

Aanvraag gegevens ten behoeve van wetenschappelijk onderzoek

Registratie waarvan gegevens worden opgevraagd: **NBCA**

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Achtergrond van onderzoek:

Breast cancer is the most common non-cutaneous malignancy affecting women worldwide and the second leading cause of mortality.(1) Several prospective randomized trials have demonstrated an equivalent survival rate after breast conserving therapy (BCT) and radiotherapy compared to survival rate after mastectomy. Moreover, rates of local recurrence after breast conserving surgery are similar as those seen after mastectomy.(2-4) In spite of this, there has been a significantly increasing trend toward the utilization of mastectomy and specifically contralateral prophylactic mastectomy (CMP) in patients diagnosed with unilateral breast cancer.(5-8) However, this trend has been reported primarily in the United States, as opposed to studies in Europe.(9)

Concurrent with the more utilized mastectomy trends, immediate breast reconstruction (IBR) has increased significantly over the last decades in the United States, increasing from 20 percent in 1998 to 38 percent in 2008.(10, 11) Accordingly, the availability of IBR may represent access to high-quality comprehensive breast cancer treatment. Despite the demonstrated benefits of immediate breast reconstruction after mastectomy on body image, self-esteem,(12-14) sexuality, and quality of life,(12, 15-17) only 25% to 40% of patients diagnosed with breast cancer opt for immediate breast reconstruction (IBR) after total mastectomy.(5, 10, 18-23) Interestingly, also in this discussion, no European center contributed profound data supporting or opposing the current trends in IBR.

Onderzoeksvraag:

The aim of this study is to

- (1) Compare breast cancer treatment (e.g. mastectomy or breast conserving therapy) between the Netherlands and the United States.
- (2) Conduct a trend analysis comparing post-mastectomy immediate breast reconstruction rates between the Netherlands and the United States.
- (3) Conduct a trend analysis and comparing types of immediate breast reconstruction (e.g. implant/autologous BR) between the Netherlands and the United States.

Titel onderzoek:

Surgical treatment and reconstruction in women diagnosed with breast cancer: Comparison between practices in the USA and the Netherlands.

Onderzoeksopzet:

Inclusion criteria:

All women diagnosed with non-metastatic breast cancer, undergoing mastectomy, and breast conserving therapy will be included in this study. Furthermore, in patients who underwent mastectomy, data on immediate breast reconstruction, type of breast reconstruction and patient and tumor characteristics will be obtained and analyzed. Trends will be plotted and analyzed for both mastectomy rates as well as (type of) immediate breast reconstruction rates. All male patients, patients with unknown age or gender, those under 18 years of age, and patient undergoing.

Analyzed data:

- United States
 - The Nationwide Inpatient Sample (NIS) database is the largest all-payer inpatient care database in the United States, containing data from over 1000 hospitals and more than 8 million hospital stays annually.(24) It is designed to approximate a 20% sample of all hospital discharges, which includes all nonfederal, short-term, general, and other specialty hospitals, including public hospitals and academic institutions.
 - The American College of Surgeons National Surgical Quality Improvement Program (NSQIP) is a prospective, multicenter clinical registry that was created to provide feedback on risk-adjusted outcomes to hospitals for quality improvement purposes. More than 130 patient and operative variables are recorded, including patient demographics, pre-operative risk factors, laboratory values, intraoperative variables, and postoperative 30-day morbidity and mortality. All information in the database is deidentified, and informed consent is obtained from patients before data collection.
 - The Surveillance, Epidemiology and End Results (SEER) database of the National Cancer Institute contains data from about 28% of the breast cancer patients diagnosed annually in the United States. The SEER database collects patient-level data for all index malignant tumors in 18 cancer registries across the United States and captures 28% of the nation's population. This database is regarded as nationally representative and contains detailed demographic, socioeconomic, oncologic, and therapeutic information.

- The Netherlands
 - The NABON (National Breast Cancer Organization the Netherlands) Breast Cancer Audit (NBCA) is a continuous multidisciplinary quality improvement project, starting in 2011, containing information of over 60.000 patients diagnosed with breast cancer in all 92 hospitals in the Netherlands.

Statistiek:

In order to facilitate trend analysis using multiple years of NIS data, the discharge weight factor provided by the NIS will be utilized, and national estimates will be calculated by uniformly applying the weight factor to the discharges.(25) For all other databases, we will utilize the incidence to obtain the trend over time. Descriptive statistics will be reported as proportions and compared using Pearson's Chi-square. Trends will be analyzed using the Cochran-Armitage test for trend. All statistical analyses will be performed using IBM SPSS version 22.0 (IBM Corp.,

Armonk, NY) and significance will be set at $p < 0.05$.

Preliminary Data!

We conducted a preliminary analysis using the Nationwide Inpatient Sample Database. This data will be used for this study.

Cohort selection

Our cohort comprised all female patients diagnosed with breast cancer (ICD-9 diagnosis codes 174.0, 174.1, 174.2, 174.3, 174.4, 174.5, 174.6 and 174.8) or at increased risk of breast cancer (ICD-9 diagnosis codes 233.0, v16.3, v10.3, v84.01) undergoing unilateral or bilateral total, subcutaneous, simple, extended simple, radical and extended radical mastectomy (ICD-9 procedure codes unilateral mastectomy: 85.34, 85.41, 85.43, 85.45, 85.47, 85.33 and bilateral mastectomy: 85.36, 85.42, 85.44, 85.46, 85.48, 85.35) (Table 1). Patients with multiple ICD-9 procedure code 85.40 (“mastectomy”) and v50.41 (“prophylactic removal of the breast”) were classified as having bilateral mastectomy (table 1). Implant-based breast reconstructions (BR) were defined as any type of mastectomy with concurrent, immediate tissue expander followed by implant insertion at a later date, or as an immediate implant placement (ICD-9 procedure codes 85.33, 85.35, 85.53, 85.54, 85.95, 85.96) (Table 2). Autologous breast reconstructions were included LD, pTRAM, fTRAM, DIEP, SIEA and GAP flap (ICD-9 procedure codes 85.71, 85.72, 85.73, 85.74, 85.75 and 85.76, respectively) (Table 2). For this analysis, all flaps were combined into “autologous breast reconstruction” group. Male patients, those under 18 years of age, those of unknown gender or age, and those who underwent reconstruction using combined methods (autologous plus implant) were excluded. Furthermore, cases of breast reconstruction without a concurrent mastectomy were considered delayed breast reconstruction and therefore excluded from analysis.

Analyzed variables

The analyzed data included age, calendar year, primary payer (private insurance and other insurance types), race, hospital status (teaching/non-teaching, urban/rural), and hospital bedsize. Patients’ ages were divided into groups (<39, 40-49, 50-59, <60). Hospital teaching status is determined by the Nationwide Inpatients Sample as those hospitals with American Medical Association-approved residency programs, or are members of the council of Teaching Hospitals, or have a ratio of full-time residents to beds of 0.25 or greater.(22) In the NIS, race is classified into similar categories as census population data (White, Black, Hispanic, Asian or

Pacific Islander, Native American and other). Due to limited sample sizes, Native Americans were combined into the “other” category for analysis. Hospital bed size categories were determined by the Nationwide Inpatient Sample based on hospital beds and are specific to the hospital’s location and teaching status. Small bedsize was determined as 1-49 for a rural hospital, 1-99 for an urban non-teaching hospital and 1-299 for an urban, teaching hospital. Medium bedsize was determined as 50-99 for a rural hospital, 100-199 for an urban non-teaching hospital and 300-499 beds for an urban teaching hospital. Large bedsize was determined as 100+ for a rural hospital, 200+ for an urban non-teaching hospital and 500+ for an urban teaching hospital.(22) Estimated household income, as determined by median household income for the patient’s zip code, was recorded directly from the NIS database and stratified by quartile, indicating the poorest to wealthiest populations.

Results

Between 2008 and 2012 a total of 427,272 patients were diagnosed with breast cancer or increased risk of breast cancer. Of these, 343,164 (80.3%) underwent mastectomy and a total of 118,258 (77.7%) patients underwent immediate implant-based breast reconstruction, and 25,511 (16.8%) patients immediate autologous breast reconstruction. The overall characteristics of the patients are presented in table 3. In both autologous BR group as the implant-based BR group, most patients were Caucasian, with an estimated household income of the 4th quartile, were operated on in an urban teaching hospital with a large bedsize, and were private insured. However, most patients undergoing autologous breast reconstruction were aged 50-59 years old (36.2%) undergoing unilateral reconstruction (55.6%) while patients with implant-based BR were aged 40-49 (33.8%) and underwent a bilateral reconstruction (60.8%). Over time, autologous BR increased significantly from 5.1% in 2008 to 9.3% in 2012 and implant-based BR increased significantly from 29.9% to 40.0% over the same time period (data not shown).