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Prognostic significance of resection line involvement after gastric cancer surgery: a single western centre experience

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Background: Curative gastrectomy represents the treatment of choice for gastric cancer. A variety of clinicopathologic features, such as resection line involvement (RLI) has been suggested as prognostic indicators for gastric cancer. The aim of this study was to investigate whether microscopic positive margins are detrimental to the outcome of gastric cancer patients treated with gastrectomy.
Methods: Among 1087 consecutive patients who had undergone gastrectomy with curative intent for gastric cancer between January 1990 and December 2008, 116 patients (10.7%) had positive resection margins on final histology.
Results: Among these 116 patients, 48 had proximal and distal involved margins, 33 had proximal involved margins, and 35 had distal involved margins. No one patient had reoperation. The mean distance between proximal gastric margin and the neoplasia was 4±3.8 (min 0, max 21) and from the distal margin and the neoplasia 4±3.9 (min 0, max 24). In the multivariate analysis the TNM stage and status of the oesophageal margin were the only independent prognostic factors for survival. The negative margin group had a significantly longer median survival time ($P < 0.00001$). When both groups of patients were stratified according to nodal stage, a positive resection margin determined a worse prognosis only in patients with node-positive disease (mean survival time: 63 months vs. 21 months, $P = 0.0001$). In early gastric cancer (EGC) the resection margin involvement did not influenced survival. On the contrary, in more advanced diseases the positive margins is a negative prognostic factor for survival.
Conclusions: A positive gastric or oesophageal margin is an independent poor prognostic factor for long-term survival in stomach cancer in advanced disease or node positive patients.

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Minimally invasive esophagectomy for cancer: monoistitutional experience

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Background: Minimally invasive esophagectomy is rapidly emerging as a suitable surgical alternative to the open technique. Our retrospective study aimed to evaluate the feasibility and efficacy of laparoscopic and thoracoscopic esophagectomy.
Methods: This retrospective study consider 41 consecutive patients treated with mininvasive curative esophagectomy for cancer in our Istitution from May 2002 to December 2007.
Results: Patients were 33 men (80.5%) and 8 women (19.5%) that underwent minimally invasive esophageal resection. Mean age was 65±10 years (range 37−80). Surgical indication was: adenocarcinoma (n = 23, 56%), and squamous cell carcinoma (n = 18, 44%). Ten patients (24.4%) received neoadjuvant radiochemotherapy. Transhiatal laparoscopic esopphagectomy was employed in 6 cases (14.6%), while in the remaining 35 cases a combined laparoscopic gastric mobilisation and right transthoracic incision (n = 19) or thoracoscopic approach (n = 16) was performed. Esophagogastric anastomosis was performed in the left neck (n = 30) or intrathoracic (n = 11). The mean operative time was 430±80 min (range 290–630). Conversion rate was 35% (7% during the abdominal operation and 28% during the thoracic operation). The mean time of hospital stay was 22±12 days (range 10−64). The median critical care unit stay was 3.6±5.4 days (0−26). In 10 patients (24.4%) there was an anastomotic leakage that no required a surgical treatment. Perioperative mortality was 4.8% (n = 2). The histological examination demonstrated a radical excision (R0) in 92% of the cases; in the remaining 3 there was a positive radial margin. Stage of the neoplasm was: stage I in 9 patients (22%), IIa in 5 (12.2%), IIb in 8 (19.5%), III in 15 (36.6%), IV in 2 (4.8%). In 2 patients, previously treated with neo-adjuvant therapy, there was a complete pathological response. The mean number of lymph node retrieved was 17±11 (max 52). The mean time of follow-up was 17 months, whereas the mean survival was 28 months. Overall patient survival was 75% and 45% at 1 and 3 years, respectively.
Conclusion: In our experience, laparoscopic surgery for cancer of the oesophagus appears to show satisfactory results as regards the operative outcome, the number of resected lymph nodes and resection margins.

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The incidence, risk factors and prognostic implications of venous thromboembolism in patients with gastric cancer

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Background: This study was conducted to determine the incidence, risk factors and prognostic implications of venous thromboembolism (VTE) in patients with gastric cancer (GC).
Methods: Using prospectively collected databases, GC patients diagnosed between May 2003 and April 2008 (N = 2,085) were consecutively enrolled. The occurrence of an objectively defined VTE was identified.
Results: Two-year cumulative incidence of VTE after the GC diagnosis was 3.8%. In multivariate models, significant predictors of developing VTE were advanced stage (⩾stage II), older age (⩾60 years), and no major operation (P-values <0.05). Although perioperative pharmacologic thromboprophylaxis was not routinely performed, the VTE incidence after major abdominal operation was only 0.2%. When VTE cases were classified into pulmonary thromboembolism (PTE), extremity venous thrombosis (EVT) or intra-abdominal venous thrombosis (IVT), IVT (62%) was more common than EVT (21%) or PTE (17%). Patients receiving chemotherapy developed EVT/PTE more frequently than IVT; however, during untreated or treatment-refractory periods, IVT developed more frequently than EVT/PTE (P-values <0.05). In risk-adjusted multivariate models, although the EVT/PTE development was a significant predictor of early death when compared with no occurrence of VTE ($P < 0.05$), IVT did not affect survival.
Conclusion: The incidence of VTE in Korean patients with GC was similar to that in Western reports. Advanced stage, older age and no major surgery increased the risk of VTE. Considering different clinical situation and prognostic impact between EVT/PTE and IVT development, therapeutic approach should be also different.

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Clinical outcome of endoscopic mucosal resection (EMR) in stage I esophageal cancer

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Background: When a tumor invades to the muscularis mucosa or submucosal layer (T1a-MM or T1b, in Japan), clinical stage I (cSt I) esophageal cancer (EC) has 10−50%. risk of lymph node metastasis (LNM). Surgery, though very invasive, is the standard radical therapy for the patients (pts.) with such stage EC. Endoscopic mucosal resection (EMR), which conserves the esophagus, is a minimally invasive and attractive therapeutic modality for such pts. However, the clinical outcomes of EMR for these pts. have been not fully elucidated.
Methods: We conducted retrospective analysis of the clinical courses of 44 pts. who underwent EMR for newly diagnosed T1a-MM or T1bcN0M0 EC between 1994 and 2007at our hospital, and who could be followed up for at least 1 year. Statistical analysis was performed by the Kaplan-Meier methods and the Cox proportional hazard model. A P value of <0.05 was considered statiscally significant.
Results: Patients decided on the following treatments immediately after EMR based on informed consent and their general condition; 2 underwent surgery, one underwent prophylactic chemotherapy (CHT) and 41 selected follow-up without any additional therapy. Of the 41, 20 selected this course by choice, 12 because of severe concurrent disease; 2 because of poor performance status and 7 because of other multiple primary cancers (MPCs). Twelve pts. died; 2 were cause specific; (4.5%), 8 from MPCs, 1 from severe concurrent disease, and, 1 from unknown causes. Median age was 67 years old (range 53−80), and 5 were female. No critical comlications were noted. Median follow-up time was 1542 days (375–3786). 5 developed LNM. One with prophylactic CHT, was followed by surgery, and another was followed by CHT, who showed cause specific deaths later. Other 3 pts. followed by chemoradiotherapy, has not shown cause specific death. Overall and cause specific survival rates at 5 years were 67.3% and 91.8%, respectively. Multivariate analysis revealed that severe concurrent disease including MPCs, and the experience of 5-Fuluorouracil based CHT for MPCs significanctly influenced survival (p = 0.035, HR 11.783 (95%CI 1.197–116.007) and p = 0.011, HR 6.542 (95%CI 1.139−37.562), respectively). 8 and 6 pts.

developed metachronous EC and local recurrence, respectively. Apart from one, they could be retreated endoscopicaly.
Conclusions: EMR is a very useful therapeutic modality for cSt I EC, not only for local control but also as a clinically sufficient treatment; especially in pts. with severe concurrent disease.

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Bevacizumab combined with chemotherapy in the treatment of advanced/metastatic gastro-entero-pancreatic tumours: interim safety results from the phase II BETTER study

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Background: Gastro-entero-pancreatic (GEP) tumours are known to be highly vascular with elevated expression levels of vascular endothelial growth factor (VEGF). The aim of this study was to assess the efficacy and safety of adding bevacizumab (BV), a VEGF inhibitor, to two chemotherapy regimens in patients (pts) with previously untreated, progressive locally advanced/metastatic well-differentiated GEP tumours (pancreatico-duodenal and gastrointestinal [GI] tract).
Materials and Methods: Prospective, open-label, two-arm, non-comparative, multicentre phase II trial (EUDRACT 2007–003381−18). Pts with pancreatico-duodenal tumours received 5-FU 400 mg/m^2/day + streptozotocin 500 mg/m^2/day every 6 weeks + BV 7.5 mg/kg i.v. every 3 weeks (Arm 1); pts with GI tract tumours received capecitabine 1000 mg/m^2 per day on days 1−14 + BV 7.5 mg/kg i.v. every 3 weeks (Arm 2). After 6 months of treatment the physicians judged whether further chemotherapy was required. BV was administered until disease progression, unacceptable toxicity, or pt or physician decision to discontinue. The primary endpoint was progression-free survival. Secondary endpoints included response rate, overall survival and safety. The trial was funded by Roche France.
Results: Here we report interim safety findings on the first 40 pts enrolled (from a planned total of 81 pts) between June 07 and May 08. These findings relate to the first 6 months of treatment. Baseline characteristics are as follows: 21 male, 19 female; median age 59 years (range 37−82); 20 pancreatico-duodenal, 20 GI tract tumours. Grade 3/4 adverse events (AEs) were observed in 10 pts (50%) in Arm 1 and 12 pts (60%) in Arm 2. Main grade 3/4 AEs included hypertension (2 pts in Arm 1, 5 pts in Arm 2), asthenia (1 in Arm 1, 2 in Arm 2), embolism (1 in each Arm), haemorrhage (1 in each Arm), abdominal pain (1 in Arm 1), nausea (1 in Arm 1), diarrhea (2 in Arm 2) and febrile neutropenia (1 in Arm 2). Grade 3/4 BV-related AEs were observed in 3 pts in Arm 1 and 5 pts in Arm 2. Serious AEs were reported in 3 pts in each arm (1 BV-related SAE in Arm 1 and 2 in Arm 2). Treatment discontinuation due to toxicity was reported in 2 pts in Arm 1 and 1 pt in Arm 2. One pt died due to BV-related haemorrhagic stroke.
Conclusions: These results showed no unanticipated toxicity with BV plus standard chemotherapy for pts with previously untreated, progressive locally advanced/metastatic well-differentiated GEP tumours.

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Irinotecan and low-dose capecitabine combination as first-line chemotherapy in advanced or metastatic gastric cancer: results of a phase II study

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Background: Chemotherapy has a proven palliative role in advanced or metastatic gastric cancer. However, none of the currently explored regimens have shown compelling improvements without an impact on patients' quality of life. This phase II pilot study investigated the combination of irinotecan (CPT11) plus low-dose capecitabine as first-line therapy in advanced or metastatic gastric cancer.
Materials and Methods: For a period of 3 years patients with advanced or metastatic gastric cancer were enrolled to receive a combination of irinotecan 80 mg/m^2 on days 1, 8 and 15 plus capecitabine 625 mg/m^2 twice daily on days 1−14 every 4 weeks for a maximum of 8 cycles. Outcomes included response rate, time to progression, overall survival and safety. Outcomes were evaluated every 2 cycles.
Results: 32 patients, with a median age of 55 years, were evaluable. A total of 153 cycles were administered with a median of 4.7 cycles per patient. The objective response rate was 47%, with 9 patients having stable disease. The overall tumour control rate was 75%. Median time to progression and overall survival were 5 months and 8 months, respectively. Treatment was well tolerated with only 7 reported cases of grade 3/4 toxicities. No treatment-related deaths or hand-foot syndrome were observed during the study. Grade 3/4 toxicities were neutropenia (2 patients), diarrhoea (2 patients), nausea and vomiting (2 patients), asthenia (1 patient). Dose reduction was required for at least one cycle in 7 cases (22%).
Conclusion: The monthly regimen of low-dose capecitabine plus irinotecan appears to be active with a good toxicity profile in the treatment of advanced or metastatic gastric cancer. In cases where there is contraindication of platinum-based therapy, the more recent oxaliplatin- or docetaxel-based chemotherapies can be applied to this regimen.

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A randomized phase II trial of weekly docetaxel plus either cisplatin or oxaliplatin in patients with previously untreated advanced gastric cancer: Preliminary results

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Background: Docetaxel, in combination with cisplatin or oxaliplatin, has demonstrated efficacy against advanced gastric cancer (AGC). This randomized phase II trial evaluated two weekly docetaxel-based regimens to see which would be most promising according to objective response rate (ORR) as first-line therapy in AGC.
Methods: Chemotherapy-naïve patients with measurable unresectable and/or metastatic gastric adenocarcinoma and a performance status $\leqslant 2$ were randomly assigned to receive docetaxel (35 mg/m^2) weekly on days 1 and 8 of a 21-day cycle plus either cisplatin (60 mg/m^2 on day 1) (arm A) or oxaliplatin (120 mg/m^2 on day 1) (arm B). Toxicity was assessed on days 1, 8, and 21 of each cycle, and response was evaluated every 2 cycles.
Results: Between March 2007 and April 2009, 75 eligible patients entered. In Arm A, 35 patients were evaluable for objective response and 36 for safety. In Arm B, 37 patients were evaluable for objective response and 37 for safety. Median age was 57 years and disease status was comparable for both arms. Fourteen of 35 (40.0%) patients had a confirmed objective response in the arm A (95% confidence interval [CI] 23.7−56.2%) and 16 of 37 (43.2%) patients had a confirmed objective response in the arm B (95% CI 27.2−59.2%). No significant difference was noted between the arms both for ORR ($p = 0.641$) or for disease control (62.9% and 81.1%, respectively, $p = 0.116$). Median progression free survival time was 4.8 month in the arm A and 4.3 months in the arm B (Hazard ratio = 1.040; 95% CI, 0.602−1.797; $p = 0.889$). Median overall survival time was 9.6 months in the arm A and not reached in the arm B (Hazard ratio = 0.501; 95% CI, 0.243−1.036; $p = 0.062$). There was no relevant difference in the occurrence of overall grade 3/4 toxicity between the two arms (58.3% vs. 54.1%, respectively; $p = 0.815$). Neutropenia was the most common grade 3/4 toxicity (33.3% vs. 37.8%, respectively). There was one treatment related death in each arm.
Conclusions: The preliminary results showed that both treatment arms have similar clinical efficacy as front-line treatment in AGC. Each regimen has a manageable tolerability profile. The accrual is ongoing.

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A randomized phase II study of irinotecan monotherapy versus irinotecan plus 5-fluorouracil/leucovorin combination as a salvage chemotherapy in previously treated patients with advanced/metastatic gastric cancer

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Background: The purpose of this study was to compare the efficacy and toxicity of adding 5-fluorouracil/leucovorin to irinotecan in locally advanced/metastatic gastric cancer as a salvage chemotherapy.
Materials and Methods: Eligible patents had performance status 0 to 2, measurable unresectable and/or metastatic gastric adenocarcinoma,