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ORIGINAL RESEARCH

Personalised Rational Drug Monitoring Combined with KABP Model Health Education to Improve Adherence and Prognosis of CAR-T Cell Therapy

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Purpose: Complications such as tumor lysis syndrome occur during the Chimeric antigen receptor (CAR)-T cell treatment process, which adversely affects the treatment effect. The aim of this study is to study the combination of personalised rational medication monitoring and the Knowledge, Attitude, and Behavior (KABP) model health education to improve the adherence and prognosis of CAR-T cell therapy.

Patients and Methods: 91 patients with lymphoma and multiple myeloma who received CAR-T cell therapy in our hospital from January 2021 to December 2024 were included in this single-retrospective study and divided into the control group (n=46, routine care) and the observation group (n=45, routine care + personalised rational medication monitoring combined with KABP model health education) based on the treatment methods. Compliance, clinical treatment efficacy, self-care ability, Functional Assessment of Cancer Therapy-General (FACT-G) scale, State-Trait Anxiety Inventory (STAI), and Knowledge, Attitude, and Behavior (KAB) scale were compared between the two groups.

Results: The observation group demonstrated significantly higher total compliance and clinical efficacy compared to the control group ($P < 0.05$). Following personalized rational drug monitoring and KABP model health education post-management, the observation group also exhibited higher scores in self-care ability, FACT-G, and KAB, along with lower STAI scores than the control group ($P < 0.05$).

Conclusion: This approach proves beneficial in enhancing patient adherence, treatment effectiveness, and quality of life in CAR-T cell therapy.

Keywords: chimeric antigen receptor T cells, KABP model health education, personalised rational medication monitoring, adherence

Introduction

With the comprehensive attention of the medical field to patients, immunotherapy has gradually attracted widespread clinical attention, especially in the clinical treatment of cancer patients.[1,2] A novel immunotherapy approach, known as Chimeric antigen receptor T (CAR-T) cell therapy, involves genetically modifying T lymphocytes to express a synthetic receptor. This receptor can specifically identify a tumor cell surface antigen, prompting the T cell to eliminate the tumor cell. The US Food and Drug Administration (FDA) has given its approval to six CAR T-cell products for the treatment of six hematologic malignancies, namely B-cell acute lymphoblastic leukemia,[3] large B-cell lymphoma,[4] follicular lymphoma,[5] mantle cell lymphoma,[6] chronic lymphocytic leukemia,[7] and multiple myeloma.[8] CAR T therapy has demonstrated improvements in progression-free survival for multiple myeloma, enhanced overall survival for large B-cell lymphoma, and achieved high remission rates for other hematologic malignancies, including acute lymphoblastic leukemia, follicular lymphoma, and

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mantle cell lymphoma.[9] In a retrospective analysis, CAR T cells have shown a superior 2-year overall survival rate in patients with relapsed/refractory B-cell precursor acute lymphoblastic leukemia (59.5% vs 36.2%) compared with standard of care therapy.[10] Although no CAR T-cell therapies have received FDA approval for solid tumors, two other T lymphocyte-based treatments have recently been approved, including TIL Therapy for unresectable and metastatic melanoma, and TCR T-Cell Therapy for treating synovial cell sarcoma after prior chemotherapy.[11]

CAR T-cell therapy faces a number of challenges, including acute and long-term adverse effects, limited efficacy and durability, lack of effective salvage treatments, and long wait times for and limited access to CAR T-cell therapy. A common adverse effect occurring with these T lymphocyte–based therapies is capillary leak syndrome, which is characterized by fluid retention, pulmonary edema, and kidney dysfunction. The possibility of malignant transformation was a major safety consideration during the development and initial deployment of engineered autologous CAR T cells.[12] There are considerable long-term adverse events for patients treated with B-cell targeted CAR T-cell therapy including chronic B-cell aplasia, hypogam maglobulinaemia, cytopenias, and infections.[9,13] Furthermore, CAR T-cell therapy is linked to reversible acute toxicities, such as cytokine release syndrome in approximately 40% to 95% of patients,[14] and neurologic disorders in approximately 15% to 65%.[15] Cytokine release syndrome is an inflammatory condition marked by fever, tachycardia, hypotension, and hypoxia. Additionally, immune effector cell-associated neurotoxicity syndrome, a neurological disorder, presents with multiple symptoms, including encephalopathy, language disturbances (dysphasias), and reduced alertness.

Complications occurred during the treatment process adversely affects the treatment effect. In addition, the disease itself causes physical and mental pain to patients, leading to adverse emotions, decreased quality of life, and poor compliance.[16] Although CAR-T cell therapy can effectively improve the clinical efficacy of patients, it is a new treatment method. Some patients have high expectations for new technologies, but it can also cause anxiety and other negative emotions, and complications during treatment can cause physical and suffering to patients, affecting disease prognosis and quality of life.[17–19] Therefore, effective management of patients receiving CAR-T cell therapy is a key concern for healthcare professionals.

Conventional nursing can provide basic measures and services for patients, but the effect is not ideal. Personalized and rational medication monitoring refers to monitoring and formulating a reasonable drug use plan for patients based on their individual physiological status, disease characteristics, and other aspects, with the aim of reducing adverse drug reactions and maximizing treatment efficacy.[20,21] The Knowledge, Attitude, and Behavior (KABP) model of health education is a new clinical model that uses knowledge as the foundation and beliefs and behaviors as the driving force to take relevant measures to promote the development of healthy behaviors in patients.[22–24]

However, research on the management strategies of personalized and rational medication monitoring combined with KABP model health education and their actual effects on patients is limited. Based on this, this study conducted research on patients with lymphoma and multiple myeloma who underwent CAR-T cell therapy in our hospital from January 2021 to December 2022. By analyzing the potential effects of personalized and rational medication monitoring combined with KABP model health education on patient compliance, prognosis, and emotions, the aim is to provide guidance for clinical practice.

Materials and Methods

Study Design and Participants

A total of 91 patients with lymphoma and multiple myeloma who underwent CAR-T cell therapy in our hospital from January 2021 to December 2022 were selected. The patients were then divided into the control group (n=46, conventional nursing) and the observation group (n=45, conventional nursing + personalized and rational medication monitoring combined with KABP model health education).

Inclusion and Exclusion Criteria

Inclusion criteria: (1) All patients received CAR-T cell therapy; (2) Age > 18 years; (3) Expected survival time ≥ 3 months; (4) Complete clinical data; (5) Normal understanding and communication ability, able to cooperate with medical staff.

Exclusion criteria: (1) Patients with severe organ diseases such as heart, liver, and kidney; (2) Patients with acute infectious diseases; (3) Patients with neurological systemic diseases or cognitive impairment; (4) Patients with a history of immunosuppressive or corticosteroid use before CAR-T cell therapy.

Sample Size

Based on the Kendall principle, the sample size is set at 5–10 times the number of research variables. According to the calculation formula $n=[(Z\alpha/2)^2\times p(1-p)]\div E^2$, considering error factors such as loss to follow-up, the sample size is increased by 10%. It is estimated that a minimum of 66 cases are needed for this study. In the end, 91 cases were included in this study, exceeding the estimated minimum sample size, which can improve the reliability of statistical analysis.

Methods

The control group received standard nursing care focused on health education post-admission, covering the rationale, methods, effects, and precautions of CAR-T cell therapy. Patient management included tailored approaches in diet, medication, psychology, and activity to ensure adequate nutrition and emotional support. Risks were assessed, medications prepared, and vital signs closely monitored, promptly reported to attending physicians for any abnormalities.

In contrast, the observation group underwent a comprehensive intervention integrating personalized medication monitoring and the KABP model of health education, expanding on the control group's practices. Firstly, a specialized nursing team, led by a head nurse and six responsible nurses, meticulously gathered patient data to establish personalized profiles considering medical history and medication specifics. Rigorous training on rational medication use, procedures, and KABP principles ensured competence before practical implementation, with ongoing skill refinement. Secondly, personalized medication monitoring was pivotal, with healthcare professionals receiving targeted training on drug utilization and safety protocols. Patients and families participated in detailed lectures on CAR-T therapy, including rationale, precautions, administration methods, and potential reactions, supported by educational materials. During therapy, rigorous symptom monitoring and specific interventions like fever management and hypotension treatment were implemented as needed. Thirdly, dynamic medication supervision included frequent communication between nurses and physicians to adjust treatment plans based on patient responses. Pre-discharge education emphasized medication adherence and involved families in overseeing routines. Fourthly, the KABP model of health education utilized patient questionnaires to tailor educational sessions, empowering patients through expert-led lectures and Q&A sessions. Regular interviews strengthened patient-nurse relationships and addressed concerns, promoting treatment adherence. Lastly, behavioral interventions encouraged patients to track daily mood, diet, treatment progress, and disease episodes, correcting any deviations and emphasizing self-management.

Observation Indicators

All observational indicators, including treatment compliance, clinical efficacy, self-care ability scores, Functional Assessment of Cancer Therapy-General (FACT-G) scores, and Knowledge-Attitude-Behavior (KAB) scores, were systematically collected and evaluated 30 days post-CAR-T cell therapy.

(1) Compliance: (a) Complete compliance: Patients actively follow the treatment plan formulated by the attending physician with a positive attitude. (b) Partial compliance: Patients reluctantly follow the treatment plan formulated by the doctor and take the treatment under the advice of the doctor and their family members. © Non-compliance: Patients do not follow the doctor's instructions for diagnosis and treatment, choose their own treatment according to their own ideas, and do not take medication as prescribed. Total compliance = (complete compliance + partial compliance) / total number × 100%.

(2) According to the tumor prognosis evaluation criteria established by the World Health Organization (WHO):[25] (a) Complete response (CR): Disappearance of lesions for ≥4 weeks. (b) Partial response (PR): Reduction in the sum of the maximum diameters of the main lesions for ≥4 weeks. (c) Stable disease (SD): The sum of the maximum diameters of the lesions does not meet the PR criteria. (d) Progression (PD): An increase in the sum of the maximum diameters of the lesions by ≥20.00%, or the appearance of new lesions. Objective response rate = (CR + PR + SD) / total number × 100%.

(3) Self-care ability scale:[26] Includes four dimensions: health knowledge, self-care responsibility, self-care skills, and self-concept, with a total of 43 items. Each item is scored from 1 to 4 points, with higher scores indicating higher self-care ability.

(4) FACT-G scale:[27] It includes physiological, social, family, emotional, and functional status, with a total of 27 items. Each item is scored on a five-point scale, with higher scores indicating a higher level of quality of life; State-Trait Anxiety Inventory (STAI):[28] The scale is divided into two dimensions: state anxiety inventory (S-AI) and trait anxiety inventory (T-AI), with a total of 40 items. The first, tension, fear, etc. The last 20 items are T-AI, which evaluates the stable and chronic tendency of anxiety. Each dimension has a total score of 80, with higher scores indicating a higher severity of current anxiety or a higher level of chronic anxiety.

(5) KAB scale:[29] It includes three dimensions: knowledge (24 points), behavior (30 points), and attitude (25 points). The scale was used to evaluate and compare the patients' management before and after the intervention, with higher scores indicating better knowledge, behavior, and attitude.

Statistical Methods

Statistical analysis was performed using IBM SPSS Statistics 25.0 (Armonk, State of New York, USA). Count data were expressed as n (%) and analyzed using the chi-square test. Continuous variables were assessed for normality using the Shapiro–Wilk test. T Continuous variables were presented as mean ± standard deviation (□X ± SD) for normally distributed data or as median (interquartile range) [M (Q1, Q3)] for non-normally distributed data. Inter-group comparisons of continuous variables used the independent samples *t*-test for normally distributed data and the Mann–Whitney *U*-test for non-normally distributed data. A *P* value of <0.05 was considered statistically significant.

Results

Comparison of General Data Between the Two Groups

A total of 91 patients who underwent CAR-T cell therapy from January 2021 to December 2022 were included following the procedure. General information of the two groups of patients showed no significant differences (*P*>0.05), as shown in Table 1.

Comparison of Compliance

Compliance is used to evaluate the degree of patient cooperation. The overall compliance of the observation group (95.56%) was higher than that of the control group (73.91%) (χ^2=6.607, *P*=0.010). The research results indicate that the compliance of patients in the observation group is higher, as shown in Table 2.

Comparison of Clinical Prognosis

At the 30-day follow-up after CAR-T cell therapy, the observation group demonstrated higher rates of CR (17.78%) and PR (44.44%) compared to the control group (8.70% and 30.43%, respectively), while experiencing lower rates of PD (13.33% vs 34.78%). The total objective response rate (combining CR and PR) was significantly higher in the observation group than in the control group (86.67% vs 65.22%, P= 0.032), as shown in Table 3.

Comparison of Self-Care Ability

Self-care ability score is an assessment of the patient's ability to take care of themselves. There was no significant difference in the comparison of self-care ability scores between the first two groups before management (*P* >0.05). However, after management, the observation had higher scores than the control group (t=3.253, 3.394, 3.178, 2.784, *P*=0.002, 0.001 0.002, 0.007), as shown in Figure 1.

Comparison of FACT-G and STAI Scores

There was no significant difference in FACT-G and STAI scores between the two groups before management (*P*>0.05). After management, the FACT-G score in the observation group was higher than that in the control group (t=3.845, *P*<0.001), and the STAI scores in the observation group were lower than those in the control group (t=3.213, 3.469, *P*=0.002, <0.001), as depicted in Figure 2.

Table 1 Comparison of General Data Between the Two Groups

Index		Observation Group (n=45)	Control Group (n=46)	χ^2/t	*P* value
Age (years)		44.89±5.05	44.93±4.86	0.042	0.967
Gender (n, %)	Male	25 (56)	23 (50)	0.103	0.748
	Female	20 (44)	23 (50)		
Body mass index (kg/m^2)		22.12±2.25	22.14±2.26	0.030	0.976
Tumor stage	I~II stage	29 (64)	27 (59)	0.121	0.728
	III~V stage	16 (35.56)	19 (41)		
Disease duration (years)		2.43±0.51	2.45±0.48	0.194	0.846
Diabetes (n, %)	Yes	11 (24)	10 (22)	0.003	0.954
	No	34 (75.56)	36 (78)		
Hypertension (n, %)	Yes	8 (17.78)	7 (15)	0.002	0.963
	No	37 (82)	39 (85)		
Education level (n, %)	Middle school and below	19 (42)	21 (46)	0.014	0.906
	High school and below	26 (58)	25 (54)		
Monthly income level (n, %)	≤3000 yuan	17 (38)	15 (33)	0.088	0.767
	>3000 yuan	28 (62.22)	31 (67.39)		
CAR-T therapy				0.130	0.718
Relmacabtagene autoleucel (relma-cel) CD19 CAR-T therapy (n, %)		6 (13%)	5 (11%)		
Axicabtagene Ciloleucel (axi-cel) CD19 CAR-T therapy (n, %)		39 (87%)	41 (89%)		
Lines of prior therapy				0.181	0.914
2		24 (53%)	25 (54%)		
3–4		18 (40%)	17 (37%)		
≥5		3 (7%)	4 (9%)		
Autologous stem-cell transplantation					
Yes		5 (11%)	4 (9%)	0.001	0.972

Table 2 Comparison of Compliance (n, %)

Index	Observation Group (n=45)	Control Group (n=46)	χ^2	*P* value
Complete compliance	29 (64.44)	20 (43.48)	–	–
Partial compliance	14 (31.11)	14 (30.43)	–	–
Non-compliance	2 (4.44)	12 (26.09)	–	–
Total compliance	43 (95.56)	34 (73.91)	6.607	0.01

Table 3 Comparison of Clinical Prognosis at the 30-Day Follow-up After CAR-T Cell Therapy (n, %)

Index	Observation Group (n=45)	Control Group (n=46)	χ^2	*P* value
CR	8 (17.78)	4 (8.70)	–	–
PR	20 (44.44)	14 (30.43)	–	–
SD	11 (24.44)	12 (26.09)	–	–
PD	6 (13.33)	16 (34.78)	–	–
Total objective response	39 (86.67)	30 (65.22)	4.599	0.032

Comparison of KAB Scores

The knowledge, attitude, and behavior scores of patients were assessed using the knowledge-attitude-behavior (KAB) scoring system. There were no significant differences in the KAB scores between the management groups before

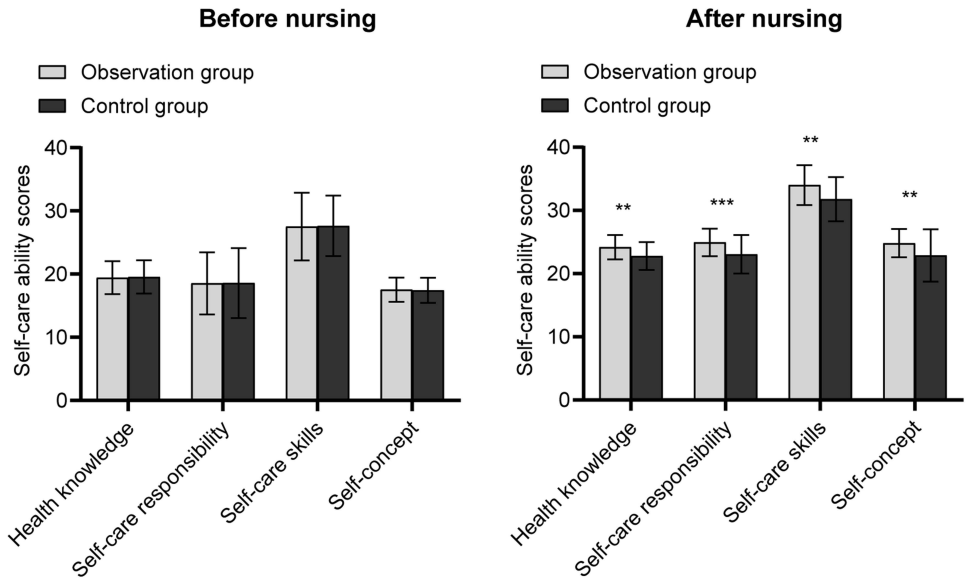

Figure 1 Comparison of self-care ability scores between the control group (n=46, routine care) and the observation group (n=45, routine care + personalised rational medication monitoring combined with the Knowledge, Attitude, and Behavior (KABP) model health education) before and after nursing managements. **P<0.01, *** P<0.001.

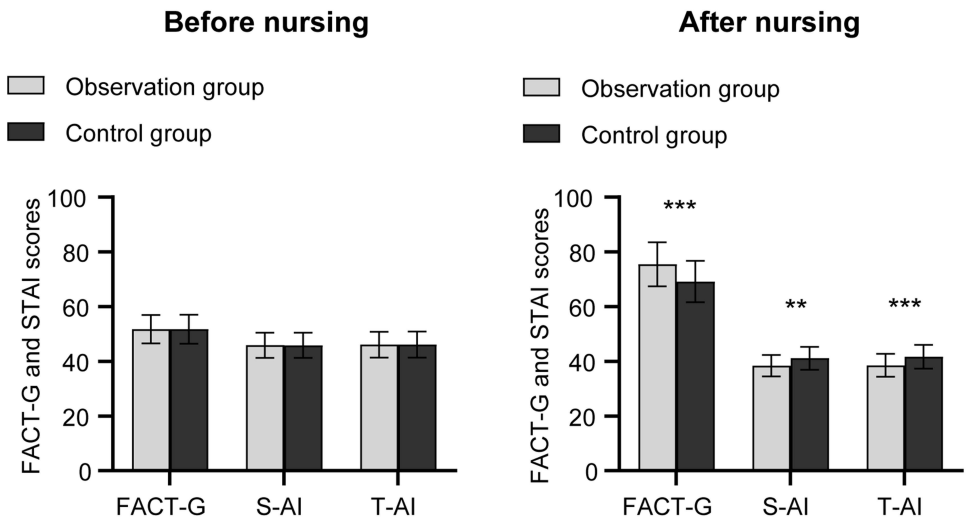

Figure 2 Comparison of Functional Assessment of Cancer Therapy-General (FACT-G) and State-Trait Anxiety Inventory (STAI) scores scores between the control group and the observation group. ** P<0.01, *** P<0.001.
Abbreviations: S-AI, State anxiety inventory; T-AI, Trait anxiety inventory.

intervention ($P>0.05$). However, after the intervention, the observation group had significantly higher scores compared to the control group (t=3.532, 3.717, 3.212; $P=<0.001$, <0.001, 0.002), as illustrated in Figure 3.

Discussion

The personalized and rational medication monitoring combined with KABP model health education can improve patients' self-care ability, compliance, knowledge, attitudes, and prognosis. Similar nursing methods have been used in clinical practice by Hu et al[30] and the results showed that it effectively improved patients' self-care ability, compliance, satisfaction, and knowledge, attitudes, and behavior, which is consistent with the results of this study. In this study, the observation group received personalized and rational medication monitoring, including explanations of the reasons for CAR-T cell therapy, precautions, and effects. Patients and their families were educated on relevant content, and

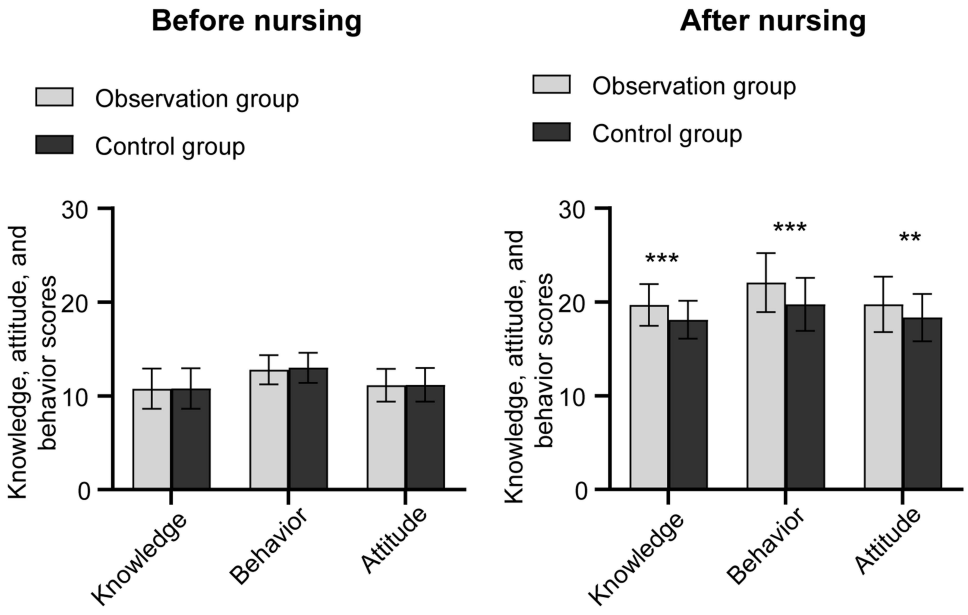

Figure 3 Comparison of Knowledge, Attitude, and Behavior (KAB) scores scores between the control group and the observation group. ** *P*<0.01, *** *P*<0.001.

medication use was dynamically supervised. Communication with attending physicians and nursing staff was strengthened, and the treatment plan was adjusted according to the actual situation. The importance of using medication on time and in the prescribed amount was emphasized before discharge, and patients and their families were encouraged to pay attention to rational medication use and ensure timely and proper use of medication to maximize the efficacy of the medication and improve patients' prognosis, and enhance patient compliance. At the same time, KABP model health education was combined, and a questionnaire related to CAR-T cell therapy was designed to understand patients' knowledge, and patients' knowledge base was strengthened through lectures and in-depth interviews to clarify the purpose of the interview and inform them of the harm of non-compliance with medical advice, the disadvantages of improper medication, and the importance of attitude and belief in disease treatment. Corresponding dietary and exercise plans were formulated for patients based on their actual conditions to correct incorrect behaviors and improve patients' self-care ability and behavior from the aspects of knowledge, attitude, and behavior. Previous studies have found that scientific and rational medication monitoring can effectively improve the clinical outcomes of tumor patients.[31,32] The study by Wei et al[33] further confirmed the positive effects of KABP model health education on patients' self-care ability and compliance.

In this study, the personalized and rational medication monitoring combined with KABP model health education can improve patients' negative emotions and quality of life to a certain extent. Dong et al[34] conducted a clinical study and applied this nursing approach to patients, and the results showed that it not only effectively alleviated postoperative pain but also improved patients' anxiety and quality of life, which is consistent with the results of this study. Although the clinical efficacy of CAR-T cell therapy has been confirmed, patients may have fear and doubt about the disease itself and the emerging treatment technology, and during the treatment process, patients may experience adverse reactions, which can have a serious impact on their physical and mental well-being. Previous studies have found that emotions such as suspicion and fear can stimulate the sympathetic nervous system, keep the brain in an excited, activate the prefrontal cortex and other regions, and affect normal emotional regulation when these regions receive signals, leading to great anxiety about the disease caused by physiological discomfort.[35–37] This study used personalized and rational medication monitoring combined with KABP model health education to take corresponding measures in various aspects of patients' knowledge, behavior, and attitudes, and conducted medication monitoring to improve patients' understanding of disease-related knowledge, effectively prevent complications, and improve patients' prognosis. This approach can reduce the stress

response of the hypothalamic-pituitary-adrenal axis and the negative impact on the nervous system from both psychological and physiological aspects, effectively alleviate patients' negative emotions, and improve their quality of life.

While the current study focuses on hematologic malignancies, the personalized rational medication monitoring combined with the KABP model health education could be effectively expanded to other disease settings, including autoimmune diseases, viral infections, and even solid tumors. In autoimmune diseases, allogeneic (off-the-shelf) CAR-T cells have shown promise as an alternative to autologous products, offering advantages like faster availability and lower costs.[38] However, the use of allogeneic cells presents challenges, including immune rejection and the risk of graft-versus-host disease (GVHD), which could impact treatment outcomes. The personalized protocol used in this study can be adapted to these new settings, but adjustments are needed to account for immune responses triggered by allogeneic products. The health education component of the KABP model would need to address the specific risks associated with allogeneic CAR-T therapy, such as GVHD and immune rejection. Additionally, personalized medication monitoring would need to be intensified to closely monitor immune-related reactions like cytokine release syndrome (CRS) and GVHD. This protocol could also be applied to solid tumors, where CAR-T therapy has shown limited efficacy, by focusing on tumor microenvironment-specific issues and improving adherence. Future research should explore this approach's broader applicability to different disease contexts.

This study has some limitations. The study was a retrospective study, and it was not possible to completely eliminate potential confounders and information bias, which may have limited the generalizability of the sample. However, we collected data from the two groups of patients as much as possible and showed that they were comparable. This study was a single-center design and was only conducted in our hospital, which may limit the generalizability of the results to other medical institutions with different backgrounds and nursing practices. Future studies can address these limitations by using more refined designs, conducting large-scale and multicenter studies.

Conclusion

This study provides preliminary support for the implementation of personalized and rational medication monitoring combined with KABP model health education for patients receiving CAR-T cell therapy. This simple and feasible clinical management measure is expected to be widely used in actual nursing practice to improve the overall treatment with KABP model health education for patients receiving CAR-T cell therapy can improve patients' prognosis to a certain extent. It is also beneficial for improving patients' compliance, self-care ability, quality of life, knowledge, attitudes, and behavior, and alleviating patient anxiety.

Data Sharing Statement

The raw data supporting the conclusions of this article will be made available by the corresponding author on request.

Ethics Statement

This study has obtained the approval of the Ethics Committee of Jiangxi Cancer Hospital (No.2021ky202), and all procedures are in accordance with the ethical standards of the 1964 Helsinki Declaration and its subsequent amendments. Informed consent was waived for this retrospective study due to the exclusive use of de-identified patient data, which posed no potential harm or impact on patient care.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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