Risk factor count per sample

Appropriate utilization of the prognostic 40-gene expression profile (40-GEP) test for cutaneous squamous cell carcinoma (cSCC) demonstrated by clinical reports and physician evaluation of real-world cases

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Six real-world cases, representing the spectrum of those submitted for clinical testing, were presented toTo evaluate demographics of clinicians and usage of the 40-GEP test from one year of clinical orders. To evaluate appropriate utilization of the 40-GEP via analysis of a clinician survey, in which real-world

Methods

For real-world cases, representing the spectrum of those submitted for clinical testing, were presented to 40-GEP test users (10+ orders/year minimum), first without 40-GEP result (pre-test) and then with 40-GEP results (post-test).

Clinicians were asked what treatment recommendations they would make for each pre- and post-test patient case. Assessments from the 34 responding clinicians were ordered and compared using Wilcoxon rank or Kruskal-Wallis.

Summary metrics on the 2515 samples received during the first year of clinical ordering (August 31, 2020- August 31, 2021) that met clinical testing criteria, including 40% tumor content and sufficient RNA, were generated.

The 40-GEP Class call and patient risk factors were captured by clinical acquisition form review. Risk factors included lesion located on the H or M area, ≥2cm diameter, poorly defined borders, patient immunosuppression, rapidly growing tumor, site of prior RT or chronic inflammation, History & Physical- other factor noted, high-risk subtype, Clark Level IV, ≥2mm invasion, poorly differentiated, UV, PNI invasion beyond the subcutaneous fat.

Results

Clinicopathologic factors for the 6 real-world cases are shown in Table 1. Clinicians were well-aligned in their pre-test risk strategy levels among the real-world cases, despite randomization prior to presentation to clinicians (Figure 1).

Post-testing, clinicians’ overall management plan intensity was significantly changed depending on GEP prognostic risk (Figure 2A). Recommendations for specific treatment decisions were altered depending on 40-GEP result (Figure 2B-D). Asterisks indicate significant change from baseline, corrected for family-wise error, p < 0.016.

40-GEP testing resulted in 68.8% Class 1, 28.3% Class 2A, 2.9% Class 2B primary SCC lesions (Figure 3A). Of the 2515 samples received meeting clinical testing criteria, 98.1% generated successful test results (n=2468 samples generated).

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Figure 2. 40-GEP impacts clinician management planning in real-world patient scenarios

Baseline Class 1 Class 2A Class 2B
A) Overall Management Intensity Strategy

B) Nodal Assessment via Imaging

C) Frequency of follow-up (3 years)

Figure 3A. 40-GEP with satisfying high-risk factor reported

Figure 3B. The 40-GEP test has high technical reliability

Figure 3C. Most tested patients have 2 or more high risk factors

Conclusions

Summary metrics from one year of clinical orders of the 40-GEP test demonstrate that clinicians are ordering the test for the intended use population. Survey findings revealed that when incorporating 40-GEP testing into their decision-making process for high-risk cSCC patients, clinicians do so in a risk-aligned manner.

These results indicate that the additional information provided by the 40-GEP test can appropriately assist in management decisions when included with traditional risk factor assessment.

References

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