O. KANAT*
U. YALCINKAYA†
T. AKBUNAR‡
E. KURT*
T. EVRENSEL*
O. MANAVOGLU*

*Uludag University, Faculty of Medicine, Department of Medical Oncology, Gorukle, Bursa, Turkey; †Uludag University, Faculty of Medicine, Department of Pathology, Gorukle, Bursa, Turkey; ‡Uludag University, Faculty of Medicine, Department of Nuclear Medicine, Gorukle, Bursa, Turkey

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doi:10.1016/j.clon.2007.09.003

Cetuximab is Effective, but more Toxic than Reported in the Bonner Trial

Sir — In 2006, the Scottish Medicines Consortium approved the use of cetuximab concurrently with external beam radiation (EBRT) in patients who have locally advanced squamous cell carcinoma of the head and neck. They have to be of good performance status, but not appropriate for, or are unable to tolerate, concurrent chemoradiation. This followed the publication of the Bonner trial [1]. We present our experience of treating 14 patients with this regimen.

All patients had stage III or IV disease as per TNM staging. Two had disease that required surgical treatment due to bone involvement, but were unfit for a general anaesthetic. All had co-morbidities that precluded the safe administration of concurrent cisplatin chemotherapy, the usual standard of care. They therefore proceeded to EBRT using 68 Gy in 34 fractions with daily treatments Monday to Friday over 6.5 weeks, giving cetuximab 400 mg/m^2 intravenously as a loading dose 1 week before the start of radiotherapy and then cetuximab 250 mg/m^2 weekly until the completion of radiotherapy, receiving a maximum of eight infusions.

Ten patients had oropharyngeal primary tumours, four had laryngeal primaries. Four patients were women, 10 were men. The median age was 67 years (range 55—81). All patients completed the full course of EBRT. Seven (50%) completed the full course of cetuximab. Five patients (36%) developed grade 3/4 toxicity. Of these, two had grade 4 dermatitis within the radiation field, (Fig. 1) three had grade 3 dermatitis within the radiation field, one had grade 4 mucositis and one had grade 3 cetuximab-associated acneiform rash. Ten patients (71%) developed staphylococcal infection requiring antibiotic therapy affecting the skin within the radiation field. Nine patients (64%) required assisted feeding either by nasogastric tube or gastrostostomy.

At the completion of treatment, all patients had a complete response, assessed by a clinical examination, except the two patients who had disease that initially required surgery but were unfit for anaesthetic. In these two patients there has been a partial response, with residual disease confirmed by biopsy.

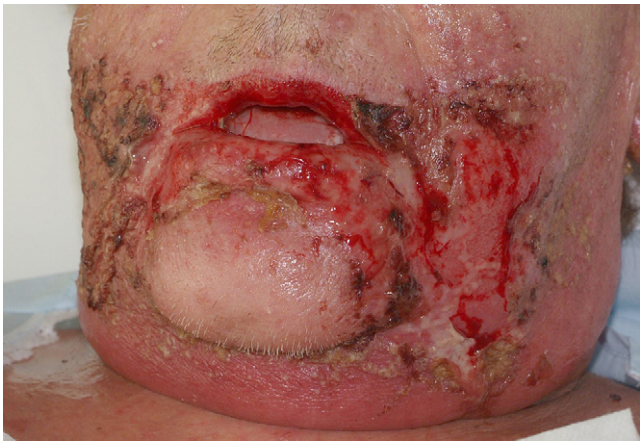

Fig. 1 — Grade 4 skin reaction in a patient receiving concurrent cetuximab and radiotherapy for a head and neck squamous cell carcinoma.

Our experience shows that the combination of cetuximab with EBRT in head and neck cancer patients is successful. It also shows that it is toxic, with an unexpectedly high incidence of grade 3 and 4 toxicity, complicated by staphylococcal infection. This is in contrast to the original trial, but in keeping with other published reports [2,3].

H. K. LORD
E. JUNOR
J. IRONSIDE

Edinburgh Cancer Centre, Edinburgh, UK

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