

## **A REVIEW OF PREGNANCY OUTCOMES FOLLOWING LAPAROSCOPIC OVARIAN DRILLING FOR INFERTILE WOMEN WITH CLOMIPHENE RESISTANT POLYCYSTIC OVARIAN SYNDROME (PCOS) AT A PUBLIC HEALTH FACILITY IN ILORIN, NIGERIA.**

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### **ABSTRACT**

**Background:** Polycystic ovarian syndrome (PCOS) is the common endocrine disorder in women and its prevalence is on the increase due to availability of diagnostic tools. It is usually managed medically but for some resistant cases may require surgical intervention in the form of laparoscopic ovarian drilling (LOD). LOD is a one-off therapy avoids the need of medical therapy and its attendant complications.

**Aim and Objectives:** The objective of this study was to determine the impact of LOD on reproductive outcomes of infertile women with clomiphene resistance PCOS among clients attending the Assisted Reproduction Technology unit of University of Ilorin Teaching Hospital.

**Materials and Methods:** This is a prospective / longitudinal study of twenty three (23) patients of clomiphene resistant PCOS who underwent LOD between January and December 2012.

**Results:** The patients were aged 24-45years with a mean age of  $31.7 \pm 5.2$  years. Twenty (87%) out of twenty three were nulliparous and majority (87%) belong to middle social class. Eleven (47.8%) had primary infertility while 12 (52.2%) had secondary infertility. The mean duration of infertility is  $4.5 \pm 2.9$  years and the number of drills per ovary ranged from 4 to 15 (mean, right ovary= $8.6 \pm 3.24$ ; left ovary= $9.3 \pm 3.4$ ). Majority (95.7%) had at least one patent tube. The mean age of patients' husbands is  $38.8 \pm 5.7$  years with majority (82.6%) having normozoospermia. In the follow-up period, all 23 patients (100%) resumed menstruation and achieved ovulation (ovulation rate=

100%). The mean time of menstruation and ovulation were  $4.1 \pm 1.9$  days and  $5.3 \pm 3.2$  weeks respectively. Seven pregnancies were recorded from 23 patients giving a cumulative pregnancy rate of 30.4%. Of the remaining four pregnancies, one of the patients had successfully delivered, giving a live birth rate of 14.3%,

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while others are on-going. The mean time interval from LOD to pregnancy was  $4.7 \pm 1.6$  months. The pregnancy outcomes had no significant association with age of the women, parity, duration of infertility and types of infertility with  $p > 0.05$ .

**Conclusion:** LOD is a safe and effective one-off treatment for PCOS related infertility in patients who failed to respond to CC with efficacy equal to gonadotrophins and metformin. We recommend the need for its domestication in our locality.

**Keywords:** Anovulatory infertility, Laparoscopic ovarian drilling, Polycystic ovarian syndrome, Live birth

## INTRODUCTION

Polycystic ovarian syndrome (PCOS) is the most common endocrine disorder affecting 20-25% of women of child bearing age. The frequency ranges between 30-40% among infertile women, 70-80% in women with an ovulation and over 80% in women with hyperandrogenaemia<sup>1</sup>.

The exact underlying defect in PCOS is unknown; a genetic component is likely as PCOS tend to run in families and the pattern of inheritance is X-linked dominant<sup>2</sup>. Family studies have shown that about 50% of first degree relatives have PCOS.

The diagnosis of polycystic ovarian syndrome is by clinical and ancillary investigations revealing the presence of irregular menstrual cycles, an ovulation, elevated total and free testosterone levels (hyperandrogenaemia), and the presence of polycystic ovaries as recognized at the European Society of Human Reproduction and Embryology (ESHRE)/ American Society of Reproductive Medicine (ASRM) consensus meeting in Rotterdam 2003<sup>3</sup>. The diagnosis was based on the above criteria fulfilling sufficient specificity and sensitivity to define the ovarian morphology in PCOS as the presence of 12 or more follicles measuring 2 to 9 mm in diameter and increased of ovarian volume ( $>10\text{cm}^3$ )<sup>4</sup>. Patients

presenting with this description are termed to be clomiphene citrate (CC) resistant if they fail to ovulate after 3 to 4 cycles of treatment with CC.

The modalities of treatment of women who are non-responsive to ovulation induction with clomiphene (clomiphene resistant ovaries) include medical treatment with Gonadotrophins and / or Metformin as well as ovarian drilling<sup>5</sup>

Surgical wedge resection was established as a treatment for anovulatory polycystic ovaries by Stein Leventhal in 1935<sup>6</sup> but was largely abandoned due to risk of postsurgical adhesions and with the advent of medicine for ovulation induction. First choice for ovulation induction is clomiphene citrate and in case of resistance options are gonadotrophins or LOD. Clomiphene is successful in 80% of the cases; the 20% patients who fail to ovulate are declared clomiphene resistant<sup>7</sup>.

Introduction of LOD (first described by Gjonnaess in 1984)<sup>8</sup> reawakened interest in the surgical management of CC resistant PCOS patients. LOD involves use of cautery or laser vaporization to cause multiple perforations in the ovary. Many studies have claimed an increase in rates of spontaneous ovulation and conception after LOD along with improved responsiveness to subsequent medical therapy<sup>5, 7, 9</sup>. LOD can be done on outpatient basis with less trauma and

fewer postoperative adhesions<sup>9</sup>. On the other hand, gonadotrophins, although effective, expose the patients to risks of multiple pregnancy and hyperstimulation<sup>5</sup>. Also gonadotrophins are expensive and require repeated doses and intensive monitoring<sup>5,9</sup>.

The mechanism of action of LOD is not fully understood. Stein and Levantahl proposed that the thick capsule of the polycystic ovaries prevented ovulation and postulated that surgical wedge resection decreases the mechanical crowding of the cortex by cysts thereby enabling ovulation<sup>6</sup>. Others believe that ovarian diathermy works by increasing the sensitivity of the ovaries to endogenous FSH with resultant decrease in serum Luteinizing Hormone (LH) and androgen level<sup>7,10</sup>.

The objective of this observational study is to review the characteristics of the patients who underwent LOD at our centre and to evaluate the clinical pregnancy and live birth in these patients.

## **MATERIALS AND METHODS**

### **Setting**

This is a prospective / longitudinal study of patients who underwent LOD at ART unit of the department of Obstetrics and Gynaecology, University of Ilorin Teaching Hospital, Ilorin from 1<sup>st</sup> of January to 31<sup>st</sup> December 2012. The centre commenced laparoscopic surgeries since 2010, though majorly diagnostics; but started therapeutic laparoscopy since 2011 following commencement of activities at ART unit of the hospital.

### **Inclusion criteria**

Only patients who were diagnosed with PCOS using the Rotterdam criteria (2003) were scheduled for LOD. They had been treated with

clomiphene citrate up to a daily dose of 200mg for at least six menstrual cycles. Failure of ovulation after this period qualifies them for the procedure.

## **METHODS**

Information on biosocial data and other general information of the patients were documented at presentation. Investigation results i.e. transvaginal ultrasound and hormonal profile results and number of drills per ovary at surgery were noted. Patients were followed up during subsequent visits and also with the aid of mobile telephone to obtain information as regards resumption of menstruation and ovulation. Ovulation was confirmed using ovulation test kit (predict®), day 12- 14 follicular transvaginal ultrasound study and any pregnancy after the procedure. Statistical analysis was done using a commercial statistical package (SPSS/PC version 16.0, SPSS Inc., Chicago, III, USA). A p-value of < 0.05 was considered as statistically significant.

## **PROCEDURE**

Informed consent was taken for laparoscopic ovarian drilling which was done under general anesthesia. Pneumoperitoneum was created with Veress needles using the inferior crease of the umbilicus in the midline. The 10 mm infra-umbilical port was placed on the infra umbilical crease through a transverse incision and two 5mm lateral ports were placed in the lower abdomen just above the anterior superior iliac spine lateral to inferior epigastric vessels using base-ball diamond concept. The laparoscope was then introduced through the infra- umbilical port. A general inspection of the pelvis was done looking for other infertility factors. The tubes are examined and chromotubation for tubal

patency was carried out.

A mono polar hook was introduced at right angle to the ovary avoiding injury to the hilum. Forty (40) watts of cutting current was used making 4 to 15 holes each lasting 4 seconds at a depth of 3-4 mm to the ovaries. A thorough suction irrigation of the ovaries and peritoneal lavage with normal saline was done after the drill to cool the ovaries and clear the pelvis of any blood clots and debris. The port wound was closed by subcuticular suturing using Vicryl 2/0.

### **Treatment protocol**

Following the procedure, patient was observed for 3 months for natural conception to occur. However, if it fails, they were subjected to ovulation induction (OI) with timed intercourse (TI) or intrauterine insemination (IUI) on case to case basis. Patients who failed to conceive by these methods were offered In vitro Fertilization.

### **RESULTS**

Of the one hundred and twenty six patients who had infertility consultation during the study period, 39 (31%) were diagnosed as a case of PCOS; out of which 23 (59%) underwent successful LOD with a mean duration of follow-up time of  $9.3 \pm 6.5$  months (Range: 3-24 months). The patients aged 24-45 years with a mean age of  $31.7 \pm 5.2$  years. Twenty (87%) out of twenty three were nulliparous and majority (87%) belong to middle social class. Eleven (47.8%) had primary infertility while 12 (52.2%) had secondary infertility. The mean age of their husband was  $38.8 \pm 5.7$  years (range 30-50 years), with more than two- third (82.6%) having normozoospermia. Their duration of infertility ranges from 1 to 13 years ( $4.5 \pm 2.9$ ) and the number of drills per ovary ranged from 4

to 15 (mean, right ovary= $8.6 \pm 3.24$ ; left ovary= $9.3 \pm 3.4$ ) (Table 1).

Table 2 showed gender infertility factors and investigation results. Male alone factors and female alone factors accounted for 19 (82.6%) and 4 (17.4%) of cases respectively. Twelve (52.2%) had bilateral patent tubes, followed by 10 (43.5%) with unilateral patent tube. Only one patient (4.3%) had bilateral blocked tubes. Majority (82.6%) of their spouse had normozoospermia; followed by 2 (8.7%) with oligospermia and 1 (4.3%) each with oligoasthenozoospermia and azoospermia respectively. More than half (52.5%) of the patients had normogonadotropic normogonadism while 10 (43.5%) had hyperprolactinaemia.

All patients achieved spontaneous resumption of menses and ovulation following ovarian drilling with mean durations of  $4.1 \pm 1.9$  days and  $5.3 \pm 3.2$  weeks respectively. However, most of them 13 (56.5%) achieved return of menses within 4-6 days, followed by 9 (39.1%) within 1-3 days and one (4.4%) within 7-9 days respectively. Seven pregnancies were recorded from 23 patients giving a cumulative pregnancy rate of 30.4%. Out of which 3 (42.9%) resulted in early first trimester miscarriage. Of the remaining four pregnancies, one of the patients had successfully delivered, giving a live birth rate of 14.3%, while others are on-going. The mean time interval from LOD to pregnancy was  $4.7 \pm 1.6$  months. (Table 3).

Pregnancy outcome was not significantly affected by age of the woman ( $x^2=2.8$ ;  $p=0.27$ ), parity ( $x^2=0.01$ ;  $p=1.00$ ), husband age ( $x^2=2.61$ ;  $p=0.176$ ), duration of infertility ( $x^2=0.46$ ,  $p=1.00$ ), social class ( $x^2=1.51$ ;  $p=0.53$ ), types of infertility ( $x^2=0.35$ ;  $p=0.67$ ) and serum prolactin levels ( $x^2=0.00$ ;  $p=1.00$ ). (Table 4).

## **DISCUSSION**

The prevalence rate of PCOS in this study was 31%. This compares favorably with prevalence of 32%, 19-33% and 32-45% in Tanzania<sup>11</sup>, western<sup>12</sup> and African<sup>13</sup> populations respectively. However, a lower prevalence of 12.2%<sup>14</sup>, 18.1%<sup>15</sup> and 2.2%<sup>16</sup> was reported in a new teaching hospital in southern Nigeria, Enugu and Nnewi, respectively. The higher prevalence rate recorded in this study may be attributed to the fact that our centre is a dedicated infertility unit; therefore the study was conducted among infertile women attending ART clinic within the study period. Also majority (87%) of our patients belong to middle social class this is because our centre offers specialist services which is beyond the reach of the poor therefore there is need to subsidize this beneficial treatment modality to enhance its accessibility. Achieving spontaneous menstruation and ovulation following laparoscopic drilling was observed in all the patients. Similar findings have been documented in Nnewi, Nigeria<sup>9</sup>. However, our ovulation rate is slightly higher than 84.2%, 77.7% and 82% reported in Japan<sup>17</sup>, Poland<sup>18</sup> and Benin<sup>19</sup>, Nigeria respectively. The use of clomiphene citrate following menses for ovulation induction may be responsible for this increase. The cumulative pregnancy rate of 30.4% recorded in this study is slightly lower than 44.5% reported in Nnewi, Nigeria<sup>9</sup>. This is because the sample size in the present study was more (i.e. twenty three as against nine). However, this has demonstrated the relevance of LOD in the management of infertile women with clomiphene resistant PCOS. On the contrary, our pregnancy rate is lower than 83.3%<sup>20</sup>, 73%<sup>21</sup> and 76.9%<sup>17</sup> reported in Taiwan, France and Japan respectively. The difference

may be accounted for by other factors involved in the aetiology of infertility. The mean time interval from LOD to pregnancy of  $4.7 \pm 1.6$  months in this study is similar to reports from other previous studies<sup>5,9</sup>.

It has been observed that PCOS patients have higher miscarriage rates as compared to general population. It was also postulated that Leutenizing Hormone (LH) is the culprit. Hyperinsulinaemia and obesity are also known to be contributory in the increased miscarriage rate in PCOS<sup>22</sup>. LOD causes reduction in LH level and reduces the risk of miscarriage. In this study, the miscarriage rate of 42.9% following LOD is far higher than 14%<sup>9</sup> and 6.7%<sup>7</sup> reported from previous studies. However, other co-existing infertility factors may be responsible as 43.5% of our patients had hyperprolactinaemia. Observational studies showed that four major factors significantly and independently influence the successful outcome following LOD : the duration of infertility more than 3 years, increased Body Mass Index (BMI), the energy source used to treat the ovary and preoperative LH >10IU/L<sup>7, 9</sup>. On the contrary, findings from this study revealed that the pregnancy outcome was not significantly affected by age of the woman ( $x_2=2.8$ ;  $p=0.27$ ), parity ( $x_2=0.01$ ;  $p=1.00$ ), husband age ( $x_2=2.61$ ;  $p=0.176$ ), duration of infertility ( $x_2=0.46$ ,  $p=1.00$ ), social class ( $x_2=1.51$ ;  $p=0.53$ ), types of infertility ( $x_2=0.35$ ;  $p=0.67$ ) and serum prolactin levels ( $x_2=0.00$ ;  $p=1.00$ ). This may be attributed to the limited sample size in this study. However, a larger multicentre studies is required to validate these findings. Also, the influence of BMI, and serum LH on pregnancy outcome was not assessed in this study.

**CONCLUSION**

LOD ovarian drilling is an effective and safe treatment modality for clomiphene resistant polycystic ovarian syndrome patients with anovulatory infertility. Therefore, increasing access by way of subsidizing its cost and domestication of laparoscopic surgeries in our locality will go a long way in achieving optimal fertility care among PCOS patients.

**Table 1:** Socio-Demographic Variables (N=23)

Variable	Frequency	Percentage (%)
<b>Age wife (years)</b>		
24-29	9	39.0
30-35	9	39.0
>35	5	22.0
Range-24-45years	mean= 31.7±5.2	
<b>Parity</b>		
0	20	87.0
1	3	13.0
Range- 0-1	mean=0.1±0.3	
<b>Age husband (years)</b>		
30-34	7	30.4
35-39	7	30.4
40-44	5	21.7
≥45	4	17.4
Range-30-50 years	mean=38.8±5.7	
<b>Social Class</b>		
Low	3	13.0
Middle	20	87.0
<b>Type of Infertility</b>		
Primary	11	47.8
Secondary	12	52.2
<b>Duration of Infertility(years)</b>		
1-5	17	74.0
6-10	5	22.0
>10	1	4.0
Range-1-13 years	Mean=4.5±2.9 years	

**Table 2:** Gender Infertility Factors and

Variable	Frequency	Percentage (%)
(N=23)		
<b>Gender cause of infertility</b>		
Male alone	19	82.6
Female alone	4	17.4
<b>Sono-HSG</b>		
Unilateral patent tube	10	43.5
Bilateral patent tube	12	52.2
Bilateral tubal blockage	1	4.3
<b>Sperm Count</b>		
Normospermia	19	82.6
Oligospermia	2	8.7
Oligoteratosperm	1	4.3
Azoospermia	1	4.3
<b>Hormonal profile</b>		
Normogonadism	12	52.2
Hypogonadism	2	8.7
Hypergonadism	5	21.7
Normogonad/hperpro	1	4.3
Normogonad/normopro	3	13.0
<b>Prolactin Assay</b>		
Normoprolactinaemia	13	56.5
Hyperprolactinaemia	10	43.5

**Table 3:** Outcome Following Laparoscopic Drilling (N=23)

Variable	Frequency	Percentage (%)	p value
<b>Resumption of menses(days)</b>			
1-3	9	39.1	
4-6	13	56.5	
7-9	1	4.4	
Range=1-7 days mean=4.1±1.9 days			
<b>Conception after drilling (months) n=7</b>			
1-3	2	28.6	
4-6	4	57.1	
≥7	1	14.3	
Range=3-7 months mean=4.7±1.6 months			
<b>Pregnancy outcome</b>			
Yes	7	30.5	
No	16	69.5	
<b>Miscarriage n=7</b>			
Yes	3	42.9	
No	4	57.1	

**Table 4:** Pregnancy Outcome and Socio-Demographic Variables

Variables	Pregnancy outcome					
	Yes (%)	No (%)	χ <sup>2</sup>	OR	95% CI	p value*
<b>Age (years)</b>						
24-35			7(38.9)	11(61.1)		
>35	0(0.0)		5(100.0)	2.80	0.0-0.272	
<b>Parity</b>						
0	6(30.0)	14(70.0)				
1	1(33.3)	2(66.7)	0.01	0.86	0.04-29.32	1.000
<b>Education</b>						
Secondary	1(16.7)	5(83.3)				
Tertiary	6(35.3)	11(64.7)	0.73	0.37	0.01-5.00	0.621
<b>Age-Husband(years)</b>						
30-39	6(42.9)	8(57.1)				
≥40	1(11.1)	8(88.9)	2.61	6.00	0.47-165.93	0.176
<b>Duration Infertility(years)</b>						
1-10	7(31.8)	15(68.2)				
>10	0(0.0)	1(100.0)	0.46	0.00-1.000		
<b>Social Class</b>						
Low	0(0.0)	3(100.0)				
Middle	7(35.0)	13(65.0)	1.51	0.00	0.00-5.80	0.526
<b>Occupational status-wife</b>						
Employed	5(23.8)	16(76.2)				
Unemployed	2(100.0)	0(0.0)	5.01	0.00	0.00-1.74	0.083
<b>Occupation status-husband</b>						
Employed	7(31.8)	15(68.2)				
Unemployed	0(0.0)	1(100.0)	0.46	0.00	-1.000	
<b>Type of infertility</b>						
Primary	4(36.4)	7(63.6)				
Secondary	3(25.0)	9(75.0)	0.35	1.71	0.21-14.83	0.667
<b>Prolactin</b>						
Normal	4(30.8)	9(69.2)				
Abnormal	3(30.0)	7(70.0)	0.00	1.04	0.12-8.81	1.000

\*Fishers exact

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