Assessing risk of nodal metastasis and relapse-free survival by CP-GEP (Merlin™ Test) in a single-centre retrospective case series of stage pT1a-4b cN0M0 melanoma patients

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Introduction

There is a pressing need for individualized prognostic markers to guide follow-up and adjuvant treatments in pT1a-4b cN0M0 melanoma patients. Previous validation studies have shown that the Merlin assay is a promising tool for risk assessment regarding nodal metastasis and risk of recurrence in this population.

Methods

We conducted a single-center academic retrospective study and included melanoma patients diagnosed between January 2018 and May 2024. Primary tumors were resected and followed by sentinel lymph node biopsy (SLNB). The Merlin™ test integrates CP variables age and Breslow thickness and the expression of eight genes from primary melanoma samples. The test produces a binary output: High Risk or Low Risk.

Results

51 pts were included, of which 27 female, with a median age at diagnosis of 65 years (range 26-90), median Breslow thickness of 1.5 mm (range 0.31-11.1) and a SLNB positivity rate of 15.7%. T-stage distribution: pT1a was 1 pt, pT1b 9 pts, pT2a 20 pts, pT3a 6 pts, pT3b 5 pts, pT4a 2 pts, and pT4b 8 pts. Merlin assay classified 15 pts as Low Risk, and 36 pts as High Risk. After a median follow-up of 26 months (0-83), no recurrences were observed in the Low Risk group, compared to 8 recurrences in the High Risk group. Three-year relapse-free survival rate was 100% versus 68% (95% CI 19-87) in the Low- and High-risk groups, respectively (log rank, p=0.062). Patients were further stratified according to sentinel lymph node biopsy results. In pts with a Low Risk score, one positive sentinel node was detected. In the 36 pts with a high-risk score, 7 pts had a positive node, of which 5 had recurrent disease (3y RFS 28% [95% CI 0-62]). Conversely, only 3 recurrences were observed in the 29 high-risk pts with a negative SLNB (3y RFS-rate 89.7% [95% CI 62-100]). RFS of pts with a positive SLNB and Low Risk Merlin test was significantly lower as compared to all other groups (log rank, p<0.001).

In this cohort, Merlin assay could have achieved a theoretic SLNB reduction rate of 29% with a NPV of 93.3%. SLNB identified 5 out of 8 relapses whereas CP-GEP captured all.

Conclusion

The predictive value of the Merlin assay for sentinel node positivity was confirmed in our single center retrospective case series. Risk assessment based on the Merlin assay and sentinel node status allows for risk stratification that deserves further investigation regarding personalized risk adapted management of cN0M0 melanoma patients.

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