

2445 Frequency and Predictors of Parotid Sparing in a Cohort of Patients Managed With Bilateral Neck IMRT for Head and Neck Cancer

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Purpose/Objectives: To assess the frequency of dosimetric parotid sparing and to determine which volumetric and dosimetric quantities affect the degree to which parotids can be spared during intensity modulated radiotherapy of the head and neck.

Materials/Methods: Seventy patients with primary sites in the oral cavity, pharynx or larynx were retrospectively selected from our treatment planning system (Pinnacle 7.6c, Philips Medical Systems, Madison, USA). All cases were planned to receive 70 Gy in 2-Gy fractions to sites of gross disease; bilateral necks including zones 2A and 2B were treated to at least 56 Gy with grossly involved nodes planned to receive 63 or 70 Gy. For planning purposes gross disease volumes were expanded with a margin of at least 2 mm to form CTVs; a margin of 5 mm was added isotropically to CTVs to produce PTVs. Parotid contours included both superficial and deep lobes. Parotid-sparing dose-volume criteria were mean dose, $D_{mean} \leq 26$ Gy, or median dose, $D_{median} \leq 30$ Gy. Patients were treated with 9 equally spaced beams on linacs. Parotids were categorised according to their proximity to gross disease (either nodal or primary) as *ipsilateral*, *contralateral* or *bilateral* for midline primary sites and/or N2c cases. Treatment plans were retrospectively evaluated for parotid doses and coverage of adjacent elective and higher-dose PTVs within 5 mm of the parotid.

Results: One hundred forty parotid volumes in 70 patients were studied. The mean parotid volume was 30 cm³ (range 14.9 to 81.4 cm³). The mean parotid volume outside PTVs was 68.7% (s.d. 16%, min 7%, max 97%). Parotid mean doses ranged from 12 to 71 Gy (mean, 37 ± 16 Gy). Dosimetric sparing of a single parotid was achieved with $D_{mean} < 26$ Gy in 21/70 patients (30%); bilateral sparing was achieved in 3 cases (4%). Median parotid doses <30 Gy in single parotids occurred in 53/70 cases (75%) and bilateral sparing was achieved in 17/70 cases (24%). Parotids contralateral to gross disease were spared in 25 of 27 cases by the $D_{median} < 30$ Gy criterion, and in 16 cases by the $D_{mean} < 26$ Gy criterion. In the presence of bilateral gross disease, 36 of 88 parotids had $D_{median} < 30$ Gy, and 7/88 had $D_{mean} < 26$ Gy. Ipsilateral sparing occurred in 4 of 25 parotids for $D_{median} < 30$ Gy and 1/25 cases for $D_{mean} < 26$ Gy. The frequency of dosimetric parotid sparing was correlated with the fraction of the parotid outside PTVs; no parotids were spared by either criterion when less than 60% of the parotid was outside adjacent PTVs. Parotid volume did not predict mean parotid dose. In the region within 5 mm of parotids with $D_{median} < 30$ Gy, elective PTVs were covered by >97% of the prescribed dose in 17 of 53 cases and gross disease PTVs were covered by >97% of the prescribed dose in 20 of 38 cases.

Conclusions: Dosimetric parotid sparing occurred more frequently with the D_{median} criterion. For the majority of cases it was possible to keep D_{median} of at least one parotid below 30 Gy; however, bilateral parotid sparing with this criterion was achieved in only a quarter of patients and in some cases the resultant dose to adjacent PTVs was compromised. The frequency of sparing correlates with the fraction of parotid outside PTVs. No parotids were spared when less than 60% of the parotid was outside adjacent PTVs. The frequency of dosimetric parotid sparing will depend on the extent of the CTVs and the margins used to generate PTVs.

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2446 BIOMAb EGFRTM (Nimotuzumab/h-r3) in Combination With Standard of Care in Squamous Cell Carcinoma of Head and Neck (SCCHN)

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Purpose/Objective(s): EGFR is over expressed in most malignant tumors of epithelial origin. BIOMAb EGFRTM, a humanized recombinant anti-EGFR mAb acts specifically as an active inhibitor of EGFR resulting in blockade of growth factor binding receptor activation and subsequent signal transduction events. Preclinical studies demonstrated antiproliferative, antiangiogenic and pro apoptotic activity of h-R3.

Materials/Methods: An open label, multicentric randomized study was conducted in India using BIOMAb EGFRTM in combination with RT and Chemotherapy (CT) and Standard RT alone, in treatment of SCCHN.

Subjects with stage III and stage IVA SCCHN suitable for CT + RT and RT alone were randomly assigned to BIOMAb EGFRTM + RT or RT alone and BIOMAb EGFRTM + CT + RT or CT + RT. 80 evaluable subjects were planned to be recruited considering a sample size of 20 per arm. BIOMAb EGFRTM was given at a dose of 200 mg weekly once for 6 weeks. The primary endpoints were Response rates and Safety.

RECIST was used for Tumor evaluation. Adverse events were classified according to toxicity grades [CT-CTC AE (version 3) and RT, (RTOG)].

Results: 76 subjects were evaluable at 24 weeks post treatment: 17 in BIOMAb EGFRTM +RT arm, 19 in RT arm, 20 in BIOMAb EGFRTM +CT+RT and 20 in CT+RT arm.

BIOMAb EGFRTM related toxicity was limited to expected and reversible grade 1 & 2 toxicity. Of these, only chills and rashes were rated as certainly related to BIOMAb EGFRTM.

An objective response rate of 76% was achieved in BIOMAb EGFRTM +RT arm, 40% in RT arm ($p = 0.023$); 100% in BIOMAb EGFRTM +CT+RT arm and 70% in CT +RT arm ($p = 0.020$).

The Overall Survival % at 15 months was 64.7% in BIOMAb EGFRTM + RT arm, 57.9% in RT arm, 95% in BIOMAb EGFRTM +CT+RT arm and 70% in CT + RT arm.

Conclusions: BIOMAb EGFRTM has a favourable safety profile and addition of this drug to standard of care in SCCHN can help to achieve better tumor responses and also increase survival without potentiating toxicity.

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