



# READ IT BEFORE YOUR PATIENTS

## Breast

### Hypofractionated Versus Standard Fractionated Radiotherapy in Patients With Early Breast Cancer or Ductal Carcinoma In Situ in a Randomised Phase III Trial: The DBCG HYPO Trial.

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#### PURPOSE

Given the poor results using hypofractionated radiotherapy for early breast cancer, a dose of 50 Gy in 25 fractions (fr) has been the standard regimen used by the Danish Breast Cancer Group (DBCG) since 1982. Results from more recent trials have stimulated a renewed interest in hypofractionation, and the noninferiority DBCG HYPO trial (ClinicalTrials.gov identifier: NCT00909818) was designed to determine whether a dose of 40 Gy in 15 fr does not increase the occurrence of breast induration at three years compared with a dose of 50 Gy in 25 fr.

#### PATIENTS AND METHODS

One thousand eight hundred eighty-two patients > 40 years of age who underwent breast-conserving surgery for node-negative breast cancer or ductal carcinoma in situ (DCIS) were randomly assigned to radiotherapy at a dose of either 50 Gy in 25 fr or 40 Gy in 15 fr. The primary end point was three-year grade 2-3 breast induration assuming noninferiority regarding locoregional recurrence.

#### RESULTS

A total of 1,854 consenting patients (50 Gy, n = 937; 40 Gy, n = 917) were enrolled from 2009-2014 from eight centers. There were 1,608 patients with adenocarcinoma and 246 patients with DCIS. The three-year rates of induration were 11.8% (95% CI, 9.7% to 14.1%) in the 50-Gy group and 9.0% (95% CI, 7.2% to 11.1%) in the 40-Gy group (risk difference, -2.7%; 95% CI, -5.6% to 0.2%; P = .07). Systemic therapies and radiotherapy boost did not increase the risk of induration. Telangiectasia, dyspigmentation, scar appearance, oedema, and pain were detected at low rates, and cosmetic outcome and patient satisfaction with breast appearance were high with either no difference or better outcome in the 40-Gy cohort compared with the 50-Gy cohort. The nine-year risk of locoregional recurrence was 3.3% (95% CI, 2.0% to 5.0%) in the 50-Gy group and 3.0% (95% CI, 1.9% to 4.5%) in the 40-Gy group (risk difference, -0.3%; 95% CI, -2.3% to 1.7%). The nine-year overall survival was 93.4% (95% CI, 91.1% to 95.1%) in the 50-Gy group and 93.4% (95% CI, 91.0% to 95.2%) in the 40-Gy group. The occurrence of radiation-associated cardiac and lung disease was rare and not influenced by the fractionation regimen.

#### CONCLUSION

Moderately hypofractionated breast irradiation of node-negative breast cancer or DCIS did not result in more breast induration compared with standard fractionated therapy. Other normal tissue effects were minimal, with similar or less frequent rates in the 40-Gy group. The nine-year locoregional recurrence risk was low.