sites other than colon/rectum after mCRC diagnosis. By anatomic locations, 17.6% of patients had major surgeries on liver or lung (13.4% on liver and 4.9% on lung); and 32.3% had major surgeries on all other anatomic sites. Major surgeries on colon or rectum occurred in 35.9% of patients (32.9% on colon and 4.1% on rectum).
Conclusions: Major surgeries are highly prevalent in patients with mCRC from this commercially insured population after mCRC diagnosis. This might have implications for anticancer drug therapy in mCRC patients.

6163 POSTER

Electric Stimulation of Anal Sphincter as a Treatment Option for Fecal Incontinence After Ultra-low Coloanal Anastomosis With or Without Intersphincteric Resection

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Background: Progress in combined treatment makes possible sphincter saving treatment for patients with low rectal tumour. Many clinics report about good oncological outcome. But functional results after ultra low coloanal anastomosis (CAA) with or without intersphincteric resection (ISR) sometimes disappointing. The purpose of this study was to prospectively investigate patients with fecal incontinence after ultra low CAA with or without ISR and evaluate the efficacy of electromiostimulation (EMS) as a treatment option.
Patients and Methods: 36 patients were treated for fecal incontinence. All patients had low rectal cancer and received preoperative chemoradiotherapy following by proctectomy with or without ISR with hand-sewn CAA. For electromiostimulation we use Neurotrac ETS device in “incontinence” mode.
Technics: Bipolar probe introduced into anus. Each session lasts 20 minutes. Usually started with 20−30 mAh to maximal amplitude up to 80 mAh. Total number of sessions was 10. Success was evaluated by anometry, water infusion test, Wexner scale and FIQL score.
Results: Mean squeeze pressure increased significantly after stimulation from 1.52 to 2.4. Mean score by Wexner scale improve from 16.6 to 8.3. Mean index according Wexner scale for hard and liquid stool and flatus incontinence improve from “2.96”, “3.59” and “3.44” to “1.14”, “1.92” and “1.55” respectively. Naturally, group without ISR showed better results. Mean FIQL score increase from 1.49 to 3.27.
Conclusion: Preliminary results for EMS have shown that patients achieved higher maximum voluntary squeeze pressures, and showed a marked improvement in their continence. Given the advantage of ambulatory use and non-invasive approacg the EMS seems promising in terms of achieving improved fecal continence and quality of life in selected patients.

6164 POSTER

Vitamin E Supplementation Against Oxaliplatin Induced Peripheral Neuropathy

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Background: Chemotherapy induced peripheral neuropathy (CIPN) is a common and dose-limiting side effect of anticancer drugs. Typically, the clinical presentation reflects an axonal peripheral neuropathy with glove-and-stocking distribution sensory loss, combined with features suggestive of nerve hyperexcitability such as paresthesia, dysesthesia and pain. These symptoms may be disabling, adversely affecting activities of daily living and thereby quality of life. We assessed the efficacy and safety of vitamin E supplementation to evaluate the reduction in intensity of oxaliplatin-induced peripheral neuropathy.
Materials and Methods: We have observed 80 patients (average 66 yrs) with no hystory of peripheral neuropathy due to any cause (diabetes, alcohol, toxines) affected by colon cancer (stage III) and undergoing oxaliplatin-based chemotherapy. In our sample 40 patients were scheduled to receive vitamin E at dose of 400 mg/die at the occurrence of neuropathy until the end of the treatment (group 1), meanwhile the other 40 patients did not take vitamin E (group 2). Neurologic clinical examination and nerve conduction study were performed for each patient at the start of symptoms and at the end of chemotherapy using NCI-CTC for grading the severity of neuropathy. The concentration of calcium and magnesium were evaluated before every course of chemotherapy.
Results: All the patients who received vitamin E (group 1) showed a significative reduction in intensity of neuropathy. We have found a significant reduction of sural sensory nerve action potential (SNAP) amplitude and a reduction of speed of nerve conduction in group 2 compared to the group 1 ($p < 0.001$).
Conclusions: CIPN is a limiting side effect for patients undergoing oxaliplatin based therapy. Evaluate a treatment without side effect, not expensive, easy to recruit is important to ensure a good quality of life, to keep the dose dense of chemotherapy, to avoid therapy dose reduction due to the neuropathy. Vitamin E might prevent and/or lessen the side effects to CIPN.

6165 POSTER

Systemic Inflammatory Response in Predicting Survival in Patients With Operable Colorectal Cancer

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Background: Several inflammatory response materials could be biomarkers for prediction of prognosis of cancer patients; elevated C-reactive protein (CRP), increased white cell, neutrophil, platelet, and decreased albumin. The Glasgow Prognostic Score (GPS) combines circulating CRP and albumin level, the neutrophil/lymphocyte ratio (NLR), and the platelet/lymphocyte ratio (PLR) has been introduced for prognostic scoring system in colorectal cancer (CRC). Thus, in this study, we attempted to identify an more adequate prognostic model related with systemic inflammatory response for CRC.
Methods: Between Mar 2005 and Dec 2008, 200 patients who underwent curative resection for colorectal cancer were enrolled in this study. Systemic inflammatory parameters (CRP, albumin, neutrophil, lymphocyte, and platelet count) were checked for making 3 scoring systems. Based on clinical survival data, we then compared PFS and OS with GPS, NLR, and PLR.
Results: Male to female was 123:77. Median age of the patients was 64 years (range, 26−83 years). Median follow-up duration was 27.2 months (range 7.8–52.7 months). 36 patients were observed disease progression or death. 19 patients were passed away during follow-up duration. 3 year PFS and OS were 72% and 86%, respectively. Numbers of GPS 0, 1, and 2 patients were 154 (77%), 44 (22%), and 2 (1%), respectively. Survival analysis according to GPS, PFS and OS could not be able to show the prognostic significance ($P = 0.313$ and $P = 0.263$). Cut-off value of NLR and PLR were determined 3 and 180 by ROC curve. Both of NLR and PLR were observed as a good prognostic biomarker of PFS and OS ($P = 0.009$ and $P < 0.001$ in PFS, $P = 0.006$ and $P = 0.001$ in OS).
Conclusions: Although GPS, NLR, and PLR were introduced as prognostic scoring systems for operable CRC, PLR which is constructed of platelet/lymphocyte count may represent a useful prognostic index for the prediction of PFS and OS in operable CRC.

Oral Presentations (Mon, 26 Sep, 14:45−16:30)
Gastrointestinal Malignancies − Noncolorectal Cancer

6500 ORAL

Second Interim Results of the GIDEON (Global Investigation of Therapeutic DEcisions in HCC and of Its Treatment With SorafeNib) Study − Barcelona-Clinic Liver Cancer (BCLC) Stage Subgroup Analysis

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Background: GIDEON is an ongoing, global, prospective, non-interventional study of HCC patients (pts) receiving sorafenib (Sor) in real-life practice. Its aim is to evaluate Sor safety and efficacy in diverse settings and pt subgroups. The predefined subgroup analysis by the BCLC is presented.
Material and Methods: Demographics, medical/disease/treatment history are recorded. At follow-up visits Sor dose, concomitant treatment, liver function, adverse events (AEs) and efficacy are recorded. From Jan 2009 to April 2011, over 3000 pts have been enrolled from 39 countries, achieving study target enrollment. Per protocol, the 2nd interim analysis (IA) was planned when ~1500 treated pts were followed $\geqslant$4 months.

Results: 1571 pts comprise the safety population; 54% were BCLC stage C. Sor treatment duration was longer in the early stage (A/B) pts (Table). BCLC stage did not appear to determine Sor dosing. Early stage pts received more prior locoregional treatment (LRT), and more prior and concomitant transarterial chemoembolization (TACE). Early and advanced staged pts had comparable percentages of drug-related AEs (DRAEs) and drug-related serious AEs (DRSAEs). In the ITT population (N = 1612), the preliminary median overall survival (OS) was 9.1 months (mos). OS according to BCLC stage at study entry was 13.6 mos in stage A pts (n = 117), 12.6 mos in B (n = 311), 7.9 mos in C (n = 877) and 3.4 mos in D (n = 93).

Conclusions: Preliminary 2nd IA results indicate that Sor is used across all BCLC stages. The Sor safety profile was generally similar across BCLC stages. Treatment duration and preliminary OS data of Sor in the BCLC subset supports the robust nature of the GIDEON study data.

	BCLC stage (safety population) n (%)				Total
	A, 115 (7)	B, 298 (19)	C, 851 (54)	D, 92 (6)	N = 1571[a]
Sor treatment duration					
Median treatment duration, wks[b]	20	16	10	7	12
Prior/concomitant LRT, n (%)					
Prior LRT	76 (66)	178 (60)	466 (55)	36 (39)	871 (55)
Prior TACE	58 (50)	151 (51)	388 (46)	29 (32)	722 (46)
Concomitant TACE	13 (11)	29 (10)	52 (6)	6 (7)	118 (8)
Treatment-emergent AEs, n (%)					
AEs	82 (71)	244 (82)	718 (84)	76 (83)	1307 (83)
DRAEs	70 (61)	206 (69)	562 (66)	45 (49)	1010 (64)
SAEs	27 (24)	94 (32)	324 (38)	51 (55)	587 (37)
DRSAEs	10 (9)	35 (12)	75 (9)	6 (7)	142 (9)
Deaths	14 (12)	48 (16)	198 (23)	34 (37)	343 (22)

[a]Not evaluable, 215 pts; [b]Data missing, 23 pts.

6501 ORAL

Observations of Hepatocellular Carcinoma (HCC) Management Patterns From the Multinational HCC BRIDGE Study − First Overall Analysis of the European Cohort

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Background: HCC is a major health problem in many regions of the world, including Europe. The objective of the HCC BRIDGE study, the first multinational, large-scale, observational study in HCC, is to document the real-life HCC patient experience, from diagnosis to death, to better understand unmet needs in HCC management. This interim analysis of the HCC BRIDGE study focuses on the European patient cohort.

	France n = 761	UK n = 445	Sweden n = 151	Italy n = 351	Spain n = 210	Overall N = 1918
Risk factor, %						
n	500	269	103	325	96	1293
Alcoholic liver disease	61.8	45.4	45.6	20.6	51.0	45.9
HBV	9.8	8.6	19.4	14.8	6.3	11.3
HCV	28.2	19.7	44.7	75.4	55.2	41.6
NASH	18.2	7.8	5.8	13.2	2.1	12.6
Primary biliary cirrhosis	0	22.7	3.9	2.5	0	5.6
Other	10.6	10.4	6.8	3.7	2.1	7.9
Child-Pugh at diagnosis, %						
n	378	266	135	270	73	1122
A	0	1.5	0	72.2	72.6	22.5
B	93.9	97.0	99.3	24.8	23.3	74.1
C	6.1	1.5	0.7	3.0	4.1	3.5
Median baseline LFT, U/L						
ALT	43	40	51	66	42	48
AST	59	57	81	71	50	63
All treatment recorded, %						
n	1364	944	383	734	209	3634
Resection	5.1	4.4	7.6	9.7	6.7	6.2
Transplant	4.0	2.9	0.3	0.4	2.4	2.5
RFA/PEI	17.1	11.3	4.2	39.1	32.1	19.5
TACE	25.9	21.9	36.3	20.2	40.7	25.6
Palliation	10.5	9.7	26.1	0.8	0	9.4
Systemic	30.7	38.0	21.7	15.9	10.0	27.5
Sorafenib	73.5	85.0	100	90.6	100	82.4
Other systemic	26.5	15.0	0	9.4	0	17.6
Other	6.8	11.7	3.9	13.9	8.1	9.3
Mean systemic treatment time, days	212	225	194	481	602	272

Methods: This longitudinal study includes HCC patients newly diagnosed between 1 January 2005 and 30 June 2011. Patients are followed from diagnosis to death, or to 31 December 2011, whichever comes first, for demographic/clinical characteristics, treatments, and outcomes. This analysis includes patients diagnosed after January 1, 2008, and treated at 16 European tertiary care sites.

Results: As of March 2011, data from 1918 European patients were available. Mean age was 65.5 years and 78.8% were male. Baseline BCLC in the 535 patients for whom this staging could be determined was 0 (5%), A (44%), B (26%), C (10%) and D (16%). Patient characteristics and treatments are shown in the table. Updated data will be presented at the meeting.

Conclusions: This interim analysis of the HCC BRIDGE study documents variation among European countries in HCC characteristics and treatment. Differences in some risk factors between countries confirm well-known trends, while differences in other factors (eg, CP status, transplant rate, systemic therapy rate, and median systemic therapy time) may be related to site-specific practices and patient characteristics. A more detailed analysis of treatment course and associated baseline staging will be presented at the meeting.

6502 ORAL

Preoperative Chemotherapy Does Not Influence the Number of Evaluable Lymph Nodes in Resected Gastric Cancer

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Background: While it is suggested that more than 15 lymph nodes (LNs) should be evaluated for accurate staging of gastric cancer, LN yield in western countries is generally low. With the increasing use of preoperative chemotherapy in gastric cancer, the effect of this treatment on LN yield is unknown. The aim of the present study is to determine whether preoperative chemotherapy is associated with any difference in the number of LNs obtained from specimens of patients who underwent curative surgery for gastric adenocarcinoma.

Material and Methods: In 1205 patients from a high-volume US center and 1220 patients from the Netherlands Cancer Registry (NCR) who underwent a total or distal gastrectomy with curative intent for gastric adenocarcinoma without receiving preoperative radiotherapy, LN yield was analyzed, comparing patients who received preoperative chemotherapy and patients who received no preoperative therapy. Multivariate Poisson regression was used to identify significant predictors of LN retrieval.

Results: Of the 2425 patients who underwent a gastrectomy, 340 patients (14%) received preoperative chemotherapy. Median LN yields were 23 in the US-institution and 10 in the NCR. Despite this twofold difference in LN yield between the two populations, with multivariate Poisson regression, chemotherapy was not associated with LN yield of either population. Variables associated with increased LN yield were institution, female sex, lower age, total (vs. distal) gastrectomy and increasing T-stage.

Conclusions: LN yield in the high-volume US center (annual volume >100) was higher as compared to the Netherlands, where gastric cancer surgery is performed in lower volumes (annual volumes all <40). In both the high-volume cancer center, and the population-based cancer registry, female sex, younger age, total gastrectomy and advanced tumour stage were associated with an increase in lymph node retrieval in surgical specimens. Preoperative chemotherapy was not associated with a decrease in LN yield. The threshold for what should constitute an adequate assessment of regional lymph nodes after curative surgery for gastric cancer should not be changed after administration of preoperative chemotherapy.

Multivariate model based lymph node yields

	High-volume US center		NCR	
	LNs	*P*	LNs	*P*
Preoperative chemotherapy	27.3	0.87	13.2	0.44
No preoperative chemotherapy	27.4		12.6	