

Original Article

Application value of whole-course health management for patients with nonvalvular atrial fibrillation with oral warfarin treatment

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Abstract: Objective: To explore the effect of the whole-process health management model on the compliance of oral warfarin treatment in patients with non-valvular atrial fibrillation in primary hospitals. Methods: We retrospectively analyzed the clinical data of 130 patients with non-valvular atrial fibrillation treated in the Department of Cardiovascular Medicine, Hai'an People's Hospital from January 2019 to December 2019. Among them, 63 patients who received routine continuing care were included in the control group, and 67 patients treated with whole-course health management model of primary hospitals were included in the observation group. The two groups were compared in terms of the following parameters: Warfarin anticoagulation knowledge, medication compliance, compliance rate (international normalized ratio, INR) monitoring, bleeding events (gingival bleeding, subcutaneous bleeding, gastrointestinal bleeding, etc.), embolic events (vascular thrombosis), negative emotions before and after management, and patient satisfaction. Logistic analysis was used to analyze independent risk factors affecting the effect of warfarin anticoagulation in patients with non-valvular atrial fibrillation. Results: Compared with the control group, the warfarin anticoagulation knowledge, medication compliance, and INR compliance rate of the observation group were significantly higher, and the incidence of adverse events was significantly lower. Self-rating Anxiety Scale (SAS) and Self-rating Depression Scale (SDS) scores were not significantly different between the two groups before management. After management, SAS and SDS scores decreased significantly in both groups, and were lower in the observation group compared with the control group. The management satisfaction was also significantly higher in the observation group. Conclusion: Compared with the conventional continuation care model, the whole-process management in primary hospitals can improve patients' compliance with medical advice and treatment efficacy, with lower risk of bleeding and higher patient satisfaction, providing a better option for the out-of-hospital management of anticoagulation for non-valvular atrial fibrillation patients. Age, hypertension, diabetes, knowledge of warfarin anticoagulation and medication compliance were independent risk factors for the effect of warfarin anticoagulation in patients with non-valvular atrial fibrillation.

Keywords: Primary hospital whole-course health management model, non-valvular atrial fibrillation, warfarin, compliance

Introduction

Atrial fibrillation is a supraventricular tachyarrhythmia characterized by rapid and disordered atrial electrical activity, which is a common arrhythmia in clinical practice [1]. With the aging of the global population, the incidence of atrial fibrillation is increasing year by year, which has become a serious public health problem [2]. It can be divided into valvular and non-valvular atrial fibrillation, depending on the underlying condition of patients. Of them, non-

valvular atrial fibrillation refers to atrial fibrillation occurring in patients with mitral stenosis, bioprosthesis, mechanical valve replacement, or valve repair other than rheumatic heart disease. These patients do not suffer from valvular disease, and the occurrence of atrial fibrillation may be related to other organic diseases [3]. Studies [4, 5] have pointed out that anticoagulation therapy is an important means to improve the prognosis of patients with atrial fibrillation, which can reduce the risk of ischemic cerebrovascularization by 60% and mortality by 30%.

Some scholars [6] suggest that all patients with atrial fibrillation should receive anticoagulation therapy.

Warfarin is a coumarin anticoagulant that plays anticoagulant role by reducing the synthesis of coagulation factors II, VII, IX and X [7]. Studies have shown that warfarin anticoagulation can significantly reduce the risk of stroke and death in patients with non-valvular atrial fibrillation [8]. Patients with non-valvular atrial fibrillation generally require life-long anticoagulation therapy; so, improving patients' compliance with oral warfarin is critical. However, due to various factors such as the patient's age, education level, and disease awareness, the compliance of patients with warfarin treatment is still not high, clinically [9, 10]. In terms of the current medical model in China, the lack of professional anticoagulation management institutions, professional management personnel, and comprehensive and systematic management models result in a great challenge to provide effective health management services for patients, thus significantly affecting the clinical application of warfarin [11]. As to the current management of oral warfarin application in patients with non-valvular atrial fibrillation, the domestic studies are limited to anticoagulation clinics, anti-thrombotic groups, group management, etc., and there is no research on the application of the whole-process health management model in primary hospitals.

Therefore, this study applied continuous, comprehensive and seamless management for non-valvular atrial fibrillation patients with oral warfarin through the whole-process health management model (primary hospitals) to improve their compliance, reduce complications (e.g. cerebral embolism and stroke), and lower the mortality and disability rate, which we believe, can ultimately enhance patients' life quality, reduce related socio-economic and family burdens, and provide new references for the prevention and management of chronic diseases in the elderly.

Materials and methods

Clinical information

We retrospectively analyzed the clinical data of 130 patients (male to female ratio: 75:55) with

non-valvular atrial fibrillation treated in the Department of Cardiovascular Medicine, Hai'an People's Hospital from January 2019 to December 2019. Among them, 63 patients who received routine continuous care were included in the control group, and 67 patients treated with whole-course health management model of primary hospitals were included in the observation group. Inclusion criteria: patients who were first diagnosed with non-valvular atrial fibrillation by ECG, Holter, and cardiac ultrasonography; patients who met the indications for warfarin anticoagulation therapy according to the "Guidelines for the Management of Patients with Atrial Fibrillation in 2014" [12]; patients who took warfarin for the first time; patients with normal consciousness and communication ability, without cognitive impairment, language impairment or mental illness. Exclusion criteria: patients with hyperthyroidism or other serious complications; patients with severe coagulopathy; patients with severe organ dysfunction; patients with infectious diseases; and patients with poor compliance. All patients agreed to participate in the study with a written informed consent. This study had been approved by the hospital Ethics Committee and was conducted in strict accordance with the Declaration of Helsinki.

Management plan

Patients in the control group were given routine continuous care, including health education, informing patients to monitor the international normalized ratio (INR) after discharge from the hospital, regular follow-up visits, telephone return visits 1 week after discharge, and home visits within 1 month.

Patients in the observation group were treated with the whole-process health management (primary hospitals), specifically as follows: (1) A hospital-community-family whole-process health management team was established, including medical staff from our hospital and community cooperative units, and the main caregivers of patients after discharge. Specifically, 1 associate chief physician of cardiovascular specialty, 1 resident physician, 1 health manager, 2 nurses in charge with rich experience in cardiology, 4 health managers from community cooperative units, and 1 main caregiver of patients after discharge comprised of

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the team. (2) The specific responsibilities of the team members were clarified. The chief nurses and health managers of the Department of Cardiovascular Medicine in our hospital trained the community health service personnel, including professional knowledge of atrial fibrillation and precautions for warfarin use; intervention measures; and the filling of survey scales, with the aim of establishing a communication network. (3) An electronic patient file was established, and the purpose, methods and principles of this study were explained to the patients. In addition, a doctor-patient communication WeChat group was established, and patients' detailed personal files including demographic data, health behavior data and clinical data were obtained upon their consent. (4) Nursing implementation: Hospital support: Patients had been given health guidance, medication guidance, diet guidance, as well as prevention and observation of common complications since the implementation of oral warfarin anticoagulation treatment, and health education prescriptions were issued by nurses in charge. In addition, the warfarin oral administration manual was distributed to patients with atrial fibrillation when discharged from the hospital. Furthermore, family follow-up was carried out once a month to help those patients who did not meet the standard to analyze the reasons, and to jointly adjust and improve the nursing plan by focusing the shortcomings, so as to better carry out the next cycle of intervention. Community support: After the patient was discharged from the hospital, the health management manual was handed over to the community nursing staff for unified management. Community nurses were responsible to follow up patients at home according to the requirements of the manual and improve its content. In addition, non-valvular atrial fibrillation patients and their families were organized monthly to attend health knowledge lectures, mainly including the main hazards and complications of atrial fibrillation, precautions for oral warfarin, INR monitoring time, and dietary precautions. Family support: Family members were given systematic health education to encourage and supervise patients to adhere to oral warfarin anticoagulant therapy, including time, dosage and frequency. At the same time, they accompanied patients to review INR regularly and helped patients develop good living habits.

The implementation cycle of both management models was 12 months.

Outcome measures

(1) A questionnaire survey was conducted on the knowledge of warfarin anticoagulation in both groups with the "Warfarin Anticoagulation Knowledge Questionnaire for Patients with Atrial Fibrillation" made by our hospital. The questionnaire had a total of 11 questions, with 1 point for each correct answer and a full score of 11 points. The patient's mastery of knowledge is divided into 3 levels, with a score of <7, 7-8, and ≥ 9 indicating poor, medium and good mastery, respectively. The questionnaire was self-made by our hospital according to relevant references [13].

(2) The compliance rate (INR) of the two groups of patients was evaluated and compared before and after intervention. A INR value between 2-3 was considered as reaching the standard, while <2 or >3 was considered as not reaching the standard; the compliance rate = (the number of times within the target range/the total number of monitoring times) * 100%. The compliance rate reflects the patient's ability of properly using warfarin, and higher compliance rates indicate better control of warfarin by patients.

(3) The bleeding events (gingival bleeding, subcutaneous bleeding, gastrointestinal bleeding, etc.) and embolic events (vascular thrombosis) during the management were recorded and compared. All patients were treated with symptomatic hemostasis and thrombolysis after the occurrence of bleeding events and embolism events, and their conditions were improved significantly after management.

(4) Before and after management, the negative emotions of patients in the two groups were using the Self-rating Depression Scale (SDS) and Self-rating Anxiety Scale (SAS) [14].

(5) Management satisfaction, which was divided into satisfaction, basic satisfaction and dissatisfaction, was evaluated and compared between the two groups. Management satisfaction = number of cases with (satisfied + basically satisfied)/total number of cases * 100%.

(6) Independent risk factors affecting the therapeutic effect of warfarin anticoagulation in

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Table 1. General information [n (%)]

Factors	Observation Group n=67	Control Group n=63	t/ χ^2	P
Gender			0.229	0.623
Male	40 (59.70)	35 (55.56)		
Female	27 (40.30)	28 (44.44)		
Age (years)			0.024	0.878
≥ 63	31 (46.27)	30 (47.62)		
< 63	36 (53.73)	33 (52.38)		
BMI (kg/m ²)			0.021	0.886
≥ 23	30 (44.78)	29 (46.03)		
< 23	37 (55.22)	34 (53.97)		
Smoking history			0.018	0.894
YES	38 (56.72)	35 (55.56)		
NO	29 (43.28)	28 (44.44)		
Drinking history			0.001	0.996
YES	34 (50.75)	32 (50.79)		
NO	33 (49.25)	31 (49.21)		
Education level			0.073	0.787
Elementary school and below	41 (61.19)	40 (63.49)		
Above elementary school	26 (38.81)	23 (36.51)		
Complicated by Hypertension			0.024	0.878
YES	36 (53.73)	33 (52.38)		
NO	31 (46.27)	30 (47.62)		
Complicated by diabetes			0.120	0.730
YES	35 (52.24)	31 (49.21)		
NO	32 (47.76)	32 (50.79)		

Table 2. Comparison of warfarin anticoagulation knowledge rating levels between two groups

Knowledge rating	Observation Group n=67	Control Group n=63	χ^2	P
Good	42 (62.69)	22 (34.92)	10.02	0.002
Medium	21 (31.34)	19 (30.16)	0.069	0.793
Poor	4 (5.97)	22 (34.92)	4.124	< 0.001

patients with non-valvular atrial fibrillation were analyzed.

Statistical methods

The statistical analysis and image rendering of the collected data were performed by SPSS 19.0 statistical software and prism 8, respectively. Count data were expressed as number of cases/percentage [n (%)]. Chi-square test was applied when theoretical frequency was greater than 5, and Fisher exact probability method was used when it was less than 5. Measurement data were expressed as mean \pm SD; Student's

t-test was used for comparison between groups, paired t-test was for comparison before and after intervention within the group, and Logistic analysis was for multivariate analysis. $P < 0.05$ indicated that the difference was statistically significant.

Results

Clinical information

There were no significant differences in general data such as gender, age, and smoking history between the two groups ($P > 0.05$), indicating the two groups were comparable (**Table 1**).

Comparison of warfarin anticoagulation knowledge rating levels between two groups of patients

The number of patients who had good, medium and poor mastery of warfarin knowledge in the observation group was 42, 21, and 4, respectively. Those in the control group was 22, 19 and 22 respectively. The data revealed more cases with good mastery of warfarin knowledge and fewer cases with poor mastery of warfarin knowledge in the observation group compared with the

control group ($P < 0.05$). However, no significant difference was observed in the number of cases with medium mastery of warfarin knowledge between the two groups ($P > 0.05$). More details can be found in **Table 2**.

Comparison of medication compliance between the two groups after management

In observation group, the number of patients who took warfarin and insisted on long-term medication, regular anticoagulation, and reached the standard of anticoagulation was 53, 55 and 57 respectively, with an average compli-

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Table 3. Comparison of medication compliance between the two groups after management

Contents	Observation Group n=67	Control Group n=63	χ^2	P
Adherence to medication	53 (79.10)	40 (63.49)	-	-
Regular anticoagulation	55 (82.09)	39 (61.90)	-	-
Anticoagulation standard	57 (85.07)	41 (65.08)	-	-
Average compliance rate	55 (82.09)	40 (63.49)	5.708	0.017

Table 4. Comparison of the compliance rate of INR between the two groups before and after management

Period	Observation Group n=67	Control Group n=63	χ^2	P
Before Management	34 (50.75)	31 (49.21)	0.031	0.860
After Management	55 (82.09)	42 (66.67)	4.078	0.044

Table 5. Comparison of the incidence of adverse events between the two groups [n, (%)]

Adverse events	Observation Group n=67	Control Group n=63	χ^2	P
Gingival bleeding	2 (2.99)	1 (1.59)	-	-
Subcutaneous bleeding	1 (1.49)	1 (1.59)	-	-
Gastrointestinal bleeding	1 (1.49)	1 (1.59)	-	-
Incidence of bleeding events	4 (5.97)	3 (4.76)		
Incidence of embolism	1 (1.49)	10 (15.87)	8.144	0.004

ance rate of 82.09% (55 cases); while those in control group was 40, 39 and 41, respectively, with an average compliance rate of 63.49% (40 cases). This showed that the warfarin medication compliance of the observation group was significantly higher than that of the control group ($P<0.05$) **Table 3**.

Comparison of INR compliance rate between the two groups before and after management

Through comparison, it was found that before management, there was no significant difference in INR compliance rate between the two groups ($P>0.05$). After management, the INR compliance rate of the observation group was significantly higher than that of the control group ($P<0.05$) **Table 4**.

Comparison of bleeding events and embolic events between the two groups during management

In the observation group, the number of patients who had gingival bleeding, subcutane-

ous bleeding, gastrointestinal bleeding, and vascular thrombosis during management were 2, 1, 1 and 1 respectively, with an incidence of bleeding events of 5.97% and embolism events of 1.49%. Those in the control group were 1, 1, 1, and 10, respectively, with an incidence of bleeding events of 4.76% and embolic events of 15.87%. The results showed no significant difference in the incidence of bleeding events between two groups ($P>0.05$), and a significantly lower incidence of embolic events in the observation group compared with the control group ($P<0.05$), as shown in **Table 5**.

Comparison of negative emotions between the two groups before and after management

There were no significant differences in SAS and SDS scores between the two groups before management ($P>0.05$). After management, SAS and SDS

scores decreased significantly in both groups, and were lower in the observation group compared with the control group ($P<0.05$) **Figure 1**.

Comparison of management satisfaction between the two groups

The number of patients in the observation group who were satisfied, basically satisfied, and dissatisfied with the management were 45, 20, and 2, respectively, with a satisfaction rate of 97.01%. Those in the control group were 29, 18, and 16 respectively, with a satisfaction rate of 74.60%. The management satisfaction of the observation group was significantly higher than that of the other group ($P<0.05$) **Table 6**.

Univariate analysis of therapeutic effect of warfarin anticoagulation on patients with non-valvular atrial fibrillation

Among the 130 patients with non-valvular atrial fibrillation treated with warfarin anticoagulation, 97 patients achieved INR value, while 33

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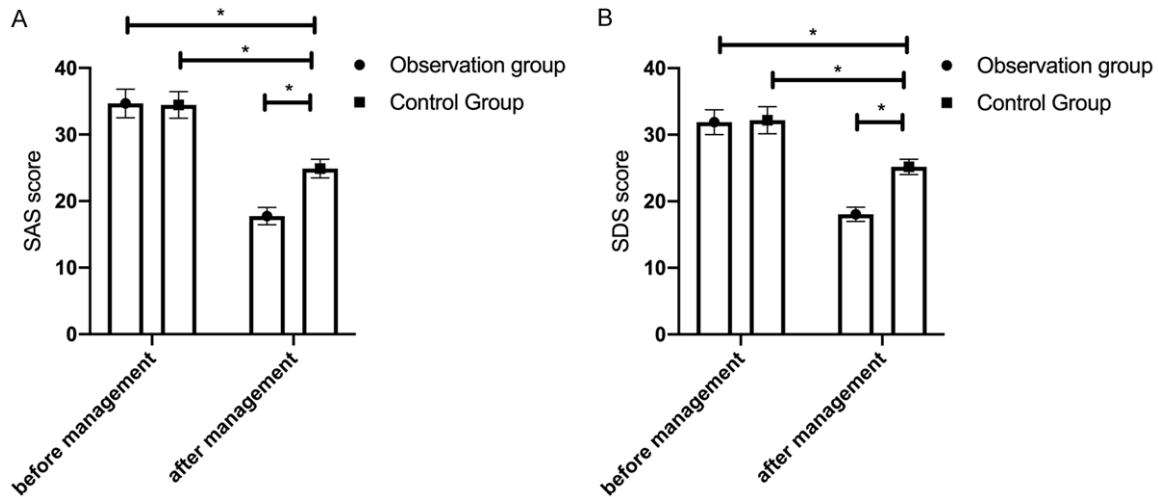


Figure 1. Comparison of the negative emotions between the two groups before and after management; A: Comparison of SAS scores between the two groups before and after management; B: Comparison of SDS scores between the two groups before and after management. * indicates $P < 0.05$.

Table 6. Comparison of management satisfaction between the two groups

Items	Observation Group n=67	Control Group n=63	χ^2	P
Satisfied	45 (67.16)	29 (46.03)	-	-
Basically satisfied	20 (29.85)	18 (28.57)	-	-
Dissatisfied	2 (2.99)	16 (25.40)	-	-
Management satisfaction	65 (97.01)	47 (74.60)	13.67	<0.001

patients failed to, with the total compliance rate of INR value of 74.62%. There was no marked difference in term of gender data between two groups ($P > 0.05$). Statistically significant differences existed between two groups in terms of hypertension, diabetes, knowledge of warfarin anticoagulation, medication compliance, age factors ($P < 0.05$) **Table 7**.

Logistic regression analysis of therapeutic effect of warfarin anticoagulation on patients with non-valvular atrial fibrillation

Logistic regression analysis showed that age, hypertension, diabetes, knowledge of warfarin anticoagulation and medication compliance were all independent risk factors affecting the effect of warfarin anticoagulation on patients with non-valvular atrial fibrillation ($P < 0.05$). Details are shown in **Table 8**.

Discussion

Systemic thromboembolism is one of the most serious complications of atrial fibrillation, and

stroke is the most serious clinical hazard. Previous studies have shown that the risk of stroke in patients with non-valvular atrial fibrillation is 5-6 times that of patients without atrial fibrillation, and 1 in every 6 patients with non-valvular atrial fibrillation suffers a stroke [15].

China is gradually becoming an aging society, and the increasing elderly population has caused the rise of incidence of senile non-valvular atrial fibrillation. Therefore, prevention and treatment of non-valvular atrial fibrillation, especially in elderly patients, has become a hot spot for clinicians.

Warfarin, which can effectively reduce the risk of thromboembolism in patients with atrial fibrillation, has been used as an anticoagulant for half a century. Anticoagulation treatment of warfarin is considered to be effective, safe, and economical, and plays an essential role in the prevention and treatment of thromboembolism [16]. However, due to its slow efficacy, metabolic receptors, nutrition and high risks such as narrow window during treatment, it is often necessary to frequently test and measure to adjust the dosage of the drug, which will reduce the compliance of many patients with oral warfarin and affect the anticoagulant effect of the drug [17]. At present, due to the uneven distribution of medical resources and the busy clinical working situation in China, the current non-valvular atrial fibrillation anticoagulation man-

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Table 7. Univariate analysis of therapeutic effect of warfarin therapy in patients with non-valvular atrial fibrillation

Possible Influencing Factors	Category	Accredited Group n=97	Non-accredited Group n=33	χ^2	P
Gender	Male	55 (56.70)	20 (60.61)	0.154	0.695
Age	≥ 63	31 (31.96)	30 (90.91)	33.85	<0.001
Hypertension	Yes	40 (41.24)	29 (87.88)	21.59	<0.001
Diabetes	Yes	40 (41.24)	26 (78.79)	13.89	<0.001
Warfarin Anticoagulation Knowledge Level	Good	56 (57.73)	8 (24.24)	11.05	<0.001
Medication compliance	Achieved	80 (82.47)	15 (45.45)	17.15	<0.001

Table 8. Logistic regression analysis of therapeutic effect of warfarin anticoagulation in patients with non-valvular atrial fibrillation

Influencing factors	β	SE	Wald χ^2	P	OR	95% CI
Age	0.547	0.192	8.004	0.001	5.372	1.978-5.964
Hypertension	0.221	0.115	3.601	0.005	4.211	1.172-5.038
Diabetes	0.359	0.133	7.132	0.001	2.043	1.981-5.722
Warfarin Anticoagulation Knowledge Level	0.469	0.275	2.874	0.010	3.077	1.043-3.415
Medication compliance	0.421	0.183	4.921	0.005	3.932	2.011-4.146

agement model is not yet mature and is still in the exploratory stage. Therefore, the establishment of a nurse-led and physician-supervised anticoagulation management model is an inevitable trend in the management of atrial fibrillation, which is in line with the goal of sustainable development [18]. Our study established a whole-course management model for non-valvular atrial fibrillation patients with oral warfarin for continuous, full-course, seamless management. It is observed that mastery of warfarin anticoagulation knowledge, medication compliance, and INR value of patients given the whole-course management model of primary hospitals were significantly better than those of patients in the control group. This suggested the implementation of the whole-process management model in our primary hospitals could help improve the compliance of oral warfarin for non-valvular atrial fibrillation. In addition, it was found that the use of simple, easy and straightforward language was helpful and effective when administering drugs for patients with lower education level. Meanwhile, patients and their families were educated on warfarin medication to ensure that they could grasp accurate information. Previous studies have shown [19, 20] that a full grasp of the disease itself and the knowledge of warfarin anticoagulation could help improve the medication compliance of patients with non-valvular atrial fibril-

lation. A previous study on Chinese people found that warfarin-related knowledge was associated with the medication compliance behaviors of patients. It also pointed out that the improved adherence may be due to the higher knowledge score and stronger belief in the necessity of using a specific drug, as well as less worry about adverse reactions [21], which was basically consistent with our findings, that is, patients with good medication compliance had a relatively higher rating of anticoagulation-related knowledge about warfarin. It should be noted that no notable difference presented in terms of educational level between two groups of patients, and it may be due to the fact that health education and community communication network were promoted for comparatively less-educated patients as well as their family members. This approach enables patients at different levels to master the administration of warfarin better.

Subsequently, we compared the occurrence of bleeding events and thromboembolic events between two groups of patients. The results showed significantly fewer thromboembolic events in the observation group, but no marked difference in the incidence of bleeding events between the two groups. Warfarin is a commonly used clinical anticoagulant, whose effects would be reflected by the occurrence of

thromboembolic events and the safety by related bleeding events [22]. Our results suggested that patients with higher medication compliance had better anticoagulant effects without increasing the risk of bleeding. For patients with non-valvular atrial fibrillation, both physical burden and financial stress may lead to negative emotions. SAS and SDS scores are commonly used negative emotion evaluation scales, which can better reflect the emotional state of patients [23, 24]. Our research suggested that the implementation of the whole-process management model could effectively alleviate the negative emotions of patients, which may be due to the improved medication compliance of patients and better curative effects, contributing to enhanced life quality and improved mood of patients. Finally, we compared the management satisfaction of two groups, and the results showed that observation group had a significantly higher satisfaction rate than the control group. This reminded us that the implementation of the whole-process management model (primary hospitals) helped patients with non-valvular atrial fibrillation enter a virtuous circle, that is, improving warfarin anticoagulation knowledge can improve patients' medication compliance, thereby improving curative effects and quality of life and alleviating negative emotions. Finally, logistic regression analysis showed that age, hypertension, diabetes, knowledge of warfarin anticoagulation and medication compliance were all independent risk factors that could affect the anticoagulation effect of warfarin in patients with non-valvular atrial fibrillation. We believe that chronic diseases should be treated first in view of the influence of hypertension, diabetes and medication compliance on the effect of warfarin anticoagulation, and targeted drug treatment should be used according to the patient's condition to maintain normal blood pressure and blood sugar. It is also necessary to strengthen drug advocacy to patients to enhance medication compliance.

Conclusion

To sum up, compared with the conventional continuous care model, the whole-process management model of (primary hospitals) can improve patients' compliance with medical advice, medication compliance, and curative effects, with lower risk of bleeding and higher patient satisfaction, providing a better option

for out-of-hospital management of anticoagulation for non-valvular atrial fibrillation patients. However, this study still has certain limitations. First, due to the lack of relevant research on the whole-process management model (primary hospitals) in China, more follow-up studies are needed for in-depth demonstration for our conclusions. Second, the conventional nursing model was regarded as the only comparison object in present study, and we should consider and analyze more advantageous management modes in future studies, so as to show the advantages of the whole-process management mode of primary hospitals.

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Disclosure of conflict of interest

None.

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