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Breast reconstruction with an expander prosthesis following mastectomy does not cause additional persistent pain: A nationwide cross-sectional study

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Summary *Introduction:* Few studies have examined the prevalence of persistent pain after breast reconstruction with an implant after tissue expansion in comparison to mastectomy without breast reconstruction. Our primary objective was to evaluate the prevalence of persistent pain after breast reconstruction with a subpectoral implant after tissue expansion in a population-based study. Secondary objectives were to evaluate sensory disturbances, lymphoedema and functional impairment.
Method: This was a nationwide cross-sectional questionnaire study of breast cancer patients aged 18–69 years who were treated with or without reconstruction after mastectomy for primary breast cancer in Denmark between 1 January 2005 and 31 December 2006. The response rate was 84% for mastectomy without reconstruction and 83% for patients treated with breast reconstruction.
Results: A total of 129 patients treated with mastectomy and breast reconstruction with a subpectoral implant were compared with 1131 patients treated with mastectomy without reconstruction. Prevalence of persistent pain for patients treated with mastectomy followed by reconstruction with an implant was 40% compared to 48% of patients treated only with mastectomy. We found no increased risk of persistent pain in patients having a reconstruction with an implant compared with mastectomy without reconstruction (odds ratio (OR) 0.82, 95% confidence interval (CI) 0.55–1.22, $P = 0.33$) when adjusting for age, axillary procedure,

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radiotherapy and chemotherapy. We observed no difference in the prevalence of pain between patients treated with immediate or delayed breast reconstruction ($P = 0.116$).
Conclusion: Breast reconstruction with a subpectoral implant after tissue expansion does not confer increased prevalence of persistent pain.

Persistent post-surgical pain has been demonstrated to be a major problem affecting 10—50% of patients undergoing various common operations.[1] Our group has previously demonstrated that the prevalence of persistent pain after breast cancer treatment (PPBCT) was between 25% and 60%, depending on surgical and adjuvant treatment.[2] Several risk factors for the development of PPBCT have been proposed most consistently, including axillary lymph node dissection (ALND), young age and radiotherapy.[3]

Persistent pain after breast reconstruction with a subpectoral breast implant after tissue expansion has been examined in different study set-ups. Among these are case series, study designs without a control group[4,5] and studies comparing post-surgical complications after breast reconstruction, including pain, between tissue expansion and other reconstruction modalities, for example latissimus dorsi (LD) flap and transverse rectus abdominis myocutaneous (TRAM) flap.[6,7] The prevalence of pain after breast reconstruction with a tissue expander is reported from 2% to 49% in population sizes ranging from 12 to 240 patients, and with follow-up time varying from 2 to 6 years.[4,6—10]

Data sampling in the present study was conducted concurrently with that in previously published studies by Gärtner et al.[2,11] The study is population based and benefits from the unique possibilities in Denmark with a national database managed by the Danish Breast Cancer Cooperative Group (DBCG),[12] which prospectively collects detailed clinical data, histopathological status, treatment and data on recurrence and mortality.[13] Furthermore, treatment principles are standardised in Denmark according to European guidelines[14] and national protocols designed by the DBCG.[13]

The primary aim of this study was to investigate whether breast reconstruction with a tissue expander and implant caused additional risk for PPBCT in comparison to mastectomy without reconstruction. Secondarily, the aim was to examine the prevalence of sensory disturbances, lymphoedema and functional impairment in the same population.

Methods

Study design and setting

The study was a nationwide cross-sectional questionnaire study comparing breast cancer patients treated with mastectomy with or without breast reconstruction. Data were collected between 1 January and 30 April 2008 in conjunction with a study of prevalence of persistent pain in a nationwide cohort of patients treated for breast cancer in Denmark in 2005 and 2006, using an identical questionnaire.[2,11] Reminders were sent after 3 weeks. Data were collected in two separate cohorts: one cohort consisted of patients treated with mastectomy without reconstruction and the other cohort consisted of patients treated with various types of breast reconstruction. The latter was subsequently sorted according to breast reconstruction modality. By 1 June 2008, 1131 of 1347 (84%) questionnaires had been returned from the cohort of patients treated with mastectomy without reconstruction and 264 of 319 (83%) from the cohort of patients treated with breast reconstruction. Data collection was done at Rigshospitalet, Copenhagen, Denmark.

Participants

Patients were identified in the DBCG database. This database prospectively collects data on treatment and disease characteristics.[13] Inclusion criteria were women aged between 18 and 69 years, treated with mastectomy for primary operable breast cancer. Exclusion criteria were patients with treatment not following the DBCG treatment protocol, recurrence or new primary breast cancer, other malignancy and emigration. Moreover, reconstructive surgical treatment (including replacement of the expander prosthesis with a permanent breast implant) had to be finished before 30 September 2007 resulting in a minimum of 3 months' follow-up. Data on patients who had received reconstructive surgery were retrieved from the Danish National Patient Registry (NPR),[15] where all treatment in the Danish health-care system is reported, as a prerequisite for funding. Further identification of treatment details in patients with a reconstruction was done by obtaining patient records. The study has been approved by the Danish Data Protection Agency (J.nr 2007-58-0015) and by the Regional Bioethics committee of the capital region of Denmark, H-D-2007-0099. This study is registered in clinicaltrials.gov, NCT01738048.

Treatment

The surgical and adjuvant treatments were standardised according to DBCG guidelines; surgical treatment consisted of mastectomy with either sentinel lymph node biopsy (SLNB) or ALND levels I and II. Radiotherapy and chemotherapy were offered to patients according to their risk profiles. Patients allocated to chemotherapy received cyclophosphamide, epirubicin and fluorouracil according to the DBCG04 protocol.[13] Patients with hormone receptor-positive tumours were offered endocrine treatment, if