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 (31-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 31-GEP has been validated to predict risk-of-recurrence.

Methods

› Patients from a previously published multicenter cohort study4 with pre-SLNB stage I tumors (T1a-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 31-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 31-GEP accuracy calculations.

Results

Table 1. The 31-GEP for SLNB has high sensitivity to identify patients likely to have SLN metastasis

<table>
<thead>
<tr>
<th>31-GEP for SLNB</th>
<th>Percent</th>
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</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>100%</td>
</tr>
<tr>
<td>Specificity</td>
<td>39.1%</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>100%</td>
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</tbody>
</table>

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

References


Clinical Impact

› Using the 31-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 2. The 31-GEP for SLNB can reduce SLNB rate while increasing the positivity rate

Without sacrificing sensitivity, the 31-GEP for SLNB could reduce the number of unnecessary SLNBs by 37% overall and 63% for T1a tumors and 50% for T1b tumors, specifically.

The 31-GEP for SLNB can help guide risk-aligned patient care decisions in patients considering SLNB.

Conclusions

Acknowledgments & Disclosures

N/A and MM have no conflicts of interest. BM is an employee and shareholder/option holder of Castle Biosciences, Inc.

Figure 1.  SLNB reduction rates in each T-category when using the 31-GEP for SLNB to guide decisions

63%

T1a SLNB reduction rate using 31-GEP for SLNB

50%

T1b SLNB reduction rate using 31-GEP for SLNB

16%

T2a SLNB reduction rate using 31-GEP for SLNB

No patient (0/59) with an 31-GEP predicted SLN positivity risk of <5% had a positive SLNB.