

Assessment of Health-Related Quality of Life Among Patients Management Program of Chronic Diseases Type 2 Diabetes Mellitus

Fajriansyah^{1,2}, Iskandarsyah A³, IM Puspitasari^{1,4}, Keri Lestari^{1,4}

¹Department of Pharmacology and Clinical Pharmacy, Faculty of Pharmacy, Universitas Padjadjaran, Jatinangor-Sumedang, West Java, Indonesia; ²School of Pharmacy Makassar, South Sulawesi, Indonesia; ³Department of Clinical Psychology, Faculty of Psychology, Universitas Padjadjaran, Jatinangor-Sumedang, West Java, Indonesia; ⁴Centre of Excellence for Pharmaceutical Care Innovation, Universitas Padjadjaran, Jatinangor-Sumedang, West Java, Indonesia

Abstract

Type 2 Diabetes Mellitus (T2DM) has significant adverse effects on health-related quality of life. PROLANIS program is a system of governance of health services and health education for social health insurance participants who suffer from type 2 diabetes mellitus to achieve the optimal quality of life independently. This research aims to measure quality of life in T2DM patient. The research was an analytical non-experimental study according to the patient's perspective using prospective data collection techniques. The subjects are PROLANIS patient T2DM who comply inclusion and exclusion criteria. The data were collected by using the European Quality of Life 5 Dimensions 5 Levels (EQ-5D-5L) Indonesian questionnaire. Data analysis using EQ-5D preference weight for each health state using Indonesian EQ-5D-5L Value Set. Furthermore, the percentage of the patients' problems, EQ-5D index (utility) and EQ-5D VAS were calculated. A total of 220 patients were included. Seventy-two different EQ-5D index values were described by the patients. Obtained 37 subjects (16.82%) had no problems. The EQ-5D index value highest is 1,000 (n = 32, 14,54%) and EQ-5D index value lowest is -0,384 (n = 1, 0,45%). EQ-5D index value has an average is 0.57 (SD 0,32) and EQ VAS value has an average is 72.19 (SD 14.73). This study also confirmed that T2DM remains a critical predictor of health outcomes among patients. Results from this study could be constructive in clinical practice, particularly in the early treatment of T2DM patients where improving HRQoL is still possible.

Keywords: Type 2 Diabetes Mellitus, PROLANIS, Quality of life, EQ-5D-5L

Introduction

World Health Organization (WHO) defines Diabetes mellitus as a chronic disease caused by inherited and/or acquired deficiency in production of insulin by the pancreas, or by the ineffectiveness of the insulin produced.^[1] The International Diabetes Federation (IDF) has estimated that approximately 592 million adults in worldwide will have diabetes in 2035.^[2] Diabetes has an adverse effect on quality of life. Most patients suffer from a variety of long-term complications including micro-vascular complications (e.g. neuropathy, nephropathy and retinopathy) and macro-vascular complications (e.g. myocardial infarction, angina pectoris, stroke and amputation).^[3] Besides, the trouble of taking oral antidiabetic agents several times a day, the

fear of subcutaneous injection of insulin, and incidents of hypoglycaemia might depress diabetic patients and further reduce Health-Related Quality of Life (HRQoL).^[4]

HRQoL is depicted as an individual's perceived quality of life, demonstrating satisfaction in the domains that are influenced by health status.^[5] The concept of HRQoL is frequently used in clinical research for assessing pharmaceutical care and treatment outcomes. Moreover, the literature reports HRQoL as a predictor of optimal health care service utilization.^[6-8] HRQoL is a multidimensional construct highlighting a person's physical, cognitive, emotional, psychological and spiritual eminence towards the current health status.^[9, 10] Today, evaluation of the patients' HRQoL is recognized

as an important area of scientific knowledge, since the concept is related to the notion of health, satisfaction and well-being in the physical, psychological, socioeconomic and cultural spheres.^[11]

The EQ-5D-5L is a widely used generic preference based HRQoL questionnaire.^[12] It consists of 5 dimensions (mobility, self-care, usual activities, pain or discomfort, and anxiety or depression), equipped with five possible levels of problem. Health states can be described with a 5-digit number, where the first number is the answer of the first question, the second number is the answer of the second question, accordingly. Given that EQ-5D is a preference-based questionnaire, these health states can be converted into a utility index by applying the appropriate formula. This instrument also includes a Visual Analog Scale (VAS) with a range from 0 (worst imaginable health state) to 100 (best imaginable health state).

In Indonesia, one of the new strategies cultivated is the management program of chronic diseases (PROLANIS). PROLANIS was initiated by Social Insurance Administration Organization (BPJS). The main objective of PROLANIS is to diminish the risk of complications and attain a better quality of life by using of effective cost and rational measures. The PROLANIS program is a system of governance of health services and health education for social health insurance members who suffer from hypertension and type 2 diabetes mellitus to accomplish the optimal quality of life independently.^[13] Activities in PROLANIS include medical /educational consulting activities, home visit, reminder, club activities and health status monitoring.^[14] The aim of the present study was to assessment of HRQoL among PROLANIST2DM.

Materials and Method

Study design, settings and recruitment of subjects

A questionnaire-based cross-sectional survey was carried out to assess the HRQoL of Patient Chronic Disease Management Program (PROLANIS) T2DM who comply inclusion and exclusion criteria attending primary health care Antang, Batua, Jongaya, Tamalanrea, primary health care Makassar City, Indonesia, in August 2017 – January 2018.

Inclusion and exclusion criteria

Patients enrolled in the PROLANIS program,

adult patients aging 20 years and above, fasting blood sugar levels of patients > 126 mg/dL for 3 consecutive months, patients have been treated for at least 3 months, with a confirmed diagnosis of T2DM and willing to follow the research by signing the informed consent were included in the study. Patients with irregular or non-routine control schedules (not every month of control), patients with incomplete medical record data, patients in circumstances where it is not possible to fill in questionnaires (unable to speak, see and hear) were excluded from this study.

Ethical considerations

The study protocol was approved by the Health Research Ethics Committee of the Faculty of Medicine, Hasanuddin University No. 146/H4.8.4.5.31/PP36-KOMETIK/2017. Prior to data collection, patients who agreed to participate were explained nature and the objectives of the study and were assured of the confidentiality of the information. Written consent was also taken from the patients prior to data collection.

Instrument/QoL measurement

To measure HRQoL, we chose the EQ-5D instrument, which was developed in 1987 by EuroQol15 research groups and is widely used in domestic studies.^[15] EQ-5D is applicable to a wide range of health index values for health status. We used the official EQ-5D-5L Bahasa Indonesia version provided by the EuroQol Group. This translation of EQ-5D-5L was produced using a standardized translation protocol that followed international recommendations.^[16]

Data collection

The EQ-5D-5L assesses health status across five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) each with five response levels (none, slight, moderate, severe and extreme/unable). For example, state '11111' indicates 'no problems on any of the five dimensions', while state '54321' indicates 'unable to walk about, severe problems washing or dressing, moderate problems doing usual activities, slight pain or discomfort, and no anxiety or depression'.^[17] The Indonesian value set index ranges from -0.865 to 1, where 1 represents preferred health, 0 represents death and a score of less than 0 represents health states worse than death.^[18] The second part of the EQ-5D consists of a 20 cm visual analogue scale (VAS) with endpoints of 0, representing the worst imaginable

state, and 100, representing the best. This is used to record the participant's perception of his or her quality of life.

Data Analysis

Descriptive statistics were used to investigate the distribution of variables among PROLANIS T2DM patients. Continuous EQ-5D preference weight for each health state using Indonesian EQ-5D-5L Value Set.

Furthermore, the percentage of the patients' problems, EQ-5D index (utility) and EQ-5D VAS were calculated.

Result

Patient's demographics

Two hundred and twenty T2DM patients were included in the study. The description of sociodemographic variables and frequency distribution of the respondents are summarized in Table 1.

Table 1: Characteristics of survey respondents (n=220)

Characteristics	Frequency	Percentage (%)
Gender		
Male	79	35.91
Female	141	64.09
Age		
<50 years	20	9.09
50-59 years	94	42.73
60-65 years	106	48.18
Marital status		
Married	194	88.18
Unmarried	26	11.82
Monthly Income (IDR)		
<RMS*	103	46.82
>RMS	117	53.18
Occupation		
Working	159	72.27
Not working/retired	61	27.73
Level of last education		
Elementary	102	46.36
Junior high school	29	13.18
Senior high school	52	23.64
University	37	16.82
Duration of diabetes		
≤5 years	106	48.18
>5 years	114	51.82
Other diagnosis		
Hyperlipidemia	39	17.73
Hypertension	138	62.72
Kidney failure	15	6.82
Heart failure	8	3.64
No comorbidities	20	9.09

RMS: Regional Minimum Salary, IDR: Indonesian Rupiah

*Regional Minimum Salary of Makassar City: IDR 2.504.500

A sample of 220 T2DM patients were investigated in this study. Table.1 shows the socio-demographic and clinical characteristics of these respondents. The average age of the respondents was $57,71 \pm 5,6$ years, and 64,09% of respondents were female. Most patients had only graduated from elementary (46.36%), were married (88.18%), were working (72.27%), and had an average monthly household income above the regional minimum salary (53.18%). Most respondents (51.82%) were diagnosed with diabetes over 5 years prior to participation and 62.72% diagnosed with hypertension.

EQ-5D health status

Seventy-two different EQ-5D index values were described by the patients. The EQ-5D index value highest is 1,000 (n = 32, 14,54%) and EQ-5D index value lowest is -0,384 (n = 1, 0,45%). The EQ-5D index value has an average is 0.567. Within 72 different health states, the majority (n=32, 14,54%) started no problems /difficulties in the first, second, third, fourth and fifth domain respectively (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) of HRQoL.

In 220 patients the average EQ-5D utility index score was 0.54 (SD 0.32). The highest EQ VAS value is 100 (n 20, 9,09%) and EQ VAS values lowest is 50 (n 22, 10%). The EQ VAS value has an average is 72.19 SD ± 14.73 as presented in Table 2.

Table 2. EQ VAS values

EQ VAS	Frequency n=220	Percentage (%)
100	20	9,09
95	5	2,27
90	13	5,91
89	1	0,45
88	3	1,36
87	1	0,45
86	2	0,91
85	9	4,09
82	2	0,91
80	23	10,45
78	2	0,91
76	1	0,45
75	16	7,27

Cont... Table 2. EQ VAS values

73	1	0,45
72	2	0,91
70	27	12,27
69	1	0,45
68	1	0,45
66	1	0,45
65	20	9,09
64	2	0,91
62	2	0,91
60	31	14,09
55	12	5,45
50	22	10

Discussion

HRQoL is a multidimensional construct referring to an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. It was revealed that the patients with diabetes had generally a negative impact on the QoL. These findings are in line to the studies whereby HRQoL decreased with disease progression and complications.^[19] Another study supposed that diabetes has an adverse effect on quality of life. Most patients suffer from a variety of long-term complications as well as micro-vascular complications and macro-vascular complications. In addition, a decreased HRQoL was reported by patients of other chronic diseases from various areas of Indonesia which further augments that chronic diseases have a negative impact of the HRQoL of the patients.

As part of strategies developed to encounter chronic diseases in Indonesia, PROLANIS has main objective to reduce the risk of complications and achieve a better quality of life with the use of cost-effective and rational. In this study, it was found that PROLANIS members are dissatisfied and has negative impact on the QoL proven by the results of assessment on health status of patients rated EQ-5D index score 0,54 (SD 0,32) and EQVAS values is 60 (n 31, 14,09%). Hence, it indicates that PROLANIS has not been functioned optimally in the primary healthcare. Furthermore, a previous study by Perwitasari *et al* (2017) in Indonesian T2DM outpatients (n=86) reported that the EQ-5D index score was 0.75 (SD 0.22) (20). Moreover, on clinical condition, Perwitasari *et al* (2017) also found that T2DM complications were indeed aligned with decreases in EQ-5D index scores.

Notably, despite the similarities, Perwitasari *et al* (2017) utilized dissimilar methods to calculate and analyze the data, i.e., the EQ-5D-3L instrument and the Thailand TTO value set, which complicates comparison.^[20]

Based on a report from BPJS in 2016, the number of PROLANIS DMT2 members in 2016 in primary health care Makassar city was 1,165 patients. Even though they have joined as PROLANIS members, they were still not able to be serviced on primary health care. It happened as it lacks of socialization about the importance of PROLANIS services so that patients felt this program was useless for them. In addition, the maximum home visit program, drug information services and counselling are not running well due to time constraints. It was also found that some PROLANIS members only see a doctor and take medication without taking part in gymnastics and education. In addition, the factors that trigger a patient's quality of life to be low may be due to the patient's lack of controlled lifestyle. Moreover, there is no family or party monitoring it. Most PROLANIS members whose conditions are uncontrolled are those who are old enough and have no relatives or family who can take them to visit the primary health care.

Conclusion

The findings concluded that T2DM has a negative effect on HRQoL. From total of 220 patients, obtained 37 subjects (16.82%) had no problems. EQ-5D index value has an average of 0.57(SD 0,32) and EQ VAS value has an average of 72.19. This study also confirmed that T2DM remains a critical predictor of health outcomes among patients. Results from this study could be constructive in clinical practice, particularly in the early treatment of T2DM patients where improving HRQoL is still possible.

Financial support and sponsorship: Ministry of Research, Technology and Higher Education of the Republic of Indonesia

Conflict of Interest: There are no conflicts of interest.

Acknowledgement: We would like to thank Ministry of Research, Technology and Higher Education of the Republic of Indonesia for funding this research and the authors wish to acknowledge the patients for participating in the study and the staff at the primary health care for their support in conducting the study.

References

1. WHO. Diabetes mellitus. [Cited 2010 Jan 18]. Available from: <http://www.who.int/diabetesactiononline/diabetes/en/>
2. Al-Aboudi IS, Hassali MA, Shafie AA, et al. A cross-sectional assessment of health-related quality of life among type 2 diabetes patients in Riyadh, Saudi Arabia. *SAGE Open Med.* 2015;3:2050312115610129. doi: 10.1177/2050312115610129.
3. Grandy S, Fox KM. EQ-5D visual analog scale and utility index values in individuals with diabetes and at risk for diabetes: findings from the study to help improve early evaluation and management of risk factors leading to diabetes (SHIELD) Health Qual Life Outcomes. 2008;6:18. doi: 10.1186/1477-7525-6-18.
4. Vancampfort D, Mitchell AJ, De Hert M, et al. Type 2 diabetes in patients with major depressive disorder: a meta-analysis of prevalence estimates and predictors. *Depress Anxiety.* 2015;32(10):763–773. doi: 10.1002/da.22387.
5. Centers for Disease Control and Prevention. Health-Related Quality of Life (HRQOL). [<https://www.cdc.gov/hrqol/>] Accessed 10 August 2016.
6. Browne GB, Arpin K, Corey P, Fitch M, Gafni A. Individual correlates of health service utilization and the cost of poor adjustment to chronic illness. *Med Care.* 1990;43–58.
7. Konstam V, Salem D, Pouleur H, Kostis J, Gorkin L, Shumaker S, Mottard I, Woods P, Konstam MA, Yusuf S. Baseline quality of life as a predictor of mortality and hospitalization in 5,025 patients with congestive heart failure. SOLVD investigations. Studies of left ventricular dysfunction investigators. *Am J Cardiol.* 1996;78:890–895. doi: 10.1016/S0002-9149(96)00463-8.
8. Memel D. Chronic disease or physical disability? The role of the general practitioner. *Br J Gen Pract.* 1996;46:109–113.
9. El Achhab Y, Nejari C, Chikri M, Lyoussi B. Disease-specific health-related quality of life instruments among adults diabetic: a systematic review. *Diabetes Res Clin Pract.* 2008;80:171–184. doi: 10.1016/j.diabres.2007.12.020.
10. Grey M, Jaser SS, Whittemore R, Jeon S, Lindemann E. Coping skills training for parents of children with type 1 diabetes: 12-month

- outcomes. *Nurs Res.* 2011;60:173–181. doi: 10.1097/NNR.0b013e3182159c8f.
11. Saleem F, Hassali MA, Shafie AA. A cross-sectional assessment of health-related quality of life (HRQoL) among hypertensive patients in Pakistan. *Health Expect.* 2014;17:388–395. doi: 10.1111/j.1369-7625.2012.00765.x.
12. Herdman M, Gudex C, Lloyd A, *et al.* Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011; 20(10): 1727-36.
13. Idris, F., 2014. Pengintegrasian Program Preventif Penyakit Diabetes mellitus Tipe 2 PT Askes (Persero) ke BPJS Kesehatan. *J Indon Med Assoc*, 64(3), pp.115–121.
14. BPJS Kesehatan, 2015. Panduan Praktis Prolanis (Program Pengelolaan Penyakit Kronis), Jakarta: Badan Penyelenggara Jaminan Sosial Kesehatan.
15. EuroQol Group EuroQol – a new facility for the measurement of health-related quality of life. *Health Policy.* 1990;16:199–208. doi: 10.1016/0168-8510(90)90421-9.
16. Rabin R, Gudex C, Selai C, Herdman M. From translation to version management: a history and review of methods for the cultural adaptation of the EuroQol five-dimensional questionnaire. *Value Health.* 2014;17(1):70–6.
17. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, *et al.* Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res.* 2011;20(10):1727–36. doi:10.1007/s11136-011-9903-x.
18. Purba, F.D., Hunfeld, J.A.M., Iskandarsyah, A. *et al.* *PharmacoEconomics* (2017) 35: 1153. <https://doi.org/10.1007/s40273-017-0538-9>.
19. Armstrong DG, Lavery LA, Wrobel JS, Vileikyte L. Quality of life in healing diabetic wounds: Does the end justify the means? *J Foot Ankle Surg* 2008;47:278-82.
20. Perwitasari, D. A., Urbayatun, S., Faridah, I. N., & Masyithah, N. (2017) Relationship of therapeutic outcome with quality of life on type 2 diabetes mellitus patients in Abdul Azis Singkawang hospital. *IOP Conference Series: Materials Science and Engineering*, 259, 1–7.