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55 pts (52%). Most common grade 3/4 toxicity was thrombocytopenia (10%) followed by neutropenia (9%) and vomiting (3%). With a median follow-up duration of 46 months (range 20–67), 3-year progression-free survival (PFS) and overall survival (OS) rates were 45% and 48%. The median PFS and OS were 27 months [95% confidence interval (CI) 17–37] and 34 months [95% CI 22–47]. In a subgroup analysis, the pts who achieved clinical CR after concurrent CRT showed a significant better PFS (15 vs 56 months, p = 0.002 by log-rank) and OS (20 vs 56 months, p = 0.005 by log-rank) than those not. Treatment failure with loco-regional progression or distant metastases was observed less frequently in pts with clinical CR than in pts without clinical CR (20% vs 44%, p = 0.007 for overall failure rate; 10% vs 30%, p = 0.014 for failure rate due to distant metastases). Conclusions: This treatment regimen is well tolerated, effective for resectable esophageal squamous cell carcinoma with excellent major clinical response rate and survival outcomes.

6557 POSTER

Discordant ErbB2 status between primary gastric carcinomas and metastatic/recurrent carcinomas

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Background: To evaluate the ErbB2 status in primary gastric carcinoma (GC) and secondary (metastatic or recurrent) lesions, 614 cases of GC were examined.

Materials and Methods: Primary GC consisted of 325 cases resected over one year at one institute, and 3 different areas were examined per case. Paired samples of primary GC and metastasis from 124 cases of regional lymph node metastasis, 65 cases of synchronous distant metastasis and 61 cases of metachronous distant metastasis were collected. Paired samples of 39 cases of primary GC and local recurrence were also collected. IHC to detect ErbB2 protein was performed using HercepTest Kits, and ErbB2 immunostaining was scored using the 4 grade system. Dual color Vysis kits (PathVysion) were used for FISH analysis of ErbB2. Results: Similar to breast cancer, IHC and FISH results were well correlated in GC, except for IHC 2+ cases. None of the IHC 0 cases showed ErbB2 amplification, and all IHC 3+ cases showed ErbB2 amplification. About one-sixth of IHC 2+ cases showed ErbB2 amplification. FISH analysis of secondary lesions showed that positive conversion (no amplification in primary GC but amplification in secondary carcinoma) occurred in 2.1%, and negative conversion (amplification in primary GC but no amplification in secondary carcinoma) occurred in 0.7%. Heterogeneous amplification was found in 2.5% of primary GC, while 2.8% of the secondary lesion showed the different amplification result with that of primary GC. Among the cases with ErbB2 amplification, heterogeneous amplification was found in 23% (8/35) of primary GC, while different amplification result between primary and secondary lesions was found in 19.5% (8/41).

Table 1. ErbB2 IHC and FISH result in paired primary and secondary GC

IHC	Amplification (%)	
	Primary lesion	Secondary lesion
0	0/126 (0.0)	0/113 (0.0)
1+	2/83 (2.4)	1/83 (1.2)
2+	10/57 (17.5)	10/65 (15.4)
3+	23/23 (100)	28/28 (100)
Total	35/289 (12.1)	39/289 (13.5)

Conclusion: ErbB2 amplification was found in 12.1% of primary GC and 13.6% of secondary lesion. IHC and FISH results correlated very well in primary and secondary GCs, similar to breast cancer. There is heterogeneity within each GC tissue and also between primary and secondary lesions. Discordant amplification between primary and secondary carcinomas may represent heterogeneous amplification in primary GC.

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Optimal treatment for superficial esophageal cancer: surgery or endoscopic therapy?

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Background: Interest in endoscopic therapies for superficial esophageal cancer has been increasing. The aim of this study was to clarify the optimal

treatment strategy for superficial esophageal cancer, mucosal (Tis and T1a) and submucosal cancer (T1b), based on the results of surgical treatment. **Patients and Methods:** Between 1986 and 2006, 139 patients (124 males and 15 females, median age 62 years) with a superficial esophageal cancer (129 with squamous cell carcinoma, 7 with adenocarcinoma, and 3 with others) underwent radical esophagectomy with extended lymphadenectomy. We reviewed the clinicopathologic results and postoperative survival of these patients.

Results: The depth of tumors resected were Tis in 5 patients, T1a in 32, and T1b in 102. Patients with Tis had no lymph node involvement. Three of the 32 patients with T1a cancer had lymph node involvement (9.4%). All of them had T1a cancer adjacent to the layer of muscularis mucosae. Forty-two (41.2%) of the 102 T1b cancer patients had nodal involvement (N1), and 13 had M1-lym (12.7%). The operative mortality was 0.7%, and the in-hospial mortality rate was 1.4%. The 5- and 10-year overall survival rate of the Tis and T1a cancer patients were 94.2% and 61.1%, and those of the T1b patients were 72.1% and 56.1%, respectively. One patient of the Tis and T1a cancer patients died of recurrent disease (2.7%), and 14 patients with T1b cancer died of recurrent disease (13.7%). Other cooccurring primary malignancy was presented in 51 patients (36.7%), and 17 patients died of this other malignancy. Cause of death in half of patients who survived more than 5 years was other malignancies. While there was no difference in the survival in patients with superficial esophageal cancer between N0 and N1, there was a significant difference in the survival between those with other primary malignancy and those without (p = 0.008). Conclusions: Most of Tis and T1a esophageal cancer could be curatively treated by endoscopic treatment, such as EMR or ESD, while radical esophagectomy with lymph node dissection is necessary for patients with T1b cancer. Control of other primary malignancies is important to improve the survival of patients with superficial esophageal cancer.

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Phase II trial of S-1 for elderly patients (pts) over 75 years with advanced gastric cancer as first-line treatment (OGSG0404)

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Introduction: S1-based regimens are commonly used for advanced gastric cancer (AGC) in Japan. The usefulness of S-1 +CDDP in the treatment of AGC has been demonstrated by the SPIRITS phase III trials conducted in Japan. However, because over 75 years pts were excluded from this trial, the significance of S-1 based chemotherapy for elderly AGC pts is unclear. We therefore conducted a multicenter cooperative phase II study of S-1 monotherapy for AGC in elderly pts.

Methods: Between 11–2007 and 06–2008, elderly chemotherapy-naïve pts over 75 years with AGC were enrolled at 9 institutions. The primary endpoint was the response rate (RR; the Japanese Research Society for Gastric Cancer criteria or RECIST), and the secondary endpoints were safety, progression free survival (PFS) and overall survival (OS). S-1 (40–60 mg) was given twice daily. The starting dose was determined on the basis of body surface area (BSA) and the creatinine clearance value (Ccr), and courses of administration for 4 weeks followed by a 2-week rest period were repeated.

Results: 35 pts were enrolled: median age 78 (75–86), 21 M; 14 F. The RR was 14.3%, and the disease control rate was 57.1%: 0 CR; 5 PR; 15 NC; 10 PD; 5 NE. Median PFS was 95 days, and the median OS was 511 days, 1-year survival rate was 61.1%, Grade 3 or more adverse events consisted of anemia (9%), neutropenia (3.3%), anorexia (3.3%), and fatigue (6.6%) without no treatment-related death.

Conclusions: Our study indicates that S-1 is safe, well tolerated and mild active in elderly chemotherapy-naïve pts over 75 years with AGC.