**FAST Phase III RCT of Radiotherapy Hypofractionation for Treatment of Early Breast Cancer: 10-Year Results (CRUKE/04/015)**

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**Purpose/Objective(s):** The UK FAST trial tested 5 fractions (Fr) of 5.7 Gy and 6.0 Gy against 25 Fr of 2.0 Gy in women prescribed whole breast radiotherapy (no boost) after local excision of early breast cancer. Analysis

of primary endpoint (normal tissue effects [by photograph]) showed that the 28.5 Gy/5 Fr regimen appeared similar to control. Further follow-up now enables analysis of 10-year outcomes.

**Materials/Methods:** The FAST trial (ISRCTN62488883) randomised women aged ≥50 years with invasive breast carcinoma (pT1-2 pN0) to 3 whole breast radiotherapy schedules: 50 Gy in 25 Fr over 5 weeks (control), 30 Gy or 28.5 Gy in 5 Fr over 5 weeks (1:1:1). Exclusion criteria were planned lymphatic/breast boost radiotherapy or (neo)adjuvant cytotoxic therapy. Normal tissue effects (NTE) were assessed annually to 10 years by clinicians and photographs at 2 and 5 years compared with a preradiotherapy baseline. Breast tumour recurrence was a secondary endpoint.

**Results:** 915 women were recruited from 18 UK centres (2004-2007). Composite endpoint of any clinician-assessed breast NTE showed significantly higher levels at 5 and 10 years for 30 Gy compared with 50 Gy (Table). Prevalence of marked NTEs at 5 and 10 years were very low. Compared with 50Gy excess of moderate/marked effects for 30Gy were: 5 years +10.5%, 95%CI 4.9 to 16.1%; 10 years +9.4%, 95%CI 1.1 to 17.6% and for 28.5 Gy, were +2.4%, 95%CI -2.5 to 7.3%at 5 years and +5.5%, 95%CI -2.3 to 13.3%at 10 years. At 9.9 years median followup, 10 local recurrences (50Gy: 3, 30Gy: 3, 28.5Gy: 4) and 96 deaths (50 Gy: 33, 30 Gy: 33, 28.5 Gy: 30) have been reported.

**Conclusion:** Marked NTEs were rare for all schedules. Late moderate/marked NTE after 28.5Gy/5 Fr/5 weeks were similar to 50Gy/25 Fr/5 weeks, but higher after 30Gy/5 Fr/5 weeks. Local recurrence rates were very low at 10 years for all schedules. Further research of a 5-Fr regimen is warranted; the UK FAST-Forward trial is testing 5 Fr delivered in 1 week. 15 or 16-Fr schedules of adjuvant radiotherapy for early breast cancer have now been shown to be effective and safe but a once-weekly 5-Fr schedule may be considered for patients in whom a daily visit for 3 or 5 weeks is not acceptable however careful consideration of the dose per Fr is required.