A Retrospective Case Series to Evaluate the Clinical Utility of a 31-Gene Expression Profile Test in Cutaneous Melanoma Patients

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Background

- Significant variability exists within the established guidelines for cutaneous melanoma patient follow-up and surveillance.[1]
- A validated prognostic 31-gene expression profile (GEP) test has been shown to accurately classify a patient's risk of metastasis within five years post-diagnosis as either low (Class 1) or high (Class 2).[2,3]
- The test has been shown to impact management decisions, including frequency of clinical visits, imaging and blood work recommendations, and physician referrals as measured by changes in surveillance practices following receipt of the test result.[4-6]

Objective

- To determine differences in management strategies and surveillance between Class 1 and Class 2 patients at a single surgical oncology center.

Methods

- A retrospective case review was performed following IRB approval at Desert Surgical Oncology, Rancho Mirage, CA. Data were collected from October 2015 through June 2016.
- Eligible patients had a diagnosis of stage I-III cutaneous melanoma and underwent GEP testing as part of their routine clinical care.
- Medical records were reviewed by the managing surgical oncologist. A questionnaire was completed for each patient describing the intended management strategy prior to and following the receipt of a GEP test result.
- Recommendations for follow-up were categorized as blood work (labs), imaging, frequency of clinical visits, and referral to medical oncology.
- Documented management changes were categorized as increased intensity, decreased intensity, or no change, based on comparison of management plans before and after receipt of GEP test result. Group comparisons were evaluated using Fisher's exact tests.

Results

Table 1. Cohort demographics

Clinical Characteristic	Overall (n = 70)	Class 1 (n = 45)	Class 2 (n = 25)
AJCC stage (v7)			
I	39 (56%)	36 (80%)	3 (12%)
II	29 (41%)	7 (16%)	22 (88%)
III	2 (3%)	2 (4%)	0 (0%)
Breslow thickness			
Median (range), mm	1.3 (0.4-6.8)	1.0 (0.4-2.5)	2.5 (0.8-6.8)
≤1 mm	25 (36%)	21 (47%)	2 (8%)
>1 mm	45 (64%)	24 (53%)	23 (92%)
Mitotic index			
<1/mm^2	18 (26%)	15 (33%)	3 (12%)
≥1/mm^2	52 (74%)	30 (67%)	22 (88%)
Regression			
Absent	67 (96%)	43 (96%)	24 (96%)
Present	3 (4%)	2 (4%)	1 (4%)
Ulceration			
Absent	48 (69%)	39 (87%)	9 (36%)
Present	22 (31%)	6 (13%)	16 (64%)

Table 2. Pre-test management plan

Management modality	Frequency
Labs	q3 months x 2 years and q6 months x 3 years
Imaging	CT scan q1 year x 5 years or none
Office visits	q3 months x 2 years and q6 months x 3 years
Referral	none

Table 3. Changes by class for each surveillance method

	Class 1		Class 2	
	Decrease	Increase	Decrease	Increase
Labs	45	0	0	0
Imaging*	13	0	0	25
Visits	45	0	0	0
Referral	1	1	0	5

*p<0.0001, Fisher's exact test

Figure 1. Schematic showing management changes after inclusion of GEP test result to existing surveillance plans. GEP class was a significant predictor of change in management (p<0.0001, Fisher's exact test). C/A/P: chest, abdomen and pelvis.

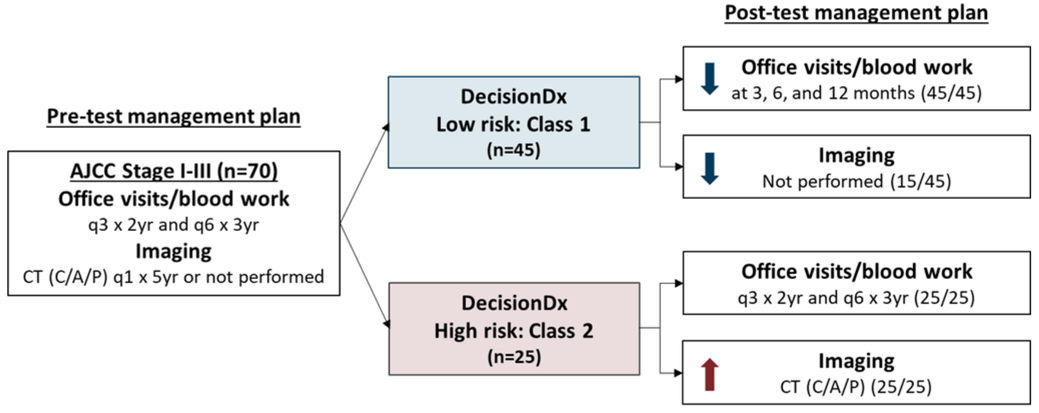

Table 4. Review of clinical impact studies

Study	n	Result
Berger (2016) Prospective, multicenter	163 patients	53% changed management after inclusion of GEP result
Farberg (2017) Dermatologist survey	169 physicians	47-50% changed management after inclusion of GEP result
Schuitevoerder (2017) Prospective, single center	90 patients	52% of management decision based on GEP result using decision tree model
Current study Retrospective, single center	70 patients	100% changed management after inclusion of GEP result

Conclusions

- The inclusion of GEP testing as part of the management strategy at our institution has resulted in significant risk-driven follow-up and surveillance differences between low- and high-risk patients.
- Results of this study are consistent with previously published reports of the GEP's impact on clinical management.
- GEP testing in combination with conventional staging methods can be employed to develop a more efficient and individualized follow-up plan based on clinical factors as well as intrinsic biological risk.

References

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Disclosures

RWC and FAM are employees and stockholders of Castle Biosciences, Inc.
The proprietary GEP test is clinically available through Castle Biosciences as the DecisionDx®-Melanoma test (www.SkinMelanoma.com).