Annals of Oncology 26 (Supplement 4): iv101–iv107, 2015
doi:10.1093/annonc/mdv234.11

poster discussions

PD – 012

Validation study of the 12-gene Recurrence Score (RS) in patients (pts) with stage II and III colon cancer (CC) without adjuvant chemotherapy; SUNRISE Study

M. Ikeda[1], T. Yamanaka[2], K. Yamazaki[3], K. Yamaguchi[4], K. Muro[5], T. Kusumoto[6], H. Uetake[7], T. Sato[8], T. Kato[9], T. Nishina[10], A. Kanazawa[11], E. Oki[12], C. Chao[13], T. Maddala[13], J. Krishnakumar[13], K. Akagi[14], A. Ochiai[15], Y. Ohashi[16], A. Ohtsu[17], T. Yoshino[18]

[1]*National Hospital Organization, Osaka National Hospital, Osaka, Japan*
[2]*Yokohama City University School of Medicine, Yokohama, Japan*
[3]*Shizuoka Cancer Center, Sunto-gun, Japan*
[4]*Saitama Cancer Center, Kita-adachi-gun, Japan*
[5]*Aichi Cancer Center Hospital, Nagoya, Japan*
[6]*Clinical Research Center Cancer Research, Division and Department of Gastroenterological Surgery, National Kyushu Medical Center, Fukuoka, Japan*
[7]*Tokyo Medical and Dental University, Tokyo, Japan*
[8]*Kitasato University School of Medicine, Sagamihara, Japan*
[9]*Kansai Rosai Hospital, Dept of Surgery, Amagasaki, Japan*
[10]*National Shikoku Cancer Center, Matsuyama, Japan*
[11]*The Tazuke Kofukai Medical Research Institute Kitano Hospital, Osaka, Japan*
[12]*Department of Surgery and Science, Graduate School of Medical Sciences, Kyushu University, Fukuoka, Japan*
[13]*Genomic Health Inc., Redwood City, California*
[14]*Saitama Cancer Center, Kitaadachi-Gun, Japan*
[15]*National Cancer Center, Tokyo, Japan*
[16]*Chuo University, Tokyo, Japan*
[17]*National Cancer Center, Kashiwashi, Japan*
[18]*National Cancer Center Hospital East, Kashiwa-city, Japan*

Introduction: The 12-gene RS is validated for stage II surgery alone and stage II & III chemotherapy-treated CC pts as a predictor of recurrence. We conducted a prospective analysis to perform a confirmatory study of RS to predict recurrence in stage II & III CC pts treated with surgery alone. This is the first validation study of RS in Asian pts and in stage III CC pts treated with surgery alone.

Methods: We identified consecutive stage II & III CC pts with complete resection without adjuvant chemotherapy at 12 hospitals from 2000-05. A cohort sampling design was used with a recurrence and non-recurrence sampling of 1:2. Gene expression was analyzed by RT-PCR using fixed primary tumor tissue. Mismatch repair (MMR) status was assessed by IHC for MLH1 and MSH2. Primary aims: prognostic value of continuous RS alone and in presence of conventional clinical/pathologic variables. Weighted Cox regression models were used.

Results: 630 pts (210 recurrences) were sampled from 1,487 eligible pts. Of 624 with available samples, RT-PCR succeeded in 597 (96%): stage II/III, 41/59%; male, 53%; age > 70 years, 33%; MMR-deficient, 5%; nodes examined < 12, 20%. Continuous RS was associated with recurrence-free interval after adjustment for stage (HR/25 units, 2.05; 95%CI, 1.47–2.86; $p < 0.001$) and in a pre-specified analysis with stage, T-stage, and MMR (HR, 1.92; 95%CI, 1.35–2.72; $p < 0.001$). 5-year recurrence risk estimates from the primary analysis model are shown below. Continuous RS was associated (all $p < 0.001$) with recurrence-free, disease-free, and overall survival: (HR/25 units) 1.77, 1.90 and 2.02, respectively.

Conclusion: RS predicts recurrence risk in stage II and III CC pts with surgery alone, providing information beyond conventional factors. Results reconfirm RS as a prognostic marker in resectable colon cancer and establish clinical validity of RS in Asian pts. Study ID: UMIN000009395.

Table: PD-012

RS Group	Stage II (N=247)		Stage IIIA/B (N=278)		Stage IIIC (N=72)	
	Pts %	5yr Risk % (95% CI)	Pts %	5yr Risk % (95% CI)	Pts %	5yr Risk % (95% CI)
Low (0-29)	60	9 (7, 12)	46	20 (14, 25)	45	38 (25, 50)
Intermediate (30-40)	26	14 (11, 17)	31	29 (23, 35)	29	51 (38, 64)
High (41-100)	14	19 (13, 24)	23	38 (29, 47)	26	62 (48, 77)

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