

STUDY ON THE MISUSE OF OVULATION INDUCTION MEDICINES IN
PATIENTS WITH PRIMARY INFERTILITY WITHOUT STANDARDIZED
INFERTILITY WORKUPS IN PRIMARY CARE SETTING

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Abstract

Background: Ovulation induction therapy has significantly improved fertility outcomes for women struggling with ovulatory disorders. These agents play a pivotal role in assisted reproduction by stimulating follicular development and improving the chances of conception. However, concerns have arisen over their unregulated use in primary care settings without comprehensive infertility evaluations, leading to significant public health risks and suboptimal patient care.

Objective: To evaluate the frequency of ovulation induction medicine misuse in primary infertility cases.

Study Design: Cross-sectional study.

Place and Duration of Study: Infertility OPD of MSK Hospital from January 2025 to June 2025.

Methods: Study included 116 women diagnosed with primary infertility. Medical records and prior prescriptions of patients were studied to assess previous treatment protocols comprising type, dose, duration, number of cycles of ovulation induction medicines, as well as documentation of any previous infertility workup. Data was gathered through proforma, which was entered and analyzed utilizing SPSS software version 25.0.

Results: Among 116 patients, mean age was 30.18 ± 6.720 years, mean duration of infertility was 5.66 ± 4.574 years, 100.0% patients used ovulation induction medication, 55.9% patients were prescribed medication by general practitioners, followed by, Obs/Gyn specialist (39.6%) and self-medication (3.5%). Standardized infertility workup was performed among 56.9% patients before initiating treatment, 50.0% patients had confirmed ovulation with medication use and 10.3% patients conceived. There were 3.4% (4) ectopic pregnancies and 6.9% (8) ongoing pregnancies. The reported sides effects / complication syndromes were ovarian hyperstimulation syndrome (34.5%) and multiple pregnancies (3.4%).

Conclusion: Infertility is a leading problem and most of the healthcare providers in primary care settings prescribe ovulation induction medications without conducting standardized workups. Study concluded that 96.5% patients used ovulation induction medicines prescribed by general practitioner and Obs/Gyn specialist but 56.9% health care providers performed standardized workups before initiating the treatment.

INTRODUCTION

Infertility is a complex and emotionally challenging condition that affects millions of couples worldwide, with anovulation being one of the leading causes of female infertility.^[1] Ovulation induction (OI) therapy, involving medications such as clomiphene citrate, letrozole, and gonadotropins, has significantly improved fertility outcomes for women struggling with ovulatory disorders. These agents play a pivotal role in assisted reproduction by stimulating follicular development and improving the chances of conception.^[2] However, concerns have arisen over their unregulated use in primary care settings without comprehensive infertility evaluations, leading to significant public health risks and suboptimal patient care.^[3]

The American Society for Reproductive Medicine (ASRM) and the European Society of Human Reproduction and Embryology (ESHRE) emphasize that a thorough infertility workup, including hormonal profiling, imaging studies, and male fertility assessments, is essential before initiating ovulation induction therapy. According to ASRM guidelines, comprehensive diagnostic procedures help tailor treatment plans and minimize risks such as ovarian hyperstimulation syndrome (OHSS), multiple pregnancies, and prolonged untreated underlying conditions. Bypassing these evaluations not only reduces the effectiveness of OI therapy but also increases the likelihood of adverse reproductive outcomes, potentially leading to further complications and distress for affected individuals.^[1,4]

Despite these recommendations, many healthcare providers in primary care settings prescribe ovulation induction medications without conducting standardized workups.^[3,5] ESHRE

highlights that empirical prescribing without appropriate diagnostic evaluation is a growing concern, as it disregards the fundamental principles of evidence-based medicine. Research indicates that in some cases, underlying infertility issues, such as diminished ovarian reserve, polycystic ovary syndrome (PCOS), or tubal factor infertility, remain undiagnosed, leading to ineffective treatment plans and prolonged patient suffering.^[1,6]

Furthermore, the unregulated use of ovulation induction agents can result in preventable complications, including increased risks of OHSS, ectopic pregnancies, and an unsustainable financial burden on healthcare systems due to the management of unintended multiple pregnancies.^[7] In addition, mismanagement of OI therapy can delay access to appropriate assisted reproductive technologies (ART), such as in-vitro fertilization (IVF), for patients who may require advanced interventions.^[8,9]

A study was done by de Jong-van den Berg et al. (1992) to describes the utilization of ovulation stimulating drugs clomifene, hMg (human menopausal gonadotropin) and hCG (human chorionic gonadotropin) among females of child-bearing age. Among the females, 30% who utilized clomifene were treated for ≥ 6 cycles. These results argue for relative "overuse" & "misuse" of drug clomifene.^[10]

Zagami and fellows (2020) conducted a study among 29 infertile couples who experienced unsuccessful treatment. Many respondents stated their experiences regarding immediate & long-term side effects of medicine utilized for the ovulation induction. Study revealed that immediate complications comprised frequent & painful injections, hyper stimulation and

progesterone injections local complications. Long-term side effects of using medicines were thromboembolic events birth defects and weight gain.^[11]

Husain and teammates (2025) undertook a study among 464 females healthcare specialists regarding the fertility treatment. Study highlighted that only 10.3 percent participants showed positive attitude towards screening and treatment. Among them, 40.1 percent had good practices. Study highlighted that healthcare professionals had negative attitude and inadequate practices for starting fertility therapy within twelve months of marriage.^[12]

The lack of awareness among patients and inconsistent regulations in primary care settings further exacerbate the misuse of OI medications. Many individuals' undergoing treatment are often not informed about the potential risks or the need for careful monitoring.^[13]

This study aims to investigate the frequency of ovulation induction medication misuse in primary care settings.

Material And Methods

It was a cross-sectional study conducted at Infertility OPD of MSK Hospital from January 2025 to June 2025. The sample size of the study was 116 patients. It was calculated using the WHO sample size calculator (OpenEpi) with 90% confidence level, 7% precision and 30% misuse of ovulation induction medicine (clomifene).^[10] Non-probability convenience sampling technique was used. Informed consent was taken from the participant and the clinical practice.

Women diagnosed with primary infertility and those who have used ovulation induction medicines in the last 2 years were included in the study. Women with secondary infertility; cases involving comorbidities like untreated PCOS or endometriosis; and patients unwilling to participate in the study were excluded.

Data was collected utilizing structured and pre-tested proforma. Relevant information was acquired through two major sources: review of the

medical records and patient direct interviews. Medical records and prior prescriptions of patients were studied to assess previous treatment protocols comprising type, dose, duration, number of cycles of ovulation induction medicines, as well as documentation of any previous infertility workup.

The patients fulfilling inclusion criteria were selected from the outpatient records and contacted either during their hospital visit or, if needed, through telephone utilizing contact number available in health facility records. Purpose of study was clearly explained to all patients, and written informed consent was acquired before data collection. The patients were entirely voluntary and had right to refuse/withdraw at any stage with no any effect on their medical care.

A face-to-face interview was performed utilizing a pre-designed questionnaire to acquire thorough information about previous diagnostic evaluations (such as semen analysis, tubal patency testing and ovulation assessment), medication use, duration of treatment, and any related complications or side effects.

Data was gathered through proforma, which was entered and analyzed utilizing SPSS software version 25.0. For quantitative variables, mean $\pm$ SD were calculated and for qualitative variables, frequency & percentages were calculated. Data was presented in tables and graphs for both quantitative and qualitative variables. Data was stratified as per patient demographics such as age, BMI, socioeconomic status, residence, education level, and marriage duration, to control for effect modifiers. Post-stratification, chi-square test was applied to evaluate association of treatment outcomes. A p-value ≤ 0.05 was considered statistically significant.

Results

Table-1 shows that among 116 patients, mean age was 30.18 $\pm$ 6.720 years, mean BMI was 22.96 $\pm$ 2.533, majority (73.3%) was living in urban areas, 62.9% patients belonged to middle socioeconomic status, 32.8% had secondary

education, 62.1% had marriage duration up to 5 years.

Among these patients, 62.1% had duration of fertility up to 5 years, 50.0% had regular menstrual cycle, 35.8% had PCOS and 84.5% patients had no family history of infertility, however, 6.9%, 10.3% and 10.3% patients had known chronic illness i.e., diabetes, hypertension and thyroid disorders, respectively.

All (100.0%) patients used ovulation induction medication and 55.9% patients were prescribed medication by general practitioners, followed by, Obs/Gyn specialist (39.6%) and self-medication (3.5%). Most of the patients (59.9%) used Clomiphene citrate (CC) and the duration was ≤ 6 months. Among 73 patients monitoring was performed during treatment such as ultrasound follicular monitoring (62.9%), FSH (33.6%), LH (33.6%), estradiol (24.1%) and progesterone (34.5%).

Result shows that standardized infertility workup was performed among 66 patients before initiating treatment such as FSH (56.9%), LH (56.9%), TSH (53.4%), prolactin (53.4%), AMH (50.9%), semen

analysis (for male partner) (56.9%), hysterosalpingography / sonohysterography (40.5%) and transvaginal ultrasound (44.0%). Likewise, 57.8% male partner were evaluated for infertility before the medication use.

Among these patients, 50.0% had confirmed ovulation with medication use and 10.3% (12) patients conceived. There were 3.4% (4) ectopic pregnancies and 6.9% (8) ongoing pregnancies. The reported sides effects / complication syndromes were ovarian hyperstimulation syndrome (34.5%) and multiple pregnancies (3.4%).

Out of 116 patients, 43.1% were referred to fertility specialist, 47.4% patients used medications as per evidence-based guidelines and 56.9% patients were educated on the risks and benefits of ovulation induction.

Table-2 depicts the association between patients demographics and confirmed ovulation with medication use; significant results ($P \leq 0.05$) were found regarding age, BMI, socioeconomic status, education level, marital duration while insignificant results ($P > 0.05$) regarding residence.

Table-1: Patient Information (n = 116)

Patient Demographics	
Age, n (%)	
≤ 30 years	60 (51.7%)
> 30 years	56 (48.3%)
Mean $\pm$ SD	30.18 $\pm$ 6.720
Body mass index (kg/m²), n (%)	
18.5–24.9 (normal weight)	81 (69.8%)
25.0–29.9 (over weight)	31 (26.7%)
> 30 (obese)	4 (3.5%)
Mean $\pm$ SD	22.96 $\pm$ 2.533
Residence, n (%)	
Urban	85 (73.3%)
Rural	31 (26.7%)
Socioeconomic status, n (%)	
Low	31 (26.7%)
Middle	73 (62.9%)
High	12 (10.3%)
Education level, n (%)	
No formal education	23 (19.8%)

Primary	27 (23.3%)
Secondary	38 (32.8%)
Graduation	24 (20.7%)
Postgraduation	4 (3.4%)
Marital duration, n (%)	
≤5 years	72 (62.1%)
>5 years	44 (37.9%)
Mean±SD	5.66±4.574
Clinical History	
Duration of infertility, n (%)	
≤5 years	72 (62.1%)
>5 years	44 (37.9%)
Mean±SD	5.66±4.574
Menstrual cycle regularity, n (%)	
Regular	58 (50.0%)
Irregular	58 (50.0%)
Known gynecological disorders, n (%)	
PCOS	45 (38.8%)
Endometriosis	12 (10.3%)
Uterine fibroids	16 (13.8%)
None	43 (37.1%)
Past obstetric history, n (%)	
No prior pregnancy	116 (100.0%)
Family history of infertility, n (%)	
Yes	18 (15.5%)
No	98 (84.5%)
Known chronic illnesses, n (%)	
Diabetes	8 (6.9%)
Hypertension	12 (10.3%)
Thyroid Disorders	12 (10.3%)
None	84 (72.4%)
Ovulation Induction Medication Use	
Has the patient used ovulation induction medication? n (%)	
Yes	116 (100.0%)
If yes, who prescribed the medication? n (%)	
General practitioner	66 (56.9%)
Obs/Gyn specialist	46 (39.6%)
Self-medication	4 (3.5%)
Type of medication used, n (%)	
Clomiphene citrate (CC)	66 (56.9%)
Letrozole	34 (29.3%)
Gonadotropins (FSH, HMG, hCG)	16 (13.8%)
Duration of ovulation induction treatment, n (%)	

≤6 months	77 (66.4%)
>6 months	39 (33.6%)
Was any monitoring performed during treatment? n(%)	
Yes	73 (62.9%)
No	43 (37.1%)
If yes, specify:	
Ultrasound follicular monitoring	73 (62.9%)
Hormonal profile:	
• FSH	39 (33.6%)
• LH	39 (33.6%)
• Estradiol	28 (24.1%)
• Progesterone	40 (34.5%)
Diagnostic Workup Before Medication Use	
Was any standardized infertility workup performed before initiating treatment? n (%)	
Yes	66 (56.9%)
No	50 (43.1%)
Investigations conducted prior to treatment, n (%)	
Hormonal profile:	
• FSH	66 (56.9%)
• LH	66 (56.9%)
• TSH	62 (53.4%)
• Prolactin	62 (53.4%)
• AMH	59 (50.9%)
Semen analysis (for male partner)	66 (56.9%)
Hysterosalpingography (HSG)/ sonohysterography	47 (40.5%)
Transvaginal ultrasound (TVS)	51 (44.0%)
Was the male partner evaluated for infertility? n(%)	
Yes	67 (57.8%)
No	49 (42.2%)
Treatment Outcomes and Complications	
Was there any confirmed ovulation with medication use? n (%)	
Yes	58 (50.0%)
No	24 (20.7%)
Unknown	34 (29.3%)
Did the patient conceive? n (%)	
Yes	12 (10.3%)
No	104 (89.7%)
If yes, pregnancy outcome, n (%)	
Ectopic Pregnancy	4 (3.4%)
Ongoing Pregnancy	8 (6.9%)
Any side effects or complications reported? n (%)	

Ovarian Hyperstimulation Syndrome (OHSS)	40 (34.5%)
Multiple Pregnancy	4 (3.4%)
None	72 (62.1%)
Was the patient referred to a fertility specialist? n(%)	
Yes	50 (43.1%)
No	66 (56.9%)
Physician's Notes and Observations	
Were the medications used as per evidence-based guidelines? n (%)	
Yes	55 (47.4%)
No	61 (52.6%)
Was the patient educated on the risks and benefits of ovulation induction? n (%)	
Yes	66 (56.9%)
No	50 (43.1%)

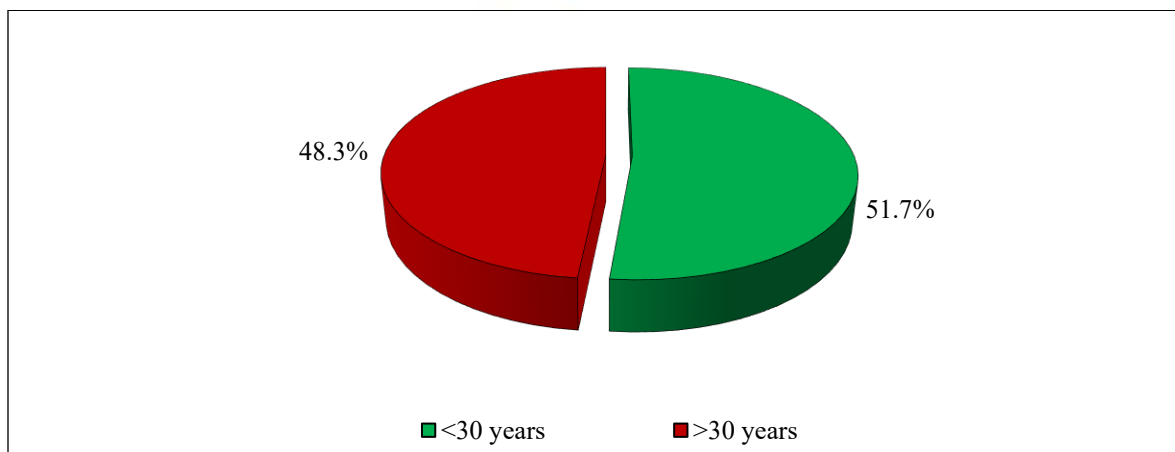


Figure-1: Age distribution of patients

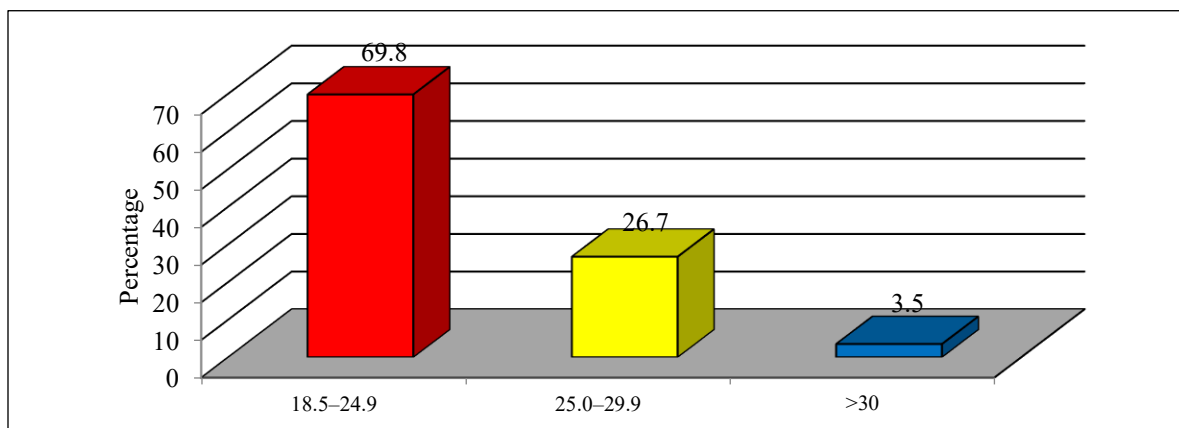


Figure-2: BMI distribution of patients

Table-2: Association between patient demographics and confirmed ovulation with medication use

Demographics	Confirmed ovulation with medication use		95% CI	P-value
	Yes (n=58)	No/Unknown (n=24/34)		
Age (years)	27.45±6.134	32.91±6.188	-7.732 – -3.199	0.000
BMI	22.10±2.322	23.82±2.457	-2.6036 – -.8446	0.000
Residence:				
• Urban	43 (37.1%)	16 (13.8%)	-.147 – .181	0.836
• Rural	15 (12.9%)	8 (6.9%)		
Socioeconomic status:				
• Low	7 (6.0%)	8 (6.9%)	-.569 – -.155	0.001
• Middle	43 (37.1%)	12 (10.3%)		
• High	8 (6.9%)	4 (3.4%)		
Education level:				
• No formal education	7 (6.0%)	4 (3.4%)	-1.164 – -.388	0.000
• Primary	8 (6.9%)	8 (6.9%)		
• Secondary	19 (16.4%)	8 (6.9%)		
• Graduation	24 (20.7%)	0 (0.0%)		
• Postgraduation	0 (0.0%)	4 (3.4%)		
Marital duration (years)	4.83±4.780	6.48±4.240	-3.317 – .007	0.051

Discussion

Infertility is a complex and emotionally challenging condition that affects millions of couples worldwide. Present study was carried out to assess the misuse of ovulation induction medicines in patients with primary infertility without standardized infertility workups in primary care setting. To acquire appropriate outcomes, 116 patients were included in the study and found that more than half of the patients were up to 30 years old and mean age was 30.18±6.720 years. The findings of our study are almost comparable with a study performed by Shafiq and coworkers (2021) who reported that mean age of the females was 29.82±4.64 years.^[14]

It was found during study that majority of patients (69.8%) had normal weight and the mean BMI was 22.96±2.533 (normal weight). The findings of our study are better than the study undertaken by Mandelbaum and associates (2024) who stated that mean BMI of females was 32.1 (obese).^[15] The results of our study further showed that most of

the patients were residing in urban areas, had middle socioeconomic status, studied up to secondary and above. Among these patients, 62.1% had marriage duration up to 5 years and the mean duration was 5.66±4.574. But a study conducted by Shafiq and coworkers (2021) highlighted that patients mean duration of marriage was 4.23±1.42 years.^[14]

The results of our study highlighted that among patients, 62.1% had duration of infertility up to 5 years and mean duration of fertility was 5.66±4.574 but Ibrahim and collaborators (2019) confirmed in their study that among women the mean duration of fertility was 3.57±1.14 years.^[16] The findings of our study also indicated that 50.0% patients had regular while 50.0% patients had irregular menstrual cycle. However, Zhu and partners (2023) exhibited different scenario that 100.0% patients had menstrual dysfunction.^[17] Our study also identified gynecological disorders and reported that most of the patients were found with PCOS, followed by uterine fibroids and

endometriosis. In our study 100.0% females had no prior pregnancy but Mejia and assistants (2019) confirmed in their study that 40.0% females had history of live birth.^[18]

It is important to mention that 84.5% patients had no family history of infertility, however, 6.9%, 10.3% and 10.3% patients had known chronic illness i.e., diabetes, hypertension and thyroid disorders, respectively. Study revealed that all patients used ovulation induction medication and significant majority of patients was prescribed these medications by general practitioners and Obs/Gyn specialist except only 3.5% who used self-medication. The most commonly utilized medications were clomiphene citrate and letrozole while the duration of ovulation induction treatment for majority of females was up to 6 months.

Study revealed that standardized infertility workup was performed among 56.9% patients before initiating treatment. Likewise, male partners of 57.8% patients were also evaluated for infertility before the medication use. A study performed by Khraiweh and teammates (2022) showed almost comparable results that 63.7% patients were tested for infertility before initiating the treatment.^[19] The results of our study indicated that 50.0% patients had confirmed ovulation with medication use. But the studies performed by Aiman et al. (2020)^[20] and Elsemary et al. (2018)^[21] reported that ovulation rates were 74.5% and 68.2%, respectively. It was very disturbing to know that in our study only 10.3% patients conceived while Imani and fellows (1999) showed very encouraging results that 51.0% patients conceived.^[22]

When the pregnancy outcomes were assessed during study, it was found that 6.9% (8) were ongoing pregnancies and 3.4% (4) were ectopic pregnancies. The results of a study done by Badawy and comrades (2009) are better than our study who reported that only 0.67% (1) ectopic pregnancy occurred among patients.^[23] The results of our study further highlighted that reported side effects / complication syndromes among 34.5% patients was ovarian hyperstimulation syndrome and 3.4% patients had multiple

pregnancies. Stanford and companions (2013) reported in their study that 56.0% females had twin pregnancies.^[24] Another study carried out by Wasim and colleagues (2024) elucidated that 1.81% (2) women had multiple pregnancies.^[25]

It was very discouraging to know that according to study findings, more than half of the patients did not use medication as per evidence-based guidelines but these patients were educated regarding risks and benefits of ovulation induction.

During study association between patient demographics and confirmed ovulation with medication use was assessed, significant results ($P \leq 0.05$) were found regarding age, BMI, socioeconomic status, education level, marital duration while insignificant results ($P > 0.05$) were found regarding residence.

Conclusion

Infertility is a leading problem and most of the healthcare providers in primary care settings prescribe ovulation induction medications without conducting standardized workups. Study concluded that 96.5% patients used ovulation induction medicines prescribed by general practitioner and Obs/Gyn specialist but 56.9% health care providers performed standardized workups before initiating the treatment.

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