

Original Article

Risk factor analysis and outcome evaluation of adverse reactions in patients with advanced non-small cell lung cancer treated with icotinib hydrochloride targeted therapy

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Abstract: Objective: To identify the risk factors of adverse reactions in patients with advanced non-small cell lung cancer (NSCLC) treated with icotinib hydrochloride targeted therapy, and to observe the effect of targeted nursing. Methods: In total, 170 patients with advanced NSCLC receiving targeted treatment with icotinib hydrochloride from February 2017 to May 2018 and were selected for a retrospective study. According to the occurrence of adverse reactions, they were divided into group A (with adverse reactions) and group B (without adverse reactions), respectively as the observation group and the control group. Self-designed questionnaires were applied to investigate the clinical data, psychological level, cognition level of patients on disease knowledge, treatment compliance and professional level of staff. The independent risk factors influencing the occurrence of adverse reactions of patients were analyzed with a multivariate regression model. Then, 200 patients of the same type of disease who were admitted from February 2018 to May 2019 were randomly divided into the study group (group C) and the conventional group (group D), with 100 patients in each group. In view of the risk factors in the retrospective study, targeted nursing measures were designed, and the research group implemented targeted nursing to observe the impact of targeted nursing on patients' quality of life, mental health level, professional level of responsible nurses, treatment compliance, incidence of complications and other indicators. Results: Psychological level, self-cognition of disease knowledge, age, nutritional status, smoking history, gender, treatment compliance and professional level of nursing staff were all influencing factors of adverse reactions. After targeted nursing in group C, patients' quality of life, SDS, SAS scores and treatment compliance improved significantly ($P < 0.05$). Group C presented markedly higher overall satisfaction of nursing service ($P < 0.05$), and the notably lower incidence of adverse reactions than that in group D ($P < 0.05$). The incidence of adverse reactions in group C was significantly lower than that in group D. Conclusion: Targeted nursing programs can improve the quality of life, reduce the incidence of adverse reactions and enhance the mental health of patients with NSCLC treated with icotinib hydrochloride.

Keywords: Icotinib hydrochloride targeted therapy, advanced non-small cell lung cancer, adverse reactions, BMI, quality of life score, nursing satisfaction

Introduction

Among the malignancies in China, non-small cell lung cancer (NSCLC) holds a major seat with high incidence and serious conditions, and is characterized by multiple episodes within a short time and rapid metastasis. The proportion of NSCLC patients in China keeps increasing year by year, and the situation is extremely grim. No effective treatment plan has been developed in clinical practice, and the effect of existing treatment methods still fails to reach

expectations [1]. Among the targeted therapeutic drugs, the small molecular drug icotinib hydrochloride enjoys significant advantages in the clinical treatment of patients with NSCLC, such as strong efficacy and high selectivity. The drug belongs to oral epidermal growth factor receptor tyrosine kinase inhibitor, and it has become a research hotspot in the clinic at present. However, certain literature has pointed out that some patients had adverse reactions such as nausea and vomiting during the treatment, but the incidence of these adverse reactions

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was less than 15% [2, 3], studies on the specific efficacy of this drug and its adverse reactions in NSCLC are relatively limited. Apart from that, litter research has been carried out on the influence of psychological level of patients and professional level of medical staff on adverse reactions during the treatment of icotinib hydrochloride. Therefore, in this study, icotinib hydrochloride was applied for targeted treatment of patients with NSCLC to analyze the occurrence of adverse reactions and related factors of patients after drug treatment, and to study the changes of various indicators of patients after giving targeted nursing programs based on the above conclusions.

Materials and methods

General information

Among patients with advanced NSCLC treated with icotinib hydrochloride targeted therapy in Cancer Hospital of China Medical University, Liaoning Cancer Hospital and Institute from February 2017 to May 2018, 120 cases without adverse reactions (group B) and 50 cases with adverse reactions (group A) after treatment were studied retrospectively. The nurses in charge of each group were investigating cases by groups.

In addition, another 200 patients with advanced NSCLC, all receiving icotinib hydrochloride for targeted therapy in our hospital from February 2018 to May 2019 were randomly grouped into the study group (group C) and the conventional group (group D), with 100 patients in each group. After referring to the clinical data in the retrospective study to obtain the risk factors affecting the treatment effect, specific nursing measures were formulated to give targeted nursing to patients in the study group.

Before the implementation of this study, it was reviewed and approved by the relevant authorities of the research hospital. All the enrolled patients understood the detailed research process and voluntarily signed a consent form to participate in the study in a conscious state.

The inclusion criteria of patients in the retrospective study were: Patients diagnosed with advanced NSCLC after clinical diagnosis, who received targeted treatment with icotinib hydrochloride (including those with adverse reactions), and those who volunteered to partici-

pate in the study and actively cooperated until the end of the study, with complete clinical data.

The inclusion criteria of the targeted nursing program were as follows: Patients diagnosed with advanced NSCLC after clinical examination, who did not receive icotinib hydrochloride targeted therapy or other drugs with the same efficacy before participating in the study, those with high compliance to treatment, and without anaphylaxis to icotinib hydrochloride, other critical acute diseases or history of mental illness. The exclusion criteria were as follows: Patients not diagnosed with advanced NSCLC after clinical examination; Patients who had received targeted therapy with icotinib hydrochloride or a drug with a similar effect within one month prior to participating in the study; Patients with anaphylaxis to icotinib hydrochloride; Patients with poor treatment compliance; Patients with other critical illnesses or with a family history of hereditary mental disorders.

Methods

Analysis of risk factors for adverse reactions in patients with advanced NSCLC treated with icotinib hydrochloride targeted therapy

When collecting patients' baseline data such as family relationship, age and previous medical history, the possible adverse reactions of all patients participating in the study were investigated and recorded. The questionnaire was jointly drawn up by hospital physicians and relevant personnel in this study, and the corresponding score scale was applied to evaluate the patients' disease cognition, mental health level, treatment compliance and the professional level of responsible nurses in each group. The independent influencing factors of adverse reactions in patients were analyzed by multivariate analysis. Total compliance rate = (full compliance + partial compliance)/total number of cases ×100%.

Analysis of the effect evaluation of targeted nursing for patients with advanced NSCLC treated with icotinib hydrochloride targeted therapy

According to the independent influencing factors that affect the incidence of adverse reactions of patients obtained in 1.2.1, targeted nursing was developed, and routine nursing

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measures were given to the conventional group, such as medication guidance and monitoring of heart rate changes. While the study group (group C) were treated with targeted nursing on its basis. (1) Health education and medication guidance. ① Rash: According to the patient's own understanding of the disease and nursing knowledge, appropriate guidance was given, and the patient was instructed to choose clothing made of soft fabrics to reduce the possibility of skin scratches. In addition, patients were advised to pay attention to the growth of nails and trim them in time when they grow too long. Meanwhile, the family members of the patients were instructed to actively assist the patients if they could not trim their nails by themselves to avoid scratching the skin and aggravating the infection. The importance of the above measures was explained and emphasized to increase the cognitive degree of disease knowledge for patients and their families. The changes of various clinical signs during the treatment and nursing of patients were closely monitored, and the patients' physical abnormalities were reported to the responsible doctors in a timely manner, and effective measures were taken for emergency treatment [4]. ② Diarrhea: The patient's family members were instructed to observe and record the patient's defecation characteristics and frequency, and report to the doctor or nursing staff in case of any abnormality, such as stool obstruction or thinness, and take the corresponding medicine according to the doctor's order. Nursing staff guided patients to take medicine in strict accordance with the doctor's advice, and explained relevant precautions for patients and their families, so as to improve the cooperation degree of patients in medication and treatment. Accordingly, the number of ward visits for patients with serious illness or fewer accompanying staff was increased, and the nursing measures related to accompanying family members were appropriately guided to prevent errors or safety accidents due to insufficient cognition [5]. Moreover, a strict nutrition program for food was carried out. The patient's family was instructed to supervise the patient's food intake according to the plan, forbid the patient to eat stimulating food, and instructed the family member to appropriately add food with high sodium and potassium content in the patient's diet [6]. (2) Psychological nursing. The intolerable pain caused by the patient's own disease and tedious

treatment process brings about psychological problems in patients to a certain extent, which are manifested in their pessimistic attitudes and poor enthusiasm for treatment. What's more, as a new type of drug, icotinib hydrochloride is relatively expensive because its application has not yet been popularized. To some extent, the huge medical expenses incurred by the use of this drug had caused serious psychological and economic burdens for patients, leading to a series of adverse emotions for patients [7]. As to the countermeasures, nursing staff increase communication and exchange with patients about daily life, regularly offer patients good clinical efficacy to share their experience, and set a good treatment example for patients, thus improving patients' cooperation with hospital treatment [8]. (3) In order to ensure the treatment effect and reduce the psychological and mental stimulation to patients, measures were taken to make sure that patients live in a relatively quiet treatment environment. At the same time, to prevent people from moving around and polluting the air in the ward, all corners of the ward were regularly disinfected and indoor ventilation was carried out. A healthy living plan was also developed for the patient in accordance with his/her own situation to prevent the formation of bad habits from affecting the treatment. In addition, supervision over the implementation of the patient was performed with the assistance of the patient's family to strictly control the nutritional intake of patients, reminded them to eat less greasy and stimulating food as much as possible, and to increase the intake of high fiber substances such as melons and fruits [9, 10]. (4) Improvement on nurse training and management system. Professional training and assessment activities were regularly organized to establish a strict medical resource allocation system, so as to improve the theoretical knowledge level and operation standardization of medical staff and reduce the possibility of aggravation of patients due to medical staff's operational errors [11, 12].

Outcome measures

Analysis and outcome measures of influencing factors

The age, gender and other clinical data of patients in each group were collected. Self-de-

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Table 1. The general data of patients in groups A and B were compared (n (%), $\bar{x} \pm sd$)

Indexes	Group A (n = 50)	Group A (n = 120)	P
Ages (years)	37.2±10.2	31.5±10.2	0.023
Male	30 (60.0)	45 (37.5)	0.018
Hypertension	30 (60.0)	70 (58.3)	0.065
Smoking	35 (70.0)	35 (29.2)	0.027
BMI	19.33±1.43	17.33±1.03	0.076
Nutriture			0.012
Good	5 (10.0)	80 (66.7)	
General	11 (22.0)	19 (15.8)	
Poor	34 (68.0)	21 (17.5)	

Note: BMI: body mass index.

signed questionnaires were adopted to investigate the disease cognition degree, treatment compliance and professional level of nurses in each group. Patient's mental health level, including psychological stress and psychological depression, were evaluated by self-designed psychological assessment questionnaires. The lower the score, the higher the mental health level of the patient. The cognition of patients and their families was assessed by questionnaires.

Outcome measures of targeted nursing effect evaluation

Main outcome measures: According to the quality of life rating scale (Short form 36 questionnaire, SF-36), the quality of life of the two groups of patients before and after treatment was evaluated. The higher the score, the better the recovery. Self-rating depression scale (SDS) and self-rating Anxiety scale (SAS) were employed to assess the psychological emotions of patients. The lower the score, the better the psychological emotions of patients. The changes of professional level of responsibility for nurses in each group were recorded and compared. The cases of adverse reactions in the two groups were recorded, calculated and compared. Treatment compliance was recorded and compared between the two groups.

Secondary outcome measures: Questionnaires were distributed to patients to evaluate their nursing service satisfaction. Satisfaction rate = (satisfaction + general)/total cases × 100%.

Statistical analysis

After integrating all the data obtained from the study, they were sequentially entered into SPSS 20.0 statistical software for unified calculation and analysis. The measurement data were expressed in the form of mean ± standard deviation ($\bar{x} \pm SD$), and the research data between groups was assessed by t test of independent samples. The counting data were expressed as percentage (%), and the Chi-square test was employed to test the data difference between groups. The statistically significant data with $P < 0.05$ in the univariate analysis in the study was substituted into the multivariate Logistic regression model for detailed analysis and the detailed variable assignments can be found in 2.6. Independent risk factors in the process of adverse reactions were screened. $P < 0.05$ indicated that the difference was statistically significant.

Results

Comparison of baseline data of patients between groups A and B

Compared with the control group, the patients in the observation group were older, the proportion of male patients and those with a history of smoking were significantly higher, and the overall nutritional status was lower ($P < 0.05$, **Table 1**).

Comparison of mental health levels of patients in groups A and B before treatment

Before treatment, the self-designed mental health questionnaire was adopted to evaluate the degree of psychological stress and mood depression of the patients in the two groups. It turned out that the scores in both groups were relatively high, while the scores of the patients in group A were significantly higher than those in group B, and the overall assessment of mental health of the patients in group B was markedly better than that in group A (both $P < 0.001$, **Figure 1**).

Comparison of disease cognition of patients in groups A and B

The results showed that the overall cognition level of group A and group B was poor, but comparatively, the cognition level of patients or

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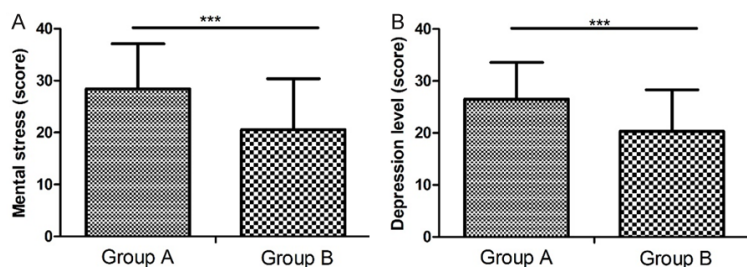


Figure 1. Comparison of mental health levels of patients in groups A and B before treatment. A. Comparison of psychological stress levels between group A and group B; B. The depression level of group A and group B was compared. Both *** $P < 0.001$.

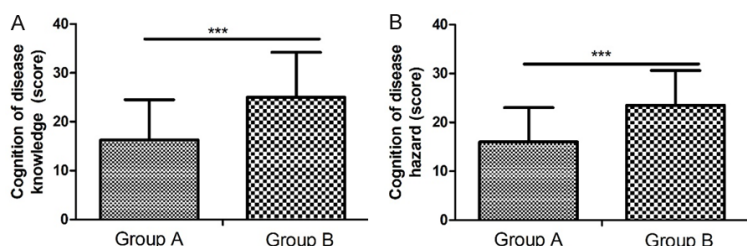


Figure 2. Comparison of disease cognition of disease in groups A and B. A. The cognition level of the two groups' disease knowledge; B. The cognitive level of two groups of diseases at the knowledge level of harm. Both *** $P < 0.001$.

Table 2. Comparison of treatment compliance between groups A and B (n (%))

Groups	Group A (n = 50)	Group A (n = 120)	χ^2	P
Treatment compliance				
Very compliance	7 (14.0)	58 (48.3)		
Part of compliance	14 (28.0)	36 (30.0)		
Nonadherence	29 (58.0)	26 (21.7)		
Total compliance rate	42.0	78.3	9.943	0.015

their families in group B was significantly better than that in group A (both $P < 0.001$, **Figure 2**).

Comparison of treatment compliance between groups A and B

The overall treatment compliance of patients in group B were relatively higher than group A ($P < 0.05$, **Table 2**).

Comparison of the professional level of responsible nurses in groups A and B

According to the investigation, the professional scores of the two groups of responsible nurses in both treatment and nursing were relatively low. Inter-group comparison between groups A

and B revealed that the overall professional level of responsible nurses in group B was remarkably higher than that in group A in terms of treatment operation and treatment theory, and the overall professional level of patients and relatives in group B was relatively higher concerning nursing operation and theory (all $P < 0.001$, **Figure 3**).

Multivariate analysis of adverse reactions in patients

The corresponding clinical manifestations of the patients were comprehensively analyzed, and the independent risk factors for adverse reactions of the patients were screened. Variables with statistically significant difference ($P < 0.05$) in the single factor were then substituted into the multivariate Logistic regression model for analysis, and the specific values were: Treatment compliance (1 = high, 2 = low), professional level of responsible nurses (1 = >15 points, 2 = ≤ 15 points), disease cognition degree (1 = >25 points, 2 = ≤ 25 points), mental health (1 = >15 points, 2 = ≤ 15 points), age (1 = >35 years old, 2 = ≤ 35 years old), gender (1 = male, 2 = female), smoking history (1 = yes, 2 = no), nutritional

status (1 = good, 2 = average or poor). The obtained data exhibited that the professional skills of the responsible nurses of less than 15 points, low treatment compliance, the disease cognition of less than 25 points, the mental health level of less than 15 points, the age of being older than 35 years, male, smoking history and poor nutrition status were all independent risk factors for adverse reactions (**Table 3**).

Comparison of baseline data of patients between groups C and D

There was no significant difference in the number of hypertension cases, average age range

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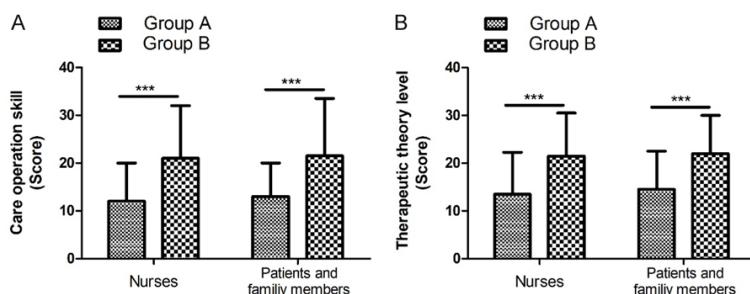


Figure 3. The professional level of the responsible nurses and patients and their family members in groups A and B were compared. A. The two groups of nurses and patients and family members of the care operation skill level of treatment professional comparison; B. The treatment of two groups of nurses and patients and their family members' therapeutic theory skill level. All *** $P < 0.001$.

Table 3. Multivariate Logistic regression analysis of adverse reactions in patients

Factors	OR	Multivariate analysis (95%, CI)	P
Treatment compliance	0.472	1.942-9.581	0.011
Professional level of responsible nurses	0.456	1.891-9.557	0.010
Disease cognition degree	0.434	1.887-9.483	0.012
Mental health level	0.564	1.867-9.485	0.021
Age	0.454	1.892-9.468	0.013
Gender	0.625	1.885-9.512	0.014
Smoking history	0.416	1.871-9.443	0.020
Nutritional status	0.370	1.881-9.474	0.018

Note: OR: odd ratio.

Table 4. The general data of patients in groups C and D were compared (n (%), $\bar{x} \pm sd$)

Indexes	Group A (n = 100)	Group A (n = 100)	P
Ages (years)	31.2±10.2	31.3±10.2	0.153
Female	55 (55.0)	54 (54.0)	0.160
Hypertension	62 (62.0)	63 (63.0)	0.105
Smoking	70 (70.0)	71 (71.0)	0.144
BMI	19.33±3.43	17.33±3.03	0.152

Note: BMI: body mass index.

and mean body mass index (BMI) between group C and group D ($P > 0.05$, **Table 4**).

Comparison of the quality of life and treatment compliance between groups C and D at each time point

After continuous nursing for a certain period, the quality of life level and treatment compli-

ance of patients in group C and D were significantly improved. The overall level of treatment compliance and treatment quality of life in group C was higher than that in group D, with significant differences ($P < 0.05$, **Tables 5, 6**).

Comparison of the psychological states of groups C and D after nursing

After continuous nursing for a certain period, the scores of anxiety and depression in groups C and D decreased significantly. The data showed that the psychological states of both groups were relatively good, and the mental health level of group C was markedly better than that of group D (both $P < 0.001$, **Figure 4**).

Comparison of the improvement of professional level scores of responsible nurses between the two groups

After a period of training, the professional level of responsible nurses in the two groups improved significantly compared with the initial survey, among which group C enjoyed a higher overall level ($P < 0.05$), and the difference was statistically significant.

Comparison of adverse reactions between groups A and B

The proportion of adverse reactions in each group was calculated in detail, and the incidence of adverse reactions in group C and group D was 2.0% and 10.0%, respectively. By comparison, group C had a more significant advantage over group D in controlling adverse reactions, with statistically significant difference ($P < 0.05$, **Table 7**).

Comparison of nursing satisfaction between the two groups

After investigating the nursing satisfaction of each group, it was found that the proportion of patients' satisfaction in group C and D was relatively higher, which were more than 80% in

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Table 5. Comparison of treatment compliance between groups C and D (n (%))

Groups	Group C (n = 100)	Group D (n = 100)	χ^2	P
Treatment compliance				
Very compliance	56 (56.0)	27 (27.0)	5.173	0.032
Part of compliance	36 (36.0)	38 (38.0)	6.179	0.027
Nonadherence	8 (8.0)	35 (35.0)	7.321	0.023
Total compliance rate	92 (92.0)	65 (65.0)	7.767	0.031

group C and less than 80% in group D. The data showed that the group with slightly higher satisfaction was group C, with $P < 0.05$, indicating a statistically significant data difference. See **Table 8** for detailed data.

Discussion

In this study, patients were all given the same icotinib hydrochloride targeted therapy and grouped according to whether they had adverse reactions or not. The overall mental health level of patients in group B was significantly better than that in group A regarding disease cognition, treatment compliance and professional level of nurses. After the statistical test of the data in this study, there is a significant statistical significance between the two groups. The independent risk factors were screened and analyzed by multivariate regression model. The data demonstrated that there was more than one independent risk factor affecting the incidence of adverse reactions, which were patients' own disease cognition, treatment compliance and mental health level, as well as the professional level of responsible nurses. The above results confirm that the lack of understanding of their own diseases, and the failure to face the disease with a positive attitude when the disease breaks out, are susceptible to induce a series of psychological problems in patients, resulting in doubts and contradictions about their own lives, which in turn results in self-negation and self-contradiction, reducing the enthusiasm of treatment and affecting the clinical efficacy. Long-term lack of improvement will have serious adverse effects on the treatment process, significantly prolonging the treatment process of patients and increasing the incidence of adverse reactions in patients [13-15]. While the low professional level of the responsible nurse appears to add insult to injury, elevating the possibility of operational errors

in the course of treatment, which in turn increases the risk of adverse reactions of patients [16, 17].

Based on preceding literature, it was found that the patients can have severe cognitive deficiency, heavy psychological burden, and poor treatment compliance caused by poor diet and exercise. While on the other side, the imperfect training and management system of hospital medical staff affected the working

enthusiasm of medical staff to a certain extent, which led to the problem that their overall professional level was lower than the normal range. The above problems result in poor nursing quality and affect the evaluation results of patients on nursing services [18]. After individualized nursing for the above problems, the quality of life score, mental health level, treatment compliance and professional level of responsible nurses in groups C and D improved dramatically. Compared with group D, the improvement of the above indicators in group C was higher after nursing, and the proportion of adverse reactions in group C was lower. After the professional statistical test, there were significant data differences between the two groups of patients in this study, and the differences were in line with the statistical standards. At the same time, it is also proved that in the process of implementing personalized nursing programs for patients, giving patients a certain degree of health education and psychological counseling, while improving hospital medical training and management system can significantly improve patients' psychological and physiological problems. On this basis, targeted nursing measures for patients can effectively avoid adverse reactions and play an important role in ensuring the safety of patients [19]. Under the premise that patients were treated with the same targeted measures, patients in group C had significantly higher disease cognition and treatment compliance, as well as superior basic standard of mental health level and professional level of responsible nurses than group D, so the overall improvement degree of all indicators in group D was notably lower than that in group C when targeted nursing was implemented at the same time [20, 21]. Although the difference in overall nursing satisfaction between groups C and D was statistically significant, the level of group C

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Table 6. The quality of life of group C and D patients was compared ($\bar{x} \pm sd$, points)

Groups	Emotional function	Physiological functions	Body pain	Role physical	Social function	General health	Dynamic	Mental health
Before the nursing								
Group D	10.89±1.47	9.27±1.75	10.78±1.18	11.85±1.54	47.38±5.74	45.94±5.43	9.28±1.47	13.82±1.84
Group C	10.79±1.52	9.36±1.83	10.67±1.25	11.42±1.64	47.65±5.48	45.77±5.53	9.22±1.53	13.68±1.77
t	0.401	0.301	0.531	1.601	0.291	0.181	0.241	0.461
P	0.801	0.772	0.602	0.113	0.782	0.862	0.813	0.651
After the nursing								
Group D	15.75±2.33	14.52±2.28	16.57±2.48	17.67±2.40	54.36±6.54	51.88±6.58	15.23±2.58	16.57±2.38
Group C	20.29±3.48	19.28±3.57	21.48±3.92	23.85±3.53	61.33±7.29	57.12±6.46	21.88±3.53	20.56±2.95
t	9.011	9.402	8.861	12.112	5.951	4.752	10.811	8.802
P	0.004	0.003	0.005	0.001	0.019	0.020	0.002	0.006

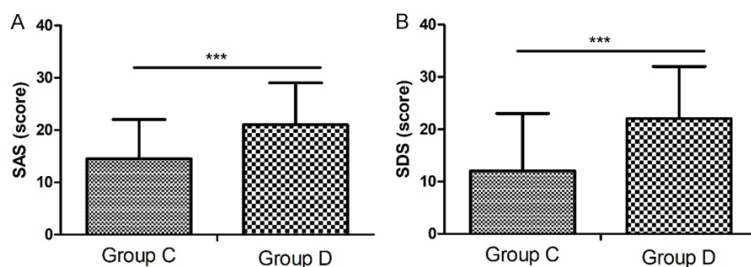


Figure 4. Comparison of the psychological states of groups C and D after nursing. A. SAS scores were compared between the two groups; B. SDS scores were compared between the two groups. Both *** $P < 0.001$. SAS: self-rating anxiety scale; SDS: self-rating depression scale.

Table 7. The proportion of adverse reactions in each group was compared (n (%))

Groups	Nausea and vomiting	Diarrhea	Erythra	Total incidence rate
Group C	1	0	1	2 (2.0)
Group D	3	3	4	10 (10.0)
χ^2	5.342	5.513	6.013	6.198
P	0.046	0.043	0.039	0.013

Note: $P < 0.05$, there were statistically significant differences between the groups.

Table 8. The nursing satisfaction of the two groups was compared (n (%))

Groups	n	Satisfaction	General	Dissatisfaction	Total incidence rate
Group C	100	47 (47.0)	35 (35.0)	18 (18.0)	82 (82.0)
Group D	100	39 (39.0)	36 (36.0)	25 (25.0)	75 (75.0)
χ^2		5.254	5.249	5.253	5.251
P		0.047	0.049	0.046	0.048

Note: $P < 0.05$, the difference was statistically significant.

was only slightly higher than that of group D, and the difference between groups was not significant. The reason behind the above results

may be that although the nursing basis of group D is lower than that of group C, the overall nursing effect is good, so the nursing evaluation of patients and their families is higher [22].

There are some deficiencies in this study. All the evaluation results during the survey were filled in by the patients themselves, so the accuracy of the study data was relatively low, but it had no significant impact on the overall conclusions of the study.

Taken together, improving the training system and management system of hospital nursing staff, strengthening the nursing intensity at the psychological level of patients, as well as preventive nursing and daily nursing for patients with complications will help to enhance patients' own awareness of the disease, thereby reducing the possibility of misunderstanding of hospital treatment, and fundamentally improve the treatment compliance of patients on the one hand. On the other hand, it can indirectly solve the patients' psychological problems

and eliminate negative emotions to a great deal, markedly enhance their living standards, and obtain higher nursing evaluation, which

plays an important part in facilitating the treatment and follow-up nursing of clinical diseases.

Disclosure of conflict of interest

None.

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