



Long GnRH Agonist versus GnRH Antagonist Protocols in Women with Endometrioma and Good Ovarian Reserve Undergoing IVF/ICSI Cycles

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Abstract

Background: The best ovarian stimulation protocol in the case of endometrioma-related infertility is still debated. In this study, we examined the effect of two ovarian stimulation protocols on in vitro fertilization (IVF)/intra-cytoplasmic sperm injection (ICSI) outcome in patients with good ovarian reserve suffering from endometrioma.

Methods: In a retrospective study, 101 women with endometrioma and good ovarian reserve were recruited. Women received either gonadotropin-releasing hormone (GnRH) agonists (n=65) or GnRH antagonists (n=36) in an IVF or ICSI cycle. Clinical and chemical pregnancy rate, live birth rate, implantation rate, fertilization rate and fertilization proportion, as well as miscarriage rate, were evaluated in both groups.

Results: Chemical (25% vs. 28.6%), clinical (19.6% vs. 25%), and live birth rates (19.6% vs. 25%) as well as implantation rate (11.7% vs. 15%) were not significantly different between the two groups. Miscarriage rate, fertilization rate and fertilization proportion were similar in the two groups.

Conclusion: GnRH antagonist protocol with the main advantages of short duration and lower cost of treatment could be applied in infertile patients with endometrioma and good ovarian reserve.

Keywords: Endometrioma, Controlled ovarian hyperstimulation, GnRH-agonist, GnRH-antagonist, ART

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Introduction

Endometriosis is a condition in which the endometrial-like tissue grows outside the uterus and affects 2% to 10% of women of reproductive age, and up to 50% of infertile women (1). Approximately 17% to 44% of women with endometriosis have been diagnosed as endometrioma (2). The best treatment approach in cases of endometriosis-related infertility is still debated and not well established. In vitro fertilization (IVF) or intra-cytoplasmic sperm injection (ICSI) are introduced as efficient methods for these patients with or without surgery (3). On the other hand, controlled ovarian hyperstimulation (COH) is the main part of an IVF/ICSI cycle. The efficacy of the most two common COH protocols, the gonadotropin-releasing hormone (GnRH) agonists and the lately developed one (GnRH antagonists), is still under debate in women with endometriosis (4).

Some studies indicated that both GnRH agonist and GnRH antagonist protocols have a similar effect on IVF outcome in patients with endometriosis (5,6) and endometrioma (7). However, using long GnRH

agonists may result in a higher number of embryos (5). Nevertheless, the others stated that a long period of GnRH agonist administration prior to conventional IVF could significantly increase clinical and ongoing pregnancy rates as well as live birth among women with endometriosis (8-10). As the trend is toward modified therapy based on the patients' characteristics, individualizing of ovarian stimulation in women with endometriosis-related infertility could improve IVF/ICSI outcome. Therefore in this study, we examined the effect of two ovarian stimulation protocols on IVF/ICSI outcome in patients with good ovarian reserve suffering from endometrioma.

Materials and Methods

This retrospective cohort study was directed at Yazd Reproductive Sciences Institute between February 2018 and February 2020.

Subjects

We reviewed the hospital-based records of 101



women with endometrioma and good ovarian reserve undergoing a COH protocol consecutively. Women with confirmed endometrioma and good ovarian reserve undergoing agonist or antagonist ovarian stimulation protocol were included in the study. Endometrioma was diagnosed based on history and physical investigation, transvaginal ultrasound examination, and confirmed by magnetic resonance imaging (MRI) and/or laparoscopy surgery (11). Ovarian reserve was determined by the antral follicle count (AFC) on day 3 of the cycle using transvaginal ultrasound and serum anti-Mullerian hormone (AMH) levels. We considered an $AFC > 5$ or $1.1 < AMH < 3.5$ ng/mL as a normal ovarian reserve (12). The exclusion criteria were the history of endocrine dysfunctions such as diabetes mellitus, thyroid disorders, hyperprolactinemia, polycystic ovary syndrome, congenital adrenal hyperplasia, Cushing syndrome along with congenital uterine anomalies and azoospermia.

Ovarian stimulation protocols

Women received either GnRH agonists ($n=65$) or GnRH antagonists ($n=36$) in an IVF or ICSI cycle. In long agonist group, women received 3.75 mg GnRH analogue (Leuprolide acetate Lupron®, Abbvie, Inc., Chicago, IL, USA) for three intramuscular injections every 28 days (13). Fifteen days after the last injection, ovarian stimulation was started with 150-300 IU of human recombinant follicle-stimulating hormone, rFSH (Gonal-F, Serono, Aubonne, Switzerland). Women were monitored by serial vaginal ultrasonography. Ovarian stimulation was started in the antagonist group from the second day of the menstrual cycle with 150 to 300 IU of human rFSH (Gonal-F, Serono, Aubonne, Switzerland) monitored by serial vaginal ultrasonography. Once the dominant follicles reached the 14 mm in mean diameter, 0.25 mg of GnRH antagonist (Cetrotide, Serono, Aubonne, Switzerland) per day was administered and continued until the day of oocyte triggering (14). In both groups, when at least two follicles with a mean diameter of 17 mm or one dominant follicle > 18 mm were observed, 10000 IU human chorionic gonadotropin (hCG) (Pregnyl, Organon, Netherland) was injected. Endometrial thickness and serum E2 levels were measured for all of the patients on the day of hCG injection.

Outcome parameters

Chemical pregnancy was confirmed by the serum β hCG positive test two weeks after the embryo transfer. Also, clinical pregnancy was approved by detecting fetal heartbeats in ultrasonography two weeks following the positive β hCG. Losing pregnancy prior to the 20th week of gestation was considered as miscarriage. Implantation rate was defined as the percentage of gestational sacs per transferred embryos. Oocyte maturity rate was determined using the number of metaphase II (MII)

oocytes divided into the number of oocytes retrieved. Fertilization proportion was explained as the number of 2 pronuclear (2PNs) divided by the number of oocytes retrieved and fertilization rate was the ratio of the number of 2PNs over the total number of MII oocytes (15,16).

Statistical analysis

The Statistical Package for the Social Science version 20 for Windows (SPSS Inc, Chicago, IL, USA) was applied for data analysis. Differences between continuous variables with and without normal distribution were compared using Student t-test and Mann-Whitney U test respectively. The chi-square test was used to analyze categorical variables. Data are presented as mean \pm SD and number (%) for continues and categorical variables respectively. $P < 0.05$ was considered as the significant level in this study.

Results

Patients' basal characteristics for both groups were shown in Table 1. Age, duration of infertility, body mass index (BMI), AMH level, and endometrial thickness were similar between groups. Although, the total gonadotropin dose was significantly different in the two groups ($P=0.000$), duration of stimulation, serum estradiol level on the day of trigger, number of total follicles on the day of trigger, and number of retrieved oocytes, as well as the number of MII oocytes and 2PNs, were not significantly different in comparison of the two groups. The number of transferred embryos was significantly higher in the GnRH antagonist group ($P=0.023$); however, the quality of the transferred embryos was similar in both groups (Table 2). The treatment cycles of 8 women in the antagonist group and 9 women in the agonist group were canceled due to the risk of ovarian hyperstimulation syndrome or lack of embryo formation. Therefore, 56 women in the agonist group and 28 women in the antagonist group were finally analyzed for IVF/ICSI outcome. Oocyte maturity rate (0.96 ± 0.13 vs. 0.94 ± 0.12), fertilization proportion (0.59 ± 0.25 vs. 0.57 ± 0.23) and fertilization rate (0.62 ± 0.25 vs. 0.61 ± 0.24) were comparable between

Table 1. Baseline characteristics of GnRH-agonist group versus GnRH-antagonist group

Variables	GnRH-agonist (n=65)	GnRH-antagonist (n=36)	P value
Age (year)	31.36 \pm 4.19	29.77 \pm 5.24	0.099 ^a
BMI (kg/m ²)	23.14 \pm 2.14	23.45 \pm 2.63	0.516 ^a
Duration of infertility (year)	5.51 \pm 4.01	5.09 \pm 3.53	0.664 ^b
AMH (ng/mL)	2.20 \pm 0.82	2.59 \pm 1.20	0.161 ^b
Endometrial thickness (mm)	9.34 \pm 1.10	9.28 \pm 1.33	0.435 ^b

Δ GnRH, Gonadotropin-releasing hormone; BMI, Body mass index; AMH, Anti Mullerian hormone.

Note: Data are presented as mean \pm SD. "GnRH-agonist" group versus "GnRH-antagonist" group using ^a Independent samples t-test; ^b Mann-Whitney U test.

Table 2. ART cycle characteristics of GnRH-agonist group versus GnRH-antagonist group

Variables	GnRH-agonist (n = 65)	GnRH-antagonist (n = 36)	P value
Total gonadotropin dose (IU)	2804.46±854.61	1896.42±535.74	0.000 ^a
No. of days of stimulation	14.67±2.31	14.02±2.07	0.177 ^a
Serum estradiol on the day of trigger (pg/mL)	1276.56±796.12	1462.88±791.01	0.204 ^a
No. of total follicles on the day of trigger	6.66±4.03	8.27±5.45	0.222 ^a
No. of oocyte retrieved	5.70±3.73	6.50±4.15	0.349 ^a
No. of MII oocytes	5.46±3.82	6.13±4.07	0.349 ^a
No. of 2PNs	3.18±2.82	3.27±2.49	0.556 ^a
No. of total embryos	2.63±2.34	2.77±2.19	0.489 ^a
No. of embryos transferred	(n=56) 1.66±0.47	(n=28) 1.89±0.31	0.023 ^a
Quality of embryo transferred	(n=56)	(n=28)	
A	16 (28.6)	8 (28.5)	0.979 ^b
B	29 (51.8)	15 (53.6)	
C	11 (19.6)	5 (17.9)	

Δ ART, assisted reproductive technology; GnRH, Gonadotropin-releasing hormone; MII, metaphase II; 2PN, 2 pronuclear; quality of embryos A-C as described in Materials and Methods.

Note: Data are presented as mean±SD and number (%); "GnRH-agonist" group versus "GnRH-antagonist" group using ^aMann-Whitney U test; ^bChi-square test.

agonist and antagonist groups respectively (Table 3). With regard to cycle outcome in agonist versus antagonist group, implantation rate (11.7 vs. 15%), chemical (25% vs. 28.6%) and clinical (19.6% vs. 25%) pregnancy rates along with live birth rate (19.6% vs. 25%) presented no remarkable difference between the two groups (Table 3). In addition, there was no significant difference between the two groups regarding abortion rate; however, abortion was lower in the antagonist group compared with the agonist group ($P=1.000$) (Table 3).

Discussion

To the best of our knowledge, there is no study comparing long agonist and antagonist protocols for ovarian stimulation among women with endometrioma who have a normal ovarian reserve. We found that GnRH antagonist protocol is as effective as long GnRH agonist protocol with regard to the laboratory findings and pregnancy rate as well as live birth rate in fresh embryo transfer cycles of women with endometrioma and good ovarian reserve.

The significant detrimental effect of endometriosis on assisted reproductive technology (ART) outcomes has been indicated previously (17-19). On the other hand, there is no agreement regarding the optimal protocol for ovarian stimulation in women with endometriosis/endometrioma to result in better pregnancy outcome. Previously, it had been revealed that long-term GnRH agonist therapy prior to ovarian hyperstimulation during IVF cycles correlates with higher pregnancy and live birth rates in women with endometriosis (8,9,17). However, the result of a recent Cochrane systematic review has shown an unclear effect of long-term GnRH agonist therapy on clinical pregnancy rate in addition to live birth rate (18).

Table 3. ART outcome of GnRH-agonist group versus GnRH-antagonist group

Variables	GnRH-agonist (n = 56)	GnRH-antagonist (n = 28)	P value
Oocyte maturity rate	0.96±0.13	0.94±0.12	0.266 ^a
Fertilization proportion	0.59±0.25	0.57±0.23	0.487 ^a
Fertilization rate	0.62±0.25	0.61±0.24	0.560 ^a
Implantation rate	11/94 (11.7)	8/53(15)	0.555 ^b
Chemical pregnancy rate	14 (25)	8 (28.6)	0.795 ^b
Clinical pregnancy rate	11(19.6)	7 (25)	0.583 ^b
Live birth rate	11 (19.6)	7 (25)	0.583 ^b
Abortion	3/14(21.4)	1/8 (12.5)	1.000 ^b

Δ ART: assisted reproductive technology.

Note: Data are presented as mean±SD and number (%); "GnRH-agonist" group versus "GnRH-antagonist" group using ^aMann-Whitney U test; ^bChi-square test.

Otherwise, it has been shown that ovarian stimulation using GnRH antagonists besides its advantages such as flexibility and a short period of usage may be similarly effective as GnRH agonists in women with endometriosis (6,7).

There are comparative studies on IVF/ICSI outcomes in women with endometriosis-related infertility after COH with long agonist or antagonist protocols. Kolanska et al reported a similar pregnancy rate between two protocols, but a higher live birth rate in the GnRH agonist group (20). In a retrospective study, 386 endometriosis patients who received either a long GnRH agonist or GnRH antagonist protocol were classified according to the endometriosis stage. Women in stage I and II had higher chemical, clinical, and live birth rates with using GnRH agonist. However, the pregnancy outcome was comparable between the two stimulation protocols

among women with stage III and IV endometriosis (4). In addition, another study indicated that a higher number of available embryos could be attained in the GnRH antagonist protocol. Also, using antagonist protocol resulted in equal clinical pregnancy in comparison with long or prolonged agonist protocols, particularly in women with endometriosis and diminished ovarian reserve (21).

In the population of women with endometrioma, there are one prospective randomized trial and two retrospective studies that have assessed the differences between the long GnRH agonist and GnRH antagonist protocols (5,7,22). In a retrospective study, Bastu and colleagues compared the effect of long GnRH agonist and GnRH antagonist protocols on IVF/ICSI outcome after endometrioma resection. They found significantly higher follicles, retrieved metaphase II oocytes, and good quality embryos in the long GnRH agonist protocol (5). Conversely, in the current study, the number of retrieved and MII oocytes along with the number of 2PNs and total embryos were comparable between GnRH agonist and antagonist groups. The reasonable number of good quality oocytes in this study is in line with the previous findings that ovarian damage secondary to endometrioma per se cannot impair oocyte quality (23). Similar to our results, Zhao and colleagues found no difference regarding the number of retrieved and fertilized oocytes in women with diminished ovarian reserve after endometrioma resection. They compared three groups based on their COH protocols, including prolonged GnRH agonist, GnRH antagonist, and long GnRH agonist. Higher implantation and pregnancy rates were reported in prolonged GnRH agonist group. But, no significant differences were established in the fertilization rate, implantation rate, and clinical pregnancy rate between the other two groups (22). Similarly, Bastu et al showed no significant differences in the rate of chemical and ongoing pregnancy per patient between GnRH agonist and antagonist protocols (5). In line with the aforementioned studies, regardless of the significant difference in the number of transferred embryos, we found no significant differences between the GnRH agonist and antagonist groups in oocyte maturity rate, fertilization proportion, and fertilization rate. Likewise, implantation rate, chemical and clinical pregnancy rates, and live birth rate were comparable between the two protocols. Also, a prospective randomized trial evaluated two groups of women who had endometrioma with and without a history of ovarian surgery. The patients underwent COH with either GnRH agonist or GnRH antagonist during ICSI cycles. The implantation and clinical pregnancy rates were similar among women with or without a history of endometrioma surgery in both GnRH agonist and GnRH antagonist groups. However, they found significant differences in the number of MII

oocytes and available embryos after COH with GnRH agonist or GnRH antagonist protocols between women who had active or resected endometrioma (7).

The conflicting results of different studies may be due to the heterogeneity of the evaluated population, different stages of endometrioma, history of ovarian surgery along with the other parallel infertility causes. Our findings have clinical suggestions for women with endometrioma and good ovarian reserve on the equality of COH protocols. Although previous studies investigated the efficacy of different COH protocols among women affected by endometrioma, none of these studies assessed women with endometrioma and good ovarian reserve followed until delivery (13,20,22). An important limitation of this study was the limited sample size due to the retrospective design.

In conclusion, COH with both GnRH agonist and GnRH antagonist protocols presents similar laboratory findings and pregnancy outcome in IVF/ICSI cycles among women with endometrioma and normal ovarian reserve. Therefore, GnRH antagonist protocol could be safely applied to these patients with the main advantages of short duration and lower cost of treatment; even though, further prospective randomized trials with a large sample size have to be carried out to confirm these findings.

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Conflict of Interests

None.

Ethical Approval

The study was approved by the Ethics Committee of Yazd Reproductive Sciences Institute, Shahid Sadoughi University of Medical Sciences (IR.SSU.RSI.REC.1398.042).

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