of patient distress, and these discrepancies are useful for identification of patients with a low HRQOL.

504 POSTER DISCUSSION

Advanced esophageal cancer patients treated with hydroxyurea, leucovorin, 5-fluorouracil and cisplatin (HLFP regimen)

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Aim: Treatment with a multimodulation of 5-fluorouracil (5-FU), with leucovorin and hydroxyurea, plus cisplatin has been shown to be active in advanced gastric carcinomas. We studied response rate, survival and tolerance in patients with nonresectable, locally advanced or metastatic esophageal carcinoma treated with this combination.

Patients and Methods: Eighty one patients (pts) were prospectively enrolled in the study: 72 men, 9 women; mean age 60.5 years; metastatic disease in 44 pts, locally advanced in 37 pts; baseline performance status (OMS) 0 (29 pts), 1 (35 pts), 2 (17 pts). Sixty nine pts had squamous cell carcinoma and 12 had adenocarcinoma. Treatment consisted of oral administration of hydroxyurea 1 g/m^2 per square meter on days −1, 1 and 2, 2 hour infusion of leucovorin 200 mg/m^2, 5-FU bolus 400 mg/m^2 followed by 5-FU 22-hour infusion 600 mg/m^2 on 2 consecutive days, every two weeks; and cisplatin 80 mg/m^2 on day 3 every two cycles.

Results: Response rate in 79 pts with mesurable disease was 54%. A weight increase was observed in 46%, and dysphagia disappeared in 60% of our pts. Surgery (7 pts) or radiotherapy (16) was performed in 62% (27/33) of nonmetastatic pts. Median progression free survival and overall survival were 9 and 13 months, respectively; there was no significant difference for these data between adeno- and squamous cell carcinomas. Grade 3/4 toxicity occurred in 34.5% of the patients, with grade 3–4 neutropenia in 19% and grade 3 thrombocytopenia, vomiting or diarrhea in 5% of the patients.

Conclusion: The HLFP regimen is an active and well tolerated chemotherapy for advanced or metastatic esophageal cancer.

505 POSTER DISCUSSION

Tobacco, alcohol and the risk of stomach cancer in Canada

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Purpose: To examine the influence of tobacco and alcohol on the risk of stomach cancer.

Methods: Mailed questionnaires were used to obtain data on 1173 newly diagnosed histologically confirmed stomach cases and 4778 population controls between 1994 and 1997 in eight provinces of Canada. Data were collected on socioeconomic status, smoking, alcohol use and diet. Odds ratios (OR) and 95% confidence intervals (CI) were derived by logistic regression.

Results: Compared with never smokers, the risk of stomach cancer increased with increasing cigarettes per day. The adjusted ORs were 1.6 (CI = 1.2–2.0) and 1.36 (CI = 1.0–1.9) for >=20 cigarettes per day among males and females, respectively. The risk also increased with total smoking years and decreased with number of years since quitting. Liquor use was associated with stomach cancer in males, but not in females.

Conclusions: This study adds further support to the role of tobacco and liquor use in the development of stomach cancer.

506 POSTER DISCUSSION

5FU as protracted continuous IV infusion (5FUpiv) can be added to full dose taxotere-cisplatin (TC) in advanced gastric carcinoma (AGC)

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Based on the reported efficacies of TC (ASCO Proc. 17, 283a, 1998) and of 5FUpiv with cisplatin and epirubicin (J clin Oncol 15, 261, 1997) in AGC, we conducted a phase I–II trial investigating the tolerability and, as secondary endpoint, the activity of 5FUpiv added to TC (TCF) in AGC. Pts with AGC, without prior palliative chemotherapy, with evaluable disease, PS ≤ 1, normal blood counts and hepatic and renal functions received up to 8 cycles of TCF q3w at the following dose levels (DL):

DL	Pts	Cisplatin	Taxotere	5FUpiv 2 wks/3
1	12	60 mg/m^2	70 mg/m^2	200 mg/m^2/d.
2	6	60 mg/m^2	85 mg/m^2	200 mg/m^2/d.
3	6	75 mg/m^2	85 mg/m^2	200 mg/m^2/d.
4	3	75 mg/m^2	85 mg/m^2	225 mg/m^2/d.
5	6	75 mg/m^2	85 mg/m^2	250 mg/m^2/d.
6	3	75 mg/m^2	85 mg/m^2	275 mg/m^2/d.
7	3	75 mg/m^2	85 mg/m^2	300 mg/m^2/d.
8	4	75 mg/m^2	85 mg/m^2	350 mg/m^2/d.

To date, 188 cycles of treatment have been given to 43 pts with a median of 4 cycles/pt. 82% of the cycles could be given on time. Two dose limiting toxicities (tox) – defined as grade (gd) 4 neutropenia with fever and/or gd 3 tox of any other kind apart from alopecia in cycle 1 – consisting in gd 3 diarrhea + mucositis and in febrile neutropenia in 2 pts occurred in DL8. We conclude that DL7 is the MTD and recommended dose, and that TCF, with a preliminary response rate of 50%, is active in AGC.

507 POSTER DISCUSSION

Eight-hour infusion versus bolus injection of doxorubicin in EAP regimen in patients with advanced gastric cancer (AGC): A prospective randomised trial

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Purpose: Doxorubicin is carrier of myelotoxicity in EAP (doxorubicin 40 mg/m^2, etoposide 360 mg/m^2, cisplatin 80 mg/m^2) regimen. The aim of this study was to compare a 8-hour infusion doxorubicin (arm A) and i.v. doxorubicin injection (arm B) in EAP regimen with respect to toxicity esspecially doxorubicin-related, objective response, time to progression (TTP) and survival in pts. with AGC.

Methods: 120 chemotherapy-naive pts. with measurable AGC were randomised between September 1994 and August 1998. 58 pts. in arm A and 50 pts. in arm B were considered as evaluable. Arms were balanced in relation to age, sex distribution, previous therapy, histological grade and performance status. 180 cycles were applied in arm A (median 2) and 201 in arm B (median 4).

Results: No difference was detected (p = 0.12) in the response rate achieved: arm A 21% (CR 3/58; PR 9/58; 95%CI: 12.5–23.7) and B 34% (CR 3/50; PR 14/50; 95%CI: 22.4–47.8). There was significant difference in PD (p = 0.005) between arm A (50%) and arm B (24%). TTP (p = 0.01) and survival (p = 0.02) analyses detected an advantage for arm B vs. arm A. WHO grades 3–4 toxicity were (arms A%/B%): anemia 8/10, leucopenia 24/26, thrombocytopenia 6/16 (significance p = 0.05), nausea/vomiting 5/8, diarrhea 6/2, mucositis 8/5. Four treatment related death was occurred, 2 in each arm.

Conclusion: Bolus injection of doxorubicin is superior to 8-hour doxorubicin infusion in EAP regimen, in terms of survival, TTP and PD rate without being significantly more toxic.

508 POSTER DISCUSSION

Randomized trial of preoperative (PRT) and intraoperative (IORT) radiotherapy versus surgery alone in resectable gastric cancer

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Purpose: To evaluate the outcome of adjuvant PRT and IORT in resectable gastric cancer a prospectively randomized clinical trial was performed from 1993 to 1998.

Methods: Eighty five patients underwent curative operation were included in the study. Forty three patients in the experimental group were treated with PRT (27 Gy/11 days), gastrectomy and IORT (20 Gy using 8–12 MeV electrons); 42 patients in the control group- with surgery alone.

Results: Experimental treatment regime showed good acute and late tolerance. The median follow-up time is 27 months. Loco-regional recurrence was diagnosed in 2 (5%) patients in the experimental and in 7 (16%) – in the control group, distant metastases – in 9 (21%) patients in each group. Recurrence-free interval was significantly longer in the experimental group comparing with the control one: 22.4 (5–50) months and 9.9 (4–24) months respectively. Overall survival was slightly better in the experimental group: 77% (33/43 patients) and 66% (28/42).