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Value of preoperative luteinizing hormone before laparoscopic ovarian drilling in polycystic ovarian syndrome with clomiphene resistance

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Abstract

Background

Polycystic ovary syndrome (PCOS) is considered the most common endocrine-metabolic disorder in women in reproductive age with decreased rates of ovulation and metabolic alterations, with resulting subfertility. Clomiphene citrate (CC) is a widely used first-line treatment for infertile women with PCOS, but approximately 20% of patients have been shown to be CC resistant. Laparoscopic ovarian drilling (LOD) is a treatment option for infertile women with CC resistant PCOS. The use of a clinical biomarker such as luteinizing hormone (LH) to identify the subgroup of patients who are sensitive to LOD may be an important and consistent way to increase the efficiency of this treatment.

Objective

To evaluate the efficiency of the preoperative LH serum level assay to predict fertility improvement of the LOD in CC resistant PCOS.

Patients and methods

A prospective interventional clinical study was carried out on 44 patients with PCOS diagnosed via clinical, laboratory, and sonographic criteria. All cases had failed to respond to CC 150 mg/day for 5 days of 6 successive cycles. Before LOD, the mean serum levels of follicle stimulating hormone, LH, and LH/follicle stimulating hormone ratio were estimated. LOD was done using a probe of endocoagulation to produce a maximum of four punctures for each ovary with 4-mm depth. All patients were followed up for 6 months postoperatively after the LOD procedure to evaluate the effect of the procedure on the spontaneous ovarian follicular growth (primary outcome), and the secondary outcomes of the occurrence of the ovulation, gain of conception, and clinical regulation of the menstrual abnormalities.

Results

LOD was an efficient treatment modality to achieve good ovarian follicular growth response in 34 (77.2%) cases. The preoperative serum LH cutoff level of 8.35 mIU/ml was a good predictor of LOD follicular response with 89% sensitivity and 83% specificity. Preoperative serum LH level of greater than or equal to 8.35 mIU/ml was a good prognostic marker for the satisfactory follicular response with normalization of menstrual rhythm in 30 (68.2%) cases and ovulation with subsequent pregnancy in 26 (59%) cases within 6 months of follow-up period.

Conclusion

Preoperative LH greater than or equal to 8.35 mIU/ml may be an efficient predictor and prognostic factor for LOD outcomes of improved menstrual pattern, spontaneous follicular growth, ovulation, and increased pregnancy rate in patients with PCOS with clomiphene resistance.

Keywords: Clomiphene resistance, infertility, laparoscopy, ovarian drilling, polycystic ovary syndrome

INTRODUCTION

The polycystic ovary syndrome (PCOS) diagnosis is based on an international consensus that at least two out of three criteria have to be met in order to fit, including oligo/anovulation,

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clinical or biochemical hyperandrogenism, and polycystic ovaries picture by ultrasonography [1].

Clomiphene citrate (CC) is commonly used as the first-line treatment for ovulation induction in anovulatory patients with PCOS [2]; however, resistance to clomiphene together with its adverse effects like multifollicular development and cyst formation are areas of concern [3]. The options for women with clomiphene resistance include insulin sensitizers, gonadotropins, laparoscopic ovarian drilling (LOD), and assisted reproductive techniques [4].

LOD had minimal morbidity associated with the laparoscopic procedure, less need for cycle monitoring, low risk of multiple pregnancies, and a significant reduction in both direct and indirect costs [5]. Additionally, in women with clomiphene-resistant PCOS, LOD was effective as an ovulation induction technique with follicle stimulating hormone (FSH) treatment in terms of live births and reduction in the need for ovulation induction or assisted reproductive techniques [6].

The use of a clinical marker to detect the subgroup of patients who are sensitive to LOD may be an important way to increase the efficiency of this treatment [7]. Preoperative serum luteinizing hormone (LH) level may be a good predictor of LOD efficacy in patients with PCOS. Therefore, application of strict criteria for LOD should be considered, as LOD for patients with low LH levels is not only ineffective but also may impair ovarian reserve [8].

Objective

The objectives of the research study were to evaluate the efficiency of preoperative LH serum level assay to predict the potential of LOD to improve the follicular response, normalize the menstrual pattern, and increase the conception rate in patients with PCOS with CC resistance.

PATIENTS AND METHODS

This research was a prospective interventional clinical study that was carried out at Shebin Elkom Teaching Hospital during the period from July 2016 till March 2018. The local hospital ethical research rules were followed, and all patients signed a written informed consent after explaining to them the nature of the procedure. Patients were subjected to full history taking; general, abdominal, and local examination; laboratory investigation; and pelvic ultrasound investigation.

The study population included 44 infertile women with PCOS, who were CC resistance and scheduled for LOD.

Criteria for diagnosis of PCOS included at least two of the following: oligoovulation and/or anovulation, clinical signs of hyperandrogenism (hirsutism, acne, and androgenic alopecia), and/or biochemical signs of hyperandrogenism (increased free testosterone or free androgen index), and ultrasound picture of polycystic ovaries: presence of 12 follicles or more in one ovary measuring 2–9 mm in diameter and/or increase ovarian volume ($>10 \text{ ml}^3$) [9].

Criteria of clomiphene resistance was failure to ovulate with CC 150 mg/day for 5 days for six successive cycles of clomiphene.

The exclusion criteria included factors that may contribute to infertility other than PCOS (as abnormal seminogram of the male partner, anatomical uterine anomalies or blocked fallopian tubes detected by ultrasound and/or hysterosalpingography, and medical or surgical contraindications to laparoscopy).

- (1) Interventional laboratory investigations were as follows: serum LH and FSH were evaluated on the second day of the menstrual cycle (either spontaneous or induced by progesterone).
 - (a) Sample collection: fasting blood samples were taken from all women in vacutainer tubes. All samples were kept at room temperature for at least 30 min to allow the blood to clot and were then centrifuged at 2000 for 15 min. Serum was collected and stored at -20°C until assayed.
 - (b) Hormonal assay: the concentrations of LH and FSH were assayed using reagents supplied by Dpc (Diagnostic Products Corporation, Los Angeles, California, USA) by enzyme chemiluminescence immunoassay. All hormonal assays were performed at the same laboratory.
- (2) LOD: after hormonal evaluation, LOD was done using Storz laparoscopic tower and instruments (Karl Storz GmbH, Tutlingen, Germany).

Technique of laparoscopic ovarian drilling

Under general anesthesia and good muscle relaxation, and after the routine preoperative preparation and sterilization, the urinary bladder was evacuated with catheter and then examination under anesthesia was performed. CO_2 pneumoperitoneum was achieved by insertion of veress needle usually at small incision made at the inferior rim of the umbilicus followed by safe entry of a primary 10-mm trocar and two lateral secondary 5-mm trocars 5–7 cm apart from the primary one with transillumination site guidance to avoid injury of viscera or pelvic blood vessels. Visualization of pelvic organs was done to exclude other possible causes of infertility. Afterward, the ovary was held from the ovarian ligament by nontraumatic forceps, and then monopolar diathermy needle passed against the ovarian antimesenteric surface performing four punctures on each ovary in most of the cases through the ovarian cortex to a depth of 4 mm graduated on the specific needle used for the procedure. The number of punctures was tailored according to the size of the ovary in some patients. The ovaries were immediately cooled by normal saline solution. The minimal effective current of electricity and application time were used to avoid thermal damage to the normal ovarian tissue and potential deleterious effect to the ovarian reserve.

Follow-up

All patients were followed up monthly for 6 months after the operation to detect follicular growth and ovulation by transvaginal folliculometry and serum progesterone:

- (1) Folliculometry: transvaginal sonographic monitoring of follicle growth at a frequency of 6.5 MHz was performed using Sonoace 3200 machine (MEDISON CO., LTD 1003, Daechi-dong, Gangnam-gu, Seoul 135-280 Korea) starting at the eighth day of menstrual cycle and continued every 2 days thereafter for 10 days until the appearance of a preovulatory follicle (mean diameter ≥ 18 mm) and subsequent follicle rupture and presence of free fluid in Douglas's pouch or not:
- (a) Accordingly, patients were then divided into two groups: group 1 (responders) included patients who showed follicular growth greater than or equal to 18 mm and group 2 (nonresponders); patients who did not show follicular growth greater than or equal to 18 mm.
 - (i) Serum progesterone:
 - (b) With the same technique of sample collection for the previous estimation of FSH and LH, the concentration of progesterone (P) was assayed using reagents supplied by Dpc (Diagnostic Products Corporation) by enzyme chemiluminescence immunoassay. The serum progesterone level was an indicator of the corpus luteum function.

Statistical methods

The sample size was calculated taking in consideration type 1 (α) and type 2 (β) errors to be 5 and 20%, respectively. The equation used to calculate the sample size was as follows:

$$N = \frac{16\sigma^2}{d^2}$$

where N = sample size; σ^2 = variability of the test used for discrimination between LH values, which was stated by the manufacturer of the LH assay to be around 10%; and d = the effect size, which is the amount by which the researchers would expect the difference and considered to be 60% elevation corresponding to the normal LH variation range.

Statistical analysis

SPSS V. 25 (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp) was used for data analysis. Data were expressed as both number and percentage for categorized data and mean \pm SD for quantitative data. χ^2 -Test was used to study the association between each two variables or comparison between two independent groups regarding the categorized data whereas t -test was used to study the difference between independent groups and paired t -test for the difference between related groups regarding the numerical data. The probability error P less than 0.05 was considered significant and P less than 0.001 was highly significant.

Accuracy tests were used to study the efficacy of the response prediction, they included sensitivity, specificity, the positive predictive value (PPV) and negative predictive value (NPV).

Limitations

No limitations were encountered during the whole research procedures except the effort to maintain the communication with patients and keep the maintenance of regular follow-up of the 6 months of the postoperative period, but fortunately none of them were lost during follow-up period.

RESULTS

Patients had shown a mean age of 28.3 ± 4.6 years, a mean BMI of 27.3 ± 1.78 kg/m², and infertility, either primary (59.1%) or secondary infertility (40.9%), with a mean duration of 4.73 ± 2.57 years (Table 1).

Insignificant differences were encountered between responders and nonresponders regarding patient characteristics (age, BMI, and duration of infertility) and preoperative data (menstrual pattern and the infertility type) (Table 2).

Significant higher preoperative LH serum level and LH/FSH ratio were present in responders than nonresponders (Table 3).

The frequency of response groups at LH category levels revealed the highest numbers of responders were at 8–9 mIU/ml LH stratum (Table 4).

The frequency of follicular responses outcome as regards to the means of the preoperative different LH category levels (6.72, 7.41, 8.35, 9.68, and 11.2 mIU/ml respectively) and the related prognostic accuracies (Table 5a–e, respectively).

Assignment of cutoff points (means of the major frequent strata of preoperative LH) using receiver operating characteristic curve analysis revealed the highest sensitivity, specificity, and accuracy of 88.24, 80, and 86.36%, respectively, at the LH cutoff level of 8.35 mIU/ml (Table 6).

Table 1: Patient characteristics and preoperative data

	Range (mean \pm SD)
Age	20-35 (28.30 \pm 4.63)
Duration of infertility	2-11 (4.73 \pm 2.57)
BMI	25-30 (27.30 \pm 1.87)
Preoperative menstrual abnormalities [n (%)]	
Oligomenorrhea	35 (79.5)
Secondary amenorrhea	9 (20.5)
Infertility type	
Primary	26 (59.1)
Secondary	18 (40.9)

Table 2: Differences of follicular responses regarding the patient characteristics and preoperative data

	Responders (n=34) (mean \pm SD)	Nonresponders (n=10) (mean \pm SD)	P
Age (years)	27.9 \pm 3.2	29.4 \pm 4.1	>0.05
Infertility duration (years)	4.62 \pm 1.7	5.10 \pm 2.5	>0.05
BMI (kg/cm ²)	27.24 \pm 2.1	27.50 \pm 6.8	>0.05
Menstrual abnormalities [(n) %]			
Oligomenorrhea	27 (79.4)	8 (80)	<0.05
Secondary amenorrhea	7 (20.6)	2 (20)	
Infertility type [(n) %]			
Primary	20 (58.8)	6 (60)	>0.05
Secondary	14 (41.2)	4 (40)	

Table 3: Comparison between follicular responses as regarding preoperative measurements of hormonal parameters

	Responders (n=34) (mean±SD)	Nonresponders (n=10) (mean±SD)	P
FSH (mIU/ml)	6.2±1.2	5.9±3.4	>0.05
LH (mIU/ml)	12.5±2.4	5.2±4.1	<0.001
LH/FSH ratio	2.04±0.9	0.98±0.6	<0.05

FSH, follicle stimulating hormone; LH, luteinizing hormone.

Table 4: Description of frequencies of follicular responses at different luteinizing hormone categories

LH categories (mIU/ml)	Responders (n=34) [n (%)]	Nonresponders (n=10) [n (%)]
≤7	1 (2.9)	6 (60)
7-8	3 (8.9)	2 (20)
8-9	18 (52.9)	0 (0)
9-10	7 (20.6)	1 (10)
>10	5 (14.7)	1 (10)
Total	34 (100)	10 (100)

LH, luteinizing hormone.

There was significant improvement of menstrual abnormalities after LOD, with restoration of regular cycles of 77.2% of cases (Fig. 1).

The frequency of ovulation confirmed by ultrasound assessment after LOD revealed approximately 71% of the follicular responder within the follow-up period (Fig. 2).

The frequency of postoperative serum progesterone greater than 10 ng/ml as an indicator of good corpus luteum function was higher in the responder group with LH greater than 8.35 mIU/ml subgroup (86.7%) (Table 7).

Significant higher frequency of positive pregnancy was observed (59%) after LOD in cases with preoperative LH greater than or equal to 8.35 mIU/ml (Table 8).

DISCUSSION

In the current research, the patients' age ranged between 20 and 35 years with a mean of 28.30 ± 4.63 years, the mean BMI was about 27.3 ± 1.78 kg/m², and the mean duration of infertility was approximately 4.7 years (Table 1). Comparison between responders and nonresponders regarding patient preoperative data showed no statistical significance regarding the age, infertility type or duration, and BMI (Table 2). These findings may be coincident with the report of Martinez-Guisasola et al. [10] that PCOS had no correlation with obesity, but may be criticized by others [11] who found that the mean of BMI was higher in patients with PCOS than in control group (28.4 ± 6 vs. 25.7 ± 4.4 kg/m², respectively). Moreover, an inverse relationship has been reported between the duration of infertility and the chances of success of LOD [12].

Table 5: Comparison of the follicular response as a primary outcome after LOD as regards to the LH cut offs (means of LH categories)

	Responders (n=34)	Nonresponders (n=10)	P
(a) Comparison between follicular responders and nonresponders regarding LH category (LH<7) represented by its mean value of 6.72 mIU/ml			
LH category of 6.72 mIU/ml [n (%)]			
LH≥6.72	33 (88.2)	7 (20)	<0.05
LH<6.72	1 (11.8)	3 (80)	
Sensitivity	Specificity	PPV	NPV
82.50%	75.00%	97.06%	30.00%
(b) Comparison between follicular responders and nonresponders regarding LH category (LH 7-8) represented by its mean value of 7.41 mIU/ml			
LH category of 7.41 mIU/ml [n (%)]			
LH≥7.41	32 (88.2)	5 (20)	<0.05
LH<7.41	2 (11.8)	5 (80)	
Sensitivity	Specificity	PPV	NPV
86.49	71.43%	94.12%	50%
(c) Comparison between follicular responders and nonresponders regarding LH category (LH 8-9) represented by its mean value of 8.35 mIU/ml			
LH category of 8.35 mIU/ml [n (%)]			
LH≥8.35	30 (88.2)	2 (20)	<0.05
LH<8.35	4 (11.8)	8 (80)	
Sensitivity	Specificity	PPV	NPV
88.24	80%	93.75%	66.67%
(d) Comparison between follicular responders and nonresponders regarding LH category (LH 9-10) represented by its mean value of 9.68 mIU/ml			
LH category of 9.68 mIU/ml [n (%)]			
LH≥9.68	8 (88.2)	9 (20)	<0.05
LH<9.68	26 (11.8)	1 (80)	
Sensitivity	Specificity	PPV	NPV
47.06%	3.70%	23.53%	10.00%
(e) Comparison between follicular responders and nonresponders regarding LH category (LH>10) represented by its mean value of 11.2 mIU/ml			
LH cut-off level of 11.2 mIU/ml [n (%)]			
LH≥11.2	2 (88.2)	0 (20)	<0.05
LH<11.2	32 (11.8)	10 (80)	
Sensitivity	Specificity	PPV	NPV
16.67%	100%	100%	76.19%

LH, luteinizing hormone; NPV, negative predictive value; PPV, positive predictive value.

Table 6: Assignment of cutoff points (means of the major frequent strata of preoperative luteinizing hormone) using receiver operating characteristic curve analysis

LH (mIU/ml)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Diagnostic accuracy (%)
6.72	82.50	75.00	97.06	30.00	81.82
7.41	86.49	71.43	94.12	50.00	84.09
8.35	88.24	80	93.75	66.67	86.36
9.68	47.06	3.70	23.53	10.00	20.54
11.2	16.67	100	100	76.19	77.27

LH, luteinizing hormone; NPV, negative predictive value; PPV, positive predictive value.

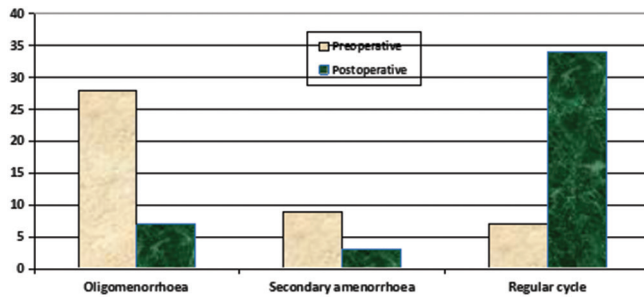


Figure 1: The menstrual pattern before and after ovarian drilling.

The preoperative menstrual abnormalities were present in most of our patients in the form of oligomenorrhea (79.5%) and secondary amenorrhea (20.5%) (Table 1), with the frequency distribution differences of those parameter were significant between the responder and non-responder groups before LOD (Table 2). These observations may reflect that most abnormal menstrual patterns of PCOS were oligomenorrhea caused by the associated hyperandrogenic condition [13].

Concerning the preoperative gonadotropin hormonal profile and its association with the follicular response after LOD, a statistical significant difference was present with a higher mean (12.46 mIU/ml) within the responder group compared with nonresponders (a mean of 5.2 mIU/ml). The same situation was obvious regarding the LH/FSH ratio in predicting follicular response after drilling. The current results showed LH/FSH ratio was significantly higher in women who responded after LOD than in those who did not respond (2.04 vs. 0.98, respectively) (Table 3). These findings may be criticized by a previous research that reported that high preoperative LH levels were predictive of a better outcome, whereas the LH/FSH ratio was not [14].

Stratification of the preoperative LH levels and their association with the follicular response after LOD revealed the highest response was related to the LH category level of 8–9 mIU/ml (frequency of 52.9%) (Table 4).

Finer assessment to detect the best cutoff value of LH level represented by the mean value of each category (Table 5a–e) for follicular response prediction with the related sensitivity and specificity that revealed that the cutoff level of LH greater than 8.35 mIU/ml had the best accuracy to predict ovulation after LOD at 87.50%, with the sensitivity of 88.24%, the specificity of 80.%, the PPV of 93.75%, and the NPV of 66.67% (Tables 5c and 6). The current study results were similar to the study [8] that reported that at LH cutoff level of 8.0 IU/l, the overall accuracy to predict ovulation after LOD was 73% [95% confidence interval (CI): 56–85%], the sensitivity was 73% (95%CI: 54–87%), the specificity was 71% (95%CI: 29–96%), and the PPV was 92% (95%CI: 75–99%). However, the NPV differed to be 36% (95%CI: 13–65%). Other cutoff LH value was described as 12 mIU/ml, with a sensitivity and PPV of (89 and 90%, respectively) [15].

Significantly higher frequency of follicular response was revealed at preoperative serum level of LH greater than or equal

Ovulation Frequency After LOD

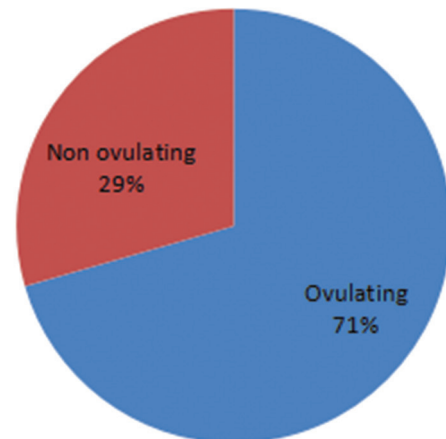


Figure 2: The frequency distribution of ovulating cases after laparoscopic drilling related to the total number of responder patients within 6 months of follow-up period.

to 8.35 mIU/ml (88.2%), with best sensitivity, specificity, and accuracy (88.24%, 80%, and 66.67% respectively) (Table 5c). Others reported that LH greater than or equal to 10 mIU/ml was an optimal level to yield LOD success follicular response [16].

Regarding the menstrual pattern after LOD, results of the current study showed a significant changes in the menstrual pattern among the studied patients in the form of a highly significant increase in the rate of regular cycles (77.2%), a significant decrease in the rate of the patients complaining of oligomenorrhoea and a significant decrease in the rate of the patients complaining of secondary amenorrhea (Fig. 1). Similarly, the increase incidence of regular cycle after LOD was reported to be 86% [17], as a result of the decrease of LH and androgen levels.

Satisfactory ovulation was considered if the leading follicle disappeared in the follow-up ultrasound. Accordingly, the number of responding patients was 34 (77.3%) cases, the number of nonresponding patients was 10 (22.7%) cases, and ovulation occurred in 32 (72.7% of the total) cases (Fig. 2), which represented approximately 94% of the responder group. Our results were comparable to LOD response rates of 83 [18], 86 [19], and 70% [20], respectively. In contrast, it was reported that, ~45% of participants in PCOS group remained with anovular cycles after LOD in spite of decreased level of LH and testosterone, and the satisfactory follicular size was gained only in 52.8% [21]; this may be explained by the nonconcomitant weight reduction with the sequelae of increased central fat and insulin resistance [22].

In another aspect, there was statistically significant higher frequency of progesterone level greater than 10 ng/ml as a denominator for satisfactory corpus luteum function among the responder subgroup of patients who have had LH greater than 8.35 mIU/ml (Table 7), and this may be attributed to the

Table 7: The postoperative serum progesterone (done on day 6 postovulatory) as an indicator for corpus luteum function (an outcome of the response after laparoscopic ovarian drilling) compared with the cutoff luteinizing hormone level (8.35 mIU/ml)

	Group I (LH <8.35) [n (%)]	Group II (LH ≥8.35) [n (%)]	P
Serum progesterone			
<10	6 (42.8)	4 (13.3)	<0.05
>10	8 (57.2)	26 (86.7)	

LH, luteinizing hormone.

Table 8: Pregnancy rate within 6 months of follow-up after laparoscopic ovarian drilling as related to the cutoff luteinizing hormone level (8.35 mIU/ml)

	Group I (LH <8.35) [n (%)]	Group II (LH ≥8.35) [n (%)]	P
Pregnancy			
Positive	2 (17)	26 (82)	<0.05
Negative	10 (83)	6 (18)	

LH, luteinizing hormone.

good ovulation and the release of the inhibitory environment of hyperandrogenism [23]. Moreover, the cumulative pregnancy rate was approximately 82% within 6 months after LOD in cases with preoperative LH greater than or equal to 8.35 mIU/ml. (Table 8). Comparably, it was reported that a trend toward higher conception rates of 69% existed with LH level greater than 10 mIU/ml [7], whereas a pregnancy rate of 32% with LH level of greater than 13.5 mIU/ml was prescribed [15]. In contrary, claims were provoked that high LH level before ovarian drilling did not predict pregnancy rate after drilling [24,25].

In the current study, mild postoperative fever in two patients was detected. No serious complications regarding anesthesia, hemorrhage, and the need of blood transfusion, injury to vital organs, sepsis, and amenorrhea were reported.

CONCLUSION

Preoperative LH greater than or equal to 8.35 mIU/ml may be an efficient predictor and prognostic factor for LOD outcomes of improved menstrual pattern, spontaneous follicular growth, ovulation, satisfactory luteal phase and increased cumulative pregnancy rate in patients with PCOS with clomiphene resistance.

Recommendation

There should be incorporation of high preoperative LH level as an indication for LOD as an alternative to gonadotrophins in patients with CC resistant with the potential prognostic value of good response after LOD.

More research may be required with recommendation to prolong the follow-up period to 1 year after LOD, which may reveal higher cumulative pregnancy rates.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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