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Original Research Article

Effect of Elagolix in comparison to Dienogest in the treatment of symptomatic adenomyosis

Umme Jubaida^{1*}, Farzana Deebea², Shakeela Ishrat², Shaheen Ara Anwary², Rebeka Sultana¹, Chowdhury Faisal Alamgir³, Maliha Darmini⁴, Jesmine Banu²

¹Department of Reproductive Endocrinology and Infertility (OSD), Directorate General of Health Services (DGHS), Dhaka, Bangladesh

²Department of Reproductive Endocrinology and Infertility, Bangladesh Medical University, Dhaka, Bangladesh

³Department of Urology, New Cross Hospital, The Royal Wolverhampton NHS Trust, United Kingdom

⁴Department of Gynecology, Mymensingh Medical College and Hospital, Mymensingh, Bangladesh

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*Correspondence:

Dr. Umme Jubaida,

E-mail: jyoti.saffana@gmail.com

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ABSTRACT

Background: Adenomyosis, a benign gynecological disorder, is diagnosed with increasing frequency in infertile patients since women delay their first pregnancy. Common symptoms of adenomyosis are dysmenorrhea and heavy menstrual bleeding (HMB), resulting in poor quality of life. Elagolix, the oral GnRH antagonist, acts by reducing the occurrence of ectopic endometrial implants in the myometrium. It diminishes uterine volume, reduces dysmenorrhea and heavy bleeding, and improves fertility outcomes. Dienogest, a synthetic oral progestin highly selective for progesterone receptors, reduces the painful symptoms in women with adenomyosis. The aim of this study was to compare the effect of Elagolix with Dienogest in the treatment of symptomatic adenomyosis.

Methods: This randomized controlled trial was conducted in the department of reproductive endocrinology and infertility, Bangabandhu Sheikh Mujib medical university (BSMMU), Dhaka, from January 2024 to December 2024. A total of 58 participants with symptomatic adenomyosis were randomly assigned to 2 groups (n=29). Each group received either Elagolix (200 mg) or Dienogest (2 mg) once daily for 3 months.

Results: Compared between the two groups, post-treatment mean changes of VAS score (6.25 ± 1.83 vs 4.84 ± 1.56), hemoglobin (-1.21 ± 0.97 vs -0.20 ± 0.56), and median uterine volume (5.1 vs 1.2) were significantly higher in the Elagolix group than the Dienogest group. HMB was also significantly reduced (3.7% vs 23.1%) in the Elagolix than the Dienogest group after 3 months of treatment.

Conclusion: Elagolix significantly reduced VAS score, HMB, and uterine volume in symptomatic adenomyosis compared to Dienogest.

Keywords: Symptomatic adenomyosis, Dysmenorrhoea, Heavy menstrual bleeding, Elagolix, Dienogest

INTRODUCTION

Adenomyosis is a common gynecological disease in women of reproductive age, which is characterized by the proliferation of ectopic endometrial tissue within the myometrium.¹ It is a chronic estrogen-dependent condition affecting approximately 20% of the gynecological

patients.² The prevalence of adenomyosis in infertile women below 40 years of age is around 7.5-22%, and at and above 40 years, around 24.4%.^{3,4} Adenomyosis usually presents with HMB, infertility, and chronic pelvic pain.⁵

About 2/3rd of women with adenomyosis are symptomatic and the most common symptoms include menorrhagia and

dysmenorrhea.⁶ The average age of presentation is usually above 40 years, but it can also be seen in young women.⁷ Depending on diagnosis method, this disease's prevalence varies widely from 5% to 70%. It is diagnosed during hysterectomy at approximately 20-30%.⁸

Regardless of the prevalence and severity of symptoms, pathogenesis and etiology of adenomyosis yet not clearly understood. The most common theory is the invasion of endometrial basalis into myometrium due to traumatized endometrial myometrial junctional zone mostly occurs after multiple childbirth, abortion, and curettage. Another theory is adenomyotic change results from metaplasia of embryonic pluripotent Mullerian remnant or differentiation of adult stem cells.⁹ Adenomyosis and endometriosis both are estrogen-dependent disorders.¹⁰

Several studies show there is an association between infertility and adenomyosis where probable mechanisms involved include impairment of sperm transport, aberrant uterine contractility, alterations of adhesion molecules, cell proliferation, apoptosis, and free radical metabolism.¹¹ Adenomyosis had adverse effects on ART outcomes, increased miscarriage, and recurrent pregnancy loss.¹²

Although the diagnosis of adenomyosis was based on clinical findings and pathologic confirmation after hysterectomy, transvaginal ultrasonography (TVS) and magnetic resonance imaging are accurate, noninvasive methods for diagnosis.¹³

The MUSA (Morphological uterus sonographic assessment) criteria help identify adenomyosis through ultrasound. They categorize features as direct or indirect signs of the condition. Direct signs, like myometrial cysts, hyperechogenic islands, and echogenic subendometrial lines, directly indicate the presence of ectopic endometrial tissue in the myometrium. Indirect signs, such as asymmetrical myometrial thickening, globular uterus, fan-shaped shadowing, translesional vascularity, and interrupted or irregular junctional zone, reflect secondary changes in the myometrium due to adenomyosis.¹⁴

Sonographic findings of adenomyosis are echogenic nodules and striation radiating from the endometrium into the myometrium, a globular uterus, focal and diffuse myometrial thickening, myometrial cysts, and blurring of the endometrial border. Color Doppler study shows increased uterine vascularity.⁸

The definitive treatment for patients with adenomyosis is hysterectomy, who do not need to preserve fertility.¹¹ Minimally invasive surgery often results in adhesion, distortion of uterus, and occlusion of fallopian tube.¹⁵ Conservative interventions include uterine artery embolization (UAE), high-intensity focused ultrasound (HIFU), laparoscopy or US-guided radiofrequency ablation, and microwave ablation. But these techniques are not suitable for infertile patients.¹⁶ Nowadays, other medical treatments using suppressive hormonal treatment,

such as oral contraceptive/low-dose estrogen (OC/LEP), danazol, aromatase inhibitor (AI), gonadotropin-releasing hormone analog (GnRH a) have been used to control symptoms of adenomyosis among women who are unwilling to undergo hysterectomy/who need to preserve fertility.¹¹

The objective of this study was to compare the effect of Elagolix with Dienogest in the treatment of symptomatic adenomyosis.

METHODS

This randomized controlled trial was conducted at the department of reproductive endocrinology and infertility, Bangabandhu Sheikh Mujib medical university (BSMMU), Dhaka, from January 2024 to December 2024. A total of 58 women aged 25-40 years with symptomatic adenomyosis, presenting with HMB and/or dysmenorrhea and diagnosed via transvaginal ultrasonography, were enrolled using simple random sampling. Patients were randomly allocated into two groups using a computer-generated randomization sequence and sealed opaque envelopes: one group received Elagolix 200 mg once daily, and the other received Dienogest 2 mg once daily for three months.

Inclusion criteria included women with confirmed adenomyosis and infertility (primary or secondary). Patients were excluded if they had ovarian endometrioma, uterine fibroids, pelvic inflammatory disease, recent hormonal therapy, or a history of significant systemic illness. The primary outcomes were changes in pain (measured by a 10-point visual analogue scale), menstrual blood loss (based on pad count and clot passage), and uterine volume (calculated using the ellipsoid formula on ultrasound). The secondary outcome was the change in hemoglobin level, measured by a hematology auto-analyzer and confirmed manually.

Data were collected using structured case report forms through clinical examination, patient interviews, and investigations at baseline and after three months of treatment. The research instrument included a pre-tested checklist covering socio-demographic, clinical, and outcome variables. Data were analyzed using SPSS version 26.0. Continuous variables were expressed as mean±SD and compared using t-tests; categorical variables were analyzed using chi-square or Fisher's exact test. A $p < 0.05$ was considered statistically significant.

Ethical approval was obtained from the institutional review board of BSMMU. Written informed consent was taken from all participants. Patient confidentiality was maintained by assigning unique identification codes, and data were securely stored. The study adhered to the declaration of Helsinki guidelines and involved no use of experimental or placebo treatments.

RESULTS

Table 1 shows that age, occupational status, residence, monthly income, and parity were not statistically significant when compared between 2 groups ($p>0.05$).

Table 2 shows that at baseline mean VAS score, uterine volume, heavy menstrual flow and hemoglobin were not statistically significant when compared between the two groups ($p>0.05$).

Table 3 shows that in the Elagolix group, after 3 months of treatment, the mean VAS score and uterine volume were significantly reduced compared to baseline. Heavy bleeding was significantly reduced after 3 months of treatment compared to before treatment (3.7% vs 82.8%). The hemoglobin level was significantly increased compared to baseline.

Table 4 shows that in the Dienogest group, after 3 months of treatment mean VAS score was significantly reduced than the baseline. Uterine volume was also decreased after 3 months of treatment; the difference was not significant. Heavy bleeding was significantly reduced after 3 months of treatment than before treatment (23.1% vs 86.2%). After 3 months of treatment, the mean hemoglobin level was increased than baseline, but the difference was not significant.

Table 5 shows that after 3 months of treatment, the mean VAS score was significantly decreased in the Elagolix group than in the Dienogest group. Uterine volume was not statistically significant between the two groups. The heavy flow was 3.7% and 23.1% in the Elagolix group and Dienogest group, respectively. The difference was statistically significant between the two groups ($p<0.05$). After 3 months of treatment, significant improvement in hemoglobin levels in the Elagolix group than the Dienogest group.

Table 1: Socio-demographic characteristics of the study population, (n=58).

Demographic characteristics	Elagolix group, (n=29)		Dienogest group, (n=29)		P value
	N	%	N	%	
Age (in years)					
25-30	11	37.9	14	48.3	0.340 ^{ns}
31-35	13	44.8	13	44.8	
36-40	5	17.2	2	6.9	
Mean±SD	31.8	±3.4	31.0	±3.2	
Range (min-max)	25.0	-38.0	25.0	-37.0	
Occupational status					
Housewife	22	75.9	24	82.8	0.447 ^{ns}
Service holder	5	17.2	2	6.9	
Teacher	2	6.9	1	3.4	
Business	0	0.0	1	3.4	
Garments worker	0	0.0	1	3.4	
Residence					
Rural	15	51.7	20	69.0	0.180 ^{ns}
Urban	14	48.3	9	31.0	
Monthly income (in Taka)	42413.8	±16236.0	35172.4	±14849.4	0.082 ^{ns}
Range (min-max)	15000.0	-80000.0	15000.0	-70000.0	
Parity					
Nulipara	22	75.9	21	72.4	0.764 ^{ns}
Multipara	7	24.1	8	27.6	

*ns=not significant, p value reached from unpaired t-test and chi-square test.

Table 2: Baseline assessment of VAS score, uterine volume, heavy menstrual flow, and hemoglobin level compared between Elagolix and Dienogest groups, (n=58).

Variables	Elagolix group, (n=29)	Dienogest group, (n=29)	P value
VAS score (Mean±SD)	8.37±1.20	8.44±1.18	0.827 ^{ns}
Uterine volume (cm³) (Mean±SD)	189.2±8.7	188.6±6.8	0.761 ^{ns}
Heavy menstrual flow	24/29 (82.8%)	25/29 (86.2%)	0.500 ^{ns}
Hemoglobin (gm/dl) (Mean±SD)	10.10±1.08	10.24±0.94	0.582 ^{ns}

*ns=not significant; p value reached from unpaired t-test and fisher's exact test.

Table 3: Pain score (VAS), uterine volume, heavy menstrual flow and hemoglobin level compared before and after treatment in the Elagolix group.

Variables	Before treatment (n=29)	After 3 months of treatment (n=27*)	Mean difference (95% CI)	Effect size	P value
VAS score (Mean±SD)	8.37±1.20	2.03±1.12	6.25 (5.53 to 6.98)	3.41	0.001 ^s
Uterine volume (cm ³) (Mean±SD)	189.2±8.7	183.7±11.5	5.17 (1.54 to 8.80)	0.56	0.007 ^s
Heavy menstrual flow	24/29 (82.8%)	1/27 (3.7%)			0.001 ^s
Hemoglobin (gm/dl) (Mean±SD)	10.10±1.08	11.32±0.97	-1.21 (-1.51 to -0.92)	1.63	0.001 ^s

*2 cases dropped out. One was lost to follow up and 1 opted for surgery, s=significant; p value reached from paired t and chi-square test.

Table 4: Pain score (VAS), uterine volume, heavy menstrual flow and hemoglobin level compared before and after treatment in the Dienogest group.

Variables	Before treatment, (n=29)	After 3 months of treatment, (n=26*)	Mean difference (95% CI)	Effect size	P value
VAS score (Mean±SD)	8.44±1.18	3.57±1.39	4.84 (4.21 to 5.47)	3.10	0.001 ^s
Uterine volume (cm ³) (Mean±SD)	188.6±6.8	187.6±7.3	0.81 (-0.42 to 2.05)	0.26	0.187 ^{ns}
Heavy menstrual flow	25/29 (86.2%)	6/26 (23.1%)			0.001 ^s
Hemoglobin (gm/dl) (Mean±SD)	10.24±0.94	10.51±1.1	-0.20 (-0.43 to -0.02)	0.35	0.080 ^{ns}

*In the Dienogest group, 3 cases dropped out. Two cases were lost to follow-up and the other patient discontinued treatment after for irregular vaginal bleeding. s=significant, ns=not significant; p value reached from paired t-test and chi square test.

Table 5: Post-treatment VAS score, uterine volume, heavy menstrual flow, and hemoglobin level compared between Elagolix and Dienogest groups.

Variables	Elagolix group, (n=27)	Dienogest group, (n=26)	Mean difference (95% CI)	Effect size	P value
VAS score (Mean±SD)	2.03±1.12	3.57±1.39	-1.53 (-2.23 to -0.84)	1.22	0.001 ^s
Uterine volume (cm ³) (Mean±SD)	183.7±11.5	187.6±7.3	-3.92 (-9.26 to 1.41)	0.40	0.146 ^{ns}
Heavy menstrual flow	1/27 (3.7%)	6/26 (23.1%)			0.040 ^s
Hemoglobin (gm/dl) (Mean±SD)	11.32±0.97	10.51±1.1	0.82 (0.24 to 1.39)	0.78	0.006 ^s

*s=significant, ns=not significant; p value reached from unpaired t test and Fisher's exact test.

Table 6: Post-treatment mean changes of VAS score, hemoglobin, and uterine volume level compared between the Elagolix and Dienogest groups.

Variables	Elagolix group, (n=27), mean±SD	Dienogest group, (n=26), mean±SD	Mean difference (95% CI)	Effect size	P value
VAS score	6.25±1.83	4.84±1.56	1.41 (0.17 to 2.35)	0.82	^a 0.004 ^s
Hemoglobin (gm/dl)	-1.21±0.97	-0.20±0.56	-0.01 (-1.38 to -0.64)	1.44	^a 0.025 ^s
	Median (IQR)	Median (IQR)			
Uterine volume (cm ³)	5.1 (2.8-11.8)	1.2 (0.1-1.9)			^b 0.001 ^s

*s=significant, ns=not significant; ^aP value reached from unpaired t-test; ^bP value reached from Mann-Whitney U test.

Table 7: Distribution of the study patients by side effect.

Side effects	Elagolix group, (n=27)		Dienogest group, (n=26)		P value
	N	%	N	%	
Headache	1	3.7	1	3.8	0.745 ^{ns}
Weight gain	0	0.0	1	3.8	0.491 ^{ns}
Irregular bleeding	0	0.0	4	15.4	0.051 ^{ns}
Hot flash	2	7.4	0	0.0	0.255 ^{ns}
GIT symptoms	1	3.7	2	7.7	0.486 ^{ns}

*ns=not significant p value reached from Fisher's exact test.

Table 6 shows that when compared between the two groups, post-treatment mean changes of VAS score, hemoglobin, and median uterine volume were significantly higher in the Elagolix group than the Dienogest group.

Table 7 shows that the side effects were comparatively less in Elagolix group than Dienogest group, but the difference was not statistically significant between two groups.

DISCUSSION

Adenomyosis, a benign condition where endometrial tissue grows within the myometrium, affects about 20% of gynecology patients.⁵ It commonly causes dysmenorrhea, pelvic pain, and menorrhagia in reproductive-aged women. There is a need for effective, well-tolerated medical therapies.¹⁷

Elagolix, a nonpeptide oral GnRH antagonist, has emerged as a promising treatment. It induces rapid, reversible, dose-dependent suppression of gonadotropins and ovarian steroids, alleviating dysmenorrhea and heavy menstrual bleeding.^{18,19} Conversely, Dienogest, a 19-nor testosterone and progesterone derivative, is a widely used progestin that effectively reduces adenomyosis symptoms.²⁰ This study aimed to compare the therapeutic efficacy of Elagolix and Dienogest in symptomatic adenomyosis.

The mean age of participants was 31.8 ± 3.4 years in the Elagolix group and 31.0 ± 3.2 in the Dienogest group, with no significant difference. This aligns with previous studies by Osuga et al showing no significant age differences between treatment groups.¹

Patients in the Elagolix group received 200 mg orally once daily for three months. Post-treatment, a significant reduction in VAS pain score (mean 6.25) was observed. Although no prior Elagolix-specific VAS studies for adenomyosis were found, similar effects were noted with Relugolix (a GnRH antagonist) in studies by Osuga et al and Yamanaka et al both reporting significant reductions in pain scores.^{1,21}

Elagolix treatment also significantly reduced uterine volume by a mean of 5.17 cm^3 ($p=0.007$). This was consistent with findings by Muneyyirci-Delale et al where Elagolix 300 mg plus add-back therapy over six months reduced uterine volume by 48.9 cm^3 .²² Our results suggest even a lower dose over a shorter period offers a measurable benefit.

Regarding heavy menstrual bleeding, Elagolix showed marked improvement. At baseline, 82.8% reported heavy flow, which decreased to 3.7% post-treatment ($p=0.001$). This is comparable to results from Muneyyirci-Delale et al where 63.6% of women achieved suppression of heavy bleeding with Elagolix plus add-back.²² Taylor et al reported similar outcomes with higher doses of Elagolix and combination therapy.¹⁹

Hemoglobin levels improved significantly in the Elagolix group, with a mean increase of 1.21 g/dL (95% CI -1.51 to -0.92, $p<0.001$), reflecting reduced blood loss. Although no previous Elagolix-specific hemoglobin studies exist, Yamanaka et al. found that Relugolix significantly increased hemoglobin in adenomyosis patients, supporting our findings.²¹

In the Dienogest group, patients received 2 mg daily for three months. The mean VAS score decreased significantly by 4.84. This aligns with Ali et al who found a reduction of 5.86 cm on a 10-cm VAS.²³ Hirata et al and Osuga et al also reported significant reductions in pain with Dienogest.^{1,17}

However, uterine volume reduction in the Dienogest group (mean 0.81 cm^3) was not statistically significant. Ali et al and Hirata et al similarly found non-significant volume reductions, suggesting limited effect on uterine size.^{17,23}

Heavy menstrual bleeding in the Dienogest group dropped from 86.2% to 23.1% after treatment ($p=0.001$), consistent with findings from Yang et al who observed significant reductions in menstrual volume at 3, 6, and 12 months.²⁴

Hemoglobin levels in the Dienogest group increased slightly from 10.24 ± 0.94 to 10.51 ± 1.1 g/dL (mean difference -0.27 g/dL), but this change was not statistically significant. Hirata et al, Xu et al also reported minor, non-significant increases in hemoglobin following Dienogest therapy.^{17,25}

To date, no comparative studies have evaluated Elagolix versus Dienogest in adenomyosis. This study fills that gap by comparing improvements in dysmenorrhea, menstrual bleeding, uterine volume, and hemoglobin levels between both drugs.

After three months, the Elagolix group showed a significantly lower mean VAS score (2.03 ± 1.12) compared to the Dienogest group (3.57 ± 1.39), with a between-group difference of -1.53 ($p=0.001$). This confirms superior pain relief with Elagolix. Findings by Osuga et al support the efficacy of GnRH antagonists and Dienogest respectively in pain reduction.¹

While uterine volume reduction was statistically significant in the Elagolix group (183.7 ± 11.5) and not in the Dienogest group (187.6 ± 7.3), the between-group difference (-3.92) was not significant. Muneyyirci-Delale et al and Osuga et al observed similar trends in uterine size changes with Elagolix and Dienogest.^{1,22}

Regarding bleeding control, 3.7% of Elagolix patients and 23.1% of Dienogest patients continued to report heavy flow after treatment. This difference was significant ($p=0.040$), reinforcing Elagolix's superior efficacy in reducing menstrual bleeding. Similar trends were noted by Muneyyirci-Delale et al for Elagolix plus add-back therapy.²²

Limitations

The study was conducted with a small sample size and for a short period due to a restricted time frame. Participants and investigators were not blinded to the treatment after randomization.

CONCLUSION

Elagolix significantly reduced VAS score, heavy menstrual bleeding, and uterine volume in symptomatic adenomyosis compared to Dienogest. Trials with higher doses and longer duration for significant reduction of the volume of the large uterus in adenomyosis are recommended.

Recommendations

Elagolix may be recommended for infertile women having adenomyosis as a pretreatment for reducing the severity of the disease. Elagolix may be an effective option for reproductive age group women with symptomatic adenomyosis who do not want surgical treatment. Further studies with large sample sizes and long duration are necessary to establish the long-term efficacy and safety of Elagolix and Dienogest.

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