the patient. Improvement of salivary function after radiotherapy may lead to better swallowing function. In this study we focus on the correlation between prospectively measured parotid salivary output and quality of life items concerning xerostomia and swallowing based on the EORTC H&N questionnaire.
Materials and Methods: Since 1996 we prospectively perform measurements of stimulated parotid salivary output, using Lashley-cups, before and 6 weeks, 6 months and 1 year after radiotherapy. For 167 patients the relative parotid salivary output is correlated with the mean parotid dose and quality of life measurements using the EORTC H&N quality of life questionnaires. The tumour was located in the larynx, pharynx, oral cavity and other locations in 22%, 56%, 10% and 12%, resp. Advanced T-stage and positive nodes were noted in 31% and 50%, resp. Conventional RT, IMRT and Chemo (IMRT) RT was used in 91, 55 and 21 patients, resp. The mean dose of the parotid glands was 34 Gy. A parotid flow complication was defined as <25% of pre-RT flow. For analysis three groups were defined: both (A), one (B), or no parotid glands (C) with a flow complication.
Results: One year after radiotherapy the distribution of group A, B, and C was 27%, 34% and 39%, resp. At one year, on a scale of 1 (not at all) to 4 (severe) the distribution for complaints of dry mouth was 21%, 27%, 33% and 19%, and of sticky saliva 37%, 29%, 25% and 9%, respect. For the same scale, difficulty in swallowing solid food was seen in 50%, 27%, 13% and 11%, resp. Tube feeding was given in 5%, namely after chemoRT (18%). In univariate analysis, the grade of difficulty in swallowing solid food significantly correlated with therapy, tumor localization (grade 4 20% oropharynx, 0% larynx), N-stage, dry mouth and sticky saliva. After logistic regression three independent variables remained: treatment ($p = 0.006$), dry mouth symptom ($p = 0.001$), and, marginally, the number of parotid glands with a complication ($p = 0.04$).
Conclusion: One year after RT swallowing complaints strongly correlated with complaints of a dry mouth, however not with complaints of sticky saliva. Sparing one or both parotid glands was marginally related to swallowing complaints. Sparing one submandibular gland may further decrease dry mouth complaints, and is subject of on-going research.

8513 POSTER

Image guidance with bone matching alone is insufficient for conformal radiation of early glottic cancers − an analysis of laryngeal positional uncertainty based on daily cone beam CT

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Background: Highly conformal radiation therapy for early glottic cancers will require accurate daily image guidance to be safe and maximally spare voice and swallowing function. This study uses daily cone beam CT (CBCT) imaging to investigate the daily positional uncertainties of the glottis during a course of treatment and its relationship to the skeletal anatomy.
Methods: 160 CBCT image-sets of 8 patients with T1aN0M0 glottic cancer treated with intensity modulated radiation therapy (IMRT) with daily kilovoltage CBCT were used in this offline study. Daily setup variations were measured with the Elekta Synergy XVI 4 ® platform using an automatic bone match and a manual match of laryngeal soft-tissues by a radiation oncologist. Discrepancies between these matches were calculated to evaluate the extent of laryngeal displacement in relation to vertebral bodies. An internal target volume (ITV) was generated using the formula suggested by van Herk (2000).

Table 1: Setup errors with different image match protocols

Axis	Manually verified soft-tissue match	Automatic Bone Match	Setup disparity between manual and bone match
ML			
Mean	0.7 mm	0.8 mm	0.7 mm
Range	0.0−2.3 mm	0.1−2.9 mm	−0.1 to +0.7 mm
SE	0.9 mm	1.0 mm	0.4 mm
SI			
Mean	1.1 mm	0.0 mm	2.5 mm
Range	0.1−3.9 mm	0.3−2.9 mm	−1.0 to +5.9 mm
SE	2.0 mm	1.7 mm	2.6 mm
AP			
Mean	0.3 mm	0.7 mm	1.0 mm
Range	0.1−2.0 mm	0.1−1.7 mm	−0.6 to +1.4 mm
SE	0.9 mm	0.9 mm	0.3 mm

SE: systematic error

Results: The mean translational setup errors in the mediolateral (ML), supero-inferior (SI) and antero-posterior (AP) directions for each type of match and the anatomical discrepancies are summarized in Table 1. Errors were most pronounced in the SI axis. There was an anatomical disparity in the bone-match compared to the manual soft-tissue match that was most pronounced in the SI axis (mean 2.5 mm, range −1.0 to +5.9 mm, SD = 2.6 mm) suggesting an independent daily positional variation of the laryngeal soft-tissues relative to the vertebral bodies. The calculated ITV margins for the larynx in relation to the bone match were 2, 8 and 2 mm in the ML, SI and AP axes.
Conclusions: There is a considerable daily variation in laryngeal position in relation to the vertebral anatomy. Image matching based on skeletal anatomy alone is inadequate and should not be regarded as a surrogate for laryngeal position. Image guidance and manual verification of soft-tissue setup errors is essential in order to proceed with highly conformal radiation therapy of early larynx cancer.

8514 POSTER

SPECTRUM, a phase III trial for patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck (SCCHN) receiving chemotherapy with or without panitumumab: interim pooled safety analysis

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Background: Panitumumab (pmab) is a fully human monoclonal antibody against the epidermal growth factor receptor (EGFR), a therapeutic target in patients (pts) with SCCHN. SPECTRUM is assessing the safety and efficacy of pmab + standard platinum-based chemotherapy (CT) in pts with recurrent and/or metastatic (R/M) disease (ClinicalTrials.gov ID: NCT00460265; sponsor: Amgen Inc).
Methods: This is a global, phase III, open-label study. As of March 2009, the trial has completed enrollment of 658 pts. Pts with R/M SCCHN were randomized (1:1) to receive cisplatin (100 mg/m^2) IV on day 1+5 FU (1000 mg/m^2) continuous IV daily on days 1−4 Q3W for up to 6 cycles ± pmab (9 mg/kg). Pts receiving pmab without disease progression after 6 cycles may continue pmab monotherapy until disease progression. Substitution of carboplatin (AUC 5) is allowed for specific toxicities. Primary endpoint is overall survival. Key secondary endpoints include progression-free survival, response rate, and safety. This trial is overseen by an independent Data Monitoring Committee (DMC).

AEs of Interest[a] (N = 446[b])

AE (MedDRA terms)	Any grade, n (%)	Grade 3/4, n (%)
Nausea	248 (56)	24 (5)
Skin and subcutaneous tissue SOC[c]	207 (46)	31 (7)
Neutropenia	206 (46)	141 (32)
Vomiting	177 (40)	23 (5)
Stomatitis/mucosal inflammation	172 (39)	40 (9)
Anemia	166 (37)	64 (14)
Diarrhea	143 (32)	15 (3)
Hypomagnesemia	122 (27)	27 (6)
Fatigue	111 (25)	18 (4)
Anorexia	110 (25)	16 (4)
Thrombocytopenia	91 (20)	29 (7)
Weight decreased	91 (20)	5 (1)
Leukopenia	65 (15)	34 (8)
Febrile neutropenia	29 (7)	27 (6)

[a]Treatment-related (CT ± pmab) grade 5 AEs included cardiac/vascular disorders (n = 8), febrile neutropenia/neutropenia-related complications (n = 4), multi-organ/hepatic or renal failure (n = 3), and 1 each of hemorrhagic diarrhea, tumor hemorrhage and aspiration pneumonia; [b]Excludes 5 pts who did not receive any protocol treatment; [c]SOC, System organ class

Results: Pooled data from this interim safety analysis includes the first 451 pts of 650 planned pts; 99% received any study treatment; 86% are male; median age is 58 years (range 26−84); ECOG PS 0/1 = 33%/67%. Median follow-up time is 17.1 weeks; 85% have ended CT. 18 pts (4%) had