

RESEARCH ARTICLE

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Adherence to Oral Hormonal Treatment among Breast Cancer Patients in Egypt

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Abstract

Background: Adjuvant endocrine therapy has been shown to improve treatment outcomes in breast cancer patients. However, not all patients can complete their scheduled treatment protocols. The purpose of this study was to evaluate the adherence to oral hormonal therapy among Egyptian breast cancer patients. **Patients and methods:** A cross-sectional study was conducted at the National Cancer Institute, Breast Cancer Hospital, from February 2022 to May 2022. An interview and a survey were administered to assess the adherence of breast cancer patients to oral hormonal treatment. Adherence was measured using the Morisky Medication Adherence Scale-8 (MMAS-8). **Results:** The survey was fully completed by 300 patients, of whom 98.3% were females and 1.7% were males. Among the patients, 30% fell into the age group of 40-50 years. Most patients were postmenopausal (90.3%). In terms of education, 18% had a high level of education, while 53.3% were illiterate. Additionally, 50.7% of patients had other chronic diseases. Regarding medication information, 44.7% preferred to receive it from a physician, 27.7% from pharmacists, and 27.7% from both. Proper medication counseling was received by 99.7% of patients. According to the MMAS-8 survey, 40.3% of all patients demonstrated high adherence to their oral hormonal treatment, 32.7% had moderate adherence, and 27% had low adherence. No significant associations were found between adherence levels and subgroups such as gender, age, educational level, duration of endocrine therapy, breast cancer stage, or other co-morbidities. **Conclusion:** This study reveals a substantial level of adherence, both high and moderate, to oral endocrine therapy among breast cancer patients in Egypt. Possible contributing factors include proper medication counseling within the healthcare setting and regular patient follow-up.

Keywords: Adherence- Tamoxifen- Aromatase inhibitor- Breast cancer

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Introduction

Breast cancer mortality rates have been declining over the past 20 years, and breast cancer patients now make up most cancer survivors [1]. Hormone receptor-positive breast cancer accounts for approximately 70% of all cases, and endocrine therapy is the backbone of treatment [2]. Tamoxifen or aromatase inhibitors reduce recurrence and improve overall survival in hormone receptor-positive breast cancer patients [3, 4]. Weight gain, bone density loss, hot flashes, musculoskeletal symptoms, sexual dysfunction, depression, cognitive dysfunction, and

fatigue are all common side effects of adjuvant endocrine therapy [5, 6]. There is substantial evidence that these long-term side effects notably impair patients' quality of life and treatment adherence [7].

Health systems and individual providers should prioritize improving patients' education about the value of endocrine therapy use, sharing endocrine therapy decisions, offering proper support for side effects and other endocrine therapy-associated worries, and delivering survivorship care equitably, with endocrine therapy adherence evaluation [8]. It is critical to identify endocrine therapy support strategies that are feasible and have a

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positive impact on endocrine therapy adherence. While providers emphasized that side effect identification and management are important components of promoting adherence, they also perceived endocrine therapy tolerance problems as persistent or unsolvable [9].

A systematic review evaluated the factors influencing adherence in patients receiving oral anticancer agents and concluded that social support, the use of aromatase inhibitors, and lower out-of-pocket expenses for oral antineoplastic medications appear to have a definite effect on adherence. Depression and the variety of medications appear to have a negative impact on adherence. Adherence appears to be associated with low and very high age. The remaining factors had either little or no influence or were inconsistent in terms of effect direction and statistical significance [10].

A large, randomized trial that collected patient-reported outcomes and assessed adherence to aromatase inhibitors by urine metabolites discovered that emotional, social, and functional well-being, as well as medication beliefs, predicted adherence levels [11]. A study was conducted in Egypt to assess the effect of fasting during Ramadan on adherence to oral hormonal therapies among breast cancer patients. Adherence to oral hormonal therapy was 94.2% during Ramadan and 95.7% in the preceding month ($p=0.77$) [12]. To date, no other studies have been conducted to evaluate the adherence to oral hormonal therapy among Egyptian patients with breast cancer.

Materials and Methods

This study aimed to assess the adherence of oral hormonal therapy in Egyptian patients with breast cancer. A cross-sectional study was conducted at the National Cancer Institute, Breast Cancer Hospital, The First Settlement, Egypt, from February 2022 to May 2022. The study included breast cancer patients who met certain eligibility criteria: being ≥ 18 years old, diagnosed with breast cancer, and treated with hormonal therapy (tamoxifen) or aromatase inhibitor medication for at least 6 months. Patients were required to provide written or text informed consent, be able to communicate in Arabic or English, and have a survival rate of ≥ 12 weeks. Exclusion criteria included pregnancy or lactation, previous systemic therapy such as targeted therapies, and comorbidities that could interfere with adherence scoring evaluation.

The adherence of breast cancer patients to oral hormonal treatment was assessed through a face-to-face interview using a survey. The questionnaire collected patient history, therapy-related information, and medication adherence elements. Adherence was measured using MMAS-8, which consists of yes/no questions and one Likert scale question. The MMAS-8 scores range from 0 to 8 and are categorized into three levels of adherence: high adherence (score = 8), medium adherence (score of 6 to < 8), and low adherence (score < 6) [13].

Sample Size Calculation

The sample size for the study was calculated using the online sample size calculator RaoSoft® based on the eligible study population, which was estimated to be

around 20,000 patients according to the GLOBOCAN database.

Statistical analysis

The statistical package for social sciences (SPSS), version 20.0, was used to analyze the data. Quantitative data were expressed as mean \pm standard deviation (SD). Qualitative data were expressed as frequency and percentage. Independent-samples t-test, Chi-square (χ^2) test, a one-way analysis of variance (ANOVA) was used. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p -value < 0.05 was considered significant. Cronbach's reliability coefficient alpha was used for the internal consistency of the MMAS-8.

Results

Patients' demographics and clinical characteristics

A survey was conducted from February to April 2022, involving 300 eligible patients who agreed to participate. Most patients were female (98.3%), versus males (1.7%). The final analysis included all 300 patients. Among the age groups, 30% fell within the range of 40-50 years. Most patients were postmenopausal (90.3%). In terms of education, 18% had a high level of education, while 53.3% were illiterate. Most patients were married (70.3%), and a significant percentage were widowed (22.3%). Regarding employment status, (6%) had stable jobs, while 92.7% were unemployed. Among the patients, 50.7% had chronic diseases, with high blood pressure being the most prevalent ($n=113$) (Table 1).

Patient knowledge about oral hormonal treatment

Patients' knowledge about oral hormonal therapy and their preferred sources of information were assessed using seven questions. Results showed that (44.7%) preferred to obtain medication information from physicians, (27.3%) preferred pharmacists, and 28% relied on both sources. Almost all patients (99.7%) received proper counseling about their medications. Most patients (98.7%) fully understood how to take their medication. When seeking information, (27.3%) of patients consulted pharmacists, (41.0%) consulted physicians, and (31.7%) consulted both. Among the patients, (8.3%) stopped taking the medication due to drug-related side effects, with (49.3%) informing their healthcare providers and (42.3%) not experiencing any side effects (Table 2).

Morisky Questionnaire

The MMAS-8 was used to assess patients' adherence to oral hormonal treatment. The scale consists of yes/no questions and one Likert scale question. Results from the MMAS-8 questionnaire showed that some patients forget to take their medication (25.3%), miss their medication for reasons other than forgetting (13.7%), stop taking their medication without informing their healthcare provider (9.7%), forget to take medication when traveling or leaving home (12.7%), do not take the last dose when asked (6.7%), stop taking the medication when feeling well (18%), and feel bored and tired from taking the

Table 1. Patients' Demographic and Clinical Characteristics	n (%)
Patients' Demographic and clinical characteristics (n=300)	
Gender	
Female	295 (98.3)
Male	5 (1.7)
Age Group	
<30years	4 (1.3)
30-40years	28 (9.3)
>40-50years	88 (29.3)
>50-60years	90 (30.0)
>60-70years	61 (20.3)
>70-80years	23 (7.7)
>80years	6 (2.0)
Married status	
Divorced	14 (4.7)
Married	211 (70.3)
Single	8 (2.7)
Widowed	67 (22.3)
Educational level	
Illiterate	161 (53.7)
Primary	22 (7.3)
Secondary	23 (7.7)
Post-graduate	17 (5.7)
Higher education	53 (17.7)
Diploma	24 (8.0)
Menopausal status	
Post-menopausal	271 (90.3)
Pre-menopausal	29 (9.7)
Employment status	
Employee	18 (6.0)
Self-employee	3 (1.0)
Unemployed	279 (93.0)
Smoking	
No	300 (100.0)
Regular sports	
No	129 (43.0)
Yes	171 (57.0)
Breast cancer diagnosis stage	
I	8 (2.7)
II	239 (79.7)
III	46 (15.3)
IV	7 (2.3)
Duration of hormonal treatment (years)	
≤1 years	44 (14.7)
>1-5 years	216 (72.0)
>6-10 years	36 (12.0)
>10 years	4 (1.3)
Neo-Adjuvant therapy?	
No	234 (78.0)
Yes	66 (22.0)

Table 1. Continued	n (%)
Patients' Demographic and clinical characteristics (n=300)	
Adjuvant therapy (other than hormonal therapy)	
No	48 (16.0)
Yes	252 (84.0)
Number of concomitant medications	
No concomitant medications	131 (43.7)
1-5 Medications	162 (54.0)
6-10 Medications	7 (2.3)

medication (26.7%) (Table 3).

Adherence levels

Based on MMAS-8, the distribution of adherence levels among patients was as follows: (40.3%) had high adherence, (32.7%) had moderate adherence, and (27%) had low adherence

Relation between adherence and various factors

There was no significant difference in adherence levels based on gender, age group, educational level, duration of

Table 2. Patient Knowledge about the Oral Hormonal Treatment

Patient knowledge about the oral hormonal treatment (n=300)	n (%)
Did your doctor explain how to take your medication to you?	
No	1(0.3)
Yes	299 (99.7)
Is the patient properly counselled about the medications?	
No	1(0.3)
Yes	299 (99.7)
Did you fully comprehend how to use the medications?	
No	4 (1.3)
Yes	296 (98.7)
Relationship with healthcare providers in terms of medication information?	
Both	84 (28.0)
Would prefer pharmacists	82 (27.3)
Would prefer physicians	134 (44.7)
Who do you consult the most about your medications and disease?	
Both	95 (31.7)
Pharmacist	82 (27.3)
Physician	123 (41.0)
The patient's reaction after experiencing drug-related side effects	
Non	127 (42.3)
Stopped taking drug	25 (8.3)
Told health care provider	148 (49.3)
Would you stop your treatment if someone you trusted told you to?	
No	265 (88.3)
Yes	35 (11.7)

Table 3. Morisky Questionnaire

Questions	No	Yes
	n (%)	n (%)
1) Do you sometimes forget to take your medication?	76 (25.3)	224 (74.7)
2) People sometimes miss taking their medications for reasons other than forgetting. Over the past 2 weeks, were there an days when you did not take your medication?	41 (13.7)	259 (86.3)
3) Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?	29 (9.7)	271 (90.3)
4) When you travel or leave home, do you sometimes forget to bring your medication?	38 (12.7)	262 (87.3)
5) Did you take all your medication yesterday?	20 (6.7)	280 (93.3)
6) When you feel like your symptoms are under control, do you sometimes stop taking your medication?	54 (18.0)	246 (82.0)
7) Taking medication every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	79 (26.3)	221 (73.7)
	All the time/Once in a while/Sometimes/ Usually	
8) How often do you have difficulty remembering to take all your medications?	169 (56.3)	131 (43.7)

hormonal treatment, presence of other chronic diseases, or breast cancer diagnosis stage (Table 4).

Predictors of adherence levels

In univariate analyses, significant differences were

observed among patients who stopped taking medication after experiencing side effects, those who informed their healthcare providers about side effects, and those who took no action. The mean MMAS-8 scores were 5.08±1.63, 6.33±1.67, and 6.83±1.52, respectively (p-value <0.001)

Table 4. Relation between Adherence with Gender, Age Group, Educational Level, duration of Hormonal Treatment (Years), Other Chronic Disease and Breast Cancer Diagnosis Stage (n=300).

Parameters (x) ²	Measures	Adherence						p-value*
		Low		Moderate		High		
		n	%	n	%	n	%	
Gender	Female	81	100	96	98	118	97.5	0.378
	Male	0	0	2	2	3	2.5	
Age Group	<30years	1	1.2	1	1	2	1.7	0.459
	30-40years	10	12.3	7	7.1	11	9.1	
	>40-50years	29	35.8	32	32.7	27	22.3	
	>50-60years	20	24.7	32	32.7	38	31.4	
	>60-70years	14	17.3	15	15.3	32	26.4	
	>70-80years	5	6.2	10	10.2	8	6.6	
	>80years	2	2.5	1	1	3	2.5	
Educational level	Illiterate	34	42	50	51	77	63.6	0.247
	Primary	8	9.9	9	9.2	5	4.1	
	Secondary	7	8.6	10	10.2	6	5	
	Higher education	18	22.2	15	15.3	20	16.5	
	Post-graduate	6	7.4	5	5.1	6	5	
	Diploma	8	9.9	9	9.2	7	5.8	
Duration of hormonal treatment (years)	≤1 years	13	16	10	10.2	21	17.4	0.486
	>1-5 years	57	70.4	77	78.6	82	67.8	
	>6-10 years	11	13.6	9	9.2	16	13.2	
	>10 years	0	0	2	2	2	1.7	
Other chronic disease	No	38	46.9	50	51	63	52.1	0.762
	Yes	43	53.1	48	49	58	47.9	
Breast cancer diagnosis stage	I	2	2.5	1	1	5	4.1	0.376
	II	67	82.7	74	75.5	98	81	
	III	10	12.3	19	19.4	17	14	
	IV	2	2.5	4	4.1	1	0.8	

Table 5. Univariate Analyses of Predictors vs. 8-item Morisky Medication Adherence Scale (MMAS-8) (n=300).

Patient knowledge	MMAS-8 Mean± SD	p-value*
Did your doctor explain how to take your medication? ¥		
No	6.00±0.00	0.792
Yes	6.44±1.67	
Is the patient properly counselled about the medications? ¥		
No	6.00±0.00	0.792
Yes	6.44±1.67	
Did you fully comprehend how to use the medications? ¥		
No	6.50±0.58	0.942
Yes	6.44±1.68	
Relationship with healthcare providers in terms of medication information? #		
Would prefer pharmacists	6.52±1.57	0.582
Would prefer physicians	6.33±1.70	
Both	6.54±1.72	
Who do you consult the most about your medications and disease? #		
Pharmacist	6.38±1.75	0.878
Physician	6.43±1.65	
Both	6.51±1.64	
The patient's reaction after experiencing drug-related side effects #		
Stopped taking drug	5.08±1.63	<0.001**
Told health care provider	6.33±1.67	
Non	6.83±1.52	
Would you stop your treatment if someone you trusted told you to? ¥		
No	6.48±1.67	0.312
Yes	6.17±1.62	

#, One way ANOVA test was performed; ¥, Independent sample t-test; *p-value <0.05 is considered significant; **p-value <0.001 highly significant

(Table 5).

Discussion

Treatment for cancer is trending toward oral therapies, which patients can self-manage from home. Proper adherence to oral therapy is vital to safe and optimal care in this setting [14]. Adherence to endocrine therapy reduces relapses and improves survival in breast cancer patients. As a result, non-compliance remains a largely unreported issue, particularly in developing countries [15]. Kimmick and colleagues found that adherence in low-income patients with primary breast cancer was as low as 60% after one year [16]. Finding methods to accurately assess oral hormonal therapy adherence and persistence, as well as identifying factors that influence adherence, is critical for optimizing outcomes [17].

In this study, the adherence to oral endocrine therapy was evaluated using the MMAS-8 questionnaire in the Egyptian patients with breast cancer. Face-to-face interviews were conducted at the hospital during the patients' monthly follow-up visit. Demographic data and baseline characteristics were collected [18]. None of the sociodemographic nor clinical characteristics significantly affected the adherence level, which is consistent with findings from previous studies on chronic diseases

[18–20].

The MMAS-8 scale was used in a study to assess patient adherence to aromatase inhibitor therapy. They reported that high adherence was more common in Caucasian women than in African American women (58% vs. 38%), in women with stage II and III disease (54%) than in stage I disease (41%), and in patients who did not receive chemotherapy (62%) versus patients who did (43%). Adherence was also associated with advanced age, chronic disorders, and medical insurance, but not with elevated net cost [17]. In the current study, the age group > 50-60 years, the patients who received the oral hormonal therapy for a duration >1-5 years, and the patients with stage II disease showed the highest MMAS-8 score (31.4%, 67.8%, 81%; respectively).

A descriptive cross-sectional survey measured the adherence in women with breast cancer with the MMAS-8. The level of education was one of the factors that affecting adherence significantly [21]. In contrast, the current study showed that illiterate patients represent the highest adherence percentage (63.6%). Pharmacy practice has been expanded to include responsibility for the medication therapy outcome with the goal of ensuring medication adherence. Yet, in developing countries, the pharmacist's role is still restricted to dispensing prescriptions [22]. In this study, questions were used to evaluate the preference

of the patients in getting medication information and if they trust the physician or the pharmacist in collecting disease and medication information. The patients who prefer taking medication information from a physician were 218 out of 300 patients, while 166 patients preferred pharmacists. This reflects confidence in healthcare professionals. Furthermore, (99.7%) of patients were fully informed about their medication. (27.3%) of patients were consulting their pharmacists regarding their drugs and disease, while (41.0%) of patients were consulting their physicians, and (31.7%) of patients were consulting both.

Adherence and quality of life in women with breast cancer being treated with oral hormone therapy were assessed by Stahlschmidt et al. Fifty-eight women were interviewed: 42 were treated with tamoxifen and 16 were treated with an aromatase inhibitor. The study showed a relation between incomplete adherence and systemic therapy side effects as well as higher stages of the disease, with no difference between the two drugs [23]. However, data from survivors' surveys and qualitative research show that the relationship between side effects and adherence is more complex than health care providers realize, encompassing the patient's perception of whether a given side effect is tolerable, the health care provider's relationship, and the balance between drug benefit and side effects [24].

In the present study, 8.3% of the patients discontinued their medication due to drug-related side effects, while 49.3% of the patients reported the side effects to their healthcare providers, and 42.3% did not experience any drug-related side effects. There was a significant difference observed among patients who stopped taking their medication due to side effects, those who informed their healthcare providers about the side effects, and those who took no action (p-value <0.001). Another study highlighted the importance of social and emotional support, as well as information from other survivors and organizations, in promoting adherence [25]. However, in the current study, when patients were asked if they would stop their treatment if someone, they trusted advised them to do so, 88.3% of patients answered no, indicating a lack of confidence in the opinions of individuals they trust regarding their disease and medications.

A previous single study conducted in Egypt assessed adherence to oral hormonal therapy for breast cancer during the month of Ramadan and found no negative impact on compliance. The adherence rate during Ramadan was 94.2%, which was not significantly different from other months of the year [12]. However, the present study is the first to evaluate adherence to oral hormonal therapy specifically in Egyptian patients with breast cancer, showing significantly high and moderate adherence rates. The study emphasizes the importance of proper medication counseling and regular follow-up to improve patient compliance and adherence. The authors recommend conducting a multicenter prospective study to explore additional risk factors such as geography, socioeconomic status, age, low literacy, supportive care, and knowledge about medication that may contribute to non-adherence

In conclusion, this study reveals a substantial level

of adherence, both high and moderate, to oral endocrine therapy among breast cancer patients in Egypt. Possible contributing factors include proper medication counselling within the healthcare setting and regular patient follow-up.

Limitations

The limitation of this study was that it was conducted solely in one governmental center. Therefore, it is recommended to carry out this study on a broader scale, encompassing multiple centers across various health sectors such as private, military, and non-governmental sectors.

Author Contribution Statement

Conceptualization, Noha Salaheldin ElBaghdady, May Mohamed El Gazzar; Methodology, Noha Salaheldin ElBaghdady, May Mohamed El Gazzar; Abdelrahman Magdy Abdo; Ahmed Mohamed Magdy; Farah Abdelghaffar Youssef; Kareem Amr Sayed; Mohamed Mahmoud Hussien; Joseph Essam Megala; Salma Hossam Eldien; Zeyad Mohsen Elmaboud; Hesham Mohamed Mostafa; Writing—Original Draft Preparation, Noha Salaheldin ElBaghdady; Nada H. Farrag; Writing—Review & Editing, Noha Salaheldin ElBaghdady; Nada H. Farrag. All the authors have read and agreed to the published version of the manuscript.

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Approval by any scientific body or inclusion as part of an approved student thesis

The research work has been approved by the NCI-breast cancer hospital, Cairo, Egypt.

Availability of data and materials

The data sets used in this study are available from the corresponding author upon reasonable request.

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Ethical approval and Consent to participate

The study was ethically approved from the ethical committee, faculty of pharmacy, the British University in Egypt (approval serial: CL-2201). Patients were required to provide written or text informed consent, be able to communicate in Arabic or English.

Conflict of interest

The authors declare that they have no competing interests.

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