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Epidemiology and management of infertility: A hospital-based study in North and Central Kashmir region

Nisar Ahmad Wani^{1*}, Surjeet Kumar², Suzaira Bashir³

¹PhD Scholar, Department of Clinical Embryology and Reproductive Genetics, Rayat Bahra University, Krarer, Mohali, Punjab

²Professor, Department of Clinical Embryology and Reproductive Genetics, Rayat Bahra University, Krarer, Mohali, Punjab

³Assistant Professor and In-charge Head, Department of Gynaecology and Obstetrics, Government Medical College, Handwara, Kashmir

ABSTRACT: Introduction: Infertility is an important reproductive health concern that is affected by demographic, physiological, psychological, and healthcare-related parameters. Kashmir's unique socioeconomic and environmental parameters enhanced the risk of infertility. The study evaluated the prevalence of infertility, identify related factors associated with the risk factors and assessed the healthcare management strategies among women in North and Central Kashmir.

Aim: The study is aimed to evaluate the association of age, menstrual factors, hormonal profile, diagnostic findings, and management practices with the type of infertility (primary or secondary) among infertile women.

Method: This observational study included 150 infertile women diagnosed with either primary (n=120) or secondary infertility (n=30). Demographic and menstrual histories were recorded, followed by laboratory evaluation of FBS, TSH, FSH, LH, prolactin, and AMH levels. Diagnostic investigations included ultrasonographic folliculometry, pelvic ultrasonography, HSG, and TORCH screening. Clinical diagnoses and treatment modalities were documented. Data were analyzed using ANOVA and Pearson's Chi-square test, with $p < 0.05$ considered statistically significant.

Result: Among 150 infertile women, 80.0% had primary infertility and 20.0% had secondary infertility. Women with secondary infertility were significantly older (39.47 vs. 31.06 years; $p < 0.01$), had longer marriage duration (8.93 vs. 2.98 years; $p < 0.01$), higher FSH, LH, and prolactin levels ($p < 0.01$), and lower AMH levels (1.34 vs. 2.24 ng/mL; $p < 0.01$).

Conclusion: The study has concluded that secondary infertility is associated with significantly greater age-related, hormonal, and ovarian reserve abnormalities than primary infertility, necessitating more targeted reproductive evaluation and management.

1. INTRODUCTION

According to medical guidelines, infertility is diagnosed when a couple cannot get pregnant after trying for 12 months of frequent interactions without using contraception. The many possible causes of infertility can be divided into three categories: male; female; and unknown. Infertility is often caused by physical problems in one or both partners that interfere with getting pregnant. According to the National Family Health Survey (NFHS) data, primary infertility (not able to get pregnant for the first time) has decreased from 19.5% to 28.6%, while there has been a corresponding increase in secondary infertility (not able

to become pregnant again). Some of the contributing factors to these changing rates included delayed marriage, higher levels of education, and lifestyle-related health issues [1].

Researchers conducting the NFHS-4 survey on 402,807 married women found that only 1.9% of all participants were unable to achieve pregnancy, based on data regarding the association between their ability to get pregnant and their characteristics. Urban women who consume fish or sweetened drinks daily, are considered overweight or have high blood pressure, thyroid problems, or heart disease, or anemic with a severe form of anemia have an increased likelihood of being unable to have a baby. Conversely, women who consume substantial amounts of dairy products, fruits, or leafy greens are less likely to be unable to get pregnant. [2]. While many infertile couples experience societal stigma associated with being unable to have a baby, women tend to receive the most significant share of the blame and suffer extensively from the psychological distress as a result. As a result, many women seek traditional or religious healing before obtaining mainstream medical assistance with their infertility [3].

The Northern and Central valleys of Kashmir are characterized by high-altitude terrain with limited access, rural populations and multiple layers of geographical and social constraints impacting movement, access to food and access to numerous types of employment and income-generating activities. These geographic limitations have resulted in unique adaptations in food consumption; increased tobacco use and widespread deficiencies in micronutrient sufficient foods that significantly increase the risk of developing cardiometabolic diseases and disordered mood and anxiety within communities [4]. In addition to geographic and socioeconomic barriers, persistent experiences of militarism and insecurity contribute to high levels of psychological distress for individuals living in Kashmir [5]. As a result, the burdens of social and psychological problems disproportionately affect poor and rural community members and affect women's reproductive health through high rates of depression, anxiety and post-traumatic stress symptoms [4,5].

Kashmiri couples exhibit unique fertility risks that stem from a number of prominent environmental variables and endocrine/metabolic changes [6]. Research in this area indicates that affluent dietary patterns typified by junk food are associated with more severe varieties of polycystic ovarian syndrome (PCOS) manifested by features such as central obesity, insulin resistance, dyslipidemia, and hirsutism producing an endocrine profile closely correlated to female subfertility [6,7].

Infertility services in India operate through multiple avenues of care from both formal biomedical and traditional medicine where barriers to access and social stigma lead couples through a fragmented, often delayed, process of obtaining diagnoses from both types of providers [8]. Within publicly funded health services, the lack of appropriate infrastructure, standards of care, and training contribute to patients seeking variable quality private care [9].

Therefore, this study aims to: 1) assess the prevalence of infertility regionally; 2) identify independent demographic risk factors; and 3) map the process of managing care-seeking behaviour related to infertility to improve strategies for the creation of integrated public reproductive health policies.

2. MATERIALS AND METHODS

2.1 Research design

The study was a hospital-based observational study to characterize the demographic, menstrual, hormonal, diagnostic, etiological, and management characteristics of women with infertility. The study is aimed to evaluate the association of age, menstrual factors, hormonal profile, diagnostic findings, and management practices with the type of infertility (primary or secondary) among infertile women. The study was conducted at a tertiary care Hospital for 1 year. A total of 150 patients were selected for the study, aged between 18 and 45 years of age, comprising 120 women with primary infertility and 30 with secondary infertility. Those patient who were unmarried, divorced, widowed, or in the menopausal stage were not included in the study. Written informed consent was obtained for the study from all participants before enrolment. Pre-defined inclusion and exclusion criteria were considered for the study. The study was conducted following approval from the Institutional Ethics Committee.

2.2 Inclusion Criteria

1. Women diagnosed with infertility and attending the infertility/gynecology outpatient department during the study period.

2. Women aged 18 to 45 years
3. Patients diagnosed with either primary or secondary infertility according to standard clinical definitions.

2.3 Exclusion Criteria

1. Women who declined to participate or did not provide informed consent.
2. Women with incomplete clinical records or missing laboratory/imaging data required for analysis.
3. Women with known malignancies of the reproductive system.
4. Women with severe systemic illnesses that could independently affect fertility assessment, such as advanced renal, hepatic, or cardiac disease.

2.4 Procedure

After obtaining approval from the Institutional Ethics Committee and informed written consent from all participants, women presenting with infertility at the infertility clinic/gynecology outpatient department were screened for eligibility and enrolled in the study. A total of 150 infertile women were included and categorized into primary infertility (n=120) and secondary infertility (n=30) groups based on their reproductive history. Primary infertility was defined as the inability to conceive despite regular unprotected sexual intercourse without any previous conception, whereas secondary infertility referred to the inability to conceive following at least one previous conception.

A detailed clinical assessment was conducted for each participant using a structured data collection proforma. Demographic information including age, age at marriage, and duration of marriage was recorded. Comprehensive menstrual history was obtained, including age at menarche, menstrual cycle regularity, and duration of menstrual bleeding. General physical and gynecological examinations were performed by qualified clinicians to identify any clinical abnormalities associated with infertility. All participants underwent laboratory investigations as part of the infertility evaluation. Venous blood samples were collected under aseptic precautions and analyzed for fasting blood sugar (FBS), thyroid stimulating hormone (TSH), follicle stimulating hormone (FSH), luteinizing hormone (LH), prolactin (PRL), and anti-Müllerian hormone (AMH). Hormonal tests were conducted using the protocol of infertility evaluation in the institution. The determination of the levels of FSH and LH was done in the early follicular phase of the cycle when clinically indicated, whereas AMH, TSH, and prolactin determinations were done following the protocol of the laboratory. Standardized laboratory procedures were used in processing the specimens.

Radiological and diagnostic evaluations were subsequently performed. Ultrasonographic folliculometry was conducted to assess follicular development, ovarian morphology, ovulation status, and ovarian reserve. Ultrasonographic folliculometry was performed as part of the infertility evaluation to assess follicular development and ovarian response. Follicular growth and the presence of dominant follicles in the ovaries were assessed during serial ultrasonographic examinations according to the treating clinician's protocol. Findings suggestive of diminished ovarian reserve or small follicles were recorded where identified. Transabdominal and/or transvaginal ultrasonography of the abdomen and pelvis was performed to identify structural abnormalities such as fibroids, endometriosis, adenomyosis, ovarian cysts, polycystic ovarian morphology, and other pelvic pathologies. Hysterosalpingography (HSG) was carried out during the proliferative phase of the menstrual cycle to evaluate uterine cavity abnormalities and fallopian tube patency. TORCH screening was also performed according to the institutional infertility workup protocol. Based on clinical examination, laboratory findings, imaging studies, and reproductive history, the probable etiological diagnosis of infertility was established. Patients were classified into diagnostic categories including unexplained infertility, tubal factor infertility, ovulatory disorders, PCOS/PCOD, poor ovarian reserve, uterine fibroids, endometriosis, pelvic inflammatory disease, male factor infertility, and other relevant causes. Pelvic ultrasonography was performed to evaluate the uterus, ovaries, adnexa, and other pelvic structures for abnormalities relevant to infertility. Hysterosalpingography (HSG) was performed where clinically indicated to assess uterine cavity morphology and fallopian tube patency. The findings obtained from ultrasonography, folliculometry, HSG, and clinical evaluation were incorporated into the final infertility diagnosis.

Following diagnosis, individualized treatment plans were prescribed according to the underlying etiology and standard infertility management guidelines. Therapeutic interventions included ovulation induction agents such as letrozole and clomiphene citrate, hormonal therapies including progesterone, thyroxine, follicle-stimulating hormone injections, human chorionic gonadotropin (hCG) injections, and leuprolide. Adjunctive treatments such as metformin, myo-inositol, coenzyme Q10, vitamin E, folic acid, and antibiotics were administered when clinically indicated. Details of all prescribed medications and treatment modalities were documented. The medications and therapeutic interventions recorded in the study represented the infertility management prescribed to the participants during the study period. Treatment was documented according to the clinical management plan of the treating physician, and participants were categorized according to whether each medication or intervention was prescribed.

2.5 Statistical analysis

The data collection was conducted and was analysed by SPSS of version 27. The collected data were entered into a computerised database and analysed using appropriate statistical software. Continuous variables were expressed as mean $\pm$ standard deviation and compared between primary and secondary infertility groups using analysis of variance (ANOVA) or equivalent parametric tests. Categorical variables were presented as frequencies and percentages and analysed using Pearson's Chi-square test. A p-value less than 0.05 was considered statistically significant for all analyses.

3. RESULTS AND DISCUSSION

Figure 1 shows the number of patients in each age range. The age range of 30-39 years has shown the highest number of infertile patients, followed by the 20-29 years old.

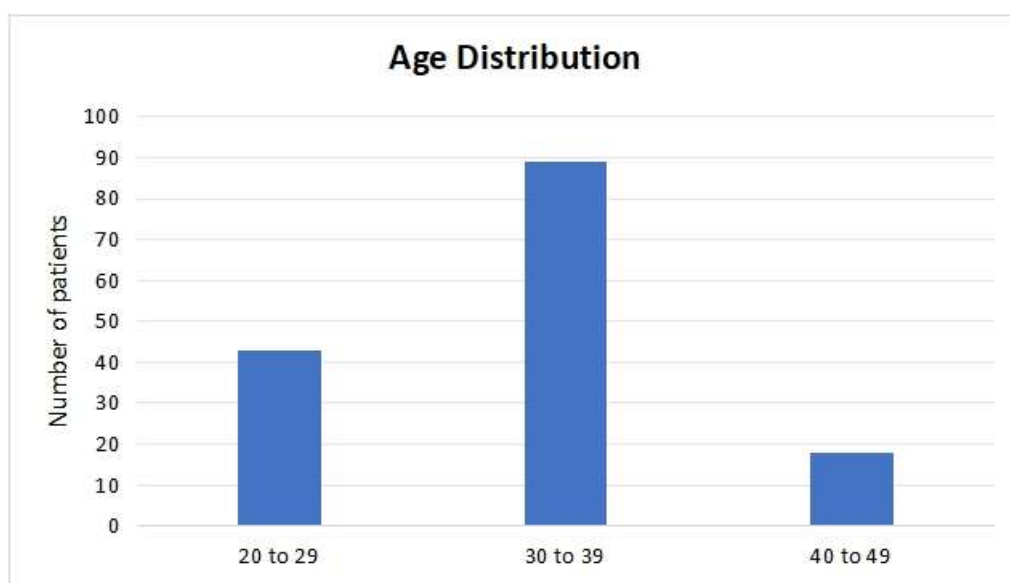


Figure 1: Distribution of patients with respect to the age

The majority of infertile women belonged to the 30–39 years age group (59.34%), followed by 20–29 years (28.67%) and 40–49 years (12.0%). Most patients were married between 25–34 years of age, with the highest proportion marrying at 30–34 years (51.34%). Primary infertility constituted the predominant type of infertility, affecting 80.0% of the study population, whereas secondary infertility accounted for 20.0% (Table 1).

Table 1: Age and Menstrual History of the patients of this study

Patient's age	Number of Patients	% of the total sample
20 to 29	43	28.67
30 to 39	89	59.34

40 to 49	18	12
Age at Marriage	Number of Patients	
20 to 24	7	4.67
25 to 29	64	42.67
30 to 34	77	51.34
35 to 39	2	1.34
Marriage_Duration	Number of Patients	
1 year	8	5.34
2 years	53	35.34
3 years	40	26.67
4 years	13	8.67
5 years	3	2
6 years	4	2.67
7 years	5	3.34
8 years	9	6
9 years	1	0.67
10 years	7	4.67
11 years	3	2
12 years	1	0.67
13 years	1	0.67
14 years	1	0.67
42 years	1	0.67
Infertility_Type	Number of Patients	
Primary	120	80
Secondary	30	20
Menarche and Menstruation		0
Menarche_Age	Number of Patients	
10	8	5.34
11	56	37.34
12	62	41.34
13	23	15.34
14	1	0.67
Menstruation_Duration	Number of Patients	

3	17	11.34
4	51	34
5	46	30.67
6	26	17.34
7	8	5.34
8	2	1.34
Menstruation_Regularity	Number of Patients	
Irregular	6	4
Regular	144	96

Women with secondary infertility were significantly older than those with primary infertility (39.47 ± 2.95 vs. 31.06 ± 2.93 years; $p < 0.01$). The mean age at marriage was also significantly higher in the secondary infertility group (30.5 ± 2.39 vs. 28.37 ± 2.75 years; $p < 0.01$), and they had a substantially longer duration of marriage (8.93 ± 2.07 vs. 2.98 ± 3.75 years; $p < 0.01$) (Table 2).

Table 2: Association of Age and Menstrual Factors among Primary and Secondary Infertility

Age and Menstrual Factors	Infertility_Type	Mean $\pm$ SD	F-value	P-value
Age	Primary	31.06 ± 2.93	0.696	< 0.01
	Secondary	39.47 ± 2.95		
Age_Marriage	Primary	28.37 ± 2.75	4.231	< 0.01
	Secondary	30.5 ± 2.39		
Marriage_Duration	Primary	2.98 ± 3.75	0.838	< 0.01
	Secondary	8.93 ± 2.07		
Menstruation_Duration	Primary	4.63 ± 0.97	12.448	0.005
	Secondary	5.27 ± 1.51		
Menarche_Age	Primary	11.61 ± 0.78	0.617	0.019
	Secondary	12 ± 0.95		

No significant difference was observed in fasting blood sugar levels between primary and secondary infertility groups (89.86 ± 8.88 vs. 89.62 ± 8.62 mg/dL; $p = 0.892$). However, women with secondary infertility demonstrated significantly higher mean FSH levels (22.11 ± 9.71 vs. 11.97 ± 5.72 mIU/mL; $p < 0.01$), LH levels (13.65 ± 8.13 vs. 8.47 ± 6.23 mIU/mL; $p < 0.01$), and prolactin levels (20.22 ± 13.94 vs. 13.99 ± 8.83 ng/mL; $p = 0.003$) (Table 3).

Table 3: Comparison of Laboratory Parameters between Women with Primary and Secondary Infertility

Laboratory Parameter	Infertility_Type	Mean $\pm$ SD	F-value	P-value
FBS	Primary	89.86 ± 8.88	0.004	0.892
	Secondary	89.62 ± 8.62		
TSH	Primary	3.26 ± 1.62	7.169	0.19

	Secondary	2.84±1.16		
FSH	Primary	11.97±5.72	21.483	<0.01
	Secondary	22.11±9.71		
LH	Primary	8.47±6.23	6.864	<0.01
	Secondary	13.65±8.13		
PRL	Primary	13.99±8.83	18.457	0.003
	Secondary	20.22±13.94		
AMH	Primary	2.24±1.06	1.655	<0.01
	Secondary	1.34±1.65		

Menstrual irregularity was more common among women with secondary infertility (10.0% vs. 2.5%), although the association was not statistically significant ($p=0.061$). Folliculometry findings differed significantly between groups ($p<0.001$), with dominant follicles in both ovaries observed predominantly in primary infertility (83.3% vs. 33.3%), while diminished ovarian reserve and small follicles were more frequent in secondary infertility (Table 4).

Table 4: Diagnostic Findings among the patients of Primary and Secondary Infertility

Parameter	Sub-Parameter	Primary Infertility n (%)	Secondary Infertility n (%)	Pearson Chi-square	P-value
Menstruation Regularity	Irregular	3 (2.5)	3 (10.0)	3.516	0.061
	Regular	117 (97.5)	27 (90.0)		
TORCH	Negative	120 (100.0)	30 (100.0)	NA	NA
USG Folliculometry	Diminished Ovarian Reserve	0 (0.0)	4 (13.3)	42.803	<0.001
	Dominant Follicle in Both Ovaries	100 (83.3)	10 (33.3)		
	PCOD with Uterine Fibroid	1 (0.8)	0 (0.0)		
	Right Ovary Dominant Follicle, Left Ovary	19 (15.8)	14 (46.7)		
	Small Follicles in Both Ovaries	0 (0.0)	2 (6.7)		
USG Abdomen & Pelvis	Adenomyosis	3 (2.5)	0 (0.0)	11.762	0.382
	Bartholin Cyst	3 (2.5)	2 (6.7)		
	Cyst Detected	9 (7.5)	0 (0.0)		
	Endometrioma	4 (3.3)	1 (3.3)		
	Endometriosis	2 (1.7)	0 (0.0)		
	Fibroids	6 (5.0)	4 (13.3)		

	Normal	66 (55.0)	17 (56.7)		
	Ovaries in Pelvis/POD	6 (5.0)	0 (0.0)		
	PCOD/PCOS Morphology	14 (11.7)	6 (20.0)		
	Pelvic Inflammatory Disease	2 (1.7)	0 (0.0)		
	Poor Ovarian Reserve	1 (0.8)	0 (0.0)		
	Small Fibroids	4 (3.3)	0 (0.0)		
HSG	Normal	104 (86.7)	25 (83.3)	7.781	0.733
	Tubal Block	7 (5.8)	3 (10.0)		
	Other HSG Findings*	9 (7.5)	2 (6.7)		
Female Diagnosis	Cervicitis	4 (3.3)	0 (0.0)	24.174	0.044
	Cystitis	5 (4.2)	0 (0.0)		
	Endometriosis	6 (5.0)	0 (0.0)		
	Genetic Factor	4 (3.3)	0 (0.0)		
	Hormonal Disorders	1 (0.8)	1 (3.3)		
	Male Factor Infertility	9 (7.5)	0 (0.0)		
	Ovulation/Follicular Disorders	3 (2.5)	3 (10.0)		
	PCOD/PCOS	11 (9.2)	4 (13.3)		
	PID/Hydrosalpinx	4 (3.3)	1 (3.3)		
	POD/Ovarian Position Anomaly	2 (1.7)	0 (0.0)		
	Polyps	2 (1.7)	2 (6.7)		
	Poor Ovarian Reserve	11 (9.2)	2 (6.7)		
	Tubal Factor Infertility	12 (10.0)	4 (13.3)		
	Unexplained Infertility	41 (34.2)	7 (23.3)		
	Uterine Fibroids	5 (4.2)	6 (20.0)		

Letrozole was the most frequently prescribed medication in both groups, being administered to 80.8% of primary and 90.0% of secondary infertility patients, without significant difference ($p=0.235$). The use of hCG injections was significantly higher among women with secondary infertility compared with primary infertility (46.7% vs. 26.7%; $p=0.034$) (Table 5).

Table 5: Management Practices observed among the patients

Parameter	Sub-Parameter	Primary Infertility n (%)	Secondary Infertility n (%)	Pearson Chi-square	P-value
Letrozole	No	23 (19.2)	3 (10.0)	1.407	0.235
	Yes	97 (80.8)	27 (90.0)		

Clomiphene	No	101 (84.2)	27 (90.0)	0.653	0.419
	Yes	19 (15.8)	3 (10.0)		
Progesterone	No	55 (45.8)	9 (30.0)	2.46	0.117
	Yes	65 (54.2)	21 (70.0)		
Metformin	No	94 (78.3)	23 (76.7)	0.039	0.844
	Yes	26 (21.7)	7 (23.3)		
Thyroxine	No	96 (80.0)	28 (93.3)	2.978	0.084
	Yes	24 (20.0)	2 (6.7)		
FSH Injection	No	99 (82.5)	24 (80.0)	0.102	0.75
	Yes	21 (17.5)	6 (20.0)		
hCG Injection	No	88 (73.3)	16 (53.3)	4.515	0.034
	Yes	32 (26.7)	14 (46.7)		
Leuprolide	No	116 (96.7)	26 (86.7)	4.754	0.029
	Yes	4 (3.3)	4 (13.3)		
Coenzyme Q10	No	84 (70.0)	24 (80.0)	1.19	0.275
	Yes	36 (30.0)	6 (20.0)		
Vitamin E	No	103 (85.8)	29 (96.7)	2.667	0.102
	Yes	17 (14.2)	1 (3.3)		
Folic Acid	No	97 (80.8)	27 (90.0)	1.407	0.235
	Yes	23 (19.2)	3 (10.0)		
Antibiotic	No	99 (82.5)	29 (96.7)	3.849	0.05
	Yes	21 (17.5)	1 (3.3)		
Myo-Inositol	No	42 (35.0)	5 (16.7)	3.749	0.053
	Yes	78 (65.0)	25 (83.3)		

3.4 Discussion

The issue of infertility in the Kashmir area has many different contributing factors related to the maleness or femaleness of genes that affect reproduction. A large, cross-sectional regional study found a considerable proportion of women in the area had problems related to ovulation, with approximately 35.3% of women satisfying the criteria for polycystic ovarian syndrome (PCOS) by Rotterdam criteria and 28.9%-34.3% of the same population satisfying the National Institutes of Health/American Endocrine Society criteria for PCOS. Additionally, a local case-control study has shown that there are genetic susceptibility factors for males, who can be subfertile due to chromosome errors, and found that one of the DNA repair genes, PARP14, has a significant effect on the development of male infertility (estimated odds ratio of 4.41) and that PARP15 has a significant protective effect. Addressing the complex spatial distribution of infertility in the region will require the implementation of a systematic metabolic diagnostic screening program, standardized clinical pathways for the diagnosis and treatment of PCOS, and for male genetic testing [4, 10].

In this study, it was observed that the age of women with secondary infertility was higher and their marriage duration was more compared to the women with primary infertility. Also, there was high level of FSH, LH, and prolactin hormones, while AMH level was low in women with secondary infertility. This was along with the presence of folliculometry differences. Data from an analysis of India's National Family Health Survey-4 shows that primary infertility occurs less than 3.9% of the time, but as high as 16.8% of the time depending upon the length of the individual's marriage. The risk factors associated with primary infertility include older ages at the time of marriage, being rural and having low education levels, inadequate income, and being employed. Contraceptive use was associated with significantly lower rates of infertility for individuals considered at risk of being unable to conceive due to their demographic characteristics (illiterate, employed, low socio-economic status) were significantly more likely to be at risk for being unable to conceive than women who were using contraceptive methods to avoid pregnancy [11]. In a separate study conducted prospectively to identify reproductive-aged women's incidence of polycystic ovary syndrome (PCOS) and the incidence of any thyroid dysfunction, a high prevalence of both conditions existed. Thirteen participants met the criteria for polycystic ovary syndrome as defined by the Rotterdam criteria and 22.5% of those individuals met the criteria for autoimmune thyroiditis, which is an abnormal antibody marker. 27.5% of participants with PCOS possessed goiter and had a mean TSH level higher than females in the control group without PCOS [12].

A recent cross-sectional study showed that 18.4% of Indian women with a diagnosis of polycystic ovary syndrome (PCOS) [using the Rotterdam criteria] tested positive for anti-nuclear antibodies (ANA), indicating that the majority have an autoimmune etiology for their hyperandrogenism and that this was associated with changes in plasma blood glucose [13]. Simultaneously, a multi-center study of reproductive-aged women (N=1,530) experiencing delayed conception in Northern India found that 54.31% of the participants reported psychological distress; 16.07% experienced anxiety, and 20% reported depression, as measured by PHQ-4 scores [14]. North and Central Kashmir are showing an increasing incidence of infertility due to national trends such as increasing age at marriage, increased urbanization, education level, and lower income levels, with an overall pattern of infertility across all of India [2, 15].

The limitation of the study includes the hospital observational study design, unequal group sizes, and referral or selection bias can affect generalization of the results. The lack of a control group consisting of women who are not infertile is another issue to consider. Age and other reproductive factors may act as confounders.

4. CONCLUSION

The study has concluded that primary infertility was more prevalent than secondary infertility among the study population. Women with secondary infertility were significantly older, had longer marital duration, higher gonadotropin and prolactin levels, and lower AMH levels, indicating reduced ovarian reserve. The findings of this study emphasize the importance of comprehensive hormonal and reproductive evaluation in infertile women, particularly those with secondary infertility. The significant association of secondary infertility with advanced age, longer marital duration, elevated FSH, LH, and prolactin levels, lower AMH levels, and impaired follicular development highlights the need for early assessment of ovarian reserve and endocrine function.

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AUTHOR CONTRIBUTIONS

Nisar Ahmad Wani: Conceptualization, Methodology, Investigation, Data Curation, Formal Analysis, and Writing—Original Draft.

Surjeet Kumar: Supervision, Methodology, Critical Review, and Writing—Review & Editing.

Suzaira Bashir: Clinical supervision, Investigation, Interpretation of findings, and Writing—Review & Editing.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ETHICS STATEMENT

Ethical approval was not required for this study.

DATA AVAILABILITY STATEMENT

The data supporting the findings of this study are available from the corresponding author upon reasonable request, subject to appropriate ethical and institutional restrictions.

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