

EVALUATION OF EFFECT OF PHARMACIST PROVIDED EDUCATION ON MEDICATION ADHERENCE BEHAVIOR OF PATIENTS WITH POLYCYSTIC OVARIAN SYNDROME: A PROSPECTIVE STUDY

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ABSTRACT

Background: Polycystic ovarian syndrome is a heterogeneous endocrine disorder that affects 1 in 15 women worldwide. The incidence rate appears to be on the increase due to change in lifestyle and stress. There are few studies with inconsistent data in the Indian literature regarding medication adherence behavior of PCOS patients. It is estimated that 50% of prescriptions fail to produce desired results because of improper use. Increasing the effectiveness of adherence interventions may have greater impact on therapeutic outcome.^[2,3,5]

Objective: To evaluate the effect of pharmacist provided education on medication adherence behavior of PCOS patients. **Study Setting and Methodology:** A Prospective Observational study conducted in 120

patients diagnosed with PCOS as per Rotterdam's criteria in a Tertiary Care Teaching Hospital for a period of 5 months after getting approval from Human Ethical Committee. Medication adherence was assessed using Brief Medication Questionnaire. The questionnaire was administered to the patient before and after counseling to find out the impact of pharmacist provided counseling on medication adherence. **Results and Discussion:** The Questionnaire consists of four screens- Regimen screen, Belief screen, Recall screen and Access screen. The total screen for adherence was decreased from 5.6 to 2.5 and the change was significant at 0.01 level. Regimen screen, Belief screen, Recall screen and Access screen scores were significantly reduced and medication adherence improved after Pharmacist provided counseling. Total score for medication adherence was decreased significantly and patients become more adherent to medications after pharmacist provided education.

KEYWORDS: Polycystic ovarian syndrome adherent provided education.

INTRODUCTION

Polycystic ovarian syndrome is a multisystem endocrinopathy affecting women in reproductive age, with ovarian expression of metabolic disturbances and a wide spectrum of clinical features such as hyperandrogenism, menstrual disorders and obesity along with metabolic disorders and is a leading cause of anovulatory infertility. 5-8% of general population and up to 40% of women with infertility suffers from PCOS.^[3] In India nearly 40% of women were affected by PCOS.

But among them, only 60% were coming to hospitals for treatment, when they recognize that they have got infertility.^[2,16] Polycystic morphology seen in ultrasound is approximately 22% of women.^[3] Hirsutism is a common problem in India as elsewhere in the world. The incidence rate appears to be on the increase due to change in lifestyle and stress.^[3,6] The principle features of PCOS include obesity, menstrual disorders like oligomenorrhoea or amenorrhea, an ovulation or hypoovulation, hyperandrogenism, hirsutism, obesity, hyperinsulinemia/ insulin resistance and dyslipidemia.^[3,26] Microscopically, the ovaries are often enlarged bilaterally with a thick capsule. Multiple cysts more than 10 in no., 0.5-1 mm, rarely up to 2cm in size are located along the surface of the ovary giving a necklace appearance on ultrasound scan.^[3]

In 2003 in Rotterdam, ESHRE/ASRM sponsored workshop on PCOS defined PCOS. Affected individuals must have two out of the following 3 criteria after excluding other causes of androgen excess.

- 1) Oligo or anovulation.
- 2) Clinical or biochemical signs of hyperandrogenism
- 3) Polycystic ovaries on Sonographic examination defined as the presence of 12 or more follicles in each ovary and an increased ovarian volume of >10 ml.^[3-5]

Medication adherence is defined as the extent to which a patient's medication taking behavior coincides with the intention of health advice he or she has been given. Medication adherence is one of the most important factors that determine therapeutic outcomes. Increasing the effectiveness of adherence interventions may have greater impact on the health of population. Pharmacist is in unique position to improve medication adherence because they can actually

show the medication to the patient and relate any information to the medication itself.^[7,17] As there are few studies with inconsistent data in the Indian literature regarding the present study is taken up to generate some valid and useful data. This study was done in the Fertility Clinic of department of Gynecology and Obstetrics, SAT Hospital, Govt. Medical College, Thiruvananthapuram. Patients from different part of Kerala and from the parts of Tamil Nadu adjacent to Kerala came to the clinic mainly due to better patient care and comparatively low cost of therapy. So the study includes patients with different lifestyles. There is little published drug related study in patients with PCOS and no similar study was done in the study set up. So, study on medication adherence is relevant in the present situation.

MATERIALS AND METHODS

Objective

To evaluate the effect of pharmacist provided education on medication adherence behavior of PCOS patients.

Study setting

Tertiary Care Setting, Fertility Clinic, Department of Gynecology and Obstetrics SAT Hospital, Govt. Medical College, Thiruvananthapuram.

Study population

All patients reported to Fertility Clinic, diagnosed with PCOS.

Sample size and study design: 120 patients, Prospective Observational study.

Study period: 5 months after getting clearance from the Human Ethics Committee.

Inclusion criteria: Subjects in the reproductive age diagnosed as Polycystic Ovarian as per Rotterdam's criteria.

Exclusion criteria

- a) Subjects with other endocrine disorders like Congenital Adrenal Hyperplasia, Cushing's syndrome.
- b) Subjects with present or past neoplasia, hepatic or renal dysfunction or concurrent alcohol use.
- c) Patients who are unwilling to give written consent.

Study procedure: After obtaining approval and clearance from the Institutional Ethics

Committee, patients with PCOS were enrolled for the study. Written informed consent was collected from all of the study population after fully explaining the study procedure to their satisfaction. A structured interview with the patient was conducted by using Medication adherence was assessed using Brief Medication Questionnaire to elicit information about medication adherence and a counseling regarding the importance of medication adherence was given to the patient. The information about the adherence was collected during the next follow up to assess the effect of pharmacist provided education on medication adherence.

BRIEF MEDICATION QUESTIONNAIRE

1. Please list below the medication took in the past week

- a) Medication name and strength
- b) How many days did you take it?
- c) How many times per day did you take it?
- d) How many doses did you take at each time?
- e) How many times did you missed to take it?
- f) For what reason were you taking medication?
- g) How well the medicine works for you?

☐ Well = 1 ☐ okay = 2 ☐ not well = 3

2. Do your medication bother you in any way? ☐ Yes ☐ No

a) If yes, how much it bothers you?

☐ A lot ☐ some ☐ a little ☐ never

b) In what way did it bother you?

3) How much problem are you having in the following areas?

	None	A little	A lot
a) Medication causes side effect:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Hard to remember the doses:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Hard to pay for the medication:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Hard to administer medication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Hard to get refill on time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Dosage times are inconvenient:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SCORING PROCEDURE FOR BMQ SCREENS

SCREENS (R = respondent) SCORING

Regimen screen (Question 1a-1e)

Did R fail to list the prescribed drug in the initial report?	Yes=1	no=0
Did R stop/interrupt therapy due to late refill/other reason?	Yes=1	no=0
Did R report on any missed days or dose?	Yes=1	no=0
Did R reduce or cut down prescribed amount per dose?	Yes=1	no=0
Did R take any extra doses than prescribed?	Yes=1	no=0
Did R report 'don't know' for any question?	Yes=1	no=0
Did R refuse to answer any question?	Yes=1	no=0

Score 0 indicate the presence of adherence and **score ≥ 1** indicates positive screens for potential non-adherence.

Belief screen (Questions 1g and 2-2a)

Did R report 'don't know' or not well to Q 1g?	Yes=1	no=0
Did R name the drug that bothers him/her to Q 2a?	Yes=1	no=0

Score 0 indicate adherence and **score of ≥ 1** indicates positive screens for belief barriers.

Recall screen (Questions 1c and 3b)

Did R receive a multiple dose regimen?	Yes=1	no=0
Did R report any difficulty in remembering medication to Q3b?	Yes=1	no=0

Score 0 indicate adherence and **score of ≥ 1** indicates positive screen for recall barriers

Access barrier screen (Questions 3c and 3e)

Did R report any difficulty in pay for the medicine?	Yes=1	no=0
Did R report any difficulty in getting refills in time?	Yes=1	no=0

Score 0 indicate adherence and **score of ≥ 1** indicates positive screens for access barriers

Statistical analysis

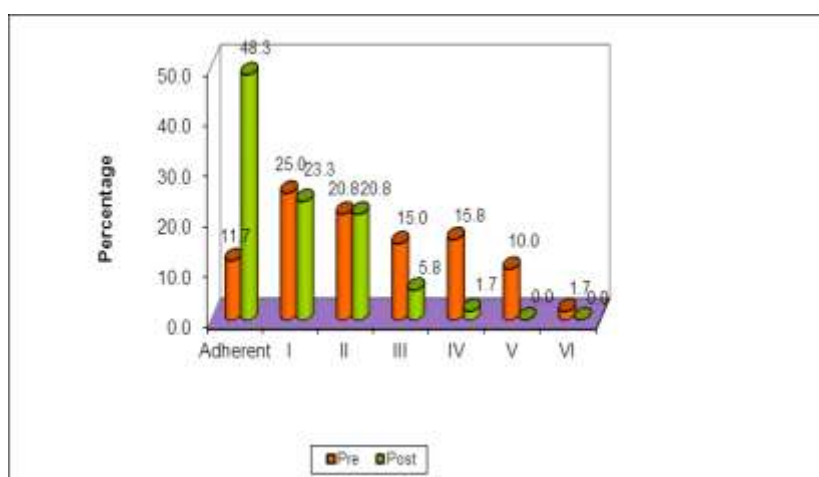
Analysis of the data was done by using computer software, Statistical Package for Social Sciences (SPSS) version 11. Wilcoxon signed Rank Test and Paired t test were used to compare selected variables. Bar and Pie charts were used to present percentage distribution of selected variables in the study.

RESULTS

Table. 1: Distribution of the Regimen screen at different stages.

Regimen Screen	Before counseling		After counseling		Z#	P
	Count	Percent	Count	Percent		
Adherent	14	11.7	58	48.3	8.29**	0.000
Non Adherent Grade I	30	25.0	28	23.3		
Non Adherent Grade II	25	20.8	25	20.8		
Non Adherent Grade III	18	15.0	7	5.8		
Non Adherent Grade IV	19	15.8	2	1.7		
Non Adherent Grade V	12	10.0	0	0.0		
Non Adherent Grade VI	2	1.7	0	0.0		

#Wilcoxon Signed Rank Test **: - Significant at 0.01 level.

**Fig. 1: Distribution of the Regimen screen at different stages.**

The effect of pharmacist provided education on regimen screen was found to be statistically significant at 0.01 level.

Table. 2: Distribution of the Belief screen at different stages.

BELIEF SCREEN	Before Counseling		After Counseling		Z#	P
	Count	Percent	Count	Percent		
Adherent	12	10.0	63	52.5	7.75**	0.000
Non Adherent Grade I	60	50.0	47	39.2		
Non Adherent Grade II	48	40.0	10	8.3		

#Wilcoxon Signed Rank Test **: - Significant at 0.01 level.

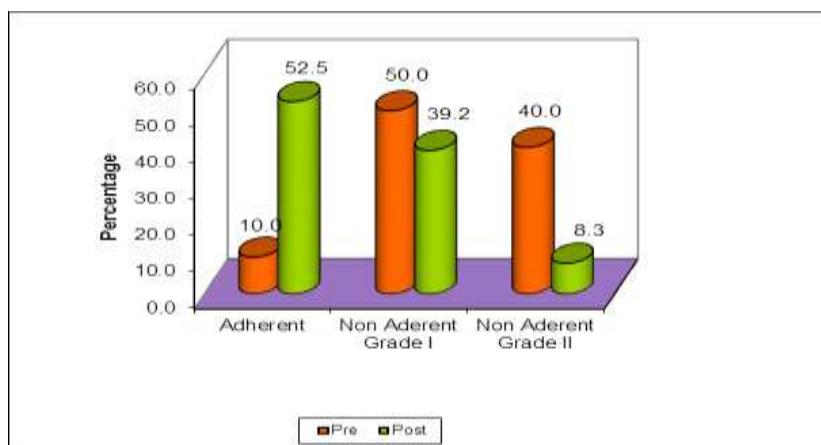


Fig. 2: Distribution of Belief screen at different stages.

It was observed that patients with no belief barrier increased from 12 to 63 and Non adherent grade I decreased from 60 to 47, Non adherent grade II decreased from 48 to 10. The effect of pharmacist provided education on belief screen was statistically significant at 0.01 level.

Table: 3 Distribution of Recall screen at different stages.

RECALL SCREEN	Before Counseling		After Counseling		Z#	P
	Count	Percent	Count	Percent		
Adherent	18	15.0	38	31.7	4.91**	0.000
Non Adherent Grade I	78	65.0	77	64.2		
Non Adherent Grade II	24	20.0	5	4.2		

#Wilcoxon Signed Rank Test **: - Significant at 0.01 level.

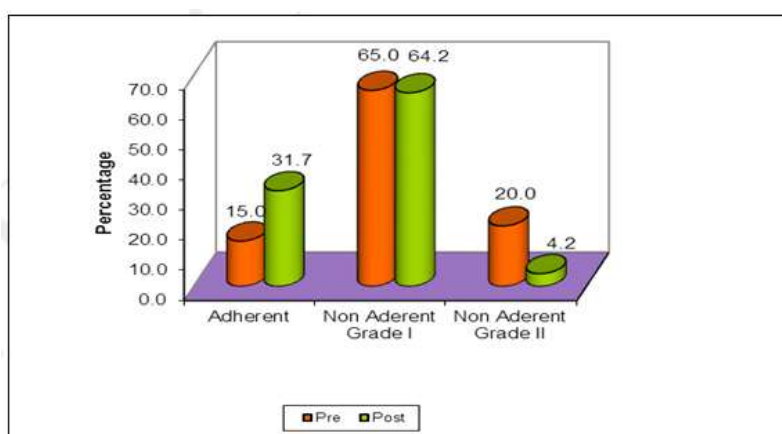


Fig. 3: Distribution of Recall screen at different stages.

Table 3 show that patients with no recall barrier was increased from 18 to 38. Non adherent grade I was decreased from 78 to 77, Non adherent grade II was decreased from 24 to 5. The effect of pharmacist provided education on belief screen was statistically significant at 0.01 level.

Table. 4: Distribution of Access screen at Different stages.

ACCESS SCREEN	BC		AC		Z#	P
	Count	Percent	Count	Percent		
Adherent	26	21.7	85	70.8	7.33**	0.000
Non Adherent Grade I	76	63.3	32	26.7		
Non Adherent Grade II	18	15.0	3	2.5		

#Wilcoxon Signed Rank Test **: - Significant at 0.01 level.

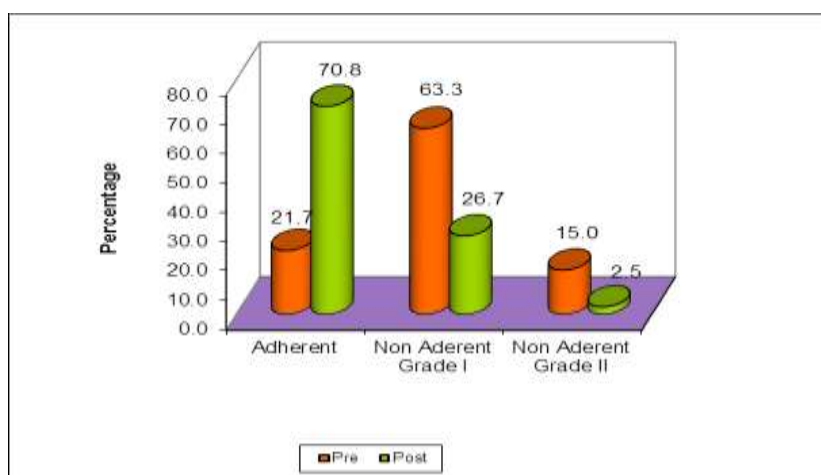
**Fig. 4: Distribution of Access screen at different stages.**

Table 4 shows that patients with no recall barriers increased from 26 to 85. Non adherent grade I was decreased from 76 to 32, non adherent grade II was decreased from 18 to 3. The effect of pharmacist provided education on belief screen was statistically significant at 0.01 level.

Table. 5: Distribution of Total screen at different stages.

OVERALL ADHERENT SCORE	Before Counseling		After Counseling		Z#	P
	Count	Percent	Count	Percent		
0	1	0.8	14	11.7	9.15**	0.000
1	4	3.3	26	21.7		
2	12	10.0	22	18.3		
3	11	9.2	25	20.8		
4	12	10.0	18	15.0		
5	18	15.0	12	10.0		
6	20	16.7	1	0.8		
7	13	10.8	0	0.0		
8	8	6.7	2	1.7		
9	12	10.0	0	0.0		
10	5	4.2	0	0.0		
11	4	3.3	0	0.0		
Mean ± SD	5.6 ± 2.6		2.5 ± 1.7			

#Wilcoxon Signed Rank Test **: - Significant at 0.01 level.

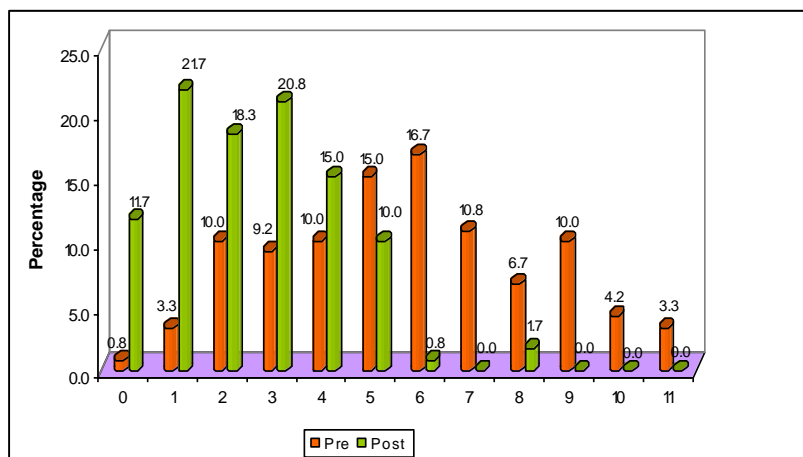


Fig. 5: Distribution of Total screen at different stages.

DISCUSSION

The medication adherence in this study was assessed by Brief Medication Questionnaire. The tool was developed by B.L Svarstad et al. The Questionnaire consists of four screens- Regimen screen, Belief screen, Recall screen and Access screen. The questionnaire was administered to the patient before and after counseling to find out the impact of counseling on medication adherence.

REGIMEN SCREEN

The regimen screen consists of 7 questions related to therapy. A score of zero indicate adherence and greater than zero indicate non-adherence. The result shows that number of patients having zero score (adherent) increases from 14 to 58 after counseling. Non adherent grade I (score 1) decreased from 30 to 28. Non adherent grade II (score 2) remain same (25), Non adherent grade III decreased from 18 to 7, Non adherent grade IV decreased from 19 to 2, Non adherent grade V decreased from 12 to zero, Non adherent grade VI decreased from 2 to zero. The effect of pharmacist provided education on regimen screen was statistically significant at 0.01 level.

BELIEF SCREEN

Belief screen consist of 2 questions. A score of zero indicate adherence and greater than zero indicate positive screen for adherence. From Table 2, it was observed that patients with no belief barrier increased from 12 to 63 and Non adherent grade I decreased from 60 to 47, Non adherent grade II decreased from 48 to 10. The effect of pharmacist provided education on belief screen was statistically significant at 0.01 level.

RECALL SCREEN

Recall screen consist of 2 questions. A score of zero indicate adherence and greater than zero indicates positive screen for adherence. The result shows that patients having recall barrier was increased from 18 to 38. Non adherent grade I was decreased from 78 to 77, Non-adherent grade II was decreased from 24 to 5. The effect of pharmacist provided education on belief screen was statistically significant at 0.01 level.

ACCESS SCREEN

Access screen consists of 2 questions. A score of zero indicate adherence and greater than zero indicates positive screen for adherence. Table 4 shows that patients with no recall barriers increased from 26 to 85. Non adherent grade I was decreased from 76 to 32, non adherent grade II was decreased from 18 to 3. The effect of pharmacist provided education on belief screen was statistically significant at 0.01level. Even though all patients express difficulty in pay for medicines, they were willing to spend for even costly medicines during the course of infertility treatment due to their urge to have children.

TOTAL SCREEN FOR ADHERENCE

From table 5, it was clear that patients become more adherent to their medications after pharmacist provided counseling. The total screen for adherence was decreased from 5.6 to 2.5 and the change was significant at 0.01level. The results show that pharmacist provided education increased patient's knowledge about the use and dose of drugs, consequences of missing dose, late refill, reducing the dose without permission of doctors.

CONCLUSION

- Regimen screen, Belief screen, Recall screen and Access screen scores were significantly reduced and medication adherence improved after Pharmacist provided counseling.
- Total score for medication adherence was decreased significantly and patients become more adherent to medications after pharmacist provided education.

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