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## Breast

### De-escalation of radiotherapy after primary chemotherapy in cT1-2N1 breast cancer (RAPCHEM; BOOG 2010-03): 5-year follow-up results of a Dutch, prospective, registry study.

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## BACKGROUND

Primary chemotherapy in breast cancer poses a dilemma with regard to adjuvant locoregional radiotherapy, as guidelines for locoregional radiotherapy were originally based on pathology results of primary surgery. We aimed to evaluate the oncological safety of de-escalated locoregional radiotherapy in patients with cT1-2N1 breast cancer treated with primary chemotherapy, according to a predefined, consensus-based study guideline.

## METHODS

In this prospective registry study (RAPCHEM, BOOG 2010-03), patients referred to one of 17 participating radiation oncology centres in the Netherlands between 1 Jan 2011, and 1 Jan 2015, with cT1-2N1 breast cancer (one to three suspicious nodes on imaging before primary chemotherapy, of which at least one had been pathologically confirmed), and who were treated with primary chemotherapy and surgery of the breast and axilla were included in the study. The study guideline comprised three risk groups for locoregional recurrence, with corresponding locoregional radiotherapy recommendations: no chest wall radiotherapy and no regional radiotherapy in the low-risk group, only local radiotherapy in the intermediate-risk group, and locoregional radiotherapy in the high-risk group. Radiotherapy consisted of a biologically equivalent dose of 25 fractions of 2.0 Gy, with or without a boost. During the study period, the generally applied radiotherapy technique in the Netherlands was forward-planned or inverse-planned intensity modulated radiotherapy. Five-year follow-up was assessed, taking into account adherence to the study guideline, with locoregional recurrence rate as primary endpoint. We hypothesised that five-year locoregional recurrence rate would be less than 4.0% (upper-limit 95% CI 7.8%). This study was registered at ClinicalTrials.gov, NCT01279304, and is completed.

## FINDINGS

838 patients were eligible for five-year follow-up analyses: 291 in the low-risk group, 370 in the intermediate-risk group, and 177 in the high-risk group. The five-year locoregional recurrence rate in all patients was 2.2% (95% CI 1.4-3.4). The five-year locoregional recurrence rate was 2.1% (0.9-4.3) in the low-risk group, 2.2% (1.0-4.1) in the intermediate-risk group, and 2.3% (0.8-5.5) in the high-risk group. If the study guideline was followed, the locoregional recurrence rate was 2.3% (0.8-5.3) for the low-risk group, 1.0% (0.2-3.4) for the intermediate-risk group, and 1.4% (0.3-4.5) for the high-risk group.

## INTERPRETATION

In this study, the five-year locoregional recurrence rate was less than 4%, which supports our hypothesis that it is oncologically safe to de-escalate locoregional radiotherapy based on locoregional recurrence risk, in selected patients with cT1-2N1 breast cancer treated with primary chemotherapy, according to this predefined, consensus-based study guideline.

