

Evaluation of Controlled Ovarian Hyperstimulation Gonadotropin Stimulation and Clomiphene Citrate Stimulation Cycles in Infertile Women

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ABSTRACT

Objective: The aim of this study was to evaluate the success of intrauterine insemination (IUI) treatment, the factors affecting success, and current recommendations.

Methods: This study was conducted by retrospectively investigating 300 cycles of IUI treatment performed in 183 patients between 2005 and 2009. The results of a single IUI treatment session performed 32 to 36 hours after a dose of 10,000 units of chorionic gonadotropin was administered to patients with unexplained infertility were analyzed. The patients were aged between 19 and 42 years with a median follicle-stimulating hormone test result of 7.15 mIU/L, a total motile sperm count exceeding 5 million/mL, and a follicle size of at least 15 mm with treatment.

Results: The successful pregnancy rate with spontaneous coitus after clomiphene citrate (CC) treatment was 12.5% (13/104). The successful pregnancy rate with IUI after CC treatment was 11.7% (16/136), and the successful pregnancy rate with IUI after gonadotropin treatment was 23.4% (14/60). A total of 43/300 pregnancies were achieved and the overall success rate was 14.3%. When the results of the 43 pregnancies obtained were examined, 32 term pregnancies (10.7%) were achieved, there were 9 (3.0%) cases of abortus, 1 (0.7%) ectopic pregnancy, and 1 (0.7%) chemical pregnancy.

Conclusion: CC is still the best agent for first-line treatment in couples with unexplained infertility. In cases refractory to gonadotropins, IUI promotes clinical success. IUI has the advantages of low cost, easy applicability and accessibility, low morbidity, and a significant success rate.

INTRODUCTION

Infertility is still an important issue and it is a concern for nearly 10% of healthy couples.^[1] Important improvements have been achieved with the goal of solving infertility problems.^[2-5] Intrauterine insemination (IUI) is first among these treatment modalities.^[6]

Clomiphene citrate (CC) is one of the most frequently used drugs in IUI treatment. Worldwide, it is the most commonly used drug to stimulate ovulation.^[7] CC remains the first choice agent in the treatment of infertility in pa-

tients with anovulatory or normal ovulation but inadequate follicular and luteal development. In cases refractory to clomiphene citrate, gonadotropins are the most used second-line agents.^[8,9] Gonadotropins are used both in IUI and in in vitro fertilization (IVF).

The greatest advantages of IUI are its simplicity, easy applicability, low cost, and low morbidity rates.^[2] However, the rate of successful pregnancy obtained in IUI procedures performed with CC or gonadotropins differs in each clinic. Variations in application play a fundamental role in the achievement of success.

The objective of this study was to comparatively evaluate the success rate of one clinic and to analyze the relevant factors in the light of the literature.

MATERIAL AND METHODS

In this study, 300 cycles of IUI treatment for 183 patients who registered with the infertility clinic of the hospital were retrospectively evaluated.

Patients experiencing infertility for at least 1 year were enrolled in the study. Baseline infertility examinations (hormone analysis, spermograms, and gynecological examination) of the couples were performed. The patients were asked about age, gynecological and obstetric history, duration of infertility and the marriage, the presence of galactorrhea, family and personal medical history in the initial examination. Their medical history was also examined for previous abdominal surgeries, past or current presence of myoma, polycystic ovary syndrome, hyper- and hypothyroidism, hyperprolactinemia, cysts (endometriosis, ovarian, paraovarian cyst), hypogonadotropic hypogonadism, coagulation disorders (MTHFR enzymatic deficiencies), familial Mediterranean fever, and diabetes mellitus.

Hormonal analyses (thyroid-stimulating hormone, follicle-stimulating hormone [FSH], luteinizing hormone (LH), estradiol [E2], prolactin) and tests of fasting blood sugar and insulin were performed. Routine transvaginal ultrasound (TVUS), hysterosalpingography (HSG) and/or laparoscopy were performed. If an intrauterine lesion was detected as a result of these tests (polyp, myoma, septum, adhesion, etc.) a hysterectomy was performed, and if tubal occlusion, peritoneal adhesion, endometriosis, or adnexal mass was detected, laparoscopy was performed. If an intracavitary lesion, stage 3 or 4 endometriosis, and/or tubal adhesion were found as a result of laparoscopy and/or hysteroscopy, the patient was referred to the gynecology service for further tests and treatment. Patients with oligoanovulation, hyperprolactinemia, or hypothalamic amenorrhea were included in the ovulatory dysfunction group. Hyperprolactinemic patients were included in the study if their prolactin values returned to normal after medical treatment.

Semen analyses were performed to assess male fertility. After 3 to 5 days of abstinence, ejaculate was collected in a sterile container following masturbation, and the seminal parameters of liquefaction, warmth, volume, pH, viscosity, sperm count and motility, and morphology were evaluated according to the World Health Organization criteria (sperm count $>20 \times 10^6/\text{mL}$, total number of spermatozoa $>40 \times 10^6/\text{mL}$, and forward progression $>50\%$). Patients with normal or only slightly abnormal seminal parameters were included in the study. Sperm morphology and motility of less than 40% while the remainder of the seminal parameters were within normal limits was considered male

factor subfertility.^[10] IUI was performed using samples of semen prepared according to the swim-up method. While preparing the semen samples for IUI, the sperm count should be at least 1 million/mL before the washing process.

Three treatment protocols were used: CC+spontaneous coitus, CC+IUI, and gonadotropins+IUI. Before initiation of CC cycles, the patients underwent an US examination, and oral CC treatment was initiated on the fifth day of menstruation at once daily doses of 50 mg, and continued for 5 days. Both spontaneous coitus and IUI cycles were monitored. After IUI, human chorionic gonadotropin (HCG) treatment was administered. TVUS-guided folliculometry was performed. If the patient had at least 1 follicle with a diameter of at least 22 mm detected during a CC cycle, she was given 10,000 IU HCG, and 32 to 36 hours later, a single session of artificial insemination was performed. Sexual intercourse on alternate days was recommended for patients on the spontaneous coitus protocol who had at least 1 follicle with a minimum diameter of 22 mm.

The patients included in the gonadotropin stimulation group were evaluated based on the number of antral follicles detected with US as well as FSH and E2 values on the third day of the menstrual cycle. Individually adjusted doses of HCG were administered, and on specific days according to the response, the patients underwent a follow-up TVUS at intervals of at most 3 days. In the presence of at least 1 dominant follicle larger than 10 mm in size, the patient was given 1000 IU HCG and insemination was planned 34 to 36 hours later.

Measurements with TVUS were performed at the level of the corpus uteri on a longitudinal plane. The dominant follicle was defined as an ovular follicle of at least 18 mm in diameter in the gonadotropin cycle and 22 mm in the CC cycle. Clinical pregnancy was defined as a pregnancy in which a gestational sac was visualized on TVUS at 4 weeks accompanied by beta HCG values of 1000–2000 IU.

Pregnancies in which the beta HCG value was positive without the visualization of a gestational sac on TVUS were considered chemical pregnancies. Pregnant women who developed cardiac problems were monitored in the risky pregnancy polyclinic.

Statistical analyses were performed using SPSS for Windows, Version 13.0 (SPSS Inc., Chicago, IL, USA). Arithmetical means were used to evaluate the distribution pattern of variables in each group, and SD was employed to measure the dispersion of values relative to the mean. Data were expressed as mean \pm SD.

RESULTS

A total of 183 patients were retrospectively evaluated during 300 ovulation cycles. CC was administered in 240

cycles, and gonadotropin treatment was used in 60 cycles. A total of 43 pregnancies were achieved.

The mean age of the patients was 27.41 ± 4.85 years (min: 19, max: 42 years). The mean length of infertility was 46.66 ± 34.63 months (min: 9, max: 204 months). The couples had been married for a mean period of 64.88 ± 47.87 months (min: 12, max: 240 months). Most ($n=137$, 74.8%) were instances of primary infertility, while 25.1% ($n=46$) were cases of secondary infertility. The mean sperm count was 67.22 ± 49.25 million/mL (min: 2.40, max: 248.0 million/mL) and the mean sperm motility was 58.19% (min: 5.0%, max: 96.6%).

The medical history of 121 (66.1%) patients was unremarkable. There were 10 cases of polycystic ovary syndrome (5.5%), 8 cases of hypothyroidism (4.4%), 3 cases of ovarian cyst (1.6%), 5 cases of hyperprolactinemia (2.7%), and 1 case each (0.5%) of hypogonadotropic hypogonadism, diabetes mellitus, and myoma. In addition, 28 patients had a history of an operation. HSG examinations revealed the presence of a uterine septum in 6 (3.3%) patients. Radiological examinations did not disclose any evidence of a polyp (Table 1).

The patients began the spontaneous coitus protocol following 104 cycles (34.7%) of CC, and IUI was implemented after 136 (45.3%) cycles of CC or 60 (20%) cycles of gonadotropin treatment. A total of 300 cycles of treatment were administered (Table 2). The outcome of the total of 300 cycles was pregnancy in 43 (14.3%) cycles and no pregnancy in 257 (85.7%) cycles (Table 3).

Successful pregnancies were seen in 13 (4.3%) cycles who were included in the spontaneous coitus protocol following CC stimulation and in 16 (5.3%) IUI cycles. In the gonadotropin and IUI treatment group, there were 14 (4.7%) cycles leading to successful pregnancies. In all, 43 pregnancies were achieved, a success rate of 14.3% (Table 4).

Table 1. Characteristics of the patients' medical histories

Patients	n	%
Unremarkable	121	66.1
Polycystic ovary syndrome	10	5.5
Surgery	28	15.3
Hypothyroidism	8	4.4
Ovarian cyst	3	1.6
Hyperprolactinemia	5	2.7
Hypogonadotropic hypogonadism	1	0.5
Coagulopathies	4	2.2
Familial Mediterranean fever	1	0.5
Diabetes mellitus	1	0.5
Myoma	1	0.5
Total	183	100

Table 2. The type and number of treatment cycles

Treatment protocol	Number of cycles	%
CC + Spontaneous coitus	104	34.7
CC + IUI	136	45.3
Gonadotropin + IUI	60	20.0
Total	300	100

CC: Clomiphene citrate; IUI: Intrauterine insemination.

Table 3. Number of cycles and pregnancy rates

Pregnancy	Number of cycles	%
No	257	85.7
Yes	43	14.3
Total	300	100

Table 4. Pregnancy rate based on treatment modality

Pregnancy rates	Number of cycles	%
CC + Spontaneous coitus	13	4.3
CC + IUI	16	5.3
Gonadotropin + IUI	14	4.7
Total	43	14.3

CC: Clomiphene citrate; IUI: Intrauterine insemination.

The rates of successful pregnancy was also analyzed based on the type of treatments. CC stimulation followed by spontaneous coitus had a success rate of 13/104 (12.5%), IUI after CC treatment yielded 16/136 (11.7%), and IUI after gonadotropin treatment achieved a successful pregnancy in 14/60 (23.4%) cases.

The outcomes of the 43 pregnancies achieved were 32 term pregnancies (10.7%), 9 miscarriages (3.0%), 1 ectopic pregnancy (0.7%), and 1 chemical pregnancy (0.7%).

DISCUSSION

IUI, CC, and gonadotropin are still the subject of much discussion in the treatment of infertility. The global success rates of these procedures are a matter of interest. There are investigations indicating diverse rates of success rates and lack of any success.^[9]

In research concerning IUI success rates, the potential impact of a patient's history on success, the effects of hormonal factors on fertility, the effect of primary/secondary infertility, the choice of the catheter used for IUI, the follicle diameter suitable for ovulation, the number of follicles

required, the timing of HCG therapy, the interval after HCG treatment which is appropriate for the application of IUI, the effect of holding the cervix with a tenaculum forceps during the procedure, the decision to continue medical therapy after the procedure, the application of IUI twice within the same cycle, and sperm parameters have been frequently raised issues.

Significant increases in clinical success have been observed when all these variables were performed with the appropriate techniques, and the effects of careful attention to treatment have been demonstrated in many clinical trials.^[10-13]

Each clinic has its own success rates. We evaluated the success rate in CC+spontaneous coitus, CC+IUI, and gonadotropin+IUI groups.

Sikandar et al.^[10] evaluated 290 IUI procedures. They found a pregnancy rate per cycle of 10%, a 13.8% incidence of abortus, and an 8.6% rate of ongoing pregnancy in patients aged between 20 and 44 years with unexplained infertility and follicles with a diameter of at least 16 mm. As a result, they indicated that young individuals, those with mature follicles of a diameter over 16 mm, and a sperm count of more than 10 million/mL had a greater chance of obtaining successful results. They also stated that pregnancy rates per cycle did not demonstrate significant changes between controlled ovarian stimulation regimens. Although their pregnancy rate per cycle was slightly lower than those reported in the literature, it is noteworthy that their rate of abortus was higher than ours. However, it should not be forgotten that the risk of miscarriage ranges between 10% and 15% even in normal, spontaneous pregnancies.

Demiroglu et al.^[8] retrospectively investigated the records of 241 patients with unexplained infertility. They compared follitropin alfa (n=81) urinary FSH (n=80), and HCG (n=80) groups, and determined a clinical pregnancy rate of 25.9%, 13.8%, and 12.5%, respectively. A relatively greater number of follicles with a diameter over 16 mm were detected in the FSH group, and it was noted that lower drug doses were used in this group. The authors concluded that FSH provided better results. When our clinical success rate for IUI procedures per cycle using gonadotropins was assessed, gonadotropins appeared to be more effective than CC (14/60, 23.4% vs 16/136, 11.7%).

Zafar et al.^[11] investigated 89 infertile couples. A total of 205 cycles of IUI procedures were performed in patients having follicles with a diameter ranging between 18 and 22 mm, and 31 pregnancies were achieved. As a result of their investigation, they indicated that IUI may be a valuable procedure in young patients with a shorter duration of infertility and unexplained subfertility.

Ahinko-Hakamaa et al.^[12] retrospectively investigated 1171 cycles of CC and HCG treatments in 532 infertile couples, and estimated a pregnancy rate per cycle of 19.2%, adding

that the patient's age, number of follicles, the protocol applied, and the number of inseminated motile spermatozoa were significant factors.

Steures et al.^[13] performed a large-scale study in Holland analyzing the pregnancy rate achieved with IUI. They determined a pregnancy rate per cycle of 9%, of which 7.3% were ongoing.

In the international literature, the pregnancy rate per cycle has been expressed as 8.7%. In our clinic, 32 term pregnancies were achieved with a success rate of 10.7%.

Hughes et al.^[9] investigated the efficacy of CC and reviewed 7 publications on randomized controlled studies. They analyzed the pregnancy outcomes of 1159 participants, and did not find that CC was superior in terms of live births when compared with untreated patients and a placebo group. (Odds ratio: 0.79, 95% confidence interval: 0.45 vs 1.38; p=0.41) No difference in clinical pregnancy rate was observed between IUI patients, and non-IUI patients, and only HCG patients. As an outcome of their investigation, they indicated that the use of CC in infertility did not confer any clinical benefit in unexplained infertility. Of course, this article contradicts the arguments of many other publications.

Yousefi et al.^[14] investigated the success rate of IUI in 26 infertile couples with an infertility history of more than 10 years. They achieved pregnancy in 7 couples (27%) after treatment.

Chung et al.^[15] researched the pregnancy rate achieved with IUI in 340 patients, and aimed to determine the ideal stimulation protocols for an acceptable rate of pregnancy and a lower rate of multiple pregnancies. They treated 203 patients with daily doses of 150 IU FSH, and 137 cases with 100 IU FSH plus 100 mg CC, and determined a pregnancy rate of 14.8% (30/203) and 20.4% (28/203), respectively. As a result, they reported that combined use of lower doses of FSH and CC not only ensured cost-effectiveness, but also prevented multiple pregnancies with a high level of satisfaction.

Almeida et al.^[6] investigated 220 IUI cycles in 139 couples and found a pregnancy rate per cycle of 18.6% with 5 twin pregnancies among 41 clinical pregnancies. The pregnancy rate with the use of CC was 13%, with gonadotropins it was 26.1%, and CC with gonadotropins yielded a rate of 28.6%. A statistically significant difference in the clinical pregnancy rate was noted with the use of CC and gonadotropin. It has been also indicated that IUI is still the first-line treatment in selected infertility cases, and gonadotropins significantly increase pregnancy rates. These evaluations also coincide with our clinical success rates and conclusions.

Jasović et al.^[2] performed 97 cycles of IUI with HCG and HCG induction for 50 couples with unexplained infertility,

and achieved 9 (18%) singleton pregnancies. They stated that it was an effective, inexpensive, and safe treatment.

M Isa et al.^[3] investigated IUI treatments in 296 women, and compared the success rates achieved with HCG and FSH. They found a significantly higher pregnancy rate was obtained with FSH, 13.28%, compared with 7.14% for HCG.

Leanza et al.^[16] used CC (n=34) and a multivitamin (n=34) as a placebo in 68 patients with unexplained infertility. Based on IUI outcomes, they reported the development of 15 (44.1%) pregnancies with CC and 4 (11.7%) among the multivitamin patients. The pregnancy rates in this research are much higher than those reported in most of the literature. However, the use of CC is considerably more successful than a multivitamin placebo.

Panda et al.^[17] investigated the outcomes of IUI in 300 infertile couples and reported an IUI success rate of 17.3% in patients aged 20 to 39 years with follicles ≥ 15 mm, an LH value < 10 mIU/L, and an endometrial thickness > 5 mm on the 10th day posttreatment with a total motile sperm count > 5 million/mL

Farland et al.^[7] investigated the treatment outcomes of 10,031 patients who had undergone treatment for their infertility between the years 1993 and 2009. They reported that 94% of the women had used CC and 73% of them had received CC stimulation therapy. Thirteen percent of these patients had received only gonadotropin injections, and 11% of them were in IVF treatment. As in our clinic, CC is still the most frequently used infertility treatment agent in our country and worldwide.

Aanesen et al.^[4] investigated the outcomes of 380 infertile couples. In 43 patients (11.3%) spontaneous pregnancy developed, while pregnancy was determined following IUI in 64 (14.5%), controlled ovarian hyperstimulation and ovulation induction led to 16 (4.2%), and 113 (28.4%) were observed in IVF. There were 280 pregnancies and 58 spontaneous abortions (22.3%) in the group.

Xu et al.^[5] retrospectively investigated 5167 IUI cycles in China and detected a pregnancy rate of 12.8% per cycle.

In our investigation, the outcomes of 300 treatment cycles in 183 patients were evaluated. A total of 43 pregnancies (14.3%) were achieved after CC+spontaneous coitus (n=13; 12.5%), CC+IUI (n=16; 11.7%), and gonadotropin therapy (n=14; 23.4%).

In a comparison of general success rates, the success of IUI and of individual drug treatments, and overall or per cycle CC and gonadotropin, our results are consistent with those of the literature. We observe that IUI application techniques, application criteria, patient and drug selection, and drug protocols have not changed significantly in worldwide routine practice.

Conclusion

CC is still an ideal first-line treatment for couples with infertility of unknown etiology. In refractory cases, gonadotropins combined with IUI increase clinical success. The low cost, low morbidity, easy applicability, accessibility, and significant success rates of IUI procedures means that they are still a preferred initial treatment.

Ethics Committee Approval

Ethics committee approved.

Informed Consent

Retrospective study.

Peer-review

Internally peer-reviewed.

Authorship Contributions

Concept: Y.O., B.K.; Design: Y.O., B.K.; Data collection &/ or processing: Y.O., O.S.; Analysis and/or interpretation: Y.O., B.K.; Literature search: O.S.; E.E.S.; Writing: O.S., E.E.S.; Critical review: O.S., E.E.S.

Conflict of Interest

None declared.

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Kontrollü Overyan Hiperstimülasyonu Uygulanan İnfertil Olgularda Klomifen Sitratlı Stimülasyon İle Gonadotropinli Stimülasyon Sikluslarının Değerlendirilmesi

Amaç: Amacımız günümüzde intrauterin inseminasyon (İÜ) tedavisinin başarısını, başarıyı etkileyen faktörleri ve güncel önerileri incelemektir.

Gereç ve Yöntem: Bu çalışma hastanemizde 2005–2009 tarihleri arasında 183 hastanın 300 siklus tedavisi geriye dönük olarak incelenerek yapıldı. Hastalar 19–42 yaş arası, açıklanamayan infertilitesi olan, FSH değeri ortalama 7.15 mIU/L olan, total hareketli sperm sayısı 5 milyon/mL üzerinde olanlarda, tedavi ile follikül boyutu 15 mm üzerinde olan, HCG dozu 10.000 ünite sonrası 32–36 saat sonra tek seans İÜ tedavisinin başarısı ve sonuçları geriye dönük olarak incelendi.

Bulgular: Hastalara klomifen sitrat sonrası spontan koit tedavisi ile başarılı gebelik 13/104 (%12.5), klomifen sitrat sonrası İÜ tedavisi ile başarılı gebelik 16/136 (%11.7), gonadotropin tedavisi sonrası İÜ işlemi ile başarılı gebelik 14/60 (%23.4) olarak belirlendi. Toplamda 43/300 gebelik sağlanmış olup başarı oranı %14.3 idi. Elde edilen 43 gebeliğin sonuçları incelendiğinde 32 term gebelik (%10.7) abortus gerçekleşen 9 (%3.0), ektopik gebelik 1 (%0.7) ve kimyasal gebelik 1 (%0.7) olarak belirlendi.

Sonuç: Klomifen sitrat nedeni bilinmeyen infertil çiftlerde halen ilk basamak tedavi için ideal bir ajandır. Cevap alınamayanlarda gonadotropinler ile İÜ klinik başarıyı artırmaktadır. İntrauterin inseminasyon işlemleri; düşük maliyeti, kolay uygulanabilirliği, kolay ulaşılabilirliği, düşük morbiditesi ve anlamlı başarısı ile infertil çiftlerde ilk basamak tedavide öncelikli uygulanması gereken yöntem olarak yerini korumaktadır.

Anahtar Sözcükler: Açıklanamayan infertilite; gebelik oranları; intrauterin inseminasyon.