Assessing quality of life using WHOQOL-BREF: A cross-sectional insight among patients on warfarin in Malaysia

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1. Introduction

HRQoL is an individual’s perceived quality of life (QoL) demonstrating satisfaction in areas of life that are affected by patients’ general health state (WHO, 2017). The HRQoL is a patient-reported outcome (PRO) which helps to identify the difficulties of living with diseases which may be subjective and varied for each patient (Vanheusden et al., 2007). Furthermore, in chronic disease patients, the HRQoL determination highlights the perceptions of the patients about their health status and overall disease effects on their daily life, including physical, social, psychological and environmental aspects. HRQoL measurement also aids in supervising therapy interventions and designing different healthcare policies to reinforce overall health state of a population (Hakeem et al., 2018; Peterson and Bredow 2009; Hasan et al., 2015).

Cardiovascular diseases (CVDs) are among the major public health concerns worldwide (Haitjema et al., 2014). According to the Department of Statistics Malaysia 2016, the mortality rate due to various CVDs in Malaysia was 23% of the total deaths (DOSM, 2016). Studies predicted that in the near future, CVDs would be a greater threat for heart patients affecting their overall HRQoL and causing significant impairment in their body functions (Khaldoon and Laila, 2018; Yusuf et al., 2001). Prolonged oral anticoagulation therapy (OAT) is an essential treatment for several...
CVDs like atrial fibrillation, coronary heart disease (CHD), peripheral vascular diseases, mechanical heart valve, ischemia, stroke, and for the prophylaxis of thromboembolic conditions (Khaldoon and Laila, 2018; Reynolds et al., 2019). However, usage pattern of warfarin is a little complex due to variability of its biological response, narrow therapeutic index, the occurrence of potential bleeding incidences or events and drug-drug and drug-food interactions (Khaldoon and Laila, 2018). Warfarin’s pharmacotherapy requires frequent international normalized ratio (INR) measurement, strict adherence to the treatment regimen, therapy duration and limited alcohol consumption. Furthermore, the chronic use of warfarin affects the patients’ perception about their HRQoL and health status due to the changes they face in their daily activities, overall lifestyle, dietary restrictions regarding vitamin K and the fear of compromised physical activity which eventually results in a negative impact on patient-reported HRQoL (Crader et al., 2019; Matalqah, 2019; Schulman, 2003; Nutescu et al., 2013).

Sometimes, warfarin exhibits severe adverse drug reactions (ADRs) that require immediate hospital admission and may further lead to morbidity or mortality (Kimmel, 2008; Pirmohamed et al., 2004). These hospital stays and immediate management along with precarious fear of death also negatively affect health status of patients on warfarin (Sobhonslidsuk et al., 2006; Svirtlih et al., 2008). Additionally, prolonged warfarin therapy can also cause loss of self-esteem, develop anxiety and depression, inability to work, and numerous other emotional problems which ultimately result in compromised and poor HRQoL (Corbi et al., 2011; Azizam and Shamsuddin, 2015; Mainela et al., 2015). Similarly, socioeconomic and sociodemographic changes, diversity in patients’ care planning and treatment outcomes also affect overall HRQoL of patients taking warfarin (Casais et al., 2005; Anees et al., 2014; Barcelona et al., 2000). The inconvenience of warfarin dose adjustments and regular INR monitoring, along with the fear of minor injury, bruising or major bleeding are also among influential factors affecting overall HRQoL among patients on warfarin. Perceived reduction in HRQoL of patients is an essential factor, which may influence the patient’s use and patient medication adherence for warfarin therapy (Raparelli et al., 2017). Likewise, perceived reduction in HRQoL is another contributory factor that may influence the prescribers in prescribing warfarin to patients who require warfarin (Corbi et al., 2011; Reynolds et al., 2019; McCahon et al., 2010).

Existing literature reveals that HRQoL among patients on oral anticoagulants including warfarin has been determined in various countries across the globe (Corbi et al., 2011; Almeida et al., 2011; Ng et al., 2019; Khaldoon and Laila, 2018; Matalqah 2019; AlSaikh, 2018) but nothing is reported regarding the HRQoL among patients on warfarin in Malaysia. Malaysia is a country in Southeast Asia that has three main ethnic communities, i.e. Malays, Chinese and Indians. This study was designed to fill the scarcity of the literature regarding HRQoL among patients on warfarin in Malaysia. This study determined the overall HRQoL of patients on warfarin and its relationship with numerous sociodemographic variables like age, gender, marital status, educational level, working environment, indication and duration of warfarin use.

2. Materials and methods

2.1. Sample and setting

A cross-sectional observational study was done at the outpatient anticoagulation clinic of a public hospital in Kualalumpur, Malaysia. The hospital is currently providing generalized and specialized services to the patients. The study protocol was approved by the Clinical Research Centre of the hospital and the Medical Research & Ethics Committee of the Malaysian Ministry of Health, under NMRR-14-1623-20026 (IIR) however participation to this study was voluntary. All aspects regarding patients’ identity and personal information were kept confidential. Patients were also briefed about their right to withdraw from the study at any time. All of the participants were ≥18 years and on warfarin from at least 2 months due to any clinical indication. The period of 2 months is the average time needed to adjust the therapeutic dose of the warfarin (Eltayeb et al., 2017). A written consent according to the declaration of Helsinki (1964) and its amendments on comparable ethical standards was taken from all the participants. Patients who gave written consent and were familiar with Bahasa Melayu (National language of Malaysia) were included in the study. For exclusion criteria, non-Malaysians (who do not read and understand Bahasa Melayu), age below 18 years, pregnant women or planning to conceive, and those who refused to sign the consent form were excluded from the study. The convenience sampling technique was used to collect data. Convenience sampling technique is a type of non-probability sampling method which is cost-effective and time-saving (Gravetter and Forzano, 2012; Elfie and Negida, 2017). In the current study, a written consent form and the research tools were given to all available participants in the specific study location at a particular time capsule.

HRQoL was assessed using a pre-validated Malaysian version of the WHOQOL-BREF questionnaire (Hasanah et al., 2003), which is comprised of 26 questions. Out of these 26 questions, 2 questions assess the perception of QoL and overall health satisfaction, whereas the remaining 24 questions/items belong to 4 different domains, i.e. physical, psychological, social and environmental. Overall, these 26 questions explain how respondents attribute to each aspect of their life and how problematic or satisfactory they perceive them for their overall HRQoL. The score of each question for each domain was used to obtain as summarized domain score, and finally, all the scores were linearly transformed according to the “WHOQOL-BREF guidelines”. Higher score of a domain indicated higher levels of HRQoL while comparing to the rest of the domains and vice versa. Demographic characteristics measured were gender, age, marital status, educational level, employment status, comorbidities other than CVDs, indication, and duration of warfarin use.

2.2. Statistical analyses

Data were analyzed using SPSS version 22.0. Descriptive statistics were used to evaluate the demographic and disease characteristics of the patients. Percentages and frequencies were used for the categorical variables, while means and standard deviations were calculated for the continuous variables. Normality distribution of the data was determined by Skewness, Kurtosis and Q-Q plots which was further confirmed by Shapiro–Wilk test. Independent samples t-test was used to evaluate statistical differences for continuous data between demographics and domains, and to know the differences in overall HRQoL and its domains. Spearman’s correlation coefficient was used to correlate all domains with each other to find the association between them. The correlation coefficient was interpreted in positive and negative values and categorized into weak, moderate and strong correlations (agreements) among the domains of the WHOQOL-BREF.

3. Results

The demographic characteristics of the study participants (n = 319) are presented in Table 1. Females participants were comparatively more than the males (n = 221, 69.3%, and n = 98, 30.7% respectively). One hundred and six (33.2%) were less than 30-years,
whereas two hundred and thirteen (66.8%) were above the age of 30-years. Four (1.3%) had a primary level of education, and 315 (98.7%) had a higher level of education. Eighty-five (26.6%) had comorbidities other than CVDs, and two hundred and thirty-four (73.4%) had no comorbidity.

Table 2 depicts the individual responses against each item of the questionnaire. Overall, more number of participants are categorized under the category of good health in the WHOQOL-BREF questions. On the contrary, in few questions like Q3 of the physical domain and Q11 and Q26 of the psychological domain, more number of patients showed inadequate health (responses) as compared to the rest of the questions.

Table 3 presents the mean and standard deviation scores of the four domains of the WHOQOL-BREF among the study respondents. The mean score for the psychological health domain was the highest (68.58 ± 16.11) among all four domains of WHOQOL-BREF whereas the physical domain had the lowest (61.14 ± 15.96) mean score among all four domains of the WHOQOL-BREF.

Table 4 shows the correlations between the first two questions and four domains of the WHOQOL-BREF. Based on the observed findings, a statistically significant positive correlation was observed between the first two questions and among four domains of the WHOQOL-BREF. The strength of the association between environmental and physical domain was the strongest (moderate positive correlation, i.e. Spearman’s “r” 0.628) and weakest (weak positive correlation, i.e. Spearman’s “r” 0.153) between social and overall health domains of the WHOQOL-BREF.

Table 5 represents correlation coefficients and the bivariate relationship between demographic variables and the domain scores. Patients in the age group of ≥30 years had higher HRQoL scores in their psychological, social and environmental domains than those in <30 years (69.67 ± 15.12, 64.20 ± 26.59 and 62.91 ± 16.72 respectively). Statistically, a significant difference was observed in education levels vs psychological domain (p = 0.022). Patients having less or primary education had significantly lower HRQoL in almost all attributes.
of the WHOQOL-BREF. Patients with comorbidities other than CVDs had compromised HRQoL in QoL and health satisfaction and all four domains (p-value ranged from <0.001 to 0.077). Patients on warfarin for more than one year had higher HRQoL in all domains than those who were under one year of the therapy.

4. Discussion

The severity of the chronic diseases demands primary healthcare providers should pay due attention to the HRQoL of the affected individuals. Researchers from different parts of the world explored numerous aspects of HRQoL among patients on anticoagulation and warfarin therapy (Elbur et al., 2015; Almeida et al., 2011; Corbi et al., 2011; Al-Saikhan, 2018). Warfarin therapy patients require optimum care because they often face severe changes in their daily routine activities and overall lifestyle, especially in bleeding disorders (Schulman 2003). These lifestyle changes usually affect their dietary habits, especially with vitamin K intakes. Consequently, some of the warfarin patients start consuming alcohol, stop performing daily physical activities, non-adherence to warfarin therapy, feeling stress and anxiety and changing eating habits. These precautionary measures often negatively affect patient-reported HRQoL (Nutescu et al., 2013). According to some other studies, inadequate access to medication use, frustration, the burden of the therapy, and negative psychological impacts are among the significant apprehensions that affect patients’ HRQoL while they are on warfarin (Corbi et al., 2011; Al-Saikhan, 2018; Barcellona et al., 2000; Elbur et al., 2015; Almeida et al., 2011).

The occurrence of a bleeding episode may affect general health status and overall HRQol among patients on warfarin. In a study done by Corbi et al., the HRQoL of anticoagulant therapy patients was greatly associated with sociodemographic and clinical variables (Corbi et al., 2011). According to two other studies, the intensity of bleeding events, the presence of comorbidities, various drug-drug and drug-food interactions, education level differences, patients’ age, INR values and therapy duration had a direct impact on the overall HRQoL of warfarin patients (Almeida et al., 2011; Al-Saikhan, 2018).

The present study evaluates different aspects of HRQoL among warfarin patients using the WHOQOL-BREF. According to the results of the study, the highest mean score was found for the psychological domain (68.58 ± 16.11), that may show patients’ satisfaction from healthcare facilities, their body appearance, positive feelings, a greater level of self-esteem, personal beliefs, religious freedom and less dependence on self-pocket. On the other hand, the lowest mean score was observed for the physical domain (61.14 ± 15.96) indicating compromised activities of daily living, more dependence on medicines and medical aids, less mobility and more fatigue, discomfort, and less work capacity. Furthermore, moderate mean scores were observed for social and environmental domains (63.55 ± 27.06 and 62.78 ± 17.58, respectively) showing satisfactory personal relationships, social support and sexual activities, sufficient financial resources, opportunities for acquiring new information and skills, performing religious deeds, adequate safety and security, quality healthcare and frequent access to cheap and convenient transport.

In the current study, females had better scores than males in all domains except the physical domain. The probable reason could be that the no. of females were more than males at the study site. These results are similar to a study conducted in Saudi Arabia, where the investigators also found similar findings among both genders in health satisfaction, social and environmental domains (Al-Saikhan, 2018). Our study results are opposite to the findings of Ng et al where they reported no significant difference between males and the females (Ng et al., 2019). These differences are may be due to different patients and different study sites.

This study reported that younger patients had considerably better perceived HRQoL scores than elders in the QoL, health satisfaction and physical domain whereas, in psychological, social, and environmental domains, elderly patients had better HRQoL than youngsters. The main reason behind these results could be that older people may have a better feeling and understandings of their social, psychological and environmental life as they are more satisfied although they are on warfarin (Almeida et al., 2011; Abray et al., 2007). Furthermore, another reason could be that elders may embrace their diseases and their management as a challenge and started living a happier life as compared with the youngsters. These findings are similar to two earlier studies that reported HRQoL but among different populations (Casais et al., 2005; Schulman, 2003). The other salient differences were the use of different types of research tools like SF-36, patients with different disease states, comorbidities, different lifestyles, gender ratio differences, ethnicity, family income, and religious beliefs. However, another study did not report any significant association between HRQOL scores and the age (Gadisseur et al., 2004). According to Gadisseur et al, different factors like different treatment plans, self-handling of the medicines and attitude of the special-

| Table 4 | Correlation coefficients in overall health and domains of WHOQOL-BREF. |
|---------|-------------------------------------------------------------|
| QoL     | Health Satisfaction | Physical Domain | Psychological Domain | Social Domain | Environmental Domain |
| Correlation (r) | 1 | 0.431 | 0.496 | 0.343 | 0.310 | 0.506 |
| Sig. (2-tailed) | <0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 |

Table 3

Mean HRQoL scores for four domains of WHOQOL-BREF.

| Domains       | HRQoL Scores (Mean ± SD) |
|---------------|--------------------------|
| Physical      | 61.14 ± 15.96            |
| Psychological | 68.58 ± 16.11            |
| Social        | 63.55 ± 27.06            |
| Environmental | 62.78 ± 17.58            |
Comparison of WHOQOL-BREF mean scores, standard deviations, and significance level based on sociodemographics.

Arabia, where they reported similar results (Al-Saikhan, 2018). In findings are in accordance with the findings of Al-Saikhan in Saudi perceived HRQoL scores social and psychological domains. These and physical domain, whereas singles or separated had a bit higher was observed in the marital status variable with health satisfaction that can affect overall HRQoL of the patients (Gadisseur et al., 2004).

This study depicted that a statistically significant association was observed in the marital status variable with health satisfaction and physical domain, whereas singles or separated had a bit higher perceived HRQoL scores social and psychological domains. These findings are in accordance with the findings of Al-Saikhan in Saudi Arabia, where they reported similar results (Al-Saikhan, 2018). In some of the previous studies, marital status did not have any effect (Nejat et al., 2006). Conversely, two studies reported non-significant differences regarding education level and patient-reported HRQoL (Barcellona et al., 2000; Casais et al., 2005).

In this study, the education level had a statistically significant effect on the psychological domain of WHOQOL-BREF regarding perceived HRQoL of warfarin patients. However, in all other domains, higher mean scores were observed in secondary or higher education levels as compared with primary education levels. These findings are similar to the results of Almeida et al where a positive perception of HRQoL was observed in patients with higher education level. Higher education level often upholds self-motivation and self-care, which helps in improving general health states. Highly educated patients would have a better understanding of different dosage forms, drug regimens and potential side effects (Nejat et al., 2006). Conversely, two studies reported non-significant differences regarding education level and patient-reported HRQoL (Barcellona et al., 2000; Casais et al., 2005).

Current study findings showed that employed or self-employed individuals had better HRQoL in three domains (physical, psychological and social) of the WHOQOL-BREF than unemployed. Workplace environment with excellent amenities and high earnings could significantly improve perceived HRQoL as reported in two different studies (Casais et al., 2005; Satilik et al., 2008).

Presence of comorbidities often promote changes in perception about HRQoL among patients. Warfarin patients with various comorbidities had compromised HRQoL when compared with patients without any comorbidity (Almeida et al., 2011). Our study showed much better scores (p < 0.05) in all four domains of the WHOQOL-BREF and health satisfaction among patients without any comorbidity. In this context, our results in accordance with a study done by Gadisseur et al where they also found similar results (Gadisseur et al., 2004).

In bivariate analysis, our findings exhibit that the duration of warfarin usage had a statistically significant effect on the physical and social domains of the WHOQOL-BREF. Patients who were on warfarin for more than a year had higher perceived HRQoL. These findings are also consistent with the results of another study done by Gadisseur et al where statistically significant difference was observed regarding the duration of warfarin therapy and the HRQoL (Gadisseur et al., 2004). According to another study of Casais et al, the negative perceptions about HRQoL were more in patients who were on warfarin for less than a year which also corroborates our study findings.

Malaysia has an advanced and specialized setup of Medication Therapy Adherence Clinics (MTACs) for warfarin patients where pharmacists are providing essential patients education and counseling regarding warfarin therapy (Aidit et al., 2015; Aidit et al., 2017). Frequent INR measurement, adherence to varied medication regimens, compliance with the lifestyle modifications and awareness about drug interactions could play a more significant role in

| Table 5 | Comparison of WHOQOL-BREF mean scores, standard deviations, and significance level based on sociodemographics. |
|---------|---------------------------------------------------------------------------------------------------------------|
| Variable | Domains                                                                                                       |
|         | QoL | Health Satisfaction | Physical | Psychological | Social | Environmental |
| Gender  | Male | 3.75 ± 0.97 | 3.57 ± 1.01 | 61.22 ± 16.45 | 67.83 ± 17.05 | 63.51 ± 25.93 | 60.95 ± 18.13 |
|         | Female | 3.91 ± 0.86 | 3.67 ± 0.90 | 61.10 ± 15.78 | 68.91 ± 15.71 | 63.57 ± 27.60 | 63.59 ± 17.31 |
|         | P Value | 0.146 | 0.348 | 0.952 | 0.1583 | 0.984 | 0.217 |
| Age     | < 30 Years | 3.88 ± 0.90 | 3.69 ± 0.87 | 63.26 ± 16.48 | 66.38 ± 17.82 | 62.25 ± 28.05 | 62.52 ± 19.27 |
|         | ≥ 30 Years | 3.85 ± 0.89 | 3.61 ± 0.97 | 60.08 ± 16.53 | 69.67 ± 15.12 | 64.20 ± 26.59 | 62.91 ± 16.72 |
|         | P Value | 0.763 | 0.484 | 0.094 | 0.086 | 0.546 | 0.853 |
| Marital Status | Single/Separated | 3.82 ± 0.92 | 3.51 ± 1.01 | 58.56 ± 15.75 | 68.80 ± 15.41 | 63.68 ± 26.93 | 62.26 ± 16.72 |
|         | Married | 3.89 ± 0.87 | 3.76 ± 0.85 | 63.43 ± 15.85 | 68.39 ± 16.76 | 63.43 ± 27.24 | 63.25 ± 18.35 |
|         | P Value | 0.472 | 0.018 | 0.006 | 0.821 | 0.935 | 0.615 |
| Education Level | ≤ Primary | 3.50 ± 1.29 | 3.50 ± 0.57 | 53.25 ± 19.13 | 50.25 ± 10.21 | 68.75 ± 23.93 | 56.50 ± 22.29 |
|         | Secondary or higher | 3.86 ± 0.89 | 3.64 ± 0.94 | 61.24 ± 15.93 | 68.81 ± 16.05 | 63.48 ± 27.12 | 62.86 ± 17.55 |
|         | P Value | 0.607 | 0.755 | 0.320 | 0.202 | 0.700 | 0.473 |
| Employment Status | Employed | 3.92 ± 0.93 | 3.63 ± 0.92 | 62.93 ± 16.22 | 60.63 ± 17.13 | 64.59 ± 24.46 | 62.00 ± 17.24 |
|         | Unemployed | 3.83 ± 0.87 | 3.65 ± 0.94 | 60.17 ± 15.78 | 68.01 ± 15.55 | 62.99 ± 28.41 | 63.20 ± 17.79 |
|         | P Value | 0.355 | 0.869 | 0.140 | 0.393 | 0.613 | 0.562 |
| Comorbidities other than CVDs | Yes | 3.71 ± 0.98 | 3.37 ± 1.06 | 56.18 ± 16.72 | 59.07 ± 17.98 | 56.20 ± 28.79 | 57.35 ± 18.20 |
|         | No | 3.91 ± 0.86 | 3.74 ± 0.87 | 62.94 ± 15.32 | 72.03 ± 13.88 | 66.22 ± 25.95 | 64.76 ± 16.97 |
|         | P Value | 0.077 | 0.002 | 0.001 | <0.001 | 0.003 | 0.001 |
| Warfarin Indication | A/F/Valve replacements | 3.86 ± 0.90 | 3.67 ± 0.93 | 60.00 ± 16.37 | 68.14 ± 16.56 | 65.02 ± 26.48 | 62.87 ± 17.20 |
|         | DVTs/PEs | 3.86 ± 0.89 | 3.62 ± 0.94 | 62.15 ± 15.57 | 68.97 ± 16.54 | 62.25 ± 27.57 | 62.71 ± 17.97 |
|         | P Value | 0.978 | 0.622 | 0.231 | 0.649 | 0.363 | 0.934 |
| Warfarin Duration | <1 Year | 3.80 ± 0.93 | 3.65 ± 0.97 | 58.65 ± 17.08 | 67.49 ± 16.08 | 59.79 ± 27.87 | 61.57 ± 18.74 |
|         | ≥1 Year | 3.91 ± 0.87 | 3.64 ± 0.91 | 62.96 ± 14.88 | 69.38 ± 16.14 | 66.11 ± 26.18 | 63.67 ± 16.68 |
|         | P Value | 0.268 | 0.921 | 0.017 | 0.303 | 0.033 | 0.291 |
achieving better patient-reported HRQoL among patients on warfarin.

This study is novel among its types as there is no previous study reported in the literature that measured HRQoL among warfarin patients using the WHOQOL-BREF in Malaysia.

This study had some limitations. First, it was performed in a single-centre, hence limiting the generalizability of the obtained results. Second, the cross-sectional design of the study might not be able to actually reflect the HRQoL as HRQoL may vary over time. Third, the WHOQOL-BREF is also a self-reported study tool and in the case where patients get help from their attendants or family members may result in some bias. Fourth, there was no control group to make applicable comparisons for the findings obtained. Fifth, the number of female respondents was more than males which may lead to a bias. Despite some limitations, the results of this study shed significant light on the overall status of perceived HRQoL among patients on warfarin in Malaysia.

5. Conclusion

This study confirms that patients on warfarin enjoy a good HRQoL in all domains of the WHOQOL-BREF in Malaysia. However, in some of the variables, they showed relatively moderate HRQoL scores. The findings of this study could help physicians, pharmacists, allied healthcare professionals, and the family members of the patients to better understand the physical, psychological, social and environmental difficulties which patients usually face during warfarin therapy.

CRediT authorship contribution statement

Muhammad Shahid Iqbal: Conceptualization, Data curation, Project administration, Supervision, Resources, Writing - original draft, Writing - review & editing. Yaman Walid Kassab: Conceptualization, Data curation, Project administration, Supervision, Resources, Writing - review & editing. Fahad I. Al-Saikhan: Methodology, Formal analysis, Writing - original draft, Writing - review & editing. Ziyad S. Almalki: Methodology, Formal analysis, Writing - original draft, Writing - review & editing. Abdur Raheem: Project administration, Supervision, Resources, Methodology, Formal analysis, Writing - review & editing. Muhammad Zahid Iqbal: Methodology, Formal analysis, Writing - original draft, Writing - review & editing. Majid Ali: Methodology, Formal analysis, Writing - original draft, Writing - review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Ethics approval

The study protocol was approved by the Clinical Research Centre of the hospital and the Medical Research & Ethics Committee of the Malaysian Ministry of Health.

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