Results: Median follow-up time was 23.8 months (range, 3.5–76.5 months). Of 162 patients, 42 of 89 (47.2%) definitive CRT and 42 of 73 (57.5%) preoperative CRT patients achieved PET-CR. The 2-year OS of trimodality and definitive CRT groups were 61.6% and 39.3%, respectively ($p = 0.0106$). But it was 57.1% in PET-CR subgroup among definitive CRT patients and which was equivalent to that of trimodality group ($p = 0.736$). The 2-year LRFS was higher in trimodality group than in entire definitive CRT or PET-CR subgroup among definitive CRT patients (88.1% vs 56.8% and 62.3%, respectively, $p = 0.002$). The 2-year DFS was also higher in trimodality than in both entire CRT and PET-CR subgroup (72.8, 38.2% and 47.3%, respectively, $p = 0.007$). On multivariate analysis on prognostic factors, PET-CR was the only factor which was significant for OS (hazard ratio (HR) 2.076, $p < 0.001$), LRFS (HR 2.295, $p = 0.001$), and DFS (HR 2.050, $p < 0.028$). Surgical resection was also significant for LRFS (HR 2.674, $p < 0.001$) and DFS (HR 4.501, $p < 0.001$), but marginally significant for OS (HR 1.530, $p = 0.053$).
Conclusions: Trimodality treatment showed superior outcomes than definitive CRT in OS, DFS, and LRFS. When trimodality was compared to PET-CR subgroup of CRT patients, it was also beneficial in DFS and LRFS. It seems that surgical resection should be reserved as a component of current standard treatment until prospective study verify a subgroup which can omit surgical resection.

6520 POSTER

Concurrent Chemoradiation as Definitive Treatment in Anal Squamous Cell Carcinoma − Efficacy and Safety in HIV+ Patients Under HAART

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Background: HIV seropositivity is a known risk factor for anal squamous cell carcinoma (ASCC), but the efficacy and safety of concurrent chemoradiation (CRT) as definitive therapy for ASCC in HIV+ pts under highly active antiretroviral therapy (HAART), in comparison with HIV-negative/unknown ASCC pts, remains under discussion.
Materials and Methods: We retrospectively analysed all consecutive pts diagnosed and treated in a single institution from Apr/2000 to Jun/2010. Definitive CRT consisted of 45−54 Gy (180 cGy/d, 5 fractions/week), with concurrent mitomycin-C 15 mg/m^2 D1 IV and 5-fluoruracil (5FU) 1 g/m^2/d IV, continuous infusion, D1-D4 and D29-D32. The same treatment was delivered irrespective of HIV-status. HIV+ pts were under HAART according to standard recommendations.
Results: 102 pts were studied: median age 57 y (23−86 y), 83% female. Stage: Tis (3 pts), I (5), II (36), IIIA (15), IIIB (30), IV (4). Eleven pts were identified as HIV+. They were younger (41.2 vs. 60.1 y, $p < 0.0001$) and predominantly male (10/11). Mean CD4 count was 412±160 cells/microliter (210–664). No difference in tumour stage was detected. For all pts, the median dose of RT was 45 Gy, delivered over 46 d. No difference in terms of treatment duration or administered CRT intensity between HIV+ or HIV-negative/unknown pts was observed. Treatment was well tolerated and only one treatment-related death was seen in a pt with unknown HIV-status. 84 pts were evaluated for response, and complete response (CR) was achieved in 59 pts (70%). No difference was seen in HIV+ pts [7/9 CR (77.8%), $p = 0.890$] in terms of CR rate. With a mean follow-up of 23 months, 17 deaths have occurred. Overall, the median overall survival (mOS) was not reached (NR) and the 2-year OS rate was 79%. No difference in mOS was seen between HIV+ or HIV-negative/unknown pts (NR in both groups, HR 2.03, 95% CI 0.38–7.73, $p = 0.480$), and a 2-year OS rate of 89% was observed in HIV+ pts. Longer 2-y OS rate was observed in those pts that needed no colostomy (85% vs. 63%, HR 0.33, 95% CI 0.05–0.89, $p = 0.034$), and also in those pts who achieved CR after concurrent CRT (97% vs. 21%, HR 0.06, 95% CI 0.00–0.04, $p < 0.0001$).
Conclusions: In this group of ASCC, no differences in terms of efficacy and safety of concurrent CRT as definitive therapy for ASCC were detected based on HIV seropositivity. 5FU/MMC-based CRT can be delivered successfully in HIV+ pts under HAART.

6521 POSTER

Prospective Randomized Controlled Phase II Trial of Alternate-day Vs Consecutive-day Treatment With S-1 as Postoperative Adjuvant Therapy for Gastric Cancer: San-in Clinical Oncology Group Study No. 9

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Background: The adverse effects of S-1 can lead to discontinuation of treatment. In the ACTS-GC study, 28% of patients discontinued S-1 because of adverse events and 42.4% of the patients required dose reduction. Strategies for reducing toxicity without compromising therapeutic efficacy are required.
Methods: We prospectively examined 70 eligible patients with stage II or III gastric cancer who received S-1 on alternate-days (AD) or on consecutive-days (CD) following curative gastrectomy between November 2005 and October 2008. S-1 (80 mg/m^2 per day) was orally administered twice daily for 4 weeks, followed by a 2-week rest during 1 year in the CD group (standard regimen established by ACTS-GC) and was administered every other day for 1.3 years in the AD group. The planed administration schedule was 224 days in both groups. The primary end points were treatment accomplishment rate and relative dose intensity.
Results: We randomly assigned 35 patients to the AD group and 35 to the CD group. The two groups were well balanced with regard to clinical characteristics, surgical procedures and pathological findings. The complete clinical data was obtained from 31 patients in each group. The treatment accomplish rate was 93.5% (n = 29) in the AD group and 74.2% (n = 23) in the CD group. The relative dose intensity was 85.6% in the AD group and 72.1% in the CD group. The rates of grade 1−3 adverse events in the AD and CD groups were respectively as follows; 46% and 19% in anorexia, 29% and 14% in diarrhea, 20% and 5% in nausea, and 20% and 14% in mucositis. With a median follow-up duration of 18 months, the 1-year overall survival rates were 96.9% in the AD group and 93.8% in the CD group.
Conclusions: The AD group revealed a higher treatment accomplish rate and higher relative dose intensity than the CD group. Therefore, alternate-day treatment with S-1 may have milder adverse effects without compromising therapeutic efficacy.

6522 POSTER

Neoadjuvant Chemoradiation Therapy With Gemcitabine for Cholangiocarcinoma − Three-years Results After Phase I Study and Interim Analysis of Phase II Study

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Background: To improve the prognosis of cholangiocarcinoma, we are applying neoadjuvant chemoradiation therapy for cholangiocarcinoma (NACRAC) followed by conventional resection for possibly resectable cholangiocarcinoma. Three years have passed since Phase I study (P-1), and Phase II study (P-2) has been continued. Here, we evaluated the three-years' safety of P-1 and the feasibility of P-2.
Material and Methods: P-1 was designed to determine the recommended dose (RD) of gemcitabine. Patients with histologically or cytologically confirmed adenocarcinoma of the extra and hilar cholangiocarcinoma were enrolled from August 2007 to June 2008 at Tohoku University Hospital. The RD of gemcitabine was determined as 600 mg/m^2 with external beam radiation therapy (1.8-Gy daily fractions to a total dose of 45 Gy). NACRAC did not increased peri-operative complications like operative duration, surgical site infection (SSI), and hospital stay. Original results of P-1 were presented at European Society of Surgical Oncology 2008 (ESSO). P-2 was started in March 2009 at Tohoku University Hospital. Quality control of radiation therapy is very difficult, and then P-2 was started at our hospital only. The aim of this interim analysis is to evaluate pathological curability and adverse events. And assess the feasibility of this trial. The primary endpoint is rate of no residual tumour (R0-resection rate).
Results: Twelve patients were enrolled in P-1. After three years, seven patients were died because of primary disease. The most remarkable point is there is no severe adverse event and vascular occlusions related with radiation therapy while three years. This showed NACRAC with conventional resections were safe and tolerable. In P-2, 14 patients have enrolled. 8 patients were male, and 6 patients were female. Median age was 70.5 years old. 2 patients were not able to operated; one was not enough liver function for operation, and the other was occurred heart