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# Preoperative staging and tumor resectability assessment in pancreatic cancer. Prospective study comparing endoscopic ultrasonography (EUS), computed tomography (CT), magnetic resonance imaging (MRI) and angiography

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**Background/Aim:** So far, there is no consensus about the best strategy for staging and tumor resectability assessment in pancreatic cancer. In this prospective study, efficacy of EUS, helical CT, MRI and angiography were compared.

**Method:** All patients with pancreatic or periampullar cancer judged fit for laparotomy were studied by EUS, CT, MRI and angiography. Analyses included: extension of primary tumor, loco-regional, lymph-node, vascular and metastatic invasion, TNM stage, and tumor irresectability. Imaging results were correlated with surgical findings.

**Results:** Sixty-two patients were included, 51 (82%) with pancreatic and 11 (18%) with periampullar cancer. Of them, 44 (71%) patients had loco-regional invasion, 26 (42%) lymph-node involvement, 25 (40%) vascular invasion, and 12 (19%) distance metastases. In addition, tumor was irresectable in 25 (40%) patients. CT had the highest accuracy in assessing extension of primary tumor (73%), loco-regional invasion (74%), vascular invasion (83%), distance metastases (88%), and TNM stage (41%). By contrast, EUS had the highest accuracy for lymph-node involvement (65%). CT was the most effective individual technique for establishing tumor irresectability (table).

	Se	Sp	PPV	NPV	A
EUS	23	100	100	64	67
CT	67	97	95	77	83
MRI	57	90	81	73	75
ANG	37	100	100	65	71

Se, sensitivity; Sp, specificity; PPV, positive predictive value; NPV, negative predictive value; A, accuracy. ANG, angiography. All values in %.

When imaging techniques were evaluated altogether, combination of CT and EUS had the highest sensitivity (74%) for tumor irresectability. If both tests were in agreement, specificity was maximum (100%). In discordant cases, angiography contributed to reestablish 100% specificity.

**Conclusions:** Helical CT is the most useful individual imaging technique for tumor staging in pancreatic cancer. Combination with EUS may represent the most effective strategy for establishing tumor irresectability, being angiography only needed in discordant cases.

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# Prospective assessment of functional results and quality of life in patients treated for locally advanced anal canal carcinoma by high dose radio-chemotherapy:

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**Objectives:** Functional results of conservative treatments must be evaluated, especially in locally advanced tumors, when the sphincter can be destroyed by the tumour or late treatment effects. Quality of life (QOL) is an end point of a four arms prospective phase III study of treatment intensification by induction chemotherapy (CT) and a higher dose of irradiation (RT). The prime objective of this trial is to improve the colostomy-free survival. We studied the functional results of the first 60 patients included in the study.

**Patients and Methods:** There were 48F/12M (mean age = 65, range 31-79). The T-stages were 3 T1, 37 T2, 13 T3, 7 T4, 30 N0, 15 N1, 15 N2-3, 60 M0. They received a pelvic RT (45Gy in 25 fractions over 5 weeks) combined with concomitant 5-FU-CDDP CT in weeks 1 and 5, followed by a RT boost (15Gy). Two cycles of induction CT were delivered in two arms, and a higher dose (20-25Gy) in two arms. QOL was assessed by two validated questionnaires: the EORTC QLQ-C30, and the Anal Sphincter Conservative Treatments Questionnaire. The forms are filled at inclusion, at 2 and 6 months after the end of the treatment and annually.

**Results:** The first two questionnaires were analysed in 56/60 patients. Diarrhea was present in 17% and 9.4% of the cases respectively and an adjunctive treatment prescribed in 23% and 16.6% of the cases respectively. Constipation was present in 12% and 3.1% of the cases respectively, and an adjunctive treatment was prescribed in 22.4% and 9.4% of the cases respectively. Incontinence for gas, stools, and mucous was not modified (77.6% and 81.8%, 96% and 100%, 91.7% and 96.9% respectively). The need of a protective pad, and imperious bowel movements were not modified. Diet was modified in 28.5% and 48.5% of the cases respectively. The patients were unsatisfied for their bowel work in 20.8% and 9.7% of the cases respectively and moderately satisfied in 33.3% and 42% respectively. The health status perception was qualified of median in 45.6% and 40.6%, and very good in 42.5% and 47% of the cases respectively.

**Conclusion:** This prospective evaluation of the digestive function and QOL shows the improvements partially linked to the adjunctive treatments. The proper role of the specific cancer treatment will be analyzed from the different treatment modalities. The high rate of responses depicts the high interest of the QOL in patients and physicians considering the conservative treatment of anal canal carcinoma.

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# Pemetrexed disodium (Alimta™) with folic acid (FA) in advanced or metastatic gastric cancer

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**Purpose:** A clinical trial was undertaken in order to evaluate the efficacy of the new antifolate Alimta in chemonaive patients (pts) with locally advanced or metastatic gastric cancer. After the first few pts, an oral supplementation with FA was also given due to major drug-related toxicity observed. In fact an early clinical study and preclinical studies with Alimta suggested that FA should reduce antifolate toxicity, especially in pts likely to have folate deficiency, and have little or no impact on efficacy.

**Methods:** In this ongoing study Alimta is administered at a dose of 500 mg/m<sup>2</sup> as a 10-minute infusion every 21 days (d). In addition, an oral supplementation with 5 mg FA/d for 5d starting 2d before Alimta is given.

**Results:** Each of the first 6 pts had at least one episode of Grade (Gr) 3/4 toxicity; Gr 3/4 neutropenia occurred in 10 of 15 cycles completed. One pt discontinued, and three died, all due to toxicity related to study drug. As a result, subsequent pts were given oral supplementation with FA. Twenty-five pts with measurable disease have since enrolled receiving 97 cycles (median 2, range 1-8). Median age was 60 years (range 44-76); all but one pt had a ECOG PS of 0-1. Main metastatic sites were liver (15/25), abdominal lymph nodes (12/25) and lung (6/25). Thus far, 6 of these 25 pts have had confirmed objective responses (2 CRs + 4 PRs) with an overall response rate of 24%; an additional pt had an unconfirmed complete remission. Gr 3/4 treatment-related toxicities have been neutropenia (24%), leucopenia (4%), thrombocytopenia (8%) and raised transaminases (4%).

**Conclusion:** Although the trial is still in progress, the early clinical findings show that Alimta has a very promising activity in gastric cancer, while supplementation with low-dose FA orally is able to dramatically improve safety profile of the antifolate.

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# Final results of a phase 1 and PK study of capecitabine (XEL) in combination with epirubicin (E) and cisplatin (C) [ECC] in patients with advanced oesophagogastric (OG) adenocarcinoma

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The standard treatment of advanced OG adenocarcinoma in the UK is with EC and continuous infusion 5-FU by an indwelling central venous catheter [ECF] which has a significant complication and morbidity rate. Capecitabine is an orally-available tumour-selective fluoropyrimidine carbamate which is bio-activated by a 3-enzyme process to provide prolonged high levels of the active moiety, 5-FU, within tumour cells, and is active in breast and colorectal cancers. To reduce the morbidity of ECF associated with Hickman line insertion we have conducted a dose-finding and PK study of capecitabine in combination with EC.

32 patients (28M/4F) median age 63 (range 32-76) years, ECOG performance status 0-2, with histologically proven unresectable (10) or metastatic