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Medication use in breast cancer survivors compared to midlife women

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Abstract

Purpose—Many breast cancer survivors (BCS) take multiple medications for health problems associated with the treated cancer and other non-cancer co-morbidities. However, there is no published, large scale descriptive evaluation of medication use in BCS compared to midlife women. The purpose of this study was (1) To compare the number and types of prescription medications and over-the-counter medications between BCS and midlife women without cancer and (2) to assess possible drug-drug interactions by evaluating the cytochrome P450 isoform properties of medications (inductors and inhibitors) in both groups.

Methods—A cross-sectional, descriptive, comparative design was used. Baseline data from 98 BCS and 138 midlife women without cancer was analyzed from a behavioral intervention trial for menopausal symptoms.

Results—BCS were taking significantly more prescription medications and a larger variety of different types of medication classifications ($p<0.05$) after controlling for group differences (race, non-cancer comorbid conditions, marital status, income and smoking) in demographics. Twenty four women were taking at least one medication considered to be a cytochrome P450 isoforms (CYP) inhibitor or inducer capable of clinical drug-drug interactions with no differences in CYP inhibitors or inducers found between groups.

Conclusion—BCS are taking a vast array of medications during survivorship. It is unclear if prescription medications are managed by a single health care provider or several providers. Clinical implications are to monitor for possible interactions among the various prescription medications, over-the-counter medications, and supplements. Implications for behavioral and biomedical research are that clinical studies need to carefully assess and account for multiple medication uses.

Keywords

breast cancer survivor; medication use; drug interaction; self-management

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Introduction

It has been reported that 67% of breast cancer survivors (BCS) have at least 2 or more non-cancer related co-morbid conditions [1]. Consequently, BCS are taking multiple prescription medications and over-the-counter medications (including dietary and herbal supplements) for their health problems associated with the treated cancer and also associated with non-cancer-related co-morbidities. BCS represent 22% or 2.2 million of the estimated 9.8 million cancer survivors in the United States [2]. Demographic shifts and the aging of the baby boomer generation indicate the number of survivors will continue to grow. Most women who are diagnosed with breast cancer are members of the larger population of midlife women who are also at risk for metabolic syndrome, diabetes, heart disease, and other chronic illnesses. High usage of prescription and over-the-counter medications has ramifications for medication compliance/discontinuation, drug-drug interactions, and pharmacogenetics, all of which can affect the tolerability and efficacy of life-saving endocrine therapies [3–6].

To our knowledge, there are no published, large scale comprehensive descriptions of medication use or drug-drug interactions in BCS compared to midlife women of the same age without cancer. Studies that report medication use are limited to specific types of medications or changes in medication use (e.g., over-the-counter use) during the cancer trajectory. For example, two articles described prescription sleep medication use before, during, and after treatment (n=124, 219) [7, 8]. Both studies found that breast cancer patients increased their use of sleep medications during treatment but that use tapered off post-treatment [7, 8]. However, neither article reported the full range or number of medications being used to manage other non-cancer co-morbid conditions nor describe the full range of possible medications used for sustained adjuvant treatment (e.g., tamoxifen). In addition, two studies reported changes in supplement use in breast cancer survivors and long-term cancer survivors [9, 10]. Both studies reported that 63–74% of patients and survivors took some type of supplement (e.g., multivitamin, fish oils, and minerals) and one study found this use increases after diagnosis [10]. However these studies did not assess use of prescription or over-the-counter medications. One additional study described co-morbid conditions and medication use in 64 BCS with lymphedema compared to non-cancer controls [11]. BCS with lymphedema reported more osteoporotic pain and higher body mass index ($p<.001$) compared to midlife women without cancer. BCS were taking more cardiac medications, hormone blockers, and osteoporosis medication or calcium supplements compared to midlife women [11]. However, this study did not report assess drug-drug interactions. Therefore, the purposes of this study were to (1) compare the number and types of prescription and over-the-counter medications used by BCS and mid-life women and (2) evaluate cytochrome P450 isoform properties (inducers and inhibitors) to determine the extent of possible drug-drug interactions that could be present in both groups.

Methods

The data for this analysis is from baseline data in a three-group randomized clinical trial comparing a behavioral intervention to attention control and no treatment control for menopausal symptoms. Baseline data collection occurred between May, 2009 and February, 2011. Recruitment involved mass mailings to purchased mailing lists of women living in the community and to research registry participants. Women who met inclusion criteria for this study provided informed consent and approval to use health information. They completed a baseline assessment and were then stratified by group and randomized. Only baseline data prior to randomization was used for this study.

Sample Criteria

Inclusion criteria for both groups were: adult females, reporting 2 or more hot flashes per 24-hour day of moderate or greater severity (≥4 using 0 to 10 point numeric rating scale) at initial screening, desirous of hot flash treatments, self-reported peri- or post-menopausal status, in good general physical and mental health, no self-reported breathing difficulties, living within the local metropolitan area, and English literate. All survivors had to be at least 4 weeks post-completion of surgery, radiation, and/or chemotherapy for non-metastatic breast cancer and without a history of other cancers. The menopausal non-cancer group had to have no history of breast or other cancers (exception: basal cell skin carcinoma allowed).

Procedures

Interested women telephoned a research office to be screened by trained staff. Eligible women were mailed a study packet containing a cover letter, two copies of the consent and health information authorization, and a pre-paid envelope. Once the signed consent and authorization were returned to the research office, trained data collectors contacted women by email or phone to arrange a baseline assessment session. Sessions typically lasted 30–45 minutes and were conducted in a private room at the university or in the woman's home. Relevant to this analysis is that trained data collectors measured height and weight and ensured that questionnaires were appropriately completed by participants.

Measures

Demographics, menopausal status, and breast cancer disease and treatment variables were assessed by the study team to describe the sample using an investigator-designed form. Participants answered questions regarding age, race, ethnicity, marital status, employment status, socio-economic status, education, smoking status, menopausal status, medication, and number and type of non-cancer comorbid conditions. In addition, breast cancer disease and treatment information was verified by review of medical records by trained personnel. Collected information included date of diagnosis, stage of disease, and dates and types of treatments including surgery, chemotherapy, radiation, selective estrogen receptor modulators, and aromatase inhibitors [12]. Height and weight were measured by a trained data collector, recorded on a form, and used to calculate body mass index. Height and weight were measured using a portable stadiometer (Harpenden Pocket Stadiometer, Crosswell, UK) and portable scale (UC-321S, A&D Weighing, Milpitas, CA). Breast cancer disease and treatment information was verified by review of medical records by trained personnel.

Current medications were assessed using self-report. Participants listed the name of all current prescription and over-the-counter medications. Each reported medication was coded according to its therapeutic classification (e.g., lipid lowering agents) and as prescription or over-the-counter using standard classifications [13]. Combination medications were listed under the major therapeutic category (e.g., antihypertensive agents). A total of 1245 medications were reported and classified into 77 different therapeutic categories by trained staff. Because of the large number of therapeutic categories represented by the raw data noted, two categories of medication classifications were further truncated by the authors. First, calcium, vitamin D, and bisphosphonates were labeled as osteoporosis prevention. If women reported taking combination calcium plus vitamin D as one supplement, this pill was counted as 1 data entry point. Second, pain medications were truncated into antipyretics included non-steroidal and narcotic analgesics. Other classifications were kept within the reported therapeutic categories.

When single-pill vitamin supplements were reported by women (e.g., vitamin A, C), each consumed pill was given a separate data entry point and labeled as dietary supplements.

Therefore, for this manuscript, dietary supplements reflect the individual types of supplements reported by women. If women reported taking a single multivitamin, this pill was labeled as a single dose multivitamin category. The rationale for this categorization was to capture the vast number of women taking single dose dietary supplements with multivitamins.

Medications were also classified as a substrate or inhibitor of the major Cytochrome P450 isoforms based on the Cytochrome P450 Drug Interaction Table [4, 14]. The table contains lists of medications that are inducers or inhibitors of cytochrome P450 isoforms (CYP1A2, 2C8, 2C9, 2C19, 2D6, 3A4, 3A5, and 3A7). A medication appears in the table if there is published clinical evidence that it induces or inhibits the activity of a specific enzyme and is further categorized into strong, moderate, weak or unknown in terms of its potential for inhibiting on inducing the enzyme activity.

Statistical analysis

Baseline characteristics were reported and compared between the two groups, breast cancer survivors and midlife women. Mean values and standard deviations were calculated for continuous variables and frequencies and percentages for categorical variables. Both t-tests and chi-square tests were used to assess group differences. For categorical variables with relatively small sample sizes in any categories, Fisher's exact tests were applied. For medication type, Poisson regression with an extra parameter to model the over-dispersion was used for count outcomes and logistic regression model was used for the binary outcome (i.e. the osteoporosis supplement). Demographic variables that differ significantly between groups were included in both models to control for potential confounding. Frequencies of medication classification stratified by groups were sorted and the top ten were reported. Pearson correlations were calculated between the number of comorbidities and the number of prescription and over-the-counter medications Cytochrome P450 isoform inhibitors and inducers were evaluated using frequency and descriptive statistics. All data analyses were performed using SAS version 9.3 (SAS Institute Inc., Cary, North Carolina) and Statistical Package for the Social Sciences 19 (SPSS Inc., Armonk, New York).

Results

Sample description

A total of 236 women (98 BCS and 138 midlife women) were included in the analysis. Sample characteristics are shown in Table 1. Significantly more BCS were Caucasian, married, able to pay for basics, and had never smoked ($p<0.05$). Significantly more non-cancer disease conditions were reported by midlife women than BCS ($p<0.05$).

Number of medications

As shown in Table 2, after controlling for group differences (race, non-cancer comorbid conditions, marital status, income and smoking), BCS were taking a greater number of prescription medications, probably due to use of selective estrogen-receptor modulator (SERM) and aromatase inhibitor (AI), and were taking a greater variety of medications as reflected in the higher number of drug classes. BCS were more likely to be taking concurrent prescription and over-the-counter medications ($p<.0001$) and more likely to be taking supplements to prevent osteoporosis ($p=.0176$).

The top 10 medication classifications reported by each group are listed in Table 3. The top three classifications (vitamins, osteoporosis prevention and other supplements) were similar in both groups. However, BCS's more commonly used selective estrogen receptor modulators (6.6% vs. 0%), aromatase inhibitors (5% vs. 0%), and analgesics (3.1% vs. 0%)

whereas midlife women more commonly used antihypertensives (3.3% vs. 7.3%). The number of prescription medications were significantly correlated with the number of comorbid conditions in both BCS (r=0.50; p <0.05) and midlife women (r=0.57; p <0.05). There were no significant correlations between the number of over-the-counter medications and comorbidities in BCS (r=0.15; p>0.05) and midlife women (r=0.09; p >0.05). Upon further examination of the types of medications (prescription only, over-the counter, taking both, taking neither) it was found that the majority of BCS (84%) and midlife women (60%) were taking both prescription and over-the-counter medications.

Cytochrome P450 isoforms

Twenty-four women (10%) were taking at least one medication considered to be a CYP inhibitor or inducer capable of causing clinical drug-drug interactions. BCS (n=11) were taking a total of 26 CYP inhibitors (M=2.20, SD= 0.58, R=1–3) and 1 inducer. Midlife women (n=13) were taking a total of 28 CYP (M=2.15, SD=0.55) inhibitor medications and 1 inducer medication. The majority of medications were 2D6 inhibitors. There were no significant differences in the number of CYP inhibitor or inducers between the BCS and midlife women (p=.90). The BCS and midlife women group were taking the same number of medications considered to be a moderate or severe inhibitor or inducer.

The medications were also reviewed by a local clinical and research expert for potential cytochrome P450-mediated pharmacokinetic drug interactions at the individual level. Of all reviewed medications, only five minor potential interactions were noted. There were two women that were taking both diphenhydramine and duloxetine. The inhibition of CYP2D6-mediated metabolism of diphenhydramine by duloxetine may cause an increased sedative effect of the diphenhydramine. Conversely, the diphenhydramine may also inhibit the CYP2D6-mediated metabolism of duloxetine and cause an increased efficacy and/or toxicity of the duloxetine; however, since diphenhydramine is usually only give for a short time, this is likely to be a minor concern. There was one participant taking both omeprazole, a potent inhibitor of CYP2C19, and citalopram, which is metabolized to a large extent by CYP2C19. This may increase the plasma concentrations of citalopram and possibly increase its efficacy and/or toxicity. There were also two women on omeprazole and escitalopram, which may increase the plasma escitalopram concentrations, although since escitalopram clearance is less dependent on CYP2C19, this is less likely to cause a notable interaction.

Discussion

This is the first study that quantifies the variety of different prescription medications, over-the-counter medications, and supplements reported by BCS and compared to midlife women. This information is important in light of the current initiatives to personalize treatments based on concurrent comorbid conditions and the medications needed to manage those diseases. Understanding the concurrent medications that these women are taking is important for personalizing treatments that maximize tolerability, compliance, and efficacy. It is also important to understand the frequencies of these concurrent medications for designing future clinical studies that test therapies or outcomes that may be confounded by these medications. The high correlation between the comorbidities and prescription medications is not surprising as it is likely that the comorbidities are the reasons for many of the prescription medications.

Medication classifications

In terms of medication use, the significant differences found in the medications in the BCS can be attributed to the reported use of selective estrogen receptor modulators or aromatase inhibitors taken by BCS which are typically not taken by midlife women. This is expected

since BCS with estrogen positive cancers take these medications for up to 5 years post-diagnosis.

Findings also suggest that BCS are managing a mean of 6 different medication classifications and midlife women almost 5 classifications per day, many of which include multiple daily doses. Only 41–45% of those pills were prescribed or likely to be managed by a health care practitioner. From these data it is unclear if women disclosed all non-prescribed medications during regular medical visits. This type of self-management can have a large impact on the efficacy of prescribed medications if not properly managed. It has been reported that approximately 68% of health care practitioners are unaware of non-prescribed supplement use in their patients [15]. Even though the largest percentage of over-the-counter medications were vitamin supplements, those only accounted for 13–15% in both groups leaving a wide range of self-managed medications. This finding is supported in a review of vitamin and mineral supplement use in mixed samples of adult cancer patients where breast cancer patients reported the highest use of these types of medications [15]. Even though vitamin supplements can be health promoting the biological effects of these medications among cancer patients remain unclear and could potentially cause unfavorable problems [15].

The top three ranked types of medications were similar between groups. The percentage of BCS and midlife women taking antidepressants are also essentially the same. As expected, BCS are taking selective estrogen receptor modulators and aromatase inhibitors as continued treatment for cancer. However, for the number of BCS in the study there were relatively fewer women than expected taking breast cancer endocrine therapies, Although we did not collect information from the subjects as to why, it is most likely due to a combination of some of the subjects being past the 5 years of treatment and some having estrogen receptor negative tumors. In addition, a large number of BCS are taking analgesics which can be attributed to developing research findings that SERM and AI use is related to joint pain [16]. Interestingly, midlife women had a higher use of antihypertensive medications compared to BCS. It is unclear if this is because BCS have a lower incidence of high blood pressure or if it is an undertreated problem. It is discouraging that only 60% of BCS and only 33% midlife women were taking osteoporosis prevention supplements such as calcium with vitamin D [17]. To obtain optimal calcium intake, supplementation should be considered for the majority of midlife women since diet alone has been shown to be inadequate [18]. With osteoporosis a known comorbid condition in midlife women, it is concerning that more women might not be getting the preventative care needed. This unexpected result suggests that there is the opportunity for healthcare providers and researchers to improve care through improved education and future research endeavors for these women.

Cytochrome P450 isoform

Our study indicates that approximately 10% of the BCS and midlife women are taking drugs that can cause pharmacokinetic drug interactions. This is likely an underestimate of the drug interaction potential because many of the over-the-counter and herbal supplements have not been tested for drug interactions. Since these interactions can alter the efficacy, toxicity, tolerability, and compliance of many test therapies, these data further emphasize the need to carefully document concurrent medications in clinical trials in both BCS and midlife women [3, 5, 14].

Limitations

The results are limited to women seeking treatment for menopausal symptoms; however, these are a common phenomenon (> 75%) in both BCS and midlife women. A larger descriptive trial without such inclusion criteria could be used to confirm the information

reported here. With the emergence of electronic medical records and large prescription drug database, prescription drug data could be confirmed through such sources [19]. The electronic medical record would also eliminate any self-reporting errors potentially present in this study; however, they would not include over-the-counter medications and may include prescribed drugs that are not actually taken by the patients. Our approach of relying on reported usage, allowed for a more comprehensive assessment and mirrors what has been done for years in clinical practice prior to the advent of electronic records. Lastly, since the midlife women were not specifically chosen to match the BCS patients, the demographic characteristics were different between the groups. The attempt to adjust differing patient baseline characteristics between BCS and the midlife women was completed by incorporation of these characteristics as marginal effect terms in the model. Conceivably, interaction terms among patient baseline characteristics may need to be used in case of finer imbalance of these baseline characteristics. However such complex modeling is not feasible considering the moderate amount of data collected in this study. Although these differences were controlled in the statistical analyses, replicating our findings in more diverse patient populations would be helpful in extrapolating the results to other populations.

Conclusions

To the best of our knowledge, this is the first report to describe the medication use, along with the frequency of co-medications that are CYP inducers and inhibitors, in BCS in comparison to midlife women without cancer. The differences in the number and types of medications taken by these women indicate that medications should be carefully assessed in both clinical practice and clinical research studies. Findings also point to the importance of accurate electronic capturing and classification of medication and over-the-counter (supplement) use in research studies, particularly symptom management studies where medications might confound results.

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Table 1

Group Differences in Background Characteristics (Baseline data)

	Breast Cancer Survivors	Midlife Women	
Background characteristics	**N (%)**	**N (%)**	**p**
Ethnicity			
Non-Latina	97 (99%)	135 (98%)	0.6434
Latina	1 (1%)	3 (2%)	
Race			
White/Caucasian	84 (86%)	78 (57%)	**<.0001**[a]
Other	14 (14%)	60 (43%)	
Marital			
Married / living with partner	74 (76%)	73 (53%)	**0.0004** [a]
Single, widowed, other	24 (24%)	65 (47%)	
Employment			
Full time	62 (63%)	90 (65%)	0.9042
Part time	13 (13%)	19 (14%)	
Not currently working	23 (24%)	29 (21%)	
Difficulty paying for basics			
None	80 (82%)	91 (66%)	**0.0078** [a]
Some / a lot	18 (18%)	47 (34%)	
Smoker			
Never	70 (71%)	81 (59%)	**0.0447** [a]
Ever (Former, current)	28 (29%)	57 (41%)	
Menopausal status			
Early peri / late peri	1 (1%)	6 (5%)	0.0961
Early post	9 (9%)	21 (16%)	
Late post	85 (90%)	102 (79%)	
Type of non-cancer comorbid conditions			
Arthritis	28 (29%)	43 (31%)	0.6693
Asthma	8 (8%)	15 (11%)	0.4897
Back pain	20 (20%)	36 (26%)	0.3123
Chronic obstructive pulmonary disease	0 (0%)	1 (1%)	1.0000
Diabetes	4 (4%)	12 (9%)	0.1967
Emphysema	0 (0%)	1 (1%)	1.0000
Heart disease	1 (1%)	2 (1%)	1.0000
High blood pressure	17 (17%)	43 (31%)	**0.0163** [a]
Kidney disease	0 (0%)	0 (0%)	n/a

	Breast Cancer Survivors	Midlife Women	
Liver disease	1 (1%)	0 (0%)	0.4153
Ulcer or stomach disease	1 (1%)	4 (3%)	0.4056
Other	26 (27%)	34 (25%)	0.7421
Use of SERM/AI or Tamoxifen			
Currently	58 (59%)	1 (1%)	**<.0001** [a]
Not Currently	40 (41%)	137 (99%)	
	M (SD)	**M (SD)**	**p**
Age	52.94 (7.98)	52.36 (5.17)	0.5260
Body mass index	28.84 (6.04)	30.17 (8.01)	0.1490
Number of comorbid conditions including cancer	2.11 (1.05)	1.46 (1.35)	**< .0001** [a]

[a] Significant at $p<0.05$.

Table 2

Primary Outcome Variables for Medications

	Breast Cancer Survivors n=98	**Midlife Women n=138**	
			p[a]
Number of prescription (Rx) meds, Mean(SD)	2.71 (1.96)	1.94 (1.89)	**<0.0001**[b]
Number of over-the-counter (OTC) meds, Mean(SD)	3.29 (2.19)	2.72 (2.59)	0.6457
Number of drug classes per person, Mean(SD)	6.00 (3.19)	4.66 (3.34)	**0.01242** [b]
Taking osteoporosis supplement, N(%)	39 (40%)	N=92 (67%)	**0.00922** [b]
No	59 (60%)	N=46 (33%)	
Yes			

[a] p value for group differences from Poisson/logistic regression controlling for race, non-cancer comorbid conditions, marital status, income and smoking.

[b] Significant at p<0.05.

Table 3

Ranking of top 10 drug classifications by group

Breast Cancer Survivors (n=98) n (%)	**Midlife Women (n=138) n (%)**
1. Multivitamin or vitamin 65 (66.3%)	1. Multivitamin or vitamin 76(55.1%)
2. Osteoporosis prevention 59(60.2%)	2. Dietary supplements 52(37.7%)
3. Dietary supplements 47 (48.0%)	3. Osteoporosis prevention 46(33.3%)
4. Antidepressants 37(37.8%)	4. Antihypertensive agent 38(27.5%)
5. Selective Estrogen Receptor Modulator 32(32.7%)	5. Antipyretics 37(26.8%)
6. Antipyretics 26(26.5%)	6. Antidepressants 34(24.6%)
7. Aromatase inhibitors 24(24.5%)	7. Antiulcer agent 25(18.1%)
8. Lipid lowering agent 17(17.3%)	8. Lipid lowering agent 21(15.2%)
9. Antihypertensive agent 16(16.3%)	9. Allergy/cold 20(14.5%)
10. Analgesics 15(15.3%)	10. Anti-angina 14(10.1%)
	10. Herbal 14(10.1%)