



## Original article

# Association between satisfaction with and adherence to warfarin therapy on the control of international normalized ratio: A hospital-based study in Saudi Arabia



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## ABSTRACT

**Background:** High satisfaction with, and adherence to, warfarin therapy are linked to better international normalized ratio (INR) control and good therapeutic outcomes.

**Objective:** This study was conducted to identify the association between satisfaction with, and adherence to, warfarin therapy and the control of the INR within the target therapeutic range.

**Methods:** A cross-sectional study was conducted from June 1 to August 31, 2016, at the Anticoagulation Clinic in the Cardiology Center at King Fahad Hospital, Qassim, Saudi Arabia. All adult patients included in the study were 18-years-old or older and were on warfarin therapy for 6 months or more. The data were collected through face-to-face interviews using a structured questionnaire.

**Results:** A total of 298 patients were included. Of them, 194 patients (65.1%) were males and 152 (51.0%) were classified as satisfied with their warfarin therapy. Secondary educational level and above ( $P = .001$ ) and being non-Saudi ( $P = .026$ ) were identified as determinants of a high level of satisfaction. Ninety-five (31.8%) participants were classified as adherent to the therapy, and satisfaction with treatment was the only predictor of adherence ( $P = .009$ ). One hundred thirty-six patients (45.6%) achieved their target INR range. Satisfaction ( $P = .038$ ) and adherence ( $P = .023$ ) were significantly associated with better INR control.

**Conclusion:** Substantial efforts are needed to improve patient satisfaction and adherence to treatment through different strategies in order to achieve the target therapeutic goal for warfarin treatment.

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## 1. Introduction

Warfarin is a widely used drug for the treatment and prevention of multiple disease states such as atrial fibrillation (AF), venous thromboembolism (VTE), and prosthetic heart valves (Tadros and Shakib, 2010). Despite the fact that the drug was introduced decades ago, it is still considered difficult to use due to its narrow therapeutic range (Jaffer and Bragg, 2003). Both drug efficacy and safety depend on keeping the international normalized ratio

(INR) within a target range (Kuruvilla and Gurk-Turner, 2001). An INR below the target range is linked to risk for, and severity of, a stroke; and even an increased risk of mortality (Hylek et al., 2003). Conversely, an INR above the therapeutic range is associated with serious bleeding complications (Garcia et al., 2006). Among patients on warfarin therapy, INR values were found to be out of the target therapeutic range approximately half of the time (Samsa et al., 2000).

It is well-known that vitamin K is antagonistic to warfarin therapy and it can decrease the patient's quality of life and influences the patient's adherence to the treatment (Wild et al., 2008). Poor adherence to warfarin therapy has been documented in the literature (Platt et al., 2010; Kim et al., 2011). Researchers have identified non-adherence to therapy as among the multiple factors that predict poor INR control (Schein et al., 2016).

Frequent laboratory monitoring, fear of side effects, and the psychological impact of treatment influence patient satisfaction with warfarin therapy (Murray et al., 2005). Higher patient satisfaction

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with warfarin therapy was found to be strongly associated with good INR control (Wang et al., 2014). In addition, dissatisfaction with anticoagulation leads to decreased adherence, poorer INR control, and poorer clinical outcomes (Samsa et al., 2004).

Satisfaction with, and adherence to, a warfarin regimen are important factors needed to ensure the optimal therapeutic outcome. In Saudi Arabia, few studies have been conducted to identify the association between these factors and the achievement of INR control. Identifying associations between satisfaction, adherence, and INR control is crucial for developing educational interventions that can improve patient care. Therefore, this study was conducted to identify the association between satisfaction and adherence to warfarine therapy and achievement of INR control

## 2. Material and methods

A cross-sectional study was conducted during a period of three months (June 1 to August 31, 2016) among patients on warfarin therapy. The study was carried out at the Anticoagulation Clinic in the Cardiology Center at King Fahad Hospital, Qassim, Saudi Arabia. This clinic was established for the monitoring of patients on anticoagulation therapy.

The study included adult patients 18-years-old or older who were on warfarin therapy for six months or more. Each patient had at least six previous INR readings in the medical record and gave verbal consent to participate. Patients incapable of communicating verbally or who refused to give consent were excluded from the study. Patients enrolled in this study were selected using convenience sampling.

The data was collected through face-to-face interviews using a structured questionnaire. The questionnaire was composed of four parts. The first part was designed to collect background data (age, gender, nationality, educational level, marital status, residence, employment status, indication for warfarin use, and duration). The second part measured patient satisfaction with warfarin therapy using the 17-item Anti-Clot Treatment Scale (ACTS). It includes two subscales to measure the burdens and benefit of ACT. The burden subscale contains 13 item (12-items and one global question about the negative impact of ACT on the patient's life). The benefit subscale is a 4-item subscale (including a 3-item and one global question about the positive impact of ACT on the patient's life). This tool was translated into Arabic using Mapi Research Institute guidance, which involved forward and backward translation with pilot testing by Elbur et al. (2015). The patients were asked to rate their experiences with anticoagulant treatment during the past 4 weeks on a 5-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 the burden subscale so that higher scores indicated higher satisfaction. The burden subscale score ranged from 12 to 60 and the benefit subscale score ranged from 3 to 15. These subscales created a total range of 15–75 for all 17 items. The patient was considered satisfied with anticoagulant treatment if he/she scored above the mean score for all patients. The patient was considered dissatisfied when scoring below the mean. The third part of the questionnaire assessed medication adherence using the Medication Adherence Questionnaire (MAQ) (Morisky et al., 1986). This scale assesses patient forgetfulness, carelessness, stopping or if they stop the treatment due improvement or worsening of the patient's condition. Patients considered to be non-adherent if they responded positively to at least 1 question.

The last questionnaire was used to collect data on INR readings during the previous consecutive six months. The American Heart Association/American College of Cardiology guidelines were adopted to classify the patients as follows: for all indications an INR from 2 to 3 was considered controlled, except in cases of prosthetic heart valve disease, where the anticoagulation control was

be defined as an INR value of 2.5–3.5 (Jaffer and Bragg, 2003; Hasan et al., 2011). For all other values, the patient's INR was considered uncontrolled (Mayet, 2016; Ansell et al., 2008). Good INR control was defined by the Time in Therapeutic Range (TTR) using the Rosendaal method. A TTR of greater than 75% was considered controlled (Rosendaal et al., 1993).

Data were processed by the Statistical Package for Social Sciences (SPSS) version 21. Descriptive statistics were used to describe all variables. Logistic regression analysis was performed to identify predictors (demographic variables) of satisfaction, adherence, and anticoagulation control.

## 3. Results

A total of 298 patients participated in this study and 194 (65.1%) were males. The majority of the participants, 257 (86.2%), were Saudi and 41.3% were 60-years-old or older. One hundred sixty-four participants (55%) lived in rural areas. The demographic characteristics of the patients are reported in Table 1.

Warfarin was indicated for 111 (37.1%) patients with atrial fibrillation (AF) and 109 (36.5%) patients with mitral valve replacement. A detailed list of the indications for warfarin therapy is presented in Table 2.

Table 3 shows the mean scores of the participants' responses to anti-clot scale. The mean level of satisfaction was  $46.0 \pm 13.2$ . Overall, 152 (51.0%) patients were classified as satisfied with the warfarin therapy and 146 (49.0%) patients were not satisfied.

**Table 1**  
Patients' background characteristics.

Characteristic	Frequency (n = 298)	Percentage %
<i>Gender</i>		
Male	194	65.1
Female	104	34.9
<i>Age group in years</i>		
<60 years	175	58.7
≤60 years	123	41.3
<i>Nationality</i>		
Saudi	257	86.2
Non-Saudi	41	13.8
<i>Residence</i>		
Town	134	45
Outside town	164	55
<i>Educational level</i>		
Secondary & above	110	36.9
Below secondary	188	63.1
<i>Marital status</i>		
Married	255	85.6
Single	43	14.4
<i>Occupation</i>		
Working	101	33.9
Not working	197	66.1

**Table 2**  
Indications for warfarin.

Indication	Frequency	Percent
Mitral valve replacement	111	37.2
Atrial fibrillation	109	36.6
Pulmonary Embolism	14	4.7
Deep vein thrombosis	25	8.4
Stroke	9	3.0
Others	30	10.1
Total	298	100

**Table 3**  
Mean scores of participants' responses to Anti-clot scale (n = 298).

Item	Mean score ± SD
<i>Burden subscale</i>	
How much does the possibility of bleeding as a result of your anti-clot treatment limit you from doing physical activity?	3.4 ± 1.2
How much does the possibility of bleeding as a result of your anti-clot treatment limit you from taking part in your usual activities?	3.3 ± 1.2
How bothered are you by the possibility of bruising as a result of your anti-clot treatment?	3.1 ± 1.2
How bothered are you by having to avoid other medicines as a result of your anti-clot treatment?	3.2 ± 1.1
How much does your anti-clot treatment limit what you eat and drink?	3.0 ± 1.2
How much of a hassle are the daily aspects of your anti-clot treatment?	3.0 ± 1.2
How much of a hassle (inconvenience) are the occasional aspects of your anti-clot treatment?	2.7 ± 1.3
How difficult is it to follow your anti-clot treatment?	3.3 ± 1.2
How time-consuming is your anti-clot treatment?	3.2 ± 1.1
How much do you worry about your anti-clot treatment?	3.1 ± 1.1
How frustrating is your anti-clot treatment?	3.1 ± 1.2
How much of a burden is your anti-clot treatment?	3.0 ± 1.2
Overall, how much of a negative impact has your anti-clot treatment had on your life?	3.0 ± 1.2
<i>Benefit subscale</i>	
How confident are you that your anti-clot treatment will protect your health?	2.8 ± 1.2
How reassured do you feel because of your anti-clot treatment?	2.7 ± 1.2
How satisfied are you with your anti-clot treatment?	2.7 ± 1.1
Overall, how much of a positive impact has your anti-clot treatment had on your life?	2.8 ± 1.2

**Table 4**  
Predictors of satisfaction with warfarin therapy.

Predictor	P value	Adjusted OR	95% CI	
			Lower limit	Upper limit
Nationality (Non-Saudi 65.9% vs. Saudi 48.6%)	0.026	0.4	0.2	0.9
Educational level (secondary & above 68.2% vs. below secondary 41%)	0.001	2.9	1.6	5.3

### 3.1. Predictors of satisfaction with warfarin therapy

Multivariable analysis showed that higher education (secondary education level and above), being non-Saudi were strong predictors of a high level of satisfaction with the warfarin therapy. These results are shown in [Table 4](#).

### 3.2. Adherence to warfarin therapy

The results of the MAQ are presented in [Table 5](#). Ninety-five (31.8%) of the participants were classified as adherent to warfarin therapy, while 204 (68.2%) were non-adherent.

The analysis showed that high education level [OR 1.8 (1.1–3.0), ( $P = .022$ )], and satisfaction with anti-clot treatment [OR 2.2 (1.3–3.7), ( $P = .002$ )] were significantly associated with adherence to warfarin therapy. Finally, satisfaction with the treatment remained the only predictor of adherence to treatment, [adjusted OR 2.0 (1.2–3.4), ( $P = .009$ )].

Overall, 136 (45.6%) patients achieved the target INR range.

**Table 5**  
Responses to medication adherence questionnaire (MAQ) (n = 298).

Item	No	Yes
Do you ever forget to take your warfarin?	153 (51.3%)	145 (48.7%)
Are you careless at times about taking your warfarin?	247 (82.9%)	51 (17.1%)
When you feel better, do you sometimes stop taking your warfarin?	219 (73.5%)	79 (26.5%)
Sometimes if you feel worse when you take your warfarin, do you stop taking it?	153 (51.3%)	145 (48.7%)

### 3.3. Association between satisfaction and adherence and INR control

Multivariable logistic analysis showed satisfaction ( $P = .038$ ) and adherence ( $P = .023$ ) were significantly associated with INR control, as shown in [Table 6](#).

## 4. Discussion

Managing patients on anticoagulation therapy includes verifying that the therapy is indicated, monitoring with lab testing, and adjusting the dose based on the lab results ([Testa et al., 2012](#)). In addition, the clinic assesses for potential drug interactions, provides health education, and takes care of patients in need of surgical intervention.

This study attempted to identify if an association exists between INR control and both the level of patient satisfaction and adherence to the treatment. To our knowledge, this association has never been investigated before in Saudi Arabia.

Our results showed that slightly above half of the recruited patients were satisfied with their treatment. In a study conducted in another part of the country, the level of satisfaction was higher at 63.7% ([Elbur et al., 2015](#)). The level of satisfaction found in our study is similar to the that found among Sudanese patients ([Eltayeb et al., 2017](#)). The two previous studies utilized the same tool used here to determine patient satisfaction. The differences observed in the level of satisfaction between the patients in these studies may be attributed to the differences in health services between the hospitals.

Regarding the factors that determined the level of satisfaction in the current study, a secondary education level and above significantly increased the level of satisfaction with treatment. This was an expected finding due to the fact that higher education was

**Table 6**  
Predictors of INR control.

Predictor	P value	Adjusted OR	95% CI	
			Upper limit	Lower limit
Satisfaction (satisfied 52.0% vs. not satisfied 34.9%)	0.038	1.5	1.0	2.7
Adherence (adherent 55.8% vs. non-adherent 37.9%)	0.023	1.8	1.1	3.0

associated with more knowledge about the disease and treatment; which was reflected by higher satisfaction. In the case of warfarin therapy, more knowledge about the treatment may reduce patient concerns and worries and positively affect the level of satisfaction. In previous work, those with secondary education level and above experienced 8 times greater satisfaction than those with lower levels of education (Eltayeb et al., 2017).

Another factor associated with a high level of satisfaction was non-Saudi nationality, although statistically this association was weak. The reasons for lower satisfaction among Saudi patients must be explored in future research. Identifying such reasons and rectifying the problems are important to improve the level of care.

The results showed that slightly more than 30% of the interviewed patients were classified as adherent to treatment. This is a very low percentage given the seriousness of the complications that can result as a consequence of poor adherence to the treatment schedule. Comparatively, other researchers have reported a higher percentage (57.8%) using the same scale (Naderiravesh et al., 2015). Previous research strongly links adherence with the patient's warfarin knowledge (Ababneh et al., 2016). Providing educational interventions focused on the need to commit to warfarin therapy and reducing patient concerns about the side effects can significantly improve patient adherence (Clarks Smith et al., 2013).

The results of this study showed a significant association between patient satisfaction and adherence. Satisfied patients were two times more adherent than non-satisfied ones. This finding emphasizes the importance of exploring the factors that link satisfaction with adherence. Improving adherence to treatment can be achieved through educating the patients on the role of treatment in improving their quality of life. Researchers have found that the level of adherence to warfarin therapy increases with an increased recognition of the treatment benefits and decreases with an increase in perceived barriers (Orensky and Holdford, 2005).

Only 45.6% of patients achieved the target INR range. This is a serious finding that raises multiple questions about the quality of patient care provided at this clinic. This result is in agreement with the result of a study conducted in Qatar where the authors reported that only 44% of their warfarin patients achieved the therapeutic target (Kakkar and Kaur, 2004).

Interestingly, both the level of patient satisfaction and adherence to warfarin were found to be significant predictors of INR control. Another study, that measured adherence using the same scale utilized in the current study, likewise found patient satisfaction and adherence to be significant determinants of anticoagulation control (Davis et al., 2005).

In the literature, few studies have linked patient satisfaction with warfarin therapy and INR control. Samsa et al. (2004) demonstrated a strong association between knowledge about warfarin, high levels of satisfaction with treatment, fewer concerns about side effects, missing warfarin doses, drug-drug interactions, and adherence and better INR control. Other researchers documented that patient satisfaction with the information provided about the drug resulted in significantly better INR control (Sahm et al., 2011).

This study has the following limitations. It was a cross-sectional study and was conducted during a three-month period in one clinic

that only cares for outpatients. Therefore, it is difficult to generalize the obtained results to all patients in the region or in the country. Our choice to use the anti-clot scale was limited by the lack of standardized tools to measure patient satisfaction with warfarin. The study did not assess warfarin dose per indication. Errors in dosing can be considered a major risk factor for INR values outside of the therapeutic range.

## 5. Conclusion

The results of this study call for urgent educational interventions and strategies to improve both adherence and satisfaction; factors that are important determinants of better INR control. The educational interventions should be simple and understandable for less educated patients. In addition, other factors that may influence INR values should be investigated.

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