S64 Monday 22 September 2003 Poster Session

primary tumor in cervical esophagus versus those with in intrathoracic esophagus (46.2% vs. 64.9%, p=0.0231). Patient age, sex and hemoglobin level were not associated with survival. By multivariate analyses, stage and chemoradiotherapy were significant factors. Local control (including salvage cases by endoscopical mucosal resection) at 2 years was 61.9%. By multivariate analyses, stage and sex were significant factors. Patient age, hemoglobin level, serum albumin level, anatomical subsites and using chemotherapy were not associated with local control.

Conclusion: This study showed high survival rate and local control rate for patients with localized esophageal cancer treated by radiation therapy with or without chemotherapy. By multivariate analyses, stage and chemotherapy were significant factors on survival, and stage and sex were significant factors on local control.

204 POSTER

## Stent placement in malignant superior vena cava syndrome

A. Stamatelopoulos<sup>1</sup>, N. Baltayiannis<sup>1</sup>, D. Magoulas<sup>2</sup>,
 D. Anagnostopoulos<sup>1</sup>, N. Bolanos<sup>1</sup>, N. Tsirikos<sup>1</sup>, D. Doltsiniadis<sup>1</sup>,
 V. Siemekis<sup>1</sup>, E. Kayianni<sup>2</sup>, A. Chatzimichalis<sup>1</sup>. <sup>1</sup> Metaxa Anticancer Hospital, Thoracic Surgery, Athens, Greece; <sup>2</sup> Metaxa Anticancer Hospital, Radiology, Athens, Greece

Background: Superior vena cava (SVC) syndrome is caused by SVC stenosis or occlusion, frequently as a consequence of a lung cancer or mediastinal tumor. SVC syndrome is characterized by unpleasant symptoms that usually lead to death. Treatment with radiation therapy and chemotherapy may produce an initial relief, whereas operations with bypass are associated with high mortality and morbidity. The purpose of our study is to show the efficiency of percutaneous stenting in he superior vena cava for relieving SVC syndrome secondary to malignant disease.

Material and methods: From January 1999 to March 2002, 17 patients with malignant SVC syndrome were evaluated at Metaxa Cancer Hospital. Their caval stenoses were confirmed by computed tomography and venography. There were 15 males and 2 females with an average age of 62 years (range from 47 to 79 years old). The SVC syndrome was caused by malignant disease in all patients: broncho-pulmonary cancers in 14 and lymphoma in 3. All patients underwent placement of a self-expandable (Wallstent) endovascular (vena cava) prosthesis. Results: All procedures were successfully carried out and there were no immediate complications. The average time for wallstent placement was 37 min. There was no sign of bleeding and the wallstent was well positioned on chest roentgenograms. All patients, without exception, noticed an immediate improvement, with relief of pressure and rapid resolution of headache. Cyanosis disappeared over the first hour and swelling resolved over the first 24h.

Conclusion: Percutaneous venous wallstent placement in the superior vena cava is a simple, safe and effective technique to relieve rapid SVC syndrome caused by malignancies.

205 POSTER

## Weekly gemcitabine with concurrent radiation for unresectable pancreatic cancer

A. Cringeanu<sup>1</sup>, D. Stanculeanu<sup>1</sup>, R. Anghel<sup>2</sup>, L.N. Minea<sup>1</sup>, D. Mitulescu<sup>2</sup>.

<sup>†</sup> Institute of Oncology Bucharest, Medical Oncology, Bucharest, Romania;

<sup>2</sup> Institute of Oncology Bucharest, Radiation Therapy, Bucharest, Romania

Background: Combined chemo-radiotherapy may improve local control, resection rate and long term survival in patients with locally advanced pancreatic cancer. Many oncologists consider concurrent 5 fluorouracil and radiotherapy as standard treatment for these patients.

Gemcitabine is an active agent in advanced pancreatic cancer resulting in clinical benefit in 30-50% of pts. and an objective response rate of 5-11%. Gemcitabine has known radiosensitizing properties. Various schedules have been tested with gemcitabine and radiotherapy.

Material and methods: From January 1999 to July 2002, 21 patients with locally advanced, unresecable pancreatic cancer were enrolled onto this study. Patients characteristics: there were 15 male and 6 female, median age 63 years (range 42 ñ 69), performance status ECOG 0-2, bilirubin plasma level < 2 mg/dl. A chemo-radiotherapy regimen consisting of weekly gemcitabine (200 mg/m²) with 45 Gy of external beam radiotherapy (1.8 Gy / fraction, 5 days / week) was delivered in five weeks. Patients were re-staged with chest radiographs and CT scans 4-6 weeks after treatment. Those with down-staging tumors and good performance status underwent pancreaticoduodenectomy.

Results: 17 patients completed chemo-radiotherapy schedule. 3 patients interrupted the treatment 2 because of grade 4 toxicity and 1 because of

progressive disease. Clinical benefit was found in 13 of the 17 patients (5 partial response and 8 stable disease). Progressive disease was found in the four remained patients. Six patients received surgery. Adverse effects, especially hematologic, were common but manageable. No chemoradiation-associated deaths were observed with this gemcitabine-based regimen. Grade 3 ñ 4 hematological toxicity (neutropenia and/or trombocitopenia) occurred in 7 and 2 patients respectively. Grade 3 gastrointestinal toxicity (nausea, vomiting and diarhea) occurred in 3 patients. There was no grade 4 gastrointestinal toxicity. The median time to progression was 8 month and the median survival was 14 month.

Conclusions: This schedule of Gemcitabine and radiation therapy is well tolerated, and has shown to provide prolonged clinical benefit response and disease stabilization in patients with localized, unresectable pancreatic carcinoma. The potential of this regimen to downstage a subset of previously unresectable patients should be further investigated using modern techniques of radiation delivery like three dimensional conformal radiotherapy.

206 POSTER

## Fortnightly intravenous irinotecan plus oral capecitabine as treatment for gastroesophageal cancer – a phase 1 and 2 study.

<u>D.P. Jackson</u><sup>1</sup>, D. Smith<sup>2</sup>, C. Topham<sup>3</sup>, D.A. Anthoney<sup>1</sup>, K. Patel<sup>1</sup>, A. Forsyth<sup>1</sup>, F. Halstead<sup>1</sup>, M.T. Seymour<sup>1</sup>. <sup>1</sup> Cancer Research UK Clinical Centre, Cookridge Hospital, Leeds, United Kingdom; <sup>2</sup> Clatterbridge Hospital, Liverpool, United Kingdom; <sup>3</sup> St. Luke's Oncology Centre, Royal Surrey Hospital, Surrey, United Kingdom

We investigated a combination of intravenous irinotecan and oral capecitabine (IrinoCap) in patients (pts) with locally advanced or metastatic gastroesophageal adenocarcinoma. The design employed cohort dose-escalation during phase I to establish maximum tolerated dose (MTD), then a 31-patient phase II study at MTD to estimate efficacy. In phase I, cohorts of at least 4 pts received each of the following dose levels: *Level 1*: irinotecan 150 mg/m² i.v. infusion, d1; capecitabine 850 mg/m² p.o. 12-hourly d1-9, 14-day cycle. *Level 2*: as level 1 but capecitabine 1000 mg/m². *Level 3*: as level 2 but irinotecan 180 mg/m². *Level 4*: as level 3 but capecitabine 1250 mg/m². For pts entered at levels 1 and 2 only, intra-cohort dose escalation atter 3 cycles was allowed. Pts were monitored for toxicity, and assessed for response after 6 cycles.

21 pts were entered in Phase I. Dose-limiting toxicity occurred in 1 of 5 pts started at dose level 1 (Gr 3 lethargy); 1 of 8 pts started at or escalated to dose level 2 (Gr 3 mucositis); 0 of 6 pts treated at dose level 3; and 6 f 7 pts treated at dose level 4 (1 Gr 3 vomiting, 3 Gr 3 lethargy, 1 Gr 3 diarrhoea and 1 Gr 4 diarrhoea). Accordingly, level 3 was declared MTD, and used during Phase II.

31 chemo-naïve pts were entered in Phase II. A total of 165 cycles were delivered, 61% of pts receiving at least 6 (mean = 5.3). Grade 3 toxicities were lethargy (6 pts), diarrhoea (5 pts), nausea (3 pts) and anorexia (3 pts). During the first 6 cycles 74% of treatment cycles were given at full dose, but 15 pts underwent dose reduction (of both drugs) for toxicity. 3 pts stopped treatment before cycle 6 because of toxicity and 8 because of early PD. There were no treatment-related deaths. 28 pts were assessable for response (RECIST): PR = 9 (32%), SD = 9 (32%) and PD = 10 (36%). Of the 9 pts with SD, 4 had evidence of treatment activity (3 minor response on CT, 1 tumour marker response, all with symptomatic improvement).

This forthnightly IrinoCap schedule is active in gastroesophageal adenocarcinoma with a response rate, in this unrandomised trial, similar to standard chemotherapy schedules. In the Phase II study at dose level 3 (irinotecan 180 mg/m² d1; capecitabine 1000 mg/m² 12 hourly d1-9, q14d), a relatively high proportion of pts (16/31, 52%) required dose reduction or stoppage for toxicity during the first 6 cycles; further modification of the schedule is therefore required to reduce the toxicity profile for further study.

Supported by an unconditional grant from Aventis Pharma Ltd, UK.