**Validation of a model combining clinicopathologic risk factors and a gene expression profile to identify primary melanoma patients who can safely forgo sentinel lymph node biopsy**

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## Introduction

The sentinel lymph node biopsy (SLNB) procedure has gained importance now that primary cutaneous melanoma (PCM) patients with a positive sentinel lymph node are considered candidates for adjuvant systemic therapy. However, SLNB is an invasive procedure, and approximately 80% of patients lack nodal metastasis. Many SLNB negative patients are exposed to invasive surgery but enjoy no discernible therapeutic benefit. Therefore, there is a need for a non-invasive test to accurately identify PCM patients who may forgo the SLNB procedure due to low risk of nodal metastasis. Previously, a clinicopathological and gene expression profile model (CP-GEP model) has been developed to identify PCM patients who can safely forgo SLNB. Moreover, a validation of the CP-GEP model in a European cohort has been reported. Here, we describe the validation of the CP-GEP model in a US cohort.

## Material and Methods

We identified 162 patients who underwent SLNB at the Mayo Clinic or West Virginia University within 90 days of PCM diagnosis. Formalin-fixed paraffin-embedded diagnostic PCM biopsy tissue from all patients were analyzed using the CP-GEP model. The CP-GEP model combines Breslow thickness and patient age with the expression of eight genes to classify patients as CP-GEP High Risk or CP-GEP Low Risk for nodal metastasis.

## Results

At diagnosis, the median patient age was 56 years (IQR, 41 to 69 years) and the median Breslow thickness was 1.9 mm (IQR, 0.9 to 2.1 mm). 62 of 162 patients (38.2%) presented with T1 melanoma while 58 of 162 patients (35.8%) presented with T2 melanoma. Overall, 19.8% of patients had a positive sentinel lymph node. In patients with stage T1 to T2 melanoma, the CP-GEP model achieved an SLNB reduction rate of 44.2% at a negative predictive value of 98.1%.

## Discussion

The CP-GEP model is a non-invasive and validated tool that is able to predict nodal metastasis in an US cohort that can be used to identify PCM patients who can safely forego SLNB. The CP-

GEP model is a promising tool for patient care, preventing unnecessary surgery in a large group of patients.