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Community-based Assessment of Adjuvant Hormone Therapy in Women with Breast Cancer, 1991–1997

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Abstract

This study used population-based tumor registry data to describe the patterns of adjuvant hormone therapy and to examine the correlates of hormone therapy for women with breast cancer. The study population included 5101 women (age 20 years) who were diagnosed with breast cancer in 1991 through 1997 in the entire state of New Mexico. Overall, 32% of women with stage I, II, or IIIA breast cancer received adjuvant hormone therapy. The likelihood of receiving adjuvant hormone therapy increased with tumor stage at diagnosis. Women less than 50 years of age were significantly less likely to receive adjuvant hormone therapy compared to those age 50 to 54 years, but there was no significant difference in the use of adjuvant hormone therapy for women age 55 years and older. The use of adjuvant hormone therapy was influenced by hormone receptor status and lymph node status. Patients who received adjuvant chemotherapy were also more likely to receive adjuvant hormone therapy than those who did not. The use of adjuvant hormone therapy alone was relatively stable over time and the use of adjuvant chemotherapy alone increased, but the receipt of chemotherapy combined with hormone therapy decreased from 1991 to 1997. There was no significant difference with age in the use of adjuvant hormone therapy among 55-year-old women compared to those age 50 to 54 years, whereas women less than 50 years of age were significantly less likely to receive this therapy. The use of adjuvant hormone therapy varied significantly by tumor stage, lymph node status, hormone receptor status, and the receipt of adjuvant chemotherapy.

Keywords

adjuvant therapy; breast cancer; chemotherapy; hormone therapy; population-based; women

Adjuvant hormone therapy, of which tamoxifen represents the most commonly used pharmacologic agent, significantly improves survival in women age 50 years and older who have been diagnosed with early stage breast cancer. The conclusion was reached by the Early Breast Cancer Trialists' Collaborative Group in 1988 after a review was concluded of 28 clinical trials (1). This review also showed an unclear benefit of using adjuvant tamoxifen for women with breast cancer who were less than 50 years of age. More recent reviews involving more

clinical trials conducted by this group in 1992 and in 1998 demonstrated that adjuvant hormone therapy substantially improves the 10-year survival of both pre- and post-menopausal women with positive or unknown hormone receptors (2–4). Both the 1990 National Institutes of Health (NIH) consensus statement for the treatment of early stage breast cancer (5) and the 1985 NIH consensus statement on the use of adjuvant chemotherapy for breast cancer (6) recommended that adjuvant tamoxifen be regarded as a standard therapy for postmenopausal women with positive lymph nodes and positive estrogen receptor (ER) status, but not for premenopausal women. NIH did not reconvene the consensus conference until November 2000, at which point the latest statement on the use of adjuvant hormone therapy was issued, recommending that all women with positive hormone receptor status, regardless of age, menopausal status, involvement of axillary lymph nodes, or tumor size, receive this type of treatment (7).

It is not well documented how adjuvant hormonal therapy is used in the community outside clinical trial settings. There have been several reports from hospital-based settings (8–18) and only two population-based studies reporting the patterns of adjuvant hormone therapy in women with breast cancer (8,9). Our study used population-based and statewide data from the New Mexico Tumor Registry to describe the patterns of adjuvant hormone therapy use in women with early stage breast cancer, as well as women with later stages, and to examine the correlates and predictors of hormone therapy for women of all ages who were diagnosed with breast cancer in 1991 through 1997 across the state of New Mexico.

Because NIH issued no further consensus statement on the use of adjuvant hormone therapy for breast cancer between 1990 and 1997, medical oncology practices during our study period probably mainly relied on the consensus statement delivered in 1990 (5). We therefore hypothesized that the use of adjuvant hormone therapy would vary significantly with age in breast cancer patients with positive hormone receptor status. In patients for whom this therapy was not recommended (5,6), that is, those women with negative hormone receptor status regardless of menopausal status, we hypothesized that the use of this therapy would be either minimal or would not vary by age. We focused on a group of patients for whom adjuvant hormone therapy was generally recommended as a standard of care. These subjects included postmenopausal women (age 50 years and older) with positive lymph nodes who did not receive adjuvant chemotherapy, for whom the use of adjuvant hormone therapy was expected to be high compared to those who received adjuvant chemotherapy.

Patients and Methods

Data Source

The New Mexico Tumor Registry (NMTR) is a statewide, population-based tumor registry that was established in 1966; it is one of the seven original members of the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program, which was initiated in 1973 (19). The NMTR collects all incident cases of neoplasm occurring among state residents, and widely dispersed facilities voluntarily cooperate with the tumor registry's case identification efforts. These facilities include acute care hospitals, ambulatory care facilities, private pathology laboratories, radiotherapy facilities, medical oncology clinics, dermatopathology laboratories, physician offices, and nursing homes throughout the area of coverage. New Mexico residents who are diagnosed and treated at facilities outside the state are identified through a data exchange program with surrounding state registries in Colorado, Arizona, Utah, and Texas, and through the New Mexico Bureau of Vital Records and Health Statistics and pathology laboratories and hospitals that operate close to New Mexico's state borders (20).

Study Population

The study population consisted of female patients of all ages who were diagnosed with incident breast cancer during the period from 1991 to 1997 (which is the most recent year of cases available at the time this study was begun). Thus 5101 patients with stage I, II, or IIIA (American Joint Committee on Cancer [AJCC] stage) breast cancer were included in the analysis, since these cases involve patients who are the most likely candidates for adjuvant therapy after surgery.

Hormone Therapy and Chemotherapy

The tumor registry collected information on hormone therapy based on the SEER manual (21). Information on hormone therapy was coded as 0, none ($n = 3435$); 1, hormones, not otherwise specified, including antihormones ($n = 1568$); 2, endocrine surgery and/or endocrine radiation ($n = 5$); 3, a combination of 1 and 2 ($n = 0$); 4–6, not used for coding; 7, patient or patient's guardian refused hormone therapy ($n = 26$); 8, hormone therapy recommended but unknown if administered ($n = 65$); and 9, unknown ($n = 2$). For the current analyses, we recoded 1, 2, 3, 8, and 9 as having received hormone therapy, and 0 and 7 as having not received hormone therapy. The pattern of the results did not change if we recoded 8 and 9 as having not received hormone therapy, or if we excluded the 67 cases in codes 8 and 9 from the analysis.

Similarly information on chemotherapy was coded as follows (21): 0, none ($n = 3574$); 1, chemotherapy, not otherwise specified ($n = 129$); 2, chemotherapy, single agent ($n = 21$); 3, chemotherapy, multiple agents or a combination regimen ($n = 1248$); 4–6, not used for coding; 7, patient or patient's guardian refused chemotherapy ($n = 61$); 8, chemotherapy recommended but unknown if administered ($n = 68$); and 9, unknown ($n = 0$). For the current analyses, we recoded 1, 2, 3, and 8 as having received chemotherapy, and 0 and 7 as having not received chemotherapy. The pattern of the results did not change if we recoded 8 as not receiving chemotherapy, or if we excluded the 77 cases in code 8 from the analysis.

Analyses

The following variables were included and categorized in the bivariate and multivariate analyses: age (<45, 45–49, 50–54, 55–59, 60–64, 65–69, 70–74, ≥ 75 years), tumor stage (I, II, IIIA), lymph node status (positive, negative, or unknown), and hormone receptor status (ER or progesterone receptor [PR] positive, negative, or unknown), chemotherapy (yes or no), and year of diagnosis.

The Mantel-Haenszel chi-squared statistic was used to test for trends in the data. The odds ratios of receiving adjuvant hormone therapy for women with various patient and tumor characteristics were generated from multivariate logistic regression analyses. These analyses adjusted for age, nodal status, hormone receptor status, chemotherapy use, and year of diagnosis, all of which have been determined to likely affect the use of adjuvant hormone therapy in women with breast cancer. All computer programming and analyses were completed using the SAS system (22).

Results

Table 1 presents the age and tumor stage-specific prevalence of women receiving adjuvant hormone therapy. Overall, 32% of women received hormone therapy, and the rates of receiving adjuvant hormone therapy for stage I, II, and IIIA were 28%, 36%, and 40%, respectively. The use of adjuvant hormone therapy was higher in women with stage IIIA breast cancer than in those with lower stages, particularly in women age 65 to 69 years (71%) and in those age 70 to 74 years (86%). The overall use of adjuvant hormone therapy seemed to increase with advancing age ($p < 0.001$). This increasing trend with age was significant for women with stage

II and IIIA breast cancer, but there was no significant increase in adjuvant hormone therapy use in those with stage I cancer.

Table 2 presents the use of adjuvant hormone therapy by patient age, lymph node status, and hormone receptor status in women with stage I, II, or IIIA breast cancer. The use of adjuvant hormone therapy was affected by lymph node status and hormone receptor status. As expected, much higher percentages of patients with hormone receptor-positive tumors received adjuvant hormone therapy. Those with lymph node-positive tumors also tended to have greater use of this therapy. There was a significant increase in the use of adjuvant hormone therapy with age in women with lymph node-positive tumors regardless of hormone receptor status. There was no significant trend of increasing use of adjuvant hormone therapy in cases with node-negative tumors.

We next examined the receipt of adjuvant hormone therapy for a group of women with hormone receptor-positive tumors. This group of women was then divided into two categories: those who received adjuvant chemotherapy, and those who did not receive chemotherapy for whom adjuvant hormone therapy is generally expected. The rate of receiving adjuvant hormone therapy in women who already received adjuvant chemotherapy was even higher than in those who did not receive adjuvant chemotherapy (43.3% versus 38.0% overall, $p < 0.001$), except in patients ≥ 75 years of age, where the rate of adjuvant hormone therapy was slightly higher in those not receiving adjuvant chemotherapy.

Table 3 presents a multivariate logistic regression analysis of the odds of receiving adjuvant hormone therapy, adjusting for lymph node status, hormone receptor status, and chemotherapy use. Compared to women 50 to 54 years of age, women less than 50 years of age were statistically significantly less likely to receive adjuvant hormone therapy. However, none of the five groups of older women (age 55–59 years through ≥ 75 years) was significantly different in the receipt of adjuvant hormone therapy. Table 3 also shows that the receipt of adjuvant hormone therapy was influenced by lymph node status and hormone receptor status. Patients with adjuvant chemotherapy were also more likely to receive adjuvant hormone therapy than those without adjuvant chemotherapy.

Table 4 further examined the receipt of adjuvant chemotherapy and/or hormone therapy by the year of diagnosis. The percentage of women receiving no adjuvant therapy was stable from 1991 to 1997, and the percentage of women receiving adjuvant hormone therapy alone was also relatively stable over this time. However, the number of women receiving adjuvant chemotherapy plus hormone therapy decreased significantly over time, while women receiving adjuvant chemotherapy alone slightly increased.

Discussion

This study has described the patterns of adjuvant hormone therapy use among women with breast cancer according to age, tumor stage, hormone receptor status, lymph node status, adjuvant chemotherapy use, and the year of diagnosis. Overall, 32% of women with stage I, II, or IIIA breast cancer received adjuvant hormone therapy. The likelihood of receiving adjuvant hormone therapy increased with tumor stage at diagnosis. Women less than 50 years of age were significantly less likely to receive adjuvant hormone therapy compared to those age 50 to 54 years, but there was no significant difference in the use of adjuvant hormone therapy for women age 55 years and older. The use of adjuvant hormone therapy was influenced by hormone receptor status and lymph node status. Patients who received adjuvant chemotherapy were also more likely to receive adjuvant hormone therapy than those who did not. The use of adjuvant hormone therapy alone was relatively stable over time, and the use of adjuvant chemotherapy alone increased, but the receipt of chemotherapy combined with

hormone therapy decreased from 1991 to 1997. There was no association found between the use of adjuvant hormone therapy and household income at the census tract level (data not shown).

There is very little population-based information available on the use of hormone therapy. A series of national hospital-based surveys of breast cancer in the United States, organized by the American College of Surgeons, reported a very low rate (less than 10%) of hormone use in women of all ages with breast cancer in the 1970s and 1980s (10–14). The prevalence of tamoxifen use in the 17 community hospitals across the nation in 1982 in women age 65 to 74 years was 44% for regional stage and 54% for distant stage (13). Several local studies of patterns of breast cancer treatments reported percentages of hormone therapy ranging from 15% to 65% in older women (14–18). A recent report from the San Antonio breast cancer databases, which contain 50,828 cases of women with invasive breast cancer, showed that 36% of women age 55 to 64 years received adjuvant hormone therapy, and 38% of women age 65 to 84 years and 36% of those ≥ 85 years of age received this therapy (23). Harlan et al. (8) recently reported from a population-based random sample of the selected SEER areas that overall use of adjuvant hormone therapy in women of all ages with stage I, II, or IIIA breast cancer was 25% in 1987, 38% in 1990, and 47% in 1995. However, Mariotto et al. (9) assessed adjuvant therapy use for breast cancer in the SEER areas from 1975 to 1999 and found a decreasing trend in the use of tamoxifen since 1990.

Age is a strong factor in determining treatment for patients with breast cancer (8,9,13,24,25), particularly in the choice of chemotherapy (26–29). The perception may be that the efficacy of tamoxifen (the most commonly used adjuvant hormone therapy) increases with age, but in fact, about 5 years of tamoxifen treatment showed similar benefit for premenopausal women (1–3). For example, there was a 34% mortality reduction in women ≥ 70 years of age compared to 32% in women less than 50 years of age (3). Our study's finding of no significant age difference for women ≥ 50 years of age in the use of adjuvant hormone therapy might reflect what was shown in previous trials (3). The prevalence of receiving hormone therapy in women age 75 years or older seemed low and different from the rest of the groups age 50 to 74 years. However, analysis of the results without the 75 years or older age group showed similar patterns of hormone therapy use associated with other factors.

Breast-conserving surgery without adjuvant radiotherapy is generally considered inadequate treatment because of the high rate of local recurrence (5), although mastectomy alone versus mastectomy plus radiotherapy was not significantly different in the rates of recurrence and survival, as shown recently in the National Surgical Adjuvant Breast and Bowel Project (30). However, it has been argued that perhaps radiotherapy might be foregone in certain situations after breast-conserving surgery, if hormone therapy (tamoxifen) is given. According to the clinical guideline on adjuvant systemic therapy in women with early stage breast cancer (5, 6), women who receive breast-conserving surgery without radiation therapy should receive some type of adjuvant systemic therapy such as chemotherapy, hormone therapy, or both. However, even women at higher risk (i.e., those with positive lymph nodes and positive hormone receptor tumors who did not receive chemotherapy) tended to not receive adjuvant hormone therapy. This suggests that adjuvant hormone therapy is not merely used as a substitute for adjuvant chemotherapy. However, the underutilization of the therapy observed in community settings is not what can be seen in the clinical trials. Further research may be required to ascertain the reasons for undertreatment of adjuvant hormone therapy and its impact on survival and recurrence in women with early stage breast cancer in the community.

As mentioned in the introduction, the guideline for using adjuvant hormone therapy that clinicians were likely to use during the study period was the one released in the 1990 NIH consensus conference for early stage breast cancer. There is no doubt that the development and

dissemination of clinical guidelines is regarded as a major force in improving quality of care and decreasing variation in medical practices (31–33). However, it has been documented that with increasing time there may be less compliance with previously proposed guidelines (31–33). With limited evidence, postmenopausal women with positive lymph nodes and positive hormone receptors were recommended to receive adjuvant hormone therapy in the 1985 statement (6), but the 1990 guidelines did not make it clear as to which women should receive adjuvant hormone either with or without adjuvant chemotherapy.

Furthermore, during this period an increasing number of patients with early stage breast cancer began to receive breast-conserving surgery followed by adjuvant radiation therapy (24). Breast-conserving surgery plus radiotherapy might have been considered to accomplish a goal similar to that of adjuvant hormone therapy, which may have led to the decreasing number of women receiving adjuvant hormone therapy. Since the early 1990s, several clinical trials have reported information regarding the efficacy of adjuvant hormone therapy (5), but it seems that evidence really becomes convincing in 1998, when a meta-analysis of 55 clinical trials on adjuvant hormone therapy concluded that adjuvant tamoxifen substantially improves the 10-year survival of women with positive or unknown hormone receptors (3). These findings and data from more recent studies provided the foundation for the 2000 NIH consensus statement. This statement made it very clear that all women with positive hormone receptors, regardless of age, menopausal status, involvement of axillary lymph nodes, or tumor size, should be treated with adjuvant hormone therapy (7). However, these findings and recommendations would not have any impact on medical practices during the study period from 1991 to 1997. Nevertheless, it would be reasonable to expect a greater increase in adjuvant hormone therapy since 1998, particularly after the 2000 consensus conference.

It should be kept in mind that the low percentage of adjuvant hormone therapy use could be due in part to underreporting of the information on hormone therapy in the SEER registry. As explained above, information on hormone therapy from the tumor registries may be under-reported, because the SEER registry requires only treatment information that was initiated within 4 months of diagnosis and because this type of therapy was often prescribed in the outpatient oncologist's office, where checking medical records was not required by the SEER registry (9,21). For the initial treatment of adjuvant hormone therapy, the time frame may vary from 4 months after initial primary surgery and chemotherapy to even longer time periods. Therefore it is possible that hormone therapy may have been initiated after this time frame, but not included in the SEER registry (9).

A similar concern regarding underreporting was raised for chemotherapy data found in the SEER registry (9,29,34). For example, more than 71% of women age 65 to 69 years with node-positive and hormone receptor-negative tumors received chemotherapy, versus 4% of women in the same age group with negative nodes and positive hormone receptors (29). Information on hormone therapy might be more likely to be missed by medical records than chemotherapy because chemotherapy is usually administered intravenously, whereas the most commonly used hormone therapy—tamoxifen—is taken orally. External validation (through medical chart reviews or physician and patient interview surveys) may be needed for an accurate estimate of adjuvant hormone therapy in women with breast cancer in the community.

Other study limitations included the unavailability of information on the duration of adjuvant hormone therapy used, no information on the reasons why the therapy was not used, no adjustment for comorbidity, and no information on how hormone replacement therapy was used in this cohort. The pharmacologic databases have not been checked. This study only used data from the NMTR, which is only 1 of 11 SEER areas. The actual use of adjuvant hormone therapy for breast cancer in other SEER areas may vary.

In conclusion, there was no significant difference with age in the use of adjuvant hormone therapy among women age 55 years or older compared to those age 50 to 54 years, whereas women less than 50 years of age were significantly less likely to receive this therapy. The use of adjuvant hormone therapy varied significantly by tumor stage, hormone receptor status, and receipt of adjuvant radiotherapy and chemotherapy.

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Table 1
Use of Adjuvant Hormonal Therapy in Women with Breast Cancer, 1991–1997, by Patient Age and Tumor Stage

Age (years)	Number (%) of women receiving adjuvant hormone therapy			
	Stage I (<i>n</i> = 2692)	Stage II (<i>n</i> = 2235)	Stage IIIA (<i>n</i> = 174)	Total (<i>n</i> = 5101)
<45	56 (19.4)	91 (21.0)	14 (29.2)	770 (20.9)
45–49	64 (28.1)	73 (25.9)	6 (25.0)	534 (26.8)
50–54	88 (31.8)	117 (43.7)	3 (16.7)	563 (36.9)
55–59	94 (31.3)	88 (36.8)	3 (18.8)	555 (33.3)
60–64	106 (33.4)	96 (47.8)	9 (47.4)	537 (39.3)
65–69	107 (29.2)	99 (45.8)	10 (71.4)	596 (36.2)
70–74	123 (32.8)	98 (47.8)	12 (85.7)	594 (39.2)
≥75	125 (23.1)	146 (37.4)	12 (57.1)	952 (29.7)
Total	763 (28.3)	808 (36.2)	69 (39.7)	5101 (32.2)
<i>p</i> -value for trend with age ^a	0.6082	<0.001	<0.001	<0.001

^a Mantel-Haenszel chi-squared test for trend with age groups.

Use of Adjuvant Hormone Therapy in Women with Stage I, II, or IIIA Breast Cancer, 1991–1997, in New Mexico by Age, Lymph Node Positivity, and Hormone Receptor Status

Lymph node and HR status ^a	Percent of women receiving adjuvant hormone therapy, by age (years)								p-value ^b
	No. (%) of cases	<45	45–49	50–54	55–59	60–64	65–69	70–74	≥75
Node-positive, HR positive	1030 (48.2)	32.1	34.6	52.3	48.6	58.9	56.6	64.1	52.9
Node-positive, HR negative	320 (25.3)	16.1	15.4	26.1	22.2	29.6	39.3	58.8	36.0
Node-positive, HR unknown	150 (25.3)	3.9	20.8	33.3	27.3	10.0	61.2	18.2	32.4
Node-negative, HR positive	1959 (36.1)	28.4	32.6	44.3	40.5	42.5	37.6	37.8	27.5
Node-negative, HR negative	490 (15.1)	8.8	18.3	18.4	11.9	20.9	15.2	25.8	15.8
Node-negative, HR unknown	456 (14.0)	9.1	10.8	22.5	6.8	19.6	14.1	16.5	12.4
Lymph node not examined	696 (25.7)	10.6	15.6	18.0	22.5	23.8	27.9	38.4	28.0
Total	5101 (32.2)	20.9	26.8	36.9	33.3	39.3	36.2	39.2	29.7

^aHormone receptor (HR) positive (ER positive or PR positive); hormone receptor negative (ER negative and PR negative); hormone receptor status unknown.

^bMantel-Haenszel chi-squared test for trend with age groups.

Table 3
Multivariate Analysis for the Odds of Receiving Adjuvant Hormone Therapy in Women with Breast Cancer, 1991–1997, in New Mexico

Patient and tumor characteristics, and treatment status	Number of cases (<i>n</i> = 5101)	Percent of women receiving hormone therapy	Odds ratio ^a (95% confidence interval) of receiving hormone therapy
Age (years)			
<45	770	20.9	0.42 (0.32–0.54)
45–49	534	26.8	0.57 (0.43–0.74)
50–54	563	36.9	1 (reference)
55–59	555	33.3	0.86 (0.67–1.11)
60–64	537	39.3	1.14 (0.88–1.47)
65–69	596	36.2	1.06 (0.82–1.36)
70–74	594	39.2	1.25 (0.97–1.62)
>75	952	29.7	0.85 (0.67–1.08)
Node and hormone receptor status ^b			
Node-positive, HR positive	1030	48.2	1.64 (1.38–1.94)
Node-positive, HR negative	320	25.3	0.59 (0.44–0.79)
Node-positive, HR unknown	150	25.3	0.63 (0.43–0.92)
Node negative, HR positive	1959	36.1	1 (reference)
Node negative, HR negative	490	15.1	0.33 (0.25–0.43)
Node negative, HR unknown	456	14.0	0.28 (0.21–0.37)
Lymph node not examined	696	25.7	0.61 (0.50–0.75)
Adjuvant chemotherapy			
No	3702	31.4	1 (reference)
Yes	1398	34.3	1.23 (1.03–1.47)

^a Adjusted for lymph node status, hormone receptor status, and chemotherapy use as listed in the table.

^b Hormone receptor (HR) positive (ER positive or PR positive); hormone receptor negative (ER negative and PR negative); hormone receptor status unknown.

Table 4
Percentage of Women with Breast Cancer Receiving Adjuvant Chemotherapy and Hormone Therapy by the Receipt of Axillary Node Dissection, Radiation Therapy, and Year of Diagnosis

Year of diagnosis	Chemotherapy plus hormone therapy	Chemotherapy alone	Hormone therapy alone	No adjuvant therapy	Number of cases (%)
1991	17.0	13.2	24.9	44.9	666 (100.0)
1992	12.4	17.4	28.8	41.5	709 (100.0)
1993	10.4	20.7	22.5	46.4	644 (100.0)
1994	7.4	22.8	18.6	51.3	721 (100.0)
1995	7.3	20.4	21.6	50.7	779 (100.0)
1996	6.0	18.1	21.2	54.6	811 (100.0)
1997	8.0	21.1	21.0	49.8	771 (100.0)
Total	9.6	19.2	22.6	48.7	5101 (100.0)