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台北國際乳癌研討會

Speech Abstract

Topic:

Real World Evidence: Astragalus Polysaccharides Injection and Breast Cancer Patients with Cancer-Related Fatigue

Abstract

In Taiwan, 92% of cancer patients experience CRF during their cancer journey. The primary life impacts for hospitalized and outpatient populations include walking ability and the ability to work, and perform daily chores, with fatigue significantly interfering with overall daily functioning more so in hospitalized patients. The more cancer treatments a breast cancer patient undergoes, the more fatigued they become, with stage II-IV breast cancer patients exhibiting higher fatigue scores than stage I patients.

As per the treatment guidelines, for moderate to severe CRF with a severity score of 4 or above, significantly affecting patients' quality of life and functioning, pharmacological interventions are recommended in clinical practice. The recommended medications in the guideline include psychostimulants, steroids, polysaccharide injection of Astragalus membranaceus (PG2 Lyo. Injection), and herbal medicines (ginseng). Among them, PG2 Lyo. Injection is recommended as a Level IA and Grade A treatment option in the guideline, and has been included in the National Health Insurance coverage since March 1, 2021, for stage IV breast cancer patients with moderate to severe fatigue and an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2, with coverage for up to six doses over a lifetime.

Based on real-world data collected after National Health Insurance coverage, the clinical utility of PG2 Lyo. Injection in breast cancer patients meeting insurance criteria was evaluated in terms of clinical usage, fatigue improvement, and satisfaction. Data collection occurred at three time points: before receiving PG2 treatment, after receiving four doses of PG2 treatment, and upon completing six doses of PG2 treatment. Regarding primary efficacy endpoints, statistically significant improvements in the Visual Analog Scale (VAS) fatigue score were observed after the fourth and sixth doses of PG2 treatment compared to baseline (both $P<0.001$), with fatigue scores reduced to below four after completing six doses of PG2 treatment. After completing six doses of PG2 treatment, a higher proportion of patients experienced fatigue improvement greater than 30% or VAS fatigue score improvement of more than 3 points. Regarding secondary efficacy endpoints, approximately 90% of patients rated themselves as improved (Clinical Global Impression- Improvement scale [CGI-I] scores of 1-3) after receiving the sixth doses of PG2 treatment, and expressed willingness to continue PG2 treatment based on physician assessment. Approximately 90% of patients were assessed by physicians as having a positive overall outcome from the medication.

Following the publication of a large-scale clinical trial involving over 300 patients in 2019, PG2 Lyo. Injection demonstrated efficacy in treating fatigue, with over 65% of patients experiencing effective fatigue improvement after four weeks of PG2 Lyo. Injection treatment. Assessment using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC- QLQ-C30) revealed significant improvements in patients' quality of life, particularly in sleep, appetite, and fatigue, with physical status (Karnofsky Performance Status [KPS] ≥ 60, corresponding to an ECOG performance status of 0-2) identified through multivariable analysis as predicting higher chances of fatigue improvement and progression with PG2 Lyo. Injection treatment.