

to examine the differences in practice patterns across countries based on resources utilized among advanced NET patients.

Materials and Methods: Physicians were asked to record the resource utilization for a sample of their NET patients via an online data survey. The survey focused on patients with advanced, progressive NET. The survey was administered to physicians in the US, UK, Germany, France, Brazil and Italy with the aim to collect data on use of various treatments, routine monitoring and hospitalizations. Resource utilization was assessed across all available follow up from the time of advanced NET diagnosis.

Results: A total of 4,100 surveys were sent to physicians across 6 countries, with 197 (4.8%) choosing to participate. Data on 394 patients was obtained. Resource utilization was high across all countries (Table 1).

Table 1. Resource utilization during follow up stratified by country (N = 394)

	US %(n = 110)	UK %(n = 64)	Germany %(n = 52)	France %(n = 54)	Brazil %(n = 60)	Italy %(n = 54)
Surgery	45.5 (50)	32.8 (21)	38.5 (20)	55.6 (30)	46.7 (28)	63.0 (34)
Chemotherapy	38.2 (42)	39.1 (25)	51.9 (27)	59.3 (32)	60.0 (36)	55.6 (30)
PRRT	5.5 (6)	14.1 (9)	17.3 (9)	5.6 (3)	15.0 (9)	7.4 (4)
Somatostatin analogs	78.2 (86)	85.9 (55)	69.3 (36)	61.1 (33)	73.3 (44)	88.9 (48)
Routine monitoring*	99.1 (109)	100.0 (64)	100.0 (52)	100.0 (54)	100.0 (60)	100.0 (54)
Hospitalization	56.4 (62)	53.1 (34)	69.3 (36)	68.5 (37)	71.7 (43)	77.8 (42)
Targeted therapy†	6.4 (7)	1.6 (1)	7.7 (4)	18.5 (10)	3.3 (2)	0.0 (0)

*Routine monitoring includes visits, ultrasounds, CT Scans [conventional or helical] other imaging tests, bio markers and other lab tests.

† Targeted therapy includes everolimus, sunitinib, imatinib, and bevacizumab.

Conclusions: Results of this study demonstrate variations in treatment patterns in the countries studied. In particular, rates of use for chemotherapy, targeted therapies, and PRRT are inconsistent. These findings are likely due to the shortage of evidence and lack of consensus surrounding the most effective treatment alternatives.

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POSTER

Percutaneous Hepatic Perfusion (PHP) With Melphalan for Patients With Unresectable Liver Metastases of Neuroendocrine Tumours (MNET) – NCT0096083

J. Pingpank¹, R.E. Royal², U.S. Kammula³, A.W. Kam⁴, B.J. Wood³, S.K. Libutti⁵, M.S. Hughes³, S.E. Ohl⁶, H.R. Alexander⁷. ¹UPMC, Div of Surgical Oncology, Pittsburgh PA, USA; ²MDACC, Surgical Oncology, Houston TX, USA; ³NCI, Surgery Branch, Bethesda MD, USA; ⁴Johns Hopkins Bayview Medical Center, Imaging Department, Baltimore MD, USA; ⁵Montefiore Medical Center, Surgical Oncology, New York, USA; ⁶Practice, Surgical Oncology, Allentown PA, USA; ⁷University of Maryland, Surgical Oncology, Baltimore MD, USA

Background: There are few treatment options for unresectable hepatic MNET. Fewer than 10% of pancreatic NET patients demonstrate objective response to everolimus, sunitinib or octreotide. Regional therapies are used, but treatment options for patients with diffuse hepatic disease are limited.

Materials and Methods: We used minimally-invasive PHP to give a 30 minute hepatic artery infusion of melphalan 3 mg/kg with extracorporeal hemofiltration using specially-designed catheters positioned in the retro-hepatic IVC and jugular venous return of filtered blood. Treatment was every 4–5 wks up to 4 cycles in consecutive IRB-approved phase 1 and 2 studies at NCI Surgery Branch, Bethesda. Delcath Systems, Inc., NY, USA sponsored the studies. Patients had MNET, limited treatable extrahepatic disease, adequate hepatic reserve (Bili <3.0, PT within 2 seconds of normal, LFTs <10× ULN), no portal hypertension and adequate hepatic vascular access. The primary objective of this analysis was objective response rate by RECIST. We also studied acute peri-procedural events, later-onset AEs post-day 5 of each cycle, progression-free (PFS) and overall survival (OS).

Results: From Dec 2001 to Feb 2010, we treated 23 MNET patients (9 with extrahepatic disease), median 15 lesions, 12 with <25%, 5 with 25–50% and 6 >50% liver replacement; the majority had pancreatic NET (n = 17). Median cycles were 3/pt, total 68; median dose 180 mg (126–220); 2 cycles not given due to sclerotic hepatic artery and hypercalcemia. 1 patient received 4 cycles in 2004 and a further 3 cycles upon progression in 2008. Acute procedure-related grade 3–4 changes were transaminitis (22% cycles), thrombocytopenia (21% cycles), anemia (16% cycles) and hyperbilirubinemia (9% cycles) plus 1 tumour lysis, 1 carcinoid crisis and 1 CNS hemorrhage. Later-onset grade 3–4 AEs were mainly hematological: neutropenia (47% cycles), thrombocytopenia (29% cycles) and anemia (15% cycles). The 1 treatment-related death was due to gastric ulcer at day 74 post-cycle 1. There were 79% objective responses in 15 of 19 evaluable patients (2 CR, 13 PR, 3 SD, 1 PD). Median hepatic PFS was 39 months (n = 20) and OS was not yet reached (n = 23).

Conclusions: Percutaneous hepatic perfusion with melphalan has substantial efficacy in patients with diffuse MNET of the liver too extensive

for resection, ablation or embolization strategies. Responses to therapy are durable, with a 39-month PFS and the option of retreatment upon progression.

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POSTER

AJCC 7th Edition of TNM Staging Accurately Discriminates Outcomes of Patients With Gastric Cancer

J. Baek¹, Y. Min¹, J. Park¹, B. Kim², I. Jeong², G. Kim³, H. Choi⁴, J. Lee⁵, H. Cho³. ¹Ulsan University Hospital, Oncology/Hematology, Ulsan, South Korea; ²Ulsan University Hospital, Gastroenterology, Ulsan, South Korea; ³Ulsan University Hospital, Surgery, Ulsan, South Korea; ⁴Ulsan University Hospital, Pathology, Ulsan, South Korea; ⁵Ulsan University Hospital, Radiology, Ulsan, South Korea

Background: Gastric cancer remains the second leading cause of cancer-related deaths. Surgery is still the only possible means to cure gastric cancer, and postoperative clinical pathological classification can best predict prognosis of the patients. The depth of primary tumour infiltration and number of metastatic lymph nodes (LNs) are known to be the most important prognostic factors of gastric cancer after curative surgery. The American Joint Committee on Cancer/International Union against Cancer (AJCC/UICC) published the TNM classification of Malignant Tumours (seventh edition) for gastric cancer recently. In this study, we retrospectively compared the predictivity of 6th and 7th edition AJCC/UICC TNM staging systems for gastric cancer.

Materials and Methods: The clinicopathologic data of 527 patients with gastric cancer treated by surgical resection in Ulsan University Hospital between December 2002 and December 2005 were analyzed retrospectively. We excluded the following patients from the study: 1) patients with recurrent cancer or stump cancer after undergoing subtotal gastrectomy for gastric cancer; 2) patients with distant metastasis, residual macroscopic or microscopic tumour; 3) patients with <15 LNs histologically examined; 4) patients with mortality within 30 days after surgery. A total of 450 cases were included.

Results: The median age of 450 patients was 56 years (range 24–83); 299 were male and 151 were female. The median number of retrieved LNs was 31 (range 15–90 LNs). The overall 5-year survival for the whole group of patients was 80.9%, with median survival was not reached. The median follow up for the entire cohort was 2277 days (range 47–3032). In univariate analysis, age, tumour site, tumour size, T stage (6th edition), T stage (7th edition), N stage (6th edition), and N stage (7th edition) were significantly correlated with patients' survival. In multivariate analysis, age, T stage (6th edition), T stage (7th edition), N stage (6th edition), and N stage (7th edition) were significantly correlated with patients' survival. The 5YSR for seventh-TNM T2 and T3 classifications were significantly different in every seventh-TNM N classification patient. The 5YSR for the seventh-TNM N1 and N2 were also slightly different in seventh-TNM T1–3 patients. The seventh-TNM stage IB, IIA, IIB, IIIA, and IIIB demonstrated no significant different survival rates (P = 0.578, P = 0.820, P = 0.749, P = 0.680, and P = 0.291). However, the subgroup of the seventh-TNM stage IIIC and N3 patients (N3a and N3b) demonstrated significantly different survival rates (P = 0.002 and P = 0.034).

Conclusions: The seventh-TNM staging system for the gastric cancer appeared to provide better categorized grouping, especially between T2 and T3 categories and N1 and N2 categories. It demonstrated increased homogeneity in each TNM stage. Further studies and understandings are needed for the value of the N3a and N3b classifications.

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POSTER

Distal Bile Duct Adenocarcinoma – Does Location Influence Survival?

K. Kamposioras¹, D.A. Anthoney¹, A. Cairns², A.M. Smith³, K. Menon³, G. Ferentinos⁴, C.S. Verbeke². ¹The Leeds Teaching Hospitals NHS Trust, Medical Oncology Department, Leeds, United Kingdom; ²The Leeds Teaching Hospitals NHS Trust, Department of Histopathology, Leeds, United Kingdom; ³The Leeds Teaching Hospitals NHS Trust, Department of Surgery, Leeds, United Kingdom; ⁴Hellenic Centre for Disease Control and Prevention, Athens, Greece

Background: To date, clinicopathological data on distal bile duct adenocarcinoma (DBDA) are limited, and the factors that influence survival following curative resection remain unknown. Aims of this study were to retrospectively analyse clinicopathological features of a series of resected DBDA and their influence on outcome. In particular, the significance of tumour location, i.e. entirely confined to the intrapancreatic bile duct (distal DBDA) or with involvement of the extrapancreatic bile duct stump (proximal DBDA), was assessed.

Materials and Methods: Patients undergoing curative pancreato-duodenectomy for DBDA between January 2001 and April 2009 were

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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POSTER

The Characteristics and Prognosis of Advanced Gastric Cancer With Bone Metastasis

Y. Choi¹, J. Kim¹, S. Kim¹, K. Park¹, S. Oh¹, J. Seo¹, S. Shin¹, J. Kim¹, Y. Kim¹. ¹Korea University Medical Center, Oncology, Seoul, South Korea

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 metastatic 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 stage IV AGC.

Most of them (18/19) recieved palliative chemotherapy but only 6 patients recieved palliative radiotherapy. Although receiving chemotherapy with large percentage, 10 patients showed progressive disease after only 1–2 cycles. Also, the response of bone metastasis was often inconsistent 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 modalities are considered to control bone metastatic lesions of AGC.

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POSTER

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

S.H. Choi¹, M.G. Choi², J.H. Noh², T.S. Sohn², K.M. Kim³, J.M. Bae².

¹Samsung Changwon Hospital, General Surgery, Changwon, South Korea; ²Samsung Medical Center, General Surgery, Seoul, South Korea;

³Samsung Medical Center, Pathology, Seoul, South Korea

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 patients with pT3 gastric cancer who underwent radical operation were included. The immunohistochemical 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 JCV T-Ag expression and clinicopathological parameters of gastric cancer.

	JCV T-Ag(+) (n=56)	JCV T-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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POSTER

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

R. Buzzoni¹, S. Pusceddu¹, P. Biondani¹, M. Cantore², E. Altini³, A. Bertolini⁴, O. Alabiso⁵, L. Isa⁶, G. Pinotti⁷, E. Bajetta⁸. ¹Fondazione IRCCS Istituto dei Tumori, Medical Oncology Unit 2, Milan, Italy; ²ASL 1, Medical Oncology, Massa e Carrara, Italy; ³Azienda Ospedaliera C.Poma, Medical Oncology, Mantova, Italy; ⁴Ospedale di Sondrio, Medical Oncology, Sondrio, Italy; ⁵Ospedale Maggiore della Carità, Medical Oncology, Novara, Italy; ⁶Presidio Ospedaliero di Gorgonzola, Medical Oncology, Gorgonzola, Italy; ⁷Ospedale di Circolo e Fondazione Macchi, Medical Oncology, Varese, Italy; ⁸Policlinico di Monza, Oncology Institute, Monza, Italy

Background: BTCs are uncommon but highly fatal malignancies, with an increasing incidence in the Western World. 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). Eligibility criteria also included performance status ECOG ≤2, adequate 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. Thrombocytopenia was the main haematologic side effect in 35% (G3 4 pts), followed by neutropenia in