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Study of serum prolactin level among infertile women

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Abstract
Background: Infertility is a common reproductive health problem, with endocrine disorders playing a crucial role in its etiology. Hyperprolactinemia is a frequent and treatable hormonal abnormality that can impair ovulation and cause menstrual disturbances.
Objectives: To assess serum prolactin levels in infertile women and evaluate their association with menstrual abnormalities in comparison with fertile women.
Materials and Methods: This observational cross-sectional study was conducted at Rajshree Medical & Research Institute, Bareilly, and Ganesh Shanker Vidyarthi Memorial Medical College, Kanpur. Fifty-three infertile women aged 18–45 years were included as cases, along with an equal number of fertile women as controls. Serum prolactin levels were measured during the mid-cycle (day 14–16) using a sandwich immunoassay technique. Participants were categorized according to age groups and menstrual patterns. Statistical analysis was performed using SPSS software, with $p < 0.05$ considered statistically significant.
Results: The mean serum prolactin level was significantly higher in infertile women (28.25 ± 7.5 ng/mL) compared to fertile women (20.35 ± 5.8 ng/mL) ($p = 0.0001$). Hyperprolactinemia was significantly associated with menstrual abnormalities, including oligomenorrhoea and amenorrhoea ($p < 0.001$). Most infertile women belonged to the 26–35-year age group.
Conclusion: Hyperprolactinemia is a significant and potentially reversible cause of female infertility and is strongly associated with menstrual irregularities. Routine screening of serum prolactin levels should be incorporated into infertility evaluation protocols to facilitate early diagnosis and management.

Keywords: Infertility, hyperprolactinemia, serum prolactin, menstrual abnormalities, ovulatory dysfunction

Introduction
Infertility is defined as the inability to conceive after 12 months of unprotected intercourse [1]. This condition affects up to 15% of couples worldwide and exerts significant psychosocial and economic impacts. It is estimated that infertility affects globally 50 to 80 million people and currently 8-10 million infertile couples are estimated to be in India [2]. Among the myriad causes, endocrine dysfunctions—such as thyroid disorders, obesity-related hormonal imbalances, and pituitary abnormalities—play an important role [3, 4]. Prolactin, a peptide hormone produced by the anterior pituitary gland, primarily regulates lactation but also influences reproductive function. Physiologically, prolactin modulates ovarian steroidogenesis and inhibits GnRH release when elevated, leading to reduced secretion of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), and subsequent anovulation or oligo-ovulation [5, 6].

Hyperprolactinemia is one of the most common endocrinological abnormalities in infertile women, reported in both primary and secondary infertility. Causes include pituitary adenomas (prolactinomas), medication side effects, hypothyroidism, and idiopathic conditions. Despite its prevalence, routine prolactin testing is not universally performed in all infertility clinics, potentially delaying diagnosis and treatment. Several studies have found a link between age and infertility. Women's fertility decreases as they get older [7].

This study evaluates serum prolactin levels in a cohort of infertile women, investigates its association with menstrual irregularities, and highlights clinical implications for infertility management.

Material & Methods
An observational cross sectional descriptive study was conducted in department of biochemistry

in collaboration with department of Obs & Gynae at Rajshree Medical & Research Institute, Bareilly and Ganesh Shanker Vidyarthi Memorial Medical college, Kanpur.

Inclusion Criteria: All female patients of reproductive age group (18-45 yrs) attending infertility clinic at outpatient department of Obs & Gynae with the chief complaint of failure to conceive despite one-year regular un protected sexual intercourse (i.e. Infertility) and are willing to give written informed consent; were enrolled in the study.

Exclusion criteria

- Females who are not willing to give consent.
- Females with other co-morbid conditions like diabetes mellitus and hypertension e.t.c.
- Male factor infertility.
- Females on hormone supplementation

Females who fulfill the inclusion and exclusion criteria were served as *study group.*
A Similar group size of patients having at least one child were served as *control group.*
According to age, participant females were divided into three age groups.

- Age group-1 18yrs- 25 yrs
- Age group-2 26yrs-35 yrs
- Age group-3 36yrs-45yrs

Pattern of serum prolactin level in women having regular or irregular menstrual cycles was also seen.

Sample Collection: Venous blood sample (5ml blood) was collected using sterile syringe under aseptic condition from every participant at mid (14-16 day) of menstrual cycle in both case and control group. After collection of venous blood sample, it was allowed to clot then it was centrifuged for serum separation. Serum was stored at -18 degree centigrade. Test was performed within three days of sample collection. Then serum Prolactin level was be measured using sandwich immunoassay detection method.

Principle of Test: The detector antibodies in buffer bind to antigen in the sample, forming antigen-antibody complexes, migrate onto nitrocellulose matrix to be captured by the other immobilized streptavidin on a test strip. More antigen in the sample will form more antigen-antibody complex which lead to stronger fluorescence signal by detector antibody fluorescence instrument.

Definitions

- **Normal prolactin:** Serum prolactin level ≤ 25 ng/mL was considered as normal.
- **Hyperprolactinemia:** Serum prolactin level > 25 ng/mL was considered as hyperprolactinemia.
- **Oligomenorrhea:** Menstrual cycles longer than 35 days were considered as oligomenorrhea.
- **Amenorrhea:** Absence of menstruation for ≥3 months was considered as amenorrhoea.

Statistical Analysis: Statistical analyses were performed using SPSS software. Means were compared using t-tests, associations using chi-square tests, and logistic regression was used to adjust for confounders. A p-value < 0.05 was considered statistically significant.

Results

A total number of 53 infertile women were included in the present study. The maximum infertile women population was found between the age group of 26-35 years (Figure:1). The ratio of patients to control was 1:1.

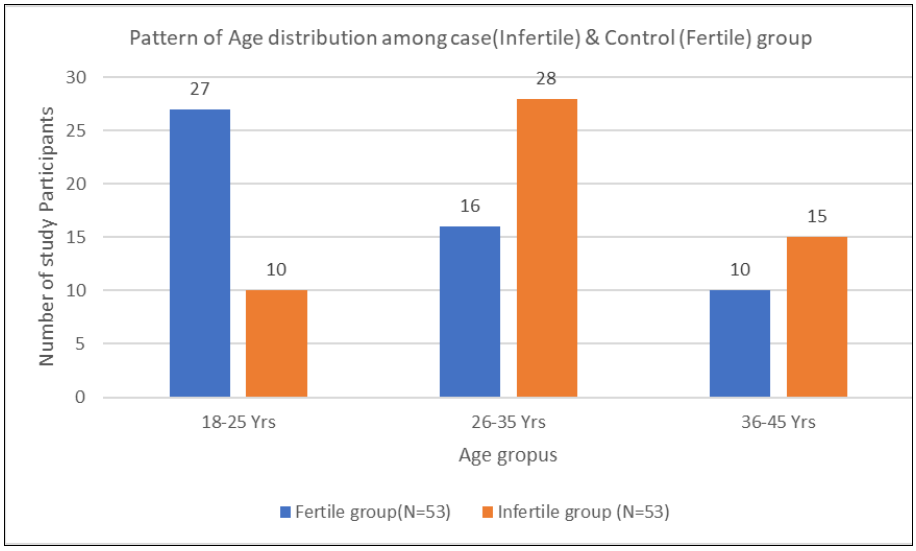

Fig 1: Pattern of age distribution in fertile and infertile women

Women with hyperprolactinemia had significantly higher rates of menstrual disturbances. (Table-1)

Table 1: Association of menstrual abnormalities with serum prolactin level

Menstrual Pattern	Normal Prolactin	Hyperprolactinemia	p-value
Regular Cycles	65%	28%	<0.001
Oligomenorrhoea	24%	45%	
Amenorrhoea	11%	27%	

The mean serum level of Prolactin was 28.25±7.5 ng/ml in infertile women was higher than the mean serum level of Prolactin of 20.35±5.8 ng/ml in fertile women which was highly significant (p=0.0001). (Table-2)

Table 2: Prolactin level in fertile and infertile women

Parameter	Case (Infertile group)	Control (Fertile group)	t-value	p-value
Serum Prolactin (ng/ml)	28.25+/- 7.5	20.35+/-5.8	6.05	0.0001

Discussion

The purpose of this study was to examine the levels of prolactin in patients with infertility and compare the results to those obtained from fertile participants. For a substantial number of people, infertility is a serious life issue, affecting them as individuals, married couples, and members of families and society [8]. Elevated prolactin likely impairs ovulation through excessive suppression of GnRH, leading to insufficient LH surges and compromised folliculogenesis. Anovulation and female infertility are both caused by hyperprolactinemia, which is a common finding in reproductive diseases [9].

In this study, the level of Prolactin in infertile women was determined. When compared to the control group, the infertile group had higher levels. Similar findings were found in studies done by Ban et.al, Aroma *et al*, Parijatham and Saikumar, Goswami *et al*. and Kumkum *et al*. [10-14].

In this study most common age group which encountered infertility was between 26-35 years. This finding is in line with the study conducted by Bheem Prasad *et al*. [15] and is in contrast with study conducted by Behera *et al*. [16] in which women of age group between 21-28 years were more in infertile group. This difference may be due to different demographic profile of patients attending the infertility clinic.

In this study menstrual abnormality viz. oligomenorrhoea and amenorrhoea was associated with increased serum prolactin levels. This finding is in line with study conducted by Bindu Kulshrestha *et al*. [17]

Conclusion

Hyperprolactinemia is a significant and treatable endocrine contributor to female infertility. Assessment of serum prolactin should be standard practice in fertility evaluations. Future research should investigate longitudinal outcomes and the impact of prolactin-targeted therapies on fertility success rates.

Limitation of Study: This is a Cross-sectional design which limits causal inference. Multicentre study should be done for generalization of results. Repeated measurement of serum prolactin level (k/a Prolactin dynamic testing) should be done to confirm chronic elevation of levels.

Conflict of Interest: Not available

Financial Support: Not available

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