



# READ IT BEFORE YOUR PATIENTS

## Breast

### Randomised Phase III Trial Evaluating Radiation Following Surgical Excision for Good-Risk Ductal Carcinoma In Situ: Long-Term Report From NRG Oncology/RTOG 9804

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#### PURPOSE

To our knowledge, NRG/RTOG 9804 is the only randomised trial to assess the impact of whole breast irradiation (radiation therapy [RT]) versus observation (OBS) in women with good-risk ductal carcinoma in situ (DCIS), following lumpectomy. Long-term results focusing on ipsilateral breast recurrence (IBR), the primary outcome, are presented here.

#### PATIENTS & METHODS

Eligible patients underwent lumpectomy for DCIS that was mammogram detected, size  $\leq 2.5$  cm, final margins  $\geq 3.0$  mm, and low or intermediate nuclear grade. Consented patients were randomly assigned to RT or OBS. Tamoxifen use was optional. Cumulative incidence was used to estimate IBR, log-rank test and Gray's test to compare treatments, and Fine-Gray regression for hazard ratios (HRs).

#### RESULTS

A total of six hundred thirty-six women were randomly assigned from 1999 to 2006. Median age was 58 years and mean pathologic DCIS size was 0.60 cm. Intention to use tamoxifen was balanced between arms (69%); however, actual receipt of tamoxifen varied, 58% RT versus 66% OBS ( $P = .05$ ). At 13.9 years' median follow-up, the 15-year cumulative incidence of IBR was 7.1% (95% CI, 4.0 to 11.5) with RT versus 15.1% (95% CI, 10.8 to 20.2) OBS ( $P = .0007$ ; HR = 0.36; 95% CI, 0.20 to 0.66); and for invasive LR was 5.4% (95% CI, 2.7 to 9.5) RT versus 9.5% (95% CI, 6.0 to 13.9) OBS ( $P = .027$ ; HR = 0.44; 95% CI, 0.21 to 0.91). On multivariable analysis, only RT (HR = 0.34; 95% CI, 0.19 to 0.64;  $P = .0007$ ) and tamoxifen use (HR = 0.45; 95% CI, 0.25 to 0.78;  $P = .0047$ ) were associated with reduced IBR.

#### CONCLUSION

RT significantly reduced all and invasive IBR for good-risk DCIS with durable results at 15 years. These results are not an absolute indication for RT but rather should inform shared patient-physician treatment decisions about ipsilateral breast risk reduction in the long term following lumpectomy.