A clinical impact study of dermatologists' use of the 23- or 35-gene expression profile tests to guide surgical excision and enhance management plan confidence

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Background

The 23-gene expression profile (GEP) and 35-GEP tests are clinically available, objective ancillary diagnostic tools that facilitate diagnosis of melanocytic lesions with ambiguous histopathology. The tests use proprietary algorithms to produce results of suggestive of benign neoplasm (sBN), uncertain (cannot rule out malignancy), or suggestive of malignant neoplasm with high accuracy.1-4 Communication between the diagnosing dermatopathologist/pathologist and the treating clinician is key to establishing appropriate patient management.5,6 There are circumstances when a dermatologist may find additional diagnostic information helpful in determining excision and follow-up actions.7-10

Here we present dermatologist management plans and confidence utilizing diagnostic GEP results in uncertain clinical and diagnostic scenarios.

Methods

Clinicians were invited for study participation based on prior use of diagnostic GEP testing (minimum 3 encounters with GEP results). Thirty-two board certified dermatologists participated in the Review Board (IRB)-approved study. Clinicians were asked three questions per scenario: 1) How would you treat the patient? No further treatment necessary, no further treatment necessary if lesion appears completely excised, Excise <5 mm margins (narrow but complete), Excise ≥5 mm margins (but <1 cm). Wide local excision (Excise ≥1 cm). 2) Which follow-up schedule would you recommend? Every 12, 6, 3, or every month? 3) How confident are you in this management plan? (1) (not confident), (2) (slightly confident), (3) (somewhat confident), (4) (confident), (5) (very confident). Clinical and diagnostic information for six uncertain patient scenarios was provided to the clinicians (Table 1). Diagnostic information was taken from real-world pathology reports of melanocytic lesions and divided in mock form including the diagnosis and microscopic description. Clinical information was based on common clinical situations that may alter patient treatment. GEP test results were either not provided (benign), benign, or malignant for each patient scenario.

Results

Table 1. Ambiguous lesion scenarios from real-world pathology reports

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Clinical Impression</th>
<th>Diagnosis</th>
<th>GEP Result</th>
<th>Excision</th>
<th>Follow-up Confidence</th>
<th>% Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Personal history of melanoma</td>
<td>Benign</td>
<td>Malignant GEP</td>
<td>No Excision</td>
<td>Baseline</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Personal history of melanoma</td>
<td>Benign</td>
<td>Malignant GEP</td>
<td>No Excision</td>
<td>Baseline</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Personal history of melanoma</td>
<td>Benign</td>
<td>Malignant GEP</td>
<td>No Excision</td>
<td>Baseline</td>
<td></td>
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<tr>
<td>4</td>
<td>Personal history of melanoma</td>
<td>Benign</td>
<td>Malignant GEP</td>
<td>No Excision</td>
<td>Baseline</td>
<td></td>
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<tr>
<td>5</td>
<td>Personal history of melanoma</td>
<td>Benign</td>
<td>Malignant GEP</td>
<td>No Excision</td>
<td>Baseline</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Personal history of melanoma</td>
<td>Benign</td>
<td>Malignant GEP</td>
<td>No Excision</td>
<td>Baseline</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions

GEP results can aid dermatologists in decision making to achieve appropriate management plans.

Management changes, including surgical excisions and follow-up frequency, were aligned with GEP results for these uncertain clinical scenarios.

Scenario-specific details demonstrate that a personalized approach can be achieved with GEP.

References


Figure 1. Overall clinical impact across all ambiguous scenarios

Figure 3. GEP results after follow-up frequency

Figure 2. GEP results impact surgical excision planning, including margin decisions

Clinical impact: The vast majority of excision decisions and follow-up changes were aligned with GEP results across the uncertain scenarios. In addition, there was an increase in overall management plan confidence with a GEP result.

Table 2. GEP Impact

- GEP Result
  - Benign GEP
  - Malignant GEP
  - Baseline

Table 3. GEP Impact

- Excision
  - No Excision
  - Excision

Table 4. GEP Impact

- Follow-up Frequency
  - None
  - Annual
  - Biannual

Table 5. GEP Impact

- % Respondents
  - Malignant GEP
  - Benign GEP
  - Baseline

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