Forthy one of those patients were treated with only RT (Group A), and 83 of them with RT and cisplatinium based chemotherapatic regimens (Group B). The ages were between 18–82 and 78 of the patients were men and the other 46 patients were women. The number of patients with T1, T2; T3 and T4 tumors were 12 (9.7%), 25 (20.2%), 52 (41.9%) and 35 (28.2%) respectively. The nodal stage distribution was as follows: N0, N1, N2, N3 were 11 (8.8%), 11 (8.8%), 75 (60.6%), and 27 (21.8%). The mean follow up period was 38 months (24–130).

The five years overall survival rate was 40.3% for the whole group. The survival rates were 34.2% and 43.9% for the only RT arm and combination therapy arm, respectively (P: 0.3). Distant metastases rates were 29.2% and 31.3% for Group A and B. Those factors were found to be effective on overall survival statistically; interruption of radiotherapy (p: 0.02), tumoral complete response (P: 0.03), sex (p: 0.04) and age (p: 0.04). Total dose of radiation therapy (p: 0.05) and RT and CT combination therapy (p: 0.02) were the other factors effecting the local progression free survival. The most common acute toxicity was mucositis and the late one was xerostomy, since there was no treatment related deaths. It,s concluded that the patients should be treated with radiation and chemotherapy combination regimens until the development of new treatment modalities where long therm survival advantage is established in randomised trials.

639 PUBLICATION

Amifostine – A radioprotector in locally advanced head and neck cancer

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Purpose: There are some preliminary informations about the beneficial use of amifostine in avoiding side effects in patients with head and neck tumors who underwent radiotherapy.

Patients: Amifostine was given as daily intravenous application (500 mg) 10–15 minutes prior to radiotherapy in 22 patients. The results were compared with another collective of patients which was similar.

Results: According to the WHO-score mucositis became manifest in 12 patients (grade I) and 4 patients (grade II) in the amifostine group versus 10 patients (grade II), 7 patients (grade III) and 1 patient (grade IV) in the control group. Xerostomia has been seen in 16 patients (grade I) and 6 patients (grade II) after administering amifostine. Without the drug 2 patients suffered from xerostomia (grade I), 10 patients (grade II) and 8 patients (grade III), respectively. Administering amifostine had been feasible and non problematic. Only a small rate of toxic side effects like nausea (11%) or emesis (4%) has been document.

Conclusions: We feel that amifostine is an effective radioprotector decreasing acute and late side effects in patients with head and neck tumors.

640 PUBLICATION

Bifractionated radiotherapy (RT) in locally advanced head and neck cancer (LAHNC) – Is it feasible in daily practice?

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Purpose: Recent studies showing local control and/or survival benefit of hyperfractionated RT ± chemotherapy (CT) in LAHNC prompted us to introduce these new strategies into clinical practice. We present the results of bifractionated RT (bRT) ± CT in LAHNC along with its economical and organisational aspects.

Methods: Out of 70 patients (pts), 34 were treated with induction CT (iCT) followed by bRT, 28 with bRT alone, 6 with iCT followed by concomitant bRT + CT (cbRT + CT) and 2 with cbRT + CT. bRT dose was 74.4 Gy given with 1.2 Gy bid for 5 d/week. iCT included up to 4 cycles of cisplatin (DDP) and fluorouracil (FU) or DDP, FU and navelbine (VNL). cCT included weekly DDP. A prophylactic supportive care protocol with fluconazole, pilocarpin etc. has been introduced. Economical (cost of RT) and organisational (staff and machine workload, patient's care) aspects of therapy have been evaluated.

Results: All but 7 pts completed therapy; the mean bRT time was 46.5 days, mean follow-up 10 months. Response was achieved in 37 pts (84%) out of 44 evaluable pts; 31 CR and 6 PR. Acute toxicity included: mucositis (62 pts), skin toxicity (58 pts), weight loss (46 pts), myelotoxicity (22 pts), nausea, vomiting (15 pts) and others. In 31 pts (44%) G3 or G4 mucositis and in 13 pts (18%) G3 leukopenia were observed. Late xerostomy was observed in the majority of pts and mandible necrosis in 1 pt. The cost of our bRT scheme is 20% more expensive than the conventional RT (70 Gy/35 fr), however as far as the machine workload is concerned, bRT should be considered as a RT of 2 separate pts. Then one has to add the costs of medical and nurse staff workload as well as the costs of supportive care increased due to higher acute toxicity (detailed assessment of workload and time of RT set-up will be presented).

Conclusion: Interesting results of bRT ± CT have been observed, however, its high acute toxicity and increased staff and machine workload require particular organisation of the work of a RT department. Thus these new treatment strategies should be employed within clinical studies in the specialised centres.

641 PUBLICATION

Concomitant radiochemotherapy with 5-fluorouracil and mitomycin c in locally advanced head and neck carcinoma

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Purpose: Giving chemotherapy and radiotherapy simultaneously (concomitant therapy) is one approach to improve results in advanced head and neck cancer.

Materials and Methods: 35 patients with advanced squamous carcinoma of the head and neck were treated from March 1995 to June 1998 with a continuous intravenous infusion of 5-fluorouracil, 600 mg/m^2 per 24 h for days 1 to 5 (120 h) and mitomycin-C 10 mg/m^2 intravenously on day 5 during the first week of radiotherapy and on day 36. Thirty-two patients had stage IV disease; two stage III; and one stage II. Ages ranged from 42 to 69 years (median 56.7 years). The tumours involved were as follows: oral cavity (11); oropharynx (14), hypopharynx/larynx (10). Radiotherapy was delivered to a total dose of 70 Gy with conventional fractionation (2 Gy/fraction, 5 times a week).

Results: Chemotherapy was well tolerated and all patients received the intended dose. Mild nausea occurred in five patients. With a mean follow-up of 11.8 months (8–46), 8 patients (23%) are alive (7, 8, 9, 18, 18, 31, 38, 41 months after treatment). A complete response was seen in 28 (80%). When a recurrence appeared, it was in the first year after treatment. One and 2-year survival rates were 46 and 20% for overall and disease-free survival, respectively. Grade 3 or 4 mucositis occurred in 17%. Grade 1–2 thrombopenia occurred in 3 patients (8%), grade > 2 leukopenia in 4 patients (11%), grade "2 anaemia in 2 patients (6%). We observed a treatment interruption of one week for 3 patients because of mucositis. Febrile neutropenia or aplasia were not observed.

Conclusion: The concomitant use of 5-fluorouracil, mitomycin C and radiotherapy in locally advanced head and neck carcinoma is well tolerated in this group of patients. This protocol showed good locoregional response with a very low toxicity profile.

642 PUBLICATION

Resection and reconstruction with the use of pectoralis major flap, in patients receiving radio/chemotherapy

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Purpose: Radiotherapy (RTH) and chemotherapy (CHTH) may impair the survival of island flaps used for reconstruction after extensive resection of head and neck cancer. We assessed the value of pectoralis major (PM) island flap used for reconstruction in patients receiving additional RTH or CHTH.

Methods: The PM flap was used in 51 patients (42 M 9 F, aged 26–78 years, mean 55). In 9 cases (17.6%) surgery was followed by RTH, in 26 (51%) – surgery was performed after neoadjuvant CHTH. Additionally, there were 16 (31.3%) cases of salvage surgery after previous radical RTH. The primary site of cancer was: oropharynx, floor of mouth, tongue – 43 cases, lower lip – 4, submandibular – 3 and parotid – 1. In three cases, flap pedicle could not be tunnelled under the skin, and was covered by a skin graft.

Results: Partial necrosis of skin island was observed in 2 cases, none of them required subsequent surgery other, than necrectomy. A fistula developed in further 2 patients, one of them requiring surgical closure. Thus, serious complications ocurred in 4/51 (7.8%) cases.

Conclusion: PM flap is extremely reliable for reconstruction after wide cancer resection in head and neck region, in patients receiving additional RTH or CHTH.