An-Najah National University
Faculty of Graduate Studies

Medication Beliefs, Adherence, and LDL-C Level among Statin Users at Al-Rahma clinic in Nablus City

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Dedication

My Family, Friends and Colleagues.

Acknowledgment

Special thanks for my supervisor Professor Waleed M. Sweileh for his guidance, encouragement and help through this study.

Many thanks also for all workers at Al-Rahmah clinic lab, my thanks for the participants who willingly accepted to share for the purpose of this study.

الاقرار

انا الموقع ادناه مقدم الرسالة التي تحمل العنوان :

المعتقدات الدوائية والالتزام الدوائي ومستويات كوليسترول البروتين الشحمي منخفض الكثافة عند مستخدمي الستاتين في مستوصف الرحمة بمدينة نابلس

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Declaration

The work provided in this thesis, unless otherwise referenced, is the researcher's own work, and has not been submitted elsewhere for any other degree or qualification.

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Date: **التاريخ:**

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List of abbreviations

Abbreviation	Explanation
CV	Cardiovascular
CCT	The Cholesterol Treatment Trialists'
LDL-C	Low Density Lipoprotein Cholesterol
MMAS-8©	Morisky Medication Adherence Scale
BMQ	Beliefs about Medicines Questionnaire
ASCVD	Atherosclerotic cardio vascular disease
WHO	World health organization
IRB	Institutional Review Board
SPSS	Statistical Package for Social Sciences
Q1-Q3	Lower – Upper quartiles
SD	Standard Deviation
OR	Odds Ratio
CI	Confidence interval
MOH	Ministry of Health
CHD	Coronary Heart Disease
SRM	Self-Regulatory Model
USA	United state of America
BMI	Body Mass Index

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Abstract

Objective: To assess beliefs about statin medications and its association with statin adherence.

Methods: a cross- sectional study was carried out on One hundred and ninety six statin users attending a non-governmental charitable clinic in Nablus, Palestine. The study was carried out from February to June 2012, using a self-reported questionnaire that consists of Morisky Medication Adherence scale (MMAS-8©), Beliefs about medicines Questionnaire (BMQ), and potential demographic and clinical factors that might affect adherence to statins. LDL-C level was also measured for all the participants. Univariate and multivariate analysis was done to find factors associated with non-adherence.

Results: The mean age of the studied sample was 58±8.1 years. On Morisky scale, 55.1% participants were non-adherence. Participants ≥ 65 years and those with longer duration of statin use had lesser odds [0.45 (0.23 – 0.9], [0.46 (0.3-0.8] with confidence interval (CL) 95% of being non-adherent than participant < 65 year and those with lower duration of statin use respectively. Participants who did not have a history of invasive heart procedure OR [2(1.1-3.0] with CL 95%and those with stronger concerns about statin medications OR [2(1.1-3.0] with CL 95% had higher odds of being non-adherent. Multivariate analysis showed that stronger concerns about statins was associated with higher odds [1.094 (1.09 – 1.18)] with CL 95% of non-adherence.

Conclusions: In our study, non-adherent is common among statin users. Patient's concerns about potential harm of statin were the most significant factor associated with non-adherence. Future interventions for improving adherence to statin therapy should rely heavily on patients' education concerning potential benefits or harms from statin therapy.

Chapter one
Introduction

1.1.1Overview

Medication non-adherence in general and to statin in specific is widely recognized as a major public health concern and contributes to patient morbidity, mortality and healthcare costs [1]. Statins are one of the most commonly recommended lipid lowering agents which have been shown to significantly decrease cardiovascular (CV) events [2]. Despite that, medication non-adherence to statin medications is reportedly high [3]. Several studies have sought to find clinical and demographic factors associated with medication non-adherence [4], but very few focused on the impact of patient's beliefs on medication adherence. Many studies carried out in the Arab world about medication adherence [5]; however few focused on the influence of beliefs about statin medications on the adherence to statins.

The "Beliefs about Medicines Questionnaire (BMQ)" was developed to measure patients' beliefs about medicines in a range of diseases [6]. Since then, the BMQ has been translated into several languages to assess beliefs about medicines across a wide range of diseases [6]. Similarly, the 8-item Morisky Medication Adherence Questionnaire (MMAS-8©) had been translated into different languages, and had been validated in patients with different types of chronic illnesses [7].

1.1.2 LDL-C

Dyslipidemia is characterized by abnormal level of lipids in the blood stream [8]. The most common type of dyslipidemia is hypercholesterolemia, which manifested by the presence of high level of cholesterol in the blood [8]. There is free cholesterol and protein bound cholesterol which transports in the blood stream as lipoprotein particles that consists of protein and lipids. Lipoproteins are classified by their density to: very low density lipoprotein (VLDL), intermediate density lipoprotein (IDL), low density lipoprotein (LDL) and high density lipoprotein (HDL) [8].

High levels of LDL-Cholesterol was proved to be one of the most important modifiable risk factors associated with the increased risk of cardiovascular events, atherosclerosis, and coronary heart disease [9, 10]. Current guidelines recommend decreasing the level of the LDL-C to less than 70 mg/mL , as a therapy goal in order to reduce cardiovascular events, especially in patients with multiple risk of developing stroke or cardiac arrest [11], It has been also proven that lowering LDL-C levels were significantly reduce cardiovascular morbidity and mortality in patients with elevated cholesterol levels [12-14]. The new guidelines had set the levels of LDL-C to be optimal if it was less than 100 mg/mL, near optimal (100-129 mg/mL), above optimal (130-159 mg/mL), high (160-189 mg/mL) and very high (more than 190 mg/mL) [14]. Lipid lowering therapies has been recommended to

lower the risk of CV diseases; the most common therapies include diet therapy, physical activity, non-statin and statin drug therapy [14].

1.1.3 Statins

Statins are 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors, they reduce cholesterol synthesis in the liver and lower intracellular cholesterol concentrations; which lead to up regulation (increase in number of receptors of LDL-C on hepatocytes membranes), thereby increasing the clearance of LDL from the blood circulation [15]. It is used to reduce LDL-C, apolipoprotein B, and triglycerides, and to increase HDL-cholesterol in the treatment of hyperlipidaemias. It's also utilized in patients with atherosclerosis or diabetes in order to reduce the risk of CV events [15].

As Statins have become the cornerstone in the management of abnormal LDL-C levels, several studies have been conducted to illustrate the effectiveness and benefits of using such treatment to lower risk of CHD [16, 17]. By lowering LDL-C, statins have been shown to decrease CV events in both primary and secondary CV disease prevention trials [18, 19]. In a study conducted by Law MR. et al., statins have been reduced LDL-C level by 30%-50% in a sample of patients, which reduced the relative risk by 30%-35%i those patients [20].In another study it was shown that lowering LDL-C by 1mmol/L will reduce the incidence of CV events by around 20%, and further reduction in LDL –C level with more intensive statin regimen yielded further reduction in CV risk [21]. There is evidence of benefits for using statin

in patients with clinical atherosclerotic cardiovascular diseases (ASCVD), patients with LDL-C levels of 190 mg/dL or more, and for patients aged 40-75 years with diabetes or ASCVD risk [17].

As conclusion, statins are recommended as common lipid lowering therapies, that could decrease cardiovascular (CV) events significantly for patients with all case morbidity associated with dyslipidemia [2, 12, 22, 23].

1.1.4 Adherence to Medications

Adherence is defined as "active, voluntary, and collaborative involvement of the patient in a mutually acceptable course of behavior to produce a therapeutic result "[24]. This definition implied the relationship between the physician as a caregiver and the patient in a covalent relation that guarantees positive health outcomes, some experts like to call it; ``the therapeutic alliance``. Adherence includes whether patients take their medications as prescribed and continue taking them during the duration of therapy [24]. Given the magnitude and importance to poor adherence, the World Health Organization (WHO) has published a guide to healthcare givers to improve strategies of medication adherence [25]. Non-adherence in patients with acute conditions is typically low, as compared with non-adherence in those with chronic conditions which is increased after the first six months of therapy, [26]. There is no standard for adherence acceptable rate, but it is considered greater than 80% to be adequate adherence [26, 27].

1.1.5 Measures of Adherence

Although there is no gold standard for measuring adherence, it could be measured by direct or indirect methods; measuring the level of medication or its metabolite in blood or urine and detection of a biologic marker in blood are examples of direct method. However, direct approaches are most accurate, but they are expensive and not practical in routine clinical use. While examples of indirect methods include self-reports, pill count, prescription refills, and electronic monitors, Self-reporting is considered the simplest and the least expensive method [28]. The most commonly used indirect methods include patient self-report, pill counts, and prescription refills. The Morisky scale is a commonly used, validated; 8-item self-reported adherence measure that has been shown to be predictive of adherence to cardiovascular medications and blood pressure [27, 29]. The 8-item Morisky Medication Adherence Questionnaire (MMAS-8©) was developed in USA, it is one of the most widely used self-reported measures of medications adherence [27], it had been translated into different languages, and had been validated in patients with different types of chronic illnesses [7, 29-31].

1.1.6 Adherence to Statin Medications

Although statin medications are effective treatment for elevated LDL-C levels, some patients doesn't achieve the recommended LDL-C level. Two third of statin treated patients in the Arab world had inadequate control for LDL-C level [32]. Statins non-adherence is reportedly high [3, 22, 33-35], and

there appears to be a progressive decline in adherence to prescribed cardio-protective medications such as statins over time [36]. Improving adherence to statin therapy has significant value to patients with CV diseases; for example, adherence to statin therapy in the first two years of prescribing them, may reduce hospitalization rates and direct medical costs in the subsequent years [37]. Shroufi and Powles showed that improving adherence to statins would prevent twice as many additional deaths compared to a strategy of lowering the CV threshold for statin therapy [38].

Several studies have sought to find predictors of statin non-adherence, it was concluded that there were inconsistencies and wide variation in socio-demographic and clinical predictors associated with statin non-adherence [4, 39], such variation might stem from the diversity of study designs, populations, and measurement methodologies, as well as secular trends in statin use [26, 39]. Medication adherence is believed to be influenced by factors beyond the clinical and demographic factors [4, 6], for example, the extended Self-Regulatory Model (SRM), which includes both illness and treatment beliefs, was successful in explaining variations in adherence among patients with certain chronic diseases [40], medication beliefs have also been considered as predictors of medication non-adherence [41].

1.1.7 Beliefs about Medication

Beliefs about medications among patients have been assessed quantitatively with a scale developed by Horn et al., the "Beliefs about Medicines Questionnaire (BMQ)" which was developed in the United Kingdom (UK) to measure patients' beliefs about medicines in a wide range of diseases. Since then, BMQ has been translated into several languages to assess beliefs about medicines, like diabetes mellitus, mental health illnesses rheumatoid arthritis and others [6, 42]. It assessed medications beliefs using four different dimensions including specific necessity to use medications, concerns about efficacy or side effects related to those medications, perceptions about overuse of medications by physicians and general harmful nature of medications [6].

1.2 Beliefs Contextual Framework

The beliefs about medications necessity and concern explain non-adherence attitudes for patients taking chronic medications [43]. This suggest that patients weight up their needs for the treatment against their concerns about adverse consequences when they taking medications. The Necessity-Concerns Framework was assessed in explaining adherence to prescribed medications [44], Horne R. et al. found that higher adherence was associated with stronger perceptions of necessity of treatment, and fewer concern about the treatment [44]. Figure 1.2.1 illustrates the suggested relations between variables and medication beliefs on medication adherence and the therapeutic

outcome obtained. The more beliefs about the importance of a certain medication the more adherent the patients will be then they get their goaled therapeutic outcome. Figure (1.2.1)

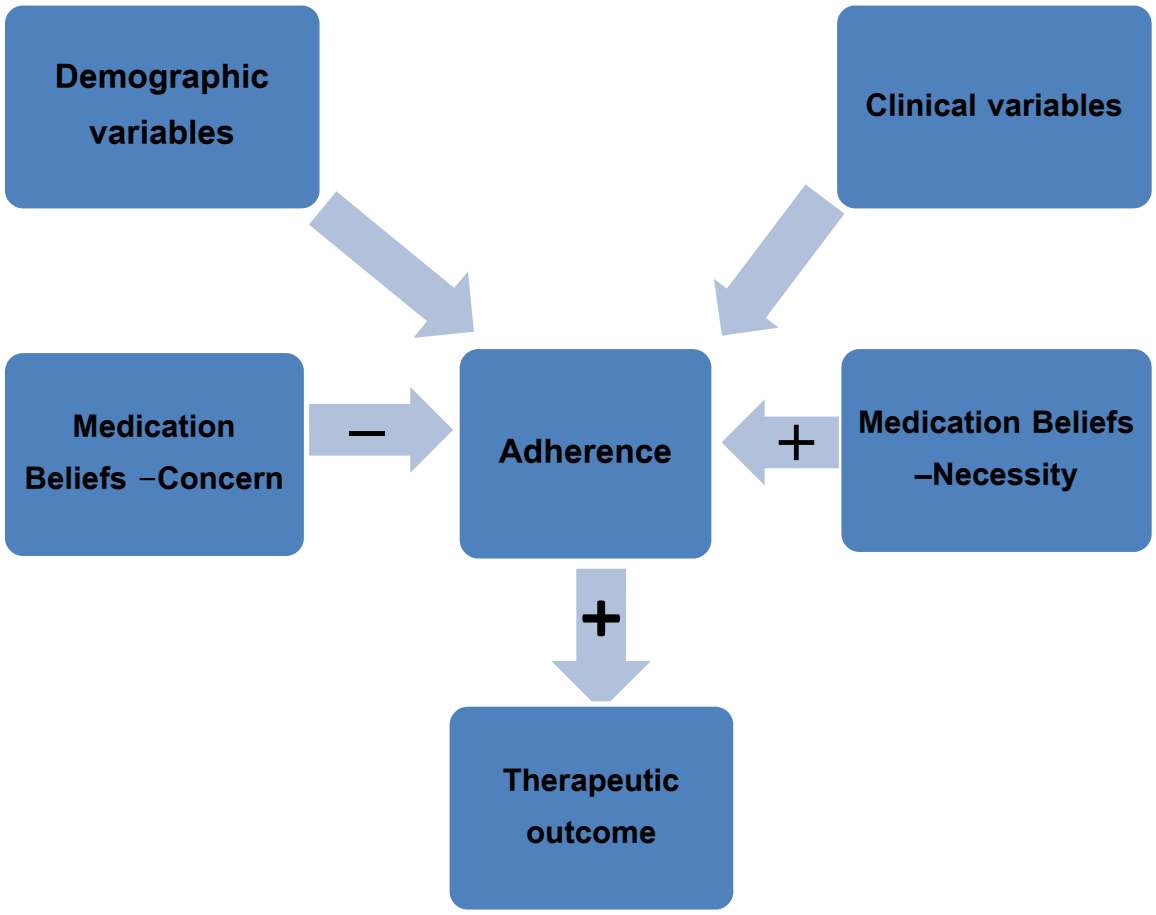

Figure 1.2.1 the contextual framework for medications

1.3 Objectives of the study

1.3.1 General objective

The objective of this study was to assess beliefs about statin medications and its association with statin adherence.

1.3.2 Specific objectives

1. To measure adherence to statin medication using 8-items Morisky Medication Adherence Scale (MMAS-8).
2. Assess patients' medication beliefs about statin medications using Beliefs about Medicines Questionnaire (BMQ).
3. To find if there is association between CV risk factors and non-adherence to statins.
4. To find if there is any correlation between self-reported adherence to statins and patients' beliefs about medications in general and statins in specific.
5. To find if LDL-C goal achievement correlate significantly with self-reported adherence and beliefs.

1.4 Significance of the study

Several studies were carried out in the Arab world about medication adherence [5, 45]. However, none of these studies investigated the effects of beliefs about statins on adherence to statin therapy. Most of these studies focused on influence of demographic and clinical factors on medication adherence. Furthermore, it has been reported that adherence to statin therapy is different from adherence to other cardiovascular or anti-diabetic medications [36, 46]. In the Arab world, beliefs about medicines and illnesses are supposed to be different from those in Asia and Europe due to differences in culture, religion and degree of public health awareness [47]. Identifying the predictors of statin adherence will help to implement strategy to improve adherence to statin mediations. In addition, it will help to implement awareness about the importance of statin medication in patients with risks of CV diseases.

1.5 The expected outcomes of the study

The expected outcomes of the study is to find the prevalence of adherence to statin medication among Palestinian patients, which help the clinicians and other health care provider detect patients trends of anon-adherence and to identify patients with high potential for non-adherence. Also to help health care planners and public health workers look for methods to minimize modifiable risk factors associated with non-adherence to statin medications.

Chapter Two
Literature review

2.1 Prevalence of statin adherence

Non-adherence to statins medications was common around the world. One study found that nearly 34% of patients discharged on Aspirin, Beta-blockers and Statin stopped at least 1 medication and 12% stopped all three medications within one month of hospital discharge. It was also found that patients who discontinue taking evidence-based medications are at increased risk of mortality [48]. Adherence to statins was low as seen in a cohort study conducted in Canada and published in 2002; two-year adherence rate was found to be 40.1% in patients with acute coronary syndrome, 36.1% for patients with chronic coronary syndrome and 25.4% for primary prevention patients, this low rate of adherence, patients received limited benefits from statins [49]. Although the period after hospital discharge appears to be particularly high-risk period, statin non-adherence continues to decline over the time [36]. Another study conducted in USA found that 68% of the statin users were adherent to these medications. Adherent statin users were more likely to achieve recommended LDL-C level [50]. In another study conducted in Denmark 83% of the studying patients was adherent to statin medications [51]. In a study conducted in Netherlands between 2008 and 2009 less than 90% of patients reported adherence to statin medications, non-adherence was associated with younger age, high total cholesterol level during prescription period and a relatively low untreated total cholesterol level [52].

2.2 Predictors of statin adherence

The factors that influence patient adherence to statin medications can be categorized into patient factors, physician factors and health system factors. While Factors which patient involved are sociodemographic factors, and clinical factors. In a study conducted in USA in 2011 used an internet survey found that side effect 63% and cost 32% was the primary reason for statin therapy discontinuation [53]. Another study conducted in USA in 2005 in primary care clinics found that reported adherence was 45% at 6-months follow up, the perception of risk, toxic effect of medication, expected treatment duration, Hispanic and younger age were predictors of statin non-adherence [54]. In another cohort study conducted in USA in 2009 concluded found that patients with younger age, fewer comorbidity, lower rates of hospitalization, fewer concurrent prescription and fewer clinic visits were associated with poorer adherence to statin medications [55].

A study conducted in Denmark to explore effects of socioeconomic factors on statin adherence found that adherence to statin medication was decreased with decreasing income especially in men aged 40-64 years [56]. A study conducted in Hong Kong in 2003 found that the adherence to statins was high among Chinese patients at high risk of coronary heart disease (CHD), it was also found that living with family and duration of therapy were negative predictors of adherence to statin therapy [57]. In A meta-analysis study published in 2013 conducted to evaluate the effect of race and gender on

adherence to statin therapy for primary or secondary prevention found that women and nonwhite patients was at increased risk of non-adherence to statin medications [58]. A study conducted in Canada in a family practice clinics in 2005 found that high adherence rates was reported by 63% of patients using statins measured by Morisky scale. Being an elderly taking four to six medications and having regular exercise or healthy diet were associated with high adherence to statin therapy [59].

2.3 Beliefs about medications and adherence

Robert Horne presented in 1999 the BMQ a novel method for assessing cognitive representations of medication [60]. He conducted a study to assess relationships between reported adherence and medication beliefs among four chronic illness patients; he found that higher reported adherence was correlated with higher necessity score and higher concerns score correlated with lower reported adherence, medication beliefs were more powerful predictors of reported adherence than the clinical and sociodemographic factors [6].

A study published in 2009 studied the relationships between beliefs about medication used BMQ and self reported adherence used MMAS-8 found that 53% of patients reported low medication adherence. Negative beliefs about medications, patients < 65 years of age, low medication self-efficacy, and hyperlipidemia was associated with low self reported adherence [61]. Another study conducted in Sweden in 2009 to identify factors which

could predict reported adherence measured by MMAS to patients using statin, found that necessity of the lipid lowering medical treatment and side effects were associated with high and low adherence rates respectively [62].

A cohort study conducted in Ireland in 2005 to evaluate the relationship between LDL-C goal achievement and both medication adherence measured by MMAS and beliefs measured by BMQ concluded that BMQ were a predictor for self-reported adherence, but not of LDL-C goal achievement. Statin non-adherence could be responsible failing to achieve goaled LDL-C level [63]. In a study conducted in Spain in 2012 on psychiatric outpatients used MMAS and BMQ found that no correlation between socio-demographic variables and adherence was found, but adherence was correlated with BMQ Harm and Concern, and also non-adherence was associated with severity of illness [64]. Another cohort study conducted in USA on diabetic patients used MMAS and BMQ found that modifiable patient disease and medication beliefs were predictors of medication adherence [65].

2.4 In the Arab world

In a study conducted in a family practice clinic in Jordan in 2011 to identify factors associated with adherence to statin medications measured by MMAS found that 75.5% of patients reported high adherence, patients who take more than 7 medications, hypertensive patients, who were non-depressed reported high adherence to statin medication [66].

Sweileh et al. found that non-adherence to antipsychotic medications and oral hypoglycemic medications measured by MMAS was common in Palestinian people [45, 67]. In another study conducted by Zyoud et al. on hypertensive patients found that 37% of patients reported low adherence to their medications measured by MMAS and low treatment satisfactions was associated with low adherence to medications [68].

Chapter Three
Materials and Methods

3.1 Methods

3.1.1 Study design and Settings

This was a cross-sectional analytical study for the purpose of evaluating the influence of beliefs about medicines, demographic and clinical factors on adherence to statin therapy among Palestinians. This study was carried out at a non-governmental charitable primary healthcare clinic (Al-Rahma) in Nablus city. Al-Rahma center is a non-governmental center that provides care for patients with chronic illnesses. Nablus is the largest city in northern West-Bank of Palestine. Residents of Nablus city are predominantly Arabs. There are five main healthcare providers of health services in Palestine: Ministry of health, United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNRWA), Non-governmental organizations (NGOs), Palestinian Military Medical Services (PMMS) and Private for section, the latter is profitable.

3.1.2 Study Sample population

This study included a convenience sample of adult population. Participants were recruited from Al-Rahma clinics while waiting to be seen by their health care providers.

3.1.3 Inclusion criteria

The inclusion criteria for this study were:

1. Males and females 18 years old and older who self-report using statin medications for at least 2 months.
2. Willing to participate in this study.

The use of statin by the participants was confirmed by the attending healthcare provider. The focus was made on atorvastatin because it is the most commonly prescribed and dispensed statin in the Palestinian ministry of health since it is listed in the Palestinian essential drug list 2013.

3.1.4 Exclusion criteria

The exclusion criteria were based on:

1. Availability of any physical and or mental conditions that interfere with participation.
2. Inability to obtain venous blood sample.
3. Patients taking other medication with statin for reducing LDL-C level.

3.1.5 Sample size

Previous studies in Palestine indicated that medication non-adherence among patients with chronic illness is in the range of 40 – 50%. The sample size was estimated based on the following assumptions: a descriptive study with dichotomous outcome (adherent versus non-adherent), rate of medication non-adherence to be as low as 40%, confidence interval width of 20% and confidence limit to be 95%. Therefore, a prevalence-based sample of a minimum of 92 statin users was calculated for this study based on the Mendenhall equation (1983) [69]:

$$S=4Z^2P(1-P)W^2$$

- Z value is derived from our anticipated confidence level. Recommended value of Z score is 1.96 to give confidence level of 95%.
- P was derived from the prevalence of adherence to statins medication.
- W is the confidence interval intended width.

In order to minimize erroneous results and increase the study reliability, the target sample size was increased to 200 patients.

3.1.6. Ethical approval

This study received approval from Institutional Review Board (IRB) at An-Najah National University, and the approved from the Public health department of the Faculty of Graduate Studies at An-Najah National University was also obtained. Written consent was also obtained from the patients prior to the commencement of the study. All participants completed the questionnaires in a private area in the clinic.

3.1.7 Participant recruitment procedure

A brief screening for recruitment of participants was conducted by the investigators to identify potential participants in the following manner: every person in the waiting area was asked if he is willing to talk to the investigator. If the person agreed to talk to the investigator for possible participation, then an informed consent was read and obtained by the investigators at the clinic. Once the consent was signed, verification of inclusion and exclusion criteria took place. The questionnaires required for the study were presented and explained for its completion during this session.

3.1.8 Pilot study

A pilot study of approximately 30 participants was carried out at Al-Rahma clinics and the questionnaire was adjusted accordingly. The questionnaires that required for the study were completed included:

1. Demographic and clinical data about the participants.
2. Morisky Medication Adherence Scale (MMAS-8) to determine level of medication adherence.
3. Beliefs about medicines questionnaire (BMQ) to determine beliefs about medicines.

3.2 Instruments

3.2.1. Medication adherence

Adherence to statin therapy was measured using Morisky Medication Adherence Scale (MMAS-8) [29]. Approval to use and translate the MMAS-8 into Arabic language was obtained from the developer. The translation was carried out according to standard forward and backward method. The Arabic-translated version of MMAS-8 was used in previous publication [45]. The MMAS-8 is an eight items questionnaire designed to measure medication adherence. It is composed of seven Yes/No questions. Details of the Arabic translation and its use were described previously [45]. The eighth question is a 5-points likert scale. In this study, patients with a total score of MMAS-8 less than 6 are considered to have poor medication adherence. The internal consistency of the MMAS-8© was alpha = 0.74.

3.2.2. Beliefs about medicines

Beliefs about Medicines was assessed using Beliefs about Medicines Questionnaire (BMQ) [70]; Approval to use and translate BMQ was obtained from the developer. Translation of BMQ was also carried out according to the standard forward and backward method. BMQ consists of two sections, general and specific. The Specific section assesses patients' beliefs about medications prescribed for a particular illness and comprises two scales assessing personal beliefs about the necessity of prescribed medication for controlling their illness (5 statements) and concerns about the potential adverse consequences of taking it (5 statements). Each statement has a five - point likert scale answers (strongly disagree, disagree, uncertain, agree, and strongly agree). The answers are scored from one (strongly disagree) to five (strongly agree). Points of each scale are summed to give a scale score. Higher scores indicate stronger beliefs in the concepts of the scale.

Specific-necessity and specific-concerns scales have 5 items and scores range from 5 to 25. Higher specific-necessity scores represent stronger perceptions of personal need for the medication to maintain health now and in the future. Higher specific-concerns scores represent stronger concerns about the potential negative effects of the medication. The Internal consistency for the BMQ subscales showed values between alpha = 0.72 – 0.78.

3.2.3 Demographic and health Information

Demographic obtained include age, gender, years of education, and body mass index (BMI) as calculated form body weight and height. Information about medical history and medications was also obtained. The medical history components is a list of illnesses commonly identified with dyslipidemia where the response is in a dichotomous (yes/no) format with an option to write additional illnesses not included in the list. All the participants were asked to report all the medications that they use on chronic basis. The questionnaire was available in Arabic.

Blood samples were collected from an ante-cubital vein punctures and was collected while the subject or client in a sitting position. The blood sample was taken by well trained and experienced lab technician, the blood sample was separated immediately, and the serum was kept in the refrigerator until it's carried daily in a cool bag to the university lab where LDL-C level was measured using HUMAN kit, Germany, the procedure was doe as elucidated in the leaflet (Appendix 6).

3.2.4 Data management and statistical analysis

During the pre-analysis phase, the data were coded to maintain confidentiality for all participants. Participants were given an identification number assigned by the investigator for use throughout the study.

Descriptive statistics was carried out for all variables and expressed as mean (±SD) for continuous variables with normal distribution. Non-normally distributed continuous variables were expressed as median (inter-quartile range: Q1-Q3). Normality of the data was tested by Kolomogrov-Smirnov test. Internal consistency was assessed using Cronbach's alpha. Factors associated with non-adherence (MMAS-8 score < 6) were analyzed with binary logistic regression followed by multiple logistic regression analysis. The dependent variable was non-adherence (coded as 1). A p value of < 0.05 was considered statistically significant. The association between non-adherence and a particular variable of interest was evaluated by calculating an odds ratio (OR) at 95% confidence interval (Cl 95).

Chapter Four

Results

4. Results

4.1 General characteristics of the participants

During the study period, a total of 210 patients who reported having dyslipidemia and using statin medications were asked to participate. The majority of the participants (196; 93.3%) were using atorvastatin and 14 participants were using other statin medication. To avoid any mis-interpretation of the data, analysis was made on those using atorvastatin and the remaining 14 patients were excluded from analysis. The mean (± SD) of the age of the 196 participants was 58 (±8.1) (range = 39 – 80) years; 45 patients were elderly (≥65 years). About two thirds (123; 62.8%) of the participant were males, while 73 (37.2%) were females.

Eighty seven (44.4%) participants reported that they had college education, while 109 (55.6%) had school education or lesser. The mean (SD) of body mass index (BMI) for the participants was 30.6 (±4.8) kg/m^2 and most (87.2%) participants had BMI above normal level. The majority (143; 73%) of the participants were non-smokers. When participants were asked about their life style, 53 (27%) reported that they neither exercise nor eat healthy diet; 123 (62%) reported that they either exercise or eat healthy diet, and finally 20 (10.2%) reported that they exercise and eat healthy diet. Table (4.1.1)

Table (4.1.1): Sociodemographic characteristics for the studying patients.

Variable	Statistic Mean (± Std) or Frequency (percent)
Age (years)	58 (± 8.1)
≥ 65	45 (23%)
<65	151 (77%)
Gender	
Male	123 (62.8%)
Female	73 (37.2%)
Education	
< college	109 (55.6%)
≥ college	87 (44.4%)
BMI	30.6 (± 4.8)
Normal < 25 kg/m^2	25 (12.8%)
Above normal ≥ 25 kg/m^2	171 (87.2%)
Smoking	
Yes	53 (27%)
No	143 (73%)
Life style	
- Neither exercise nor healthy diet.	53 (27%)
- Either exercise or a healthy diet.	123 (62.8%)
- Exercise and healthy diet.	20 (10.2)

Abbreviations: Std: stander deviation, BMI: body mass index

The participants reported a mean of 5 (±2.5) medications taken on regular daily basis. The mean (±SD) duration of statin use was 39.2 (± 45.2) months. The majority (174; 88.8%) was taking atorvastatin ≤ 20 mg daily while the remaining 11.2% were taking atorvastatin ≥ 20 mg daily. Seventy three (37.2%) participants reported having cardiovascular diseases combined with dyslipidemia, 28 (14.3%) reported having diabetes mellitus combined with dyslipidemia, 84 (42.9%) participants reported having both cardiovascular diseases and diabetes mellitus combined with dyslipidemia, and only 11 (5.6%) participants reported having dyslipidemia alone. About one third (33.7%) of the participants reported having at least one heart attack during their life and 93 (47.4%) of the participants reported having invasive heart procedure. The mean (±SD) of measured low density lipoprotein cholesterol LDL-C for the participants was 90.3 (±32.72) mg/dl. Table (4.1.2)

Table (4.1.2): Clinical characteristics for the studying patients.

Variable	Statistic Mean (± Std) or Frequency (percent)
Number of chronic Number of medications other than statin < 5	98 (50%)
≥ 5	98 (50%)
Duration of statin use	
≤ 2 years	112 (57.1%)
>2 years	84 (42.9%)
Had a history of MI	
Yes	66 (33.7%)
No	130 (66.3%)
Had Invasive heart procedure	
Yes	93 (47.4%)
No	103 (52.6%)
Dyslipidemia comorbidity	
-None	11 (5.6%)
-CVD	73 (37.2%)
-DM	28 (14.3%)
-CVD & DM	84 (42.9%)
LDL-C level (mg/ dL)	90.3(±32.7)
Atorvastatin daily dose	
- ≤ 20mg	174 (88.8%)
- ≥ 40mg	21 (11.2%)

Abbreviations: Std: stander deviation, MI: myocardial infarction, CVD: cardiovascular disease, DM: diabetes mellitus, LDL-C: low density lipoprotein cholesterol.

4.2 Adherence to and Beliefs about Statins

One hundred and eight (55.1%) patients were considered non-adherent (MMAS-8© adherence score < 6) while 88 (44.9%) were considered adherent (MMAS-8© adherence score ≥ 6). Ninety (45.9%) of the participants reported that they sometimes forgot to take their statin medications; 53.1% of the participants reported that they did not take their medications on at least one occasion in the two weeks before the interview; 14.8% of the participants reported that they discontinued taking their medications without telling their doctor when they felt worse upon taking their medications; 21.9% of the participants reported that they sometimes forgot to take their medications with them when they traveled or left home; 75.5% of the participants reported taking their statin medications on the day before the interview; 35.7% reported that they stopped taking their medicines when they felt like their LDL-C level is under control; 45.4% of the participants reported feeling hassled by their treatment plans; and finally 73.5% reported that they never or rarely had difficulty remembering to take all their medicines. Figure (4.2.1)

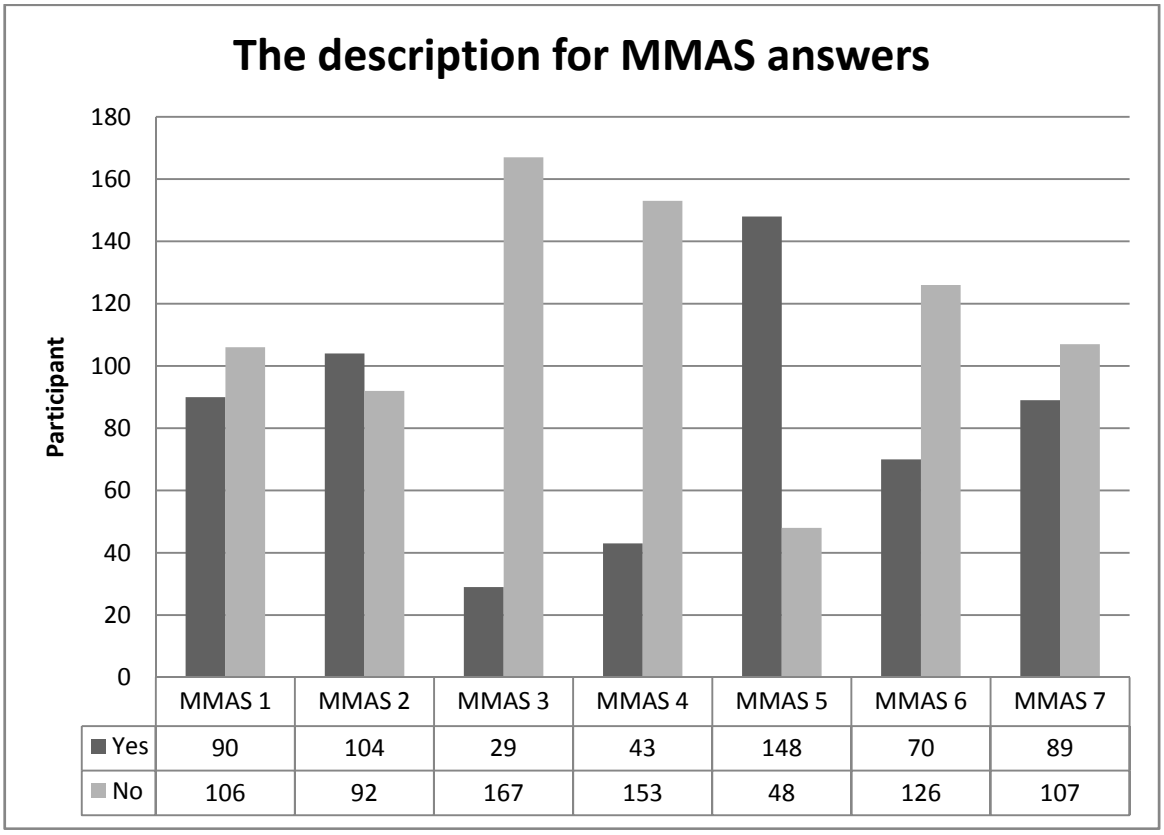

Figure (4.2.1) the description for MMAS-8 answers for the studying patients.

4.3 Beliefs about statins

The majority (74%) of the participants endorsed the beliefs that their statin medications protected them from getting worse, and that 53.5% endorsed the belief that their health status in the future will depend on statin medications. Concerns about medicines were also reported. Many participants (38.3%) indicated that they are worried about long term effects of statin medications and 35.2% reported that having to take statin medications worries them. Table (4.3.1)

Table (4.3.1) the description for BMQ answers for the studying patients.

Beliefs about Medicines Questionnaire	Agree or Strongly agree
BMQ 1	85 (43.4%)
BMQ 2	87(44.4%)
BMQ 3	92 (47%)
BMQ 4	145 (74%)
BMQ 5	105 (53.5%)
BMQ-specific necessity score mean (±SD)	16.1(±4.4)
BMQ 6	75 (38.3%)
BMQ 7	69 (35.2%)
BMQ 8	80 (13.8%)
BMQ 9	14 (7.1%)
BMQ 10	44 (22.5%)
BMQ-specific concerns score mean (±SD)	12.3(±4.2)

4.4 Factors associated with adherence

Univariate analysis of tested variables showed that age, duration of statin use, history of invasive heart procedure and concerns about statin medications were significantly associated with non-adherence (Table 4.4.1, 4.4.2). Elderly patients had lesser odds [0.45 (0.23 – 0.9] of being non-

adherent. Similarly, patients with longer duration of statin use had lesser odds [0.46 (0.3 – 0.8)] of being non-adherent. Participants who did not have a history of invasive heart procedure had higher odds [2 (1.1 – 3.0)] of being non-adherent. Finally, patients with stronger concerns about statin medications had higher odds [2 (1.1 – 3.0)] of being non-adherent.

Table 4.4.1 Univariate analysis of sociodemographic factors associated with non-adherence.

Variable	Non-Adherent N = 108 (55.1%)	Adherent N = 88 (44.9%)	OR (95% CI)	P-value
Age (years)			Reference	
- < 65	90 (83.3%)	61 (69.3%)	0.45 (0.23 –	0.022
- ≥ 65	18 (16.7%)	27 (30.7%)	0.9)	
Gender			Reference	
- Male	62 (57.4%)	61 (69.3%)	1.7 (0.93 –	0.087
- Female	46 (42.6%)	27 (30.7%)	3.0)	
Education			Reference	
- < college	65 (60.2%)	44 (50.0%)	0.66 (0.38 –	0.154
- ≥ college	43 (39.8%)	44 (50.0%)	1.17)	
Smoking			Reference	
- Yes	32 (29.6%)	21 (23.9%)	0.74 (0.4 –	0.37
- No	76 (70.4%)	67 (76.1%)	1.4)	
BMI			Reference	
- Normal < 25	12 (11.2%)	13 (14.8%)	1.4 (0.6 –	0.46

- Above normal ≥ 25	95 (88.2%)	75 (85.2%)	3.2)	
Life style Neither exercise nor healthy diet. Either exercise or a healthy diet. Exercise and healthy diet.	 26 (24.1%) 74 (68.5%) 8 (7.4%)	 27 (30.7%) 49 (55.7%) 12 (13.6%)	Reference 1.6 (0.8 – 3) 0.7 (0.24 – 2.0)	 0.15 0.17 0.5

Table 4.4.2 Univariate analysis of clinical factors associated with non-adherence

Variable	Non-Adherent N = 108 (55.1%)	Adherent N = 88 (44.9%)	OR (95% CI)	P-value
Number of chronic medications other than statin - < 5 - ≥ 5	 58 (53.7%) 50 (46.3%)	 40 (45.5%) 48 (45.5%)	Reference 0.72 (0.4 – 1.3)	 0.25
Duration of statin use - ≤ 2 years - >2 years	 71 (65.7%) 37 (34.3%)	 41 (46.6%) 47 (53.4%)	Reference 0.46 (0.3 – 0.8)	 0.007
Had a history of MI Yes No	 34 (31.5%) 74 (68.5%)	 32 (36.4%) 56 (63.6%)	Reference 0.8 (0.4 – 1.5)	 0.47

Had Invasive heart procedure Yes No	43 (39.8%) 65 (60.2%)	50 (56.8%) 38 (43.2%)	Reference 2 (1.1 – 3.0)	0.018
Dyslipidemia comorbidity -None -CVD -DM -CVD & DM	6 (5.5%) 42 (38.9%) 19 (17.6%) 41 (38.0%)	5 (5.7%) 31 (35.2%) 9 (10.2%) 43 (48.9%)	Reference 1.1 (0.32-4.0) 1.8 (0.42 – 7.33) 0.8 (0.2 – 2.8)	0.35 0.85 0.44 0.72
LDL-C level (mg/ dL)	93.6±33.2	86.3±31.9	1.0 (0.99 – 1.06)	0.12
Atorvastatin daily dose - ≤ 20mg - ≥ 40mg	99 (50.5%) 9 (4.6%)	75 (38.3%) 13 (6.6%)		
Specific-necessity belief	15.5 ± 4.3	16.8± 4.4	0.94 (0.88 – 1.0)	0.054
Specific-concern belief	13.04 ± 4.2	11.5 ± 4.0	2 (1.1 – 3.0)	0.009

Level of significance is $P<0.05$

Multivariate analysis showed that stronger concerns about statins was associated with higher odds [1.094 (1.094 – 1.178)] of non-adherence while longer duration of statin use was associated with lower odds [0.533 (0.288 - .987)] of non-adherence (Table 4.4.3).

Table 4.4.3 Multivariate analysis of factors associated with non-adherence

Variable	B	S.E.	Wald	p-value	OR	95% CI for OR	
						Lower	Upper
Age 65 (≤ 65 years)	-0.569	0.362	2.465	0.116	0.566	0.278	1.152
Duration of statin use (< 2 years)	-0.629	0.314	4.009	0.045	0.533	0.288	0.987
Had no Invasive heart procedure	0.484	0.310	2.438	0.118	1.622	0.884	2.978
Specific-concern belief	0.090	0.037	5.813	0.016	1.094	1.094	1.178

Abbreviations: CI: confidence interval, β: coefficient of predictor variables, S.E.: Standard error, OR: odd ratio. Level of significance is P< 0.05.

Chapter Five

Discussion and Conclusions

5.1 Discussion

We assessed the influence of patients' beliefs, demographic and clinical factors on adherence to statin therapy. We used self-reporting method to measure medication adherence because it is considered the simplest and the least expensive method. George et al. had found that when a valid scale, like Morisky questionnaire, is used to assess medication adherence, the obtained scores will be accurate with both sensitivity and specificity of over 70% [71]. The 8-item Morisky Medication Adherence Questionnaire (MMAS-8©) has been translated into different languages and has been validated in patients with different types of chronic illnesses [29-31, 72, 73]. We used the "Beliefs about Medicines Questionnaire (BMQ)" to measure patients' beliefs about medicines. The BMQ [29] has been translated into several languages to assess beliefs about medicines across a wide range of diseases like diabetes mellitus, mental health illnesses, rheumatoid arthritis and others [6, 42].

The Multivariate analysis carried out in the study showed that concern or negative beliefs about statin about statin medications was the most significant factor associated with non-adherence. This result is in accordance with several international studies that confirmed the relationship between non-adherence and individual beliefs about medication non-adherence [53, 55, 62, 74]. A study carried out in United States (USA) to examine the relationships between beliefs about medications, health literacy, and self-reported

medication adherence concluded that patients who had negative beliefs about medications reported low medication adherence [61]. Another study carried out in a community-dwelling sample of older adults found that beliefs about medication can be powerful barriers to a successful adherence strategy [75]. A study by Phatak, et al., found a positive bivariate associations between specific concerns about medications, perceived general harmful effects of medications, and perceived overprescribing of medications by physicians and medication non-adherence[76]. Another study in Japan by Iihara, et al., concluded that beliefs on which individual Japanese patients with chronic diseases attach value were potential factors for - intentional non adherence [77]. A study by Clifford, et al., concluded that when patients start a new medication for a chronic condition, intentional non-adherers hold beliefs significantly different from those of adherers and unintentional non-adherers [78]. A study by Mardby, et al., concluded that increased awareness of the patient's beliefs about medicines is needed and that healthcare providers should encourage patients to express their views about medicines in order to stimulate concordance and adherence to medication [79].

5.2 Contextual framework for LDL-C levels

We found there is no significant relation between adherence and LDL-C level in this study, but non-adherence to statin medication was associated significantly with high concern about the adverse effect of the statin medication. Taking statin for more than two years was slightly associated with high adherence to statin medications. There are many variables interfere in the level of LDL-C in the blood beyond adherence to medication, statin itself, dose of statin, type of dyslipidemia, genetics, physical activity, diet and other factors may affect the LDL-C level more than adherence to stain medication. Figure (5.2.1)

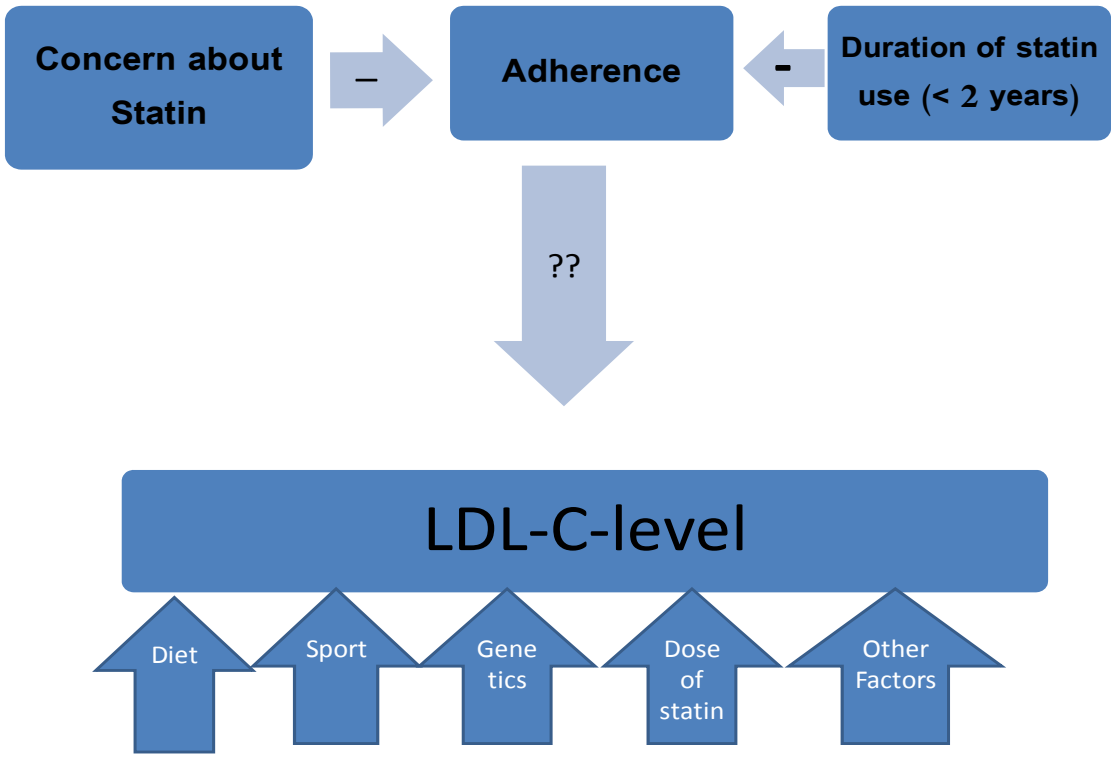

Figure 5.2.1 the Contextual framework for LDL-C levels

5.3 Limitations of the study

Our study had some limitations. A self-report method was used to assess medication adherence. Although more precise estimates of medication adherence can be obtained through direct methods, the self-report assessment of medication adherence provided a practical measure for this study. The validity of the Arabic version of adherence and belief scales has not been tested and further studies are needed to confirm validity of both scales among patients in the Arab world. Regardless, this is one of the few studies in the Arab world to investigate beliefs about medicines and to investigate the association between beliefs and adherence. Caution should be exercised in generalizing our study's findings due to the use of convenient sample from one institution. Overestimation of adherence may have occurred because self-reporting was used for assessment. Although the sample size used in our study was relatively large, it is not representative of all statin users in Palestine.

5.4 Conclusion

As a conclusion, lesser concerns in one's statin therapy is significantly associated with high adherence and that assessment of medication belief is important in understanding non-adherence among statin users. The Beliefs about Medicines Questionnaire may identify people at risk of poor adherence and therefore providing opportunities to improve adherence. Increasing awareness and education to statin users regarding statin therapy and their disease might positively influence their medication adherence and therapeutic outcome.

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Appendices

1. **IRB:**

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National University
Faculty of Medicine

بسم الله الرحمن الرحيم

جامعة
النجاح الوطنية
كلية الطب

IRB Approval letter

Study title:
Relationship between Beliefs about Medicines and Adherence on LDL-C Level among Statin Users at Al-Rahma clinic in Nablus City

Submitted by:
Khaled Qadah

Date Reviewed:
Dec 19, 2011

Date approved:
Dec 21, 2011

Your study titled" Relationship between Beliefs about Medicines and Adherence on LDL-C Level among Statin Users at Al-Rahma clinic in Nablus City."Was reviewed by An-Najah National University IRB committee & approved on Dec 21, 2011

IRB

Samar Musmar,MD, FAAFP
IRB Committee Chairman,
An-Najah National University

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2. MMAS-8

Morisky 8-Item Medication Adherence Questionnaire

Question	Patient Answer (Yes/No)	Score Y=1; N=0
Do you sometimes forget to take your medicine?		
People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past 2 weeks, were there any days when you did not take your medicine?		
Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along your medicine?		
Did you take all your medicines yesterday?		
When you feel like your symptoms are under control, do you sometimes stop taking your medicine?		
Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?		
How often do you have difficulty remembering to take all your medicine? __ A. Never/rarely __ B. Once in a while __ C. Sometimes __ D. Usually __ E. All the time		A = 0; B-E = 1
	Total score	

Scores: >2 = low adherence
1 or 2 = medium adherence
0 = high adherence

Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. *Med Care.* 1986;24:67-74.

3. BMQ

BMQ-specific necessity	
BMQ 1	My life would be impossible without my statin medicine
BMQ 2	Without my statin medicine I would be very ill
BMQ 3	My health , at present ,depends on my statin medicine
BMQ 4	My statin medicine protect me from becoming worse
BMQ 5	My health in the future will depend on my statin medicine
BMQ-specific concerns	
BMQ 6	I sometimes worry about the long-term effects of my statin medicine.
BMQ 7	Having to take statin medicine worries me.
BMQ 8	I sometimes worry about becoming too dependent on my statin medicine.
BMQ 9	My statin medicines disrupt my life.
BMQ 10	My statin medicines are a mystery to me.

4. The study questionnaire:

دراسة لقياس العلاقة بين معتقدات والتزام الدوائي عند المرضى المستخدمين للستاتين على مستويات البروتين الشحمي منخفض الكثافة في مستوصف الرحمة بمدينة نابلس(LDL)

هدف الدراسة: هذا البحث يقوم به طالب ماجستير في الصحة - جامعة النجاح الوطنية لقياس مدى ارتباط ادراك والتزام المرضى على مستويات البروتين الشحمي منخفض الكثافة، هذه المعلومات ستستخدم لأغراض البحث العلمي فقط ولن يتم استخدامها لأي أغراض أخرى.

رقم الاستبيان:..... التاريخ:...../...../.....

نتيجة فحص المختبر TC.....

.....LDL

القسم الأول: معلومات خاصة بالمريض:

1. الجنس: A.□ ذكر B.□ انثى
2. العمر: .....
3. عدد سنوات الدراسة:
   A. اقل من 12 سنة
   B. 12سنة فأكثر
4. منذ متى بدأت بتناول دواء خافض الدهنيات؟ (.....) أشهر، (.....) سنوات.
5. ما هو نوع الدواء الذي تستخدمه؟ ..... ما هي جرعته؟ .....
6. هل أنت مدخن (يتضمن الارجيلة):
   A. نعم.
   B. لا
7. ما هو وزنك: .....

8. طولك.....

9. BMI.....

10. هل تمارس النشاط البدني (الرياضة) بشكل منتظم (نصف ساعة يوميا لمدة خمسة ايام في الاسبوع)؟

1) نعم

2) لا

3) لا اعلم

11. هل تمارس حمية غذائية (تبتعد عن الاغذية التي ترفع الدهنيات)؟

1) نعم

2) لا

3) لا اعلم

12. هل تتناول الخضروات والفواكه يوميا؟

1) نعم

2) لا

3) لا اعلم

القسم الثاني: قياس مدى الانضباط الدوائي:

#	السؤال	نعم	لا	
1	هل تنسى أحيانا أن تتناول دواء الخافض للدهون الخاص بك؟			
2	لا يتناول الناس أحيانا الأدوية الخاصة بهم لأسباب أخرى غير			

	النسيان. هل كان هناك أية أيام على مدى الأسبوعين الماضيين لم تتناول فيها دواء الخافض للدهنيات؟						
3	هل سبق لك أن خفضت أو توقفت عن تناول الدواء الخافض للدهنيات دون أن تخبر طبيبك وذلك لأنك شعرت بأن حالتك الصحية أصبحت أسوأ عندما تناولت الدواء؟						
4	عندما تسافر أو تغادر المنزل، هل تنسى أحيانا اصطحاب الدواء الخافض للدهنيات؟						
5	**هل تناولت الدواء الخافض للدهنيات بالأمس؟**						
6	عندما تشعر بأن مستوى الدهنيات تحت السيطرة، هل تلجأ أحيانا إلى التوقف عن استعمال الدواء؟						
7	تناول العلاج بشكل يومي قد لا يروق لبعض الناس. هل تشعر بعدم رضا أو امتعاض أو تشويش بسبب التزامك اليومي بالدواء؟						
8	كم من الأحيان تواجه صعوبة في تذكر تناول جميع أدويتك؟	**نادرا/ أبدا**	**قليلا**	**أحيانا**	**عادة**	**دائما**	
8	**Score**						

القسم الثالث: المعتقدات حول الأدوية

آراؤك حول الأدوية الموصوفة لك، نحن نرغب في سؤالك حول رأيك في الأدوية الموصوفة لك، هذه عبارات قام أناس آخرين بتكوينها حول أدويتهم. الرجاء تحديد إلى أي مدى أنت توافق أو لا توافق على هذه العبارات بوضع إشارة في المربع المناسب. لا يوجد إجابات صحيحة أو خاطئة. نحن مهتمون في آرائك الخاصة.

استبيان المعتقدات حول الأدوية-الجزء الخصوصي:

#	السؤال	أعارض بشدة 1	أعارض 2	غير متأكد 3	أوافق 4	أوافق بشدة 5
Specific- Necessity						
1	حياتي ستكون مستحيلة بدون أدوية خافضة الدهنيات					
2	بدون أدوية خافضة الدهنيات، سوف أكون مريضا جدا					
3	صحتي في الوقت الحالي تعتمد على أدوية خافضة الدهنيات					
4	أدوية خافضة الدهنيات تحميني من أن أصبح بحالة أسوأ					
5	صحتي في المستقبل سوف تعتمد على أدوية خافضة الدهنيات					
	Score					
Specific-Concerns						
6	أحيانا، أقلق بشأن الآثار طويلة المدى لأدويتي الخافضة للدهنيات					
7	الحاجة إلى تناول الدواء خافض الدهون تسبب لي القلق					
8	أحيانا أقلق من أن أصبح معتمدا جدا على أدويتي خافضة الدهنيات					
9	أدويتي خافضة الدهنيات تعطل حياتي					
10	أدويتي خافضة الدهنيات تعد لغزا بالنسبة لي					
	Score					

استبيان المعتقدات حول الأدوية-الجزء العمومي:

#	السؤال	أعارض بشدة 1	أعارض 2	غير متأكد 3	أوافق 4	أوافق بشدة 5
General-Overuse						
11	الأطباء يصفون أدوية كثيرة					
12	الناس الذين يستخدمون الدواء، عليهم أن يتوقفوا عن استخدامه بين الحين والآخر					
13	معظم الأدوية تسبب الإدمان					
14	العلاجات الطبيعية أكثر أمانا من الأدوية					
	Score					
General-Harm						
15	الأدوية تسبب ضررا أكثر من النفع					
16	كل الأدوية هي سموم					
17	الأطباء يضعون كثيرا من الثقة في الأدوية					
18	إذا أمضى الأطباء وقتا أطول مع مرضاهم، لكانوا وصفوا لهم أدوية أقل					
	Score					

13. عدد الأدوية المزمنة المتناولة بخلاف خافض الدهنيات: .....

14. هل تعلم المدة التي يجب على المريض فيها تناول دواء خافض الدهنيات؟

1) نعم .....

2) لا

15. هل تعلم مستوى الدهنيات الطبيعي في الدم (LDL)؟

1) نعم.....

2) لا

16. هل تعمل حاليا؟

1. نعم 2.لا

17. كيف تصف صحتك بشكل عام؟

1. ممتازة 2.جيدة جدا 3. جيدة4. مقبولة 5. ضعيفة 6.لا اعلم

18. هل لديك تامين صحي يؤمن لك ادوية الدهنيات عادة؟

1. نعم 2. لا 3. لا اعلم

19. إذا لم تأخذ الدواء على نفقة التامين الصحي هل تقوم بشراء الدواء على نفقتك الخاصة؟

1-نعم دائما 2-احيانا 3-لا 4-لا اعلم

20. هل تعاني من الأمراض التالية (يمكن اختيار أكثر من مرض):

A. أمراض قلب. B مرض السكري. .C ارتفاع في ضغط الدم .D توتر وعصبية E أمراض العظام والمفاصل .F سرطان .G أمراض مزمنة أخرى.....

21. هل عانيت من نوبات قلبية أو سكتات (جلطة) في السابق؟

1. نعم 2. لا 3. لا اعلم

22. هل تعرضت لقسطرة او عمليات جراحية في القلب؟

1. نعم 2.لا 3.لا علم

6. HUMAN LDL-C kit leaflet:

LDL CHOLESTEROL liquicolor

Direct Homogeneous Test for the Determination of LDL-Cholesterol
Enzymatic Colorimetric Test

Package Size

REF	10094	80 ml	Complete Test Kit
	10294	200 ml	Complete Test Kit

IVD

Intended Use

LDL CHOLESTEROL liquicolor is a direct homogeneous enzymatic assay for the quantitative determination of LDL-cholesterol (LDL). LDL is regarded as a lipid component increasing the risk for coronary heart disease (CHD). Together with HDL-cholesterol (determined e.g. with HUMAN's HDL CHOLESTEROL liquicolor, REF 10084) it is of diagnostic importance to estimate the individual risk for CHD.

Method

The assay combines two steps: In the 1st step chylomicrons, VLDL and HDL cholesterol are specifically removed by enzymatic reactions. In the 2nd step remaining LDL-cholesterol is determined by well established enzymatic reactions, also employing specific surfactants for LDL.

Reactions Principle

1st step:

HDL, VLDL, and chylomicrons —(CHE + CHO, specific conditions)→ cholestenone + H_2O_2

$2\,H_2O_2$ —(Catalase)→ $2\,H_2O + O_2$

2nd step:

LDL —(CHE + CHO, specific surfactants)→ cholestenone + H_2O_2

H_2O_2 + chromogen —(Peroxidase)→ quinone dye

Contents

	10094	10294
REF		
ENZ	1 x 60 ml	1 x 150 ml
SUB	1 x 20 ml	1 x 50 ml
CAL	1 x 4 ml	1 x 4 ml

ENZ Enzymes (red cap)

Good's buffer, pH 7.0 (25°C)	50 mmol/l
Magnesium chloride	20 mmol/l
Cholesterol esterase	600 U/l
Cholesterol oxidase	500 U/l
Catalase	600 kU/l
N-Ethyl-N-(2-hydroxy-3-sulfopropyl)-3-methylaniline (TOOS)	2.0 mmol/l
Detergents	0.3 % w/v
Preservatives	< 0.1 % w/v

SUB Substrate (blue cap)

Peroxidase	5000 U/l
4-Aminophenazone	4 mmol/l
Good's buffer, pH 7.0 (25°C)	50 mmol/l
Sodium azide	0.05 %
Detergents	1 % w/v
Preservatives	< 0.1 % w/v

CAL 1 x 4 ml Calibrator

LDL-Cholesterol	concentration see vial label

Reagent Preparation and Stability

ENZ and SUB are ready for use.

Stability: After opening the reagents are stable up to 2 months when stored at 2...8°C. Avoid contamination. **Do not freeze. Do not mix caps.** Protect ENZ from light.

CAL : Reconstitute the content of the vial with exactly 4 ml dist. germ free water, close the vial and swirl carefully to dissolve all lyophilisate. Avoid foaming. Let stand for at least 30 minutes before use.

Stability: 10 days at 2...8°C. If required, freshly prepared calibrator can be divided into portions and kept frozen at -20°C for maximum 30 days. Freeze and thaw only once, mix carefully after thawing.

Specimen

Serum, plasma

Stability: We recommend to test directly after sampling. Serum can be stored at 2...8°C up to 5 days.

In plasma following concentrations of the anticoagulant should not be exceeded: EDTA-2Na <1000 mg/l; Na-citrate <5000 mg/l; heparin < 750 mg/l; NaF < 2000 mg/l, Na-oxal. < 3000 mg/l.

Assay

Wavelength:	Hg 578 nm, **555 nm**, (546 to 604 nm)
Optical path:	1 cm
Temperature:	37°C
Measurement:	against reagent blank (RB)
	one blank per series is sufficient

Procedure (manual procedure)

Warm the reagents and the cuvette to 37°C. Temperature must be kept constant (± 0.5°C) for the duration of the test.

Pipette into cuvettes	Reagent blank (RB)	CAL /sample
Water	10 µl	---
CAL / Sample	---	10 µl
ENZ	750 µl	750 µl

Mix gently and incubate exactly for 5 min. at 37°C

SUB	250 µl	250 µl

Mix gently, incubate at 37°C and read the absorbance ΔA of CAL / samples against RB after 5 min. $\Delta A_{CAL/sample} = A_{CAL/sample} - A_{RB}$

Calculation

Calculate the concentration of the sample as follows:

$$C_{sample} = C_{CAL} \times \frac{\Delta A_{sample}}{\Delta A_{CAL}} \text{ (mg/dl)}$$

Conversion factor: C (mg/dl) x 0.02586 = C (mmol/l)

Performance Characteristics

Linearity: Up to 1000 mg/dl LDL-cholesterol (manual procedure).

When used on analyzers, the linearity limit depends on the respective application.

If the serum concentration of LDL exceeds the measuring range, dilute the sample 1 + 1 with saline (0.9%) and repeat the test. Multiply the result by 2.

Interference: Dilute samples with triglycerides exceeding 1000 mg/dl with phys. saline (0.9%) 1 + 1 and multiply the result by 2.

Typical performance data can be found in the Verification Report, accessible via

www.human.de/data/gb/vr/su-ldl.pdf or
www.human-de.com/data/gb/vr/su-ldl.pdf

Reference Values

	Male	Female
reduced risk for CHD	< 50 mg/dl	< 63 mg/dl
increased risk for CHD	> 172 mg/dl	> 167 mg/dl

This range is given for orientation only; each laboratory should establish its own reference range, as sex, diet, age, geographical location and other factors affect the expected values.

Quality Control

All control sera based on human serum with LDL-cholesterol values determined by this method can be employed.

Automation

Proposals to apply the reagents on analyzers are available on request. Each laboratory has to validate the application in its own responsibility.

References

1. Okada M. *et al.*; J. Lab. Clin. Med. **132**, 195 - 201 (1998)
2. In-house data

SU-LDL INF 1009401 GB 02•2011•09

CE

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جامعة النجاح الوطنية
كلية الدراسات العليا

المعتقدات الدوائية والالتزام الدوائي ومستويات كوليسترول البروتين الشحمي منخفض الكثافة عند مستخدمي الستاتين في مستوصف الرحمة بمدينة نابلس

إعداد
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إشراف
أ.د. وليد صويلح
د. أنسام صوالحة

قدمت هذه الأطروحة استكمالا لمتطلبات الحصول على درجة الماجستير في الصحة العامة بكلية الدراسات العليا في جامعة النجاح الوطنية بنابلس فلسطين.

2014م

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إشراف

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الملخص

الهدف من الدراسة: دراسة معدل عدم الالتزام الدوائي لأدوية خافضة الدهنيات(الستاتين) وتحديد العوامل المرتبطة بعدم بالالتزام بعلاج الستاتين.

المنهجية: اجريت هذه الدراسة المستعرضة في مستوصف الرحمة غير الحكومي في مدينة نابلس بفلسطين على 194 مريض مراجع يستخدم دواء الستاتين، اشترط بالمشاركين في الدراسة ان تكون اعمارهم أكبر من 18 سنة وان يستخدموا دواء الستاتين في الشهرين الماضيين. أجريت الدراسة في الفترة ما بين شهري شباط وحزيران من عام 2012 وذلك بواسطة استبيان مكون من مقياس موريسكي لقياس الالتزام الدوائي (MMAS-8) ومقياس المعتقدات حول الادوية (BMQ) والعوامل الديموغرافية والسريرية المحتملة التي قد تؤثر على الالتزام بدواء الستاتين.

النتائج: كان متوسط عمر العينة المدروسة 58.73 عاما بانحراف معياري (9.8 ±). وفقا لمقياس موريسكي فان 44.9٪ من المرضى أفادوا بمستوى عال من الالتزام الدوائي، وكان معدل احتمالية عدم الالتزام عند المرضى المسنين هو الاقل [0.9 – 0.23) 0.45]، وكذلك كان معدل احتمالية عدم الالتزام عند مستخدمي الستاتين لفترة طويلة [(0.8 – 0.3) 0.46]. وكان معدل احتمالية عدم الالتزام للمشاركين الذين لم يخضعوا لإجراء عمليات في القلب هو الاكثر [(3.0 – 1.1) 2]. واخيرا فان معدل احتمالية عدم الالتزام عند المرضى الذين يحملون مخاوف حول ادوية الستاتين هو الاكثر. وقد

اظهر التحليل متعدد المتغيرات ان المخاوف حول ادوية الستاتين كان مرتبطا بمعدل احتمالية أكثر من حيث عدم الالتزام الدوائي [(1.178 – 1.094) 1.094] بينما استخدام ادوية الستانين لفترة طويلة كان مترافقا مع اقل معدل احتمالية عدم الالتزام.

الخلاصة: نسبة التزام المرضى في الدراسة لأدوية الدهنيات الخاصة بهم هي 44.9% فقط، ووجدنا ان مخاوف المريض عن الأضرار المحتملة وفوائد الستاتين كان أهم عامل يرتبط مع عدم الالتزام الدوائي، يجب ان تعتمد التداخلات لتحسين الالتزام بأدوية الدهنيات على تعليم المرضى بشأن الفوائد أو أضرار المحتملة من علاج الدهنيات.