

WOMEN WITH BREAST CANCER: ADHERENCE TO TAMOXIFEN TREATMENT¹

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ABSTRACT

The objective was to identify adherence to tamoxifen treatment in women with breast cancer and to evaluate the factors that may be related to their adherence. This study was transversal and quantitative. Were interviewed 67 women with breast cancer, attended in a mastology outpatient clinic of a University Hospital of Recife, between April and July 2017. To obtain the independent variables, a structured questionnaire was used, elaborated by the team itself. To investigate tamoxifen adherence, the Morisky and Green test was chosen and the questionnaire "Factors that may influence adherence to treatment" was chosen to check potential influencing factors in adherence to treatment. The side effects of tamoxifen and the affective relationships proved to be sensitive points for adherence, as presented in the results. The rate of adherence was 55.2% and 85.1% of women were on treatment for less than a year. The longtime of therapy with tamoxifen is a predictor that may hinder adherence. The evaluation of potential factors influencing adherence highlights the relevance of multiprofessional teams in this context, since its variety of approaches makes it possible to elucidate the effectiveness of the active role of individuals in the process of health rehabilitation.

Keywords: Breast neoplasms. Tamoxifen. Drug Therapy. Medication. Adherence.

INTRODUCTION

Malignancies are a serious public health problem worldwide, especially in developing countries, where the impact of cancer in the population is expected to account for 80% of the estimated 20 million new cases by 2025. Estimates for the Brazil were 600,000 new cases in the 2018-2019 biennium, 10% of which correspond to breast cancer, which is the most frequent malignant neoplasm among women and the leading cause of cancer death in the world⁽¹⁾.

Changes in the demographic profile linked to lifestyle changes interfere with reproductive factors such as late onset of motherhood, low parity and breastfeeding for short periods, explaining trends in breast cancer incidence in all regions of the country⁽²⁾.

However, there are cost-effective interventions in all approaches and cancer control, such as primary prevention, early diagnosis, timely treatment and palliative care⁽³⁾. Within this conjuncture there are chemo preventives, such as tamoxifen, which can be used by patients before or after menopause and acts by binding to the tumor receptor for estrogen, thereby

competing with this hormone. This drug can also be used for palliative purposes or as an adjuvant therapy and is associated with the longer survival of women affected by malignant tumors in the breast and the reduction of the odds of contralateral breast cancer⁽⁴⁾.

Based on this context, it is worth emphasizing the relevance of adherence to drug therapy as one of the priorities for coping with and controlling chronic diseases. In 2003, the World Health Organization (WHO)⁽⁵⁾ defined adherence as the degree of agreement between a person's behavior towards medical or other health care professionals and was influenced by multiple factors.

Brazil has a public policy supported by the Ministry of Health, Decree 874 of May 16, 2013⁽⁶⁾ that addresses the adherence to cancer treatment in the context of the Unified Health System (SUS), when it is defined as one of the components of support of the health care network of people with cancer; the necessary pharmaceutical care for the treatment. However, there is still a lag in the country regarding studies on adherence to antineoplastic drugs, since most of them are of a foreign nature.

Given the lack of studies aimed at adherence as a

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step in the line of care and humanization of oncology policies, this research aims to identify compliance with tamoxifen treatment in women with breast cancer, as well as to evaluate the factors that may be present related to its adherence.

METHODOLOGY

This is a descriptive, cross-sectional study with a quantitative approach. Using the non-probabilistic sampling technique for convenience, 67 women interviewed in a mastology outpatient clinic of a university hospital in Recife, Pernambuco, were interviewed, who had cumulatively: a registry in said service, 18 years or more, diagnosis of breast cancer and were undergoing treatment c o m tamoxifen for at least 6 months.

Data were collected between April and July 2017, through individual interviews, before or after the medical visit. To obtain the sociodemographic and clinical data, a structured questionnaire was used, prepared by the team and composed of socioeconomic data such as age, race / ethnicity, marital status, schooling, occupational situation and monthly family income, and clinical data, discovery of the disease, time of tamoxifen use, therapeutic method for neoplasia and use of other medications for chronic diseases. To evaluate the socioeconomic profile and the clinical characterization of the participants, the percentage frequencies of the evaluated variables were calculated and the respective frequency distributions were constructed.

To investigate the prevalence of tamoxifen adherence, the Morisky and Green Test (TGM)⁽⁷⁾ was used, which contains four questions whose answers are given by Yes or No, where Yes = 0 and No = 1. The women who scored four were considered adherents, that is, they answered no on all questions.

To verify the factors that may influence adherence to treatment, a questionnaire entitled "Factors that may influence adherence to treatment"⁽⁸⁾ was chosen, consisting of seventeen questions that are answered on a likert five-level scale: I agree completely, I agree partially, undecided, totally disagree and partially disagree, with values of 5,4,3,2 and 1. Questions 09, 14, 15, 16 and 17 have inverted values 1,2,3,4 and 5. The result is provided by the sum of the values of the answers, being the minimum sum of the scores 17 and the maximum 85. The totally agree and partially agree levels were grouped, in the same way as the levels totally disagree and partially disagree, for the construction of table 4.

The degree of difficulty in adhering to the treatment measured by the instrument "Factors that can influence adherence to treatment"⁽⁸⁾ is represented by the following scale: 17-34 points, no difficulty in adhering to treatment; 35- 51 points, little difficulty adhering to treatment; 52- 68 points, moderate difficulty adhering to treatment and 69-85 points, very difficult to adhere to treatment. Complete adherence is assigned to patients who get a score of up to 34 points.

To store the data a bank was built in the Microsoft Excel 2016 spreadsheet which was exported to the software Statistical Package for the Social Sciences (SPSS), version 18.0, where the statistical analysis was performed. The proportion comparison test was applied to compare the prevalence's found between the response levels of the variables under study. All conclusions were drawn considering the level of significance of 5%.

For the development of this scientific work, the norms and guidelines contained in Resolution No. 466/12 of the National Health Council of the Ministry of Health, which deals with researches with human beings, were respected. The study was evaluated and approved by the Research Ethics Committee of the Hospital Complex of HUOC / PROCAPE, with the opinion number 1,972,466. Prior to the interview participants were explained the research objectives and all signed the Informed Consent Term.

RESULTS

The age extremes of the women interviewed ranged from 40 to 68 years, mean and standard deviation were respectively 52 years and ± 7.94 years. There was predominance of black women (73.1%), married (52.2%) and with up to 8 years of schooling (53.8%).

In the distribution of the factor related to the mode of discovery of the disease and the clinical characterization of the participants (Table 2), it was verified that the majority of the women found the cancer through breast self-palpation - APM (34.3%), time of tamoxifen was from 6 months to 7 years, with a mean of 1.21 years and a standard deviation of ± 2.32 years. More than 70% of the participants underwent mastectomy.

Table 3 shows that 44.8% (n = 30) of the participants did not adhere to the treatment, that is, they answered Yes in at least one question and even though it was identified that more than half of the interviewees (n = 37; 55.2%) adhered to the treatment, the proportion comparison test was not significant (p-value = 0.392), indicating that the number of adherent and non-adherent participants is similar.

Table 1. Distribution of the socioeconomic profile of the participants, Recife, 2017.

Rated factor	n	%	p-value ¹
Age			
40 to 49 years	26	38.8	0.022
50 to 59 years	24	35.8	
60 or more	17	25.4	
Ethnicity			
White	18	26.9	<0.001
Brown	39	58.2	
Black	10	14.9	
Marital status			
Not married	21	31.3	<0.001
Married or live with partner	35	52.2	
Separate	2	3.0	
Widower	9	13.4	
Education			
Illiterate	4	6.0	<0.001
Elementary School	32	47.8	
High school	22	32.8	
Higher education	9	13.4	
Occupational Situation			
Retired	21	31.3	0.001
Unemployed	8	11.9	
Freelancer	5	7.5	
Worker with a formal contract	10	14.9	
From home	23	34.3	
Monthly family income			
Up to a minimum wage ²	37	55.2	<0.001
From 1 to 2 minimum wages	18	26.9	
From 2 to 3 minimum wages	8	11.9	
From 3 to 4 minimum wages	2	3.0	
More than 4 minimum wages	2	3.0	

¹p-value Chi-square test for proportion comparison (if p-value <0.05 the percentages of factor levels assessed differ).
²Minimum wage in 2017 was R \$ 937.00 (Nine hundred and thirty-seven reais).).

Table 2. Distribution of the factor related to the mode of discovery of the disease and clinical characterization of the participants, Recife, 2017.

Rated factor	n	%	p-value ¹
How did you discover the disease?			
You started to feel symptoms	19	28.4	0.100
Routine medical examination	16	23.9	
APM	23	34.3	
Others	9	13.4	
How long have you been taking tamoxifen?			
Less than 1 year	57	85.1	<0.001
From 1 to 2 years	3	4.5	
From 3 to 5 years	4	6.5	
More than 5 years	3	4.5	
What other treatment (besides the hormone therapy) you performed for breast cancer *			
Surgery (mastectomy)	49	73.1	<0.001
Radiotherapy	36	53.7	
Immunotherapy	3	4.4	
Chemotherapy	67	100.0	
It makes use of other medicines for other chronic diseases			
Yes	34	50.7	0.903
No	33	49.3	

¹p-value Chi-square test for proportion comparison (if p-value <0.05 the percentages of factor levels assessed differ). * Multiple answer.

Table 3. Distribution of Morisky and Green Test responses, Recife, 2017.

IssueEvaluated	Answer		p-value ¹
	Yes N (%)	No N (%)	
Do you ever forget to take your medicine?	23 (34.3)	44 (65.7)	0.010
Are you careless at times about taking your medicine?	22 (32.8)	45 (67.2)	0.005
When you feel good, do you ever stop taking the medicine?	15 (22.4)	52 (77.6)	<0.001
When you feel bad with the medicine sometimes fails to take it?	18 (26.9)	49 (73.1)	<0.001
TGM RESULTS	Positive	Negative	
	30 (44.8)	37 (55.2)	0.392

p-value Chi-square test for proportion comparison.

In the fourth table there is the distribution of the agreement / disagreement of the participants regarding the factors that can influence the adherence to the treatment. Scores ranged from 35 to 73 points, with an average of 54 points. Most women (n = 45, 68.7 %)

had a moderate degree of difficulty in joining the drug, 28.3% (n = 19) had little difficulty and 3% (n = 2) showed great difficulty in adherence. The side effects of tamoxifen and the affective relationships revealed sensitive points for adhesion.

Table 4. Distribution of agreement / discordance of participants with factors that may influence adherence to treatment with tamoxifen, Recife, 2017.

Factors assessed	Patient assessment			p-value ¹
	I totally agree/ in part N (%)	I amun decided N (%)	I disagree in part / Fully N (%)	
1. drugs cause undesirable effects	44 (65.7)	2 (3.0)	21 (31.3)	<0.001
2. I forget to take the pills.	23 (34.3)	—	44 (65.7)	0.10
3. I need help getting the pills.	15 (22.4)	—	52 (77.6)	<0.001
4. I have many remedies to take.	15 (22.4)	3 (4.5)	49 (73.1)	<0.001
5. I do not know if I should take the medicines before, during or after meals.	4 (6.0)	2 (3.0)	61 (91.0)	<0.001
6. The treatment is complicated, I find it difficult.	31 (46.3)	—	36 (53.7)	0.541
7. I have difficulty remembering the day of the re-initiation of the oral medicine.	25 (37.3)	11 (16.4)	31 (46.3)	0.009
8. I have trouble getting the pills.	15 (22.4)	—	52 (77.6)	<0.001
9. Oral drug treatment provides less work shortage.	49 (73.1)	—	18 (26.9)	<0.001
10. I need company to come to the consultations, I cannot or I do not want to go alone.	46 (68.7)	—	21 (31.3)	0.002
11. Health professionals do not help me.	3 (4.5)	—	64 (95.5)	<0.001
12. The opening hours are bad, inconvenient.	12 (17.9)	—	55 (82.1)	<0.001
13. I forget or sometimes I cannot attend the consultations.	2 (3.0)	—	65 (97.0)	<0.001
14. I have the right time to take the medication.	57 (85.1)	—	10 (14.9)	<0.001
15. I check the dosage and name of the medicines before taking them.	50 (74.6)	2 (3.0)	15 (22.4)	<0.001
16. I keep the remedies in proper places.	57 (85.1)	5 (7.5)	5 (7.5)	<0.001
17. I take the medicine even when I feel bad.	49 (73.1)	1 (1.5)	17 (25.4)	<0.001

¹p- value Chi-square test for proportion comparison.

DISCUSSION

The identification of the socioeconomic profile is important because it allows to know the regional disparities and singularities. Studies carried out in states of other Brazilian regions⁽⁹⁻¹¹⁾ reveal different scenarios regarding color, schooling and monthly family

income.survey carried out in Rio Grande do Sul⁽⁹⁾ had a prevalence of white women with low schooling, that is, less than eight years of schooling and had monthly family income of up to two minimum wages.

investigation⁽¹⁰⁾ the socio-demographic profile of women with breast cancer in Rio de Janeiro, the researchers observed a predominance of women who

did not work or worked informally and they lived up to one minimum wage, like the present study. However, it found a preponderance of women with more than eight years of study. Scholars evaluating the quality of life of women with breast cancer in Paraná⁽¹¹⁾ observed that the majority of their sample had up to 12 years of study and monthly family income of up to 4 minimum wages. The three scientific papers mentioned above were consonant with this research regarding the marital status and age group.

The central point for the prevention of breast neoplasm is early detection, since delayed diagnosis implies a reduction in patient survival, indicating that the reduction in mortality is associated with both adequate and timely screening and treatment⁽¹²⁾.

Prevalence study⁽¹³⁾ on the clinical profile of 23 women with breast cancer performed in a municipality in the state of Espírito Santo obtained that 78.2% of these women discovered the disease from APM, highlighting its importance as a clinical method of prior identification of breast tumors. The association of this propaedeutic method with the imaging exams increases the accuracy of the diagnosis. Therefore, educational campaigns that increase their visibility should be adopted as coping strategies.

When the diagnosis is not made early, the disease can be seriously affected to the point where the woman needs to undergo a mastectomy, which aims at the total or partial removal of the mammary gland in order to increase the life expectancy of women considered to be at high risk⁽¹⁴⁾. But this surgery is a traumatic experience for women affecting their interrelationships and causing major impacts on their psychological health⁽¹⁵⁾ which may affect adherence to therapy with oral antineoplastic.

The rate of adherence to adjuvant hormone therapy is quite heterogeneous among studies from other localities. In a multi-centered study conducted in France⁽¹⁶⁾, where TGM was applied to assess adherence to adjuvant hormone therapy in 280 women with breast cancer, 68.6% were adherent to this therapy. A retrospective cohort conducted in the United States⁽¹⁷⁾, with 21,255 women diagnosed with breast cancer, obtained a non-adherence rate of 15.6%, and in Chicago researchers⁽¹⁸⁾ observed adherence rate to adjuvant endocrine therapy of 97%.

In the present study, the adherence rate was 55.2%, and was below the expected value. The reason for the variations in the prevalence of adherence may be related to the level of awareness about the treatment of

the women participating in the studies, as well as the financing of national breast cancer control policies.

Tamoxifen has side effects such as hot flushes, water retention, amenorrhea, altered menstrual cycle, vaginal discharge and bleeding, nausea, weight loss and mood swings⁽⁴⁾. More than a third of the participants agreed that this drug has undesirable effects, which may have interfered in the prevalence of adherence found.

The set of side reactions is related to the decreasing trends of adherence over the years, so the longer the treatment time, the higher the non-adherence rates⁽¹⁹⁾. It is noteworthy that in the present study, the majority of women (85.1%) used tamoxifen for less than 1 year, corroborating that the adherence rate was relatively low. This warns of the risk of increased chances of breast cancer recurrence and mortality in the study population. Therefore, elucidations about adverse effects and other factors that may interfere with adherence are essential for continuity of treatment.

This circumstance points to an antagonism with regard to the question "I forget or sometimes I cannot attend the consultations" (item 13 of table 4), where almost all patients (97%) reported attending appointments periodically, indicating that this momentum may not be being used to clarify doubts. It should be stressed that the participants in this study have low levels of education, that is, they have little access to information, in general, and little understanding about the disease and treatment. This scenario reflects, also, the fact that the expressive portion of the sample (46.3%) found the treatment with complicated oral antineoplastic.

The answers reported in items 2 and 3 of the fourth table "I forget to take the drugs and I need help to take the pills", respectively, show that the greater part of the participants has the potential to act as co-responsible for the production of care with their health, provided their potentialities are worked out, reinforcing the importance of health education during consultations in the health services.

Depressive symptomatology and lack of social support predict a weakening of adherence⁽¹⁹⁾, this may justify the allusion (68.7%) of needing a company to attend consultations. Satisfactory placements were observed regarding the storage of tamoxifen, name and dosage conference, time to take medication, and if their intake was not felt well, these factors had good results and had values inverted because they had a positive influence on adherence⁽⁸⁾.

The questions "I have difficulty getting the medicine" and "The health professionals do not help me", have obtained unexpected results, since there is a free distribution of tamoxifen and other antineoplastic medications by SUS. This is indispensable for the control and coping of cancer, since these drugs are expensive and the majority of the population is covered only by the public health system⁽²⁰⁾. The relevance of a multiprofessional health team that works in an interdisciplinary way, in order to welcome the users, is also highlighted.

The duration of hormone treatment for breast cancer is long, at least five years, and may hinder adherence. In this way, the best way to get patients to join therapy is to make them co-responsible for their health, making them aware of the harm of non-adherence. This study identified a low prevalence rate of adherence, especially since most patients were in the first year of treatment, revealing the need to strengthen public policies for breast cancer control and alert health services invest more in educational actions.

The multiprofessional teams have a crucial role in this work, because with their variety of approaches they can elucidate the effectiveness of the active role of individuals in the process of health rehabilitation and guide the importance of attendance with treatment.

CONCLUSION

In evaluating the factors that have the potential to influence the prevalence of adherence, we noticed that the majority of women with breast cancer had a moderate degree of difficulty in adhering to the medication, with the side effects and psychosocial aspects of the treatment being the most critical. We observed, therefore, a compromise of the proposed treatment with the oral antineoplastic tamoxifen, whose adhesion rate was 55.2%.

Because of this, it is necessary to be attentive to the early identification of possible modifiable causes, contributing, therefore, for a better adhesion and consequent increase of the chances of cure. The identification of the factors that has the potential to influence the membership aims to contribute to the construction of information supporting the development of public policy control of breast cancer.

As a cross-sectional study, we present as limitations the impossibility of establishing causal links and rates of persistence of adherence over time. However, the research exposes data referring to factors influencing therapeutic adherence, alerting to the possible impacts generated treatment.

MULHERES COM CÂNCER DE MAMA: ADESÃO AO TRATAMENTO COM TAMOXIFENO

RESUMO

O objetivo foi identificar a adesão ao tratamento com tamoxifeno em mulheres com câncer de mama e avaliar os fatores que podem estar relacionados à sua aderência. Este estudo foi transversal e quantitativo. Foram entrevistadas 67 mulheres com câncer de mama, atendidas em um ambulatório de mastologia de um Hospital Universitário de Recife, entre abril e julho de 2017. Para obtenção das variáveis independentes foi utilizado um questionário estruturado, elaborado pela própria equipe. Para investigar a adesão ao tamoxifeno optou-se pelo Teste de Morisky e Green e para verificar potenciais fatores influentes na adesão ao tratamento, foi escolhido o questionário "Fatores que podem influenciar a adesão ao tratamento". Os efeitos colaterais do tamoxifeno e as relações afetivas se mostraram pontos sensíveis para adesão, conforme apresentado nos resultados. A taxa de adesão foi de 55,2% e 85,1% das mulheres fazem o tratamento há menos de um ano. O tempo longo da terapia com o tamoxifeno é um preditivo que pode tolher a adesão. A avaliação de potenciais fatores influentes na adesão destaca a relevância das equipes multiprofissionais nesse contexto, pois sua variedade de enfoques torna possível elucidar a efetividade do papel ativo dos indivíduos no processo de reabilitação da saúde.

Palavras-chave: Neoplasias da Mama. Tamoxifeno. Tratamento Farmacológico. Adesão à Medicação.

MUJERES CON CÁNCER DE MAMA: ADHESIÓN AL TRATAMIENTO CON TAMOXIFENO

RESUMEN

El objetivo fue identificar la adhesión al tratamiento con tamoxifeno en mujeres con cáncer de mama y evaluar los factores que pueden estar relacionados a su adhesión. Este estudio fue transversal y cuantitativo. Fueron entrevistadas 67 mujeres con cáncer de mama, atendidas en un ambulatorio de mastología de un Hospital Universitario de Recife-Brasil, entre abril y julio de 2017. Para recolección de las variables independientes fue utilizado un cuestionario estructurado, elaborado por el propio equipo. Para investigar la adhesión al tamoxifeno se optó por el Test de Morisky-Green y para verificar potenciales factores influentes en la adhesión al tratamiento, fue elegido el cuestionario "Factores que pueden influir la adhesión al tratamiento". Los efectos colaterales del tamoxifeno y las relaciones afectivas se mostraron puntos sensibles para la adhesión, conforme presentado en los resultados. La tasa de adhesión fue de 55,2% y 85,1% de las mujeres hacen el tratamiento a menos de un año. El largo tiempo de la terapia con el tamoxifeno es un predictivo que puede perjudicar la adhesión. La evaluación de potenciales factores influentes en la adhesión destaca la relevancia de los equipos

multiprofissionais en este contexto, pues su variedad de enfoques vuelve posible dilucidar la efectividad del papel activo de los individuos en el proceso de rehabilitación de la salud.

Palabras clave: Neoplasias de la Mama. Tamoxifeno. Tratamiento Farmacológico. Adhesión a la Medicación.

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