Study of 400 dermatologic clinicians corroborates the clinical impact of the prognostic 40-gene expression profile (40-GEP) test in patients with high-risk cutaneous cell carcinoma (SCC)

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Synopsis

- Cutaneous squamous cell carcinoma (SCC) is the second most common skin cancer in the United States and its incidence is increasing at an alarming rate.
- Treatment planning for SCC patients is complicated by a lack of standardized and accurate risk assessment methods. Treatment guidelines have a range of options for patients broadly categorized as at high risk for metastasis.
- The 40-GEP test was developed and validated to augment traditional assessment approaches to improve risk-directed patient management for high-risk SCC patients with one or more risk factors.
- The 40-GEP test has shown significant stratification for regional, nodal, or distant metastasis independent of clinicopathologic factors and staging systems using these factors.

40-GEP

- Quantifies expression of 40 genes from primary tumor FFPE using RT-PCR
- Applies a validated neural network algorithm
- Accurately classifies patients as low, moderate or high biological risk for metastasis

Objective

- To confirm the clinical impact of the 40-GEP test result in a large group of dermatologic clinicians who are treating high-risk SCC patients.

Methods

- Clinicians attending the 2021 Fall Clinical Dermatology Conference were offered an anonymous online survey (n=400 respondents) with questions about their familiarity with the 40-GEP test and the impact a Class 1 test result would have on their management of invasive SCC.
- De-identified data were collected and analyzed for demographic information. Interactions between different variables were visualized using heatmaps.

Results

- Most clinicians were dermatologists (~80%), with the next most common specialties being Mohs surgeons (~10%) and nurse practitioners or physician assistants (9%).
- A majority of clinicians (59.5%) manage more than 100 SCC cases/year.
- The increasing size of lesions would lead to an increase in recommendations for 40-GEP testing in a risk-aligned manner; except for a lesion located on the lip, where, regardless of size, 32% of clinicians would recommend testing with the 40-GEP with an additional 40.8% recommending if the lesion was ≥1cm.
- Approximately 80% (range 74.2%-82.7%) of clinicians would recommend 40-GEP testing for lesions occurring at high-risk locations when also taking size into consideration (Figure 2B).
- Of the clinicians who recommended radiologic nodal imaging, sentinel lymph node biopsy, or adjuvant radiation therapy for their patients, 64%, 68%, and 66%, respectively, would consider forgoing these treatments for at least some patients receiving a Class 1 result, due to their low biological risk of metastasis (Figure 3A). Intention to further reduce recommendations for radiologic nodal imaging or sentinel lymph node biopsy were seen in those clinicians who had already adopted the 40-GEP test in their clinical practice (Figure 3B).

Conclusions

- This study confirms clinicians’ intentions to de-escalate treatment plan decisions with the addition of a low risk Class 1 test result, consistent with the reduced biologically determined risk of metastasis.
- In previous findings, 40-GEP Class 1, 2A, or 2B test results led to risk-aligned decreases or increases in clinician directed treatment plans. The results of this clinical utility study further supported that Class 1 results lead clinicians to forgo interventions in a risk-appropriate manner.
- For SCC patients classified as high risk per traditional clinical risk factors, the use of the 40-GEP as an adjunct to current methods to determine cases of low biological metastatic risk can support the avoidance of unnecessary invasive interventions, therefore improving upon the appropriate allocation of resources and health outcomes.

Disclosures

- This study was sponsored by Castle Biosciences, Inc.
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