



Original article

A nationwide pathology study on surgical margins and excision volumes after breast-conserving surgery: There is still much to be gained



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ABSTRACT

Aim of the study: The current study aims to assess margin status in relation to amount of healthy breast tissue resected in breast-conserving surgery (BCS) on a nationwide scale.

Methods: Using PALGA (a nationwide network and registry of histology and cytopathology in the Netherlands), all patients who underwent BCS for primary invasive carcinoma in 2012–13 were selected (10,058 excerpts). 9276 pathology excerpts were analyzed for a range of criteria including oncological margin status and distance to closest margin, specimen weight/volume, greatest tumor diameter, and with or without localization method. Calculated resection ratios (CRR) were assessed to determine excess healthy breast tissue resection.

Results: Margins for invasive carcinoma and in situ carcinoma combined were tumor-involved in 498 (5.4%) and focally involved in 1021 cases (11.0%) of cases. Unsatisfactory resections including (focally) involved margins and margins ≤ 1 mm were reported in 33.8% of patients. The median lumpectomy volume was 46 cc (range 1–807 cc; SD 49.18) and median CRR 2.32 (range 0.10–104.17; SD 3.23), indicating the excision of 2.3 the optimal resection volume.

Conclusion: The unacceptable rate of tumor-involved margins as well as margins ≤ 1 mm in one third of all patients is also achieved at the expense of healthy breast tissue resection, which may carry the drawback of high rates of cosmetic failure. These data clearly suggest the need for improvement in current breast conserving surgical procedures to decrease tumor-involved margin rates while reducing the amount of healthy breast tissue resected.

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Background

Breast-conserving therapy (BCT) involves a combination of lumpectomy and adjuvant radiotherapy and is currently the treatment of choice for early stage breast cancer. The two main goals of breast-conserving surgery (BCS) are to obtain tumor-free resection

margins and achieve good cosmetic outcomes and thereby maintain quality of life. Obtaining tumor-free resection margins is important as it avoids the need for additional local treatments such as radiotherapy boost, re-excision or mastectomy [1–4]. Internationally, palpable tumors and non-palpable tumors are excised using different operative techniques. It should be stressed that the excision of palpable breast cancer is mostly based on the tactile (blind) skills of the surgeon, and that the excision of non-palpable breast cancer requires an intra-operative localization method such as wire-guided excision, radio occult lesion localization (ROLL), iodine-125 seeds localization or ultrasound guidance.

Incidences for tumor-involved margins in BCS have been reported in literature worldwide in up to 40% of patients [3,5–7].

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However, direct comparison of studies is difficult due to the use of varying definitions for positive margins, for instance “close margin” is used for either a positive and negative margin. Internationally, close margins are defined as tumor cells ≤ 1 mm from the resection margin.

In the United Kingdom previous guidelines recommended a margin >2 mm, however current guidelines do not encompass a clear definition on margin status and they recommend breast units to have local guidelines regarding acceptable margin width [8]. For instance Danish National Guidelines recommend tumor-free margins ≥ 2 mm [9]. Amongst others, Germany, Scotland and France, in contrast to the United Kingdom, have national and regional BCS guidelines on margin status which indicate that margins should be >1 mm, and that patients with margins ≤ 1 mm should undergo additional surgery [10–12].

Other countries, such as the Netherlands and the United States, have guidelines for BCS stating that tumor-free margins are all specimens without tumor-cells at the inked margins, and that these patients do not necessitate a re-excision [13,14]. However, two surveys in the United States have reported that 85% of breast surgeons do not accept a margin ≤ 1 mm [15,16]. Another survey performed in 2014 by Parvez et al. describes that, respectively, only 20% and 8% of the responding Canadian and American breast surgeons would never recommend a re-excision when the tumor is <2 mm of the closest margin, meaning that the remaining surgeons could recommend a re-excision in patients with tumor negative margins [17]. The latter results in re-excisions to attain wider clear margins although this is against the national breast cancer guidelines [18].

Despite the international controversy regarding the definition of tumor margins, it is important to note that a tumor-free resection margin of >1 mm is unrelated to local recurrence or overall survival, and local recurrence rates range from 2% to 5% [1,3,19–22].

Although the secondary goal of BCS is a satisfactory cosmetic outcome, cosmetic failures still occur in up to 30% of cases [23–26]. Factors influencing cosmetic outcomes include the volume of resected breast tissue [27], the site of the tumor [28,29], post-operative wound complications [30] and the amount of radiotherapy, including the radiotherapy boost (which increases the total amount of Gy administered) [30–32].

Of these factors, the total lumpectomy volume has a major impact on cosmetic outcomes following BCS and is considered the main determinant [27,33]. Literature shows that cosmetic failure rates are significantly higher when a lump exceeds 50–85 cm³, regardless of the size of the breast [27,31–33]. The lumpectomy volume is determined by the size of the tumor and the amount of healthy breast tissue resected. A way to quantify excess healthy breast tissue resection is by using the Calculated Resection Ratio (CRR) [7].

In recent years, indicators in breast cancer care have been formulated in a number of countries [34]. After a careful review of literature, quality indicators have been established from diagnostic work-up, to treatment and to follow-up. However, quality indicators for specimen volume, cosmetic outcome or quality of life are lacking. In the Netherlands quality indicators have been formulated in order to improve breast cancer care. One of the indicators is achieving tumor-free margins for invasive breast cancer in at least 85% of patients, thereby fulfilling the primary goal of BCS. However, the secondary goal of achieving a satisfactory cosmetic outcome with BCS and issues such as excision volume or resection of excess healthy breast tissue are not addressed by any indicator. Therefore the Dutch national guidelines solely concentrate on the oncological outcomes whilst ignoring possible consequences due to excess healthy breast tissue resection, such as poor cosmetic outcomes. This exclusive focus on the primary goal of BCS has made

the attainment of tumor-free resection margins paramount. While a large volume of resected tissue could improve the chances of achieving tumor-free resection margins, this approach may impair final cosmetic results.

A better understanding of this issue will require not only data on tumor involvement, but also data on the volume of healthy breast tissue resected – data that are currently lacking.

The aim of this study is to determine margin status (including margins ≤ 1 mm) in relation to specimen volume and the amount of healthy breast tissue resected in patients with invasive breast cancer who underwent BCS in the Netherlands.

Patients and methods

Patient selection

All women with primary invasive breast cancer undergoing BCS in 2012 and 2013 were prospectively registered in PALGA (a nationwide network and registry of histology and cytopathology in the Netherlands) (a total of 10,058 excerpts) [35]. Patients with solely in situ carcinoma were excluded, as were patients who underwent only a lymph node or breast biopsy, patients who underwent a mastectomy or oncoplastic breast surgery, patients who received neo-adjuvant treatment, patients with metastases and reports lacking margin status. This resulted in the analysis of 9276 pathology excerpts.

Breast cancer pathology excerpts

The information as provided by the PALGA registry, according to National Dutch pathology guidelines, include: report identifier (encrypted patient identifiers ensuring patient privacy), date of specimen receipt, gender, age, pathology excerpt conclusion, pathological macroscopy report, excision method, tumor-involvement, type of carcinoma and greatest diameter of tumor. In the Netherlands, all pathology reports on breast conserving surgery should at least include a description of these items.

Patients, tumors and excision methods

Pathology excerpts described several tumor types, which we categorized as invasive ductal carcinoma, invasive lobular carcinoma and “other” (all other tumor types).

Five excision methods were initially defined but we chose to group them as ‘excision without localization’ (standard lumpectomy, wide local excision and segmentectomy) and ‘excision with localization’ (majority wire-guided excision and minority iodine-125 seeds). Ultrasound-guided surgery and radio occult lesion localization (ROLL) were not described in pathology excerpts, and could theoretically be in both with and without localization groups.

Margin status

According to Dutch national guidelines, resection margin status is categorized as tumor-free, focally involved or as a tumor-involved margin. A tumor-free margin is defined as the absence of tumor cells at the inked margins of the specimen, focally-involved margins show an area of tumor cells ≤ 4 mm, while specimens with tumor-involved margins have grossly distinguishable tumor at the inked edge of the specimen [13]. Close margins are defined as tumor cells ≤ 1 mm from the closest margin and were also assessed, as internationally close margins may have clinical consequences such as re-excision or even mastectomy [8,10,12,36].

As additional unexpected carcinoma in situ can be found during pathological examination, the present study also assessed margin status for patients with limited or extensive carcinoma in situ, in combination with the invasive carcinoma. Both the margin status

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