Real World Evidence in Taiwan:
Breast Cancer and
Astragalus Polysaccharide Lyo. Injection

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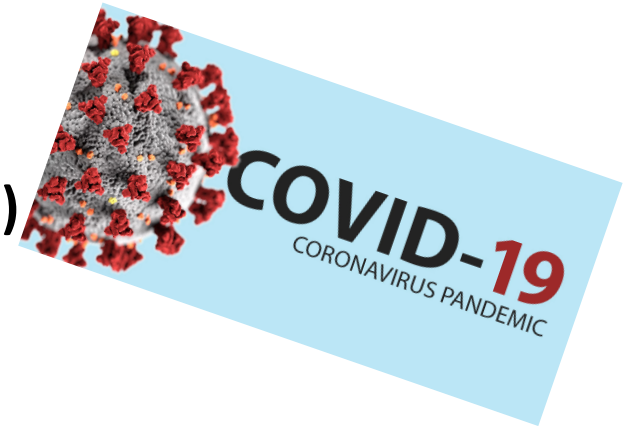
Polysaccharides of Astragalus membranaceus (PG2 Lyo. Injection) 健保給付規定

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®健保給付真實世界驗證(RWE)

✓ Effective in Fatigue Improvement:

- 完成**6劑PG2**治療病人疲憊改善程度明顯高於使用4劑PG2治療病人
- 約**6成**病人使用**6劑PG2**後疲憊指數**可降到4分以下(VAS<4)**

✓ Satisfaction with treatment outcomes:

- **91%** **病人完成 6 劑** PG2 治療後覺得**疲憊有所改善**
- **85%** 醫師對於完成**6 劑** PG2 治療後的**效果感到滿意**
- **92%** 醫師在完成**6 劑** PG2 治療後**會建議病人持續PG2治療**

! Early intervention to help patients:

- 此260位以上病人健保給付使用經驗，完成前已死亡分別在4劑和6劑，各約6%和5%，共約11% (29位病人)

PG2 NHI RWE final report presented at TSCPM CME regional meeting, Taichung, Jul. 2024.

PG2 RWE Study

REBORN: Real-world Effects of Breast Cancer Patients On Receiving PG2 Treatment

- ✓ This study is accepted for an ePoster (No. C082) and luncheon symposium presentation at the 2024 Taipei International Breast Cancer Symposium (TIBCS), Taipei, on October 26-27, 2024.
- ✓ Accepted as Abstract #745 for the 2024 San Antonio Breast Cancer Symposium (SABCS).

PG2 RWE Study

Study Center

1. Taichung Veterans General Hospital
2. Kaohsiung Medical University Hospital
3. E-Da Cancer Hospital
4. Taipei Chang Gung Memorial Hospital
5. Tri-Service General Hospital
6. China Medical University Hospital
7. Linkou Chang Gung Memorial Hospital
8. MacKay Memorial Hospital
9. Keelung Chang Gung Memorial Hospital

Data Collection Period for Analysis

01/Mar/2021~31/Dec/2023

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PG2 RWE Study

Study Aim	To assess **fatigue improvement** and **patient satisfaction** in **breast cancer patients** receiving **PG2 injections covered by Taiwan's NHI** through real-world data analysis.
Design	Multi-center **retrospective** study
Patients	**Stage IV breast cancer patients** diagnosed with **moderate to severe cancer-related fatigue (CRF)** based on ICD-10 criteria, after failing to respond to other interventions, with an ECOG performance status of 0-2. R53.0
Efficacy outcomes	Primary Endpoint: **Fatigue improvement.** Secondary Endpoints: Fatigue treatment satisfaction**: Clinical Global Impression-Improvement (CGI-I)** and overall clinical evaluation by physicians

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PG2 RWE Study

Objectives	This study was performed to evaluate the clinical use, **fatigue improvement**, and **treatment satisfaction** of breast cancer patients with PG2 Lyo. injection.
Methodology	This was a single arm, multicenter, and retrospective study.
Inclusion Criteria	**Breast cancer** patients treated by PG2 Lyo. injection under Taiwan National Health Insurance (NHI). ✓ Aged 20 years and above; ✓ Stage IV breast cancer; ✓ Experienced moderate to severe fatigue that met the diagnostic criteria of ICD-10, with other interventions proving ineffective; ✓ ECOG 0-2.

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Study Design

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**
Planned Number of Subjects	• Enrolled: **335** • Analyzed*: at least **200** * Subjects who had any available data for primary endpoint analyzation (at least have 2 data: baseline and 4-Dose or 6-Dose VAS Fatigue Score data).
Data Collection Period	**Mar 1, 2021 to Dec 31, 2023**

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Study Design

Collect Item	1 Pre-treatment Baseline	2 Interim 4-Dose	3 EOS 6-Dose
Demographic[1]	V		
Disease Characteristic[2]	V		
Cancer Treatment Information[2]	V	V	V
Visual Analog Fatigue Scale (0-10) by Patients	V	**V**	**V**
Fatigue Clinical Global Impression-Improvement (CGI-I) by Patients		**V**	**V**
ECOG	V	V	V
Weight	V	V	V
Lab data-Hematology	V	V	V
Cancer drug compliance record	V	V	V
CRF Pharmacological Treatment Record		V	V
Patient Expectations to Continue Use Record			V
Overall Evaluation by Physician			**V**

1: Demographic information: height, weight, age, sex etc.

2: Disease characteristics and cancer treatment information: primary tumor diagnosis, current tumor diagnosis, menopausal status, hormone receptor status, HER-2 Status, proliferation index, molecular type and categories of previous/concurrent cancer therapies etc.

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Incomplete Reason

	N	%
Before V2	**55**	**21.07%**
Data collection deadline expired	19	7.28%
Death	16	6.13%
Patient's Willingness	5	1.92%
Lost to follow-up	2	0.77%
Others*	13	4.98%
Before V3	**44**	**16.86%**
Data collection deadline expired	15	5.75%
Death	13	4.98%
Patient's Willingness	6	2.30%
Lost to follow-up	4	1.53%
Others*	6	2.30%

**Rejected by NHI, case closed, disease condition issue, AE, incomplete signature on new version of ICF, hospital transfer or PG2 Injection self-funded*

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Disease Characteristics

Characteristics	*Results*
Histological type	
N	261
Ductal	**233 (89.27%)**
Lobular	9 (3.45%)
Mixed	6 (2.30%)
Others	10 (3.83%)
Unknown	3 (1.15%)
Sites of Metastases	
N	261
Bone	**155 (59.39%)**
Lung	**138 (52.87%)**
Liver	**93 (35.63%)**
Lymph nodes	89 (34.10%)
Brain	33 (12.64%)
Skin	26 (9.96%)
Others	37 (14.18%)

Characteristics	*Results*
Menopausal Status	
N	261
Premenopausal	28 (10.73%)
Postmenopausal	**229 (87.74%)**
Unknown	4 (1.53%)
Molecular Type	
N	261
Lumina A	38 (14.56%)
Luminal B	**136 (52.11%)**
Her-2 enriched	43 (16.48%)
Triple-negative	40 (15.33%)
Unknown	4 (1.53%)

- The majority were **postmenopausal** women **(88%)**.
- The predominant histologic type of breast cancer was **ductal carcinoma (89%).**
- Patients with stage IV breast cancer primarily had metastases to the **bone (59%), lung (53%) and liver (36%)**.
- Among the molecular subtypes, Luminal B was the most common (52%).

Demographic and disease characteristics

- Majority of enrolled patients were diagnosed with ductal carcinoma, with Luminal B as the predominant molecular subtype.
- Most patients were postmenopausal women with visceral metastases.

Characteristics	*N=204*
Age	
Mean(SD)	58.82 (10.84)
Range	27.57 ~ 83.70
BMI	
Mean(SD)	24.00 (4.50)
Range	14.83 ~ 41.41
Histological type	
Ductal	**180 (88.24%)**
Lobular	9 (4.41%)
Mixed	5 (2.45%)
Others	7 (3.43%)
Unknown	3 (1.47%)
Visceral Metastases	
Yes	**157 (76.96%)**
No	47 (23.04%)

Characteristics	*N=204*
Menopausal Status	
Premenopausal	20 (9.80%)
Postmenopausal	**180 (88.24%)**
Unknown	4 (1.96%)
Molecular Type	
Luminal A	24 (11.76%)
Luminal B	**110 (53.92%)**
Her-2 enriched	37 (18.14%)
Triple-negative	32 (15.69%)
Unknown	1 (0.49%)

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Previous and Current Cancer Therapy

82% of patients received PG2 Injection treatment in conjunction with **chemotherapy or chemo-combo therapy.**

No. Cancer Therapies/type N	Previous 261	4-Dose 205	6-Dose 162	Treatment period 161
0	**5 (1.92%)**	**0 (0.00%)**	**4 (2.47%)**	**0 (0.00%)**
1	**121 (46.36%)**	**98 (47.80%)**	**66 (40.74%)**	**63 (39.13%)**
Surgery	1 (0.38%)	1 (0.49%)	0 (0.00%)	0 (0.00%)
Chemotherapy	**82 (31.42%)**	**65 (31.71%)**	**46 (28.40%)**	**45 (27.95%)**
Target	23 (8.81%)	24 (11.71%)	15 (9.26%)	13 (8.07%)
Hormone	14 (5.36%)	7 (3.41%)	4 (2.47%)	4 (2.48%)
Others	1 (0.38%)	1 (0.49%)	1 (0.62%)	1 (0.62%)
2	**100 (38.31%)**	**85 (41.46%)**	**73 (45.06%)**	**67 (41.61%)**
Chemotherapy + Surgery	2 (0.77%)	1 (0.49%)	0 (0.00%)	0 (0.00%)
Chemotherapy + Target	**38 (14.56%)**	**38 (18.54%)**	**35 (21.60%)**	**36 (22.36%)**
Chemotherapy + CCRT	1 (0.38%)	2 (0.98%)	2 (1.23%)	1 (0.62%)
Chemotherapy + Hormone	22 (8.43%)	14 (6.83%)	12 (7.41%)	11 (6.83%)
Chemotherapy + Immunotherapy	2 (0.77%)	2 (0.98%)	2 (1.23%)	2 (1.24%)
Chemotherapy + Others	0 (0.00%)	1 (0.49%)	0 (0.00%)	0 (0.00%)
Target + CCRT	1 (0.38%)	0 (0.00%)	2 (1.23%)	1 (0.62%)
Target + Hormone	**31 (11.88%)**	**23 (11.22%)**	**19 (11.73%)**	**15 (9.32%)**
Hormone + Others*	3 (1.15%)	4 (1.95%)	1 (0.62%)	1 (0.62%)
3	**25 (9.58%)**	**18 (8.78%)**	**14 (8.64%)**	**22 (13.66%)**
Chemotherapy + Surgery + Target	6 (2.30%)	4 (1.95%)	4 (2.47%)	4 (2.48%)
Chemotherapy + Surgery + CCRT	1 (0.38%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chemotherapy + Surgery + Immunotherapy	1 (0.38%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chemotherapy + Target + CCRT	5 (1.92%)	1 (0.49%)	2 (1.23%)	3 (1.86%)
Chemotherapy + Target + Hormone	9 (3.45%)	10 (4.88%)	8 (4.94%)	10 (6.21%)
Chemotherapy + Target + Others	2 (0.77%)	0 (0.00%)	0 (0.00%)	1 (0.62%)
Chemotherapy + Hormone + Others	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.62%)
Surgery + Target + Hormone	1 (0.38%)	1 (0.49%)	0 (0.00%)	1 (0.62%)
Target + Hormone + Others*	0 (0.00%)	2 (0.98%)	0 (0.00%)	2 (1.24%)
4 and above	**10 (3.83%)**	**4 (1.95%)**	**5 (3.09%)**	**9 (5.59%)**
Chemotherapy + Surgery + Target + CCRT	4 (1.53%)	0 (0.00%)	2 (1.23%)	1 (0.62%)
Chemotherapy + Surgery + Target + Hormone	3 (1.15%)	1 (0.49%)	1 (0.62%)	1 (0.62%)
Chemotherapy + Surgery + Target+ Immunotherapy	0 (0.00%)	1 (0.49%)	1 (0.62%)	2 (1.24%)
Chemotherapy + Target + CCRT + Hormone	0 (0.00%)	1 (0.49%)	1 (0.62%)	2 (1.24%)
Chemotherapy + Target + Hormone + Others*	2 (0.77%)	1 (0.49%)	0 (0.00%)	1 (0.62%)
Chemotherapy + Surgery + Target + CCRT + Hormone	1 (0.38%)	0 (0.00%)	0 (0.00%)	2 (1.24%)

VAS Fatigue Score Change from Baseline

Patients who received 6 doses of PG2 Lyo Injection experienced significantly lower fatigue scores compared to those who received 4 doses.

Past 24-hrs

visit	N	Mean	SD	Median	Min	Max	95% CI	Paired t-test from baseline
Baseline	204	6.37	1.27	6.00	3.00	10.00	6.19 ~ 6.54	
4-Dose	203	4.14	1.73	4.00	0.00	10.00	3.91 ~ 4.38	***<0.001***
6-Dose	158	**3.49**	1.72	3.00	0.00	8.00	3.23 ~ 3.76	***<0.001***

Paired t-test between 4-Dose and 6-Dose is ***<0.001***

Last-treatment or within 4 weeks

visit	N	Mean	SD	Median	Min	Max	95% CI	Paired t-test from baseline
Baseline	199	6.60	1.29	6.00	4.00	10.00	6.42 ~ 6.78	
4-Dose	203	4.31	1.79	4.00	0.00	9.00	4.06 ~ 4.55	***<0.001***
6-Dose	158	**3.57**	1.75	3.00	0.00	9.00	3.30 ~ 3.84	***<0.001***

Paired t-test between 4-Dose and 6-Dose is ***<0.001***

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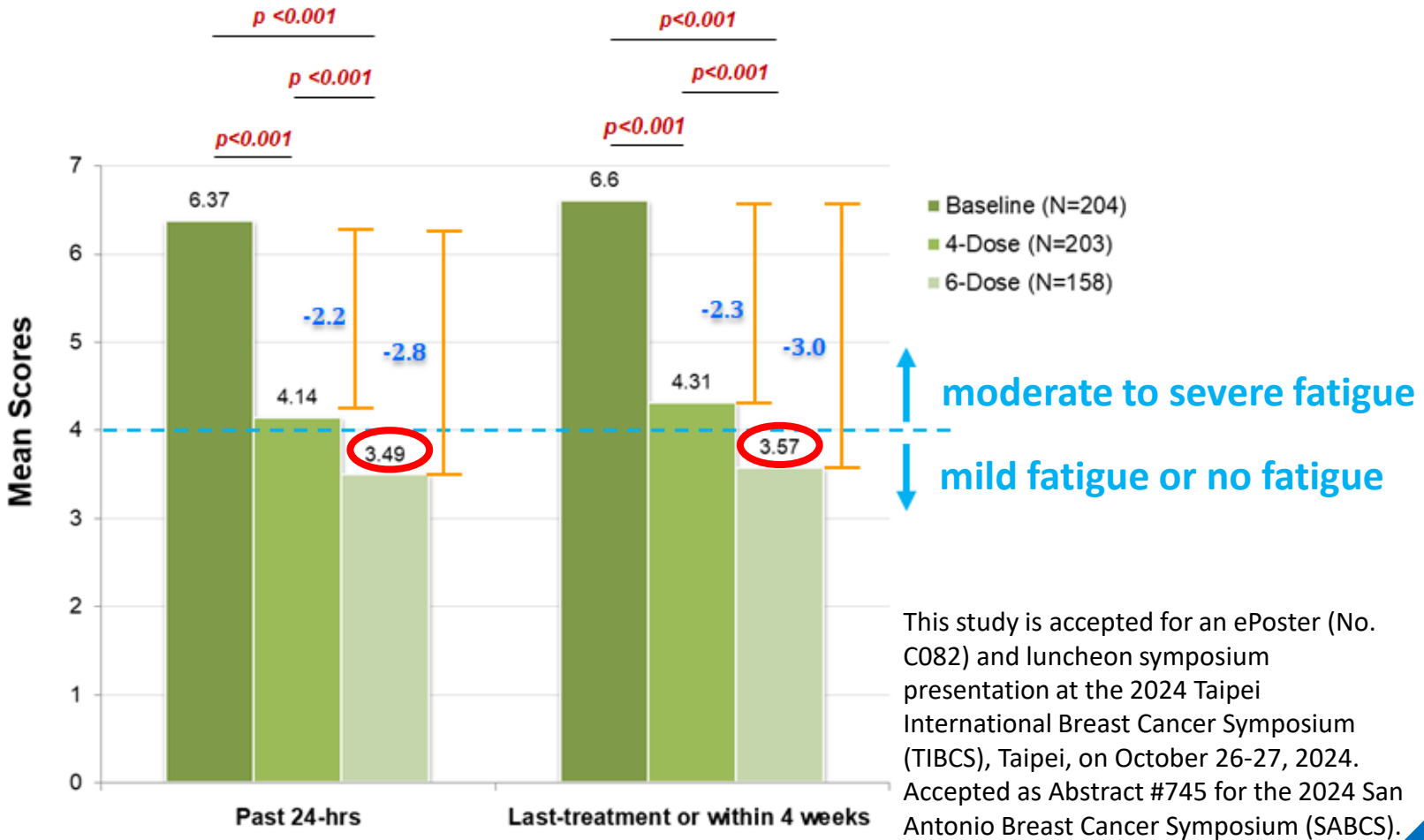
VAS Fatigue Score by Visits

Patients who received 6 doses of PG2 Lyo. Injection had significantly lower fatigue scores than their baseline measurements (VAS score 3.49~3.57), achieving the treatment goal of a VAS score < 4



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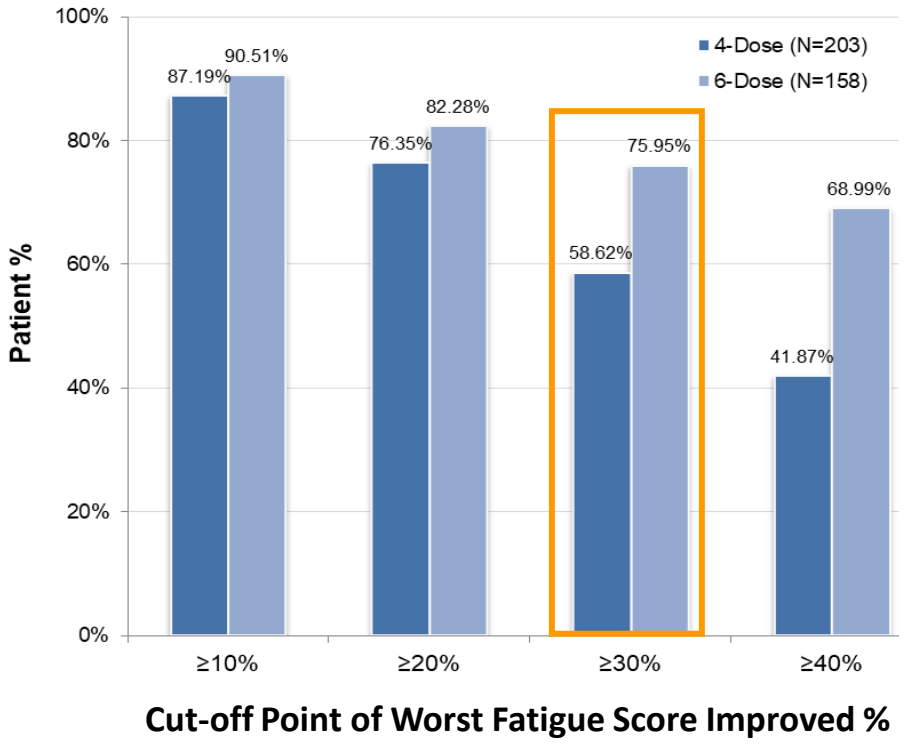
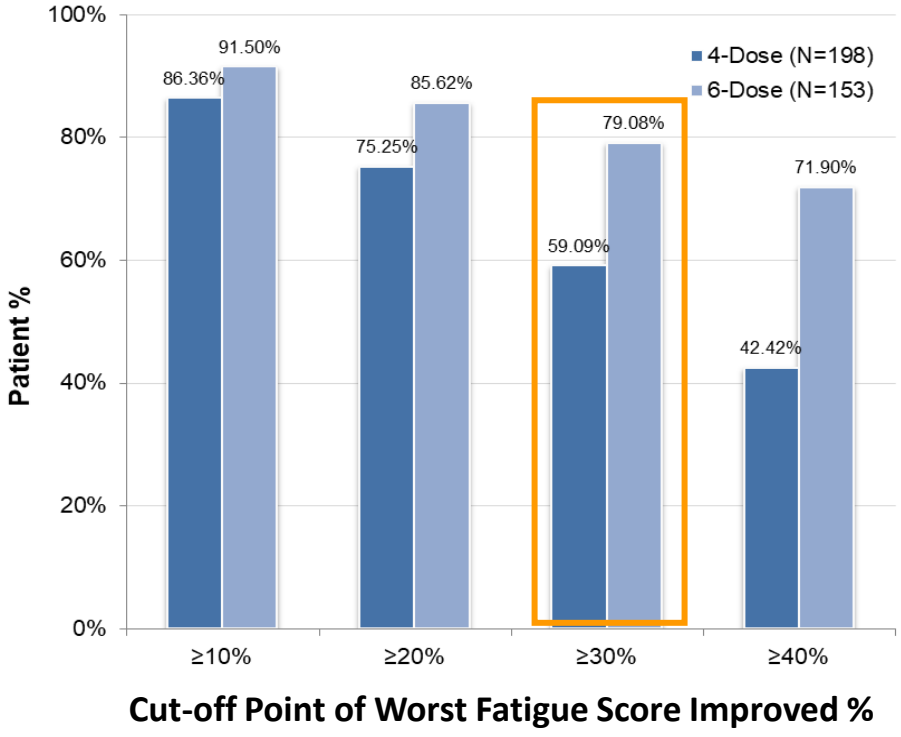
Fatigue Improvement Response Rate (by Score Change %)

Past 24-hrs



Last-treatment or within 4 weeks



With **6 doses** of PG2 Lyo. Injection treatment, fatigue scores improved from baseline by **at least 30%** in **76% to 79%** of patients

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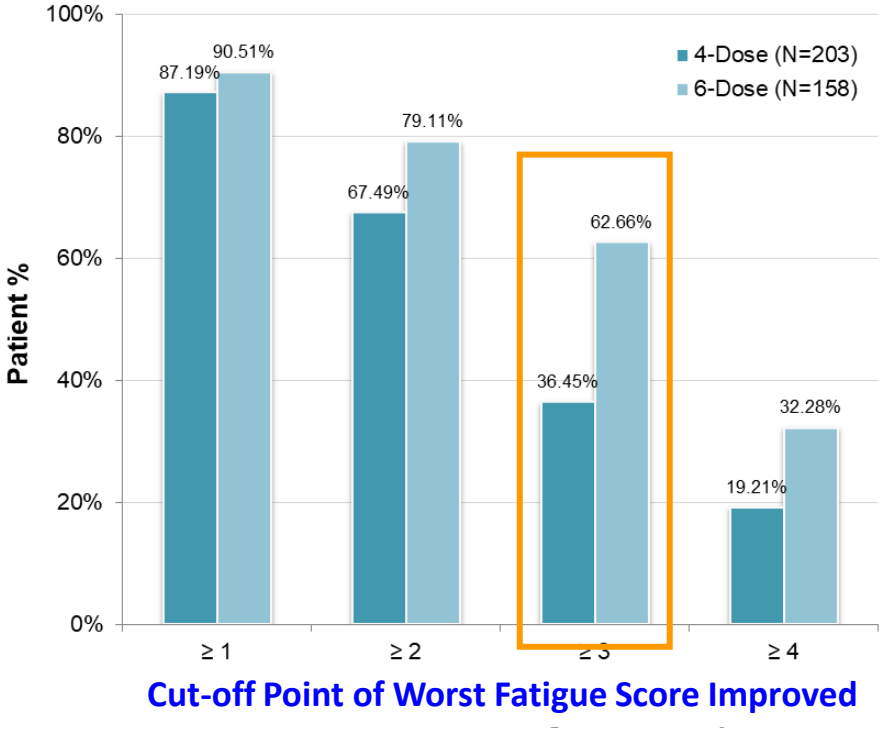
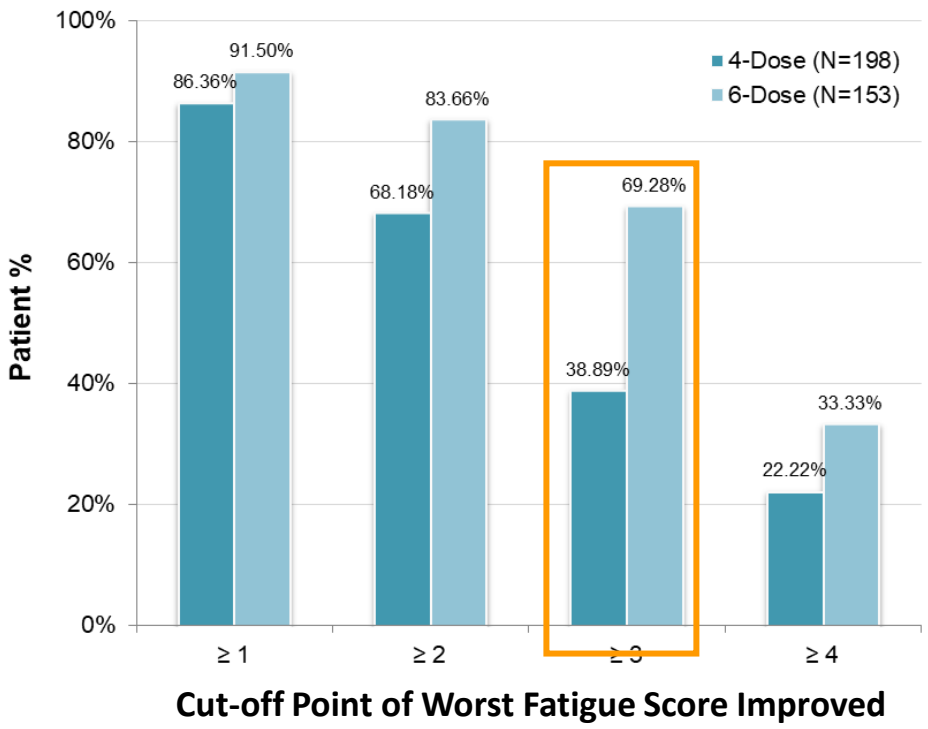
Fatigue Improvement Response Rate (by Score Change)

Past 24-hrs



Last-treatment or within 4 weeks



- Fatigue scores **improved by at least 3 points** from baseline in **63% to 69%** of patients with **6 doses** of PG2 Lyo. Injection treatment.
- Patients who received **6 doses** of PG2 Lyo. Injection **experienced greater fatigue improvement** compared to those who received only 4 doses.

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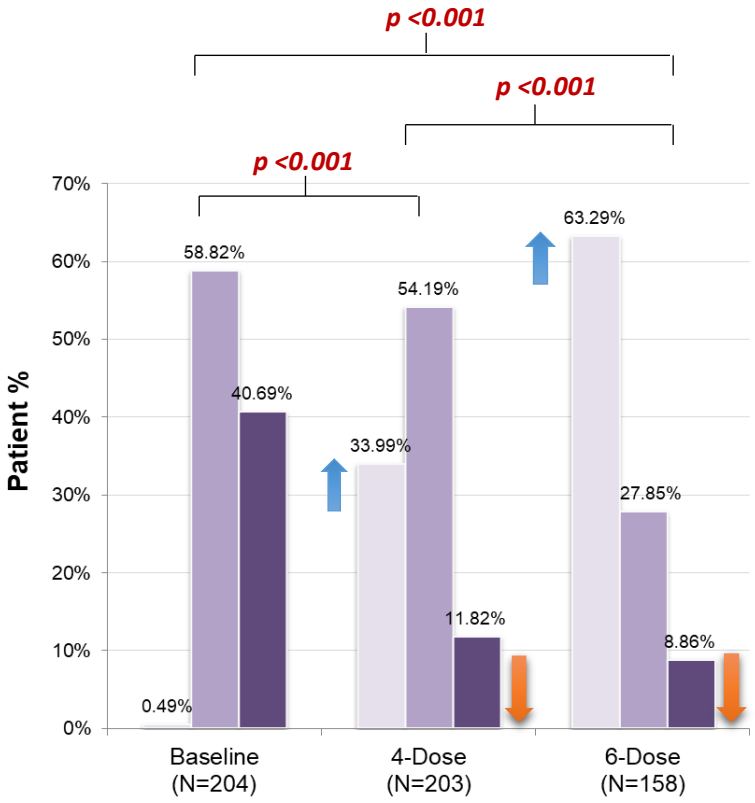
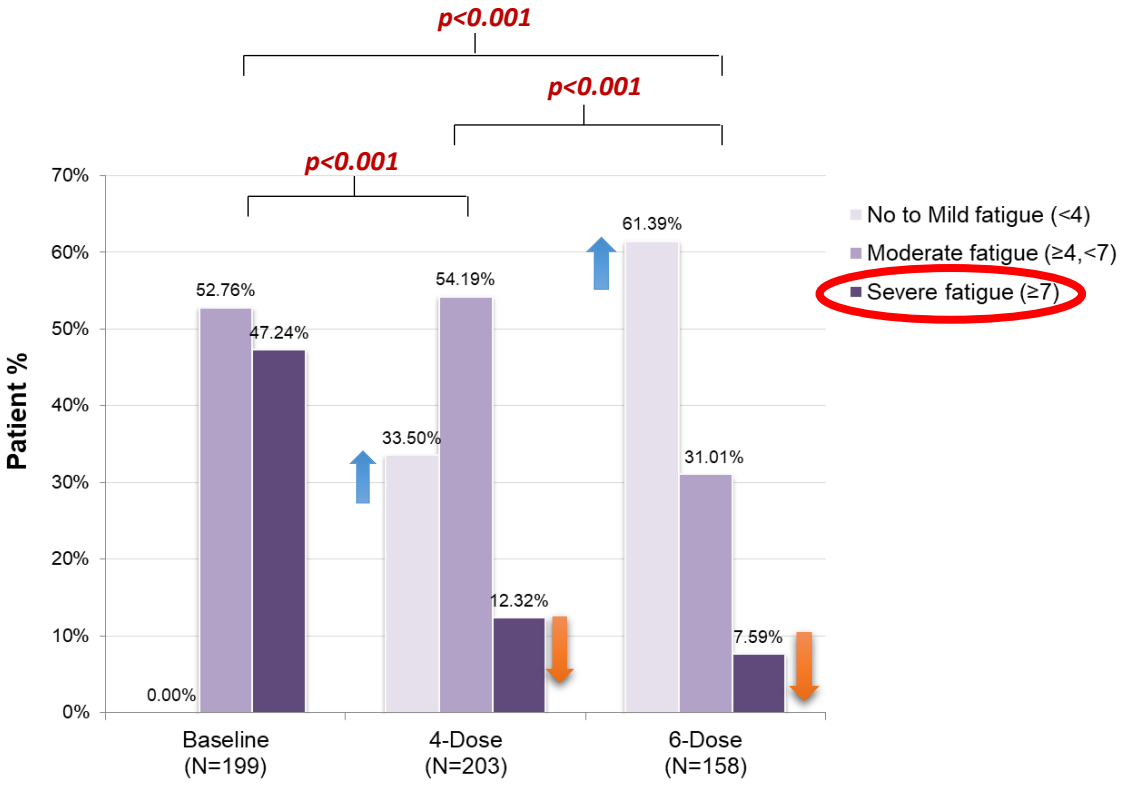
Categorized of Fatigue Severity

Past 24-hrs



Last-treatment or within 4 weeks



- After **6 doses** of PG2 Lyo Injection treatment, more than **60%** of patients improved to having **no or mild fatigue**, and the proportion of **patients with severe fatigue decreased by 32% to 40%**.

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Fatigue Treatment Satisfaction:

Patient-Reported Clinical Global Impression-Improvement (CGI-I)

- **91%** of patients who received **6 doses** of PG2 Lyo Injection treatment reported an improvement in fatigue.
- Among these patients, **77%** reported being "**Much improved**" or "**Very much improved**".

CGI-I Score	*4-Dose (N=202)*		*6-Dose (N=161)*		
Improved (1-3)	**176**	**87.13%**	**146**	**90.68%**	
Very much improved	15	7.43%	22	**13.66%**	**77%** among "improved" patients
Much improved	88	43.56%	91	**56.52%**	
Minimally improved	73	36.14%	33	20.50%	
No Improved (4-7)	**26**	**12.87%**	**15**	**9.32%**	
No change	24	11.88%	11	6.83%	
Minimally worse	2	0.99%	2	1.24%	
Much worse	0	0.00%	2	1.24%	
Very much worse	0	0.00%	0	0.00%	

**chi-square between improved/no Improved and 4-Dose/6-Dose is 0.724.*

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Fatigue Treatment Satisfaction:

Physician Evaluation

After receiving **6 doses** of PG2 Lyo Injection treatment, **85%** of patients achieved a **positive overall outcome** as evaluated by physicians, and **92%** of patients were **recommended to continue** with PG2 Lyo Injection treatment.

Overall outcome (N=159)	*No. of subject/proportion (%)*	
Good	**135**	**84.91%**
Excellent(very good)	13	8.18%
Good	122	76.73%
Fair	**22**	**13.84%**
Poor	**2**	**1.26%**
Poor	1	0.63%
Very poor	1	0.63%

Recommendations for Continuous Use (N=159)	*No. of subject/proportion (%)*	
Much	**147**	**92.45%**
High	103	64.78%
Moderate	44	27.67%
Not Much	12	7.55%

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Fatigue Treatment Satisfaction:

Patient Expectations to Continue Use

64.56% of patients **were willing to receive to continue PG2 treatment** upon patient's consumption of all NIH covered PG2 treatment

Patient Expectations for Continuous Use (N=158)	*N*	*%*
Yes	**102**	**64.56%**
No	**56**	**35.44%**
Patient's willingness	17	10.76%
Change to non-pharmacological CRF therapy	1	0.63%
No fatigue without CRF therapy	1	0.63%
Other reason	**37**	**23.42%**

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Fatigue Treatment Satisfaction

Patient Reported Fatigue CGI-I score distribution

CGI-I Score	*4-Dose (N=202)*		*6-Dose (N=161)*	
Improved (1-3)	**176**	**87.13%**	**146**	**90.68%**
Very much improved	15	7.43%	22	**13.66%**
Much improved	88	43.56%	91	**56.52%**
Minimally improved	73	36.14%	33	20.50%
No Improved (4-7)	**26**	**12.87%**	**15**	**9.32%**
No change	24	11.88%	11	6.83%
Minimally worse	2	0.99%	2	1.24%
Much worse	0	0.00%	2	1.24%
Very much worse	0	0.00%	0	0.00%

Overall outcome evaluation by physicians

Overall Outcome (N=159)	*N*	*%*
Good	**135**	**84.91%**
Fair	22	13.84%
Poor	2	1.26%

- **91%** of patients who received **6 doses** of PG2 Lyo Injection treatment reported an **improvement in fatigue**.
- **85%** of patients were assessed by physicians as having achieved a **positive overall treatment outcome**.

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Conclusions

✓ Effective in Fatigue Improvement:

- The efficacy in reducing fatigue is notably **higher with 6 doses** compared to 4 doses.
- Nearly **60%** of patients transitioned to experiencing **no to mild fatigue**, and the proportion of patients with **severe fatigue decreased by 32% to 40%** following treatment.

✓ Satisfaction with treatment outcomes:

- **91%** of patients receiving **6 doses** of PG2 Lyo Injection treatment reported improvement in fatigue.
- A total of **85%** of patients experienced a **positive overall outcome** as evaluated by physicians, with **92%** of patients **recommended to continue** treatment.

This study is accepted for an ePoster (No. C082) and luncheon symposium presentation at the 2024 Taipei International Breast Cancer Symposium (TIBCS), Taipei, on October 26-27, 2024.
Accepted as Abstract #745 for the 2024 San Antonio Breast Cancer Symposium (SABCS).

PG2®健保給付真實世界驗證(RWE)

✓ Effective in Fatigue Improvement:

- 完成**6劑PG2**治療病人疲憊改善程度明顯高於使用4劑PG2治療病人。
- 約**6成**病人使用**6劑PG2**後疲憊指數**可降到4分以下(VAS<4)**。

✓ Satisfaction with treatment outcomes:

- **91%** 病人完成 **6 劑** PG2 治療後覺得疲憊有所改善。
- **85%** 醫師對於完成**6 劑** PG2 治療後的效果感到滿意。
- **92%** 醫師在完成**6 劑** PG2 治療後會建議病人持續PG2治療。

! Early intervention to help patients:

- 此260位以上病人健保給付使用經驗，完成前已死亡分別在4劑和6劑，各約6%和5%，共約11% (29位病人)

PG2 NHI RWE final report presented at TSCPM CME regional meeting, Taichung, Jul. 2024.

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

個案分享

46 y/o female left breast cancer, HER2 subtype

2023/03/22 cT2N1M0

2023/11/15 ypT2(m)N1aM0

2024/09/04 rcT0N0M1

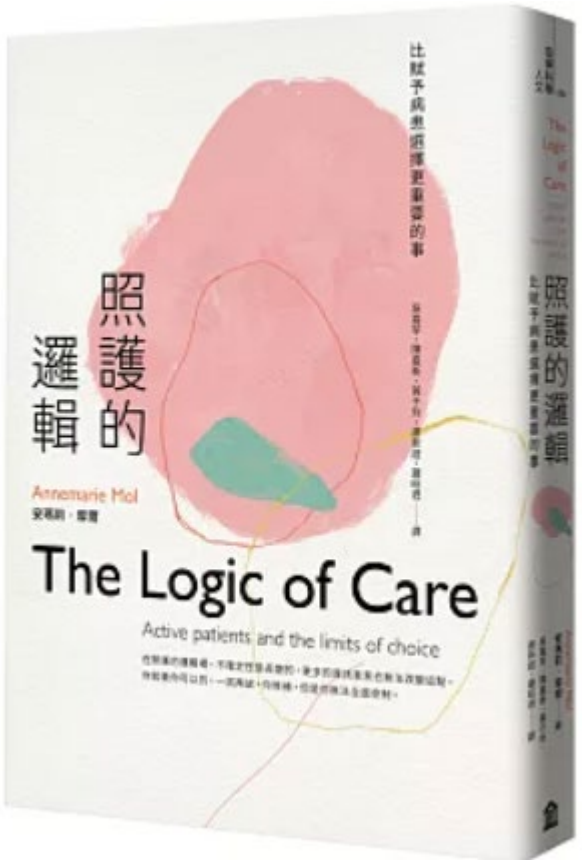
Therapeutic regimens

- NACT: 6 Carboplatin + Docetaxel followed by 3 cycles Epirubicin + Cyclophosphamide but failed
- Concurrent Herceptin + Perjeta with above
- TM + ALND with flap reconstruction(2023/11/15)
- Adjuvant: T-DM1(Kadcyla)(2023/12/28-2024/04/06) but recurrence
- Salvage: T-Dxd(Enhertu)(2024/10 - now)

Cancer Related Fatigue
癌因性疲憊

- 自始看中醫(調理)及精神科(眠障)
- 2024/12/09 門診說在家快要累死了，躺著不想起床(VAS score: 8-9)
- 2025/02/07 6 cycles Enhertu and 有精神抱怨自費藥燒錢哪! (VAS score: 3)

Cure(治癒) & CARE(照護)



照護的邏輯：比賦予病患選擇更重要的事

The Logic of Care: Active patients and the limits of choice