(13p/4p: 5Fu/xeloda w or w/o platinum compounds). From these, 43p were evaluable for response, 33p had SD and 10p had PD. PFS for 2nd line CT was 6 mo (95% CI 4.1−7.9). PFS for FU based regimen 2nd line was 3.2 mo (95% CI 0.2−6.9) and for Gem based regimen 2nd line: 6.1 mo (95% CI 3.1−9) p = 0.09. OS, for all 96pts was 9.9 mo (95% CI 8.8−11) and for 46p with 2nd line CT was 13.6 mo (95% CI 11.2−16) with better OS for pts with FU based 1st line and Gem in 2nd line: 19 mo (95% CI 8.9−2) vs 13.2 mo (95% CI 12–14.4) p < 0.001 (s).
Conclusions: Our results indicate that the FU based CT in 1st line and Gem in 2nd line gave a better survival than the opposite, therefore this nonrandomized trial showed that this regimens' order could be relevant and necessitates a phase III trial randomized to check the impact of CT lines sequence in advanced BTC.

6581 POSTER

Phase II Study of RAD001 Monotherapy in Patients With Non-functioning Carcinoid or Pheochromocytoma/Paraganglioma

D. Oh[1], T. Kim[2], Y. Park[3], S. Shin[4], S. Shin[5], E. Song[6], H. Lee[7], K. Lee[8], Y. Bang[1]. *[1]Seoul National University Hospital, Department of Internal Medicine, Seoul, South Korea; [2]Asan Medical Center, Department of Internal Medicine, Seoul, South Korea; [3]Samsung Medical Center, Department of Internal Medicine, Seoul, South Korea; [4]Yonsei Cancer Center, Department of Internal Medicine, Seoul, South Korea; [5]Kosin University Gospel Hospital, Department of Internal Medicine, Pusan, South Korea; [6]Chonbuk National University Hospital, Department of Internal Medicine, Chonbuk, South Korea; [7]Chungnam National University Hospital, Department of Internal Medicine, Chungnam, South Korea; [8]Seoul National University Bundang Hospital, Department of Internal Medicine, Seungnam, South Korea*

Background: To examine the efficacy and toxicity of RAD001 in patients with non-functioning carcinoid or pheochromocytoma/paragaglioma.
Methods: Patients with histologically confirmed non-functioning carcinoid or pheochoromocytoma/paraganglioma, with at least one measurable lesion were eligible for the study. Other eligibility criteria included; documented disease progression according to RECIST criteria within12 months prior to the entry, not amenable to curative-intent treatment, ECOG PS 0 or 1, and adequate organ function. RAD001 was given at a dose of 10 mg daily every 4 weeks. Response was assessed according to RECIST (v 1.0) every 8 weeks. Primary end-point was 4-month progression-free survival rate. Hypothesis was that 4m-PFSR would be improved from 50% to 65%.
Results: A total of 34 patients were enrolled into this study. 27 patients had nonfunctioning carcinoid, 5 pheochromocytoma, and 2 paraganglioma. Thirty-three patients were evaluable for response. Partial responses were achieved in 3 patients. Twenty-eight patients had stable disease and 3 progressive disease. Response rate and overall disease control rate was 9.0% and 93.9%, respectively. The median PFS was 15.3 months (95% CI, 4.6–26.0 months) and 4-month PFSR was 78%. Mean treatment duration was 9.1 months (range 1.1–30.6 months).
In case of carcinoid, 3 patients had PR and the others had SD (RR 11.1%, DCR 100%), with a median PFS of 17.1 months (95% CI, 11.1–23.0 months) and 4-month PFSR of 90.0%. Twenty-one patients (80.8%) showed tumour shrinkage.
In case of pheochromocytoma/paraganglioma, 5 patients showed SD, 2 PD. Meidan PFS was 3.8 months (95% CI, 0.5−7.0 months) and 4-month PFSR 42.9%. Two patients with paraganglioma showed tumour shrinkage. The most common AEs (all grades) were rash (29.4%), diarrhea (26.5%), and stomatitis (17.6%). The major Gr 3/4 toxicities were thrombocytopenia (14.7%), hyperglycemia (5.9%), stomatitis (5.9%) and anemia (5.9%).
Conclusions: RAD001 showed very promising efficacy (11% PR and 100% disease control rate) in unresectable non-functioning carcinoid and good tolerability in the entire study population. However, RAD001 monotherapy in pheochromocytoma/paraganglioma requires further larger investigation in its efficacy.
Clinicaltrial.gov: NCT01152827

6582 POSTER

Sorafenib Dose Ramp-up Scheme for the Treatment of Advanced Hepatocellular Carcinoma

J.E. Kim[1], B.Y. Ryoo[1], M.H. Ryu[1], H.M. Chang[1], D.J. Suh[2], H.C. Lee[2], Y.S. Lim[2], K.M. KIm[2], Y.K. Kang[1]. *[1]Asan Medical Center, Oncology, Seoul, South Korea; [2]Asan Medical Center, Gastroenterology, Seoul, South Korea*

Background: Sorafenib is the only drug to date that has shown survival benefit in hepatocellular carcinoma (HCC). Many patients, however, require sorafenib discontinuation or dose reduction due to adverse events (AEs), suggesting the need for a treatment strategy avoids AEs. We have applied a sorafenib dose ramp-up scheme for this purpose.
Materials and Methods: Of 267 patients with HCC treated with sorafenib as first line therapy, 25 had risk factors for increased AEs; advanced liver cirrhosis, post liver transplantation status, or neutropenia and/or thrombocytopenia. These 25 patients were started on a reduced dose of sorafenib, which was increased to the standard dosage according to tolerance. Efficacy and safety were compared in patients treated according to the ramp-up and standard non ramp-up schemes.
Results: Patients were divided into three groups; non ramp-up without risk factors, non ramp-up with risk factors, and ramp-up. There were no significant differences in disease control rate and time to progression among the 3 groups. Grade 3/4 AEs were more frequent in the non ramp-up groups without significant difference. The incidence rates of sorafenib discontinuation and dose reduction related to AEs were lower in the ramp-up group. Sorafenib was ramped up to standard dose in 16 patients (64.0%), and the sorafenib dose intensity in this group did not differ from that in the non ramp-up groups.
Conclusions: Sorafenib ramp-up may be an option in patients at higher risk of AEs or with poorer tolerance. Future trials should test this dosage scheme in patients without any risk factors.

6583 POSTER

Phase I Dose-finding Study of Epirubicin, Oxaliplatin and S-1 (EOS) in Patients With Previously Untreated Advanced Gastric Cancer (AGC)

S.J. Sym[1], J. Hong[1], M. Jung[1], J. Park[1], E.K. Cho[1], W.K. Lee[2], M. Chung[2], Y.H. Park[2], J.H. Lee[1], D.B. Shin[1]. *[1]Gachon Medical School Gil Medical Center, Internal Medicine, Incheon, Korea; [2]Gachon Medical School Gil Medical Center, General Surgery, Incheon, Korea*

Purpose: To determine the recommended dose (RD) and dose-limiting toxicity (DLT) of EOS combination in patients with previously untreated AGC.
Materials and Methods: Previously untreated patients with histologically proven metastatic or recurrent AGC and ECOG performance status 0−2 were enrolled. Fixed dose of epirubicin (50 mg/m^2) and oxaliplatin (130 mg/m^2) was administered i.v. on day 1. The dose of S-1 was escalated as following schedule: Level I: 30 mg/m^2, Level II: 40 mg/m^2, Level III: 45 mg/m^2, Level IV: 50 mg/m^2. S-1 was administered orally twice a day on days 1−14. Each cycle was repeated every 21 days. DLTs were evaluated during the first two cycles of treatment.
Results: Nineteen patients were enrolled: 13 patients in dose-escalation phase and 6 patients in the extension at the RD. Median age was 53 years (range, 40−71 years). At dose level II, 1 DLT (grade 4 neutropenia lasting more than 5 days) was found among 6 patients while at dose level III, 2 DLTs (grade 3 diarrhea and nausea) were observed among 4 patients. Therefore, the dose level II was determined as RD. Cumulative (all cycles) grade 3/4 toxicity included neuropenia (58%), leucopenia (32%), thrombocytopenia (11%), diarrhea (11%), and nausea (5%). Of 13 patients with measurable lesions, 8 achieved partial response and 3 showed stable diseases, and the objective response rate was 62% (95% confidence interval [CI], 36−88%). The median progression-free survival was 6.5 months (95% CI, 4.7−8.2 months).
Conclusions: The RD of the EOS regimen in patients with previously untreated AGC was epirubicin 50 mg/m^2 and oxaliplatin 130 mg/m^2 on day 1 and S-1 40 mg/m^2 twice a day on days 1−14 of every 21-day cycle. This regimen seems to have promising preliminary activity.

6584 POSTER

Epirubicin, Oxaliplatin & Capecitabine Combination for Untreated Advanced Esophagogastric Cancer

A. Alam[1]. *[1]Enam Medical College, Oncology, Dhaka, Bangladesh*

Background: Gastric and esophageal cancers are the fourth most common causes of cancer-related deaths in Bangladesh. The regimen containing epirubicin, cisplatin, and infused fluorouracil (ECF) is used as a standard therapy for untreated advanced esophagogastric cancer in Bangladesh. Combination of epirubicin, capecitabine and oxaliplatin has shown significant results. To confirm we evaluated oxaliplatin and capecitabine as alternatives to infused cisplatin and fluorouracil, respectively for the treatment of untreated advanced esophagogastric cancer in Bangladesh perspective.
Methods: We randomly assigned 122 patients to receive triplet therapy with epirubicin and cisplatin plus either fluorouracil (ECF) or capecitabine (ECX) or triplet therapy with epirubicin and oxaliplatin plus either fluorouracil (EOF) or capecitabine (EOX). The primary end point was overall survival for