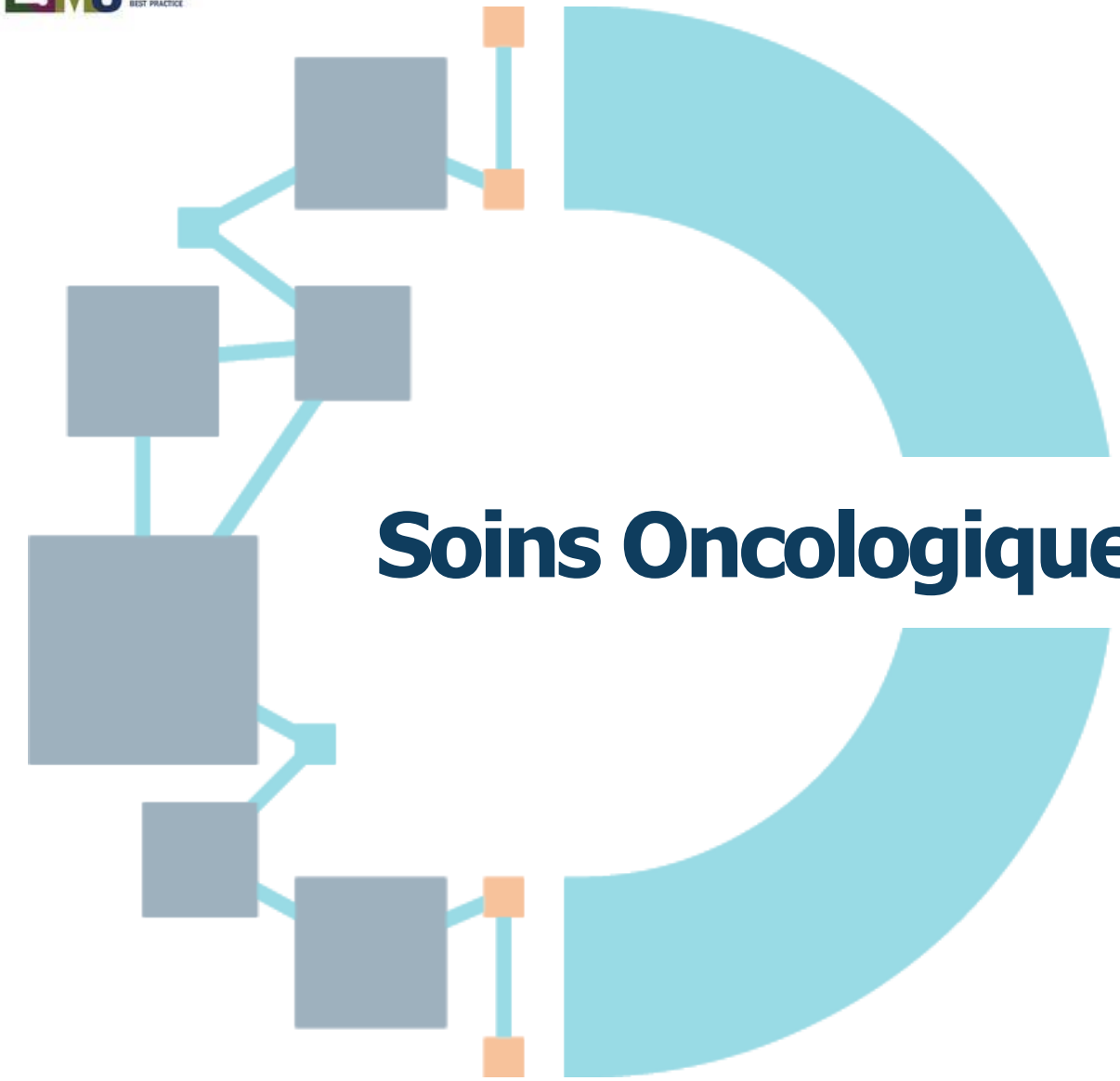


Soins Oncologiques de Support

Mardi 21 novembre 2023

Palais de la Bourse - Bordeaux

Dr Amandine Quivy CHU Bordeaux

Les « Actus » de l'ESMO – Soirée Post-ESMO Bordeaux 2023

Liens d’intérêts

- Aucun

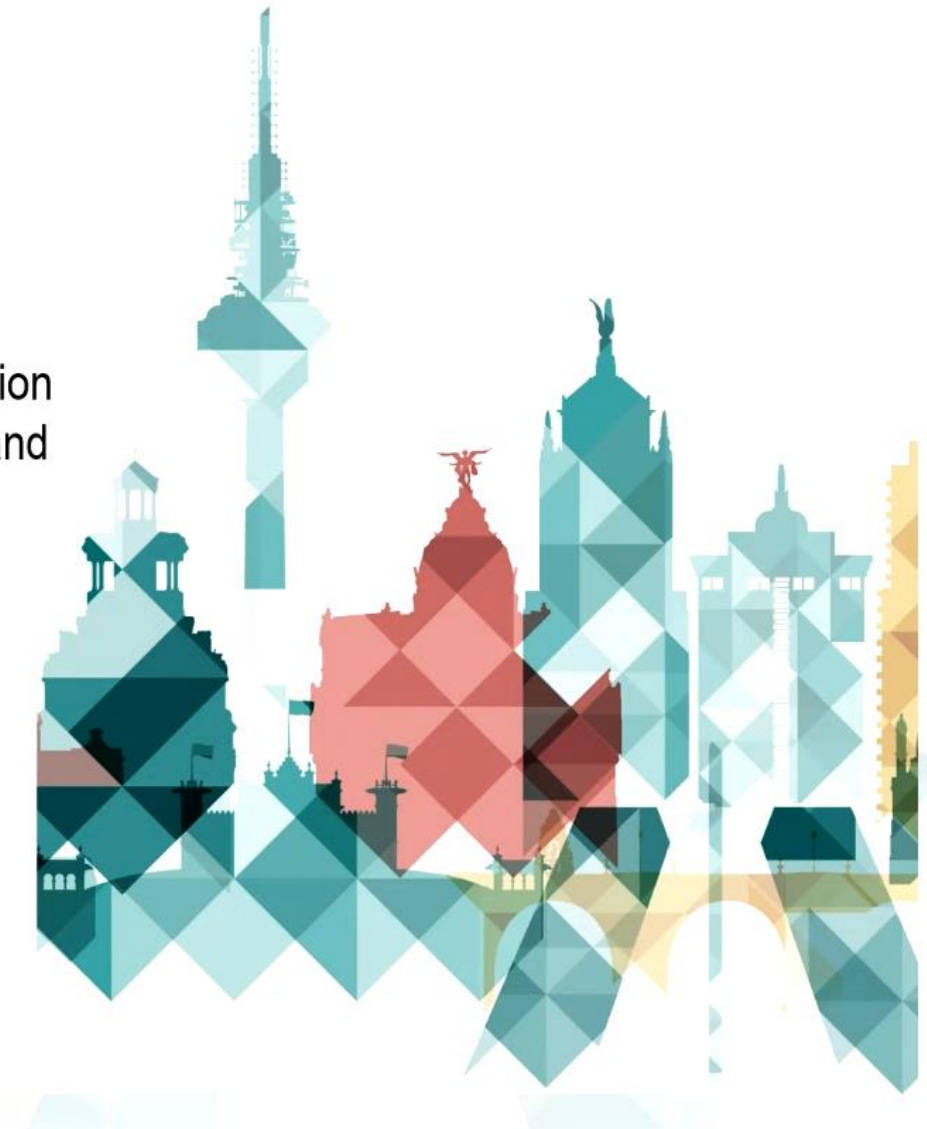
MADRID 2023 ESMO congress

ANTIEMETICS

2023 MASCC/ESMO guideline update for the prevention of chemotherapy- and radiotherapy-induced nausea and vomiting.

Jørn Herrstedt[1,2], R Clark-Snow, CH Ruhlmann, A Molassiotis, I Olver, BL Rapoport, M Aapro, K Dennis, PJ Hesketh, RM Navari, L Schwartzberg, ML Affronti, MA Garcia-Del-Barrio, A Chan, L Celio, R Chow, M Fleury, RJ Gralla, R Giusti, F Jahn, H Iihara, E Maranzano, V Radhakrishnan, M Saito, P Sayegh, S Bosnjak, Li Zhang, J Lee, V Ostwal, T Smit, A Zilic, K Jordan, F Scotté.

1. Zealand University Hospital, Roskilde, Denmark
2. Copenhagen University, Copenhagen, Denmark



COMMITTEE I (1/5)

MASCC/ESMO emetic risk groups 2023*

INTRAVENOUS AGENTS	EMETIC RISK	ORAL AGENTS**	EMETIC RISK
HIGH	Risk in > 90% of patients	High/Moderate	Risk in ≥ 30% of patients
MODERATE	Risk in 30% to 90% of patients		
LOW	Risk in 10% to 30% of patients	Low/Minimal	Risk in < 30% of patients
MINIMAL	Risk in < 10% of patients		

*Proportion of patients experiencing emesis in the absence of effective antiemetic prophylaxis. The incidence of nausea is not part of the risk classification.

**The emetic potential of the oral anticancer agents is based upon a full course of therapy and not a single dose within the first cycle.

COMMITTEE II (5/5)

Recommended Olanzapine Dosing

The best investigated dose is 10 mg. 5 mg is superior to placebo, but it is unknown if it is as effective as 10 mg, because no robust studies have compared the 5 mg and 10 mg doses. The only schedule investigated is once daily for 4 days (see note below about sedation).

Level of Evidence:	II
Grade of Recommendation:	B

NOTE: If sedation is a concern a starting daily dose of 5 mg and/or administration at bedtime is an option.

MASCC | ESMO Antiemetic Guideline 2023

ACUTE Nausea and Vomiting: SUMMARY

EMETIC RISK GROUP	ANTIEMETICS						
High Non-AC	5-HT_3	+	DEX	+	NK_1	+	OLZ
High AC	5-HT_3	+	DEX	+	NK_1	+	OLZ
Moderate Carboplatin ≥ AUC 5 Oxaliplatin women ≤ 50 years	5-HT_3	+	DEX	+	NK_1		
Moderate (other than above)*	5-HT_3	+	DEX				
Low	5-HT_3	OR	DEX	OR	DOP		
Minimal	No routine prophylaxis						

*The emetic potential of sacituzumab-govitecan and trastuzumab-deruxtecan appears to be at the high end of the moderate category, most closely resembling that of carboplatin. While prospective studies are needed it is suggested to prevent emesis as for carboplatin.

5-HT_3 = serotonin$_3$ receptor antagonist	DEX = DEXAMETHASONE	NK_1 = neurokinin$_1$ receptor antagonist such as APREPITANT or FOSAPREPITANT or ROLAPITANT or oral or i.v. NEPA (combination of netupitant and palonosetron)	OLZ = OLANZAPINE	DOP = dopamine receptor antagonist

DELAYED Nausea and Vomiting: SUMMARY

EMETIC RISK GROUP	ANTIEMETICS		
High Non-AC*	OLZ	+	DEX
High AC*	OLZ		
Moderate Carboplatin ≥ AUC 5* Oxaliplatin women ≤ 50 years*	No additional routine prophylaxis		
Moderate (other than above)	No additional routine prophylaxis		
Low and Minimal	No additional routine prophylaxis		

*If aprepitant 125 mg is used on day 1, then aprepitant 80 mg x 1 should be administered days 2-3.

DEX = DEXAMETHASONE	OLZ = OLANZAPINE

- Olanzapine 10mg J1 J4 pour HE
- Corticoïdes seulement à J1 sauf pour HE non AC J1 J3
- sacituzumab-govitecan et trastuzumab deruxtecan ME comme carboplatine > AUC 5 donc NK1

Recommandations AFSOS actualisées cette année à suivre

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Geriatric assessment: It is primetime now?

Laura Biganzoli

Department of Medical Oncology
Hospital of Prato
Italy

Practical Assessment and Management of Vulnerabilities in Older Patients Receiving Systemic Cancer Therapy: ASCO Guideline Update

Recommendation
Recommendation 1.1. (Updated) All patients with cancer age 65 years and over with GA-identified impairments should have GAM included in their care plan. GAM includes using GA results to (1) inform cancer treatment decision-making and (2) address impairments through appropriate interventions, counseling, and/or referrals. ***Amendment 1.1a.*** This includes older adults receiving systemic therapy, including chemotherapy, targeted therapy, or immunotherapy

Type; Evidence Quality; Strength of Recommendation
Type: Evidence based, benefits outweigh harms Evidence quality: High Strength of recommendation: Strong

GAM, Geriatric assessment-guided management

Dale et al. J Clin Oncol 2023

Implementation of the recommendation in clinical pratice

Practical Assessment and Management of Vulnerabilities in Older Patients Receiving Systemic Cancer Therapy: ASCO Guideline Update

Recommendation 2.1. (Updated) A GA should include high priority aging-related domains known to be associated with outcomes in older patients with cancer to include assessment of physical and cognitive function, emotional health, comorbid conditions, polypharmacy, nutrition, and social support

Type: Evidence based, benefits outweigh harms
Evidence quality: High

Strength of recommendation: Strong

- Physical function
- Cognitive function
- Emotional health
- Comorbid conditions
- Polypharmacy
- Nutrition
- Social support

Barriers to implementation of GA

- Time required to perform GA
- Lack of adequate resources (qualified staff and financial support) to integrate GA into routine clinical practice
- Lack of relevant knowlwdge or training

Dale et al. J Clin Oncol 2023

Practical Assessment and Management of Vulnerabilities in Older Patients Receiving Systemic Cancer Therapy: ASCO Guideline Update

Clinical interpretation

GAM vs SOC:

- Less chemotherapy toxicity
- Improved adherence to chemotherapy
- Improved patient and caregiver satisfaction with care, communications about aging concerns, and completion of advanced directives

- Evidence more strong for patients who are older and are most vulnerable.
- More evidence for older adults receiving chemotherapy

GAM, Geriatric assessment-guided management; SOC, standard of care

Dale et al. J Clin Oncol 2023

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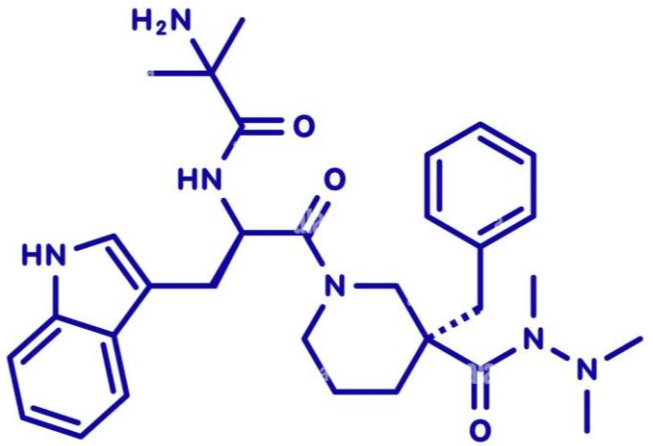
Anamorelin and weight gain in patients with advanced Non-Small Cell Lung Cancer (NSCLC) and cachexia

Efficacy and safety in the multinational phase 3 SCALA program

Prof. David Currow, FAHMS

Faculty of Science, Medicine and Health,
University of Wollongong,
Wollongong, New South Wales, Australia
20 Oct 2023



Anamoreline: agoniste du récepteur à la ghreline

Ghreline : hormone stimulant l'appétit

SCALA Studies: Inclusion Criteria

Female or male ≥18 years of age

Body mass index < 20 kg/m² with involuntary weight loss of >2% within 6 months prior to screening

Ongoing problems with appetite/eating associated with the underlying cancer,

- ≤ 17 points on the 5-IASS AND ≤ 37 points on the 12-item FAACT A/CS

Documented histologic or cytologic diagnosis of unresectable Stage III or IV NSCLC.

ECOG performance status 0, 1 or 2 at screening

A total of **636 patients** (**318** per study) with advanced non-small cell lung cancer (NSCLC) with cachexia were randomized **1:1** to anamorelin 100 mg or placebo

Total of **24 weeks** double-blind treatment with anamorelin or placebo.

A follow-up telephone visit scheduled at Week 26

SCALA Studies: Objectives

Primary Objective

To demonstrate superiority of anamorelin over placebo on body weight gain and improvement in anorexia symptoms

Secondary Objective

To evaluate the safety and tolerability of anamorelin, and to further evaluate the anamorelin efficacy profile

SCALA Primary Efficacy Endpoints

Treatment difference (Anamorelin – Placebo) in:

- Mean change in body weight from baseline over 12 weeks
- Mean change in 5-item Anorexia Symptom Subscale (5-IASS) from baseline over 12 weeks

SCALA Studies: Baseline Characteristics

		Anamorelin (N=313)	Placebo (N=323)
Male	n (%)	228 (72.8%)	226 (70.0%)
White	n (%)	302 (96.5%)	309 (98.7%)
Age (years)	Mean (SD)	64.3 (8.85)	62.9 (10.15)
Age ≤ 65 years	n (%)	169 (54.0%)	185 (57.3%)
Body Mass Index	Mean (SD)	18.4 (1.36)	18.2 (1.58)
Recent Body Weight Loss (%)	Mean (SD)	11.05 (6.76)	10.95 (6.54)
Body weight loss ≤ 10%	n (%)	171 (54.6%)	171 (52.9%)
Stage IV	n (%)	250 (79.9%)	264 (81.7%)
ECOG 2	n (%)	37 (11.8%)	54 (16.7%)
First-line therapy	n (%)	216 (69.0%)	216 (66.9%)
Immunotherapy	n (%)	86 (27.5%)	94 (29.1%)

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Body Weight

Changes from Baseline over 12 weeks*

Study Number	Treatment	n	Mean ± SE	95% CI	p-value
ANAM-17-20	Anamorelin	148	1.960 ± 0.287		
	Placebo	154	0.591 ± 0.287		
	Anamorelin vs. Placebo		**1.369 ± 0.322**	**0.737; 2.001**	**<0.0001**
ANAM-17-21	Anamorelin	150	1.833 ± 0.264		
	Placebo	159	0.536 ± 0.251		
	Anamorelin vs. Placebo		**1.297 ± 0.290**	**0.720; 1.865**	**<0.0001**

SCALA Studies: Treatment Discontinuation

Pooled Studies

	Anamorelin (N=313), n (%)	Placebo (N=323), n (%)
Treatment discontinuation	156 (50%)	165 (51%)
≤6 weeks	54 (17%)	54 (17%)
>6 to ≤12 weeks	41 (13%)	49 (15%)
>12 weeks	61 (19%)	62 (19%)
Reason for treatment discontinuation		
Withdrawal by Subject	62 (20%)	54 (17%)
Adverse Event	32 (10%)	37 (11%)
Death	27 (9%)	31 (10%)
Physician decision	15 (5%)	21 (7%)
Other	13 (4%)	9 (3%)
Lost to follow-up	7 (2%)	13 (4%)

Treatment Emergent Adverse Events Summary

Pooled Studies

	Anamorelin (N=313)			Placebo (N=323)		
	n	%	Events	n	%	Events
Any TEAEs	223	71.2%	868	237	73.4%	903
Drug-related TEAEs	40	12.8%	72	27	8.4%	47
Serious Adverse Events	87	27.8%	116	85	26.3%	119
Drug-Related SAEs	-	-	-	1	0.3%	3
TEAEs CTCAE Grade 3-5	105	33.5%	185	123	38.1%	209
TEAEs leading to treatment Discontinuation	53	16.9%	61	61	18.9%	70
Drug Related TEAEs leading to treatment Discontinuation	2	0.6%	2	5	1.5%	5
Any TEAEs of Special Interest	5	1.6%	5	10	3.1%	12
TEAEs resulting in death	43	13.7%	45	45	13.9%	45

Treatment Emergent Adverse Events of Special Interest

Pooled Studies

	Anamorelin (N=313)		Placebo (N=323)	
	n	%	n	%
Adverse Events of Special Interest	5	1.6%	10	3.1%
Aspartate aminotransferase increase (CTCAE Grade ≥3)	0	0.0%	4	1.2%
Alanine aminotransferase increase (CTCAE Grade ≥3)	1	0.3%	2	0.6%
Presyncope (any CTCAE Grade)	0	0.0%	0	0.0%
Syncope (any CTCAE Grade)	0	0.0%	2	0.6%
Ventricular arrhythmia (CTCAE Grade ≥3)	0	0.0%	0	0.0%
Cardiac failure (CTCAE Grade ≥3)	1	0.3%	1	0.3%
Sudden death	0	0.0%	1	0.3%
Seizure (CTCAE Grade ≥3)	1	0.3%	1	0.3%
Hyperglycemia (CTCAE Grade ≥3)	2	0.6%	0	0.0%

Conclusions:

- gain de poids : 1,3 kgs
- tolérance acceptable

- impact sur sarcopenie ? Gain de masse musculaire ?
- impact sur la survie ?

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The impact of proton pump inhibitor (PPI) exposure before immune checkpoint inhibitor (ICI) therapy on overall survival (OS): A population-based study

Lawson Eng MD, SM, FRCPC, S. Saibil, R. Sutradhar, V. Aghanya, Y. Niu, N. Liu, Y. Liu, Y. Kaliwal, M. Powis, G. Liu, J. Peppercorn, P. Bedard, M. Krzyzanowska

Lawson.eng@utoronto.ca
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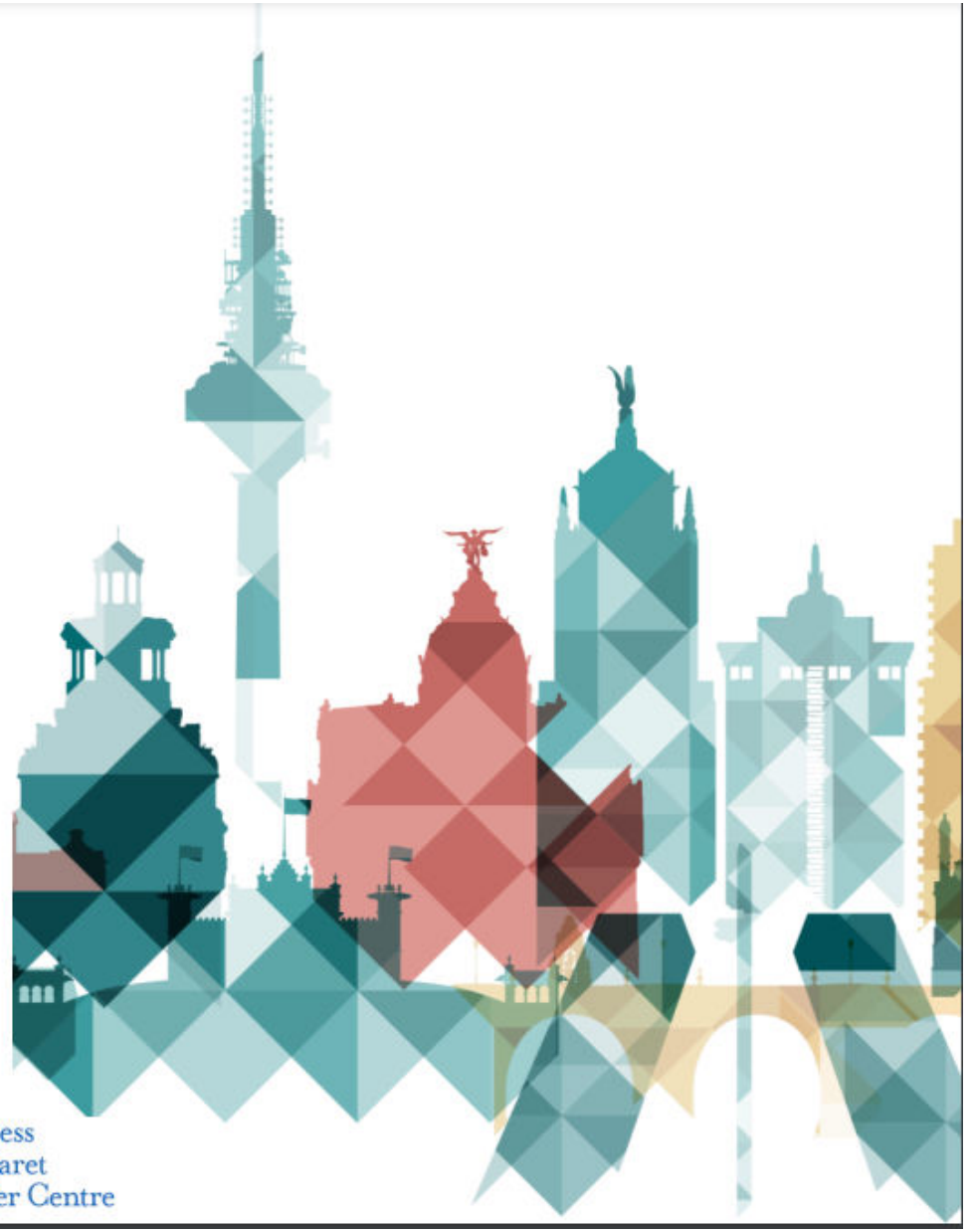
Division of Medical Oncology and Hematology, Princess Margaret Cancer Centre, University of Toronto, Toronto, Canada

Cancer Research Program, Institute for Clinical Evaluative Sciences, Toronto, Ontario, Canada



Medicine UNIVERSITY OF TORONTO

IC/ES Data Discovery Better Health

UHN Princess Margaret Cancer Centre

Rationnel

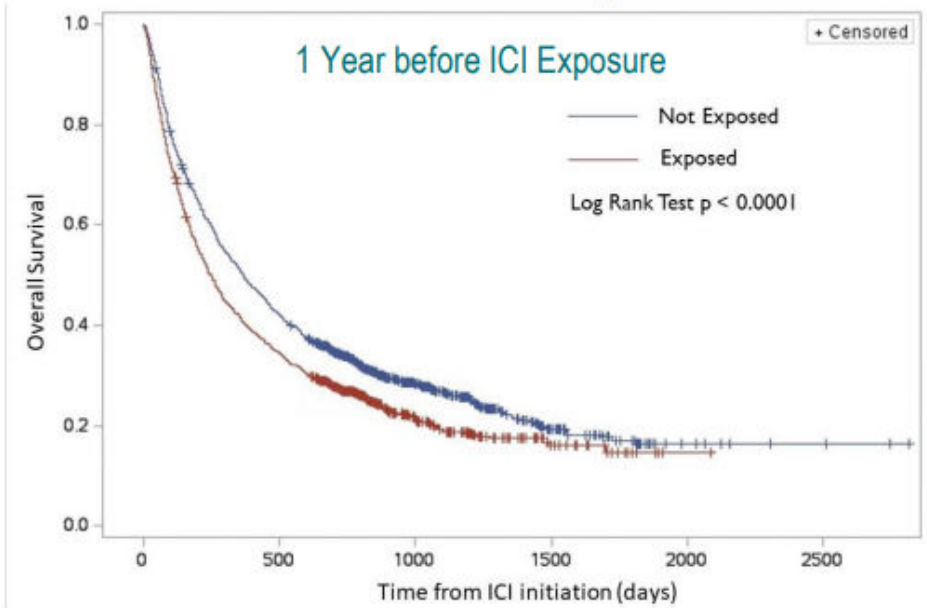
- We have previously used population-level administrative data to demonstrate the negative association of prior antibiotic exposure, in particular fluoroquinolones on ICI outcomes. (En *et al*, Journal of Clinical Oncology June 2023)
- Here we performed a population-level retrospective cohort study to evaluate the impact of PPI exposure prior to starting ICI on overall survival

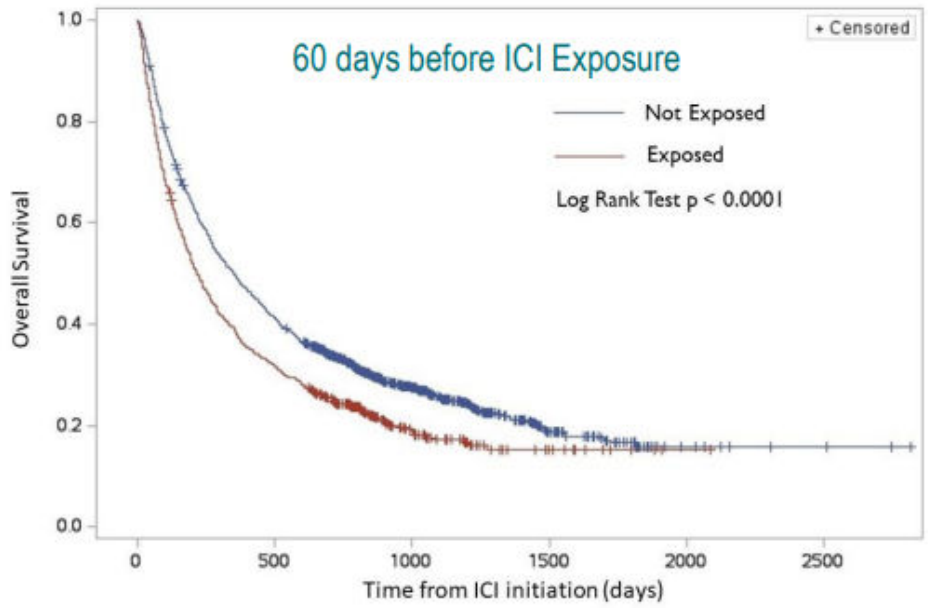
Méthode

- Population-level administrative data for the province of Ontario from the Institute for Clinical Evaluative Sciences (IC/ES) (Ontario, Canada)
- All adult solid tumor patients initiating on ICIs from June 2012 until October 2018
  - Limited to patients age ≥ 65 due to use of prescription claim data for PPIs
- Exposure: PPI exposure within 1 year and within 60 days before starting ICI using claims data
  - Further information collected on specific PPI, doses and duration of exposure
- Primary outcome: Overall survival after initiating on ICI therapy; follow-up until July 2020
- Co-variates: gender, age, BMI, John Hopkin's ACG comorbidity score, history of autoimmune condition, recent hospitalization, treatment facility level, disease site
- Multivariate cox-proportional hazard models were applied to evaluate the impact of PPI exposure prior to ICI on overall survival

Results - Impact of PPI Exposure on Overall Survival

Median Overall Survival: 306 days





Variable	Comparison	1 year before ICI exposure	60 days before ICI exposure
Any PPI Exposure	Yes vs No	aHR = 1.21 95% CI (1.09-1.33), p < 0.001	aHR = 1.26 95% CI (1.13-1.40), p < 0.001
Total weeks of PPI of Exposure	Per 1 week increase	aHR = 1.00 per week (1.00-1.01), p = 0.05	aHR = 1.01 per week (1.00-1.02), p = 0.009

Multivariate results adjusted for age, sex, BMI, facility level of cancer centre administering treatment, autoimmunity history, the John Hopkin's ADG score and hospitalization within the last year

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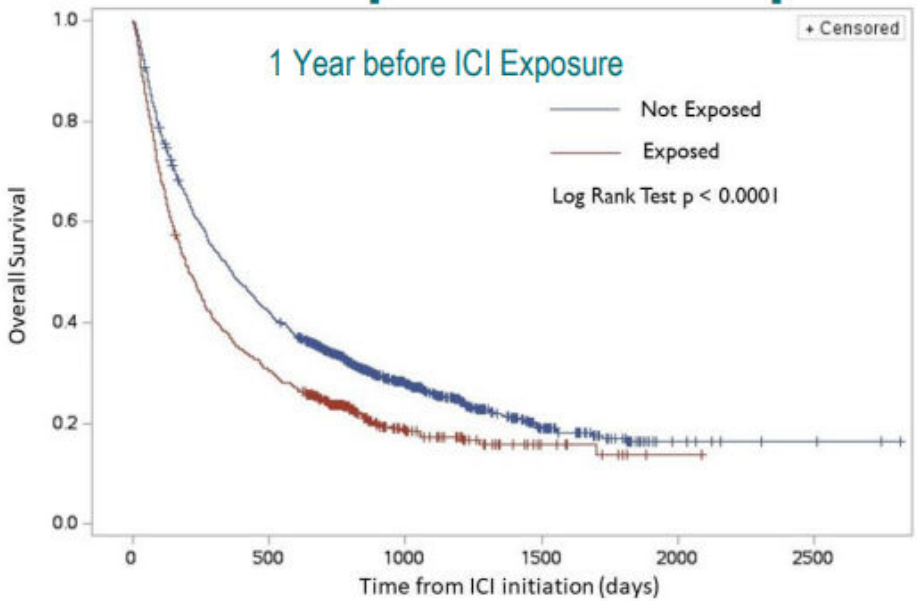
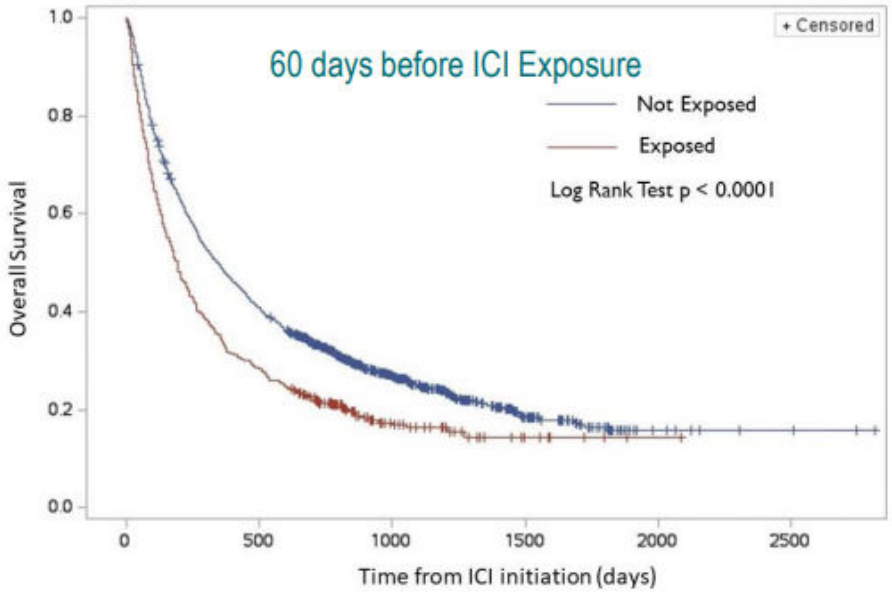
Lawson Eng MD, SM, FRCPC

Results - Impact of Pantoprazole Exposure on Overall Survival





Variable	Comparison	1 year before ICI exposure	60 days before ICI exposure
Any pantoprazole exposure	Yes vs No	aHR = 1.27, 95% CI (1.14-1.41), p < 0.001	aHR = 1.34, 95% CI (1.19-1.52), p < 0.001
Total weeks of pantoprazole of exposure	Per 1 week increase	aHR = 1.00 per week, 95% CI (1.00-1.01), p < 0.02	aHR = 1.02 per week, 95% CI (1.01-1.03), p < 0.001

Multivariate results adjusted for age, sex, BMI, facility level of cancer centre administering treatment, autoimmunity history, the John Hopkin's ADG score and hospitalization within the last year

No other significant associations seen with other PPIs (Rabeprazole, Omeprazole, Lansoprazole)

Subgroup analysis showed consistent associations for patients with lung cancer and melanoma and patients receiving Ipilimumab or Pembrolizumab

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Lawson Eng MD, SM, FRCPC

Conclusions

- Many cancer patients are exposed to PPIs prior to receiving immune checkpoint inhibitors
- Exposure to PPIs prior to starting immune checkpoint inhibitors, and specifically pantoprazole exposure is associated with worse overall survival; with an observed dose effect based on weeks of exposure
- Effects of PPI exposure up to 1 year before starting ICI can impact ICI outcomes
- Interventions aimed at altering the gut microbiome may be required to help improve outcomes for patients receiving immune checkpoint inhibitors previously exposed to PPIs and other exposures that are known to impact the gut microbiome

Posters 2174P et 1514P

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The Effect of Psychological Stress on the Efficacy of First-line Therapy of ICIs in Advanced NSCLC (STRESS-LUNG-1 study)

Fang Wu [1, 2, *], Yue Zeng, Yizheng Li, Junqi Liu, Zhenhua Qiu, Chao Deng, Fang Ma, Chunfang Xia, Mengdong Liu, Bing Zhang, Zemin Xiao, Chaojiu Xu, Zengmei Sheng, Ping Liu, Xiaoyuan Zeng, Yang Zhao, Jiansong zhou, Xianling Liu, Chunhong Hu

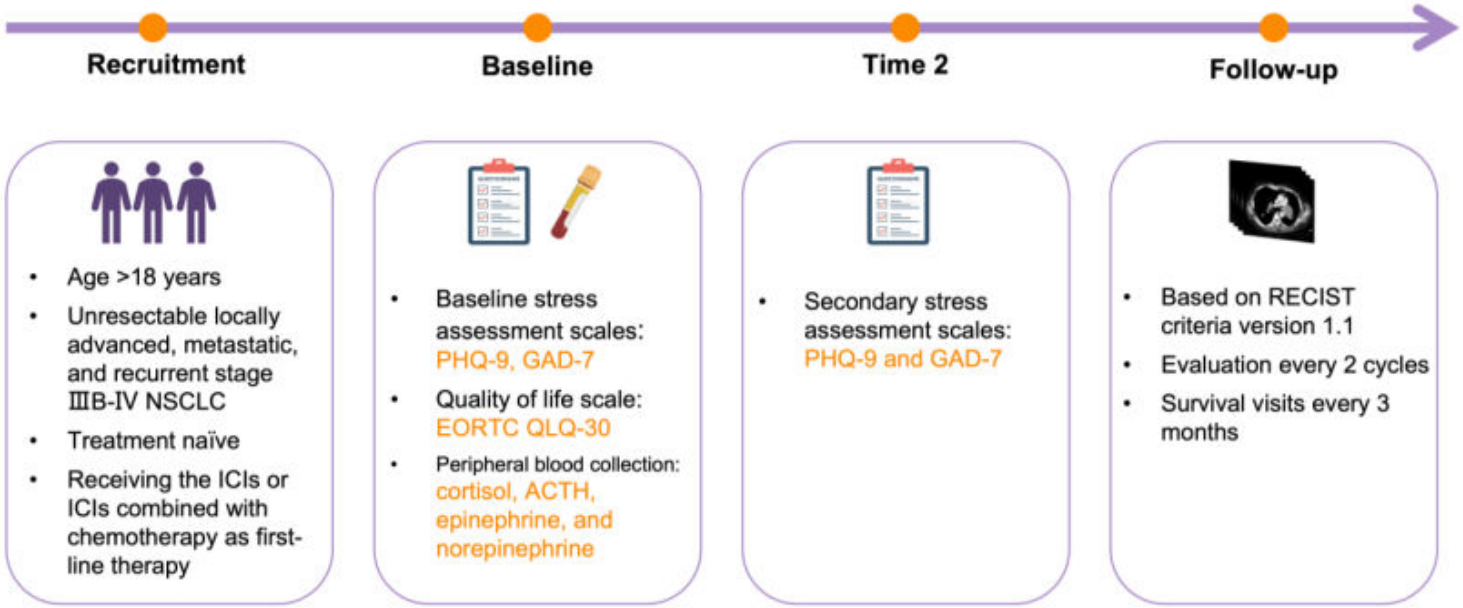
[1] Department of Oncology, The Second Xiangya Hospital, Central South University, Changsha, Hunan, China;

[2] National Clinical Research Center for Mental Disorders, The Second Xiangya Hospital of Central South University, Changsha, Hunan, China

* wufang4461@csu.edu.cn

Study design (STRESS-LUNG-1, NCT05477979)

- An observational, prospective cohort study



Primary endpoint: investigators assessed progression-free survival (PFS)

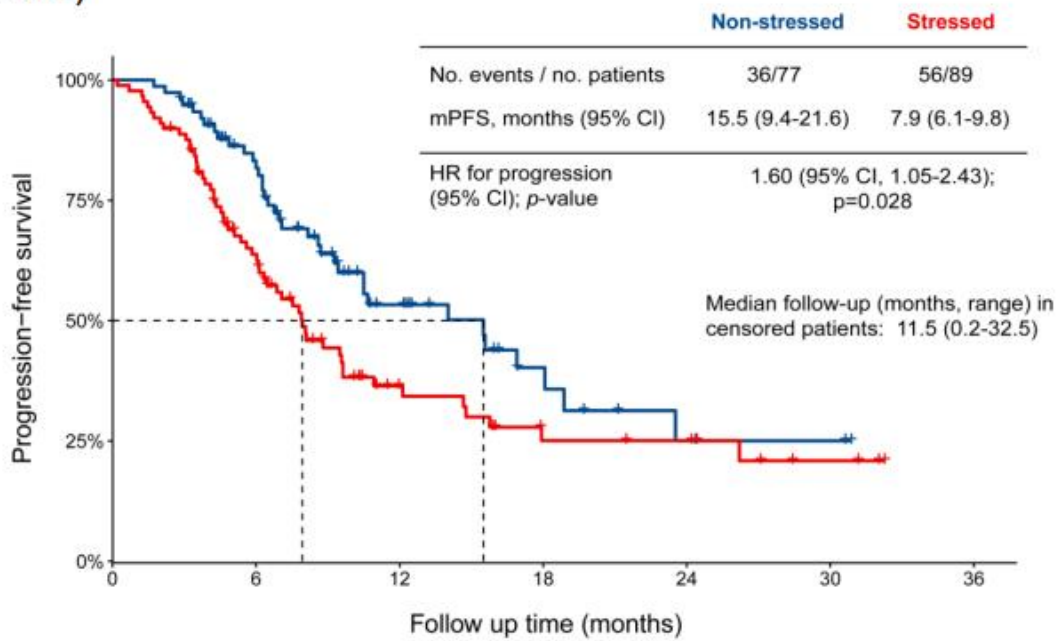
Secondary endpoints: objective response rate (ORR), overall survival (OS), and quality of life (QoL)

Exploratory outcomes: stress dynamics, peripheral blood stress biomarkers and gut microbiota

Fang Wu, M.D., Ph.D. The Second Xiangya Hospital of CSU

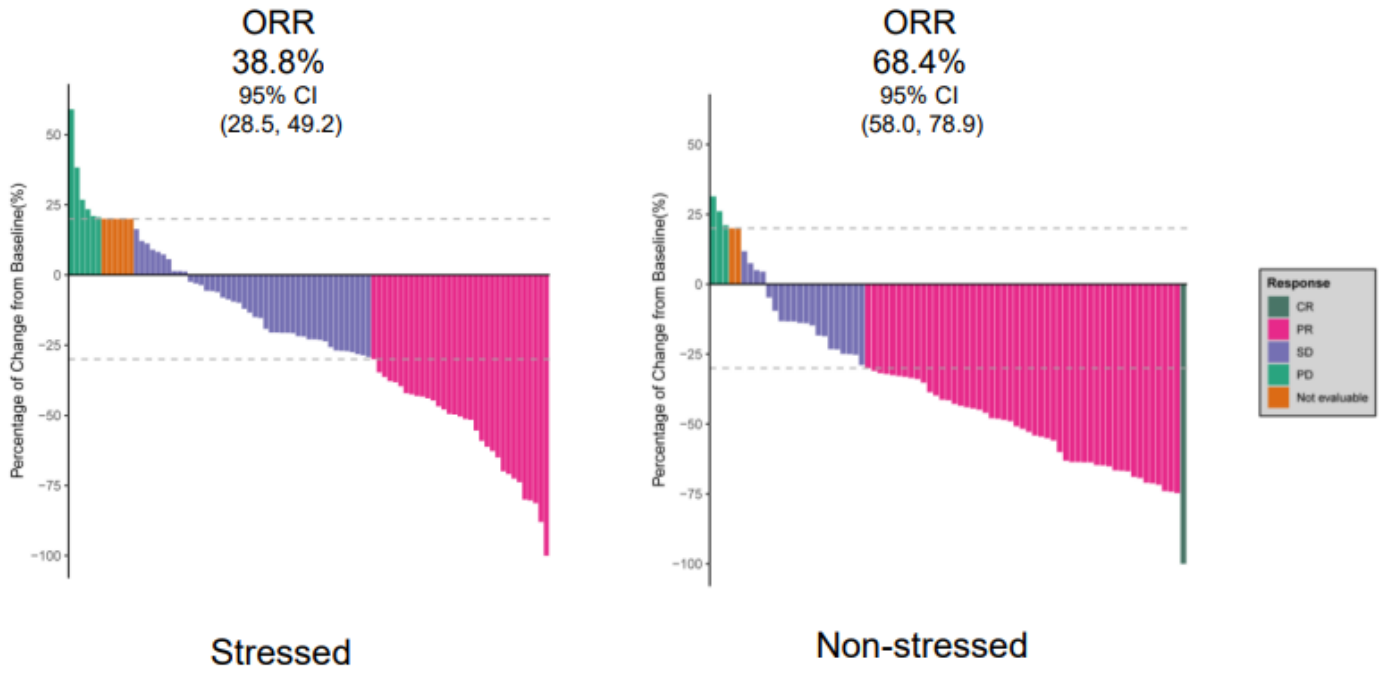
Primary endpoint: progression-free survival (PFS)

- The median PFS was 7.9 months vs 15.5 months for stressed vs non-stressed group (HR 1.60; 95% CI, 1.05 to 2.43)



Secondary endpoint: objective response rate (ORR)

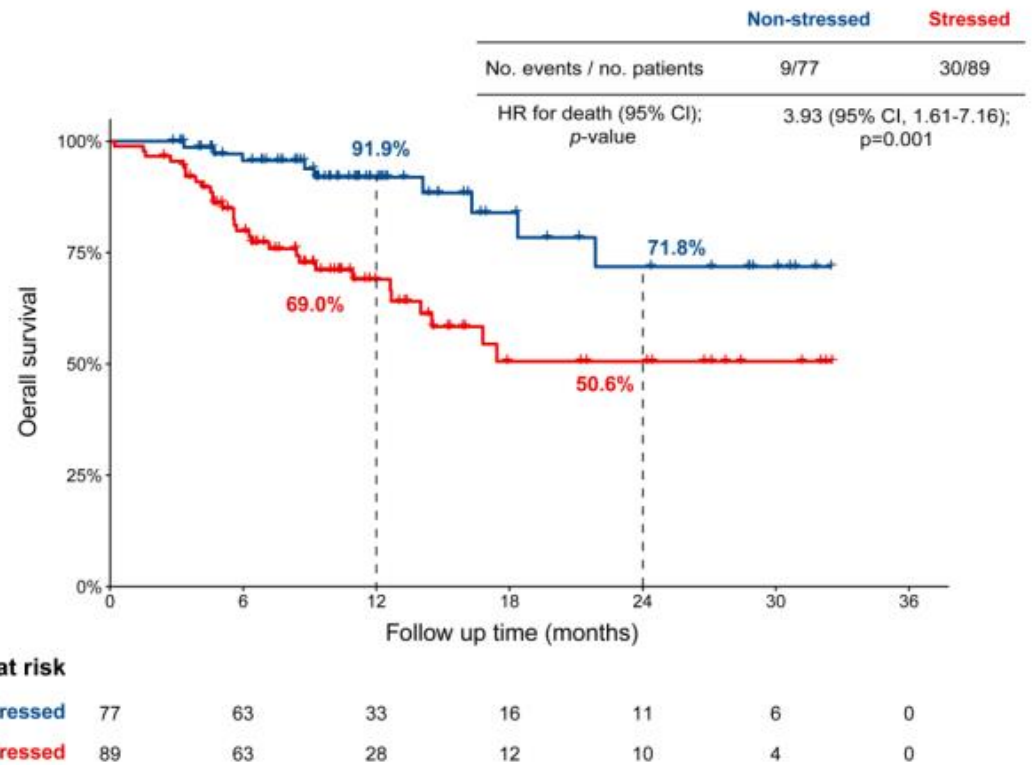
- The ORR was 38.8% vs 68.4% for stressed vs non-stressed group (OR 3.41; 95% CI, 1.78 to 6.55; p<0.001)



Fang Wu, M.D., Ph.D. The Second Xiangya Hospital of CSU

Secondary endpoint: overall survival (OS)

- The 2-year OS rates were 50.6% vs 71.8% for stressed vs non-stressed group (HR 3.93; 95% CI, 1.61 to 7.16)



Fang Wu, M.D., Ph.D. The Second Xiangya Hospital of CSU

Conclusions

- Psychological stress was associated with diminished efficacy of ICIs in advanced NSCLC patients
  - PFS 7.9mo vs 15.5mo, HR 1.60
  - ORR 38.8% vs 68.4%, OR 2.43
  - OS is immature, HR 3.93
- Psychological stress was linked to detrimental QoL
- To explore the effect of intervention for psychological stress is needed (BRIO study, NCT05967910)

Fang Wu, M.D., Ph.D. The Second Xiangya Hospital of CSU

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Caregivers' needs along the patient journey

What do the oncologists need to know?

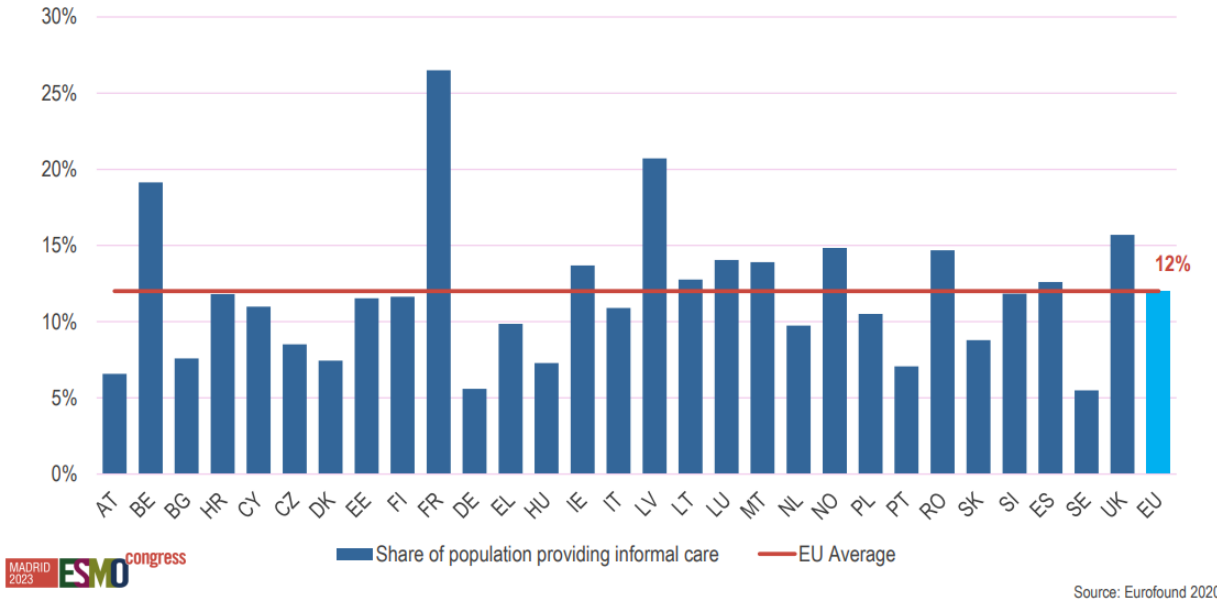
Bettina Ryll, MD/ PhD
Melanoma Patient Network Europe

ESMO2023, Madrid, Spain

Who are informal carers?

A carer is any person who provides care - **usually unpaid** - to someone with a chronic illness, a disability or any other long-lasting care needs, **outside a professional or formal framework**.

How many carers are there ?



Source: Eurofound 2020

Exploring the role and needs of cancer carers

- ✓ **Daily help**: shopping, cooking, cleaning, administrative tasks, personal care, etc.
- ✓ **Financial management** and planning
- ✓ **Emotional support** to the patient and other relatives: open communication about the diagnosis and prognosis
- ✓ **Information retrieval** about disease and treatment + **communication** with health and care professionals regarding treatment options

I have served as a bridge between the external world and the patient, I explained the treatment and prognosis, and I took part in managing household affairs and activities.

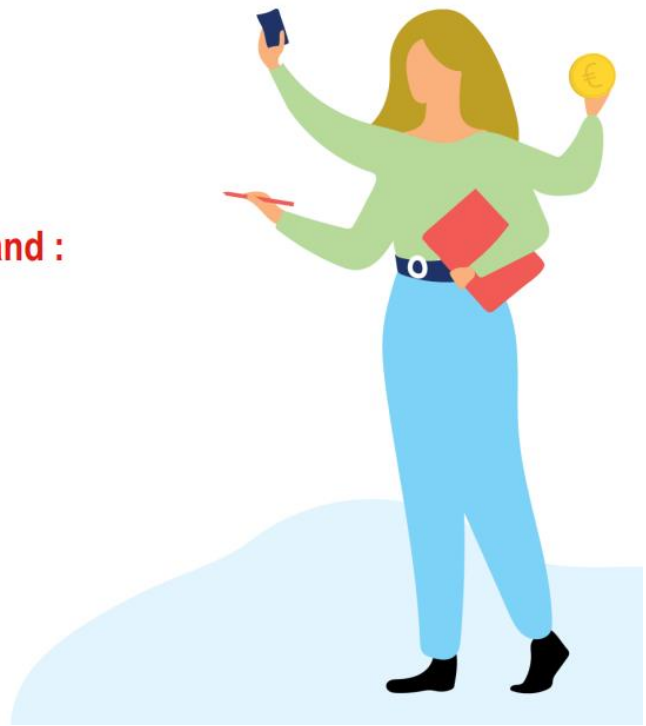
Exploring the role and needs of cancer carers (2)

- Facilitate the patient's **adherence to treatment** (e.g. attendance of medical appointments, medication compliance, etc.)
- In case of **at-home treatment**:
  - coordination of health and social care interventions,
  - diverse healthcare tasks such as injections, dressing changes, management of side-effects of treatment,...
- Supporting a **cancer survivor** (fatigue, long-lasting impact of treatment, social aspects)

Impact of caring

Correlation between caregiving and :

- Work-life/care balance
- Social exclusion and poverty
- Health and well-being



What do carers want?

- **Financial support**: income based on a minimum wage
- **Employment**: flexible working, paid and/or unpaid leave
- **Pension credits** for care time
- **Regular breaks** from caring
- **Training**

Still UNequal Partners in Care !

MADRID 2023 ESMO congress

Prognostic evaluation in patients with advanced cancer in the last months of life

ESMO Clinical Practice Guideline

Prof Paddy Stone

London, UK
22nd October 2023

Clinical Predictions of Survival - recommendations

- Clinicians should use their experience to predict the survival of patients with advanced incurable cancer (i.e. a prognosis of a few months or less), but should be aware of their limitations and understand that, in general, there is a tendency to overestimate survival [III, A]
- It is suggested that clinicians might use estimates of survival based on input from multiple professionals to supplement their own clinical judgement [III, C]

Prognosticating in patients still on treatment (survival of "months")

- Prognostic factors
  - Performance status
  - Biomarkers of systemic inflammatory response
    - C-Reactive Protein; Albumin; Glasgow Prognostic Score; Neutrophil to Lymphocyte ratio
  - Age/Frailty
- Individualised risk prediction models
  - Various models have been developed/validated but are not extensively used
    - SAP models (albumin; LDH; neutrophil count)
    - PRONOPALL model (performance status; metastases; albumin; LDH)
    - Paiva nomogram (sex; metastases; performance status; white cell count; albumin)

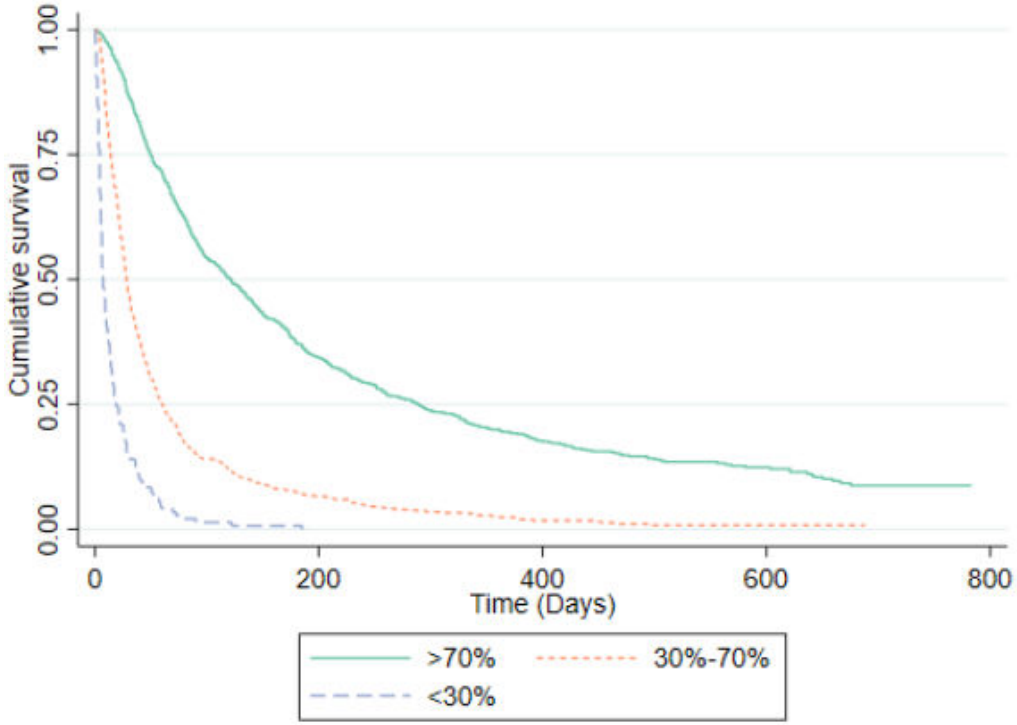
Prognosticating in patients with survival of "weeks" to "months"

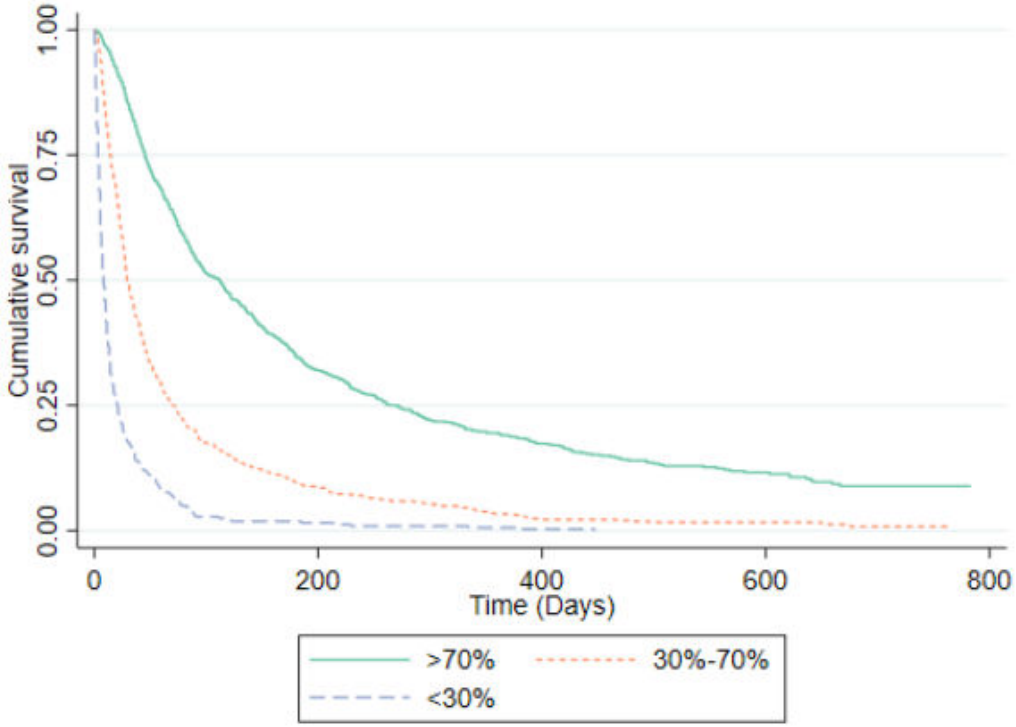
- Prognostic Factors
  - Similar to patients with a prognosis of months
    - Markers of inflammatory response
    - Performance status - Palliative Performance Scale (PPS) has greater discrimination t Karnofsky Performance Status (KPS) at lower levels of functioning
- Individualised risk prediction models
  - Palliative Prognostic Score (PaP)
  - Palliative Prognostic Index (PPI)
  - Prognosis in Palliative care Study predictor models (PiPS)
  - Feliu Prognostic Nomogram (FPN)

Prognosticating in patients with survival of "days"

- Clinical prediction of survival
  - More accurate as death approaches
- Prognostic factors
  - Symptoms: fatigue; dry mouth; drowsiness; dyspnoea; agitation; sedation; dysphagia
  - Clinical Signs: performance status; lower body oedema; low systolic BP; increased heart decreased oxygen saturations; respiration with mandibular movement; urine output
  - Lab results: urea; haemoglobin; C-Reactive Protein; albumin; platelets
- Individualised risk prediction models
  - Several models in development
  - Not yet externally validated
  - Not compared to accuracy of clinical prediction

PaP versus clinician





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Stone et al. PLoS ONE 16(4): e0249763; doi.org/10.1371/journal.pone.0249763

Communication of prognosis - recommendations

- It is suggested that clinicians should clarify patients' understanding of their condition [V, B]
- Clinicians might start by asking patients about the type of information they want to learn about and how it should be presented to them [V, B]
- Clinicians might aim to identify, acknowledge and name emotions in response to patients' verbal and non-verbal cues [V, B]
- It is suggested that clinicians should allow room for silence during the conversation, control verbal flow and develop self-awareness [V, B]

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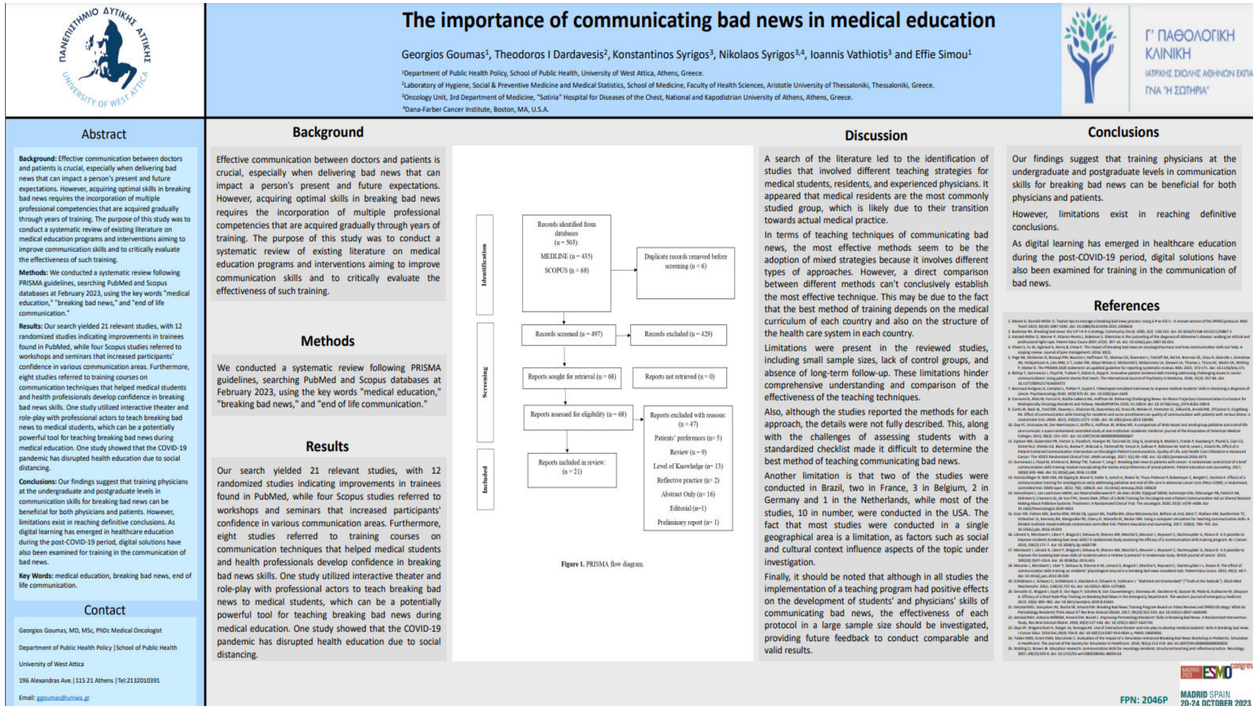
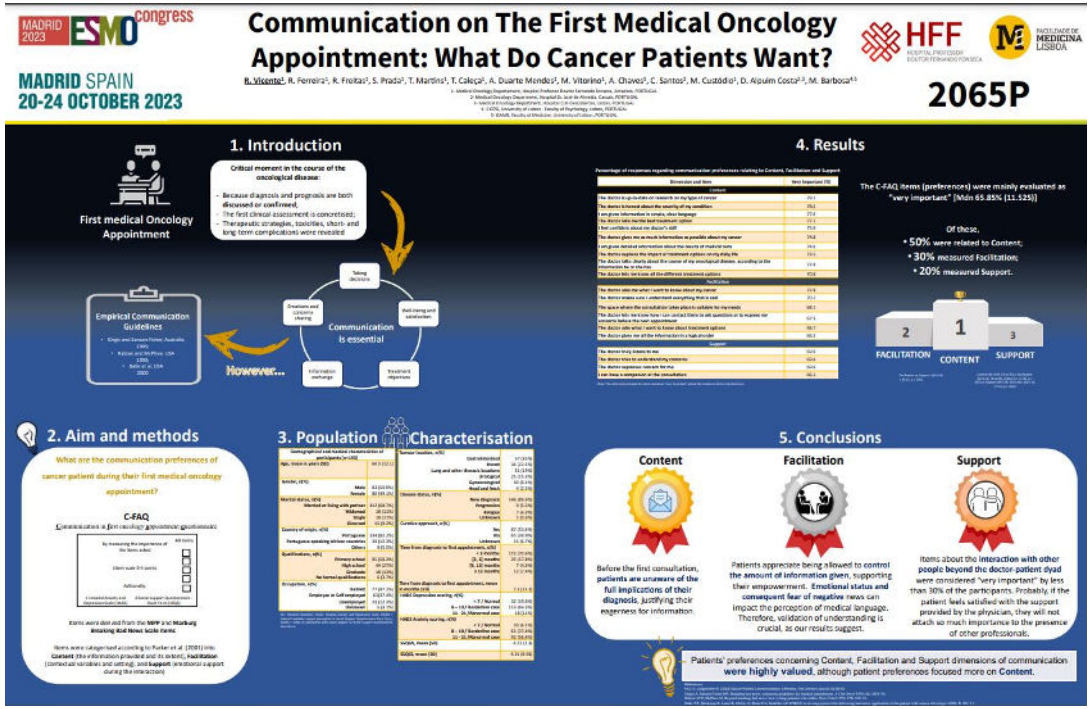




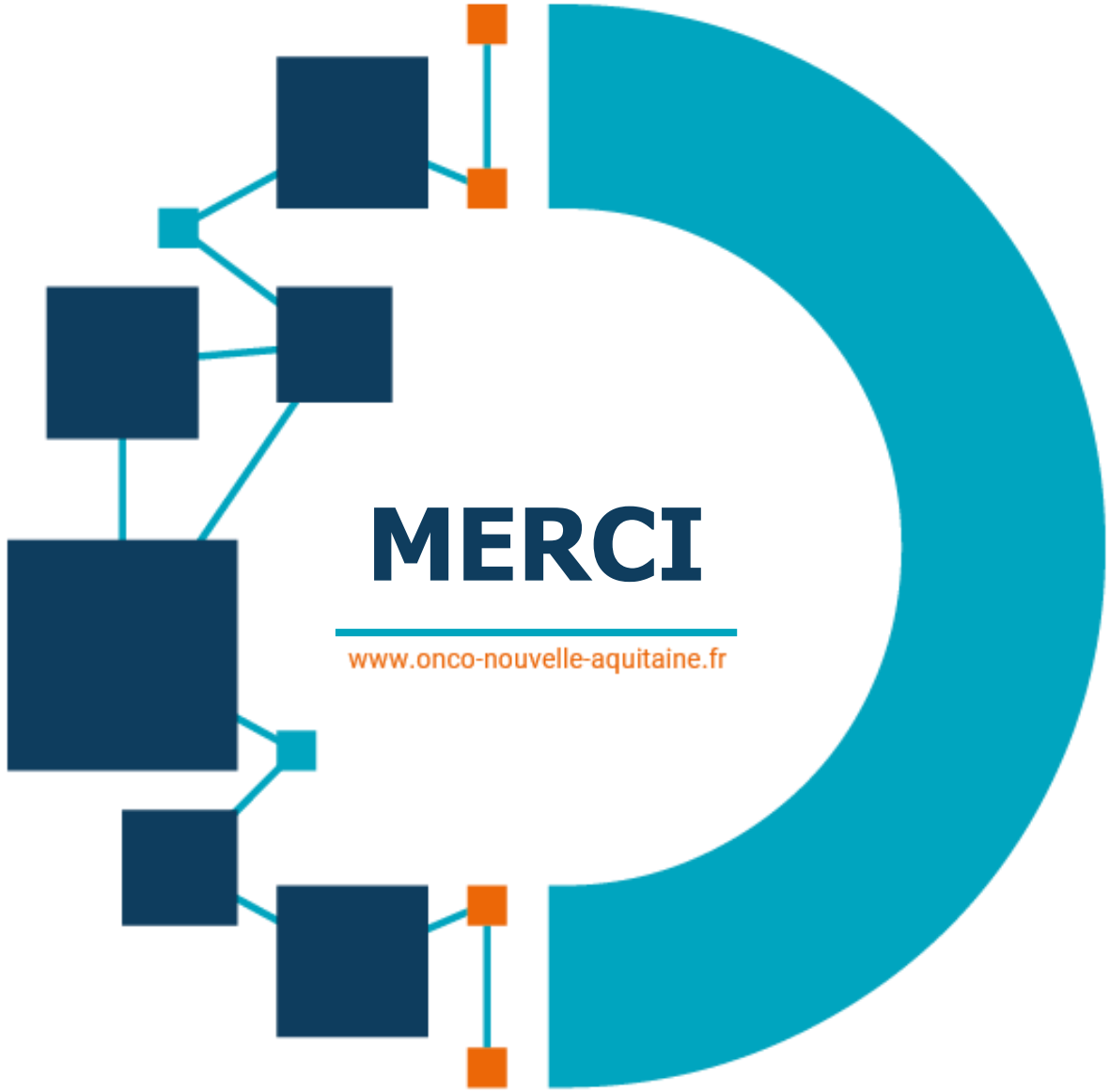
Posters 2046P et 2065P

Conclusion

- Actualisation des recommandations NVCI : olanzapine!!
- Evaluation onco-gériatrique +++
- ePRO : diminution des consultations et hospitalisations en urgence
- Lutte contre la cachexie : Anamoréline
- Impact négatif du stress et des IPP chez les patients ayant un cancer du poumon sous immuno
- Importance des aidants
- Savoir communiquer

NO

YES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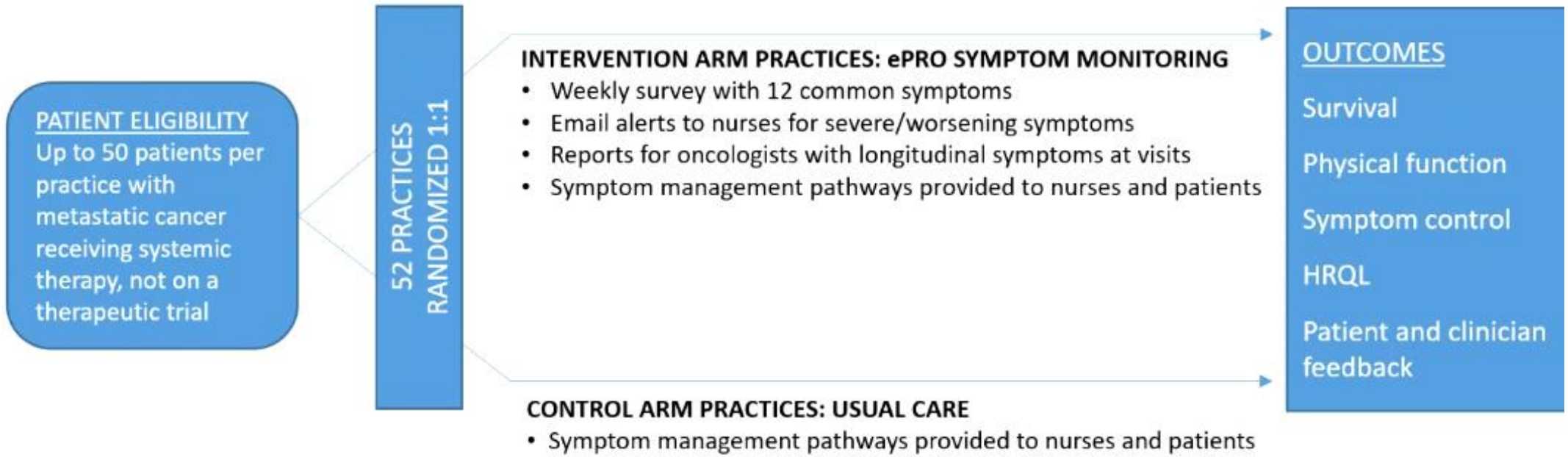
The PRO-TECT trial (Alliance AFT-39): Remote symptom monitoring with electronic patient-reported outcomes (ePROs) during treatment for metastatic cancer

Ethan Basch, MD
Professor and Chief of Oncology
University of North Carolina, USA

October 20, 2023

PRO-TECT
Cancer Symptom Study

- Cluster randomized trial at 52 US community oncology practices, across 25 states
- Funded by PCORI, sponsored by Alliance Foundation Trials



Statistics

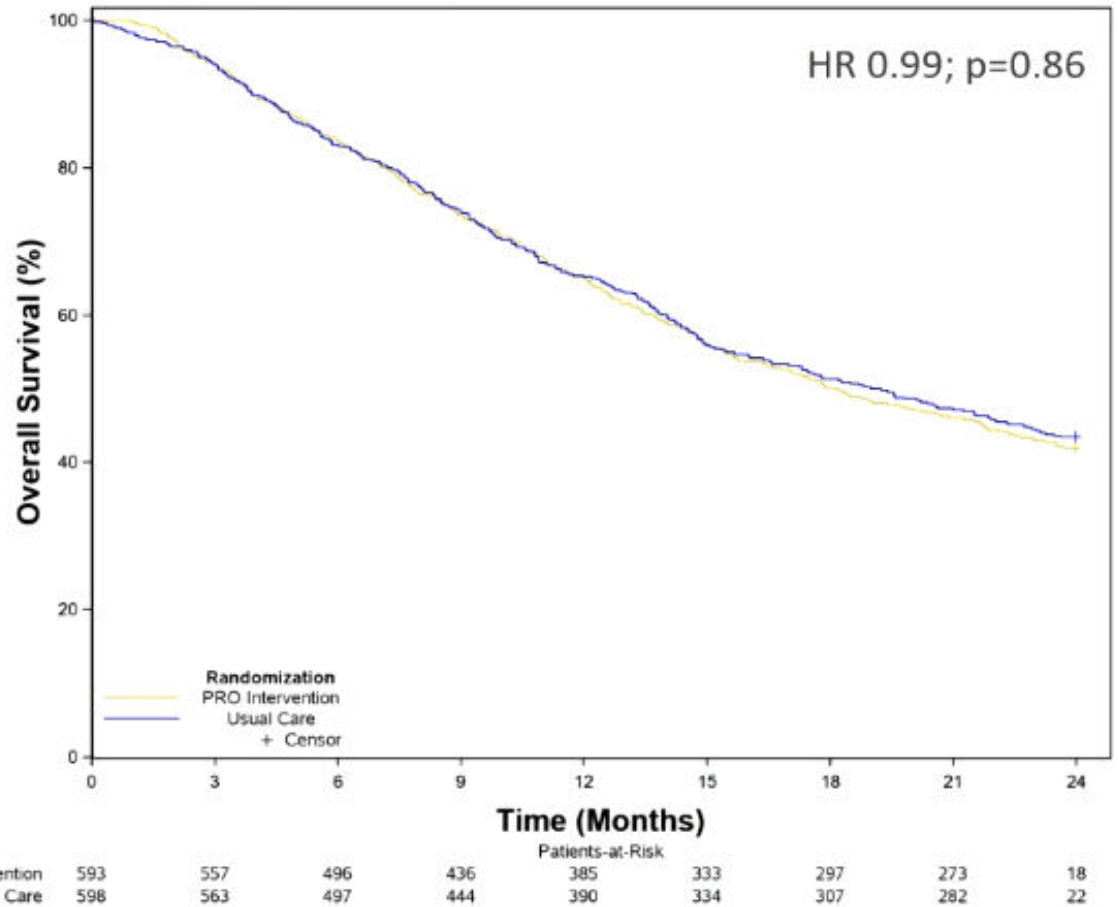
- Primary outcome: Overall survival (all cause)
  - Analysis included all deaths (with censoring on last date known alive)
  - Based on medical chart abstraction and linkage to US National Death Index
  - Designed for 90% power to detect hazard ratio of 0.76 using a 2-sided alpha = 0.05 log rank test with 576 observed deaths, with intracluster correlation coefficient 0.001
  - All patients followed for 2 years after date of enrollment
- Secondary outcomes:
  - Emergency visits/hospitalizations (within 1 year of enrollment)
  - Health-related quality of life, symptoms, physical function (by EORTC QLQ-C30)
    Previously reported: JAMA 2022;327:2413-2422
- Exploratory outcomes:
  - Compliance with weekly ePRO surveys; patient & clinician feedback on using ePROs

Results

1,191 patients enrolled between July 2017 and March 2020, participation through March 2021

BASELINE CHARACTERISTICS		ePRO (Intervention) (N=593)	Usual Care (Control) (N=598)
Age - median (range)		**64** (29-89)	**62** (28-93)
Female sex – no. (%)		359 (**60.5%**)	335 (**56.1%**)
Race – no. (%)	White	473 (**80.4%**)	452 (**78.5%**)
	Black	99 (**16.8%**)	94 (**16.3%**)
	Other	13 (**2.1%**)	29 (**5.1%**)
Cancer type – no. (%)	Thoracic	118 (**19.9%**)	110 (**18.4%**)
	Breast	97 (**16.4%**)	80 (**13.4%**)
	Gastrointestinal	173 (**29.2%**)	219 (**36.6%**)
	Genitourinary	69 (**11.6%**)	44 (**7.4%**)
	Gynecologic	64 (**10.8%**)	53 (**8.9%**)
	Hematologic	31 (**5.2%**)	31 (**5.2%**)
	Other	41 (**6.9%**)	61 (**10.2%**)
Education – no. (%)	≤High School	218 (**36.8%**)	250 (**41.8%**)
Rural		154 (**26.0%**)	163 (**27.3%**)
Never use email/computer		114 (**19.2%**)	158 (**26.5%**)
Receiving ≥3rd line cancer treatment at baseline		211 (**35.6%**)	169 (**28.3%**)
Receiving palliative care services		542 (**91.4%**)	504 (**84.3%**)

Results: Overall Survival



- No significant difference in overall survival between groups
- Unadjusted estimated survival at two years was:
  42.0% (95% CI 38.2-46.2%) for the ePRO group
  43.5% (95% CI 39.7-47.6%) for the usual care control

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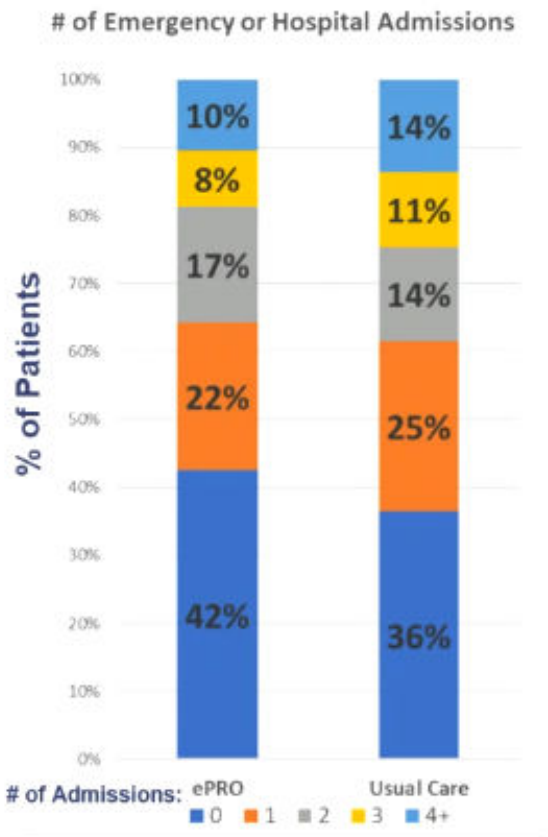
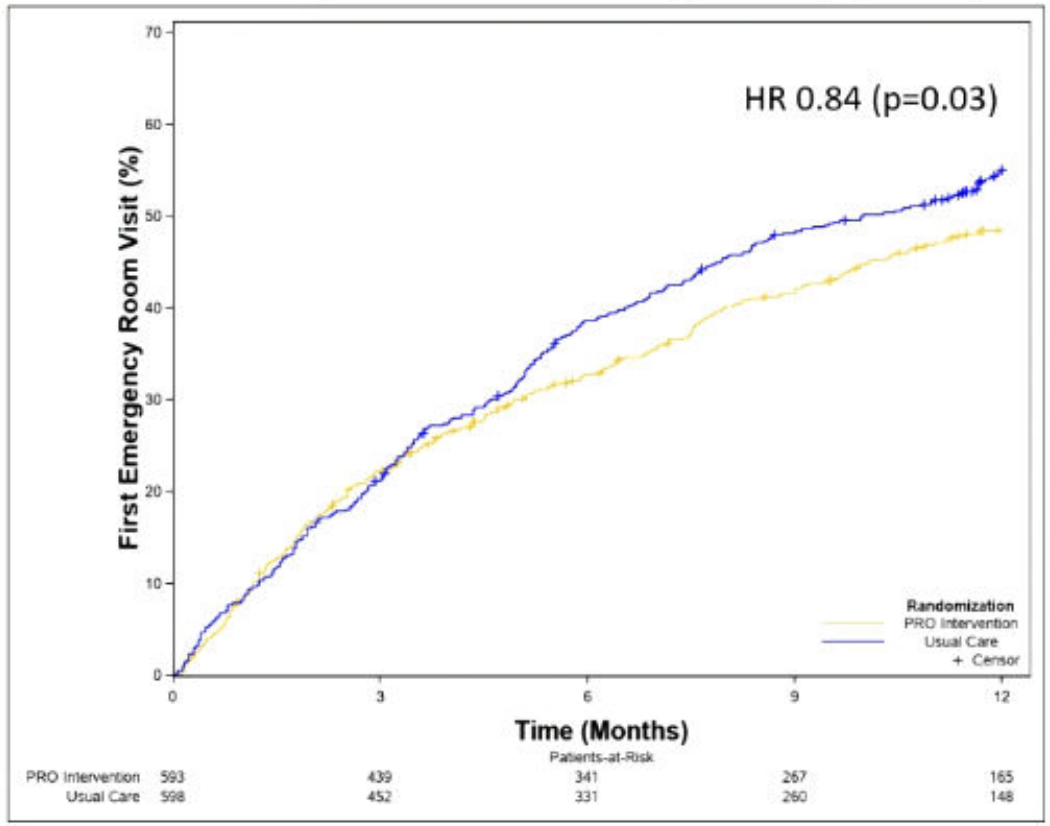
Ethan Basch, MD

Results: Emergency and Hospital Admissions

6% reduction in emergency or hospital admissions in ePRO arm compared to usual care

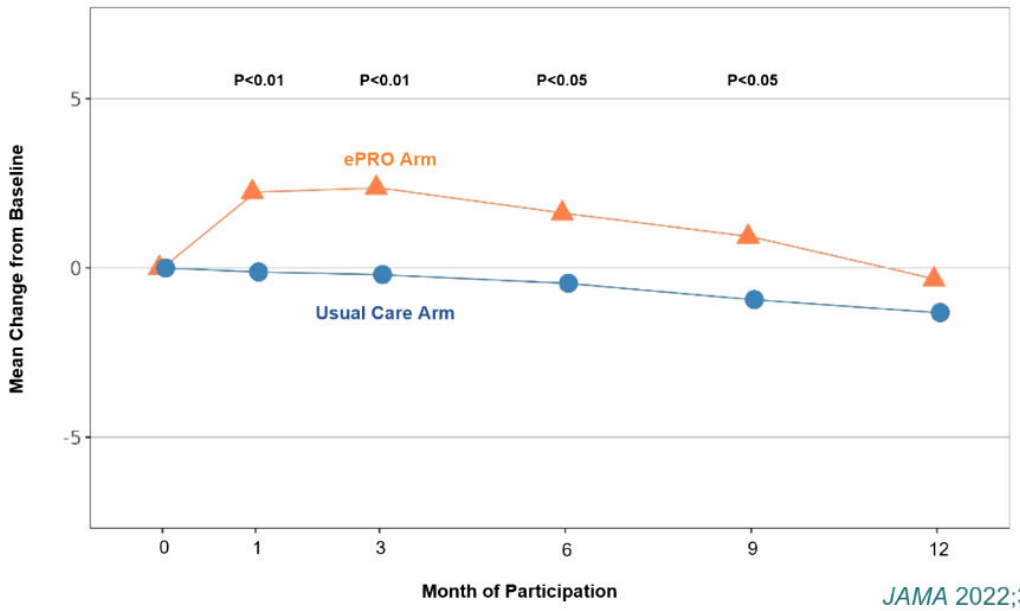


Lengthened (improved) time to first emergency admission in ePRO arm compared to usual care (HR 0.84; p=0.03)



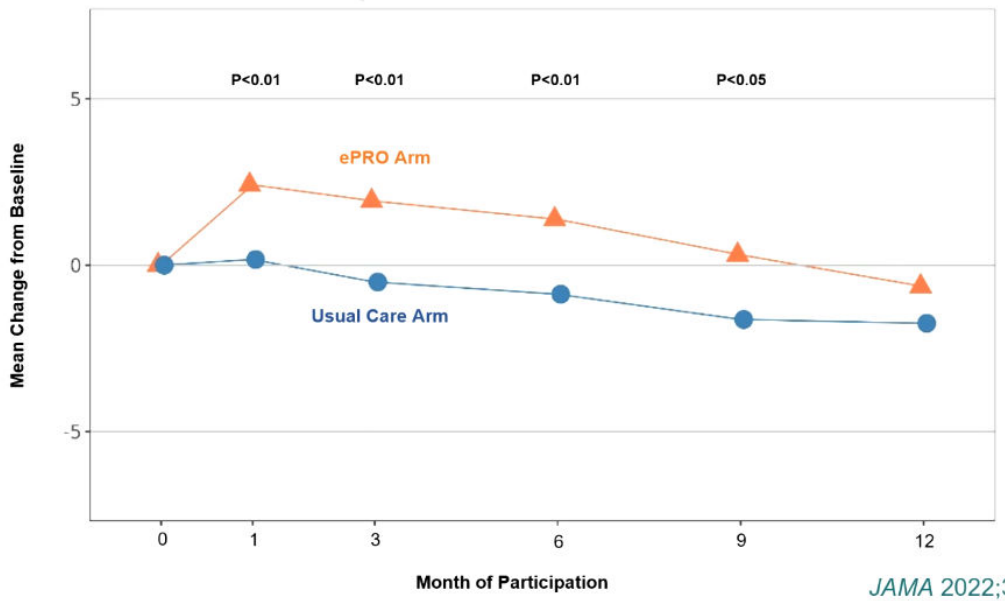
Decreased mean # of admissions per patient over one year with ePROs vs Usual Care: 1.48 vs. 1.81 (p=0.006)

Results: Symptom Control



JAMA 2022;327:2413-2422

Results: Health-Related Quality of Life



JAMA 2022;327:2413-2422

Conclusions

- Symptom monitoring with ePROs is feasible during routine treatment for advanced cancers across diverse practices in the US
- Although survival was not impacted in this trial, patients found the intervention valuable and experienced improved quality of life and decreased hospitalizations
- Future ePRO implementations should use technologies that are easily accessible for patients, adjust nurse responsibilities to allow time for ePRO work, and integrate ePROs into care processes