Male-to-female ratio was 5:2. In more than 90% of cases, the pathology was squamous-cell carcinoma. Adenosquamous carcinoma and adenocarcinoma were less than 10%. Cancers staged as IV, III, and II made up 38.2%, 53.7%, and 10.1% of cases, respectively, and 23.6% of cases involved metastasis. 22 patients (2.63%) had adverse reactions that were unlikely to be due to nimotuzumab, including chills and fever in eight cases (0.96%), rash in five cases (0.6%), oral mucositis in three cases (0.36%), gastrointestinal symptoms (vomiting or diarrhoea) in two cases (0.24%), and dizziness in one case (0.12%). One patient had significant fatigue (0.12%), five had thrombocytopenia (0.6%), and five had decreased white blood-cell count. Nimotuzumab-induced allergy occurred in one case (0.12%).

Interpretation: Nimotuzumab combined with chemotherapy, radiotherapy, or chemoradiotherapy for patients with advanced carcinoma is well tolerated and safe.

Funding: China national Twelfth Five-year Program Funds and Beijing Science Plan.

The authors declared no conflicts of interest.

doi:10.1016/j.ejcsup.2011.02.047

P47 CLINICAL OBSERVATION IN NASOPHARYNGEAL CARCINOMA TREATED WITH ANTI-EGFR MONOCLONAL ANTIBODIES FOLLOWED BY HELICAL TOMOTHERAPY

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Background: We evaluated clinical outcomes and acute toxicity in nasopharyngeal carcinoma treated with tomotherapy followed by anti-EGFR monoclonal antibodies.

Methods: Between March, 2008, and November, 2009, 34 patients with newly diagnosed nasopharyngeal carcinoma were treated with helical tomotherapy combined with nimotuzumab (group N) or cetuximab (group C). All patients received tomotherapy at 70 Gy/33F for the gross tumour volume (pGTVnx) and positive lymph nodes (GTVnd), 60Gy/33F for the high-risk clinical target volume (CTV1), and 56 Gy/33F for the low-risk clinical target volume (CTV2). 17 patients in group N were given a weekly injection of 200 mg/m^2 for 6–7 weeks, and 17 patients in group C were given an initial intravenous dose of 400 mg/m^2 in the first week, followed by weekly injections of 250 mg/m^2 for 6–7 weeks. Acute lesions were evaluated with the RTOG/EORTC criteria.

Findings The median follow-up was 22 months. Effective rates (complete + partial responses) at 3, 6, and 12 months were 82.4% (14/17), 70.6% (12/17), and 70.6% (12/17) in group N, and 88.2% (15/17), 82.4% (14/17), and 82.4% (14/17) in group C. 1-year survival was 88.2% (15/17) in group N and 100% (17/17) in group C. Nimotuzumab was associated with less acute mucositis ($u = 2.245$, $p < 0.05$), weight loss ($t' = 2.563$, $p = 0.0153$) and rash ($u = 4.362$, $p < 0.01$) than cetuximab.

Interpretation: Helical tomotherapy combined with nimotuzumab or cetuximab was effective for nasopharyngeal carcinoma, and there was no difference in short-term efficacy or 1-year survival. Nimotuzumab has fewer acute reactions than cetuximab. More studies should be done to ascertain the long-term effects.

Funding: China national Twelfth Five-year Program Fund and Beijing Science Plan.

The authors declared no conflicts of interest.

doi:10.1016/j.ejcsup.2011.02.048

P48 PILOT STUDY OF TARGETED THERAPY WITH EGFR ANTIBODY (NIMOTUZUMAB) IN PATIENTS WITH UNRESECTABLE HEAD AND NECK CANCER

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Background: We explored the efficacy of biological targeted therapy combined with chemotherapy.

Methods: 71 patients (54 men and 17 women; age 30–83 years, mean 60) were enrolled in this study. All patients had locally advanced oral-maxillofacial and head and neck tumours (no indication for surgery or radiotherapy) confirmed by histology and radiology, with indication for biochemotherapy. The chemotherapy regimen given was cisplatin 75 mg/m^2 day 1, paclitaxel 75 mg/m^2 day 1, fluorouracil 750 mg/m^2 days 1–5, and nimotuzumab 200 mg/m^2 weekly.

Findings: Patients completed 2–4 cycles of chemotherapy (mean 2.2). Nimotuzumab was given 2–8 times (mean 4.3). The prognosis was as follows: complete response in four patients, partial response in 39, stable disease in 18, and progressive disease in 3. Seven patients could not be evaluated. The total effective rate, calculated as complete plus partial responses, was 61%. 29 patients had surgery after biochemotherapy. No serious adverse reactions were noted during the course of the treatment, only one case of slight erythra infection.

Interpretation: Nimotuzumab was effective in increasing chemosensitivity and had a good tolerability profile.

Funding: International Technology Cooperation Fund and Beijing Science Plan.

The authors declared no conflicts of interest.

doi:10.1016/j.ejcsup.2011.02.049

P49 ESCALATING WEEKLY FIXED-DOSE OF NIMOTUZUMAB WITH CONCURRENT CHEMORADIOTHERAPY IN PATIENTS WITH ADVANCED OESOPHAGEAL CANCER – A PHASE 1 STUDY

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