Barriers to Adherence to Oral Hormonal Therapy Among Breast Cancer Women

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Abstracts: BACKGROUND: Oral hormonal medication is an essential part of the management of breast cancer for hormone receptor-positive patients. **OBJECTIVE**: This study aimed to evaluate barriers to adherence to oral hormonal therapy among breast cancer women. **METHOD:** A descriptive study was utilized on 200 adult women diagnosed with metastatic breast cancer, newly received oral hormonal therapy. Those women were admitted to the outpatient clinic at South Egypt Cancer Institute at Assiut University. Using interview questionnaire sheet included, demographics, medical data, patient knowledge assessment, Morisky Medication adherence scale, and factors affecting drug adherence checklist. **RESULTS:** The highest percentage among the studied sample their age was above 4o years (91%). Around (50%) the duration of illness was more than 5 years. 57% of patients the duration of oral hormonal therapy was more the three years. Our study explores that studied patients nearly had no knowledge regarding all items of oral hormonal therapy. In addition, most of them are not compliant with oral hormonal therapy. The most important predictor factors for medication compliance are psychological/behavioral factors. **CONCLUSION:** Most of the patients are not compliant with oral hormonal therapy, so, nurses should counsel cancer patients about oral hormonal therapy, addressing reasons for no adherence and handling them.

Keywords: Adherence; Barriers; Breast Cancer Women; Oral Hormonal Therapy**.**

1. INTRODUCTION

Hormone therapy is a treatment for breast cancers that are sensitive to hormones. Some forms of hormone therapy for breast cancer work by blocking hormones from attaching to receptors on cancer cells. Other forms work by decreasing the body's production of hormones. (Chen, et al., 2019).

Hormone therapy is a form of treatment that deprives breast cancer of estrogen and progesterone, the two main female hormones that it needs to survive and grow. (Paranjpe, et al., 2019).

Oral hormonal medication is an essential part of the management of breast cancer for hormone receptor-positive patients. Adjuvant hormonal medication is recommended to be taken daily for 5-10 years. Adjuvant hormonal medication reduces mortality and the recurrence rate in receptor-positive patients. (Bui, et al., 2020).

Adherence to long-term adjuvant hormonal therapy in hormonal receptors (HR)-positive breast cancer is really challenging and can affect the survival outcome. (Davies & Voutsadakis. 2022).

Factors were identified for non-adherence to oral agents for cancer treatment: complex regimens, lack of supervision, and communication between health professionals, social support, cognitive or mental problems, and beliefs on drug efficacy, side effects, and economic burden/drug cost **(Saeed et al. 2021)**.

This study aimed to evaluate barriers for adherence of oral hormonal therapy among breast cancer women.

1.1. SUBJECTS AND METHOD

A descriptive study designed was utilizes on 200 adult women diagnosed by metastatic breast cancer , newly received oral hormonal therapy .Those women admitted in outpatients clinic at South Egypt Cancer Institute at Assiut University. Using interview questionnaire sheet included, demographic, medical data, patient knowledge assessment, Morisky Medication adherence scale and factors affecting drug adherence checklist.

A structured interviewing Questionnaire was used in this study to assess demographic data (age, sex, level of education, occupation, marital status, occupation and residence) ; medical history (family history of cancer, duration of illness, type, stage, and site of cancer, types and response to oral hormonal therapy, etc.…).) for breast cancer patients undergoing oral hormonal therapy.

Knowledge assessment for breast cancer patients about oral hormonal therapy. Score of knowledge as one grade for each correct answer and zero for incorrect answer and doesn't know. Scores of items were summed-up and converted into a percentage. The patients' knowledge was considered (poor if <50%, Fair if 50% <70% and Good if >70 %) .

Morisky Medication adherence scale (MMAS-8). The MMAS evaluate items addressing the circumstances surrounding adherence behavior, it was developed by **Morisky et al.(2008)**. It included 8 items with yes/no responses and is thus quick and simple to use. A score of zero was given for positive response while score of one was given for negative response for questions 1, 2,3,4,6 and 7 (Yes= 0, No=1). Contrariwise, for item 5, a score of zero was given for a negative response while a score of one was given for positive response (Yes =1, No = 0).

*For item 8 is on a five – point Likert scale, a score of one was given for Never/ Rarely while a score of zero was given for once in while/ Sometimes/ Usually/ All the time. The total score was eight. Patients who had a score below 6 were considered having low adherence. Patients who had a score between 6 < 8 were considered having medium adherence. While patients who had a score equal 8 were considered having high adherence.

Factors affecting drug adherence. Checklist as reported by **Behnood-Rod (2016**) which include five main dimensions: (a) Social and Economic Dimension (11 items), (b) Health Care System Dimension (12 items), (c) Condition-Related Dimension (6 items), (d) Therapy related Dimensions (8 items) and (e) Patient Related Dimension (18 items). It covered 55 statements with Yes/no. The reliability analysis yielded an acceptable Cronbach's α coefficient score of 0.7.

1.2. METHODS

Ethical approval

Permission to carry out the study was obtained from the ethical committee of the Faculty of Nursing. An official letter was issued from the dean of the faculty of nursing, Assiut University, was prepared and delivered to the dean at South Egypt Cancer Institute for permission to collect the necessary data for this study. The researcher emphasized that the participation was voluntary and the patients had the right to refuse to participate in the study and can withdraw at any time. Verbal consent was obtained from each patient prior to his/ her contribution in the present study. Confidentiality and anonymity of any obtained information was assured through coding of all data.

Content validity was done by 5 expertise from medical & nursing staff, modifications were made accordingly, and then the tools were designed in their final format

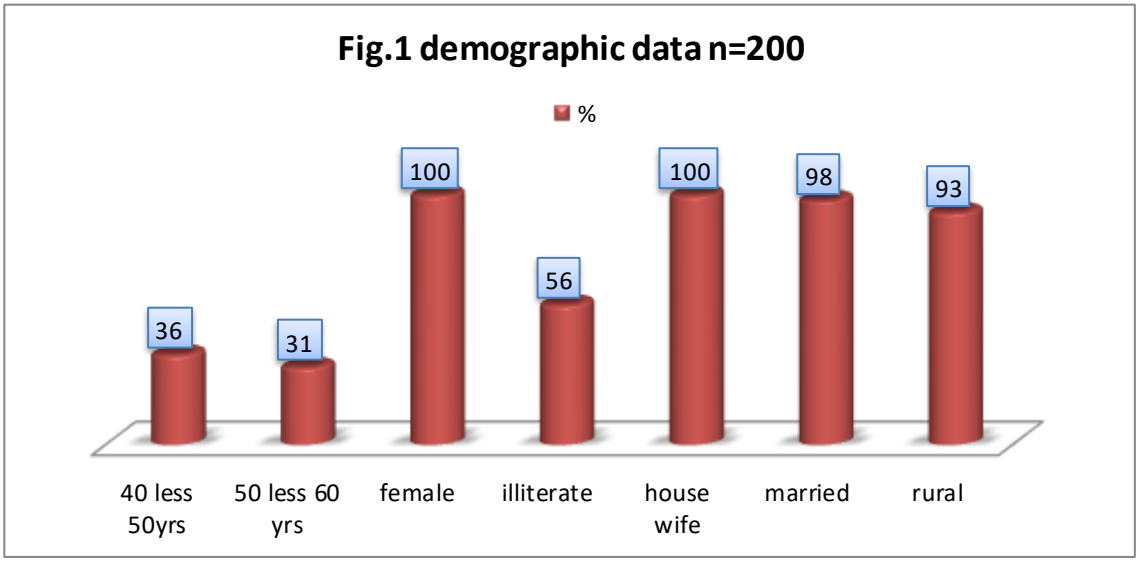
An official permission was obtained from the head of the South Egypt cancer institute at Assiut University to conduct the study after explaining the aim of the study. **A pilot study:** Pilot study was conducted on 10% of the sample (20 patients) to evaluate the applicability & clarity of the tools. According to this pilot study, the required modifications were made. Patients who were involved in the pilot study were included from the study. **Content**

reliability were designed in their final format and tested for reliability using internal consistency for all of the tools which was measured using Cronbach test. The tools proved to be reliable at (0.73.0.71 and 0.81, respectively).

2. STATISTICAL ANALYSIS

Data were tested for normality using the Anderson-Darling test and for homogeneity variances. Categorical variables were described by number and percent (N, %), where continuous variables described by mean and standard deviation (Mean, SD). Chi-square test and fisher exact test used to compare between categorical variables, t-test and ANOVA TEST were used to compare between continuous variables. A two-tailed $p < .05$ was considered statistically significant. Person Correlation was used to appear the association between scores. Data analysis was performed with IBM SPSS 20.0 software.

RESULTS



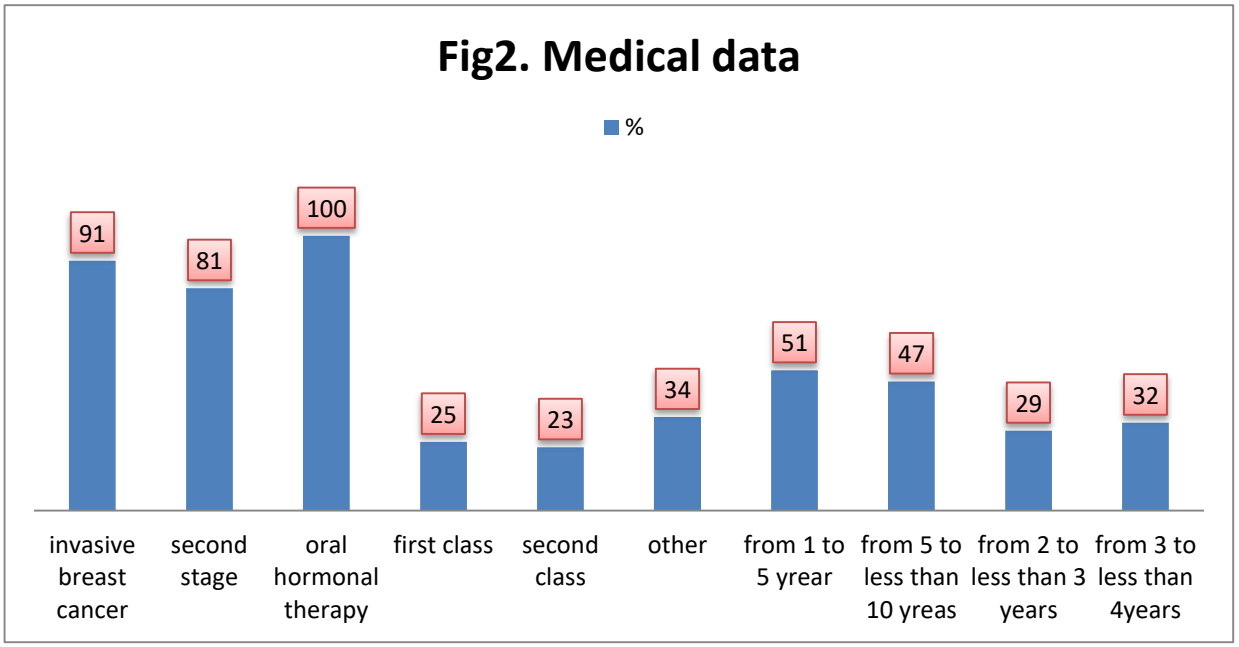


Figure (1&2): Shows that, highest percentage among studied sample with aged from 4o to 50 years(36%).The Majority of them (98%) were married, (56%) were Illiterate. Concerning occupation and residence most of them (100%) were house wife, and (93%) of them from living in rural area.

Nearly all the patients neither invasive breast cancer (91%), nor all patients receive oral hormonal therapy (100%).According to family history about one third of patient (34%) are fourth class. As regards duration of illness around half of patient (47%) the duration of illness is (5 -10 years). About one third (32%) of them, the duration of oral hormonal therapy from (3-4 years as represented in **Table (1)**

Table 1: Total level of knowledge on adherence of breast cancer women undergoing oral hormonal therapy n=200

Total knowledge 0-12 score	No.	%
	N	%
Poor knowledge < 50	200	100.0
Good knowledge > 50	0	0.0

Chi-Square Tests *=Significant difference *p≤0.05

**= highly significance *p≤0.01 Ns= Non significant difference P≤0.05

Our results explored that all studied patient had poor level of knowledge regarding oral hormonal therapy.

Table (2): Patient's level of adherence with oral hormonal therapy among breast cancer women undergoing oral hormonal therapy n=200

Medication compliance attributes 0-8 score	No	%
Low adherence (> 6)	160	80.0
Medium adherence (6 > 8)	40	20.0
High adherence (8)	0	0.0

Chi-Square Tests *=Significant difference *p≤0.05

**= highly significance *p≤0.01 Ns= Non significant difference P>0.05

Table (2): Shows that 80 % non-compliance to oral hormonal

Table (3): Correlation between factors and patient medication compliance.

Medication compliance attributes	Correlation matrix	
	Pearson Correlation	Sig. (1-tailed)
Medication compliance attributes	1.000	----------
Health care system Dimension	.078	.221ns
Condition related dimension	.565	.000**
Therapy related dimension	.485	.000**
Patient related dimension (Physical Factors)	.242	.008**

Psychological/Behavioral Factors	-.150	.068ns
Social and Economic Dimension	.373	.000**

Table (3): This table mentions that; there is statistical significant difference as regard condition related dimension therapy, physical and social and economic no statically significance as regard health care system and Psychological/Behavioral factor.

DISCUSSION

The present study had four aims. The first aim was to assess the adherence of breast cancer women undergoing oral hormonal therapy. The second aim was to identify factors affecting drug adherence in breast cancer patients undergoing oral hormonal therapy.

According to the family history of our studied patients, this is the second class of family history. As regards the duration of illness, about half of patients have duration of illness of 5–10 years, and about one-third of them have duration of oral hormonal therapy of 3–4 years.

This agrees with Brewer et al. (2017) study about family history and risk of breast cancer: an analysis accounting for family structure. Family history is an important breast cancer risk factor and one that can cause considerable anxiety for women . It is therefore important to measure the risk associated with it with as much discriminatory power as possible, both to improve overall risk prediction and for advice and information for women, especially those with affected relatives. Breast cancer incidence risk in relation to family history has been assessed in published studies by various parameters of the cases of breast cancer occurring in a woman's first-degree relatives. However, it appears in principle that assessment of familial breast cancer risk should consider not only breast cancers observed in the family but also the family size and age structure, and hence the expected number of cases if general population rates by age and calendar period prevailed in the family. This result explores how to detect breast cancer early. All relatives with a history of breast cancer were asked to consent to the examination. As well as provide sufficient information about treatment modalities and compliance with medication.

This result is in agreement with Tan et al. (2021), who conducted a study entitled beliefs about medicines and adherence in women with breast cancer on adjuvant endocrine therapy and founded that the majority of participants had an unsatisfactory level of knowledge about breast cancer and hormonal therapy. Women are in need of a simplified and comprehensive Arabic booklet, including information about action, side effects, and the best effective period for medication. Also, rely on the fact that the effectiveness of treatment depends on the efficacy of the medication and patient adherence to the therapeutic regimen.

This agrees with Yussof et al. (2022) study about factors influencing five-year adherence to adjuvant endocrine therapy in breast cancer patients, who noted that adhering to the full course of treatment for at least five years is necessary to obtain the full benefits of hormone treatment. Although there are some studies evaluating adherence that compare the data obtained from these different studies, very little is reported in the literature on the research on the compliance of endocrine therapy for breast cancer in China. Therefore, studies that address this subject are important as they are able to identify possible problems and suggest measures to promote and improve adherence to medication in China. This result is in agreement with Toivonen et al. (2020), who found that there was a positive correlation between total knowledge, self-efficacy, social support, and medication adherence among women with breast cancer receiving hormonal therapy.

Koni et al. (2023) discovered that greater treatment satisfaction led to greater adherence to oral cancer drugs, including hormonal medications, in a previous study about adherence to oral anticancer hormonal therapy in breast

cancer patients and its relationship with treatment satisfaction. Higher treatment satisfaction, especially with regard to side effects, was strongly associated with good adherence to oral hormonal therapy.

Our study shows that most of the studied patients poor achieved a score of compliance with oral hormonal therapy .These indicators the need of implementation of the nursing protocol, to improve patient knowledge regarding this issue..

This agrees with Stahlschmidt et al. (2019) study about adherence and quality of life in women with breast cancer being treated with oral hormone therapy, who noted that adherence is key for successful hormonal therapy (HT), which is proven to increase survival rates and reduce recurrence and mortality. Also, it is important to study treatment adherence in hormonal therapy and the factors related to it, as this is a treatment modality that is administered for a long period of time.

More than half of the women in this study had low or medium adherence, mostly defined by forgetting to take the medication. Most of them reported forgetting once or twice a year or not taking it at about the same time every day, either due to schedule changes or forgetfulness. Only one woman wanted to stop taking her medication because she was not feeling well (dizziness and vaginal discharge with tamoxifen). Studies vary in methods to measure and rate adherence. Clinical trials show that 72–92% of women are compliant with their treatment for the prescribed duration. However, these women are closely monitored and encouraged to take their medication properly. In clinical settings, this number can be as low as 50%.

Our study stated there are statistically significant differences regarding social and economic dimension factors and patient medication adherence. There was a significant negative correlation between physical and psychological symptoms, including pain, depression, and fatigue, stress, and medication adherence, among women with breast cancer receiving hormonal therapy in the study sample.

This result is in agreement with Toivonen et al. (2020) study about a survey of potentially modifiable patient-level factors associated with self-report and objectively measured adherence to adjuvant endocrine therapies after breast cancer, which found that there was a positive correlation between total knowledge, self-efficacy, social support, and medication adherence among women with breast cancer receiving hormonal therapy.

(Gamze & Sultan, 2017) in their study about the effect of structured education on patients receiving oral agents for cancer treatment on medication adherence and self-efficacy, who noted that factors were identified for non-adherence to oral agents for cancer treatment: complex regimens, lack of supervision, communication between health professionals, social support, cognitive or mental problems, beliefs on drug efficacy, side effects, and economic burden/drug cost .Studies of chronic diseases indicate that patients decrease adherence to medications decreases as symptoms and adverse effects occur. Adverse events may substantially impinge on the quality of life and are related to no adherence and early discontinuation of oral anticancer agents. Importance of all health care providers, namely the nurses, to take into consideration all the studied factors affecting women's adherence to hormonal therapy in planning and managing care for such a group of women.

Also, Saeed et al.'s (2021) study (Fears and Barriers: Problems in Breast Cancer Diagnosis and Treatment, which found that in many cases, most of the cost is borne by the patient and his or her family, and their income is insufficient.

A study by Koni et al. (2023) who examined the degree of adherence to oral anticancer hormonal therapy in breast cancer patients and its relationship with treatment satisfaction and described its correlation with treatment satisfaction. The domain of side effects represented an essential impact on treatment satisfaction and adherence. Adverse effects from hormonal therapy were considered the main barrier to no adherence, and it negatively impacts the quality of life . In our study, the highest beta coefficient was for the variable side effects. This suggests that side effects contributed the most to explaining differences in hormonal drug adherence. Close follow-up is recommended increasing compliance to medication.

CONCLUSION & RECOMMENDATION

Most of patient not compliance to oral hormonal therapy, so, nursing should counsel cancer patients about oral hormonal therapy, addressing reasons for no adherence and handling them. Nursing should counsel cancer patients about oral hormonal therapy, addressing the reasons for no adherence and handling them.

Patients are calling for the opening of a clinic to raise awareness and give instructions for oral hormonal therapy before the start of oral hormonal therapy to know the side effects and what are the harms that the patient is exposed to if he stops taking oral hormonal treatment.

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