juvant and postoperative adjuvant setting of stage III–IV squamous cell carcinoma of the H&N.

Treatment Schedule: 25 pts with a primarily inoperabel stage III and IV of SCC of the H & N were includes. Karnofsky-Index 80–100. All pts received on day 1 and 29 P 175 mg/m^2 as a 3-hour infusion, followed by a 24-hour-CVI of 1000 mg/m^2 5-FU for 5 days. Locally irradiation was given ad 40 Gy (2 Gy/d/day 1–26). Operative intervention followed about day 56. Postoperatively pts received again 2 cycles of P/5-FU and simultaneous irradiation with 30 Gy.

Results: So far 25 pts were treated. Hemtaologic and non hematologic toxicity was mild and distinctly less compared with standard combination DDP/5-FU. There was no WHO grade III–IV toxicity. Tumorresection about day 56 was done in 23/25 pts. No active tumor was found in 13/23 pts in the primary tumor as well as in 1nn. 22/25 pts are at time disease free for a follow up of 4–24 mos. 1 pt refused surgery and relapsed after 11 mos. 2 pts developed a second neoplasia (esophagus and bronchogenic cancer) after 11 + 14 mos.

Conclusion: The treatment of SCC of the head and neck with P/5-FU and simultaneous radiation and operative intervention is a highly effective schedule with very moderate toxicity. The results of the ongoing study are encouraging.

870 PUBLICATION

Chemoprevention with interferon alfa and 13-CIS retinoic acid in patients with advanced head and neck cancer

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Purpose: A lot of chemopreventive treatments with retinoids are discontinued because of the toxicities associated with a higher dose of these drugs. In-vitro experiments have shown that it is possible to reduce the retinoid dosage without decrease of antitumor activity when interferon alfa is injected simultaneously. Aim of our phase-II-study was it to ivestigate the toxicity profile of this combined treatment.

Material and Methods: Between 1993 and 1995 50 patients (41 men, 9 woman, median age 57 years) with a head neck cancer stage IV of UICC were integrated into the study. All patients got 3 times the week 3 mio IU Interferon alfa sc and 0.5 mg/kg body weight per day 13-cis retinoic acid. The treatment was completed after 6 month or in the case of side effects grade 3 or 4 of WHO or in the case of tumor progression. At the start of the adjunctive treatment all patients had no clinical sign of tumor. Clinical picture and paraclinical data were investigated every 6 weeks. The local and distant control of the tumor disease were examined every 3 month.

Results: The treatment was interrupted in 5 out of 50 patients because of treament toxicity. In 13 patients the therapy was finished previously because of cancer progression. The local tumor control is 72% after 12 month, 66% after 24 month, and 58% after 36 month. The rate of distant metastasis is 2% after 12 month, 6% after 24 month, and 8% after 36 month. Second malignancies were not observed at the follow-up time of 36 month. The typical side effects of 13 cis retinoic acid were xerostomia in 60%, dysphagia in 66%, cheilitis in 70%, all of these side effects were moderate. The minimal toxicities of interferon were anemia (20%) leucocytopenia (34%) and increased body temperature (54%).

Conclusion: The combined chemopreventive therapy with interferon and 13-cis retinoic acid is acceptable for patients with advanced head and neck cancer. The therapy is characterized by a high level of patients compliance and improves the prognosis of this high risk group.

871 PUBLICATION

Immediate results of the locally advanced larynx cancer $T_{3-4}N_{0-3}M_0$ treatment using non-conventional dose fractionation radiotherapy

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Purpose: To improve the effectiveness of the locally advanced larynx cancer $T_{3-4}N_{0-3}M_0$ treatment and the patient life quality.

Methods: Two groups of primary patients were treated & analyzed. The 1st group – 22 patients were irradiated with 64.2 Gy of total dose:

1 week 1.7 Gy × 2 fr./day, 6 h interval, 5 days/week;
2 and 3 week 1.0 Gy × 2 fr./day, 6 h interval, 5 days/week;
4 and 5 week 1.7 Gy × 2 fr./day, 6 h interval, 5 days/week.

The 2nd group – 68 patients were treated with 70 Gy of total dose by conventional fractionation. 1st group: T3N0M0 – 13 pts, T3N1M0 – 5 pts, T3N2M0 – 2 pts, T4N0M0 – 2 pts. 2nd group: T3N0M0 – 42 pts, T3N1M0 – 21 pts, T3N2M0 – 3 pts, T4N0M0 – 2 pts.

Results: After radiotherapy 12 pts of 1st group (54.5%) and 17 pts of the 2nd group (25.0%) had full tumor regression.

Conclusions: The non-conventional dose fractionation of radiotherapy has significant antitumor activity and improves patient life quality. In general all patients satisfactory carried out the new regimen of radiotherapy.

872 PUBLICATION

Phase I–II study of simultaneous radiotherapy and paclitaxel (taxol) in a twice a week (TIW) schedule for recurrent squamous cell carcinomas of the head and neck (SCCHN)

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Purpose: Taxol has a significant single agent activity in SCCHN and a synergistic activity with irradiation has been demonstrated in preclinic models. Therefore this study investigated the max tolerated dose (MTD) of taxol (tiw) in combination with simultaneous normal fractionated radiotherapy and the anti-tumor activity in pre-treated and recurrent SCCHN.

Method: 16 patients pretreated with surgery plus adjuvant irradiation alone (2/16) or combined with chemotherapy (14/16) were enrolled. **Schedule:** Taxol was escalated in cohorts of 3 patients (20/30/35/40/45 mg/m^2) given two times a week for 8 doses with concomitant irradiation daily (d1–d28; 30–46 Gy depending on prior irradiation dose).

Results: Toxicity (% pts): mucositis °3 (12%), °2 (62.5%), °1 (25.5%). No further toxicity was observed. The MTD in this schedule is unexpectedly high and not yet reached. **Response:** PR 13/16 patients (81%), MR 3/16 patients (19%), 0/16 patients had progressed (during treatment).

Conclusions: In the presented schedule the combination of radiotherapy and taxol is well-tolerated and possible in an outpatient setting. The tumor response rate in this heavily pretreated patients is very high and justifies a comparison of radiochemotherapy versus radiotherapy alone after definition of MTD.

873 PUBLICATION

Useful or useless? B-scan sonography of malignant cervical lymph nodes during primary radiotherapy (RT) for squamous cell carcinoma of the head and neck

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Purpose: Sonography (SONO) is considered a valuable tool in assessment of head and neck tumors. In contrast, SONO is only rarely used during RT. For 2 years, we scan cervical lymph nodes (LN) with SONO during RT for various tumors. Below, we report about our experiences with SONO of LN's during RT for head and neck carcinoma (HNC).

Methods: A total of 27 LN's (20 patients) were examined. All pat. had advanced squamous cell HNC. 5 pat. received radiotherapy alone (46–70 Gy total dose), and 15 were treated with radiochemotherapy (70 Gy total dose, two courses of fluorouracil and mitomycin). We used a 7.5 MHz ultrasound probe. Sonomorphological and volumetric changes of LN's and clinical utility were analysed.

Results: The margins of all LN's became progressively fuzzy. The remaining sonomorphologic parameters were constant. Volume before and during RT varied on a large scale. Thus, pretherapeutic volume reached from 1 to 41 cm^3 and the time volume 50%, i.e. time until volume had decreased by 50%, reached from 8 to 55 days. SONO could always be used for therapy monitoring and nearly always (15/20 pat.) for treatment planning.

Conclusion: SONO of LN's during RT of advanced HNC is a valuable examination. It can be used for therapy monitoring and treatment planning. Invasive and expensive methods can be saved. In our estimation, SONO should be used more often during RT. Future research with respect to newer sonographic methods like high resolution SONO, color duplex SONO or power doppler is required.