Long-term follow-up of melanoma patient risk stratified by a clinicopathologic and gene expression profile (CP-GEP) model: a multi-center United States cohort study

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Intro: The CP-GEP model (Merlin Assay) is able to identify cutaneous melanoma (CM) patients with a low risk of nodal metastasis undergoing sentinel lymph node biopsy (SLNB). Long-term follow-up (LTFU) for CM patients stratified by CP-GEP has been previously reported in multiple independent European cohorts to accurately stratify patients by their risk of recurrence. Here, we report the LTFU of patients classified as low and high Risk by CP-GEP in a combined US-based multi-center cohort.

Methods: This is a retrospective study of CM patients undergoing SLNB as part of usual care at six centers. Using primary melanoma tissue, the CP-GEP model stratified patients as high or low risk of recurrence. The primary aim was to assess the 5-year recurrence-free survival (RFS), distant metastasis-free survival (DMSF), and melanoma specific-free survival (MSS) of CP-GEP high risk vs. low risk patients. Survival was assessed by Kaplan–Meier curves, stratified on CP-GEP low risk vs. high risk.

Results: A total of 594 CM patients (317 Stage I, 164 Stage II and 109 Stage III) were included. Median follow-up was 52 months. CP-GEP classified 198 (33.3%) patients as low risk and 396 (66.7%) as high risk. CP-GEP low risk patients had 5-yrs RFS, DMFS and MSS of 92.4%, 96.9%, and 98.2% respectively. CP-GEP high risk patients had 5-yrs RFS, DMFS and MSS of 72.2%, 82.9%, and 88%, respectively. CP-GEP identified 16 patients (14.9%) of the 107 patients with a positive SLNB and LTFU data as low risk and 91 patients (85.0%) as high risk. The 5-yrs RFS rate for low risk and high risk Stage III patients were 91.7% and 44.6%, respectively. Furthermore, CP-GEP is able to classify SLNB negative patients (476) into low risk (37.8%) and high risk (62.2%) groups with 5-yrs RFS of 92.5% and 81.1%, respectively. CP-GEP risk stratification was independent from clinical staging for RFS and DMFS by multivariable analyses.

Conclusion: In this multi-center US-based retrospective study, the CP-GEP model was able to stratify patients by their risk of recurrence. CP-GEP low risk patients showed a highly favorable outcome versus CP-GEP high risk patients, who have a nearly five times higher risk of recurrence. Therefore, this molecular prognostic test can provide valuable information in personalized treatment and surveillance recommendations.