



## Dienogest- role in preventing bleeding in endometriosis and PLAB scoring, in central India population

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### I. INTRODUCTION

The growth of endometrial tissue (both glands and stroma) outside the uterine cavity which causes a chronic inflammation inside or outside the pelvis<sup>[1]</sup> is known as Endometriosis. It is a common estrogen-dependent disease which affects up to 15% of women<sup>[1]</sup> of reproductive age. Endometriosis is identified by dysmenorrhea, noncyclic pelvic pain and/or dyspareunia<sup>[2,3]</sup>. It hampers the quality of life, as it can be both physically and emotionally exhausting for her<sup>[4-7]</sup>.

The diagnosis based on clinical symptoms<sup>[15,16]</sup>, Thus, when a woman is diagnosed by the symptoms, caused by endometriosis<sup>[17,18]</sup> an empirical hormonal treatment is recommended.

Progestins are suggested as a first-line hormonal therapy for the treatment of endometriosis-related pain, is effective.<sup>[19]</sup>

European Union in 2009 gave approval to Dienogest, which is a fourth-generation progestin for the treatment of endometriosis.<sup>[20-23]</sup> Dienogest binds to the progesterone receptor. When it is taken continuously it inhibits systemic gonadotropin secretion and has local anti-proliferative and anti-inflammatory effects on endometriotic lesions<sup>[20,24-26]</sup>.

Dienogest differs from other progestins in the same class<sup>[23,26]</sup> due its anti-proliferative and anti-angiogenic properties. Depending upon the chronic nature of the condition, medical treatments for endometriosis need to balance clinical efficacy and symptom relief with an acceptable long-term safety profile<sup>[16]</sup>.

Thus, the focus of present work is to evaluate the effectiveness of dienogest in controlling bleeding in endometriosis and also to assess the effect of dienogest on quality of life during treatment.

### AIMS AND OBJECTIVES

- To evaluate the effectiveness of dienogest in controlling bleeding abnormalities in endometriosis
- To evaluate PLAB score in patients.

### II. MATERIALS AND METHODS

This “Prospective Cohort Study of Role of Dienogest in Management of Bleeding in cases of Endometriosis” was conducted in the Department of Obgy, MGM Medical College and M.Y. Group of Hospital, Indore (M.P) during the period of 12 months from **September 2019 to August 2020**. Also evaluate the PLAB scoring. Study was done according to the regulations of the IEC.

#### SAMPLE SIZE:

50 women in the reproductive age group 18-45 years.

#### INCLUSION CRITERIA

Women in the reproductive age group 18-45 years with endometriosis and presence of at least one of the symptoms dysmenorrhea, infertility, chronic pelvic pain, dyspareunia and who give consent.

#### EXCLUSION CRITERIA

Women with congenital or acquired uterine anomaly, with genital bleeding of unknown etiology, with other medical disorder like thyroid and bleeding disorder, with liver and heart disease, who had undergone a therapeutic surgical procedure in past 6 months and with pregnancy as well as those with a desire immediate pregnancy.

#### STUDY PROCEDURE

Detailed history was taken, general and gynecological examinations were done.

According to patient's symptoms PLAB Scoring was done

Either USG, MRI was done.

Patients either admitted to the ward or not were instructed to take a daily dose of Tab Dienogest 2mg, post dinner.

Explained the side effect.

Follow up was done at 1, 3 and 6 months by follow up card and assessment of pain and bleeding by PLAB Score was done.

After follow up of the 6 months repeat USG was done.

Patient satisfaction, side effects, safety profile of dienogest was assessed.



**STATISTICAL PLAB (PICTORIAL BLOOD LOSS SCORE) ANALYSIS**

Score	Number of pads per day	Number of days							
		1	2	3	4	5	6	7	8
1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Small blood clots	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Big Blood Clots	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Pictorial Blood Loss Assessment Chart**

DAY	DAY1	DAY2	DAY3	DAY4	DAY5	DAY6	DAY7	DAY8	DAY9	DAY10	TOTAL TALLIES	MULTIPLYING FACTOR	ROW TOTAL
												X1	
												X5	
												X20	
												X1	
												X5	
												X10	
Small blood clots (= Dime)												X1	
Large blood clots (≥ Quarter)												X5	
Menstrual accidents												X5	
<b>Total Score (Sum of rows)</b>													

**How to use the Pictorial Blood Assessment Chart:**

- Record the number of tampons and sanitary pads used each day during your period by placing a tally mark under the day next to the box representing the amount of bleeding noted each time you change your pads or tampon (see example at right)
- Record clots by indicating whether they are the size of a dime or a quarter coin in the small and in the large blood clot row under the relevant day.
- Record any incidences of flooding (accidents) by placing a tally mark in the menstrual accident row.

**Scoring the Chart:**

At the end of your period tabulate a "Total Score" by multiplying the total number of tallies in each row by the "Multiplying Factor" at the end of the row. Then sum the "Row Totals" to obtain the final "Total Score".

**Example:**

Ms. Smith in the first day of her period, she used 7 pads (5 lightly stained, 1 moderately and 1 heavily stained). She also used 1 moderately stained tampon and had 3 blood clots 1 small and 2 large. She also had one incidence of flooding.

Days	D1	D2	D3	D4
Small blood clots (= Dime)				
Large blood clots (≥ Quarter)				
Menstrual accidents				
<b>Total Score:</b>				



### III. OBSERVATIONS AND RESULTS

**Table 1**  
**Cases Based on Age**

Age Group (years)	No. of Cases	%
<25	5	10
25-30	9	18
31-35	11	22
36-45	20	40
>46	5	10
Total	50	100

The highest percentage of patients 40% belonged to 36-45 Years followed by 22% who were of 31-35 Years of Age group. Most patient comes under 25-45years age group.

The higher percentage of patients 70% were from Urban area while, only 30% belonged to Rural Area. The highest percentage of patients 28% belonged to Lower Middle socioeconomic status.

**Table 2**  
**Cases Based on Parity**

Parity	No. of Cases	%
P0	12	24
P1	4	8
P2	20	40
P3	4	8
P4 & above	10	20
Total	50	100

The highest percentage of patients 40% had Parity P2 followed by 24% who were having P0, 20% had P4 and above while, remaining 16% had P1 and P3 equally.

**Table 3**  
**Status of Prior to Treatment**

Any Prior T/T	No. of Cases	%
OCP	14	28
Surgery [ $\geq$ 6 months]	9	18



None	27	54
Total	50	100

According to prior T/T, the highest percentage of patients 54% were not having any prior T/T, 28% who reported to have it on OCP while 18% were having it on Surgery.

Basis of past history of Endometriosis, the higher percentage of patients 76% were not having History of Endometriosis while, 24% were having it.

**Table 4**  
**Duration of 1<sup>st</sup> Symptom**

Duration of Symptom	No. of Cases	%
<1 year	7	14
1-2 year	19	38
3-5 year	22	44
>5 year	2	4
Total	50	100

The highest percentage of patients 44% had 1st symptom for 3-5 years followed by 38% who had it for 1-2 years, 14% had it for <1 year while, only 4% had 1<sup>st</sup> symptom for >5 years.

**Table 5**  
**Symptoms of Endometriosis**

Symptoms	No. of Cases	%
CPP + Dysmenorrhea	20	40
CPP + Dysmenorrhea + Heavy Menses	20	40
CPP + Dyspareunia + Dysmenorrhea	5	10
CPP + Infertility	4	8
CPP + Infertility + Heavy Bleeding	1	2
Total	50	100

An equal percentage of patients, 40% had CPP+ Dysmenorrhea and CPP + Dysmenorrhea+ Heavy Menses followed by 10% who were having CPP + Dyspareunia + Dysmenorrhea, 8% had CPP + infertility while, the lowest percentage 2% had CPP+ infertility+ Heavy Bleeding.



**Table 6**  
**USG /Lap Finding**

USG Finding	No. of Cases	%
<2×3 cm Endometriotic Cyst	7	14
3 to 5 cm Endometriotic Cyst	10	20
5 to 8 cm Endometrioma	8	16
>8cm Endometrioma	2	4
Adenomyosis	8	16
Laparoscopic Done	15	30
Total	50	100

based on their USG Finding, an equal percentage of patients 16% had 5 to 8 cm endometrioma and adenomyosis followed by 7%

who were having <2×3 cm endometriotic cyst, 4% had >8cm endometrioma while, the lowest percentage 2% had 3 to 5cm endometriotic cyst.

**Table no -7**  
**Patients Satisfaction Score**

Patients Satisfaction Score	No. of Cases	%
Not satisfied (0-3)	10	14
Satisfied (4 to7)	15	30
Very satisfied (8 -10)	25	50
Total	50	100

based on this, 50% were Very Satisfied followed by 30% who were Satisfied while, 14% were Not Satisfied.

**Table 8**  
**Drug Side Effect**

Drug Side Effect	No. of Cases	%
Headache	12	42
Nausea And Vomiting	14	28
Spotting	6	12
Weight Gain	13	26
Others	5	10



Total	50	100
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The highest percentage of patients 42% had Headache followed by 28% who were having Nausea and Vomiting, 26% had Weight Gain, 12% had Spotting while, the lowest percentage 10% were having other side effects.

**Table 9**  
**Most Common Concomitant Disease**

MC Concomitant DS	No. of Cases	%
Adenomyosis	15	30
Endo polyp	2	4
Fibroid	5	10
PCOS	3	6
No	25	50
Total	25	50

MC Concomitant DS they had 50% were not having any Concomitant DS, 30% who reported to have Adenomyosis, 10% had Fibroid, 6% had PCOS while, 4% were having Endo polyp.

**Table 9**  
**Site of Disease**

Site	No. of Cases	%
Ovary	24	48
Uterus	9	18
Ovary + Fallopian Tubes	12	24
Peritoneum	5	10
Total	50	100

Based on site of disease, 48% were having Ovary followed by 24% who reported to have it in Ovary + Fallopian Tubes, 18% had it in Uterus, and only 10% had it in Peritoneum.

**Table 10**  
**Final Treatment after 6 months**

Final Treatment	No. of Cases	%
Drug	33	66
Drug followed by IVF	2	4
Drug + Cystectomy	3	6



Drug + TAH	4	8
Drug + TAH +Cystectomy	3	6
Other	5	10
Total	50	100

Final Treatment after 6 month they had, 66% were given Drug followed by 10% who reported to have Other Treatment, 8% had Drug + TAH, an equal percentage 6% had Drug + Cystectomy and Drug + TAH +CYSTECTOMY while, 4% had DRUG f/b IVF.

The highest percentage of patients 60% wanted to Continue Drug while, an equal percentage 20% did not want it and want other treatment.

**Table 11**  
**Comparison of Mean PLAB among Site Groups**  
**(Before Treatment)**

Site Groups	N	Mean PLAB Score	Std. Deviation	F Test	P value	Pre-Result
Ovary	24	208.13	62.673	1.839	0.153	Non-Significant
Uterus	9	241.11	69.001			
Ovary + Fallopian tubes	12	229.58	69.812			
Peritoneum	5	162.00	64.962			
Total	50	214.60	67.428			

**(After 1 Month Treatment)**

Site Groups	N	Mean PLAB Score	Std. Deviation	F Test	P value	1 Month Result
Ovary	24	163.88	52.166	2.025	0.124	Non-Significant
Uterus	9	207.44	67.445			
Ovary + Fallopian tubes	12	183.42	66.100			
Peritoneum	5	136.00	51.284			
Total	50	173.62	60.333			

**(After 6 Month Treatment)**

Site Groups	N	Mean PLAB Score	Std. Deviation	F Test	P value	6 Month Result
Ovary	21	63.81	20.119	1.842	0.156	Non Significant
Uterus	8	72.50	12.817			



Ovary + Fallopian tubes	10	56.00	10.750			
Peritoneum	3	53.33	5.774			
Total	42	62.86	17.006			

The comparison of mean PLAB (%) of patients among Site Groups before treatment, one month and 6-month treatment.

The difference among the four groups was found to be statistically non-significant ( $P > 0.05$ ), showing that mean PLAB (%) of patients do not

change significantly with different Site groups for before treatment, one month and 6-month treatment. The mean PLAB is the highest for Uterus (241.11) and it shows the lowest score for Peritoneum (162.00).

**Table 12**  
**Comparison of Mean PLAB among Prior Treatment Groups (Before Treatment)**

Prior Treatment	N	Mean PLAB Score	Std. Deviation	F Test	P value	Pre Result
Yes OCP	14	218.57	66.663	0.047	0.954	Non Significant
Yes Sx	9	216.44	77.452			
None	27	211.93	66.960			
Total	50	214.60	67.428			

**(After 1 Month Treatment)**

Prior treatment	N	Mean PLAB Score	Std. Deviation	F Test	P value	1 Month Result
Yes OCP	14	183.43	67.675	0.249	0.780	Non Significant
Yes Sx	9	169.44	63.563			
None	27	169.93	57.053			
Total	50	173.62	60.333			

**(After 6 Months Treatment)**

Prior treatment	N	Mean PLAB Score	Std. Deviation	F Test	P value	6 Month Result
Yes OCP	14	64.29	22.089	0.270	0.765	Non Significant
Yes Sx	7	65.71	19.024			
None	21	60.95	12.611			
Total	42	62.86	17.006			





The above table shows the comparison of mean PLAB (%) of patients among Prior Treatment Groups before, one month, 6-month Treatment.

The difference among the three groups was found to be statistically non-significant ( $P > 0.05$ ), showing that mean PLAB (%) of patients

do not change significantly with different Prior Treatment groups for before, one month, 6-month Treatment. The mean PLAB is the highest for OCP (218.57) and it shows the lowest score for None (211.93).

**Table 13**  
**Comparison of Mean PLAB among Previous Disease Groups (Before Treatment)**

Previous Groups	DS	N	Mean PLAB Score	Std. Deviation	F Test	P value	Pre Result
Adenomyosis		12	218.33	54.244	2.507	0.071	Non Significant
Fibroid		12	246.25	41.622			
PCOS		4	147.50	70.415			
Others		22	207.50	77.206			
Total		50	214.60	67.428			

(After 1 Month Treatment)

Previous Groups	DS	N	Mean PLAB Score	Std. Deviation	F Test	P value	1 Month Result
Adenomyosis		12	176.67	53.144	2.592	0.064	Non Significant
Fibroid		12	207.17	46.338			
PCOS		4	125.00	52.599			
Others		22	162.50	65.314			
Total		50	173.62	60.333			

(After 6 Month Treatment)

Previous Groups	DS	N	Mean PLAB Score	Std. Deviation	F Test	P value	6 Month Result
Adenomyosis		11	70.00	25.298	1.180	0.330	Non Significant
Fibroid		8	65.00	14.142			
PCOS		3	56.67	5.774			
Others		20	59.00	12.524			



Total	42	62.86	17.006			
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The above table shows the comparison of mean PLAB (%) of patients among Previous DS Groups Before, one month, and 6-month Treatment.

The difference among the three groups was found to be statistically non-significant

( $P > 0.05$ ), showing that mean PLAB (%) of patients do not change significantly with Previous DS groups. The mean PLAB is the highest for FIBROID (246.25) and it shows the lowest score for PCOS (147.50).

**Table 14**  
**Comparison of Mean PLAB among Duration of Disease Groups (Before Treatment)**

Duration of Disease	N	Mean PLAB Score	Std. Deviation	F Test	P value	Pre Result
< 1 Year	8	212.50	76.858	0.144	0.933	Non Significant
1-3 Years	18	208.17	71.492			
3-5 Years	17	223.24	64.975			
>=5 Years	7	212.57	64.443			
Total	50	214.60	67.428			

**(After 3 Months Treatment)**

Duration of Disease	N	Mean PLAB Score	Std. Deviation	F Test	P value	3 Month Result
< 1 Year	8	115.00	40.708	0.228	0.876	Non Significant
1-3 Years	15	111.73	30.788			
3-5 Years	17	107.18	34.366			
>=5 Years	7	120.00	47.958			
Total	47	111.87	35.656			

The above table shows the comparison of mean PLAB (%) of patients among Duration of Disease Groups before and after 3 Months of Treatment.

The difference among the three groups was found to be statistically non-significant

( $P > 0.05$ ), showing that mean PLAB (%) of patients do not change significantly with different Duration of Disease groups. The mean PLAB is the highest for >=5 Years (120.00) and it shows the lowest score for 3-5 Years (107.18).



**Table 15**  
**Pre-Post Comparison of Mean PLAB score**

Variable	Time Interval	N	Mean PLAB Score	Std. Deviation	T Test	P Value	Result
All Patients	Pre treatment	50	214.60	67.428	12.216	0.000	Sig
	After 1 Month	50	173.62	60.333			
	Pre treatment	47	216.38	63.077	14.175	0.000	Sig
	After 3 Month	47	111.87	35.656			
	Pre treatment	42	225.36	55.876	18.375	0.000	Sig
	After 6 Month	42	62.86	17.006			

The above table shows the Pre-Post comparison of all the patients Mean PLAB score at different follow-up durations.

Paired t test was applied and it was found that the mean PLAB score reduces significantly on

all the follow-up time intervals as compare to Pre-treatment value. (P<0.05)

The mean value at Pre-treatment (214.60) reduces significantly to 173.62 after 1 month, 111.87 after 3 month and finally 62.86 after 6 months.

**Table 16**  
**Pre-Post Comparison of Mean PLAB score for Different Prior Treatments**

Prior Treatment	Time Interval	N	Mean PLAB Score	Std. Deviation	T Test	P Value	Result
OCP	Pre treatment	14	218.57	66.663	5.744	0.000	Sig
	After 1 Month	14	183.43	67.675			
	Pre treatment	14	218.57	66.663	7.398	0.000	Sig
	After 3 Month	14	122.14	40.226			
	Pre treatment	14	218.57	66.663	8.692	0.000	Sig
	After 6 Month	14	64.29	22.089			
SX	Pre treatment	9	216.44	77.452	6.677	0.000	Sig
	After 1 Month	9	169.44	63.563			
	Pre treatment	7	234.00	34.234	7.221	0.000	Sig
	After 3 Month	7	130.00	26.458			
	Pre treatment	7	234.00	34.234	8.810	0.000	Sig
	After 6 Month	7	65.71	19.024			
None	Pre treatment	27	211.93	66.960	8.701	0.000	Sig



	After 1 Month	27	169.93	57.053			
	Pre treatment	26	210.46	67.843	10.050	0.000	Sig
	After 3 Month	26	101.46	32.651			
	Pre treatment	21	227.00	55.669	13.828	0.000	Sig
	After 6 Month	21	60.95	12.611			

In case of OCP or surgery, prior treatment patients the mean PLAB score reduces significantly at 1 Month, 3 Month and 6 Month duration as compare to Pre PLAB score.(P<0.05).

**Table 17**  
**Pre and Post treatment Comparison of Mean PLAB score for Different Disease Site**

Site	Time Interval	N	Mean PLAB Score	Std. Deviation	T Test	P Value	Result
Ovary	Pre treatment	21	220.48	44.775	14.349	0.000	Sig
	After 6 Month	21	63.81	20.119			
Uterus	Pre treatment	8	260.00	42.088	10.652	0.000	Sig
	After 6 Month	8	72.50	12.817			
Ovary + fallopian tube	Pre treatment	10	227.50	74.648	7.327	0.000	Sig
	After 6 Month	10	56.00	10.750			
Peritoneum	Pre treatment	3	160.00	34.641	5.747	0.029	Sig
	After 6 Month	3	53.33	5.774			

In case of patients with Ovary Site, uterus site, peritoneum site, and ovary with peritoneum, the mean PLAB score reduces significantly at 1 Month, and 6 Month duration as compare to Pre PLAB score.(P<0.05).

**Table 18**  
**Pre-Post Comparison of Mean PLAB score for Different Previous Disease**

Previous DS	Time Interval	N	Mean PLAB Score	Std. Deviation	T Test	P Value	Result
Adenomyosis	Pre treatment	11	230.91	33.898	10.369	0.000	Sig
	After 6 Month	11	70.00	25.298			
Fibroid	Pre treatment	8	247.50	47.434	11.563	0.000	Sig
	After 6 Month	8	65.00	14.142			



Previous DS	Time Interval	N	Mean PLAB Score	Std. Deviation	T Test	P Value	Result
Pcos	Pre treatment	3	166.67	72.342	2.750	0.111	Sig
	After 6 Month	3	56.67	5.774			
Other	Pre treatment	20	222.25	63.042	11.769	0.000	Sig
	After 6 Month	20	59.00	12.524			

In case of patients with Adenomyosis, fibroid, pcos as previous Disease the mean PLAB score reduces significantly at 1 Month, and 6 Month duration as compare to Pre PLAB score. (P<0.05).

Finally for patients with other previous disease also the reduction in mean PLAB was observed to be significant at all durations.

**Table 19**  
**Pre and Post treatment Comparison of Mean PLAB score for Different Duration of Disease**

Duration of Disease	Time Interval	N	Mean PLAB Score	Std. Deviation	T Test	P Value	Result
Below one year	Pre treatment	7	230.00	63.509	8.262	0.000	Sig
	After 6 Month	7	61.43	13.452			
1-3 year	Pre treatment	13	232.08	29.457	16.385	0.000	Sig
	After 6 Month	13	65.38	15.064			
3-5 year	Pre treatment	15	223.33	68.938	9.296	0.000	Sig
	After 6 Month	15	59.33	12.228			
≥5 Year	Pre treatment	7	212.57	64.443	5.179	0.002	Sig
	After 6 Month	7	67.14	30.394			

Finally for patients with long disease duration of ≥5 years the reduction in mean PLAB was observed to be significant at all time intervals of follow-ups and hence pain reduces significantly with time.

**IV. RESULTS AND DISCUSSION**

Endometriosis is a common gynaecologic condition and it is affecting 10% of woman of reproductive age group. In our study, study of prevalence of endometriosis is nearly 6%. most of the women belonged to the age group of 31-50

years (72.2%)<sup>5</sup>, this is same as a study of Schindler AE<sup>[29]</sup> (2011)

Majority of women were resident of urban area (70%), were housewives (60%) and educated.

In our study majority of women are multiparous (Para 2 and more than P2) (68%), Nulliparous woman were 24%. This is same as in study done by Grandi G<sup>[31]</sup> (2015) done in 34 women where 60% were multiparous.

In the study Techatraisak K et al<sup>[34]</sup> (2019), 514 patients had prior type of treatment, in which 179 (34%) received hormonal treatment and



87%(449)received surgical treatment of endometriosis and 17.5% of women received only pain therapy.In our study, 20% women received other hormonal treatment like OCPS and GnRH agonists.4% patients were having surgery and 20% received only pain therapy.

In our study most of patients were who had symptoms for 3-5 years are 44% and then 38% patients were symptomatic for 1-2 years. Only 4%(2 patients) had symptoms more than 5 years.In the study Techatraisak K et al<sup>[34]</sup> (2019), endometriosis was diagnosed within 1 year before initial visit.

In the study Caruso S. et al<sup>[33]</sup> (2018) mc symptom was chronic pelvic pain in 100%(n=51) women, dysmenorrhea n=50(78.4%) and dyspareunia n=38 (74.5%).In our study almost same results were found. Most common symptom of endometriosis was chronic pelvic pain (100%), dysmenorrhea(50%) and 42% women who presented with heavy bleeding.Only 10% women had infertility.

In the study Techatraisak K et al<sup>[34]</sup> (2019) most common symptom of endometriosis was dysmenorrhea (n=684/865 ;79.1%) and chronic pelvic pain (n=279/865;32.3%), dyspareunia (5.9%).

In our study after 6 months, headache was the most common complaint given by 42% of patients followed by nausea and vomiting in 26% of patients and weight gain in 12% of patients.

In the study Schindler AE<sup>[29]</sup> (2011), the most commonadverse effect was metrorrhagia (71.9%) followed by headache(18.5%) and constipation (10.4).

In the study Techatraisak K et al<sup>[34]</sup> (2019)N=616(71.2%) women were diagnosed surgically or laparoscopically and n=247(28.6%) were diagnosed clinically.In our study n=15(30%) of women were diagnosed laparoscopically and by USG(TAS/TVS) n=35(70%) was diagnosed.

In our study, 50% were not having concomitant disease while 30% were having adenomyosis and 10% were having fibroid. While in the study of Techatraisak K et al<sup>[34]</sup> (2019) out of 865 patients 146 patients had 1 concomitant disease in which adenomyosis was most concomitant disease (31.5% n=46/146) and then uterine leiomyoma (n=39/146; 26.7%) and anemia 12.3% (n=18/146).

In the studyTechatraisak K et al<sup>[34]</sup> (2019), endometriotic lesion were evaluated in 768 patients in which single lesion were found 54.3% (n=417/768) and multi lesion were found in n=351/768 (45.5%).

In our study highest percentage of patient (n=30/50) 60% had single lesion while 40% (n=20/50) were having multi endometriotic lesion.

Tab Dienogest has also been found to be cost effective and to increase the quality of life(QUL).The quality of women treated with dienogest is markedly improved high level of patient satisfaction.

In our study the number of very satisfied patients are 50% which is statistically significantly higher than number of satisfied (30%) and not satisfied patients(14%).No satisfaction was due to persistence of heavy bleeding and chronic pelvic pain.

In the study of Kohler G<sup>[28]</sup> (2010)after three months of use of dienogest 57.5% patients were satisfied.

At the end of six months 92.5% patients were more satisfied and whereas 7.4 % patients were not completely satisfied due to side effects.

In the study Vercellini P<sup>[32]</sup> (2016)done on 180 patients higher proportion 76.5% of patients were satisfied with dinogest.

In the study of Techatraisak K et al<sup>[34]</sup> (2019)large proportion of patient 66% (n=322/488) were satisfied with dienogest.

In our study, 52% had ovarian endometriotic cyst 15% had uterus and peritoneum deposit endometriosis and other pelvic organ like POD and bladder base had 10%. None had it in extra pelvic region.Most of the case were having ovarian endometriosis.

In the study Techatraisak K et al<sup>[34]</sup> (2019)(n=640/865) 88.4% were having ovarian endometriosis and 39% had other pelvic organ and extra pelvic endometriosis were only 2.9%.

In our study, highest percentage of patients 42% were not having any previous disease.

22% were had adenomyosis and fibroid was previous disease in 16% of women and 6% women were having PCOS and endometriotic polyp.

In Techatraisak K et al<sup>[34]</sup> (2019)out of 865 women only 141 women were had any previous disease in which uterine leiomyoma in (n=69/141) 48.9% women.N=36/141 (25.5%) were had endometrial polyp.PID was, which was found only in 14.2 % (n=20/141).

In our study 60% (n=30/50) wanted to continue drug while an equal percent 20% did not want it and wanted other drugs.In the study Schindler AE<sup>[29]</sup> (2011)about 60% of women want to continue drug.In the study of Techatraisak K et al<sup>[34]</sup> (2019)majority of patients continued treatment with dinogest (n=430/488) 88.1% after 6 month.



The difference among the four groups was found to be statistically non-significant ( $P>0.05$ ), showing that mean PLAB score of patients do not change significantly with different site.

The mean PLAB is the highest at Uterus (9.22) and it shows the lowest score at Ovary.

After one month of the treatment, the difference among the four groups was found to be statistically non-significant ( $P>0.05$ ), showing that fall in the mean PLAB of patients do not change significantly with different site.

Similar results were found after 3 month and 6 months of treatment, that fall in the mean PLAB % of patients do not change significantly with different site.

It means, the efficiency of dienogest in reducing PLAB score does not depend upon the site of the disease.

In our study, before Treatment, mean PLAB score was ( $216\pm 66$ ) among all 3 groups.

The difference among the three groups was found to be statistically non-significant ( $P>0.05=0.6$ ), showing the mean PLAB score of patients do not change significantly with Prior Treatment Groups.

Similar Results were found after 3 months and 6 months of treatment,

That is-Efficiency of dienogest in reducing the PLAB score doesn't depend on whether person has taken prior treatment or not, the PLAB score decreases equally in all three groups.

In the Study, Techatrasak K et al<sup>[34]</sup> (2019)

The difference among the three groups was found to be statistically significant ( $p<0.05=0.03$ ), showing that mean VAS (%) of patients change significantly with Prior Treatment Groups.

In the study, Vercellini P<sup>[32]</sup> (2016), similar Improving in all groups for the pain score ( $p>0.05$ ).

In our study, before Treatment, mean PLAB was ( $214\pm 67$ ) among all 4 groups.

The difference among the four groups was found to be statistically non-significant ( $P>0.05=0.6$ ), showing that mean PLAB score (%) of patients do not change significantly with Previous Groups.

Similar Results were found after 3 months and 6 months of treatment,

That is-Efficiency of dienogest in reducing the PLAB score doesn't depend on whether person has taken prior disease or not

In our study, before Treatment, mean PLAB score ( $214\pm 67$ ) among all 4 groups, showing that the mean PLAB score do not change significantly with duration of disease. Similar

Results were found after 3 months and 6 months of treatment,

That is-efficiency of dienogest in reducing PLAB score doesn't depend on the duration of the disease.

## V. CONCLUSION

Endometriosis is a disease that requires a long term management. Dienogest seems to be effective for the treatment of pain and bleeding abnormalities, associated with endometriosis.

In conclusion our data indicates that dienogest could improve health related quality of life of woman and decreases in the perception of endometriosis associated pain and heavy bleeding.

A good satisfaction score and compliance are found, so dienogest might be an effective therapeutic option for the long term management of Endometriosis. It is also effective in the patients with fibroid, adenomyosis, polyp, and PID

Dienogest is a safe, effective and first line treatment for endometriosis. Due to the side effects of dienogest, some of the women experience change in menstrual pattern.

Counseling plays an important role in continuation of drug dienogest. Thus, our study concluded that dienogest is a good drug for medical management of endometriosis and it should be used as the first line therapy for the same. It may be considered before Surgery.

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