IMMUNOTHERAPY

Recurrence-free survival versus quality of life—where do we draw the line?

Interferon alpha (INF- α) is widely used as adjuvant therapy for patients with melanoma. Although this treatment improves recurrence-free survival and distant-metastasis-free survival, it is associated with notable adverse effects, and few studies have demonstrated an overall survival advantage. Therefore, health-related quality of life (HRQOL) must be carefully assessed. A study by Bottomley *et al.* demonstrated a significant and sustained improvement in recurrence-free survival with pegylated INF- α -2b (PEG-INF- α -2b) in patients with stage III melanoma; however, there was a negative effect on HRQOL.

The researchers enrolled 1,256 patients with stage III melanoma who had undergone full lymphadenectomy. Patients were randomly assigned to receive PEG-INF- α -2b at an induction dose of 6 μ g/kg weekly for 8 weeks followed by a maintenance dose of

3 μ g/kg weekly for 5 years ($n=627$), or observation ($n=629$). HRQOL was assessed by the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30, which measures five functioning scales (physical, role, emotional, cognitive and social), three symptom scales (fatigue, nausea/vomiting and pain), six single-item scales (dyspnea, sleep disturbance, appetite loss, constipation, diarrhea and financial impact) and the Global Health scale.

“There was a significant decrease in global HRQOL...”

At a median follow-up of 3.8 years, PEG-INF- α -2b decreased the risk of recurrence by 18% compared with the observation arm. There was a significant decrease in global HRQOL at 3 months

and 2 years for patients treated with PEG-INF- α -2b. The researchers found worse scores for two functioning scales (social role and functioning) and three symptom scales (appetite loss, fatigue and dyspnea) for patients who received PEG-INF- α -2b treatment.

“Although adjuvant PEG-INF- α -2b had a significant sustained impact on recurrence-free survival, it had a negative impact on global HRQOL and on patient functioning and symptoms compared with the observation arm,” conclude the researchers.

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Original article Bottomley, A. *et al.* Adjuvant therapy with pegylated interferon alfa-2b versus observation in resected stage III melanoma: a phase III randomized controlled trial of health-related quality of life and symptoms by the European Organisation for Research and Treatment of Cancer Melanoma Group. *J. Clin. Oncol.* **18**, 2916–2923 (2009).