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ARTICLE

Application of Intelligent Management Model Based on Electronic Patient-Reported Outcome During Immunotherapy in Patients with Gastric Cancer: A Single-Center Retrospective Study

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Abstract

Aims/Background Gastric cancer is the third leading cause of cancer-related death worldwide, which seriously affects the health of patients. Immunotherapy is a commonly used clinical treatment for gastric cancer, but the adverse events caused by it seriously affect the prognosis of patients. Therefore, it is necessary to control and manage the disease risk of patients during immunotherapy. To explore the effect of applying an intelligent management model based on electronic patient-reported outcome (ePRO) in patients with gastric cancer during immunotherapy.

Methods The clinical data of 184 gastric cancer patients receiving immunotherapy in The Fourth Hospital of Hebei Medical University from September 2021 to September 2023 were retrospectively analyzed. Ninety patients receiving ePRO-based intelligent management were selected, and 85 patients were included in the observation group after excluding 5 patients. For the reference group, 94 patients receiving common case management were selected, with 90 patients being included after excluding 4 patients. After 6 months of follow-up, the nutritional status score, quality of life, treatment compliance and adverse events were compared between the two groups.

Results No significant difference was detected in nutritional status and World Health Organization Quality of Life-BREF (WHOQOL-BREF) scores of the patients before discharge ($p > 0.05$). After 2 months of follow-up, compared with the reference group, the observation group had a higher proportion of patients in grade A and grade B, which was not statistically significant ($p > 0.05$), and significantly higher physiological and psychological scores ($p < 0.001$), but showed no meaningful differences in other fields ($p > 0.05$). After 4 months of follow-up, the nutritional status in the observation group was significantly improved ($p < 0.05$), and the subjects displayed higher WHOQOL-BREF scores ($p < 0.05$) than those in the reference group. No significant difference in the incidence of adverse events was detected ($p > 0.05$). After 6 months of follow-up, the treatment compliance of the observation group was 83.53%, which was significantly higher than that of the reference group (70.00%; $p < 0.05$).

Conclusion The intelligent management model based on ePRO is conducive to improving the nutritional status of patients with gastric cancer during immunotherapy, as well as enhancing their quality of life and treatment compliance, making it worthy of clinical application.

Key words: electronic patient-reported outcome; gastric cancer; immunotherapy; nutritional status

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Introduction

Gastric cancer is the third leading cause of cancer-related death worldwide (Ajani et al, 2022). Most patients are diagnosed at an advanced stage and face poor prognosis due to the scarce availability of treatment options (Chang et al, 2022). Tumor cells can evade the host immune system through various mechanisms. For instance, cancer cells escape immune detection via programmed cell death 1/programmed cell death-ligand 1 (PD-1/PD-L1) interactions that inactivate T cells (Li et al, 2022). In light of this, immunotherapy has become the key approach to treating multiple types of cancers (Qing et al, 2022). Despite the beneficial effects, immunotherapy may result in diverse immune-related adverse events (Zhang et al, 2023). Particularly, delayed follow-up after discharge will increase the risk of disease progression or recurrence, severely affecting the prognosis of patients. Therefore, it is essential to control and manage the disease risk during immunotherapy for patients with gastric cancer.

Case management has been regarded as the vanguard of transformation in the fragmented healthcare system (Zhang et al, 2022), and a patient-centered model can persistently provide holistic and coordinated care for patients facing high medical costs and varying disease conditions. Mere observation of symptoms by medical staff or reliance on objective examination results are inadequate for evaluating and recording patients' adverse reactions. As the foundation of clinical medical care, timely and effective symptom management is indispensable to improve clinical outcomes and achieve patient satisfaction. An electronic system that facilitates the analysis of cancer patient-reported outcomes enables early detection of symptoms, which prompts planned and appropriate intervention by clinicians (Basch et al, 2022). Electronic patient-reported outcome (ePRO) systems have attracted attention in symptom research and management due to their capability to reduce physicians' burdens, enhance patients' compliance and improve communication efficiency. Nowadays, these systems have been widely used in clinical assessment, monitoring and management of symptoms across different countries (Krusche et al, 2020; Thestrup Hansen et al, 2022), but related studies in the context of China remain relatively scanty. This study was designed to examine the effect of applying an intelligent management model based on ePRO to patients with gastric cancer during immunotherapy, providing a reference for clinical management.

Methods

Study Participants

The clinical data of 184 patients with gastric cancer receiving immunotherapy in The Fourth Hospital of Hebei Medical University from September 2021 to September 2023 were retrospectively analyzed and categorized according to the management methods used. In this study, 90 patients who received ePRO-based intelligent management were selected. Eighty-five patients were included in the observation group after excluding one patient with pleural effusion, two patients with other malignant tumors, one patient with autoimmune disease, and one patient with renal failure. A total of 94 patients receiving common case management were

selected. Following the exclusion of one patient with ascites, two patients with dysfunctions in liver and kidney and one patient with coagulation disorders, 90 cases were included in the reference group. Fig. 1 shows the flow chart of this study. This study was conducted in conformance to the Declaration of Helsinki (2013) (World Medical Association, 2013) and was approved by the ethics committee of The Fourth Hospital of Hebei Medical University (approval no.: 2023KS158). Informed consent was obtained from all the patients and their families prior to their participation in this study.

Inclusion and Exclusion Criteria

Individuals who met the following criteria were included: (1) patients diagnosed with gastric cancer through pathologic and cytological means; (2) patients who were receiving immunotherapy treatment in our hospital; (3) patients without coagulation disorders, anemia and dysphagia, other malignant tumors, and vascular disease in heart and lung; and (4) patients with a predicted survival time of >1 year.

Patients with hydrothorax, ascites and edema, autoimmune disease, dysfunctions in vital organs like heart, liver and kidney, or mental diseases were excluded.

Methods Management

The subjects in both observation and reference groups received immunotherapy treatment, taking pembrolizumab plus chemotherapy (fluorouracil, cisplatin and capecitabine) as first-line treatment.

Common case management was implemented in the reference group: (1) During hospitalization, medical staff informed the patients of the purpose, significance and importance of immunotherapy. (2) Before discharge, medical staff instructed patients to eat digestible food packed with high nutrients and informed patients of the possible adverse reactions and the next treatment time. (3) Telephone follow-up was conducted on the third day after discharge to assist the patients in handling any adverse reactions that could possibly arise, to give them clear guidance about their diet, and to remind them to reach the hospital on time for treatment.

An intelligent management model based on ePRO was implemented in the observation group (management during hospitalization followed the methods in the reference group): (1) A WeChat mini program path (doctor-end ePRO) was established for attending physicians to fill in patient-reported data after follow-up when patients did not fill in the data by themselves or their WeChat accounts were not active. Secondly, the medical staff deployed the WeChat mini program path (patient-end ePRO) for patients to fill in and view report data. (2) To monitor symptoms, the system would automatically send text messages to patients' mobile phones at a predetermined time to remind the patients to commit symptom reporting. (3) The physicians would receive a real-time warning about patients' symptoms if ≥ 1 core symptom (pain, cough, fatigue, sleep disturbance and shortness of breath), which was reported by the patients, reached the preset threshold (≥ 4 points) based on the symptom score range of 0–10 points. (4) Physicians would then take corresponding intervention measures according to the early symptom scores self-reported by patients.

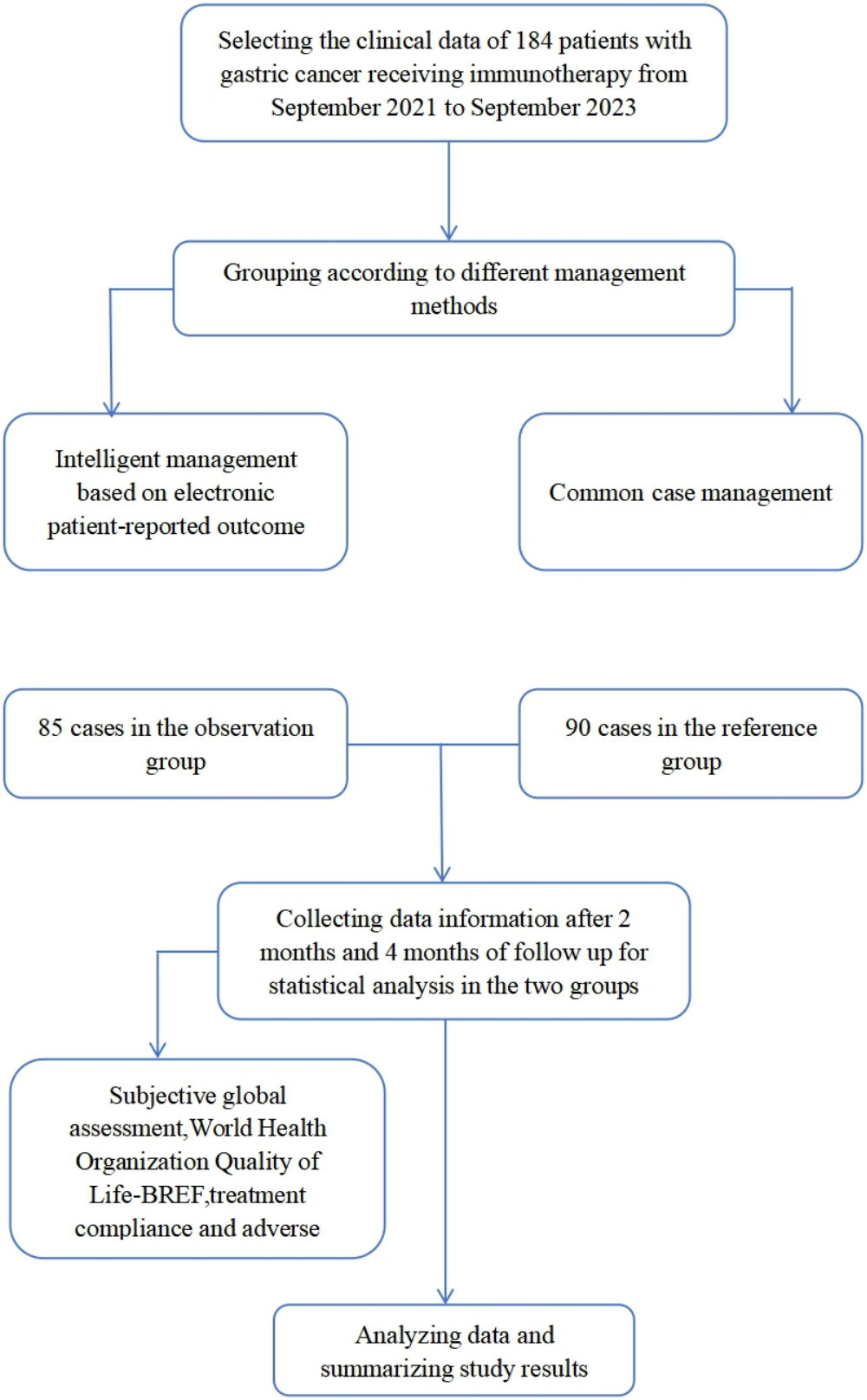

Fig. 1. Flow chart of the study.

Table 1. Assessment of nutritional status.

Indicators	Grade A	Grade B	Grade C
Recent body weight change	No/increased	Weight loss <5%	Weight loss >5%
Dietary changes	No	Decreased	No food intake/fluid with low energy
Gastrointestinal symptom (2 weeks)	No/normal appetite	Mild nausea and vomiting	Severe nausea and vomiting
Exercise capacity changes	No/decreased	Out-of-bed activity	Lying in bed
Stress reaction	No/low	Severe	High
Muscle depletion	No	Slight	Severe
Triceps skin fold thickness	Normal	Slight decrease	Severe decrease
Crotch edema	No	Slight	Severe

Observation Indexes

The data information of each index before discharge (T0), after 2 months (T1) and 4 months of follow-up (T2) were compared between the two groups.

Baseline Information

Baseline data such as sex, age, tumor location, Tumor Node Metastasis (TNM) stage, and payment methods were collected.

Assessment of Nutritional Status

Subjective global assessment (SGA) (Ottery, 1994) covering aspects such as medical history, symptoms and physiological parameters was performed to determine the risk of comorbidities in malnourished patients and the benefits gained from nutritional therapy, providing a general and comprehensive assessment of the patient's nutritional status. This assessment encompassed 8 indicators, including grade A, grade B and grade C (as detailed in Table 1), with the assessment criteria as follows: (1) The assessment of at least 5 indicators in grade A was regarded as good nutrition. (2) The assessment of at least 5 indicators in grade B was regarded as moderate malnutrition. (3) The assessment of at least 5 indicators in grade C was regarded as severe malnutrition.

World Health Organization Quality of Life-BREF (WHOQOL-BREF)

WHOQOL-BREF (Saxena et al, 2001) contained 26 items in four categories, i.e., physiological domain, psychological domain, social relationship domain, and environmental domain. Each item was rated with 1 to 5 points, and a single dimension was converted into a percentile through standardization. Taking the average score of each dimension as the total score, a higher score represented a better quality of life.

Treatment Compliance

Complete compliance refers to patients completing the entire immunotherapy course without interruptions. Partial compliance refers to the situation when the patients are able to complete the immunotherapy even if there is an unplanned sus-

pension or delay during treatment, or the treatment plan is adjusted due to adverse reactions—a sign that patients could tolerate the treatment. Patients who did not complete the immunotherapy were classified as treatment dropouts. The treatment cycle lasted for 6 months.

Compliance rate = (complete compliance + partial compliance)/total number of patients.

Adverse Reactions

The adverse reactions of the two groups were compared, including dermatologic toxicities such as rash, itching and vitiligo, endocrine adverse reactions such as thyroiditis and colitis, and buccal mucosal adverse reactions like mouth ulcer and xerostomia.

Statistical Analysis

Statistical Product and Service Solutions (SPSS) 25.0 software (International Business Machines Corporation, Armonk, NY, USA) was used for data processing. The Shapiro–Wilk method was employed to test the normal distribution of continuous variables. The data conforming to the normal distribution are expressed as mean ± standard deviation (SD) and were analyzed using a *t*-test. The data that are not normally distributed are expressed as median [M (P_{25}, P_{75})] and were tested using the Mann–Whitney *U* test. The difference was considered statistically significant at $p < 0.05$.

Results

General Data

Table 2 shows no significant difference in general data between the observation and reference groups ($p > 0.05$).

Nutritional Status

No significant difference in nutritional status between the observation and reference groups at T0 ($p > 0.05$). At T1, there was a higher proportion of patients with good nutrition or moderate malnutrition in the observation group than in the reference group, albeit no statistical significance was detected ($p > 0.05$). At T2, in comparison with the reference group, the observation group displayed significantly higher nutritional status ($p < 0.05$), as shown in Table 3.

Quality of Life

The WHOQOL-BREF scores presented no significant differences between observation and reference groups at T0 ($p > 0.05$). At T1, the observation group scored significantly higher in the physiological and psychological domain than the reference group ($p < 0.001$), but no significant difference was found in other domains ($p > 0.05$). At T2, the WHOQOL-BREF scores corresponding to all quality-of-life domains in the observation group were significantly higher than those in the reference group ($p < 0.05$), as shown in Table 4.

Table 2. Comparison of general data between the observation and reference groups.

Parameter		Observation group (n = 85)	Reference group (n = 90)	z/χ^2	p
Sex	Male Female	51 (60.00) 34 (40.00)	52 (57.78) 38 (42.22)	0.089	0.765
Age [years, M (P_{25}, P_{75})]		45.00 (36.00, 57.00)	46.50 (37.00, 55.00)	–0.124	0.901
Course of disease [months, M (P_{25}, P_{75})]		9.00 (7.00, 11.00)	9.50 (7.00, 11.00)	–0.696	0.487
Types of gastric cancer	Adenocarcinoma Squamous cell carcinoma Signet-ring cell carcinoma Mucinous carcinoma	29 (34.12) 22 (25.88) 15 (17.65) 19 (22.35)	34 (37.78) 21 (23.33) 17 (18.89) 18 (20.00)	0.430	0.934
Tumor location	Gastric body Gastric fundus Gastric sinus Multiple sites	25 (29.41) 21 (24.71) 24 (28.24) 15 (17.65)	24 (26.67) 25 (27.78) 23 (25.56) 18 (20.00)	0.520	0.915
TNM stage	Stage II Stage III	49 (57.65) 36 (42.35)	55 (61.11) 35 (38.89)	0.218	0.641
Marital status	Married Unmarried/widowed	65 (76.47) 20 (23.53)	71 (78.89) 19 (21.11)	0.148	0.701
Payment methods	Medical insurance Self-payment	68 (80.00) 17 (20.00)	71 (78.89) 19 (21.11)	0.033	0.856

TNM, Tumor Node Metastasis.

Treatment Compliance

After 6-month follow-up, the subjects in the observation group exhibited significantly higher treatment compliance than those in the reference group (83.53% vs 70.00%), as shown in Table 5.

Adverse Events

Both the observation and reference groups did not present significant differences in the incidence of adverse events at T2 ($p > 0.05$; Table 6).

Discussion

In recent years, immunotherapy has emerged as a new treatment strategy for gastric cancer (Wang et al, 2018). However, due to the inadequate efficacy of immunotherapy, patients' compliance during treatment is significantly lower than that during conventional treatment. As a new symptom management system powered by the network, ePRO is increasingly gaining recognition in the healthcare sector (Bänziger et al, 2023). For example, palliative outcomes from ePRO allow early monitoring and management of symptoms, exerting a positive impact on patient's daily lives to the greatest extent possible (Consolo et al, 2023). The implementation

Table 3. Comparison of nutritional status between the observation and reference groups.

Parameter		Observation group (n = 85)	Reference group (n = 90)	χ^2	*p*
T0	Good nutrition	0 (0.00)	0 (0.00)	0.040	0.842
	Moderate malnutrition	29 (34.12)	32 (35.56)		
	Severe malnutrition	56 (65.88)	58 (64.44)		
T1	Good nutrition	11 (12.94)	7 (7.78)	3.896	0.143
	Moderate malnutrition	39 (45.88)	33 (36.67)		
	Severe malnutrition	35 (41.18)	50 (55.56)		
T2	Good nutrition	22 (25.88)	11 (12.22)	11.557	0.003
	Moderate malnutrition	42 (49.41)	36 (40.00)		
	Severe malnutrition	21 (24.71)	43 (47.78)		

T0, before discharge; T1, after 2 months; T2, 4 months of follow-up.

Table 4. Comparison of quality of life between the observation and reference groups.

Items		Observation group (n = 85)	Reference group (n = 90)	z	*p*
T0	Physiological domain	34.00 (28.00, 40.00)	35.50 (29.00, 42.00)	–1.252	0.211
	Psychological domain	27.00 (19.00, 36.00)	26.00 (19.00, 34.00)	–0.517	0.605
	Social relationship	23.00 (19.00, 29.00)	23.00 (16.00, 27.00)	–0.720	0.471
	Environmental domain	29.00 (22.00, 37.00)	28.00 (22.00, 35.00)	–0.732	0.464
T1	Physiological domain	42.00 (35.00, 49.00)	36.00 (28.00, 43.00)	–4.317	<0.001
	Psychological domain	44.00 (36.00, 53.00)	37.50 (30.00, 43.00)	–4.641	<0.001
	Social relationship	39.00 (32.00, 43.00)	36.00 (31.00, 42.00)	–1.509	0.131
	Environmental domain	46.00 (38.00, 52.00)	45.00 (37.00, 51.00)	–0.683	0.495
T2	Physiological domain	50.00 (41.00, 57.00)	45.00 (37.00, 51.00)	–3.113	0.002
	Psychological domain	52.00 (39.00, 58.00)	45.00 (37.00, 54.00)	–2.596	0.009
	Social relationship	37.00 (31.00, 43.00)	34.50 (27.00, 40.00)	–2.292	0.022
	Environmental domain	50.00 (39.00, 58.00)	47.00 (37.00, 54.00)	–2.197	0.028

Data are expressed as M (P_{25}, P_{75}).

of ePRO is expected to play an important role in the development of new digital health interventions for palliative cancer care (Karamanidou et al, 2020), and to improve the health outcomes of gastric cancer patients undergoing immunotherapy.

The data of this study showed that at T2, the nutritional status of the observation group described was significantly higher than that in the reference group, suggesting that ePRO could effectively improve the nutritional status of patients with gastric cancer. The benefits of ePRO lie in its ability to monitor and detect severe and worsening symptoms in patients during the early phase (Basch et al, 2023), facilitating timely interventions and adjustment of nutrition plans with the aim of improving outcomes. Regarding patients' interests as the focal point, ePRO presents a conducive approach to fine-tuning the focus and direction of out-of-hospital nutrition management and further improving the nutritional status of patients.

Table 5. Comparison of treatment compliance between the observation and reference groups.

Group	Complete compliance	Partial compliance	Treatment dropout	Compliance rate
Observation group (n = 85)	42 (49.41)	29 (34.12)	14 (16.47)	71 (83.53)
Reference group (n = 90)	38 (42.22)	25 (27.78)	27 (30.00)	63 (70.00)
χ^2	-	-	-	4.460
p	-	-	-	0.035

Data are expressed as [n, (%)].

Table 6. Comparison of adverse reactions in both groups [n, (%)].

Groups	Dermatologic toxicities	Buccal mucosal adverse reactions	Endocrine adverse reactions
Observation group (n = 85)	24 (28.24)	27 (31.76)	37 (43.53)
Reference group (n = 90)	30 (33.33)	32 (35.56)	35 (38.89)
χ^2	0.533	0.281	0.389
p	0.466	0.596	0.533

At present, there is an increase in the utilization of ePRO systems to support the management of patients with chronic kidney disease (Anderson et al, 2023), and the application of this system in cancer management is also gradually gaining traction (Li et al, 2023). The present study revealed that at T1, the physiological and psychological scores in the observation group were significantly higher than those in the reference group. At T2, the WHOQOL-BREF scores in the observation group were significantly higher than those in the reference group, indicating that ePRO effectively improves the quality of life of gastric cancer patients undergoing immunotherapy—a beneficial feature that is attributed to the ePRO-based symptom monitoring system that allows monitoring and managing symptoms and side effects (Lai-Kwon et al, 2023) and provides a complete picture of patient's health status. Moreover, the system also allows the collection of genuine and reliable data that are not easily influenced by external factors, thus posing a significant advantage in improving the quality of care. ePRO can be used to evaluate a wide range of non-organic diseases through the diagnosis of patients' subjective symptoms, and offer additional information that could reflect the overall health status of patients. More importantly, it can also be utilized for evaluating drug efficacy and aiding in the selection of treatment options.

ePRO holds great potential in improving patients' health outcomes and advancing the healthcare sector (Lostelius et al, 2023). The present study showed that after 6 months of follow-up, the subjects in the observation group became significantly more treatment-compliant than those in the reference group (83.53% vs 70.00%), indicating that ePRO effectively improves the compliance of gastric cancer patients undergoing immunotherapy. The enhanced treatment compliance is probably due to the usefulness of ePRO that helps clinicians proactively carry out the assessment and management of patients' symptoms (Sandhu et al, 2020). Moreover, ePRO is a patient-centered system, with an array of functions such as monitoring, warning,

symptom feedback, etc. that greatly facilitate the daily out-of-hospital management for patients and meet their actual needs. In the meantime, through the warning feature in ePRO, patients would instantly receive the most professional and individualized guidance regarding symptom management from medical staff, easing any efforts for further treatment and enhancing treatment compliance. The research data also showed no significant difference in the incidence of adverse reactions between the two groups at T2, indicating that ePRO had no significant effect on the incidence of adverse reactions among the patients. We believe that most of the adverse reactions are caused by drug toxicity, and thus out-of-hospital management has very little or no effect in controlling adverse reactions.

The limitations of this study are as follows: Firstly, the findings might not be representative enough across populations because of the small sample size and single-center nature of this study. Secondly, this study did not measure the survival endpoint of patients and observe the long-term effect of ePRO. In addition, the evaluation criteria applied in this study were rather subjective. Therefore, in future research, objective evaluation indicators should be added to investigate the effect of applying the ePRO-based management model on patients with gastric cancer during immunotherapy.

Conclusion

The application of the ePRO-based intelligent management model in the clinical management of gastric cancer patients undergoing immunotherapy can effectively improve the nutritional status of patients, enhance their quality of life and treatment compliance, and ensure the therapeutic effect, underscoring the worthiness of promoting the application of this model in a broader clinical context.

Key Points

- ePRO could effectively improve the nutritional status of patients with gastric cancer during immunotherapy.
- ePRO could effectively improve the quality of life of patients with gastric cancer during immunotherapy.
- ePRO could effectively enhance the compliance of patients with gastric cancer during immunotherapy.
- The application of the ePRO-based intelligent management model in the clinical management of patients with gastric cancer during immunotherapy has an obvious beneficial effect.

Availability of Data and Materials

All the data used for analysis in this study are supported by existing data in the network database, and in this published article, all the study's generated data are presented.

Author Contributions

CL and DW designed the study; both authors conducted the study; DW collected and analyzed the data; CL participated in drafting the manuscript, and both authors contributed to the critical revision of the manuscript for important intellectual content. Both authors gave final approval of the version to be published. Both authors participated fully in the work, took public responsibility for appropriate portions of the content, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or completeness of any part of the work are appropriately investigated and resolved.

Ethics Approval and Consent to Participate

This study has been approved by the ethics committee of The Fourth Hospital of Hebei Medical University (approval No. 2023KS158). Informed consent was obtained from patients and their families.

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Conflict of Interest

The authors declare no conflict of interest.

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