

Using the clinicopathologic and gene expression (CP-GEP) model to predict sentinel node status in patients with primary melanoma: A prospective cohort study during the COVID-19 pandemic

Background In light of the current COVID-19 pandemic, avoiding unnecessary interventions and keeping patients out of the hospital becomes increasingly important. The CP-GEP model (Merlin Assay) has been developed and validated to identify patients with primary melanoma (pT1b-pT3) that can safely forgo the sentinel lymph node biopsy (SLNB) due to their low risk for nodal metastasis. During the current pandemic, a prospective trial was conducted to assess the accuracy of using the CP-GEP model to identify patients that have a low risk for nodal metastasis and therefore could forgo the SLNB.

Methods During the COVID-19 pandemic, from July 2020 to February 2021, all newly diagnosed cutaneous melanoma (pT1b-pT3) patients elected to undergo SLNB at the Erasmus MC Cancer Institute were included. Formalin-fixed paraffin-embedded tissue (FFPE) from the primary melanoma tissue was analyzed using CP-GEP. The CP-GEP model combines patient age and Breslow thickness with the expression of eight target genes. Patients were classified as CP-GEP High Risk or CP-GEP Low Risk for having nodal metastasis.

Results From all eligible patients (n=19), consent was obtained and FFPEs could be retrieved for further analysis. Patients had a median age of 53 years (interquartile range [IQR] 37 - 67) and median Breslow thickness was 2.0 mm (IQR 1,4-2.8). In two out of 19 patients, the surgeon determined preoperatively not to proceed with SLNB (as a result of locally advanced melanoma). Of the remaining 17 patients, five had a positive SLNB (e.g. nodal metastasis, 29.4%). All SLNB positive patients (n=5) were identified by CP-GEP as being High Risk for nodal metastasis. Of all SLNB negative patients (n=12), CP-GEP identified five patients (41.7%) as being Low Risk for nodal metastasis. Overall, the potential SLNB reduction rate in this cohort was 29.4% while having a negative predictive value of 100%.

Conclusions The CP-GEP (Merlin Assay) model is a non-invasive and validated tool that can be used to identify patients with a primary cutaneous melanoma (pT1b-pT3) who are at low risk for nodal metastasis and therefore could safely forgo SLNB. Also, during the current COVID-19 pandemic, the CP-GEP model could be a promising tool to deselect patients for elective surgery (Figure).

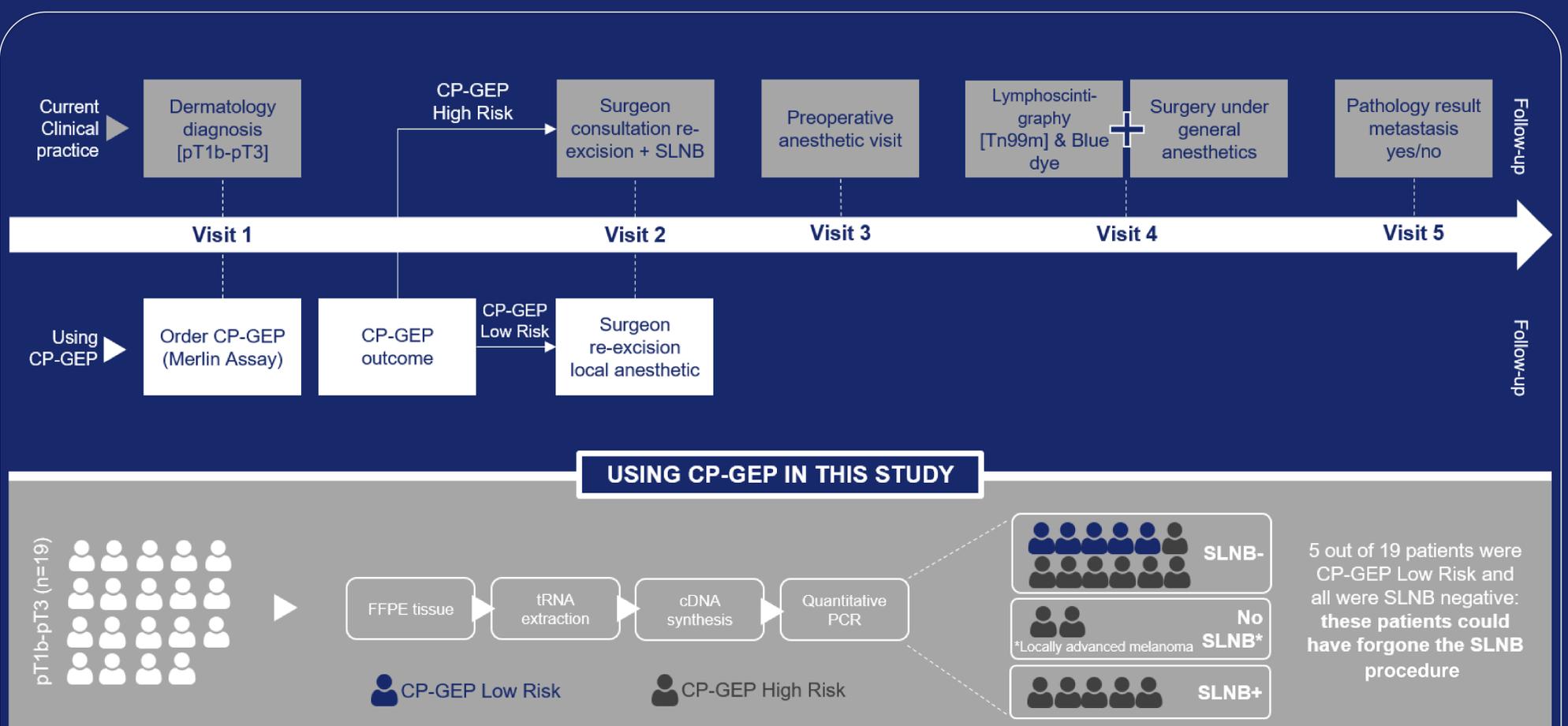


Figure. Patient pathway: SLNB is a more complex and time-consuming procedure than is often appreciated because it requires the extensive use of hospital infrastructure and medical specialists. CP-GEP (Merlin Assay) may shorten this path and may deselect patients that can safely forgo this SLNB procedure.