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Original Research Article

Assessment of the prescription pattern of dydrogesterone in obstetrics and gynaecological disorders in adult women in an outpatient setting across India

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ABSTRACT

Background: Dydrogesterone is a prescribed progestogen used in infertility, threatened abortion, recurrent pregnancy loss, endometriosis, and menstrual disorders. However, large-scale real-world evidence describing its utilisation patterns in clinical practice in India remains limited.
Methods: This multicentric, cross-sectional, observational study included adult women receiving dydrogesterone therapy across India. Data on demographic and reproductive characteristics, clinical indications, comorbidities, treatment regimens, and duration of therapy were collected from routine clinical records and analysed using descriptive and inferential statistics.
Results: A total of 7,160 women were included. Infertility was the most common indication for dydrogesterone therapy (45.0%; n=3219), followed by threatened abortion (27.2%; n=1946) and recurrent pregnancy loss (13.6%; n=972). Dydrogesterone 10 mg twice daily was the most frequently prescribed regimen (49.8%; n=3564), followed by Dydrogesterone 10 mg once daily (30.9%; n=2211) and sustained-release 20 mg once daily (12.4%; n=886). Most patients were aged 18-30 years (73.4%; n=5256), had a normal body mass index (58.9%; n=4218), and were nulligravida (89.3%; n=6394). Significant associations were observed between treatment regimen and clinical indication, age category, body mass index, gravida status, parity status, comorbidity status, and duration of therapy (all $p<0.05$).
Conclusions: This large multicentric real-world study demonstrates extensive utilisation of dydrogesterone in Indian obstetric and gynaecological practice, with 10 mg twice-daily and once-daily regimens representing the predominant treatment approaches. The findings provide valuable real-world evidence on patient profiles and contemporary prescribing patterns associated with dydrogesterone use in routine clinical care.

Keywords: Drug utilisation, Dydrogesterone, Prescription pattern, Real-world evidence

INTRODUCTION

Progesterone is a key hormone in female reproductive physiology, regulating ovulation, endometrial receptivity, embryo implantation, and maintenance of early pregnancy.[1] Inadequate progesterone action has been implicated in infertility, threatened abortion, recurrent pregnancy loss, menstrual irregularities, and endometriosis. Progesterone supplementation is therefore widely used for luteal phase support, miscarriage prevention in selected high-risk women, and the management of various gynaecological conditions.[1,2] Recent evidence and international guidelines support the important role of progesterone therapy in optimising reproductive and pregnancy outcomes across a range of clinical settings.[3-5]

Dydrogesterone is an orally active retro progesterone with pharmacological activity similar to natural progesterone.[6] Owing to its high selectivity for progesterone receptors and favourable safety and tolerability profile, it is widely used for luteal phase insufficiency, infertility, threatened abortion, and recurrent pregnancy loss.[7] Clinical studies and meta-analyses have demonstrated its efficacy in improving reproductive and pregnancy outcomes, leading to its incorporation into contemporary clinical practice and guideline recommendations.[1,5]

Current evidence and international guidelines support the use of progesterone supplementation in several reproductive conditions.[3,4] Oral dydrogesterone has demonstrated efficacy comparable to vaginal progesterone for luteal phase support and is recognised as an effective and patient-friendly treatment option.[8] A recent systematic review and meta-analysis further reported comparable reproductive outcomes between oral dydrogesterone and vaginal progesterone in frozen-thawed embryo transfer cycles.[8] Consequently, dydrogesterone has become an important therapeutic option in infertility management, threatened abortion, recurrent pregnancy loss, and other reproductive disorders.[9,10]

Although dydrogesterone is widely used across obstetric and gynaecological indications, most available evidence is derived from randomised controlled trials and systematic reviews.[8] Real-world evidence complements these findings by providing insights into prescribing patterns, patient characteristics, and treatment practices in routine clinical care.[11] However, large-scale multicentric data describing the real-world utilisation of dydrogesterone in Indian clinical practice remain limited.

The significance of the present study lies in its ability to provide contemporary real-world evidence on the utilisation of dydrogesterone across a broad spectrum of obstetric and gynaecological conditions in India. Understanding current prescribing patterns, patient profiles, treatment regimens, and duration of therapy can help assess the extent to which routine clinical practice aligns with existing evidence and guideline recommendations. Furthermore, such data may enhance understanding of treatment trends, support evidence-based clinical decision-making, and identify areas for future research in reproductive medicine.

Therefore, the present multicentric, cross-sectional, observational study was conducted to evaluate the prescribing patterns and clinical utilisation of dydrogesterone in routine clinical practice across India. Specifically, the study aimed to characterise patient demographics, reproductive and clinical profiles, treatment indications, comorbidity patterns, dosing regimens, and duration of therapy associated with dydrogesterone use, thereby generating real-world evidence on contemporary prescribing practices in obstetric and gynaecological care.

METHODS

Study design

This multicentric, cross-sectional, observational study was conducted between September 2025 and March 2026 across 631 participating outpatient obstetrics and gynaecology centres, including private clinics, multispecialty hospitals, and fertility centres, across India. The study evaluated real-world prescribing patterns across different dydrogesterone formulations and dosing regimens, focusing on clinical indications, dosage, treatment duration, patient characteristics, and associated clinical factors.

Study population

Adult women aged ≥18 years prescribed dydrogesterone for any approved obstetric or gynaecological indication were included. Women with documented hypersensitivity to dydrogesterone or severe hepatic or renal dysfunction were excluded.

Data collection

Data were retrospectively collected using structured case report forms (CRFs) from available patient medical records. Variables included age, BMI, gravida, parity, abortion and live birth history, clinical indication, comorbidities, past medical and obstetric history, prior treatments, dydrogesterone regimen, formulation, and treatment duration.

Study outcomes

The primary objective was to assess dydrogesterone prescribing patterns in adult women with obstetric and gynaecological disorders. Secondary objectives included evaluation of dosage regimens, treatment duration, patient characteristics, comorbidity burden, obstetric history, and prescribing practices.

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics version 27. Continuous variables are presented as mean±SD and categorical variables as frequencies and percentages. Continuous variables were compared using one-way ANOVA and categorical variables using the chi-square test. All tests were two-sided, with $p<0.05$ considered statistically significant. Missing data were excluded without imputation.

RESULTS

Data from 7,160 women receiving dydrogesterone therapy for various obstetric and gynaecological indications were included in the final analysis. The distribution of treatment regimens and their association with patient characteristics and prescribing patterns are presented below.

Study population and baseline characteristics

A total of 7,160 women receiving dydrogesterone therapy were included in the analysis. Dydrogesterone 10 mg twice daily (BD) was the most frequently prescribed regimen, accounting for 49.8% (n=3564) of prescriptions, followed by dydrogesterone 10 mg once daily (OD) in 30.9% (n=2211) and sustained-release (SR) 20 mg once daily (OD) in 12.4% (n=886) of patients. Dydrogesterone 10 mg three times daily (TID) was prescribed in 4.2% (n=303) of patients. Less commonly prescribed regimens included SR 30 mg OD in 1.1% (n=79), other regimens in 1.5% (n=108), a 40 mg loading-dose regimen in 0.08% (n=6), and day 5-25/continuous therapy in 0.04% (n=3) of patients (Figure 1).

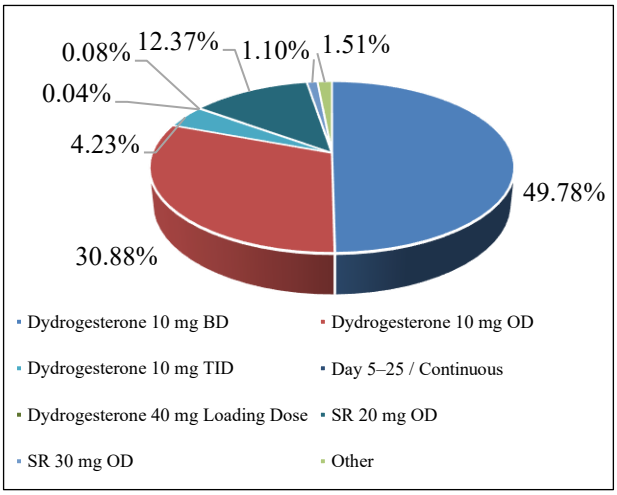

Figure 1: Distribution of dydrogesterone treatment regimens (n=7160).

Table 1 presents the demographic and reproductive characteristics across treatment regimens. Across all major regimens (BD, OD, TID, and SR 20 mg OD), most patients were aged 18-30 years, had normal BMI, were nulligravida and nulliparous, and had no previous history of abortion or live birth. Patients receiving Day 5-25/continuous therapy, 40 mg loading-dose therapy, SR 30 mg OD, and other regimens represented only a small proportion of the study population. Significant differences were observed in age, BMI, gravida, parity, abortion history, and live birth history across treatment regimens (all $p<0.05$).

Table 1: Baseline demographic and reproductive characteristics of the study population (n=7160).

Variables	Total	DYG 10 mg BD	DYG 10 mg OD	DYG 10 mg TID	Day 5-25/ continuous	40 mg loading dose	SR 20 mg OD	SR 30 mg OD	Other	P value
Age category (years), N (%)										
18-30	5256 (73.4)	2544 (71.4)	1721 (77.8)	172 (56.8)	2 (66.7)	5 (83.3)	658 (74.3)	65 (82.3)	89 (82.4)	<0.0001
31-40	1814 (25.3)	969 (27.2)	472 (21.3)	125 (41.3)	1 (33.3)	1 (16.7)	214 (24.2)	14 (17.7)	18 (16.7)	
41-50	86 (1.2)	49 (1.4)	16 (0.7)	6 (2.0)	0	0	14 (1.6)	0	1 (0.9)	
51-60	3 (0.04)	2 (0.1)	1 (0.0)	0	0	0	0	0	0	
>60	1 (0.01)	0	1 (0.0)	0	0	0	0	0	0	
BMI category, N (%)										
Underweight	541 (7.6)	255 (7.2)	168 (7.6)	28 (9.2)	0	1 (16.7)	63 (7.1)	13 (16.5)	13 (12.0)	<0.0001
Normal weight	4218 (58.9)	2085 (58.5)	1301 (58.8)	152 (50.2)	1 (33.3)	5 (83.3)	554 (62.5)	49 (62.0)	71 (65.7)	
Overweight	1783 (24.9)	893 (25.1)	566 (25.6)	89 (29.4)	1 (33.3)	0	206 (23.3)	15 (19.0)	13 (12.0)	
Obese	618 (8.6)	331 (9.3)	176 (8.0)	34 (11.2)	1 (33.3)	0	63 (7.1)	2 (2.5)	11 (10.2)	
Gravida category, N (%)										
Nulligravida	6394 (89.3)	3163 (88.7)	2001 (90.5)	284 (93.7)	3 (100.0)	2 (33.3)	787 (88.8)	64 (81.0)	90 (83.3)	<0.0001

Continued.

Variables	Total	DYG 10 mg BD	DYG 10 mg OD	DYG 10 mg TID	Day 5-25/ continuous	40 mg loading dose	SR 20 mg OD	SR 30 mg OD	Other	P value
Primigravida	368 (5.1)	200 (5.6)	106 (4.8)	4 (1.3)	0	1 (16.7)	39 (4.4)	10 (12.7)	8 (7.4)	
Multigravida	333 (4.7)	166 (4.7)	91 (4.1)	12 (4.0)	0	2 (33.3)	51 (5.8)	5 (6.3)	6 (5.6)	
Grand multigravida	65 (0.9)	35 (1.0)	13 (0.6)	3 (1.0)	0	1 (16.7)	9 (1.0)	0	4 (3.7)	
Parity category, N (%)										
Nulliparous	6797 (94.9)	3395 (95.3)	2097 (94.8)	289 (95.4)	3 (100.0)	3 (50.0)	837 (94.5)	75 (94.9)	98 (90.7)	
Primiparous	307 (4.3)	148 (4.2)	93 (4.2)	12 (4.0)	0	3 (50.0)	41 (4.6)	3 (3.8)	7 (6.5)	<0.0001
Multiparous	52 (0.7)	19 (0.5)	20 (0.9)	2 (0.7)	0	0	8 (0.9)	1 (1.3)	2 (1.9)	
Grand multiparous	4 (0.1)	2 (0.1)	1 (0.0)	0	0	0	0	0	1 (0.9)	
History of abortion, N (%)										
None	6913 (96.6)	3436 (96.4)	2152 (97.3)	294 (97.0)	3 (100.0)	4 (66.7)	846 (95.5)	75 (94.9)	103 (95.4)	
Single abortion	156 (2.2)	74 (2.1)	44 (2.0)	5 (1.7)	0	1 (16.7)	24 (2.7)	4 (5.1)	4 (3.7)	0.001
Multiple abortions	91 (1.3)	54 (1.5)	15 (0.7)	4 (1.3)	0	1 (16.7)	16 (1.8)	0	1 (0.9)	
Live birth history, N (%)										
None	6860 (95.8)	3413 (95.8)	2119 (95.8)	291 (96.0)	3 (100.0)	4 (66.7)	859 (97.0)	72 (91.1)	99 (91.7)	
Single live birth	266 (3.7)	139 (3.9)	81 (3.7)	10 (3.3)	0	2 (33.3)	23 (2.6)	5 (6.3)	6 (5.6)	<0.0001
Multiple live births	34 (0.5)	12 (0.3)	11 (0.5)	2 (0.7)	0	0	4 (0.5)	2 (2.5)	3 (2.8)	

DYG= Dydrogesterone; BD=Twice daily; OD=Once daily; SR=Sustained release; BMI=Body mass index; SD=Standard deviation

Clinical indications and prescription patterns of dydrogesterone

Figure 2 presents the distribution of clinical indications across different dydrogesterone treatment regimens. Overall, infertility accounted for 45.0% (n=3219) of patients, followed by threatened abortion (27.2%, n=1946), recurrent pregnancy loss (13.6%, n=972), irregular menstrual cycle (9.7%, n=696), and endometriosis (4.6%, n=327). Among patients receiving dydrogesterone 10 mg BD (n=3564), infertility was reported in 43.5% (n=1550) of patients, threatened abortion in 27.3% (n=973), recurrent pregnancy loss in 14.3% (n=511), irregular menstrual cycle in 10.3% (n=367), and endometriosis in 4.6% (n=163).

Infertility predominated among patients receiving BD (43.5%), OD (48.9%), and SR 20 mg OD (44.9%), whereas threatened abortion was the leading indication among patients receiving TID (38.0%). Patients receiving day 5-25/continuous therapy, 40 mg loading-dose therapy, SR 30 mg OD, and other regimens constituted a small proportion of the cohort. A significant association was observed between clinical indication and treatment regimen (χ^2=110.500, p<0.0001).

Association of obstetric history categories with clinical indications for dydrogesterone use

Table 2 presents the association between obstetric history categories and clinical indications. Overall, 89.3% (n=6394) of patients were nulligravida and 94.9% (n=6797) were nulliparous. Nulligravida women predominated across all indications (87.8-96.0%), and gravida category was significantly associated with clinical indication (p<0.001). In contrast, parity distribution was comparable across indications and was not significantly associated with clinical indication (p=0.103).

Most patients had no previous history of abortion (96.6%, n=6913), whereas 2.2% (n=156) reported a single abortion and 1.3% (n=91) reported multiple abortions. Previous abortions were more common among patients with recurrent pregnancy loss, resulting in a significant association between abortion history and clinical indication (p<0.001). Live birth history also differed significantly across indications (p=0.009), with relatively higher proportions among infertility and recurrent pregnancy loss.

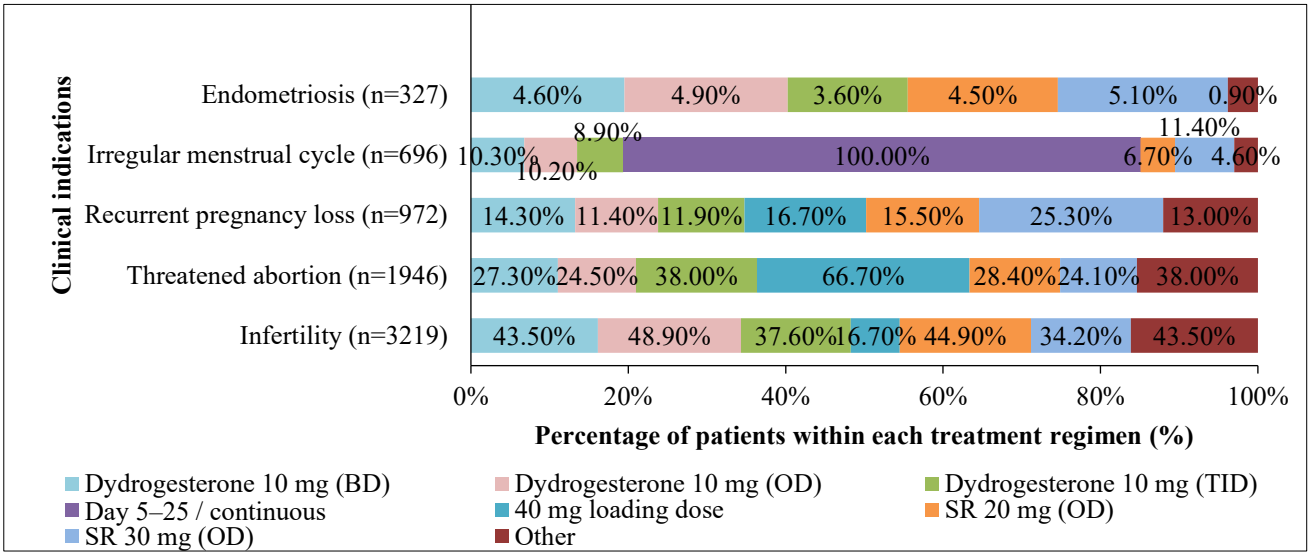

Figure 2: Distribution of clinical indications across dydrogesterone treatment regimens (n=7160).

BD, twice daily; OD, once daily; TID, three times daily; SR, sustained release; n, number of patients; %, percentage. Percentages within each bar represent the proportion of patients within each dydrogesterone treatment regimen (column percentages). Therefore, a value of 100% indicates that all patients receiving that treatment regimen belonged to the respective category

Comorbidity profile according to dydrogesterone treatment regimens

Table 3 presents the distribution of comorbidity status and specific comorbidities. Overall, 18.1% (n=1297) of patients had at least one comorbidity, whereas 81.9% (n=5863) had none. Across the major treatment regimens, PCOS, anaemia, thyroid disorders, and other comorbidities were the most frequently reported conditions.

Most patients across treatment groups had no reported comorbidities. Significant associations were observed between treatment regimen and overall comorbidity status (p<0.0001), as well as PCOS, thyroid disorders, diabetes, uterine fibroids, pre-eclampsia, hyperprolactinaemia, and other comorbidities.

Table 2: Comorbidity status, specific comorbidities, and number of comorbidities according to dydrogesterone treatment regimens (n=7160).

		DYG 10 mg (BD)		DYG 10 mg (OD)		DYG 10 mg (TID)		Day 5–25/ continuous		40 mg loading dose		SR 20 mg (OD)		SR 30 mg (OD)		Other		P value
	N	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
Comorbidities status																		
No	5863	2875	80.7	1842	83.3	254	83.8	0	0.0	4	66.7	724	81.7	75	94.9	89	82.4	<0.0001
Yes	1297	689	19.3	369	16.7	49	16.2	3	100	2	33.3	162	18.3	4	5.1	19	17.6	
Total	7160	3564	100	2211	100	303	100	3	100	6	100	886	100	79	100	108	100	
Comorbidities conditions																		
PCOS	454	264	7.4	139	6.3	14	4.6	0	0.0	1	16.7	33	3.7	0	0.0	3	2.8	<0.0001
Thyroid disorder	186	115	3.2	41	1.9	11	3.6	0	0.0	0	0.0	17	1.9	1	1.3	1	0.9	0.033
Anemia	321	171	4.8	96	4.3	11	3.6	1	33.3	0	0.0	36	4.1	2	2.5	4	3.7	0.269
Hypertension	44	28	0.8	9	0.4	3	1.0	0	0.0	0	0.0	4	0.5	0	0.0	0	0.0	0.591
Diabetes	21	11	0.3	5	0.2	1	0.3	0	0.0	0	0.0	2	0.2	2	2.5	0	0.0	0.044
Uterine fibroids	28	18	0.5	5	0.2	0	0.0	0	0.0	0	0.0	1	0.1	0	0.0	4	3.7	<0.0001
Dyslipi-demia	10	4	0.1	6	0.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0.675
Pre-eclampsia	17	3	0.1	11	0.5	0	0.0	1	33.3	0	0.0	1	0.1	0	0.0	1	0.9	<0.0001
Thrombo-philia	7	4	0.1	3	0.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0.972

Continued.

		DYG 10 mg (BD)		DYG 10 mg (OD)		DYG 10 mg (TID)		Day 5–25/ continuous		40 mg loading dose		SR 20 mg (OD)		SR 30 mg (OD)		Other		P value
	N	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
Autoimmune disorder	6	3	0.1	2	0.1	0	0.0	0	0.0	0	0.0	1	0.1	0	0.0	0	0.0	0.999
Hyperpro-lactinemia	14	6	0.2	6	0.3	1	0.3	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0	<0.0001
Other comorbidities	433	209	5.9	116	5.2	19	6.3	0	0.0	1	16.7	78	8.8	0	0.0	10	9.3	0.002
Number of comorbidities																		
No comorbidity	5863	2875	80.7	1842	83.3	254	83.8	0	0.0	4	66.7	724	81.7	75	94.9	89	82.4	0.001
One comorbidity	1108	576	16.2	313	14.2	43	14.2	3	100	2	33.3	152	17.2	3	3.8	16	14.8	
Two comorbidities	137	81	2.3	42	1.9	2	0.7	0	0.0	0	0.0	9	1.0	1	1.3	2	1.9	
Three comorbidities	49	30	0.8	14	0.6	3	1.0	0	0.0	0	0.0	1	0.1	0	0.0	1	0.9	
Four comorbidities	3	2	0.1	0	0.0	1	0.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	
Five comorbidities	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	
Total	7160	3564	100	2211	100	303	100	3	100	6	100	886	100	79	100	108	100	

DYG= Dydrogesterone BD=Twice daily; OD=Once daily; SR=Sustained release; PCOS=Polycystic ovary syndrome

Past medical and obstetric history according to dydrogesterone treatment regimens

Figure 3 illustrates the distribution of past medical history across different dydrogesterone dosage regimens. Across all regimens, 98.7% to 100.0% of patients had no documented past medical history, while only 0.0% to 1.3% reported prior medical conditions. No significant association was observed between past medical history and treatment regimen (p=0.856).

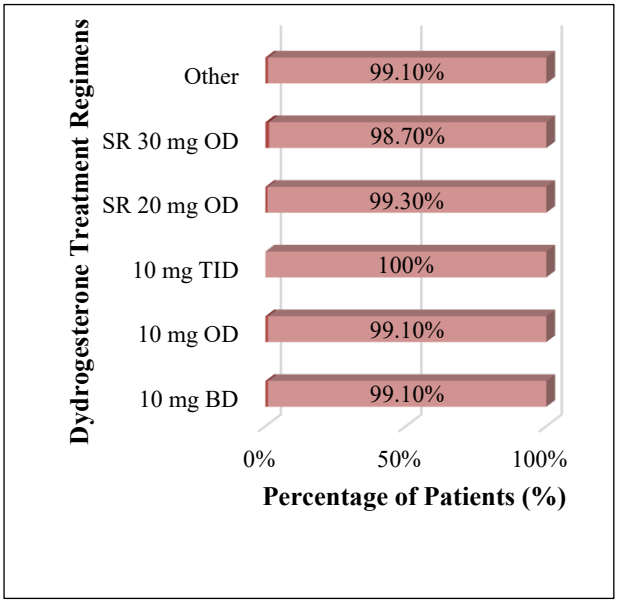

Figure 3: Distribution of past medical history across major dydrogesterone regimens.

Duration of therapy according to dydrogesterone treatment regimens

Table 4 presents the duration of dydrogesterone therapy across treatment regimens. Overall, "Other" treatment durations were most common (55.6%; n=3982), followed by 4 weeks (40.9%; n=2932). Treatment durations of 8, 12, and 20 weeks were uncommon.

Across the major regimens, "Other" and 4-week treatment durations predominated. Patients receiving day 5-25/continuous therapy, 40 mg loading-dose therapy, SR 30 mg OD, and other regimens represented only a small proportion of the study population. Duration of therapy differed significantly across treatment regimens (p<0.0001).

Figure 4 resents the distribution of documented information on prior treatments across treatment regimens. Overall, follow-up/clinical advice was the most frequently documented category (55.7%; n=3990), followed by treatment details (2.5%; n=177), pregnancy-related conditions (0.1%; n=9), and gynaecological disorders (0.1%; n=4).

Follow-up/clinical advice predominated across all treatment regimens, while treatment details and pregnancy-related conditions were documented in only a small proportion of patients. Significant associations were observed between treatment regimen and treatment details (p<0.0001), pregnancy-related conditions (p<0.0001), and follow-up/clinical advice (p<0.0001), whereas no significant association was observed for gynaecological disorders (p=0.490).

Table 4: Duration of dydrogesterone therapy according to treatment regimens (n=7160).

		DYG 10 mg (BD)		DYG 10 mg (OD)		DYG 10 mg (TID)		Day 5–25/ Contin-uous		40 mg loading dose		SR 20 mg (OD)		SR 30 mg (OD)		Other		P value
	N	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
Duration of therapy in weeks																		
4	2932	1370	38.4	1041	47.1	105	34.7	0	0.0	4	66.7	363	41.0	24	30.4	25	23.1	<0.0001
8	113	45	1.3	37	1.7	6	2.0	0	0.0	0	0.0	25	2.8	0	0.0	0	0.0	
12	124	63	1.8	39	1.8	6	2.0	0	0.0	0	0.0	15	1.7	0	0.0	1	0.9	
20	9	7	0.2	1	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	
Other	3982	2079	58.3	1093	49.4	186	61.4	3	100	2	33.3	483	54.5	55	69.6	81	75.0	
Total	7160	3564	100	2211	100	303	100	3	100	6	100	886	100	79	100	108	100	

BD=Twice daily; OD=Once daily; TID=Three times daily; SR=Sustained release; N=Number of patients; %=Percentage. Variable/Other durations include all treatment schedules other than 4, 8, 12, and 20 weeks

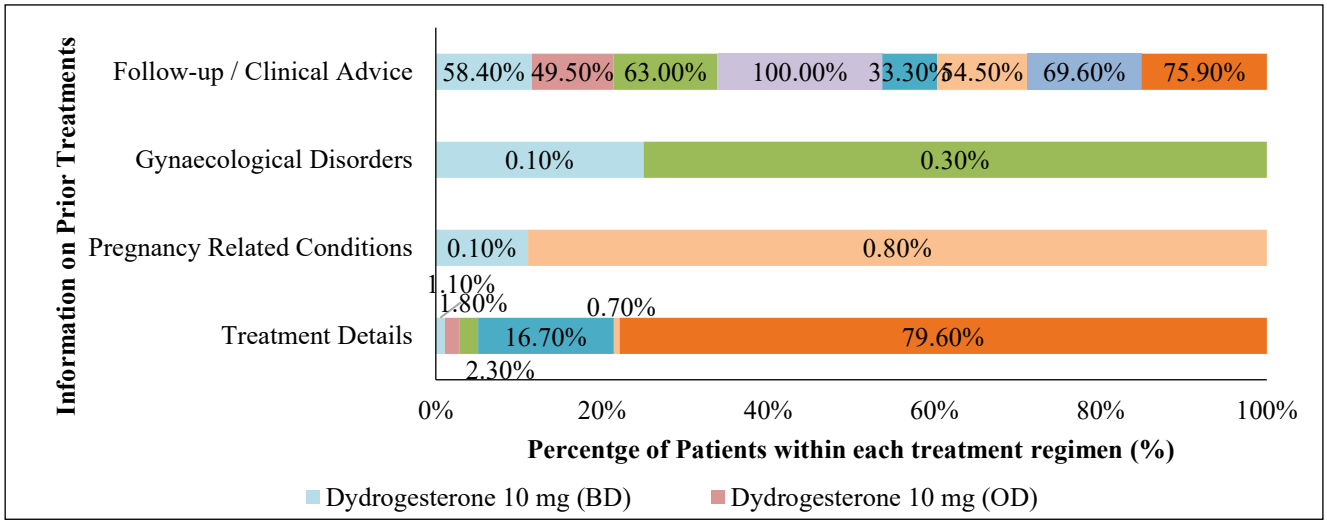

Figure 3: Information on Prior Treatments According to Dydrogesterone Treatment Regimens (n=7160).

BD=Twice daily; OD=Once daily; TID=Three times daily; SR=Sustained release; N=Number of patients; %=Percentage. Percentages represent the proportion of patients within each treatment regime

DISCUSSION

The present large-scale, multicentric, real-world observational study provides insights into the utilisation patterns of different dydrogesterone regimens across obstetric and gynaecological indications in India. Among 7,160 patients, dydrogesterone 10 mg twice daily was the most frequently prescribed regimen, followed by Dydrogesterone 10 mg once daily and SR 20 mg once daily. In contrast, dydrogesterone 10 mg three times daily, SR 30 mg once daily, and other regimens were used less commonly. Infertility, threatened abortion, and recurrent pregnancy loss were the predominant indications across treatment groups. Most patients had no documented comorbidities, and treatment duration varied according to the clinical indication and prescribed regimen. These findings highlight the continued preference for conventional oral dydrogesterone dosing schedules in routine clinical practice. They are consistent with previous studies demonstrating the widespread use of dydrogesterone for luteal phase support, infertility management, threatened miscarriage, and recurrent pregnancy loss because of its established efficacy, favourable safety profile, and convenience of oral administration.[1,5,7]

The baseline demographic, anthropometric, and reproductive characteristics observed in the present study provide important context for prescribing patterns. Dydrogesterone 10 mg BD, followed by 10 mg OD and SR 20 mg OD, were the most frequently prescribed regimens. Most patients were aged 18-30 years, had a normal BMI, and were nulligravida and nulliparous, reflecting the reproductive-age population commonly seeking treatment for infertility and pregnancy-related conditions. These findings are consistent with the epidemiology of infertility and early pregnancy complications.[12] Excess body weight has been associated with ovulatory dysfunction, impaired fertility, adverse pregnancy outcomes, and conditions such as PCOS, which are commonly associated with infertility and menstrual dysfunction.[3,13,14] Significant differences in

age, BMI, gravida status, parity status, abortion history, and live birth history across treatment regimens suggest that patient characteristics may influence regimen selection in routine practice.

The association between obstetric history and clinical indication further highlights the diversity of patients receiving dydrogesterone therapy. Nulligravida women constituted the majority across all indications, particularly among patients with infertility and endometriosis, whereas relatively higher proportions of multigravida and grand multigravida women were observed among those with recurrent pregnancy loss and threatened abortion. Similarly, previous abortion history was more frequently reported among patients with recurrent pregnancy loss and threatened abortion, while parity distribution remained broadly comparable across indications. These findings suggest that reproductive history contributes to the selection of progesterone support according to the underlying clinical condition.[12]

Infertility was the most common indication for dydrogesterone therapy, followed by threatened abortion and recurrent pregnancy loss. Across these indications, dydrogesterone 10 mg BD was the most frequently prescribed regimen, followed by dydrogesterone 10 mg OD and SR 20 mg OD. These prescribing patterns are consistent with current evidence and guideline recommendations supporting progesterone supplementation for luteal phase support and early pregnancy maintenance. The ESHRE guideline recognises progesterone as an essential component of assisted reproductive treatment cycles.[3] At the same time, oral dydrogesterone has demonstrated efficacy comparable to vaginal progesterone for supporting implantation and pregnancy outcomes.[8,9,15] Similarly, its extensive use in threatened abortion and recurrent pregnancy loss aligns with NICE recommendations supporting progesterone therapy in women with early pregnancy bleeding and a history of miscarriage.[4,16] Evidence from randomised trials and meta-analyses has further demonstrated improved pregnancy continuation and live birth outcomes with progesterone supplementation in selected high-risk women. [2,10]

Although irregular menstrual cycle and endometriosis accounted for a smaller proportion of prescriptions, conventional oral regimens, particularly dydrogesterone 10 mg BD and 10 mg OD, remained the most commonly utilized treatment approaches. The significant association between clinical indication and treatment regimen ($p<0.0001$) suggests that regimen selection varied according to the underlying clinical condition, while sustained-release formulations were prescribed less frequently.[17]

Among the various treatment regimens, dydrogesterone 10 mg BD and dydrogesterone 10 mg OD were the most frequently prescribed formulations across all major indications, whereas sustained-release formulations accounted for a smaller proportion of prescriptions. The predominance of conventional oral regimens is consistent with the established efficacy, tolerability, and convenience of oral dydrogesterone in reproductive medicine. A recent systematic review and meta-analysis reported comparable reproductive outcomes between oral dydrogesterone and vaginal progesterone for luteal phase support in frozen-thawed embryo transfer cycles, supporting the continued use of oral dydrogesterone in routine clinical practice.[8] Furthermore, commonly recommended treatment protocols for luteal phase support, threatened miscarriage, and recurrent pregnancy loss frequently utilise oral dydrogesterone administered in divided daily doses.[3,5] The significant association between clinical indication and treatment regimen observed in the present study suggests variation in prescribing patterns across different reproductive conditions. Although sustained-release formulations were prescribed less frequently, they represent an alternative dosing approach that may be considered in selected patients.

Comorbid conditions can influence reproductive health, fertility outcomes, and the management of obstetric and gynaecological disorders. In the present study, most patients receiving dydrogesterone 10 mg BD, dydrogesterone 10 mg OD, dydrogesterone 10 mg TID, and SR 20 mg OD had no documented comorbidities, indicating that dydrogesterone was predominantly prescribed to otherwise healthy women of reproductive age. Among patients with comorbidities, PCOS, anaemia, and thyroid disorders were the most frequently reported conditions across treatment regimens. The high prevalence of PCOS is consistent with its well-established association with ovulatory dysfunction, infertility, menstrual irregularities, and adverse reproductive outcomes.[3,14,18] Similarly, thyroid disorders and anaemia are common among women of reproductive age and have been associated with reduced fertility and unfavourable pregnancy outcomes.[19,20] The significant association observed between comorbidity status and treatment regimen suggests variation in prescribing patterns according to patients' clinical profiles. Nevertheless, the overall low burden of comorbidities across all treatment groups indicates that dydrogesterone was primarily prescribed for reproductive indications rather than coexisting medical conditions.

Consistent with the low burden of comorbidities, most patients across all treatment regimens had no documented past medical history. Furthermore, no significant association was observed between past medical history and dydrogesterone regimen selection, suggesting that prescribing decisions were primarily driven by reproductive indications rather than previous medical conditions.

The duration of dydrogesterone therapy varied across treatment regimens, reflecting the diverse clinical indications for which the drug was prescribed. Dydrogesterone 10 mg BD, 10 mg OD, and SR 20 mg OD

accounted for the majority of prescriptions across all duration categories. Four-week therapy was the most commonly reported predefined treatment duration, while more than half of the patients received treatment schedules classified under the "Other" category. Treatment duration is likely individualised according to the underlying condition, gestational age, treatment response, and current clinical recommendations.[3,4,9] The significant association between treatment regimen and duration of therapy ($p<0.0001$) further suggests that clinicians tailor dydrogesterone treatment schedules according to therapeutic objectives and clinical circumstances.

Information regarding prior treatment patterns demonstrated that follow-up and clinical advice represented the most frequently documented category across all dydrogesterone regimens. Dydrogesterone 10 mg BD, 10 mg OD, and SR 20 mg OD accounted for the majority of patients with documented follow-up information. Although treatment details and pregnancy-related conditions were reported in only a small proportion of patients, significant associations were observed between treatment regimen and prior-treatment categories, likely reflecting differences in clinical monitoring and documentation.

The present study has several strengths, including its large sample size of 7,160 patients and multicentric real-world design, providing a comprehensive overview of contemporary dydrogesterone prescribing practices across obstetric and gynaecological indications. The inclusion of multiple dydrogesterone regimens enabled assessment of indication-specific prescribing patterns in routine clinical practice. However, as an observational, cross-sectional study, causal relationships between treatment regimens and clinical outcomes cannot be established. In addition, treatment effectiveness, safety, adherence, and long-term reproductive outcomes were not evaluated. Despite these limitations, the findings provide valuable real-world evidence on contemporary dydrogesterone utilisation in reproductive medicine.

CONCLUSION

This large-scale, multicentric, real-world observational study provides valuable insights into the contemporary utilisation patterns of dydrogesterone across a broad spectrum of obstetric and gynaecological indications. Infertility, threatened abortion, and recurrent pregnancy loss were the most common indications for dydrogesterone therapy. Among the various treatment regimens, conventional oral formulations, particularly dydrogesterone 10 mg twice daily and dydrogesterone 10 mg once daily, accounted for the majority of prescriptions, while sustained-release formulations were used in a smaller proportion of patients. Most patients were women of reproductive age with a low burden of comorbidities, and considerable variation was observed in treatment duration across regimens and clinical indications. Overall, the observed prescribing patterns were consistent with current evidence and guideline recommendations supporting progesterone supplementation in reproductive medicine. These findings provide important real-world evidence on the utilisation of different dydrogesterone regimens and enhance understanding of contemporary prescribing practices in routine reproductive healthcare settings.

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