

Research Application of Patient-Reported Outcomes in Assessing the Nutritional Status of Patients with Gastrointestinal Tumors

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Abstract: *Objective:* To investigate and analyze the changes of nutritional status in patients undergoing postoperative adjuvant chemotherapy for gastrointestinal tumors based on patient-reported outcomes. *Methods:* From July 2020 to March 2021, 60 patients with gastrointestinal tumor who received adjuvant chemotherapy for the first time after surgery under the oncology department of a third-level, first-class hospital in Shaanxi Province were recruited by convenience sampling. The patient-reported nutritional evaluation outcomes within 24 hours after admission and during the fourth chemotherapy cycle incorporated nutritional risk screening 2002 (NRS2002), Functional Assessment of Anorexia/Cachexia Therapy (FAACT), psychological pain screening, Generalized Anxiety Disorder Assessment (GAD-7), Patient Health Questionnaire-9 (PHQ-9) to screen for depression, dietary self-assessment, health index scale (EQ-5D), and nutrition supervisor overall assessment scale. *Results:* The self-reported nutritional evaluation outcomes by adjuvant chemotherapy patients showed an upward trend along with their chemotherapy cycle. Their PG-SGA score, FAACT score, psychological pain score, and EQ-5D score during the fourth cycle were better than those during the first chemotherapy cycle ($p < 0.05$). *Conclusion:* Based on the patient-reported nutritional evaluation outcomes, the nutritional status and quality of life of patients with gastrointestinal tumors during chemotherapy did not worsen. Medical staff should timely evaluate the nutritional status of patients with gastrointestinal tumors during chemotherapy and implement reasonable nutritional intervention to improve the quality of life of patients. In the future, patient-reported outcomes should be considered for integration into clinical practice in order to facilitate patient participation in decision-making and improve their medical experience.

Keywords: Gastrointestinal tumors; Chemotherapy; Nutritional status; Patient-reported outcomes

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1. Introduction

Malignant tumors have become one of the leading causes of death across the world, and the incidence and mortality rates of diseases are rising. China ranked first in the world in terms of new cancer cases and cancer mortality in 2020, with 4.57 million new cancer cases, accounting for 23.7% of worldwide new cancer cases, and 3 million cancer mortality cases, accounting for 30% of worldwide cancer mortality^[1]. In 2018, the global cancer burden report showed that colorectal cancer and gastric cancer ranked third and fifth, respectively, in terms of cancer incidence rate, and ranked second and third, respectively, in terms of mortality rate^[2]. Chemotherapy is the most common treatment approach in cases of malignant tumors. However, it is inevitable that while killing tumor cells, chemotherapeutic drugs also have negative effects on normal human tissues due to poor selectivity, which often leads to various adverse reactions^[3]. The

incidence of nutritional risk in patients with malignant tumors is generally 30% to 40% higher than that in other hospitalized patients, and the incidence of moderate malnutrition reaches up to 58% [4]. Malnutrition is likely to reduce patients' sensitivity to drugs and increase the toxic and side effect rates of chemotherapy, resulting in poor treatment, chemotherapy postponement, or even worse, chemotherapy suspension [5]. Timely screening nutritional risk in patients with gastrointestinal tumors, carrying out nutritional assessment, and providing proper nutritional therapy are important aspects in clinical decision-making and also crucial factors that affect the rehabilitation of malignant tumors [6]. The Food and Drug Administration (FDA) of United States defines patient-reported outcomes (PROs) as any information related to a patient's health condition that is learned directly from the patient's chief complaint, without explanation by other healthcare professionals [7]. At present, foreign countries are routinely using the patient-reported outcome measurement tool as an effective indicator in cancer care practice, and many medical institutions have incorporated it into clinical practice [8,9]. The PRO concept was introduced relatively late in China, and the development of related measurement tools is still in its infancy. In order to promote the clinical application of patient-reported outcomes in The First Affiliated Hospital of Xi'an Jiaotong University, it is presently being used in assessing the nutritional status of patients with gastrointestinal tumors.

2. Subjects and methods

2.1. Research subjects

Using the convenient sampling method, 60 patients with gastrointestinal tumors who received their first postoperative standard adjuvant chemotherapy under the care of the oncology department of a third-level, first-class hospital in Shaanxi Province from July 2020 to March 2021 were selected as the research subjects.

Inclusion criteria: patients with gastrointestinal malignancy confirmed by pathological diagnosis; patients with advanced gastrointestinal tumors receiving chemotherapy or radiotherapy; Karnofsky Performance Status (KPS) score > 70; patients with good compliance; expected survival time > 6 months; patients ≥ 18 years old; informed consent given.

Exclusion criteria: grade 3/4 adverse events that cannot be reversed due to cancer treatment; nutritional intervention by a professional; patients with massive pleural effusion and ascites and/or severe edema; patients with poor cognitive ability, unable to answer questions, or fill in questionnaires; patients who withdrew midway.

The study was approved by the hospital ethics committee, informed consent was taken from the participants, and all the participants participated voluntarily in the study.

2.2. Research tools

A patient self-reported manual was used. The manual was divided into eight sections, which included the basic information of patients, nutritional risk screening 2002 (NRS2002), Functional Assessment of Anorexia/Cachexia Therapy (FAACT) scale, psychological pain screening, Generalized Anxiety Disorder Assessment (GAD-7) scale, Patient Health Questionnaire-9 (PHQ-9) depression-screening scale, concise dietary self-assessment scale, health index scale (EQ-5D), and nutrition supervisor overall assessment scale. The manual was filled by the patients themselves, except for items 5 to 7 under the nutrition supervisor overall assessment scale, which were completed by the attending doctors.

2.3. Data collection

A cross-sectional questionnaire survey was used. A patient-reported team was formed, consisting of two doctors and two nurses, all of whom had worked for more than five years, had professional titles of treating physician or head nurse, and had been trained in the research objectives as well as implementation methods. Two trained nurses distributed the questionnaires to the patients within 24 hours of their admission to the

hospital and collected data at the first and fourth chemotherapy cycles. In order to ensure the filling quality, the manual issuing personnel explained about the manual and guided the patients to fill in the manual. Before recycling, they were required to check the integrity of the manual, address the patients' doubts, and guide the patients to fill in the manual thoroughly and truthfully.

2.4. Statistical analysis

All data collected were entered into the software by two people and statistically analyzed by using SPSS 22.0. The basic information data of the patients were described in frequency and percentage. The scores of their nutritional status, quality of life, and anxiety and depression scales were described in mean \pm standard deviation ($\bar{x} \pm s$). The longitudinal changes of patients' self-reported score at each time point were described by using paired t-test. $p < 0.05$ indicated a statistically significant difference and a test level of $\alpha = 0.05$.

3. Results

3.1. Basic information of the research subjects

A total of 60 newly admitted patients with gastrointestinal tumors were included in this study. Their age ranged from 34 to 75 (55.15 ± 10.21), and their KPS score was 80 to 90 (89.26 ± 3.28). There were 33 male patients and 21 female patients. There were 27 cases of upper gastrointestinal tumors (esophageal cancer, gastric cancer, or liver cancer), 23 cases of lower gastrointestinal tumors (rectal cancer or colon cancer), and a case under the category of others. Among them, six participants withdrew from the study due to their own reasons before starting the fourth chemotherapy cycle. In the first and fourth cycles of chemotherapy, 54 self-reported manuals were distributed, and 50 valid questionnaires were recovered, in which the effective recovery rate was 92.6%. The basic information of the patients is shown in **Table 1**.

Table 1. Basic information of the patients (n = 54)

Features	Classification	Number of cases	Percentage (%)
Gender	Male	33	61.1
	Female	21	38.9
Cancer metastasis	Yes	28	51.9
	No	26	48.1
Types of cancer	Gastric cancer	17	31.4
	Esophageal cancer	2	3.7
	Pancreatic cancer	8	14.8
	Colorectal cancer	23	42.6
	Liver cancer	2	3.7
	Gallbladder cancer	1	1.9
	Other	1	1.9
Cancer staging	Phase I	3	5.6
	Phase II	7	13.0
	Phase III	16	29.6
	Phase IV	28	51.8

3.2. Comparison of patients' self-reported scores

From the self-reported outcomes, the PG-SGA score, FAACT score, psychological pain score, and EQ-5D score during the fourth chemotherapy cycle were significantly better than those during the first chemotherapy cycle ($p < 0.05$) (**Table 2**).

Table 2. Comparison of relevant indices between the two cycles ($\bar{x} \pm s$)

Indices	First cycle	Fourth cycle	<i>p</i> value
BMI	21.29 ± 2.99	21.30 ± 3.33	0.977
KPS	89.04 ± 2.98	89.23 ± 3.34	0.709
NRS2002	3.04 ± 0.93	2.77 ± 0.67	0.099
PG-SGA	7.63 ± 4.62	6.09 ± 4.24	0.007*
FAACT	34.50 ± 7.15	37.12 ± 6.64	0.008*
Dietary assessment	3.84 ± 0.90	3.77 ± 1.01	0.689
Psychological pain	2.19 ± 1.87	1.15 ± 1.14	0.001*
EQ-5D (VAS)	80.36 ± 15.65	86.60 ± 7.52	0.005*
EQ-5D (weighted rank)	0.91 ± 0.14	0.95 ± 0.07	0.034*

**p* < 0.05

4. Discussion

4.1. Patient-reported outcomes in nutritional assessment

There are usually four ways to evaluate the health status of patients; namely, patient-reported outcomes, doctor-reported outcomes, observer-reported outcomes, and objective test results. At present, clinical practice mostly relies on objective test results and doctor-reported outcomes. Symptom management based on these outcomes has received more attention lately [10]. PRO emphasizes on the patient-centered concept and attaches importance to the subjective feelings of patients as direct participants who can provide firsthand information to healthcare providers, which carries more weight and concrete information, thus providing a better basis for clinical diagnosis and treatment, as well as helping healthcare providers to form better medical plans for ideal symptom management [11]. Many studies have shown that there are great differences between medical staff's reports and patients' own reports. Patients' self-assessments are more sensitive, concrete, and reliable to their own symptoms compared to an observer's assessment [12]. Healthcare providers often underestimate or fail to recognize the incidence and severity of patients' responses, which might be caused by their in-depth understanding of diseases but the lack of understanding about patients. A study conducted by Wu and other researchers revealed that the incidence of self-reported adverse reactions was higher than that of nursing records [13]. A similar view was also proposed by Gravis [14]. As the most direct and core participant in medical activities, patients have the best understanding of the changes in their physical state and feelings before and after treatment; hence, they should be given more authority over the care of their own illnesses. The clinical outcome based on patients' report can provide more accurate information and contribute to the further improvement of clinical diagnosis and treatment plan [15,16]. According to a study on patient-reported symptoms and adverse reactions carried out by Lineberger Comprehensive Cancer Center, PRO should be used as an evaluation indicator to ensure the quality of routine care for cancer patients [17].

In this study, the self-reported nutritional-related indicators had significant differences during different cycles. The results during the fourth cycle of chemotherapy were significantly better than those during the first cycle, indicating an increasing trend in the nutritional status of patients with gastrointestinal cancer during chemotherapy. Contrary to the conclusions reached by Zhou and other researchers in a longitudinal study on the nutritional status and quality of life of patients with gastrointestinal cancer during chemotherapy [9], the study revealed a decreasing trend in the nutritional status of patients during chemotherapy. This is mainly attributed to the influence of the digestive function during chemotherapy along with the toxic and side effects of chemotherapeutic drugs [19]. The findings of this study might be related to the effectiveness of chemotherapy, the improvement of adverse reactions after completing

chemotherapy, the deepening of patients' concern about their nutritional status in the form of self-report, and the improvement of patient engagement. Self-report helps in improving the efficiency of doctor-patient communication, determining the condition of patients in a timely manner, realizing real-time monitoring and evaluation of symptoms ^[20], identifying medical issues in a timely manner to provide the necessary care, improving the outcomes and quality of life of cancer patients ^[21], reducing unnecessary doubts, forming treatment plans, and assisting medical staff in evaluating medical activities as well as the outcomes from the patients' perspective, so as to point out the direction for improving medical services, medical quality, and patients' medical experience ^[11].

4.2. Limitation

This was a single-center cross-sectional study, in which all the subjects were under the department of oncology in the same provincial third-level, first-class general hospital. This study did not include a control group, and the universality of the conclusion requires further discussion. There were many patients in the department, the conditions of the research subjects varied, and the treatment plans were not consistent. The patients' hospitalization duration was generally short, the turnover was high, the nurses were overworked, the data collection time was limited, and the subsequent visit time was short, all of which have an impact on the results. Furthermore, the sample size was small. Hence, it is necessary to further conduct a prospective multicenter cohort study for in-depth investigation.

5. Conclusion

This study showed that patients with gastrointestinal cancer who received standard adjuvant chemotherapy could complete nutritional assessment reports, thus highlighting the importance of nutritional management and regulation of nutritional supplies through feedback during the treatment cycle. Domestic healthcare providers should strengthen the publicity and promotion of concepts related to patient-reported outcomes as well as make use of patients' value identification and influencing factors of patient-reported outcomes to strengthen patients' consciousness in active reporting and improve the overall recognition and participation of these patients in PRO. In the future, PRO should be incorporated into clinical practice to promote patients' participation in clinical decision-making as an evaluation indicator of the quality of routine clinical care, so as to provide an effective basis for the execution and evaluation of treatment plans as well as the formulation and implementation of relevant medical policies.

Disclosure statement

The authors declare no conflict of interest.

References

- [1] Xia C, Chen W, 2022, The Proportion and Trend of the Burden of Malignant Tumors in China Attributable to the Aging Population. *Chinese Journal of Oncology*, 44(1): 79-85.
- [2] Bray F, Ferlay J, Soerjomataram I, et al., 2018, Global Cancer Statistics 2018: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA Cancer J Clin*, 68(6): 394-424. DOI: 10.3322/caac.21492
- [3] Fan K, Dai L, Wu Z, et al., 2017, Research Progress of Bone Marrow Suppression Induced by Radiotherapy and Chemotherapy. *China Journal of Traditional Chinese Medicine and Pharmacy*, 32(1): 210-214.

- [4] White Paper on Dietary Nutrition, 2020, The Incidence of Moderate to Severe Malnutrition in Malignant Tumor Patients in My Country Reaches 58%. *Cancer Prevention and Treatment Research*, 47(11): 904.
- [5] Ryan AM, Power DG, Daly L, et al., 2016, Cancer-Associated Malnutrition, Cachexia and Sarcopenia: The Skeleton in the Hospital Closet 40 Years Later. *Proc Nutr Soc*, 75(2): 199-211.
- [6] Xu J, 2018, Investigation of Nutritional Risk, Malnutrition and Nutritional Treatment in Elderly Cancer Patients. *Electronic Journal of Metabolism and Nutrition of Cancer*, 5: 159-164.
- [7] Department of Health and Human Services FDA Center for Drug Evaluation and Research, 2006, Guidance for Industry: Patient Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims: Draft Guidance. *Health Qual Life Outcomes*, 4(79): 1-20.
- [8] Ikorskii A, Victorson D, Oconnor P, et al., 2018, PROMIS and Legacy Measures Compared in A Supportive Care Intervention for Breast Cancer Patients and Caregivers: Experience from A Randomized Trial. *Psychooncology*, 27(9): 2265-2273.
- [9] Silverberg JI, Laj J, Kantor RW, et al., 2020, Development, Validation and Interpretation of the PROMIS Itch Questionnaire: A Patient-Reported Outcome Measure for the Quality of Life Impact of Itch. *J Invest Dermatol*, 140(5): 986-994.
- [10] Wu C, Zhou H, Jiang Y, et al., 2021, A Cross-Sectional Survey of Self-Reported Symptom Burden and Quality of Life in Lung Cancer Patients Before Surgery. *Cancer Prevention and Treatment*, 34(3): 234-240.
- [11] Zhu R, Huang Q, Cai T, et al., 2021, Application Progress of Patient-Reported Outcome Measurement Information System in Different Tumor Care. *Journal of Nursing Advancement*, 36(5): 405-408.
- [12] Gao W, Yuan C, 2018, Application Progress of Patient Self-Reported Outcome Measurement Information System in Foreign Countries. *Chinese Journal of Nursing*, 53(11): 1401-1405.
- [13] Wu B, Zhang L, Zhu P, et al., 2019, Consistency Research Between Self-Report and Nursing Records of Adverse Reactions to Chemotherapy in Breast Cancer Patients. *Chinese Journal of Nursing*, 54(2): 165-169.
- [14] Gravis G, Marino P, Joly F, et al., 2014, Patients' Self-Assessment Versus Investigators' Evaluation in A Phase III Trial in Non-Castrate Metastatic Prostate Cancer. *Eur J Cancer*, 50(5): 953-962.
- [15] Basch E, 2017, Patient-Reported Outcomes – Harnessing Patient's Voices to Improve Clinical Care. *N Engl J Med*, 376(2): 105-108.
- [16] Faithfull S, Turner L, Poole K, et al., 2019, Prehabilitation for Adults Diagnosed with Cancer: A Systematic Review of Long-Term Physical Function, Nutrition and Patient-Reported Outcomes. *Eur J Cancer Care (Engl)*, 28(4): 1-22.
- [17] Stover AM, Basch EM, 2016, Using Patient Reported Outcome Measures as Quality Indicators in Routine Cancer Care. *Cancer*, 122(3): 355-357.
- [18] Zhou W, Xu Q, Yan K, et al., 2017, Longitudinal Study of Nutritional Status and Quality of Life in Patients with Gastrointestinal Cancer Undergoing Chemotherapy. *Chinese Nursing Research*, 31(2): 189-193.
- [19] Liu M, Zhu Z, Lv F, et al., 2016, Perioperative Nutritional Support for Patients with Digestive Tract Tumors. *Chinese Journal of Gastrointestinal Surgery*, 19(7): 830-832.
- [20] Cai T, Li D, Huang Q, et al., 2021, Research Progress on Quality of Life Measurement Tools for Breast Cancer Patients Based on Patient Reports. *Shanghai Nursing*, 21(10): 47-51.

- [21] Gordon B-BE, Chen RCC, 2017, Patient-Reported Outcomes in Cancer Survivorship. *Acta Oncol*, 56(2): 166-173.
- [22] Huang Y, Zhang X, Yang Y, et al., 2020, Qualitative Study of Malignant Tumor Patients' Perception and Willingness to Participate of Patient Report Outcome. *Journal of Nurses Training*, 35(20): 1837-1842.

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