T4 (p = 0.06), N0 (p = 0.0007), RT dose 54 Gy or more (p = 0.006), surgery (p = 0.01), and total resection (p = 0.009) or R0/R1 resection (p = 0.01) in operated patients. In multivariate analysis, best independent factors were T1-T3 (RR = 0.69; p = 0.05), N0 (RR = 0.60; p = 0.05), R0 or R1 resection (RR = 0.33; p = 0.008), and RT dose 54 Gy or more (RR = 0.30; p = 0.007).
Conclusions: Olfacfactory neuroblastoma had the best outcome especially treated with R0/R1 surgical resection followed by at least 54-Gy postoperative RT. Novel therapies including concomitant chemotherapy and/or higher dose IMRT should be prospectively investigated in this rare disease.

1046 POSTER

Dose escalation of daily carboplatin concurrent with accelerated radiation by delayed concomitant boost for locally advanced head and neck cancer

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Background: Accelerated radiation by delayed concomitant boost (AFX-CB) and concurrent chemoradiation represent two major advances in head and neck cancer treatment; however, the optimal regimen integrating these advances has yet to be defined.
Methods: We investigated escalating small daily doses of carboplatin prior to each fraction of AFX-CB to maximize radiosensitization and avoid severe hematologic toxicity. Thirty five patients (27M;8F) with 2002 AJCC Stage II-IVB [12 resectable cancers requiring total laryngectomy and 23 unresectable cases (T4b: 20 or N3: 3)] were treated with AFX-CB to 70 Gy/6weeks (BID RT last 2 weeks) with daily doses of carboplatin escalating from 10 to 17.5 mg/m^2/d and given within 1 hour prior to radiation. Treatment sites were primarily oropharynx n = 16 or larynx n = 12. Dose limiting toxicity (DLT) was defined as NCI common toxicity grade 2 hematologic toxicity or grade Gr 4 mucositis. Erythropoietin (EPO) was initiated if hemoglobin (Hgb) fell below 12 g/dl.
Results: 94% (33/35) completed a full course of chemoradiation. Median radiation dose: 70 Gy (53–71.6 Gy). Ten patients were treated at 10 mg/day; 12 at 12.5 mg, 9 at 15 mg and 4 at 17.5 mg. The maximum tolerated dose was 15 mg/m^2. 9 patients required a treatment break with a median duration of 3 days (1–5d). Grade 2 or 3 hematologic toxicities were as follows: anemia 0%/3%, leukopenia 15%/3% and thrombocytopenia 0%/0%. One patient had a Gr 4 mucositis. Acute Gr 3 toxicities were as follow: 1) mucositis:58%, 2) pharyngitis 58% and 3) dermatitis:12%. Median weight loss was 4.6% (0–14.4%). EPO raised Hgb levels by a median increment of 1.5 g/dl (0.2–3.0 g/dl) and above 12 g/dl in 13 of 15 pts. 3 patients are PEG dependent.
At a median followup of 15 mos, actuarial estimates of 1-year locoregional control are 72% among unresectable cancers and 89% for organ preservation patients. One year overall survival are 77% and 89%, respectively. Distant metastases at 1 year are 24% and 11%, respectively.
Conclusion: The addition of carboplatin to AFX-CB is well tolerated and the MTD is 15 mg/m^2. Organ preservation rates with daily carboplatin are comparable to high-dose cisplatin but without associated severe hematologic toxicity. Daily carboplatin with AFX-CB for unresectable patients yields excellent locoregional control and allows for further intensification of therapy due to its relatively low toxicity profile. EPO can effectively correct mild anemia during chemoradiation.

1047 POSTER

Factors affecting immediate postoperative outcome in surgically treated patients of oral cancers

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Introduction: Due to the tobacco chewing habit, oral cancer is the most common cancer in our country. Most of the patients with these cancers are treated with major ablative surgery with or without flap reconstruction. The goal of this study is to determine the risk factors for post-operative complications and overall morbidity for patients of oral cancers who underwent surgical excision with or without flap reconstruction.
Material and Methods: A prospective study of 185 surgically treated patients of oral cancers was conducted in a tertiary cancer hospital over a period of eight months. These patients were evaluated after various surgical and reconstructive procedures during perioperative and postoperative period. The outcomes were classified into major and minor complications and morbidity was calculated in terms of prolonged hospital stay. Multiple variables were recorded and cross tabulated against major and minor complications. The statistical analysis was done with SPSS 11.5 software using Chi square test and Fisher's exact test.
Results: The major complication rate was 8.1% (15 out of 185 cases) and the minor complication rate was 43.2% (80 out of 185 cases). The total morbidity was 37.5% (69 patients). The univariate analysis showed that requirement of flap reconstruction was the most important prognostic factor for major complications ($p < 0.001$). The factors responsible for minor complications were advanced disease ($P < 0.001$), Blood loss >500 cc ($P < 0.001$), Intra-operative tracheostomy ($P < 0.001$).
Conclusions: The incidence of complications in postoperative setting of advanced oral cancer (T3, T4) is high so also is the morbidity. Various factors which influence the outcome are highlighted and taking adequate precaution would help in progressing towards decreasing the morbidity, complications and hospital burden thus decreasing the hospital stay and improving quality of life.

1048 POSTER

Adjuvant IMRT for esthesioneuroblastoma – the early MD Anderson experience

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Background: Esthesioneuroblastoma is a rare cancer of the sinonasal tract that presents in an anatomically challenging region. Intensity-modulated radiation therapy (IMRT) promises to improve local control without increasing the risk for radiation morbidity. We examined our initial results with the use of IMRT for adjuvant treatment of this disease.
Material and methods: Eight patients presenting with esthesioneuroblastoma were treated from 2001 through 2004 with resection and adjuvant IMRT for local management. Stage was Kadish B in 4 patients, and Kadish C in 4. All patents had clear surgical margins, except for one Kadish C patient with microscopically positive margins. Treatment planning goals included delivery of 60 Gy in 30 fractions to a clinical tumor volume (CTV1) encompassing the surgical resection bed, and 54 Gy in 30 fractions to a CTV2 encompassing adjacent at-risk tissues and nodal levels. Average follow-up duration was 25 months (range: 12–42).
Results: Mean IMRT doses delivered to CTV1 and CTV2 were 62.2±0.8 Gy and 58.6±1.1 Gy, respectively. Mean total CTV coverage with target doses was 96.3%±1.7. Mean optic chiasm, optic nerve, eye, lens, and temporal lobe doses were 38.6±6.1 Gy, 48±5.5 Gy, 23±4.4 Gy, 10.5±3.6 Gy, and 21.1±6.6 Gy, respectively. Mean number of beams used was 9.1±1.2. All patients remain free of disease progression and have no severe late radiation morbidity.
Conclusion: Our early results suggest that adjuvant IMRT for esthesioneuroblastoma permits conformal delivery of high dose radiation with excellent tumor control and tolerance

1049 POSTER

Photodynamic therapy and fluorescent diagnostics with different second-generation photosensitizers in head and neck cancer patients

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Aim: Photodynamic Therapy (PDT) and fluorescent diagnostics (FD) using Photosense 've been provided in 50 patients with head and neck cancer (HNC) T1–3 stage and in 89 patients with skin cancer, using Radaclorin (RC) – in 42 patients with T1–4 stage basal cell carcinoma (BCC), in 6 patients with oral cancer, FD with Alasense (5-aminolevulenic acid, ALA) in 127 patients with T1–3 BCC, squamous cell carcinoma (SCC).
Materials: FD with detecting the borders of tumor growth, accumulation in tumor, normal tissues 've been done by Spectral-fluorescent Complex (He-Ne-laser). Using light sources (380–440 nm) we've got 2-dimensional pictures of fluorescence. We used semiconductive lasers for PDT: Milon – 660+2 nm, light dose was 200–300 J/cm^2 and Biospec (672+2 nm), multiple laser surface and interstitial irradiation was performed 24 hours after PS injection with total light dose till 400–600 J/cm^2 and single light irradiation with light dose 200–300 J/cm^2 using RC.
Results: We've got fluorescence of all tumors using AS: in 52% of patients it exceeded the borders of clinically detected sites. The intensity of fluorescence in SCC was positively higher then in BCC. In 35.7% patients with BCC additional fluorescence zones were found, cytological verification in 93.3%. We've got fluorescence of all tumors using PS and RC, additional fluorescence zones were found, cytological verification was got in most of cases. 2 months after PDT with PS in 50 patients with HNC we've had

complete response (CR) in 66.0% and partial response (PR) in 30.0% of patients with overall response rate (ORR) 96.0%. Cancer of larynx T1N0M0 and cancer of low lip T1–3N0M0 were more sensitive to the PDT-CR 90% and 76.5% accordingly. 2 months after PDT with RC there was ORR – 100% with CR in patients with BCC T1–2NOMO – 92.9%, in patients with recurrrencies of cancer CR – 60.6%, PR – 39.4%. The efficacy of PDT with PS was higher (CR – 86.7%, PR – 13.3%) and the recurrence rate in 6 months is significantly lower in patients with T3–4 stage BCC.
Conclusion: Our experience show pronounced efficacy of PDT for head and neck tumors of different localization and histology. Response to PDT depended upon several factors including photosensitizer, tumor size, localization and previous treatment. FD is providing diagnostically significant information about disease advance, allowed identification of subclinical lesions, demonstrated high sensitivity and specificity.

1050 POSTER

Weekly paclitaxel in patients with recurrent or metastatic head and neck cancer

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Introduction: Patients who failed to the standard first line chemotherapy 5FU–cisplatin have poor prognosis and survival. Paclitaxel is an emergent drug in Head & Neck cancer and it has showed moderate activity in these cancers. Weekly paclitaxel seems less toxic and probably more efficient that monthly paclitaxel possible because of the proapoptotic and antiangiogenic activity, the dose intensity is quiet higher and the toxicities are mild. The aim of this study was to assess the efficacity and toxicity of weekly paclitaxel in patients with recurrent or metastatic sq.c.c. of H & N.
Patients and methods: Twenty patients with recurrent or metastatic sq.c.c. of H & N during the period April 2001 to August 2003 were enrolled. Patients characteristics: median age 50 y, M/F 15/5, PS < 2, adequate renal, liver and bone marrow functions, main location of disease were local in 9 pts, local and nodes in 6 pts and nodes in 5 pts.
All patients (previously pretreated with the standard 5 FU–cisplatin regimen, and radiotherapy or surgery) were assigned to receive paclitaxel 80 mg/m^2 D1, 8, 15 and paraplatin 400 mg/m^2 D1 every 4 weeks for 8 courses.
Results: All patients were evaluable for response and toxicity, median age 50 years (range 42–60 y), PS < 2. A total of 153 cycles has been delivered with a median of 7 cycles/patient (4–8), with no dose reduction. The overall response rate was 55% (CR 10%, PR 45%), 7 patients had stable disease (35%) and 2 pts had progressed disease (10%). Haematological toxicity was one pt (5%) with G2 neutropenia, 2 pts (10%) with G2 anemia, no G3/G4 toxicity. Other toxicity was G2 mucositis in 2 pts (10%), G2 peripheral neuropathy in one pt (5%). Median time to progression was 10 months (4–24 months) and median overall survival was 14.2 months (9–30 months).
Conclusion: The results confirm that the combination of weekly paclitaxel & paraplatin is an effective, active, safe and well tolerated regimen for treatment of advanced or metastatic Head & Neck carcinoma.

1051 POSTER

The "quad shot" – palliative radiotherapy in locally advanced head and neck squamous cell carcinoma

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Background and Purpose: Few prospective studies of palliative radiotherapy in locally advanced head and neck squamous cell carcinoma (LAHNSCC) have been reported. The primary objective of this study was to estimate the rate of tumour response to a cyclical hypofractionated palliative radiotherapy regimen (QUAD SHOT) in patients with LAHNSCC. Secondary objectives were to prospectively evaluate toxicity, quality of life (QoL) and survival in these patients.
Materials and Methods: This was a single arm prospective study. The QUAD SHOT consisted of 14 Gy in 4 fractions, given twice a day and at least 6 hours apart, for 2 consecutive days. This regimen was repeated at 4 weekly intervals for a further 2 courses if there was no tumour progression and the side effects were tolerable.
Results: Thirty eligible patients had at least one treatment and 16 patients completed all three cycles. The median age was 73 years (52–88 years). The oral cavity was the predominant primary site of disease (13 patients). Twenty-nine patients (97%) had Stage IV disease, of which 5 were Stage IVC. Sixteen patients (53%) had an objective response (2CR, 14PR) and a further 7 had stable disease. Median overall survival was 5.7 months (range 0.6–26.7 months) and median progression free survival was 3.1 months (range 0.6–11.4 months). The majority of evaluable patients had improvement or stabilisation of their symptoms. There was minimal treatment toxicity – grade 0 or 1 mucositis only in 24/27 patients (89%). Overall QoL compared to pre-treatment levels was improved in 11 of 25 evaluable patients (44%).
Conclusion: The QUAD SHOT regimen is an effective palliative treatment with minimal toxicity and a good response rate which impacts positively on patients' QoL.

1052 POSTER

Interleukin-6 levels in thyroid cancer and nodular goitre

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Interleukin-6 (IL-6) appears to play multiple functions in thyroid physiology and disease. Cultured normal human thyroid follicular cells constitutively release IL-6, and IL-6 levels have been shown to correlate with serum T3 and free T4. Furthermore, IL-6 expression has been related with aggressiveness in papillary thyroid cancer. IL-6 is thought to act over the extrinsic pathway of coagulation through tissue factor expression. Haemostatic abnormalities have been reported in patients with thyroid diseases, depending on its severity. Thus, the present study was aimed at analyzing the possible association between IL-6, hormone profile and coagulation parameters in patients with thyroid cancer or benign diseases, to better characterize their possible link. To this purpose, 28 patients with early stages papillary thyroid cancer (n = 14) or benign nodular goitre (n = 14), and 14 healthy euthyroid subjects, all matched for age and sex, were evaluated. Eight patients were under replacement therapy at entry time. In each subject, plasma IL-6 levels (R&D Systems), prothrombin time (PT), activated thromboplastin time (PTT), fibrinogen and D-dimer, free T3, free T4 and TSH concentration were determined. The results obtained are expressed as mean±SD or median (interquartile range) and summarized as follows.

	Age	IL-6 (pg/ml)	Fibrinogen (mg/dl)	D-dimer (g/ml)
Euthyroid controls	56±13	0.7 (0.4–1.3)	259±58	147 (122–202)
Nodular goitre	50±16	1.4 (0.7–2.0)	307±60	161 (89–269)
Papillary cancer	56±13	2.1 (1.2–3.3)	313±48	207 (139–371)
P value	=0.388	=0.019	=0.041	=0.769

No significant differences were observed for TSH, free T3 or T4 after adjustment for replacement therapy. IL-6 significantly correlated with fibrinogen (Rho = 0.31, p = 0.04) and TSH (Rho = −0.55, p < 0.001) levels in the overall population. The correlation between IL-6 and TSH was maintained in benign or cancer patients without replacement therapy (Rho = −0.54, p < 0.01). Multivariate analysis including age, sex, hormonal therapy, PT, PTT, d-dimer, fibrinogen, free T3, free T4 and TSH showed that both TSH (β = −0.44, p = 0.03) and free T4 (β = 0.41, p = 0.04) were predictive of IL-6 levels in thyroid diseases, independently of replacement therapy. No association was found between IL-6 and coagulative parameters. We conclude that the increased IL-6 levels observed in patients with thyroid diseases are related to the hormone profile, probably reflecting the functional status of follicular cells.

1053 POSTER

Accelerated hyperfractionated intensity modulated radiotherapy (AHI) for T2–3 oropharyngeal carcinoma: preliminary results from a phase I-II study

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Purpose: We designed a novel schedule combining IMRT and accelerated hyperfractionation for oropharyngeal carcinoma in order to exploit both the clinically proven benefit of altered fractionation and the dosimetric advantage of a more conformal dose distribution with a simultaneous integrated boost technique. Here we report early outcome data.
Methods: Between November 2002 and January 2005, 23 patients with T2 (12 pts) or T3 (11 pts) squamous cell carcinoma of the oropharynx