of pts experienced Grade 3 or higher adverse events (AEs). ORR was significantly associated with PD-L1 expression and DNA damage repair (DDR)-related mutations in tumor samples.

Conclusions: The combination of toripalimab, lenvatinib with Gemox chemotherapy was tolerable and showed promising ORR in patients with advanced ICC. These findings warrant further study in a large randomized trial.

Clinical trial identification: NCT03951597.

Legal entity responsible for the study: Zhongshan Hospital, Fudan University.

Funding: Has not received any funding.

Disclosure: All authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2020.08.034

57P Third-line chemotherapy in advanced biliary cancers (ABC): Pattern of care, treatment outcome and prognostic factors from a multicenter study

A. Rizzo[1], M. Salati[2], V. Merz[3], C. Messina[4], A.D. Ricci[1], A. Palloni[1], G. Frega[1], S. De Lorenzo[1], F. Caputo[2], F. Gelsomino[2], A. Spallanzani[2], V. Mollica[1], F. Abbati[1], P. Carotenuto[5], E. Pettorelli[2], S. Benatti[2], G. Luppi[2], D. Melisi[3], M. Dominici[2], G. Brandi[1]

[1]Department Of Experimental, Diagnostic and Specialty Medicine, AOU Policlinico S. Orsola-Malpighi, Bologna, Italy; [2]Division of Oncology, Department of Oncology and Hematology, University Hospital of Modena, Modena, Italy; [3]Digestive Molecular Clinical Oncology Research Unit, University of Verona, Verona, Italy; [4]Department of Medical Oncology, Santa Chiara Hospital, Trento, Italy; [5]Telethon Institute of Genetics and Medicine, Pozzuoli, Naples, Italy

Background: While chemotherapy has recently been established as a standard second-line treatment in ABC, its role in the third-line setting is controversial. Indeed, only very sparse data exist in the literature on the topic. In this study, we aim at describing the pattern of care, survival outcome and prognostic factors of ABC patients (pts) receiving third-line chemotherapy in a real-world scenario.

Methods: Institutional registries across three academic medical centers were reviewed to identify ABC pts who had received third-line chemotherapy from September 2005 to January 2020. Pre-treatment demographics, clinicopathologic and biochemical variables of interest were retrieved. Kaplan-Meier estimators were used to calculate survival, while the log-rank test was implemented to make comparisons. The impact of variables on survival was assessed through univariate and multivariate analysis.

Results: Overall, 101 pts were included in the analysis. The median age was 64 years (range 35-84) and 58 (57.4%) were females. Overall, 68 (67.3%), 19 (18.8%) and 14 (13.8%) pts had intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer, respectively. A total of 63 (62.3%) pts received monochemotherapy, while 38 (37.6%) were treated with a doublet. The median OS and PFS were 4.4 and 2.8 months, respectively. Disease control rate was achieved in 23 (22.7%) pts, with 2 (2%) partial responses. No difference in efficacy between different third-line regimens has been recorded ($p=0.89$). Grade 3-4 treatment-related adverse events were reported in 22 (21.7%) pts, more frequently represented by myelotoxicity, fatigue and mucositis. At multivariate analysis, ECOG PS ($p<0.001$), tumour burden ($p=0.01$) and lymphocyte-to-monocyte ratio ($p=0.02$) were independent predictors of survival.

Conclusions: Third-line chemotherapy displayed limited activity in this real-world cohort of ABC, although prognostic factors have been identified that may assist in treatment decision. The results of this multicenter experience, the largest so far, highlight the need for more effective therapies and provide a benchmark for future trials of third-line chemotherapy in ABC.

Legal entity responsible for the study: The authors.

Funding: Has not received any funding.

Disclosure: All authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2020.08.035

58P Quality of life (QoL) outcomes with futibatinib treatment in FOENIX-CCA2 - A phase II study in patients (pts) with intrahepatic cholangiocarcinoma (iCCA) harboring FGFR2 gene fusions/ rearrangements

J.W. Valle[1], A. Hollebecque[2], J. Furuse[3], L. Goyal[4], F. Meric-Bernstam[5], R. Morlock[6], Y. He[7], K. Benhadji[8], J. Bridgewater[9]

[1]Division of Cancer Sciences, University of Manchester/The Christie NHS Foundation Trust, Manchester, UK; [2]DITEP - Drug Development Department, Gustave Roussy, Villejuif, France; [3]Department of Medical Oncology, Kyorin University School of Medicine, Tokyo, Japan; [4]Department of Medicine (Hematology/Oncology), Massachusetts General Hospital, Boston, MA, USA; [5]Investigational Cancer Therapeutics, The University of Texas M. D. Anderson Cancer Center, Houston, TX, USA; [6]Scientific Collaborator, YourCareChoice, Ann Arbor, AL, USA; [7]Biostatistics, Taiho Oncology, Princeton, NJ, USA; [8]Clinical Development Department, Taiho Oncology Inc., Princeton, NJ, USA; [9]Department of Medical Oncology, UCL Cancer Institute, London, UK

Background: Cancer treatment can produce AEs that result in a reduced QoL. Futibatinib, a highly selective irreversible FGFR1–4 inhibitor, demonstrated an objective response rate (ORR) of 37.3% and median 8.3-mo duration of response in the interim analysis of FOENIX-CCA2, a mutlicenter phase II trial of pts with advanced, refractory iCCA harboring an *FGFR2* fusion/rearrangement; grade $\geq$3 treatment-related AEs (TRAEs) occurred in 57% of pts (most commonly, hyperphosphatemia [26.9%]). Change in pt-reported outcomes (PROs) from baseline (BL) for the interim data of the phase II trial are presented here.

Methods: Pts enrolled into FOENIX-CCA2 (NCT02052778), had locally advanced/metastatic unresectable iCCA and received oral futibatinib 20 mg once daily (QD) until disease progression/intolerance. PRO measures included EORTC-QLQ-C30 (5 functional and 9 physical measures) and EQ-5D-3L (utility index and 5 dimensions: anxiety/depression, mobility, pain/discomfort, self-care, and usual activity). PROs were collected at screening, cycles 2 and 4, every 3 cycles after cycle 4 and at the end of treatment. Change in mean score from BL was assessed using predefined clinically meaningful thresholds for each time point with $\geq$19 observations (through cycle 13).

Results: Sixty-seven of 103 enrolled pts had $\geq$6 months of follow-up and 57 (85.1%) had PRO completion data at BL and $\geq$1 assessment. EORTC mean global health status score was high at BL (68.7) and maintained through cycle 13 (70.8), a trend observed across all EORTC measures. The only clinically meaningful changes ($\geq$10-point changes) in this timeframe were for constipation symptoms at cycles 2 and 4 (worsened +12.4 and +10.7, respectively) and dyspnea at cycle 10 (improved -12.2). Mean EQ-5D-3L index scores improved from 70.9 at BL to 79.1 at cycle 13 (approximately 273 days on treatment).

Conclusions: Overall, the interim PROs from FOENIX-CCA2 were encouraging. These data suggest that despite the occurrence of TRAEs, a 20-mg-QD dose of futibatinib in pts with iCCA provides a promising clinical response without adversely impacting QoL.

Clinical trial identification: NCT02052778; EudraCT: 2013-004810-16.

Editorial acknowledgement: Professional medical writing and editorial assistance were provided by Ashfield Healthcare Communications (Lyndhurst, NJ, USA) and funded by Taiho Oncology, Inc.

Legal entity responsible for the study: Taiho Oncology, Inc.

Funding: Taiho Oncology, Inc.

Disclosure: J.W. Valle: Honoraria (self), Advisory/Consultancy, Speaker Bureau/Expert testimony: Ipsen; Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (self): Novartis; Advisory/Consultancy: AstraZeneca; Advisory/Consultancy: Merck; Advisory/Consultancy: Delcath Systems; Advisory/Consultancy: Agios; Advisory/Consultancy, Travel/Accommodation/Expenses: Pfizer; Advisory/Consultancy: PCI Biotech; Advisory/Consultancy: Incyte; Advisory/Consultancy: Keocyt; Advisory/Consultancy: QED Therapeutics; Advisory/Consultancy: Pieris Pharmaceuticals; Advisory/Consultancy: Genoscience Pharma; Advisory/Consultancy: Mundipharma EDO GmbH; Advisory/Consultancy: Wren Laboratories; Advisory/Consultancy, Speaker Bureau/Expert testimony, Travel/Accommodation/Expenses: Nucana; Advisory/Consultancy: Servier; Advisory/Consultancy, Speaker Bureau/Expert testimony: Imaging Equipment Limited; Travel/Accommodation/Expenses: Celgene. A. Hollebecque: Honoraria (self), Research grant/Funding (self), Travel/Accommodation/Expenses: Incyte; Honoraria (self): Amgen; Travel/Accommodation/Expenses: Servier; Honoraria (self): Merck Serono; Travel/Accommodation/Expenses: Lilly; Honoraria (self): Eisai .J. Furuse: Advisory/Consultancy, Travel/Accommodation/Expenses: Debiopharm Group; Advisory/Consultancy: Alentis Therapeutics; Advisory/Consultancy: QED Therapeutics; Advisory/Consultancy: H3 Biomedicine; Advisory/Consultancy: AstraZeneca; Advisory/Consultancy: Klus Pharma; Advisory/Consultancy: Agios; Advisory/Consultancy, Research grant/Funding (self), Travel/Accommodation/Expenses: Taiho Pharmaceutical Co.F. Meric-Bernstam: Advisory/Consultancy, Research grant/Funding (institution): Genentech; Advisory/Consultancy: Inflection Biosciences; Advisory/Consultancy: Pieris Pharmaceuticals; Advisory/Consultancy: Clearlight Diagnostics; Advisory/Consultancy: DarwinHealth; Advisory/Consultancy: Samsung Bioepis; Advisory/Consultancy: Spectrum Pharmaceuticals; Advisory/Consultancy: Aduro Biotech; Advisory/Consultancy: Origimed; Advisory/Consultancy: Xencor; Advisory/Consultancy, Research grant/Funding (institution): Debiopharm Group; Advisory/Consultancy: Mersana; Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses: Seattle Genetics; Advisory/Consultancy: Silverback Therapeutics; Advisory/Consultancy: Immunomedics; Advisory/Consultancy: IBM Watson Health; Advisory/Consultancy: Roche; Advisory/Consultancy: PACT Pharma; Advisory/Consultancy, Research grant/Funding (institution): eFFECTOR Therapeutics; Research grant/Funding (institution), Travel/Accommodation/Expenses: Taiho Pharmaceutical; Speaker Bureau/Expert testimony: Chugai Pharma; Travel/Accommodation/Expenses: Beth Israel Deaconess Medical Center; Honoraria (self): Sumitomo Group; Honoraria (self): Dialectica; Research grant/Funding (institution): Novartis; Research grant/Funding (institution): AstraZeneca; Research grant/Funding (institution): Calithera Biosciences; Research grant/Funding (institution): Bayer; Research grant/Funding (institution): Aileron Therapeutics; Research grant/Funding (institution): PUMA Biotechnology, CytomX Therapeutics, Jounce Therapeutics, Zymeworks, Curis, Pfizer, Abbvie, Boehringer Ingelheim, Guardant

Health, Daiichi Sankyo. R. Morlock: Advisory/Consultancy: Taiho Oncology; Advisory/Consultancy: Johnson and Johnson; Advisory/Consultancy: Heron; Advisory/Consultancy: Evofem; Advisory/Consultancy: Horizon Therapeutics. Y. He: Full/Part-time employment: Taiho Oncology. K. Benhadji: Shareholder/Stockholder/Stock options, Full/Part-time employment: Lilly; Full/Part-time employment: Taiho Oncology. J. Bridgewater: Advisory/Consultancy: Taiho. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2020.08.036

59P Evolution of adjuvant therapy in radically resected carcinoma gallbladder (GBC) over a decade: A real world experience from a regional cancer centre

S. Agrawal[1], M.N. Alam[2], N. Rastogi[1], R. Saxena[3]

[1]Radiation Oncology, Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Lucknow, India; [2]Radiation Oncology, Kamla Nehru Hospital, Allahabad, India; [3]Surgical Oncology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, India

Background: Because of the high mortality and rarity of GBC, the best adjuvant modality of radically resected GBC is not well established.

Methods: We audited the records of radically resected GBC who received adjuvant therapy over a decade (2007-2017) to gain an insight on the efficacy of various modalities of treatment. In the period 2007-2012 only concurrent chemo-radiation (CTRT, n=40) was practised. Since 2013, very low risk patients were kept on observation (R0, T2, T3, N0), low risk patients (R0, T2, T3 and N0, N1) received CT and high risk patients (R1, N2, T3, T4, LVI, PNI) received CTRT. The lack of concrete guidelines for adjuvant therapy according to risk and treatment offered according to physician discretion resulted in overlap in risk criteria in the three groups. Univariate and multivariate analysis was done to ascertain the effect of different treatment modalities on prognostic factors using spss (v.20).

Results: The median age of patients (n=142) was 50 years. At a median follow-up of 50 months, the median OS of all patients was 34 months.The median OS was NR vs 46 mo vs 30 mo with CT, CTRT and observation respectively (p=0.24). Young aged women had better OS with CTRT. On univariate analysis, the median OS of patients less than 50 was 48 months (p=0.29), females had better OS (50 mo vs 26 mo, p=0.07), those with co-morbidity were worse (26 mo vs 48 mo, p=0.29). T2 patients had the best OS [72 mo vs 40 mo (T3) vs 16 mo (T4), p = 0.13], node negative had better OS (72 months vs 40 mo, (p=0.08)). The effect of various adjuvant modalities on OS based on the prognostic factors is given in the table below. On multivariate analysis the hazard ratio of various prognostic factors influencing OS were resection status (HR 2.49, p=0.00), male (HR 1.3, p=0.25), T status (HR 2.1, p=0.15) and nodal status (HR 1.3, p=0.2).

Table: 59P

	Observation	CT	CTRT
Age group <50 (73) >50 (64)	30 26	48 NR	108 (p=0.44) 34
Male (35) Female (107)	6 32	NR 50	27 (p=0.07) 72
T2 (79) T3 (58) T4 (5)	25 50 -	NR 39 20	34 (0.13) 46 16
Node negative (65) Node positive (77)	32 18	NR 48	51 (p=0.08) 34
R0 (107) R1 (35)	32 -	NR -	NR (p=0.00) 23

Conclusions: CT should be the standard of care as adjuvant therapy for all GBC patients. CTRT should be used in high risk features like R1, LVI and PNI.

Legal entity responsible for the study: Sushma Agrawal.

Funding: Has not received any funding.

Disclosure: All authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2020.08.037

60P Epidemiology and patterns of care of intrahepatic cholangiocarcinoma (iCCA) in France: Real life data from the French National Hospital-Discharge Summaries database system (PMSI)

C. Neuzillet[1], C. Emery[2], C. Teissier[2], S. Bouée[3], A. Lièvre[4]

[1]Medical Oncology Department, Curie Institute, Saint Cloud, France; [2]Biostatistics, CEMKA, Bourg-La-Reine, France; [3]Real World Evidence, CEMKA, Bourg-La-Reine, France; [4]Gastroenterology and GI Oncology, CHU Pontchaillou, Rennes, France

Background: Little is known about epidemiology of iCCA in daily practice. We aimed to estimate from real-life data the incidence of iCCA in France and to describe the healthcare pathways of these patients (pts).

Methods: A retrospective analysis was carried out using the nationwide prospective French PMSI database. All pts with new diagnosis of "carcinoma of the intrahepatic bile duct" who had a 1st hospital stay (S1) in Medicine, Surgery and Obstetrics departments (MSO) between 2014-2015 with a 2-year follow-up were included. Data related to the S1 in MSO and on all subsequent stays in MSO, Aftercare and Rehabilitation or Home Hospitalizations were analyzed.

Results: A total of 3,650 new iCCA cases were identified. At S1 (admission via emergency room [ER] in 28%), median age of pts was 73y, 57% were male and 35% had metastases. Jaundice/anemia/ascites/cholangitis were reported in 17%/16%/12%/7%, respectively. Pts care at S1 was mainly provided in general hospitals (CHG, 60%), rather than university hospitals (CHU, 15%), private (20%) or cancer centers (CLCC, 6%). 896 (24%) pts died during S1: they were more often hospitalized via ER (48% vs 23%), metastatic (52% vs 35%) and symptomatic. Subsequent stays were identified for 2,507 pts (69%). Most pts were managed in CHG during their follow-up (70% vs 20% in CHU and 12% in CLCC). Centers were classified as low (≤5 pts treated over the study period, 68%), intermediate (5-20 pts, 26%) or high volume (>20 pts, 6%). 47% of the high-volume centers were CHU/CLCC. Three healthcare pathways were defined: surgery (n=519; 14%), chemotherapy (CT; n=812; 22%) and best supportive care (BSC; n=2,319; 63%). CT, surgery and BSC were most frequently performed in CLCC, CHU and CHG, respectively. Pts who received CT were younger, less frequently hospitalized via ER and less symptomatic at S1. A palliative care code was associated with S1 in 25% of pts and with a subsequent stay in 60%.

Conclusions: This real-life medico-administrative study reveals a higher incidence of iCCA in France than that previously reported and highlights the severity of this disease, the central role of CHG in the management of pts and the expertise of CHU and CLCC for surgery and CT, respectively.

Legal entity responsible for the study: The authors.

Funding: Incyte Biosciences.

Disclosure: C. Neuzillet: Honoraria (self), Advisory/Consultancy: Servier; Honoraria (self), Advisory/Consultancy, Clinical trial: AstraZeneca; Honoraria (self), Advisory/Consultancy, Clinical trial: Bristol-Myers Squibb; Honoraria (self), Advisory/Consultancy: Amgen; Honoraria (self), Advisory/Consultancy: Merck; Honoraria (self), Advisory/Consultancy: MSD; Honoraria (self), Advisory/Consultancy: Novartis; Honoraria (self), Advisory/Consultancy: Incyte; Honoraria (self), Advisory/Consultancy: Nutricia; Honoraria (self), Advisory/Consultancy: Baxter; Honoraria (self), Advisory/Consultancy: Fresenius Kabi; Travel/Accommodation/Expenses, Clinical trial: OSE Immunotherapeutics; Research grant/Funding (institution): Roche. C. EMERY: Full/Part-time employment: CEMKA. C. TEISSIER: Full/Part-time employment: CEMKA. S. BOUÉE: Full/Part-time employment: CEMKA. A. LIÈVRE: Honoraria (self), Advisory/Consultancy: AAA; Honoraria (self), Advisory/Consultancy: Amgen; Honoraria (self), Advisory/Consultancy: Bayer; Honoraria (self): BMS; Honoraria (self): Celgene; Honoraria (self): HalioDX; Advisory/Consultancy, Research grant/Funding (institution): Incyte; Honoraria (self), Advisory/Consultancy: Ipsen; Honoraria (self): Lilly; Honoraria (self), Advisory/Consultancy: Merck; Honoraria (self), Advisory/Consultancy, Research grant/Funding (institution): Novartis; Honoraria (self), Advisory/Consultancy: Pierre Fabre; Honoraria (self): Roche; Honoraria (self), Advisory/Consultancy: Sandoz; Honoraria (self), Advisory/Consultancy: Servier; Research grant/Funding (institution): Integragen.

https://doi.org/10.1016/j.annonc.2020.08.038

61P Gender and race/ethnicity differences in outcomes of biliary cancers (BC): A SEER database analysis

H.J. Lenz[1], C. Luo[2], P. Jayachandran[1], H. Arai[1], J. Wang[1], N. Kawanishi[1], S. Soni[1], A.B. El-Khoueiry[1], W. Zhang[1], J. Millstein[2], F. Battaglin[1]

[1]Oncology, USC - Norris Comprehensive Cancer Center, Los Angeles, CA, USA; [2]Preventive Medicine, Keck School of Medicine, USC - Norris Comprehensive Cancer Center, Los Angeles, CA, USA

Background: Strong evidence supports the impact of gender and race/ethnic background on patients (pts) outcomes across several cancer types. Here we present a comprehensive analysis of the Surveillance, Epidemiology, and End Results database (SEER 1975-2016) in BC.

Methods: 53718 pts with BC (22068 gallbladder, 12502 intrahepatic bile duct, 16111 extrahepatic bile duct, 3037 unspecified) were included. Primary end point was 5-year survival probability. Log-rank tests were used to evaluate the effects of gender and race/ethnicity on overall survival (OS). Subgroups analyses included primary tumor site, disease stage, and treatment.

Results: 43% of pts in our series were male (M) and 57% female (F); 66% were White/Caucasian (W), 15% Hispanic (H), 11% Asian (A), 8% Black/African American (BA). Significant differences in baseline pts characteristics were found between M and F for: age of diagnosis (68 vs 70 yr), stage (25 vs 28% local disease), primary tumor site (38% extrahepatic in M, 50% gallbladder in F), surgical treatment (39 vs 47%), $P < .001$. Significant differences in gender proportions and age were observed across race/ethnic groups, with youngest mean age at diagnosis and highest prevalence of F pts in H (66 yr, 64%) and BA (66 yr, 61%). Overall, F pts had higher 5-year OS probability compared to M (0.13 vs 0.11, $P < .001$). This difference was significant regardless of age in F, however, younger F pts showed higher OS probability rates (0.23 in age <50 vs 0.13 in age ≥ 50 yr, $P < .0001$). Among race/ethnic groups, higher 5-year OS probability was observed for H and A while lower for BA and W (0.16 vs 0.14 vs 0.13 vs 0.12, $P < .0001$). The gender related survival difference was largest in H (0.17 vs 0.13, $P < .001$) but was also significant in BA (0.13 vs 0.11, $P = .01$); no significant difference was found in W and A. When stratified by both gender and ethnicity, the highest survival probabilities were observed for H and A female pts, the lowest for W