The i31-gene expression profile test for cutaneous melanoma identifies patients with head and neck tumors who could forego sentinel lymph node biopsy

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Background

- Up to 25% of patients with cutaneous melanoma (CM) have tumors on the head or neck (HN).[1] These patients have a worse prognosis than those with tumors at other locations.[2]
- HN tumors present additional complexities for sentinel lymph node biopsy (SLNB) due to complex lymphatic drainage systems, technical challenges related to the location, and complex surgical techniques required around cranial nerves and vasculature.[3]
- An algorithm integrating the 31-gene expression profile (31-GEP) molecular risk stratification test with clinical and pathological features (i31-GEP) provides a precise risk prediction for SLNB positivity, which can help patients and clinicians make risk-aligned decisions about undergoing SLNB among a high-risk population.[4] Separately, the i31-GEP has been validated to predict risk-of-recurrence.

Methods

- Patients from a previously published multicenter cohort study[4] with pre-SLNB stage I tumors (T1-T2a) located in the HN region and **who had undergone SLNB** were included in the analysis (n=159). Patients with <5% and ≥5% risk predicted by the i31-GEP were considered low or high-risk, respectively. A low-risk prediction was considered a negative test result, and a high-risk prediction was considered a positive test result for i31-GEP accuracy calculations.

Results

Table 1. The i31-GEP for SLNB has high sensitivity to identify patients likely to have SLN metastasis

i31-GEP for SLNB	Percent
Sensitivity	100%
Specificity	39.1%
Negative predictive value	100%

Sensitivity: true positive/(true positive + false negative); specificity: true negative/(true negative + false positive); negative predictive value: true negative/(true negative + false negative)

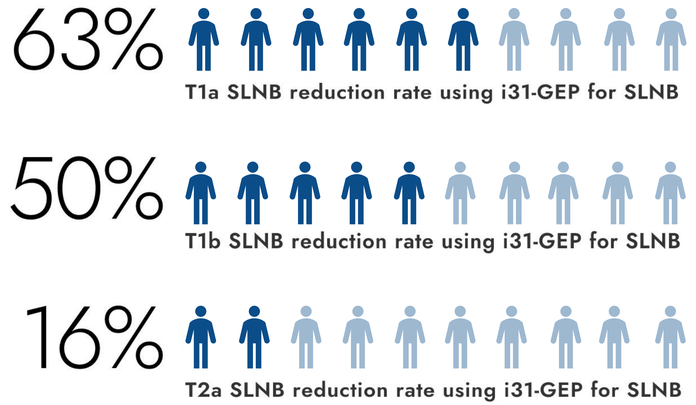
References

1. Zito PM, et al: Melanoma Of The Head And Neck [Internet], in StatPearls. Treasure Island (FL), 2020. 2. Shashanka R, et al: Head and Neck Melanoma. ISRN Surg 2012:948302, 2012. 3. Giudice G, et al: Sentinel lymph node biopsy in head and neck melanoma. G Chir 35:149–55, 2014. 4. Whitman ED, et al: Integrating 31-Gene Expression Profiling With Clinicopathologic Features to Optimize Cutaneous Melanoma Sentinel Lymph Node Metastasis Prediction. JCO Precision Oncology 1466–1479, 2021

Clinical Impact

- Using the i31-GEP to identify patients for SLNB can:
  - Personalize melanoma clinical management plans
  - Reduce the number of unnecessary SLNBs
  - Reduce SLNB-associated complications
  - Reduce healthcare costs

Figure 1. SLNB reduction rates in each T-category when using the i31-GEP for SLNB to guide decisions



No patient (0/59) with an i31-GEP predicted SLN positivity risk of <5% had a positive SLNB.

Acknowledgments & Disclosures

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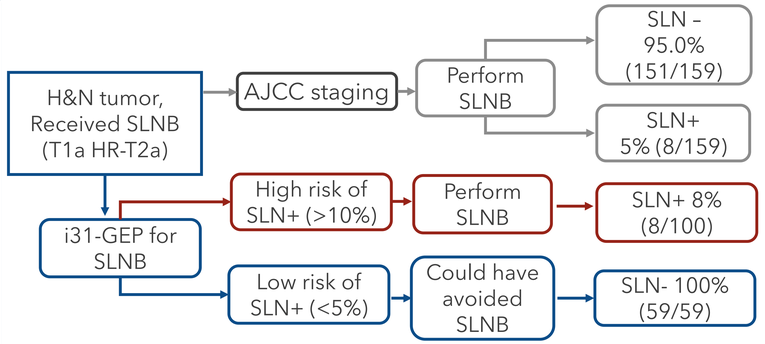
Figure 2. The i31-GEP for SLNB can reduce SLNB rate while increasing the positivity rate



Using the i31-GEP for SLNB to guide SLNB decisions for T1-T2a tumors on the H&N achieved a 37% (59/159) SLNB reduction rate and increased the positivity rate from 5% (8/159 using AJCC staging) to 8% (8/100 using i31-GEP risk prediction).

Conclusions

- Without sacrificing sensitivity, the i31-GEP for SLNB could reduce the number of unnecessary SLNBs by 37% overall and 63% for T1a tumors and 50% for T1b tumors, specifically.
- No patients with an i31-GEP predicted SLN positivity risk of <5% had a positive SLNB.
- The i31-GEP for SLNB can help guide risk-aligned patient care decisions in patients considering SLNB.

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