

15% (G3-G4 2 pts). Stomatitis was evident in 20% (G3 1 pt). A CR (lasting 9 months) and a PR (lasting 10 months) were reported. Disease control rate was achieved in 45% of cases. On the entire group TTP was about 3 months but in 25% TTP exceeded 5 months. Long lasting SD (>6 months) was reported in 19.4% of cases.

Conclusions: The initial results are encouraging both in terms of safety and of disease control rate and support the employ of mTOR inhibitors also in this aggressive neoplasm. In addition, RAD001 has been here utilized as second line therapy and the next step will be its use in front line therapy. A longer follow up is needed to know median survival and correlations between mTOR expression and clinical response.

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POSTER

Preoperative F-18 FDG-PET/CT and CT Scanning Correlation in Curatively Operated Gastric Cancer Patients

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Background: The role of F-18 FDG-PET/CT in gastric cancer is limited. This retrospective study was designed to assess the positivity rate of F-18 FDG-PET/CT and CT in stomach cancer and its correlation with other clinicopathologic findings.

Materials and Methods: Four hundred and thirty two patients with gastric cancer (age = 62±11.6 years, M:F = 265:167) who underwent F-18 FDG-PET/CT before operation were included for this study from January 2008 to December 2009.

Results: Detection rates of primary tumours with F-18 FDG-PET/CT and CT images were 52.7% (T1 34.1%, T2 71.1%, T3 70.8%, T4 83.3%) and 65.4% (T1 42.8%, T2 81.1%, T3 94.7%, T4 100%) ($p < 0.001$). Accuracy of lymph node identification with image tools were 32.0% (47/147) in PET and 38.2% (42/110) in CT scan ($p < 0.001$). Detection rate of FDG-PET/CT showed significant difference with T, N stage, tumour grade, tumour size, lymphovascular invasion and nerve invasion ($p < 0.001$). By multivariate analysis, tumour size ($p < 0.001$) and nerve invasion ($p = 0.004$) were significantly related with detection rate of FDG-PET/CT scan.

Conclusions: Detection rate of FDG-PET/CT scan showed significant difference with T, N stage, tumour grade, tumour size, lymphovascular invasion and nerve invasion. By multivariate analysis, tumour size and nerve invasion were significantly related with detection rate of FDG-PET/CT scan.

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POSTER

A Combination of RAD001 and Octreotide LAR as First-line Treatment of Well Differentiated Neuroendocrine Tumours – an I.T.M.O. (Italian Trials in Medical Oncology) Group Study

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Background: RAD001 is an oral inhibitor of mTOR (mammalian target of rapamycin). It has shown antitumour activity in advanced pancreatic neuroendocrine tumours (NETs) and it seems to work synergistically with somatostatin analogues. The primary objective of this multicentric study is to assess the activity and safety of RAD001 combined with Octreotide LAR as first-line treatment of advanced neuroendocrine tumours of the lung and the gastro-entero-pancreatic tract.

Material and Methods: From March 2009 to June 2010, 50 patients (21 female and 29 male) enrolled in 11 sites and affected with advanced neuroendocrine carcinoma were treated with RAD001 10 mg/day and Octreotide LAR 30 mg/month, until disease progression and/or unacceptable toxicity. Forty-two pts had a well differentiated endocrine carcinoma of the gastro-intestinal tract and 8 had a typical or atypical lung carcinoid. The median age was 60.5 yrs (range 25–76).

Results: An interim analysis has been performed, and the results about the response rate and toxicity of this drug combination are as follows: The clinical benefit is 96%; in more detail: SD 83.7%, PR 9.3% and CR 2.3%. The mild and moderate adverse events (G1 and G2) were: diarrhoea 12 pts (24%), stomatitis 7 pts (15%), skin rash 13 pts (28%), hypercholesterolaemia 7 pts (14%), hyperglycemia 5 pts (10%), thrombocytopenia 3 pts (6%) and

interstitial lung disease in 1 patient (2%). We also reported G3 mucosal inflammation (stomatitis and anal inflammation) in 4 pts (9%), hypokalaemia G3 in 1 pts due to diarrhoea, and stomatitis G4 in only 1 patient. No adverse events led to withdrawal from study treatment.

Conclusions: In our experience, the preliminary analysis shows that RAD001 and Octreotide LAR is safe and effective. The combination seems to be effective not only in pancreatic NETs, as reported, but also in lung and other gastro-entero-pancreatic neuroendocrine neoplasms.

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POSTER

Clinical Outcome of Local Recurrence Cases After Endoscopic Mucosal Resection(EMR) for Mucosal Esophageal Squamous-cell Cancer

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Background: Endoscopic mucosal resection (EMR) is minimally invasive. When esophageal squamous-cell cancer (ESCC) is limited to mucosal layer, EMR is the standard curative therapy with good outcome. Although local recurrence (rec.) is reportedly from 2.8% to 7.8%, their clinical outcome has not been reported fully, so far. Herein, we investigated the detailed outcome of local rec. cases after EMR for mucosal ESCC.

Patients and Methods: We conducted retrospective research on patients(pts.) who underwent EMR for mucosal ESCC and could be followed-up for at least one year. Local rec. was determined by finding a new lesion around the EMR scar without residual Lugol-voiding area (LVL) at the end of EMR. Patients who had received prior radiotherapy or chemotherapy were excluded. Follow-up endoscopy was performed every six months, basically.

Results: Between January 2002 and December 2010, 140 pts. with 154 lesions underwent EMR for mucosal ESCC. Twelve of them (12 lesions) had local rec. (7.8%). Two were female and the median age was 67.0 years (range: 62–79). The median follow-up and local rec. free period were 61.7 months (range: 17.9–97.1) and 8.0 months (range: 2.2–46.2), respectively. The median diameter of primary lesions was 30 mm (range: 20–50). Most recurrent lesions were superficial type, after piecemeal resection. Six cases had multiple LVL. Although one patient needed chemoradiation for recurrence, the others could be re-treated endoscopically (re-EMR: 3, EMR + argon plasma coagulation (APC): 2, APC: 6). Six of the latter pts. experienced second local recurrence, and were treated by radical surgery (1); radiotherapy (1); and re-EMR or APC (4). Two cases experienced third local rec. One of them was treated by radiotherapy after palliative re-EMR and APC for 1st recurrence which invaded submucosal layer. Another had not been treated because of other severe illness. The median time to second local rec. was 14.9 months (range: 2–24.6). Finally, 7 of the rec. cases could be managed endoscopically, and the overall ratio of endoscopically salvaged cases was 96.7% (149 of 154). Two cases dropped out endoscopic treatment because of too large lesion. None experienced systemic metastasis. Two cases had died. One had died of multiple primary cancer. Another one was dead of unknown cause, suddenly.

Conclusions: Most local rec.cases could avoid invasive treatment, repeating endoscopic treatment. The overall outcome of EMR for mucosal ESCC was good. Routine close follow-up endoscopy is important after the first EMR.

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POSTER

Evaluation of the Efficacy and the Safety of Lanreotide on Tumour Growth Stabilization in Patients With Progressive Neuroendocrine Tumours (NETs) Who Are Not Eligible to Be Treated With Either Surgery or Chemotherapy – TTD Group Study

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Background: Somatostatin analogs (SSTAs) are the treatment of choice for hormonal symptoms associated with NETs. Clinical studies have suggested stabilization or, in rare cases, partial response in the tumour mass. In a population of documented progressive NETs no data of

antitumoral activity of SSTAs analogs given as sole treatment has been presented. We undertook a phase II trial (NCT0032646) to evaluate the efficacy of lanreotide Autogel 120 mg on tumour growth stabilisation in patients with documented progressive NETs.

Material and Methods: Sample size was based on the assumption that 25% and 12% of the patients with progressive NETs, on SSTA analog treatment, are progression-free after first and second year, respectively. Thirty Caucasian patients from 17 Spanish hospitals with advanced and/or metastatic well-differentiated NETs progressive within the last 6 months were treated with lanreotide Autogel 120 mg every 28 days until progression. Treatment with SSTA during the previous 6 months was an exclusion criterion. No patients received chemotherapy (CT) or interferon (IFN) during the 4 weeks before study inclusion. Radiologic evaluation was performed every 3 cycles. Primary endpoint was Progression Free Survival (PFS) per central blind review (RECIST). Clinical baseline characteristics were: Age median: 63 y (40–78), M/F (50%/50%), Median time since diagnosis 5.5 y (0.2–22.2), ECOG 0/1/2: 63%/30%/7% Foregut/Midgut/Unknown: 47%/40%/13%; Ki index: median 2.0 (1–20); Functioning/Non Functioning (63%/37%); Previous pharmacological treatment: naive/CT/IFN/SSTAs (50%/33%/23%/20%).

Results: Median PFS (95% CI) was 12.9 months (7.9–16.5) both in ITT and PP populations. Best tumour responses were: 4%PR/ 89%SD/ 7%PD. Ki 67 index was the most likely prognostic factor for PFS ($n=21$, HR 1.17; $p=0.017$). Discontinuation of treatment because of adverse events (AE) occurred in one patient. Only one severe related AE was detected (aerophagia). No impairment in EORTC QLQ-C30 for the whole group was detected during treatment.

Conclusions: In this study, the sole treatment with lanreotide Autogel 120 mg in progressive NET patients provides a median PFS >12 months with a very low toxicity. This apparent tumoral control effect should be confirmed in a phase III ongoing trial (Clarinet, NCT00842348).

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POSTER

Relationship Between Degree of Helicobacter Pylori Colonization and Prognosis in Advanced Gastric Cancer

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Introduction: Helicobacter pylori (HP) infection is an important factor for the development of gastric cancer. Some studies showed that prognosis in patients with positive HP status had no significant difference from the patients with negative cases. The others provided evidence of a better prognosis in patients with HP infection compared with negative cases. However these contradictory results have not been explained well enough. Most of these studies used serological analysis as the only method to assess HP status. At present, there is no convincing data for the relationship between degree of HP colonization and prognosis of advanced gastric cancer. Here we report the results of a study of the relationship between the density of HP colonization around the tumour sites and prognosis of patients with gastric cancer.

Materials and Methods: Sixty one patients with advanced gastric cancer were enrolled in this study. They were tested HP status around the tumour site and received the chemotherapy between March 2006 and February 2011 in Ansan Korea University Hospitals. Tissue sections (4 µm thick) were cut and stained with H & E stain and Cresyl-violet stain. The density of H. pylori colonization was graded as no, mild, moderate and severe around the tumour site. HP density determinations were made according to Sydney classifications.

Results: The overall median survival of patients with advanced gastric cancer was 10 months (7.7–12.3 months 95% CI). Ten patients had severe HP colonization around tumour sites. Forty one patients had no HP colonization around the tumour sites. Patients with severe HP colonization had a median survival time of 18 months (95% CI, 1.8–34.2 months) which was significantly longer than that for negative or mild to moderate HP colonization (median 18 months vs. 8 months; $P<0.001$, log-rank test). Interestingly, patients with moderate HP colonization had a median survival time of 4 months (95% CI, 2.7–5.3 months).

Conclusions: Patients with severe HP colonization around gastric cancer appeared to be associated with a good prognosis. These results suggest that HP colonization around tumour sites may be used as a prognostic factor in patients with advanced gastric cancer. And we might consider HP colonization around tumours as a predictive factor to determine and modify the treatment provided. Further study is warranted to confirm these findings in patients with advanced gastric cancer.

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POSTER

BRCA1/2 Mutations in Pancreatic Cancer Patients and Their Clinical Characteristics

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Background: Carriers of germline BRCA1/2 mutations have an increased risk of developing breast and ovarian cancer. Studies have also demonstrated that BRCA1/2 mutations increase the risk of pancreatic cancer (PC). The present study aimed to evaluate the frequency and clinical relevance of BRCA1/2 predominant mutations in Ashkenazi PC patients.

Material and Methods: A cohort of 70 PC patients was recruited from the Institute of Oncology at Rambam Health Care Campus. Of these, 58 of Ashkenazi origin were included, 35 (60%) males and 23 (40%) females. Following informed consent, socio-demographic and clinical profiles were collected at patient-researcher encounter. Data were complemented via the patients' oncology charts, when needed. A blood sample was drawn for genetic testing. The three predominant Jewish mutations (185delAG and 5382insC in BRCA1 and 6174delT in BRCA2) were tested for each PC patient. Mutation analysis schemes were based on PCR and restriction enzyme digests.

Results: Ten patients (17.2%) were defined carriers (8 patients carried the 6174delT mutation and 2 patients carried the 185delAG mutation). Earlier age at diagnosis was noted among mutation carriers compared to non-carriers (58.7 ± 7.2 and 66.0 ± 9.7 , respectively, $p=0.029$). Six (60%) PC patients with BRCA1/2 mutations compared to 12 (25%) non-carriers reported positive family history of breast, ovarian or pancreatic cancer ($p=0.03$). No differences between carriers and non-carriers were found as regards gender and history of diabetes mellitus or heart disease.

Conclusions: Mutations in BRCA1/2 constitute a major cause for PC in Ashkenazi Jews and carriers are diagnosed about 7 years earlier than non-carriers. As the identification of a BRCA mutation in an individual with PC may have significant implication for other family members, genetic diagnosis for PC patients and family members at risk is warranted. It may also have a significant benefit for the treatment of these patients, related to the anti-tumour activity of the new poly-ADP-ribose polymerase (PARP) inhibitors in cancer patients with genetic BRCA mutations.

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POSTER

Conditional Probability of Survival Nomogram After an R0 Resection for Gastric Cancer

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Background: Survival estimates after curative surgery for gastric cancer are based on UICC staging, or on multivariable nomograms. However, the risk of dying of gastric cancer is not constant over time, with most deaths occurring in the first two years after resection. Therefore, the prognosis for a patient who survives this critical period, improves. This improvement in prognosis over time is termed Conditional Probability of Survival (CPS). The aims of this study were to develop a CPS nomogram predicting 5-year disease-specific survival (DSS) from the day of surgery for patients surviving a specified period of time after a curative gastrectomy, to explore whether variables becoming available during follow-up improve the nomogram in the follow-up setting, and to compare the nomogram with the UICC staging system.

Materials and Methods: A CPS nomogram was developed from a combined US-Dutch dataset, containing 1642 patients who underwent an R0 resection with or without chemotherapy/radiotherapy for gastric cancer. Baseline variables used in the nomogram were age, sex, tumour location, tumour size (cm), invasion depth, Lauren classification, number of positive and number of negative nodes. Weight loss, performance status (PS), hemoglobin (HGB), and albumin (ALB) at one year after resection were added to the baseline variables in a new nomogram. Predictive accuracy of the nomogram was compared with the 7th ed. UICC staging system.

Results: The CPS nomogram based on baseline variables was highly discriminating (concordance index: 0.772). Surviving one, two, or three years after surgery translates into a median improvement of 5-year DSS from surgery of 7.2%, 19.1%, and 31.6%, respectively, as compared to the baseline prediction directly after surgery. Introduction of additional