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Phase II study of docetaxel (D) as salvage chemotherapy in patients with advanced gastric cancer

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Introduction: D has considerable antitumor activity as first line chemotherapy in gastric cancer. The present study investigated D as second line treatment in metastatic disease. D was given at a dose of 100 mg/m² i.v. every 3 weeks.

Patients and Methods: 27 pts. with documented disease progression while receiving 5-FU containing regimens (17 pts. with 5-FU/Cisplatin) were entered onto the study. Median age 57 years (46–66), M/F ratio 20/2, WHO PS 1 (0–2).

Results: 25 pts. with a total of 98 cycles are evaluable for response and safety. Short lasting Neutropenia of NCI-CTC grade 4 occurred in 60% of pts. No other toxicities of NCI-CTC grade 4 have been observed. The incidence of non-hematological toxicities of NCI-CTC grade 3 was 8% for neuropathy and asthenia, 4% for mucositis and diarrhea respectively. No treatment related death occurred.

Response: One CR and 4 RP corresponding with an overall response rate of 20% (95% CI: 7–41%) were achieved. Stabilization of disease have been observed in 8 (32%) of response evaluable patients, resulting in a tumor growth control rate of 52% (95% CI: 31–72). 4 PR have been observed in a subgroup of 17 pts. after prior exposure to HD Fol/5-FU and Cisplatin.

Conclusion: Docetaxel is active as second line CT in metastatic gastric cancer after prior exposure to 5-FU and Cisplatin based regimens

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Transhiatal oesophagectomy in the treatment of carcinoma of the lower oesophagus and cardia of the stomach – Influence of preoperative risk factors

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Background/Aims: Despite all advances in surgical treatment and efforts in the postoperative management of patients with carcinoma of the lower oesophagus and cardia, morbidity, mortality and late results are disappointing. A comparative randomised study evaluate preoperative risk factors in three groups.

Materials and Methods: One-hundred and twenty-five patients with adenocarcinoma of the lower oesophagus and the cardia of the stomach referred to Surgical Clinic between 1990 and 1996. In fifty patients the disease was staged T₂N₁M₀ with the tumour supposedly restricted to oesophageal or gastric wall. Based on the "scoring system" reported by Siewert all patients who subsequently underwent transhiatal oesophagectomy had detailed preoperative assessment and were divided in three groups of risk.

Risk	Score Points	N	Complications	Mortality
Low Risk	12–15	12	8	1
Moderate Risk	16–21	22	8	3
High Risk	22–37	16	12	6
Total	–	50	28	10 (20%)

Conclusions: Siewert's scoring system is reliable and highly predictive for morbidity and mortality after transhiatal oesophagectomy in cancer patients.

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3-Dimensional planned conformal radiation technique (3D-RT) compared to standard 2 isocentric fields AP-PA radiation technique (APPA-RT) in anal cancer

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Purpose: Escalation of radiation dose intensity (RDI-total dose per overall treatment time) in chemoradiation for anal cancer seems to be necessary

to improve locoregional control, but APPA-RT then results in more severe toxicity. 3D-RT, which spares radiation sensitive regions of vulva and ventral parts of the bladder, may allow to raise RDI without increasing toxicity or relapse risk.

Methode: 23 anal cancer patients were treated with chemoradiation 12/96–2/99. All patients had prior to radiation a computer tomography for 3-dimensional planning. The dose-volume histograms (DVH) of vulva, bladder, planning target volume (PTV-derived from a Co60 radiation technique used 1990–1996) and two high dose volumes (HDV-body volume confined by the 80% (HDV-80%) and 100% (HDV-100%) isodoses) of APPA-RT and 3D-RT were compared. 3D-RT consists of 4 isocentric MLC-shaped fields with gantry angle 40°–45°, 90°, 270° and 315°–320°.

Results: A significant reduction of Dmedian to vulva ($p < 0.001$) and bladder ($p < 0.001$), Dmax to PTV ($p < 0.001$) and of volume of the HDV-80% ($p < 0.001$) and HDV-100% ($p < 0.001$), but a significant increase of Dmin to PTV by the 3D-RT in comparison to APPA-RT.

Conclusion: 3D-RT may reduce the risk of acute toxicity in anal cancer patients and allow to increase RDI without severe toxicity. The dose distribution in PTV is more homogenous in 3D-RT than in APPA-RT. Clinical data of chemoradiation with 3D-RT will be provided.

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Whole body hyperthermia (WHB, 41.8°C) in combination with chemotherapy in gastrointestinal (GI) cancer

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Purpose: Platinum derivatives are promising substrates in the treatment of GI-tumors. Since hyperthermia is known to enhance their therapeutic index, the aim of the present study was to investigate toxicity and efficacy of WHB (41.8°C) in combination with carboplatin (CBDCA) and 5-fluorouracil (5-FU)/leucovorin in patients with advanced pancreatic or biliary tract cancer.

Methods: 14 pts. with pancreatic (7) or biliary tract (7) cancer, median age 60 (37–64) and performance status (WHO) 0–2 are so far included. WHB was administered by a radiant heat device (Enthermics Medical Systems). CBDCA (AUC 4.5, 30 min i.v. infusion) was administered after reaching the core temperature of 41.8°C, which was maintained for 60 min. Thermochemotherapy was preceded or followed by 5 days of 5-FU 425 mg/m² and leucovorin 20 mg/m². This regimen was repeated every 28 days. Tumor assessment was done following cycle 2 and 4.

Results: 40 cycles were evaluable. No objective responses were seen in pts. with pancreatic cancer (3 SD, 4 PD after 2 cycles). In pts. with biliary tract cancer there were 2 partial responses, disease stabilisation in 4 pts. with clinical improvement in 2 and one death due to septic complications. Toxicities (WHO 3–4) included: neutropenia (1 cycle); thrombocytopenia (6); anemia (4); mucositis (2); diarrhea (4). Due to severe thrombocytopenia or leukopenia treatment had to be delayed in 6 cycles. Delays were only seen, when 5-FU/leucovorin preceded CBDCA.

Conclusion: No unexpected toxicities were seen with concurrent systemic hyperthermia. Thermochemotherapy is active in biliary tract carcinoma and is warranted for further evaluation. As a result of this study we initiated a trial to investigate the effect of WHB in combination with oxaliplatin in pt. with colorectal cancer.

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The role of different preoperative treatment modality in esophageal carcinoma management

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Purpose: The routine use of adjuvant radiotherapy as a single modality is presently not warranted on the basis of majority randomized trials. Investigation of influence of additional use of intracavitary brachytherapy (IBT), hyperthermia (HT) and hyperglycaemia (HG)

Methods: 243 untreated cases of esophageal squamous cell carcinoma were entered in the study. 54 patients were treated with surgery alone, the rest 189 received external beam radiotherapy (RT) to a total dose 30 Gy/6 fractions/8 days in preoperative period. The 57 patients of 2nd group received in preoperative period external RT only. IBT was administered to 59 patients in 2–3 days after RT (the 3rd group). The average dose delivered by IBT (¹³⁷Cs, LDR-MDR or ⁶⁰Co, HDR-MDR) was 15 Gy/3 fractions. Thermochemotherapy was used for 37 patients in the 4th group. Intracavitary SHF-HT sessions ($t = 42.5–44^{\circ}\text{C}$) were provided in 2 hours after RT each