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Brief Communication

Prognostic Factors in Male Breast Cancer: A Retrospective Nationwide Study in South Korea by the Study of SMARTSHIP Group

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ABSTRACT

This study evaluated the incidence, the survival outcomes and its prognostic factors for male breast cancer (MBC) in Korea. Using the National Health Insurance Service database of Korea, we identified MBC patients who had the new claim code of C50. Medical records including type of surgeries and radiotherapy within one year of the first claim and death records were reviewed. Between 2005 and 2016, 838 newly diagnosed MBC patients were included (median follow-up, 1,769 days). The 70–74-year age group had the highest incidence of MBC. The 5-year survival rate was 73.7%. Age > 65 years, low income, no surgical intervention, no tamoxifen use, and > 2 comorbidities correlated with a worse outcome. MBC incidence has increased over time, and its peak is noted at age > 70 years. Age > 65 years, > 2 comorbidities, no surgical intervention, and no tamoxifen use correlate to poor prognosis.

Keywords: Breast Neoplasms, Male; Incidence; Prognosis; Therapeutics

Male breast cancer (MBC) is a rare disease that accounts for less than 1% of all cancers in men and approximately 1% of all breast cancers [1]. In Korea, the age-standardized MBC to female breast cancer (FBC) ratio was reported to be 0.0055:1, and the annual number of MBC cases has steadily increase from 39 in 1999 to 91 in 2016. The age-standardized rate of MBC increased from 0.17 in 1999 to 0.22 in 2016 [2]. MBC patients tend to be diagnosed with advanced-stage disease because of delayed detection due to a low index of suspicion [3,4]. MBC is typically low-grade and shows a higher proportion of hormone receptor–positive tumors [5]. Approximately 95% of all breast cancers diagnosed in men express estrogen receptor (ER) and progesterone receptor [6]. Some studies have shown that MBC

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Conflict of Interest

The authors declare that they have no competing interests.

Author Contributions

Data curation: Lee JS, Yoon J, Lee J; Formal analysis: Lee JS, Yoon J; Investigation: Park S, Lee J; Methodology: Lee JS; Resources: Park S; Supervision: Hur H, Hur SM, Chung IY, Lee JW, Youn HJ, Lim CW; Validation: Hur H, Chung IY, Lee JW, Youn HJ, Oh SJ, Lim CW; Visualization: Oh SJ; Writing - original draft: Park S, Hur H, Lee J; Writing - review & editing: Park S, Hur H, Lee J.

has a poorer prognosis than FBC [1,7], whereas other studies have failed to demonstrate a significant difference [8]. These conflicting results have led to diverse opinions regarding adequate treatment strategies and survival outcomes for those with MBC. The management of MBC is based mainly on the guidelines for FBC [9], despite both having different characteristics. We evaluated the incidence and survival outcomes of MBC using data from the National Health Insurance Service (NHIS) database in Korea. We also studied the treatment outcomes and prognostic factors affecting survival.

We reviewed the NHIS database from 2005 to 2016 and identified patients with the new claims C50 codes from January 1, 2005, to December 31, 2016, with sufficient follow-up period. Patients with fewer than 5 claims for C50 code within 6 months of the first claim were excluded in order to avoid cases that could potentially be coding errors. To review the treatment undertaken for breast cancer, such as surgery, radiation, chemotherapy, or endocrine therapy, we extracted the data for up to one year after the first claim with the C50 code was made. As the C50 code could be assigned to patients with suspected breast cancer in advance of pathologic confirmation, we considered a patient as having breast cancer only when he had a V193 code (given to cancer patients) within 6 months of the first claim with a C50 code. As the insurance claims for taxanes were reimbursed only for node-positive tumors until 2014, we checked taxane prescription records independently during these periods to identify those with advanced-stage disease. In terms of surgery, a patient who had undergone surgery for the removal of a benign breast mass within 3 months prior to the breast cancer diagnosis was also considered to have undergone surgery for breast cancer. We also obtained information about the economic status (below the 20th percentiles of income compared to above the 20th percentile), region (metropolitan, provincial), Charlson comorbidity index (CCI) (0, 1, ≥ 2),and *BRCA1/2* (breast cancer gene) test prescription. CCI was calculated based on the International Classification of Diseases, 10th Revision codes within a year after breast cancer diagnosis to include diseases that might have been ignored until the breast cancer diagnosis.

Statistical analyses were performed using Statistical Analysis System (SAS) version 9.4 (SAS Institute, Cary, USA). To calculate the crude rates of MBC in Korea, we used registered population figures published annually by the Korea National Statistical Office. The Cochran-Armitage trend test was performed to analyze the trend of treatments and the *BRCA* gene-testing rate. Overall survival was calculated from the date of breast cancer diagnosis to the date of death due to any cause or the date of the last follow-up. The last follow-up date was either the date of withdrawal from the NHIS or December 31, 2018. The Kaplan-Meier method and log-rank test were used to draw survival curves and compare survival distributions. The Cox proportional hazards model was used to identify the prognostic factors for survival. All *p*-values were 2-sided, and statistical significance was set at $p < 0.05$. This study was approved by the Institutional Review Board of the Soonchunhyang University, Seoul Hospital (No. 2018-11-002). We obtained data from the NHIS database after de-identification; thus, the requirement for informed consent was waived by the board.

A total of 838 men were newly diagnosed with breast cancer between 2005 and 2016. Information on health insurance status was available for 822 patients. Of these, 6.5% (n = 53) received medical aid due to low income. Patients below 20% of the income distribution included in the medical aid program and national health insurance ranks 1–4 comprised 18.0% of the study population, while 82% constituted ranks 5–20. Most patients had more than 2 comorbidities (n = 660, 78.8%). As can be seen from **Table 1**, 82 (9.8%) patients had no comorbidity (CCI = 0), while 96 (11.5%) had one comorbidity.

Table 1. Patients characteristics

Characteristics	No. (%)
Age at diagnosis	
0–49	136 (16.2)
50–59	194 (23.2)
60–69	223 (26.6)
70–79	213 (25.4)
≥ 80	72 (8.6)
Economic status*	
Below 20 percentiles	148 (18.0)
Above 20 percentiles	674 (82.0)
Residence*	
Metropolitan	382 (45.6)
Provincial	455 (54.4)
Surgery	
No	163 (19.5)
Yes	675 (80.5)
Chemotherapy	
No	367 (43.8)
Yes	471 (56.2)
Radiation therapy	
No	608 (72.6)
Yes	230 (27.4)
Tamoxifen treatment	
No	252 (30.1)
Yes	586 (69.9)
BRCA1/2 test	
No	711 (84.8)
Yes	127 (15.2)
Charlson comorbidity index	
0	82 (9.8)
1	96 (11.5)
≥ 2	660 (78.8)

*Missing values exist.

Less than 100 new cases of MBC have been reported each year. The incidence rate was 0.172 per 100,000 men in 2005, which increased to 0.376 in 2016. The number of new cases and the incidence ratio were comparable to the annual crude incidence and crude incidence rates, listed in the National Central Cancer Registry (NCCR) database (**Supplementary Table 1**). The incidence of MBC was the highest in the age group of 70–74 years, followed by that in those aged 60–64 years and 65–69 years. Comparing the cumulative incidence from the NHIS and NCCR databases between 2005 and 2014, a similar peak of high incidence was noted in the age group of 55–74 years (**Supplementary Figure 1A**). In the NHIS data, dividing the study period into 2 groups, 2005–2010 and 2011–2016, the proportion of elderly patients was higher in the later time period ($p = 0.048$ by χ^2 test, **Supplementary Figure 1B**).

During the observation period, almost 80% of the patients underwent breast surgery after diagnosis (**Supplementary Table 2**). More than 50% of the patients received chemotherapy. Approximately 68.3% of the patients received tamoxifen. Trastuzumab was administered to 8.8% of the patients between 2008 and 2016. There was no significant difference in the proportion of patients who underwent surgery or received radiation or chemotherapy during the study period (p-values for trend were 0.556, 0.453, and 0.346, respectively). Until the end of 2013, the insurance claims for taxanes were only reimbursed in a metastatic setting or in lymph node-positive patients, and the prescription rate of taxanes had not changed over time ($p = 0.536$, shown in **Supplementary Figure 2**). The prescription rate of the *BRCA1/2* gene mutation test also increased significantly during the study period ($p < 0.001$). Approximately

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15.2% of the total patients underwent genetic tests (**Supplementary Table 3**), and most of these patients (n = 103, 81.1%) underwent testing within one year after the diagnosis (**Supplementary Table 4**).

A total of 268 deaths were observed during the median follow-up period of 5 years (median follow-up, 1,769 days; range, 32–5,036 days). The survival probabilities are shown in **Figure 1**. More than half of the men with breast cancer survived for at least 5 years, with a survival probability of 0.737. Four years after diagnosis, the event probability was more than 0.2, and it was maintained at less than 0.5 until 13 years of the available observation period.

The factors related to overall survival are shown in **Table 2**. Men older than 65 years had worse overall survival than those younger than 65 years (hazard ratio [HR], 2.454; 95% confidence interval [CI], 1.909–3.154; $p < 0.001$). Patients with more than 2 coexisting comorbidities also had a poor prognosis. Low income, no surgical treatment, and not receiving chemotherapy were all associated with a probability of decreased survival. Residence status was not correlated with survival. The relationship between the use of taxanes within one year after diagnosis and the prognosis was also not statistically significant. On multivariate analysis, the most significant factor associated with a poor prognosis was the presence of greater than 2 comorbidities (HR, 4.439; 95% CI, 2.084–9.453; $p = 0.001$). The other independent predictors of survival were age over 65 years, low income, no history of surgery, and no tamoxifen use. As can be seen in **Figure 1**, patients were stratified by age as follows: ≤ 49, 50–59, 60–69, 70–79, and ≥ 80 years. The prognosis of the subgroup aged ≥ 80 years was worse than that of the subgroup aged ≤ 49 years (HR, 7.458; 95% CI, 4.489–12.389; $p < 0.001$ by univariate analysis).

Table 2. Factors associated with overall survival

Characteristics	Univariate analysis			Multivariate analysis	
	HR (95% CI)	*p*-value	*p*-value*	HR (95% CI)	*p*-value
Age			< 0.001		
< 65	Ref.			Ref.	
≥ 65	2.454 (1.909–3.154)	< 0.001		2.054 (1.582–2.665)	< 0.001
CCI			< 0.001		
0	Ref.			Ref.	
1	2.228 (0.917–5.417)	0.077		2.265 (0.931–5.511)	0.072
≥ 2	5.929 (2.796–12.573)	< 0.001		4.439 (2.084–9.453)	0.001
Residence			0.427		
Metropolitan	Ref.			Ref.	
Provincial	1.102 (0.866–1.403)	0.429		1.155 (0.906–1.473)	0.244
Income			0.001		
≥ 20 percentiles	Ref.			Ref.	
< 20 percentiles	1.601 (1.203–2.132)	0.001		1.479 (1.108–1.973)	0.008
Surgery			< 0.001		
Yes	Ref.			Ref.	
No	5.902 (4.603–7.568)	< 0.001		4.008 (3.017–5.324)	< 0.001
Chemotherapy			0.031		
Yes	Ref.			Ref.	
No	1.300 (1.023–1.652)	0.032		0.951 (0.740–1.223)	0.697
Tamoxifen			< 0.001		
Yes	Ref.			Ref.	
No	2.679 (2.107–3.406)	< 0.001		1.588 (1.215–2.077)	< 0.001
Taxane†			0.978		
Yes	Ref.			NA	NA
No	1.004 (0.744–1.355)	0.978		NA	NA

CCI = Charlson comorbidity index; HR = hazard ratio; CI = confidence interval; NA = not available.
*The *p*-value by log-rank test; †Taxane prescriptions after 2013.12.31 were not included.

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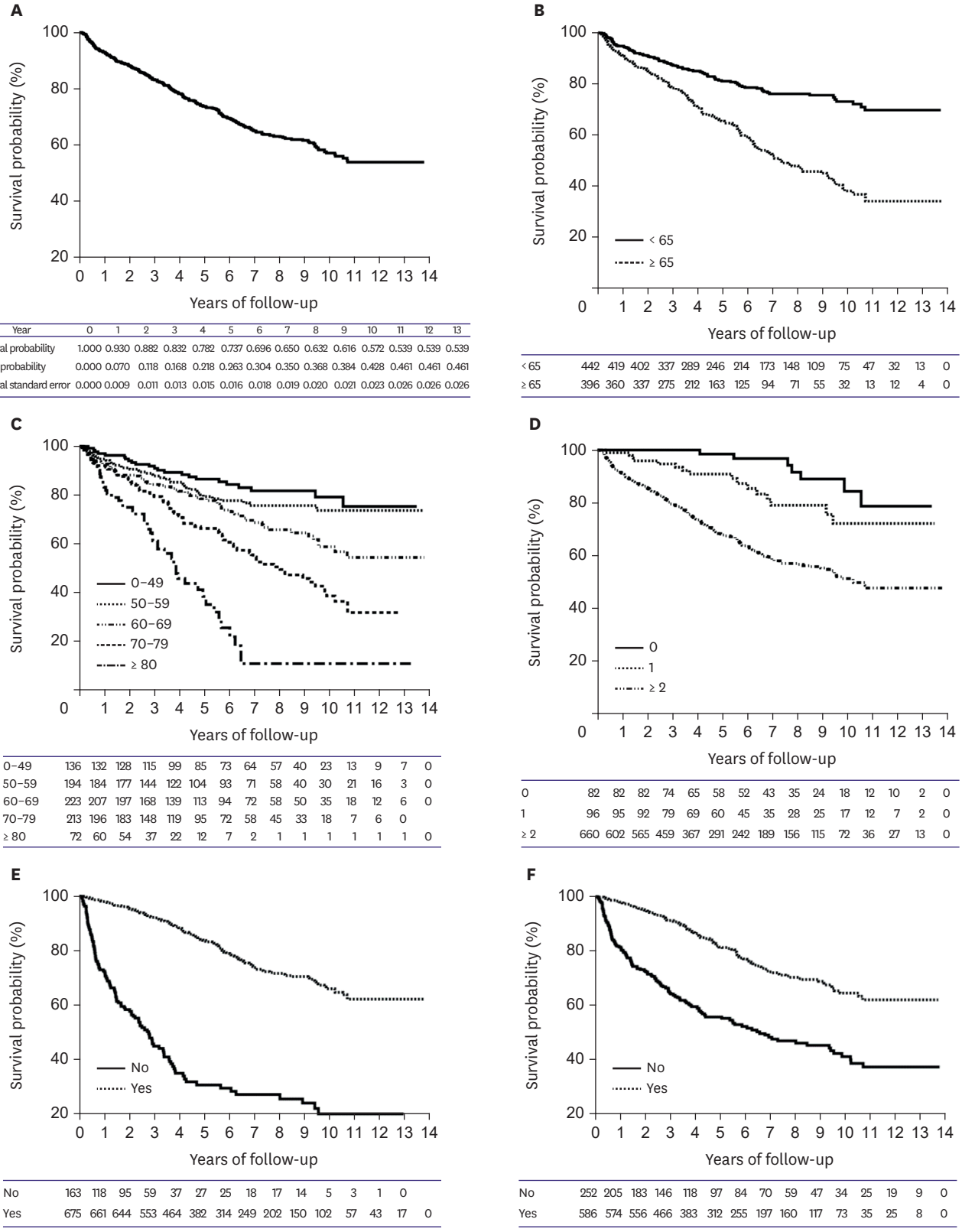

Year	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Survival probability	1.000	0.930	0.882	0.832	0.782	0.737	0.696	0.650	0.632	0.616	0.572	0.539	0.539	0.539
Event probability	0.000	0.070	0.118	0.168	0.218	0.263	0.304	0.350	0.368	0.384	0.428	0.461	0.461	0.461
Survival standard error	0.000	0.009	0.011	0.013	0.015	0.016	0.018	0.019	0.020	0.021	0.023	0.026	0.026	0.026

< 65	442	419	402	337	289	246	214	173	148	109	75	47	32	13	0
≥ 65	396	360	337	275	212	163	125	94	71	55	32	13	12	4	0

0–49	136	132	128	115	99	85	73	64	57	40	23	13	9	7	0
50–59	194	184	177	144	122	104	93	71	58	40	30	21	16	3	0
60–69	223	207	197	168	139	113	94	72	58	50	35	18	12	6	0
70–79	213	196	183	148	119	95	72	58	45	33	18	7	6	0	
≥ 80	72	60	54	37	22	12	7	2	1	1	1	1	1	1	0

0	82	82	82	74	65	58	52	43	35	24	18	12	10	2	0
1	96	95	92	79	69	60	45	35	28	25	17	12	7	2	0
≥ 2	660	602	565	459	367	291	242	189	156	115	72	36	27	13	0

No	163	118	95	59	37	27	25	18	17	14	5	3	1	0	
Yes	675	661	644	553	464	382	314	249	202	150	102	57	43	17	0

No	252	205	183	146	118	97	84	70	59	47	34	25	19	9	0
Yes	586	574	556	466	383	312	255	197	160	117	73	35	25	8	0

Figure 1. Survival probability based on subgroups. (A) Overall survival probability. Survival probability based on subgroups: (B) survival probability in those aged younger than 65 years compared to that in those aged 65 years or older; (C) age subgroups (age 49 years or under; age 50–59; age 60–69; age 70–79; age 80 years or over), subgroups by (D) Charlson comorbidity index, (E) surgery, and (F) tamoxifen prescription.

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In this study, 56.2% (471/838) of the patients received chemotherapy, which is comparable to that seen in previous reports [2]. Tamoxifen was administered to 68.3% of the patients in this study. Previous studies have reported the use of adjuvant endocrine therapy in 76.8% and 79.3% of patients [10,11]. Considering that ER was highly positive in > 90% of cases [10], there is a possibility of a lower ER-positive rate in the Korean MBC population or lower tamoxifen adherence. No tamoxifen use within one year was related with a worse prognosis.

Patients older than 65 years showed poorer survival compared to that in younger age groups. Notably, men older than 80 years had the worst prognosis. The 5-year survival probability of the entire study cohort was 0.737. Previous studies have reported that for stage I to III disease, men have poorer survival than women [9]. However, at more advanced stages of the disease, an older age at diagnosis and a shorter life expectancy may explain this difference [12,13]. Ioka et al. [14] evaluated this sex-related difference in a population-based study in Japan. They reported that the difference disappeared with the increased survival of males during the 1990s. A recent study reported the best survival in men diagnosed at the age of < 40 years, whereas women diagnosed at ages < 40 years showed only moderate survival outcomes in Korea [15].

Consistent with previous studies [16,17], patients with more than 2 comorbidities, low income, no surgical treatment, and not receiving chemotherapy had a worse prognosis. This study showed that men with more than 2 comorbidities had significantly poorer prognoses (**Figure 1D**). Another recent study suggested that a high burden of comorbid conditions could negatively influence both disease-free survival and overall survival in patients with breast cancer [18].

In the present study, 15.2% of patients underwent genetic testing for *BRCA1/2* mutations, and most of them (81.1%) underwent the test within one year of diagnosis (**Supplementary Table 4**). Men carrying a *BRCA1/2* mutation have a greater risk of cancer susceptibility. Several studies have reported that among MBC patients with no family history of the disease, 4%–14% tested positive for a germline *BRCA2* mutation [19,20]. For men with *BRCA2* mutations, the cumulative lifetime risk of breast cancer has been estimated at 7%–8%, and it is therefore important to test for *BRCA1/2* mutations in men with breast cancer. The prescription rate of 15% for the test seems to be relatively low considering that men with MBC have a higher probability of *BRCA1/2* mutation. However, in this study, we noted a statistically significant increase in the prescription rate of *BRCA1/2* mutation testing over time ($p < 0.001$).

To the best of our knowledge, this is one of the largest population-based studies on MBC to evaluate factors related to survival in Korea. A unique feature of this study is the use of the largest dataset to date that includes the prescription rate of *BRCA1/2* gene mutation testing and the trend in mutation testing. However, this study had several limitations. First, we indirectly assumed hormone receptor status or cancer stage using data from adjuvant treatment claims. Second, we did not have information regarding the surgical procedures performed. Third, we could not ascertain the patient's smoking and drinking status, history of medication use, and social characteristics (such as occupation from the NHIS database, which could be a limitation as the patients' epidemiological characteristics were not considered. Lastly, information regarding family history and results of *BRCA1/2* mutation testing were also not available.

In conclusion, the incidence of MBC has increased over time, and the peak incidence of MBC is noted in patients aged > 70 years. Age over 65 years, the presence of more than 2 comorbidities, undertreatment of the tumor (including no surgery), and no tamoxifen use were related to poor prognosis. A more comprehensive analysis of prospective data on the

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biology of MBC is required to develop optimal treatment strategies for MBC with resultant improvement in survival rates.

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This study used data from the Korean National Health Insurance Service (NHIS).

SUPPLEMENTARY MATERIALS

Supplementary Table 1
Annual incidence rate of MBC compared to that in the NCCR database

Click here to view

Supplementary Table 2
Trends of adjuvant treatment of breast cancer within one year from initial diagnosis

Click here to view

Supplementary Table 3
BRCA1/2 genetic testing rate among patients with male breast cancer patients within 5 years from the initial diagnosis

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Supplementary Table 4
BRCA1/2 genetic testing rate among patients with male breast cancer patients based on follow-up periods

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Supplementary Figure 1
(A) Cumulative incidence from NHIS and NCCR database between 2005 and 2014. (B) Comparison of the cumulative incidence between the 2 study periods: 2005–2010 and 2011–2016.

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Supplementary Figure 2
Proportion of taxane prescription.

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