

VIRTUAL
2020

ESMO

congress

Impact of the COVID-19 pandemic on management of medical cancer treatments and psychological consequence for the patients : the COVIPACT study.

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DISCLOSURE INFORMATION

No conflict interest in link with the topic

COVIPACT study design

ONGOING COVIPACT Study (NCT04366154)

PATIENTS in OUTPATIENT DEPARTMENT *

Study information to patient and information note

If no opposition of the patient to participate

Patient asked to complete self-questionnaires on

- **Stress** → Perceived Stress Scale
→ Impact of Event Scale-revised (IERS-R)
- **Sleep quality** → ISI
- **Quality of Life** → Fact-G
- **Cognition** → Fact-Cog
- *Containement questionnaire (at 3 months only)*

Data collection on medical records

Medical oncological dpt

At inclusion

*(during the French lockdown
2020, April 8th to May 29th)*

Thereafter
At 3 months
At 6 months

HEALTHCARE PROFESSIONALS in OUTPATIENT DEPARTMENT

Study information to caregiver and information note

If no opposition of the caregiver to participate

Caregiver asked to complete self-questionnaires on

- **Stress** → Perceived Stress Scale
→ Impact of Event Scale-revised (IERS-R)
(at 3 months only)
- **Scale of professional exhaustion**
→ Maslach Burnout Inventory (MBI)
- **Feeling of personal efficiency**
→ Generalized Self Efficacy Scale, GSES

* Medical oncological treatment carried out at the day care hospital, initiated before or during the pandemic

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Results during lockdown

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COVIPACT ENDPOINTS – Questionnaires during lockdown

Main endpoint:

Proportion of patients with medical oncological treatment modifications in linked with the pandemic situation

Secondary endpoints : psychological impact of the pandemic-related lockdown

◆ Among **cancer pts** and medical **oncologists** and oncological day care Unit **Caregivers**

Questionnaires	Items/ scores	Pts	Caregivers
Perceived Stressed Scale (PSS)	10 items : score 0 to 40 (categorized in Low/Medium/High)	+	+
Impact of Event Scale-Revised Scale (IES-R)	22 items : score 0 to 88 (categorized in Low/Medium/High)	+	-
Sleep difficulty severity (ISI)	7 items : score 0 to 28 (categorized in No or slight/Moderate or severe)	+	-
Quality of life (Fact-G)	27 items grouped in 4 dimensions	+	-
Cognitive complaint (Fact-Cog)	37 items grouped in 4 dimensions	+	-
Professional accomplishment (BMI Scale)	22 items, 3 dimensions categorized in Low/Medium/High)	-	+
Personal Efficiency (GSES)	10 items : score 0 to 40	-	+

Population recruitment during lockdown

ONCO-HEMATOLOGY PATIENTS

CAREGIVERS IN ONCO-HEMATOLOGY

Eligibility criteria

- Adult patient, treated for a solid or hematological tumor
- Medical oncological treatment carried out at the day care hospital, initiated before or during the pandemic
- No opposition from the patient to participate

- Medical oncologist, hematologist, intern, nurse and caregiver in day hospital agreeing to participate

N = 735

N = 73

Sample size
(for the main endpoint)

at least 385 patients to estimate the rate of lockdown-induced treatment modifications with 5% margin error

Recruitment
(April 8th to May 29th 2020)



*To date, data collected for **621 patients** (575 questionnaires) for the first baseline analysis during lockdown period*

Populations description

Patients : N = 621

	N	(%)
Female	443	(71%)
Median age [range]	64	[24-89]
OMS 0-1*	576	(94%)
Solid tumors	611	(98%)
Primary tumor site		
<i>Breast</i>	273	(45%)
<i>Digestive</i>	105	(17%)
<i>Lung – Head and neck</i>	123	(20%)
<i>Urologic – Genital</i>	25	(4%)
<i>Gynecological</i>	68	(11%)
<i>Other</i>	17	(3%)
Metastatic disease	364	(59%)

* 7 missing values

Caregivers : N = 73

	N	(%)
Female	59	(81%)
Median age [range]	40	[22-63]
Position		
<i>Nurse</i>	35	(48%)
<i>Nursing assistant</i>	4	(6%)
<i>Medical oncologist*</i>	23	(31%)
<i>Resident</i>	5	(7%)
<i>Other</i>	6	(8%)
Years of experience		
≤10	36	(49%)
11-20	18	(25%)
>20	19	(26%)

* 1 hematologist

Treatments during the lockdown

	Total (n=621)	Start of treatment with regard to lockdown period	
		during (n=227)	before (n=394)
Lines of treatments			
<i>First line</i>	295 (48%)	118 (40%)	177 (60%)
<i>Relapse</i>	328 (52%)	109 (34%)	217 (66%)
Treatments			
<i>Chemotherapy alone</i>	345 (55%)	160 (46%)	185 (54%)
<i>Chemotherapy + other*</i>	99 (16%)	36 (36%)	63 (64%)
<i>Immunotherapy alone</i>	70 (11%)	15 (21%)	55 (79%)
<i>Targeted therapy +/- other*</i>	97 (16%)	6 (6%)	91 (94%)
<i>Non anti-cancer treatment</i>	10 (2%)	10 (100%)	0 (0%)

* Other: immunotherapy or hormonotherapy

Among the *de-novo* treated patients (1st line medical treatment), 33% had a metastatic disease.

% of treatment modifications : Total 27%

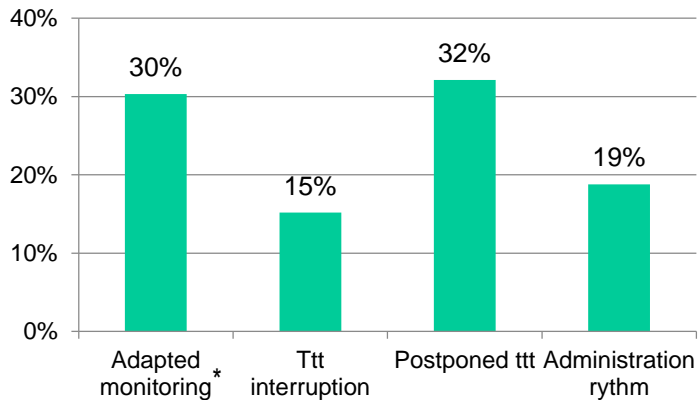
		Total	
		N=165	p
Age	> 65	72 (29%)	0.16
	≤ 65	93 (25%)	
Gender	Male	48 (27%)	0.97
	Female	117 (26%)	
OMS*	0-1	150 (26%)	0.84
	2-3	11 (29%)	
Primary tumor site	Breast	75 (27%)	<0.001
	Digestive	11 (10%)	
	Lung – Head and neck	50 (41%)	
	Urologic – Genital	5 (20%)	
	Gynecological	15 (22%)	
	Other	6 (35%)	
Disease status	Metastatic	103 (29%)	0.21
	Localized	59 (24%)	

- More treatment modifications among lung and head and neck cancers pts.
- ~ 25% of pts with modifications whatever the metastatic/localized status.

* 4 Missing values

Type of treatment modifications

Total (n = 165)



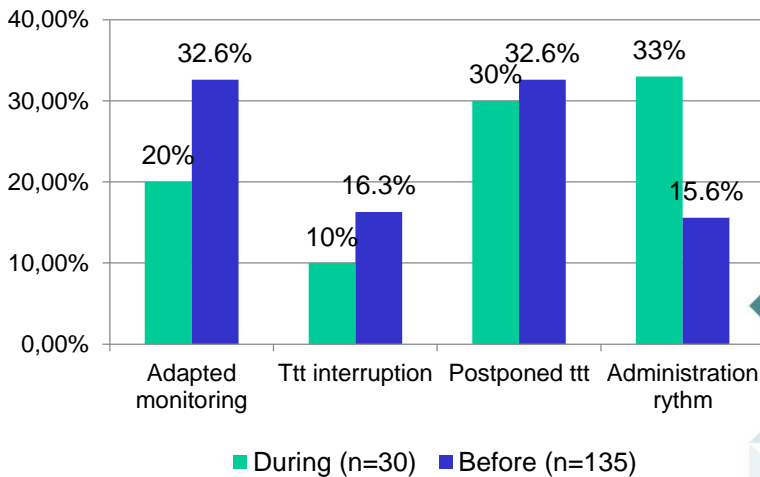
**phone consultation and visio consultation*

Among the 2 pts with Covid infection : Chemo postponed for 1 pt and no modification of immunotherapy for the other pt

Type of treatment modifications

According to start of treatments with regard to lockdown

- More frequent adapted monitoring among pts with ongoing tt
- More revised rythms of administration for pts who initiated tt during the lockdown



% of treatment modifications : Total 27%

	Total	P
	N=165	
Line of treatments		<i>0.007</i>
<i>First line</i>	63 (21%)	
<i>Relapse</i>	102 (31%)	
Treatments		<i><0.001</i>
<i>Chemotherapy alone</i>	61 (18%)	
<i>Chemotherapy + other</i>	23 (23%)	
<i>Immunotherapy alone</i>	34 (49%)	
<i>Targeted therapy + other</i>	46 (47%)	

- Less modifications when 1st line TTs.
- Half of immunotherapy treatments have been modified (including 18% interruption, 38% postponed and 38% modified TT rythm*)

- Half of TTs including targeted therapy have been modified (including 39% of tele-or phone consultations and 46% postponed treatments*)
- Only 18% of chemotherapy alone TTs have been modified (including 43% of tele- or phone consultations*)

*Not exclusive

Patients' psycho-emotional status during lockdown

Scores	Total	Pts with ttt modifications		P
		Yes	No	
Stress related to event (IES-R) (n=575)				0.049
<i>Low</i>	190 (33%)	53 (35%)	137 (32%)	
<i>Medium</i>	263 (46%)	58 (38%)	205 (49%)	
<i>High</i>	122 (21%)	41 (27%)	81 (19%)	
Perceived stress (PSS) (n=571)				0.061
<i>Low</i>	272 (48%)	75 (50%)	197 (47%)	
<i>Medium</i>	265 (46%)	61 (41%)	204 (49%)	
<i>High</i>	34 (6%)	14 (9%)	20 (5%)	
Insomnia (ISI) (n=570)				0.55
<i>No or slight</i>	434 (76%)	111 (75%)	323 (77%)	
<i>Moderate or severe</i>	136 (24%)	38 (25%)	98 (23%)	

- High level of stress among the pts
- Stress related to event more often observed in patients with modified treatments

Patient's Quality-of-life during lockdown

Scores	Total	Pts with ttt modifications		P
		Yes	No	
FACT-G*				
<i>Global</i>	75.1 (15.5)	74.5 (16.3)	75.3 (15.2)	0.81
<i>Physical</i>	20.8 (5.5)	21 (5.4)	20.7 (5.5)	0.55
<i>Social/Family</i>	21.1 (5.1)	20.7 (5.3)	21.3 (4.9)	0.31
<i>Emotional</i>	16.9 (15.1)	16.7 (5.3)	16.9 (5.1)	0.78
<i>Functional</i>	16.3 (5.7)	16.1 (5.9)	16.4 (5.6)	0.68
FACT-COG*				
<i>PCI</i>	60.1 (12.6)	60 (12.2)	60.1 (12.7)	0.61
<i>QoL</i>	10.6 (4.6)	10.5 (4.6)	10.7 (4.6)	0.5
<i>Oth</i>	15.1 (2)	14.9 (2.2)	15.2 (1.9)	0.12
<i>PCA</i>	19.8 (6.1)	19.6 (5.9)	19.9 (6.2)	0.4

* Fact G: quality of life ; Fact Cog: cognition

- No impact of treatment modifications on quality of life of the patients

Caregiver emotional, personal and professional accomplishment

Caregivers	
Perceived stress (PSS)	
Continuous score	16.3 (\pm 7.1)
Categorized score	
<i>Low</i>	27 (37%)
<i>Medium</i>	39 (53%)
<i>High</i>	7 (10%)

High level of :

- Perceived stress

However high level as well of:

- Professional Accomplishment
- Personal self efficacy

Total	
Professional accomplishment (MBI)	
Emotional exhaustion	
<i>Low</i>	41 (56%)
<i>Medium</i>	17 (23%)
<i>High</i>	15 (21%)
Depersonalization	
<i>Low</i>	40 (55%)
<i>Medium</i>	19 (26%)
<i>High</i>	14 (19%)
Personal accomplishment	
<i>Low</i>	5 (7%)
<i>Medium</i>	24 (33%)
<i>High</i>	43 (60%)
Personal self-efficacy	
Score (/40)	32.8 (\pm 4.5)

Caregiver emotional, personal and professional accomplishment

	Caregivers	Patients	p
Perceived stress (PSS)			
Continuous score	16.3 (±7.1)	14.3 (±7.5)	0.035
Categorized score			0.17
<i>Low</i>	27 (37%)	272 (48%)	
<i>Medium</i>	39 (53%)	265 (46%)	
<i>High</i>	7 (10%)	34 (6%)	

	Total
Professional accomplishment (MBI)	
Emotional exhaustion	
<i>Low</i>	41 (56%)
<i>Medium</i>	17 (23%)
<i>High</i>	15 (21%)
Depersonalization	
<i>Low</i>	40 (55%)
<i>Medium</i>	19 (26%)
<i>High</i>	14 (19%)
Personal accomplishment	
<i>Low</i>	5 (7%)
<i>Medium</i>	24 (33%)
<i>High</i>	43 (60%)
Personal self-efficacy	
Score (/40)	32.8 (±4.5)

- Higher level of perceived stress among caregivers than among patients.

Conclusions

Summary

- Among this large series of pts treated with medical oncological treatments during the lockdown period **> ¼ of treatment modifications** have been induced by pandemic context whatever the situation of the disease (advanced/localized)
 - mainly modification of monitoring follow-up and postponed treatments administrations
 - few interruption of treatments
- **Negative impact** of treatments modifications **on stress** related to event among **patients**
- Even if **caregivers** expressed a high level of perceived stress during the lockdown period, they reported **high levels of self efficacy and professional accomplishment**

Perspectives

- The Covid-19 pandemic is not over ! ... The next step of the study is the evaluation of the **evolution of psychosocial parameters over time** (3 and 6 months) after the lockdown among patients and caregivers



We encourage rapid implantation of psychosocial support for ongoing treated cancer patients to promote emotional resilience in order to avoid post-traumatic stress

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