Original Article : Pharmaceutical Care

A Randomized Trial of a Pharmacist Practitioner Model to Improve Glycemic Control in Type 2 Diabetic Patients

การศึกษาเชิงทดลองแบบสุ่มโดยใช้แบบจำลองเภสัชกรเวชปฏิบัติต่อการควบคุมระดับน้ำตาลในเลือดให้ดีขึ้นในผู้ป่วยเบาหวานชนิดที่ 2

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This study aimed to assess the effectiveness of a pharmacist practitioner model designed to improve hemoglobin A1c (A1c) levels and to reduce cardiovascular risk factors in vulnerable patients with poorly controlled diabetes. A randomized controlled trial of 98 patients with type 2 diabetes and poor glycemic control (A1c≥8.0 percent) was conducted at Diabetes Clinic, Out-patient Department, Nongbualamphu Hospital from April 2006 to October 2007. One group of 48 patients received intensive management by pharmacist practitioners (PP) model. They received an assessment of medication-taking adherence and their understanding of diabetes then applied algorithms for managing glucose control and other cardiovascular risk factors. Other 50 patients in the control group received the usual care (UC) from their physicians. Primary clinical outcomes improvement was demonstrated by A1c and fasting plasma glucose (FPG) levels while secondary clinical outcomes improvement was demonstrated by blood pressure, low density lipoprotein (LDL) cholesterol, and microalbuminuria level.

It was found that patients' primary clinical outcomes in the PP group had significantly greater improvement than that of the control group (respectively improved A1c and FPG level were 2.1 vs 0.9 percent and 48 vs 27 mg%, p<0.01). However, changes in lipid profiles and systolic blood pressure were not significantly different in both groups. In addition, by the purpose of prevention and diabetes complications treatment, patients in the PP group were monitored more closely than those in the UC group. Thus, implementation of a pharmacist practitioner model substantially improved the process measurements and clinical outcomes of type 2 diabetic patients with poor glycemic control.

Keywords: Type 2 diabetes, glycemic control, pharmacist practitioner model, clinical outcomes improvement

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อังกูร ภาวสุทธิไพศิฐ, รัตนาภรณ์ อาวิพันธ์, กนกพร นิวัฒนนันท์, วรรณดี แต้โสติกุล, สุรเกียรติ อาชานานุภาพ, พักตร์วิภา สุวรรณพรหม, อริสรา จันทร์ศรีสุริยวงศ์, พินิจ อัศวะแสงรัตน์, วิพล รัชตะพงศ์ธร. การศึกษาเชิงทดลองแบบสุ่มโดยใช้แบบจำลองเภสัชกรเวชปฏิบัติต่อการควบคุมระดับน้ำตาลในเลือดให้ดีขึ้นในผู้ป่วยเบาหวานชนิดที่ 2. วารสารเภสัชกรรมโรงพยาบาล 2554; 21(1):9-23.

งานวิจัยนี้มีวัตถุประสงค์เพื่อประเมินประสิทธิผลของแบบจำลองเภสัชกรเวชปฏิบัติต่อการปรับลดระดับน้ำตาลในเม็ดเลือดแดงและปัจจัยเสี่ยงทางหลอดเลือดและหัวใจในผู้ป่วยโรคเบาหวานที่ไม่สามารถควบคุมระดับน้ำตาลได้ โดยการศึกษาทดลองแบบสุ่มในผู้ป่วยโรคเบาหวานชนิดที่ 2 ที่ไม่สามารถควบคุมระดับน้ำตาลในเลือดได้จำนวน 98 ราย (A1c≥8.0%) ที่คลินิกเบาหวาน กลุ่มงานผู้ป่วยนอก โรงพยาบาลหนองบัวลำภู ระหว่างเดือนเมษายน พ.ศ. 2549 ถึงเดือนตุลาคม พ.ศ. 2550 จำแนกเป็นผู้ป่วยกลุ่มแรก 48 รายที่ได้รับการดูแลรักษาอย่างเข้มงวดโดยใช้แบบจำลองเภสัชกรเวชปฏิบัติ ซึ่งประกอบด้วยการประเมินความร่วมมือในการใช้ยา การทำความเข้าใจเกี่ยวกับโรคเบาหวานในมุมมองของผู้ป่วยและพิจารณาปรับเปลี่ยนการใช้ยาเพื่อรักษาระดับน้ำตาลและปัจจัยเสี่ยงของโรคหลอดเลือดหัวใจอื่นๆ ตามข้อกำหนดที่ได้รับการรับรองจากแพทย์ ผู้ป่วยกลุ่มที่สอง 50 รายเป็นกลุ่มควบคุมที่ได้รับการดูแลรักษาตามปกติจากแพทย์ ประเมินผลลัพธ์ทางคลินิกขั้นต้นจากระดับน้ำตาลในเม็ดเลือดแดงและระดับน้ำตาลในเลือดช่วงอดอาหาร รวมทั้งผลลัพธ์รองจากระดับความดันโลหิต ระดับไขมันในเลือดชนิด LDL และภาวะโปรตีนในปัสสาวะ

ผลการศึกษาพบว่า ผลลัพธ์ทางคลินิกของผู้ป่วยกลุ่มที่ได้รับการดูแลโดยเภสัชกรเวชปฏิบัติดีขึ้นกว่าผู้ป่วยกลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ (ค่าการปรับลดระดับน้ำตาลในเม็ดเลือดแดงและระดับน้ำตาลในเลือด เท่ากับ 2.1 กับ 0.9 เปอร์เซ็นต์ และ 48 กับ 27 มิลลิกรัมเปอร์เซ็นต์ ตามลำดับ, p<0.01) ในขณะที่ระดับไขมันในเลือดและความดันโลหิตตัวบน (ซิสโตลิค) ทั้งสองกลุ่มแตกต่างกันอย่างไม่มีนัยสำคัญทางสถิติ ทั้งนี้ ผู้ป่วยกลุ่มที่ได้รับการดูแลโดยใช้แบบจำลองเภสัชกรเวชปฏิบัติจะได้รับการตรวจติดตามอย่างใกล้ชิด เพื่อป้องกันและรักษาภาวะแทรกซ้อนของโรคเบาหวานมากกว่ากลุ่มควบคุม จึงอาจสรุปได้ว่า การดำเนินการตามแบบจำลองเภสัชกรเวชปฏิบัติ ทำให้ผลลัพธ์จากการตรวจหาภาวะแทรกซ้อนและผลลัพธ์ทางคลินิกดีขึ้นอย่างชัดเจนในผู้ป่วยโรคเบาหวานชนิดที่ 2 ที่ไม่สามารถควบคุมระดับน้ำตาลในเลือดได้

คำสำคัญ: โรคเบาหวานชนิดที่ 2 ควบคุมระดับน้ำตาลในเลือด แบบจำลองเภสัชกรเวชปฏิบัติ ผลลัพธ์ทางคลินิกที่ดีขึ้น

Introduction

Type 2 diabetes mellitus (T2DM) is the most common form of DM[1] and the prevalence of T2DM has increased dramatically in the past decade.[2] Patients with diabetes are likely to experience morbidity and mortality from microvascular (retinopathy, nephropathy, and neuropathy) and macrovascular (heart attacks, stroke, and peripheral vascular disease) complications.[3] Several intensive controlled prospective studies showed the efficacy of diabetic treatments.[4-8] However, these clinical trials may not reflect the effectiveness in real clinical environments,[9-11] where many factors are

uncontrollable. Previous study[12] addressed the three major barriers of achieving quality of healthcare services, which included healthcare system, provider, and patient-related factors. In order to redesigning the healthcare organization to improve diabetic care, multidisciplinary model was needed. The elements of fundamental theories used in development of pharmacist practitioner (PP) model were disease stage management (DSM), collaborative drug therapy management (CDTM), pharmaceutical care (PC), and explanatory model (EM) to overcome the three major barriers (Figure 1). The structure of pharmacist practitioner (PP) model was developed base on the DSM model. The model was comprised an organization, provider, and patient components including: 1) collaborative practice model, 2) evidence-base practice guidelines, 3) self-management 4) process and outcomes measure 5) feedback report. The CDTM is an interdisciplinary approach that physician delegates prescriptive authority to pharmacist within the terms of a formal agreement.[13,14] The DSM along with CDTM in T2DM studies showed that diabetic patients improved glycemic, blood pressure, and lipid levels.[15-17] However, these studies did not provide the details regarding what actions were taken during interactions between pharmacists and patients that may have resulted in improvements in clinical outcomes.[18,19] Additionally, these studies were not focused on drug-therapy problems (DTPs) such as medication-taking non-adherence which have been commonly found in current medical practices.[20,21] Therefore the PC model, a new professional practice in which the practitioner takes responsibility for a patient's drug-related needs and holds accountable for this commitment, was integrated to the pharmacist practitioner model. The CDTM and PC models have similar essential features (assessment, care plan, and evaluation). The difference between CDTM and PC is that CDTM focusing on initiating or adjusting medication regimens for achieving the clinical outcomes, whereas the PC model emphasizing on identification, prevention, and correction of the DTPs.

The DSM includes additional interventions which are diabetes self-management education, the process of teaching people to manage their diabetes.[22] However, several studies regarding patient's perspective of diabetes by using EM showed that patients' and professionals' understanding about diabetes seem to emphasize on different domains.[23,24] Patients emphasized on difficulties in the social domain and the impact of diabetes on their lives, while healthcare staffs concerned diabetes primarily as a patho-physiological problem with the impact on patients' physical bodies.[25,26] Therefore, in the PP model, EM was used for helping the pharmacist practitioners understand the attitudes and beliefs of their patients regarding their illnesses before

providing the education. Therefore, this study was carried out to develop an effective health-care system for caring type 2 diabetic patients under the chronic care concept. The study emphasized the role of pharmacists in the system, aiming at patients' best clinical and humanistic outcomes. However, this article represented only the clinical results.

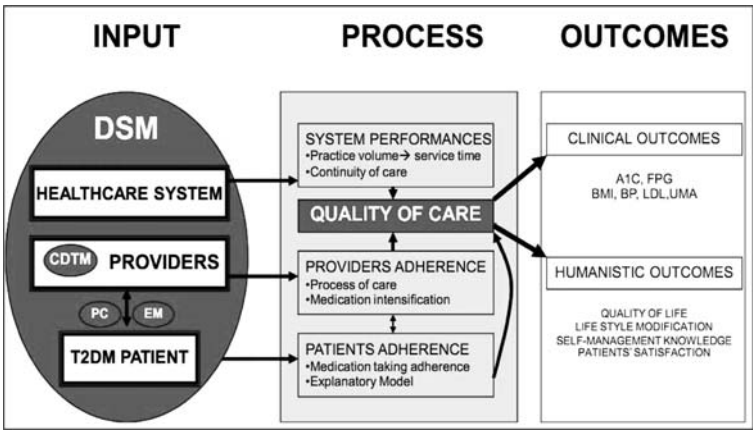

Figure 1. Conceptual model of the relationship between the four fundamental theories, the quality of care and the outcomes.[13,14,18,24]

Objective

To assess the effectiveness of the PP model on process measurements and clinical outcomes in providing care for vulnerable patients with poorly glycemic controlled diabetes.

Methods

Study Design and Setting. A randomized controlled trial was undertaken to examine the effectiveness of the PP model for type 2 diabetic patients with poor glycemic control from April 2006 to October 2007. All of the clinical practice agreements were approved by the head of medicine department and Nongbualamphu Hospital director. The study protocol was approved by the Institutional Review Board of Faculty of Pharmacy, Chiang Mai University (protocol number 1/2006), and written informed consent was obtained from all participants.

Patients and Randomization. The sample size calculation was based on the assumption that the intervention would result in the change of A1c at the level of 1.3 percent (effect size, *d*), the difference found in a prior study of case management[17] and parameters: $\alpha = 0.05$, $\beta = 0.2$.

Therefore, this study needed at least 40 patients in each study arm. The whole population of patients with type 2 diabetes at March 2006 was at 3,523 persons. Only 444

patients, who had at least one A1c performed, were recruited. After checking against the study's selection criteria, 98 patients were eligible for the study. They were high-risk individuals whose recent A1c levels were 8.0 percent or greater without macrovascular complications.

Inclusion criteria

1. Diagnosed with type 2 diabetes for longer than one year
2. Baseline A1c level ≥8.0 percent
3. Well-communicated (reading, listening) in Thai
4. Estimated glomerular filtration rate (e-GFR) ≥60 mL/min/1.73 m^2
5. Signed informed consent

Exclusion criteria

1. Pregnant women
2. Diagnosed with macrovascular complications (eg. myocardial infarction, stroke, etc.)
3. Diagnosed as having severe concurrent illness (eg. cancer, renal failure, etc.)
4. Have been previously provided care by clinical pharmacists

Eligible patients were, then, randomly assigned into the study arms. Patients were assigned into the PP or controlled group, using stratified random sampling technique to ensure balanced randomization across levels of glycemic control and were randomized to each group by using block of four methods. Patients in controlled group were provided UC by their physicians or interns. In the PP group, patients were provided care by two pharmacist practitioners. All patients were followed up for 1 year, with data collection occurring at baseline, 6 and 12-month.

Intervention and Follow-up.

The UC Group. Eligible patients were scheduled by an OPD nurse liaison who explained the study to the patient and obtained baseline blood determinations (Figure 2). Patients' blood sugar level were measured directly by a blood glucose testing kit. However, some were investigated by a technician at a clinical laboratory unit, Nongbualamphu Hospital if the physician need to monitor fasting plasma glucose (FPG) level with other laboratory testings (e.g. A1c, lipid profile, etc.). The nurse used appointment sheet in white color for UC group (the green sheet for PP group). The interventions were patients' assessment (interpreted patient's laboratory results, provided physical examination as patient's complaint), development of an individual care plan (physician gathered all data and provided knowledge to the patient), implementation of the care plan (physician provided diabetes-specific pharmacotherapy by evaluation, initiation, intensification and advised dietary regulation or exercise plan), and monitoring outcomes (physician made new appointment and planned to order the next visit).

The PP Group. The eligible patients were also appointed by OPD nurse who

obtained baseline vital sign and blood determinations as shown in Figure 2. Process of care was developed from the essential features of the general practitioner or case manager[18] and steps approach was modified from CDTM, PC, and EM. Before initiation of the study, the pharmacist practitioners attended a medical education courses, provided by the internist (supervisor), on the topic of the American Diabetes Association's Standards of Medical Care for Management of Type 2 Diabetes and Treatment Algorithms. Then the final treatment algorithms were approved by the internist, head of medical department, and the director of Nongbualamphu Hospital. Following these treatment algorithms, steps of care by a pharmacist practitioner were 1) evaluated patient's understanding of diabetes by interviewing with the EM open-ended questions, 2) assessed of medication-taking adherence by pill counting and patient's self-report, 3) assessed and managed other drug therapy problems, 4) interpreted patient's laboratory results, 5) gathered all data then individualized treatment plan and provided knowledge, 6) provided diabetes-specific pharmacotherapy by evaluation, initiation, and intensification following by clinical practice agreements, 7) prescribed a new medication or intensified a new dose and a pharmacist practitioner provided information regarding common adverse drug reaction, 8) educated regarding dietary control and exercise, and 9) made the new appointment and ordered laboratory tests for the next visit. All approved treatment and medication intensifications by PP were recorded in patient's medical record without co-signed by internist. PP had accessed to a supervisor if there were complication diabetes managed problems (eg. serum creatinine level rising greater than 1.8 mg/dL, mix-typed dyslipidemia, etc.).

Data Collection. The primary outcomes of interest were A1c and FPG levels. A1c was measured by a boronate affinity binding assay (NycoCard, Reader II, Axis-Shield, Olso, Norway; normal range 4.5-6.3 percent). FPG was measured by using a hexokinase method (enzymatic UV test) (Olympus AU 400, Olympus Diagnostica GmbH, Hamburg, Germany; normal range 74 to 106 mg/dL). The secondary outcomes included blood pressure, low-density lipoprotein (LDL) and microalbuminuria levels. Blood pressure was obtained by nurses who were blinded for the study assignment, using automated blood pressure monitor (Udex II, Ueda, Japan). The patients, who had the first time blood pressure level higher than 140/90 mmHg, would be suggested to rest at least five minutes before the second measurement. The lipid and mico-albuminuria testings were calculated using a Automated Chemistry Analyzer AU 400 (Olympus Diagnostica GmbH, Germany). The LDL cholesterol levels were estimated indirectly using the Friedewald formular for patients with plasma triglyceride levels lower

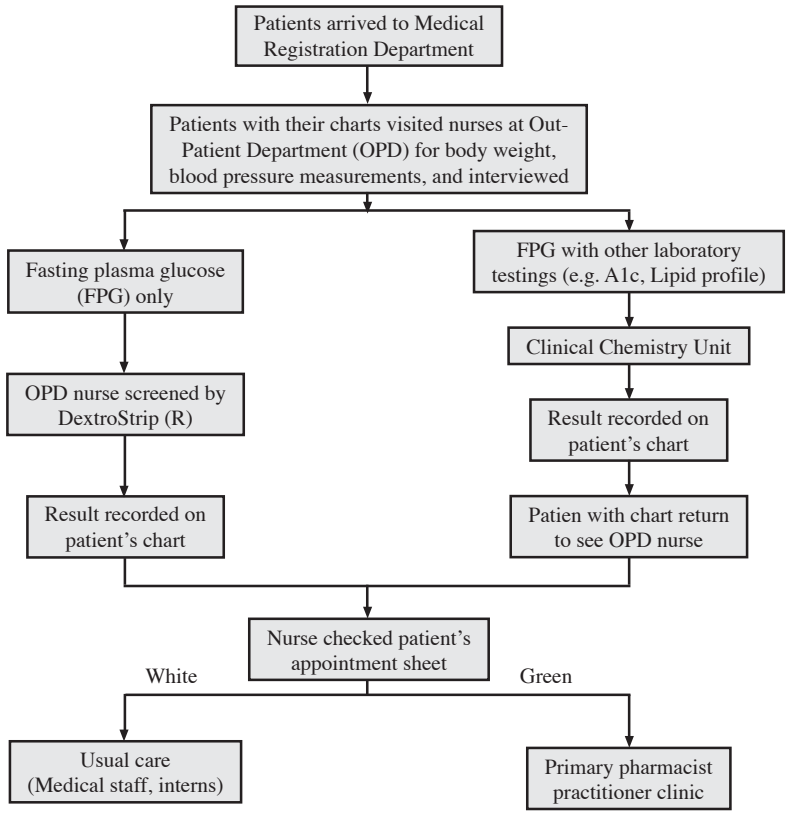

Figure 2. Patient flow diagram

than 400 mg/dL.[27] All blood samples were analyzed in the Clinical Chemistry Unit, Laboratory Department, Nongbualamphu Hospital.

Data Analysis. The Statistical Package for the Social Sciences (SPSS) 11.0 was used to analyze the data. A two-sided significance level of 5 percent was used for all statistical inferences. Baseline variables were compared using descriptive statistics. Continuous outcomes were compared using repeated-measure ANOVA to account for data collection at baseline, 6 and 12-month. A two sample t-test of differences (baseline to 12 months) was performed between comparison and intervention groups. For categorical variables, the Pearson chi-square (χ^2-test) was used to test for significant difference in demographic characteristics between the comparison and intervention groups. These analyses were conducted by intention-to-treat.

Results

The baseline demographic characteristics of the PP and UC groups were similar (Table 1). Their clinical characteristics were not statistically different, except the high density lipoprotein (HDL) cholesterol level. The HDL level of patients in the UC group were significantly higher (46±12 mg/dL vs 39±9 mg/dL, p=0.012) (Table 2).

Table 1. Baseline demographic characteristics of the patients

Characteristics	UC (n=50)	PP (n=48)	p-Value
	Number (%) or Mean±SD		
Women (%)	80	85	.479[a]
Age (years)	51.4 ± 9.5	55.4 ± 10.2	.051[b]
Duration of treatment (years)	5.8 ± 3.5	6.2 ± 3.3	.519[b]
Family members	4.5 ± 1.3	4.6 ± 1.8	.776[b]
Income (baht)	4,240 ± 3,691	4,666 ± 4,172	.593[b]
Health insurance status (%)			1.000[a]
Universal coverage	44 (88)	42 (88)	
Others	5 (12)	5 (12)	
Education level			.739[a]
No formal education	5 (10)	2 (4)	
Elementary	42 (84)	43 (90)	
Others	3 (6)	3 (6)	
Occupation			.270[a]
No occupation or agriculture	41 (82)	43 (90)	
Others	9 (18)	5 (10)	
Concomitant diseases			.245[a]
No concomitant	15 (30)	19 (40)	
Hypertension or hyperlipidemia or proteinuria	35 (70)	29 (60)	
Medications			.459[a]
Monotherapy[c]	18 (36)	16 (33)	
Combination therapyd	32 (64)	32 (67)	

[a]Using chi-square tests, [b]using t-tests, [c]monotherapy = used sulfonylurea (SU) or biguanide (BG) or insulin (ISL) [d]combination therapy = used combination of SU+BG or SU+ISL or BG+ISL or SU+BG+ISL

Table 2. Baseline clinical characteristics

Characteristics	UC (n=50)	PP (n=48)	p-Value
	Mean±SD		
Body mass index (kg/m^2)	27 ± 4	26 ± 4	.102
Systolic blood pressure (mm Hg)	129 ± 19	123 ± 18	.161
Diastolic blood pressure (mm Hg)	79 ± 11	76 ± 12	.303
Hemoglobin A1c (%)	9.9 ± 1.6	9.8 ± 1.4	.639
Fasting plasma glucose (mg/dL)	178 ± 62	176 ± 52	.878
Creatinine clearance (mL/min/1.73 m^3)	74 ± 14	71 ± 11	.176
Total cholesterol (mg/dL)	193 ± 44	178 ± 46	.185
Triglycerides (mg/dL)	247 ± 166	230 ± 150	.653
HDL-cholesterol (mg/dL)	46 ± 12	39 ± 9	.012*
LDL-cholesterol (mg/dL)	103 ± 35	93 ± 33	.266

*Indicate a statistically significant difference at an alpha level of 0.05 using t-tests.

HDL = high-density lipoprotein, kg/m^2 = kilograms per square meters, LDL = low-density lipoprotein, mg/dL = milligrams per deciliters, mL/min/1.73m^2 = milliliters per minute per 1.73 square meters, mm Hg = millimeters mercury, SD = standard deviation

1. Process Measurements. The process measurements highlighted two particular issues,

1.1 Provider Adherence to ADA's Recommendation to Process-of-Care. (Table 3) At baseline, the proportions of patients receiving clinical parameter tested were similar between two groups. However, at the end of the study, the effect of the providers management was assessed by using the rate of adhering to diabetes process of care.

Table 3. Provider adherence to ADA's recommendations to process-of-care in UC and PP groups

Parameters	Baseline (%)			12-Month (%)		
	AUC (n=50)	PP (n=48)	*p*-Value[a]	UC (n=50)	PP (n=48)	p-Value[a]
Retinal examination	2 (4)	0	.162	2 (4)	23 (48)	<.01*
Proteinuria screening	5 (10)	2 (4.2)	.262	12 (24)	40 (83)	<.01*
Foot screening	0	0		0	29 (60)	<.01*
ASA prescribed	5 (10)	7 (15)	.489	11 (22)	42 (88)	<.01*
ACE inhibitor prescribed	17 (34)	14 (29)	.607	20 (40)	36 (75)	<.01*
Lipid profile testing	40 (80)	33 (69)	.202	41 (82)	44 (91)	.158

[a]Using chi-square tests, *indicate a statistically significant difference at an alpha level of 0.05.
ASA = acetyl salicylic acid, ACE = angiotensin-converting enzyme

Adherence to ADA guidelines in the PP group was significantly greater than the UC group. Referrals for evaluation of diabetic retinopathy were 48 and 4 percent (p<0.01) and urine sample screening were 83 and 24 percent (p<0.01) in the PP and the UC group, respectively. Foot examinations were performed for only patients in the PP group. Aspirin and ACE inhibitors were significantly more prescribed in the PP group compared to the UC group (88 vs 22 percent, p<0.01 and 75 vs 40 percent, p<0.01, respectively). The frequencies of lipid profile testing in the PP group was higher than the UC group but not statistically significant differences (91 vs 82 percent, p=.158).

1.2. Providers Intensified Medications among Patients with Poorly Controlled Clinical Parameters over the ADA's Recommendations. Patients in the PP group were significantly more likely to have their regimens justified or intensified than those in the UC group (56 percent vs 19 percent, p< 0.01). Patients in the PP group underwent more aggressive treatment for hyperglycemia, hypertension, and dyslipidemia than patients in the UC group. (Table 4)

2. Clinical Outcomes. The model effectiveness was measured by comparing several clinical indicators at baseline at 6 and 12-month after intervention..

Table 4. Frequency of medication regimen intensification in response to poorly controlled clinical parameters

Clinical Parameters	Medication Intensification Rate (%)		p-Value
	UC	PP	
FPG>130 mg/dL	65/287 (22)	123/214 (57)	<0.01*
A1c>7.0 %	29/213 (13)	125/234(53)	<0.01*
SBP>140 mm Hg or DBP>90 mm Hg	3/25 (12)	20/36(55)	<0.01*
LDL-C>100 mg/dL	9/24 (38)	23/29 (79)	<0.01*
Total medication intensified/total visits	106/549 (19)	291/513 (56)	<0.01*

*Indicate a statistically significant difference at an alpha level of 0.05 using chi-square tests for medication intensification.

A1c = hemoglobin A1c, DBP = diastolic blood pressure, FPG = fasting plasma glucose, LDL-C = low-density lipoprotein cholesterol, mg/dL= milligrams per deciliters, mm Hg = millimeters mercury, SBP = systolic blood pressure

2.1 Primary Outcomes. The mean A1c and FPG levels are shown in Figures 3. Hyperglycemic patients were treated primarily with sulfonylurea (PP: 93 percent, UC: 92 percent), metformin (PP: 85 percent, UC: 92 percent), and insulin (PP: 52 percent and UC: 30 percent). The A1c and FPG levels improved more in the PP group (Figure 3). From baseline to 12 months, patients in the UC group demonstrated a decrease of 0.8 percent, compared with a decrease of 2.0 percent among patients in the PP group (difference, 1.2 percent, p<0.01).

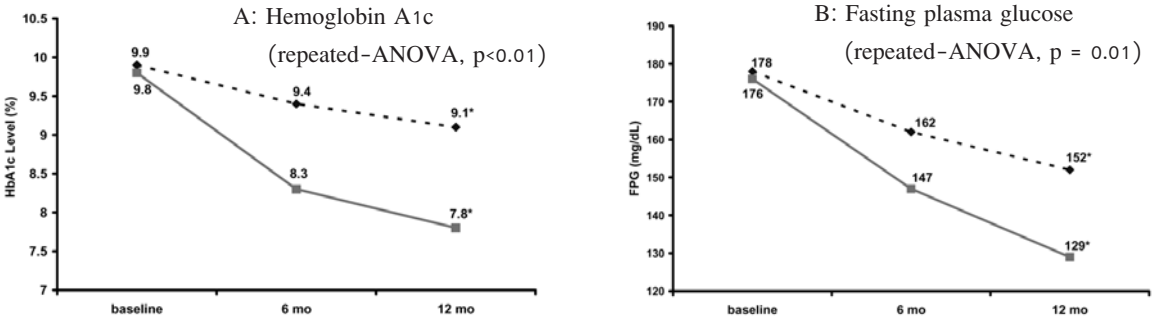

Figure 3. Change in clinical outcomes over time in the PP (solid line) and UC (dashed line) groups.

The proportion of patients whose A1c level achieved the ADA's target of the PP group was significantly greater than the proportion of patients in the UC group (25 vs 4 percent respectively, p<0.01). The results were unchanged when controlling for baseline difference in HDL-cholesterol level (Table 5)

Table 5. The proportion of patients whose A1c level achieved ADA's recommendation at the end of study

Hemoglobin A1c Levels	UC	PP
<7.0%	2 (4)	12 (25)*
>7.0%	48 (96)	36 (75)

*tested by chi-square and p<0.01

*2.2 **Secondary Outcomes*** (Table 6)

2.2.1 Blood pressure (BP). Thirty-two percent of all patients were considered as hypertensive since their systolic blood pressure (SBP) at baseline greater than 140 mmHg or diastolic blood pressure (DBP) greater than 90 mmHg. In both groups, practitioners were equally effective in reducing SBP. However, reduction of DBP in the PP group was significantly greater than those of the UC group (p=0.047).

2.2.2 Low-density lipoprotein cholesterol. The mean LDL-cholesterol value improved more in the PP group, but the difference was not statistically significant.

2.2.3 Urine microalbumin. Microalbumin excretion was measured by spot urine collection method. The test was ordered for only in PP group. The mean baseline microalbuminuria of seventeen patients, who received the test, was 389±168 mcg/mg creatinine. Only five patients were ordered to have the second test. Results showed that the microalbumin level decreased slightly to 372±161 mcg/mg creatinine after initiating ACE inhibitor.

Table 6. Comparison of the secondary clinical outcomes of patients within group between before and after study

	Pre-test			Post-test		
	UC	PP		UC	PP	
Clinical Parameters	Mean ± SD (n)		p-Value	Mean ± SD (n)		p-Value
SBP>140 mm Hg	150 ± 11 (25)	151 ± 12 (36)	.498	129 ± 15 (25)	131 ± 16 (36)	.747
DBP>90 mm Hg	89 ± 9 (25)	88 ± 9 (36)	.485	82 ± 9 (25)	77 ± 9 (36)	.047*
LDL-C>100 mg/dL	128 ± 16 (17)	138 ± 19 (19)	.070	112 ± 38 (11)	97 ± 20 (16)	.230

*Indicate a statistically significant difference at an alpha level of 0.05 using t-tests

DBP = diastolic blood pressure, LDL-C = Low-density lipoprotein cholesterol, SBP = systolic blood pressure SD = standard deviation

Discussions

Results showed that pharmacist practitioner model setting in outpatient department at Nongbualumpoo Hospital can improve both process measurements and clinical outcomes in a high-risk diabetic population. The patients in the PP group were more likely to be monitored for prevention and treatment of complications than those in the UC group. The results were consistent with previous studies1[5,17]. However, the rate of non-adherence was lower than that required in the ADA guidelines for two indices, eye and foot examinations. This may be due to several reasons, including: 1) this study has been conducted only for one year; 2) for eye examinations, the thirty-three patients (60 percent) were recommended from pharmacist practitioner for eye examination appointment, but only twenty-three patients (48 percent) had the examination caused by personal reasons such as no one took them to the hospital, there were no symptoms at that time, some were busy, and bad impression about eye examinations due to other people experience of blurred vision, etc. ; and 3) for foot screening, the pharmacist practitioners found only some patients suffering from feet numbness because the patients in the PP group received dosage adjustments (53 to 79 percent) from the evaluation and laboratory testing resulted more often than those in the UC group (12 to 38 percent) (Table 4). One of the reasons for the PP model's success may be the ability of the program to overcome "*clinical inertia*". Clinical inertia has been defined as "*failure to perform a needed service or make a change in treatment when the health status of the patient indicates that such an action is necessary*".[28] Studies on physician management of blood pressure, and diabetes suggest that physicians often fail to make changes in a patient's medications when indicated.[29-32] The other reasons are practice volume and continuity of care. The higher practice volume of patients in the UC group related to less time of service and patients in the PP group often met the same pharmacist practitioners while the patients in the UC would not met the same physicians in next visit. However, the hypoglycemic agents used in PP group were adjusted around fifty percent from hypoglycemic symptoms, medication-taking non-adherence, and diet problems.

This study demonstrated the effectiveness of using pharmacist practitioners model with treatment algorithms in hospital-based outpatient clinics that have low income patients with type 2 diabetes mellitus. The duration of this study was too short to evaluate the effect of improved glycemic control on chronic microvascular complications. It represents only surrogate outcomes. However, in a 10-year follow up study,[7] the UKPDS data showed a continuous relationship between the risks of microvascular complications and glycemic, such that for every percentage point decrease

in A1c, there was 35 percent reduction in the risk of microvascular complications, 25 percent reduction in diabetes related deaths, 7 percent reduction in all cause mortality, and 18 percent reduction in fatal and nonfatal myocardial infarction. In addition, by following up ten years later, the UKPDS study found that, the benefits gained from intensive glucose level control in type 2 diabetic patients since the beginning continued to be found at least next ten years after intensive treatment had stopped.[33] Other clinical outcome showed that reduction DBP of high blood pressure patients in the PP group was greater than those in the UC group. This outcome was important for DM patients because there was report that the application of hypertension optimal treatment (HOT) study had a capability to reduce DBP from 85 to 81 mmHg and thus will reduce the risk of cardiovascular events in the diabetes patients by fifty percent.[34] Although LDL-cholesterol level was reduced in both groups when compared to the baseline, the mean LDL-cholesterol level at twelve-month in the PP group tended to be lower than those of UC group (97±20 vs 112±38, p=.230).

Results of this study demonstrated that pharmacist practitioners can improve quality of care similar to the results of previous studies.[15,17] This model can improve glycemic control and the use of recommended screening procedures among high-risk patients. By implementing this model in a Primary Care Unit (PCU), pharmacists can visit patients at home and learn more regarding the problems whereas the physicians can supervise and caring all patients through health care team. The key success factors are: 1) supporting practice environment, 2) targeting patients likely to benefit from interventions, 3) delegating prescriptive privileges, 4) increasing patient adherence through EM concepts and education, and 5) providing continuity and sufficient time for care. The first key difference from other management interventions is the physician (supervisor) allowed pharmacist practitioners directly intensified the medications following the scope of clinical practice agreements while the other study, physicians had to approve all anticipated medication changes.[15] Second, this study adopted the EM in order to help the pharmacist practitioners understand diseases and illnesses from the patients' perspective[35] which other studies have not been evaluated.[15-17] However, there are some limitations in this study. This was a small study involving only 98 patients at a single diabetic clinic in a hospital setting and follow-up only one year, not longer enough for an evaluation of vascular complications. Another, patients did not examine blood glucose levels by themselves. The information of low blood sugar levels might not have been accurate and hypoglycemic information relied on the patients' own views. As a result, the adjustment of treatment could have been delayed.

Conclusions

This study showed that pharmacist practitioners model with treatment algorithms improved glycemic control and adherence to ADA's recommendations among high-risk patients with type 2 diabetes mellitus in a hospital setting. The pharmacist practitioners can work in conjunction with physicians to overcome clinical inertia. Today, decision makers address the high-cost and continuously growing clinical and public health problems of the prevalence of type 2 diabetes in Thai people. These findings have important implications for healthcare policy related to the treatment of type 2 diabetes.

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