



**A STUDY ON ADHERENCE AND OUTCOME OF *myo*- INOSITOL IN PATIENTS
WITH OLIGOMENORRHEA**

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ABSTRACT

Every woman may experience an irregular menstrual cycle once in a while. The late menstruation or missed period may be the irregularity. But, when this irregularity reaches a long interval, the condition is called as oligomenorrhea. Myo-inositol is one of the molecules which plays a key role in the mechanism of ovulation. The goal of the study is to assess the adherence and outcome of *myo*-Inositol in the patients who are reported for the complaints of oligomenorrhea in RMMCH and to establish that this molecule can be used as safer in treating patients with oligomenorrhea. It is a Prospective observational study. The data were collected based on the questions involved in the data collection form with consent to the patient willingness. Patient's medication adherence was checked using Morisky medication adherence scale. Patient counselling was provided in terms of oral method. The report showed that there is a

significant improvement in the patient's medication adherence after the patient counseling as the calculated 't' value 7.298 is greater than the critical or two sided table 't' value, 2.0096. The study also shown a strong evidence ($t = 21.025$, $p < 0.05$) and these data support the beneficial outcome of myo- inositol in women with oligomenorrhea, as the calculated 't' value 21.025 is greater than the critical or two-sided table 't' value 2.0154. The study concludes that patient counselling improved the medication adherence significantly among the study population. This study also suggests that there is a positive role for *myo*-inositol in regularising the menstrual cycle in patients with oligomennorrhea. No Adverse Drug Reactions were reported during the study. This may be due to the small sample size.

Keywords: Myo-inositol, oligomennorrhea, Morisky medication

INTRODUCTION

Every woman may experience an irregular menstrual cycle once in a while. The late menstruation or missed period may be the irregularity. But, when this irregularity reaches a long interval condition is called as oligomenorrhea [1-3].

In oligomenorrhea, women may have infrequent or irregular menstrual cycle being lesser than six or eight times a year [4-6].

The causes include use of oral contraceptives, thyroid disorder, eating disorder, Insulin resistance and diseases such as polycystic ovarian syndrome. These causes may lead to FSH imbalance which results in oligomenorrhea [8-11].

Hormonal therapy like progesterone and estrogen where used in treating the oligomenorrhea due to the role of hormone in the etiopathology. Because of various side

effects, *myo*- Inositol is investigated in recent years instead of hormonal therapy [6, 11-15].

Myo-inositol is one of the molecules which plays a key role in the mechanism of ovulation. The *myo*-Inositol has important roles in synthesis of lipids, creation of cell membranes, cellular cytogenesis and morphogenesis. In ovary it has mechanism in the embryonic development [16-21].

All these pieces of evidence have opened a new clinical interest on *myo*-inositol, as a supplement to produce recurrence of the normal menstrual cycle and hence an effective option in patients with oligomenorrhea.

The goal of the study is to assess the adherence and outcome of *myo*-Inositol in the patients who are reported for the complaints of oligomenorrhea in RMMCH and to establish that this molecule can be

used as safer in treating patients with oligomenorrhea.

MATERIALS AND METHODOLOGY

STUDY TYPE

Prospective observational study.

STUDY SITE

The study was conducted in the Department of Obstetrics and Gynaecology, Rajah Muthiah Medical College Hospital, (1250 bedded teaching hospital) Annamalai university, Annamalai Nagar, Chidambaram, Tamil Nadu.

STUDY PERIOD

- The study was carried out for a period of six months (November 2018-April 2019)

SUBJECT RECRUITMENT

PROCEDURES

- The recruitment of subjects was done with help of physician.
- The subjects treated as out patients based on inclusion and exclusion criteria were selected.
- The study procedure was completely explained to the patient and a patient consent form will be collected from them.

INCLUSION CRITERIA

1. Patients belonging to the age group of 20 to 45 years.

2. Patients who were treated for oligomenorrhea and co-morbid conditions.

EXCLUSION CRITERIA

1. Patients who had attained menarche before one year.
2. 2. Patients above 45 years.
3. 3. Patients not willing to participate in this study.

STUDY METHOD

- A patient data collection form was designed to collect all the details like out-patient number, name, age, chief complaints, gynecological history, socio-economic history, lab investigations, abdominal scan report, diagnosis and therapeutic management.
- Based on the selection criteria patients were selected and enrolled.
- A thorough clinical examination was carried out and noted.
- The data were collected based on the questionnaires involved in the data collection form with consent to the patient willingness.
- The treatment was of three month course
- Patient's medication adherence was checked using Morisky medication adherence scale.

- Patient counselling was provided in terms of oral method.
- After the patient counselling the patient's medication adherence was again recorded using Morisky medication adherence rating scale.
- The medication adherence score of the patients enrolled in the study was statistically interpreted using paired 't' test.
- The duration of previous menstrual cycle at the onset of treatment (baseline data) and the number of days between each menstrual cycle during the course of the treatment (3 months) were recorded.
- The average of the menstrual cycle data during the course of the treatment was calculated.
- The report and results were interpreted based on the comparison of the data at the onset of the treatment and the average data collected during the treatment course.
- The Adverse Drug Reactions were monitored if any.

RESULTS AND DISCUSSION

In this study the authors have made an attempt to study the menstrual regulation by *myo*-inositol in patients with oligomenorrhea and other comorbid conditions on out

patients of Rajah Muthiah Medical College Hospital, Chidambaram. These conditions may be due to imbalance of hormones like FSH and LH. Due to the key role of hormone in the etiopathology, for many years the hormonal therapy like estrogen and progesterone were used. But these hormonal therapies were tending to cause various side effects (weight gain, memory problem, menopausal symptoms, hair thinning) hence in recent years instead of hormonal therapy, *myo*-inositol was investigated.

Demographic Details

In the study it was observed that within the age group of 20-24yrs, 16 patients were with co-morbidity and 16 were without co-morbidity. In the age group of 25-29yrs, 4 were without co-morbidity and 9 were with co-morbidity. In 30-34yrs, age group 1 patient was without co-morbidity and 3 were with co-morbidity. In 35-39yrs, 1 patient was without co-morbidity and there were no patients with co-morbidity (**Table 1**).

In this study, 50 patients were enrolled out of which majority (64%) belong to the age group of 20-24 years.

After the enrolment of the subjects, it was found that majority of patients (62%) were unmarried. 26% were with body weight range of 51-60kg, 20% were within the range of 71-80kg, 18% were within range of 61-70kg,

16% with range of 81-90kg, 12% with range of 41-50kg and 2% were with the range of 101-110kg.

After the treatment commence, the patient medication adherence score was recorded and divided into categories of poor (≤ 5), moderate ($5 \geq 8$) and good (8) based on the morisky adherence rating scale score. Out of 50, 21(42%) were poorly adhered, 16(32%) were moderately adhered and 13 (26%) were having good adherence. After the scoring procedure patient counselling was provided. The mode of patient counselling was oral and the duration was one week. After the counselling it was found that there was an improvement in the medication adherence (good adherence = 90 %). The scores obtained before and after patient counseling were statistically (paired t test) compared (Figure 1).

Patient medication adherence data (paired t test)

The report showed that there is a significant improvement in the patient's medication adherence after the patient counseling as the calculated 't' value 7.298 is greater than the critical or two sided table 't' value, 2.0096.

After checking the medication adherence out of 50 patients, 5 couldn't be monitored (hence they are not included in the study) and the patients were re-grouped based on

morbidity condition. Out of 45, majority of the patients were in the age group of 20-24 (62.23%) in which 12 were without co-morbidity and 16 were with co-morbidity (Table 4).

Out of 45 patients, 16 had the condition of oligomenorrhea without any co morbidities. The rest 29 patient had oligomenorrhea with other co morbid conditions such as PCOD 12(41.4 %), infertility 3(10.3%), hypothyroidism 3(10.3%), PCOD with hypothyroidism 4(13.8%), PCOD with infertility 6(20.7%) and infertility with hypothyroidism 1(3.4%) (Figure 2).

The baseline data of menstrual cycle and the mean number of days between two periods after 3 months of therapy, were compared by using paired 't' test. The report showed a strong evidence ($t = 21.025$, $p < 0.05$) and these data support the beneficial outcome of myo- inositol in women with oligomenorrhea, as the calculated 't' value 21.025 is greater than the critical or two-sided table 't' value 2.0154 (Table 5, 6).

After the therapy 93.3% of patients showed an improvement with 3 to 5 average number of days of menstrual flow. There were no adverse drug effects due to the drug in any patients (Figure 3).

Our study correlates with the study by Pedro-Antonio Regidor, Adolf Eduard Schindler,

Bernd Lesoine, Rene Druckman – ‘Management of women with PCOS using *myo*-inositol and folic acid new clinical data review of the literature’. *Myo*-inositol has proven to be new treatment option for PCOS and infertility. It also represents an improvement in IVF protocol for patients with PCOS. No moderate to severe side effects were observed when *myo*-inositol was used at a dosage of 4000 mg/day.

The study by Alberto Corticelli, Maura Grimaldi, Giorgio Piastra, Valeria Trifiletti, Rosaria Falivene, Sabrina Bosi, Pietro Fugazza, Alessandro Castagnino and Massimiliano Saltarini- ‘taekwondo and *myo*inositol supplementation on regularization of menstrual cycle in adolescent athletes” shows similar positive effect of *myo*-inositol in oligomenorrhea as our study [22-25].

Table 1: Age-wise disease condition distribution

AGE (YRS)	OLIGOMENORRHEA WITHOUT CO-MORBID CONDITION	OLIGOMENORRHEA WITH CO-MORBID CONDITION	Total No. Of Patients
20-24	16	16	32
25-29	4	9	13
30-34	1	3	4
35-39	1	0	1
Total	21	29	50

Table 2: Data based on BMI

BMI	Frequency (N=45)	Percentage (%)
Under weight	2	4.4%
Normal weight	15	33.37%
Over weight	11	24.44%
Obese	17	37.78%

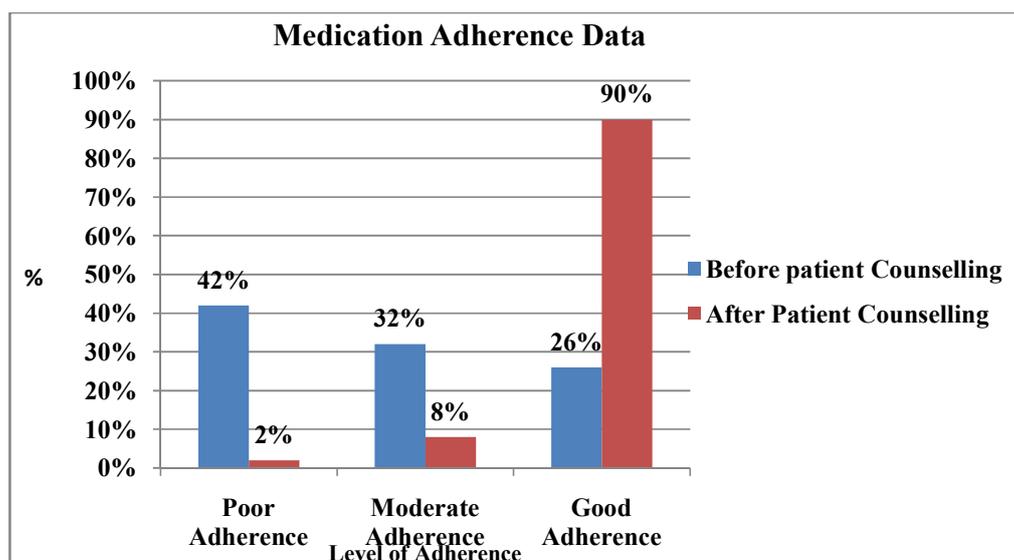


Figure 1: Medication nadherence data before and after patient counselling

Table 3: Patient medication adherence data paired ‘t’ test

	Mean	N	Std. Deviation	Std. Error Mean
Score before intervention	5.86	50	1.750	0.247
Score after intervention	7.58	50	1.326	0.188

	Paired differences					t	df	Critical value (2-tailed)
	mean	Std. deviation	Std. error mean	95% confidence interval of the difference				
				lower	upper			
Score after intervention – Score before intervention	1.72	1.666	0.236	1.246	2.194	7.298	49	2.0096

Table 4: Patient data after intervention

Age (Yrs)	OLIGOMENORRHEA WITHOUT CO- MORBID CONDITIONS	OLIGOMENORRHEA WITH CO- MORBID CONDITIONS	FREQUENCY (N=45)	PERCENTAGE (%)
20-24	12	16	28	62.23%
25-29	2	10	12	26.67%
30-34	1	3	4	8.88%
35-39	1	0	1	2.22%
Total	16	29	45	100%

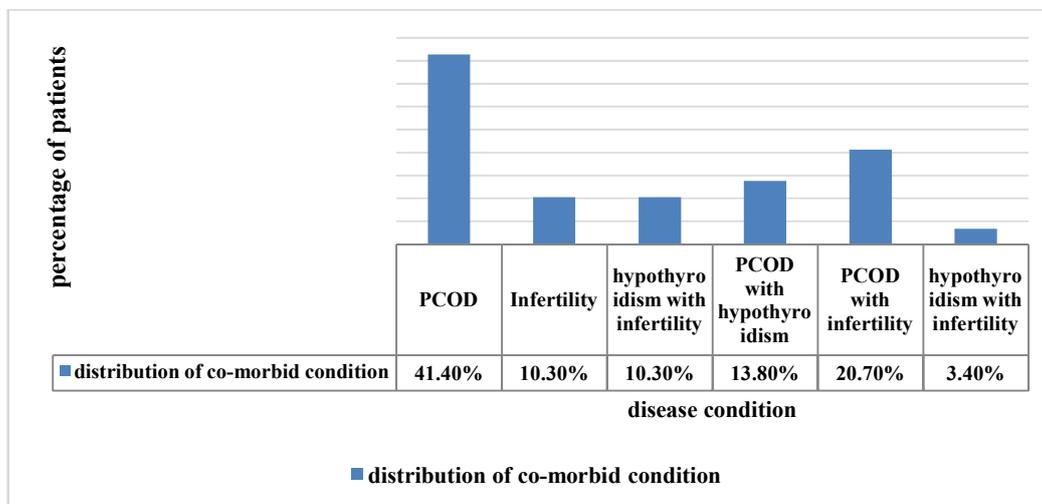


Figure 2: Distribution of co-morbid condition

Table 5: Menstrual cycle data
Patient menstrual cycle data before treatment and during treatment with myo-inositol for 3 months:

	Baseline	After 1 month	After 2 months	After 3 months
Menstrual cycle data	55.84 ± 8.17	31.09 ± 2.7	29.67 ± 1.86	30.2 ± 2.42

Comparative data of menstrual cycle before and after the therapy (mean number of days between two menstruation after 3 months of therapy)

	Mean	N	Std. Deviation	Std. Error Mean
Before treatment	55.84	50	8.174	1.219
After treatment	30.28	50	0.922	0.137

Table 6: Comparative data of menstrual cycle data

	Paired differences				t	df	Critical value (2-tailed)	
	mean	Std. deviation	Std. error mean	95% confidence interval of the difference				
				lower				upper
Before treatment- After treatment	25.564	8.157	1.216	23.114	28.015	21.025	45	2.0154

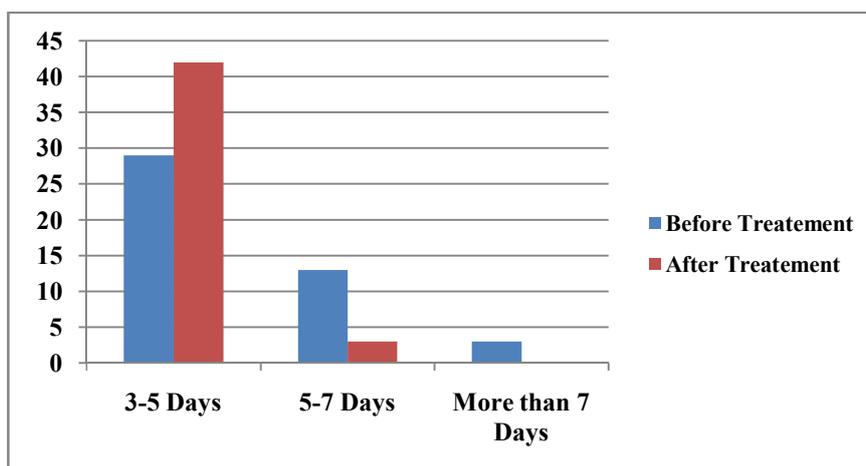


Figure 3: Average No. of days of menstrual flow in patients

CONCLUSION

In the study population patients with oligomenorrhea belonged to the age group of 20-45 years, majority (64%) of the patients was between 20-24 years and 62% were unmarried.

Patient counselling improved the medication adherence significantly among the study population.

This study suggests that there is a positive role for *myo*-inositol in regularising the menstrual cycle in patients with oligomenorrhea.

No Adverse Drug Reactions were reported during the study. This may be due to the small sample size.

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