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**Article** · January 2015

DOI: 10.1044/1980-iajpr.14451

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# *TESTO* INDUCED OVULATION SUCCESSFULLY IN WOMEN OF POLYCYSTIC OVARIAN SYNDROME

**Sanjeeda Parveen[1], Shabnam Ansari[2*]**
[1]*Tetotia Hospital Test-Tube Baby Center, Bulandshehar, India.*
[2]*Faculty of Medicine [U], Jamia Hamdard, India.*

**ARTICLE INFO**

**Article history**
Received 23/06/2015
Available online
30/06/2015

**Keywords**
Testo,
PCOD,
PCOS,
Anovulation,
Infertility,
Ovulation,
Polycystic Ovaries.

**ABSTRACT**

Polycystic ovary syndrome (PCOS) is characterized by anovulation, hyper-androgenism and polycystic ovaries on scanning and is the most common endocrine disorder in women of reproductive age. Testo, is an Ayurvedic poly-herbal preparation has been used by physician for infertility and menstrual irregularity since centuries. To assess the effect of Testo as the first-line medication to be used in anovulatory cycles in patients with PCOS for ovulation induction. We conducted a case series on 11 females of PCOS with anovulatory cycles. After informed consent, patients were treated with Testo, one capsule twice daily. Outcomes were based on serum progesterone test at day 22nd of each treatment cycle, ultrasonography finding of ovulation and effect on menstrual cycle irregularity. We observed, the rate of ovulation in 1st treatment cycle was 45.45% while in 2nd treatment cycle, the rate of ovulation was highly significant 81.81% without any adverse effects. Menstrual cycle got regulated in all the patients along with relief in dysmenorrhea. The rate of ovulation observed with Testo treatment in second cycle of treatment, was 81.81% while with clomiphene citrate [CC], ovulation rate was 59 % and with combination therapy (metformin + clomiphene citrate), was 68% in a clinical trial, revealing potential of Testo in ovulation over CC and metformin. We reviewed the literature related to the Testo, its constituents, have exhibited potential folliculogenetic, estrogenic, progesteronic, anti-inflammatory, analgetic, astringent activities, suggesting plausible mechanisms of action in these patients. The preliminary findings indicate the safe and potential ovulation inducing role of Testo. Further trials is undergoing, which is aimed to explore the therapeutic potential of this medicine in anovulatory infertility.

***Corresponding author***
**Dr. Shabnam Ansari**
MD Scholar,
Department of Moalejat,
Faculty of Medicine [U],
Jamia Hamdard, India.
drshabnamansari.md@gmail.com

*Please cite this article in press as **Sanjeeda Parveen** et al. Testo Induced Ovulation Successfully In Women of Polycystic Ovarian Syndrome. Indo American Journal of Pharm Research.2015:5(06).*

## INTRODUCTION

Polycystic ovarian syndrome (PCOS) is also known as Stein-Leventhal syndrome. It is a complex endocrinal and metabolic disorder that affect a women menstrual cycle, hormone, fertility, insulin production, circulatory system and appearance. It affects 5–10% of premenopausal women [1] Woman's affected with this condition experiences a lot of symptoms such as irregular or absent menstrual cycles, increased number of small follicles in ovary, abnormal hair growth, and acne. In addition, metabolic syndrome in the form of glucose intolerance, insulin resistance, hypertension, dyslipidemia, increased risk of DM type 2, cardiovascular disorders and increase incidence of endometrial cancer, are manifested in PCOS woman's. [2]

This disorder, affecting 5% to 10% of women of reproductive age based on U.S. National Institutes of Health (NIH) criteria and as high as 15% when the broader Rotterdam criteria are applied [3], can and has caused physical and emotional strain on women and families when left undiagnosed.

The first-line medical treatment for ovulation induction in PCOS women is clomiphene citrate (CC), which can result in an ovulation rate of 60–85% but a conception rate of only about 20%. [4-7] Anti-oestrogenic effects of CC on the endometrium and cervix mucus are thought to cause the low conception rate. [8] Also, CC may have a number of side effects including hot flushes, breast discomfort, abdominal distension, nausea, vomiting, nervousness, sleeplessness, headache, mood swings, dizziness, hair loss and disturbed vision. [7] PCOS and metformin is widely chosen. [9] Although a newly published meta-analysis showed that metformin has not improved live birth rates and associated with a higher incidence of gastrointestinal disturbances which hampered its clinical compliance with high dropout rates. [10]

On the other hand, *Testo* (trade name), a poly-herbal preparation has been used since centuries in Ayurveda for infertility, ovulation induction and menstrual disturbances. The advantage of herbal preparation in inducing ovulation is that they induced ovulation without any side effect as well as also correct the irregular menstrual bleeding and associated constellation of symptoms. So we performed present case series to assess the impact of *Testo* in ovulation induction in PCOS and to collect data to warrant further clinical trial.

## MATERIAL & METHODS

Informed consent was taken from the patients in their known languages. Human data included in this case series was obtained in compliance with the Helsinki Declaration.

### *Intervention*

*Testo*, is a trade name of poly-herbal Ayurvedic preparation, available in the capsule form is prepared and distributed by Otegen Global incorporation®, Faridabad, a GMP, ISO, HACCP certified company. The capsule contain extract of following constituents. [Table 1].

**Table 1: Composition of *Testo.***

| No. | Botanical name | Common name | Quantity |
|---|---|---|---|
| 1 | *Alchemilla vulgaris* | Lady's Mantle | 100 mg |
| 2 | *Achillea millefolium* | Yarrow | 50 mg |
| 3 | *Capsella bursa-pastoris* | Stephard's Purse | 50 mg |
| 4 | *Glycyrrhiza glabra* | Licorice Root | 100 mg |
| 5 | *Oenothera biennis* | Evening Primorose | 50 mg |
| 6 | *Putranjiva roxburghii* | Putrak jeevak | 50 mg |
| 7 | *Bryonia laciniosa* | shivlingi | 30 mg |
| 8 | *Mucuna pruriens* | Sh. Kaunch | 20 mg |
| 9 | *Asparagus racemosus* | Satawari | 20 mg |
| 10 | *Withania somnifera* | Ashwagandha | 25 mg |

One capsule was advised twice daily at 9 am and 6 pm for 2 months.

### *Case presentation*

11 woman's of PCOS diagnosed by abdominal and trans-vaginal ultrasonography and hormonal evaluation were administered with *Testo*, one capsule twice daily, starting on the day 1st day after a spontaneous period or a withdrawal bleeding. Following inclusion criteria were used.

a. Age between 20 and 40 years
b. Oligo-ovulation or anovulation
c. Confirmed diagnosis of PCOS according to the Rotterdam 2003 criteria (2 of 3)
d. Clinical and/or biochemical signs of hyperandrogenism
e. Exclusion of other causes of hyperandrogenism like Cushing's syndrome.
f. Exclusion of Diabetic with renal, liver and neurological disorders.

***Outcome Measures***

a. Serum progesterone test at day 22nd of each treatment cycle.
b. Follicular monitoring, ovulation on 10th -14th day
c. Effect on Menstrual bleeding irregularity
d. Side effect: The patient will be asked to record adverse events and report to the coordinator during each visit. Haemogram and kidney function test (KFT), liver function test (LFT), urine routine and blood sugar (fasting and post-parandial) analysis were done pre and post-*Testo*-treatment to assess any side effects.

## RESULTS

After 2 months of treatment with *Testo* extremely significant relief in the patient's condition were observed. Improvements in following parameters were observed after treatment,

***Effect on serum progesterone:***

[Table 2] showing the summary of serum progesterone levels performed at 22nd day of each treatment cycle. Progesterone levels >3 ng/mL was considered as ovulation. The rate of ovulation in first treatment cycle was 45.45% while in second treatment cycle, the rate of ovulation was highly significant 81.81 %.

**Table 2: Effect of *Testo* on Serum Progesterone.**

| S. No | 1st treatment cycle | 2nd treatment cycle |
|---|---|---|
| Case 1 | >3 ng/mL | >3 ng/mL |
| Case 2 | >3 ng/mL | >3 ng/mL |
| Case 3 | <3 ng/mL | >3 ng/mL |
| Case 4 | <3 ng/mL | <3 ng/mL |
| Case 5 | >3 ng/mL | >3 ng/mL |
| Case 6 | <3 ng/mL | <3 ng/mL |
| Case 7 | >3 ng/mL | >3 ng/mL |
| Case 8 | <3 ng/mL | >3 ng/mL |
| Case 9 | <3 ng/mL | >3 ng/mL |
| Case 10 | <3 ng/mL | >3 ng/mL |
| Case 11 | >3 ng/mL | >3 ng/mL |

***Effect on follicular monitoring in ultrasonography*:**

The ovum size of 18-22 mm were observed during follicular monitoring of ovulating patients, presented good follicular size in the 2nd treatment cycle with *Testo*. The ovulation rate corresponded equally with progesterone levels in women.

***Effect on irregular menstrual cycle***:

Regularity in menstrual cycle is observed in 100% of the PCOS patients, validating its usage in regularization of menstrual cycle and improvement in constellation of symptoms**.** Dysmenorrhea was present in 65 % of patients and all the patients got relieved after first cycle of treatment with *Testo*.

***Assessment of adverse events:***

No adverse events were observed during and post-treatment with *Testo*. Haemogram, blood sugar (fasting and post-prandial), LFT, KFT remained normal post-treatment with *Testo*, provided its safe profile for usage in patients of anemia, diabetes, kidney and liver dysfunction.

## DISCUSSION

Patients struggling with PCOS are experiencing infertility, and depression. In unmarried woman's, PCOS is associated with menstrual irregularity and depression due to virilization.

In present study, 11 patients of PCOS with anovulatory cycles, diagnosed according to the Rotterdam 2003 criteria [2 of 3] were treated with *Testo* capsule, twice daily for two months started from 1st day of spontaneous or withdrawal bleeding. *Testo*, capsule is a trade name of an Ayurveda preparation containing extract of 10 herbal constituents: *Alchemilla vulgaris, Achillea millefolium, Capsella bursa-pastoris, Glycyrrhiza glabra, Oenothera biennis, Putranjiva roxburghii, Bryonia laciniosa, Mucuna pruriens, Asparagus racemosus,* and *Withania somnifera.*

In first cycle of usage of *Testo*, ovulation occurred in 45.45% of PCOS patients. In the second treatment cycle, the rate of ovulation by *Testo*, was considerably high, 81.81% marked by progesterone levels >3 ng/mL on 22nd day of cycle which was highly significant in ovulation induction than clomiphene citrate with a rate of ovulation, 59% and combination therapy (metformin + clomiphene citrate), 68%. [11] The ovulation was also confirmed by ultrasonography abdomen and by trans-vaginal approach in these patients. Follicular sizes in these patients were ranged between 18-22 mm. In addition to ovulation induction, *Testo* also corrected irregular menstrual cycle and resolved dysmenorrhea complain in all the patients.

This finding showed the preliminary potential efficacy of *Testo* in ovulation induction and its benefit in correcting PCOS-associated menstrual irregularity over clomiphene citrate and combination therapy of metformin and clomiphene citrate without any adverse effects. However limitation of the study was its small sample size.

The constituents of *Testo* such as alchemilla (ladies mantle) is reported to be a progesteronic herb. [12] Licorice (*Glycyrrhiza glabra*) is known to exhibit many pharmacological actions, such as estrogenic, anti-testosterone, aldosterone-like, anti-inflammatory [cortisol-like]. It is proposed to balance estrogen levels in the body. It also supports healthy insulin levels and liver health for hormonal balance support. Licorice is excellent for proper immune, inflammation and stress response as well. Women with PCOS have been shown to benefit from reducing inflammation. Shivling seeds (*Bryonia laciniosa)* are reported to produce ovulation in older anovulatory females of diminished ovarian reserve (DOR). [16] In a rat model, methanolic extract of *Mucuna pruriens*, resulted in dose dependent increase in FSH and LH ($p < 0.05$ at 200 mg/kg) levels with an increase in the number of oocytes released at ovulation compared to control. [17] Shatavari is reported to enhance folliculogenesis and ovulation, prepares womb for conception, prevents miscarriages, normalizing uterus and changing hormones. [18] All these properties of constituents of *Testo*, probably resulted in increasing progesterone levels through proper estrogen secretion and metabolism, balanced insulin levels, and overall Support on endocrine system function, leading to regular ovulation, could be the plausible mechanism of action of *Testo* in these PCOS patients. [13, 14, 15] *Glycyrrhiza glabra* extract may contain many growth factors, and energy sources that supporting the FR and normal development of early cleavage stages of mice embryos in vitro .This result can be utilized for IVF program in mammals [13] Moreover constituents such as achillea, alchemilla (ladies mantle), capsella (stephard's purse) are found to be helpful in correcting a heavy menstrual flow and other menstrual irregularity, can be the reason for regularization of menstrual cycle. [12] Alchemilla, withania, shatavari contain salicylates, anti-inflammatory, astringents, analgesic compounds, probably the cause for relief in dysmenorrhoea and associated constellation of symptoms. [12]

## CONCLUSION

This case series provides an important novel direction in which *Testo* can be used for induction of ovulation in PCOS women. In our experience, *Testo* therapy can significantly induce ovulation as well cure the menstrual irregularity and dysmenorrhea without any adverse events. *Testo* is under further trial for its effect on fertility in anovulatory infertility in PCOS.

**Conflicts of interest**

None declared

## ACKNOWLEDGEMENTS

We appreciate the co-operations of patients in this study. We are grateful to the Otegen Global incorporation®, Faridabad, for their funding and support in this study.

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