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Effect of Oral anticoagulant Therapy (Warfarin) on Quality of life of Cardiac Patients.

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Abstract: *Warfarin is the most commonly used oral anticoagulant that can be available in different doses. The chronic use of oral anticoagulants can affect patient's Quality of life (QoL) and health condition* ***Aim:*** *This study aim toevaluate the effect of oral anticoagulant therapy on qualityof life of cardiac patients.* ***Methods:*** *thestudy used A descriptive design.* ***Setting:*** *This study was conducted at Specialized Medical Hospital at Mansoura University.* ***Study sample****: waspurposeful sample of 125 adult patients attend cardiac outpatient clinic on oral anticoagulant therapy (warfarin)for more than four weeks.* ***Tools :*** *Structured interview Questionnaire 1) Sociodemographic and Health History Data Sheet 2) Quality of Life Questionnaire* ***Results:*** *This study showed that (60.8%) of studied sample suffer from moderate negative effect from using warfarin, above one quarter(26.0%) suffer from low negative effect, while only (12.8%) suffer from high negative effect. There is statistically significant relation between total effect of oral anticoagulant therapy and patient' sex (p 0.038), living status (p= 0.039), diagnosis (p 0.001) and oral anticoagulant duration (p= 0.013).* ***Recommendations:*** *study recommended development of health educating programs for the patients about oral anticoagulant therapy.*

Key words*: Cardiac Patients, Oralanticoagulant, Quality of life,Warfarin*

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I. Introduction

The term "quality of life" (QOL) or health related quality of life (HRQL) came into use during the 1970s as a multidimensional concept that reflect the overall subjective status of the mental and physical welfare of the person, which is a finding not only to the illness but also to the family and social conditions that form the person's environment (Dueñas, Salazar, Ojeda &Failde ,2012).

The chronic use of oral anticoagulant therapy (OAT) has great effect on the patient's perception regarding his quality of life and health condition because of the changes it promotes in the person's life style, and mainly because patients are submitted to medication that gives no symptomatic benefit, but shows a well-defined risk. Thus, it is observed the importance of getting to understand the difficulties of living with OAT (Almeida, Noblat, Passos&Nascimento, 2011)

Anticoagulant medications are widely taken for both treatment and prophylaxis of thrombotic diseases and are some of the medications that lead to medication errors, as showed by previous data these medications often cause dangerous or fatal effects, and so considered one of the most high risk medications. Especially, if persons are transferred from one sector to the other, unintended events related to drug can occur .Warfarin was one of the first anticoagulant medications on the market, and has been available since 1964 .In 2014, a total of 88.158patients were treated with warfarin in Denmark (Henriksen , Nielsen, Hellebek&Poulsen ,2017).

Although warfarin can be a life saving drug, its clinical management is very difficult because of its narrow therapeutic index which make it necessary to regularly monitor the anticoagulation state as reflected by INR value to do dose modifications (Anthony etal.,2009).

There are a number of warfarin characteristics that lead to dissatisfaction with and decrease in person quality of life. Patient anticoagulant management is complicated and need frequent analytic check-up for monitoring and regulating INR values , restrictions on food consuming and specific activities, potential preoccupation with hemorrhage or hematoma and interactions with other medications (Diana, Consuelo, Paz&Pia ,2015).

Aim of the Study:

Evaluate the effect of oral anticoagulant therapy on qualityof life of cardiac patients.

Research question:
What are the effects of administering oral anticoagulant therapy on quality of life domains of cardiac patients?

II. Subjects & Method

Research Design:A descriptive design was used in the present study.
Setting: This study was conducted at cardiac outpatient clinic in specialized medical hospital at Mansoura University in delta region.
Sample: Purposeful sample of 125 adult cardiacpatients from both sex attend cardiac outpatient clinic on oral anticoagulant therapy (warfarin) for more than four weeks and willing to participate in the study.
Data collectionTools
1-Sociodemographic and Health History Data Sheet
Developed by The researcher to assess patients' age, sex, marital status, level of education, etc.)
2-Quality of Life Questionnaire
Measure the effect of oral anticoagulant therapy onpatient quality of life that developed by Abdelrahman (2012**)** and modified by the researcher to include 7 parts.
Part1 General Health Questionnaire (7 items) (Question 1 to Question 7)
Part2 Physical Activities Questionnaire (5 items) (Question 1 to Question 5)
Part3 Physical Health Problems Questionnaire (3 items) (Question 1 to Question 3)
Part4 Emotional Health Problems Questionnaire (3 items) (Question1 to Question 3)
Part5 Social Activities Questionnaire (2 items) (Question 1 to Question 2)
Part6 Pain Questionnaire (1 item) (Question 1)
Part7 Vitality Questionnaire (7 items) (Question 1 to Question 7)
scoring system : It was consisted of 28 items in total questions in the form of Multiple Choice Questions (MCQ) In each domain the patients are asked to range their answer from zero to two where (zero) represent the worst quality of life and highest negative effect and (two)) represent the best quality of life and absence of negative effect. i.e The higher The score The best quality of life and absence of negative effect & The lower The score The worst quality of life and highest negative effect. This marks summed and the effect of oral anticoagulant therapy on quality of life evaluated as the following.

- Score (<50.0%) =<28 was classified as High negative effect and worst QOL.
- Score (50-<75.0%) =28-<42 was classified as Moderate negative effect.
- Score (≥75.0%)= ≥42 was classified as Low negative effect, and high QOL.
- Score (100%)=56 was classified as no negative effect and best QOL.(Abdelrahman,2012)

Procedure

1. An official approval was obtained from Research Ethical Committee of the Faculty of Nursing, Mansoura University and the Director of Specialized Medical Hospital at Mansoura University.
2. Validity: Tool was tested for validity by 7 experts (jury) from Mansoura University, (two assistant nursing professors, three nursing lecturer. one cardiology professor, and one cardiac lecturer) from the field of the study.
3. Reliability of the tool was estimated using cronbach's Alpha test to measure internal consistency of the tool r =.914
4. The researcher started data collection by introducing her self and explaining the purpose of the study for all participants.Data collection started from beginning of April to the end of May 2017. The researcher collected data every day from 9AM to 1 PM every day except Friday .filling questionnaire required 20-30 minute.
5. A pilot study was conducted on 10% (12 patients) of total number of cardiac patients treated with warfarin to test simplicity, clarity of questions and time frame needed for interview and minor modification done accordingly. These participants in pilot study were excluded from the study group.

Field of Work:
Tool collected from each patient interviewed individually and through using patient medical records. Patients were interviewed during the morning in cardiac outpatientclinic.

Human Rights and Ethical Consideration:

- An approval was taken from Research Ethical Committee of faculty of nursing –Mansoura University.
- Oral consent from participant Patient in the study was obtained after clarification the nature and the purpose of the study.
- Participants were assured that information is confidential and used only for purpose of the study.
- Official permission to use patient medical record was obtained from administrative authority.

- The investigator emphasized participation is voluntary and confidential.
- Anonymity, privacy, safety and confidentiality were absolutely assured throughout the whole study.
- Each participant had the right to withdraw from the study at any time without any explanation.
- The investigator coded the questionnaires to assure the anonymity of the subjects. Finally the investigator scored the responses and complied them for data analysis.

Statistical analysis

Data were analyzed with SPSS version 21. The normality of data was first tested with one-sample Kolmogorov-Smirnov test, Qualitative data were described using number and percent, and Association between categorical variables was tested using Chi-square tests. When more than 25% of the cells have expected count less than 5, Monte Carlo exact test was used, Continuous variables were presented as mean ± SD(standard deviation),For all above mentioned done statistical tests. Significant level value was considered when p .value ≤ .05 and highly significant level was considered when p.value ,01-,001 and very highly significant level was considered when p.value< ,001.cronbach's Alpha reliability analysis for the study tool is 0.914

III. Results

Table (1): As regard Socio-demographic characteristics of studied sample Table (1) illustrate that above half of studied sample at age group >55 and (60.8%) were female, above two third were married, above half (57.6%) were illiterate ,nearly three quarters (74.4%) from rural residence, (38.4%) occupied as house wife, Majority of sample (86.4%) were living with their family and as regard health insurance coverage most of them (97.6%) were private.

Table (1): *Socio-demographic characteristics of studied sample(N=125)*

Socio-demographic variable	studied sample (n=125)	
	No.	%
Age:		
• ≤35 yrs	13	10.4
• >35 – <55yrs	44	35.2
• 55-60 yrs	68	54.4
Mean(SD)	54.6(13.15)	
Sex:		
• Male	49	39.2
• Female	76	60.8
Marital status:		
• Single	4	3.2
• Married	88	70.4
• Widow	31	24.8
• Divorced	2	1.6
Educational level:		
• Illiterate	72	57.6
• Read&write	27	21.6
• Intermediate education	17	13.6
• High education	9	7.2
Residence:		
• Urban	32	25.6
• Rural	93	74.4
Occupation:		
• Housewife	48	38.4
• Retired	7	5.6
• Worker	30	24.0
• Non-working	40	32.0
Health insurance coverage:		
• Private	122	97.6
• Health insurance	3	2.4
Living status:-		
• Living with family	108	86.4
• Living with others	0	0.0
• Living with friends	0	0.0
• Living alone	17	13.6

Table(2): As regardhealth history of studied sample Table(2) illustrate that (51.2%) were receiving marevan , (60.0%) were taking dose from (3mg-5mg/day),68.8% taking oral anticoagulant for more than one year and (63.2%)of patients were suffering from (AF)

Table (2): *Health history of studied sample (N=125)*

Health history of studied sample	studied sample (n=125)	
	No.	%
Oral anticoagulant medication used:		
• Marevan	64	51.2
• Marevanil	56	44.8
• Coumadin	0	0.0
• Haemofarin	5	4.0
Oral anticoagulant dose:		
• <3mg	9	7.2
• 3mg-5mg	75	60.0
• >5mg	41	32.8
Oral anticoagulant duration:		
• 4weeks	8	6.4
• >4weeks-6months	16	12.8
• >6months-1year	15	12.0
• >1year	86	68.8
Cardiac diseases treated by oral anticoagulant therapy:		
• Atrial fibrillation	79	63.2
• Left ventricular thrombus	7	5.6
• Pulmonary embolism & deep vein thrombosis	6	4.8
• Mechanical heart valve	24	19.2
• Other	9	7.2

Table(3):As regard level of affection for each Quality of life domainsTable(3) illustrate that high negativity of taking warfarin appear more with Physical health problem domain while Social activities and pain domains are less affected from taking it.

Table (3): *Effects of oral anticoagulant on all quality of life domains*

Quality of life domains	**Deviation in QOL**			
	High negative effect	Moderate negative effect	Low negative effect	No negative effect
	%	%	%	%
General health	11.2%	53.6%	34.4%	0.8%
Physical activity	14.4%	48.8%	18.4%	18.4%
Physical health problem	40.0%	41.6%	16.0%	2.4%
Emotional health problem	20.8%	56.0%	12.8%	10.4%
Social activities	7.2%	23.2%	42.2%	27.2%
Pain	0.8%	44.0%	0.0%	55.2%
Vitality	12.0%	48.8%	33.6%	5.6%

High negative effect <50.0%
Moderate negative effect 50-<75.0%
Low negative effect ≥75.0%
No negative effect 100.0%

Table(4):As regard total effect of oral anticoagulant therapy on quality of life Table(4) illustrate that(60.8%) of studied samplesuffer from moderate negative effect, above one quarter(26.0%)suffer from low negative effect, while only (12.8%)suffer from high negative effect.

Table (4): *Total effect score and categories of oral anticoagulant therapy on quality of life of studied sample.(N=125)*

Total effect	studied sample (n=125)	
	No.	%
High negative effect (<50.0%)	16	12.8
Moderate negative effect (50.0-<75.0%)	76	60.8
Low negative effect	33	26.4

(≥75.0)		
	Mean	(SD)
Total score	36.4	7.95

IV. Discussion

Part 1: Concerningsociodemographic characteristics of studied sample .The study findings regarding sociodemographic characteristics revealed that mean age of studied sample 54.6(13.15) and above half of studied sample age group >55 .This findings supported by Mayet (2015) who conductedacross-sectional prospective survey on association between oral anticoagulation knowledge, anticoagulation Control, and sociodemographic characteristics of Patients using itand stated that mean age of patients studied taking oral anticoagulants was 55.4 SD ± 15.3 .

As regard sex above half of participants in our study were females. This result in the same line with Borji ,Molavi, and Rahimi (2016) who studied cross-sectional study on the impact of sexual satisfaction on the QOL on persons with cardiovascular disease and mentioned that above half of cardiacpatients were female .

As regard marital status of the patients in thisstudy above two third were married followed by widows .This result accepted by Serra, Ribeiro, Gemito, Mendes and Parreira (2016) whoconducted descriptive, exploratory, cross-sectional study on therapeutic management of persons with OAT andMayet (2015). They reported that most of patients treated by oral anticoagulant therapy are married, followed by widows.

As regard the level of education the present study illustrate that above half were illiterate and above fifth were able to read and write .This result supported by Borji, Molavi and Rahimi (2016) who reported that above half of patients taking OAT were illiterate.

As regard residence nearly three quarters from rural areas this findings go in the same line with Balkhi, Al-Rasheedi , Elbur and Alghamadi (2017) who conducted cross sectional study on relation between satisfaction with and adherence to warfarin therapy on the control of INR and reported that above half live in rural areas.

As regard occupation the highest percentage of sample was house wife nearly above third and the lowest percentage was retired this result supported by Sharaf et al., (2017) whostated that majority of the studied sample are house wives .

As regard health insurance coverage and living status nearly all of them were private, above three quarters were living with their family this result go in the same line withCarvalh, Ciol, Tiu, Rossi and Dantas (2013) who conducted a prospective observationalstudy onthe impact of OAT onHRQOL at six-month follow-up and stated that despite decreased income most of the patients paid the OAT treatment from their own resources and only very small percentage lived alone.

As regard oral anticoagulant dose ,above half were taking dose from (3mg-5mg/day) this finding contraindicated with Wiley et al., (2016) who reported that nearly third of patients taking warfarin dose of 5mg or less .

As regard duration for using oral anticoagulant above two thirds taking oral anticoagulant for more than one year. This result goes in the same line with Wiley et al., (2016) who reported that most of patients treated bywarfarin for more than one year.

As regard indication nearly two third of patients were suffering from atrial fibrillation followed by one fifth suffering from mechanical heart valve. This finding supported by Verret et al., (2012) who studied Prospective, randomized, controlled, trial on effect of a pharmacist-led warfarin self-Management program on QOL and anticoagulation control and reported that main usage for warfarin was atrial fibrillation or atrial flutter followed by mechanical heart valve.

Part 2 : Concerning effect of warfarin on QOLdomain **.**When considering quality of life (QOL) domains for patients taking oral anticoagulant therapy , As regard effect of oral anticoagulant therapy on quality of life (general health) this study illustrate that there is significant deterioration in general health of patients onoral anticoagulant therapy (OAT) in which above half of studied sample suffer from moderate negative effect from using (OAT) .

This result go in the same line with Alli et al., (2013) who concluded that, there was a decline in HRQOL among patients taking warfarin therapy at 12 months and there is a significant decline in perceived health among patients on warfarin who had a bleeding event.

As regard effect of oral anticoagulant therapy on quality of life (physical activities domain) the study result illustrate significant limitation in physical activity as result of using warfarin. This result go in the same line with Alli et al.,(2013) who stated that obvious lifestyle changes can be significantly troublesome for many patients. In which the effect of anticoagulant therapy restrict their activities that have a negative effect on the HRQOL that often intended to be presentwith the long period , may be for the rest of person's life.

As regard effect of oral anticoagulant therapy on quality of life (physical health problems) this result illustrate that above three quarters suffer from high and moderate negative effect from using oral anticoagulant .This result go in the same line with Boonyawat, O'Brien andBates (2017) who state thatHeavy Menstrual

Bleeding (HMB) has been reported with taking VKA . In which, the incidence significantlyincreased in females treated with VKA. VKA significantly increase the duration of menstruation flooding, intermenstrualbleeding, and passage of clots.

As regard effect of oral anticoagulant therapy on quality of life (emotional health problems and vitality (energy and emotion) this result illustrate that there is decrease in patient quality of life with using warfarin this result supported by Liu (2011) who stated that takingVKA is a factor that causedepression and anxiety. That happensas result of management challenges of VKA or due to fearing frombruising/ bleedingrisk.

As regard effect of oral anticoagulant therapy on quality of life (social activities) this result illustrate that above third of studied sample suffer from Low negative effect from using oral anticoagulant, more than one quarter with no negative effect .This result supported by K- Das (2009) who performed prospective study to compare patient's QOL before and after six month of using warfarin. He reported that when assessment done on how much of the time persons' emotional and physical problems affected social activities,we did not find any significant difference after taking warfarin for six months.

As regard effect of oral anticoagulant therapy on quality of life (pain domain) this result illustrate that above half of studied sample without any negative effect from using oral anticoagulant , while only one patient from all sample suffer from high negative effect. So pain domain is the most less affected from taking it.This result contraindicated with Radaideh and Matalqah (2018) who said that pain is one of the most negatively affected HRQoL domains.

V. Conclusion and Recommendations

The finding of this study concluded that:

(60.8%) of studied samplesuffer from moderate negative effect on quality of life from taking oral anticoagulant therapy, above one quarter(26.0%)suffer from low negative effect, while only (12.8%)suffer from high negative effect.

The Study recommended the Following:

- Health educating programs for the patients about oral anticoagulant therapy.
- Further researches are proposed to focus on studying factors affecting quality of life for patients on oral anticoagulant therapy (OAT).
- Further researches are proposed to evaluate patient's knowledge and practice about (OAT).

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