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Improving pregnancy rate in infertile patients with polycystic ovarian syndrome receiving clomiphene citrate and cabergoline in euprolactinomic women in single cycle treatment

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ABSTRACT

Objectives: To assess the therapeutic efficacy of cabergoline when given routinely with clomiphene citrate (CC) in infertile women with polycystic ovarian syndrome (PCOS) and normal serum prolactin in single cycle therapy.

Material and methods: This prospective study included a total of 110 infertile women with polycystic ovaries and normal serum prolactin divided into two groups. The first group received only a single cycle CC 100 mg in two divided doses (50 mg × 2) from Day 2 to Day 6. The second group received the same regimen of CC along with cabergoline in two divided doses of 0.5 mg each week at Day 2 and Day 9, respectively. All patients were evaluated through full history and physical examination. Blood was extracted from all patients for hormonal assay and ultrasound for the assessment of ovulation.

Results: The success rate of ovulation induction was statistically significant. Biochemical pregnancy elevated to (36.0%, n = 18) with using combined drugs while it was 14.0%, n = 7, with the use of CC alone (p = 0.011). The clinical pregnancy rate in the study group was elevated to 32.0%, n = 16, which is statistically significant. No significant association was found between abortion and the type of treatment. There were no significant differences between the groups regarding drug side effect like ovarian hyper stimulation rate, multiple pregnancy rate as well as other adverse effects.

Conclusions: Adding cabergoline in small doses together with CC in PCOS infertile women and normal serum prolactin increases the success rate of ovulation & significantly improves pregnancy rate with minimal drug side effects.

Key words: cabergoline; clomiphene citrate; euprolactinemia; infertility; polycystic ovarian syndrome; prolactin

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INTRODUCTION

Polycystic ovarian syndrome (PCOS) is one of the most common procreative and metabolic diseases among females of reproductive age. It occurs in 4–12% of women. Also, it is described as hyper androgenic anovulation [1].

Polycystic ovarian syndrome is diagnosed, according to the Rotterdam criteria, by at least two out of three criteria: evidence of oligo- or anovulation; ultrasound features of polycystic ovaries of more than 12 tiny follicles measured 2–9 mm in one or both ovaries; the ovarian volume exceeds 10 mL; and the signs of clinical or biochemical hyperandrogenism [2].

In 2003, at the Rotterdam European Society of Human Reproduction and Embryology/American Society for Reproductive Medicine (ESHRE/ASRM) Consensus workshop, an attempt was made to standardize the working definition of the PCOS. Since then, the presence of two of three of the following criteria have been required for the diagnosis of PCOS: (i) oligo and/or anovulation, (ii) clinical and/or biochemical signs of hyperandrogenism and (iii) echo graphic PCOS, after the exclusion of other pathologies with similar clinical presentation such as congenital adrenal hyperplasia, Cushing's syndrome and androgen-secreting tumors (The Rotterdam ESHRE/ASRM-Sponsored PCOS Consensus Workshop Group, 2004) [3].

Seventy-five percent of an ovulatory infertility is caused by polycystic ovarian syndrome. Elevated serum prolactin presents in 20–30% of patient with PCOS [4].

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A temporary gush of serum prolactin level occurs during the last part of the follicular and luteal phases of all usual and exaggerate menstrual period [5]. Hypothalamic dopamine is the principal suppressor of serum prolactin releasing and may be a possible part for essential dopaminergic tools in the excretion of luteinizing hormone (LH). Many studies reported that the indirect effect of dopamine on release of gonadotropin, and low dopamine inhibitors lead to unusual secretion of prolactin and LH like in females with high prolactin as in PCOS [6].

Polycystic ovarian syndrome is a disorder of complex etiology, and the mechanism is still unclear as some studies revealed that dopamine agonist may significantly suppress LH levels and may disrupt the normal menstrual cycle [4].

About 50% of women with PCOS suffer from infertility due to ovulation with the principle treatment being ovulatory induction drugs. Clomiphene citrate (CC) is the first agent used for ovulation induction with a success rate of 70–80% and pregnancy rate of about 20% in a single cycle therapy [4]. However, 20% of women show clomiphene resistance.

Cabergoline, ergot-derived dopamine agonists with a prolonged half-life, is a good prolactin inhibitor. Cabergoline oral therapy contains a weekly dose of 0.5–3 mg, and can be increased, if required to twice a week. This drug has slight side effects, headache being the most common. Treatment usually starts with a half a pill at bedtime and a small amount of food. Fewer side effects and its weekly dose has made Cabergoline the drug of choice for treating related disorders [7].

Cabergoline has a significant effect on dopamine receptors (D2) and has 43 hours as half-life. A recent study stated that there is better uterine flow of the blood and high response of ovulation in females that use it [8].

Many studies have proven that a surge in LH and prolactin levels were common in PCOS due to insufficiency of dopamine agonist which suppresses ovulation, so sometimes dopamine assisted ovulation induction may also be utilized to treat infertility in PCOS [9, 10]. Enrico also showed that dopamine agonist suppresses LH level in women with PCOS and resumes a normal menstruation [11].

However, several studies have shown that the administration of dopamine agonist cabergoline can restore regulation of the menstrual cycle and improve ovulation in women with PCOS, implying that it has the effect of regulating endocrine disturbance to maximize ovulation [12].

MATERIAL AND METHODS

Setting

This study was carried out on women attending the infertility clinic and outpatient clinic of Maternity and Children hospital in Babylon province, Iraq, and a private clinic including 110 women through a period from November 21, 2018 to September 21, 2019.

Inclusion criteria

1. Age: 15–45 years old.
2. Primary and 2nd history of infertility.
3. Previous history of PCOS.
4. Normal seminal fluid analysis.
5. Normal serum prolactin & absence of galactorrhea.

Exclusion criteria

1. Hyperprolactinemia.
2. Patient using other medications like metformin, aromatase inhibitors, tamoxifen or gonadotropins.
3. Thyroid dysfunction.
4. Other factors of infertility such as tubal factor, uterine factor or male factor.
5. Menstrual dysfunction.
6. Body mass index (BMI) > 25 kg/cm^2.

A total of 110 women were enrolled in this study. They were divided into two groups of 55 patients each. The first group received only clomiphene 100 mg in two divided doses, from Day 2–6 of the regular menstrual cycle and ovulation was followed through trans-vaginal U/S at day 13 of the cycle. The second group received the same regimen of CC in addition to a small dose of cabergoline (0.5 mg) at Day 2 of the cycle and the second dose after one week despite normal serum prolactin. Only 50 patients in each group completed the entire regimen. Then patients in both groups received 10000 INU of Human Chorionic Gonadotropin for induction of ovulation, when dominant follicle diameter is more than 18 mm by U/S. The sexual activities were advised, and guided, and oral progesterone 20 mg/day was given for 10 days after ovulation. Pregnancy test (blood B-HCG) was detected for patients who didn't show menstruation to diagnose pregnancy. Pregnant patients were confirmed by ultrasonography.

Study protocol

A particularly designed history formula was applied for recording information about each woman including history of menstrual irregularity, history of infertility whether primary or secondary, duration of infertility, gynecological history, and any history of medications, physical examination, hormonal assay, and ultrasound findings.

Hormonal analysis

The hormonal analysis includes Day 2 menstrual cycle serum prolactin, as level of < 35 ng/mL was regarded as normal [13]. Five mL of venous blood were aspirated in blood collecting tubes, centrifugation was done after standing whole blood at room temperature, then 50 microns of the serum was taken through the pipette for prolactin assessment using commercially available kits [MAGLUMI Fully-auto chemiluminescence immunoassay (CLIA) analyzer including

Table 1. Mean ± standard deviation (SD) of study variables [age, body mass index (BMI), serum prolactin and duration of infertility]

Study variables	Mean ± SD	Range
Age [years]	28.70 ±7.85	15–44
BMI [kg/m^2]	21.65 ± 2.41	18–33
Serum prolactin [ng/dL]	13.83 ± 8.14	2.9–34
Duration of infertility [years]	2.811 ± 1.39	1–6

MAGLUMI 800 through Snibe device]. Serum thyroid levels were not assessed routinely for all women unless for patients who had clinical symptoms indicating thyroid dysfunction or on thyroid therapy (as they excluded from the study). Serum B-HCG was done for women who had a missed their period to confirm pregnancy. Quantitative serum hCG measurement was done using immunometric assays as 5 mL of blood was aspirated through venipuncture & level more than 5 mlU/mL regarded positive. Confirmed PCOS was established by ultrasound.

Statistics: data analysis

Statistical analysis was carried out using SPSS version 21 (SPSS, IBM Company, Chicago, IL 60606, USA), percentage categorical data, while continuous data present as [mean ± standard deviation (SD)]. Chi-square and Fisher-exact tests were used to show the association between categorical groups, while a T-test was used to show the mean difference between the two groups. A p-value less than or equal to 0.05 is significant.

RESULTS

No statistical difference was found between either group regarding the basal criteria (Tab. 1).

Figure 1 shows the distribution of patients according to the type of infertility. Primary infertility represented (38.0%), secondary infertility represented (38.0%), and patients with both types of infertility represented (24.0%).

Table 2 illustrating the Gravida and Parity distribution among patients' group, while Table 3 shows the mean differences of study variables including (age, body mass index, serum prolactin, and duration of infertility) between the types of treatment including (CC or Clomid and cabergoline). There were significant differences between the means of duration of infertility between study groups.

Figure 2 shows the ovulation rate (positive or negative) in together groups. A significant connotation between ovulation rates apart from the type of management. Ovulation rate elevated to be (86.0%, n = 43) with using of CC and cabergoline while it was (64.0%, n = 32) with the use of CC only (X^2 = 6.45, p = 0.011*, odds ratio = 3.455,95% CI = 1.289–9.259).

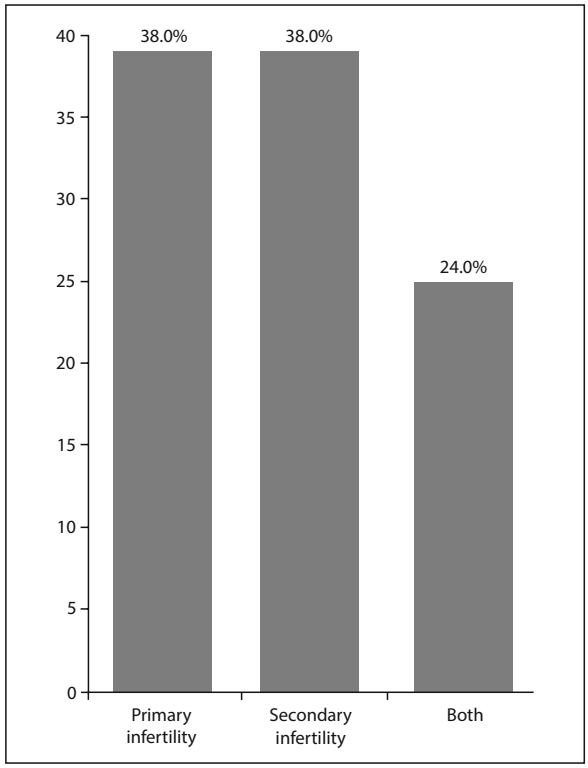

Figure 1. Spreading of patients conferring to kind of infertility

Table 2. Gravida and parity distribution

Variables	No.	[%]
Gravida		
G0	34	34.0
G1	32	32.0
G2	24	24.0
G3	6	6.0
G4	3	3.0
G5	1	1.0
Total	100	100.0
Parity		
P0	55	55.0
P1	28	28.0
P2	15	15.0
P3	2	2.0
Total	100	100.0

Figure 3 shows the association between biochemical pregnancy including (positive or negative pregnancy tests) and the type of treatment. There was a significant association between biochemical pregnancy and type of treatment. Biochemical pregnancy elevated to be (36.0%, n = 18) with

Table 3. The mean differences of study variables between type of treatment

Study variables	Type of treatment	N	Mean	SD	t-test	p value
Age [years]	Clomiphene citrate (clomid)	50	28.00	7.96	–0.89	0.376
	Clomiphene citrate and cabergoline	50	29.40	7.76		
BMI [kg/m^2]	Clomiphene citrate (clomid)	50	21.26	2.03	–1.639	0.104
	Clomiphene citrate and cabergoline	50	22.04	2.70		
Serum prolactin [ng/d]	Clomiphene citrate (clomid)	50	12.75	5.90	–1.324	0.189
	Clomiphene citrate and cabergoline	50	14.90	9.84		
Duration of infertility [year]	Clomiphene citrate (clomid)	50	2.51	1.24	–2.20	0.03*
	Clomiphene citrate and cabergoline	50	3.11	1.48		

BMI — body mass index; SD — standard deviation

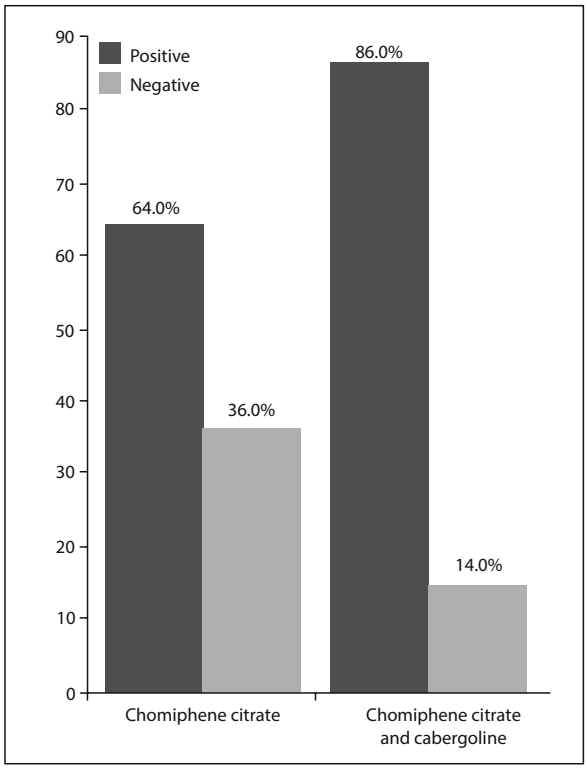

Figure 2. The association between ovulation rate and type of treatment

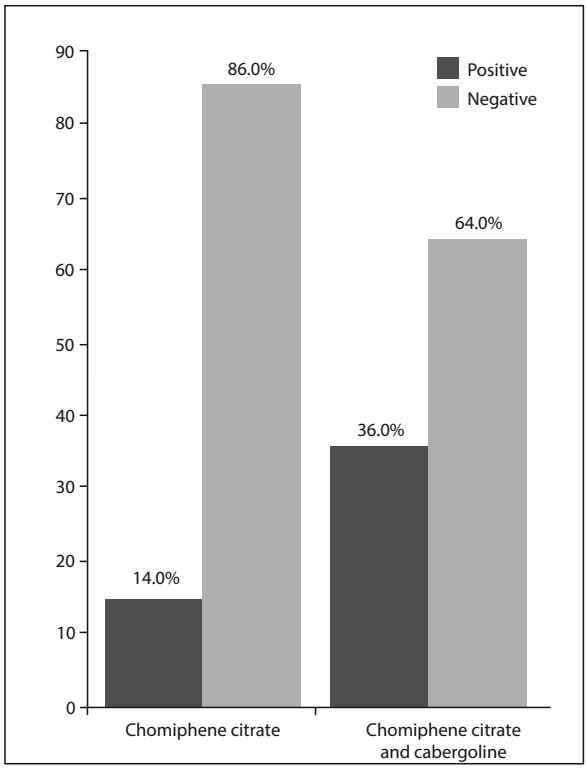

Figure 3. Relation between biochemical gestation and kind of management

using both drugs while it was (14.0%, n = 7) with the use of CC only (X^2 = 6.45, p = 0.011*, odds ratio = 3.455,95% CI = 1.289–9.259).

Figure 4 shows the association between clinical pregnancy (diagnosed by ultrasound) including (positive or negative) and the type of treatment included. A significant relation between clinical gestation and type of management was found. The clinical pregnancy elevated to be (32.0%, n = 16) with the use of both drugs while it was (10.0%, n = 5) with the use of CC only (X^2 = 7.294, p = 0.007*, odds ratio = 4.235,95% CI = 1.412–12.705).

Figure 5 shows the association between abortion and type of treatment including (CC or CC and cabergoline). There was no significant association between abortion and the type of treatment (p = 1.000, odds ratio = 1.000, 95% CI = 0.135–7.392). Fisher-exact test.

Table 4 shows the association between the type of treatment and side effects developed by the patients including (ovarian hyper stimulation syndrome, multiple pregnancy, headache and dizziness, GIT side effect, hot flush, and tachycardia). There was no significant association between the type of treatment and the side effects developed by the patients.

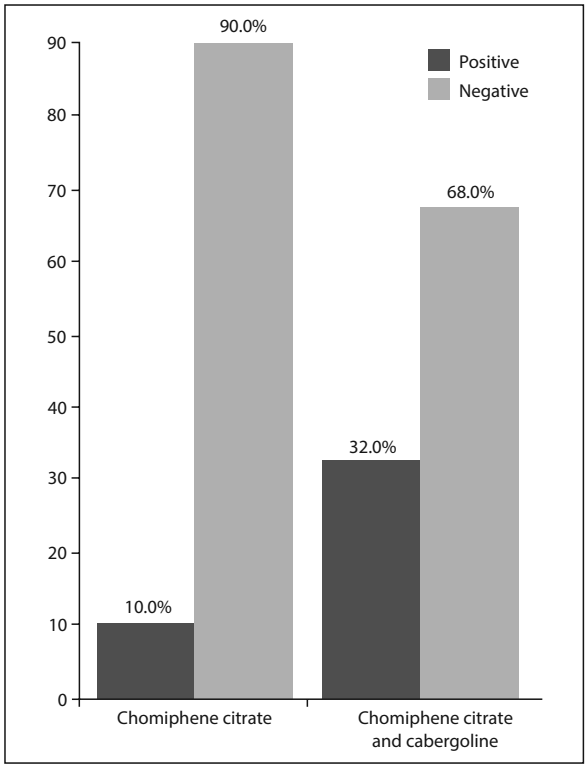

Figure 4. The association between clinical pregnancy and type of treatment

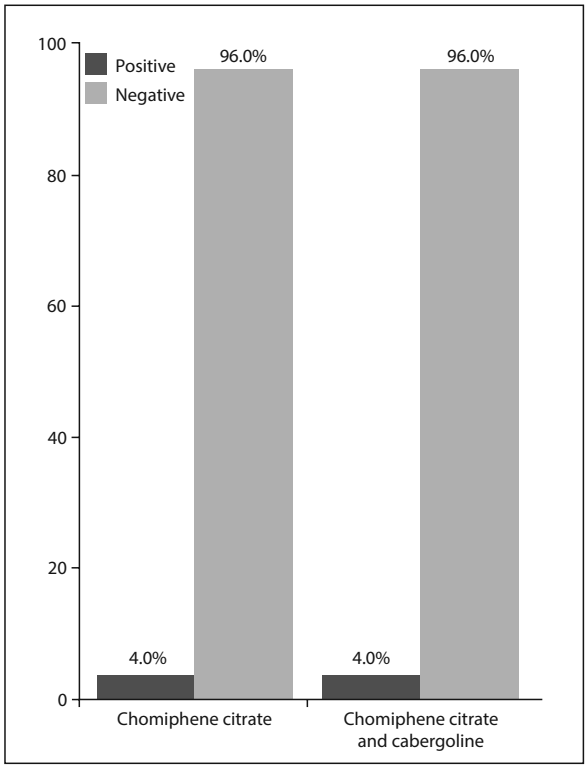

Figure 5. The association between abortion and type of treatment

DISCUSSION

Polycystic ovarian syndrome featured as irregular releasing of gonadotropin, in specifically high LH, low follicle stimulating hormone (FSH), and LH/FSH ratio increase more than two. Thirty percent of females with transient hyperprolactinemia is occurring in PCOS, so decrease dopamine inhibitor leads to increase prolactin and LH [5]. PCOS is a more usual endocrine disease in females that leads to decrease ovulation and increase infertility. Clomiphene citrate more common drug for stimulation of ovulation that is more common and beneficial use in PCOS due to its cost-effectiveness and suitability [14]. In the current study, three cycles out of 50 are deleted due to slight ovary overstimulation through ovulation stimulation (in control group), while in the study group one cycle deleted.

The purpose of this study is to assess the ovulation and pregnancy rate in infertile patients with polycystic ovaries receiving ovulatory induction drugs (CC) and cabergoline despite normal serum prolactin.

This study showed that the ovulation rate was 64% in the study group while it elevated to 86%. This result revealed that cabergoline may improve the efficacy of CC in ovulation induction in infertile women with PCOS (Fig. 2).

All studies were done using dopamine agonist (bromocriptine) with clomiphene with the exception of a study achieved by Zahran et al. [7], who used cabergoline and showed that the cumulative ovulation rate was 58.3% in the clomiphene group versus 76.7% in the cabergoline group ($p < 0.05$).

In our study, we found that the pregnancy rate was 36% in the cabergoline group versus 14% in the clomiphene group ($p = 0.001$). This result was comparable to that of the Zahran study which revealed that the pregnancy rate was 31.7% in the cabergoline group versus 13.3% in the clomiphene group ($p = 0.004$) [7].

Kubota et al. [15] stated a lesser ovulation rate of 57.3% and pregnancy rate of 27% of infertile females that have euprolactinemia used CC and bromocriptine. Parsanezhad et al. [16] evaluated that the influence of addition bromocriptine to CC in PCOS euprolactinemic females that resist CC, no significant difference in gestational rate and ovulation in the study group. However, there is only a significant effect of bromocriptine in lowering PRL [16]. In addition, Tripathy et al. [17] stated that there is no usefulness of using bromocriptine with CC for stimulation of ovulation in females with PCOS who have euprolactinemia. The ovulation rate was 69% in females who have taken only CC, while 76% in females who have taken both bromocriptine and CC, and bromocriptine has a more adverse effect and low affectivity than cabergoline [17].

Table 4. Association between type of treatment and side effect developed by the patients

Study variables	Type of treatment		Total	χ^2	p value	Odds ratio	95% CI
	Clomiphene citrate	Clomiphene citrate and cabergoline					
OHSS							
Positive	1 (2.0)	2 (4.0)	3 (3.0)				
Negative	49 (98.0)	48 (96.0)	97 (97.0)		1.000 f	2.04	0.179–23.26
Total	50 (100.0)	50 (100.0)	100 (100.0)				
Multiple pregnancy							
Positive	3 (6.0)	4 (8.0)	7 (7.0)				
Negative	47 (94.0)	46 (92.0)	93 (93.0)		1.000 f	1.362	0.289–6.426
Total	50 (100.0)	50 (100.0)	100 (100.0)				
Headache and dizziness							
Positive	4 (8.0)	6 (12.0)	10 (10.0)	0.444			
Negative	46 (92.0)	44 (88.0)	90 (90.0)		0.505	1.568	0.414–5.935
Total	50 (100.0)	50 (100.0)	100 (100.0)				
GIT side effect							
Positive	5 (10.0)	5 (10.0)	10 (10.0)	0.00			
Negative	45 (90.0)	45 (90.0)	90 (90.0)		1.000	1.000	0.271–3.694
Total	50 (100.0)	50 (100.0)	100 (100.0)				
Hot flush							
Positive	7 (14.0)	5 (10.0)	12 (12.0)	0.379			
Negative	43 (86.0)	45 (90.0)	88 (88.0)		0.538	0.683	0.201–2.315
Total	50 (100.0)	50 (100.0)	100 (100.0)				
Tachycardia							
Positive	1 (2.0)	2 (4.0)	3 (3.0)				
Negative	49 (98.0)	48 (96.0)	97 (97.0)		1.000 f	2.04	0.179–23.26
Total	50 (100.0)	50 (100.0)	100 (100.0)				

*p-value ≤ 0.05 was significant; CI — confidence interval; f — Fisher exact test; GIT — gastrointestinal tract; OHSS — ovarian hyperstimulation syndrome

Xue et al. [18] described the efficacy of bromocriptine and CC in infertile females with the usual level of prolactin and female with galactorrhea. Also, they found that both bromocriptine and CC led to an increase in gestation rate and a decrease in miscarriage [18]. These results were compatible with the results of the current study.

Another study showed that cabergoline can enhance endometrial perfusion and ameliorate menstrual cycle in PCOS patients which indirectly increases endometrial receptivity and thus improve pregnancy outcome [19].

In the current study, cabergoline fine tolerated by all females in the study with no side effects. There was no significant association between abortion in both groups (p = 1.000, odds ratio = 1.000, 95% CI = 0.135–7.392), Fisher--exact test (Fig. 5).

There were no significant differences between the groups regarding drug side effects like ovarian hyper stimulation rate (p =1.000 f), multiple pregnancy rate (p = 1.000), as well as other side effects of drugs (headache and vertigo, gastrointestinal adverse effects, hotness and increase pulse rate) (Tab. 4). These results were compatible with Mohammadbygi et al. [19] who stated that cabergoline has a low rate of ovarian hyperstimulation syndrome (OHSS) and multiple gestations, so it can be used safely through pregnancy.

CONCLUSIONS

Adding cabergoline (dopamine agonist drug) in small doses together with CC for stimulation of ovulation in females' euprolactinemic and infertile that had PCOS led to increasing ovulation and gestational rates and (on the other

hand) decreased in miscarriage rate, multiple gestations, and OHSS rate (if compared with using CC alone).

Recommendation

The clinician should be aware of using dopamine agonist together with CC even has normal serum prolactin to raise drug efficacy in form of ovulation and pregnancy rate with fewer drug side effects. Upcoming studies for the effects of a mixture of both cabergoline and CC on the endometrial receptiveness and Doppler directories in the uterine artery in PCOS females.

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Conflict of interest

The author declares that there are no conflicts of interest relevant to what is written.

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