Medication Adherence, Illness Perception and Beliefs about Medications among Patients with Type II Diabetes Mellitus Attending Diabetes Clinic in Assiut University Hospital, Egypt

Thesis Protocol
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By

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Introduction

Diabetes mellitus (DM) is considered one of the oldest fast-growing public health problems. It's a chronic metabolic disorder characterized mainly by high level of glucose level, associated globally with increased morbidity and mortality particularly in developing countries [1].

DM leads to serious problems in heart, blood vessels, kidney and nerves. The World Health Organization (WHO) had anticipated that DM is going to become the seventh most significant primary cause of death worldwide by the year 2030 [2].

Main types of DM include type1 DM where the body stops making insulin, and type 2 DM which is more common, usually in adults when the body becomes resistant to insulin or doesn't make enough insulin [3].

Currently, 463 million persons suffer from diabetes worldwide. In addition, 55 million in Middle East and North Africa (MENA) Region suffer from diabetes, and it is estimated that by 2045 this will rise to 108 million according to the International Diabetes Federation (IDF) [4]

Egypt is considered the ninth leading country in the world for the number of type 2 diabetes patients and its prevalence was nearly tripled over the last 2 decades, reaching 15.2% as nearly 8 million of adults suffer from type 2 DM, expecting to be doubled by 2045, urging the global community to recognize DM as one of the most important health challenges of the twenty first century [4].

Hence comes the importance of self-management in patients with type 2 DM in reducing complications from the disease and improving overall health outcomes. These important self-management behaviors include taking medications regularly, healthy diet, doing physical activities, quitting smoking, foot care and self-monitoring blood glucose level [5].

Adherence of patients with type 2 DM to medication is associated with better balanced glycemic control (HbA1c <7%), thus helping in reduction of microvascular and macrovascular complications [6].

Adherence to medication is mainly influenced by several factors such as demographic, socioeconomic, cultural, health system related factors, educational and personal factors such as patient's age, complexity of medication, side effects, cost, availability, accessibility and whether they're receiving emotional and social support from their families [7].

Mental representation of DM affect patients' coping behavior**.** Many patients lack the understanding of type 2 DM. Perception of the disease is important, it's not just about taking the prescribed medication, it's about the extent to which the patient follows medical instructions [8].

Studies have showed that illness perception and beliefs about medication by type 2 DM patients is commonly linked with their adherence to medication and in return better glycemic control [9].

Perception is about everything regarding the illness such as illness identity, time line of the disease, consequences, comorbid conditions, number of hospital admission, whether it can be controlled or not, and emotional response to being diabetic [10]. Beliefs in self-control and self-management over health will affect adherence to treatment regimens and glycemic control [9].

Perception about illness shapes self-management behavior. If patients have strong perception about treatment plan and regimen with personal control, it'll lead to lower level of HbA1c and better health outcome [10].

Patients' beliefs about medication are mainly about the necessity of taking the prescribed medication to maintain their health now and in the future, and concerns about the possible negative effects of taking the medication such as

addiction or long-term adverse effects from regular use. Some patients believe that medication helps them, while others believe that multiple harmful effects of the treatment may outweigh any positive outcomes. Some of the patients who have strong opinions about their medication avoid taking it or, conversely, abuse it [11].

Patients who are convinced that a specific medication is essential for their health are much more likely to adhere to the treatment than those who do not hold such a belief [12].

We hypothesize that some factors associated with non-adherence to medication can be investigated so that interventions can be implemented to increase adherence to medication, helping in achieving better glycemic control and better health outcomes and reducing complications.

As data concerning diabetic patients' adherence are deficient in upper Egypt, this study will help in filling the gap on illness perception and beliefs about medication, which in turn affects patients' adherence to medication and thus better glycemic control in type 2 DM.

Rationale

Data regarding predictors of adherence to diabetes medication is limited in Egypt. This study aims to investigate whether illness perception, beliefs about medication were associated with adherence to medication and glycemic control (HbA1c) in Egyptian patients with type 2 diabetes in Diabetes Clinic in Assiut University Hospital. To the best of our knowledge, no previous studies on adherence to medication were done in Assiut Governorate.

Objectives of the study

1- Assess medication adherence among diabetic patients attending Diabetes Clinic in Assiut University Hospital.

2- Identify patients' beliefs about medication and illness perception.

3- Link patient's beliefs about medication and illness perception with medication adherence.

4- Investigate the correlates of medication adherence, illness perception, and beliefs about medication.

Subjects and methods

Study Design and setting

The present study will be cross sectional. This study will be conducted in Assiut University Hospital. The target population will include diabetic patients attending Diabetes Clinic in Assiut University Hospital. The clinic offers various services including clinician consultations, health education, medication dispensing, foot, and vision screening. The clinic is also responsible for treating and monitoring patients with diabetes. All patients who fulfill the inclusion criteria and presented to Diabetes Clinic in Assiut University Hospital will be included in the present study

Sample size estimation

The sample size was calculated using the Epi info version 7 StatCalc, based on the following assumption: prevalence rate of non-adherence among Egyptian population (55.5%) [13], level of confidence 95%, precision 5%, and design effect 1. The calculated sample size was raised to 417 after adding 10% as non-response rate.

Inclusion criteria

1- Patients who are diagnosed with type 2 DM for at least 1 year according to the diagnostic criteria of the 10th revision of the International Classification of Diseases (ICD-10).

2- Patients treated with insulin or oral medication or both for at least 6 months.

3- Age group: adult patients (> 18 years old) will be included in the present study.

Exclusion criteria

1- Newly diagnosed diabetic patients or ill on the day of recruitment, or not taking any medications for type2 DM

2- Patients with type1 DM

3- Psychiatric patients or on anti-depressant treatment or using psychotropic drugs affecting their cognitive ability.

Data collection tool

Data will be collected through semi-structured questionnaires which will be filled by the researcher herself. The questionnaire will be composed of five parts:

The first part will inquire about sociodemographic data such as age, sex, educational level, occupation, residence, and marital status.

The second part is about clinical data including BMI, duration of diabetes, type and number of prescribed medications, number of comorbid conditions, number of diabetes-related complications, and patients' most recent HbA1c levels were taken from medical records. HbA1c levels of ≥ 8% indicate suboptimal glycemic control in patients with T2D.

The third part of the questionnaire is the Arabic version of Morisky Medication Adherence Scale (MMAS-8) [14]. It remains one of the most widely used mechanisms to assess patient adherence [14]. It consists of 8 questions.

Response choices are “yes” or “no” for items 1 through 7 and Item 8 has a five-point Likert response scale. Each “no” response is rated as 1 and each “yes” response is rated as 0 except for item 5, in which each “yes” response is rated as 1 and each “no” response is rated as 0. For Item 8, the code (0-4) must be standardized by dividing the result by 4 to calculate a summated score [14]. Total scores on the MMAS-8 range from 0 to 8, with scores of 8 reflecting high adherence, 7 or 6 reflecting medium adherence, and <6 reflecting low adherence [14].

The fourth part of the questionnaire is the Brief Illness Perception Questionnaire (B-IPQ). B-IPQ is a rapid assessment tool with a Cronbach’s alpha of 0.65 that measures eight different aspects of illness perception: consequences, timeline, personal control, treatment control, identity, concerns, understanding, and emotional representation [15]. The B-IPQ is a 9-item instrument that measures illness perception from eight different aspects using an 11-point Likert scale. A higher score reflects a more threatening view of the illness, while a lower score indicates a benign view of the illness [15].

The fifth part of the questionnaire is the Beliefs about medicine which is assessed using the Arabic version of the Beliefs about Medicines Questionnaire Specific (BMQ-Specific). It includes two subscales, which evaluate patients’ perceptions of the necessity of medicine in controlling their illness (Necessity-Specific) and concerns about potential adverse effects of medicine (Concerns-Specific). Each subscale consists of 5 items and is scored on a 5-point Likert scale. High scores on the Necessity-Specific subscale indicate that the patient perceives their medicine as necessary, whereas high scores on the Concerns-Specific subscale indicate that the patient is concerned about potential adverse effects [16].

Statistical analysis

Data entry and analysis will be carried out using SPSS version 24. Descriptive statistics will be done in the form of frequencies, mean and SD then analytic statistics will be done as chi square, independent sample test and correlations tests. Values will be considered significant when P values are equal to or less than 0.05.

Pilot study

Before starting to collect data, a pilot study will be carried out to fulfill the following purposes:

1- Testing the questionnaire form and detecting any modification required.

2- Estimation of the time needed to fill the questionnaire.

3- Detection of the difficulties that may arise and how to deal with them.

Ethical Considerations

1- The research proposal will be reviewed and approved by the Ethical Committee of Assiut Faculty of Medicine.

2- Administrative permission will be obtained from the University authority.

3- Informed written consent will be obtained from subjects before being included in the study.

4- Privacy and confidentiality of the data will be assured.

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