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Research Article

Effect of Drug Information Service on Clinical Outcome of Patients with Type 2 Diabetes Mellitus in Padang, Indonesia

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Abstract

Type 2 diabetes mellitus (T2DM) has been a health burden worldwide, including Indonesia. However, T2DM therapy needs a long and complex process, which patients often do not favor, thus making them not take medications as instructed and negatively affecting the clinical outcomes. This study aimed to understand the effect of Drug Information Service provision on the clinical outcomes of T2DM patients. This quasi-experimental study was conducted using one group pre-post-test design. The fasting blood glucose levels as the clinical outcome were measured before and after the intervention. A drug information service was provided through direct explanation to the patients. Sociodemographic data were analyzed descriptively. The difference in fasting blood glucose before and after the intervention was assessed using Wilcoxon signed-rank test. Forty patients participated in this study. Most participants are female (N=34; 85%) and receive two-drugs combination therapy of metformin and sulfonylureas (N=32; 77.5%). Although there is a decrease in mean fasting blood glucose level after intervention (174.92±59.561 vs. 184.20±49.768), there is no significant difference between fasting blood glucose levels pre-intervention and post-intervention ($p > 0.05$). It is concluded that despite the noticeable decline in blood glucose level after drug information service, its effect on blood glucose control is insignificant.

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INTRODUCTION

Diabetes mellitus (DM) has been a health burden worldwide, including Indonesia. Type 2 diabetes mellitus (T2DM) is the most common type of DM characterized by insulin resistance[1]. In 2019, it was estimated that 463 million (9.3%) adults worldwide suffered from DM. This number is predicted to increase to 578 million in 2030. It is also estimated that 4.2 million people lost their lives due to DM and its complications. Meanwhile, over 700,000 people over 15 in Indonesia suffer from DM, while more than 13,000 originated from West Sumatra[2,3].

Persistent hyperglycemic conditions in uncontrolled DM can cause acute or chronic complications. Among acute complications were diabetic ketoacidosis and diabetic coma. Meanwhile, the chronic complications of DM are nephropathy, neuropathy, and cerebrovascular disease[4].

Blood glucose control is essential to prevent those complications, observed through several parameters such as fasting blood glucose, postprandial blood glucose, and glycated hemoglobin[5]. Blood glucose control is influenced by several factors, such as demographic and clinical characteristics. However, it was also well understood that patients who take antidiabetic medications as instructed are likely to have lower glycated hemoglobin levels and better control of DM-related

comorbidities[6]. Nevertheless, T2DM therapy needs a long and complex process, often not favored by patients[7]. Several studies also suggested that many patients have low adherence to T2DM medication regimens[8-10].

Several interventions can improve patients' understanding and behavior related to their medications, for example, educational video and smartphone-based education[11]. However, in Indonesia, patients may not always have adequate access to technology. Thus, there is a need to develop a simple approach to implement in Indonesia's primary health care setting[12].

Drug information service is one of the pharmaceutical services that can improve clinical outcomes in T2DM. Drug information service is a part of pharmaceutical care delivered in public health centers and other settings like hospitals or pharmacies[13]. Drug information service is defined as a service by pharmacists to provide accurate, precise, and up-to-date information to doctors, pharmacists, other health professionals, and patients. This service includes providing and disseminating information to consumers, both actively and passively, answering questions from patients and health professionals, and creating media of information such as leaflets, drug labels, posters, and newsletters[14].

Few studies have examined the impact of drug information on patient outcomes. A review by Rutter *et al*.[15] from 20 studies concluded that drug information service affects patient outcomes positively. Previous studies and a review article also shows that pharmaceutical care intervention, which includes providing medication information to patients with T2DM, had a positive impact on clinical outcome[16-18]. A study in France shows that tailored information about the disease, diet, and drug treatment improved patients' HbA1c levels[19]. However, studies that reported the effect of drug information services on clinical outcomes in T2DM patients are relatively rare. Thus, we conduct a quasi-experimental study to understand the effect of drug information service provision on the clinical outcome of T2DM patients at Andalas Public Health Center in Padang, Indonesia.

MATERIALS AND METHODS

Materials

This study was conducted at Andalas Public Health Center in Padang, West Sumatra, Indonesia, from August to October 2021. The tools used in this study were data collection forms, stationery, and laptops. Meanwhile, the materials used were drug information sheets and patients' data compiled by the public health center.

Methods

Study design

This quasi-experimental study was conducted using one group pre-post-test design. All participants in this study were given a drug information service. The fasting blood glucose level was measured before and after the intervention. The staff at the public health center performed the blood glucose level measurement.

Population and sampling

The population of this study was the patients with T2DM who were registered in a Chronic Disease Management Program (*Program Pengelolaan Penyakit Kronis*/PROLANIS) at Andalas Public Health Center in Padang, West Sumatra, Indonesia. The sample was chosen according to the inclusion criteria and exclusion criteria. The inclusion criteria were adult T2DM patients ≥18 years who received oral antidiabetic medication and consented to participate. The exclusion criteria were the patients who dropped out from the study or were referred to other healthcare facilities.

Intervention

A drug information service was provided through direct explanation to the patients. The drug information in this study consisted of the medication indication, instruction on medication use, and the side effects of each medication. A drug information guide (https://doi.org/10.5281/zenodo.6496273) was developed for oral antidiabetic agents that were commonly used in the public health center. Patients were also reminded to take their medications as instructed and to return 30 days later for a follow-up period.

Data analysis

Sociodemographic data were analyzed descriptively. The data distribution of fasting blood glucose was analyzed using the Shapiro-Wilk test. The association between patients' gender, age group, and the number of medications with fasting blood glucose levels were measured using the independent t-test method. Meanwhile, the difference between types of comorbidities with blood glucose levels was measured by one-way ANOVA. A Pearson correlation test was also performed to analyze the correlation between the duration of DM and patients' blood glucose levels. The difference in fasting blood glucose before and after the intervention was assessed using Wilcoxon signed-rank test because the data on blood glucose levels after intervention were not normally distributed.

Ethical approval

This study had obtained ethical approval from the Research Ethics Committee, Faculty of Medicine Universitas Andalas, and registered under No. 391/UN.16.2/KEP-FK/2021.

RESULTS AND DISCUSSION

From August to October 2021, 73 patients were recruited for this study. Six patients did not attend the follow-up, four moved to other healthcare facilities for control or medical treatment, while 23 did not attend the healthcare center on time (30 days after the previous visit). Thus, only the data from 40 patients were included for further analysis. Most participants were female (N=34; 85%) and did not work, either homemakers or pensionary (N=35; 90%), as seen in **Table I**. **Table II** shows that most patients also had T2DM for 1 to 5 years (N=36; 90%). Besides, most patients (N=29, 72.5%) also had comorbidities, mostly hypertension (N=17, 42.5%), although other comorbidities such as hypercholesterolemia were also found.

Table I. Sociodemographic characteristics of participants

Characteristics	Number of subjects (N=40)	Percentage (%)
Gender		
Male	6	15
Female	34	85
Age (years)		
18-59	20	50
≥60	20	50
Last education		
Elementary school	15	37.5
Junior high school	9	22.5
Senior high school	12	30
Diploma/bachelor degree	5	10
Occupation		
Worked	5	10
Not worked	35	90

Table II. Clinical characteristics of participants

Characteristics	Number of subjects (N=40)	Percentage (%)
Duration of T2DM		
< 1 year	4	10
1-5 years	36	90
Number of comorbidities		
0	11	27.5
1	20	50
2-3	9	22.5
Type of comorbidities		
Hypertension	17	42.5
Hypercholesterolemia	3	7.5
Hypertension + hypercholesterolemia	6	15
Other	3	7.5

Generally, most participants received the combination of two oral antidiabetic drugs from biguanide (metformin) and sulfonylurea class of therapy (N=29; 72.5%), as shown in **Table III**. The most common sulfonylurea drugs administered to the patients were glimepiride, used by 31 participants (77.5%). According to the T2DM management guideline in Indonesia, the first-line medication for T2DM is metformin due to its good effectiveness, low hypoglycemia risk, neutral effect on body weight, improved cardiovascular outcome, and low cost. Meanwhile, sulfonylurea monotherapy could cause side effects such as hypoglycemia and body weight gain[2,20]. Combined antidiabetic therapy is recommended when the glycemic target is not reached. Hence, the high percentage of combination therapy in this study implies that the patients may need more than one antidiabetic medication to achieve the glycemic target[21].

Table III. Participants' medication profile

Characteristics	Number of subjects (N=40)	Percentage (%)
Number of medication		
1 oral antidiabetic agent	8	20
2 oral antidiabetic agents	32	80
Type of antidiabetics		
Metformin	5	12.5
Glimepiride	2	5
Gliquidone	1	2.5
Metformin+glimepiride	29	72.5
Metformin+glibenclamide	2	5
Glimepiride+gliquidone	1	2.5

Indonesian National Formulary has a set of criteria that manage the administration and restrictions of the different antidiabetic drug classes. Metformin and specific sulfonylurea agents (glibenclamide, glimepiride, and glipizide) can be administered in primary health care facilities[22]. The availability of these drugs on the national formulary may explain why participants received these drug classes for antidiabetics. Although gliquidone is not listed as the medication for patients in primary health care, it can be administered for the back-referral program[23]. A back-referral program is a health service that provides treatments and medications based on the recommendation of a specialist physician for patients with chronic diseases in primary health care[24].

Due to the restrictions at the time of the study and the high cases of COVID-19 in the area, we could obtain fasting blood glucose data as the clinical outcome. Besides HbA1c, fasting blood glucose is also one of the monitoring parameters useful in T2DM patients[25,26]. Compared to HbA1c, fasting blood glucose is a direct, widely accepted, and inexpensive measure[27]. For patients taking oral antidiabetics, blood glucose monitoring also can be considered to assess changes in blood glucose control, monitor the effect of foods on postprandial blood glucose, and changes in blood glucose levels during illness[28].

Before the intervention, participants' fasting blood glucose levels ranged from 95-295 mg/dL. An analysis of the difference in blood glucose levels across different comorbidities and medications was also conducted (**Table IV**) to check for any significant differences. However, no characteristics were associated with patients' blood glucose levels before intervention ($p > 0.05$). It showed that the pre-intervention blood glucose levels were not different among participants of different gender, ages, duration of T2DM, type of comorbidities, and a number of medications. In other words, this means that patients had no difference in baseline blood glucose levels. In contrast, other studies reported otherwise. A study in China suggested that older age and fewer than 12 years of education were associated with poor glycemic control[29]. Meanwhile, another study in Ethiopia found that comorbidities, disease duration (more than seven years), and combination therapy that included insulin were predictors of poor glycemic control in patients with T2DM[30].

Thirty days after the intervention, patients' fasting blood glucose levels ranged from 113-364 mg/dL (**Table V**). This data showed that not all participants successfully achieved the target of blood glucose control. Guidelines released by the American Diabetes Association and the Indonesian Association of Endocrinology (*Perhimpunan Endokrinologi Indonesia*/PERKENI) recommend that adults with diabetes achieve pre-prandial capillary plasma glucose of 80-130 mg/dL[31].

Table IV. Relationship between participants' characteristics with fasting blood glucose levels (pre-intervention)

Characteristics	p-value
Gender	0.430
Age	0.670
Duration of T2DM	0.075
Type of comorbidities	0.208
Number of medication	0.665

Table V. Comparison of fasting blood glucose levels (pre-intervention and post-drug information service intervention)

Variable	Pre-intervention		Post-intervention	
	N	%	N	%
Blood glucose level (mg/dL)				
<130	5	12.5	10	25
130-199	18	45	21	52.5
≥200	17	42.5	9	22.5
Mean±SD	184.20±49.768		174.92±59.561	
Median	182.5		158	
*p**	0.096			

*Mann Whitney U Test, significance level is indicated by p <0.05

Despite an increase in both minimum and maximum levels of fasting blood glucose post-intervention, patients' fasting blood glucose levels under 130 mg/dL increased from 12.5% to 25% (**Table V**). The mean and median of this parameter also decreased slightly. However, there was no significant difference between fasting blood glucose levels pre-intervention and post-intervention (p >0.05). Although post-interventional blood glucose was not significantly different from the baseline level, the slight decrease in the mean and median in this study might be worth exploring further. This finding differs from previous studies that documented pharmacists-led interventions could improve patients' blood glucose control.

In a study in Pakistan[32], the intervention involved pictorial charts and verbal communication related to diabetes management. The patients were followed up one month after the baseline. Meanwhile, in a study in Nigeria[33], the intervention was given in two consecutive face-to-face interviews and educational sessions, with a three-month follow-up period. Other studies in Indonesia suggested that educational videos, patient counseling, and drug information provided by pharmacists could improve patients' HbA1c[34,35]. However, another study in Indonesia also did not find a significant effect of drug information service on blood glucose levels, despite lower blood glucose levels observed in the intervention group[36]. These studies suggested the advantages of using a multimodal educational method for patients, not only relying on direct explanation to significantly affect patients' blood glucose control. Moreover, glycemic control was also influenced by multiple factors which are not always related to medications, such as dietary control[37], and other physical-related factors, such as BMI and central obesity[38]. This study was conducted when the COVID-19 cases were still high in Indonesia, which made more intensive and comprehensive educational provision to patients impossible. Besides, the fasting blood glucose monitoring needs to be accompanied by other glucose monitoring parameters such as HbA1c, as it reflects blood glucose control in the longer term. The sample of this study is also relatively small, which may not be representative of T2DM patients who received care at primary health care facilities in Indonesia. Further studies involving more patients and control groups are needed to examine drug information's effect in a more robust study design.

CONCLUSION

It is concluded that the provision of drug information results in lower blood glucose levels of T2DM patients at Andalas Public Health Center, Padang, Indonesia, even though the effect is not statistically significant.

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AUTHORS' CONTRIBUTION

Lailaturrahmi: conceptualization, methodology, formal analysis, writing – original draft, writing – review & editing, project administration, funding acquisition. **Fuji Araswati**: investigation, formal analysis, writing – original draft. **Armenia**: conceptualization, methodology, supervision. **Rahmi Yosmar**: conceptualization, methodology, writing – review & editing, supervision, funding acquisition.

DATA AVAILABILITY

None.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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