and dysphagia (41.6% vs 24.1%, p = 0.046) compared to those with RCT. Hematologic toxicity was significantly higher in RCT-HT group. Stage 2–4 anemia developed in 43% and 25% (p = 0.004), respectively. No patient developed grade 3+4 neurotoxicity, ototoxicity or nephrotoxicity. Six month after treatment, 100% of survivors reported a dry mouth, with no difference between two groups. Lymph edema was observed in 47% patients in RCT-arm and in 76% in RCT-HT arm (p = 0.04).
Conclusion: Local microwave hyperthermia in combination with radiochemotherapy doesn't improve loco-regional control in patients with advanced pharynx and larynx cancer, but significantly increases toxicity of the treatment.

1029 POSTER

A Phase II study of Sorafenib (BAY 43–9006) in patients with recurrent and/or metastatic head and neck squamous cell carcinoma (HNSCC) and nasopharyngeal cancer (NPC)

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Background: Sorafenib (Bay 43–9006), a novel bi-aryl urea, is a potent inhibitor of kinases of Raf-1 (c-Raf) and BRAF which are critical members of the RAS/RAF/MEK/ERK signalling pathway. In addition, Sorafenib inhibits other pro-angiogenic protein tyrosine kinases, including VEGFR-2/3 and PDGFR-β. Over-expression of these signal transduction and angiogenic markers has been associated with poor prognosis in epithelial malignancies. We conducted a phase II study to examine the efficacy of Sorafenib in advanced HNSCC and NPC.
Methods: Patients (pts) with advanced HNSCC and NPC with measurable disease, no more than one prior chemotherapy regimen for recurrent and/or metastatic disease, performance status (PS) ECOG 0–2, and adequate organ functions were eligible. Sorafenib was administered orally at 400 mg BID on a continuous basis, in 28-day cycles. Responses were evaluated every 8 weeks according to RECIST criteria.
Results: Twenty-three patients have been enrolled (13m/10f). One patient withdrew prior to beginning of treatment, 22 pts were evaluable for toxicity and response. Median age was 53 years (range 37 – 77); 87% had PS 0 or 1 and 13% PS 2; 70% HNSCC and 30% NPC; 15 pts had received prior chemotherapy, 4 had received prior erlotinib and 22 had received prior radiation therapy. One pt (4%) with HNSCC has a confirmed partial response, 9 pts (39%) (4 HNSCC and 5 NPC) had stable disease ranging from 2 to 6 cycles, and 12 pts (52%) had progressive disease. A total of 57 cycles had been administered (median number/patient: 2; range 1–6). No grade 4 toxicity was seen. Main haematological toxicity was grade 3 lymphopenia in 7 (30%) pts. Common grade 3 non-hematological toxicity included non-specific pain in 10 (43%), hyponatremia in 4 (17%), dyspnea in 4 (17%), and infection in 3 (13%) pts. Grade 1/2 non-hematolgical toxicity included fatigue in 21 (91%), hyponatremia in 15 (65%), hypertension in 9 (39%), mucositis in 9 (39%), and hand–foot syndrome in 7 (30%) pts respectively. One pt died of intracranial tumoral hemorrhage, deemed to be unlikely related to treatment. The median survival was 3.6 months with a 6-month survival of 12% (95% CI: 17–58%).
Conclusions: Sorafenib was well tolerated in this group of heavily pre-treated patients. Single agent Sorafenib has similar efficacy as single agent erlotinib or gefitinib in this patient population. Further evaluation of Sorafenib in combination with other agents may be are warranted in these tumor types.

1030 POSTER

Capecitabine and cisplatin combination chemotherapy as salvage therapy for recurrent unresectable or metastatic squamous cell carcinoma of the head and neck

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Background: Head and neck squamous cell carcinoma (HNSCC) accounts for most malignant neoplasm of head and neck. About two thirds of the patients present with locally or regionally advanced disease, and in spite of combined modality including surgery, radiation, and chemotherapy, regional and distant progression occurs in 60% and 25% of these patients, respectively.
This prospective study was conducted to assess the efficacy and safety of the salvage chemotherapy of capecitabine and cisplatin for the patients with relapsed unresectable HNSCC.
Patients and method: Patients with measurable, metastatic or unresectable HNSCC who had received prior systemic chemotherapy (docetaxel and cisplatin regimen) and local treatment such as radiotherapy or surgery were eligible. Treatment consisted of cisplatin (75mg/m^2 as a 2 hours infusion on day 1) and capecitabine (1000 mg/m^2 orally twice daily, on day 2–15), repeated every 21 days.
Results: Twenty four patients were evaluable for toxicity and response. A total of 79 cycle with median of 4 cycles per patients were administered. The most common grade 3/4 hematologic adverse events were neutropenia and anemia, which documented in 5 (21%) and 4 (17%) patients, respectively. The most common treatment-related non-hematologic adverse event (all grades) were diarrhea (58%), hand–foot syndrome (45%), stomatitis (42%), and emesis (38%). However, the majority were tolerable in intensity. Treatment related mortality was absent. Overall The response rate was 42% with 1 complete response (4%) and 9 partial responses (38%). Five patients (21%) were stable disease and 9 patients(38%) presented progressive disease.
Conclusion: This regimen of capecitabine and cisplatin is an effective and tolerable treatment for patients with recurrent unresectable or metastatic HNSCC who are refractory to platinum/taxane-based chemotherapy.

1031 POSTER

Weekly chemotherapy with cisplatin and docetaxel for recurrent metastatic head and neck cancer: a phase II study

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Background: A phase II study was conducted to evaluate the activity and toxicity of a weekly combination of cisplatin and docetaxel in patients with recurrent end-stage head and neck cancer.
Material and methods: From 07/2003 to 11/2004, 21 patients (5 female, 16 male, median age: 60 years) with proven recurrent unresectable head and neck cancer were enrolled. All 21 patients had metastatic neck disease. 7 patients presented additionally with distant metastases. 1 patient was previously treated by surgery alone, 2 had surgery and radiotherapy, and 18 surgery and radiochemotherapy. On an outpatient basis treatment consistent of 25 mg/m^2 cisplatin and 35 mg/m^2 docetaxel once a week for three weeks followed by one week without treatment for each cycle. A maximum of 5 cycles were given. The primary endpoint was median survival. Secondary endpoints were response rate (RECIST), time-to-progression, toxicity (NCI-CTC), and quality-of-life (EORTC QLQC30, QLQHN35).
Results: All 21 patients were assessable for toxicity and quality-of-life analysis. 19 patients were assessable for response analysis. The median number of weeks on chemotherapy was 9 (range: 1–15). 8 patients (38%) had a partial response and 8 patients a stable disease (38%). The median time to progression was 3.5 months (95% CI 2.0–5.0) and the median overall survival was 10.7 months (95% CI 6.4–15.0). The combination was well tolerated, a grade 3 hypohemoglobinemia occurred in 1 patient, and a grade 3 hand–foot skin reaction in another patient. The performance status did not decrease significantly during therapy. The quality-of-life scores did not show a significant alteration during therapy.
Conclusions: The combination of cisplatin and docetaxel, administered weekly in an outpatient setting in a lower dosage than in typical 3-week schedule, is an active regimen in recurrent end-stage head and neck cancer with comparable efficacy to a 3-week schedule. It appears to have a much more favourable toxicity profile in comparison to a 3-week regimen of cisplatin and docetaxel or to other taxane combinations. The work was supported by an unrestricted grant from Sanofi-Aventis