**Genitourinary Tumours, Non-Prostate**

**B14PD**

**Genomic Renal Score for Assessing Risk of Recurrence in Renal Cancer: Subgroup Analyses from the Validation Study**


1Medical Oncology, Institut de Cancérologie Gustave Roussy, Villejuif, FRANCE
2Department of Biostatistics and Epidemiology, Institut Gustave Roussy, Villejuif, FRANCE
3Biostatistics, Genomic Health, Inc., Redwood City, CA, USA
4Medical Affairs, Genomic Health, Geneva, SWITZERLAND
5Service d’Anatomie et de Cytologie Pathologiques, Hôpital Necker-Enfants Malades, Paris, FRANCE
6Pathology, Hôpital Foch, Suresnes, FRANCE
7Urology, Hôpital Foch, Suresnes, FRANCE
8Urology Dept., Hôpital Européen Georges Pompidou / Necker, Paris, FRANCE
9Pathology, Genomic Health, Inc., Redwood City, CA, USA

**Aim:** New clinical tools are needed to improve risk assessment in ccRCC. The 16-gene (11 cancer related, 5 reference) Recurrence Score (RS) was developed in a cohort of 931 stage I-III ccRCC patients. The present analysis assesses the performance of the score in clinically relevant subgroups.

**Methods:** The genes, algorithm, endpoints, methods, and analysis plan were pre-specified prior to merging clinical and molecular data. RT-PCR in fixed paraffin-embedded primary ccRCC tissue was performed without knowledge of clinical data. Recurrence-free interval was analyzed using Cox regression stratified by stage with data censored at 5 years, and Kaplan-Meier methods.

**Results:** RS was successfully generated in 626/645 pts (97%): 398 stage I, 54 stage II, 174 stage III. Most (71%) patients were male, 29% were 70 years or older, 36% with partial nephrectomy, 46% with tumors ≤4 cm, 65% with Fuhrman grade 3-4, and 27% with invasion. Median follow-up was 5.5 yrs. The continuous RS predicted recurrence risk (HR per 25 point increase in RS (HR/25) = 3.9, 95% CI 2.6-5.8, p < 0.001). RS continued to predict recurrence after adjustment for tumor size and Fuhrman grade (p < 0.001). RS identified 39% of stage I pts with an average 5-yr recurrence risk of 2% (95% CI 0-7%) and 15% of pts with a 23% (95% CI 13-39%) risk. In stages II-III, RS identified 19% of pts with a 2% (95% CI 0-16%) and 44% of pts with a 39% (95% CI 29-50%) recurrence risk. The performance of RS was similar across the age groups (<60, 60-70 or ≥70), gender, partial or radical nephrectomy, tumor size (<4, 4-7 or ≥7 cm), Fuhrman grade, and presence/absence of invasion (all interaction p > 0.29).

**Conclusions:** The 16-gene RS is validated as a predictor of clinical outcome in pts with stage I-III ccRCC and provides significant information beyond conventional pathologic measures. The performance of the score was similar across a wide range of clinically relevant covariates indicating potential broad utility.

**Disclosure:** B. Escudier: has an interest in relation with Genomic Health for sponsored research; M. Lopatin: is an employee of Genomic Health; C. Svedman: I am an employee of Genomic Health; T. Tsiafas: Employee of Genomic Health; T. Lebret: Part of research grant from Genomic Health to perform the study (with the IGR institution, not personally); A. Mejean: Part of research grant from Genomic Health to perform the study (with the IGR institution, not personally). All other authors have declared no conflicts of interest.