was evaluated in a multicenter phase II study. Patients and treatment: 56 chemotherapy-naive patients with locally advanced or metastatic disease were enrolled. The median age was 60 years; men were 34 and women 22; PS was 0 (n = 15 pts), 1 (n = 21 pts) and 2 (n = 20 pts). G (1000 mg/m^2) was administered on day 1 and 8 and D (100 mg/m^2) on day 8, every 3 weeks; G-CSF (150 igr/m^2, sc) was given (day 9–15).

Results: All patients were evaluable for toxicity and 43 of them for response. Five (11.6%) pts achieved PR while 17 pts (39.5%) had SD and 21 pts (48.8%) PD. The median duration of response and the median TTP were 3 and 9 months respectively while the median survival was 8 months and the probability for one year survival 32%. Grade 3/4 neutropenia occurred in 15 pts (23%) and in 6 (11%) of them it was complicated with fever; 1 septic death occurred. Grade 3 anemia and grade 3/4 thrombocytopenia occurred in 6 (10.7%) and 4 (8%) pts respectively. Non hematologic toxicity: grade 3/4 diarrhea in 2 pts (4%), grade 2 neurotoxicity in 3 pts (5.4%) and grade 3/4 fatigue in 7 pts (13%); moderate hypersensitivity reactions in 4 pts (7.1%) and moderate fluid-retention syndrome in 14 pts (25%). A total of 201 cycles were administered (median number/patient: 3). The median administered dose was 90% and 94% of the planned doses for D and G, respectively.

Conclusions: Although, the D + G combination is well tolerated and seems to have a marginal activity in patients with advanced pancreatic cancer, conferring to them some clinical benefit, it does not seem to be superior to single-agent therapy with either G or D.

522 POSTER

Direct endoscopic injection of cisplatin/adrenaline gel for palliation of dysphagia in patients with advanced esophageal cancer

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Purpose: We evaluated the safety and efficacy of direct endoscopic injection of cisplatin/adrenaline [epinephrine] injectable gel (CDDP/epi gel) for sustained local chemotherapy in the palliation of dysphagia in advanced esophageal cancer.

Methods: Open-label, Phase III studies enrolled patients with advanced esophageal cancer. CDDP/epi gel was injected intratumorally weekly for up to 6 wk or until all exophytic tumor was ablated.

Results: 23 patients enrolled; 17 evaluable. Median dysphagia grade: 3 (scale, 1–5; range 2–5). Median no. of treatments: 3 (1–6). Evaluations follow:

Evaluation	Dysphagia[a]	Duration, days (median [range])	Lumen Patency	Duration, days (median [range])
Improved[b]	3 patients	55 (43–56)	5 patients	46 (36–56)
Unchanged	9 patients	39 (28–111)	11 patients	29 (28–111)
Worsened	3 patients	–	1 patient	–

[a]Not available in 2 patients; [b]>1 point improvement.

Median survival for all 17 patients from first treatment was 146 d (44–301 d). The 5 patients with sustained tumor-volume reductions had a median survival of 242 d (158–301 d). No medically significant toxicities typically associated with systemic administration of cisplatin were reported.

Conclusion: Intratumoral CDDP/epi injectable gel is a simple method for relieving dysphagia due to predominantly exophytic esophageal cancer. This local chemotherapy may be complementary to stent insertion.

523 POSTER

Radiochemotherapy in anal canal carcinoma (ACC). A randomized clinical trial comparing FluoroUracil-Cisplatinum (5FU-CDDP) and CDDP alone

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Purpose: 5 FU-CDDP and 5FU-Mitomycin are the most commonly used chemotherapy regimens for ACC in combination wih radiotherapy (RT). CDDP is also an attractive drug due to its high rate of clinical response in squamous cell carnicoma. This randomized trial aimed at comparing 5FU-CDDP versus CDPP given concomitantly with RT in ACC.

Methods: Between 1992 and 1995, 26 patients (pts) were included in this randomized trial. Inclusion criteria were: squamous cell carcinoma of ACC, without distant metastases, patients who could receive RT and chemotherapy for curative intent. Radiotherapy was given with external beam RT (direct perineal field: 30 Gy/10 F/12 days and sacral fields 18 Gy/6 F/3 weeks) followed by Iridium implant (15–25 Gy/1–2 days). One course of chemotherapy was given during EBRT: 5FU J1J4: 800 mg/m^2 continuous infusion CDDP: 80 mg/m^2 J2 (5FU-CDDP) or CDDP J1–J3: 30 mg/m^2 continuous infusion (CDDP alone).

Results: the two groups were identical sex ratios (11 female vs 2 male) median age (65 vs 66 years). T1-2 (9 vs 10) T3-4 (4 vs 3). NO (7 vs 6). N1-2-3 (6 vs 7). Median followup was 52 months. Two months alter the end of treatment a complete remission was seen in 11 pts in 5FU-CDDP group (I) vs 12 pts in CDDP group (II). There was no local recurrence in group I and one in group II. At 4 years the overall survival was 91% in both groups. There was 2 grade 3 complications in group I and none in group II.

Conclusion: This small randomized trial shows no significant difference in local survical and toxicity between 5FU-CDDP and CDDP alone conbined with RT in ACC. CDDP alone which has an excellent tolerance could be tested on a large scale for T1-2 NO tumors of the ACC.

524 POSTER

Complete peritonectomy associated with intra peritoneal hyperthermic perfusion in the treatment of Pseudomyxoma Peritonei: Experience at the National Cancer Institute of Milan

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Introduction: Pseudomyxoma Peritonei is a rare disease characterized by a complete redistribution of mucin into the peritoneal cavity. Pseudomyxoma Peritonei could be classified into three diagnostic categories: disseminated peritoneal adenomucinosis (DPAM), peritoneal mucinous carcinomatosis (PMCA) and Intermediate Group (IG). DPAM is characterized by little cytologic atypia or mitotic activity often associated with an appendiceal mucinous adenoma, while PMCA shows cytologic features of adenocarcinoma. The intermediate group shows features between DPAM and PMCA and derived from well-differentiated appendiceal or intestinal mucinous adenocarcinoma.

Procedures: The natural history of PMP was strongly modified by the introduction of a new methodology proposed by Sugarbaker: the cytoreductive surgery that may require six peritonectomy procedures associated with Intra Peritoneal Hyperthermic Perfusion (IPHP) that combines hyperthermia and high drugs doses. Since November 1996, 12 patients with PMP syndrome have undergone surgical procedure in order to be treated by Sugarbaker's technique. Six cases were classified as DPAM, 4 as PMCA and finally 2 as intermediate histology. In the DPAM group three patients underwent appendicectomy before.

Results: All DPAM patients have been treated by Complete Peritonectomy and IPHP. Into the intermediate histology group 1 patient received Complete Peritonectomy and IPHP while 1 patient previously treated elsewhere 3 times by surgery received only induction IPHP. Unfortunately no patients in the PMCA group were eligible for the proposed treatment and received only an explorative laparotomy and partial debulking. IPHP was conducted by the closed abdomen technique using CDDP and MMC. All patients showed high CEA marker values that drastically decreased in those treated by Complete Peritonectomy and IPHP. All treated patients are NED.

Conclusion: Patients with PMP originated from undifferentiated mucinous adenocarcinoma were not eligible for this technique. Complete Peritonectomy associated with IPHP is the most indicated approach to cure this rare disease. This study was partially supported by the Associazione Italiana per la Ricerca sul Cancro.

525 POSTER

Concurrent high dose radiotherapy and cisplatinum-based chemotherapy ± immunotherapy versus radiotherapy alone in esophageal carcinoma. Molecular biology in assesment of response to chemoradiotherapy

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Purpose: In current study, we compared concurrent chemoradiotherapy (CRT) ± Immunotherapy to radiotherapy alone (RT) in patients with esophageal Ca. Molecular biology including DNA ploidy status, SPF and