Abstract

The assessment of pigmented lesions suspicious for melanoma remains a challenge. The non-invasive Pigmented Lesion Assay (PLA) guides biopsy decisions and detects melanoma at its earliest stages based on genomic atypia. The TRUST Study was designed to determine the proportion of true negative lesions among those that previously tested negative with the PLA. The objective of the study was to determine the proportion of true negative outcomes related to the test’s routine use.

Methods

Five geographically dispersed trial sites that routinely use the PLA in clinical practice were recruited to participate in this trial. Samples were to be collected from patients who previously had a PLA negative result and retested over an approximate 12- to 24-month period. In addition, patient charts were reviewed over up to a 36-month period to determine:

- Did the patient returned to the trial site post-PLA?
- If yes, was the PLA- lesion biopsied?
- If biopsied, was melanoma diagnosed?
- Evidence of mortality caused by melanoma?

All samples were processed in DermTech’s CLIA commercial laboratory located in La Jolla, CA. The DermTech PLA is a non-invasive adhesive patch test to sample lesions clinically suspicious for melanoma.

The test assesses the expression of two genes associate with melanoma, LINC00518 (long intergenic noncoding RNA 518) and/or PRAME (preferentially expressed antigen in melanoma). The PLA is used to guide biopsy decision and rule out melanoma based on the gene expression results.

Results

The results of the chart review from 2575 lesions is depicted below in Figure 1.

- 2575 PLA lesions
- 2400 patients
- Excludes PLA+, QNS, enrolled subjects, and those not reviewed
- 69.2% returned to the clinic post-PLA
- 45.4% returned in the last year
- 12.8% hx of melanoma
- 0.81% PLA+ lesions melanoma+

Of the reviewed charts, there were 10 PLA+ lesions histopathologically assessed as melanoma. Of the 10 melanoma diagnoses 6 (0.5%) were noted to be Stage 1A and 4 (0.3%) melanoma in situ. The time from the PLA- result to the date of melanoma diagnosis ranged from 1 to 33 months after the initial PLA test with an average of 13.5 months (5 - less than 12 months, 2 - 12 to 24 months and 3 - greater than 24 months. The negative predictive value calculated from this cohort was 99.2% (CI95%: 98.5 - 99.6) based on the 1233 reviewed charts.

Of the patients who underwent repeat testing of the lesion with the PLA, basic demographic data is presented in Figure 2.

Conclusions

- Ten lesions from the screening cohort (1233) received a melanoma diagnosis. Four (0.3%) at Stage 0 (in situ) six (0.5%) at Stage 1a
- NPV of the 1233 lesions with confirmed follow-up evaluations was 99.2% (CI95%: 98.5 - 99.6)
- Of the 323 enrolled subjects, 34 lesions were PLA+ and all went on to surgical biopsy with 3 (1%) diagnosed as Stage 0 (in situ) melanoma
- No adverse outcomes related to the test’s routine use

Reference


Disclosures

J Rock, Z Yao, MD Howell, and B. Jansen are employees and shareholders at DermTech, Inc. MK Skelsey, G Peck, B Brouha are consultants for DermTech.