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Original Research Article

Is cabergoline mystical in euprolactemic polycystic ovarian syndrome

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ABSTRACT

Background: Polycystic ovarian syndrome (PCOS) is most common in reproductive age females. Cabergoline is a potent long-acting dopamine agonist play an important role in decreasing high prolactin secretion which is present in 30–40% of PCOS and induce ovulation in those with normal prolactin level also. This is attributed to reduction of an occult hyperprolactinemia in PCOS patients.
Methods: This is a randomized, prospective, controlled study includes 100 Euprolactinemic infertile PCOS, 50 in each group, Group A (letrozole cabergoline group) patients received tablet letrozole 5 mg/day in 2 divided doses 2.5 mg from cycle day 3 to day 7 plus cabergoline tablet 0.25 mg, half tablet twice weekly for 4 weeks starting from cycle day 3 with letrozole despite normal serum prolactin level. Group B (letrozole Group):patients received only letrozole same as group A. Primary outcomes-ovulation rate, number of dominant follicles and secondary outcomes-pregnancy, miscarriage, multiple pregnancies, OHSS, side-effects of cabergoline were studied. Statistical analysis was done.
Results: Study groups compared for the demographic characters, basic clinical data, duration and type of infertility which showed no significant difference. Statistically significant difference in group A ovulation rate 76% (p value 0.0124), number of dominant follicles (p value 0.029). Pregnancy rate 72% in group A and 48% in group B (p value 0.014). No statistical difference in miscarriage (p value 0.15), twin pregnancies (p value 0.86), OHSS (p value 1.0) and no side effects.
Conclusions: Addition of cabergoline to Letrozole in induction of ovulation in euprolactinemic infertile PCOS results in increased ovulation, high pregnancy rate compared to use of letrozole alone, with very few side-effects.

Keywords: Cabergoline, Euprolactinemic PCOS, Letrozole

INTRODUCTION

PCOS is one of the most common procreative and metabolic diseases among females of reproductive age. 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 oligo and/or anovulation, clinical and/or biochemical signs of hyperandrogenism and 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).[1] PCOS represent 5-10% of women in reproductive age affecting their fertility and their health.[2] Seventy-five percent of anovulatory infertility is caused by polycystic ovarian syndrome. Elevated serum prolactin presents in 20–30% of patient with PCOS. 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 . 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. 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. About 50% of women with PCOS suffer from infertility due to anovulation with the principal treatment being ovulatory induction drugs.[3] Cabergoline is a potent long-acting dopamine agonist with high binding affinity and specificity for D2 receptors of dopamine. Its approved that presence of dopaminergic inhibitory control on gonadotrophin secretion and suggested that a reduction of this inhibitory effect might cause abnormal PRL and LH release, as found in PCOS patient. Different studies concluded that the administration of cabergoline can improve insulin resistance and consequently normalize androgen levels in PCO anovulatory women and thus improving their menstrual irregularity. In addition, cabergoline as dopamine agonist play an important role in decreasing high prolactin secretion that was present in about 30–40% of PCO women. So dopamine agonists can induce ovulation in PCOS anovulatory women with increased prolactin through reduction of its serum level in patient with high level, moreover they may induce ovulation in those with normal prolactin level. This could be attributed to reduction of an occult hyperprolactinemia (a transient rise in plasma prolactin (PRL) concentrations could be noticed during the late follicular and luteal phases of both natural and stimulated cycles) in PCOS patients.[2]

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. A recent study stated that there is better uterine flow of the blood and high response of ovulation in females that use it.[3] Cabergoline was administered before the hCG trigger (when the leading follicle reached a size of 15 mm). They found that early administration of cabergoline was effective and safe in preventing early OHSS and that it did not compromise pregnancy rates. the dose of cabergoline may be too low to impact the final oocyte maturation and that the high levels of VEGF produced by multiple follicles and the long duration hCG trigger may overcome the effect of partially blocking VEGF receptor function.[4] For prevention of OHSS cabergoline is administered during controlled ovarian stimulation (with gonadotropins or other ovarian stimulating agents) prior to triggering final maturation/ovulation with, e.g., hCG.[5] Letrozole, an aromatase inhibitor, is now used as a choice to induce ovulation. Compared with clomiphene, side effects of letrozole are rare and occur with continued use.[6]LE is a third-generation aromatase inhibitor. It blocks the conversion of C-19 androgens to C-18 estrogen by competitively inhibiting the enzyme, aromatase (cytochrome P-450), which is an essential step in estrogen biosynthesis in the ovary and other tissues. The subsequent feedback to the hypothalamus containing reduced estrogen levels, triggers a compensatory increase in hypothalamic gonadotropin-releasing hormone (GnRH) secretion and thus an increased release of pituitary gonadotropins (FSH) & amp; LH. These gonadotropins subsequently promote growth of the follicles and stimulate ovulation. (LE) has 99.9% bioavailability after oral administration. It has a single dose terminal half-life of 42 hours. As the combined use of Cabergoline which normalizes prolactin level and (LE) which stimulates ovulation, could be effective in management of menstrual cycle irregularities, ovulation induction and increase pregnancy rate in (PCOS) patients, therefore, in this in this study, we will investigate their efficacy and the reproductive outcomes in those patients in comparison to (LE) alone.[7]

Other studies documented that cabergoline in PCOS patients produce better ovarian response, reduced the risk of ovarian hyperstimulation syndrome (OHSS) and decreased serum prolactin concentration. Therefore, this present study was designed to detect effect of using cabergoline in patient with anovulatory PCO with normal prolactin level regarding ovarian response (ovulation rate, pregnancy rate) as primary and secondary outcome during aromatase inhibitor (letrozole) stimulation protocol in PCOS.

METHODS

Type and place of study

This is randomized, prospective, controlled study was conducted in outpatient clinic of obstetrics and gynaecology department of Gandhi Hospital, Secunderabad, Telangana, during the period from April 2024 to April 2025 where around 8000 patients attended the Infertility out patient, all participants gave their written informed consent before their inclusion in the study. Institutional ethical clearance taken.

Patients

Study included (100) infertile women with anovulatory PCOS, based on the Rotterdam criteria (2003 ESHRE/ ASRM consensus) 8, whereby the diagnosis of PCOS requires the presence of two of three criteria, i.e., oligomenorrhea and/or anovulation, clinical and/or biochemical signs of hyperandrogenism and/or polycystic ovaries on ultrasound.

Inclusion criteria

Age 18-45 years, primary or secondary infertility for period up to 6 years, basal serum follicle stimulating hormone level (FSH)<24 ng/dl, in the early follicular phase.[2] Normal seum prolactin level<24 ng/dl, with no galactorrhea.[2] Normal AMH level≤3.9 ng/ml.[9] Previous history of PCOS. All women with bilateral tubal patency detected by hysterosalpingography or laparoscopy. Normal semen analysis for their partner according to the modified WHO criteria 2010.[10]

Exclusion criteria

Patients with history of laparoscopic ovarian drilling or ovarian cystectomy hyperprolactinemia, thyroid disorders, uterine pathology such as leiomyoma, adenomyosis or congenital uterine malformation, patients with male factor or hypersensitivity or contraindications to letrozole & or cabergoline are excluded. Patients with medical disorders-diabetes, renal disorders, asthma, heart disease were excluded. Patients who are not willing for follow up.

Ethical approval

The institutional ethical review board approved the study.

Stimulation protocol

Group A (letrozole cabergoline group)

Patients received tablet letrozole 5 mg/day on two divided doses each 2.5 mg starting from cycle day 3 for 5 days plus cabergoline tablet 0.5 mg, half tablet twice weekly for 4 weeks starting from cycle day 3 with letrozole despite normal serum prolactin level.

Group B (letrozole Group)

Patients received letrozole only with the same dose and duration as 1st group. For all participants in both groups a designed history formula was applied for recording Age, Parity, BMI, Duration of infertility, Type of infertility and the results of basal investigations including USG, FSH, LH, TSH, AMH and prolactin. On day 10 of cycle ultrasound folliculometry was done for all patients in both groups, (by the same sonographer, who was blinded by their intervention group, for evaluation of number, size of ovarian follicles in each ovary, ovulation.

Frequency of visit was tailored according to size of follicle till dominance was confirmed or excluded when the leading follicle size≥18 mm in diameter, 10,000 IU of highly purified hCG was given intramuscular injection, timed coitus is asked within the following 36 hours.[4] weeks after the end of treatment. Midluteal progesterone (one week after presumed ovulation or one week after the last observation) was assayed. Only one complete treatment cycle was offered to each woman of both groups. Urine pregnancy test was used for the patients who didn't show menstruation by the end of treatment to diagnose pregnancy followed by ultrasound evidence of pregnancy.

Outcome measures

The primary outcome was the rate of ovulation in both groups, number of dominant follicles overall, how many dominant follicles in each group with the use of drugs. The secondary outcomes included clinical pregnancy rate (number of patients with intra uterine gestational sac with fetal pulsation detected by ultrasound), miscarriage rate (the number of cases with pregnancy loss within 10 weeks of gestation), the multiple pregnancy rate, OHSS. Authors have also evaluated the side-effects of cabergoline in the group A, to know its tolerance and significant side-effect.

Statistics analysis

Data analysis statistical analysis was carried out using 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

100 PCOS patients were recruited in this study, All patients met the inclusion criteria and were there for the follow up, so the final analysis on 100 patients with 50 patients in each group. We divided Group A as letrozole plus cabergoline patients, Group B as only letrozole group. Both the groups were comparable for the demographic characters and basic clinical data with no significant difference (Table 1) shows the mean differences of study variables including (Age, Body mass index, Duration of infertility, Type of infertility, Serum prolactin, Serum TSH and Serum AMH) between the groups.

In the study there were no significant differences between the duration of infertility between study groups (Table 2). Authors have noticed that there is no significant differences between the type of infertility (p=0.54) between study groups (Figure 1). Authors have noticed statistically significant difference in ovulation rate and number of largest follicle follicle≥17 mm (Table 3). Ovulation was achieved in 38 patients about,76.0% ovulation rate (group A, received cabergoline –letrozole), while in (group B received letrozole only) it is achieved in 26 patients (52.0% ovulation rate) with p value 0.0124). In addition, over-all the number of follicles≥17 mm was significantly more in the letrozole cabergoline group than in other letrozole group with (p value 0.029) (Table 3). Authors also analysed how many numbers of dominant follicles drugs can stimulate in each group and there was no statistically significant difference in number of dominant follicles that is follicle≥17 mm in both the groups (p value 0.615) (Table 4). Clinical pregnancy defined as sonographically visualized intra-uterine gestational sac with pulsating fetal pole was achieved in 36 cases with (72.0%) among letrozole cabergoline group and only in 24 (48.0%) cases in letrozole group with (p value 0.014) (Table 5). No statistical difference noted in miscarriage (p value 0.15), twin pregnancy rate (p value 0.86) and OHSS (p value 1.0) (Table 5). Table 6 shows the use of cabergoline and its side effects developed by the patients including headache, dizziness, GIT side effect, hot flush, visual disturbances and tachycardia). There was no significant type of side effects developed by the patients. In the current study, cabergoline fine tolerated by all females, Figure 2.

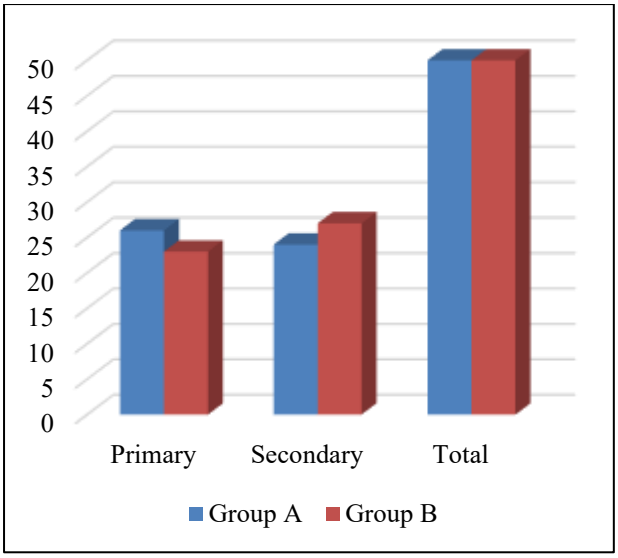

Figure 1: Type of infertility.

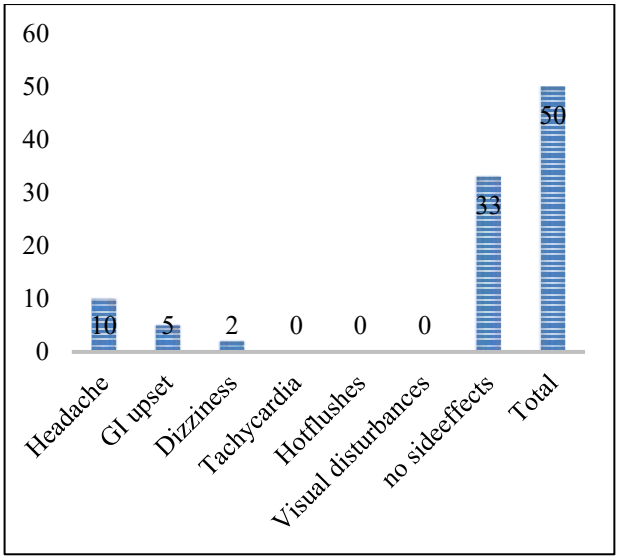

Figure 2: Side-effects of cabergoline.

Table 1: Basic demographic and clinical data distribution between studied groups.

Study variables	Group A	Group B	χ	P value
Age (in years)	28.02±5.71	27.71±6.71	-	-
BMI	21.79±1.51	21.87±1.35	-	-
PRL	11.44±2.98	11.77±3.72	1.105	0.255
TSH	2.38±0.54	2.42±0.54	1.312	0.125
AMH	2.17±0.61	2.22±0.62	1.621	0.0841

Table 2: Duration of infertility.

Duration of infertility	Group A	Group B	χ	P value
1 year	10	8	0.048	0.82
2 years	25	28		
>3 years	15	14		
Total	50	50		

Table 3: Primary outcome.

Primary outcome	Group A	Group B	χ	P value
Ovulation rate	38	26	6.25	0.012
Dominant follicles	40	30	4.761	0.029

Table 4: Number of dominant follicles.

Number of dominant follicles	Group A	Group B	χ	P value
3	20	15	0.972	0.615
2	10	10		
1	10	5		

Table 5: Secondary outcomes.

Secondary outcomes	Group A	Group B	χ	P value
Pregnancy	36	24	6	0.014
Miscarriage	2	4	1.975	0.15
Twins	4	3	0.027	0.86
OHSS	1	1	0	1

Table 6: Side effects of cabergoline in group A.

Side-effects of	Cabergoline
Headache	10
GI upset	5
Dizziness	2
Tachycardia	0
Hot flushes	0
Visual disturbances	0
No side-effects	33
Total	50

DISCUSSION

The study addresses the effect of adding cabergoline to Letrozole in induction of ovulation in euprolactinemic PCOS patients. Moreover, all patients were euprolactinemic with no galactorrea and diagnosed PCOS according to Rotterdam criteria. Diurnal variation of prolactin secretion could leads to occult hyperprolactinemia in some patients. We hypothesized that adding cabergoline for induction of ovulation with Letrozole in euprolactinemic PCOS patients may have a role in decreasing this occult hyperprolactinemia and in turn improve and induce ovulation in PCO infertile patients. In the current study both the groups (group A as letrozole plus cabergoline patients, group B as only letrozole group) were comparable for the demographic characters like Age, BMI, duration and type of infertility and basic clinical data (serum TSH, serum prolactin serum AMH) found no significant difference. Mervat et al there was no significant difference or association regard basic demographic and clinical data (serum TSH, serum Prolactin) in group A received letrozole plus cabergoline and group B received letrozole.[2]

Suha et al also had no statistical difference between either group (clomiphene citrate plus cabergoline or clomiphene citrate alone) regarding the basal criteria.[3] Kamal et al also found no statistical difference between both groups (Clomiphene Citrate plus cabergoline or Clomiphene Citrate alone) regarding the basal criteria- Age, BMI, duration and type of infertility and basic clinical data (serum TSH, serum Prolactin).[11] In the study, we found that the ovulation rate was 76% in the cabergoline plus letrozole group versus 52% in the letrozole alone group (p=0.012) and number of dominant follicles in the cabergoline plus letrozole group 80% versus 60% in the letrozole alone group (p=0.029). And we found no statistical difference in maximum how many numbers of dominant follicles drugs can stimulate in group A and group B. The result was comparable to that of Mervat et al study ovulation rate in the letrozole cabergoline (group 1) was 75% versus 60% in the letrozole (group 2) with p value 0.023, number of dominant follicles ≥17 mm was significantly more in the letrozole cabergoline group than in other letrozole group with (p value 0.00).[2] There was noticed also that stimulation days are less in letrozole cabergoline group than letrozole only group but not reach significance. In Suha et al study where ovulation rate was more 86% in clomiphene citrate plus cabergoline group than 64% in clomiphene citrate alone.[3] Aisha et al study found that ovulation rate was higher in (A- letrozole plus cabergoline) (50.6%) in comparison to (B-letrozole alone) (26.5%), (p<0.05).[7] In kamal et al study, the largest follicle size in each cycle was significantly more in the CC plus cabergoline group (p<0.05), though study used clomiphene.[11] In the study, we found that the pregnancy rate was 72% in the cabergoline plus letrozole group versus 48% in the letrozole alone group (p=0.014). This result was comparable to that of Mervat et al patients in letrozole cabergoline group had a higher clinical pregnancy rate reaching 27.0% versus 15.0 % in patients of the letrozole group (p value 0.037).[2]

Suha et al, study found biochemical pregnancy elevated to (36.0%, n=18) with using combined drugs CC plus cabergoline while it was 14.0%, n=7, with the use of CC alone (p=0.011).[3] The clinical pregnancy rate in the study group was elevated to 32.0%, n=16, which is statistically significant. Aisha et al study found that clinical pregnancy rate in (A-letrozole plus cabergoline) (41.6%) and (21.6%) in (B-letrozole alone) (p<0.05).[7] Kamal et al study which revealed that the pregnancy rate was 31.7% in the cabergoline group versus 13.3% in the clomiphene group (p=0.004).[11] Kubota et al stated a lesser ovulation rate of 57.3% and pregnancy rate of 27% of infertile females that have euprolactinemia used CC and bromocriptine.[12] This difference could be explained by different pharmacological effect of cabergoline and bromocriptine in addition patients are not PCOS.

Parsanezhad et al declared that no significant differences in the ovulation and pregnancy rates with adding bromocriptine to CC in CC resistant euprolactinemic PCOS patients and the only benefit of bromocriptine therapy in CC-resistant PCOS patients was to normalize the level of the serum prolactin.[13] But this study differ from current study in studied group are clomiphene resistant PCOS female. In addition, Tripathy et al, stated that there is no usefulness of using bromocriptine with CC for stimulation of ovulation in females with PCOS who have euprolactinemia.[14] 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 have a more adverse effect and low affectivity than cabergoline. Xue et al described the efficacy of bromocriptine and CC in infertile females with the usual level of prolactin and female with galactorrhea.[15] Also, they found that both bromocriptine and CC led to an increase in gestation rate and a decrease in miscarriage. These results were compatible with the results of the current study. Another study showed that cabergoline can enhance endometrial perfusion and regulate menstrual cycle in PCOS patients which indirectly increases endometrial receptivity and thus improve pregnancy outcome.[16] This effect of cabergoline is explained by its ability to inhibit the vascular endothelial growth factor (VEGF) secretion in luteinized granulosa cells.[17] In addition to its inhibitory effect on LH and androgen secretion, with improving insulin resistance helping in good ovulation response 75%.[18]

In the study we found no statistical difference in miscarriage (p=0.15), twin pregnancy (p=0.86) and OHSS rate (p=1.0). Our results were comparable with of Mervat et al, no difference between both groups as regard the miscarriage multiple gestation, ovarian hyperstimulation rate.[2] Suha et al where there were no significant differences between the groups regarding effect like ovarian hyper stimulation rate, multiple pregnancy rate as well as other adverse effects.[3] In Kamal et al study no difference between both groups as regard the miscarriage rate (p=0.74), multiple pregnancy rate (p=0.83), ovarian hyperstimulation rate (p=0.62).[11] In Niyazi et al incidence of OHSS is significantly reduced in cabergoline group 60% in IVF/ICSI.[19] Mohammad et al stated that low rate of OHSS and multiple gestation rate with the use of cabergoline so it can be used safely through pregnancy.[20]

In the current study, cabergoline fine tolerated by all females with no significant side effects which was comparable to Mervat et al no difference between both groups as regard the side effects of the study medications.[2] Suha et al where cabergoline was well tolerated with no side effects in patients.[3] In kamal et al study, cabergoline was well tolerated by all patients and no adverse effects were observed.[11]

CONCLUSION

In conclusion, this study showed that addition of cabergoline to letrozole in induction of ovulation in euprolactinemic infertile women with PCOS results in high ovulation rate, high pregnancy rate with no difference in miscarriage, multiple pregnancy and OHSS rates compared to use of Letrozole alone. Future studies are needed to address the effects of adding cabergoline to Letrozole on the endometrial receptivity, Doppler indices in the uterine artery in PCOS patients, in treatment of unexplained infertility and in context of controlled ovarian hyperstimulation of IVF.

The main strength of our study is the randomized design. We were able to recruit our calculated sample size for achieving adequate power to detect a clinically significant difference in our primary and secondary outcomes.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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