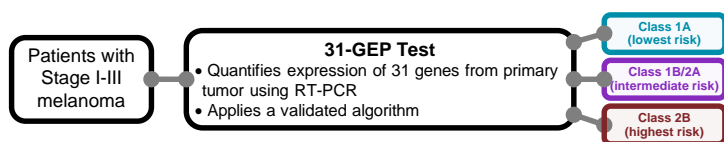


Identification of patients with T1-T2 melanoma and low risk of sentinel lymph node positivity using a 31-gene expression profile test

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BACKGROUND

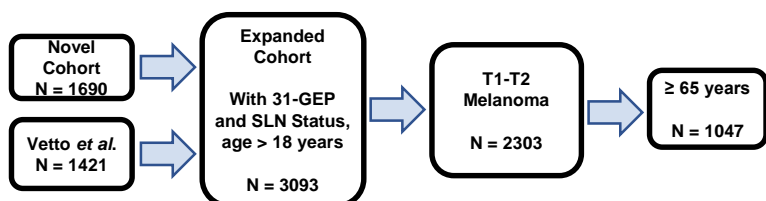
- Sentinel lymph node (SLN) positivity for metastasis predicts poor prognosis¹, however, SLN biopsy (SLNB) does not improve survival, has a false negative rate of 5-21%^{1,2}, a complication rate of 11%³, and high cost.⁴
- Only 5-10% of patients diagnosed with T1-T2 thickness cutaneous melanoma (CM) who undergo a SLNB have a positive result.^{5,6}
- The 31-gene expression profile (31-GEP) test stratifies CM patients' metastatic risk as low (Class 1A), intermediate (Class 1B/2A) or high (Class 2B), and its use for informing which patients are at a low risk for SLN-positivity has been validated.⁷⁻¹³



OBJECTIVE:

To identify patients with T1-T2 melanoma likely to have low SLN-positivity rates

METHODS



RESULTS

Table 1. Demographics of patients with T1-T2 melanoma

	All patients N=2303	Class 1A N=1621	Class 1B/2A N=468	Class 2B N=214
Age*, years (range)	63 (18-101)	61 (18-101)	65 (20-92)	69 (24-94)
Breslow thickness*, mm (range)	0.9 (0.0-2.0)	0.8 (0.0-2.0)	1.2 (0.2-2.0)	1.4 (0-2.0)
Ulceration present	13% (306/2303)	6% (92/1624)	24% (114/471)	48% (102/214)
SLNB performed	73% (1681/2309)	67% (1082/1624)	88% (414/471)	86% (185/214)
SLN positive	10% (166/1681)	7% (72/1082)	14% (56/414)	21% (38/185)

* Median

Table 2. SLN positivity in T1-T2 melanoma patients ≥ 65 years stratified by 31-GEP Class

31-GEP Class	N	SLN assessed	SLN positive	% SLN positive in assessed	% SLN positive in all
Class 1A	677	64% (431/677)	12	2.8% (1.4 – 4.8)	1.8% (0.9 – 3.1)
Class 1B/2A	240	86% (206/240)	26	12.6%**** (8.4 – 17.9)	10.8%**** (7.2 – 15.5)
Class 2B	130	85% (110/130)	19	17.3%**** (10.7 – 25.7)	14.6%**** (9.0 – 21.9)

Fisher's exact test compared to Class 1A rates, **** p value < 0.0001

Table 3. 31-GEP test identifies patients ≥ 65 years with low risk of SLN positivity by T substage

T substage	31-GEP Class	N	SLN assessed	SLN positive	% SLN positive in assessed	% SLN positive in all
T1a	Class 1A	270	72	2	2.8%	0.7%
	Class 1B/2A	25	14	2	14.3%	8.0%
	Class 2B	4	2	1	50.0%	25.0%
T1b	Class 1A	200	168	0	0%	0%
	Class 1B/2A	48	39	3	7.7%	6.3%
	Class 2B	20	18	4	22.2%	20.0%
T2a	Class 1A	186	171	9	5.3%	4.8%
	Class 1B/2A	121	112	13	11.6%	10.7%
	Class 2B	53	41	6	14.6%	11.3%
T2b	Class 1A	21	20	1	5.0%	4.8%
	Class 1B/2A	46	41	8	19.5%	17.4%
	Class 2B	53	49	8	16.3%	15.1%

Figure 1. Distribution of 31-GEP Class results in T1-T2 SLNB eligible patients ≥ 65 years

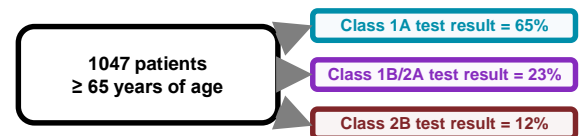
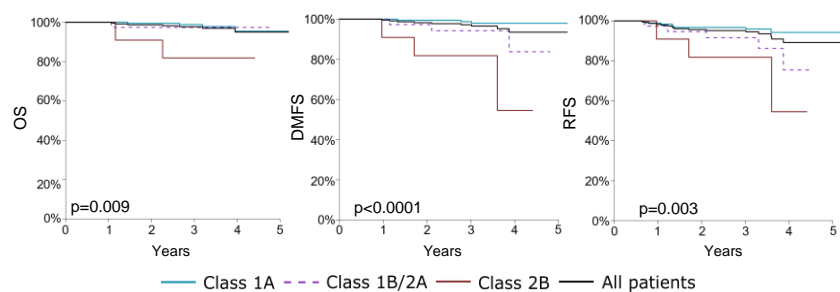


Figure 2. Outcomes of T1-T2 melanoma stratified by 31-GEP Class in a prospective cohort (n=246, 3.2 years median follow-up)



CONCLUSIONS

- The 31-GEP test can be used in T1-T2 melanoma patients 65 years and older to identify those with low probability of SLN positivity that are unlikely to benefit from SLNB.
- Class 1A results are correlated with high rates of overall and metastasis-free survival in a prospectively collected cohort with long follow-up.
- In this cohort, 65% of patients 65 years and older could avoid SLNB procedure based on 31-GEP classification, which could reduce health care costs and result in more efficient utilization of healthcare resources.

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DISCLOSURES

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