

# Daniek Viviandhari -A Strategic Approach to Increase the Compliance of Patients with Type 2 Diabetes Mellitus

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# A Strategic Approach to Increase the Compliance of Patients with Type 2 Diabetes Mellitus

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## ABSTRACT:

There are still found high levels of noncompliance of some patients with diabetes mellitus (DM). This study aimed to assess the effectiveness of public counselling and booklet handout to increase compliance of patients with type 2 DM. The study was a prospective quasi-experimental pretest-posttest study. Glycated hemoglobin (HbA1c) test and Morisky Medication Adherence Scale (MMAS-8) questionnaire were performed before and 12 weeks after intervention. The given intervention were public counselling and educational booklets which performed three times during the study period. The experiment was conducted in Makasar and Kebon Pala primary health care in East Jakarta. Among 30 patients with type 2 DM who completed interventions, there were 63.3% patients had HbA1C  $\geq$  7% and 53.4% who had MMAS-8 score  $\geq$  2. However, after intervention, the percentages inclined significantly ( $p < 0.05$ ) to 23.3% and 33.3%, respectively. In conclusion, public counselling and booklet handout were effective to improve the compliance of patients with type 2 DM.

## Keywords:

Type 2 DM, HbA1c levels, MMAS-8 scores, compliance, primary health care

Diabetes mellitus (DM) is a group of chronic metabolic disorder characterized by hyperglycemia and abnormalities in carbohydrate, fat, and protein metabolism. Whereas, the type 2 DM is characterized by a combination of some degree of insulin resistance and relative insulin deficiency. Insulin resistance is manifested by increased lipolysis and free fatty acid production, increased hepatic glucose production, and decreased skeletal muscle uptake of glucose (DiPiro *et al.* 2015). If it is not tackled well, this metabolic disorder can cause microvascular and macrovascular complications which would increase the treatment cost of the patients (Koda-Kimble *et al.* 2009).

DM is a worldwide health problem, which prevalence globally estimated of 6.4%, affecting 285 million adults in 2010 and is projected to increase to 7.7%, 439 million adults in 2030. It was estimated that between 2010 and 2030, there will be an increase of 69% of the number of adults with DM in developing countries and 20% in developed countries (Shaw, Sicree, & Zimmet, 2010). Data from the International Diabetes Federation (IDF) in 2015 showed the prevalence of DM in adults (20-79 years) in Indonesia was 6.2%. The highest prevalence of DM diagnosed by a doctor in the special region of Yogyakarta (2.6%) and Jakarta (2.5%) (Balitbangkes, 2013).

One of the causes of the failure of the patient's blood glucose control in DM is non-adherence of patients to their treatment. The poor adherence to the treatment of DM patients is still a matter of considerable importance in the management of DM. Several studies have reported that compliance of patients with type 1 DM ranged between 70-83% while patients with type 2 DM approximately 64-78%. The level of compliance of patient with type 2 DM are lower than type 1 DM, this can be caused by treatment regimens in type 2 DM generally more complex and polypharmacy and adverse drug reactions arise more frequent during treatment (Kocurek, 2009).

One way to improve adherence to treatment can be done through the provision of education. Education can be done in various ways, including counselling and providing educational booklet for the patients. Education for patients can be performed by pharmacists as one form of pharmaceutical services to improve the knowledge and understanding of patients (Malathy, Narmadha, Ramest, Jose, and Babu 2011). In one study, educational programs were also known to be effective in improving HbA1c, fasting glucose, cholesterol, BMI, triglycerides tests (Rashed, Al Sabbah, Younis, Kisa, and Parkash, 2016).

Giving education to every patients individually, such as personal counselling is hard to do in society, especially in primary health care in Indonesia. This is because the number of pharmacists who work in primary health care are usually limited. Therefore, there is a need to find an alternative provision of education that enhance the knowledge and understanding of DM patients on the diseases and treatment, such as the public counselling and delivering educational booklets for the DM patients. These can be simpler method which can provide information to patients when they visit primary health care and also when they are at home. Nevertheless, the effectiveness is still questioned. Thus, the researcher found it interesting to assess the effectiveness of the public counselling and booklet handouts.

## METHODS

This was an interventional prospective study conducted from September 2016 to January 2017 at Makassar Sub-district and Kebon Pala primary health care in East Jakarta Indonesia. A quasi-experimental pretest-posttest was designed to assess effectiveness of interventions which were public counselling and booklet handouts given during period of the study. The public counselling performed as public lecture for DM patients while the booklets provided information diabetes treatment related. The interventions were given 3 times during 12 weeks study period. The collected data were glycated hemoglobin (HbA1c) levels and *Morisky Medication Adherence Scale (MMAS-8)* scores from pretest and posttest performed before and 12 weeks after interventions.

This study used total patients with type 2 DM, in which

Inclusion criterias:

- a. Patients Aged > 18 years
- b. Patient had diabetes for more than 1 year
- c. Patients speak and understand Indonesian
- d. Patients used oral antidiabetic oral (OAD)
- e. Patients with fasting glucose test > 126 mg/dl
- f. Patients who came regularly to the two primary health cares for the routine checkup

Exclusion criterias:

- a. Patients cannot answer the questionnaire independently due to have a mental illness, dementia, or other comorbid medical conditions which were not as stable.
- b. Patients with hearing or vision problems

c. Pregnant women

The tools used to collect data in this study was the HbA1C level gauges i-Chroma™ and MMAS-8 questionnaires. The questionnaire was a list of statements or questions structured so that the respondent was given the ease in completing them by providing check mark (✓) in the answer choices or write a brief answer (Morisky and DiMatteo 2011).

Descriptive analysis was used to obtain a distribution frequency as well as the proportion of various variables of the study. These variables were divided into 3 groups of characteristic *i.e* socio-demographic, clinical and life style characteristics. Paired t-test was used to determine the changes in HbA1c levels, while Wilcoxon test was performed to determine the changes in MMAS-8 scores. P values < 0.05 were considered to indicate a statistically significant relationship. All statistical analyses were performed using Statistical Package for Social Sciences software for Windows version 22.0 (SPSS Inc., Chicago, USA).

RESULTS AND DISCUSSIONS

During September 2016 to January 2017, 44 patients were obtained as respondents, but only 30 patients completed the interventions as requirement of the study.

a. Patient characteristics

Distribution characteristics of the patients based on socio-demographic is shown in Table 1.

Tabel 1. Socio-demographic Characteristics

Characteristic	n (%)
<b>Sex</b>	
Male	8 (26.7)
female	22 (73.3)
<b>Total</b>	<b>30 (100.0)</b>
<b>Age</b>	
< 60 yo	13 (43.3)
≥ 60 yo	17 (56.7)
<b>Total</b>	<b>30 (100.0)</b>
<b>Level of Education</b>	
Low	11 (36.7)
middle	14 (46.7)
High	5 (16.7)

Characteristic	n (%)
<b>Total</b>	<b>30 (100.0)</b>
<b>Occupation</b>	
Unemployed	25 (83.3)
Employed	5 (16.7)
<b>Total</b>	<b>30 (100.0)</b>

The majority of respondent was female (73.3%). A similar study conducted by Yuniarti (2013) had showed similar results with the prevalence of DM type 2 patients was greater in women. Most of the respondent (56.7%) aged greater than or equal to 60 years. This is reasonable because of the risk of disease progression of type 2 DM increases with age (Perkeni 2006). In terms of level of education and occupation, they were mostly in middle (46.77%) and unemployment (83.3%), respectively. These were because most of the respondents were housewives and some of them were retired due to their age.

The clinical characteristics of the respondents were shown in Table 2. Respondents who had duration of type 2 DM for < 5 years was 63.3% and 83.3% of respondents had comorbidity, particularly hypertension. The prevalence of DM patients with hypertension depends on the type of diabetes, age, obesity and ethnicity. Hypertension is a major risk factor for both cardiovascular and microvascular disease (American Diabetes Association, 2012).

Tabel 2. Clinical Characteristics

Characteristic	n (%)
<b>Duration of type 2 DM</b>	
< 5 years	19 (63.3)
≥ 5 years	11 (36.7)
<b>Total</b>	<b>30 (100.0)</b>
<b>Comorbidity</b>	
no	5 (16.7)
yes	25 (83.3)
<b>Total</b>	<b>30 (100.0)</b>
<b>No. of OAD</b>	
1	7 (23.3)
2	20 (66.7)
3	3 (10.0)

Total	30 (100.0)
Adverse drug reactions	
No	26 (86.7)
Yes	4 (13.3)
Total	30 (100.0)

Most of the patients (66.7%) received combination two OADs which were the sulfonylurea class (glibenclamide or glimepiride) and the class of biguanide (metformin). *Perkumpulan Endokrinologi Indonesia* (2011) had recommended to use 2 to 3 type of ADOs when monotherapy was not able to stabilize blood glucose levels after 2-3 months (with HbA1c level > 7%).

There were 4 patients (13.3%) had experienced side effects such as fatigue, dizziness, limp and shaking after using glibenclamide as well as nausea after taking metformin. Fatigue, dizziness, limp and shaking are symptoms of hypoglycemia that may occur after using antidiabetic sulfonylureas such as glibenclamide (Lacy *et al.*, 2011). Symptoms of hypoglycemia usually occur when the blood glucose less than 60 mg/dl. This can be handled by sweets (sweet tea, syrup, etc.) but not with artificial sweeteners or carbohydrate such as rice (Soegondo *et al.* 2011). Digestive tract disorders are the major side effects that often occur in the use of metformin. The percentage of side effects on the digestive tract disorders due to metformin, which were 10-53% of diarrhea, nausea or vomiting 7-26%. Although side effects of metformin can be reduced by taking metformin concurrently or after the meal and dose titration, there are some patients who still cannot tolerate the side effects (Lacy *et al.* 2011).

Lifestyle characteristics of the respondents are presented in Table 3. Respondents who use herbs in addition to their medication accounting for 16.67%. Herbs used by the respondents such as insulin leaf, bay leaves, bitter leaf and mangosteen peel were believed can control blood glucose levels. Respondents used such plants with by boiling it with water and drink it as a medicine decoction. More than 400 different plants and the extracts believed to be beneficial for patients with diabetes. Most of these plants have been reported to have hypoglycemic properties, but there is no sufficient evidence to describe a definite conclusion about the efficacy of medicinal plants against diabetes (Yeh *et al.* 2003).

Table 3. Lifestyle Characteristics

Characteristic	n (%)
Herbs	

No	25 (83,3)
Yes	5 (16.7)
Total	30 (100.0)
Dietary habit	
Not adjusted	11 (36.7)
Adjusted	19 (63.3)
Total	30 (100.0)
Exercise	
No	24 (80.0)
Yes	6 (20.0)
Total	30 (100.0)

A total of 63.3% of respondents confessed that they adjusted their diet with restriction of sugar and carbohydrates (rice) as well as 56.7% of respondents said to do exercise. Weight loss and diet (in patients who are obese) may improve short-term blood glucose levels and have the potential to improve long-term metabolic control. Meal planning should be at sufficient nutrient content and accompanied by a reduction in total fat, especially saturated fat (Soegondo *et al.*, 2011). Based on physical activity, "The Canadian Diabetes Association (CDA) 2003 Clinical Practice Guidelines" recommend patients with type 2 DM do moderate-intensity physical activity such as fast walking and cycling for at least 150 minutes per week, at least 3 days but not consecutively (Plotnikoff 2004).

#### b. Effectiveness of Educations

This study used HbA1c levels to assess compliance of patients with type 2 DM because HbA1C measurement results are not too affected by variations daily plasma glucose levels as a result of diet, exercise, and medication. However, compared to other blood glucose tests, the cost of HbA1C examination is more expensive (WHO 2011). HbA1C is the gold standard for monitoring long-term blood glucose control in order to describe the level of patient compliance. Patients Compliance correlated positively with a decrease in HbA1C. HbA1C value of equal or more than 7% showed a low-level compliance to their treatment (Chua and Chan, 2011). Patients who have a low glucose control associated with poor adherence to treatment so that the therapy high possibly ineffective. Every 25% increase medication adherence is associated with decreased HbA1c (Rumsfeld, 2006).

HbA1c measurement in this study conducted at the Indonesian Center for Health Laboratory Ministry of Health that has been accredited to ISO/IEC 17025: 2005.



The analytical method used<sup>12</sup> the measurement refers to the methods used in the DCCT (The Diabetes Control and Complications Trial), i.e HPLC method (high performance liquid chromatography) (Sacks, 2011). Mean HbA1c levels before and after interventions are shown in Table 4.

Table 4. HbA1c levels Before and After Intervention

	Before		After	
	n	%	n	%
HbA1c value < 7	11	36.7	23	76.7
HbA1c value ≥ 7	19	63.3	7	23.3
Mean ± SD	7.72 ± 1.356		6.18 ± 0.988	
p	0.00			

The results of measurements performed using paired t test shows that there were significant differences (p<sup>10</sup> < 0.05) HbA1c levels before and after the intervention. At the beginning of the study the mean level of compliance of respondents based on HbA1c was 7.72 ± 1.356% and 63.3% of respondents have HbA1c levels were equal or over 7%. However, after given interventions the mean declined to 6.18 ± 0.988 with 23.3% respondents still had poor HbA1c levels. The decline in the mean of HbA1c levels showed that there was an increase of the compliance in patients with type 2 DM after being given educations.

Measuring the level of compliance of the respondents in<sup>2</sup> addition to using HbA1c levels was also conducted using questionnaires *Morisky Medication Adherence Scale* (MMAS-8). MMAS is an assessment tool from WHO that has been validated and is often used to assess patients' adherence to treatment (Morisky & DiMatteo 2011).

MMAS-8 is the result of the revision of the MMAS-4 which has higher sensitivity and specificity, which were 93% and 53%, respectively. Sensitivity of 93% indicates that the scale is pretty well used to identify patients with a low level of adherence, while specificity of 53% indicates that the scale has sufficient ability to identify patients who do not have problems of treatment adherence (Krapek 2004).

MMAS questionnaire was used because it was cheap and can be used easily in health care. MMAS-8 consists of 8 questions with yes and no answers. MMAS-8 assessment scores are divided into three categories, namely low compliance with a score of more than 2, moderate adherence to the score of 1-2, and a high compliance with a score of 0 (Coppel *et al.* 2008). Mean

MMAS-8 scores before and after interventions are shown in Table 5.

Table 5. MMAS-8 Scores Before and After Intervention

	Before		After	
	n	%	n	%
High compliance	4	13.3	8	26.7
Middle compliance	10	33.3	12	40.0
low compliance	16	53.4	10	33.3
Mean ± SD	2.83 ± 2.086		1.90 ± 1.605	
p	0.002			

The results of measurements performed using the Wilcoxon test shows that there was also a significant difference (p < 0.05) of MMAS-8 scores before and after the interventions. It found that before the interventions mean of MMAS-8 score was 2.83 ± 2.086 with 53.4% respondents had low compliance. The mean of the scores then declined to 1.90 ± 1.605 with low compliance respondents became 33.3% which also shows that the compliance of patients with type DM had increased after given interventions.

Study conducted by Abdo and Mohamed (2010) who carried an health education program for type 2 DM patients also shows that the education was an effective tool that implicated change in diabetes patients' knowledge, attitude towards diabetes, random blood glucose and HbA1c levels.

Patient education is an important pillar in the management of diabetes to optimize the treatment. If education can be implemented effectively, it would improve adherence and self-management by patients against the disease (Farsaei *et al.*, 2011).

WHO in 2006 declared that the pharmacist plays a fairly important to help overcome the problem of poor adherence to long-term therapy in chronic diseases, such as diabetes. Patients with type 2 DM may be given medications are manifold so that pharmacists are well positioned to provide education to patients about their treatment and explains the treatment regimen to improve the compliance (Farsaei *et al.*, 2011). Various studies on educational interventions by pharmacy staff has been shown to improve control and compliance of patients with type 2 DM. A study by Lindenmeyer (2011) states that there were potential benefits of a given pharmaceutical interventions to improve the effectiveness of treatment, especially in education. Educational intervention provided by the pharmacy also could improve blood

glucose control and compliance of patients with type 2 DM (Jennings *et al.* 2007).

#### LIMITATION

This study had small number of samples and the measurement level of compliance based on MMAS-8 questionnaire could be answered subjectively by respondents. Hence, further study with more respondents and involving their family need to be conducted to get better picture of their compliance.

#### CONCLUSIONS

The public counselling and booklet <sup>22</sup>out were effective to improve patient compliance in patients with type 2 DM.

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