Enhanced metastatic risk assessment in cutaneous squamous cell carcinoma with the 40-gene expression profile test

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Key points

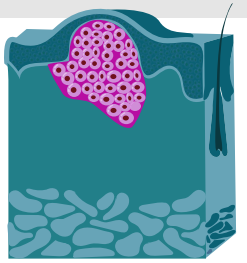
The incidence of cutaneous squamous cell carcinoma (cSCC) is high (~2 million cases diagnosed/year in the USA) and continues to grow, with a substantial number of patients having poor outcomes (~2-6% of cSCC patients develop regional or distant metastasis, and approximately 2% die from the disease annually).
The annual death toll is likely to surpass that for melanoma.

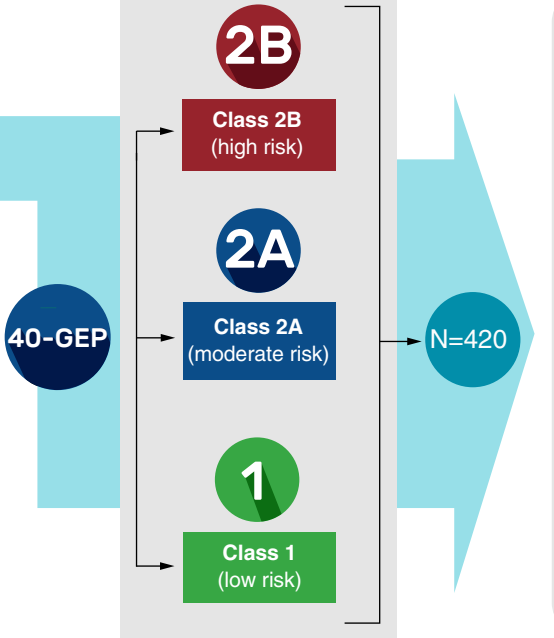
Most deaths are due to progressive locoregional disease (e.g., regional lymph node metastasis), which underscores the clinical need for accurate identification of patients at risk for metastasis to inform decision-making for risk-appropriate patient management.

Current risk-assessment methods (e.g., tumor staging systems and other clinicopathologic risk factor-based assessment methods) are helpful clinically, but have limitations for predicting metastatic risk; also, a universally accepted system for risk stratification in cSCC has not yet been adopted.

Aim of study

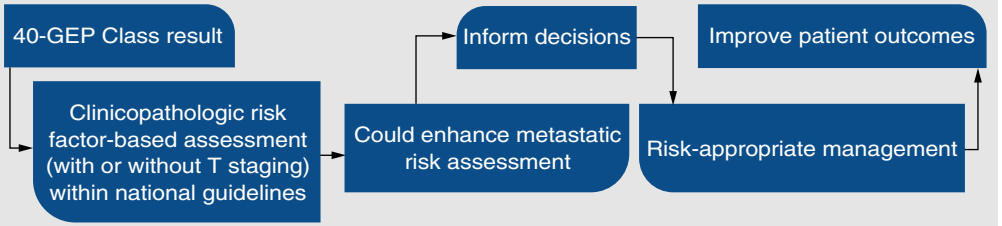
Demonstrate clinical validity of the 40-GEP test for classifying low (Class 1), moderate (Class 2A), and high (Class 2B) metastatic risk in high-risk cSCC within 3 years of diagnosis, along with the ability of the 40-gene expression profile (40-GEP) to further stratify risk when combined with clinicopathologic factor-based risk assessment.





The 40-GEP test demonstrated significant prognostic value for stratifying metastatic risk and refined risk classification via integration of 40-GEP results with clinicopathologic factor-based assessment, identifying patients with metastasis rates near the general cSCC population (Class 1) and those with rates >50% (Class 2B).

The 40-GEP test is clinically validated to classify risk for metastasis in patients with cSCC with one or more risk factors (the intended use population) and provides independent prognostic information that can enhance clinicopathologic risk factor-based assessment and established staging systems.



Incorporating the 40-GEP into risk assessment for patients with high-risk cSCC, within national guidelines, could facilitate better-informed decision-making for more personalized, risk-appropriate patient management and, subsequently, improved outcomes.