief, as we learn more about AM and develop new treatments and formulations, we can expect more personalized and effective drug therapies. The combination of traditional and Western medicine treatment model is expected to become mainstream, providing AM patients with more comprehensive and efficient non-invasive treatment options.

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