

Which Menopausal Symptoms after Adjuvant Endocrine Breast Cancer Therapy are Addressed by Health Care Providers? Medical Records Notes Versus Self-Reported Side-Effects

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Abstract

Objective: This study examines reports from healthcare providers and patients concerning menopausal side-effects associated with adjuvant endocrine breast cancer therapy (AET) after a breast cancer diagnosis.

Methods: This study is based on data from 81 women between 32 - 62 years old with hormone receptor-positive breast cancer. The study consists of: i) a longitudinal medical record cohort study and ii) self-reported data from a questionnaire in the same cohort. The medical record cohort study covered up to five years of data from the start to completion of AET. Two years after completing AET, the women were mailed a questionnaire that addressed the side-effects they had experienced during the therapy.

Results: The reported side-effects in the questionnaire were significantly higher in terms of vaginal dryness ($P = 0.0026$), genital sexual pain ($P < 0.001$) and decreased sexual desire ($P < 0.001$) than in the medical records. With regard to sweating and flushes, the differences between what was reported in the medical records and what the women stated in the questionnaire were not significant.

Conclusion: Communication and counselling about menopause-related side-effects, especially sex-life-related issues, need to be improved and the reasons for this poor communication need to be elucidated.

Keywords: Breast Cancer; Endocrine Side-Effects; Sexuality; Questionnaire

Introduction

In all Western countries, breast cancer is the most common form of cancer among women. In Sweden, 30% of all female cancer cases are breast cancer. According to the National Board of Health and Welfare, five-year survival rates have improved [1] as a result of better diagnostics and more effective oncological treatment such as chemotherapy [1,2], adjuvant endocrine breast cancer therapy (AET) [3], radiotherapy, and sometimes targeted therapy [4]. Breast cancer is often hormone receptor-positive - i.e. the cancer is stimulated to grow by the woman's own sex hormones. Therefore, women who have undergone breast cancer surgery and have a hormone receptor-positive tumour are offered AET for five or ten years to reduce the risk of relapse [5-7]. However, AET carries the risk of several side-effects that can negatively affect women's daily life including menopausal side-effects, and sexual dysfunction [8-11].

Irrespective of treatment modalities, several studies have found sexual dysfunctions to be common after breast cancer. There are, however, quite large differences regarding the prevalence; for example decrease in sexual interest/desire varied between 24% - 71% [12-16],

arousal and lubrication dysfunctions 51% - 74% [12,14,15] genital sexual pain 39% - 51% [12,14,16]. We have only been able to locate one study regarding orgasmic dysfunction which was found in 42% [14]. Moreover, decrease in sexual satisfaction/low sexual satisfaction has been reported to exist in 54% - 71% [14,15,17].

Due to the high frequency of documented side-effects, it is essential to understand how healthcare providers address this knowledge when they discuss treatment options and their side-effects with patients. That there are shortcomings in this area among healthcare providers has been shown in, for example, a Swedish study where it has been reported that patients were not given comprehensive advice regarding treatment to relieve AET side-effects [18].

Purpose of the Study

The purpose of this study was to illustrate the extent to which women’s menopausal side-effects were addressed by the health care providers by studying the documentation in the medical record and then comparing the results with those reported in a questionnaire of self-reported symptoms completed by the women in the same cohort.

Ethics

All procedures performed in these studies were in accordance with the ethical standards of the National Research Committee and with the 1964 Helsinki Declaration and its later amendments. The medical record study was approved by the Research Ethics Committee South in Stockholm and the supplemented questionnaire study with an additional application from the Regional Ethical Review Board in Stockholm. Informed consent was obtained from all individual participants included in the study.

Methods and Participants

The present investigation consists of two parts: i) a longitudinal observational cohort study of medical records and ii) self-reported data from questionnaires covering menopausal side-effects of AET. The medical record cohort study covered up to five years of data from the start to completion of the endocrine therapy. Two years after completing AET, the women were mailed a questionnaire that addressed the side-effects they had experienced during the therapy.

The study took place at the Department of Oncology, Södersjukhuset, Stockholm, Sweden. Women with breast cancer were enrolled consecutively from November 2002 to January 2003 and from November 2003 to August 2004. They agreed to participate in a study concerning social issues and different aspects of health (See Johansson., *et al.* 2007). Inclusion criteria were: diagnosed with a hormone receptor-positive tumour, younger than 65 years (i.e. of working age), able to understand and read Swedish. During the study period, a total of 89 women fulfilled these criteria. Eight women relapsed in breast cancer or died during the period and thus, 81 women remained for the medical record cohort study (See figure 1). All medical files were retrospectively explored. During the five-year follow-up, a total of 1,000 notes were written in the 81 medical records.

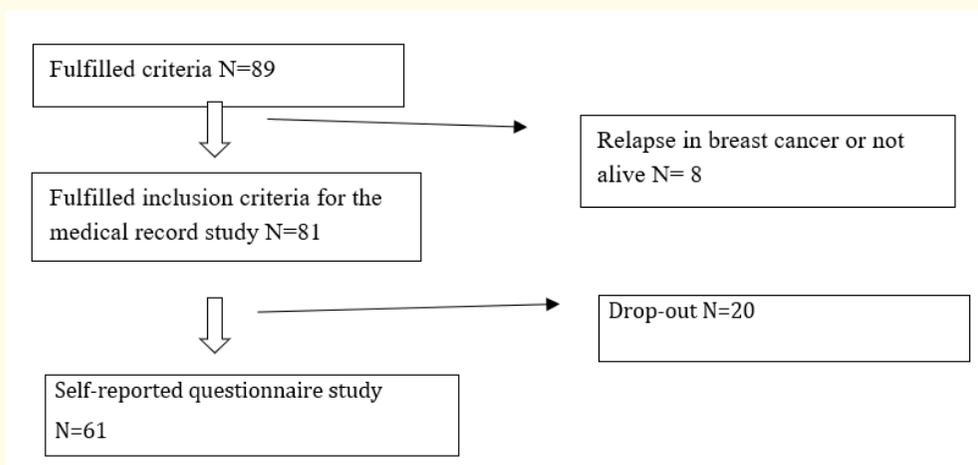


Figure 1: Flowchart-Including.

Two year after completing AET the women were contacted to answer a mail questionnaire addressing their own experiences of endocrine side-effects (sweating, hot flushes, vaginal dryness, genital sexual pain, decreased sexual desire and interest) during the time they been under treatment with AET. The questionnaire was answered by 75% (61 out of 81). For each item, the women had to state the level of the disorders during the treatment period on a five-point grade scale: (1) no problem, (2) minor problem, (3) moderate problem, (4) severe problem, and (5) very severe problem. The scores for each item were dichotomized as no problems/minor problems (scores 1 - 2) or moderate/severe/very severe (scores 3 - 5) problems. A two-year follow-up was chosen due to earlier studies where it has been shown that women treated with AET regained a health condition that corresponds to the health status of the population after two to three years [19,20]. We, therefore, expected that the majority of the women in the present study had returned to a normal health state, which in turn may increase the chance of being able to view what were the side-effects of AET and what were the results of natural menopause.

The results from the medical records were compared with the women’s own experiences.

Statistical methods

Range, mean, and SD are presented for age. Percentage values are presented for descriptions (demographic and clinical characteristics). Either the Pearson Chi-Square Test or Fisher’s Exact Test was used to calculate the differences between data reported in the records and self-reported data. All tests were two-tailed with a significance level of $P < 0.05$. The statistical program SPSS (version 22.0) was used for all tests.

Results

The medical record study

The mean age at inclusion was 53 years (range 35 - 62; SD 6.7). A majority of the women (68%) lived with partners, 81% had biological children, and 78% were born in Sweden. Most of them (63%) had at least an upper secondary school education. All women had undergone some form of surgery as a treatment for breast cancer. Close to 65% had undergone breast-conserving surgery and 35% had undergone mastectomy. The majority of the participating women (79%) had undergone axillary node dissection and one-third (32%) had also gone through adjuvant chemotherapy. Aromatase inhibitors (AI) were prescribed for 49% of the women and tamoxifen was prescribed for 48%.

During the study period, the 81 included women had altogether a total of 1,000 registered contacts with the oncology clinic. In these 1,000 medical records, anti-hormonal side-effects were mentioned 247 times. The distributions of studied side-effects mentioned in the medical records are shown in table 1. Table 2 shows the proportion of women who, according to notes in the medical records, have respective side-effects.

Side effect	Number of notes
Sweating	82
Hot flushes	79
Night sweating	33
Vaginal discharge	5
Vaginal irritation	9
Vaginal bleeding	6
Vaginal dryness	29
Genital sexual pain	3
Decreased sexual desire	1

Table 1: Type of side-effects registered in the 1000 studied medical records of 81 women with breast cancer.

Side effect	Women n (%)
Sweating	38 (47)
Hot flushes	39 (48)
Night sweating	22 (27)
Vaginal discharge	5 (6)
Vaginal irritation	7 (9)
Vaginal bleeding	6 (7)
Vaginal dryness	20 (25)
Genital sexual pain	3 (4)
Decreased sexual desire	1 (1)

Table 2: Type of side-effects registered in the medical records of 81 women with breast cancer. Number and percentages are given.

The questionnaire study

Of the women included in the medical record study, 61 (75%) completed the menopausal side-effects questionnaire. There were no significant differences in demographic, clinical, and treatment characteristics between the participants in the medical record cohort study and the participants in the questionnaire study except for age: 63% of the younger women (< 55 years at baseline in the medical record cohort study) and 81% of the older women (≥ 55 years at baseline in the medical record cohort study) answered the questionnaires. The women reported the following menopausal side-effects in the questionnaires: sweating (39%), hot flushes (63%), vaginal dryness (43%), genital sexual pain (44%), and decreased sexual desire (68%).

The medical records study versus the questionnaire study

When comparing, all menopausal side-effects were reported to a higher extent in the questionnaire than in the medical records (Table 3). Significant discrepancies were found when comparing vaginal dryness (P = 0.0026), genital sexual pain (P < 0.001) and decreased sexual desire (P < 0.001). The latter two side-effects were almost never reported in the medical records but were frequently mentioned in the questionnaires (Table 3).

Moderate/severe/very severe problems	Side-effects in medical records n (%)	Self-reported side-effects n (%)	p-value
Sweating (n = 61)	19 (31)	24 (39)	0.45
Flushes (n = 60)	27 (45)	38 (63)	0.067
Vaginal dryness (n = 61)	10 (16)	26 (43)	0.0026
Genital sexual pain (n = 43)	1 (2)	19 (44)	< 0.001
Decreased sexual desire (n = 56)	1 (2)	38 (68)	< 0.001

Table 3: Number of side-effects documented in the medical records versus reported in the questionnaires by 61 women after anti-hormonal breast cancer therapy.

Discussion

The purpose of this study was to illustrate the extent to which women's menopausal side effects were documented in the medical records among women who visited an oncology department in the capital of Sweden for follow-up of side-effects due to AET. Altogether, 1,000 recorded visits were found for 81 women and 25% of these notes addressed menopausal side-effects.

This study also compared reported side-effects of AET in the medical records and in self-reported questionnaires. The women reported considerably more menopausal side-effects than found in the medical records. The discrepancies concerning the items 'genital sexual pain' and 'decreased sexual desire' were particularly significant although discrepancies concerning 'vaginal dryness' were also significant. Interestingly, the prevalence of menopausal side-effects following AET found in the questionnaires but not in the medical records are in line with the results of other studies addressing the same issue [9,12,14-17,21-26].

It is noteworthy, however, that as the mean age at inclusion in the study was 53 years, most women were probably already in menopause when they started AET. The genital problems that the women reported in the study may therefore to some extent be a result of changes caused by natural menopause. Regarding sexual dysfunction in connection with a breast cancer diagnosis, studies have shown that in addition to AET, for example, surgery, chemotherapy, and psychological reactions in connection with the diagnosis can cause sexual dysfunction [14,15].

Whether the healthcare providers asked about these side-effects within the genital and sexual context or whether they were unwilling to record this kind of data could not be determined by this study design. In Sweden, however, healthcare providers have a statutory obligation to record all important observations, so it is likely that sexual health is viewed as unimportant or as private information to be kept from public records. That the shortcomings are real when it comes to addressing these issues is supported by Langlet [18] and Taylor, *et al* [26]. In the present study, the questionnaire data and medical record data of the side-effects sweating and hot flushes showed no significant differences. We can just speculate, or interpret, that this 'less sensitive' data were recorded by the healthcare providers as it was viewed as appropriate for medical journals and not a violation of patient privacy.

Notably, a multi-faceted approach has been reported to be necessary when meeting women with breast cancer and issues regarding sexuality [24,26]. Medical treatments are available that can reduce some side-effects. For example, hormone-free vaginal gels can provide relief and should be introduced early in the treatment, but vaginal gels containing oestrogen is safe and more effective than hormone-free vaginal gels [27]. Furthermore, several studies have noted that women need advice regarding appropriate and feasible treatments. It is also well-documented that women affected by cancer want to talk about issues related to sexuality [23,25,28,29]. If healthcare providers do not raise these issues, it seems that women are at risk of unnecessary suffering [30].

Strengths and Limitations

The strength of this study is its long-term follow-up in the longitudinal medical record cohort study and a high response rate. A limitation might be that only Swedish-speaking survivors of working age were included, so the results may not be representative of women with early-stage breast cancer who do not speak Swedish and/or who are not of working age. Although, the study began as far back as 2002, this is negated by the fact that the prescribed treatments are the same as those given today. Studies have also shown that the problem of women with genital and sexual effects of AET still not being prescribed treatments that could minimise these genital and sexual problems [23].

Conclusion

The difference between the information provided by self-reported questionnaires and the information noted in the medical records is notable. Communication and counselling about menopause-related side-effects, especially sex-life-related issues, need to be improved and the reasons for this poor communication need to be elucidated.

Acknowledgements

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