

# Utilization of Gonadotropin-Releasing Hormone Antagonist in Uterine Adenomyosis Particularly on Association with Fibroids & Infertility - Offers Some Hope for Saving Uterus & Future Fertility - A Short Communication

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## ABSTRACT

Earlier we had reviewed the detailed etiopathogenesis, treatment of uterine adenomyosis inclusive of how its origination takes place. Additionally, we have detailed mechanistic modes by which GnRH analogues work on adenomyosis. There exist variable hormonal along with non-hormonal therapies that have been prescribed for symptomatic relief, inclusive of nonsteroidal anti-inflammatory drugs, combined estrogen–progestin possessing contraceptives, as well as systemic in addition to intrauterine progestins, inclusive of 52 mg levonorgestrel-releasing intrauterine devices, along with gonadotropin-releasing hormone (GnRH) agonists as well antagonists. Despite that, all GnRH analogues inclusive of 300 mg of elagolix twice daily with add-back therapy (1 mg of estradiol/0.5 mg of norethindrone acetate once a day) significantly abridged HMB in women with uterine fibroids along with concurrent adenomyosis, pointing that elagolix efficaciousness was not inimically impacted by the existence of adenomyosis. However, that rapid recurrence of symptoms is canonically found subsequent to culmination of therapy. Results from the aforementioned study corroborated, that linzagolix delivered at a greater dose for 12 weeks, with subsequent lesser maintenance dose for a further 12 weeks, is a viable alternative for treatment of adenomyosis-associated symptoms. To our misfortune, the quick return to baseline readings in reference to uterine volume as well as bleeding pointed that modified regimens are

the requirement for long-term therapy recent studies of Relugolix combination therapy, comprising of 40 mg of relugolix, 1 mg of estradiol, along with 0.5 mg of norethindrone acetate, is a once-daily single-tablet therapy was recently explored in 2 different ways to give some hope for persistence of regression of uterine adenomyosis in patients with infertility

## **KEYWORDS**

Uterine Adenomyosis; GnRH analogues; Elagolix twice daily with add-back; 40 mg of Relugolix; Linzagolix

## **INTRODUCTION**

Adenomyosis is a disorder possessing the properties of the existence of endometrial glands as well as stroma amongst the myometrium. Regions of ectopic endometrium are usually encompassed by reactive hypertrophic myometrial tissue, commonly resulting in uterine enlargement <sup>[1]</sup>. Adenomyosis has canonically been diagnosed histopathologically subsequent to hysterectomy, a strategy that led to the belief that the condition was restricted basically to those in their latter reproductive years <sup>[2,3]</sup>. Previously, canonical risk factors for adenomyosis correlated with a histopathological diagnosis are inclusive of

- i) continued estrogen exposure (late reproductive years),
- ii) early menarche,
- iii) short menstrual cycles,
- iv) escalated body mass index (BMI),
- v) earlier utilization of oral contraceptives or tamoxifen,
- vi) parity, as well as
- vii) previous uterine surgery <sup>[1]</sup>.

Nevertheless, with improvements in ultrasound in addition to the advent of magnetic resonance imaging (MRI), it is now feasible to isolate adenomyosis with greater dependable methodologies through imaging, with properties that are inclusive of a

- i) globular, along with
- ii) usually asymmetrically enlarged uterine corpus,
- iii) aberrations in the endometrial–myometrial junction as well as myometrial observations that are
- iv) inclusive of cysts in addition to
- v) other properties for instance fan-shaped shading,
- vi) along with multifaceted appearance on ultrasound <sup>[4]</sup>. Improvements in imaging further yield the chance to diagnose influenced women earlier <sup>[2]</sup>.

More recently, clarification has emerged that imaging properties of adenomyosis possess the capacity of

- i. more commonly be observed in up to 35% of reproductive-age girls as well as
- ii. women aged 30 years in addition to under with no history of pregnancy or uterine surgery <sup>[5,6]</sup>, a context that has resulted in a reassessment of the pathogenesis of this condition. The determined prevalence of adenomyosis differs broadly in view of unstandardized radiologic diagnostic criteria, along with definitions well as historical botherations with diagnosis <sup>[2]</sup>, varying from 10% in women with subfertility <sup>[7]</sup> up to 89% in women with endometriosis <sup>[8]</sup>. Because the precision of imaging observations possess the properties of persistence of refining in addition to standardized, this aids in advantageous determinates of the actual disease prevalence <sup>[2]</sup>.

Symptoms of adenomyosis are inclusive of

- i) aberrant uterine bleeding— especially heavy menstrual bleeding (HMB)—
- ii) dysmenorrhea,
- iii) dyspareunia,
- iv) infertility, as well as a
- v) plethora of conditions correlated with pregnancy, inclusive of a) miscarriage, b) preterm delivery, c) pre-eclampsia, d) fetal malpresentation, in addition to e) postpartum hemorrhage <sup>[9]</sup>. It has previously been documented that minimal of 30% of women with adenomyosis are asymptomatic <sup>[1]</sup>; Nevertheless, the existence of symptoms for instance dysmenorrhea, dyspareunia, along with pelvic pain is not more commonly documented by clinicians or might be accounted by other uterine pathologies, affecting assessment of adenomyosis symptomatology <sup>[3]</sup>. Updated adenomyosis guidelines from the Society of Obstetricians and Gynecologists of Canada stated that “Transvaginal sonography needs to be the first-line modality for imaging of suspected adenomyosis with HMB, pelvic pain, infertility, miscarriage, as well as inimical pregnancy outcomes [strong, high],” <sup>[10]</sup>. in addition to terminology for the non-invasive diagnosis of adenomyosis has been validated by the Morphological Uterus Sonographic Assessment (MUSA) group to detail, along with document ultrasound characteristics of adenomyosis in the myometrium <sup>[11]</sup>. In women with adenomyosis, there is a positive association amongst the number of ultrasound characteristics isolated as well as both the volume of menstrual blood loss (MBL) <sup>[12]</sup>, in addition to the robustness of menstrual pain <sup>[13,14]</sup>. Additionally, adenomyosis might exist concurrently with uterine fibroids (UFs) <sup>[14]</sup>, non-cyclic pelvic pain has been found more commonly in such patients in contrast to women who have loneUF <sup>[12]</sup>. In women whose symptoms seem unbalanced to fibroid, concurrent adenomyosis needs to be taken into account in the differential diagnosis <sup>[15]</sup>.

## **MECHANISTIC MODES OF GnRH ANALOGUES**

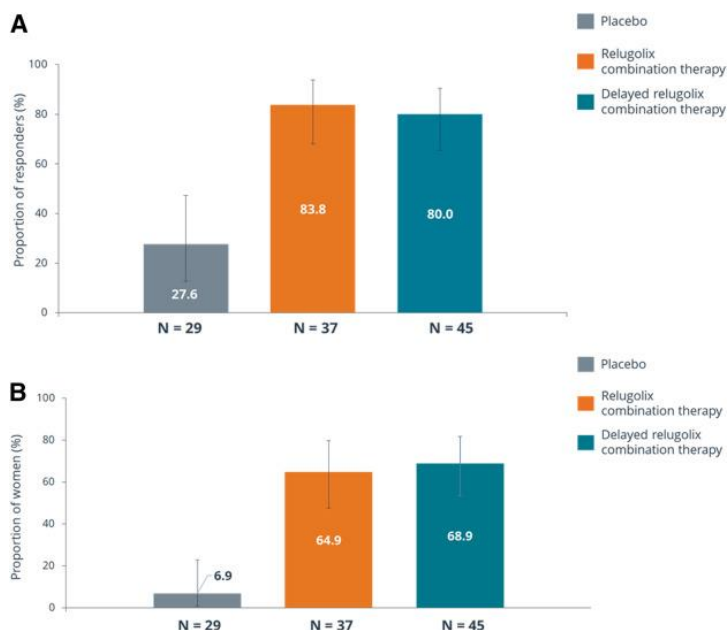
Point of using GnRH analogues for medical treatment of adenomyosis is the direct antiproliferative action within the myometrium via action on GnRH receptors expressed on adenomyotic lesions, together with a systemic and local

hypoestrogenic action via central downregulation along with deep suppression of gonadotropin liberation [rev in 16]. Actually adenomyosis has property of hyperestrogenism (E2) in view of escalation of E2 receptors, activation of sulphatase in addition to aromatase as well as decreased catabolism of E2. This, in turn causes down regulation of progesterone (P) receptors, elimination of their action, along with ultimate P resistance [rev in 16]. Nonetheless, GnRH analogues further work on other pathogenesis modes, ii) by induction of apoptosis in adenomyosis tissues, iii) decreased inflammation as well as iv) angiogenesis [rev in 16]. v) Additionally GnRH analogues can cause marked decrease in nitric oxide synthase (NOS) as well as peroxy nitrite, repressing serum amount of nitrite /nitrate, stable metabolites of NO, that are mostly escalated in adenomyosis [rev in 16].

At present, the treatment of women with symptomatic adenomyosis is a continued problem with maximum of the literature concentrated on addressing symptoms of pain as well as abnormal bleeding correlated with adenomyosis [17]. Uterine-sparing surgical in addition to, image-guided modalities have restricted supportive long-term validation, specifically for fertility [18-21]. There exist variable hormonal along with non-hormonal therapies that have been prescribed for symptomatic relief, inclusive of nonsteroidal anti-inflammatory drugs, combined estrogen–progestin possessing contraceptives, as well as systemic in addition to intrauterine progestins, inclusive of 52 mg levonorgestrel-releasing intrauterine devices, along with gonadotropin-releasing hormone (GnRH) agonists as well antagonists [15,22-25]. Relugolix is an orally active, nonpeptide GnRH receptor antagonist that represses the liberation of gonadotropins, decreasing follicular growth as in addition to hampering ovulation, resulting in a pacey, along with reversible reduction in ovarian generation of estrogen as well as progesterone. A retrospective cohort study found that relugolix treatment significantly decreased uterine volume in patients with concurrent adenomyosis in addition to UF in contrast to UF alone [26]. Relugolix combination therapy, comprising of 40 mg of relugolix, 1 mg of estradiol, along with 0.5 mg of norethindrone acetate, is a once-daily single-tablet therapy recommended in the United States for the management of HMB associated with UF in premenopausal women, as well as for the management of moderate-to- robust pain correlated with endometriosis. In the EU in addition to variable other jurisdictions, along with administrative districts, relugolix combination therapy is recommended for the management of moderate-to- robust symptoms of UF in adult women of reproductive age as well as symptomatic treatment of endometriosis in women with a history of prior medical or surgical treatment for their endometriosis. Thus, Catherino et al. [27], had the objective of evaluating the actions of relugolix combination therapy in women with uterine fibroids (UFs) as well as concomitant ultrasound diagnosed adenomyosis. This study was designed in the form of post hoc analysis utilized pooled outcomes from completers of the pivotal LIBERTY studies. The subgroup of women with adenomyosis in addition to UFs were contrasted with the total study population on selected effectiveness, along with safety endpoints. Premenopausal women (aged 18–50 years) with diagnosed UFs (validated by ultrasonography) as well as heavy menstrual bleeding (evaluated by the alkaline hematin method) the subjects recruited. The arbitration was once-daily relugolix combination therapy (40 mg relugolix, 1 mg estradiol, in addition to 0.5 mg of norethindrone acetate) or placebo for 24 weeks, or postponed relugolix combination therapy (40 mg of relugolix monotherapy for 12 weeks, subsequent to relugolix combination therapy for

12 weeks). Endpoints were inclusive of the proportion of women with concurrent adenomyosis, the percentage of treatment responders (attained or sustenance of sustained menstrual blood loss volume from baseline over the last 35 days of treatment), the percentage of women attaining or sustenance of amenorrhea over the last 35 days of treatment, along with the alteration from baseline to week 24 in uterine volume as well as inimical sequelae. Of the overall 111 women (18.2%) possessed a baseline diagnosis of concurrent adenomyosis (37 in the relugolix combination therapy group, 45 in the postponed relugolix combination therapy group, 29 in the placebo group) in addition to were inclusive of in this assessment.

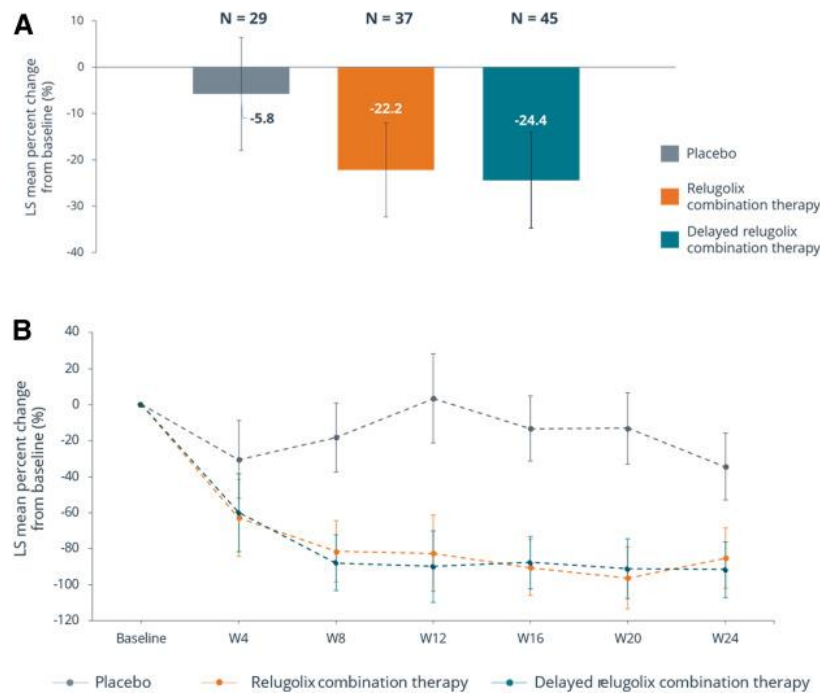
Of women with adenomyosis, 83.8% in the relugolix combination therapy group were treatment responders contrasted to 27.6% in the placebo group. Amenorrhea was attained in 64.9% of women with adenomyosis treated with relugolix combination therapy along with in 6.9% of women treated with placebo. The minimal square average uterine volume of women with adenomyosis decreased by 22.2% as well as 5.8% in the relugolix combination therapy in addition to placebo groups, respectively. Results for the above data in the relugolix combination therapy population were analogous to the postponed relugolix combination therapy group. Thereby conclusions drawn regarding effectiveness data in women with adenomyosis, along with UFs were commensurate with those in women from the overall LIBERTY study population (Figures 1-3).



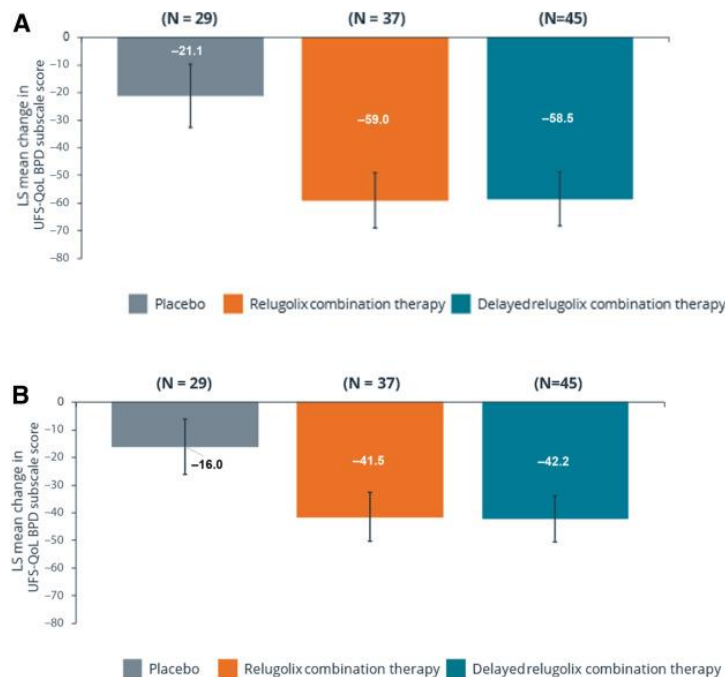
**Figure 1A:** Courtesy ref no.27-Women with adenomyosis achieving an MBL volume <80 mL and a  $\geq 50\%$  reduction in MBL volume (treatment responders) from the pivotal study baseline to the last 35 days of treatment. <sup>a</sup>*P* value is based on the Cochran–Mantel–Haenszel test stratified by baseline MBL volume (<225 mL,  $\geq 225$  mL) and geographic region (North America, Rest of World). Error bars show upper and lower limits of 95%

**Figure 1B:** Confidence Intervals. Proportion of women with adenomyosis who achieved amenorrhea over the last 35 days of treatment. Error bars show upper and lower limits of 95% confidence intervals. MBL = menstrual blood loss.

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**Figure 2:** Courtesy ref no.27-Percent change in uterine volume of women with adenomyosis from baseline at week 24. Error bars show upper and lower limits of 95% confidence intervals. (B) Percent change in MBL volume of women with adenomyosis from baseline to the last 35 days of treatment. Error bars show upper and lower limits of 95% confidence intervals. LS = least square; MBL = menstrual blood loss; W = week.



**Figure 3A:** Courtesy ref no.27. Change from baseline in UFS-QoL Bleeding and Pelvic Discomfort scale score in women with adenomyosis at baseline. Error bars show upper and lower limits of 95% confidence intervals.

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**Figure 3B:** Change from baseline in UFS-QoL Symptom Severity scale score in women with adenomyosis at baseline. Error bars show upper and lower limits of 95% confidence intervals. LS = least square; UFS-QoL BPD subscale = Uterine Fibroid Symptom Health-Related Quality of Life Bleeding and Pelvic Discomfort Subscale.

## DISCUSSION

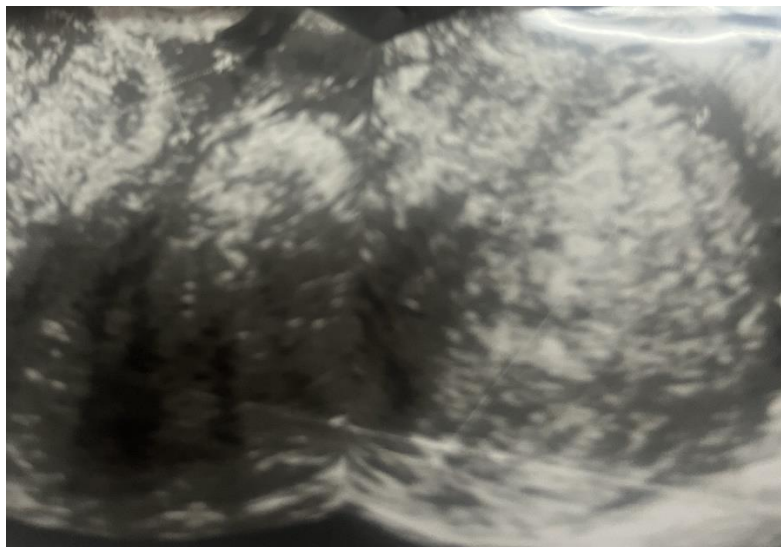
Uterine adenomyosis is detailed in the form of an estrogen- based benign uterine disease possessing the properties of infiltration of the myometrium by endometrial glands to a depth of over 2.5 mm. Recognized its greater prevalence as well as crippling symptoms, the requirement for nonsurgical treatment of the disease is assuming greater significance particularly for young patients. At present treatment modalities for adenomyosis are little restricted, in addition to plethora of women influenced by adenomyosis pursue explicit treatment with hysterectomy. Utilization of uterine artery embolization, along with image- driven endometrial ablation methodologies are made regarding amelioration of symptoms in persons possessing adenomyosis; nevertheless, following pregnancy is not advocated in view of considerable risks, inclusive of placenta accreta as well as perinatal mortality. Conversely, conservative surgery remains a source of discord. Actually, excisional techniques for adenomyosis possess the risk of causing considerable thinning of the uterine walls, therefore generating the botherations of uterine rupture at the time of pregnancy. There is presence of an explicit requirement for medical therapy for adenomyosis. The basic aim of treatment needs to be symptom management; nevertheless, the decision is based on both clinical symptoms as well as patient age along with reproductive status. Current, medical therapy strategies are restricted in addition to implicate off-label utilization of hormone treatments or utilization of analgesics. Apparently, uptill now, no drug has received recommendations for treatment of adenomyosis. Progestogens might be believed to be the methodology in view of they do theoretically possess the capacity of exerting antiproliferative as well as anti-inflammatory actions; nevertheless, progesterone resistance is found in adenomyotic endometrium in addition to stroma blocks their effectiveness<sup>[28]</sup>. Pain relief in addition to bleeding was documented in a long-term study with dienogest, nevertheless it was not corroborated in case of robust adenomyosis. Apparently, oral gonadotropin-releasing hormone (GnRH) antagonists yield a favourable new probability of treatment alternative, aiding in dose- based regulation of estradiol quantities presence with pacey reversibility as well as no flare-up actions. These drugs are indicated for management of heavy menstrual bleeding (HMB) linked to uterine fibroids or moderate-to- robust pain associated with endometriosis. Certain studies pointed that GnRH antagonists might comprise a plausible methodology for treatment of adenomyosis. Actually, delivery of 200 mg of linzagolix daily without add-back therapy has illustrated the capacity of GnRH antagonists to significantly decrease uterine volume (by greater than 50%) along with manage symptoms in women with robust adenomyosis<sup>[29]</sup>. There is requirement for emphasizing, however, that rapid recurrence of symptoms is canonically found subsequent to culmination of therapy. Results from the aforementioned study corroborated, that linzagolix delivered at a greater dose for 12 weeks, with subsequent lesser maintenance dose for a further 12 weeks, is a viable alternative for treatment of adenomyosis- associated symptoms<sup>[29]</sup>. To our misfortune, the quick return to baseline readings in reference to uterine volume as well as bleeding pointed that modified regimens are the requirement for long-term therapy<sup>[30]</sup>. In Elaris UF-1 in addition to UF-2 clinical trials, 300

mg of elagolix twice daily with add-back therapy (1 mg of estradiol/0.5 mg of norethindrone acetate once a day) significantly abridged HMB in women with uterine fibroids along with concurrent adenomyosis, pointing that elagolix efficaciousness was not inimically impacted by the existence of adenomyosis <sup>[31]</sup>. Catherino et al. [27], documented in their article a post hoc evaluation of analysing the effectiveness of relugolix combination therapy in women with uterine fibroids as well as concurrent adenomyosis. All of them had completed the pivotal LIBERTY 1 in addition to 2 clinical trials fashioned to examine the safety, along with efficaciousness of relugolix combination therapy in women with HMB associated with uterine fibroids. In the post hoc analysis, 111 women (18.2% of LIBERTY 1 as well as 2 completers) met the diagnostic ultrasound criteria for adenomyosis, analogous to rates (16%) of coexisting adenomyosis documented observations in UF-1 in addition to UF-2 trials. This is consistent with the literature documenting concomitant adenomyosis in 15%–57% of hysterectomy specimens with uterine fibroids <sup>[31]</sup>. In the LIBERTY 1, along with 2 post hoc analysis, the subgroup of women with adenomyosis as well as uterine fibroids was investigated against the total study population on selected efficaciousness in addition to safety endpoints. Of subjects with adenomyosis, 83.8% in the relugolix combination therapy group responded to treatment as opposed to 27.6% in the placebo group. Amenorrhea was achieved in 64.9% of women with adenomyosis treated with relugolix combination therapy; however, just 6.9% of those received the placebo. The minimal square average uterine volume of women with adenomyosis decreased by 22.2%, along with 5.8% in the relugolix combination therapy as well as placebo groups, respectively. Safety outcomes in the subgroup of women with adenomyosis were correspondent with those of the total LIBERTY 1 in addition to 2 population, with an analogous number of inimical processes in the relugolix combination therapy, along with placebo groups. Taken together, efficacy as well as safety observations in women with uterine fibroids in addition to concurrent adenomyosis were correspondent with those in the total LIBERTY study population. Noticeably, a greater analogous percentage of women in the relugolix combination therapy arm were White (62%), compared with the placebo arm (35%). However, in the overall LIBERTY study population, analogous data were documented for Black/African American women treated with relugolix combination therapy <sup>[27]</sup>. As emphasized by the researchers themselves <sup>[27]</sup>, restrictions of this study are inclusive of the germanely small number of participants in the analyzed subgroup as well as absence of stratification upon recruitment as per the existence of adenomyosis. Furthermore, being based on retrospective evaluation of ultrasound images instead of magnetic resonance imaging (MRI) images, disease diagnosis in this study population might be subject to bias. In women with both uterine fibroids as well as adenomyosis, relugolix combination therapy provided analogous effectiveness to the total LIBERTY population, diminishing HMB, uterine volume, symptom robustness, in addition to pain, along with was well tolerated over the course of 24 weeks. This suggests to no elimination of efficaciousness in the treatment of fibroids, in patients with adenomyosis as well. There is, thereby, a serious need to investigate in future studies the potential medical management of women with both uterine fibroids and adenomyosis. Nevertheless, data documented in the study by Catherino et al. [27], cannot be extrapolated to women with uterine adenomyosis– correlated infertility. Randomized controlled trials need to be performed definitely to corroborate the therapeutic actions of oral GnRH antagonists in women with adenomyosis based on the symptoms (bleeding or infertility or both), age, as well as reproductive status <sup>[32]</sup>.

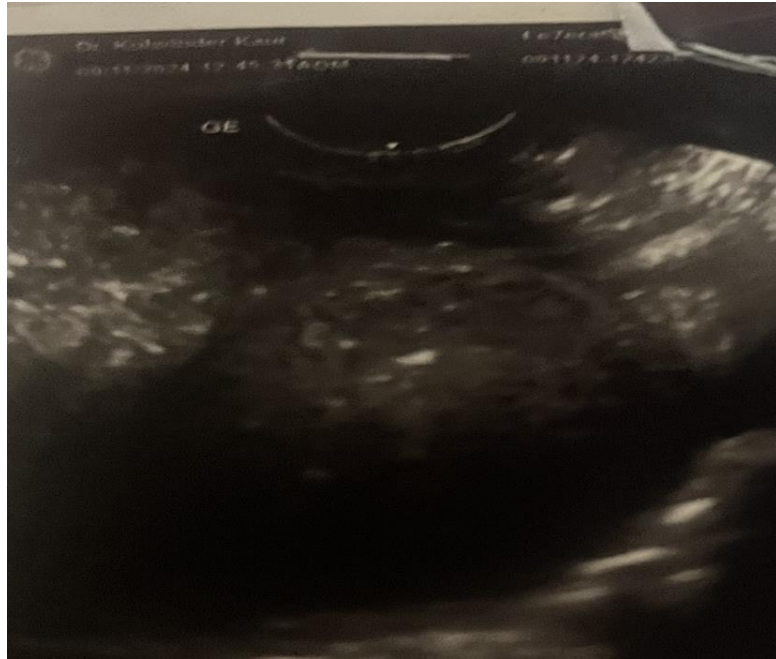
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## CONCLUSIONS ALONG WITH DIRECTIONS

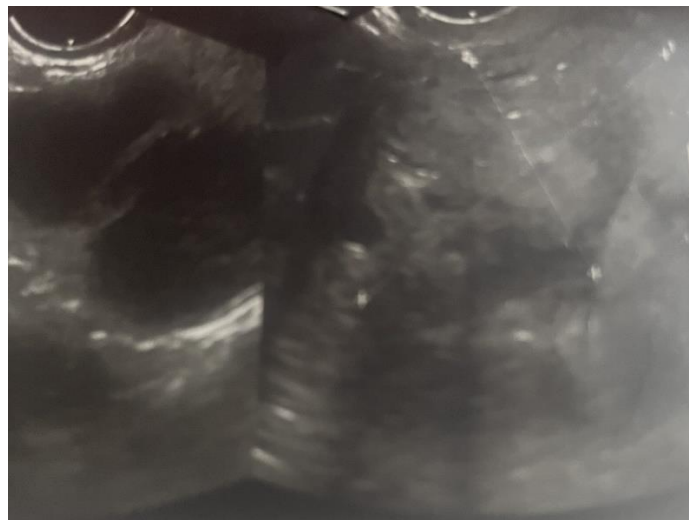
Earlier we have comprehensive reviewed etiopathogenesis of adenomyosis where despite etiology along with as well as pathogenesis not being clear 2 basic theories have been posited in the literature namely i) invagination of the endometrial basalis in view of activation of the tissue injury as well as repair (TIAR) mechanism in addition to, metaplasia of displaced embryonic pluripotent mullerian remnants or differentiation of adult stem cells [33]. Additionally, we documented a spontaneous conception in a patient of Adenomyosis with submucous fibroid subsequent to treatment with mifepristone in a 38-year-old patient with 10year secondary infertility [34]. Nevertheless, another patient s with massively enlarged uterus due to uterine fibroids in addition to concurrent adenomyosis only partly responded to mifepristone due to her being not keen for surgery. Earlier she gave history of failure of donor egg IVF. Thus 2 yrs back we had been giving her mifepristone due to non-availability of elagolix as well as relugolix. Right now elagolix availability is there so we have started it with mifepristone. Thus, there is greater need for efficacious medical therapies specifically in patient with infertility (Figure1-3) of the said patient.



**Figure 1:** Massive Adenomyosis.



**Figure 2:** Part Fibroid Left.



**Figure 3:** Adenomyosis left with cysts in left ovary after mife therapy.

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