Breast Cancer Patients with Cancer-related Fatigue Management

乳癌病人之癌因性疲憊症照護

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什麼是
CANER RELATED
FATIGUE ?

https://cornerstone-pt.net/cancer-therapy/cancer-related-fatigue/

National Comprehensive Cancer Network®

NCCN Guidelines Version 2.2022
Cancer-Related Fatigue

NCCN Guidelines Index
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Discussion

DEFINITION OF CANCER-RELATED FATIGUE

Cancer-related fatigue is a distressing, persistent, subjective sense of physical, emotional, and/or cognitive tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning.

與癌症或癌症治療相關而且和近期活動量不成比例的疲累感，具有持續、令人感到不適、而主觀的特性，且足以影響正常生活

1. NCCN. NCCN Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue, Version 2.2022.
2. Yeh ET et al. BMC Cancer 2011; 11:387.

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

因化療讓患者感到痛苦的事

Ranking #1: Fatigue

Ranking of adverse effect	1983[1]	1995[1]	2003[2]
1	Vomiting	Nausea	**Fatigue**
2	Nausea	Hair loss	Nausea
3	Hair loss	Vomiting	Sleep disturbance

1. De Boer-Dennert M, et al. Patient perceptions of the side-effects of chemotherapy: the influence of 5HT3 antagonists. Br J Cancer. 1997;76:1055-1061.
2. Hofman M, et al. Cancer Patients' Expectations of Experiencing Treatment-Related Side Effects. Cancer. 2004;101:851-857.

Fatigue in Different Adjuvant Chemotherapy Regimens Had the same pattern Over Time

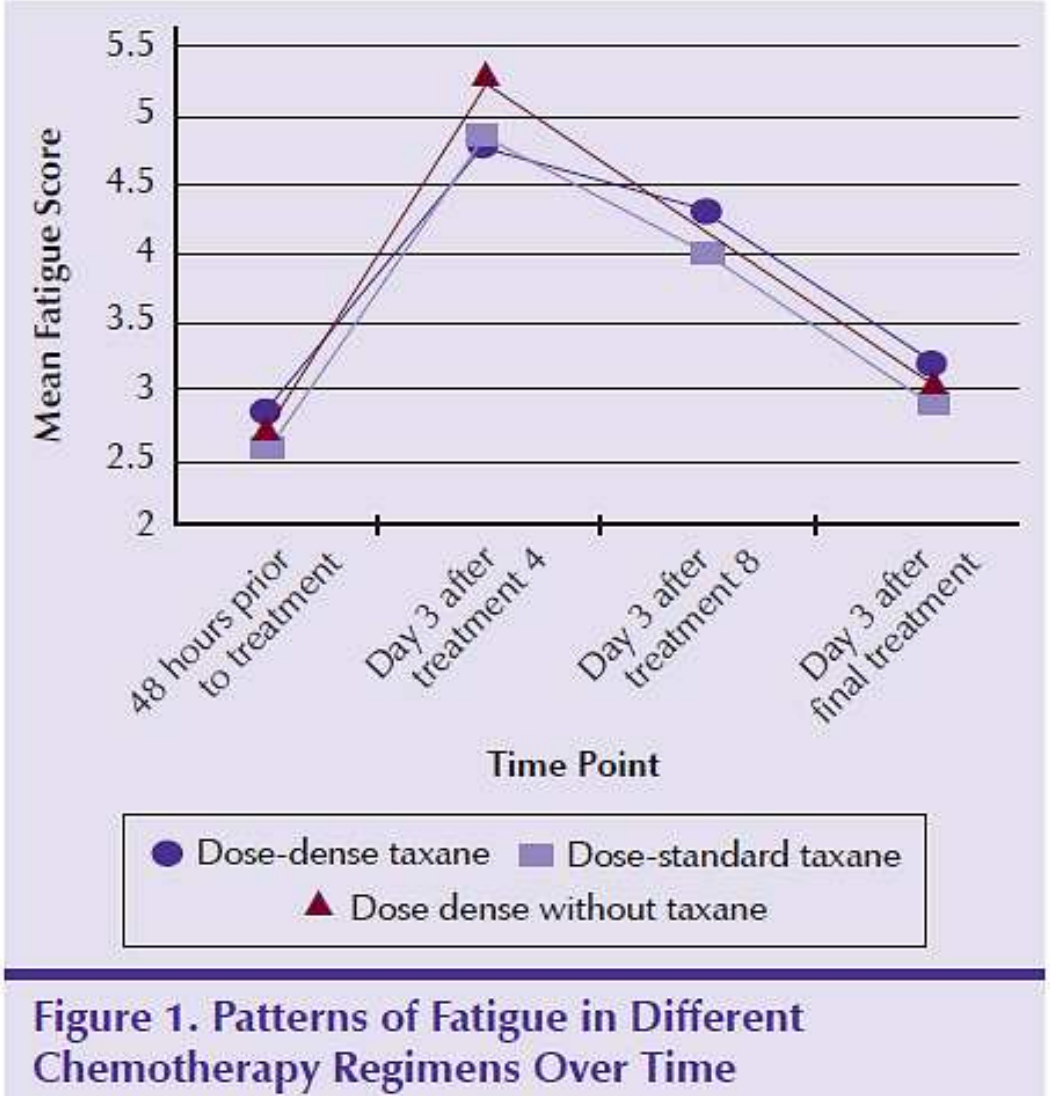


Figure 1. Patterns of Fatigue in Different Chemotherapy Regimens Over Time

- Participants rated their fatigue **highest at treatment 4**.
- Fatigue levels for all regimens **did not return to baseline levels by the 30-day measurement**.

Oncology Nursing Forum 2009; 36 (5): 563-569.

Fatigue is common at adjuvant chemotherapy for Breast Cancer

	Epirubicin, cyclophosphamide, and paclitaxel plus gemcitabine (n=1565)			Epirubicin, cyclophosphamide, and paclitaxel (n=1567)		
	Grade 1–2	Grade 3	Grade 4	Grade 1–2	Grade 3	Grade 4
Neutropenia	397 (25%)	323 (21%)	204 (13%)	364 (23%)	212 (14%)	200 (13%)
Myalgia and arthralgia	1140 (73%)	200 (13%)	7 (<1%)	1147 (73%)	175 (11%)	11 (1%)
Fatigue	1254 (80%)	198 (13%)	9 (1%)	1287 (82%)	140 (9%)	12 (1%)
Infection	578 (37%)	194 (12%)	8 (1%)	601 (38%)	131 (8%)	10 (1%)
Vomiting	786 (50%)	134 (9%)	9 (1%)	736 (47%)	101 (6%)	7 (1%)
Nausea	1271 (81%)	132 (8%)	0	1255 (80%)	102 (7%)	0

Table 3. Frequency of Patient-Reported Adverse Events During Chemotherapy

	No. of Patients (%)									
	EC-D (n = 994)					DC (n = 1,006)				
Adverse Event	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	*P*
Nausea	103 (10)	465 (47)	340 (34)	71 (7)	7 (1)	255 (25)	552 (55)	182 (18)	11 (1)	4 (0)	< .001
Fatigue	8 (1)	255 (26)	427 (43)	249 (25)	48 (5)	33 (3)	290 (29)	436 (43)	225 (22)	20 (2)	< .001
Peripheral edema	387 (39)	464 (47)	110 (11)	25 (3)	—	334 (33)	463 (46)	181 (18)	26 (3)	—	< .001

J Clin Oncol. 2017 Aug 10;35(23):2639-2646.
Lancet Oncol. 2017 Jun;18(6):755-769.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Trastuzumab Deruxtecan versus Trastuzumab Emtansine for Breast Cancer

J. Cortés, S.-B. Kim, W.-P. Chung, S.-A. Im, Y.H. Park, R. Hegg, M.H. Kim, L.-M. Tseng, V. Petry, C.-F. Chung, H. Iwata, E. Hamilton, G. Curigliano, B. Xu, C.-S. Huang, J.H. Kim, J.W.Y. Chiu, J.L. Pedrini, C. Lee, Y. Liu, J. Cathcart, E. Bako, S. Verma, and S.A. Hurvitz, for the DESTINY-Breast03 Trial Investigators*

ABSTRACT

Event	Trastuzumab Deruxtecan (N=257)		Trastuzumab Emtansine (N=261)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
	number of patients (percent)			
Most common drug-related adverse events				
Blood and lymphatic system disorders				
Neutropenia*	110 (42.8)	49 (19.1)	29 (11.1)	8 (3.1)
Anemia†	78 (30.4)	15 (5.8)	37 (14.2)	11 (4.2)
Leukopenia‡	77 (30.0)	17 (6.6)	20 (7.7)	1 (0.4)
Thrombocytopenia§	64 (24.9)	18 (7.0)	135 (51.7)	65 (24.9)
Gastrointestinal disorders				
Nausea	187 (72.8)	17 (6.6)	72 (27.6)	1 (0.4)
Vomiting	113 (44.0)	4 (1.6)	15 (5.7)	1 (0.4)
Diarrhea	61 (23.7)	1 (0.4)	10 (3.8)	1 (0.4)
Constipation	58 (22.6)	0	25 (9.6)	0
General disorders				
Fatigue¶	115 (44.7)	13 (5.1)	77 (29.5)	2 (0.8)

隨著癌症多種合併治療的進行，可預測患者發生重度疲憊的風險更高

整合分析12,327位乳癌存活者，1/4病患在癌症治療後有重度疲憊

Table 3. Risk factors of severe fatigue in breast cancer survivors

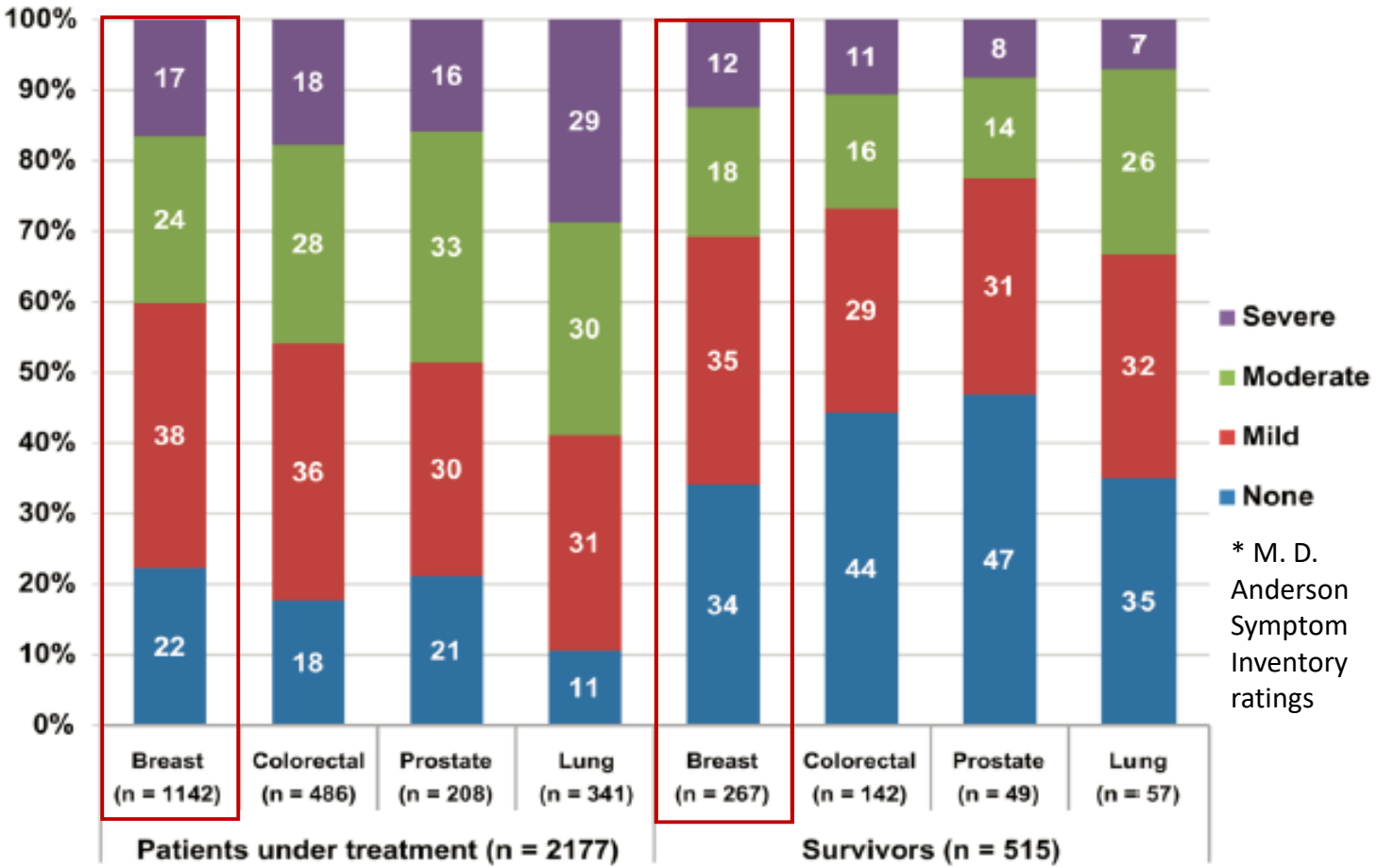
Variables	References	Number of studies	Sample size (*N*)	Risk ratio (CI)
Treatment combinations				
SU	[26, 38, 42, 45, 47, 56, 57]	6	3028	0.83 (0.70 to 0.98)*
SU + CT	[32, 38, 42, 47, 55–57]	7	3379	1.33 (0.97 to 1.82)
SU + RT	[26, 32, 38, 45–48, 50, 55–57]	11	4164	0.87 (0.78 to 0.96)*
SU + HT	[38, 42, 45–47]	4	981	0.83 (0.57 to 1.20)
SU + CT + RT	[26, 32, 38, 45–48, 55–57]	10	3882	1.18 (1.05 to 1.33)*
SU + CT + HT	[38, 42, 45–47]	4	981	0.99 (0.66 to 1.49)
SU + RT + HT	[26, 38, 45–48]	6	1264	0.89 (0.74 to 1.07)
SU + CT + RT + HT	[26, 38, 45–48]	6	1264	1.38 (1.15 to 1.66)*

*$P < 0.05$.

SU, surgery; CT, chemotherapy; RT, radiotherapy; HT, hormone therapy; SMD, standardized mean difference; SD, standard deviation.

Abrahams HJ et al. Risk factors, prevalence, and course of severe fatigue after breast cancer treatment: a meta-analysis involving 12 327 breast cancer survivors. Ann Oncol. 2016 Jun;27(6):965-74.

High prevalence of moderate/severe fatigue in both actively treated cancer patients & survivors



* M. D. Anderson Symptom Inventory ratings

Prevalence of fatigue by cancer type

Wang et al. Prevalence and characteristics of moderate-to-severe fatigue: a multicenter study in cancer patients and survivors. Cancer. 2014; 120(3): 425–432.

癌因性疲憊的定義: NCCN, ICD-10

癌因性疲憊的定義：NCCN, ICD-10

美國國家綜合癌症網絡[1] (National Comprehensive Cancer Network, NCCN)

與癌症或癌症治療相關而且和近期活動量不成比例的疲累感，
具有持續、令人感到不適、而主觀的特性，且足以影響正常生活

國際疾病分類第 10 版 (ICD-10)[2]

符合 A–D 四大要件

A. 症狀	B. 影響生活	C. 引起原因	D. 排除
最近一個月至少有連續兩週期間，每天或幾乎每天出現至少六項 A1–A11 的症狀 (A1 為必需)。	疲累不堪的感覺會干擾到職場工作、家務處理、或人際互動。	病歷、身體檢查、或生化檢查有記錄顯示疲憊症狀為癌症或癌症治療所引起。	疲憊不是由精神共病（如重度憂鬱、身體化疾患、心身症、或譫妄）所引起。

1. NCCN. NCCN Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue, Version 2.2020.
2. Yeh ET et al. BMC Cancer 2011; 11:387.

癌因性疲憊的定義: ICD-10

A

最近**一個月至少有連續兩週**期間，每天或幾乎每天出現**至少六項 A1-A11 的症狀**（A1 為必需）

ICD-10 Code:
R53.0

國際疾病分類第10版 (ICD-10)[1]

A1 **感到明顯的疲累、缺少活力、或需要增加休息，且與近期活動程度不成比例**
A2 感到**全身**虛弱、沉重
A3 感到很**難集中精神**或注意力
A4 感到平常習慣做的事都變得**乏味**而不想去做
A5 感到**難以入睡**、睡得不安穩、早起有困難、或是睡得太多
A6 感到**睡覺起來還是覺得疲累**，精神沒有恢復
A7 感到做什麼事情都必須經過一番掙扎，**勉強**自己去做
A8 因為疲累而感到**悲傷**、失意、或煩躁
A9 因為疲累不堪而事情做一半就**做不下去**了
A10 感到**記性變差**
A11 只要做了**費力的事**就會**持續感到病懨懨、不舒服**

Yeh ET et al. BMC Cancer 2011; 11:387.

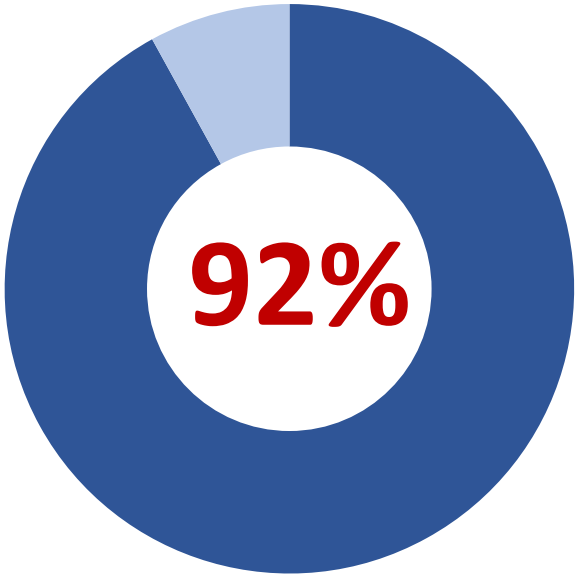
92% 台灣癌症患者罹癌期間有疲憊問題

- 台灣癌症安寧緩和醫學會年會進行第一次全台灣癌症病患「癌因性疲憊症」流行病學調查研究
  - 期間為2015年2月至5月
  - 共23家醫院進行研究
  - 共1,207病患參與調查
- 問卷

  癌因性疲憊(BFI-T, ICD-10)

  生活品質量表(FACT-G7)

  癌症症狀困擾嚴重度量表



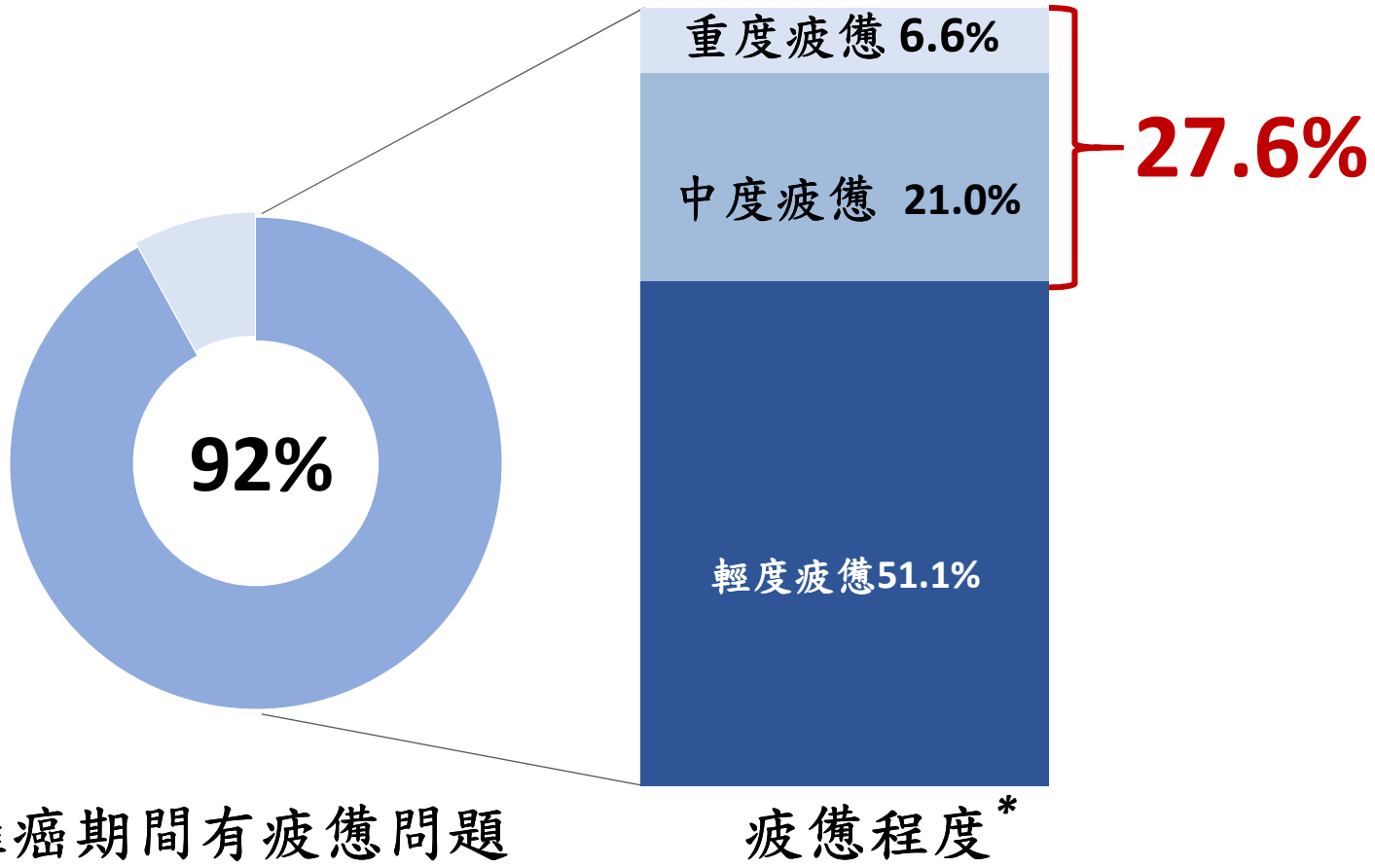
罹癌期間有疲憊問題

K. M. Rau et. al., Japanese Journal of Clinical Oncology, 2020, 1–9

2015 Palliative Care in Oncology Symposium, Boston; Oct 9-10, 2015, Abstract # 155471. 2016 MASCC Poster # MASCC-0488.

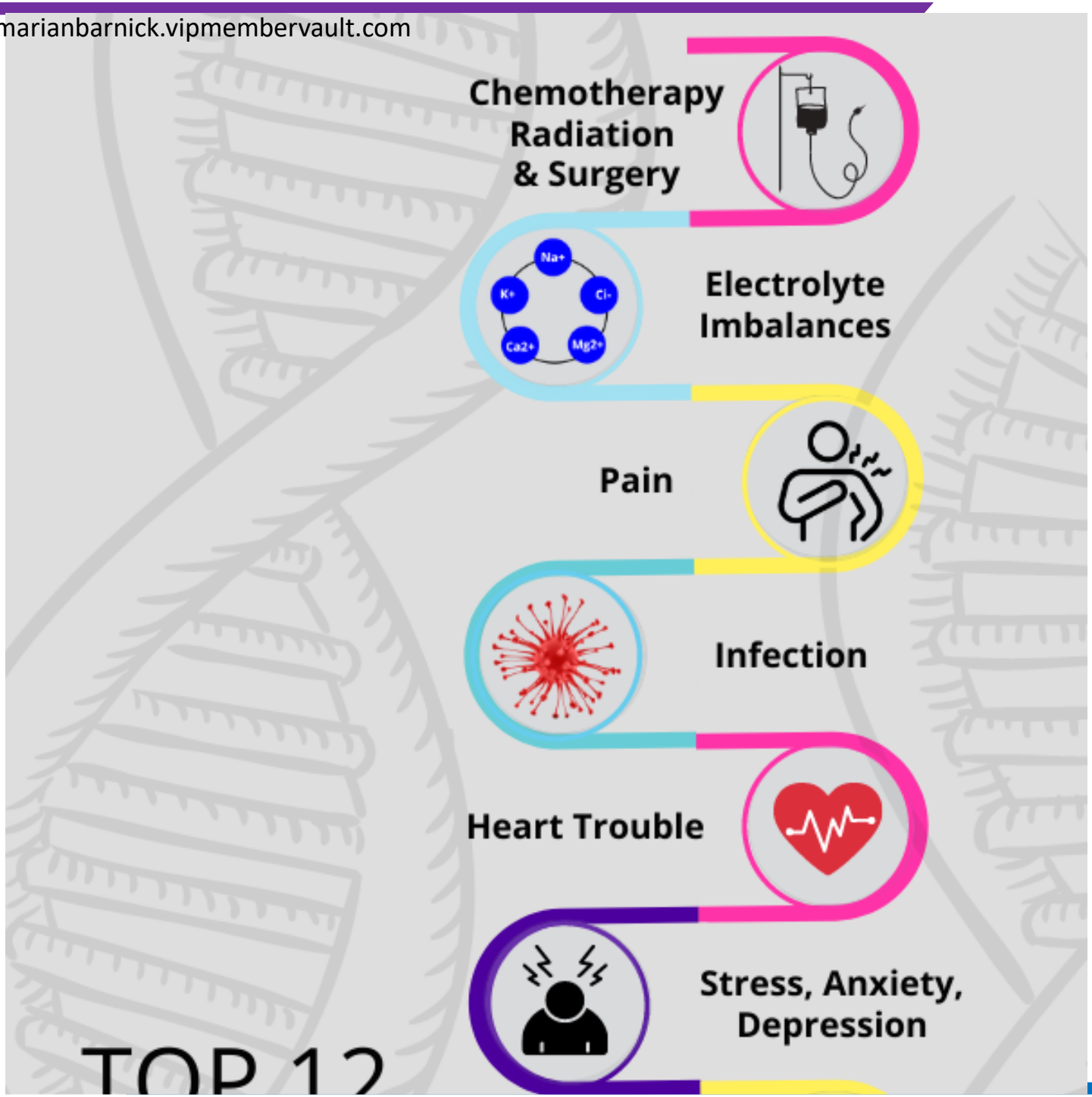
2015 第一次全台灣癌症病患「癌因性疲憊症」流行病學調查研究報告

大於1/4 癌症病患有中重度疲憊

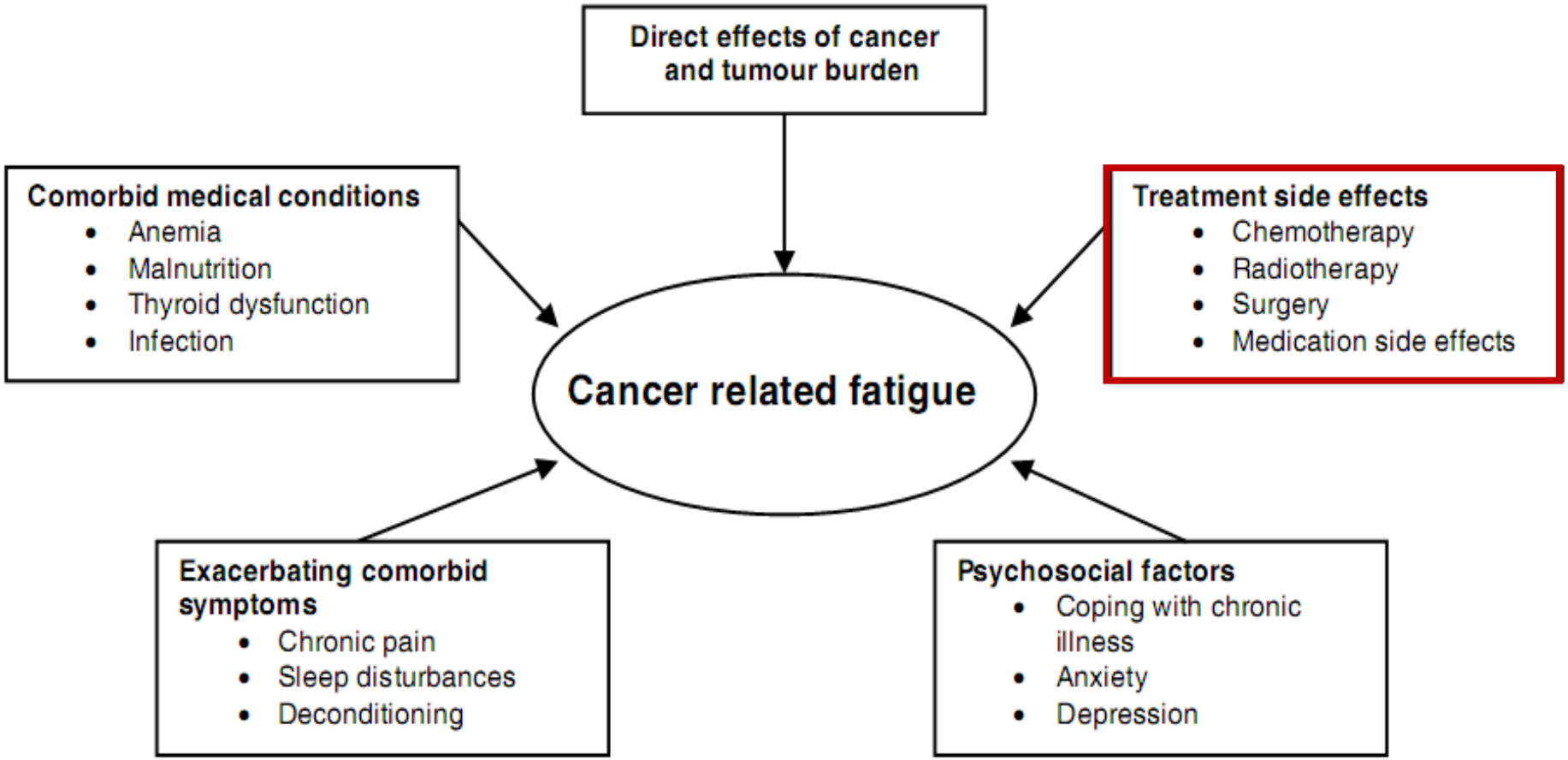


* The three groups were calculated from the average of nine items from BFI and categorize into mild (<4), moderate (4-6.99), Severe (≧ 7).

2015 第一次全台灣癌症病患「癌因性疲憊症」流行病學調查研究報告

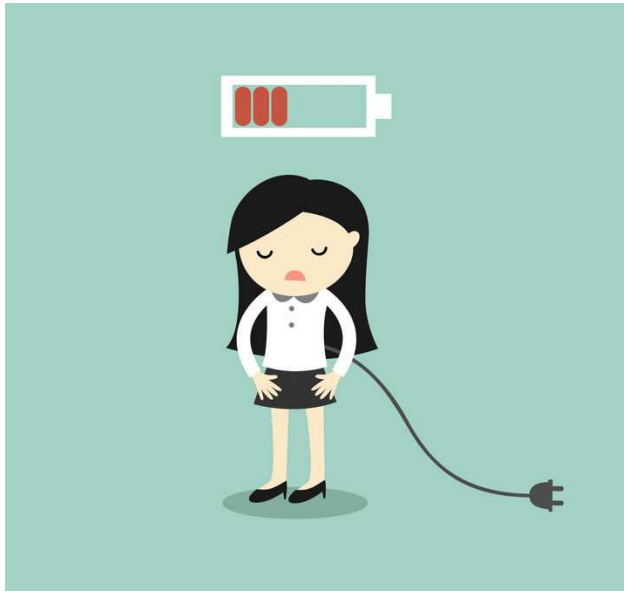

Chemotherapy
Radiation
& Surgery
Na+
K+
Cl-
Ca2+
Mg2+
Electrolyte
Imbalances
Pain
Infection
Heart Trouble
Stress, Anxiety,
Depression
TOP 12

癌因性疲憊症 諸多原因



British Journal of Cancer (2004) 91, 822–828

CRF 會造成...



Drains physical energy
Induces loss of interest in daily activities,
Reduces function,
Increases stress,
Causes sleep disturbances
Contributes to poor quality of life (QoL)

(Psychosocial, Functional, Cognitive, socioeconomic)

https://www.rogelcancercenter.org/living-with-cancer/mind-body-and-side-effects/cancer-related-fatigue

JJCO Japanese Journal of Clinical Oncology

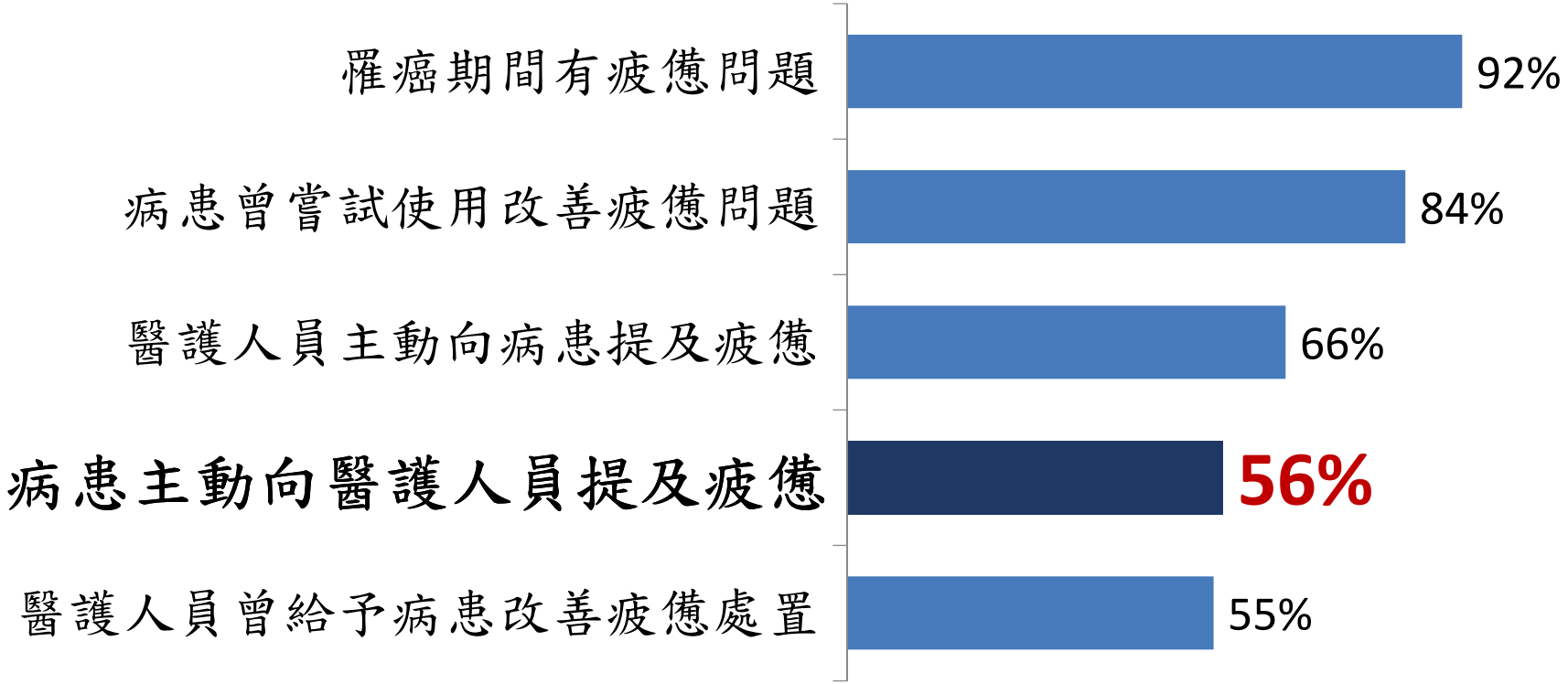
Japanese Journal of Clinical Oncology, 2020, 50(6)693–700
doi: 10.1093/jjco/hyaa038
Advance Access Publication Date: 18 April 2020
Original Article

Original Article

A nationwide survey of fatigue in cancer patients in Taiwan: an unmet need

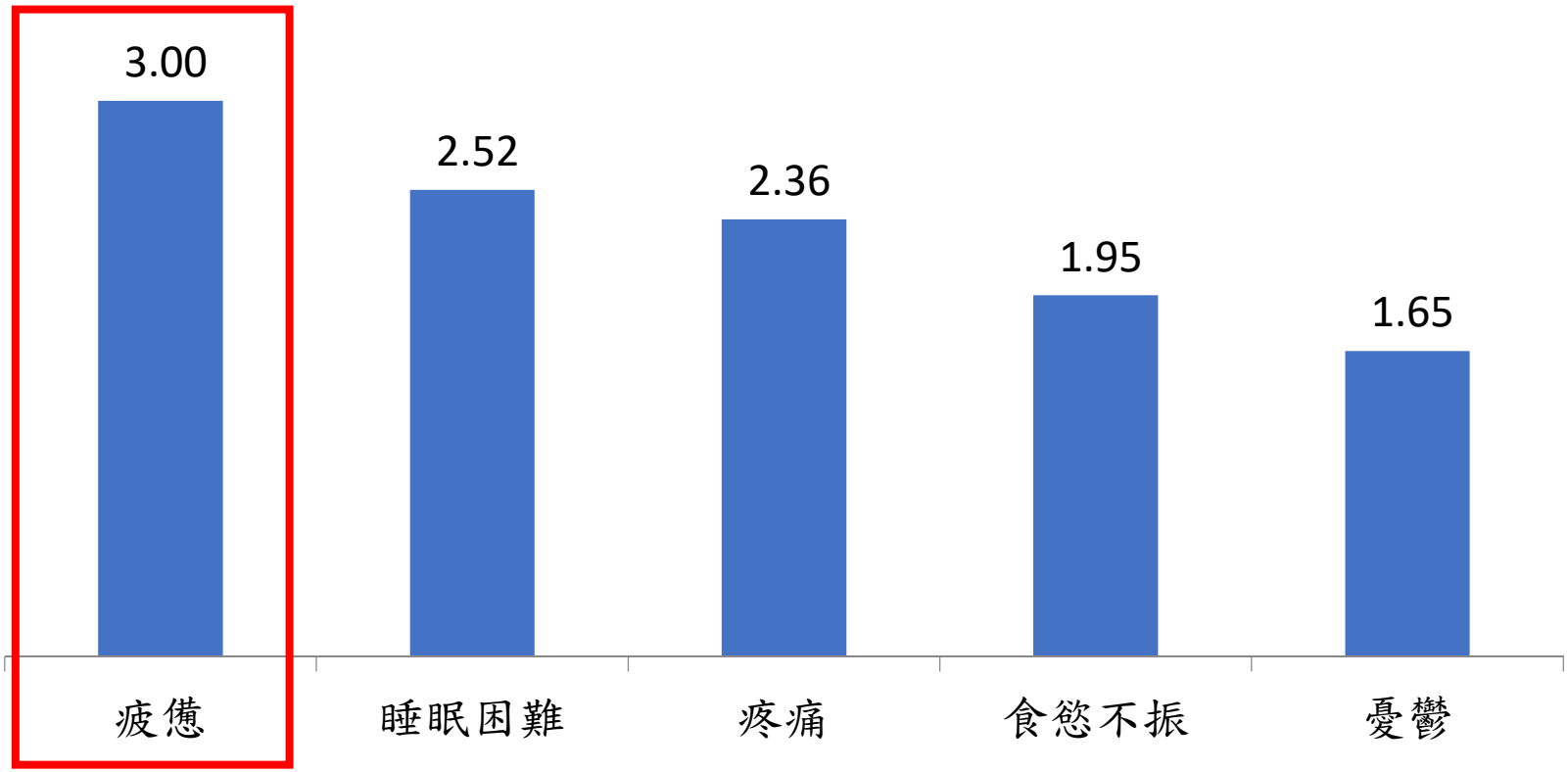
Kun-Ming Rau[1,2], Shiow-Ching Shun[3], Tzeon-Jye Chiou[4], Chang-Hsien Lu[5,6], Wei-Hsu Ko[7,8], Ming-Yang Lee[9], Wen-Tsung Huang[10], Kun-Huei Yeh[11], Cheng-Shyong Chang[12,13], and Ruey-Kuen Hsieh[14,*]

約一半癌症病患主動向醫護人員提及疲憊



K. M. Rau et. al., Japanese Journal of Clinical Oncology, 2020, 1–9
2015 Palliative Care in Oncology Symposium, Boston; Oct 9-10, 2015, Abstract # 155471. 2016 MASCC Poster # MASCC-0488.

疲憊：最嚴重的症狀困擾

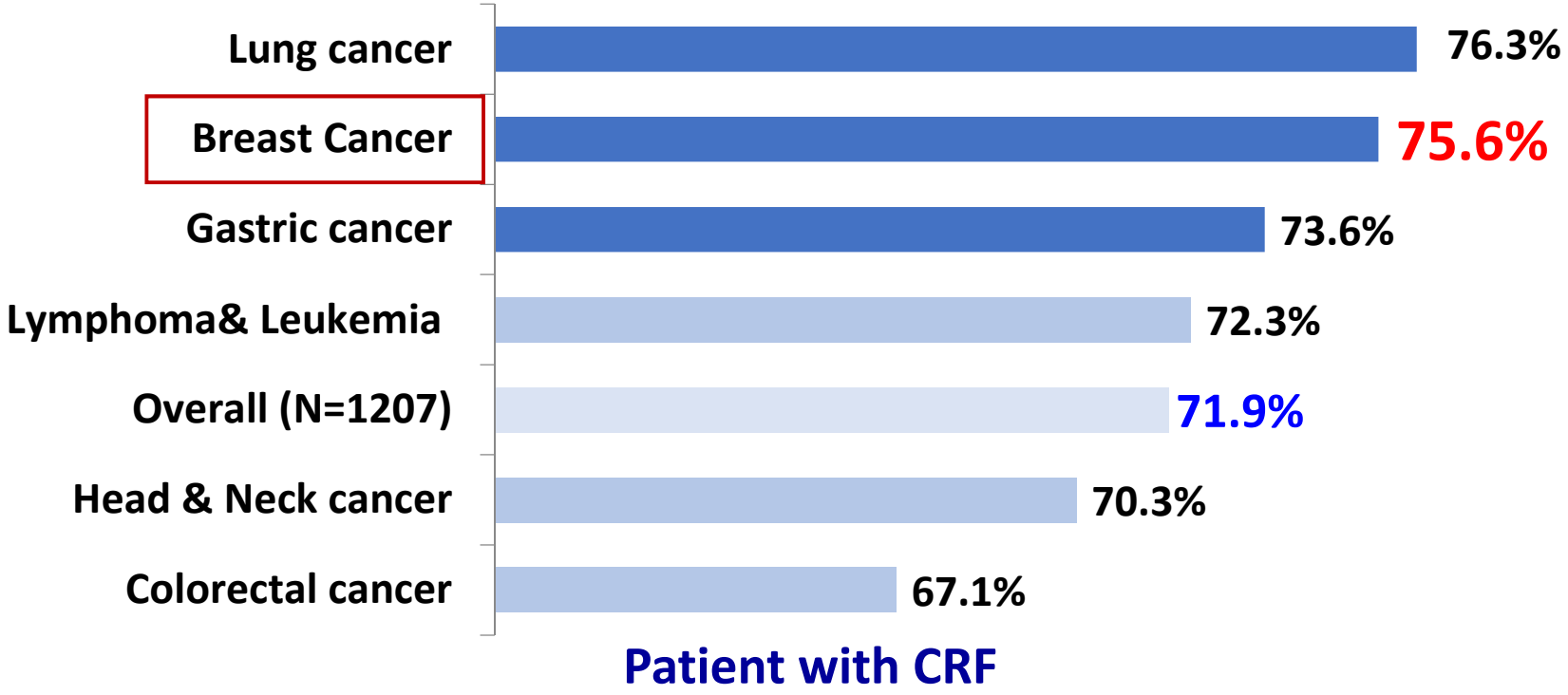


*Symptom distress scale in patients with cancer: ranging from 0 to 10, the higher score means the higher distress.

K. M. Rau et. al., Japanese Journal of Clinical Oncology, 2020, 1–9
2015 Palliative Care in Oncology Symposium, Boston; Oct 9-10, 2015, Abstract # 155471. 2016 MASCC Poster # MASCC-0488.

經BFI-T評估，72%癌症患者有癌因性疲憊

乳癌患者3/4有癌因性疲憊



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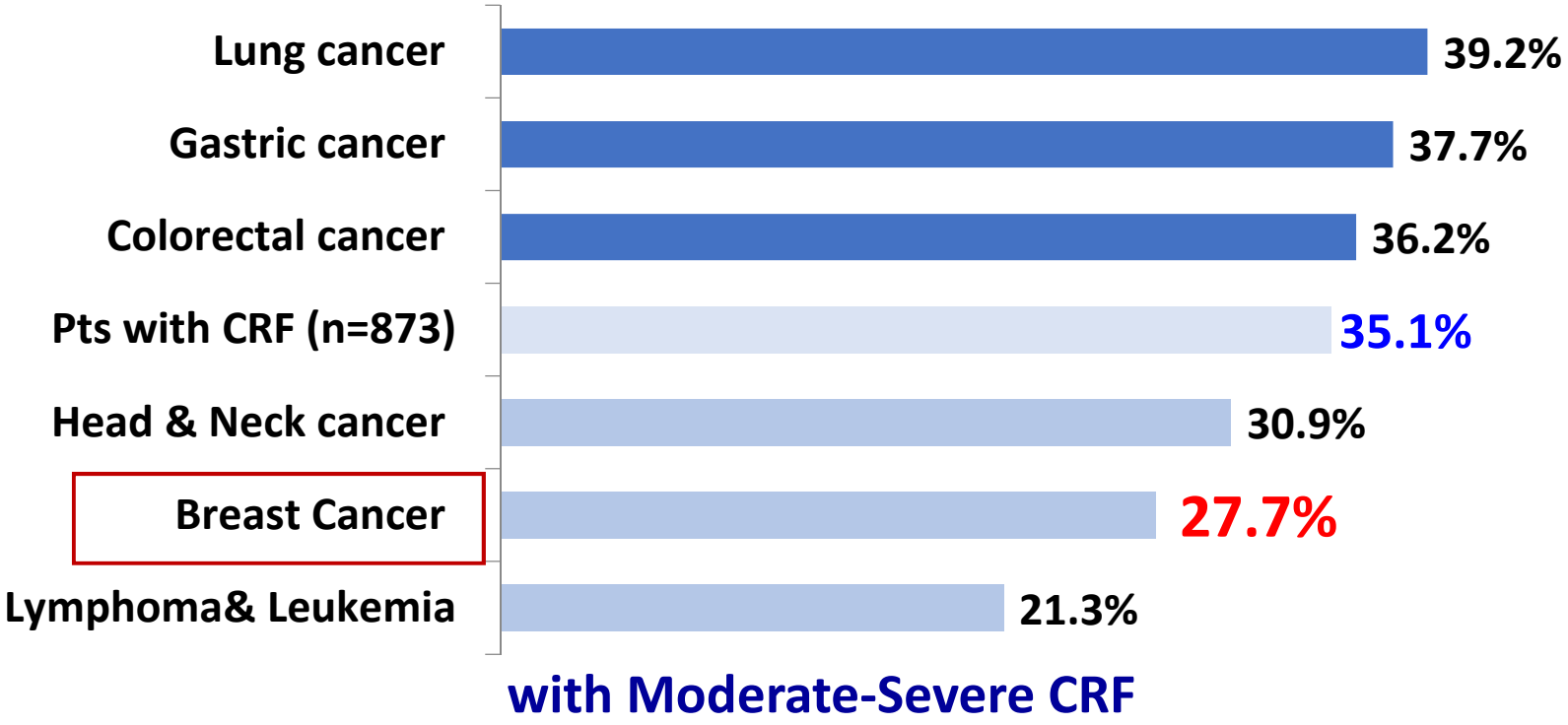
癌因性疲憊患者，35%為中重度疲憊

乳癌癌因性疲憊症患者，約28%為中重度疲憊



**The severity was calculated from the average of nine items from BFI –T and categorized into mild (<4), moderate (4-6.99), Severe (≧7).*

K. M. Rau et. al., Japanese Journal of Clinical Oncology, 2020, 1–9
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乳癌住院病人80%有疲憊，其中具中重度疲憊佔40%

BFI Evaluation	Overall (N=201)			Inpatient (N=66)			Outpatient (N=135)			P value in vs. out
Non-fatigue (%)	49	24.38%		13	19.70%		36	26.67%		0.3002
Fatigue (%)	152	**75.62%**		53	**80.30%**		99	**73.33%**		
-Mild	110	54.73%	72.37%	32	48.48%	60.38%	78	57.78%	78.79%	
-Moderate	34	16.92%	22.37%	17	25.76%	32.08%	17	12.59%	17.17%	
-Severe	8	3.98%	5.26%	4	6.06%	7.55%	4	2.96%	4.04%	
			27.63%			**39.62%**			**21.21%**	

**The severity was calculated from the average of nine items from BFI –T and categorized into mild (<4), moderate (4-6.99), Severe (≧7).*

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各期別乳癌病人之疲憊發生率為69~79%，Stage II-IV 疲憊分數高於 Stage I

BFI Evaluation	Stage I (N=26)		Stage II (N=59)		Stage III (N=39)		Stage IV (N=74)	
	N	%	N	%	N	%	N	%
Non-fatigue (%)	7	26.92%	18	30.51%	8	20.51%	16	21.62%
Fatigue (%)	19	**73.08%**	41	**69.49%**	31	**79.49%**	58	**78.38%**
BFI Score	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Global fatigue (Average all items)	1.59	1.86	2.24	2.54	1.87	1.62	**2.55***	2.28
Worst fatigue (Past 24 hours)	**2.88**	3.17	**3.88***	3.54	**3.72**	2.88	**4.09***	3.24
Interference of fatigue (Past 24 hours)	1.23	1.73	1.73	2.54	1.32	1.40	**2.14***	2.28

*: $P < 0.05$ with statistical significance compared with stage I

K. M. Rau et. al., Japanese Journal of Clinical Oncology, 2020, 1–9
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- 不論是否治療中，約3/4乳癌病人感覺疲憊
- 一週內有接受治療之乳癌病人，感受最累時的疲憊分數略高於未治療者

BFI Evaluation	Accept Cancer therapy (N=134)		No Cancer therapy (N=67)		p-value
	%	N	%	N	
Non-fatigue (%)	23.13%	31	26.87%	18	0.603
Fatigue (%)	**76.87%**	103	**73.13%**	49	
BFI Score	**Mean**	**SD**	**Mean**	**SD**	
Global fatigue (Average all items)	2.23	2.25	2.09	2.12	0.666
Worst fatigue (Past 24 hours)	**4.01**	3.41	**3.33**	2.85	0.134
Interference of fatigue (Past 24 hours)	1.70	2.17	1.76	2.15	0.866

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乳癌病人合併越多種癌症治療越疲憊

Cancer Therapies (in past 7 days)	N	%	BFI Global Score	
			Mean	SD
1	104	77.61%	**1.12**	**0.97**
Chemotherapy	57	42.54%	2.48	2.28
Hormone therapy	36	26.87%	2.02	2.42
Target therapy	8	5.97%	1.89	1.39
Radiation therapy	3	2.24%	4.11	3.63
2	27	20.15%	**1.90**	**1.80**
Chemotherapy + Other	21	15.67%	1.89	1.97
Chemotherapy + Target therapy	13	9.70%	1.95	1.90
Chemotherapy + Hormone	7	5.22%	1.08	0.88
Chemotherapy + Radiation therapy	1	0.75%	6.89	-
Others	6	4.48%	1.93	1.19
3	3	2.24%	**2.23**	**4.71**
Radiation therapy + Target therapy + Hormone therapy	2	1.49%	3.35	3.34
Chemotherapy + Target therapy + Hormone therapy	1	0.75%	0.00	-

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癌因性疲憊症之臨床治療指引

MANAGEMENT OF CANCER-RELATED FATIGUE

– A GUIDELINE FOR TAIWAN –

2017年 11月 第一版

台灣癌症安寧緩和醫學會

台灣腫瘤護理學會

Rau KM, Shun SC, Hung SH, Chou HL, Ho CL, Chao TC, Liu CY, Lien CT, Hong MY, Wu CJ, Tsai LY, Jane SW, Hsieh RK. Management of cancer-related fatigue in Taiwan: an evidence-based consensus for screening, assessment and treatment. Jpn J Clin Oncol. 2022 Nov 9:hyac164. doi: 10.1093/jjco/hyac164.

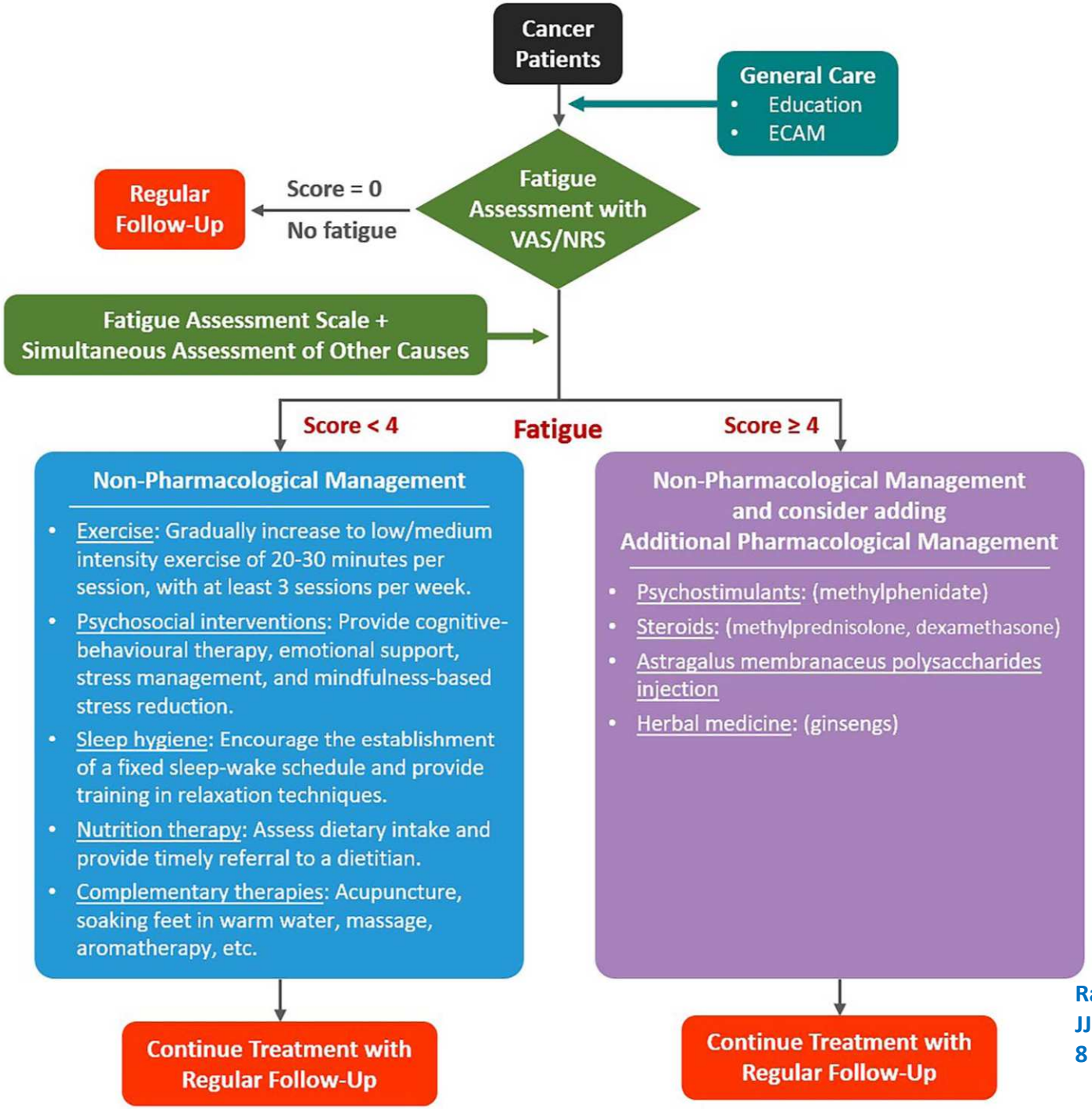
JJCO Japanese Journal of Clinical Oncology

Japanese Journal of Clinical Oncology, 2022, 1–12
https://doi.org/10.1093/jjco/hyac164
Original Article

Original Article

Management of cancer-related fatigue in Taiwan: an evidence-based consensus for screening, assessment and treatment

Kun-Ming Rau[1,2,†], Shiow-Ching Shun[3,†], Shih-Hsin Hung[4], Hsiu-Ling Chou[5,6,7], Ching-Liang Ho[8,9], Ta-Chung Chao[10,11], Chun-Yu Liu[12,13,14], Ching-Ting Lien[15], Ming-Ying Hong[16], Ching-Jung Wu[17,18,19], Li-Yun Tsai[20], Sui-Whi Jane[21,22] and Ruey-Kuen Hsieh[23,*]



Rau KM, et al.
JJCO, Accepted
8 October 2022

癌因性疲憊評估與治療

以VAS或BFI-T
評估疲憊

<4分
輕度疲憊

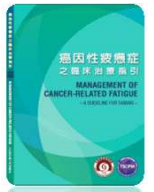
非藥物治療
運動、營養飲食、
認知行為治療、瑜珈
睡眠衛生等

≥4分
中重度疲憊

加上藥物治療
- 癌因性疲憊適應症處方用藥
  PG2 Injection
- 其他用藥
  類固醇、中樞神經興奮劑

Rau KM, Shun SC, Hung SH, Chou HL, Ho CL, Chao TC, Liu CY, Lien CT, Hong MY, Wu CJ, Tsai LY, Jane SW, Hsieh RK. Management of cancer-related fatigue in Taiwan: an evidence-based consensus for screening, assessment and treatment. Jpn J Clin Oncol. 2022 Nov 9:hyac164. doi: 10.1093/jjco/hyac164.

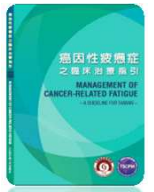
癌因性疲憊症之藥物治療



Methylphenidate 臨床研究顯示使用於疲憊程度或病情較嚴重的病人較具效果；但在用藥前應審慎考量劑量、用藥時間、濫用風險、及病人個人疾病等臨床情形，充分評估相關風險與效益。 (Level IA, Grade A)	**Methylprednisolone、dexamethasone**等類固醇藥物有臨床證據顯示可以改善癌症病人的疲憊和生活品質，但長期使用有安全風險，故建議只用於癌症末期、合併疲憊與厭食症、或有腦部或骨骼轉移而疼痛的癌症病人。 (Level IB, Grade B)

Rau KM, Shun SC, Hung SH, Chou HL, Ho CL, Chao TC, Liu CY, Lien CT, Hong MY, Wu CJ, Tsai LY, Jane SW, Hsieh RK. Management of cancer-related fatigue in Taiwan: an evidence-based consensus for screening, assessment and treatment. Jpn J Clin Oncol. 2022 Nov 9:hyac164. doi: 10.1093/jjco/hyac164.

癌因性疲憊症之藥物治療



	蔘類在臨床試驗顯示可以改善癌因性疲憊，但因中藥在使用上會因原料製備等影響，建議使用前應諮詢醫療團隊。(Level IB, Grade B)
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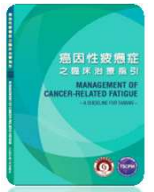
癌因性疲憊症之藥物治療



黃耆多醣注射劑有初步臨床試驗顯示可改善中重度癌因性疲憊症。 (Level IA, Grade A)	蔘類在臨床試驗顯示可以改善癌因性疲憊，但因中藥在使用上會因原料製備等影響，建議使用前應諮詢醫療團隊。 (Level IB, Grade B)
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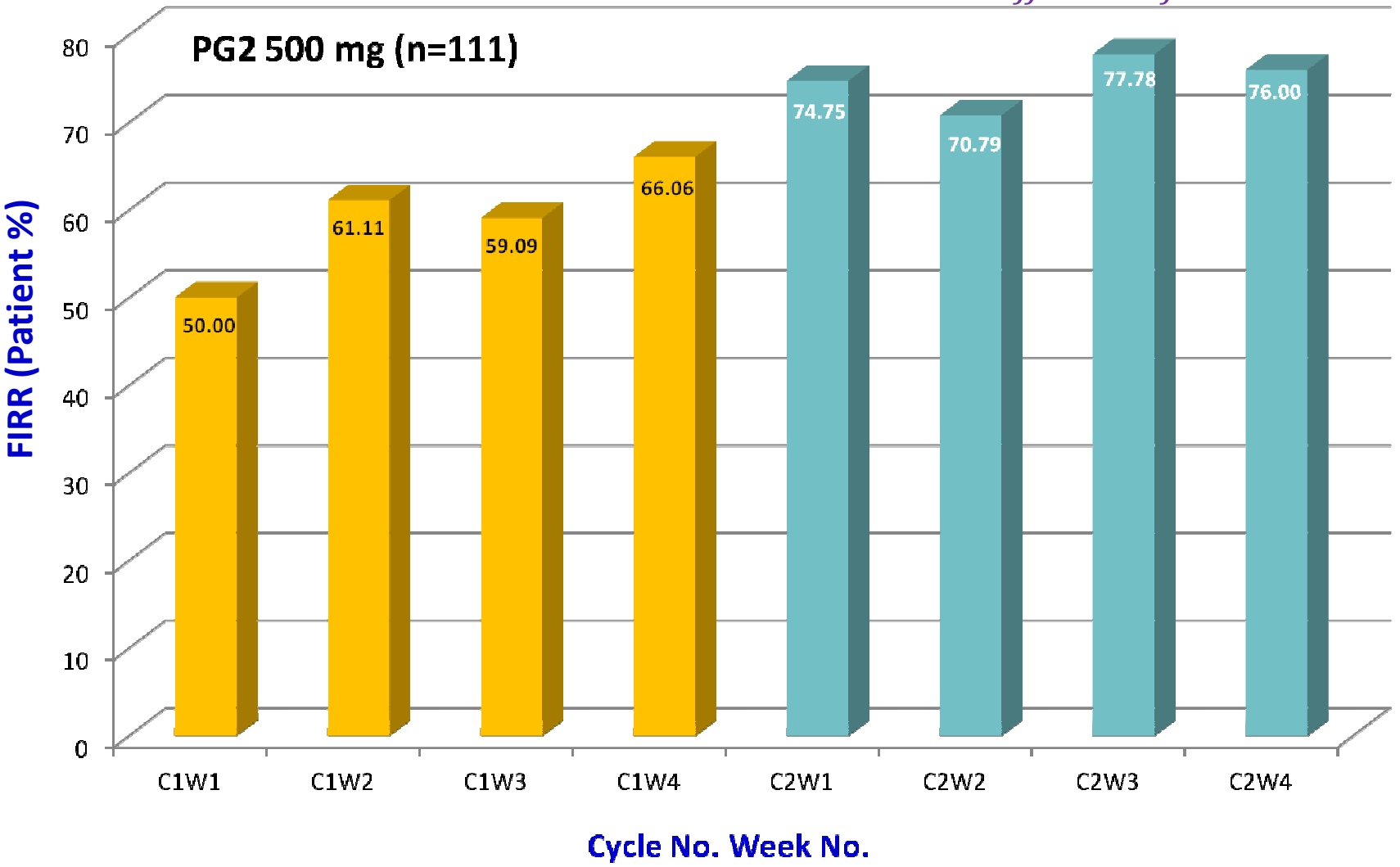
PG2 Phase IV Trial

Center	馬偕，雙和，基隆長庚情人湖院區，三總，彰基，奇美柳營，中醫大，林口長庚，高雄長庚
Trial Objective	To evaluate the **efficacy and safety** of different doses of PG2 for relieving fatigue among advanced cancer patients who are under standard palliative care (SPC).
Blinding/ Randomization	Double-blinded/Randomized
Population	Advanced progressive cancer patients with moderate to severe fatigue (**BFI Fatigue score ≥ 4**) under palliative care.
Treatment Regimens	Two parallel arms: (1:1 ratio) 1. PG2 500 mg by IV infusion for 3 days per week 2. PG2 250 mg by IV infusion for 3 days per week
Study Period	8 weeks
Primary Endpoint	Fatigue Improvement Response Rate (FIRR)
Sample Size	Enrolled Patient No.: 323 Evaluable Patient No.: 214

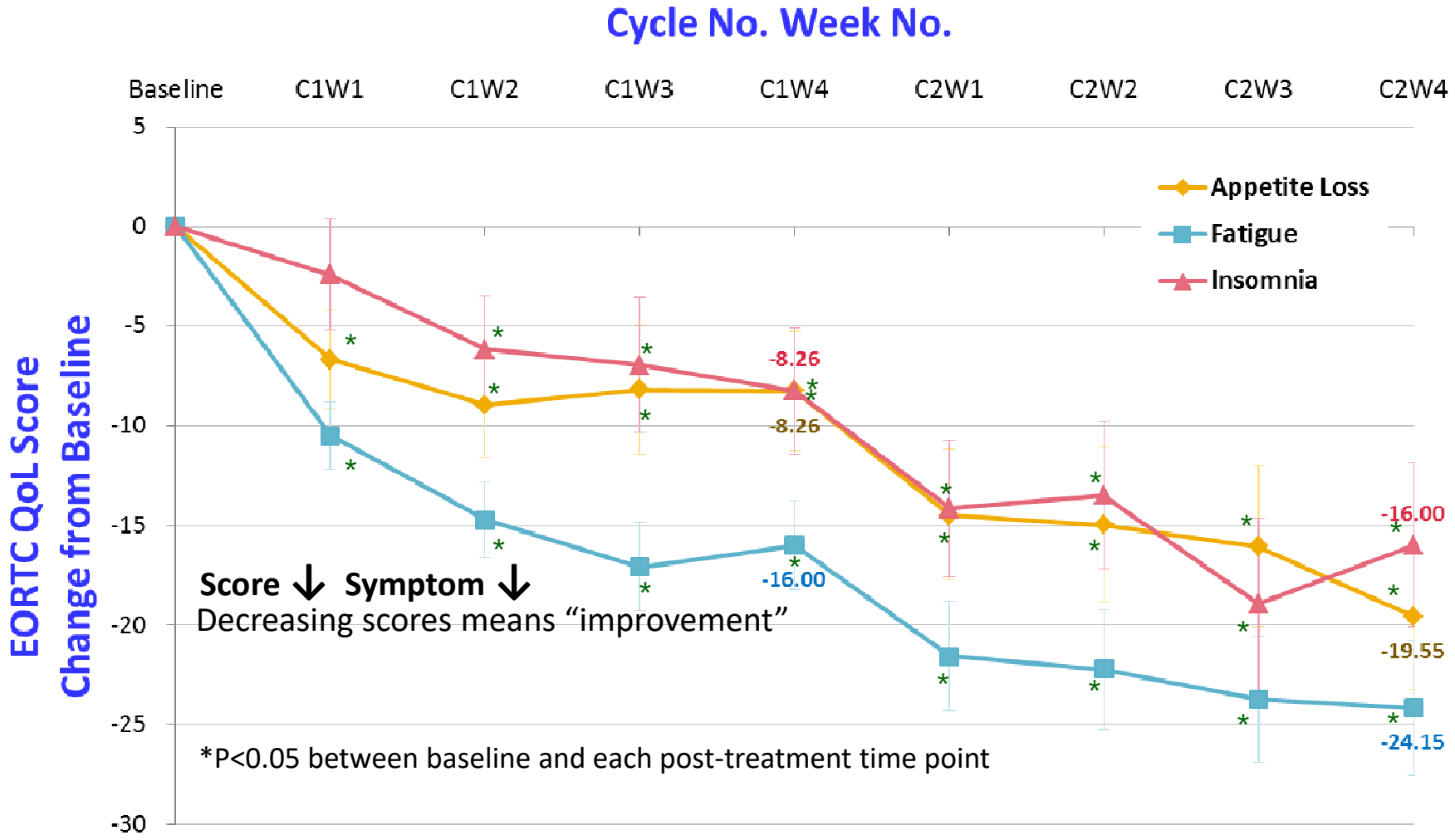
FIRR by Week during the Whole Study Period

Cut-off Point of FIR: 10 %



J Clin Oncol 36, 2018 (suppl; abstr 10091); 2018 ASCO Annual Meeting, Poster Presentation Abstract #: 10091. PhytoHealth In-house Data

Global Health Status: domains with significant improvement



2018 MASCC e-Poster Presentation; J Clin Oncol 36, 2018 (suppl; abstr 10091); 2018 ASCO Annual Meeting, Poster Presentation Abstract #: 10091. PhytoHealth In-house Data

cancers

MDPI

Article

Karnofsky Performance Status as A Predictive Factor for Cancer-Related Fatigue Treatment with Astragalus Polysaccharides (PG2) Injection—A Double Blind, Multi-Center, Randomized Phase IV Study

Cheng-Hsu Wang [1], Cheng-Yao Lin [2], Jen-Shi Chen [3,4], Ching-Liang Ho [5], Kun-Ming Rau [6,7,8], Jo-Ting Tsai [9,10], Cheng-Shyong Chang [11], Su-Peng Yeh [12], Chieh-Fang Cheng [13] and Yuen-Liang Lai [14,15,*]

Received: 22 October 2018; Accepted: 15 January 2019; Published: 22 January 2019

check for updates

Cancers **2019**, *11*, 128; doi:10.3390/cancers11020128

www.mdpi.com/journal/cancers

Cancers . 2019 Jan 22;11(2):128-140.

Multivariate analysis for responders and non-responders to PG2

- Higher KPS responded better to PG2.

	Cut-off Points = 10%			Multivariate Analysis	
Variable/Status	Responder (*N* = 140)	Non-Responder (*N* = 74)	Univariate Analysis *p*-value *	Odds Ratio (95% CI)	*p*-value **
Baseline KPS score					
30–50	22 (15.71%)	31 (41.89%)	<0.0001 [C]	0.253 (0.126, 0.504)	<0.0001
60–90	118 (84.29%)	43 (58.11%)			

Single Patient

Baseline KPS score	Responder %
30-50 (N=53)	22 (42%)
60-90 (N=161)	118 (73%)

Cancers. 2019 Jan 22;11(2): 128-140.

Summary of PG2® Phase IV Study

- **Fatigue improvement**

✓ PG2® treatment showed efficacy in relieving fatigue as early as the first week of treatment.

✓ Clinically meaningful fatigue improvement (≥ 10%) was observed in **more than 65%** of subjects receiving PG2® after the cycle 1 treatment when compared to baseline.

✓ Patients with **higher KPS showed better chance** to respond to PG2 treatment in BFI-T score.

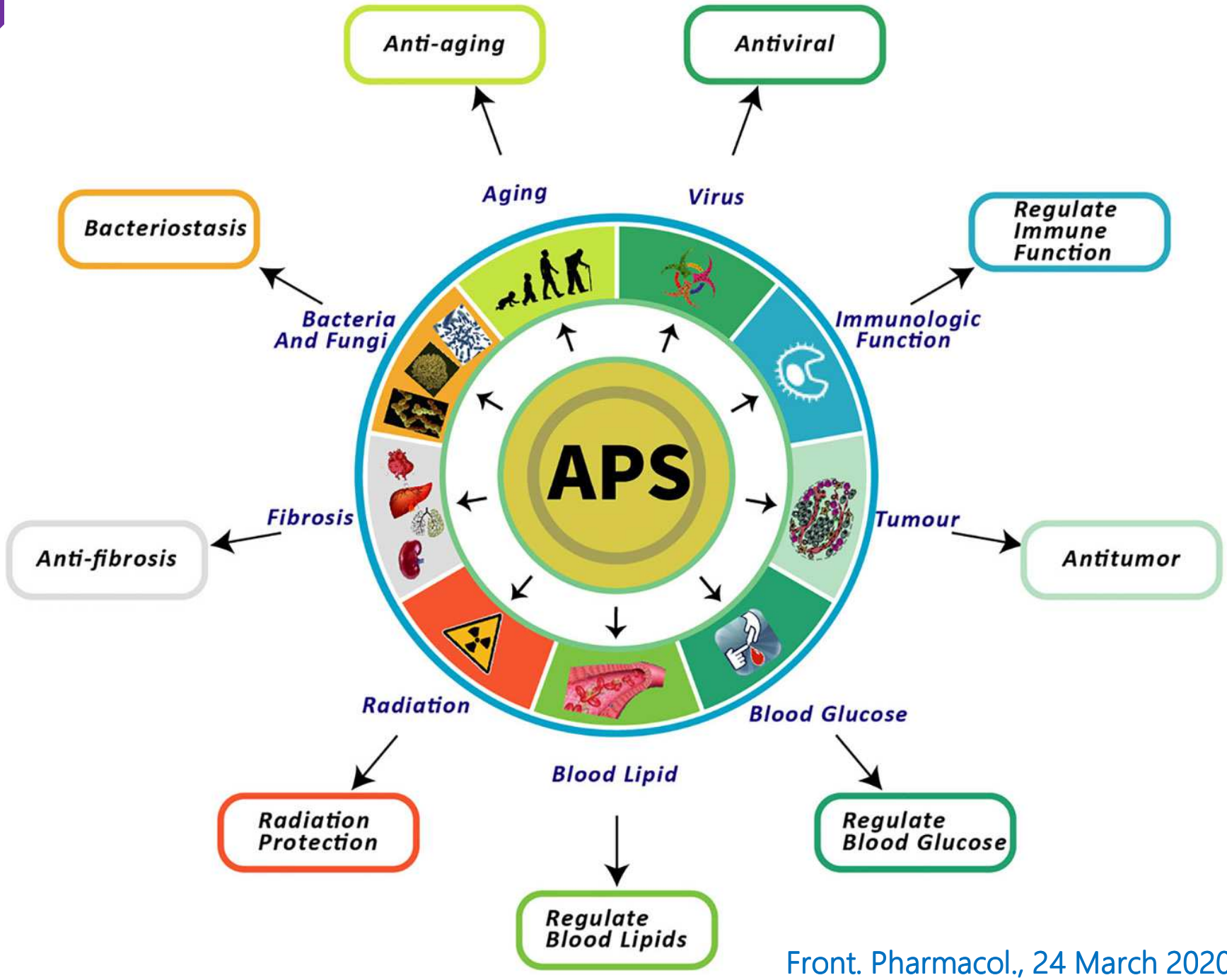
J Clin Oncol 36, 2018 (suppl; abstr 10091); 2018 ASCO Annual Meeting, Poster Presentation Abstract #: 10091. Cancers. 2019 Jan 22;11(2): 128-140.

https://riordanclinic.org/2019/08/cancer-related-fatigue/

癌因性疲憊治療適應症之處方用藥
PG2® Injection

- 成份：黃耆多醣 (Polysaccharides of *Astragalus membranaceus*)
  萃取物 500 mg ，不含任何賦形劑。
  分子量約20,000~60,000 Da
- 適應症：**治療癌症療程中所導致的中、重度疲憊症**
- **機轉：增強免疫功能及刺激骨髓造血功能**
- 用法及用量：
  - 成人每次劑量 500 mg，
    2.5 - 3.5 小時點滴靜脈滴注。
  - 每週2 - 4次，使用2 - 4週。

食品藥物管理署(TFDA)核准之第一個植物性處方用藥：**西藥藥證衛部藥製字第058837號**


Anti-aging
Antiviral
Aging
Virus
Bacteriostasis
Regulate Immune Function
Bacteria And Fungi
Immunologic Function
APS
Fibrosis
Anti-fibrosis
Tumour
Antitumor
Radiation
Blood Glucose
Blood Lipid
Radiation Protection
Regulate Blood Glucose
Regulate Blood Lipids

PG2®: beyond Cancer-related Fatigue Treatment

- **A therapeutically-relevant role for PG2 in modulating the M1/M2**
  - ✓ The treatment with PG2 elicited significant depletion of the tumor-associated M2 population.
- **Synergistically enhanced the anticancer effect of chemotherapeutic agent, cisplatin**
  - ✓ Inhibited tumor growth and metastasis.
  - ✓ In the presence of PG2, cisplatin-associated dyscrasia and weight-loss was markedly suppressed.

Nutrients_2019(11)2264-2283.

nutrients

MDPI

Article

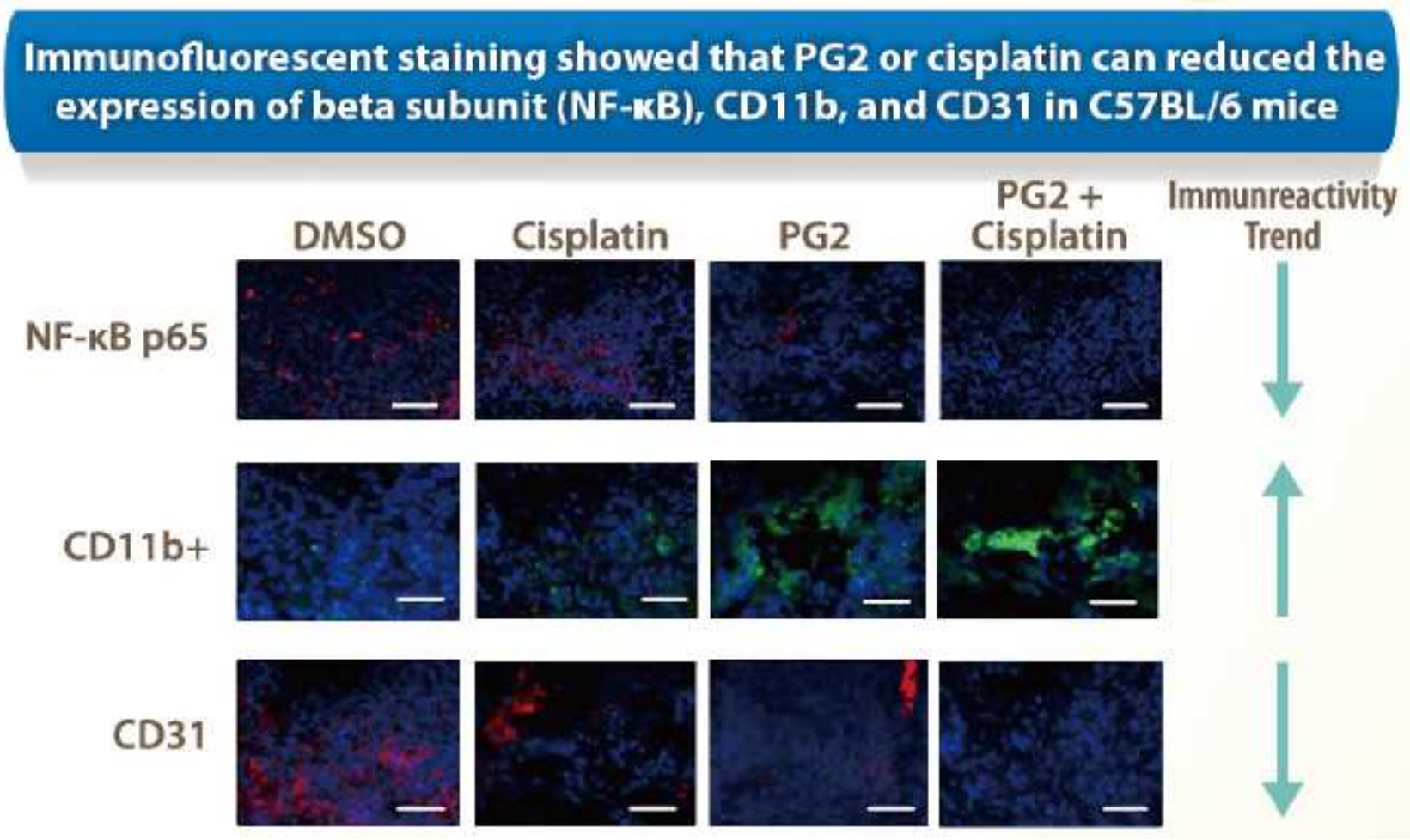
Astragalus polysaccharides (PG2) Enhances the M1 Polarization of Macrophages, Functional Maturation of Dendritic Cells, and T Cell-Mediated Anticancer Immune Responses in Patients with Lung Cancer

Oluwaseun Adebayo Bamodu [1,2,†], Kuang-Tai Kuo [3,4,†], Chun-Hua Wang [5,6], Wen-Chien Huang [7,8], Alexander T.H. Wu [9], Jo-Ting Tsai [10,11], Kang-Yun Lee [12], Chi-Tai Yeh [1,2,13,*] and Liang-Shun Wang [3,4,*]

1 Division of Hematology & Oncology, Department of Medicine, Shuang Ho Hospital, Taipei Medical University, New Taipei City 235, Taiwan; 16625@s.tmu.edu.tw
2 Department of Medical Research and Education, Shuang Ho Hospital, Taipei Medical University, New Taipei City 235, Taiwan
3 Division of Thoracic Surgery, Department of Surgery, Shuang Ho Hospital, Taipei Medical University, New Taipei City 235, Taiwan; doc2738h@gmail.com
4 Division of Thoracic Surgery, Department of Surgery, School of Medicine, College of Medicine, Taipei Medical University, Taipei City 110, Taiwan

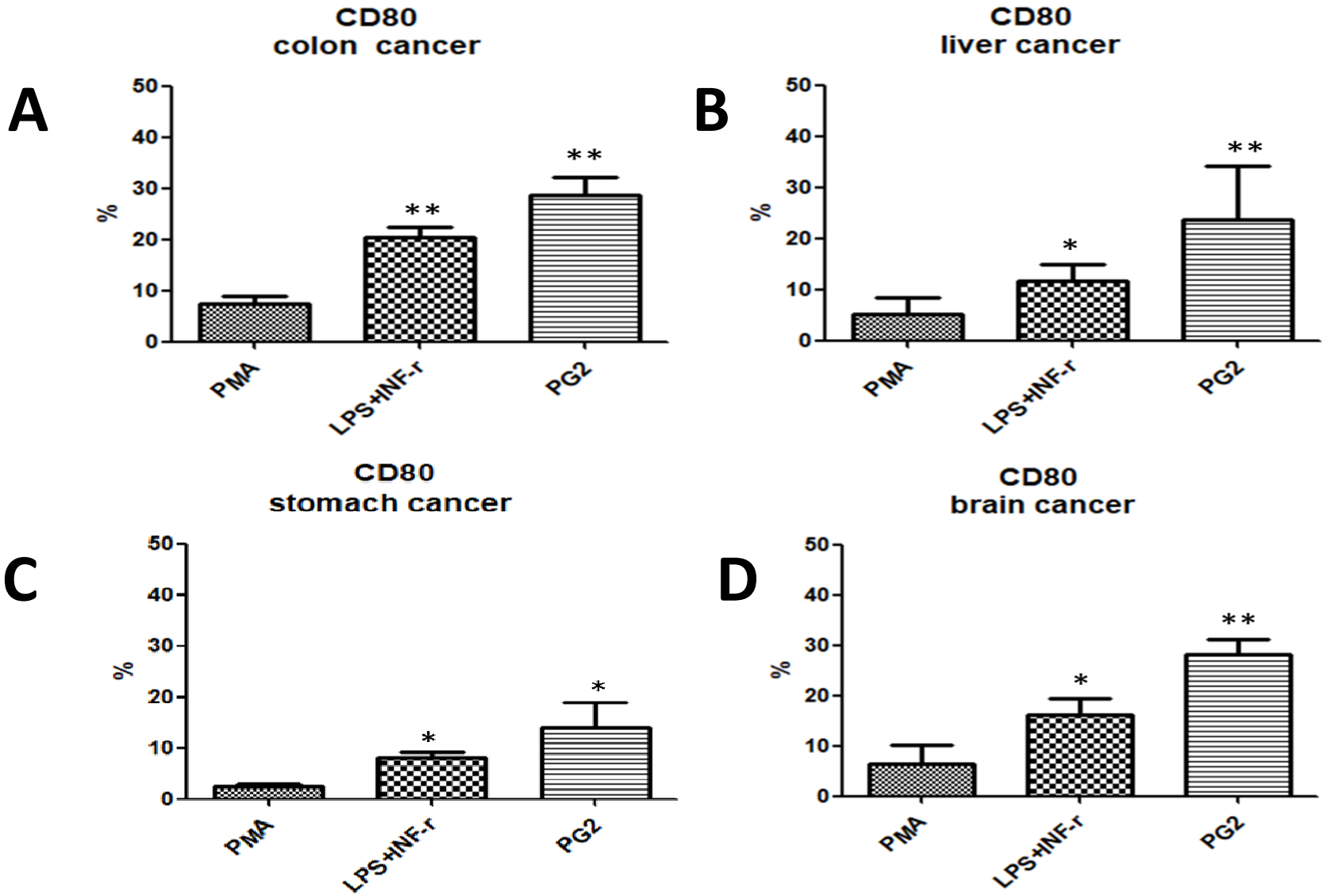
Nutrients_2019(11)2264-2283.

Regulating tumor micro-environment & suppressing tumorigenicity



Nutrients_2019(11)2264-2283.

PG2 modulated the population of CD80+ M1 macrophages derived from PBMCs of different type of cancer patients



U.S. Patent. Patent No.: US 10,478,468 B2. Method for enhancing effect of immunotherapy for cancer

Nutrients_2019(11)2264-2283.

Research Article

Astragalus Polysaccharide Injection (PG2) Normalizes the Neutrophil-to-Lymphocyte Ratio in Patients with Advanced Lung Cancer Receiving Immunotherapy

Integrative Cancer Therapies
Volume 20: 1–7

DOI: 10.1177/1534735421995256
journals.sagepub.com/home/ict
SAGE

Shih Ming Tsao, PhD, MD[1], Tz Chin Wu, PhD, MD[1], JiZhen Chen, Msc[2], Feichi Chang, BS[1], and Thomos Tsao, PhD, MD[1]

cancers

MDPI

Article

Astragalus polysaccharide (PG2) Ameliorates Cancer Symptom Clusters, as well as Improves Quality of Life in Patients with Metastatic Disease, through Modulation of the Inflammatory Cascade

Wen-Chien Huang [1,2,†], Kuang-Tai Kuo [3,4,†], Oluwaseun Adebayo Bamodu [5,6], Yen-Kuang Lin [7], Chun-Hua Wang [8,9], Kang-Yun Lee [10], Liang-Shun Wang [3,4], Chi-Tai Yeh [5,6,*] and Jo-Ting Tsai [11,12,*]

Cancers 2019, 11, 1054

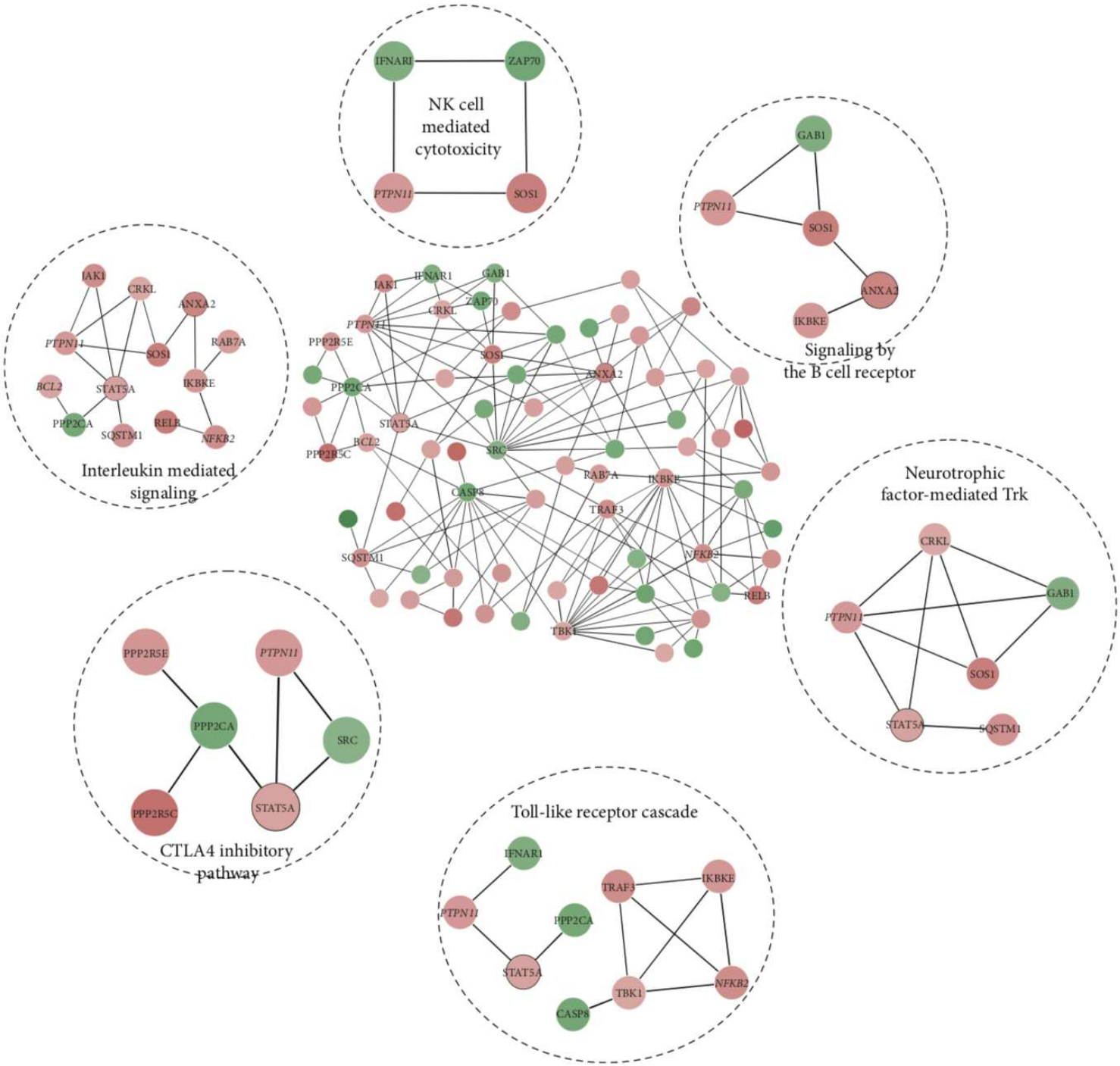
PG2 anti-inflammatory effects and improved QoL in patients with advanced stage cancers

Hindawi Publishing Corporation
Evidence-Based Complementary and Alternative Medicine
Volume 2015, Article ID 917345, 15 pages
http://dx.doi.org/10.1155/2015/917345

Research Article

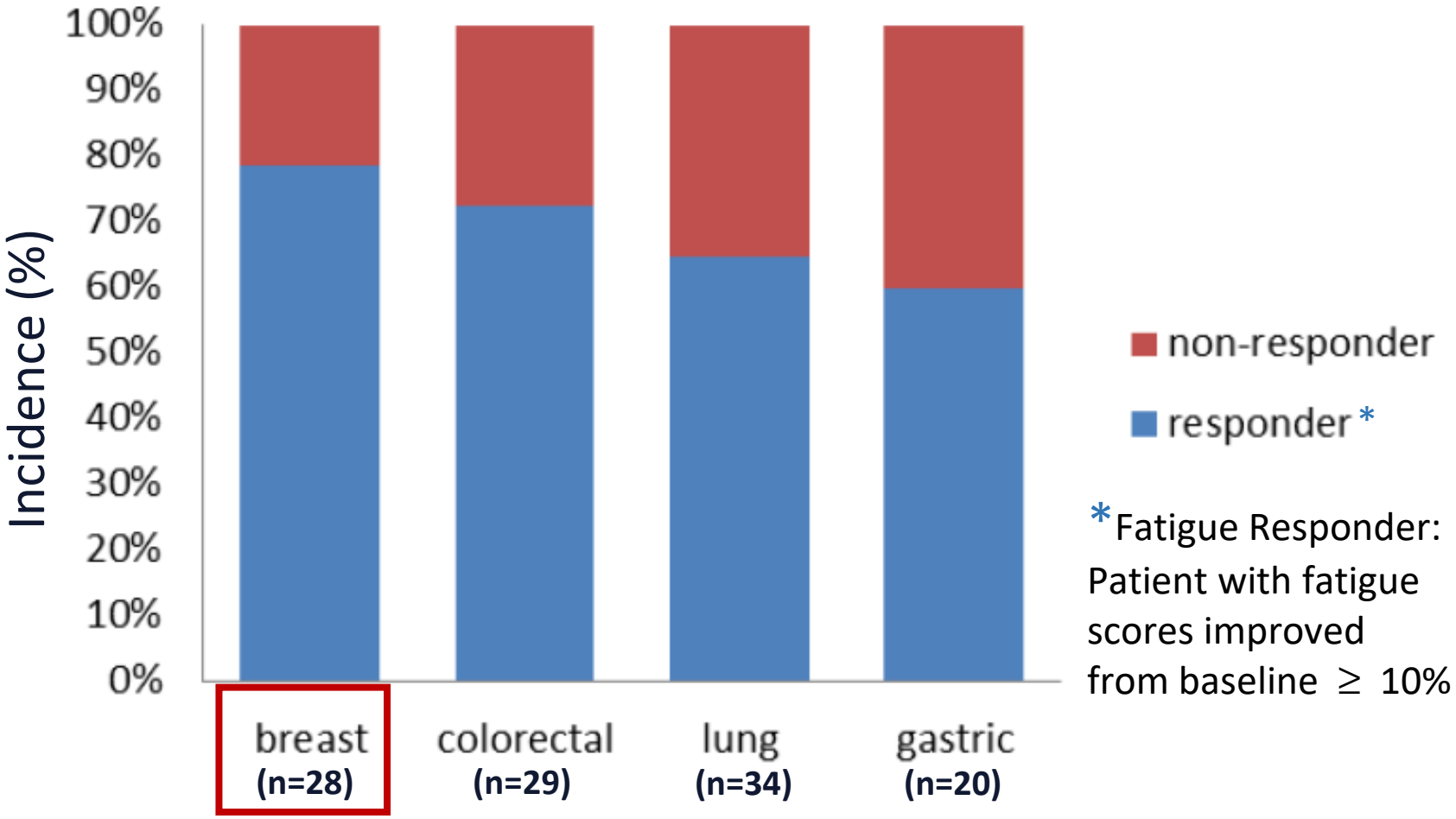
Gene Expression Profiling and Pathway Network Analysis Predicts a Novel Antitumor Function for a Botanical-Derived Drug, PG2

Yu-Lun Kuo,[1] Chun-Houh Chen,[2] Tsung-Hsien Chuang,[3] Wei-Kai Hua,[4] Wey-Jinq Lin,[4] Wei-Hsiang Hsu,[4] Peter Mu-Hsin Chang,[5,6] Shih-Lan Hsu,[7] Tse-Hung Huang,[8,9,10] Cheng-Yan Kao,[1,11] and Chi-Ying F. Huang[4,5,12]


NK cell mediated cytotoxicity
IFNAR1
ZAP70
PTPN11
SOS1
Signaling by the B cell receptor
GAB1
PTPN11
SOS1
ANXA2
IKBKE
Interleukin mediated signaling
JAK1
CRKL
ANXA2
PTPN11
SOS1
RAB7A
BCL2
STAT5A
IKBKE
PPP2CA
SQSTM1
RELB
NFKB2
PPP2R5E
PPP2CA
SRC
STAT5A
PPP2R5C
PTPN11
CTLA4 inhibitory pathway
Neurotrophic factor-mediated Trk
CRKL
GAB1
PTPN11
SOS1
STAT5A
SQSTM1
Toll-like receptor cascade
IFNAR1
PTPN11
PPP2CA
STAT5A
TRAF3
IKBKE
TBK1
NFKB2
CASP8

https://cinj.org/living-well-cancer-related-fatigue

Fatigue Improvement Response Rates (FIRR) by Cancer Type



*Fatigue Responder: Patient with fatigue scores improved from baseline ≥ 10%

Cancers 2019, 11, 128; doi:10.3390/cancers11020128

Polysaccharides of Astragalus membranaceus (PG2 Lyo. Injection) 健保給付規定

第三節 代謝及營養劑 (自110年3月1日生效)

使用本藥品應符合下列各條件：

1. 用於**第四期**因疾病進展導致**中重度疲憊之乳癌**成人患者(不含住院安寧療護病患) 。
2. 臨床上需符合ICD-10診斷標準，病歷上應詳細記載**疲憊分數≥4** (BFI-T或 VAS)，經其他處置無效之中重度癌因性疲憊症患者。
3. ECOG需為0-2之患者。
4. 每位病人終生給付6支為上限。
5. 需經事先審查核准後使用。

PG2 RWE Study

Study Center	Taichung Veterans General Hospital Kaohsiung Medical University E-Da Cancer Hospital Taipei Chang Gung Memorial Hospital Tri-Service General Hospital China Medical University Hospital Linkou Chang Gung Memorial Hospital
Data Collection Period for Analysis	01/Mar/2021~31/May/2023

PG2 RWE Study

Objectives	This study is performed to evaluate the clinical use**, fatigue improvement**, and **treatment satisfaction** of breast cancer patients with PG2 Lyo. injection.
Methodology	This is a single arm, multicenter, and retrospective study.
Inclusion Criteria	**Breast cancer** patients treated by PG2 Lyo. injection under Taiwan National Health Insurance (NHI).
Endpoint for Clinical Benefit Evaluation	Primary Endpoint: - **Fatigue improvement.** Secondary Endpoints: - Fatigue treatment satisfaction: Clinical Global Impression-Improvement (**CGI-I**) and **overall clinical evaluation by physicians, and patient's expectation to continue CRF treatment**

Demographic Information

Characteristics	Results
Gender	
N	106
Male	0 (0.00%)
Female	106 (100.00%)
Age	
N	106
Mean(SD)	57.30 (11.45)
Range	27 ~ 80
Weight (kg)	
N	106
Mean(SD)	58.55 (10.32)
Range	36.9 ~ 89.7
Height (cm)	
N	106
Mean(SD)	156.87 (5.22)
Range	143.0 ~ 168.5
BMI	
N	106
Mean(SD)	23.77 (3.85)
Range	15.36 ~ 33.71

Disease Characteristics

Characteristics (N=106)	Results	
Histological type	**N**	**%**
Ductal	**81**	**76.42%**
Lobular	3	2.83%
Mixed	2	1.89%
Other	5	4.72%
Unknown	15	14.15%
Locally Advanced or Distant Metastasis	**N**	**%**
Locally Advanced	1	0.94%
Distant Metastasis	105	99.06%
Bone	**60**	**56.60%**
Liver	**40**	**37.74%**
Lymph nodes (Regional LN)	**38**	**35.85%**
Lymph nodes (Distant LN)	**41**	**38.68%**
Lungs	**56**	**52.83%**
Brain	16	15.09%
Skin	6	5.66%
Other	11	10.38%

Characteristics (N=106)	Results	
Menopausal Status	**N**	**%**
Premenopausal	12	11.32%
Premenopausal with ovary function suppression	11	10.38%
Postmenopausal	**83**	**78.30%**
Molecular Type	**N**	**%**
Lumina A	12	7.04%
Lumina B	**52**	**46.48%**
Her-2 enriched	17	15.49%
Triple-negative	**19**	**21.13%**
Unknown	6	9.86%

- Most were **postmenopausal** women **(78%)**.
- The major histologic type of breast cancer was **ductal carcinomas (76%).**
- Patients with stage IV breast cancers that had spread mainly to **lymph nodes (75%), bone (57%), Lungs (53%) and Liver (38%).**

Previous and Current Cancer Therapy

79% of patients received PG2 Injection treatment under chemotherapy or chemo-combination therapy.

No. Cancer Therapies/type	Previous		4-Doses		6-Doses		Treatment period	
N	106		106		85		85	
0	0	0.00%	0	0.00%	1	1.18%	0	0.00%
1	39	36.79%	46	43.40%	37	43.53%	26	30.59%
Chemotherapy	28	26.42%	33	31.13%	27	31.76%	19	22.35%
Targeted Therapy	8	7.55%	12	11.32%	9	10.59%	6	7.06%
Hormone Therapy	1	0.94%	0	0.00%	0	0.00%	0	0.00%
Surgery	1	0.94%	0	0.00%	0	0.00%	0	0.00%
Immunotherapy	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Others	1	0.94%	1	0.94%	1	1.18%	1	1.18%
2	56	52.83%	48	45.28%	40	47.06%	42	49.41%
Chemotherapy + Surgery	0	0.00%	1	0.94%	1	1.18%	1	1.18%
Chemotherapy + Targeted Therapy	25	23.58%	22	20.75%	14	16.47%	20	23.53%
Chemotherapy + CCRT	0	0.00%	2	1.89%	2	2.35%	1	1.18%
Chemotherapy + Hormone Therapy	14	13.21%	9	8.49%	8	9.41%	10	11.76%
Chemotherapy + Immunotherapy	1	0.94%	1	0.94%	1	1.18%	1	1.18%
Targeted Therapy + Hormone Therapy	12	11.32%	12	11.32%	13	15.29%	7	8.24%
Targeted Therapy + CCRT	1	0.94%	0	0.00%	0	0.00%	1	1.18%
Hormone Therapy + Others	1	0.94%	1	0.94%	0	0.00%	0	0.00%
CCRT + Others	1	0.94%	0	0.00%	0	0.00%	0	0.00%
Targeted Therapy + Others	1	0.94%	0	0.00%	1	1.18%	1	1.18%
3	10	9.43%	10	9.43%	6	7.06%	13	15.29%
Chemotherapy + Targeted Therapy + Hormone Therapy	4	3.77%	6	5.66%	5	5.88%	6	7.06%
Chemotherapy + Targeted Therapy + CCRT	2	1.89%	1	0.94%	1	1.18%	2	2.35%
Chemotherapy + Targeted Therapy + Others	1	0.94%	0	0.00%	0	0.00%	1	1.18%
Chemotherapy + Surgery + Hormone Therapy	1	0.94%	1	0.94%	0	0.00%	1	1.18%
Chemotherapy + Surgery + Immunotherapy	1	0.94%	0	0.00%	0	0.00%	1	1.18%
Surgery +Targeted therapy +Hormone Therapy	1	0.94%	1	0.94%	0	0.00%	1	1.18%
Targeted Therapy + Hormone Therapy + Others	0	0.00%	1	0.94%	0	0.00%	1	1.18%
4 and above	1	0.94%	2	1.89%	1	1.18%	4	4.71%
Chemotherapy + Targeted Therapy + Hormone Therapy + Surgery	1	0.94%	1	0.94%	0	0.00%	1	1.18%
Chemotherapy + Targeted Therapy + Hormone Therapy + CCRT	0	0.00%	1	0.94%	1	1.18%	3	3.53%

VAS Fatigue Score by Visits

Patients received **6 doses** of PG2 Lyo. Injection had significantly **lower fatigue scores** than baseline
(VAS score 3.38~3.49; achieve the treatment goal of **VAS score < 4**)

VAS Fatigue Score of the WORST Level during **Past 24 hours**

visit	N	Missing Data	Mean	SD	Median	Min	Max	95% CI	Paired t-test from baseline
Baseline	106	0	**6.52**	1.43	6	3	10	6.24 ~ 6.79	
4-Doses	105	1	**4.03**	1.78	4	0	10	3.68 ~ 4.37	**< 2.2e-16**
6-Doses	84	1	**3.38**	1.52	3	0	8	3.05 ~ 3.71	**< 2.2e-16**

VAS Fatigue Score of the WORST Level after the **Last Anti-cancer Treatment (or within 4 weeks until now)**

visit	N	Missing Data	Mean	SD	Median	Min	Max	95% CI	Paired t-test from base line
Baseline	101	5	**6.83**	1.41	7	2	10	6.55 ~ 7.11	
4-Doses	105	1	**4.21**	1.80	4	0	9	3.86 ~ 4.56	**< 2.2e-16**
6-Doses	84	1	**3.49**	1.60	3	0	9	3.14 ~ 3.84	**< 2.2e-16**

VAS Fatigue Score Change from Baseline

Patients received 6 doses of PG2 Lyo. Injection had significantly lower fatigue scores than received 4 doses

The WORST Level during **Past 24 hours**

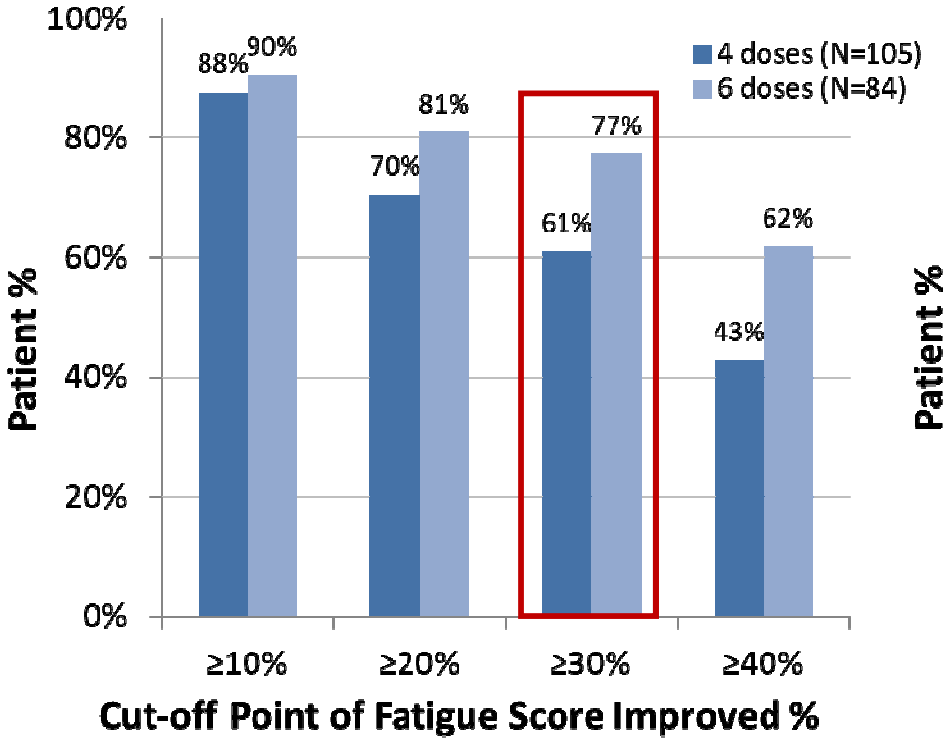
visit	N	Missing Data	Mean	SD	Median	Min	Max	95% CI
4-Doses	105	1	-2.48	1.99	-2	-9	2	-2.86 ~ -2.09
%	105	1	-36.66%	27.12%	-37.50%	-100.00%	40.00%	-41.91% ~ -31.42%
6-Doses	84	1	**-2.98**	2.14	-3	-7	4	-3.44 ~ -2.51
%	84	1	**-43.16%**	32.72%	-50.00%	-100.00%	100.00%	-50.26% ~ -36.06%

The WORST Level after the **Last Anti-cancer Treatment (or within 4 weeks until now)**

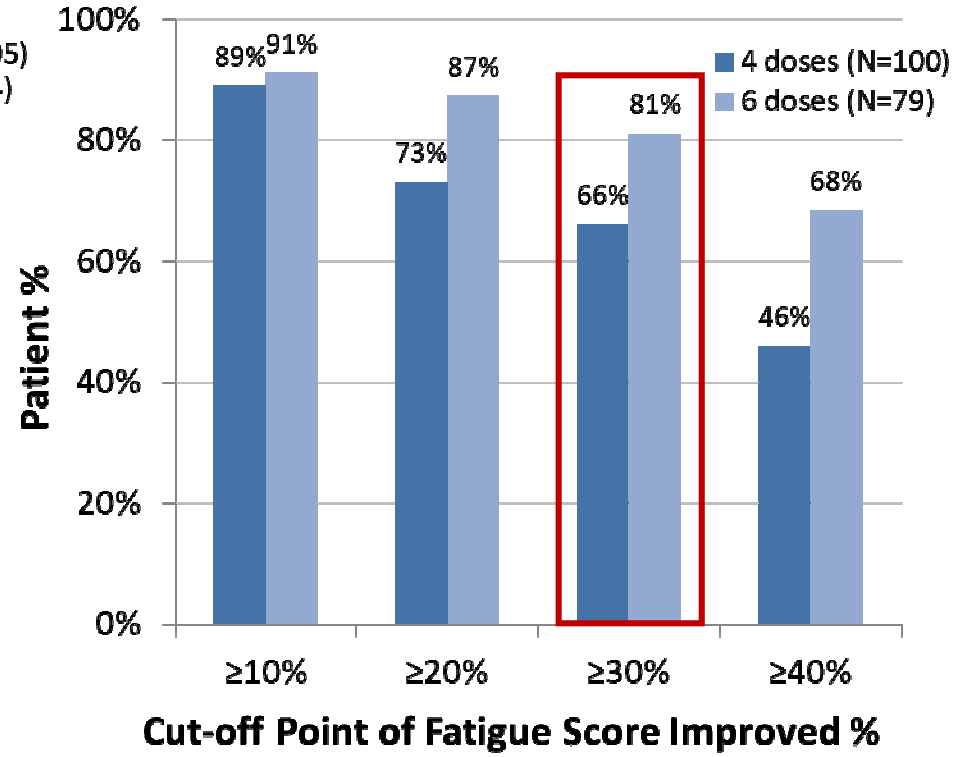
visit	N	Missing Data	Mean	SD	Median	Min	Max	95% CI
4-Doses	100	6	-2.59	2.02	-2.5	-8	3	-2.99 ~ -2.19
%	100	6	-36.36%	27.18%	-37.50%	-100.00%	50.00%	-41.75% ~ -30.96%
6-Doses	79	6	**-3.30**	2.03	-3	-8	3	-3.76 ~ -2.85
%	79	6	**-46.73%**	25.95%	-50.00%	-100.00%	50.00%	-52.54% ~ -40.92%

Fatigue Improvement Response Rate (by Score Change%)

The WORST Level during **Past 24 hours**



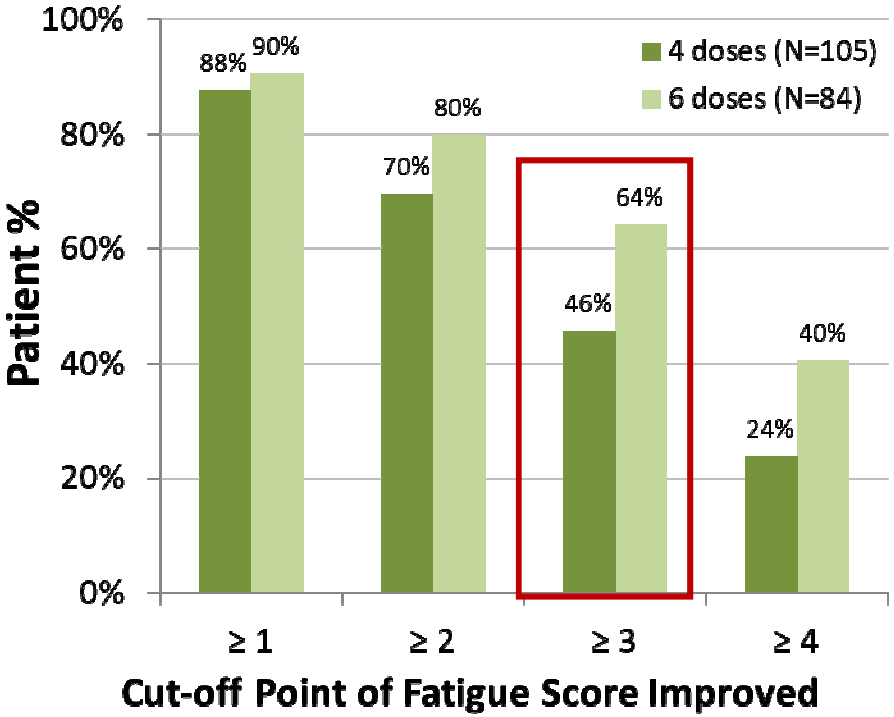
The WORST Level after the **Last Anti-cancer Treatment (or within 4 weeks until now)**



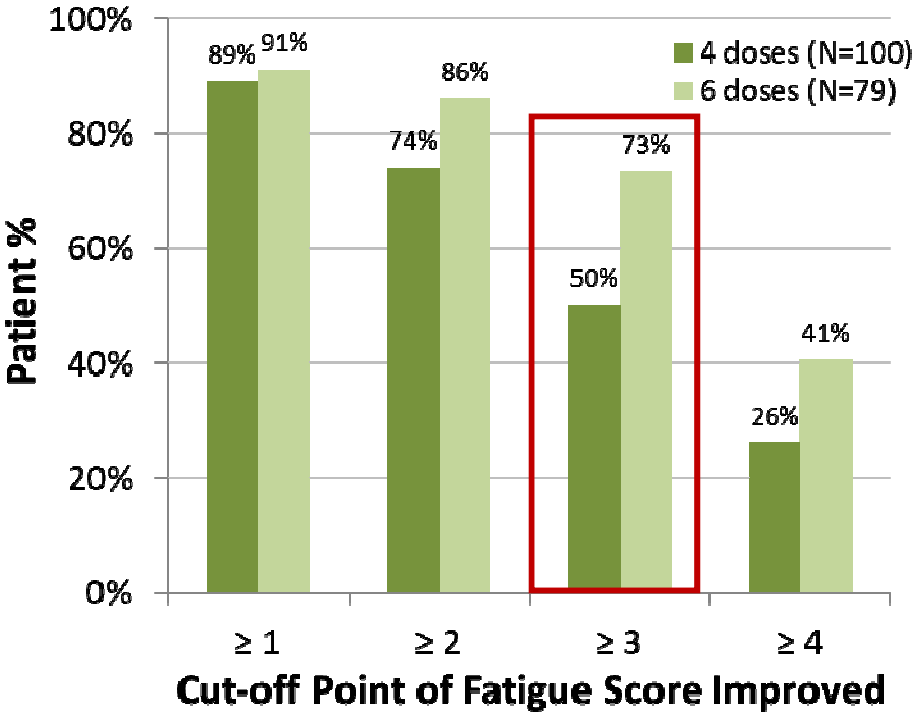
With **6 doses** of PG2 Lyo. Injection treatment, fatigue scores improved from baseline by **at least 30%** in **77%~81%** of patients

Fatigue Improvement Response Rate (by Score Change)

The WORST Level during **Past 24 hours**



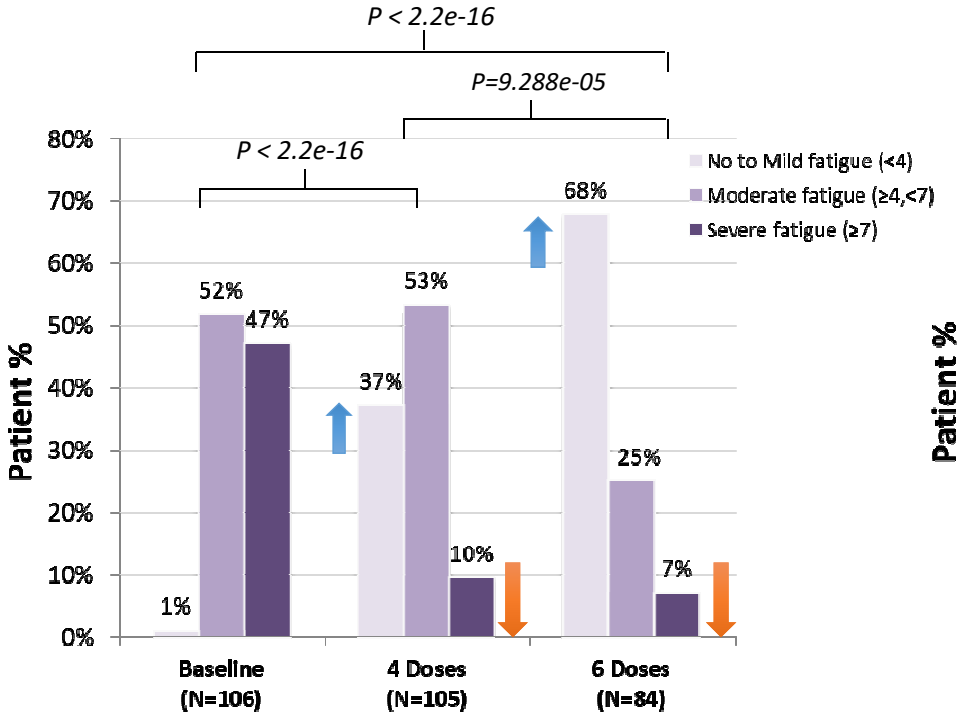
The WORST Level after the **Last Anti-cancer Treatment (or within 4 weeks until now)**



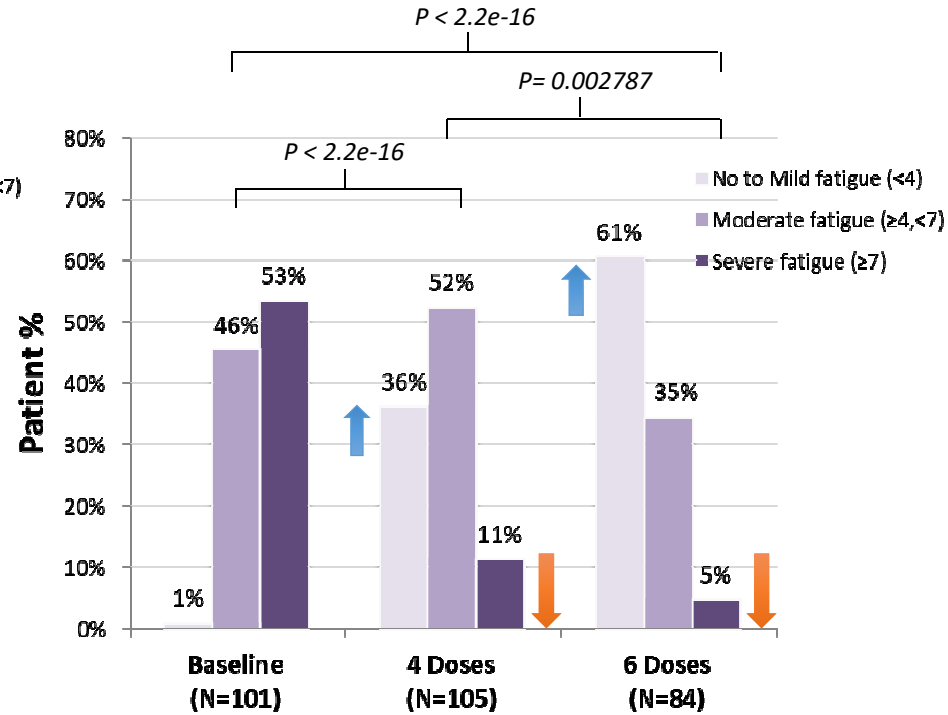
- Fatigue scores **improved by at least 3** from baseline in **64-73%** of patients with **6 doses** of PG2 Lyo. Injection treatment.
- The patients with **6 doses** of PG2 Lyo. Injection **had more fatigue improvement** than that received only 4 doses.

Categorized of Fatigue Severity

The WORST Level during **Past 24 hours**



The WORST Level after the **Last Anti-cancer Treatment (or within 4 weeks until now)**



- **Less** patients suffering from **severe** fatigue (5-7%) and **more** patients who had **no** fatigue or experiencing **mild** fatigue (61-68%) after 6 doses of PG2 Lyo. Injection treatment are observed.
- The distribution of patient groups experiencing different levels of fatigue severity compared between before and after PG2 Lyo. Injection treatment are shown a significantly **statistical difference**.

Fatigue treatment satisfaction:

Clinical Global Impression-Improvement (CGI-I) by Patients

- **91%** of patients with **6 doses** of PG2 Lyo. Injection treatment reported fatigue improvement.
- Of these improved patients with **6 doses** of PG2 Lyo. Injection treatment, **80%** of patients reported **" Much improved" and "Very much improved"**.

CGI-I Score	4-Doses		6-Doses		
	N	%	N		%
Overall	**105**		**81**		
Missing Data	**1**		**4**		
Improved (1-3)	**94**	**89.52%**	**74**		**91.36%**
Very much improved	11	10.48%	12	**79.7% of Improved**	14.81%
Much improved	49	46.67%	47		58.02%
Minimally improved	34	32.38%	15		18.52%
No Improved (4-7)	**11**	**10.48%**	**7**		**8.64%**
No change	10	9.52%	5		6.17%
Minimally worse	1	0.95%	0		0.00%
Much worse	0	0.00%	2		2.47%
Very much worse	0	0.00%	0		0.00%

**chi-square between improved/no Improved and 4-Doses/6-Doses is* 1.

Fatigue treatment satisfaction:

Evaluation by Physicians

91% of patients **had positive overall outcome** evaluated by physicians after 6 doses of PG2 Lyo. Injection treatment, and **72%** of patients **were recommended to continue** receiving PG2 Lyo. Injection treatment.

Overall Outcome Evaluation	No. of subject/proportion (%)	
N	85	
Excellent	**6**	**7.06%**
Good	**71**	**83.53%**
Fair	7	8.24%
Poor	1	1.18%

Recommendations for Continuous Use	No. of subject/proportion (%)	
N	85	
Very High	**11**	**12.94%**
High	**50**	**58.82%**
Moderate	20	23.53%
Low	4	4.71%

Summary of PG2® RWE Study

✓ Had good satisfaction

- Total **91%** of patients **had positive overall outcome** evaluated by physicians, and **72%** of patients **were recommended to continue** receiving treatment.
- **91%** of patients with **6 doses** of PG2 Lyo. Injection treatment reported fatigue improvement

✓ Had efficacious improvement on fatigue

- The patients with **6 doses** of PG2 Lyo. Injection **had more fatigue improvement** with achieving the treatment goal of VAS score <4.
- Less patients suffering from severe fatigue (5-7%) and **more patients who had no fatigue or experiencing mild fatigue** (61-68%) after 6 doses of PG2 Lyo. Injection treatment

https://oncologyrecovery.com.au/cancer-related-fatigue/

- **43/F, 1st diagnosed Breast cancer in 2004**
- **Stage IIIC, MRM**
- **Adjuvant chemotherapy TACx6, RT, Tamoxifen**
- **Lung and bone metastasis in 2013**
- **Letrozole→ Anastrozole**
- **Examestane + Everolimus**
- **Fulvestrant + Palbociclob**
- **Capecitabine**
- **Vinorelbine+Capecitabine**
- **Eribulin**
- **Lipo-Doxorubicin**

- **61/F**
- **Ixabepilone (Mar 2022 ~)**
- **Fatigue VAS 8~9, ECOG PS 1**
- **PG2 from 2nd Ixabepilone**

- **Fatigue VAS 8 → 3**

- **After PG2 6th infusion**
- **Fatigue VAS 8 → 3 → 1**

https://www.hindustantimes.com/lifestyle/health/cancer-related-fatigue-a-long-term-side-effect-of-breast-cancer-chemotherapy-study-101661067018851.html

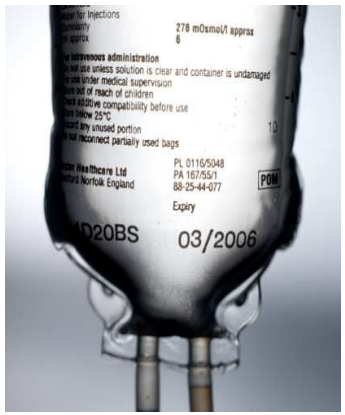
懷特血寶注射劑 (PG2® Injection)
臨床用藥資訊

- 機轉：增強免疫功能及刺激骨髓造血功能
- 適應症：適用於癌症末期因疾病進展所導致中重度疲勞症狀之改善
- 用法及用量：

  成人每次劑量 500 mg，以 2.5 - 3.5 小時點滴靜脈滴注。

  每週2 - 4次，使用2 - 4週。

- 靜脈滴注溶液製備:
  - ✓ 從500 mL注射用生理食鹽水點滴瓶中抽取10mL，注入本品藥瓶中，充分混合至完全溶解後，注射回原500 mL生理食鹽水點滴瓶中，混合均勻，即完成製備。。



- 安全性:

  依據上市後第四期臨床試驗，懷特血寶注射劑常見的不良反應(>2%)包括皮疹(9.21%)、發燒(7.24%)、感覺冷(5.26%)、寒顫(2.63%)及過敏(2.63%)。預防輸注反應可考慮事先給予抗組織胺，及/或以較慢輸住速率，延長輸注時間完成輸注療程

幫助病患改善癌因性疲憊

- 92% 台灣癌症患者罹癌期間有疲憊問題，1/4 癌症病患有中重度疲憊
  - ✓ 癌因性疲憊症之ICD-10 code：**R53.0**
- 癌症病患應在初診和回診時，接受規律性疲憊評估
  - ✓ 住院患者為每日評估，門診患者則每次回診時評估
- 癌症病患依疲憊嚴重程度給予相對應的治療，治療後再評估疲憊程度
  - ✓ 輕度：非藥物治療，**VAS≧4**中重度：加上藥物治療
- 台灣癌因性疲憊症臨床指引建議：中度以上癌因性疲憊症之具適應症藥物為黃耆多醣注射劑(PG2)。
- 合併使用黃耆多醣注射劑(PG2)，可改善癌症患者之疲憊症，使癌症療程能順利完成，但不影響治療效果。

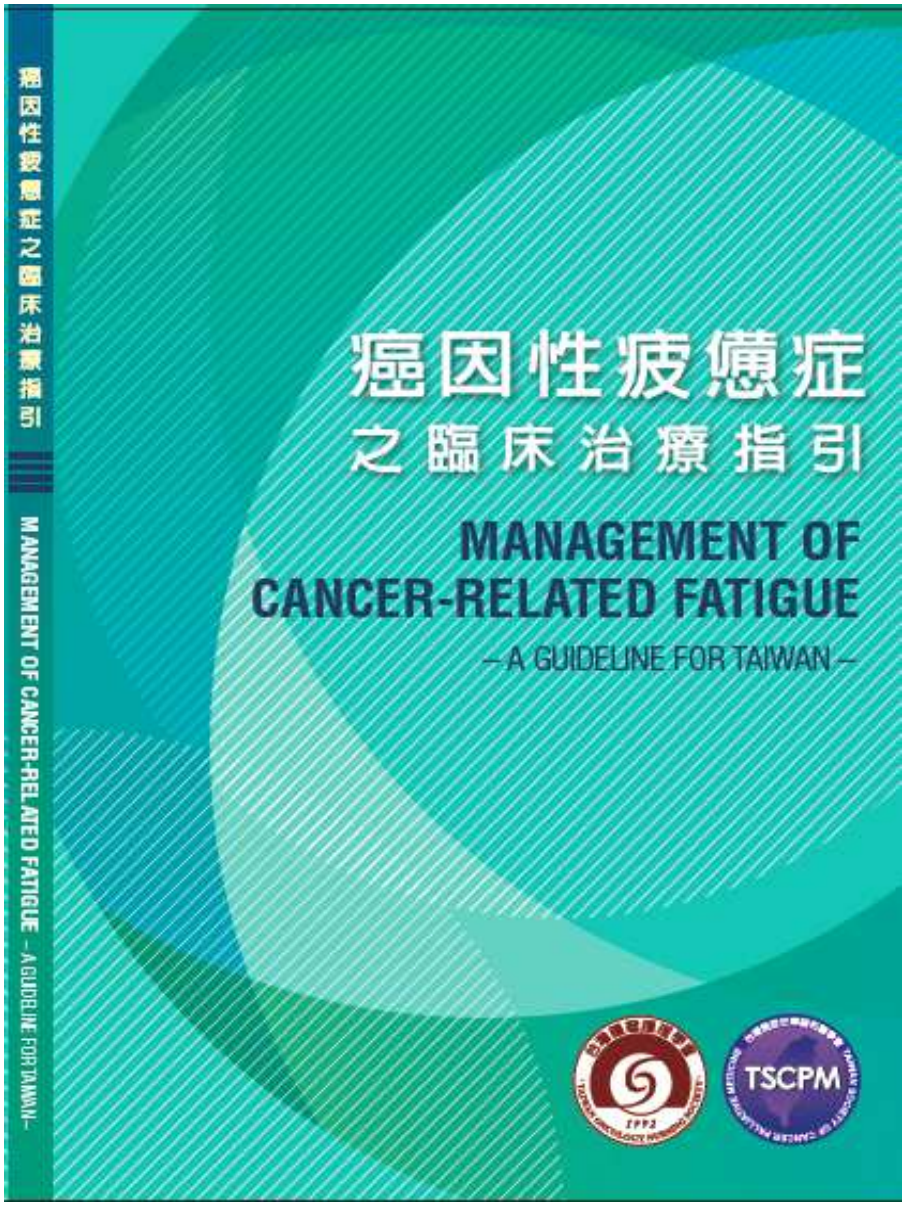
National Comprehensive Cancer Network®

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Cancer-Related Fatigue

Version 2.2022 — February 9, 2022

NCCN.org



癌因性疲憊症之臨床治療指引電子版連結由此去

總結

- 癌因性疲憊症是由癌症或癌症治療引起之重大疲憊感，並足以影響正常生活等特徵。
- 輕度疲憊可以非藥物處置改善疲憊症狀，而 4 分或以上的中、重度疲憊需特別關注，應考慮合併藥物治療。
- 黃耆多醣注射劑PG2有臨床試驗顯示可改善中重度癌因性疲憊症。
- 乳癌RWE收案中，同樣顯示優異效果

Thank you !