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Can breast cancer register data on recommended adjuvant treatment be used as a proxy for actually given treatment?

Agneta Wennman-Larsen [a, b, *], Marie I. Nilsson [a, c, d], Fredrik Saboonchi [a, e], Mariann Olsson [d], Kristina Alexanderson [a], Tommy Fornander [f, g], Kerstin Sandelin [h, i], Lena-Marie Petersson [a]

[a] Division of Insurance Medicine, Department of Clinical Neuroscience, Karolinska Institutet, 171 77 Stockholm, Sweden
[b] Sophiahemmet University, Box 5605, 114 86 Stockholm, Sweden
[c] Department of Social Work, Karolinska University Hospital, 141 86 Stockholm, Sweden
[d] Division of Social Work, Department of Neurobiology, Care Sciences and Society, Karolinska Institutet, 171 77 Stockholm, Sweden
[e] Red Cross University College, Teknikringen 1, 114 28 Stockholm, Sweden
[f] Department of Oncology-Pathology, Karolinska Institutet, 171 77 Stockholm, Sweden
[g] Department of Oncology, Karolinska University Hospital, 171 76 Stockholm, Sweden
[h] Department of Molecular Medicine and Surgery, Karolinska Institutet, 171 77 Stockholm, Sweden
[i] Department of Breast and Endocrine Surgery, Karolinska University Hospital, 171 76 Stockholm, Sweden

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ABSTRACT

Purposes: To study agreement between recommended adjuvant treatment after primary breast cancer (BC) surgery from the clinical based National Breast Cancer Register and initiated adjuvant treatment from medical records; factors associated with agreement; and reasons for discontinuation or change of planned treatment.

Method: Included were 970 women who had undergone BC surgery, aged 20–63 years, living in Stockholm County, and literate in Swedish. Exclusion criteria: Distant metastases, pre-surgical chemotherapy, and/or a previous BC diagnosis.

Information on clinical tumor stage, surgical treatment, recommended adjuvant radiotherapy, chemotherapy, and endocrine therapy was obtained from the BC register. Type of initiated adjuvant treatments, if treatment plan was followed, and reasons for discontinuation were extracted from medical records.

Results: The register had high completeness and agreement was high, 94–96%, (κ 0.801–0.908) for all types of treatment. Disagreement regarding radiotherapy and chemotherapy was associated with having ≥1 lymph node metastases and more extended axillary surgery, and for radiotherapy also more extended breast surgery. There were no such associations with age, tumor size, or invasiveness. None of these factors were associated with disagreement regarding recommended versus initiated endocrine therapy. Endocrine therapy was most often discontinued (24%), mostly due to toxicity which was also the most common reason for discontinuation of chemotherapy.

Conclusions: Swedish register data on recommended treatment has high validity in women aged 24–63 years, with limited BC, and demonstrates utility as a proxy for initiated treatment in this group. This is of interest since extracting data from medical records is resource demanding.

1. Introduction

The advantages of using the Nordic registers in research were recently discussed in an article by Olsen (Olsen, 2011) in relation to economy, time consumption, as well as from a reliability perspective with respect to e.g., selection bias in collecting primary data. Pointed out was also the important topic of how to incorporate the growing number of clinical databases into research. The importance of this has also been pointed out and discussed by others (Stenbeck and Allebeck, 2011). In clinical and epidemiological cancer studies, information on adjuvant treatment is crucial,

* Corresponding author. Karolinska Institutet, Division of Insurance Medicine, Department of Clinical Neuroscience, SE-171 77 Stockholm, Sweden.
E-mail address: agneta.wennman-larsen@ki.se (A. Wennman-Larsen).

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however, it is both time consuming and costly to extract this information from medical records. When data on given treatment is not available or is difficult to retrieve, clinical-based registers with data on recommended initial course of treatment serve as a valuable source of such information. An important consideration when using treatment data from registries is, however, the completeness and accuracy in relation to actually given treatment (Cress et al., 2003; Warren and Harlan, 2003). Clinical-based registers constitute all from small locally held hospital registers, to multi-regional registers, such as the Surveillance Epidemiology, and End Results Program (SEER) in the US. The several nationwide Swedish healthcare registers cover both organ specific disorders and symptoms (Emilsson et al., 2015), the majority being cancer diagnoses. The aim of these registers is to collect individual-based clinical data to ensure quality and delivery of healthcare and to identify regional differences (Emilsson et al., 2015). The registers enable research based on high quality data when monitored properly. One example is the Swedish National Breast Cancer Register (The Swedish National Breast Cancer Register, 2008), a nationwide register established in 2007 that includes information on the structure, process, and outcome of newly diagnosed breast cancer cases (Emilsson et al., 2015). It includes information on the clinical pathway, initial treatment recommendation, performed treatment, reoperations, histopathological results including tumor biology, and recommended and initial course of adjuvant treatment (Emilsson et al., 2015). For clinical research purposes, the question arises how reliable the registered information on recommended initial course of treatment is compared to information on actual given treatment.

To the best of our knowledge, only three studies (Du et al., 2006; Jensen et al., 2002; Mallin et al., 2013) have evaluated the actual given adjuvant treatment data (radio-, chemo-, and endocrine therapy), based on the often used recommended initial course of treatment. In one of these studies (Jensen et al., 2002), treatment data from the Danish Cancer Register regarding breast cancer was validated by linkage of a nationwide trial register and a local oncology department register based on clinical record data; the results showed high agreement (88.5–95.4%) for all treatment modalities, including combinations, except for chemotherapy where the agreement was lower; 72.3%. In a US study (Du et al., 2006), a moderate agreement was found (κ 0.45–0.75) between the registrations in the SEER cancer register and in medical charts regarding chemo- and hormone therapy in women with breast cancer. While Mallin et al. (Mallin et al., 2013) found an agreement of $\kappa > 0.70$ between radiotherapy, and chemotherapy in a comparison of registrations in a Cancer Incidence Surveillance System and registered claims from private insurance payers, endocrine therapy showed only moderate agreement in the two data sources. The agreement between recommended and initiated treatment is highly dependent on high consistency in treatment recommendations. Breast cancer treatment follows consistent treatment recommendations in Sweden, as well as in other countries, structured in national guidelines (National guidelines for treatment of breast cancer, 2013). In Sweden, prevailing regional care plans emerge from these national guidelines.

1.1. Aim

The aim of this study was to evaluate the agreement between information about recommended adjuvant treatment after primary breast cancer surgery from the Swedish National Breast Cancer Register and initiated adjuvant treatment from patient medical records, as well as factors associated with such agreement. A second aim was to describe reasons, as recorded in the medical records, for discontinuation or change of treatment from the initial adjuvant treatment plan.

2. Methods

Data for the present study is based on data collected within the frame of an overarching prospective cohort project on “Life situation and return to work after breast cancer surgery” (Petersson et al., 2011) concerning women in working ages. As the focus of the study included work aspects, only women below the age of 63 years were included. Included were 970 women who had undergone breast cancer surgery. The women were screened for eligibility consecutively after surgery at their first visit for discussion of further treatment, June 2007–November 2009. Data were collected from three hospitals in Stockholm, Sweden of which two belonged to the same oncological clinic. **Inclusion criteria**: Women who had undergone primary breast cancer surgery at one of these hospitals when aged 20–63 years, living in Stockholm County, and literate in Swedish. **Exclusion criteria**: Known distant metastasis, presurgical chemotherapy, and/or a previous breast cancer diagnosis. The study was approved by the Regional Ethical Review Board in Stockholm.

2.1. Register data

Data from the Swedish National Breast Cancer Register (Emilsson et al., 2015) on clinical TNM (Sobin et al., 2009), final breast and axillary surgery, recommended postoperative adjuvant radiotherapy, chemotherapy, and endocrine therapy were used in the comparison. In case of bilateral breast cancer, data from the most advanced tumor, based on the clinical tumor status, invasiveness, and size was used. In Sweden all breast cancer patients are discussed during a multidisciplinary team conference (MDT) before and after initial surgery and/or neoadjuvant treatment. The recommendations for adjuvant treatment from the postoperative MDT-conference are made with consideration taken to the patients' age, co-morbidities, hormone receptor status, and tumor grade. Data entry for the register is performed after the postoperative MDT. After the postoperative MDT-conference the women are invited to a consultation for discussion of further adjuvant treatment and an initial adjuvant treatment plan is agreed upon. From the recommendation made on the MDT-conference other factors may also turn up that may change the initial adjuvant treatment plan, for example, unknown co-morbidities or changes in tumor status.

2.2. Medical record data

Data were extracted from the medical records of all 970 women, from the first visit after surgery up to 2.5 years later. A template for data extraction was developed and tested. Data extracted were: type of initiated adjuvant treatments, i.e., radiotherapy, chemotherapy, and endocrine therapy; initial treatment plan; if the initial treatment plan was not followed; and reasons for discontinuation or change of the adjuvant treatment. The data extractors were experienced from clinical oncology and trained for uniform data extraction.

2.3. Factors tested for association with disagreement

Age at inclusion in the prospective cohort study was dichotomized by median into younger $\leq$52 and older >52 years.

From the breast cancer register: Clinical T-classification dichotomized into tumor $\leq$50 mm and tumor >50 mm. Clinical N-classification dichotomized into no lymph node metastases and one or more lymph node metastases. Type of final axillary surgery