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The use of a clinicopathologic and gene expression model (Merlin Assay) to risk stratify cutaneous melanoma patients in clinical practice: A pilot study

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Abstract

The management of primary cutaneous melanoma (PCM) faces new challenges during the COVID-19 pandemic. National guidelines aiming to optimize medical resource usage have led to delays in elective surgical procedures such as the sentinel lymph node (SLN) biopsy, which causes stress and anxiety in patients. We recently reported on the development of a model which combines clinicopathologic variables and a gene expression profile (CP-GEP) to identify patients who may safely forgo SLN biopsy due to their low risk of nodal metastasis. The CP-GEP model combines Breslow thickness and patient age with the expression of eight genes in diagnostic biopsy tissue. Here, we report on the feasibility of running the CP-GEP model – which we refer to as the Merlin Assay – in an independent Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory accredited by the College of American Pathologists (CAP). 50 micron recuts of T1 to T3 diagnostic biopsy tissue were requested from 50 PCM patients who were seen in the fall of 2019. Turnaround time from sample receipt at the laboratory to test reporting was within five working days. 3/50 samples (6%) did not contain sufficient RNA for molecular analysis; 47/50 samples (94%) were tested successfully. Of the 47 patients with Merlin test results, 34/47 (72.3%) underwent SLN biopsy. Of the 34 patients with known SLN status, 13/34 (38.2%) were T1, 13/34 (38.2%) were T2 and 8/34 (23.6%) were T3 patients. 1 of 13 (7.7%) T1, 4 of 13 (30.1%) T2 and 1 of 8 (12.5%) T3 patients were SLN positive. All SLN positive patients were correctly classified as high risk by the Merlin Assay. We conclude that the implementation of the Merlin Assay in clinical practice is feasible as a send-out test and may be used for deselecting low risk PCM patients for SLN biopsy during the ongoing COVID-19 pandemic.

