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INTRAUTERINE INSEMINATION IN UNEXPLAINED SUBFERTILITY IN TERTIARY CARE HOSPITAL

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ABSTRACT

Background: The cause of unexplained subfertility has remained a persistent clinical dilemma and intrauterine insemination (IUI) has been employed as an initial treatment method. Nonetheless, the results of treatment depend on the population of patients and the clinical conditions.

Objective: To evaluate the clinical outcomes of IUI, and determinants of success in couples with unexplained subfertility receiving treatment at a tertiary care hospital.

Methods: The retrospective observational study was carried out in the Department of Gynecology and obstetrics, Lady Willingdon Hospital, Lahore with the sample population of 120 couples undergoing 240 IUI cycles. Demographic information, cycle variations, semen variables, and pregnancy results were studied. The factors that were found to be independent predictors of clinical pregnancy were identified by means of multivariable logistic regression.

Results: The live birth rate was 8.3 and the clinical pregnancy rate per cycle was 10.8. Increased age of women at the time of birth, reduced infertility years, endometrial thickness with 8-mm cut-offs, and post-wash total motile sperm count with 10-million cut-offs were found to be associated with the increased rate of pregnancy. The rate of multiple and ectopic pregnancy was low.

Conclusion: Intrauterine insemination can be used as a viable and availed therapy to unexplainable subfertility in tertiary care. With the correct selection of patients and personalized control of the cycles, it is possible to optimize the outcomes.

1. INTRODUCTION

Infertility and subfertility are major health issues of social concern across the globe, which affects an approximate of 10-15 percent of couples of reproductive ages, and has a great emotional, social and economic cost to the sufferers (1). In addition to the biological impossibility of conception, infertility is often connected with mental pain, husband-wife tension, and poor-quality life, especially in the context of sociocultural commitment, when childbearing is strongly tied to social identity and family stability (2). These difficulties are further aggravated in low- and middle-income nations where not everybody can access the most advanced assisted reproductive technologies, and cost-effective and minimally invasive treatment methods become particularly important (3). Subfertility is usually referred to as the inability to conceive following at minimum 12 months of frequent intercourse without contraception or six months in women who are 35 years old and above (4). Of the couples that are evaluated, a significant proportion of 15 percent to 30 percent is declared as an unexplained subfertility in which routine diagnostic tests show no abnormal ovulatory activity, tubal patency, uterine structure, and seminogenesis (5). It is the diagnosis of unexplained subfertility, thus, a diagnosis of exclusion because of the inability of conventional diagnostic aids to reveal subtle abnormalities in gamete interactions, fertilization, or in early embryonic growth (6). Management of unexplained subfertility is also difficult to be clinically managed because an etiological factor cannot be identified. Couples are likely to feel frustrated and doubtful in the face of counseling which is premised on probabilistic explanations as opposed to causal explanations (7). The commonly used treatment approaches are expectancy treatment, followed by ovarian stimulation, timed intercourse, intrauterine insemination (IUI) and finally in vitro fertilization (IVF) as the treatment approach according to the age of the patient, duration of infertility, and response to treatment (8). In various environments, IUI is viewed as an intermediate measure, which is not as effective as invasive or as inexpensive (9). In intrauterine insemination, the processed motile sperm is inserted into the uterine cavity during the period during ovulation and as a result raises the level of sperm at the fertilization point and circumvents possible cervical obstacles (10). IUI can be used together with controlled ovarian stimulation and may increase the chances of fertilization by augmenting the quantity of accessible oocytes but this methodology should be well-timed in relation to the danger of multiple gestation (11). The biological justification of IUI in unexplained subfertility is to maximize the approach to gametes and time, which may surpass the existence of barrier to natural conception, which are often too subtle to be discerned (12).

There is a range of reported rates of pregnancy and live birth after IUI, which are dependent on the selection of the patients, the semen preparation method, and the nature of the cycles (13). The age of females, infertility, endometrial thickness, preovulatory follicle count, total motile sperm count following processing had always been observed to act as predictors of IUI success (14). Nevertheless, the relative role of these factors and their interplay in practice remain a topic of controversy, specifically in the environment of resource deficits where personalized treatment regimens might not be possible in practice (15). High-income countries have provided evidence on which most of the current guidelines on the use of IUI to unexplained subfertility were informed but the findings may not be directly applicable to the populations in developing countries because of the differences in demographic variables, health facilities, and the availability of treatment (9). IUI is frequently the simplest

form of assisted reproductive intervention that may be readily offered in tertiary care hospitals with high and varied patient volumes before submission to sophisticated methods. It is critical to create local data on effectiveness and predictors of success because it leads to evidence-based counseling and rational allocation of healthcare sources (3).

It is against this backdrop that the current research was aimed at assessing clinical outcomes arising when intrauterine insemination was applied in couples with unexplained subfertility that had undergone treatment in a tertiary care hospital. This study will help to give context-specific evidence to inform clinical decision-making and patient counseling optimization in healthcare settings with the assistance of baseline characteristics, cyclical parameters, and treatment predictors of pregnancy.

2. Materials and Methods

2.1 Study Design and Setting

This research was designed as a retrospective observational study in the Department of Gynecology and obstetrics, Lady Willingdon Hospital, Lahore, a tertiary care referral center that offers infertility services to a wide range of patients. The retrospective design was chosen to enable systematic assessment of actual clinical outcome of intrauterine insemination (IUI) in the basis of routinely gathered medical documentation, which is representative of routine clinical practice in a resource limited environment.

2.2 Study Duration

Eligible couples that are undertaking IUI had their medical records reviewed in more than a year. This timeframe was deemed to be adequate to obtain enough treatment cycles and outcomes of the pregnancy besides reducing time differences in clinical protocol and laboratory practice (16).

2.3 Study Population

The study involved couples that presented with infertility and unexplained subfertility. Unexplained subfertility was determined once all had been evaluated as normal ovulatory performance, tubal patency, uterine anatomy, and semen parameters, based on internationally accepted criteria (4). Each couple had the opportunity to supply many IUI cycles in the process of the study that met the eligibility criteria of each cycle.

2.4 Inclusion Criteria

The couples were included when the female partner was of reproductive age and had a diagnosis of unexplained subfertility, at least one patent fallopian tube as indicated by hysterosalpingography or laparoscopy, regular ovulatory cycles or previous ovulation after induction, and a partner with normal semen parameters based on normal reference values (17). Cycles that had undergone intrauterine insemination were only included in the analysis.

2.5 Exclusion Criteria

Couples were not included in case infertility could be attributed to identifiable factors including tubal obstruction, moderate or severe endometriosis, polycystic ovary syndrome with prolonged anovulation, uterine anomalies affecting implantation, and male factor infertility. Other complicated cycles such as premature ovulation, incomplete records, or transformation to in vitro fertilization were also not included as they would affect the consistency and reliability of data (18).

2.6 Baseline Evaluation

Baseline evaluation involved extensive clinical history, age, body mass index, and infertility duration and type (primary, secondary) and hormonal analysis, which involved follicle-stimulating hormone and anti-Mullerian hormone. Transvaginal ultrasonography was done to determine the number of antral follicles and the structure of the uterus. The tubal patency was confirmed before IUI treatment was initiated, and semen analysis was done on the basis of standard laboratory procedures (19).

2.7 IUI Protocol

IUI cycles were conducted in the natural cycles or after ovarian stimulation with letrozole, clomiphene citrate, or gonadotropins, depending on the choice of the clinician and the specifics of the patients. Serial transvaginal ultrasonography was used in follicular monitoring. Human chorionic gonadotropin was used to induce ovulation, when one dominant follicle was found to be mature enough. Natural cycles ovulation was determined or detected and insemination was performed between 36 and 48 hours after these events (20).

2.8 Semen Collection and Preparation

Masturbation was done after 25 to 5 days of abstinence in order to collect samples of semen. The samples were treated with the normal sperm preparation methods to focus the motile sperm and eliminate seminal plasma. The total motile sperm count pre-wash and post-wash were recorded per cycle and aseptic insemination was done through the use of soft catheter (21).

2.9 Outcome Measures

Clinical pregnancy which was defined as being in the form of a gestational sac on transvaginal ultrasound was the primary measure of outcome. Biochemical pregnancy, continued pregnancy to 12 weeks of gestational age, delivery of a live birth, miscarriage, ectopic pregnancy, multiple pregnancy, and cycle cancellation were considered the secondary outcomes. Results were determined on a per-cycle and a per-couple basis (22).

2.10 Statistical Analysis

Normal statistical software was used to analyze data. Continuous variables were measured as mean standard deviation or median with interquartile range whereas categorical variables were measured in frequencies and percentages. Inter-group comparisons were done whereby the necessary parametric or non-parametric tests were used. The multivariate logistic regression analysis was performed to determine independent predictors of clinical pregnancy and the outcomes were in terms of adjusted odds ratios and 95% confidence intervals. The p-value below 0.05 was taken as statistically significant (23).

2.11 Ethical Considerations

The research was done within the framework of the ethical principles specified in the Declaration of Helsinki. Since this was a retrospective review of anonymized clinical data, formal informed consent was not used. During data collection and analysis, patient confidentiality was greatly observed (24).

3. Results

3.1 Baseline Characteristics of the Study Population

One hundred and twenty couples who were diagnosed with unexplained subfertility were involved in the study. The average age of women in intrauterine insemination was 28.7 with a standard deviation of 4.1 years and the average age of male counterparts was 32.1 and the standard deviation was 5.2. The weighted mean of the female participants was 25.6 +/- 3.5kg/m 2 and average subfertility was 3.4 +/- 1.6 years. Prevalence of primary subfertility was found in 65.0% of the couples with 35.0% having secondary subfertility.

Table 1: Baseline Characteristics of Couples/Women Undergoing IUI

Variable	IUI Cohort (n = 120)
Female age (years)	28.7 ± 4.1
Male age (years)	32.1 ± 5.2
BMI (kg/m²)	25.6 ± 3.5
Duration of subfertility (years)	3.4 ± 1.6
Primary subfertility	78 (65.0%)
Secondary subfertility	42 (35.0%)

Baseline FSH (IU/L)	6.8 ± 1.9
AMH (ng/mL)	2.7 ± 1.1
Antral follicle count	12.4 ± 4.6
Normal HSG/tubal patency	120 (100%)
Normal semen analysis	120 (100%)

The average follicle-stimulating hormone level (6.8) and anti-Mullerian hormone level (2.7) were found to be 6.8/1.9 IU/L and 2.7 /1.1 ng/ml, respectively. The antral follicle count was 12.4 +4.6. The uterine cavity and tubal patency of all women were within the normal reference limits of the hysterosalpingography and the parameters of semen analysis were within the normal reference limits of the male partners. **Table 1** and **Figure 1** summarize in detail and present in detail, the baseline demographic, hormonal, and infertility-related characteristics of the study population.

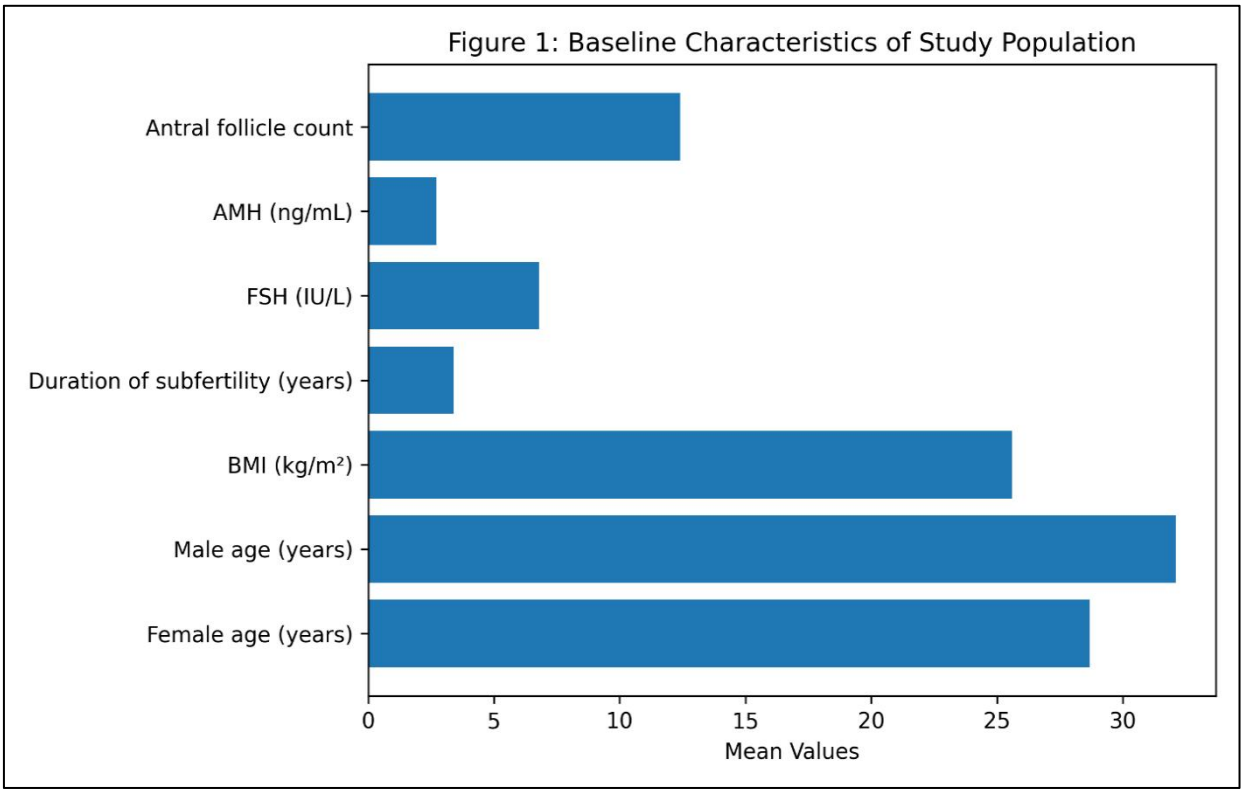

Figure 1: Baseline demographic and hormonal characteristics of couples undergoing intrauterine insemination for unexplained subfertility. Values represent mean measurements for the study population.

3.2 IUI Cycle Characteristics and Semen Parameters

The number of intrauterine insemination cycles analyzed was 240 during the period of the study. The percentage of natural cycle insemination was 26.7% and the percent of ovarian stimulation was 73.3% of the cycles. Letrozole, clomiphene citrate as well as gonadotropins were the commonest stimulated cycles used. In the 82.5% of ovulated cycles, Ovulation was induced by the use of human chorionic gonadotropin.

Table 2: IUI Cycle Characteristics and Semen Parameters

Parameter	Value
Total IUI cycles analyzed	240
Natural cycle IUI	64 (26.7%)
Stimulated cycle IUI	176 (73.3%)
Letrozole stimulation	108 (45.0%)
Clomiphene citrate stimulation	42 (17.5%)
Gonadotropin stimulation	26 (10.8%)
hCG trigger used	198 (82.5%)
Endometrial thickness (mm)	8.6 ± 1.4
Dominant follicles ≥18 mm	1.6 ± 0.7
Single follicle cycles	138 (57.5%)
Two follicle cycles	76 (31.7%)
≥3 follicle cycles	26 (10.8%)
Pre-wash TMSC (million)	42 (30–58)
Post-wash TMSC (million)	16 (10–24)

The average endometrial thickness at the time of insemination was 8.6275 +1.4 mm. The dominant follicles of at least 18 mm were 1.6 with a mean of 0.7. A single follicle was developed in 57.5% of the cycles, two follicles in 31.7, and three or more follicles in 10.8. The mean total number of motile sperms in pre-wash samples was 42 million, and the mean number of motile sperms in post-wash samples was 16 million, after the preparation of semen. **Table 2** contains a detailed description of cycle characteristics and semen parameters whereas **Figure 2** represents the distribution of stimulation protocol.

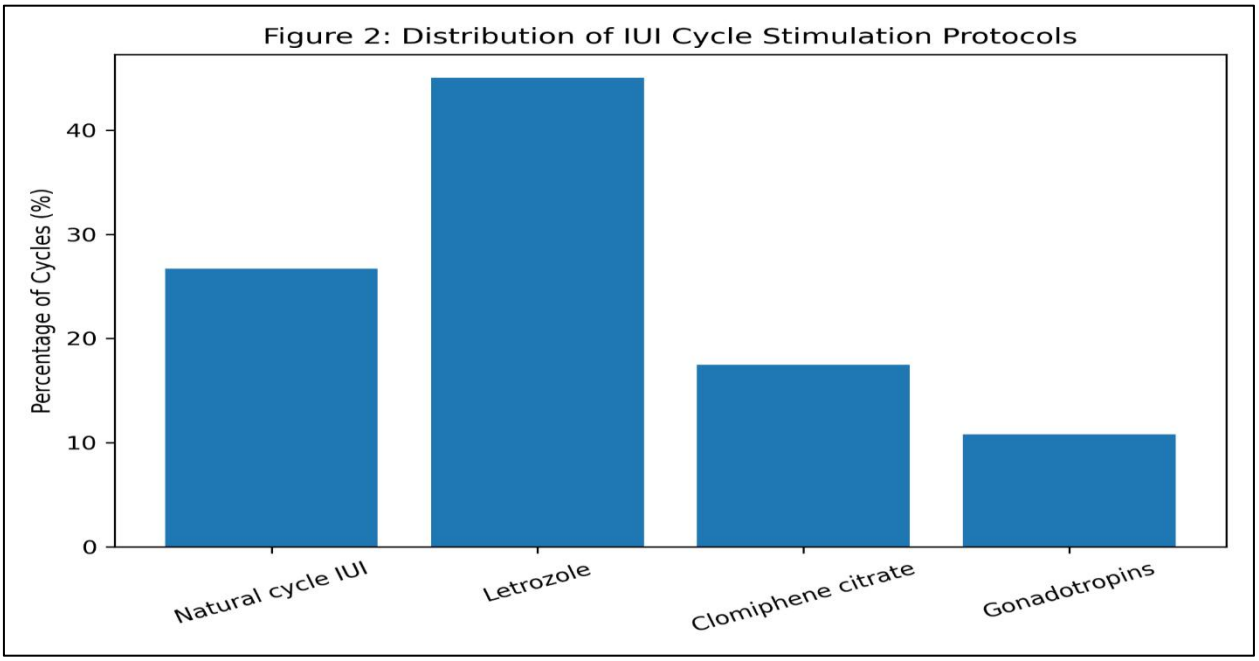

Figure 2: Distribution of intrauterine insemination cycles according to ovarian stimulation protocols, including natural cycles and pharmacologically stimulated cycles.

3.3 Clinical Outcomes of IUI Cycles

Pregnancy was obtained biochemically in 13.3% of the cycles and clinically in 10.8% of the cycles. Continued pregnancy after the 12th gestation week was noted in 9.2% of the cycles and live birth rate per cycle was 8.3%. Multiple pregnancy was found in 1.3 percent of the cycles and there was one ectopic pregnancy. Abnormal pregnancy terminations were 19.2 percent of the successful pregnancies and cycle termination was 5.8 percent of cycles.

Table 3: Clinical Outcomes of IUI

Outcome	Value
Biochemical pregnancy rate	32 (13.3%)
Clinical pregnancy rate	26 (10.8%)
Ongoing pregnancy ≥12 weeks	22 (9.2%)
Live birth rate	20 (8.3%)
Multiple pregnancy	3 (1.3%)
Ectopic pregnancy	1 (0.4%)
Miscarriage among pregnancies	5 (19.2%)
Cycle cancellation	14 (5.8%)
At least one pregnancy per couple	24 (20.0%)
At least one live birth per couple	19 (15.8%)

When results were measured by a per-couple measure, at least one pregnancy was realized by 20.0 percent of the couples, and at least one live birth was obtained in 15.8 percent of couples. **Table 3** presents detailed clinical outcomes of intrauterine insemination cycles and compares the outcome rates with each other, which is visualized in **Figure 3**.

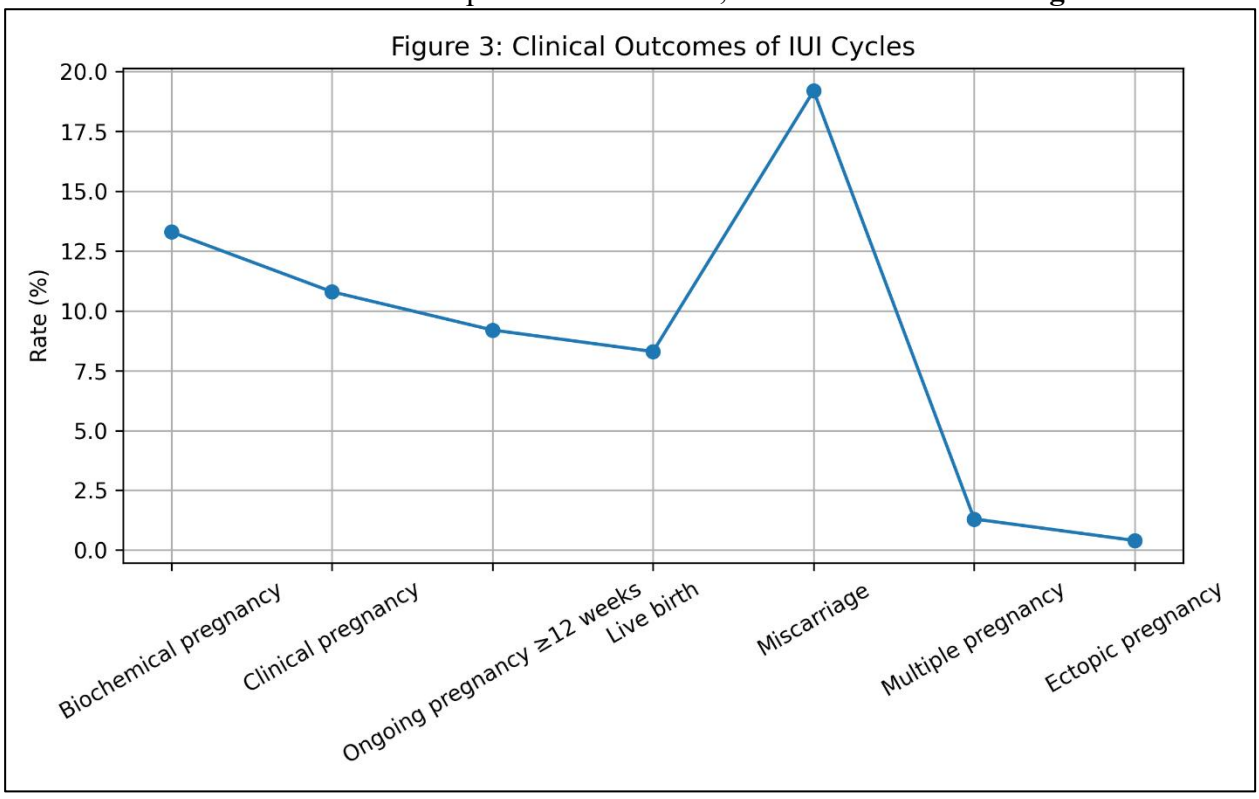

Figure 3: Clinical outcomes of intrauterine insemination cycles, expressed as percentage rates per cycle, including pregnancy outcomes and adverse events.

3.4 Pregnancy Rates According to Key Predictors

The area of clinical pregnancy rates was dependent on patient- and cycle-related traits. The pregnancy rates were greater among women below 30 years of age than those women who were 30 years or more. Likewise, the couples that had subfertile periods of less than three years had better pregnancy rates than those with longer periods. Thickness of endometrium of 8 mm and above was linked with increased pregnancy rates as compared to a thinner endometrium.

Table 4: Pregnancy Rates by Key Predictors (Per Cycle)

Predictor	Cycles (n)	Clinical Pregnancy n (%)	p-value
Age <30 years	142	20 (14.1%)	0.03
Age ≥30 years	98	6 (6.1%)	
Duration <3 years	106	15 (14.2%)	0.02
Duration ≥3 years	134	11 (8.2%)	
Endometrium ≥8 mm	158	21 (13.3%)	0.01
Endometrium <8 mm	82	5 (6.1%)	
Post-wash TMSC ≥10 million	171	23 (13.5%)	0.004
Post-wash TMSC <10 million	69	3 (4.3%)	
Two follicles	76	12 (15.8%)	0.04
One follicle	138	10 (7.2%)	
≥3 follicles	26	4 (15.4%)	0.18

The cycles with a post-wash total motile sperm count of at least 10 million had significantly high pregnancy rates when compared to cycles with low sperm count. Two-follicle cycles were found to have high pregnancy rates than one-follicle cycle, whereas those with three or more follicles did not show statistical significance. The stratified pregnancy rates with important predictors are presented in **Table 4** and summarized graphically in **Figure 4**.

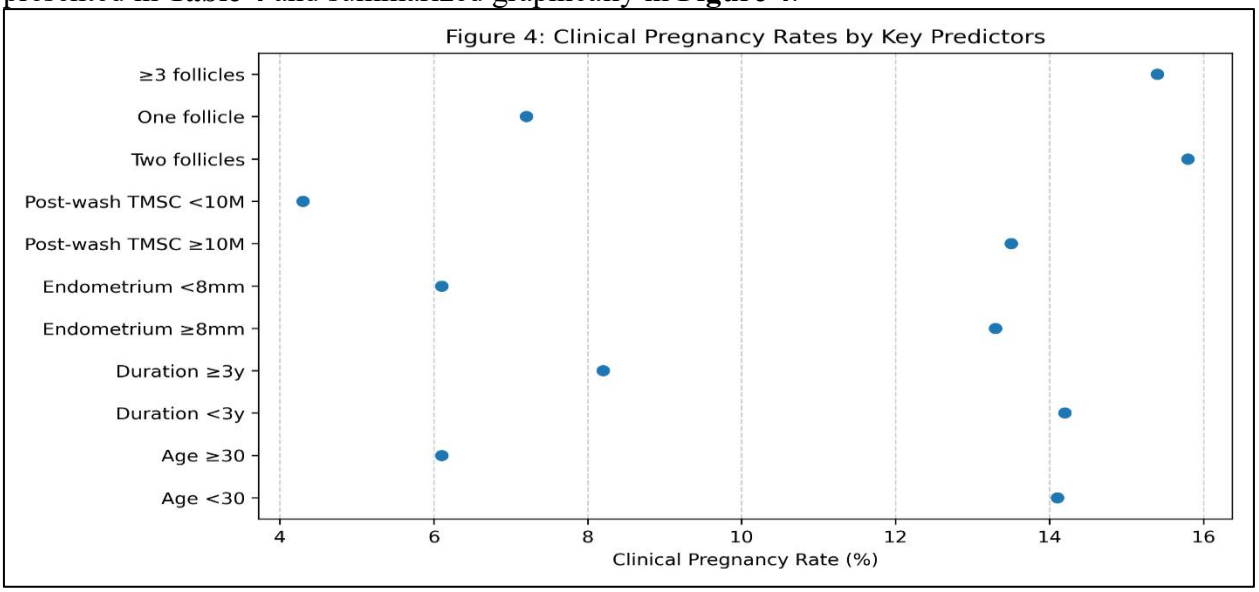

Figure 4: Clinical pregnancy rates per IUI cycle according to key patient- and cycle-related predictors, including age, duration of infertility, endometrial thickness, post-wash total motile sperm count, and number of dominant follicles.

3.5 Multivariable Logistic Regression Analysis

Multivariate logistic regression analysis showed that female age and infertility period were independent variables that were associated with a low likelihood of clinical pregnancy. Conversely, endometrial thickness of 8 mm and more and post-wash total motile sperm count of 10 million and above was independently linked with higher chances of clinical pregnancy.

Table 5: Multivariable Logistic Regression Predicting Clinical Pregnancy

Variable	Adjusted OR	95% CI	p-value
Female age (per year)	0.92	0.86–0.98	0.01
Duration of infertility (per year)	0.84	0.71–0.98	0.03
Endometrium ≥8 mm	2.21	1.03–4.77	0.04
Post-wash TMSC ≥10 million	3.05	1.22–7.62	0.02
Two follicles vs one	1.89	0.88–4.05	0.10
Gonadotropin stimulation	1.46	0.62–3.46	0.39

The independent association of both two-follicle development and gonadotropin stimulation was statistically not significant after adjusting the interaction with confounding variables. **Table 5** shows the results of the multivariate regression analysis and **Figure 5** shows the adjusted effect estimates.

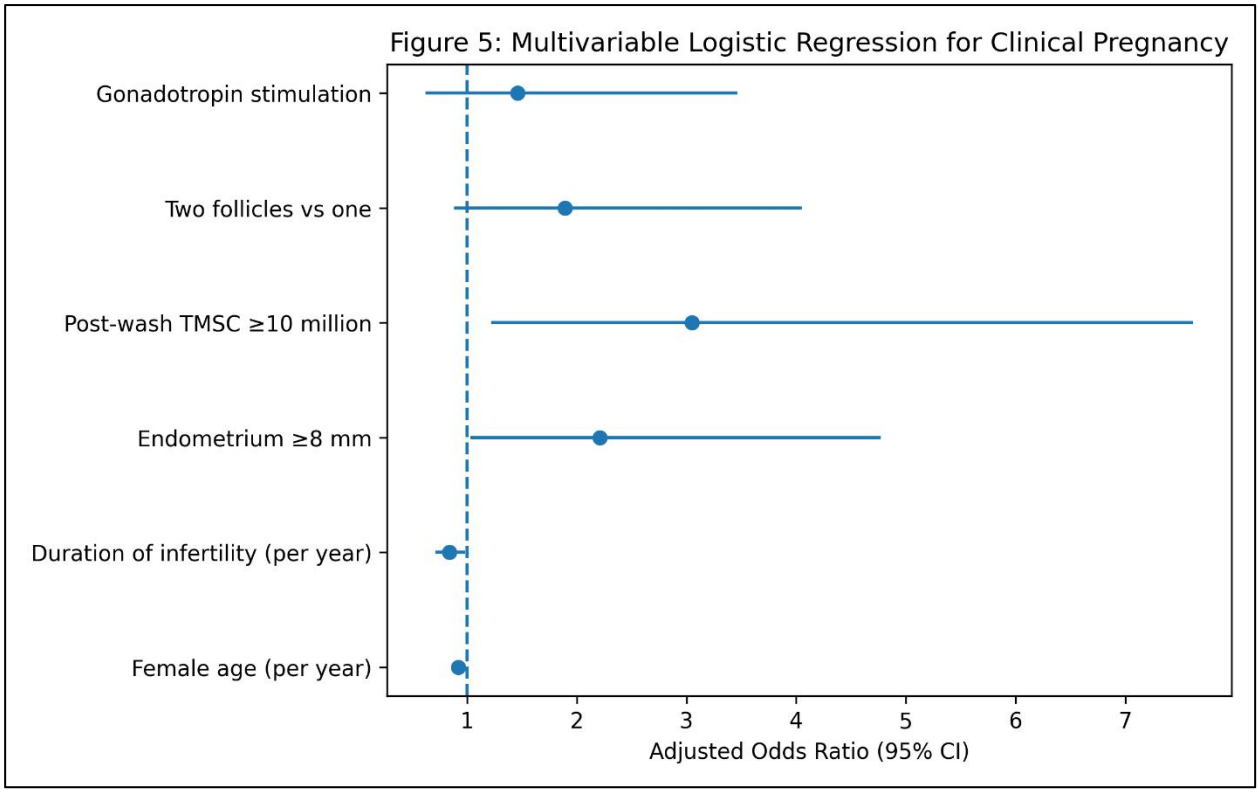

Figure 5: Forest plot showing adjusted odds ratios with 95% confidence intervals for factors associated with clinical pregnancy following intrauterine insemination in couples with unexplained subfertility.

4. Discussion

The current research has assessed the clinical efficacy of intrauterine insemination among couples with unexplained subfertility under the care of a tertiary care center and has shown that IUI could still be used as a first-line assisted reproductive treatment method in such groups of patients. The clinical pregnancy rate and the live birth rate per cycle are low to mid-range publications similar to those in the literature, which supports the idea that IUI provides small yet significant success in case of using it with properly selected couples (25). Such conclusions hold special importance in resource-restrained environments where the availability of such high-technology assistance reproductive technologies as in vitro fertilization could be limited. Female age was found to be a significant factor in IUI success as women of younger age proved to have the highest pregnancy rates and very low chances of treatment failure. This result is in line with established facts that associate the increasing age of the maternal body with deteriorating oocyte quality, diminished ovarian reserve, and diminished ovarian endometrial receptivity, all of which have adverse consequences on fertility outcomes (26). Results of the independent correlation between the rising age and the reduced pregnancy odds in the multivariate analysis further underscore the role of timely referral and intervention in the couples with unexplained infertility.

Infertility duration was also selected to be an independent negative predictor of clinical pregnancy. Those couples that had longer periods of subfertility had better pregnancy rates, which implied that the long-term infertility could be a sign of underlying dysfunctions of the reproductive system too subtle to be detected by the routine investigations (27). This finding confirms the existing guidelines that extended expectancy care in idiopathic infertility is not advisable especially in presence of other adverse prognosis factors. The day of insemination endometrial thickness showed a strong correlation with treatment success, where endometrial thickness showed independent predictability of clinical pregnancy. Improved endometrial development is essential in implantation and it has also been established in the past that a lack of endometrial thickness correlates with lower implantation and pregnancy rates in both IUI and IVF cycles (28). The current evidence supports the clinical significance of the endometrial assessment during the cycle monitoring process and potentially lead to the case-specific cycle optimization in patients with suboptimal endometrial response.

The number of total motile sperm count post-wash was one of the best independent predictors of pregnancy in this study. Post-wash sperm counts of 10 million or more indicated significantly higher pregnancy rates, which can be compared with previously documented literature that noted the events of pregnancy as being significantly dependent on sperm concentration and motility (21). It is a significantly important discovery of semen preparation methods and justifies the value of post-wash sperm parameters as a useful instrument of counseling couples on what to anticipate. There was a subtle correlation between follicular response and pregnancy results. Although the two-follicle cycles showed more pregnancy rates than the one-follicle cycles, the relationship could not be found to be statistically significant when all confounding factors were considered. This implies that follicle number increases which are modest could lead to the promotion of fertilization but will not act independently of

other factors in promoting success. Notably, the three or more follicle cycles failed to show any definite advantage, and it is necessary to weigh off ovarian response and the possibility of multiple gestation, which is a known side effect of stimulated IUI cycles (29).

The total rate of multiple pregnancy in this research was low which shows the practice of cautious stimulation and close monitoring of the cycles. This is in line with modern clinical methods to reduce treatment morbidity and still maintain the achievement of reasonable success rates (30). The miscarriage rate in achieved pregnancy was similar to the one in natural conception and assisted reproduction which indicated that IUI does not have an extra risk of premature loss of pregnancy in unexplained subfertility (31). The strengths of this study are that, a well-defined unexplained subfertility population has been used, both per-cycle and per-couple results have been evaluated and there has been multivariate analysis to determine independent predictors of success. But the retrospective nature makes causal inference difficult and the results can be subject to unmeasured confounding effects e.g. subtle ovulatory dysfunction or immunological aspects as are not readily measured. Also, the study was single-centered, which could be a limitation to generalization, but this design also contributes to internal consistency and the real-life practice of tertiary care (32).

Overall, this study findings suggest that intrauterine insemination can still be used as a suitable and efficient treatment of unexplained subfertile couples, especially young women with shorter infertility, developed endometria and a positive post-wash sperm profile. The findings have context-sensitive information to inform patient education and clinical decision-making in tertiary care units and emphasize the value of patient-centered treatment plans to maximize health outcomes.

5. Conclusion

To sum up, this research also indicates that intrauterine insemination is a successful and viable first-line intervention in the management of unexplained subfertility among couples that are under the care of tertiary care. Clinical pregnancy and live birth rates observed prove that a good outcome can be obtained with the help of IUI, especially in the right patients. The age of females and the years of infertility became significant negative predictors of success, thus the necessity to start the evaluation and early treatment. On the other hand, positive endometrial thickness and greater post-wash total motile sperm count showed a positive correlation with improved pregnancy outcomes, which clearly indicated the importance of close monitoring of the cycle and semen preparations. The findings indicate the need to counsel patients and plan their treatment individually and enable clinicians to establish realistic expectations and optimize IUI protocols according to prognostic factors. IUI could also be proposed to provide an inexpensive and less invasive option in resource limited healthcare systems where access to sophisticated assisted reproductive procedures might be limited before advanced procedures are instituted. In general, findings of this study will give context-focused evidence to make informed clinical decisions and endorse the further use of intrauterine insemination as a method of management of unexplained subfertility in tertiary care hospitals.

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