Quality of life at diagnosis for unresectable stage III NSCLC : initial results from the national prospective study OBSTINATE (GFPC 06-2019)

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GFPC Groupe Français de Pneumo-Cancérologie French Lung Cancer Group

PARIS 2022 ESMO congress

BACKGROUND

Consolidation immunotherapy (IO) has deeply modified the prognosis of patients with locally advanced NSCLC.
However, its impact on health-related quality of life (HRQoL) has not been assessed outside the clinical trial context.
The aim of the OBSTINATE (GFPC 06-2019) study is to prospectively evaluate HRQoL in unresectable stage III NSCLC in «real-world» setting.

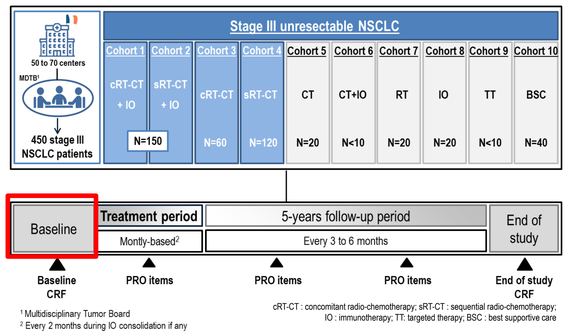
METHODS

Objectives

Primary objective:
- Assess HRQoL for unresectable stage III NSCLC in a "real-world" oncological practice.

Main secondary objectives:
- Characterize the stage III unresectable NSCLC patients (baseline patient demographics, clinical, pathological and molecular characteristics)
- Describe the "real-life" management of the stage III unresectable NSCLC (e.g. time from diagnosis to treatment, modality of follow-up)
- Describe the therapeutic strategy (e.g., dose, reduction, interruptions, duration)
- Estimate the progression-free-survival, time-to-progression, type of progression and overall survival
- Describe therapeutic management after disease progression: type of treatments and outcomes
- Assess the socio-economic and occupational impact of stage III NSCLC diagnosis and treatment for patients

Patients and study design



- Design: prospective observational national multicentric study
- First inclusion : déc. 2020 ; 450 planned to be enrolled
- Main inclusion criteria: treatment-naïve unresectable TNM stage III NSCLC (8th TNM IASLC edition), patient willing and able to complete collection of data via self-assess-questionnaires
- Exclusion Criteria: early stage NSCLC initially treated locally (surgery or others) and classified as pathological TNM stage III, inability to read and/or fill out self-assess questionnaires
- HRQoL evaluation : QLQ-C30; QLQ-LC13 and 5QD5-5L self-assessment questionnaires
- ClinicalTrials regristration: NCT05049044

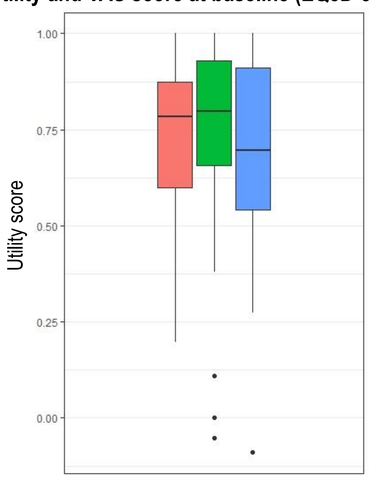
RESULTS

Demographics according pre-specified therapeutic strategy defined by MTB

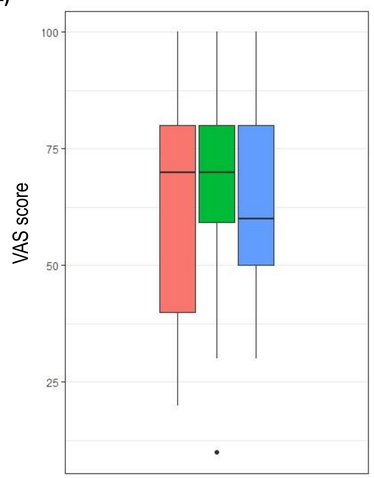
		cRT-CT(+/-IO)	sRT-CT(+/-IO)	CT(+/-IO)	RT	IO	BSC	Others *	All *
N		84	27	41	1	5	1	3	**162**
Age	Mean (SD)	65.7 (8.0)	70.8 (9.3)	67.6 (7.8)	73.0	74.0 (9.2)	81.0	71.0	**67.4 (8.4)**
	Median (min; max)	66.0 (45; 92)	72.0 (49; 86)	67.0 (49; 83)	73.0 (73; 73)	75.0 (63; 87)	81.0 (81; 81)	71.0 (71; 71)	**67.0 (45; 92)**
Gender	M	66 (78.6%)	17 (63.0%)	23 (56.1%)	1	4 (80.0%)	1 (100%)	2 (100%)	**114 (70.8%)**
	F	18 (21.4%)	10 (37.0%)	18 (43.9%)	0	1 (20.0%)	0	0	**47 (29.2%)**
WHO performans status at diagnosis	0	48 (64.0%)	11 (44.0%)	18 (51.4%)	0	2 (40.0%)	0	0	**79 (55.2%)**
	1	22 (29.3%)	11 (44.0%)	15 (42.9%)	0	3 (60.0%)	0	2	**53 (37.1%)**
	2	5 (6.7%)	3 (12.0%)	2 (5.7%)	0	0	0	0	**10 (7.0%)**
	3	0	0	0	0	0	1	0	**1 (0.7%)**
	Unknown	9	2	6	1	0	0	1	**19**
Smoking history	Current	38 (45.2%)	13 (48.1%)	18 (43.9%)	0	4 (80.0%)	0	1	**74 (46.0%)**
	Former	44 (52.4%)	13 (48.1%)	17 (41.5%)	1	1 (20.0%)	1	1	**78 (48.4%)**
	Non smoker	2 (2.4%)	1 (3.7%)	6 (14.6%)	0	0	0	0	**9 (5.6%)**
	Unknown	0	0	0	0	0	0	1	**1**
Pathology subtype	ADC	32 (40.5%)	8 (30.8%)	20 (48.8%)	0	3 (60.0%)	1	2	**66 (42.6%)**
	LCC	2 (2.5%)	2 (7.7%)	3 (7.3%)	0	0	0	0	**7 (4.5%)**
	SCC	38 (48.1%)	14 (53.8%)	15 (36.6%)	1	2 (40.0%)	0	0	**70 (45.2%)**
	Others	7 (8.9%)	2 (7.7%)	3 (7.3%)	0	0	0	0	**12 (7.7%)**
	Unknown	5	1	0	0	0	0	1	**7**
TNM stage	IIIA	37 (46.3%)	8 (29.6%)	12 (30.0%)	0	2 (40.0%)	1	0	**60 (38.5%)**
	IIIB	36 (45.0%)	13 (48.1%)	18 (45.0%)	1	3 (60.0%)	0	1	**72 (46.8%)**
	IIIC	7 (8.8%)	6 (22.2%)	9 (22.5%)	0	0	0	0	**22 (14.1%)**
	Others	0	0	1 (2.5%)	0	0	0	0	**1 (0.6%)**
	Unknown	4	0	0	0	0	0	2	**6**
PD-L1 status	Positive	57 (71.3%)	16 (66.7%)	26 (65.0%)	1	5 (100.0%)	1	1	**107 (69.9%)**
	Négative	21 (26.3%)	8 (33.3%)	13 (32.5%)	0	0	0	0	**42 (27.5%)**
	Unknown	6	3	2	0	0	0	2	**13**

* Missing data for 1 patients

Utility and VAS score at baseline (EQ5D-5L)



Utility score : assigns a numerical value to health status (from 0 to 1)



VAS score : visual analogic scale evaluating patients global health status

CT(+/-IO)
cRT-CT(+/-IO)
sRT-CT(+/-IO)

- Mean utility score tend to be higher in patients referred to cRT-CT(+/-IO) : 0.75+/-0.23 (vs 0.65+/-0.27 and 0.70+/-0.25)

NB : 0.08 point difference is considered clinically significant for utility score

- No clinically significant difference in mean VAS score was observed between the cohorts

NB : 7 points difference is considered clinically significant for VAS score

- Mean QLQ-C30 score tend to favor patients referred to cRT-CT(+/-IO) vs sRT-CT(+/-IO):
  . Role functioning : 76.5±26.0 vs 65.3±34.7
  . Emotional functioning : 77.2±22.7 vs 66.7±25.7
  . Cognitive cognitive functioning : 88.3±17.6 vs 78.0±22.6

NB : 10 points difference is considered clinically significant for QLQ-C30 scores

Completion rates of the HRQoL questionnaires at baseline

		cRT-CT (+/-IO) N=84	sRT-CT (+/-IO) N=27	CT(+/-IO) N=41	All N=162
QLQ-C30	Completed	74 (88.1%)	24 (88.9%)	33 (80.5%)	**140 (86.4%)**
	Not done	2 (2.4%)	0	2 (4.9%)	**4 (2.5%)**
	Unknown	8 (9.5%)	3 (11.1%)	6 (14.6%)	**18 (11.1%)**
QLQ-LC13	Completed	74 (88.1%)	24 (88.9%)	33 (80.5%)	**140 (86.4%)**
	Not done	2 (2.4%)	0	2 (4.9%)	**4 (2.5%)**
	Unknown	8 (9.5%)	3 (11.1%)	6 (14.6%)	**18 (11.1%)**
EQ-5D	Completed	74 (88.1%)	24 (88.9%)	33 (80.5%)	**140 (86.4%)**
	Not done	2 (2.4%)	0	2 (4.9%)	**4 (2.5%)**
	Unknown	8 (9.5%)	3 (11.1%)	6 (14.6%)	**18 (11.1%)**

- Completion rates of the HRQoL questionnaires at baseline: **140/162 (86%)**
- Median delay from diagnosis to HRQoL evaluation: **26 days**
- Mean delay from HRQoL evaluation to treatment initiation: **3 days**

Rador plot of median QLQ-C30 QoL scores at baseline

QL: Global QoL, PF: Physical functioning, RF: Role functioning, EF: Emotional functioning, CF: Cognitive functioning, SF: Social functioning, FA: fatigue, NV: nausea, PA : pain, DY : dyspnea, SL : insomnia, AP : appetite loss, CO : constipation, DI : Diarrhoea, FI : Financial difficulties

CONCLUSION

- → **OBSTINATE is the first study to prospectively evaluate HRQoL in unresectable stage III NSCLC on a large national scale.**
- → **At baseline, patients referred to concomitant cRT-CT+/-IO treatment tend to show better HRQoL.**
- → **Further follow-up is ongoing to evaluate modification of HRQoL during treatment**

The OBSTINATE (GFPC 06-2019) is supported by Astrazeneca

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Presenter conflict of interest statement: C. Ricordel declares personal and institutional financial interest as invited speaker for Takeda, Astrazeneca and as advisory role for BMS, MSD and Takeda

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