Primary cutaneous melanoma patients stratified by the Merlin assay (CP-GEP): risk of nodal metastasis and long-term survival outcome in a U.S. cohort

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Introduction
Sentinel lymph node biopsy (SLNB) is still the gold standard for nodal assessment, even though 80-85% of patients return negative for metastases. Also, most patients who relapse or die from melanoma are initially diagnosed as early-stage primary cutaneous melanoma (CM) patients. Here, we report the ability of CP-GEP to risk stratify patients for nodal metastasis and evaluate their long-term survival outcome.

Methods
Primary CM patients undergoing SLNB as part of usual care between 2007 and 2017 – University Hospitals Cleveland Medical Center. The Merlin assay that uses the CP-GEP model combines Breslow thickness and patients' age at diagnosis with the expression of eight genes from the primary CM tissue – binary output: High Risk or Low Risk.

Results
176 patients were included for analysis with a 12.5% SLNB positivity rate. CP-GEP identified 66 patients as Low Risk – achieving an SLNB reduction rate of 37.5% at an NPV of 94%. For CP-GEP Low Risk patients, the five-years RFS, DMFS and MSS rates were 93.6%, 96.6% and 98% respectively. CP-GEP stratified 110 patients as High Risk (62.5%), having a higher SLNB positivity rate of 16.4% and capturing 21 out of 25 recurrences (84%). CP-GEP High Risk patients had five-years RFS, DMFS and MSS rates of 79.4%, 83.1% and 91.4% respectively.

Conclusion
CP-GEP improves risk stratification for nodal metastasis and disease recurrence, thereby supporting clinical decision making and optimizing healthcare resources. Specifically, recurrence events may be more effectively captured by CP-GEP as compared to current standard of care.