

Comparison of Quality of Life and Treatment Satisfaction among Sample of Iraqi Patients Using Anticoagulant Therapy (Warfarin or non-vitamin K Antagonist Oral Anticoagulants)

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Abstract:

Background: Oral anticoagulation medication, warfarin and non-vitamin K antagonist oral anticoagulants (NOAC) may require long term use which may affect patients' satisfaction with their treatment and their quality of life (QOL).

Objective: To compare the quality of life and treatment satisfaction among groups of patients using different anticoagulant therapies (warfarin and NOAC).

Methods: A cross-sectional study was performed at Ibn Al-Bitar Hospital for cardiac surgery in Baghdad in the period from December 2022 to May 2023. The study population included a convenient sample of patients receiving either warfarin or non-vitamin k antagonist oral anticoagulant treatment. The Arabic version of the short form 12 (SF-12) questionnaire and the Anti-Coagulant Treatment Satisfaction Scale (ACTS) questionnaire were used to assess the quality of life and satisfaction with treatment respectively.

Results: The study included 181 patients in total. The mean physical and mental quality of life scores for study participants were 42.3±9.92 and 52.6±10.36 respectively. There was no significant difference in the QOL between patients taking warfarin and those on non-vitamin k antagonist oral anticoagulants treatment. The mean total satisfaction score was 65.4±6.73. Patients receiving non-vitamin k antagonist oral anticoagulants had significantly higher satisfaction compared to those receiving warfarin. The physical score correlated significantly with gender, educational level, employment status, number of chronic medications, and number of chronic diseases. The total satisfaction score correlated significantly with gender, number of chronic medications, number of side effects, and duration of anticoagulation. There was a significant correlation between the QOL and treatment satisfaction.

Conclusion: Treatment with non-vitamin K antagonist oral anticoagulants showed comparable QOL and higher treatment satisfaction than that of warfarin. Better treatment satisfaction can improve patients' QOL which may ultimately enhance their adherence to treatment.

Keywords: Iraqi patients; NOAC; Quality of life; Satisfaction; Warfarin.

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Introduction

With the aging population, the number of people on anticoagulants has been increasing. (1) Oral anticoagulants (OACs) have distinctive ways of action and are indicated for several different conditions including prevention and treatment of thromboembolic diseases in stroke secondary to atrial fibrillation (AF), pulmonary embolism, deep vein thrombosis, myocardial infarction, and valvular heart disease. (2) Vitamin-K antagonist (VKA) warfarin, has been available for over 50 years and is still prescribed. Several factors can make warfarin therapy challenging, like its narrow therapeutic index, the need for frequent laboratory assessment of the international normalized ratio (INR), food-drug and drug-drug interactions, and a slow onset and offset of action. (3) Despite that, warfarin is still a commonly used OAC, because of its affordability and availability. Non-vitamin k antagonist oral

anticoagulants (NOACs) have only recently been utilized in clinical settings. (4) NOACs include dabigatran, a direct thrombin inhibitor, and the direct factor Xa inhibitors apixaban, edoxaban, and rivaroxaban. These drugs have reliable anticoagulation, shorter onset and offset of action, predictable pharmacokinetic parameters, fewer drug-food and drug-drug interactions, consistent dosing regimens and they don't require routine laboratory monitoring. (5) However, being newer OACs, there is no enough evidence on their usage in patients during hemodialysis, cancers, additionally to their lack of effectiveness in specific clinical situations, such as antiphospholipid syndrome or mechanical heart valves. (6-7) While OACs effectively treat the disease, they also possess several characteristics that may significantly impact patients' compliance, satisfaction, and QOL. These may include restrictions in activity and diet, requirements of regular laboratory testing, and bleeding adverse effects. As a result, this may adversely affect treatment. Quality of Life is defined by the World Health Organization

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(WHO) as “an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns”. (8) Health-related QOL is a crucial measure that helps medical practitioners understand patients’ perspectives on diseases. (9) Socio-demographic and socio-economic changes, treatment outcomes and different patient care planning may affect patient’s QOL while on OACs. (10) Treatment with an OAC affects patients’ QOL as it is linked to a higher risk of bleeding, and needs a change in lifestyle with no objective relief in symptoms. (11). Patient satisfaction remains an important factor that influences patients’ adherence to their treatment plans. Satisfaction with the treatment is defined as “an individual’s rating of important attributes of the process and outcomes of his/ her treatment experience, which involves the interaction of expectation, preference, and satisfaction”. (12) Treatment satisfaction includes aspects of both the therapeutic process and outcome. Factors that are linked to treatment satisfaction are treatment preference, medication beliefs, and adherence. (13) A high level of satisfaction with treatment is crucial as it has been linked to better QOL. (14). Globally, many studies have compared the QOL and satisfaction with the treatment between users of warfarin versus NOACs. A study to assess satisfaction with treatment and QOL in patients taking OACs for atrial fibrillation showed that, when compared to warfarin groups, NOAC users report better satisfaction and similar QOL. (15) Another study conducted to compare satisfaction with treatment and QOL in patients on warfarin versus NOACs found that there was no statistically significant difference in the QOL between the warfarin and NOAC groups. Nevertheless, patients receiving NOACs showed significantly higher satisfaction level compared to those receiving warfarin. (16) In Iraq, there were no previous studies assessing QOL or treatment satisfaction with OAC therapy, although there were some studies assessing QOL in other chronic diseases (17-20). One study assessed the knowledge of patients using OACs for AF. (21) this study aimed to compare the quality of life and treatment satisfaction among patients using anticoagulant therapy (warfarin and NOAC).

Patients and Methods

Study design: The study was designed as a single-center, cross-sectional study. It was performed at Ibn Al-Bitar Hospital for cardiac surgery in Baghdad in the period from December 2022 to May 2023.

Study population and sampling technique

The study population included adult patients who were 18 years of age or older, receiving oral anticoagulation therapy with warfarin or NOACs (rivaroxaban or apixaban) for at least two months, irrespective of the underlying medical condition. They were able to speak and understand Arabic and

verbally agreed to participate in this study. They were a convenient sample of patients.

Individuals who were unable to speak had a history of mental illness, refused to participate in the study, provided incomplete responses, and those with end-stage liver disease or end-stage renal disease or malignancy were excluded from this study.

Data Collection: After receiving verbal consent, data was collected from the participants through face-to-face interviews. A data collection sheet was employed to collect the information needed for the study which included: Socio-demographic characteristics (age, gender, marital status, occupational status, educational level, smoking habit, body mass index (BMI)). The collected clinical characteristics of the patients included: Indication for anticoagulant, medical history, medication history, type of anticoagulant used, duration of anticoagulant, concomitant use of antiplatelet drugs, and adverse effects (bleeding). The QOL was assessed using the Arabic version of the Short Form 12 Health Survey (SF12) questionnaire. (22) The SF-12, which consists of 12 items, is a valid substitute for the SF-36 in large-scale surveys of general and specific populations. (23) SF-12 includes eight dimensions: General health, physical functioning, social functioning, bodily pain, mental health, vitality, role limitations resulting from emotional issues, and role limitations resulting from physical health issues. The SF-12 questionnaire’s scoring system was based on the SF-12 scoring system developed by Ware and colleagues (24) A weighted number was given to each physical and mental item of the SF-12 questionnaire. The mean physical component score (PCS) and mental component score (MCS) were derived by using specific online calculations (SF-12 – OrthoToolKit®). These means were used as measures of physical QOL and mental QOL. Treatment satisfaction was assessed using the Arabic version of the Anti-Coagulant Treatment Satisfaction Scale (ACTS) questionnaire. (25) ACTS is a condition-specific tool that is designed to measure patient satisfaction with anticoagulant therapy. ACTS contains 15 items; twelve items to assess treatment burdens and three items to evaluate treatment benefits. A five-point rating system is used to assess the patients’ experiences with anticoagulant treatment over the last four weeks (1 being not at all, 2 being a little, 3 being moderately, 4 being quite a bit, and 5 being extremely). The ACTS burden scores are reverse-scored, with higher scores indicating less burden and ranging from 12 to 60. On the other hand, the benefit scores are directly scored, ranging from 3 to 15. Greater satisfaction with treatment is indicated by higher ACTS Burdens and Benefits scores. (26)

Statistical analyses:

The Statistical Package for Social Sciences (SPSS) version 25 was used to analyze the data. Descriptive statistics were performed on all study items. Continuous variables were expressed as means \pm

standard deviation (SD), while categorical variables were expressed as frequencies and percentages. The independent T-test was utilized to compare the differences in the means of continuous variables between the two treatment groups (NOAC vs warfarin). One-way ANOVA was used to measure the difference in means of the continuous variables (total scores) across demographics with more than two categories. Pearson correlation was used to measure the relationships between the continuous variables. A P-value of less than 0.05 was considered to be statistically significant.

Results

Socio-demographic and clinical data of the participants: A total of 181 patients participated in the current study. The patients had a mean age of 57.1 ± 10.72 years and a mean BMI of 28.7 ± 5.09 kg/m². Males constituted 60.2% of the patients, 92.8% were married, and 58.6% had primary or secondary education, table 1.

Table 1: Distribution of the participants by socio-demographic characteristics

Variables	Categories	Frequency (%)	
Gender	Male	109 (60.2)	
	Female	72 (39.8)	
Education level	No formal education	41 (22.7)	
	Primary school	45 (24.9)	
	Secondary school	61 (33.7)	
	College	34 (18.8)	
Marital status	Married	168 (92.8)	
	Unmarried	13 (7.2)	
Employment status	Employed	52 (28.7)	
	Retired	35 (19.3)	
	Unemployed	94 (51.9)	
Cigarette smokers	Non-smoker	106 (58.6)	
	Smoker	20 (11.0)	
	Ex-smoker	55 (30.4)	
Alcohol drinker	Yes	1 (0.6)	
	No	180 (99.4)	
	Minimum	Maximum	Mean±SD
Age (years)	24.0	78.0	57.1±10.72
BMI (kg/m ²)	16.3	46.90	28.7±5.09

The mean duration of anticoagulant use was (6.0±8.11) years. More than half (56.9%) of the patients were taking warfarin with the most frequent indication for use being AF (56.4%). Non-valvular AF was the most frequent type of AF (40.3%). Hypertension was the most frequent chronic disease among the participants (45.3%). Moreover, 73.8% of the participants were on chronic use of beta-blockers, and 81.2% had no concomitant use of antiplatelet drugs (aspirin or clopidogrel). Epistaxis was the most frequent adverse effect of anticoagulants (23.2%), table 2.

Table 2: Distribution of the participants by their clinical characteristics

Variables	Categories	Frequency (%)	
Anticoagulants type	Warfarin	103 (56.9)	
	Apixaban	46 (25.4)	
	Rivaroxaban	32 (17.7)	
Indications for anticoagulant use	Atrial fibrillation	102 (56.4)	
	Prosthetic valve	99 (54.7)	
	Other indications*	9 (5.0)	
AF type	Non-valvular AF	73 (40.3)	
	Valvular AF	29 (16.0)	
Prosthetic valve type	Aortic	64 (35.4)	
	Mitral	55 (30.4)	
	Aortic & mitral	20 (11.0)	
Number of chronic diseases	0	25 (13.8)	
	1	72 (39.8)	
	2	61 (33.7)	
	≥3	23 (12.7)	
	Number chronic medications	0	10 (5.5)
	1	14 (7.7)	
	2	22 (12.2)	
	3	29 (16.0)	
	4	42 (23.2)	
	5	29 (16.0)	
	≥6	35 (19.3)	
Antiplatelet drugs	None	147 (81.2)	
	Clopidogrel	19 (10.5)	
	Aspirin	11 (6.1)	
	Asiprin & clopidogril	4 (2.2)	
Bleeding adverse reactions of anti-coagulants (minor bleeding) †	Epistaxis	42 (23.2)	
	Bleeding gums	39 (21.5)	
	Hematuria	11 (6.1)	
	Menorrhagia	6 (3.3)	
	Other adverse effects ‡	12 (6.6)	
	Minimum	Maximum	Mean±SD
Duration of anticoagulants (years)	0.17	50.00	6.0±8.11

* Other indications: deep venous thrombosis, atrial flutter, and pulmonary embolism.

† Minor bleeding: Not requiring treatment according to WHO bleeding scale.

‡ Other adverse effects: Bruising, melena, bleeding per rectum, hematemesis, hemoptysis, ecchymosis, otorrhagia.

Assessment of quality of life: The mean physical component score (PCS) of all participants was 42.3±9.92 (range: 21.7-62.9). There was no statistically significant difference in PCS subscale of QOL between participants taking warfarin and NOACs (P=0.052). The mean mental component score (MCS) of all participants was 52.6±10.36 (range: 14.5-66.1). There was no statistically significant difference in MCS between patients receiving warfarin and NOACs treatment (P = 0.322), table 3.

Table 3: The quality of life across the study groups

Variable	Anticoagulant	N	Mean of score±SD	P-value*
PCS	Warfarin	103	43.6±9.72	0.052
	NOAC	78	40.7±10.00	
MCS	Warfarin	103	51.9±10.88	0.322
	NOAC	78	53.5±9.62	
Variable	N	Minimum score	Maximum score	Mean±SD
PCS	181	21.7	62.9	42.3±9.92
MCS	181	14.5	66.1	52.6±10.36

Relationships of sociodemographic and clinical variables to QOL:

Patients' gender, educational level and employment status had statistically significant effects on the PCS. The mean PCS was significantly higher in males compared to females (44.5 ± 9.54 vs 39.0 ± 9.62, p = 0.000). Patients with college education had significantly higher PCS compared to those with other educational levels (45.7 ± 9.13, p = 0.006). Patients who were employed had significantly higher PCS compared to those with other employment status (45.4 ± 9.98, p = 0.011). There was no significant difference between QOL according to the patient's age, marital status, cigarette smoking and BMI. PCS had significant negative correlations with the number of chronic diseases (r = - 0.314, p = 0.000) and chronic medications (r = - 0.153, p = 0.041). When the number of chronic diseases and medications decreases, the PCS increases. **Assessment of treatment satisfaction:** The mean total anticoagulant treatment satisfaction scale (ACTS) score for the whole study participants was 65.4±6.73 (range: 42-75). There was a statistically significant difference in the total ACTS score between patients receiving warfarin treatment and those receiving NOACs treatment (P=0.000). There was a statistically significant difference in the burden ACTS score between the two study groups (P=0.000) whereas there was no significant difference in the benefit ACTS score (P=0.083), table 4.

Table 4: Anticoagulant treatment satisfaction across the study groups

Variable	Anti-coagulant	N	Mean of score±SD	P-value*
Total ACTS score	Warfarin	103	62.6±7.45	0.000
	NOAC	78	69.1±2.92	
Total burden ACTS score	Warfarin	103	50.0±6.34	0.000
	NOAC	78	55.8±1.96	
Total benefit ACTS score	Warfarin	103	12.7±2.37	0.083
	NOAC	78	13.2±1.90	
Variable	N	Min. score	Max. score	Mean±SD
Total ACTS score	181	42.00	75.00	65.4±6.73
Total burden ACTS score	181	30.00	60.00	52.5±5.73
Total benefit ACTS score	181	3.00	15.00	12.9±2.19

Relationship of sociodemographic and clinical characteristics of treatment satisfaction

There was a statistically significant difference in the total ACTS score according to the patients' gender with males having significantly higher ACTS scores than females (66.5 ± 6.15 vs 63.8 ± 7.25, p = 0.007). There was no significant difference between treatment satisfaction and the patient's age, education level, employment status, marital status, cigarette smoking, and BMI. The total ACT and burden ACT scores had significant negative correlations with the duration of anticoagulation (r= - 0.214 p=0.004, r= - 0.255 p=0.001) and the number of adverse effects (r= - 0.227 p = 0.002, r= - 0.240 p=0.001) respectively. In contrast, they had a significant positive correlation with the number of chronic medications used by the patients (r= 0.153 p=0.041, r= 0.149 p=0.047) respectively.

Correlation of QOL with treatment satisfaction:

There was a statistically significant correlation between the two study parameter scores. The total ACTS scores, burden ACTS scores and benefit ACTS scores had significant positive correlations with QOL (PCS & MCS). Regarding PCS, the total ACTS score, burden ACTS score, and benefit ACTS score showed a positive correlation of 0.329 (P=0.000), 0.310 (P=0.000), and 0.199 (P=0.007) respectively. Concerning MCS, the total ACTS score, the burden ACTS score, and the benefit ACTS score displayed a substantial positive correlation of 0.385 (P=0.000), 0.338 (P=0.000), and 0.298 (P=0.000) respectively.

Discussion

The primary focus of clinical trials and observational studies has been on evaluating the safety and effectiveness of anticoagulant medications but not on QOL or treatment satisfaction. Similar to the results of the current study on QOL of patients taking warfarin or NOACs, other studies reported the same findings of non-significant differences between mean PCS or MCS. (16,27,28) This may be due to the fact that anticoagulants do not provide objective relief for symptoms. Furthermore, QOL assessed after two months of treatment may lead patients to adapt to the treatments. (16) The finding of the current study of a non-significant difference between patients' age and PCS and MCS is in line with other studies that assessed QOL in other chronic diseases where there was no significant difference of age with QOL. (29-30) However, Fang et al. showed there was a

significant difference between higher MCS scores and lower PCS scores with older age. (27) The finding of the current study of a significant relationship between gender and PCS (males having a higher QOL than females) are in line with other studies which showed that both PCS and MCS are higher in males than females. (27,31,32) This may be due to physiological and biological factors that contribute to the differences between genders, as females tend to experience more discomfort and pain. It is believed that males may give less attention to healthcare than females. Previous Iraqi studies found no significant association between gender and QOL. (33) The finding of the current study that showed the level of education had a significant positive relationship with the PCS domains but not with MCS domains of QOL, was in line with other studies showing a direct correlation between higher education levels and high QOL score. (10,31,34) Highly educated people were found to live longer lives with better health than those with low educated, suggesting that higher levels of education improve self-care and self-motivation, which improve health status. (35) The finding of the current study that showed a significant higher score in PCS were observed in employed patients is in agreement with the results of another study that showed higher PCS and MCS scores in employed patients. (31) This may be due higher monthly incomes which in turn improve the living conditions resulting in a better QOL. In addition, employment provides social support and engagement in social activities. (36) Comorbidities were found to significantly impair the physical domain of the QOL in the current study, which is consistent with an earlier study that reported comorbidities significantly impact the QOL. (37) Patients with comorbidities tend to have a lower positive perception of their QOL. They can contribute to decreased self-care, daily activities and mobility. Patients with comorbidities reported higher levels of discomfort and depression than patients without comorbidity. (38) The current study found that patients on NOACs had higher satisfaction levels than patients on warfarin, with both higher mean ACTS burden scores and higher ACTS benefit scores, in consistence with earlier studies. (16,39) This is because dosing and administration of NOACs are simple, with no need for INR monitoring or drug/food restrictions, and a lower risk of fatal bleeding. (5) Patients on warfarin may have a substantial burden as a result of these limitations. The current study found a significantly higher mean satisfaction score in men than women. Woman may have lower satisfaction due to the increased risk of side effects from menstruation and pregnancy, and a greater responsibility and workload at home. Women are perceived to have a lower health perception and QOL than men in several chronic clinical conditions. (14) These results were similar with those of another study which showed that men have higher satisfaction scores in most domains than women. (39) In contrast,

a study conducted in Canada, showed that women had higher satisfaction scores than men. (40) The current study results found a significantly negative correlation between the duration of therapy and the burden of ACTS and total ACTS scores, in line with other studies. (14) Frequently used anticoagulants for long duration with bleeding side effects, limitation in physical activity, and restriction of some drugs or foods can all have a negative effect on patient's QOL and lower their compliance and satisfaction levels. The number of side effects experienced by the patients had a significant negative correlation with satisfaction, in line with other studies that showed the side effects of warfarin can negatively affect patient satisfaction levels. (41,42) It is thought that the bleeding history of patients may restrict them by increasing their obligations, such as taking medications regularly and not stopping INR follow-ups, which can lead to decreased satisfaction. (42) The significant positive correlation between satisfaction and number of chronic medications found in the current study is in disagreement with a previous study which showed a significant negative correlation of poly-medication with the ACTS burden scale and a non-significant association with the ACTS benefit scale. (14) This may be due to differences between study populations, duration of treatment, and sample size. In the current study, QOL was significantly correlated with satisfaction. In contrast, previous studies showed no significant correlation between them. Ingre et al found no significant correlation between QOL and satisfaction. (11) Michaël et al reported no significant association between the three parameters (QOL, satisfaction, and adherence). (15)

Conclusion

Treatment with NOACs showed comparable QOL and greater satisfaction with treatment than warfarin. Better satisfaction with treatment can improve patients' quality of life which may ultimately enhance their treatment adherence.

Authors' declaration

We confirm that all Tables in the manuscript are mine.

The project was approved by the local ethical committee in (College of Pharmacy, University of Baghdad) according to the code number (RECAUBLP4120225). In addition, approval of the Ibn Al-Bitar Hospital was obtained. While verbal agreement was obtained from patients to participate in the study.

Conflict of interest: None

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Authors' Contribution

Study conception & design: (Tuqa Maitham AL-Ameen & Basma Zuheir Al-Metwali). Literature search: (Tuqa Maitham AL-Ameen). Data

acquisition: (Tuqa Maitham AL-Ameen). Data analysis & interpretation: (Tuqa Maitham AL-Ameen & Basma Zuheir Al-Metwali). Manuscript preparation: (Tuqa Maitham AL-Ameen & Basma Zuheir Al-Metwali). Manuscript editing & review: (Tuqa Maitham AL-Ameen & Basma Zuheir Al-Metwali).

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مقارنة نوعية الحياة والرضا عن العلاج بين عينة من المرضى العراقيين الذين يستخدمون العلاج المضاد للتخثر (الوارفرين أو مضادات التخثر الفموية غير المضادة لفيثامين ك)

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الخلاصة

الخلفية: قد يتطلب العلاج المضاد للتخثر بما في ذلك الوارفارين ومضادات التخثر الفموية غير المضادة لفيثامين ك (NOAC) استخدامًا طويل الأمد مما قد يؤثر على رضا المرضى عن علاجهم ونوعية حياتهم.

الهدف: مقارنة نوعية الحياة والرضا عن العلاج بين المرضى الذين يستخدمون العلاج المضاد للتخثر (الوارفرين ومضادات التخثر الفموية غير المضادة لفيثامين ك).

المنهجية: أجريت هذه الدراسة المقطعية في مستشفى ابن البيطار لجراحة القلب في بغداد في الفترة ما بين كانون الأول 2022 إلى أيار 2023. شمل مجتمع الدراسة عينة مناسبة من المرضى الذين يتلقون علاج الوارفارين أو مضادات التخثر الفموية غير المضادة لفيثامين ك (NOACs) وقد تم استخدام النسخة العربية من الاستبيان القصير (SF-12) واستبيان مقياس الرضا عن العلاج المضاد للتخثر (ACTS) لتقييم جودة الحياة والرضا عن العلاج على التوالي.

النتائج: شملت الدراسة 181 مريضاً، كان متوسط درجة جودة الحياة الجسدية والعقلية لديهم (9.92 ± 42.3) و (10.36 ± 52.6) على التوالي. ولم يكن هناك فرق كبير في جودة الحياة بين المرضى الذين يتلقون الوارفارين وأولئك الذين يتلقون مضادات التخثر الفموية غير المضادة لفيثامين ك (NOAC). اما متوسط درجة الرضا الإجمالي فقد كان (6.73 ± 65.4). كان المرضى الذين يتلقون مضادات التخثر الفموية غير المضادة لفيثامين ك أكثر رضاً عن العلاج بشكل ملحوظ مقارنةً بمرضى الوارفارين (P = 0.000). ترتبط نتائج جودة الحياة البدنية بشكل كبير بالجنس ومستوى التعليم والحالة الوظيفية وعدد الأمراض المزمنة وعدد الأدوية المزمنة. اما درجة الرضا الإجمالية فترتبط بشكل كبير بالجنس وعدد الأدوية المزمنة وفترة اخذ العلاج المضاد لتخثر الدم وعدد الآثار الجانبية. وقد كان هناك ارتباط كبير بين جودة الحياة والرضا عن العلاج (P = 0.000).

الاستنتاج: أظهر العلاج باستخدام مضادات التخثر الفموية غير المضادة لفيثامين ك جودة مماثلة ورضا أعلى مقارنةً بالمرضى الذين يتلقون علاج الوارفارين. إن الرضا الأفضل عن العلاج يمكن أن يحسن نوعية حياة المرضى مما قد يعزز في النهاية التزامهم بالعلاج.

الكلمات المفتاحية: وارفارين، مضادات التخثر الفموية غير المضادة لفيثامين ك، جودة الحياة، الرضا، المرضى العراقيين.