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Original Article

The Impact of Intrauterine Insemination Timing on Pregnancy Outcomes in Unexplained Infertility

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ABSTRACT

Objective: Currently, there is no consensus on the timing of intrauterine insemination (IUI). The aim of this study is to compare whether simultaneous, 24 hours later, or 36 hours later IUI after triggering with human chorionic gonadotropin (hCG) following ovulation induction influences clinical pregnancy outcomes.

Methods: This randomized controlled prospective study was conducted between December 2017 and December 2018 with 123 patients who applied to the infertility clinic for pregnancy demand and underwent IUI. All patients underwent basal ovarian testing and transvaginal ultrasonography for infertility assessment on days 2-4 of menstruation, hysterosalpingography (HSG) performed in the follicular phase, and semen analysis after 3-5 days of abstinence. Patients were categorized into three groups based on IUI timing, ensuring it did not fall on a weekend. Group 1 consisted of patients who underwent IUI on the same day as hCG-triggered ovulation, Group 2 included those who underwent IUI 24 hours after hCG trigger, and Group 3 comprised patients who underwent IUI 36 hours after hCG trigger.

Results: Data from 123 patients meeting the study criteria and a total of 198 cycles were analyzed. IUI was performed simultaneously with trigger in 48 cycles, 24 hours after trigger in 66 cycles, and 36 hours after trigger in 84 cycles. A total of 29 pregnancies (14.6%) were achieved out of 198 cycles, with a pregnancy success rate of 23.5% per patient. In Group 1, 9 pregnancies (18.8%) were achieved in 48 cycles, 9 pregnancies (13.6%) in Group 2 out of 66 cycles, and 11 pregnancies (13.1%) in Group 3 out of 84 cycles. There was no statistically significant difference in pregnancy success rates among the groups based on IUI timing after trigger (p=0.65).

Conclusion: There was no statistically significant effect of performing IUI simultaneously, 24 hours later, or 36 hours later after hCG trigger on clinical pregnancy outcomes.

INTRODUCTION

Infertility is defined as the inability to achieve clinical pregnancy after 12 months of regular, unprotected sexual intercourse.[1] Unexplained infertility occurs when, despite a complete evaluation, the inability to achieve pregnancy within 12 months cannot be associated with any known etiological factors.[2]

The management of couples with unexplained infertility should balance the effectiveness, cost, safety, and risks of various treatment alternatives. A common approach is to start with low-cost and patient-oriented treatments (such as lifestyle changes or timed intercourse) and progress proportionally to more costly treatments, such as clomiphene citrate (CC) plus intrauterine insemination (IUI). In cases where pregnancy is not achieved after three cycles of CC+IUI, in vitro fertilization (IVF) is recommended. IVF is a procedure that can yield high success rates, but it is also the most expensive treatment option.[3]

In the treatment of infertility, intrauterine insemination (IUI) is a significant step. IUI is considered one of the most commonly used treatment methods due to its lower cost, ease of application, and less invasiveness compared to other assisted reproductive techniques. It is often the initial treatment for infertility stemming from various conditions in both women and men, showing an acceptable success rate. IUI is commonly used in cases where at least one fallopian tube is patent. The success of IUI depends on a detailed evaluation of couples before treatment, considering factors that may affect IUI success in treatment planning.[4,5] Success rates for IUI vary, generally ranging from 5% to 15%.[6]

IUI is a widely used method to increase pregnancy success in infertile couples.[7] Controlled ovarian stimulation plus intrauterine insemination (COS+IUI) is an effective treatment in cases of cervical factors, unexplained infertility, and mild male factor infertility.[8] While Cochrane reviews suggest that single or double IUI does not make a difference in pregnancy outcomes, there is no consensus on the timing of IUI.[9,10] The success of IUI seems not to be affected by the technique of IUI or sperm preparation methods but using prepared sperm within approximately 1 hour is recommended.[11,12] However, there is controversy regarding the timing of IUI. Some studies have shown higher pregnancy rates when IUI is performed shortly after the beginning of LH surge-triggered by human chorionic gonadotropin (hCG).[13] Studies have compared IUI timing at 24-36 hours or 24-48 hours after hCG.[9,14] There are very few studies comparing IUI performed on the day of hCG trigger. This is the most significant feature that sets our study apart from similar studies in the literature.

This prospective randomized controlled study aims to compare the clinical pregnancy outcomes of intrauterine insemination performed simultaneously, 24 hours later, or 36 hours later following hCG trigger after ovulation induction with clomiphene citrate (CC), aromatase inhibitors (AI), or gonadotropins.

In comparing this effect, attention was paid to factors such as the patient's age, type of infertility, smoking status, presence of additional medical conditions, duration of infertility, and the choice of agents used for ovulation induction, which could vary.

MATERIALS AND METHODS

Our study was planned as a prospective randomized controlled trial at our hospital, in Department of Obstetrics and Gynecology.

The study was initiated with the approval of our hospital's Ethics Committee on December 26, 2017, with the approval number 2017/514/120/6. The principles stated in the Helsinki Declaration were adhered to in the study.

This study was conducted on 123 patients who applied to our infertility clinic between December 2017 and December 2018, seeking pregnancy through intrauterine insemination. Informed consents were obtained from the patients.

For the study, detailed anamnesis, including age, duration of infertility, height and weight, alcohol and cigarette use, weekly coitus frequency, total pregnancies, miscarriages, abortions, and ectopic pregnancies, detailed gynecological examinations, endometrial thickness and regularity on transvaginal ultrasound on the 2nd-4th day of the menstrual cycle, and cervical smears were obtained from all patients. Basal hormone levels, hysterosalpingography (HSG) taken in the follicular phase, and spouses' spermograms were also evaluated for all patients.

Patients were categorized into three groups:

Group 1 (control group): IUI performed 36 hours after ovulation trigger with hCG.

Group 2 (study group): IUI performed 24 hours after ovulation trigger with hCG.

Group 3 (study group): IUI performed on the same day as ovulation trigger with hCG.

As a result of this evaluation, women aged 20-37, with a body mass index (BMI) between 18-35 kg/m², experiencing unexplained infertility for at least 1 year, signing the informed voluntary consent form, having hormonal profiles desired on the 2nd-4th day of the menstrual cycle, normal cervical smear results, and no uterine anomalies, and couples with a total progressive motile sperm count (TPMSS) of over 10 million were included in the study.

Cases with thyroid hormone disorders, hyperprolactinemia, and other endocrine disorders, anovulatory cycles, tubal pathology in HSG, intrauterine adhesion, polyps, mullerian canal anomalies (T-shape uterus, uterus didelphys, etc.), and cases with uterine anomalies, as well as couples with TPMSS below 10 million, were not included in the study because they did not meet the criteria for unexplained infertility. Additionally, patients who underwent ovulation induction and had more than 2 follicles larger than 17mm were either canceled or referred to IVF.

Ovulation induction started after evaluating basal ultrasound control and basal hormone profile on the 2nd or 3rd day of menstruation. CC usage continued for 5 days at a dose between 50-150 mg/d as deemed appropriate. Letrozole was given at a dose of 2.5-5 mg daily on the 3rd-7th days. Gonadotropin dose started at 37.5-50-75-100 IU/d and continued until the trigger day. The ovulation induction dose was determined based on the patient's weight, age, basal ultrasound evaluation, and basal hormone levels. If 1 or 2 follicles ≥17mm were observed, hCG triggering was planned. Cycles with 3 follicles or more were either canceled or referred to IVF. On the day of hCG triggering, LH, progesterone, and estradiol were checked to rule out early ovulation. A value of 1.4 ng/ml was taken as the threshold for progesterone. LH>10 mIU/mL was considered the beginning of the LH peak. Ovulation triggering with Ovitrelle 250 subcutaneously was performed when appropriate follicle size was achieved. IUI was planned after 36 hours for patients whose hCG triggering coincided with Saturday, Sunday, Monday, Tuesday, and Wednesday, 24 hours later for patients whose hCG triggering coincided with Thursday, and on the same day for patients whose hCG triggering coincided with Friday. Prepared sperms were used for IUI within 1 hour. BHCG levels were checked on the 12th day after IUI. If BHCG was positive, patients were followed up weekly. Pregnancies with positive intracavitary fetal heartbeats were recorded during follow-ups.

All these examinations and procedures were performed under the supervision of the responsible specialist physician of the day at the Department of Obstetrics and Gynecology, Infertility Clinic.

All statistical analyses were performed using SPSS 20.0.

Continuous and categorical data were compared using T-test and chi-square test, respectively. Results with $p<0.05$ were considered statistically significant.

RESULTS

Our study included patients who applied to Department of Obstetrics and Gynecology, Infertility Clinic, between December 2017 and December 2018, with the desire for pregnancy and diagnosed with unexplained infertility based on the results of examinations.

Data from 123 patients and 198 cycles meeting the study criteria were analyzed. In 48 cycles, IUI was performed at 0 hours, in 66 cycles at 24 hours, and in 84 cycles at 36 hours after ovulation trigger. The mean age of the patients was determined as 28.6±4, with the youngest being 20 and the oldest 38. The average duration of infertility was found to be 2.9±1.5 years, ranging from 1 to 7 years. The average body mass index (BMI) was calculated as 24.4±3.4 (Table 1). The mean basal hormone values on the 2nd-5th day of menstruation for 198 cycles were as follows: FSH 7±1.5 IU, LH 6.2±2.9, estradiol 55±25.3, prolactin 14.4±5.8, and TSH 1.8±0.7. The average size of the dominant follicle obtained in 198 cycles was calculated as 19.2±2 mm. Out of 123 patients, 39 were smokers, and 84 were non-smokers. According to this, clomiphene was used in 131 cycles, gonadotropin in 59 cycles, and aromatase inhibitor in 8 cycles. IUI was performed with 1 follicle in 105 cycles and 2 follicles in 93 cycles.

Accordingly, IUI was performed at 36 hours for 84 patients, 24 hours for 66 patients, and 0 hours for 48 patients.

In our study, 29 pregnancies were achieved in 198 cycles, resulting in a pregnancy rate of 14.6%. When calculated based on the number of patients, the pregnancy success rate was 23.5%.

Regarding smoking habits in the groups formed according to IUI timing, 9 out of 32 individuals (28.1%) in the 1st group, 17 out of 42 individuals in the 2nd group, and 13 out of 49 individuals in the 3rd group were smokers. There was no significant difference in smoking rates among the three groups (p=0.319) (Table 2).

Considering the distribution of follicle numbers, in the 1st group, out of 48 cycles, 25 had 1 follicle, and 23 had 2 follicles. In the 2nd group, out of 66 cycles, 34 had 1 follicle, and 32 had 2 follicles. In the 3rd group, out of 84 cycles, 46 had 1 follicle, and 38 had 2 follicles. There was no significant difference in the distribution of follicle numbers among the groups (p=0.914) (Table 3).

Table 1. Demographic data of the patients

	n	Min-Max	Mean ± SD
Age	123	20-37	28.67±4.046
Duration of infertility (years)	123	1-7	2.90±1.5
BMI (kg/m^2)	123	18.1-34.2	24.44±3.48

Table 2. Smoking habits in the groups formed according to IUI timing

Timing of IUI (hour)	Smoking (n)	Non-Smoking (n)	Total
0 h	9	23	32
24 h	17	25	42
36 h	13	36	49
Total	39	84	123
	32%	68%	100.0%

Table 3. Distribution of follicle numbers

Timing of IUI (hour)	1 follicle (n)	2 follicles (n)	Total
0 h	9	23	32
24 h	17	25	42
36 h	13	36	49
Total	39	84	123
	32%	68%	100.0%

Table 4. The impact of intrauterine insemination (IUI) timing on pregnancy outcomes

Timing of IUI (hour)	Pregnant (n)	Non-Pregnant (n)	Total
0 h	39	9	48
	81.3%	18.8%	100.0%
24 h	57	9	66
	86.4%	13.6%	100.0%
36 h	73	11	84
	86.9%	13.1%	100.0%
Total	169	29	198
	85.4%	14.6%	100.0%

In terms of pregnancy outcomes, 9 pregnancies were achieved in 48 cycles in the 1st group, 9 pregnancies in 66 cycles in the 2nd group, and 11 pregnancies in 84 cycles in the 3rd group. When all groups were compared, it was observed that the timing of IUI did not significantly affect the success of pregnancy (p=0.65) (Table 4).

DISCUSSION

The study involved 123 patients with a total of 198 cycles of intrauterine insemination (IUI). The clinical pregnancy success rates obtained in the randomly created 0-hour, 24-hour, and 36-hour groups were 18.8%, 13.6%, and 13.1%, respectively. Statistically, no significant difference was observed among the three groups (p=0.65).

Due to the lack of a clear consensus on IUI timing, numerous studies have been conducted in the literature. In a retrospective study by Wang et al.[15] in 2006, including 135 couples with unexplained infertility, no significant difference was found in clinical pregnancy outcomes between IUI performed 24 hours and 36 hours after hCG administration.

In a study by Tonguç et al.[16] in 2010, aiming to find the correct timing, three groups were formed with IUI performed 24 hours, 36 hours, and 12 hours and 36 hours after hCG administration. The clinical pregnancy success rates in the three groups were 11.3%, 14%, and 17.2%, respectively, with no statistically significant differences among them.

Huang et al.[17] conducted a prospective study in 2000 with a different approach to timing. In one group, IUI was performed 26-28 hours after hCG administration, followed by coitus 12-18 hours later. In the other group, IUI was performed 36-38 hours after hCG administration, followed by coitus 12-18 hours later. No significant difference was found between the groups.

In a retrospective study by Robb et al.[18] in 2006, involving 182 couples with unexplained infertility undergoing clomiphene citrate-induced ovulation, no significant difference was found in clinical pregnancy outcomes between IUI performed 24 and 36 hours after hCG administration.

A retrospective cohort study by Yumusak et al.[13] in 2017 showed that when IUI+COS cycles were applied, different IUI timings were associated with pregnancy rates in specific infertile groups. The authors observed that early IUI (24 hours after hCG trigger) achieved a superior clinical pregnancy rate in couples with unexplained infertility compared to standard IUI (36 hours after hCG trigger). In the group where IUI was performed 24 hours after hCG administration, the clinical pregnancy success rate was 39.5%, while it was 18.7% in the group where IUI was performed 36 hours later, and the difference between the groups was significant (p=0.017). However, this significant difference was not reflected in polycystic ovary syndrome (PCOS) patients. The authors explained that in couples with unexplained infertility, the primary cause of unsuccessful pregnancy is fertilization defect. Therefore, early insemination in unexplained infertility couples increased the fertilization potential of sperm, leading to better pregnancy outcomes. The timing of IUI did not affect pregnancy outcomes in anovulatory PCOS patients.

The authors claimed that early IUI could increase sperm fertilization potential and attempted to validate their hypothesis by investigating whether early IUI would increase pregnancy rates in mild male infertility patients.[19]

On the contrary, a prospective randomized study by Rahman and colleagues provided contradictory data. In this study, 461 IUI+COS cycles were conducted, and 204 couples with mild male factor, unexplained infertility, and mild endometriosis were randomized into two groups: Group I (IUI 36 hours after hCG) and Group II (IUI 24 hours after hCG). The results showed that patients who underwent IUI 36 hours after hCG had marginally better pregnancy rates compared to the 24-hour group, although not statistically significant.[8]

A Cochrane meta-analysis, including 18 randomized controlled trials, examining 14 of them and involving 2279 couples, compared IUI timing 24 hours, 36 hours, and 48 hours after hCG trigger. Although the evidence levels of all studies were considered low or very low, no significant difference was found among these timings. However, it was emphasized that more randomized controlled trials are needed.[20]

We did not perform a statistical analysis of the distribution of pregnancy success rates according to ovulation induction methods. This can be mentioned as a notable limitation of the study.

Conclusion

Our study challenges established norms regarding the strict timing of IUI in unexplained infertility. The absence of a significant difference in pregnancy rates across different IUI timing groups calls for a reevaluation of clinical practices. A shift toward a more personalized, patient-centered approach, considering individual characteristics and responses, may be warranted. As we navigate the complexities of fertility treatments, ongoing research will refine our understanding and contribute to the evolution of evidence-based practices.

Ethics Committee Approval

The study was approved by the Kartal Dr. Lutfi Kırdar Training and Research Hospital's Ethics Committee (Date: 26.12.2017, Decision No: 2017/514/120/6).

Informed Consent

Retrospective study.

Peer-review

Externally peer-reviewed.

Authorship Contributions

Concept: M.G., I.G.; Design: M.G., I.G.; Supervision: M.G., I.G.; Fundings: M.G., I.G.; Materials: M.G., I.G.; Data collection &/or processing: M.G., I.G.; Analysis and/or interpretation: M.G., I.G.; Literature search: M.G., I.G.; Writing: M.G., I.G.; Critical review: M.G., I.G.

Conflict of Interest

None declared.

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Açıklanamayan İnfertilitede İntrauterin İnseminasyon Zamanlamasının Gebelik Sonuçlarına Etkisi

Amaç: Günümüzde intrauterin inseminasyonunun (IUI) zamanlaması konusunda net bir fikir birliği yoktur. Bu çalışmada, amacımız ovülasyon indüksiyonunu takiben *human chorionic gonadotropin* (hCG) ile yapılan tetikleme sonrası eş zamanlı, 24 saat sonra veya 36 saat sonra IUI'un yapılmasının klinik gebelik sonuçları üzerinde etkisi olup olmadığını karşılaştırmaktır.

Gereç ve Yöntem: Bu randomize kontrollü prospektif çalışma Aralık 2017- Aralık 2018 tarihleri arasında infertilite polikliniğine gebelik istemiyle müracaat eden ve intrauterin inseminasyon yapılan 123 hastayla yapıldı. Bütün hastalara infertilite değerlendirmesi için mensin 2-4. günleri bazal over testleri ve transvaginal ultrason, foliküler fazda çekilen histerosalpingografi (HSG) ve 3-5 günlük abstains sonrası spermiyogram yapıldı. Hastalar IUI zamanlaması hafta sonuna gelmeyecek şekilde 3 gruba kategorize edildi. Grup 1 hCG ile ovülasyon tetiklenmesi sonrası aynı gün IUI yapılanlar, Grup 2 hCG ile ovülasyon tetiklenmesinden 24 saat sonra IUI yapılanlar ve Grup 3 hCG ile ovülasyon tetiklenmesinden 36 saat sonra IUI yapılanlardan oluşturuldu.

Bulgular: Çalışma kriterlerine uygun olan 123 hasta ve onlara ait olan 198 siklusun verileri incelendi. 48 siklusta triger ile eş zamanlı, 66 siklusta trigerden 24 saat sonra ve 84 siklusta trigerden 36 saat sonra IUI yapıldı. 198 siklusta 29 (%14.6) gebelik elde edildi. Hasta sayısı üzerinden gebelik başarısı %23.5 olarak hesaplandı. Grup 1'de 48 siklusta 9 (%18.8), Grup 2'de 66 siklusta 9 (%13.6) ve Grup 3'te 84 siklusta 11 (%13.1) gebelik elde edildi. Gruplar triger sonrası IUI zamanlamasına göre gebelik başarısı açısından karşılaştırıldığında istatistiksel olarak bir fark olmadığı görüldü (p=0.65).

Sonuç: İntrauterin inseminasyonun, hCG ile tetikleme sonrası eş zamanlı, 24 saat sonra veya 36 saat sonra yapılmasının klinik gebelik sonuçları üzerinde istatistiksel olarak herhangi bir etkisi görülmemiştir.

Anahtar Sözcükler: İnfertilite; intrauterin inseminasyon; ovülasyon indüksiyonu.