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Safety and Feasibility of Adjuvant Chemotherapy With S-1 in Korean Patients With Curatively Resected Advanced Gastric Cancer

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Background: Adjuvant chemotherapy with S-1 has been proven effective for patients with curatively resected advanced gastric cancer with D2 lymph node dissection in Japan. We assessed the safety and feasibility of adjuvant S-1 chemotherapy in Korean patients with stage II, III or IV(M0) gastric cancer.
Material and Methods: A total of 305 patients with stage II, III or IV(M0) gastric cancer received adjuvant S-1 chemotherapy following curative gastrectomy with D2 lymph node dissection in Asan Medical Center between October 2007 and December 2009. Adjuvant chemotherapy with S-1 was started 3−6 weeks after surgery and it was administered orally twice daily at the dose of 40 mg/m^2 for 4 weeks followed by 2 weeks of rest, every 6 weeks 8 times for 1 year. We retrospectively reviewed the medical records of the patients and evaluated the safety and feasibility of adjuvant S-1 chemotherapy in Korean patients.
Results: Among the 305 patients, 248 (81.3%) and 198 (64.9%) patients completed 4 and 8 cycles of adjuvant chemotherapy, respectively. The most common reasons for discontinuation of treatment were adverse event (43.9%) and recurrence (26.2%). Among the 305 patients, 75 (24.6%) patients required dose reduction because of toxicities. The most common grade 3/4 toxicities were neutropenia (12.8%), diarrhea (5.3%), abdominal pain (3.8%), and anemia (3.3%). Multivariate analysis showed that total gastrectomy (H.R. 2.50; 95% C.I. 1.32–4.72, p = 0.005) and female gender (H.R. 1.95; 95% C.I. 1.03–3.66, p = 0.039) were independent risk factors for grade 3/4 hematologic toxicities, and old age (>65 years) (H.R. 2.92; 95% C.I. 1.50–5.69, p = 0.002) was an independent risk factor for grade 3 non-hematologic toxicities.
Conclusions: Adjuvant chemotherapy with S-1 for 1 year was safe and feasible in Korean patients. Old age, female gender, and total gastrectomy were independent risk factors for severe toxicities of adjuvant S-1 chemotherapy.

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Phase II Study of ABI-007 Given as an Every Three Weeks Schedule for Japanese Patients With Unresectable or Recurrent Gastric Cancer Refractory to 5-fluorouracil (5-FU) Containing Regimen

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Background: ABI-007 is a novel Cremophor®-free nanoparticle albumin-bound paclitaxel. Cremophor®-free formulation allows for to be administered using a shorter infusion schedule (30 minutes) and without the need for premedicaion to prevent hypersensitivity reactions.
This single arm phase II study trial was to evaluate the efficacy and safety of ABI-007 given every three weeks for unresectable or recurrent gastric cancer patients (pts) who have received one prior chemotherapy regimen containing fluoropyrimidine and developed disease progression or recurrence.
Patients and Methods: Pts were eligible as follows: histologically or cytologically confirmed gastric adenocarcinoma, received one prior regimen containing fluoropyrimidine analogs and developed disease progression or recurrence, age: 20−74, at least one measurable lesion by RECIST criteria, PS:0−2, adequate organ function and written informed consent. Study duration was until disease progression or unacceptable toxicity develops.
Received one prior regimen containing fluoropyrimidine analogs and developed disease progression or recurrence. Gastric cancer pts received ABI-007(260 mg/m^2, i.v. on day 1 of each 21 day cycle) without premedication.
The primary endpoint was the overall objective response rates (ORR); other efficacy parameters and safety profile.
Results: From April 2008 to July 2010, Total of 56 pts were enrolled, 55 pts received the study treatment, and 54 pts were eligible. Median age was 63.5, Male/Female was 43/13, PS:0/1/2 was 33/23/0 and the presence or absence of primary site was 21/35. ORR as primary endpoint was 27.8% (15 of 54) [95% CI 16.5–41.6] and DCR (disease control rate: rates of CR+PR+SD) was 59.3% (32 of 54) [95% CI 45.0–72.4] for all eligible patients. In addition, other secondary endpoints of efficacy are under investigation.
The most common grade 3/4 toxicities were as follows: lymphopenia, 10.9%; neutropenia, 49.1%; leukopenia, 20.0%; and peripheral sensory neuropathy, 23.6%.
Conclusions: ABI-007 shows promising activity with well-tolerated toxicities. It was suggested that ABI-007 was dose-dense treatment of paclitaxel for unresectable or recurrent gastric cancer refractory to 5-fluorouracil (5-FU) containing regimen.
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Fuoropirimidines(FU) Versus Gemcitabine(Gem) Based Chemotherapy in Locally Advanced and Metastatic Biliary Tract Carcinoma(BTC)

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Background: Between 2004 and 2008, we conducted a prospective study on 96 patients (p) with advanced BTC, nonrandomized, nonblinded crossover to test the effectiveness in every day practice of 2 types of CT:FU and Cisplatin(Cis) (arm A) vs Gem w or w/o Cis (arm B).
Material and Methods: Eligibility criteria included patients with histologically proven locally advanced/metastatic BTC and chemonaive: 57 p (arm A) received FU based CT and 39 p (arm B) Gem based CT. On disease progression, 46 p were crossed over to 2nd line CT (Gem/FU w or w/o platinum compounds). Clinical characteristics (median age: 56.7 y (26−81), F/M 35/61, ECOG at baseline 0/1/2: 47/41/8 and first line CT: 30p 5Fu+Cis, 27p xeloda+Cis, 26p Gem+Cis and 13p Gem), response to CT and survival are in the table.

	All pts	Arm A (FU+Cis)	ArmB (Gem+/−Cis)	p
Number(n)	96	57	39	
First line CT (n)		30 5Fu+Cis; 27 Xeloda+Cis	26 Gem+Cis; 13 Gem	
Age(y)	56.7(26−81)	56.4(26−76)	57(36−81)	
ECOG at baseline(n)	0/1/2:47/41/8	0/1/2:32/20/5	0/1/2:15/21/3	
F/M (n)	35/61	22/35	13/26	
PR/SD(n)	4/71	3/37	1/34	
ORR/DCR(%)	4/78	5.2/70	2.5/90	
PFS(1^{stl}ine CT)	6.0 mo (95% CI 5.5−6.5)	5.9 mo (95% CI 5−6.9)	6.3 mo (95% CI 5.4−7.1)	0.66 (ns)
OS	9.9 mo (95% CI 8.8−11)	10.3 mo (95% CI 7.5−13.1)	9.1 mo (95% CI 7−11.2)	0.09 (ns)
Second line CT (n)	46	29 24 Gem; 5 Gem + platinum compounds	17 FU + platinum compounds	
PFS (2ndline CT)	6.0 mo (95% CI 4.1−7.9)	6.1 mo (95% CI 3.1−9)	3.2 mo (95% CI 0.2−6.9)	0.09 (ns)
OS (2ndline CT)	13.6 mo (95% CI 11.2−16)	19 mo (95% CI 8.9−29)	13.2 mo (95% CI 12−14.4)	0.001 (s)

Results: From 90p evaluable for response: arm A/arm B − 13p/2p had PD; 3p/1p had PR and 37p/34p had SD. Overall response rate (ORR) of arm A was 5.2% and disease control rate (DCR) 70% and ORR of arm B was 2.5% and DCR 89%. PFS for 1st line for all pts was 6 mo (95% CI 5.5−6.5); for arm A − 5.9 mo (95% CI 5−6.9); for arm B − 6.3 mo (95% CI 5.4−7.1) p = 0.66 (ns). 46p received 2nd line CT: 29p Gem based regimen (24p/5p Gem/Gem + platinum compounds) and 17p FU based regimen