Effect of Diabetes Drug Counseling by Pharmacist, Diabetic Disease Booklet and Special Medication Containers on Glycemic Control of Type 2 Diabetes Mellitus: A Randomized Controlled Trial

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Background: *type 2 diabetes mellitus continues to increase in prevalence worldwide. Many factors have been cited as contributing to compliance, such as family and social support, education, number of tablets per dose, frequency of administration and health care provider communication. Toward these goals, the present study was developed to measure the effect of factors on glycemic control such as diabetes education by pharmacists, a diabetes disease booklet and special medication containers.*

Material and Method: *A total of 360 volunteers with type 2 DM patients were recruited, participants were simple randomized to control 180 and intervention 180 patients. Which intervention categorized to 4 groups; all intervention groups received diabetes drug counseling by a pharmacist, one group received plus a diabetes booklet, one received plus special medical containers and the last group received all of them. The interventions were done at the 1st time of visit. Both the control and intervention groups were monitored for fasting plasma glucose and HbA1c at 0,3,6 months and glycemic level in both groups was compared.*

Results: *After 3 months, mean fasting plasma glucose and HbA1c decreased with the intervention group vs control group (152.36$\pm$39.73 to 131.52$\pm$35.22 mg%) and (150.16$\pm$41.78 to 153.98$\pm$47.95 mg%) respectively; (p<0.001). HbA1c level 8.16$\pm$1.44 to 7.72$\pm$1.26 vs 8.01$\pm$1.51 to 8.38$\pm$1.46 respectively; (p<0.001). After 6 months, mean fasting plasma glucose and HbA1c decreased with the intervention group vs control group (152.36$\pm$39.73 to 145.20$\pm$46.07 mg%) and (150.16$\pm$41.78 to 159.16$\pm$54.90 mg%) respectively; (p<0.013).). HbA1c level 8.16$\pm$1.44 to 7.91$\pm$1.27 vs 8.01$\pm$1.51 to 8.80$\pm$1.36 respectively; (p<0.001). The most favorable glycemic outcome was the group that received all of the interventions; mean FPG was reduced from 147.46$\pm$36.07 to 125.38$\pm$31.12 mg% (p<0.000) in 1nd visit (3 months later) and still reducing effect on the 2nd visit (6 month later) mean FPG from 147.46$\pm$36.07 to 130.21$\pm$33.96 mg% (p<0.016) also the same way in HbA1c level. The group that received only drug counseling by pharmacist had no significant reduction in FPG and HbA1c.(p>0.05).*

Conclusion: *Drug counseling by a pharmacist has little beneficial effect on diabetes management outcome compared to the diabetes booklet and special drug container. To improve glycemic control of type 2 DM is to integrate self-management in daily life, wide a variety of education, drug taken behavior and health care provider available communication produce improvement in patient management and is somewhat better when used in combination.*

Keywords: *Diabetes mellitus, Compliance, Education, Disease booklet, Special medication containers*

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Diabetes is the 7th leading cause of death in the U.S.. As the prevalence of type 2 diabetes continues to increase worldwide, there is an enhanced need for effective disease management, type 2 diabetes is managed through a stepwise program of intensive therapy that consists of lifestyle modifications and sequential addition of oral antihyperglycemic agents and insulin as necessary[(1)]. Successful implementation of this approach lessens the microvascular complication of the disease and promotes a lifestyle that may reduce macrovascular complications and comorbidities[(2)]. DM is a chronic disease that requires long-term continuing medical care and patient self-management education to prevent acute complications. Evidence clearly improved metabolic control via drug therapy to better outcomes. Because of this linkage, one can expect that greater adherence to medical regimens would be associated with better metabolic control, both due to a direct effect and possibly as a marker of adherence to other diabetes self management behaviors[(3,4)] and supports a range of interventions to improve diabetes outcomes[(5)].

Reviews of compliance literature, concerning all illness regimens, reveal that at least one-third of all patients do not comply with their medical regimens[(6)], Sackett's[(7)] review of compliance literature noted the level of patients with long-term therapy is about 50%. In view of this lack of success, compliance may currently be one of the greatest therapeutic challenges facing the health professions[(8)]. However, it is difficult to compare compliance studies because the magnitude of noncompliance varies with the behavior measured, the manner in which it is measured, the amount of deviance accepted, and the point in therapy at which it is measured. While sociodemographic variables have been found to be predictive of entry into the health care system, they have not been predictive of compliance levels once treatment has been initiated. Therefore, the authors studied the intervention to improve glycemic outcome of type 2 diabetes management.

Material and Method

The present study was conducted in King Chulalongkorn Memorial Hospital from January to December 2004. Patients were enrolled in the study if they were type 2 diabetes, older than 40 years, treated at the endocrine clinic as out-patients and willing to participate in the present study; the excluded were patients unable to verbally communicate, dementia or Alzheimer's disease, uncontrolled hypertension, heart failure, coronary artery disease, stroke and peripheral

vascular disease. 360 diabetic patients with the following characteristics were selected and a simple randomized technique was performed. 180 patients were control and 180 patients were intervention; 4 groups were divided: diabetic drug counseling by a pharmacist applied to all intervention groups, one had an added diabetes booklet, one had special medication containers and one was applied all diabetes education & diabetes booklet & special medication containers. All patients were interviewed for demographic information, medical history, physical examination was performed and signed the informed consent. Blood test was considered in 0, 3, 6 months after the first visit and the intervention was performed. Medical records were used to obtain the patient's responses to the intervention.

Statistics analysis

Data were tested for its distribution with the Kalmogrov-Smirnov tests and if data showed normal distribution, parametric test was used, Categorical data were presented as percentage and analyzed using Chi-square or Mcnemar tests as appropriate. Ordinal or interval data were presented as mean or median and statistically tested using T-test or Mann-Whitney U test for two group comparison. The statistical significance was set at 0.05. The association of reduction in noncompliance problems due to various factors were tested by chi-square test or Fisher's exact test, if the sample was not large and expected values were less than 5. Variations of continuous data were analyzed using ANOVA with repeated measurement and multiple comparisons (Bonferroni).

Results

The study was conducted at the Endocrine Clinic in King Chulalongkorn Memorial Hospital. Three hundred and sixty diabetes type 2 patients were recruited into the present study and randomly allocated into 2 groups, control and intervention group. There were more female patients than male patients in the control and intervention group, and most of them were older than 60 years old. The averaged ± SD age was 59.9 ± 11.5 years in the control and 61.4 ± 10.6 years in the intervention group, the difference was not statistically significant (p=0.073).

Patients were mainly diagnosed with diabetes for more than 10 years but less than 20 years, 34.4% and 41.7% of control and intervention group respectively. Most of patients managed themselves to take the medication, 69.4% of the control and 67.2% of the

intervention group. For the marital status, 76.7% and 78.3% were married in the control and intervention group, respectively. About 40% of both groups had no income while one third of the rest had an income>10,000 baht/month. Most of the patients had education in primary level, 45.0% of the control group and 38.9% of intervention group. Patients in the control group paid by themselves for care in the higher number than using the government reimbursement for care (40.0% and 38.9%), while the reverse was found in the intervention group (31.2% and 51.1%). the difference of frequency distribution in all parameters between the two groups were not statistically significant (P>0.05). As shown in Table 1.

Concomitant disease; hypertension was the most common disease found in both groups, 78.9% and 80.6% of control and intervention group, respectively. Dyslipidaemia was in the second rank with the incidence of 56.7% in the control and 61.7% in the intervention group. Each of the patients had more than one concomitant disease 1.76 and 1.85 diseases of the control and intervention group, respectively. Therefore, no statistic significance was found in the prevalence of concomitant disease between the two groups (Table 2).

Table 3 shows the data including the number of item, type and pattern changes in DM medications. Most patients of both groups had 4-6 items of all medications and 2 items of DM medication. The average number of non-DM medication per patients was 4.6 and 5.0 in the control and intervention group, respectively. While the average number of DM medications per patient was 1.9 in both groups. A large proportion of study patients used oral hypoglycaemic drug, 71.7% and 67.8% of the control and intervention group, respectively. Sulfonylurea and metformin were mostly used in combination 41.1% and 37.8% of control and intervention group, respectively. 83.3% of control group and 86.1% of intervention group reported no changes in the use of DM medications before being enrolled into the study.

Table 1. Demographic and general data

Variable	Control (n = 180)	Intervention (n = 180)	p-value
Sex			0.754
Male	64 (35.6%)	59 (32.88%)	
Female	116 (64.4%)	121 (67.2%)	
Age			0.241
40-60 years	91 (50.6%)	76 (42.2%)	
>60 years	89 (49.4%)	104 (57.8%)	
Age Mean$\pm$SD	59.9$\pm$11.5	61.4$\pm$10.6	0.073
Median / range	60 / 40-86	62 / 40-87	
Duration of DM			0.416
< 1 Year	4 (2.2%)	2 (1.1%)	
1-5 Years	39 (21.7%)	39 (2.17%)	
5-10 Years	61 (33.9%)	49 (27.2%)	
>10 Years	62 (34.4%)	75 (41.7%)	
>20 Years	14 (7.8%)	15 (8.3%)	
Marital status			0.198
Single	26 (14.4%)	31 (17.2%)	
Married	138 (76.7%)	141 (78.3%)	
Widow / divorce	16 (8.9%)	8 (4.4%)	
Income / month			0.402
No income	82 (45.6%)	74 (41.1%)	
<5,000 baht	4 (2.2%)	9 (5.0%)	
5,000-10,000 baht	31 (17.2%)	37 (20.6%)	
>10,000 baht	63 (35.0%)	60 (33.3%)	
Education			0.833
No education	7 (3.9%)	9 (5.0%)	
Primary school	81 (45.0%)	70 (38.9%)	
Secondry school	45 (25.0%)	46 (25.6%)	
Diploma degree	22 (12.2%)	29 (16.1%)	
Bachelor degree	20 (11.1%)	20 (11.1%)	
Postgraduate	5 (2.8%)	6 (3.3%)	

Table 2. Concomitant disease

Concomitant disease	Control (n=180)	Intervention (n=180)
Hypertension	142 (78.9%)	145 (80.6%)
Dyslipidaemia	102 (56.7%)	111 (61.7%)
Heart disease	14 (7.8%)	19 (10.6%)
Thyroid disease	18 (10.0%)	35 (19.4%)
Renal disease	21 (11.7%)	17 (9.4%)
Others	21 (10.5%)	6 (3.4%)
Average No. of concomitant disease/patient	1.76	1.85

Table 3. Type and number of medication taken by the study population

Variable	Control (n = 180)	Intervention (n = 180)	p-value
No. of medications**			0.995**
Mean±SD of	4.6±2.1	5.0±1.8	
Median / range	5/0-12 items	5/0-12 items	
No.of DM medications**			0.57**
Mean±SD of	1.9±0.8	1.9+0.8	
Median / range	1/0-4 items	1/0-5 items	
Type of DM medications	128 (71.1%)	122 (67.7%)	0.369
Oral DM dug	14 (7.8%)	18 (10.0%)	
Insulin Both	38 (21.1%)	40 (22.3%)	
Group of oral DM medications			0.386
G1 (Sulfonylures group)	38 (21.1%)	44 (24.4%)	
G2 (Biguanide group)	35 (19.2%)	34 (18.9%)	
G3 (alpha-glucosidase Inhibitor)	4 (2.2%)	4 (2.2%)	
G4 (Insulin sensitizer group)	2 (1.1%)	4 (2.2%)	
G1,2	74 (41.1%)	68 (37.8%)	
G1,2,3	14 (7.8%)	14 (7.8%)	
G1,2,4	6 (3.3%)	6 (3.3%)	
G2,3	7 (3.9%)	6 (3.3%)	
Change of DM medications			0.585
No change in DM drug use	150 (83.3%)	155 (86.1%)	
Change of DM durg	5 (2.8%)	3 (1.7%)	
Add DM drug	2 (1.1%)	1 (0.6%)	
Increase/decrease dose	2 (1.1%)	4 (2.2%)	
Change Dose	21 (11.7%)	17 (9.4%)	

180 patients were intervened by the study. At baseline (visit 0) FPG value were 150.16±41.78 mg% vs 152.36±39.73 mg% in the control and intervention group, respectively, no statistic significance but there were significant changes after visit 1,2. By means of FPG at visit 1,2 of the control group 153.98±47.95 mg% and 159.16±54.90 mg% and of the intervention group 131.52±35.22 mg% and 145.20±46.07 mg%, (P-value< 0.001, 0.013) respectively. HbA1c value at baseline visit 0 were 8.01±1.51 vs 8.16±1.44 in control and intervention group, respectively; there was no significance in the statistics. The reduction of HbA1c value at visit 1,2 of the intervention group was significant in statistics, by 8.16±1.44 to 7.72±1.26 and 7.91±1.27, respectively (P-value <0.001 and 0.001) (Table 4).

All 4 intervention groups 180 patients were given counseling and diabetes education. 50 patients (INT1) were given all of them, 50 patients (INT2) were plus special medication container, 30 patients (INT3) were only given disease counseling and education, 50 patients(INT4) were plus the diabetes information booklet, While 180 patients in the control group had conventional treatment. AT visit 0, the glycemic control was not significant according to different interventions. At visit 1; there were signification changes in the reduction of fasting plasma glucose in INT1 and INT 2, p=0.000 and p=0.001 respectively. At visit 2; there was only INT1 significant reduction in fasting plasma glucose level 130.21±33.96 mg% (p=0.016). Nevertheless, in HbA1c level were significant reduction in INT1 and

INT 4 in visit 1 : 7.70±1.06 and 7.62±1.37, respectively. (p=0.027 and 0.006). HbA1c in visit 2, there were significant changes in INT1, INT2 and INT4 of value 7.91±1.11, 7.96±1.31 and 7.87±1.47, respectively. There was no change in both fasting plasma glucose level and HbA1c of INT3 at visit1 and 2 (Table 5).

Discussion

In a US survey of adults type 2 diabetes mellitus treated with glucose-lowering medication required several different medications, 50% reported using ≥ 7 medications in their prescribed treatment regiment, including ≥ 2 glucose-lowering agents[9]. According to the present study, mean of medications 4.6±2.1 in the control group and 5.0±1.8 items of medication, including 1.9±0.8 glucose-lowering agents. The reason for the large number of prescriptions is clear, due to concomitant disease average 1.76-1.85 disease per patient. Many studies of treatment adherence in patients with type 2 DM have been reported with inclusive of several used protocols, used large prescription databases, health maintenance organizations, education, counseling and the effective drug monitoring systems, special medical containers, medical calendars and compliance packaging strategies for improving compliance , developed an individualized treatment plan that simplifies the regimen as possible[10-20].

Most of these studies reported that adherence to oral blood glucose-lowering therapy ranged from 65%-85%, although few reported lower rates of 36%-54%. Of the factors that may affect treatment adherence, the most common and most overlooked is patients'

Table 4. Fasting plasma glucose level and HbA1c at visit 0,1,2 in both control and intervention group

Variable	Control group Mean ± SD	Intervention group Mean ± SD	p-value
FPG at visit 0 (mg%)	150.16±41.78	152.36±39.73	0.608
FPG at visit 1 (mg%)	153.98±47.95	131.52±35.22	< 0.001*
FPG at visit 2 (mg%)	159.16±54.90	145.20±46.07	0.013*
HbA1c at visit 0 (%)	8.01±1.51	8.16±1.44	0.407
HbA1c at visit 1 (%)	8.38±1.46	7.72±1.26	< 0.001*
HbA1c at visit 2 (%)	8.80±1.36	7.91±1.27	< 0.001*

* Statistical significant different with the independent t-test

Table 5. Distribution of mean fasting plasma glucose, HbA1c of control and 4 difference interventions at visit 0,1,2

Variable	Control	INT 1	INT2	INT 3	INT 4
Frequency (%)	180 (50.0%)	50 (13.9%)	50 (13.9%)	30 (8.3%)	50 (13.9%)
Mean of FPG at visit 0 (mg%)	150.16±41.78	147.46±36.07	139.78±33.15	168.60±39.30	162.42±44.42
Mean of FPG at visit 1 (mg%)	153.98±47.95	125.38±31.21	127.06±27.32	141.20±51.47	137.14±32.65
p-value		*0.000	*0.001		
Mean of FPG at visit 2 (mg%)	159.16±54.90	130.21±33.96	141.21±45.84	158.34±57.81	160.98±50.39
p-value		*0.016			
HbA1c at visit 0	8.01±1.51	8.20±1.07	7.92±1.40	8.36±1.74	8.07±1.53
HbA1c at visit 1	8.38±1.46	7.70±1.06	7.72±1.45	7.90±0.99	7.62±1.37
p- value		*0.027			*0.006
HbA1c at visit 2	8.80±1.36	7.91±1.11	7.96±1.31	7.92±1.04	7.87±1.47
p- value		*0.001	*0.005		*0.000

INT 1= Disease counseling and education + diabetic information booklet + special medication container
INT 2 = Disease counseling and education + special medication container
INT 3 = Disease counseling and education
INT 4 = Disease counseling and education + diabetic information booklet
* Statistical significant different
Posthoc = Bonferroni Alpha (0.05)

comprehension of the treatment regiment, which clinicians often overestimate[21]. In 2001; Ciechanowski et al found that patients who rated the communication provided by their physicians as good were significantly more adherent to oral antidiabetic drugs and to recommendations for self-monitoring blood glucose who were rated as poor communications. Others found similar advantages in glycemic control, health status and satisfaction among good communicators[22-26]. In the present study , FPG was increased by 4.05±40.65 mg% in the control group while it was decreased by 20.85± 29.95 mg% in the intervention group at the 1st visit (P<0.001). It was emphasized that patients are more likely to adhere to treatment which they perceive as helpful in alleviating their symptoms than to those do not, and effective communication to patients who may not be aware of the potential benefits of treatment were very helpful contributing to attaining their benefits, additionally; disease brochures, diabetes personal booklets and special drug containers can effectively improve disease adherence. In the 2nd visit (6 months later) FPG was increased by 8.42±49.75 mg% in control and decreased by 8.35±38.43 mg% in the intervention group; p<0.001. This suggested counseling should be conducted from time to time in every visit. HbA1c level was in the same way. This confirmed the efficiency of the intervention. Moreover, the present study results revealed that patients were more improved in glycemic control when they received the compliance aids such as the diabetic information book and special medication containers than these who received only diabetic education.(Table 5) the effect of the intervention can last long up ot 6 months with only one time of intervention. Clinicians can minimize barriers to medication adherence by prescribing not to much medicine and discussing potential information with the patients. At each visit ask the patient these simple questions: How are things going with your medication? Are you having any problems? The patient should be regularly asked about adverse effects for all medication and add some medical device such as disease brochures, booklets, medical containers to improve effective treatment.

Conclusion

Compliance is regarded as important primarily because following the recommendation of health personnel is considered essential to patient recovery. Nowadays medical practice faces the problems with non compliance patients which leads to rapidly progressively development of chronic illness. Then diabetic patients will lose the quality of life, their productivity, their own economy even though their life. To improve health outcomes for individuals with diabetes depends on integrating self-management into daily life, wide variety of education, behavioral and affective interventions available which produce modest improvements in patient adherence to treatment recommendations in diabetes and related chronic illnesses and that work somewhat better when used in combination.

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การศึกษาผลของการให้การศึกษาเรื่องยาโดยเภสัชกรสมุดคู่มือประจำตัวผู้ป่วยเบาหวานและกล่องบรรจุยาพิเศษในการควบคุมระดับน้ำตาลในเลือดของผู้ป่วยเบาหวานประเภทที่2

สุชาติ ศุภปีติพร, บุษบา จินดาวิจักษ์, เสาวภา อ่อนสนิท

หลักการและเหตุผล: *อุบัติการณ์ของโรคเบาหวานเพิ่มขึ้นตลอดเวลาทั่วโลก การดูแลรักษาเบาหวานเพื่อให้ได้ผลดีที่สุดจึงเป็นสิ่งที่ต้องคำนึง การศึกษาวิจัยนี้เพื่อเปรียบเทียบดูผลของการให้การศึกษาด้านโรคเบาหวาน ให้สมุดคู่มือประจำตัวผู้ป่วยเบาหวาน การให้กล่องบรรจุยาพิเศษแก่ผู้ป่วย ว่าองค์ประกอบใดมีผลต่อการควบคุมระดับน้ำตาลในเลือดของผู้ป่วยเบาหวานชนิดที่ 2 มากกว่ากัน*

วัสดุและวิธีการ: *คัดเลือกผู้ป่วยเบาหวานจำนวน 360 คนโดยความสมัครใจ และใช้วิธีการสุ่มเป็น 2 กลุ่ม, 180 คน สำหรับกลุ่มควบคุม และ 180 คนสำหรับกลุ่มทดลอง ในกลุ่มทดลองยังแบ่งเป็น 4 กลุ่มย่อยโดยกลุ่มที่ 1 จะได้รับการศึกษาแนะนำเกี่ยวกับความรู้ด้านยาเบาหวานโดยเภสัชกร กลุ่ม 2 จะได้รับความรู้ด้านเบาหวานและสมุดคู่มือการดูแลเบาหวาน กลุ่ม 3 จะได้รับความรู้ด้านเบาหวานและกล่องบรรจุยาพิเศษ กลุ่มที่4 จะได้รับทุกชนิด ในทุกกลุ่มทดลองจะได้รับสิ่งต่าง ๆ ในครั้งแรกที่เข้าพบเท่านั้น และทั้งกลุ่มทดลองและกลุ่มควบคุมจะได้รับการตรวจระดับน้ำตาลในเลือดในเดือนที่ 0, 3, 6 เดือนแล้วเปรียบเทียบผลการลดลงของน้ำตาลของทั้งสองกลุ่ม*

ผลการศึกษา: *ในเดือนที่ 3 ระดับน้ำตาลในเลือดของกลุ่มทดลองลดลงอย่างมีนัยสำคัญเมื่อเปรียบเทียบกับกลุ่มควบคุม โดยระดับ fasting plasma glucose จาก152.36+39.73 ลดลงสู่ 131.52+35.22 mg% และ 150.16+41.78 สู่ระดับ 153.98+47.95 mg% ตามลำดับ; (p<0.001). ระดับ HbA1c level 8.16+1.44 ลดลงสู่ 7.72+1.26 เทียบกับกลุ่มควบคุมที่ 8.01+1.51 สู่ 8.38+1.46 (p<0.001). หลังจาก 6 เดือน,ระดับ fasting plasma glucose และ HbA1c ยังคงลดลงจาก 152.36+39.73 สู่ 145.20+46.07 mg%ในกลุ่มทดลองและ150.16+41.78 สู่ 159.16+54.90 mg% ในกลุ่มควบคุม (p<0.013) ระดับ HbA1c จาก 8.16+1.44 สู่ 7.91+1.27 ในกลุ่มทดลองและ 8.01+1.51 สู่ 8.80+1.36 ในกลุ่มควบคุม (p<0.001). โดยพบว่ากลุ่มที่ได้รับทั้งความรู้เรื่องเบาหวาน สมุดคู่มือผู้ป่วยเบาหวาน และกล่องบรรจุยาพิเศษ โดยระดับน้ำตาล fasting ในเลือดจาก147.46+36.07 สู่ 125.38+31.12 mg% (p<0.000) ในช่วง 3 เดือนหลังจากได้รับการทดลองและยังคงมีการลดลงของระดับน้ำตาลในเลือดในเดือนที่ 6 หลังการทดลองจากระดับ 147.46+36.07 สู่ 130.21+33.96 mg% (p<0.016) ซึ่งผลนี้ยังพบได้จากระดับ HbA1c ด้วย แต่ในกลุ่มที่ได้รับเฉพาะความรู้เกี่ยวกับเบาหวานอย่างเดียวกลับไม่พบว่ามีการลดลงของระดับน้ำตาล ในเลือดทั้งในเดือนที่3 และเดือนที่ 6 (p>0.05).*

สรุป: *การให้ความรู้ด้านเบาหวานอย่างเดียวไม่เพียงพอในการดูแลรักษาเบาหวานให้ได้ผลสูงสุดเมื่อเปรียบเทียบกับการให้ทั้งสมุดคู่มือเบาหวาน กล่องบรรจุยาพิเศษ เพื่อที่จะให้การดูแลเบาหวานมีประสิทธิภาพมากที่สุด ควรจะมีการรวมวิธีหลาย ๆ วิธีเข้าด้วยกัน*