Results: 121 courses were administered, median 4.8 per patient (1–10). WHO grade 3–4 toxicities: diarrhea in 5 patients (20%), leucopenia in 2 (8%) and thrombocytopenia in 1 (4%). Twenty-two patients are evaluable for response so far: 3 had a partial response (14%, 95%CI 2–35%), 12 stable disease (54%) and 7 a progression (32%). Clinical improvement appeared in 13 patients (59%). The median time to progression was 6 months and the median survival 8 months.

Conclusions: although preliminary, these results suggest that the combination of gemcitabine-UFT-ILV is moderately active, convenient for the patient and has an acceptable toxicity.

584 PUBLICATION

Phase II study of docetaxel as first line chemotherapy (CT) in metastatic adenocarcinoma of the pancreas

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Introduction: The therapeutic outcome obtained with CT in metastatic pancreatic cancer is poor. A response rate of 22% (95% CI 6–34%) has been reported in 30 pts. with metastatic disease for Docetaxel (D) in an earlier phase 2 study. Based on these results D was investigated in a confirmatory phase 2 study.

Patients: 15 pts. with bidimensionally measurable metastatic disease were entered onto the study and were evaluable for response and safety. Male/Female ratio: 8/7, median age 58 (39–64), median WHO PS: 1 (0–2).

Treatment: D was given at a dose of 100 mg/m^2 i.v. over 1 h. every 21 days.

Results: 15 pts. received a total of 55 cycles with a median no. of 3 cycles/patient (range 1–8).

Safety: Short lasting neutropenia of NCI-CTC grade 4 and anaemia grade 3/4 occurred in 73% and 13% of pts. respectively. The incidence of non hematological toxicities of NCI-CTC grade 3/4 was asthenia 13%, vomiting 6%, stomatitis 6% and edema in 6% of pts. respectively.

Response: 1 PR (7% [95% CI 0–32%]) was achieved. In addition 10 (67%) pts. had stable disease resulting in a tumor growth control rate (PR/NC) of 74% (95% CI 45–92%). The median time to progression of disease was 5 month.

Conclusion: The present trial confirmed the results of newer phase 2 studies. However, the high rate of tumor growth control and the relatively long median time to progression suggest that patients may benefit from treatment with Docetaxel.

585 PUBLICATION

Necrotic solitary nodule of the liver: Case reports and pathogenetic hypothesis

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Introduction: we observed 2 cases of a rare and non tumoral lesion of the liver, misinterpreted as (necrotic) tumor: the necrotic solitary nodule. It is a lesion well delimited by a dense hyalinised fibrotic capsule with a necrotic center in a granular tissue. Different aetiophatogenetic hypothesis have been postulated: evolution of a liver hemangioma or other benign lesions, traumas, parasitics or abscess infections, hematomas.

Methods: The first case concerns a 43 years female with continuous abdominal pain. US showed a polylobated lesion (35 × 35 × 38) at segment 8, with an hypoechoic core and an hyperechoic edge associated with cholelithiasis. Color-doppler signaled a compression of the celiac axis (Dunbar syndrome). Arteriography revealed a subtotal stenosis of the celiac tripod due to compression. CT scan confirmed the same lesion at segment 8 without contrast enhancement. FNAB-CT guided showed an highly-cellulated tissue with a necrotic core. The patient underwent surgery: cholecystectomy and correction of Dunbar syndrome (liberation of the celiac tripod from the fight pillar of the diaphragm; mechanic dilatation of the celiac tripod through trasversal arteriotomy sutured with 7/0 prolene). Follow-up revealed a progressive reduction in diameter of the lesion suggestive for an ischemic pathogenetic role. The second case concerns a 69 years male, with an hypoechoic lesion (32 × 32 × 30 mm) at segment 6 as occasional US finding during the staging for prostatic cancer. FNAB-CT guided was positive for malignant cells. Surgical treatment consisted in a wide excision of the lesion. Histologically it was highly cellulated, completely necrotic: solitary necrotic nodule.

Conclusion: The diagnosis of this rare lesion is accidental. According with literature (50% of cases), we founded an associated tumor. Thus, the correct diagnosis is achievable only with an histologic exam as demonstrated in the second clinical case reported.

586 PUBLICATION

Phase II trial of gemcitabine (GEM), 5-Fluoruracil (5-FU) and leucovorin (LV) in advanced pancreatic cancer (PC)

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Purpose: PC remains as one of the deadliest diseases. The high incidence of unresectable and disseminated disease has led clinical investigators to recognize that improved palliation of PC will require more effective systemic therapy. Many studies have failed to evaluate the palliative benefit of treatments, although many patients consider such benefit to be the utmost importance. Gemcitabine (GEM), a novel nucleoside analogue and 5-Fluorouracil (5-FU) are the most active agents in PC. Their combination could result in higher activity.

Methods: A multi-institutional phase II study was initiated in November 97, to determine the clinical benefit, response rate and toxicity of the combination chemotherapy regimen. Schedule was: G 1000 mg/m^2 iv., 5-FU 600 mg/m^2 bolus iv. and LV 25 mg/m^2 iv. All drugs were given weekly for 3 weeks every 4 weeks. 18 pts. were accrued, male/female 12/6, median age 60.5 years (r 39–76), PS (ECOG) 0–2, 1–3, 2–13. All pts. were symptomatic: pain, weight loss, anorexia, impaired (PS); 11 pts. had locally advanced and 7 pts. had metastatic disease.

Results: 4 pts. achieved a PR and 11 a SD (RR 22.2%) (95% CI 6.4–47.6%). Median survival for all the pts. was 11 months. We observed only 11.2% of grade 3–4 hematological toxicity (WHO).

Conclusions: This chemotherapy regimen shows promising activity with low toxicity in this chemoresistant malignancy.

587 PUBLICATION

Cryosurgery for locally advanced pancreatic cancer

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Cancer of the exocrine pancreas remains a therapeutic challenge and continues to have a por prognosis. Only 10–15% of patients present with localized disease amenable for surgery with curative intent. Most patients with unresectable cancer die within 6 months of diagnosis, and thus novel treatment methods are needed. The aim of the study was to evaluate results of cryosurgery in patients with unresectable pancreatic cancer. Fifty-three patients with mean age 62.6 (range 26–74) with locally advanced exocrine pancreatic cancer were operated on in our Department. In 11 cases tumour was located in the head of the pancreas, in the body or tail in 25 cases. Seventeen patients had total pancreatic cancer. Cryosurgery alone was performed in 32 patients, other 21 underwent combined operative procedure consisted of cryosurgery and cholecystojejunostomy in patients with jaundice or gastrojejunostomy in patients with gastric obstruction. Cryosurgery of primary lesion in pancreas and solitary metastases in liver was performed in 5 cases. The size of the lesion determined the size of the cryoprobe to be used. In cases of big tumours (more than 5 cm in diameter) we performed destruction with two freeze-thaw cycles. The process of destruction was monitored effectively with intraoperative ultrasonsgraphy. Patient follow-up ranged from 8 to 40 months. Three patients (5.6%) died within 30 days after operation. Causes of death were disease progression in two cases and hepatorenal syndrome in one. Postoperative complications occurred in 14 cases (26.4%) and included pneumonia, wound infection and pancreatic fistula. Fifty patients (94.3%) were alive at 8 months of follow-up. The 1-, 2-, 3-year survivals were 64.1%, 28.3%, and 13.2%, respectively. Two patients lived 40 months. Thus, cryosurgery proved to be effective for the management of patients with locally advanced pancreatic cancer.