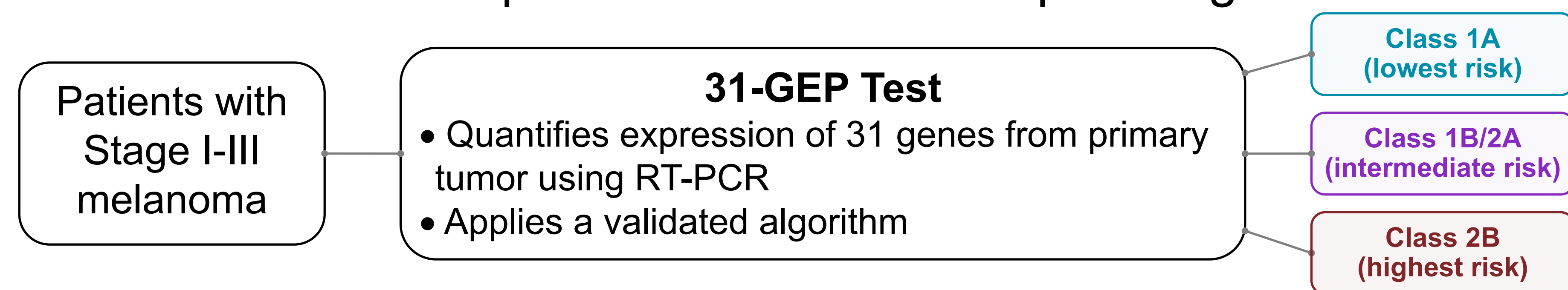


Identification of melanoma patients with low risk of sentinel lymph node positivity and favorable prognosis using a 31-gene expression profile (GEP) test

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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
- National guidelines recommend that SLNB be considered if SLN positivity risk is between 5-10%, and offered if the risk is $\geq 10\%$, but additional tools are needed to evaluate a patient's individual risk of SLN positivity.⁵
- The 31-GEP test is a significant predictor of 5-year risk of recurrence and distant metastasis independent of clinical and pathological features.⁶⁻¹²

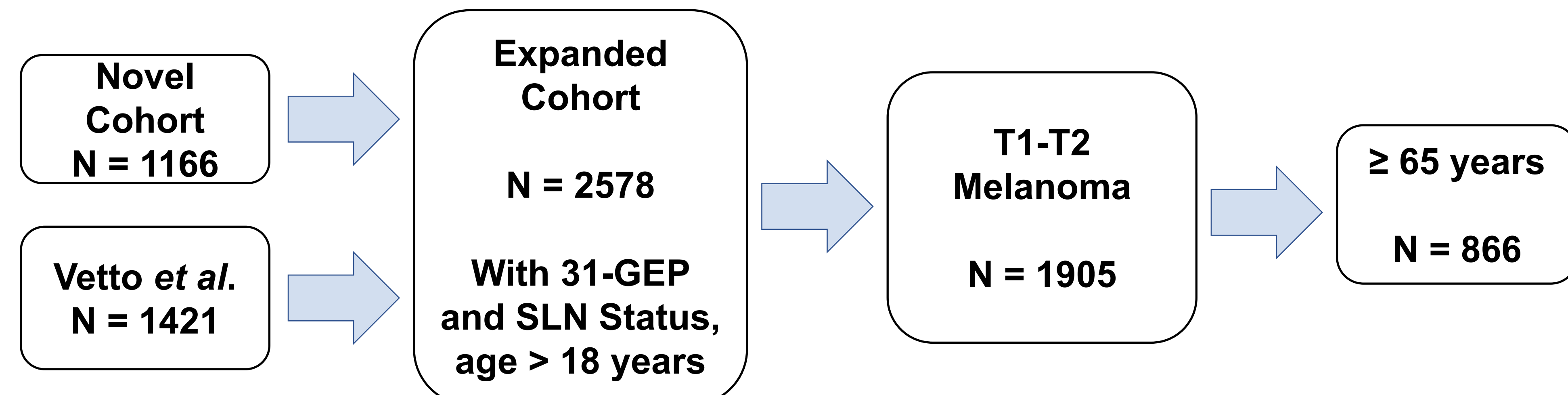


- The use of 31-GEP to predict SLN positivity has been recently validated in patients 55 years and older with T1-T2 melanoma, in a study reporting that patients with a Class 1A result had SLN positivity rates below the 5% threshold at which national guidelines recommend SLNB consideration.¹³

OBJECTIVE:

Use the 31-GEP with clinical features to identify patients in an expanded and prospectively tested cohort who are likely to have low SLN positivity rates

METHODS



RESULTS

Table 1. Demographics of T1-T2 melanoma patients

	All patients n=1905	Class 1A n=1317	Class 1B/2A n=398	Class 2B n=190
Age* (yrs), range	64 (18-101)	61 (18-101)	64 (20-92)	68 (24-94)
Breslow thickness* (mm), range	1.2 (0-2.05)	0.8 (0-2.05)	1.2 (0.2-2.05)	1.4 (0-2.02)
Ulceration present	13% (257/1905)	6% (74/1317)	23% (93/398)	47% (90/190)
SLNB performed	75% (1421/1905)	69% (903/1317)	89% (353/398)	87% (165/190)
SLN positive	10% (144/1421)	7% (65/903)	12% (44/353)	21% (35/165)

* 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	559	66% (367/559)	10	2.7% (1.3 – 5.0)	1.8% (0.9 – 3.3)
Class 1B/2A	197	86% (170/197)	15	8.8%** (5.0 – 14.1)	7.6%*** (4.3 – 12.2)
Class 2B	110	84% (92/110)	17	18.5%**** (11.1 – 27.9)	15.5%**** (9.3 – 23.6)

Fisher's exact test compared to Class 1A rates, * p value < 0.05, ** p value < 0.01, *** p value < 0.001, **** 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	217	63	2	3.2%	0.9%
	Class 1B/2A	18	8	1	12.5%	5.6%
	Class 2B	3	1	0	0%	0%
T1b	Class 1A	161	136	0	0%	0%
	Class 1B/2A	39	34	3	8.8%	7.7%
	Class 2B	18	16	4	25.0%	22.2%
T2a	Class 1A	161	149	7	4.7%	4.3%
	Class 1B/2A	97	90	7	7.8%	7.2%
	Class 2B	46	35	6	17.1%	13.0%
T2b	Class 1A	20	19	1	5.3%	5.0%
	Class 1B/2A	43	38	4	10.5%	9.3%
	Class 2B	43	40	7	17.5%	16.3%

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

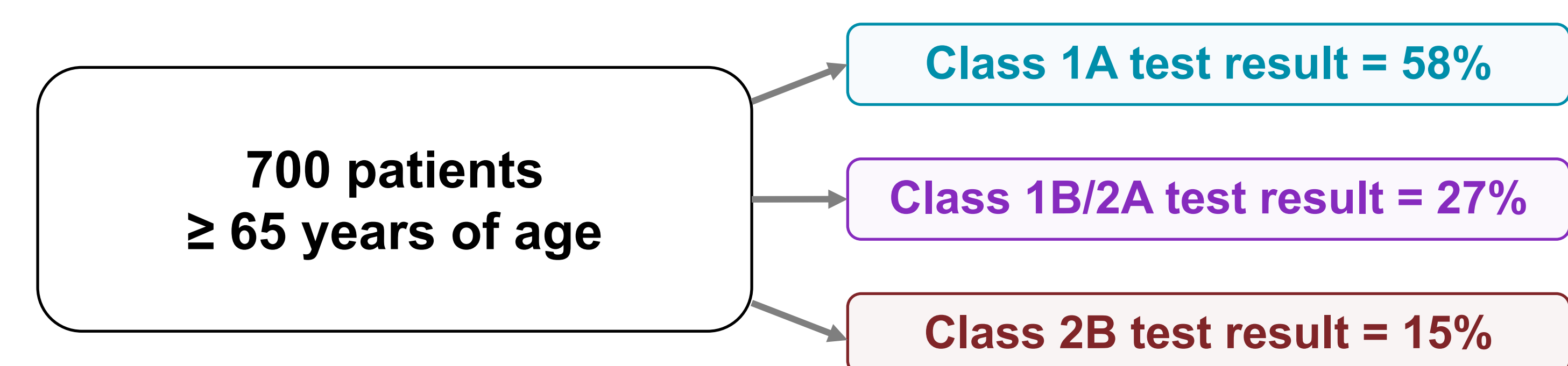
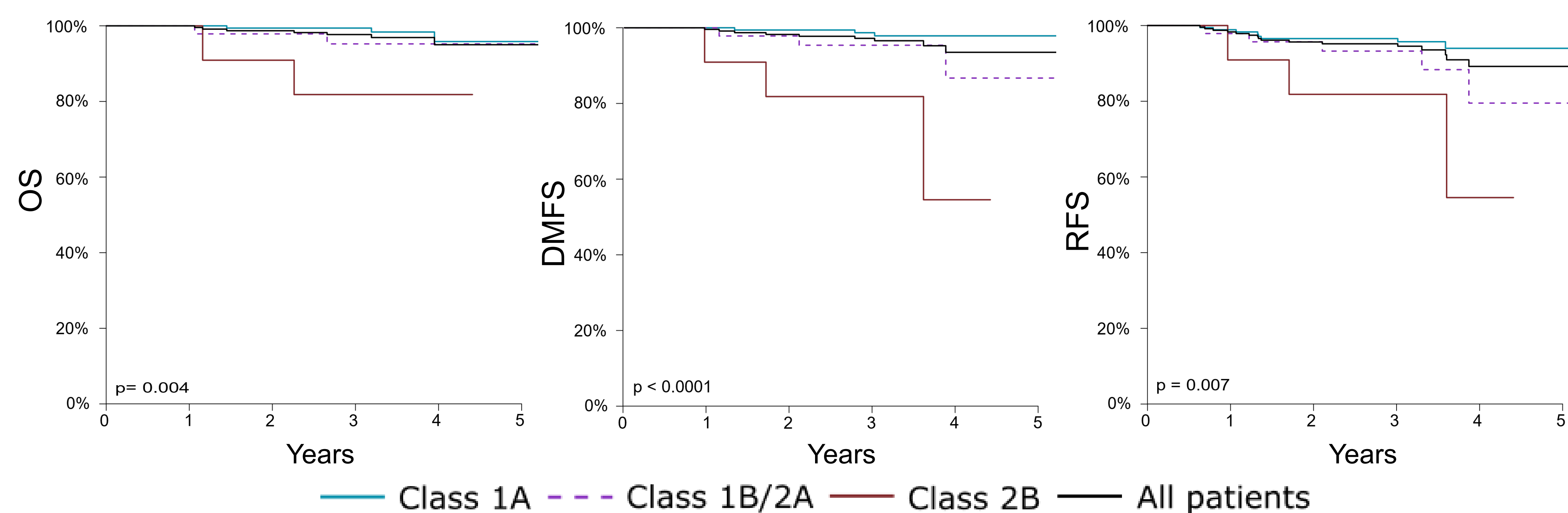


Figure 2. Outcomes of T1-T2 melanoma stratified by 31-GEP Class in a prospective cohort (n=246, 3.2 years median follow-up)



CONCLUSIONS

- The 31-GEP test can be used in T1-T2 melanoma patients ages 65 years and older to identify those with <5% predicted probability of a positive SLN.
- In a prospective cohort, T1-T2 melanoma patients with Class 1A GEP have very low rates of metastatic recurrence, distant metastasis, and mortality.
- In this cohort, 58% of patients could avoid a 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

This study was sponsored by Castle Biosciences, Inc. KRC, HGC, RWC, and FAM are employees and options holders of Castle Biosciences, Inc. EW is on the Speaker's Bureau for Castle Biosciences, Inc. DH is a consultant for Castle Biosciences, Inc. and is on the Speaker's Bureau.