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HEALTH ECONOMIC IMPLICATIONS OF A NONINVASIVE GENE EXPRESSION TEST FOR PRIMARY CUTANEOUS MELANOMA

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INTRODUCTION

The majority (>90%) of about 2.5 million surgical biopsies performed in the US to rule out melanoma are benign and categorized as neither invasive melanomas nor melanomas in situ by histopathology. A recently described adhesive patch skin biopsy based non-invasive gene expression test (pigmented lesion assay, PLA) demonstrated utility and differentiated benign from malignant pigmented skin lesions with a test performance that exceeded visual inspection (VI) and a sensitivity that matching the gold standard of dermatopathology. [1-4] However, cost and outcome implications of using this molecular test versus VI have not been evaluated.

STUDY AIM, DESIGN AND METHODS

We set out to determine potential cost savings and impact on outcome of PLA use versus VI in patients with pigmented cutaneous lesions suggestive of melanoma.

We performed health economic analyses from average US insurance reimbursement values comparing the real-world impact the PLA may have with VI. Data sources were from published clinical validation and utility studies as well as from routine use of the test in US dermatology practices, augmented by fee schedules of CMS.

RESULTS

A biopsy ratio reduction from 12.5 for VI to 2.4 for PLA use was observed. The number needed to excise (NNE) declined from 2.85 for VI to 1.37 for PLA use. The 1.77-fold increase in specificity of PLA over VI also resulted in lower costs for initial biopsy ($211), subsequent excisions ($86), surveillance management ($77), and management of melanoma ($508). There was $31 average savings from avoidance of lost work productivity, and improvement in patient experience as assessed by quality adjusted life years (gain of 0.016 years). Figure 1 depicts the decision diagram.

CONCLUSION

The improved accuracy of PLA use versus VI led to fewer unnecessary procedures and office visits, without negative impact on the early detection of melanoma. This results in potentially reduced direct medical costs, reduced loss of work productivity and improved patient care and experience.

REFERENCES

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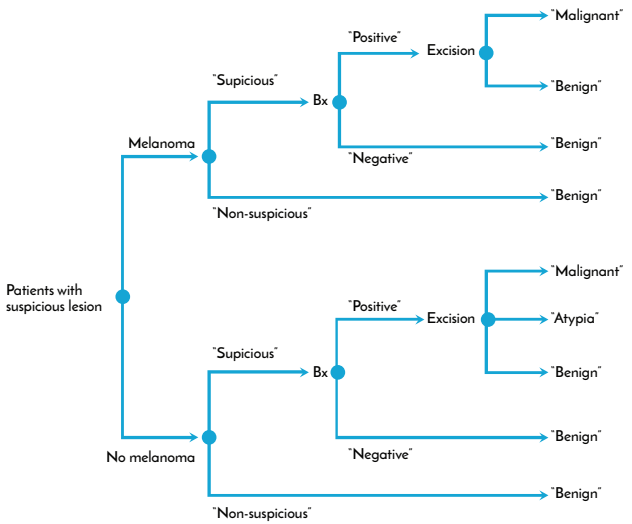

Figure 1. Decision Diagram

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