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Full Length Research Paper

Evaluation of the compliance of women with breast cancer to treatment in a reference hospital in a city of North-east, Brazil

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For the translation, transcultural adaptation and a pilot test of the instrument were done. Also, the compliance of the breast cancer patients to the treatment was measured. The questionnaire "Cancer Patient Self-Report Questionnaire Non-Adherence" was translated and adapted; and a pilot test with 30 patients was performed. For this study, the questionnaire, Morisky-Green test, was also used. A hundred and thirteen patients diagnosed with breast cancer and who used oral chemotherapy were evaluated. The evaluated patients' average age was 57 years. 82.5% of them had invasive lobular carcinoma cancer, and almost 50% had a family history of breast cancer. The evaluation of the compliance shows that only 31.85% of the patients completed the medical treatment. Patients who presented adverse reactions were more susceptible to stopping the treatment. The low compliance on the medicated treatment is worrying and shows the need to improve it and further research to identify which factors contribute to the non-compliance to such treatment.

Key words: Breast cancer, compliance, oncology.

INTRODUCTION

Breast cancer is the second most present type of cancer in Brazil and in the world. In the last years, the incidence of breast cancer increased. Due to the rise of early diagnosis of the cancer, the mortality has fallen, highly increasing the prevalence of breast cancer (Ferlay et al., 2015). The breast neoplasia has a genetic origin, be it through mutation or hereditary matters (Bilimoria and Morrow, 1995). The therapeutics focuses on surgery, with or without the use of radiotherapy and chemotherapy as well as oral chemotherapy which prevents the recurrence of the disease (WHO, 2003).

The use of chemotherapy for a long time turns compliance into a challenge. As in developed countries, the compliance of long-term treatment is approximately 50% and in developing countries, this number is lower due to lack of financial resources (Vermeire et al., 2001;

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Souza et al., 2013).

Several reasons and factors may influence compliance. Non-compliance is higher among women under 35 years of age, with more advanced stages of the disease (stages III and IV), drinkers, those undergoing chemotherapy and the increase on the number of months between diagnosis and starting of treatment (Brito et al., 2014). For these and other reasons, it is necessary to assess compliance on chemotherapy so that health staff can take appropriate decisions.

Therefore, we aimed to carry out the translation, cultural adaptation and a pilot test of the instrument and measure compliance to the treatment by patients with breast cancer.

MATERIALS AND METHODS

This is an observational, descriptive and exploratory study with a cross-sectional design. Data collection was performed at the Oncology Center of Emergency Hospital (HUSE), located in the municipality of Aracaju, from October to December 2012. Female patients with breast cancer were treated at HUSE Oncology Center. The sample consists of the target population of patients who met the following inclusion criteria: Age less than 18; breast cancer diagnosis using oral adjuvant therapy; agreed to participate by signing a free and informed consent form (ICF).

The sample size was determined by estimating a ratio of registered patients at the Oncology Center, considering a non-compliance rate of 76%, with absolute estimate precision of 8% and a confidence level of 95%. The calculated value was 109 patients and 113 patients were collected.

Socio-demographic data were collected on the diagnosis: type, histological grade, staging and date of diagnosis, hormonal stage as premenopausal or postmenopausal of the woman on the day of the diagnosis, the age of the woman at menarche, menopause if the woman has already been affected by it, parity, age of children if the woman has any, abortions, family history regarding breast cancer occurrence. It was verified whether treatment was already started or not, and if started, what form of treatment such as surgery, radiation therapy or chemotherapy and which is the current treatment. When was it started and how long has the woman been undergoing treatment? It will be checked for other diseases and medications used in addition to oral chemotherapy.

Compliance and non-compliance to treatment as a dependent variable

Three instruments for data collection were used: one for socio-demographic and clinical data, and two questionnaires for assessing compliance in women with breast cancer and using oral adjuvant therapy.

For assessing treatment compliance, Morisky and Green test was applied; it was translated into Portuguese language (Strelec et al., 2003; Abreu and Koifman, 2002). A questionnaire of self-reporting of non-compliance in cancer patients (Cancer Patient Self-Report Non-Adherence Questionnaire) was used (Kondryn et al., 2009).

The process of translation and cultural adaptation of the Cancer Patient Self-Report Non-Adherence Questionnaire was conducted based on methodologies described in the literature. The entire process was executed in five stages: (1) translation into Portuguese by two translators; (2) consensus of the two translations; (3) back-translation into English, (4) evaluation of semantic equivalence and (5) pilot test with 30 patients (Guillemin et al., 1993; Wild et al., 2005).

Step 1: Translation of the instruments from mother tongue, English to Portuguese by two people, independently; the translators were fluent in English language, had no idea of the issued addressed in the questionnaire and without knowledge of health supply.

Step 2: Consensus of the two translations was done by a meeting between the translators and a mediator. The mediator reconciled the differences in translation and did the final translation in consensus with everyone.

Step 3: Back-translation of the Portuguese version was made in step 2 by two translators independently; they have different life experiences, are native English speakers and are fluent in the target language. The translators were blinded during the process from the original version of the questionnaire and production of consensus.

Step 4: Semantic equivalence evaluation by two experts, ALF and WB, along with the back-translators; the translated versions were equivalent to the questionnaire in its original version. They came up with a consensus on the final version of the questionnaire in Portuguese.

Step 5: To assess the applicability of the instrument, a pilot test with cross section was performed in 30 women diagnosed with breast cancer; they were undergoing treatment at the Oswaldo Leite oncology unit, located in the Emergency Hospital of Sergipe in September 2012. Data collection was performed by personal contact of researchers with patients at the time they were in the hospital waiting for an outpatient visit. There were no refusals by the participants or sample loss at any stage of the study.

Data analysis was done using the *EPI-info software v.3.5*. The vision statistical analysis was used to investigate the distribution and relationship between the variables. Means or medians and standard deviations were used to summarize the data when needed. Two-way significance tests, including chi-square or Fisher's exact test were performed to verify the association between categorical variables. Student tests or Mann-Whitney tests were used to compare means between continuous variables. A 95% confidence interval ($\alpha \leq 0.05$) was used.

In accordance with Resolution CNS 196/96 of the National Board of Health, the project was registered in SISNEP and submitted to the Committee of Ethics and Research of the Federal University of Sergipe where it was given favorable opinion with CAAE: 00841712.4.0000.0058. To the research subjects, the right to confidentiality was assured, as well as non-maleficence, autonomy and information on the purpose, procedures, possible discomforts and benefits of the research; their agreement to participate in the study was attested by signing a free and informed consent form (ICF).

RESULTS

The items were translated independently by two professionals in step 1. Item 5 is expressed in the sentence "How Often do you forget to take a dose of your prescribed oral (taken by mouth) medicines?" in the original instrument. The translation process generated two results “Com que frequência você se esquece de tomar uma dose de seu medicamento oral prescrito? (Ingerido pela boca)” and “Com que frequência você esquece de tomar a dosagem de seus medicamentos

orais prescritos?". The difference between "dose" and "dosage" was found in translations to Portuguese in step 2. We opted for the "dose" term, which means the amount needed to elicit a desired therapeutic response in the patient, since "dosagem" refers to how often the dose is taken.

Verbs were translated mostly into the past tense of the indicative case of a recall questionnaire; for example, the Item 7: "Have you ever taken the wrong dose?" was translated into: "Você já tomou a dose errada?"

Item 16 "Have you ever forgotten to care for your central line?" generated two results in step 1: "Você alguma vez esqueceu de cuidar da sua linha central?" and "Você já se esqueceu de cuidar do seu eixo central?" Translations into Portuguese were literal and the term "central line" was not consistent in any translation with cancer treatment; as Brazil refers to central venous access done in some patients (Table 1).

For the pilot study 30 patients were interviewed with an average age of 57 years (± 12.6). All were diagnosed positive for breast cancer during the period of 17/09/2012 to 28/09/2012, in Oswaldo Leite Oncology Unit, located in the Emergency Hospital of Sergipe. The studied population was 113 patients with an average age of 57 ± 13 years. The evaluated patients were all women. The most present breast cancer subtype with 82.5% is the invasive lobular cancer followed by lobular carcinoma *in situ* with 10%. Hormonal status of 72% women were postmenopausal; only 20% were premenopausal, 5.5% had undergone hysterectomy and 1.8% stopped menstruating as a result of chemotherapy. As for menarche 12 4% happened to be less than 12 years. Other risk factors, such as hormone replacement were present in only 6.2% of the studied population. As nulliparity was observed in 12.3% of patients, looking at the family history of breast cancer we obtained a percentage of 49.1%. The assessment of compliance with the adjuvant pharmacotherapy made by Morisky and Green questionnaire shows a fulfillment of only 31.85% (36) of patients, and 68.14% (77) was considered non-adherent.

The second tool used to determine compliance with not only pharmacotherapy, but treatment as a whole, is a self-report questionnaire that consists of two parts. The first is composed by two questions in which in positive cases, the patient has a high risk of non-compliance to the treatment. The questions are dichotomous and only 9.7% already thought about stopping all treatments. The second part, also called low risk of non- compliance made in the form of Likert scale, obtained a score of 2.6 (± 2.4).

Comparing the average scores of patients who considered quitting with those who did not consider quitting, we achieved a statistically significant difference (Mann-Whitney = 19.97, p = 0.04). The average scores of the patients who had diarrhea were statistically higher than those patients who did not have (Mann-Whitney = 10.48, p = 0.001). But when we evaluated the scores of people who had bleeding or fever with the scores of people who had no bleeding or fever, there were no significant differences. Ingestion of 5 or more medicaments is characterized as polypharmacy. These values were found in over 10% of patients in this study and studies of literature.

DISCUSSION

The translation was well accepted by patients, since there was little or no difficulty in understanding the issues. It was also effective in identifying people with the most prone behavior of not completing their treatment, making it necessary for further monitoring by health professionals.

The sample population of more than 80% has lobular cancer attacker, which, according to literature, is also the most frequent between the breast cancers; also lobular carcinoma *in Situ* was observed, with 10%, which is also the value found in literature (Adami et al., 2008). And contrary to the study of Santa Catarina, over 70% of invasive ductal carcinoma was found (Moreno et al., 2012).

The hormonal status of women is a risk factor for the onset of breast cancer. Literature shows that the greater the exposure time to the female hormones, for example, the difference between menarche and menopause the higher the probability of breast cancer (Brazil, 2009). And for every year that menarche delays, the risk of having breast cancers diminishes by 5%(Key et al., 2001). Hormone replacement is an important risk factor that increases the vulnerability of women towards breast cancer and was found in 6.2% (Kirk and Hudis, 2008). It is already known that the use of hormone replacement therapy for more than five years may increase the risk of breast cancer by 34% with isolated estrogens and by 53% when combined with progesterone (Key et al., 2001). Another important risk factor is genetic inheritance; all cancers are genetic. This risk factor is very important and appears in almost 50% of patients (Brazil, 2009).

Non-compliance in this study was found in around 70% of patients. This demonstrates a low compliance rate and increases the likelihood of recurrence. Closer values found in literature were 43.6% of non- compliance (Kirk and Hudis, 2008). The self-reported questionnaire for evaluating any treatment consists of two parts: the first part is called high risk of non- compliance to treatment. It has two questions with dichotomous answers and only 9.7% already think about stopping treatment. This demonstrates that patients like the treatment. The second part, also called low risk of non- compliance made in the form of Likert scale, obtained a score of 2.6 (± 2.4); the literature article scores a 4.3 (± 4.2), which shows the good compliance to the treatment (Kondryn et al., 2009).

The average scores of patients that thought about stopping the treatment compared to the average scores

Table 1. Transcultural translation and semantic equivalence of the original instrument in English (O), consensus of versions for the Portuguese (TC), consensus of back-translation to English (RC) and final version in Portuguese (F).

O	TC	RC	F
1. Have you ever considered stopping ALL your treatment?	1.Você já pensou em parar TODO o seu tratamento?	1. Have you ever thought about stopping ALL of your treatment?	1. Você já pensou em parar TODO o seu tratamento?
2. Have you ever considered stopping PARTS of your treatment? IF YES, please say which part(s) of treatment you have considered stopping?	2. Você já pensou em parar PARTES do seu tratamento? SE SIM, por favor, diga que parte(s) do tratamento você pensou em parar?	2. Have you ever thought about stopping PARTS of your treatment? IF YES, please say which part (s) of the treatment you have thought about stopping?	2. Você já pensou em parar PARTES do seu tratamento? SE SIM, por favor, diga que parte(s) do tratamento você pensou em parar?
3. Have you ever tried to change with the medical team the timing of any aspect of your treatment?	3. Você já tentou mudar com a equipe médica qualquer aspecto do seu tratamento?	3. Have you ever consulted with your medical professionals about changing any aspects of your treatment?	3. Você já tentou mudar com a equipe médica qualquer aspecto do seu tratamento?
4. Have you ever tried to change the type of treatment you are receiving/will be receiving?	4. Você já tentou mudar o tipo de tratamento que você está recebendo ou vai receber?	4. Have you ever tried to change the type of treatment that you are receiving or will receive?	4. Você já tentou mudar o tipo de tratamento que você está recebendo ou vai receber?
5. How often do you forget to take a dose of your prescribed oral (taken by mouth) medicines? If you have forgotten to take a dose(s), can you give a reason(s) for this	5. Com que frequência você se esquece de tomar uma dose de seu medicamento oral prescrito? (ingerido pela boca) Se você se esqueceu de tomar uma dose (s) do seu medicamento pode dizer o por quê?	5. How often do you forget to take your prescribed oral medication? (taken by mouth) If you have missed a dose (s) of your medication, why?	5. Com que frequência você se esquece de tomar uma dose de seu medicamento oral prescrito? (ingerido pela boca) Se você se esqueceu de tomar uma dose (s) do seu medicamento pode dizer o por quê?
6. Do you ever take your oral drugs at the wrong time?	6. Alguma vez você já tomou seus medicamentos orais na hora errada?	6. Have you ever taken your prescribed oral medications at the wrong time? If yes. How often?	6. Alguma vez você já tomou seus medicamentos orais na hora errada?
7. Have you ever taken the wrong dose?	7. Você já tomou a dosagem errada?	7. Have you ever taken the wrong dosage? If yes. How often?	7. Você já tomou a dosagem errada?
8. When you feel well, do you ever stop taking your oral prescribed drugs?	8. Quando se sente bem, alguma vez já parou de tomar seu medicamento oral prescrito?	8. When you feel good, have you ever stopped taking your prescribed oral medication?	8. Quando se sente bem, alguma vez já parou de tomar seu medicamento oral prescrito?
9. When you feel worse, do you ever stop taking your medicines?	9. Quando se sente pior, já parou de tomar seus medicamentos?	9. When you feel worse, have you ever stopped taking your prescribed oral medication?	9. Quando se sente pior, já parou de tomar seus medicamentos?
10. Are you the one responsible for making sure you take your prescribed tablets/medicines? If NO, who is responsible?	10. Você é o único responsável por certificar-se de tomar os comprimidos/medicamentos prescritos? Se não, quem é o responsável?	10. Are you solely responsible for making sure you take your medication? (prescribed and injection) If not, who is responsible?	10. Você é o único responsável por certificar-se de tomar os comprimidos/medicamentos prescritos? Se não, quem é o responsável?
11. Have you ever missed any out-patient appointments?	11. Você já perdeu uma consulta ambulatorial?	11. Have you ever missed any outpatient appointment (treatment, exams and consultations)? If yes, how often?	11. Você já perdeu uma consulta ambulatorial?
12. Have you ever missed any in-patient admissions?	12. Você já perdeu alguma admissão hospitalar?	12. Have you ever missed any inpatient appointments (treatment, examinatiobs and consultations)? If yes, how often?	12. Você já perdeu alguma admissão hospitalar?

Table 1. Contd.

13. Have you ever refused help at home from any of the following people - District Nurse, GP, Liaison Nurse? If you have ever refused help at home from these people, can you give a reason for this	13. Alguma vez você já recusou a ajuda em domicilio de algum desses profissionais – Enfermeiro ou Medico? Se você já se recusou a receber a ajuda de alguns desses profissionais, você poderia dar uma razão para isso?	13. Have you ever refused medical care at your home from any of these medical professionals - Nurse or Doctor? If you have refused to receive help from these professionals, could you please give a reason(s) why?	13. Alguma vez você já recusou a ajuda em domicilio de algum desses profissionais – Enfermeiro ou Medico? Se você já se recusou a receber a ajuda de alguns desses profissionais, você poderia dar uma razão para isso?
14. Since diagnosis have you ever failed to seek medical help for: a temperature, diarrhea, bleeding, If you have answered YES to any part of Question 14, how long is the longest period of time before you have got medical help?	14. Desde o diagnóstico você já teve dificuldades ao procurar ajuda médica quando você teve febre, diarreia, sangramento. Se você respondeu sim para qualquer parte da pergunta 14, quanto tempo demorou para você consegui ajuda medica?	14. Since your medical diagnosis, have you ever had difficulties in finding medical attention when you had: If you answered yes to any part of this question, how long did it take you to get medical attention?	14. Desde o diagnóstico você já teve dificuldades ao procurar ajuda médica quando você teve febre, diarreia, sangramento. Se você respondeu sim para qualquer parte da pergunta 14, quanto tempo demorou para você consegui ajuda medica?
15. Have you ever forgotten to follow your mouth care routine?	15. Você já se esqueceu de seguir sua rotina de cuidados com a boca?	15. Have you ever forgotten to follow your routine for oral health care?	15. Você já se esqueceu de seguir sua rotina de cuidados com a boca?
16. Have you ever forgotten to care for your central line?	16. Você já se esqueceu de cuidar de seu acesso central?	16. Have you ever forgotten to take care of your central line? If yes, how often?	16. Você já se esqueceu de cuidar de seu acesso central?
17. Since diagnosis have you ever refused a medical examination?	17. Desde o diagnóstico você já se recusou a fazer um exame médico?	17. Since your diagnosis, have you ever refused to do any medical examination?	17. Desde o diagnóstico você já se recusou a fazer um exame médico?
18. Do you feel you have been adequately supported in dealing with your treatment? If yes, by whom? mother, father, siblings, friend, partner, doctors, nurses, psychologists, other (please state)	18. Você sente que foi apoiado de forma adequada ao lidar com seu tratamento? Se sim, por quem? Mãe, Pai, Irmãos, Amigo, Parceiro, Médicos, Enfermeiros, Psicólogos ou Outros (por favor, indique)	18. Do you feel that you have received adequate support to deal with your treatment? If yes, from whom? Mother, Father, Brother, Friend, Partner, Doctors, Nurses, Psychologists and/or others (please specify)	18. Você sente que foi apoiado de forma adequada ao lidar com seu tratamento? Se sim, por quem? Mãe, Pai, Irmãos, Amigo, Parceiro, Médicos, Enfermeiros, Psicólogos ou Outros (por favor, indique)
19. Please feel free to comment upon any other aspects of the cancer treatment you have found particularly demanding.	19. Por favor sinta-se a vontade para comentar sobre qualquer outro aspecto do tratamento de câncer que você considerou particularmente exigente?	19. Please feel free to comment on any aspect of your cancer treatment that you have found particularly challenging:	19. Por favor sinta-se a vontade para comentar sobre qualquer outro aspecto do tratamento de câncer que você considerou particularmente exigente?

*Questions 1, 2, 10, 14 and 18 are dichotomous, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 15, 16, 17 are structured through the Likert scale and the question 19 is an essay question.

of patients who did not think of stopping had a statistically significant difference (Mann-Whitney = 19.97, p = 0.04). This demonstrates that patients who thought about quitting the treatment are more likely not to comply with it.

The average scores of the patients who had diarrhea were statistically higher than those patients who did not have (Mann-Whitney = 10.48, p = 0.001). This was also observed by other authors (Kondryn et al., 2009). But when we evaluated the scores of people who had bleeding or fever with the scores of people who did not have bleeding or fever, there was no significant difference. This data show that adverse effects are an obstacle to the continuity of the treatment, as also found by daCosta et al., (2014). Therefore, knowledge of the patients about possible adverse events improves compliance as already reported in the literature (Flores and Mengue, 2005).

Ingestion of 5 or more medicaments is characterized as polypharmacy. Polypharmacy was defined in the literature as one of the factors that negatively influence performance; although not found in a similar study, because they have different populations (Lessa, 1998; Flowers and Mengue, 2005; Kondryn et al., 2009).

Conclusion

It is concluded that the translation and cultural adaptation

of the "Cancer Patient Self-Report Non-Adherence Questionnaire" was well accepted and understood by the targeted audience. There is a low level of compliance with drug therapy and a good level of compliance with treatment. Therefore, it is necessary to further research on identifying the factors that lead to non-compliance with drug therapy.

Conflict of interest

The authors have not declared any conflict of interest

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