THE EFFECTIVENESS OF PATIENT DECISION AID IN THE MANAGEMENT OF DIABETES MEDICATION TO IMPROVE PATIENT DECISION, MEDICATION KNOWLEDGE AND THERAPEUTIC OUTCOME

by Lisa Aditama

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Lisa Aditama, Fiorentina Yulia

Faculty of Pharmacy The University of Surabaya Indonesia

ABSTRACT

Background: The effectiveness of medication therapy can be influence by patient decision in the drug use processes. There might be lack of knowledge about medication and regiment therapy, so then influence the therapeutic outcome. While taking a decision for their medication, patient need the collaboration with their health practitioner to decide the optimal therapy. To support patients in decision-making, required an innovation instrument as patient decision aid (PDA).

Objective: The study aimed to see the effectiveness of PDA to help patients in decision-making for their medication also improve medication knowledge and therapeutic outcome.

Methods: The study designed by experimental one group (pre-post study), involved of 25 patients in the community pharmacy at House of Diabetes University of Surabaya. The measure of patient decision used the Decision Conflict Scale (DCS) with 5 domains (uncertainty, informed, clarity values, support, effective decision), patient medication knowledge and blood glucose level as therapeutic outcome, each analyzed by statistical tests.

Results: The study obtained that there is no significant difference after provision of PDA, but significant improve in patient medication knowledge and therapeutic outcome.

Conclusion : For the successful helping patients participate in decision-making for their treatment need pharmacist roles to improve their medication knowledge, blood glucose monitoring also continuous follow-up and evaluation the treatment of type 2 diabetes mellitus.

Keywords: Patient Decision Aid, Medication Knowledge, Type 2 Diabetes Melitus Treatment.

BACKGROUND

Diabetes is a chronic, progressive disease characterized by elevated levels of blood glucose. Diabetes of all types can lead to complications in many parts of the body and can increase the overall risk of premature death. Countries have committed to stop the rise in diabetes, to reduce diabetes-related mortality and to improve access to essential diabetes medicines and basic technologies. Effective tools are available to prevent type 2 diabetes and to improve management to reduce the complications and premature death that can result from all types of diabetes¹.

In general, primary health-care practitioners in low-income countries do not have access to the basic technologies needed to help people with diabetes manage their disease properly. Only one in three low- and middle-income countries report that the most basic technologies for diabetes diagnosis and management are generally available in primary health-care facilities¹.

Diabetes and its complications are major causes of death and has a substantial economic impact on countries and national health systems. Most countries have seen a continuous increase in diabetes. International Diabetes Federation (IDF) estimated 1 in 10 adults will have diabetes for the year 2040, and 1 in 2 adults with diabetes was undiagnosed. Educational programmes needed to improve the management of people with diabetes, public health education is needed at the population level to encourage behaviour change to prevent type 2 diabetes. Countries which high prevalence for diabetes need to develop and implement cost-effective program to improve the health outcomes for people with diabetes and prevent new cases².

Indonesia was the 7th in top ten countries for number of adult with diabetes². Health systems in Indonesia just started a managed care health coverage BPJS from 2014. There are many condition need to improve for better control of the disease, especially in chronic care disease. The most problems in Indonesia was highly need access to medication and increase care of disease complication especially caused by diabetes, hypertension and cancer. It need an action to promote diabetes care, prevention and cure the disease, also takes a leading role in influencing policy, increasing public awareness and encouraging improvements in health³.

Many factors may affect treatment compliance, particularly commitments to taking medication in treating the disease, concerns about side effects, and medical expenses. Patients with Type 2 DM, have a wide and diverse range of issues, which can be a tremendous challenge for doctors and patients. Several factors may affect adherence to the treatment of diabetes patients, knowledge of the disease, perceptions of the benefits and roles of antidiabetic drugs, treatment costs, actual or potential side effects, complex dosing regimens, and patient characteristics⁴.

Things that may affect the success of therapy are in making treatment decisions. Therefore, to achieve results in the success of the treatment it is necessary to care that can be in the form of counseling and information that helps patients participate in health care decision making, by health care providers, to improve the quality of life and prevent patients from worsening conditions and complications⁵. Therefore, an instrument or media that can help collaboration between patients and health providers, called Patient Decision Aid (PDA), which may be formed as leaflet, brochure, interactive media, video /DVD or audio cassette. These media are not intended to replace patient interactions with healthcare providers, but are intended to assist patients in decision-making treatment⁶.

The use of PDA is important because the perception of each patient may be different from the intervention of the health care providers. PDA will help patient to increase knowledge and understanding of information, to choose the type of medicine to gain better expectations and more realistic clinical outcomes.

The important role of healthcare professional was to enhance patient's knowledge and self management for better outcomes⁷. There is many condition that affect patient's readiness to

change after receiving an information from health practitioner. This led patients hard to make a decision to use the medication on the right rule to control the disease⁶.

In this study patients were given interventional use of PDA, to get outcome in the form of increased patients understanding on their diabetes treatment as well as more effective decision-making on treatment and therapeutic outcome.

MATERIALS AND METHOD

This study used a pre-experimental research design "the one group pre-test and post-test design". The population of this study were patients with type 2 diabetes outpatients who used oral antidiabetic (OAD) therapy, who had not reached the therapeutic target, managed by Rumah Diabetes University of Surabaya. The sample size was 25 subjects, calculated using slovin formula. The subjects were given PDA in the form of a card as a tool to assist patients in making decisions of their diabetes treatment (Figure 1).

EFE	KTIVITAS GULA E		NAN	A.	TURAN	PEMAKAIA	N OBAT	PE	MERI		AN G AND		DAF	AH	
KERJA OBAT	GOLONGAN OBAT	NAMA OBAT	PENURUNAN HBA 1C	GOLONGAN OBAT	NAMA OBAT	ATURAN PEMAKAIAN	KETERANGAN		OBAT	ANTIDIA	BETES (RAL (TA	(BLET)		
Meningkatkan jumlah insulin	Sulfonilurea	Glibenclamid Glimepirid Glidazid Glipizid Glikuidon	1-2%	Sulfonilurea	Glimepirid Glipizid Glibenclamid	1x sehari 1x sehari 1-2x sehari	Diminum sesaat sebelum atau pada waktu makan yang pertama (jangan digunakan bila tidak	Sebelum makan	Senin Pagi	Selasa	Rabu	Kamis Siang	Jumat	Sabtu	Minggs Malam
	Glinid	Repaglinid Nateglinid	1-2%		Gliclazid Glikuidon	2x sehari 2-3x sehari	makan)	2 jam Sesudah	_			J			,
Meningkatkan jumlah insulin & menghambat pelepasan glukagon	DPP 4 - inhibitor	Vildaglipitin Sitagliptin Linagliptin Saxaglipitin	0,5-0,8%	Glinid	Repaglinid Nateglinid	3x sehari 3x sehari	Diminum sesaat sebelum atau pada waktu makan yang pertama (jangan digunakan bila tidak	Makan	•	INSII	LIN ONJ				_
(cadangan gula)	Incretin Mimetics	Liraglutid	0,5-1%				makan)			IIIO	T CIND		_		
Menekan produksi glukosa hati & menambah sensitifitas terhadap insulin	Biguanid	Metformin	1-2%	DPP 4 - inhibitor	Vildagliptin Sitagliptin Linagliptin Saxagliptin	1-2x sehari 1x sehari 1x sehari 1x sehari	Diminum sebelum, pada waktu atau sesudah makan (jangan digunakan bila tidak makan)	Sebelum makan	Senin Pagi	Selasa	Rabu	Kamis Siang	Jumat	Sabtu	Minggs Malam
Menghambat penyerapan gula setelah makan Menambah	Penghambat glukosidase alfa	Acarbose	0,5-0,8%	Biguanid	Metformin	1-3x sehari	Diminum pada waktu atau sesudah makan (jangan digunakan bila tidak makan)	2 jam Sesudah Makan	~	~	~	~	~	~	~
kepekaan insulin Menekan produksi	Tiazolidindion	Pioglitazon	0,5-1,4%	Penghambat Glukosidase alfa	Acarbose	1-3x sehari	Diminum pada suapan pertama makan		eriksaan b Metode SA						_
glukosa hati, stimulasi	Insulin	Insulin	1,5-3,5%	Tiazolidindion	Pioglitazon	1x sehari	Diminum sesudah makan		_						
pemanfaatan glukosa				Incretin Mimetics	Liraglutid	Sesuai rekomendasi Dokter	Disuntikkan di bawah kulit	1	100		dMak	olas did	a le a le s	didates	Mil
Pustaka: Perkeni 2 Konversi: HbA1c = Gula Darah = (28.7 Gula Darah (mg/dl (diabeteschort.ora)	(46.7 + Gula Dara * HbA1c) - 46.7) ; HbA1c (%)	sh) / 28.7		Insulin	Insulin	Sesuai rekomendasi Dokter	Disuntikkan di bawah kulit						- A		

EFEK HIPOGLIKEMI & PERUBAHAN			I	EFEK SAMPING				PERTIMBANGAN HARGA				
GOLONGAN	NAMA OBAT	EFEK Hipoglikemi	PERUBAHAN BERAT BADAN		GOLONGAN OBAT	NAMA OBAT Glimepirid	EFEK SAMPING	KETERANGAN LAIN	GOLONGAN OBAT	NAMA OBAT	HARGA	KEUNTUNGAN
Sulfonilurea	Glibenclamid Glimepirid Gliclazid Glipizid Glikuidon	Glibenclamid dan Glimepirid lebih sering menyebabkan hipoglikemi	Sullfonilurea rata-rata meningkatkan berat badan		Sulfonilurea	Glipizid Glibenclamid Gliclazid Glikuidon	Pada awal penggunaan dapat menimbulkan mual, gatal, diare	Pada pasien dengan gangguan fungsi hati dan ginjal, Glipizid tidak direkomendasikan	Sulfonilurea	Glibenclamid Glimepirid Glipizid Glibenclamid	Ekonomis	Sangat Efektif
Glinid	Repaglinid Nateglinid	Dapat menyebabkan Hipoglikemi	Dapat meningkatkan berat badan		Glinid	Repaglinid Nateglinid	Mual, diare			Gliclazid		
DPP 4 - inhibitor	Vildaglipitin Sitagliptin Linagliptin Saxaglipitin		Tidak berkaitan dengan peningkatan berat badan		DPP 4 - inhibitor	Vildagliptin Sitagliptin Linagliptin Saxagliptin	Sebah, Muntah, Sakit Kepala, hidung tersumbat	Linagliptin dapat diberikan pada gangguan fungsi hati dan ginjal (tanpa penyesuaian dosis)	Glinid	Glikuidon Repaglinid Nateglinid	Mahal	Sangat Efektif
Biguanid	Metformin	-	Tidak berkaitan dengan peningkatan berat badan Tidak berkaitan		Biguanid	Metformin	Pada beberapa minggu pertama dapat menimbulkan gangguan	Pada pasien diabetes dengan gangguan fungsi ginial berat tidak	DPP 4 - inhibitor	Vildagliptin Sitagliptin Linagliptin	Mahal	Tidak ada kaitar dengan berat bad
Penghambat glukosidase alfa	Acarbose		dengan peningkatan berat badan				pencernaan (mual, diare, kembung)	direkomendasikan	Biguanid	Saxagliptin	Fkonomis	Tidak ada kaitan
Tiazolidindion	Pioglitazon	-	Tidak berkaitan dengan peningkatan berat badan		Penghambat Glukosidase alfa	Acarbose	Menimbulkan gangguan pencer- naan (buang angin), tinia lembek		Penghambat Glukosidase alfa	Acarbose	Mahal	dengan berat bad Tidak ada kaitan dengan berat bad
Incretin Mimetics	Liraglutid		Menurunkan berat badan		Tiazolidindion	Pioglitazon	Bengkak pada jari tangan, tungkai kaki	Tidak disarankan pada pasien gagal jantung dan	Tiazolidindion	Pioglitazon	Mahal	Memperbaiki pro lipid/kolesterol
		Sering menyebabkan	Meningkatkan berat		Incretin		karena retensi cairan Sebah, muntah,	riwayat fraktur	Incretin Mimetics	Liraglutid	Mahal	Dapat menurunk berat badan
Insulin	Insulin	hipoglikemi, terutama insulin kerja pendek dan cepat	badan		Mimetics	Liraglutid Insulin	diare	Perlu pemantauan gula darah ketat	Insulin	Insulin	Mahal	Memperbaiki pro lipid/kolesterol di sangat efektif

Figure 1. PDA Cards

Subjects were given an explanation of how to use PDA. After four weeks, had been measured the differences in patient knowledge, decision making, blood glucose level and analyzed using statistic paired t-test (Figure 2).

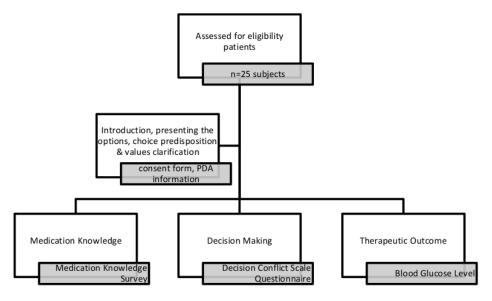


Figure 2. Participant Flow Diagram

The measuring instruments used were medication knowledge survey (derived from Case Management Adherence Guideline⁸), decision conflict scale (DCS) questionnaire (AM O'Connor⁹) and accuchek[®] glucometer.

Medication knowledge survey ask the patient the following questions about every one of their medications⁸:

- a. Name of the medication? (Can the patient read the label? Note: Incorrect pronunciation is not considered a failure on the patient's part to identify medication.
- b. Why is the medication being taken? (for what disease or condition?)
- c. How much medication (number of pills) are to be taken each time?
- d. When is the medication to be taken? (morning, before meals, twice a day, etc.)
- e. What effects should the patient be looking for ? (both positive and negative)
- f. Where is the medication kept? (to ascertain special storage conditions needed)
- g. When is the next refill due? (and plan or methods for obtaining refills of the medication)

The score for calculating the Medication Knowledge Survey is to use the value of the total ratio examined from each question to the total of questions on a scale of 0 to 8. There are a total of 8 answers for each drug. Code 0 if score of the survey <50% was classified as low patient's medication knowledge. Code 1 if score of the survey >50-70% was classified as moderate patient's medication knowledge. Code 2 if score of the survey >70-90% was classified as high patient's medication knowledge. Code 3 if score of the survey >90% was

classified as very high patient's medication knowledge. If the patient gets more than one drug, the number of drugs will be multiplied by eight. Then the result or value is divided by the value obtained by the patient. Medication knowledge level will analyze with Wilcoxon matched pairs test.

The decisional conflict scale measures personal perception of uncertainty in chosing options, feeling uninformed, unclear about personal values, unsupported in decision making, and effective decision making⁹.

Each part of the question consists of 5 ranking scores: 0 = 'strongly agree'; 1 = 'agree'; 2 = 'doubt'; 3 = 'disagree'; 4 = 'strongly disagree'. Calculate 16 parts of each answered question, A) Summed, then; B) divided by number 16 then; C) multiplied by the number 25. The range of score scores from the value 0 (no decision conflict) to 100 (a very high conflict conflict), classified into 3 category: if score 0-25 was classified as good decision making, 26-50 was classified as moderate decision making and >50 as low decision making.

RESULTS AND DISCUSSION

Intervention in this study was conducted for four weeks for each subject in the period of March to June 2016. The variables studied include independent variable, that is PDA as a tool for medication aid and dependent variable, that is patient's medication knowledge, blood glucose levels and treatment decisions using the DCS questionnaire. Patient baseline characteristics describe as in table 1:

Patient Chara	cteristics	n=25	Proportion (%)	
Gender	Male	19	76	
Gender	Female	6	24	
	>18-25	1	4	
	26-35	1	4	
Age (years old)	36-45	4	16	
	46-55	8	32	
	56-65	11	44	
Duration of Dishetes	1 - 5	12	48	
Duration of Diabetes	6 - 10	8	32	
(year)	11- 15	5	20	

Table 1. Patient Baseline Characteristics

Medication Knowledge Survey After PDA Administration

Medication knowledge includes the knowledge of name of the medicine, the composition, the purpose and the amount of medicine at each use, the positive effects and the negative effects, the drug storage, also the date of drug next purchase. PDA administration will help patient to manage their medication regiment for the beneficial outcomes. In this study the average knowledge of research subjects was good. Results of a medication knowledge survey conducted over four weeks after provide PDA, that shows all respondents have a high knowledge of the antidiabetic drugs used.

Table 2. Patient's Medication Knowledge after PDA Administration

Medication Knowledge	Se	belum	Sesudah		
Medication Knowledge Category	Frekuensi	Presentase (%)	Frekuensi	Presentase (%)	
Code 0 (low patient's medication knowledge)	0	0	0	0	
Code 1 (moderate patient's medication knowledge)	3	12	0	0	
Code 2 (high patient's medication knowledge)	22	88	19	76	
Code 3 (very high patient's medication knowledge)	0	0	6	24	
Total	25	100	25	100	

Table 3. Statistical Analysis of Patient's Medication Knowledge After PDA Administration

Test Statistics b,c

			sesudah - sebelum
Z			-3.000°
Asymp. Sig. (2-tailed)			.003
Monte Carlo Sig. (2-tailed)	Sig.		.004
	95% Confidence Interval	Lower Bound	.002
		Upper Bound	.005
Monte Carlo Sig. (1-tailed)	95% Confidence Interval	Lower Bound	.001
		Upper Bound	.002
	Sig.		.001

Based on the above results shows p value (Asymp Sig 2 tailed) of 0.003, less than the critical limit of the study 0.05 so it can be concluded that there is a difference significance of drug knowledge on the pre and post PDA administration.

Blood Glucose Level After PDA Administration

In major clinical trials, the use of Self Monitoring Blood Glucose (SMBG) for glycemic control is useful as a multifactorial intervention. In this intervention with PDA, shows that SMBG can be an effective therapy component. SMBG allows patients to evaluate their individual response to therapy and assess whether the target glycemic is or has been achieved. SMBG results can be useful in preventing hypoglycemia and drug adjustment (especially prandial insulin dose), nutritional therapy, and physical activity. In a recent meta-analysis it was shown that SMBG patients with Type 2 DM of OAD therapy could decrease HbA1c values by 0.25% in the first 6 months, while from Review Cochrane concluded that the overall SMBG effect in Type 2 DM patients was relatively small at 6 months After initiation and decreased after 12 months (Diabetes Care, 2013).

Table 4. Blood Glucose Monitoring After PDA Administration

Subject	Week-1	Week-2	Week-3	Week-4
No	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)
1	276.0	449.0	291.0	271.0
2	222.0	336.0	146.0	101.0
3	207.0	140.0	243.0	176.0
4	216.0	201.0	170.0	155.0
5	222.0	179.0	181.0	158.0
6	339.0	305.0	324.0	292.0
7	254.0	186.0	131.0	126.0
8	278.0	143.0	144.0	304.0
9	214.0	85.0	122.0	108.0
10	187.0	135.0	170.0	72.0
11	281.0	380.0	204.0	79.0
12	266.0	188.0	167.0	276.0
13	214.0	170.0	186.0	125.0
14	230.0	184.0	105.0	163.0
15	330.0	480.0	381.0	288.0
16	136.0	110.0	109.0	128.0
17	340.0	397.0	302.0	260.0
18	199.0	155.0	167.0	154.0
19	198.0	103.0	88.0	109.0
20	216.0	108.0	176.0	116.0
21	186.0	130.0	142.0	191.0
22	360.0	321.0	292.0	341.0
23	185.0	130.0	107.0	120.0
24	272.0	262.0	214.0	186.0
25	368.0	226.0	121.0	270.0

Note: Blood glucose level measure as random blood glucose (about 3 hours after first meal) from capillary blood vessel using $Accuchek^{@}$ glucometer.

Table 5. Statistical Analysis of Blood Glucose Level After PDA Administration

ANOVA

_HASIL					
	Sum of Squares	df	Mean Square	F	Siq.
Between Groups	69742.990	3	23247.663	3.176	.028
Within Groups	702694.000	96	7319.729		
Total	772436.990	99			

Based on the above results shows the significance of 0.028 where less than the critical limit of the research 0.05 which means there are significant differences in the study subjects on the effect of blood glucose level before and after PDA administration.

Decision Conflict Scale After PDA Administration

Table 6. Decision Conflict Scale After PDA Administration

Domain	Test	Sig Value	Conclusion
Informed Subscale (feeling uninformed)	Wilcoxon Matched Pairs Test	0,480	No significant differences
Values Clarity Subscale (unclear about personal values)	Wilcoxon Matched Pairs Test	0,257	No significant differences
Support Subscale (unsupported in decision making)	Wilcoxon Matched Pairs Test	0,655	No significant differences
Uncertainty (personal perception of uncertainty in chosing options)	Wilcoxon Matched Pairs Test	0,527	No significant differences
Effective Decision Subscale (effective decision making)	Wilcoxon Matched Pairs Test	0,157	No significant differences

From the results of the research indicating there were no significant differences between pre and post PDA administration. It can be concluded that decision making may be influenced by many factors such as the delivery of PDA information to the patient, the patient's condition includes emotional level and stress level with their disease condition. The degree of uncertainty as in making decisions involving the benefits and risks of OAD also affects the patient in making a decision. On the other hand the provision of PDA is successful in assisting in digging things that have not been submitted by doctors or other health care provider to patients ^{10,11,12,13}. For example, regarding weight change, when patients and physicians discuss weight changes in a treatment, generally weight changes refer to the context of glycemic control rather than as a potential side effect of the drug. However PDA also received rave reviews from research subjects as many of the research subjects had never received an explanation of OAD before.

LIMITATIONS

This study was conducted at single treatment cycle period, while the patient characteristics had never received previous PDA intervention, so it has not been able to give any changes in the decision making process. PDA card has not provided information related to the description of the condition of diabetes and the need to manage treatment continuously.

CONCLUSIONS

From the intervention of PDA administration, there are several things that change in the research subjects include: increased medication knowledge, and better therapeutic target as seen in random blood glucose level monitoring. PDA will succeed in becoming one of the tools in engaging or involving patients in clarifying values and expectations that are more

realistic in their medication knowledge, but less contribute to decision making, this is possible because PDA are still new to the research subject, so they have no experience in making decisions treatment.

For the successful helping patients participate in decision-making for their treatment need pharmacist roles to improve their medication knowledge, blood glucose monitoring also continuous follow-up and evaluation the treatment of type 2 diabetes mellitus.

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