

NEWS BRIEFING 1

PLENARY

3 Adjuvant Radiotherapy Improves Regional (Lymph Node Field) Control In Melanoma Patients After Lymphadenectomy: Results Of An Intergroup Randomised Trial (TROG 02.01/ANZMTG 01.02)

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Purpose/Objective(s): Adjuvant Radiotherapy after lymphadenectomy for isolated lymph node relapse of melanoma has been used for patients at high risk of further regional relapse. The only data available to support this strategy comes from retrospective and phase II trials. This report presents the results of the first randomised trial designed to assess the effect of RT on the subsequent risk of regional relapse and survival.

Materials/Methods: This is a multicentre randomised trial of patients at high risk of regional relapse. Inclusion criteria included ≥ 1 parotid, ≥ 2 cervical or axillary or ≥ 3 groin positive nodes; or extra nodal spread of tumour; or minimum metastatic node diameter of 3cm (neck or axilla) or 4cm (groin). After lymphadenectomy patients were randomised to receive radiotherapy (RT; 48Gy in 20 fractions) or initial observation (Obs). Guidelines for techniques used at each of the node sites were developed in a preceding study. Relapsed patients with isolated disease in the Obs arm could be offered further surgery followed by RT. Regional relapse, as a 1st relapse, was the primary endpoint; morbidity, QOL, patterns of relapse, disease free and overall survival were secondary endpoints. A target sample size of 250 enabled a difference in 3 year relapse rates of 30% and 15% to be detected (using a 2-sided logrank test) with a power of 80%.

Results: 250 patients from 16 centres were randomised from Mar 02 to Sept 07 (123 RT; 127 Obs). 2 patients withdrew consent and 31 were excluded from the primary analysis of regional relapse following an independent blinded review by two reviewers of eligibility compliance, leaving 217 patients (109 RT, 108 Obs). Median follow-up was 27 months. Compliance to the RT protocol was 79%. There was a statistically significant improvement in lymph node field control with radiotherapy: 20 RT and 34 Obs patients relapsed regionally (HR 1.77; 95% CI 1.02-3.08; $P=0.041$). Median survival times were 31 months (RT) and 47 months (Obs) ($P=0.14$).

Conclusions: Adjuvant radiotherapy improved regional control in melanoma patients at high risk of regional relapse after lymphadenectomy, although there was no statistically significant effect on survival.

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