The 31-gene expression profile test stratifies patient risk of recurrence and metastasis in patients with a negative sentinel lymph node biopsy

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Background

A positive sentinel lymph node biopsy (SLNB) is a prognostic indicator of poor outcomes in cutaneous melanoma (CM); however, most SLNBs are negative[1].

Despite a good overall prognosis within patients with negative SLNBs, 10-29% will experience recurrence or metastasis, and melanoma specific survival rates span from 82-99%[2-4]. These patients are currently eligible for adjuvant therapy or consideration in adjuvant trials, underpinning a need for use of prognostic tools beyond clinicopathologic features.

The 31-gene expression profile (31-GEP) is validated to predict recurrence or metastasis risk, and patients are classified as low risk (Class 1A), intermediate risk (Class 1B/2A), or high risk (Class 2B)[5-10]. Previous studies have demonstrated the ability of the 31-GEP to further stratify patient risk in the SLNB negative patient population[9, 13].

Objective

Confirm the ability of the 31-GEP test to stratify patient risk of recurrence, metastasis, and death in patients with CM and a negative SLN.

Methods

Patients enrolled in previous studies and with a pathologically negative SLN (n=917) were included in the analyses. Recurrence-free survival (RFS), distant metastasis-free survival (DMFS), and melanoma-specific survival (MSS) were assessed using Kaplan-Meier analysis and the log-rank test. Multivariable analyses were conducted using Cox regression. Tumors were staged according to AJCC version 8 guidelines.

Conclusions

- The 31-GEP test stratified patients with a negative SLNB into groups with high and low risk of recurrence and metastasis.
- A high-risk (Class 2B) 31-GEP test result was an independent and significant predictor of poor outcomes.
- Because more than 80% of CM patients have a negative SLN at diagnosis[12], utilizing the 31-GEP test in this patient population can identify patients at the highest risk of poor outcomes who should receive more intensive care.

References

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Acknowledgments & Disclosures

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Results

Figure 1. The 31-GEP stratifies risk of recurrence in patients with SLN negative tumors

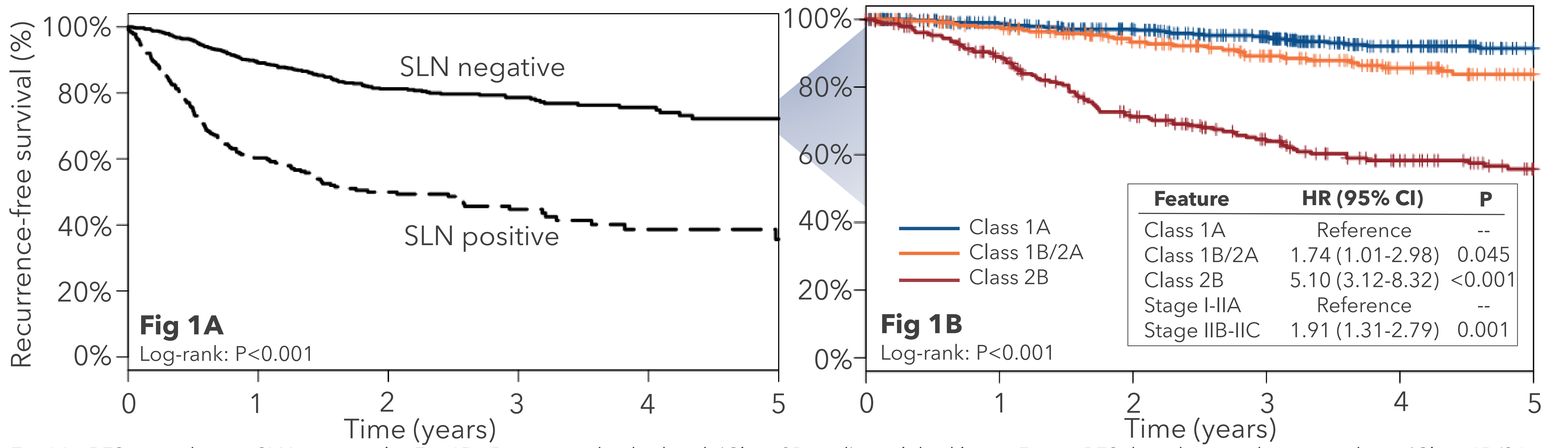

Fig 1A: RFS according to SLN status only. Fig 1B: Patients with a high-risk (Class 2B; red) result had lower 5-year RFS than those with intermediate- (Class 1B/2A; orange) and low-risk (Class 1A; blue) test results (55.8% vs. 83.8% vs. 91.5%). Box inset: Using NCCN threshold for 'low risk' (Stage I-IIA) vs. 'high risk', multivariable analyses showed Class 1B/2A and Class 2B results and a stage IIB-IIC diagnosis were significant predictors of RFS.

Figure 2. The 31-GEP stratifies risk of distant metastasis in patients with SLN negative tumors

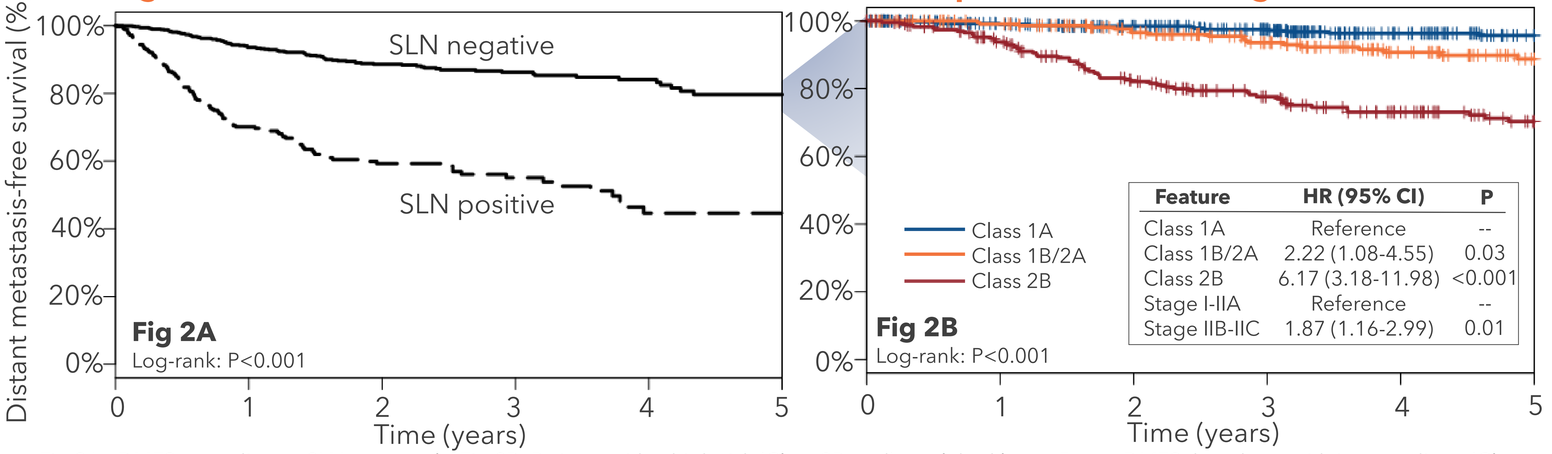

Fig 2A: DMFS according to SLN status only. Fig 2B: Patients with a high-risk (Class 2B; red) result had lower 5-year DMFS than those with intermediate- (Class 1B/2A; orange) and low-risk (Class 1A; blue) test results (70.3% vs. 88.8% vs. 95.7%). Box inset: Using NCCN threshold for 'low risk' (Stage I-IIA) vs. 'high risk', multivariable analyses showed Class 1B/2A and Class 2B results and a stage IIB-IIC diagnosis were significant predictors of DMFS.

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