Comparison quality of life patients treated with insulin and oral hypoglycemic drugs

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Abstract. Diabetes mellitus (DM) is a group of chronic metabolic diseases with characteristic hyperglycemia that occurs due to abnormalities in insulin secretion, insulin action or both. Improved quality of life is one of the goals of DM management. This study aims to compare the quality of life in 40 patients with type 2 diabetes using insulin therapy and 40 patients using oral hypoglycemic drugs in H. Adam Malik Hospital year 2015. This study is an observational study with cross-sectional study design and consecutive sampling method. Evaluation of the patient’s quality of life taken through interviews and questionnaires using the Short Form-36 questionnaire consisting of 8 domains of quality of life. Statistical analysis using unpaired t-test and Mann-Whitney test. Results of the quality of life-based on patient characteristics showed significant differences in education factor (\( p=0.005 \)) and employment factor (\( p=0.001 \)). Quality of life-based on therapy showed significant differences in domain role of physical (\( p=0.005 \)) and domain role of emotional (\( p=0.038 \)). The quality of life of patients with type 2 diabetes using insulin better than using hypoglycemic drug significantly in domain role of physical and domain role of emotions.

1. Introduction
Diabetes mellitus (DM) is a group of metabolic diseases with characteristics of hyperglycemia that occurs due to abnormalities of insulin secretion, insulin action or both. Diabetes mellitus is a chronic disease requiring medical treatment, self-management education and ongoing support to prevent acute or chronic complications.\textsuperscript{1}

DM has been categorized as a global disease by the World Health Association (WHO) whose prevalence continues to increase year by year. WHO states that Indonesia ranks fourth largest DM case after India, China, and the United States.\textsuperscript{2} The report of WHO and the International Diabetes Federation (IDF) predicts a 2-3 fold increase in the number of people with diabetes in Indonesia by 2030.\textsuperscript{3} Based on Riskesdas data, there is also an increase in prevalence of diabetes mellitus nationally, including in North Sumatra Province itself from 2007 to 2013. Although epidemiological data indicate the prevalence of DM that continues to increase every year both in the world and in Indonesia, but so far more research has been revolving around the DM clinical problem alone so more research needs to be done about the quality of life, considering the improved quality of life is one of the targets of DM management therapy based on the consensus on the management and prevention of type 2 diabetes mellitus in Indonesia by PERKENI 2011.\textsuperscript{3}
Diabetes is a chronic disease that requires continuous therapy (long life) and so many amountsof drugs (polypharmacy) so that the effectiveness and side effects of treatment can affect the quality of life of the patients. There are several studies that have proven the benefits of insulin use earlier in the treatment of type 2 diabetes mellitus. A study by Akinci et al. concluded that patients taking insulin had a better quality of life than those using Oral Hypoglycemic Drugs. However, there are studies suggesting that between patients with type 2 diabetes Mellitus who use insulin and oral hypoglycemic drugs without insulin have the same quality of life.4

Although the benefits of early insulin provision have been proven in scientific studies, the problem of delaying initiation of insulin therapy is still common in daily practice, which will affect the quality of life of the patients. Also there are other factors that affect the quality of life of patients such as complications suffered by patients and the characteristic of the patients.5

The purpose of this study was to determine the magnitude of comparison of quality of life with the SF-36 questionnaire in patients with type 2 diabetes mellitus who use insulin therapy and who use oral hypoglycemic drugs in RSUP H. Adam Malik Medan in 2015.

2. Method

Its analytic observation uses a cross-sectional study design to examine the magnitude of comparison of quality of life of patients with type 2 diabetes mellitus treated with insulin therapy and oral hypoglycemic drugs. This study conducted from September to November 2015 in Endocrinology Polyclinic of Internal Medicine Department of Haji Adam Malik General Hospital in Medan.

The population in this study were all patients with type 2 diabetes mellitus who came to the Endocrinology Polyclinic at Haji Adam Malik General Hospital Medan on the day of the research. The sample of this study was a consecutive sampling; the subjects met the inclusion and exclusion criteria were included in the study until the required amount fulfilled. The inclusion criteria in this study were patients over the age of 18 years, patients had been using insulin or oral hypoglycemic drugs >3 months, and patients were willing to be respondents. While the exclusion criteria in this study were patients, who used insulin one time only or irregular, patients who did not have complete medical record data, patients who did not complete all questions of the SF-36 questionnaire, so it was not possible to be a respondent, and patients who had a history of psychiatric disorders.

The type of data collected in this study consists of primary data and secondary data. The primary data on patient’s quality of life were obtained directly from outpatient type 2 diabetes mellitus at Endocrinology Polyclinic of Haji Adam Malik General Hospital Medan through interview and filling out the questionnaires of Short Form-36 (SF-36) consisting of 8 domains of quality of life (physical functioning domain, limitations due to physical problems domain, bodily pain domain, general health perception domain, energy / vitality domain, social functioning domain, limitations due to emotional problems domain, and mental health domain). The short form-36 scale is then divided into 2 dimensions, namely Mental Component Summary / MCS (domain mental health, energy / vitality, social functioning, and limitations due to emotional problems) and Physical Component Summary / PCS (domain physical functioning, limitations due to physical problems, bodily pain, general health perception). The secondary data about the status of type 2 diabetes mellitus patients who have been previously diagnosed by a doctor were from the patient’s medical record at the time of treatment.

This research uses univariate data analysis and bivariate data analysis technique. Univariate data analysis uses distribution of the proportion and bivariate data analysis uses unpaired t-test, the term of use t-test is if the distribution of data is a normal distribution.6

3. Result

The proportion distribution of the samples of type 2 diabetes mellitus patients based on the characteristics of patients in endocrinology polyclinic of RSUP H. Adam Malik Medan is in the table below.

Table 1. Proportion distribution of patients with diabetes mellitus types 2 by age.
The comparison of quality of life of samples based on the patient characteristics is in the table below.

Table 2. Comparison of quality of life of sample patient of type 2 diabetes mellitus based on patient characteristics.

| Variables                  | N     | Mean of Score ± SD | P value |
|---------------------------|-------|--------------------|---------|
| **Age**                   |       |                    |         |
| ≤40 yo                    | 2     | 63.8 ± 8.9         | 0.577   |
| >40 yo                    | 78    | 70.2 ± 16.0        |         |
| Sex                       |       |                    |         |
| Man                       | 42    | 72.6 ± 16.2        | 0.127   |
| Woman                     | 38    | 67.2 ± 15.1        |         |
| **Education**             |       |                    |         |
| ≤ Senior High School      | 43    | 65.5 ± 17.0        | 0.005   |
| > Senior High School      | 37    | 75.3 ± 12.6        |         |
| **Employment status**     |       |                    |         |
| Employed                  | 33    | 76.8 ± 12.1        | 0.001   |
| Unemployed                | 47    | 65.3 ± 16.5        |         |
| **Income**                |       |                    |         |
| < Rp 1.625.000.00         | 32    | 68.3 ± 15.8        | 0.430   |
| ≥ Rp 1.625.000.00         | 48    | 71.2 ± 15.9        |         |
| **Duration of suffering DM** | |                  |         |
| < 5 years                 | 32    | 69.8 ± 15.8        | 0.926   |
| ≥ 5 years                 | 48    | 70.2 ± 15.9        |         |
| **HbA1c level**           |       |                    |         |
| < 7 gr/dL                 | 25    | 71.4 ± 19.0        | 0.612   |
| ≥ 7 gr/dL                 | 55    | 61.4 ± 14.3        |         |
| **Complications of DM**   |       |                    |         |
| Present                   | 65    | 69.7 ± 15.6        | 0.698   |
| Not present               | 15    | 71.5 ± 17.3        |         |

The results of the data analysis in Table 2 above with unpaired t-test showed that there is a significant difference between the quality of life of patients who have education level up to senior high school and patients who have higher education level above senior high school (p<0.05) and there is significant difference between the quality of life of employed patients and unemployed patients (p<0.05).

The comparison of 8 domains of quality of life of SF-36 questionnaire in samples is in the table below.

Table 3. Comparison of 8 domains of quality of life by therapy.

| Domains of Quality of Life | Therapy | N     | Mean of Score ± SD | P value |
|----------------------------|---------|-------|--------------------|---------|
| Physical Functioning       | OHD³    | 40    | 72.0 ± 30.9        | 0.537   |

³ OHD: Oral Hypoglycemic Drugs
In Table 3 the quality of life analysis on domain limitations due to physical problems and domain limitations due to emotional problems showed a significant difference between the patient’s group using insulin and the patient's group using OHD (p<0.05).

The comparison of quality of life dimension on the SF-36 questionnaire in the samples is in the table below.

### Table 4. Comparison of health dimensions by therapy.

| Health Dimension               | Therapy | N  | Mean of score ± SD | P value |
|--------------------------------|---------|----|--------------------|---------|
| Physical Component             | OHD     | 40 | 64.1 ± 21.7        | 0.146   |
| Summary (PCS)                  | Insulin | 40 | 70.7 ± 18.0        |         |
| Mental Component               | OHD     | 40 | 71.8 ± 17.0        | 0.206   |
| Summary (MCS)                  | Insulin | 40 | 76.6 ± 17.2        |         |

In Table 4 the results of data analysis of physical health dimension were no significant difference between the patients using insulin and the patients using OHD (p>0.05).

The comparison of the total life quality score with the SF-36 questionnaire in the samples can be seen in the table below.

### Table 5. Comparison of total life quality score by therapy.

| Score of Quality of Life | Therapy | N  | Mean of Score ± SD | P value |
|--------------------------|---------|----|--------------------|---------|
| TOTAL                    | OHD     | 40 | 67.0 ± 16.9        | 0.096   |
|                          | Insulin | 40 | 73.0 ± 14.3        |         |

In Table 5, the data analysis there was no significant difference between the quality of life of the patient’s group using insulin and the quality of life of the patient’s group using OHD (p>0.05).

### 4. Discussion

The research conducted by Sepulveda et al. in 2015 and Johnson et al. in 1998 using the SF-36 questionnaire showed different results with the results obtained in this study, i.e., patients who use insulin actually have a lower quality of life than patients who use OHD in the domain of physical functioning, limitations due to physical problems, social functioning, and general health perceptions. This may be because patients taking insulin have side effects from treatment with insulin that affect the scheduling and regulation of their daily activities, the fear of weight gain, and the impact of insulin treatment on the social environment. According to the researchers, this can be overcome by providing a complete explanation to the patient about the large risk of side effects obtained from the use of
insulin and provide solutions to the patients regarding the schedule and procedure of using insulin so as not to interfere with patient activity. And according to Moses, Chawla, and John (2013), the use of insulin has a large change of effect on HbA1c as well as no marked weight gain or increased hypoglycemia. Also, according to Sepulveda et al. (2015) patients who use insulin usually have a longer duration of suffering diabetes, have complications and increased frustration after failing with OHD treatment. Therefore, according to the researcher recommended to early insulin administration since the patient is diagnosed with diabetes mellitus, so the patient has no longer suffered from diabetes mellitus, the patient has no complication yet, and the patient does not feel frustrated due to the failure of oral hypoglycemic drug therapy.

The result of comparison of total quality of life score of type 2 diabetes mellitus patient based on therapy showed that the total quality of life score of type 2 diabetes mellitus patients using insulin was higher than those using OHD, but no significant difference (p = 0.096). This result is in accordance with a study by Akinçi et al. in 2008 used the Diabetes Quality Of Life (DQOL) questionnaires which concluded that patients taking insulin had a better quality of life than those using OHD. Another study by Houlden et al. in 2007 using the Audit Diabetes-Dependent Quality of Life (ADDQoL) questionnaire also showed a significant improvement in the quality of life for individuals treated with early insulin at week 12 (P = 0.025) and week 24 (P = 0.024) compared with customized oral therapy. Research by Porojan, Poanta, and Dumitrascu in 2012 using the SF-36 questionnaire concluded that insulin therapy did not decrease the patient's quality of life, possibly associated with better blood sugar control and decreased the patient complaints, and insulin therapy reduced the negative effects on patient quality of life.

Better quality of life in the use of insulin is associated with better glycemic control although very few can achieve the target levels of HbA1c <7 g/dL. This is in accordance with research by Sehgal and Khanolkar in 2015 which states that all insulin types can significantly reduce HbA1c levels, but very few can achieve the HbA1c targets. If HbA1c levels fall then the risk of long-term complications decreases so that the patient's quality of life will be better maintained. Also, when the patient is first diagnosed, the patient has had diabetes mellitus for 9-12 years, and approximately 50% of beta cell function has disappeared at the time of diagnosis. This beta cell failure will continue progressively at a rate of approximately about 4% per year. Therefore it is very useful to administer insulin earlier because of the effect of insulin protection in maintaining beta cells so it can prevent the disease progression.

From the results of the study showed that in addition to all the positive effects provided by insulin therapy on improving the quality of life of patients, it turns out that the patient's characteristic factors also affect the quality of life of patients with type 2 diabetes mellitus.

5. Conclusion
The quality of life of patients using insulin therapy is better than those using OHD that statistically significant in the domain of limitations due to physical problems and the domain of limitations due to mental problems.

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