



Contents lists available at ScienceDirect

## Journal of Cancer Research and Practice

journal homepage: <http://www.journals.elsevier.com/journal-of-cancer-research-and-practice>

## Original article

## The adherence and tolerance of adjuvant endocrine therapy in geriatric breast cancer patients

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## ARTICLE INFO

## Article history:

Received 31 July 2015

Accepted 3 November 2015

Available online 8 June 2016

## Keywords:

Geriatric oncology

Geriatric breast cancer

Hormone therapy

Adjuvant

## ABSTRACT

**Background:** Adherence to and tolerance of oral adjuvant endocrine therapy (ET) are important to improve survival for hormone receptor (HR)-positive breast cancer patients. To date, there has been limited literature discussing this issue in elderly patients. Herein we have presented a retrospective study to analyze the tolerance to and completion rate of ET in a single medical center in Taiwan.

**Patients and methods:** From 1996 to 2009, a total of 269 female patients over 70 years of age with primary HR-positive operable breast cancer were registered and analyzed for this study.

**Results:** In our study, the completion rate was 49.4% for all 269 patients and was 56.7% for those willing to initiate ET. Of the 72 patients that discontinued ET early but not due to recurrence, 9.7% had well-documented ET-related adverse events, 33.3% refused to undergo ET but remained in follow-up, 44.4% did not undergo ET because of loss of follow-up before a complete ET period, and 12.5% of the patients discontinued ET arising from other medical conditions. The switch therapy, tamoxifen followed by aromatase inhibitor, showed a greater completion rate, compared with upfront tamoxifen or aromatase inhibitor.

**Conclusions:** The completion rate for patients who underwent oral ET in our study was similar to previous studies. The switch method of adjuvant oral endocrine therapy demonstrated a better tolerance and adherence in elderly breast cancer patients, compared with tamoxifen or aromatase inhibitor alone.

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## 1. Introduction

Adjuvant oral endocrine therapy (ET) demonstrates significant survival benefits in postmenopausal breast cancer patients with positive hormone receptor (HR).<sup>1–4</sup> However, some of the patients taking either tamoxifen or aromatase inhibitor (AI) experienced ET-related adverse events. For tamoxifen, common adverse events include hot flash, endometrial thickening, vaginal spotting or thromboembolic events.<sup>4–6</sup> For AI, arthralgia and loss of bone density may occur.<sup>1,2</sup> These adverse events may affect patients'

adherence to a daily pill regimen, not to mention further medication intake for the next five years.

Elderly patients, especially those in excess of 70 years of age, are often quite fragile<sup>7</sup>; such fragility may be secondary to aging or comorbidity. In this "susceptible" patient population, the negative influence of ET-adverse events on patient adherence to a medication regimen can be elevated.<sup>8,9</sup> This may occur because the drug toxicities could more significantly impact elderly patients with a declining quality of life, compared with the general population. Therefore, the tolerance of and adherence to adjuvant oral endocrine therapy has become an important issue as we continue to treat this patient population and hopefully improve survival. However, there has been limited literature discussing this topic. Therefore, we retrospectively analyzed the completion of and tolerance to adjuvant oral endocrine therapy in elderly early breast cancer patients in a single medical center in Taiwan.

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Peer review under responsibility of The Chinese Oncology Society.

## 2. Methods and materials

According to the Cancer Registry Databank of Chang Gung Memorial Hospital, Linkuo branch, a total of 444 elderly female patients with primary early breast cancer were treated between 1996 and 2009. These 444 patients were all above 70 years of age and received curative breast surgery at our institute, either modified radical mastectomy or partial mastectomy. Two hundred and sixty-nine of these patients were classified as positive HR, defined by positive estrogen receptor (ER) and/or progesterone receptor (PR).

The pathologic diagnosis of HR-positive primary breast cancer was confirmed by pathologists, based on the customary criteria at that time. Axillary lymph node sampling or dissection could be performed depending upon the surgeon's judgment. Additionally, adjuvant chemotherapy would be recommended if a high risk of recurrence was involved.<sup>10</sup> The choice of chemotherapy regimens, such as modified CMF or anthracycline-based regimens, was also dependent on the decision of each physician. Adjuvant radiotherapy would be suggested if certain factors were present including partial mastectomy, >3 positive lymph node involvement, positive surgical margins, tumor size  $\geq 5$  cm or skin involvement. Oral endocrine therapy was given for patients with HR-positive breast tumors, and the choice of tamoxifen or AI again was based on the decision of the physician. Furthermore, administration of adjuvant treatment, including chemotherapy, radiotherapy and ET, would be discussed with the patients and their families.

We obtained the ages of the patients, the year of diagnosis, TNM stage, status of ER, PR and HER2 and histologic grading from primary chart review. The duration of oral endocrine therapy, causes of discontinuation, and the switches of medications were also recorded. Data was summarized as N (%) for categorical variables, and medians with interquartile ranges (IQR; 25–75%) for continuous characteristics. We used the Chi-square test to compare parameters between different subgroups, and Fisher's exact test for comparisons with small event numbers. Statistic assessments were considered as significance when the *p* value was less than 0.05. SPSS 22.0 software (SPSS Inc., Chicago, USA) was used for statistic analysis.

## 3. Results

A total of 269 female elderly patients over the age of 70 were registered and diagnosed with HR-positive operable primary breast cancer, with a median age of 75 (IQR 72–78). The median follow-up period was 76.4 months. Only 88 patients (32.7%) had no known systemic underlying diseases. One hundred and ninety-four patients (72.1%) had both positive ER and PR, and 55 patients (20.4%) had positive ER but negative PR. There were 21 patients (7.8%) who showed positive PR but negative ER. Other patients' baseline characteristics, including the year of diagnosis, TNM stage, HER2 status and histologic grading, were shown in Table 1.

Adjuvant chemotherapy was completed in 16.7% of the 252 patients with high recurrent risks; thirty-nine (33.3%) patients received adjuvant radiotherapy.

## 4. The completion rate and the time of discontinuation of oral endocrine therapy in elderly patients

One hundred and thirty-three patients took a complete course of oral adjuvant ET. The completion rate of adjuvant oral ET was 49.4% in the intention-to-treat patients in our study, which would increase to 56.7% if only patients willing to initiate ET were taken into account. Neither patients with a larger tumor size (T2–T4), positive lymph node involvement, higher histologic grade (grade 2/

**Table 1**  
Patients' baseline characteristics.

Characteristics (n = 269)	Patient number	Percentage (%)
The year of diagnosis		
1996–2000	48	17.8%
2001–2005	110	40.9%
2006–2009	111	41.3%
Age		
70 ≤ Age < 75	147	54.6%
75 ≤ Age < 80	79	29.4%
80 ≤ Age < 85	29	10.8%
85 ≤ Age	14	5.2%
Comorbidities		
Diabetes mellitus	81	30.1%
Stroke	20	7.4%
Hypertension	135	50.2%
Heart disease*	23	8.6%
No known systemic disease**	88	32.7%
Stage		
I	80	29.7%
II	130	48.3%
III	59	21.9%
Tumor size		
T1m–T1b	23	8.6%
T1c	80	29.7%
T2	143	53.2%
T3 and T4	23	8.6%
Nodal status		
N0	151	56.1%
N1	64	23.8%
N2	28	10.4%
N3	26	9.7%
Status of hormone receptor (HR)		
Positive ER and PR	194	72.1%
Positive ER but negative PR	55	20.4%
Negative ER but positive PR	21	7.8%
Status of human epidermal receptor-2 (HER2)		
Positive HER2	41	15.2%
Negative HER2	201	74.7%
Unknown	27	10.0%
Histologic grade		
1	78	29.0%
2	123	45.7%
3	32	11.9%
Unknown status	36	13.4%

Heart disease\* includes atrial fibrillation, ischemic heart disease or congestive heart failure.

No known systemic disease\*\* means no known diabetes mellitus, stroke, hypertension, heart disease, dementia, liver cirrhosis, chronic lung disease (asthma, chronic obstructive lung disease or bronchiectasis).

3), positive HER2 status, known systemic disease, of younger age, nor a complete adjuvant chemotherapy showed a significantly higher completion rate (*p* = 0.08, 0.46, 0.27, 0.12, 0.50, 0.46, and 0.87, respectively, using the Chi-square test). However, patients with a completed adjuvant radiotherapy presented with a significantly higher rate of a complete ET: 58.8% versus 27.4, *p* = 0.04. Ninety-eight patients (37.4%) had an ET duration of less than 5 years, 64 patients (24.8%) took oral endocrine agents less than two years, and 38 patients (14.1%) never initiated medication at all (Table 2).

Twenty-six of the 98 patients had an early discontinuation due to recurrence: there were 14 patients with distant metastasis and 12 with local recurrence. Most distant metastatic events (71.4%) occurred within the initial two years. Of the other 72 patients with early discontinuation of ET, only seven patients (9.7%) had well-documented ET-related adverse events in the medical records, 24 patients (33.3%) refused to take ET but remained in follow-up, 9 patients (12.5%) were attributed to other medical conditions, and 32 patients (44.4%) were lost in follow-up before a complete ET period (Table 3).

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