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ORIGINAL RESEARCH

Quality of Life of Patients Receiving Warfarin Therapy at a Tertiary Care Centre in Indonesia Using DASS (Duke Anticoagulation Satisfaction Scale)

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Purpose: This study aimed to examine the quality of life of patients receiving warfarin therapy at Dr. Hasan Sadikin Central General Hospital, and its relationship with demographic factors.

Patients and Methods: The procedures started with the submission of a study permit, followed by validation of the Duke Anticoagulation Satisfaction Scale (DASS) questionnaire. In addition, the validated questionnaire was completed by the participants, and significant variables were analyzed using the chi-square method for multivariate analysis.

Results: The results showed that the questionnaire was valid and could be used for further analyses. Among the 88 selected participants, 52 and 36 had scoring categories <56.266 and 56.266 ≤ x ≤ 143.734, respectively, with no patients having a scoring category > 143.734. In addition, participants with low education and aged ≥ 52 years were 4.916 and 3.161 times more at risk of having quality of life score of 56.266 ≤ x ≤ 143.734, respectively. Based on the results, the average quality of life score of patients was 59.66. Participants with low educational levels and those aged ≥ 52 years were at a higher risk of having quality of life score of 56.266 ≤ x ≤ 143.734.

Conclusion: In summary, a lower quality of life score was linked to increased comfort and satisfaction among patients receiving warfarin treatment. Additionally, these patients experienced fewer feelings of limitations and inconveniences related to their treatment plans.

Keywords: anticoagulant, questionnaire, INR, demographic factors

Introduction

Warfarin is an oral anticoagulant drug approved by the Food Drug Administration (FDA) since the 1950s. In addition, it is the first-line therapy for the prevention and treatment of various conditions including venous thromboembolism, thromboembolic complications, myocardial infarction, and stroke. Despite the increasing interest in the usage of *Direct Oral Anticoagulants* (DOAC), such as dabigatran, apixaban, and rivaroxaban in the last eight years, the use of warfarin still persists at relatively high levels in several health facilities across Indonesia.[1]

According to previous studies, anticoagulant users typically experience an increased risk of bleeding complications, with approximately 50% of the reported cases classified as significant.[2] Compared to the use of DOAC, warfarin has been reported to have a higher risk of causing major bleeding episodes, often leading to increased hospitalizations.[3,4] In addition, the frequent occurrence of this complication can be attributed in part to decreased patient compliance with monitoring protocols, such as routine International Normalized Ratio (INR) checks.[5] Several studies have shown that adherence to established protocols can mitigate associated risks, leading to increased satisfaction and enhanced quality of life.[6]

In the context of clinical practice, the measurement of quality of life is essential for various purposes, including screening, monitoring therapy usage and therapeutic effects, assessing satisfaction with treatment, planning appropriate treatment, and providing materials for evaluating the quality of services provided.[7] A study by Almeida et al, 2011 in

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Brazil, the Duke Anticoagulation Satisfaction Scale (DASS) was used to assess this variable[8] in 72 patients undergoing warfarin therapy for atrial fibrillation and mechanical heart valve conditions. The results showed that The average score was 67.1, showing a relatively high quality of life.

DASS is a widely recognized instrument for measuring the quality of life of patients receiving anticoagulant therapy.[9] This instrument has also been used extensively in several countries, including Brazil, Saudi Arabia, and Malaysia. Despite its widespread use, there is a significant absence of studies in Indonesia that use DASS. Therefore, this study aimed to examine the quality of life of patients receiving warfarin therapy at Dr. Hasan Sadikin Central General Hospital using DASS. During the procedure, the instrument was translated into Indonesian, followed by validation and reliability testing.

Material and Methods

The DASS questionnaire used in this study was adopted from the study by Samsa et al,[9] which consisted of 25 questions assessing limitations (10 questions, eg, limitations on physical activities due to fear of bleeding, dietary restrictions), hassles (9 questions, eg, both daily hassles such as remembering to take the medicine, as well as occasional hassles such as having to wait while visiting a provider for blood testing), and burdens and positive impacts (six questions, eg, reassurance because of anticoagulation treatment). Details of the questions in the DASS questionnaire can be found in Supplementary File 1.

The questions had seven possible answers: not at all, little, somewhat, moderately, quite a bit, a lot, and very much. Specifically, certain 5 questions have responses whose point calculations will be coded in reverse because these questions are inverse to the other questions. So the total score that will be obtained is in the range 25–175. A lower total score indicates a better quality of life, while a higher total score indicates a poor quality of life.[6,9]

According to Sugiyono (2013), the rating scale was in the form of raw data, which were presented as numbers and interpreted qualitatively.[10] DASS score had a vague rating scale in several categories. In this study, three categories were created using quartiles, with a mean value of 100 and standard deviation of 43.734.

Validity Test

A validity test was conducted to determine the accuracy and thoroughness of the instrument in performing its measurement function. According to WHO (2019), the questionnaire was first adapted using the back-translation method before conducting a statistical validation test. The first stage was forward translation, which was translated by a translator from the English Education Department at Ahmad Dahlan University, namely Dr. Ani Susanti S. Pd., M. Pd. BI. The second stage was an assessment by an expert in English and Indonesian who had expertise in the questionnaire, namely a Lecturer at the Faculty of Pharmacy, Padjadjaran University, apt. Sofa Dewi Alfian, MKM, Ph.D.

The back-translation stage involved translating the results of the translators from the Language Center of the Faculty of Cultural Sciences, Padjadjaran University. The fourth stage was the trial phase, which involved 30 participants who met the inclusion criteria. The fifth stage was the final and best version, which was ready to be distributed to respondents.

Reliability Test

Reliability is a measure of instrument consistency at various intervals.[11] In addition, a reliability test was conducted using internal consistency by examining the Cronbach's alpha values.

$$11 = \left(\frac{k}{k-1}\right)\left(1 - \frac{\sum \sigma_b^2}{V_t^2}\right)$$

Information:

r11 = The computed Cronbach's alpha

k = The number of items

σ_b^2 = variance of items.

V_t^2 = variance of the total scale.

Study Population

The technique used in this study was purposive sampling with certain inclusion criteria and determining the sample size using the binomunal proportion formula as follows:

The technique we used in the research was purposive sampling with certain inclusion criteria and determining the sample size using the following binomunal proportion formula:

$$N = \frac{N.Z^2.P(1-P)}{G^2(N-1) + Z^2.P(1-P)}$$

$$N = \frac{96,04}{1,2079}$$

$$N = 80$$

Information:
n = sample
N = population
Z =standard value (1,96)
P = population proportion (0,5)
G =Precision (0,05)
Based on this formula, the minimum sample taken is 80. However, we added 10% of the total sample (8 subjects) to become 88 subjects so that the results are more representative.

The study population comprised 88 outpatients receiving warfarin anticoagulant therapy at Dr. Hasan Sadikin Central General Hospital from October 2021 to January 2022 who were selected based on predetermined criteria. The inclusion criteria were patients (1) who were willing to participate, (2) aged >18 years, (3) only received warfarin as anticoagulant therapy, and (4) had at least one Prothrombin Time (PT) – INR value. Meanwhile, the exclusion criteria were 1) patients who did not have medical or incomplete medical records and 2) had a psychiatric diagnosis.

Primary data were collected using the DASS questionnaire administered to respondents, which consisted of 25 questions. Technical data were collected through direct hospital visits to interact with the patients. In addition, the patients were directly approached and asked for permission to collect data, with subsequent explanations of the aims, objectives, and results of the study. Once consent was obtained, a letter of consent to participate was signed, followed by the completion of the questionnaire. During the completion process, the investigators provided assistance and clarification. Secondary data was in the form of data obtained from Dr. Hasan Sadikin Central General Hospital through inquiries, such as examining medical records.

Study Ethics

This study was approved by Dr. Hasan Sadikin Central General Hospital (permit number LB.02.01/X.2.2.1/3870/2021. A study permit was submitted to and approved by the Research Ethics Commission of the Faculty of Medicine, Padjadjaran University, to obtain *ethical clearance* with Ethics Approval letter number 28/UN6. KEP/EC/2021.

This research study adheres to the ethical principles outlined in the Declaration of Helsinki. All procedures performed in this study involving human participants are in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Data Analysis

The analysis simplified the data obtained by using statistics to make it easier to read and interpret the results.[12] Data analysis was carried out using statistics and was processed using SPSS 25.0. Univariate analysis was used to analyze demographic data, including age, sex, education level, type of disease, comorbidities, dose, and PT-INR value. The results obtained were presented in the form of frequency and percentage measurements. Bivariate analysis using the chi-square test was used to determine the relationship between each independent variable and the dependent variable, namely,

quality of life and age. Multivariate analysis with logistic regression was used to determine the relationship between independent and dependent variables, both categorical and continuous, with binary results.

Results

Validity Test

The results of the translated questionnaire were subjected to correlation analysis by examining the corrected item-total correlation to determine the validity of each question item using the Pearson product-moment correlation analysis. The validity value of each item was determined based on a significance value or *p-value* < 0.05. All 25 questions were valid, with a significance value of <0.05.

Instrument Reliability

The reliability test showed that each item had a Cronbach's alpha value of 0.866. Based on Guilford's Empirical Rule, this value showed strong reliability, indicating that all question items were reliable.

Univariate Analysis

The majority of participants were females, aged ≥ 52 years, with low education levels, a non-rheumatic heart disease (RHD) diagnosis, and others (besides RHD). In addition, most of them did not have comorbidities, had INR values that did not meet the target, and received weekly doses of category x ≥ 21.175, as shown in Table 1.

Table 1 Respondents Demographic Characteristics

Description	Frequency	Percentage (%)
Education		
Higher	57	64.8
Low	31	35.2
Concomitant Diseases		
There is not any	70	79.5
There is	18	20.5
Warfarin indications		
RHD	40	45.5
Other	48	54.5
Weekly Dose		
x ≥ 21.175	50	56.8
x < 21.175	38	43.2
INR value		
Meet targets	36	40.9
Did not meet the target	52	59.1
Age		
<52 years	43	48.9
≥52 years	45	51.1

(*Continued*)

Table 1 (Continued).

Description	Frequency	Percentage (%)
Sex		
Man	41	46.6
Woman	47	53.4

Abbreviations: RHD, rheumatic heart disease; INR, International Normalized Ratio.

Quality of Life

The quality of life of the warfarin therapy patients at Dr. Hasan Sadikin Central General Hospital is presented in Table 2. A lower score indicates better quality of life, and a higher score indicates worse conditions. In addition, the results showed that the highest percentage score was included in the category < 56,266. This shows that most patients who received warfarin therapy had a better quality of life.

Table 3 presents the average scores for each aspect and the total scores. Negative aspects, such as limitations, hassles, and burdens, had an average score of 41.13, whereas positive aspects, including comfort, satisfaction, and certainty, had an average of 18.53. The average total quality of life score of the patients receiving warfarin therapy at Dr. Hasan Sadikin Central General Hospital was 59.66.

In this study, patients whose INR values were within the target range had an average score of 51.278, which was lower than that of the others (66.2). In addition, participants with a weekly dose of $x \geq 21.175$ had an average quality of life score of 68.02, whereas those with a weekly dose of $x < 21.175$ had 48.63. The results showed that the average QoL scores for female and male patients were 56.76 and 62.97, respectively. Participants aged < and ≥ 52 years had values of 50.15 and 68.44, respectively. Patients with and without comorbidities had average score of 54.38 and 61.014, respectively. Based on these results, those with low and high levels of education obtained values of 74.367 and 52.351, respectively. Patients with warfarin indications for RHD had an average score of 59.1, while those with other indications was 60.12, as shown in Table 4.

Table 2 Quality of Life Score Category

Quality of Life category	Frequency	Percentage (%)
(x < 56,266)	52	59.1
(56,266 ≤ x ≤ 143,734)	36	40.9
(x > 143,734)	0	0

Table 3 Quality of Life Score for Negative and Positive Aspect

	Minimum	Maximum	Mean (SD)
Negative Aspect	21.00	90.00	41.13 (18.19)
Positive Aspect	6.00	31.00	18.53 (6.31)
Total Score	32.00	118.00	59.66 (22.50)

Abbreviation: SD, standard deviation.

Table 4 Average of Quality of Life Score

Description			Total Score
INR Value	Meet targets	Mean	51.27
		SD	12.24
	Did not meet the target	Mean	66.2
		SD	26.26
Weekly Dose	x ≥ 21.175 mg	Mean	68.02
		SD	25.97
	x < 21.175 mg	Mean	48.63
		SD	9.88
Sex	Woman	Mean	56.76
		SD	19.83
	Man	Mean	62.97
		SD	25.05
Age	< 52 years	Mean	50.15
		SD	13.78
	≥ 52 years	Mean	68.44
		SD	25.64
Concomitant Diseases	There is not any	Mean	61.01
		SD	23.11
	There is	Mean	54.38
		SD	19.62
Education	Low	Mean	74.36
		SD	26.25
	Higher	Mean	52.35
		SD	15.76
Warfarin Indications	RHD	Mean	59.1
		SD	20.77
	Other	Mean	60.125
		SD	24.054

Abbreviations: SD, standard deviation; INR, International Normalized Ratio.

Relationship of Respondent Characteristics to Quality of Life

Bivariate analysis was performed to determine the independent variables that were significant to quality of life, including age, sex, warfarin indication, level of education, comorbidities, weekly doses, and INR values, using the chi-square test. The process was performed by examining the continuity correction value because the data used were in the form *of* two *categories* and there was no expected count of more than 20%.

Table 5 shows that educational level (p = 0.002), weekly dose (p = 0.008), and age (p = 0.027) were significantly related to the quality of life of the participants at Dr. Hasan Sadikin Central General Hospital. The INR value, comorbidities, RHD, and sex were not significantly associated. Variables with p-values <0.25 were continued to multivariate analysis using logistic regression, as shown in Table 6.

As shown in Table 6, only education level had a significant value of 0.007 (p <0.05). Meanwhile, the weekly dose and age variables were insignificant because of the presence of a p-value of > 0.05. The re-analysis was performed by removing the weakest significant variable, namely, the weekly dose (p = 0.150). A second stage of logistic regression was then carried out with the variables of age and level of education (Table 7), and the results showed that the level of education had a p-value of 0.001 (95% CI 1.460–11.177).

Table 5 Bivariate Analysis of Demographic Factors with Quality of Life

No.	Variable	Quality of Life				P-value
		X < 56,266		56,266 ≤ x ≤ 143,734		
		n	%	n	%	
1.	Education					
	Low	41	71.9	16	28	0.002*
	Higher	11	354	20	645	
2.	Weekly Dose					
	< 21,175 mg	23	46	27	54	0.008*
	≥ 21,175 mg	29	76.1	9	23.6	
3.	INR					
	Did not meet the target	24	66.7	12	33.3	0.326
	Meet target	28	53.8	24	46.1	
4.	Age					
	< 52 years	31	72.1	12	27.8	0.027*
	≥ 52 years	21	46.7	24	53.2	
5.	Concomitant Diseases					
	There's not any	40	57.1	30	32.8	0.642
	There is	12	66.7	6	33.3	
6.	Warfarin Indications					
	RHD	22	55	18	45	0.621
	Other	30	62.5	18	37.5	
7.	Sex					
	Man	24	58.5	17	41.4	1.000
	Woman	28	59.5	19	40.4	

Notes: *p ≤ 0.05: significant. p > 0.05: not significant.
Abbreviations: RHD, rheumatic heart disease; INR, International Normalized Ratio.

Table 6 Multivariate Analysis of Demographic Factors with Stage One Quality of Life

No	Variable	*p-values*	OR	95% CI
1	Level of Education			
	Low	0.007*	4.040	1.460–1.177
	Higher	–		
2	Weekly Dosage			
	≥ 21.175 mg <21.175 mg	0.150	0.469	0.167–1.315
3	Age			
	>52 years	0.060	2.604	0.961–7.059
	≤52 years	–		

Notes: *p ≤ 0.05: significant. p > 0.05: not significant.
Abbreviations: OR, odds ratio; CI, confidence intervals.

Table 7 Multivariate Analysis of Demographic Factors with Stage Two Quality of Life

No.	Variable	*p-values*	OR	95% CI
1.	Level of education			
	Low	0.001*	4.916	1.460–11.177
2.	Age			
	≥ 52 years	0.019*	3.161	0.961–7.059

Notes: *p ≤ 0.05: significant. p > 0.05: not significant.
Abbreviations: OR, odds ratio; CI, confidence intervals.

Discussion

The DASS is a questionnaire designed to measure patients' level of satisfaction with their anticoagulant therapy. DASS scoring has been performed by summing the scores of each item, which is then interpreted to determine the patient's overall satisfaction level. These scoring results can be used to identify areas for improvement in anticoagulant therapy management, such as improving communication between patients and healthcare providers or adjusting treatment regimens to reduce side effects. Recent evidence shows that the DASS has good validity and reliability in various patient populations receiving anticoagulant therapy. The use of DASS can help healthcare practitioners understand patient experience and improve quality of care, but it needs to be balanced with a comprehensive clinical evaluation to get a more complete picture of patient satisfaction and needs.[9,13]

In this study, the questionnaire was translated into Indonesian for assessment. According to one of the questionnaire owners, Professor David B. Matchar, MD, a Professor at Duke-NUS Medical School Singapore, had a good translation, and there was no significant difference in meaning because the questions used were related to daily activities. In addition, the validation test conducted on the 25 questions yielded favorable results, showing that the adaptation stage of the fifth questionnaire, which typically comprised repeating the adaptation process in case of invalid results, was deemed unnecessary.

The score obtained determined the quality of life, with a low score indicating excellent quality of life and patient satisfaction with anticoagulants. A high score indicates poor quality of life and low satisfaction levels.[6] The average score obtained for patients receiving warfarin therapy at the Dr. Hasan Sadikin Central General Hospital was 59.66. A previous study conducted by Oliveria et al on the quality of life of patients receiving warfarin therapy, using the same

questionnaire, recorded an average total score of 46.4. This shows that the participants in this study had a better quality of life because of their higher total scores.

The results showed that patients with INR values that met the target had better quality of life than those with INR values below the target. When the INR value was on target, it increased the therapeutic success of the participants taking anticoagulants and reduced the risk of thrombosis and bleeding.[14]

A weekly dose of < 21.175 leads to a better quality of life than a weekly dose of x ≥ 21.175. This disparity was caused by differences in the dosage of warfarin administered and was influenced by factors unique to individuals, such as INR response and genetic variation.[15] Women had a lower average score than men, indicating better quality of life. This was inconsistent with a study by AlAmmari et al, which showed that men had better anticoagulant treatment.[16] In addition, Indrayani and Sudarto (2018), on the quality of life of the elderly, showed that men had higher levels than women because of greater satisfaction with several economic, health, and social aspects.[17]

The quality of life of younger patients was better than that of older patients, consistent with the results of Iqbal et al. This could affect the physical aspects of young patients with greater strength. These individuals often believe that their disease is not a big challenge because it is supported by their good physical condition.[18]

The results showed that the quality of life of patients with comorbidities was better than that of those without comorbidities. This was inconsistent with the findings of Almeida et al, who found that comorbidities resulted in a lower perception of quality of life than the absence of comorbidities.[8] In addition, this was related to higher risk factors for other diseases. However, research conducted by Pasha et al and Shirish et al that comorbidities did not have a significant relationship with quality of life.[19,20] Patients with comorbidities feel more comfortable getting anticoagulants to reduce risk factors for other diseases such as stroke compared to not taking anticoagulants to avoid the risk of bleeding.[21] So it can be concluded that in this study patients with comorbidities felt that their quality of life was better and felt calmer due to the administration of medication so that patients could freely carry out their activities, In contrast to patients without comorbidities who felt more worried and had excessive fear regarding the disease they were currently suffering from get worse in the future.

The quality of life was better in patients with higher education than in those with lower education. These results are consistent with those of Balkhi et al, where the variable was further improved in patients on anticoagulant therapy who had a higher level of education.[22] In addition, the results of this study were supported by (2010), who found that participants with high levels of education had a more rational mindset and response, along with higher potential compared to others.[23]

Patients with indications for warfarin for RHD had an average score of 59.1, whereas those with other indications obtained 60.12. Based on the results, participants with warfarin RHD indications had a better quality of life than the others. This was in line with a study by Poungvarin et al in which warfarin was more effective than aspirin in primary stroke prevention in RHD patients.

Education level (p = 0.002), weekly dose (p = 0.008), and age (p = 0.027) were reported to have significant effects. These results are consistent with those of Panonsih et al, who reported similar results.[24] Educational level had a statistically significant relationship with quality of life. Individuals with a high level of education quickly felt relaxed, which could impact the decisions to be taken as well as behavior.[24,25]

Although no studies have directly analyzed the relationship between drug dosage, particularly warfarin, and quality of life, Lakshmi et al asserted that warfarin, a drug with a narrow therapeutic range, requires individualized dosing to attain the desired therapeutic effect.[26] Therefore, the dose did not have a significant effect on patients' quality of life.

Younger patients have a better quality of life than older patients do because of their greater physical strength. These individuals often believe that their disease is not a big challenge because it is supported by their good physical condition.[18] Additionally, studies on the relationship between quality of life and age in patients with type 2 DM have shown a significant negative relationship.[19]

Education (p = 0.002), weekly dose (p = 0.008), and age (p = 0.027), which showed significant results, were included in the multivariate analysis. Logistic regression was performed using the *enter* principle, which included all independent variables simultaneously. Based on this method, the weekly dose and age had *a p-value* greater than 0.05, whereas the level of education had a p-value of 0.007 (p<0.05).

The results showed that educational level had a partial effect on quality of life, with a p-value of 0.001 (95% CI 1.460–11.177). Low education level was at risk of having a quality of life score of 56.266 ≤ x ≤ 143.734 4.916. According to previous studies, education is one of the main variables that can improve the quality of life.[27] Education level is also important because it maximizes welfare in daily life. Higher education was not always interpreted only to master a particular field but to satisfy the overall quality of life.[28] This variable also affects the level of knowledge possessed, and the higher its level, the more comprehensive the knowledge and the better when facing a problem (Panonsih et al, 2020).[24] In terms of health, a higher level of education was related to more vital awareness of the disease and a better ability to cope, thereby affecting the quality of life to make living easier.[29]

Age also had a partial effect on quality of life, with a p-value of 0.019 (95% CI, −0.961–7.059), showing that patients aged ≥ 52 years had the opportunity to have a score of 56.266 ≤ x ≤ 143.734, 3.161 times. These findings are consistent with those of Hasan et al, who found that younger patients had a better quality of life in various domains, such as mental health, social functioning, and physical health.[30] At an older age, there is typically a two-fold decrease in quality of life. In addition, other studies have reported that younger patients have a better quality of life than others in the physical domain. This was because in the physical domain, the patients had strong physical conditions. At an older age, there is a better understanding of the meaning of social, psychological, and environmental life, leading to dissatisfaction despite warfarin treatment.[18]

This study has some limitations. The findings cannot be generalized to all of the possible settings. Oral anticoagulated patients have several options of monitoring their therapy. General practitioner, cardiologist, hematologists, internists, pharmacists and other specialists could take care of these patients. Moreover, self-testing and self-management is another choice to handling warfarin therapy. As regard non warfarin treatment, often patients are not regularly followed by means of laboratory and clinical checks so lowering their adherence and persistence to the therapy. The DASS instrument could therefore give different results when applied to these various conditions.

Conclusion

In conclusion, a lower quality of life score correlated with greater comfort and satisfaction among patients undergoing warfarin treatment. In addition, the patients reported fewer feelings of limitations and hassles associated with their treatment regimens. The results showed that participants with higher education levels were 4.916 times more at risk of having quality of life score of 56.266 ≤ × 143.734, while those aged ≥ 52 years were 3.161 times more at risk of having a score of < 56.266 ≤ × 143.734. Future studies should expand their scope by incorporating additional locations, thereby increasing the pool of participants and facilitating a more comprehensive analysis of the independent variables.

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Disclosure

The authors report no conflicts of interest in this work.

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