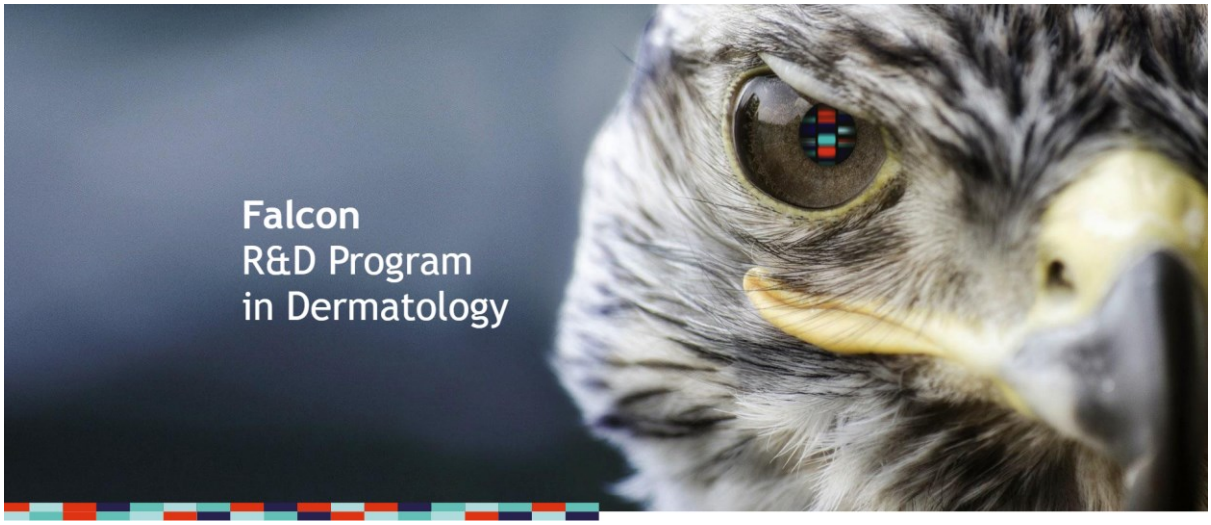

Merlin

Use of CP-GEP to identify primary cutaneous melanoma patients with a low risk for SN metastasis in a prospective multicenter Dutch study during COVID-19

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Abstract

Introduction

Approximately 70%-85% of patients who undergo sentinel lymph node biopsy (SLNB) show no nodal metastasis in the sentinel node (SN). CP-GEP, a model that combines clinicopathologic and gene expression variables from the primary tumor was developed and validated to identify patients that may forgo the SLNB surgery due to their low risk for SN-metastasis. This study was initiated during the first wave of COVID-19 pandemic to allow for surgical triage on SLNB and evaluate the implementation of the CP-GEP model in clinical practice.

Methods

This study was conducted in four designated melanoma centers in the Netherlands. Patients (age>18y) with newly diagnosed melanoma of the skin, eligible to undergo SLNB were screened for study inclusion. Main exclusion criteria was prior history of primary melanoma (>T1b) in the past 5 years. After enrollment, tissue sections of the primary melanoma were evaluated to determine Breslow thickness at primary diagnosis. FFPE tumor tissue was dispatched for molecular analysis of eight target genes known to play a role in cancer development. In combination with age, Breslow thickness, and GEP outcome, risk of having SN-metastasis was calculated. Results were binary presented as 'CP-GEP Low Risk' and 'CP-GEP High Risk'. SLNB status was used as gold standard for comparison.

Results

A total of 177 patients were analyzed using the CP-GEP model. Median age was 64 years (IQR 52-73) Median Breslow thickness was 1.4mm (IQR 1.0-2.4). Of all patients 28.2% was diagnosed with T1, 40.7% with T2 and 20.9% with T3 melanoma. Corresponding positivity rate was 7%, 14% and 29% respectively. A total of 24 out of 177 patients had a positive SLNB (13.6%). Median turn-around time from inclusion to CP-GEP result was 15 days. Overall 37.1.% of patients had a CP-GEP Low Risk outcome. The CP-GEP model had a NPV of 94.6%.

Conclusion

This is the first prospective multicenter implementation study for the CP-GEP model. Results are in line with previous validation studies. The CP-GEP model could accurately identify patients at low risk for SN metastasis. Implementation in clinical practice is feasible based on current turn-around time. In the future, using the CP-GEP model to deselect patients for SLNB may allow for a reduction of surgery in patients with melanoma.