than expected. This study confirms OS benefit of IPI in treatment-naïve metastatic melanoma.
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9319 POSTER

A Regional Review of Outcomes of Systemic Therapy in Patients With Metastatic Malignant Melanoma

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Background: The incidence of malignant melanoma (MM) has risen steadily over recent decades. NCI data from 2005–2007 have suggested that 1.93% of individuals born today in the US will develop melanoma at some stage [1]. Approximately 15% of patients with MM either present with metastatic disease or develop metastases during the course of their illness. Unfortunately, metastatic MM remains a challenge with limited treatment options and median overall survival (OS) reported as 6−9 months. Dacarbazine (DTIC) remains the standard first line treatment with published response rates of less than 10% and infrequent durable responses. We reviewed our data for the treatment of metastatic MM over a period of four years.
Material and Methods: Data from all patients with metastatic MM treated with systemic therapy outwith clinical trials from 2006 to 2009 were reviewed. Response rate was determined as per RECIST criteria.
Results: Sixty-four patients were treated with one or more lines of cytotoxic therapy. Median age was 62 years (range 23−82 years) with 53% males. Primary site of disease was skin in 75%, mucosal in 12.5%, ocular in 9.3% and nodal with occult primary in 3.1%. Visceral metastases were present in 75% of patients at the start of treatment, including pulmonary (39.6%) and hepatic (34.4%). All patients were screened for brain metastases: these were present in 26.5% of patients. ECOG performance status (PS) was 0 in 7.8%, 1 in 68.7%, 2 in 9.4% and undocumented in the remaining 14%. Patients without brain metastases received single agent DTIC first-line; those with brain metastases received temozolomide. Response rate was 7% for DTIC and 28% for temozolomide, with median progression free survival (PFS) of 2.1 and 2.4 months respectively. Seven patients who received DTIC are alive on follow-up, 2 have ongoing stable disease post-DTIC at 41 months and 18 months respectively. Second line therapy with vinblastine was given to 21 patients (32%), with a response rate of 9.5% and median PFS of 3.4 months. Median OS from initiation of therapy was 7.7 months for DTIC and 3.6 months for patients with brain metastases receiving temozolomide. PS of 2 was associated with shorter median OS (2.0 months).
Conclusions: Our results are comparable to those in published data [2]. MM is a disease with rising incidence and limited treatment options. These patients are best treated in the context of clinical trials as new targeted therapies are promising as future strategies.

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9320 POSTER

PolyMEL, a Polyepitope DNA Vaccine − Results From a Phase 1 Study for Metastatic Melanoma

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Background: Metastatic melanoma carries a poor prognosis. Although promising therapies are emerging, new approaches are still needed.
Materials and Methods: A phase I dose escalation study with PolyMEL, a DNA polyepitope vaccine encoding 8 nine-amino acid epitopes derived from 45 shared melanoma antigens, was devised. The objectives of this study were to establish the safety and feasibility of DNA vaccination with polyMEL, to determine the maximum tolerated dose, and to see whether polyMEL vaccination elicits a clinical anti-tumour response. Cohorts of 3 patients with stage IV melanoma who were either HLA-A1 or -A2 positive received 3 intramuscular injections of increasing doses of polyMEL DNA vaccination: 30 μg, 100 μg, 300 μg or 1000 μg/ injection.
Results: 15 patients were entered into the trial between October 2003 and September 2008. Two patients withdrew early from the study with clinical deterioration and were replaced, and a third was found to have brain metastases at baseline and did not receive study drug. 12 patients were therefore assessable for response, and 14 were assessable for toxicity. Nine patients had cutaneous melanoma and five had ocular melanoma. The vaccine was well tolerated, with no haematological or biochemical toxicity, and mainly grade 1 or 2 non-haematological toxicity. All 9 patients with cutaneous melanoma had progressive disease at the end of the study protocol. By contrast, 3 of the 5 patients with ocular melanoma had stable disease at the end of the study protocol (60% disease control rate), and 2 had progressive disease. Median progression-free survival was 64 and 102 days for patients with cutaneous or ocular primary melanoma respectively, and the respective median overall survival was 182 and 336 days.
Conclusions: Administration of polyMEL polyepitope vaccine at doses ranging from 30 μg to 1000 μg, given every 2 weeks to a total of 3 injections, is safe and associated with minimal toxicity. The tolerability of polyMEL should allow its combination with established or experimental agents in future studies. Patients with ocular melanoma had better outcomes compared with patients with metastatic cutaneous melanoma. This agent may therefore be of particular interest for patients with metastatic ocular melanoma, for whom no effective treatment exists.

9321 POSTER

Prognostic Factors in a Cohort of Dacarbazine Treated Patients for Metastatic Melanoma

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Background: Incidence and mortality of melanoma in Europe is increasing. Metastatic melanoma (mM) has poor prognosis with 5-year survival rates of 15%. Dacarbazine (DTIC) is considered a standard treatment for mM despite response rates of 10−20% and median response duration 3−6 months. Our purpose was to identify prognostic factors associated with improved survival in mM patients (pts) treated with DTIC.
Methods: Retrospective cohort study, in a Portuguese cancer centre, of mM pts treated with DTIC as 1st line systemic treatment. Survival time was defined as a difference between the start date of DTIC and death. Pts alive were censored on the date they were last seen in the clinic. Potential prognostic variables were assessed in univariate analysis with a log rank test and in multivariate analysis through a Cox proportional hazards model.
Results: From 2005 through 2009, 109 pts with mM were treated with DTIC in our centre. Median age was 58 years (range 20−77), 45% were male and 60% had an ECOG performance status of 0. Visceral metastases were present in 66% of pts.
Half of the patients completed at least 4 cycles of DTIC and 27% completed $\geqslant$ 6 cycles. A relative dose-intensity of DTIC $\geqslant$90% was achieved in 77%. Main reason for treatment interruption was disease progression (68%). Serious adverse events occurred in 19% and 2 pts died on treatment due to unknown causes. Overall response rate was 32% and median duration of response was 3 months (m). Median overall survival was 6 m (95CI: 4.1−7.9).
In univariate analysis, normal LDH was associated with improved survival (median survival: 9 m *vs* 4 m; $p = 0.005$) as was ECOG status 0 *vs* $\geqslant$ 1 (median survival: 8 m *vs* 4 m; $p = 0.013$). Patients with visceral metastases tended to have a worst prognosis (median survival 5 m *vs* 7 m), however this was not statistically significant ($p \geqslant 0.05$). Age and gender had no impact on survival. In multivariate analysis, normal LDH was the only factor associated with increased survival (HR, 0.50; [95CI, 0.28–0.93]).
Conclusion: Of the known prognostic factors in metastatic melanoma only LDH had a significant impact on survival. The small sample size limits the power of our study which may explain our inability to identify other probably less discriminating prognostic factors. The strong prognostic information conveyed by LDH should be incorporated in patient stratification in trials of new treatment for metastatic melanoma.

9322 POSTER

Immunological and Biological Changes and Their Correlation With Clinical Response and Survival During Ipilimumab in Metastatic Melanoma Compassionate Use Program

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Background: Recentely FDA has approved ipilimumab at 3 mg/kg as first and second line of therapy in patients with metastatic melanoma. This is sustained by an impact on overall survival in this setting of patients of 10.1 months. Anyway no clinical parameter has been consistentely found to be a surrogate or a predictive marker for response to ipilimumab therapy