

## **Impact of general health state, therapy satisfaction, and INR control on quality of life in warfarin patients**

**Running title: Health state, therapy satisfaction and QoL in warfarin patients**

### **ABSTRACT**

**OBJECTIVE:** This study aimed to assess impact of general health state, health literacy and INR control on quality of life in warfarin patients.

**METHODS:** A cross-sectional study using a newly developed and validated research tool was conducted in warfarin patients. Data was collected by convenience sampling method. Descriptive, comparative, and inferential statistics were used by Statistical Package for the Social Sciences (SPSS) ver. 24 to determine the sociodemographic correlates of warfarin knowledge in warfarin patients.

**RESULTS:** Among total 275 studied warfarin patients, the majority of the studied warfarin patients were females than males (n=184, 62.4%, and n=111, 37.6% respectively). A total of 188 (63.7%) patients were satisfied from-with their healthcare providers while 107 (36.3%) were not satisfied from-with healthcare providers. Around 128 (43.4%) of the patients were actively managing their disease while 167 (56.6%) of the patients were not able to actively manage their disease.

**CONCLUSION:** These results confirmed that overall study participants had moderate general health state, moderate therapy satisfaction, and better INR control.

**Keywords:** Warfarin, general health state, therapy satisfaction, INR control, QoL

**Comment [A1]:** Should be "patients on warfarin"

## INTRODUCTION

Health literacy deals with various ~~different~~ aspects like understanding a disease state, empowerment about a disease, ability of a patient to comprehend, appraise and best use of health information to manage his/her disease and therapy and make appropriate healthcare decisions <sup>1</sup>.

In literature, few preliminary studies ~~are evident~~provide evidence that ~~determined~~indicate effects of health literacy on patients' overall disease management, their awareness about disease and therapy outcomes and patients' medication adherence. It is also reported that patients with insufficient or inadequate health literacy levels often result in poorer disease outcomes, complex health complications and worsening of the diseases <sup>2,3</sup>.

Warfarin always requires frequent and careful laboratory monitoring to minimize or avoid bleeding complications and to obtain optimum therapy due to its narrow therapeutic window. ~~outcomes~~<sup>4-8</sup>. It also has high inter- and inpatient variability, and is only effective if its therapeutic range is maintained. ~~and if~~ its blood levels are above or below its therapeutic window, it exhibits greater risks of bleeding and thrombosis ~~respectively~~<sup>6-9</sup>. Warfarin is amongst the most frequently used oral anticoagulants, that is often prescribed to control and prevent various thromboembolic diseases like venous thromboembolism, stroke, atrial fibrillation, and valvular heart disease <sup>7-9</sup>.

Quality of Life (QoL) is not only measured in healthy individuals but also in patients to estimate the overall health status of the society which ultimately helps in designing and

implementing healthcare policies to improve the overall health status of the society <sup>10-12</sup>. The QoL is a multi-dimensional model generally used to observe the impact of health status on individuals' quality of life <sup>13,14</sup>. The WHOQOL-BREF tool is comprised of four different domains named physical, psychological, social and environmental domains <sup>10</sup>. Several studies across the globe are evident in the literature regarding the impact of warfarin therapy on disease outcomes, warfarin therapy duration and its anticoagulation control, the association of warfarin therapy duration and INR, treatment satisfaction and association of knowledge and beliefs with anticoagulation control <sup>13-20</sup>. This study aimed to determine impact of general health state, health literacy and INR control on quality of life in patients on warfarin-patients.

## **Materials and methods**

This was a cross-sectional study done and a self-administered questionnaire was employed. The study subjects were screened for inclusion and exclusion criteria. At first, information sheet was handed to patients and informed consent was taken. The questionnaire was delivered personally to the patients by the researcher who also collected them back after they completed the study. The sampling method employed was convenient sampling. Content validity of the questionnaire was checked before start of the study. Reliability of the questionnaire was assessed using Cronbach's alpha which is the most common tool to be used to measure internal consistency.

## **Statistical analyses**

Percentages and frequencies were used for the categorical variables, while means and standard deviations were calculated for the continuous variables. Chi square and Spearman's correlation coefficient were used to evaluate correlations and impact of various variables on

**Comment [A2]:** The study site and time of study are not described

**Comment [A3]:** What was the Cronbach alpha measurement obtained?

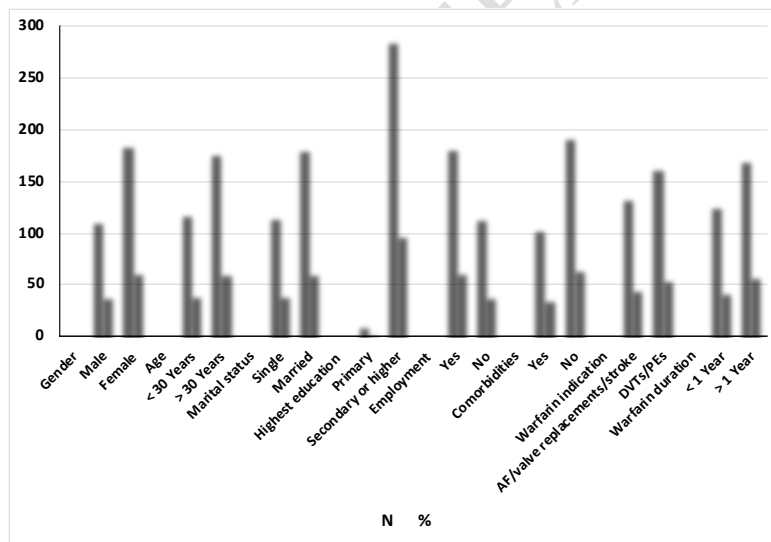
overall QoL of the studied warfarin patients. Data from the research questionnaire were analyzed using Statistical Package for the Social Sciences (SPSS) version 24.0.

## RESULTS and DISCUSSION

Figure 1 represents the demographic data of the study participants. According to the results obtained, there was a total of 295 participants with more females than males (n=184, 62.4%, and n=111, 37.6% respectively). One hundred and eighteen (40.0 %) were less than 30-years whereas one hundred and seventy-seven (60.0%) were above 30-years. Ten (3.4%) had a primary level of education and 285 (96.6 %) had a higher level of education. One hundred and three (34.9 %) had comorbidities other than CVDs and one hundred and ninety-two had no comorbidity. Figure 1 describes the detailed demographic parameters used in this study.

**Comment [A4]:** How was the sample size determined?

**Comment [A5]:** This data can be better displayed with a table



**Figure 1: Demographic details of the warfarin patients**

Table 1 shows the key responses of warfarin patients about general health state, health literacy and INR control. A total of 188 (63.7%) patients were satisfied ~~from~~ with their healthcare providers while 107 (36.3%) were not satisfied from healthcare providers. Around 128 (43.4%) of the patients were actively managing their disease while 167 (56.6%) of the patients were not able to actively manage their disease. A total of 147 (49.8%) of the patients were satisfied from their healthcare system while 148 (50.2%) of the patients were not satisfied from their healthcare system.

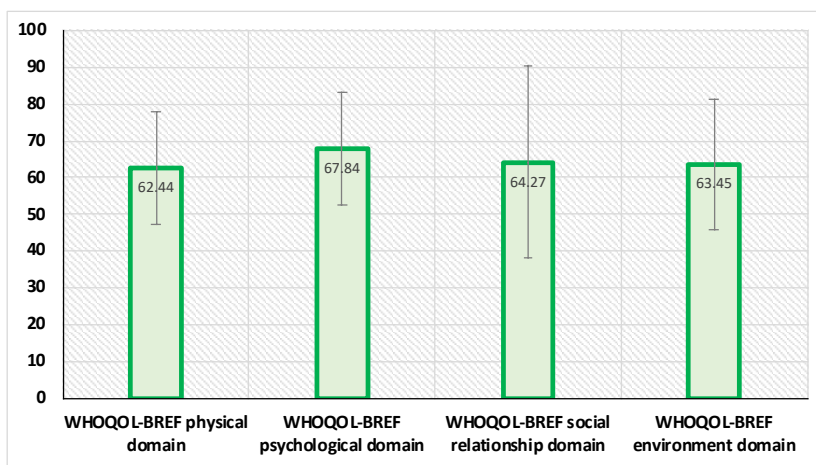
**Table 1: General health state, health literacy and INR control**

Items	Yes		No	
	N	%	N	%
I am satisfied with my HCP	188	63.7	107	36.3
I have enough information about my disease	155	52.5	140	47.5
I am actively managing my disease	128	43.4	167	56.6
I have social support for my disease	153	51.9	142	48.1
I have family support for my disease	273	92.5	22	7.5
I have an easy access to my HCP	198	67.1	97	32.9
I am satisfied with the healthcare system	147	49.8	148	50.2
I know what to do in any emergency	129	43.7	166	56.3
I know about my diet restrictions	209	70.8	86	29.2
I have easy access to pharmacy	168	56.9	127	43.1
I always have good counseling about my health	137	46.4	158	53.6
I know what is INR	98	33.2	197	66.8
I know about INR normal range	204	69.2	91	30.8
I know my INR is controlled	189	64.1	106	35.9
I know my INR was measured within last 6 months	232	78.6	63	21.4

Figure 2 presents the mean QoL scores for all the four domains of the WHOQOL-BREF among the study respondents. The mean score for the physical health domain was 62.44±15.36.

Mean scores for the psychological domain, social relationship domain, and environment domain were 67.84±15.54, 64.27±26.28 and 63.45±17.66 respectively.

**Comment [A6]:** Some of these standard deviations suggest a non-normal distribution. It would be helpful to also state the median and range for each of these measurements



**Figure 2: WHOQOL-BREF domains' scores**

Table 2 shows the Spearman Rank order correlation coefficient scores between QoL domains and the obtained scores of the research tool. The association coefficient between WHOQOL-BREF four domains (physical, psychological, social and environment) vs total scores of the research tool were 0.134, 0.147, 0.162 and 0.111 respectively. There was statistically a significant correlation ( $p < 0.05$ ) observed between the psychological domain and social domain of WHOQOL-BREF vs scores obtained from the research tool.

**Comment [A7]:** This is not shown in the table

**Table 2: Correlation of general health state, health literacy and INR control and QoL**

WHOQOL-BREF domains	r-Value	p-Value
Physical domain	0.134	0.389

**Comment [A8]:** The table is not clear. It should show what variables were correlated to produce the r-value and the p-value

Psychological domain	0.147	0.033*
Social domain	0.162	0.039*
Environment domain	0.111	0.237

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The patients' information about general health state, therapy satisfaction, and INR control is vital in optimizing its therapy outcomes, minimizing drug interactions and reducing adverse drug reactions<sup>21-23</sup>. The current study determined the general health state, therapy satisfaction, and INR control and their effect on QoL in warfarin patients. Several factors were explored and their relationships towards general health state, therapy satisfaction, and INR control was determined using a newly developed and validated research tool in warfarin patients.

Assessment of the general health state, therapy satisfaction, and INR control is crucial to determine the exact health states of warfarin patients. According to the WHO's social and psychological determinants model for chronic disease patients, the social and psychological aspects of the patients are important to be evaluated in order to diminish healthcare and health state inequalities. Indeed, the general health state, therapy satisfaction, and INR control determination can help warfarin patients to understand well and deal fairly with their healthcare issues and improve their QoL.

Our study results confirmed that good healthcare literacy regarding patients' health state can help warfarin patients in improving their therapy adherence, enhancing treatment outcomes, and improvement in treatment satisfaction. A profound health literacy can also result in minimizing treatment complications and to avoid adverse drug reactions and drug or food

**Comment [A9]:** Your study did not aim to show this relationship and did not measure or report therapy adherence and treatment outcomes

interactions among warfarin patients. Furthermore, life style modifications and treatment adherence can also act synergistically to further improve the patients' overall QoL.

## CONCLUSION

In conclusion, our study highlights that overall study participants had average to moderate general health state, moderate therapy satisfaction, and better INR control. The present study also showed a positive and statistically significant association between health state, treatment satisfaction and QoL.

**Comment [A10]:** State the limitations of the study, modify the conclusions to only the data confirmed by the study, and include key recommendations flowing out of the conclusion

**Comment [A11]:** This is unclear. Better in what sense?

## COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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