

Satisfaction with and adherence to warfarin treatment: A cross-sectional study among Sudanese patients



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Background: Satisfaction with and adherence to oral anticoagulant treatment are important measures that decrease morbidity and mortality. Higher satisfaction and adherence to warfarin therapy was found to be associated among other factors with good International Normalized Ratio (INR) control.

Objectives: To assess patient satisfaction with and adherence to oral anticoagulant therapy and to identify predictors of the two studied domains.

Methods: A cross-sectional study was conducted at the Cardiothoracic Clinic in Alshaab Teaching Hospital; Khartoum; Sudan during March-April 2015. A representative sample of patients on oral anticoagulant treatment was recruited. Data was collected through face-to-face interview method using oral Anti-Clot Treatment Scale (ATCS) to measure satisfaction and the 4-items Morisky Scale to measure adherence to therapy. Data was processed using SPSS. Logistic regression analysis was performed. P value <0.05 was considered statistically significant.

Results: A total of 93 patients was included, of them 46 were males. Overall, 47 (50.5%) were classified as satisfied with anti-clot treatment. Patients attained secondary and above educational level were approximately 8 times more satisfied with their anti-clot treatment, compared to those educated below this level, [OR 7.9 (2.9–21.7), P < 0.001]. Similarly, patients currently working were found to be approximately 3 times more satisfied with warfarin therapy, compared those who had no jobs, [OR 2.9 (1.1–7.6), P = 0.035]. Overall, 5.4% of the patients were found to be adherent to warfarin therapy. No definite background characteristic variable was found to be associated with adherence to treatment. No association was found between patient satisfaction and adherence to treatment, (P = 0.490).

Conclusions: Ensuring health education on warfarin together with continuous patients motivation are needed, specifically among patients with low educational level. Efficient multidisciplinary effort from all healthcare providers is needed to make warfarin treatment more successful.

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Keywords: Satisfaction, Adherence, Warfarin, Treatment, Sudan

Disclosure: Authors have nothing to disclose with regard to commercial support.

Received 2 May 2016; revised 7 October 2016; accepted 14 October 2016.
Available online 29 October 2016

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Peer review under responsibility of King Saud University.
URL: www.ksu.edu.sa
<http://dx.doi.org/10.1016/j.jsha.2016.10.007>



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Introduction

Thrombosis is a common pathology underlying ischemic heart disease, ischemic stroke, and venous thromboembolism (VTE) [1]. Globally, ischemic heart disease and ischemic stroke collectively cause approximately 25% of deaths [1]. The use of anticoagulant therapy has increased in recent decades due to its documented efficacy and its use in numerous disease states by millions of patients [2].

Warfarin, the most commonly used oral anti-coagulant, requires frequent laboratory monitoring to ensure optimal therapeutic outcomes and to minimize bleeding complications [3]. Management of patients on warfarin therapy is difficult due to its narrow therapeutic index, putting them at significant risk of life threatening bleeding complications or thromboembolism [4]. Warfarin is known as one of the drugs that most frequently causes adverse drug reactions that require hospital admission and increased length of hospitalization, accounting for considerable morbidity, mortality, and extra cost [5].

Treatment satisfaction is defined as the individual's rating of important attributes of the process and outcomes of their treatment experience [6]. Multiple domains of satisfaction with treatment include: condition improvement; the disappearance of symptoms; drug efficacy; absence of drug side effects; ease and convenience; and impact on health relate quality of life [7].

It has been documented that improving and enhancing satisfaction with the therapeutic regimen, are very important to the care of patients with chronic illnesses [8]. Characteristics of warfarin such as the need for a regular blood testing, limitations of lifestyle (e.g. restrictions on diet and activities) and the fear of bleeding can result in a reduction of both patient satisfaction and quality of life [9]. Higher satisfaction and adherence to warfarin therapy was found to be associated among other factors with good international normalized ratio control [10].

The aims of this study were to measure patient satisfaction with and their adherence to warfarin therapy, to identify sociodemographic predictors of the two studied domains and to identify the relationship between satisfaction and adherence, if any.

Abbreviations

ACTS	Anti-clot Treatment Scale
OAT	Oral Anticoagulant Treatment
VTE	Venous Thromboembolism

Methods

Study design

A cross-sectional study was conducted during a 1-month period (March–April 2015).

Setting and participants

The study was conducted among patients on warfarin therapy at the Cardiothoracic Clinic in Alshaab Teaching Hospital, Khartoum, Sudan. The clinic was established in the 1950s, and is managed by physicians.

Inclusion criteria

Adult (age >18 years) patients on warfarin therapy due to any clinical indication (for a duration of at least 2 months) and who attended the clinic for follow-up were recruited. The period of 2 months is the average time needed to adjust the therapeutic dose of the medication. Verbal informed consent was obtained from eligible patients. To minimize selection bias, the patients' medical histories and history of starting warfarin were obtained directly from the patients or their records with the help of the attending staff.

Exclusion criteria

Patients who were taking warfarin for <2 months, were incapable to communicate verbally, were previously diagnosed with mental diseases, or refused to participate in the study were immediately excluded.

Sample size and sampling techniques

A convenience method of sampling was adopted and a total of 93 patients was finally included.

Data collection

Data were collected through face-to-face interview using a structured questionnaire by the principle author (clinical pharmacist). The questionnaire was composed of three parts:

1. Demographic characteristics (age, sex, residence, educational level, marital status, and employment status) and indication for warfarin.

2. Patient satisfaction with anticoagulant treatment using the anticlot treatment scale (ACTS). The ACTS is a standardized tool that has been used in previous studies. It is a 17-item patient-report measure of satisfaction with anticoagulant treatment. It includes 13 items about the burdens of ACT (including a 12-item burdens scale and one global question about the treatment burden) and four items about the benefits of anticoagulants (including a 3-item benefits scale and 1 global question about treatment benefits). The tool was translated into Arabic Language as per Mapi Research Institute guidance and previously used by Elbur et al. [11] in a study in another Arabic country. To account for the difference in dialect between Sudanese and Saudi patients, the questionnaire was revised by the authors independently and no major observation or change in the construction was made. The patients were asked to rate their experiences of anticoagulant treatment during the past 4 weeks on a five-point scale of intensity (1 = not at all, 2 = a little, 3 = moderately, 4 = quite a bit, 5 = extremely). Reverse coding was adopted for the calculation of burden scale in order that higher scores indicated higher satisfaction. The Burden subscale score took values between 12 and 60 and the Benefit subscale score ranged from 3 to 15 to end up with a total range of 15–75 for all the seventeen items. The patient was considered satisfied with anticlot treatment if they scored above the mean score for all patients and dissatisfied if their score was below this cutoff point.
3. Adherence to oral anticoagulant therapy. Medication non-adherence was measured using the self-reported four-item Morisky scale [12], which assesses patient forgetfulness about taking medications, carelessness about taking medications, stopping medication when feeling better, and stopping medication when feeling worse. Questions were answered as *yes* and *no* and scored one point for *yes* and zero point for a *no* response. Scores were summed to give a total score, ranging from 0 to 4. Nonadherence was defined as a score greater than zero.

Data analysis

Data were processed by SPSS version 20 (SPSS Inc., Chicago IL, USA). Descriptive statistics were used to describe all variables. The Chi-square test was used to test the association between satisfaction and adherence to treatment. Cronbach α was used to measure the internal consistency reliability of both ACTS and Morisky scale. Logistic regression analysis was performed to identify predictors of satisfaction and adherence (sex, age in years, residence, educational level, marital status, and current working status). Crude logistic regression analyses were performed as initial steps of qualifying covariates to be included in multivariate logistic regression analyses. Covariates with $p < 0.05$ were included in the final model. Finally, variables with $p < 0.05$ on the multivariate logistic model were considered as the predictors of satisfaction with warfarin therapy.

Ethical approval

The study proposal was reviewed and approved by the Ethics Committee, Ministry of Health, Khartoum State, Khartoum, Sudan.

Results

Demographic characteristics

A total of 93 patients were included; 47 (50.5%) were female. Slightly more than 40% of the patients were aged >60 years. There were 40 town dwellers and 25 were illiterate (26.9%). Table 1 shows the distribution of patients by demographic characteristics.

Indications for warfarin

For 57 (61.3%) of the patients, warfarin was indicated for mitral valve replacement. Indications for warfarin are presented in Table 2.

Satisfaction with warfarin therapy

The internal consistency of anticlot was found to 0.66. Mean scores to the items of ACTS are presented in Table 3. Overall, 47 (50.5%) of the patients were classified as satisfied with anticlot treatment.

Table 1. Patients' background characteristics.

Background characteristic	Frequency	Percentage
Sex		
Male	46	49.5
Female	47	50.5
Age group		
<60 y	54	58.1
>60 y	39	41.9
Residence		
Town	40	43.0
Outside town	53	57.0
Educational level		
Below secondary	39	41.9
Secondary and above	54	58.1
Marital status		
Married	70	75.3
Single	23	24.7
Occupation		
Employee	12	12.9
Laborer	16	17.2
Private business	17	18.3
Housewife	22	23.7
Retired	9	9.7
Not working	17	18.3
Total	93	100

Table 2. Indications for warfarin.

Indication	Frequency	Percent
Mitral valve replacement	57	61.3
Atrial fibrillation	7	7.5
Pulmonary embolism	2	2.2
Deep vein thrombosis	1	1.1
Stroke	1	1.1
Others	25	26.8
Total	93	100

Predictors of satisfaction with warfarin therapy

Initially, univariable analysis showed that male sex, educational level, and having current jobs were significantly associated with satisfaction with warfarin therapy. However, on multivariate analysis, patients who had attained secondary and above educational level were approximately eight times more satisfied with their anticlot treatment than those educated below this level (odds ratio, 7.9; 95% confidence interval, 2.9–21.7; $p < 0.001$). Similarly, patients who had current jobs were found to be approximately three times more satisfied with oral anticoagulant treatment, than respondents who were not working (odds ratio, 2.9; 95% confidence interval, 1.1–7.6; $p = 0.035$). Table 4 shows predictors of patient satisfaction with anticlot treatment.

Adherence to warfarin

The internal consistency of Morisky scale was found to be 0.71. Responses to the Morisky scale items are shown in Table 5. Overall, 5.4% of the

patients were found to be adherent to warfarin therapy. No definite background characteristic variable was found to be associated with adherence to treatment.

Association between patient satisfaction and adherence to treatment

No association was found between patient satisfaction and adherence to treatment ($p = 0.490$).

Discussion

This study was carried out among patients on oral warfarin to measure their satisfaction with and adherence to treatment.

Analysis of the demographic variables of the studied sample showed that 41.9% of the patients were aged >60 years. Wieloch et al. [13], in a follow-up study found that elderly patients are predisposed to thromboembolic and bleeding complications, despite the fact that their international normalized ratios were within the target therapeutic range.

More than 25% of the patients recruited in the current study were illiterate. This was an important demographic variable to be considered as may affect anticoagulant control. Estrada et al. [14] found a strong link between both low literacy and numeracy and poor anticoagulation control.

Slightly more than 60% of the participants used warfarin for the prophylaxis after mitral valve replacement. According to McKenzie et al. [15] the risk of valve thrombosis is five-fold and the

Table 3. Mean scores of participants' responses to anticlot scale.

MItem	Mean score \pm SD
How much does the possibility of bleeding as a result of your anticlot treatment limit you from doing physical activity?	2.7 \pm 1.4
How much does the possibility of bleeding as a result of your anticlot treatment limit you from taking part in your usual activities?	3.1 \pm 1.3
How bothered are you by the possibility of bruising as a result of your anticlot treatment?	3.2 \pm 1.2
How bothered are you by having to avoid other medicines as a result of your anticlot treatment?	3.3 \pm 1.3
How much does your anticlot treatment limit what you eat and drink?	3.5 \pm 1.3
How much of a hassle are the daily aspects of your anticlot treatment?	3.7 \pm 1.2
How much of a hassle (inconvenience) are the occasional aspects of your anticlot treatment?	3.2 \pm 1.3
How difficult is it to follow your anticlot treatment?	3.5 \pm 1.3
How time-consuming is your anticlot treatment?	3.7 \pm 1.2
How much do you worry about your anticlot treatment?	3.2 \pm 1.3
How frustrating is your anticlot treatment?	3.0 \pm 1.3
How much of a burden is your anticlot treatment?	3.1 \pm 1.3
Overall, how much of a negative impact has your anticlot treatment had on your life?	2.8 \pm 1.4
How confident are you that your anticlot treatment will protect your health?	2.9 \pm 1.3
How reassured do you feel because of your anticlot treatment?	2.6 \pm 1.3
How satisfied are you with your anticlot treatment?	2.9 \pm 1.3
Overall, how much of a positive impact has your anticlot treatment had on your life?	2.9 \pm 1.3

SD = standard deviation.

Table 4. Determinants of satisfaction with oral anticoagulant therapy.

Covariates	% Satisfied	n	Univariable analysis crude OR (95% CI)	p	Multivariable analysis adjusted OR (95% CI)	p
Sex						
Female	40.4	46	1			
Male	60.9	47	2.3 (1.0–5.3)	0.029		
Age group						
<60 y	48.1	54	1			
>60 y	53.8	39	0.8 (0.3–1.8)	0.588		
Residence						
Outside town	45.3	53	1			
Town	57.5	40	1.6 (0.7–3.7)	0.245		
Educational level						
Below secondary	20.5	39	1		1	
Secondary & above	72.2	54	10.1 (3.8–26.8)	<0.001	7.9 (2.9–21.7)	<0.001
Marital status						
Married	47.1	70	1			
Single	60.9	23	0.6 (0.2–1.5)	0.256		
Occupation						
Not working	33.3	48	1		1	
Working	68.9	45	4.4 (1.8–10.6)	0.001	2.9 (1.1–7.6)	0.035
Total		93				

CI = confidence interval; OR = odds ratio.

Table 5. Responses to Morisky scale.

	Yes (%)	No (%)
Do you ever forget to take your warfarin?	28.0	72.0
Do you ever have problems remembering to take your warfarin?	31.2	68.8
When you feel better, do you sometimes stop taking your warfarin?	22.6	77.4
Sometimes if you feel worse when you take your warfarin, do you stop taking it?	26.9	73.1

risk of major embolism increases 1.5-fold among patients with mitral valves compared to those with aortic ones.

In the current study, the ACTS was used to measure patient satisfaction. Although the tool was validated for patients on anticoagulant treatment for venous thromboembolism patients and pulmonary embolism, it can also be used for patients receiving long-term anticoagulation irrespective of the underlying condition [16].

Overall, nearly half of the patients were classified as satisfied with anticlot treatment. Comparatively, in the above mentioned study, which was conducted among Saudi patients, satisfaction was higher (63.7%) [11]. Both studies used the same tool to evaluate satisfaction with warfarin therapy. The difference in the degree of satisfaction between the two studied samples may be attributed to the difference in demographic characteristics of the patients, indications of warfarin, and the level of patient education and their motivation. In this respect, the univariable analysis in both studies showed that men were to be more

satisfied than women. Female sex was identified among other factors to be associated with negative perception regarding oral anticoagulant therapy [17].

By contrast, analysis of a cohort of patients using warfarin for thromboembolism prophylaxis after total hip replacement concluded that 83.38% of the patients were very or extremely satisfied with oral antithrombotic medications [18]. Neither sociodemographic characteristics nor the type of concomitant treatment received showed differences in satisfaction with treatment. Again, the difference in the level of satisfaction between the studied samples may be attributed to the difference in the demographic characteristics of the patients, indications for warfarin, and health system factors.

Generally, to attain high satisfaction among patients on warfarin therapy, the items of the ACTS that cause burden, limit activity, limit food and drinks, or cause frustration should be studied in depth. In addition, female concerns and dissatisfaction are important areas for future research to

improve the level of satisfaction among this subgroup of patients.

Multivariate analysis showed that patients attained secondary and above educational level were approximately eight times more satisfied with their anticlot treatment compared to those educated below this level. Higher education, clearly helps the patients to understand the educational message and improve their communication with healthcare providers. In addition, such patients have the ability to come across considerable information about their disease state from other sources that increase their level of awareness and perception.

Unfortunately, only 5.4% of all patients were found to be adherent to warfarin treatment. A possible reason for the observed low rate of adherence was the insensitivity of the recruited patients to the Morisky scale. Future research is needed to explore this issue in depth. The observed low level of adherence did not allow for statistical comparison to identify predictors of this domain. However, certain patient demographic characteristics, such as advanced age, low level of education and residence outside towns may contribute to this finding. Other researchers identified education below high school, employment status, and impaired cognition as important factors associated with nonadherence to warfarin therapy [19].

Poor patient adherence documented in the current was a serious finding and very important area for further future researches. The issue of adherence is certainly very complex. In-depth investigation of different factors related to both the patients and the health care system is needed in order to develop interventions to improve patient commitment to therapy. In a recently published Sudanese study, the researchers targeted both patient knowledge about and adherence to warfarin, and introduced an educational intervention [20]. Verbal education by a clinical pharmacist and written information were provided for the patients periodically for 12 months. The intervention resulted in a significant improvement in both studied domains. Despite the fact that there were clinical pharmacists appointed at the hospital where the current study was conducted, a real clinical pharmacy service was not provided for patients on warfarin treatment.

This study was not without limitations. First, it was conducted among patients in one clinic in one hospital, and among specific patients, so this limits the generalizability of the study to all patients in the region or the entire country. Sec-

ondly, the scarcity of options of valid and reliable instruments to measure satisfaction related to Oral Anticoagulant Treatment (OAT) allowed us too few choices and at this point, there is not enough evidence that the measures we used are the best ones for the Sudanese population. Finally, self-reported method was adopted to measure patients' adherence to therapy. In this respect, patients' responses were subjected to recall bias or they may not give the truth.

Conclusions

Nearly half of the patients were considered as satisfied with warfarin treatment. Satisfaction with warfarin treatment was higher among patients who had current jobs and those with secondary education and above. Adherence to warfarin treatment was very low and no definite background characteristic variable was found to be associated with this domain.

Recommendations

Ensuring adequate health education on warfarin together with motivating patients is needed, specifically among illiterate patients and those with low educational level. Efficient multidisciplinary efforts from all healthcare providers are needed to make warfarin treatment more successful. Special efforts are needed from clinical pharmacists to develop and implement an anticoagulation clinical pharmacy service at hospital.

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