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### **Breast**

## Ten-Year Results of FAST: A Randomised Controlled Trial of 5-Fraction Whole-Breast Radiotherapy for Early Breast Cancer

Brunt AM, Haviland JS, Sydenham M, Agrawal RK, Algurafi H, Alhasso A, Barrett-Lee P, Bliss P, Bloomfield D, Bowen J, Donovan E, Goodman A, Harnett A, Hogg M, Kumar S, Passant H, Quigley M, Sherwin L, Stewart A, Syndikus I, Tremlett J, Tsang Y, Venables K, Wheatley D, Bliss JM, Yarnold JR.

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#### PURPOSE

Previous studies of hypofractionated adjuvant whole-breast radiotherapy for early breast cancer established a 15- or 16-fraction (fr) regimen as standard. The FAST Trial (CRUKE/04/015) evaluated normal tissue effects (NTE) and disease outcomes after five-fr regimens. Ten-year results are presented.

#### METHODS

Women  $\geq$  50 years of age with low-risk invasive breast carcinoma (pT1-2 pN0) were randomly assigned to 50 Gy/25 fr (five weeks) or 30 or 28.5 Gy in five once-weekly fr of 6.0 or 5.7 Gy. The primary end point was change in photographic breast appearance at two and five years; secondary end points were physician assessments of NTE and local tumor control. Odds ratios (ORs) from longitudinal analyses compared regimens.

#### RESULTS

A total of 915 women were recruited from 18 UK centers (2004-2007). Five-year photographs were available for 615/862 (71%) eligible patients. ORs for change in photographic breast appearance were 1.64 (95% Cl, 1.08 to 2.49; P = .019) for 30 Gy and 1.10 (95% Cl, 0.70 to 1.71; P = .686) for 28.5 Gy versus 50 Gy.  $\alpha/\beta$  estimate for photographic end point was 2.7 Gy (95% Cl, 1.5 to 3.9 Gy), giving a 5-fr schedule of 28 Gy (95% Cl, 26 to 30 Gy) estimated to be isoeffective with 50 Gy/25 fr. ORs for any moderate/marked physician-assessed breast NTE (shrinkage, induration, telangiectasia, edema) were 2.12 (95% Cl, 1.55 to 2.89; P < .001) for 30 Gy and 1.22 (95% Cl, 0.87 to 1.72; P = .248) for 28.5 Gy versus 50 Gy. With 9.9 years median follow-up, 11 ipsilateral breast cancer events (50 Gy: 3; 30 Gy: 4; 28.5 Gy: 4) and 96 deaths (50 Gy: 30; 30 Gy: 33; 28.5 Gy: 33) have occurred.

#### CONCLUSION

At 10 years, there was no significant difference in NTE rates after 28.5 Gy/5 fr compared with 50 Gy/25 fr, but NTE were higher after 30 Gy/5 fr. Results confirm the published 3-year findings that a once-weekly 5-fr schedule of whole-breast radiotherapy can be identified that appears to be radiobiologically comparable for NTE to a conventionally fractionated regimen.