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Original Research Article

Accuracy of Clinical and Biochemical Methods for Detection of Ovulation in Infertile Women: A Hospital-Based Observational Study

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Conflict of interest: Nil

Abstract:

Background: Ovulatory dysfunction is one of the most common and potentially treatable causes of female infertility. Accurate identification of ovulation is essential for appropriate infertility evaluation and management. Various clinical and biochemical methods are used to detect ovulation; however, their diagnostic accuracy varies, and a comparative evaluation is required to guide optimal clinical practice.

Aim and Objectives: To assess the accuracy of clinical and biochemical methods for the detection of ovulation in infertile women.

Materials and Methods: This hospital-based retrospective observational cross-sectional study was conducted in the Department of Obstetrics and Gynaecology at Kamala Nehru Memorial Hospital, Prayagraj, over a period of two years from October 2020 to October 2022. A total of 100 infertile women of reproductive age were included. Ovulation was assessed using basal body temperature charting, cervical mucus examination, and mid-luteal serum progesterone estimation. Detection of the urinary luteinizing hormone (LH) surge using a commercial LH kit was considered the reference standard. Diagnostic accuracy parameters, including sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy, were calculated. Statistical analysis was performed using SPSS version 23.0, and a p-value <0.05 was considered statistically significant.

Results: Out of 100 infertile women, 78 (78.0%) were ovulatory and 22 (22.0%) were anovulatory based on LH surge detection. Serum progesterone estimation showed the highest diagnostic accuracy (84.0%) with high specificity (94.87%), followed by cervical mucus examination with an accuracy of 80.0%. Basal body temperature monitoring demonstrated lower sensitivity and an overall accuracy of 71.0%. Serum prolactin levels were significantly higher in anovulatory women ($p<0.05$), while other hormonal parameters showed no significant difference between ovulatory and anovulatory groups.

Conclusion: Ovulatory dysfunction contributes significantly to female infertility. Among the evaluated methods, serum progesterone estimation is the most accurate biochemical marker for ovulation detection, while cervical mucus examination serves as a reliable and cost-effective clinical indicator. Basal body temperature monitoring alone is insufficient for accurate ovulation assessment. A combined approach incorporating clinical assessment and biochemical confirmation provides a more reliable strategy for ovulation detection, particularly in resource-limited settings.

Keywords: Female Infertility; Ovulation Detection; Anovulation; Serum Progesterone; Cervical Mucus; Luteinizing Hormone.

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Introduction

Infertility is a significant global health concern with profound medical, psychological, and social implications. It is defined as the inability to achieve pregnancy after 12 months of regular, unprotected sexual intercourse in women of reproductive age [1]. The worldwide prevalence of infertility is estimated to range between 8% and 12%, with female-related factors accounting for approximately one-third of all cases [2]. Among the various etiologies of female infertility, disorders of ovulation constitute the most frequent and potentially treatable cause, contributing to nearly 25% of cases [3].

Ovulation is a complex, hormonally regulated process involving the hypothalamic–pituitary–ovarian (HPO) axis, culminating in the release of a mature oocyte capable of fertilization. Disruption at any level of this axis may result in anovulation or oligo-ovulation, thereby impairing fertility [4]. According to the World Health Organization, ovulatory dysfunctions are broadly classified into hypothalamic–pituitary failure, hypothalamic–pituitary–ovarian dysfunction, and ovarian failure, with polycystic ovary syndrome being the most common underlying disorder [5]. Early and accurate detection of ovulation is therefore central to the evaluation and management of infertile women.

Several clinical and biochemical methods are available for assessing ovulation, each varying in accuracy, invasiveness, cost, and ease of use. Clinical indicators such as menstrual regularity, basal body temperature (BBT), and cervical mucus characteristics have traditionally been employed due to their simplicity and low cost [6]. However, these methods are indirect and may be influenced by multiple physiological and environmental factors, thereby limiting their reliability when used in isolation [7].

Biochemical methods, including detection of the urinary luteinizing hormone (LH) surge and measurement of mid-luteal serum progesterone levels, offer more objective evidence of ovulation. The urinary LH surge precedes ovulation by approximately 24–36 hours and is widely used as a point-of-care method for identifying the fertile window [8]. Serum progesterone estimation during the mid-luteal phase reflects corpus luteum function and is considered a reliable marker of ovulation when levels exceed established thresholds [9]. Despite their widespread use, variability in sensitivity and specificity across different populations necessitates comparative evaluation.

Transvaginal ultrasonography with serial follicular monitoring remains the most accurate modality for confirming ovulation, as it allows direct visualization of follicular growth and rupture. However, its routine use is limited by cost, need for expertise, and patient inconvenience [10]. Consequently, there is continued interest in identifying non-invasive, cost-effective, and reliable alternatives for ovulation detection, particularly in resource-limited settings.

Given the clinical importance of precise ovulation detection and the lack of consensus regarding the optimal diagnostic approach, systematic assessment of commonly used clinical and biochemical methods is warranted. The present study was therefore undertaken to evaluate and compare the accuracy of selected clinical indicators and biochemical tests for ovulation detection, using urinary LH surge as the reference standard. Such evaluation may help optimize infertility work-up and guide evidence-based clinical decision-making.

Materials and Methods

The present study was a hospital-based retrospective observational cross-sectional study conducted in the Department of Obstetrics and Gynaecology in collaboration with the Department of Pathology at Kamala Nehru Memorial Hospital, Prayagraj, Uttar Pradesh, India. The study was carried out over a period of two years from October 2020 to October 2022 and included infertile women attending the outpatient and inpatient services of the hospital.

Study Population and Sample Size: A total of 100 women in the reproductive age group presenting with infertility were enrolled in the study. Infertility was defined as failure to conceive after at least one year of regular, unprotected sexual intercourse. Both primary and secondary infertility cases were included to ensure adequate representation of ovulatory patterns.

Eligibility Criteria: Women of reproductive age presenting with primary or secondary infertility and willing to participate in the study were included after obtaining written informed consent. Women who were pregnant, diagnosed with chronic liver disease, chronic kidney disease, active tuberculosis, or other significant gynecological disorders, as well as those unwilling to give consent, were excluded from the study.

Ethical Considerations: The study protocol was approved by the Institutional Ethics Committee (Human) of Kamala Nehru Memorial Hospital, Prayagraj, Uttar Pradesh, India. Written informed consent was obtained from all participants prior to enrollment, and confidentiality of patient information was strictly maintained throughout the study in accordance with ethical guidelines.

Data Collection Procedure: Data were collected using a predesigned and pretested proforma. Patient history was obtained in the local language or English, as appropriate, and included demographic details, socio-economic status, menstrual history, obstetric history, duration of infertility, and relevant medical history. Clinical findings and investigation reports were recorded from patient case files and laboratory records.

Clinical Evaluation: All participants underwent detailed general, systemic, and gynecological examinations. Anthropometric measurements including height and weight were recorded to calculate body mass index. Clinical evaluation focused on identifying signs of endocrine disorders such as hirsutism, acne, galactorrhea, thyroid enlargement, and pelvic abnormalities, including uterine size and adnexal tenderness or masses.

Assessment of Ovulation: Ovulation was assessed using a combination of clinical and biochemical methods. Detection of the mid-cycle urinary luteinizing hormone (LH) surge using a commercially available LH kit was considered the reference (gold standard) for ovulation. Participants were advised to perform daily LH testing starting from day 10 of the menstrual cycle until a positive result was obtained. Based on LH kit results, women were categorized as ovulatory or anovulatory.

Clinical Methods of Ovulation Detection: Basal body temperature was recorded daily by participants using a standardized thermometer immediately upon waking and before any physical activity. A biphasic temperature pattern with a sustained post-ovulatory rise of at least 0.2°C was considered indicative of ovulation. Cervical mucus examination was performed during the peri-ovulatory period, and mucus was assessed for quantity, consistency, spinnbarkeit, and ferning pattern. The presence of copious, thin, stretchable mucus with a positive fern pattern was considered suggestive of ovulation.

Biochemical Method of Ovulation Detection: Serum progesterone estimation was carried out during the mid-luteal phase, approximately seven days prior to the expected onset of menstruation. Venous blood samples were collected and analyzed using standard laboratory techniques. A serum progesterone level of ≥3 ng/mL was considered evidence of ovulation.

Hormonal and Biochemical Investigations: All participants underwent hormonal evaluation, including serum follicle-stimulating hormone, luteinizing hormone, estradiol, prolactin, thyroid-stimulating hormone, and anti-Müllerian hormone estimation. Total serum cholesterol was also measured. All assays were performed using standardized immunoassay methods in the hospital laboratory following routine quality control protocols.

Ultrasonographic Evaluation: Transvaginal ultrasonography was performed for assessment of ovarian morphology and follicular development. Follicular monitoring was carried out where indicated to support clinical and biochemical findings related to ovulation.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using the Statistical Package for Social Sciences (SPSS), version 23.0. Continuous variables were expressed as mean ± standard deviation, while categorical variables were expressed as frequency and percentage. Comparisons between ovulatory and anovulatory groups were performed using the independent sample t-test for continuous variables and the Chi-square test for categorical variables. Diagnostic accuracy parameters including sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy were calculated for each ovulation detection method. A p-value of less than 0.05 was considered statistically significant.

Results

A total of 100 infertile women in the reproductive age group were included in the present study. Ovulatory status was determined using urinary LH surge detection kit, which was considered the reference (gold standard) for ovulation.

Distribution of Ovulatory Status: Out of 100 infertile women, 78 (78.0%) were found to be ovulatory, while 22 (22.0%) were anovulatory based on LH surge detection (Table 1).

Table 1: Distribution of Ovulatory Status (LH Kit as Reference Standard)

Ovulatory Status	Frequency (n)	Percentage (%)
Ovulatory	78	78.0
Anovulatory	22	22.0
Total	100	100.0

Age Distribution and Baseline Characteristics: The mean age of women in the ovulatory group was 29.17 ± 3.75 years, while that in the anovulatory group was 28.68 ± 3.71 years. The difference in mean age between the two groups was not statistically significant ($p = 0.562$). However, the mean duration of unprotected marital life was significantly higher in the anovulatory group (4.07 ± 1.21 years) compared to the ovulatory group (2.92 ± 1.34 years) ($p < 0.001$) (Table 2).

Table 2: Age and Marital Characteristics of Study Participants

Parameter	Ovulatory (n=78)	Anovulatory (n=22)	p-value
Mean age (years)	29.17 ± 3.75	28.68 ± 3.71	0.562
Mean husband age (years)	31.63 ± 3.45	32.00 ± 2.20	0.634
Duration of unprotected marriage (years)	2.92 ± 1.34	4.07 ± 1.21	<0.001

Menstrual Pattern Distribution: Menstrual irregularities were significantly associated with ovulatory dysfunction. Normal menstrual cycles were more commonly observed in the anovulatory group, whereas irregular cycles were significantly higher in the ovulatory group (Table 3).

Table 3: Distribution of Menstrual Patterns

Menstrual Pattern	Ovulatory (n=78)	Anovulatory (n=22)	p-value
Normal cycles	14 (17.9%)	11 (50.0%)	0.004
Oligomenorrhoea	42 (53.8%)	10 (45.5%)	0.630
Amenorrhoea	8 (10.3%)	1 (4.5%)	0.679
Irregular cycles	14 (17.9%)	0 (0.0%)	0.035

Comparison of Hormonal Parameters: The mean levels of FSH, LH, estradiol, AMH, total cholesterol, and TSH were comparable between the two groups. However, serum prolactin levels were significantly higher in the anovulatory group ($p = 0.033$) (Table 4).

Table 4: Comparison of Hormonal Parameters Between Groups

Parameter	Ovulatory (Mean ± SD)	Anovulatory (Mean ± SD)	p-value
FSH (IU/mL)	5.90 ± 1.65	6.30 ± 1.87	0.324
LH (IU/mL)	6.63 ± 2.78	6.04 ± 1.83	0.357
Estradiol (pg/mL)	47.52 ± 11.00	45.00 ± 6.50	0.309
AMH (ng/mL)	7.13 ± 2.90	6.94 ± 2.13	0.778
TSH (mIU/L)	2.46 ± 0.84	2.63 ± 0.98	0.414
Prolactin (ng/mL)	13.50 ± 4.59	15.94 ± 4.94	0.033

Clinical Methods for Ovulation Detection: Clinical indicators including basal body temperature (BBT), cervical mucus examination, and serum progesterone were compared against LH kit results (Table 5).

Table 5: Clinical Findings Compared with LH Kit

Method	LH Positive (n=22)	LH Negative (n=78)	p-value
Basal body temperature – positive	10 (45.5%)	17 (21.8%)	0.027
Cervical mucus – positive	15 (68.2%)	13 (16.7%)	<0.001
Serum progesterone – positive	10 (45.5%)	4 (5.1%)	<0.001

Diagnostic Accuracy of Clinical and Biochemical Methods: Serum progesterone demonstrated the highest diagnostic accuracy (84.0%), followed by cervical mucus examination (80.0%) and basal body temperature (71.0%) (Table 6).

Table 6: Diagnostic Performance of Ovulation Detection Methods

Method	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Basal body temperature	45.45	78.21	37.04	83.56	71.00
Cervical mucus	68.18	83.33	53.57	90.28	80.00
Serum progesterone	45.45	94.87	71.43	86.05	84.00

Discussion

Infertility remains a major reproductive health problem worldwide, with ovulatory dysfunction constituting one of the most common and treatable causes of female infertility. Accurate identification of ovulation is therefore a cornerstone in the evaluation and management of infertile women. The present study assessed the accuracy of commonly used clinical and biochemical methods for ovulation detection, using urinary luteinizing hormone (LH) surge detection as the reference standard.

In the present study, anovulation was observed in 22.0% of infertile women, while 78.0% were found to be ovulatory. This incidence is consistent with previously published literature, which reports ovulatory disorders in approximately 20–25% of infertile women [3,5]. Similar findings were reported by Singangutti et al., who documented a substantial proportion of infertility cases attributable to ovulatory dysfunction [11]. These observations reaffirm the clinical relevance of ovulation assessment in infertility work-up.

The mean age of women in both ovulatory and anovulatory groups was comparable, and no statistically significant age difference was observed. This finding aligns with studies by Ali et al. and Elhussein et al., which reported that ovulatory dysfunction can occur across a broad reproductive age range [12,13]. However, the duration of unprotected marital life was significantly longer in the anovulatory group, suggesting delayed diagnosis or prolonged untreated ovulatory dysfunction. Prolonged infertility duration has also been associated with anovulation in earlier studies [14].

Menstrual irregularities showed a significant association with ovulatory status in the present study. Oligomenorrhoea and amenorrhoea were more frequently observed among women with

ovulatory dysfunction, consistent with the well-established association between irregular cycles and anovulation [4]. However, it is noteworthy that a proportion of anovulatory women reported regular menstrual cycles, emphasizing that menstrual regularity alone cannot reliably confirm ovulation, as previously reported by Ecochard et al. [6].

Hormonal analysis revealed no significant difference in mean serum FSH, LH, estradiol, AMH, TSH, or lipid levels between ovulatory and anovulatory groups. In contrast, serum prolactin levels were significantly higher in anovulatory women, indicating its contributory role in ovulatory dysfunction. Hyperprolactinemia is known to suppress gonadotropin-releasing hormone secretion, leading to impaired LH pulsatility and anovulation [15]. Similar observations have been reported in multiple studies, supporting the role of prolactin in ovulatory failure [16]. Although recent guidelines suggest selective prolactin testing, the present findings highlight its relevance in patients with ovulatory disturbances [9].

With regard to clinical methods of ovulation detection, basal body temperature (BBT) demonstrated low sensitivity but moderate specificity, resulting in an overall accuracy of 71.0%. These findings are comparable to those reported by Guermandi et al. and Gunardi et al., who noted wide variability in the diagnostic reliability of BBT due to external influences and inconsistent post-ovulatory temperature rise [17,18]. The limited sensitivity observed in the present study further supports the view that BBT should not be used as a sole diagnostic tool for ovulation detection.

Cervical mucus examination showed better diagnostic performance, with 80.0% accuracy, moderate sensitivity, and high negative predictive value. Estrogen-mediated changes in cervical mucus around ovulation make this method physiologically sound, and its diagnostic value has been demonstrated in previous studies [19]. Alliende et al. reported comparable sensitivity and specificity when cervical mucus findings were correlated with ultrasound-confirmed ovulation [20]. The present study supports cervical mucus assessment as a useful, non-invasive, and cost-effective clinical indicator, particularly in low-resource settings.

Among all evaluated methods, serum progesterone estimation demonstrated the highest accuracy (84.0%), with excellent specificity. Mid-luteal serum progesterone reflects corpus luteum function and is widely accepted as a reliable biochemical marker of ovulation [10]. The high specificity observed in the present study is consistent with prior research, which has shown progesterone levels to be highly indicative of ovulation when measured at the appropriate time in the cycle [9]. However, its moderate sensitivity highlights the importance of correct timing of sample collection.

Overall, the findings of the present study indicate that no single clinical or biochemical method fulfills all criteria of an ideal ovulation detection tool. While serum progesterone showed the highest diagnostic accuracy, cervical mucus examination emerged as the most reliable clinical method. Basal body temperature, though simple and inexpensive, demonstrated limited reliability. These findings support the use of a combined approach to ovulation detection, integrating clinical observation with biochemical confirmation, to improve diagnostic accuracy and guide infertility management effectively.

Conclusion

The present study demonstrated that ovulatory dysfunction is a significant contributor to female infertility, with anovulation identified in nearly one-fourth of infertile women. Accurate detection of ovulation is essential for appropriate evaluation and management of infertility. Among the methods assessed, serum progesterone estimation showed the highest diagnostic accuracy and specificity, making it the most reliable biochemical marker of ovulation, while cervical mucus examination proved to be a useful, non-invasive, and cost-effective clinical method with good diagnostic performance. Basal body temperature monitoring, although simple and inexpensive, exhibited lower sensitivity and therefore should not be used as a standalone tool for ovulation detection. Overall, the findings indicate that no single clinical or biochemical method can independently detect ovulation with complete accuracy, and a combined approach incorporating clinical assessment, urinary LH surge detection, and biochemical confirmation provides a more reliable and practical strategy for ovulation evaluation in infertile women, particularly in resource-limited settings.

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