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identified from the pathology database. Demographics, histopathology and survival data were analysed.

**Results:** 66 patients were analysed (median age: 64 years, range: 37–86). 97% of cases were stage pT3 (TNM 7) with 76% showing nodal metastasis and 76% vascular invasion. Margin involvement was found in 71%, the R1 rate differing between distal DBDA (41% of cases, R1: 48%), and proximal DBDA (R1: 87%; p=0.001). Tumours >2 cm were more frequently found in proximal DBD cancers (p=0.016). Overall median survival was 23.3 months; 20.9 in the proximal and 27.5 in the distal subgroup (p=0.018). Higher rates of negative margins in distal DBDA and larger tumours in proximal DBDA may attribute to this difference.

Conclusion: This study suggests that the location of resected DBDA within the pancreas is associated with different pathological characteristics that affect overall survival. Confirmation of these findings in larger series could result in changes to the management of such patients in future.

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## The Characteristics and Prognosis of Advanced Gastric Cancer With Bone Metastasis

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**Background:** Although bone metastasis is a very rare event in advanced gastric cancer (AGC), AGC with bone metastasis is often troublesome, aggressive and incurable. However, there is shortage of data on characteristics, pathophysiology and prognosis of AGC with bone metastasis.

Methods: We reviewed 672 patients with advanced gastric cancer patients who were first diagnosed to obtain incidence, characteristics and prognosis of bonemetastasis in single institute.

**Results:** Of 672 advanced gastric cancer patients, 19 patients (2.8%) diagnosed bone metastasis. Of 19 AGC patients with bone metastasis, 11 showed poorly differentiated carcinoma or signet-ring cell type. Most frequent other metastaic site of patients with bone metastasis is liver (10/19), followed by carcinoma peritonei (7/19), adrenal gland (2/19) and muscle (2/19). Most of them (14/19) showed elevated alkaline phosphatase (ALP) (median: 139 IU/L, range: 61–777 IU/L) and C-reactive protein (median: 32.5 mg/L, range: 3.95–127.6 mg/L).

Median progression free survival of AGC patients with bone metastasis was 79 days (range: 36–396 days) and median overall survival was 132 days (range: 22–1279 days). They were significantly shorter than survival of stace IV AGC.

Most of them (18/19) recieved palliative chemotherapy but only 6 patients recieved palliative radiotherapy. Although recieving chemotherapy with large percentage, 10 patients showed progressive disease after only 1–2 cycles. Also, the response of bone metastasis was often inconsistant the response of main lesion or other metastatic sites.

Conclusion: The incidence of bone metastasis in AGC patients was very rare (2.8%) but its prognosis was very poor and mostly chemoresistant. Therefore, the intensive chemotherapy with more doses than usual chemotherapy regimens or other modalites are considered to control bone metastatic lesions of AGC.

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## The Expression of Jamestown Canyon Virus(JCV) T-Antigen and Clinical Manifestation in PT3 Gastric Cancer

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**Background:** Jamestown Canyon Virus(JCV) belongs to the polyomavirus family. It was first discovered in the cerebrospinal fluid of an immunocompromised patient suffering progressive multifocal leukoencephalopathy in 1971. It was reported that JCV is ubiquitous in the human population and 80–90% of adults have specific antibodies to JCV. It was suggested that JCV T-antigen(Ag) is a potential multifunctional oncoprotein. This current study investigated JCV T-Ag expression in gastric cancer and metastatic lymph nodes and examined its association with clinical outcome.

**Materials and Methods:** A total of 285 paitents with pT3 gastric cancer who underwent radical operation were included. The immuohistochemical staining for JCV T-Ag was performed in gastric cancer tissue, adjacent normal gastric mucosa and metastatic lymph nodes.

**Results:** The number of patients with JCV T-Ag expression was 56(19.6%). There was no JCV T-Ag expression in adjacent normal gastric mucosa. The frequency of lymph node metastasis (p < 0.001) and the number of metastatic lymph nodes (p = 0.003) in JCV T-Ag expression positive group were higher than JCV T-Ag negative group. There were no differences in overall survival (p = 0.183) and disease free survival (p = 0.253) between the 2 groups.

Conclusions: JCV T-Ag expression is associated with gastric cancer. The expression of JCV T-Ag in gastric cancer may have an effect on lymph node metastasis. There is no difference for overall survival and disease free survival between JCV T-Ag expression positive group and negative group.

Table 1. The correlation between JCVT-Ag expression and clinicopathological parameters of gastric cancer.

	JCVT-Ag(+) (n = 56)	JCVT-Ag(-)(n = 229)	p-value
Gender [Male (%); Female (%)]	36 (64.3); 20 (35.7)	145 (63.3); 84 (36.7)	0.893
Age [years]	55.9 11.4	53.7 12.6	0.162
Tumour location			0.482
Upper	8 (14.3)	43 (18.8)	
Middle	17 (30.3)	70 (30.6)	
Lower	31 (55.4)	110 (48.0)	
Whole	0 (0)	6 (2.6)	
Retrieved lymph node number	41.3 17.3	44.6 16.8	0.107
Lymphnode metastasis			< 0.001
Negative	8 (14.3)	88 (38.4)	
Positive	48 (85.7)	141 (61.6)	
Metastatic lymph node number	12.3 15.1	7.9 12.5	0.003
Borrmann type			0.546
Others	49 (87.5)	193 (84.3)	
IV	7 (12.5)	36 (15.7)	
Lauren classification			0.070
Intestinal	27 (48.2)	73 (31.9)	
Diffuse	27 (48.2)	147 (64.2)	
Mixed	2 (3.6)	9 (3.9)	
Histology			0.023
Differentiated	25 (44.6)	66 (28.8)	
Undifferentiated	31 (55.4)	163 (71.2)	
Lymphatic invasion			0.759
Negative	32 (57.1)	136 (59.4)	
Positive	24 (42.9)	93 (40.6)	
Venous invasion			0.567
Negative	50 (89.3)	210 (91.7)	
Positive	6 (10.7)	19 (8.3)	
Perineural invasion			0.016
Negative	47 (83.9)	155 (67.7)	
Positive	9 (16.1)	74 (32.3)	

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Efficacy and Safety of RAD001 as Second Line Therapy in Biliary Tract Cancer (BTC) Patients (pts) – a Phase II I.T.M.O. (Italian Trials in Medical Oncology) Group Study

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Background: BTCs are uncommon but highly fatal malignancies, with an increasing incidence in the Western Word. Even after radical surgery, the rate of disease relapse is high and median survival in metastatic pts is in the range of only a few months. Being the results with front line chemotherapies disappointing, new options are under investigation. RAD001 (Everolimus) is a Rapamycin derivative which acts as a signal transduction inhibitor and its target is m-TOR, a key protein kinase which regulates cell growth, proliferation and survival.

Methods: The purpose of this multicentric Phase II study is to assess the efficacy (disease control rate, tumour progression) and safety of oral RAD001 10 mg daily/28 day cycle. Patients accrual started in February 2009 until December 2009. As planned according to a Simon two stage design 39 pts from 8 Italian centres were enrolled. All the cases were pretreated with one regimen for their metastatic disease (gemcitabine in the large majority). Elegibility criteria also included performance status ECOG ≤2, adeguate organ functions and absence of clinically significant cardiovascular disease. Radiological assessment was performed every two months.

**Results:** Patient median age 63 yrs, male/female = 22/17, ECOG 0/1/2 = 31/5/3. No toxic death was reported. Thrombocitemia was the main haematologic side effect in 35% (G3 4 pts), followed by neutropenia in

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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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## 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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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: RAD001is 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 somatostatine 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%), hypercolesterolaemia 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%), hypokaliemia G3 in 1 pts due to diarrhoea, and stomatitis G4 in only 1 patient. No adverse events leaded 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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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 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 lugoul-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 Decenbar 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 illuness. 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 dead of multiple primary cancer. Another one was dead of unknown cause,

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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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