NORMAL FASTING BLOOD SUGAR LEVELS AND MEDICATION ADHERENCE IMPROVE THE QUALITY OF LIFE OF TYPE 2 DIABETES MELLITUS PATIENTS IN PRIMARY HEALTH FACILITIES

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INTRODUCTION

Health-related quality of life (HRQOL) is a concept that is often used as a basis for evaluating acute and chronic disease medication surveillance programs including diabetes mellitus (DM) [1]. The World Health Organization defines QOL as individual perceptions of values, concepts, and cultures in which they live and are interconnected to achieve life goals and expectations [2-4]. Although the measurement of the patient's QOL is subjective, HRQOL has been used as a method to evaluate the cost-effectiveness of therapy management. Assessment of the QOL of DM patients in primary health facilities in Indonesia has not become a priority, even though the patient's QOL data can be used as an indicator of management success and management evaluation of DM patients management at the Puskesmas (Indonesia's primary health facilities). In contrast to Indonesia, the quality-adjusted life year (QALY) assessment as one of the outcome parameters for DM management and the basis for policymaking in primary health facilities has been widely carried out in Asian and Southeast Asian countries [5] such as Malaysia [6] and Singapore [7].

The QOL reflects therapy success and supports disease management success. Study of DM patients' QOL in primary health facilities is important because DM is a chronic disease, with its increasing incidence, prevalence, treatment costs, and complications every year [8]. The IDF Diabetes Atlas/ADA latest report [9] estimates that currently there are 415 million people with diabetes with a prevalence of 2.8-4.4%. The facts show that DM patients are susceptible to various complications [10,11] and decreased QOL [12]. In Southeast Asia, by 2030 it is estimated that there will be 58.1 million people with more than 25% having less than the average QALY [13]. QALY assessment in DM patients needs to be done to achieve better governance to increase therapeutic success and decrease the complication incidence in Indonesia so that cost efficiency can be realized.

Chronic diseases, such as type 2 DM (T2DM), will cause medical, socioeconomic, and psychological problems that will limit the ability to engage in activities that will affect the QOL [14-18]. DM is a chronic disease characterized by an increase in blood sugar levels [19-22]. Uncontrolled blood sugar levels can cause acute or chronic complications [20,23]. T2DM requires long-term therapy to control blood sugar levels and prevent complications [24]. In addition, more than 50% of T2DM patients over the age of 65 experience functional disorders that affect their autonomy and QOL [25]. T2DM patients have been shown to have a higher risk for the incidence of nephropathy, retinopathy, hypertension, stroke, peripheral neuropathy, and heart failure due to their failure to control blood sugar levels [26]. In Indonesia, DM patients, in 2030, are estimated to reach 21.3 million people, 20-30% of them with uncontrolled blood sugar or therapy target not achieved.

The medication therapy targets (MTP) in T2DM not be met were not only caused by the inappropriate use of drugs but also by patients' lifestyle and psychosocial problems. Pharmacists need to consider the most common MTPs when counseling patients with T2DM [27].

Many factors can be attributed to the QOL of DM patients. Research in Singapore and Malaysia shows that distress, poor sleep quality, and comorbidity are associated with a decrease in DM patients' HRQOL [6,27-29]. It has been proven that controlled blood sugar levels...
are an important factor in maintaining the QOL of DM patients [30]. Research in Singapore and Indonesia shows that both hypoglycemia and hyperglycemia conditions are associated with a decrease in the QOL of DM patients [31,32]. Factors that play a role in failure of blood glucose control such as patients’ medication adherence need to be considered in the care of DM patients in the primary health center (PHC) [33]. Blood glucose levels that are not appropriately controlled can cause both acute and chronic complications. As many as, 63.1% of patients with T2DM have a risk of developing hypertension complications. DM can trigger various complications and causes a decrease in QALY [34].

Non-adherence or nonconcordance in undergoing therapy is a problem that often occurs so that patients experience therapy failure [35] and decreased QOL [36]. Non-adherence can prolong the illness duration and severity [37-39]. Various studies have shown that patient adherence with chronic disease treatment is generally low at 50% or lower. Non-adherence can be caused by various factors such as lack of knowledge and understanding of drugs and the use of drugs for therapy [40,41], complexity of drug regimens, drug costs, age (increased age is inversely proportional to medication adherence), lack of family/social support, and cognitive problems in geriatrics. Other factors that have been shown to be related to adherence are perceptions about the disease and duration of illness and psychological factors such as awareness, drug safety, and tolerability [42]. Therapy results will not reach optimal levels without patients’ awareness [43]. Several methods have been developed to assess therapeutic adherence. The self-report scale is generally used to assess adherence to the use of antidiabetic and antihypertensive drugs, and many have been modified for use in Indonesia [44-46]. The medication adherence rating scale (MARS) method is one of the methods of measuring adherence with tested validity and reliability and may be used in research in primary health facilities. Therefore, the relationship of blood sugar and therapy adherence with the QOL of T2DM patients in Puskesmas Jetis 1 Bantul needs to be examined.

METHOD

Research design and subjects
This study is an analytic observational study with a cross-sectional design of DM patients in Puskesmas Jetis 1, Bantul, Yogyakarta. Respondents were all T2DM patients who met the inclusion and exclusion criteria. Inclusion criteria included adult patients (1) both men and women aged 18 years or older; (2) diagnosed as DM patients who received medication at the study site during the study period, and (3) consentual to be the study subjects. This study excluded DM patients diagnosed with bearing loss, pregnancy, kidney disorders, complications or a history of comorbid TB, HIV AIDS, heart failure, coronary heart disease, endocrine disorders (hypothyroidism or hyperthyroidism), chronic musculoskeletal disorders, or mental disorders.

Research protocols and inform consent forms were reviewed by the Medical and Health Science Faculty, Universitas Muhammadiyah Yogyakarta health research Ethics Committee and have received ethical clearance. This research has also obtained research permission from the Bantul Regency Regional Development Planning Agency (BAPPEDA).

Sample size
The number of all T2DM patients in Jetis 1 PHC based on the database was 216. The sample size is calculated with the Lemeshow formula below:

\[ n = \frac{Z_{a}^{2} + Z_{p}^{2} \times \ln OR}{p_{x} (1-p_{x}) p_{y} (1-p_{y})} \]

\[ n = \frac{1.96^{2} + 0.84^{2} \times \ln 8.2}{0.5 (0.5) 0.5 (0.5)} \]

\[ n = 118.4 \]

Data collection form
Data collection form is used to collect data taken from medical records or patient status which includes name, age, gender, hospital diagnosis, diabetes type, comorbid diseases, medication adherence, exposure to cigarette smoke. The dependent variable in the study is the patients’ QOL. The preparation of operational variable definitions is done to determine the appropriate data collection tool [47] (Table 1).

Research instruments and procedures

Research instruments
Questionnaires used in this study include: (1) Respondents’ characteristics questionnaire to obtain primary data from patients in the form of demographic data (education, marital status, and occupation) and life habits (smoking and exercise); (2) MARS questionnaire to assess patient adherence in undergoing anti-DM drug therapy; and (3) SF-36 questionnaire to assess the patient’s QOL. The SF-36, whose Indonesian version has been validated, is an instrument that has been used in various countries and used as a gold standard in assessing QOL because this instrument consists of 36 short questions covering various aspects, namely physical, emotional, social, physical health, emotional health, pain, fatigue, and general health aspects. Physical components consist of physical function, physical role, pain, and general health, while the mental component consists of the role of emotions, vitality, social function, and mental health. This questionnaire has three stages: Scoring, the average of each domain, and grouping components by domain. The average score range is 0–100 with a normative average score of 50 [48]. The validity and reliability of the SF-36 questionnaire were tested, and the results showed that this questionnaire could be used to measure QOL [49].

Operational variable definition
The independent variables in this study were blood sugar levels, medication adherence, and exposure to cigarette smoke. The dependent variable in the study is the patients’ QOL. The preparation of operational variable definitions is done to determine the appropriate data collection tool [47] (Table 1).

Research variables and operational definitions
Variables in this study include independent variables, namely clinical outcomes (fasting blood sugar levels and blood pressure), medication adherence, exposure to cigarette smoke, anti-DM drugs, and comorbid diseases and the dependent variables include patients’ QOL using the SF-36 questionnaire form.

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Research procedure
The research procedure is divided into three stages, namely preparation, implementation, and end. (1) Preparation phase: In the first stage, the researcher took care of the cleaning data through the BA PAPEDA, collected secondary data (including general description of Jetis 1 PHC, Bantul in Yogyakarta, number of visits, diabetes incidence from medical records, and other sources), developed protocols on filling out questionnaires and data collection forms and prepared supporting facilities and infrastructure (writing facilities, etc.). Data collectors were trained on how to use
Table 1: Variables operational definitions and measurement scales

| No | Variables | Operational definitions | Measurement Categories | Scales |
|----|-----------|-------------------------|------------------------|--------|
| 1  | Education | Information on patients’ education levels obtained from interviews or health questionnaire. The levels are no school/elementary school (SD), junior high school (SMP), senior high school (SMA), DI, DIII, S1, S2, S3, and others. | 1=No school/SD; 2=SMP; 3=SMA | Ordinal |
| 2  | Profession | Information on the patients’ type of work or profession in earning a living obtained from interviews or health questionnaire, categorized as employed or unemployed. | 1=Employed; 2=Unemployed | Nominal |
| 6  | Cigarette exposure | Active smokers, namely patients who are currently smoking and have smoked at least 100 cigarettes (3–4 packs) in their lifetime, or passive smokers, namely patients who do not smoke but there are active smokers in their homes. | 1. Not exposed; 2. Exposed | Nominal |
| 7  | Adherence | Measured with the MARS questionnaire with the highest score of 25 and lowest of 0. The average adherence score is measured and then compiled in the following adherence ratings: 1. High adherence: 21–25; 2. Moderate adherence: 16–20; 3. Low adherence: <16 | Adherence levels: 1. High adherence; 2. Low adherence | Nominal |
| 8  | QOL | QOL is a state of well-being which is a combination of two components: The ability to carry out daily activities (reflecting physical function, emotional function, social function, physical condition, emotional state, pain, fatigue, and general health) and patient satisfaction at the levels of function and disease control (Gotay et al, 1992). The SF-36 is an instrument used to measure QOL with 36 short questions and 8 health domains and is available in the Indonesian version. QOL scores are then classified into 4: Low, adequate, good, and very good. 1=Low (0–25); 2=Adequate (26–50); 3=Good (51–75); 4=Very good (76–100). QOL is then categorized as good or not good. | 1.Good QOL (score>75); 2. Not good QOL (score≤75) | Nominal |
| 9  | Age | The age of DM patients is obtained from medical record or interview results and is classified into two: 18–65 years and >65 years. | 1=Aged<65 tahun; 2=Aged≥65 tahun | Ordinal |

DM: Diabetes mellitus

questionnaires and data collection forms. (2) Implementation phase: This stage begins with subject recruitment, namely patients who are positively diagnosed with diabetes that meet the inclusion criteria. Prospective subjects then received an explanation of the purpose and benefits of the study. Patients who agreed to be the subject were provided with information about the study’s aims, methods, risks, and benefits of the study. Patients who agreed to be the subject were asked to give a sign of approval by signing an informed consent form. Following that, interviews were conducted to obtain data for the lifestyle questionnaire, treatment history, adherence questionnaire, and QOL questionnaire (3). The final stage: At this stage data analysis, report preparation, preparation of publication texts, and dissemination of results are carried out.

Data analysis
Univariate analysis was used to obtain an overview of the frequency distribution (proportion) of patients’ characteristics based on demographics and Chi-square test to determine the relationship between independent variables, namely age, body mass index (BMI), adherence, fasting sugar levels, and smoking status with patients’ QOL.

RESULTS AND DISCUSSION
Respondents’ characteristics
There were 153 DM patients in Jetis I PHC involved in the study. Their characteristics are presented in Table 2.

Table 2 shows that most of the respondents were women, aged over 45 years, and had elementary school education. Clinical characteristics of DM patients at Jetis I PHC are presented in Table 3.

Table 3 shows that most DM patients in the PHC suffer from comorbidities between 1 and 4 types of disease. Hypertension is the most common comorbid disease found in 58 patients followed by dyslipidemia in 18 patients. Metformin is the most widely prescribed anti-DM drug for patients with 50.17% followed by a combination of metformin and glimepiride with 32.68%.

Description of the patients’ clinical characteristics based on fasting blood sugar levels, medication adherence, and QOL
An overview of the DM patients’ clinical condition in I JetisPHC is presented in Table 4.

Table 4 shows that the average age of the patient was 57.39 years and the mean of the random blood sugar and the fasting blood sugar levels exceeded the normal values, with 261.70 ± 121.15 mg/dl and 167.43 ± 10.23, respectively. Other clinical parameters are within normal limits. The average adherence score of 22.44 ± 2.99 was classified as adherent, and the average QOL of 73.81 ± 12.40 was categorized as good QOL (score range 51–75). Furthermore, the mean score of patients’ perceptions of DM can be categorized as good because it was <40.

Description of medication adherence behavior and QOL of patients
Patients’ distribution based on the level of adherence is presented in Table 5.

Table 5 indicates that most of the patients were adherent (80.39%), with a small proportion less and non-adherent. It is also known that most patients had a very good QOL (52.94%), followed by good QOL (41.83%) and relatively low QOL (5.23%).

Bivariate analysis of factors associated with QOL
Table 6 shows the analysis results of the relationship between demographic factors (age), clinical output (normal fasting glucose
Table 3: Distribution of Subject’s clinical characteristic (illness duration, presence of comorbidities, type and number of comorbidities and medications received by DM patients) at I Jetis PHC, Bantul, DIY

| Characteristic of DM patients | Frequency (%) |
|-------------------------------|---------------|
| Sex                           |               |
| Male                          | 49 (32)       |
| Female                        | 104 (68)      |
| Marital status                |               |
| Married                       | 153 (100)     |
| Not married                   | 0 (0)         |
| Age group (year)              |               |
| ≤45                           | 12 (7.85)     |
| 46–64                         | 112 (73.20)   |
| ≥65                           | 29 (18.95)    |
| Educational                   |               |
| Elementary school             | 90 (58.8)     |
| Junior high school            | 21 (13.7)     |
| Senior high school            | 25 (16.3)     |
| University                    | 17 (11.1)     |
| Employment type               |               |
| Civil servants-retirees       | 22 (14.4)     |
| Private-entrepreneur          | 29 (19)       |
| Housewife                     | 45 (29.4)     |
| Farmer                        | 8 (5.2)       |
| Laborer                       | 25 (16.3)     |
| Unemployment                  | 24 (15.7)     |
| Health assurance              |               |
| BPJSS                         | 124 (81)      |
| Others                        | 29 (19)       |
| Exercise habit                |               |
| Yes                           | 61 (39.9)     |
| No                            | 92 (60.9)     |
| Tobacco smoke exposure        |               |
| Yes                           | 26 (17)       |
| No                            | 127 (83)      |
| Diet                          |               |
| Yes                           | 131 (85.6)    |
| No                            | 22 (14.4)     |

Table 4: Description of the demographic and clinical condition of DM patients (n=153) at I Jetis PHC, Bantul, DIY

| Clinical Characteristic | Unit | Mean±SD | Min-max |
|-------------------------|------|---------|---------|
| Age                     | Year | 57.39±8.27 | 34–83   |
| BMI                     | Kg/m²| 22.90±2.00 | 15–33   |
| Fasting glucose level   | mg/dl| 167.43±10.23 | 40–330  |
| Random glucose blood level | mg/dl | 261.70±121.15* | 82–637  |
| Compliment score        |      | 22.44±2.99 | 0–25    |
| HRQALY score            |      | 73.81±12.40 | 0–100   |

Table 5: Distribution of level of compliance and QAL of DM patients in Jetis I PHC, Bantul DIY

| Variable                  | Frekuensi | Persentase |
|---------------------------|-----------|------------|
| Level of complient        |           |            |
| Obey                      | 123       | 80.39      |
| semi-obedient             | 25        | 16.34      |
| not obedient              | 5         | 3.27       |
| Level of QOL              |           |            |
| pretty good (QALY score=26–50) | 8          | 5.23       |
| Good (QALY score=51–75)   | 64        | 41.83      |
| Very good (QALY score=76–100)   | 81        | 52.94      |
| Total                     | 153       | 100        |

Table 6: Distribution of demographic characteristics of DM patients in Jetis I PHC, Bantul, Yogyakarta

| Variable                  | Frequency (%) |
|---------------------------|---------------|
| Age                       |               |
| 1–5                       | 77 (50.3)     |
| 6–10                      | 34 (27.2)     |
| >10                       | 42 (27.5)     |
| Marital status            |               |
| No                        | 62 (40.52)    |
| Yes                       | 91 (59.48)    |
| Comorbidity status        |               |
| No                        | 62 (31.8)     |
| Hypertension              | 57 (29.2)     |
| Hypertension+dyslipidemic | 18 (9.2)      |
| Hypertension+gout         | 7 (3.6)       |
| Hypertension+asthma       | 5 (2.6)       |
| Others                    | 4 (2.1)       |
| Comorbidity number        |               |
| No comorbidity            | 62 (31.8)     |
| 1 comorbidity             | 68 (34.9)     |
| 2 comorbidity             | 19 (9.7)      |
| ≥ 3 comorbidity           | 4 (2.0)       |
| Anti-DM drug              |               |
| Metformin                 | 89 (58.17)    |
| Metformin+glimepiride     | 50 (32.68)    |
| Metformin+glibenklamid    | 4 (2.61)      |
| Glimepiride               | 4 (2.61)      |
| Metformin+insulin         | 6 (3.92)      |

DM: Diabetes mellitus

DISCUSSION

Based on the results of this study, T2DM patients’ QOL is influenced by many factors, namely (1) the pathobiological condition and DM degree or type, (2) comorbidity, (3) distress level, (4) anti-DM drugs and medication adherence, (5) lifestyle (exercise/physical activity habits, smoking), and (6) patient’s perception of DM. Other influencing factors include (a) age, because most patients are adults over the age of 40 and insulin resistance in type 2 diabetes tends to increase at the age of 40–65 years; (b) gender, because the QOL of women and men is different, where women generally have a lower QOL; and (c) level of education, because this is closely related to the processing of knowledge and information obtained. Education is an important factor in T2DM patients to be able to understand and manage independently; (d) socioeconomic status, because this is related to income, where low status can be a predictor of the patients’ low QOL; (e) duration of illness, because this is related to the level of anxiety that can lower the patient’s QOL; and (f) complications due to DM, both acute and chronic complications are serious problems because they can increase patients’ physical, psychological and social disability, and ultimately can affect patients’ QOL [36,50-55]. Al-Qasem et al. suggested that in addition to demographic factors (age, gender, and socioeconomic status), comorbidity and perception of disease, treatment regimen complexity also affects the patients’ QOL [39,56].

Patients’ medication adherence and QOL

The results of the univariate analysis revealed that most patients were very adherent in undergoing anti-DM drug therapy, and the results of the
bivariate analysis showed that the patients’ adherence was associated to their QOL. Adherence to treatment regimens is generally defined more broadly to describe how patients use prescription drugs. The word adherence is much preferred by many health workers because the word compliance giving the impression that the patient follows the doctor’s instructions passively and the treatment plan is determined unilaterally by the doctor [41-44]. Dulmen et al. [4] defined medication adherence as a level of behavior in which patients use drugs and adhere to all the rules and advice recommended by health workers. The concept of adherence is often used in chronic diseases. There are various important terms to describe patient adherence, namely compliance is the patient’s behavior to follow what is recommended or requested by a doctor or health worker. The concept of compliance feels negative because it is similar to the attitude of being obedient or submitting to the direction of a health worker. In contrast, adherence is based on patients’ awareness that arises based on commitment, principles, and trust. Concordance is compliance that is formed as a result of discussions between patients and health workers or doctors to form an agreement or cooperation in taking treatment measures [52,53]. The concept of adherence is preferred by many health workers because compliance gives the impression that the patient follows the doctor’s instructions passively and the treatment plan is determined unilaterally by the doctor [54]. Factors that can influence the level of patient adherence have been identified in several studies. Sabaté (2003) claimed that adherence will increase with clear treatment instructions, individual beliefs and attitudes to heal, pleasant and authoritative health workers, social and family support, knowledge, minimum drug effects, simple treatment, affordable prices, and good relationships between health workers and patients [40,55]. In general, the factors related to the level of adherence in DM patients are age, education, patient knowledge about drugs and disease, social and economic status, therapeutic regimens, and patient interactions with health workers [56,57].

CONCLUSION
DM patients in Jetis I PHC, Bantul, have good QOL. Patients’ controlled fasting blood sugar levels and medication adherence in undergoing anti-DM drug therapy can increase the patients’ chance of having a good QOL.

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AUTHORS CONTRIBUTION
TH conceived the study. TH, SF, and SI designed the research. TH performed the analysis and wrote the manuscript. SF and SI interpreted the results and contributed to the discussion. All authors read and approved the final manuscript.

CONFLICTS OF INTEREST
All authors declare that they have no conflicts of interest.

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| Parameter                        | QOL status | OR (CI 95%; p)  |
|----------------------------------|------------|----------------|
|                                   | Very good  |               |
| Age ≤60 tahun                     | 58 (71.6)/23 (28.4) |               |
| Unexposed smoke                  | 68 (84)/13 (16) |               |
| BMI ≤25                           | 61 (80.3)/15 (19.7) |               |
| Normal fasting glucose level      | 73 (90.1)/8 (9.9) |               |
| Good compliance                   | 62 (76.5)/19 (23.5) |               |
|                                   | Pretty good|               |
|                                  | 44 (61.1)/28 (38.9) | 1.61 (0.82–3.16;0.17) |
|                                  | 59 (81.9)/13 (18.1) | 1.20 (0.50–2.61;0.74) |
|                                  | 45 (65.2)/24 (34.8) | 2.17 (1.02–4.60;0.04)* |
|                                  | 49 (68.1)/23 (31.9) | 4.28 (1.77–10.35;0.001)* |
|                                  | 43 (59.7)/29 (40.3) | 2.2 (1.1–4.42;0.02)* |
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