

and toxicity (T). Pts and Methods: 20 pts, M/F = 10/10; PS 0–2; Median age 64y (40–75). Types of tumors: 5 pts Advanced Pancreatic Cancer (APC) and 2 pts Advanced Gastric Cancer (AGC), both resistant to FAM; 5 pts Advanced Head & Neck Cancer (AHNC) resistant to 5-FU-CDDP; 3 pts Advanced Ovarian Cancer (AOC) resistant to Taxol and 5 pts Advanced Prostate Hormonotherapy Resistant Cancer (APHRC). Treatment: T 100 mg/m², 1 hr. infusion every 21 days, until disease progression. Response: OR (CR + PR): 7/20 (35%) (CR: 1 AOC; PR: 2 APC, 1 AHNC, 2 AOC, 1 APHRC); SD: 10/20 (50%) (2 APC, 1 AGC, 4 AHNC, 3 APHRC); PD3/20 (15%). Toxicity: Neutropenia G3/4: 6/20 p (30%) and G2: 7/20 p (35%); 12/20 p (60%) required CSF.

Conclusion: T is very active as single agent in Advanced and Resistant Tumors (APC, AOC, APHRC and AHNC). Neutropenia is important but reversible.

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PUBLICATION

Curative and palliative therapy of pancreatic cancer: A retrospective analysis

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Background: Pancreatic cancer is responsible for 3% of all tumors and 10% of the digestive tumors. The 5-year survival rate is only 1–3%, in which the first diagnosis 80% of the patients are nonresectable primary.

Methods: We report about the treatment of 177 patients (85 women, 92 men) with pancreatic cancer from 1993–1998. The histological types of carcinoma were: 147 ductal adenocarcinoma, 10 carcinoma of the papilla, 5 endocrine tumors and 1 epithelioma. In 67.2%, the tumor was localized in the head, 12.4% in corpus/tail and in 5.5% in the papilla. 14 patients were without secure histological diagnosis, and definitive location of the tumor was unknown. At the time the tumor was first diagnosed 17.3% were lymph node negative. 17.3% were Stage III and 65.3% of the patients were Stage IV.

Results: A primary surgical curative treatment was performed: 54 Whipple's operation, 5 leftside resection, 1 transduodenal extirpation of the papilla with a hospital lethality of 5.5% and a 30-day lethality of 1.8%. 82 patients had a histologically proven nonresectable primary (primary palliative operation). 26 patients were treated with locoregional chemotherapy (aortic stop flow; i.a. truncus coeliacus), 53 patients with a primary chemotherapy (gemcitabine and gemcitabine/docetaxel). The median survival time was 6.9 month in this group, patients with locoregional therapy it was 4–4.5 months and in the group of the patients who underwent complete surgical resection it was found to be 14.8 month.

Conclusion: A possibility to improve the survival time of patients with pancreatic cancer is the early first diagnosis and the improvement of combinations multimodal therapy options.

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PUBLICATION

Improvement of efficacy of Gemcitabine (G) on xenografts of human pancreatic carcinomas in nude mice by combination with Mitomycin-C (M-C)

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Stimulated by clinical data (R. Klapdor et al, J. Cancer Res. Clin. Oncol. 124, 1998, R11) we investigated the antitumor efficacy of Gemcitabine in xenografts of human pancreatic carcinomas established in nude mice in comparison to a combination of Gemcitabine (G) + Mitomycin-C (M-C).

Methods: 5 different human pancreatic carcinoma xenografts established in our own lab were treated with 20, 40, 80, 160 mg/kg b.w. G resp., and in a second study with a combination of 30, 80 and 130 mg/b.w. G + 1.9 mg/kg M-C and 120 mg/kg b.w. G + 0.5, 1.1 and 1.9 mg/b.w. M-C resp., given weekly for 3–5 weeks by i.p. application. Each group comprised 5–6 nude mice. Treatment was started at tumor sizes between 200–400 cm.

Results: G showed a dose dependent tumor growth inhibition in 2/5 xenografts (2/5 partial responses after 3 weeks treatment with 160 mg/kg b.w.). Combination with M-C (120 mg/kg b.w. G + 1.9 mg/kg M-C) resulted in 4/5 partial remission and 1/5 stable diseases. In the nude mice bearing xenografts resistant against G monotherapy also a subsequent treatment with a combination of G + M-C like a second line therapy induced partial responses. Combined treatment did not affect body weight of the nude mice more than G alone. Also in an additional experimental study in nude mice bearing xenografts of a human gastric carcinoma combined treatment with

G + M-C resulted in a significant tumor growth inhibition with PR after 3 weeks, as also found for 5-FU (110 mg/kg b.w. weekly i.p.) and Oxaliplatin (15 mg/kg b.w. weekly i.p.).

Conclusions: a) Combined treatment of exocrine pancreatic cancer with a combination of G + M-C seems to be more effective than G alone. b) This combination might also be of clinical relevance in patients suffering from other tumor entities, at least in single cases.

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PUBLICATION

Docetaxel as salvage chemotherapy in advanced gastric cancer patients (AGC): A phase II study of the Southern Italy oncology group (GOIM)

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Purpose: Gastric cancer is considered the most responsive of all digestive tract cancers, and various combinations of cytostatic agents (generally containing 5-fluorouracil and anthracyclines) have been employed in advanced disease. After first-line failure, no standard salvage treatment was identified and then new drugs were explored. In particular, docetaxel showed considerable activity in patients with AGC (Sulkes, Br. J. Cancer 1994; Einzig, Medical Onco 1996). Following these results, from November 1998, patients with AGC previously treated with first-line chemotherapy were enrolled in this phase II multicentric trial.

Methods: Patients received Docetaxel 100 mg/m² as a 1-hr infusion, every 3 weeks. Up to now 11 pts were enrolled in the study. All pts were pretreated with 5-Fluorouracil and Epimycin containing regimens. The main characteristics of the entered pts were as follows: sex (M/F): 9/2; median age 65 yr (range: 22–69); median ECOG PS 1; sites of disease: liver 6, lymphnodes 4, relapse 2, other 5.

Results: Seven patients are actually evaluable for response and toxicity: Two objective responses, 2 stable disease and 3 progressive disease with an overall response rate of 29%. With regard to toxicity (WHO criteria) 2 patients showed grade 3–4 leukopenia. No other grade 3–4 toxicities were observed.

Conclusion: The study is still ongoing. These preliminary results suggest that docetaxel is active in previously treated patients with AGC.

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PUBLICATION

A prospective study of MRI in the staging, and response assessment of patients treated with chemo-radiation (CRT)

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Purpose: To prospectively use the recognised soft tissue contrast sensitivity of MR in the staging, and assessment of response to treatment following CRT, in patients with anal cancer.

Method: Ten patients entered prospectively into UKCCR Anal Cancer Trials employing chemo-radiation were assessed by sequential MRI. The technique included small field of view axial and coronal T2 and STIR images. These images were obtained pre-treatment, 3–4 weeks after completion of chemo-radiation phase I and prior to phase II, 1 month and 6 months after completion of all treatment. Clinical evaluation was performed at each MR assessment.

Results: By MR criteria, staging was allocated as follows T1-1, T2-2, T3-4 and T4 – 3 patients; 2 patients had N2 disease. Response status, as assessed by MR is summarised below.

Assessment time point	MR Response			
	CR	PR	PD	OTHER
Post Ph I CRT	3	7	–	–
1 Month post ph II	8	–	1	1
6 Months post ph 2	7	–	–	3

There was no instance where clinical examination conflicted with the MR assessment of response. The one instance of PD was confirmed clinically and histologically.

Conclusion: MRI provides detailed anatomical information on tumour extent leading to confident non surgical TN staging. The use of MR with its inherent soft-tissue contrast has recorded detailed changes during, and following, CRT. This response assessment was in keeping with clinical examination.