9567 - Identification of patients at high risk for relapse by Merlin assay (CP-GEP) in an independent cohort of melanoma patients (pts) that did not undergo sentinel lymph node biopsy: An H&N subgroup analysis.

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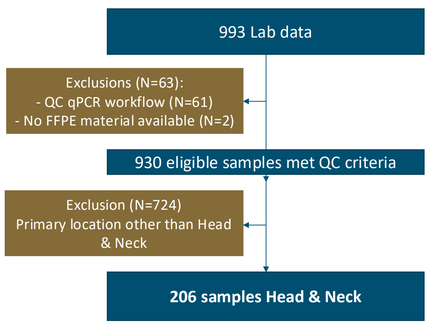
Background: Sentinel lymph node biopsy (SLNB) is still the gold standard for clinical staging of cutaneous melanoma (CM) pts by AJCC v8. Identification of early-stage CM pts at risk, including pts that did not undergo SLNB, is warranted. Recently we showed that CP-GEP has the potential to stratify pts who did not undergo SLNB in low- and high-risk for recurrence (*Amaral et al., EJC 2025*). In pts with Head and Neck (H&N) melanoma SLNB may be challenging due to the regional course of cranial nerves and lymphatic drainage.

Aim: Validate CP-GEP's ability to stratify pts with H&N melanoma, in particular those with lentigo maligna, who did not undergo SLNB for their risk of recurrence.

Methods: formalin-fixed paraffin-embedded primary tumor samples of CM pts diagnosed between 2000-2017 who did not undergo SLNB were analyzed. The CP-GEP model used combines the expression of 8 genes (SERPINE2, GDF15, ITGB3, CXCL8, LOXL4, TGFBR1, PLAT and MLANA) by qPCR with age and Breslow thickness to obtain a binary output: CP-GEP **Low Risk** or **High Risk**. Relapse-free survival (RFS), distant metastasis free survival (DMFS), melanoma Specific Survival (MSS), and overall survival (OS) were evaluated using Kaplan-Meier curves. Median follow-up time was 10 years.

Figure 1: Generation of the study cohort



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Pts with H&N melanoma that did not undergo SLNB can be risk stratified by CP-GEP based risk of recurrence.

Pts with **CP-GEP Low Risk** have a **good long-term survival** compared to CP-GEP High Risk.

CP-GEP may be used to risk stratify pts with H&N melanoma beyond SLNB.

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Table 1: Patients characteristics

Variable	Level	n (%)
Gender	Female	85 (41%)
	Male	**121 (59%)**
Age (years)	Median [1QR, 3QR]	73 (62, 80)
Breslow Thickness (mm)	Median [1QR, 3QR]	0.5 (0.4, 0.7)
Ulceration	**Absent**	**184 (89%)**
	Present	13 (6%)
	Unknown	9 (4%)
CP-GEP	**Low-risk**	**188 (91%)**
	High-risk	18 (9%)
Stages	**IA**	**169 (82%)**
	IB	10 (5%)
	IIA	8 (4%)
	IIB	6 (3%)
	IIC	4 (2%)
	Unknown	9 (4%)
T-categories	T1	5 (2%)
	T1a	**146 (71%)**
	T1b	23 (11%)
	T2	4 (2%)
	T2a	10 (5%)
	T2b	1 (1%)
	T3a	7 (3%)
	T3b	4 (2%)
	T4a	2 (1%)
	T4b	4 (2%)
Location	**Head & Neck**	**206 (100%)**
	Trunk	0
	Upper extremities	0
	Lower extremities	0
Histological type	Superficial spreading	41 (20%)
	Lentigo maligna	**155 (75%)**
	Nodular	3 (2%)
	Other	4 (2%)
	Unknown	3 (2%)

Multivariate Cox regression analysis for 10y RFS showed that **CP-GEP** (HR = 6.12, p = 0.0127) remained **independently significant** compared to age (HR = 1.03, p = 0.0704), Breslow (HR = 0.80, p = 0.2255) and ulceration (HR = 5.30, p = 0.0078)

Figure 2: 10-year RFS, DMFS, MSS, and OS stratified by CP-GEP as **Low Risk** or **High Risk**

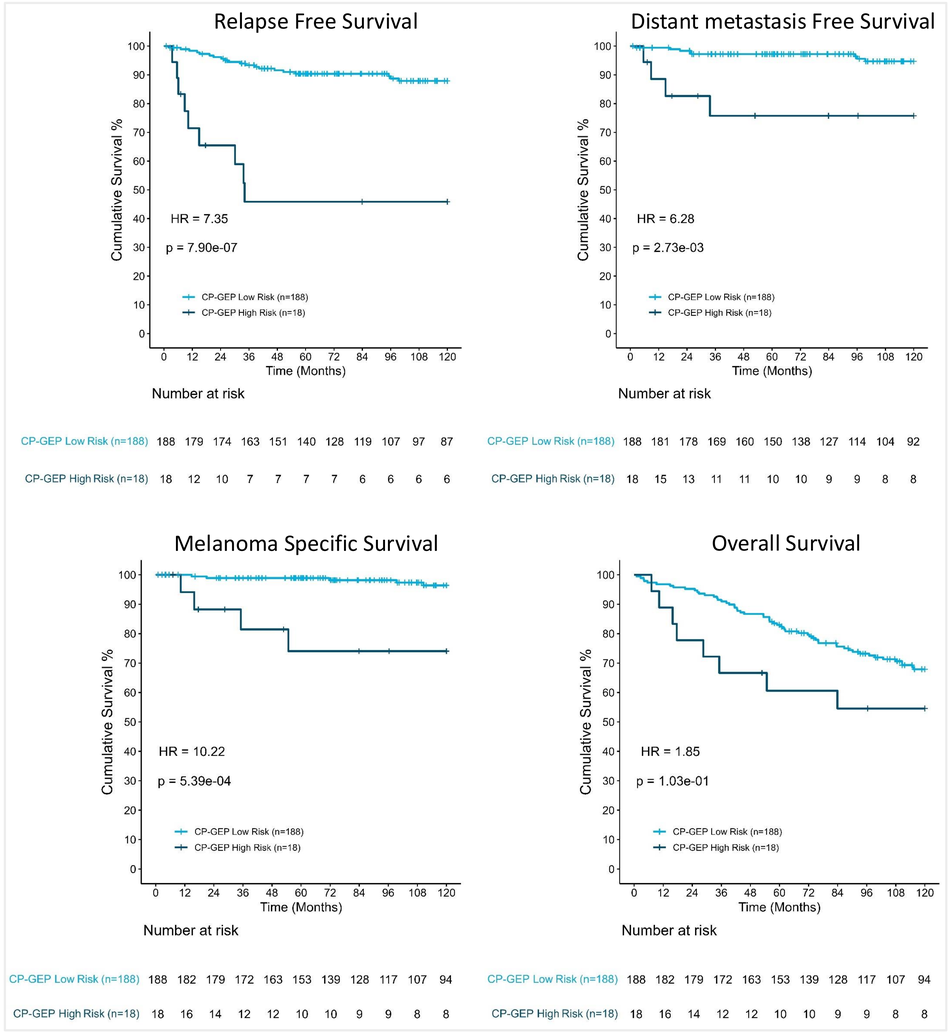

Table 2: 10-year survival rates of CM H&N pts according to CP-GEP **Low Risk** or **High Risk**

		10-years RFS			10-years DMFS			10-years MSS			10-years OS		
	N	Events	%	95%CI	Events	%	95%CI	Events	%	95%CI	Events	%	95%CI
Complete Cohort	206	29	84.4	[78-89]	12	93.2	[88-96]	9	94.6	[90-97]	65	66.7	[60-73]
CP-GEP Low Risk	188	20	87.9	[82-92]	8	94.7	[90-97]	5	96.4	[91-99]	57	67.9	[60-74]
CP-GEP High Risk	18	9	45.8	[21-67]	4	75.8	[47-90]	4	74.0	[44-90]	8	54.5	[29-74]