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의학석사 학위논문

**The rate of ovarian failure in 12 months
following adjuvant chemotherapy
in breast cancer patients
according to age group**

유방암 환자에서 보조항암화학요법 종료 12개월
후 난소기능부전의 연령대별 빈도에 관한 연구

2016년 2월

서울대학교 대학원

의학과 산부인과 전공

신 재 준

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지도교수 최 영 민

이 논문을 의학석사 학위논문으로 제출함

2016년 2월

서울대학교 대학원

의학과 산부인과 전공

신 재 준

신재준의 의학석사 학위논문을 인준함

2016년 1월

위 원 장 _____ 전 중 관 (인)

부위원장 _____ 최 영 민 (인)

위 원 _____ 임 석 아 (인)

Abstract

The rate of ovarian failure in 12 months following adjuvant chemotherapy in breast cancer patients according to age group

Jae Jun Shin

Obstetrics and Gynecology

The Graduate School

Seoul National University College of Medicine

Introduction: Chemotherapy induced ovarian failure (CIOF) is an unwanted complication following adjuvant chemotherapy. Previous reports on the rate of CIOF in breast cancer patients have been inconsistent among studies, and there was no reliable report on the rate of CIOF according to age group. The purpose of this study was to identify the rate of chemotherapy-induced ovarian failure (CIOF) in breast cancer patients in Korea.

Methods: A retrospective review of medical records was performed on 726 candidates with operable breast cancer that received adjuvant chemotherapy between January 2009 and December 2012. Patients of age 20-44 that had serum follicle stimulating hormone (FSH) reported between 9 and 15

months following completion of chemotherapy were included. Patients that have received gonadotropin-releasing hormone agonist for fertility preservation during chemotherapy were excluded.

Results: A total of 296 patients were included. The overall rate of CIOF was 16.2%. The rate of CIOF in age groups 20-24, 25-29, 30-34, 35-39, and 40-44 were 0% (0/1), 0% (0/8), 3.8% (1/26), 12.9% (13/95), and 20.8% (35/168), respectively. There was a significant increasing trend of CIOF with increasing age ($P = 0.006$). The CMF chemotherapy regimen showed a higher rate of CIOF compared to anthracycline and/or taxane containing chemotherapy regimen, but the difference was statistically not significant (36.4% and 15.4%, respectively, $P = 0.084$).

Conclusion: We report the rate of CIOF in Korean breast cancer patients following adjuvant chemotherapy. The overall rate of CIOF was, 16.2% in women between ages 20 and 44. The rate of CIOF showed a statistically significant trend of increase with increasing age.

Keywords: breast cancer, chemotherapy-induced ovarian failure, follicle stimulating hormone

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I. Introduction

Breast cancer is the second most common malignancy among women in the west, and it is also the most common malignancy in the reproductive age women in the United States (American Cancer Society, 2012). About 25% of new cases of breast cancer occurred in premenopausal women (Jemal, *et al.*, 2007).

Breast cancer is the second most common cancer among women in Korea. According to the year 2011 cancer statistics in Korea, there were 15,942 newly diagnosed cases of breast cancer, which accounted for 14.8 percent of total cancer incidence that year (Jung, *et al.*, 2014).

The age distribution of breast cancer is different from that of the west. The incidence of breast cancer in women younger than 40 is about 15 percent, which is about three times that in the west (GLOBOCAN 2012). The standard treatment for women with early stage breast cancer is chemotherapy, either as a neoadjuvant (prior to surgery) or an adjuvant (following surgery), and they reduce the risk of recurrence and mortality (Gradishar, 2003, Kelly and Hortobagyi, 2010). Five-year survival rate of breast cancer in Korea was as high as 91.3 percent in 2012. Put together, young survivors of breast cancers are increasing in Korea, and the quality of life after treatment became more and more important.

In women before menopause, chemotherapy may adversely affect the ovarian function. The most frequently used surrogate marker of ovarian function is chemotherapy-induced amenorrhea (CIA). However, the definition of this term varies from 3 to 12 months of amenorrhea.

Furthermore, amenorrhea does not always mean permanent ovarian

failure, because there are patients with transient amenorrhea for a long period after chemotherapy. On the other hand, restoration of regular menstruation does not always represent sufficient ovarian reserve. Patients with regular, albeit short menstrual periods may have diminished ovarian reserve (Klein, *et al.*, 1996).

There is no unified definition of chemotherapy-induced ovarian failure (CIOF), and different definitions were used in many papers (Clemons and Simmons, 2007). The national cancer comprehensive network (NCCN) suggested the use of postmenopausal range follicle stimulating hormone (FSH) levels for diagnosis of CIOF in breast cancer patients. Therefore, the assessment of ovarian failure must rely on the value of the FSH.

CIOF may impair fertility, which is a huge part of the quality of life after anticancer treatment. In a survey based study of young early breast cancer patients, 29% of patients responded that infertility concerns influenced treatment decisions (Partridge, *et al.*, 2004). Ovarian damage following chemotherapy may also lead to estrogen deficiency in premenopausal women. Insufficient estrogen may cause hot flashes, excessive sweating, impaired cognitive function, depression, and osteoporosis. Cardiovascular problems are known to occur higher in women whose menopause occurred before the age of 40. The effect of chemotherapy upon the ovaries depend on the type of drug and their combinations, dose, patients' age and their ovarian reserve before chemotherapy (Brydoy, *et al.*, 2007, Chapman, 1982, Lee, *et al.*, 2006, Sonmezer and Oktay, 2006).

In the previous studies that assess the rate of CIOF in breast cancer,

the rate was reported to be between 22-85.2% (Badawy, *et al.*, 2009, Del Mastro, *et al.*, 2011, Moore, *et al.*, 2015, Song, *et al.*, 2013, Tiong, *et al.*, 2014). The wide range in the rate of CIOF depends on different definitions of CIOF, small sample size, difference in ethnicity, difference in chemotherapeutic agents and duration of treatment.

The women within the age of perimenopause range should be excluded from the analysis of CIOF in order to reach a reliable conclusion. It is difficult to differentiate the cause of ovarian failure in ages over 45 years. In that age, some women may have either been menopausal before the initiation of chemotherapy, ovarian failure may occur due to natural aging, or induced by chemotherapy afterwards.

The aim of this study was to investigate the rate of chemotherapy-induced ovarian failure according to age group using the random measurements of FSH in women with breast cancer around 12 months' post chemotherapy, and to search for risk factors for this unwanted complication of chemotherapy.

II. Materials & methods

II-1. Patients and records

A retrospective review of medical records was performed on 726 candidate patients that have been diagnosed with operable breast cancer in Seoul National University Hospital, and received chemotherapy between January 2009 and December 2012. Women of age 20-44 that have agreed to have their serum FSH levels tested between 9 months and 15 months following completion of chemotherapy were included in this study. Any concurrent use of gonadotropin releasing hormone agonists for fertility preservation were excluded. This study was approved by Seoul National University IRB: 1512-091-728

II-2. Data collection and analysis

Information on age, BMI, type of surgery, cell type and pathologic stage of malignancy, hormone receptor status of the tumor, chemotherapy regimen type and duration, and the usage of other adjuvant treatments was collected. As mentioned above, serum FSH values between 9 and 15 months following completion of chemotherapy were collected. CIOF was diagnosed by a serum FSH level above 40 IU/L at a random blood sample. The rate of ovarian failure was calculated both overall, and according to age group.

II-3. Statistical analysis

The Student's t-test was used to compare continuous parametric variables. Pearson's Chi-square test and Fisher's exact test was used to compare proportions between two groups. Pearson's Chi-square test for trend was

used to validate the linear increase of variables. A *P*-value of < 0.05 was considered statistically significant. Statistical analysis was performed using SPSS version 22.0 (SPSS Inc. Chicago, USA).

III. Results

A total of 296 women were eligible for analysis (Figure 1). Overall, the age of the patients was 39.5 ± 3.8 years (mean \pm standard deviation), and the duration of chemotherapy was 138.0 ± 38.4 days.

The basic patient characteristics are shown in Table 1. The majority of patients (90.5%) were diagnosed with invasive ductal carcinoma. Breast conserving surgery was more commonly performed (67.9%) than mastectomy (32.1%). More than half of the patients had stage II disease ($n = 180$, 60.8%), and 78 women (26.4%) had stage I disease. Regarding the receptor status, most of the patients had either estrogen receptor (ER) or progesterone receptor (PR), and 27 patients (9.1%) had triple negative breast cancer.

A majority of patients received chemotherapy that includes anthracycline and/or taxane (96.3%). Only 11 patients received cyclophosphamide, methotrexate, and 5-fluorouracil (CMF) regimen, and was a minority in our study.

The age distribution of the 296 women was not different from that of the 726 candidate patients (Table 2). The overall rate of CIOF was 16.2%, and the rate of CIOF in age groups 20-24, 25-29, 30-34, 35-39, and 40-44 were 0% (0/1), 0% (0/8), 3.8% (1/26), 12.9% (12/93), and 20.8% (35/168), respectively, and a significant pattern of gradual increase with increasing age was found (Table 3).

CMF showed a higher rate of CIOF compared to anthracycline and/or taxane containing chemotherapy regimens, but the difference was not statistically significant (Table 4).

Figure 1. Study flowchart and CONSORT diagram

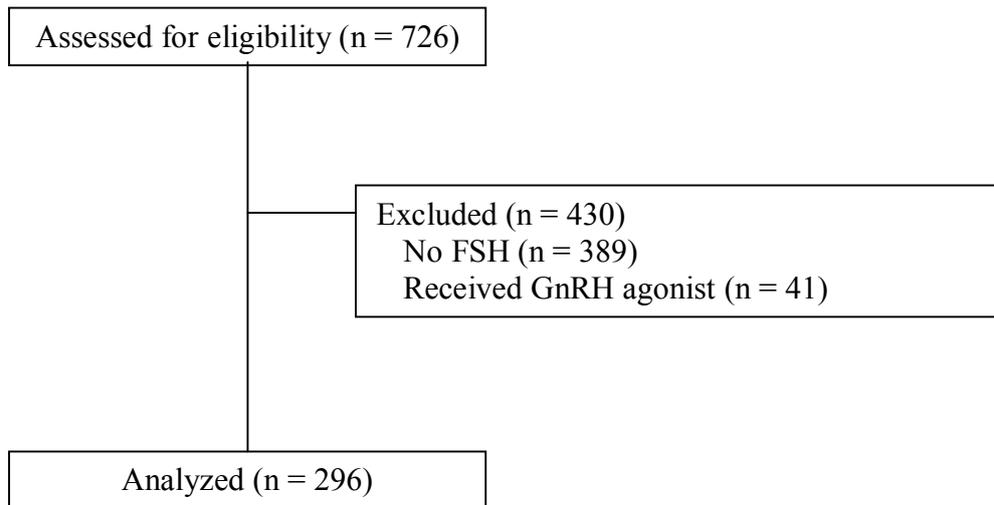


Table 1. Patient Characteristics of breast cancer

	No. of patients (n = 296)	%
Cell type		
Invasive ductal carcinoma (IDC)	268	90.5
Invasive lobular carcinoma (ILC)	7	2.4
Mixed IDC & ILC	7	2.4
Mucinous carcinoma	11	3.7
Others	3	1.0
Type of surgery		
Breast conserving surgery (BCS)	201	67.9
Mastectomy	95	32.1
Breast cancer stage		
IA	78	26.4
IIA	127	42.9
IIB	53	17.9
IIIA	21	7.1
IIIB	3	1.0
IIIC	13	4.4
IV	1	0.3

Receptor status

ER and/or PR + HER2 -	225	76.0
ER and/or PR + HER2 +	27	9.1
ER - PR - HER2 +	13	4.4
ER - PR - HER2 - (triple negative)	27	9.1
Unknown	4	1.3

Adjuvant therapy

Radiation therapy	198	66.9
Tamoxifen	252	85.1
Trastuzumab	30	10.1

Adjuvant and/or neoadjuvant chemotherapy

Anthracycline and/or taxane containing	285	96.3
CMF	11	3.7

CMF: 5-FU + Methotrexate + Cyclophosphamide

Table 2. Age distribution of the 726 candidate patients and the 296 patients that met the eligible criteria

Age group	726 candidates	296 study patients	<i>P</i>
20-24	7 (1.0%)	1 (0.3%)	0.085*
25-29	33 (4.5%)	8 (2.7%)	
30-34	93 (12.8%)	26 (8.8%)	
35-39	238 (32.8%)	93 (31.4%)	
40-44	355 (48.9%)	168 (56.8%)	

*Fisher's exact test

Table 3. The overall and age-group specific chemotherapy-induced ovarian failure (CIOF) rates

Age group	No. of CIOF/total	Rate of CIOF (%)	<i>P</i>
Overall	48/296	16.2	
20-24	0/1	0	0.006*
25-29	0/8	0	
30-34	1/26	3.8	
35-39	12/93	12.9	
40-44	35/168	20.8	

*Chi-square test, test for trend

Table 4. Chemotherapy-induced ovarian failure (CIOF) according to chemotherapy regimen

Chemotherapy regimen	Age (mean \pm SD)	No. of CIOF/total	Rate of CIOF (%)	<i>P</i>
Anthracycline and/or taxane containing	39.5 \pm 3.8	44/241	15.4	0.084*
CMF	39.7 \pm 4.0	4/11	36.4	

SD: standard deviation;

CMF: cyclophosphamide + methotrexate + 5-FU for 6 cycles

*Fisher's exact test

IV. Discussion

This is the first study in Korea to assess the rate of ovarian failure 12 months after completion of chemotherapy in breast cancer patients using serum FSH level. There were numerous reports on the incidence of chemotherapy induced amenorrhea in Korea as well as worldwide. The problem with reporting ovarian failure based on chemotherapy-induced amenorrhea is that the definitions vary from paper to paper, from 3 months to 12 months. Furthermore, the rate of CIOF may be overestimated when using amenorrhea as a surrogate marker, because amenorrhea does not always mean total absence of ovarian function.

To our knowledge, there were several papers that reported the rate CIOF based on serum FSH values (excluding poster presentations). In one report on fertility preservation with gonadotropin-releasing hormone agonist in breast cancer patients, the CIOF rate was 66.6% in the control group (n=39) (Badawy, *et al.*, 2009). This value was thought to be too high for a group of women of age 29.2 ± 2.93 years old (range 18-40 years old) that received FAC chemotherapy regimen (Peccatori and Demeestere, 2009). The definition of CIOF was not mentioned in their original article, but was later stated as a reply to the letter to the editor in the consecutive volume of the journal that it was the absence of previously regular menstruation along with serum FSH > 40 IU/L (Peccatori and Demeestere, 2009). The follow-up period was 8 months after the last dose of chemotherapy, and this may have been too short a period to assess the rate of CIOF.

In another randomized controlled trial on breast cancer patients that was published in 2011, the rate of CIOF was estimated to be 25.9% among

133 control patients (Del Mastro, *et al.*, 2011). The definition of CIOF was no resumption of menstrual activity and postmenopausal levels of follicle-stimulating hormone and estradiol 1 year after the last cycle of chemotherapy, but the postmenopausal level was not signified. The median age of participants in this study was 39, and the age range was 25-45. Considering the age range, this also may be higher than expected from our study.

In a randomized controlled trial performed in China, the rate of CIOF was 28.7% in the chemotherapy only group of patients with breast cancer (Song, *et al.*, 2013). There were 94 patients in the chemotherapy only group, and the age was 42.1 ± 5.9 years (range 26-44). The value reported in this study is also higher than expected in our study. In that age group, 141 patients were included in our study, granting us more statistical power. As mentioned in the introduction, the age distribution of breast cancer women in Korea is different from that of the western countries. The ethnic difference may have contributed to this difference in the rate of CIOF between that study and ours.

According to the study by Tiong *et al.*, the rate of CIOF was reported to be 57% < 35 years, 95% at 35-45 years, and 97.9% > 50 years (Tiong, *et al.*, 2014). The rate of CIOF in patients aged 22-45 years was 85.2% (46/54) when calculated based on their data. This rate is considered too high, and moreover, the rate was higher than the rate of reversible amenorrhea which was also reported in the paper. The high rate of ovarian failure is due to lower cutoff value of FSH for the definition ovarian failure. They defined it as $FSH > 25.8$ IU/L. We used a cutoff value for FSH of 40 IU/L, which is used for the definition of menopause by the NCCN. Also, the

study was a mixed prospective and retrospective study, and the prospective arm was a small group. Only 33 patients were in the prospective arm where FSH levels were available, and the number of patients would be insufficient for deriving CIOF rates for each age group.

In the most recent study of a phase III trial of goserelin for ovarian protection, the rate of CIOF in the chemotherapy only group was 22% (Moore, *et al.*, 2015). The ovarian function was assessed 2 years after the completion of chemotherapy, and the total number of patients in the chemotherapy only group that had serum FSH measured was only 69. The age distribution of these 69 women was not shown in that study. The small sample size and the difference in the timing of assessment makes it difficult to directly compare with the rate of CIOF in our study. There may be a possibility that the women that had their serum FSH measured may consist of elderly women.

A study by Demeestere *et al.*, is worth mentioning although the subjects were not breast cancer patients. The subjects were 84 women with either Hodgkin or non-Hodgkin lymphoma, and they had serial FSH levels measured during the first year following chemotherapy. The FSH values tend to increase till the 6th month following chemotherapy, but was found to decrease thereafter (Demeestere, *et al.*, 2013). This data shows that measuring FSH too early may mislead us to a conclusion of higher rate of CIOF. In our opinion, FSH should be measured at 1 year following chemotherapy, and the rate of CIOF should be assessed accordingly.

The rate of ovarian failure is easily anticipated to be increased with aging, but the actual rate has not been reported till now. This is thought to be due to the inadequate number of participants in the previous studies. In our

study, in order to achieve a sufficient number of patients to deduce the rate of CIOF in each age groups, review of medical records was performed on 726 candidate patients.

The low rate of CIOF in young patients in our study may be questioned. In the cohort of 726 patients, young patients were relatively few. There were only nine patients that were aged ≤ 29 , none of which suffered from CIOF. For further evaluation, another source of patients was used. From a list of 206 women with age below 30 that underwent surgery for breast cancer, 11 women were found to have serum FSH measured, and did not receive GnRH agonist therapy for fertility preservation. Among the 11 patients, only one women had CIOF. This implies that although the rate of CIOF may be very low in women aged < 30 , but it may not be zero.

CIOF has been reported to be influenced by the chemotherapy regimen used. The risk of permanent amenorrhea was well summarized in the ASCO recommendations on fertility preservation (Lee, *et al.*, 2006). In our study, the rate of CIOF in patients that received CMF was as high as 36.4%, but the number of patients that received CMF was too small (11 patients) to show a statistical difference.

There were some limitations in our study. This was a retrospective review study of patients that have been diagnosed with breast cancer. Detailed information concerning menstruation or other gynecologic history were generally unavailable unless the patients were consulted to the gynecology clinic for evaluation, and could not be introduced in this study.

V. Conclusion

We report the rate of CIOF in Korean women with breast cancer. The overall rate of CIOF is estimated to be 16.4% in Korean women with breast cancer between ages 20 and 44. The rate of CIOF in age groups 20-24, 25-29, 30-34, 35-39, and 40-44 were 0%, 0%, 3.8%, 13.7%, and 20.8%, respectively. The rate of CIOF showed a steady increase with increasing age.

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국문 초록

목적: 유방암 환자에서 보조항암화학요법 종료 12개월 후 난소기능부전의 전체 빈도 및 연령대별 빈도를 파악하고자 하였다.

방법: 서울대학교병원에서 2009년 1월부터 2012년 12월까지 유방암으로 진단 받고 보조항암화학요법을 시행 받은 20세 이상 44세 이하의 환자를 대상으로 후향적 의무기록 조사를 통해 난소기능부전의 발생 빈도를 알아보았다. 난포자극호르몬의 수치를 기준으로 40 IU/L 이상인 경우 난소기능부전으로 정의하였다. 5년 간격으로 대상 환자의 연령대를 구분하여 각 연령대별 난소부전의 빈도를 분석하였다.

결과: 전체 726명의 환자에서 난포자극호르몬 검사 결과가 없는 389명 및 가임력 보존 목적으로 성선자극호르몬유리호르몬 효능제를 투약 받은 환자 41명을 제외한 296명을 대상으로 분석을 시행하였다. 난소기능부전이 발생한 여성은 48명으로, 항암제유발 난소기능부전의 전반적인 빈도는 16.2% 였다. 난소기능부전의 연령대별 빈도는 20-24세에서 0%, 25-29세에서 0%, 30-34세에서 3.8%, 35-39세에서 12.9%, 40-44세에서 20.8%였다. 연령대가 증가함에 따라 난소기능부전의 발생 빈도가 증가하는 추세가 관찰되었으며, 이는 통계적으로 유의하였다($P = 0.006$).

결론: 20세 이상 44세 이하의 한국 여성 유방암 환자에서의 항암화학요법 유발 난소기능부전의 빈도는 16.2%이며, 나이가 증가함에 따라 난소부전의 빈도가 유의하게 증가한다.

주요어: 항암화학요법, 난소기능부전, 유방암, 연령대

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