HEALTH-RELATED QUALITY OF LIFE (HRQoL), IN PATIENTS WITH DURABLE RESPONSE TO IMMUNE CHECKPOINT INHIBITORS (ICIs) FOR ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) OR MELANOMA: QUALICI STUDY

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Background and study objectives

- With ICIs, the prognosis of advanced forms of cancer has significantly improved and has led to the emergence of patients with durable response to ICIs (ICI-DR).
- These patients face specific HRQoL problems and may experience specific physical, emotional and neurocognitive impairments related to the long-term direct or indirect effects of their disease and treatment. Psychological consequences leading to distress among their relatives, colleagues and friends may be experienced as well (1,2). Financial toxicity may also be a concern, due to the direct costs of care and difficulties in finding or keeping a job (2).
- QUALICI study aimed to provide an overview of quality of life, experiences and expectations regarding HRQoL management in ICI-DR patients for either melanoma or metastatic non-small cell lung cancer (NSCLC).

Methods

- All patients with ICI-DR, defined as ICIs started for ≥2 years without subsequent treatment, were prospectively screened in 16 French hospitals and randomly selected to participate in this cross-sectional study.
- Participants completed generic and specific instruments including the EQ-5D-5L, the Social Difficulties Inventory (SDI), the Chalder Fatigue Scale (CFQ-11) and emotional items from the QoL Patient-Cancer Survivor Version (QoL-CSV) questionnaire:
  - The EQ-5D-5L (4) assesses mobility, self-care, usual activities, pain/discomfort, and anxiety/depression; each of which has 5 response levels from no to extreme problems. A score on a vertical visual analogue scale (VAS) indicates the perceived health from 0 to 100 (the best full health).
  - SDI (5) comprised 3 dimensions (everyday living, self and others, money matters) to assess everyday problems experienced by cancer patients. The 21 items of the SDI were graded on a 4-level Likert scale from no to very much difficulty. The three dimension sub scores and the total SDI distress score were estimated.
  - The CFQ-11 (6) assesses physical and mental fatigue through 11 items graded on a 4-level Likert scale (from asymptomatic to maximum symptomology). A total score and 2-dimension sub-scores were estimated.
  - Four items from the survival QoL CSV focusing on the apprehension about the future for themselves or their loved ones were used (7),
- Endpoint variables were summarized using descriptive statistics in each group separately: A) NSCLC and B) melanoma.
- QoL was assessed in different subgroups of interest: by patient age at inclusion (<65 years/ ≥65 years), type of professional occupation (active/ inactive), time since ICI treatment initiation ([24 to 30 months[, [30 to 36 months[, ≥36 months), ongoing ICI treatment or not and prior cancer treatment (chemotherapy-based, other treatment, none).

Results

A total of 469 patients were screened, 372 were randomly selected to be invited to participate in the study, 302 agreed to participate, and 234 completed and returned the questionnaires, 117 in each cohort.

Baseline characteristics

Table 1. Baseline and Demographic Characteristics

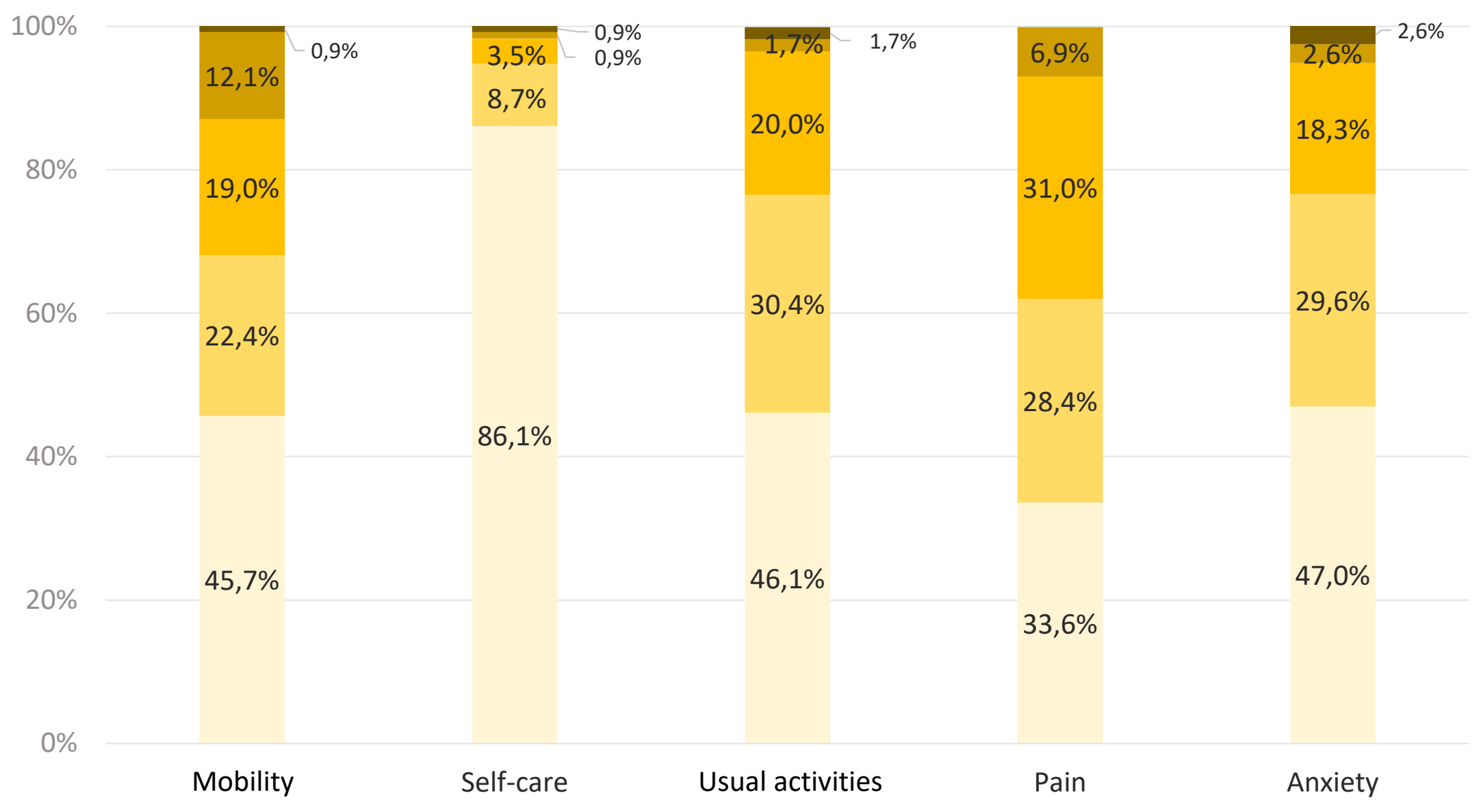
		NSCLC (N=117)	Melanoma (N=117)
Sex	Male	74 (63.2%)	60 (51.3%)
Age at inclusion (years)	Mean ±SD	65.8 ±9.7	67.5 ±12.8
	Median (Q1-Q3)	66 (58-72)	70 (59-77)
	< 65	52 (44.4%)	40 (34.2%)
	≥ 65	65 (55.6%)	77 (65.8%)
Size of town of residence (inhabitants)	≤ 2000	40 (36.4%)	49 (42.2%)
	2001 to 10 000	28 (25.5%)	26 (22.4%)
	10 001 to 50 000	24 (21.8%)	18 (15.5%)
	> 50 000	18 (16.4%)	23 (19.8%)
Annual household income before tax (euros)	≤ 18 000	32 (29.4%)	19 (17.4%)
	18 001 to 25 000	30 (27.5%)	23 (21.1%)
	25 001 to 35 000	23 (21.1%)	30 (27.5%)
	35 001 to 50 000	14 (12.8%)	20 (18.3%)
	> 50000	10 (9.2%)	17 (15.6%)
Professional situation at inclusion	Active	20 (17.2%)	35 (29.9%)
	Inactive	96 (82.8%)	82 (70.1%)
Patient living alone	Yes	39 (33.9%)	29 (24.8%)
Help or support related to cancer	Help	107 (91.5%)	102 (87.2%)
	No help	10 (8.5%)	15 (12.8%)
ICI-DR (months)	Mean ±SD	48.2 ±15.1	49.4 ±13.8
	Median (Q1-Q3)	45 (36.8-61.8)	49 (37.8-59.5)
Year of initiation of ICI treatment	2017	15 (12.9%)	10 (8.5%)
	2018	18 (15.4%)	22 (18.8%)
	2019	27 (23.1%)	35 (29.9%)
	2020	39 (33.3%)	28 (23.9%)
	2021	18 (15.4%)	22 (18.8%)
Duration of ICI treatment (months)	Mean ±SD	33.3 ±15.6	23.6 ±17.5
	Median (Q1-Q3)	28.1 (24-40.6)	19.9 (12-29.9)
Patient still on ICI treatment	Yes	43 (36.8%)	26 (22.2%)
	No	74 (63.2%)	91 (77.8%)
If not, Duration of ICI treatment (months)	Mean ±SD	26.5 ±11.7	16.4 ±9.9
	Median (Q1-Q3)	25 (22-29)	13 (11-22)
Treatment prior to ICI	Radiotherapy	32 (28.8%)	16 (13.9%)
	Chemotherapy	51 (45.9%)	2 (1.7%)
	Immunotherapy	4 (3.6%)	9 (7.8%)
	Targeted therapy	1 (0.9%)	11 (9.6%)
	Cancer surgery	28 (25.2%)	72 (62.6%)
	No previous treatment	42 (37.8%)	29 (25.2%)
	Adjuvant treatment	4 (3.6%)	2 (1.7%)

EQ-5D-5L assessment

- Most patients (NSCLC ≥62.0%; melanoma ≥69.7%) reported no or slight problems on the 5 EQ-5D-5L dimensions. Overall, 17.0% and 21.9% of NSCLC and melanoma patients, respectively, reported no problems in all dimensions. A minority of patients had severe or very severe problems (3.4% to 13.0% in the NSCLC population and 1.7% to 8.7% in the melanoma population, depending on the dimension) (**Figure 1**).
- The dimension where the most problems were reported was “pain and discomfort”, with 62.8% of patients reporting problems (66.4% in NSCLC and 59.1% in melanoma).
- Mean EQ-5D-5L Index Utility Score were 0.9±0.2 in NSCLC and 0.9±0.1 in melanoma patients.
- Visual Analogic Scores on the perceived health were 67.0±19.3 and 74.8±19.0 in NSCLC and melanoma patients, respectively (**Figure 2**).
- Age group: the VAS was 67.2±21.7 in patients <65 years and 66.8±17.2 in those ≥ 65 years in NSCLC patients (p=0.93), 81.3±12 and 71.4±21 (p= 0.02) in melanoma patients (**Figure 3**). Distribution by subgroups of age are showed in **Figure 4**.
- Occupational activity: the VAS was 74.4±18.8 in active patients and 65.8±18.8 in non active NSCLC patients (p= 0.073), 82.2±11.8 and 71.6±20.5 (p=0.007) in melanoma group.
- There were no significant differences in the VAS score between NSCLC and melanoma patients:
  - who were still on ICI and those who were not (p=0.64 and p=0.17, respectively),
  - with time since starting ICI (p=0.68 and p=0.41 in the NSCLC and melanoma groups, respectively),
  - or with prior treatment (p=0.86 and p=0.74 in the NSCLC and melanoma groups, respectively).

Figure 1. EQ-5D-5L profiles

Patients with NSCLC (N=117)



Patients with melanoma (N=117)

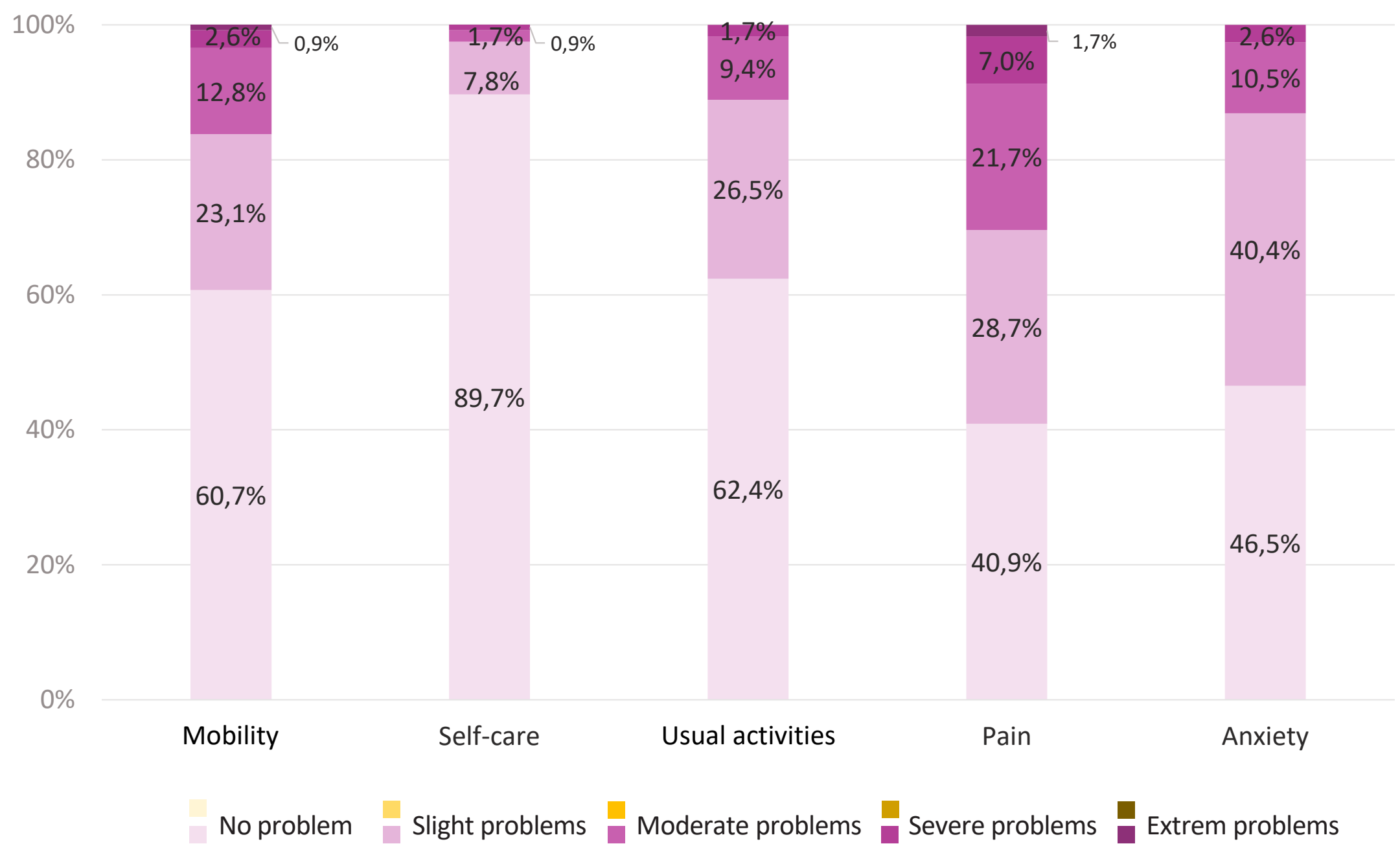


Figure 2. Mean EQ-5D-5L VAS in patients with NSCLC (N=117) and with melanoma (N=117)

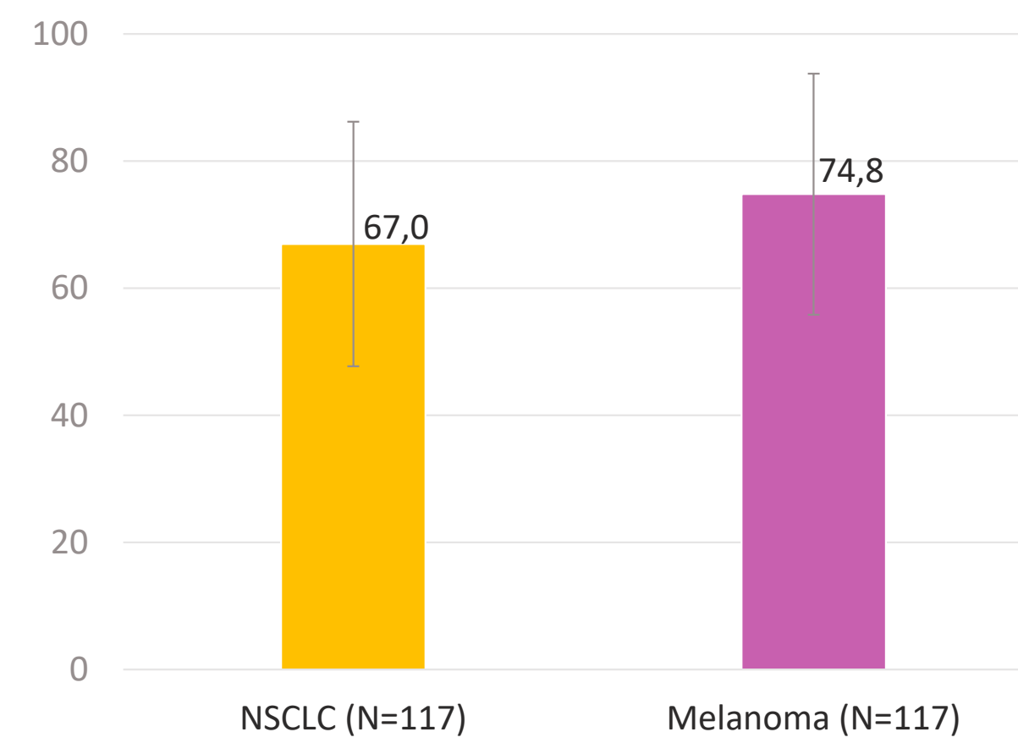


Figure 3. Mean EQ-5D-5L VAS by age in patients with NSCLC (N=117) and with melanoma (N=117)

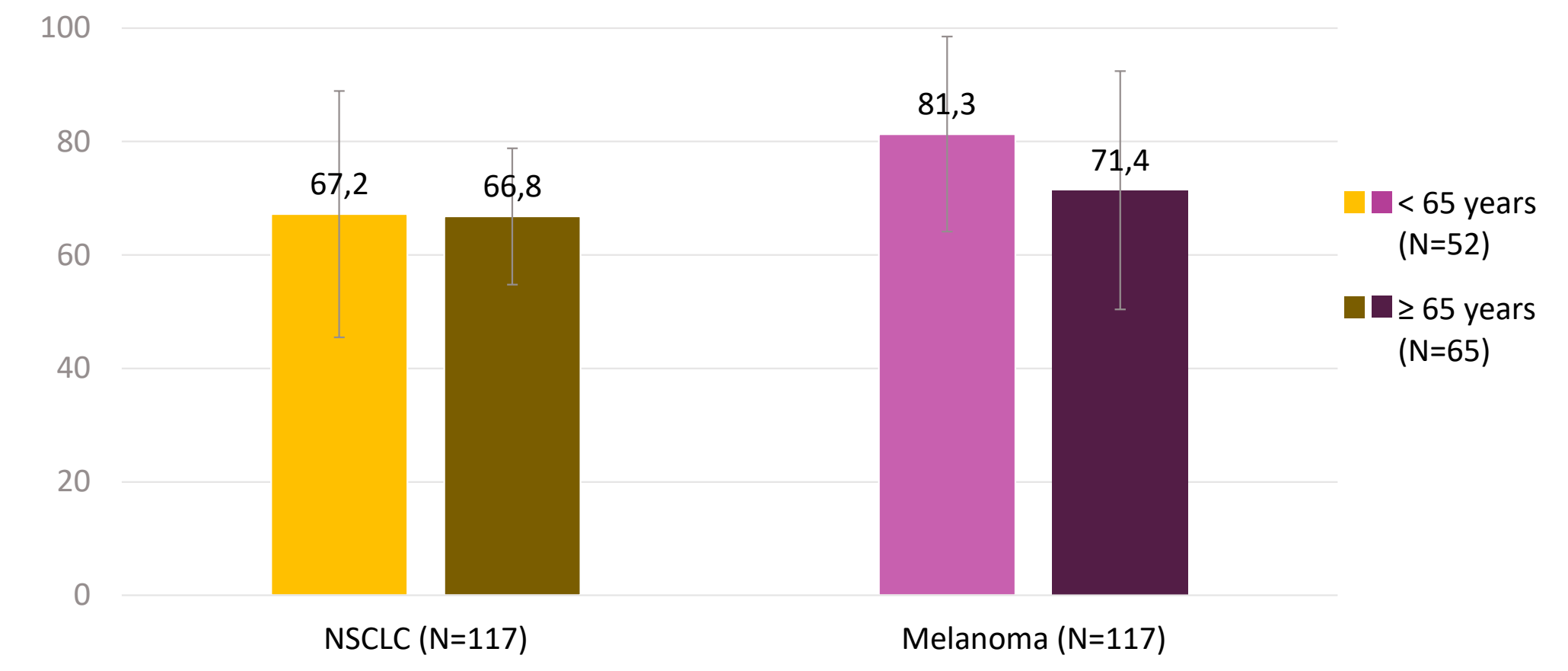
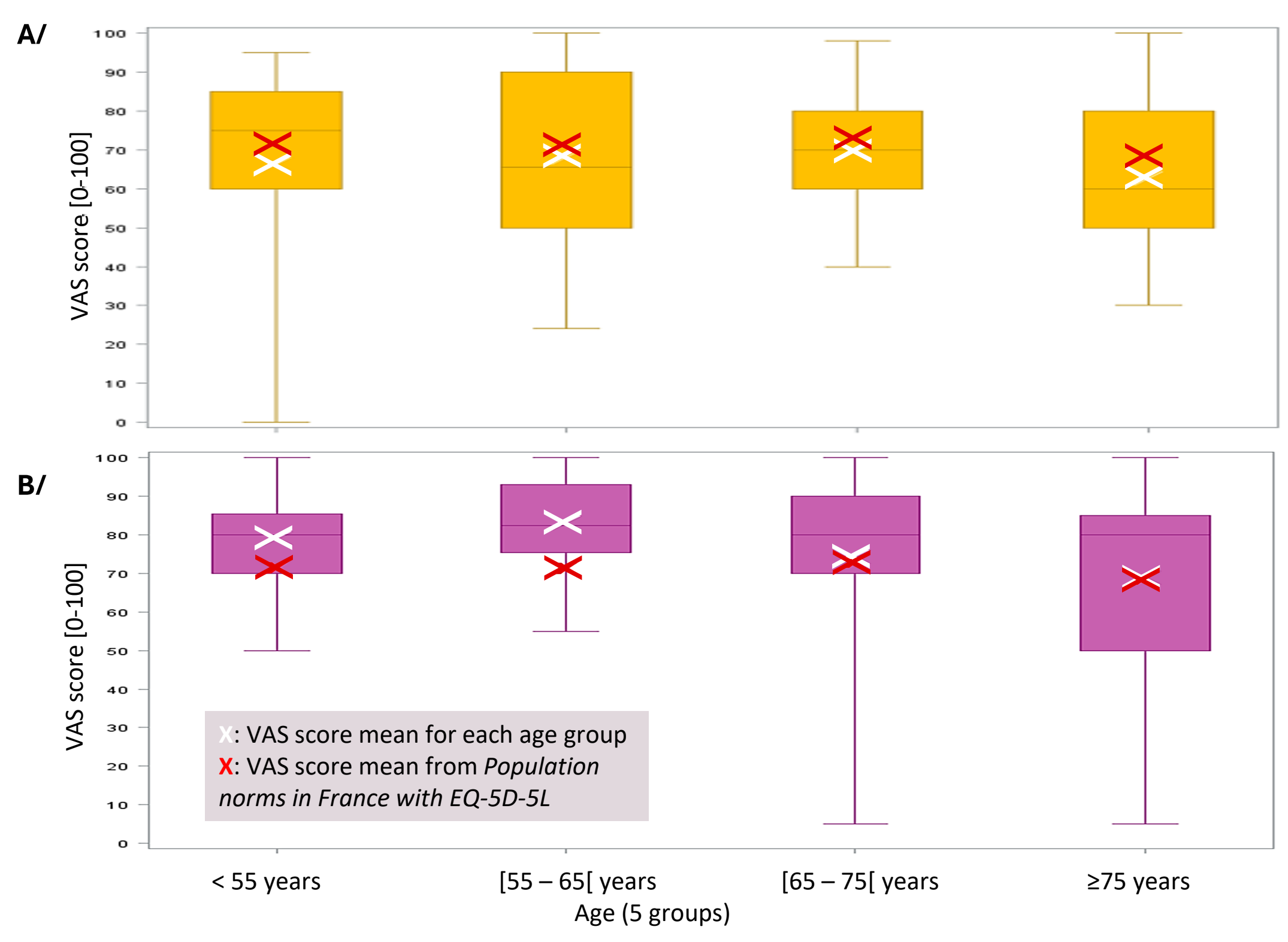


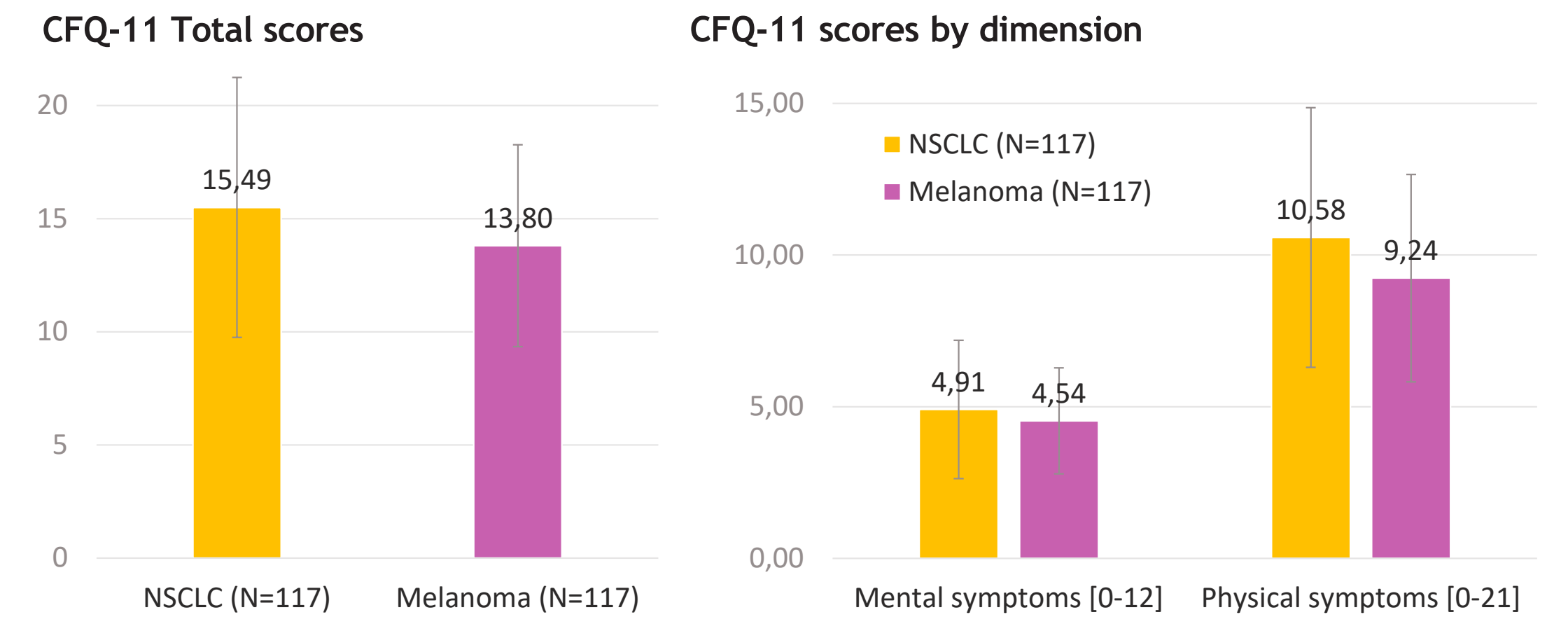
Figure 4. Distribution of VAS by age



CFQ-11 assessment

- Mean CFQ-11 total scores were 15.5±5.7 in NSCLC patients and 13.8±4.5 in melanoma group (**Figure 5A**).
- Proportions of patients with moderate and severe fatigue were respectively 68.3% and 21.2% in NSCLC cohort; 84.0% and 4.7% in melanoma patients.
- Mean CFQ-11 mental symptoms score was 4.9±2.3 in the NSCLC and 4.5±1.7 in the melanoma population (p=0.09). Mean CFQ-11 physical symptoms score was 10.6±4.3 in the NSCLC and 9.2±3.4 in the melanoma population (p=0.01) (**Figure 5B**).
- The CFQ-11 total score was assessed in the following subgroups of interest:
  - A significant difference was associated with occupational activity in the melanoma group (12.5 in active patients and 14.4 in inactive patients, p=0.05). In NSCLC patients, the difference was not significant (p=0.88).
  - No differences were observed between subgroups for age (p=0.43 in NSCLC and p=0.07 in melanoma groups), treatment discontinuation (p=0.66 in NSCLC and p=0.13 in melanoma groups), time since ICI initiation (p=0.10 in NSCLC and p=0.32 in melanoma groups) and prior treatment (p=0.54 in NSCLC and p=0.32 in melanoma groups).

Figure 5. Mean CFQ-11 (fatigue) scores

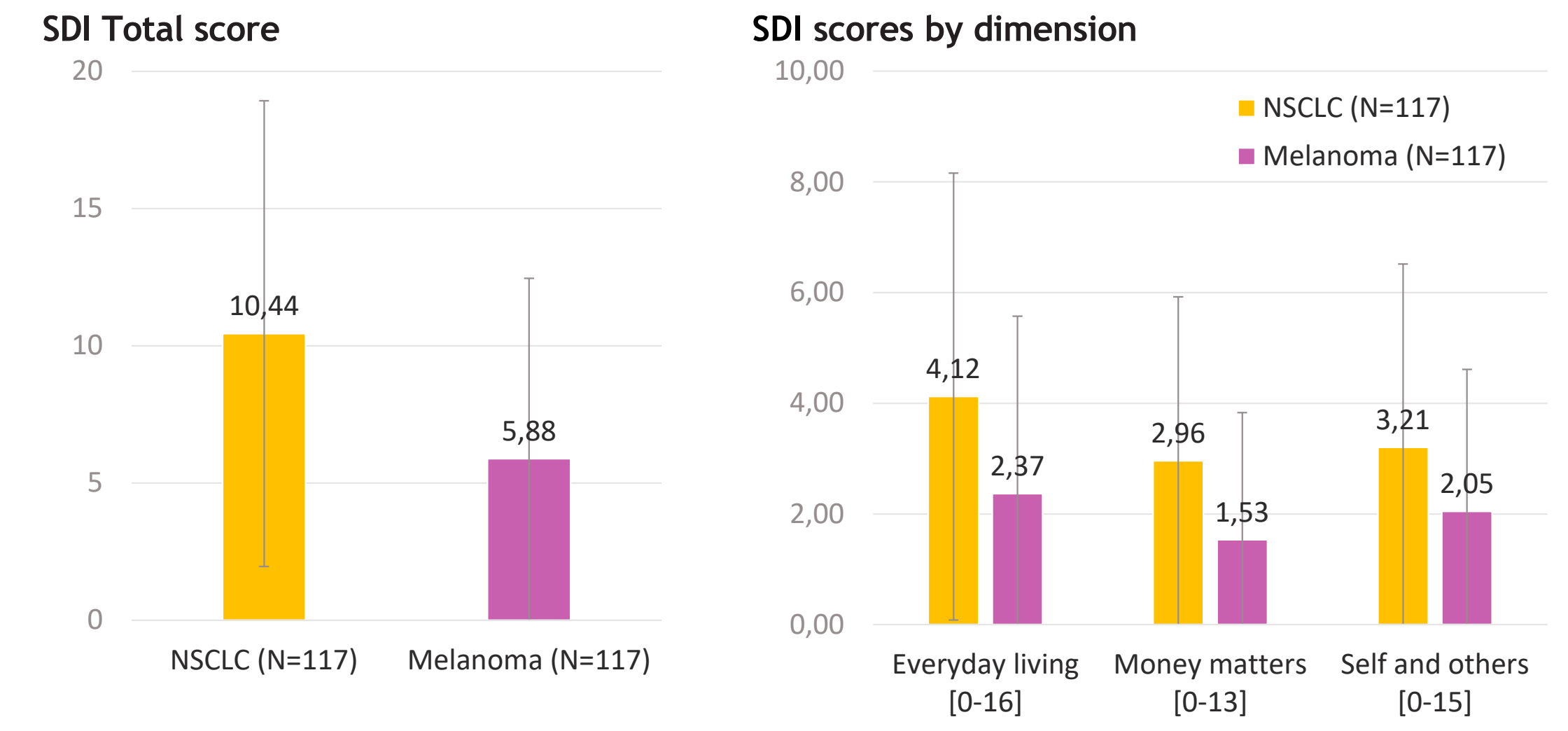

CFQ-11 Total scores

CFQ-11 scores by dimension

SDI assessment

- Total SDI scores were 10.4±8.5 in NSCLC cohort and 5.9±6.6 in melanoma cohort (**Figure 6**).
- Approximately half of the patients in the NSCLC group and a quarter of the patients in the melanoma group scored over the threshold of 10 beyond which patients are considered as having difficulty.
- These differences were observed by dimension for the daily life score (4.1±4 in the NSCLC and 2.4±3.2 in the melanoma population, p<0.001), for the financial problems score (3±3 in the NSCLC and 1.5±2.3 in the melanoma population, p<0.001), and for the personal and other score (3.2±3.3 in the NSCLC and 2±2.6 in the melanoma population, p=0.01) (**Figure 6**).

Figure 6. Mean SDI scores


SDI Total score

SDI scores by dimension

- The SDI total score was **associated with age** in the NSCLC cohort (12.7±8.8 in <65 years patients and 8.5±7.7 in ≥65 years patients, p=0.02), and in melanoma cohort (8.4±7.3 in <65 years patients and 4.3±5.6 in ≥65 years patients, p<0.01).
- The SDI total score was **not associated with the professional activity in the NSCLC group** (p=0.5). It was **associated with professional activity in the melanoma group** (8.0±7.2 in the active and 4.8±6 in the inactive patients, p=0.02).
- No difference was observed between subgroups for treatment discontinuation (p=0.14 in NSCLC and p=0.92 in melanoma groups) and for to time since ICI was started (p=0.63 in NSCLC and p=0.41 in melanoma groups).

Emotional state

- Overall, 33.1% of NSCLC and 34.2% of melanoma patients were quite or very worried about future outcomes, 45.3% of NSCLC and 42.6% of melanoma were quite or very worried that someone else in their family might have cancer and 45.5% of NSCLC and 33.4% of melanoma felt quite to very uncertain about the future.
- In addition, 35.6% of NSCLC and 20% of the melanoma patients felt that the disease had brought quite a lot or a lot of positive changes in their lives.

Table 2. Items from the QoL-CSV questionnaire in patients with NSCLC (N=117) and with melanoma (N=117)

		NSCLC (N=117)	Melanoma (N=117)	p (chi² test)
Anxious/worried about future test results	Not at all	30 (26,1%)	32 (27,4%)	0,7
	A little	47 (40,9%)	45 (38,5%)	
	Quite	30 (26,1%)	27 (23,1%)	
	Many	8 (7,0%)	13 (11,1%)	
Afraid that someone else in the family had cancer	Not at all	29 (25,2%)	28 (24,3%)	0,27
	A little	34 (29,6%)	38 (33,0%)	
	Quite	21 (18,3%)	29 (25,2%)	
	Many	31 (27,0%)	20 (17,4%)	
Feel uncertain about future	Not at all	21 (18,1%)	27 (23,7%)	0,08
	A little	41 (35,3%)	49 (43,0%)	
	Quite	31 (26,7%)	28 (24,6%)	
	Many	23 (19,8%)	10 (8,8%)	
Positive changes in life with the cancer	Not at all	56 (48,7%)	61 (53,0%)	0,03
	A little	18 (15,7%)	31 (27,0%)	
	Quite	26 (22,6%)	16 (13,9%)	
	Many	15 (13,0%)	7 (6,1%)	

Conclusion

- QUALICI was the first collection of real-life HRQoL data in durable ICI responders in France and one of the first in Europe. It provided comprehensive results on patient QoL with questionnaires covering a broad range of dimensions, rarely explored in previous studies.
- Patients with ICI-DR had an overall satisfying HR-QoL, although EQ-5D-5L assessments remained below those of the general population of their age (8).
- However, patients' situations were miscellaneous and some continued to have impairments in different domains, including their physical and social role, emotional functioning or financial conditions and fatigue.
- A few of them particularly among NSCLC ICI-DR patients experienced significant QoL issues, which would require a specific management.

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