

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 N = 1571 ^a
	A, 115 (7)	B, 298 (19)	C, 851 (54)	D, 92 (6)	
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)

^aNot evaluable, 215 pts; ^bData 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	