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Nimotuzumab with concurrent chemoradiotherapy in patients with locally advanced head and neck cancer (LASCCHN).

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Background: Nimotuzumab is a humanized monoclonal antibody targeting EGFR receptors. Unlike other anti-EGFR monoclonal antibodies, it has demonstrated to be safe and effective when combined with chemotherapy or/and radiotherapy. We evaluated safety and efficacy of concurrently administrating nimotuzumab with chemo-radiotherapy in patients with locally advanced inoperable squamous cell carcinomas of head and neck region in a usual health care setting. **Methods:** Open-label single-arm study. Patients of age 18 years and above with histologically confirmed squamous cell cancer of head and neck region in an inoperable stage (stage III & IV) having an ECOG ≤ 2 were included in the study. Informed consent was obtained from all the patients. The patient were administered injection cisplatin (30 mg/m^2 IV) and nimotuzumab (200 mg IV) weekly for six weeks along with radiotherapy of 6600cGy over 33 fractions. Patients were evaluated based on RECIST criteria 24 weeks after the last cycle of chemotherapy. **Results:** Fifty seven patients were enrolled in the study. Mean age of the patients was 51yr (29 yr-79 yr). Most common site of cancer was oral cavity 32 (56.14%). Fourty six (80.70%) patients completed 6 cycles of therapy. ORR was 80.7%, 34 with CR (59.6%), 12 with PR (21%), 8 with SD (14%), 3 with PD (5.2%). Most common adverse event seen was mucositis (33%) but there was no grade III or IV adverse event. **Conclusions:** Addition of anti-EGFR monoclonal antibody (nimotuzumab) is safe and efficacious based on the loco-regional response and confirms the available phase II data. The long-term survival benefits based on this encouraging response rate needs to be further evaluated especially in patients with inoperable LASCCN.