

**XXVII CICLO** - Anno Accademico 2015/2016

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**Titolo tesi:** Adherence to oral endocrine therapy in women with breast cancer

### **ABSTRACT**

Survival rates for this kind of cancer have increased thanks to early diagnosis, as well as to improvements in innovative treatment. The treatment strategies that are available today consist in loco-regional (surgery and radiotherapy) and general treatment (chemotherapy, endocrine therapy and monoclonal antibodies) (Badwe et al, 2015).

Adjuvant therapy with AI and TAM is the main treatment for women with hormone-receptor-positive breast cancer. Treatment involves taking medication for a period of at least 5-10 years, but women have difficulty in continuing to adhere to this regimen for such a long period (Burstein et al, 2014).

The Management Board, however, requires patient adherence to take therapy drugs at home. Like for any chronic treatment regimen, the literature has emphasized how adherence has become a significant problem, interfering with the disease prognosis. In fact, within the first 4 years of treatment, about 20% of patients discontinue taking oral therapy (Chlebowski & Geller, 2007). The main factors that influence patient therapeutic adherence were classified as: "patient-related factors (perceptions about the drug), treatment-related factors (side effects), disease-related factors (comorbidities), health system factors (follow up, conflicting information) and social and economic factors (age, additional costs) (Mathes et al, 2014). Furthermore, even psychological factors (anxiety and depression), the quality of information received, the patient's beliefs, and especially distress may contribute to non-adherence.

A strong emphasis is placed in the literature on the need to differentiate adherence from compliance. Adherence is based on a therapeutic alliance, and requires more patient agreement on a shared plan of care than compliance is based on a paternalistic approach by health professionals (WHO, 2003).

Adherence is however a complex and multi-factorial phenomenon closely linked to cultural and motivational aspects (Haynes et al, 2005), so it can be investigated both through qualitative and quantitative studies.

Quantitative studies allow to identify objective measures and help plan medical care for the patient with objectivity while qualitative studies explore the broader range of experience of the subject providing an in-depth analysis. In order to provide a better understanding for nurses a literature review was carried out regarding the predictors of non-adherence, side effects and interventions that can be implemented to promote adherence to treatment.

The literature on adherence to endocrine therapy in women with breast cancer, is in fact extensive and mostly characterized by quantitative studies, while studies in Italy are unknown. Since adherence has a greater impact on the population's health compared to what any possible specific therapeutic improvement may have, it would be useful to investigate this phenomenon in oncology in the Italian population. For this reason, our aim is to explore the experiences of patients and measure adherence and distress levels to endocrine therapy in Italian women with breast cancer with a quantitative and qualitative studies, respectively. The idea was to highlight non-adherence to treatment also in Italian women.

The quantitative studies were conducted on a sample of 151 cancer patients. Adherence was measured by the 8 item Morisky questionnaire, extensively tested on its psychometric properties (Chronbach's alpha = 0.83). Distress was instead measured by the Distress Thermometer (sensitivity = 0.73, specificity = 0.82) and a list of 34 issues grouped

into five categories (practical, relational, emotional, spiritual and physical issues). Counter pills were used as objective measurement of adherence.

Data showed an adhesion layer in the media and a medium-low level of distress. The qualitative study was conducted on 27 patients with the aim of exploring the experience of adhesion in women during treatment with endocrine therapy. The study used a qualitative exploratory design by adopting Richie and Spencer's contextual approach. The women were interviewed individually, and the study generated seven themes: the different faces of adherence, fear of the drugs, adherence stimulates the balance of experiencing illness, adherence influences the future of disease, adherence requires paying attention to the person, information seeking, and forgetfulness activates the search for functional strategies. The results show that adherence assumes different connotations that are mainly influenced by the type of relationship established with health professionals, the attention paid to the person, the information received and the influence the drug has on the disease history.

The results of both studies were not sufficient alone to understand the trend. It was therefore necessary to combine quantitative and qualitative data in a secondary study: the mixed method. The Mixed-Methods design with an explanatory sequential approach and quantitative priority for data collection and analysis.

This study started out by collecting quantitative data. The second qualitative phase was based on the quantitative one, and the two phases were connected in the intermediate stage of the study.

Data analysis started out by performing a statistical analysis of quantitative data, then the elements of the quantitative results needing further explanation (such as significant and non-significant results, outliers and demographics) were discussed. Finally qualitative analysis of qualitative data was conducted, focusing on those findings which could shed light on the quantitative data needing more explanation. Data demonstrated that patients albeit presenting numerous side effects, lack of information on treatments and a paternalistic doctor-patient relationship, were found to be on average adherent to therapy and with medium-low distress levels.

Nursing implications of the study are aimed primarily at raising awareness among nurses to have a more active role in providing information on endocrine drugs, in order to improve the intake of these and be a point of reference in case of any rising doubt or difficulties in women during the follow-up period.