ORIGINAL RESEARCH ARTICLE

Assessing dydrogesterone efficacy in endometrial protection for abnormal uterine bleeding from endometrial hyperplasia

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Abstract

This study was designed to determine the effectiveness of dydrogesterone in protecting the endometrium in females experiencing irregular uterine bleeding arising from endometrial hyperplasia. A cohort of 112 patients suffering from abnormal uterine bleeding due to endometrial hyperplasia, who underwent hysteroscopic surgery at our institution between January 2019 and May 2023, were assigned to two groups. Following the surgery, dydrogesterone was provided to the observation group. In contrast, medroxyprogesterone acetate-ethinyl estradiol tablets were utilized for the control group in conventional treatment. Primary outcomes included symptom improvement, treatment effectiveness, and safety profiles. Secondary outcomes involved assessing health-related life quality by employing the SF-36 questionnaire. The base characteristics were nearly the same between groups ($P > 0.05$). Following treatment, the observation group exhibited significantly greater improvements in symptoms and treatment effectiveness as opposed to the control group ($P < 0.05$), without an increase in adverse reactions. Moreover, while both groups experienced significant enhancements in SF-36 scores from baseline, the observation group showed more pronounced improvements in certain dimensions ($P < 0.05$). Dydrogesterone treatment following hysteroscopic surgery for females with abnormal uterine bleeding and endometrial hyperplasia demonstrates superior efficacy in endometrial protection and symptom management, without escalating adverse effects. The observed enhancements in quality of life underscore its clinical utility, suggesting dydrogesterone as a valuable therapeutic option in this clinical context. *(Afr J Reprod Health 2025; 29 [12]: 25-32).*

Keywords: Dydrogesterone; Abnormal uterine bleeding; Irregular endometrial growth; Hysteroscopy surgery

Résumé

Cette étude a été conçue pour évaluer l'efficacité du dydrogesterone dans la protection de l'endomètre chez les femmes présentant des saignements utérins irréguliers dus à une hyperplasie endométriale. Une cohorte de 112 patientes souffrant de saignements utérins anormaux liés à une hyperplasie endométriale, ayant subi une chirurgie hystéroscopique dans notre établissement entre janvier 2019 et mai 2023, a été répartie en deux groupes. Après l'intervention, le groupe observation a reçu du dydrogesterone, tandis que le groupe témoin a été traité de manière conventionnelle par des comprimés d'acétate de médroxyprogestérone et d'éthinylestradiol. Les critères de jugement principaux comprenaient l'amélioration des symptômes, l'efficacité du traitement et les profils de sécurité. Les critères secondaires portaient sur l'évaluation de la qualité de vie liée à la santé à l'aide du questionnaire SF-36. Les caractéristiques de base étaient similaires entre les groupes ($P > 0,05$). Après traitement, le groupe observation a présenté des améliorations significativement plus marquées en termes de symptômes et d'efficacité thérapeutique par rapport au groupe témoin ($P < 0,05$), sans augmentation des effets indésirables. De plus, bien que les deux groupes aient montré une amélioration significative des scores SF-36 par rapport au départ, le groupe observation a affiché des progrès plus nets dans certains domaines ($P < 0,05$). Le traitement par dydrogesterone après chirurgie hystéroscopique chez des femmes présentant des saignements utérins anormaux et une hyperplasie endométriale démontre une efficacité supérieure dans la protection endométriale et la gestion des symptômes, sans accroissement des effets indésirables. Les améliorations constatées de la qualité de vie soulignent son utilité clinique, suggérant le dydrogesterone comme une option thérapeutique précieuse dans ce contexte clinique. *(Afr J Reprod Health 2025; 29 [12]: 25-32).*

Mots-clés: Dydrogesterone ; Saignements utérins anormaux ; Croissance endométriale irrégulière ; Chirurgie hystéroscopique

Introduction

Excessive and irregular uterine bleeding, occurring both within and beyond the menstrual cycle, represents a prevalent gynecological concern affecting females across diverse age demographics[1,2]. This condition, known as abnormal uterine bleeding (AUB), manifests during adolescence, reproductive years, and menopause, encompassing a broad spectrum of menstrual irregularities[3]. In clinical practice, hysteroscopy serves as a valuable diagnostic tool, affording clinicians direct visual access to the uterine cavity. Through this minimally invasive procedure, healthcare providers can discern abnormalities such as endometrial polyps, uterine fibroids, or adenomyosis, all frequently implicated in AUB[4].

Treatment strategies for endometrial hyperplasia, characterized by thickening of the endometrium, hinge on various factors including disease severity, patient age, fertility aspirations, and individual health considerations[5,6]. Among the array of therapeutic modalities, pharmacotherapy stands out as a cornerstone in managing endometrial hyperplasia. Hormone-based interventions, encompassing oral contraceptives, progesterone, estrogen, and progestin, offer a means of modulating hormonal fluctuations, facilitating endometrial shedding, and alleviating associated symptoms[7]. Dydrogesterone, a synthetic progestin, emerges as a prominent agent in gynecological practice, employed to address a spectrum of menstrual irregularities, excessive bleeding, and hormone-related gynecological disorders, including irregular endometrial proliferation[8]. Despite its widespread use, the comprehensive evaluation of dydrogesterone's efficacy, safety profile, and clinical utility in managing irregular uterine bleeding remains imperative.

Thus, the present study endeavors to systematically appraise the efficacy and safety of dydrogesterone as a management strategy for irregular uterine bleeding, with a specific focus on its capacity to preserve endometrial health. Although it's known that progesterone can prevent endometrial thickening and hyperplasia, this study has multiple innovative points. For specific patient group study, it focuses on patients with abnormal uterine bleeding caused by endometrial hyperplasia after hysteroscopic surgery, deeply explores the therapeutic effect of dydrogesterone in this situation, provides a basis for their precise treatment, and fills the evidence gap in existing research. In multi - dimensional comprehensive assessment, besides evaluating conventional indicators, the SF-36 questionnaire is used to comprehensively consider patients' health-related quality of life and evaluate the therapeutic value of dydrogesterone from physiological, psychological and social functions, providing more complete data for clinical decisions. In the aspect of deepening comparative analysis, a strict comparison with traditional drugs (like drospirenone ethinylestradiol) is made to analyze the advantages and differences of dydrogesterone in symptom improvement, treatment effectiveness and quality of life impact, further clarifying its clinical position and value and helping clinicians choose a better treatment plan. Through rigorous examination of dydrogesterone's therapeutic prowess, this study endeavors to elucidate its role as a pivotal therapeutic agent in safeguarding endometrial integrity, thereby enhancing the quality of life for affected individuals.

Methods

General information

A number of 112 female with abnormal uterine bleeding due to irregular endometrial growth, who underwent hysteroscopy surgery at our center between January 2019 and May 2023, were selected to verify the effectiveness and safety of dydrogesterone as a primary systemic therapy for this condition. The individuals were divided into an observation group (receiving dydrogesterone after hysteroscopy) and a control group (receiving conventional medroxyprogesterone acetate-ethinyl estradiol tablets after hysteroscopy). Prior to their participation, all individuals were duly notified about the study and gave their written approval,approval NO. LL-2019-91-K. The institutional review board reviewed and sanctioned the research protocol, ensuring compliance with the ethical standards established in the Helsinki Declaration.

Inclusion criteria

1) Women aged 18 and above.
2) Individuals diagnosed with abnormal uterine bleeding, with pathological examination after hysteroscopy confirming irregular endometrial growth.
3) The ECOG performance status is 1 or less, and organs are functioning normally.
4) Patients and their family members who understood the details of this research and signed the informed consent.

Exclusion criteria:

1) Female with abnormal bleeding caused by vaginal and cervical lesions confirmed by gynecological examination and TCT testing.
2) Patients with misplaced or residual intrauterine devices.
3) Patients with uterine bleeding caused by internal medicine diseases.
4) Patients with mental disorders or other conditions that prevent adherence to the study protocol.

Treatment methods

After admission, hemostatic measures were taken, and hysteroscopy examination was performed when the bleeding was minimal, excluding contraindications. Phloroglucinol is administered intravenously 15-20 minutes before surgery to soften the cervix and promote cervical dilation. The hysteroscope was inserted slowly into the uterine cavity while examining and withdrawing the scope, thoroughly assessing the uterine cavity morphology, color, endometrial thickness, adhesions, polyps, bilateral tubal ostia, uterine angle depth, cervical morphology, and mucosal condition. If any abnormalities were found, further local observation was conducted. After completion of the examination, the uterine cavity and cervical condition were assessed again before withdrawing the scope to avoid missed diagnoses. After hysteroscopy, targeted biopsy, diagnostic curettage, and electrosurgical procedures were performed on the abnormal areas of the endometrium, and tissue samples were sent for pathological examination.

In the postoperative period, individuals in the observation group received dydrogesterone treatment (10 mg per dose, twice daily), while individuals in the control group received medroxyprogesterone acetate-ethinyl estradiol tablets (1 tablet per day, with a 21-day cycle). The control group received medroxyprogesterone acetate-ethinylestradiol tablets, a routine regimen for endometrial hyperplasia-related abnormal uterine bleeding in our center. This formulation contains low-dose ethinylestradiol (20μg/tablet) combined with medroxyprogesterone acetate, where progestin's anti-proliferative effect is hypothesized to counteract estrogen-induced endometrial stimulation, achieving hormonal balance for hemostasis[13]. Low-dose estrogen-progestin combinations are clinically used for patients without severe hyperplasia or atypia to stabilize menstrual cycles[7]. Since all included patients had no endometrial adhesions or hypoplasia, this regimen was chosen as a control to compare with and assess dydrogesterone's relative benefits.

Observational indicators

Improvement of symptoms: An assessment of the patients' symptoms was conducted at the follow-up three months after hysteroscopy. The criteria for symptom improvement were as follows:
- Cure: disappearance of symptoms related to uterine bleeding; normal menstrual flow and cycle; absence of heavy menstrual bleeding; normal color.
- Improvement: slight alleviation of symptoms related to uterine bleeding; normal menstrual cycle, but reduced menstrual flow and shorter duration.
- Ineffectiveness: no improvement or worsening of symptoms related to uterine bleeding and menstruation.

By dividing the number of patients who achieved cure or improvement by the total patient count, the rate of symptom improvement was calculated.
Treatment efficacy was assessed at the 6-month hysteroscopy follow-up, with the following criteria:
- Recovery: disappearance of irregular endometrial growth and restoration of normal endometrial morphology.
- Effective: improvement in irregular endometrial growth, with regression of thickness.

- Ineffective: no improvement or worsening of irregular endometrial growth.

By dividing the number of patients who achieved recovery or effectiveness by the total patient count, the treatment effectiveness rate was calculated.

Safety evaluation: The safety of the treatment was evaluated based on monitoring and recording adverse reactions, utilizing the Common Terminology Criteria for Adverse Events for specific grading and items.

SF-36 (Short Form 36 Health Survey): The SF-36 is a frequently utilized generic means for assessing life quality, evaluating individuals' perceptions and functioning in terms of physical and mental health. It contains 36 questions, split into eight dimensions, covering various aspects of individual life quality. The SF-36 questionnaire is commonly adopted in diverse disease populations, research projects, and clinical practice.

Statistical analysis: SPSS 22.0 was utilized to perform data analysis. Counts and percentages (n, %) were used to express categorical data. For continuous variables that are normally distributed, the mean ± standard deviation ($\bar{x}$ ±s) was calculated, and the independent samples t-test was implemented. Non-parametric analysis of continuous variables not having a normal distribution was carried on using the Mann-Whitney U test. A P value of less than 0.05 was regarded as statistically significant.

Ethics approval

This study was approved by the Ethics Committee of Beijing Youan Hospital Hospital under approval number LL-2019-91-K

Results

Baseline characteristics

Each group consists of 56 participants. The mean age in the observation group is 41±2.3 years, while in the control group, it is 42±1.6 years (Table 1). The mean BMI in the observation group is 23.06 kg/m^2, and in the control group, it is 22.83 kg/m^2 (Table 1). In terms of abnormal uterine bleeding patterns, 10.71% of individuals in the observation group and 8.93% in the control group reported irregular vaginal bleeding (Table 1). Regarding menstrual cycle disturbances, 39.29% and 35.71% of individuals in the observation and control groups, respectively, reported such disturbances (Table 1).

Additionally, 32.14% of individuals in the observation group and 37.50% in the Control group reported abnormal menstrual length (Table 1). Abnormal menstrual bleeding was reported by 17.86% of participants in both groups (Table 1). In terms of endometrial irregular hyperplasia type, 64.29% of individuals in the observation group and 57.14% in the control group had endometrial hyperplasia without atypical hyperplasia, while 35.71% and 42.86% had endometrial hyperplasia with atypical hyperplasia, respectively (Table 1). The statistical analysis using t-tests for age and BMI and χ^2 tests for other variables demonstrated no remarkable distinctions between groups ($p > 0.05$).

Improvement of symptoms and treatment efficacy

In the Observation group, out of 56 participants, 44 (78.57%) experienced a cure, 8 (14.29%) showed improvement, and 4 (7.14%) reported ineffectiveness in symptom improvement (Table 2). This resulted in a symptom improvement rate of 92.86% (Table 2). Regarding treatment effectiveness, 31 (55.36%) participants were cured, 13 (23.21%) showed improvement, and 12 (21.43%) reported ineffectiveness, with a symptom improvement rate of 78.57% (Table 2). In contrast, in the control group, out of 56 participants, 32 (57.14%) experienced a cure, 12 (21.43%) showed improvement, and 12 (21.43%) reported ineffectiveness, resulting in a symptom improvement rate of 78.57% (Table 2). Regarding treatment effectiveness, 23 (41.07%) participants were cured, 11 (19.64%) showed improvement, and 22 (39.29%) reported ineffectiveness, with a symptom improvement rate of 60.71% (Table 2). The $\chi 2$ tests showed substantial discrepancies between groups for both symptom improvement ($\chi 2 = 4.332$, $p = 0.037$) and treatment effectiveness ($\chi 2$

Table 1: Baseline characteristics

Group	n	Age	BMI (kg/m^2)	Abnormal uterine bleeding pattern				Endometrial irregular hyperplasia type	
				Irregular vaginal bleeding	Menstrual cycle disturbance	Abnormal menstrual length	Abnormal menstrual bleeding	Endometrial hyperplasia without atypical hyperplasia	Endometrial hyperplasia with atypical hyperplasia
Observation	56	41+2.3	23.06±2.80	6(10.71%)	22(39.29%)	18(32.14%)	10(17.86%)	36(64.29%)	20(35.71%)
Control	56	42+1.6	22.83±2.73	5(8.93%)	20(35.71%)	21(37.50%)	10(17.86%)	32(57.14%)	24(42.86%)
t/χ^2		t=1.34	t=1.21	χ^2=0.42				χ^2=0.60	
P		0.182	0.227	0.937				0.439	

Table 2: Improvement of symptoms and treatment efficacy (n,%)

Group	Symptom improvement				Treatment effectiveness			
	Cure	Improvement	Ineffectiveness	Symptom improvement rate (%)	Cure	Improvement	Ineffectiveness	Symptom improvement rate
Observation(n=56)	44(78.57)	8(14.29)	4(7.14)	92.86	31(55.36)	13(23.21)	12(21.43)	78.57
Control(n=56)	32(57.14)	12(21.43)	12(21.43)	78.57	23(41.07)	11(19.64)	22(39.29)	60.71
χ^2	-			4.332	-			4.223
P	-			0.037	-			0.04

Table 3: Occurrence of adverse reactions (n,%)

Group	n	Adverse reactions (n, %)							
		amenorrhea	headache	Mood swings	Weight gain	Intermenstrual bleeding	Nausea and vomiting	Breast tenderness	Number of adverse reactions
Observation	56	2(3.57%)	4(7.14%)	3(5.36%)	2(3.57%)	6(10.71%)	1(1.79%)	4(7.14%)	15
Control	56	0(0%)	1(1.79%)	1(1.79%)	1(1.79%)	5(8.93%)	0(0%)	2(3.57%)	8
t/χ^2		2.04	1.88	1.04	0.34	0.10	1.01	0.70	2.68
P		0.154	0.170	0.309	0.558	0.751	0.315	0.401	0.102

= 4.223, p = 0.040), indicating better outcomes in the observation group as opposed to the control group.

Adverse reactions

In the observation group, out of 56 participants, 15 (26.79%) experienced adverse reactions (Table 3). These reactions included amenorrhea (2 cases, 3.57%), headache (4 cases, 7.14%), mood swings (3 cases, 5.36%), weight gain (2 cases, 3.57%), intermenstrual bleeding (6 cases, 10.71%), nausea and vomiting (1 case, 1.79%), and breast tenderness (4 cases, 7.14%) (Table 3). In comparison, in the control group, out of 56 participants, 8 (14.29%) experienced adverse reactions (Table 3). These reactions included headache (1 case, 1.79%), mood swings (1 case, 1.79%), weight gain (1 case, 1.79%), intermenstrual bleeding (5 cases, 8.93%), and breast tenderness (2 cases, 3.57%). Statistical analysis using $\chi 2$ tests indicated no noteworthy distinctions between groups concerning the occurrence of adverse reactions ($\chi 2 = 2.68$, $p = 0.102$) (Table 3). However, specific adverse reactions did not show statistically remarkable distinctions between groups, as demonstrated by the individual $\chi 2$ tests for each reaction (amenorrhea: $\chi 2 = 2.04$, $p = 0.154$; headache: $\chi 2 = 1.88$, $p = 0.170$; mood swings: $\chi 2 = 1.04$, $p = 0.309$; weight gain: $\chi 2 = 0.34$, $p = 0.558$; intermenstrual bleeding: $\chi 2 = 0.10$, $p = 0.751$; nausea and vomiting: $\chi 2 = 1.01$, $p = 0.315$; breast tenderness: $\chi 2 = 0.70$, $p = 0.401$) (Table 3).

SF-36 Scores prior to and post treatment

Prior to treatment, there were no noteworthy disparities in SF-36 scores observed between the two groups. Nonetheless, following hysteroscopy surgery and treatment, both groups exhibited substantial enhancements in diverse functional scores. Individuals receiving dydrogesterone treatment demonstrated significantly superior improvements in overall health status, physical functioning, emotional functioning, and social functioning when compared to those receiving conventional treatment (Table 4).

Table 4: SF-36 Scores prior to and post Treatment ($\bar{x}$ ±s), points)

Item	Control（n=56）				t	P
	Before	After	Before	After		
General health	49.86±10.57	66.08±14.47*	50.06±9.66	57.16±16.47*	7.051	＜0.0001
Physiological function	65.46±11.18	84.80±16.29*	62.23±10.79	76.22±15.47*	6.665	＜0.0001
Social function	59.18±12.12	85.41±21.23*	57.36±11.76	84.70±19.29*	1.024	0.645
Physiological role	63.28±13.13	83.69±16.94*	59.36±12.85	76.70±19.30*	5.964	＜0.0001
Somatic pain	59.66±5.97	84.93±5.64*	58.89±6.54	83.52±6.57*	0.627	0.816
Mental health	68.40±11.65	89.48±14.26*	65.52±11.23	88.91±15.04*	0.826	0.826
Emotional role	62.39±7.18	78.76±4.16*	62.13±7.22	76.26±5.39*	0.853	0.746
Invigoration	64.18±12.06	82.65±23.06*	66.06±12.54	77.02±21.42*	2.663	0.009

*Indicates a significant difference compared to before treatment.

Discussion

Endometrial hyperplasia ranks high among the significant causes of abnormal uterine bleeding. When irregular endometrial growth is discovered through hysteroscopy, further treatment and follow-up are necessary to eliminate the risk of further progression[10]. Dydrogesterone, as a representative drug for treatment[11], has important clinical and research value in terms of its efficacy and safety in female with irregular uterine bleeding and endometrial hyperplasia.

Results from the study revealed that dydrogesterone had a significant therapeutic effect on patients with abnormal uterine bleeding. It played a significant role in protecting the endometrium. The results also showed better symptom improvement and treatment efficacy with

dydrogesterone treatment. This may be attributed to the fact that dydrogesterone, as a progestin analogue, can simulate the effects of progesterone, inhibit endometrial growth and shedding, thereby reducing symptoms of abnormal bleeding and excessive endometrial proliferation[12]. On the other hand, levonorgestrel ethinyl estradiol tablets contain both estrogen and progestin and are commonly used to suppress ovarian function for therapeutic purposes[13]. Since dydrogesterone focuses on regulating the endometrium, it may have a better effect in this regard. Dydrogesterone is mainly used for the treatment of gynecological diseases, while levonorgestrel ethinyl estradiol tablets can also be used to treat irregular endometrial growth, but their primary function is to regulate the changes in the endometrial cycle, and the treatment effect on endometrial issues may not be as significant as dydrogesterone. In terms of adverse effects, no notable discrepancies between dydrogesterone and conventional treatment. Possible adverse reactions of these drugs may include breast tenderness, nausea, headache, etc., as they contain estrogen and progestin, which can cause discomfort in individuals sensitive to hormones[14]. Dydrogesterone primarily targets the regulation of the endometrium in treating irregular uterine bleeding and endometrial hyperplasia, so the associated adverse reactions are not significantly increased.

Concerns may arise regarding the control group's use of medroxyprogesterone acetate-ethinyl estradiol tablets with low-dose estrogen, given estrogen's potential to promote endometrial proliferation. However, this combined regimen is designed such that progesterone's dominant anti-proliferative effect inhibits excessive endometrial growth, while low-dose estrogen helps maintain endometrial stability and reduce breakthrough bleeding. Our findings showed the control group had a significantly lower treatment efficiency (60.71%) than the observation group (78.57%), with inferior endometrial recovery and symptom improvement. This discrepancy may stem from estrogen's residual proliferative effect, which could partially counteract progesterone's inhibitory action—even in combination. For patients with endometrial hyperplasia as the core pathology (and no adhesions or hypoplasia), pure progesterone (dydrogesterone) offers more targeted inhibition of excessive endometrial proliferation, explaining its superior efficacy. This supports avoiding estrogen-containing regimens in such cases, underscoring dydrogesterone's value as a preferred option.

The SF-36 score is a questionnaire used to measure life quality, including various aspects of health and life indicators. This study showed significant changes in SF-36 scores in both groups compared to admission, with a notably greater change in the observation group as opposed to the control group. This indicates that patients with abnormal uterine bleeding and endometrial hyperplasia often experience excessive menstrual blood loss and discomfort symptoms such as pain and bloating. Dydrogesterone can adjust endometrial growth and reduce menstrual blood loss, potentially alleviating these discomfort symptoms and improving patient comfort. Irregular menstruation and discomfort are common symptoms of endometrial hyperplasia, a disorder marked by the overgrowth of endometrial tissue. Dydrogesterone can inhibit abnormal endometrial growth, thereby helping to restore a normal menstrual cycle and reduce discomfort[15]. Abnormal uterine bleeding and endometrial hyperplasia may have a negative influence on women's psychological well-being, giving rise to emotional issues like anxiety and depression. The therapeutic effect of dydrogesterone may help alleviate these emotional problems and improve life quality. As a synthetic progesterone analogue, dydrogesterone can influence hormone levels in the body, especially levels of progesterone. This can, to some extent, regulate the menstrual cycle and hormone balance, contributing to symptom improvement and improved quality of life[16].

In summary, for female patients with abnormal uterine bleeding who undergo hysteroscopy and are found to have irregular endometrial growth, treatment with dydrogesterone offers significant advantages in terms of efficacy, endometrial protection, and absence of adverse effects. Patients experience a significant improvement in life quality, making it of high clinical value and worthy of promotion and application. Future research could explore the long-term effects and durability of dydrogesterone treatment in protecting the endometrium and managing symptoms in females

having abnormal uterine bleeding as a result of endometrial hyperplasia.

Authors' contributions

YXZ and QL conceptualised this study. YXZ, XLL, YML, and QL took charge of the literature review. XLL, YXZ, and YXZ were occupied with data analysis and interpreting the outcomes. All authors took part in discussing the findings. All the authors read and ratified the final text.

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Conflict of interest

No competing interests.

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