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Single Agent Paclitaxel in Advanced Squamous Cell Head and Neck Carcinoma

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TREATMENT OF recurrent squamous cell carcinomas of the head and neck region (SCHNC) still represents a major challenge for both medical oncologists and radiotherapists. Most chemotherapeutic regimens currently employed include active drugs such as cisplatin, methotrexate, infusional 5-fluorouracil, bleomycin and vinca alkaloids [1, 2]. Recently, paclitaxel, a taxane diterpenoid, isolated and extracted from *Taxus Brevifolia*, has been successfully employed in the treatment of several human malignancies, notably ovarian carcinoma [3]. Initial trials have shown that paclitaxel's maximum tolerated dose depends on the extent of pretreatment, being as high as 250 mg/m^2 every 21 days in previously or minimally pretreated patients, and as low as 175 mg/m^2 in pretreated patients [3, 4]. Recently, Forastiere and associates [5–7] tested paclitaxel at a dose of 250 mg/m^2 as a 24-h continuous infusion, achieving a 40% overall response rate. These interesting results prompted us to test paclitaxel in advanced SCHNC.

With the aim of evaluating the clinical efficacy and toxicity profile of paclitaxel in the treatment of recurrent SCHNC, we carried out a phase II trial on a series of 21 patients. Before entry into the trial, all patients had to fulfil the following entry criteria: verbal informed consent, histologically confirmed diagnosis of recurrent and/or metastatic SCHNC, with the exception of nasopharyngeal origin; performance status according to Karnofsky Index >50; life-expectancy >2 months; absence of uncontrolled metabolic, cardiovascular, infective or renal diseases. Patients were thoroughly staged with physical and othorhinolarygology examination, chest X-ray, abdominal sonogram, CT scan of the head and neck, EKG, haemocromocytometric analysis and routine serum chemistry tests.

The treatment plan included paclitaxel 175 mg/m^2 given in 500 ml of normal saline as a 3-h infusion every 21 days. A premedication with dexamethasone 8 mg plus diphenhydramine 50 mg and ranitidine 50 mg were given intravenously 1 h before paclitaxel administration. Anti-emetic therapy was tropisetron 5 mg, i.v. bolus, 15 min before chemotherapy. Patients were re-staged after three full cycles of chemotherapy with physical examination, ORL examination, chest X-ray and CT scan as needed. Definition of response was based on the standard WHO criteria.

21 patients were treated. There were 19 males (90%) and two females (10%) with a mean age of 61.4 years (range 48–70 years) and a mean performance status according to Karnofsky index of 70 (range 60–90). Tumour sites were tongue (3 patients), oral cavity (6 patients), larynx (10 patients) and maxillary sinus (2 patients). All patients had previous surgery and/or radiotherapy and, at entry, had recurrent disease previously treated with chemotherapy. 15 patients had received neoadjuvant chemotherapy with cisplatin, continuous venous infusion 5-fluorouracil and i.v. bolus vinorelbine (2 patients). 7 patients had received chemotherapy for recurrent disease. One patient was lost to follow-up and so not evaluable. No complete response was seen. Partial tumour regression was recorded in 4 of the 20 evaluable patients (20%) with a mean duration of 4.5+ months (range 3.0+–7.5 months). 6 patients (30%) had stable disease and 10 progressed (50%). The treatment was very well tolerated by most patients with no severe allergic adverse events. Minor allergic reactions, such as skin rash, were noted in 2 cases. All patients experienced alopecia. Leucopenia was recorded in 13 cases (65%): grade 3 leucopenia was observed in 5 patients (25%). Grade 2 thrombocytopenia was seen in 4 cases (20%) and grade 3 thrombocytopenia in 1 case. Despite the pretreatment with cisplatin and 5-fluorouracil, neurotoxicity was not a major side-effect. However, grade 1–2 paresthesias were noted in 11 patients (55%) and grade 2 myalgias in 9 patients. Constipation was a complaint in several cases, but it was not possible to discern if this was due to paclitaxel or the antiemetic therapy. Nausea/vomiting was generally mild, with only 2 patients complaining of grade 3 vomiting.

In conclusion, paclitaxel, given as single agent at a dose of 175 mg/m^2, was well tolerated by most patients with recurrent SCHNC and can be safely given on an outpatient basis. The 20% overall response rate achieved here demonstrates that single agent paclitaxel is active in recurrent SCHNC. However, its degree of efficacy does not seem better than that reported for other drugs both in terms of objective response rate and duration of remission. These data are in accordance with those reported by Thornton and associates [7], where a 25% overall response rate in a series of 26 evaluable patients

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was reported, but are not consistant with those reported by others who used higher doses (250 mg/m^2). Moreover, it should be stressed that our data have been achieved in a series of pretreated patients. Despite these contradictory data, in our opinion, the use of paclitaxel in advanced SCHNC deserves further study and should be carefully evaluated with particular attention to a cost-benefit analysis.

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Primary Ki-1 Lymphoma and the Aetiology of B Symptoms

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PRIMARY Ki-1 POSITIVE anaplastic large cell lymphoma (ALCL) is now recognised as a distinct clinical and pathological entity [1]. It is commonly associated with T cell phenotype, advanced stage disease and extranodal involvement, particularly of the skin. However, it is clear that, despite the histological appearances, cutaneous Ki-1 positive ALCL may pursue a relatively indolent course [2, 3].

We report an unusual case of stage IB E Ki-1 positive ALCL. A 22-year-old woman presented in September 1991 with a 6 month history of drenching sweats, worse over the preceding 2 months and associated with bouts of vomiting, and the recent appearance of a 2 cm subcutaneous mass on the right chest wall below the breast. There was no history of weight loss or other symptoms. The mass was excised under local anaesthetic and the histology was reported as high grade non-Hodgkin's lymphoma of immunoblastic type. Staging investigations failed to show the presence of disease elsewhere, but the drenching sweats and vomiting persisted, and the patient lost 5 kg in weight and the wound did not heal. Within 8 weeks, there was a recurrent mass at the same site, measuring 3 cm diameter. Wide local excision was performed and, on this occasion, the histology was reported as T cell, large cell pleomorphic, non-Hodgkin's lymphoma, positive for Ki-1. After removal of the lesion, the patient's symptoms resolved rapidly and completely and the wound healed. Postoperative radiotherapy was prescribed to the site of excision to prevent further local recurrence (35 Gy in 15 daily fractions using 10 MeV electrons). It is now 4 years since the original presentation and the patient remains well and disease-free. No chemotherapy was ever given.

At the time of the second excision, staging investigations were normal, immunoglobulins were all within the normal range, and an auto-antibody screen was negative. The single positive finding was of discrete rearranged bands, seen with the T cell receptor C-beta probe in Southern blot analysis, indicating the presence of a small, but abnormal T cell clone in peripheral blood. This T cell clone was not detected in the excision biopsy. It was still visible in the peripheral blood 1 month after excision, but at a reduced level, and it had disappeared completely 9 months later.

This good clinical outcome accords with other reported cases of isolated cutaneous Ki-1 positive lymphoma [3] and with the observation that this disease may even regress spontaneously [2]. However, this case is unusual in that the patient had marked constitutional symptoms. Indeed, her sweats were so severe that she had to change clothes several times a day. The mechanism of B symptoms in lymphoma remains unclear, but is rarely associated with small volume stage I disease. In previous series, there have been no reported cases of Ki-1 positive lymphoma isolated to skin, which have had associated B symptoms [3, 4].

Interleukin-6 has been implicated in the development of B symptoms and has been shown to be produced in Ki-1 positive ALCL [5]. Prior to the second excision in this patient, when the sweats were severe, serum was analysed for both IL-6 and tumour necrosis factor (TNF). Neither cytokine was detected.

In conclusion, we report a case of isolated cutaneous Ki-1 positive ALCL which resolved with local excision and postoperative radiotherapy. We are unable to explain the severe B symptoms experienced by the patient, but it appears that they were due to some factor secreted by the tumour and therefore resolved with excision of the tumour. In view of the small volume of disease, this factor must be very potent.

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