

The Impact of Pharmacist Intervention on Clinical Outcome, Adherence, and Quality of Life of Patients with Type 2 Diabetes Mellitus

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Abstract. Type 2 Diabetes Mellitus (T2DM) remains as a global health problem. This cohort study aimed to analyze the effect of pharmacy intervention (PI) on blood glucose level (BGL), adherence, and quality of life (QOL) of T2DM outpatients (n=48) admitted to Dr. Tengku Mansyur hospital, Tanjung Balai, Indonesia period December 2020 to May 2021. The patients' BGLs were recruited from their medical records, their adherence to medication was analyzed using MMAS-8 questionnaire, and their QOLs were analyzed using EQ-5D-3L questionnaire (< 0.60 = bad, 0.6 - <0.80 = moderate, ≥0.80 = good). These outcomes were compared before and after PI. The obtained data were analyzed using descriptive and Wilcoxon Signed-Rank tests in the SPSS Program. Mean age of the patients was 59.20 ± 8.20 (years). Mean BGLs (mg/dL) of the patients: before PI 1, 262.02±5.91; follow up after PI, 168.60±3.07; Mean adherence scores: before PI 1, 4.833 ± 0.08; before PI 2 4.70±0.07; after PI 6.833±0.09; follow up after PI 7.793±0.05. Mean QOLs of the patients: before PI 1, 0.719±0.005; follow up after PI 0.977 ± 0.009. There were significant differences among BGLs, patients' adherence, and their QOLs before and after PI. p=0.000. This study proved that PI improved the outcomes of T2DM patients.

Keyword: Pharmacist Intervention, T2DM, Adherence, QOL

Abstrak. Diabetes Mellitus Tipe 2 (DMT2) masih merupakan masalah kesehatan global. Penelitian kohort ini bertujuan untuk menganalisis pengaruh intervensi farmasi (IF) terhadap kadar glukosa darah (KGD), kepatuhan, dan kualitas hidup (QOL) pasien DM Tipe 2 (T2DM) (n=48) yang dirawat jalan di RSUD Dr. Tengku Mansyur, Tanjung Balai, Indonesia periode Desember 2020 hingga Mei 2021. KGD pasien yang direkrut dari rekam medis mereka, kepatuhan terhadap pengobatan yang dianalisis menggunakan kuesioner MMAS-8, dan QOL pasien yang dianalisis menggunakan kuesioner EQ-5D-3L (<0,60 = buruk, 0,6 - <0,80 = sedang, ≥0,80 = baik) dibandingkan sebelum dan setelah IF. Data yang diperoleh dianalisis secara deskriptif dan uji Wilcoxon Signed-Rank dalam Program SPSS. Usia rerata pasien adalah 59,20 ± 8,20 (tahun). Rerata KGD (mg/dL) pasien: sebelum IF 1, 262,02 ± 5,91; tindak lanjut setelah IF, 168,60±3,07. Rerata skor kepatuhan: sebelum IF 1, 4,833 ± 0,08; tindak lanjut setelah IF 7,793±0,05. Rerata QOLs pasien: sebelum IF 1, 0,719±0,005; tindak lanjut setelah IF 0,977 ± 0,009. Terdapat perbedaan yang signifikan antara KGD, kepatuhan, dan QOLs pasien sebelum dan sesudah IF, p=0,000. Penelitian ini membuktikan bahwa IF meningkatkan outcomes pasien DMT2.

Kata Kunci: Intervensi Apoteker, DM Tipe 2, Kepatuhan, QOL

Received 03 February 2022 | Revised 03 April 2022 | Accepted 30 April 2022

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1. Introduction

Diabetes mellitus is a degenerative disease with continue increasing prevalence. The increase in the number of people with diabetes is mostly caused by a lifestyle that lacks of physical activity and unbalanced nutrition. The number of people with DM globally has increased from 108 million people in 1980 to 422 million people in 2014 [1]. According to the International Diabetes Federation (IDF), the global number of people with DM was 463 million in 2019 and Indonesia was ranked as the third country with the largest DM patients with an age range of 20-79 years. Almost half (46.2%) or 4.2 million of deaths in the world are caused by DM [2]. In Indonesia, DM patients increased from 6.9% in 2013 to 10.9% in 2018 [3, 4].

Diabetes mellitus is defined as a metabolic disorder in the body marked by chronic hyperglycemia accompanied by impaired carbohydrate, lipid and protein metabolisms as a result of insulin insufficiency. Insulin insufficiency can be caused by impaired or deficient insulin production by the beta cells of Langerhans of the pancreas gland or caused by a lack of responsiveness of the body's cells to insulin. Inappropriate management of DM could result in uncontrolled BGL, causing many complications such as diabetic neuropathy, diabetic nephropathy, and diabetic retinopathy. These complications require polypharmacy which can lead to DRPs which in turn can worsen the patient's condition and even death. Therefore, controlling the patients' BGL, increasing adherence, and minimizing the incidence of DRPs are important to optimize therapy [1, 5].

Several studies have been conducted to identify the incidence of DRPs in T2DM patients. A study identified 406 events of DRPs in inpatients and outpatients at Regional Hospitals in Malaysia [6]. A more recent study was conducted to identify the incidences of DRPs at the Hiwot Fana University specialist hospital in Eastern Ethiopia period May to August 30 2018. This study found as many as 365 cases of DRP's [7]. Another study found as much as 75.55% of DM patients admitted to the Kalooran GMIM hospital, Amurang Minahasa period December 2016 to March 2017 experienced DRP's. Efforts should always be made to identify, analyze, and resolve DRPs in the management of T2DM patients. This study aimed to determine the impact of pharmacist interventions on clinical outcomes, adherence and quality of life of outpatients with T2DM [8].

2. Methods

This retrospective prospective comparative cohort study was conducted on T2DM outpatients admitted to the clinic of internal medicine in Tanjung Balai Hospital, Sumatera Utara, Indonesia period December 2020 to May 2021. Ethical clearance was obtained from ethics committee Faculty of Medicine, University of Sumatera Utara. Number of the patients recruited were 48. The BGL, adherence, and QOL of the patients were compared before and after PI. The patients' BGLs were recruited from their medical records, adherence was analyzed using MMAS-8

questionnaire that consists of 8 questions; 1) do you often forget to take your medicine? 2) Apart from forgetting, what makes you forget to take your medicine? In the past two weeks, how many times have you forgotten to take your medicine? 3) Have you ever reduced or stopped taking medication without telling your doctor because you felt that while taking medication your condition got worse? 4) when you travel or leave the house, do you sometimes forget to bring your medicine? 5) Did you take all your medicine yesterday? 6) When you feel your symptoms are under control, do you sometimes stop taking your medication? 7) taking medication every day is a real inconvenience for some people. Have you ever been bothered by your medication? 8) How often do you have trouble remembering to take all your medications? Then after all the data was obtained, the adherence score of T2DM patients was calculated, and categorized them into 3 categories, namely high adherence (total score 8), moderate (6-7), and low adherence (total score <6) [9]. The patients' QOLs were analyzed using the EQ-5D-3L questionnaire that comprises 5 dimensions (mobility/walking, self-care, usual activities, pain/discomfort, anxiety/depression) with each dimension has 3 levels of questions, namely 1) no problem, 2) moderate problem and 3) severe problem [10]. The scores of the patients' QOL were grouped into 3 categories (< 0.60 = bad, 0.60 - <0.80 = moderate, \geq 0.80 = good). A value of 100% or 1,000 indicates perfect health. The obtained data were analyzed using descriptive and Wilcoxon Signed-Rank tests in the SPSS Program.

3. Results and Discussion

Of the 124 T2DM patients admitted to the hospital during the study period, only 48 patients met the inclusion criteria. Characteristics of the patients is shown in Table 1. Mean age of the patients was 59.20 ± 8.20 (years). Most (58.3%) of them were female. More than one third (47.9%) of the patients graduated from senior high school. By the disease duration, most (70.83%) of the patients have suffered from the disease for 1-5 years.

Table 1. Characteristics of the patients with T2DM admitted to Dr. Tengku Mansyur Hospital period December 2020 to May 2021

Characteristics of patients		Number (48)	Percentage (%)
Gender	Male	20	41.7
	Female	28	58.3
Age	<40	1	2.1
	41-50	7	14.6
	51-60	17	35.5
	61-70	21	43.7
	>70	2	4.1
Education	University	11	22.9
	Senior high school	23	47.9
	Junior high school	14	29.2

Duration of T2DM (in years)	<1	3	6.25
	1-5	34	70.83
	>5	11	22.92
T2DM patients	With	29	60.42
	Complication		
	Without complication	19	39.58

Clinical outcome

The consensus of the Indonesian Endocrinology Association states that one of the criteria to diagnose DM is ad random BGLs was higher than 200 mg/dl [11]. It is also an indicator of therapeutic successfulness. If the ad random BGLs of DM patients is lower than 200 mg/dl means the required BGL target is achieved. The results of patients' ad random BGLs before and after PIs can be seen in Table 2. Mean of the patients' BGLs (mg/dl) before PI 1 was 262.02±5.91, before PI 2 was 259.39±5.53, after PI was 202.354±4.80, and follow up after PI was 168.604±3.07 (p = 0.000).

Table 2. Distribution of T2DM patients according to BGL (mg/dl) before and after PIs

BGL	Before PI 1	Before PI 2	After PI	Follow up after PI
Mean	262.02±5.91	259.39±5.53	202.354±4.80	168.604±3.07
Percentage of patients				
BGL	Before PI 1	Before PI 2	After PI	Follow up after PI
<200	0	0	58.3	93.75
>200	100	100	41.7	6.25

Before PI, BGLs were monitored twice and did not show a decrease in BGLs <200 mg/dl. After PI, 28 (58.3%) of the patients had BGLs of lower than 200 mg/dl. After follow up, as many as 45 (93.75%) of the patients had BGLs of lower than 200mg/dl. This present study proved that PI improved the clinical outcomes of the T2DM patients. A study found that pharmaceutical service program was effective in improving clinical outcomes of patients with T2DM [12]. Shareef also said that PI through education and counseling for DM patients can control the patient's BGLs [13]. Pharmacy intervention plays a crucial role to improve the management of T2DM patients.

Adherence Level

The results patients' adherence to their medication is shown in Table 3. The patients' adherence level was low with mean score per patient of 4.833±0.08 before PI 1 and 4.708±0.07 before PI

2, while the adherences level after PI were high with mean score of 6.833 ± 0.09 per patient and follow up after PI was 7.793 ± 0.059 per patient ($p = 0.000$).

Table 3. Distribution of the patients' medication adherence (n=48) before and after PIs

	Before PI 1	Before PI 2	After PI	Follow up after PI
Mean patients' adherence	4.833 ± 0.08	4.708 ± 0.07	6.833 ± 0.09	7.793 ± 0.059
Percentage of Patients				
Adherence level	Before PI 1	Before PI 2	After PI	Follow up after PI
High	0	0	14.6	77.1
Moderate	8.3	4.2	85.4	22.9
Low	91.7	95.8	0	0

The difference in adherence scores before and after PI indicated that the role of pharmacists in providing counseling to T2DM patients is important to increase the patients' adherence to their medication. The increase in patients' adherence proved that the information obtained after counseling had a positive impact on the patients' behavior to take their medication. By knowing the mechanism of drugs action, the effects, and risks if the patients do not take their medications properly as explained by the pharmacists, they were motivated to improve their adherence to their medication which in turn improve the treatment outcomes.

The finding of the present study supported the study obtained by [14] in which there was an increase in adherence of T2DM patients after receiving education provided by pharmacists at the Satellite Health Center and Kedaton Health Center Bandar Lampung City. More recent study conducted by [15] at the Halmahera Health Center, Semarang also obtained that pharmacist counseling could increase the adherence of T2DM patients to their medications.

Quality of life (QOL)

One example of a generic instrument to measure quality of life is the 5-Dimensional EuroQoL (EQ-5D) questionnaire [16]. The European Quality of Life-5 Dimensions-3 Level version (EQ-5D-3L) instrument was used to assess the QOL of T2DM patients in this study. The QOL of T2DM patients before and after PIs can be seen in **Table 4**.

Table 4. Distribution of the T2DM patients (n=48) by QOL level before and after PIs

Patients'	Before PI 1	Before PI 2	After PI	Follow up after PI
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QOL				
Mean	0.719±0.005	0.719±0.001	0.801±0.009	0.977±0.009
Percentage of patients				
QOL Level	Before PI 1	Before PI 2	After PI	Follow up after PI
Good (≥0.80)	0	0	8.3	89.5
Moderate (0.60 - <0.80)	100	100	91.7	10.5
Bad (0.60)	0	0	0	0

Mean of the patients' QOL was 0.719±0.005 before PI 1, 0.719±0.001 before PI 2, and increase to 0.801±0.009 after PI, follow up after PI to 0.977±0.009 (p=0.000). Before the intervention all patients had moderate QOL, while after the intervention, 43 (89.5%) of the patients had good QOL.

In this study, the patients' QOL have increased due to several factors, such as the patients' adherence to treatment after being given counseling, information, and education and controlled from adherence to medication use, patient awareness for a healthy life, and increased physical activity and exercise on a daily basis, and a healthy diet in T2DM patients.

Pharmacists have full duties and responsibilities for clinical outcomes and QOL of the patients. Education and counseling related to therapeutic regimens, effectiveness of treatment, healthy lifestyle and physical activity, and adherence to taking medication are the main pillars in improving the patients' QOL.

Several similar studies have been undertaken by researchers elsewhere. A study conducted on the management of T2DM patients in a hospital, Tebing Tinggi year 2019. This study also found that PIs improved QOL of patients [17, 18] obtained that QOL of patients with T2DM was affected by their adherences, meanwhile PIs had positive impact on patients' adherence and QOL [19].

4. Conclusion

Most of the patients with T2DM were females with age range of 61-70 years. Pharmacy intervention improved BGLs, adherence, and QOLs of the patients with T2DM. This finding is important to consider by healthcare providers and policy-maker to improve the management of T2DM patients in the near future.

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